U.S. Food and Drug Administration

Center for Devices and Radiological Health

FOI RELEASABLE MATERIAL – PUBLIC RELEASABLE

REPORT NAME: ESSURE REPORTS – 2/9/2016

REPORT DESCRIPTION: THIS IS THE FOI RELEASABLE VERSION OF THE ESSURE MDR REPORTS RECEIVED AND ENTERED INTO THE DATABASE PRIOR TO JANUARY 1, 2016 AND THAT WERE AVAILABLE IN REDACTED FORM FOR DOWNLOADING ON FEBRUARY 9, 2016.

CRITERIA: ALL VARIATIONS OF THE BRAND NAME "ESSURE"

TOTAL NUMBER OF REPORTS: 9,884

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1031305	CONCEPTUS INC.	2/19/2004	3/5/2004

Event Information:

Event Date (B3): 2/12/2004 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): 12245204

Single Use:
Implant Date (E6): 2/12/2004
Explant Date (E7): 2/12/2004
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PT SCHEDULED FOR BILATERAL ESSURE TUBAL OCCLUSION, ENDOMETRIAL BALLOON ABLATION, AND HYSTEROSCOPY AND LAPAROSCOPIC CHOLECYSTECTOMY. FIRST DR DID HIS PROCEDURES AND THEN THE SCOPE WAS INSERTED INTO THE ABDOMEN FOR THE LAPAROSCOPIC GALLBLADDER. SECOND DR TOOK A LOOK AT THE UTERUS AND THE ESSURE SPRINGS (COILS) WERE PROTRUDING OUT OF THE UTERUS. FIRST DR WAS CALLED BACK INTO THE ROOM. HE REMOVED THE ESSURE SPRINGS AND APPLIED FALOPE RINGS BILATERALLY. SECOND DR PROCEEDED ON WITH THE LAPAROSCOPIC GALLBLADDER WITHOUT INCIDENT. PT AND PT'S FAMILY MEMBER WERE INFORMED OF ALL PROCEDURES IN THE RECOVERY ROOM AFTER PT WAS AWAKE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTS INCORPORATED	4/16/2004	11/4/2015

Event Information:

Event Date (B3): 3/30/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL LIGATOR
Model # (E4): REF ESS205
Catalog # (E4):
Lot #(E4): 12248978

Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

COIL DID NOT ADVANCE WHEN APPLIED TO FALLOPIAN TUBE. COIL DAMAGED WHILE REMOVING FROM FALLOPIAN TUBE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	7/21/2004	9/7/2004

Event Information:

Event Date (B3): 3/5/2004 **Report Date (B4): 7/21/2004** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 12247705

Single Use:
Implant Date (E6): 3/5/2004
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT UNDERWENT HYSTEROSCOPIC ESSURE TUBAL STERILIZATION PROCEDURE. ESSURE COMPANY REPRESENTATIVE WAS PRESENT FOR THE PROCEDURE. A HYSTEROSCOPE WAS INSERTED INTO THE DILATED CERVIX. BILATERAL TUBAL OSTIA WERE VISUALIZED WITH THE LEFT NOTED TO BE ENLARGED AND THE RIGHT NORMAL IN APPEARANCE. THE LEFT TUBAL OSTIA WAS CANNULATED WITH THE ESSURE DEVICE WITH THE COIL VISUALIZED TO BE WITHIN THE LEFT TUBAL OSTIA AND LOCATED IN THE LEFT TUBE. UPON DETACHMENT UNDER DIRECT VISUALIZATION, THE LEFT COIL WAS NOTED TO RETRACT INTO THE TUBE BEYOND THE TUBAL OSTIA WITH NO COILS REMAINING WITHIN THE UTERUS. THE RIGHT TUBAL OSTIA WAS VISUALIZED, THE ESSURE INTRODUCER WAS PLACED INTO THE TUBAL OSTIA AND THE INTRODUCER REMOVED. THE COIL REMAINED IN THE TUBAL OSTIA WITH TWO LOOPS OF COIL REMAINING IN THE ENDOMETRIAL CAVITY. ATTENTION WAS TURNED BACK TO THE LEFT TUBAL OSTIA. A GRASPER WAS INSERTED AND THE OSTIA PROBED WITHOUT VISUALIZATION OF THE COIL. THE ENDOMETRIAL CAVITY WAS EXPLORED AND THERE WAS NO EVIDENCE OF A COIL. THE ESSURE MICRO-INSERT WAS FELT TO BE WITHIN THE TUBE ON THE LEFT, GIVEN THE DIRECT VISUALIZATION OF THE PLACEMENT. A FEW MONTHS LATER, PATIENT RETURNED FOR A HYSTEROSALPINGOGRAM. IT REVEALED SUCCESSFUL BLOCKAGE OF THE RIGHT FALLOPIAN TUBE AND A FAILED LEFT ESSURE TUBAL MICROINSERT. A LAPAROSCOPIC LEFT TUBAL LIGATION WITH BIPOLAR CAUTERY WAS DONE LESS THAN A MONTH LATER. THERE WAS NO EVIDENCE OF THE ESSURE DEVICE IN THE PERITONEAL CAVITY. AN INTRAOPERATIVE X-RAY OF THE PELVIS SHOWED THE APPEARANCE OF THE ESSURE DEVICE IN THE LEFT TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1032971	CONCEPTUS	8/11/2004	10/22/2004

Event Information:

Event Date (B3): 7/19/2004 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): HYSTEROSCOPIC PROCEDURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 12256351

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PART OF COIL APPEARED TO BE ON ESSURE WHEN REMOVED FROM PT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2004-00001	CONCEPTUS, INC.	11/26/2004	12/3/2004

Event Information:

Event Date (B3): 10/20/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM FOR PERMANENT BIRTH CONTROL
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESSURE SYSTEM
Catalog # (E4): ESS 205
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 6/7/2004
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD BILATERAL PLACEMENT OF ESSURE FALLOPIAN TUBAL OCCLUSION DEVICES IN 2004. PT FAILED TO COMPLY WITH REQUIRED ALTERNATIVE CONTRACEPTION PRIOR TO 3-MONTH HYSTEROSALPINGOGRAM (HSG) AND BECAME PREGNANT. HSG AND HCG LEVEL AT 17 WEEKS POST-PLACEMENT AND ULTRASOUND AT 19 WEEKS WERE INDICATIVE OF ABNORMAL PREGNANCY. ULTRASOUND RESULTS SHOWED A CYSTIC MASS AT THE RIGHT ADNEXA (AND COULD NOT RULE OUT AN ECTOPIC PREGNANCY) AND A HETEROGENEOUS ECHOGENICITY IN THE UTERINE CAVITY (POSSIBLY SUGGESTIVE OF A FAILED INTRAUTERINE PREGNANCY). PREGNANCY TERMINATION BEGAN 2004 WITH METHOTREXATE. PT WAS ASYMPTOMATIC PRIOR TO DIAGNOSIS AND REMAINS IN GOOD HEALTH, ACCORDING TO THEIR PHYSICIAN. INTERIM DIAGNOSIS: SUSPECTED ECTOPIC PREGNANCY, BUT NOT CONFIRMED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	3/1/2005	3/12/2005

Event Information:

Event Date (B3): 2/15/2005 **Report Date (B4): 3/1/2005** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION DEVICE
Model # (E4): *
Catalog # (E4): REF ESS205
Lot #(E4): 12267472

Single Use:
Implant Date (E6): 2/15/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT WAS IN OUTPATIENT SURGERY FOR HYSTEROSCOPY, D & C, ENDOMETRIAL ABLATION, AND HYSTEROSCOPIC TUBAL ('ESSURE' DEVICE). THE 'ESSURE' MICRO INSERT WAS PLACED INTO THE LEFT OVARIAN TUBE AND THEN TO THE BLACK MARK ON THE INSERT AND BACKED UP A NOTCH. THE PHYSICIAN WAITED 10 PLUS SECONDS THEN NOTED INITIAL RELEASE. THE COIL DID NOT RELEASE PROPERLY FROM THE INSERTION GUIDE. THE PHYSICIAN WAITED A FEW MORE SECONDS THEN TRIED TO TWIST AND UNCOIL IT COUNTERCLOCK WISE THEN CLOCKWISE DIRECTION. THIS DID STRETCH IT OUT SOMEWHAT AND IT FINALLY RELEASED APPEARING TO BE IN THE FALLOPIAN TUBE. THE MANUFACTURER CLINICAL SPECIALIST WAS CONTACTED INTRA-OPERATIVELY AND RECOMMENDED THE DEVICE BE LEFT AND GO AHEAD AND GET AN HSG, HYSTEROSALPINGOGRAM IN 12 WEEKS. THE REST OF THE PROCEDURES WERE COMPLETED WITHOUT INCIDENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC	3/18/2005	3/22/2005

Event Information:

Event Date (B3): 2/22/2005 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL LIGATION SYSTEM
Model # (E4): ESS205
Catalog # (E4): *
Lot #(E4): 12266007

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

GUN DID NOT FIRE TO LIGATE TUBE DURING PROCEDURE. INSTRUMENT WAS FIRED PRIOR TO PATIENT INVOLVEMENT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2005-00001	CONCEPTUS, INC.	3/23/2005	4/26/2005

Event Information:

Event Date (B3): 9/28/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION DEVICE, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 9/28/2004
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT REPORTED SEVERAL MONTHS OF CHRONIC LEFT SIDED PELVIC PAIN. AN INITIAL DIAGNOSTIC LAPAROSCOPY WAS PERFORMED IN 2004 BUT DID NOT REVEAL ANY INTRA-ABDOMINAL ABNORMALITIES. AFTER THE LAPAROSCOPY, THE PT CONTINUED TO HAVE LEFT SIDED PAIN. A CT SCAN WAS PERFORMED SUBSEQUENTLY WHICH IDENTIFIED A METALLIC OBJECT IN THEIR ABDOMEN. THEY WERE REFERRED FOR A REPEAT LAPAROSCOPY THE FOLLOWING MONTH. AT THIS TIME A METAL COIL IN THE RETRO-PERITONEAL SPACE WAS FOUND. THE COIL WAS REMOVED. NO ADD'L PROCEDURES WERE DONE AND THE PT IS NOW COMPLETELY ASYMPTOMATIC. AT THE TIME THAT THE COIL WAS REMOVED, THE PHYSICIAN STILL DID NOT KNOW WHAT IT WAS. IT WAS ONLY AFTER THE SURGERY, WHEN HE QUESTIONED THE PT ABOUT WHAT THEY WERE USING FOR BIRTH CONTROL, THAT THEY MENTIONED THE ESSURE TUBAL OCCLUSION DEVICE PLACEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1035128	CONCEPTUS, INC.	4/5/2005	4/11/2005

Event Information:

Event Date (B3): 3/15/2005 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 1226996

Single Use:
Implant Date (E6): 3/15/2005
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN WAS PERFORMING A STERILIZATION PROCEDURE. WHEN THE COIL WAS PLACED IN THE FALLOPIAN TUBE, THE PHYSICIAN ATTEMPTED TO RETRACT THE ESSURE DEVICE AND THERE WAS SOME RESISTANCE. ONCE THE DEVICE WAS RETRACTED, PART OF THE COIL REMAINED ON THE DEVICE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	6/29/2005	7/22/2005

Event Information:

Event Date (B3): 5/17/2005 **Report Date (B4): 6/28/2005** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE SYSTEM
Model # (E4): ESS205
Catalog # (E4): *
Lot #(E4): 12264292

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 6/28/2005

Event Description (B5):

PHYSICIAN ADVISED INSTRUMENT DEFECTIVE - NO SPECIFICS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1036693	CONCEPTUS	9/22/2005	8/14/2006

Event Information:

Event Date (B3): 8/31/2005 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS ESSURE
Device Type (E2): CONTRACEPTIVE
Model # (E4): ESSURE
Catalog # (E4): ESS205
Lot #(E4): 12280461

Single Use:
Implant Date (E6): 8/31/2005
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING INSERTION OF CONCEPTUS ESSURE DEVICE, THE COIL BROKE OFF IN THE FALLOPIAN TUBE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2005-00002	CONCEPTUS, INC.	10/19/2005	10/25/2005

Event Information:

Event Date (B3): 9/19/2005 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ENSURE
Device Type (E2): TUBAL OCCLUSION DEVICE, CONTRACEPTIVE
Model # (E4): ESS2C5
Catalog # (E4): ESS205
Lot #(E4): NA

Single Use: Y
Implant Date (E6): 8/14/2005
Explant Date (E7): 9/28/2005
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2005 THE PHYSICIAN REPORTED TO CONCEPTUS THAT HE PLACED ENSURE MICRO-INSERTS IN A PATIENT IN 88/24/2005. SOON THEREAFTER, THE PT COMPLAINED OF PERSISTENT PAIN, WHICH WAS INITIALLY RELIEVED WITH PAIN MEDICATION. HOWEVER, THE PT CLAIMED THAT THE PAIN SYMPTOMS AFFECTED HER JOB AND SHE REQUESTED TO HAVE THE MICRO-INSERTS REMOVED. IN 2005 THE PHYSICIAN CONFIRMED THAT THE PT IS INSISTENT ON HAVING THE MICRO-INSERTS REMOVED. AN EMAIL WAS RECEIVED FROM THE PHYSICIAN SIX DAYS LATER REPORTING THE HYSTEROSCOPIC REMOVAL OF THE MICRO-INSERTS THE PREVIOUS DAY. THE REMOVAL WAS COMBINED WITH A TUBAL LIGATION PROCEDURE. AN EMAIL WAS RECEIVED FROM PHYSICIAN IN 2005 STATING THE PT'S PAIN HAS RESOLVED SINCE THE MICRO-INSERTS WERE REMOVED, EXCEPT SOME "SORENESS" WHERE THE TUBES WERE CAUTERIZED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1036980	CONCEPTUS INC	10/21/2005	8/16/2006

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): STERILIZATION
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6): 5/20/2005
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACEMENT. WAS HAVING SEVERE PAIN FROM THE START. WENT BACK TO THE ER 4 DAYS LATER FOR BLEEDING AND SEVERE PAIN. THEN RETURNED TO 1 HOSP'S ER FOR BLEEDING AND PUS COMING FROM THE VAGINA. THE DR WAS NOT FAMILIAR WITH THE PRODUCT SO THEY TOOK PT TO ANOTHER HOSP. WAS ADMITTED FOR SEVERAL DAYS. FIVE MOS LATER PT STILL CONTINUES TO HAVE ABNORMAL BLEEDING AND SEVERE PAIN. HAVE SEEN 2 DIFFERENT DRS ON POSSIBILITY OF REMOVING THE ESSURE. BOTH HAD DIFFERENT APPROACHES AS HOW TO REMOVE IT. STILL LOOKING FOR AN ANSWER AND MORE INFO BEFORE THEY LET ANYONE OPERATE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	11/3/2005	11/23/2005

Event Information:

Event Date (B3): 10/25/2005 **Report Date (B4): 11/3/2005** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION DEVICE
Model # (E4): REF ESS205
Catalog # (E4): UNK
Lot #(E4): 12281414

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE MICRO-INSERT DID NOT RELEASE FROM THE DELIVERY WIRE MECHANISM. THE ESSURE DEVICE WAS REMOVED AND ANOTHER DEVICE TRIED WITH SUCCESSFUL RELEASE OF MICRO-INSERT. NO INJURY TO THE PATIENT. DEVICE AVAILABLE FOR RETURN TO MANUFACTURER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1037102	CONCEPTUS	11/8/2005	8/15/2006

Event Information:

Event Date (B3): 8/30/2005 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): *
Model # (E4): FSS 205
Catalog # (E4): *
Lot #(E4): 12247754

Single Use:
Implant Date (E6): 6/18/2004
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD AN ESSURE COIL PALCED FOR BIRTH CONTROL. ESSURE COIL FAILED & PATIENT REQUESTED A DILATATION & EVACUATION FOR PRODUCTS OF CONCEPTION. PATIENT IS SCHEDULED FOR REMOVAL OF COIL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2005-00007	CONCEPTUS, INC.	11/28/2005	12/8/2005

Event Information:

Event Date (B3): 11/2/2005 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): ESS205
Lot #(E4): *

Single Use: Y
Implant Date (E6):
Explant Date (E7): 11/2/2005
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ENSURE PERMANENT BIRTH CONTROL DEVICE PLACEMENT AND ENDOMETRIAL ABLATION BY A PHYSICIAN (NAME NOT PROVIDED) APPROX ONE YEAR AGO. THE REQUIRED 3-MONTH HYSTEROSALPINGOGRAM WAS NEVER DONE SECONDARY TO PATIENTS' HISTORY OF ABLATION. PT REPORTED TO A SECOND PHYSICIAN THAT SHE HAD PAIN POST-PROCEDURE THAT WORSENED OVER A ONE-YEAR PERIOD AND REQUESTED REMOVAL OF THE DEVICES. A RECENT CT SCAN SHOWED ONE ESSURE MICRO-INSERT TO BE IN THE PRITONEAL CAVITY. IN 2005 THE PHYSICIAN CALLED CONCEPTS TO REPORT THAT THE SURGERY TO REMOVE THE DEVICE WENT VERY WELL; HE LOCATED THE MICRO-INSERT IN THE "MID-TUBE" AND WAS ABLE TO REMOVE IT WITHOUT DIFFICULTY. THE MICRO-INSERT WAS APPARENTLY PLACED TOO DISTAL INTO THE FALLOPIAN TUBE BUT WAS NOT ACTUALLY LOCATED IN THE PERITONEAL CAVITY. HE CALLED CONCEPTS AGAIN IN ABOUT 3 WEEKS LATER TO REPORT THE PT WAS DOING VERY WELL AND HER PAIN HAD RESOLVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1037413	CONCEPTUS, INC.	12/9/2005	12/19/2005

Event Information:

Event Date (B3): 11/29/2005 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE COIL USED THROUGH HYSTEROSCOPE
Model # (E4): ESS205
Catalog # (E4): *
Lot #(E4): 508290

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3): 11/29/2005

Event Description (B5):

COIL BROKE DURING A HYSTEROSCOPE PROCEDURE FOR STERILIZATION. RIGHT TUBE COMPLETE, LEFT TUBE ABORTED DUE TO PROBLEMS WITH ESSURE DEVICE. DEVICE REMOVED, TAKEN APART, COULD NOT REMOVE OCCLUSION AND REP DID NOT HAVE ANOTHER DEVICE. THIS RESULTED IN THE PT HAVING TO RETURN FOR THE LEFT FALLOPIAN STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2005-00010	CONCEPTUS, INC.	12/21/2005	12/22/2005

Event Information:

Event Date (B3): 12/1/2005 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/8/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTEDLY HAD DIFFICULTY WITH VISUALIZATION AT THE TIME OF ESSURE MICRO-INSERT DEPLOYMENT IN THE RIGHT FALLOPIAN TUBE. SHE DISENGAGED THE DELIVERY WIRE WITH 20 COUNTER-CLOCKWISE ROTATIONS WITHOUT DIRECT VISUALIZATION. NO TRAILING COILS WERE SEEN AT THE OSTIUM. A FLAT-PLATE X-RAY WAS ATTEMPTED TO LOCALIZE THE DEVICE BUT NOT COMPLETED. NO FURTHER INFORMATION WAS GIVEN REGARDING WHY THIS COULD NOT BE ACCOMPLISHED. THE PHYSICIAN ATTEMPTED TO CANNULATE THE RIGHT TUBE AGAIN BUT MET RESISTANCE AND DISCONTINUED THE ATTEMPT. THE LEFT DEVICE WAS PLACED WITHOUT DIFFICULTY WITH 4 TRAILING COILS. THERMACHOICE ENDOMETRIAL ABLATION PROCEDURE FOLLOWED. PATIENT PRESENTED WITH CRAMPING AND MILD PELVIC PAIN 4 DAYS POST-PLACEMENT THAT WAS NOT LOCALIZED ON THE RIGHT SIDE. A FLAT PLAT X-RAY SHOWED 2 DEVICES, WITH THE RIGHT DEVICE APPEARING "ANGLED". THE PHYSICIAN PLANNED TO WAIT UNTIL THE 3-MONTH HSG TO EVALUATE FURTHER. HOWEVER, THE PATIENT COMPLAINED OF PERSISTENT PAIN ON THE RIGHT SIDE AND EARLY THE NEXT MONTH UNDERWENT A SALPHINGECTOMY. THE RIGHT TUBE WAS CUT OPEN AND THE MICRO-INSERT WAS FOUND DISTAL IN THE TUBE WITHOUT PERFORATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2005-00011	CONCEPTUS, INC.	12/21/2005	12/22/2005

Event Information:

Event Date (B3): 11/17/2005 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNI-I-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/17/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN CALLED CONCEPTUS TO REPORT A POSSIBLE ALLERGIC REACTION TO THE ESSURE MICRO-INSERTS. THE PT HAD ESSURE PLACED IN 2005 AND DEVELOPED ITCHING AND A RASH SHORTLY AFTER PLACEMENT. SHE WAS HOSPITALIZED OVERNIGHT AND TREATED WITH IV STEROIDS WITH GOOD RESULTS. THE PHYSICIAN SUSPECTS POSSIBLE DRUG REACTION BUT SCHEDULED THE PT WITH AN ALLERGIST NEXT MONTH FOR NICKEL ALLERGY TESTING. THE PHYSICIAN'S OFFICE MGR STATED SHE WOULD CONTACT CONCEPTUS IN ABOUT 10 DAYS WITH THE RESULTS. NO FURTHER INFO HAS BEEN RECEIVED TO DATE, SO CONCEPTUS IS FILING THIS INITIAL REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00001	CONCEPTUS, INC.	1/16/2006	1/20/2006

Event Information:

Event Date (B3): 11/22/2005 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): ESS205
Lot #(E4): 508015

Single Use: Y
Implant Date (E6): 11/1/2005
Explant Date (E7): 11/22/2005
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN WAS PERFORMING HER SECOND TRAINING CASE ON A PATIENT WHO WAS 7 WEEKS POSTPARTUM. THE CONCEPTUS REPRESENTATIVE THAT PRECEPTORED THIS PHYSICAN REPORTED A DIFFICULT CASE, BUT THE OSTIA WERE VISUALIZED (UTERINE DISTENSION REQUIRED TWO TENACULUMS) AND BILATERAL PLACEMENT ACHIEVED. THE PATIENT COMPLAINED OF EXTREME ABDOMINAL PAIN THE FOLLOWING DAY. SHE WAS SENT TO THE ER AND A CT SCAN SHOWED THE ESSURE MICRO-INSERTS IN THE PERITONEAL CAVITY. THE PHYSICIAN REMOVED THE DEVICES BY OPEN ABDOMINAL SURGERY AND REPORTED THAT EACH FALLOPIAN TUBE "LOOKED FINE" WITH NO MENTION OF ANY PERFORATION.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	3/21/2006	4/6/2006

Event Information:

Event Date (B3): 3/9/2006 **Report Date (B4): 3/21/2006** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): 12281414

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PATIENT WAS UNDERGOING A VOLUNTARY STERILIZATION PROCEDURE. THE DOCTOR ATTEMPTED TO FIRE THE SPRING INTO THE FALLOPIAN TUBE. THE PATIENT'S FALLOPIAN TUBE SPASMED AT THAT TIME EXPELLING THE SPRING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1036560	CONCEPTUS INC	3/22/2006	4/7/2006

Event Information:

Event Date (B3): 3/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4): ESSURE
Catalog # (E4): E59205
Lot #(E4): 508291

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

COIL DEPLOYED PREMATURELY AND HAD TO BE RETRIEVED. PERMANENT DAMAGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1038329	CONCEPTUS INC	3/22/2006	4/7/2006

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4): ESSURE
Catalog # (E4): *
Lot #(E4): 508296

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

TIP BENT; PROCEDURE COMPLETED USING ANOTHER DEVICE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	4/6/2006	5/3/2006

Event Information:

Event Date (B3): 2/9/2006 **Report Date (B4): 4/6/2006** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): STERILIZATION DEVICE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE WAS INSERTED INTO PLACE. PHYSICIAN PULLED BACK ON UN-DEPLOYED DEVICE AND LOST VISUALIZATION. DEVICE BROKE LEAVING PIECES IN PATIENT. PHYSICIAN RETRIEVED BROKEN PIECES WITHOUT INCIDENT. ESSURE REPRESENTATIVE PRESENT IN OPERATING ROOM DIRECTING PHYSICIAN ON PROPER USE OF DEVICE THROUGHOUT CASE. THIS INCIDENT WAS DUE TO IMPROPER USE OF DEVICE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00002	CONCEPTUS, INC.	4/18/2006	4/20/2006

Event Information:

Event Date (B3): 3/21/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): ESS205
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 3/21/2006
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT HAD A BILATERAL ESSURE PLACEMENT BY DR. AND SHOWED UP IN OFFICE WITH ABDOMINAL PAIN MULTIPLE TIMES.THE PATIENT STARTED TO HAVE PAIN ALMOST IMMEDIATELY FOLLOWING THE ESSURE PROCEDURE AND SHE HAD NO HISTORY OF PELVIC PAIN PRIOR TO THE PLACEMENT PROCEDURE.DR. EVALUATED THE PATIENT 2 DAYS POST-PROCEDURE AND TREATED HER WITH A COURSE OF ANTIBIOTICS,BUT THE PATIENT CONTINUED TO COMPLAINT OF PELVIC PAIN.ANOTHER DR. EVALUATED THE PATIENT ON AN EMERGENCY BASIS WHEN FIRST DR. WAS OUT OF TOWN.THE PATIENT HAD INTRACTABLE PAIN,SO SHE ADMITTED HER TO THE HOSPITAL FOR OBSERVATION.LAB WORK WAS WITHIN NORMAL LIMITS.SHE PROCEEDED WITH AN ABDOMINAL HYSTERECTOMY AND NOTED THAT ONE OF THE DEVICES WAS IN THE SEROSAL LAYER OF THE FALLOPIEN TUBE.SHE ALSO NOTED THAT THE ANATOMY OF THE TUBES WAS UNUSUAL AND THER APPEARED TO BE AT A 90 DEGREE ANGLE.THE PATIENT'S PAIN HAS COMPLETELY RESOLVED POST-OPERATIVELY.SECOND DR. STATES HER MEDICAL OPINION IS THAT THE PATIENT'S PAIN WAS RELATED TO THE DEVICES.IT WAS MENTIONED THAT THE PATIENT "WANTED A HYSTERECTOMY FROM THE START."

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1039297	CONCEPTUS INC.	5/29/2006	6/8/2006

Event Information:

Event Date (B3): 4/11/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): *
Model # (E4): ESS205
Catalog # (E4): *
Lot #(E4): 50815

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

SHEATH DETACHED FROM TIP AND GAVE RESISTANCE TO INSERTION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00003	CONCEPTUS, INC.,	7/21/2006	7/27/2006

Event Information:

Event Date (B3): 4/7/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/7/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN CALLED THE CONSULTATION LINE DURING A CASE TO REPORT SHE HAD DETACHMENT DIFFICULTIES WITH THE ESSURE DEVICE. SHE USED 3 ESSURE DEVICES IN EACH FALLOPIAN TUBE, BECAUSE SHE WAS UNSURE WHETHER THE MICRO-INSERT DETACHED FROM THE DELIVERY WIRE. SHE REPORTS SHE DID NOT SEE ANY TRAILING COILS AFTER ATTEMPTED PLACEMENT OF THE FIRST DEVICE IN EACH SIDE, SO SHE ATTEMPTED PLACEMENT USING A SECOND DEVICE IN EACH TUBE. SHE DIDN'T SEE TRAILING COILS AGAIN, SO SHE ATTEMPTED PLACEMENT OF TWO ADDITIONAL DEVICES (FOR A TOTAL OF 6 ATTEMPTS, 3 IN EACH TUBE). HOWEVER, ALL SIX MICRO-INSERTS DID DETACH, AND THE PATIENT HAS THREE MICRO-INSERTS INSIDE EACH FALLOPIAN TUBE. THE PATIENT WAS ASYMPTOMATIC POST-PROCEDURE. DR CALLED CONCEPTUS TO REPORT THE PATIENT IS NOW COMPLAINING OF PELVIC PAIN AND HAS CONCERNS OVER HAVING SO MANY DEVICES IN HER BODY. PATIENT COMPLAINS OF ACUTE, INTERMITTENT ABDOMINAL PAIN 2-3 TIMES PER WEEK. DR OFFERED THE PATIENT SURGICAL REMOVAL OF THE DEVICES, AND BILATERAL TUBAL LIGATION WHICH THE PATIENT AGREED TO. SURGERY IS INTENDED TO BE SCHEDULED, BUT HAS NOT OCCURRED YET.

Manufacturer Narrative (H10):

A CONCEPTUS REPRESENTATIVE SPOKE WITH DR. DISTAL PLACEMENT AND HSG PROTOCOL, WERE DISCUSSED AT LENGTH. THE APPEARANCE OF THE DELIVERY WIRE AFTER A DEVICE HAS BEEN DEPLOYED WAS DESCRIBED IN DETAIL. DR. STATED THAT A CONCEPTUS REPRESENTATIVE CAME OUT TO PRE

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00004	CONCEPTUS, INC.	8/17/2006	8/23/2006

Event Information:

Event Date (B3): 4/7/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): 508291

Single Use: Y
Implant Date (E6): 4/7/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

MAUDE EVENT REPORT STATES THE TIP OF ONE ESSURE DEVICE BENT DURING A PLACEMENT PROCEDURE. BILATERAL PLACEMENT WAS ULTIMATELY ACHIEVED WITH A NEW DEVICE.

Manufacturer Narrative (H10):

RPTR FIRST FILED THE BENT TIP INCIDENT THROUGH MEDWATCH. CONCEPTUS FIRST BECAME AWARE OF THIS INCIDENT ON 7/19/06. A CONCEPTUS REP SPOKE OF THIS INCIDENT ON 7/19/06. A CONCEPTUS REP SPOKE WITH RPTR WHO INDICATED "OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)"

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00005	CONCEPTUS, INC.	8/17/2006	8/23/2006

Event Information:

Event Date (B3): 2/9/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): 508296

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS EVENT WAS VOLUNTARILY REPORTED THROUGH MEDSUN MANDATORY AND VOLUNTARY REPORT FORM IN 2006, BY THE USER FACILITY). THE ESSURE DEVICE WAS INSERTED INTO THE TUBE CORRECTLY. HOWEVER, AS THE PHYSICIAN WAS ABOUT TO DEPLOY THE DEVICE, HE LOST VISUALIZATION. HE DID NOT WANT TO DEPLOY BLINDLY, SO HE ATTEMPTED TO REMOVE THE DELIVERY CATHETER. THE MICRO INSERT WAS INADVERTENTLY DEPLOYED AND REMOVED AT THE SAME TIME CAUSING THE OUTER COIL TO STRETCH. THE PHYSICIAN ATTEMPTED TO REMOVE THE DEVICE WITH GRASPERS WHICH CAUSED THE MICRO INSERT TO BREAK. HE WAS ABLE TO REMOVE ALL PIECES OF THE COIL AND THE CASE WAS TERMINATED. NO INJURY CAUSED TO THE PT.

Manufacturer Narrative (H10):

THE PHYSCIAN TRAINING MANUAL DOES NOT RECOMMEND REMOVAL OF A MICRO INSERT UNLESS THERE ARE 18 OR MORE TRAILING COILS. PHYSICIAN ACTED IN ACCORDANCE WITH THE INSTRUCTION FOR USE BY TERMINATING THE CASE AFTER THE BROKEN MICRO INSERT HAD BEEN REMOVED BECAUSE

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00006	CONCEPTUS, INC.	8/18/2006	8/23/2006

Event Information:

Event Date (B3): 3/1/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): 508291

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONCEPTUS DID NOT RECEIVE THE MAUDE EVENT REPORT UNTIL 7/19/06. THE MAUDE EVENT BRIEFLY STATES...."COIL DEPLOYED PREMATURELY AND HAD TO BE RETRIEVED. PERMANENT DAMAGE." A CONCEPTUS REP FIRST SPOKE WITH INITIAL REPORTER SHORTLY AFTER THE INCIDENT. SHE REPORTED THAT THE PHYSICIAN HAD DIFFICULTY ON 3 SEPARATE OCCASIONS WITH ESSURE DEVICES DEPLOYING PREMATURELY DURING PROCEDURE.

Manufacturer Narrative (H10):

REPORTED DR. HAS HAD DIFFICULTY WITH DEPLOYMENT ON 3 SEPARATE OCCASIONS. SHE IS CONCERNED THIS MAY BE DUE TO A TRAINING ISSUE. THE SALES REP WAS CONTACTED AND HE STATES DR DID EXPERIENCE SOME DIFFICULTIES WITH THE PROCEDURE STEPS WHEN HE WAS INITIALLY TRA

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	8/21/2006	9/11/2006

Event Information:

Event Date (B3): 7/26/2006 **Report Date (B4): 8/21/2006** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): 509408

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 8/22/2006

Event Description (B5):

THE PATIENT WAS UNDERGOING A VOLUNTARY STERILIZATION PROCEDURE. THE DEVICE FAILED TO DEPLOY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1040420	CONCEPTUS INCORPORATED	9/12/2006	10/3/2006

Event Information:

Event Date (B3): 9/7/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE - PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 620728

Single Use:
Implant Date (E6): 9/7/2006
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE WAS INSERTED INTO THE RIGHT FALLOPIAN TUBE W/O INCIDENT. DEVICE FAILED TO SEPARATE THE COILS FROM THE INTRODUCING CATHETER. THE INSERTING DEVICE WAS REMOVED - WHILE DOING THIS, THERE WAS PARTIAL RELEASE OF THE COILS, IN THE QUILLS BREAKING OFF ALONG WITH A PIECE OF THE COIL AND FALLING INTO THE UTERINE CAVITY. BOTH PIECES WERE RETRIEVED. UNCLEAR IF STERILIZATION WAS ACHIEVED IN THE RIGHT FALLOPAIN TUBE - WILL NEED F/U IN 3 MONTHS TO KNOW.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00007	CONCEPTUS, INC.	9/26/2006	10/2/2006

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2006, PHYSICIAN REPORTED A CONCEPTUS SALES REPRESENTATIVE HE HAD A PATIENT WHO HAD MULTIPLE INFECTIONS REQUIRING IV ANTIBIOTICS POST ESSURE PLACEMENT. A CONCEPTUS REPRESENTATIVE SPOKE WITH PHYSICIAN 17 DAYS LATER. HE STATED THERE WERE NO PROBLEMS AT THE TIME OF PLACEMENT AND ATHE PATIENT DID WELL UNTIL 6-8 WEEKS POST PLACEMENT AT WHICH TIME SHE PRESENTED WITH THE "CLASSIC PID PICTURE" INCLUDING PELVIC PAIN AND FEVER. SHE WAS HOSPITALIZED FOR IV ANTIBIOTICS AND HER SYMPTOMS RESOLVED WITHIN 3-5 DAYS. SHE RETURNED AGAIN A FEW WEEKS LATER WITH IDENTICAL SYMPTOMS AND WAS AGAIN TREATED WITH IV ANTIBIOTICS. GC/CT CULTURES WERE NEGATIVE, VAGINAL CULTURES WERE NEGATIVE, BUT URINE CULTURE GREW ENTEROBACTERCLOACAE. SHE WAS TREATED FOR THIS INFECTION AND REFERRED TO A UROLOGIST TO DETERMINE IF HER RECURRENT SYMPTOMS WERE BLADDER RELATED. THE UROLOGIST DID NOT THINK HER SYMPTOMS WERE GU RELATED. PATIENT DID NOT HAVE A HISTORY OF PELVIC PAIN PRIOR TO ESSURE PLACEMENT, BUT HAS A COMPLICATED GI HISTORY INCUDING COLECTOMY FOR GASTROPARESIS. PATHOLOGY REPORT FROM THE HYSTERECTOMY SHOWED ADENOMYOSIS. DR. HARLE STATES HE EXPECTED TO SEE "CHRONIC ENDOMETRITIS" BECAUSE OF HER RECURRENT INFECTIONS AND PAIN. PATIENT'S SYMPTOMS HAVE COMPLETELY RESOLVED SINCE HER HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1040526	CONCEPTUS INC	9/27/2006	10/2/2006

Event Information:

Event Date (B3): 4/11/2006 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): E99205
Catalog # (E4): *
Lot #(E4): 508296

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PER THE OPERATIVE REPORT, "ESSURE DEVICE MALFUNCTIONED DURING PROCEDURE. -ITEM NOT FIRED - NOTICED MALFUNCTION PRIOR TO USE."

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1040559	CONCEPTUS, INC.	10/3/2006	10/5/2006

Event Information:

Event Date (B3): 6/21/2006 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): *
Model # (E4): ESS205
Catalog # (E4): *
Lot #(E4): 508297

Single Use:
Implant Date (E6): 6/21/2006
Explant Date (E7): 6/21/2006
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3): 6/22/2006

Event Description (B5):

SURGEON WAS INSERTING THE ESSURE CONTRACEPTIVE DEVICE INTO THE PATIENT FULLOPIAN TUBE WHEN THE TIP BROKE OFF INTO THE FALLOPIAN TUBE (A SMALL PIECE APPROXIMATELY 2MM IN SIZE).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00009	CONCEPTUS, INC.	10/26/2006	10/31/2006

Event Information:

Event Date (B3): 9/26/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 9/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS EVENT WAS INITIALLY REPORTED AS A PREGNANCY POST ESSURE. A CONCEPTUS REPRESENTATIVE ATTEMPTED TO CONTACT THE PHYSICIAN ON 3 SEPARATE OCCASIONS AND DID NOT RECEIVE A CALL BACK. PHYSICIAN REPORTED TO CONCEPTUS THAT THE PATIENT HAD HER ESSURE PROCEDURE IN 2005 AND BECAME PREGNANT APPROXIMATELY ONE YEAR LATER. AN ADNEXAL MASS WAS NOTED AT THE TIME OF ULTRASOUND. HE PROCEEDED WITH LAPAROSCOPY AND FOUND AN ECTOPIC PREGNANCY WHICH HE REMOVED FROM THE TUBE. NO MENTION WAS MADE REGARDING DEVICE PLACEMENT AT TIME OF LAPAROSCOPY. PATIENT'S POST-OPERATIVE COURSE WAS UNEVENTFUL.

Manufacturer Narrative (H10):

SEVERAL ATTEMPTS HAVE BEEN MADE TO CONTACT THIS PHYSICIAN, BUT HE HAS NOT RESPONDED. CONCEPTUS WILL CONTINUE ITS ATTEMPTS TO GATHER MORE INFORMATION ON THIS EVENT. MORE INFORMATION WILL BE ADDED TO THIS REPORT AS IT BECOMES AVAILABLE.

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00008	CONCEPTUS, INC.	10/31/2006	11/9/2006

Event Information:

Event Date (B3): 9/29/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 2/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED AN ECTOPIC PREGNANCY THAT OCCURRED 1 YR POST-ESSURE PLACEMENT. PT HAD THE ESSURE PROCEDURE IN 2005 AND AN HSG 4 MOS LATER WHICH SHOWED BILATERAL OCCLUSION. SHE WAS COUNSELED TO RELY ON THE ESSURE DEVICES FOR CONTRACEPTION. IN 2006 PHYSICIAN REPORTED THE PT HAD A "SHAGGY ENDOMETRIUM" AT THE TIME OF THE ESSURE PROCEDURE, BUT DEVICE PLACEMENT WENT WELL. HSG WAS DONE IN 2005 AND THE RADIOLOGIST REPORTED BILATERAL OCCLUSION, BUT NO MENTION OF DEVICE LOCATION WAS MADE IN THE REPORT. PHYSICIAN STATES THE PT PRESENTED WITH PELVIC PAIN, BUT HAD NOT SKIPPED HER MENSES. AN ULTRASOUND SHOWED A COMPLEX ADNEXAL MASS ON HER RIGHT SIDE. HE SCHEDULED THE PT FOR SURGERY, BUT DIDN'T FIND OUT SHE WAS PREGNANT UNTIL HER PRE-OPERATIVE LABS WERE DONE AT WHICH TIME IT WAS NOTED HER BETA HCG WAS 250. AT THE TIME OF LAPAROSCOPY, HE DID NOT SEE ANY EVIDENCE OF DEVICE PERFORATION. HE DID A SALPINGECTOMY AND OOPHORECTOMY. PATHOLOGY CONFIRMED AN ECTOPIC PREGNANCY SHOWING CHORONIC VILLI. PT HAS RECOVERED WITHOUT INCIDENT.

Manufacturer Narrative (H10):

HSG FILMS WERE REC'D AND REVIEWED BY 2 CONCEPTUS CONSULTING PHYSICIANS ON 10/16/06. THEY STATE THE HSG STUDY IS INADEQUATE, DUE TO POOR UTERINE DISTENTION WITH CONTRAST. THE RIGHT DEVICE APPEARS TO BE SUPERIOR TO THE CORNUAL AREA AND MAY BE IN PARALLEL PO

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00011	CONCEPTUS, INC.	11/2/2006	11/8/2006

Event Information:

Event Date (B3): 10/3/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 9/11/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS THE ESSURE CASE WAS DONE IN 2005 AND THERE WERE NO PROBLEMS AT THE TIME OF MICRO-INSERT PLACEMENT. THREE MONTH HSG WAS PERFORMED AND BILATERAL OCCLUSION WAS NOTED BY PHYSICIAN; PT BEGAN RELYING ON THE DEVICES FOR CONTRACEPTION. IN 2006, PHYSICIAN REPORTED PT HAD A RUPTURED ECTOPIC PREGNANCY. THERE WAS NO EVIDENCE OF DEVICE PERFORATION AT THE TIME OF SURGERY AND SHE PUT CLIPS ON THE TUBES. PT RECOVERED WITHOUT INCIDENT. PHYSICIAN WILL SEND HSG FILMS TO CONCEPTUS FOR REVIEW.

Manufacturer Narrative (H10):

ADD'L INFO WILL BE AVAILABLE AFTER HSG FILM REVIEW IS COMPLETED BY CONCEPTUS.

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Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	12/4/2006	9/12/2012

Event Information:

Event Date (B3): 12/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 620757

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PT WAS TO UNDERGO A BILATERAL TUBAL LIGATION USING THE CONCEPTUS ESSURE PRODUCT. THE SYSTEM USED ON TE LEFT FALLOPIAN TUBE FAILED. THE SPRING BROKE, LEAVING PARTS OF THE SPRING INSIDE THE FALLOPIAN TUBE AND PART OF THE WIRE HANGING OUT OF THE FALLOPIAN TUBE. THE SURGEON SUCCESSFULLY EXTRACTED THE PIECES OF THE SPRING, BUT NOT THE WIRE. THE PT WAS RE-DRAPED, PREPPED, FOLEY INSERTED FOR A LAPAROSCOPY AND TUBAL LIGATION WITH THE KLEPPINGER UNIT. AS TENSION WAS HELD ON THE FALLOPIAN TUBE BY AN ASSISTANT SURGEON, THE PRIMARY SURGEON WENT IN VAGINALLY AND REMOVED THE WIRE FROM THE TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1041259	CONCEPTUS, INC	12/6/2006	12/7/2006

Event Information:

Event Date (B3): 11/27/2006 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4): *
Lot #(E4): 620749

Single Use:
Implant Date (E6): 11/27/2006
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE SHOT 2 SPRINGS INTO EACH FALLOPIAN TUBE DUE TO MALFUNCTION. CONSIDERED INJURY WITH NO NECESSARY INTERVENTION.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	12/13/2006	1/8/2007

Event Information:

Event Date (B3): 10/20/2006 **Report Date (B4): 12/13/2006** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION DEVICE
Model # (E4): *
Catalog # (E4): ESS 205
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

RIGHT FALLOPIAN TUBE PERFORATED WITH THE ESSURE DEVICE FOR STERILIZATION. ESSURE DEVICE ADVANCED ACCORDING TO INSTRUCTIONS PER SURGEON. PROCEDURE CONVERTED TO LAP TUBAL LIGATION COVERED IN INFORMED CONSENT. PT DOING WELL ON FOLLOW-UP.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/19/2006	1/17/2007

Event Information:

Event Date (B3): 12/11/2006 **Report Date (B4): 12/19/2006** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE
Model # (E4): ESS205
Catalog # (E4): ESS205
Lot #(E4): 581531

Single Use:
Implant Date (E6): 7/27/2006
Explant Date (E7): 12/11/2006
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 12/19/2006

Event Description (B5):

DEVICE WAS IMPLANTED FIVE MONTHS AGO AND MIGRATED INTO THE ABDOMINAL CAVITY CAUSING PAIN AND REQUIRING A SECOND PROCEDURE. THIS PAST MONTH A DIFFERENT DEVICE WAS INSTALLED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00010	CONCEPTUS, INC.	12/20/2006	1/4/2007

Event Information:

Event Date (B3): 11/21/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 8/24/2006
Explant Date (E7): 11/21/2006
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS ESSURE PROCEDURE WAS DONE IN 2006. HE EXPERIENCED PROBLEMS AT THE TIME OF PLACEMENT WITH TUBAL SPASM AND DEVICE DETACHMENT AND WENT THROUGH 11 DEVICES IN ORDER TO ACHIEVE BILATERAL PLACEMENT. THERE WERE 18 TRAILING COILS ON THE LEFT AND 3 TRAILING COILS ON THE RIGHT. AN X-RAY WAS DONE TO CHECK PLACEMENT AND SHOWED 2 DEVICES IN ONE TUBE AND ONE IN THE CONTRALATERAL TUBE. THIS PATIENT HAS HAD PAIN ON THE RIGHT SIDE AND WANTS THE DEVICES REMOVED. PHYSICIAN PLANS DEVICE REMOVAL AND WAS REFERRED TO ANOTHER PHYSICIAN FOR SURGICAL CONSULATION. SEVERAL ATTEMPTS HAVE BEEN MADE TO CONTACT THIS PHYSICIAN REGARDING THE FINDINGS AND OUTCOME OF THE DEVICE REMOVAL PROCEDURE; HOWEVER, HE HAS NOT RETURNED OUR CALLS. DEVICES HAVE NOT YET BEEN REC'D FOR EVAL.

Manufacturer Narrative (H10):

ADDITIONAL INFORMATION MAY BE AVAILABLE WHEN THE PHYSICIAN IS REACHED AND/OR IF DEVICES ARE RETURNED FOR EVALUATION.

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2006-00012	CONCEPTUS, INC.	12/20/2006	1/5/2007

Event Information:

Event Date (B3): 10/1/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/27/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED TO CONCEPTUS REPRESENTATIVE A PT WHO HAD THE ESSURE DEVICES PLACED IN 2006 IN CONJUNCTION WITH AN HTA (DONE FOLLOWING ESSURE) RETURNED APPROX 3 MONTHS LATER COMPLAINING OF ABDOMINAL PAIN AND FEVER. CAT SCAN SHOWED BILATERAL TUBO-OVARIAN ABCESSES AND HER WHITE COUNT WAS ELEVATED AT 22. SHE WAS HOSPITALIZED AND TREATED WITH IV ANTIBIOTICS, BUT DID NOT RESPOND. SHE CONTINUED TO HAVE PAIN AND REMAINED FEBRILE. SHE ULTIMATELY UNDERWENT TAH/BSO WITHOUT COMPLICATIONS. PHYSICIAN REPORTS NOTHING UNUSUAL WITH THE DEVICES AND THEY APPEARED TO BE PROPERLY PLACED WHEN HE PERFORMED THE HYSTERECTOMY. THE PT HAD AN EXTREMELY ANTEVERTED UTERUS WHICH MADE PLACEMENT SOMEWHAT DIFFICULT, AND HE BENT THE TIP OF ONE ESSURE DEVICE TRYING TO CANNULATE THE TUBE, BUT DID ACHIEVE SUCCESSFUL BILATERAL PLACEMENT. HTA PROCEDURE WAS UNEVENTFUL. PATIENT HAD NO COMPLICATIONS POST-OPERATIVELY.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	12/29/2006	1/29/2007

Event Information:

Event Date (B3): 12/13/2006 **Report Date (B4): 12/29/2006** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM, ESSURE
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): 624678

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE WAS DEFECTIVE AND ACTIVATED BEFORE PUSHING IT. ANOTHER DEVICE WAS USED WITHOUT PROBLEM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1041963	ESSURE	2/13/2007	2/22/2007

Event Information:

Event Date (B3): 1/23/2007 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DELIVERY CATHETER WITH MICROINSERT
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): 621683

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PRODUCT OPENED TO STERILE FIELD. PRODUCT PLACED ACCORDINGLY BY MD. PRODUCT FAILED TO WRAP PROPERLY ON FALLOPIAN TUBE. PRODUCT REMOVED FROM PT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1042059		2/26/2007	3/5/2007

Event Information:

Event Date (B3): 2/16/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** *

Device Information:

Product Code: INSERT, TUBAL OCCLUSION ()
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): *
Model # (E4): *; *
Catalog # (E4): *
Lot #(E4):

Single Use:
Implant Date (E6): 2/16/2007
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DR ATTEMPTED TO PLACE ESSURE DEVICE INTO RIGHT TUBE. DEVICE DID NOT TRIGGER - LOT# 621809. SHE THEN ATTEMPTED TO PLACE ITEM #622306 (#1). NOTED LIP OF DEVICE #622306 (#2) WAS SUCCESSFULLY PLACED INTO LEFT FALLOPIAN TUBE. DR THEN ATTEMPTED TO PLACE #621800 (#1) INTO RIGHT FALLOPIAN TUBE. THE ITEM AGAIN DID NOT TRIGGER CORRECTLY AND REMOVED FROM PT. ITEM #621800 (#2) RETURNED UNOPENED. DR AT THAT TIME MADE DECISION TO PERFORM CAP TUBAL TO RIGHT TUBE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00001	CONCEPTUS, INC.	4/5/2007	4/12/2007

Event Information:

Event Date (B3): 2/28/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 2/28/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PHYSICIAN CALLED CONCEPTUS REP ON 2/27/2007 TO NOTIFY HIM SHE WAS EXPLANTING DEVICES IN 2007, THAT WERE IMPLANTED IN 2006. SHE CLAIMED THAT THE HSG SHOWED THE RIGHT DEVICE WAS PLACED IN A FALSE PASSAGE. THE PT STATED SHE WAS HAVING PAIN ON HER LEFT SIDE. SHE REQUESTED THAT THE PHYSICIAN REMOVE BOTH DEVICES. CONCEPTUS REP WAS PRESENT AT THE CASE FOR DEVICE REMOVAL. PHYSICIAN SUCCESSFULLY REMOVED BOTH DEVICES USING GRASPERS AND A HYSTEROSCOPE. SHE THEN PERFORMED A LAPAROSCOPIC TUBAL LIGATION USING FELSHIE CLIPS. THE CASE WAS SUCCESSFUL. CONCEPTUS REP REPORTS PT'S PAIN RESOLVED AFTER ESSURE DEVICES WERE REMOVED.

Manufacturer Narrative (H10):

PERFORATIONS OF THE UTERUS OR FALLOPIAN TUBES WERE OBSERVED IN THE CLINICAL TRIALS AT A RATE OF 2.9% (6/206) IN THE PHASE II TRIAL AND 1.1% (5/476) IN THE PIVOTAL TRIAL. THE RATE OF REPORTED PERFORATIONS IN COMMERCIAL USE IS SIGNIFICANTLY LOWER AND IS TYP

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1042653	CONCEPTUS INC.	4/6/2007	4/30/2007

Event Information:

Event Date (B3): 4/10/2007 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 622943

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING PROCEDURE THE DR TRIED TO IMPLANT BUT WAS UNSUCCESSFUL AND THE IMPLANT WAS PUT ASIDE, ANOTHER OPENED AND THE SURGICAL PROCEDURE WAS SUCCESSFUL. AFTER THE PROCEDURE THE DEVICE WAS LOOKED AT AND A BENT TIP WAS DISCOVERED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW1042660	CONCEPTUS INC.	4/19/2007	5/1/2007

Event Information:

Event Date (B3): 4/17/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CENTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): 509 405

Single Use:
Implant Date (E6): 3/22/2007
Explant Date (E7): 4/17/2007
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT SCHEDULED AT SURGERY CENTER FOR LAPAROSCOPY, REMOVAL OF ESSURE DEVICE. THE ESSURE DEVICE HAD FRACTURED AND WAS IN THE ABDOMEN. ONE PIECE WAS REMOVED FROM (EMBEDDED) THE TERMINAL ILIUM AND THE OTHER WAS EMBEDDED IN MENSENTERY. BOTH PIECES REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00002	CONCEPTUS, INC.	6/12/2007	9/5/2007

Event Information:

Event Date (B3): 5/11/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/27/2007
Explant Date (E7): 5/11/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS PT COMPLAINED OF INCREASING PELVIC PAIN POST ESSURE PROCEDURE. NOVASURE ENDOMETRIAL ABLATION WAS PERFORMED PRIOR TO THE ESSURE PROCEDURE, AND THE PHYSICIAN HAD DIFFICULTY CANNULATING THE LEFT TUBE AND BENT THE TIP OF ONE DEVICE. HE ULTIMATELY ACHIEVED BILATERAL PLACEMENT WITH 4 TRAILING COILS ON THE LEFT AND 2 ON THE RIGHT. HSG WAS DONE TO EVALUATE DEVICE PLACEMENT AND REVEALED THE LEFT DEVICE WAS PERFORATED THROUGH THE UTERINE WALL. PT UNDERWENT LAPAROSCOPY TO REMOVE THE PERFORATED DEVICE AND THE LEFT FALLOPIAN TUBE WAS LIGATED. DEVICE WAS REMOVED WITHOUT DIFFICULTY. PHYSICIAN STATES HE HAS EVALUATED THE PT ON TWO SEPARATE OCCASIONS POST-OPERATIVELY AND HER SYMPTOMS ARE RESOLVING.

Manufacturer Narrative (H10):

THE ESSURE PROCEDURE IS NOT APPROVED FOR CONCOMITANT USE WITH NOVASURE ABLATION. THE PHYSICIAN DID NOT ACT IN ACCORDANCE WITH THE ESSURE INSTRUCTIONS FOR USE.

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC	6/13/2007	9/19/2013

Event Information:

Event Date (B3): 2/2/2007 **Report Date (B4): 5/31/2007** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 633029

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FAILURE TO DEPLOY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00003	CONCEPTUS, INC.	7/11/2007	11/2/2007

Event Information:

Event Date (B3): 6/6/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 6/1/2006
Explant Date (E7): 6/6/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED TO A CONCEPTUS MEDICAL LIAISON OF A PATIENT PRESENTING WITH CONTINUED PAIN OF THE LEFT ADNEXAL REGION. THE PATIENT'S INITIAL 3-MONTH POST ESSURE PROCEDURE HSG IN 2006, INDICATED PROPER BILATERAL PLACEMENT AND TUBAL OCCLUSION; HOWEVER, A FOLLOW UP PELVIC EXAM, ULTRASOUND (SHOWING EQUIVOCAL EXPULSION OF LEFT DEVICE), AND ADDITIONAL LAB STUDIES PERFORMED IN 2007 DID NOT IDENTIFY THE ETIOLOGY OF THE PATIENT'S PAIN. A SUBSEQUENT REPEAT HSG (ONE MONTH LATER) CONFIRMED PROPER DEVICE PLACEMENT AND TUBAL OCCLUSION. AFTER DISCUSSION WITH PATIENT, IT WAS MUTUALLY DECIDED BY THE PHYSICIAN AND THE PATIENT THAT THE DEVICES BE REMOVED VIA LAPAROSCOPY WITH (LEFT) PARTIAL SALPINGECTOMY (ONE MONTH LATER). A POST OPERATIVE FOLLOW UP WAS CONDUCTED SIX DAYS LATER AND THE PATIENT WAS DOING WELL. THE PHYSICIAN ALSO REPORTED THAT SHE COULD NOT FIND ANY OTHER PATHOLOGY THAT WOULD EXPLAIN THE PATIENT'S SYMPTOMS, BUT WOULD CONTACT CONCEPTUS, SHOULD THERE BE A CHANGE IN THE PATIENT'S STATUS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00004	CONCEPTUS, INC.	7/17/2007	9/24/2007

Event Information:

Event Date (B3): 6/6/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/15/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS OF A PATIENT COMPLAINING OF PROGRESSIVE PAIN SHORTLY AFTER THE ESSURE PROCEDURE WAS PERFORMED IN 2007. THE PHYSICIAN INDICATES THAT THE ESSURE PROCEDURE WENT WELL (I.E. PROPER PLACEMENT AND APPROPRIATE TRAILING COILS) WITH NO SEQUELAE. ADDITIONAL PELVIC EXAM, KUB, AND CT SCAN CONDUCTED THE FOLLOWING MONTH, CONFIRMED PROPER DEVICE LOCATION. THOUGH THE PHYSICIAN STATES THAT THE PATIENT BELIEVES HER PAIN MAY BE DUE TO AN ALLERGIC REACTION TO THE DEVICES, ANY SUSPECTED HYPERSENSITIVITY TO NICKEL WAS NOT CONFIRMED BY SKIN TEST THOUGH RECOMMENDED FOR/TO THE PATIENT BY CONCEPTUS/PRODUCT LABELING AND THE PHYSICIAN, RESPECTIVELY. THE PHYSICIAN ACQUIESCED TO THE PATIENT'S DESIRE TO HAVE THE DEVICES REMOVED; THE PATIENT UNDERWENT HYSTEROSCOPY AND LAPAROSCOPIC REMOVAL OF THE DEVICES THE FOLLOWING MONTH. AFTER THE PROCEDURE, THE PHYSICIAN REPORTED NO ETIOLOGY FOR THE PAIN WAS SEEN (I.E. PELVIS NORMAL, NO EVIDENCE OF PERFORATION). BOTH FALLOPIAN TUBES AND DEVICES WERE SENT TO PATHOLOGY, AND THE PHYSICIAN INDICATED THAT SHE WOULD CONTACT CONCEPTUS AFTER RECEIPT OF A PATHOLOGY REPORT AND/OR PATIENT FOLLOW-UP. NO COMMUNICATION FROM THE PHYSICIAN HAS BEEN RECEIVED TO DATE AFTER TWO SUBSEQUENT ATTEMPTS TO FOLLOW-UP.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00005	CONCEPTUS, INC.	7/17/2007	9/24/2007

Event Information:

Event Date (B3): 6/14/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 6/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED PERFORMING A LAPAROSCOPIC HYSTERECTOMY TO REMOVE THE ESSURE MICRO-INSERTS BECAUSE THE PATIENT HAD EXPERIENCED INTERMITTENT CRAMPING AND SPOTTING SINCE HER ESSURE PROCEDURE IN 2005. AS THE PHYSICIAN WAS NOT THE ORIGINAL PHYSICIAN THAT PERFORMED THE ESSURE PROCEDURE. HE DID NOT HAVE INFORMATION ON THE PLACEMENT PROCEDURE (I.E., NUMBER OF TRAILING COILS AFTER PLACEMENT; CONCERNS, IF ANY, REGARDING PLACEMENT, VISIBLE TRAILING LENGTH OR ID OF TUBAL OSTIUM). HE STATES THE DEVICES WERE IN THE TUBES, ONE WAS SLIGHTLY TORQUED AT THE TIP. HE WILL SEE HER POST-OP IN 4 WEEKS. HE COULD NOT FIND ANY OTHER CAUSE FOR HER SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00006	CONCEPTUS, INC.	7/17/2007	9/24/2007

Event Information:

Event Date (B3): 4/13/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/1/2004
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED TO A FIELD-BASED CONCEPTUS EMPLOYEE, A CASE OF PELVIC PAIN THAT ULTIMATELY LEAD TO REMOVAL OF AN ESSURE DEVICE FROM THE PATIENT IN 2007. A CONCEPTUS MEDICAL LIAISON CONTACTED THE PHYSICIAN WHO PERFORMED THE SURGERY. HE STATED, THAT HE DID NOT ORIGINALLY PLACE THE ESSURE MICRO-INSERTS; RATHER, THE PATIENT CAME TO HIM FOR A SECOND OPINION. THE PATIENT HAD THE ESSURE PROCEDURE IN 2004. THE 3 MONTH HSG POST ESSURE INDICATED A PERFORATION WITH ONE OF THE DEVICES LOCATED IN THE ABDOMINAL CAVITY. THE PHYSICIAN THAT ORIGINALLY PLACED THE DEVICES PERFORMED A BTL, BUT COULD ONLY LOCATE ONE DEVICE FOR REMOVAL. THE PATIENT HAS EXPERIENCED INTERMITTENT LLQ/ABDOMINAL PAIN FOR THE PAST TWO YEARS DURING WHICH TIME SHE HAS HAD A COUPLE OF CT SCANS AND AN MRI TO IDENTIFY A POSSIBLE CAUSE FOR THE PAIN. THE LATEST CT SCAN SHOWED THE REMAINING MICRO-INSERT TO BE WITHIN THE OMENTUM UP UNDER THE LEFT RIB CAGE. SHE LATER PRESENTED TO THE ER WITH SEVERE LLQ PAIN AND NAUSEA AND VOMITING. THE OPERATING PHYSICIAN (INITIAL REPORTER) PERFORMED A LAPAROSCOPY UNDER FLUOROSCOPY AND WAS ABLE TO LOCATE THE MICRO-INSERT AND REMOVE IT SUCCESSFULLY. THE PATIENT STATES HER PAIN HAS RESOLVED FOLLOWING SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5003186	CONCEPTUS	7/25/2007	8/10/2007

Event Information:

Event Date (B3): 7/25/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE DEVICE
Device Type (E2): NONE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 624097

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PRODUCT DID NOT FIRE, BACK-UP NOT AVAILABLE. PT UNABLE TO HAVE OTHER METHOD OF STERILIZATION 20 TO ANESTHESIA RISK.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00007	CONCEPTUS, INC.	8/30/2007	11/6/2007

Event Information:

Event Date (B3): 6/28/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): 620723

Single Use: Y
Implant Date (E6): 2/9/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS EVENT WAS REPORTED TO CONCEPTUS ON 8/3/2007. PHYSICIAN REPORTED PT UNDERWENT THE ESSURE PROCEDURE IN 2007, AT WHICH TIME SHE WAS 6 WEEKS POST PARTUM. NO PROBLEMS WERE ENCOUNTERED AT THE TIME OF THE PROCEDURE. PT FAILED TO FOLLOW-UP FOR HER 3 MONTH HSG TO CONFIRM PROPER DEVICE LOCATION AND TUBAL OCCLUSION. ADDITIONALLY, SHE DISCONTINUED HER PROGESTIN-ONLY BIRTH CONTROL PILL IN 200, WHEN HER HSG CONFIRMATION TEST WAS DUE. PT PRESENTED TO THE PHYSICIAN'S OFFICE WITH SEVER RIGHT-SIDED PAIN THE FOLLOWING MONHT. SHE WAS ADMITTED TO THE HOSPITAL: SERIAL HCGS AND PELVIC ULTRASOUND CONFIRMED AN ECTOPIC PREGNANCY. PT UNDERWENT LAPAROSCOPIC REMOVAL OF THE ECTOPIC PREGNANCY THE NEXT DAY. PATHOLOGY REPORT SHOWED CHRONIC VILLI, CONFIRMING THE DIAGNOSIS. THE OPERATIVE REPORT DID NOT MENTION STATUS OF THE ESSURE MICRO-INSERTS. PT DID NOT HAVE ANY OPERATIVE OR POST-OPERATIVE COMPLICATIONS. PHYSICIAN PLANS TO SCHEDULE THE PT FOR FOLLOW UP HSG. RESULTS STILL PENDING.

Manufacturer Narrative (H10):

LABELING FOR THE ESSURE DEVICE STATES PT CANNOT RELY ON THE ESSURE DEVICES UNTIL THE HSG CONFIRMATION TEST HAS BEEN COMPLETED AND RESULTS DEMONSTRATE PROPER DEVICE LOCATION AND BILATERAL TUBAL OCCLUSION. IN THIS CASE, THE PT FAILED TO COMPLETE THE HSG AND

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5003698	CONCEPTUS	9/6/2007	9/18/2007

Event Information:

Event Date (B3): 9/6/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT HAD ESSURE PLACED IN 2006 BY ANOTHER PHYSICIAN IN ANOTHER GYN PRACTICE. ONE SPRING PASSED VAGINALLY SPONTANEOUSLY ABOUT 4-6 WEEKS AFTER THE SPRINGS WERE PLACED. SHE CAME TO SEE ME FOR MENORRHAGIA IN 2007. ENDOMETRIAL BIOPSY REVEALED ENDOMETRIAL POLYPS, SO A SALINE SONOGRAM -HYSTEROSONOGRAM- WAS PERFORMED. THIS REVEALED NO POLYPS, BUT SHOWED PROTRUSION OF THE DEVICE INTO THE ENDOMETRIUM BY 2-3 CM. IN MY OPINION, THE MENORRHAGIA IS EITHER CAUSED BY THE POLYPS -NOW REMOVED VIA BIOPSY- OR DISRUPTION OF THE ENDOMETRIUM BY THE PROTRUSION OF THE DEVICE. THE MFR'S PHONE REP "JENNIFER" WAS NOT ABLE TO RECOMMEND A COURSE OF ACTION FOR ME AT THIS POINT, AND WAS UNABLE TO TELL ME IF THE PROTRUDING TAIL CAN BE CUT OFF HYSTEROSCOPICALLY. DATES OF USE: 2006 - 2007. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	9/17/2007	10/16/2007

Event Information:

Event Date (B3): 9/6/2007 **Report Date (B4): 9/17/2007** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 624472

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WAS ADVANCED THROUGH THE OSTIA TO ABOUT 3/4'S OF ITS LENGTH AND AT THAT TIME, RESISTANCE WAS FELT. A HYSTEROSCOPE WAS USED TO STRAIGHTEN THE DEVICE. THEN ANOTHER ATTEMPT WAS MADE TO ADVANCE THE ESSURE FURTHER INTO THE OSTIA WITH MORE RESISTANCE FELT. THE HANDLE WAS TURNED TO ALLOW THE DEVICE TO EXPAND. THEN THE ESSURE DEVICE WAS REMOVED, BUT THE COIL WAS NOTED TO REMAIN IN THE TUBE AND WAS PROTRUDING INTO THE UTERINE CAVITY. THIS WAS GRASPED WITH THE GRASPER TO REMOVE IT. AT THAT TIME, THE ESSURE COIL BROKE INTO MULTIPLE PIECES, AND THESE WERE REMOVED WITH DIRECT VISUALIZATION USING A GRASPER. A VERY SMALL PIECE REMAINED INSIDE OF THE TUBAL OSTIA (ABOUT 3 MM), AND ATTEMPTS TO REMOVE IT WERE UNSUCCESSFUL. BECAUSE OF THE DEVICE ISSUE, A DECISION WAS MADE TO PROCEED WITH LAPAROSCOPIC TUBAL LIGATION. THE PATIENT TOLERATED THE PROCEDURE WELL AND WAS DISCHARGED HOME WITHOUT COMPLICATIONS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00008	CONCEPTUS, INC.	9/21/2007	11/15/2007

Event Information:

Event Date (B3): 8/20/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/28/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PHYSICIAN REPORTED TO A CONCEPTUS REPRESENTATIVE THAT HIS PATIENT WITH AN ESSURE PLACEMENT IN 2006 HAD REPORTED INTERMITTENT PELVIC PAIN AND BLEEDING SINCE HAVING THE PROCEDURE DONE. IN 2007, THE PATIENT REPORTED TO THE OFFICE WITH CONTINUED POST-PROCEDURE PAIN AND BLEEDING. A PELVIC ULTRASOUND WAS SCHEDULED; THE PATIENT DID NOT FOLLOW UP. AS WELL, THE 3 MONTH POST-PLACEMENT CONFIRMATION TEST/HSG WAS NEVER PERFORMED TO DEMONSTRATE BOTH BILATERAL TUBAL OCCLUSION AND SATISFACTORY LOCATION OF THE MICRO-INSERTS AS PER THE IFU. ON SEVEN MONTHS LATER, THE PATIENT ELECTED TO UNDERGO A DIAGNOSTIC LAPAROSCOPY AND HYDROTUBATION WHICH SHOWED THE RIGHT MICRO-INSERT TO BE WITHIN THE TUBE, BUT BENT IN HALF. NO PERFORATION OF THE TUBE WAS EVIDENT AND THE TUBE APPEARED TO BE OCCLUDED. DUE TO THE PATIENT'S SYMPTOMS AND MISORIENTATION OF THE RIGHT MICRO-INSERT, THE PHYSICIAN SCHEDULED SURGERY FOR THE FOLLOWING MONTH. THE PATIENT UNDERWENT AN EXPLORATORY LAPAROTOMY AND HAD THE RIGHT MICRO-INSERT REMOVED VIA RIGHT CORNUAL RESECTION. NO OTHER PATHOLOGY WAS FOUND TO BE CONTRIBUTING TO HER SYMPTOMS AND THE PHYSICIAN BELIEVES THE OTIOLOGY OF THE PAIN WAS RELATED TO THE DEVICE. THE PATIENT IS SCHEDULED FOR A POST OPERATIVE EXAM ON SIXTEEN DAYS LATER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

ADDITIONAL INFORMATION MAY BE AVAILABLE AFTER POST OPERATIVE EXAM.

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00009	CONCEPTUS, INC.	9/21/2007	11/15/2007

Event Information:

Event Date (B3): 8/20/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/26/2007
Explant Date (E7): 8/20/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PHYSICIAN REPORTED TO A CONCEPTUS REPRESENTATIVE THAT HIS PATIENT WITH AN ESSURE PLACEMENT IN 2007 HAD CRAMPING AND WORSENING PAIN FOR TWO WEEKS POST-PROCEDURE. THE PATIENT WAS NOT TESTED WITH ANY PAIN MEDICATION AND HAD NO HISTORY OF PELVIC PROBLEMS. THE PHYSICIAN STATED THAT SHE TOOK THE PATIENT INTO THE OR ON THE FOLLOWING MONTH AND NOTED THAT MOST OF THE RIGHT MICRO-INSERT HAD PERFORATED THROUGH THE TUBE. THE DEVICE WAS REMOVED AND A BILATERAL TUBAL LIGATION WAS PERFORMED. ALSO NOTED BY THE PHYSICIAN AT THE TIME OF THE SURGERY WAS A SMALL AMOUNT OF FILMY ADHESIONS TO THE OMENTUM THAT NEED MINIMAL DISSECTION, OTHERWISE THE PROCEDURE WAS UNCOMPLICATED. THE PATIENT WAS KEPT OVERNIGHT FOR OBSERVATION AND IS REPORTED TO BE DOING WELL. THERE WAS NO FEVER OR INFECTION NOTED WITH THE PATIENT.

Manufacturer Narrative (H10):

PERFORATIONS OF THE UTERUS OR FALLOPIAN TUBES WERE OBSERVED IN THE ESSURE SYSTEM CLINICAL TRIALS AT A RATE OF 2.9% (6/206) IN THE PHASE II TRIAL AND 1.1% (5/476) IN THE PIVOTAL TRIAL. THE RATE OF REPORTED PERFORATIONS IN COMMERCIAL USE IS LOWER THAN REPOR

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00010	CONCEPTUS, INC.	9/21/2007	11/15/2007

Event Information:

Event Date (B3): 8/16/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 8/16/2007
Explant Date (E7): 9/13/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PHYSICIAN REPORTED TO A CONCEPTUS REPRESENTATIVE, THAT HER PATIENT COMPLAINED OF PELVIC AND/OR ABDOMINAL PAIN SINCE HAVING THE ESSURE PROCEDURE IN 2007. THE PHYSICIAN TREATED THE PATIENT WITH PAIN AND LATER SENT THE PATIENT FOR A HSG WHICH SHOWED THE MICRO-INSERTS WITH GOOD BILATERAL PLACEMENT. ON 9/7/07, THE PHYSICIAN FOLLOWED UP WITH A CONCEPTUS REPRESENTATIVE AND INDICATED THAT THE PATIENT WAS STILL EXPERIENCING PAIN. A CONCEPTUS CONSULTING PHYSICIAN DISCUSSED WITH THE REPORTING PHYSICIAN TREATING THE PATIENT SYMPTOMATICALLY FIRST AND AWAITING RESOLUTION OF THE ABDOMINAL DISCOMFORT/PAIN PRIOR TO A DECISION TO REMOVE THE MICRO-INSERTS. ON 9/13/07, THE PHYSICIAN REPORTED SUCCESSFULLY REMOVING BOTH MICRO-INSERTS VIA LAPAROSCOPY. NO SIGNS OF INFLAMMATION OR INFECTION WERE NOTED BY THE PHYSICIAN DURING THE PROCEDURE AND A BILATERAL TUBAL LIGATION WAS PERFORMED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	10/17/2007	11/15/2007

Event Information:

Event Date (B3): 10/5/2007 **Report Date (B4): 10/17/2007** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): 624470

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE TIP OF THE ESSURE INSERTER FELL OFF BEFORE EVEN ATTEMPTING TO USE IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5004299	CONCEPTUS INC.	10/31/2007	11/14/2007

Event Information:

Event Date (B3): 10/19/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 621668

Single Use:
Implant Date (E6):
Explant Date (E7): 10/19/2007
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING ESSURE HYSTEROSCOPIC STERILIZATION, THE DEVICE FOR THE RIGHT FALLOPIAN TUBE DID NOT DEPLOY PROPERLY -DEVICE MALFUNCTION-. NO HARM TO PT BUT PRODUCT WAS RETRIEVED AND ANOTHER DEPLOYED SUCCESSFULLY.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	11/19/2007	12/17/2007

Event Information:

Event Date (B3): 9/6/2007 **Report Date (B4): 11/19/2007** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): 624482

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PER THE OPERATIVE REPORT: THE ESSURE COIL WAS LOADED APPROPRIATELY THROUGH THE OPERATING SCOPE UNTIL IT CAME INTO VIEW OF THE CAMERA. THE COIL WAS THEN PLACED AT THE BASE OSTIA AND APPEARED TO GO TO THE LEVEL OF BLACK ON THE COIL. THE SHEATH WAS RATCHETED BACK UNTIL IT STOPPED. AT THIS POINT, THE ORANGE ASPECT OF THE COIL WAS UNABLE TO BE VISUALIZED AND BY ROTATING THE CAMERA. IT BECAME APPARENT THAT THE COIL DID NOT SEEM TO BE WELL WITHIN THE FALLOPIAN TUBE. AS A RESULT, IT WAS BROUGHT BACK WITH SOME DIFFICULTY NOTING THAT THE VERY DISTAL ASPECT OF THE COIL APPEARED TO BE SOMEWHAT DISPLACED. AFTER A NEW ESSURE DEVICE WAS LOADED INTO THE HYSTEROSCOPE, THE SCOPE WAS PLACED UPRIGHT TO OPEN THE OSTIA AND THIS COIL THREADED TO THE OSTIA WITHOUT DIFFICULTY. IT WAS THREADED UP TO THE MID LEVEL OF THE BLACK. THE SHEATH WAS RATCHETED BACK WITHOUT DIFFICULTY. THE ORANGE ASPECT OF THE CATHETER WAS WELL NOTED AND BROUGHT APPROXIMATELY 5 TO 7 MM OUT FROM THE OPENING IN THE OSTIA. THE BUTTON ON THE DEVICE WAS THEN DEPLOYED WITH A CLICK AND THE REST OF THE DEVICE WAS RATCHETED BACK. THE APPROXIMATELY 3 COILS THAT WERE OUTSIDE THE OSTIA, APPEARED TO SPRING OPEN. AFTER APPROXIMATELY 20 SECONDS, THE HANDLE WAS ROTATED COUNTER-CLOCKWISE IN ATTEMPT TO UNTWIST THE DEVICE. AFTER A RELATIVELY LONG TIME OF TWISTING, THE DEVICE WAS NOT ABLE TO BE DETACHED. EXAMINATION OF THE OSTIA AND UTERINE CAVITY REVEALED THAT THE ESSURE COIL HAD TORQUED AROUND ON ITSELF, AND HAD EXTRACTED ITSELF FROM THE OSTIA. THE COILS OF THE DEVICE DID NOT APPEAR TO HAVE SPRUNG OPEN. AFTER CONSULTATION BY PHONE WITH THE REPRESENTATIVE FROM CONCEPTUS, THE DECISION WAS MADE TO PULL BACK ON THE CAMERA AND TO ALLOW FOR REMOVAL OF THE COIL. AT THIS POINT, THE HANDLE DETACHED FROM THE COIL ITSELF. BLUNT GRASPER WAS THEN PLACED BACK DOWN THROUGH THE HYSTEROSCOPE AND USED TO

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GRASP THE COIL AND WITH GENTLE TRACTION, REMOVE THE COIL. THE DECISION TO REMOVE THE COIL WAS UNDERTAKEN BECAUSE AT LEAST 18 UNSPRUNG COILS WERE NOTED OUTSIDE THE OSTIA.MANUFACTURER RESPONSE FOR BIRTH CONTROL SYSTEM, ESSURE: MEETING WITH DEVICE REPRESENTATIVE SET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5004614	CONCEPTUS, INC.	12/4/2007	12/17/2007

Event Information:

Event Date (B3): 12/4/2007 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESSE03
Catalog # (E4):
Lot #(E4): 625503

Single Use:
Implant Date (E6): 12/4/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER INSERTION OF THE ESSURE DELIVERY SYSTEM INTO THE RIGHT FALLOPIAN TUBE, THE RELEASE MECHANISM DID NOT RELEASE THE CATHETER PROPERLY. NITINOL COIL WAS NOT RELEASED COMPLETELY INTO THE DISTAL PORTION OF TUBE. COILING APPEARED STRETCHED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/10/2007	1/9/2008

Event Information:

Event Date (B3): 11/6/2007 **Report Date (B4): 12/10/2007** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 621803

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO ESSURE DEVICES DID NOT DEPLOY WHEN FIRED. PATIENT HAS TO HAVE A LAPARASCOPIC BILATERAL TUBAL LIGATION INSTEAD.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00011	CONCEPTUS, INC.	12/12/2007	5/6/2008

Event Information:

Event Date (B3): 11/12/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 305
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/8/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE CONCEPTUS REP REPORTED ON 11/12/2007 THAT THE PHYSICIAN PERFORMED THE ASSURE PLACEMENT PROCEDURE FOUR DAYS EARLIER. PHYSICIAN ATTEMPTED PLACEMENT OF ONE DEVICE, BUT PERFORATED THE UTERUS DURING THE PROCEDURE. BOTH SHE AND THE PT WERE NOT AWARE OF ACTIVE PID AT THE TIME OF THE PROCEDURE, UNTIL CHANGES CONSISTENT WITH PID WERE NOTED DURING THE HYSTEROSCOPY. THERE WAS LOSS OF DISTENTION AND FLUID SO THE CASE WAS ABORTED. THE PHYSICIAN REPORTED THAT THE UTERUS WAS VERY FRAGILE AND "CRUMBLY" CONSISTENT WITH PID. THE PT WAS OBSERVED THEN DISCHARGED HOME IN GOOD CONDITION. THE FOLLOWING DAY THE PT RETURNED TO THE HOSPITAL VIA THE ER. SHE WAS COMPLAINING OF SEVERE PAIN. SHE WAS ADMITTED AND FOUND TO HAVE PERITONITIS. THE PHYSICIAN PERFORMED A SUPRA-CERVICAL HYSTERECTOMY ON THE SAME DAY, AND THE PT WAS TREATED SUCCESSFULLY WITH IV ANTIBIOTICS. OUR CONSULTING PHYSICIAN WAS CONTACTED REGARDING THIS CASE, AND HE AGREES WITH THE MGMT OF THIS PT. THE PHYSICIAN REPORTED THAT THE PT RETURNED TO THE OFFICE FOR HER POST-OPERATIVE VISIT AND PRESENT WITH DEHISCENCE OF HER ABDOMINAL WOUND WHICH REQUIRED SURGICAL REPAIR BY A GENERAL SURGEON. THE PT IS SCHEDULED FOR ONE MORE POST-OPERATIVE VISIT. INFO WILL BE ADDED AS IT IS RECEIVED TO COMPLETE THIS INVESTIGATION.

Manufacturer Narrative (H10):

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ADDITIONAL INFO WILL BE AVAILABLE AFTER THE LAST POST OPERATIVE IS COMPLETED.

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2007-00012	CONCEPTUS, INC.	12/12/2007	6/10/2008

Event Information:

Event Date (B3): 11/16/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2004
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PATIENT STATES SHE HAD ESSURE PLACED IN 2004 BY ANOTHER PHYSICIAN. NO POST-ESSURE HSG AVAILABLE. SHE HAD BEEN COMPLAINING OF PELVIC PAIN FOR SOME TIME SO WENT TO ANOTHER PHYSICIAN FOR A SECOND OPINION. A PELVIC ULTRASOUND SHOWED ONLY ONE DEVICE ON THE RIGHT SIDE, AND THE DEVICE APPEARED TO BE PERFORATED. THE PHYSICIAN PERFORMED A HYSTEROSCOPY AND LAPAROSCOPY TO EVALUATE THE PELVIC PAIN AND ESSURE DEVICE ON THE RIGHT. THE PATIENT'S ANATOMY APPEARED NORMAL DURING LAPAROSCOPY, NO DEVICES WERE SEEN PERFORATED OUT OF THE FALLOPIAN TUBES OR UTERUS, NOR COULD HE IDENTIFY ANY PATHOLOGY TO EXPLAIN THE CAUSE OF HER PELVIC PAIN. HE THEN PERFORMED HYSTEROSCOPY AND NOTED THE DEVICE ON THE RIGHT TO BE PARTIALLY EMBEDDED IN THE MYOMETRIUM AND THE REMAINDER TRAILING INTO THE UTERINE CAVITY. HE WAS ABLE TO REMOVE THE ENTIRE DEVICE SUCCESSFULLY WITH GRASPERS. NO DEVICE ON THE LEFT SUGGESTED A PREVIOUS EXPULSION OF THE ESSURE MICRO-INSERT. DURING SURGERY, HE INJECTED SOME DYE INTO THE UTERINE CAVITY TO CHECK FOR TUBAL PATENCY; IT APPEARED THE TUBES WERE OCCLUDED. OF NOTE, HE DID NOT PERFORM A LAP TUBAL AS PATIENT STATES SHE DESIRES TO CONCEIVE AGAIN. POST-OPERATIVELY SHE HAS RECOVERED AND STATES THE PAIN HAS RESOLVED. THE PHYSICIAN STATES THAT IN HIS OPINION, THE PAIN WAS DIRECTLY RELATED TO THE PERFORATED ESSURE DEVICE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00001	CONCEPTUS, INC.	1/8/2008	4/25/2008

Event Information:

Event Date (B3): 12/7/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS 205
Catalog # (E4): UNK
Lot #(E4): 623193

Single Use: Y
Implant Date (E6): 9/2/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS PHYSICIAN REPORTED ON 12/6/07, THAT HE WAS GOING TO REMOVE THE ESSURE MICRO-INSERTS THE NEXT DAY DUE TO PERSISTENT PAIN, THIS PT EXPERIENCED AFTER HAVING THEM PLACED IN 2007. THE PHYSICIAN EVALUATED THE PAIN WITH PELVIC EXAMINATIONS WHICH WERE NORMAL, AND A CT SCAN WHICH SHOWED THE MICRO-INSERTS TO BE PROPERLY LOCATED WITHIN THE RESPECTIVE FALLOPIAN TUBES. A WHITE BLOOD CELL COUNT WAS NORMAL. THE DAY AFTER SURGERY, HE REPORTED BOTH MICRO-INSERTS WERE REMOVED LAPARASCOPICALLY WITHOUT DIFFICULTY; THEY APPEARED NORMAL IN THE RIGHT LOCATION WITHOUT ANY INFLAMMATION. THERE WAS NO PATHOLOGY HE COULD FIND TO EXPLAIN THE PELVIC PAIN. HE PERFORMED A D&C, HYSTERECTOSCOPY AND LAPAROSCOPY. HE REPORTED TO CONCEPTUS ON 1/7/08 VIA FAX, THAT DURING HER POST OPERATIVE VISIT 2 WEEKS LATER, HER SYMPTOMS WERE MUCH IMPROVED AND PAIN SEEMED TO BE RESOLVED, BUT HE WOULD CONTINUE TO MONITOR HER. THIS PHYSICIAN FEELS THE PAIN WAS ESSURE RELATED AS HE COULD NOT FIND ANY OTHER PATHOLOGY TO EXPLAIN HER SYMPTOMS.

Manufacturer Narrative (H10):

ADD'L INFO WILL BE ADDED IF PHYSICIAN SENDS A PATHOLOGY REPORT INFO AND ANY INFO FROM ADD'L POST OPERATIVE VISITS.

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Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	1/10/2008	1/29/2008

Event Information:

Event Date (B3): 11/16/2007 **Report Date (B4): 1/10/2008** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 624831

Single Use:
Implant Date (E6): 11/16/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

UTERINE PERFORATION. THE ESSURE DEVICE WAS INSERTED. WHEN TRYING TO ADVANCE IT INTO A BLACK POSITIONING MARKER, IT POPPED OUT. A SECOND ATTEMPT WAS MADE. IT POPPED OUT AGAIN. IT WAS GOING THROUGH A FALSE CHANNEL. WHILE WATCHING IT, THE COILS WENT THROUGH, FURTHER INTO THE LESION AND THEN A PERFORATION WAS RECOGNIZED. PERFORATION SUTURED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	1/28/2008	2/1/2008

Event Information:

Event Date (B3): 12/21/1997 **Report Date (B4): 1/28/2008** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WHILE USING MORCELLATOR DURING PROCEDURE, A SMALL SPRING FELL OFF INTO PTS ABDOMINAL CAVITY. DR REMOVED PIECE PLACED IN SPECIMEN CONTAINER. DEVICE ORIGINALLY GIVEN TO ETHICON REPRESENTATIVE AND THEY INFORMED US THAT THE SPRING WAS NOT FROM THEIR MORCELLATOR. INSTEAD IT WAS THE SPRING FROM ESSURE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	2/1/2008	2/19/2008

Event Information:

Event Date (B3): 1/29/2008 **Report Date (B4): 2/1/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): 624488

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE COIL FAILED TO DEPLOY. IT WAS REMOVED FROM THE FIELD. A DIFFERENT DEVICE WAS OBTAINED AND USED TO COMPLETE THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00002	CONCEPTUS, INC.	2/27/2008	9/2/2008

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO DAYS AFTER UNCOMPLICATED ESSURE PROCEDURE, PT WITH NO PRIOR HISTORY OF CHRONIC PELVIC PAIN REPORTED RIGHT-SIDED CRAMPING AND WAS TREATED WITH ORAL NSAIDS. TWENTY DAYS AFTER PROCEDURE, PT RETURNED TO PHYSICIAN WITH FURTHER COMPLAINTS OF BILATERAL PELVIC PAIN AND FAIRLY CONSTANT "POKING" PAIN RADIATING TO HER RIGHT LEG. UNREMARKABLE PHYSICAL EXAMINATION, NO FEVER, DISCHARGE OR VAGINAL BLEEDING. ULTRASOUND WAS NOTABLE FOR PROPER MICRO-INSERT LOCATION AND SUGGESTED A HYDROSALPINX. FLAT-PLATE X-RAY WAS UNREMARKABLE. PT WAS TREATED WITH DOXYCYCLINE FOR 10 DAYS AND REQUIRED ORAL NARCOTIC PAIN RELIEF. TEN WEEKS AFTER PROCEDURE, PT UNDERWENT LAPAROSCOPY FOR EVALUATION AND TREATMENT OF PAIN. AT TIME OF SURGERY, MICRO-INSERTS WERE FOUND TO BE PROPERLY PLACED WITH NO EVIDENCE OF PERFORATION OR PATHOLOGY. BILATERAL SALPINGECTOMY PERFORMED. FINAL TISSUE PATHOLOGY SHOWED NO DIAGNOSTIC ABNORMALITY AND GROSSLY UNREMARKABLE MICRO-INSERTS. THE PT'S POSTOPERATIVE COURSE WAS UNREMARKABLE AND PAIN WAS RESOLVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5005737	CONCEPTUS	2/28/2008	3/13/2008

Event Information:

Event Date (B3): 2/27/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE 305
Model # (E4): ESSURE 305
Catalog # (E4):
Lot #(E4): 626164

Single Use:
Implant Date (E6): 2/27/2008
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/27/2008

Event Description (B5):

NEW ESSURE DEVICE FROM CONCEPTUS. PATIENT ELECTED HYSTEROSCOPIC STERILIZATION. REP FROM CONCEPTUS PRESENT AND ASSISTING IN PROBLEM SOLVING ENTIRE CASE. INITIAL DIFFICULTY WITH TUBAL SPASM ON RIGHT, BUT ABLE TO ADEQUATELY CANNULATE. DEVICE WHEEL AFTER 2-3 THUMBWHEELS BECAME INCREASINGLY DIFFICULT TO WHEEL AND REQUIRED FORCE THAT WORE THROUGH A LATEX SURGICAL GLOVE. FINALLY ABLE TO WHEEL TO HARD STOP, PRESSED BUTTON AND UNABLE TO THUMBWHEEL FURTHER. DEVICE ATTEMPTED TO BE REMOVED, BUT WAS PARTIALLY EXPANDED IN TUBE. WOULD NOT RELEASE DEVICE FROM INTRODUCER, NOR WAS I ABLE TO PULL THE DEVICE FROM THE TUBE. INTERNAL COIL UNWOUND TO A LENGTH OF 2CM INTO UTERUS. PER MY EXAM AND THE EXAMINATION OF THE REMOVED PORTION OF THE DEVICE BY MYSELF AND THE CONCEPTUS REP, IT WAS HER OPINION THAT THERE APPEARED TO BE ENOUGH COIL TO CAUSE TUBAL SCARRING, SO PROCEEDED TO LEFT SIDE, WHERE THE SAME OCCURRENCE HAPPENED MINUS THE TUBAL SPASM, THIS TIME THE INTERNAL COIL STRETCHING THE ENTIRE LENGTH OF THE UTERUS. NOT ABLE TO REMOVE OR CUT WIRE WITH HYSTEROSCOPIC SCISSORS. CONVERTED TO LAPAROTOMY TO PERFORM FILSHIE CLIP STERILIZATION. MULTIPLE PRIOR LAPAROTOMIES AND MORBID OBESITY. DATES OF USE: DEVICE IMPLANTED. ONE DAY IN 2008. DIAGNOSIS OR REASON FOR USE: UNDESIRED FERTILITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00003	CONCEPTUS, INC.	2/29/2008	9/2/2008

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED A CORNUAL ECTOPIC PREGNANCY POST-ESSURE PLACEMENT WHICH REQUIRED SURGERY. PHYSICIAN REPORTED THAT HSG SHOWED TUBAL OCCLUSION. SEVERAL ATTEMPTS WERE MADE TO OBTAIN FURTHER INFO FROM PHYSICIAN, BUT NO RESPONSE WAS RECEIVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00004	CONCEPTUS, INC.	2/29/2008	9/3/2008

Event Information:

Event Date (B3): 2/7/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT PT WHO HAD UNDERGONE THE ESSURE PROCEDURE, 6-8 WEEKS POSTPARTUM BY ANOTHER PHYSICIAN REPORTED PAIN IN 2008. PT REQUESTED MICRO-INSERT REMOVAL. ON THE NEXT DAY, PT UNDERWENT LAPAROSCOPY. LEFT ESSURE MICRO-INSERT WAS REMOVED INTACT. THE RIGHT MICRO-INSERT OUTER COIL WAS REMOVED BUT INNER COIL COULD NOT BE LOCATED. U/S WAS DONE AND INNER COIL WAS LOCATED. PT REPORTED THAT THE PAIN ON HER LEFT SIDE HAD RESOLVED POST-OPERATIVELY. ON NINETEEN DAYS LATER, PHYSICIAN REPORTED THAT THE PT UNDERWENT HYSTERECTOMY ON FIFTEEN DAYS AFTER THE ORIGINAL DATE, AND HER PAIN HAS RESOLVED. PATHOLOGY SHOWED THAT THE INNER COIL WAS PROPERLY LOCATED IN HER RIGHT FALLOPIAN TUBE AND THAT NO ABNORMAL PATHOLOGY WAS NOTED ON REPORT. ALL PARTS OF BOTH MICRO-INSERTS WERE REMOVED FROM THE PT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00005	CONCEPTUS, INC.	3/3/2008	11/7/2008

Event Information:

Event Date (B3): 2/22/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT WHO HAD UNDERGONE THE ESSURE PROCEDURE IN 2007, REPORTED PERSISTENT RIGHT LOWER QUADRANT PAIN TO HER PHYSICIAN NINE MONTHS LATER. NO OTHER SYMPTOMS WERE REPORTED. PT HAD NORMAL THREE MONTHS HSG. PT REQUESTED MICRO-INSERT REMOVAL IN 2008. THE FOLLOWING MONTH, PHYSICIAN REPORTED THAT SHE REMOVED THE RIGHT MICRO-INSERT THREE DAYS PRIOR. PHYSICIAN STATED THAT THE ANATOMY LOOKED NORMAL AND THE IMPLANT APPEARED TO BE IN THE PROPER LOCATION. PHYSICIAN STATED THAT SHE IS NOT CONVINCED THAT THE PT'S PAIN WAS DUE TO THE MICRO-INSERT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00006	CONCEPTUS, INC.	4/3/2008	5/5/2009

Event Information:

Event Date (B3): 3/11/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MICRO-INSERTS WERE PLACED IN 2007, WITHOUT COMPLICATIONS DURING THE PROCEDURE; FOLLOW UP 3 MONTHS HSG SUGGESTED PROPERLY LOCATED MICRO-INSERTS WITH TUBAL OCCLUSION. THE PATIENT DEVELOPED PAIN IN 2008, AND DUE TO CONTINUED PERSISTENT PAIN, PHYSICIAN PERFORMED A LAPAROSCOPY THE FOLLOWING MONTH. BOTH MICRO-INSERTS MAY HAVE PERFORATED THE FALLOPIAN TUBES. PHYSICIAN REMOVED BOTH MICRO-INSERTS AND PERFORMED A PARTIAL SALPINGECTOMY ON THE LEFT SIDE. LAPAROSCOPIC TUBAL WAS ALSO PERFORMED. AT THE 2-WEEK POST-OPERATIVE VISIT PATIENT STILL COMPLAINED OF PAIN. PHYSICIAN DOES NOT FEEL THAT THE ESSURE MICRO-INSERTS ARE THE CAUSE OF PATIENT'S PAIN. HE COULD NOT IDENTIFY ANY OTHER PATHOLOGY FOR PATIENT'S PAIN DURING THE LAPAROSCOPY, BUT DID STATE SHE IS HAVING OTHER PROBLEMS WITH HER URINARY TRACT THAT WILL ALSO BE EVALUATED AS A POSSIBLE CAUSE OF HER PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	4/17/2008	8/18/2011

Event Information:

Event Date (B3): 4/9/2008 **Report Date (B4): 4/15/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS ESSURE COIL
Device Type (E2): ESSURE - COIL FOR STERILIZATION
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626160

Single Use:
Implant Date (E6):
Explant Date (E7): 9/1/2009
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 4/9/2008

Event Description (B5):

DURING DEPLOYMENT, COIL BROKE OFF FROM AREA OF DEVICE. COIL AND BROKEN PIECE OF METAL REMOVED BY SURGEON. PRODUCT DID GO TO MFR REP FOR EVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00009	CONCEPTUS, INC.	5/16/2008	5/5/2009

Event Information:

Event Date (B3): 4/23/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): 626159

Single Use: Y
Implant Date (E6): 4/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MICRO-INSERTS WERE PLACED WITH NO ABNORMAL EVENTS. AFTER APPROX TWO WEEKS, PT COMPLAINED OF SPOTTING, CRAMPING AND LEFT SIDE PAIN. A FLAT PLATE X-RAY AND HSG SUGGESTED PROPER LOCATION OF MICRO-INSERTS. PT REQUESTED DEVICE REMOVAL. SURGERY OCCURRED IN 2008. LEFT ESSURE MICRO-INSERT WAS REMOVED; RIGHT MICRO-INSERT WAS NOT REMOVED. FOLLOWING SURGERY AND RECOVERY, PT HAD COMPLETE RESOLUTION OF HER PAIN AND BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00008	CONCEPTUS, INC.	5/16/2008	5/12/2009

Event Information:

Event Date (B3): 10/10/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MICRO-INSERTS WERE PLACED POST PARTUM. PT STARTED TO EXPERIENCE SEVERE PAIN AND HAD THEM REMOVED BY ANOTHER PHYSICIAN. NO INFO WAS ABLE TO BE OBTAINED FROM THE PHYSICIAN WHO REMOVED THE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00007	CONCEPTUS, INC.	5/16/2008	11/13/2009

Event Information:

Event Date (B3): 4/1/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): 624838

Single Use: Y
Implant Date (E6): 2/15/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MICRO-INSERTS WERE PLACED IN 2008. THREE DAYS LATER, THE PT STARTED TO EXPERIENCE SEVERE LOWER BACK PAIN. A FLAT PLATE X-RAY SUGGESTED THAT THE DEVICE SEEMS TO HAVE SEPARATED/BROKEN ON ONE SIDE. AN HSG SHOWED A PERFORATION AND A DETACHMENT OF A PORTION OF THE MICRO-INSERT. TWO MONTHS LATER, PHYSICIAN INFORMED FIELD REP THAT MICRO-INSERTS WERE REMOVED; NO FURTHER DETAILS ON DATE, OUTCOME OR RESOLUTION OF SYMPTOMS WERE GIVEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00011	CONCEPTUS, INC.	5/22/2008	5/6/2009

Event Information:

Event Date (B3): 3/18/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS205
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS A PT WITH POST PROCEDURAL PAIN SINCE HAVING ESSURE PLACED IN 2008. SHE WAS EVALUATED WITH PELVIC EXAM AND CULTURES WHICH DIAGNOSED GONORRHEA. SHE WAS TREATED WITH ANTIBIOTIC THERAPY AND PAIN SUBSIDED, BUT DID NOT COMPLETELY RESOLVE. A FLAT PLATE OF THE ABDOMEN WAS OBTAINED CONFIRMING A COMPLETE EXPULSION OF THE RIGHT MICRO-INSERT AND A NORMAL APPEARING LEFT MICRO-INSERT. PHYSICIAN REMOVED THE LEFT MICRO-INSERT. NO FURTHER INFO HAS BEEN PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00010	CONCEPTUS, INC.	5/22/2008	11/13/2009

Event Information:

Event Date (B3): 1/22/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS205
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/24/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD CONCURRENT ESSURE PROCEDURE AND IMPLANON REMOVAL ON (B) (6) 2007. BOTH OSTIA VISUALIZED WELL AND 4 TRAILING COILS NOTED ON BOTH SIDES. AFTER THE PROCEDURE, PATIENT PRESENTED DIFFERENT SYMPTOMS: NAUSEA, SHIVERING, AND DISCOMFORT, SOMETIMES ASSOCIATED WITH ILIAC PAIN ON THE RIGHT SIDE. PATIENT ALSO HAD A NICKEL ALLERGY CONFIRMED. ON (B) (6) 2008, THE PATIENT HAD A HYSTEROSCOPY AND A LAPAROSCOPY TO REMOVE BOTH TUBES. RESULT FROM HYSTEROSCOPY: THE CAVITY APPEARS NORMAL. THE ENDOMETRIUM IS PALE, WITH SOME TISSUES. NO POLYPE, AND NOTHING ABNORMAL. A BIOPSY WAS DONE WITH A CURETTE. RESULT FROM LAPAROSCOPY: ABDOMINAL CAVITY EXPLORED WITH FOCUS ON THE RIGHT SIDE. THE UTERUS WAS SLIGHTLY GLOBULAR WITH 2 HEALTHY ADNEXA. NO GRANULATION, NO INFLAMMATORY REACTION, NO ADHESION, NO ENDOMETRIOSIS NOTED. A BILATERAL SALPINGECTOMY WAS DONE. ENDOMETRIAL BIOPSY SHOWED AN HYPERPLASIA POLYP IN A PROLIFERATIVE PHASE. THE RIGHT TUBE HAD NO MACROSCOPIC ABNORMALITIES; THE LEFT TUBE HAD NO INFLAMMATORY SIGNS. SMALL BILATERAL HYPERPLASIA NOTED, WITH ATYPICAL SIGN AND NO DYSPLASIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	5/23/2008	6/3/2008

Event Information:

Event Date (B3): 5/15/2008 **Report Date (B4): 5/23/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS 05
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 5/15/2008

Event Description (B5):

IMPROPERLY DEPLOYED ESSURE DEVICE IN THE RIGHT TUBAL OSTIA WITH SUCCESSFUL REMOVAL OF THE ENTIRE DEVICE PROMPTING CONVERSION TO LAPAROSCOPIC PROCEDURE. WITH THE RIGHT TUBE UNDER DIRECT VISUALIZATION THE ESSURE DEVICE WAS SLOWLY ADVANCED THROUGH THE TUBAL OSTIA. UPON TRYING TO RELEASE THE DEVICE PER MANUFACTURER'S SPECIFICATIONS, THE DEVICE DID NOT RELEASE PROPERLY. THE DEVICE WAS WITHDRAWN. THERE WAS SOME RESIDUAL WIRE LEFT WITHIN THE TUBE. THIS WAS GRASPED WITH A GRASPER AND REMOVED ENTIRELY. NO LASTING SEQUELAE FOR PATIENT. THE ESSURE SALES REP WAS PRESENT IN THE OR AND TOOK THE DEVICE. WE DO NOT HAVE KNOWLEDGE OF THE LOT NUMBER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00013	CONCEPTUS, INC.	6/16/2008	6/24/2008

Event Information:

Event Date (B3): 5/11/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/9/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED A PT WHO COMPLAINED OF SEVERE PELVIC PAIN TWO DAYS FOLLOWING ESSURE MICRO-INSERT PLACEMENT. NOVASURE ENDOMETRIAL ABLATION WAS PERFORMED PRIOR TO ESSURE PROCEDURE. PT WAS DIAGNOSED WITH UTERINE PERFORATION, BOWEL BURNS, AND A FOREIGN BODY IN THE PERITONEAL CAVITY (ESSURE MICRO-INSERT). PT UNDERWENT A BOWEL RESECTION, GALLBLADDER REMOVAL AND LAPAROSCOPIC BILATERAL TUBAL LIGATION. PT IS DOING WELL POST-OPERATIVELY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00014	CONCEPTUS, INC.	6/16/2008	5/12/2009

Event Information:

Event Date (B3): 3/1/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED A PATIENT WHO COMPLAINED OF DYSMENORRHEA AND DYSPAREUNIA. PATIENT UNDERWENT ESSURE PROCEDURE SIX WEEKS POSTPARTUM BY ANOTHER PHYSICIAN. PT DELIVERED VIA C-SECTION PRIOR TO PLACEMENT. HSG WAS REPORTED TO BE "NORMAL" BUT PHYSICIAN HAS NOT REVIEWED FILMS. PT UNDERWENT A LAPAROSCOPY IN 2008, WHICH SHOWED AN ENLARGED UTERUS AND ADENOMYOSIS. PT THEN UNDERWENT A HYSTERECTOMY 2008. PHYSICIAN DID NOT SEE ANY SIGN OF PERFORATION DURING THE HYSTERECTOMY. THE PATHOLOGY REPORT SHOWED NORMAL FINDINGS; PHYSICIAN BELIEVES THAT PAIN MAY HAVE BEEN RELATED TO ESSURE. PT'S PAIN RESOLVED FOLLOWING HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00012	CONCEPTUS, INC.	6/16/2008	11/16/2009

Event Information:

Event Date (B3): 6/4/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED A PT WHO WAS DIAGNOSED WITH AN ECTOPIC PREGNANT REQUIRING INTERVENTION APPROX 6-MONTHS POST-ESSURE MICRO-INSERT PLACEMENT. PT DID NOT RETURN FOR THE REQUIRED ESSURE CONFIRMATION TESTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	6/20/2008	7/1/2008

Event Information:

Event Date (B3): 6/12/2008 **Report Date (B4): 6/20/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM ESS305
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): 626287

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 6/12/2008

Event Description (B5):

ATTEMPTED TO DEPLOY ESSURE ON RIGHT SIDE, BUT DEVICE FAILED TO DEPLOY. PART OF GUIDEWIRE BROKE LOOSE, AND WAS RETRIEVED WITH GRASPER. MOVED TO LEFT SIDE, DEVICE WOULD NOT ADVANCE. PROCEDURE ABORTED AND LAP TUBAL DONE INSTEAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00015	CONCEPTUS, INC.	7/18/2008	8/7/2009

Event Information:

Event Date (B3): 6/3/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE DONE IN 2007; NO ABNORMAL EVENTS DURING PLACEMENT. HSG SHOWED PROPER PLACEMENT AND OCCLUSION. FOLLOWING THE HSG, PT BEGAN TO EXPERIENCE RIGHT SIDE PAIN WHICH INCREASED IN SEVERITY OVER TIME. PELVIC ULTRASOUND WAS PERFORMED WHICH SUGGESTED THAT THE RIGHT MICRO-INSERT WAS PERFORATED INTO THE MYOMETRIUM. PHYSICIAN NOTIFIED CONCEPTUS THAT THE PT OPTED FOR DEVICE REMOVAL DUE TO PAIN AND POSSIBLE PERFORATION. UPON HYSTEROSCOPY AND LAPAROSCOPY, THE DEVICES WERE FOUND TO BE IN NORMAL POSITION WITHIN THE FALLOPIAN TUBES AND NOT PERFORATED. THE PHYSICIAN PROCEEDED WITH BILATERAL SALPINGECTOMIES. THERE WAS INFLAMMATION, HYPERVASCULARITY AND POSSIBLE ENDOMETRIOSIS NOTED DURING LAPAROSCOPY. PHYSICIAN NOTED THAT IT IS STILL UNCLEAR WHY THIS PT HAD A SUDDEN ONSET OF RIGHT SIDE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00016	CONCEPTUS, INC.	7/28/2008	4/15/2009

Event Information:

Event Date (B3): 7/2/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE PERFORMED APPROX ONE YR AGO. HSG DOCUMENTED BILATERAL TUBAL OCCLUSION. PREGNANCY REPORTED BY PHYSICIAN IN 2008. AN ULTRASOUND REVEALED A SAC IN THE UTERUS WITHOUT THE PRESENCE OF A FETAL POLE. AT 2-3 WEEKS LATER, PT EXPERIENCED SIGNIFICANT BLEEDING, SO A SUPERCERVICAL HYSTERECTOMY WAS PERFORMED TO TREAT THE MENORRHAGIA THOUGHT TO BE ASSOCIATED WITH A BLIGHTED OVUM AND SAB. UPON LAPAROSCOPY, THE RIGHT DEVICE WAS FOUND TO BE PERFORATED AT THE CORNUA, AND THROUGH THE MYOMETRIUM. PT ALSO HAD A LARGE ECTOPIC THAT WAS REMOVED AT THIS TIME. PT WAS ASYMPTOMATIC REGARDING THE ECTOPIC PREGNANCY. PT IS DOING FINE POST-OP. FOLLOWING THE SURGERY, PHYSICIAN REVIEWED THE HSG FILMS, AND NOTED THAT THE RIGHT DEVICE WAS CLEARLY PERFORATED. THE HSG AND SURGICAL FINDINGS WERE CONSISTENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00017	CONCEPTUS, INC.	7/28/2008	5/1/2009

Event Information:

Event Date (B3): 6/29/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT A PT WHO HAD ESSURE PLACED IN 2006 PRESENTED WITH A COMPLAINT OF PERSISTENT PAIN. PHYSICIAN REMOVED BOTH MICROINSERTS VIA LAPAROSCOPY WITHOUT EVENT. NO FURTHER INFO PROVIDED BY PHYSICIAN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	7/31/2008	8/12/2008

Event Information:

Event Date (B3): 7/21/2008 **Report Date (B4): 7/31/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 626218

Single Use:
Implant Date (E6): 7/21/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE SURGEON IMPLANTED THE BIRTH CONTROL DEVICE AND THE DEVICE BROKE INSIDE THE UTERUS. ALL PIECES WERE RECOVERED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00019	CONCEPTUS, INC.	8/15/2008	5/5/2009

Event Information:

Event Date (B3): 7/31/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): N/A
Lot #(E4): 626812

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT A PATIENT WHO HAD ESSURE PLACED PRESENTED WITH A COMPLAINT OF PAIN IN THE LOWER QUADRANT SINCE PLACEMENT. PATIENT WAS HOSPITALIZED FOR PAIN MANAGEMENT. MICRO-INSERTS REMOVED VIA LAPAROSCOPY, BILATERAL SALPINGECTOMY. PATIENT WAS DOING BETTER POSTOPERATIVELY AND SENT HOME ON ORAL NARCOTICS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00018	CONCEPTUS, INC.	8/15/2008	11/18/2009

Event Information:

Event Date (B3): 8/5/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): N/A
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 2/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT PATIENT HAD PAIN WITH MENSES ONE MONTH POST-ESSURE PLACEMENT. INITIALLY, PAIN OCCURRED BEFORE AND DURING MENSES; IT THEN RECURRED INTERMITTENTLY. FLAT PLATE X-RAY APPEARED NORMAL. HSG IN 2008 SHOWED BILATERAL SATISFACTORY LOCATION OF THE MICRO-INSERTS AND BILATERAL TUBAL OCCLUSION. FOUR MONTHS LATER, CONSULTING PHYSICIAN NOTIFIED CONCEPTUS THAT HE WOULD REMOVE THE MICRO-INSERTS ON 08/05/08. PHYSICIAN REPORTED THAT BILATERAL SALPINGECTOMY WENT WELL AND THE MICRO-INSERTS WERE REMOVED INTACT. NO THER PATHOLOGY WAS REPORTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5008041	CONCEPTUS, INC.	8/19/2008	8/28/2008

Event Information:

Event Date (B3): 7/23/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6): 7/23/2008
Explant Date (E7): 7/28/2008
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE OUTSIDE PACKAGING FOR THE ESSURE DOES NOT NOTE A WARNING TO NOT UTILIZE THIS DEVICE WITH A PT WITH A ALLERGY TO NICKEL. IN ADDITION, THE INSIDE PACKAGING THAT HOLDS THE DEVICE DOES NOT WARN OF SUCH ALLERGY AS WELL. THE LOCATION OF THIS NOTIFICATION IS FOUND WITHIN THE PACKAGE FOUND INSIDE THE BOX, WHICH CAN BE MISSED OR DISCARDED PRIOR TO A PROCEDURE. IMPLANTABLE DEVICES SHOULD HAVE SPECIAL ATTENTION TO ALLERGIC REACTION ISSUES IN CLEARLY VISIBLE LOCATIONS WHERE BOTH THE OPERATOR AND CIRCULATING RN/SCRUB CAN SEE THEM PRIOR TO USAGE. DIAGNOSIS OR REASON FOR USE: PREVENTION OF UNWANTED FERTILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5008227	CONCEPTUS INC.	9/8/2008	9/16/2008

Event Information:

Event Date (B3): 7/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): 626219

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER DEPLOYMENT OF ESSURE DEVICES BY PELVIC X-RAY, IT APPEARED THAT ONLY PART OF DEVICE WAS IN LEFT TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00020	CONCEPTUS, INC.	9/9/2008	9/10/2009

Event Information:

Event Date (B3): 8/29/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT PRESENTED WITH AN ECTOPIC PREGNANCY DURING THE 3-MONTH ALTERNATIVE CONTRACEPTION PERIOD PRIOR TO HSG. PATIENT REPORTEDLY DID NOT USE ALTERNATIVE CONTRACEPTION DURING THIS TIME (NON-COMPLIANCE). PHYSICIAN TREATED WITH METHOTREXATE. PER ESSURE SYSTEM LABELING (PHYSICIAN'S INSTRUCTIONS FOR USE), THE PATIENT MUST BE INSTRUCTED TO USE ALTERNATIVE CONTRACEPTION UNTIL AN HSG CONFIRMS PROPER DEVICE LOCATION AND OCCLUSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00021	CONCEPTUS, INC.	9/9/2008	11/17/2009

Event Information:

Event Date (B3): 8/22/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS205
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/29/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE PERFORMED IN 2007. THE PROCEDURE WENT WELL WITH BILATERAL PLACEMENT BEING ACHIEVED. THE PATIENT RETURNED FOR HER HSG FIVE MONTHS LATER AND THE RADIOLOGIST REPORTED THAT DEVICES APPEARED TO BE IN THE CORRECT PLACE AND BOTH SIDES APPEARED TO BE OCCLUDED. IN 2008, THE PATIENT PRESENTED AT THE EMERGENCY ROOM WITH SEVERE PAIN. IT WAS DETERMINED THAT PATIENT HAD A 5-6 WEEK ECTOPIC PREGNANCY IN LEFT FALLOPIAN TUBE. FILMS WERE REVIEWED BY CONCEPTUS CONSULTING PHYSICIAN; IT APPEARS THAT THE LEFT DEVICE IS PERFORATED AND THERE IS A HINT OF DYE INTO THE VERY PROXIMAL PART OF THE LEFT TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00022	CONCEPTUS, INC.	9/15/2008	8/7/2009

Event Information:

Event Date (B3): 7/3/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSUE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED DIFFICULT DETACHING MICRO-INSERT FROM DELIVERY SYS DURING PROCEDURE. MICRO-INSERT WAS SUCCESSFULLY DEPLOYED BUT FAILED TO DETACH AFTER TROUBLESHOOTING STEPS ATTEMPTED. PHYSICIAN CUT THE DELIVERY SYS AT THE MICRO INSERT, LEAVING SOME PIECES OF THE DELIVERY SYS ATTACHED TO THE MICRO INSERT. MEDICAL INTERVENTION WAS REQUIRED TO REMOVE THE REMAINING PIECES OF DELIVERY CATHETER AS IT IS NOT INTENDED TO BE A PERMANENT IMPLANT. PT WAS TRANSFERRED TO OR. PHYSICIAN PERFORMED A SECOND HYSTEROSCOPY AND REMOVED ALL REMAINING PIECES OF GREEN DELIVERY CATHETER. THE MICRO-INSERT SEEMED TO BE PROPERLY LOCATED SO IT WAS LEFT IN PLACE. DELIVERY SYS WAS RETURNED TO CONCEPTUS. EVAL OF DEVICE SHOWED THAT ALL SYS COMPONENTS WITHIN SPEC, THUS THE CAUSE OF THE DETACHMENT DIFFICULTIES COULD NOT BE CONFIRMED. DETACHMENT DIFFICULTIES MAY BE EXACERBATED BY TUBAL TORTUOSITY, FIBER INTERFERENCE OR COMPONENT DEFORMATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00023	CONCEPTUS, INC.	9/18/2008	2/3/2009

Event Information:

Event Date (B3): 5/15/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED DIFFICULTY DEPLOYING MICRO-INSERT DURING PROCEDURE. THE MICRO-INSERT WAS PLACED TOO PROXIMALLY, SO THE PHYSICIAN ATTEMPTED WITHDRAWAL OF MICRO-INSERT THROUGH HYSTEROSCOPE. THE MICRO-INSERT BROKE, SO THE PATIENT WAS TRANSFERRED TO OPERATING ROOM FOR REMOVAL OF THE REMAINDER OF THE MICRO-INSERT. THE REMAINDER OF THE MICRO-INSERT WAS REMOVED AND A NEW MICRO-INSERT WAS SUCCESSFULLY PLACED. DELIVERY SYSTEM WAS RETURNED TO CONCEPTUS. EVALUATION OF THE DELIVERY SYSTEM SHOWED THAT DEPLOYMENT DIFFICULTIES WERE MOST LIKELY CAUSED BY AN OUT-OF-SPECIFICATION LANDING AREA (DISTANCE BETWEEN INNER CATHETER AND INNER COIL). CONCEPTUS IS CURRENTLY ADDRESSING THE OUT-OF-SPECIFICATION LANDING AREA VIA CAPA.

Manufacturer Narrative (H10):

REPORT SUBMITTED AFTER 30 DAYS BECAUSE REEVALUATION OF EVENT BY COMMITTEE DETERMINED THAT THIS EVENT WAS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00025	CONCEPTUS, INC.	9/30/2008	10/10/2008

Event Information:

Event Date (B3): 7/28/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** *

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/23/2008
Explant Date (E7): 7/28/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

MEDWATCH REPORTED THAT A MICRO-INSERT IMPLANTED IN 2008 WAS REMOVED 5 DAYS POST-IMPLANT. INCIDENT DESCRIPTION SUGGESTS THAT DEVICE WAS IMPLANTED IN A PT WITH ALLERGY TO NICKEL. EVENT REPORTED ANONYMOUSLY; NO FURTHER INFO COULD BE OBTAINED. ACCORDING TO THE ESSURE INSTRUCTIONS FOR USE, IT IS CONTRAINDICATED FOR THE ESSURE SYS TO BE USED IN A PT WITH "KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST." PTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY PRIOR TO ESSURE PLACEMENT PROCEDURE. ADDITIONALLY, PHYSICIAN TRAINING EMPHASIZES THAT NICKEL ALLERGY IS A CONTRAINDICATION FOR MICRO-INSERT PLACEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00024	CONCEPTUS, INC.	9/30/2008	5/7/2009

Event Information:

Event Date (B3): 7/17/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): 626908

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED PATIENT COMPLAINT OF CRAMPING AND PAIN ONE WEEK POST-PROCEDURE. NOVASURE ENDOMETRIAL ABLATION ALSO DONE DURING ORIGINAL PLACEMENT PROCEDURE. THE PATIENT REFUSED TO SEE THE ORIGINAL DOCTOR AND WENT TO A SECOND PHYSICIAN. THE SECOND PHYSICIAN SURGICALLY REMOVED THE COILS AND DISCOVERED A PERFORATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	10/10/2008	10/28/2008

Event Information:

Event Date (B3): 10/8/2008 **Report Date (B4): 10/10/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): ESS205
Catalog # (E4): *
Lot #(E4): 624001

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

SURGEON WAS TRYING TO LOAD THE ESSURE FOR TUBAL WHEN THE SPRING WOULD NOT UNLOAD. ITEM WAS REPLACED. NO PATIENT HARM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00026	CONCEPTUS, INC.	10/10/2008	6/24/2009

Event Information:

Event Date (B3): 9/18/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED PLACING ESSURE MICRO-INSERT A FEW WEEKS AGO. THE NEXT DAY PATIENT PRESENTED WITH SEVERE PAIN, SO HE ADMITTED HER TO THE HOSPITAL AND PERFORMED A DIAGNOSTIC LAPAROSCOPY. EVERYTHING APPEARED NORMAL; NO PERFORATION OF THE MICRO-INSERTS. POST-OPERATIVELY THAT SAME EVENING, PATIENT DEVELOPED A RASH, HIVES AND MORE SEVERE PAIN. SHE WAS TREATED WITH BENADRYL AND HER SYMPTOMS IMPROVED. PHYSICIAN REMOVED THE MICRO-INSERTS VIA LAPAROSCOPIC CORNUAL RESECTION & BILATERAL SALPINGECTOMY FOR THE SUSPECTED DIAGNOSIS OF NICKEL ALLERGY/ ALLERGY TO THE MICRO-INSERTS. PATHOLOGIST IDENTIFIED WBC'S AND EOSINOPHILS WITHIN THE SPECIMEN. THE PATIENT IS DOING WELL POST-OPERATIVELY. ACCORDING TO THE ESSURE INSTRUCTIONS FOR USE, IT IS CONTRAINDICATED FOR THE ESSURE SYSTEM TO BE USED IN A PATIENT WITH "KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST." PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY PRIOR TO AN ASSURE PLACEMENT PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00027	CONCEPTUS, INC.	10/10/2008	11/24/2009

Event Information:

Event Date (B3): 9/29/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): 627301

Single Use: Y
Implant Date (E6): 9/16/2008
Explant Date (E7): 9/29/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED A PATIENT WHO EXPERIENCED SEVERE EPIGASTRIC PAIN 10 DAYS FOLLOWING ESSURE MICRO-INSERT PLACEMENT IN WHICH MULTIPLE MICRO-INSERTS WERE PLACED IN EACH FALLOPIAN TUBE. PATIENT PRESENTED TO THE ER FOR PAIN AND WAS HOSPITALIZED. FLAT PLATE X-RAY SHOWED PERFORATION: ONE MICRO-INSERT IN THE EPIGASTRIC AREA AND ANOTHER IN THE CUL-DE-SAC. PATIENT UNDERWENT SURGERY; ONE MICRO-INSERT WAS REMOVED FROM THE BOWEL AND ONE WAS REMOVED FROM THE POSTERIOR CUL-DE-SAC. THE OTHER MICRO-INSERT APPEARED PROPERLY POSITIONED IN THE CONTRALATERAL TUBE AND WAS LEFT IN PLACE. BOTH TUBES WERE LIGATED. PATIENT WAS LATER DISCHARGED ON PAIN MEDICATIONS AND STATED HER PAIN HAD SUBSTANTIALLY DECREASED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5008709	CONCEPTUS	10/21/2008	10/30/2008

Event Information:

Event Date (B3): 9/12/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/12/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PLACEMENT OF ESSURE TUBAL OCCLUDER DEVICE -STERILIZATION- PLACED HYSTEROSCOPICALLY 1ST HAD A UTERINE PERFORATION WITH ESSURE DEVICE DEPLOYED IN THE MYOMETRIUM. TWO OTHER ESSURE DEVICES - PLACED SUCCESSFULLY IN THE BILATERAL FALLOPIAN TUBAL OSTIA. THE PT WAS AT A SURGICAL CENTER AND WAS DISCHARGED WITHOUT DELAY AND IN A STABLE CONDITION TO HER HOME, BUT WAS RECOMMENDED AND SHE COMPLIED THAT SHE SEEK OVERNIGHT OBSERVATIONAL STATUS IN WEST HILLS HOSPITAL UNDER MY CARE. NO SEQUELAE. CONFIRMATORY HSG - HYSTEROSALPINGOGRAM SHOULD BE DONE IN LATE 2008.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	10/23/2008	11/7/2008

Event Information:

Event Date (B3): 6/20/2008 **Report Date (B4): 10/23/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 626625

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE SURGEON ATTEMPTED TO DEPLOY THE DEVICE ON THE RIGHT SIDE, IT DID NOT DEPLOY. THE SURGEON THEN ATTEMPTED TO DEPLOY THE DEVICE ON THE LEFT SIDE. THE DEVICE CAME OUT AFTER IT WAS INSERTED. THERE WAS NO HARM TO THE PATIENT.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	10/23/2008	11/7/2008

Event Information:

Event Date (B3): 8/14/2008 **Report Date (B4): 10/23/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 626625

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ATTEMPTED TO USE, BUT DEVICE WOULD NOT DEPLOY.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	10/23/2008	11/7/2008

Event Information:

Event Date (B3): 9/18/2008 **Report Date (B4): 10/23/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 627310

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

COIL ON DEVICE DID NOT RELEASE AS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	10/23/2008	11/7/2008

Event Information:

Event Date (B3): 9/18/2008 **Report Date (B4): 10/23/2008** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 627310

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

COIL ON THE DEVICE DID NOT RELEASE AS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00028	CONCEPTUS, INC.	11/5/2008	11/14/2008

Event Information:

Event Date (B3): 7/10/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): 626219

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

MEDWATCH REPORT STATED THAT "AFTER DEPLOYMENT OF ESSURE DEVICES BY PELVIC X-RAY, IT APPEARED THAT ONLY PART OF DEVICE WAS IN LEFT TUBE." AFTER RECEIPT OF THIS REPORT FROM FDA, CONCEPTUS REPRESENTATIVES FOLLOWED UP WITH THE RPTR OF THIS EVENT. CONCEPTUS WAS NOT CONTACTED BY THE PHYSICIAN OR HOSP ABOUT THIS PROCEDURE. RISK MGMT NOTED THAT PHYSICIAN HAD NOT BEEN TRAINED ON THE ESSURE PROCEDURE BY A CONCEPTUS REP. A SECOND PHYSICIAN WHO HAD EXPERIENCE WITH THE ESSURE WASPROCTORING THE PHYSICIAN. DURING THE PROCEDURE, PHYSICIAN USED AT LEAST THREE DEVICES DURING PLACEMENT. IT WAS REPORTED THAT THE UTERUS OR FALLOPIAN TUBES WAS PERFORATED TWO OR MORE TIMES DURING THE PROCEDURE. DURING THE REQUIRED F/U HSG (NOT AN X-RAY AS REPORTED TO MEDWATCH), IT WAS OBSERVED THAT MORE THAN ONE MICRO-INSERT WAS LOCATED OUTSIDE OF THE PT'S FALLOPIAN TUBES. AT LEAST ONE OF THE INCORRECTLY PLACED DEVICES WAS REMOVED. FROM THE FACTS RELAYED TO CONCEPTUS BY THE RPTR, THERE IS NO INFO INDICATING THAT THE DEVICES WERE OUT OF SPEC OR FAILED TO PERFORM AS INTENDED.

Manufacturer Narrative (H10):

PER THE PHYSICIAN'S INSTRUCTIONS FOR USE (IFU), FEDERAL LAW RESTRICTS THE SALE OF ESSURE BY ORDER OF A PHYSICIAN. ESSURE SHOULD ONLY BE USED BY PHYSICIANS WHO ARE KNOWLEDGEABLE HYSTEROSCOPISTS, HAVE READ AND UNDERSTOOD THE INFO IN THE IFU AND IN THE PHYSI

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5009041		11/19/2008	12/8/2008

Event Information:

Event Date (B3): 4/29/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/29/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PROCEDURE DONE. THEIR WEBSITE LED ME TO BELIEVE THAT IT WOULD BE A VERY SIMPLE PROCEDURE, VERY LITTLE PAIN AND COULD EVEN GO OUT TO EAT THAT NIGHT. MOST HAD VERY LITTLE DISCOMFORT AND RETURNED TO WORK THE NEXT DAY. MET WITH MY DOCTOR ABOUT A WEEK BEFORE I HAD THIS DONE AND SHE HAD NOT HAD ANY PROBLEMS WITH ANY SHE HAD DONE BEFORE. EVERYTHING I HAD READ AND FROM WHAT SHE SAID, I FELT GOOD ABOUT HAVING THIS DONE I WAS TO TAKE A VALIUM ON MY WAY THERE TO HELP ME RELAX. THE PROCEDURE WAS EXTREMELY PAINFUL, I TURNED WHITE AND ALMOST PASSED OUT. SHE HAD A DIFFICULT TIME INSERTING THEM, I WISH I WOULD HAVE HAD HER STOP. I BECAME VERY SICK AND THREW UP FIVE TIMES WHEN SHE WAS FINISHED. I HAD TO LAY THERE OVER AN HOUR BEFORE I COULD GET UP AND LEAVE. I WAS IN EXTREME PAIN THE REST OF THE NIGHT AND WAS TAKING PAIN PILLS. I DID RETURN TO WORK THE NEXT DAY, BUT WAS STILL IN PAIN. I HAVE SOME PAIN EVERY DAY, SOME DAYS WORSE THAN OTHERS. THREE TO FOUR MOS AFTER THE PROCEDURE YOU HAVE TO GO BACK TO HAVE DYE PUT IN YOU TO SEE IF IT WORKED. I WAS TOLD THAT I COULD DRIVE MYSELF AND THAT IT WAS A SIMPLE PROCEDURE. IT TURNED OUT TO BE JUST AS BAD AS HAVING THE PROCEDURE DONE. I GOT JUST AS SICK AND THREW UP AND HAD TO LAY OR OVER ONE HOUR BEFORE I COULD LEAVE. I HAD TO CALL MY HUSBAND TO COME AND GET MET, I COULD NOT DRIVE HOME. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00029	CONCEPTUS, INC.	11/25/2008	12/1/2009

Event Information:

Event Date (B3): 11/17/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT UNDERWENT THE ESSURE PROCEDURE IN (B)(6) 2007. NOVASURE ENDOMETRIAL ABLATION WAS PERFORMED IMMEDIATELY PRIOR TO PLACEMENT OF ESSURE. PT REPORTED EXPERIENCING PAIN FOLLOWING NOVASURE AND DEVICES WERE PLACED BEFORE PAIN RESOLVED. IMMEDIATELY FOLLOWING THE PROCEDURE, PT REPORTED PAIN, WHICH PERSISTED THROUGH REMOVAL. PT WAS TREATED FOR ENDOMETRITIS. PT DECIDED TO SEEK CARE AND SECOND OPINION BY ANOTHER PHYSICIAN, WHO WAS REPORTER OF THIS EVENT. PT HAD NOT UNDERGONE HSG. SECOND PHYSICIAN PERFORMED A HYSTERECTOMY ON THE PT. ONE MICRO-INSERT WAS REMOVED FROM THE UTERUS/FALLOPIAN TUBE; THE OTHER WAS REMOVED FROM THE OMENTUM. PT DID WELL AFTER THE SURGERY. THERE WERE NO COMPLICATIONS WITH THE SURGERY AND NO INJURY TO ANY OTHER ORGANS OR BOWEL. PHYSICIAN STATED THAT HE WAS UNABLE TO DETERMINE IF PAIN WAS RELATED TO ESSURE MICRO-INSERTS OR NOVASURE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00030	CONCEPTUS, INC.	12/9/2008	11/17/2009

Event Information:

Event Date (B3): 11/13/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH, DEVICE, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/31/2008
Explant Date (E7): 11/13/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED A PT WITH SEVERE PAIN POST ESSURE PLACEMENT. ESSURE PLACED IN 2008. PAIN IS LOCALIZED IN THE RIGHT LOWER QUADRANT AREA. ULTRASOUND WITHIN NORMAL LIMITS. PHYSICIAN REPORTED THAT SHE REMOVED THE DEVICES TWO WEEKS LATER LAPAROSCOPICALLY. MICRO-INSERT ON THE RIGHT SIDE HAD PERFORATED THROUGH THE CORNUA. NO OTHER PROBLEMS NOTED DURING SURGERY. PT TO F/U WITH PHYSICIAN NEXT WEEK, HOWEVER, HAS NOT CALLED TO REPORT ANY CONTINUED PAIN SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5009332	CONCEPTUS	12/16/2008	1/15/2009

Event Information:

Event Date (B3): 7/17/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 626908; 626907

Single Use:
Implant Date (E6): 7/17/2008
Explant Date (E7): 8/18/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PRODUCT EQUIPMENT MALFUNCTION. LOT # 626908. THE DEVICE DID NOT PROPERLY UNCOIL. DEVICE REMOVED, ANOTHER DEVICE USED PER OPERATIVE REPORT. PICTURES SHOW PROPER COIL PLACEMENT AFTER PROCEDURE. I CONTINUED TO EXPERIENCE PAIN IN THE RIGHT LOWER QUADRANT TWO WEEKS POST ESSURE PROCEDURE. SONOGRAM DONE. X-RAY OBTAINED SHOWED RIGHT ESSURE COIL TO BE LOOPED OVER. I HAD HYSTEROSCOPIC PROCEDURE AT ANOTHER HOSPITAL UPON THE ADVICE OF ANOTHER PHYSICIAN. OPERATIVE REPORT INDICATES THAT BOTH OSTIA WERE VISIBLE BUT NEITHER ESSURE DEVICE COULD BE SEEN. A LAPAROSCOPIC SURGERY WAS THEN PERFORMED TO REMOVE LEFT DEVICE WHICH HAD MIGRATED UP THE FALLOPIAN TUBE AND THE RIGHT DEVICE WHICH HAD PERFORATED THE UTERUS. THE LEFT TUBE LOT# 626908, RIGHT TUBE LOT # 626907. DR PERFORMED NOVASURE ABLATION DURING PROCEDURE. I WAS TOLD BALLOON ABLATION WOULD BE DONE. MY UNDERSTANDING WAS THAT THE ESSURE AND THE NOVASURE COULD NOT BE PERFORMED TOGETHER PER THE DR. I WAS TOLD THAT THEY WOULD BE PERFORMING THE BALLOON ABLATION. I WAS TOLD BY DR IN PREOP THAT NOVASURE COULD NOT BE USED WITH ESSURE. I WAS TOLD THAT AN ESSURE REP WAS PRESENT DURING PROCEDURE BUT CANNOT VERIFY DUE TO THE FACT THAT I WAS UNDER GENERAL ANESTHESIA. I WAS NOT INFORMED ABOUT THE NICKEL ALLERGY, THE MRI CONCERNS NOR WAS I INFORMED ABOUT THE NEED FOR THE HSG TEST. AFTER PROCEDURE, I QUESTIONED AND WAS TOLD THAT THE HSG TEST COULD NOT BE RELIABLY PERFORMED ON PT WHO HAS HAD AN ABLATION. THIS PRODUCT SHOULD NOT BE ON THE MARKET. TOO MANY IF'S WITH THE PROCEDURE. IF THEY CAN PLACE THEM. IF THEY STAY IN PLACE. IF THE TUBES OCCLUDE. I WAS NOT INFORMED THAT IF THERE IS A PROBLEM, IT TAKES MAJOR SURGERY TO CORRECT. IF THE COMPANY IS TRAINING DOCTORS THEN WHY DON'T THE DRS KNOW THE PROBLEMS ASSOCIATED WITH THIS PRODUCT. IT IS DIFFICULT, IF NOT IMPOSSIBLE TO FIND A DR TO HELP YOU WHEN THE

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PROCEDURE GOES BAD. ONE DR SAID HE WENT TO A SEMINAR THAT SAID FDA WASN'T GOING TO REQUIRE THE HSG TEST ANYMORE. DATES OF USE: 2008 (1 MONTH). REASON FOR USE: UNDESIRED FERTILITY. EVENT ABATED AFTER USE STOPPED: YES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00031	CONCEPTUS, INC.	12/17/2008	8/13/2009

Event Information:

Event Date (B3): 10/29/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): ESS205
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 8/1/2007
Explant Date (E7): 10/29/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT A PATIENT PRESENTED TO HER OFFICE FOR A SECOND OPINION REGARDING PERSISTENT RIGHT SIDE PAIN POST-ESSURE PROCEDURE IN 2007. IN 2008, PHYSICIAN REPORTED THAT THE PATIENT UNDERWENT A TOTAL ABDOMINAL HYSTERECTOMY ONE MONTH PRIOR. POST-OPERATIVELY, THE PATIENT'S PAIN HAS COMPLETELY RESOLVED AND PATIENT REPORTS DOING QUITE WELL. PHYSICIAN REPORTED THAT IN HER MEDICAL OPINION THE PAIN WAS DIRECTLY RELATED TO THE MICRO-INSERTS ALTHOUGH THEY WERE FOUND TO SHOW SATISFACTORY PLACEMENT. PER THE IFU: A VERY SMALL PERCENTAGE OF WOMEN IN THE ESSURE CLINICAL TRIALS REPORTED RECURRENT OR PERSISTENT PELVIC PAIN, AND ONLY ONE WOMAN REQUESTED DEVICE REMOVAL DUE TO PAIN; HOWEVER, IF DEVICE REMOVAL IS REQUIRED FOR ANY REASON, IT WILL LIKELY REQUIRE SURGERY, INCLUDING AN ABDOMINAL INCISION AND GENERAL ANESTHESIA, AND POSSIBLE HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00032	CONCEPTUS, INC.	12/17/2008	12/3/2009

Event Information:

Event Date (B3): 10/30/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): ESS305-R1
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 7/1/2008
Explant Date (E7): 10/30/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS THAT PATIENT HAS COMPLAINED OF PERSISTENT BACK PAIN SINCE MICRO-INSERT PLACEMENT THREE MONTHS AGO. ESSURE CONFIRMATION TEST DEMONSTRATED SATISFACTORY LOCATION OF THE MICRO-INSERTS WITH BILATERAL TUBAL OCCLUSION. PATIENT REQUESTED MICRO-INSERT REMOVAL DUE TO PERSISTENT BACK PAIN. MICRO-INSERTS WERE REMOVED VIA PARTIAL SALPINGECTOMY ON (B) (6) 2008. THE OP REPORT DOCUMENTED REMOVAL OF THE MICRO-INSERTS INTACT. THE PHYSICIAN' BELIEVES THAT PAIN IS NOT ESSURE RELATED AS PATIENT IS EXPERIENCING BACK PAIN AND THE HSG WAS NORMAL. PER THE IFU: A VERY SMALL PERCENTAGE OF WOMEN IN THE ESSURE CLINICAL TRIALS REPORTED RECURRENT OR PERSISTENT PELVIC PAIN, AND ONLY ONE WOMAN REQUESTED DEVICE REMOVAL DUE TO PAIN; HOWEVER, IF DEVICE REMOVAL IS REQUIRED FOR ANY REASON, IT WILL LIKELY REQUIRE SURGERY, INCLUDING AN ABDOMINAL INCISION AND GENERAL ANESTHESIA, AND POSSIBLE HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00037	CONCEPTUS, INC.	12/19/2008	1/7/2009

Event Information:

Event Date (B3): 11/25/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TIBIAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/12/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT A PATIENT COMPLAINED OF PAIN SINCE ESSURE PROCEDURE IN 2008. PATIENT HAD AN X-RAY, WHICH SHOWED THE MICRO-INSERT IN THE ABDOMINAL CAVITY. LAPAROSCOPY ON THIRTEEN DAYS LATER, REVEALED THAT MICRO-INSERT HAD PERFORATED THE FALLOPIAN TUBE CORNUA AS A WOUND WAS NOTICED IN THE RIGHT CORNUA. OPERATING PHYSICIAN NOTED THAT PORTIONS OF THE MICRO-INSERT APPEARED TO BE IMBEDDED IN THE APPENDIX AND THE ILEUM. THE MICRO-INSERT AND A PORTION OF THE APPENDIX WAS REMOVED. IN ADDITION, THE PATIENT UNDERWENT BILATERAL TUBAL LIGATION. AS OF THE FOLLOWING MONTH, PATIENT HAS NOT REPORTED ADDITIONAL PAIN. A REVIEW OF THE CASE BY A CONSULTING PHYSICIAN NOTED THAT THE PATHOLOGY REPORT SHOWS NO EVIDENCE OF APPENDICITIS OR A PERFORATION OF THE APPENDIX ITSELF. IF THERE WAS TRULY A PERFORATION OR EMBEDMENT OF THE DEVICE INTO THE LUMEN OF THE APPENDIX OR ILEUM, THIS SHOULD HAVE BEEN REVEALED BY THE PATHOLOGY REPORT OR SOME OOZING OR OPENING SEEN IN THE BOWEL AT THE TIME OF THE SURGERY. ANY FOREIGN OBJECT FLOATING IN THE PELVIS OR ABDOMEN WILL NORMALLY ATTACH TO SOME SURFACE WHICH IS USUALLY THE OMENTUM OR FAT SURROUNDING THE BOWEL OR TO THE SIDEWALLS. DIRECT ATTACHMENT TO AN ORGAN OR BOWEL IS UNUSUAL DUE TO THE FAT SURROUNDING THE ABDOMINAL ORGANS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FROM THE PHYSICIAN'S INSTRUCTIONS FOR USE: THE FOLLOWING ADVERSE EVENTS WERE NOT EXPERIENCED BY WOMEN WHO PARTICIPATED IN CLINICAL STUDIES EVALUATING THE ESSURE SYSTEM BUT ARE STILL POSSIBLE: PERFORATION OF INTERNAL BODILY STRUCTURES OTHER THAN THE UTERUS

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00036	CONCEPTUS, INC.	12/19/2008	8/11/2009

Event Information:

Event Date (B3): 11/25/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4): ESS205
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT PT COMPLAINED OF PAIN SINCE MICRO-INSERT PLACEMENT. PHYSICIAN SCHEDULED MICRO-INSERT REMOVAL IN 2008. NO FURTHER INFO WAS PROVIDED BY PHYSICIAN. PER THE IFU: A VERY SMALL PERCENTAGE OF WOMEN IN THE ESSURE CLINICAL TRIALS REPORTED RECURRENT OR PERSISTENT PELVIC PAIN, AND ONLY ONE WOMAN REQUESTED DEVICE REMOVAL DUE TO PAIN; HOWEVER, IF DEVICE REMOVAL IS REQUIRED FOR ANY REASON, IT WILL LIKELY REQUIRE SURGERY, INCLUDING AN ABDOMINAL INCISION AND GENERAL ANESTHESIA, AND POSSIBLE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00033	CONCEPTUS, INC.	12/19/2008	11/17/2009

Event Information:

Event Date (B3): 12/5/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS THAT PT HAS COMPLAINED OF PAIN SINCE MICRO-INSERT PLACEMENT. PHYSICIAN CONDUCTED DIAGNOSTIC HYSTEROSCOPY AND NOTED AN "EXTENDED WIRE" PROTRUDING FROM RIGHT OSTIUM. PHYSICIAN CUT OFF THE WIRE. PT'S PAIN SUBSIDED. PER THE IFU: A VERY SMALL PERCENTAGE OF WOMEN IN THE ESSURE CLINICAL TRIALS REPORTED RECURRENT OR PERSISTENT PELVIC PAIN, AND ONLY ONE WOMAN REQUESTED DEVICE REMOVAL DUE TO PAIN; HOWEVER, IF DEVICE REMOVAL IS REQUIRED FOR ANY REASON, IT WILL LIKELY REQUIRE SURGERY, INCLUDING AN ABDOMINAL INCISION AND GENERAL ANESTHESIA, AND POSSIBLE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00034	CONCEPTUS, INC.	12/19/2008	12/3/2009

Event Information:

Event Date (B3): 10/15/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 626685

Single Use: Y
Implant Date (E6): 5/28/2008
Explant Date (E7): 10/15/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT PATIENT EXPERIENCED RIGHT LOWER QUADRANT PAIN WHICH STARTED AFTER SUCCESSFUL BILATERAL MICRO-INSERT PLACEMENT. PHYSICIAN PERFORMED HYSTERECTOMY ON PATIENT WHICH GAVE HER SOME RESOLUTION OF PAIN. PATHOLOGICAL EXAMINATION REVEALED NORMAL PATHOLOGY. PATIENT CONTINUES TO EXPERIENCE MILD RIGHT LOWER QUADRANT PAIN. PHYSICIAN DOES NOT BELIEVE THAT THE PAIN WAS ASSOCIATED WITH MICRO-INSERTS. PER THE IFU: A VERY SMALL PERCENTAGE OF WOMEN IN THE ESSURE CLINICAL TRIALS REPORTED RECURRENT OR PERSISTENT PELVIC PAIN, AND ONLY ONE WOMAN REQUESTED DEVICE REMOVAL DUE TO PAIN; HOWEVER, IF DEVICE REMOVAL IS REQUIRED FOR ANY REASON, IT WILL LIKELY REQUIRE SURGERY, INCLUDING AN ABDOMINAL INCISION AND GENERAL ANESTHESIA, AND POSSIBLE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00035	CONCEPTUS, INC.	12/19/2008	12/3/2009

Event Information:

Event Date (B3): 12/5/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE ESSURE PROCEDURE, A COMPONENT OF THE DELIVERY SYSTEM (LARGE TIGHT PITCH COILS) STRETCHED. PHYSICIAN WAS CURIOUS ABOUT HOW MUCH FORCE/TENSION REQUIRED TO BREAK THE DELIVERY SYSTEM LARGE TIGHT PITCH COILS IN HALF AND PULLED ON THE COILS. DURING HER ATTEMPT TO BREAK IT, PHYSICIAN CUT HER HAND ON THE LARGE LIGHT PITCH COILS. PHYSICIAN REQUIRED STITCHES TO CLOSE THE WOUND. THE ESSURE SYSTEM IS INTENDED FOR SINGLE USE, THEN DISPOSAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2008-00038	CONCEPTUS, INC.	12/22/2008	12/4/2009

Event Information:

Event Date (B3): 10/21/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KHN - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627454

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

UTERINE CAVITY WAS PERFORATED WITH MICRO-INSERT DURING ESSURE PROCEDURE AND MICRO-INSERT WAS PLACED INTO MYOMETRIUM/ENDOMETRIUM. BECAUSE SUCCESSFUL PLACEMENT OF MICRO-INSERT WAS NOT ACHIEVED, PATIENT REQUESTED LAPAROSCOPIC TUBAL LIGATION. DURING TUBAL LIGATION PROCEDURE, PHYSICIAN REMOVED THE MICRO-INSERT AND DISCARDED IT. PERFORATIONS OF THE UTERUS OR FALLOPIAN TUBES WERE OBSERVED IN THE CLINICAL TRIALS AT A RATE OF 2.9% (6/206) IN THE PHASE II TRIAL AND 1.1% (5/476) IN THE PIVOTAL TRIAL. THE RATE OF REPORTED PERFORATIONS IN COMMERCIAL USE IS SIGNIFICANTLY LOWER AND IS TYPICALLY NOT DIAGNOSED UNTIL THE TIME OF HSG. MOST OF THESE PATIENTS REMAIN ASYMPTOMATIC. THE PHYSICIAN'S INSTRUCTIONS FOR USE STATES: IF TUBAL OR UTERINE PERFORATION OCCURS OR IS SUSPECTED, IMMEDIATELY DISCONTINUE THE ESSURE DEVICE PLACEMENT PROCEDURE, AND WORK-UP THE PATIENT FOR A PERFORATION. A VERY SMALL PERCENTAGE OF WOMEN IN THE ESSURE PROCEDURE CLINICAL TRIALS (1.8% OR 12/682 PATIENTS) WERE IDENTIFIED AS HAVING DEVICE RELATED TUBAL PERFORATIONS. RETRIEVAL OF PERFORATING MICRO-INSERTS, IF NECESSARY, WILL REQUIRE LAPAROSCOPY OR OTHER SURGICAL METHODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5009549	CONCEPTUS INC.	1/7/2009	1/26/2009

Event Information:

Event Date (B3): 7/17/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE TUBAL OCCLUSION INSERTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/17/2008
Explant Date (E7): 8/1/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT UNDERWENT HYSTEROSCOPY, DILATATION, CURETTAGE, NOVASURE THERMAL ABLATION AND ESSURE TUBAL OCCLUSION. THE ESSURE DEVICE IN THE LEFT TUBE DID NOT PROPERLY UNCOIL, SO WAS REMOVED AND REINSERTED. GOOD DECOILING WAS NOTED. THE ESSURE WAS APPLIED UNEVENTFULLY IN RIGHT TUBE. THE PT HAD SIGNIFICANT POST OPERATIVE PAIN AND AT ABOUT TWO WKS POST OP UNDERWENT FLAT PLATE OF THE ABDOMEN, REVEALING A CORKSCREW APPEARANCE TO THE RIGHT ESSURE DEVICE. SHE ULTIMATELY UNDERWENT REOPERATION FOR LAPAROSCOPIC REMOVAL OF THE ESSURE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00001	CONCEPTUS, INC.	1/14/2009	12/15/2009

Event Information:

Event Date (B3): 11/21/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN INITIALLY REPORTED DEPLOYMENT DIFFICULTIES FOR A PROCEDURE PERFORMED ON (B) (6) 2008. FOLLOWING THE PROCEDURE, PT COMPLAINED OF DISCOMFORT AND PAIN. HYSTERECTOMY WAS PERFORMED, AND 4 MICRO-INSERTS WERE FOUND IN ONE TUBE. ALL MICRO-INSERTS WERE REMOVED (INCLUDING THE SINGLE MICRO-INSERT PLACEMENT ON THE OTHER SIDE). THE PHYSICIAN'S INSTRUCTIONS FOR USE STATES: DO NOT PLACE MORE THAN ONE ESSURE MICRO-INSERT IN A SINGLE FALLOPIAN TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	1/19/2009	2/4/2009

Event Information:

Event Date (B3): 1/7/2009 **Report Date (B4): 1/19/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6): 9/14/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANT WAS PLACED IN PATIENT A YEAR AGO. X-RAYS SHOWED PROPER PLACEMENT TWO MONTHS POST OPERATIVELY. APPROXIMATELY 13 MONTHS LATER, SURGEON WAS PERFORMING A LAPAROSCOPIC PROCEDURE ON THE PATIENT. HE FOUND THE ESSURE IMPLANT PUT IN PATIENT HAD FAILED BY EXTRUDING THROUGH HER UTERUS. HE CALLED COMPANY DURING SURGERY, BUT THERE WAS NO RESPONSE FROM COMPANY. COMPANY RESPONDED TO OUR RISK DEPARTMENT SEVERAL DAYS FOLLOWING THE PROCEDURE.
==========
MANUFACTURER RESPONSE FOR PERMENANT BIRTH CONTROL, ESSURE
==========
MANUFACTURER IS AWARE OF ISSUE AND NOTES THAT IS IS A KNOWN RISK IN APPROX 3.4% OF PATIENTS IN CLINICAL TRIALS

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00002	CONCEPTUS, INC.	1/20/2009	12/28/2009

Event Information:

Event Date (B3): 1/13/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305-R1
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/9/2008
Explant Date (E7): 1/13/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS THAT ONE OF THE PTS HAD THE ESSURE PROCEDURE ON (B) (6) 2008. HSG ON (B) (6) 2008 STATES: BILATERAL TUBAL OCCLUSION BY THE ESSURE DEVICES. AN ULTRASOUND DEMONSTRATED NO GESTATIONAL SAC, SO POSSIBLE EARLY OR ECTOPIC PREGNANCY. THE HCG LEVEL WAS 300. PT TREATED WITH METHOTREXATE BECAUSE SHE WANTED TO CONSULTING REVIEW OF THE ORIGINAL HSG NOTES THAT UTERUS APPEARS EITHER SEVERELY ANTEVERTED OR RETROVERTED. THE LEFT DEVICE IS IN THE TUBE WITH OCCLUSION. THE RIGHT IS MORE DIFFICULT TO ASSESS BECAUSE IT IS DISTALLY PLACED; MOREOVER, CONTRAST DOES NOT FILL THE TUBE OR MEET THE TIP OF THE PROXIMAL END OF THE MICROINSERT, THUS DEVICE LOCATION CANNOT ACCURATELY BE EVALUATED. PHYSICIAN PERFORMED A LAPAROSCOPIC TUBAL LIGATION AND CONFIRMED THE ECTOPIC PREGNANCY. THE ECTOPIC MASS WAS AT THE FIMBRIAL END WHERE SOME ADHESIONS OCCURRED ATTACHING THE FIMBRIAL END OF THE FALLOPIAN TUBE TO THE OMENTUM. HE NOTED THAT THE MICRO-INSERTS WERE WITHIN THE FALLOPIAN TUBES BUT ONE OF THE MICRO-INSERTS MAY HAVE BEEN LOCATED DISTALLY; HE DOES NOT KNOW IF IT WAS MORE OR LESS THAN 30 MM FROM THE CORNUA. THE PT IS DOING FINE POST OPERATIVELY. INITIAL COMPLAINT RECEIVED 11/24/2008; REPORTABLE INFO RECEIVED 01/13/2009.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00003	CONCEPTUS, INC.	1/20/2009	12/28/2009

Event Information:

Event Date (B3): 12/22/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628191

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS THAT ONE OF HIS PATIENTS COMPLAINED OF PAIN TWO DAYS FOLLOWING ESSURE PROCEDURE IN WHICH ONLY UNILATERAL PLACEMENT WAS OBTAINED. ONE WEEK FOLLOWING PLACEMENT, PHYSICIAN REMOVED THE DEVICE LAPAROSCOPICALLY AND PERFORMED A TUBAL LIGATION ON THE PATIENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00005	CONCEPTUS, INC.	1/21/2009	9/30/2009

Event Information:

Event Date (B3): 12/23/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/1/2006
Explant Date (E7): 12/23/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN CALLED TO REPORT PAIN IN A PT 2 YEARS POST-ESSURE PLACEMENT. PT STATED THAT SHE HAS HAD PERSISTENT PELVIC PAIN SINCE HER HSG WAS DONE IN 2007. THE HSG REPORT WAS REVIEWED, AND THERE WERE NO NOTES OF ABNORMAL MICRO-INSERT PLACEMENT. PHYSICIAN NOTED THAT PT HAS OTHER MEDICAL PROBLEMS THAT ARE BOTH METABOLIC AND AUTOIMMUNE IN NATURE (FIBROMYALGIA AND SCLERODERMA). PT HAS SEEN A DERMATOLOGIST AND BELIEVES THAT SHE IS SENSITIVE TO NICKEL, BUT HAS NOT BEEN FORMALLY TESTED BY PHYSICIAN OR DIAGNOSED WITH NICKEL ALLERGY. PT REQUESTED REMOVAL, WHICH OCCURRED ON 2008. PT IS DOING WELL FOLLOWING MICRO-INSERT REMOVAL. PHYSICIAN STATES THAT HE DOES NOT FEEL HER PAIN IS RELATED TO THE MICRO-INSERTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00004	CONCEPTUS, INC.	1/21/2009	1/4/2010

Event Information:

Event Date (B3): 12/1/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/11/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS THAT ONE OF HIS PT'S REPORTED A PREGNANCY, FIVE MONTHS FOLLOWING ESSURE MICRO-INSERT IMPLANTATION. PT DID NOT RETURN FOR AN ESSURE CONFIRMATION TEST (HSG). BECAUSE IT WAS AN ECTOPIC PREGNANCY, THE PREGNANCY WAS TERMINATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5009741	CONCEPTUS	1/24/2009	2/3/2009

Event Information:

Event Date (B3): 1/28/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/28/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON THE EVENT DATE, I WENT IN TO HAVE THE ESSURE COILS PLACED. IT WAS A VERY LONG PAINFUL EXPERIENCE. THE COIL WENT INTO MY LEFT SIDE FAIRLY EASILY BUT THE RIGHT SIDE TOOK 45 MINUTES. AT MY 3 MONTH DYE TEST, WE FOUND THAT THE COIL ON MY RIGHT SIDE HAD FALLEN OUT. I BELIEVE IT IS STILL IN MY BODY AS I DID NOT SEE OR FEEL IT EXPEL FROM MY BODY. MY DOCTOR WAS VERY SURPRISED BECAUSE I WAS THE FIRST ONE IN HER OFFICE TO EVER HAVE PROBLEMS. SHE SUGGESTED THAT I GO INTO THE HOSPITAL AND HAVE A TUBAL LIGATION ON THAT SIDE WHICH I DID 2008. ALSO, SINCE I HAD THE ESSURE I HAVE HAD HORRIBLE PERIODS AND HEAVY BLEEDING. DATES OF USE: 2009 TILL PRESENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5009790	CONCEPTUS, BOSTON SCIENTIFIC	1/29/2009	2/9/2009

Event Information:

Event Date (B3): 12/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE, HTA
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/10/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD UNCOMPLICATED, UNEVENTFUL TRANSCERVICAL STERILIZATION UTILIZING ESSURE, FOLLOWED IMMEDIATELY BY ENDOMETRIAL ABLATION UTILIZING BOSTON SCIENTIFIC HTA SYSTEM. PATIENT WAS SEEN POST OPERATIVELY IN LATE 2008, AND THE ONLY COMPLAINT WAS NO BOWEL MOVEMENT. PATIENT WAS SEEN IN THE ER NINE DAYS LATER AND WAS EVALUATED, THEN HOSPITALIZED WITH PELVIC INFLAMMATORY DISEASE. APPROPRIATE BROAD SPECTRUM ANTIBIOTIC INITIATED. NO IMPROVEMENT, THEREFORE, TAKEN TO SURGERY THREE DAYS LATER, FOR LAPAROSCOPIC EVALUATION. UNABLE TO SAFELY LYSE BOWEL ADHESIONS COVERING PRESUMED TUBAL OVARIAN ABSCESSES. PROCEDURE TERMINATED, BOWEL PREPARATION IMPLEMENTED, RETURNED TO OPERATING ROOM THREE DAYS LATER, WITH ENTEROLYSIS TUBOOVARIAN ABSCESSES DRAINED SATISFACTORILY. PIC LINE PLACED FOR LONG TERM IV ANTIBIOTICS - TERMINATED EARLY 2009. SEEN IN OFFICE TWO WEEKS LATER, DOING WELL. I DID LITERATURE REVIEW. ONE OTHER CASE REPORT OUT OF THE NETHERLANDS DESCRIBED A SIMILAR SITUATION WITH 2 YEAR OLD ESSURE, SUBSEQUENT BALLOON THERMAL ABLATION FOLLOWED BY SEVERE PID. THE AUTHORS SUGGESTED PROPHYLACTIC ANTIBIOTIC USE AT TIME OF THERMAL ABLATION IF ESSURE IN PLACE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	2/5/2009	2/20/2009

Event Information:

Event Date (B3): 1/22/2009 **Report Date (B4): 2/5/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 627751

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE HAD A BENT TIP AND SURGEON WAS UNABLE TO PLACE THE DEVICE SUCCESSFULLY. THE SURGEON REMOVED THE DEVICE FROM TUBE. NO PATIENT INJURY NOTED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	2/5/2009	2/20/2009

Event Information:

Event Date (B3): 1/22/2009 **Report Date (B4): 2/5/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 626975

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE DID NOT DEPLOY. THE SURGEON WAS NOT ABLE TO ROLL THUMB WHEEL BACK BECASUE IT BECAME STUCK. THE SURGEON WITHDREW THE DEVICE SUCCESSFULLY. NO PATIENT INJURY WAS NOTED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	2/5/2009	2/20/2009

Event Information:

Event Date (B3): 1/22/2009 **Report Date (B4): 2/5/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 627301

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE DID NOT DEPLOY. THE SURGEON WAS NOT ABLE TO "THUMBWHEEL" BACK A SECOND TIME AFTER DEPRESSING BUTTON. THE SURGEON SUCCESSFULLY WITHDREW THE DEVICE. NO INJURY TO THE PATIENT WAS NOTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5010022	CONCEPTUS, NORTHERN CALIFORNIA	2/14/2009	3/3/2009

Event Information:

Event Date (B3): 1/22/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/22/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

MY OBGYN PERFORMED THE ESSURE PROCEDURE - COMPANY NAME CONCEPTUS - IN EARLY 2009. HE WAS ONLY SUCCESSFUL IN INSERTING THE COIL IN THE LEFT TUBE, BUT WAS UNABLE TO COMPLETE THE PROCEDURE ON THE RIGHT SIDE. HIS OFFICE RESCHEDULED THE PROCEDURE ON THE RIGHT SIDE 2 WEEKS LATER -THE FOLLOWING MONTH-. THE SECOND TIME AROUND TOOK AT LEAST A HALF HOUR, BUT HE WAS STILL UNSUCCESSFUL. THE ESSURE REP WAS ALSO PRESENT AND WITNESSED THE PROCEDURE. MY OBGYN THEN REALIZED THAT ONE OF THE COMPONENTS, 'THE INTRODUCER' HAD DEPLOYED THE PREVIOUS 2 WEEKS, AND WAS LEFT IN THE RIGHT TUBE, THUS PREVENTING HIM FROM INSERTING THE DEVICE THIS TIME AROUND. HE WAS UNSUCCESSFUL IN RETRIEVING THE INTRODUCER AND IT IS STILL IN THE RIGHT TUBE. THE ESSURE REP INDICATED THAT THIS SOMETIMES HAPPENS AND MAY BE EXPELLED ON ITS OWN. MY OBGYN SUGGESTED TO ME LATER, THAT THE DEVICE MAY HAVE BEEN FAULTY. HE NOW PLANS TO SCHEDULE A TUBAL ON BOTH SIDES. DATES OF USE: 2009. DIAGNOSIS OR REASON FOR USE: CONTRACEPTION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00006	CONCEPTUS, INC.	2/19/2009	1/21/2010

Event Information:

Event Date (B3): 2/3/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/30/2008
Explant Date (E7): 2/3/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAS COMPLAINED OF PELVIC PAIN SINCE THE ESSURE PROCEDURE FOUR WEEKS PRIOR AND REQUESTED MICRO-INSERT REMOVAL. PT HAS BEEN TREATED WITH TORADOL WITHOUT RELIEF. LAPAROSCOPY OCCURRED IN 2009. PHYSICIAN STATED THE REMOVAL WAS WITHOUT COMPLICATIONS. THE PT IS DOING "BETTER", BUT HER PAIN IS NOT COMPLETELY RESOLVED. IN PHYSICIAN'S MEDICAL OPINION, THE PT'S PAIN WAS NOT RELATED TO ESSURE.

Manufacturer Narrative (H10):

IN THE ESSURE CLINICAL TRIAL, WOMEN WERE ASKED ABOUT UNUSUAL PAIN THEY EXPERIENCED SINCE THE LAST CONTACT. OF THE WOMEN WHO REPORTED PAIN, ONE WOMAN REPORTED "PERSISTENT" PELVIC PAIN AT 2 YEARS OF F/U. NONE OF THE PTS REPORTING AT 3, 4, AND 5 YR F/U INDIC

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00007	CONCEPTUS, INC.	2/19/2009	1/21/2010

Event Information:

Event Date (B3): 2/12/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/19/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FOUR WEEKS FOLLOWING THE ESSURE PROCEDURE, PT COMPLAINED OF POST-PROCEDURE PAIN. CONCEPTUS FIRST BECAME AWARE OF THE POST PROCEDURE PAIN ON (B) (6) 2009. PHYSICIAN STATED THAT ONE MICRO-INSERT DEPLOYMENT APPEARED DEEP WITH ZERO TRAILING COILS VISIBLE. ON (B) (6) 2009, PHYSICIAN'S OFFICE NOTIFIED CONCEPTUS REP THAT PHYSICIAN REMOVED THE ESSURE MICRO-INSERTS LAPAROSCOPICALLY BECAUSE THE PT WAS CONTINUING TO EXPERIENCE PAIN. THE SURGERY REPORTEDLY WENT WELL; BOTH MICRO-INSERTS WERE REMOVED WITHOUT TOO MUCH DIFFICULTY AND THE PT DID WELL POST-OPERATIVELY. DATE OF EXPLANTATION NOT REPORTED TO CONCEPTUS.

Manufacturer Narrative (H10):

IN THE (B) (4) CLINICAL TRIAL, WOMEN WERE ASKED ABOUT UNUSUAL PAIN THEY EXPERIENCED SINCE THE LAST CONTACT. OF THE WOMEN WHO REPORTED PAIN, ONE WOMAN REPORTED "PERSISTENT" PELVIC PAIN AT 2 YEARS OF F/U. NONE OF THE PTS REPORTING AT 3, 4, AND 5 YR F/U INDI

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5010053	CONCEPTUS	2/20/2009	3/2/2009

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS PLACED WITHOUT COMPLICATION. THE PATIENT FOLLOWED UP WITH HER 3 MONTH HSG, WHICH WAS READ BY RADIOLOGY AS BILATERAL TUBAL OCCLUSION. THE PATIENT ENDED UP WITH AN ECTOPIC PREGNANCY AND WAS TREATED WITH METHOTREXATE. THE PATIENT THEN UNDERWENT AN UNCOMPLICATED LAPAROSCOPIC TUBAL LIGATION AT WHICH POINT THE RIGHT ESSURE DEVICE APPEARED TO BE JUST UNDER THE SEROSA. THE HSG WAS REVIEWED AND IT WAS ORIGINALLY MISREAD AND ACTUALLY DOES SHOW UNILATERAL SPILL. DATES OF USE: 2007 - EARLY 2009. DIAGNOSIS: MULTIPARTY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00008	CONCEPTUS, INC.	2/27/2009	8/26/2009

Event Information:

Event Date (B3): 1/29/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** PO

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 9/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FOUR MONTHS FOLLOWING ESSURE MICRO-INSERT PLACEMENT, PATIENT REPORTED PAIN. PATIENT HAD DEVELOPED ABSCESS (INFECTION) IN ONE FALLOPIAN TUBE NEAR THE MICRO-INSERT. PATIENT UNDERWENT LAPARASCOPIC PROCEDURE TO DRAIN ABSCESS AND WAS GIVEN ANTIBIOTICS. FOLLOWING TREATMENT, PATIENT'S INFECTION RESOLVED AND PATIENT WAS IN GOOD CONDITION. A PELVIC ULTRASOUND WAS NORMAL. A FOLLOW-UP PELVIC X-RAY SHOWED THAT THE TWO MICRO-INSERTS REMAINED PROPERLY PLACED FOLLOWING TREATMENT; THE PATIENT WILL CONTINUE TO RELY ON THEM FOR CONTRACEPTION. ACCORDING TO THE ESSURE INSTRUCTIONS FOR USE, ADNEXAL INFECTION/SALPINGITIS IS A POTENTIAL ADVERSE EVENT THAT MAY BE RELATED TO THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00009	CONCEPTUS, INC.	2/27/2009	9/3/2009

Event Information:

Event Date (B3): 1/27/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 2/1/2007
Explant Date (E7): 1/27/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO YEARS FOLLOWING CONCOMITANT ABLATION AND ESSURE MICRO-INSERT PLACEMENT, PATIENT REPORTED BILATERAL PELVIC PAIN. PATIENT UNDERWENT HYSTERECTOMY AND PATHOLOGY REVEALED ACUTE ENDOMETRITIS, ACUTE AND CHRONIC SUPERFICIAL MYOMETRITIS, AND SALPINGITIS. PATIENT DIAGNOSED WITH ADENOMYOSIS. PATIENT IS DOING WELL POST-OPERATIVELY. PHYSICIAN FELT THE PAIN WAS RELATED TO THE ADENOMYOSIS AND NOT THE ESSURE MICROINSERTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5010190		3/4/2009	5/13/2009

Event Information:

Event Date (B3): 2/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE COILS FOR TUBAL STERILIZATION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/30/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONFIRMED UTERINE PREGNANCY -VIA ULTRASOUND AND BLOODWORK- AFTER HAVING THE ESSURE DEVICES INSERTED IN BOTH FALLOPIAN TUBES BACK IN 2007. DOSE OR AMOUNT: 2.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5010282	CONCEPTUS INCORPORATED	3/11/2009	5/14/2009

Event Information:

Event Date (B3): 2/26/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4): 627433

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE DIDN'T FUNCTION CORRECTLY WHEN USED DURING PROCEDURE. FOLLOWED UP WITH REP IN REGARDS TO FAULTY DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5010444	CONCEPTUS	3/21/2009	4/27/2009

Event Information:

Event Date (B3): 3/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/10/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE VIA HYSTEROSCOPY. MINOR SEDATION, NUMBING. DOCTOR HAD SEVERAL PROBLEMS INSERTING IN THE LEFT TUBE. ONE OF THE INSERTION DEVICES BENT ON INSERTION. DR HAD TO USE ANOTHER. A 15 MINUTE PROCEDURE TOOK WELL OVER AN HOUR. I WAS IN EXCRUCIATING PAIN, AND HAVE SINCE BEEN BLEEDING NONSTOP FOR 11 DAYS, WITH PINCHING PAIN ON THE LEFT SIDE. THE PAIN I FELT DURING THIS PROCEDURE IS NOT ONE ANY PERSON SHOULD FEEL. IT WAS DEFINITELY A NECESSARY ANESTHESIA PROCEDURE, PERHAPS DUE TO THE DR NOT ABLE TO FULLY SEE THE LEFT TUBE, AND FORCING THE DEVICE REPEATEDLY. I BELIEVE MORE THAN HALF THE COIL IS HANGING OUT, DUE TO THE EXCESSIVE BLEEDING AND CLOTS BEING PASSED. I CALLED DR'S OFFICE TO EXPLAIN THE PROBLEMS, AND WAS ADVISED TO GO TO E.R. IF ANYTHING SERIOUS AROSE. I SERIOUSLY FELT LIKE A LIVE DEER BEING FIELD DRESSED DURING THE PROCEDURE. NOT SURE WHAT CONSTITUTES GOING TO THE E.R., AS I CANNOT AFFORD TO SIT FOR HOURS ON END. I CAN SIT AT HOME AND BE MISERABLE AND BLOW CLOTS ALL DAY LONG. THIS PRODUCT/PROCEDURE NEEDS MUCH MORE TESTING, OR THE MD'S NEED MORE TRAINING IN THE IMPLANTATION OF THIS DEVICE. I AM NOT THE ONLY ONE. DATE OF USE: 2009.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5010450	CONCEPTUS INCORPORATED	3/23/2009	5/14/2009

Event Information:

Event Date (B3): 3/4/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626000

Single Use:
Implant Date (E6): 3/4/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE INSTRUMENT FAILED TO DEPLOY PROPERLY DURING PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00011	CONCEPTUS, INC.	3/24/2009	10/5/2009

Event Information:

Event Date (B3): 2/27/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305-R1
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/29/2009
Explant Date (E7): 3/18/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED PT COMPLAINT OF PAIN 4 WKS POST PROCEDURE. ESSURE PLACED IN LEFT TUBE IN 209, THEN THE PT RETURNED FOR SECOND PLACEMENT ONE WK LATER. PT HAS HAD WORSENING LEFT SIDE PAIN SINCE PLACEMENT AND SPOTTING. ULTRASOUND SHOWS THE RIGHT MICRO-INSERT APPEARS PROPERLY PLACED, BUT THE LEFT APPEARS "COILED UP". LAPAROSCOPY PERFORMED APPROX 1 1/2 MONTHS LATER. ON THE DAY OF LAPAROSCOPY, PT COMPLAINED OF RIGHT SIDED PAIN AND REQUESTED BOTH MICRO-INSERTS OUT. DURING LAPAROSCOPIC PROCEDURE, PHYSICIAN CHECKED THE PLACEMENT OF THE DEVICES AND THEY APPEARED TO BE IN THE RIGHT LOCATION. PHYSICIAN REMOVED BOTH MICRO-INSERTS VIA LAPAROSCOPY THEN PERFORMED BILATERAL TUBAL LIGATION. PT'S PAIN HAS RESOLVED SINCE MICRO-INSERT REMOVAL; PHYSICIAN STATES THAT NO DEFINITIVE CAUSE COULD BE FOUND FOR THE PT'S PAIN, BUT PT'S PAIN MAY HAVE BEEN RELATED TO HER "PERCEPTION" OF HAVING AN IMPLANT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00010	CONCEPTUS, INC.	3/24/2009	2/5/2010

Event Information:

Event Date (B3): 6/23/2005 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/20/2005
Explant Date (E7): 6/28/2005
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED AN ESSURE PT WHO COMPLAINED OF SEVERE BACK AND PELVIC PAIN AND AN INABILITY TO WALK EIGHT DAYS POST-PROCEDURE. THE PT SAID SHE IS ALLERGIC TO INEXPENSIVE JEWELRY AND THE PHYSICIAN WAS INTERESTED IN KNOWING IF THIS WAS AN ALLERGIC REACTION TO NICKEL. PHYSICIAN BELIEVED PT'S SYMPTOMS WERE RELATED TO A NICKEL ALLERGY AND THE ESSURE MICRO-INSERTS WERE REMOVED TO ADDRESS THE PT'S SYMPTOMS. A RETROSPECTIVE EVAL OF THE ADVERSE EVENT DATA FROM THE PHASE II AND PIVOTAL TRIAL WAS PERFORMED TO DETERMINE IF POTENTIAL CORROSION OF THE ESSURE MICRO-INSERT MAY HAVE RELEASED ADVERSE QUANTITIES OF NICKEL IONS. THE EVAL OF CLINICAL ADVERSE EVENT DATA FOUND NO EVIDENCE OF NICKEL ALLERGY IN 650 WOMEN FOLLOWED FOR 3 TO 27 MONTHS. THERE WERE NO CHRONIC REPORTS OF SKIN RASH OR ITCHING.

Manufacturer Narrative (H10):

THIS MDR IS BEING SUBMITTED AFTER AN INTERNAL AUDIT FOUND IT HAD INADVERTENTLY NOT BEEN PREVIOUSLY FILED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00012	CONCEPTUS, INC.	3/24/2009	2/5/2010

Event Information:

Event Date (B3): 3/6/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/1/2008
Explant Date (E7): 3/6/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THREE MONTHS FOLLOWING ESSURE PLACEMENT, HSG SHOWED A POSSIBLE PERFORATION OF ONE MICRO-INSERT. THE PT EXPERIENCED PAIN SINCE THE PROCEDURE. SHE REQUESTED MICRO-INSERT REMOVAL AND LAPAROSCOPIC TUBAL LIGATION. SURGERY ON (B) (6) 2009 WENT FINE AS REPORTED BY PHYSICIAN. PHYSICIAN WAS ABLE TO REMOVE THE PERFORATED MICRO-INSERT FROM THE UTERUS INTACT. BILATERAL TUBAL LIGATION ALSO PERFORMED. PHYSICIAN STATES IN HER OPINION, "NO WAY THE ESSURE MICRO-INSERT COULD BE CAUSING THE PAIN". PT REPORTS DOING WELL POST-OPERATIVELY, BUT HAS THE SAME PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5010501	NA	3/27/2009	4/8/2009

Event Information:

Event Date (B3): 3/26/2007 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4): 626910

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PERMANENT BIRTH CONTROL INSTALLED - PASSED THE DYE TEST 3 MONTHS AFTER AND NOW, 5MOS LATER, I AM PREGNANT - 8 WEEKS PREGNANT. DATES OF USE: 2008 - 2009. DIAGNOSIS OR REASON FOR USE: MISSED MENSTRUAL CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00014	CONCEPTUS, INC.	3/31/2009	9/22/2009

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED PT COMPLAINT OF DAILY BLEEDING BEGINNING ON THE DAY FOLLOWING HER ESSURE PROCEDURE (2008). THE PT HAD NO HISTORY OF BLEEDING PRIOR TO THE ESSURE PROCEDURE; NO MEDICATIONS WERE CHANGED FOLLOWING THE ESSURE PROCEDURE. [IN ORDER TO TREAT THE BLEEDING], PHYSICIAN PERFORMED AN ENDOMETRIAL ABLATION IN 2009. PT HAD NOT FOLLOWED UP WITH THE PHYSICIAN'S OFFICE, SO IT IS UNK WHETHER PT'S SYMPTOMS HAVE RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00013	CONCEPTUS, INC.	3/31/2009	2/12/2010

Event Information:

Event Date (B3): 2/20/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2007
Explant Date (E7): 2/20/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ECTOPIC PREGNANCY. PHYSICIAN REPORTED PT WITH ECTOPIC PREGNANCY (DATE OF REPORTED PREGNANCY (B) (6) 2008) 14 MONTHS FOLLOWING THE ESSURE PROCEDURE (DATE OF PROCEDURE (B) (6) 2007). HSG ((B) (6) 2008) REPORTED THAT MICRO-INSERTS APPEARED PROPERLY PLACED AND THAT OCCLUSION WAS DEMONSTRATED. CONCEPTUS HAS NOT REVIEWED HSG FILMS. THE PREGNANCY WAS DISCONTINUED IN (B) (6) 2008 AND A HYSTERECTOMY WAS PERFORMED ON (B) (6) 2009. DURING THE HYSTERECTOMY, IT WAS NOTED THAT THE MICRO-INSERT WAS NO LONGER IN THE PROPER LOCATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	4/7/2009	4/21/2009

Event Information:

Event Date (B3): 3/17/2009 **Report Date (B4): 4/7/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE, PERMANENT
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 627754

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE TIP WOULD NOT COME OFF OF HANDPIECE AND WIRE- HAD TO UNSCREW BUT STILL DIFFICULT. FINALLY, THE WIRE WAS CUT, AND A HYSTEROSCOPIC FORCEP RETRIEVED THE PIECE NEAR END THAT FINALLY CAME APART. STAFF REPORT OTHER DIFFICULTIES WITH THIS PRODUCT BUT NO DETAILS.
==========
MANUFACTURER RESPONSE FOR PERMANENT BIRTH CONTROL, ESSURE
==========
NOTIFIED 4/8/09. RECEIVED RETURN NUMBER SO DEVICE CAN BE RETURNED FOR EVALUATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5010651	CONCEPTUS	4/7/2009	4/22/2009

Event Information:

Event Date (B3): 2/13/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESS205
Device Type (E2): TUBAL OCCLUSION
Model # (E4): ESS205
Catalog # (E4): ESSURE
Lot #(E4): 12245206

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT SCHEDULED FOR BILATERAL ESSURE TUBAL OCCLUSION, ENDOMETRIAL BALLOON ABLATION, AND HYSTEROSCOPY AND LAPAROSCOPIC CHOLECYSTECTOMY. FIRST DR DID HIS PROCEDURES, AND THEN THE SCOPE WAS INSERTED INTO THE ABDOMEN FOR THE LAPAROSCOPIC GALLBLADDER. SECOND DR TOOK A LOOK AT THE UTERUS, AND THE ESSURE SPRINGS -COILS- WERE PROTRUDING OUT OF THE UTERUS. FIRST DR WAS CALLED BACK INTO THE ROOM. HE REMOVED THE ESSURE SPRINGS AND APPLIED FALOPE RINGS BILATERALLY. SECOND DR PROCEEDED ON WITH THE LAPAROSCOPIC GALLBLADDER WITHOUT INCIDENT. PT AND PT'S FAMILY MEMBER WERE INFORMED OF ALL PROCEDURES IN THE RECOVERY ROOM AFTER PT WAS AWAKE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5010652	CONCEPTUS	4/7/2009	5/11/2009

Event Information:

Event Date (B3): 12/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): CONTRACEPTIVE COIL, ESS 305
Model # (E4):
Catalog # (E4):
Lot #(E4): 626978; 626975

Single Use:
Implant Date (E6): 12/5/2008
Explant Date (E7): 3/2/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS PLACED IN 2008. I EXPERIENCED CONSTANT PAIN IN MY PELVIC AREA ON THE RIGHT SIDE. PREVENTING ME FROM SITTING COMFORTABLY FOR LONG PERIODS OF TIME, BENDING OVER, STRETCHING, OR LIFTING HEAVY OBJECTS. MY DOCTOR PUT ME ON MUSCLE RELAXANTS AND PAIN MEDICATION, TO NO AVAIL. SHE SURGICALLY REMOVED THE DEVICES, ALONG WITH SECTIONS OF MY FALLOPIAN TUBES IN 2009. DATES OF USE: 2008 - 2009. EVENT ABATED AFTER USE STOPPED: YES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INCORPORATED	4/13/2009	4/28/2009

Event Information:

Event Date (B3): 4/10/2009 **Report Date (B4): 4/13/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE, PERMANENT
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING STERILIZATION PROCEDURE, PHYSICIAN FIRED THE ESSURE PERMANENT BIRTH CONTROL DEVICE, AND DID NOT SEE THE COILS COME OUT AS USUAL. THE COILS WERE NOT IN THE ESSURE PERMANENT BIRTH CONTROL DEVICE WHEN IT WAS REMOVED. COILS WERE NOT FOUND IN PATIENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	4/20/2009	5/19/2009

Event Information:

Event Date (B3): 1/16/2009 **Report Date (B4): 4/20/2009** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): PERMANENT STERILIZATION SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 628434

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PATIENT'S INITAL PROCEDURE WAS PERFORMED SEVERAL MONTHS AGO. DURING THIS PROCEDURE, PRIOR TO ATTEMPTED PLACEMENT OF THE ESSURE DEVICE, A 2CM ENDOMETRIAL FIBROID WAS DETACHED VIA CAUTERY; HOWEVER WAS VERY DIFFICULT TO REMOVE. SEVERAL ATTEMPTS WERE MADE TO REMOVE THE FIBROID WITHOUT SUCCESS AND THE DECISION WAS MADE TO LEAVE IT IN SITU. ESSURE PLACEMENT WAS THEN ATTEMPTED. DIFFICULT VISUALIZATION WAS REPORTED ON THE RIGHT SIDE AS THE TUBAL OSTIUM WAS SOMEWHAT OCCLUDED BY ENDOMETRIAL TISSUE AND ON THE LEFT SIDE, IT WAS OCCLUDED BY AREA OF DISSECTION OF THE PREVIOUS FIBROID. THE PATIENT RETURNED TO SURGERY 3 DAYS LATER FOR ABDOMINAL PAIN. DURING DIAGNOSTIC LAPAROSCOPY, THE ESSURE SPRING WAS IDENTIFIED PARTIALLY IMBEDDED IN THE PATIENT'S BOWEL. THE PHYSICIAN SUCCESSFULLY REMOVED THE SPRING AND THE PATIENT TOLERATED THE PROCEDURE WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00015	CONCEPTUS, INC.	4/21/2009	3/3/2010

Event Information:

Event Date (B3): 2/22/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628432

Single Use: Y
Implant Date (E6): 2/20/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

BOTH PHYSICIAN AND PT REPORTED THIS EVENT TO CONCEPTUS. PHYSICIAN REPORTS THAT A PT DEVELOPED A RASH AND ITCHING SHORTLY AFTER THE ESSURE PROCEDURE - ABOUT 2-3 DAYS. PT WAS ASKED SEVERAL TIMES REGARDING ANY ALLERGIES SHE MAY HAVE, ESPECIALLY METAL ALLERGIES, WHICH SHE DENIED. AFTER SEVERAL WEEKS THE PT REMEMBERED THAT SHE COULD NOT WEAR "CHEAP JEWELERY" AS A CHILD AND REPORTED THIS TO THE PHYSICIAN. THE PT WAS REFERRED TO AN ALLERGIST WHERE A FORMAL NICKEL ALLERGY TEST WAS PERFORMED, WHICH RETURNED A POSITIVE ALLERGY TO NICKEL. UPON LEARNING THE RESULTS, PATIENT REQUESTED REMOVAL, WHICH WAS PERFORMED VIA HYSTERECTOMY. PT'S SYMPTOMS RESOLVED FOLLOWING SURGERY. PHYSICIAN IS UNSURE WHETHER NICKEL ALLERGY TO MICRO-INSERTS CAUSED PT'S SYMPTOMS, BUT HE COULD NOT IDENTIFY ANY OTHER REASONS FOR HER SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00016	CONCEPTUS, INC.	4/21/2009	3/3/2010

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS THAT A PATIENT HAS PRESENTED WITH A PREGNANCY. THE ESSURE MICRO-INSERTS WERE IMPLANTED IN THE PT IN 2007. THE PT FOLLOWED UP WITH HER 3-MONTH HSG WHICH WAS READ BY RADIOLOGY AS "BILATERAL TUBAL OCCLUSION." BECAUSE IT WAS AN ECTOPIC PREGNANCY, THE PREGNANCY WAS TERMINATED. PT THEN UNDERWENT AN UNCOMPLICATED TUBAL LIGATION AT WHICH POINT THE RIGHT ESSURE DEVICE APPEARED TO BE JUST UNDER THE SEROSA. THE HSG WAS REVIEWED AND IT WAS ORIGINALLY MISREAD AND ACTUALLY DOES SHOW UNILATERAL SPILL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00017	CONCEPTUS, INC.	4/29/2009	9/3/2009

Event Information:

Event Date (B3): 4/9/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/28/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS THAT ONE OF HER PATIENTS REPORTED A PREGNANCY 12 MONTHS FOLLOWING ESSURE MICRO-INSERT IMPLANTATION. BECAUSE IT WAS AN ECTOPIC PREGNANCY, THE PREGNANCY WAS TERMINATED. A REVIEW OF THE 3-MONTH HSG FILMS SHOWS THAT THE LEFT DEVICE WAS NOT SATISFACTORILY PLACED ACCORDING TO THE ESSURE CONFIRMATION TEST INSTRUCTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5011040		5/7/2009	5/18/2009

Event Information:

Event Date (B3): 4/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/21/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE ESSURE APPLICATION - I EXPERIENCED SEVERE PAIN AND CRAMPING. THE PROCEDURE WAS EXPLAINED TO BE A SIMPLE 13 MINUTE-APPROX-PROCEDURE. I WAS IN THE OFFICE OVER AN HOUR AND EXPERIENCED EXTREME PAIN AND WAS GIVEN 2 DOSES OF PAIN MEDICINE, STILL PAIN WAS EXCRUCIATING. THE PROCEDURE WAS NOT COMPLETED DUE TO THE SHOCK I WAS GOING THROUGH. ONLY ONE SIDE WAS COMPLETED AND THE DOCTOR HAS ADVISED ME TO TRY HOSPITALIZATION TO COMPLETE THE OTHER SIDE WHICH I AM TERRIFIED TO ATTEMPT NOW. THIS WAS AN IN OFFICE PROCEDURE THAT WENT TERRIBLY WRONG. AFTER 2 WEEKS, I AM STILL IN DISCOMFORT BUT HAVE BEEN GIVEN PAIN MEDICATION THAT HELPS THE PAIN. I AM CURIOUS IF OTHERS HAVE HAD THIS HAPPEN AND IS STILL REALLY A SAFE PRODUCT. DOSE: 1 APPLICATION. DATES OF USE: 2009. DIAGNOSIS: BIRTH CONTROL. EVENT ABATED AFTER USE STOPPED: NO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00018	CONCEPTUS, INC.	5/8/2009	9/22/2009

Event Information:

Event Date (B3): 7/3/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORTED THAT DURING AN IMPLANTATION PROCEDURE FOR THE ESSURE MICRO-INSERTS THE PHYSICIAN WAS UNABLE TO DETACH THE DELIVERY WIRE FROM THE MICRO-INSERT. THE PATIENT WAS TAKEN TO A HOSPITAL WHERE GENERAL SURGERY WAS PERFORMED IN ORDER TO REMOVE THE MICRO-INSERTS.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS AR FILE RESULTED IN A CHANGE IN THE DETERMINATION OF REPORTABILITY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00019	CONCEPTUS, INC.	5/12/2009	8/21/2010

Event Information:

Event Date (B3): 4/1/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORTED CENTRAL LOW PELVIC AND VAGINAL PAIN TO HER PHYSICIAN AFTER UNCOMPLICATED ESSURE PLACEMENT. A TOTAL VAGINAL HYSTERECTOMY AND SALPINGECTOMY WERE PERFORMED AND THE ESSURE MICRO-INSERTS WERE REMOVED. PATIENT ALSO HAS A POSSIBLE NICKEL ALLERGY AS SHE RECALLED THAT "CHEAP JEWELRY" CAUSED HER TO BREAK OUT IN THE PAST AND SHE HAS ONLY WORN "GOOD" JEWELRY IN RECENT YEARS. IT IS UNKNOWN WHETHER A DERMATOLOGICAL SKIN TEST WAS PERFORMED ON THE PATIENT; ADDITIONALLY, THERE IS NO INFORMATION ON WHETHER THE PHYSICIAN BELIEVES PATIENT'S SYMPTOMS ARE RELATED TO THE REPORTED NICKEL ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5011101	CONCEPTUS	5/13/2009	5/21/2009

Event Information:

Event Date (B3): 12/31/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/31/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

UNDERWENT ESSURE PLACEMENT. PHYSICIAN STATED THAT HE HAD TROUBLES PLACING THE LEFT IMPLANT. AT THE 3 MONTH HSG, LEFT IMPLANT WAS "APPEARS TO BE DISPLACED INFERIORLY AND MEDIALLY FROM THE LOCATION OF THIS TUBE. DOES NOT PROJECT OVER THE DISTINCT LOCATION OF THE OPACIFIED ENDROMETRIAL CANAL, IT COULD BE WITHIN THE VAGINAL VAULT". PT SCHEDULED FOR A TUBAL LIGATION IN 2009. PT REQUESTED PHYSICIAN REMOVE THE LEFT IMPLANT IF IT IS NOT IN THE TUBE. PHYSICIAN REPLIED THAT "IF THEY SEE THE IMPLANT THEY WILL REMOVE IT, BUT IT'S IN THE UTERUS, WHERE IT'S SUPPOSED TO BE." PT WILL BE MORE ASSERTIVE ABOUT HAVING THE LEFT IMPLANT FOUND AND REMOVED AS WELL AND MAKING SURE PHYSICIAN PERFORMS TUBAL LIGATION ON BOTH LEFT AND RIGHT TUBES AT TIME OF SURGERY. DATES OF USE: 2008 - 2009. DIAGNOSIS OR REASON FOR USE: UNWANTED FERTILITY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5011184	CONCEPTUS	5/19/2009	6/1/2009

Event Information:

Event Date (B3): 5/19/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 628435

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN THE SURGEON WENT TO FIRE THE ESSURE, IT DEPLOYED BUT UNRAVELLED IN THE PT. THERE WAS NO HARM TO THE PT. SURGEON JUST REMOVED THE PIECE WITH FORCEPS. THE RN GAVE UP ANOTHER ESSURE KIT AND TUBAL WAS SUCCESSFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5011260	CONCEPTUS INCORPORATED	5/27/2009	6/8/2009

Event Information:

Event Date (B3): 10/24/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626977

Single Use:
Implant Date (E6): 10/24/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE DONE IN 2008. I HAVE HAD 2 XRAYS AND HSG TEST PERFORMED TO MAKE SURE THE PROCEDURE HAS WORKED. IT HAS NOT WORKED, ONE OF THE IMPLANTS CAME OUT OF MY FALLOPIAN TUBE AND IS NOW SITTING IN MY UTERUS. MY DOCTOR WILL NOT REFUND ANY OF THE COST, AND IS NOW WANTING ME TO HAVE MY TUBES TIED. I HAD THIS PROCEDURE DONE BECAUSE IT HAD SUCH A HIGH SUCCESS RATE AND NOW I'M OUT OF MONEY AND IT DOESN'T EVEN WORK. WHAT'S WORSE IS NOW THERE IS A FOREIGN OBJECT FLOATING AROUND IN MY BODY, MY MONTHLY CRAMPS HAVE GOTTEN WORSE. I HAVE NOW READ ON SEVERAL FORUMS OF WOMEN HAVING THIS SAME PROBLEMS AND WORSE. I THINK MORE NEEDS TO BE DONE TO MAKE SURE THIS DOESN'T HAPPEN TO ANOTHER VICTIM. ALSO IN ORDER TO TAKE THESE OUT, IT INVOLVES A MAJOR SURGERY. I FEEL THIS PRODUCT IS A DANGER TO ANYONE WHO USES IT. DATES OF USE: 2008 - 2009 - CURRENT. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00020	CONCEPTUS, INC.	5/27/2009	8/14/2009

Event Information:

Event Date (B3): 1/16/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628434

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED A PATIENT COMPLAINT OF ABDOMINAL PAIN FOLLOWING ESSURE PROCEDURE. PRIOR TO PLACEMENT OF THE ESSURE MICRO-INSERTS, PHYSICIAN ATTEMPTED TO REMOVE A 2 CM ENDOMETRIAL FIBROID VIA CAUTERY. SEVERAL ATTEMPTS WERE MADE TO REMOVE THE FIBROID WITHOUT SUCCESS AND THE DECISION WAS MADE TO LEAVE IT IN SITU. ESSURE MICRO-INSERT PLACEMENT WAS THEN ATTEMPTED. DIFFICULT VISUALIZATION WAS REPORTED FOR BOTH SIDES; RIGHT OSTIUM WAS SOMEWHAT OCCLUDED BY ENDOMETRIAL TISSUE AND LEFT OSTIUM WAS OCCLUDED BY AREA OF ATTEMPTED FIBROID REMOVAL. SUCCESSFUL BILATERAL PLACEMENT WAS REPORTED. PATIENT RETURNED FOR A DIAGNOSTIC LAPAROSCOPY THREE DAYS FOLLOWING THE ESSURE PROCEDURE FOR ABDOMINAL PAIN. DURING DIAGNOSTIC LAPAROSCOPY, THE ESSURE MICRO-INSERT WAS IDENTIFIED PARTIALLY EMBEDDED IN THE PATIENT'S BOWEL. THE PHYSICIAN SUCCESSFULLY REMOVED THE MICRO-INSERT.

Manufacturer Narrative (H10):

THE ESSURE PHYSICIAN'S INSTRUCTIONS FOR USE STATES: IF TUBAL OR UTERINE PERFORATION OCCURS OR IS SUSPECTED, IMMEDIATELY DISCONTINUE THE ESSURE DEVICE PLACEMENT PROCEDURE, AND WORK-UP THE PATIENT FOR A PERFORATION. A VERY SMALL PERCENTAGE OF WOMEN IN THE E

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00021	CONCEPTUS, INC.	6/3/2009	3/22/2011

Event Information:

Event Date (B3): 5/8/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 629142

Single Use: Y
Implant Date (E6): 5/7/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING AN ESSURE PROCEDURE, PHYSICIAN CANNULATED THE FALLOPIAN TUBE WITH THE MICRO-INSERT TIP AND ATTEMPTED TO DEPLOY AND DETACH IT. HE HAD DIFFICULTIES WITH DEPLOYMENT, THUS, HE TRIED TO WITHDRAW THE ENTIRE DELIVERY SYSTEM BEFORE COMPLETING PLACEMENT STEPS. DURING WITHDRAWAL OF THE DELIVERY SYSTEM, THE MICRO-INSERT FULLY DEPLOYED AND BECAME ANCHORED IN THE FALLOPIAN TUBE. PHYSICIAN TRIED TO REMOVE THE MICRO-INSERT WITH GRASPERS, BUT THE MICRO-INSERT BROKE. PHYSICIAN SCHEDULED A FOLLOW-UP HYSTEROSCOPY AND ATTEMPTED TO REMOVE THE MICRO-INSERT AGAIN WITH GRASPERS, BUT WAS UNABLE TO COMPLETELY REMOVE IT. MOST OF THE MICRO-INSERT WAS REMOVED, HOWEVER, IT IS BELIEVED THAT THE BALL TIP OF THE MICRO-INSERT AND AN OUTER COIL FRAGMENT REMAIN INSIDE THE PT'S FALLOPIAN TUBE; PT HAS REPORTED NO ISSUES AT THIS POINT. THE PT ELECTED TO HAVE A SECOND ATTEMPT AT ESSURE MICRO-INSERT PLACEMENT; DURING THE PROCEDURE, THE PHYSICIAN DID NOT ENCOUNTER ANY RESISTANCE OR DIFFICULTY, AND THE SECOND PLACEMENT ATTEMPT WAS SUCCESSFUL.

Manufacturer Narrative (H10):

THE FOLLOWING WARNING APPEARS IN THE ESSURE INSTRUCTIONS FOR USE: WARNING: MICRO-INSERT REMOVAL SHOULD NOT BE ATTEMPTED HYSTEROSCOPICALLY ONCE THE MICRO-INSERT HAS BEEN PLACED. THE ONLY EXCEPTION IS DURING THE ACTUAL PLACEMENT PROCEDURE WHEN REMOVAL MAY B

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00022	CONCEPTUS, INC.	6/11/2009	6/22/2009

Event Information:

Event Date (B3): 5/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING ESSURE PROCEDURE AND PRIOR TO IMPLANTATION ATTEMPT, A PERFORATION WAS CREATED IN THE PT'S UTERUS (POSSIBLY CAUSED BY DILATOR). BECAUSE OF A 5300CC FLUID DEFICIT, PT WAS TAKEN TO AN OR FOR A DIAGNOSTIC LAPAROSCOPY; FLUID WAS DRAINED FROM ABDOMEN AND A TUBAL LIGATION PERFORMED. PERFORATION WAS CAUTERIZED. PT HAD REPORTED SATISFACTORY STATUS AND IS DOING FINE FOLLOWING ADDITIONAL TREATMENT.

Manufacturer Narrative (H10):

PRODUCT IFU WARNING: IN ORDER TO REDUCE THE RISK OF HYPERVOLEMIA, THE PROCEDURE SHOULD BE IMMEDIATELY ABORTED, IF THE FLUID DEFICIT OF THE PHYSIOLOGIC SALINE DISTENSION MEDIUM EXCEEDS 1500CC.

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00023	CONCEPTUS, INC.	6/11/2009	2/19/2010

Event Information:

Event Date (B3): 5/14/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/8/2009
Explant Date (E7): 5/15/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED A PATIENT IMPLANTED WITH THE ESSURE BIRTH CONTROL DEVICES EXPERIENCED PELVIC PAIN RADIATING TO HER LOWER BACK AND DOWN HER LEG LESS THAN ONE WEEK FOLLOWING IMPLANTATION PROCEDURE. DOCTOR PERFORMED ULTRASOUND WHEREIN NOTHING ABNORMAL WAS FOUND; MICRO-INSERTS APPEARED TO BE IN PROPER LOCATION. PATIENT'S PAIN WAS MANAGED WITH ORAL ANALGESICS BUT PATIENT REPORTED THAT PAIN CONTINUED WITH INCREASING SEVERITY. PATIENT REQUESTED REMOVAL OF MICRO-INSERTS. PHYSICIAN HOSPITALIZED PATIENT, TREATED HER WITH HYDRATION AND IV ANTIBIOTICS. CT SCAN AND CBC WERE NORMAL. A LAPAROSCOPY WAS PERFORMED TO REMOVE IMPLANTS AND TO PERFORM A TUBAL LIGATION. PATIENT REPORTS THAT HER PAIN HAS RESOLVED FOLLOWING MICRO-INSERT REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5011590	CONCEPTUS	6/18/2009	6/24/2009

Event Information:

Event Date (B3): 6/18/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE FEMALE STERILI DEVICE X 2
Device Type (E2): SAME
Model # (E4):
Catalog # (E4):
Lot #(E4): 628318

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE STERILIZATION PROCEDURE WAS NOT SUCCESSFUL. BOTH CATHETERS APPEARED IN RETROSPECT TO HAVE BEEN LOADED INTO INTRODUCERS FRONT FOR BACK AND BACK FOR FRONT. GOLD BANDS WERE NOTED TO BE NEAR TIP OF DEVICES AND THEY SHOULD BE ON TRAILING END OF THE DEVICE. ROUND KNOB DOES NOT APPEAR TO BE END OF DEVICES AS IS NORMALLY SEEN. THERE WAS NO ADVERSE OUTCOME FOR PATIENT OTHER THAN PROCEDURE NOT BEING ACCOMPLISHED. THE SUPPLIER OF THE ESSURE DEVICE HAS BEEN NOTIFIED AND THE PLAN IS TO HAVE THE CONCEPTUS REP PICK UP THE DEVICES AND RETURN THEM TO CONSEPTUS. LOT # 628318. DATES OF USE: 2009. DIAGNOSIS OR REASON FOR USE: DESIRED STERILIZATION. EVENT ABATED AFTER USE STOPPED OR DOSE REDUCED: #1 YES. #2 YES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5011625	CONCEPTUS INC.	6/19/2009	6/30/2009

Event Information:

Event Date (B3): 4/29/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL BY CONCEPTUS
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 619695

Single Use:
Implant Date (E6): 4/29/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE, THE INTRODUCER BROKE OFF AFTER DEPLOYMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5011816	CONCEPTUS	6/24/2009	7/14/2009

Event Information:

Event Date (B3): 2/11/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4): 628147

Single Use:
Implant Date (E6): 2/11/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTS IMPROPERLY INSERTED, ONE CAME OUT AND IS IN AN INCORRECT LOCATION. MUST HAVE LAPROSCOPIC SURGERY TO REMOVE INCORRECT IMPLANT AND CORRECT PREVIOUS PROCEDURE. DIAGNOSIS OR REASON FOR USE: PREVENTION OF PREGNANCY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00025	CONCEPTUS, INC.	6/25/2009	7/31/2010

Event Information:

Event Date (B3): 3/4/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIV
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/22/2009
Explant Date (E7): 3/4/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT UNDERWENT NOVASURE AND ESSURE PROCEDURES CONCOMITANTLY ON (B)(6) 2009. PATIENT PRESENTED ONE MONTH POST NOVASURE AND ESSURE PROCEDURES WITH CRAMPING. PATIENT WAS TREATED WITH MOTRIN. PATIENT VISITED ER APPROXIMATELY 2 WEEKS LATER WITH PELVIC PAIN. A CT SCAN REVEALED THAT THE ESSURE INSERT ON THE LEFT SIDE HAD BEEN EXPELLED INTO THE UTERUS. ON (B)(6) 2009 PATIENT HAD LAPAROSCOPIC SURGERY TO REMOVE BOTH ESSURE MICRO-INSERTS; A TUBAL LIGATION WAS ALSO PERFORMED. ONE OF THE ESSURE MICRO-INSERTS (RIGHT SIDE) WAS FOUND EMBEDDED IN THE BOWEL AND REMOVED.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS AR FILE RESULTED IN A CHANGE IN THE DETERMINATION OF REPORTABILITY.

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00026	CONCEPTUS, INC.	6/25/2009	7/31/2010

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): OTHER	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD ESSURE PROCEDURE PERFORMED WHICH RESULTED IN BILATERAL PLACEMENT OF ESSURE MICRO-INSERTS. A HYSTEROSALPINGOGRAM WAS PERFORMED (DATE UNKNOWN) WHICH SHOWED AN OBVIOUS PERFORATED RIGHT DEVICE (DEVICE IN LEFT UPPER ABDOMEN) WITH ONE OF THE PROXIMAL BANDS DETACHED AND PROBABLY EMBEDDED IN THE UTERUS WITH A VERY PATENT RIGHT TUBE. DOCTOR PERFORMED AN ADDITIONAL PROCEDURE TO REMOVE THE PERFORATED MICRO-INSERT AND COMPLETED A LAPAROSCOPIC TUBAL LIGATION ON THE RIGHT FALLOPIAN TUBE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00027	CONCEPTUS, INC.	6/29/2009	3/21/2011

Event Information:

Event Date (B3): 6/3/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627295

Single Use: Y
Implant Date (E6): 10/18/2008
Explant Date (E7): 6/3/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE PERFORMED ON (B)(6) 2008 WITH BILATERAL PLACEMENT AND NO PROBLEMS NOTED DURING PLACEMENT PROCEDURE. PT PRESENTED POST ESSURE PROCEDURE WITH ABDOMINAL PAIN THAT PERSISTED FOR 8 MONTHS. RIGHT FALLOPIAN TUBE WAS PERFORATED. PHYSICIAN REMOVED MICRO-INSERT AND PERFORMED TUBAL LIGATION ON RIGHT SIDE. PHYSICIAN'S OPINION IS THAT THE ESSURE MICRO-INSERT WAS DIRECTLY RELATED TO THE PAIN THE PT WAS EXPERIENCING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00029	CONCEPTUS, INC.	6/29/2009	3/21/2011

Event Information:

Event Date (B3): 3/2/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/5/2008
Explant Date (E7): 3/2/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT REPORTS PELVIC PAIN AFTER HAVING THE ESSURE MICRO-INSERTS IMPLANTED ON (B)(6), 2008. PT STATES THAT SHE WAS PLACED ON PAIN MEDICATION BY HER PHYSICIAN, HOWEVER, THE PAIN PERSISTED. THE PT'S PHYSICIAN SURGICALLY REMOVED THE ESSURE MICRO-INSERTS AS WELL AS SECTIONS OF HER FALLOPIAN TUBES ON (B)(6), 2009. PT REPORTS THAT HER PAIN ABATED AFTER REMOVAL OF ESSURE MICRO-INSERTS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00028	CONCEPTUS, INC.	6/29/2009	3/22/2011

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 632032

Single Use: Y
Implant Date (E6): 6/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING AN ESSURE PROCEDURE, THE PHYSICIAN PERFORATED THE PT'S UTERUS WITH A HYSTEROSCOPE; PT'S BOWELS WERE VISIBLE. PHYSICIAN WAS ASKED TO DISCONTINUE PROCEDURE BY COMPANY REPRESENTATIVE IN ATTENDANCE WHEN FLUID DEFICIT OF PHYSIOLOGIC SALINE USED FOR DISTENSION WAS GREATER THAN RECOMMENDED BY PRODUCT INSTRUCTIONS FOR USE. PHYSICIAN CONTINUED, PLACING RIGHT SIDE MICRO-INSERT. PHYSICIAN WAS AGAIN ASKED TO DISCONTINUE PROCEDURE AS FLUID DEFICIT OF DISTENSION MEDIUM REACHED 3100CC. PHYSICIAN DISCONTINUED ESSURE PROCEDURE AND PERFORMED A LAPAROSCOPIC TUBAL LIGATION ON THE LEFT SIDE, DRAINED FLUID FROM PT'S ABDOMEN (3100CC REMOVED), AND CAUTERIZED UTERINE PERFORATION. UPON COMPLETION, FLUID DEFICIT WAS ZERO. PHYSICIAN REMARKED THAT SHE DID NOT OBSERVE DAMAGE TO PT'S BOWEL.

Manufacturer Narrative (H10):

SECTION VI OF THE IFU STATES: IN ORDER TO REDUCE THE RISK OF HYPERVOLEMIA, THE PROCEDURE SHOULD BE IMMEDIATELY ABORTED IF THE FLUID DEFICIT OF THE PHYSIOLOGIC SALINE DISTENSION MEDIUM EXCEEDS 1500CC.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5011898	CONCEPTUS	7/9/2009	7/20/2009

Event Information:

Event Date (B3): 6/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626211

Single Use:
Implant Date (E6): 6/3/2008
Explant Date (E7): 5/13/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PT UNDERWENT ROUTINE HYSTEROSCOPIC PLACEMENT OF BILATERAL ESSURE DEVICES. HER POST OPERATIVE HYSTEROSALPINGOGRAM IN 2008 SHOWED BILATERAL TUBAL OCCLUSION. SHE PRESENTED WITH AN INTRAUTERINE PREGNANCY IN 2009. THE PT UNDERWENT ELECTIVE PREGNANCY TERMINATION BECAUSE OF THE HIGH-RISK NATURE OF HER PREVIOUS PREGNANCIES. SHE WAS TAKEN TO SURGERY SIX DAYS EARLIER, AND IT WAS DISCOVERED THAT THE DISTAL RIGHT ESSURE DEVICES HAD PERFORATED THROUGH THE PROXIMAL ISTHMIC PORTION OF THE RIGHT FALLOPIAN TUBE. DIAGNOSIS OR REASON FOR USE: VOLUNTARY PERMANENT STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00030	CONCEPTUS, INC.	7/9/2009	3/27/2010

Event Information:

Event Date (B3): 6/11/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 5/21/2009
Explant Date (E7): 6/11/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTED PELVIC PAIN ONE WEEK FOLLOWING ESSURE MICRO-INSERT IMPLANTATION. THE PT'S PHYSICIAN PERFORMED A FLAT PLATE X-RAY AND IT WAS OBSERVED THAT THE INSERT ON THE PT'S RIGHT SIDE APPEARED TO BE PLACED SATISFACTORILY; INSERT ON PT'S LEFT SIDE APPEARED TO BE PLACED PROXIMALLY AND WAS DESCRIBED AS "TWISTED IN A BALL." A BILATERAL LAPAROSCOPIC TUBAL LIGATION WAS PERFORMED AND THE RIGHT SIDE MICRO-INSERT WAS REMOVED. THE LEFT SIDE MICRO-INSERT WAS REMOVED HYSTEROSCOPICALLY. THE PHYSICIAN COULD NOT FIND ANY EVIDENCE OF WHAT THE SOURCE WAS OF PT'S PAIN. PT'S PAIN RESOLVED COMPLETELY FOLLOWING DEVICE REMOVAL. THE PHYSICIAN DOES NOT KNOW IF THE ESSURE MICRO-INSERTS WERE DIRECTLY RELATED TO THE PAIN THAT THE PT EXPERIENCED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00031	CONCEPTUS, INC.	7/9/2009	3/27/2010

Event Information:

Event Date (B3): 12/15/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: N
Implant Date (E6): 2/15/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTS CONTINUOUS NAUSEA SINCE SHE UNDERWENT THE ESSURE PROCEDURE ON (B) (6) 2008. PT HAD A NICKEL ALLERGY TEST PERFORMED BY AN ALLERGIST AND RESULT WAS POSITIVE FOR NICKEL ALLERGY. ALLERGIST STATES THAT HE/SHE BELIEVES PT'S NAUSEA IS A SYSTEMIC REACTION TO THE NICKEL CONTAINED IN THE ESSURE MICRO-INSERT AND WILL NEED TO TAKE PREDNISONE INDEFINITELY OR HAVE MICRO-INSERTS REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	7/12/2009	7/23/2009

Event Information:

Event Date (B3): 6/11/2009 **Report Date (B4): 7/12/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE, PERMANENT
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 638494; 637215

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 6/12/2009

Event Description (B5):

ON FIRST ATTEMPT TO PLACE THE ESSURE ON THE PATIENT'S RIGHT SIDE, DR. EXPERIENCED A "FAILURE TO DEPLOY" (REF #ESS305, LOT# 637215). THERE WAS A SECOND ATTEMPT TO PLACE AN ESSURE WITH A DIFFERENT LOT# BY DR. (REF # ESS305, LOT # 638494). SHE EXPERIENCED "SUBSEQUENT DIFFICULTY WITH VISUALIZATION ONCE LOCATED-NEXT ESSURE DIDN'T EXPAND." THE PROCEDURE WAS ABORTED WITH A HYSTEROSCOPIC TIME OF 40 MIN. BOTH SETS OF ESSURE DEVICES WITH PACKAGING WERE TO RETURN TO THE COMPANY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00052	CONCEPTUS, INC.	7/16/2009	6/7/2010

Event Information:

Event Date (B3): 8/12/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/31/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED AN ECTOPIC PREGNANCY FOR A PATIENT THAT HE IMPLANTED WITH THE ESSURE MICRO-INSERTS ON (B)(6) 2009. ON (B)(6) 2009, THE PATIENT PRESENTED IN THE ER WITH PAIN; ECTOPIC PREGNANCY DIAGNOSED. A SALPINGECTOMY WAS PERFORMED (DATE UNKNOWN) AND PREGNANCY TERMINATED; PATIENT IS DOING WELL FOLLOWING THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00048	CONCEPTUS, INC.	7/16/2009	8/21/2010

Event Information:

Event Date (B3): 8/18/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/16/2009
Explant Date (E7): 8/18/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT ONE OF HER PTS EXPERIENCED LOWER EXTREMITY SWELLING OF ONE LEG FOLLOWING THE IMPLANTATION OF ESSURE MICRO-INSERTS. THE PT WAS REFERRED TO AN ALLERGIST; NICKEL ALLERGY WAS CONFIRMED BY THE ALLERGIST. THE ESSURE MICRO-INSERTS WERE REMOVED FROM THE PT AND THE PT'S SWELLING HAS RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00024	CONCEPTUS, INC.	7/17/2009	8/21/2010

Event Information:

Event Date (B3): 2/25/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REMOVAL OF ESSURE IMPLANTS DUE TO PELVIC PAIN. PROCEDURE INCLUDED REMOVAL OF TWO PHLEBOLITHS FROM THE UTERINE WALL. PT REPORTED TO PHYSICIAN THAT THERE HAS BEEN COMPLETE RESOLUTION OF PAIN POST REMOVAL OF THE TWO MICRO-INSERTS.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00032	CONCEPTUS, INC.	7/17/2009	8/21/2010

Event Information:

Event Date (B3): 6/17/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 12/3/2008
Explant Date (E7): 6/17/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT UNDERWENT ESSURE MICRO-INSERT IMPLANTATION ON (B)(6)2008. ON (B)(6)2008, PT REPORTED TO HER PHYSICIAN THAT SHE HAD BEEN EXPERIENCING CONSTANT PELVIC PAIN SINCE THE ESSURE MICRO-INSERTS WERE IMPLANTED. ON (B)(6)2009, THE MICRO-INSERTS WERE SURGICALLY REMOVED FROM THE PT. PHYSICIAN STATED A SMALL FRAGMENT FROM ONE OF THE MICRO-INSERTS, PROBABLY LESS THAN 1/4 CM IN LENGTH, WAS SEEN IN AN HSG IMAGE; THE FRAGMENT WAS NOT LOCATED DURING THE PROCEDURE AND MIGHT REMAIN INSIDE THE PT. PT'S PHYSICIAN BELIEVES THAT THE SOURCE OF THE PAIN WAS DIRECTLY RELATED TO THE ESSURE MICRO-INSERTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5012221		7/22/2009	8/12/2009

Event Information:

Event Date (B3): 3/25/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): REF ESS305
Catalog # (E4):
Lot #(E4): 628144

Single Use:
Implant Date (E6): 3/25/2009
Explant Date (E7): 3/25/2009
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE WAS OPENED AND PLACED THROUGH THE OPERATIVE PORT OF THE HYSTEROSCOPE. THE LEFT TUBAL OSTIUM WAS EASILY CANNULATED WITH THE ESSURE DEVICE. THE DEVICE WAS DEPLOYED PER PROTOCOL. UPON DEPLOYMENT, DEVICE GOT COMPLETELY TANGLED WITHIN ITSELF, THE COILS WERE WRAPPED AROUND EACH OTHER AND KNOTTED AND THE DEVICE DID NOT RELEASE FROM ITS APPLICATOR APPROPRIATELY. THE KNOTTED AND COILED DEVICE THAT WAS IN THE LEFT TUBE WAS GRASPED WITH A HYSTEROSCOPIC GRASPER AND REMOVED. NO CIRCUMSTANCES OR EVENTS KNOWN TO ADVERSELY AFFECT DEVICE. PT UNDER CONSCIOUS SEDATION REMAINED COMPLETELY STABLE THROUGHOUT COURSE OF PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00034	CONCEPTUS, INC.	7/24/2009	10/14/2009

Event Information:

Event Date (B3): 5/26/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/25/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MICRO-INSERT PLACEMENT PROCEDURE PERFORMED ON A PT IN 2008. IN 2009, PT WAS DIAGNOSED WITH AN ECTOPIC PREGNANCY. METHOTREXATE WAS ADMINISTERED TO THE PT THE FOLLOWING DAY. PT PRESENTED WITH PAIN ON LEFT SIDE THREE DAYS LATER; A SALPINGECTOMY WAS PERFORMED ON THE LEFT SIDE AND FILSHIE CLIPS WERE PLACED BILATERALLY. IT WAS REPORTED THAT THE PT WAS DOING WELL POST-OP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00035	CONCEPTUS, INC.	7/24/2009	8/21/2010

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT EXPERIENCED PELVIC PAIN DURING AND IMMEDIATELY FOLLOWING ESSURE MICRO-INSERT IMPLANTATION PROCEDURE (DATE OF PROCEDURE UNK) FOR 6 WEEKS. PT'S PHYSICIAN PRESCRIBED NSAIDS FOR PAIN MANAGEMENT, BUT NO ALLEVIATION OF PAIN SYMPTOMS WAS REPORTED BY THE PT. MICRO-INSERTS WERE REMOVED (DATE UNK) LAPAROSCOPICALLY BY THE PHYSICIAN. UNK IF PAIN HAS RESOLVED FOLLOWING DEVICE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5012108	CONCEPTUS	7/27/2009	8/4/2009

Event Information:

Event Date (B3): 7/5/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A PROCEDURE CALLED ESSURE PLACED INSIDE MY TUBES TO PREVENT PREGNANCY IN LATE 2008. IN 2009, THE PRODUCT AND CONCEPTUS AS THE MANUFACTURER DID NOT WORK. I AM 9 WEEKS PREGNANT. DATES OF USE: PREGNANCY, LATE 2008 - 2009. DIAGNOSIS: PREVENT PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00037	CONCEPTUS, INC.	8/4/2009	4/7/2010

Event Information:

Event Date (B3): 4/13/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2004
Explant Date (E7): 4/13/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT HAD ESSURE MICRO-INSERTS PLACED IN 2004, AND FOR 2 YEARS EXPERIENCED INTERMITTENT LEFT LOWER QUADRANT ABDOMINAL PAIN. THE 3 MONTH HSG POST ESSURE SHOWED A PERFORATED DEVICE IN THE ABDOMINAL CAVITY. PHYSICIAN PERFORMED A BILATERAL TUBAL LIGATION BUT COULD NOT LOCATE THE DEVICE FOR REMOVAL. SINCE THEN, SHE HAS HAD CT SCANS AND AN MRI TO IDENTIFY A CAUSE FOR THE PAIN. ONE OF THE CT SCANS SHOWED A MICRO-INSERT TO BE WITHIN THE OMENTUM UNDER THE LEFT RIB CAGE. THE PATIENT LATER PRESENTED TO THE ER WITH SEVERE LEFT LOWER QUADRANT PAIN, NAUSEA AND VOMITING. LAPAROSCOPY PERFORMED UNDER FLUOROSCOPY AND WAS ABLE TO LOCATE THE MICRO-INSERT AND REMOVE IT SUCCESSFULLY. THE PATIENT STATED HER PAIN HAS RESOLVED FOLLOWING SURGERY.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00036	CONCEPTUS, INC.	8/4/2009	8/21/2010

Event Information:

Event Date (B3): 6/25/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/19/2009
Explant Date (E7): 6/25/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE MICRO-INSERTS IMPLANTED ON (B)(6)2009. TWO MONTHS LATER, PT PRESENTED WITH PELVIC PAIN. NO SIGNS OF OBVIOUS INFECTION DURING INITIAL PT EXAMINATION. DIAGNOSTIC LAPAROSCOPY PERFORMED - FOUND INFECTION IN PT AND HAD TO OPEN UP PT ABDOMINALLY; TOTAL ABDOMINAL HYSTERECTOMY PERFORMED AND THE MICRO-INSERTS WERE REMOVED. DOCTOR DOES NOT BELIEVE THAT ESSURE DEVICES WERE DIRECTLY RELATED TO PT'S PAIN. PT'S PAIN CONTINUED FOLLOWING DEVICE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00033	CONCEPTUS, INC.	8/4/2009	3/21/2011

Event Information:

Event Date (B3): 12/19/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/19/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

WHILE UNDERGOING AN ESSURE PLACEMENT PROCEDURE, A PT SUFFERED A UTERINE PERFORATION (BELIEVED TO BE CAUSED BY THE HYSTEROSCOPE); FLUID DEFICIT OF 5000 ML SALINE REPORTED FOR THE UNILATERAL PLACEMENT PROCEDURE. A F/U X-RAY REVEALED DISTAL PLACEMENT OF THE ESSURE IMPLANT IN THE PERITONEAL CAVITY. A LAPAROSCOPIC TUBAL LIGATION WAS PERFORMED AND THE ESSURE MICRO-INSERT WAS REMOVED.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00038	CONCEPTUS, INC.	8/4/2009	3/21/2011

Event Information:

Event Date (B3): 12/20/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 624499

Single Use: Y
Implant Date (E6): 10/17/2007
Explant Date (E7): 12/20/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO WEEKS FOLLOWING ESSURE MICRO-INSERT PLACEMENT (PROCEDURE PERFORMED ON (B)(6) 2007), THE PATIENT REPORTED PAIN. ON (B)(6) 2007 IT WAS REPORTED THAT THE PATIENT HAD TO HAVE THE DEVICES REMOVED DUE TO HER PAIN; ONE HYSTEROSCOPICALLY AND THE OTHER LAPAROSCOPICALLY.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	8/5/2009	8/24/2009

Event Information:

Event Date (B3): 7/14/2009 **Report Date (B4): 7/28/2009** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INTRAUTERINE DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

AN ESSURE IUD MIGRATED IN TWO SEPARATE PIECES INTO THE FALLOPIAN TUBE, AND THROUGH THE WALL OF THE UTERUS, TO THE OMENTUM AND BOWEL, REQUIRING SURGERY FOR REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5012397	CONCEPTUS INC	8/10/2009	8/19/2009

Event Information:

Event Date (B3): 1/22/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/22/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING 5 PREGNANCIES, MY HUSBAND AND I DECIDED WE DID NOT WANT ANYMORE CHILDREN. CONSULTING WITH MY OB, SHE SUGGESTED HAVING THE ESSURE PROCEDURE. AS A WORKING MOTHER, IT WAS BEST FOR THE LITTLE DOWN TIME. I HAD AN EXTREMELY PAINFUL EXPERIENCE. WENT IN 3 MONTHS LATER FOR CONFIRMATION TEST. THEY SAID IT WAS 100% SUCCESSFUL AND I COULD NO LONGER HAVE CHILDREN. HERE IT IS A FEW MONTHS LATER, I WAS HAVING VERY IRREGULAR BLEEDING AND THEN ALL OF A SUDDEN NO PERIOD AT ALL. I TOOK SEVERAL HOME PREGNANCY TESTS. ALL POSITIVE, I WAS IN SHOCK. DATES OF USE: 2009 - CURRENT. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5012410	CONCEPTUS	8/11/2009	8/24/2009

Event Information:

Event Date (B3): 3/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/5/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS IMPLANTED IN 2007. HSG TEST FOUND FULL BLOCKAGE OF TUBES 3 MONTHS LATER. PATIENT BECAME PREGNANT IN 2009. DATES OF USE: 2007 -- 2009. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5012447	CONCEPTUS INC.	8/13/2009	8/24/2009

Event Information:

Event Date (B3): 8/11/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4): 637223

Single Use:
Implant Date (E6): 8/11/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE PREMATURELY DEPLOYED RESULTING OF IMPROPER IMPLANTATION AND RETENTION OF SMALL PORTION OF WIRE. DATES OF USE: 2009. DIAGNOSIS: ESSURE DEVICE USED IN SURGICAL PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00039	CONCEPTUS, INC.	8/13/2009	8/21/2010

Event Information:

Event Date (B3): 7/14/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): 3SS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/14/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MICRO-INSERT WAS REMOVED FROM A PT. THE MICRO-INSERT HAD BROKEN INTO TWO PIECES AND PERFORATED THE PT; ONE PIECE WAS FOUND EMBEDDED IN THE PT'S BOWEL AND THE OTHER PIECE WAS FOUND ENCAPSULATED IN THE BOWEL. IT WAS REPORTED THAT THE PT IS DOING FINE FOLLOWING REMOVAL OF THE DEVICE, AND THERE ARE NO PLANS FOR ADD'L TREATMENT FOR THE DEVICE PERFORATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00040	CONCEPTUS, INC.	8/20/2009	3/21/2011

Event Information:

Event Date (B3): 7/9/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 7/9/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTED PELVIC PAIN 1-2 WEEKS FOLLOWING ESSURE MICRO-INSERT IMPLANTATION. AN X-RAY TAKEN SHOWED PROPER LOCATION OF DEVICES. PHYSICIAN STATED THE PT HAS A NICKEL SENSITIVITY. PT ELECTED TO HAVE TOTAL HYSTERECTOMY AND MICRO-INSERTS WERE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00041	CONCEPTUS, INC.	8/20/2009	3/21/2011

Event Information:

Event Date (B3): 7/17/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/29/2009
Explant Date (E7): 7/17/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT UNDERWENT ESSURE MICRO-INSERT IMPLANTATION ON (B)(6) 2009 AT A HOSPITAL UNDER GENERAL ANESTHESIA. PT REPORTED THAT IMMEDIATELY FOLLOWING THE ESSURE IMPLANTATION PROCEDURE, SHE HAD CRAMPING, BLEEDING, FEVER, AND CHILLS. PT REPORTED THAT SHE RETURNED TO HER DOCTOR THAT PERFORMED THE ESSURE PROCEDURE AND WAS TOLD THAT SHE HAD AN INFECTION. PT STATED THAT ON (B)(6) 2009 SHE HAD A SALPINGECTOMY DUE TO INFECTION AND THE ESSURE MICRO-INSERTS WERE REMOVED AS WELL. PT REPORTED ALL SYMPTOMS HAVE CEASED FOLLOWING DEVICE REMOVAL AND SALPINGECTOMY. PT STATED SHE WAS TOLD BY HER PHYSICIAN THAT THE INFECTION WAS CAUSED BY THE ESSURE MICRO-INSERTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5012530		8/23/2009	8/31/2009

Event Information:

Event Date (B3): 6/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

"ESSURE COILS" ARE 45% NICKEL WHICH I'M ALLERGIC TO MY SYMPTOMS; DOUBLE CYCLES, RE-OCCURRING OVARIAN CYSTS, CHRONIC FATIGUE, SEVERE ABDOMINAL PAIN. DEVICES REMOVED IN EARLY 2009, SUCCESS.. HOW CAN MFR USE NICKEL IN A MEDICAL IMPLANT WHEN IT'S SUCH A COMMON ALLERGY METAL? IT TOOK SEVERAL YEARS, DOCTORS AND OF COURSE MONEY TO DIAGNOSE. OTHER WOMEN NEED TO KNOW. DEVICES INSTALLED, AND REMOVED BY THE SAME SURGEON WHO INSTALLED AS EXPERIMENTAL SURGERY. I WAS ONE OF THE PTS TO RECEIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00042	CONCEPTUS, INC.	8/26/2009	8/21/2010

Event Information:

Event Date (B3): 7/20/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 641436

Single Use: Y
Implant Date (E6): 7/16/2009
Explant Date (E7): 7/20/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT UNDERWENT ESSURE MICRO-INSERT IMPLANTATION ON (B)(6)2009. ON (B)(6)2009, PT PRESENTED WITH PAIN AND BLEEDING. PT EXPERIENCED PAIN AND BLEEDING UNTIL (B)(6)2009, AT WHICH TIME THE MICRO-INSERTS WERE REMOVED. PT'S SYMPTOMS RESOLVED FOLLOWING DEVICE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00043	CONCEPTUS, INC.	8/26/2009	8/21/2010

Event Information:

Event Date (B3): 7/27/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626218

Single Use: Y
Implant Date (E6): 7/27/2009
Explant Date (E7): 7/27/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING AN ESSURE MICRO-INSERT IMPLANTATION PROCEDURE, A PERFORATION OCCURRED, CAUSED BY THE MICRO-INSERT. THE PT'S PHYSICIAN STATED THAT SINCE THE MICRO-INSERT WAS IN THE PT'S ABDOMEN, IT WAS MEDICALLY NECESSARY TO REMOVE IT IN ORDER TO PREVENT FURTHER HARM TO THE PT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00044	CONCEPTUS, INC.	9/3/2009	4/6/2010

Event Information:

Event Date (B3): 10/1/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 6/1/2006
Explant Date (E7): 10/1/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT A PT WHO HAD THE ESSURE MICRO-INSERTS PLACED ON (B) (6) 2006 HAD CONTINUED PAIN AND BLEEDING. THE PT REQUESTED REMOVAL OF THE DEVICES AND STATED THAT IT WAS AFFECTING HER QUALITY OF LIFE. ONE DEVICE WAS SUCCESSFULLY REMOVED HYSTEROSCOPICALLY AND A BILATERAL LAPAROSCOPIC TUBAL LIGATION WAS SUCCESSFULLY PERFORMED. THE PT'S PHYSICIAN WAS UNABLE FIND ANY OTHER ETIOLOGY FOR THE PT'S SYMPTOMS EXCEPT FOR "IN-UTERO COILS" FROM THE MICRO-INSERT THAT SHE REPORTED AS THE CAUSE OF IRRITATION TO THE ENDOMETRIAL LINING.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00047	CONCEPTUS, INC.	9/3/2009	6/16/2010

Event Information:

Event Date (B3): 11/19/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/19/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED A PREGNANCY FOR A PT WHO UNDERWENT THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE. PT WAS 4 WEEKS PREGNANT (ECTOPIC) ON THE DATE OF INITIAL REPORT. PT SUCCESSFULLY TREATED WITH METHOTREXATE AND WAS DOING WELL FOLLOWING TREATMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00045	CONCEPTUS, INC.	9/3/2009	8/21/2010

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 6/1/2006
Explant Date (E7): 1/1/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT REPORTED INTERMITTENT BLEEDING FOR TWO YEARS FOLLOWING ESSURE MICRO-INSERT IMPLANTATION. THE PT'S PHYSICIAN REPORTED THAT THIS PT HAD AN ULTRASOUND WHICH SHOWED THAT THE MICRO-INSERT TRAILING COILS WERE TANGLED AND INTERTWINED; PHYSICIAN BELIEVED THAT THE TRAILING COILS MAY HAVE BEEN RELATED TO THE PT'S BLEEDING. THE MICRO-INSERTS WERE REMOVED DURING A LAPAROSCOPIC HYSTERECTOMY.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00046	CONCEPTUS, INC.	9/3/2009	8/21/2010

Event Information:

Event Date (B3): 8/5/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 8/4/2009
Explant Date (E7): 8/5/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY FOLLOWING ESSURE MICRO-INSERT PLACEMENT ON (B)(6)2009, PT EXPERIENCED SEVERE PAIN. PT WAS OBSERVED IN THE PHYSICIAN'S OFFICE FOR 2 HOURS AND PAIN NEVER IMPROVED. PT WENT TO THE EMERGENCY ROOM ON THE NIGHT OF (B)(6)2009 AND WAS GIVEN MEDICATION TO MANAGE THE PAIN AND ADMITTED TO THE HOSPITAL. ON (B)(6)2009, PT HAD A BILATERAL SALPINGECTOMY PERFORMED AND THE ESSURE MICRO-INSERTS WERE REMOVED. PT'S PAIN IMMEDIATELY RESOLVED FOLLOWING THE PROCEDURE. PT IS NO LONGER EXPERIENCING ANY PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00049	CONCEPTUS, INC.	9/3/2009	8/21/2010

Event Information:

Event Date (B3): 7/21/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION. TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/27/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED AN ECTOPIC PREGNANCY FOR A PT THAT UNDERWENT THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE ON (B)(6)2008. PT DID NOT RETURN FOR AN ESSURE CONFIRMATION TEST (HSG). PT WAS TREATED WITH METHOTREXATE AND PREGNANCY TERMINATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00050	CONCEPTUS, INC.	9/3/2009	8/21/2010

Event Information:

Event Date (B3): 7/16/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/27/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED AN ECTOPIC PREGNANCY FOR A PT THAT UNDERWENT THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE ON (B)(6)2008. PT DID NOT RETURN FOR AN ESSURE CONFIRMATION TEST (HSG). ON (B)(6)2009, PT WAS TREATED WITH METHOTREXATE; PREGNANCY WAS TERMINATED. ON (B)(6)2009, PT WAS SEEN BY HER PHYSICIAN FOR FOLLOW UP, POST-TREATMENT. ON (B)(6)2009, PHYSICIAN'S NURSE REPORTED THAT PT IS DOING WELL.

Manufacturer Narrative (H10):

THIS MEDICAL DEVICE REPORT IDENTIFIES A SECOND ECTOPIC PREGNANCY, POST ESSURE, FOR THE SAME PT. THE FIRST ECTOPIC PREGNANCY WAS REPORTED AS: MDR 2951250-2009-00049.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00051	CONCEPTUS, INC.	9/3/2009	8/21/2010

Event Information:

Event Date (B3): 7/1/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/1/2009
Explant Date (E7): 1/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT A PT UNDERWENT THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE IN (B)(6) 2009. ONE TO TWO DAYS FOLLOWING THE PROCEDURE, PT BEGAN TO EXPERIENCE PAIN. PAIN PROGRESSED OVER A COURSE OF 2 WEEKS. A CT SCAN INDICATED THE LEFT DEVICE WAS PARTIALLY PERFORATED AT THE CORNUA. PT UNDERWENT LAPAROSCOPY FOR REMOVAL OF BOTH DEVICES AND EXPERIENCED IMMEDIATE PAIN RELIEF; LAP TUBAL WAS PERFORMED. IT WAS OBSERVED DURING THE LAPAROSCOPY THAT THE LEFT DEVICE WAS PARTIALLY ADHERED TO THE OMENTUM.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	9/22/2009	9/30/2009

Event Information:

Event Date (B3): 9/17/2009 **Report Date (B4): 9/22/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE, PERMANENT
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 619695

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE FAILED TO DISCHARGE PROPERLY.
MANUFACTURER RESPONSE (AS PER REPORTER) FOR PERMANENT BIRTH CONTROL, ESSURE,
LEFT MESSAGE TO RETURN FOR EVALUTAION.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	9/24/2009	9/30/2009

Event Information:

Event Date (B3): 9/23/2009 **Report Date (B4): 9/24/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE, PERMANENT
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 664434

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING ESSURE PROCEDURE ONLY ONE DEVICE WAS PLACED. THE SECOND DEVICE RECOILED DURING PLACEMENT AND WAS UNABLE TO BE USED. THIS DEVICE IS AVAILABLE AT OUR FACILTY FOR THE MANUFACTURER.
MANUFACTURER RESPONSE (AS PER REPORTER) FOR BIRTH CONTROL, ESSURE,
HOSPITAL WILL REQUEST FINDINGS OF ANLAYSIS FROM MANUFACTURER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00053	CONCEPTUS, INC.	9/25/2009	10/2/2009

Event Information:

Event Date (B3): 7/13/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 623824

Single Use: Y
Implant Date (E6): 7/13/2007
Explant Date (E7): 7/13/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN PERFORMED A NOVASURE ABLATION PROCEDURE CONCOMITANTLY WITH THE ESSURE MICRO-INSERT IMPLANTATION PROCEDURE. WHILE PERFORMING THE NOVASURE ABLATION, A PERFORATION OCCURRED AND THE ABLATION PROCEDURE WAS ABORTED. THE PHYSICIAN PROCEEDED WITH THE ESSURE MICRO-INSERT IMPLANTATION. FOLLOWING COMPLETION OF PLACEMENT OF THE ESSURE MICRO-INSERTS, THE PHYSICIAN NOTED THE PRESENCE OF HYPERVOLEMIA AND A SIGNIFICANT VOLUME OF FLUID ON THE PATIENT'S ABDOMEN. THE PHYSICIAN PERFORMED A LAPAROSCOPY TO REMOVE THE FLUID AND DISCOVERED A PERFORATION AT THE LEFT MICRO-INSERT. THE LEFT MICRO-INSERT WAS REMOVED, THE PERFORATION WAS CAUTERIZED AND A LAPAROSCOPIC TUBAL LIGATION WAS COMPLETED ON THE PATIENT.

Manufacturer Narrative (H10):

IFU STATEMENT: THERE ARE NO DATA TO SUPPORT THE USE OF ABLATIVE TECHNOLOGIES CONCOMITANTLY WITH ESSURE, THEREFORE, IT IS NOT RECOMMENDED. IFU WARNING: DO NOT PERFORM THE ESSURE PROCEDURE CONCOMITANTLY WITH ENDOMETRIAL ABLATION. MDR IS BEING REPORTED OUTSI

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5012869	CONCEPTUS	9/25/2009	10/5/2009

Event Information:

Event Date (B3): 8/27/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE BIRTH CONTROL SYSTEM
Model # (E4): ESS 205 - M5
Catalog # (E4): ESS305
Lot #(E4): 638493

Single Use:
Implant Date (E6): 8/27/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT IN SURGERY FOR ESSURE PLACEMENT VIA HYSTEROSCOPY. DURING HYSTEROSCOPY, THE OPENINGS TO BOTH TUBES WERE IDENTIFIED. ONE ESSURE DEVICE WAS OPENED, AND PLACED IN POSITION WITH THE BLACK INDICATOR NOTED AT THE OSTIUM. THE DEVICE WAS DEPOYED. AFTER DEPLOYMENT, THERE WERE NO COILS VISUALIZED IN THE UTERUS. THE SURGEON ELECTED TO PROCEED WITH DIAGNOSTIC LAPAROSCOPY AND BILATERAL TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5012870	CONCEPTUS INC USA	9/25/2009	10/5/2009

Event Information:

Event Date (B3): 12/30/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4): 628046

Single Use:
Implant Date (E6): 12/30/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE STERILIZATION DONE IN 2008. I WENT BACK FOR MY HSG TEST IN 2009, AND WAS TOLD THAT MY TUBES WERE BLOCKED. A COUPLE OF WEEKS AFTER THE TEST, I GOT PREGNANT. I WENT TO MY DOCTOR AND HE CONFIRMED THE PREGNANCY, AND TOLD ME THAT IT WAS A PRODUCT MALFUNCTION. HE SAID THAT HE CONTACTED THE COMPANY, BUT NO ONE RETURNED HIS CALL. DATES OF USE: 2008 TO PRESENT. DIAGNOSIS OR REASON FOR USE: PREVENT PREGNANCY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00054	CONCEPTUS, INC.	9/25/2009	8/21/2010

Event Information:

Event Date (B3): 8/28/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 8/5/2009
Explant Date (E7): 8/28/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT COMPLAINED OF GENERALIZED INTENSE ITCHING AND BURNING ON HER SKIN FOLLOWING PLACEMENT OF ESSURE MICRO-INSERTS. PHYSICIAN TREATED PT SYMPTOMS INITIALLY WITH A STEROID PACK, BUT PT WAS NON-COMPLIANT WITH THE MEDICAL TREATMENT. PT UNDERWENT REMOVAL OF ESSURE DEVICES BECAUSE OF SUSPECTED NICKEL ALLERGY; NO ALLERGY TEST WAS PERFORMED TO CONFIRM NICKEL ALLERGY. PT IS DOING WELL FOLLOWING REMOVAL OF DEVICES.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PTS WITH SUSPECTED HYPERSENSITIV

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5012929	CONCEPTUS INCORPORATED, USA	10/1/2009	10/15/2009

Event Information:

Event Date (B3): 4/12/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 627754

Single Use:
Implant Date (E6): 2/17/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PINCHING, PULLING, BURNING FEELING IN PELVIC AREA NOTED THROUGHOUT THE DAY. LOWER ABDOMINAL CRAMPING -WENT TO THE REST ROOM THINKING BOWEL MOVEMENT-. BRIGHT RED BLEEDING INSTEAD-NOT MENSTRUAL CYCLE- NOTED WITH WIPING DURING URINATION. AFTER ABOUT 15 MINS IN THE RESTROOM PAIN CEASED AS WELL AS BLEEDING. CHECKED ESSURE WEBSITE BUT I DID NOT FIND ANY OF THE DESCRIBED SYMPTOMS. PAIN OFF AND ON THROUGHOUT THE WEEK. DURING FLIGHT -DESCENDING - INCREASED PAIN FELT AGAIN. SOME SPOTTING NOTED. NO PAIN FOR NEXT 2 WEEKS. STARTED AGAIN ON THE 3RD WEEK. SCHEDULED HSG CONFIRMATION TEST FOR 2009. FELT THE SAME PINCHING, PULLING, BURNING FEELING THROUGHOUT THAT DAY. HSG CONF. TEST/PAIN WAS UNBEARABLE. I WAS UNABLE TO TOLERATE THE "USUAL" AMOUNT OF DYE. THE RESULT WAS BOTH TUBES WERE BLOCKED. NO DISCOMFORT UNTIL TWO MONTHS LATER. THE ABOVE DESCRIBED PAIN WAS OFF AND ON FOR ABOUT 2 WEEKS WORSE WITH FLYING -DESCENDING-. I GOOGLED PROBLEMS WITH ESSURE AND I FOUND SEVERAL SITES WITH WOMEN COMPLAINING OF SIMILAR PROBLEMS. I PHONED AN ESSURE CERTIFIED OB/GYN IN MY AREA TWO MONTHS PRIOR, TO ASK ABOUT REMOVAL AND I WAS TOLD IT IS PERMANENT AND THERE WASN'T ANYTHING THEY COULD DO ABOUT MY PROBLEM. I WAS VERY EXCITED ABOUT MY ESSURE OUTCOME FOR THE FIRST MONTH AND A HALF. I AM NOT EXCITED ABOUT THE DISCOMFORT I HAVE BEEN EXPERIENCING OFF AND ON SINCE 2009. I HAVE FOUND THAT REMOVAL OF THE ESSURE WITHOUT HYSTERECTOMY -I DEFINITELY DO NOT WANT A HYSTERECTOMY- IS POSSIBLE. I DO NOT WANT TO LIVE WITH THIS PAIN MUCH LONGER. I PLAN TO HAVE THEM REMOVED. IF THERE IS A RECALL OF THE COILS I WOULD LIKE TO KNOW ABOUT IT. IT WILL MAKE ME FEEL BETTER KNOWING THE COILS ARE TRULY THE PROBLEM. DOSE: 1 IN EACH FALLOPIAN TUBE. FREQUENCY: CONTINUOUS. ROUTE: UNK. DATES OF USE: PRESENTLY, 2009. DIAGNOSIS: PERMANENT BIRTH CONTROL.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00055	CONCEPTUS, INC.	10/9/2009	10/16/2009

Event Information:

Event Date (B3): 7/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ES305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/2/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT COMPLAINED OF BLEEDING AND PAIN (DATE OF ONSET UNK) FOLLOWING PLACEMENT OF ESSURE MICRO-INSERTS. THE PHYSICIAN OBSERVED THAT 1 DEVICE APPEARED CURLED UP IN THE LEFT CORNUA OF THE PT'S UTERUS ON A HYSTEROSALPINGOGRAM TEST. A DIAGNOSTIC HYSTEROSCOPY WAS PERFORMED IN 2009, AND IT WAS CONFIRMED THAT ONE DEVICE HAD CURLED UP IN PT'S LEFT UTERINE CORNUA; THE DEVICE WAS REMOVED WITH GRASPERS WITHOUT INCIDENT. A LAPAROSCOPY WAS ALSO PERFORMED, AT WHICH TIME THE SECOND ESSURE MICRO-INSERT WAS REMOVED, AND A TUBAL LIGATION PERFORMED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00056	CONCEPTUS, INC.	10/9/2009	10/16/2009

Event Information:

Event Date (B3): 6/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7): 6/8/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT WAS IMPLANTED WITH THE ESSURE MICRO-INSERTS IN 2006; AN HSG CONFIRMATION TEST, PERFORMED 3 MONTHS LATER, SHOWED BOTH FALLOPIAN TUBES OCCLUDED AND THE DEVICES WITH SATISFACTORY PLACEMENT. THE PT BEGAN EXPERIENCING SEVERE PELVIC PAIN ON HER RIGHT SIDE IN 2009; AN ULTRASOUND WAS DONE WHICH SHOWED THAT THE ESSURE MICRO-INSERT ON THE RIGHT SIDE HAD BEEN EXPELLED AND WAS IN THE PT'S UTERUS; ONE MONTH LATER, THE PT HAD LAPAROSCOPIC SURGERY TO REMOVE THE EXPELLED DEVICE. THE DEVICE ON PT'S LEFT SIDE WAS ALSO REPORTED BY PT TO BE IN THE PROCESS OF MIGRATING OUT OF THE FALLOPIAN TUBE; THIS MICRO-INSERT WAS REMOVED AND A BILATERAL TUBAL LIGATION WAS PERFORMED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00057	CONCEPTUS, INC.	10/9/2009	10/16/2009

Event Information:

Event Date (B3): 9/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 646531

Single Use: Y
Implant Date (E6): 8/17/2009
Explant Date (E7): 9/10/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT UNDERWENT AN ESSURE IMPLANTATION PROCEDURE AND A NOVASURE ABLATION PROCEDURE CONCOMITANTLY IN 2009. PT COMPLAINED OF SEVERE PAIN FOLLOWING PROCEDURES (DATE OF ONSET AND FREQUENCY UNK).THE PHYSICIAN ATTEMPTED TO MANAGE PAIN WITH NSAIDS AND ANTIBIOTICS; PAIN PERSISTED DESPITE TREATMENT. THE FOLLOWING MONTH, THE ESSURE MICRO-INSERTS WERE REMOVED. FOLLOWING REMOVAL, PAIN RESOLVED AND THE PT IS DOING WELL.

Manufacturer Narrative (H10):

IFU STATEMENT: THERE ARE NO DATA TO SUPPORT THE USE OF ABLATIVE TECHNOLOGIES CONCOMITANTLY WITH ESSURE, THEREFORE IT IS NOT RECOMMENDED. IFU WARNING: DO NOT PERFORM THE ESSURE PROCEDURE CONCOMITANTLY WITH ENDOMETRIAL ABLATION.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00058	CONCEPTUS, INC.	10/16/2009	10/29/2009

Event Information:

Event Date (B3): 9/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 646519

Single Use: Y
Implant Date (E6): 9/3/2009
Explant Date (E7): 9/16/2009
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3): 9/1/2009

Event Description (B5):

A PHYSICIAN REPORTED DIFFICULTY WITH THE ROLLBACK PROCEDURE DURING AN ESSURE PLACEMENT. THE PHYSICIAN REPORTED THAT EVENTUALLY THE DELIVERY CATHETER AND MICRO-INSERT FELL APART AS HE WAS TRYING TO REPOSITION TO DELIVERY CATHETER. THE PHYSICIAN BELIEVED THAT HE RETRIEVED ALL OR MOST OF THE ESSURE DEVICE FROM THE PATIENT. THE PHYSICIAN REPORTED THAT HE COMPLETED THE PROCEDURE WITH A NEW DELIVERY CATHETER AND OBTAINED BILATERAL PLACEMENT. THE PATIENT LATER PRESENTED WITH PAIN (DATE OF ONSET UNKNOWN). IN 2009, THE PHYSICIAN PERFORMED A HYSTERECTOMY AND THE ESSURE MICRO-INSERTS WERE REMOVED. PHYSICIAN DID NOT FIND ANY ADDITIONAL PIECES OF AN ESSURE DEVICE IN THE PATIENT. NUMEROUS ATTEMPTS WERE MADE TO CONTACT THE PHYSICIAN TO DETERMINE IF THE PATIENT'S PAIN WAS RELATED TO THE ESSURE MICRO-INSERTS, HOWEVER, NO RESPONSE WAS RECEIVED FROM THE PHYSICIAN. NO INFORMATION WAS RECEIVED THAT WOULD LINK THE PATIENT'S PAIN TO THE ESSURE PROCEDURE. NO INFORMATION WAS RECEIVED REGARDING DIAGNOSIS AND/OR TREATMENT OF PATIENT'S PAIN. NO INFORMATION RECEIVED REGARDING PATIENT'S PREVIOUS MEDICAL HISTORY.

Manufacturer Narrative (H10):

VISUAL INSPECTION: CONDITION OF CATHETER APPEARS NORMAL. CONDITION OF MICRO-INSERT WAS NOT RETURNED WITH CATHETER. IMPLANT FROM LOT 12407573 STRETCHED AND STILL ATTACHED TO DELIVERY SYSTEM. EVENT/INCIDENT DESCRIPTION CONFIRMED: YES. INSPECTION SUMMARY: A

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5013102	CONCEPTUS INCORPORATED	10/19/2009	10/27/2009

Event Information:

Event Date (B3): 1/20/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/20/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE PRESSURE PERMANENT TUBAL LIGATION PUT IN 5 YEARS AGO AND SINCE, I HAVE GOTTEN A NICKEL ALLERGY THAT I NEVER HAD BEFORE. I BREAK OUT IN RASHES ALL OVER MY BODY FROM IT. I ALSO HAVE CONSTANT LOWER ABDOMEN AND LOWER BACK PAIN, AND BLOATING IN MY LOWER ABDOMEN. I NEED TO HAVE THESE REMOVED AND HAVE A TOTAL HYSTERECTOMY DUE TO THE ALLERGY TO THE NICKEL IT HAS SWOLLEN MY UTERUS. DOSE OR AMOUNT: 2 COILS; FREQUENCY: ONCE; ROUTE: VAG. DATES OF USE: 2005 - 2009, PERMANENT. DIAGNOSIS OR REASON FOR USE: TO PREVENT PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00059	CONCEPTUS, INC.	10/21/2009	10/27/2009

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/26/2009
Explant Date (E7): 9/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORTED ONE OF HER ESSURE MICRO-INSERTS PERFORATED HER FALLOPIAN TUBE AND MIGRATED INTO THE PELVIC CAVITY. PATIENT EXPERIENCED PAIN AND REPORTED IT TO HER PHYSICIAN, WHO THEN SURGICALLY REMOVED SOME OF THE IMPLANT (METHOD AND DATE OF REMOVAL UNKNOWN). PATIENT REPORTED A SECOND SURGERY IS PLANNED BECAUSE HER PHYSICIAN WAS UNABLE TO REMOVE ALL OF THE IMPLANT; A PORTION IS LODGED IN HER APPENDIX. EFFORTS TO CONTACT THE PATIENT WERE MADE, HOWEVER, ALL 4 ATTEMPTS TO OBTAIN ADDITIONAL INFORMATION WERE UNSUCCESSFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00061	CONCEPTUS, INC.	10/28/2009	11/4/2009

Event Information:

Event Date (B3): 9/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 9/11/2009
Explant Date (E7): 9/25/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT A PATIENT, WHO HAD AN ESSURE PLACEMENT PROCEDURE IN 2009, PRESENTED WITH PAIN AND HEAVY BLEEDING FOLLOWING THE PROCEDURE (DATE UNKNOWN). PHYSICIAN REPORTED POOR VISUALIZATION OF INTRAUTERINE ANATOMY DUE TO HEAVY ENDOMETRIUM DURING IMPLANTATION. TWO WEEKS LATER, THE PHYSICIAN PERFORMED A DIAGNOSTIC HYSTEROSCOPY AND DISCOVERED AN ESSURE MICRO-INSERT IN THE PATIENT'S UTERINE TISSUE. THE PHYSICIAN REMOVED ONE MICRO-INSERT AND REPORTED THAT THE PATIENT IS DOING WELL WITH NO MORE PAIN OR BLEEDING. THE PHYSICIAN BELIEVES THAT THE ESSURE MICRO-INSERT WAS DIRECTLY RELATED TO THE PAIN AND BLEEDING THE PATIENT WAS EXPERIENCING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00062	CONCEPTUS, INC.	10/28/2009	11/4/2009

Event Information:

Event Date (B3): 4/16/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 4/1/2007
Explant Date (E7): 4/16/2007
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PATIENT BEGAN EXPERIENCING SEVERE PAIN WITHIN THE FIRST WEEK AFTER AN ESSURE MICRO-INSERT IMPLANTATION PROCEDURE. A CT SCAN REVEALED NOTHING REMARKABLE. THE PHYSICIAN INDICATED THAT SHE PERFORMED TESTS TO RULE OUT POTENTIAL SOURCES OF PATIENT'S PAIN - IT IS UNKNOWN WHAT TESTS WERE PERFORMED, AND THE RESULTS OF THE TESTS. THE MICRO-INSERTS WERE EVENTUALLY REMOVED DURING A LAPAROSCOPY. THE PATIENT'S PHYSICIAN STATED THAT 1 MICRO-INSERT WAS REMOVED FROM THE NORMAL DEPLOYED POSITION, WHILE THE OTHER WAS REMOVED FROM THE BOWEL AREA; PHYSICIAN STATED THAT THIS MICRO-INSERT BROKE INTO PIECES DURING REMOVAL, AND SHE BELIEVES THAT SHE RETRIEVED ALL THE PIECES. SEVERAL ATTEMPTS WERE MADE TO CONTACT THE PHYSICIAN AND THE PHYSICIAN'S OFFICE MANAGER, WITH NO SUCCESS.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME, BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	10/30/2009	11/12/2009

Event Information:

Event Date (B3): 10/28/2009 **Report Date (B4): 10/30/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH; KNH)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): BIRTH CONTROL DEVICE, PERMANENT
Model # (E4): *; *
Catalog # (E4): ESS305
Lot #(E4): 20183089; 20183089

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PERFORMING HYSTEROSCOPIC TUBAL LIGATION AND DEVICE WAS DEFECTIVE. IT WAS NOTICED ON THE MONITOR WHILE INSIDE THE PAIENT. THE DEVICE WAS REMOVED IMMEDIATELY BEFORE BEING USED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00060	CONCEPTUS, INC.	10/30/2009	11/30/2009

Event Information:

Event Date (B3): 9/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 664653

Single Use: Y
Implant Date (E6): 9/25/2009
Explant Date (E7): 9/30/2009
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT BEGAN EXPERIENCING PAIN DURING THE PLACEMENT OF AN ESSURE MICRO-INSERT AND CONTINUED FOLLOWING THE PROCEDURE. THE PHYSICIAN PRESCRIBED AN ANTIBIOTIC AND 800MG MOTRIN, HOWEVER, PT'S PAIN PERSISTED. PHYSICIAN PERFORMED A HYSTEROSCOPY ON PT AND REMOVED THE ESSURE MICRO-INSERT. THE PATIENT'S PAIN IMMEDIATELY RESOLVED AND PT IS DOING WELL. THE DOCTOR BELIEVES THE PT'S PAIN WAS DIRECTLY RELATED TO THE ESSURE MICRO-INSERT.

Manufacturer Narrative (H10):

ANALYSIS OF RETURNED DEVICE: FAILURE MODE SUMMARY; A PHYSICAL EXAMINATION WAS PERFORMED ON RETURNED PRODUCT: ON ESSURE DELIVERY SYSTEM WITHOUT MICRO-INSERT. THE PRODUCT WAS ASSESSED FOR DAMAGE AND OTHER DEFORMATION THAT WOULD INDICATE NON-CONFORMANCE TO S

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	11/2/2009	11/18/2009

Event Information:

Event Date (B3): 10/30/2009 **Report Date (B4): 11/2/2009** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH; KNH)
Brand Name (E1): ESSURE ESS 305; ESSURE ESS 305
Device Type (E2): BIRTH CONTROL DEVICE, PERMANENT
Model # (E4): *; *
Catalog # (E4): *
Lot #(E4): 646522; 646522

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AS THE SURGEON WAS ATTEMPTING TO PLACE THE ESSURE, SHE MET RESISTANCE. THE SURGEON DID NOT "FEEL" THAT SHE HAD PROPER PLACEMENT SO ATTEMPTED TO REMOVE SOME EXTRA TISSUE AND SHE SAW SOME BLEEDING. SHE EXPLORED AND SAW A PERFORATION; THEREFORE DID NOT PLACE THE ESSURE. SHE STOPPED THE PROCEDURE AND DID A LAPAROSCOPIC BILATERAL TUBAL LIGATION WITH ANOTHER DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00063	CONCEPTUS, INC.	11/5/2009	8/21/2010

Event Information:

Event Date (B3): 2/11/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628147

Single Use: Y
Implant Date (E6):
Explant Date (E7): 2/11/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

EVENT REPORT NUMBER (B)(4) RECEIVED BY FDA THROUGH MEDWATCH PROGRAM AND FORWARDED TO CONCEPTUS FOR REVIEW. EVENT DESCRIPTION: ESSURE IMPLANTS WERE IMPROPERLY INSERTED; ONE IMPLANT CAME OUT AND IS IN AN INCORRECT LOCATION. REPORT STATED THAT PT NEEDED TO HAVE LAPAROSCOPIC SURGERY TO REMOVE INCORRECTLY LOCATED IMPLANT AND CORRECT THE RESULT OF THE INITIAL PROCEDURE. NO ADDITIONAL INFO WAS PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00064	CONCEPTUS, INC.	11/6/2009	11/13/2009

Event Information:

Event Date (B3): 7/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/2/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTED THAT SHE EXPERIENCED FEVER AND CRAMPS/ DISCOMFORT FOLLOWING THE ESSURE PLACEMENT PROCEDURE. PT WAS GIVEN ANTIBIOTICS AND REPORTED THAT IT ALLEVIATED HER FEVER SYMPTOMS, BUT THE DISCOMFORT PERSISTED. THE ESSURE MICRO-INSERTS WERE RECENTLY REMOVED SURGICALLY, AND THE PT REPORTED THAT SHE IMMEDIATELY FELT BETTER FOLLOWING REMOVAL AND HAS BEEN DOING FINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00065	CONCEPTUS, INC.	11/6/2009	11/13/2009

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT REMOVAL OF TWO ESSURE MICRO-INSERTS WAS NECESSARY, DUE TO SEVERE PELVIC PAIN HIS PT WAS EXPERIENCING. THE PAIN RESOLVED FOLLOWING REMOVAL. THE PHYSICIAN DID NOT HAVE FURTHER DETAILS AT THE TIME THIS EVENT WAS REPORTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00066	CONCEPTUS, INC.	11/6/2009	11/13/2009

Event Information:

Event Date (B3): 4/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,C ONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 4/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT REMOVAL OF TWO ESSURE MICRO-INSERTS WAS NECESSARY, DUE TO SEVERE PELVIC PAIN HIS PT WAS EXPERIENCING. THE PAIN RESOLVED FOLLOWING REMOVAL. THE PHYSICIAN DID NOT HAVE FURTHER DETAILS AT THE TIME THIS EVENT WAS REPORTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00067	CONCEPTUS, INC.	11/6/2009	11/16/2009

Event Information:

Event Date (B3): 10/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/28/2009
Explant Date (E7): 10/16/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT A PT IMPLANTED WITH ESSURE MICRO-INSERTS IN 2009 REPORTED THAT SHE HAD BEEN EXPERIENCING PAIN SINCE IMPLANTATION. THIS PT DID NOT HAVE AN ESSURE CONFIRMATION TEST (HSG) PERFORMED. THE PHYSICIAN PROVIDED RESULTS OF AN ULTRASOUND WHICH INDICATED ONE OF THE MICRO-INSERTS WAS LOCATED IN THE MYOMETRIUM. THE PHYSICIAN REPORTED THAT SHE PERFORMED A HYSTEROSCOPY ON THIS PT AND COULD NOT MAINTAIN DISTENTION, SO SHE ASSUMED THERE WAS A PERFORATION. PHYSICIAN OPENED THE PT'S LOWER QUADRANT WITH ABDOMINAL INCISION AND FOUND A PERFORATION IN THE UTERUS. PHYSICIAN REMOVED THE PERFORATED MICRO-INSERT AND REPAIRED THE PERFORATION IN THE LEFT TUBE. THEN, THE PHYSICIAN PERFORMED A TUBAL LIGATION ON THE PT. PHYSICIAN LEFT THE MICRO-INSERT IN THE RIGHT TUBE. FOLLOWING REMOVAL OF THE MICRO-INSERT, IT WAS REPORTED THAT THE PT IS STILL EXPERIENCING PAIN SYMPTOMS AND TAKING MEDICATION TO MANAGE THE PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00068	CONCEPTUS, INC.	11/6/2009	8/21/2010

Event Information:

Event Date (B3): 10/8/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/23/2008
Explant Date (E7): 11/3/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT PRESENTED WITH PAIN ECTOPIC PREGNANCY WAS DIAGNOSED ON (B)(6)2009 AND THEN CONFIRMED VIA LAPAROSCOPIC EXCISION AND PATHOLOGIC EVAL ON (B)(6)2009. THE ECTOPIC PREGNANCY WAS TREATED VIA THE LAPAROSCOPIC INCISION. THE PHYSICIAN REPORTED THAT THE ESSURE MICRO-INSERT ON THE PT'S RIGHT SIDE HAD EXPELLED AND WAS REMOVED HYSTEROSCOPICALLY. PHYSICIAN PERFORMED A BILATERAL SALPINGECTOMY AS WELL. THE MICRO-INSERT ON THE PT'S LEFT SIDE WAS NOT VISUALIZED. PT CONTINUED TO EXPERIENCE PAIN. A CT SCAN REVEALED THE SECOND MICRO-INSERT TO BE LOCATED IN THE ANTERIOR MYOMETRIUM OF THE FUNDUS. ON (B)(6)2009, PHYSICIAN PERFORMED A HYSTERECTOMY AND REMOVED THE MICRO-INSERT FOUND IN THE ANTERIOR MYOMETRIUM.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00069	CONCEPTUS, INC.	11/13/2009	11/24/2009

Event Information:

Event Date (B3): 10/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 638495

Single Use: Y
Implant Date (E6): 10/14/2009
Explant Date (E7): 10/14/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FOLLOWING THE PLACEMENT OF 2 ESSURE MICRO-INSERTS IN A PATIENT, THE PHYSICIAN SUSPECTED THAT A PERORATION HAD OCCURRED IN THE PATIENT'S RIGHT FALLOPIAN TUBE. THE PHYSICIAN PERFORMED A DIAGNOSTIC LAPAROSCOPY AND CONFIRMED THAT THE MICRO-INSERT ON THE PATIENT'S RIGHT SIDE HAD PERFORATED THE TUBE, AND WAS LODGED IN THE SEROSA OF THE SMALL BOWEL. THE MICRO-INSERT WAS REMOVED; NO DAMAGE TO THE BOWEL WAS OBSERVED BY THE PHYSICIAN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00070	CONCEPTUS, INC.	11/13/2009	11/27/2009

Event Information:

Event Date (B3): 10/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628443

Single Use: Y
Implant Date (E6): 9/18/2009
Explant Date (E7): 10/16/2009
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3): 11/11/2009

Event Description (B5):

THE PHYSICIAN STATED THAT IT WAS NECESSARY TO REMOVE 2 ESSURE MICRO-INSERTS FROM A PATIENT IN 2009, DUE TO SEVERE ABDOMINAL PAIN, THE PATIENT WAS EXPERIENCING SINCE HER ESSURE IMPLANTATION THE MONTH PRIOR. THE LEFT DEVICE WAS REMOVED HYSTEROSCOPICALLY AND THE RIGHT DEVICE WAS REMOVED LAPAROSCOPICALLY, AS IT WAS NOT VISIBLE HYSTEROSCOPICALLY. THE DOCTOR REPORTED THAT THE UTERUS AND ABDOMEN APPEARED NORMAL; THE DEVICES WERE NOT PERFORATED AND APPEARED TO BE NORMAL AFTER REMOVAL. IT WAS REPORTED THAT THE PATIENT'S PAIN HAS RESOLVED FOLLOWING DEVICE REMOVAL. THE DOCTOR STATED THAT HE BELIEVES THAT THE PATIENT'S PAIN WAS DIRECTLY RELATED TO THE ESSURE MICRO-INSERTS.

Manufacturer Narrative (H10):

ANALYSIS OF RETURNED DEVICE: A PHYSICAL EXAMINATION WAS PERFORMED ON RETURNED PRODUCT: ONE ESSURE MICRO-INSERT WITHOUT DELIVERY SYSTEM. THE PRODUCT WAS ASSESSED FOR DAMAGE AND OTHER DEFORMATION THAT WOULD INDICATE NON-CONFORMANCE TO SPECIFICATION AND/OR A

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5013638	CONCEPTUS	11/18/2009	11/30/2009

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/7/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANT FAILURE CAUSING A PREGNANCY. DATES OF USE: 2008 - 2009. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00072	CONCEPTUS, INC.	11/19/2009	11/25/2009

Event Information:

Event Date (B3): 10/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 10/6/2009
Explant Date (E7): 10/16/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT PRESENTED TO HER PHYSICIAN WITH PAIN 2 WEEKS AFTER IMPLANTATION OF ESSURE MICRO-INSERTS. THE PHYSICIAN ORDERED A CT SCAN WHICH WAS NORMAL AND IT APPEARED THE ESSURE DEVICES WERE PRESENT AND WELL POSITIONED. THE PATIENT'S PAIN CONTINUED, SO THE PHYSICIAN DECIDED ON HYSTEROSCOPIC REMOVAL OF THE MICRO-INSERT ON THE PATIENT'S RIGHT SIDE. THE PHYSICIAN STATED THAT THE MICRO-INSERT WAS FOUND INTACT AND WAS EASILY REMOVED; THE PATIENT'S PAIN RESOLVED FOLLOWING REMOVAL. FOUR DAYS FOLLOWING MICRO-INSERT REMOVAL, THE PATIENT REPORTED A FEVER TO HER PHYSICIAN AND THAT SHE WAS AGAIN EXPERIENCING PAIN. PATIENT'S WHITE COUNT WAS FOUND TO BE ELEVATED. THE PATIENT WAS ALSO DEALING WITH A VIRAL INFECTION. A SECOND CT SCAN WAS PERFORMED WHICH ALSO SHOWED NO ABNORMALITIES. THE PATIENT WAS ADMITTED TO THE HOSPITAL AND GIVEN ANTIBIOTICS. THE PATIENT'S WHITE COUNT RETURNED TO NORMAL AND SHE WAS DISCHARGED FROM THE HOSPITAL. THE PHYSICIAN REPORTED THAT THE PATIENT IS CURRENTLY DOING WELL WITH NO PAIN OR OTHER SYMPTOMS REPORTED BY PATIENT. THE PHYSICIAN BELIEVES THAT THE PATIENT'S PAIN AND SYMPTOMS FOLLOWING REMOVAL WERE DIRECTLY RELATED TO THE ESSURE MICRO-INSERT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00071	CONCEPTUS, INC.	11/19/2009	6/30/2010

Event Information:

Event Date (B3): 10/21/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED AN ECTOPIC PREGNANCY OF A PATIENT FOLLOWING ESSURE MICRO-INSERT IMPLANTATION (DATE OF PROCEDURE UNKNOWN). PATIENT HAD AN HSG AND WAS TOLD THAT HER FALLOPIAN TUBES WERE OCCLUDED. PREGNANCY WAS SUCCESSFULLY TERMINATED USING METHOTREXATE. PHYSICIAN REPORTED THAT THE PATIENT IS DOING WELL FOLLOWING TREATMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00073	CONCEPTUS, INC.	11/19/2009	10/13/2010

Event Information:

Event Date (B3): 10/23/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT ONE OF HER PTS PRESENTED WITH AN ECTOPIC PREGNANCY 3 MONTHS FOLLOWING PLACEMENT OF ESSURE MICRO-INSERTS. THE PHYSICIAN STATES THAT THE PT DID NOT USE CONTRACEPTION AND BECAME PREGNANT 1 MONTH POST PLACEMENT OF THE MICRO-INSERTS. THE PHYSICIAN ORDERED AN HSG WHICH SHOWED ONE SIDE WITH SATISFACTORY PLACEMENT AND OCCLUSION; HOWEVER, THE OTHER TUBE IS OCCLUDED BUT NO MICRO-INSERT WAS OBSERVED. PT WAS SUCCESSFULLY TREATED WITH METHOTREXATE, AND IS DOING WELL FOLLOWING TREATMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5013683	CONCEPTUS	11/21/2009	12/3/2009

Event Information:

Event Date (B3): 10/6/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE MICRO IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/6/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2008, I UNDERWENT THE ESSURE PROCEDURE FOR PERMANENT BIRTH CONTROL AFTER HAVING FIVE CHILDREN. I CURRENTLY JUST DISCOVERED THAT I AM PREGNANT ONCE AGAIN. HENCE, THIS PROCEDURE DID NOT WORK AS LED TO BELIEVE. DIAGNOSIS OR REASON FOR USE: USED TO PREVENT PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5013679		11/23/2009	12/3/2009

Event Information:

Event Date (B3): 11/20/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 664443

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS WOULD NOT DEPLOY. QTY 2 WERE DEFECTIVE/WASTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5013642	CONCEPTUS	11/25/2009	11/25/2009

Event Information:

Event Date (B3): 7/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): HYSTEROSCOPIC TUBAL LIGATION DEVICE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use:
Implant Date (E6): 12/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE IMPLANTED FOR BIRTH CONTROL - 6 MONTHS LATER, PATIENT IS PREGNANT. IN 2008, PATIENT HAS ENDOMETRIAL ABLATION DUE TO PERCRETA, A COMPLICATION OF PREGNANCY. PATENT'S UTERUS WAS BURNED. PATIENT REQUIRED MULTIPLE BLOOD TRANSFUSIONS, CAESAREAN SECTION AND HYSTERECTOMY. AS A RESULT, BABY WAS BORN PREMATURE. PHYSICIAN FEELS THAT OUTCOME FOR BABY AND PATIENT ARE DUE TO DEVICE MALFUNCTIONS (MULTIPLE INJURIES).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00074	CONCEPTUS, INC.	11/25/2009	12/2/2009

Event Information:

Event Date (B3): 8/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/15/2009
Explant Date (E7): 8/17/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT BEGAN EXPERIENCING SPORADIC FEVERS AT NIGHT AND A FEELING OF BEING MENTALLY FOGGY SHORTLY FOLLOWING IMPLANTATION WITH ESSURE MICRO-INSERTS. IN 2009, THE PHYSICIAN ULTIMATELY PERFORMED A HYSTERECTOMY AND REMOVED THE MICRO-INSERTS AFTER BEING UNABLE TO DETERMINE THE CAUSE OF THE FEVERS. NO NICKEL ALLERGY TEST WAS PERFORMED. THE PHYSICIAN STATED THAT AFTER REMOVAL OF THE MICRO-INSERTS, THE PT'S FEVERS RESOLVED AND PT WAS ASYMPTOMATIC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00075	CONCEPTUS, INC.	11/25/2009	12/2/2009

Event Information:

Event Date (B3): 10/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 2/3/2009
Explant Date (E7): 10/28/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT A PT PRESENTED TO HER WITH PERSISTENT PELVIC PAIN. A CT SCAN AND AN HSG REVEALED THAT ONE OF THE ESSURE MICRO-INSERTS HAD PERFORATED THE PT'S LEFT FALLOPIAN TUBE. A DIAGNOSTIC LAPAROSCOPY WAS PERFORMED AND THE LEFT MICRO-INSERT WAS FOUND IN THE PT'S LEFT UTEROSACRAL LIGAMENT, AND A PORTION WAS ALSO FOUND LODGED IN THE DESCENDING COLON. THE MICRO-INSERT WAS REMOVED LAPAROSCOPICALLY. IT WAS REPORTED THAT THE PT'S PERSISTENT PAIN RESOLVED, HOWEVER, THE PT CURRENTLY REPORTS PAIN AND BLEEDING WITH EACH BOWEL MOVEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5013752	CONCEPTUS	12/1/2009	12/8/2009

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): OTHER	Event Country: US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626976

Single Use:
Implant Date (E6): 9/17/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED, HYSTEROSALPINGOGRAM CONFIRMED TUBAL BLOCKAGE, PREGNANCY INTRAUTERINE 6 MONTHS POST ESSURE. DATES OF USE: 2008. DIAGNOSIS OR REASON FOR USE: STERILITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5013802	CONCEPTUS INC.	12/2/2009	12/11/2009

Event Information:

Event Date (B3): 8/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2009, WITH NO PROBLEM DURING PROCEDURE. PREGNANCY TESTS WERE TAKEN AND CAME BACK NEGATIVE. THE FOLLOWING MONTH, STOMACH PAIN AND BLOAT. I WENT TO EMERGENCY ROOM, AND THEY SAID I WAS PREGNANT -ABOUT 6 WEEKS- AND IT WAS ECTOPIC AND HAD BURST. I WAS TAKEN TO ANOTHER HOSPITAL THAT DID EMERGENCY SURGERY, REMOVING MOST OF MY RIGHT OVARY AND PART OF FALLOPIAN TUBE. DATES OF USE: 2009. DIAGNOSIS: PREVENT PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00080	CONCEPTUS, INC.	12/4/2009	10/13/2010

Event Information:

Event Date (B3): 6/1/2008 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT REPORTED REMOVAL OF TWO ESSURE MICRO-INSERTS DUE TO A NICKEL SENSITIVITY/ALLERGY. THE PATIENT REPORTED SYMPTOMS OF DOUBLE MENSTRUAL CYCLES, RECURRING OVARIAN CYSTS, CHRONIC FATIGUE AND SEVERE ABDOMINAL PAIN, POST IMPLANTATION. IT IS UNKNOWN IF PATIENT WAS SCREENED FOR A HISTORY OF NICKEL SENSITIVITY, WHETHER A NICKEL ALLERGY TEST WAS PERFORMED, OR ANY RESULT OF SUCH TEST. THE ORIGINAL VOLUNTARY REPORT, (B)(4), FOR THIS ADVERSE EVENT WAS RECEIVED THROUGH THE FDA'S MEDWATCH PROGRAM.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PATIENT WITH KNOWN HYPERSENSITIVITY TO NICKEL, CONFIRMED BY SKIN TEST.
IFU WARNING: PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5013994	CONCEPTUS INC	12/11/2009	12/22/2009

Event Information:

Event Date (B3): 12/9/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 646520

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THERE WAS NO HARM TO THE PATIENT. WHEN THE SURGEON START THE PROCEDURE, THE PRODUCT SPRUNG AND DID NOT WORK. IT WAS DYSFUNCTIONAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/12/2009	1/12/2010

Event Information:

Event Date (B3): 9/10/2009 **Report Date (B4): 12/12/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE, PERMANENT
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 654830

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/10/2009

Event Description (B5):

DURING A HYSTEROSCOPY PROCEDURE, THE FIRST ESSURE FROM THE KIT, WAS APPARENTLY DEFECTIVE WITH A BENT TIP, AND THE SECOND ESSURE FROM THE KIT WAS APPARENTLY UNSUCCESSFUL- QUESTION RELATED TO THE PATIENT'S ANATOMY. DURING THE LAPAROSCOPIC TUBAL LIGATION, THE FIRST FALOPE-RING BAND DID NOT DEPLOY APPROPRIATELY; IT APPEARED TO HAVE SPRUNG OFF THE APPLICATOR NEAR THE END OF APPLICATION. MD DID NOT CONTINUE USING THE FALOPE-RING BAND TO COMPLETE THE PROCEDURE. BOTH THE ESSURE AND THE DISPOSABLE FALOPE-RING BAND APPLICATOR KIT WERE LEFT FOR ADMINISTRATION TO RETURN TO THE RESPECTIVE COMPANIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5013999	CONCEPTUS INC.	12/14/2009	12/24/2009

Event Information:

Event Date (B3): 12/4/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE DEVICE
Device Type (E2): ESSURE DEVICE
Model # (E4): ESSURE PERMANENT
Catalog # (E4): ESS305
Lot #(E4): 664588; 654842

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 12/15/2009

Event Description (B5):

DURING ELECTIVE STERILIZATION PROCEDURE, AN ESSURE DEVICE WAS UTILIZED AND FAILED TO DEPLOY. PROCEDURE WAS ABANDONED WITHOUT INJURY TO PATIENT. PATIENT WILL NEED TO BE RESCHEDULED FOR ANOTHER PROCEDURE. DATES OF USE: SINGLE USE DEVICE - 2009. DIAGNOSIS OR REASON FOR USE: ELECTIVE STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00076	CONCEPTUS, INC.	12/17/2009	12/28/2009

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PT WAS EXPERIENCING PROLONGED BLEEDING AFTER IMPLANTATION WITH ESSURE MICRO-INSERTS. THE PHYSICIAN DECIDED IT WAS MEDICALLY NECESSARY TO REMOVE THE ESSURE MICRO-INSERTS AND PERFORM A BILATERAL TUBAL LIGATION BECAUSE OF THE PT'S BLEEDING, ALONG WITH THE RESULTS OF A HYSTEROSALPINGOGRAM, WHICH SHOWED PATENCY ON THE PT'S RIGHT SIDE AT 6 MONTHS. DURING MICRO-INSERT REMOVAL, THE PHYSICIAN DISCOVERED THAT THE INSERT ON THE RIGHT SIDE HAD EXPELLED INTO THE UTERINE CAVITY. THE PHYSICIAN REPORTED THAT THE BLEEDING HAS STOPPED. THE PHYSICIAN STATED THAT HE IS UNSURE IF THE BLEEDING WAS CAUSED BY THE ESSURE MICRO-INSERTS.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00077	CONCEPTUS, INC.	12/17/2009	12/28/2009

Event Information:

Event Date (B3): 6/20/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 6/20/2008
Explant Date (E7): 6/20/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT A PT EXPERIENCED A SEVERE VASO-VAGAL RESPONSE, SEVERE PAIN AND CRAMPING DURING AND IMMEDIATELY AFTER AN ESSURE PROCEDURE. THE PHYSICIAN TRANSPORTED THE PT TO A HOSPITAL WHERE SHE REMOVED THE ESSURE MICRO-INSERTS.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00078	CONCEPTUS, INC.	12/17/2009	9/29/2010

Event Information:

Event Date (B3): 9/11/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 9/11/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED HER PT EXPERIENCED TOTAL BODY ITCHING FOLLOWING IMPLANTATION WITH ESSURE MICRO-INSERTS. AN ALLERGY TEST WAS PERFORMED ON THE PT, WHICH RULED OUT NICKEL ALLERGY; HOWEVER, PT WAS DIAGNOSED WITH AN ALLERGY. THE PHYSICIAN STATED THAT IT WAS THE PT'S ALLERGIC REACTION WHICH LED TO THE MICRO-INSERTS BEING EXPLANTED. THE PHYSICIAN PERFORMED A HYSTERECTOMY AND SALPINGECTOMY, AND REMOVED THE MICRO-INSERTS. THE PT'S ITCHING RESOLVED ONCE THE MICRO-INSERTS WERE EXPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/21/2009	1/12/2010

Event Information:

Event Date (B3): 12/11/2009 **Report Date (B4): 12/21/2009** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE, PERMANENT
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): 20210352

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT DESIRING PERMANENT STERILIZATION UNDERWENT DEPLOYMENT OF ESSURE DEVICE. PER THE OPERATIVE NOTE, "UTERUS SOUNDED TO 7 CM, DILATED UP TO 21 PRATT DILATOR; LEFT OSTIA EASILY VISUALIZED; RIGHT OSTIA QUITE LATERALIZED
TO RIGHT CORNU, BUT WAS SEEN. ESSURE COIL NOT ABLE TO GO THROUGH RIGHT OSTIA MORE THAN APPROXIMATELY HALF OF COIL; LEFT OSTIA CANNULATED, BUT ESSURE COIL DID NOT PROPERLY DEPLOY."

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2009-00079	CONCEPTUS, INC.	12/22/2009	1/7/2010

Event Information:

Event Date (B3): 11/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 10/20/2009
Explant Date (E7): 11/20/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A PT COMPLAINING OF PAIN FOLLOWING IMPLANTATION WITH THE ESSURE MICRO-INSERTS. THE PHYSICIAN STATED THAT NSAIDS WERE GIVEN TO PT TO MANAGE THE PAIN; THE PT REQUESTED REMOVAL OF THE MICRO-INSERTS. THE PHYSICIAN EXPLANTED THE MICRO-INSERTS AND REPORTED THAT SHE FOUND BOTH IMPLANTS TO BE PROPERLY PLACED. THE PHYSICIAN ALSO REPORTED THAT THE MICRO-INSERT ON THE PT'S RIGHT SIDE, WHERE THE PT WAS PRIMARILY EXPERIENCING PAIN, MAY HAVE BEEN "A LITTLE KINKED." THE PT REPORTED TO THE PHYSICIAN THAT SHE IS NOW FREE FROM PAIN FOLLOWING EXPLANTATION. THE PHYSICIAN STATED THAT SHE DOES NOT KNOW WHY THE PT WAS EXPERIENCING PAIN. THE PHYSICIAN STATED THAT, IN HER MEDICAL OPINION, THE ESSURE DEVICES WERE NOT DIRECTLY RELATED TO THE PT'S PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5014107	CONCEPTUS	12/29/2009	12/29/2009

Event Information:

Event Date (B3): 10/29/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/28/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT WAS DIAGNOSED WITH DILATED CARDIOMYOPATHY. PT HAD ESSURE DEVICE IMPLANTED IN 2008 TO PREVENT PREGNANCY. PT WAS TOLD THAT PREGNANCY COULD RESULT IN DEATH. PT HAD BLOCKAGE TEST AND WAS TOLD THAT COIL WAS IN PROPER PLACE AND WAS EFFECTIVE. APPROX 2 MONTHS AGO, PT STARTED CRAMPING. CAT SCAN WAS DONE. PT WAS SENT TO OB. URINE TEST POSITIVE FOR PREGNANCY. PT SICK AND DEHYDRATED. PT WAS TOLD COIL SHIFTED AND IS NOW IN UTERINE WALL. PT HAS HIGH RISK OB APPT TO DETERMINE IF COIL WILL HAVE TO BE REMOVED DUE TO RISK OF INJURY TO BABY. PT WAS TOLD THAT COIL WAS 99.95% EFFECTIVE, AFTER BLOCKAGE TEST.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00001	CONCEPTUS, INC.	1/6/2010	1/14/2010

Event Information:

Event Date (B3): 11/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 11/30/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PATIENT PRESENTED WITH PAIN 2 YEARS FOLLOWING THE ESSURE IMPLANTATION PROCEDURE. AN HSG SHOWED THAT ONE OF THE ESSURE MICRO-INSERTS WAS LOCATED OUTSIDE OF THE FALLOPIAN TUBE. THE PHYSICIAN REMOVED THE ESSURE MICRO-INSERTS LAPAROSCOPICALLY AND ALSO PERFORMED A HYSTERECTOMY. ONE OF THE MICRO-INSERTS WAS FOUND ADHERED TO THE PATIENT'S BOWEL; NO BOWEL PERFORATION OBSERVED. THE PHYSICIAN BELIEVES THAT THE PATIENT'S PAIN WAS DIRECTLY RELATED TO THE ESSURE MICRO-INSERTS. THE PATIENT WAS STILL EXPERIENCING DISCOMFORT FOLLOWING HER HYSTERECTOMY AND MICRO-INSERT REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00002	CONCEPTUS, INC.	1/6/2010	1/14/2010

Event Information:

Event Date (B3): 11/4/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 11/4/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PATIENT WAS EXPERIENCING PAIN APPROXIMATELY 1 YEAR FOLLOWING AN ESSURE MICRO-INSERT IMPLANTATION. AN HSG REVEALED THAT ONE MICRO-INSERT WAS LOCATED OUTSIDE OF THE FALLOPIAN TUBE. DURING A DIAGNOSTIC LAPAROSCOPY, THE PHYSICIAN REMOVED THIS MICRO-INSERT, WHICH WAS FOUND PROTRUDING OUT OF THE UTERUS THROUGH THE FUNDUS INTO THE PATIENT'S ABDOMEN. THE PHYSICIAN STATED THAT REMOVAL OF THE MICRO-INSERT WAS MEDICALLY NECESSARY AND THAT SHE BELIEVES THE PATIENT'S PAIN WAS DIRECTLY RELATED TO THE ESSURE MICRO-INSERT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00004	CONCEPTUS, INC.	1/15/2010	1/22/2010

Event Information:

Event Date (B3): 12/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20196135

Single Use: Y
Implant Date (E6): 11/17/2009
Explant Date (E7): 12/16/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT WAS EXPERIENCING PAIN DURING AND FOLLOWING AN ESSURE MICRO-INSERT IMPLANTATION PROCEDURE PERFORMED IN 2009. THE FOLLOWING MONTH, THE PT WENT TO A HOSP DUE TO SEVERE PAIN. THE ACTUAL DATE OF THE ONSET OF SEVERE PAIN IS UNK. AN X-RAY SHOWED ONE OF THE MICRO-INSERTS HAD PERFORATED THE FALLOPIAN TUBE AND SMALL BOWEL. A GENERAL SURGEON WAS CALLED IN TO REPAIR THE BOWEL. SEVERAL ATTEMPTS HAVE BEEN MADE TO CONTACT THE PHYSICIAN IN ORDER TO GATHER ADD'L INFO REGARDING THIS REPORT. ALL ATTEMPTS HAVE BEEN UNSUCCESSFUL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00003	CONCEPTUS, INC.	1/20/2010	1/26/2010

Event Information:

Event Date (B3): 12/18/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 664666

Single Use: Y
Implant Date (E6): 12/15/2009
Explant Date (E7): 12/18/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING AN ESSURE MICRO-INSERT IMPLANTATION PROCEDURE IN 2009, A PERFORATION OCCURRED THAT WAS RELATED TO PLACEMENT OF AN ESSURE MICRO-INSERT. IT WAS REPORTED THAT THE PT WAS ASYMPTOMATIC, AND NO TREATMENT WAS PROVIDED FOR THE PERFORATION. DURING A LAPAROSCOPIC TUBAL LIGATION THREE DAYS LATER, THE PHYSICIAN REPORTED THAT IT WAS NECESSARY TO REMOVE THE ESSURE MICRO-INSERT THAT HAD PERFORATED THE FALLOPIAN TUBE IN ORDER TO PREVENT FURTHER HARM TO THE PT; THE MICRO-INSERT WAS FOUND EMBEDDED IN FATTY TISSUE SURROUNDING THE PT'S BOWEL. THE PHYSICIAN REPORTED THAT THE PT IS DOING WELL FOLLOWING THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00005	CONCEPTUS, INC.	1/20/2010	4/6/2011

Event Information:

Event Date (B3): 12/21/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/17/2009
Explant Date (E7): 12/21/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PT, WHO HAD UNDERGONE AN ESSURE MICRO-INSERT IMPLANTATION PROCEDURE ON (B)(6) 2009, PRESENTED TO AN EMERGENCY ROOM WITH SEVERE PAIN ON ONE SIDE AND WAS ADMITTED TO THE HOSPITAL. ALL LABORATORY TESTS AND ULTRASOUNDS WERE NORMAL AND NO SIGNS OR SYMPTOMS OF INFECTION WERE PRESENT. THE PHYSICIAN STATED THAT THE ESSURE PLACEMENT PROCEDURE WAS UNCOMPLICATED. THE PHYSICIAN LATER REPORTED THAT IT WAS NECESSARY TO REMOVE THE ESSURE MICRO-INSERTS DURING A TUBAL LIGATION PROCEDURE ON (B)(6) 2009 DUE TO THE PAIN THE PT WAS EXPERIENCING; ONE SIDE WAS REMOVED HYSTEROSCOPICALLY AND THE OTHER SIDE LAPAROSCOPICALLY. THE PT'S PAIN RESOLVED FOLLOWING MICRO-INSERT REMOVAL. THE PHYSICIAN BELIEVES THAT THE PT'S PAIN WAS DIRECTLY RELATED THE ESSURE MICRO-INSERTS. DURING FOLLOW UP AFTER HYSTEROSCOPY AND LAPAROSCOPY, PT REPORTED TO PHYSICIAN THAT SHE HAS A HISTORY OF SENSITIVITY TO CHEAP JEWELRY. IT IS UNK IF PT WAS SCREENED FOR A HISTORY OF NICKEL SENSITIVITY, WHETHER A NICKEL ALLERGY TEST WAS PERFORMED OR ANY RESULT OF SUCH TEST.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. IFU WARNING: PTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY PRIOR TO AN

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5014574	CONCEPTUS INC, USA	1/28/2010	2/4/2010

Event Information:

Event Date (B3): 10/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL; ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 654839

Single Use:
Implant Date (E6): 10/21/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL FELL OUT OF TUBE. REQUIRES ADD'L PROCEDURES AND/OR SURGERIES. COULD CAUSE TUBAL PREGNANCY. DATES OF USE: (B) (6) 2009 - CURRENT. DIAGNOSIS: STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5014758	CONCEPTUS	2/4/2010	3/3/2010

Event Information:

Event Date (B3): 10/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): FALLOPIAN TUBE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/6/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

GYNECOLOGIST DR (B) (6) RECOMMENDED ESSURE FOR PERMANENT BIRTH CONTROL. I WAS ADVISED TO HAVE THE DEVICES INSERTED WHILE UNDER GENERAL ANESTHESIA IN THE HOSPITAL - (B) (6). PROCEDURE WAS DONE ON (B) (6) 2009. I EXPERIENCED SIGNIFICANT PAIN AND BLEEDING FOR MANY WEEKS AFTER THE PROCEDURE WAS COMPLETED. HSG WAS PERFORMED THREE MONTHS LATER AND ONE ESSURE WAS SHOWN TO BE IN THE WRONG PLACE AND IT FAILED THE HSG TEST. DYE FLOWED FREELY TO ONE OVARY. THE DAY AFTER THE HSG, I PASSED A THUMB-SIZED HUNK OF BLOODY TISSUE OUT OF MY VAGINA INTO THE BATHTUB WHILE I WAS TAKING A SHOWER. I THOUGHT I'D HAD A MISCARRIAGE! I CALLED MY GYNECOLOGIST FOR A FOLLOW-UP APPOINTMENT. THEN SHE RECOMMENDED A TRADITIONAL TUBAL. I'VE HAD SEVERAL PREVIOUS ABDOMINAL SURGERIES AND WAS WORRIED ABOUT HAVING ANOTHER SURGERY. DR (B) (6) SAID SHE'D USE A HYSTEROSCOPE TO CHECK THE ESSURE, AND POSSIBLY INSERT ANOTHER. IF SHE DEEMED THE REPLACEMENT ESSURE TO BE A BAD IDEA, SHE WOULD DO A TRADITIONAL TUBAL. SECOND ESSURE PROCEDURE WAS DONE ON (B) (6) 2009. THIS TIME THERE WAS ALMOST NO PAIN AND NO BLEEDING AFTERWARDS. HSG WAS DONE TODAY, (B) (6) 2010 AND SHOWED THREE ESSURES...ONE IN MY RIGHT FALLOPIAN TUBE DOING ITS JOB CORRECTLY, AND TWO THAT WERE NOT. THE LEFT FALLOPIAN TUBE WAS TOTALLY CLEAR AND DYE FLOWED FREELY TO THE OVARY. THE TWO ESSURES WERE DEFINITELY DISPLACED, NOT IN THE TUBE AT ALL. THE RADIOLOGIST SHOWED ME THE HSG RESULTS AND SAID, IT LOOKED LIKE ONE ESSURE DEVICE WAS INSIDE THE UTERUS AND THE OTHER WAS PROBABLY OUTSIDE THE UTERUS AND DEFINITELY NOT IN THE FALLOPIAN TUBE. IT IS MY UNDERSTANDING THAT HAVING AN ESSURE DEVICE RANDOMLY LOCATED INSIDE MY ABDOMINAL CAVITY IS DANGEROUS. I AM SCARED AND FRUSTRATED, SCARED ABOUT WHAT MIGHT HAPPEN NEXT - HYSTERECTOMY OR ABDOMINAL SURGERY? AND FRUSTRATED BECAUSE I'VE ALREADY SPENT OVER (B) (6) OUT OF POCKET FOR THESE

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PROCEDURES. DOSE OR AMOUNT: ONE-TIME PROCEDURE. FREQUENCY: ONE TIME. ROUTE: #1 & #2: INTRACERVICAL. DIAGNOSIS OR REASON FOR USE: PERMANENT STERILIZATION. EVENT REAPPEARED AFTER REINTRODUCTION? YES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00006	CONCEPTUS, INC.	2/5/2010	2/23/2010

Event Information:

Event Date (B3): 12/3/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 12/3/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A PATIENT, WHO WAS IMPLANTED WITH ESSURE MICRO-INSERTS 2 YEARS PREVIOUSLY, COMPLAINED OF PAIN. PATIENT WAS DIAGNOSED 6 WEEKS PREGNANT WITH TWINS. PATIENT DID NOT RETURN FOR AN ESSURE CONFIRMATION TEST (HSG). A DIAGNOSTIC ULTRASOUND WAS PERFORMED TO HELP DETERMINE THE CAUSE FOR PATIENT'S PAIN; IT SHOWED THE MICRO-INSERTS TO BE IN A SATISFACTORY LOCATION. THE PATIENT DELIVERED THE TWINS BY C-SECTION. DURING DELIVERY, THE PHYSICIAN REPORTED THAT THE MICRO-INSERTS COULD NOT BE SEEN OR FELT, BUT WERE PRESENT ON X-RAY. PATIENT CONTINUED TO EXPERIENCE PAIN; A DIAGNOSTIC HYSTEROSCOPY WAS PERFORMED IN THE OR. DURING THE HYSTEROSCOPY, THE PHYSICIAN WAS UNABLE TO FIND THE MICRO-INSERT ON THE PATIENT'S LEFT SIDE BUT WAS SUCCESSFUL IN LOCATING AND REMOVING THE MCRO-INSERT ON THE PATIENT'S RIGHT SIDE. THE PHYSICIAN STATED THAT IT IS TOO EARLY TO DETERMINE IF THE PATIENT'S PAIN HAS RESOLVED. THE PHYSICIAN WAS ASKED IF HE BELIEVED THE REMOVED ESSURE MICRO-INSERT WAS DIRECTLY RELATED TO THE PAIN THE PATIENT WAS EXPERIENCING, HOWEVER, NO RESPONSE TO THIS QUESTION WAS RECEIVED.

Manufacturer Narrative (H10):

MDR IS BEING REPORTED OUTSIDE OF THE 30-DAY TIME FRAME BECAUSE THIS WAS INITIALLY EVALUATED AS NOT REPORTABLE, BUT LATER REVIEW OF THIS COMPLAINT RESULTED IN A DETERMINATION THAT THE EVENT IS REPORTABLE.

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00007	CONCEPTUS, INC.	2/5/2010	4/6/2011

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2009
Explant Date (E7): 12/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT HAD UNDERGONE THE ESSURE PROCEDURE AND WAS PRESENTING TO HER WITH PELVIC PAIN 6 WEEKS FOLLOWING THE PROCEDURE. THE PT WAS DIAGNOSED WITH ENDOMETRITIS AND TREATED WITH ANTIBIOTICS AND ANALGESICS; THE PT'S PAIN CONTINUED. THE PHYSICIAN SAID THAT ESSURE MICRO-INSERT REMOVAL WAS REQUESTED BY THE PT AND THE PHYSICIAN AGREED THAT REMOVAL WAS THE BEST COURSE OF ACTION. THE PHYSICIAN REMOVED THE MICRO-INSERTS VIA LAPAROSCOPY; THE RIGHT COIL CAME OUT INTACT EASILY AND THE LEFT COIL CAME OUT IN PIECES AND APPEARED TO BE SOMEWHAT KINKED INSIDE THE TUBE. NO PERFORATION OF THE TUBES WAS OBSERVED ON A CT SCAN NOR DURING THE LAPAROSCOPY. THE PHYSICIAN STATED THAT THE PT'S PAIN HAS SUBSIDED. THE PHYSICIAN BELIEVES THAT THE ESSURE MICRO-INSERTS WERE DIRECTLY RELATED TO THE PT'S PAIN BECAUSE, AS STATED BY THE PHYSICIAN, THE PAIN WAS LOCALIZED TO THE TUBES AND WAS WORSE ON THE LEFT THAN THE RIGHT.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	2/11/2010	3/3/2010

Event Information:

Event Date (B3): 2/11/2010 **Report Date (B4): 2/11/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 685785

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE FAILED TO DEPLOY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00009	CONCEPTUS, INC.	2/19/2010	3/1/2010

Event Information:

Event Date (B3): 11/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/8/2009
Explant Date (E7): 11/30/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT BEGAN EXPERIENCING SEVERE PAIN ON HER LEFT SIDE IMMEDIATELY FOLLOWING ESSURE PLACEMENT. THE PHYSICIAN STATED THAT THE PT'S LEFT EXTERNAL FALLOPIAN TUBE AND OVARY HAD BEEN REMOVED, WHICH SHE HAD NOT BEEN MADE AWARE OF PRIOR TO THE ESSURE PROCEDURE, AS A RESULT OF PRIOR SURGERY. THE DOCTOR REPORTED SATISFACTORY PLACEMENT OF THE ESSURE MICRO-INSERTS DURING THE ESSURE PROCEDURE. THE PHYSICIAN PERFORMED A LAPAROSCOPY TO REMOVE THE ESSURE MICRO-INSERTS AND THEN PERFORMED AN ABDOMINAL HYSTERECTOMY. THE PHYSICIAN REPORTS THAT THE PT'S PAIN RESOLVED FOLLOWING MICRO-INSERT REMOVAL. THE PHYSICIAN BELIEVES THAT THE ESSURE MICRO-INSERT WAS DIRECTLY RELATED TO THE PT'S PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00008	CONCEPTUS, INC.	2/19/2010	4/6/2011

Event Information:

Event Date (B3): 1/13/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 1/13/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A PATIENT WITH SYMPTOMS 2 YEARS POST ESSURE PLACEMENT DESCRIBED AS ARTHRALGIA AND FATIGUE. THE PHYSICIAN LATER REPORTED THAT THE PATIENT TESTED POSITIVE FOR NICKEL ALLERGY; THE PHYSICIAN STATED THAT THE PATIENT NEVER EXHIBITED SYMPTOMS OF NICKEL ALLERGY. BECAUSE OF THE PATIENT'S NICKEL ALLERGY, THE PHYSICIAN STATED THAT 1 MICRO-INSERT WAS REMOVED LAPAROSCOPICALLY FROM THE PATIENT'S MYOMETRIUM (SECOND MICRO-INSERT HAD ALREADY BEEN REMOVED DUE TO A PERFORATION). THE PHYSICIAN STATED THAT THE PATIENT WAS DOING WELL FOLLOWING REMOVAL OF THE MICRO-INSERT BUT WAS STILL EXPERIENCING SYMPTOMS OF ARTHRITIS. THE DOCTOR SAID HE DOES NOT BELIEVE THE PATIENT'S ARTHRITIS SYMPTOMS ARE DIRECTLY RELATED TO THE ESSURE MICRO-INSERTS.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PATIENT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST.

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5014896	CONCEPTUS INCORPORATED	2/22/2010	3/12/2010

Event Information:

Event Date (B3): 2/10/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628430

Single Use:
Implant Date (E6): 2/10/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE MICRO-INSERT DID NOT DEPLOY PROPERLY IN THE RIGHT FALLOPIAN TUBE, COILING UP IN THE UTERUS. UNKNOWN LENGTH OF THE DEVICE DID ENTER THE TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015015	CONCEPTUS INCORPORATED	3/2/2010	3/12/2010

Event Information:

Event Date (B3): 5/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 5/25/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B) (6) 2009, PT HAD ESSURE COILS PLACED. PT FOLLOWED ALL INSTRUCTIONS FOLLOWING THE PROCEDURE AND ALSO HAD CONFIRMATION DYE TEST TO VERIFY TUBES WERE COMPLETELY CLOSED. IN (B) (6) 2010, PT BECAME PREGNANT. AFTER CONFIRMING PREGNANCY WITH OB, THEY DOUBLE CHECKED FILMS FROM TEST AND THE TUBES SHOW COMPLETELY CLOSED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015016	CONCEPTUS INC.	3/2/2010	3/12/2010

Event Information:

Event Date (B3): 12/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/14/2009
Explant Date (E7): 2/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

TIMELINE: (B) (6) 2009 CONSULT W/GYN DR (B) (6) RE: ABLATION; HIS SUGGESTION WAS TO ALSO HAVE ESSURE STERILIZATION PROCEDURE; WE AGREED TO ESSURE AT THE SAME TIME AS THE HYSTEROSCOPY WAS REQUIRED BEFORE ABLATION. - WE ARE INFORMED THAT ESSURE CAN NEVER BE REMOVED. - IT EXPANDS WHEN INSERTED AND IT HAS FLANGES ON BOTH ENDS. - WE HAD NEVER HEARD OF ESSURE BEFORE THIS TIME/DATE. ON (B) (6) 2009 HAD A TRANSVAGINAL ULTRASOUND PERFORMED, - DID SHOW A FIBROID ON UTERUS. ON (B) (6) 2009, HYSTEROSCOPY/ESSURE PROCEDURES BY DR (B) (6). DURING THE PROCEDURE, WE CAN SEE THAT THE ESSURE DEVICE ON THE RIGHT SIDE DOES NOT GO IN LIKE THE ONE ON THE LEFT. DURING THE CONSULTATION AFTER THE PROCEDURE, DR (B) (6) SHOWS ME PHOTOS OF THE IMPLANTATION RESULTS. ON (B) (6) 2009, PELVIC PAIN, NAUSEA, CRAMPING BEGAN IMMEDIATELY AFTER PROCEDURE. I TOOK SICK LEAVE FROM WORK FOR 4 DAYS AND WORKED ONLY ONE DAY/ (B) (6) 2009 THAT WEEK. AS I AM A SCHOOL TEACHER, I DID NOT NEED TO TAKE MORE SICK LEAVE THE FOLLOWING WEEK DUE TO SNOW FOR 3 DAYS THE NEXT WEEK AND WINTER BREAK STARTING (B) (6) 2009 UNTIL (B) (6) 2010. ON (B) (6) 2009 TWO-WEEK FOLLOW-UP PELVIC EXAM: I HAVE HAD PELVIC PAIN, NAUSEA AND CRAMPING CONTINUALLY SINCE THE PROCEDURE. DR (B) (6) IS BAFFLED; HAS NEVER HAD A PT WITH THIS PROBLEM/SYMPTOMS AND HAS BEEN DOING ESSURE PROCEDURES FOR ALMOST 7 YRS AND EVEN TEACHES OTHER DOCS HOW TO DO IT. WE DECIDE TO SCHEDULE SECOND HYSTEROSCOPY TO REMOVE AT LEAST THE ESSURE DEVICE FROM MY RIGHT FALLOPIAN TUBE AS DR (B) (6) THOUGHT PERHAPS IT DID NOT GO IN CORRECTLY AND WAS THE CAUSE OF MY PAIN. HE DOES NOT THINK HE CAN REMOVE THE LEFT ESSURE DEVICE. HE HAS NEVER REMOVED THESE DEVICES FROM ANYONE. ON (B) (6) 2010 SECOND HYSTEROSCOPY. DURING THE HYSTEROSCOPY DR (B) (6) THOUGHT BOTH DEVICES WERE IN PLACE AND SINCE THE RIGHT DEVICE LOOKED THE SAME AS THE LEFT AT THIS POINT, RATHER

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THAN CAUSE MORE PAIN, HIS PROFESSIONAL OPINION WAS TO LEAVE IT IN. I AGREED AS I DID NOT WANT/WAS FEARFUL OF MORE PAIN AND PROBABLY WAS NOT THINKING CLEARLY DUE TO THE MEDICATION FOR THE HYSTEROSCOPY. ON (B) (6) 2010 TWO-WEEK FOLLOW-UP PELVIC EXAM: I AM STILL IN PELVIC PAIN. DURING THE CONSULT AFTER THE EXAM DR (B) (6) SUGGESTS A LAPAROSCOPY. HE ALSO SUGGESTS THAT THIS MAY END UP BEING A TOTAL HYSTERECTOMY DEPENDING ON HOW THE SURGERY GOES BECAUSE HE IS NOT SURE HE CAN REMOVE IT WITHOUT DAMAGING THE UTERUS. BY THIS TIME AND EARLIER MY HUSBAND IS DOING RESEARCH ON ESSURE; ITS REMOVAL AND COMPLICATIONS. HE HAS FOUND MANY POSTS FROM WOMEN WITH MY SYMPTOMS BUT ONLY FOUND TWO FACILITIES THAT HAVE SUCCESSFULLY REMOVED ESSURE DEVICES. THE CLOSEST ONE WAS IN (B) (6). ON (B) (6) 2009 MADE AN APPOINTMENT WITH (B) (6) TUBAL REVERSAL CENTER -(B) (6). ON (B) (6) 2009 DID BLOOD LAB WORK FOR (B) (6). ON (B) (6) 2010 TRANSVAGINAL ULTRASOUND, MYOMECTOMY -1-4- AND ESSURE REMOVAL AT (B) (6) WITH DR (B) (6). IMMEDIATELY UPON WAKING FROM ANESTHESIA, I FELT NO MORE PELVIC PAIN/CRAMPING/NAUSEA, ONLY SURGERY PAIN. DR (B) (6) ALSO FOUND/REMOVED A SECOND FIBROID ON MY LEFT FALLOPIAN TUBE AS WELL AS THE ONE SEEN ON ULTRASOUND ON THE UTERUS. HE THINKS THAT IT IS A STRONG POSSIBILITY THAT MY PAIN/DISCOMFORT WAS DUE TO THE FIBROID ON MY FALLOPIAN TUBE. NOTE: (B) (6) DID NOT AGREE WITH DR (B) (6) USING ESSURE DEVICES FOR A (B) (6) FEMALE WHO IS PROBABLY GOING TO BE IN MENOPAUSE IN A COUPLE OF YEARS AND HAS A VERY LOW CHANCE OF BECOMING PREGNANT. I AM INCREDULOUS ABOUT THIS PAST 7 WEEKS OF MY LIFE BEING TURNED UPSIDE DOWN, AND HOW I TRUSTED A PROFESSIONAL WITHOUT DOING MORE RESEARCH. DATES OF USE: (B) (6) 2009 - (B) (6) 2010 - 7 WEEKS. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00010	CONCEPTUS, INC.	3/4/2010	3/10/2010

Event Information:

Event Date (B3): 1/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/18/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PT PRESENTED TO HIM WITH BLEEDING FOLLOWING AN ESSURE MICRO-INSERT IMPLANTATION. AN HSG WAS PERFORMED AND THE HSG REPORT INDICATED THAT THE MICRO-INSERTS MAY NOT BE IN A SATISFACTORY LOCATION. ON (B) (6) 2010 THE PHYSICIAN REMOVED BOTH MICRO-INSERTS HYSTEROSCOPICALLY; BOTH MICRO INSERTS WERE LOCATED IN THE MYOMETRIUM AND EASILY REMOVED. THE PHYSICIAN HAD NOT COMMUNICATED WITH THE PT AT THE TIME THIS EVENT WAS REPORTED SO IT IS UNK IF THE BLEEDING RESOLVED FOLLOWING MICRO-INSERT REMOVAL. THE PHYSICIAN STATED THAT HE BELIEVES THE ESSURE MICRO-INSERTS WERE DIRECTLY RELATED TO THE PT'S BLEEDING AND IT WAS MEDICALLY NECESSARY TO REMOVE THEM.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00011	CONCEPTUS, INC.	3/4/2010	3/10/2010

Event Information:

Event Date (B3): 1/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/15/2010
Explant Date (E7): 1/29/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PT PRESENTED WITH CONSISTENT PAIN 2 WEEKS FOLLOWING ESSURE MICRO-INSERT IMPLANTATION. A PELVIC SONOGRAM AND X-RAY WERE TAKEN WHICH SHOWED PROPER PLACEMENT OF THE MICRO-INSERTS. THE PELVIC SONOGRAM REVEALED A COMPLEX OVARIAN CYST. THE PHYSICIAN THEN PERFORMED A LAPAROSCOPIC TOTAL HYSTERECTOMY WITH LEFT OVARIAN CYSTECTOMY. THE PHYSICIAN REPORTED THAT AT THE TIME OF SURGERY, BOTH ESSURE MICRO-INSERTS WERE IN THE PROPER LOCATION; THE PT'S PAIN RESOLVED FOLLOWING MICRO-INSERT REMOVAL. THE PHYSICIAN STATED THAT HE BELIEVES THE MICRO-INSERTS WERE DIRECTLY RELATED TO THE PT'S PAIN AND THE CYST DID NOT CONTRIBUTE TO THE PT'S PAIN. THE PHYSICIAN STATED THAT INITIAL EXAM 5 DAYS POST ESSURE REVEALED BILATERAL ADNEXAL TENDERNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015073	CONCEPTUS	3/6/2010	3/15/2010

Event Information:

Event Date (B3): 4/11/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE MICRO-INSERT
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 625643

Single Use:
Implant Date (E6): 4/11/2008
Explant Date (E7): 8/7/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE BIRTH CONTROL DEVICES WERE IMPLANTED IN (B) (6) 2008. IMMEDIATELY AFTER AND UNTIL THE DEVICES WERE REMOVED, I BEGAN EXPERIENCING EXCRUCIATING PAIN IN MY LOWER BACK AS WELL AS TWO-WEEK LONG MENSTRUAL CYCLES AND SPOTTING IN THE REMAINING TWO WEEKS OF EACH MONTH. I SAW SEVERAL DOCTORS AND SHARED WITH EACH OF THEM MY OPINION THAT THE UNBEARABLE PAIN AND MENSTRUAL ISSUES WERE CAUSED BY THE ESSURE IMPLANTS, AS THAT IS WHEN IT ALL BEGAN . EACH DOCTOR HAD A DIFFERENT OPINION OF WHAT WAS CAUSING THESE PROBLEMS; PERI-MENOPAUSE, ENDOMETRIOSYS, S-I JOINT PROBLEMS, ETC. I WAS TREATED WITH PHYSICAL THERAPY, ORAL CONTRACEPTIVES, AND HEAVY PAIN MEDICATION. NONE OF THOSE TREATMENT WORKED AND AFTER BEING IN CONSTANT EXTREME AGONY EVERY SECOND OF EVERY DAY FOR 16 VERY LONG MONTHS, I FINALLY MET WITH A DOCTOR WILLING TO ENTERTAIN THE POSSIBILITY THAT THE ESSURE WAS THE CAUSE OF THE PROBLEMS. IN (B) (6) 2009, THE ESSURE IMPLANTS WERE REMOVED, AND THEREFORE, ALSO MY FALLOPIAN TUBES -FORTUNATELY THIS DOCTOR WAS ABLE TO DO SO WITHOUT REMOVING MY UTERUS-, AND MY BACK PAIN WAS 100% COMPLETELY GONE BEFORE I EVEN LEFT THE HOSPITAL AN HOUR AFTER SURGERY. THE SPOTTING AND EXTRA-LONG MENSES ALSO ENDED AFTER THE ESSURE REMOVAL. THIS PROVES TO ME AND THE DOCTORS THAT THE ESSURE DEVICES WERE THE CAUSE OF HE HORRIBLE PAIN I ENDURED AND THE MENSTRUATION ISSUES. BECAUSE OF THE BACK PAIN, I MISSED OVER 100 DAYS OF WORK AND WAS LABELED IN MY MEDICAL FILE AS A DRUG ABUSER BECAUSE THE PAIN LED ME TO USE MORE PAIN MEDICATION THAN I WAS PRESCRIBED JUST TO GET A SMALL AMOUNT OF RELIEF FROM THE MISERY I WAS EXPERIENCING. I HAVE SINCE FOUND VIA THE INTERNET THAT THERE ARE THOUSANDS OF WOMEN HAVING SIMILAR PROBLEMS FROM THE ESSURE DEVICES. MOST HAVE TO HAVE A HYSTERECTOMY TO GET THEM REMOVED AND SOME, LIKE ME, HAD TROUBLE FINDING A DOCTOR WILLING TO

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REMOVE THEM AS THE DOCTORS -ESPECIALLY THOSE TRAINED BY THE ESSURE MFR- ARE QUITE UNWILLING TO ADMIT ESSURE COULD BE CAUSING THE PROBLEMS. SOMETHING NEEDS TO BE DONE ABOUT THIS. THIS WASN'T A MILD DISCOMFORT. IT WAS THE WORST PAIN I'VE EVER HAD, INCLUDING CHILDBIRTH, AND IT WAS CONSTANT FOR WELL OVER A YEAR. IF IT CAN BE PREVENTED IN OTHERS, IT CERTAINLY SHOULD BE. ROUTE: DATES OF USE: (B) (6) 2008 - (B) (6) 2009. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL. EVENT ABATED AFTER USE STOPPED: YES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00012	CONCEPTUS, INC.	3/10/2010	3/17/2010

Event Information:

Event Date (B3): 1/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/27/2009
Explant Date (E7): 1/14/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT PRESENTED WITH CONSTANT PELVIC PAIN APPROXIMATELY 1 WEEK FOLLOWING AN ESSURE MICRO-INSERT IMPLANTATION PROCEDURE. MEDICATION WAS GIVEN TO THE PT TO MANAGE THE PAIN, BUT THE PT CONTINUED TO EXPERIENCE PAIN 2 MONTHS POST ESSURE PROCEDURE. A CT SCAN REVEALED A PERFORATION WITH 1 MICRO-INSERT IN THE PELVIS. THE OTHER MICRO-INSERT APPEARED TO BE IN A SATISFACTORY LOCATION. A LAPAROSCOPY WAS PERFORMED ON THE PT. A PERFORATION WAS DISCOVERED DURING THE LAPAROSCOPY PROCEDURE IN THE PT'S LEFT FALLOPIAN TUBE AND THE MICRO-INSERT WAS SEEN PROTRUDING FROM THE TUBE SLIGHTLY; A SALPINGECTOMY WAS PERFORMED AND THE MICRO-INSERT WAS REMOVED. THE PHYSICIAN STATES SHE WAS UNABLE TO LOCATE THE SECOND ESSURE MICRO-INSERT DURING LAPAROSCOPY. THE PT CONTINUES TO EXPERIENCE PAIN AND THE PHYSICIAN PLANS ON ANOTHER ATTEMPT TO RETRIEVE THE SECOND MICRO-INSERT. THE DOCTOR BELIEVES THAT THE MICRO-INSERTS ARE DIRECTLY RELATED TO THE PAIN THE PT IS EXPERIENCING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00013	CONCEPTUS, INC.	3/10/2010	3/17/2010

Event Information:

Event Date (B3): 2/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/6/2010
Explant Date (E7): 2/4/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT PRESENTED TO HER WITH ABDOMINAL PAIN APPROXIMATELY 4 WEEKS FOLLOWING ESSURE MICRO-INSERT PLACEMENT; NO PROBLEMS WERE NOTED AT TIME OF PLACEMENT. A CT SCAN WAS PERFORMED ON THE PT; ONLY 1 MICRO-INSERT WAS OBSERVED ON THE CT SCAN. THE PHYSICIAN PERFORMED SURGERY TO REMOVE THE MICRO-INSERTS. DURING MICRO-INSERTS REMOVAL THE OUTER COILS OF 1 MICRO-INSERT WERE FOUND NEXT TO THE PT'S BOWEL; THE INNER COILS OF THE SAME MICRO-INSERT WERE ADHERED TO THE BOTTOM OF THE PT'S APPENDIX. AN APPENDECTOMY WAS ALSO PERFORMED ON THE PT. IT IS UNK WHAT THE PT'S CURRENT STATUS IS. THE PHYSICIAN HAS NOT RESPONDED TO SEVERAL ATTEMPTS FOR F/U INFO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015154	CONCEPTUS INC.	3/11/2010	3/23/2010

Event Information:

Event Date (B3): 5/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305 62824

Single Use:
Implant Date (E6): 5/25/2009
Explant Date (E7): 9/29/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANT PERFORATION IN UTERUS ADHERING TO APPENDIX. CORKSCREWING ORGANS TOGETHER REQUIRING APPENDECTOMY AND SALPINGECTOMY. DATES OF USE: (B) (6) 2009 - (B) (6) 2009. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00014	CONCEPTUS, INC.	3/12/2010	3/18/2010

Event Information:

Event Date (B3): 12/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNKNOWN
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7): 12/30/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT A PATIENT PRESENTED TO HIM IN (B) (6) 2009 WITH A COMPLAINT OF PAIN THAT SHE SAID SHE HAD BEEN EXPERIENCING SINCE PLACEMENT OF ESSURE MICRO-INSERTS IN 2006. THE PATIENT STATED THAT DUE TO THE PAIN, SHE HAD VISITED THE EMERGENCY ROOM SEVERAL TIMES AND WAS TAKING PAINKILLERS. THE PHYSICIAN STATED HE PERFORMED AN ULTRASOUND WHICH REVEALED NO OBVIOUS PROBLEMS. THE PHYSICIAN STATED THAT HE COULD FIND NO ETIOLOGY FOR THE PATIENT'S PAIN, SO HE DECIDED TO PERFORM A HYSTERECTOMY AND REMOVE THE ESSURE MICRO-INSERTS; THE PHYSICIAN SAID THAT DURING THE HYSTERECTOMY, HE DISCOVERED ONE OF THE MICRO-INSERTS AT THE DISTAL END APPEARED TO HAVE CAUSED A VERY SMALL PERFORATION OF THE FALLOPIAN TUBE; BOTH MICRO-INSERTS APPEARED TO BE IN A SATISFACTORY LOCATION AS REPORTED BY THE PHYSICIAN. THE PHYSICIAN SAID HIS PATIENT'S PAIN HAS IMPROVED SINCE THE HYSTERECTOMY AND MICRO-INSERT REMOVAL AND THE PATIENT IS NO LONGER TAKING PAINKILLERS. THE DOCTOR STATED THAT HE DOES NOT KNOW IF THE MICRO-INSERTS WERE DIRECTLY RELATED TO HIS PATIENT'S PAIN BUT HE COULD FIND NO OTHER CAUSE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00015	CONCEPTUS, INC.	3/17/2010	3/23/2010

Event Information:

Event Date (B3): 2/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/1/2007
Explant Date (E7): 2/9/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT PRESENTED TO HER PHYSICIAN WITH PAIN AND BLEEDING THAT SHE REPORTED EXPERIENCING FOR 2 YEARS FOLLOWING PLACEMENT OF ESSURE MICRO-INSERTS. THE PHYSICIAN PERFORMED A HYSTEROSCOPY ON THE PT AND FOUND 18 COILS IN THE PT'S UTERUS AND THE PART OF THE INNER COILS COMING FROM THE RIGHT FALLOPIAN TUBE; PHYSICIAN REPORTED THAT THE LEFT SIDE APPEARED NORMAL WITH A SMALL AMOUNT OF COILS OBSERVED. THE PHYSICIAN USED HYSTEROSCOPIC SCISSORS AND CUT THE OUTER COILS WITH EASE ON THE RIGHT SIDE NEAR THE TUBAL OSTIUM. AN HSG WAS THEN PERFORMED ON THE PT AND BILATERAL TUBAL OCCLUSION WAS CONFIRMED. THE PT'S PAIN AND BLEEDING RESOLVED FOLLOWING THIS PROCEDURE. THE PHYSICIAN BELIEVES THAT THE MICRO-INSERT WAS RESPONSIBLE FOR THE PT'S SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015263	CONCEPTUS INCORPORATED	3/17/2010	3/30/2010

Event Information:

Event Date (B3): 3/5/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1):
Device Type (E2): IMPLANT ESSURE ESS305
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 678819

Single Use:
Implant Date (E6): 3/5/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT UNDERGOING BILATERAL TUBAL LIGATION. THE RIGHT SIDE WAS COMPLETED. THE SURGEON HAD DIFFICULTY WITH THE LEFT SIDE, EITHER RELATED TO PATIENT ANATOMY OR A PROBLEM WITH THE DEVICE. HE ATTEMPTED 2 ADDITIONAL ESSURE DEVICES ON THE LEFT SIDE. ONE WOULD NOT DEPLOY AND THE OTHER WAS BENT AND COULD NOT BE PASSED INTO THE TUBE. THE PROCEDURE WAS ENDED, AND THE PATIENT WILL BE SCHEDULED AT ANOTHER TIME FOR THE LEFT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00016	CONCEPTUS, INC.	3/17/2010	8/24/2010

Event Information:

Event Date (B3): 2/15/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/14/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT WAS DIAGNOSED WITH AN ECTOPIC PREGNANCY FOLLOWING AN ESSURE MICRO-INSERT PLACEMENT PROCEDURE. ESSURE PROCEDURE WAS PERFORMED ON (B)(6)2008; AN HSG CONFIRMATION TEST WAS PERFORMED ON (B)(6)2008. THE HSG REPORT NOTED OCCLUSION OF BOTH TUBES, HOWEVER, IT ALSO STATED THAT THE MICRO-INSERT ON THE LEFT SIDE APPEARED "TORTUOUS." THE ECTOPIC PREGNANCY OCCURRED WITHIN THE PATIENT'S LEFT TUBE. THE PATIENT WAS TREATED FOR THE ECTOPIC PREGNANCY AND WAS RESPONDING WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015256	CONCEPTUS, INC.	3/22/2010	3/30/2010

Event Information:

Event Date (B3): 2/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE TUBAL OCCLUDER
Device Type (E2): TUBAL OCCLUSION DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4): 686080

Single Use:
Implant Date (E6): 2/19/2010
Explant Date (E7): 3/19/2010
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/19/2010

Event Description (B5):

PT CONSENTED TO HAVE PLACEMENT OF AN ESSURE STERILIZATION DEVICE BILATERALLY INTO HER TUBES. THIS WAS DONE WITH HYSTEROSCOPY AND LOCAL ANESTHESIA AND VICODIN. THE R TUBAL OSTIUM WAS VISUALIZED AND THE DEVICE ADVANCED INTO THE TUBE, THERE WAS A SMALL FLAP OF TISSUE THAT THEN BLOCKED THE TUBAL OSTIUM AND AT THAT MOMENT, WE COULD NOT VISUALIZE THE OSTIA BUT THOUGHT OUR DEVICE WAS STILL IN THE TUBE, SO THE DEVICE WAS DEPLOYED. ONCE DEPLOYED, IT WAS OBVIOUS THAT IT WAS WITHIN THE UTERINE CAVITY, NOT THE TUBE. THE L TUBAL OSTIUM WAS EASILY SEEN AND THE DEVICE DEPLOYED UNDER DIRECT VISION INTO THE TUBE. THE R TUBAL OSTIUM WAS THEN VISUALIZED AGAIN AND THE DEVICE PLACED IN THE TUBE - THIS TIME WE WERE ABLE TO VISUALIZE IT THE ENTIRE TIME, AND THE DEVICE WAS CORRECTLY DEPLOYED. I DID NOT HAVE THE APPROPRIATE INSTRUMENT TO REMOVE THE EXTRA DEPLOYED DEVICE, BUT TOLD THE PT IT WOULD LIKELY PASS ON IT'S OWN OVER THE NEXT 2 WEEKS WITH HER MENSES. SHE HAD A MENSES AND DID NOT PASS THE DEVICE. ROUTE: INTRA-UTERINE, DATES OF USE: (B) (6) 2010 - (B) (6) 2010. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015262	CONCEPTUS (CONCEPTUS)	3/24/2010	3/30/2010

Event Information:

Event Date (B3): 3/27/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE CONTRACEPTIVE DEVICE (KNH)
Device Type (E2): TUBAL OCCLUSION CONTRACEPTIVE DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/27/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE IMPLANTED (B) (6) 2009. PATIENT TOOK BIRTH CONTROL AS DIRECTED FOR 3 MONTHS FOLLOWING PROCEDURE. HSG DONE (B) (6) 2009 - POSITIVE TUBAL OCCLUSION. POSITIVE PREGNANCY TEST ON (B) (6) 2009. PATIENT (B) (6) PREGNANT. NO COMPLICATIONS TO FETUS. DEVICE CANNOT BE REMOVED PER PHYSICIAN. PATIENT WILL HAVE ADDITIONAL PROCEDURE AFTER GIVING BIRTH TO ENSURE PREGNANCY WILL NOT HAPPEN AGAIN. PATIENT FEELS THAT PREGNANCY TEST SHOULD BE MANDATORY BEFORE HSG TEST DONE TO ELIMINATE UNNECESSARY XRAY EXPOSURE. ALSO, IT SHOULD BE RECOMMENDED THAT BIRTH CONTROL BE EXTENDED TO 5 OR 6 MONTHS POST PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00019	CONCEPTUS, INC.	3/25/2010	2/7/2011

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT REPORTED, AN ECTOPIC PREGNANCY THAT OCCURRED 2 YEARS FOLLOWING ESSURE MICRO-INSERT IMPLANTATION. SHE STATED THAT THE PREGNANCY WAS TERMINATED AND SHE IS DOING WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00017	CONCEPTUS, INC.	3/25/2010	4/6/2011

Event Information:

Event Date (B3): 2/24/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 9/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT PRESENTED TO HER PHYSICIAN AND REPORTED CONSTANT BURNING PAIN FOLLOWING IMPLANTATION WITH ESSURE MICRO-INSERTS. THE PHYSICIAN REPORTED THAT HE REMOVED THE MICRO-INSERTS AND DRAINED FLUID FROM THE PATIENT'S PERITONEUM DURING 2 LAPAROSCOPIC SURGERIES. THE PATIENT CONTINUED TO COMPLAIN OF PAIN FOLLOWING REMOVAL OF THE MICRO-INSERTS. ADDITIONALLY, A SMALL PIECE OF MICRO-INSERT COIL REMAINED IN THE PATIENT'S CORNUA SO THE PHYSICIAN DECIDED UPON A HYSTERECTOMY. THE DOCTOR REPORTED THAT THE PATIENT'S PAIN RESOLVED FOLLOWING THE HYSTERECTOMY AND REMOVAL OF THE PIECE OF MICRO-INSERT COIL; THE PHYSICIAN BELIEVES THAT THE PATIENT WAS EXPERIENCING AN ALLERGIC REACTION TO THE NICKEL CONTAINED IN THE ESSURE MICRO-INSERTS. NO NICKEL ALLERGY TEST WAS PERFORMED ON THE PATIENT BEFORE OR AFTER THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PATIENT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. IFU WARNING: PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY P

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00018	CONCEPTUS, INC.	3/25/2010	4/6/2011

Event Information:

Event Date (B3): 10/6/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 10/6/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PATIENT EXPERIENCED A RASH AND ITCHING FOLLOWING IMPLANTATION WITH ESSURE MICRO-INSERTS. THE PATIENT WAS REFERRED TO A DERMATOLOGIST AND A NICKEL ALLERGY WAS CONFIRMED. THE PHYSICIAN REMOVED THE MICRO-INSERTS AND THE PATIENT'S SYMPTOMS RESOLVED FOLLOWING REMOVAL. THE PHYSICIAN BELIEVES THAT THE SYMPTOMS THE PATIENT WAS EXPERIENCING WERE DIRECTLY RELATED TO THE ESSURE MICRO-INSERTS.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PATIENT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL).

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00020	CONCEPTUS, INC.	3/30/2010	4/7/2010

Event Information:

Event Date (B3): 3/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/1/2010
Explant Date (E7): 3/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HE PLACED 2 ESSURE MICRO-INSERTS INTO WHAT HE THOUGHT WERE OSTIA. HE SUBSEQUENTLY DISCOVERED THAT THEY WERE NOT THE OSTIA AND REMOVED ONE MICRO-INSERT; THE PHYSICIAN WAS UNABLE TO LOCATE THE SECOND MICRO-INSERT AS IT HAD PERFORATED THE UTERUS AND WAS IN THE PERITONEUM - REVEALED BY CT SCAN PERFORMED LATER DURING AN EMERGENCY ROOM VISIT BY PATIENT. THE PHYSICIAN STATED THAT HE PLACED 2 MORE MICRO-INSERTS SUCCESSFULLY IN THE PATIENT'S FALLOPIAN TUBES. THE PHYSICIAN SAID HE PERFORMED A LAPAROSCOPY SEVERAL DAYS LATER IN ORDER TO REMOVE THE MICRO-INSERT THAT WAS IN THE PATIENT'S PERITONEUM. HE SAID NOTHING WAS DONE TO TREAT THE UTERINE PERFORATION; A TUBAL LIGATION WAS PERFORMED AND THE 2 MICRO-INSERTS SUCCESSFULLY PLACED IN THE PATIENT WERE LEFT IN PLACE. THE PHYSICIAN SAID THE PATIENT WAS EXPERIENCING ABDOMINAL DISTENSION DUE TO THE HYSTEROSCOPIC DISTENSION MEDIA USED DURING THE ESSURE PROCEDURE; SOME OF THIS FLUID WAS REMOVED FROM THE PATIENT'S ABDOMEN DURING THE LAPAROSCOPY. THE PHYSICIAN REPORTED THAT THE PATIENT IS DOING WELL FOLLOWING TREATMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015457		4/4/2010	4/12/2010

Event Information:

Event Date (B3): 1/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1):
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/29/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DEBILITATING SIDE EFFECTS FROM ESSURE PROCEDURE DONE (B) (6) 2010. INTENSE PAIN DURING SURGERY, HEAVY BLEEDING AND CRAMPING FOR OVER 4 WEEKS AFTER PROCEDURE. DISCOMFORT ON LEFT SIDE - LIKE A VIBRATING CELL PHONE - FOR MONTHS NOW, CRAMPING AND BLOATING. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015449	CONCEPTUS INCORPORATED	4/5/2010	4/12/2010

Event Information:

Event Date (B3): 3/17/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1):
Device Type (E2): ESSURE IMPLANT
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 699884

Single Use:
Implant Date (E6): 3/17/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING ATTEMPTED TUBAL OCCLUSION, THE ESSURE DEVICE WAS DEPLOYED BUT WHEN WITHDRAWN, IT WAS NOTED THAT THE COIL WAS POSSIBLY STILL ON THE SHEATH. THIS WAS REPEATED ON THE OTHER SIDE WITH THE SAME RESULTS. THE MANUFACTURER'S REP WAS NOTIFIED AND THE PRODUCT WILL NOT BE USED UNTIL THE REP CAN BE PRESENT FOR THE CASES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00021	CONCEPTUS, INC.	4/9/2010	4/14/2010

Event Information:

Event Date (B3): 3/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNKNOWN
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7): 3/12/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED AN ECTOPIC PREGNANCY AND EMERGENCY SURGERY FOR A PATIENT THAT WAS IMPLANTED WITH ESSURE MICRO-INSERTS IN 2005. THE PHYSICIAN STATED THAT IT WAS NECESSARY TO PERFORM A LAPAROTOMY DUE TO CORNUAL RUPTURE WHERE THE ECTOPIC PREGNANCY OCCURRED; A HYSTERECTOMY WAS ALSO PERFORMED. THE PHYSICIAN REMOVED THE MICRO-INSERT LOCATED ON THE SAME SIDE AS THE ECTOPIC PREGNANCY; THE PHYSICIAN REPORTED THAT HALF OF THE MICRO-INSERT WAS IN THE FALLOPIAN TUBE AND HALF WAS EXTENDING OUT OF THE UTERUS WHERE THE ECTOPIC PREGNANCY/CORNUA RUPTURE OCCURRED; THE PHYSICIAN WAS UNABLE TO LOCATE A MICRO-INSERT ON THE CONTRALATERAL SIDE. THE PHYSICIAN REPORTED THAT THE ECTOPIC PREGNANCY WAS TREATED SUCCESSFULLY AND THE PATIENT IS DOING WELL FOLLOWING TREATMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00022	CONCEPTUS, INC.	4/9/2010	4/14/2010

Event Information:

Event Date (B3): 2/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNKNOWN
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7): 2/12/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PATIENT PRESENTED TO A EMERGENCY ROOM WITH PAIN 3.5 YEARS FOLLOWING IMPLANTATION WITH ESSURE MICRO-INSERTS. A CT SCAN WAS PERFORMED ON THE PATIENT AND IT REVEALED THAT MICRO-INSERT HAD PERFORATED THE PATIENT'S FALLOPIAN TUBE AND WAS LOCATED IN THE PERITONEAL CAVITY. THE PHYSICIAN EXPLANTED THE MICRO-INSERT LAPAROSCOPICALLY 10 DAYS FOLLOWING THE EMERGENCY ROOM VISIT DUE TO CONTINUED PAIN EXPERIENCED BY THE PATIENT; THE MICRO-INSERT WAS FOUND INTACT IN THE OMENTUM AND REMOVED, ACCORDING TO THE PHYSICIAN. THE PHYSICIAN REPORTED THAT HER PATIENT'S PAIN HAS RESOLVED; THE DOCTOR STATED THAT SHE IS UNDER THE ASSUMPTION THAT THE PATIENT'S PAIN WAS DIRECTLY RELATED TO THE ESSURE MICRO-INSERT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00023	CONCEPTUS, INC.	4/14/2010	4/6/2011

Event Information:

Event Date (B3): 3/15/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 2/18/2010
Explant Date (E7): 3/5/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT PRESENTED TO HER PHYSICIAN WITH PAIN AND CRAMPING, DESCRIBED AS INTOLERABLE, SEVERAL WEEKS FOLLOWING IMPLANTATION WITH ESSURE MICRO-INSERTS. A NICKEL ALLERGY WAS SUSPECTED SO THE PT WAS REFERRED TO A DERMATOLOGIST FOR A NICKEL ALLERGY TEST; A NICKEL ALLERGY WAS CONFIRMED. THE PHYSICIAN REMOVED THE MICRO INSERTS AS A RESULT OF THE NICKEL ALLERGY AND PAIN THE PT WAS EXPERIENCING. THE PHYSICIAN REPORTED THAT THE PT'S SYMPTOMS RESOLVED FOLLOWING MICRO-INSERT REMOVAL. THE PHYSICIAN STATED THAT SHE BELIEVES THE ESSURE MICRO-INSERTS WERE DIRECTLY RELATED TO THE SYMPTOMS THE PT WAS EXPERIENCING.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYS SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PT WITH SUSPECTED HYPERSENSITIVITY

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015612	CONCEPTUS	4/17/2010	4/26/2010

Event Information:

Event Date (B3): 1/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 000000000

Single Use:
Implant Date (E6): 1/13/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE, MFR CONCEPTUS, PLACED IN (B) (6) OUTPATIENT SURGERY CENTER (B) (6) ON (B) (6) 2010. F/U X-RAY TO CHECK PLACEMENT ON (B) (6) 2010 SHOWS ONE COIL COMPLETELY PUNCTURED THROUGH THE FALLOPIAN TUBE -RIGHT- AND IS POSSIBLY LODGED OUTSIDE OF THE UTERINE WALL. OTHER COIL -LEFT- HAS NOT PROPERLY OCCLUDED AND RADIOLOGIST STATES NOT PROPERLY PLACED. F/U APPT WITH MD (B) (6) 2010.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00024	CONCEPTUS, INC.	4/21/2010	4/27/2010

Event Information:

Event Date (B3): 3/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 638494

Single Use: Y
Implant Date (E6): 3/11/2010
Explant Date (E7): 3/22/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT COMPLAINED OF PAIN PRIOR TO AND FOLLOWING IMPLANTATION WITH ESSURE MICRO-INSERTS. DURING THE ESSURE PROCEDURE, A TOTAL OF 4 MICRO-INSERTS WERE PLACED IN THE PATIENT; 3 MICRO-INSERTS WERE PLACED IN 1 FALLOPIAN TUBE. ONE MICRO-INSERT HAD PERFORATED THE PATIENT AND WAS LOCATED AND REMOVED FROM THE ABDOMINAL CAVITY. THE OTHER 3 MICRO-INSERTS WERE LOCATED IN THE FALLOPIAN TUBES AND WERE ALSO REMOVED. THE MICRO-INSERTS WERE REMOVED USING LAPAROSCOPIC AND HYSTEROSCOPIC METHODS. FOLLOWING REMOVAL, THE PATIENT REPORTED THAT HER PAIN HAD IMPROVED. THE PHYSICIAN BELIEVES THAT THE ESSURE MICRO-INSERTS WERE DIRECTLY RELATED TO THE PAIN THE PATIENT WAS EXPERIENCING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	4/22/2010	5/6/2010

Event Information:

Event Date (B3): 4/22/2010 **Report Date (B4): 4/22/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION DEVICE FOR STERILIZATION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 20227514

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE REMOVED FROM INTACT ESSURE BOX; NO VISIBLE DAMAGE TO BOX OR INNER PACKAGE. DEVICE VISIBLE THROUGH CLEAR PLASTIC PACKAGE INSERT. DEVICE TIP MALFORMED IN A BENT ELBOW POSITION; DEVICE SHOULD BE STRAIGHT.
==========
HEALTH PROFESSIONAL'S IMPRESSION
==========
NO ADVERSE EVENT; NEVER USED ON PATIENT: NEW ESSURE DEVICE OPEND AND USED ON PATIENT WITH NO ADVERSE OUTCOME.
==========
MANUFACTURER RESPONSE FOR TUBAL OCCLUSION DEVICE FOR STERILIZATION, ESSURE
==========
NO RESPONSE YET. RECEIVED VOICE MAIL MESSAGE STATING A REPRESENTATIVE WILL CALL WITHIN 24 HOURS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00027	CONCEPTUS, INC.	4/23/2010	8/4/2010

Event Information:

Event Date (B3): 3/26/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 678815

Single Use: Y
Implant Date (E6): 3/26/2010
Explant Date (E7): 3/26/2010
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN ENCOUNTERED A PROBLEM DURING AN ESSURE MICRO-INSERT PLACEMENT PROCEDURE; 1 ESSURE MICRO-INSERT WOULD NOT DETACH FROM THE DELIVERY HANDLE; THE INNER COIL OF THE MICRO-INSERT STRETCHED OUT AS A RESULT AND WAS HANGING OUTSIDE OF THE PT'S UTERUS WHILE THE MICRO-INSERT WAS IN THE PT'S FALLOPIAN TUBE. AN ATTEMPT WAS MADE TO CUT THE WIRE AT THE TUBAL OSTIUM BUT THIS WAS NOT SUCCESSFUL. THE PHYSICIAN THEN PERFORMED A LAPAROSCOPY TO REMOVE THE MICRO-INSERT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00026	CONCEPTUS, INC.	4/23/2010	9/16/2010

Event Information:

Event Date (B3): 3/25/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 689930

Single Use: Y
Implant Date (E6): 3/25/2010
Explant Date (E7): 3/25/2010
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN ENCOUNTERED A PROBLEM DURING PLACEMENT OF ESSURE MICRO-INSERTS IN HIS PT; 1 ESSURE HANDLE DID NOT DETACH FROM THE MICRO-INSERT. THE PHYSICIAN STRETCHED THE DELIVERY WIRE UNTIL IT WAS OUTSIDE OF THE CERVIX AND THEN CUT IT. THE INNER COIL WAS INSIDE THE PT'S UTERINE CAVITY BUT STILL FIRMLY ATTACHED TO THE OUTER COIL, WHICH WAS IN THE PT'S FALLOPIAN TUBE WITH 3 TRAILING COILS. AT THAT POINT, THE PT'S CERVIX WAS TOO DILATED AND IT WAS IMPOSSIBLE TO OBTAIN ADEQUATE DISTENSION; PT WAS ALSO IN A GREAT DEAL OF DISCOMFORT WHEN THE PHYSICIAN ATTEMPTED TO REMOVE THE MICRO-INSERT WITH GRASPING FORCEPS. THE PHYSICIAN SENT THE PT TO A HOSPITAL, WHERE GENERAL ANESTHESIA WAS ADMINISTERED AND THE MICRO-INSERT WAS REMOVED HYSTEROSCOPICALLY. THE PHYSICIAN THEN PERFORMED A BILATERAL TUBAL LIGATION. IT WAS REPORTED THAT THE PT WAS DOING WELL FOLLOWING THE ESSURE PROCEDURE AND TUBAL LIGATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00025	CONCEPTUS, INC.	4/23/2010	4/6/2011

Event Information:

Event Date (B3): 3/25/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/29/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT WAS EXPERIENCING ITCHY RED BLOTCHES OVER HER ENTIRE BODY 24 TO 48 HOURS FOLLOWING IMPLANTATION WITH ESSURE MICRO-INSERTS. THE PHYSICIAN TAPED AN ESSURE MICRO-INSERT TO THE PT'S ARM AND THE PT REACTED WHERE THE ESSURE MICRO-INSERT CAME INTO CONTACT WITH THE PT'S SKIN. THE PHYSICIAN DETERMINED THAT MICRO-INSERT REMOVAL WAS NECESSARY DUE TO THE PT'S REACTION. FOLLOWING MICRO-INSERT REMOVAL, THE PHYSICIAN REPORTED THAT THE PT'S SYMPTOMS RESOLVED COMPLETELY. THE PHYSICIAN BELIEVE THAT THE ESSURE MICRO-INSERTS WERE RESPONSIBLE FOR THE PT'S SYMPTOMS.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNING SECTION BELOW FOR PATIENT WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PATIENTS WITH SUSPECTED HYPER

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015707	CONCEPTUS, INC.	4/26/2010	5/4/2010

Event Information:

Event Date (B3): 4/22/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE - ESS305
Model # (E4):
Catalog # (E4):
Lot #(E4): 669936

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT'S ANATOMY PLACED TORQUE ONTO DEVICE MAKING IT DIFFICULT TO DEPLOY. ATTEMPTS WERE MADE TO REMOVE DEVICE AND IT SEPARATED. ONE SECTION REMOVED WITHOUT DIFFICULT AND ONE REMOVED VIA GRASPER. COMPANY REP WILL INVESTIGATE POTENTIAL PRODUCT MALFUNCTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	4/27/2010	5/6/2010

Event Information:

Event Date (B3): 4/19/2010 **Report Date (B4): 4/27/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 20214173

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN WHILE ATTEMPTING TO DEPLOY THE ESSURE DEVICE FOUND THAT THE SHEATH WOULD NOT PULL BACK. PHYSICIAN UNABLE TO PERFORM PROCEDURE AND ELECTED TO COMPLETE AT A LATER DATE.
==========
HEALTH PROFESSIONAL'S IMPRESSION
==========
UNKNOWN
==========
MANUFACTURER RESPONSE FOR PERMANENT BIRTH CONTROL SYSTEM, ESSURE
==========
MANUFACTURER PROVIDED RGA# FOR PRODUCT RETURN EVALUATION. MANUFACTURE SENDING SHIPPING CONTAINER AND PRODUCT WILL BE RETURNED UPON RECEIPT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00028	CONCEPTUS, INC.	4/28/2010	4/6/2011

Event Information:

Event Date (B3): 3/17/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/8/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PATIENT HAD THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE ON (B)(6) 2010. AN ESSURE CONFIRMATION TEST (3 MONTH HSG) REVEALED THAT THE MICRO-INSERTS HAD PERFORATED THE PATIENT'S FALLOPIAN TUBES AND WERE LOCATED IN THE PATIENT'S ABDOMEN; THE PATIENT WAS ASYMPTOMATIC. THE PHYSICIAN REMOVED THE MICRO-INSERTS LAPAROSCOPICALLY AND PERFORMED A TUBAL LIGATION. THE DOCTOR STATED THAT IT WAS NECESSARY TO REMOVE THE MICRO-INSERTS TO PREVENT INJURY TO THE PATIENT. THE PHYSICIAN STATED THAT THE MICRO-INSERTS APPEARED NORMAL FOLLOWING REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015786	CONCEPTUS	4/30/2010	5/7/2010

Event Information:

Event Date (B3): 9/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE DONE ON (B) (6) 2009. I FOLLOWED UP ON (B) (6) 2009, FOR THE HSG TESTING,. THE TESTING CAME BACK IDENTIFYING THE DYE COULD NOT GO THROUGH MY TUBES. I WENT TO THE DOCTORS IN (B) (6), HE TOLD ME I DIDN'T NEED TO TAKE THE BIRTH CONTROL PILL ANY LONGER. IN (B) (6), I WAS HAVING PROBLEMS. WHEN I CALLED THE DOCTOR, SHE SAID TO TAKE A PREGNANCY TEST JUST IN CASE. I DID SO AND IT SHOWED I WAS PREGNANT. THE NEXT DAY, I WENT TO THE HOSP TO GET AN ULTRASOUND DONE. I WAS ALREADY 8 WEEKS ALONG. HOWEVER, THE BIGGEST SHOCK WAS I AM CARRYING "TWINS". THIS WAS A PAINFUL PROCEDURE FOR ME TO GET DONE CONSIDERING IT TOOK THE DOCTORS SOME TIME TO GET THESE CORALS THROUGH MY TISSUE AND INTO MY TUBES. I HAVE THREE CHILDREN AND DIDN'T PLAN ON HAVING ANY MORE. HAVING THIS PROCEDURE DONE HAS FOREVER CHANGED MY LIFE AND MY FAMILY'S LIFE. I FOLLOWED THROUGH WITH ALL OF MY DOCTOR VISITS AND FOLLOW UPS. AT THIS MOMENT, I AM NOT SURE WHAT TO DO. NOT ONLY WAS I NOT PREPARED FOR THIS TO HAPPEN, I AM NOT SURE HOW I AM GOING TO AFFORD 2 MORE CHILDREN. I FEEL VERY STRONGLY THAT THE FDA SHOULD DO SOMETHING ABOUT THIS PROCEDURE. IT DEFINITELY DOES NOT WORK!!!!!! DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015840	CONCEPTUS	5/4/2010	5/13/2010

Event Information:

Event Date (B3): 4/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/15/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

WHILE USING THE ESSURE DEVICE FOR BIRTH CONTROL THE PATIENT'S UTERUS WAS PERFORATED. THE PROCEDURE WAS NOT COMPLETED. THE PATIENT WAS GIVEN ANTIBIOTICS TO PREVENT COMPLICATIONS. THE PATIENT RETURNED APPROX 2 WEEKS LATER WITH NAUSEA, VOMITING, AND SEVERE DIARRHEA. CONCERN FOR INFECTION AT PERFORATION SITE OR CLOSTRIDIUM DIFFICILE. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL/TUBAL LIGATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00029	CONCEPTUS, INC.	5/5/2010	5/12/2010

Event Information:

Event Date (B3): 4/7/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 4/7/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PATIENT, WHO HAD UNDERGONE AN ESSURE PLACEMENT PROCEDURE, PRESENTED TO HIM WITH PAIN; THE PHYSICIAN DID NOT KNOW WHEN THE PATIENT HAD THE ESSURE PROCEDURE. THE PHYSICIAN STATED THAT THE ESSURE MICRO-INSERTS IN THE PATIENT'S ABDOMEN AND HER FALLOPIAN TUBES WERE NOT OCCLUDED. ONE MICRO-INSERT WAS REMOVED LAPAROSCOPICALLY. THE SECOND MICRO-INSERT WAS FOUND ADHERED TO THE SIGMOID COLON AND WAS NOT REMOVED. THE PHYSICIAN STATED THAT HE IS UNSURE IF THE PATIENT'S PAIN IS DIRECTLY RELATED TO THE ESSURE MICRO-INSERTS; DURING THE LAPAROSCOPY THE PATIENT WAS FOUND TO HAVE ENDOMETRIOSIS. THE PHYSICIAN REPORTED THAT THE PATIENT IS DOING OK FOLLOWING THE LAPAROSCOPY, BUT STILL EXPERIENCING SOME PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00030	CONCEPTUS, INC.	5/5/2010	5/12/2010

Event Information:

Event Date (B3): 3/24/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/10/2010
Explant Date (E7): 3/24/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT REPORTED THAT SHE WAS EXPERIENCING PELVIC PAIN FOLLOWING AN ESSURE PROCEDURE; THE ESSURE MICRO-INSERTS WERE REMOVED BY HER PHYSICIAN AND A PARTIAL HYSTERECTOMY WAS PERFORMED. THE PATIENT'S PHYSICIAN WAS CONTACTED AND THE PHYSICIAN STATED THAT THE HYSTERECTOMY WAS AN ELECTIVE PROCEDURE BY THE PATIENT AND THAT HE DOES NOT BELIEVE THAT THE PATIENT'S PAIN WAS RELATED TO THE ESSURE MICRO-INSERTS; THE POST-OPERATIVE REPORT INDICATED THAT THE PATIENT'S FALLOPIAN TUBES APPEARED "NORMAL" GROSSLY AND MICROSCOPICALLY AND THE ESSURE MICRO-INSERTS NOTED TO HAVE PROPER PLACEMENT DURING THE PROCEDURE. THE PATIENT'S SYMPTOMS RESOLVED FOLLOWING MICRO-INSERT REMOVAL AND HYSTERECTOMY AND THE PATIENT IS DOING WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00033	CONCEPTUS, INC.	5/5/2010	5/12/2010

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 2/1/2010
Explant Date (E7): 4/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PT UNDERWENT AN ESSURE PLACEMENT PROCEDURE AND BEGAN EXPERIENCING PAIN IMMEDIATELY FOLLOWING THE PROCEDURE. AFTER 2-3 WEEKS, THE PHYSICIAN REMOVED 1 ESSURE MICRO-INSERT HYSTEROSCOPICALLY. THE PT WAS THEN REFERRED TO ANOTHER PHYSICIAN FOR POSSIBLE HYSTERECTOMY AND REMOVAL OF THE SECOND MICRO-INSERT. THE PT UNDERWENT LAPAROSCOPY AND THE MICRO-INSERT WAS REMOVED ALONG WITH A PORTION OF THE PT'S FALLOPIAN TUBE. THE PHYSICIAN STATED THAT THE PT'S PAIN CONTINUES FOLLOWING REMOVAL OF BOTH MICRO-INSERTS; THE PHYSICIAN BELIEVES, THE ESSURE MICRO-INSERTS WERE DIRECTLY RELATED TO THE PT'S PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00031	CONCEPTUS, INC.	5/5/2010	6/15/2010

Event Information:

Event Date (B3): 3/26/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 637215

Single Use: Y
Implant Date (E6): 3/26/2010
Explant Date (E7): 3/26/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT AN ESSURE MICRO-INSERT CAUSED A PERFORATION DURING AN ESSURE PLACEMENT PROCEDURE; 2/3 OF THE MICRO-INSERT WAS OUTSIDE OF THE FALLOPIAN TUBE. THE PHYSICIAN RESECTED THE MICRO-INSERT AND PLACED A FILSHIE CLIP TO COMPLETE THE PT'S CONTRACEPTION. THE PHYSICIAN STATED IT WAS NECESSARY TO REMOVE THE MICRO-INSERT IN ORDER TO PREVENT INJURY TO THE PT'S INTESTINE. THE PHYSICIAN REPORTED THAT NO TREATMENT WAS NECESSARY FOR THE PERFORATION; THE PHYSICIAN STATED THE PT IS ASYMPTOMATIC AND DOING WELL FOLLOWING THE PROCEDURE. THIS INCIDENT ALSO REPORTED BY USER FACILITY TO FDA UNDER MEDWATCH REPORT # (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00032	CONCEPTUS, INC.	5/5/2010	6/15/2010

Event Information:

Event Date (B3): 4/11/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 625643

Single Use: Y
Implant Date (E6): 4/11/2008
Explant Date (E7): 1/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PT REPORTED THAT SHE EXPERIENCED SEVERE PAIN, 2 WEEK LONG MENSTRUAL CYCLES, AND SPOTTING OF BLOOD THE REMAINDER OF THE MONTH. DESPITE SEVERAL FORMS OF TREATMENT THE PT REPORTED THAT SHE EXPERIENCED NO RELIEF FROM THE PAIN AND IRREGULAR MENSTRUAL CYCLES. EVENTUALLY, THE MICRO-INSERTS WERE REMOVED AND A SALPINGECTOMY PERFORMED. THE PT STATED THAT HER PAIN AND IRREGULAR MENSTRUAL CYCLES COMPLETELY RESOLVED FOLLOWING ESSURE MICRO-INSERT REMOVAL. THE PT BELIEVES THAT THE ESSURE MICRO-INSERTS WERE RESPONSIBLE FOR THE SYMPTOMS SHE WAS EXPERIENCING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015835	CONCEPTUS (CONCEPTUS)	5/7/2010	5/12/2010

Event Information:

Event Date (B3): 7/13/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM (KNH)
Model # (E4):
Catalog # (E4):
Lot #(E4): 641422

Single Use:
Implant Date (E6): 7/13/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAS HAD EXCESSIVE BLEEDING AND CRAMPING SINCE IMPLANTATION OF DEVICE. PT HAS BEEN BLEEDING NON STOP SINCE (B) (6) 2010. PT HAS PAIN THAT IS BEING TREATED WITH VICODIN. PHYSICIAN STATES THAT PATIENT IS FACING A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5015998	CONCEPTUS INCORPORATED	5/18/2010	5/25/2010

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4): 678811

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

MD WAS DOING A STERILIZATION WITH ESSURE. THE CONCEPTUS REP, (B) (4), WAS AVAILABLE DURING THE PROCEDURE AND ADVISING MD REGARDING THE PRODUCT. UPON INSERTING THE MICRO-INSERT INTO THE LEFT OS, THE PLACEMENT WAS NOT ACCEPTABLE. THE MICRO- INSERT WAS REMOVED AND A NEW ONE INSERTED INTO THE LEFT OS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016034		5/18/2010	5/26/2010

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PUT IN 11-06 CONSTANT PAIN, DISCOMFORT, AND ALOT OF BLEEDING, SOMETIMES, I BLEED FOR 2 MONTHS STRAIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016090	CONCEPTUS INC.	5/24/2010	6/1/2010

Event Information:

Event Date (B3): 5/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/15/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

UNDERWENT THE ESSURE PERMANENT BIRTH CONTROL PROCEDURE IN (B) (6) 2009. ESSURE MICRO-IMPLANTS WERE PLACED IN MY FALLOPIAN TUBES ON (B) (6) 2009 AT AN OUT-PATIENT FACILITY IN (B) (6). THE DOCTOR THAT PERFORMED THE PROCEDURE WAS DR (B) (6) OF (B) (6). I HAD A CONFIRMATION TEST PERFORMED ON (B) (6) 2009. THE TEST WAS A HYSTEROSALPINGOGRAM -HSG- WHICH WAS PERFORMED AT (B) (6) MEDICAL CENTER IN (B) (6). THE HSG WAS ALSO PERFORMED BY DR (B) (6). THE RESULTS OF THE HSG CONFIRMED CORRECT PLACEMENT OF THE ESSURE MICRO-IMPLANTS AND COMPLETE BLOCKAGE OF THE FALLOPIAN TUBES. IT WAS DETERMINED -VIA ULTRASOUND- DURING MY ANNUAL OB/GYN EXAM ON (B) (6) 2010 THAT I WAS APPROX 7 WEEKS PREGNANT. THE CAUSE OF THE DEVICE FAILURE CANNOT BE FULLY DETERMINED AT THIS TIME, ALTHOUGH IT APPEARS THAT ONE OF THE ESSURE MICRO-IMPLANTS BECAME DISLODGED AND MIGRATED. THEREFORE, AT SOME TIME AFTER IT WAS CONFIRMED THAT BOTH OF MY FALLOPIAN TUBES WERE BLOCKED - (B) (6) 2009-, ONE OF THEM BECAME UNBLOCKED. DATES OF USE: (B) (6) 2009 - (B) (6) 2010. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00034	CONCEPTUS, INC.	5/28/2010	6/3/2010

Event Information:

Event Date (B3): 2/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/21/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT WAS FOUND TO HAVE A PERFORATION OF THE FALLOPIAN TUBE - DUE TO AN ESSURE MICRO-INSERT - ON THE ESSURE CONFIRMATION TEST 3 MONTHS FOLLOWING THE ESSURE PROCEDURE. THE PHYSICIAN REPORTED THAT IT WAS NECESSARY TO REMOVE THE MICRO-INSERT LAPAROSCOPICALLY. THE PHYSICIAN REPORTED THAT THE PT WAS ASYMPTOMATIC PRIOR TO REMOVAL OF THE MICRO-INSERT AND WAS DOING WELL FOLLOWING REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016213	UNK	5/31/2010	6/9/2010

Event Information:

Event Date (B3): 5/30/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/30/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT IS A SINGLE MOTHER OF 3 CHILDREN. PT STATES TO BE FERTILE AND HAS EXHAUSTED ALL OTHER METHODS OF BIRTH CONTROL. PT RECEIVED THE ESSURE INSERTS AFTER BEING TOLD THERE WOULD BE NO SIDE EFFECTS, PT WAS ALSO TOLD THAT THE PROCEDURE IS PERMANENT AND CANNOT BE REVERSED. THE PT FOLLOWING THE ESSURE BEGAN HAVING LONG, HEAVY AND PAINFUL PERIODS. FOLLOWED BY SIGNIFICANT WEIGHT GAIN, ANXIETY AND DEPRESSION. OTHER SIDE EFFECTS LISTED BY PT ARE, INSOMNIA, TINGLING OF HANDS AND FEET, ITCHY SKIN, SWELLING THROUGHOUT THE BODY, JOINT PAIN AND RAPID HEART BEAT AT TIMES. DOCTORS DENIED THIS HAS TO DO WITH THE ESSURE BUT PT WAS HEALTHY WITH NONE OF THESE SYMPTOMS PRIOR TO HAVING THE ESSURE PROCEDURE. PT HAS NOW FOUND OUT THAT THE ESSURE IS REVERSIBLE AND IS OPTING FOR SURGERY TO HAVE IT DONE. DATES OF USE: (B) (6) 2008-(B) (6) 2010. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	6/1/2010	10/15/2010

Event Information:

Event Date (B3): 5/24/2010 **Report Date (B4): 6/1/2010** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1):
Device Type (E2): ESSURE COIL
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 654831

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PROCEDURE: HYSTEROSCOPIC ESSURE STERILIZATION PROCEDURE, (B)(4). DURING THE PROCEDURE, SURGEON STATED THE DEVICE MISFIRED AS HE WAS ATTEMPTING TO INSERT THE RIGHT ESSURE COIL. IT DID NOT REACH ALL THE WAY INTO THE FALLOPIAN TUBE. SURGEON WAS ABLE TO GRASP THE COIL AND REMOVE IT. COIL WAS DISCARDED BUT HAND PIECE WAS SAVED. ANOTHER ESSURE COIL WAS OBTAINED AND FUNCTIONED WITHOUT INCIDENT. PATIENT TOLERATED PROCEDURE WELL AND WAS DISCHARGED HOME THE SAME DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	6/10/2010	6/15/2010

Event Information:

Event Date (B3): 6/1/2010 **Report Date (B4): 6/10/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESS305 ESSURE COIL CATHETER
Device Type (E2): DEVICE, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 664654

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT UNDERWENT A HYSTEROSCOPIC RIGHT TUBAL CLOSURE. THE PROCEDURE FAILED WHEN THERE WAS A MALFUNCTION OF THE ESSURE INSERTION DEVICE CAUSING THE COIL NOT TO BE RELEASED. THE COIL WAS MISPLACED AND MUTIPLE UNSUCCESSFUL ATTEMPTS WERE MADE TO LOCATE THE COIL.
==========
HEALTH PROFESSIONAL'S IMPRESSION
==========
UNSURE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016402	CONCEPTUS INCORPORATED	6/15/2010	6/22/2010

Event Information:

Event Date (B3): 1/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/8/2010
Explant Date (E7): 6/15/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PT HAD THE ESSURE COILS PLACED AT AN OUTSIDE HOSPITAL (B) (6) 2010. SHE NOTED RIGHT LOWER QUADRANT PAIN FOLLOWING PLACEMENT WHICH CONTINUED UNTIL HER SURGERY IN (B) (6) 2010. SHE UNDERWENT HSG IN (B) (6) 2010. BOTH FALLOPIAN TUBES WERE NOTED TO BE PATENT ON HSG, AND THE COILS NOTED TO BE WITHIN THE PELVIS. ON PELVIC ULTRASOUND THE RIGHT COIL WAS NOTED TO ORIGINATE IN THE MYOMETRIUM AND SUSPECTED TO BE PERFORATED THROUGH THE UTERUS. THE LEFT COIL WAS SUSPECTED TO BE WITHIN THE PELVIS. ON LAPAROSCOPIC EVALUATION, THE RIGHT COIL HAD PERFORATED JUST POSTERIOR TO THE TUBAL OSTEA AND WAS NOTED TO BE IMBEDDED AND RUNNING PARALLEL TO THE RIGHT FALLOPIAN TUBE. THE DISTAL PORTION OF THE RIGHT ESSURE COIL WAS BENT BACK AND EXTRUDING MEDIALLY AWAY FROM THE TUBE. THE LEFT FALLOPIAN TUBE WAS NORMAL. THE REMAINING ESSURE COIL WAS IMBEDDED AND WRAPPED INTO COLONIC FAT. THE PT UNDERWENT A LEFT TUBAL LIGATION, RIGHT SALPINGECTOMY WITH REMOVAL OF THE IMBEDDED MYOMETRIAL CORE, AND EXCISION OF THE BOWEL FAT WITH COIL. DATES OF USE: (B) (6) 2010 - (B) (6) 2010. DIAGNOSIS OR REASON FOR USE: CONTRACEPTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016439	CONCEPTUS	6/16/2010	6/24/2010

Event Information:

Event Date (B3): 5/27/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH; KNH)
Brand Name (E1):
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/21/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2007, I HAD AN ESSURE PUT IN. AS OF TODAY, I AM (B)(6) PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00036	CONCEPTUS, INC.	6/21/2010	6/25/2010

Event Information:

Event Date (B3): 4/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/26/2010
Explant Date (E7): 4/29/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT REPORTED TO CONCEPTUS THAT ONE OF HER ESSURE MICRO-INSERTS HAD PERFORATED HER UTERUS AND WAS FOUND LODGED IN HER SMALL INTESTINE DURING SURGERY TO REMOVE BOTH MICRO-INSERTS; PT ALSO REPORTED PAIN IMMEDIATELY FOLLOWING IMPLANTATION WITH THE MICRO-INSERTS. THE PT BELIEVES THE ESSURE MICRO-INSERTS WERE THE SOURCE OF HER PAIN. THE PT DID NOT RESPOND TO REQUESTS FOR FURTHER INFO REGARDING HER EXPERIENCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00035	CONCEPTUS, INC.	6/21/2010	2/7/2011

Event Information:

Event Date (B3): 5/24/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PATIENT HAS AN ECTOPIC PREGNANCY SEVERAL MONTHS FOLLOWING AN ESSURE PROCEDURE. THE PATIENT HAD AN ESSURE CONFIRMATION TEST (HSG) PERFORMED ON (B)(6) 2010, AND THE PATIENT'S PHYSICIAN STATED THAT THE REPORT INDICATED PROPER PLACEMENT WITH BILATERAL OCCLUSION. FOLLOWING THE HSG TEST, THE PATIENT BECAME PREGNANT AND WAS TREATED FOR THE ECTOPIC PREGNANCY. THE PATIENT WAS DOING WELL FOLLOWING TREATMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016509	CONCEPTUS, INC. USA	6/22/2010	6/29/2010

Event Information:

Event Date (B3): 6/8/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/29/2009
Explant Date (E7): 6/8/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL FELL OUT AFTER BEING IN PLACE FOR ONE YEAR. DATES OF USE: (B)(6) 2009--(B)(6) 2010. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016518	CONCEPTUS INCORPORATION	6/24/2010	7/2/2010

Event Information:

Event Date (B3): 6/23/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): KIT BIRTH CONTROL PERMANENT - LOG 101338
Device Type (E2): ESSURE
Model # (E4): ESS 305
Catalog # (E4): ESS 305
Lot #(E4): 50502885

Single Use:
Implant Date (E6): 6/23/2010
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DID NOT PROPERLY FIRE THE COIL. METAL TIP OF FLEXIBLE HANDLE COULD NOT BE REMOVED FROM PT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	6/28/2010	7/9/2010

Event Information:

Event Date (B3): 6/17/2010 **Report Date (B4): 6/28/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 20222096

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

TIP WAS BENT BEFORE REMOVING FROM THE PACKAGE. COULD NOT BE USED.
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HEALTH PROFESSIONAL'S IMPRESSION
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DEVICE IS DEFECTIVE.
==========
MANUFACTURER RESPONSE FOR PERMANENT BIRTH CONTROL SYSTEM, ESSURE
==========
LEFT VOICE-MAIL MESSAGE AND INTEND TO RETURN PRODUCT FOR EVALUATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	7/1/2010	7/16/2010

Event Information:

Event Date (B3): 6/18/2010	**Report Date (B4): 6/30/2010**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): OBSTETRICS/GYNECOLOGY
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3): 6/30/2010

Event Description (B5):

ON (B)(6) 2010 03:32 PM, ((B)(4)) PROCEDURE TO BE PERFORMED; HYSTEROSCOPIC ESSURE OCCLUSION. PROCEDURE DONE: HYSTEROSCOPIC ESSURE OCCLUSION TO RIGHT TUBE. SURGEON WAS INSERTING THE MICROINSERT TO THE RIGHT FALLOPIAN TUBE, WHEN HE DETACHED THE WIRE FROM THE INSERT, A PART OF THE INTRODUCER WAS SEEN IN THE MONITOR LEFT IN THE TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	7/2/2010	7/9/2010

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4): 7/2/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 20222096

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STAFF NOTICED THE TIP OF THE ESSURE DEVICE WAS BENT AFTER OPENING THE PACKAGE BUT PRIOR TO USE.
==========
HEALTH PROFESSIONAL'S IMPRESSION
==========
DEVICE IS DEFECTIVE.
==========
MANUFACTURER RESPONSE FOR PERMANENT BIRTH CONTROL SYSTEM, ESSURE
==========
WILL REPLACE PRODUCT AND SEND RETURN KIT FOR EVALUATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	7/7/2010	7/16/2010

Event Information:

Event Date (B3): 6/15/2010 **Report Date (B4): 7/7/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 695927

Single Use:
Implant Date (E6): 6/15/2010
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT UNDERGOING TUBAL STERILIZATION. ESSURE WAS SUCCESSFULLY PLACED ON THE LEFT. WHEN THE PROCEDURE WAS ATTEMPTED ON THE RIGHT, THE SECOND ACTION OF THE WHEEL DID NOT RELEASE THE ESSURE, AND THE WHEEL DID NOT COME BACK TO THE FULL STOP. THE INSTRUMENT WAS REMOVED, BUT THE ESSURE WAS LEFT PARTIALLY IN THE OS, BUT NOT COILED PROPERLY. THE ESSURE WAS REMOVED WITH A GRASPER. A SECOND ESSURE WAS THEN PLACED WITHOUT DIFFICULTY. THERE WAS NO PATIENT HARM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00037	CONCEPTUS, INC.	7/9/2010	7/14/2010

Event Information:

Event Date (B3): 6/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 713451

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT, WHO HAD UNDERGONE THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE, LATER PRESENTED TO HER PHYSICIAN WITH PAIN ON HER LEFT SIDE. THE PHYSICIAN REMOVED THE MICRO-INSERT ON THE PATIENT'S LEFT SIDE HYSTEROSCOPICALLY AND PLACED ANOTHER ESSURE MICRO-INSERT ON THAT SIDE. THE PHYSICIAN STATED THAT THE FIRST MICRO-INSERT WAS PLACED PROXIMALLY, AND HE BELIEVES THE MICRO-INSERT WAS DIRECTLY RELATED TO THE PATIENT'S PAIN. THE PHYSICIAN STATED THAT THE PATIENT CONTINUES TO HAVE MINIMAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016692	CONCEPTUS INCORPORATED	7/9/2010	7/19/2010

Event Information:

Event Date (B3): 6/30/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 50502885

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

COIL DID NOT PROPERLY DEPLOY FROM THE SHEATH UPON INSERTION INTO RIGHT FALLOPIAN TUBE. PROCEDURE WAS ABORTED AND CONVERTED TO LAPAROSCOPY WITH STERILIZATION USING FILSHIE CLIPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00038	CONCEPTUS, INC.	7/14/2010	7/21/2010

Event Information:

Event Date (B3): 6/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/8/2010
Explant Date (E7): 6/15/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PATIENT HAD ESSURE MICRO-INSERTS PLACED ON (B)(6)2010 BY ANOTHER PHYSICIAN. THE PATIENT BEGAN EXPERIENCING PAIN IMMEDIATELY FOLLOWING THE ESSURE PROCEDURE AND AN HSG PERFORMED REVEALED BOTH TUBES WERE PATENT; AN X-RAY SHOWED THAT 1 DEVICE WAS ADJACENT TO THE FALLOPIAN TUBE AND 1 WAS LOCATED IN THE PELVIS. THE PATIENT PRESENTED TO THE PHYSICIAN WITH PERSISTENT LOW GRADE PAIN AND THE PHYSICIAN PERFORMED AN ULTRASOUND WHICH SHOWED THAT 1 DEVICE HAD PERFORATED THROUGH THE MYOMETRIUM. THE PHYSICIAN PERFORMED A LAPAROSCOPY ON (B)(6)2010 AND REMOVED BOTH MICRO-INSERTS; SHE SAID 1 DEVICE WAS FOUND PERFORATED THROUGH THE POSTERIOR ASPECT OF THE CORNUA RUNNING PARALLEL TO THE TUBE AND THE 2ND DEVICE WAS FOUND IN THE PATIENT'S PELVIS ADHERED TO BOWEL. THE PHYSICIAN SAYS THE PATIENT IS DOING WELL FOLLOWING THE LAPAROSCOPY AND IS FREE FROM PAIN. THE PHYSICIAN STATED THAT SHE BELIEVES THE ESSURE DEVICES WERE THE SOURCE OF THE PATIENT'S PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016741	CONCEPTUS	7/14/2010	7/21/2010

Event Information:

Event Date (B3): 10/29/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/29/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2008 AND TO THIS DAY I AM IN MODERATE TO SEVERE PAIN EVERYDAY. WHEN I WAS PREGNANT WITH MY SECOND CHILD I DECIDED TO HAVE ANY TUBES TIED AFTER I GAVE BIRTH, I KNEW TWO KIDS WERE ENOUGH FOR ME AND I WAS READY TO HAVE MY TUBES TIED 6 WEEK AFTER GIVING BIRTH TO MY SECOND SON. I ASKED MY DOCTOR ABOUT TUBAL LIGATION AND IF I WOULD BE ABLE TO HAVE THIS PROCEDURE DONE. HE TALKED ME INTO UNDERGOING THE ESSURE PROCEDURE INSTEAD. HE STATED THAT IT DIDN'T HURT AND THAT HIS PTS ONLY FELT "MILD" DISCOMFORT DURING THE 45 MINUTE PROCEDURE. I WAS HESITANT, I DIDN'T LIKE THE IDEA OF BUILDING UP SCAR TISSUE OR HAVING ANY PERMANENT "SPRINGS" INSERTED INTO MY BODY. HOWEVER, MY DOCTOR KEPT PUSHING IT AND I RELUCTANTLY TOOK HIS ADVISE, AFTER ALL HE KNOWS WHAT HE IS TALKING ABOUT, RIGHT? WRONG. FIRST OF ALL, HE GAVE ME ONE LORITAB AND ONE ANTI-NAUSEA PILL AND TOLD ME I WOULDN'T FEEL ANYTHING PAINFUL. HE SAID I MIGHT HAVE MILD CRAMPING FOR A DAY OR TWO AFTER THE PROCEDURE AND THAT I MIGHT ALSO EXPERIENCE SOME BLEEDING OR SPOTTING OVER THE NEXT FEW DAYS, BUT NOTHING TOO INCONVENIENT. WELL, AS HE INSERTED THE FIRST COIL THE RIGHT SIDE OF MY BODY SEIZED UP AS I BEGAN TO FEEL THE MOST PAINFUL EXPERIENCE OF MY LIFE. THE PAIN WAS SO INTENSE I COULDN'T MOVE, MY LEG STARTED TO SHAKE UNCONTROLLABLY AND I JUST SCREAMED. THE PAIN WAS INSTANT AND UNBEARABLE, AND IT DIDN'T STOP. MY DOCTOR SAID THAT SOMETIMES THE TUBE WILL HAVE A SPASM AS THE COIL IS INSERTED SINCE THE TUBE IS CURVED AND THE COIL IS STRAIGHT. HE ASSURED ME IT WOULD RELAX IN A FEW MINUTES. RELUCTANTLY, I LET HIM INSERT THE OTHER SIDE - I FIGURED IF I WAS GOING TO EXPERIENCE THIS PAIN, I MIGHT AS WELL RECEIVE THE BENEFIT OF PERMANENT BIRTH CONTROL. THE LEFT SIDE WAS JUST AS TERRIBLE; I COULDN'T MOVE OFF OF THE TABLE BACK TO MY ROOM FOR OVER 30 MINUTES. ONCE THEY GOT ME BACK TO MY ROOM, MY

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DOCTOR SAID I COULD HAVE ONE MORE PAIN PILL AND THEN I SHOULD JUST GO HOME AND THE PAIN WOULD STOP. SO I WENT HOME AND NOW ALMOST 2 YEARS LATER, I AM STILL IN MODERATE TO SEVERE PAIN EVERYDAY. AFTER THE PROCEDURE, I BLED FOR 5 MONTHS STRAIGHT - EVERYDAY. THEN AFTER 5 MONTHS, THE BLEEDING SLOWED DOWN TO 15 - 20 DAYS OUT OF THE MONTH. I FEEL LIKE I AM HAVING CONSTANT "SPASMS" AROUND MY COILS, I CAN ACTUALLY FEEL THEM THROBBING. I HAVE GONE BACK TO THAT DOCTOR FOR VARIOUS TESTS AND THEY JUST KEPT SENDING ME HOME SAYING TO WAIT A FEW MORE MONTHS FOR THE BLEEDING TO STOP. I HAVE FOUND A NEW OBGYN AND THEY ARE GOING TO REMOVE MY ESSURE AS SOON AS I CAN AFFORD TO HAVE THE PROCEDURE DONE. UNTIL THEN, I HAVE TO TAKE LORITAB EVERYDAY JUST TO MAKE IT THROUGH MY WORK DAY. I WILL HOPE THAT YOU WOULD HAVE THE DOCTOR TELL US THAT SOMETIMES THIS HAPPENS AND THAT SOME PEOPLE EXPERIENCE SEVERE, LONG TERM CRAMPING AND BLEEDING. I WAS NEVER INFORMED THAT THIS WAS A RISK; I ALSO READ ALL OF THE "RISKS" ON YOUR WEBSITE PRIOR TO HAVING THIS PROCEDURE DONE AND THE WORST POSSIBLE SIDE EFFECT I COULD FIND WAS "SYMPTOMS DURING OR IMMEDIATELY AFTER THE PROCEDURE MAY INCLUDE MILD TO MODERATE CRAMPING, NAUSEA/VOMITING, DIZZINESS/LIGHT-HEADEDNESS, AND BLEEDING/SPOTTING." AFTER GOOGLING THIS ISSUE I SEE THAT I AM NOT ALONE, NOT BY A LONG SHOT. MANY WOMEN ARE REPORTING VERY SIMILAR PROBLEMS. I WISH THAT SOMEONE HAD FULLY INFORMED ME OF THE RISKS, AS I WOULD HAVE OPTED FOR A TRADITIONAL TUBAL LIGATION. NOW I FIND MYSELF TRYING TO HAVE THIS "FIXED" WITH (B)(6), NO SICK LEAVE AND TWO KIDS TO TAKE CARE OF. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016823	ESSURE STERILIZATION	7/21/2010	7/29/2010

Event Information:

Event Date (B3): 7/8/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE COIL
Model # (E4):
Catalog # (E4):
Lot #(E4): 50502885

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING PLACEMENT OF ESSURE COIL, ACCESS SHEATH WAS DISCOVERED TO HAVE BEEN DAMAGED DURING THE PROCEDURE, LEAVING A 0.5 CM FRAGMENT LODGED IN THE SEAL AND A 1 CM FRAGMENT REMAINED IN THE UTERUS. THE UTERUS WAS FLUSHED WITH NORMAL SALINE ALLOWING THE SHEATH TO FLOAT FREELY, EXITING THE BODY CAVITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00039	CONCEPTUS, INC.	7/21/2010	7/30/2010

Event Information:

Event Date (B3): 5/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 5/28/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT HAD THE ESSURE MICRO-INSERTS PLACED IN (B)(6) 2010. SHE PRESENTED TO HER PHYSICIAN COMPLAINING OF PELVIC PAIN AND REQUESTED REMOVAL OF THE ESSURE MICRO-INSERTS. THE PHYSICIAN REMOVED THE MICRO-INSERTS LAPAROSCOPICALLY; THE MICRO-INSERTS WERE IN THE FALLOPIAN TUBES AND APPEARED NORMAL; NO PERFORATION OBSERVED. THE PHYSICIAN NOTED THAT THE MICRO-INSERTS CAME OUT VERY EASILY. THE PT'S PAIN RESOLVED FOLLOWING REMOVAL OF THE MICRO-INSERTS. THE PHYSICIAN WAS ASKED IF THE ESSURE MICRO-INSERTS WERE, IN HER OPINION, DIRECTLY RELATED TO THE PT'S PAIN; SHE RESPONDED THAT IT WAS UNCLEAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016829		7/22/2010	7/29/2010

Event Information:

Event Date (B3): 7/9/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 725763

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) STATED THAT DEVICE WOULDN'T RELEASE COIL - NEVER IMPLANTED IN PT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5017004	CONCEPTUS INC	7/22/2010	8/11/2010

Event Information:

Event Date (B3): 12/29/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL STERILIZATION COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/29/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED ON (B)(6) 2009. HSG (B)(6) 2010: BILATERAL TUBAL OCCLUSION. POSITIVE PREGNANCY (B)(6) 2010.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016880	CONCEPTUS	7/26/2010	8/5/2010

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1):
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/5/2005
Explant Date (E7): 7/1/2010
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/1/2010

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(6) 2005. I HAD THE HSG PERFORMED IN (B)(6) 2005, WHICH SHOWED THAT MY TUBES WERE TOTALLY BLOCKED. IN (B)(6) 2005, IT WAS DETERMINED THAT I WAS PREGNANT. DURING THE PREGNANCY, I HAD PAIN IN MY LOWER RIGHT SIDE CONTINUOUSLY. I STRESSED THE WHOLE PREGNANCY THAT SOMETHING WOULD BE WRONG WITH THE BABY. EVERYTHING TURNED OUT FINE. IMMEDIATELY AFTER DELIVERY, I CONTINUED TO HAVE THE LOWER RIGHT BACK PAIN. I DID PHYSICAL THERAPY BUT THE PAIN RETURNED. I HAVE LIVED WITH THE PAIN FOR 4 YRS. IN (B)(6) 2010, I HAD EXTREME LOWER RIGHT ABDOMINAL PAIN. IT WAS DECIDED TO GO IN AND REMOVE THE ESSURE DEVICES. ON (B)(6) 2010, THE SURGERY WAS PERFORMED LAPAROSCOPICALLY. THE LEFT ESSURE WAS IN PLACE AND LEFT THERE. THE RIGHT ESSURE WAS LOCATED ON THE OUTSIDE OF MY UTERUS AND REMOVED. THE BACK PAIN WAS IMMEDIATELY RELIEVED. DATES OF USE: (B)(6) 2005 - 07(B)(6) 2010. DIAGNOSIS OR REASON FOR USE: TUBAL LIGATION. EVENT ABATED AFTER USE: YES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00041	CONCEPTUS, INC.	7/28/2010	8/4/2010

Event Information:

Event Date (B3): 4/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/29/2010
Explant Date (E7): 6/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT PRESENTED TO HER PHYSICIAN WITH HEAVY BLEEDING AND RIGHT LOWER QUADRANT PAIN 1 WEEK FOLLOWING THE ESSURE PROCEDURE. THE PHYSICIAN TREATED HER WITH ADVIL AND ANTIBIOTICS. THE PT'S PAIN AND BLEEDING CONTINUED FOR ANOTHER 3 WEEKS AND, EVENTUALLY, SHE WAS UNABLE TO WORK WITHOUT PAIN MEDICATION. AN HSG WAS PERFORMED ON THE PT; THIS SHOWED THE LEFT ESSURE MICRO-INSERT IN GOOD POSITION WITH TUBAL OCCLUSION. THERE WAS NO OCCLUSION ON THE RIGHT AND THE PHYSICIAN SAID, THE MICRO-INSERT APPEARED TO BE BENT BACK ON ITSELF LIKE A HAIRPIN. THE PHYSICIAN PERFORMED A HYSTEROSCOPY WHERE HE FOUND ONE END OF THE RIGHT MICRO-INSERT PROTRUDING THROUGH THE TUBAL OSTIUM AND THE OTHER END PROTRUDING THROUGH A NEARBY "FALSE OSTIUM" IN THE ENDOMETRIUM. THE PHYSICIAN REPORTED THAT HE REMOVED THE MICRO-INSERT EASILY AND THEN CAUTERIZED THE RIGHT TUBE THROUGH THE LAPAROSCOPE. EIGHT WEEKS FOLLOWING THE ESSURE MICRO-INSERT REMOVAL, THE PT REPORTED TO HER PHYSICIAN THAT SHE IS PAIN FREE AND ONLY COMPLAINED OF WEAKNESS AND FATIGUE. THE PHYSICIAN STATED THAT HE BELIEVES THE ESSURE MICRO-INSERT WAS RESPONSIBLE FOR THE PT'S PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00042	CONCEPTUS, INC.	7/28/2010	8/4/2010

Event Information:

Event Date (B3): 6/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED TO CONCEPTUS ON (B)(6)2009 THAT HER PT WAS EXPERIENCING GENERALIZED ITCHING AND FELT IT MIGHT BE RELATED TO THE ESSURE MICRO-INSERTS IMPLANTED IN THE PT 1-2 MONTHS PRIOR. A NICKEL ALLERGY WAS BEING CONSIDERED AND DEVICE REMOVAL WAS POSSIBLE. IT WAS REPORTED IN (B)(6) 2009 THAT A NICKEL ALLERGY HAD BEEN RULED OUT AND THERE WERE NO PLANS TO REMOVE THE ESSURE MICRO-INSERTS. ON (B)(6)2010, IT WAS REPORTED THAT THE PT HAD UNDERGONE A SALPINGECTOMY AND IT WAS NOTICED THAT A MICRO-INSERT HAD PERFORATED THE CORNUA REGION. IT WAS ALSO REPORTED THAT THE PT'S SYMPTOMS OF PAIN AND DISCOMFORT RESOLVED FOLLOWING REMOVAL OF THE ESSURE MICRO-INSERT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016907	CONCEPTUS INCORPORATED	7/28/2010	8/6/2010

Event Information:

Event Date (B3): 7/15/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BITH CONTROL SYSTEM
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 740658

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING ESSURE STERILIZATION PROCEDURE, MD WAS UNABLE TO RELEASE COIL INTO RIGHT OSTIUM. ESSURE DEVICE AND COIL WERE REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00040	CONCEPTUS, INC.	7/28/2010	4/6/2011

Event Information:

Event Date (B3): 6/23/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT A PATIENT PRESENTED WITH AN ECTOPIC PREGNANCY. PATIENT HAD UNDERGONE THE ESSURE PLACEMENT PROCEDURE (DATE UNKNOWN). THE PATIENT WAS TREATED FOR THE ECTOPIC PREGNANCY AND WAS DOING FINE FOLLOWING TREATMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5016944	CONCEPTUS	8/3/2010	8/9/2010

Event Information:

Event Date (B3): 7/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): MIRENA
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/21/2010
Explant Date (E7): 8/2/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED ON (B)(6) 2010. F/U (B)(6) 2010. PAIN STARTED ON (B)(6) 2010. PAIN STARTED ON (B)(6) 2010. SENT FOR ULTRASOUND, CAT SCAN AND XRAYS. DEVICE LOST IN PELVIS. REMOVAL ON (B)(6) 2010.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00043	CONCEPTUS, INC.	8/6/2010	8/16/2010

Event Information:

Event Date (B3): 7/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 713457

Single Use: Y
Implant Date (E6): 7/2/2010
Explant Date (E7): 7/9/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT REPORTED PAIN TO HER PHYSICIAN 4 DAYS FOLLOWING PLACEMENT OF ESSURE MICRO-INSERTS. AN ULTRASOUND SHOWED THAT THE MICRO-INSERT WAS NOT IN THE PT FALLOPIAN TUBE. A DIAGNOSTIC LAPAROSCOPY WAS PERFORMED AND IT WAS OBSERVED THAT THE MICRO-INSERT HAD PERFORATED THE CORNUA ON THE SIDE WHERE THE PT WAS EXPERIENCING PAIN; GRASPERS WERE USED TO REMOVE THE MICRO-INSERT. NO MICRO-INSERT WAS OBSERVED ON THE OPPOSITE SIDE AND NO ATTEMPT AT REMOVAL WAS UNDERTAKEN. FOLLOWING REMOVAL OF THE MICRO-INSERT, THE PT¿S PAIN RESOLVED. THE PHYSICIAN BELIEVES THAT THE ESSURE MICRO-INSERT WAS DIRECTLY RELATED TO THE PT¿S PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5017045		8/8/2010	8/17/2010

Event Information:

Event Date (B3): 10/23/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/23/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2009, I GOT THE ESSURE DEVICE PLACED IN MY OB/GYN OFFICE. AFTER THE PLACEMENT, I EXPERIENCED LOWER ABDOMINAL PAIN, CRAMPING AND BLEEDING. I WAS TOLD THAT THIS WOULD BE TEMPORARY AND TO NOT WORRY. AFTER A MONTH PASSED, I STARTED TO HAVE TERRIBLE HEADACHES, MONTH LONG MENSTRUAL CYCLES, HIVES AND PAIN IN BOTH AREAS WHERE THE DEVICE WAS PLACED. I WAS NOT TESTED FOR NICKEL ALLERGY BEFORE THE PROCEDURE. NOW I CAN BARELY GET OUT OF BED SOME DAYS DUE TO THE PAIN. I AM CURRENTLY BEING TREATED FOR AN OVARIAN CYST THAT HAS GROWN IN MY OVARY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	8/9/2010	8/18/2010

Event Information:

Event Date (B3): 8/5/2010 **Report Date (B4): 8/9/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 20222096

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE ONLY PARTIALLY DEPLOYED. ANOTHER PRODUCT WAS USED TO COMPLETE PROCEDURE.
==========
HEALTH PROFESSIONAL'S IMPRESSION
==========
DEVICE FAILED TO DEPLOY PROPERLY.
==========
MANUFACTURER RESPONSE FOR PERMANENT BIRTH CONTROL, ESSURE
==========
LEFT A MESSAGE AND EXPECT TO RETURN PRODUCT FOR EVALUATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5017095	ESSURE	8/11/2010	8/19/2010

Event Information:

Event Date (B3): 8/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/5/2010
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT PREGNANT AFTER I HAD THE ESSURE PROCEDURE DONE. I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2010, I CONFIRMED MY TUBES WERE BLOCKED WITH THE HSG TEST IN (B)(6) 2010. AND I FOUND OUT I WAS PREGNANT ON (B)(6) 2010.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00044	CONCEPTUS, INC.	8/12/2010	8/31/2010

Event Information:

Event Date (B3): 6/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/16/2010
Explant Date (E7): 6/28/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT COMPLAINED OF BLEEDING TO HER PHYSICIAN FOLLOWING PLACEMENT OF ESSURE MICRO-INSERTS. THE PHYSICIAN PERFORMED AN HYSTEROSALPINGOGRAM (HSG) AND DISCOVERED ONE OF THE MICRO-INSERTS HAD PERFORATED THE FALLOPIAN TUBE; THE MICRO-INSERTS WAS OBSERVED IN THE PERITONEAL CAVITY. THE PHYSICIAN PERFORMED A LAPAROSCOPY AND REMOVED THE MICRO-INSERT; THE PHYSICIAN SAID THE MICRO-INSERT APPEARED INTACT AND SLIGHTLY STRETCHED OUT. THE PHYSICIAN ALSO REMOVED THE SECOND MICRO-INSERT, LOCATED IN THE MYOMETRIUM OF THE UTERINE CAVITY, HYSTEROSCOPICALLY. THE PHYSICIAN STATED THAT THE PATIENT'S SYMPTOMS RESOLVED FOLLOWING REMOVAL OF THE MICRO-INSERTS. THE PHYSICIAN BELIEVES THE PATIENT'S BLEEDING WAS CAUSED BY IRRITATION FROM THE MICRO-INSERT IN THE MYOMETRIUM OF THE UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00045	CONCEPTUS, INC.	8/12/2010	2/7/2011

Event Information:

Event Date (B3): 4/22/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628064

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2010
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

A REPORT OF DETACHMENT DIFFICULTY WAS RECEIVED. IT WAS REPORTED THAT AN ESSURE MICRO-INSERT WOULD NOT RELEASE FROM THE DELIVERY CATHETER DURING A PLACEMENT PROCEDURE. EVENTUALLY THE CATHETER BROKE AWAY FROM THE MICRO-INSERT WITH PART OF THE CATHETER STILL ATTACHED TO THE MICRO-INSERT THAT WAS LOCATED DEEP IN THE PT'S FALLOPIAN TUBE. A WEEK AFTER THIS INITIAL ESSURE PLACEMENT PROCEDURE THE PHYSICIAN PERFORMED A LAPAROSCOPY AND HYSTEROSCOPY AND REMOVED THE PORTION OF THE CATHETER THAT REMAINED ATTACHED TO THE MICRO-INSERT. THE PHYSICIAN LEFT THE MICRO-INSERT IN PLACE IN THE PT'S FALLOPIAN TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5017166	CONCEPTUS INC.	8/18/2010	8/31/2010

Event Information:

Event Date (B3): 8/11/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): M418ESS3051Q
Catalog # (E4):
Lot #(E4): 689940

Single Use:
Implant Date (E6): 8/11/2010
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

L ESSURE INSERTED WITHOUT COMPLICATION. R ESSURE DID NOT RELEASE COMPLETELY AND PARTIALLY PULLED FROM THE R FALLOPIAN TUBE, REMNANT OF R ESSURE PROTRUDING FROM R FALLOPIAN TUBE INTO THE UTERINE CAVITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5017245	CONCEPTUS INC	8/26/2010	9/3/2010

Event Information:

Event Date (B3): 8/16/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 689940

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING A TUBAL PROCEDURE IN CLINIC, ESSURE WIRE STRETCHED IN LENGTH AND NEEDED TO BE REMOVED. PROCEDURE ABORTED WITH ONLY ONE TUBE CLOSED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00046	CONCEPTUS, INC.	9/1/2010	9/10/2010

Event Information:

Event Date (B3): 6/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 664666

Single Use: Y
Implant Date (E6): 2/26/2010
Explant Date (E7): 6/22/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT REPORTED THAT IT WAS NECESSARY TO UNDERGO SURGERY TO REMOVE ONE OF HER ESSURE MICRO-INSERTS. THE PATIENT STATED THAT THE ESSURE MICRO-INSERT HAD PERFORATED HER FALLOPIAN TUBE AND WAS OBSERVED IN HER PELVIS ON A 3 MONTH HSG. THE PATIENT DID NOT REPORT ANY SYMPTOMS. IT WAS CONFIRMED WITH THE PATIENT'S PHYSICIAN THAT THE PATIENT DID NOT UNDERGO A LAPAROSCOPY TO REMOVE THE MICRO-INSERT; THE MICRO-INSERT WAS FOUND BROKEN, IN 2 PIECES, IN THE UPPER RIGHT QUADRANT OF HER ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00047	CONCEPTUS, INC.	9/1/2010	9/10/2010

Event Information:

Event Date (B3): 7/23/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/12/2010
Explant Date (E7): 7/23/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PATIENT BEGAN EXPERIENCING PAIN IMMEDIATELY FOLLOWING PLACEMENT OF ESSURE MICRO-INSERTS. THE PATIENT VISITED AN EMERGENCY ROOM SHORTLY FOLLOWING THE ESSURE PROCEDURE WHERE AN ULTRASOUND WAS PERFORMED; THE DEVICE ON THE RIGHT SIDE APPEARED THAT IT WAS NOT IN THE PROPER POSITION; NO TREATMENT WAS GIVEN TO THE PATIENT. THE PATIENT LATER PRESENTED TO THE PHYSICIAN REPORTING PAIN ON HER LEFT SIDE. THE PHYSICIAN DISCUSSED TREATMENT OPTIONS WITH THE PATIENT AND THE PATIENT CHOSE TO HAVE THE MICRO-INSERTS REMOVED. THE MICRO-INSERTS WERE REMOVED LAPAROSCOPICALLY AND A BILATERAL SALPINGECTOMY WAS PERFORMED. NOTHING UNUSUAL WAS NOTED REGARDING THE ESSURE MICRO-INSERTS DURING REMOVAL; BOTH MICRO-INSERTS WERE INTACT AND IN PROPER POSITION WITH NO PERFORATION OBSERVED. THE PATIENT HAS NOT HAD FOLLOW UP WITH HER PHYSICIAN SO, IT IS UNKNOWN IF THE PATIENT'S SYMPTOMS HAVE RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00048	CONCEPTUS, INC.	9/10/2010	9/17/2010

Event Information:

Event Date (B3): 8/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 8/4/2010
Explant Date (E7): 8/11/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT BEGAN EXPERIENCING PAIN IMMEDIATELY FOLLOWING ESSURE MICRO-INSERT PLACEMENT; ONLY 1 MICRO-INSERT WAS PLACED. THE MICRO-INSERT WAS EVENTUALLY REMOVED LAPAROSCOPICALLY; DURING REMOVAL, IT WAS DISCOVERED THAT THE MICRO-INSERT PERFORATED THAT PT'S FALLOPIAN TUBE AND THE MICRO-INSERT WAS FOUND IN THE OMENTUM. THE PHYSICIAN HAS NOT COMMUNICATED WITH THE PT FOLLOWING REMOVAL, SO IT IS UNK IF THE PT'S SYMPTOMS HAVE RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00049	CONCEPTUS, INC.	9/10/2010	1/31/2011

Event Information:

Event Date (B3): 6/2/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50500535

Single Use: Y
Implant Date (E6): 6/2/2010
Explant Date (E7): 1/1/2010
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING AN ESSURE MICRO-INSERT PLACEMENT PROCEDURE, AN ESSURE MICRO-INSERT BROKE; PART OF THE MICRO-INSERT WAS REMOVED WHILE SOME PIECES WERE LEFT IN THE PT'S FALLOPIAN TUBE. THE PHYSICIAN PERFORMED A HYSTEROSCOPY SEVERAL WEEKS LATER TO REMOVE THE PIECES OF THE ESSURE MICRO-INSERT FROM THE PT'S FALLOPIAN TUBE. THE PT WAS STABLE FOLLOWING THE PROCEDURE TO REMOVE THE BROKEN ESSURE MICRO-INSERT.

Manufacturer Narrative (H10):

THE RETURNED PRODUCT WAS RECEIVED AND ANALYZED, 1 DELIVERY SYSTEM WITH 1 MICRO INSERT ATTACHED WAS INVESTIGATED. THE RETURNED PRODUCT WAS INVESTIGATED TO VERIFY THE INCIDENT REPORT AND DETERMINE IF IT HAD ANY DAMAGE, DEFORMATION OR OUT OF SPEC CONDITIONS.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00051	CONCEPTUS, INC.	9/17/2010	9/27/2010

Event Information:

Event Date (B3): 8/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7): 8/18/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT BEGAN EXPERIENCING RIGHT LOWER QUADRANT ABDOMINAL PAIN SHORTLY FOLLOWING THE ESSURE PROCEDURE. THE PHYSICIAN REMOVED THE ESSURE MICRO-INSERTS VIA LAPAROSCOPY; ONE MICRO INSERT HAD PERFORATED THROUGH THE UTERINE WALL IN THE CORNUA REGION. THE PHYSICIAN HAS NOT HAD F/U WITH THE PT SO IT IS UNK IF THE PT'S SYMPTOMS HAVE RESOLVED FOLLOWING REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5017488	CONCEPTUS INC., USA	9/17/2010	9/28/2010

Event Information:

Event Date (B3): 9/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 654832

Single Use:
Implant Date (E6): 9/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE APPROXIMATELY (B)(6) 2009. THREE MONTHS AFTER THE PROCEDURE, I HAD A HSG TEST TO MAKE SURE THE FALLOPIAN TUBES WERE BLOCKED BY THE COILS AND WAS TOLD THEY WERE. SINCE THAT TIME I HAVE BEEN HAVING VAGINAL BLEEDING ABOUT 3 WEEKS OUT OF THE MONTH AND FREQUENT VAGINAL INFECTIONS. I HAVE HAD ABDOMINAL PAIN THAT HAS GRADUALLY INCREASED AS TIME WENT ON. I HAD AN ABDOMINAL CAT SCAN THAT SHOWED THAT ONE OF MY ESSURE STENTS WAS PROTRUDING OUT OF MY UTERINE WALL. I AM SCHEDULED FOR AN OPEN COMPLETE ABDOMINAL HYSTERECTOMY (B)(6)2010. I TALKED TO THE DOCTOR ABOUT THE POSSIBLE OTHER LESS INVASIVE OPTIONS, AND HE FELT THIS WAS THE MOST DEFINITE ANSWER TO MY PROBLEMS. I AM A REGISTERED NURSE AND HAD THE ESSURE PROCEDURE DONE SO, I DID NOT HAVE TO HAVE SURGERY-TUBAL LIGATION-. I DID NOT WANT TO BE OUT OF WORK 2-3 WEEKS FOR A TUBAL. NOW DUE TO MY HAVING PREVIOUS ABDOMINAL SURGERIES, MY HYSTERECTOMY HAS TO BE DONE OPEN AND I WILL BE OUT OF WORK 6-8 WEEKS. SINCE I FOUND ALL THIS OUT, I HAVE BEEN DOING SOME RESEARCH ONLINE TO SEE IF OTHER WOMEN HAVE HAD PROBLEMS WITH ESSURE AND THERE ARE NUMEROUS ISSUES. SINCE I AM AN RN, I WANT THIS PRODUCT TO BE INVESTIGATED SO, OTHER WOMEN DO NOT HAVE TO GO THROUGH WHAT I HAVE BEEN THROUGH IN THE LAST YEAR. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00050	CONCEPTUS, INC.	9/17/2010	4/6/2011

Event Information:

Event Date (B3): 8/22/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT REPORTED AN ECTOPIC PREGNANCY 4 YEARS FOLLOWING THE ESSURE PROCEDURE. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00052	CONCEPTUS, INC.	9/17/2010	4/6/2011

Event Information:

Event Date (B3): 7/12/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 7/12/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PATIENT WAS EXPERIENCING INCREASED ASTHMA SYMPTOMS 1 YEAR POST ESSURE PROCEDURE. THE PATIENT HAD A NICKEL ALLERGY TEST PERFORMED AND A NICKEL ALLERGY WAS CONFIRMED. THE PHYSICIAN REMOVED THE ESSURE MICRO-INSERTS AND PERFORMED A HYSTERECTOMY ON THE PT. THE PT'S SYMPTOMS RESOLVED FOLLOWING ESSURE MICRO-INSERT REMOVAL AND SHE IS DOING WELL.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. IFU WARNING: PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY PRIOR

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00053	CONCEPTUS, INC.	9/22/2010	10/1/2010

Event Information:

Event Date (B3): 7/23/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 6/16/2010
Explant Date (E7): 7/23/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT REPORTED THAT SHE HAD BEEN EXPERIENCING SEVERE PAIN IN HER RIGHT ABDOMINAL AREA AND BLEEDING FOLLOWING THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE. THE PATIENT STATED THAT THE PHYSICIAN HAD SOME DIFFICULTY DURING THE ESSURE PLACEMENT PROCEDURE, AND IT RESULTED IN 2 MICRO-INSERTS BEING PLACED INTO THE RIGHT FALLOPIAN TUBE. THE PATENT REPORTED THAT IMAGING TESTS FOLLOWING THE ESSURE PROCEDURE REVEALED THAT ONE OF THE MICRO-INSERTS HAD PERFORATED HER RIGHT FALLOPIAN. THE MICRO-INSERTS WERE REMOVED LAPAROSCOPICALLY AND A SALPINGECTOMY WAS PERFORMED. THE PHYSICIAN THAT REMOVED THE MICRO-INSERTS STATED THAT THE MICRO-INSERTS ALL WERE IN GOOD POSITION WITHIN THE TUBES WITH NOTHING UNUSUAL NOTED; NO PERFORATION WAS OBSERVED. THE PHYSICIAN ALSO STATED THAT HE FOUND NO EVIDENCE THAT PATIENT'S SYMPTOMS WERE DUE TO THE ESSURE MICRO-INSERTS. THE PHYSICIAN REPORTED THAT THE PATIENT IS NO LONGER EXPERIENCING SEVERE PAIN FOLLOWING REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	9/23/2010	9/30/2010

Event Information:

Event Date (B3): 7/20/2010 **Report Date (B4): 9/23/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): *
Catalog # (E4): ESS205 CATALOG NUMBER
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE PROCEDURE THE DOCTOR INSERTED THE ESSURE DEVICE INTO THE VAGINAL CANAL AND THE DEVICE BROKE AT THE TIP, THE DOCTOR TRIED A SECOND ONE AND IT BROKE AS WELL.
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HEALTH PROFESSIONAL'S IMPRESSION
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THE DOCTOR FELT THAT IT WAS A POORLY MADE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5017754	CONCEPTUS, INC.	10/1/2010	11/9/2010

Event Information:

Event Date (B3): 6/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE METAL MICRO-INSERTS
Model # (E4):
Catalog # (E4):
Lot #(E4): 727086

Single Use:
Implant Date (E6): 6/2/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL SYSTEM PROCEDURE DONE (B)(6) 2010. THE METAL MICRO-INSERT COIL WAS PLACED IN THE RIGHT FALLOPIAN TUBE WITH NO DIFFICULTIES. THE COIL PLACED IN THE LEFT FALLOPIAN TUBE WAS INCORRECTLY PLACED TOO FAR INTO TUBE AND ANOTHER COIL WAS THEN INSERTED. PRODUCT USE ERROR. THIS ERROR WAS NOT KNOWN UNTIL I RECEIVED A COPY OF ALL MY RECORDS WITH THIS PHYSICIAN. AT 3 MONTHS POST PROCEDURE, I HAD THE HSG DONE TO CONFIRM PROPER PLACEMENT AND OCCLUSION OF TUBES. THE HSG CONFIRMED CORRECT PLACEMENT OF RIGHT FALLOPIAN TUBE COIL, HOWEVER, BOTH ESSURE COILS PLACED ON LEFT WERE VISUALIZED OUT OF THE FALLOPIAN TUBE INTO THE PERITONEUM. ADVERSE EVENT. I NOW HAVE TO HAVE SURGERY TO REMOVE THOSE COILS. DATES OF USE: (B)(6) 2010 TO PRESENT. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5017833	CONCEPTUS INC.	10/18/2010	11/1/2010

Event Information:

Event Date (B3): 9/23/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): HYSTEROSCOPY ESSURE STERILIZATION
Model # (E4):
Catalog # (E4):
Lot #(E4): 753646

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PT BROUGHT TO OPERATING ROOM # 1 FOR HYSTEROSCOPY ESSURE STERILIZATION. MD WAS PERFORMING THE SURGERY WHEN SHE ATTEMPTED TO IMPLANT THE ESSURE DEVICE AND IT WOULD NOT DISCHARGE PROPERLY. SHE REMOVED THE DEVICE AND IMPLANTED A SECOND DEVICE SUCCESSFULLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5018525	CONCEPTUS	10/28/2010	12/16/2010

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE COILS
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PURPOSE OF THIS LETTER IS TO REPORT ABOUT NEGATIVE EFFECTS OF A PARTICULAR MEDICAL DEVICE THAT THE FDA HAS APPROVED. THE DEVICE MENTIONED EARLIER IS THE ESSURE COILS THAT ARE MFG BY CONCEPTUS. THESE DEVICES HAVE CAUSED SO MANY WOMEN HEALTH PROBLEMS TO THE POINT WHERE THEY NEEDED TO GET HYSTERECTOMIES. I PERSONALLY HAD THIS PROCEDURE AND HAD THE COILS IN ME FOR ONE YR. THAT WAS LITERALLY A YR OF GREAT PAIN AND SUFFERING. I WAS VERY LUCKY IN BEING ABLE TO FIND A PHYSICIAN WHO WAS ABLE TO REMOVE THE COILS WITHOUT HAVING TO DO A HYSTERECTOMY. ASIDE FROM MY SELF, I PERSONALLY KNOW OF 5 OTHER WOMEN WHO HAVE HAD THE SAME PROBLEMS WITH THE ESSURE COILS. TWO OF THEM HAD TO HAVE HYSTERECTOMIES AND THE OTHER THREE ARE AWAITING TO HAVE SURGERY WITH MY DOCTOR. I HAVE DONE A LOT OF RESEARCH AND HAVE CONTACTED WOMEN ALL OVER THE COUNTRY WHO ARE SUFFERING FROM THIS DEVICE. I CAN'T UNDERSTAND WHY THIS DEVICE IS STILL ON THE MARKET. I WOULD THINK THAT A FEDERAL ORGANIZATION SUCH AS THE FDA WOULD BE MORE CAREFUL AS TO WHAT THEY APPROVE IS SAFE. I ASK THAT YOU PLEASE INVESTIGATE THIS MATTER. IT IS NOT FAIR THAT WOMEN HAVE TO GO THROUGH SUCH SUFFERING AND LOSE A PART OF THEIR BODY. THIS DEVICE IS SUPPOSED TO MAKE WOMEN'S LIVES EASIER BY NOT WORRYING ABOUT CONTRACEPTION, BUT WHAT IT DOES IS CAUSE PAIN AND MANY HEALTH PROBLEMS. THIS CASE MUST BE INVESTIGATED. I AM VERY SURE THAT IT'S ONLY A MATTER OF TIME BEFORE SOME ONE WILL SUFFER FATALLY FROM THIS PRODUCT. THANK YOU, (B)(6).

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	11/1/2010	11/17/2010

Event Information:

Event Date (B3): 10/26/2010 **Report Date (B4): 11/1/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 50512938

Single Use:
Implant Date (E6): 10/26/2010
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING SURGICAL IMPLANT ATTEMPT ON RIGHT FALLOPIAN TUBE, PT BEGAN HAVING TUBAL SPASMS AND THE SURGEON ASKED THE ANESTHESIOLOGIST TO ADMINISTER 30MG TORADOL. GUIDEWIRE AND COIL WERE INSERTED INTO TUBE AND WHEN DEVICE WAS DEPLOYED, THE DOCTOR FELT THE TIP OF THE ESSURE BROKE OFF IN RIGHT FALLOPIAN TUBE OF PT. AT THE SURGEON'S REQUEST THE SALES REP WAS CALLED FOR ADVICE. SURGEON THEN ADMINISTERED 30MG ADDITIONAL TORADOL AND THEN WENT TO THE OTHER TUBE (LEFT). SURGEON COULD NOT GET ESSURE IMPLANT INSERTED DUE TO SPASM OF PT. THEN SURGEON TRIED TO REMOVE THE TIP AND COIL (ESSURE IMPLANT) FROM RIGHT TUBE, SHE FELT THE TIP WAS REMOVED BUT THE COIL BROKE AND WAS PARTIALLY LEFT IN TUBE. CASE ABORTED.
*THE GUIDEWIRE WHICH NORMALLY SEPARATES FROM THE COIL DID NOT DO SO AND AFTER SOME EFFORT IT WAS REMOVED. THE PATIENT WILL RETURN TO THE MD'S OFFICE FOR EVALUATION AND PROBABLY SCHEDULE AGAIN FOR INSERTION OF ANOTHER ESSURE DEVICE IN THE LEFT FALLOPIAN TUBE AND POSSIBLY THE RIGHT FALLOPIAN TUBE IF THE COILS IN THE RIGHT DID NOT CAUSE THE INTENDED BLOCKAGE.
PICTURES OF USED/PULLED OUT DEVICE AVAILABLE ALONG WITH PICTURES OF A NEW DEVICE/OUT OF THE PACKAGE.
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HEALTH PROFESSIONAL'S IMPRESSION
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This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

THE SURGEON EXPLAINED THAT THE GUIDE WHICH NORMALLY SEPARATES FROM THE COIL DID NOT DO SO AND AFTER SOME EFFORT IT WAS REMOVED; THEREFORE, NO UNINTENDED PART WAS RETAINED.
COMMON TO HAVE FALLOPIAN TUBE SPASM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00057	CONCEPTUS, INC.	11/3/2010	11/15/2010

Event Information:

Event Date (B3): 10/7/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 748471

Single Use: Y
Implant Date (E6): 9/27/2010
Explant Date (E7): 10/7/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PT HAD THE ESSURE PLACEMENT PROCEDURE ON (B)(6) 2010, AND LATER PRESENTED WITH PAIN ON HER LEFT SIDE ON (B)(6) 2010. AN ULTRASOUND AND CT SCAN WERE PERFORMED; IT WAS DISCOVERED THAT THE MICRO-INSERT ON THE PT'S RIGHT SIDE HAD EXPELLED AND WAS IN THE UTERINE CAVITY. THE PHYSICIAN PERFORMED A HYSTEROSCOPY TO REMOVE THE ESSURE MICRO-INSERT IN THE UTERINE CAVITY AND PLACED ANOTHER MICRO-INSERT ON THE RIGHT SIDE. THE PT'S PAIN RESOLVED FOLLOWING REMOVAL OF THE MICRO-INSERT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00055	CONCEPTUS, INC.	11/3/2010	11/16/2010

Event Information:

Event Date (B3): 9/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 8/27/2010
Explant Date (E7): 9/15/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT BEGAN COMPLAINING OF BACK AND LEG PAIN WITHIN 4 DAYS OF AN ESSURE PLACEMENT PROCEDURE. AN ULTRASOUND WAS PERFORMED AND NOTHING UNUSUAL NOTED. THE PHYSICIAN DEEMED IT NECESSARY TO REMOVE THE ESSURE MICRO-INSERTS; THE PT'S PAIN RESOLVED FOLLOWING REMOVAL.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	11/3/2010	11/17/2010

Event Information:

Event Date (B3): 10/28/2010 **Report Date (B4): 11/3/2010** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): STERILIZATION DEVICE
Model # (E4): *
Catalog # (E4): LIKE SAMPLE EFS305
Lot #(E4): LIKE SAMPLE 725762

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WAS PASSED THROUGH THE HYSTEROSCOPE AND BENT REQUIRING A SECOND ESSURE DEVICE TO BE USED. THE SECOND ESSURE DEVICE WAS RELEASED INTO THE LEFT TUBAL OSTIUM WITHOUT COMPLICATION. IN ADDITION, A MIDLINE UTERINE FUNDAL PERFORATION WAS BELIEVED TO HAVE OCCURRED UPON INITIAL INSERTION OF THE HYSTEROSCOPE. THE PROCEDURE WAS COMPLETED AND THE PATIENT WAS TRANSFERRED TO THE RECOVERY ROOM IN STABLE CONDITION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00056	CONCEPTUS, INC.	11/3/2010	12/1/2010

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7): 1/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PATIENT REPORTED THAT SHE HAD THE ESSURE PROCEDURE PERFORMED IN 2005; AN HSG WAS PERFORMED AND THE PATIENT STATED THAT IT SHOWED BILATERAL TUBAL OCCLUSION. THE PATIENT STATED THAT SHE BECAME PREGNANT IN 2005, AND DURING THE PREGNANCY DEVELOPED, CONSTANT PAIN ON HER LOWER RIGHT SIDE. THE PATIENT DELIVERED AND, ACCORDING TO THE PATIENT, EVERYTHING WAS NORMAL. THE PATIENT SAID SHE CONTINUED TO HAVE LOWER RIGHT ABDOMINAL AND BACK PAIN FOR 4 YEARS AND IN 2010, IT WAS DECIDED TO REMOVE THE ESSURE MICRO-INSERTS LAPAROSCOPICALLY; THE LEFT MICRO-INSERT WAS FOUND IN PROPER POSITION AND LEFT IN PLACE; THE MICRO-INSERT ON THE RIGHT SIDE WAS FOUND OUTSIDE OF THE UTERUS AND REMOVED. THE PATIENT REPORTED THAT HER PAIN IMMEDIATELY RESOLVED FOLLOWING REMOVAL OF THE MICRO-INSERT. THIS REPORT RECEIVED THROUGH THE FDA MAUDE ADVERSE EVENT REPORTING SYSTEM; (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00054	CONCEPTUS, INC.	11/3/2010	4/6/2011

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/7/2008
Explant Date (E7): 9/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED SHE FOUND IT NECESSARY TO REMOVE A PATIENT'S ESSURE MICRO-INSERTS DUE TO CONFIRMATION OF NICKEL ALLERGY AND SEVERE PAIN THE PT WAS EXPERIENCING; 1 MICRO-INSERT WAS REMOVED ON (B)(6) 2010 AND THE SECOND MICRO-INSERT WAS REMOVED ON (B)(6) 2010. THE SECOND MICRO-INSERT HAD PERFORATED THE FALLOPIAN TUBE AND WAS FOUND IN THE ROUND LIGAMENT. THE PHYSICIAN STATED THE PT TOLD HER SHE WAS NEVER ASKED IF SHE HAD A NICKEL ALLERGY PRIOR TO PLACEMENT OF THE ESSURE MICRO-INSERTS. THE PHYSICIAN REPORTED THAT THE PATIENT'S PAIN HAS RESOLVED FOLLOWING REMOVAL.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PATIENT'S WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PATIENT'S WITH SUSPECTED H

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5018227		11/12/2010	11/26/2010

Event Information:

Event Date (B3): 11/6/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE TUBAL AND I AM NOW PREGNANT AND I AM ALSO WORRIED ABOUT THE COILS HARMING MY UNBORN CHILD OR PLACENTA AT ANY POINT. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	11/18/2010	12/2/2010

Event Information:

Event Date (B3): 6/11/2010 **Report Date (B4): 11/18/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): CONTRACEPTIVE, TUBAL, OCCLUSION
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 50512909

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING STERILIZATION WITH ESSURE DEVICE, THE FIRST ESSURE MISFIRED. THE NEXT 3 ESSURE DEVICES BENT AND WERE NOT ABLE TO BE USED. ALL HAD THE SAME LOT NUMBER. THE 4TH ESSURE SET FUNCTIONED AND SURGERY WAS COMPLETED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00058	CONCEPTUS, INC.	11/18/2010	12/7/2010

Event Information:

Event Date (B3): 10/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/1/2008
Explant Date (E7): 10/19/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT PRESENTED TO HER PHYSICIAN WITH PELVIC PAIN 1 YEAR POST ESSURE PLACEMENT PROCEDURE. THE PHYSICIAN PERFORMED A BILATERAL SALPINGECTOMY AND REMOVED THE ESSURE MICRO-INSERTS. THE PHYSICIAN REPORTED THAT THE DEVICES APPEARED TO BE IN THE PROPER LOCATION AND WERE INTACT. THE PHYSICIAN ATTRIBUTED THE PT'S PAIN TO THE ESSURE MICRO-INSERTS. THE PHYSICIAN HAS NOT HAD F/U WITH PT SO IT IS UNK IF THE PT'S PAIN RESOLVED FOLLOWING ESSURE MICRO-INSERT REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00059	CONCEPTUS, INC.	11/18/2010	3/24/2011

Event Information:

Event Date (B3): 10/20/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 761438

Single Use: Y
Implant Date (E6): 10/20/2010
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3): 11/5/2010

Event Description (B5):

A PHYSICIAN REPORTED THAT AN ESSURE MICRO-INSERT FAILED TO DETACH FROM THE HANDLE AFTER COMPLETION OF ALL PLACEMENT STEPS. AFTER ATTEMPTING TROUBLESHOOTING TECHNIQUES TO NO AVAIL THE PHYSICIAN FOUND IT NECESSARY TO TAKE THE PT TO A HOSP OPERATING ROOM WHERE THE PT WAS ADMINISTERED GENERAL ANESTHESIA. THE MICRO-INSERT DETACHED FROM THE HANDLE AFTER PT WAS GIVEN ANESTHESIA. IT WAS REPORTED THE PT WAS DOING WELL FOLLOWING THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	11/19/2010	12/2/2010

Event Information:

Event Date (B3): **Report Date (B4): 11/19/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): CONTRACEPTIVE DEVICE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 632025

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DOCTOR STATED THAT THE DEVICE WOULD NOT RELEASE THE COIL AS IT WAS SUPPOSED TO DO. THE DEVICE WAS REMOVED FROM THE PATIENT AND A NEW ONE WAS USED WITH NO FURTHER INCIDENT.
==========
HEALTH PROFESSIONAL'S IMPRESSION
==========
MALFUNCTION- WOULD NOT RELEASE COIL
==========
MANUFACTURER RESPONSE FOR CONTRACEPTIVE DEVICE, ESSURE
==========
WILL SEND PACKAGING TO RETURN IT TO COMPANY FOR EVALUATION. WILL SEND NEW PRODUCT FREE OF CHARGE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	11/22/2010	12/15/2010

Event Information:

Event Date (B3): 9/15/2010 **Report Date (B4): 11/22/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): STERILIZATION DEVICE
Model # (E4): *
Catalog # (E4): REF ESS305
Lot #(E4): 752412

Single Use:
Implant Date (E6): 9/15/2010
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE FAILED TO DEPLOY A COIL.
FROM OP REPORT: ATTENTION WAS PLACED TO THE RIGHT FALLOPIAN TUBE. THE ESSURE DEVICE WAS BROUGHT INTO THE FIELD AND PLACED WITHIN THE FALLOPIAN TUBE AND THEN ACTIVATED. AT THE END OF THIS PROCEDURE THERE WERE 3 COILS EXTENDING INTO THE UTERINE CAVITY. ATTENTION WAS THEN TURNED TO THE PATIENT'S LEFT FALLOPIAN TUBE WHERE AGAIN THE ESSURE DEVICE WAS THREADED INTO THE FALLOPIAN TUBE. IT WAS ACTIVATED AND THEN REMOVED. AT THE END OF THIS PROCEDURE THERE WERE 4 COILS EXTENDING INTO THE UTERINE CAVITY. THE REMAINDER OF THE UTERINE CAVITY WAS COMPLETELY NORMAL. THE HYSTEROSCOPE WAS REMOVED. AT THIS POINT THE THERMACHOICE ENDOMETRIAL ABLATION WAND WAS ADVANCED INTO THE UTERINE CAVITY AND D5W WAS INSTILLED INTO THE BALLOON UNTIL A STABLE PRESSURE OF 165 WAS REACHED. THE TREATMENT CYCLE WAS INITIATED AND CONTINUED FOR 8 FULL MINUTES. DURING THE TREATMENT PRESSURE WAS MAINTAINED BETWEEN 130 AND 152. AT THE END OF THE TREATMENT CYCLE AND COOL DOWN THE DEVICE WAS REMOVED. THE HYSTEROSCOPE WAS REINSERTED. THERE WAS A GOOD PALING OF THE ENDOMETRIUM THROUGHOUT ALL QUADRANTS. THE ESSURE COILS WERE PATENT AND UNDISTURBED AND THE UTERINE CAVITY WAS PATENT. AT THIS POINT ALL INSTRUMENTS WERE REMOVED FROM THE PATIENT
==========
HEALTH PROFESSIONAL'S IMPRESSION
==========

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DEVICE FAILED TO DEPLOY COIL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5018988	CONCEPTUS	11/24/2010	1/20/2011

Event Information:

Event Date (B3): 10/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 621809

Single Use:
Implant Date (E6): 10/15/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I HAVE HAD ESSURE PLACED IN TUBES, I HAVE HAD PROBLEMS. I HAVE BEEN TO THE DOCTOR MANY TIMES FOR BLEEDING FOR LONG PERIODS OF TIME WHICH WAS OVER 30 DAYS, ALSO SEVERE STOMACH CRAMPING WITH SHARP SHOOTING PAIN WHICH STILL GOES ON EVERYDAY. I DID NOT EXPERIENCE ANY OF THIS BEFORE I HAD THEM INSERTED. THE PAIN IS IN MY LOWER ABDOMEN AND IT IS VERY SORE IF I PRESS DOWN ON MY ABDOMEN IN THAT AREA. IT GETS WORSE WITH SEXUAL INTERCOURSE. PLEASE DO SOMETHING ABOUT THIS PROCEDURE. I REALLY WISH I CAN AFFORD TO HAVE THEM REMOVED SO I CAN HAVE MY BODY BACK PAIN FREE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00061	CONCEPTUS, INC.	12/1/2010	12/10/2010

Event Information:

Event Date (B3): 10/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 2/15/2010
Explant Date (E7): 10/21/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PATIENT BEGAN EXPERIENCING ABDOMINAL PAIN IMMEDIATELY POST ESSURE MICRO-INSERT PLACEMENT PROCEDURE. AN HSG PERFORMED AT 3 MONTHS POST ESSURE PROCEDURE INDICATED PROPER POSITION OF THE ESSURE MICRO-INSERTS AND BILATERAL OCCLUSION. THE PHYSICIAN STATED THAT THIS PATIENT HAS AN EXTENSIVE AND COMPLICATED MEDICAL HISTORY, INCLUDING PAIN, BUT THE PHYSICIAN BELIEVED THE PATIENT'S "NEW" PAIN WAS DUE TO THE ESSURE MICRO-INSERTS. THE PHYSICIAN PERFORMED A HYSTERECTOMY ON THE PATIENT AND REMOVED THE ESSURE MICRO-INSERTS; THE PHYSICIAN STATED THAT SHE FOUND ONE MICRO-INSERT EMBEDDED IN THE PATIENT'S ENDOMETRIUM AND THE PHYSICIAN BELIEVES THIS WAS RESPONSIBLE FOR PATIENT'S PAIN. THE PATIENT'S SYMPTOMS RESOLVED FOLLOWING ESSURE MICRO-INSERT REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00062	CONCEPTUS, INC.	12/1/2010	12/10/2010

Event Information:

Event Date (B3): 9/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7): 9/17/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PATIENT EXPERIENCED BACK PAIN FOLLOWING THE ESSURE MICRO- INSERT PLACEMENT PROCEDURE. THE PHYSICIAN REMOVED THE ESSURE MICRO-INSERTS DURING A LAPAROSCOPY. ONE MICRO-INSERT WAS FOUND EMBEDDED IN THE ENDOMETRIUM AND THE PHYSICIAN BELIEVES THAT THIS MICRO-INSERT WAS RESPONSIBLE FOR THE PATIENT'S PAIN. THE PATIENT'S PAIN RESOLVED COMPLETELY FOLLOWING MICRO-INSERT REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00064	CONCEPTUS, INC.	12/1/2010	12/10/2010

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 9/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PATIENT WAS EXPERIENCING PAIN 2 YEARS POST ESSURE MICRO-INSERT PLACEMENT PROCEDURE. THE PHYSICIAN PERFORMED A LAPAROSCOPY AND REMOVED ONE MICRO-INSERT; THE PHYSICIAN STATED HE DISCOVERED THE MICRO-INSERT HAD MIGRATED THROUGH THE PATIENT'S MYOMETRIUM DURING THE LAPAROSCOPY. THE PATIENT CONTINUED TO EXPERIENCE PAIN SO THE PHYSICIAN PERFORMED AN ADDITIONAL PROCEDURE TO REMOVE THE SECOND ESSURE MICRO-INSERT AND PERFORMED A HYSTERECTOMY; THE PHYSICIAN DID NOT REPORT ANYTHING UNUSUAL REGARDING PLACEMENT AND APPEARANCE OF THE SECOND MICRO-INSERT DURING REMOVAL. THE PATIENT'S PAIN COMPLETELY RESOLVED FOLLOWING REMOVAL OF THE SECOND MICRO-INSERT; THE PHYSICIAN BELIEVES THAT THE ESSURE MICRO-INSERTS WERE DIRECTLY RELATED TO THE PATIENT'S PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00060	CONCEPTUS, INC.	12/1/2010	4/6/2011

Event Information:

Event Date (B3): 10/22/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 2/26/2010
Explant Date (E7): 10/22/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT PRESENTED TO HER COMPLAINING OF SKIN IRRITATION AND WELTS OVER HER BODY FOLLOWING THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE. A NICKEL ALLERGY TEST WAS PERFORMED ON THE PT AND THE PT WAS CONFIRMED POSITIVE FOR NICKEL ALLERGY. THE PHYSICIAN REMOVED THE ESSURE MICRO-INSERTS AND BELIEVED IT WAS NECESSARY DUE TO THE PATIENT'S NICKEL ALLERGY. PHYSICIAN IS NOT AVAILABLE FOR FOLLOW UP INQUIRIES, SO IT IS UNK AT THIS TIME IF THE PATIENT'S SYMPTOMS HAVE RESOLVED FOLLOWING ESSURE MICRO-INSERT REMOVAL.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PATIENTS WITH SUSPECTED HYP

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00063	CONCEPTUS, INC.	12/1/2010	4/6/2011

Event Information:

Event Date (B3): 11/3/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/1/2010
Explant Date (E7): 11/3/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HER PT WAS EXPERIENCING PAIN FOLLOWING THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE. ADDITIONALLY, A NICKEL ALLERGY TEST WAS PERFORMED AND THE PT WAS POSITIVE FOR NICKEL ALLERGY. THE PHYSICIAN REMOVED THE ESSURE MICRO-INSERTS; THE PHYSICIAN STATES SHE DID NOT OBSERVE ANY INFLAMMATION, PROPER PLACEMENT WAS OBSERVED AND NOTHING ABNORMAL WAS NOTED REGARDING THE MICRO-INSERTS. THE PT STATED THAT THE PT EXHIBITED "MARKED OVERALL IMPROVEMENT" UPON FOLLOW UP EXAM. THE PHYSICIAN STATED THAT SHE BELIEVES THE ESSURE MICRO-INSERTS WERE RESPONSIBLE FOR THE PATIENT'S PAIN.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PATIENTS WITH SUSPECTED HYP

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/3/2010	12/21/2010

Event Information:

Event Date (B3): 11/24/2010 **Report Date (B4): 12/3/2010** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): UTERO MICRO COIL FOR PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): 50512931

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING A STERILIZATION PROCEDURE WITH THE ESSURE DEVICE, THE COIL MALFUNCTIONED IN THE LEFT FALLOPIAN TUBE. THIS CAUSED THE HYSTEROSCOPY TO CHANGE TO AN OPEN PROCEDURE, AS THE DEFECTIVE COIL HAD TO BE REMOVED.
==========
HEALTH PROFESSIONAL'S IMPRESSION
==========
COIL MALFUNCTIONED.
==========
MANUFACTURER RESPONSE FOR UTERO MICRO COIL FOR PERMANENT BIRTH CONTROL, ESSURE
==========
THE MANUFACTURER BELIEVED THE DEVICE MALFUNCTIONED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5018508	ESSURE	12/6/2010	12/16/2010

Event Information:

Event Date (B3): 11/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS30S/774400
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PER PHYSICIAN, "THE MICRO INSERT WAS PLACED IN THE ROUTINE FASHION. AS THE APPLICATOR PIECE WAS WITHDRAWN, THE OUTER PLASTIC CASING SEPARATED, LEAVING A PORTION INSIDE THE LEFT TUBAL OSTIA. SUBSEQUENTLY, THE APPLICATOR WAS THEN DIVIDED AT THE CERVICAL OS. THE HYSTEROSCOPE WAS REPLACED WITH A HYSTEROSCOPY GRASPER. THE CLEAR PLASTIC OUTER SHEATH WAS MANUALLY RETRACTED, LEAVING THE MICRO INSERT IN THE TUBAL OSTIUM. SEVEN LOOPS OF COIL WERE COUNTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00065	CONCEPTUS, INC.	12/8/2010	1/10/2011

Event Information:

Event Date (B3): 9/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/4/2010
Explant Date (E7): 9/28/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PT WAS EXPERIENCING INTERMITTENT PELVIC PAIN FOLLOWING AN ESSURE MICRO-INSERT PLACEMENT PROCEDURE. THE PHYSICIAN STATED HE TRIED VARIOUS PAIN MEDICATIONS WITH NO RESOLUTION OF SYMPTOMS. A HSG REVEALED THAT THERE WAS A MICRO-INSERT IN THE LEFT TUBE BUT NO INSERT IN RIGHT TUBE; PT CONTINUED TO REPORT PAIN PROBLEMS. A FULL HYSTERECTOMY WAS PERFORMED AND THE ESSURE MICRO-INSERTS WERE REMOVED. POST-OP EXAMINATION OF THE TISSUE REMOVED FROM THE PT WAS PERFORMED AND BOTH MICRO-INSERTS WERE FOUND IN THE FALLOPIAN TUBES WITH PROPER PLACEMENT; NO PERFORATION WAS OBSERVED. THE PT'S PAIN RESOLVED FOLLOWING HYSTERECTOMY AND MICRO-INSERT REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5018547	CONCEPTUS INC.	12/9/2010	12/21/2010

Event Information:

Event Date (B3): 12/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS 305
Catalog # (E4):
Lot #(E4): 12463246

Single Use:
Implant Date (E6): 12/8/2010
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 12/8/2010

Event Description (B5):

AFTER PLACEMENT OF THE RIGHT ESSURE IMPLANT, THE LEFT ESSURE IMPLANT WAS PROPERLY PLACED IN THE FALLOPIAN TUBE IN PREPARATION FOR DEPLOYMENT. FOLLOWING THE USUAL DEPLOYMENT SEQUENCE, THE COIL RELEASED, BUT THE DELIVERY CATHETER WOULD NOT RELEASE THE DEPLOYED IMPLANT. UPON PULLING THE DELIVERY CATHETER FROM THE UTERINE CAVITY, HALF OF THE PET FIBER WAS NOTED TO BE INTRACAVITARY. ATTEMPT AT USING A GRASPER TO REMOVE THE IMPLANT FROM THE TUBE RESULTED IN APPROXIMATELY 10% OF THE COIL BEING LEFT BEHIND IN THE PROXIMAL TUBE. REPEATED ATTEMPTS AT REMOVAL WERE UNSUCCESSFUL. THIS PREVENTS FUTURE PLACEMENT OF ANOTHER ESSURE IMPLANT OR USE OF ANY OTHER HYSTEROSCOPIC STERILIZATION TECHNOLOGY -ADIANA-. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5018601	CONCEPTUS	12/14/2010	12/22/2010

Event Information:

Event Date (B3): 5/25/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4): 626598

Single Use:
Implant Date (E6): 5/20/2005
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2008, SINCE THEN, I HAVE BEEN HAVING BAD HEALTH PROBLEMS. STARTED OUT WITH BLEEDING ALL THE TIME, NOW IN THE PAST MONTH, I'VE BEEN TO THE ER, 3 TIMES WITH NO LUCK FINDING OUT WHAT IS WRONG. I HAVE SEVERE STOMACH PAINS, TERRIBLE NAUSEA AND HEADACHES, SINCE I HAVE HAD THE IMPLANTS, ONLY NOW THEY SEEM TO BE GETTING WORSE, SENDING ME TO THE HOSPITAL! I HAVE NO HEALTH INSURANCE, SO I HAVEN'T BEEN ABLE TO GO TO THE DOCTOR, WITH THESE PROBLEMS. THE LAST ER VISIT, I WAS TOLD IT COULD BE THE ESSURE COILS, CAUSING MY PROBLEMS, BUT NOT FOR SURE. EVERY DOCTOR OR MEDICAL PERSON THAT I MENTION ESSURE TO, HAS NEVER HEARD OF IT!!! KINDA SCARY, I HAVE BEEN ON LINE AND FOUND COUNTLESS NUMBER OF WOMEN WITH THE SAME PROBLEMS, AFTER ESSURE! I WANT THESE THINGS OUT OF ME, THEY ARE MAKING ME SO SICK, I CANNOT TAKE CARE OF MY BABIES, THE WAY I NEED TO! I FOUND A DOCTOR THAT WILL TAKE THEM OUT FOR (B)(6), WHICH I SEE NO WAY OF PAYING THAT KIND OF MONEY! BUT I NEED SOME HELP OR ADVICE, ON WHAT TO DO. THANKS. DATES OF USE: (B)(6) 2008 - (B)(6) 2010. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL (CANNOT HAVE ANY MORE BABIES).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2010-00066	CONCEPTUS, INC.	12/16/2010	1/12/2011

Event Information:

Event Date (B3): 11/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 12/29/2009
Explant Date (E7): 11/12/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT HIS PT WAS EXPERIENCING PELVIC PAIN AND DYSPAREUNIA. THE PT HAD ESSURE MICRO-INSERTS PLACED ON (B)(6) 2009. THE PT DID NOT HAVE THE REQUIRED HSG CONFIRMATION TEST DUE TO FINANCIAL DIFFICULTIES. AN ULTRASOUND WAS PERFORMED AND IT WAS OBSERVED THAT THE ESSURE MICRO-INSERT FROM THE PT'S LEFT FALLOPIAN TUBE WAS IN THE LOWER UTERINE SEGMENT AND CERVIX. THE PHYSICIAN REMOVED THE ESSURE MICRO-INSERT WITH FORCEPS DURING A HYSTEROSCOPY PROCEDURE. THE PHYSICIAN HAS NOT HAD F/U WITH THE PT SINCE REMOVAL OF THE ESSURE MICRO-INSERT AND DOES NOT KNOW IF THE PT'S SYMPTOMS HAVE RESOLVED FOLLOWING REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5018963		1/11/2011	1/20/2011

Event Information:

Event Date (B3): 12/2/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): IMPLANT FOR PERMANENT STERILIZATION IN FEMALE PATIENTS
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 685787

Single Use:
Implant Date (E6):
Explant Date (E7):

Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3): 1/3/2011

Event Description (B5):

AS DEVICE WAS DEPLOYED, IT BROKE APART. BROKEN PIECES WERE ALL RETRIEVED BY THE MD., COIL LEFT INSIDE PT'S TISSUE AS PER MANUFACTURER'S INSTRUCTIONS. PER OP REPORT; IT FELL APART INTO THREE PIECES. EACH INDIVIDUAL PIECE WAS REMOVED WITH THE GRASPER AND THE REMAINING PART THAT WAS PROTRUDING FROM THE CERVICAL OS WAS ALSO REMOVED. THE OS WAS CLOSELY INSPECTED. THERE WAS ANOTHER COIL VISIBLE INSIDE THE TUBAL OSTIUM. IT WAS APPROX 2 MM INSIDE THE OSTIUM, SO ATTEMPTS WERE NOT MADE TO RETRIEVE IT. A SECOND ESSURE WAS USED WITH NO DIFFICULTY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019051	CONCEPTUS	1/15/2011	2/1/2011

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2009
Explant Date (E7): 10/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE BROKE OFF, PERFORATED FALLOPIAN TUBE, AFTER 18 MONTHS OF INSERTION AND MIGRATED TO OUTSIDE OF UTERUS AND ATTACHED ITSELF THERE. DUE TO THIS, I HAD 2 SURGERIES ULTIMATELY LEADING TO A COMPLETE HYSTERECTOMY. AFTER THE FIRST SURGERY BECAUSE OF THE FOREIGN OBJECT ON MY UTERUS, IT WAS EXTREMELY INFECTED AND I WAS ON A SERIOUS OF ANTIBIOTICS. THIS DID NOT CLEAR UP AND AFTER CONSULTING WITH MY DR WE OPTED FOR THE HYSTERECTOMY. AFTER READING MY MEDICAL RECORDS, THE DOCTOR CLEARLY STATES THAT THE PROBLEMS I HAD BEEN HAVING WERE CLEARLY RELATED TO THE MALFUNCTION OF THE ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00001	CONCEPTUS, INC.	1/17/2011	2/1/2011

Event Information:

Event Date (B3): 12/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/5/2010
Explant Date (E7): 12/18/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT REPORTED PAIN TEN DAYS FOLLOWING AN ESSURE MICRO-INSERT PLACEMENT PROCEDURE. A CT SCAN WAS PERFORMED AND IT WAS OBSERVED THAT THE MICRO-INSERT ON THE PT'S LEFT SIDE HAD POSSIBLY BROKEN INTO 2 PIECES. A LAPAROSCOPY WAS PERFORMED TO REMOVE THE MICRO-INSERT ON THE LEFT SIDE. THE MICRO-INSERT WAS FOUND INTACT AND TO HAVE PERFORATED THE FALLOPIAN TUBE; THE INNER COIL OF THE MICRO-INSERT WAS WRAPPED IN THE PT'S BOWEL. THE PHYSICIAN REPORTED THE PT'S STATUS AS "FINE" FOLLOWING REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00002	CONCEPTUS, INC.	1/17/2011	2/1/2011

Event Information:

Event Date (B3): 12/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627072

Single Use: Y
Implant Date (E6): 3/10/2009
Explant Date (E7): 12/14/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT WHO HAD UNDERGONE AN ESSURE MICRO-INSERT PLACEMENT PROCEDURE ON (B)(6) 2009 RECENTLY PRESENTED TO HER PHYSICIAN WITH A PAIN. AN HSG PROCEDURE AND A CT SCAN WERE PERFORMED ON THE PT AND IT WAS OBSERVED THAT 1 MICRO-INSERT HAD PERFORATED THE UTERUS AND WAS LOCATED IN THE PERITONEAL CAVITY; THE PHYSICIAN REMOVED THE MICRO-INSERT. THE PHYSICIAN REPORTED THAT THE PT IS NO LONGER EXPERIENCING SYMPTOMS. THE PHYSICIAN DOES NOT BELIEVE THE PT'S PAIN WAS RELATED TO ESSURE MICRO-INSERTS BUT SHE IS NOT CERTAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00003	CONCEPTUS, INC	1/18/2011	1/27/2011

Event Information:

Event Date (B3): 12/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 11/1/2010
Explant Date (E7): 12/20/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT REPORTED PAIN A FEW HOURS POST "HEROPTION CRYOABLATION" WHICH WAS PERFORMED ABOUT 3 WEEKS FOLLOWING AN ESSURE MICRO-INSERT PLACEMENT PROCEDURE. PHYSICIAN REPORTS THAT THE PROCEDURE WAS STRAIGHTFORWARD AND UNEVENTFUL. THE PT WENT HOME AND LATER BEGAN HAVING PAIN WHICH GOT STEADILY WORSE THROUGHOUT THE NIGHT. PHYSICIAN SAW HER THE NEXT AFTERNOON, SENT HER TO THE EMERGENCY ROOM, WHERE SHE WAS ADMITTED AND OBSERVED. WHEN SHE DID NOT GET BETTER THE NEXT DAY, SHE WAS TAKEN TO THE OPERATING ROOM, WHERE A SMALL BUT SIGNIFICANT THERMAL INJURY TO THE SEROSA OF THE BOWEL AND AN INFRACTED AREA OF THERMAL INJURY OVERLYING THE RIGHT ADNEXA OF THE UTERUS IN THE AREA OF THE ESSURE WERE NOTED. THE REMAINDER OF THE UTERUS APPEARED NORMAL. THERE WAS NO PERFORATION INJURY APPARENT AT THE TIME OF SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00004	CONCEPTUS, INC.	1/18/2011	1/27/2011

Event Information:

Event Date (B3): 11/23/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 11/1/2008
Explant Date (E7): 12/16/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT WHO HAD UNDERGONE AN ESSURE MICRO-INSERT PLACEMENT PROCEDURE IN 2008 HAS HAD INCREASING SEVERE PELVIC PAIN OVER THE PAST YEAR. ON ULTRASOUND, IT WAS CONFIRMED THE DEVICE ON THE LEFT SIDE WAS IN THE ENDOMETRIAL CAVITY AND PT'S PAIN HAS BEEN CHRONIC ON THE LEFT SIDE. SPOKE WITH PHYSICIAN ON (B)(6) 2010 WHO CONFIRMED DEVICE REMOVAL AND HYSTERECTOMY ON THE PT ON (B)(6) 2010. DR CONFIRMED, SHE COULD SEE 12 TRAILING COILS FROM THE DEVICE ON THE LEFT SIDE AND IS THE SIDE WHERE PT COMPLAINED OF PAIN. DOCTOR CONFIRMED IT WAS MEDICALLY NECESSARY TO REMOVE THE DEVICES AND PAIN WAS FROM THE DEVICE. THE PHYSICIAN REPORTED THAT THE PT IS NO LONGER EXPERIENCING SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019066	CONCEPTUS	1/18/2011	2/1/2011

Event Information:

Event Date (B3): 2/1/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING MY THIRD CHILD, I DECIDED THAT I WAS FINISHED HAVING CHILDREN AND THAT I WANTED PERMANENT BIRTH CONTROL. I DID SOME RESEARCH, TALKED TO MY FAMILY AND MY DR AND DECIDED THAT ESSURE WAS RIGHT FOR ME. IN (B)(6) 2008, I ELECTED TO HAVE THE ESSURE PROCEDURE. THE PROCEDURE WENT SMOOTHLY. IN (B)(6) 2008, I GOT THE HSGC TEST TO CONFIRM THAT THE ESSURE IMPLANTS WERE PLACED PROPERLY AND THAT MY TUBES WERE BLOCKED. I GOT CONFIRMATION FROM MY DR AND FROM THE RADIOLOGIST THAT MY TUBES WERE BLOCKED AND THAT I COULD RELY ON ESSURE AS A METHOD OF PERMANENT BIRTH CONTROL. FAST FORWARD TO 2011. I AM NOW (B)(6) PREGNANT. WHAT HAPPENED? I HAD AN EMERGENCY ULTRASOUND TO MAKE SURE THAT THE PREGNANCY WAS NOT IN ONE OF MY FALLOPIAN TUBES. THE DR CAME BACK AND TOLD ME THAT ONE OF THE ESSURE COILS HAD WORKED ITSELF OUT AND IT IS NOW IMBEDDED AT THE TOP OF MY UTERUS! MY PREGNANCY HAS BEEN CONFIRMED WITH A BLOOD TEST AT THE DR'S OFFICE. I GOT THE RESULTS TODAY (B)(6) 2011. I DON'T UNDERSTAND HOW THIS COULD HAPPEN. THIS SEEMS TO BE THE CASE FOR MULTIPLE WOMEN. MANY ARE GETTING SICK FROM ESSURE AND THERE ARE MANY OTHERS LIKE ME THAT ARE ENDING UP PREGNANT AFTER THEY HAVE MADE THE DECISION NOT TO HAVE ANY MORE KIDS. THIS HAS TURNED MY WHOLE LIFE UPSIDE DOWN. I AM GOING THROUGH A DIVORCE RIGHT NOW!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019095	CONCEPTUS	1/19/2011	2/1/2011

Event Information:

Event Date (B3): 9/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 641430

Single Use:
Implant Date (E6): 9/20/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2009. I WAS TOLD IT WAS A SHORT AND MOSTLY PAINLESS PROCEDURE. IT WAS TERRIBLE PAIN AND NOT SHORT AT ALL. SHORTLY AFTER IT WAS PLACED, I STARTED HAVING PROBLEMS. NEVER THOUGHT IT COULD BE ESSURE. AS TIME WENT ON I KEPT GETTING MORE AND MORE SYMPTOMS, PAIN, CRAMPING, FEELING I WAS GOING TO PASS OUT, HEADACHES, BUT MOST OF ALL CHEST PAIN. I HAD MANY TEST RAN AND ALL WERE NORMAL. MY DR CAME UP WITH INFLAMMATION AND STARTED TREATING ME WITH ADVIL FOR THAT, BUT COULD NOT TELL ME WHY AND EVEN REFERED ME TO A NEUROLOGIST. I HAVE BEEN SEEN BY MY OBGYN AND HAD AN ULTRASOUND AND OTHER TEST RUN TO CHECK ON THE ESSURE. THE PLACEMENT IS FINE, I AM TOLD, BUT HAD AN ALLERGY TEST DONE AND MY ALLERGY TEST CAME BACK POSITIVE TO NICKEL AND A FEW OTHER THINGS. ESSURE NEEDS TO REQUIRE AN ALLERGY TEST BEFORE PUTTING ANY PERMANENT METAL IN ANYONE. NOW I KNOW WHY FOR THE PAST YEAR AND A HALF THAT THIS IS MY PROBLEM AND NOW HAVE TO HAVE IT REMOVED. I AM NOT HAPPY. IT IS A VERY EXPENSIVE AND DANGEROUS PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00006	CONCEPTUS, INC.	1/27/2011	2/3/2011

Event Information:

Event Date (B3): 12/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 12/28/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN EXPERIENCED SINCE ESSURE PROCEDURE IN 2007, REPORTED ON (B)(6) 2010. FOLLOW UP CONFIRMED THAT SALPINGECTOMY WAS PERFORMED ON PT. DATE OF SALPINGECTOMY IS UNK BUT THE CONFIRMATION OF PROCEDURE WAS PROVIDED ON (B)(6) 2010. MEDICAL OPINION OF THE PHYSICIAN IS THAT THE ESSURE MICRO-INSERTS WERE LIKELY RESPONSIBLE FOR PT'S SYMPTOMS. PHYSICIAN TO HAVE F/U IN 3 WEEKS WITH PT AND WILL EVALUATE HER SYMPTOMS AT THAT TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	1/31/2011	2/11/2011

Event Information:

Event Date (B3): 1/28/2011 **Report Date (B4): 1/31/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/28/2011

Event Description (B5):

UPON DEPLOYMENT OF DEVICE, THE GREEN SHEATH REMAINED WITH ITEM AND THE CATHETER CAME OUT. THE ITEM WAS REMOVED USING A GRASPER. ESSURE REP WAS NOTIFIED, CAME TO THE HOSPITAL AND PICKED ITEM UP FOR FURTHER EVALUATION BY COMPANY.
==========
MANUFACTURER RESPONSE FOR ESSURE, ESSURE
==========
REPRESENTATIVE HAS DEVICE FOR FURTHER EVALUATION.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	2/3/2011	2/11/2011

Event Information:

Event Date (B3): 1/31/2011 **Report Date (B4): 2/3/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 740665 & 50500530

Single Use:
Implant Date (E6): 1/31/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE PLACED IN LEFT FALLOPIAN TUBE, DEVICE FELT LIKE IT DID NOT DEPLOY. ATTEMPTED A SECOND TIME, METAL SHARD REMOVED. PHYSICIAN THEN WENT TO UTILIZE SECOND ESSURE DEVICE WITH DIFFERENT LOT NUMBER AND DEVICE DEPLOYED IN RIGHT FALLOPIAN TUBE. ATTEMPTED LEFT FALLOPIAN TUBE, ESSURE DEVICE AGAIN UNSUCCESSFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019316	CONCEPTUS, INC.	2/4/2011	2/14/2011

Event Information:

Event Date (B3): 8/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 695932

Single Use:
Implant Date (E6): 8/16/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PHYSICIAN, DR (B)(6) OF (B)(6), HAD DIFFICULTY PLACING THE ESSURE COIL IN MY RIGHT FALLOPIAN TUBE. THE COIL PERFORATED THE TUBE AND IS NOW CURLED OUTSIDE THE TUBE. THE PROXIMAL END APPEARS TO BE IN THE CORRECT POSITION BUT THE DISTAL END IS CURLED OUTSIDE THE TUBE. THE IMPLANT DID NOT SUCCESSFULLY BLOCK THE TUBE AS CONFIRMED BY HSG ON (B)(6) 2010. THE ESSURE PROCEDURE WAS UNSUCCESSFUL FOR STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019353		2/7/2011	2/15/2011

Event Information:

Event Date (B3): 1/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/28/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2007, I HAD ESSURE DONE IN MY DR'S OFFICE. AFTER ABOUT A YR, I BEGAN TO EXPERIENCE SEVERE BACK PAIN, VAGINAL DISCHARGE AND CONSTANT BACTERIA VAGINOSIS, BLEEDING, EXTREME FATIGUE AND HEADACHES. OVER THE COURSE OF THREE YRS, THESE SYMPTOMS HAVE WORSENED, I HAD NONE OF THESE SYMPTOMS PRIOR TO ESSURE. MY DOCTOR HAS TRIED EVERYTHING TO ALLEVIATE THE PAIN. THE ONLY SOLUTION IS THAT ALL OF THIS BEGAN WHEN I HAD ESSURE DONE. I AM CURRENTLY SAVING TO HAVE THEM REMOVED SO THAT I CAN GET MY LIFE BACK. THE COST IS (B)(6)WHICH IS A LOT. I WAS NEVER TOLD THAT THESE SIDE EFFECTS WERE ASSOCIATED WITH ESSURE. I AM TELLING EVERYONE THAT ASKS ME, NOT TO GET IT DONE UNTIL THEY DO MORE RESEARCH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019360	CONCEPTUS	2/8/2011	2/16/2011

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 651391

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY ESSURE PROCEDURE DONE IN (B)(6) 2009. I JUST FOUND OUT THAT I AM (B)(6) PREGNANT. I AM SO DISAPPOINTED IN THIS PROCEDURE. IT HAS BEEN NOTHING BUT PROBLEMS SINCE DAY ONE. BACK, SIDE, AND LEG PAIN, HEADACHES, DEPRESSION, NAUSEA, BODY ACHES, DIZZINESS, HEAVY CRAMPING AND HEAVY PERIODS THAT LASTS FOR 7-10 DAYS. I DID THIS PROCEDURE BECAUSE I LIKED THAT IT WAS NOT AS INVASIVE AS A REGULAR TUBAL LIGATION. HOWEVER, IF I KNEW IT WAS GOING TO FAIL, I WOULD HAVE SAID NO. I ALREADY HAVE A SON (B)(6) AND MY DAUGHTER IS (B)(6). ME AND MY HUSBAND HAD ALREADY MADE UP OUR MINDS NO MORE KIDS, ESPECIALLY SINCE I AM ON MEDICATIONS THAT CAN CAUSE BIRTH DEFECTS TO THE BABY. I REALLY BELIEVED IT WAS ALL IN MY HEAD, ALL THE PAIN AND SYMPTOMS I HAD FOR THE LAST YEAR. I NEVER THOUGHT ESSURE WAS THE CULPRIT. I ALSO WAS NOT TOLD THAT THERE IS NICKEL IN THE COILS NOT SURE IF I AM ALLERGIC TO IT, I HAVE NOT FOUND ANYTHING TO AS TO WHETHER MY TUBE INSERTS ARE STILL IN PLACE OR IF THEY ARE FLOATING AROUND. FEEL SO FRUSTRATED THIS IS HAPPENING TO ME. I HAVE HAD HORMONAL IMBALANCES SINCE THE PROCEDURE THOUGHT IT WAS ALL IN MY HEAD. I AM VERY FRUSTRATED AND HOPE THIS PRODUCT GETS RECALLED. I REGRET RECOMMENDING THIS TO ANY OF MY FAMILY AND FRIENDS. CONCEPTUS NEEDS TO BE HELD RESPONSIBLE FOR THIS!! NOW I WILL HAVE NO OTHER CHOICE BUT TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6). PRAYING THAT THE BABY WILL COME OUT HEALTHY AND OKAY. WOULD NEVER WISH THIS ON ANYONE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00007	CONCEPTUS, INC.	2/8/2011	2/17/2011

Event Information:

Event Date (B3): 11/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 709952

Single Use: Y
Implant Date (E6): 11/29/2010
Explant Date (E7): 12/23/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2010 REPORT, THAT PT HAS 2 INSERTS IN 1 TUBE; NO DETACHMENT DIFFICULTY. PT IS NOW COMPLAINING OF PAIN ON THAT SIDE. PHYSICIAN WILL PERFORM A SALPINGECTOMY AND REMOVE DEVICES ON THAT SIDE (SCHEDULED FOR (B)(6) 2010); PHYSICIAN ATTRIBUTES PAIN TO THE DEVICES; ULTRASOUND PERFORMED AND APPEARS 1 DEVICE ON THAT SIDE IS FOLDED ON ITSELF. FOLLOW UP CONFIRMED THAT SALPINGECTOMY WAS PERFORMED ON RIGHT SIDE AND LIGATION OF LEFT SIDE ON (B)(6) 2010. NO MICRO-INSERTS REMOVED. PAIN CONTINUED AND X-RAY WAS PERFORMED ON (B)(6) 2010. TWO MICRO-INSERTS WERE OBSERVED IN THE UTERINE AREA, SO SHE WAS TAKEN TO SURGERY AGAIN ON (B)(6) 2010; HYSTERECTOMY PERFORMED AND LEFT FALLOPIAN TUBE WAS REMOVED; ALSO REMOVED 3 MICRO-INSERTS: 1 IN THE TUBAL MYOMETRIAL JUNCTION AND 2 MORE IN THE UTERUS. PHYSICIAN BELIEVES THAT THE ESSURE DEVICES MAY HAVE CONTRIBUTED TO PT'S PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019390		2/9/2011	2/17/2011

Event Information:

Event Date (B3): 4/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/6/2010
Explant Date (E7): 4/14/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICES PUT IN PLACE ABOUT 6 WKS BEFORE THE EVENT. I HAD PAIN IN BOTH SIDES FROM THE TIME THEY WERE PLACED. TWO WEEKS AFTER, I BEGAN TO NOTICE PAIN WAS MORE SPECIFIC TO MY LEFT SIDE. AS A COUPLE MORE WEEKS WENT BY THIS PAIN BECAME MUCH MORE INTENSE. I WAS ON A VACATION WITH MY FAMILY AND THEY NOTICED THAT I COULD BARELY WALK AND SPENT MOST OF THE TRIP IN BED IN A MASSIVE AMOUNT OF PAIN. AFTER WE RETURNED HOME, I COULD NO LONGER HANDLE THE PAIN SO I SCHEDULED AN APPT WITH MY OB THE NEXT DAY. WHEN I GOT THERE I COULD BARELY WALK. I WAS TAKEN INTO THE ULTRASOUND ROOM. SECONDS LATER, THE TECH WAS CALLING IN THE DR. I HAVE A HUGE MASS ON MY LEFT SIDE. THEY HAD NO IDEA AT THAT TIME WHAT HAD CAUSED IT. I WAS TAKEN TO ANOTHER ROOM. BENT OVER AND CRYING FROM PAIN I'VE HAD 3 KIDS, 2 NATURAL AND THIS HURT WAY MORE, THE DR CAME IN AND TOLD ME I WAS TO GO IMMEDIATELY TO THE ER FOR EMERGENCY ABDOMINAL SURGERY. MY WHOLE STOMACH HAD TO BE CUT OPEN. WHILE WAITING FOR SURGERY SITTING THERE NOT HAVING A CLUE WHAT WAS GOING ON AND HAVING TO TELL MY CHILDREN AND FAMILY GOODBYE BEFORE SURGERY NOT KNOWING WHAT WAS GOING TO HAPPEN IN THERE AND THE WORST FEELING I HAVE EVER HAD IN MY LIFE. AFTER SURGERY, THE DR TOLD ME THAT I HAD A HUGE FLUID FILLED MASS AND IT WAS A MASSIVE INFECTION. I SPENT 5 DAYS IN THE HOSP IN EXTREME PAIN AND BEING PUMPED FULL OF ANTIBIOTICS BECAUSE A TINY LITTLE COIL HAD CAUSED A TEAR IN MY TUBE. I LOST MY LEFT OVARY AND TUBE. I COULD NOT PICK UP MY CHILDREN FOR NEARLY 3 MONTHS. WHICH WAS HARD SINCE MY YOUNGEST HAD NOT EVEN TURNED (B)(6). I STILL FACE DAILY PAIN, CRAMPS, AND HUGE HORMONAL PROBLEMS. THE LOSS OF AN OVARY HAS REALLY CAUSED ME PROBLEMS. IF ANYTHING GOES WRONG WITH THE COIL IN MY RIGHT TUBE I RUN THE RISK OF LOSING MY LAST OVARY, THEN WOULD BE ON HRT AT (B)(6). I HAVE TALKED TO MANY WOMEN WHO HAVE HAD PROBLEMS

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WITH THESE DEVICES. ALTHOUGH MINE IS A MORE EXTREME CASE I FELT THAT WOMEN ARE BEING TERRIBLY MISINFORMED ABOUT THIS PROCEDURE. THAT THE RISKS ARE NOT STRESSED ENOUGH AND THAT WOMEN ARE HAVING SERIOUS PROBLEMS WITH THESE DEVICES. THIS COMPLAINT IS MY FIRST STEP TOWARDS A LAWSUIT AGAINST ESSURE FOR WHAT HAS HAPPENED TO ME AND ALL THE PAIN MYSELF AND MY FAMILY HAD TO ENDURE. MY PARENTS HAD MY 3 CHILDREN FOR MORE THAN 2 WEEKS WHILE I RECOVERED, MY (B)(6) HAD NEVER BEEN AWAY FROM ME AND MY (B)(6) ONLY ONCE IT WAS EXTREMELY HARD FOR THEM. MY HUSBAND MISSED OVER A WEEK OF WORK TO BE AT MY BEDSIDE AT THE HOSP AND CARE FOR ME WHEN I WAS RELEASED. DATES OF USE: (B)(6) 2010 - (B)(6) 2011; ONE REMAINS ON RIGHT SIDE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00009	CONCEPTUS, INC.	2/11/2011	2/28/2011

Event Information:

Event Date (B3): 1/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/20/2010
Explant Date (E7): 1/14/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED ON (B)(6) 2010. THE PT COMPLAINED OF MODERATE TO SEVERE PAIN AND CRAMPING SINCE THE ESSURE PLACEMENT. DEVICES CONFIRMED IN THE FALLOPIAN TUBES ON CT AND NO OTHER PATHOLOGY FOUND TO ACCOUNT FOR THE PELVIC PAIN. DR WANTED TO TRY TO PULL THEM OUT HYSTEROSCOPICALLY; CLINICAL LIAISON TOLD HIM THAT PER THE IFU IT WAS NOT RECOMMENDED. ON (B)(6) 2011, CONFIRMED HE WENT IN HYSTEROSCOPICALLY, AND NO COILS WERE VISIBLE. HE CONVERTED TO LAPAROSCOPY AND HE COULD SEE THE MICRO INSERTS AT THE CORNU AND IN THE FALLOPIAN TUBE. HE THEN PERFORMED THE RECOMMENDED LINEAR SALPINGOTOMY AND WAS ABLE TO REMOVE BOTH DEVICES SUCCESSFULLY AND PERFORMED A TUBAL. PT DID WELL AND HE WILL SEE HER IN A FEW WEEKS FOR POST-OP FOLLOW UP. ON (B)(6) 2011: CONFIRMED WITH DR (B)(6) THAT PATIENT'S SYMPTOMS HAVE RESOLVED AFTER DEVICE REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019585	CONCEPTUS	2/23/2011	3/7/2011

Event Information:

Event Date (B3): 2/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE-PERMANENT BIRTH CONTROL. I RECEIVED THIS PROCEDURE ABOUT 1 YEAR PRIOR. SUFFERED FROM SHARP PAINS, LONG TERM BLEEDING, AND PAIN DURING INTERCOURSE. I COMPLAINED TO MY DOCTOR CONSTANTLY AND THE ONLY TEST HE DID WAS MAKE SURE IT TOOK, AND HE SAID IT DID. HOWEVER, 3 DAYS AGO I FOUND OUT I WAS PREGNANT. I WENT TO THE HOSPITAL BECAUSE I WAS LATE FOR MY PERIOD AND WAS HAVING SEVERE PAINS, AND THE DOCTOR WHO PUT THE DEVICE IN COULD NOT GET ME IN FOR AT LEAST A WEEK. FOUND OUT AT THE HOSPITAL THAT THE RIGHT COIL IS NO LONGER COMPLETELY IN MY TUBE, IT IS NOW PARTIALLY IN THE UTERUS ALONG WITH A FETAL SAC. I AM NOW HAVING COMPLICATIONS AND AM HAVING TO RECEIVE SEVERAL ULTRASOUNDS TO SEE IF THE BABY IS OKAY AND THIS IS STILL UNDETERMINED. HOWEVER, I WILL HAVE TO HAVE A TUBAL LIGATION AFTER I HAVE ANOTHER PREGNANCY DUE TO THIS DEVICE. DATES OF USE: (B)(6) 2010 - (B)(6) 2011.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019682		3/4/2011	3/15/2011

Event Information:

Event Date (B3): 9/8/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 713458

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE DISPLACED WITHOUT BEING ACTIVATED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5019706	CONCEPTUS	3/4/2011	3/18/2011

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/8/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER A SUCCESSFUL PLACEMENT OF THE ESSURE BIRTH CONTROL DEVICE IN (B)(6) 2009 AND A SUCCESSFUL FOLLOW UP FOR A CONTRAST DYE X-RAY TO ENSURE CORRECT PLACEMENT AND ABSOLUTE BLOCKAGE IN (B)(6) 2010, I HAVE NOW LEARNED THAT I AM PREGNANT WITH AN UNWANTED CHILD. ONCE FAILURE RATES BEGIN TO CLIMB DRASTICALLY, FROM WHAT I'M TOLD BY MY OB/GYN, HE'S HAD 2 FAILURES RECENTLY IN HIS OWN OFFICE RESULTING IN PREGNANCY. I AM A MATHEMATICIAN, SO I KNOW THIS IS MUCH HIGHER THAN .2%. PATIENTS SHOULD HAVE BEEN NOTIFIED BY THE MFR THAT THIS IS NOT A RELIABLE FORM OF BIRTH CONTROL. ONCE THEY LEARNED THAT THE INSERTS HAD BEGUN TO MIGRATE IN A LARGE NUMBER OF WOMEN, PATIENTS SHOULD HAVE BEEN NOTIFIED. THIS IS A SIMPLE FIX FOR WOMEN WANTING TO PREVENT PREGNANCY! USE AN ALTERNATE FORM OF BIRTH CONTROL UNTIL A SOLUTION IS REACHED. I WOULD NOT BE PREGNANT, FACING AN ABORTION, IF THE COMPANY HAD BEEN RESPONSIBLE ENOUGH TO LET PATIENTS KNOW THAT THE DEVICE WAS NOT AS RELIABLE AS ADVERTISED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00008	CONCEPTUS, INC.	3/8/2011	3/16/2011

Event Information:

Event Date (B3): 2/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20226502

Single Use: Y
Implant Date (E6): 1/28/2011
Explant Date (E7): 2/11/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED ON (B)(6) 2011. PT CALLED PHYSICIAN'S OFFICE ON (B)(6) 2011 TO REPORT SEVERE PAIN. A SONOGRAM WAS PERFORMED, WHICH SHOWED PROPER PLACEMENT OF THE DEVICE ON THE RIGHT SIDE, UNABLE TO VISUALIZE THE DEVICE ON THE LEFT SIDE. PT HAS REQUESTED REMOVAL OF THE DEVICES AND A TUBAL LITIGATION, WHICH IS SCHEDULED FOR (B)(6) 2011. ON (B)(6) 2011 - COILS WERE NOT ABLE TO BE VISUALIZED WITH HYSTEROSCOPE, SO THE PHYSICIAN WENT IN LAPAROSCOPICALLY AND SUCCESSFULLY REMOVED THE DEVICES. SALPINGECTOMY WAS PERFORMED PER THE PT'S REQUEST. ON (B)(6) 2011 - PHYSICIAN CONFIRMED THAT PT IS NO LONGER EXPERIENCING PAIN AND WAS RECOVERING WELL AFTER THE SALPINGECTOMY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00010	CONCEPTUS, INC.	3/9/2011	3/16/2011

Event Information:

Event Date (B3): 2/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2009
Explant Date (E7): 10/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORT PAIN POST-OF ESSURE IMPLANT APPROX (B)(6) 2009. ON (B)(6) 2011, PT REPORTED THAT AN MRI WAS PERFORMED IN (B)(6) 2010 WHICH DETERMINED THAT THE DEVICE WAS BROKEN; FOLLOWED BY SURGERY FOR DEVICE REMOVAL IN (B)(6) 2010. PHYSICIAN'S OFFICE CALLED TO GATHER ADD'L INFO. DR. (B)(6) (ORIGINAL DR.) CONFIRMED THAT SHE HAD DIFFICULTY WITH PLACEMENT OF THE DEVICE ON ONE SIDE, BUT COULD NOT CONFIRM IF PT HAD THE FOLLOW UP HSG. ON (B)(6) 2011, CURRENT PHYSICIAN, DR. (B)(6), CONFIRMED PT WAS IN EXTREME PAIN AND DEVICE REMOVAL WAS MEDICALLY NECESSARY. DR. PERFORMED ONE DEVICE REMOVAL IN (B)(6) 2010. DR. CONFIRMED THAT THE ESSURE WAS BROKEN IN MULTIPLE PIECES AND SHE REMOVED ALL THE PIECES OF THE DEVICE. A FEW WEEKS LATER, THE PT HAD A HYSTERECTOMY AND OTHER REMAINING DEVICE WAS REMOVED DURING THAT TIME. PT HAS RECOVERED FROM THE PROCEDURES AND NO LONGER HAS ANY SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	3/9/2011	3/22/2011

Event Information:

Event Date (B3): 1/11/2011 **Report Date (B4): 3/9/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): OCCLUSION, CONTRACEPTIVE DEVICE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 774399

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

COIL DEPLOYED BUT PULLED OUT.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC	3/11/2011	3/24/2011

Event Information:

Event Date (B3): 3/3/2011 **Report Date (B4): 3/11/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): STERILIZATION DEVICE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 802745

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

SURGEON WAS ATTEMPTING TO ADVANCE ESSURE THROUGH THE FALLOPIAN TUBE AND NOTICED THE TIP WAS MISSING ON THE PRODUCT. UPON FURTHER INSPECTION, SURGEON NOTICED THE TIP WAS IN THE HYSTEROSCOPE. TIP WAS REMOVED FROM THE SCOPE IN ITS ENTIRETY (ACCORDING TO SURGEON).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00011	CONCEPTUS, INC.	3/11/2011	4/6/2011

Event Information:

Event Date (B3): 1/13/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/13/2011
Explant Date (E7): 2/3/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACEMENT ON (B)(6) 2011 AND HAS SINCE EXPERIENCED EXCESSIVE WEIGHT GAIN, NAUSEA, CRAMPING AND VOMITING. THE PT HAD ABDOMINAL FILMS AND THE COILS APPEAR TO BE IN PLACE. CBC DOESN'T SHOW AN ELEVATED WBC BUT SHE DOES HAVE A HIGHER PERCENTAGE OF LYMPHOCYTES THAN NORMAL. SHE HAD A NICKEL PATCH TEST WHICH SHOWED A POSITIVE RESPONSE TO NICKEL. ON (B)(6) 2011, DUE TO PT SYMPTOMS AND RESULTS OF ALLERGY TEST, THE PHYSICIAN WENT IN LAPAROSCOPICALLY AND REMOVED THE INSERTS. ON (B)(6) 2011, FOLLOW UP WITH PHYSICIAN WHO CONFIRMED REMOVAL AND HAS NOT HEARD BACK FROM THE PT AND SO ASSUMES THAT HER SYMPTOMS HAVE RESOLVED. PHYSICIAN ALSO CONFIRMED POSITIVE AND SEVERE RESPONSE TO NICKEL.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. IFU WARNING: PTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY PRIOR TO AN

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00012	CONCEPTUS, INC.	3/11/2011	4/6/2011

Event Information:

Event Date (B3): 2/11/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED IN (B)(6) 2010. PT PRESENTED WITH ABDOMINAL PAIN AND ABNORMAL UTERINE BLEEDING SINCE THE TIME OF THE ESSURE PROCEDURE. THE PT REPORTS BLEEDING/SPOTTING DAILY. PT ALSO NOW REPORTING A HISTORY OF REACTIONS TO NICKEL JEWELRY. NO CONFIRMATORY HSG PERFORMED DUE TO LOSS OF INSURANCE. THE PHYSICIAN BELIEVES THAT THE PAIN AND ABNORMAL BLEEDING THAT THE PT IS COMPLAINING OF IS LIKELY DUE TO THE ESSURE DEVICE. THE PT IS BEING SCHEDULED FOR ALLERGY TESTING FOR CONFIRMATION OF POSSIBLE REACTIONS TO NICKEL.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARING: PTS WITH SUSPECTED HYPERSENSITIVI

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	3/18/2011	3/30/2011

Event Information:

Event Date (B3): 3/8/2011 **Report Date (B4): 3/18/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 802743

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN THE SURGEON WAS DEPLOYING THE COIL FROM SHEATH, THE SHEATH WOULD NOT RELEASE COIL.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	3/28/2011	4/6/2011

Event Information:

Event Date (B3): 3/24/2011 **Report Date (B4): 3/28/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 740656

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING HYSTEROSCOPIC FALLOPIAN TUBE OCCLUSION ESSURE WAS REMOVED FROM BOX AND TIP OF DELIVERY SYSTEM WAS NOTICED TO BE BENT ABNORMALLY. MD COULD NOT MANIPULATE THE DEFECTIVE ESSURE DEVICE CORRECTLY AND DISCARDED THE DEVICE, OR STAFF RETAINED THE PACKAGING. A SECOND ESSURE DEVICE WAS OBTAINED FOR THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	3/28/2011	4/6/2011

Event Information:

Event Date (B3): 3/24/2011 **Report Date (B4): 3/28/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 12441794

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING HYSTERSCOPIC FALLOPIAN TUBE OCCULUSION, FIRST ESSURE DEVICE WAS INSERTED AND FAILED TO DEPLOY CORRECTLY. SPRING DID NOT EXPAND AND REMAINED INSIDE PATIENT. SPRING WAS REMOVED FROM PATIENT BY MD AND SAVED ALONG WITH PRODUCT PACKAGING. DELIVERY DEVICE WAS DISCARDED BY OR STAFF.
==========
MANUFACTURER RESPONSE FOR PERMANENT BIRTH CONTROL SYSTEM, ESSURE
==========
MANUFACTURER REP WAS CONTACTED BY OR CASE STAFF.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5020021	ESSURE	3/28/2011	4/6/2011

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL/STERILIZATION
Device Type (E2): ESSURE
Model # (E4): UNSURE
Catalog # (E4): UNSURE
Lot #(E4): UNSURE

Single Use:
Implant Date (E6): 5/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I REC'D THE ESSURE PROCEDURE AFTER BEING ASKED BY MY PHYSICIAN IF I WAS ALLERGIC TO NICKEL OR NOT. I REPLIED YES BECAUSE I AM ON MY SKIN. MY PHYSICIAN REPLIED THAT IT DID NOT MATTER BECAUSE I WAS ONLY ALLERGIC ON MY SKIN. HE RAN NO TESTS TO COME TO THAT CONCLUSION. THIS QUESTION WAS ASKED WHILE PREPPING ME FOR THE PROCEDURE. SINCE THE PROCEDURE I HAVE HAD NOTHING BUT PAIN, DISCOMFORT, AND SOME CHANGES IN MY MOODS. I NEVER HAD PROBLEMS PRIOR, WHEN I CONTACTED THE PHYSICIAN THAT DID THE PROCEDURE I WAS INFORMED THE PROCEDURE IS NOT REVERSIBLE AT ALL NO ONE CAN DO IT AND THAT MY DISCOMFORT AND PAIN IS NOT CAUSED BY THE PROCEDURE. HE KNEW ALL THIS IN SPEAKING WITH ME ON THE PHONE SUPPORTIVELY. ALL I WANT IS THE WRONG MADE RIGHT, I WANT THESE OUT AN I CAN NOT PAY FOR THE PROCEDURE. I FEEL AS THOUGH ESSURE, AND THE PHYSICIAN TO WHOM PLACED THEM SHOULD. THEY TOLD ME I WAS GOING TO BE FINE WITH THESE IN ME EVEN KNOWING OF MY NICKEL ALLERGY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00015	CONCEPTUS, INC.	3/29/2011	4/11/2011

Event Information:

Event Date (B3): 2/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 3/1/2010
Explant Date (E7): 2/28/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, DOCTOR REPORTED THAT A PATIENT WHO UNDERWENT ESSURE PLACEMENT IN (B)(6) 2010, HAS HAD PERSISTENT AND INCREASING LT LOWER QUADRANT PAIN. HSG SHOWS SATISFACTORY LOCATED LEFT MICRO INSERT. NO RIGHT DEVICE WAS PLACED DUE TO INABILITY TO CANNULATE TUBE AND PATIENT'S HISTORY. THE HSG SHOWED THE TUBE WAS EITHER OCCLUDED OR ABSENT. HE HAS THE PATIENT SCHEDULED FOR ESSURE MICROINSERT REMOVAL SECONDARY TO PELVIC PAIN. ON (B)(4) 2011, DOCTOR REMOVED THE ESSURE MICRO INSERT (B)(6) 2011. WAS ABLE TO REMOVE BOTH THE INNER/OUTER COILS COMPLETELY, ALTHOUGH THEY WERE SEPARATED UPON REMOVAL (NO CLINICAL SIGNIFICANCE). HE SAID THERE WAS NO DIFFICULTY REMOVING THE MICRO INSERT AND IT DID APPEAR TO BE IN THE FALLOPIAN TUBE. HE DID NOTE THE PATIENT HAD A LARGE OVARIAN CYST ON THE CONTRALATERAL SIDE WHICH MAY HAVE CAUSED SOME OF THE PELVIC PAIN THE PATIENT WAS EXPERIENCING, ALTHOUGH HE DID FEEL THE MICRO INSERT WAS ALSO CONTRIBUTING TO HER PAIN. THE PATIENT IS DOING WELL, NO OTHER PROBLEMS AT THIS TIME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00016	CONCEPTUS, INC.	3/29/2011	4/11/2011

Event Information:

Event Date (B3): 2/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN
Single Use: Y
Implant Date (E6): 9/1/2009
Explant Date (E7): 2/21/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, DOCTOR REPORTED A PATIENT WHO HAD ESSURE PLACED IN (B)(6) 2009 BY ANOTHER DOCTOR. PATIENT REPORTED HAVING THE 3 MONTH POST PROCEDURE HSG WHICH DOCUMENTED TUBAL OCCLUSION. A FEW DAYS AGO, SHE PRESENTED TO THE EMERGENCY ROOM AT (B)(6) WITH FEVER, SEVERE PAIN, ELEVATED WBC CONSISTENT WITH SOME INFECTION PROCESS. LAPAROSCOPY PERFORMED, CORNUAL ABSCESSES DRAINED, IV-ANTIBIOTICS ADMINISTERED. ADDITIONAL FOLLOW-UP: PATIENT TAKEN BACK INTO OPERATING ROOM AFTER ABOUT 36 HOURS AND A LAPAROSCOPIC SUPRACERVICAL HYSTERECTOMY WAS PERFORMED. PHYSICIAN STATED HE DID NOT FEEL THE INFECTION WAS CAUSED BY THE ESSURE DEVICES, BUT THE POSSIBILITY THAT THEY CONTRIBUTED TO THE LACK OF RESPONSE TO ANTIBIOTICS. THE MORNING FOLLOWING THE HYSTERECTOMY, THE PATIENT'S CONDITION IMPROVED DRAMATICALLY.

Manufacturer Narrative (H10):

COMMENTS: CONFERRED WITH CONSULTING PHYSICIANS WHO SPOKE W/ REPORTING DOCTOR. THEY DISCUSSED THE POSSIBILITY OF SEEDING THE INFECTION INTO THE PELVIS AFTER DRAINING THE ABSCESS, AS OPPOSED TO PERFORMING A HYSTERECTOMY RIGHT THEN AND THERE. THE TWO DOCTORS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5020030	CONCEPTUS INC., USA	3/30/2011	4/7/2011

Event Information:

Event Date (B3): 12/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626908

Single Use:
Implant Date (E6): 8/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2008, I HAD THE ESSURE PROCEDURE DONE. FOR THE PAST 18 MONTHS, I HAVE HAD SO MANY HEALTH PROBLEMS RELATED TO THIS. I HAVE HAD SIGNIFICANT WEIGHT GAIN, PAIN, HEADACHES AND ON A DAILY BASIS I HAVE TO FIGHT PAIN FROM THIS. I HAVE BEEN TO MANY DOCTORS AND SPECIALISTS WHO ALL AGREE THAT IT IS DIRECTLY RELATED TO THIS AND THE ONLY WAY TO STOP THE PAIN IS POSSIBLY HYSTERECTOMY, WHICH I CANNOT DO AS I HAVE NOW LOST MY INSURANCE. THE COMPANY HAS NOT RESPONDED TO MY CALLS OR COMPLAINTS OTHER THAN TO SAY THEY CANNOT COMMENT IF ANY OTHER PTS HAVE THE SAME PROBLEMS. THIS DEVICE IS UNSAFE, AS IS CLEAR FROM THE NEW RESEARCH I HAVE READ ON THE INTERNET WITH HUNDREDS OF OTHERS WHO HAVE THE SAME PROBLEMS AND SYMPTOMS I HAVE HAD. DATES OF USE: (B)(6) 2008 -- (B)(6) 2011.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00018	CONCEPTUS, INC.	3/31/2011	4/14/2011

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORT OF AN ECTOPIC PREGNANCY 3 YEARS FOLLOWING THE ESSURE PROCEDURE. A (B)(6) WOMAN PRESENTED TO THE EMERGENCY ROOM, COMPLAINING OF SEVERE LOWER ABDOMINAL PAIN THAT HAD BEGUN EARLY THAT SAME MORNING. THIS WAS ACCOMPANIED BY NAUSEA AND DIZZINESS BUT NO OTHER ASSOCIATED SYMPTOMS. THE PATIENT STATED THAT SHE HAD A HISTORY OF AN ESSURE PROCEDURE PERFORMED IN 2008, WITH A HYSTEROSALPINGOGRAM CONFIRMING TUBAL OCCLUSION 3 MONTHS AFTER THE PROCEDURE. ON ARRIVAL IN THE EMERGENCY ROOM, THE PATIENT WAS IN HYPOVOLEMIC SHOCK. A URINE PREGNANCY TEST RESULT WAS POSITIVE, AND FREE FLUID WAS OBSERVED IN THE ABDOMEN ON BEDSIDE EMERGENCY ULTRASONOGRAPHY. RUPTURED ECTOPIC PREGNANCY WAS SUSPECTED, AND SHE UNDERWENT AN EMERGENCY EXPLORATORY LAPAROTOMY. AN ECTOPIC PREGNANCY WAS IDENTIFIED IN THE LEFT FALLOPIAN TUBE, BUT THE ESSURE DEVICES APPEARED TO BE CORRECTLY PLACED IN BOTH TUBES. THE PATIENT HAD AN UNEVENTFUL HOSPITAL COURSE AND WAS DISCHARGED HOME ON POSTOPERATIVE DAY 2.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00019	CONCEPTUS, INC.	3/31/2011	4/14/2011

Event Information:

Event Date (B3): 1/26/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 761440

Single Use: Y
Implant Date (E6): 11/22/2010
Explant Date (E7): 1/26/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED MICRO-INSERT PLACEMENT PROCEDURE OCCURRED ON (B)(6) 2010. THE 3 MONTH POST PLACEMENT HSG REVIEW REFLECTED 3 TRAILING COILS ON LEFT SIDE AND 1 TRAILING COIL ON RIGHT. PET FIBERS IN PLACE BUT MICRO INSERT MIGRATED AND EMBEDDED INTO THE MYOMETRIUM LINING. LAPAROSCOPIC REMOVAL OF RIGHT TUBE (B)(6) 2011.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00017	CONCEPTUS, INC.	3/31/2011	5/26/2011

Event Information:

Event Date (B3): 2/9/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 2/9/2011
Explant Date (E7): 2/18/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A DR ENCOUNTERED A PROBLEM DURING AN ESSURE MICRO-INSERT PLACEMENT; THE DEVICE DID NOT DEPLOY FROM THE DELIVERY CATHETER AND THE MD PULLED MUCH OF THE DEVICE OUT WITH THE HYSTEROSCOPE, HOWEVER, SOME OF THE MICRO INSERT WAS STRETCHED AND LEFT PROTRUDING FROM THE PATIENT'S CERVIX. THE MD DID NOT HAVE A PAIR OF STERILE SCISSORS OR GRASPERS AND AT THIS POINT, LEFT THE DEVICE ALONE. THE MD IS TAKING THE PATIENT TO THE OPERATING ROOM NEXT WEEK TO DO A LAPAROSCOPIC TUBAL ON THAT INCOMPLETE SIDE AND IS GOING TO ATTEMPT TO REMOVE THE REMAINDER OF THE DEVICE AT THAT TIME. IN OPERATING ROOM. DR PARTIALLY REMOVED THE DEVICE ON THE LEFT, HYSTEROSCOPICALLY, BY SNIPPING THE MICRO INSERT OFF AT THE OPENING OF THE TUBAL OSTIUM AS IT WAS IMBEDDED AND COULD NOT BE REMOVED. THEN, A BILATERAL TUBAL LIGATION WAS PERFORMED, FOUND THAT THE MICRO-INSERT HAD PARTIALLY PERFORATED THE FALLOPIAN TUBE, LIKELY THE CAUSE OF INABILITY TO REMOVE. ON (B)(6) 2011, SPOKE W/ DR WHO CONFIRMED REMOVAL, SUCCESSFUL BTL AND PATIENT DOING WELL AT ONE WEEK POST-OP.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00013	CONCEPTUS, INC.	4/4/2011	6/6/2012

Event Information:

Event Date (B3): 1/7/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7): 3/11/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, A PT REPORTED THE POSSIBILITY THAT THEY WERE ALLERGIC TO NICKEL, BUT HAS NOT BEEN CONFIRMED BY FORMAL PATCH TESTING OR DERMATOLOGIST. F/U PERFORMED AND ON (B)(6) 2011 IT WAS CONFIRMED BY FACILITY NURSE THE NICKEL ALLERGY WAS CONFIRMED BY DERMATOLOGIST. PT BEING TREATED WITH PREDNISONE AND OTHER STEROID MEDS TO REDUCE SYMPTOMS OF ITCHING AND RASH OVER THE BODY. DOCTOR CONFIRMED NICKEL ALLERGY IS RELATED TO ESSURE DEVICE. SCHEDULED FOR HYSTERECTOMY ON FRIDAY, (B)(6) 2011. WILL F/U WITH CLINIC TO CONFIRM DEVICE REMOVAL AND PT STATUS 1-2 WEEKS POST REMOVAL. ON (B)(6) 2011: SPOKE TO NURSE AND PT DID HAVE HYSTERECTOMY WITH DEVICE REMOVAL ON (B)(6) 2011. PT WAS DOING FINE POST PROCEDURE, BUT POST--OP VISIT NEEDS TO BE SCHEDULED TO CONFIRM RESOLUTION OF SYMPTOMS. ON (B)(6) 2011: SPOKE TO NURSE (B)(6) AND PT HAD POST-OP ON (B)(6) 2011 AND PT WAS DOING WELL. HER RASH SYMPTOMS HAVE BEEN RESOLVED.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PTS WITH SUSPECTED HYPERSENSITIV

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00020	CONCEPTUS, INC.	4/6/2011	2/22/2012

Event Information:

Event Date (B3): 3/8/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 3/7/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, DR. SAW PT FROM ANOTHER STATE, WHO PRESENTED WITH PAIN. PT STATED SHE HAD HER 3 MONTH HSG REPORT THAT REFLECTED THE DEVICES WERE NOT IN CORRECT POSITION. CURRENT DR. FOUND ONE DEVICE IN CERVIX AND ONE IN VAGINAL WALL AND REMOVED BOTH COILS. PT IS NOW NO LONGER IN PAIN. NAME OF PHYSICIAN WHO IMPLANTED THE ESSURE DEVICES IS UNK AT THIS TIME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00014	CONCEPTUS, INC.	4/7/2011	6/11/2012

Event Information:

Event Date (B3): 10/21/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/21/2010
Explant Date (E7): 3/3/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, A PATIENT REPORTED THE A RASH ON HER ABDOMINAL AREA SINCE HER ESSURE PROCEDURE IN (B)(6) 2010. NOTIFIED DOCTOR WHO WILL SEND HER TO AN ALLERGIST. FOLLOW UP PERFORMED ON (B)(6) 2011, IT WAS CONFIRMED BY SALES REP THAT NICKEL ALLERGY HAD BEEN CONFIRMED AND INSERTS HAD BEEN REMOVED OUT OF MEDICAL NECESSITY ON (B)(6) 2011 (LAPAROSCOPIC BILATERAL SALPINGECTOMY). THE PATIENT'S SYMPTOMS HAVE SINCE RESOLVED.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PATIENT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PATIENTS WITH SUSPECTE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00022	CONCEPTUS, INC.	4/13/2011	5/16/2011

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED, A PT WHO CAME BECAUSE OF CONSTANT PAIN 3 MONTHS AFTER INSERTION BY ANOTHER PRACTICE. ULTRASOUND SHOWED, THE MICRO-INSERT MISSING FROM ONE SIDE AND HER OTHER GYN KEPT TELLING HER THE PAIN WOULD GET BETTER. THE PHYSICIAN PERFORMED LAPAROSCOPY AND DID A BILATERAL SALPINGECTOMY AND COULD NOT FIND THE 2ND DEVICE. A FLAT PLATE AND CROSS TABLE LATERAL OF THE PELVIS SHOWED THE LOCATION OF THE MICRO-INSERT. PHYSICIAN FOUND THE DEVICE DENSELY PLASTERED TO 2 LOOPS OF SMALL BOWEL WITH A LARGE AMOUNT OF INFLAMMATION SURROUNDING THE AREA. THE TUBE IT CAME FROM APPEARED INTACT AS IF IT CAME ALL THE WAY THRU THE FIMBRIATED END. PHYSICIAN CONFIRMS NECESSITY/OBSERVATION TO MAKE AN EFFORT TO FIND AND REMOVE THE DEVICE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00021	CONCEPTUS, INC.	4/13/2011	3/9/2012

Event Information:

Event Date (B3): 8/17/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 4/21/2010
Explant Date (E7): 8/17/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A PATIENT WHO REQUIRED SURGERY POST ESSURE PLACEMENT. ON (B)(6) 2010 FOLLOW UP WITH PHYSICIAN: DR. REPORTED IT WAS MEDICALLY NECESSARY TO REMOVE THE DEVICE AS IT WAS FOUND OVERLYING THE LOWER ANTERIOR BODY. IT WAS SURGICALLY REMOVED AND A RIGHT TUBAL LIGATION WAS PERFORMED. THE PATIENT WHO WAS EXPERIENCING SEVERE LOWER QUADRANT PAIN, WAS GIVEN MEDICATION AND IS NOW MUCH IMPROVED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	4/19/2011	5/2/2011

Event Information:

Event Date (B3): 3/29/2011 **Report Date (B4): 4/19/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE STENT
Device Type (E2): ESSURE STENT
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6): 3/29/2011
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT UNDERGOING STERILIZATION VIA ESSURE STENTING. DURING INSERTION THE PRODUCT MISFIRED AND IT WAS UNCLEAR WHETHER A PIECE OF THE EQUIPMENT WAS RETAINED IN THE PATIENT'S FALLOPIAN TUBE. SHE WAS TRANSFERRED TO THE PACU WHERE SHE UNDERWENT A PELVIC X-RAY REVEALING THAT THERE HAD BEEN SUCCESSFUL IMPLANTATION ON THE RIGHT SIDE, HOWEVER ONLY A FRAGMENT OF THE STENT WAS SEEN ON THE LEFT SIDE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC	4/21/2011	5/9/2011

Event Information:

Event Date (B3): 4/20/2011 **Report Date (B4): 4/21/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PREMANENT BIRTH CONTROL SYSTEM
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 789036

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE WOULD NOT THREAD. IT SEEMED LIKE THE PLASTIC TIP WAS LOOSE AND COMING OFF. CAME OUT OF THE PACKAGE WITH THE MALFUNCTION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00024	CONCEPTUS, INC.	4/26/2011	3/26/2012

Event Information:

Event Date (B3): 3/4/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 6/4/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, DOCTOR REPORTED PATIENT WHO PRESENTED WITH VAGUE ABDOMINAL PAIN. A CT SCAN AND FLAT-PLATE X-RAY WERE PERFORMED, SHOWING ONE ESSURE DEVICE TO BE IN THE ABDOMINAL CAVITY. (B)(6) 2011 FOLLOW UP WITH DOCTOR FOR ADDITIONAL INFO: INITIAL HSG PERFORMED ON (B)(6) 2009 WITH BILATERAL OCCLUSION. NO ISSUES UNTIL (B)(6) 2011 WHEN SEEN FOR A BLOATED FEELING. ALL LABS AND PLAIN FILMS WERE NORMAL AT THAT TIME. PATIENT RETURNED ON (B)(6) 2011 WITH PELVIC PAIN. CT FOUND 2.7CM OVARIAN CYST WITH ASSOCIATED FREE FLUID. RIGHT ESSURE OBSERVED TO BE PROPERLY PLACED. LEFT ESSURE NOTED TO BE OUTSIDE OF THE TUBE IN THE ANTERIOR LOWER PELVIS. (B)(4) 2011 - AFTER ADDITIONAL FOLLOW UP, PHYSICIAN REPORTS THAT THE PATIENT IS SCHEDULED FOR LAPAROSCOPIC DEVICE REMOVAL AND TUBAL LIGATION IN APPROXIMATELY 30 DAYS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00023	CONCEPTUS, INC.	4/26/2011	6/7/2012

Event Information:

Event Date (B3): 6/7/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 6/7/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, PATIENT CALLED TO REPORT A NICKEL ALLERGY AND THAT SHE DID NOT KNOW THERE WAS NICKEL IN THE INSERTS PRIOR TO HAVING THEM INSERTED. FOLLOW UP CALLS TO PATIENT TO OBTAIN ADDITIONAL INFORMATION WHICH WAS PROVIDED ON (B)(6) 2011. PATIENT WILL NOT DISCLOSE NAME OF HER PHYSICIAN. SHE HAS VISITED HER PHYSICIAN WHO RECOMMENDS REMOVAL, HOWEVER THE PATIENT STATES SHE CANNOT AFFORD REMOVAL AND HAS CHOSEN TO LIVE WITH THE PAIN. HER SYMPTOMS ARE PAIN DURING OVULATION AND BODY ACHES, SHE HAS BEEN TO THE EMERGENCY ROOM 4-5 TIMES FOR ABDOMINAL PAIN AND THEY TELL HER IT IS COMING FROM HER OVARIES. SHE HAS NOT HAD A CONFIRMATION TEST FROM AN ALLERGIST AS SHE SAYS SHE DOESN'T NEED TO BECAUSE SHE KNOWS SHE HAS A NICKEL ALLERGY AS SHE BREAKS OUT ANYTIME SHE WEARS CHEAP JEWELRY, WATCHES OR EARRINGS; SAYS IT IS HEREDITARY FROM MOTHER AND GRANDMOTHER, WHO HAVE EXPERIENCED THE SAME ISSUES.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PATIENT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PATIENTS WITH SUSPECTE

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00025	CONCEPTUS, INC.	4/26/2011	6/7/2012

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 9/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, PATIENT CALLED TO REPORT A NICKEL ALLERGY. DEVICES PLACED (B)(6) 2010, HSG PERFORMED (B)(6) 2010. PATIENT REPORTS AN ALLERGY REACTION AND HER DOCTOR CONFIRMED IT NOW. SHE HAS A SEVERE RASH FROM HER TORSO TO HER FEET, HER LIVER IS SHUTTING DOWN, HER IMMUNE SYSTEM IS FAILING AND HER ADRENAL STOPPED WORKING. FOLLOW UP: SALES REP SPOKE TO DR. (B)(6), WHO SAID ALLERGY IS CONFIRMED WITH ALLERGIST. DR. LOOKED UP HER LAB RESULTS, AND WBC WAS NORMAL, THYROID WAS SLIGHTLY ELEVATED. DR. REQUESTED PATIENT TO BRING IN NICKEL ALLERGY CONFIRMATION, NO ONE HAS RECEIVED IT YET. ON (B)(6) 2011 - SALES REP RECEIVED CALL FROM DR. (B)(6), AND PATIENT WANTED HIM TO REMOVE DEVICES, NOT DR. (B)(6). REP SUGGESTED TO DR. (B)(6) TO HAVE ALLERGY REPORTS. RECEIVED CONFIRMATORY NICKEL ALLERGY TEST RESULTS FROM DR. (B)(6) HER PRIMARY CARE PHYSICIAN, AND IS TRYING TO SCHEDULE REMOVAL OF DEVICES. ON (B)(6) 2011 - REPORTED THAT DEVICES WERE REMOVED ON (B)(6) 2011 OUT OF MEDICAL NECESSITY AND CONFIRMED ALLERGY TESTS. PATIENT SYMPTOMS ARE RESOLVING.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PATIENT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. IFU WARNING: PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY P

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5020453	CONCEPTUS	4/28/2011	5/6/2011

Event Information:

Event Date (B3): 4/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH; KNH)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4):

Single Use:
Implant Date (E6): 12/10/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I FOUND OUT THAT I WAS PREGNANT AFTER HAVING AN ESSURE. I HAD THE ESSURE DONE ON (B)(6) 2009, THEN THE HSG FOLLOWING, IN (B)(6) 2010. THE HSG REPORTED THAT ONE TUBE WAS BLOCKED, THE OTHER WAS OPEN. I HAD A TUBAL LIGATION ON THE TUBE THAT WAS FOUND TO BE OPEN BY THE HSG, THIS WAS IN (B)(6) 2010. ON (B)(6) 2011, I FOUND OUT THAT I WAS PREGNANT WITH AN INTRAUTERINE PREGNANCY. IT IS THE PHYSICIAN'S BELIEF THAT THIS WAS CAUSED BY FAILURE OF THE ESSURE IN THE TUBE THAT WAS REPORTED TO BE CLOSED ON THE HSG TEST RESULTS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00026	CONCEPTUS, INC.	4/29/2011	5/17/2011

Event Information:

Event Date (B3): 3/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 689941

Single Use: Y
Implant Date (E6): 3/21/2011
Explant Date (E7): 3/30/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICES PLACED ON (B)(6) 2011. ON (B)(6), THE PT CALLED THE PHYSICIAN'S OFFICE REPORTING PAIN. VAGINAL ULTRASOUND PROVIDED NO RESOLUTION SO A CT SCAN WAS PERFORMED AND THE DEVICE WAS LOCATED IN THE PELVIS. SURGERY WAS PERFORMED, DEVICE WAS REMOVED AND TIBIAL LIGATION WAS PERFORMED. FOLLOW UP WITH PHYSICIANS OFFICE BUT RESOLUTION OF PAIN HAS NOT BEEN CONFIRMED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00029	CONCEPTUS, INC.	4/29/2011	3/27/2012

Event Information:

Event Date (B3): 3/23/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/1/2010
Explant Date (E7): 3/23/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT WAS EXHIBITING PAIN AND SPOTTING, SO PHYSICIAN REMOVED INSERT HYSTEROSCOPICALLY. THE PT HAD THE PROCEDURE DONE SOMEWHERE ELSE, SO THE PHYSICIAN HAS LIMITED INFO. THERE WERE APPROX 13-17 TRAILING COILS IN THE UTERUS WHEN PHYSICIAN WENT IN WITH THE HYSTEROSCOPE. A LARGE PORTION OF THE INNER COIL WITH THE PET FIBER WAS VISIBLE IN THE CAVITY. THE PHYSICIAN WAS ABLE TO EASILY REMOVE THE INSERT FROM THE TUBE. THE PT THEN HAD LAPAROSCOPIC TUBAL LIGATION. REMOVAL OF DEVICE AND LAPAROSCOPY WENT WELL WITH NO COMPLICATIONS. NAME OF PHYSICIAN WHO IMPLANTED THE ESSURE DEVICES IS UNK AT THIS TIME. ADD'L FOLLOW-UP PROVIDED NO ADD'L INFO. THEREFORE, RESOLUTION OF PAIN IS UNK AT THIS TIME.

Manufacturer Narrative (H10):

CONFIRMATION OF PAIN AND RESOLUTION OF SYMPTOMS COULD NOT BE OBTAINED. HOWEVER, A CONSERVATIVE DECISION WAS MADE TO SUBMIT THIS INCIDENT AS AN MDR AS IT IS POSSIBLE THE PAIN COULD HAVE BEEN RELATED TO THE PLACEMENT OF THE DEVICE.

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00027	CONCEPTUS, INC.	4/29/2011	6/6/2012

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 2/1/2011
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

BILATERAL PLACEMENT OF ESSURE MICRO INSERTS PERFORMED WITHOUT DIFFICULTY. THE PATIENT TOLERATED THE PROCEDURE WELL AND WAS DISCHARGED HOME. THREE DAYS AFTER THE PROCEDURE, HOWEVER, SHE BEGAN TO EXPERIENCE GENERALIZED PRURITUS AND INTERMITTENT NAUSEA. SHE REPORTED NO VISIBLE RASH. SHE HAD NOT HAD SIMILAR SYMPTOMS IN THE PAST. THE PATIENT WAS SEEN BY HER PHYSICIAN AND GIVEN GENERALIZED PRURITUS, SHE WAS REFERRED TO AN ALLERGY SPECIALIST. SHE DENIED HAVING ANY ALLERGIES OR PRIOR SKIN REACTIONS TO JEWELRY, WATCH STRAPS, OR BELTS. ON FURTHER QUESTIONING, HOWEVER, SHE DID RECALL THAT SHE BEGAN TO ITCH WHEN SHE WORE A HALTER TOP THAT HAD A METALLIC WIRE AROUND THE NECK. THE PATIENT UNDERWENT SKIN PATCH TESTING FOR ALLERGENS AND WAS FOUND TO HAVE HYPERSENSITIVITY TO NICKEL AND NITINOL (A NICKEL-TITANIUM ALLOY). THE DECISION WAS MADE TO REMOVE THE ESSURE MICROINSERTS. SHE UNDERWENT HYSTEROSCOPIC REMOVAL WITHOUT DIFFICULTY 8 DAYS AFTER THE INITIAL PROCEDURE, AND HER SYMPTOMS IMPROVED AFTER REMOVAL.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PATIENT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. IFU WARNING: PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY P

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00028	CONCEPTUS, INC.	4/29/2011	6/6/2012

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, PT CALLED TO REPORT A NICKEL ALLERGY AND THAT SHE DID NOT KNOW THERE WAS NICKEL IN THE INSERTS PRIOR TO HAVING THEM INSERTED. PT STATES THAT SHE IS ALLERGIC TO NICKEL BUT THE PHYSICIAN DID NOT INFORM HER. PT NO LONGER HAS INSURANCE AND CANNOT HAVE THEM REMOVED. ON (B)(6) 2011, FOLLOW UP CALLS TO PT TO OBTAIN ADDITIONAL INFO WERE NOT RETURNED. FOLLOW UP WITH PHYSICIAN CONFIRMS THAT PT DID HAVE ESSURE DEVICES PLACED IN (B)(6) 2009, BUT DR HAS NOT HEARD FROM PT SINCE. ACCORDING TO RECORDS, DURING THE PT'S VISIT, SHE REPORTED ONLY AN ALLERGY TO PENICILLIN ON HER MEDICAL FORMS. THE ESSURE DISCLOSURE FORM THAT THE PT SIGNED CONTAINED INFO THAT ESSURE IS NOT RECOMMENDED FOR WOMEN WITH NICKEL ALLERGIES.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. IFU WARNING: PTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY PRIOR TO AN

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5020642	CONCEPTUS INCORPORATED	5/17/2011	5/26/2011

Event Information:

Event Date (B3): 4/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): MICRO-INSERTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/22/2010
Explant Date (E7): 4/21/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2010, I HAD THE ESSURE STERILIZATION COILS INSERTED INTO MY TUBES. IN (B)(6) 2011, I HAD AN HSG TO CONFIRM MY TUBES WERE BLOCKED. THE LEFT TUBE WAS AND THE RIGHT WAS NOT. THE COIL ON THE RIGHT SIDE HAD FALLEN OUT OF THE TUBE INTO MY ABDOMEN AND HAD MIGRATED TO THE OTHER SIDE OF MY UTERUS, ON THE OUTSIDE. I HAD BOTH COILS REMOVED DUE TO NICKEL BEING IN THEM (WHICH I WAS NEVER TESTED FOR NOR TOLD TO ME ABOUT) AND DULL AND SOMETIMES SHARP PAIN ON THE LEFT SIDE. DURING THE INTERVENTION, THE SURGEON HAD TO REMOVE 2 PIECES OF THE COIL THAT HAD FALLEN OUT BECAUSE IT HAD BROKEN. SCAR TISSUE HAD FORMED AS WELL. THEREFORE, THE COIL FELL OUT AND BROKE INTO 2 PIECES DURING AN ATTEMPTED BILATERAL OCCLUSION OF THE FALLOPIAN TUBES. I HAD A REACTION TO THE ANESTHESIA AND NEEDED SEVERAL DAYS TO RECUPERATE. BECAUSE THIS PROCEDURE DID NOT WORK AND THE PRODUCT WAS DEFECTIVE, I ALSO HAD A TUBAL LIGATION DURING THE LAPAROSCOPIC SURGERY. IT STATES ON THE LITERATURE THAT 2.2% OF WOMEN IN THEIR STUDIES EXPERIENCED EXPULSION. I CAN BE ADDED TO THAT PERCENTAGE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00030	CONCEPTUS, INC.	5/20/2011	7/21/2011

Event Information:

Event Date (B3): 3/8/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 782774

Single Use: Y
Implant Date (E6):
Explant Date (E7): 2/11/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, SALES REP CALLED IN AN ISSUE REPORTED BY A PHYSICIAN WHERE A PT PRESENTED WITH PAIN AND AT HER (THE PT'S) REQUEST, DR (B)(6) REMOVED THE DEVICES LAPAROSCOPICALLY. FOLLOW UP TO GATHER ADDITIONAL INFORMATION FROM PHYSICIAN / PHYSICIAN'S OFFICE WAS PERFORMED ON (B)(6) 2011. CONFIRMATION OF MEDICAL NECESSITY AND RESOLUTION OF PT SYMPTOMS WAS NEVER PROVIDED. THE SALES REP DID STATE IN A FOLLOW UP CALL THAT THE DR DID NOT MENTION MEDICAL NECESSITY. THE PT FELT PAIN, A TEST WAS DONE TO RULE OUT INFECTION, AND PT WANTED REMOVAL. NO OTHER TREATMENT WAS ATTEMPTED BEFORE SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00031	CONCEPTUS, INC.	5/20/2011	9/28/2011

Event Information:

Event Date (B3): 3/8/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 4/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN CALLED TO REPORT PAIN FOLLOWING PLACEMENT OF ESSURE DEVICES. THE DEVICES WERE PLACED IN PT (B)(6) 2011. PHYSICIAN FOLLOWED THE ESSURE PROCEDURE WITH A THERMACHOICE ABLATION AND STATES THAT SHE IS NOT SURE IF THE PT'S PAIN IS DUE TO THE ESSURE DEVICES OR FROM THE ABLATION. ALLERGY TESTS PERFORMED AND RULED OUT. HYSTERECTOMY BEING CONSIDERED. SEVERAL ATTEMPTS WERE MADE TO GATHER ADDITIONAL INFO. RETURNED CALL ON 05/02/2011 FROM PHYSICIAN. THE DR. CONFIRMED THAT A HYSTERECTOMY WAS PERFORMED AND DEVICES REMOVED. PT'S PAIN HAS RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00032	CONCEPTUS, INC.	5/20/2011	4/5/2012

Event Information:

Event Date (B3): 4/21/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 823468

Single Use: Y
Implant Date (E6): 4/21/2011
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3): 5/3/2011

Event Description (B5):

A PHYSICIAN ENCOUNTERED A PROBLEM DURING PLACEMENT OF ESSURE MICRO-INSERTS IN HIS PT; 1 ESSURE HANDLE DID NOT DETACH FROM THE MICRO-INSERT. UPON ENCOUNTERING PLACEMENT DIFFICULTY, THE PHYSICIAN ATTEMPTED TO PULL THE CATHETER AND DEVICE OUT OF THE PT'S OSTIUM, BUT NEITHER WOULD RELEASE. THE PHYSICIAN UTILIZED WIRE CUTTERS TO DETACH PURPLE HANDLE FROM CATHETER IN ORDER TO REMOVE HYSTEROSCOPE FROM PT AND THEN WALKED THE PT TO THE OPERATING ROOM FOR EMERGENCY SURGERY. THE PHYSICIAN REMOVED THE CATHETER AND DELIVERY WIRE FROM DEVICE TRANS-VAGINALLY/TRANS-CERVICALLY, THEN VISUALIZED PROPERLY PLACED MICRO-INSERT IN THE RIGHT OSTIUM. THE PHYSICIAN REPORTED 'NO INJURY' TO PT AND NO FURTHER ACTION TAKEN OTHER THAN THAT DESCRIBED ABOVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5020830	CONCEPTUS INC.	5/27/2011	6/10/2011

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/20/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED IN FALLOPIAN TUBES IN 2007. TOOK THE 3 MONTH VERIFICATION TEST. CONFIRMED 100% BLOCKED. HAVE HAD HEAVY BLEEDING, PAINFUL CRAMPS SINCE THEN. BECAME PREGNANT (B)(6) 2010. HAD A BABY (B)(6) 2010. I HAVE COME ACROSS MANY WOMEN THROUGH INTERNET WITH SAME PROBLEMS. SPOKE TO ESSURE TO REPORT PROBLEMS PREGNANCY AND BIRTH. THEY SAY SOME ONE WILL CALL BACK BUT NUMEROUS CALLS SINCE LAST YR AND STILL NO CALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00034	CONCEPTUS, INC.	6/10/2011	6/29/2011

Event Information:

Event Date (B3): 4/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 2/6/2010
Explant Date (E7): 4/14/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INITIAL INFORMATION PROVIDED TO CONCEPTUS THROUGH MEDWATCH FORM: (B)(4). ESSURE DEVICES PLACED ON (B)(6) 2010. THE PATIENT REPORTED EXPERIENCING PAIN SOON AFTER IMPLANTATION AND WITHIN TWO WEEKS, THE PAIN BECAME MORE LOCALIZED ON HER LEFT SIDE. ON (B)(6) 2010, THE PATIENT PRESENTED WITH PAIN AND WAS TAKEN TO THE ER FOR ABDOMINAL SURGERY, AT WHICH TIME THE DEVICES WERE REMOVED. THE PATIENT REPORTS CONTINUED PAIN, CRAMPING, AND HORMONAL PROBLEMS, BUT THAT THE MAJORITY OF THE PAIN HAS SUBSIDED. FOLLOW UP INFORMATION PROVIDED BY MEDICAL OFFICE: THE PHYSICIAN HAS REQUESTED SHE HAVE AN HSG BUT THE PATIENT HAS NOT RETURNED SINCE THE SURGERY. ADDITIONALLY, THE PATIENT IS RELYING ON THE REMAINING DEVICE IN HER RIGHT TUBE FOR STERILITY. PATIENT WAS RELIEVED OF PAIN UPON RELEASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00033	CONCEPTUS, INC.	6/10/2011	9/26/2011

Event Information:

Event Date (B3): 3/22/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 725763

Single Use: Y
Implant Date (E6): 3/1/2011
Explant Date (E7): 3/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT PRESENTED WITH PELVIC PAIN 2 WEEKS POST-ESSURE PLACEMENT. THE PHYSICIAN PERFORMED LAPAROSCOPY AND FOUND THAT ESSURE HAD PERFORATED THE FALLOPIAN TUBE. THE PHYSICIAN REMOVED BOTH MICRO-INSERTS DUE TO THE LOCATION OF THE DEVICES. RESOLUTION OF SYMPTOMS HAS NOT YET BEEN CONFIRMED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00036	CONCEPTUS, INC.	6/22/2011	8/24/2011

Event Information:

Event Date (B3): 4/29/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 11/22/2010
Explant Date (E7): 4/21/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORT OF PAIN FOLLOWING MICRO-INSERT PLACEMENT. HSG CONFIRMATION TEST WAS PERFORMED AND IT SHOWED THAT THE MICRO-INSERT MIGRATED FROM THE RIGHT FALLOPIAN TUBE, WAS FOUND IN THE ABDOMEN, AND WAS REMOVED VIA SURGERY ON (B)(6) 2011. PATIENT RESPONDED TO ADDITIONAL REQUEST FOR INFORMATION, STATING THAT THE PHYSICIAN DEEMED REMOVAL MEDICALLY NECESSARY TO REMOVE THE DEVICE THAT PERFORATED THE TUBE AND MIGRATED INTO ABDOMEN. THE PATIENT REPORTS THAT, IN GENERAL, HER PAIN HAS SUBSIDED, ALTHOUGH HER ONLY MENSTRUAL CYCLE SINCE REMOVAL WAS MORE PAINFUL THAN USUAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00035	CONCEPTUS, INC.	6/22/2011	6/18/2012

Event Information:

Event Date (B3): 4/29/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/15/2009
Explant Date (E7): 4/25/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

POST ESSURE PLACEMENT REPORT OF NICKEL ALLERGY; PT IS EXPERIENCING MIGRAINE HEADACHES SINCE DEVICE PLACEMENT, ABOUT 2 YEARS. CURRENT PHYSICIAN IS NOT THE DOCTOR WHO PLACED THE DEVICES. THE PT HAS NOT HAD NICKEL ALLERGY PERFORMED, HOWEVER, THE PHYSICIAN FELT THE BEST SOLUTION WOULD BE TO REMOVE THE DEVICES. THE DEVICES WERE REMOVED BY LAPAROSCOPY WITHOUT DIFFICULTY. SYMPTOMS HAVE RESOLVED SINCE DEVICE REMOVAL.

Manufacturer Narrative (H10):

IFU CONTRAINDICATION: THE ESSURE SYSTEM SHOULD NOT BE USED IN ANY PT WITH KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST (SEE WARNINGS SECTION BELOW FOR PTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL). IFU WARNING: PTS WITH SUSPECTED HYPERSENSITIV

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021133	CONCEPTUS INC.	6/23/2011	7/1/2011

Event Information:

Event Date (B3): 6/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 626207

Single Use:
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE OBTAINING THE ESSURE DEVICE IN 2007. I HAD MY F/U TEST DONE TO DETERMINE THAT BOTH TUBES WERE FULLY BLOCKED. I HAVE HAD DEBILITATING BLEEDING DURING MY MENSTRUAL CYCLES AND EXCESSIVE PAIN IN MY ABDOMEN. DATES OF USE: (B)(6) 2007 - (B)(6) 2011.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	6/23/2011	7/6/2011

Event Information:

Event Date (B3): 4/5/2011 **Report Date (B4): 6/23/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE TUBAL OCCLUSION DEVICE
Device Type (E2): TRANSCERVICAL TUBAL ACCESS CATHETER
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 806704

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE TUBAL OCCLUSION DEVICE WAS PLACED IN THE RIGHT FALLOPIAN TUBE PER PROTOCOL. THE DEVICE WAS DEPLOYED. THE COIL REMAINED IN THE DEVICE AND METAL GUIDING WIRE REMAINED IN THE PATIENT. THE WIRE WAS GRASPED VIA THE PORT ON THE SIDE OF THE HYSTEROSCOPE AND REMOVED. THERE WAS MINIMAL RESISTANCE, AND THE WIRE BROKE INTO PIECES ON ITS WAY OUT THROUGH THE HYSTEROSCOPE. THE PIECES WERE SUCCESSFULLY REMOVED BY THE SURGEON USING FORCEPS. THE SURGEON ELECTED NOT TO TRY A SECOND ESSURE TUBAL OCCLUSION DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021156	CONCEPTUS, INC.	6/24/2011	7/6/2011

Event Information:

Event Date (B3): 6/21/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): CONCEPTUS
Model # (E4):
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use:
Implant Date (E6): 9/15/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I WOULD LIKE TO UNDERSTAND WHETHER A PRODUCT I USED FOR STERILIZATION (ESSURE PERMANENT BIRTH CONTROL) IS BEING CORRECTLY REPRESENTED BY THE MANUFACTURER CONCEPTUS. LAST (B)(6), I SELECTED ESSURE BECAUSE IT WAS ADVERTISED AS THE MOST EFFECTIVE METHOD OF PERMANENT BIRTH CONTROL WITH A 99.74% RATE OF EFFECTIVENESS, AND ADVERTISED AS BEING THE ONLY PERMANENT BIRTH CONTROL WITH NO PREGNANCIES DURING THE CLINICAL TRIALS, BOTH OF WHICH I ASSUME ARE TRUE AND VETTED BY THE FDA. I AM ONE OF THE .26% FOR WHOM THE PRODUCT DID NOT WORK, EVEN THOUGH THE FOLLOW-UP DYE TEST AFTER THREE MONTHS INDICATED MY TUBES WERE COMPLETELY BLOCKED AND WOULD LIKE TO UNDERSTAND IF THE FAILURE RATE IS STILL BEING CORRECTLY REPRESENTED NOW THAT THIS PRODUCT HAS BEEN ON THE MARKET FOR MORE THAN EIGHT YEARS. COMMENTARY ON VARIOUS INTERNET CHAT ROOMS INDICATES THERE ARE SEVERAL WOMEN FOR WHOM ESSURE HAS FAILED. I HAVE NO IDEA HOW THIS NUMBER COMPARES WITH THE NUMBER OF ESSURE PROCEDURES THAT HAVE BEEN DONE. HOWEVER, I DO KNOW MY OB-GYN ALONE HAS REPORTED TWO PREGNANCIES POST THIS PROCEDURE - AND I DOUBT SHE'S DONE 800 PROCEDURES TO MAKE HER FAILURE RATE CONSISTENT WITH THAT ADVERTISED. AFTER MY PREGNANCY, SHE HAS SINCE STOPPED ADMINISTERING ESSURE ALTOGETHER. THE COMPANY ALSO ADVERTISES THAT NO GENERAL ANESTHESIA IS REQUIRED; HOWEVER MY OB-GYN STRONGLY SUGGESTED IT TO ENSURE THAT NO MOVEMENT COMPROMISE THE PROCEDURE. HAD I KNOWN GENERAL ANESTHESIA WAS CRITICAL TO ENSURE PROPER IMPLEMENTATION, I WOULD NOT HAVE CONSIDERED ESSURE. I HOPE YOU ARE ABLE TO AUDIT OR OTHERWISE COMPEL THE COMPANY TO BE TRANSPARENT WITH THE FAILURE RATES OF THIS PRODUCT TO HELP AVOID UNPLANNED PREGNANCIES OF OTHER WOMEN IN THE FUTURE. DATES OF USE: (B)(6) 2010 - (B)(6) 2011.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021164		6/24/2011	7/6/2011

Event Information:

Event Date (B3): 5/26/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): IUD
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT DEVELOPED RASH AFTER ESSURE IUD WAS IMPLANTED. PATIENT HAD TO BE STARTED ON PREDNISONE AND DIPHENHYDRAMINE. UNCLEAR IF IUD HAS BEEN REMOVED. DATES OF USE: UNKNOWN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021241	CONCEPTUS INC	6/30/2011	7/12/2011

Event Information:

Event Date (B3): 7/28/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE CONTRACEPTIVE 99.74%
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 7/28/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2010, I WENT TO THE WOMEN'S CTR IN (B)(6) TO HAVE THE ESSURE PROCEDURE DONE WITH NO ANESTHESIA BECAUSE I AM ALLERGIC TO ASPIRIN. ACCORDING TO THE DR EVERYTHING WAS FINE AND THE COILS WERE SUCCESSFULLY PLACED. THREE MONTHS LATER I WENT FOR A F/U AND WAS TOLD THAT THE PROCEDURE WAS SUCCESSFUL AND MY TUBES WERE BLOCKED. ON (B)(6) 2011, I TOOK AN OVER THE COUNTER PREGNANCY TEST THAT HAD A POSITIVE RESULT. AT THIS TIME I CALLED THE DR AT THE WOMEN'S CTR AND TOLD THEM WHAT HAD OCCURRED AND SET AN APPOINTMENT FOR (B)(6) 2011. I WENT IN THE MORNING AND SAW THE DR AND THEY CONFIRMED WITH A URINE TEST THAT I WAS PREGNANT. AT THIS TIME THE DR TOLD ME MY BODY MUST HAVE HEALED THE SCARRING AND I WAS 1 OF THE 3 IN 1,000. I WENT BACK LATER THAT DAY AND GOT A SONOGRAM AND WAS TOLD I WAS (B)(6) PREGNANT AND THE BABY WAS IN THE UTERUS AND HEALTHY. THIS HAS CAUSED EMOTIONAL AND MENTAL DISTRESS AS NOW I AM FORCED TO TERMINATE A HEALTHY BABY. I TRULY DO NOT BELIEVE THIS PROCEDURE IS 99.74% EFFECTIVE AS I HAVE SINCE COME ACROSS LOTS OF SITES WITH WOMEN EXPERIENCING THE SAME THING AND ON TOP OF THAT I HAVE CRAMPING TYPE PAINS WHICH I DID MAKE THE DR AWARE OF AND SHE SAID NOTHING. I ALSO ASKED WHERE THE COILS WERE AND WAS TOLD THAT THEY COULD NOT SEE THEM IN THE SONOGRAM BECAUSE THE OVARIES HAD MOVED DUE TO THE PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021261	UNKNOWN	7/1/2011	7/12/2011

Event Information:

Event Date (B3): 4/14/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THERE SEEMS TO BE A PROBLEM WITH THE CONTRACEPTIVE ESSURE. I HAD THE PROCEDURE DONE IN (B)(6) 2011 AND HAVE HAD NOTHING BUT COMPLICATIONS FROM IT SUCH AS SEVERE CRAMPING, ABDOMINAL PAIN, AND SEVERE BACK PAIN. ALSO THERE SEEMS TO BE MISCONCEPTION ABOUT ESSURE THE INFO PROVIDE TO PTS BEFORE SURGERY ONLY TELLS PT WHAT TO EXPECT DURING AND A FEW HOURS AFTERWARDS THERE IS NOTHING THAT TELLS YOU THE LONG TERM EFFECT THIS PROCEDURE WILL HAVE ON YOUR BODY SUCH AS SPOTTING ALL THE TIME OR SEVERE BLEEDING DUE TO THE UTERUS BEING SHIFTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021356	CONCEPTUS	7/13/2011	7/19/2011

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/25/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL DONE IN (B)(6) 2011. I HAVE HAD PAIN WHERE THE DEVICE ARE LOCATED, EACH TIME THE PAIN GETS WORSE AND LASTS LONGER. IT IS A SHARP PAIN WITH PRESSURE AND HAS DEVELOPED MORE SYMPTOMS, SEVERE BACK PAIN, WEAKNESS IN MY LEGS, EXTREMELY BAD HEADACHES THAT MAKE ME NAUSEOUS AND HAVE TO LAY DOWN. I'M ALWAYS TIRED NOW. I HAVE HAD EPISODES OF BLEEDING DURING SEXUAL INTERCOURSE WITH MY HUSBAND THAT LEAVES HIM COVERED IN BLOOD AND I WORK OUT, DOING CARDIO EXERCISE FOR 1.5 TO 2 HRS 3 TO 4 TIMES A WEEK WITH A HALF HOUR WEIGHTS 2 DAYS A WEEK. I EAT VERY HEALTHY BUT CAN NOT LOSE THE WEIGHT THAT HAS DEVELOPED IN MY MID SECTION, NO MATTER WHAT I DO. I JUST WANT TO FEEL LIKE MYSELF AGAIN. I DIDN'T GO THROUGH ANY OF THIS UNTIL AFTER I HAD THIS PROCEDURE DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00039	CONCEPTUS, INC.	7/13/2011	7/21/2011

Event Information:

Event Date (B3): 3/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/21/2011
Explant Date (E7): 4/11/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT PRESENTED WITH PELVIC PAIN WITH DAYS OF ESSURE PLACEMENT. THE PHYSICIAN PERFORMED LAPAROSCOPY TO PERFORM A TUBAL LIGATION AND REMOVE THE DEVICES. AFTER REMOVAL, THE PT'S SYMPTOMS RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00040	CONCEPTUS, INC.	7/13/2011	7/21/2011

Event Information:

Event Date (B3): 3/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/21/2011
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT PRESENTED WITH PELVIC PAIN WITHIN DAYS OF ESSURE PLACEMENT. C-SECTIONS AND MESH, PT WAS REFERRED FOR REMOVAL. DEVICES WERE REMOVED LAPAROSCOPICALLY. AFTER REMOVAL, THE PT'S SYMPTOMS RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00037	CONCEPTUS, INC.	7/13/2011	9/13/2011

Event Information:

Event Date (B3): 3/24/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 3/1/2011
Explant Date (E7): 5/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT PRESENTED WITH LOCALIZED, LEFT SIDED PAIN POST-ESSURE PLACEMENT. THE PHYSICIAN PRESCRIBED PAIN MEDICATION BUT THE PAIN PERSISTED. THE PHYSICIAN PERFORMED HYSTEROSCOPY AND REMOVED WHAT HE BELIEVED TO BE PART OF THE DELIVERY CATHETER FROM THE LEFT SIDE TUBE. THE PATIENT IS FINE AND THE PHYSICIAN IS SCHEDULING AN ADDITIONAL HSG IN ONE MONTH'S TIME TO CONFIRM OCCLUSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00038	CONCEPTUS, INC.	7/14/2011	7/22/2011

Event Information:

Event Date (B3): 3/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/14/2008
Explant Date (E7): 3/9/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT PRESENTED WITH PELVIC PAIN AND HEAVY BLEEDING DURING MENSTRUATION 1.5 YEARS POST-ESSURE PLACEMENT. THE PHYSICIAN PERFORMED LAPAROSCOPY/SALPINGECTOMY ON RIGHT TUBE AND FOUND THAT THE DEVICE WAS EMBEDDED IN THE WALL OF THE TUBE. THE PHYSICIAN THEN WENT IN USING HYSTEROSCOPY IN ORDER TO REMOVE THE REMAINDER, WHICH CAME OUT IN PIECES. PHYSICIAN THEN PERFORMED D&C AS A MEANS TO REMOVE ALL REMAINING PIECES FROM THE UTERUS. SYMPTOMS HAVE RESOLVED SINCE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00041	CONCEPTUS, INC.	7/15/2011	7/25/2011

Event Information:

Event Date (B3): 1/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 11/26/2010
Explant Date (E7): 6/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT PRESENTED WITH PAIN POST-ESSURE PLACEMENT. PHYSICIAN RAN ALL TYPES OF TESTS TO RULE OUT ANY OTHER ISSUES AND FINALLY DECIDED TO REMOVE THE DEVICES. DEVICES WERE REMOVED LAPAROSCOPICALLY/SALPINGECTOMY. PT'S PAIN SUBSIDED AND IS FINE POST PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021421	CONCEPTUS INC., USA	7/18/2011	7/26/2011

Event Information:

Event Date (B3): 12/23/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS INC. USA
Device Type (E2): ESSURE IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4): 627759 LEFT TUBE; 627436 RIGHT TUBE

Single Use:
Implant Date (E6): 12/23/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS DONE IN (B)(6) 2008. WHAT WAS SUPPOSED TO BE A 12-15 MIN PROCEDURE TOOK OVER 45 MIN DUE TO THE DOCTOR HAVING DIFFICULTIES PLACING THE IMPLANTS INTO MY FALLOPIAN TUBES. THE DOCTOR FIRST TRIED TO DO THE PROCEDURE IN (B)(6) 2008 WITHOUT SUCCESS AND I HAD TO GO BACK AGAIN IN (B)(6) 2008. I HAVE BEEN SICK FOR OVER 2 YRS NOW AND DIDN'T KNOW WHY. I WAS HOSPITALIZED 4 TIMES IN A 2 WEEK PERIOD THIS (B)(6) 2011 WITH SEVERE ABDOMINAL PAIN, CHEST PAIN, FAINTING, HEADACHES, MUSCLE ACHES, DIARRHEA, ETC. THE ER DOCTOR HAD A CT SCAN DONE AND IT SHOWED THAT I HAVE AN ESSURE COIL LODGED IN MY RECTAL WALL! I HAVE AN APPOINTMENT WITH A COLORECTAL SURGEON TODAY TO DISCUSS SURGERY TO REMOVE THE LODGED COIL AND ANOTHER APPOINTMENT WITH AN OB/GYN TO DISCUSS REMOVAL OF THE COIL IN MY FALLOPIAN TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021465		7/20/2011	8/2/2011

Event Information:

Event Date (B3): 4/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/7/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE DONE, IN THE OPERATING ROOM, THE DISPOSABLE DEVICE MALFUNCTIONED, MY PHYSICIAN STATED SHE WAS NOT AWARE THAT THE ESSURE COIL HAD DEPLOYED. DURING THE RECOMMENDED HSG 3 MONTHS AFTER, IT WAS FOUND THAT I HAVE TWO DEVICES PLACED IN MY LEFT FALLOPIAN TUBE. ONE OF WHICH IS COILED COMPLETELY IN A CIRCLE. I HAVE BEEN HAVING CONSTANT PAIN SINCE THIS PROCEDURE WAS DONE. NOW I KNOW WHY. AS A RESULT, I HAVE TO NOW UNDERGO A SECOND SURGERY TO REMOVE MY FALLOPIAN TUBES, IF NOT MY UTERUS ALSO. I FEEL THAT IF THE DEVICE USED TO PLACE THE COILS, IS DEPLOYED, AND A PHYSICIAN IS NOT AWARE WHETHER OR NOT THE COIL WENT IN, THAT THEIR SHOULD DEFINITELY BE A WAY OF CHECKING TO MAKE SURE BEFORE AUTOMATICALLY ASSUMING IT DID NOT GO IN AND PLACING ANOTHER ONE. I FEEL THAT THE SECOND COIL BEING PLACED HIT THE FIRST ONE AND CAUSED THE SECOND COIL TO BE IN CIRCLE AT THE LEVEL OF MY UTERINE CORNUA. THE FIRST ONE PLACED IS NOW IN MY DISTAL FALLOPIAN TUBE. NOT SURE YET WHETHER OR NO THIS PERFORATED MY TUBE. SURGERY IS SCHEDULED FOR (B)(6). TO SAY THE LEAST, I AM NOT AT ALL HAPPY ABOUT THIS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00042	CONCEPTUS, INC.	7/21/2011	8/1/2011

Event Information:

Event Date (B3): 3/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/1/2008
Explant Date (E7): 6/14/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORT OF PAIN, POST-ESSURE PLACEMENT (IMPLANTED (B)(6) 2008). PAIN STARTED ABOUT 1 YEAR POST PLACEMENT; EXPLORATORY LAPAROSCOPIC SURGERY IN (B)(6) 2010 AND FOUND SCAR TISSUE ATTACHED TO THE BOWEL AND REMOVED IT. THE PATIENT SAID THE PAIN SUBSIDED FOR ABOUT 6 MONTHS AND THEN STARTED UP AGAIN IN (B)(6) OF 2010, INCLUDING PAINFUL MENSTRUAL CYCLES AND WAS GIVEN DEPO TO HELP ALLEVIATE THE PAIN. ON (B)(6), 2011, DR (B)(6) DID A HYSTERECTOMY AND REMOVED THE UTERUS AND FALLOPIAN TUBES. MICRO-INSERTS HAD PERFORATED BOTH TUBES, AND THAT MOST LIKELY THAT WAS THE SOURCE OF HER PAIN. FOLLOW UP WITH PATIENT (B)(6) 2011, WHO REPORTS RESOLUTION OF PAIN SINCE REMOVAL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00043	CONCEPTUS, INC.	7/21/2011	8/1/2011

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 752413

Single Use: Y
Implant Date (E6): 9/1/2010
Explant Date (E7): 6/8/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORT OF PAIN, POST-ESSURE PLACEMENT (IMPLANTED (B)(6) 2010). THREE-MONTH POST-OP HSG SHOWED PROPER PLACEMENT AND OCCLUSION, BUT PATIENT REPORTED PAIN ABOUT 2 WEEKS LATER. TREATMENT FOR PELVIC INFLAMMATORY DISEASE DID NOT RESOLVE SYMPTOMS. ON (B)(6), 2011, THE PHYSICIAN PERFORMED A HYSTERECTOMY AS PREVIOUS INTERVENTION DID NOT RESOLVE PAIN AND THERE WAS NO OTHER OBVIOUS CAUSE FOR THE PAIN. POST-OP CONCLUSION REPORTS THAT PAIN HAS SUBSIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00044	CONCEPTUS, INC.	7/21/2011	8/1/2011

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/28/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORT OF CHRONIC PELVIC PAIN BEING EXPERIENCE FOR 1-YEAR. PAIN BEGAN POST-ESSURE PLACEMENT AND DOCTOR REPORTS THAT PATIENT DENIES ANY HISTORY OF PAIN PRIOR TO ESSURE PLACEMENT. THE PHYSICIAN PERFORMED LAPAROSCOPIC HYSTERECTOMY WITH BILATERAL SALPINGECTOMY. AT THE TIME OF LAPAROSCOPY, THE LEFT ESSURE COIL WAS NOTED TO HAVE PERFORATED THE LEFT CORNUA. PHYSICIAN CONCLUDED THAT THE PAIN IS MOST LIKELY ASSOCIATED WITH THE PERFORATION CAUSED BY ESSURE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	7/22/2011	7/29/2011

Event Information:

Event Date (B3): 4/26/2011 **Report Date (B4): 7/22/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DELIVERY CATHETER
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 825626

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WAS INTRODUCED THROUGH THE INTRODUCER TO THE LEFT CORNUA UP TO THE BLACK MARKER BY THE PHYSICIAN. THE WHEEL WAS ATTEMPTED TO BE ACTIONED BUT DID NOT MOVE. NO ACTION OF THE WHEEL OCCURRED. THE BUTTON WAS COMPLETELY DEPRESSED, BUT THERE WAS NO MOTION OF THE WHEEL EITHER FORWARD OR BACKWARD. THE ESSURE APPARATUS WAS RETRACTED BUT DID NOT MOVE. THE PHYSICIAN USED GRASPERS TO REMOVE THE DEVICE AND ESSURE COILS WERE NOTED IN THE UTERINE CAVITY. THE COILS WERE REMOVED COMPLETELY BY THE PHYSICIAN. A SECOND DEVICE WAS OPENED AND FUNCTIONED PROPERLY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00045	CONCEPTUS, INC.	7/22/2011	8/9/2011

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INITIAL INFORMATION PROVIDED TO CONCEPTUS THROUGH JOURNAL OF WOMEN'S HEALTH, VOLUME 20, NUMBER 5, 2011. PATIENT PRESENTED WITH ACUTE ONSET OF LOWER QUADRANT ABDOMINAL PAIN 3 YEARS POST-ESSURE PLACEMENT. PATIENT DEMONSTRATED SIGNS OF ACUTE PERITONITIS SO EXPLORATORY LAPAROSCOPY WAS PERFORMED AND REVEALED RUPTURED TUBO-OVARIAN ABSCESS. ANTIBIOTICS INITIATED. POST-OP DAY 7, PATIENT HAD RECURRENCE OF ACUTE PERITONITIS NECESSITATING EVENTUAL HYSTERECTOMY. THE INFECTIOUS DISEASE CONSULTANT SUGGESTED REMOVAL OF ALL FOREIGN BODIES, INCLUDING MICRO-INSERTS, FROM PELVIS. HYSTERECTOMY WAS PERFORMED AND MICRO-INSERTS FOUND TO BE PROPERLY PLACED IN BOTH FALLOPIAN TUBES.

Manufacturer Narrative (H10):

COMMENTS: THE AUTHOR/PHYSICIAN HAS NOT IMPLIED THAT THE ESSURE MICRO-INSERT IS THE SOURCE OF THE INFECTION, BUT DOES SUGGEST THAT THE DEVICE MAY SERVE AS A 'NIDUS' FOR INFECTION. CONCEPTUS HAS MADE THE CONSERVATIVE DECISION TO REPORT THIS EVENT ON THIS MD

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00046	CONCEPTUS, INC.	7/22/2011	8/22/2011

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 5/28/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORT OF AN ECTOPIC PREGNANCY FOLLOWING THE ESSURE PLACEMENT PROCEDURE. THE PATIENT HAD A PREVIOUS LEFT SALPINGECTOMY, THEREFORE, ONLY THE RIGHT FALLOPIAN TUBE REQUIRED A MICRO-INSERT. THE 3 MONTH POST-OP, HSG WAS PERFORMED AND REVEALED OCCLUSION AND PROPER PLACEMENT WHILE THERE WAS NOTED SOME SPILLAGE INTO THE PERITONEAL CAVITY ON THE LEFT SIDE. PHYSICIAN BELIEVES THE EGG WAS FERTILIZED ON THE LEFT SIDE AND MIGRATED INTO THE FAR DISTAL PORTION OF THE RIGHT FALLOPIAN TUBE NEAR THE OVARY. DR PERFORMED SURGERY TO REMOVE THE PREGNANCY AND AT THAT TIME, PERFORMED A SALPINGECTOMY OF THE RIGHT TUBE. AT THE TIME OF THE REMOVAL, SHE DID NOT FIND THE DEVICE. THE PATIENT'S PAIN DID SUBSIDE POST SURGERY.

Manufacturer Narrative (H10):

THE PHYSICIAN CLEARLY INDICATED HER ASSUMPTION THAT "THE EGG WAS FERTILIZED ON THE LEFT SIDE AND MIGRATED INTO THE FAR DISTAL PORTION OF THE RIGHT FALLOPIAN TUBE NEAR THE OVARY." THE LEFT SIDE BEING THE SIDE WHERE NO DEVICE PLACEMENT OCCURRED DUE TO THE S

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021589	CONCEPTUS	8/2/2011	8/10/2011

Event Information:

Event Date (B3): 7/18/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE STERILIZATION
Device Type (E2): STERILIZATION COIL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 825629

Single Use:
Implant Date (E6): 7/18/2011
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/18/2011

Event Description (B5):

DOCTOR ATTEMPTED TO DEPLOY ESSURE COIL INTO THE TUBE ON LEFT SIDE. DOCTOR STATED THE SHEATH WAS TORN AS HE STARTED TO DEPLOY THE COIL CAUSING THE COIL NOT TO GO IN PROPERLY. HE THEN TRIED TO PULL OUT THE ESSURE COIL AND IT BROKE OFF 3 DIFFERENT TIMES. THREE PIECES OF THE COIL WERE TAKEN OUT LEAVING SOME COIL STILL IN THE TUBE. A NEW ESSURE WAS ATTEMPTED ON THE LEFT SIDE AND THEY WERE NOT ABLE TO INSERT IT INTO THE TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021632	CONCEPTUS	8/2/2011	8/11/2011

Event Information:

Event Date (B3): 7/21/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 10/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2008, I GOT ESSURE (PRODUCT BY CONCEPTUS) DONE - NON INVASIVE PERMANENT FORM OF BIRTH CONTROL. IT TOOK 12 MONTHS FOR MY FALLOPIAN TUBES TO BE FULLY BLOCKED, AS WHERE NO EGG WILL GET OUT AND NO SPERM WILL BE ABLE TO PASS. SHORTLY AFTER GETTING ESSURE, I EXPERIENCED HEAVIER THAN NORMAL MENSTRUAL BLEEDING AND CRAMPING, WHICH I DIDN'T HAVE ISSUES WITH BEFORE THE PROCEDURE. IT SEEMS LIKE, AS THE MONTHS WENT BY, THE MORE HEAVIER THE PERIODS AND MORE SEVERE THE CRAMPS. SINCE I DIDN'T BLEED THROUGH A TAMPON IN 1 HR (EVEN THOUGH IT WAS MORE LIKE A TAMPON EVERY 1 HR AND A HALF) THE DR SAID TO JUST TAKE IT EASY AND TAKE MOTRIN FOR THE PAIN. AFTER READING SEVERAL FORUMS ONLINE ABOUT OTHER PTS WHO'VE HAD ESSURE; THEY HAVE SIMILAR STORIES AS ME OR WORSE, SPRINGS/COILS MIGRATE TO OTHER PARTS OF THE BODY CAUSING SEVERE PAIN OR OTHER HEALTH PROBLEMS. NOW, ON (B)(6) 2011, I WAS TOLD THAT I WAS PREGNANT. WE CONFIRMED THE PREGNANCY ON (B)(6) 2011. HOW AM I PREGNANT IF ESSURE IS A PERMANENT FORM OF BIRTH CONTROL?

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021651	CONCEPTUS	8/3/2011	8/15/2011

Event Information:

Event Date (B3): 7/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/20/2010
Explant Date (E7): 7/21/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, I WAS ADMITTED INTO THE HOSP WITH SEVERE ABDOMINAL PAIN. IT WAS WORSE THAN GIVING BIRTH. NOW, FOR OVER A YEAR, I HAVE BEEN DEALING WITH CRAMPING ON MY RIGHT SIDE, FATIGUE AS WELL. ON (B)(6), I HAD EMERGENCY SURGERY. THE SURGEON THOUGHT IT WAS MY APPENDIX; HOWEVER, HE DID REMOVE THE APPENDIX. THAT WASN'T THE PROBLEM. I HAD THE MEDICAL DEVICE ESSURE IN MY FALLOPIAN TUBES. IT HAD RIPPED THROUGH MY TUBE AND AS A RESULT OF IT, THE SURGEON HAD TO REMOVE MY TUBE WHICH WAS NOT FAIR TO ME TO HAVE GONE THROUGH SOMETHING LIKE THIS WHEN I WAS REASSURED IT WAS SAFE. IN FACT, THE DR ONLY PUT ONE COIL IN. NOT IN MY LEFT TUBE EITHER, ONLY IN THE RIGHT. AS A RESULT OF THIS, I HAVE OUTSTANDING HOSPITAL BILLS AND NOW HAVE TO SUFFER WITH THE CRAMPING. THE DR HAD TOLD MY FIANCE I WOULD' VE DIED IF I HADN'T COME IN. THIS PRODUCT IS DANGEROUS AND SHOULDN'T BE ON THE MARKET TO USE ON WOMEN AT ALL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021801	CONCEPTUS	8/17/2011	8/26/2011

Event Information:

Event Date (B3): 12/27/2006 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE TUBAL LIGATION
Device Type (E2): ESSURE METAL COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/27/2006
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE TUBAL LIGATION. WITHIN ONE YEAR OF GETTING THE ESSURE PRODUCT, I STARTED EXPERIENCING TERRIBLE CHANGES IN MY BODY. SHARP PAINS IN STOMACH AND LOWER LEFT SIDE. STARTED BECOMING UNBEARABLY AGGRAVATED, TERRIBLE MOOD CHANGES AND OUT OF NOWHERE CRYING SPELLS. AS THE CHANGES HAPPENED, I WENT TO MY DOCTOR THAT PERFORMED THE PROCEDURE AND QUESTIONED IF I COULD BE EXPERIENCING ANY SIDE EFFECTS FROM ESSURE. HE STATED "NO WAY AT ALL." HE SAID THAT I WAS GOING THROUGH PMDD, WHICH I WAS ONLY (B)(6) AT THE TIME, BUT I FELT THAT MY DOCTOR KNEW BETTER THAN MYSELF. HE GAVE ME ANTIDEPRESSANTS. I WENT TO SEVERAL MORE DOCTORS AND AS SOON AS I SAY THE WORD ESSURE THEY CUT ME OFF AND SAY " NO WAY THAT ESSURE CAN CAUSE ANY PAINS AT ALL OR THAT THEY CAN EVER MOVE." BUT THAT IS NOT A TRUE STATEMENT. MY MAIN PROBLEM IS THE DOCTORS ARE REFUSING TO EVEN LOOK INTO THIS AT ALL. IT MAKES ME WONDER HOW MUCH OF A BONUS ARE THESE DOCTORS REALLY GETTING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021945	CONCEPTUS, INC	8/19/2011	9/8/2011

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): ESSURE
Model # (E4): P020014
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 7/11/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE MONTH AFTER ESSURE PROCEDURE SUBJECT HAS BEEN EXPERIENCING PELVIC PAIN, BLOATING, WEIGHT GAIN, PAINFUL MENSES, VAGINAL DISCHARGE, VAGINAL ODOR, AND HOT FLASHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021869	CONCEPTUS	8/23/2011	9/1/2011

Event Information:

Event Date (B3): 5/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE MICRO-INSERT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/20/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

RECEIVED ESSURE PROCEDURE ON (B)(6) 2011 AND HAVE HAD ADVERSE SYMPTOMS EVER SINCE: ABDOMINAL PAIN, IRREGULAR BLEEDING, BROWN DISCHARGE, PAIN DURING SEX, HEADACHES, ETC. I WAS NOT INFORMED OF ANY OF THESE RISKS WHEN I WAS TOLD ABOUT THE PROCEDURE BY MY DOCTOR. NOR WAS I INFORMED ON THE ESSURE WEBSITE ABOUT ANY OF THESE POSSIBLE SIDE EFFECTS. I HAVE SINCE TALKED TO A LARGE NUMBER OF OTHER WOMEN WHO HAVE HAD THIS PROCEDURE. THEY ALL REPORT SIMILAR SYMPTOMS, AND A LARGE PORTION OF THEM REPORT EVEN MORE SEVERE COMPLICATIONS FROM THIS PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00047	CONCEPTUS, INC.	8/26/2011	9/8/2011

Event Information:

Event Date (B3): 6/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50534019

Single Use: Y
Implant Date (E6): 6/2/2011
Explant Date (E7): 6/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORT OF PAIN POST-ESSURE PLACEMENT. THE DEVICE WAS REMOVED HYSTEROSCOPICALLY, AFTER WHICH, THE PAIN BEING EXPERIENCED BY THE PT RESOLVED.

Manufacturer Narrative (H10):

CONCLUSION: AS RECEIVED, THE MICRO-INSERT WAS FOUND TO BE DETACHED FROM THE DELIVERY CATHETER AS EXPECTED. THE OUTER COIL OF MICRO-INSERT WAS TANGLED AND THE PET FIBER IS VISIBLE AND WRAPPED AROUND THE INNER COIL. ALL COMPONENTS OF THE MICRO-INSERT ARE PR

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5021936	ESSURE	8/27/2011	9/8/2011

Event Information:

Event Date (B3): 6/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/17/2010
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE AND NOW HAVE TO LIVE WITH A TOTAL CHANGE IN MY LIFE!!! I WENT FROM A VERY HEALTHY ACTIVE FIT WOMAN TO A WOMAN WITH LITTLE OR NO ENERGY. I CANNOT GO THROUGHOUT THE DAY WITHOUT A NAP BECAUSE I AM ALWAYS DRAINED. I NOW HAVE BAD MIGRAINES, LOWER BACK PAIN, SHARP PAINS IN STOMACH THAT IS UNBEARABLE AND UNEXPLAINED EXCESSIVE WEIGHT GAIN. I HAVE WENT FROM A (B)(6) TO A (B)(6) IN LESS THAN A YEAR. I HAVE NEVER HAD ANY PROBLEM WITH WEIGHT GAIN OR FEELING SO TIRED ALL THE TIME! I JUST WANT MY LIFE BACK!!! I WISHED I WOULD HAVE NEVER HAD THE ESSURE PROCEDURE DONE IT HAS RUINED MY LIFE!!!

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00051	CONCEPTUS, INC.	9/14/2011	9/21/2011

Event Information:

Event Date (B3): 2/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50534019

Single Use: Y
Implant Date (E6): 2/7/2011
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORT OF DETACHMENT DIFFICULTY, MICRO-INSERT STRETCHING AND PORTION OF OUTER COIL BREAKING FOLLOWED BY PT PRESENTING WITH PAIN. A NUMBER OF FOLLOW-UPS PERFORMED AND ON (B)(6) 2011, IT WAS REPORTED THAT LAPAROSCOPIC REMOVAL OF THE DEVICE OCCURRED ALONG WITH UNILATERAL STERILIZATION. PT IS NOW FREE OF PAIN.

Manufacturer Narrative (H10):

INVESTIGATION OF RETURNED DEVICE COULD NOT FIND ANY EVIDENCE OF DEVICE FAILURE. INVESTIGATION WAS ABLE TO CONFIRM THAT NOT ALL STEPS IN THE IFU WERE COMPLETED DURING THE PROCEDURE.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5022368	CONCEPTUS	9/18/2011	9/28/2011

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): IMPLANT
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HI MY NAME IS (B)(6). I HAD THE ESSURE PROCEDURE AND NOW I HAVE BACK PROBLEMS. I STAY THROWING UP LIKE I HAVE THE FLU MY LEGS STAY NUMB EVERY DAY. SOME TIMES I FEEL LIKE I'M FLOATING I HAVE MIGRAINE HEADACHES, VERY BAD MOOD SWINGS, DEPRESSION I HAVE TO URINATE SO MUCH IT HURTS WHEN I HAVE INTERCOURSE, BLURRED VISION, PELVIC OVARIES HURT. WHEN THESE PROBLEMS STARTED I TOLD THE DOCTORS. THE DOCTOR WHO DID THE PROCEDURE (HIS NAME IS DR (B)(6) THE OTHER DOCTOR WHO SUGGESTED IT HER NAME IS DR (B)(6)) GAVE ME A DYE TEST AND HE SAID HE GUESSED MY TUBES ARE BLOCKED. THAT'S NOT A GOOD OF ENOUGH ANSWER. THEY JUST ACT LIKE I WAS CRAZY WHEN I TOLD THEM DOCTORS I WANT TO GET THESE STINTS OUT OF ME SO I CAN HAVE MY LIFE BACK BUT IT COSTS SO MUCH MONEY. I FEEL LIKE MY BODY IS DETERIORATING. I'M TOO YOUNG TO FEEL LIKE THIS MY ASTHMA IS EVEN WORSE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00048	CONCEPTUS, INC.	9/26/2011	9/30/2011

Event Information:

Event Date (B3): 8/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 771092

Single Use: Y
Implant Date (E6): 8/2/2011
Explant Date (E7): 8/4/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORT OF PAIN, POST-ESSURE PLACEMENT. THE DEVICES WERE REMOVED LAPAROSCOPICALLY ON (B)(6) 2011. ON (B)(4) 2011, THE PHYSICIAN'S OFFICE REPORTS THAT THE PAIN HAS RESOLVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00050	CONCEPTUS, INC.	9/28/2011	10/4/2011

Event Information:

Event Date (B3): 5/19/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/28/2010
Explant Date (E7): 5/19/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORT OF POST-ESSURE PLACEMENT PAIN, CATEGORIZED AS MINOR. THREE-MONTH HSG SHOWS LEFT MICRO-INSERT POSITIONED IN THE LEFT ADNEXA AND TUBAL PATENCY. PT TAKEN TO SURGERY CENTER ON AND CUT A PORTION OF THE COIL OFF THAT HE BELIEVED WAS CAUSING THE PAIN AND LEFT REMAINING PORTION OF THE DEVICE IN THE PT. ADDITIONALLY, AT THE TIME OF INTERVENTION, THE PHYSICIAN NOTED A URINARY TRACT INFECTION. AS OF TODAY, 08/31/2011, WE BELIEVE THE PT'S SYMPTOMS HAVE RESOLVED. THE UTI MAY HAVE CONTRIBUTED TO THE REPORTED PAIN, BUT THE PHYSICIAN WHO PERFORMED THE PARTIAL EXTRACTION DID THE MEDICAL INTERVENTION SPECIFICALLY TO REMOVE A PORTION OF THE MICRO-INSERT DUE TO THE PT EXPERIENCING PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00053	CONCEPTUS, INC.	9/30/2011	10/12/2011

Event Information:

Event Date (B3): 9/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 7/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORT OF AN ECTOPIC PREGNANCY 4 YEARS FOLLOWING THE ESSURE PROCEDURE. (B)(6) 2007, PT PRESENTED TO THE PHYSICIAN WITH A POSITIVE PREGNANCY TEST AND COMPLAINING OF PAIN. AFTER 48 HOURS OF THE INITIAL EVAL, THE PAIN INCREASED AND BECAME SEVERE. PT SCHEDULED FOR EMERGENCY SURGERY AND TAKEN TO THE OPERATING ROOM FOR POSSIBLE CORNUAL ECTOPIC PREGNANCY. IT WAS NOTED DURING THE SURGERY THAT ONE MICRO-INSERT WAS MAINLY IN THE UTERINE CAVITY. RIGHT SALPINGECTOMY WAS PERFORMED AND D&C. HCG LEVELS CONTINUED TO RISE FOLLOWING THE SURGICAL TREATMENT, SO SHE THEN WAS TREATED SUCCESSFULLY WITH METHOTREXATE. PT FULLY RECOVERED AND IS DOING WELL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00052	CONCEPTUS, INC.	10/5/2011	10/13/2011

Event Information:

Event Date (B3): 6/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/13/2011
Explant Date (E7): 6/24/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT PRESENTED WITH POST-ESSURE PLACEMENT PAIN, MENORRHAGIA AND DYSMENORRHEA. FOR THESE SYMPTOMS, THE PHYSICIAN DECIDED TO PERFORM A HYSTERECTOMY, WHICH WAS PERFORMED ON (B)(6) 2011. ADDITIONALLY, AFTER THE REMOVING THE UTERUS, HE DISSECTED THE TUBES TO SEE WHERE THE MICRO-INSERTS WERE LOCATED AND NOTED WHAT APPEARED TO BE AN INFECTION. AS OF TODAY, (B)(6) 2011, THE PTS SYMPTOMS HAVE SUBSIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00054	CONCEPTUS, INC.	10/5/2011	10/13/2011

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 857599

Single Use: Y
Implant Date (E6): 8/24/2011
Explant Date (E7): 9/2/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE PERFORMED (B)(6) 2011 WITH PT PRESENTING WITH PAIN DURING A POST-OP VISIT ON (B)(6) 2011. ANTIBIOTICS ADMINISTERED WITH NO IMPROVEMENT SHOWN BY (B)(6) 2011. THE PHYSICIAN REMOVED THE DEVICES DURING A DIAGNOSTIC LAPAROSCOPIC PROCEDURE ON (B)(6) 2011. THE PAIN HAS RESOLVED SINCE REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5022665	CONCEPTUS	10/12/2011	10/20/2011

Event Information:

Event Date (B3): 2/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE TUBAL LIGATION PROCEDURE DONE IN (B)(6) 2010. I WAS SUPPOSED TO HAVE MY HSG DONE 3 MONTHS LATER TO INSURE ALL WENT WELL, BUT MY APPOINTMENT WAS CANCELLED DUE TO MY MENSTRUAL CYCLE. I FINALLY WENT IN FOR MY HSG ON (B)(6) 2010 AND THE X-RAY SHOWED ONE OF MY COILS COMPLETELY BENT LIKE A BOOMERANG AND IT HAD PERFORATED MY TUBE AND ENDED UP IN MY ABDOMEN. I STARTED TO DO SOME ONLINE RESEARCH AND FOUND THAT MANY WOMEN WENT THROUGH THE SAME THING AND I FOUND MYSELF RELATING TO THEIR SYMPTOMS THAT I HAD THOUGHT WERE NORMAL SIDE EFFECTS OF THE ESSURE PROCEDURE. I HAVE HAD ABNORMAL EXCESSIVE BLEEDING, IRREGULAR PERIODS, WEIGHT GAIN, CRAMPS. IN ONE OF THE WOMEN THAT HAD THE COIL PERFORATE HER TUBE, THE COIL WAS LOST AND FOUND LODGED IN HER COLON. THESE COILS ARE NOT SAFE. THEY COME LOOSE, PERFORATE THE TUBE AND MAKE THEIR WAY IN PARTS OF THE BODY IN WHICH THEY DO NOT BELONG, POSSIBLY CAUSING HARM TO THE PT AND REQUIRING THEM TO HAVE SURGERY TO HAVE THEM REMOVED. I CHOSE TO HAVE THIS PROCEDURE BECAUSE IT WAS RECOMMENDED TO ME BY MY DOCTOR AS A LOW RISK PERMANENT TUBAL LIGATION. NOW I NEED TO HAVE SURGERY TO HAVE THE COILS REMOVED FROM MY TUBE AND ABDOMEN (IF IT'S STILL THERE AND HASN'T MOVED TO ANOTHER PLACE IN MY BODY) AND HAVE A REAL TUBAL LIGATION. WHAT DOES THIS MEAN TO ME? IT MEANS A FAILED PROCEDURE THAT IS RISKING MY HEALTH, MORE SURGERIES, MORE MONEY. I AM A MOTHER OF THREE BOYS WHO NEED ME HEALTHY. THERE ARE NO WORDS TO DESCRIBE HOW SCARED AND DISAPPOINTED I AM THAT THIS PROCEDURE IS EVEN APPROVED. ALL I HAD TO DO WAS GOOGLE "ESSURE FAILURE" TO FIND THOUSANDS OF POSTS OF WOMEN WHO HAVE THEIR OWN ESSURE NIGHTMARE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5022715	CONCEPTUS, INC	10/13/2011	10/24/2011

Event Information:

Event Date (B3): 5/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 2951250-2010-00009

Single Use:
Implant Date (E6): 5/10/2009
Explant Date (E7): 2/28/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

RPTR HAD TO HAVE A FULL HYSTERECTOMY. ON SURGERY, DOCTOR SAW THAT ONE COIL WAS NOT IN THE TUBE. IT HAD BEGUN TO UNRAVEL AND WAS IN HER BOWEL (EMBEDDED). IT SURPRISED DOCTOR THAT THE DEVICE WAS NOT IN HER TUBE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	10/18/2011	10/26/2011

Event Information:

Event Date (B3): 9/29/2011 **Report Date (B4): 10/18/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS306
Catalog # (E4): ESS306
Lot #(E4): 855630

Single Use:
Implant Date (E6): 9/29/2011
Explant Date (E7): 9/29/2011
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

FAILURE OF DEVICE TO DEPLOY DURING INSERTION DURING SURGERY. REMOVED DEVICE AND REPLACED WITH FUNCTIONAL ESSURE. DELAY IN LENGTH OF PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00055	CONCEPTUS, INC.	10/19/2011	10/25/2011

Event Information:

Event Date (B3): 9/7/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 9/7/2011
Explant Date (E7): 9/7/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

MICRO-INSERT PERFORATION OF UTERINE WALL OCCURRED DURING DEVICE PLACEMENT FOLLOWED BY BLEEDING. THE DOCTOR DID AN IMMEDIATE LAPAROSCOPY, FOUND THAT THE MICRO-INSERT WAS PROTRUDING FROM THE UTERUS AND THEREFORE, USED HYSTEROSCOPIC GRASPERS TO REMOVE THE MICRO-INSERT LAPAROSCOPICALLY. PHYSICIAN PROVIDED FOLLOW-UP DETAILS: DEEMED REMOVAL MEDICALLY NECESSARY TO REMOVE THE DEVICE THAT PERFORATED THE UTERINE WALL. PT IS FINE. PHYSICIAN FEELS THE BLEEDING "COULD" BE DUE TO DAMAGE TO A LOCAL VEIN AND MAY POSSIBLY BE RESULT OF ABNORMALLY SOFT UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00056	CONCEPTUS, INC.	10/26/2011	7/12/2012

Event Information:

Event Date (B3): 12/20/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN
Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 12/20/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT EXPERIENCED PAIN FOLLOWING THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE. THE PHYSICIAN CONFIRMED HE REMOVED THE DEVICES (B)(6) 2010 LAPAROSCOPICALLY DUE TO A CONFIRMED ALLERGY TEST. THE PATIENT REPORTS THAT MOST (90%) OF HER SYMPTOMS ARE GONE. CONFIRMATION OF MEDICAL NECESSITY HAS NOT BEEN PROVIDED, DESPITE ADDITIONAL FOLLOW UP WITH PHYSICIAN.

Manufacturer Narrative (H10):

IFU WARNING: PATIENTS WITH SUSPECTED HYPERSENSITIVITY TO NICKEL SHOULD UNDERGO A SKIN TEST TO ASSESS HYPERSENSITIVITY PRIOR TO AN ESSURE PLACEMENT PROCEDURE. CONFIRMATION OF MEDICAL NECESSITY HAS NOT BEEN PROVIDED, DESPITE ADDITIONAL FOLLOW UP WITH PHYSIC

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00057	CONCEPTUS, INC.	10/28/2011	7/16/2012

Event Information:

Event Date (B3): 8/12/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 8/4/2011
Explant Date (E7): 8/12/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT PRESENTED ON (B)(6) 2011, WITH SEVERE ABDOMINAL PAIN POST-ESSURE MICRO-INSERT PLACEMENT ((B)(6) 2011). ON (B)(6) 2011, THE PHYSICIAN REMOVED THE DEVICES LAPAROSCOPICALLY AND PERFORMED A BILATERAL TUBAL LIGATION. SURGICAL NOTES REFLECT PT HAD BILATERAL SALPINGITIS AND FIBROSIS. PT WAS LAST SEEN ON (B)(6) 2011 AND HER PAIN HAD SUBSIDED. F/U TO OBTAIN THE MEDICAL NECESSITY OF REMOVAL WAS PERFORMED AND THE PHYSICIAN RESPONDED STATING THE PT HAD AN ALLERGY TO TITANIUM, THEREFORE, SHE REMOVED THE DEVICES.

Manufacturer Narrative (H10):

SEVERAL ATTEMPTS WERE MADE TO OBTAIN THE MEDICAL NECESSITY OF REMOVAL WITH NO SUCCESS. THE PHYSICIAN FINALLY RESPONDED STATING THE PT HAD AN ALLERGY TO TITANIUM, THEREFORE, SHE REMOVED THE DEVICES. IT WAS NOT DETERMINED THE DEVICES WERE THE ROOT CAUSE OF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00058	CONCEPTUS, INC.	11/1/2011	11/8/2011

Event Information:

Event Date (B3): 7/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/1/2008
Explant Date (E7): 9/21/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT PRESENTED WITH SEVERE ABDOMINAL PAIN LOCATED ON THE RIGHT SIDE (THE ESSURE DEVICES WERE IMPLANTED IN (B)(6) 2008). EXPLORATORY LAPAROSCOPY ON (B)(6) 2011, NOTED PERFORATIONS BUT REMOVAL OF DEVICES NOT PERFORMED. ON (B)(6) 2011 - THE PHYSICIAN REPORTED A PARTIAL HYSTERECTOMY WAS PERFORMED (B)(6) 2011 REMOVING THE UTERUS DUE TO CONSTANT BLEEDING FROM AN EARLIER ABLATION, AND A BILATERAL SALPINGECTOMY WAS PERFORMED AT THE SAME TIME. THE PHYSICIAN FELT THAT SINCE THE RIGHT DEVICE HAD SLIGHTLY PROTRUDED THROUGH THE ABDOMINAL WALL, SHE FELT THE PT'S PAIN WAS COMING FROM THE PROTRUDING MICRO-INSERT. POST SURGERY PT WAS CONTACTED FOR A FOLLOW UP (B)(6) 2011 AND IS FEELING FINE AND PAIN FREE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00061	CONCEPTUS, INC.	11/2/2011	7/16/2012

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 7/1/2009
Explant Date (E7): 7/13/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT PRESENTED WITH ABDOMINAL PAIN IN (B)(6) 2011, ALSO REPORTING THAT SHE HAD BEEN FEELING PAIN SINCE (B)(6) 2010. ESSURE PROCEDURE WAS PERFORMED IN (B)(6) 2009. PHYSICIAN PERFORMED A DIAGNOSTIC HYSTEROSCOPIC AND LAPAROSCOPIC PROCEDURE AND FOUND NOTHING UNUSUAL. PATIENT CONTINUED TO HAVE PAIN AND PHYSICIAN DECIDED TO PERFORM A PARTIAL HYSTERECTOMY ON (B)(6) 2011. SOURCE OF PAIN IS INDETERMINATE, THE POST OPERATIVE REPORT SHOWED NO PATHOLOGY TO LINK THE PAIN WITH THE UTERUS OR THE FALLOPIAN TUBES. PHYSICIAN CAN ONLY SAY THE PATIENT HAD NO PAIN PRIOR TO THE ESSURE DEVICES AND ONCE THEY WERE REMOVED, HER PAIN SUBSIDED. PHYSICIAN FOLLOWED UP WITH PATIENT (B)(6) 2011 TO CONFIRM PATIENT IS NOW PAIN FREE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023127	CONCEPTUS, INC.	11/14/2011	11/21/2011

Event Information:

Event Date (B3): 11/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 00000

Single Use:
Implant Date (E6): 3/3/2009
Explant Date (E7): 11/2/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAS ESSURE PLACED IN TUBES 2009. PT HAD BODY ACHES AND PAINS VERY HEAVY PERIODS OF DURATION OF 3 YEARS. PT HAD DEVICE REMOVED FOR TUBAL LIGATION ONLY TO FIND ONE COIL. THE OTHER COIL WAS FOUND IN PTS SACRUM IN TWO PIECES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023133	CONCEPTUS, INC.	11/18/2011	11/23/2011

Event Information:

Event Date (B3): 9/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 626918

Single Use:
Implant Date (E6): 7/22/2008
Explant Date (E7): 9/15/2011
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PT STATES AFTER THREE YRS OF IMPLANT, ONE OF THE ESSURE COILS CAME OUT OF HER VAGINA. POSSIBILITY THAT SHE MIGHT BE PREGNANT AS SHE HAS BEEN HAVING PAIN AND ABDOMEN CRAMPING. FEELS THE MFR IS NOT TELLING THE PTS ABOUT THE RISK FACTOR OF THE POSSIBILITY OF THE COIL COMING OUT BECAUSE IF SHE HAD KNOWN, SHE WOULD NOT HAVE DONE THE PROCEDURE. GAVE COIL TO GYNECOLOGIST.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	11/21/2011	12/1/2011

Event Information:

Event Date (B3): 11/9/2011 **Report Date (B4): 11/21/2011** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE DEVICE
Device Type (E2): ESSURE DEVICE
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

SHEATH CRACKED EXPOSING COILS THAT COULD DAMAGE PATIENT'S FALLOPIAN TUBE. DEVICE REMOVED FROM SURGERY AND REPLACED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00059	CONCEPTUS, INC.	11/22/2011	11/30/2011

Event Information:

Event Date (B3): 10/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/21/2011
Explant Date (E7): 10/28/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED HE PERFORMED A NOVASURE PROCEDURE FOLLOWED BY AN ESSURE PROCEDURE ON PT (B)(6). HE REPORTED BOTH PROCEDURES WENT WITHOUT INCIDENT. THERE WERE 2-3 COILS LEFT ON BOTH THE RIGHT AND LEFT SIDE AND THE PT OFFERED NO COMPLAINTS FOLLOWING THE PROCEDURE. THE PT PRESENTED MONDAY, (B)(6), WITH PAIN. PHYSICIAN STATED HER UTERUS WAS NON-TENDER AND SHE WAS AFEBRILE BUT HE DID FIND TRACE AMOUNTS OF BLOOD IN HER URINE AND THOUGHT SHE MAY BE EXPERIENCING EITHER A SLIGHT URINARY INFECTION OR A SMALL KIDNEY STONE SO HE TREATED HER WITH SOME ANTIBIOTICS. THE PT CONTINUED TO HAVE PAIN ON HER FOLLOW UP (B)(6) 2011 AND WOKE (B)(6) 2011 WITH SEVERE PAIN. THE PHYSICIAN BROUGHT HER IN AND PERFORMED AN ULTRASOUND AND FLUID WAS DISCOVERED IN THE ABDOMINAL CAVITY. A CT SCAN REVEALED FREE AIR IN THE ABDOMEN. A DIAGNOSTIC LAPAROSCOPY WAS DONE (B)(6) 2011 AND A BOWEL TEAR WAS DISCOVERED. THE PHYSICIAN REPAIRED THE TEAR, CLEANED UP THE ABDOMEN AND PERFORMED A PARTIAL SALPINGECTOMY TO REMOVE BOTH DEVICES THAT HAD MIGRATED/PERFORATED OUTSIDE THE TUBES. PHYSICIAN IS SENDING PT HOME TODAY (B)(6) 2011 AS SHE IS FEELING BETTER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00060	CONCEPTUS, INC.	11/29/2011	6/12/2012

Event Information:

Event Date (B3): 8/22/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/1/2011
Explant Date (E7): 10/28/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE ESSURE PROCEDURE IN (B)(6) 2011. HER HSG REPORT REFLECTED QUESTIONABLE PLACEMENT FOR BOTH LEFT AND RIGHT TUBES, A PT RIGHT FALLOPIAN TUBE AND POSSIBLE PERFORATION. INCISIONAL STERILIZATION WAS RECOMMENDED BY RADIOLOGIST (B)(6) MD. DR. (B)(6) SENT THE HSG TO BE REVIEWED AT CONCEPTUS AND ON 09/11/2011 SENT A RESPONSE TO THE SALES REP THAT THE PT WAS HAVING MILD PAIN ISSUES SO SHE SCHEDULED A LAPAROSCOPIC TUBAL LIGATION FOR (B)(6) 2011. DR. (B)(6) REPORTED THE SURGERY WENT WELL AND HER SURGICAL FINDINGS REVEALED THE RIGHT MICRO-INSERT HAD PERFORATED AND EMBEDDED ITSELF INTO THE BOWEL. SHE WAS ABLE TO EASILY CUT THE PROTRUDING DEVICE AND LEAVE THE REMAINING COIL EMBEDDED. SHE THEN PERFORMED A BILATERAL LAP TUBAL. PHYSICIAN INFORMED US ON (B)(6) 2011 THE PT WAS DOING FINE POST OP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023361		12/5/2011	12/12/2011

Event Information:

Event Date (B3): 12/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2009, I HAD THE ESSURE PROCEDURE DONE. AFTER IT WAS COMPLETED, I BEGAN TO NOTICE STRANGE CRAMPING. I BEGAN HAVING SERIOUS NIGHT SWEATS THAT MY HUSBAND AND I ATTRIBUTED TO POSSIBLE PRE-MENOPAUSE. I GAINED (B)(6) AND I HAD SERIOUS LOWER BACK PAIN IN THE SAME SPOT. I ASSUMED ALL OF THESE SYMPTOMS WERE DUE TO OTHER ISSUES. IN THE MEAN TIME, MY HUSBAND AND I CONTINUED TO HAVE INTERCOURSE ON A REGULAR BASIS BUT I NOTICED SOME PAIN WITH INCREASING IN CERTAIN POSITIONS THAT HAD NEVER OCCURRED BEFORE. I RECENTLY HAD XRAYS DONE FOR AN UNRELATED SPORTS INJURY AND THE XRAY SHOWS THAT ONE OF THE COILS HAS MIGRATED OUT OF POSITION AND IS NOW LODGED SOMEWHERE IN MY UTERUS WHICH WILL REQUIRE SURGERY TO REMOVE. I NOW WISH TO HAVE THEM BOTH REMOVED IN ORDER TO RELIEVE MYSELF OF THESE SYMPTOMS THAT I AM NOW ATTRIBUTING TO THE METAL COILS. IT WAS PUT IN (B)(6).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2011-00062	CONCEPTUS, INC.	12/14/2011	7/26/2012

Event Information:

Event Date (B3): 5/13/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 9/1/2009
Explant Date (E7): 11/18/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD ESSURE PLACEMENT IN (B)(6) 2009 AND DID NOT RETURN FOR CONFIRMATION TEST. PATIENT PRESENTED WITH PAIN AND CONFIRMATION TEST PERFORMED IN (B)(6) 2011 SHOWED RIGHT DEVICE WAS CURLED UP BY THE RIGHT CORNUA AND THE RIGHT TUBE WAS PATENT. LAP TUBAL PERFORMED ON (B)(6) 2011 AND RIGHT DEVICE WAS DISCOVERED EMBEDDED IN THE MYOMETRIUM. PHYSICIAN ELECTED TO CONDUCT TOTAL HYSTERECTOMY ON (B)(6) 2011 AND THE PATIENT'S SYMPTOMS HAVE RESOLVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023448	CONCEPTUS, INC.	12/15/2011	12/19/2011

Event Information:

Event Date (B3): 11/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 740666

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE DONE ON (B)(6) 2011, HSG TEST PERFORMED 3 MONTHS LATER CONFIRMED THAT FALLOPIAN TUBES WERE BLOCKED. DATES OF USE: (B)(6) 2010 - PRESENT. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023517	CONCEPTUS, INC.	12/15/2011	12/22/2011

Event Information:

Event Date (B3): 12/9/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE DEVICE
Device Type (E2): CONTRACEPTIVE TOOL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3): 12/9/2011

Event Description (B5):

PT WAS IN FOR ESSURE PROCEDURE. UPON TRYING TO INSERT DEVICE, THE DEVICE FAILED TO DEPLOY CORRECTLY, UNRAVELED, CAUGHT ON SOME LINING OF THE PT'S TISSUE, CAUSING PAIN/DISCOMFORT WHILE TRYING TO REMOVE DEVICE. PROCEDURE WAS STOPPED, ONE STITCH HAD TO BE APPLIED TO PT. ESSURE REP RETURNED DEVICE TO MFR FOR QUALITY REVIEW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023518	CONCEPTUS INC.	12/16/2011	12/22/2011

Event Information:

Event Date (B3): 10/25/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4): 863568

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE PERMANENT BIRTH CONTROL IMPLANT TIP WAS BENT, MD ATTEMPTED TO IMPLANT THE ITEM WITH NO SUCCESS. IMPLANT EXCHANGED FOR NEW ONE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023613	CONCEPTUS INCORPORATED	12/24/2011	1/3/2012

Event Information:

Event Date (B3): 9/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305 641431

Single Use:
Implant Date (E6): 9/8/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2009 - ESSURE IMPLANTS. ON (B)(6) 2010, I FIRST BEGAN HAVING PAIN AND EXCESSIVE SWELLING IN MY LOWER RIGHT ABDOMEN AFTER SEX. AS TIME PROGRESSED SYMPTOMS BEGAN TO GET WORSE. I WOULD HAVE PAIN WITHOUT A REASONABLE CAUSE. PAIN BEGAN TO OCCUR DURING ANY ACTIVITY AND SEX AND SWELLING WOULD LAST FOR DAYS. I WOULD HAVE DIFFICULTY WALKING AND MOVING AROUND. PAIN WAS NOW SPREAD TO MY ENTIRE LOWER ABDOMEN AND LOWER BACK. THERE WAS NO RECORDABLE PATTERN TO EXPLAIN SYMPTOMS (PERIOD, OVULATING CERTAIN ACTIVITY). ON (B)(6) 2011, AFTER SEVERAL DOCTOR APPOINTMENTS, TEST, LAB WORK AND EXAMS MY DOCTOR DECIDED TO PERFORM AN ENDOSCOPY AND LAPAROSCOPY TO REMOVE THE ESSURE COILS FROM MY TUBES. SURGERY WAS UNSUCCESSFUL AND COILS WERE NOT ABLE TO BE REMOVED. DOCTOR DID REMOVE SCAR TISSUE. ONCE I RECOVERED FROM SURGERY I CONTINUED TO HAVE SAME PAIN AND SWELLING. MY DOCTOR SENT ME TO SPECIALIST AND THEY BELIEVED IT MAY HAVE BEEN A TRIGGER SPOT AND INJECTED A NEEDLE INTO MY ABDOMEN TO STOP PAIN. THIS DID NOT WORK. I WAS SENT TO A PHYSICAL THERAPIST AND FIT FOR A TENS UNIT. THIS DID NOT WORK. I WAS PUT BACK ON BIRTH CONTROL. THIS DID NOT WORK. MY DOCTOR HAS RAN OUT OF IDEAS AND WAS AGAINST DOING A HYSTERECTOMY WITHOUT KNOWING IT WAS ABSOLUTELY CERTAIN THIS WOULD HELP ME. ON (B)(6) 2011 - I WAS HAVING SEVERE ABDOMINAL PAIN AND WENT TO THE HOSPITAL EMERGENCY ROOM. THEY DID LABS AND FOUND MY WHITE BLOOD COUNT TO BE ELEVATED. DOCTOR ORDERED A ULTRASOUND OF MY GALLBLADDER, TEST CAME BACK NORMAL. DOCTOR ORDERED CT SCAN AND RESULTS SHOWED SWELLING IN MY LOWER RIGHT ABDOMEN AND A CYST IN MY RIGHT OVARY. I WAS THEN ADMITTED AND TRANSFERRED TO ANOTHER HOSPITAL. DOCTORS ORDERED MORE BLOOD TEST IN ADDITION TO A CHEST XRAY, ULTRASOUNDS - ON STOMACH AND TRANSVAGINAL. THE DOCTORS WERE NOT ABLE TO EXPLAIN ANY OF THE PAIN OR

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SYMPTOMS AND SIMPLY TOLD ME THEY COULD NOT HELP ME, ALL THEY COULD DO IS MANAGE MY PAIN. HOWEVER, MORPHINE AND VICODIN DO NOT HELP WITH THE PAIN. I HAD TO WAIT FOR GYN CONSULT AND THE DOCTOR SAID AFTER REVIEWING EVERYTHING THE CYST WAS NOT BIG ENOUGH TO CAUSE ANY PAIN. I HAVE MADE A FOLLOW UP APPOINTMENT WITH GYN ON (B)(6). THE DOCTORS AND I BELIEVE THAT MY ESSURE IMPLANTATIONS MAY BE THE DIRECT CAUSE FOR THE PROBLEMS MY BODY HAS BEEN HAVING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023682	CONCEPTUS INC	12/29/2011	1/9/2012

Event Information:

Event Date (B3): 11/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 735707

Single Use:
Implant Date (E6): 10/25/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2010. BY (B)(6) 2011, I BEGAN HAVING ITCHING EYES AND RASHES, WELTS. I WORKED WITH MY DOCTORS THINKING PERHAPS A MEDICATION ALLERGY. NO CHANGES OVER A FEW MONTHS. IN THE FALL I WORE A PAIR OF COSTUME JEWELRY EARRINGS. I HAD BLISTERS BEHIND BOTH EARS WITH 20 HRS. I HAD ALLERGY TESTING DONE LAST WEEK AT AN ALLERGIST OFFICE. I AM FOR THE FIRST TIME IN MY LIFE ALLERGIC TO NICKEL, AND CAN NO LONGER EVEN WEAR MY MEDICAL ALERT BRACELET ANY LONGER. THE ALLERGY HAS BECOME SYSTEMIC AND NOT JUST LOCAL ANYMORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023740	CONCEPTUS INC.	1/5/2012	1/13/2012

Event Information:

Event Date (B3): 12/9/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use:
Implant Date (E6): 12/9/2011
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 12/9/2011

Event Description (B5):

AS DOCTOR WAS PLACING ESSURE THE DEVICE STUCK TO THE INTRODUCER. THE DOCTOR HAD TO REPOSITION IT AND CUT THE INTRODUCER SO IT WOULD SEPARATE FROM THE DEVICE. AS THE INTRODUCER WAS REMOVED SMALL PIECES OF METALLIC DEBRIS WERE FOUND IN THE UTERUS. THESE WERE REMOVED BY THE PROVIDER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023771	CONCEPTUS	1/6/2012	1/13/2012

Event Information:

Event Date (B3): 12/13/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE 99.82% EFFECTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): 00000000

Single Use:
Implant Date (E6): 1/21/2011
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2011 AND WENT BACK FOR THE HSG TEST ON (B)(6) 2011 AND WAS TOLD THAT MY TUBES WERE COMPLETELY BLOCKED. I MISSED MY PERIOD (B)(6) 2011 AND TOOK TWO HOME PREGNANCY TESTS ON (B)(6) 2011 WHICH CAME BACK POSITIVE. I WENT TO THE DOCTOR, THE SAME DAY AND THEY DID A TEST AND ULTRASOUND AND TOLD ME THAT I WAS 6 WEEKS AND 5 DAYS PREGNANT AND THE BABY IS IN THE UTERUS AND THEY CAN'T FIND THE COIL THAT IS SUPPOSED TO BE BLOCKING MY LEFT TUBE, HOWEVER MY RIGHT TUBE IS STILL BLOCKED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023911	CONCEPTUS	1/10/2012	1/26/2012

Event Information:

Event Date (B3): 12/12/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): INTRODUCER
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 12/14/2011

Event Description (B5):

INSERTION INTRODUCER DEVICE OF ESSURE DEVICE BROKE WHILE IN PT. NO INJURY TO PT. THE DEVICE WAS DECONTAMINATED, PACKAGED AND SENT BACK TO THE MFR. ALL PIECES OF DEVICE THOUGHT TO BE STILL PRESENT AFTER INSPECTION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00003	CONCEPTUS, INC.	1/11/2012	1/19/2012

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/13/2011
Explant Date (E7): 12/16/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE (B)(6) 2011 AND HER HSG (B)(6) 2011. SHE REPORTED SHE BEGAN HAVING SYMPTOMS OF LOW BACK PAIN, HEAVY DISCHARGE AND PAIN WITH URINATION SHORTLY AFTER THE PROCEDURE AND INFORMED HER PHYSICIAN WHO PERFORMED THE PROCEDURE. THIS PHYSICIAN DID NOT ATTRIBUTE HER PAIN TO THE ESSURE DEVICES. SHE SOUGHT OUT ANOTHER PHYSICIAN AND MADE AN APPOINTMENT ON (B)(6) 2011. ON (B)(6) 2011 THE PHYSICIAN COUNSELED THE PT ON THE NECESSITY OF A PARTIAL HYSTERECTOMY TO REMOVE THE DEVICES. SURGICAL FINDINGS REVEALED BOTH FALLOPIAN TUBES WERE HYPEREMIC AND MOST OF ONE COIL WAS LOCATED IN THE UTERINE CAVITY. PHYSICIAN FOUND NO OTHER ABNORMALITIES AT THE TIME OF SURGERY. FOLLOW UP WITH PT ON (B)(6) 2011 FOUND HER FEELING MUCH BETTER. FOLLOW UP WITH PHYSICIANS OFFICE ON (B)(6) 2011 CONFIRMED THE DEVICES WERE THE ROOT CAUSE OF THE PT'S PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00001	CONCEPTUS, INC.	1/11/2012	7/30/2012

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/27/2011
Explant Date (E7): 11/30/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE ESSURE PROCEDURE (B)(6) 2011 AND BEGAN EXPERIENCING PAIN SHORTLY THEREAFTER. HER (B)(6) MONTHS HSG PERFORMED (B)(6) 2011, REFLECTED THE DEVICE HAD PERFORATED THE TUBE AND WAS IN THE ABDOMINAL CAVITY. THE PHYSICIAN PERFORMED A LAPAROSCOPY FILSHIE CLIP TUBAL LIGATION ON THE PATENT SIDE (B)(6) 2011 AND REMOVED THE PERFORATED DEVICE AT THE SAME TIME. CONTACTED THE PHYSICIAN'S OFFICE (B)(6) 2011 AND THE PHYSICIAN'S NURSE REPORTED HER F/U VISIT WAS (B)(6) 2011 AND HER SYMPTOMS HAVE RESOLVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00002	CONCEPTUS, INC.	1/11/2012	7/30/2012

Event Information:

Event Date (B3): 9/16/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/1/2011
Explant Date (E7): 10/26/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED TO CONCEPTUS (B)(6) 2011, THAT SHE HAS A PT WHO HAD THE ESSURE PROCEDURE APPROX (B)(6) 2011 BY ANOTHER PHYSICIAN AND THE PT BEGAN HAVING SYMPTOMS POST PROCEDURE OF IRREGULAR HEAVY BLEEDING AND SHARP ABDOMINAL PAIN LOCALIZED ON THE RIGHT SIDE. PHYSICIAN DISCOVERED THROUGH A HSG THAT THE RIGHT DEVICE WAS PROTRUDING INTO THE ENDOMETRIAL CAVITY AND THE PHYSICIAN THOUGHT THIS COULD BE CAUSING HER PAIN. THE PHYSICIAN DISCUSSED SEVERAL MEDICAL INTERVENTION OPTIONS WITH THE PT AND THEY DECIDED ON A VAGINAL HYSTERECTOMY. THE PHYSICIAN PERFORMED A LAPAROSCOPIC VAGINAL HYSTERECTOMY ON (B)(6) 2011. SURGICAL FINDINGS REVEALED A NORMAL UTERUS, OVARIES AND FALLOPIAN TUBES WITH NO EVIDENCE OF ESSURE COIL PERFORATION, HOWEVER, CHRONIC ENDOMETRITIS AND INFLAMMATION WERE PRESENT. THE PHYSICIAN REPORTED AT HER TWO WEEK POST OP VISIT THE PT'S PAIN HAD IMPROVED OVERALL. THE PHYSICIAN REPORTED IN AN E-MAIL (B)(6) 2011, THAT THE PT HAD NOT RETURNED HER PHONE CALLS FOR FURTHER F/U.

Manufacturer Narrative (H10):

FOR CONSERVATIVE MEASURES WE ARE REPORTING THIS EVENT DUE TO THE SYMPTOMS OCCURRING POST ESSURE PLACEMENT AS REPORTED BY THE PT TO THE PHYSICIAN. THERE WAS NO CONCLUSIVE EVIDENCE THAT THE ESSURE DEVICES WERE THE ROOT CAUSE OF THE PT'S PAIN.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023859		1/12/2012	1/24/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2001
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANT CAUSING PELVIC PAIN AND OTHER MAJOR ISSUES FOR PATIENT. THIS PATIENT WAS GIVEN JUST ONE IMPLANT ON HER LEFT FALLOPIAN TUBE AGAINST INDICATIONS. PATIENT BECAME PREGNANT WITHIN ONE YEAR AFTER IMPLANT AND HAD TO HAVE TUBAL LIGATION WITH THE IMPLANT STILL IN PLACE. PATIENT HAS HAD CONTINUED MEDICAL PROBLEMS FROM THIS IMPLANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5023890	NA	1/17/2012	1/24/2012

Event Information:

Event Date (B3): 8/7/2007 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 8/7/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE SUMMER OF 2007, I WENT IN FOR THE ESSURE PROCEDURE. THE PROCEDURE WAS VERY EASY AND I FELT GREAT AFTERWARDS, JUST SOME MILD CRAMPING. I NOTICED MY FIRST MENSTRUAL CYCLE AFTER THE PROCEDURE I FELT A DIFFERENT PAIN IN MY LOWER RIGHT ABDOMEN. IT FELT AS IF SOMETHING WAS POKING ME JUST UNDER THE SKIN. IT WAS VERY PAINFUL AND I TALKED TO MY OB ABOUT THIS PAIN AND HE STATED IT WAS AN UNFORTUNATE SIDE EFFECT AND SHOULD GO AWAY AFTER A COUPLE OF MONTHS AND RECOMMENDED I TAKE IBUPROFEN AROUND THE CLOCK DURING MENSTRUATION. THE PAIN GOT PROGRESSIVELY WORSE EACH MONTH. A YEAR LATER, I CHANGED JOBS AND MOVED SO WHEN I WENT TO SEE AN OB ABOUT MY PAIN I WENT TO A DIFFERENT OB SPECIALIZING IN THE ESSURE PROCEDURE. I TOLD HER ABOUT THE PAIN ABOUT IT BEING UNBEARABLE. SHE FELT ON MY ABDOMEN TO FIND THE SOURCE OF THE PAIN AND IT WAS RIGHT IN PLACE OF MY RIGHT FALLOPIAN TUBE. I KNEW THEN I WANTED THE COILS TO COME OUT BECAUSE OF THE PAIN. MY DOCTOR PERFORMED A PARTIAL HYSTERECTOMY REMOVING MY UTERUS AND FALLOPIAN TUBES. I STILL HAD BOTH OVARIES AT THE TIME SO I STILL WENT THROUGH MY MONTHLY MENSTRUATION MINUS THE ACTUAL PERIOD ITSELF. THE VERY FIRST TIME I WOULD HAVE HAD A PERIOD I RECEIVED THE PAIN AGAIN ON MY RIGHT SIDE. IT CAME EVERY 3-4 WEEKS LASTING ABOUT 4-5 DAYS LONG. I WENT BACK TO THE OB WITH MY PAIN AND SHE PERFORMED AN ULTRA SOUND. SHE FOUND A CYST ON MY OVARY. SHE THEN DETERMINED THAT MY PAIN WAS PROBABLY FROM THE OVARY ITSELF AND NOT FROM THE ESSURE COILS. SHE REMOVED THE RIGHT OVARY VIA ANOTHER SURGERY, LEAVING ME WITH ONLY MY LEFT OVARY. SINCE MY OOPHORECTOMY WAS PERFORMED I HAVE STILL BEEN IN SEVERE PAIN ON MY LOWER RIGHT SIDE. MY OB STATED THAT IT WAS PROBABLY MUSCLE DAMAGE. I HAVE BEEN ON SEVERAL DIFFERENT PAIN MEDICINES FOR THE PAIN AND MUSCLE RELAXERS AND NOTHING WORKS. THE PAIN IS NOW ON MY LEFT SIDE OF

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MY LOWER ABDOMEN AS WELL. SIX MONTHS AGO, I WENT TO MY FAMILY PHYSICIAN FRUSTRATED BECAUSE I HAD NO ANSWERS AND SHE FELT THAT IT WAS POSSIBLE NERVE DAMAGE DUE TO THE PAIN BEING SO CLOSE TO THE SURFACE OF MY SKIN. MY PAIN FEELS JUST UNDER MY SKIN AND FEELS AS IF IT IS LOCATED IN THE FATTY TISSUE OF MY LOWER ABDOMEN. MY FAMILY PHYSICIAN SENT ME TO A PHYSICAL THERAPIST TO WORK THROUGH THE SCAR TISSUE THINKING THAT IT WAS POSSIBLE THAT SCAR TISSUE HAD TRAPPED A NERVE. MY PHYSICAL THERAPIST WORKED OUT THE SCAR TISSUE AND CANNOT DETERMINE WHAT IS WRONG WITH ME. SHE FEELS THAT THERE IS DEFINITE NERVE DAMAGE THERE BECAUSE PART OF MY ABDOMEN AROUND THE BELLY BUTTON IS COMPLETELY NUMB WHEREAS PARTS OF THE ABDOMEN HAS A LOT OF PAIN. THE PAIN HAS BEEN CONSTANT FOR 5 YEARS. I ALWAYS FEEL PAIN IN THAT AREA BUT DURING MENSTRUATION THE PAIN GETS SO UNBEARABLE. I NEVER HAD THIS PAIN UNTIL I HAD THE ESSURE PROCEDURE. IT STARTED MY VERY FIRST PERIOD AFTER THE PROCEDURE AND IN ALMOST 5 YEARS I'VE NOT HAD A NORMAL MENSTRUATION. I KNOW THAT IT ISN'T MENSTRUAL CRAMPS BECAUSE THE PAIN FEELS VERY CLOSE TO THE SURFACE. I DON'T KNOW IF IT IS NERVE DAMAGE OR IF A COIL HAS BEEN LODGED ALONG THE PELVIC WALL. I HAVE HAD 2 SURGERIES AND BEEN IN CARE OF A PHYSICAL THERAPIST. I HAVE BEEN ON MEDICATION FOR 5 YEARS TRYING TO ALLEVIATE THE PAIN. I HAVE MISSED WORK FROM THIS PAIN AND I AM A SINGLE MOTHER, I CANNOT AFFORD TO DO THAT. HYSTERECTOMY TO REMOVE, ESSURE PROCEDURE, AFTER PAIN STILL OCCURED HAD OOPHORECTOMY AND REMOVAL OF REMAINING RIGHT FALLOPIAN TUBES. PHYSICAL THERAPY WAS PERFORMED AS WELL TO REMOVE SCAR TISSUE, STILL IN PAIN.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	1/18/2012	1/24/2012

Event Information:

Event Date (B3): 11/18/2011 **Report Date (B4): 1/18/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 871974

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING DEPLOYMENT OF DEVICE INTO FALLOPIAN TUBE, DEVICE MALFUNCTIONED AND WOULD NOT DEPLOY PROPERLY. WHILE TRYING TO REMOVE DEVICE, IT BROKE AND IMBEDDED ITSELF INTO THE FALLOPIAN TUBE. WHEN THE PIECE WAS FINALLY REMOVED, SOME TISSUE WAS TORN. NO HARM TO THE PATIENT.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	1/27/2012	2/3/2012

Event Information:

Event Date (B3): 1/9/2012 **Report Date (B4): 1/27/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUDER COIL
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): 910508

Single Use:
Implant Date (E6): 1/9/2012
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/19/2012

Event Description (B5):

MD DEPLOYED THE ESSURE COIL INTO THE RIGHT FALLOPIAN TUBE WITHOUT INCIDENT. WHEN THE MD DEPLOYED THE COIL INTO THE LEFT FALLOPIAN TUBE, IT WAS REALIZED THAT HALF OF THE COILS WERE IN THE LEFT FALLOPIAN TUBE AND HALF SNAPPED BACK INTO THE DEVICE. TWO DEVICES WERE USED, ONE FOR THE RIGHT AND ANOTHER FOR THE LEFT TUBE.
==========
MANUFACTURER RESPONSE FOR TUBAL OCCLUDER COIL, ESSURE (PER SITE REPORTER).
==========
WE ARE AWAITING A RESPONSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024040	CONCEPTUS INC USA	1/30/2012	2/2/2012

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): IMPLANT
Model # (E4): REF# EF305
Catalog # (E4):
Lot #(E4): 628-144; 6277-43

Single Use:
Implant Date (E6): 11/1/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER COMPLAINS SHE HAS HAD MANY ISSUES WITH THE (B)(4) BIRTH CONTROL PRODUCTS AND THIS HAS MADE HER SO SICK THAT NOW SHE HAS TO HAVE A COMPLETE HYSTERECTOMY AND DEFINITELY BELIEVES IT IS DUE TO (B)(4). SHE SAYS SHE HAS SUFFERED FROM SEVERE CRAMPING, EXCESSIVE BLEEDING, PREMATURE OVARIAN FAILURE, LEG AND ARM PAIN, HEADACHES, MOOD SWING, BLOATING, PAINFUL SEXUAL INTERCOURSE AND VAGINAL INFECTION. SHE HAS TO UNDERGO HER COMPLETE HYSTERECTOMY ON (B)(6) 2012 BY THE SAME DOCTOR WHO INSERTED THE ESSURE PRODUCT IN HER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024116	CONCEPTUS	1/31/2012	2/9/2012

Event Information:

Event Date (B3): 9/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): E55305, 859591

Single Use:
Implant Date (E6): 9/23/2011
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/23/2011

Event Description (B5):

ON (B)(6) 2011, I WENT INTO MY DR.'S OFFICE FOR THE ESSURE PROCEDURE. WHEN I CAME OUT I WAS INFORMED DUE TO MY BEING ACTIVE UNDER SEDATION THE DOCTOR WAS NOT ABLE TO PERFORM THE PROCEDURE. A FEW WEEKS LATER, I HAD ANOTHER PROCEDURE COMPLETED SINCE THE FIRST WAS NOT ABLE TO BE DONE. ON (B)(6) 2012, I WENT TO HAVE THE CONFIRMATION TEST (HSG) DONE TO VERIFY THAT MY TUBES WERE INDEED BLOCKED FROM THE SECOND PROCEDURE. DURING THE COURSE OF THIS, THE RADIOLOGIST INFORMED ME THAT I HAD MISPLACED ESSURE IMPLANTS (FROM THE FIRST PROCEDURE SINCE THE SECOND WAS NOT ESSURE) AND SUGGESTED THAT I SPEAK TO MY DOCTOR. MY DOCTOR HAS NOW CLAIMED THAT SHE OPENED THREE PACKAGES OF ESSURE DEVICES AND TWO OF THEM WERE BENT, WHICH SHE TRIED TO USE ANYWAY, AND THAT THE DEVICES MALFUNCTIONED AND MUST HAVE DEPLOYED THE IMPLANTS WITHOUT HER KNOWLEDGE. HAVING TWO THIRDS OF THE DEVICES BENT AND THEN MALFUNCTIONING ON INSERTION NEEDS TO BE REPORTED TO THE FDA BUT MY DOCTOR DID NOT WANT TO. IMPLANTS ARE NOT WHERE THEY SHOULD BE AND IT CAN NOT BE PIN POINTED ON X-RAY AND BOTH MY DOCTOR AND THE COMPANY THAT MAKES ESSURE ARE REFUSING TO FIND THEM SAYING IT IS NOT "STANDARD OF CARE" TO KNOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024143		2/2/2012	2/9/2012

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2008
Explant Date (E7): 10/1/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER BIRTH OF HER LAST CHILD, PT WAS ADVISED BY HER DR THAT THE ESSURE WAS SIDE EFFECT FREE. SHE DECIDED TO HAVE THE PROCEDURE DONE AND IT TOOK 3 HOURS INSTEAD OF 45 MINUTES. DURING PLACEMENT SHE WAS IN EXCRUCIATING PAIN AND DISCOMFORT. THE REP WAS PRESENT AND WAS GUIDING THE DR THROUGH THE PROCEDURE. SINCE DEVICE IMPLANTATION, USER EXPERIENCED CONTINUAL BLEEDING FOR 9 MONTHS, NAUSEA, FATIGUE, RASHES, SCAR TISSUE, CRAMPING AND LESIONS. PT STATES THAT AN ALLERGY FOR NICKEL, WHICH IS STANDARD PROCEDURE, WAS NEVER DONE AND IT WAS REVEALED AFTER THIS EPISODE THAT SHE INDEED HAS A NICKEL ALLERGY. DURING SURGERY FOR REMOVAL, ONE COIL WAS FOUND FLOATING IN HER PELVIS. CURRENTLY, THE PATIENT SYMPTOMS HAVE STOPPED AND SHE BELIEVED THAT THE DEVICE CAUSED HER PAIN AND INJURY WHICH INCLUDES A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024240	CONCEPTUS INC.	2/9/2012	2/16/2012

Event Information:

Event Date (B3): 1/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use:
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/31/2012
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2009, THIS PT HAD A HYSTEROSCOPIC TUBAL STERILIZATION PROCEDURE VIA THE ESSURE SYSTEM. SINCE THEN SHE HAS EXPERIENCED SHARP, SEVERE AND TRANSIENT LOWER ABDOMINAL PAIN. RECENT COMPUTED TOMOGRAPHY DIAGNOSED EXTRUSION OF HER LEFT ESSURE IMPLANT OUTSIDE HER FALLOPIAN TUBE INTO HER ABDOMINAL CAVITY. LAPAROSCOPIC SURGICAL EVAL (B)(6) 2012 CONFIRMED THIS DIAGNOSIS. THE ESSURE IMPLANT WAS FOUND ADHERENT TO A LAYER OF OMENTAL FAT. IT WAS SURGICALLY REMOVED DURING THAT PROCEDURE. THE RIGHT ESSURE IMPLANT APPEARED TO BE IN PLACE IN THE RIGHT FALLOPIAN TUBE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00004	CONCEPTUS, INC.	2/21/2012	3/16/2012

Event Information:

Event Date (B3): 1/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 5/21/2007
Explant Date (E7): 1/18/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2012, PT CAME IN FOR ANNUAL CHECK UP AND PHYSICIAN DISCOVERED SHE HAD A CORNUAL MOLAR PREGNANCY. ON (B)(6) 2012, PHYSICIAN PERFORMED A HYSTERECTOMY ON THE PT. PT WAS ASYMPTOMATIC. PT DP HAD THE ESSURE PROCEDURE ON (B)(6) 2007 AND HER HSG ON (B)(6) 2007, SHE HAD FOUR TRAILING COILS ON EACH SIDE. THE PT IS FINE POST SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024399	CONCEPTUS	2/22/2012	3/1/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/27/2011
Explant Date (E7): 12/23/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTS PUT IN PLACE ON (B)(6) 2007. HAD HSG TO CONFIRM PROPER PLACEMENT. PRODUCT WAS IN PLACE AND FUNCTIONING. I GOT NEW JOB IN (B)(6) 2009 AND CALLED MFR TO MAKE SURE NEW WORK ENVIRONMENT WAS COMPATIBLE WITH IMPLANTS. I WAS WORKING WITH STRONG MAGNETS. COMPANY STATED I WAS FINE TO PURSUE MY WORK. I HAD PAIN, BLEEDING, AND DAILY PROBLEMS SINCE PLACEMENT IN (B)(6) 2007. THESE BECAME MUCH WORSE IN (B)(6) 2009 AFTER CALLING THE COMPANY AND BEING CLEARED TO WORK. I HAD SEVERE DAILY PAIN, HEAVY MENSTRUAL BLEEDING, AND HAD TO MISS WORK BECAUSE OF THESE ISSUES. IN (B)(6) 2011, I HAD AN ULTRASOUND. MY IMPLANT IN MY LEFT TUBE WAS BENT AND WAS OUT OF PLACE. THE IMPLANTS NEEDED TO BE REMOVED DUE TO DISPLACEMENT AND BLEEDING. THE DOCTOR STATED THAT THE CAUSE OF MOVEMENT AND BLEEDING WERE THE IMPLANTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024400	CONCEPTUS INC.	2/22/2012	3/1/2012

Event Information:

Event Date (B3): 8/27/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/27/2009
Explant Date (E7): 4/6/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2009, I HAD THE ESSURE PROCEDURE DONE BY MY OBGYN IN HIS OFFICE. HIS NAME IS DR. (B)(6) IN (B)(6). HE FAILED TO GIVE ME THE 3 MONTH FOLLOW UP PROCEDURE. I HAD OVER A YEAR OF PAIN, CRAMPING AND EXTENSIVE BLEEDING. I CALLED THE OFFICE TO REPORT, BUT WAS TOLD THIS WAS NORMAL. ON MY ANNUAL VISIT TO THE OFFICE, I REPORTED TO THE MIDWIFE THAT I HAD BEEN BLEEDING FOR OVER 30 DAYS IN A ROW. SHE SUGGESTED TO HAVE AN INTERNAL ULTRASOUND TO INVESTIGATE. UPON THAT INVESTIGATION AT A LATER APPOINTMENT, IT WAS DISCOVERED THAT ONE OF MY ESSURE COILS WAS EMBEDDED IN MY UTERUS AND THE OTHER WAS NOT CORRECTLY PLACED. AFTER BEING MADE VERY UNCOMFORTABLE AFTER SPEAKING WITH DR. (B)(6), I DECIDED TO GO ELSEWHERE TO HAVE THEM REMOVED. I CHOSE A FEMALE DOCTOR AND HAD THEM REMOVED ON (B)(6) 2011. I HAD TO HAVE GENERAL ANESTHESIA TO HAVE THEM REMOVED AND I ALSO HAD TO HAVE A TUBAL LIGATION DONE. ONE WAS COMPLETELY EMBEDDED IN MY UTERINE WALL, THE OTHER WAS BARELY STILL IN THE OTHER FALLOPIAN TUBE AND WAS HANGING MOSTLY OUT INTO MY UTERUS. UPON FURTHER INVESTIGATION, I HAVE DISCOVERED THAT MANY WOMEN ARE HAVING THIS SAME PROBLEM AMONGST MANY OTHER PROBLEMS DUE TO THIS PROCEDURE. IT NEEDS TO BE TAKEN OFF THE MARKET IMMEDIATELY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00008	CONCEPTUS, INC.	2/29/2012	7/31/2012

Event Information:

Event Date (B3): 9/20/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 7/26/2010
Explant Date (E7): 10/17/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD ESSURE DEVICES PLACED (B)(6) 2010. HER HSG ON (B)(6) 2010, REFLECTED A PERFORATION AND PATENCY OF THE RIGHT TUBE. SHE PRESENTED TO HER PHYSICIAN ON (B)(6) 2011, WITH PAIN IN HER LOWER RIGHT QUADRANT PELVIS AREA ACCOMPANIED WITH NAUSEA AND VOMITING. AN ULTRASOUND INDICATED THE RIGHT DEVICE WAS IN THE ENDOMETRIAL CAVITY AND SITTING ON TOP OF THE UTERUS. ON (B)(6) 2011, A HYSTERECTOMY WAS PERFORMED BY HER PHYSICIAN. THE PHYSICIAN DECIDED TO REMOVE THE UTERUS DUE TO THE PATIENT'S PAIN. PHYSICIAN DID NOT RETURN ANY COMMUNICATIONS REGARDING MEDICAL NECESSITY OF THE HYSTERECTOMY OR RESOLUTION OF PATIENT'S SYMPTOMS. ON (B)(6) 2012, WE RECEIVED CONFIRMATION THAT THE PATIENT'S PAIN SYMPTOMS HAD RESOLVED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	3/1/2012	3/12/2012

Event Information:

Event Date (B3): 2/23/2012 **Report Date (B4): 3/1/2012** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 893011

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WOULD NOT DEPLOY AFTER POSITIONING PER SURGEON. ANOTHER ESSURE DEVICE FROM THE SAME LOT NUMBER WAS PLACED WITHOUT DIFFICULTY. IT WAS INITIALLY DEPLOYED ON THE PATIENT'S RIGHT, THE TUBE WAS CANNULATED, AND THE DEVICE WAS RELEASED REVEALING APPROXIMATELY 3-4 RINGS. THE SAME PROCEDURE WAS CARRIED OUT ON THE CONTRALATERAL SIDE WITHOUT DIFFICULTY. THERE WAS NO HARM TO THE PATIENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024581	CONCEPTUS	3/6/2012	3/13/2012

Event Information:

Event Date (B3): 2/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305915880

Single Use:
Implant Date (E6): 2/2/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A (B)(6) G2P2 WITH DESIRED STERILITY AND NO OTHER SIGNIFICANT PMH. HAD ESSURE STERILIZATION PERFORMED (B)(4) 2012 UNDER GENERAL ANESTHESIA. PT WITH VAGINAL DISCHARGE A FEW WEEKS LATER AND SUBSEQUENTLY ADMITTED TO HOSPITAL (B)(4) 2012 WITH PELVIC INFLAMMATORY DISEASE BASED ON CERVICAL MOTION TENDERNESS, LEFT SHIFT/BANDEMIA/ELEVATED WHITE COUNT AND FEVER. PT PREVIOUSLY STARTED ON OUTPATIENT CIPROFLOXACIN AND FLAGYL ONE DAY PRIOR TO ADMISSION WITH RESOLUTION OF HER FEVER OR PAIN. ON ADMISSION, CT SCAN NEGATIVE FOR ABSCESS AND PT STARTED ON DOXYCYCLINE PO, CEFOXITIN AND FLAGYL WITH IMPROVEMENT WITH IV ANTIBIOTICS. PT CURRENTLY ON HOSPITAL DAY NUMBER 2.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024576		3/9/2012	3/13/2012

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use:
Implant Date (E6): 4/1/2008
Explant Date (E7): 12/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER HAS HAD TO HAVE HER UTERUS REMOVED BECAUSE OF THE DEVICE. SHE SAYS MANY OTHER WOMEN HAVE HAD THE SAME, SOME WITH FULL HYSTERECTOMY. SHE HAD SEVERE CRAMPING AND BLEEDING ABOUT A MONTH AFTER DEVICE INSERTED. SHE WAS HAVING PAIN SO SEVERE SHE COULDN'T HAVE SEX WITH HER HUSBAND. SHE ALSO HAD BLEEDING EVERY DAY. THE ESSURE WAS LODGED IN HER UTERUS SO SEVERELY THE HYSTERECTOMY WAS NECESSARY. DOCTOR SAYS AFTER IT IS IN SO LONG, SCAR TISSUE IS FORMED AND THAT'S WHY IT HAS TO BE REMOVED WITH A HYSTERECTOMY. APPARENTLY, THE DEVICE SHIFTS AND EMBEDS IN THE UTERUS, PER MFR TO REPORTER'S GYN. REPORTER IS AWARE OF A WEBSITE WHERE MANY WOMEN REPORT THEY ARE HAVING THE SAME PROBLEMS (B)(6). REPORTER HAD THE HYSTERECTOMY A YEAR AGO BUT SHE STILL HAS PAIN IN HER OVARIES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024622		3/9/2012	3/16/2012

Event Information:

Event Date (B3): 4/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/28/2011
Explant Date (E7): 2/21/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS PLACED IN FALLOPIAN TUBES FOR THE PURPOSE OF STERILIZATION. CONSTANT CRAMPING, PAIN, DIZZINESS UPON PLACEMENT. CONTINUED SYMPTOMS FOR 10 MONTHS WITH THE ADDITION OF NEW PROBLEMS. EXCESSIVE BLEEDING, AND LENGTH OF CYCLES (23 DAYS STRAIGHT), EXTREME FATIGUE, NAUSEA, WEIGHT LOSS WITHOUT DIETING. THE LONGER DEVICE WAS IN THE MORE SEVERE PROBLEMS BECAME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024627	CONCEPTUS	3/9/2012	3/16/2012

Event Information:

Event Date (B3): 7/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/16/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

WENT TO DR. (B)(6), ON (B)(6) 2010 FOR ESSURE CONTRACEPTIVE DEVICE PLACEMENT. DURING PROCEDURE, BEGAN TO HAVE SEVERE PAIN IN LEFT LOWER ABDOMEN THAT RADIATED THROUGH LEFT SIDE UP TO LEFT SIDE OF CHEST, THROUGH LEFT ARM AND INTO LEFT SIDE OF NECK AND HEAD. DR. (B)(6) STOPPED PROCEDURE AND STATED IN PERSON TO ME WITH HIS NURSE, (B)(6) PRESENT AND STATES IN MY MEDICAL RECORD FROM THAT PROCEDURE THAT HE ABANDONED THE PROCEDURE AND THE ESSURE COIL "WAS NOT DEPLOYED AND WAS REMOVED." I HAVE CONTINUED TO HAVE LOWER ABDOMINAL PAIN AND A SEVERE CONSTANT HEADACHE THAT CANNOT BE RELIEVED BY ANY OTC OR PRESCRIPTION MEDICATION. ON (B)(6) 2011, I WENT TO AN URGENT CARE FACILITY FOR POSSIBLE UTI ALONG WITH LOWER ABDOMINAL PAIN. CT SCAN OF ABDOMEN WAS PERFORMED AND AN ESSURE DEVICE WAS FOUND IN MY LEFT FUNDAL AREA. ON (B)(6) 2011, HAD A HYSTEROSALPINGOGRAM PERFORMED AND A DEFINITE ESSURE COIL WAS SEEN IN THE LEFT FUNDAL AREA THAT OCCLUDES THE LEFT FALLOPIAN TUBE BUT DEFINITE OPTIMAL/PROPER PLACEMENT OF THE ESSURE COIL COULD NOT BE DETERMINED. DR. (B)(6) WAS INFORMED AND STATES THAT HE EMPHATICALLY DID NOT DEPLOY THE ESSURE COIL AND HAS BEEN VERY INSISTENT OF SUCH. HE ACTUALLY STATES THAT "YOU MUST HAVE HAD AN ESSURE COIL PLACED BY ANOTHER DOCTOR EITHER BEFORE MY PROCEDURE ON (B)(6) 2010 OR SOMETIME THEREAFTER." I HAVE MADE IT VERY CLEAR TO DR. (B)(6) AND ANYONE ELSE INVOLVED THAT I DID NOT HAVE ANY OTHER ESSURE PROCEDURE PERFORMED AT ANY TIME OF MY LIFE, WHETHER A FAILED OR SUCCESSFUL PROCEDURE. DR. (B)(6) ALSO STATED THAT IF IN FACT THERE IS AN ESSURE COIL IN MY LEFT FALLOPIAN TUBE OR IN MY LEFT FUNDAL AREA THAT "IT IS A MIRACLE AND WE SHOULD ALL GONE TO CHURCH" I FOUND THAT STATEMENT VERY OFFENSIVE AND FELT AS THOUGH DR. (B)(6) DID NOT TAKE THIS SITUATION SERIOUS AT ALL. THE ISSUE WAS BROUGHT TO THE ATTENTION OF THE CHIEF MEDICAL OFFICER OF THE COMPANY

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DR. (B)(6) WORKS FOR WHO ALSO STATES THERE IS NO WAY THAT DR. (B)(6) COULD HAVE PLACED THE ESSURE COIL W/O MAKING SEVERAL MANEUVERS ON THE INSERTION DEVICE. DR. (B)(6), THE CHIEF MEDICAL OFFICER OF (B)(4) STATED ON (B)(4) 2012 THAT HE HAD BEEN IN CONTACT WITH CONCEPTUS THE MAKER OF ESSURE AND WAS ADVISED THERE HAS NEVER BEEN ANY INSTANCE OF AN ESSURE COIL SPONTANEOUSLY DEPLOYING BUT DR. (B)(6) STATED TO ME THAT IS WHAT MUST HAVE HAPPENED IN MY CASE SINCE DR. (B)(6) STATES W/O A DOUBT THAT HE DID NOT DEPLOY THE COIL AND THE ESSURE COIL WAS REMOVED. I MUST TELL YOU THAT FIRST OF ALL I AM SKEPTICAL OF DR. (B)(6)'S STATEMENT THAT HE DID NOT DEPLOY THE ESSURE COIL. HOWEVER, IF SUCH AN OCCURRENCE COULD POSSIBLY HAPPEN, I BELIEVE THIS MUST BE LOOKED INTO. IT APPEARS THAT THE ESSURE COIL IN MY INSTANCE DID NOT GO THROUGH THE UTERINE WALL INTO MY ABDOMEN BUT THAT IS NOT TO SAY THAT IT COULD NOT HAPPEN ON ANOTHER FEMALE PT IF THIS DEVICE WERE TO "SPONTANEOUSLY" DEPLOY THE COIL W/O THE DOCTOR'S KNOWLEDGE. DR. (B)(6), ACCORDING TO DR. (B)(6) OBVIOUSLY DID NOT CHECK THE END OF THE DEVICE THAT IS USED FOR THE INSERTION OF AN ESSURE COIL TO MAKE CERTAIN THAT THE COIL WAS STILL ATTACHED AND NOT IN MY BODY AT THE END OF MY PROCEDURE. THIS IS A SERIOUS IMPLICATION THAT ALL PRECAUTIONS ARE NOT BEING TAKEN WHEN IT COME TO THE INSERTION OF THE ESSURE CONTRACEPTIVE DEVICE. JUST AS I AM REPORTING TO YOU AT THE FDA I AM ALSO FILING A COMPLAINT WITH THE (B)(4) DEPARTMENT OF HEALTH AGAINST DR. (B)(6) FOR NEGLIGENT AND UNETHICAL BEHAVIOR.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00007	CONCEPTUS, INC.	3/15/2012	6/8/2012

Event Information:

Event Date (B3): 11/30/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/7/2011
Explant Date (E7): 11/30/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD THE PROCEDURE (B)(6) 2011 AND WAS FEELING PAIN POST PROCEDURE THAT DID NOT DISSIPATE. THE HSG ON (B)(6) 2011, REFLECTED THREE COILS WERE PLACED IN PATIENT'S LEFT TUBE AND ONE COIL ON THE RIGHT. TWO OF THE COILS APPEARED PERFORATED INTO THE PERITONEAL CAVITY ON THE LEFT SIDE AND THE RIGHT SIDE APPEARED ADEQUATE. PATIENT WENT TO ANOTHER PHYSICIAN FOR ANOTHER OPINION. THIS PHYSICIAN DECIDED TO REMOVE PERFORATED COILS LAPAROSCOPICALLY ON (B)(6) 2011. PATIENT IS LEFT WITH ONE COIL ON RIGHT SIDE AND ONE COIL ON LEFT SIDE. PATIENT IS DOING FINE POST SURGERY WITH RESOLUTION OF PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00018	CONCEPTUS, INC.	3/15/2012	6/8/2012

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): OTHER	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/5/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORTED SHE HAD THE ESSURE PROCEDURE (B)(6) 2008. HSG WAS (B)(6) 2009 REFLECTING BOTH TUBES WERE OCCLUDED. SOMETIME IN (B)(6) OF 2010 SHE BEGAN EXPERIENCING SYMPTOMS OF PAIN ACCOMPANIED BY DIZZINESS, NAUSEA, DIARRHEA, RASH, ITCHING, BLOATING WITH STRANGE UNPREDICTABLE PERIODS. ON (B)(6) 2010 THE PHYSIC PERFORMED A RIGHT SALPINGECTOMY TO REMOVE THE DEVICE BUT DID NOT SEE ANY EVIDENCE OF A PROTRUSION, HE DID FIND THE UTERUS WAS ODDLY LEVO-ROTATED AND REMOVED A LARGE OVARIAN BENIGN TUMOR. HER SYMPTOMS SUBSIDED AND CAME BACK IN (B)(6) 2011. HER PHYSICIAN PERFORMED ANOTHER SALPINGECTOMY ON THE LEFT SIDE (B)(6) 2011. PATHOLOGY FINDINGS REFLECTED A CHRONICALLY INFLAMED FALLOPIAN TUBE. POST OPERATIVE STATUS FROM PHYSICIAN (B)(6) 2012, PATIENT IS DOING WELL AND IS SYMPTOM FREE. PHYSICIAN CANNOT CONFIRM WHETHER THE PATIENTS SYMPTOMS DERIVED 100% FROM THE ESSURE DEVICES.

Manufacturer Narrative (H10):

EXPLANTED: (B)(6) 2011. ON (B)(4) 2012 - UPON REVIEW OF THE DETAILS OF THIS INVESTIGATION, ALTHOUGH THE PHYSICIAN COULD NOT ATTRIBUTE THE PATIENT'S SYMPTOMS TO THE ESSURE DEVICE, WE HAVE CONSERVATIVELY DECIDED TO FILE THIS CASE. THE ESSURE IFU CONTAINS TH

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00014	CONCEPTUS, INC.	3/16/2012	3/23/2012

Event Information:

Event Date (B3): 12/9/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/12/2009
Explant Date (E7): 1/31/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE PROCEDURE (B)(6) 2009. PT WAS NON-COMPLIANT AND NEVER HAD THE HSG TEST. SHE COMPLAINED OF PAIN IN HER LOWER ABDOMINAL CAVITY. PHYSICIAN REQUESTED THE HSG TEST AGAIN AND SHE FAILED TO HAVE IT DONE. THROUGH ULTRASOUND PHYSICIAN FOUND DEVICE HAD MIGRATED OR PERFORATED THE TUBE AND WAS IN THE PERITONEAL CAVITY. PHYSICIAN REMOVED THE DEVICE LAPAROSCOPICALLY (B)(6) 2012 THAT WAS ADHERED TO THE OMENTAL FAT IN HER ABDOMINAL CAVITY. CURRENT STATUS OF PT IS STABLE POST REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00005	CONCEPTUS, INC.	3/16/2012	6/8/2012

Event Information:

Event Date (B3): 11/22/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 2/14/2008
Explant Date (E7): 11/22/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE ESSURE PROCEDURE (B)(6) 2008. SIX MONTHS POST PROCEDURE, PT DEVELOPED SYMPTOMS OF RASHES, PELVIC PAIN, HEAVIER PERIODS AND CRAMPING. SHE HAD AN EXTENSIVE WORK UP AND NOTHING WAS FOUND, SHE WENT TO A DERMATOLOGIST WHO CONFIRMED A NICKEL ALLERGY. ON (B)(6) 2011, HER PHYSICIAN PERFORMED A LAPAROSCOPIC HYSTERECTOMY TO REMOVE THE UTERUS, OVARIES AND TUBES. AT THE TIME OF SURGERY THE PHYSICIAN FOUND NO OBVIOUS PELVIC ADHESIVE DISEASE, ENDOMETRIOSIS, ERYTHEMA, AND NOTHING ON PATHOLOGY. THE DECISION TO PERFORM A HYSTERECTOMY WAS TO SEE IF THIS IMPROVED THE PT'S SYMPTOMS. AT THE PT'S POST OPERATIVE VISIT (B)(6) 2011, HER RASHES LESSENED, HOWEVER NOT COMPLETELY RESOLVED. PHYSICIAN SAID SHE WOULD SEE HER IN ONE MONTH. PT FOLLOWED UP WITH PHYSICIAN (B)(6) 2012 AND HER RASHES HAVE CLEARED AND SHE HAS NO ABDOMINAL PAIN. THE PHYSICIAN BELIEVES THE ESSURE DEVICES WERE THE ROOT CAUSE OF HER PT'S PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00009	CONCEPTUS, INC.	3/16/2012	6/8/2012

Event Information:

Event Date (B3): 4/6/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 4/6/2011
Explant Date (E7): 2/20/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD THE ESSURE PROCEDURE (B)(6) 2011 AND HAS EXPERIENCED PAIN ON HER RIGHT SIDE SINCE THE PROCEDURE. AN X-RAY REVEALED THE LEFT TUBE WAS PATENT AND THE COIL WAS LOCATED IN THE PERITONEAL CAVITY. LAPAROSCOPIC SURGERY WAS SCHEDULED (B)(6) 2012 TO REMOVE THE COIL AND PERFORM A BILATERAL LAP TUBAL LIGATION. IT WAS REPORTED BY THE PATIENT THE SURGEON REMOVED THE LEFT COIL AND FOUND THE RIGHT COIL TO BE PERFORATED INTO THE PERITONEAL CAVITY. THEY CONCLUDED THIS WAS THE SOURCE OF HER PAIN ON HER RIGHT SIDE. IT WAS REPORTED THE PATIENT'S PAIN HAS RESOLVED POST SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00010	CONCEPTUS, INC.	3/16/2012	6/8/2012

Event Information:

Event Date (B3): 11/2/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN
Single Use: Y
Implant Date (E6): 3/3/2009
Explant Date (E7): 11/2/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD THE PROCEDURE (B)(6) 2009. PATIENT BEGAN HAVING SYMPTOMS OF BODY ACHES AND PAINS AND VERY HEAVY PERIODS FOR 3 YEARS. SHE HAD THE DEVICES REMOVED (B)(6) 2011 AND OPTED FOR A BILATERAL TUBAL LIGATION. PHYSICIAN FOUND ONE COIL IN THE PERITONEAL CAVITY IN TWO PIECES. NO PHYSICIAN NAME WAS OBTAINED, THEREFORE, NO VERIFICATION OF INFORMATION OR FOLLOW UP COULD BE CONFIRMED. AS A CONSERVATIVE MEASURE, THIS REPORT IS BEING FILED.

Manufacturer Narrative (H10):

SEVERAL ATTEMPTS WERE MADE TO FOLLOW UP WITH PATIENT: 12/22/2011 - PHONE CALL TO PATIENT'S CELL PHONE. PATIENT WOULD NOT ANSWER ANY QUESTIONS AND SAID SHE WOULD CALL BACK AND NEVER DID. ON 12/29/2011 - EMAIL WAS SENT TO PATIENT REQUESTING INFORMATION. NO

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00013	CONCEPTUS, INC.	3/16/2012	6/8/2012

Event Information:

Event Date (B3): 12/27/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 12/20/2011
Explant Date (E7): 2/6/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT UNDERWENT THE ESSURE PROCEDURE (B)(6) 2011. THE PATIENT RETURNED TO PHYSICIAN 1 WEEK LATER WITH REPORT OF PAIN ON LEFT SIDE. U/S SHOWED A HEMORRHAGIC CYST. PAIN EVENTUALLY SUBSIDED BUT RETURNED A WEEK LATER. PATIENT WENT TO THE EMERGENCY ROOM. CT SCAN SHOWED THE SAME DIAGNOSIS, HOWEVER, THE LEFT INSERT APPEARED TWISTED. PATIENT DECIDED TO HAVE THE DEVICES REMOVED. PHYSICIAN REMOVED BOTH DEVICES THROUGH PELVISCOPIC BILATERAL SALPINGECTOMY. SURGICAL FINDINGS SHOWED LEFT COIL HAD MIGRATED INTO THE UTERINE CAVITY. PATIENT SHOWED IMPROVEMENT OF PAIN POST SURGERY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00017	CONCEPTUS, INC.	3/16/2012	6/8/2012

Event Information:

Event Date (B3): 10/13/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/10/2009
Explant Date (E7): 2/23/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD DEVICES IMPLANTED (B)(6) 2009 AND CLAIMS SHE HAS HAD A VARIETY OF SYMPTOMS INCLUDING; PAINFUL CRAMPS, LOWER BACK PAIN, HEADACHES, NUMBNESS IN HANDS AND FEET, AND MAJOR DEPRESSION SINCE SHE HAD THE ESSURE PROCEDURE. SHE HAD THE DEVICES REMOVED LAPAROSCOPICALLY THROUGH A BILATERAL SALPINGECTOMY ON (B)(6) 2012 AND THE PHYSICIAN FOUND THE LEFT COIL HAD PERFORATED AND WAS ADHERED TO THE OMENTUM IN HER BOWEL. THE RIGHT COIL WAS IN SATISFACTORY LOCATION. PT REPORTED ON (B)(6) 2012 THAT SHE HAS BEEN PAIN FREE SINCE THE SURGERY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00006	CONCEPTUS, INC.	3/16/2012	8/1/2012

Event Information:

Event Date (B3): 1/18/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/4/2010
Explant Date (E7): 2/6/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORTED SHE HAD PROCEDURE (B)(6) 2010 AND THE HSG TEST (B)(6) 2010, WHICH REFLECTED OCCLUDED TUBES. SHE HAS SINCE HAD A MISCARRIAGE (B)(6) 2010 AND A PREGNANCY IN (B)(6) 2011, WHICH WAS TERMINATED. PATIENT CLAIMS SHE HAS BEEN IN PAIN AND HAS HAD HEAVIER BLEEDING SINCE THE PROCEDURE. AN ULTRASOUND WAS PERFORMED WHICH REFLECTED THE RIGHT COIL MIGRATED INTO THE PERITONEAL CAVITY. HER PHYSICIAN REMOVED THE COIL LAPAROSCOPICALLY (B)(6) 2012, WHICH WAS DISCOVERED ADHERED TO THE FATTY TISSUE OF THE BOWEL AND PERFORMED A SALPINGECTOMY. THE LEFT COIL WAS IN PLACE AND LEFT ALONE BUT THE TUBE WAS CAUTERIZED. PATIENT REPORTED (B)(6) 2012, SHE WAS FEELING BETTER POST SURGERY. ANOTHER FOLLOW UP WITH PATIENT ON (B)(6) 2012, (B)(6) WEEKS POST-OP, SHE IS FEELING GOOD WITH NO ISSUES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00011	CONCEPTUS, INC.	3/16/2012	8/1/2012

Event Information:

Event Date (B3): 9/29/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 638494

Single Use: Y
Implant Date (E6): 9/29/2011
Explant Date (E7): 10/6/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT RECEIVED THE ESSURE DEVICES (B)(6) 2011 AND REPORTED HAVING EXCRUCIATING PAIN DURING THE PROCEDURE. SHE WAS SENT HOME WITH PAIN MEDICATION BUT SHE REPORTED THIS DID NOT ALLEVIATE HER PAIN. AFTER SEVERAL DAYS OF FEELING THIS PAIN SHE REQUESTED THE DEVICES TO BE REMOVED. THE PHYSICIAN REMOVED THE DEVICES (B)(6) 2011. THE PHYSICIAN REPORTED HE HAD NO DIFFICULTY PLACING THE DEVICES ON (B)(6) 2011 AND THE PROCEDURE WAS SUCCESSFUL, ALSO REMOVING THE DEVICES WAS CONSIDERABLY EASY AND STRAIGHTFORWARD. THE PHYSICIAN IS UNCERTAIN IF THE ESSURE DEVICES CONTRIBUTED TO HER PAIN. PATIENT REPORTED SIX WEEKS POST SURGERY SHE IS FEELING MUCH BETTER. AS A CONSERVATIVE MEASURE THIS REPORT IS BEING FILED.

Manufacturer Narrative (H10):

ON (B)(4) 2012 - UPON REVIEW OF THE DETAILS OF THIS INVESTIGATION, ALTHOUGH THE PHYSICIAN COULD NOT ATTRIBUTE THE PATIENT'S SYMPTOMS TO THE ESSURE DEVICE, WE HAVE CONSERVATIVELY DECIDED TO FILE TIS CASE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00015	CONCEPTUS, INC.	3/16/2012	8/1/2012

Event Information:

Event Date (B3): 2/3/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 2/3/2012
Explant Date (E7): 3/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD THE ESSURE PROCEDURE (B)(6) 2012. SHE PRESENTED SHORTLY AFTER WITH SEVERE SIGNS OF AN ALLERGIC REACTION; ASTHMA, ITCHING IN MOUTH AND EARS, RUNNY NOSE, AND WATERY EYES. NO NICKEL ALLERGY TEST WAS CONFIRMED, HOWEVER, PATIENT SAID SHE HAS A SENSITIVITY TO SOME METALS. PHYSICIAN DECIDED TO REMOVE THE DEVICES (B)(6) 2012 AND PERFORMED A HYSTEROSCOPIC REMOVAL OF BOTH DEVICES WHICH CAME OUT EASILY AND PERFORMED A LAPAROSCOPIC BILATERAL TUBAL LIGATION. PHYSICIAN NOTED INFLAMMATION OF BOTH TUBES AND FEELS THE PATIENT WAS HAVING AN ALLERGIC REACTION. SHE FELT IT WAS MEDICALLY NECESSARY TO REMOVE COILS TO RELIEVE HER PATIENTS SYMPTOMS. PATIENT FOLLOW UP SHOWED WITHIN TWO DAYS POST SURGERY ALL SIGNS OF ALLERGIC SYMPTOMS DISSIPATED AND PATIENT IS FEELING MUCH BETTER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00016	CONCEPTUS, INC.	3/16/2012	8/1/2012

Event Information:

Event Date (B3): 1/23/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/15/2007
Explant Date (E7): 1/23/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE ESSURE PROCEDURE (B)(6) 2007. SHE STATED THE PHYSICIAN ONLY PLACED A COIL ON THE LEFT FALLOPIAN TUBE AS THE RIGHT TUBE SEEMED ALREADY OCCLUDED. AN HSG REPORT LATER SHOWED SPILLAGE OF CONTRAST ON RIGHT SIDE INTO PERITONEAL CAVITY. SHE OPTED FOR A UNILATERAL TUBAL LIGATION ON THE RIGHT SIDE. PT CLAIMS SHE EXPERIENCED PAIN ON HER LEFT SIDE SINCE THE DEVICE WAS INSERTED. DUE TO VARIOUS MEDICAL REASONS PT OPTED FOR A FULL HYSTERECTOMY WHICH TOOK PLACE (B)(6) 2012. PATHOLOGY FINDINGS REFLECTED NUMEROUS CYSTS ON HER OVARIES AND TUBES WITH NO MENTION OF THE ESSURE DEVICE. PHYSICIAN HAS SINCE LEFT THE PRACTICE, MEDICAL NECESSITY CANNOT BE CONFIRMED IF THE ESSURE DEVICE ATTRIBUTED TO THE PT'S PAIN. POST SURGERY F/U FOUND PT'S PAIN ON HER LEFT SIDE RESOLVED. FOR CONSERVATIVE MEASURES THIS REPORT IS BEING FILED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00019	CONCEPTUS, INC.	3/20/2012	8/1/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED HE REMOVED DEVICES FROM A PT A FEW YEARS BACK. HE COULD NOT RECALL HER NAME OR DATE OF BIRTH. HE REMEMBERS SHE HAD COMPLAINTS OF PAIN SO HE REMOVED THE DEVICES. DURING THE REMOVAL HE FOUND ACUTE AND CHRONIC INFLAMMATION. HE IS NOT SURE THE DEVICES ATTRIBUTED TO THE PT'S PAIN, HOWEVER, ONCE THE DEVICES WERE REMOVED THE PT'S SYMPTOMS RESOLVED. UPON REVIEW OF THE DETAILS OF THIS INVESTIGATION, ALTHOUGH THE PHYSICIAN COULD NOT ATTRIBUTE THE PT'S SYMPTOMS TO THE ESSURE DEVICE, WE HAVE CONSERVATIVELY DECIDED TO FILE THIS CAGE.

Manufacturer Narrative (H10):

ON 10/06/2011 - EMAIL WAS SENT TO DR. (B)(6) TO RETRIEVE PT INFORMATION WITH NO RESPONSE. ON 10/10/2011 - EMAIL WAS SENT TO DR. (B)(6) TO RETRIEVE PT INFORMATION WITH NO RESPONSE. ON 10/20/2011 - CONTACT WAS MADE TO DR. (B)(6) WITH NO SUCCESS TO RETRIEVE

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00020	CONCEPTUS, INC.	3/20/2012	8/2/2012

Event Information:

Event Date (B3): 1/17/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/17/2012
Explant Date (E7): 3/2/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE ESSURE PROCEDURE (B)(6) 2012. PT PRESENTED WITH SIGNS OF ALLERGY SHORTLY AFTER HAVING PERSISTENT PRURITUS AND URTICARIA FOR 5 WEEKS WITH MINIMAL RELIEF FROM ANTIHISTAMINES. PHYSICIAN REMOVED DEVICES (B)(6) 2012, WITH A BILATERAL PARTIAL SALPINGECTOMY. PHYSICIAN REPORTED (B)(6) 2012, PT'S SYMPTOMS HAVE RESOLVED OVERALL, SHE STILL HAS OCCASIONAL ITCHING, BUT SIGNIFICANT IMPROVEMENT.

Manufacturer Narrative (H10):

THE ESSURE IFU CONTAINS THE FOLLOWING WARNING STATEMENT: THE ESSURE MICRO-INSERT INCLUDES NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. HOWEVER, IN VITRO TESTING HAS DEMONSTRATED THAT NICKEL IS RELEASED FROM THIS DEVICE. PTS WHO ARE ALLERGIC

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00012	CONCEPTUS, INC.	3/22/2012	8/2/2012

Event Information:

Event Date (B3): 2/22/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/5/2011
Explant Date (E7): 2/22/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE PERFORMED (B)(6) 2011. PT PRESENTED WITH PAIN EVERY TWO WEEKS, POST ESSURE PLACEMENT AND WANTED THE DEVICES REMOVED. ON (B)(6) 2012, PT CAME IN TO OFFICE FOR ULTRASOUND AND X-RAY AND PHYSICIAN FOUND BOTH COILS IN PROPER LOCATION. PT WANTED TO PURSUE REMOVAL OF COILS WITH THE UNDERSTANDING IT MAY NOT RELIEVE HER PAIN. ON (B)(6) 2012, PHYSICIAN PERFORMED A LAPAROSCOPIC BILATERAL SALPINGECTOMY. FINDINGS HYSTEROSCOPICALLY: NORMAL OSTIA BILATERALLY, NO TRAILING COILS WERE SEEN PROTRUDING AT THE CAVITY APPEARED NORMAL INCLUDING TUBES, OVARIES AND UTERUS. NO INFLAMMATION IN THE AREA. NOTHING ABNORMAL FOUND. ON (B)(6) 2012, F/U WITH PHYSICIANS OFFICE DETERMINED PTS SYMPTOMS HAVE RESOLVED. PHYSICIAN HAS NO OTHER EXPLANATION FOR THE PTS SYMPTOMS, NO DETERMINATION CAN BE PROVIDED. AS A CONSERVATIVE MEASURE, THIS REPORT IS BEING FILED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00021	CONCEPTUS, INC.	3/22/2012	8/2/2012

Event Information:

Event Date (B3): 8/11/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 8/11/2009
Explant Date (E7): 8/10/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE ESSURE PROCEDURE (B)(6) 2009 AND THE HSG (B)(6) 2009, REFLECTING BOTH COILS WERE IN PLACE AND THE TUBES OCCLUDED. PT BEGAN FEELING PELVIC PAIN SHORTLY AFTER THE PROCEDURE AND CONTINUED TO HAVE PAIN AFTER THE HSG. HER SYMPTOMS CONTINUED TO INCREASE AND BECAME WORSE. SHE BEGAN HAVING LOWER BACK PAIN, BLOATING IN HER STOMACH, DIARRHEA, PAINFUL INTERCOURSE, LONGER DAYS OF HER MENSES AND DEVELOPED VAGINAL INFECTIONS ON A FREQUENT BASIS. SHE HAD THE DEVICES REMOVED FROM ANOTHER PHYSICIAN ON (B)(6) 2010. SINCE THE REMOVAL SHE CLAIMS HER SYMPTOMS HAVE RESOLVED AND SHE IS FEELING MUCH BETTER ALTHOUGH STILL SUFFERS FROM RESIDUAL SIDE EFFECTS FROM THE PAIN MEDICATIONS.

Manufacturer Narrative (H10):

ON (B)(4) 2012, AFTER REPEATED UNSUCCESSFUL ATTEMPTS TO VERIFY THE DETAILS OF THIS EVENT WITH THE PHYSICIAN INVOLVED, THE CONSERVATIVE DECISION WAS MADE TO REPORT THIS EVENT.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024803	CONCEPTUS, INC.	3/26/2012	4/2/2012

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6): 10/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE FOR PREVENTING PREGNANCY. IT IS CAUSING VERY LONG PERIODS LASTING 3 OR MORE WEEKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5024867	CONCEPTUS	3/30/2012	4/5/2012

Event Information:

Event Date (B3): 8/11/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/11/2009
Explant Date (E7): 8/10/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM REPORTING THE ESSURE WHICH IS MANUFACTURED BY CONCEPTUS. IT IS A PERMANENT BIRTH CONTROL DEVICE WHICH IS INSERTED INTO THE FALLOPIAN TUBES, THE BODY IS SUPPOSED TO FORM SCAR TISSUE AROUND IT AND THE TUBES THEN ARE BLOCKED. THIS PRODUCT PRODUCES SERIOUS SIDE EFFECTS, WHICH CAUSE A LOT OF PAIN, BLEEDING, AND ADVERSE REACTIONS TO OTHER ORGANS. I HAD TO HAVE MAJOR ABDOMINAL SURGERY TO HAVE THIS DEVICE REMOVED. PLEASE NOTE THAT THIS PRODUCT IS BEING PUSHED ON DOCTORS, WHO ARE BRIBED WITH GOOD COMPENSATION AND BONUSES SO THAT THEY WOULD PUSH THIS PRODUCT TO PTS. I FOUND OUT THAT DURING THE PROCEDURE, THE COMPANY REPRESENTATIVES ARE "GUIDING" THE DOCTORS IN THE OPERATING ROOM AS TO HOW TO PLACE THE ESSURE PRODUCT IN. I ASK THAT THIS MATTER PLEASE BE INVESTIGATED, THIS IS A VERY HARMFUL DEVICE, AND A LOT OF WOMAN INCLUDING MYSELF HAVE SUFFERED GREATLY FROM IT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00023	CONCEPTUS, INC.	4/6/2012	8/1/2012

Event Information:

Event Date (B3): 12/14/2011 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7): 12/14/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ALLERGY LIKE SYMPTOMS AND PAIN SINCE THE ESSURE PROCEDURE. SHE DID NOT HAVE AN ALLERGY TEST, HOWEVER, HER PHYSICIAN DECIDED TO REMOVE THE DEVICES PER REQUEST OF THE PT AND PERFORM A BILATERAL SALPINGECTOMY ON (B)(6) 2011. NO CONFIRMATION HAS BEEN MADE WHETHER THE PT'S SYMPTOMS HAVE RESOLVED SINCE THE REMOVAL OF THE DEVICES.

Manufacturer Narrative (H10):

THIS EVENT OCCURRED IN (B)(6) AND SEVERAL ATTEMPTS HAVE BEEN MADE TO CONTACT THE PHYSICIAN BUT NO RESPONSE HAS BEEN RECEIVED, SO WE HAVE BEEN UNABLE TO CONFIRM RESOLUTION OF THE PT'S SYMPTOMS. A DECISION HAS BEEN MADE TO CONSERVATIVELY FILE THIS REPORT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025027	CONCEPTUS, INC.	4/11/2012	4/18/2012

Event Information:

Event Date (B3): 4/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM REPORTING CONCEPTUS, INC. AND THE MAKER OF THE PERMANENT BIRTH CONTROL METHOD CALLED ESSURE. I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2011. DURING THE 4 MONTHS OF THIS PROCEDURE, HAD NOTHING BUT PROBLEMS. THE PROBLEMS WERE DIZZINESS (ALMOST PASSED OUT), WEIGHT GAIN, PAIN AND BURNING IN ABDOMEN AND RIGHT SIDE, TINGLING SENSATIONS ALL OVER MY BODY, EXTREME HEADACHES, NAUSEA, FATIGUE, ELEVATED BLOOD PRESSURE, CRAMPING, BLEEDING ETC. ENDED UP HAVING A PARTIAL HYSTERECTOMY TO HAVE DEVICE REMOVED. SPENT THOUSANDS OF DOLLARS ON TESTS AND NOW SURGERY. THIS PRODUCT NEEDS TO BE RE-EVALUATED FOR LONG TERM EFFECTS. TOO MANY WOMEN ARE HAVING TROUBLE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00022	CONCEPTUS, INC.	4/24/2012	8/1/2012

Event Information:

Event Date (B3): 3/16/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/20/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE ESSURE PROCEDURE (B)(6) 2010. PT PRESENTED ON (B)(6) 2012, WITH ABDOMINAL PAIN AND PHYSICIAN DID AN ULTRASOUND AND CONFIRMED AN ECTOPIC PREGNANCY. PT WAS TREATED WITH METHOTREXATE ON (B)(6) 2012 AND IS DOING FINE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00024	CONCEPTUS, INC.	4/24/2012	8/1/2012

Event Information:

Event Date (B3): 3/20/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTED SHE HAD AN ESSURE PROCEDURE PERFORMED IN (B)(6) 2008. PT FOUND OUT SHE WAS PREGNANT ON (B)(6) 2012, AND WAS TREATED WITH METHOTREXATE AND SENT HOME SINCE SHE WAS NOT HAVING ANY ADVERSE REACTIONS OR PAIN.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	4/25/2012	5/4/2012

Event Information:

Event Date (B3): 4/17/2012 **Report Date (B4): 4/25/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL APPEARED TO BE DOUBLE LOADED INTO DEVICE THUS RESULTING IN THE PATIENT HAVING A LAPAROSCOPIC TUBAL LIGATION PERFORMED. EQUIPMENT SENT FOR EVALUATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025366	CONCEPTUS, INC.	5/9/2012	5/17/2012

Event Information:

Event Date (B3): 7/11/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): ESSURE SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 7/25/2006
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2006, AFTER GIVING BIRTH TO MY 3RD SON. I WAS (B)(6) AT THE TIME OF THE PROCEDURE. I WAS IN GOOD HEALTH WITH NO HEALTH RELATED ISSUES. AFTER GIVING BIRTH, I WANTED TO GET A NORMAL TUBAL LIGATION DONE, BUT MY OBGYN AT THE TIME, CONVINCED ME OF THIS NEW ESSURE PROCEDURE, THAT WAS 'ALLEGEDLY" FDA APPROVED AND NO SIDE EFFECTS. THE FIRST YEAR THAT I HAD THE PROCEDURE, I HAD MILD CRAMPING WHICH WAS TOLERABLE. MY OBGYN ADVISED THAT WAS THE SKIN GROWING BACK OVER MY FALLOPIAN TUBES AND WOULD EVENTUALLY STOP. A FEW WEEKS AFTER THE PROCEDURE, I WENT BACK IN TO THE OFFICE AND HAD A HSG TEST, AND WAS TOLD THAT EVERYTHING WAS FINE. NOW I HAVE LOWER LEFT ABDOMINAL/CERVICAL PAIN, NAUSEA, CONSTIPATION, VERY FREQUENT HEADACHES, AND I STARTED HAVING BLOODCLOTS WITH MY MENSTRUAL CYCLES WITH SEVERE CRAMPING. I ALSO HAVE FIBROIDS AND CYSTS AS WELL. I HAVE RELOCATED TO A DIFFERENT STATE AND CANNOT SEEM TO GET THE ANSWERS OR HELP THAT I AM LOOKING FOR. NOT TO MENTION MY PROVIDER NEVER TOLD ME THAT HE WAS PUTTING ANY FORM OF ANYTHING METAL IN ME, HE JUST DESCRIBED THEM AS SOFTSPIRAL COILS. SINCE I HAVE HAD THE PROCEDURE DONE, I HAVE GAINED WEIGHT, I ALSO HAVE A METALLIC TASTE IN MY MOUTH. I HAVE TRIED TO SEE OTHER OBGYN'S BUT CANNOT GET THE HELP THAT I AM LOOKING FOR. I DON'T UNDERSTAND WHY IN 2006 WHEN I HAD THE PROCEDURE THAT THERE WAS NO PRECAUTION IN HAVING THE WOMEN TESTED TO SEE IF THEIR BODY CAN WITH HOLD THIS PERMANENT PROCEDURE AND HAVE USE TESTED. I FEEL LIKE I WAS A HUMAN EXPERIMENT, AND NOW THAT I AM COMPLAINING ABOUT IT, I FEEL AS IF EVERYONE IS TURNING THEIR BACK ON ME. I SINCERELY HOPE THAT I DON'T HAVE TO "DROP DEAD" BEFORE THE FDA TAKE THIS MATTER SERIOUS. THERE ARE NUMEROUS

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SITES WHERE OTHER WOMEN ARE ALL COMPLAINING OF SIMILAR SIDE EFFECTS. PLEASE HELP US AND PROVIDE US WITH INFORMATION. LIST OF OTHER SITES WITH WOMEN WITH ISSUE WITH ESSURE SIDE EFFECTS: (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025417		5/14/2012	5/21/2012

Event Information:

Event Date (B3): 5/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/30/2008
Explant Date (E7): 5/7/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE FOUR YEARS AGO. AFTERWARD, I WAS IN PAIN ALL THE TIME AND SPENT TONS OF TIME IN ERS AND DOCTOR OFFICES. THEY KEPT TELLING ME NOTHING WAS WRONG. I FOUND OUT 2 MONTHS AGO THAT ONE COIL IS IN MY UTERUS AND THE OTHER IS DANGLING OUT OF MY TUBE. THIS PROCEDURE RUINED MY QUALITY OF LIFE, CAUSED ME TO LOOSE JOBS AND I EVENTUALLY HAD TO FILE BANKRUPTCY. PLEASE DO SOMETHING! THANK YOU. DATES OF USE: (B)(6) 2008 - (B)(6) 2012. DIAGNOSIS: STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025447	CONCEPTUS INCOPORATED	5/16/2012	5/24/2012

Event Information:

Event Date (B3): 5/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 901329

Single Use:
Implant Date (E6): 5/16/2012
Explant Date (E7): 5/16/2012
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE BROKE WHILE MD WAS PLACING THE DEVICE INTO THE PT. THE DEVICE WAS REMOVED AND THE PROCEDURE WAS RESCHEDULED FOR ANOTHER DATE. THERE WAS NO ADVERSE OUTCOME TO THE PT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025503	CONCEPTUS, INC	5/18/2012	5/29/2012

Event Information:

Event Date (B3): 5/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION DELIVERY SYSTEM KIT
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 7356707

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE TUBAL OCCLUSION DELIVERY SYSTEM KIT OPENED FOR CASE. FIRST COIL DEPLOYED SUCCESSFULLY WITHOUT INCIDENCE INTO FALLOPIAN TUBE. SECOND COIL FAILED TO DEPLOY CORRECTLY, COMING APART IN PIECES. SURGEON WAS ABLE TO RETRIEVE ALL THE PIECES AND WAS VISUALLY WITNESSED VIA HYSTEROSCOPE BY ENTIRE OPERATING ROOM TEAM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025519		5/18/2012	5/31/2012

Event Information:

Event Date (B3): 7/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/13/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DONE IN (B)(6) 2011 AFTER MY 3RD CHILD WAS BORN. SINCE THEN I HAVE NOT HAD A NORMAL LIFE BEEN BLEEDING FOR THE LAST 10 MONTHS NON STOP AND HAVING HEADACHES. MY INSURANCE PAID (B)(6) FOR THIS PROCEDURE TO BE DONE AND NOW I AM HAVING TO HAVE A PARTIAL HYSTERECTOMY TO HAVE THEM REMOVED WHICH I HAVE TO PAY OUT OF POCKET. WHICH IS GOING TO COST ME (B)(6) AND 20 PERCENT OF THE HOSPITAL BILL. MY NEW DOCTOR IS REMOVING MY TUBES TO TAKE THE COILS OUT AND MY UTERUS TO STOP THE BLEEDING AND I AM (B)(6). MY ORIGINAL DOCTOR WHO PUT THE COILS IN IS NO LONGER IN PRACTICE BECAUSE OF MEDICAL REASONS. HAD TO FIND ANOTHER DOCTOR LUCKILY WHO WAS WILLING TO HELP GET MY LIFE BACK TO NORMAL. MY SURGERY IS SCHEDULED FOR (B)(6) 2012. SOMETHING NEEDS TO BE DONE ABOUT THIS PROCEDURE BECAUSE MAJORITY OF THE WOMEN HAVING IT DONE HAS TO HAVE THEM REMOVED. THIS HAS CAUSED ALMOST A YEAR OF PAIN, SUFFERING, AND MONEY FOR ME. I HAVE 3 CHILDREN: A (B)(6) YEAR OLD, A (B)(6) YEAR OLD, AND A (B)(6) YEAR OLD I HAVE TO TAKE CARE. AND MY LIFE WAS COMPLETELY NORMAL BEFORE THIS PROCEDURE. I AM READY TO BE BACK TO MY NORMAL SELF. ESSURE PROCEDURE (B)(6) 2011 WENT BACK FOR A CHECK UP 2 WEEKS LATER. SCHEDULED TO HAVE THE DYE PUT IN 3 MONTHS LATER TO CHECK AND MAKE SURE THE COILS WERE IN THE RIGHT PLACE AND TISSUE SCARED AROUND THEM AND DOCTOR WAS ON MEDICAL LEAVE. WENT BACK IN (B)(6) CAUSE OF BLEEDING. FOUND A NEW DOCTOR IN THE END OF (B)(6) AND SCHEDULED TO HAVE THEM REMOVED ON (B)(6).

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025522	CONCEPTUS	5/19/2012	6/4/2012

Event Information:

Event Date (B3): 5/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE CONCEPTUS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/19/2011
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

APPROX ONE YEAR AGO, I HAD BIRTH CONTROL IMPLANTS CALLED ESSURE PUT IN BY MY PHYSICIAN. WHILE I WAS SYMPTOM FREE FOR THE FIRST FEW MONTHS, THE LIGHT CLICKED ON THURSDAY, (B)(6), WHEN I HAD A MAJOR MEDICAL CRISIS. I WAS SITTING AT WORK IN A MEETING AND SUDDENLY STARTED BLEEDING EXCESSIVELY. BECAUSE I HAD SPOTTED A VERY SMALL AMOUNT THE DAY BEFORE, I HAD HAPPENED TO BE WEARING A PAD. IN LESS THAN ONE MINUTE, THE PAD WAS SOAKED WITH BLOOD AND WAS DRIPPING DOWN MY LEG AS I WAS WALKING TO GET SOMEONE TO DRIVE ME TO THE HOSP. FROM THE LARGE AMOUNT OF BLOOD LOSS, I WAS DIZZY, LIGHTHEADED AND WEAK. I FELT LIKE I WAS HIT BY A TRAIN. THIS WAS ONE OF THE SCARIEST MOMENTS OF MY LIFE AND I TRULY THOUGHT I WAS HEMORRHAGING. WHILE THE ER PHYSICIAN TREATED THE SYMPTOMS THAT RESULTED IN MY GOING TO THE ER, HE WAS UNABLE TO TELL ME WHAT CAUSED IT. IT WAS MY MOM ASKING ME IF THE ESSURE WAS OKAY THAT MADE ME START LOOKING FOR INFO AND FOUND A VERY DETAILED BLOG. WHEN MY DR WAS FIRST TALKED TO ME ABOUT ESSURE, HE SAID THE PROCEDURE WAS PAINLESS, DONE IN THE OFFICE AND AT MOST, I'D FEEL SOME CRAMPING. MY DR HAS BEEN MY DR FOR YEARS AND I TRUSTED HIM WHEN HE SAID IT WAS SAFE AND THERE WERE NO SIDE-EFFECTS OF ANY KIND. I NOW KNOW THIS IS NOT ACCURATE. FOR THE PAST FEW MONTHS, I'VE BEEN EXPERIENCING STRANGE SYMPTOMS. AFTER ESSURE, MY PERIODS STOPPED, AND THEN THEY STARTED AGAIN, BUT THEY ARE NOT NORMAL. THEY USED TO BE LIKE CLOCK-WORK. WHAT HAPPENS TO ME NOW IS FAR FROM REGULAR. A FEW MONTHS AGO, I BLED FOR THREE WEEKS STRAIGHT. MY SAME DR CHECKED ME OUT AND DID BIOPSIES, WHICH ALL CAME BACK NEGATIVE FOR CANCER. HE NEVER EXPLAINED THE CAUSE OF THE BLEEDING TO ME. WHEN I HAVE A PERIOD NOW, THEY ARE VERY IRREGULAR. THE BLOOD NOW IS BRIGHT RED AND LOOKS MORE LIKE THE COLOR OF WOUND AND NOT MY CYCLE. I'M ALSO SUFFERING FROM TINGLING IN MY HANDS AND FEET,

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SHARP STABBING PAINS IN MY SIDES WHERE MY TUBES ARE LOCATED, I'M HAVING MOMENTS OF FORGETFULNESS AND I GENERALLY FEEL BAD MOST OF THE TIME. ALL OF THIS STARTED A FEW MONTHS AFTER THE IMPLANTS WERE INSERTED. I NOW KNOW THAT THESE ARE SIDE EFFECTS OF THIS PROCEDURE. I'LL BE SEEING MY GYN MONDAY AND MY REQUEST IS SIMPLE, GET THESE THINGS OUT OF ME, HOWEVER, THESE PRODUCTS ARE STILL ON THE MARKET AND MORE IMPORTANTLY, THEY CONTAIN NICKEL AND AN ALLERGY OR SENSITIVITY TEST IS NOT REQUIRED PRIOR TO INSERTION. THESE DEVICES NEED TO BE PULLED FROM THE MARKET. THEY ARE SLOWLY POISONING WOMEN FROM THE INSIDE AND IT'S HORRIBLY PAINFUL. DOSE OR AMOUNT: 2, FREQUENCY: ONE TIME INSERTION, ROUTE: VAG. DATES OF USE: STILL INSERTED 1 YEAR. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00025	CONCEPTUS, INC.	5/23/2012	8/3/2012

Event Information:

Event Date (B3): 2/15/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/26/2009
Explant Date (E7): 3/5/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT (B)(6) HAD THE ESSURE PLACEMENT (B)(6) 2009 AND THE HSG TEST (B)(6) 2010, REFLECTED PROPER PLACEMENT AND OCCLUSION. A YEAR LATER SHE BEGAN HAVING SEVERE CRAMPING, SPOTTING, BLEEDING DURING SEX AND PELVIC PAIN. IN 12/06/2011 SHE WENT TO HER PHYSICIAN AND HAD A SONOGRAM AND HE DISCOVERED THE RIGHT COIL HAD MIGRATED INTO HER UTERUS. ON (B)(6) 2012, SHE PRESENTED TO THE ER WITH SEVER ABDOMINAL PAIN AND THE HOSPITAL DETERMINED VIA SONOGRAM AND UTERINE CAT SCAN THAT THE LEFT COIL HAD EXPELLED, UNWOUND AND WAS LODGED INTO THE MYOMETRIUM OF HER UTERINE WALL. HER PHYSICIAN ADVISED HER TO HAVE A PARTIAL HYSTERECTOMY IN ORDER TO REMOVE THE DEVICES DUE TO THEIR LOCATION. THIS WAS PERFORMED (B)(6) 2012. PATIENT IS DOING MUCH BETTER POST SURGERY. CONCEPTUS RECEIVED HER MEDICAL RECORDS (B)(6) 2012 FROM HER PHYSICIAN.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	6/4/2012	6/13/2012

Event Information:

Event Date (B3): 2/3/2012 **Report Date (B4): 6/4/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): STERILIZATION EQUIPMENT
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6): 2/3/2012
Explant Date (E7): 2/3/2012
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/3/2012

Event Description (B5):

THREE ESSURE DEVICES MALFUNCTIONED INSIDE PATIENT'S UTERUS WITH DIFFICULT REMOVAL OF EVERY PART OF DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025824	CONCEPTUS	6/7/2012	6/21/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 822365

Single Use:
Implant Date (E6): 10/19/2011
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD CONCEPTUS ESSURE COILS PLACED IN MY FALLOPIAN TUBES FOR STERILIZATION PURPOSES. BLEEDING AND VERY INTENSE CRAMPING BEGAN TWO DAYS AFTER THE PROCEDURE AND HAS CONTINUED UNTIL CURRENTLY. THE BLEEDING WAS CONTINUALLY HEAVY FOR OVER 3 MONTHS, THEN SPOTTING, LIGHT, BACK TO HEAVY, REPEATING NOT NECESSARILY IN THAT ORDER. TO BE CLEAR, I HAVE ONLY HAD A TOTAL OF 19 DAYS FREE OF ANY BLEEDING FROM THE TIME OF THE PROCEDURE TO CURRENT. I HAVE LARGE BLOOD CLOTS PASSED, INTENSE CRAMPING, AND SUFFERED VERTIGO FOR 3 MONTHS ((B)(6) 2012-(B)(6) 2012) THE VERTIGO CEASED 2 DAYS AFTER THE FIRST BREAK OF BLEEDING ON (B)(6) 2012. I AM NAUSEOUS, MOODY, HAVE HEADACHES, AND POSSIBLY CHEST PAIN RELATED, DEPRESSION, LACK OF INTIMACY. IN (B)(6), I TRIED PROGESTIN FOR A PERIOD OF 21 DAYS, SPOTTING STILL RESULTED. MY LIFE HAS BEEN COMPLETELY ALTERED DEALING WITH SYMPTOMS SINCE ESSURE WAS PLACED. I CANNOT CONTINUE ON AS NORMAL. THEY HAVE CHANGED MY LIFE IN AN ADVERSE WAY. THE COILS ARE SAID TO BE NON-REMOVABLE. HYSTERECTOMY IS A POSSIBLE OUTCOME. I HAVE NO PREVIOUS HISTORY OF GYNECOLOGICAL PROBLEMS AS SUCH. ESSURE COILS: CONCEPTUS. NUMEROUS DOCTOR VISITS WHICH I DO NOT HAVE DATES FOR.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00026	CONCEPTUS, INC.	6/7/2012	8/6/2012

Event Information:

Event Date (B3): 2/21/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH, DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/28/2011
Explant Date (E7): 2/21/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTED TO MEDWATCH THAT SHE HAD THE ESSURE PROCEDURE (B)(6) 2011. SHE CLAIMS SHE EXPERIENCED THE FOLLOWING SYMPTOMS POST THE PROCEDURE; CRAMPING, DIZZINESS, PAIN, EXCESSIVE HEAVY BLEEDING, FATIGUE, NAUSEA, AND WEIGHT LOSS. SHE CLAIMS SHE HAD THE DEVICES REMOVED (B)(6) 2012. CONCEPTUS MADE THREE SEPARATE ATTEMPTS TO PT'S EMAIL ADDRESS TO OBTAIN PHYSICIAN NAME AND ADDRESS AND TO FOLLOW UP WITH HER OUTCOME POST REMOVAL. PT DID NOT RESPOND. AS A CONSERVATIVE MEASURE THIS REPORT IS BEING FILED WITH NO VERIFICATION TO DETERMINE WHETHER THE DEVICES WERE THE ROOT CAUSE OF THE PT'S SYMPTOMS.

Manufacturer Narrative (H10):

ON (B)(4) 2012 - EMAIL SENT FROM CONCEPTUS TO PT'S EMAIL ADDRESS TO OBTAIN PHYSICIAN INFO AND DETAILS SURROUNDING HER REPORT. ON (B)(4) 2012 - DECISION TO FILE AN MDR DETERMINED.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025887	CONCEPTUS INC	6/18/2012	6/25/2012

Event Information:

Event Date (B3): 6/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 922609

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE FAILED TO DEPLOY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00027	CONCEPTUS, INC.	6/20/2012	6/28/2012

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/1/2010
Explant Date (E7): 4/23/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT CALLED TO INFORM US SHE HAD HER DEVICES REMOVED. SHE HAD A PARTIAL HYSTERECTOMY ON (B)(6) 2012. PATIENT CLAIMS THAT THE DAY SHE HAD THE DEVICES IMPLANTED THE PHYSICIAN PERFORATED HER UTERUS WITH A COIL THAT PREMATURELY DEPLOYED AND THEY TOOK HER TO THE OPERATING ROOM AND PERFORMED A BILATERAL LAP TUBAL AND LEFT THE RIGHT DEVICE IN PLACE ALONG WITH THE FILSHIE CLIP. SINCE THAT TIME IN (B)(6) 2010, SHE SAID SHE DEVELOPED A LOWER QUADRANT RIGHT SIDE PAIN AND SHE STARTED HAVING HEAVY BLEEDING WITH LARGE CLOTS. SHE AND HER NEW PHYSICIAN DECIDED TO REMOVE THE DEVICES AND PERFORM A PARTIAL HYSTERECTOMY. PATIENT IS NOW PAIN FREE AND HAS MORE BLEEDING. THE PHYSICIAN CAN NOT DETERMINE WHETHER THE DEVICES WERE THE ROOT CAUSE OF HER PAIN. AS A CONSERVATIVE MEASURE WE ARE FILING THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00029	CONCEPTUS, INC.	6/20/2012	6/28/2012

Event Information:

Event Date (B3): 1/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 869749

Single Use: Y
Implant Date (E6): 12/9/2011
Explant Date (E7): 5/25/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT SHE REMOVED THE ESSURE DEVICES ON THE PATIENT. THE ESSURE WAS PLACED (B)(6) 2011. HSG WAS PERFORMED (B)(6) 2012, REFLECTED NO EVIDENCE OF TUBAL PATENCY BILATERALLY. THE PATIENT COMPLAINED OF DAILY VAGINAL BLEEDING AND PAIN ON (B)(6) 2012, AND WAS GIVEN SAMPLES OF OCP. ON (B)(6) 2012, PATIENT COMPLAINED OF CONTINUED BLEEDING AND PAIN AND REFUSED ADDITIONAL MEDICATIONS. PHYSICIAN DISCOVERED ONE OF THE DEVICES WAS EMBEDDED IN THE ENDOMETRIUM. PHYSICIAN REMOVED THE DEVICE HYSTEROSCOPICALLY ON (B)(6) 2012. THE PHYSICIAN BELIEVES THIS WAS CAUSING THE PATIENT'S BLEEDING. SINCE THE REMOVAL, THE PATIENT'S BLEEDING HAS CEASED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00028	CONCEPTUS, INC.	6/20/2012	8/7/2012

Event Information:

Event Date (B3): 3/9/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/9/2009
Explant Date (E7): 3/28/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE ESSURE PROCEDURE (B)(6) 2009. SHE PRESENTED TO THE ER ON (B)(6) 2009, WITH RIGHT LOWER QUADRANT PAIN IN THE PELVIC AREA. AN HSG REFLECTED SATISFACTORY LOCATION HOWEVER AN ULTRA SOUND SHOWED A DEVICE TO BE IN THE ENDOMETRIUM. ON (B)(6) 2012, SHE PRESENTED WITH COMPLAINT OF EXCESSIVE BLEEDING AND STATED SHE HAS HAD DAILY SPOTTING FOR THE PAST THREE YEARS. ON (B)(6) 2012, THE PHYSICIAN PERFORMED A BILATERAL TUBAL RING APPLICATION WITH FALLOPE RINGS AND LEFT THE LEFT COIL IN PLACE. THE PHYSICIAN REMOVED THE RIGHT ESSURE DEVICE WHICH WAS PROTRUDING INTO THE ENDOMETRIUM. SHE BELIEVES THIS IS THE REASON FOR THE CONSTANT IRRITATION TO THE ENDOMETRIUM WHICH WAS CAUSING THE SPOTTING. PT'S BLEEDING WAS RESOLVED SINCE SURGERY.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS	6/25/2012	6/27/2012

Event Information:

Event Date (B3): 12/15/2011 **Report Date (B4): 6/25/2012** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE INTRAUTERINE DEVICE
Device Type (E2): INTRAUTERINE STERILIZATION DEVICE
Model # (E4): ESS205
Catalog # (E4): *
Lot #(E4): 827927

Single Use:
Implant Date (E6): 9/15/2011
Explant Date (E7): 6/14/2012
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD HYSTEROSCOPY AND IMPLANTATION OF ESSURE INTRAUTERINE DEVICE FOR PERMANENT STERILITY. ON THE FOLLOW-UP HSG (HYSTEROSALPINGOGRAM), BOTH TUBES WERE FOUND TO BE PATENT WITH FREE SPILL OF CONTRAST. THERE WAS LATERAL MIGRATION OF THE LEFT COIL INTO THE AMPULLA AND PROBABLE AMPULLARY EXPULSION OF THE RIGHT COIL. PATIENT CONTINUED ON DEPO-PROVERA AND RETURNED TO SURGERY FOR HYSTEROSCOPY, LAPAROSCOPIC BILATERAL SALPINGECTOMY AND RETRIEVAL OF ESSURE COILS UNDER FLUORO. INTRAOPERATIVELY THE SURGEON WAS UNABLE TO VISUALIZE EITHER COIL WITH A HYSTEROSCOPE. LAPAROSCOPICALLY, THE LEFT FALLOPIAN TUBE WAS INSPECTED AND THE PROXIMAL END OF THE ESSURE COIL COULD BE SEEN THROUGH THE WALL OF THE FALLOPIAN TUBE. BILATERAL TUBES WERE REMOVED. THE COIL FROM THE RIGHT FALLOPIAN TUBE WAS FOUND PARTIALLY GROWN INTO THE OMENTUM IN THE LEFT UPPER QUADRANT OF THE ABDOMEN. IT WAS EXCISED AND REMOVED. PATIENT WAS DISCHARGED HOME FROM HOSPITAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5025983	CONCEPTUS	6/25/2012	7/5/2012

Event Information:

Event Date (B3): 4/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS PLACED ON (B)(6) 2011. SINCE THE PROCEDURE I HAVE HAD SEVERE ABDOMINAL AND BACK PAIN. I HAVE HAD RECURRING BLADDER AND URINARY TRACT INFECTIONS THAT HAVE NOT GONE AWAY WITH ANTIBIOTICS. I HAVE BEEN TO SEVERAL DOCTORS BECAUSE THE OB/GYN THAT PLACED THE COILS SAYS THAT HE WILL NOT REMOVE THEM AND THE PAIN THAT I'M HAVING CAN'T POSSIBLY BE FROM THE ESSURE IMPLANTS. I DECIDED TO GET A 2ND AND 3RD OPINION. TODAY I FOUND OUT THAT ONE OF THE COILS WAS IN MY UTERUS AND NO LONGER IN MY FALLOPIAN TUBE WHERE IT BELONGS. I FEEL THAT NO WOMAN SHOULD HAVE TO DEAL WITH THE COMPLICATIONS THAT SO MANY WOMEN REPORT. THE ESSURE SHOULD BE RECALLED AND TAKEN OFF THE MARKET AS AN ALTERNATIVE FORM OF A TUBAL LIGATION. THERE HAVE BEEN MORE BAD REPORTS THAN GOOD WHEN IT COMES TO THE ESSURE AND DOCTORS ARE DENYING THAT THE COMPLICATIONS CAN BE FROM THE ESSURE. HOW DOES THAT MAKE SENSE? ALL THE PROBLEMS I HAVE HAD WERE AFTER I HAD THESE COILS PUT IN AND THE PAIN HAS BEEN CONSTANT! I HOPE THAT I CAN FIND SOMEONE WHO CAN HELP ME BECAUSE I FEEL THAT I HAVE BEEN PUSHED FROM ONE DOCTOR TO ANOTHER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026188	CONCEPTUS	7/13/2012	7/20/2012

Event Information:

Event Date (B3): 2/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE MICRO INSERTS
Model # (E4): REF ESS305
Catalog # (E4): ESS305
Lot #(E4): 787221

Single Use:
Implant Date (E6): 2/28/2012
Explant Date (E7): 9/5/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE DONE ON (B)(6) 2012. AT (B)(6) MONTH F/U, HSG CONFIRMATION TEST, THE ESSURE INSERT ON RIGHT SIDE APPEARS IN A SATISFACTORY LOCATION AND FALLOPIAN TUBE APPEARED OCCLUDED. THE PT'S LEFT ESSURE INSERT APPEARS IN HSG IMAGE TO HAVE PERFORATED HER FALLOPIAN TUBE, AND THE ESSURE INSERT IS COILED UP IN A CIRCULAR POSITION AND CAN CLEARLY BE SEEN OUTSIDE OF THE FALLOPIAN TUBE IN THE PERITONEAL CAVITY. THE LEFT SIDE OF COURSE SHOWS PATENCY (OPEN TUBE) WITH CONTRAST DYE FREELY SPILLING INTO THE ABDOMINAL CAVITY. PT'S DOCTOR AND THE ESSURE REP ARE RECOMMENDING PLACING ANOTHER INSERT INTO THE PT'S LEFT FALLOPIAN TUBE. THEY REFUSE TO ADDRESS THE INSERT COILED IN PT'S ABDOMINAL CAVITY STATING THAT THE DEVICES ARE SOFT FLEXIBLE, AND WILL NOT CAUSE ANY DAMAGE. PT HAS REFUSED THIS AS A SOLUTION AND COURSE OF ACTION. PT HAS BEEN TO A SECOND DOCTOR DUE TO PELVIC PRESSURE ISSUE THAT HAS DEVELOPED AND SUFFERS DAILY WITH THIS SYMPTOM. SECOND DOCTOR IS RECOMMENDING REMOVAL OF UTERUS, FALLOPIAN TUBES, AND BOTH DEVICES. PHYSICIAN ALSO STRONGLY ADVISED AGAINST HAVING ANOTHER DEVICE PLACED. ADVERSE EVENT REPORTER IS THE PT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026202	CONCEPTUS	7/16/2012	7/24/2012

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD TO HAVE ESSURE IMPLANTS REMOVED DUE TO BEING IN SEVERE PAIN, AND MY BODY REJECTING THE COILS. I ALMOST LOST MY LIFE DUE TO THE IMPLANTS AND THE ONLY WAY TO REMOVE THEM WAS SURGICALLY. ROUTE: INTRA-UTERINE. DATES OF USE: 6 MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026217		7/16/2012	7/24/2012

Event Information:

Event Date (B3): 6/25/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/25/2007
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2007 AND I HAVE HAD A LOT OF PROBLEMS SINCE THEN FROM HEART RACING, NUMBNESS OF RIGHT SIDE, ABDOMINAL PAIN, UTIS, FOGGINESS, EMOTIONAL ISSUES, HORMONE ISSUES AND A LOT OF OTHER THINGS THAT ALL IF A DIRECT EFFECT FROM THE ESSURE PROCEDURE. I CAN NOT BELIEVE THAT PEOPLE ARE STILL HAVING THESE PUT IN. I AM WORKING ON GETTING MINE REMOVED ASAP, BUT THERE NEEDS TO BE A STOP TO THESE BEING DONE BECAUSE OF ALL OF THE SIDE EFFECTS. I AM UPSET THAT I DIDN'T KNOW ABOUT ALL OF THESE SIDE EFFECTS BEFORE HAVING THIS DONE AND THAT IT TOOK ME HAVING SOMEONE THAT WORKS AT A HOSP TELLING ME TO DO RESEARCH ON ESSURE THAT I HAVE FINALLY GOT ANSWERS TO ALL OF THE HEALTH PROBLEMS I HAVE BEEN HAVING THAT NOBODY COULD FIGURE OUT. I AM OUT OVER (B)(6) IN MEDICAL BILLS TO FINALLY FIND OUT THAT IT IS ALL DUE TO ESSURE. PLEASE, I BEG THAT YOU STOP THIS FROM TAKING OTHER PEOPLE'S WELLNESS FROM THEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026187	CONCEPTUS, INC	7/17/2012	7/20/2012

Event Information:

Event Date (B3): 3/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 922609

Single Use:
Implant Date (E6): 2/6/2012
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS PT WAS ADVISED BY HER PRIMARY CARE PHYSICIAN TO GET AN ABLATION OF HER FALLOPIAN TUBES WITH IMPLANTATION OF THIS ESSURE DEVICE. THE DEVICE WAS PLACED IN EACH FALLOPIAN TUBE PER PT. PT HAS BEEN EXPERIENCING SEVERE PAIN GOING FROM HER ABDOMEN TO HER VAGINAL AREA; SHE HAS BEEN RUNNING RECURRENT FEVER OF ABOUT 101 DEGREES, HAS BEEN ON ANTIBIOTICS THREE TIMES. SHE PRESENTLY IS EXPERIENCING HEAVY BLEEDING COUPLED WITH INFECTIONS. SHE IS EMOTIONALLY DOWN AND HER ENTIRE BODY IS ACHY. SHE HAS HAD AN ULTRASOUND AND CT SCAN WHICH SHOW THAT THE DEVICE IS MIGRATING. SHE IS PRESENTLY DISABLED, HAS HAD FLU-LIKE SYMPTOMS AND FEVER SINCE THE DEVICE WAS PUT IN PLACE BACK IN (B)(6) 2012. DOCTOR SAYS SHE NEEDS TO HAVE A PARTIAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026229	CONCEPTUS, INC.	7/17/2012	7/24/2012

Event Information:

Event Date (B3): 12/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 857593

Single Use:
Implant Date (E6): 12/9/2011
Explant Date (E7): 4/2/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, I HAD ESSURE COILS PLACED FOR STERILIZATION PURPOSES. (B)(6) LATER, I DEVELOPED A NEW ONSET MIGRAINE HEADACHE. NEVER EXPERIENCED A MIGRAINE BEFORE. IN THE WEEKS FOLLOWING, I DEVELOPED NUMBNESS/TINGLING IN MY EXTREMITIES, COGNITIVE FOG, BLURRED VISION, BALANCE ISSUES, AND DEEP BONE PAIN. INITIAL MRI OF MY BRAIN SHOWED WHITE MATTER CHANGES CONSISTENT WITH DEMYELINATING DISEASE. AFTER SEEING TWO DIFFERENT NEUROLOGISTS I WAS TOLD WITH "99% CERTAINTY" THAT I HAVE MULTIPLE SCLEROSIS. A (B)(6) MONTH F/U, MRI SHOWED SLIGHT IMPROVEMENT SO MY DIAGNOSIS WAS CHANGED TO COMPLICATED MIGRAINE. I DEVELOPED RIGHT SIDED ABDOMINAL PAIN AND MET WITH MY OB. I SCHEDULED A HYSTERECTOMY FOR PAIN ISSUES AND FOR ESSURE REMOVAL. I UNDERWENT THE HYSTERECTOMY ON (B)(6) 2012. AS OF TODAY, (B)(6) 2012, I NO LONGER SUFFER FROM THE ABOVE MENTION NEUROLOGICAL ISSUES OR FROM THE ABDOMINAL PAIN. I BELIEVE THAT I HAD A ADVERSE REACTION TO THE ESSURE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026249	UNK	7/18/2012	7/25/2012

Event Information:

Event Date (B3): 4/20/2010 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AND I WANT TO REPORT THAT I HAVE HAD NOTHING BUT PAIN SINCE HAVING IT DONE. I DO NOT HAVE INSURANCE NOR CAN I AFFORD TO GO HAVE THESE COILS REMOVED, SO I AM STUCK WITH THE PAIN FOR THE REST OF MY LIFE. I HAVE CONSTANT BACK PAIN, LEG PAIN, HEADACHES, GET DIZZY AND LIGHTHEADED, MAJOR HEAVY PAINFUL PERIODS LIKE ALL MY VAGINAL INSIDES ARE GOING TO FALL OUT. I HAVE FOUND A WEBSITE WITH TONS OF OTHER WOMEN THAT ARE HAVING ALL THE SAME SIDE EFFECTS. DOCTORS DO NOT BELIEVE THAT IT IS FROM ESSURE, BUT I NEVER HAD ANYTHING LIKE THIS HAPPENING TO MY BODY UNTIL AFTER THEY WERE INSERTED. PLEASE DO SOMETHING ABOUT THIS AND HELP WOMEN THAT CAN'T AFFORD TO GET RID OF THE PAIN PLEASE. I WILL CONTINUE TO FILE A COMPLAINT EVERY DAY UNTIL SOMETHING IS DONE ABOUT THIS. THANK YOU.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00030	CONCEPTUS, INC.	7/19/2012	7/24/2012

Event Information:

Event Date (B3): 6/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 9/1/2008
Explant Date (E7): 6/14/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE IN (B)(6) 2008 IN (B)(6). FOLLOWING THE PROCEDURE, PT DEVELOPED A SEVER ECZEMA ON HER BODY WHICH WAS RESISTANT TO VARIOUS MEDICAL TREATMENTS. PRIOR TO PROCEDURE, THE PT HAD NICKEL ALLERGY. THE IMPLANTS ARE REMOVED BY CELIOSCOPY WITH SALPINGECTOMY BILATERAL ON (B)(6), 2012. THREE DAYS AFTER THE REMOVAL, THE ECZEMA BEGAN TO DISAPPEAR. SINCE NO MEDICAL TREATMENTS WERE EFFECTIVE PRIOR TO REMOVAL, DOCTOR CONCLUDED THAT ESSURE DEVICES WERE CAUSING HER SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00031	CONCEPTUS, INC.	7/19/2012	7/24/2012

Event Information:

Event Date (B3): 6/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 6/13/2012
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3): 7/2/2012

Event Description (B5):

ESSURE PROCEDURE INITIALLY DONE IN (B)(6) 2012 BY DR. (B)(6). ONLY ONE DEVICE WAS PLACED. SUBSEQUENTLY, DR (B)(6) DID AN ECT TEST WHICH SHOWED THAT THE ESSURE DEVICE HAD NOT OCCLUDED. PT LATER WENT TO SEE DR (B)(6) COMPLAINING OF PELVIC PAIN. ON (B)(6) 2012, DOCTOR REMOVED THE DEVICE LAPAROSCOPICALLY AND FOUND THAT IT HAD PERFORATED THROUGH UTERUS AND WAS DANGLING OUT OF IT. DOCTOR REMOVED THE DEVICE AND THEN DID A BILATERAL LAP TUBAL WITH FILSCHIE CLIPS. PER DR. (B)(6), PROCEDURE WAS MEDICALLY NECESSARY, PAIN WAS CAUSED BY PERFORATED DEVICE AND PT'S SYMPTOMS COMPLETELY RESOLVED AFTER REMOVAL SURGERY.

Manufacturer Narrative (H10):

THE MICRO-INSERT WAS RETURNED TO CONCEPTUS AND EXAMINED. THE MICRO-INSERT APPEARS AS EXPECTED; NO DEFECTS WERE IDENTIFIED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00033	CONCEPTUS, INC.	7/26/2012	8/1/2012

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 6/1/2012
Explant Date (E7): 7/2/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED (B)(6) 2012. DOCTOR PERFORMED THE ESSURE PROCEDURE FIRST, WITH SUCCESSFUL BILATERAL PLACEMENT, FOLLOWED BY NOVASURE ABLATION. FOUR DAYS POST PROCEDURE, PT FELT SOMETHING "POP" AND BEGAN TO FEEL UNCOMFORTABLE AND ILL. PELVIC EXAM DEMONSTRATED MILD TENDERNESS, NOTHING ABNORMAL. CT SCAN WAS NORMAL - NO PERFORATION SEEN AT THAT TIME. ON (B)(6), DOCTOR LEARNED PT WAS HOSPITALIZED WITH A BOWEL PERFORATION. THE GENERAL SURGEON STATED THAT UPON LAPAROTOMY, HE HAD TO PEEL BACK A SUPERFICIAL LAYER OF THE FALLOPIAN TUBE AWAY FROM THE ILEUM. ONCE PEELED AWAY, THERE WAS TISSUE DAMAGE OVER THE AREA OF THE ESSURE DEVICE AND THE VERY DISTAL END OF THE ESSURE INSERT WAS PERFORATED OUT OF THE FALLOPIAN TUBE. THE GENERAL SURGEON REPORTED TO DOCTOR AND THE PT THAT HE FEELS THE ESSURE DEVICE PERFORATED THE BOWEL DUE TO ITS POSITION AND IT CAUSED THE TISSUE INJURY OVERLYING THE INSERT. THE ESSURE DEVICE WAS NOT REMOVED. PT WAS TREATED POST OPERATIVELY AND IS HEALING WELL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026314	CONCEPTUS	7/26/2012	8/2/2012

Event Information:

Event Date (B3): 7/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 8/18/2009
Explant Date (E7): 7/19/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD TO HAVE A HYSTERECTOMY ON (B)(6) 2012 DUE TO ADVERSE SCARRING CAUSED BY THE PET FIBERS IN MY IMPLANTED ESSURE DEVICES MADE BY CONCEPTUS. THE SCARRING DID NOT STAY LOCALIZED TO MY FALLOPIAN TUBES, INSTEAD OVER THE COURSE OF ALMOST 3 YEARS IT HAD MOVED TO COAT THE WHOLE INSIDE OF MY UTERUS, THEN MOVED OUTSIDE OF IT TO CAUSE WEB-LIKE SCARRING THAT CONNECTED TO OTHER PARTS OF MY ABDOMEN THAT RESULTED IN MY UTERUS, CERVIX, AND FALLOPIAN TUBES BEING REMOVED AS WELL AS A LOT OF SCAR TISSUE HAVING TO BE REMOVED AND FUSED. I'M VERY LUCKY TO STILL HAVE MY OVARIES AT ONLY (B)(6). THIS DEVICE WAS IMPLANTED ON (B)(6) 2009 AT (B)(6) HOSPITAL AT (B)(6). I ALSO HAD TO BE SEEN IN THE EMERGENCY ROOM ON (B)(6) 2012 FOR THE HORRIBLE PAIN, NAUSEA, ETC THAT I WAS EXPERIENCING DUE TO THESE ADVERSE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00032	CONCEPTUS, INC.	7/26/2012	8/6/2012

Event Information:

Event Date (B3): 6/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 827927

Single Use: Y
Implant Date (E6): 9/15/2011
Explant Date (E7): 6/14/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ORIGINALLY REPORTED AS MEDWATCH (B)(4). ESSURE PHYSICIAN PERFORMED ORIGINAL PROCEDURE ON UNKNOWN PT IN HOSPITAL ON (B)(6) 2011. THREE MONTH HSG ON (B)(6) 2011, SHOWED BOTH TUBES WERE PATENT WITH FREE SPILLAGE OF CONTRAST. THERE WAS LATERAL MIGRATION OF LEFT COIL INTO AMPULLA AND PROBABLE AMPULLARY EXPULSION OF RIGHT COIL. AT SOME POINT AFTER INITIAL PROCEDURE, PT MADE OFFICE VISIT TO COMPLAIN OF UNSPECIFIED BACK PROBLEMS. SINCE HSG HAD INDICATED FAILURE OF STERILIZATION, A BILATERAL SALPINGECTOMY WAS DONE BY ANOTHER SURGEON IN SAME HOSPITAL ON (B)(6). SURGEON WAS UNABLE TO VISUALIZE EITHER COIL WITH HYSTEROSCOPE. THROUGH USE OF FLUOROSCOPY, SURGEON FOUND THAT PROXIMAL END OF ONE ESSURE DEVICE COULD BE SEEN THROUGH WALL OF LEFT FALLOPIAN TUBE. THE DEVICE FROM RIGHT FALLOPIAN TUBE WAS FOUND PARTIALLY GROWN INTO OMENTUM IN LEFT UPPER. THERE ARE NO POST-OP REPORTS OF FURTHER PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026328	CONCEPTUS INCORORATED	7/27/2012	8/3/2012

Event Information:

Event Date (B3): 1/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): FSS305
Lot #(E4): 628430

Single Use:
Implant Date (E6): 1/6/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I HAD MY BABY, MY OBGYN SUGGESTED THE ESSURE PROCEDURE AND ASSURED ME IT HAD NO ADVERSE EFFECTS. IT WOULD BE JUST LIKE HAVING MY TUBES TIED AND I WOULD HAVE NO DISCOMFORT. THE PROCEDURE WAS VERY PAINFUL AND TOOK ABOUT 2 HOURS. I WAS TO HAVE AN HSG TO CONFIRM THAT THE TUBES WERE CORRECTLY INSERTED AND THAT TISSUE WAS GROWING AROUND IT. PROBLEM WAS THAT I NEVER STOPPED BLEEDING LONG ENOUGH TO HAVE ONE. I STARTED HAVING LOT OF PAIN IN MY TUBES, LONGER MORE PAINFUL PERIODS. WHEN I DISCUSSED THIS WITH THE DR, HE SAID IT WAS UNRELATED TO THE ESSURE. WHEN I HAD AN ULTRASOUND TO CHECK MY TUBES THEY COULD NOT FIND THE ONE ON MY LEFT SIDE AND THE ONE ON MY RIGHT SIDE HAD DISLODGED AND WAS POLING THROUGH MY UTERUS CAUSING SEVERE PAIN. THE REF # FOR THE PRODUCT USED WAS (B)(4) AND THE LOT # 628430. THE ESSURE IS NOT A SAFE PRODUCT AND THE MFR DOES NOT INDICATE THAT THERE IS A CHANCE IT COULD GET DISLODGED OR ARE NOT PROPERLY TRAINING DOCTORS. I NOW HAVE TO UNDERGO A HYSTERECTOMY JUST SO I CAN FUNCTION WITHOUT PAIN. I HOPE THE FDA DOES SOMETHING TO STOP THIS PRODUCT FROM HURTING OTHER WOMEN. DATES OF USE: (B)(6) 2010 - (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026357	CONCEPTUS USA	7/30/2012	8/6/2012

Event Information:

Event Date (B3): 7/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 838566

Single Use:
Implant Date (E6): 7/11/2011
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE STERILIZATION PROCEDURE DONE IN (B)(6) 2011. MY HEALTH HAS BEEN DECLINING EVER SINCE. THERE ARE THOUSANDS OF WOMEN THAT ARE NOW HAVING MAJOR HEALTH PROBLEMS AND HAVING TO HAVE THEM REMOVED AND ALSO SOME ARE EVEN HAVING HYSTERECTOMIES. THIS DEVICE WAS NOT STUDIED LONG ENOUGH AND SHOULD BE TAKEN OFF THE MARKET, IT IS RUINING OUR LIVES. PLEASE TAKE THIS INTO CONSIDERATION AND LOOK FURTHER INTO TAKING THIS OFF THE MARKET. THANK YOU.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026374	CONCEPTUS INC.	7/31/2012	8/7/2012

Event Information:

Event Date (B3): 7/24/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 919036

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANT DID NOT DEPLOY FROM ESSURE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026388	CONCEPTUS	8/1/2012	8/8/2012

Event Information:

Event Date (B3): 8/1/2009 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 8/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE TUBAL IN (B)(6) 2009. I HAVE SINCE HAD NOTHING BUT PROBLEMS ARISE. I HAVE HAD EXTREME WEIGHT GAIN, HORRIBLE HEADACHES, HUGE HAIR LOSS, VAGINAL DRYNESS, VAGINAL DISCHARGE, PAIN DURING SEX OR USE OF TAMPONS, CHEST PAIN, RAPID HEART BEATS, HIGH BLOOD PRESSURE, SEVERE JOINT PAIN, MEMORY LOSS, HOT FLASHES, FATIGUE, TROUBLE SLEEPING, AND DEPRESSION. I AM CONVINCED THAT ALL OF THESE ARE ADVERSE EFFECTS FROM THE ESSURE COILS THAT WERE PUT INTO MY FALLOPIAN TUBES IN 2009. I HAVE CONSISTENTLY HAD ISSUES SINCE THE ESSURE COILS WERE INSERTED INTO MY FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	8/3/2012	8/7/2012

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4): 8/3/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): METALIC COIL DEVICE FOR FEMALE STERILIZATION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 955782

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT FOR PERMANENT STERILIZATION PROCEDURE USING ESSURE DEVICE. A BALLOON DID NOT DEPLOY AND WAS PULLED; ANOTHER ONE WAS THEN USED. THE ESSURE DEVICE WAS PLACED AND ADVANCED INTO THE FALLOPIAN TUBE AND WAS DEPLOYED; HOWEVER, IT WAS POSITIONED DEEPER INTO THE TUBE AND AFTER DEPLOYMENT THE END OF THE ESSURE DEVICE WAS NOT VISIBLE. NO HARM TO THE PATIENT.
==========
MANUFACTURER RESPONSE FOR METALIC COIL DEVICE FOR FEMALE STERILIZATION, ESSURE DEVICE (PER SITE REPORTER).
==========
THEY WOULD LIKE TO EXAMINE THE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026414	CONCEPTUS/BAYER	8/5/2012	8/13/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627307

Single Use:
Implant Date (E6): 11/19/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2008, I HAD ESSURE IMPLANTATION, REF #(B)(4) LOT 627307, A PRODUCT OF CONCEPTUS. SEVERAL MONTHS AFTER IMPLANTATION, MY PERIOD STOPPED COMPLETELY FOR UNK REASONS, THIS WAS NOT SUPPOSED TO HAPPEN. FOR THE LAST SEVERAL YEARS, I HAVE BEEN IN PAIN FROM MY LOWER BACK TO MY HIP AREA. THIS RADIATES DOWN MY LEGS AND ACROSS MY ABDOMEN, I HAVE HEADACHES AND GET CONFUSED AS WELL. I WAS NOT GIVEN A METAL ALLERGY TEST PRIOR, AND WOULD NOT HAVE KNOWN IF I WERE ALLERGIC TO NICKEL AS IT BREAKS DOWN IN MY BODY, I DO BELIEVE THAT THIS IS THE CAUSE OF MY PAIN. AS MY INITIAL PROCEDURE AND TESTING WENT WELL. THE PAIN I FEEL IS DEEP, DEEP IN MY BONES, IT'S NOT A PAIN THAT I CAN FEEL BY TOUCHING. IT AFFECTS MY DAILY LIFE, FROM BEING UNABLE TO SLEEP BECAUSE I CAN'T FIND A COMFORTABLE POSITION IN WHICH I AM PAIN FREE. I HAVE HAD TO CUT BACK MY HOURS AT MY JOB, BECAUSE IT'S DIFFICULT TO CONCENTRATE ON THE NEEDS OF MY ELDERLY CLIENTS. SOME DAYS, I AM UNABLE TO STAND UPRIGHT BECAUSE MY PAIN IS SO BAD. I WAS NEVER GIVEN A MANUAL PRIOR TO MY PROCEDURE THAT CLEARLY WOULD HAVE INFORMED ME OF THE (B)(4) OF WOMAN, WHICH IS LIKELY MORE BY NOW, WHO HAVE THE SAME DEBILITATING PAINS I HAVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026454	CONCEPTUS	8/7/2012	8/15/2012

Event Information:

Event Date (B3): 10/9/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT STERILIZATION
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 10/7/2007
Explant Date (E7): 5/7/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2007, I HAD THE ESSURE PROCEDURE PERFORMED IN THE DOCTOR'S OFFICE. I WAS NOT ADVISED OF THE NICKEL, NOR DID I RECEIVE A PELVIC EXAM PRIOR AND TEST FOR THE CERTAIN DISEASES PER CONCEPTUS TRAINING MANUAL THAT WAS JUST PUBLISHED ONLINE IN 2011. THE PROCEDURE WAS A 3 HOUR PROCEDURE, I HAVE ALL MY DOCTORS NOTES AND A URINE TESTING IS NOT NOTED ON THAT DATE FOR PREGNANCY TEST. THE URINE RECORDS STATE (B)(6) 2008. POST ESSURE, I WAS IN DOCTOR'S OFFICE IN EXCRUCIATING PAIN, BLEEDING, CRAMPING, AND BLOATING. I WAS TOLD BY MY DOCTOR THAT MY BODY WAS ADJUSTING. I WENT BACK OVER A PERIOD OF 7 TIMES WITH THE SAME COMPLAINT, AS THE DOCTOR TOLD ME IT CAN'T BE THE ESSURE. IT IS A CYST OR FIBROID ON YOUR OVARIES OR UTERUS. IF PROPER TESTS WOULD HAVE BEEN CONDUCTED, I WOULD NOT HAVE BEEN AN IDEAL CANDIDATE WITH THESE PREVIOUS ISSUES. THE CYST AND FIBROIDS WERE FOUND OUT AFTER ESSURE BECAUSE MY DOCTOR DID NOT KNOW WHAT ELSE TO DO EXCEPT, PUT ME ON BIRTH CONTROL. I REFUSED. THEN SHE WANTED TO DO LAPAROSCOPIC SURGERY, ABLATION, UTERINE, AND DNC AND I REFUSED AND WENT TO ANOTHER DOCTOR AS SHE STILL SAID IT WAS NOT ESSURE. OVER THE COURSE OF 5 YEARS I HAVE BEEN VERY SICK, ANEMIC, FATIGUE, DUE TO EXCESSIVE BLOOD CLOTS AND FATIGUE, UNEXPLAINED FEVER, RASH, HEARING, VISION, TASTE PROBLEMS, LOSS OF CONCENTRATION, LOSS OF BALANCE, WEIGHT GAIN, SEVERE WEIGHT LOSS, IBS, ANXIETY, HIGH BLOOD PRESSURE, PANIC ATTACKS, NAUSEA, DIARRHEA, MAJOR PAIN ON RIGHT SIDE, AS I CAN ACTUALLY FEEL THE ESSURE COILS. HEADACHES, MIGRAINES, ALLERGIES, NERVOUSNESS, DIZZINESS, LEG PAIN, BACK PAIN, NECK PAIN, BLISTERS IN MY NOSE AND MOUTH, BOWLS ON MY LEGS, INSOMNIA, CRYING, SADNESS, ANGER, MISERABLE. ON (B)(6) 2012, EVERYTHING CHANGED WITH MY NEW OB/GYN: SAID IT IS YOUR COILS THAT ARE MAKING YOU SICK. I TOLD HIM I WAS ALLERGIC TO NICKEL. HE TOLD ME THAT MY BODY WAS IN CHRONIC INFLAMMATORY STATE FOR A LONG TIME.

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REFERRED MET TO SURGEON FOR HYSTERECTOMY. WAITING ON INSURANCE, MEDICAL DATA TO BACKUP ESSURE, TESTING, SONOGRAMS, MRI, CT SCANS. AND 2 OPINIONS FROM 3 DIFFERENT SURGEONS ON WHAT IS THE SAFEST AND EFFECTIVE RECOURSE TO REMOVE EVERYTHING AND MAKE SURE COILS ARE STILL IN FALLOPIAN TUBES. OH, BUT I FAILED TO MENTION I WAS NEVER GIVEN AN ESSURE CARD WITH MY COIL OR LOT NUMBERS, THE DOCTOR DOES NOT HAVE RECORDED AND I HAVE REPORTED TO CONCEPTUS AND DOCTOR AND NO ONE CAN TELL ME THESE NUMBERS, BUT MY DOCTOR IS GOING TO GIVE ME A GROUP OF NUMBERS AS ONE OF THEM MIGHT BE MINE. PER CONCEPTUS, DOCTOR AT FAULT FOR NOT FOLLOWING PROTOCOL OF MANUAL ONLINE, DOCTORS RESPONSE CONCEPTUS IS AT FAULT WE NEVER SAW THAT MANUAL AND IT JUST BECOMES PUBLIC IN 2011. LONG TERM EFFECT IS OVARIAN AND UTERINE CANCER DUE TO METAL TOXICITY. I WAS NEVER TOLD OF ALL THE SIDE EFFECTS ARE RISK. AS I WAS TOLD THERE WOULD BE MILD CRAMPING, BLEEDS, AND PAIN, BUT WOULD DISMISS WITHIN A WEEK. DOCTORS DID NOT REPORT SIDE EFFECTS TO FDA OR CONCEPTUS. I DID SEE ANOTHER DOCTOR IN 2010, WHO SAID HE SPOKE TO ESSURE AND TO GIVE ME HYSTERECTOMY AND SEND MY FALLOPIAN TUBES BACK TO CONCEPTUS AS I WOULD GET A REBATE. THIS IS NOTED IN MY MEDICAL FILE. ESSURE, PLEASE READ ALL THE INFO ON ALL THESE WOMEN LIKE MYSELF THAT ARE SUFFERING FROM THIS PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026499	CONCEPTUS	8/14/2012	8/16/2012

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS, INC. MY LOT NUMBER IS 664435 AND MY MODEL NUMBER IS ESS305. THE DEVICE HAS A THREE YEAR SHELF LIFE AND HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN (B)(6) 2010 A FEW DAYS AFTER I WAS IMPLANTED WITH ESSURE. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED WITH ESSURE. PINCHING PAIN IN SIDES THAT DEVELOPED INTO EXTREME PAIN AND STABBING, HEAVY, PAINFUL MENSTRUAL BLEEDING/CLOTTING, IRREGULAR MENSTRUAL BLEEDING, NIGHT SWEATS, SEVERE FATIGUE, CONSTANT UPSET STOMACH, HIVES, BLURRED VISION, LOSS FOR SIMPLE WORDS, MEMORY LOSS, PAIN WHILE BENDING OF LIFTING, CONSTANT FLU LIKE SYMPTOMS, BODY ACHES, PAIN IN LEGS, TINGLING IN LEGS (PINS, AND NEEDLES), PAINFUL INTERCOURSE, BLEEDING DURING INTERCOURSE, PAIN AFTER INTERCOURSE, LOSS OF SEXUAL DESIRE, CONSTANT HEADACHES, MOOD SWINGS, DEPRESSION, FLUTTERED HEART BEAT, BRAIN ZAPS, CONSTANT RUNNY NOSE, LOW VITAMIN D LEVELS, PAIN DURING OVULATION, PREGNANCY SYMPTOMS, BLOATED STOMACH, ANXIETY, OVARIAN CYSTS, RASHES, METAL TASTE IN MOUTH. I HAVE BEEN SEEN BY FIVE DIFFERENT DOCTORS AND 2 OF WHICH SAID MY PAIN IS FROM OVARIAN CYSTS. I HAVE RECENTLY HAD AN ESSURE REVERSAL ON (B)(6), 2014. THE DOCTOR WHO PERFORMED MY SURGERY SAID ESSURE HAS PUNCTURED MY FALLOPIAN TUBE AND UTERUS. HE HAD TO REMOVE PARTS OF MY UTERUS BECAUSE OF THE DAMAGE CAUSED BY ESSURE. THE ESSURE IMPLANTS HAVE NOT BEEN RETURNED TO THE MANUFACTURER AND ARE CURRENTLY IN MY POSSESSION. I HAVE FILED A PREVIOUS ADVERSE EVENT IN THE PAST AND THIS IS MY REFERENCE NUMBER. (B)(4).

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026500	CONCEPTUS, INC	8/14/2012	8/16/2012

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, TUBAL CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/20/2011
Explant Date (E7): 7/16/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THREE MONTHS AFTER IMPLANTATION OF ESSURE, X-RAY WAS DONE AND SHOWED THAT IT WAS A SUCCESS. HOWEVER, IMMEDIATELY AFTER ESSURE WAS IMPLANTED, PT HAD SEVERE BACK PAINS, SEVERE BLEEDING, CRAMPING, DIZZINESS, FAINTING AND SHARP PAINS, FOR 10 MONTHS UP UNTIL DEVICE WAS EXPLANTED ON (B)(6) 2012. PT ALSO GOT PREGNANT IN (B)(6) 2012, INSPITE OF USING ESSURE. WHEN SONOGRAM WAS DONE, BABY HAD SEVERE BIRTH DEFECTS, AND NEUROLOGICAL ISSUES THAT SHE HAD TO TERMINATE THE PREGNANCY. DIAGNOSIS OF BABY IS EXPOSURE TO CARCINOGEN, WHICH IS THE NICKEL IN THE ESSURE, PER PT AND THE BODY'S REACTION TO IT. PER PT, SHE HASN'T HAD THIS WITH HER OTHER CHILDREN AND THE ONLY EXPOSURE SHE HAD WAS THE ESSURE STILL IMPLANTED IN HER. ON (B)(6) 2012, PT HAD A TOTAL HYSTERECTOMY DONE, TO REMOVE THE ESSURE. PT ALLEGED THAT THE SIDE EFFECTS OF GETTING PREGNANT AND BIRTH DEFECTS, THE NEED FOR A NICKEL ALLERGY TEST IS NOT DISCLOSED IN THE PAMPHLET/INSERT. PT DISCLOSED HER MD AS DR (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026543		8/14/2012	8/22/2012

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION INSERT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE DONE (B)(6) 2010. PROCEDURE TOOK LONGER THAN WAS TOLD IT WOULD. WAS ON A LOT OF MEDS AND STILL WOKE TO PAIN WHEN BOTH COILS WERE PUT IN. WAS ON PAIN MEDS AND SLEPT THAT WHOLE DAY VERY PAINFUL, WOKE TO TAKE PAIN MEDS ONLY. WITHIN A YEAR, WAS HAVING PROBLEMS I'VE NEVER HAD BEFORE, VERY HEAVY PERIODS, LOTS OF CLOTTING, PAIN IN LEFT SIDE IT COMES AND GOES SOME TIMES HURTS SO BAD CAN'T MOVE. PAINFUL TO HAVE SEX MOST OF THE TIME, SOMETIMES BLEEDING DURING OR AFTER, BEEN HAVING NIGHT SWEATS. GAINED (B)(6), HEADACHES. BACK PAIN (DOWN ON MY BACK 4 TIMES), TINGLING IN FINGERS AND DOWN ARM ONCE FOR A WEEK, DEPRESSION, JUST BLAH FEELING. BETTER SINCE BEEN ON CELEXA. I'VE CONTACTED MY OBGYN A FEW TIMES ABOUT THIS, I'M TOLD IT IS AN INFECTION AND GIVEN ANTIBIOTICS OVER AND OVER, NOTHING CHANGES. HE JUST TELLS ME IT IS NOT THE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026501	CONCEPTUS	8/15/2012	8/16/2012

Event Information:

Event Date (B3): 1/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION INSERT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/1/2004
Explant Date (E7): 1/1/2006
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PER CALLER, IN 2005, SHE STARTED TO HAVE PAIN ON HER BACK, UNDER THE RIGHT RIB UPPER ABDOMINAL AREA, NAUSEA AND HEADACHES. PT GOT AN ULTRASOUND THROUGH HER FAMILY MD, WHICH SHOWED THE ESSURE COIL ON THE RIGHT SIDE OF HER FALLOPIAN TUBE WAS MISSING, A F/U X-RAY SHOWED THE DEVICE HAD MIGRATED TO HER RIGHT RIB. IN (B)(6) 2006, PER PT SHE FOUND OUT SHE WAS PREGNANT. THE MD WHO DID THE PROCEDURE SUGGESTED TO DO A D AND C AND TAKE OUT THE DEVICE AT THE SAME TIME. PT CONSULTED WITH ANOTHER SPECIALIST WHO DECLINED TO TAKE OUT THE DEVICE WHILE PT IS PREGNANT. PER PT, SHE HAD AN ABORTION IN (B)(6) 2006 AND PT HAD ANOTHER SURGERY TO HAVE THE DEVICE EXPLANTED. PER PT, A YEAR AND A HALF LATER, SHE HAD FULL TUBAL LIGATION WITH THE ESSURE COIL ON THE LEFT SIDE STILL IMPLANTED. PT ALLEGES FOR THE PAST 2 YEARS, STARTING IN 2010, PT HAD HER GALLBLADDER, REMOVED, BECAUSE OF ABDOMINAL PAIN AND SPASMS, NAUSEA AND VOMITING. PER PT WHEN SHE SNEEZES, COUGHS OR BENDS OVER, SHE FEELS A PINCHING PAIN IN HER ABDOMEN. IN 2011, PT ALLEGES WENT TO THE ER FOR SIGNS AND SYMPTOMS OF A HEART ATTACK. PT ALSO WAS RASHES FOR WHICH SHE IS SCHEDULED TO SEE A DERMATOLOGIST. PT STATED THAT FOR THE LAST 4 YEARS SHE WAS CONTINUOUS HEAVY BLEEDING AND CLOTTING DURING HER MENSTRUAL CYCLE, AND ALLEGES THAT THERE IS A POSSIBILITY FOR A TOTAL HYSTERECTOMY TO TAKE OUT THE ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00034	CONCEPTUS, INC.	8/15/2012	8/22/2012

Event Information:

Event Date (B3): 6/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 6/8/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD PELVIC PAIN IN RIGHT SIDE. DOCTOR REMOVED ONE DEVICE HYSTEROSCOPICALLY ON (B)(6) 2012. AT POST-OP VISIT ON (B)(6), PT'S SYMPTOMS WERE COMPLETELY RESOLVED. DOCTOR ATTRIBUTED PAIN SYMPTOMS TO ESSURE DEVICE REMOVED FROM RIGHT TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026557	CONCEPTUS	8/16/2012	8/23/2012

Event Information:

Event Date (B3): 12/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) WEEKS AFTER MY DAUGHTER WAS BORN, I HAD THE ESSURE PROCEDURE. I HAD BLED FOR OVER (B)(6) MONTHS STRAIGHT. I HAVE HAD MIGRAINES, HEAVY BLEEDING WITH IRREGULAR PERIODS, VERY SHARP PAIN IN BOTH OF MY SIDES WHERE THE TUBES ARE. I HAVE LOSS OF ENERGY, WHICH IS NOT GOOD BECAUSE I HAVE 3 KIDS THAT NEED MY ATTENTION. I HAVE BEEN TO THE ER NUMEROUS TIMES AND HAVE SEEN 3 DOCTORS AND HAVE AN APPOINTMENT WITH A 4TH ONE THAT MAY BE WILLING TO DO THE PARTIAL HYSTERECTOMY TO REMOVE THESE COILS FROM MY BODY. I HAVE ADVISED EVERYONE I KNOW NOT TO HAVE THIS PROCEDURE DONE. IT ISN'T WORTH LOOSING TIME WITH YOUR KIDS FOR THIS PROCEDURE. I HAVE ALSO MISSED OUT A LOT OF WORK DUE TO THESE SYMPTOMS AND NOT BEING ABLE TO FUNCTION LIKE A HUMAN. MY RELATIONSHIP WITH MY HUSBAND HAS BEEN COMPROMISED BECAUSE INTERCOURSE IS SOMETHING OF THE PAST DUE TO PAIN. THESE COILS ARE A CROCK AND NEED TO BE TAKEN OFF THE MARKET ASAP! QUIT WAISTING/DAMAGING WOMEN'S LIVES OVER THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026559	CONCEPTUS INC.	8/16/2012	8/23/2012

Event Information:

Event Date (B3): 5/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): CONTRACEPTIVE DEVICE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305 629142

Single Use:
Implant Date (E6): 5/16/2008
Explant Date (E7): 5/28/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS WERE MISPLACED OR MIGRATED CAUSING PERFORATIONS IN BOTH FALLOPIAN TUBES AND UTERUS. ALSO CAUSED ENDOMETRITIS AND SIGNIFICANT BLEEDING FOR OVER 2 WEEKS. HAD TO HAVE BILATERAL SALPINGECTOMY AND MYECTOMY TO REMOVE COILS. I ALMOST DIED DUE TO THIS DEVICE. NO DEVICE SHOULD MIGRATE OR PERFORATE. I WAS SICK FOR A LONG TIME AND DID NOT REALIZE WHAT WAS GOING ON. TAKE THIS OFF THE MARKET BEFORE OTHER WOMEN GET HURT OR DIE. IT IS UNSAFE AND PAINFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026575	CONCEPTUS INC.	8/18/2012	8/24/2012

Event Information:

Event Date (B3): 11/20/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 627439

Single Use:
Implant Date (E6): 11/20/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PREGNANCIES WERE ROUGH WITH GESTATIONAL DIABETES AND TOXEMIA. AFTER WE HAD OUR SECOND SON WE DECIDED TO DO A FORM OF PERMANENT BIRTH CONTROL. I CHOSE ESSURE BECAUSE IT WAS CONVENIENT FOR US AND I WOULD BE UP ON MY FEET THE NEXT DAY SO NO ONE ELSE WOULD HAVE TO DO ANYTHING FOR ME. AS SOON AS I HAD THE PROCEDURE DONE I BLED FOR THREE MONTHS STRAIGHT, SUPER HEAVY, AND SEVERE CRAMPS. DID THE TEST TO SEE IF MY TUBES WERE BLOCKED AND I WAS TOLD THEY WERE "100% BLOCKED." HAD TO BE PUT ON BIRTH CONTROL PILLS OFF AND ON SINCE TO GET MY CYCLES TO STOP. EVEN THEN THERE WAS ONE POINT IT DIDN'T HELP. SINCE THEN I HAVE DEVELOPED A SKIN RASH THAT COMES AND GOES, NUMBNESS AND TINGLING IN MY RIGHT AND LEFT ARMS, HANDS, LEGS, AND FEET. I HAVE ALSO HAD PAIN ISSUES TO WHERE MY MUSCLES HAVE BEEN KNOTTING UP. THERE ARE DAYS IT'S HARD TO MOVE AND I'M WALKING AROUND LIKE I'M 90 YEARS OLD. I HAVE ALSO HAD SEVERE HEADACHES TO WHERE I GO BLANK OR ABSENT MINDED AND CAN'T THINK, EYE TWITCHING, NECK PAIN, LOWER BACK PAIN THAT IS A DULL PRESSURE PAIN. I HAVE ALSO HAD TO DEAL WITH SHARP ABDOMINAL PAINS, NOT ONLY CRAMPS BUT SHARP PIERCING PAIN THAT LAST FOR LONG PERIODS OF TIME. I HAVE A HARD TIME USING THE BATHROOM, IF ITS NOT DIARRHEA IT'S CONSTIPATION, OR BLADDER URINARY TRACT INFECTIONS, PLUS YEAST INFECTIONS. IT'S BEEN ONE THING AFTER ANOTHER. IT HAS ALSO GOTTEN TO THE POINT WHERE IT IS PAINFUL TO HAVE SEX WITH MY HUSBAND AND I AM HURTING SO MUCH I CAN'T SPEND TIME WITH MY KIDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026619		8/21/2012	8/28/2012

Event Information:

Event Date (B3): 11/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION INSERT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROBLEMS. I HAVE BEEN DEALING WITH THIS FOR A WHILE AND THE DOCTOR CANNOT FIND OUT WHAT THE PROBLEM IS SO I TRIED RESEARCHING IT AND I HAVE SEEN THERE IS A LOT OF PEOPLE HAVING THE SAME SYMPTOMS AND PROBLEMS WITH THE ESSURE. I HAD FOUND OUT I HAD BLOOD CLOTS A MONTH OR SO AFTER HAVING THE ESSURE SURGICALLY INSERTED AND WAS ON COUMADIN FOR 6 MOS AND STILL NOW UNTIL THIS DAY (B)(6) 2012. I AM HAVING DIFFICULTY WITH ESSURE WHICH I THINK MY BODY IS SENSITIVE TO THE NICKEL OF THE ESSURE. I WAS NOT AWARE OF WHEN I GOT IT DONE. DID NOT GET TESTED FOR ANY ALLERGY FOR NICKEL AND NOW I HAVE TO SUFFER FROM THE ACHES AND PAIN, DIZZY, HEADACHES, HOT FLASHES, DIFFICULTY WITH INTERCOURSE, AND PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026590	CONCEPTUS	8/22/2012	8/27/2012

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): INSERT TUBAL OCCLUSION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2010
Explant Date (E7): 6/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO WEEKS AFTER DEVICE WAS IMPLANTED, PT FELT PAIN, LIKE BEING STUCK WITH A NAIL, HEAVY MENSTRUAL BLEEDING, AND CLOTTING. PT HAD ESSURE REMOVED AND HAD A TUBAL LIGATION, BUT THE MD COULDN¿T FIND THE OTHER COIL, AND ASSUMED IT MIGRATED. LATER PT DEVELOPED BENIGN TUMORS AND SCAR TISSUES IN HER FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026704	CONCEPTUS, INC.	8/27/2012	9/4/2012

Event Information:

Event Date (B3): 8/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 10/24/2011
Explant Date (E7): 8/22/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE STERILIZATION DEVICE WAS INSERTED BY ANOTHER PHYSICIAN (B)(6) 2011, IN A (B)(6) FACILITY. THE 3 MONTH HYSTEROSALPINGOGRAM SHOWED THE RIGHT FALLOPIAN TUBE STILL PATENT WITH SPILLAGE OF CONTRAST-NO ESSURE COIL DEVICE PRESENT. THE LEFT FALLOPIAN TUBE ESSURE DEVICE LOCATED FAR PERIPHERALLY. THE DEVICE THAT WAS INSERTED IN RIGHT TUBE LOCATION UNK AT THAT TIME. PT PRESENTED TO DR. (B)(6) (REPORTING PHYSICIAN) AS A NEW PT, OBTAINED HSG FILMS AND REVIEWED WITH RADIOLOGIST. PT SCHEDULED FOR LEFT SALPINGECTOMY, POSSIBLE RIGHT SALPINGECTOMY, REMOVAL OF ESSURE DEVICE FROM UTERUS, POSSIBLE HYSTERECTOMY. PT UNDERWENT SURGERY ON (B)(6) 2012, ATTEMPTED REMOVAL OF ESSURE DEVICE FROM UTERUS-HEAVY BLEEDING OCCURRED AND WAS DECIDED TO REMOVE UTERUS AND BILATERAL SALPINGECTOMY. PT IS RECOVERING WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00035	CONCEPTUS, INC.	8/28/2012	8/31/2012

Event Information:

Event Date (B3): 3/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 11/30/2011
Explant Date (E7): 3/21/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD PAIN SYMPTOMS SHORTLY AFTER PROCEDURE. AN ULTRASOUND WAS THEN DONE AND IT WAS NORMAL. THE THREE MONTH HSG IN LATE FEBRUARY SHOWED ONE DEVICE HAD PERFORATED THE LEFT FALLOPIAN TUBE. A TUBAL LIGATION REMOVAL OF ONE DEVICE DONE ON (B)(6) 2012. THE LEFT ESSURE DEVICE WAS FOUND POSITIONED IN THE FAR LATERAL LEFT PELVIS. PT'S SYMPTOMS RESOLVED AFTER SURGERY AND DOCTOR ATTRIBUTED SYMPTOMS TO THE PERFORATED ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00036	CONCEPTUS, INC.	8/28/2012	9/4/2012

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7): 5/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVEN YEARS POST ESSURE PATIENT SAW HER DOCTOR FOR PELVIC PAIN IN (B)(6) 2012. AN ULTRASOUND WAS DONE WHICH SHOWED THAT ONE DEVICE WAS OUTSIDE OF THE FALLOPIAN TUBE, POSSIBLY IN THE MYOMETRIUM OF THE UTERUS. PT REQUESTED REMOVAL OF BOTH DEVICES. DURING HYSTEROSCOPIC PROCEDURE, DOCTOR REMOVED ONE ESSURE DEVICE THAT WAS CURLED UP IN PT'S ENDOMETRIUM. THE OTHER DEVICE REMOVED FROM THE OPPOSITE TUBE WAS PROPERLY PLACED. PT'S SYMPTOMS RESOLVED AFTER SURGERY. SHE HAD NO OTHER UNDERLYING CONDITIONS. DOCTOR ATTRIBUTED PT'S PAIN TO ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	8/28/2012	10/4/2012

Event Information:

Event Date (B3): 8/17/2012 **Report Date (B4): 8/28/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): *
Lot #(E4): 927081

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO ESSURE DEVICES HAD ISSUES. FIRST ESSURE DEVICE WAS DEPLOYED, AND WHEN APPLICATOR WAS REMOVED, THE COILS CAME OUT ALSO. SECOND ESSURE DEVICE WAS DEPLOYED AND AFTER APPLICATOR WAS REMOVED, PART OF A COIL WAS OBSERVED FLOATING IN UTERUS (IT WAS RETRIEVED).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	8/30/2012	10/16/2012

Event Information:

Event Date (B3): 8/30/2012 **Report Date (B4): 8/30/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): CANNULA, INTRAUTERINE INSEMINATION
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): A22175

Single Use:
Implant Date (E6): 8/30/2012
Explant Date (E7): 8/30/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PROCEDURE WAS INTRAUTERINE DEVICE (IUD) REMOVAL AND ESSURE STERILIZATION. THE DEVICE ESSURE (LOT# A22175 REF#ESS305) FAILED WITH FIRST MICROINSERT AND DEPLOYED PREMATURELY. ESSURE DEVICE WAS REMOVED AND THE SURGEON INSERTED A NEW ONE WITHOUT COMPLICATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026848	CONCEPTUS	9/6/2012	9/14/2012

Event Information:

Event Date (B3): 8/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6):
Explant Date (E7): 8/23/2012
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2012, ESSURE MEDICAL DEVICE WAS REMOVED FROM THE PT AT THE REQUEST OF THE PT IN OUR HOSPITAL DUE TO PAIN AND DISCOMFORT OCCURRING AT THE TIME OF IMPLANT. IMPLANT OCCURRED AT ANOTHER LOCATION, DATE AND TIME ARE UNK TO THIS REPORTER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00037	CONCEPTUS, INC.	9/10/2012	9/14/2012

Event Information:

Event Date (B3): 8/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 10/1/2011
Explant Date (E7): 8/21/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

SHORTLY AFTER ESSURE PROCEDURE IN (B)(6) 2011, PT EXPERIENCED SEVERE PELVIC PAIN. HER THREE MONTH HSG TEST SHOWED SATISFACTORY PLACEMENT AND OCCLUSION. DUE TO ONGOING PAIN SYMPTOMS, MD DID A PARTIAL BILATERAL LAP TUBAL ON (B)(6) 2012, TO REMOVE BOTH DEVICES. HE ATTRIBUTED PT'S SYMPTOMS TO THE ESSURE DEVICES BECAUSE SHE HAD NO UNDERLYING CONDITIONS AND NO OTHER PATHOLOGY FOUND.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026929	CONCEPTUS, INC.	9/12/2012	9/19/2012

Event Information:

Event Date (B3): 12/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/2/2010
Explant Date (E7): 12/3/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE PROCEDURES DONE FOR THE ESSURE CONTRACEPTIVE. WITHIN A FEW MONTHS I HAD TO HAVE A LAPAROSCOPY TO REMOVE SCAR TISSUE. THIS TISSUE WAS CAUSING SEVERE PAIN. WITHIN A FEW MONTHS AFTER THAT I HAD TO HAVE A FULL HYSTERECTOMY AT (B)(6). THE SCAR TISSUE HAD GROWN BACK AND FUSED MY INSIDES TOGETHER AND WERE ON THE VERGE OF TEARING MY BOWELS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00038	CONCEPTUS, INC.	9/13/2012	9/18/2012

Event Information:

Event Date (B3): 7/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/29/2012
Explant Date (E7): 7/6/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DOCTOR PERFORMED UNEVENTFUL ESSURE PROCEDURE IN (B)(6). TWO WEEKS LATER PT PRESENTED WITH PAIN AND ASKED TO HAVE DEVICES REMOVED. DOCTOR DID A BILATERAL SALPINGECTOMY IN (B)(6). LAPAROSCOPY SHOWED DEVICES HAD SATISFACTORY PLACEMENT. PATHOLOGY REPORT INDICATED CHRONIC SALPINGITIS. PT'S SYMPTOMS RESOLVED AFTER SURGERY. DOCTOR ATTRIBUTED PT'S PAIN TO ESSURE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00039	CONCEPTUS, INC.	9/13/2012	9/18/2012

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/1/2009
Explant Date (E7): 9/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DOCTOR PERFORMED ESSURE PROCEDURE IN (B)(6) 2009. SHORTLY AFTERWARDS, PT BEGAN TO REPORT SEVERE PELVIC PAIN. DOCTOR REMOVED ESSURE DEVICES TWO MONTHS LATER ((B)(6) 2009). PT'S SYMPTOMS RESOLVED AND MD ATTRIBUTED HER SYMPTOMS TO THE ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026951	CONCEPTUS, INC.	9/13/2012	9/20/2012

Event Information:

Event Date (B3): 8/31/2012 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): STERILIZATION DEVICE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A14899

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS INVOLVES 2 PROCEDURES ON 2 PTS AND 3 DEVICES OF THE SAME LOT #A14899. DEVICE # 1 - DID NOT "FIRE". DEVICE # 2 - PIECE OF METAL FELL OFF THE DEVICE DURING THE PROCEDURE IN PT. DEVICE # 3 - PIECE OF METAL WAS FOUND IN THE SCOPE DURING THE PROCEDURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026952	NOT SURE	9/13/2012	9/20/2012

Event Information:

Event Date (B3): 6/7/2012 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 6/7/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN (B)(6) OF THIS YEAR. EVER SINCE, I HAVE HAD VERY IRREGULAR PERIODS. THE FIRST 2 MONTHS, I HAD 2 PERIODS A MONTH AND THEY WERE HEAVY, SO HEAVY THAT THEY WERE LIKE I JUST HAD A BABY AGAIN, WHICH ALSO CAME ALONG WITH BLOOD CLOTS. HERE I AM IN THE THIRD MONTH AND MY PERIOD IS 2 WEEKS LATE. ALL I'VE BEEN HAVING IS A PINKISH DISCHARGE OFF AND ON. I'VE BEEN CRAMPING EVERY NOW AND THEN AND HAVE HAD SEVERE BACK PAIN, BUT NO PERIOD. THE FIRST TWO WEEKS AFTER I HAD THIS DONE, I HAD REAL BAD STABBING PAINS WHERE THE COILS WERE SET. NOW I JUST HAVE TERRIBLE BACK PAIN, CRAMPING, LOSS OF APPETITE, AND A LOSS OF SEX DRIVE. I FOUND OUT THAT I HAVE EVEN LOST 10 POUNDS BECAUSE OF MY LACK OF APPETITE. I HAVE ALSO BEEN HAVING JUST ABOUT DAILY HEADACHES, WHICH I'VE NEVER HAD BEFORE THIS PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00040	CONCEPTUS, INC.	9/14/2012	9/20/2012

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7): 6/8/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE DONE SOME TIME AFTER 2008. SHE DID NOT HAVE HSG DONE DUE TO FINANCIAL ISSUES. SHE EXPERIENCED AN ECTOPIC PREGNANCY IN LEFT TUBE IN (B)(6) 2011. DOCTOR NOTED THAT THERE WAS A PERFORATION IN THE LEFT TUBE. HE REPORTED THAT HE PERFORMED A MINI LAP TUBAL/LEFT SALPINGECTOMY. PT BECAME PREGNANT AGAIN IN (B)(6) 2011. ULTRASOUND DONE FOR PREGNANCY NOTED THAT THERE WAS AN ESSURE COIL IN PLACE ON LEFT SIDE. ANOTHER ULTRASOUND DONE IN (B)(6) 2012, SHOWED A COIL ON RIGHT SIDE. SECOND SURGEON REMOVED RIGHT SIDE ESSURE DEVICE HYSTEROSCOPICALLY AND REMOVED A PORTION OF AN ESSURE DEVICE ON LEFT SIDE THROUGH A SALPINGOSTOMY. HE THEN PERFORMED A BILATERAL SALPINGECTOMY. PT IS FINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5026966	CONCEPTUS INC	9/14/2012	9/21/2012

Event Information:

Event Date (B3): 9/7/2010 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): 99.970
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 753646

Single Use:
Implant Date (E6): 9/7/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE STERILIZATION PLACED ON (B)(6) 2010, I WAS (B)(6) AT THE TIME OF THIS EVENT. ESSURE STATES THERE ARE NO SIDE EFFECTS. SINCE ESSURE MY PERIODS HAVE BEEN HEAVY LONG LASTING. UNEXPLAINED PAIN IN ABDOMEN, OVARIES, BACK, EXTREME BLOATING. I HAVE GAINED 6 LBS DUE TO THE ESSURE. I WORKOUT 95 MINUTES A DAY DRINK WATER ONLY AND EAT HEALTHY. I HAD AN ULTRASOUND DONE AND IT WAS NORMAL. DR SAID I JUST HAD HORMONE PROBLEMS, THAT IT COULD NOT BE THE ESSURE BECAUSE IT WAS NEW TO THE MARKET AND NO SIDE EFFECTS. MY SYMPTOMS ARE GETTING WORSE AS IN BLOATING, HEAVY PERIODS TO MISSED PERIODS TO "NASOUS SITE BREAST" AND HORRIBLE STABBING PAINS IN MY STOMACH. NEVER HAD TROUBLE BEFORE ESSURE, NOW I'M MISERABLE THAT I HAD IT PLACED WITH SO MANY PROBLEMS. AND IT'S STRANGE HOW EVERYONE WITH THE ESSURE HAS HAD THE SAME EXACT SYMPTOMS, BUT THEY ARE ALL DIFFERENT AGES AND THEY STATE IT'S PERMANENT AND IT IS NOT. DRS IN (B)(6) CAN REMOVE THE COILS. I CAN'T BELIEVE AFTER ALL REPORTS THEY ARE MAKING THEY STILL ALLOW THIS ON THE MARKET. DRS LIKE OBGYNS BLOW THE PT OFF AND TELL THEM THEY NEED TO HAVE A UTERINE ABLATION. WHEN IT'S TOTALLY THE ESSURE, THEY BACK THE PRODUCT BECAUSE THEY GET MONEY FROM THE COMPANY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	9/14/2012	9/28/2012

Event Information:

Event Date (B3): 9/13/2012 **Report Date (B4): 9/14/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS306
Catalog # (E4): *
Lot #(E4): 689938

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DISPOSABLE DEVICE WOULD NOT DEPLOY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00043	CONCEPTUS, INC.	9/24/2012	10/4/2012

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER PLACEMENT OF ESSURE DEVICES, PT HAD ALLERGIC SYMPTOMS AND DISCLOSED THAT SHE HAD A NICKLE ALLERGY. DOCTOR REMOVED THE DEVICES DURING A HYSTERECTOMY. NO OTHER DETAILS WERE PROVIDED.

Manufacturer Narrative (H10):

THE ESSURE IEU CONTAINS THE FOLLOWING WARNING STATEMENT: THE ESSURE [MICRO-INSERT INCLUDES NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. HOWEVER, IN VITRO TESTING HAS DEMONSTRATED THAT NICKEL IS RELEASED FROM THIS DEVICE. PTS WHO ARE ALLERGIC

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00044	CONCEPTUS, INC.	9/25/2012	10/1/2012

Event Information:

Event Date (B3): 6/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEIVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 5/30/2012
Explant Date (E7): 6/14/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD UNEVENTFUL ESSURE PLACEMENT ON (B)(6) 2012. SHE BEGAN TO REPORT PAIN SHORTLY AFTER PROCEDURE. PT WAS PLACED ON PERCOCET. AFTER 5 DAYS, SHE STATED HER PAIN HAD BECOME WORSE. DOCTOR FOUND POSITIVE CERVICAL MOTION TENDERNESS. PT REQUESTED THAT IMPLANT SURGEON REMOVE THE DEVICES. DOCTOR DID A MINI LAP TUBAL ON BOTH SIDES WITH A BILATERAL SALPINGOSTOMY. HE FOUND THAT DEVICES WERE CORRECTLY PLACED. PT REPORTED THE NEXT DAY THAT HER PAIN IS GONE. SINCE NO OTHER PATHOLOGY WAS FOUND THAT COULD CAUSE THESE SYMPTOMS, DOCTOR ATTRIBUTED HER PAIN TO THE ESSURE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	9/26/2012	10/2/2012

Event Information:

Event Date (B3): 9/25/2012 **Report Date (B4): 9/26/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): A14898

Single Use:
Implant Date (E6): 9/25/2012
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DEFECTIVE DEVICE UPON THE FIRST ATTEMPT TO INSERT INTO THE PATIENT'S RIGHT OVARIAN TUBE. THE DEVICE WAS PLACED APPROPRIATELY BUT UPON THE INITIAL ROLLBACK, THERE WAS INADEQUATE FEELING OF MOVEMENT. ADDITIONALLY, WHEN REMOVING THE DEVICE, IT WAS KINKED AND CAUGHT IN THE OVARIAN TUBES AND UNABLE TO BE PULLED OUT EASILY, POSSIBLY DUE TO TUBAL SPASM. THE DEFECTIVE DEVICE WAS REMOVED AND ANOTHER DEVICE WAS PLACED. THE SURGEONS/STAFF AT OUR FACILITY HAVE NOT HAD THIS PROBLEM WITH THIS DEVICE IN THE PAST.
THE PATIENT'S PAST MEDICAL HISTORY DID INCLUDE A PREVIOUS LOOP ELECTROSURGICAL EXCISION PROCEDURE (LEEP). NO OTHER PATIENT CHARACTERISTICS THAT MAY HAVE CONTRIBUTED TO THE EVENT WERE NOTED IN THE MEDICAL RECORD. THE MEDICAL RECORD REFLECTS THE PATIENT'S LAST MENSTRUAL PERIOD AS "UNKNOWN." THE MEDICAL RECORD DOES NOT INDICATE THAT A NON-STEROIDAL ANTI-INFLAMMATORY MEDICATION WAS ORDERED OR GIVEN PRIOR TO SURGERY. THERE WERE NO CHANGES TO THE PATIENT'S PLAN OF CARE AS A RESULT OF THIS EVENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027139	CONCEPTUS INCORPORATED	9/28/2012	10/5/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 810890

Single Use:
Implant Date (E6): 6/22/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL IMPLANTED WITH POSITIVE PREGNANCIES: SIX CASES IDENTIFIED (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027140	CONCEPTUS INC.	9/28/2012	10/5/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESS 305
Catalog # (E4):
Lot #(E4): 787226

Single Use:
Implant Date (E6): 1/6/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL IMPLANTED WITH POSITIVE PREGNANCIES: SIX CASES IDENTIFIED (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027141	CONCEPTUS INC.	9/28/2012	10/5/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESS-305
Catalog # (E4):
Lot #(E4): 810890

Single Use:
Implant Date (E6): 7/26/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL IMPLANTED WITH POSITIVE PREGNANCIES: SIX CASES IDENTIFIED (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027142	CONCEPTUS INC.	9/28/2012	10/5/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESS 305-R1; ESS 305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/29/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL IMPLANTED WITH POSITIVE PREGNANCIES: SIX CASES IDENTIFIED (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027143	CONCEPTUS INC	9/28/2012	10/5/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESS 305
Catalog # (E4):
Lot #(E4): 863570

Single Use:
Implant Date (E6): 9/8/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL IMPLANTED WITH POSITIVE PREGNANCIES: SIX CASES IDENTIFIED (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027144	CONCEPTUS INC.	9/28/2012	10/5/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESS 205
Catalog # (E4):
Lot #(E4): 624842

Single Use:
Implant Date (E6): 4/2/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL IMPLANTED WITH POSITIVE PREGNANCIES: SIX CASES IDENTIFIED (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027158	CONCEPTUS	10/1/2012	10/9/2012

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I ELECTED TO HAVE ESSURE IMPLANTED AS A METHOD OF PERMANENT BIRTH CONTROL. I WAS ADVISED THAT IT MAY NOT WORK DUE TO PERFORATION OR POTENTIAL MOVEMENT OF THE DEVICE BEFORE SCAR TISSUE FORMED. I WENT FOR MY HSG AT 3 MONTHS AND A LEAK WAS IDENTIFIED. I RETURNED AT APPROXIMATELY 5 MONTHS TO FIND THAT IT WAS STILL NOT WORKING PROPERLY. THERE IS NO APPARENT ISSUE WITH PLACEMENT OR PERFORATION - IT SIMPLY WILL NOT HEAL AND FULLY CLOSE THE FALLOPIAN TUBE. THE ESSURE MANUFACTURER CLAIMS THIS HAS NEVER HAPPENED, YET HAS NO DESIRE TO INVESTIGATE FURTHER. I NOW HAVE TO HAVE ANOTHER PROCEDURE DONE TO FINALIZE BIRTH CONTROL AFTER ALMOST A YEAR OF NO RESPONSE OR ANSWER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00041	CONCEPTUS, INC.	10/4/2012	10/12/2012

Event Information:

Event Date (B3): 2/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 11/1/2010
Explant Date (E7): 2/8/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD AN ESSURE PROCEDURE AND NOVASURE PROCEDURE DONE ON SAME DAY IN (B)(6) 2010. IN (B)(6) 2011, SHE WAS SEEN FOR ABDOMINAL/PELVIC PAIN. BETWEEN (B)(6) 2012 SHE WAS SEEN FOUR TIMES BY ESSURE PHYSICIAN FOR BLEEDING AND PAIN. HE TREATED HER WITH ANTIBIOTICS. IN (B)(6) 2012, SHE CONSULTED A DIFFERENT PHYSICIAN. HE PERFORMED A TOTAL HYSTERECTOMY ON (B)(6) 2012. THE LEFT SIDE ESSURE MICRO-INSERT WAS PROTRUDING FROM THE PROXIMAL PORTION OF THE UTERINE CORNUA. THE RIGHT SIDE MICRO-INSERT WAS NOT FOUND DURING SURGERY, IN PATHOLOGY OR ON POST-SURGICAL X-RAY. PATHOLOGY RESULTS WERE NORMAL. SINCE PATIENT HAD NO UNDERLYING OR PRE-EXISTING CONDITIONS AND HER SYMPTOMS RESOLVED AFTER SURGERY, SURGEON ATTRIBUTED HER SYMPTOMS TO THE PERFORATED ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00042	CONCEPTUS, INC.	10/4/2012	10/12/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A ONE MONTH POST-ESSURE PATIENT PRESENTED TO EMERGENCY ROOM COMPLAINING OF LOWER ABDOMINAL PAIN AND NAUSEA FOR PAST 24 HOURS. SENT HOME AFTER DOCTORS FOUND NO SIGNIFICANT CLINICAL OR LAB ABNORMALITIES. FOUR DAYS LATER PATIENT RETURNED TO EMERGENCY ROOM WITH WORSENING OF PAIN, NAUSEA, VOMITING, PROGRESSIVE ABDOMINAL DISTENTION AND TENDERNESS IN LOWER RIGHT QUADRANT. ABDOMINAL X-RAY SHOWED SMALL BOWEL OBSTRUCTION AND ABSENCE OF ESSURE DEVICE ON RIGHT SIDE. PT WAS ADMITTED FOR RE-HYDRATION AND PRESUMPTIVE DIAGNOSIS OF BOWEL OBSTRUCTIONS DUE TO ADHESIONS. NEXT DAY HER CONDITION WORSENED AND SURGERY WAS DONE. DURING LAPAROTOMY, A STRETCHED ESSURE DEVICE WAS FOUND ENSNARING A LOOP OF THE TERMINAL ILEUM, CAUSING STRANGULATION AND LOCAL PERFORATION OF BOWEL WALL. DEVICE WAS REMOVED AND AN ILEOCECAL RESECTION WITH SIDE TO SIDE ILEOCOLOSTOMY WAS PERFORMED. THE OTHER ESSURE DEVICE WAS IN LEFT FALLOPIAN TUBE. CLIPS WERE APPLIED TO BOTH FALLOPIAN TUBES TO STERILIZE PATIENT. POST-SURGICAL RECOVERY WAS COMPLICATED BY POST-OPERATIVE ILEUS AND SUPERFICIAL WOUND INFECTION. PT WAS DISCHARGED FROM HOSPITAL TWO AND A HALF WEEKS LATER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00045	CONCEPTUS, INC.	10/4/2012	10/12/2012

Event Information:

Event Date (B3): 9/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/1/2011
Explant Date (E7): 9/6/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE WAS DONE BY REPORTING PHYSICIAN IN (B)(6) 2011. THERE WAS SOME DIFFICULTY PLACING DEVICES DUE TO SMALL UTERINE CAVITY. DUE TO THE NUMBER OF TRAILING COILS, THERE WAS SOME CONCERN OF POSSIBLE PROXIMAL PLACEMENT. PT HAS EXPERIENCED CRAMPING, BLEEDING AND PAIN EVER SINCE PROCEDURE WAS DONE. A THREE MONTH HSG TEST SHOWED BILATERAL OCCLUSION. WHEN DOCTOR DID AN ENDOMETRIAL BIOPSY IN (B)(6), SHE SAW ONE DEVICE STICKING OUT OF CERVIX AND REMOVED IT. SUBSEQUENTLY, PATIENT STILL HAD PAIN SO ON (B)(6), THE DOCTOR REMOVED SECOND DEVICE HYSTEROSCOPICALLY AND THEN DID AN ABLATION AND BILATERAL LAP TUBAL. THE DEVICE THE DOCTOR REMOVED WAS VERY MANGLED AND THE INNER COIL HAD BROKEN. AT TWO WEEK POST-OPERATIVE VISIT, PATIENT REPORTED THAT ALL SYMPTOMS HAD BEEN RELIEVED. DOCTOR ATTRIBUTED PAIN SYMPTOMS TO THE ESSURE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027181		10/4/2012	10/15/2012

Event Information:

Event Date (B3): 6/25/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/25/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE DOING ESSURE PROCEDURE, I HAVE HAD AN EXTREME WEIGHT GAIN, LOWER BACK PROBLEMS AND IRREGULAR PERIODS. I AM EITHER BLEEDING SO BAD AND PASSING BLOOD CLOTS THAT I HAVE TO CHANGE CLOTHES THROUGHOUT THE DAY OR IT IS VERY LIGHT BUT IS BROWN MUCUS. I HAVE PINCHING SENSATIONS AND ABSOLUTELY NO SEX DRIVE. I HAVE ALSO HAD VERY BAD HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027233	CONCEPTUS, INC	10/10/2012	10/17/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 901339

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2012, I HAD THE ESSURE STERILIZATION PROCEDURE PERFORMED AS AN OUTPATIENT. I WAS ADVISED BY MY GYN DOCTOR THAT THIS WAS ONE OF THE BEST PERMANENT BIRTH CONTROL OPTIONS. PRIOR TO HAVING THE PROCEDURE PERFORMED, I EXPRESSED MY CONCERN ABOUT HAVING A NICKEL ALLERGY. IN THE PAST, I HAVE HAD AN ALLERGIC REACTION TO COSTUME JEWELRY AND I WAS CONCERNED SINCE THE ESSURE TITANIUM COIL INSERTS CONTAIN NICKEL. A NURSE AT MY DOCTOR'S OFFICE INFORMED ME THERE WAS A SMALL AMOUNT OF NICKEL IN THE ESSURE COILS AND THE FDA NO LONGER CONSIDERED A NICKEL ALLERGY TO BE A CONTRAINDICATION FOR THE ESSURE PROCEDURE. FOUR MONTHS AFTER THE PROCEDURE ((B)(6) 2012), I NOTICED A RASH ON MY ARM AND CHEST. I WENT TO A DERMATOLOGIST WHO DIAGNOSED ME AS HAVING ECZEMA. IN THE FOLLOWING WEEKS, THE RASH CHANGED IN APPEARANCE, BECAME ITCHY, AND SPREAD TO OTHER PARTS OF MY BODY. I ALSO NOTICED PAINFUL AREAS IN MY MOUTH AND A WHITE COATING ON MY TONGUE. MY SYMPTOMS DID NOT APPEAR TO BE ECZEMA RELATED. I RETURNED TO THE DERMATOLOGIST WHO DIAGNOSED ME WITH LICHEN PLANUS, A RARE SKIN CONDITION THOUGHT TO BE AN AUTOIMMUNE RESPONSE TO AN ALLERGEN. DOING MY RESEARCH, I READ THAT ORAL LICHEN PLANUS IS THOUGHT TO BE CAUSED BY A REACTION TO DENTAL METAL (SUCH AS A TOOTH FILLING). IT IS THEN THAT I THOUGHT THAT I MAY HAVE HAD A SYSTEMIC ALLERGIC REACTION TO THE NICKEL IN THE ESSURE IMPLANTS. LICHEN PLANUS HAS AFFECTED MY MOUTH, GENITALS, AND I HAVE UNSIGHTLY RASHES EVERYWHERE ON MY BODY FROM MY NECK DOWN TO MY FEET. DOES NOT APPLY. AN ESSURE CONFIRMATION TEST WAS PERFORMED IN (B)(6) 2012. CONTRAST MEDIA DYE WAS INJECTED INTO MY FALLOPIAN TUBES TO ENSURE THAT THE COILS WERE IN PLACE AND THAT MY FALLOPIAN TUBES WERE BLOCKED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027303	CONCEPTUS	10/12/2012	10/26/2012

Event Information:

Event Date (B3): 5/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE BIRTH CONTROL COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/27/2009
Explant Date (E7): 5/14/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE BIRTH CONTROL COILS: CAUSED RASH ON PT'S ARM AND CHEEKS OF FACE, RIGHT SIDE PAIN, WEIGHT GAIN, AND ABNORMAL PERIODS INCLUDING PASSING CLOTS. RESULTED IN PT HAVING TO PAY 100% OUT OF POCKET FOR REMOVAL OF DEVICES AND A REGULAR TUBAL PERFORMED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027258	CONCEPTUS INC.	10/16/2012	10/23/2012

Event Information:

Event Date (B3): 10/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE DEVICE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 959224

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WOULD NOT GO THROUGH THE SCOPE THAT IS USUALLY USED FOR THESE TYPE OF PROCEDURES. A REPLACEMENT DEVICE WAS OBTAINED AND IT WENT THROUGH AND FUNCTIONED APPROPRIATELY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027335	CONCEPTUS, INC	10/16/2012	10/26/2012

Event Information:

Event Date (B3): 10/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/16/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED. SINCE THEN, I'VE HAD WEIGHT LOSS, ABDOMINAL CRAMPS, HEAVY MENSTRUAL CYCLE, LOWER BACK PAIN, PAINFUL INTERCOURSE. IRREGULAR MENSTRUAL CYCLE, SEVERE LIGHTHEADEDNESS/DIZZINESS (HAD A TRIP TO THE ER DUE TO ALMOST FAINTING), BRAIN FOG, CONFUSION, VISION PROBLEMS, SEVERE CRAMPS WHERE COILS ARE LOCATED AFTER EXERCISE WITH A BURNING FEELING AROUND THAT AREA TOO. STRINGY/SLIMY DISCHARGE YELLOW/GREEN SOMETIMES WHITE/CREAM IN COLOR WHEN NOT HAVING PERIOD. ALSO MY STOMACH IS BLOATED MOST OF THE TIME. I HAVE HEADACHES, NUMBNESS IN FACE, LEGS AND ARMS ALONG WITH A TINGLING SENSATION. SOMETHING THAT FEELS LIKE BRAINZAPS. PALPITATIONS. ALSO HAVE BAD ACNE AND CYSTS WHICH I'VE NEVER HAD BEFORE. SINCE A CHILD I COULD NOT WEAR ANY JEWELRY MADE OUT OF NICKEL. I WAS NOT AWARE UNTIL RECENTLY THAT THEY CONTAIN NICKEL. MY DOCTOR DID NOT TEST ME FOR A NICKEL ALLERGY. I FEEL LIKE I AM BEING POISONED. I HAVE BEEN TO SEVERAL DOCTORS IN VARIOUS FIELDS AND ALL MY TESTS COME BACK NORMAL. I AM HAVING THE COILS REMOVED NEXT MONTH. THIS PRODUCT HAS TAKEN AWAY MY LIFE. ALSO HAD 1ST DEGREE AV HEART BLOCK. I HAD A PREVIOUS TUBAL AND FOUND OUT A COUPLE MONTHS AGO THAT IT'S A CONTRAINDICATION TO GET THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027270	CONCEPTUS INC	10/17/2012	10/24/2012

Event Information:

Event Date (B3): 10/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/28/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS FINE BEFORE I GOT ESSURE, IN (B)(6) 2008. ALL OF SUDDEN IN 2011 WAS MY YRS OF PROBLEMS. I HAVE BEEN IN AND OUT OF THE HOSPITAL, DOCTORS DON'T "WANT" GOING ON. MY BLOOD PRESSURE KEPT GOING UP EVERY TIME I STOOD UP, TO THE POINT I GOT DIZZY WHEN STANDING, AND NOW 2012 NO DR CAN STILL FIGURE OUT. I HAVE BEEN HAVING PELVIC PAIN AND CRAMPING. BUT, BEFORE ESSURE BARELY HAD ANY GYNECOLOGICAL PROBLEMS EXCEPT (B)(6), WHICH CLEARED UP ON ITS OWN AND YEAST INFECTIONS. IN (B)(6) 2011 I HAD A LAPAROSCOPY DONE BECAUSE I HAD SO MUCH PELVIC PAIN. MY GYNECOLOGIST TOLD ME I DEVELOPED ENDOMETRIOSIS, AND OVARIAN CYST. I NEVER HAD ENDOMETRIOSIS BEFORE ESSURE, AND ALSO I HAVE NEVER HAD PROBLEMS WITH OVARIAN CYST LIKE THIS. I NEVER FEEL GOOD ANYMORE. I AM ALWAYS TIRE AND HAVE CHRONIC BACK PAIN AND PELVIC PAIN, AND NOW WITH ENDOMETRIOSIS JUST MAKES IT WORSE. I ASKED MY DR IF ESSURE WAS PROBLEM, HE SAID IT COULD BE. THE ONLY WAY TO REMOVE THEM IS HYSTERECTOMY. I HAVE LOST ENOUGH. I DONT WANT TO LOSE ANYMORE. NOW, I HAVE NO HEALTH INSURANCE, AND THERE IS NOTHING I CAN DO ABOUT IT. I HAVE A LOT OF MEDICAL BILLS I CAN'T PAY. I ASK HOSPITAL DOCTORS ABOUT ESSURE, AND NONE OF THEM EVER HEARD OF IT. THAT DOESN'T SOUND RIGHT TO ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	10/17/2012	11/2/2012

Event Information:

Event Date (B3): 8/28/2012 **Report Date (B4): 10/17/2012** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): REF ESS305
Lot #(E4): 959221

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE WOULD NOT RELEASE WHEN FIRED DURING PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	10/24/2012	11/1/2012

Event Information:

Event Date (B3): 9/6/2012 **Report Date (B4): 10/24/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305-R1
Lot #(E4): 12522513

Single Use:
Implant Date (E6): 9/6/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PT ADMITTED, DRAPED, PREPPED IN THE USUAL FASHION, AND PROCEDURE BEGUN IN THE USUAL FASHION. THE CERVIX WAS GRABBED WITH THE TENACULUM, AND THE CERVIX WAS DILATED PER NORMAL, PER SURGEON DURING THE PROCEDURE. THE HYSTEROSCOPIC CANNULA/SHEATH WITH TELESCOPE, LIGHT CORD, CAMERA, WITH NORMAL SALINE ALL ATTACHED TO THE CANNULA FOR ENTRY AND VISUALIZATION PURPOSES. THE FIRST OS (OPENING FROM THE UTERUS INTO THE FALLOPIAN TUBE) WAS IDENTIFIED, AND THE ESSURE APPLICATOR WITH COIL IMPLANT WAS OPENED AND PLACED THROUGH THE HYSTEROSCOPIC SHEATH IN THE OS PER THE SURGEON AND THE IMPLANT UNCOILED AS PER PROCEDURE. THE SECOND OS WAS THEN IDENTIFIED, AND ANOTHER ESSURE APPLICATOR AND COIL IMPLANT WAS OPENED, AS THERE WAS ONLY ONE IMPLANT IN THE FIRST BOX, INSTEAD OF TWO. THE IMPLANT AND THE APPLICATOR WERE THEN INSERTED THROUGH THE SHEATH PER MD AND UPON VISUALIZATION, THE IMPLANT/COIL WAS ALREADY UNCOILED AND THERE WAS A WHITE MATERIAL APPEARANCE WAS NOTED. THE SURGEON THEN REMOVED THE DEFECTIVE IMPLANT AND APPLICATOR, AND EVALUATION OF THE CERVIX AND UTERUS WAS PERFORMED PER MD. NO EVIDENCE OF TISSUE INJURY, NOR ANY OTHER PT INJURY NOTED. THE PAPERWORK, LABELS, BOX, PACKAGING WERE KEPT, FOR FOLLOWUP. THE PROCEDURE CONTINUED AND ANOTHER NEW BOX WITH NEW APPLICATOR AND IMPLANT WAS UTILIZED, IN THE SAME MANNER AS PREVIOUSLY INDICATED WITHOUT EVENT. NURSING COORDINATOR FOR GYNECOLOGY, CHARGE RN, REPROCESSING MANAGER RN ALL WERE NOTIFIED AND THE FOLLOW-UP BEGAN. NO PATIENT HARM.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00046	CONCEPTUS, INC.	10/29/2012	11/9/2012

Event Information:

Event Date (B3): 7/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/19/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT CAME TO HOSPITAL REPORTING DISCOMFORT RELATED TO LEFT ADNEXAL MASS. ON AN EMERGENCY BASIS, THE OB GYN SURGEON PERFORMED AN EXPLORATORY LAPAROTOMY WITH LEFT SALPINGO-OOPHORECTOMY AND INTRAOPERATIVE PATHOLOGIC EVALUATION AND REMOVAL OF TWO FOREIGN BODIES. SURGERY REVEALED A VISUAL AND PALPABLE FINDING OF WHAT APPEARED TO BE AN ESSURE DEVICE IN THE CORNUA REGION OF THE RIGHT UTERUS ON THE LEFT. DEVICE APPEARED TO HAVE PERFORATED THROUGH THE UTERUS AND WAS TAGGED TO THE SEROSAL LAYER OF THE UTERUS. THE DEVICE WAS REMOVED BY CAUTERIZING THE SCAR TISSUE AROUND ITS BASE. PART OF A SECOND BODY THAT APPEARED TO BE AN ESSURE DEVICE WAS FOUND EMBEDDED THROUGH TWO EPIPLOICA OF THE LARGE INTESTINE BUT DID NOT SHOW ANY INJURY TOWARD THE BOWEL. THE EPIPLOICA WERE CAUTERIZED WITH CUT CURRENT TO REMOVE THE DEVICE. THE PATHOLOGY REPORT INDICATED A "MATURE CYSTIC TERATOMA, PORTION OF BENIGN FIMBRIATED FALLOPIAN TUBE ALSO PRESENT." PATIENT TOLERATED SURGERY WELL AND WAS DISCHARGED FROM HOSPITAL ON (B)(6) 2012. NO FOLLOW UP INFORMATION WAS AVAILABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5027709	CONCEPTUS INCORPORATED	11/15/2012	11/28/2012

Event Information:

Event Date (B3): 11/9/2012 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): FALLOPIAN TUBE COIL
Model # (E4): ESS 305; ESS 305
Catalog # (E4): ESS 305
Lot #(E4): A22177; A20058

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE SUCCESSFULLY DEPLOYED INTO RIGHT FALLOPIAN TUBE FOR TUBAL OCCLUSION HOWEVER WHEN SURGEON ATTEMPTED TO PLUG THE LEFT FALLOPIAN TUBE, IT WAS NOT SUCCESSFUL DUE TO DEVICE MALFUNCTION. A SECOND ATTEMPT WITH A NEW DEVICE WAS ATTEMPTED TO PLUG THE TUBE, THIS DEVICE ALSO FAILED. THE COILS DID NOT INJECT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	11/16/2012	11/21/2012

Event Information:

Event Date (B3): 11/9/2012 **Report Date (B4): 11/16/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): A33670

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE STERILIZER USED FOR PROCEDURE - ESSURE STERILIZATION. ON FIRST ATTEMPT, DEVICE DID NOT DEPLOY. SECOND DEVICE OBTAINED AND USED SUCCESSFULLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00047	CONCEPTUS, INC.	11/16/2012	11/30/2012

Event Information:

Event Date (B3): 10/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 936683

Single Use: Y
Implant Date (E6): 9/18/2012
Explant Date (E7): 10/4/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PT HAD BEEN EXPERIENCING ABDOMINAL PAIN FORM THE TIME HER ESSURE DEVICES WERE PLACED IN (B)(6). PT WAS INITIALLY TREATED WITH ANTIBIOTICS, BUT PAIN CONTINUED AND SHE REQUESTED THAT THE DEVICES BE REMOVED. DOCTOR REMOVED THE DEVICES AND PERFORMED A BILATERAL TUBAL LIGATION ON (B)(6). PATHOLOGY FINDINGS WERE NORMAL. DEVICES WERE FOUND IN CORRECT POSITION IN FALLOPIAN TUBES. SINCE PT HAD NO PRIOR HISTORY OF PELVIC PAIN, AND HER SYMPTOMS WERE COMPLETELY RELIEVED ONE MONTH POSTOPERATIVE, PHYSICIAN FELT THAT THE ESSURE DEVICES WERE THE MOST LIKELY CAUSE OF HER SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00048	CONCEPTUS, INC.	11/16/2012	11/30/2012

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 9/21/2012
Explant Date (E7): 11/2/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE WAS DONE (B)(6) 2012. PT HAD SOME PAIN ON LEFT SIDE WHICH HAD SUBSIDED UNTIL RECENTLY WHEN PAIN SYMPTOMS RE-OCCURRED. AN ULTRASOUND DONE IN (B)(6) DID NOT REVEAL ANYTHING. IN (B)(6), THE PT REQUESTED THAT BOTH ESSURE DEVICES BE REMOVED. HER ESSURE PHYSICIAN REMOVED BOTH DEVICES HYSTEROSCOPICALLY AND THEN DID A BILATERAL LAPAROSCOPIC TUBAL LIGATION. DURING SURGERY, PHYSICIAN FOUND THAT THE DEVICE ON LEFT SIDE HAD PERFORATED THE FALLOPIAN TUBE. HE ATTRIBUTED THE ESSURE DEVICE AS THE CAUSE OF HER PAIN. PT PAIN SYMPTOMS HAVE RESOLVED SINCE REMOVAL SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00049	CONCEPTUS, INC.	11/16/2012	12/12/2012

Event Information:

Event Date (B3): 10/18/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORTED TO MANUFACTURER THAT FOLLOWING HSG TEST, (B)(6) PHYSICIAN TOLD HER THAT SHE WAS NOW STERILE AND COULD RELY ON DEVICES. SHE SUBSEQUENTLY HAD AN ECTOPIC PREGNANCY FOLLOWED BY AN INTRAUTERINE PREGNANCY. DATE OF AND TREATMENT FOR ECTOPIC PREGNANCY ARE UNKNOWN. SECOND PREGNANCY OCCURED APPROXIMATELY IN (B)(6) 2011. (B)(6). MANUFACTURER HAS MADE NUMEROUS ATTEMPTS TO CONTACT PATIENT, BUT HAS BEEN UNABLE TO OBTAIN FURTHER INFORMATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00050	CONCEPTUS, INC.	11/16/2012	12/21/2012

Event Information:

Event Date (B3): 10/18/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/22/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE WAS DONE (B)(6) 2011. HSG CONFIRMATORY TEST DONE (B)(6) 2011 CONFIRMED SATISFACTORY PLACEMENT AND OCCLUSION. PATIENT WAS SEEN AT EMERGENCY ROOM ON (B)(6) 2012 DUE TO A MISCARRIAGE. PATIENT HAD POSITIVE PREGNANCY TEST ON (B)(6) 2012 AT (B)(6). ON (B)(6) 2012 AN ULTRASOUND WAS DONE WHICH DID NOT SHOW ANY PREGNANCY IN UTERUS. BHCC TESTS WERE ELEVATED, INDICATING EITHER ECTOPIC OR RESOLVING PREGNANCY. ON (B)(6) 2012 A UTERINE ASPIRATION WAS DONE AND STILL NO PREGNANCY WAS FOUND IN UTERUS. PATIENT WAS SENT TO EMERGENCY ROOM FOR METHOTREXATE AND A CHEMICAL ABORTION WAS DONE ON (B)(6) 2012. PATIENT HAS RECOVERED, IS USING ALTERNATE BIRTH CONTROL, AND WILL BE COUNSELED REGARDING PERMANENT STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00052	CONCEPTUS, INC.	11/30/2012	12/7/2012

Event Information:

Event Date (B3): 10/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7): 10/22/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PATIENT HAD THE ESSURE PROCEDURE ON (B)(6) 2012 AND THEN DEVELOPED BLOATING AND ABDOMINAL PAIN. ON (B)(6) 2012, THE MD REMOVED THE DEVICES AT PATIENT'S REQUEST. ONE DEVICE WAS FOUND IN THE OMENTUM. THE TIP OF THE OTHER DEVICE WAS FOUND IN THE UTERUS. AT THE POST SURGICAL APPOINTMENT, ALL SYMPTOMS WERE RESOLVED. MD ATTRIBUTED PAIN SYMPTOMS TO ESSURE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00053	CONCEPTUS, INC.	11/30/2012	12/7/2012

Event Information:

Event Date (B3): 9/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 12/12/2010
Explant Date (E7): 9/13/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICES WERE PLACED ON (B)(6) 2010. IMPLANT SURGEON AT THE TIME REPORTED SOME DIFFICULTY IN PLACING DEVICES DUE TO TUBAL SPASMS. PATIENT HAD SEVERE PAIN DURING AND IMMEDIATELY AFTER PROCEDURE. ULTRASOUND WAS PERFORMED ON (B)(6) 2010, PATIENT WAS PLACED ON PAIN MEDICATIONS AND TOLD PAIN WOULD SUBSIDE OVER TIME. AN HSG TEST PERFORMED ON (B)(6) 2011 CONFIRMED THAT DEVICES WERE IN PLACE AND OCCLUDED. OVER THE NEXT EIGHTEEN MONTHS, THE PATIENT HAD SPOTTING, BLEEDING, AND INCREASING PELVIC PAIN. PATIENT REQUESTED THAT DEVICES BE REMOVED. THE EXPLANT SURGEON PERFORMED A TOTAL LAPAROSCOPIC HYSTERECTOMY ON (B)(6) 2012. DEVICES WERE IN PLACE AND PATHOLOGY FINDINGS WERE NEGATIVE. PATIENT'S SYMPTOMS HAVE RESOLVED. EXPLANT SURGEON ATTRIBUTED PATIENT'S SYMPTOMS TO ESSURE DEVICES BECAUSE PATIENT HAD NO ETIOLOGY OF ANY OTHER PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00054	CONCEPTUS, INC.	11/30/2012	12/7/2012

Event Information:

Event Date (B3): 11/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 11/12/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD THE ESSURE PROCEDURE IN 2009. IN (B)(6) 2012, SHE BEGAN TO HAVE BACK PAIN. AN ULTRASOUND INDICATED THAT SHE HAD A URINARY TRACT INFECTION. A CT SCAN DONE ON (B)(6) 2012 INDICATED PATIENT HAD THREE SMALL KIDNEY STONES AND AN UNKNOWN FOREIGN BODY IN HER RIGHT UPPER QUADRANT. THE ESSURE DEVICE IN LEFT FALLOPIAN TUBE WAS VISIBLE. THERE WAS NO ESSURE DEVICE IN THE RIGHT FALLOPIAN TUBE. HER GYNECOLOGIST DETERMINED THAT THE FOREIGN IN HER UPPER RIGHT QUADRANT WAS THE OTHER ESSURE DEVICE. HER GYNECOLOGIST PERFORMED A BILATERAL LAPAROSCOPIC TUBAL LIGATION AND REMOVED BOTH ESSURE DEVICES ON (B)(6) 2012. PATHOLOGY REPORTS INDICATED THAT THE ESSURE DEVICE ON THE RIGHT SIDE WAS ADHESED TO HER BOWEL; THE DEVICE ON THE LEFT WAS IN THE PROPER PLACE. PATIENT'S PHYSICIAN ATTRIBUTED HER SYMPTOMS TO THE ESSURE DEVICE. PATIENT HAD NO PRE-EXISTING CONDITIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00051	CONCEPTUS, INC.	11/30/2012	12/31/2012

Event Information:

Event Date (B3): 11/2/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 3/1/2012
Explant Date (E7): 11/2/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE DONE IN (B)(6) 2012. HER THREE MONTH HSG TEST CONFIRMED OCCLUSION AND SATISFACTORY PLACEMENT. IN (B)(6) 2012, PT DEVELOPED A RASH AND HIVES IN PELVIC AREA. BY MID (B)(6), THE RASH WAS GETTING PROGRESSIVELY WORSE. PT ALSO HAD BEEN EXPERIENCING INCREASED MENORRHAGIA AND REQUESTED REMOVAL OF DEVICES. THE REPORTING MD PERFORMED A COMPLETE HYSTERECTOMY ON (B)(6) 2012. AT TWO WEEK POST-SURGICAL VISIT, PT'S RASH, HIVES, AND SORES WERE COMPLETELY GONE. SINCE PT HAD NO ALLERGIC SYMPTOMS OR IDENTIFIED ALLERGIES PRIOR TO ESSURE PROCEDURE AND HER SYMPTOMS RESOLVED AFTER REMOVAL, THE PHYSICIAN ATTRIBUTED THESE SYMPTOMS TO ESSURE DEVICES.

Manufacturer Narrative (H10):

THE ESSURE IFU CONTAINS THE FOLLOWING WARNING STATEMENT: THE ESSURE MICRO-INSERT INCLUDES NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. HOWEVER, IN VITRO TESTING HAS DEMONSTRATED THAT NICKEL IS RELEASED FROM THIS DEVICE. PTS WHO ARE ALLERGIC

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00055	CONCEPTUS, INC.	11/30/2012	12/31/2012

Event Information:

Event Date (B3): 11/7/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/1/2011
Explant Date (E7): 11/16/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAS HAD PROLONGED MENSTRUAL BLEEDING SINCE ESSURE PROCEDURE WAS DONE IN (B)(6) 2011. SHE BEGAN TO EXPERIENCE BACK PAIN, ABDOMINAL PAIN AND SEVERE VAGINAL ITCHING IN (B)(6) 2012. SHE HAD NUMEROUS TESTS DONE WHICH WERE NEGATIVE EXCEPT FOR URINARY TRACT INFECTION WHICH WAS TREATED WITH ANTIBIOTICS. PT WENT TO ER TWICE IN (B)(6) AFTER PASSING OUT AT WORK. HER DOCTOR DID AN ALLERGY TEST, WHICH INDICATED THAT PT HAS A NICKEL ALLERGY. PT'S UTERUS, CERVIX, FALLOPIAN TUBES AND ESSURE DEVICES WERE REMOVED VIA LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY (LAVH) ON (B)(6) 2012. ESSURE DEVICES WERE FOUND IN PROPER POSITION IN FALLOPIAN TUBES. SINCE PT'S SYMPTOMS HAVE RESOLVED POST SURGICAL AND SHE HAD NO OTHER MEDICAL HISTORY THAT CONTRIBUTED TO HER SYMPTOMS, HER DOCTOR ATTRIBUTES HER SYMPTOMS TO AN ALLERGIC REACTION TO THE ESSURE DEVICES.

Manufacturer Narrative (H10):

THE ESSURE IFU CONTAINS THE FOLLOWING WARNING STATEMENT: THE ESSURE MICRO-INSERT INCLUDES NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. HOWEVER, IN VITRO TESTING HAS DEMONSTRATED THAT NICKEL IS RELEASED FROM THIS DEVICE. PTS WHO ARE ALLERGIC

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	11/30/2012	1/2/2013

Event Information:

Event Date (B3): 11/14/2012 **Report Date (B4): 11/30/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): A20053

Single Use:
Implant Date (E6): 11/14/2012
Explant Date (E7): 11/14/2012
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT WAS UNDERGOING "HYSTEROSCOPY AND ESSURE PLACEMENT AND POLYPECTOMY." CERVIX WAS DILATED AND HYSTEROSCOPE WAS INTRODUCED. BOTH TUBAL OSTIA WERE VISUALIZED. THE FIRST ESSURE WAS PLACED IN THE RIGHT TUBE. THE COIL SNAPPED IN HALF AND WAS NOT WELL-DEPLOYED. THE PIECES OF THE FIRST ATTEMPTED ESSURE THAT BROKE WERE RETRIEVED AND WILL BE SENT TO THE COMPANY FOR THEIR ANALYSIS. A SECOND ESSURE COIL WAS PLACED IN RIGHT TUBE WITH 4 VISIBLE COILS. ANOTHER ESSURE WAS THEN PLACED IN THE LEFT TUBAL OSTIUM WITHOUT COMPLICATION WITH FOUR COILS VISIBLE. THE HYSTEROSCOPE WAS REMOVED AND RANDALL STONE FORCEPS WERE INTRODUCED TO REMOVE REMAINING PIECES OF POLYP. A SECOND ATTEMPT TO REMOVE THE REMAINING PIECES OF POLYP PICKED UP THE DISPLACED ESSURE FROM THE RIGHT TUBAL OSTIUM. THIS WAS REMOVED THE RANDALL STONE FORCEPS AND WAS NOT SAVED. THE HYSTEROSCOPE WAS REINTRODUCED. NO COIL WAS IN THE RIGHT TUBE. A THIRD ESSURE COIL WAS PLACED IN THE RIGHT TUBE. PRESENCE OF BOTH COILS WERE VERIFIED BEFORE WITHDRAWING HYSTEROSCOPE. PATIENT TO RETURN FOR CONFIRMATION OF ESSURE COILS IN 3 MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028086	CONCEPTUS	12/7/2012	12/18/2012

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6): 4/26/2004
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

RECEIVED ESSURE AFTER BIRTH OF CHILDREN IN 2004, I HAVE HAD AN ABUNDANT NUMBER OF PROBLEMS SINCE THE BEGINNING, IT WAS A PAINFUL PROCEDURE AND I HAVE BEEN IN PAIN SINCE THEN ON A DAILY, NIGHTLY BASIS, CONSTANT STABBING, PAINFUL SEX, VERY IRREGULAR PERIODS, SOMETIMES 3 A MONTH, SOMETIMES NOT FOR 3 MONTHS. QUALITY OF LIFE NOT GOOD, CAN'T LAUGH, CAN'T SNEEZE, CAN'T GET IN AND OUT OF A CAR WITHOUT BEING STABBED, TRIED TO SPEAK WITH MANY DIFFERENT DOCTORS ABOUT THE PROCEDURE AND WAS BASICALLY TOLD IT IS ALL IN MY HEAD. LIKE I'M GOING CRAZY. I HAVE NO FIBROIDS, NO ENDOMETRIOSIS, HAD NO OTHER PROBLEMS BEFORE THIS. DATES OF USE: (B)(6) 2004 - (B)(6) 2012. REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/11/2012	1/7/2013

Event Information:

Event Date (B3): 11/15/2012 **Report Date (B4): 12/11/2012** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 893031 AND 872994

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED IN LEFT TUBE AND MALFUNCTIONED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/13/2012	12/19/2012

Event Information:

Event Date (B3): 10/18/2012 **Report Date (B4): 12/13/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): A22176

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE WAS NOT ABLE TO ENTER THE FALLOPIAN TUBE. THE VENDOR REPRESENTATIVE WAS PRESENT DURING THE PROCEDURE AND NOTICED THE DEVICE WAS BENT AT A RIGHT ANGLE INSTEAD OF BEING STRAIGHT. THE DEVICE WAS REMOVED FROM THE STERILE FIELD AND REPLACED. THERE WAS NO HARM NOTED TO THE PATIENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00056	CONCEPTUS, INC.	12/13/2012	12/19/2012

Event Information:

Event Date (B3): 9/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 925785

Single Use: Y
Implant Date (E6): 4/16/2012
Explant Date (E7): 9/19/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD AN UNCOMPLICATED ESSURE PROCEDURE DONE ON (B)(6) 2012. THE RECOMMENDED THREE MONTH HSG TEST WAS NOT DONE IN (B)(6) 2012. IN MID (B)(6), THE PT PRESENTED WITH SEVERE PELVIC AND ABDOMINAL PAIN. AN HSG TEST DONE ON (B)(6) 2012 INDICATED UNSATISFACTORY PLACEMENT WITH NO DEVICES FOUND IN THE FALLOPIAN TUBES. ON (B)(6) 2012 A BILATERAL TUBAL LIGATION WAS DONE BUT THE DEVICES NOT VISIBLE BY HYSTEROSCOPY OR LAPAROSCOPY. PT'S PAIN AND BLEEDING CONTINUED TO WORSEN. THE DOCTOR PERFORMED A HYSTERECTOMY ON (B)(6) 2012. INTRA-OP FLUOROSCOPY INDICATED THAT THE DEVICES WERE EMBEDDED IN THE MYOMETRIUM OF THE FUNDUS. THE PT'S UTERUS AND CERVIX WERE REMOVED. AT HER SIX WEEK POST OPERATIVE VISIT ON (B)(6), THE PT HAD A LOW GRADE FEVER AND SOME PELVIC DISCOMFORT THAT WERE DUE TO THE SURGERY. HER PELVIC AND ABDOMINAL PAIN AND BLEEDING HAD RESOLVED. THE DOCTOR ATTRIBUTED HER PAIN SYMPTOMS TO ENSURE DEVICES DUE TO THEIR POSITION IN THE MYOMETRIUM.

Manufacturer Narrative (H10):

LOT # 915887.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00057	CONCEPTUS, INC.	12/13/2012	12/19/2012

Event Information:

Event Date (B3): 11/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 6/14/2012
Explant Date (E7): 11/30/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE WAS DONE (B)(6) 2012. DOCTOR DID TWO HSG TESTS IN PAST SIX MONTHS WHICH INDICATED BILATERAL OCCLUSION, BUT PROBLEMS WITH PLACEMENT OF DEVICE ON LEFT SIDE. PATIENT HAD BEEN COMPLAINING OF PELVIC PAIN SINCE THE ESSURE PROCEDURE. DOCTOR TREATED PATIENT SEVERAL TIMES WITH ANTIBIOTICS AND PAIN MEDICATIONS, BUT PATIENT EVENTUALLY OPTED TO HAVE BOTH DEVICES REMOVED. DOCTOR DID A BILATERAL SALPINGECTOMY ON (B)(6) 2012. SHE FOUND THAT THE ONE DEVICE HAD PERFORATED THROUGH THE LEFT FALLOPIAN TUBE AND WAS ADHERED TO LEFT PELVIC SIDE WALL. PATIENT IS NOW FEELING WELL. SYMPTOMS HAVE BEEN RELIEVED. DOCTOR ATTRIBUTED PT¿S PAIN TO THE PERFORATED ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/13/2012	12/26/2012

Event Information:

Event Date (B3): 12/5/2012 **Report Date (B4): 12/13/2012** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6): 12/5/2012
Explant Date (E7): 12/5/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

TIP OF DEVICE APPEARED BENT. DEVICE WAS REMOVED AND ANOTHER DEVICE WAS USED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00058	CONCEPTUS, INC.	12/13/2012	1/9/2013

Event Information:

Event Date (B3): 11/27/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/12/2012
Explant Date (E7): 11/27/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING A DIFFICULT ESSURE PROCEDURE IN (B)(6) 2012, M.D. PLACED BOTH DEVICES DISTALLY. DURING THE HSG TEST, ONE DEVICE WAS NOT SEEN IN FALLOPIAN TUBE. M.D. PERFORMED A LAPAROSCOPY BUT COULD NOT FIND THE DEVICE ON THE RIGHT SIDE. IT APPEARED TO BE BEHIND BOWEL. X-RAY CONFIRMED THAT ONE DEVICE WAS LYING CRANIAL TO RIGHT TUBE. PATIENT WAS ASYMPTOMATIC BUT CT SCAN DONE IN (B)(6) 2012 SHOWED THAT DEVICE WAS POSITIONED VERY CLOSE TO UTERUS AND OVARY. TO AVOID ANY POTENTIAL LONG-TERM COMPLICATIONS OF DEVICE POSSIBLY BEING IN ABDOMINAL CAVITY, THE PHYSICIAN DECIDED TO REMOVE THE DEVICE VIA LAPAROSCOPY AND THEN PERFORM A SALPINGECTOMY. DURING SURGERY, THE DEVICE WAS FOUND LYING NEXT TO TUBE WITH NO ADHESIONS. PATIENT IS DOING FINE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028300	CONCEPTUS, INC.	12/16/2012	12/28/2012

Event Information:

Event Date (B3): 12/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN 2009. THE COILS EXPELLED FROM MY TUBES INTO MY UTERUS. IN 2011, I HAD SURGERY TO REMOVE THEM. I DID NOT HAVE A HYSTERECTOMY, ONLY THE COILS WERE REMOVED. MY SYMPTOMS DID NOT IMPROVE AND HAVE RECENTLY WORSENED. ON (B)(6) 2012, I HAD A PELVIC X-RAY AT MY PRIMARY CARE PHYSICIANS OFFICE. I HAVE ENDOMETRIAL FOREIGN BODIES THROUGH OUT MY PELVIS NOW. ESSURE FRAGMENT POSSIBLY. I GO ON (B)(6) 2012, TO HAVE A CT SCAN OF MY PELVIS. IF IT PROVES TO BE ESSURE FRAGMENTS, IT WILL REQUIRE MICROSCOPIC SURGERY WITH FLUOROSCOPY TO FIND ALL OF THE FRAGMENTS. THIS IS NOT OK. THIS WILL BE MY SECOND SURGERY DUE TO ESSURE. PLEASE ISSUE A WARNING TO CONCEPTUS, MAKERS OF ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028302	CONCEPTUS	12/16/2012	12/28/2012

Event Information:

Event Date (B3): 3/29/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/29/2012
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURED PLACED ON (B)(6) 2012. I HAD ESSURED REMOVED (B)(6) 2012. THE PROCEDURE ITS SELF WAS FINE. BLEEDING WAS NORMAL. PERIODS WERE NORMAL. A WEEK AFTER I HAD THEM PLACED I WALKED IN TO MY BATHROOM TO TAKE A SHOWER AND WOKE UP ON THE FLOOR. I HAD PASSED OUT. DOCTOR SAID NOTHING WRONG ALL TEST WEER NORMAL. BLOODWORK NORMAL ETS. AFTER THAT I STARTED HAVING DIZZY SPELLS THAT TURNED INTO CONSTANT DIZZY ON A DAILY BASIS. TO THE POINT WHERE I WAS NO LONGER ABLE TO LEAVE MY HOUSE OR DRIVE A CAR. I HAVE 2 SMALL CHILDREN AND MY HUSBAND WAS DEPLOYED TO (B)(6) AT THE TIME, SO I WAS LEFT ALONE WITH ALL THESE PROBLEMS. I FINALLY DECIDED TO GET (B)(6) AND PAY FOR THE REMOVAL. MOST OF MY SYMPTOMS WERE INSTANTLY GONE. STILL TO THIS DAY I HAVE GOOD DAYS AND BAD DAYS WITH THE DIZZINESS AND NO DOCTOR HAS ANY KIND IF EXPLANATION. WORST THING I'VE DONE, IT HAS COMPLETELY RUINED MY LIFE AT (B)(6)! THIS PRODUCT NEEDS TO BE BANNED ASAP!

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00059	CONCEPTUS, INC.	12/27/2012	1/4/2013

Event Information:

Event Date (B3): 11/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 2/1/2012
Explant Date (E7): 11/7/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE WAS DONE IN (B)(6) 2011. HSG DONE IN (B)(6) 2011 SHOWED BILATERAL OCCLUSION WITH DISTAL PLACEMENT ON LEFT AND PART OF RIGHT DEVICE JUST BEYOND LEFT CORNUA AND SEPARATE FROM REMAINDER OF DEVICE. PT SAW HER FAMILY DOCTOR IN (B)(6) 2012 FOR RIGHT SIDE ABDOMINAL PAIN WITH NAUSEA AND VOMITING. A CT SCAN INDICATED DEVICES WERE IN PERITONEUM OVER THE BLADDER. DOCTOR TREATED PT FOR PAIN FOR A FEW WEEKS. DURING LAPAROSCOPY ON (B)(6) 2012, SURGEON FOUND THAT ONE PORTION OF THE LEFT DEVICE WAS SHALLOWLY EMBEDDED IN THE SURFACE OF THE UTERUS A SHORT DISTANCE FROM THE UTERINE CORNU ON THE LEFT. THE REMAINDER OF THAT DEVICE AND THE ENTIRETY OF THE OTHER DEVICE WERE FOUND DEEPLY EMBEDDED IN THE OMENTUM, WHICH WAS INFLAMED IN APPEARANCE. SURGEON DISSECTED THE PARTIAL DEVICE FORM THE SEROSAL SURFACE OF THE UTERUS AND DID A PARTIAL OMENTECTOMY IN 2 PIECES TO REMOVE THE REMAINING DEVICES. SHE THEN PERFORMED A BILATERAL SALPINGECTOMY. SURGEON ATTRIBUTED PT'S SYMPTOMS TO THE ESSURE DEVICES DUE TO THEIR LOCATION. PT'S SYMPTOMS WERE RELIEVED AS OF HER POST OP VISIT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2012-00060	CONCEPTUS, INC.	12/27/2012	1/4/2013

Event Information:

Event Date (B3): 12/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/26/2012
Explant Date (E7): 12/10/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE ON (B)(6) 2012. PT BEGAN TO EXPERIENCE PAIN ON RIGHT SIDE SHORTLY AFTER THE PROCEDURE. THE THREE MONTH HSG TEST DONE (B)(6) 2012 INDICATING A PATENCY ON THE LEFT SIDE AND A POSSIBLE PERFORATION AT THE CORNUA ON THE RIGHT SIDE. ON (B)(6) 2012, PHYSICIAN DID A HYSTEROSCOPY AND LAPAROSCOPY, FOLLOWED BY A BILATERAL SALPINGECTOMY. LAPAROSCOPY DID NOT FIND A PERFORATION OF THE CORNUA OR ANYTHING ABNORMAL. FLUOROSCOPY IMAGES SHOWED THAT THE TIP OF THE RIGHT DEVICE WAS IN UTERUS. SHE COULD NOT SEE THE LEFT DEVICE HYSTEROSCOPICALLY. DURING THE SALPINGECTOMY, IT FELT AS IF THE LEFT DEVICE WAS IN THE MESOSALPINX JUST OUTSIDE THE FALLOPIAN TUBE. SHE SENT EVERYTHING TO PATHOLOGY. PHYSICIAN ATTRIBUTED PT'S PAIN TO THE ESSURE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028462	CONCEPTUS, INC.	12/28/2012	1/10/2013

Event Information:

Event Date (B3): 11/26/2012 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 628969

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2009, AFTER THE BIRTH OF MY THIRD CHILD, I OPTED TO HAVE THE ESSURE BIRTH CONTROL DEVICES IMPLANTED. MY OB/GYN PERFORMED THE PROCEDURE IN HIS OFFICE WITH NO ISSUES. I HAD THE CONFIRMATION TEST PERFORMED AT THE REQUIRED THREE MONTH MARK AND THE TEST SHOWED THAT BOTH TUBES WERE COMPLETELY BLOCKED AND BACK UP BIRTH CONTROL WAS DISCONTINUED. IN (B)(6) 2012 I MISSED A PERIOD AND TOOK A HOME PREGNANCY TEST. IT CAME BACK POSITIVE. GIVEN THAT I HAVE ESSURE, I WAITED A WEEK AND THEN TOOK A SECOND HOME PREGNANCY TEST. AFTER THAT ONE ALSO CAME BACK POSITIVE. I CONTACTED MY OB/GYN WHO PERFORMED A VAGINAL ULTRASOUND ON (B)(6) 2012 AND CONFIRMED THAT I WAS INDEED 8 WEEKS AND 6 DAYS PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028446	CONCEPTUS, INC.	1/7/2013	1/10/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORTED THAT SINCE SHE HAD THE ESSURE IMPLANTED IN HER, SHE HAS BEEN EXPERIENCING EXCRUCIATING PAIN IN HER OVARIES, LEG AND BACK. SHE SUFFERS FROM SIGNIFICANT SWELLINGS AND BLOATING IN HER ABDOMEN WHICH MAKES HER LOOK LIKE A PREGNANT LADY. AFTER CONSULTING WITH HER DOCTOR, HE INFORMED HER THAT HER UTERUS IS SEVERELY INFLAMED AND THAT SHE WILL NEED TO HAVE A HYSTERECTOMY. SHE ALSO REPORTED, SHE SUFFERS FROM IRREGULAR AND HEAVY MENSTRUAL PERIODS AND ALSO PAINFUL SEXUAL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028447	CONCEPTUS, INC.	1/7/2013	1/10/2013

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 789-025

Single Use:
Implant Date (E6): 10/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER STATES THAT IN (B)(6) 2011, SHE HAD ESSURE IMPLANTED. SINCE THEN, SHE BEGAN EXPERIENCING EXCRUCIATING PAIN. SHE HAD IRREGULAR MENSTRUAL PERIODS, LOSS OF APPETITE, DIZZINESS, LOSS OF ENERGY AND SEVERE BLOATING THAT SOMETIMES SHE LOOKED LIKE A PREGNANT LADY. SHE ALSO SUFFERED FROM NAUSEA, STABBING BACK PAIN, INSOMNIA, PANIC ATTACKS, CONTINUOUS YEAST INFECTIONS AND SEVERE DEPRESSION. SHE HAD A CYST IN HER FALLOPIAN TUBE, AND HAD TO UNDERGO A PROCEDURE IN (B)(6) DUE TO A HYDROSALPINX (FLUID ACCUMULATION IN HER FALLOPIAN TUBE). THE DOCTOR TOLD HER THIS WAS MOST PROBABLY DUE TO ESSURE. SHE STATES THAT ON (B)(6) 2012, SHE HAD TO UNDERGO A SECOND PROCEDURE WHICH WAS A HYSTERECTOMY DUE TO THE FACT THAT SHE WAS DIAGNOSED WITH ADENOMYOSIS WHICH IS THE FORMATION AND CONTINUES GROWTH OF SCAR TISSUE IN HER UTERUS AND ADHESION OF INNER BODY ORGANS. SHE IS VERY SURE, THE CAUSE OF ALL THE ABOVE PROBLEMS WAS ESSURE, BECAUSE AS SOON AS SHE HAD THE HYSTERECTOMY DONE, SHE HAS NOT EXPERIENCED ANY MORE OF THE ABOVE SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028575	CONCEPTUS	1/7/2013	1/16/2013

Event Information:

Event Date (B3): 12/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): UTERINE COIL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS IMPLANTED AS A PERMANENT BIRTH CONTROL. I AM EXPERIENCING SPOTTING, CRAMPING, SEVERE PINCHING PAIN ON RIGHT LOWER QUADRANT, LOWER BACK PAIN, NAUSEA, VOMITING, NIGHT SWEATS. I WENT TO THE HOSP AND WAS DX WITH UTI. I'M MEETING WITH OBGYN TODAY TO DISCUSS SOME OF THESE SYMPTOMS. (B)(6). ESSURE - DEVICE STILL IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	1/11/2013	1/16/2013

Event Information:

Event Date (B3): 1/10/2013 **Report Date (B4): 1/11/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION DEVICE
Model # (E4): ESS 305
Catalog # (E4): ESS 305
Lot #(E4): A50514

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING HYSTEROSCOPIC PLACEMENT OF BILATERAL ESSURE OCCLUSION DEVICE TO RIGHT AND LEFT FALLOPIAN TUBES, THE FIRST DEVICE SUCCESSFULLY DEPLOYED TO RIGHT FALLOPIAN TUBE WITHOUT PROBLEM. DURING PLACEMENT OF THE ESSURE DEVICE TO THE LEFT FALLOPIAN TUBE, AFTER THE ESSURE PLACED, AND DURING RELEASE OF THE DEVICE THERE WAS NOTED A PIECE OF THE ESSURE COIL THAT WAS FLOATING IN THE UTERUS. THIS PIECE WAS RETRIEVED AND NOTED TO HAVE 5 COILS INTACT, ORIGINALLY THERE ARE BETWEEN 21 AND 24 COILS ON THE ESSURE DEVICE.
THE COMPANY REPRESENTATIVE WAS IN THE ROOM DURING THE PROCEDURE. MUCH DISCUSSION BETWEEN MD AND THE COMPANY REPRESENTATIVE AS TO WHETHER LAPAROSCOPY, SONOGRAM, X-RAY, AND CONTINUED ADDITIONAL PROCEDURE OF RADIOFREQUENCY ABLATION SHOULD BE DONE. IT WAS DECIDED TO DO A SONOGRAM, (DONE), FLAT PLATE ABD PELVIC X-RAY (DONE) TO CHECK PLACEMENT AND INTEGRITY OF THE RETAINED PIECE OF THE ESSURE. DR IS SATISFIED THAT THE REMAINING COILS ARE IN THE CORRECT PLACE (LEFT FALLOPIAN TUBE).
FOLLOW UP INDICATES THAT PATIENT HAD NO ILL EFFECTS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00001	CONCEPTUS, INC.	1/16/2013	1/24/2013

Event Information:

Event Date (B3): 12/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/31/2012
Explant Date (E7): 12/5/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE WAS DONE (B)(6) 2012. AN EXISTING IUD WAS ALSO REMOVED AT THAT TIME. PT WAS SEEN IN EMERGENCY ROOM ON (B)(6) 2012 FOR PERSISTENT LOWER PELVIC PAIN. THE ULTRASOUND WAS DONE BUT WAS NEGATIVE. PT WAS GIVEN PAIN MEDICATIONS. SHE THEN SAW HER DOCTOR FOR PAIN SYMPTOMS ON (B)(6) 2012. SHE WAS PLACED ON A TWO WEEK COURSE OF ANTIBIOTICS. HER DOCTOR PERFORMED A BILATERAL SALPINGECTOMY ON (B)(6). HE FOUND BOTH DEVICES IN THEIR NORMAL POSITION WITH NO SIGNS OF PERFORATION. AT (B)(6) 2012, POST SURGICAL VISIT, THE PT REPORTED THAT HER PAIN SYMPTOMS HAD RESOLVED SINCE HE COULD FIND NO OTHER REASON FOR HER PAIN AND THE PAIN RESOLVED AFTER REMOVAL, HER DOCTOR ATTRIBUTED PT'S ABDOMINAL PAIN TO THE ESSURE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00002	CONCEPTUS, INC.	1/16/2013	1/24/2013

Event Information:

Event Date (B3): 11/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A14898

Single Use: Y
Implant Date (E6): 11/1/2012
Explant Date (E7): 11/30/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING IMPLANT OF ESSURE DEVICE INTO RIGHT FALLOPIAN TUBE, THERE WAS DIFFICULTY DETACHING ONE DEVICE FROM THE CATHETER. WHILE REMOVING THE DEVICE, IT BROKE. PT EXPERIENCED PAIN DURING ATTEMPT TO REMOVE, SO ESSURE COIL WAS LEFT IN PT. THE NEXT DAY ((B)(6)), THE MD DID A BILATERAL TUBAL LIGATION WITH FILSCHIE CLIPS BUT WAS UNABLE TO REMOVE THE REMAINING PIECE HYSTEROSCOPICALLY. PT CONTINUED TO EXPERIENCE LOWER RIGHT QUADRANT PAIN. ON (B)(6) THE DOCTOR PERFORMED A HYSTERECTOMY DUE TO PELVIC PAIN. HE REMOVED UTERUS, CERVIX AND THE PROXIMAL SECTION OF BOTH FALLOPIAN TUBES. WHEN HE DISSECTED THE PROXIMAL PORTION OF THE RIGHT TUBE, THERE WAS SLIGHT EDEMA AND 12-15 MILLIMETERS OF COIL WERE FOUND IN A SCRUNCHED UP POSITION. THERE WAS NO OTHER PATHOLOGY NOTED AND THERE WERE NO INJURIES TO SURROUNDING ORGANS OR TISSUES. AT POST SURGICAL VISIT, PT REPORTED THAT HER PAIN SYMPTOMS WERE GONE. SINCE PT HAD NO PRE-EXISTING CONDITIONS, AND HER PAIN BEGAN AFTER ESSURE PLACEMENT ATTEMPT, THE DOCTOR ATTRIBUTED HER PAIN TO THE ESSURE DEVICE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00003	CONCEPTUS, INC.	1/17/2013	1/25/2013

Event Information:

Event Date (B3): 1/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 7/13/2012
Explant Date (E7): 1/4/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE WAS DONE (B)(6) 2012. A HSG TEST WAS PERFORMED IN (B)(6) 2012. PT SUBSEQUENTLY CALLED TO REPORT THAT SHE THOUGHT SHE WAS PREGNANT AND WAS HAVING PAIN SYMPTOMS AND SHE WAS ADVISED TO GO TO EMERGENCY ROOM. ON (B)(6) 2013, PT PRESENTED TO PHYSICIAN COMPLAINING OF PAIN AND HER DOCTOR IMMEDIATELY ADMITTED HER TO THE HOSPITAL. AN ECTOPIC PREGNANCY WAS CONFIRMED. THE PHYSICIAN PERFORMED A MINI LAPAROTOMY AND A BILATERAL SALPINGECTOMY TO END THE ECTOPIC PREGNANCY, REMOVED THE DEVICES AND RE-STERILIZED THE PT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028677	CONCEPTUS INCORPORATED	1/17/2013	1/25/2013

Event Information:

Event Date (B3): 1/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4): A63344

Single Use:
Implant Date (E6): 1/16/2013
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING AN IN-OFFICE PLACEMENT OF ESSURE TUBAL OCCLUSION COILS, THE DEVICE MALFUNCTIONED AND A PORTION OF THE DEVICE WAS RETAINED IN THE PT'S RIGHT FALLOPIAN TUBE. THE PHYSICIAN WAS ABLE TO REMOVE THE TRAILING COIL. THE CORPORATE REP HAS BEEN NOTIFIED AND THE EVENT WAS FULLY DISCLOSED TO THE PT. THE PLAN IS TO TAKE THE PT TO THE OPERATING ROOM FOR REMOVAL OF THE RETAINED DEVICE AND COMPLETION OF THE STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028700	CONCEPTUS, INC	1/20/2013	1/30/2013

Event Information:

Event Date (B3): 1/19/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4): UNSURE

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE COILS PLACED IN 2010 TO END THE CHANCE OF GETTING PREGNANT. FOUND OUT YESTERDAY THAT PRODUCT FAILED AND I AM 7 1/2 WEEKS PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028802	CONCEPTUS INCORPORATED	1/29/2013	2/5/2013

Event Information:

Event Date (B3): 12/10/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4): A34126

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DR NOTICED BEFORE INSERTING THE ESSURE THROUGH THE HYSTEROSCOPE THAT THE TIP OF THE ESSURE WAS BENT. TRIED TO USE THE ESSURE SO THAT IT WAS NOT WASTED, BUT WAS NOT ABLE TO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028820	CONCEPTUS	2/1/2013	2/6/2013

Event Information:

Event Date (B3): 1/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 20193381

Single Use:
Implant Date (E6): 10/21/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTED THAT SHE WAS IMPLANTED WITH AN ESSURE SYSTEM ON (B)(6) 2009, AFTER GIVING BIRTH TO HER SON. SHE RETURNED TO HER PHYSICIAN FOR HER THREE MONTH POST IMPLANT CHECK UP AND WAS TOLD THAT THE COIL ON THE RIGHT SIDE WAS MISSING. SHE WAS GIVEN A PREGNANCY TEST THAT RESULTED AS NEGATIVE. SHE STATED THAT SHE TOOK A HOME PREGNANCY TEST A FEW DAYS LATER AND SHE WAS INDEED PREGNANT. DURING HER PREGNANCY SHE WAS REFERRED TO NEUROLOGIST DUE TO SEVERE MIGRAINE HEADACHES AND DIZZINESS. AFTER GIVING BIRTH TO HER DAUGHTER SHE REQUESTED THAT SHE GET HER TUBES TIED. SHE EVENTUALLY HAD A PARTIAL HYSTERECTOMY DUE TO THE ABDOMINAL PAIN, AND HEAVY BLEEDING. SHE ALLEGES THAT HER MEDICAL RECORDS DO NOT INDICATE THAT THE ESSURE WAS EVER REMOVED. SHE STATED THAT SHE WENT TO A DIFFERENT DOCTOR TO GET A SECOND OPINION AND THEY HAVE SUGGESTED THAT SHE HAVE EXPLORATORY SURGERY TO SEE IF THE COIL HAS MIGRATED. SHE CONTINUES TO HAVE ABDOMINAL PAIN, DIZZINESS, HEADACHES AND NUMBNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00004	CONCEPTUS, INC.	2/5/2013	2/8/2013

Event Information:

Event Date (B3): 1/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/28/2012
Explant Date (E7): 1/9/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING ESSURE PROCEDURE, MD HAD DIFFICULTY PLACING DEVICE ON RIGHT SIDE DUE TO TUBAL SPASMS SO SHE USED POLYP FORCEPS TO OPEN OSTIUM. PT HAD PAIN THROUGHOUT THE PROCEDURE DESPITE PAIN TREATMENT PROTOCOLS. MD SAW PT SEVERAL TIMES AFTER PROCEDURE DUE TO BILATERAL PAIN AND PULLING SENSATION IN RIGHT ABDOMEN. ON (B)(6), MD PERFORMED A LAPAROSCOPY WHICH SHOWED A PERFORATION ON THE RIGHT SIDE WITH ADHESION FROM UTERUS INTO FAT OF APPENDIX. MD THEN DID A BILATERAL SALPINGECTOMY AND REMOVED BOTH DEVICES. AT FIVE DAYS POST SURGERY, THE PT'S PAIN WAS LARGELY RESOLVED. MD ATTRIBUTES PT'S PAIN TO ESSURE AND TO THE ADHESIONS RESULTING FROM THE PERFORATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00055	CONCEPTUS, INC.	2/5/2013	3/1/2013

Event Information:

Event Date (B3): 10/28/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/25/2012
Explant Date (E7): 12/12/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DR (B)(6) HAD A PT: (B)(6), WHO HAD THE ESSURE PROCEDURE (B)(6) 2012 AND DEVELOPED A RASH WITHIN THREE DAYS OF THE PROCEDURE. SHE WAS SENT FOR METAL ALLERGY TESTING AND IT WAS NEGATIVE. ESSURE REMOVAL WAS DONE (B)(6) 2012 VIA PARTIAL SALPINGECTOMY REMOVING 2/3RDS OF THE RIGHT TUBE AND THE LEFT TUBE HE DID A PARTIAL SALPINGECTOMY REMOVING 2/3RDS OF THE LEFT TUBE AS WELL. DIAGNOSIS BY MD WAS SEVERE ALLERGY TO ESSURE DEVICES, AS OPPOSED TO EARLIER ALLERGY TEST TO METAL THAT WAS NEGATIVE. PT IS FINE POST OP, RASH IS GONE.

Manufacturer Narrative (H10):

THE ESSURE IFU CONTAINS THE FOLLOWING WARNING STATEMENT: THE ESSURE MICRO-INSERT INCLUDES NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. HOWEVER, IN VITRO TESTING HAS DEMONSTRATED THAT NICKEL IS RELEASED FROM THIS DEVICE. PTS WHO ARE ALLERGIC

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5028942	CONCEPTUS INC	2/13/2013	2/15/2013

Event Information:

Event Date (B3): 5/12/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INTRAUTERINE DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/12/2011
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, PT HAD HAD AN ESSURE COIL, (MFG BY CONCEPTUS) IMPLANTED. BETWEEN 6 MONTHS TO A YR AGO, SHE STARTED NOTICING AN ABNORMAL WEIGHT GAIN AROUND HER STOMACH, WAISTLINE AND BACK WHICH MAKES HER LOOK MILDLY PREGNANT. IN ADDITION, SHE REGULARLY FEELS FEVERISH, HOT EVEN WHEN IT'S COLD OUTSIDE, EXPERIENCES NIGHT SWEATS, ALLERGIC TO HER WEDDING RING, (SO CAN NO LONGER WEAR IT) SHE SAID SHE'S NOW REGULARLY FEELING SICK WHICH WAS NEVER THE CASE PRIOR TO HAVING THIS DEVICE IMPLANTED. SHE FEELS HER IMMUNE SYSTEM IS SHUTTING DOWN. SHE HAS LOST SO MUCH FAITH IN THE DEVICE THAT, SHE IS NOW AFRAID SHE MAY GET PREGNANT BECAUSE OF DOUBTS SHE HAS ON IT'S EFFECTIVENESS. SHE ALSO SAID SHE HAS CONSULTED WITH SEVERAL DOCTORS AND SPECIALISTS (GASTROENTEROLOGIST, GYNECOLOGISTS ETC) AND DONE SEVERAL MEDICAL EXAMS TO PINPOINT THE SOURCE OF HER ILLNESS. YET ALL THE RESULTS HAVE RETURNED NEGATIVE. CONSEQUENTLY SHE BELIEVES THE SOURCE OF HER HEALTH PROBLEMS IS THE ESSURE DEVICE, AND SO WOULD LIKE TO HAVE IT EXPLANTED AS SOON AS POSSIBLE. SHE BELIEVES THIS DEVICE SHOULD BE DISCONTINUED BECAUSE IT IS DOING MORE HARM THAN GOOD TO WOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029011	CONCEPTUS INC.	2/15/2013	2/21/2013

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INTRAUTERINE DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4): 628442

Single Use:
Implant Date (E6): 10/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2009, PT HAD THE ESSURE INTRAUTERINE DEVICE, MANUFACTURED BY (B)(4) IMPLANTED. ALL WAS FINE, UNTIL SHE STARTED HAVING PELVIC PAIN IN 2011. YESTERDAY (B)(6) 2013, SHE CONSULTED HER DOCTOR IN ORDER FOR HIM TO EXPLANT THE DEVICE. HE COULDN'T FIND IT IN HER FALLOPIAN TUBES; IT HAD MIGRATED TO HER UTERUS. THE DOCTOR SAYS IN ORDER FOR IT TO BE EXPLANTED, SHE WOULD HAVE TO UNDERGO A HYSTERECTOMY. BECAUSE OF THE PAIN SHE'S EXPERIENCING, SHE'S WILLING TO PROCEED. THE APPOINTED DATE IS (B)(6) 2013. SHE WILL LIKE TO ASK THE MANUFACTURER TO BE AVAILABLE TO PROVIDE SUFFICIENT INFORMATION TO PHYSICIANS IN ORDER FOR THEM TO TAKE CARE OF THEIR PTS. SHE SAYS HER DOCTOR HAS CALLED (B)(4) SEVERAL TIMES AND THEY'VE NEVER HAD THE COURTESY OF RETURNING THE CALLS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029120	CONCEPTUS, INC.	2/20/2013	2/28/2013

Event Information:

Event Date (B3): 8/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 855630

Single Use:
Implant Date (E6): 8/8/2011
Explant Date (E7): 8/8/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED (B)(6) 2011, I WAS SUPPOSED TO HAVE A PLASTIC ONE PLACED, BUT UPON THE FDA TAKING OFF THE WARNING FOR THE NICKEL ALLERGY, THE DOCTOR DECIDED, I NO LONGER NEEDED THE PLASTIC ONE SINCE YOU GUYS FELT EVERYONE WOULD BE FINE. WELL, NOT EVERYONE IS FINE, I HAVE BAD ALLERGIES TO NICKEL AND I ARGUED THE POINT CONSTANTLY AND IN THE END THEY SAID IT WAS JUST A SMALL BIT OF NICKEL AND IT REALLY WOULDN'T HARM ME AND I FIGURED OK IF YOU GUYS TOOK OFF THE WARNING AND THEY WERE MY DOCTOR'S I SHOULD BE FINE. WELL TWO YEARS LATER, SIX YEAST INFECTIONS LATER AND A LOT OF PAIN LATER I CAN TELL YOU TAKING THE WARNING OFF WAS A MISTAKE AND ME HAVING IT DONE WAS A MISTAKE AND I AM IN THE PROCESS OF VISITING MY DOCTOR TO SEE WHAT OTHER DAMAGE HAS BEEN DONE WITH THE ESSURE PRODUCT AS I SEEM TO HAVE A LOT MORE PAIN. I GO IN (B)(6) TO MY DOCTOR, BUT I HAVE GONE IN JUST THIS PAST TUESDAY AND TO THE CLINIC AND SUNDAY TO THE EMERGENCY ROOM TO BE TREATED. I HAVE BEEN TREATED IN (B)(6) FOR A YEAST INFECTION ALSO, AND (B)(6) I HAD ONE IN (B)(6), IT WAS A URINARY TRACT INFECTION AND (B)(6) 2011, I HAD A YEAST INFECTION AFTER THE PROCEDURE FOLLOWED BY A URINARY TRACT INFECTION, ALL TREATED BY DOCTOR'S.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00006	CONCEPTUS, INC.	2/21/2013	2/28/2013

Event Information:

Event Date (B3): 7/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/31/2012
Explant Date (E7): 6/26/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE WAS DONE ON (B)(6) 2012. AN IUD WHICH WAS SUPPOSED TO BE IN PLACE WAS NOT VISIBLE DURING THE HYSTEROSCOPY. THE PATIENT'S LAST PERIOD PRIOR TO IMPLANT WAS ON (B)(6) 2012. ON (B)(6) 2012, A PREGNANCY WAS CONFIRMED FOR THE PATIENT. ON (B)(6) 2012, SHE WAS HOSPITALIZED IN THE EMERGENCY UNIT BECAUSE AN ECTOPIC PREGNANCY WAS DETECTED AND SHE WAS EXPERIENCING SEVERE PAIN. AN EMERGENCY SALPINGECTOMY WAS DONE THE SAME DAY. THE IMPLANT PHYSICIAN BELIEVES THE IMPLANTS WERE PLACED CORRECTLY, BUT SUSPECTS THAT THE PATIENT WAS PREGNANT THE DAY OF THE PROCEDURE AND THAT THIS WAS A CONTRIBUTING FACTOR IN THE PREGNANCY DEVELOPING ECTOPICALLY.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	3/1/2013	3/8/2013

Event Information:

Event Date (B3): 1/28/2013 **Report Date (B4): 3/1/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 50685169

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

TIP WAS BENT WHEN PACKAGE OPENED, NOT ALLOWING IT TO BE CORRECTLY PASSED THROUGH THE OPERATIVE DEVICE. THE DEVICE WAS NOT USED ON THE PATIENT. NO PATIENT HARM.
==========
MANUFACTURER RESPONSE FOR PERMANENT BIRTH CONTROL- ESSURE, ESSURE (PER SITE REPORTER).
==========
WE PLAN TO RETURN THE DEVICE TO THE REP FOR EVALUATION.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
DILATION AND HYSTEROSCOPY AND ESSURE TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	3/1/2013	3/11/2013

Event Information:

Event Date (B3): 2/27/2013 **Report Date (B4): 3/1/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS306
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6): 2/27/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCORRECT DEPLOYMENT INTO THE FALLOPIAN TUBES FOR TWO DEVICES. EQUIPMENT SENT FOR EVALUATION.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
UNKNOWN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029267	UNK	3/1/2013	3/11/2013

Event Information:

Event Date (B3): 10/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PROCEDURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE DONE WHICH HAS CAUSED ME MUCH DISCOMFORT AND MASSIVE WEIGHT GAIN. CHECK INTO THE HORRIBLE SIDE EFFECTS OF ESSURE AND PULL THIS OFF THE MEDICAL CIRCUIT BEFORE IT AFFECTS OTHER WOMAN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00007	CONCEPTUS, INC.	3/6/2013	4/18/2013

Event Information:

Event Date (B3): 1/30/2013 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7): 1/30/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD AN ESSURE PROCEDURE DONE IN (B)(6) 2012. SUBSEQUENTLY, SHE HAD SEVERAL CONSTITUTIONAL SYMPTOMS SUCH AS FATIGUE, FAINTING ETC. WHICH EVENTUALLY CAUSED HER TO VISIT THE ER. WHEN MRI AND CAT SCAN TESTS CAME BACK NORMAL, THE ER DOCTOR SUGGESTED SHE CONSULT AN OB/GYN REGARDING HER ESSURE DEVICES. THE REPORTING PHYSICIAN (WHO WAS NOT THE IMPLANT SURGEON) REMOVED HER DEVICES VIA BILATERAL SALPINGECTOMY ON (B)(6) 2013. DURING THE PROCEDURE, HE FOUND THAT HER DEVICES WERE CORRECTLY POSITIONED AND SHE HAD NO INFLAMMATION, INFECTION OR OTHER PATHOLOGY. AT HER POST SURGICAL VISIT, SHE REPORTED THAT HER SYMPTOMS HAD DRAMATICALLY IMPROVED. SINCE SHE HAD NO PRE-EXISTING CONDITIONS AND HER SYMPTOMS BEGAN AFTER HER ESSURE PROCEDURE, THE EXPLANT PHYSICIAN CONCLUDED THAT HER SYMPTOMS WERE CAUSED BY AN ALLERGIC REACTION TO THE ESSURE DEVICES.

Manufacturer Narrative (H10):

PER CURRENT ESSURE INSTRUCTIONS FOR USE (IFU) THE ESSURE MICRO-INSERT INCLUDES NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. HOWEVER, IN VITRO TESTING HAS DEMONSTRATED THAT NICKEL IS RELEASED FROM THIS DEVICE. PTS WHO ARE ALLERGIC TO NICKEL M

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029322	CONCEPTUS INC.	3/8/2013	3/14/2013

Event Information:

Event Date (B3): 2/21/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A64625

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

SURGEON NOTED THE ESSURE DEVICE WAS DEFECTIVE PRIOR TO USE ON PT. EQUIPMENT MALFUNCTION DID NOT REACH PT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029345	CONCEPTUS, INC	3/8/2013	3/18/2013

Event Information:

Event Date (B3): 3/8/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 50705834

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

CONCEPTUS ESSURE PERMANENT BIRTH CONTROL DEVICE WAS DETERMINED TO HAVE A BENT TIP RENDERING IT UNUSABLE. A SUBSEQUENT ASSURE DEVICE WAS UTILIZED.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	3/12/2013	3/14/2013

Event Information:

Event Date (B3): 3/6/2013 **Report Date (B4): 3/12/2013** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): A66680

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WAS BENT AND UNABLE TO BE INSERTED INTO PATIENT'S FALLOPIAN TUBE.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
HYSTEROSCOPY WITH TUBAL OCCLUSION.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	3/12/2013	4/4/2013

Event Information:

Event Date (B3): 3/7/2013 **Report Date (B4): 3/12/2013** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE TUBAL OCCLUSION DEVICE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): A64633

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE WAS PLACED INTO THE FALLOPIAN TUBE OS. AND THE ESSURE INSTRUMENT WOULD NOT LAUNCH THE ESSURE OCCLUSION COIL.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
HYSTEROSCOPY, WITH ESSURE PLACEMENT.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029374	CONCEPTUS INCORPORATED, USA	3/13/2013	3/20/2013

Event Information:

Event Date (B3): 3/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 959215

Single Use:
Implant Date (E6): 7/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD FLU LIKE SYMPTOMS SINCE (B)(6). I BECAME VERY ILL LAST MONDAY. I WENT TO PRIMARY CARE PHYSICIAN TWICE. FINALLY SO DIZZY I CAN'T STAND AND CHEST IS TIGHT. I WENT TO THE EMERGENCY ROOM LAST NIGHT. THEY RAN BLOOD WORK AND DID CHEST X-RAYS. THEY FOUND NOTHING. MY HEALTH WAS FINE UNTIL THESE IMPLANTS. MY HANDS AND FEET GET NUMB AND I FEEL AS IF I AM GOING TO LOSE CONSCIOUSNESS. I AM WEAK WITH PAIN IN MY PELVIC AREA. I BELIEVE THIS IS AN ADVERSE REACTION TO THE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029387	CONCEPTUS INC	3/13/2013	3/20/2013

Event Information:

Event Date (B3): 2/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE DEVICE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A36521

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE DID NOT DEPLOY COMPLETELY, STUCK IN FALLOPIAN TUBE WITH PLASTIC SHEATH CAUSING BLEEDING. DEVICE BAGGED FOR FURTHER INVESTIGATION. SURGEON STATES DISCLOSURE TO PT FAMILY, DOES NOT FEEL THERE WILL BE A NEED FOR FURTHER PROCEDURE. REP CONTACTED DURING PROCEDURE FOR SUPPORT/IDEAS. DR (B)(6) ALSO CAME TO ROOM FOR CONSULTATION AS HE USES THIS SYSTEM. SURGEON FELT THERE WAS NOTHING THAT COULD HAVE BEEN DONE PRIOR TO OR DURING FOR PREVENTION OF INCIDENT. UPON WHEELING BACK, THE ESSURE DEVICE, FOLLOWING DEPLOYMENT, THE TRAILING END OF THE WIRE REMAINED ATTACHED TO THE COILS AND THIS RESULTED IN AN EXCESSIVE AMOUNT OF WIRE LEFT WITHIN THE UTERINE CAVITY. THE WIRE INCLUDED THE GREEN PLASTIC COVERING. IN ORDER TO REMOVE THIS TRAILING WIRE FROM THE UTERINE CAVITY, THE OPERATIVE HYSTEROSCOPE NEEDED TO BE EXCHANGED FOR AN OPERATIVE CYSTOSCOPE, WHICH COULD ACCOMMODATE A LARGER SCISSOR. ONCE THE CYSTOSCOPE WAS SET UP, WAS PLACED WITHIN THE PT'S UTERINE CAVITY, THE CYSTOSCOPIC SCISSORS WERE USED TO TRIM THE WIRE SO THAT THE TRAILING END OF THAT WIRE OFF THE COILS WAS NEARLY FLUSH WITH THE TUBAL OSTIA, APPROX 2 COILS OF THAT WIRE REMAINED TRAILING FROM THE OSTIA SITE. THIS CONCLUDED THE PROCEDURE. EVENT ABATED AFTER USE STOPPED: YES. DIAGNOSIS OR REASON FOR USE: HYSTEROSCOPY WITH ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029394		3/14/2013	3/22/2013

Event Information:

Event Date (B3): 1/7/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PUT IN. STARTED HAVING BAD HEADACHES, BLEEDING BEFORE, AFTER AND DURING SEX, HEAVY BLOOD FLOW DURING PERIOD WITH BLOOD CLOTS, BACKACHES, NAUSEA, DIZZINESS, HOT FLASHES, MEMORY LOSS, UNABLE TO FOCUS, SEVERE ABDOMINAL PAIN, PAIN IN BOTH ELBOWS, VOMITING IF DRINKING ANY ALCOHOL, HAVE NO ENERGY, MOOD SWINGS, DEPRESSION, NO DESIRE FOR SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029395		3/14/2013	3/22/2013

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION INSERT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN 2010 BY DR. (B)(6), HAD MY PROPER FOLLOW-UP TESTS AND EVERYTHING SEEMED NORMAL. I DISCOVERED THAT I WAS PREGNANT IN (B)(6) 2013 AND THAT ONE OF THE COILS WAS NO LONGER THERE. TO THIS DATE I STILL HAVE NO IDEA IF IT EXPELLED ITSELF OR NOT, NO DIAGNOSTIC TEST HAS SHOWN THAT IT IS STILL INSIDE OF ME. I HAD TO TERMINATE THIS PREGNANCY AND HAVE SUFFERED SOME DEPRESSION AND NOW AM BACK ON BIRTH CONTROL PILLS. THIS PROCEDURE IS ADVERTISED TO BE PERMANENT. IT HAS CAUSED ME PHYSICAL AND EMOTIONAL DAMAGE AND NOW I WILL ALWAYS WONDER IF THE OTHER COIL CAN COME OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029419	CONCEPTUS	3/14/2013	3/22/2013

Event Information:

Event Date (B3): 6/1/2006 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/14/2012
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/21/2013

Event Description (B5):

I HAD ESSURE IMPLANTED AND DEVELOPED A SEVERE NICKEL ALLERGY. DATE OF USE: (B)(6) 2006 - (B)(6) 2013. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029406	CONCEPTUS	3/15/2013	3/22/2013

Event Information:

Event Date (B3): 1/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): COILS
Device Type (E2): ESSURE IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/15/2009
Explant Date (E7): 1/23/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE COILS IN (B)(6) 2009. MY HEALTH DECLINED FOR THE FIRST YEAR, MANY SINUS INFECTIONS, BRONCHITIS AND STOMACH FLU. I HAD MY FIRST ANAPHYLACTIC REACTION TO SOAP IN (B)(6) 2010. I HAD A SEVERE ANAPHYLACTIC REACTION IN (B)(6) 2011. THREE TRIPS TO THE EMERGENCY ROOM, ADMITTED TWICE FOR 4 AND 3 DAYS ALSO TO SOAP. DURING THE (B)(6) 2011, I HAD AN ANAPHYLACTIC REACTION TO BENADRYL LIQUI-GELS. ALL OF THE THINGS (SOAPS AND LIQUI-GEL CAPSULES) I REACTED TO HAD COCONUT IN THEM. I WENT TO THE (B)(6) IN (B)(6) 2011 AND WAS DIAGNOSED WITH POSSIBLE MULTIPLE CHEMICAL SENSITIVITY. I HAVE SINCE HAD MANY ALLERGIC REACTIONS TO MANY FOODS AS WELL AS TO SOAPS AND OTHER CHEMICALS. ANAPHYLACTIC REACTIONS ARE COMMON WITH MULTIPLE CHEMICAL SENSITIVITY. I ALSO DEVELOPED SEVERE ABDOMINAL PAIN IN THE (B)(6) 2012 WHERE MY COILS WERE LOCATED. MY GYNECOLOGIST BELIEVED THAT THE ESSURE IMPLANTS WERE RESPONSIBLE FOR MY ABDOMINAL PAIN AND THAT IF I CONTINUED TO HAVE ALLERGIC REACTIONS I MIGHT HAVE A FATAL REACTION TO THE ESSURE IMPLANTS. DR (B)(6)OF THE (B)(6) HAS PUBLISHED A PAPER NOTING THAT MANY OF HIS PATIENTS DEVELOPED MULTIPLE CHEMICAL SENSITIVITY AFTER HAVING A METAL IMPLANT WITH THE SAME METALS THAT ESSURE USES. I HAVE NOT YET RECOVERED FROM THE ALLERGIES BUT MY ABDOMINAL PAIN HAS IMPROVED SINCE I HAD A HYSTERECTOMY TO REMOVE THE COILS IN (B)(6) 2013. DOSE OR AMOUNT: 2 COILS. DATES OF USE: (B)(6) 2009- (B)(6) 2013. ALMOST 3 YEARS. REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	3/18/2013	3/25/2013

Event Information:

Event Date (B3): 1/30/2013 **Report Date (B4): 3/18/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 836499

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTABLE DEVICE MALFUCTIONED WHILE IN PATIENT. INSERTOR DEVICE WAS FIRED WHILE IN FALLOPIAN TUBE, BUT THE IMPLANT WAS NOT RELEASED FROM DEVICE. INSERTOR AND IMPLANT WERE REMOVED FROM PATIENT. NO VISIBLE HARM DONE TO PATIENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029466	CONCEPTUS INC, USA	3/19/2013	3/27/2013

Event Information:

Event Date (B3): 5/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESS305
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 922602

Single Use:
Implant Date (E6): 5/9/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE DONE, MULTIPLE ADVERSE REACTIONS. WEIGHT GAIN, NICKEL ALLERGY, PELVIC PAIN, BLEEDING, PAIN DURING INTERCOURSE WITH BLEEDING, DIZZY, BOWEL ISSUES, HAIR LOSS, HEADACHES, NIGHT SWEATS, SYNCOPAL EPISODES, AND MORE. I AM HAVING A PARTIAL HYSTERECTOMY ON (B)(6) 2013 TO HAVE THEM REMOVED DUE TO ALL OF THE ADVERSE REACTIONS. THIS PRODUCT SHOULD BE TAKEN OFF THE MARKET SO OTHER WOMEN DO NOT HAVE TO GO THROUGH THE PROBLEMS THAT I HAVE HAD, AS WELL AS OTHER WOMEN. I HAVE BEEN OUT OF WORK SINCE (B)(6) 2012 DUE TO PASSING OUT AND DIZZY SPELLS. I HAVE BEEN WORKED UP WITH A CARDIOLOGIST AND NEUROLOGIST DUE TO THESE SYMPTOMS THAT STARTED SHORTLY AFTER HAVING THE ESSURE PLACED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029563	CONCEPTUS	3/20/2013	4/4/2013

Event Information:

Event Date (B3): 10/1/2008 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): STERILIZATION DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/1/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

UPON GETTING ESSURE, I IMMEDIATELY FELT PAIN, WEAKNESS, FAINTING AND SICKNESS. AFTER 8 MONTHS OF THAT, THE DOCTOR DID EXPLORATORY SURGERY AND FOUND THE DEVICE HAD EXPELLED AND FUSED INTO MY UTERUS CAUSING IRREVERSIBLE DAMAGE WHICH HAS SINCE LED TO MULTIPLE SURGERIES INCLUDING A HYSTERECTOMY AND MASSIVE SCAR TISSUE. THE DEVICE HAD SHED METAL THROUGH MY INSIDES AS WELL. FIVE SURGERIES HAVE TAKEN PLACE SINCE THE IMPLANT TO TRY AND FIX THE ISSUES IT CAUSED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029557	CONCEPTUS	4/1/2013	4/3/2013

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/1/2010
Explant Date (E7): 10/1/2012
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ON ESSURE PERMANENT BIRTH CONTROL SYSTEM. SHE STATED SHE EXPERIENCED MANY ADVERSE REACTIONS SINCE THE DATE OF IMPLANT INCLUDING SEVERE PAIN, UTIS, PELVIC PAIN, FEVERS, DIARRHEA, VOMITING, RASHES, NEUROPATHY, HIGH BLOOD PRESSURE, WEIGHT GAIN, STREP THROAT, SEVERE INFECTION, CONSTANT MIGRAINES AND FIBROMYALGIA. PT SAID SHE WAS NEVER TOLD A HYSTERECTOMY WAS THE ONLY WAY OF REMOVAL OF THE DEVICE. SHE SAID SHE WAS ON PAIN MEDICATION AND ALSO HAD TO GO TO PAIN MANAGEMENT AND EXPERIENCED SEVERE ARTHRITIS. SHE SAID SHE HAD A PARTIAL HYSTERECTOMY ON (B)(6) 2012, WHICH REMOVED THE DEVICE AND SHE INSTANTLY FELT A LOT BETTER. SHE STATED SINCE THE REMOVAL OF THE DEVICE, HER PAIN HAS DRASTICALLY IMPROVED AND HER BLOOD PRESSURE HAS GONE BACK DOWN. PT WAS EXTREMELY UNHAPPY WITH DEVICE AND WOULD LIKE TO WARN OTHER PEOPLE ABOUT IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029558	CONCEPTUS, INC.	4/1/2013	4/3/2013

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 789025

Single Use:
Implant Date (E6): 9/1/2011
Explant Date (E7): 11/14/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ON ESSURE PERMANENT BIRTH CONTROL SYSTEM. SHE STATED SHE EXPERIENCED MANY ADVERSE REACTIONS FROM THIS DEVICE AND HAD TO HAVE 3 SURGERIES. SHE STATED SHE HAD A LOT OF HEAVY BLEEDING, SEVERE CRAMPS, STABBING PAIN, BACK PAIN, PAINFUL INTERCOURSE, LOSS OF ENERGY, NAUSEA, DIZZINESS, AND SEVERE BLOATING TO THE POINT THAT SHE LOOKED PREGNANT. THE PT ALSO STATED SHE EXPERIENCED BLURRED VISION, DEPRESSION, OVARIAN CYSTS, CYSTS ON HER RIGHT FALLOPIAN TUBE AND HYDROSALPHINX, WHICH LED TO THE REMOVAL OF HER LEFT FALLOPIAN TUBE IN (B)(6) 2012. SHE ALSO STATED SHE HAD SKIN RASHES, FORGETFULNESS, INSOMNIA, PANIC ATTACKS (ABOUT 1 PER WEEK), MOOD SWINGS WHICH WERE UNCHARACTERISTIC, AND FREQUENT YEAST INFECTIONS (AT LEAST ONCE A MONTH). SHE ALSO STATED SHE HAD A SEVERE EATING DISORDER RESULTING IN DRASTIC WEIGHT LOSS AND ANOREXIA. SHE ALSO SAID THE DEVICE GAVE HER THYROID PROBLEMS AND AFFECTED HER HYPOTHYROID TO THE POINT WHERE SHE HAD TO DOUBLE HER MEDICATION. PT STATED HER ORGANS WERE FUSING TOGETHER WHICH SHE HAD TO HAVE 3 SURGERIES FOR. SHE ALSO STATED HER LIVER FUSED TO HER ABDOMINAL WALL. PT SAID SHE HAD A HYSTERECTOMY ON (B)(6) 2012, WHICH EXPLANTED THE DEVICE. SHE SAID SHE FELT A LOT BETTER IMMEDIATELY AFTER THE REMOVAL OF THE DEVICE. SHE SAID SHE CONTACTED CONCEPTUS AND INFORMED THEM OF HER ALLERGY TO NICKEL AND SAW WARNINGS WERE REMOVED. SHE STATED CONCEPTUS WAS RATHER RUDE TO HER AND BLAMES HER DOCTOR FOR PLACING THE DEVICE INSIDE HER. SHE SAID SHE WOULD LIKE TO SEE THE CLASS 3 DEVICE PROTECTION REMOVED FROM THIS DEVICE. PT WAS EXTREMELY UNHAPPY WITH THE DEVICE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029599		4/1/2013	4/9/2013

Event Information:

Event Date (B3): 12/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): ESURE

Single Use:
Implant Date (E6): 12/15/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE HAD NOTHING BUT PROBLEMS SINCE I'VE HAD THE SPRINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029625	CONCEPTUS INC	4/1/2013	4/9/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PROCEDURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS205
Lot #(E4): 12271872

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD THE ESSURE PROCEDURE SINCE 2005. I HAVE HAD SEVERAL ISSUES WITH THIS PROCEDURE: HEADACHES, NAUSEA, CRAMPING, HEAVY BLEEDING, CLOTTING, BLOODY STOOL, DEPRESSION, WEIGHT GAIN AND SEVERAL OTHER ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029634	CONCEPTUS	4/1/2013	4/9/2013

Event Information:

Event Date (B3): 4/20/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 835431

Single Use:
Implant Date (E6): 4/20/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GAINED (B)(4) WHICH I CAN'T LOSE. WENT TO DOCTOR IN (B)(6) 2012, FOR YEARLY AND TOLD HIM MY MOODS WERE OUT OF CONTROL. I FEARED FOR MY HUSBAND'S LIFE. HE DREW BLOOD AND GAVE ME A NUMBER TO A PSYCHOLOGIST ((B)(6) OUT OF POCKET) SO HE CAN TELL MY DOCTOR WHAT TO PRESCRIBE ME. I DIDN'T GO. I TOOK A HORMONE SUPPLEMENT INSTEAD. THE SUMMER OF 2012, I STARTED GETTING NUMBNESS UP AND DOWN MY ARMS AND LEGS WHICH GOT WORSE AS TIME WENT ON. MY CRAMPS (STABBING PAINS) GOT WORSE WITH MY PERIODS EACH MONTH AND I WAS HAVING THEM WHEN I DIDN'T HAVE MY PERIOD. I HAVE BLED FROM SEX AND FROM MY VAGINA FROM A BOWEL MOVEMENT. I STARTED GETTING INTENSE, STABBING PAINS ON MY LEFT LOWER PELVIC SIDE DURING SEX. I AM HAVING MIGRAINES AT LEAST 4 DAYS A WEEK, INTENSE BACK PAIN, NECK PAIN, AND SPINE PAIN. I AM TIRED ALL THE TIME. I HAVE NO ENERGY. I STARTED GETTING MUSCLE AND JOINT PAINS ABOUT 2 MONTHS AGO. MY VISION GETS BLURRY, I HAVE MOMENTS OF DEPRESSION, NAUSEA, HEARTBURN/CHEST PAINS, INSOMNIA, VERY WATERY DISCHARGE, FOUL ODOR, EXTREMELY MOODY, BRAIN FOG, NIGHT SWEATS AND HOT FLASHES. WHEN I HAVE BEEN WORKING FOR A FEW HOURS MY BODY GETS STIFF AND HURTS AND I CAN'T MOVE. I ALSO HAVE SPASMS ON MY RIGHT LOWER PELVIC SIDE DOWN THE LEG AND MY RIGHT PELVIC BONE HURTS ON AND OFF. I USED TO BE AN ACTIVE PERSON, FULL OF LIFE AND LATELY I HAVE NO LIFE. FIRST REALIZED THIS WAS ALL ESSURE RELATED WHEN I WAS BEDRIDDEN WITH INTENSE STABBING PAIN (PELVIC AREA) IN (B)(6) 2013, FOR NO REASON. FOUND ESSURE PROBLEM PAGE ON (B)(4) AND SAW THAT THERE WERE OVER 1300 (AT THAT TIME) WITH THE SAME SYMPTOMS AS ME. NOT A COINCIDENCE. I AM HAVING A HYSTERECTOMY ON (B)(6) 2013, TO GET THESE FOREIGN BODIES REMOVED FROM MY BODY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029576	CONCEPTUS INC.	4/2/2013	4/4/2013

Event Information:

Event Date (B3): 2/1/2009 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INTRAUTERINE DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT WAS IMPLANTED WITH THE ESSURE INTRAUTERINE DEVICE MANUFACTURED BY CONCEPTUS INC. IN (B)(6) 2009. THE FIRST 2 YEARS WERE FINE. SUDDENLY SHE STARTED HAVING HEAVY PERIODS, HEAVY CLOTS, PAIN, SPOTTING BETWEEN PERIODS, BACK PAIN, WEIGHT GAIN (APPROXIMATELY 20 POUNDS EVERY MONTH), BAD HEADACHE, CRAMPS, BLOATING, HOT FLASHES, BLURRED VISION, PELVIC PAIN AND PRESSURE AND ABDOMINAL TENDERNESS. SHE BELIEVES HER IMMUNE SYSTEM HAS WEAKENED DUE TO THE FACT THAT SHE'S NOW FREQUENTLY HAVING THE COMMON COLD. DURING THE LAST 8 MONTHS ALL THE ABOVE-MENTIONED SYMPTOMS GOT WORSE SHE CONSULTED HER GYNECOLOGIST, WHO PRESCRIBED MEDICATIONS TIME AND AGAIN. BUT NO RELIEF WAS DERIVED. FINALLY AFTER UNDERGOING A SONOGRAM, SHE WAS TOLD THAT HER UTERUS, CERVIX AND FALLOPIAN TUBES WERE ALL SCARRED. SHE WAS ADVISED TO UNDERGO A HYSTERECTOMY. SHE HAS SCHEDULED THIS FOR NEXT WEEK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029577	CONCEPTUS INC.	4/2/2013	4/4/2013

Event Information:

Event Date (B3): 12/5/2007 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INTRAUTERINE DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/5/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE WAS IMPLANTED ON 2 SEPARATE DATES. (RIGHT SIDE ON (B)(6) 2007 AND THE LEFT SIDE ON (B)(6) 2008). HER FIRST COMPLAINT IS THE DIFFICULT IMPLANTATION PROCEDURE SHE HAD TO ENDURE. THE FIRST X-RAY IMAGES SHOWED THAT ONLY 1 OF HER FALLOPIAN TUBES WAS BLOCKED. ON (B)(6) 2008, THE X-RAY IMAGES SHOWED THAT BOTH FALLOPIAN TUBES WERE THEN BLOCKED. SECONDLY, SHE HAS HAD A MYRIAD OF PROBLEMS SINCE THE IMPLANTATION NAMELY, HEAVY BLEEDING, CRAMPING, SHARP STABBING PAIN, BACK PAIN, JOINT PAIN, FATIGUE, DIZZINESS, WEIGHT GAIN, SWELLING OF FEET AND LEGS, IRREGULAR HEAVY PERIODS, VITAMIN D DEFICIENCY, FORGETFULNESS, CONSTANT SPOTTING, DISCHARGE, BLADDER ISSUES AND HEAVY BLOOD CLOTS. SHE WAS EVENTUALLY DIAGNOSED WITH AN AUTOIMMUNE DISORDER (PSORIASIS). SHE'S PRESENTLY SERIOUSLY CONSIDERING EXPLANTATION. HER MESSAGE TO CONCEPTUS INC. SHE'S DISAPPOINTED THAT CONSUMERS WERE NOT INFORMED THAT THEIR RIGHTS TO SUE THE MANUFACTURER HAD BEEN WAIVED. SHE'S DISAPPOINTED AT THE WAY THE OPERATION WAS PERFORMED. SHE'S DISAPPOINTED AT ALL THE DIFFICULTIES SHE'LL HAVE TO GO THROUGH JUST TO HAVE THE DEVICE EXPLANTED. SHE THEREFORE, WANTS TO BE COMPENSATED FOR THE EXPENSES SHE HAS AND WOULD INCUR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029616	CONCEPTUS	4/2/2013	4/9/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): NONE
Model # (E4): (REF)ESS305; (REF) ESS305
Catalog # (E4):
Lot #(E4): (LEFT ONLY) 627752; (LEFT ONLY) 627752

Single Use:
Implant Date (E6): 1/14/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED AT (B)(6). BLED FOR 6 MONTHS STRAIGHT. JOINT PAIN, MUSCLE PAIN, SPASMS. "HORRIBLE" PERIODS <1 HR BEFORE NEEDING TO CHANGE A PAD. (PELVIC, PRESSURE BACK). BLOOD CLOTS, MEMORY CHANGE - LOSS OF MEMORY. BLOATING, WEIGHT GAIN >80LBS, DIZZINESS, LIGHTHEADEDNESS, "ELECTRIC SHOCK" - ARMS, HANDS, HEAD. NUMBNESS, INTERVAL OF PERIODS SHORTENING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029580	CONCEPTUS, INC.	4/3/2013	4/5/2013

Event Information:

Event Date (B3): 8/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2007
Explant Date (E7): 4/28/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ADVERSE REACTIONS TO ESSURE PERMANENT BIRTH CONTROL SYSTEM. PT STATED SHE HAS BEEN IN AND OUT OF THE HOSPITAL SINCE IMPLANTATION IN 2007, AND HAS EXPERIENCED MULTIPLE SYSTEMS INCLUDING SWELLING, MIGRAINES, BACK PAIN, PULMONARY EMBOLISM, IRREGULAR PERIODS, BLEEDING, CRAMPING, DIAGNOSED WITH FIBROMYALGIA, PAINFUL INTERCOURSE, TINGLING SENSATION ON THE RIGHT SIDE OF HER BODY AND WEIGHT GAIN OF (B)(6). SHE STATED SHE HAS BEEN PUT ON PROZAC AND WAS DIAGNOSED WITH GERD. SHE STATED THE DEVICE WAS BREAKING DOWN INSIDE HER, AND DURING A DNC A PIECE OF THE COIL WAS PULLED OUT. THE PT STATED SHE IS IN EXTREME PAIN AND IS SCHEDULED TO HAVE A HYSTERECTOMY (B)(6) 2013 FOR DEVICE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029594	CONCEPTUS, INC.	4/3/2013	4/8/2013

Event Information:

Event Date (B3): 1/4/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/4/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ADVERSE REACTIONS TO ESSURE PERMANENT BIRTH CONTROL SYSTEM. SHE STATED SHORTLY AFTER IMPLANTATION IN 2008, SHE BEGAN TO HAVE HEART PALPITATIONS. THE PT SAID IN 2010, SHE BEGAN TO EXPERIENCE PAIN IN HER STOMACH, BACK PAIN, CONFUSION, FREQUENT PERIODS (EVERY TWO WEEKS), HIP AND JOINT PAIN, AND PAIN WHEN WALKING. THE PT DESCRIBED THE PAIN TO BE SO INTENSE IT FEELS LIKE LABOR CONTRACTIONS. SHE STATED IT'S DIFFICULT TO PERFORM HER JOB. SHE IS EXTREMELY UNHAPPY WITH THE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029595	CONCEPTUS, INC.	4/3/2013	4/8/2013

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ADVERSE REACTIONS TO ESSURE PERMANENT BIRTH CONTROL SYSTEM. SHE STATED SINCE THE DEVICE WAS IMPLANTED IN 2010, SHE HAS HAD EXTREME CHANGES IN HER PERIOD, LATE PERIODS, VERY HEAVY BLEEDING, SOMETIMES SHE WILL BLEED FOR A MONTH STRAIGHT. SHE ALSO STATED SHE EXPERIENCES SHARP STABBING PAIN IN HER RIGHT ABDOMEN THAT AFFECTS HER BREATHING. SHE SAID SHE HAS SEVERE MOOD SWINGS, EXTREME PAIN, BACK PAIN, HIP PAIN, WEIGHT GAIN OF 80 POUNDS ALL IN THE ABDOMINAL AREA, DEPRESSION, ANXIETY, HOT FLASHES AND HAS BEEN PUT ON ANTI-DEPRESSANT AND ANXIETY MEDICATIONS. SHE IS VERY UPSET AND SAYS SHE DOES NOT WANT A HYSTERECTOMY FOR REMOVAL AT SUCH A YOUNG AGE. SHE IS EXTREMELY UNHAPPY WITH THE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029596	CONCEPTUS, INC.	4/4/2013	4/8/2013

Event Information:

Event Date (B3): 4/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/20/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ADVERSE REACTIONS FROM ESSURE PERMANENT BIRTH CONTROL SYSTEM. PT STATED A FEW MONTHS AFTER IMPLANTATION, SHE GAINED (B)(6) POUNDS. SHE STATED IN (B)(6) 2012, SHE STARTED HAVING SEVERE MOOD SWINGS AND WAS RECOMMENDED BY HER DOCTOR TO A PSYCHOLOGIST. SHE SAID LAST SUMMER SHE BEGAN TO EXPERIENCE TINGLING IN HER ARMS AND LEGS, MUSCLE AND JOINT PAIN, MIGRAINES (4 DAYS A WEEK). THE PT SAID IN (B)(6) 2013, SHE BEGAN TO HAVE EXTREME PELVIC PAIN ON HER LEFT SIDE, FATIGUE, HOT FLASHES, NIGHT SWEATS, STOMACH BLOATING TO THE POINT WHERE SHE LOOKED PREGNANT, SIDE PAIN SPASMS, CHEST PAIN, DEPRESSION, CONFUSION SPELLS, NECK AND SPINE PAIN, AND CONSTIPATION. SHE SAID HER PERIODS BECAME CLOTTY WITH INTENSE PAIN. THE PT SAID SHE IS SCHEDULED TO HAVE A HYSTERECTOMY (B)(6) 2013 FOR REMOVAL OF THE DEVICE. SHE ALSO STATED SHE HAS PAINFUL INTERCOURSE AND HER VAGINA FEELS DRY AND AT TIMES ITCHY. THE PT IS EXTREMELY UNSET AND UNHAPPY WITH THE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029597	CONCEPTUS, INC.	4/4/2013	4/8/2013

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/1/2008
Explant Date (E7): 11/1/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ADVERSE REACTIONS TO THE ESSURE PERMANENT BIRTH CONTROL SYSTEM. SHE STATED THAT SOON AFTER IMPLANTATION, SHE BEGAN TO HAVE IRREGULAR PERIODS WHERE THEY WOULD STOP ALL TOGETHER, OR SHE WOULD BLEED CONSTANTLY. WITHIN A YEAR OF IMPLANTATION, THE PT EXPERIENCED EXTREME PAIN, SHE DEVELOPED THYROID DISEASE, AUTOIMMUNE DISEASE, CONNECTIVE TISSUE DISEASE, CHRONIC INFLAMMATORY DISEASE AND FIBROMYALGIA. SHE SAID SHE SUFFERED FROM SEVERE MIGRAINES, CONSTANTLY FEELING SICK, RASHES, ACHES AND PAINS. THE PT SAID IN (B)(6) 2012, SHE HAD A HYSTERECTOMY FOR DEVICE REMOVAL, AND ALL HER SYMPTOMS HAVE DISAPPEARED. SHE FEELS COMPLETELY BETTER AND IS OFF MOST MEDICATIONS SHE WAS PUT ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029618	CONCEPTUS, INC	4/4/2013	4/9/2013

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ADVERSE REACTIONS TO ESSURE PERMANENT BIRTH CONTROL SYSTEM. PT SAID IMMEDIATELY AFTER IMPLANTATION, SHE HAD INTENSE, SEVERE PELVIC PAIN. SHE SAID SHE'S EXPERIENCED REPEATED PELVIC INFECTIONS, REPEATED UTIS, WEIGHT GAIN OF (B)(6) WITH SEVERE BLOATING OF HER WHOLE BODY. SHE SAID HER STOMACH IS HARD AND THAT SHE LOOKS PREGNANT. SHE ALSO SAID SHE EXPERIENCES JOINT PAIN, HIP PAIN, TROUBLE WALKING, RASHES, ALLERGY PROBLEMS, HAIR LOSS, A BURNING SMELL IN HER NOSE, REPEATED YEAST INFECTIONS, SWELLING IN HANDS AND FEET, AND A FOUL DISCHARGE ALL THE TIME. PT IS EXTREMELY UPSET AND UNHAPPY WITH DEVICE AND IS LOOKING TO HAVE IT REMOVED SOON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029619	CONCEPTUS, INC	4/4/2013	4/9/2013

Event Information:

Event Date (B3): 3/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4): 922603
Lot #(E4): 922603

Single Use:
Implant Date (E6): 3/22/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ADVERSE REACTIONS TO ESSURE PERMANENT BIRTH CONTROL SYSTEM. PT STATED EXACTLY ONE WEEK AFTER IMPLANTATION, SHE EXPERIENCED A SEVERE HEADACHE THAT HAS NEVER GONE AWAY. SHE SAID SHE EXPERIENCES DIZZINESS, FEELS LIGHT-HEADED, HAS VISION IMPAIRMENT, SHARP PAINS WHERE DEVICE IS IMPLANTED, HEART PALPITATIONS, CONFUSION AND DISORIENTATION. PT SAID HER PERIODS ARE NOW TERRIBLE WITH EXTREMELY HEAVY BLEEDING AND CLOTTING. SHE STATED SHE HAS NAUSEA, NO ENERGY, CONSTANT SEVERE BLOATING, SHOOTING PAINS DOWN HER LEGS, HOT FLASHES, HEAVY DISCHARGE, KIDNEY AND BLADDER INFECTIONS, AND WEAKNESS. PT IS VERY UNHAPPY WITH DEVICE AND IS LOOKING INTO HAVING A HYSTERECTOMY FOR REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029685	CONCEPTUS	4/8/2013	4/11/2013

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER STATES HAVING ESSURE PLACED IN 2006 AFTER HAVING LAST CHILD. CALLER REPORTS THAT HER DOCTOR INSISTED ON ESSURE AS OPPOSED TO TUBAL LIGATION. AFTER INSERTION OF DEVICE CALLER REPORTS EXPERIENCING A RASH ALL OVER HER BODY FROM NICKEL, JOINT PAIN, FATIGUE, NAUSEA, DIZZINESS, HIP/LOWER BACK/PELVIC PAIN, PERFORATION OF FALLOPIAN TUBES, AND SCAR TISSUE. CALLER STATES IMMEDIATELY POST INSERTION SHE EXPERIENCED HEMORRHAGING FOR 3 MONTHS AND HAD TO GET AN ABLATION/CAUTERIZATION. CALLER STATES THAT SHE IS NOW FORCED TO GET A HYSTERECTOMY IN ORDER TO REMOVE THE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029688	CONCEPTUS, INC.	4/8/2013	4/11/2013

Event Information:

Event Date (B3): 2/24/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/24/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ADVERSE REACTIONS TO ESSURE PERMANENT BIRTH CONTROL SYSTEM. PT STATED SOON AFTER IMPLANTATION, SHE HAD A "WEIRD", CONSTANT HEADACHE THAT SHE WAS ABLE TO TREAT WITH MEDICATION. PT SAID HER PERIODS GOT VERY BAD AND THAT SHE FEELS SICK WITH FLU-LIKE SYMPTOMS OF VOMITING, FEVER AND WEAKNESS. SHE SAID THE BLEEDING IS VERY HEAVY WITH HEAVY CLOTTING AND PELVIC PAIN. PT STATED ABOUT A YEAR AND A HALF AFTER IMPLANTATION, SHE STARTED GETTING YEAST INFECTIONS EVERY MONTH WITH SEVERE RASHES AND PELVIC PAIN. SHE SAID SHE EXPERIENCES CONSTANT HEADACHES NOW THAT WILL NOT GO AWAY, CAUSING HER TROUBLE FOCUSING AND STAYING ON TASK. SHE SAID SHE HAS NAUSEA, PROBLEMS EATING, VOMITING AFTER EATING, ALWAYS FEELS TIRED, DIZZINESS, BLOATING, HEARTBURN, GAS AND CHEST PAIN. PT STATED SHE HAS A PACEMAKER IMPLANTED, AND THE HEART PALPITATIONS FROM THE ESSURE ARE AFFECTING HER PACEMAKER AND CAUSING IT TO WORK HARDER THAN IT SHOULD. ON (B)(6) 2013, SHE SAID SHE HAD AN ULTRASOUND WHERE A FLUID FILLED MASS WAS DETECTED. SHE SAYS SHE GETS SHARP PAINS STARTING IN HER BACK, RUNNING DOWN HER LEGS, AND THROUGHOUT HER WHOLE BODY. SHE IS EXTREMELY UNHAPPY WITH THE DEVICE, BUT IS UNSURE IF SHE CAN HAVE IT REMOVED. SHE STATED SHE HAS CONTACTED AN ATTORNEY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029705	CONCEPTUS, INC	4/10/2013	4/12/2013

Event Information:

Event Date (B3): 3/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): A64637

Single Use:
Implant Date (E6): 3/28/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ADVERSE REACTIONS TO ESSURE PERMANENT BIRTH CONTROL SYSTEM. SHE SAID IMMEDIATELY AFTER IMPLANTATION PROCEDURE, SHE FELT SORE, WHICH SHE THOUGHT WAS NORMAL. HOWEVER, SHE STATED 5 DAYS AFTER IMPLANTATION, SHE BEGAN TO FEEL NAUSEOUS WHEN EATING, HAD EXTREME LOWER ABDOMINAL PAIN, HEAVY BLEEDING, DISCOMFORT AND A BURNING/TINGLING FEELING IN THE LEFT SIDE OF HER ABDOMEN SPREADING TO THE RIGHT SIDE. PT SAID SHE HAS ABDOMINAL SWELLING, IS IN CONSTANT PAIN, AND THE PRESCRIBED PAIN MEDICATIONS ARE NOT HELPING. SHE SAID SHE IS SCHEDULED TO HAVE A HYSTERECTOMY (B)(6) 2013 FOR DEVICE REMOVAL. SHE SAID SHE HAD TESTS DONE THAT RULED OUT ANY GI PROBLEMS AS THE CAUSE FOR HER PAIN. SHE ALSO MENTIONED A CT SCAN FOUND A CYST ON HER OVARY, BUT THAT TOO WAS RULED OUT AS A CAUSE FOR HER PAIN AND SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029706	CONEPTUS, INC	4/10/2013	4/12/2013

Event Information:

Event Date (B3): 9/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): A20064

Single Use:
Implant Date (E6): 9/12/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT STATED SHE ORIGINALLY HAD AN IUD IMPLANTED AND FOUND THAT IT WAS VERY PAINFUL EACH TIME SHE HAD A NEW IUD IMPLANTED. SHE SAID THAT HER DOCTOR SUGGESTED SHE HAVE AN ESSURE IMPLANTED THE NEXT TIME HER IUD EXPIRED BECAUSE THE PROCEDURE WAS VIRTUALLY PAIN FREE AND SHE COULD BE IN AND OUT OF THE SURGERY IN ABOUT THE SAME TIME AS A PAP SMEAR. SHE HAD THE ESSURE IMPLANTED ON (B)(6) 2012. SHE STATED THAT NOT ONLY DID SHE SUFFER A TREMENDOUS AMOUNT OF PAIN SHE ALSO WAS IN SURGERY OVER AN HR. DURING THE SURGERY THE 1ST COIL ON THE RIGHT SIDE HAD BEEN IMPLANTED PERFECTLY BUT HER UTERUS BEGAN TO SPASM. SHE ALLEGES THAT THE DOCTOR DID NOT WAIT FOR THE SPASM TO STOP AND ALTHOUGH HER LEFT FALLOPIAN TUBE WAS CLOSED OFF HE PROCEEDED TO PUSH THE COIL IN. THE 1ST COIL BENT. THE 2ND COIL UNRAVELED. THE 3RD COIL WAS IMPLANTED BUT BLOOD HAD SPATTERED ON THE CAMERA AND THE DOCTOR WAS UNABLE TO VERIFY IF IT WAS IMPLANTED CORRECTLY. ON THE SECOND DAY, AFTER IMPLANTATION, THE PT WENT INTO THE RESTROOM AND BEGAN TO HAVE HEAVY BLEEDING AND PAIN IN HER PELVIC REGION. THIS CONTINUED FOR 2 WEEKS AND SLOWED DOWN. SHE STATED THAT WAS WHEN THE SEVERE HEADACHES BEGAN. SHE STATED THAT SHE WENT IN FOR BLOOD WORK AND FOUND THAT HER CREATININE LEVELS DECREASED TREMENDOUSLY. SHE EVENTUALLY HAD SEVERAL IRON INFUSIONS. SHE CONTINUES TO HAVE OVARIAN PAIN, HEADACHES AND LOW CREATININE LEVELS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029707	CONCEPTUS, INC	4/11/2013	4/16/2013

Event Information:

Event Date (B3): 8/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2010
Explant Date (E7): 8/1/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT STATED SHE HAD THE ESSURE IMPLANTED ON (B)(6) 2010 SHORTLY AFTER GIVING BIRTH TO HER DAUGHTER. DURING THE SURGERY, THE 1ST COIL ON THE RIGHT SIDE HAD BEEN IMPLANTED WITHOUT ANY PROBLEM BUT HER OVARIES BEGAN TO SPASM. SHE ALLEGED THAT THE DOCTOR WAS UNABLE TO INSERT THE COIL INTO THE LEFT FALLOPIAN TUBE. SHE STATED THAT SHE SUFFERED TREMENDOUS AMOUNT OF PAIN AND WAS ONLY GIVEN SOMETHING TO NUMB THE AREA. THE DOCTOR DECIDED TO STOP THE PROCEDURE AFTER AN HR. IMMEDIATELY AFTER THE SURGERY, SHE BEGAN TO HAVE PAINFUL, HEAVY BLEEDING. A WEEK LATER, SHE DECIDED TO HAVE A TUBAL LIGATION. THE LEFT FALLOPIAN TUBE WAS TIED OFF BUT THE RIGHT COIL REMAINED IMPLANTED. SHE CONTINUED TO HAVE PAIN AND SWELLING IN HER RIGHT PELVIC REGION. SHE ALSO HAD PAINFUL INTERCOURSE, BLEEDING AND DEPRESSION. SHE OPTED FOR A PARTIAL HYSTERECTOMY A YR LATER. SHE CONTINUES TO HAVE SEVERE HEADACHES, HOT FLASHES AND OTHER MENOPAUSAL SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029740	CONCEPTUS	4/15/2013	4/17/2013

Event Information:

Event Date (B3): 11/5/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER STATES SHORTLY AFTER GETTING ESSURE IMPLANTED IN (B)(6) 2007, SHE HAS BEEN EXPERIENCING A SERIES OF ISSUES. CALLER REPORTS HAVING AN ALLERGIC REACTION TO NICKEL IN THE DEVICE, SINUS HEADACHES, SKIN RASH, ACNE, DEBILITATING MENSTRUAL CRAMPS, BLOOD CLOTS THE SIZE OF A SILVER DOLLAR, WEIGHT GAIN, AND METAL ODOR. CALLER ALSO STATES POSSIBLE CORRELATION TO A FIBROID REMOVED IN HER RIGHT BREAST TWO YEARS AFTER ESSURE WAS IMPLANTED. CALLER IS NOW SCHEDULED FOR A HYSTERECTOMY IN (B)(6) TO REMOVE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029852	CONCEPTUS	4/16/2013	4/23/2013

Event Information:

Event Date (B3): 2/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL PROCEDURE COMPLETED IN (B)(6) 2008. FROM THAT POINT ON, I HAVE HAD ISSUES WITH HEAVY BLEEDING AND PERIODS LASTING 7-14 DAYS. IN ADDITION, I HAD ABDOMINAL PAIN. IN (B)(6) 2013, I CONSULTED WITH AN OB/GYN THAT SENT ME FOR AN ULTRASOUND. THE ULTRASOUND SHOWED THAT MY LEFT ESSURE COIL IS EMBEDDED IN MY UTERUS. MY RIGHT COIL REMAINS IN MY FALLOPIAN TUBE. AS A RESULT, I HAVE LEARNED THAT ESSURE HAS NOT BEEN PROTECTING ME FROM PREGNANCY AS THE PRODUCT WAS DESIGNED TO DO AS MY TUBE WAS NOT BLOCKED AND EGGS ARE STILL BEING RELEASED. IN ADDITION, THE ONLY RESOLUTION TO THIS ISSUE OF HAVING THE COIL EMBEDDED IN MY UTERUS IS A HYSTERECTOMY IN WHICH MY OB/GYN WILL REMOVE MY TUBES AND MY UTERUS. I AM (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029776	CONCEPTUS	4/17/2013	4/19/2013

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER STATES SHE WAS IMPLANTED WITH ESSURE IN (B)(6) 2008. THE DEVICE FAILED WITHIN THE YEAR AND CALLER BECAME PREGNANT. AFTER FURTHER INVESTIGATION, IT WAS FOUND THAT ONE OF THE COILS FELL OUT OF POSITION AND WAS EMBEDDED IN THE CALLER'S ABDOMEN AND THE OTHER COIL CAUSED PERFORATION OF HER FALLOPIAN TUBE. THE DEVICE WAS LEFT IN PLACE AND SUBSEQUENTLY IT CAUSED AN IRREGULAR MENSTRUAL CYCLE, SEVERE NEUROPATHY IN THE FACE/ARM, SEVERE STOMACH ACHES, AUTOIMMUNE PSORIASIS ON HER NECK/SCALP, MIGRAINES, AND HODGKIN'S DISEASE. CALLER STATES IT WAS FOUND THAT SHE IS ALLERGIC TO NICKEL AND WAS FORCED TO HAVE A HYSTERECTOMY IN ORDER TO REMOVE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029906	CONCEPTUS	4/21/2013	4/29/2013

Event Information:

Event Date (B3): 3/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/1/2008
Explant Date (E7): 3/27/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2008. NOT LONG AFTER I DEVELOPED SEVERAL MEDICAL PROBLEMS THAT WENT UNDIAGNOSED FOR 2.5 YEARS. I BEGAN HAVING DAILY HEADACHES, NUMBNESS IN MY HANDS, FEET, LEGS, AND ABDOMEN. I WAS PUT THROUGH TEST AFTER TEST, AND SAW MULTIPLE SPECIALISTS BUT NO ONE COULD FIND ANYTHING WRONG. ALL BLOODWORK AND TEST WERE NORMAL. I BEGAN HAVING IRREGULAR AND EXTREMELY HEAVY MENSTRUAL CYCLES PASSING CLOTS THE SIZE OF QUARTERS. ON (B)(6) OF THIS YEAR, I WENT IN FOR SURGERY. AT (B)(6) I HAD A COMPLETE HYSTERECTOMY LEAVING ONLY ONE OVARY. MY RIGHT OVARY HAD TO BE REMOVED BECAUSE IT WAS FUSED TO MY COLON WITH SCAR TISSUE FOR THE ESSURE COILS. IT WAS ALSO FOUND THAT I HAD ADENOMYOSIS. AS I SIT HERE JUST 3.5 WEEKS SINCE SURGERY, ALL SYMPTOMS ARE GONE. I NO LONGER HAVE THE NUMBNESS, HEADACHES, PAINS, FOGGY FEELING, OR THE MANY OTHER ISSUES I WAS DEALING WITH ON A DAILY BASIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029914	CONCEPTUS INC.	4/22/2013	4/29/2013

Event Information:

Event Date (B3): 12/1/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): IL2843; ES6305
Catalog # (E4):
Lot #(E4): 628647; 625647

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PROCEDURE DONE IN DECEMBER OF 2007 HORRIBLE PAIN DURING OVULATION, MIGRAINES, 33 CONSISTENT DAYS OF BLEEDING AFTER 3 YEARS HAVING ESSURE. ENDOMETRIAL ABLATION DONE. DIDN'T WORK STILL. BLEEDING AND HORRIBLE PMS, WEIGHT GAIN, BLOATING, MIGRAINES BEFORE AND AFTER PERIODS EVERY MONTH, BACTERIAL INFECTIONS ALL THE TIME. YEAST INFECTIONS CONSTANTLY. CONSTANT THIGH/UPPER MUSCLE SPASMS. ENDOMETRIOSIS NOW FROM SCAR TISSUE. DOCTOR HAS ME TAKING 200 MILLIGRAMS OF ORAL FLAGYL AFTER EVERY PERIOD AND DIFLUCAN BEFORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029920	CONCEPTUS, INC	4/22/2013	4/29/2013

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6): 7/21/2012
Explant Date (E7): 12/20/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2012. I WENT BACK IN FOR THE CONFIRMATION SCAN -VERY UNCOMFORTABLE TEST- AND WAS TOLD THAT ONE SIDE LOOKED GREAT WHILE THE OTHER WAS IN THE CORRECT SPOT BUT HAD NOT CAUSED ENOUGH SCAR TISSUE TO FORM AT THAT POINT. IN (B)(6), I BEGAN HAVING SEVERE ABDOMINAL PAIN THAT MOVED EVEN LOWER IF I ATTEMPTED TO DO ANYTHING ACTIVE. I WENT AND HAD AN MRI AND THEY DISCOVERED THAT THE ESSURE HAD MOVED UP IN MY TUBE AND WAS PROTRUDING INTO MY UTERUS. I THEN SIGNED UP FOR A TUBAL LIGATION -LAPAROSCOPIC- INCLUDING THE ESSURE COIL REMOVAL ON THAT SIDE. ONCE THE DOCTOR GOT IN, HE DISCOVERED THAT THE ESSURE WAS IMBEDDED IN MY UTERINE WALL AND ACTUALLY HAD TO OPEN ME UP TO GET THE COIL REMOVED. I HAD A HORRENDOUS RECOVERY POST SURGERY, COULDN'T LIFT MY BREASTFEEDING (B)(6) OLD, AND HAD TO MISS MULTIPLE DAYS OF WORK. I ALSO HAD WORKED HARD TO MAKE SURE THAT DURING MY SECOND PREGNANCY, I WOULD NOT HAVE TO HAVE A C-SECTION UNLESS NECESSARY. I SUCCESSFULLY HAD THAT BABY VAGINALLY, ONLY TO BE CUT OPEN WITH MORE OF A RECOVERY DUE TO ESSURE LATER THE SAME YR. I LIVE IN FEAR KNOWING THAT THE OTHER COIL IS STILL IN PLACE IN MY RIGHT SIDE. WHAT IF IT DECIDES TO MOVE AND CAUSES ME FURTHER DAMAGE OR ANOTHER SURGERY. ESSURE BY CONCEPTUS INC. HAS ME VERY CONCERNED ABOUT THE FUTURE OF MY HEALTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029980		4/25/2013	5/2/2013

Event Information:

Event Date (B3): 3/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): IUD
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/15/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECENTLY HAD THE ESSURE BIRTH CONTROL PROCEDURE DONE AND I HAVE EXPERIENCED A LONG LIST OF COMPLICATIONS WHICH I FEEL ARE CONTRIBUTED TO THIS PRODUCT. I HAVE HAD CONTINUOUS BLEEDING SINCE HAVING THIS IUD. I STARTED EXPERIENCING EXTREME MIGRAINES THE WEEK AFTER HAVING THIS DONE AND THESE HAVE NOT SUBSIDED. I NEVER HAD MIGRAINES BEFORE. I ALSO AM EXTREMELY FATIGUED TO THE POINT WHERE CARING FOR MY NEWBORN IS ALMOST IMPOSSIBLE. THANKFULLY MY HUSBAND IS A GREAT SUPPORT SYSTEM FOR ME AND OUR NEWBORN. MY IRON IS CONSISTENTLY LOW AT EVERY CHECK UP AFTER THE PROCEDURE AND REMAINS THAT WAY EVEN AFTER BEING PRESCRIBED IRON SUPPLEMENTS. I RECENTLY LOOKED ONLINE FOR SIMILAR INCIDENTS WITH OTHER INDIVIDUALS AND I WAS FLOORED AT ALL THE COMPLAINTS I SAW ABOUT THIS PRODUCT. BEFORE I HAD THIS PROCEDURE DONE I DID A LITTLE RESEARCH ON THE PRODUCT AND EVEN VISITED THE PRODUCT'S WEBSITE TO PUT MY MIND AT EASE. I NEVER WOULD HAVE THOUGHT THAT A PRODUCT WHICH BOASTED RAVE RESULTS WOULD BE ACCOMPANIED BY SO MANY COMPLICATIONS. THIS HAS GRAVELY AFFECTED MY RELATIONSHIP WITH MY SIGNIFICANT OTHER DUE TO THE LACK OF INTIMACY BECAUSE OF THE CONTINUOUS BLOOD FLOW. PLEASE INVESTIGATE THIS PRODUCT BECAUSE I AM 100% SURE MY COMPLAINT WILL NOT BE THE LAST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029974	CONCEPTUS	4/26/2013	5/2/2013

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT WAS IMPLANTED WITH ESSURE IN (B)(6) 2011. ONE MONTH POST-OP, SHE BEGAN EXPERIENCING DISCOMFORT, BACKACHE, STABBING PAIN THAT RADIATES TO THE LEGS AND TO THE LEFT SIDE OF THE BODY. SHE HAD SURGERY TO EXPLANT THE DEVICE IN (B)(6) 2011. HER DOCTOR SAYS THE DEVICE HAD BEEN REMOVED, BUT A RECENT ULTRASOUND INDICATES THE DEVICE IS STILL IN PLACE. PATIENT CLAIMS THE SURGEON HAD USED A WRONG PROCEDURE PER MFR. PATIENT CLAIMS SHE WAS NOT INFORMED OF THESE ADVERSE EFFECTS PRIOR TO GETTING THE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030041	CONCEPTUS	4/30/2013	5/8/2013

Event Information:

Event Date (B3): 3/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/25/2012
Explant Date (E7): 10/30/2012
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE DEVICE IMPLANTED IN (B)(6) 2012. EVERYTHING WENT WELL. NO PROBLEMS INSERTING, HARDLY ANY PAIN, ETC. A FEW WEEKS LATER STARTED TO FEEL KIND OF DIZZY HERE AND THERE. A LITTLE OVER A MONTH AFTER HAVING THEM, I DROVE MY (B)(6) TO SCHOOL. CAME BACK HOME, JUST HAPPENED TO LAY MY (B)(6) DOWN IN HIS BED; THANKFULLY! WALKED IN MY ROOM INTO THE BATHROOM TO TAKE A SHOWER AND NEXT THING I KNEW I WAS WAKING UP ALMOST SEIZURE-LIKE ON MY BATHROOM FLOOR. I'VE NEVER HAD ANY MEDICAL PROBLEMS MY ENTIRE LIFE! HARDLY EVER EVEN A COLD. WENT TO THE HOSPITAL ALL BLOODWORK, ETC. CAME BACK NORMAL. WAS SENT HOME WITH NO ANSWERS. ABOUT A MONTH LATER, HAD ANOTHER EPISODE AT THE GROCERY STORE. PASSED OUT COLD AT THE GROCERY STORE WITH MY (B)(6) IN THE CART. WOKE UP TO PEOPLE STANDING AROUND ME. BACK TO THE HOSPITAL AND AGAIN ALL TESTS NORMAL. SENT HOME AGAIN CLUELESS, BUT THANKFUL MY CHILD WAS OK AND DIDN'T FALL FROM THE CART OR GET KIDNAPPED! DIZZINESS CONTINUED TO GET WORSE AND WORSE. IT GOT TO THE POINT TO WHERE I COULDN'T EVEN LEAVE MY HOME ALONE. I CAN'T DRIVE A CAR. I CAN'T WORK. I CAN'T GO TO ANY OF MY KIDS' EVENTS AT SCHOOL. BASICALLY RUINED MY ENTIRE LIFE. I HAD THE ESSURE REMOVED AT (B)(6). WAS SO HAPPY THEY WERE FINALLY GONE! BUT COME TO REALIZE MY DIZZINESS WAS NOT GONE. I'VE HAD EVERYTHING TESTED - HORMONES, THYROID ETC. NOW I'M ABOUT TO GO BACK FOR ANOTHER SURGERY TO GET A COMPLETE HYSTERECTOMY AT (B)(6) THANKS TO MYSELF NOT RESEARCHING ENOUGH TO THE POISON I WAS PUTTING IN MY BODY BY GETTING THE ESSURE. I DON'T KNOW HOW THIS PRODUCT EVER GOT ANY KIND OF APPROVAL. MY DEVICES WERE IN THE EXACT PLACE THEY SHOULD HAVE BEEN. THEY WERE NOT PUNCTURING MY TUBES OR ANYTHING YET THE PRODUCT CAUSES SCAR TISSUE TO GROW AND HAS CAUSED IT TO SPREAD THROUGH MY BODY AND GROW IN RANDOM PLACES. THIS NEEDS TO BE TAKEN OFF THE MARKET PERMANENTLY! IT'S

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NOT RIGHT TO MARKET AND APPROVE A PRODUCT THAT IS LEGALLY KILLING PEOPLE SLOWLY! I'M HOPING FOR A LAWSUIT TO GET MY (B)(6) IN MEDICAL BILLS AND THE YEARS OF MY LIFE THAT I'VE LOST AND NOT BEING ABLE TO BE THERE FOR MY KIDS, NOR KNOW IF I WILL EVER BE THE SAME AGAIN. IT'S REALLY SAD AND I CAN'T BELIEVE WE LIVE IN SUCH A WORLD AS TO WHERE PEOPLE ALLOW THIS TO HAPPEN! ESSURE REMOVAL (B)(6) 2012, CURRENTLY AWAITING DATE FOR COMPLETE HYSTERECTOMY BECAUSE MY UTERUS AND CERVIX ARE COVERED IN SCAR TISSUE AND NOT FUNCTIONING PROPERLY. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5029987	CONCEPTUS, INC	5/1/2013	5/3/2013

Event Information:

Event Date (B3): 10/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER STATED SHE HAD THE ESSURE (BIRTH CONTROL DEVICE) IMPLANTED ON (B)(6) 2012 AND HAD IT EXPLANTED TWO WEEKS LATER ((B)(6) 2012) DUE TO PAIN, BLOATING, SWELLING IN ABDOMEN, FEVER, ELEVATED WHITE BLOOD COUNT, AND INFECTION. IN ORDER TO TAKE THE COIL OF THREADS OUT, HER FALLOPIAN TUBE WAS ALSO TAKEN OUT. THIS RESULTED IN HAVING HER MENSTRUAL PERIOD EVERY TWO WEEKS. TISSUE WAS FORMED AROUND THE COIL WHICH WAS VERY PAINFUL. DURING THIS PERIOD BEFORE THE DEVICE WAS EXPLANTED, SHE WAS IN AND OUT OF THE DOCTOR'S OFFICE. ALSO VISITED THE ER WHERE SHE WAS MEDICATED TO RELIEVE PAIN AND WAS SENT HOME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030021	CONCEPTUS	5/1/2013	5/6/2013

Event Information:

Event Date (B3): 4/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/26/2012
Explant Date (E7): 10/29/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REC'D THE DEVICE IN (B)(6) 2012 WHEN SHE IMMEDIATELY BEGAN EXPERIENCING THE FOLLOWING ADVERSE REACTIONS: CRAMPS, HEADACHE, DIARRHEA, DIZZINESS, NUMBNESS, BLURRED VISION, FATIGUE, FEVER, CHILLS, BODY ACHES, FOOD SENSITIVITY, LOSS OF APPETITE, TENDER ABDOMEN, SHARP PAIN, BACK ACHE, CHEST PAIN FEELING LIKE HEART ATTACK, NICKLE TASTE IN THE MOUTH, HAIR LOSS, WEIGHT GAIN, PUNCTURED TUBES, PAINFUL SEX, CAN'T DRINK FLUIDS AT NIGHT. PT ENDED UP HAVING TOTAL HYSTERECTOMY AND SHE IS STILL SUFFERING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030035		5/1/2013	5/8/2013

Event Information:

Event Date (B3): 12/18/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/18/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN IN A LOT OF PAIN AND BEEN SICK AND DIZZY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030049	CONCEPTUS	5/1/2013	5/8/2013

Event Information:

Event Date (B3): 6/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 857592

Single Use:
Implant Date (E6): 7/21/2011
Explant Date (E7): 6/4/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2012, SHE HAD TO UNDERGO A HYSTERECTOMY AFTER ELEVEN MONTHS OF SUFFERING FROM SIDE EFFECTS RELATED TO ESSURE IMPLANTATION. SHE DID NOT WANT THE ESSURE DUE TO NICKEL CONTENT AND SUSPECTED ALLERGY TO NICKEL BUT OBGYN PUSHED FOR IT SAYING, "THE LABEL FOR NICKEL ALLERGY TESTING HAD BEEN REMOVED." SHE SUFFERED NAUSEA, DIZZINESS, CRAMPS, SEVERE BLEEDING, NERVE PROBLEMS, HEART PALPITATIONS, FAINTING, SEVERE ANXIETY, MULTIPLE UTERINE INFECTIONS, AND MASSIVE JOINT/MUSCLE PAIN TO NAME A FEW, SOME STARTING AS LITTLE AS 7 DAYS AFTER IMPLANTATION. SHE WAS SEEN SEVERAL TIMES IN THE EMERGENCY ROOM DUE TO PAIN AND WEAKNESS AND HEART PALPITATIONS. SHE ULTIMATELY WAS SEEN IN EMERGENCY ROOM FOR POSSIBLE APPENDICITIS OR GALL BLADDER PROBLEMS. UPON ULTRASOUND IT WAS FOUND THAT ONE OF THE ESSURE IMPLANTS WAS IN THE UTERUS. BY HYSTERECTOMY DATE LESS THAN A MONTH LATER BOTH COILS WERE IN UTERUS. MOST SYMPTOMS RESOLVED UPON REMOVAL; STILL HAS SOME RESIDUAL ONES. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030043	CONCEPTUS	5/3/2013	5/8/2013

Event Information:

Event Date (B3): 9/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/9/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAS BEEN EXPERIENCING BACK PAIN, STOMACH PAIN, HEADACHES, DIZZINESS, HOT FLASHES, LIGHT-HEADEDNESS SINCE SHE GOT THE DEVICE. NO DOCTOR IS WILLING TO TAKE THE DEVICE OUT. SHE IS CRYING FOR HELP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030066	CONCEPTUS	5/3/2013	5/9/2013

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2010
Explant Date (E7): 3/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT WAS IMPLANTED WITH ESSURE IN (B)(6) 2010. SHE WAS HOSPITALIZED IN (B)(6) 2013, WITH THE FOLLOWING SYMPTOMS: BLOATING, STOMACH PAIN, HEART BURN, INDIGESTION, DIARRHEA. PT WAS DISCHARGED FROM THE HOSPITAL WITH A DIAGNOSIS OF STOMACH VIRUS. THE NEXT MORNING WHEN SHE LOOKS UP, SHE DISCOVERED THAT THE DEVICE HAD MIGRATED OUT OF HER BODY VIA HER VAGINA. SHE IMMEDIATELY CONTACTED HER DOCTOR WHO SCHEDULED HER FOR A TOTAL HYSTERECTOMY ON (B)(6) 2013. BECAUSE OF THE CHRONIC INFLAMMATION IN HER UTERUS, THE SURGEON EXCISED HER UTERUS, FALLOPIAN TUBES AND CERVIX. PT COMPLAINS SHE ALSO HAD A POST-OP INFECTION EVIDENCED BY PURULENT DISCHARGE AT THE INCISIONAL SITE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030082	CONCEPTUS	5/3/2013	5/10/2013

Event Information:

Event Date (B3): 3/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use:
Implant Date (E6): 3/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE AROUND (B)(6) 2009. SINCE THEN I HAVE BEEN ILL, EVERYDAY, ALONG WITH MANY EPISODES OF PAIN, CRAMPING, JOINT PAIN, RASHES, HAIR LOSS, INABILITY TO WEAR ALL JEWELRY (RASHES AND SWELLING). UNEXPLAINED FEVERS, AND BRAIN FOG TO NAME A FEW. I HAVE BEEN TO MY FAMILY DOCTOR MANY TIMES FOR THESE COMPLAINTS, AND EVEN BEEN SENT TO A RHEUMATOLOGIST WITH (B)(6) OF LABS TO CHECK FOR LUPUS AND THE SUCH. THESE TESTS FOUND NO LUPUS OR DISEASE. I HAVE BEEN IN TOUCH WITH A SOCIAL WEBSITE, WITH MANY OTHERS THAT HAVE HAD THE ESSURE LIKE ME, AND THEY ALL HAVE THE SAME SYMPTOMS. NONE OF THESE ISSUES DID I HAVE UNTIL THIS PROCEDURE. MY GYN PRETTY MUCH TALKED ME INTO THIS AND I WANTED A NORMAL TUBAL LIGATION. I FEEL THIS PRODUCT IS THE CAUSE OF MY ISSUES. I WISH I WOULD HAVE BEEN TOLD OF THE SIDE EFFECTS AND I KNOW I WOULD NOT HAVE HAD THIS DONE. DATES OF USE: (B)(6) 2009 - (B)(6) 2013. REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030089	CONCEPTUS	5/3/2013	5/10/2013

Event Information:

Event Date (B3): 2/25/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE COILS
Model # (E4): ESS305-R1
Catalog # (E4): ESS305-R1
Lot #(E4): 636097; 12397881

Single Use:
Implant Date (E6): 6/1/2010
Explant Date (E7): 2/25/2013
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM A MOTHER OF 3. MY LAST TWO PREGNANCIES WERE 2007 AND 2008. I DESIRED NO MORE CHILDREN. MY GYNO SUGGESTED THE IUD MIRENA. IT WAS UNSUCCESSFUL, SO THEY SUGGESTED ESSURE. I HAD THE COILS INSERTED IN 2010. FIRST 6 MONTHS WAS FINE. NORMAL PERIOD. EVEN LIGHT AT TIMES. BUT I STARTED TO FEEL LIKE I HAD THE FLU EVERYDAY AND I WAS BLEEDING THROUGH MY CLOTHES. CONSTANT HEADACHES. DEPRESSION INCREASED. WAS TOLD I HAD A HORMONE IMBALANCE. HAD AN ABLATION THE SUMMER OF 2011. ONE DAY SURGERY AT (B)(6) HOSPITAL. PERIODS WERE SOMEWHAT NORMAL FOR ABOUT 8 MONTHS. THEN THE SIDE EFFECTS MENTIONED PREVIOUSLY PROGRESSED. MY PERIODS WERE UNSTABLE AND HEAVY AND PUT ME IN THE BED. HOW CAN YOU BE A MOTHER, WIFE, EMPLOYEE WHEN YOU FEEL LIKE YOU ARE DYING?

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030094	CONCEPTUS	5/6/2013	5/13/2013

Event Information:

Event Date (B3): 2/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/22/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE DONE (B)(6) 2010 AND HAD SEVERE PERIODS AND PAIN AND BLEEDING AFTER THAT FOR SEVERAL MONTHS. ENDED UP HAVING TO HAVE A UTERINE ABLATION DONE IN (B)(6) 2010 TO HELP STOP PERIODS SINCE THEY BECAME EXTREMELY PAINFUL. AND I HAD SO MANY HORMONAL ISSUES FOLLOWING THIS PROCEDURE. HAD THE DYE TEST DONE AFTER 3 MONTHS WHICH SHOWED SOME LEAKING STILL SO I HAD THE TEST DONE AGAIN A MONTH LATER. THEN HAD SEVERAL ULTRASOUNDS SECONDARY TO SO MUCH PAIN AND BLEEDING FROM HAVING THE ESSURE PROCEDURE DONE. I ALSO HAVE HAD NUMEROUS APPOINTMENTS WITH OTHER DOCTORS SINE I HAD BACK PAIN AND LEG PAIN THAT NO ONE COULD FIGURE OUT. (B)(6) 2012 - (B)(6) 2013 WENT TO AN ORTHOPEDIC DOC AND A NEUROSURGEON. THEY BOTH SAID THE NERVE WAS NOT GETTING PINCHED IN MY BACK TO CAUSE THE LEG PAIN I WAS HAVING. HAD AN MRI AND X-RAY OF MY BACK. (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030099	CONCEPTUS, INC.	5/6/2013	5/13/2013

Event Information:

Event Date (B3): 5/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE METAL COIL
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 3/6/2013
Explant Date (E7): 5/3/2013
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING SCHEDULED SURGICAL PROCEDURE BLOOD NOTED TO PELVIC AREA, RIGHT SIDE. FOREIGN OBJECT NOTED PROTRUDING FROM RIGHT FALLOPIAN TUBE. GYN REQUESTED FOR INTRAOPERATIVE CONSULT. ERODED ESSURE TUBAL LIGATION DEVICE REMOVED. SPECIMEN SENT TO PATHOLOGY. REASON FOR USE: TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	COVIDIEN, FORMERLY VALLEYLAB, A DIVISION OF TYCO HEALTHCARE	5/6/2013	5/14/2013

Event Information:

Event Date (B3): 3/18/2013 **Report Date (B4): 5/6/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION **(**HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 678818

Single Use:
Implant Date (E6): 4/1/2011
Explant Date (E7): 3/18/2013
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

THE GRAY TRIGGER ON THE LIGASURE WAS STICKING DURING THE CASE. MINOR DELAY TO CASE RELATED TO OPENING ANOTHER DEVICE. NO INJURY TO THE PATIENT RELATED TO THE LIGASURE; PROCEDURE COMPLETED.
THE LAPAROCOPIC ASSITED VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY, CYSTOSCOPY WAS RELATED TO A PATENT RIGHT FALLOPIAN TUBE AFTER ESSURE DEVICE STERILIZATION APPROXIMATELY 4 YEARS AGO. THE ESSURE COIL WAS PROTURDING FROM AREA OF RIGHT CORNUA AND RUNNING INFERIORLY WITH A THIN LAYER OF UTERINE SEROSE OVERLYING.
==========
MANUFACTURER RESPONSE FOR LAPAROSCOPIC SEALING CUTTING DEVICE, NEW LIGASURE 5MM (PER SITE REPORTER).
==========
SEE LETTER SENT DATE (B)(4) 2013 FROM COVIDIEN.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
LAPAROCOPIC ASSITED VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY, CYSTOSCOPY; THIS WAS RELATED TO A PATENT RIGHT FALLOPIAN TUBE AFTER ESSURE DEVICE STERILIZATION APPROXIMATELY 4 YEARS AGO. COIL WAS PROTURDING FROM AREA OF RIGHT CORNUA AND RUNNING INFERIORLY WITH A THIN LAYER OF UTERINE SEROSE OVERLYING.

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DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.
DEVICE #2
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	5/6/2013	5/15/2013

Event Information:

Event Date (B3): 3/23/2013 **Report Date (B4): 5/6/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): E55305
Lot #(E4): 50694556

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM PHYSICIAN'S OPERATIVE NOTE: THE ESSURE DEVICE WAS PASSED INTO THE PATIENT'S RIGHT FALLOPIAN TUBE. I DID NOTE THAT ON INITIAL PASS, THE END OF THE ESSURE DEVICE CAUGHT THE CORNUAL ASPECT OF THE UTERUS AND DID NOT FEEL RIGHT AS A PASS. I PULLED IT BACK AND NOTED THAT THE END OF THE ESSURE DEVICE WAS VERY BENT. I WAS ABLE TO STRAIGHTEN IT AND REPLACE IT. HOWEVER, AS IT WAS DEPLOYED, IT DID NOT UNCOIL OFF THE DEVICE AND THEREFORE THE ENTIRE DEVICE WAS REMOVED AND A SECOND ESSURE COIL WAS PLACED WHICH WAS DONE WITHOUT DIFFICULTY. MINOR DELAY TO OPEN ANOTHER DEVICE. PROCEDURE COMPLETED WITHOUT HARM TO PATIENT.
IT IS UNCLEAR IF THE DEVICE DID NOT DEPLOY CORRECTLY DUE TO THE END BEING BENT DURING INSERTION AND THEN MANUALLY STRAIGHTENED.
==========
MANUFACTURER RESPONSE FOR STERILIZATION COIL, ESSURE (PER SITE REPORTER).
==========
NOT KNOWN AT THIS TIME.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
REMOVAL OF MARENA IUD, HYSTEROSCOPY, HYSTEROPIC TUBAL, ENDOMETRIAL ABLATION.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?

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NO.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00009	CONCEPTUS, INC.	5/9/2013	5/16/2013

Event Information:

Event Date (B3): 3/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 12/1/2012
Explant Date (E7): 3/22/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD THE ESSURE PROCEDURE IN (B)(6) 2012. DURING THE PROCEDURE, THE PHYSICIAN USED THREE ESSURE DEVICES TO ACHIEVE PLACEMENT. IN (B)(6) 2013, PHYSICIAN PERFORMED AN HSG REVIEW TO CONFIRM LOCATION OF THE DEVICES. HSG SHOWED CORRECT POSITION OF THE DEVICES IN THE RIGHT AND LEFT FALLOPIAN TUBE. PHYSICIAN ALSO LOCATED THE THIRD DEVICE IN PT'S ABDOMINAL AREA. ON (B)(6) 2013, THE PHYSICIAN REMOVED THE THIRD DEVICE FROM THE ABDOMINAL AREA. DURING THE PROCEDURE, THE PHYSICIAN ALSO REMOVED THE RIGHT FALLOPIAN TUBE AND RIGHT DEVICE DUE TO A PERFORATION. PHYSICIAN ALSO NOTED AT TIME OF REMOVAL, THE PT HAS A SMALL FIBROID NEAR THE AREA OF THE ESSURE DEVICE. PHYSICIAN STATES THE FIBROID MAY HAVE BEEN A CONTRIBUTING FACTOR CAUSING IRRITATION. AFTER SURGERY, PT'S PAIN HAS SUBSIDED AND IS BETTER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030184	CONCEPTUS, INC.	5/11/2013	5/21/2013

Event Information:

Event Date (B3): 3/11/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/11/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MEDWATCHER. (B)(4). THIS DEVICE WORKED GREAT FOR 2 YRS. NOW I HAVE SEVERE BLEEDING DURING CYCLE WITH HUGE CLOTS, SEVERE CONSTANT HEADACHES WITH BAD CRAMPING. ALWAYS HAVE RED BUMPS COME UP IN PELVIC AREA, INNER THIGHS AND UNDER THE ARMS. REASON FOR USE: DR RECOMMENDED IT FOR PERMANENT BIRTH CONTROL. SAID IT WAS FAST, EASY AND NO COMPLICATIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030216	CONCEPTUS	5/15/2013	5/22/2013

Event Information:

Event Date (B3): 4/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): CONCEPTUS; CONCEPTUS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 886673; 886673

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE MADE BY CONCEPTUS AND THEIR INFORMATIONAL PAMPHLET LEFT OUT IMPORTANT DETAILS ABOUT CONTAINING NICKEL AND SAID NO SIDE EFFECTS, WHICH WAS UNTRUE, I SUFFERED MANY SIDE EFFECTS AND ULTIMATELY HAD A HYSTERECTOMY. THE WHOLE REASON FOR GETTING ESSURE AS MY FORM OF BIRTH CONTROL WAS BECAUSE IT REQUIRED NO SURGERY OR DOWN TIME AND HAD NO SIDE EFFECTS, YET I SUFFERED A LONG LIST OF SIDE EFFECTS AFTER THE IMPLANT; SUCH AS PAINFUL SEX, SHARP PAINS, MIGRAINES, CONFUSION, MIND FOG, DIFFICULTY SEEING, EXTREME WEIGHT GAIN IN ONLY MY ABDOMEN, INFLAMMATION AND MANY MORE PROBLEMS AND HAD TO HAVE SURGERY IN THE END AND DOWN TIME ANYWAYS. I WANT OTHER LADIES TO BE WARNED PLEASE. THIS COMPANY IS WRONG ALSO BECAUSE THEY PUT PET FIBERS IN THE COILS TO PURPOSELY CAUSE INFLAMMATION IN ORDER FOR FALLOPIAN TUBES TO SCAR AROUND THE DEVICES (ESSURE) AND PET FIBERS ARE NOT MEANT FOR MEDICAL DEVICES OR INSIDE THE HUMAN BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030248	CONCEPTUS INC	5/16/2013	5/23/2013

Event Information:

Event Date (B3): 9/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): A15527

Single Use:
Implant Date (E6): 9/7/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED AND HAS HAD HEALTH PROBLEMS EVER SINCE. LIST OF SYMPTOMS: HEADACHES, BRAIN SHOCK, NAUSEA, JOINT PAIN, BACK PAIN, NERVE PAIN, SPINE/NECK PAIN, MUSCLE SPASMS, HOT FLASHES, NIGHT SWEATS, BLOOD CLOTS DURING PERIOD, LONGER PERIODS, PELVIC PAIN, LEG PAIN, HAND/FOOT NUMBNESS, EAR ACHES, TINGLY SENSATIONS, NICKEL TASTE, FATIGUE, CHEST PAIN, HEART PALPITATIONS, HEARTBURN. DATE OF USE: STILL HAVE IMPLANTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030254	CONCEPTUS INC/BAYER	5/16/2013	5/23/2013

Event Information:

Event Date (B3): 5/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 740647

Single Use:
Implant Date (E6): 9/17/2010
Explant Date (E7): 5/15/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2010, I HAD THE ESSURE PROCEDURE DONE AND THE HSG TEST 3 MONTHS LATER THAT CONFIRMED MY TUBES WERE BLOCKED. EVERYTHING SEEMED FINE AT FIRST, BUT THEN I NOTICED MY ENERGY WAS DECLINING AND MY PERIODS WERE BECOMING EXTREMELY HEAVY, PAINFUL, IRREGULAR, AND FULL OF CLOTS. I ALSO BEGAN GETTING FREQUENT MIGRAINES, DIZZY SPELLS, UTIS/OTHER VAGINAL INFECTIONS, KIDNEY INFECTION, MAJOR BLOATING IN MY STOMACH, SHARP STABBING PAINS BY MY OVARIES, FREQUENT/URGENCY TO URINATE, SWELLING IN HANDS AND FEET, MOOD SWINGS, AND JUST GENERALLY FELT AS IF MY HEALTH WAS GETTING SUCKED RIGHT OUT OF ME. I HAVE BEEN TO THREE DIFFERENT DOCTORS THAT RAN TEST AFTER TEST THAT CAME BACK NORMAL. I BELIEVE MY BODY HAS REJECTED THE COILS AND REACTED TO ITS FIBROTIC RESPONSE CAUSED BY THE PET FIBERS IN THE INNER LINING OF THE ESSURE COILS. MY DOCTOR NOW HAS DECIDED TO GIVE ME A HYSTERECTOMY ON (B)(6) TO REMOVE MY UTERUS AND THE TUBES WITH COILS TO AT LEAST RELIEVE MY HEAVY PAINFUL PERIODS. ESSURE HAS RUINED MY LIFE. PRIOR TO ESSURE I WAS A VIBRANT, ENERGETIC, HAPPY MOTHER TO 3 LITTLE BOYS. POST-ESSURE I BARELY HAVE THE ENERGY TO GET OUT OF BED IN THE MORNING. I HAVE ALSO COLLECTED ALL OF MY MEDICAL RECORDS AND LEARNED THAT THE DOCTOR HAD TROUBLES PLACING THE LEFT COIL DUE TO POOR VISUALIZATION. SHE HAD TO PULL IT OUT BECAUSE IT WASN'T PLACED IN FAR ENOUGH AND REPLACED IT WITH A DIFFERENT ESSURE COIL. I ALSO HAD ANOTHER HSG TEST IN (B)(6) 2013 TO CHECK PLACEMENT. THE ENDS OF THE COILS LOOK BROKEN AND SPLIT TO ME, AND THE RADIOLOGIST THAT READ THEM SEEMED VERY INEXPERIENCED READING ESSURE HSG RESULTS. HE THOUGHT I WAS THERE FOR MY 3 MONTH BLOCKAGE TEST. CONCEPTUS NEEDS TO STOP ADVERTISING ESSURE AS THIS PERFECT MIRACLE DEVICE BECAUSE IT IS FAR FROM IT. THEY JUST KEEP SAYING THAT ESSURE IS MADE FROM THE SAME TRUSTED MATERIAL AS HEART STENTS. IF I WOULD HAVE KNOWN THEY

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WERE MADE FROM STAINLESS STEEL, NICKEL/TITANIUM, AND PET FIBERS I WOULD HAVE NEVER GOTTEN ESSURE DONE JUST BASED ON KNOWING WHAT HAPPENS TO ME WHEN I WEAR JEWELRY WITH NICKEL IN IT. I SWELL UP, ITCH, AND BLEED FROM IT. I AM VERY DISAPPOINTED THE FDA DIDN'T STUDY THE SAFETY OF ESSURE LONGER BEFORE ALLOWING CONCEPTUS TO USE THOUSANDS OF WOMEN AS LAB RATS. VERY DISAPPOINTED AND HURT BY ALL OF THIS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00010	CONCEPTUS, INC.	5/17/2013	5/24/2013

Event Information:

Event Date (B3): 5/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 4/24/2013
Explant Date (E7): 5/3/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE ON (B)(6) 2013. PT CALLED DOCTOR ON (B)(6) 2013 TO REPORT ABDOMINAL PAIN. PT WENT TO EMERGENCY ROOM ON (B)(6) 2013 FOR ABDOMINAL PAIN. DR (B)(6) (WHO WAS NOT THE IMPLANT DOCTOR) SCOPED PT, DID NOT FIND ANYTHING ABNORMAL WITH ESSURE DEVICES. DURING THE PROCEDURE, DOCTOR FOUND PUS IN PT'S ABDOMINAL AREA. DOCTOR DRAINED PUS. DID NOT REMOVE ESSURE DEVICES. DOCTOR STATES ESSURE DEVICES WERE IN THE PROPER LOCATION AND DID NOT CAUSE INJURY TO PT. DOCTOR ALSO REPORTED A SPOT ON PT'S UTERUS. THIS INJURY WAS LIKELY CAUSED BY HYSTEROSCOPIC PERFORATION DURING THE PLACEMENT PROCEDURE. PT IS DOING FINE POST PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030277		5/17/2013	5/29/2013

Event Information:

Event Date (B3): 10/2/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): COIL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

COILS WERE IMPLANTED TO PREVENT PREGNANCIES. I WAS TOLD THERE WERE NO COMPLICATIONS ASSOCIATED WITH THESE COILS. I SUFFER FROM SEVERE DEBILITATING CRAMPS, PAIN AND PAINFUL INTERCOURSE. THE COILS HAVE MIGRATED FROM THE IMPLANTED POSITION TO FURTHER INTO MY FALLOPIAN TUBES. SINCE IMPLANTATION I'VE HAD HEAVY MENSTRUAL BLEEDING AND LARGE CLOTS. I NEVER EXPERIENCED ANY OF THESE SIDE EFFECTS PRIOR TO HAVING ESSURE IMPLANTED. MEDWATCH #(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030308		5/20/2013	5/30/2013

Event Information:

Event Date (B3): 1/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE BEEN HAVING PAIN AND SWELLING SINCE IT WAS INSERTED AND LOSS OF ENERGY. HAVE PAIN DURING INTERCOURSE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030266	CONCEPTUS, INC.	5/22/2013	5/24/2013

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/1/2011
Explant Date (E7): 5/16/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE SYSTEM IMPLANTED IN (B)(6) 2011. ONE YEAR LATER SHE DEVELOPED PAIN ON HER LEFT SIDE. AN ULTRASOUND INDICATED THAT SHE HAD A CYST ON HER LEFT OVARY. DURING THE SURGERY TO REMOVE THE CYST, SHE ALLEGED THAT THE COIL ON THE LEFT SIDE HAD FRAGMENTED AND HER PHYSICIAN DECIDED TO REMOVE HER LEFT FALLOPIAN TUBE. SHE STATED THAT SHORTLY AFTER THE SURGERY SHE DEVELOPED THE FOLLOWING SYMPTOMS: MIGRAINE HEADACHES, BACK AND LEG PAIN, CRAMPING, SEVERE DIZZINESS (VERTIGO) AND INSOMNIA. ON (B)(6) 2013, SHE RETURNED TO SURGERY TO HAVE A HYSTERECTOMY. AT THIS TIME SHE STATED THAT HER SURGEON DISCOVERED THAT THE RIGHT COIL HAD MIGRATED AND EMBEDDED IN HER UTERUS. SHE SAID THAT SINCE THE HYSTERECTOMY HER SYMPTOMS HAVE SUBSIDED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030267	CONCEPTUS, INC.	5/22/2013	5/24/2013

Event Information:

Event Date (B3): 4/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): EFF305
Lot #(E4): 927077

Single Use:
Implant Date (E6): 4/6/2012
Explant Date (E7): 2/15/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

SHORTLY AFTER IMPLANT OF ESSURE, STARTED HAVING ABDOMEN CRAMPING, BACK PAIN, DECREASE PHYSICAL ACTIVITY, STOMACH SWELLING, LOST SEXUAL DRIVE, HURTS DURING INTERCOURSE, DEPRESSION AND MOOD SWINGS. A YEAR LATER HAD AN X-RAY; WAS FOUND THAT THE LEFT COIL HAD EMBEDDED IN HER UTERINE WALL. ON (B)(6) 2013, HAD A HYSTERECTOMY. FEELS BETTER NOW AFTER THE HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030291	CONCEPTUS, INC	5/22/2013	5/29/2013

Event Information:

Event Date (B3): 3/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6): 3/26/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS REPORT IS REGARDING ESSURE, MANUFACTURED BY (B)(4). AFTER HAVING PROBLEMS WITH MY CYCLE FOR A WHILE, MY DOCTOR SUGGESTED ENDOMETRIAL ABLATION (NOVASURE), BUT IN ORDER TO DO THE ABLATION, HE REQUIRED I BE STERILIZED AS HE SAID THAT WAS THE FDA RECOMMENDATION. HE SAID ESSURE WAS THE SAFEST PRODUCT, THAT IT HAD NO SIDE EFFECTS, QUICKEST RECOVERY TIME, ETC. SO, AFTER SEEKING A SECOND OPINION FROM ANOTHER DOCTOR, WHO AGREED WITH HIM, I WENT BACK TO MY DOCTOR TO HAVE ESSURE DONE. THE PROCEDURE WAS PERFORMED IN HIS OFFICE WITH ONLY SHOTS IN THE CERVIX FOR NUMBING. IT WAS INCREDIBLY PAINFUL. BY THE TIME WE WERE FINISHED, I WAS HURTING SO BADLY, MY ENTIRE BODY WAS SHAKING. THE PAIN DID NOT GET BETTER, SO I WENT BACK TO MY DOCTOR THE NEXT WEEK. WE DISCOVERED MY LEFT FALLOPIAN TUBE WAS INFECTED AND HAD ABSCESSED. HE PRESCRIBED ANTIBIOTICS AND PAIN MEDS AND FOR ME TO COME BACK THE NEXT WEEK TO F/U. I DID NOT MAKE IT TO THAT APPOINTMENT BECAUSE THE PAIN BECAME WORSE, AND I COULDN'T KEEP MY FEVER DOWN, SO I WENT TO THE ER. I ENDED UP SPENDING FOUR DAYS IN THE HOSPITAL ON THREE DIFFERENT IV ANTIBIOTICS AND PAIN MEDICINE AROUND-THE-CLOCK. WHEN I WENT BACK TO F/U WITH MY DOCTOR, HE SAID A HYSTERECTOMY WAS PRETTY MUCH MY ONLY OPTION BECAUSE OF THE INFECTION, SO THAT IS WHAT WE DID. AT (B)(6) OF AGE, I HAD TO HAVE MY CERVIX, UTERUS, BOTH TUBES AND MOST OF ONE OVARY REMOVED. DURING THE SURGERY, MY DOCTOR DISCOVERED THAT THE ABSCESS ON MY LEFT TUBE WAS THE SIZE OF A SOFTBALL, AND WHEN HE TOUCHED IT, THE INFECTION SPILLED OUT. SO, I ENDED UP SPENDING TWO NIGHTS IN THE HOSPITAL ON IV ANTIBIOTICS AGAIN. EVIDENTLY, MY BODY REJECTED ESSURE FROM THE MOMENT IT WAS PUT IN. I HAD NO IDEA THAT ESSURE CONTAINED (B)(4), WHICH I HAVE SENSITIVITY TO. WHEN I ASKED MY DOCTOR WHY HE DIDN'T DISCLOSE THAT INFO, HE SAID IT WAS BECAUSE THE FDA DID NOT REQUIRE

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HIM TO. I HAD ESSURE IN FOR ABOUT 4 WEEKS AND WAS IN EXCRUCIATING PAIN THE ENTIRE TIME. I COULD NOT WORK, COULD NOT DRIVE, AND COULD NOT DO ANYTHING TO HELP CARE FOR MY DAUGHTER AND MY HOUSEHOLD. IT HAS BEEN 4 WEEKS SINCE MY SURGERY, AND I AM STILL IN A LOT OF PAIN, STILL UNABLE TO WORK, DRIVE, CARE FOR MY DAUGHTER AND HOUSEHOLD. I HAVE LOST OVER TWO MONTHS OF WORK. I AM SELF-EMPLOYED, WHICH MEANS THAT WHEN I'M UNABLE TO WORK, I DO NOT GET PAID. THIS HAS AFFECTED MY FAMILY'S FINANCIAL HEALTH. ESSURE NEEDS TO BE TAKEN COMPLETELY OFF THE MARKET, BUT IN THE MEANTIME, I WOULD LIKE THE FDA TO GO BACK TO REQUIRING DOCTORS TO DISCLOSE THE (B)(4) INFO TO THEIR PTS. NO WOMAN SHOULD EVER HAVE TO ENDURE THIS KIND OF PAIN AND LOSS. DATES OF USE: (B)(6) 2013.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030292	CONCEPTUS, INC	5/22/2013	5/29/2013

Event Information:

Event Date (B3): 5/29/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6): 5/29/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH THE ESSURE COILS ON (B)(6) 2008. SINCE THE PROCEDURE, I HAD NEAR-CONSTANT NAUSEA FOR ABOUT TWO YEARS AFTERWARDS, MY PERIOD HAS BECOME EXTREMELY HEAVY WITH CLOTTING, PAIN DURING INTERCOURSE, MOOD SWINGS AND IRRITABILITY, SHARP, STABBING PAIN IN MY PELVIC AREA (NOT ONLY DURING OVULATION, BUT BEFORE, DURING AND AFTER), MIGRAINES, WEIGHT GAIN, FACIAL HAIR GROWTH. THE PAIN IS THE WORST I'VE EVER FELT IN MY LIFE. I'VE TRIED MANY DIFFERENT TYPES OF PRESCRIPTION PAIN KILLERS. NONE HAVE WORKED AND NOT ONE HAS EVEN TAKEN THE EDGE OF THE PAIN AWAY.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INC.	5/24/2013	5/29/2013

Event Information:

Event Date (B3): 5/13/2013 **Report Date (B4): 5/24/2013** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PROSTHESIS, FALLOPIAN TUBE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): A85501

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE FAILED TO DEPLOY COILS IN THE FALLOPIAN TUBES.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
D&C, HYSTEROSCOPY, HYDROTHERMAL ABLATION WITH ESSURE.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030271		5/28/2013	5/29/2013

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/22/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE ESSURE WAS PUT IN THE PT SHE HAS HAD SEVERE HIP AND LOWER BACK PAIN, PELVIC PAIN, SHARP PAIN THAT STARTS IN THE CHEST AND TRAVEL TO HER RIGHT LEG. ALSO COMPLAINING OF SEVERE CRAMPS AND HEAVY BLEEDING DURING CYCLE. LAST 4 WEEKS SHE ALSO HAS METAL TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030432	CONCEPTUS INC, USA	6/1/2013	6/7/2013

Event Information:

Event Date (B3): 7/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 20222097

Single Use:
Implant Date (E6): 7/9/2010
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) 2010. EVER SINCE I HAD THEM, I'VE BEEN HAVING MANY HEALTH ISSUES SINCE. LOWER BACK PAIN, PAINFUL CRAMPS, LONGER, HEAVIER AND UNPREDICTABLE MENSTRUAL CYCLE, RECURRING UTI, PELVIC PAIN, SHARP PAIN IN LOWER ABDOMEN, BLOATED STOMACH, HEADACHES, ACNE, RECURRING BACTERIAL VAGINOSIS, HEART PALPITATIONS AND LOSS OF SEX DRIVE. DATES OF USE: 3 YEARS. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030434	CONCEPTUS INC	6/1/2013	6/7/2013

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE SYSTEMS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): P020014

Single Use:
Implant Date (E6): 6/27/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE DEVICE PLACED IN (B)(6) 2011. SINCE (B)(6) 2012, I HAVE BEEN HAVING HAIR LOSE, PELVIC PAIN AND ABNORMAL PERIODS. THE SYMPTOMS ARE INTENSIFYING AND OTHER SYMPTOMS HAVE BEGAN. (B)(6) 2012, I WOKE WITH SEVERE PRESSURE, NUMBNESS, SHOOTING PAIN, AND MUSCLE SPASMS FROM MY LOWER BACK DOWN TO MY TOES AND I AM STILL EXPERIENCE THESE SYMPTOMS. I HAVE LOW VITAMIN D LEVELS, FATIGUE AND ABNORMAL CELLS ON MY CERVIX. ALL OF THESE SYMPTOMS I HAVE NEVER HAD UNTIL AFTER HAVING ESSURE DEVICE PLACE. ALL TEST FOR OTHER HEALTH CONCERNS HAVE BEEN RULED OUT AND ESSURE DEVICE IS THE ONLY POSSIBLE CAUSE. THE NICKEL IN THE ESSURE DEVICE AND I AM ALLERGIC TO NICKEL. I AM UNABLE TO GET THIS DEVICE REMOVED DUE TO NO ACCESS TO HEALTH CARE OR FINANCIAL ASSETS. DATES OF USE: (B)(6) 2011 UNTIL PRESENT. DIAGNOSIS OR REASON FOR USE: WAS NOT GIVEN ANY OTHER OPTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030431	CONCEPTUS	6/1/2013	6/10/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/16/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MANUFACTURER CONCEPTUS, PERMANENT BIRTH CONTROL ON (B)(6) 2010. IN (B)(6) 2010, CONSTANT BACK PAIN ON RIGHT SIDE. IN (B)(6) 2012, STARTED EXPERIENCING BELOW SYMPTOMS: PELVIC PAIN, CONSTANT CRAMPING, SHARP PAIN ON RIGHT SIDE, EARLY MENOPAUSE, BREAST PAIN, FORGETFULNESS, MENTALLY FOGGY, DISCHARGE, NO ODOR, FATIGUE, MOOD SWINGS, NUMBNESS/TINGLING SENSATION IN LEFT ARM, AND WEIGHT GAIN +20 POUNDS. DATES OF USE: (B)(6) 2010 - (B)(6) 2013.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030433	CONCEPTUS INC	6/2/2013	6/7/2013

Event Information:

Event Date (B3): 10/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305 787224

Single Use:
Implant Date (E6): 10/11/2012
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PERMANENT BIRTH CONTROL PLACED ON (B)(6) 2012, HAD HSG TEST ON (B)(6) 2013 TO VERIFY STERILITY AND DISCOVERED LEFT SIDE DEVICE HAD EXITED FALLOPIAN TUBE AND IS NOW IN ABDOMINAL CAVITY. WILL REQUIRE MORE SURGERY TO REMOVE, HAVEN'T DONE SO YET. I AM CONCERNED ABOUT OTHER HEALTH ISSUES THAT MAY ARISE FROM DEVICE NOT BEING WHERE IT IS SUPPOSED TO BE. DID THE TEST STUDIES ACCOUNT FOR MISPLACEMENT/EJECTION/MIGRATION OF DEVICE FROM FALLOPIAN TUBE? DATES OF USE: CURRENTLY STILL HAVE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00011	CONCEPTUS, INC.	6/3/2013	6/6/2013

Event Information:

Event Date (B3): 5/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 10/4/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD ESSURE PROCEDURE IN 2011. PATIENT REPORTED SHE HAD PAIN IN HER ABDOMEN DUE TO THE ESSURE DEVICE. PATIENT HAD A SURGEON REMOVE THE ESSURE DEVICE FROM HER ABDOMEN IN (B)(6) 2012. PATIENT STATES SHE IS FEELING BETTER.

Manufacturer Narrative (H10):

SEVERAL ATTEMPTS WERE MADE TO OBTAIN FURTHER INFORMATION FROM THE EXPLANT PHYSICIAN BUT NO RESPONSE HAS BEEN RECEIVED TO DATE. WITH NO ADDITIONAL INFORMATION AVAILABLE FROM THE EXPLANT PHYSICIAN, THIS MDR IS BEING FILED AS A CONSERVATIVE MEASURES TO ENSUR

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030476	CONCEPTUS	6/4/2013	6/12/2013

Event Information:

Event Date (B3): 2/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/16/2012
Explant Date (E7): 2/27/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE DONE (B)(6) 2012. HSG TEST (B)(6) 2012. TEST SHOWED COIL IN RIGHT DISLODGED AND PUNCHED THROUGH FALLOPIAN TUBE ON RIGHT SIDE. HAD SURGERY TO CLAMP RIGHT TUBE BUT DOCTOR HAD TO REMOVE RIGHT TUBE BECAUSE THE COIL HAD PUNCHED THROUGH THE TUBE AND BEGAN TO WRAP AROUND MY TUBE. CURRENTLY WITH ANOTHER DOCTOR DUE TO LEFT SIDE NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030528	CONCEPTUS	6/5/2013	6/17/2013

Event Information:

Event Date (B3): 6/26/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/14/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE DONE ESSURE PROCEDURE PERMANENT CONTRACEPTION MADE BY CONCEPTUS, INC ON (B)(6) 2011. AFTER THREE MONTHS LATER, (B)(6) 2011 I HAVE DONE MY F/U ON ESSURE DOING HSG PROCEDURE. THE REPORT SAID MY FALLOPIAN TUBES 100% BLOCKED. AS SOON I GOT ESSURE MY PERIODS STARTED ACTING NOT NORMAL SUCH AS HEAVY BLEEDING, ABDOMINAL SHARP PAIN, MISSING PERIODS. DURING THE INTERCOURSE, I DEFINITELY FEEL THE COILS INSIDE OF ME THAT IS VERY UNCOMFORTABLE. IN (B)(6) 2012, I HAVE MISSED MY PERIODS, CAME TO THE DOCTOR COMPLAINING ABOUT ALL OF THIS. I DID AND IT WAS NEGATIVE. NEXT MONTH, I HAVE SOME SPOTTING DURING MY PERIODS. ANOTHER MONTH, I HAVE MISSED MY PERIODS AGAIN. IN (B)(6), I WAS TRAVELING TO ANOTHER COUNTRY, WENT TO THE STORE AND HAVE HAD A HEAVY BLEEDING MISCARRIAGE. I WAS TRANSPORTED TO THE HOSPITAL WHERE THE DOCTOR HAS CONFIRMED A FACT OF MISCARRIAGE. CAME BACK HOME, WENT TO MY OB. HE DID ULTRASOUND AND BLOOD WORK. HE HAS CONFIRMED I WAS ABOUT 3 MONTHS PREGNANT. I WAS VERY FRUSTRATED AND SHOCKED. I HAVE BOUGHT A SOLUTION (ESSURE) THAT DOESN'T WORK AND PUT MY LIFE IN DANGER. NOW, I HAVE TO REMOVE IT DOING A MAJOR SURGERY. ON THE TOP OF IT, I HAVE TO LOSE MY ORGANS DUE TO THE COILS CAN'T BE REMOVED BY ITSELF. YET, I HAVE TO COVER ALL FINANCIAL EXPENSES RELATED TO ESSURE. THIS PRODUCT MUST BE OUT OF MARKET TO PREVENT RUINING WOMEN'S LIVES AND HEALTH. REASON FOR USE: PERMANENT CONTRACEPTION.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	6/7/2013	6/12/2013

Event Information:

Event Date (B3): 6/4/2013 **Report Date (B4): 6/7/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): A95862

Single Use:
Implant Date (E6): 6/4/2013
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

A LENGTH OF APPROXIMATELY 1/2 INCH (5 COILS) OF THE EXTRA-FALLOPIAN PORTION OF THE ESSURE COIL THAT WAS INSERTED INTO THE LEFT FALLOPIAN TUBE BROKE OFF AFTER DEPLOYMENT. THE BROKEN OFF PIECE WAS REMOVED. A SECOND COIL WAS PLACED INTO THE LEFT SIDE WITHOUT DIFFICULTY.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	6/12/2013	6/19/2013

Event Information:

Event Date (B3): 3/12/2013 **Report Date (B4): 6/12/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): A66679

Single Use:
Implant Date (E6): 3/12/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AS DOCTOR INSERTED DEVICE INTO THE FALLOPIAN TUBE, THE DEVICE WOULD NOT DEPLOY PROPERLY. WHEN DOCTOR PULLED BACK ON COILS, THE COIL BROKE. TWO FRAGMENTS REMOVED FROM UTERINE CAVITY. UNKNOWN NUMBER OF FRAGMENTS COULD BE LEFT IN FALLOPIAN TUBE.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
STERILIZATION.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030553	CONCEPTUS INC	6/12/2013	6/19/2013

Event Information:

Event Date (B3): 1/31/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A66679

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/11/2013

Event Description (B5):

DETACHMENT DIFFICULTY. REPORTED TO MANUFACTURER; REPORT REFERENCE (B)(4). NO INJURY OCCURRED TO THE PT. REASON FOR USE. MENORRHAGIA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030561	CONCEPTUS INC.	6/12/2013	6/19/2013

Event Information:

Event Date (B3): 2/7/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 12020464

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/11/2013

Event Description (B5):

DETACHMENT DIFFICULTY. REPORTED TO MANUFACTURER; REPORT REFERENCE (B)(4). NO INJURY OCCURRED TO THE PT. DIAGNOSIS OR REASON FOR USE: DYSFUNCTIONAL UTERINE BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030587	CONCEPTUS, INC.	6/13/2013	6/20/2013

Event Information:

Event Date (B3): 6/13/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 50708722

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED IN RIGHT FALLOPIAN TUBE WITHOUT DIFFICULTY. SECOND ESSURE IMPLANTED IN THE LEFT TUBE AND THE SHEATH THAT COVERED THE COIL WAS RETAINED IN THE TUBE AS WELL. THE SURGEON THEN ATTEMPTED TO REMOVE THE SHEATH WHICH PULLED THE COIL OUT. A THIRD ESSURE DEVICE WAS THEN UTILIZED AND IMPLANTED WITHOUT DIFFICULTY. REASON FOR USE: ELECTIVE STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030623	CONCEPTUS, INC.	6/18/2013	6/26/2013

Event Information:

Event Date (B3): 7/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 761434

Single Use:
Implant Date (E6): 7/7/2011
Explant Date (E7): 1/8/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL PROCEDURE DONE (B)(6) 2011, AFTER THE BIRTH OF MY DAUGHTER. I WILL START BY SAYING THAT I HAD THE ESSURE COILS REMOVED (B)(6) 2013 VIA LAPAROSCOPIC SUPRACERVICAL HYSTERECTOMY. I WAS 99% SYMPTOM FREE IMMEDIATELY FOLLOWING SURGERY. I HAVE BEEN SYMPTOM FREE SINCE, WITH THE EXCEPTION OF MY SYSTEMIC CONTACT DERMATITIS. IT WAS ABOUT SIX MONTHS AFTER COIL IMPLANTATION THAT I BEGAN TO BE CONCERNED ABOUT MY CHRONIC SYMPTOMS. I WAS DIZZY, NAUSEATED AND FATIGUED ALL THE TIME. W/O CHANGES IN MY DIET, I WAS CHRONICALLY BLOATED AND WOULD HAVE SUDDEN INTENSE SPELLS OF DIARRHEA, OCCASIONALLY ACCOMPANIED BY VOMITING. THAT WAS BRUSHED OFF AS RANDOM BOUTS OF IBS. IN 2011, I NOTICED A LUMP ON MY RIGHT BREAST. I HAD A MAMMOGRAM, ULTRASOUND AND MRI. ALL TEST CONFIRMED THAT THE LUMP WAS FIBROCYSTIC AND BENIGN. I SUFFERED FROM CHRONIC INTENSE LOWER BACK PAIN, WHICH I THOUGHT WAS A RESULT OF CARRYING A CHILD FOR 10 MONTHS. I BEGAN TO HAVE CHRONIC FRONTAL HEADACHES AND MOMENTS OF FOGGINESS AND CONFUSION. MY PERIODS HAVE ALWAYS LASTED 3-4 DAYS WITH LIGHT CRAMPING. THEY SLOWLY INCREASED LASTING SOMETIMES MORE THAN SEVEN DAYS AND THE CRAMPING WAS DEBILITATING. MY PERIODS WERE MUCH HEAVIER WITH MAJOR BLOOD CLOTS. I WENT TO MY OBGYN TO DISCUSS MY SYMPTOMS. I EXPRESSED CONCERN ABOUT A POSSIBLE ESSURE CONNECTION AND WAS TOLD IT HAD NOTHING TO DO WITH THE DEVICE. I WAS DIAGNOSED WITH MENORRHAGIA, ABNORMALLY HEAVY AND PROLONGED PERIODS. I BEGAN TO HAVE SUDDEN SHARP PAINS IN MY LOWER ABDOMEN, RANGING FROM MODERATELY PAINFUL TO DEBILITATING. I ALSO HAD THE SAME SHARP PAINS DURING AND AFTER SEXUAL INTERCOURSE. I BEGAN TO HAVE THE SAME SHARP PAINS AFTER ANY FORM OF EXERCISE, ESPECIALLY ABDOMINAL WORKOUTS. IT WAS THEN THAT I BEGAN TO RESEARCH AND CONNECT WITH OTHER WOMEN LIKE MYSELF THAT HAVE

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HAD UNEXPLAINED SYMPTOMS POST ESSURE. I HAD AN EXAM BY MY OBGYN WHICH WAS UNFOUNDED. AGAIN I EXPRESSED MY CONCERNS ABOUT ESSURE. I WAS TOLD THAT THERE WERE NO SIDE EFFECTS. I ALSO MENTIONED THAT I HAVE A HYPERSENSITIVITY TO JEWELRY CONTAINING NICKEL AND WAS CONCERNED BECAUSE THE COILS CONTAIN NICKEL, WHICH I WAS NOT INFORMED BEFORE IMPLANTATION. I WAS INFORMED THAT JUST BECAUSE I HAVE SENSITIVITY TO JEWELRY CONTAINING NICKEL DOESN'T MEAN THAT I AM ALLERGIC TO NICKEL. NO NICKEL TEST WAS PERFORMED. I WAS DIAGNOSED WITH DYSPAREUNIA, PAINFUL INTERCOURSE. MID 2012, I BEGAN TO NOTICE OCCASIONAL TINGLING AND NUMBING IN MY RIGHT ARM AND FINGERS. IN (B)(6) 2012, I DEVELOPED A SKIN RASH THAT WAS RED, ITCHY AND RAISED ON MY LOWER ABDOMEN. I WENT TO MY PRIMARY CARE DOCTOR ABOUT THE RASH. I EXPRESSED TO HIM MY CONCERN THAT THE ESSURE COILS CONTAINED NICKEL. HE SAID IT WAS HIGHLY UNLIKELY THAT I WOULD HAVE A REACTION TO THE COILS. NO NICKEL TEST WAS PERFORMED. I WAS DIAGNOSED WITH CONTACT DERMATITIS AND WAS GIVEN PREDNISONE FOR THE RASH. THE RASH LASTED ABOUT A MONTH. I RETURNED TO MY OBGYN BECAUSE ALL OF MY SYMPTOMS WERE SO DEBILITATING I COULD NOT PERFORM NORMAL DAILY FUNCTIONS. I HAD TWO ABDOMINAL ULTRASOUNDS ON (B)(6) 2012. THEY REVEALED I HAD A COMPLEX CYST ON MY LEFT OVARY, ABOUT THE SIZE OF A TENNIS BALL, WHICH HAD CAUSED TORSION OF MY OVARY AND TUBE. I HAD LAPAROSCOPIC SURGERY IN (B)(6) 2012 TO REMOVE THE CYST. A MONTH AFTER THE SURGERY, I CALLED MY OBGYN BECAUSE NONE OF MY SYMPTOMS HAD RESOLVED. I WENT BACK IN FOR ANOTHER ULTRASOUND (B)(6) 2013, WITH NO FINDINGS. AT THIS POINT, I HAD DEVELOPED ANOTHER SKIN RASH ON MY LOWER ABDOMEN. I EXPRESSED MY CONCERNS TO THE DOCTOR ABOUT MY ESSURE AND HE AGREED TO DO A HYSTERECTOMY, (B)(6) 2013. (B)(6) 2013, THE SKIN RASH REAPPEARED ON MY LOWER ABDOMEN. WENT TO MY PCP. I WAS DIAGNOSED AGAIN WITH CONTACT DERMATITIS AND WAS GIVEN A SIX DAY DOSE PACK OF PREDNISONE. PCP AGAIN BRUSHED OFF NICKEL CONNECTION. THREE WEEKS LATER, THE RASH WAS STILL VERY PRESENT, SO I MADE AN APPOINTMENT WITH AN ALLERGIST. HE TOO GAVE ME A PRESCRIPTION FOR PREDNISONE, A STRONGER 9 DAY DOSE PACK. HE ALSO SCHEDULED ME FOR A PATCH TEST, TWO WEEKS LATER. THE PREDNISONE SEEMED TO LESSEN THE APPEARANCE OF THE RASH; HOWEVER, MY SKIN WAS STILL VERY CHRONICALLY ITCHY. THE PATCH TEST REVEALED THAT I WAS ALLERGIC TO GOLD SODIUM THIOSULFATE. I WAS GIVEN A PACKET OF INFO IN REFERENCE TO MY ALLERGY AND WAS NOT PROVIDED WITH ANY ADD'L GUIDANCE, WITH THE EXCEPTION OF HOME REMEDIES. VERY DISCOURAGED I SOUGHT THE ADVICE OF A NATURAL/ALTERNATIVE HEALTH CONSULTANT. SHE IS GOING TO PERFORM A BIO-ENERGETIC TEST TO SEE WHAT IF ANY METALS I AM BEING OVER EXPOSED TO SYSTEMICALLY. IN THE MEANTIME SHE RECOMMENDED I TRY CHLORELLA, A NATURAL HEAVY METAL DETOX. I HAVE BEEN TAKING THE CHLORELLA FOR THREE WEEKS AND IT SEEMS TO BE CONTROLLING THE RASH. BEFORE BEING IMPLANTED WITH ESSURE, I HAD NO HISTORY OF MEDICAL PROBLEMS, ONLY VISITING MY DOCTORS ANNUALLY FOR WELL CHECKUPS. THIS BRINGS ME FULL CYCLE IN MY STORY THAT AS OF TODAY, (B)(6) 2013, I AM FIVE MONTHS POST-OP AND AM STILL 99% SYMPTOM FREE. ALTHOUGH THE MAJORITY OF THE PHYSICAL SYMPTOMS HAVE DIMINISHED, I STILL BATTLE WITH THE MENTAL AND EMOTIONAL EFFECTS THAT ESSURE HAS HAD ON NOT ONLY ME BUT MY LOVED ONES. EVENT ABATED AFTER USE STOPPED OR DOSE REDUCED: YES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030638	CONCEPTUS INC	6/19/2013	6/26/2013

Event Information:

Event Date (B3): 4/4/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A57122

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 6/18/2013

Event Description (B5):

DETACHMENT DIFFICULTY. NO INJURY OCCURRED TO THE PT. REASON FOR USE: MODERATE DYSPLASIA OF CERVIX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030676	CONCEPTUS	6/20/2013	6/28/2013

Event Information:

Event Date (B3): 1/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/29/2013
Explant Date (E7): 6/13/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED ON (B)(6) 2013. RIGHT AWAY I HAD SEVERE CRAMPING AND TINGLING FROM EXTREMITIES. THE CRAMPING WAS MOSTLY ON MY LEFT SIDE AND SEVERE. IT LASTED UNTIL (B)(6) 2013 WHEN I HAD THE COILS REMOVED. REASON FOR USE: BIRTH CONTROL. EVENT ABATED AFTER USE STOPPED OR DOSE REDUCED: YES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030679	CONCEPTUS	6/20/2013	6/28/2013

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/15/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVIER MENSTRUAL CYCLES LASTING MORE THAN 7 DAYS, INCREASED MONTHLY DISCHARGE, HEADACHES, DEPRESSION, AND PAIN IN LOWER LEFT SIDE OF BODY. MENSTRUAL CYCLES LASTING OVER 20 DAYS. GIVEN HORMONE PILL TO STOP THE BLEEDING.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	6/21/2013	6/28/2013

Event Information:

Event Date (B3): 4/26/2013 **Report Date (B4): 6/21/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): *
Catalog # (E4): ESS205
Lot #(E4): A64630

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DOCTOR INSERTED THE COIL INTO THE LEFT OSTIUM (OS) OF THE FALLOPIAN TUBE AND THE DEVICE FAILED TO DEPLOY CORRECTLY. A NEW DEVICE WAS OPENED AND THE PROCEDURE WAS COMPLETED. THERE WAS NO HARM TO THE PATIENT.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
FEMALE STERILIZATION.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030651	CONCEPTUS INC	6/21/2013	6/28/2013

Event Information:

Event Date (B3): 2/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/21/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS IMPLANTED (B)(6) 2013. THE PROCEDURE WENT WELL. THE FOLLOWING TWO DAYS WERE ALSO INCIDENT FREE. THE THIRD DAY HOWEVER, THE PT DESCRIBED FEELING A CRAMPING SENSATION DIRECTLY WHERE THE ESSURE DEVICES WERE IMPLANTED. THIS CRAMPING NEVER SUBSIDED NOR WAS IT EASILY TREATED WITH OVER THE COUNTER PAIN MEDICATION. THE PT RETURNED TO HER IMPLANTING DOCTOR TWICE BEFORE THE 3 MONTH HSG TEST AND REPORTED MORE PAIN IN THE LOWER BACK. REMOVAL IS REQUIRED FOR RELIEF OF SYMPTOMS. REASON FOR USE: PERMANENT STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030683		6/21/2013	6/28/2013

Event Information:

Event Date (B3): 10/8/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/12/2007
Explant Date (E7): 10/8/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS INSERTED, NEGATIVE SIDE EFFECTS FOLLOWING. ADENOMYOSIS, ENDOMETRIOSIS, INTERSTITIAL CYSTITIS, MIGRAINES, LOWER LUMBAR DISC DAMAGE/INJURY. SEVERE FOOD AND ENVIRONMENTAL ALLERGIES. NICKEL ALLERGY. CHRONIC FATIGUE. POSSIBLE PREGNANCIES/MISCARRIAGES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030684	CONCEPTUS INC	6/21/2013	6/28/2013

Event Information:

Event Date (B3): 2/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4): REF ESS305
Catalog # (E4):
Lot #(E4): 628434

Single Use:
Implant Date (E6): 2/25/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PROLONGED BLEEDING, ABSENT PERIODS, CYST, PAINFUL STABBING PAINS, HAIR LOSS, HAIR GROWTH NOT ON MY HEAD. DIFFICULTY LOOSING WEIGHT, MOOD SWINGS HOT FLASHES. VERTIGO, INSOMNIA. ROUTE: ENDOCERVICAL. DATE OF USE: PRESENT STILL HAVE, (B)(6) 2009 - (B)(6) 2013. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030685	CONCEPTUS, INC	6/21/2013	6/28/2013

Event Information:

Event Date (B3): 4/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE TUBAL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/26/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE A PRODUCT OF CONCEPTUS HAS CAUSED ME NOTHING BUT PAIN, INFLAMMATION, AND SWELLING, AND I AM NOW HAVING TO HAVE SURGERY TO REMOVE THE COILS AND POSSIBLY SECTIONS OF MY UTERUS AS WELL. DOSE OR AMOUNT: COILS. ROUTE: INTRACERVICAL. DIAGNOSIS OR REASON FOR USE: TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030686	CONCEPTUS INC	6/21/2013	6/28/2013

Event Information:

Event Date (B3): 6/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/5/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE FOR PERMANENT BIRTH CONTROL ON (B)(6) 2011. I HAD THE REQUIRED ESSURE "CONFIRMATION TEST" ON (B)(6) 2011. THE RESULTS OF THE HSG SHOWED THAT BOTH FALLOPIAN TUBES WERE FULLY BLOCKED AND THE PROCEDURE WAS SUCCESSFUL. ACCORDING TO ESSURE LITERATURE, "YOUR DOCTOR WILL DISCUSS THE RESULTS OF YOUR ESSURE CONFIRMATION TEST WITH YOU AS SOON AS THEY ARE AVAILABLE, USUALLY ON THE DAY OF YOUR TEST. UNTIL YOU RECEIVE CONFIRMATION DIRECTLY FROM YOUR DOCTOR, YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL. AFTER THAT, YOU CAN START ENJOYING THE FREEDOM THAT COMES FROM NEVER WORRYING ABOUT UNPLANNED PREGNANCY AGAIN." I SIGNED A CONSENT FORM ON (B)(6) 2011 STATING THAT I UNDERSTOOD THAT THE PROCEDURE MAY NOT BE SUCCESSFUL THE FIRST TIME AND MAY NEED TO BE REDONE AND ALSO THAT AN ALTERNATE FORM OF BIRTH CONTROL WOULD NEED TO BE USED UNTIL THE SUCCESSFUL "CONFIRMATION TEST". NOTHING IN THE CONSENT STATES THAT I MAY BECOME PREGNANT AFTER THE SUCCESSFUL CONFIRMATION TEST. AS A PT, AFTER HAVING A SUCCESSFUL HSG, I BEGAN TO RELY ON ESSURE AS MY SOLE FORM OF BIRTH CONTROL. ON (B)(6) 2013, I BEGAN THE START OF WHAT I BELIEVED TO BE MY PERIOD. ON (B)(6) 2013, I WENT TO THE EMERGENCY ROOM WITH SEVERE BLEEDING. IT WAS IN THE ER THAT THEY DISCOVERED THAT I WAS PREGNANT. THEY DID AN ULTRASOUND, DETERMINED THAT THE BABY/FETUS WAS DEAD, AND THE DOCTOR REMOVED THE GESTATIONAL SAC TO STOP THE MAJORITY OF THE BLEEDING. THE START OF MY PREVIOUS MENSTRUAL CYCLE WAS ON (B)(6) 2013, BUT SINCE I HAD BEEN HAVING IRREGULAR PERIODS THIS WAS NOT A CAUSE FOR CONCERN. THE REASON FOR FAILURE OF THE ESSURE PROCEDURE AFTER A SUCCESSFUL CONFIRMATION TEST STILL NEEDS TO BE DETERMINED. THE CAUSE OF MISCARRIAGE STILL NEEDS TO BE EVALUATED TO DETERMINE WHETHER IT WAS RELATED TO THE ESSURE IMPLANTS. FROM THE ESSURE PT INFO BOOKLET: "FREQUENTLY

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ASKED QUESTIONS: CAN I TRUST ESSURE TO PREVENT PREGNANCY - YES, THE ESSURE PROCEDURE IS 99.83% EFFECTIVE. IN FIVE YEARS OF CLINICAL TRIALS, THERE HAVE BEEN NO PREGNANCIES AMONG WOMEN WHO SUCCESSFULLY COMPLETED ALL 3 STEPS OF THE ESSURE PROCEDURE. A FEW PREGNANCIES HAVE BEEN REPORTED AMONG THE HUNDREDS OF THOUSANDS OF WOMEN WHO HAVE COMPLETED THE PROCEDURE SINCE IT BECAME COMMERCIALLY AVAILABLE. MOST OF THOSE PREGNANCIES WERE A RESULT OF NOT HAVING COMPLETED THE PROCEDURE OR NOT FOLLOWING INSTRUCTIONS." THEY ALSO STATE THAT THERE WERE NO PREGNANCIES IN THE MORE THAN 700 PERSON CLINICAL TRIAL OF WOMEN IN MY AGE RANGE (B)(6). MY HSG RESULTS HAVE AGAIN BEEN REVIEWED AND DETERMINED TO BE WITHIN THE ESSURE GUIDELINES. FROM THE ESSURE PT INFO BOOKLET: "UNK RISKS: THE RISKS TO YOU AND YOUR FETUS IF YOU GET PREGNANT AFTER THE ESSURE PROCEDURE ARE NOT KNOWN." I HAVE 5 CHILDREN WHICH WERE ALL HEALTHY, UNCOMPLICATED PREGNANCIES. I DID HAVE ONE MISCARRIAGE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00012	CONCEPTUS, INC.	6/24/2013	6/27/2013

Event Information:

Event Date (B3): 5/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 10/8/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DR REPORTED ECTOPIC PREGNANCY ON (B)(6) 2013. UNABLE TO OBTAIN FURTHER INFORMATION ON PT STATUS.

Manufacturer Narrative (H10):

SEVERAL ATTEMPTS WERE MADE TO OBTAIN FURTHER INFORMATION FROM THE EXPLANT PHYSICIAN BUT NO RESPONSE HAS BEEN RECEIVED TO DATE.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030727	CONCEPTUS INC.	6/27/2013	7/5/2013

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE MICRO INSERTS
Model # (E4):
Catalog # (E4):
Lot #(E4): 735707

Single Use:
Implant Date (E6): 5/25/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE PROCEDURE DONE IN (B)(6) 2012 AND HAD THE DYE TEST DONE IN (B)(6) 2012 AND IT WAS CONFIRMED THAT DEVICES WERE IN PLACE AND MY TUBES WERE BLOCKED. I HAVE BEEN HAVING SEVERE PELVIC PAIN EVER SINCE. I HAD AN ULTRASOUND DONE ON (B)(6) 2013 TO SEE WHAT COULD BE CAUSING THE PAIN. THE DOCTOR WROTE ME THE FOLLOWING DAY STATING THE COIL IS NOT IN MY TUBE ANY LONGER BUT IN MY UTERUS. ALSO, SINCE THE ESSURE PROCEDURE, I HAVE DEVELOPED QUITE A FEW CYSTS ON MY OVARIES. THIS HAS ALL TAKEN PLACE WITHIN A YEARS TIME. I STILL HAVE TO GO FIND OUT IF THE COIL IN MY UTERUS HAD CAUSED ANY FURTHER DAMAGE. NOW I HAVE TO WORRY ABOUT GETTING PREGNANT NOW THAT I HAVE TUBE OPEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030754	CONCEPTUS, INC	6/29/2013	7/9/2013

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2011. I WAS TOLD THAT THIS PRODUCT OF TREATMENT WAS VERY EFFECTIVE AND GREAT RESULTS. WHAT I FOUND WAS COMPLETELY DIFFERENT. AFTER MY SURGERY, I STARTED BLEEDING OUT. THEN I STARTED EXPERIENCING EXTREME PAIN AND CRAMPING TO THE POINT I COULD NOT WALK. THE PROCEDURE FAILED. I WENT THROUGH TWO X-RAYS WERE THE REP WAS IN THE ROOM AND COULD NOT TELL ME WHY IT FAILED. THE COILS WERE WHERE THEY SHOULD HAVE BEEN. HE THEN TOOK A CD OF THE X-RAYS BACK TO THE COMPANY AND THEY TOO COULD NOT TELL ME ANYTHING. I ENDED GOING IN FOR EMERGENCY SURGERY ABOUT 1 YEAR LATER BECAUSE OF THE REACTION TO THE COILS PLACED. I HAD A FULL TUBAL LIGATION DONE. WHEN THE DOCTOR WAS REMOVING ONE OF THE TUBES SHE ENDED UP CUTTING INTO ONE OF THE COILS THAT THEN ENDED UP FLOATING INTO MY UTERUS. SO THEY HAD TO CUT INTO THE UTERUS TO FISH OUT THE PIECE THAT BROKE OFF. I DO NOT BELIEVE THIS PRODUCT SHOULD BE ON THE MARKET ANYMORE. NOT ENOUGH RESEARCH ON FUTURE OUTCOMES AS WELL AS SO MANY WOMEN WITH THIS SAME PROBLEM. SURGERY TO REMOVE ESSURE ON (B)(6) 2012. REASON FOR USE: TO PREVENT PREGNANCY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030761		6/29/2013	7/9/2013

Event Information:

Event Date (B3): 2/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/1/2008
Explant Date (E7): 2/5/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT-IN IN 2008. BY 2010, I WAS IN PAIN ALL THE TIME AND WAS TOLD I HAD GRAVES. BY 2012, I WAS UNABLE TO HAVE SEX DUE TO PAIN. (B)(6) OF 2013, MY DOCTOR DID A HYSTERECTOMY AND FOUND THAT MY RIGHT COIL WAS PUSHING OUT OF MY RIGHT TUBE AND HAD TO REMOVE IT ALONG WITH MY RIGHT OVARY AS WELL AS MY UTERUS. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030777	CONCEPTUS	7/1/2013	7/10/2013

Event Information:

Event Date (B3): 11/20/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL NICKEL-TITANIUM CONCEPTUS ALLOY
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 626806

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2007 FOR STERILIZATION. SINCE THEN, MY HEALTH HAS GOTTEN SO THAT I CAN BARELY FUNCTION DAY TO DAY. LIST OF SYMPTOMS INCLUDE HAIR LOSS, WEIGHT GAIN, SKIN RASHES, MENTAL FOG, CONFUSION, STOMACH PAINS, SEVERE MENSTRUAL, CRAMPS AND EXTREME BLEEDING, SHARP PAINS IN REPRODUCTIVE AREAS, BLURRY VISION, UNSTEADY GAIT, LOSS OF LIBIDO, FATIGUE, JOINT PAIN, CHEST PAIN, SHORTNESS OF BREATH, AND MAY OTHER SYMPTOMS. MY PERIODS HAVE GONE FROM NORMAL TO EVERY TWO WEEKS WITH LARGE AMOUNTS OF BLEEDING AND CLOTTING FOR A MINIMUM OF 6 DAYS. MY MARRIAGE AND MY RELATIONSHIP WITH MY CHILDREN HAVE SUFFERED DRAMATICALLY, AND I AM ONE OF THE UNFORTUNATE WOMEN WHO DO NOT HAVE HEALTH INSURANCE ANYMORE AND CANNOT AFFORD THE SURGERY FOR REMOVAL. DOCTOR VISITS OVER THE YEARS HAVE BEEN INCONCLUSIVE OR NORMAL FINDINGS. THERE HAS BEEN ONE TRIP TO THE EMERGENCY ROOM FOR POSSIBLE PULMONARY EMBOLISM, ALSO INCONCLUSIVE, 2 YEARS AGO. I WAS NOT AFFECTED BY ANY OF THESE PROBLEMS BEFORE THE INSERTION OF THE ESSURE COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030779	CONCEPTUS INC.	7/2/2013	7/10/2013

Event Information:

Event Date (B3): 6/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/5/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE FOR PERMANENT BIRTH CONTROL ON (B)(6) 2011. I HAD THE REQUIRED ESSURE "CONFIRMATION TEST" ON (B)(6) 2011. THE RESULTS OF THE HSG WERE EVALUATED BY BOTH A HIGHLY RESPECTED DOCTOR AND THE RADIOLOGIST WHO CONFIRMED THAT BOTH FALLOPIAN TUBES WERE FULLY BLOCKED AND THE PROCEDURE WAS SUCCESSFUL. ACCORDING TO ESSURE LITERATURE, AFTER A SUCCESSFUL CONFIRMATION TEST "...YOU CAN START ENJOYING THE FREEDOM THAT COMES FROM NEVER WORRYING ABOUT UNPLANNED PREGNANCY AGAIN." THIS STATEMENT IS AN OUTRIGHT LIE! IT NEEDS TO BE CHANGED TO SOMETHING LIKE "...999 OUT OF 1000 WOMEN CAN ENJOY THE FREEDOM THAT COMES FROM NEVER WORRYING ABOUT UNPLANNED PREGNANCY AGAIN!" OTHERWISE, THEY ARE DECEIVING 1 OUT OF EVERY 1000 WOMEN! ON (B)(6) 2013, I BEGAN THE START OF WHAT I BELIEVED TO BE MY PERIOD. ON (B)(6) 2013, I WENT TO THE EMERGENCY ROOM WITH SEVERE BLEEDING. IT WAS IN THE EMERGENCY ROOM THAT THE STAFF DISCOVERED THAT I WAS PREGNANT AND MISCARRYING. THEY DID AN ULTRASOUND, DETERMINED THAT THE BABY/FETUS WAS DEAD, AND THE DOCTOR REMOVED THE GESTATIONAL SAC TO STOP THE MAJORITY OF THE BLEEDING. PLEASE UNDERSTAND, THE LOSS OF MY BABY IS DEVASTATING TO ME. I WOULD HAVE DONE ANYTHING TO SAVE THIS LITTLE ONE, BUT IT WAS TOO LATE! THE START OF MY PREVIOUS MENSTRUAL CYCLE WAS (B)(6) 2013, BUT SINCE I HAD BEEN HAVING IRREGULAR PERIODS THIS WAS NOT A CAUSE FOR CONCERN. THE ESSURE LITERATURE AND DOCTOR INFORMATION WAS SO CONVINCING THAT I DID NOT EVEN THINK THAT I COULD EVER AGAIN BECOME PREGNANT. THANKS TO ESSURE, I HAVE NOW SUFFERED THE LOSS OF MY UNBORN BABY, AWAIT A STACK OF EMERGENCY ROOM BILLS, HAVE NO RELIABLE FORM OF BIRTH CONTROL, AND HAVE IMPLANTS INSIDE OF ME THAT PUT ME AT AN INCREASED RISK FOR ECTOPIC PREGNANCY AND MISCARRIAGE. HOWEVER, I CANNOT HAVE THE IMPLANTS REMOVED! I ALSO PAID FOR THIS HIGHER COST PROCEDURE IN

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2011 SO THAT I WOULDN'T HAVE TO DEAL WITH WHAT I AM GOING THROUGH RIGHT NOW! I NEED CONCEPTUS TO STAND BEHIND THEIR PRODUCT AND DETERMINED WHY THIS "SUCCESSFUL PROCEDURE" HAS NOW FAILED. I WAS CONVINCED IN 2011 TO HAVE THE ESSURE PROCEDURE SINCE IT WAS THE MOST EFFECTIVE PERMANENT BIRTH CONTROL METHOD. CONCEPTUS AND ESSURE HAVE PUT ME INTO THIS HORRIBLE POSITION AND I NOW NEED THEIR HELP TO MOVE FORWARD! PLEASE DO NOT ALLOW THEM TO IGNORE ME. THE ESSURE MARKETING IS SO CONVINCING AND SIMPLY BLAMES THE FAILURES ON PT AND DOCTOR MISTAKES. HOWEVER, THESE STATEMENTS SERIOUSLY NEED TO BE EVALUATED AS TO WHETHER THEY ARE OVERLY CONVINCING. WHEN A PT, LIKE MYSELF, READS THE FOLLOWING ESSURE STATEMENT, IT GIVES AN INCREDIBLE SINCE OF CONFIDENCE -- ESPECIALLY WHEN THE PROCEDURE IS DONE BY A VERY RESPECTED PHYSICIAN! "...THE ESSURE PROCEDURE IS 99.83% EFFECTIVE. IN FIVE YEARS OF CLINICAL TRIALS, THERE HAVE BEEN NO PREGNANCIES AMONG WOMEN WHO SUCCESSFULLY COMPLETED ALL 3 STEPS OF THE ESSURE PROCEDURE. A FEW PREGNANCIES HAVE BEEN REPORTED AMONG THE HUNDREDS OF THOUSANDS OF WOMEN WHO HAVE COMPLETED THE PROCEDURE SINCE IT BECAME COMMERCIALLY AVAILABLE. MOST OF THOSE PREGNANCIES WERE A RESULT OF NOT HAVING COMPLETED THE PROCEDURE OR NOT FOLLOWING INSTRUCTIONS." I COULD NOT FIND A SINGLE PLACE IN THE ESSURE LITERATURE WHERE THEY LIST THE FAILURES THAT ARE NOT DUE TO PT/DOCTOR MISTAKES OR MISINTERPRETED TEST RESULTS. THEY SIMPLY GROUP THESE AS "UNABLE TO DETERMINE CAUSE". IN THE CASE OF MY PREGNANCY, IT WAS A "TRUE" FAILURE. THE HSG WAS EVALUATED BY A VERY RESPECTED AND THOROUGH DOCTOR AND A RADIOLOGIST BACK IN 2011 AND THIS PREGNANCY OCCURRED AFTER THE HSG WAS CONFIRMED. ESSURE NEEDS TO OWN UP TO THE FACT THAT THEIR IMPLANTS ARE NOT PERFECT (THEY DO FAIL) AND SPECIFICALLY LIST FAILURES SUCH AS THIS AS "TRUE FAILURES" SO AS NOT TO MISLEAD MORE WOMEN! A SIMPLE NOTE STATING THAT "NO FORM OF BIRTH CONTROL SHOULD BE CONSIDERED 100% EFFECTIVE" WHILE THEY SUGAR-COAT THEIR RESULTS IS UNFAIR! I ORIGINALLY TRIED TO SUBMIT THIS ON-LINE, BUT SOME OF THE INFORMATION WAS LOST. I HAVE TRIED TO CONTACT THE FDA VIA PHONE/EMAIL, BUT HAVE NOT RECEIVED ANY RESPONSE. THIS FORM SHOULD REPLACE MY FAILED ATTEMPT TO FILE ON-LINE. THANKS, (B)(6).

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	7/8/2013	7/9/2013

Event Information:

Event Date (B3): 4/18/2013 **Report Date (B4): 7/8/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): UNK
Catalog # (E4): ESS305
Lot #(E4): A27186

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 5/30/2013

Event Description (B5):

TIP OF FIRST SIDE OF ESSURE BROKE/STUCK IN PT'S FALLOPIAN TUBES.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
ESSURE COIL INSERTION.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	7/8/2013	7/9/2013

Event Information:

Event Date (B3): 6/17/2013 **Report Date (B4): 7/8/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): 50718077

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PATIENT WAS UNDERGOING A HYSTEROSCOPY WITH PERMANENT STERILIZATION. ESSURE DEVICE WAS DEPLOYED PRIOR TO ACTIVATION; MINOR DELAY TO CASE RELATED TO OPENING ANOTHER DEVICE; NO HARM TO PATIENT- NOT USED.
==========
MANUFACTURER RESPONSE FOR ESSURE, ESSURE (PER SITE REPORTER).
==========
UNKNOWN AT THIS TIME; DEVICE RETURNED TO REP- UNSURE OF DATE.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
HYSTEROSCOPY WITH PERMANENT STERILIZATION.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030862	CONCEPTUS	7/9/2013	7/16/2013

Event Information:

Event Date (B3): 1/1/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 5/1/2003
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I WAS IMPLANTED WITH ESSURE, I HAVE HAD MULTIPLE HEALTH ISSUES. I HAVE HAD EXTREME WEIGHT GAIN, CHRONIC HEADACHES, ABDOMINAL PAIN, MENORRHAGIA WHICH LASTS SEVERAL MONTHS AT A TIME. ALSO, I HAVE BATTLE DEPRESSION, ANXIETY, AND I HAVE FOUND OUT THAT I HAVE A NICKEL ALLERGY. I HAVE A CONSTANT METALLIC TASTE IN MY MOUTH. I WAS IMPLANTED 10 YEARS AGO. I WAS NOT EVEN FULLY EDUCATED ON WHAT ESSURE WAS. IT WAS A VERY NEW PROCEDURE WHEN I WAS PUSHED INTO IT BY MY DOCTOR AT THE TIME. REMOVAL/REVERSAL IS TOO EXPENSIVE AND IS NOT COVERED BY INSURANCE, EVEN THOUGH THE IMPLANTATION WAS. THE HYSTEROSALPINGOGRAM THAT WAS TO FOLLOW THE IMPLANTATION WAS NOT COVERED BY INSURANCE EITHER, AND I WAS NOT ABLE TO HAVE IT DONE WHEN I WAS IMPLANTED IN 2003.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030860	CONCEPTUS, INC.	7/11/2013	7/16/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): CONCEPTUS INCORPORATED
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAS HAD THIS DEVICE SINCE (B)(6) 2009 AND HAS BEEN EXPERIENCING PELVIC PAIN, SEVERE CRAMPING, BLOOD CLOTS WEIGHT GAIN OF 50 LBS AND MANY OTHER PROBLEMS. THE DOCTOR SAID THAT, THIS WAS AS A RESULT OF THE DEVICE GETTING USED IN HER BODY, BUT NOTHING HAS CHANGED. SHE PLANS TO GET IT REMOVED AS SOON AS SHE GETS MONEY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	7/11/2013	7/17/2013

Event Information:

Event Date (B3): 7/9/2013 **Report Date (B4): 7/11/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): NA
Catalog # (E4): ESS305
Lot #(E4): A25168

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN THE PHYSICIAN WAS READY TO ENGAGE THE ESSURE HANDPIECE, IT MISFIRED.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
ESSURE-PERMANENT STERILIZATION.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030888	CONCEPTUS INC	7/11/2013	7/18/2013

Event Information:

Event Date (B3): 9/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): REF: ESS305
Catalog # (E4):
Lot #(E4): 654832

Single Use:
Implant Date (E6): 9/29/2009
Explant Date (E7): 9/22/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED (B)(6) 2009. ONE YEAR LATER I WAS HAVING TERRIBLE ABDOMINAL PAIN. A CAT SCAN SHOWED THAT IT HAD MIGRATED THROUGH THE UTERINE WALL AND WAS STICKING OUT THE OTHER SIDE. IT WAS IN A PLACE THAT THEY DID NOT FEEL COULD BE REMOVED WITH A SCOPE. I ENDED UP HAVING A OPEN ABDOMINAL HYSTERECTOMY. I WAS OFF WORK FOR 8 WEEKS RECOVERING. I TALKED TO A LAWYER THEN, (B)(6) 2010. THEY SAID THERE WAS NOT OTHER LAWSUITS AT THAT TIME BUT TOLD ME TO KEEP THE INFO BECAUSE IT MAY COME TO COURT LATER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030920	CONCEPTUS	7/13/2013	7/19/2013

Event Information:

Event Date (B3): 3/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2010, I HAD THE ESSURE PROCEDURE DONE. EVER SINCE THEN MY BODY STARTED GIVING ISSUES THAT I HAVE NEVER HAD BEFORE. I HAVE ALWAYS BEEN THIN, AFTER ESSURE I WEIGH 165 AND MY STOMACH ALWAYS SWELLS UP MAKING ME LOOK LIKE I AM 5 MONTHS PREGNANT. I HAVE PAINS IN MY LOWER ABDOMEN, AND MY TOES CRAMP UP ONCE IN A WHILE. I GET DIZZY SPELLS AND INTERCOURSE IS ALWAYS PAINFUL. MY LOWER BACK ALSO HURTS FOR DAYS AT A TIME. SHARP PAINS DAILY ON MY RIGHT AND LEFT SIDES. I WENT TO THE DOCTOR AND THEY RELATED MY ISSUES TO IRRITABLE BOWEL SYNDROME AND GAVE ME PILLS FOR PAIN. I KNOW THIS IS NOT THE ISSUE BECAUSE I HAVE HAD THESE ISSUES EVER SINCE THE ESSURE COILS WERE INSERTED. I EAT RIGHT AND WORK OUT SO THERE IS NO REASON WHY MY STOMACH SWELLS UP THE WAY IT DOES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030921	CONCEPTUS	7/14/2013	7/19/2013

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE, TUBAL PREGNANCY 1 YEAR AFTER HAVING THEM INSERTED AND DEALING WITH ABDOMINAL PAIN, PELVIC PAIN, BLOATING, NAUSEA. MY RIGHT TUBE HAD TO BE REMOVED, RIGHT ESSURE COIL WAS FOUND OUTSIDE OF THE TUBE AND REMOVED. I WAS GIVEN PICTURES OF THIS. WEIGHT GAIN AND PREGNANCY SYMPTOMS WITH EXTREME BLOATING IS NOW HOW I LIVE WITH THE ADDED ABDOMINAL AND PELVIC PAIN THAT NEVER GOES AWAY . PLEASE, YOU HAVE TO DO SOMETHING ABOUT THIS... WOMEN SHOULD NOT HAVE TO EXPERIENCE THIS!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030930	CONCEPTUS, INC	7/15/2013	7/22/2013

Event Information:

Event Date (B3): 4/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/13/2012
Explant Date (E7): 4/26/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE COILS AND HAD TO HAVE THEM SURGICALLY REMOVED DUE TO CONSTANT SEVERE PELVIC PAIN AND I ALSO HAD A LACK OF MENSTRUAL CYCLE FROM THE TIME I HAD THEM PUT IN TILL WHEN THEY WERE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5030995	CONCEPTUS, INC.	7/21/2013	7/29/2013

Event Information:

Event Date (B3): 1/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6): 9/11/2012
Explant Date (E7): 1/25/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACE ON (B)(6) 2012. THE DOCTOR THAT IMPLANTED THEM REFUSED TO TELL ME THE PRODUCTS CONTAIN NICKEL, TO WHICH I AM HIGHLY ALLERGIC TO. AFTER FOUR MONTHS OF GOING TO DIFFERENT DOCTORS AND SPECIALISTS, ONE DOCTOR FINALLY DECIDED TO ESSURE COILS WERE THE PROBLEM AND DECIDED TO DO SURGERY BECAUSE OF THE NICKEL ALLERGY. DURING SURGERY, THE DOCTOR FOUND THAT THE COILS CAUSED SO MUCH SWELLING THAT THEY WERE BENDING MY FALLOPIAN TUBES BACKWARDS TOWARDS MY SPINE AND TEARING MY FALLOPIAN TUBES OFF OF MY UTERUS. THE SURGEON STATED TO MY SPOUSE THAT IF I WOULD HAVE WAITED ANY LONGER, THE TUBES WERE SO CLOSE TO TEARING THROUGH THAT I COULD HAVE BLED TO DEATH. I HAD A FULL TUBAL LITIGATION ON (B)(6) 2013 WHERE MY FALLOPIAN TUBES HAD TO BE COMPLETELY REMOVED AND THE TOP PORTION OF MY UTERUS HAD TO HAVE PORTIONS REMOVED AND "FIXED" BY CAUTERIZATION DUE TO THE DAMAGE THE COILS HAD CAUSED. THESE COILS ARE DANGEROUS AND CAUSED MY HEALTH TO DETERIORATE OVER A MATTER OF MONTHS. I WENT FROM A FAIRLY HEALTHY YOUNG WOMAN TO SOMEONE WHO PUT ON OVER 20 POUNDS DUE TO SWELLING AND ENDED UP HAVING TO USE A WHEELCHAIR BECAUSE THE PAIN AND NUMBNESS CAUSED BY THESE COILS MOSTLY RENDERED MY ABILITY TO WALK. SOME OF THE MORE SEVERE SIDE EFFECTS I EXPERIENCED WERE: MIGRAINE HEADACHES, NEVER EXPERIENCED ONE BEFORE ESSURE, EXTREMITY ARMS, HANDS, LEGS, AND FEET, NUMBNESS AND TINGLING, SEVERE MIDDLE AND LOWER BACK PAIN, VISION DETERIORATION. HAD TO GET PRESCRIPTION GLASSES SO I COULD SEE. APPROX 22 POUNDS IN WEIGHT GAIN, RASH ON LOWER ABDOMEN AND ON THE INSIDE OF MY THIGHS. EVENT ABATED AFTER USE STOPPED OR DOSE REDUCED: YES.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	7/23/2013	7/26/2013

Event Information:

Event Date (B3): 7/19/2013 **Report Date (B4): 7/23/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B21582; B09699

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE TUBAL OCCLUSION DEVICE WAS INSERTED THROUGH THE OPERATIVE PORT AND THE TIP OF THE ESSURE DEVICE EASILY SLID INTO THE RIGHT OSTIUM. THE ESSURE HAND PIECE WAS WHEELED BACK AS DIRECTED PER MANUFACTURER'S INSTRUCTION, BUTTON WAS RELEASED TO DEPLOY THE DEVICE. WHEN THE DEVICE WAS WITHDRAWN, IT WAS NOTED THAT THE COIL HAD NOT SEPARATED FROM IT'S PROTECTING SHEET, COIL WAS NOT PRESENT IN THE TUBE. THE ENTIRE DEVICE WAS PULLED OUT OF THE OPERATIVE PORT. ATTENTION WAS THEN TURNED TO THE LEFT OSTIUM WITH ANOTHER ESSURE DEVICE WHICH WAS AGAIN ADVANCED AND ACTIVATED IN THE USUAL FASHION. THE SHEATH AGAIN WAS STILL ATTACHED TO THE COIL, AND THE ENTIRE DEVICE WAS WITHDRAWN AGAIN. A THIRD ESSURE DEVICE WAS OPENED, AND INSERTED AFTER CONFIRMING STEPS TO DEPLOY FROM MANUFACTURER'S INSTRUCTION, THE WHEEL STOPPED MIDWAY AFTER DEPLOY BUTTON WAS PUSHED, AND THE ENTIRE DEVICE WAS PULLED OUT. DECISION WAS MADE TO PERFORM LAPAROSCOPIC TUBAL FULGURATION. ONCE INCISIONS WERE MADE THE ESSURE COIL WAS VISIBLE AND PERFORATING THROUGH THE LEFT CORUNA. SMALL AMOUNT OF BLEEDING WAS PRESENT AFTER REMOVAL OF THE COIL AND IT WAS COAGULATED.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
HYSTEROCOPIC ESSURE TUBAL OCCLUSION.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE #2
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.
DEVICE #3
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031086	BAYER / CONCEPTUS	7/23/2013	7/30/2013

Event Information:

Event Date (B3): 6/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): A96184

Single Use:
Implant Date (E6): 6/24/2013
Explant Date (E7): 7/18/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE ON (B)(6) 2013. WITHIN 24 HRS, I WAS VOMITING AND IN SEVERE PELVIC AND ABDOMINAL PAIN. THE IMPLANTING DOCTOR WOULD NOT EVEN SEE ME OR ACKNOWLEDGE THERE WAS A PROBLEM. I CONTINUED FOR 3 WEEKS WITH SEVERE NAUSEA, RASH ON LEFT SIDE, PELVIC PAIN AND PRESSURE, HEADACHE AND METALLIC TASTE IN MOUTH UNTIL SURGICAL REMOVAL ON (B)(6) 2013 BY A SURGEON IN (B)(6). DURING SURGERY, IT WAS DISCOVERED THAT THE LEFT COIL HAD FALLEN OUT OF MY TUBE AND WAS IN MY UTERUS. THE SURGEON WAS ABLE TO RETRIEVE IT INTACT AS WELL AS REMOVE THE OTHER COIL FROM MY FALLOPIAN TUBE. DATES OF USE: (B)(6) 2013. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031161	BAYER AG	7/24/2013	7/31/2013

Event Information:

Event Date (B3): 7/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): BAYER
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 5/31/2012
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE GOTTEN THE ESSURE PROCEDURE DONE IN (B)(6) 2012 AND IT IS (B)(6) 2013. CURRENTLY I HAVE SUFFERED REALLY BAD HEADACHES AND LOTS OF PELVIC PAIN. I DON'T KNOW WHO TO GO TO OR WHO TO TURN TO. DIAGNOSIS OR REASON FOR USE: BLOOD TYPE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031162	CORPORATE HEADQUARTERS	7/24/2013	7/31/2013

Event Information:

Event Date (B3): 7/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): BAYER CONTRACEEPTIVE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 748471

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE FOUR KIDS I HAD A SET OF TWINS ON (B)(6) 2010. I WENT TO CONSULT THE OBGYN ON GETTING A PERMANENT FIX BECAUSE I DO NOT WANT ANYMORE KIDS. THIS WAS DONE ON (B)(6) 2011. THE DOCTOR I SPOKE WITH SAID THERE WOULD BE NO LONG TERM PAINS, I WILL BE UP AND GOING SAME DAY AND NEXT DAY. THERE WOULD BE NO INCISIONS MADE. HE PRETTY MUCH SOLD ME ON THIS DEVICE. SAID HE WAS NEVER HEARD OF ANY PROBLEMS OR THEM GOING WRONG ON HIS BOOKS THAT IS. SO I THOUGHT HAVE TWO KIDS THEN A SET OF TWINS THAT WOULD BE GREAT. WELL EVERYTHING WAS GOOD WITH IT UNTIL RECENTLY. I HAVE HAD IT 2 1/2 YEARS AND NOW I HAVE HAD PELVIC PAINS, LOWER BACK PAINS, MEMORY LOSS, TIREDNESS, I HURT A LOT I AM NOT ABLE TO GO OUT AND HAVE FUN WITH MY KIDS, AND THERE IS A LOT MORE ISSUES I HAVE WITH THIS DEVICE CALLED THE ESSURE. EVERY TEST I HAVE HAD SO FAR HAS CAME BACK GOOD I HOPE TO HAVE AN MRI SOON. I AM NOT SURE WHAT THE OUTCOME OF THIS WILL BE YET. I AM STILL HAVING ALL KIND OF TEST DONE TO FIGURE IT OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031221	BAYER	7/25/2013	8/1/2013

Event Information:

Event Date (B3): 9/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 0000

Single Use:
Implant Date (E6): 9/15/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HELLO (B)(4), NY NAME IS (B)(6). I'M A SINGLE MOTHER OF 6 GIRLS. I HAVE THE SAME OB/GYN DOCTOR FOR THE PAST 8 YEARS, SO WHEN I ASK HER TO TIE MY TUBES AFTER MY LAST BABY, I WAS SURPRISED WHEN SHE SAID SHE PUT THE ESSURE INSIDE ME BECAUSE SHE SAID I WAS FERTILE, BUT I FEEL LIKE I WAS NOT THE ONE TO TRY SOMETHING ON MY BODY BECAUSE I'M OVERWEIGHT AND AT THE TIME, I HAD PROBLEMS WITH MY BLOOD PRESSURE. I HAD MY LAST DAUGHTER (B)(6) 2010. SHE FINALLY DID THE SURGERY FOR MY TUBES TO BE TIED AND THE ESSURE IN (B)(6). SHE ADDED THE ESSURE AT THE LAST MINUTE BECAUSE SHE BROUGHT THE PAPER WORK IN THE ROOM THE DAY OF THE SURGERY AT THE HOSPITAL. SO I DID NOT HAVE TIME TO ASK ABOUT SIDE EFFECTS, SHE DID NOT TELL ME SIDE EFFECTS ABOUT HAVING MY TUBES TIES. I STARTED HAVING PROBLEMS WITHIN 3 MONTHS OF THE SURGERY. I TOLD HER THAT I STARTED BLEEDING TWO DAYS, THEN I WOULD STOP THEN WITHIN THAT SAME WEEK I WOULD COME ON MY PERIOD. WHILE ON MY PERIOD, I STARTED BLEEDING OUT OF MY RECTUM FIRST, THEN MY VAGINA. ALSO, I WAS HAVING SHARP PELVIC PAIN, PAIN USING THE BATHROOM, HARD TO PICKUP MY YOUNGEST DAUGHTER, HURT TO LAY ON MY SIDE TOO LONG. I WAS TOSSING AND TURNING ALL NIGHT AND PAIN DURING INTERCOURSE. MY DOCTOR HAD GIVEN ME DIFFERENT PRESCRIPTIONS FOR PAIN FOR A WHOLE YEAR. SHE WOULD TELL ME THAT SHE COULD TAKE THE THING OUT BECAUSE I WAS GOING BACK AND FORTH TO EMERGENCY ROOM BECAUSE I COULD NOT MOVE, BUT THE DOCTORS AT THE HOSPITAL DID DIFFERENT TEST TO SEE IF IT WAS CAUSED BY A STD OR ANYTHING ELSE. THE DOCTORS SAID THAT THE TESTS CAME NEGATIVE, SO THEY WOULD TELL ME TO GO BACK TO MY OB/GYN DOCTOR BUT SHE SAID SHE COULD NOT TAKE IT OUT. SO AFTER GOING THROUGH SOME PERSONAL PROBLEMS AND STILL SEVERE PAIN. I GOT A PRIMARY CARE DOCTOR AND THE NEW DOCTOR HELPED ME FIND ANOTHER OB/GYN DOCTOR. SO I STARTED GOING TO THE NEW DOCTOR IN (B)(6), I TOLD HER ABOUT MY PROBLEMS. SO

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SHE REVIEWED MY FILE AND SHE SAID SHE COULD HELP ME BUT SHE WANTED TO RULE OUT ANYTHING ELSE. FIRST, I HAD TO MAKE SURE THAT MY TUBES WERE STILL TIES BECAUSE SHE SAID IN MY FILE IT SHOWED THAT SHE DID NOT SCHEDULE ME FOR A HSG TO SHOW IF THEY WERE TIED. SHE THEN REFERRED ME TO GASTROLOGY DOCTOR, TO SEE IF THAT'S WHY I'M BLEEDING OUT OF MY RECTUM. I WENT TO SEE THAT DOCTOR I HAD TO GET COLON CLEAN TO SEE IF THE BLEEDING WAS COMING BECAUSE I HAD CANCER. I HAD THE COLON CLEANING YESTERDAY, BUT THE GOOD NEWS IS THAT I DO NOT HAVE CANCER. BUT THEY STILL DO NOT KNOW WHY I'M BLEEDING, SO IT STILL LOOKS LIKE THE CAUSE GOES BACK TO THE ESSURE. I WOULD LIKE TO SEE A RECALL FOR THE ESSURE AND ALSO, A LAW FOR DOCTORS TO ALWAYS TALK TO THEIR PATIENTS ABOUT ANY SIDE EFFECTS ABOUT ANYTHING THEY PERFORM ON THEIR PATIENTS. MY OLD DOCTOR DID NOT GIVE ME ANY INFORMATION ABOUT EITHER OF THE PROCEDURES. I'M STILL IN PAIN EVERYDAY, SO PLEASE, IF YOU CAN PLEASE ME AND OTHERS, ON (B)(6) THAT HAVE TOLD THEIR STORIES ABOUT HAVING THE ESSURE. DATES OF USE: (B)(6) 2010 - (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031236	CONCEPTUS, INC	7/27/2013	8/2/2013

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE AN IMPLANT CALLED ESSURE THAT ARE IMPLANTED IN MY FALLOPIAN TUBES AND ONE OF THE COILS MIGRATED OUT OF BODY AND NOW I AM PREGNANT WITH A BABY. I HAVE GAINED A LOT OF WEIGHT, I HAVE GONE FROM A SIZE 4 TO SIZE 10. MY PREGNANCIES IN THE PAST HAVE NEVER HAD ANY PROBLEM BEFORE AND THIS CURRENT PREGNANCY HAS A LOW TESTOSTERONE COUNT AND NOW I HAVE TO TRY TO RAISE THOSE NUMBERS UP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031096	CONCEPTUS	7/29/2013	7/31/2013

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/31/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE REPORTER STATED THAT HER IMPLANT (RIGHT) FELL OUT ON (B)(6). SHE IS SURE OF THE DATE BECAUSE SHE SAW IT IN THE TOILET. SINCE THE IMPLANT, SHE HAS GAINED A GREAT DEAL OF WEIGHT FROM SIZE 4 TO SIZE 10, NOW HAS A VIRUS ON HER PAP SMEAR AND IS NOW (B)(6) WEEKS PREGNANT WITH LOW PLACENTA. SHE IS VERY CONCERNED ABOUT THE BABY SINCE ONE (LEFT) IS STILL IN AND NOT SURE HOW THAT WILL EFFECT THE FETUS. ALSO CONCERNED BECAUSE SHE IS HAVING ABDOMINAL PAIN, TINGLING IN HER LEGS, NAUSEA THAT STARTED 3 MONTHS BEFORE PREGNANCY, BAD MIGRAINES AND VAGINAL BURNING. THE REPORTER STATES THAT THIS SHOULD BE TAKEN OFF THE MARKET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031257	CONCEPTUS, INC.	7/29/2013	8/5/2013

Event Information:

Event Date (B3): 7/29/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING SO MANY PROBLEMS WITH THE ESSURE. MY DOCTOR REFUSES TO SEE ME BECAUSE THEY THINK I'M MAKING EVERYTHING UP. MY HAIR HAS BEEN FALLING OUT MORE AND MORE. I'VE GAINED A LOAD OF WEIGHT AND NOW I GOT DIAGNOSED WITH HIGH BLOOD PRESSURE AND DIABETES. EVER SINCE I GOT THIS DANGEROUS GARBAGE PUT IN MY TUBES MY BOYFRIEND NOTICE I'VE BEEN SEIZING MORE. I'M EVEN ON MESS. SO IT HAS TO BE THE ESSURE DOING IT, BECAUSE ALL MY TEST I GOT FOR THE SEIZING CAME BACK NORMAL. I CAN GO ON AND ON AND ON. REMOVE THIS PRODUCT OFF THE SHELFS. I WASN'T WARNED AND I DON'T WANT TO SEE ANOTHER FEMALE GO THRU THIS.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	7/29/2013	8/9/2013

Event Information:

Event Date (B3): 7/24/2013 **Report Date (B4): 7/29/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): A78076

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IT WAS NOTICED THAT THE TIP OF THE ESSURE COIL WAS BENT BEFORE INSERTING COULD INTO FALLOPIAN TUBE. DEPLOYMENT DEVICE REMOVED AND OTHER OPENED. THERE WAS NO HARM TO THE PATIENT.
WHAT WAS THE ORIGINAL INTENDED PROCEDURE?
STERILIZATION.
DEVICE #1
IS THIS A LABORATORY DEVICE OR LABORATORY TEST?
NO.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00013	BAYER HEALTHCARE LLC, FORMERLY CONCEPTUS, INC	7/31/2013	8/2/2013

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/16/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE ON (B)(6) 2013. PHYSICIAN PLACED ONE ESSURE DEVICE INTO PT'S RIGHT AND LEFT FALLOPIAN TUBES. ON (B)(6) 2013, PT WAS ADMITTED FOR PELVIC INFLAMMATORY DISEASE AND COMPLICATED UTI. A TRANSVAGINAL AND TRANSABDOMINAL ULTRASOUND WAS PERFORMED, SHOWED PELVIC INFLAMMATORY CHANGE WITH PELVIC FLUID. INFLAMMATORY APPEARED TO BE CENTERED IN THE RIGHT ADNEXA. OPERATIVE LAPAROSCOPY IDENTIFIED A RIGHT SIDE TUBAL OVARIAN ABSCESS. LARGE PORTION OF THE RIGHT SIDE TUBE WAS REMOVED. THE RIGHT ESSURE COIL WAS LEFT IN PLACE. PT WAS DISCHARGED ON (B)(6) 2013. ON (B)(6) 2013, POST SURGERY, IS DOING WELL. THE PHYSICIAN BELIEVES GIVEN THE SHORT INTERVAL IN BETWEEN PLACEMENT OF THE COILS AND THE ONSET OF THE PT'S SYMPTOMS, 5 DAYS, IT IS LIKELY THAT THE COILS OR THE PROCESS OF PLACING THE COILS, DID LEAD TO THE COMPLICATION. THEORETICALLY, BACTERIA COULD HAVE BEEN PUSHED INTO THE UPPER GENITAL TRACT DURING THE HYSTEROSCOPY AND THE COILS ACTED AS A NIDUS FOR THE ONSET OF INFECTION. PHYSICIAN DIAGNOSIS: RIGHT FALLOPIAN TUBE, SALPINGECTOMY: ACUTE SALPINGITIS WITH ABSCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00014	BAYER HEALTHCARE LLC (FORMERLY CONCEPTUS, INC)	7/31/2013	8/2/2013

Event Information:

Event Date (B3): 7/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE DONE IN 2006. (B)(6) 2013, PELVIC ULTRASOUND: IMPRESSION SHOWS ESSURE WIRES ARE MALPOSITIONED. (B)(6) 2013, OFFICE VISIT WITH PHYSICIAN FOR SECOND OPINION. PT STATES SHE HAS PAIN IN HER ABDOMINAL AREA, FATIGUE AND BLEEDING SINCE THE ESSURE PROCEDURE WAS FIRST DONE. PT ALSO HAS PAIN UNDER HER RIGHT RIBS. IMPLANT PHYSICIAN RECOMMENDS HYSTERECTOMY. (B)(6) 2013 CT PELVIS SCAN SHOWS THE ESSURE COILS WITHIN THE TUBAL OSTIA. (B)(6) 2013 PHYSICIAN PERFORMED A TOTAL VAGINAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY. PHYSICIAN'S DIAGNOSIS: THREE METALLIC COILED WIRES ARE PRESENT, TWO PROTRUDING FROM THE RIGHT OVIDUCT OPENING (TWO EXPOSED TURNS/COILS EACH) AND ONE FROM THE LEFT OVIDUCT OPENING (TWO EXPOSED TURNS/COILS). (B)(6) 2013 PHYSICIAN STATES PT IS DOING FINE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031292	CONCEPTUS	8/1/2013	8/8/2013

Event Information:

Event Date (B3): 12/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/13/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL PUT IN 6 WEEKS AFTER GIVING BIRTH TO MY FIFTH CHILD. WITHIN ONE WEEK OF HAVING THIS PROCEDURE, I BEGAN TO EXPERIENCE BLURRED VISION, HEART PALPITATIONS, SEIZURE LIKE SHAKES, COLD AND NUMBNESS IN MY EXTREMITIES AND BLACKING OUT/DIZZINESS. SOMETIMES IT WOULD LAST FOR DAYS, OTHER TIMES ON AND OFF THROUGHOUT A DAY OR TWO. IT HAS NOW BEEN ALMOST 3 YEARS AND I HAVE HAD NUMEROUS TEST RAN BUT EVERYTHING COMES BACK PERFECT. I AM NOW ON TOP OF EVERYTHING ELSE ALMOST CRIPPLED AT TIMES FORM JOINT AND MUSCLE ISSUES. THESE STARTED ALONG WITH THE OTHER SYMPTOMS BUT SEEM TO HAVE MULTIPLIED SINCE. THERE ARE DAYS ON END WHEN I LIVE ON IBUPROFEN AND CAN NOT GET OUT OF BED BECAUSE OF THE PAIN. I ALSO HAVE 10 DAY HEAVY PERIODS WITH BREATH TAKING PAIN AND CAN FEEL THE COILS IN MY TUBES. MY QUALITY OF LIFE WAS PEDESTAL UNTIL I CHOSE THESE HORRIBLE COILS AND I BELIEVE THEY SHOULD BE OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031320	CONCEPTUS, INC.	8/2/2013	8/9/2013

Event Information:

Event Date (B3): 2/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6): 2/20/2013
Explant Date (E7): 5/30/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE BY CONCEPTUS INC WAS IMPLANTED WITHOUT INCIDENT BY MY (B)(6) OB/GYN IN (B)(6) 2013. AFTER HAVING BEEN IMPLANTED WITH THE DEVICES, I EXPERIENCED VARIOUS, WORSENING PAINS AND ILLNESSES WHICH I HAD NEVER BEFORE EXPERIENCED. THESE SYMPTOMS LASTED UNTIL I FINALLY HAD ESSURE REMOVED ON (B)(6) 2013, AGAIN BY (B)(6). THE SICKNESS AND PAIN I HAD BEEN SUFFERING FROM HAVE STEADILY DIMINISHED, OR DISAPPEARED ENTIRELY, NOW THAT THE ESSURE COILS ARE NO LONGER IN MY BODY. THE SYMPTOMS I EXPERIENCED WHILE ESSURE WAS IN MY BODY ARE AS FOLLOWS: FEVER; CHILLS; SWEATING; LETHARGY/FATIGUE; INTENSE, DEBILITATING HEADACHES; RELENTLESS AND SHARP PELVIC PAINS; ABDOMINAL SWELLING; NAUSEA; DIZZINESS; CONFUSION; INABILITY TO CONCENTRATE; SICKLY APPEARANCE AND PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031371	ESSURE	8/7/2013	8/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6). IN (B)(6) 2012, I HAD THE ESSURE PROCEDURE DONE. SINCE THEN, I HAVE NOTICED SEVERE PAIN IN MY LEFT OVARY, BACK PAIN, ABDOMINAL PAIN AND NAUSEA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031370		8/7/2013	8/14/2013

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): B09709

Single Use:
Implant Date (E6): 7/30/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE ON (B)(6) 2013. (B)(6), AT 9:45 PM, I HAD A BOWEL MOVEMENT THAT SET OFF A MIGRAINE LASTING UNTIL (B)(6). I WENT TO THE EMERGENCY DEPT AT (B)(6), THURSDAY WHEN IT HAPPENED. HAD A CT SCAN PERFORMED WHICH CAME BACK NEGATIVE, WAS GIVEN COMPAZINE AND BENADRYL THAT DIDN'T HELP, WAS GIVEN IMITREX THAT MADE IT WORSE, THEN WAS GIVEN TORADOL THAT HELPED ENOUGH FOR ME TO GO HOME. I SLEPT FOR 2 HOURS AND WOKE UP SCREAMING IN PAIN FROM THE MIGRAINE AGAIN. SAW MY PRIMARY CARE DOCTOR, (B)(6) ON (B)(6), AND WAS GIVEN A SHOT OF DEMEROL, TOLD TO TAKE A NAP. WOKE UP SCREAMING AGAIN FROM THE NAP. (B)(6), I DID NOT SLEEP, MY MIGRAINE HAD BECOME A 10 ON THE PAIN SCALE BY THE TIME I GOT TO THE HOSPITAL ON (B)(6). I WAS GIVEN A PELVIC EXAM, CAME BACK NEGATIVE, A PELVIC ULTRASOUND, CAME BACK NEGATIVE. GIVEN COMPAZINE AND BENADRYL AGAIN, THEN FENTANYL AND WAS ABLE TO GO HOME AND SLEEP ALL NIGHT, FINALLY. I FEEL BETTER TODAY, (B)(6), BUT THE MIGRAINE IS STILL WITH ME. ALL SYMPTOMS OF MY PAIN WERE - URINATING AND STOOLS SENT 10 SCALE PAIN WAVES THROUGH MY HEAD, BENDING OVER, STANDING UP, SITTING DOWN FOR MORE THAN A MINUTE, RAISING MY ARMS, TILTING MY HEAD BACK OR FORWARD, ALL SENT 9 SCALE WAVES THROUGH MY HEAD. I WAS NAUSEOUS MOST OF THE TIME, LIGHTS AND SOUNDS BOTHERED ME WHETHER LIGHT OR DARK OR LOUD OR QUIET. MY NECK GOT STIFF, SPREAD DOWN TO MY SHOULDERS AND UPPER BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031372	CONCEPTUS, INC.	8/8/2013	8/14/2013

Event Information:

Event Date (B3): 1/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/10/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTS HAVING THE FOLLOWING SYMPTOMS SINCE IMPLANTATION OF HER ESSURE: SEVERE PELVIC AND BACK PAIN, TINGLING AND NUMBNESS OF HER LIMBS AND EXTREMITIES, METALLIC TASTE IN MOUTH, HEAVY PAINFUL MENSTRUAL CYCLES WITH LARGE BLOOD CLOTS, FLUTTERING IN ABDOMEN. SHE STATED THAT EACH TIME SHE RETURNS TO HER PHYSICIAN, HE DIAGNOSES HER WITH UTI, PID AND BACTERIAL VAGINOSIS. SHE HAS ALSO GAINED 30 LBS, MOST OF WHICH IN HER STOMACH. SHE SAID THAT SHE LOOKS PREGNANT ALTHOUGH SHE IS NOT. SHE REPORTS FEELING A STICKING SENSATION IN CERTAIN POSITIONS WHICH LEAD HER TO BELIEVE THAT THE COILS HAVE MIGRATED. SHE HAS JOINED A GROUP OF OVER 1000 WOMEN ON (B)(6) WHO ALL HAVE CLAIMS OF THE SAME SYMPTOMS SINCE ESSURE IMPLANTATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031390		8/8/2013	8/14/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT HAS RUINED MY QUALITY OF LIFE. I SUFFER PAIN FROM SEXUAL INTERCOURSE ALL THE TIME, BACK PAIN, LOWER PELVIC PAIN, SPOTTING BEFORE MY PERIODS AND WORSE PERIODS. IT'S HORRIBLE. I WOULD NEVER RECOMMEND THIS TO ANYONE. ALL MY PROBLEMS BEGAN AFTER THE INSERTION OF ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031382	CONCEPTUS INC	8/8/2013	8/15/2013

Event Information:

Event Date (B3): 8/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 8/6/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN 2010. SINCE THAT TIME I HAVE HAD HEAVY LONGER PERIODS. IN (B)(6) 2013, I WOKE TO SEVERE PAIN AND WAS TAKEN TO THE ER. THE DOCTORS DID A CAT SCAN. I COULD SEE A DEVICE NOT WHERE IT WAS SUPPOSED TO BE. I WENT TO MY OBGYN AND SHE SAID ONE OF THE ESSURE COILS RIPPED OFF OF MY TUBES AND LAID ON TOP OF MY RECTUM CAUSING SEVERE PAIN AND THE OTHER ONE WAS HANGING ON. MY DOCTOR ENDED UP PERFORMING SURGERY TO REMOVE THE ESSURE COILS AND MY TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031403		8/9/2013	8/16/2013

Event Information:

Event Date (B3): 1/5/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/5/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE TUBAL IMPLANTS IN 2009. SINCE THEN I HAVE HAD A BABY. THE COILS ARE NOT IMBEDDED IN MY BOWELS. MY DOCTOR SAID HE DOESN'T KNOW THE LONG TERM RISK OF WHERE THEY ARE OR IF THEY WILL MIGRATE AGAIN. AFTER THE BIRTH OF MY DAUGHTER, I HADN'T TUBES TIED BY DOCTOR (B)(6). DURING THE PROCEDURE HE ATTEMPTED TO FIND THE COILS AND THEY WERE IN MY BOWELS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031413		8/12/2013	8/16/2013

Event Information:

Event Date (B3): 12/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2006, I HAD THE ESSURE PROCEDURE AT (B)(6) HOSP IN (B)(6). ABOUT 6 MONTHS AFTER PROCEDURE, I HAD BEGAN TO HAVE MASSIVE MENSTRUAL FLOWS, SEVERE CRAMPING, MIGRAINES, WEIGHT GAIN AND LOWER BACK PAIN AND MYSTERIOUS RASHES THAT LASTED FOR MONTHS AND THEN MYSTERIOUSLY WENT AWAY ONLY TO REOCCUR A FEW MONTHS LATER. ALL THE DOCTORS I BEGAN TO SEE COULD NOT TELL ME WHAT WAS CAUSING ALL OF THESE THINGS AND ALL AT ONCE. MOST OF THEM THOUGHT I WAS CRAZY. NO IN PAIN. NEVER AS BAD AS I MADE IT OUT TO BE. IN 2010 I WAS RUSHED TO THE ER IN (B)(6) FOR SEVERE CRAMPS AND EXTREMELY HEAVY MENSTRUAL BLEEDING. AT SOME POINT, I PASSED OUT. THE NURSES AND DOCTORS COMMENT ON THE MASSIVE BLOOD CLOTS I WAS PASSING (BASEBALL SIZED). SEX WAS SO PAINFUL THAT ONE YR AFTER ESSURE AND TWO YRS AFTER MARRIAGE I COULD NOT STAND IT ANYMORE. THE PAIN WAS SO UNBEARABLE THAT WE CEASED ALL INTERCOURSE AND ONE YR LATER SEPARATED. OVER THE PAST SEVEN YRS, I HAVE CONTINUED TO HAVE MASSIVE CRAMPS, MIGRAINES, BACK PAIN, AND RESORTED TO TAKING THE DEPO-PROVERA SHOT TO TAME THE MASSIVE BLEEDING. I'M NOT USING 3 OR MORE PADS AN HR. IM USING 7 OR 8 PADS AN HR. ALL THE WHILE, DOCTORS ARE TELLING ME ITS NORMAL. ITS CAUSED BY X. IT COULD BE CAUSED BY Y. LAST WEEK I DECIDED TO HAVE AN ABLATION SO THAT I COULD STOP THE DEPO SHOTS AND HAVE LIGHTER CRAMPS. MY DOCTOR DILATED MY CERVIX, DID A D&C AND SEEN SOMETHING NOT NORMAL. HE FOUND BOTH OF MY INSERTS STICKING OUT OF MY UTERUS. HE ADMITTED THAT HE MAY HAVE AGGRAVATED THE INSERTS WHILE DOING THE D&C AND HAS SINCE BEEN CAUSING ME SEVERE PAIN. MY BACK PAIN HAS INCREASED AND THE SAME DAY AS THE D&C, I DEVELOPED A MIGRAINE THAT REQUIRED ME TO AGAIN GO TO THE ER FOR AN IMATREX SHOT. HE HAS NOW SCHEDULED ME FOR A SURGERY TO REMOVE THE INSERTS BUT DOES NOT PROMISE THAT HE WILL NOT HAVE TO DO A HYSTERECTOMY. I WAS NOT

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TOLD THAT THE INSERTS WERE MADE OF NICKEL, AS I HAVE A SLIGHT ALLERGIC REACTION TO MOST METAL JEWELRY AND PANTS BUTTONS, I WOULD NOT HAVE GONE AHEAD WITH THE PROCEDURE. I WAS NOT TOLD THAT THERE WAS EVEN A SLIGHT CHANCE THAT THE INSERTS WOULD MIGRATE AND POTENTIALLY PERFORATE ANY OF MY ORGANS....

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031448	BAYER	8/13/2013	8/19/2013

Event Information:

Event Date (B3): 4/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628443

Single Use:
Implant Date (E6): 4/15/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE 4 YRS AGO. I AM ALLERGIC TO NICKEL BUT DOCTOR INSISTED I WOULD BE OK. WITH NO PRIOR SYMPTOMS, SHORTLY AFTER THE PROCEDURE I GAINED 45 LBS, DIAGNOSED WITH HYPOTHYROIDISM, FIBROMYALGIA DUE TO SEVERE PAIN THROUGHOUT MY BODY, A RING IN MY ESOPHAGUS FROM AN UNK ALLERGY (MY ASSUMPTION WOULD BE THE NICKEL ALLERGY FROM THE ESSURE) WHICH CAUSES ME TO CHOKE EVEN ON WATER. WORSENING DEPRESSION DUE TO PAIN. VERTIGO AND EAR PAIN WITH NO KNOWN CAUSE (ENG WAS INCONCLUSIVE). MIGRAINES WITH AURAS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031449	BAYER	8/13/2013	8/19/2013

Event Information:

Event Date (B3): 9/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 729920

Single Use:
Implant Date (E6): 9/30/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACED WITHIN MY FALLOPIAN TUBES AND SINCE I HAVE EXPERIENCED INCREASING AND SEVERE PAIN IN MY ABDOMEN. THIS PAIN FEELS AS THOUGH MY OVARIES ARE TWISTING AND BEING STABBED. THIS PAIN IS INTERMITTENT AND USUALLY OCCURS DURING INTERCOURSE, OR ANY TYPE OF MOTION THAT FORCES ME TO BARE DOWN OR TWIST. I HAVE SOUGHT OUT MANY DOCTORS ONLY TO BE TOLD THAT IT WAS NOT THE ESSURE YET THEY COULD NOT FIND ANY REASON FOR MY PAIN. I WAS PLACED BACK ON BIRTH CONTROL AND EVEN WENT TO PHYSICAL THERAPY IN AN ATTEMPT TO SOLVE MY PAIN. THIS PRODUCT IS FAULTY AND SHOULD NOT BE ADVERTISED WITH NO LONG TERM SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031459		8/14/2013	8/21/2013

Event Information:

Event Date (B3): 8/5/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 915882

Single Use:
Implant Date (E6): 3/22/2013
Explant Date (E7): 8/5/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACED IN (B)(6) 2013. I HAD A MRI SCAN DONE AFTER I INJURED MY BACK AT WORK. THE SCAN WAS PERFORMED ON (B)(6) 2013. WHILE I WAS IN THE MRI MACHINE, AND AFTER THE MRI WAS COMPLETE, I BEGAN EXPERIENCING HORRIBLE PELVIC PAIN. I CALLED AND SET UP AN APPOINTMENT TO MEET WITH MY OBGYN THAT PLACED THE ESSURE COILS. HE ALSO SAID IT WAS TOO COINCIDENTAL THAT THE PAIN STARTED RIGHT AFTER AN MRI WAS CONDUCTED BEING THAT THE COMPANY THAT MAKES ESSURE SAYS MRI'S ARE COMPLETELY SAFE. NEEDLESS TO SAY, ON (B)(6) 2013 I LOST MY TUBES AND THE ESSURE WAS REMOVED. AFTER I CAME OUT OF SURGERY, THE ONLY PAIN THAT REMAINED WAS WHERE THE INCISIONS WERE. I HAVEN'T EXPERIENCED ANY MORE PELVIC PAIN NOW THAT THE ESSURE HAS BEEN REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031458		8/15/2013	8/21/2013

Event Information:

Event Date (B3): 12/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/2/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2011, MY DR IMPLANTED THE ESSURE DEVICE IN ME. THE DAY OF THE SURGERY, MY STOMACH BLEW UP LIKE I WAS 9 MONTHS PREGNANT. I WAS ADMITTED TO THE HOSP AND THE DR HAD TO GO BACK IN AND SEE WHAT WAS GOING ON. THEY SAID I HAD FLUID IN ME. THEY COULD NOT EXPLAIN WHY. EVER SINCE THEN I HAVE HAD HEALTH PROBLEMS. I CAN BARELY FUNCTION AND NOW AT THE AGE OF (B)(6), MY HEALTH IS DECLINING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031460		8/15/2013	8/21/2013

Event Information:

Event Date (B3): 6/23/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/23/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM (B)(6) YRS OLD, A MARRIED MOTHER OF ONE. IN 2010 AFTER I HAD A MISCARRIAGE, I DECIDED TO HAVE THE ESSURE PROCEDURE DONE. I WAS TOLD IT WOULD BE LESS PAINFUL AND LESS INVASIVE THAN SURGICAL STERILIZATION. WHILE IT IS SAD READING THESE OTHER WOMEN'S STORIES, IT IS ALSO A RELIEF TO KNOW THAT ALL OF THE THINGS GOING ON WITH ME SINCE I HAD THE ESSURE PROCEDURE DONE ARE NOT IN MY HEAD. I HAD (ACCORDING TO MY DOCTOR) A LONGER THAN NORMAL RECOVERY PERIOD AFTER THE PROCEDURE. I WAS IN SERIOUS PAIN FOR OVER 2 MONTHS. I GRADUALLY STARTED TO FEEL LIKE MYSELF AFTER THAT EXCEPT FOR THE WEEK PRIOR TO MY PERIOD. I HAVE EXTREME SHOOTING PAINS THAT SOMETIMES TAKE MY BREATH AWAY IN THE WEEK LEADING UP TO MY PERIOD. DURING MENSTRUATION, I HAVE CRAMPS SO BAD I CAN BARELY MOVE. MY PERIODS HAVE BECOME SO HEAVY THAT I SOMETIMES HAVE TO WEAR ADULT DIAPERS TO CONTAIN EVERYTHING, BECAUSE I SOAK THROUGH A PAD IN 20 MINUTES. I HAVE GAINED AN EXTREME AMOUNT OF WEIGHT, I HAVE PAIN IN MY JOINTS, SEVERE HEADACHES AND DIZZINESS. I HAVE BEEN TOLD THAT THERE IS NO WAY IT COULD BE CONNECTED TO THE ESSURE COILS, BUT NO DOCTOR WILL ACTUALLY INVESTIGATE IT. I'M FRUSTRATED AND SCARED AND IN PAIN. NO ONE TOLD ME THESE THINGS COULD OR WOULD HAPPEN BEFORE I HAD THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031479	CONCEPTUS-BAYER	8/15/2013	8/21/2013

Event Information:

Event Date (B3): 10/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50700145

Single Use:
Implant Date (E6): 4/8/2013
Explant Date (E7): 10/2/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER 3 CHILDREN I KNEW THAT THE RISK OF ME HAVING ANY MORE CHILDREN WAS HIGH, SO MY HUSBAND AND I DECIDED WE WERE DONE HAVING BABIES. THREE SHORT MONTHS AFTER DELIVERY ON (B)(6) 2013, I WENT TO MY OBGYN WHO HAD SOLD ME ON THIS BRAND NEW DEVICE ESSURE; NO SURGERY, VIRTUALLY NO PAIN AND WE WOULD BE IN AND OUT WITHIN 15-20 MINUTES. FOR MONTHS, I DID COUNTLESS HOURS OF RESEARCH LOOKING FOR THE BAD IN ESSURE AND I COULD NOT FIND ANYTHING. ONCE IN THE SMALL OFFICE PROCEDURE ROOM I WAS LAID ON THE TABLE AND DOC SAID ALRIGHT LET'S BEGIN. HE INSERTS THE "DUCK BILL" AS EVERY WOMAN CALLS THEM AND THEN I HEAR HIM SAY OHH YOUR UTERUS IS TILTED, I THEN FELT A HORRIFIC PINCH, BURN AND STING HE HAD TO CLAMP MY CERVIX OPEN AND TILT MY UTERUS UP. I HAD TAKEN 2 MOTRINS BEFORE THE VISIT BECAUSE I WAS TOLD IT WAS JUST SOME CRAMPING. I WAS NOT PREPPED FOR WHAT CAME NEXT HE INSERTED THE CAMERA AND THE ESSURE PLACEMENT DEVICE AND I SCREAMED SO LOUDLY THAT MY HUSBAND WHO WAS IN THE WAITING ROOM ACROSS THE DOCTOR'S OFFICE COULD HEAR ME. IT FELT LIKE A MILLION KNIVES STABBING ME OVER AND OVER LIKE ICE FIRE RUSHING THROUGH MY RIGHT SIDE. EXCRUCIATING. THE LEFT SIDE WAS A LITTLE BREEZIER NOT NEAR AS MUCH PAIN STILL VERY UNCOMFORTABLE. SO WE ARE FINISHED AND I IMMEDIATELY START BLEEDING NOT THE SPOTTING THEY PREP YOU FOR BUT BLEEDING. THE NEXT FEW DAYS, I AM CRAMPING AND REALLY SORE AND HAVING TO TAKE TYLENOL AND MOTRIN TOGETHER EVERY 30 TO 45 MINUTES. ON (B)(6), I AM STILL BLEEDING LIKE A PERIOD AND IT HAS NOT STOPPED AND EVERY TIME I MOVE I FEEL A PINCHING STABBING PAIN ON MY RIGHT SIDE. I HAVE NOTICED A VERY DULL BACK PAIN DOWN MY SPINE THAT IS CONSTANT NEVER LETTING UP AND I CALL MY DOCTOR. THE NURSES ALWAYS TELL ME THAT THE PAIN AND BLEEDING IS NORMAL THAT I WILL GO BACK TO BEING ME IN A COUPLE OF WEEKS. BY (B)(6), I AM EITHER AT WORK OR I AM AT HOME CURLED IN A BALL ON MY BED I

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DON'T HAVE THE ENERGY, I DON'T HAVE THE STRENGTH, AND I HAVEN'T STOPPED BLEEDING. I HAVE LOST ALL SENSE OF HAPPINESS, I AM SEVERELY DEPRESSED, WHERE AS JUST A MONTH BEFORE I WAS OUTSIDE PLAYING WITH MY KIDDOS ENJOY LIFE AND HAVING A BALL MY LIFE WAS COMPLETE THEN ALL OF A SUDDEN SOMETHING HAPPENED AND IT SHATTERED. WHAT HAS...

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00015	BAYER HEALTHCARE LLC (FORMERLY CONCEPTUS, INC., MOUNTAIN VIEW CA)	8/15/2013	8/22/2013

Event Information:

Event Date (B3): 8/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A73747

Single Use: Y
Implant Date (E6): 6/26/2013
Explant Date (E7): 7/31/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE (B)(6) 2013. APPROX 3-4 WEEKS POST ESSURE, PT REPORTED SIGNIFICANT PAIN TO PHYSICIAN. IMAGING OF ESSURE DEVICES SHOWED CORRECT PLACEMENT. PT WAS GIVEN ANTIBIOTICS AND SCHEDULED NSAIDS. PT REQUESTED REMOVAL OF ESSURE DEVICES. ON (B)(6) 2013, PHYSICIAN REMOVED ESSURE DEVICES VIA B/L LAPAROSCOPIC SALPINGECTOMY. PT'S PAIN HAS RESOLVED SINCE SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031497	CONCEPTUS INC.	8/15/2013	8/22/2013

Event Information:

Event Date (B3): 8/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE STERILIZATION
Device Type (E2): ESSURE STERILIZATION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/21/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AFTER MY FOURTH CHILD WAS BORN. MY BABY WAS BORN (B)(6) 2013. I HAVE BEEN BLEEDING FOR ALL BUT 2 WEEKS SINCE THE BIRTH AND PROCEDURE. THE DOCTOR PUT ME ON BIRTH CONTROL TO 'REGULATE MY MENSTRUATING,' BUT IT HAS NOT HELPED. INSTEAD I HAVE ONLY HAD MORE PROBLEMS. I HAVE COMPLETELY STOPPED TAKING BIRTH CONTROL PILLS AND I STILL HAVE BLEEDING, PAIN, HEADACHES, FATIGUE AND DIZZINESS. THE NURSE AT THE DOCTOR'S OFFICE WHERE THE PROCEDURE WAS DONE TOLD ME I NEED TO HAVE AT LEAST A PARTIAL HYSTERECTOMY SINCE THE DEVICE IS NOW A PART OF THE FALLOPIAN TUBES AND THE UTERUS. I AM STILL WAITING TO OBTAIN MORE INSURANCE AS MY HUSBAND'S EMPLOYER CAN ONLY ADD ME IN (B)(6) 2013. I HAVE FAMILY PLANNING (B)(6), WHICH WILL NOT COVER A VISIT TO THE DOCTOR TO VERIFY NEEDING A HYSTERECTOMY AS THE DOCTOR SAID OVER THE PHONE. I DO NOT HAVE THE MONEY FOR THIS YET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031511	CONCEPTUS	8/16/2013	8/22/2013

Event Information:

Event Date (B3): 6/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 624484; 624106

Single Use:
Implant Date (E6): 8/22/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED (B)(6) 2007 AND HAVE RECENTLY HAD A BABY. SUFFERS WITH CONSTANT HEADACHE BACK PAIN METAL TASTE IN MOTH, NAUSEA, HEAVY PERIODS, IRREGULAR PERIODS STABBING PAIN ON LEFT SIDE OF LOWER STOMACH AREA, SKIN RASHES, DIZZINESS, FATIGUE AND DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031522	BAYER	8/19/2013	8/22/2013

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 10/1/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE. HAVE MULTIPLE PROBLEMS IN ABDOMINAL CAVITY PAIN, MOOD DEPRESSION, DEGRADING HEALTH. CONSTANT METAL TASTE, FIANCEE GETS POKED OR CAUSES SERIOUS PAIN DURING INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031529		8/19/2013	8/26/2013

Event Information:

Event Date (B3): 12/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A47945

Single Use:
Implant Date (E6): 12/28/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE DONE IN DEC 2012, HAVE HAD MIGRAINES, CONSTANT IRRITATION OF SKIN, RASHES THAT BREAK OUT CONTRACTION LIKE PAIN IN LOWER BACK, MEMORY LOSS, BEEN BLEEDING SINCE THEN, SEVERE CRAMPS, STOMACH PROBLEMS, SHARP SHOOTING PAINS DOWN BOTH SIDES OF BUTTOCKS INTO LEGS, FATIGUE, NAUSEA ALONG WITH SLEEP PROBLEMS AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031530		8/19/2013	8/26/2013

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/1/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE DONE ALMOST 5 YEARS AGO, HAVE HAD SO MANY PROBLEMS, HOT FLASHES, NIGHT SWEATS, HORMONE PROBLEMS, CRAMPING A LOT, BOWEL MOVEMENTS MAKE ME LIGHT HEADED AND NAUSEOUS AND I GET DIZZY, PELVIC PAIN, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031553	BAYER	8/19/2013	8/26/2013

Event Information:

Event Date (B3): 4/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50512931/789028

Single Use:
Implant Date (E6): 1/24/2011
Explant Date (E7): 4/5/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ANYONE WHO TELLS YOU THAT A NICKEL ALLERGY IS NO BIG DEAL IS EITHER IGNORANT OR LYING; NO IFS, ANDS, OR BUTTS, I WAS ONLY "SENSITIVE" TO NICKEL AND GOT REALLY SICK FROM THESE IMPLANTS. THE FIRST YEAR I HAD LOWER BACK AND PELVIC PAIN THAT I WROTE OFF AS SCAR TISSUE DOING ITS JOB. AFTER, THE MIGRAINES STARTED. I WENT TO A NEUROLOGIST. FIVE DIFFERENT CLASSES OF DRUGS OVER THE NEXT YEAR AND A HALF COULDN'T GET RID OF THEM. THERE WAS JOINT PAIN, THYROID PROBLEMS, EXTREME FATIGUE TO THE POINT OF INABILITY TO FUNCTION, DIZZINESS, RASHES, BRAIN FOG, CRAZY PERIODS. FIRST NON EXISTENT, THEN ANYWHERE FROM 18-53 DAYS APART. CHANGING TAMPONS AND PADS EVERY HOUR. I ALSO GAINED WEIGHT DUE TO ESSURE AND ITS EFFECTS, RIDICULOUS WEIGHT. I LOST WHOLE PERIODS OF TIME BECAUSE OF ESSURE. TIME I CAN'T GET BACK WITH MY FAMILY. TIME AND WAGES LOST FROM MY JOB. TENS OF THOUSANDS OF DOLLARS IN WAGES BECAUSE I COULDN'T WORK. OH AND BY THE WAY, MOST SYMPTOMS WENT AWAY UPON MY HYSTERECTOMY/REMOVAL OF ESSURE. LIKE THE NEXT MORNING. I FIND IT HARD TO BELIEVE THERE'S NO CORRELATION. PLEASE THINK LONG AND HARD ABOUT THE DAMAGE THIS "LIFE SAVING" DEVICE IS CAUSING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031554	CONCEPTUS	8/19/2013	8/26/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/4/2010
Explant Date (E7): 8/17/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ANXIETY, LOWERED IMMUNE SYSTEM, FATIGUE, ABDOMINAL PAIN AND SWELLING, PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE, CHEST PAIN, HOT FLASHES, NIGHT SWEATS, JOINT PAIN AND SWELLING, TINGLING IN HANDS AND FEET, BODY TREMORS, HEART PALPITATIONS, EXTREME VERTIGO. HYSTERECTOMY PERFORMED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031556	CONCEPTUS	8/19/2013	8/26/2013

Event Information:

Event Date (B3): 10/9/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 5/28/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM ALLERGIC TO NICKEL. THE DOCTOR NEVER SAID THESE CONTAINED NICKEL. I ALSO HAD BAD PERIODS AND PAIN SO BAD I WAS DOUBLED OVER. I ALSO HAD RASH FROM HEAD TO TOE. WHEN I HAD ESSURE REMOVED IN (B)(6) OF 2013, SYMPTOMS WENT AWAY WHICH INCLUDED BACK PAIN PELVIC PAIN CONSTANT INFECTIONS, BLOATING, WEIGHT, ETC. YOU NAME I HAD IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031557	CONCEPTUS/BAYER	8/19/2013	8/26/2013

Event Information:

Event Date (B3): 11/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/10/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE STERILIZATION PROCEDURE DONE IN (B)(6) 2008. SINCE THE IMPLANTATION OF THE NICKEL COILS I HAVE HAD NOTHING BUT PROBLEMS. SINCE IMPLANTATION MY PERIODS HAVE GRADUALLY GOTTEN WORSE OVER THE YEARS, TO THE POINT WHERE IT IS IMPOSSIBLE FOR ME TO LEAVE THE HOUSE FOR THE FULL 7 + DAY OF MY MENSTRUAL CYCLE BECAUSE I BLEED THROUGH MY TAMPONS AND PADS SO QUICKLY. I HAVE BEEN PASSING BLOOD CLOTS THAT ARE 2-3 INCHES IN DIAMETER. I HAVE SINCE BEEN DIAGNOSED WITH FIBROMYALGIA, DEPRESSION AND ANXIETY. I HAVE PAINS IN MY LOWER ABDOMEN THAT ARE SO BAD THEY CAUSE ME TO DOUBLE OVER, CRINGING FROM THE PAIN. I SUFFER FROM MIGRAINES, INSOMNIA, MOOD SWINGS, HAIR LOSS, BREAST TENDERNESS ALONG WITH MANY OTHER COMPLICATIONS, LACK OF INSURANCE COVERAGE AND MONEY PREVENTS ME FROM BEING ABLE TO RUN TO THE DOCTOR EVERY TIME I DOUBLE OVER IN PAIN, OR PASS A CLOT SO BIG IT MAKES ME LIGHT HEADED AND SCARED TO DEATH. ALL I WANT IS TO HAVE THESE THINGS REMOVED FROM MY BODY AND GET BACK TO A SOMEWHAT NORMAL LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031561	CONCEPTUS, INC.	8/19/2013	8/26/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/26/2003
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE ESSURE IMPLANTS IN 2002 I HAVE HAD ENDLESS SIDE EFFECTS, FROM NOT GETTING MY PERIOD FOR OVER A YEAR TO CONSTANT PAINFUL BLOATING. CONSTANT PMS SYMPTOMS! BLEEDING TOO MUCH OR NOT BLEEDING AT ALL, PAIN THAT IS UN-DESCRIBABLE! SIMILAR TO CRAMPS BUT NOT! CONSTANT HEADACHES AND BLOATED ALWAYS! I DID NOT DO THIS SOONER BECAUSE I THOUGHT IT WAS JUST ME FEELING LIKE THIS. BUT AFTER MY INTENSE RESEARCH I HAVE FOUND OUT THAT THERE ARE MILLIONS OF WOMAN GOING THROUGH THE SAME THING. DATES OF USE: (B)(6) 2003 - (B)(6) 2013. REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031543	CONCEPTUS, INC.	8/20/2013	8/26/2013

Event Information:

Event Date (B3): 1/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 758631/787224

Single Use:
Implant Date (E6): 1/14/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT PLACED IN MY TUBES IN 2011. SINCE THEN I HAVE BEEN HAVING SEVERE SIDE EFFECTS WHICH ARE HEAVY CRAMPS OR STABBING PAIN IN MY UTERUS, LOWER BACK PAIN, DIZZINESS, HEADACHES, NAUSEA, MOOD SWINGS, FATIGUE. I HAVE HAD SEVERAL BLOOD TESTS DONE TO REVIEW WHAT IS CAUSING THE ISSUE AND THEY COME BACK NORMAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031548	BAYER	8/20/2013	8/26/2013

Event Information:

Event Date (B3): 3/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/2/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE ON (B)(6) 2010. SINCE HAVING ESSURE PLACED, I HAD MANY HEALTH PROBLEMS. THESE SYMPTOMS ARE: BACK PAIN (SEVERE, LOWER BACK), HIP PAIN (BOTH HIPS), HEAVY PERIODS (SOAKING AN OVER NIGHT PAD IN 1 HOUR), BLOOD CLOTS DURING PERIOD, PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE, CONSTIPATION (BOWEL MOVEMENTS SOMETIMES 3 DAYS APART), BRAIN SHOCKS (DIAGNOSED AS TRIGEMINAL NEURALGIA CHEST PAINS (BOTH SIDES, RADIATES INTO SHOULDER), SPOTTING BETWEEN PERIODS, DISCHARGE (BETWEEN PERIODS), YELLOWISH GREEN COLOR, NO INFECTIONS FOUND), DIZZINESS, SPOTS/FLOATERS IN VISION, WEIGHT LOSS (UNEXPLAINED), HAIR LOSS (FALLING OUT 10-15 STRANDS AT A TIME), LOSS OF ENERGY (EVEN AFTER FULL NIGHTS SLEEP), HEART PALPITATIONS, NICKEL TASTE IN MOUTH, NUMBNESS/SWELLING IN HANDS (BOTH), OVARIAN CYSTS, PRESSURE IN BUTTOCKS WHEN SITTING, CAVITIES IN TEETH (ORAL HYGIENE DID NOT CHANGE AFTER IMPLANTATION), VIBRATING SENSATION IN LOWER ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	8/21/2013	9/3/2013

Event Information:

Event Date (B3): 8/19/2013 **Report Date (B4): 8/21/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B15004

Single Use:
Implant Date (E6): 8/19/2013
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN ADVANCED INTO LEFT OSTIA, DEPLOYMENT DEVICE INTRODUCED INTO TUBE. AS GUIDE WHEELED BACK INNER COIL WAS STILL ATTACHED TO DEPLOYMENT DEVICE. INNER COIL MOSTLY REMOVED WITH THE DEVICE BUT A PORTION OF INNER COIL REMAINED FREE-FLOATING IN UTERINE CAVITY. HYSTEROSCOPIC GRASPERS USED TO RETRIEVE THIS SEGMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031603	BAYER	8/22/2013	8/29/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I HAVE HAD THE ESSURE PROCEDURE DONE IN 2007, I HAVE HAD PROBLEMS WITH IRREGULAR BLEEDING, CRAMPING, NAUSEA, HEADACHES, AND BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031606	ESSURE	8/22/2013	8/29/2013

Event Information:

Event Date (B3): 8/20/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE COIL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/3/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE COILS (B)(6) 2006. I HAD MADE A DOCTOR APPOINTMENT FOR YESTERDAY (B)(6) 2013. I HAD BEEN FEELING NAUSEATED, DIZZY WITH A HEADACHE. I TALKED WITH MY DOCTOR AND SHE SUGGESTED, WE ALSO DO A PREGNANCY TEST. TO MY DISBELIEF IT SHOWED UP POSITIVE. IN ADDITION SHE ORDERED AN ULTRASOUND, TO BE SURE THAT EVERYTHING WAS IN THE RIGHT PLACE. I'M (B)(6) PREGNANT AT (B)(6). NO WHERE IN MY FUTURE DID I, EXCEPT TO HAVE ANOTHER CHILD. WHEN I WAS TOLD ABOUT THE PROCEDURE, (ESSURE) IT WAS CLEAR TO ME THAT MY TUBES WERE BLOCKED, AND THERE WOULD BE NO CHANCE THAT I COULD EVER HAVE ANY MORE CHILDREN. I AM SHOCKED, I'M HURT, I WISH I WAS TOLD THAT THERE WAS A CHANCE I COULD POSSIBLY BECOME PREGNANT YEARS AFTER THE PROCEDURE. SIX YEARS HAVE GONE BY AND THIS HAPPENS TO ME. I HAVE NO CONFIDENCE IN ANY OF AMERICA'S PROCEDURES. I FEEL THAT THE DOCTORS NEED TO BE AWARE THAT SOMETHING IS DEFINITELY WRONG WITH THIS ESSURE PROCEDURE. THE COMPANY ESSURE SHOULD HAVE DONE A PROPER CASE STUDY. GIVE THEIR CONSUMERS PROPER INFO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031605		8/22/2013	8/30/2013

Event Information:

Event Date (B3): 7/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/14/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL PUT IN THREE MONTHS AFTER I HAD TWINS IN 2010. FOUR DAYS AFTER SURGERY I HAD SEVERE BLEEDING, CLOTS AND PAIN. I CONTACTED DOCTOR WHO PERFORMED SURGERY, AND SAID IT COULD BE FROM THE ESSURE STENTS, OR THE DEPOVARA SHOT THEY PUT ME ON, WHILE MY BODY WAS HEALING. THE BLEEDING LASTED TWO MONTHS, I HAD NEWBORN TWINS, AND TWO OLDER CHILDREN I WAS TAKING CARE OF. I THEN STARTED EXPERIENCING PAIN IN STOMACH ON BOTH SIDES WHERE OVARIES ARE. I HAVE GAINED 30 POUNDS AFTER EXERCISING, AND GOOD NUTRITION. I SWEAT CONSTANTLY, SO MUCH IN SOAKED. I HAVE HAD STOMACH PAINS, HEADACHES, MY FEET ACHE CONSTANTLY. I HAVE MOOD SWINGS, TIRED, CAN'T SLEEP OFTEN DO TO STOMACH PAINS. EACH MONTH DURING MY PERIOD, I BLEED SO MUCH I HAVE TO CHANGE MY SANITARY NAPKIN EVERY TWENTY MINUTES, ALONG WITH PAIN IN MY UTERUS, FALLOPIAN TUBE AREA. I CAN FEEL IT THROB, ONLY HAPPENS DURING MY MONTHLY PERIOD. I HAVE WENT TO DOCTORS FOR ALL THESE PROBLEMS, NONE STARTED UNTIL AFTER I HAD THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031613	CONCEPTUS	8/22/2013	8/30/2013

Event Information:

Event Date (B3): 5/5/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 509015

Single Use:
Implant Date (E6): 5/5/2006
Explant Date (E7): 9/6/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2006, I HAD THE ESSURE PERMANENT BIRTH CONTROL PROCEDURE DONE. I HAVE HAD A NUMBER OF ISSUES OVER THE PAST YEAR THAT ARE CAUSED BY THIS PROCEDURE, HYPOTHYROIDISM, HIGH BLOOD PRESSURE, UNEXPLAINED RAPID WEIGHT GAIN, BURNING SENSATION IN LOWER BACK, KIDNEY AND BLADDER INFECTIONS, INCREASED ALLERGIES TO THE POINT I CARRY AN EPI-PEN. MOST OF THE TIME I FEEL SICK, TIRED, WEAK, HEADACHE, METAL TESTE IN MY MOUTH. INSISTED ON A PELVIC ULTRASOUND AND FOUND THAT THE ESSURE INSERTS ARE PROTRUDING FROM THE FALLOPIAN TUBES AND REQUIRE A HYSTERECTOMY TO BE DONE ON (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031620	CONCEPTUS	8/23/2013	8/29/2013

Event Information:

Event Date (B3): 10/30/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 624493

Single Use:
Implant Date (E6): 10/30/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM A MOTHER OF (B)(6) AND I HAVE BEEN MARRIED (B)(6) YEARS. I DECIDED I DID NOT WANT ANY MORE CHILDREN, SO I SCHEDULED A FAMILY PLANNING VISIT WITH MY GYN IN (B)(6) 2007. I REQUESTED INFORMATION ON TUBAL LIGATION AND THE IUD. I WAS TOLD I DID NOT QUALIFY FOR THE IUD BECAUSE I HAD MISCARRIAGES AND AN ECTOPIC PREGNANCY AND THAT THE ESSURE WAS BETTER THAN THE TUBAL LIGATION BECAUSE I DIDN'T HAVE TO HAVE SURGERY. AFTER I HAD THE ESSURE PROCEDURE, I HAVE BEEN SUFFERING SEVERAL HEALTH ISSUES. I STARTED TO EXPERIENCE COLD/FLU/ALLERGY LIKE SYMPTOMS JUST A FEW WEEKS AFTER THE PROCEDURE. I NOW HAVE ANEMIA AND FATIGUE DUE TO THE EXCESSIVE BLEEDING AND BLOOD CLOTS DURING MY MENSTRUAL CYCLE, UNEXPLAINED RASHES THAT COME AND GO, A TERRIBLE TASTE IN MY MOUTH THAT MAKES ME NAUSEOUS AND VOMIT, MY LIPS SWELL BEYOND RECOGNITION, I'M CONSTANTLY IN A FOG, LOSS OF CONCENTRATION, LOSS OF BALANCE, WEIGHT GAIN, BACK PAIN, ANXIETY, HIGH BLOOD PRESSURE, PANIC ATTACKS, MAJOR CRAMPING ALL THE TIME AND PAINFUL INTERCOURSE, MY STOMACH BECOMES SO BLOATED I LOOK LIKE I'M PREGNANT, HEADACHES THAT END UP IN A MIGRAINE, I'M LOSING A LOT OF HAIR, JOINT AND MUSCLE PAIN THAT NEVER GO AWAY, DIZZINESS, INSOMNIA, CRYING, SADNESS. NO NICKEL TEST WAS PERFORMED. I CAN'T EVEN PLAY WITH MY CHILDREN. I FEEL LIKE I'VE MISSED OUT ON THEIR LIVES FOR THE PAST 6 YEARS. I REALLY WANT TO HAVE THIS ESSURE COIL REMOVED, SO I CAN GET MY LIFE BACK TO WHAT IT WAS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031600		8/23/2013	8/30/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED SEVERAL YEARS AGO. FROM THAT POINT ON... SEVERE MENSTRUAL CRAMPING, PAIN IN LEFT ABDOMEN, ACHING PAIN IN LOWER BACK, BLOATING (AS IF PREGNANT), HEAVY PERIODS WITH CLOTS, YEAST INFECTIONS, CHRONIC FATIGUE AND CHRONIC BACTERIAL INFECTIONS, I HAVE BEEN ON DIFLUCAN AND I BELIEVE IT IS CALLED METRONIDAZOLE (BOTH ORAL AND INTRAVAGINAL) ON AND OFF. THE BACTERIAL MEDICATIONS USUALLY HELP THE BACK AND LEFT ABDOMINAL PAIN, BUT IT NEVER GOES AWAY COMPLETELY. AT THIS POINT, I AM NOT RESPONDING TO MEDICATIONS. I JUST FINISHED A TWO WEEK LONG ORAL DOSING. I WENT TO THE DOCTOR TODAY AND MY BACTERIAL INFECTION IS STILL OFF THE CHARTS. I AM ABOUT TO START INTRAVAGINAL. I NEVER HAD THESE PROBLEMS BEFORE THE ESSURE WAS PLACED. EVERYBODY WANTS TO SAY IT'S NOT THE ESSURE (BUT COME ON) A LITTLE COMMON SENSE! NO PROBLEMS BEFORE. THEN AFTER ALL OF THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031652		8/27/2013	9/3/2013

Event Information:

Event Date (B3): 7/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/1/2008
Explant Date (E7): 12/1/2009
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED AND WAS TOLD THAT NOT ONLY WOULD IT PROVIDE TEMPORARY BIRTH CONTROL, BUT WOULD STOP SPOTTING. I BLED NON-STOP FOR 1.5 YEARS. THEY TOLD ME THEY NEVER TOLD ME IT WOULD HELP. (NOT TO MENTION- SURGERY WAS BOTCHED BECAUSE THE GYNECOLOGIST HAD TO GET THE SENIOR GYNECOLOGIST TO HELP HER PUT IT IN AND A REP FROM THE COMPANY THE PAIN WAS UNBEARABLE.) I ENDED UP HAVING TO GET A TOTAL HYSTERECTOMY TO FIX THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031653	CONCEPTUS INCORPORATED	8/27/2013	9/3/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/3/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT PROCEDURE IN (B)(6) 2009. SINCE THEN I HAVE HAD VERY PAINFUL OVULATION, MENSTRUAL CRAMPS FAR MORE PAINFUL THAN ANY I HAD PRIOR TO PROCEDURE, NAUSEA, HEAVY MENSTRUAL BLEEDING, MENSTRUAL BLEEDING CLOTS, AND IRREGULAR PERIODS THAT OCCUR BETWEEN 20 AND 24 DAYS WHEN I WAS VERY REGULAR PRE-PROCEDURE AT 28 DAY CYCLES. THE PAIN DURING THE FIRST TWO DAYS OF MENSTRUATION IS DEBILITATING, I AM DOUBLED OVER AND CAN NOT FUNCTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031654	CONCEPTUS	8/27/2013	9/3/2013

Event Information:

Event Date (B3): 6/17/2009 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 632031

Single Use:
Implant Date (E6): 6/17/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING 4 CHILDREN I WAS READY FOR STERILIZATION. I WANTED A TUBAL BUT MY OB/GYN ENCOURAGED ME TO HAVE THE ESSURE PROCEDURE BECAUSE IT IS LESS INVASIVE AND A QUICKER HEALING TIME. I TRUSTED MY DOCTOR AND AGREED. I HAD ESSURE IMPLANTED ON (B)(6) 2009 AND HAD THE HSG TEST TO CONFIRM FULL BLOCKAGE ON (B)(6) 2009. IN (B)(6) 2010 I DISCOVERED I WAS PREGNANT. IMAGINE MY SHOCK. I DELIVERED A HEALTHY BABY BOY ON (B)(6) 2011. SINCE THEN I HAVE EXPERIENCED SIDE EFFECTS FROM THIS DEVICE AND THEY CONTINUE TO WORSEN AND BECOME MORE NUMEROUS. I HAVE SHARP, STABBING PAIN IN MY LOWER ABDOMEN ON THE RIGHT SIDE MOSTLY WHERE MY TUBES ARE. I GET VERY LIGHTHEADED AND HAVE ACTUALLY PASSED OUT. MY PERIODS ARE STILL REGULAR BUT ARE SO HEAVY THAT I MUST USE 1 SUPER TAMPON PER HOUR AND SOMETIMES I STILL BLEED THROUGH. I AM EXPERIENCING MORE NUMEROUS BLOOD CLOTS WITH MY PERIODS AS WELL. I EXPERIENCE PAIN WITH OVULATION AND IT IS LIKE I CAN FEEL THE COILS INSIDE OF ME LACK OF LIBIDO, FATIGUE, PAIN DURING SEX THE LIST GOES ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031655		8/27/2013	9/3/2013

Event Information:

Event Date (B3): 6/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2013. I WOKE UP WITH PELVIC PAIN ON BOTH SIDES AND I HAVE PELVIC PAIN EVERYDAY NOW. THE RIGHT SIDE HURTS MORE THEN MY LEFT. I WAS TOLD ON (B)(6) 2013 THAT MY GALL BLADDER NEEDS TO COME OUT. I REASSURED THE DOCTOR THAT MY PELVIC PAIN HAS BEEN THERE SINCE I HAD THIS DONE. THAT MY RIGHT SIDE HURTS MORE AND SOMETHING DOESN'T FEEL RIGHT. THE DOCTOR SAID HE CAN DO A HYSTERECTOMY WHICH I TOLD HIM NO THAT IS NOT NECESSARY AND SHOULD BE A LAST RESORT. I ASKED HIM IF HE COULD JUST REMOVE THE COILS HE SAID THAT A HYSTERECTOMY WOULD BE BETTER BECAUSE HE DOESN'T KNOW IF THE PAIN IS FROM MY TUBES OR MY UTERUS. I DISAGREE WITH THIS DOCTOR SO I WILL NOT HAVE IT DONE. I WAS HEALTHY BEFORE THE ESSURE PROCEDURE AND HAVE BEEN IN PAIN SINCE I HAD IT DONE. I WAS TOLD NO SIDE EFFECTS WITH THE COILS BECAUSE THEY ARE HORMONE FREE AND ONLY COMPLICATIONS WOULD BE THE COILS MAY HAVE TO BE REINSERTED IF THEY COME OUT. I WAS LIED TO AND PUSHED INTO AN ESSURE PROCEDURE THAT TURNS OUT TO BE NOT SO GREAT. EVERYDAY IN PAIN. EVERYDAY. IT IS NOT WORTH IT. THIS PROCEDURE DOES NOT WORK FOR EVERYBODY. IT SHOULD BE ILLEGAL TO PERFORM ESSURE PROCEDURES. THE DOCTOR DOES NOT EVEN TEST FOR AN ALLERGY TO NICKEL BEFORE PLACING THE COILS. EVERY WOMEN SHOULD HAVE AN ALLERGY TEST TO NICKEL DONE. I WISH I NEVER RUINED MY LIFE AND I HEARD DOCTORS PUSH FOR THE ESSURE PROCEDURE BECAUSE THEY GET KICK BACKS FOR EVERY ONE THAT IS DONE. THAT IS WHY THEY PUSH FOR ESSURE AND NOT HAVING TUBES TIED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031637	CONCEPTUS	8/28/2013	8/30/2013

Event Information:

Event Date (B3): 4/1/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): TUBAL OCCLUSION CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER STATES THAT SHE HAD ESSURE COILS PLACED DURING AN OUTPATIENT SURGERY IN 2009; SINCE PLACEMENT THE CALLER REPORTS HAVING 3 PREGNANCIES AND 2 ABORTIONS. CALLER STATES THAT SHE IS CURRENTLY PREGNANT AND HAS EXPERIENCED INTENSE ABDOMINAL PAIN AND CRAMPING, LOW BLOOD PRESSURE AND IRREGULAR HEARTBEATS. CALLER IS CONCERNED THAT THESE PREGNANCIES ARE HARMFUL FOR HER BODY AND THE ABORTIONS HAVE CAUSED HER EMOTIONAL ANGUISH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031703	CONCEPTUS INC	9/3/2013	9/9/2013

Event Information:

Event Date (B3): 7/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/19/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER ISSUES DISCUSSED WITH MY DOCTOR, I WAS PLACED ON BIRTH CONTROL PILLS TO SLOW DOWN MY BLEEDING. AFTER 3 YEARS I BECAME PREGNANT. I WAS TOLD THAT I COULD RELY ON THE DEVICES NOT THAT I WILL HAVE PERMANENT REMINDER THAT IT WAS BAD ADVICE GIVEN FROM MY DOCTOR. RECENT HSG SHOWS BOTH COILS AND ONE TUBE OPEN. I HAD TO GO TO ANOTHER HOSPITAL TO HAVE THE HSG DONE AFTER THE DELIVERY BECAUSE NO ONE TRIED TO TELL ME WHAT HAPPENED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00016	BAYER HEALTHCARE LLC, MILPITAS, CA (FORMERLY CONCEPTUS, INC.	9/4/2013	9/11/2013

Event Information:

Event Date (B3): 8/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS EVENT WAS SUBMITTED VIA MEDWATCH FORM (B)(4). PT REPORTED ECTOPIC PREGNANCY 1 YEAR AFTER HAVING ESSURE PROCEDURE. FURTHER INFO ABOUT THIS EVENT IS NOT AVAILABLE.

Manufacturer Narrative (H10):

THIS EVENT WAS SUBMITTED VIA MEDWATCH FORM (B)(4). SEVERAL ATTEMPTS WERE MADE TO GATHER ADD'L INFO FROM THE PT, BUT WE WERE UNABLE TO CONTACT THE PT OR GET ANY PHYSICIAN IDENTIFYING INFO.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031721	CONCEPTUS INC.	9/4/2013	9/11/2013

Event Information:

Event Date (B3): 4/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/29/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE. AND SINCE IMPLANTION I'VE HAD HORRIBLE BLEEDING CLOTTING AND SEVERE PAIN AND WILL PROBABLY NEED A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031723	CONCEPTS INC	9/4/2013	9/11/2013

Event Information:

Event Date (B3): 9/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT MY ESSURE BACK IN (B)(6) OF 2013, AFTER HAVING MY SECOND CHILD. MY DOCTOR NEVER WENT OVER ANYTHING WITH ME, BUT ALL HE SAID THAT IT WAS SAFE AND EFFECTIVE. AFTER I HAD THE ESSURE DONE, I HURT FOR THE FIRST DAY AND THEN AFTER THAT I WAS FINE FOR ONLY LIKE THREE WEEKS. THEN I STARTED TO HAVE REALLY BAD ABDOMINAL PAIN AND MY OVARIES HURT ALL THE TIME. I HURT ALL DAY EVERYDAY. I WENT TO MY DOCTOR ABOUT THREE WEEKS AGO AND HE HAD ME COME IN AND GET AN ULTRASOUND DONE. AFTER GETTING THE ULTRASOUND DONE, HE SAID IT LOOKED LIKE EITHER MY COIL CAME OUT AND IS FLOATING AROUND IN MY UTERUS OR IT IS ONLY HALF WAY IN AND JUST HANGING THERE. BUT I LOOKED AT THE ULTRASOUND MYSELF AND THERE IS DEFINITELY SOMETHING IN THERE. I HAVE BEEN RESEARCHING IT AND YOU CAN STILL GET PREGNANT WHILE HAVING THE ESSURE, EVEN IF YOU HAVE HAD IT FOR A FEW YEARS. SO NOW I AM SCARED OUT OF MY MIND BECAUSE NOT I CAN EITHER BE PREGNANT WITH MY THIRD CHILD OR HAVE A COIL STUCK TO MY UTERUS. I WOULD DEFINITELY NOT RECOMMEND GETTING THIS PROCEDURE DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031724	CONCEPTUS	9/4/2013	9/11/2013

Event Information:

Event Date (B3): 5/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/29/2012
Explant Date (E7): 4/16/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE (PERMANENT BIRTH CONTROL) PLACED (B)(6) AND IT CAUSED SEVERE SIDE EFFECTS FOR 11 MONTHS UNTIL I WENT AND HAD IT REMOVED BY HYSTERECTOMY. SEVERE CRAMPING, BACK PAINS, MASSACRE BLEEDING FOR WEEKS AT A TIME AND FATIGUED ALL THE TIME AND COUNTLESS OTHER SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031734	CONCEPTUS	9/4/2013	9/11/2013

Event Information:

Event Date (B3): 4/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ES305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/8/2012
Explant Date (E7): 4/4/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH CONCEPTUS ESSURE COILS ON (B)(6) 2012. BEGAN HAVING PROBLEMS IN (B)(6) 2013, EXTREME BACK PAIN NOT RESPONDING TO DRUGS. X RAYS, CT SCAN AND ULTRA SOUNDS COULD NOT FIND ANYTHING CAUSING THE PAIN. (B)(6) BROUGHT ON A RIGHT SIDE PAIN WHICH GOT PROGRESSIVELY WORSE. TRIED TO GET APPOINTMENT WITH OB/GYN THAT IMPLANTED DEVICE AND HE CLAIMED THAT ESSURE WOULD NOT CAUSE THOSE PAINS WHICH MADE IT IMPOSSIBLE TO GET APPOINTMENT COVERED BY INSURANCE. ANOTHER DOCTOR IN INSURANCE PLAN DIRECTED BY PHONE THAT IMPLANTING DOCTOR SHOULD BE ONE TO TAKE OUT COILS. ANOTHER DOCTOR IN INSURANCE PLAN SAID IT WOULD NOT BE CAUSED BY ESSURE OR ENDOMETRIOSIS, HE WOULD NOT CONSIDER SURGERY UNTIL ALL OPTIONS WERE EVALUATED. PRIMARY DOCTOR MADE INSURANCE REQUIRED REFERRAL AND MET WITH IMPLANTING DOCTOR WHO SAID ESSURE WOULD NOT CAUSE THIS PAIN. PT DEMANDED THE COILS BE REMOVED THRU HYSTERECTOMY TO SEE IF IT WOULD RELIEVE THE PAIN. HE REFERRED PT TO ANOTHER DOCTOR IN SAME OFFICE. NEW DOCTOR AGREED TO DO HYSTERECTOMY BUT DID NOT FEEL THE PAIN WOULD BE ELIMINATED. SURGERY FINALLY HAPPENED ON (B)(6) 2013. TUBE, UTERUS AND CERVIX WERE REMOVED BY OPEN SURGERY. A SMALL VESSEL LEAK REQUIRED VAGINAL REPAIR. IN RECOVERY ROOM THE PAIN IN RIGHT SIDE AND BACK WERE GONE. AT POST OP APPOINTMENT, THE DOCTOR SAID THAT COILS WERE IN TUBES AND REMOVED. WHEN PT SAID SHE WAS GLAD THERE ARE NO PARTS OF THE COILS FLOATING IN THERE. THE DOCTOR SAID THAT WOULD NOT CAUSE ANY PROBLEMS. THIS DEVICE NEEDS TO HAVE WARNINGS THAT SAY, IT CAN CAUSE PAIN, INFECTIONS, FOGGY BRAIN, HAIR LOSS, HEAVY BLEEDING (CAUSING ANEMIA, NUMBNESS IN ARMS AND HANDS AND A HYSTERECTOMY MAY BE REQUIRED TO REMOVE COILS. AND THE NICKEL WARNING SHOULD NEVER HAVE BEEN TAKEN OFF AS DOCTORS TELL THOSE WITH NICKEL ALLERGY THAT THEY CAN HAVE ESSURE. PT'S BODY REJECTS

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOREIGN OBJECTS AS TWO MIRENA IUD'S FELL OUT, ONE RESULTING IN PREGNANCY. THE PAIN WAS CAUSED BY THE BODY TRYING TO GET RID OF FOREIGN OBJECT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031735	CONCEPTUS	9/4/2013	9/11/2013

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE AN ESSURE, WHICH IS CAUSING ME TO HAVE HEAVY BLEEDING, AND UNBEARABLE CRAMPS. I RECEIVED THE ESSURE IN 2008 AND OVER THE YEARS MY CYCLE SEEMED TO BE GETTING WORSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031747		9/5/2013	9/11/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): MALFUNCTION	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AND GOT PREGNANT AROUND TWO YEARS LATER. I HAD A SUCCESSFUL PREGNANCY AND GAVE BIRTH TO A HEALTHY BABY GIRL

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031749	CONCEPTUS	9/5/2013	9/11/2013

Event Information:

Event Date (B3): 11/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/8/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THIS PROCEDURE, MY LIFE HAS TURNED INTO A LIVING HELL. I HAVE GAINED 20 LBS (WEIGHT HAS NEVER REALLY BEEN AN ISSUE FOR ME), HAVE PASSED DOZENS OF KIDNEY STONES WHEN I NORMALLY ONLY HAD THEM DURING PREGNANCY, MY HAIR IS BRITTLE AND WIRY, MY CYCLES ARE HIGHLY IRREGULAR LASTING ANYWHERE FROM 19-41 DAYS, I BLEED BETWEEN PERIODS ALMOST EVERY MONTH AND THE LENGTH OF MENSTRUATION IS ALSO HIGHLY VARIABLE FROM 3-9 DAYS (NOT INCLUDING) ANY SPOTTING THAT PRECEDES AN ACTUAL FLOW), MY MENTAL ACUITY AND CLARITY IS GONE, I AM CONSTANTLY IN A STATE OF WHAT I REFER TO AS "FOGGINESS," I HAVE EXCRUCIATING HEADACHES, JOINT PAIN, AND SHARP STABBING PAINS IN MY ABDOMEN NEARLY EVERY DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031764	CONCEPTUS INC	9/6/2013	9/12/2013

Event Information:

Event Date (B3): 1/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 1/7/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE AFTER MY 3RD CHILD. IT WAS WONDERFUL TO BEGIN WITH, NO PILLS AND NO PREGNANCY. ABOUT A YR AND A HALF LATER I STARTED HAVING SOME PRETTY INTENSE SHARP PAINS ON MY RIGHT SIDE. I WENT TO MY OBGYN AND WE BEGAN EXPLORING FOR THE CAUSE OF THE PAIN. WE DID AN ULTRASOUND AND FOUND NOTHING. WE THEN SCHEDULED TO HAVE SOME LABS DONE TO CHECK MY KIDNEYS FOR KIDNEY STONES. THE PAIN WAS SO BAD AT THIS POINT THAT I WAS MISSING WORK AND WAS HAVING TO TAKE PAIN MEDICATION AND NOTHING REALLY SEEMED TO HELP. WHEN ALL THE LABS HAD COME BACK CLEAN, THE DOCTOR THEN DECIDED TO DO A LAPAROSCOPIC PROCEDURE TO SEE IF SHE COULD FIND THE PROBLEM. SHE FOUND MORE THAN WHAT WE EXPECTED. SHE ALSO TOOK PICTURES OF ALL THE DAMAGE THAT WAS DONE. SHE ENDED UP TAKING OUT 1.5 OF MY TUBES. THE COILS HAD BEGAN TO PROTRUDE OUT OF THE TUBES WHICH IS WHAT WAS CAUSING ALL THE PAIN. SINCE THE REMOVAL OF MY TUBES I HAVE BEEN PAIN FREE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	9/9/2013	9/18/2013

Event Information:

Event Date (B3): 4/16/2013 **Report Date (B4): 9/9/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT IN FOR ESSURE PLACEMENT. FIRST WENT IN FINE, SECOND IN BOX DID NOT DEPLOY(UNCOIL) SO HAD TO OPEN ANOTHER BOX OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031790		9/10/2013	9/16/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/15/2006
Explant Date (E7): 5/22/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED ON (B)(6) 2006, BEGAN HAVING MASSIVE VERY HEAVY AND FREQUENT MENSTRUAL, SHARP PAINS, HEADACHES, FATIGUE, HAIR LOSS, HAD GALL BLADDER REMOVED, MOODY, NAUSEA, ETC. ON (B)(6) 2013, HAD EXPLORATORY SURGERY AND ONE SPRING WAS ALMOST ALL THE WAY OUT OF THE TUBE AND ONE WAS HALF WAY OUT, THE DOCTOR REMOVED BOTH SPRINGS, ENDOMETRIOSIS, CYSTS, AND FIXED BOWELS. SINCE REMOVAL ALL OF THE SYMPTOMS ARE GONE, MENSTRUAL IS ONCE A MONTH AND AT MOST 5 DAYS LONG, AND THEY ARE LIGHT WITH BARELY ANY PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031832	CONCEPTUS	9/11/2013	9/19/2013

Event Information:

Event Date (B3): 11/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SYMPTOMS/SIDE EFFECTS: PERIOD FROM (B)(6) 2011 - (B)(6) 2012 (8 WEEKS LONG...IT WAS MIA FOR A YEAR AND 5 MONTHS. IT STARTED AGAIN (B)(6) 2013): WEIGHT GAIN/BLOATING, ABDOMINAL PAIN/CRAMPING (ESPECIALLY IN THE LEFT SIDE - FEELS LIKE A KNIFE), ACHING/TINGLING IN THE LIMBS, NUMBNESS IN FEET, HOT FLASHES, PAIN IN LEFT HIP (TO THE POINT OF LIMPING), FATIGUE (NO MATTER HOW MUCH I SLEEP), DIFFICULTY SLEEPING (MAINLY AT NIGHT...I FEEL LIKE MY BODY HAS MY DAYS AND NIGHTS MIXED UP), HEADACHES/MIGRAINES (HAVE GOTTEN WORSE...I'VE HAD HEADACHES IN THE PAST, BUT NOT EVERY DAY!), ACNE, GROWING/SORE BREASTS, PAINFUL INTERCOURSE (PAIN CONTINUES FOR A DAY OR TWO AFTER - DEVELOP ITCHING AROUND THE VAGINAL AREA AFTER INTERCOURSE), EXCESS VAGINAL DISCHARGE, MOOD SWINGS (FEEL LIKE I'M PMS-ING 24/7/365), METALLIC TASTE IN MOUTH, HEARTBURN/INDIGESTION, FREQUENT URINATION (SOMETIMES I FEEL LIKE I CAN'T GET THE STREAM STARTED OR LIKE I GET IT ALL OUT), BOWEL PROBLEMS (IF I EAT A MEAL, 30 MINUTES OR SO LATER I HAVE EXTREME STOMACH/BOWEL CRAMPS UNTIL I PASS A LOOSE STOOL), SHORT-TERM MEMORY, AT TIMES A SWEAR MY TUBES ARE TWITCHING, TWITCHING MUSCLES THROUGHOUT BODY, DISCOMFORT IN MY UPPER ABDOMEN AND DECREASED APPETITE (IT HURTS TO EAT, I ALWAYS FEEL FULL AND FOOD MAKES ME NAUSEOUS). TIMELINE: (B)(6) 2011 - HAD ESSURE PROCEDURE AT (B)(6) BY DR (B)(6). (B)(6) 2011 - PERIOD BEGAN. (B)(6) 2012 (JUST BEFORE MY PERIOD STOPPED) - HAD CHECK UP VISIT WITH DR (B)(6) AT (B)(6). EXPRESSED CONCERN THAT I WAS STILL ON MY PERIOD. WAS TOLD IT WAS NORMAL BUT THAT IF BLEEDING HAD NOT STOPPED IN A FEW MORE WEEKS WE WOULD HAVE TO CONSIDER A HORMONE BASED PILL. (B)(6) 2012 - PERIOD FINALLY STOPS (AFTER 8 WEEKS). (B)(6) 2012 (A DAY OR TWO PERIOD STOPPED) - HAD HSG TEST AT (B)(6) TO CONFIRM SUCCESS OF ESSURE PROCEDURE. PROCEDURE WAS RULED A SUCCESS AND I WAS RELEASED WITH NO FURTHER FOLLOW UP NECESSARY. (B)(6) 2012 (END OF THE

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MONTH) - CONTACTED DR (B)(6) OFFICE WITH CONCERN THAT I HAD MISSED TWO PERIODS AND WAS GAINING WEIGHT AS WELL AS HAD SORE BREASTS. HAD TAKEN HOME PREGNANCY TEST WHICH CAME BACK NEGATIVE. WAS TOLD THAT EVERY LADY'S BODY IS DIFFERENT AND THAT DUE TO SUCH A LONG PERIOD BEFORE IT WAS NORMAL FOR ME TO MISS A MONTH OR TWO. (B)(6) 2012 (END OF THE MONTH) - AFTER MISSING PERIOD FOR A THIRD MONTH, CONTACTED MY REGULAR OB CLINIC ((B)(6)) FOR A SECOND OPINION. TOOK A HOME PREGNANCY TEST WHICH WAS NEGATIVE. DOCTOR ORDERED PREGNANCY TEST WHICH WAS NEGATIVE. DOCTOR SAID HE WANTS TO HAVE A FULL PELVIC ULTRASOUND DONE. (B)(6) 2012 - CONTACTED (B)(6) FINANCE OFFICE TO GET FINANCIAL ASSISTANCE PAPERS SO I CAN SCHEDULE ULTRASOUND. (B)(6) 2012 (SECOND OR THIRD WEEK) - SENT IN FINANCIAL ASSISTANCE PAPERWORK TO (B)(6). (B)(6) 2012 - NURSE AT (B)(6) DOES AN ULTRASOUND TO MAKE SURE I AM NOT GETTING A FALSE NEGATIVE ON PREGNANCY TESTS. UTERUS WAS CORRECT SIZE/NO PREGNANCY. (B)(6) 2012 - CONTACTED (B)(6) FINANCE OFFICE TO CHECK ON PAPERWORK. (B)(6) 2012 - RELIEVED TO FIND OTHER WOMEN WHO ARE EXPERIENCING THE SAME SYMPTOMS AS ME! (B)(6) 2012 - STOPPED BY MY REGULAR OB'S OFFICE AND TALKED TO THE NURSE ABOUT MY SYMPTOMS AND FINANCIAL OPTIONS FOR MOVING FORWARD. (B)(6) 2012 - CONTACTED ANOTHER BRANCH OF (B)(6) THAT SEES UNINSURED WOMEN, BUT THEY SAID THEY ARE NOT CURRENTLY ACCEPTING NEW PTS. CONTACTED (B)(6) TO SET UP APPOINTMENT AND SET UP PAYMENTS. CANCELLED APPOINTMENT BECAUSE OF AMOUNT NEEDED UP FRONT. CONTACTED PHYSICIANS BILLING AT (B)(6). WAS TOLD THAT APPLICATION MAY HAVE BEEN LOST IN THE SHUFFLE AND NEW ONE WAS SENT OUT. CONTACTED DR (B)(6) OFFICE ((B)(6)) TO DISCUSS ALL MY NEW SYMPTOMS AND IN HOPES TO TALK TO DR (B)(6) OR HER NURSE. EXPLAIN THAT I DO NOT HAVE MONEY TO BE SEEN BY THE DOCTOR. (B)(6) 2012 - RECEIVED NEW FINANCIAL ASSISTANCE APPLICATION IN THE MAIL. TOOK HOME PREGNANCY TEST AGAIN WHICH CAME BACK NEGATIVE. RECEIVE VOICEMAIL FROM DR(B)(6) NURSE STATING THEY UNDERSTAND THAT I DO NOT HAVE MONEY TO BE SEEN BUT I STILL NEED TO MAKE AN APPOINTMENT SO THE DOCTOR CAN SEE ME AND MAKE A DIAGNOSIS. ALREADY WORKING ON SCHEDULING AN APPOINTMENT WITH MY REGULAR OB/GYN. (B)(6) 2012 - FAXED FINANCIAL ASSISTANCE APPLICATION TO (B)(6) IN PHYSICIANS BILLING AT (B)(6). TALKED TO (B)(6) (WORKS WITH UNINSURED PTS) AND EXPLAINED I WAS A PT AT ANOTHER CLINIC. HAD BLOOD DRAWN AT (B)(6) FOR HORMONE AND THYROID TESTING. SCHEDULED APPOINTMENT TO SEE DOCTOR TO DISCUSS SYMPTOMS AND SCHEDULE PELVIC ULTRASOUND...ALSO PLAN TO ASK FOR A CT SCAN OR HSG. AFTER (B)(6), I CAN TELL YOU WHAT TESTS I'VE HAD DONE, BUT I'M UNSURE OF THE DATES. I CAN TELL YOU THAT ALL VISITS AND TESTS WERE BETWEEN (B)(6) 2012 AND (B)(6) 2013. ALL OF MY BLOOD WORK FOR HORMONE TESTING AND THYROID CAME BACK NORMAL. PREGNANCY TEST CAME BACK NEGATIVE. THE MIDWIFE I SAW SUGGESTED I MAY HAVE PCOS AND STARTED ME ON THE PROGESTERONE CHALLENGE. NOTHING HAPPENED. I HAD A FULL PELVIC/TRANSVAGINAL ULTRASOUND. THE DOCTOR SAID EVERYTHING WAS NORMAL. HE STATED THAT WITH LACK OF CYSTS I PROBABLY DON'T HAVE PCOS. HE QUITE LITERALLY LOOKED AT ME AND SAID HE DIDN'T KNOW WHAT TO DO NEXT BECAUSE EVERYTHING WAS COMING BACK NORMAL. HE DECIDED TO HAVE ME DO THE SECOND STAGE OF THE PROGESTERONE CHALLENGE. NOTHING HAPPENED. SCHEDULED AN APPOINTMENT WITH A DIFFERENT DOCTOR IN THE SAME OFFICE. HE DID A PELVIC EXAM AND SAID NOT TO WRITE OFF PCOS. I MAY STILL HAVE IT EVEN THOUGH NO CYSTS WERE SEEN ON THE ULTRASOUND. I BEGGED HIM FOR ANOTHER HSG. AN HSG WAS SCHEDULED. BEFORE I COULD HAVE THE HSG, I WAS IN SO MUCH PAIN THAT I WENT TO MY LOCAL HOSPITAL ER. I REPORTED A MAJOR MIGRAINE, CHEST PAIN AND LOWER PELVIC PAIN. I TOLD THEM ABOUT ESSURE. I HAD TO EXPLAIN TO EVERYONE I SAW WHAT ESSURE IS. THE DOCTOR ORDERED A CT SCAN. AGAIN, BEFORE HAVING THE SCAN I HAD TO EXPLAIN WHAT ESSURE IS. THE RADIOLOGIST SENT A REPORT SAYING THAT EVERYTHING LOOKED FINE ASIDE FOR SOME MINOR GRAVEL IN MY GALLBLADDER. THEY FOUND A DOCTOR IN THE ER WHO KNEW ABOUT ESSURE BECAUSE HIS WIFE WAS AN OB/GYN. HE CAME IN AND TALKED TO ME, BUT SAID ALL HE COULD DO FOR ME (BECAUSE ALL TESTS WERE COMING BACK NORMAL) WAS TO GIVE ME PAIN MEDS TO MANAGE THE PAIN. HE CHECKED TO BE SURE THAT I WAS NOT EXPERIENCING IN PAIN DUE TO THE GRAVEL IN MY GALLBLADDER. I HAVE HAD SEVERE PAIN SINCE THEN BUT HAVE NOT RETURNED TO THE ER BECAUSE I KNOW I NEED SOMETHING MORE THAN

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JUST PAIN MEDS AT THIS POINT. I DON'T WANT OR NEED A BANDAID. I NEED THE CAUSE OF MY ISSUES TREATED, NOT THE SYMPTOMS. I REPORTED FOR MY HSG AS SCHEDULED. BECAUSE I HAD JUST HAD A CT SCAN, THE RADIOLOGIST CONTACTED THE HOSPITAL I HAD WENT TO AND OBTAINED THE WRITTEN REPORT. SINCE THE REPORT STATED THAT EVERYTHING LOOKED NORMAL THEY REFUSED TO THE HSG. I WENT BACK TO MY DOCTOR. HE STATED THAT AT THAT POINT WE WOULD NO LONGER CONSIDER ESSURE WHEN ADDRESSING MY ISSUES. HE SIMPLY WANTED TO MAKE SURE THAT PAIN WAS MANAGED AND THAT MY PERIOD RETURNED. HE GAVE ME A PRESCRIPTION FOR BIRTH CONTROL PILLS AND TOLD ME TO SCHEDULE ANOTHER APPOINTMENT IN (B)(6) TO CHECK UP ON MY PROGRESS. HE ALSO REFERRED ME TO A GASTROENTEROLOGIST FOR MY BOWEL ISSUES. I TOOK ONE MONTH OF THE BIRTH CONTROL PILLS. MY PAIN WAS WORSE THAN EVER AND IT WAS MESSING WITH MY HORMONE LEVELS. I CALLED THE DOCTOR AND TOLD HIM THAT IT WOULD NO LONGER BE TAKING THEM. THAT WAS IN (B)(6). AS OF(B)(6) 2013, MY PERIOD HAS RETURNED. HOWEVER, OVULATION AND MY CYCLE ARE BOTH EXTREMELY PAINFUL. I SPEND MOST OF THAT WEEK WITH A HEATING PAD. I TAKE BAYER ADVANCED EXTRA STRENGTH TO TRY TO MANAGE THE PAIN. IT TAKES THE EDGE OFF, BUT NEVER REALLY TAKES THE PAIN AWAY. MY CYCLE IS LIGHTER THAN IT EVER HAS BEEN. IT DOES NOT MAKE SENSE THAT I AM HARDLY BLEEDING AND YET I'M DOUBLED OVER IN TEARS WITH PAIN. AS FOR THE GASTRO DOCTOR, I HAD TO CANCEL THE APPOINTMENT BECAUSE OF FINANCES. I HAVE ALSO BEEN TO THE ER AT (B)(6) FOR BLADDER ISSUES. I COULD NOT URINATE. THE DOCTOR SAID THAT MY BLADDER WAS SAGGING, MY RECTUM IS DESCENDED AND THAT I HAD A BAD BLADDER INFECTION. I TOOK AN ANTIBIOTIC THAT THEY PRESCRIBED TO CLEAR UP THE INFECTION. MY MAIN CONCERN (OTHER THAN THE PAIN I ENDURE EVERY DAY) IS THAT OVER TIME MY COILS WILL MIGRATE OR MOVE. I WAS TOLD BY A MEDICAL PROFESSIONAL WHEN I WENT TO THE ER THE FIRST TIME THAT ANY DOCTOR THAT TRIED TO TELL ME THAT ESSURE CANNOT MOVE ONCE OCCLUDED IS LYING. EVERY DEVICE, NO MATTER WHAT THE TYPE OR FORM, HAS THE ABILITY TO MOVE. IT IS A FOREIGN OBJECT IN THE BODY. I WAS ALSO TOLD THAT NO MATTER HOW LONG YOU HAVE HAD A DEVICE, YOUR BODY CAN DECIDE TO REJECT IT AT ANY TIME. YOU MIGHT HAVE HAD IT FOR YEARS WITH NO ISSUES, BUT THE BODY CAN STILL REJECT IT. WHEN I ASKED IF IT WAS POSSIBLE THAT MY BODY WAS REJECTING ESSURE, I WAS TOLD THAT WAS ALWAYS A POSSIBILITY. HOWEVER, WHEN I FOLLOW UP WITH MY OB/GYN, THEY DO NOT WANT TO CONSIDER ESSURE AS A CAUSE FOR ANY OF MY ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031872	CONCEPTUS/BAYOR	9/11/2013	9/23/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/8/2012
Explant Date (E7): 11/20/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2012, I HAD ESSURE IMPLANTED FOR PERMANENT BIRTH CONTROL. WHILE THE DOCTOR PLACED THE DEVICES, MY BODY STARTED TO TREMOR AND I THREW UP TWICE. I THEN STARTED HAVING INFECTION AFTER INFECTION HAVING TO DO WITH MY FEMALE ORGANS AND CONSTANT LOWER ABDOMINAL PAIN. I HAD THEM REMOVED ON (B)(6) 2012, DUE TO THE NEGATIVE SIDE-EFFECTS. I WAS STILL HAVING ABDOMINAL PAIN, BUT MY DOCTOR SAID THERE WAS NOTHING MORE HE COULD DO AND DID NOT OFFER UP ANY OTHER TESTS, SUGGESTIONS, ETC. I WENT ON TO TREAT WITH OTHER DOCTORS, SUCH AS GI, NATUROPATH, PSYCHIATRIST, OB PAIN SPECIALIST, ACUPUNCTURE, ETC. IN (B)(6) 2013, MY OB PAIN SPECIALIST SUGGESTED AN X-RAY AND VERIFIED BETWEEN THE XRAY AND CT SCAN THAT WAS DONE AT THE ER A FEW MONTHS BEFORE THAT WHEN MY DOCTOR REMOVED THEM LAPAROSCOPICALLY IN (B)(6) 2012, THE DEVICES BROKE AND PIECES WERE LEFT INSIDE. I HAD A HYSTERECTOMY ON (B)(6) 2013, TO REMOVE THE REST OF THE METAL. I WAS OUT ON DISABILITY FOR 6 MONTHS AND EVENTUALLY LOST MY JOB. OTHER SIDE-EFFECTS I EXPERIENCED AND SOME STILL TRYING TO RESOLVE: ACNE AROUND MY NECKLINE AND CHEST DIGESTIVE ISSUES FOOD ALLERGIES/SENSITIVITIES FATIGUE WORSENED SEASONAL ALLERGIES ABDOMINAL BLOATING INCREASED ANXIETY BLURRED VISION ON OCCASION LOSS OF MOTIVATION FOR DAILY/SOCIAL/OTHER ACTIVITIES, 3 BROKEN TEETH (WHILE FLOSSING).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031873		9/11/2013	9/23/2013

Event Information:

Event Date (B3): 10/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/22/2012
Explant Date (E7): 4/9/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PERMANENT BIRTH CONTROL INSTALLED IN ME ON (B)(6) 2012, NOT EVEN A WEEK LATER I WAS DOUBLED OVER IN PAIN, COULDN'T MOVE, COULDN'T TAKE CARE OF MY KIDS, WHEN I WENT TO THE DOCTOR SHE TOLD ME IT WAS NORMAL FOR CRAMPING, AND PRESCRIBED ME PAIN MEDS, AND SENT ME ON MY WAY. I WAS STILL BLEEDING 2 WEEKS LATER AND WHEN I CALLED HER SHE TOLD ME THAT WAS NORMAL ALSO. THEN THE RASHES BEGAN ALL OVER MY FACE, AND IN MY PRIVATES. I ALSO BEGAN HAVING PAIN IN MY LEG, AND SWELLING, AND NUMBNESS AND TINGLING IN MY EXTREMITIES UNEXPLAINED. TWO DAYS AFTER THAT, I TRIED HAVING SEX WITH MY BOYFRIEND, AND IT HURT AND I BLED FOR 2 DAYS. I WENT IN AND SAW MY OB WHO IMPLANTED ME, AND SHE RAN TESTS, DID A PAP AND I BLED ON HER HAND WHEN SHE SWABBED MY CERVIX. ALL BLOOD TESTS AND PAP CAME BACK NEGATIVE SO SHE SCHEDULED ME FOR A HYSTERECTOMY FOR (B)(6) 2013. I SPENT THE NIGHT IN THE HOSPITAL AND THE NEXT DAY I WAS UP AND WALKING AROUND WITH NO ISSUES WHAT SO EVER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031874	BAYER	9/11/2013	9/23/2013

Event Information:

Event Date (B3): 11/3/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/3/2006
Explant Date (E7): 7/23/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN (B)(6) 2006. BLED FOR 3 1/2 MONTHS AFTER IMPLANTATION. MY HAIR FELL OUT, LABOR LIKE PAINS, PERIODS LASTING 7-10 DAYS EVERY TWO WEEKS, WEIGHT GAIN (70 LBS), NAUSEA, CONSTANT CRAMPS, JOINT PAIN, IRRITABILITY, BRAIN FOG, HEARING LOSS, INABILITY TO HEAL PROPERLY, CHRONIC AND ACUTE INFLAMMATION OF MY UTERUS AND CERVIX, DEVELOPED ENDOMETRIOSIS, ADENOMYOSIS, AND PCOS, AFTER PLACEMENT, NO ENERGY, AND NO SEX DRIVE. HAD A TAH WITH BSO (B)(6) 2013. ALL SYMPTOMS HAVE SINCE DISAPPEARED SINCE REMOVAL!!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031875	CONCEPTUS	9/11/2013	9/23/2013

Event Information:

Event Date (B3): 8/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A02555

Single Use:
Implant Date (E6): 8/8/2012
Explant Date (E7): 5/8/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS IMPLANTED WITH ESSURE AND FOR TEN MONTHS HAD CONSTANT PAIN AND IRREGULAR, PAINFUL PERIODS AS WELL AS JOINT PAIN, LOWER BACK PAIN, CHRONIC FATIGUE, FIBROMYALGIA. HAD TO HAVE A HYSTERECTOMY IN ORDER TO REMOVE ESSURE, COSTING ME THOUSANDS OF DOLLARS AND QUALITY OF LIFE. FOUR MONTHS AFTER MY HYSTERECTOMY, ALL THAT PAIN IS GONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031876	CONCEPTUS	9/11/2013	9/23/2013

Event Information:

Event Date (B3): 1/8/2010 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/8/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2010 AFTER 4 CHILDREN, MY HUSBAND AND I DID NOT WANT ANY MORE. I AM A STAY AT HOME MOTHER WHILE HE WORKS IN A FACTORY 12-16 HR DAYS. WITH THE WAY THE ECONOMY IS AND ITS ALREADY A FINANCIAL NIGHTMARE RAISING CHILDREN ANYWAY..WE WANTED A PERMANENT BC. AT THE TIME (2009-2010) THERE WERE NO STUDIES POSTED ON THE PROS/CONS OF ESSURE. ALL I HAD TO GO ON WAS THE ESSURE WEBSITE. I THOUGHT FROM WHAT I READ ESSURE WAS THE BEST THING FOR ME. NO DOWN TIME, NOT BEING PUT TO SLEEP ETC. SO (B)(6) 2010 I HAD IT DONE. THE PROCEDURE ITSELF WENT GREAT. NOT MUCH PAIN OR CRAMPS. AFTER THE FIRST YEAR, I STARTED HAVING SHARP STABBING PAINS IN MY ABDOMEN (IN THE AREA OF MY TUBES). EACH MONTH THE SHARP STABBING PAINS WOULD BE A LITTLE WORSE THAN THE PREVIOUS MONTHS. I WOULD ACTUALLY DOUBLE OVER FROM THE PAIN. THEN AFTER 2 YEARS MY PERIODS (WHICH BEFORE ESSURE WERE SO PREDICTABLE I COULD ALMOST GUESS THE HOUR IT WOULD START) WERE BECOMING MORE AND MORE IRREGULAR AND VERY HEAVY WITH LOTS OF BIG CLOTS. NOW, AFTER 3 YEARS AND 4 MONTHS I GET PREGNANT. I WENT IN TO SEE MY OBGYN AND DO BLOODWORK, URINALYSIS, AND ULTRASOUND. WHEN THEY DID THE TEST, I ASKED IF THEY COULD SEE MY COILS, AND WITH SHOCK FROM THE TECH, SHE BEGAN SEARCHING. SHE FOUND THE RIGHT SIDE. THE LEFT WAS NO WHERE TO BE FOUND. NOW I AM AT 16 WEEKS AND WORRIED SICK ABOUT NOT ONLY MY HEALTH AND LIFE BUT NOW MY UNBORN CHILD'S HEALTH AND LIFE. I HAVE GAINED 25 LBS SINCE HAVING ESSURE AND CAN'T SEEM TO LOSE IT. I HAVE BEEN RUNNING WITH OLDEST DAUGHTER (WHO IS ON THE LOCAL HIGH SCHOOL LACROSSE TEAM) AND STILL CAN'T LOSE ANYTHING.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031877	BAYER	9/11/2013	9/23/2013

Event Information:

Event Date (B3): 2/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE COIL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/21/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2012 I HAD THE ESSURE COILS INSERTED. (B)(6) OF THAT YEAR STARTED GETTING PAIN IN MY LEFT SIDE I DIDN'T THINK TOO MUCH ABOUT IT AT THE TIME. BY (B)(6) I STARTED GETTING THE PAIN MONTHLY AND THEY WERE GETTING STRONGER AND LASTED LONGER. TALKED TO MY DOCTOR ABOUT IT AND WE HAVE SLOWLY RULED OUT OTHER ISSUES IN (B)(6). I WAS IN THE HOSPITAL FOR THE PAIN THE DOCTORS COULDN'T FIND A REASONABLE DIAGNOSIS OR MY ISSUE AND SENT ME HOME WITH A PRESCRIPTION FOR PAIN. (B)(6) 2013 I WAS AGAIN IN THE HOSPITAL FOR THE SAME ISSUES AND SAME RESULTS COULDN'T FOUND ANYTHING. THE NEXT 3 MONTHS WERE COMPLETE "PROFANITY" I HAD TO QUIT MY JOB DUE TO THE FACT THAT I COULDN'T WORK CAUSE OF THE PAIN I HAVE BEEN TO MY GYNO AND HE HAS STATED THAT HE BELIEVES THAT THEY ARE THE COILS CAUSING ME ALL THIS PAIN AND WE ARE GOING TO REMOVE THEM AS WELL AS THE PAIN MY OTHER SYMPTOMS INCLUDE HEADACHES, WEIGHT GAIN, DIZZINESS, ANXIETY, TIREDNESS, CONSTANT BLOATING AND I'M SURE THERE ARE A FEW MORE BUT I HAVE BEEN DEALING WITH THIS FOR SO LONG IT ALMOST SEEMS NORMAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031878	CONCEPTUS	9/11/2013	9/23/2013

Event Information:

Event Date (B3): 8/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use:
Implant Date (E6): 2/18/2008
Explant Date (E7): 8/23/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2013, I HAD TO UNDERGO A HYSTERECTOMY DUE TO FAILURE OF THE CONCEPTIVE DEVICE ESSURE. I HAD ESSURE IMPLANTED ON (B)(6) 2008. FROM IMPLANTATION UNTIL MY HYSTERECTOMY, I EXPERIENCED HEAVY BLEEDING AND EXTREME FATIGUE. AT AN ULTRASOUND PERFORMED IN (B)(6) 2013, I LEARNED ONE OF MY ESSURE COULD HAD MIGRATED AND WAS EMBEDDED IN MY UTERUS. THE ONLY RESOLUTION TO THIS ISSUE WAS A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031879	BAYER	9/11/2013	9/23/2013

Event Information:

Event Date (B3): 8/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): 123456
Catalog # (E4): 123456
Lot #(E4): 123456

Single Use:
Implant Date (E6): 4/4/2008
Explant Date (E7): 8/19/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED IN 2008. NUMBNESS AND TINGLING IN EXTREMITIES, SPORADIC PARALYSIS, 2 MISCARRIAGES, FLOATERS IN VISION, MIGRAINES, BLOAT, CHRONIC INFLAMMATION, PELVIC PAIN, ABDOMINAL PAIN. SEVERAL HOSPITAL VISITS. SURGERY TO REMOVE DEVICE DUE TO REACTION TO IT IN (B)(6) 2013.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031826	CONCEPTUS/BAYER	9/12/2013	9/19/2013

Event Information:

Event Date (B3): 10/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): NEVER WAS GIVEN ANY INFO
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/19/2012
Explant Date (E7): 12/17/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2012. THE PROCEDURE WAS DONE IN MY DOCTOR'S OFFICE WITH CERVICAL BLOCK AND SOME PAIN MEDS TAKEN BEFORE THE APPOINTMENT. THE PROCEDURE WAS ONE OF THE MOST PAINFUL EXPERIENCES OF MY LIFE AND I HAVE HAD TWO VAGINAL BIRTHS. MY UTERUS WAS VERY RETROVERTED AND ONE COIL WAS VERY DIFFICULT TO PLACE. AFTER SEVERAL TRIES, THE DOCTOR FINALLY WAS ABLE TO PLACE IT. I SPENT THE REST OF THE DAY IN BED RESTING. THE NEXT DAY I BEGAN TO HAVE LABOR LIKE CRAMPING AND VERY HEAVY MENSTRUAL BLEEDING. I CALLED MY DOCTOR AND THEY ASKED ME TO KEEP THEM POSTED. AFTER A COUPLE WEEKS OF PROGRESSIVELY WORSE BLEEDING, CRAMPING, FOLLOWED WITH MIGRAINES, HORRID BACK PAIN, AND EXTREME FATIGUE, MY DOCTOR ORDERED AN X-RAY TO RULE OUT PERFORATION. THE X-RAY SHOWED THAT THE COILS WERE EXACTLY WHERE THEY WERE SUPPOSED TO BE. MY SYMPTOMS GOT WORSE AND GOT MORE COMPLICATED. HAIR LOSS, MEMORY LOSS, CONFUSION, JOINT AND MUSCLE PAIN, INSOMNIA AND CHRONIC INFECTIONS FOLLOWED. I JUST WANTED BIRTH CONTROL, BUT GOT WAY MORE THAN WHAT I WAS EXPECTING. I WAS FORTUNATE THAT MY IMPLANTING DOCTOR WANTED TO SCHEDULE A HYSTERECTOMY IMMEDIATELY. MY DR SAID THAT I WAS HAVING A BAD REACTION TO ESSURE, HE HAD NEVER SEEN IT BEFORE, BUT TOOK ME SERIOUSLY IMMEDIATELY. I HAD ONE VISIT TO THE EMERGENCY ROOM DUE TO FAINTING SPELLS. I HAVE A NICKEL ALLERGY AND SHARED THAT WITH MY DOCTOR BEFORE IMPLANTATION AND HE SAID THAT NICKEL HAD BEEN REMOVED FROM THE LIST OF CONTRA-INDICATIONS. I HAD THE ESSURE COILS IN FOR ONLY 10 WEEKS, BUT IT WAS 10 WEEKS OF TOTAL (B)(6). I STARTED FEELING BETTER WITHIN HOURS AFTER MY HYSTERECTOMY AND MOST OF MY SYMPTOMS WERE GONE WITHIN A FEW WEEKS. I NEVER THOUGHT I WOULD HAVE TO HAVE SUCH AN EXTREME SURGERY AT THE AGE OF (B)(6). I HAD TO TAKE THREE WEEKS OFF FROM WORK DURING (B)(6).

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031827	CONCEPTUS, NOW BAYER	9/12/2013	9/19/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS 205
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/18/2004
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WILL HAVE ESSURE BIRTH CONTROL COILS REMOVED AFTER YEARS OF UNEXPLAINED PELVIC PAIN ON MY LEFT SIDE. I HAVE EXPERIENCED UNEXPLAINED PELVIC PAIN, ODD RASHES, AND METAL TASTE IN MY MOUTH. MY DOCTOR SAYS HE WILL REMOVE ESSURE COILS VIA SURGERY AS IT SEEMS MY BODY IS BEGINNING TO REJECT THE COILS. WHEN I HAVE THE PAIN IT IS ON MY LOWER LEFT SIDE, FEELS LIKE A PIECE OF A TOOTHPICK POKING. THE PAIN IS VERY DISTRACTING AND IMPACTS WHAT I DO OR OPT TO NOT DO IN MY LIFE. ESSURE INSERTED IN 2004, PELVIC PAIN FIRST DOCUMENTED IN 2006. HAVE REPORTED PAIN TO PRIMARY CARE DOCTOR FOR PAST FEW YEARS. IMPLANTING DOCTOR OFFICE "LOST MY RECORDS" AND NO HSG TEST FROM RESULTS FROM 2004 CAN BE FOUND EITHER. MY PRIMARY CARE DOCTOR DID NOT KNOW SMALL AMOUNT OF NICKEL IS IN THE COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031828	CONCEPTUS/BAYER	9/12/2013	9/19/2013

Event Information:

Event Date (B3): 5/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/20/2011
Explant Date (E7): 1/21/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE (B)(6) 2011. STARTED DIZZY/LIGHTHEADEDNESS AND PAIN/ACHE IN PELVIC AREA BY (B)(6) 2011. URGENT CARE FOR CHEST PAINS AND SHORTNESS OF BREATH (B)(6) 2011; WORSENING LIGHTHEADEDNESS, "BRAIN FOG," LACK OF FOCUS, EXTREME FATIGUE, MOOD SWINGS/IRRITABILITY. FELT AS IF MY "BLOOD WAS ON FIRE." BLOATED AND SWELLING. CONSTANT ACHE ON MY LEFT SIDE WITH OCCASIONAL SHOOTING PAINS. TESTED FOR THYROID AND OTHER AT MY GENERAL CHECKUP. FOUND THYROID LOW AND RECEIVED MEDS. HELPED WITH SHORTNESS OF BREATH; ALL OTHER SYMPTOMS BECAME WORSE AND ADDED JOINT PAIN IN MY HANDS, HIPS, KNEES AND ANKLES. MORE TESTING AND SPECIALIST REFERRAL FOR LUPUS, FIBROMYALGIA AND RHEUMATOID ARTHRITIS. ALL TESTS CAME BACK NEGATIVE EXCEPT ELEVATED CPANEL VALUES INDICATING INFLAMMATION. GIVEN ANTI-INFLAMMATORY FOR ABOUT 10 DAYS AND FELT BETTER. SYMPTOMS RETURNED AFTER MEDICATION WAS COMPLETE. HAD ESSURE REMOVED VIA LAPAROSCOPY IN (B)(6) 2013. I AM FEELING SO MUCH BETTER. IMMEDIATELY FELT THE ACHE/PAIN IN PELVIC AREA WAS GONE. AFTER ABOUT A MONTH, NO BRAIN FOG, HAVE ENERGY BACK, CAN FOCUS/CONCENTRATE AND WORK AGAIN. I NO LONGER HAVE JOINT PAIN IN MY HANDS, HIPS OR KNEES AND THE SWELLING HAS COME DOWN. I NO LONGER FEEL THAT I AM "ON FIRE" OR A GENERAL "UNWELL" FEELING. MY CPANEL BLOOD VALUES ARE COMING DOWN AS OF LAST TESTING. I WILL BE TESTED AGAIN IN (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031829	CONCEPTUS/BAYER	9/12/2013	9/19/2013

Event Information:

Event Date (B3): 1/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 787230

Single Use:
Implant Date (E6): 1/14/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED (B)(6) 2011, AND SOON AFTER BEGAN HAVING PELVIC PAIN. OVER THE NEXT FEW MONTHS, I STARTED HAVING HEAVIER PERIODS, CRAMPING, BLOATING, BACK PAIN, PAIN DURING INTERCOURSE, PAIN DURING OVULATION, HAIR LOSS, FATIGUE, JOINT PAIN AND THE PELVIC PAIN CONTINUED TO GET WORSE, SOMETIMES ITS DULL AND SOMETIMES A SHOOTING PAIN. MY QUALITY OF LIFE HAS DECREASED SIGNIFICANTLY SINCE ESSURE AND I AM NOW LOOKING TO HAVE THEM REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031830	CONCEPTUS, INC.	9/12/2013	9/19/2013

Event Information:

Event Date (B3): 9/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 857594; 852530

Single Use:
Implant Date (E6): 9/9/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE ON (B)(6) 201. MY PROCEDURE TOOK PLACE AS OUTPATIENT SURGERY AT A MAJOR TEACHING HOSPITAL UNDER GENERAL ANESTHESIA. THE PROCEDURE WAS COMPLICATED DUE TO DEVICE FAILURE IN THE RIGHT TUBAL OSTIA, REQUIRING A SECOND ATTEMPT, WHICH WAS CONSIDERED SATISFACTORY. NO ADVERSE EVENT WAS FILED. I WAS IN PAIN ON THE RIGHT SIDE WHEN I WOKE UP, AND HAVE BEEN EXPERIENCING VARYING DEGREES OF PAIN EVER SINCE. AT FIRST, IT WAS WHAT I WOULD CONSIDER "NUISANCE", BUT HAS BECOME SEVERE ENOUGH TO INTERFERE WITH MY DAILY LIFE. I HAD TO QUIT MY JOB IN (B)(6), DUE TO MY SYMPTOMS. IN ADDITION TO ABDOMINAL PAIN, I HAVE EXPERIENCED PAINFUL SEX, EXTREME FATIGUE, JOINT PAIN, AND RASHES SINCE THE PROCEDURE. IN THE LAST 10 MONTHS, I HAVE A CONSTANT LOW GRADE TEMPERATURE AND BOUTS OF ABDOMINAL SWELLING, LOSS OF APPETITE, BRAIN SHOCKS, AND SWOLLEN JOINTS IN MY FINGERS. I WENT FROM VISITING THE DOCTOR AN AVERAGE OF 2 TIMES PER YEAR, PRIOR TO MY PROCEDURE, TO 17 VISITS SINCE ESSURE WAS PLACED 2 YEARS AGO. I HAVE ALSO ENDURED MULTIPLE BLOOD WORK UPS, 4 ULTRASOUNDS, A CT SCAN, PELVIC X-RAY, A MONTH OF PHYSICAL THERAPY, A CORTISONE INJECTION, AN EXPLORATORY LAPAROSCOPY WHERE ADHESIONS WERE FOUND AND CUT, AND LUPRON TO RULE OUT ENDOMETRIOSIS. THE PRESENCE OF ADHESIONS HAS NO EXPLANATION SINCE I HAVE NOT HAD ABDOMINAL SURGERY, PID, OR ANY OTHER COMMON CAUSE. MY PRIMARY CARE DOCTOR SUGGESTED A CORRELATION BETWEEN THE COILS AND MY ONGOING HEALTH PROGRAMS. MY PHYSICAL THERAPIST SUGGESTED A POSSIBLE FOREIGN BODY REACTION. I AM NOW UNDER THE CARE OF AN OBGYN AND IN THE PROCESS OF SCHEDULING A HYSTERECTOMY TO REMOVE THE COILS AND FIND RELIEF FROM INFLAMMATION AND SEVERE PAIN IN MY

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ABDOMEN/PELVIS AND HIPS. I AM NOT ABLE TO FULLY FUNCTION AS A WIFE, EMPLOYEE, HOMEMAKER OR MOTHER AND IT IS AFFECTING MY MENTAL WELL BEING AS WELL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031831	BAYER	9/12/2013	9/19/2013

Event Information:

Event Date (B3): 4/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/1/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE PROCEDURE DONE IN 2008 AT THE URGING OF MY DOCTOR. HE TOLD ME THAT I WOULD HAVE TO STOP TAKING THE PILL AFTER (B)(6), AS IT WAS NOT SAFE TO DO SO. I HAD ALL HIGH RISK PREGNANCIES AND COULDN'T TAKE THE CHANCE OF GETTING PREGNANT AFTER (B)(6) BECAUSE OF THAT. HE SAID ESSURE WAS SAFE AND NON INVASIVE AND SOLD IT AS AN ALTERNATIVE TO SURGERY TO HAVE MY TUBES TIED. I WAS NOT TOLD OF ANY RISKS INVOLVED AND GIVEN A SMALL PAMPHLET THAT MADE IT LOOK LIKE A GOOD ALTERNATIVE. I HAD IT DONE IN MY DOCTOR'S OFFICE AND WAS BACK TO WORK THE NEXT DAY, THINKING EVERYTHING WAS FINE. ONLY A MONTH OR SO AFTER THE PROCEDURE, I WAS HAVING SEVERE PAIN AND WENT TO THE ER. THEY DIDN'T KNOW WHY I WAS IN PAIN AND RAN ALL SORTS OF TESTS AND CAME TO THE CONCLUSION THAT I HAD SOME SORT OF MASS IN MY OVARY. THIS REALLY SCARED ME AND I WAITED FOR ABOUT A WEEK IN THE HOSP NOT KNOWING WHAT WAS WRONG. THEY DID SURGERY AND ENDED UP REMOVING MY OVARY AND TUBE AND PLACED A STENT IN MY KIDNEY, AS IT HAD BEEN DAMAGED. THE OVARY HAD A GRAPEFRUIT SIZED CYST THAT HAD CAUSED ALL OF THIS. I KNOW ESSURE CAUSED THIS EVEN THOUGH THE DOC WOULD NOT TELL ME THIS, BUT WHAT ELSE COULD IT HAVE BEEN. I WAS FINE BEFORE ESSURE. I WAS HEALTHY. SINCE MY PROCEDURE, MY HEALTH HAS SUFFERED. I GAINED WEIGHT THAT I CANNOT LOSE, GET STRANGE RASHES, HEADACHES, PAINS IN MY PELVIC AREAS, SEVERE BACK PAIN, HEAVY PERIODS LASTING FOR UP TO 3 WEEKS OR MORE, BLADDER/KIDNEY PROBLEMS, DEPRESSION, LACK OF ENERGY, ETC. THESE ARE JUST SOME OF THE SYMPTOMS I'VE HAD, THERE ARE MORE. NOW THE ONLY RELIEF I HAVE TO LOOK FORWARD TO IS HAVING A HYSTERECTOMY TO REMOVE THIS FROM MY BODY. I CAN'T AFFORD MY OUT OF POCKET PORTION OR I WOULD HAVE ALREADY HAD IT. NO MORE WOMEN SHOULD HAVE TO BE PUT AT RISK WITH THIS PRODUCT. THE RISKS ARE JUST NOT WORTH IT.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031843	CONCEPTUS/BAYER	9/13/2013	9/19/2013

Event Information:

Event Date (B3): 6/27/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 686077

Single Use:
Implant Date (E6): 4/14/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE (B)(6) 2010. HAD HSG CONFIRMATION TEST (B)(6) 2010 WHICH CONFIRMED TUBES WERE 100% BLOCKED. BECAME PREGNANT IN (B)(6) 2011. EXPERIENCED MANY PROBLEMS DURING PREGNANCY AND WAS HOSPITALIZED WITH PRE-TERM LABOR 3 TIMES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031844		9/13/2013	9/19/2013

Event Information:

Event Date (B3): 3/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/2/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN (B)(6) 2011 AND I HAVE BEEN HAVING PAIN DOWN THERE AND IN MY LOWER BACK AND MIGRAINES AND NAUSEA AND WEIGHT GAIN AND PAIN IN INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031845	CONCEPTUS INC.	9/13/2013	9/19/2013

Event Information:

Event Date (B3): 9/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS A YEAR AGO SINCE, I HAVE HAD SEVERE LOWER BACK PAIN, BLOATING, HOT FLASHES, HEAVIER PERIODS, NUMBNESS IN LEGS AND HANDS, DIZZINESS, RINGING IN EARS, METALLIC TASTE IN MOUTH, WEIGHT GAIN, DEPRESSION AND HOSPITALIZED. I HAD TO QUIT A JOB DUE TO PHYSICAL IMPAIRMENTS FROM THE DEVICE. I WENT TO MY DOCTOR. I WENT THROUGH MRI'S, CAT SCANS AND FOUND BEGINNING STAGES OF OSTEOARTHRITIS, HOWEVER, NEITHER MY DOCTOR OR NEUROLOGIST COULD EXPLAIN WHY I HAD SUCH EXTREME PAIN ALONG WITH THE OTHER SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031846	CONCEPTUS/BAYER	9/13/2013	9/19/2013

Event Information:

Event Date (B3): 12/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 893028

Single Use:
Implant Date (E6): 12/17/2012
Explant Date (E7): 8/1/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GETTING PREGNANT WITH MY FIFTH CHILD I DECIDED NOT TO HAVE ANY MORE CHILDREN, I TOLD MY DOCTOR I WANTED A TUBAL AND SIGNED MY CONSENT BEFORE MY LAST WAS BORN. THE PROCEDURE WAS TO BE PERFORMED 24 HOURS AFTER DELIVERY WHICH WOULD HAVE BEEN ON (B)(6) 2012. THE MORNING OF THE (B)(6), THE DOCTORS CAME AND TOLD ME THEY WERE GETTING THE OPERATING ROOM TOGETHER THAT THEY SHOULD BE COMING TO GET ME SHORTLY. AN HOUR LATER THEY CAME BACK INFORMING ME THAT THEY DIDN'T HAVE ENOUGH STAFF AND THE ONES THEY HAD THEY NEEDED FOR EMERGENCIES ONLY AND THAT I WOULD HAVE TO HAVE IT DONE IN OUT-PATIENT. I WENT FOR MY CONSULT FOR THE TUBAL WHEN I WAS THEN OFFERED ESSURE AS A DIFFERENT METHOD. I HADN'T HEARD MUCH ABOUT IT BEFORE SO I ASKED THEM WHAT IT WAS AND WERE THERE ANY SIDE EFFECTS. THEY TOLD ME IT'S LESS EVASIVE THAN TUBAL AS THEY WOULDN'T HAVE TO DO SURGERY, THAT IT GOES THROUGH THE VAGINA AND I WILL BE ABLE TO RUN AROUND THE NEXT DAY. THEY ALSO SAID I WOULD HAVE MILD CRAMPING THAT SHOULDN'T LAST BUT A WEEK. WELL WEEKS LATER I WAS STILL HAVING SEVERE PAIN IN MY ABDOMEN. I MISSED SO MUCH WORK DUE TO THE PAIN THAT I LOST MY JOB AT (B)(4) THAT I'VE HAD SINCE (B)(6) 2010. I WENT BACK AND TOLD THE DOCTORS AND WAS TOLD I WAS PROBABLY JUST CONSTIPATED. I GUESS I HAD WRITTEN ON MY FACE AS IF I DON'T KNOW THE DIFFERENCE. THEY JUST PRESCRIBED MORE PAIN MEDS WHICH ONLY PUT ME TO SLEEP. AFTER GETTING ESSURE MY STOMACH STARTED BLOATING AND BEFORE I KNEW IT, IT LOOKED AS IF I WERE 8 MONTHS PREGNANT. I GAINED OVER 25 POUNDS SINCE GETTING THE PROCEDURE AND HAVE BEEN UNABLE TO LOSE AN OUNCE EVEN WITH DIET AND EXERCISE. I'VE HAD SEVERE SWELLING IN MY FEET THAT CAME AND WENT, METALLIC TASTE IN MY MOUTH, TIRED FEELING ALL DAY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

AND I THOUGHT IT WAS JUST ME UNTIL I DECIDED TO SEARCH FOR ESSURE ON (B)(4) AND CAME ACROSS A GROUP "ESSURE PROBLEMS" WHEN I SAW I WASN'T ALONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031847	CONCEPTUS	9/13/2013	9/19/2013

Event Information:

Event Date (B3): 8/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 8/5/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVELOPED HIVES FROM ALLERGY TO NICKEL, SO BAD. HAD TO HAVE BOTH OF MY FALLOPIAN TUBES REMOVED TO GET ESSURE OUT OF MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031851	CONCEPTUS/BAYER	9/16/2013	9/23/2013

Event Information:

Event Date (B3): 12/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50667569

Single Use:
Implant Date (E6): 12/26/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ADVERSE EVENT REPORT ON A MEDICAL DEVICE CALLED ESSURE, MANUFACTURED BY CONCEPTUS/BAYER. WHEN MY DOCTOR WENT TO INSERT THE DEVICE, THE FIRST COIL WAS BENT RIGHT OUT OF THE BOX. THE SECOND COIL WOULD NOT RELEASE CORRECTLY WHEN IT WAS IMPLANTED INTO MY TUBE. I VOMITED AFTER THE PROCEDURE AND ALMOST PASSED OUT. I WAS SO SWOLLEN I LOOKED 6 MONTHS PREGNANT. STILL TO THIS DAY, I CAN NOT WEAR CLOTHES THAT I HAD WORN THE WEEK BEFORE IMPLANTATION. SINCE THE PROCEDURE, I GET SO BLOATED AT TIMES, I LOOK 6-8 MONTHS PREGNANT. I HAVE EXPERIENCED MIGRAINES, NAUSEA, CONSTANT CRAMPING (FEELS LIKE BAD MENSTRUAL CRAMPS), HEAVIER THAN NORMAL MENSTRUAL BLEEDING (I WAS NOT ON HORMONE BIRTH CONTROL BEFORE THE PROCEDURE), UNEXPLAINED HIVES, TINGLING IN MY HANDS AND FEET, MY HEART CONDITION HAS WORSENED (SMALL VESSEL DISEASE WITH CARDIAC SPASMS NOT CAUSED BY A BLOCKAGE), WORSENING OF MY PSORIASIS, ARTHRITIS, AND BACK SPASMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031853	CONCEPTUS, INC	9/16/2013	9/23/2013

Event Information:

Event Date (B3): 4/3/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/3/2009
Explant Date (E7): 9/24/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) OF 2009 AND EVER SINCE I HAVE HAD SEVERE PROBLEMS. RANGING FROM WHAT WAS THOUGHT TO BE FIBROMYALGIA, PAIN THROUGHOUT MY BODY, CONSTANT MIGRAINES, BOWEL PROBLEMS, MOOD CHANGES, NON STOP VAGINAL BLEEDING, CONSTANTLY TIRED, MOOD CHANGES THE LIST GOES ON. THE DR THAT PERFORMED THE PROCEDURE LEFT (B)(4) SHORTLY AFTER I WAS IMPLANTED, FOR (B)(4). I WENT TO NEW OBGYN WHO DISCOVERED MULTIPLE THINGS, THE COILS WERE NOT WHERE THEY WERE SUPPOSED TO BE AND I HAVE ENDOMETRIOSIS AND ALSO NICKEL ALLERGY, I WAS NEVER TESTED FOR. ON (B)(6) AT YEARS, I HAVE A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031854	CONCEPTUS	9/16/2013	9/23/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/31/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN SICK EVER SINCE I HAD ESSURE PUT IN ME, CHRONIC PAIN IN MY STOMACH AND BACK, PERIOD CHANGES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031855	BAYER	9/16/2013	9/23/2013

Event Information:

Event Date (B3): 9/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/12/2013
Explant Date (E7): 9/12/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE. MY PROCEDURE WAS DONE BY AN EXPERIENCED MEDICAL PROFESSIONAL WHO HAS PERFORMED THIS PROCEDURE MANY TIMES. THE DEVICE ITSELF FAILED, AND COULD NOT BE DEPLOYED. THIS WAS NOT USE TO THE MEDICAL PROFESSIONAL, BUT THE DEVICE ITSELF. THIS COMPLICATION IS LEADING ME TO HAVING A SURGERY IN THE COMING WEEKS, WHICH WILL RESULT IN MORE COST TO ME. MY DR HAS BEEN POLITE PROFESSIONAL AND HELPFUL THROUGH THIS PROCESS, THIS IS IN NO WAY A COMPLAINT AGAINST MY DR. THIS IS A COMPLAINT AGAINST THE COMPANY WHICH MAKES THE PRODUCT, BAYER. DUE TO THE DEVICE ITSELF FAILING, I HAD EXCRUCIATING PAIN. MY DR WAS UNABLE TO REMOVE THE DEVICE AND NEEDED TO CALL IN A SECOND DR TO HELP REMOVE THE DEVICE. THE COMPANY MUST BE MADE TO TEST PRODUCTS MORE VIGOROUSLY TO ENSURE THIS DOES NOT HAPPEN TO OTHER PTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031866	CONCEPTUS/BAYER	9/16/2013	9/23/2013

Event Information:

Event Date (B3): 8/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/10/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE PERFORMED AND EVER SINCE THEN, I HAVE HAD CONSTANT ONGOING BLEEDING (PERIODS LASTING 2+ WEEKS AND HEAVY BLEEDING DURING SEXUAL INTERCOURSE. SEXUAL ACTIVITY IS INCREDIBLY UNCOMFORTABLE AS WELL. I HAVE ALSO HAD CONTINUED WEIGHT GAIN DESPITE BEING ON THE SAME EXACT DIET AND EXERCISE REGIMEN (IF NOT BETTER DIET AND EXERCISE REGIMEN) VS BEFORE THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031970		9/16/2013	9/25/2013

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE SYSTEM WAS PUT IN ON (B)(6) 2013. I WAS TOLD I WAS SAFE AND COULD NOT GET PREGNANT. A MONTH AFTER SPEAKING WITH THE DOCTOR I FOUND OUT I WAS PREGNANT. I ALSO AM HAVING PAIN ON ONE SIDE. I HAVE ALSO FOUND OUT THAT THE SAME SIDE THE SPRING HAS RUPTURED OUT OF THE TUBE. I AM VERY UPSET WITH THIS PRODUCT. I WISH ESSURE INCLUDED THESE THINGS IN THEIR SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031909	CONCEPTUS	9/17/2013	9/24/2013

Event Information:

Event Date (B3): 3/6/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626220

Single Use:
Implant Date (E6): 3/6/2008
Explant Date (E7): 3/26/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2008, HAD ESSURE PERMANENT BIRTH CONTROL IMPLANTED. YEARS AFTER I STARTED DEVELOPING THYROID PROBLEMS, WEIGHT GAIN, DEPRESSION, SEVER PELVIC PAIN, PAIN WITH SEX, POLY-CYSTIC OVARY SYNDROME, IRREGULAR MENSTRUAL CYCLE, SEVERE BACK PAIN, HAIR LOSS, JOINT PAIN, GALLBLADDER REMOVED, IBS, FLOATERS IN EYES, DAY/NIGHT SWEATS, INSOMNIA, PTSD, DISCHARGE, FATIGUE/LOSS OF ENERGY, MOOD SWINGS, ENLARGED UTERUS,. ENDED IN A HYSTERECTOMY WITH REMOVAL OF UTERUS, CERVIX, OVARIES AND TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031910	CONCEPTUS/BAYER	9/17/2013	9/24/2013

Event Information:

Event Date (B3): 9/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/14/2009
Explant Date (E7): 1/16/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL CAUSED ME TO HAVE TO ENDURE 2 SURGERIES. FIRST SURGERY WAS A SALPINGECTOMY IN (B)(6) 2013 AND SECOND SURGERY (B)(6) 2013 WAS A FULL HYSTERECTOMY DUE TO ENDOMETRIOSIS, WHICH I WAS DIAGNOSED WITH IN (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031911	CONCEPTUS/BAYER	9/17/2013	9/24/2013

Event Information:

Event Date (B3): 5/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN MY FALLOPIAN TUBES. ONE OF THE COILS MIGRATED OUT OF MY TUBE. I BECAME PREGNANT. BABY WAS BORN VIA SECTION. ONE COIL WAS REMOVED FROM MY RIGHT TUBE. THE OTHER COIL IS STILL MISSING. I HAVE NOT HAD AN X-RAY TO FIND IT. IT IS LIKELY IT IS STILL INSIDE ME SOMEWHERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031912	BAYER	9/17/2013	9/24/2013

Event Information:

Event Date (B3): 9/16/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2011, HAD THE HSG TEST DONE IN (B)(6) 2011. I WAS CONFIRMED BLOCKED AND ON (B)(6) 2012, I FOUND OUT I WAS 5 MONTHS PREGNANT AND DELIVERED (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031913	CONCEPTUS	9/17/2013	9/24/2013

Event Information:

Event Date (B3): 10/10/2012 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 761611

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PLACED IN (B)(6) 2010. HAD THE DYE TEST COMPLETED IN (B)(6) 2011 AND DOCTOR SAID IT WAS GOOD/100% BLOCKAGE. (B)(6) OF 2012, I FOUND OUT I WAS PREGNANT. THE ESSURE COIL ON MY RIGHT SIDE MIGRATED INTO MY BODY. THE LEFT ONE PUSHED THROUGH THE LEFT FALLOPIAN TUBE AND IS HANGING OUT OF IT. THIS IS A POOR PRODUCT THAT CONCEPTUS PUT OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031922	CONCEPTUS/BAYER	9/17/2013	9/24/2013

Event Information:

Event Date (B3): 9/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE STOP DEVICE (NOW MARKETED AS ESSURE) IN 2000. I WAS PART OF THE STUDY GROUP AND WHILE INVOLVED IN THE STUDY COMPLAINED OF PAIN AND OTHER ISSUES. THESE ISSUES WERE DISMISSED BY THE STUDY STAFF AND I WAS TOLD THAT I MUST HAVE ANOTHER HEALTH ISSUE AND THAT MY COMPLAINTS WERE NOT RELATED TO THE DEVICE. NOW, 13 YEARS LATER, AND AFTER NUMEROUS SPECIALISTS AND TESTS, I AM HAVING A HYSTERECTOMY TO REMOVE THE IMPLANTS. I SUFFER FROM WILDLY ERRATIC, IRREGULAR PERIODS, PELVIC PAIN THAT IS NEARLY CONSTANT, SHARP STABBING PAINS IN THE PELVIS REGIONS, HEADACHES, SYMPTOMS OF SEVERE ALLERGIC REACTION FROM AN UNK SOURCE (PRESUMABLY FROM THE NICKEL AND/OR PET FIBERS), WIDESPREAD SEVERE SWELLING, EXTREME FATIGUE, MUSCLE PAIN AND WEAKNESS, MUSCLE SPASMS AND TREMORS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032299	BAYER	9/17/2013	10/21/2013

Event Information:

Event Date (B3): 3/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE MEDICAL DEVICE
Device Type (E2): ESSURE MEDICAL DEVICE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): A64626

Single Use:
Implant Date (E6): 3/11/2013
Explant Date (E7): 9/15/2013
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PRODUCT IMPLANTED IN MY FALLOPIAN TUBE. SINCE (B)(6) 2013, I HAVE HAD PAIN WHERE IMPLANTED, CRAMPING SCALE OF 1-10 (7 OR 8), BACK PAIN AND HEADACHES. I HAVE SEEN MY GYNECOLOGIST AND HAVE SEEN 2 DIFFERENT ONES FOR A SECOND AND THIRD OPINION. SINCE GETTING THE ESSURE IMPLANTED, I HAVE HAD NOTHING BUT PAIN, STABBING PAIN IN MY LEFT SIDE AND CRAMPING EVERY DAY. I JUST WANT THIS OUT SO I CAN BE MYSELF AGAIN WITH NO MORE PAIN. I SUFFER EVERY DAY WHERE THE DEVICE WAS IMPLANTED. PERMANENT BIRTH CONTROL WAS SUPPOSED TO BE A STERILIZATION DEVICE. QUANTITY (FOR EXAMPLE, 2 PILLS, 2 PUFFS, OR 1 TEASPOON, ETC.): 1 COIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031938	CONCEPTUS	9/18/2013	9/25/2013

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/1/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE RECEIVING THE ESSURE STERILIZATION I HAVE DEVELOPED THE FOLLOWING SIDE AFFECTS: JOINT PAIN, MUSCLE PAIN, MIGRAINES, HEADACHES, HAIR LOSS, SEVERE SKIN ITCHINESS, PAINFUL INTERCOURSE, BLEEDING DURING INTERCOURSE, IRREGULAR PERIODS, FATIGUE, I AM ALWAYS OVERHEATED AND SWEATING, DIARRHEA, VOMITING, DERMATITIS, STAPH FOLLICULITIS, EXTREME AND QUICK WEIGHT GAIN, VERTIGO/DIZZINESS, GENERAL DAILY "SICK" FEELING, BODY ACHES, CRAWLING ON SKIN SENSATION, MOUTH SORES, SHARP STABBING AND SHOOTING PAINS IN THE ABDOMEN, EAR ITCHING, ANAL ITCHING, VAGINAL ITCHING, ANXIETY, DEPRESSION, BACK PAIN, BLURRED VISION/FLOATERS, FORGETFULNESS, CONFUSION, HEARTBURN, COUGHING UP MUCUS, CRAMPING, EAR PAIN/SWELLING SHUT, LOSS OF APPETITE, INABILITY TO MAINTAIN SUGAR LEVELS, INSOMNIA, MOOD SWINGS, MUSCLE SPASMS, NAUSEA, NERVE PAIN, METAL TASTE, NIGHT SWEATS, NUMBNESS IN HANDS/FEET, PAINFUL OVULATION, PELVIC PAIN, PRESSURE/PAIN ON BOTTOM WHILE SITTING, SWELLING OF HANDS/FEET, PAINFUL OVULATION, PELVIC PAIN, PRESSURE/PAIN ON BOTTOM WHILE SITTING, SWELLING OF HANDS/FEET, VITAMIN D DEFICIENCY, LUMPS IN ARMPITS, CLUMSINESS AND TRIPPING (FALLING DOWN).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031942	CONCEPTUS	9/18/2013	9/25/2013

Event Information:

Event Date (B3): 8/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/22/2012
Explant Date (E7): 9/23/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED ONE YEAR AGO. PAINFUL CYCLES SO BAD CAN'T WALK FOR 2 DAYS TOOK PAIN MEDS PRESCRIBED AND OTC NOTHING HELPED. SEEN NEW MEDICAL DOCTOR WHO DID INTERNAL ULTRASOUND, SHE FOUND OUT ONE COIL HAS COME HALFWAY OUT AND ONE END OF IT IS EMBEDDED IN UTERUS. HAVE TO HAVE SURGERY TO SEE IF IT CAN BE REMOVED BY DOING A TUBAL TO HAVE ACCESS ON BOTH SIDES OF THE COIL TO MAYBE GET IT OUT. IF NOT WILL HAVE TO HAVE A HYSTERECTOMY RIGHT THEN. JUST BECAUSE MY OLD DOCTOR SAID ITS 100 PERCENT SAFE AND PAIN FREE. SHE CAUSED ME SO MUCH PAIN PUTTING IT IN AND THEN SAID "OH I GUESS I USED THE WRONG SIZE OF ROD TO PUT IN THE COILS". LET'S TAKE THOSE OUT AND START OVER AGAIN. 'SECOND TIME AFTER SHE WAS DONE I ALMOST PASSED OUT FROM PAIN AND NAUSEA THEY HAD ME LAY BACK DOWN AND WHEN I HAD BEEN THERE 30 MINUTES THEY SAID " HONEY YOU HAVE TO LEAVE NOW ITS TIME TO CLOSE THE OFFICE."

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00017	BAYER HEALTHCARE LLC	9/18/2013	9/27/2013

Event Information:

Event Date (B3): 8/26/2013 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNKNOWN

Single Use: Y
Implant Date (E6): 8/20/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD ESSURE PROCEDURE (B)(6) 2013. PHYSICIAN PLACED ON ESSURE DEVICE IN PATIENT'S RIGHT AND LEFT FALLOPIAN TUBE. ON (B)(6) 2013 PATIENT WENT TO EMERGENCY ROOM WITH ABDOMINAL PAIN. DR (B)(6) (WHO WAS NOT THE IMPLANT DOCTOR) PERFORMED A PELVIC EXAM FOUND THE PATIENT'S CERVIX, FALLOPIAN TUBES AND UTERUS WERE NECROTIC. PATIENT HAD BLOOD CULTURES, PATIENT TESTED POSITIVE FOR GROUP A STREP INFECTION. ON (B)(6) 2013, PATIENT WENT INTO RENAL FAILURE AND DIC, PATIENT PASSED WAY. ON (B)(6) 2013, DR (B)(6) STATED BLOOD CULTURES WERE POSITIVE FOR GROUP A STREP AND HE BELIEVES THE CAUSE OF DEATH WAS RELATED TO NECROTIZING GROUP A STREPTOCOCCUS INFECTION (STREPTOCOCCAL TOXIC SHOCK SYNDROME).

Manufacturer Narrative (H10):

THE MEDICAL OPINION OF THE ATTENDING PHYSICIAN WAS THAT THE CAUSE OF DEATH WAS NOT DIRECTLY RELATED TO THE ESSURE INSERTS OR PROCEDURE.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031985	CONCEPTUS	9/23/2013	9/27/2013

Event Information:

Event Date (B3): 9/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/19/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL PROCEDURE DONE 3 MONTHS AGO. FIVE MONTHS AFTER THE BIRTH ON MY THIRD (AND DESIRED TO BE LAST) SON. I HAVE BEEN IN NONSTOP PAIN ON MY LEFT SIDE SINCE I HAD IT DONE. I THOUGHT IT WAS BECAUSE THE DOCTOR HAD TO DO IT TWICE SINCE THE DEVICE DID NOT DEPLOY BUT THE PAIN HAS NEVER STOPPED. I NOW ALSO BLEED 21 DAYS A MONTH AS WELL. I HAVE NOT CONSULTED MY OB/GYN BECAUSE I FIGURED THESE WERE JUST NORMAL SIDE EFFECTS OF THE DEVICES AND IT WOULD TAKE MY BODY A WHILE TO GET USED TO IT. TODAY I HAD MY HSG CONFIRMATION TEST DONE. BOTH TUBES ARE BLOCKED COMPLETELY AND IN CORRECT POSITION. HOWEVER, I HAVE A THIRD COIL ATTACHED TO MY ENDOMETRIAL WALL. MY DOCTOR NEVER TOLD ME SHE WAS GOING TO JUST LEAVE THE DEVICE THAT DIDN'T DEPLOY DURING THE FIRST ATTEMPT INSERTION FLOATING AROUND INSIDE ME. THE DOCTOR DOING THE HSG PROCEEDED TO TRY TO TELL ME THAT HAVE A THIRD DEVICE WAS COMMON IF THEY HAD TO TRY TWICE I HAVE CONSTANT ABDOMINAL PAIN, HEADACHES AND EXCESSIVE BLEEDING. I NOW HAVE TO GO TO A SPECIALIST TO TRY TO HAVE THEM REMOVED WHICH MOST LIKELY MEANS A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031986	CONCEPTUS	9/23/2013	9/27/2013

Event Information:

Event Date (B3): 9/19/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/19/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED ON (B)(6) 2011, BY DR. (B)(6). I WAS TOLD BY DR. (B)(6) THAT THE PROCEDURE WAS GOING TO BE A QUICK 15 MINUTE PROCEDURE AND I WOULD BE ABLE TO RETURN TO WORK. ON THE DAY OF MY PROCEDURE EVERYTHING SEEMED TO BE GOING OK. I WAS IN MORE PAIN THAN I EXPECTED DURING THE DILATION OF MY CERVIX. DR. (B)(6) STARTED WITH THE LEFT COIL FIRST. IT FELT LIKE MY FALLOPIAN TUBE WAS ON FIRE. WHEN THE RIGHT COIL WAS BEING DEPLOYED IT BROKE. DR. (B)(6) HAD TO REMOVE THE FRAGMENTS FROM MY UTERUS. THAT WAS COMPLETELY EXCRUCIATING. I LAY THERE IN TEARS TRYING TO FOCUS ON THE CEILING. WHEN THE FRAGMENTS WERE ALL REMOVED ONE OF THE NURSES HAD TO RECEIVE ANOTHER COIL WHEN DR. (B)(6) TRIED TO DEPLOY THE RIGHT ONE, AGAIN, HE HAD TO MOVE AROUND A POLYP. ANOTHER COUPLE EXCRUCIATING MINUTES TICK BY. WHEN THE COIL IS FINALLY DEPLOYED I FEEL THE SAME BURNING SENSATION AS THE LEFT. MY PROCEDURE TOOK AROUND 2 AND A HALF HOURS. I WAS NOT ABLE TO RETURN TO WORK FOR A WEEK AND A HALF DUE TO CONSTANT BLEEDING AND PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031988	CONCEPTUS / BAYER	9/23/2013	9/27/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 626975 (RIGHT); 626919 (LEFT)

Single Use:
Implant Date (E6): 7/21/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MANUFACTURED BY CONCEPTUS, IMPLANTED AT (B)(6) 2008. DEVICE FAILED, RIGHT SIDE, FALLOPIAN TUBE PERFORATED, DEVICE IN ABDOMINAL CAVITY, CONFIRMED BY VA ORTHOPEDIC DOCTOR DURING X-RAYS, (B)(6) 2013, TWO PREGNANCIES, BOTH MEDICALLY NECESSARY TERMINATED. (2012 AND 2013).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031989	CONCEPTUS / BAYER	9/23/2013	9/27/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) OF 2012. THE PROCEDURE ITSELF WAS EXTREMELY PAINFUL. SINCE IMPLANTATION, I HAVE HAD SEVERE STABBING PAINS WHERE THE COILS ARE LOCATED. I HAVE ALSO BEEN SICK AND EXTREMELY FATIGUED SINCE IT WAS IMPLANTED, WITH NO ILLNESSES OR ISSUES PRIOR TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5031990	CONCEPTUS INCORP.	9/23/2013	9/27/2013

Event Information:

Event Date (B3): 8/27/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): B06100

Single Use:
Implant Date (E6): 8/27/2013
Explant Date (E7): 8/27/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL UNRAVELED ON DEPLOYMENT. MD HAVE REMOVE COIL AND PLACE ANOTHER DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032003	CONCEPTUS	9/23/2013	9/27/2013

Event Information:

Event Date (B3): 6/13/2012 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2013 I HAD A PROCEDURE DONE WITH THE PERMANENT BIRTH CONTROL "ESSURE." I HAVE HAD REGULAR HEADACHES, FATIGUE AND ABDOMINAL PAIN. FOR THE PAST 8 MONTHS I HAVE BEEN SUFFERING FROM DEPRESSION AND THE FEELING THAT SOMETHING ISN'T NORMAL WITH MY BODY. THOUSANDS OF WOMEN INCLUDING MYSELF FEEL STRONGLY THAT THESE COILS ARE THE REASON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032007	CONCEPTUS INC	9/23/2013	9/27/2013

Event Information:

Event Date (B3): 8/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/16/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS PLACED IN ROUGHLY (B)(6) 2012. EVER SINCE I HAVE HAD URINARY TRACT INFECTIONS, KIDNEY INFECTIONS, LOSS OF MENSTRUAL CYCLE AND PAIN AND DISCOMFORT IN THE ABDOMINAL AREA. HAVE REPORTED CONCERNS TO MY OB/GYN WHO REFERRED ME ONTO AN ENDOCRINOLOGIST. I HAVE ALSO REPORTED THESE CONCERNS TO MY FAMILY PHYSICIAN AS WELL. THIS WAS THE WORST DECISION I HAVE MADE REGARDING MY HEALTH. I CHOSE ESSURE FOR CONVENIENCE DUE TO THE FACT THAT I WAS HAPPY WITH THE THREE CHILDREN I HAVE AND DIDN'T HAVE PLANS TO HAVE ANYMORE CHILDREN. THIS PRODUCT IS PLAIN AWFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032014	BAYER	9/24/2013	9/30/2013

Event Information:

Event Date (B3): 8/28/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS306
Lot #(E4): B34597

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3): 9/18/2013

Event Description (B5):

THE SURGEON ATTEMPTED TO INSERT THE ESSURE INTO THE RIGHT FALLOPIAN TUBE AND WAS UNABLE TO DO SO. THE SURGEON STATED THAT SHE THOUGHT SOMETHING WAS WRONG WITH THE PRODUCT. THE DEVICE WAS REMOVED FROM THE PATIENT AND IT WAS NOTED THAT THE TIP OF THE DEVICE WAS NOT PRESENT. IT IS UNK IF THE TIP WAS MISSING WHEN THE PACKAGE WAS OPENED OR IF IT BROKE OFF DURING THE ATTEMPTED PROCEDURE. REASON FOR USE: DESIRES PERMANENT STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032009	CONCEPTUS	9/25/2013	9/27/2013

Event Information:

Event Date (B3): 7/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 633193

Single Use:
Implant Date (E6): 7/13/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM A (B)(6) WOMAN. I HAVE THREE CHILDREN AGES (B)(6). I HAD THE ESSURE IMPLANTED (B)(6) 2011. THAT NIGHT AND INTO THE NEXT MORNING I HAD EXCRUCIATING PAIN, THE PAIN WAS SO BAD THAT I WAS CRYING UNCONTROLLABLY AND BECAME DEHYDRATED. I WAS AS WHITE AS A GHOST AND TREMBLING SO I WENT BACK TO MY OB/GYN THE NEXT DAY AND THEY ADMITTED ME ASAP. I SAW AN INFECTIOUS DISEASE PHYSICIAN ALONG WITH MY OB/GYN AND THEY PUT ME ON MORPHINE, ANTIBIOTICS AND AN IV. THEY ASSUMED IT WAS FROM THE ESSURE PROCEDURE, THAT THERE WAS SOME SORT OF HORRIBLE INFECTION. I WAS IN THE HOSPITAL FOR 5 DAYS. I WAS AWAY FROM MY HUSBAND AT THE TIME AND CHILDREN. I CRIED CONSTANTLY IN THE HOSPITAL. SINCE I HAD THE ESSURE I NOW HAVE HEALTH PROBLEMS. CONSTANT LOWER BACK PAIN THAT SOMETIMES IS SO SEVERE I CRY. I BLOAT, NOT PERIOD BLOAT, BLOATED! IT'S AMAZING TO WATCH. I ALSO SUFFER SEVERE MIGRAINES, ANXIETY, PANIC ATTACKS, IBS, BRONCHITIS, TRIGEMINAL NEURALGIA, I HAVE A CONSTANT COUGH THAT COMES AND GOES SINCE THE ESSURE, HOT FLUSHES SO SEVERE I SWEAT, LOW GRADE FEVERS, CONSTANT LOW WHITE BLOOD CELL COUNT WITH MY PLATELETS CHANGED SHAPE - ITP IDIOPATHIC THROMBOCYTOPENIC PURPURA. I ALSO EXPERIENCE SHARP PAIN ON BOTH SIDES WHICH FEELS LIKE MY OVARIES HURT OR ACHE ALL THE TIME. OH AND I AM ON BIRTH CONTROL ALSO BECAUSE MY PERIODS ARE SO HEAVY. WHEN I WENT TO THE FOLLOW-UP FOR THE DYE TEST IT CAME BACK GREAT. NO DYE LEAKED THROUGH. THIS DOES NOT MAKE A DIFFERENCE TO ME SINCE I DEAL WITH THE AGONY OF THE ESSURE COILS IN MY BODY. I NEVER GET BETTER. EVEN WHEN I'M ON ANTIBIOTICS, WHICH I HAVE BEEN ON CIPRO NOW FOR 15 WEEKS. I NEVER SEEM TO FEEL BETTER. I THINK ITS BECAUSE MY BODY IS ALREADY INFECTED WITH A VIRUS ESSURE AND ANTIBIOTICS SEEM TO MASK OR COVER UP THE PROBLEM FOR AWHILE BUT I NEVER GET TO FEEL GOOD OR NORMAL, EVER. I WENT (B)(6) 2013 TO FINALLY GET A NICKEL TEST DONE. I WILL GET THE

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RESULTS (B)(6) 2013. IN (B)(6) 2013 I AM HAVING THE ESSURE REMOVED BY A GYNECOLOGIC SURGEON AT (B)(6). I HAD A ROOT CANAL PERFORMED (B)(6) 2013 BECAUSE I WAS IN HORRIBLE PAIN. NOW THAT TOOTH HAD TO BE REMOVED BY AN ORAL SURGEON. THAT TOOTH WAS REMOVED TUESDAY (B)(6) 2013.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032063		9/25/2013	10/2/2013

Event Information:

Event Date (B3): 12/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/20/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD NOTHING BUT PAIN, IRREGULAR PERIODS. EXTREME BLEEDING. EXTREME CRAMPING IN LOWER ABDOMEN AND LOWER BACK. HEAD ACHES, NAUSEA, DIZZY SPELLS.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS INCORPORATED	9/25/2013	10/21/2013

Event Information:

Event Date (B3): 9/18/2013 **Report Date (B4): 9/25/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS306
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PRODUCT WOULD NOT DEPLOY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032050	BAYER	9/26/2013	10/2/2013

Event Information:

Event Date (B3): 9/25/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/23/2010
Explant Date (E7): 5/9/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY OBGYN IMPLANTED THE ESSURE COILS IN MY FALLOPIAN TUBES IN (B)(6) 2010. "FROM THAT TIME FORWARD I HAD HORRIBLE EXCRUCIATION TIME IN MY LOWER RIGHT QUADRANT." IT INTERFERED WITH MY DAILY LIFE. BY THE TIME I HAD THE ESSURE REMOVED BY A DIFFERENT GYNECOLOGIST I WAS LIVING ON PAIN MEDICATIONS. I DID NOT WORK, I COULDN'T TAKE CARE OF MY FAMILY, I HAD NO QUALITY OF LIFE. I HAD A HYSTERECTOMY IN (B)(6) 2013 AND AM STILL STRUGGLING WITH MY DAILY ACTIVITIES. I ALSO HAVE CROHN'S DISEASE AND THE ESSURE MADE IT DIFFICULT TO DIAGNOSE THE SOURCE OF THE PROBLEMS BECAUSE I THOUGHT THEY WERE CROHN'S PAINI. I LIVED FOR 2 1/2 YEARS TRYING TO FIND THE SOURCE OF MY PAIN. IT HAS MADE ME INCREDIBLY DEPRESSED AND ANXIOUS ABOUT DAILY LIFE. ESSURE SHOULD BE REMOVED FROM THE MARKET OR DOCTORS SHOULD BE WARNED ABOUT ALL THE NEGATIVE POTENTIAL SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032043		9/30/2013	10/2/2013

Event Information:

Event Date (B3): 9/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/17/2012
Explant Date (E7): 10/7/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE SEVERE LOWER BACK PAIN, CONFUSION, SHORTNESS OF BREATH, INABILITY TO THINK, CRITICAL LEVELS OF SODIUM, POTASSIUM AND MAGNESIUM, LIGHT HEADED, DIZZY, DEHYDRATION, METALLIC TASTE IN MY MOUTH, CONSTANT RINGING IN EARS, EXCRUCIATING CRAMPING, NUMB LEGS, HIGH BLOOD PRESSURE, HEAVIER/LONGER PERIODS, EXTREME BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032096	BAYER	9/30/2013	10/7/2013

Event Information:

Event Date (B3): 4/16/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2008
Explant Date (E7): 8/8/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOR THE LAST YEAR AND A HALF I HAVE BECOME INCREASINGLY SICKER WITH ALL KINDS OF AUTO IMMUNE DISEASES, FEMALE ISSUES, KIDNEY BLADDER ISSUES, DIGESTIVE ISSUES, RASHES ANGIOEDEMA, HIGH BP ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032098	CONCEPTUS/ BAYER	9/30/2013	10/7/2013

Event Information:

Event Date (B3): 8/22/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/22/2013
Explant Date (E7): 9/12/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LISTENED TO THE ADVICE OF MY DOCTOR AND HAD ESSURE IMPLANTED ON (B)(6) 2013, IMMEDIATELY, I STARTED HAVING PROBLEMS INCLUDING FOUL ODOR FROM INFECTION, SEVERE BACK PAIN, CHEST PAINS WITH SHORTNESS OF BREATH, CONSTANT HEADACHE THAT WOULD NOT GO AWAY, STOMACH PAINS WITH BAD CRAMPS AND HORRIBLE STABBING PELVIC PAINS, GOT REALLY WEAK, HAD BLACK OUT SPELLS, A LOT OF PAINFUL PRESSURE ON BLADDER, AND UPSET STOMACH. WENT BACK TO MY DOCTOR TO FIND OUT WHY I FELT LIKE MY LIFE WAS BEING DRAINED FROM ME. I NEVER FELT THIS BEFORE THE COILS WERE IMPLANTED. I TOLD HIM I FOUND OUT ABOUT THE NICKEL, AND I AM VERY SENSITIVE TO NICKEL. HE DECIDED TO REMOVE THEM ON (B)(6) 2013. SAID HE WOULD REMOVE THE COILS, AND PERFORM REGULAR TUBAL. DAY OF SURGERY, I WOKE UP IN RECOVERY ROOM TO FIND OUT MY TUBES HAD TO BE REMOVED COMPLETELY DUE TO THE DAMAGE FROM THE INFLAMMATION OF NICKEL, MY DOCTOR SAID THAT I WAS IN WORST SHAPE THAN HE EVEN THOUGHT. MY BLADDER WAS CORRECTED, CYST REMOVED, AND I HAD BAD CASE OF ENDOMETRIOSIS THAT HE GOT AS MUCH AS HE COULD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032101	CONCEPTUS/BAYER	9/30/2013	10/7/2013

Event Information:

Event Date (B3): 12/12/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/12/2007
Explant Date (E7): 9/17/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2013, FIVE AND A HALF YEARS AFTER IMPLANTATION OF THE ESSURE COIL I BEGAN TO HAVE BLOATING AND PRESSURE IN MY LOWER ABDOMEN. AFTER MANY DOCTORS APPOINTMENTS AND NO SOLUTIONS TO THE CAUSE, I BEGAN HAVING DEBILITATING PAIN IN MY LOWER ABDOMEN WITH THE MOST SEVERE PAINS ON MY RIGHT SIDE WHERE MY FALLOPIAN TUBE/OVARIES WOULD BE LOCATED. THESE PAINS STARTED IN (B)(6) OF 2013. THESE PAINS AND SWELLING WOULD BECOME SIGNIFICANTLY WORSE AFTER ANY EXERCISE OR JARRING MOVEMENTS. RUNNING WOULD CAUSE SO MUCH SWELLING IN MY ABDOMEN THAT I LOOKED 4 MONTHS PREGNANT ACCOMPANIED WITH CRIPPLING PAIN. DURING THIS TIME, I DEVELOPED SIGNIFICANT INSOMNIA, ANXIETY/PANIC ATTACKS, AND SENSITIVITIES TO CHEMICALS THAT I DID NOT HAVE BEFORE. AFTER MANY VISITS TO MY PRIMARY CARE PHYSICIAN AND MY GYNECOLOGIST TO RULE OUT ANY OTHER POSSIBILITY INCLUDING HAVING A COLONOSCOPY AND LAPAROSCOPIC EXPLORATORY SURGERY. AFTER FINDING NO CAUSE OF SYMPTOMS, I HAD A DOUBLE SALPINGECTOMY TO REMOVE MY TUBES AND COILS. SINCE THE REMOVAL ON (B)(6) 2013, ALL OF THE PREVIOUSLY STATED SYMPTOMS HAVE DIMINISHED. NO MORE DEBILITATING PAIN IN MY ABDOMEN, SWELLING OR BLOATING, PANIC OR ANXIETY ATTACKS, OR INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032102	CONCEPTUS	9/30/2013	10/7/2013

Event Information:

Event Date (B3): 7/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTS
Device Type (E2): ESSURE IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/22/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE BIRTH CONTROL IMPLANTED (B)(6) 2010 WITH NO INCIDENT. FAST FORWARD 6 MONTHS SIDE EFFECTS STARTED WITH DAILY NAUSEA, HEADACHES, POSTERIOR PELVIC PAIN, SWELLING HANDS AND FEET, DISABLING JOINT PAIN, BLEEDING AFTER INTERCOURSE, UNBEARABLE PAIN WITH ORGASM, RECURRENT YEAST INFECTIONS, ABDOMINAL SWELLING AND CRAMPING THAT OFTEN LEADS TO SHARP SHOOTING PAINS WHEN CHANGING POSITION, BLURRED VISION, FATIGUE, MOOD SWINGS BORDERING ON DEPRESSION AND DIZZY SPELLS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032103	BAYER/CONCEPTUS	9/30/2013	10/7/2013

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD SEVERE PELVIC PAIN THAT STARTED A FEW MONTHS AFTER IMPLANTATION ON ESSURE. I HAVE SEVERE MIGRAINES, AUTOIMMUNE ISSUES, HAIR LOSS, SEVERE JOINT PAIN, DIZZINESS, EXTREME FATIGUE, INSOMNIA, SWALLOWING ISSUES, METAL TASTE IN MY MOUTH, STABBING PAINS IN MY SIDES, SEVERE HIP PAIN, VITAMIN DEFICIENCY, SEVERE MOOD SWINGS AND SWELLING. THE COILS HAVE MIGRATED AND ONE APPEARS BROKEN. I AM IN THE PROCESS OF TRYING TO FIND A DOCTOR TO REMOVE THEM. I AM NOT SURE OF THE EXACT DATE OF IMPLANTATION. I ALSO CAN'T PROVIDE ANY OF THE DEVICE INFORMATION, SUCH AS MODEL NUMBER, AS I WAS NEVER PROVIDED THE CARD AFTER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032122	CONCEPTUS	10/1/2013	10/9/2013

Event Information:

Event Date (B3): 9/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/30/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2010, I HAD THE ESSURE PROCEDURE DONE. WHEN I WAS IN THE ROOM HAVING IT DONE, THE DOCTOR WAS ON THE LEFT SIDE AND I WAS TOLD THAT THE COIL HAD BROKE OFF AND HE SAID THAT THEY WERE GOING TO LEAVE IT AND SEE IF THE TISSUE WOULD HEAL AROUND IT. DON'T UNDERSTAND WHY THIS WAS NOT TAKEN OUT AND REPLACED SINCE IT WAS BROKEN. SINCE 2010 I'VE HAD BAD PAINS IN THE LEFT SIDE, BACK AND STOMACH. TROUBLE SLEEPING, BLACK OUTS, HOT FLASHES ETC. I WAS JUST WONDERING IF ANYTHING COULD BE DONE ABOUT THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032123	CONCEPTUS	10/1/2013	10/9/2013

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2010
Explant Date (E7): 4/10/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

INCREASED AND WORSENING PAIN AFTER ESSURE IMPLANT. RESULTING IN HYSTERECTOMY. PAIN CONTINUES DUE TO SCAR TISSUE FROM BOTH SURGERIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032124	CONCEPTUS	10/1/2013	10/9/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 624495

Single Use:
Implant Date (E6): 2/11/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2008. A FEW YRS LATER I STARTED GETTING CHRONIC BACK, JOINT AND ABDOMINAL PAIN, IRREGULAR PERIODS INCLUDING UNPREDICTABLE MENSTRUAL FLOW, SWOLLEN LEGS, ANKLES AND FEET, SEVERE BLOATING, CONSTANT MIGRAINE, MOOD SWINGS, HAND AND ARMS "FALL ASLEEP" WHILE I AM SLEEPING, PRESSURE IN MY EARS LIKE AN EAR INFECTION, SEVERE PAIN AFTER INTERCOURSE, SHARP STABBING PAINS IN BACK AND ABDOMEN. CAN'T EVEN EAT WITH A METAL FORK DUE TO METAL TASTE IN MOUTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032156	CONCEPTUS	10/3/2013	10/9/2013

Event Information:

Event Date (B3): 10/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 11/8/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN BATTLING WITH PELVIC PAIN, BLOATING, FATIGUE, SIGNS OF BEING PREGNANT AND NOT PREGNANT, BLEEDING AFTER INTERCOURSE, PAIN DURING INTERCOURSE, BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032157	CONCEPTUS	10/3/2013	10/9/2013

Event Information:

Event Date (B3): 8/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B09706

Single Use:
Implant Date (E6): 8/12/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE BY BAYER/CONCEPTUS WAS IMPLANTED (B)(6) 2013. SINCE THEN, I'VE HAD STOMACH, LOWER BACK, AND FLANK PAIN CONSTANTLY. BLOATING, SHOOTING PAIN IN THE PELVIC AREA, NUMBNESS/TINGLING IN THE PRIVATE AREA, URINE FEELS REALLY HOT, INFLAMMATION IN STOMACH AND FEELS LIKE ITS BURNING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032158	BAYER	10/3/2013	10/9/2013

Event Information:

Event Date (B3): 11/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/6/2007
Explant Date (E7): 11/30/2009
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTS PUT IN ON (B)(6) 2007. AFTER PROCEDURE STARTED HAVING SEVERE PAIN IN RIGHT ABDOMEN. WENT TO DOCTOR WHO PERFORMED SURGERY OVER AND OVER, WAS TOLD PAIN WAS NOT RELATED TO ESSURE IMPLANTS. STARTED HAVING EVEN WORSE PAIN DURING YR 2009. HAD CT SCAN DONE AND IT SHOWED THE COIL ON THE RIGHT HAS MIGRATED FROM THE TUBE. HAD A LAPAROSCOPIC SUPRACERVICAL HYSTERECTOMY TO REMOVE THE COILS AND TUBES. DURING THE SURGERY, DOCTOR FOUND THE COIL HAD ATTACHED ITSELF TO MY SMALL BOWEL. THAT COIL WAS REMOVED. I STILL HAVE PAIN POSSIBLY FROM SCAR TISSUE EVEN AFTER REMOVAL. THIS PRODUCT SHOULD NOT BE OUT IN THE MARKET AS SYMPTOMS SOMETIMES DO NOT SHOW UNTIL YRS LATER AS HAS HAPPENED TO MANY OTHER WOMEN. THIS HAS MADE MY LIFE MISERABLE AND AFFECTS EVERYTHING I DO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032159	CONCEPTUS, INC	10/3/2013	10/9/2013

Event Information:

Event Date (B3): 4/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/12/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN (B)(6) 2011; THE FIRST COUPLE MONTHS, I WAS FINE THEN I STARTED FAINTING, I GET DIZZY EVERYDAY, NICKEL TASTE IN MY MOUTH, SHARP PAINS IN MY STOMACH AND WHERE MY TUBES ARE PRESSURE IN MY VAGINA, MIGRAINES ALMOST EVERY SINGLE DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032160	CONCEPTUS/BAYER	10/3/2013	10/9/2013

Event Information:

Event Date (B3): 10/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/14/2009
Explant Date (E7): 10/14/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE BY CONCEPTUS/BAYER HAS CAUSED MY UTERUS TO ENLARGE RESULTING IN ADENOMYOSIS AND A TOTAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032161	CONCEPTUS INC	10/3/2013	10/9/2013

Event Information:

Event Date (B3): 9/18/2013 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2011. I HAD TWO HEALTHY BABIES AND MY HUSBAND AND I DECIDED WE DID NOT WANT ANY MORE CHILDREN. I AM PRETTY HEALTHY, EXERCISE REGULARLY HAVE NO DIFFICULTY MAINTAINING AN IDEAL WEIGHT AND I AM A RUNNER. IN 2013, I STARTED TO DEVELOP EAR INFECTIONS AND ALLERGIES, WHICH I HAVE NEVER HAD BEFORE. ON (B)(6) 2013, I DEVELOPED A FULL BODY RASH, IT SEEMED TO BE AN ALLERGIC REACTION ACCORDING TO THE DR. AT THE URGENT CARE CLINIC, THE ATTENDING DR. PRESCRIBED ME A 5 DAY CYCLE OF PREDNISONE FOR THE RASH AND BENADRYL. THE RASH SEEMED TO GO AWAY WITH THE BENADRYL. THE NEXT DAY (B)(6), THE RASH RETURNED EVEN MORE AGGRESSIVELY AND NOW WAS NOT ONLY PRESENT ON MY BODY BUT ALSO MY FACE. I TOOK ANOTHER DOSE OF BENADRYL AND STARTED THE PREDNISONE. THE RASH SUBSIDED THE NEXT DAY AND HAD NOT COME BACK. I FINISHED THE 5 DAY CYCLE OF PREDNISONE AND CURRENTLY AM NOT HAVING ANY SYMPTOMS. I AM FOLLOWING UP WITH MY OB/GYN TO ASK IF ANY OTHER PTS HAD SIMILAR REACTIONS POST ESSURE PROCEDURE THIS FAR OUT, AS WELL AS WITH AN ALLERGIST TO TEST FOR METAL ALLERGIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032162	CONCEPTS, INC	10/3/2013	10/9/2013

Event Information:

Event Date (B3): 8/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/9/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM FILING A REPORT FOR ESSURE... I HAVE BEEN IMPLANTED FOR 6 YEARS NOW AND SINCE I WAS IMPLANTED I HAVE SLOWLY STARTED HAVING HORRIBLE PERIODS, DEBILITATING PAIN IN MY LEFT SIDE AND EXTREME FATIGUE... SINCE BEING IMPLANTED I HAVE DEVELOPED HIGH BLOOD PRESSURE CHOLESTEROL AT AGE (B)(6) ALSO HAVE BECOME LACTOSE INTOLERANT AND POSSIBLE GLUTEIN SENSITIVITY!! PAIN DURING INTERCOURSE!! THESE HORRIBLE THINGS HAVE AFFECTED MY QUALITY OF LIFE IN ALMOST ALL FACEST!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032179	BAYER / CONCEPTUS	10/4/2013	10/10/2013

Event Information:

Event Date (B3): 11/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 654836

Single Use:
Implant Date (E6): 11/3/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MAJOR SIDE AFFECTS POST ESSURE - WEIGHT GAIN, IRREGULAR PERIODS, HEAVY BLEEDING AND CLOTTING, STABBING PAINS IN PELVIC AREA, BLOATING, DIZZINESS, FATIGUE, NO SEX DRIVE, HEADACHES, CYSTS AND SKIN RASH, INSOMNIA AND MANY MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032180	BAYER / CONCEPTUS	10/4/2013	10/10/2013

Event Information:

Event Date (B3): 8/4/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/4/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2009. I HAVE HAD SEVERAL SERIOUS SIDE EFFECTS OVER THE LAST 4 YEARS. SIDE EFFECTS INCLUDE SEVERE CRAMPING, HEAVY PERIODS, 3 WEEK CYCLE, HAIR LOSS, WEIGHT GAIN, SKIN PROBLEMS, DIZZINESS, SEEING SPOTS, MIGRAINES, SEVERE ACHES AND PAINS. I HAD NONE OF THESE SYMPTOMS PRIOR TO ESSURE. I HAVE HAD A SKIN TEST AND I BELIEVE THAT I AM ALLERGIC TO NICKEL WHICH I THINK MAY BE THE CAUSE OF SEVERAL OF MY ISSUES. MY IMPLANTING DOCTOR DOES NOT BELIEVE ESSURE IS THE CAUSE OF THESE SYMPTOMS. I AM NOW SUFFERING FROM SEVERE DEPRESSION BECAUSE OF MY HEALTH ISSUES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00018	BAYER HEALTHCARE LLC, FORMERLY CONCEPTUS INC	10/4/2013	10/17/2013

Event Information:

Event Date (B3): 9/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** AS

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE IN 2004. PHYSICIAN FOUND THE ESSURE DEVICE HAD PERFORATED THROUGH THE RIGHT POSTERIOR ASPECT OF THE UTERINE FUNDUS AND ATTACHED TO THE DESCENDING COLON. (B)(6) 2013, PT HAD ESSURE DEVICE REMOVED LAPAROSCOPICALLY. PT HAD NO COMPLICATIONS DURING SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00019	BAYER HEALTHCARE LLC	10/4/2013	10/17/2013

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD ESSURE PROCEDURE (B)(6) 2013. PT STATES SHE HAS HAD PAIN SINCE THE PLACEMENT OF THE ESSURE DEVICES. PT REQUESTED REMOVAL OF ESSURE DEVICES. ON (B)(6) 2013, PHYSICIAN REMOVED ESSURE DEVICES VIA HYSTEROSCOPE. PHYSICIAN ALSO FOUND LEFT ESSURE DEVICE HAD PERFORATED UTERUS. AT TIME OF SURGERY, PT ALSO HAD TUBAL LIGATION. PHYSICIAN STATES PTS CONDITION WAS CAUSED BY ESSURE DEVICE. PT PAIN HAS RESOLVED POST PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032176	CONCEPTUS	10/7/2013	10/10/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4): 685785

Single Use:
Implant Date (E6): 4/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT THAT SHE IS 11 WEEKS PREGNANT. SHE STATED THAT ESSURE IMPLANTED IN (B)(6) OF 2010 AND WAS CONFIRMED TO HAVE 100% BLOCKAGE. SHE SAID THAT ESSURE DID NOT WORK AND SHE IS NOW PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032189	CONCEPTUS BAYER	10/7/2013	10/15/2013

Event Information:

Event Date (B3): 10/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/16/2013
Explant Date (E7): 10/3/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ESSURE MANUFACTURED BY CONCEPTUS/BAYER. ONE COIL MIGRATED INTO MY BOWEL AND PIERCED IT. IF IT WOULD HAVE NOT BEEN SURGICALLY REMOVED, I WOULD HAVE HAD MAJOR DAMAGE. I AM IN TONS OF PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032192	CONCEPTOUS NOW BAYER	10/7/2013	10/15/2013

Event Information:

Event Date (B3): 3/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/10/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN LEFT LOWER ABDOMEN, GROIN AND LEG PAIN ALL AFTER HAVING ESSURE STERILIZATION IMPLANTED IN MY FALLOPIAN TUBES ON (B)(6) 2009. MY RIGHT SIDE SEEMS FINE AND HAS NEVER CAUSED ANY PROBLEMS. I AM ALSO GETTING MIGRAINE HEADACHES AND HAVE HAD TO BE HOSPITALIZED FOR THE HEADACHES. I FELT PAIN IN MY LEFT SIDE IMMEDIATELY AFTER THE PROCEDURE AND WAS TOLD IT WAS NORMAL. I HAD THE FOLLOW UP HSG DONE (B)(6) 2009 AND WAS NORMAL. I HAD THE FOLLOW UP HSG DONE (B)(6) 2009 AND WAS TOLD MY TUBES WERE OCCLUDED. ALSO HAD CATSCAN OF MY PELVIS (B)(6) 2009 BECAUSE OF PAIN AND WAS TOLD EVERYTHING WAS NORMAL. I NO LONGER HAD INSURANCE AND COULD NOT HAVE FURTHER TESTS TO SEE WHAT IS CAUSING MY PAIN. I HAVE ALSO GAINED 30 LBS SINCE EVEN WALKING HAS BECOME PAINFUL. RECENTLY SAW ANOTHER DOCTOR SINCE THE PAIN HAS BECOME SEVERE AND SPREAD TO MY PELVIS AND LEG AND MY MIGRAINES HAVE BECOME CONSTANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032202	CONCEPTUS	10/7/2013	10/15/2013

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE AFTER THE BIRTH OF MY LAST CHILD IN 2010, EVER SINCE THEN I HAVE HAD HEAVY MENSTRUAL CYCLES, SEVERE HEADACHE, BACK ACHES, NAUSEOUS, LIGHT HEADED, DIZZINESS AND AT SOME INSTANCES FAINTING. AND SEVERE CRAMPING WHERE THE COILS ARE LOCATED. I'VE BEEN TO THE HOSPITAL AND THEY CAN'T LOCATE ANY PROBLEMS WITH MY BODY, I HAVE ALSO SUFFERED FROM BACTERIA INFECTIONS SINCE THE DAY THIS HAS BEEN IMPLANTED, I HAVE ASKED THE DOCTOR TO REMOVE THE DEVICE AND THEY SAY THEY ARE UNABLE TO. I AM DESPERATE FOR SOME HELP. I'M ALWAYS FATIGUE AND TAKES ME A LOT TO GET THROUGH A FULL WORK DAY COMPLETELY MISERABLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032205	CONCEPTUS-BAYER	10/7/2013	10/15/2013

Event Information:

Event Date (B3): 7/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): KSS305-871977

Single Use:
Implant Date (E6): 7/20/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED ON (B)(6) 2012, AND FOR THE LAST 9 MONTHS I HAVE HAD DAILY PAIN, FEELING SWOLLEN AND SHARP PAINS IN MY PELVIC AREA, ALSO I HAVE HAD MONTHLY ABNORMAL BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032203	CONCEPTUS/BUYER	10/7/2013	10/16/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT PREGNANT IN 2007 WITH MY THIRD CHILD. MY LAST TWO WERE A YEAR AND A HALF APART AND I WAS DONE. I TOLD MY DOCTOR FROM THE BEGINNING THAT I WAS DONE HAVING CHILDREN AND I WANTED A TRADITIONAL TUBAL LIGATION. I WAS TOLD ABOUT ESSURE AND RESEARCHED IT MY ENTIRE PREGNANCY. I NEVER FOUND ANYTHING BAD ABOUT THE DEVICE (ACTUALLY IT WAS ALL GOOD) TOO GOOD TO BE TRUE SOME WOULD SAY. I DIDN'T LISTEN TO MYSELF OR MY HUSBAND, WHO BEGGED ME NOT TO DO IT. I TRUSTED MY DOCTOR WHEN INDEED MY HEALTH AND SAFETY WAS NOT HER FIRST CONCERN. I HAD MY SON IN (B)(6) OF 2008 AND WENT AHEAD WITH THE PROCEDURE IN (B)(6) OF 2008. I WAS NOT TOLD THAT MY INSURANCE WOULD RUN OUT AND I WOULD NOT BE ABLE TO HAVE THE OH SO IMPORTANT, WHICH I WAS TOLD WAS NOT VERY IMPORTANT, HSG DONE. ABOUT A WEEK AFTER MY PROCEDURE, I WAS IN HORRIBLE PAIN SO BAD I THOUGHT I WAS DYING. I BRUSHED IT OFF AND WENT ON WITH MY LIFE. THINGS WERE FINE UNTIL ABOUT THREE YEARS LATER. I FINALLY HAD MY HSG DONE IN (B)(6) 2011. I WAS TOLD EVERYTHING WAS FINE WHEN IN FACT IT WAS NOT. I HAVE "CRIPPING" HEADACHES, MY STOMACH IS BLOATED THAT I LOOK PREGNANT. I BLEED AND HAVE CONSTANT PAIN WHEN I AM INTIMATE WITH MY HUSBAND. I HAVE SHARP STABBING PAINS WHEN I COUGH OR SIT OR STAND AND THE LIST GOES ON AND ON. THIS HAS RUINED MY LIFE AND I DO NOT HAVE THE INSURANCE TO HAVE IT REMOVED. I REQUESTED MY MEDICAL RECORDS FROM MY IMPLANTING DOCTOR AND WAS SHOCKED WHEN I READ THAT WHEN MY HSG WAS DONE. I HAD SLIGHT DISTAL MIGRATION ON THE RIGHT SIDE (WHY WAS I NEVER TOLD) WHY THE SECRETS? IT ALSO SAYS THAT MY UTERUS WAS THE SIZE OF A 12 WEEK PREGNANT WOMAN, REALLY NOBODY FELT THE NEED TO TELL ME THIS EITHER. THIS IS THE WORST DECISION I HAVE NEVER MADE FOR MYSELF AND MY FAMILY. WHEN I FINALLY GET INSURANCE, I WILL HAVE THIS EVIL DEVICE TAKEN OUT OF ME AND MAYBE THEN I CAN TRY TO GET MYSELF BACK TO

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THE PERSON I WAS BEFORE. I WOULD ALSO LIKE TO ADD THAT I WAS NEVER TESTED FOR A NICKEL ALLERGY AND I WAS NOT GIVEN MY ESSURE CARD AFTER THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032246	CONCEPTUS	10/10/2013	10/17/2013

Event Information:

Event Date (B3): 12/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 12/6/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM A (B)(6) MOTHER OF FIVE CHILDREN. I WAS IMPLANTED WITH THE ESSURE PERMANENT BIRTH CONTROL SYSTEM ON (B)(6) 2012. THE PROCEDURE WAS A LOT MORE PAINFUL THAN IT WAS MADE OUT TO BE AND SHORTLY AFTER THE PROCEDURE I BEGAN EXPERIENCING MANY NEGATIVE SIDE EFFECTS. I HAD SEVERE ABDOMINAL BLOATING AND IRREGULAR STRANGE PERIODS. INSTEAD OF MY REGULAR MONTHLY BLEEDING I WAS PASSING CLOTS AND DARK BROWN DISCHARGE. I ALSO STARTED TO HAVE PAINFUL OVULATION AND BAD CRAMPING. I ALSO GAINED 12 POUNDS EVEN THOUGH MY DIET AND EXERCISE REMAINED THE SAME. THEN I BEGAN EXPERIENCING SOME VERY DISTURBING AND FIGHTING SYMPTOMS SUCH AS RAPID HEARTBEAT, DIZZINESS, TINGLING ON THE LEFT SIDE OF MY BODY, HEADACHES, FATIGUE AND A SEVERE ITCHING OF THE SCALP. SIX MONTHS AFTER IMPLANTATION I CONTINUED TO HAVE ALL THE ABOVE SYMPTOMS AND STARTED TO SUFFER FROM LOW SEX DRIVE, DEPRESSION, FORGETFULNESS, ANXIETY, PANIC ATTACKS, MOOD SWINGS, SHORTNESS OF BREATH, INTOLERANCE TO EXERCISE AND METAL JEWELRY. I SUFFER FROM HYPOTHYROID SYMPTOM'S SUCH AS BRITTLE NAILS, SENSITIVITY TO COLD AND DRYNESS OF EYES AND SKIN. I HAD NONE OF THE SYMPTOMS BEFORE BEING IMPLANTED WITH ESSURE. I PLAN ON HAVING THEM REMOVED AS SOON AS POSSIBLE. THIS IS A FAULTY PRODUCT AND NEEDS TO BE TAKEN OFF THE MARKET BEFORE ANYMORE WOMEN ARE INJURED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032261		10/11/2013	10/18/2013

Event Information:

Event Date (B3): 9/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANT, FIRST IT CAUSED PAIN AND CONSTANT BLEEDING. NEARLY EVERYDAY BLEEDING. AMONG OTHER SYMPTOMS. THE BLEEDING WAS THE MOST BOTHERSOME. FINALLY AFTER A FEW YEARS OF HAVING THIS HORRIBLE METAL PRODUCT IN MY BODY, I WAS FAINTING FROM BLOOD LOSS. THEN I FOUND OUT I HAD A TUMOR THE SIZE OF A GRAPEFRUIT IN MY UTERUS. I HAD TO HAVE A HYSTERECTOMY IN MY 20S. THE DOCTOR HAD SAID THAT THE GUN DID NOT FIRE THE SPRINGS INTO ME, SO HE FIRED ANOTHER TIME ON BOTH SIDES THEN AFTER THE PROCEDURE, I WAS TOLD THAT I HAD 4 SPRINGS INSIDE OF ME. I DO BELIEVE THIS IS THE CAUSE OF MY TUMOR, BLEEDING AND HYSTERECTOMY. I WAS FINE BEFORE THE PROCEDURE, YOUNG AND HEALTHY. ALSO I DO HAVE A SLIGHT ALLERGY TO NICKEL JEWELRY THE DOCTOR DID NOT GIVE ME A NICKEL ALLERGY TEST, SO THAT MAYBE WHY I HAD SUCH A BAD REACTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032262	BAYER	10/11/2013	10/18/2013

Event Information:

Event Date (B3): 8/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY DOCTOR WAS SUPPOSE TO TIE MY TUBES AND INSERTED THE ESSURE INSTEAD. SINCE THEN I HAVE BEEN HOSPITALIZED FOR BLOOD CLOTS, CHEST PAIN AND TROUBLE BREATHING. AND AGAIN ON (B)(6) 2013 OF THIS YEAR TO HAVE AN EMERGENCY SURGERY TO HAVE MY GALL BLADDER REMOVED. I HAVE NOTICED THAT I CONTINUE TO HAVE SHARP STABBING PAINS IN MY LOWER BACK, STOMACH AND I HAVE REGAINED THE WEIGHT THAT I LOST WITH THE LAPBAND THAT I CURRENTLY HAVE SINCE (B)(6) 2010. I DO NOT FEEL THAT I AM OK AND DO FEEL THAT THERE IS SOMETHING WRONG WITH MY BODY. I HAVE ASKED TO HAVE THE ESSURE REMOVED OR TO HAVE A HYSTERECTOMY BUT I HEAR NO ONE KNOWS HOW TO TAKE THEM OUT AND THAT I AM TOO YOUNG FOR THE PROCEDURE. I HAVE TWO CHILDREN THAT I ALMOST LEFT BEHIND WHEN I WENT INTO THE HOSPITAL FOR SHORTNESS OF BREATH AND PAINS IN THE CHEST. I WAS DIAGNOSED WITH BLOOD CLOTS IN (B)(6) 2013, I HAD A MASSIVE CLUSTER IN BOTH MY LUNGS AND TWO BY MY HEART. I AM HAVING A HARD TIME FINDING A REPRESENTATIVE TO HELP ME FIGHT THIS BUT SOMETHING HAS TO BE DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032263	CONCEPTUS	10/11/2013	10/18/2013

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2011 I HAD THE ESSURE PROCEDURE. NEVER IN MY WILDEST DREAMS WOULD I HAVE EVER THOUGHT I WOULD REGRET MY DECISION TO DO SO. SINCE PLACEMENT I HAD SUFFERED FROM EXTREMELY HEAVY PERIODS ALONG WITH CONSTANT STOMACH ACHES. I AM A YOUNG WOMAN, (B)(6), WITH CAN NOT IMAGINE DEALING WITH THIS THE REST OF MY LIFE. THIS PROCEDURE IS NOT WHAT I HAD EVER IMAGINED AND WOULD NEVER RECOMMEND IT TO ANYONE EVER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032264	CONCEPTUS	10/11/2013	10/18/2013

Event Information:

Event Date (B3): 12/12/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 624473

Single Use:
Implant Date (E6): 12/12/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE SIDE EFFECTS HAVE BEEN PROGRESSIVELY WORSE SINCE INITIAL IMPLANT. MY PERIODS HAVE BEEN VERY HEAVY/CLOTTY; HEAVY CRAMPING; PAINFUL INTERCOURSE; WEIGHT GAIN; LOWER BACK PAIN; MUSCLE ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032266	BAYER	10/11/2013	10/18/2013

Event Information:

Event Date (B3): 10/9/2013 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/31/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED ON (B)(6) 2012. I AM NOW PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032267	CONCEPTUS, INC.	10/11/2013	10/18/2013

Event Information:

Event Date (B3): 4/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2009
Explant Date (E7): 7/1/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE COIL IMPLANTS IN 2009 AND SUFFERED COMPLICATIONS AND HORRIBLE PAIN OVER A SPAN OF 2 YEARS THAT EVENTUALLY LED TO A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032281	CONCEPTUS / NOW BAYER	10/15/2013	10/21/2013

Event Information:

Event Date (B3): 2/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A06687

Single Use:
Implant Date (E6): 2/22/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL PROCEDURE DONE IN (B)(6) 2013. SINCE THE PROCEDURE, I HAVE HAD SERIOUS PROBLEMS. I AM ATTRIBUTING THIS TO ESSURE BECAUSE PRIOR TO THE PROCEDURE, I WAS NOT HAVING SERIOUS PAIN AND PROBLEMS LIKE I AM NOW. I HAVE HAD VERY PAINFUL BREASTS, SHARP PAINS IN MY HIPS, CHRONIC BACK PAIN, SPASMS IN MY BACK, PAIN IN MY HIPS, LEG PAIN, NUMBNESS IN MY LEGS, FEELING LIKE MY LEG WOULD GIVE OUT, RED DOTS ON MY BACK AND CHEST, HUMUNGOUS PUSTULE PIMPLES ON MY BACK, NECK, AND FACE, LIMPING WHEN WALKING, INCONSISTENT AND PAINFUL PERIODS. FEELING OF BEING PREGNANT, LABOR PAINS WITH PERIOD. I HAVE PRESSURE TO URINATE ALL THE TIME, I HAVE PAIN IN MY BACK SOMETIMES WHEN I HAVE A BOWEL MOVEMENT OR URINATE. I HAVE GAINED WEIGHT AND BEEN UNABLE TO LOSE SINCE GETTING ESSURE. I HAVE HAD MY FIRST UTI OF MY LIFE SINCE I GOT ESSURE, AND HAVE A LOT OF UTI SYMPTOMS ALL THE TIME, HOWEVER, WHEN I GET CHECKED I DON'T HAVE A UTI. I GET CHILLS, FEEL ACHY, LETHARGIC; AND ALSO HAVE WAVES OF EXHAUSTION. I HAVE AT TIMES BEEN ABLE TO TAKE CARE OF MY KIDS, WORK, AND LEAD A PRODUCTIVE LIFE. I HAVE GONE TO VARIOUS DOCTORS WITH DIFFERENT ACHES AND PAINS. I HAVE HAD AN X-RAY, MRI, AND CAT SCAN. I HAVE ALSO HAD BLOOD WORK. MY FATHER IS AN ORTHOPEDIC SURGEON AND SAID MY BACK PAIN IS NOT CONSISTENT WITH ORTHOPEDIC ISSUES, MY OTHER DOCTORS HAVE ALL POINTED ME TO THE GYNECOLOGIST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032282	CONCEPTIS, INC	10/15/2013	10/21/2013

Event Information:

Event Date (B3): 4/30/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/30/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2012. I HAVE HAD SEVERE MENSTRUAL BLEEDING NEEDING ABLATION PROCEDURE TO HELP WITH IT. I HAVE CONSISTENTLY GAINED (B)(6) POUNDS TO DATE SINCE ESSURE PLACEMENT AFTER LOSING 150 BY HAVING GASTRIC SLEEVE WEIGHT LOSS SURGERY IN (B)(6) 2011, THIS IN SPITE OF NOT CHANGING ANY OF MY EXERCISE OR EATING HABITS THAT CAUSED ME TO LOSE SO MUCH WEIGHT PRIOR TO ESSURE. I HAVE A CONSTANT METALLIC TASTE IN MY MOUTH; JOINT PAIN INVOLVING MY RIGHT HIP, LEG AND KNEE; BLOATING OF MY ABDOMEN CAUSING ME TO LOOK 6 MONTHS PREGNANT MOST DAYS; MAJOR HAIR LOSS DESPITE GOOD THYROID LEVELS; EXCESSIVE TIREDNESS; EXCESSIVE BRAIN FOG AND LOSS OF CONCENTRATION; SWELLING/WATER RETENTION IN MY HANDS AND FEET; LOW BACK PAIN ALMOST DAILY; DIARRHEA AND STOMACH CRAMPS AFTER EVERY MEAL; MIGRAINES REGULARLY; PELVIC PAIN ESPECIALLY AROUND OVULATION AND MENSTRUATION REQUIRING PAIN PILLS AND HEATING PADS AND CAUSING MISSED WORK DAYS. I HAVE CONSULTED THE MEDICAL DOCTOR WHO INSERTED THE COILS AND SHE REFUSES TO REMOVE THEM STATING MY PROBLEMS ARE NOT ALL RELATED TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032288	CONCEPTUS	10/15/2013	10/21/2013

Event Information:

Event Date (B3): 9/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): 948834
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2012, I HAD THE ESSURE PROCEDURE DONE. IMMEDIATELY, I BEGUN TO EXPERIENCE INTENSE PAIN BEFORE EVERY MENSTRUAL CYCLE. OVER THE PAST 18 MONTHS THE SYMPTOMS HAVE GROWN MORE SEVERE AND LAST LONGER. MY MOST RECENT BOUT LASTED ABOUT 4 WEEKS. I NOW HAVE TO UNDERGO A BIOPSY AND AN EVENTUAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032289	CONCEPTUS	10/15/2013	10/21/2013

Event Information:

Event Date (B3): 5/19/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 623217

Single Use:
Implant Date (E6): 5/19/2009
Explant Date (E7): 2/6/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) OF 2009. EVERYTHING WENT SMOOTH FOR THE FIRST SEVERAL MONTHS TO A YR. I HAD MANY ADVERSE SIDE EFFECTS AFTER. I DEVELOPED SKIN ALLERGIES TO CLEANING SUPPLIES. I DEVELOPED MANY CAVITIES AFTER A LIFE OF HEALTHY TEETH. I HAVE HAD TO HAVE ONE ROOT CANAL AS WELL AS ONE NEEDED TO BE SCHEDULED. I FREQUENTLY DEVELOP BOILS ON MY BUTTOCKS, VAGINAL AREA, AND FACE THAT WERE DIAGNOSED AS A FORM OF (B)(6). MY DOCTOR COULD NOT FIND A SOURCE OF THE BOILS. I HAVE HAD UNEXPLAINED, RAPID WEIGHT GAIN WHILE EATING A STRICT DIET AND EXERCISING. MY ENERGY LEVEL PLUMMETED. I HAD INTENSE PAIN IN MY ABDOMEN FOR OVER 2 YRS. I WENT TO MY OB/GYN WHEN I COULDN'T TAKE THE PAIN ANY LONGER. BOTH COILS HAD COME OUT OF MY TUBES. ONE PERFORATED THROUGH MY UTERUS AND THE OTHER HAD BECOME FUSED INTO MY UTERINE WALL. I WAS SCHEDULED FOR AN EMERGENCY HYSTERECTOMY WITHIN THE SAME WEEK. I ONLY KEPT MY OVARIES. SINCE MY SURGERY, I HAVE GAINED EVEN MORE WEIGHT AND AM CONSTANTLY BLOATED. MY BLADDER HURTS CONSTANTLY AND I HAVE EXTREMELY PAINFUL GAS AND BOWEL MOVEMENTS. I HAD NONE OF THESE ISSUES PRIOR TO HAVING THE ESSURE COILS IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032290	CONCEPTUS, INC	10/15/2013	10/21/2013

Event Information:

Event Date (B3): 10/30/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/10/2008
Explant Date (E7): 10/30/2008
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2008 I HAD THE ESSURE IMPLANTS PLACED. I IMMEDIATELY HAD PAIN, HEADACHES, FOUL ODOR AND CONSTANT BLEEDING. I WENT FOR MY X-RAYS AFTER THE THREE MONTHS AND WAS TOLD BY THE TECHNICIAN THAT IT APPEARED THAT THE COILS HAD PUNCTURED MY FALLOPIAN TUBES AND ONE OF THE COILS WAS BROKEN. WHEN I WENT TO MY DOCTOR HE DISAGREED WITH THE TECHS STATEMENTS AND BLAMED MY PROBLEMS ON ENDOMETRIOSIS. HE SUGGESTED A HYSTERECTOMY. IN (B)(6) 2008 I HAD A HYSTERECTOMY. AFTER THE SURGERY MY DOCTOR FINALLY ADMITTED THAT MY TUBES HAD BEEN PUNCTURED. I HAVE UNDERGONE MENOPAUSAL SYMPTOMS SINCE MY HYSTERECTOMY. I REALLY BELIEVE THAT THESE COILS SHOULD BE TAKEN OFF THE MARKET. MY LIFE WAS FOREVER CHANGED BY THE DECISION TO HAVE THE COILS PLACED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032291	CONCEPTUS	10/15/2013	10/21/2013

Event Information:

Event Date (B3): 7/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/14/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE (CONCEPTUS) IN (B)(6) 2011. I HAD SIGNIFICANT PAIN DURING THE PROCEDURE AND SOME QUEASINESS AND DIZZINESS AFTER THE PROCEDURE BUT WENT HOME THAT DAY AND FELT FINE THE NEXT DAY. I WAITED 3 MONTHS AND GOT MY DYE TEST, WHICH INDICATED THAT ONE OF THE COILS HAD FALLEN OUT INTO MY UTERUS AND WAS EMBEDDED. MY DOCTOR SCHEDULED A SURGERY TO REMOVE THE COIL FROM MY UTERUS AND INSERT A NEW ONE INTO MY FALLOPIAN TUBE. WHEN I WENT IN FOR THE SECOND PROCEDURE, AN ESSURE REP WAS IN THE ROOM. THE DOCTOR FORGOT TO REMOVE THE COIL THAT WAS EMBEDDED IN MY UTERUS (SHE PLACED THE OTHER ONE FIRST) AND HAD ALREADY REMOVED THE EQUIPMENT SO SHE LOOKED UP AT THE REP AND SAID "DO I NEED TO GO BACK IN? I DON'T WANT TO PUT HER THROUGH THE PAIN". HE SAID NO AND THAT THE COIL WOULD MOST LIKELY BE PASSED WITH MY NEXT PERIOD. MY DOCTOR AGREED SO THEY LEFT IT IN, EXPLAINING TO ME THAT IT WAS A CLOSED ENVIRONMENT AND THUS WOULDN'T DO ANY HARM. A FEW MONTHS LATER, I STARTED HAVING INTENSE PAIN IN MY LOWER RIGHT PELVIS. I CALLED MY DOCTOR AND SHE DID AN ULTRASOUND LOOKING FOR A CYST AND FOUND NOTHING. I WENT HOME AND TREATED THE PAIN WITH IBUPROFEN (PER MY DOCTOR'S ORDERS) BUT THE PAIN CONTINUED. SIX MONTHS LATER, IT BECAME UNBEARABLE. I WENT BACK IN FOR ANOTHER SCAN AND A CT SCAN, AND THE CT SCAN REVEALED THAT THE MISSING COIL HAD SOMEHOW MOVED OUT OF MY UTERUS (NO ONE KNOWS HOW, BOTH MY DOCTOR AND ESSURE REP SAY IT'S IMPOSSIBLE) AND EMBEDDED ITSELF IN MY BLADDER. A SECOND OPINION BY A DIFFERENT OB AND A SECOND CT SCAN REVEALED THE SAME PROBLEM. NO ONE IS SURE HOW IT HAPPENED, BUT IT DID. BOTH THE ORIGINAL DOCTOR AND THE SECOND OPINION DOCTOR RECOMMENDED SURGERY TO REMOVE THE COIL AND REPAIR

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MY BLADDER, BUT MY INSURANCE DEDUCTABLE IS (B)(6). I DIDN'T HAVE THE MONEY TO PAY FOR THE SECONDARY SURGERY AND SO I HAD TO POSTPONE IT. I'VE BEEN LIVING WITH THE PAIN FOR SIX MORE MONTHS NOW, TRYING TO TREAT WITH IBUPROFEN AND HOPING THE COIL DOESN'T CAUSE DAMAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032292	CONCEPTUS	10/15/2013	10/21/2013

Event Information:

Event Date (B3): 9/14/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/14/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE JUST AT A YEAR NOW WITH SERIOUS PAINFUL CONDITIONS. I WOULD LIKE SOME INFORMATION AND HELP TO FIND A CURE TO FIX WHAT IS GOING ON. I HAVE SEVERE PAIN, IN THE ABDOMEN, AND LOWER BACK PAIN, SEVERE BLEEDING AND CLOTS, NAUSEA, HEADACHE, WEIGHT GAIN, DEPRESSION, SLEEPY. FOR ME AS A YOUNG PERSON WHO WAS IN GOOD HEALTH AND ACTIVE I FEEL THAT THE ESSURE HAS CAUSED SO MANY PAINFUL ISSUE IN MY LIFE; I'D JUST LIKE TO BE BACK TO THE WAY I WAS BEFORE I HAD THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032293	BAYER	10/15/2013	10/21/2013

Event Information:

Event Date (B3): 9/4/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/9/2013
Explant Date (E7): 10/4/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AND IT TOOK 3 HOURS DUE TO MY UTERUS BEING TILTED AND A LOT OF FLUID. I STARTED RUNNING A FEVER OF 104, BLEEDING EXCESSIVELY AND IN A MAJOR AMOUNT OF PAIN. MY BODY REJECTED THEM BECAUSE I AM AN AUTOIMMUNE PT THAT HAS BEEN ON STEROIDS DAILY FOR 3 MONTHS AND THEY HAD TO BE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032295	CONCEPTUS	10/15/2013	10/21/2013

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 727103; 717632

Single Use:
Implant Date (E6): 2/1/2012
Explant Date (E7): 10/22/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS PLACED (B)(6) 2012. I WAS ALWAYS HEALTHY UNTIL THAT POINT. SINCE THAT TIME, I HAD SUFFERED TERRIBLY WITH INCREASED MIGRAINES, SEVERE PELVIC PAIN, FATIGUE, JOINT PAIN, WEIGHT GAIN, HEAVY BLEEDING, UTERINE FIBROIDS, OVARIAN CYSTS AND HAVE BEEN DIAGNOSED WITH AN AUTOIMMUNE DISEASE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032323	CONCEPTUS	10/16/2013	10/22/2013

Event Information:

Event Date (B3): 10/2/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DONE 2010. MY COILS ARE NOW IN MY UTERUS AND HAVE TO UNDERGO A HYSTERECTOMY'S (B)(6) 2013. I'VE BEEN IN AND OUT HOSPITAL PAIN MEDS ANTIBIOTICS OVER AND OVER. IT HAS RUINED MY LIFE COMPLETELY. I DID NOT SIGN UP FOR ALL THESE PROBLEMS. THE MORE I READ FDA RELEASED THIS PRODUCT TOO EARLY. FDA LET THEM REMOVE A WARNING LABEL CLEARLY DOCTOR DIDN'T UNDERSTAND NONE OF THE ESSURE RULES. I WAS HOSPITALIZED PUT TO SLEEP WAS THERE FOR OVER FIVE HOURS WHEN IT'S SUPPOSED TO BE OFFICE VISIT. I TOLD HER I WANTED MY TUBES TIED NOW I HAVE TO GET A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032325	CONCEPTUS	10/16/2013	10/22/2013

Event Information:

Event Date (B3): 2/14/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 621675

Single Use:
Implant Date (E6): 2/15/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

INSERTION OF ESSURE IN (B)(6) 2005, WAS NOT TESTED FOR NICKEL SENSITIVITY, WAS GIVEN ID CARD REF # (B)(4) LOT 621675. THE PROCEDURE WAS DONE IN THE HOSPITAL WITH FULL ANESTHESIA. EVERYTHING SEEMED TO GO FINE. THE DYE TEST 3 MONTHS LATER WAS INCREDIBLY PAINFUL. MY MENSTRUAL CYCLE BECAME PROGRESSIVELY WORSE, INCREASING IN AMOUNT AND DURATION, AND I BEGAN HAVING CRAMPS. ABOUT A YEAR AND A HALF AFTER INSERTION, A SONOGRAM REVEALED ENDOMETRIOSIS. I HAD AN ABLATION, AFTER WHICH I HAD AWFUL PAIN. ABOUT A MONTH LATER, I HAD A UTERINE INFECTION. DURING THIS TIME, I WAS HAVING SEVERE AND RELENTLESS BACK PAIN. THIS LASTED FOR 6 MONTHS, AND WHEN IT RETURNED 6 MONTHS AFTER THAT I HAD BACK SURGERY. I SEEMED TO ENTER EARLY MENOPAUSE, HAVING MANY SYMPTOMS ASSOCIATED WITH THAT. A FEW YEARS AGO, I HAD A CHECK UP WITH MY OB/GYN AND DISCUSSED CRAMPING. A SONOGRAM REVEALED I HAD A QUARTER SIZED CYST ON ONE OF MY OVARIES. THE NEXT MONTH A FOLLOW UP SONOGRAM SHOWED THAT CYST HAD SHRUNK AND I HAD ONE ON THE OTHER SIDE. THE TECH EXPLAINED THAT MY EGGS WEREN'T RELEASING. I GET CRAMPING DAILY, ABDOMINAL AND BACK CRAMPING WHEN MY BLADDER IS FULL, WHEN I HAVE TO HAVE A BOWEL MOVEMENT, OR WHEN AIR IS MOVING IN MY INTESTINES. I ALSO HAVE TO AVOID BENDING AND LIFTING BECAUSE OF THE PAIN IT CAUSES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032326	CONCEPTUS/BAYER	10/16/2013	10/22/2013

Event Information:

Event Date (B3): 10/5/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/5/2012
Explant Date (E7): 9/11/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED (B)(6) 2012. , I BEGAN HAVING VAGINAL DISCHARGE AND ODOR. FOR THE NEXT 10 MONTHS I CONTINUED TO HAVE SYMPTOMS AFTER MANY ROUNDS OF DOCTORS VISITS AND ANTIBIOTICS. IN (B)(6) 2013, I BEGAN HAVING KNEE AND ANKLE PAIN, THAT EVENTUALLY PROGRESSED TO A STATE THAT AFFECTED MY WORK. I HAD TO HAVE AN MRI ON MY LEG, STEROID SHOTS IN MY FOOT, AND MONTHS OF PHYSICAL THERAPY. I FINALLY ASKED MY GYN TO REMOVE THE ESSURE COILS AS I FELT THEY WERE CONTRIBUTING TO ALL OF THESE SYMPTOMS. ON (B)(6) 2013, THE COILS WERE REMOVED BY REMOVING BOTH OF MY FALLOPIAN TUBES UNDER GENERAL ANESTHESIA. MY SYMPTOMS WERE ALMOST INSTANTLY RESOLVED! THESE COILS SHOULD HAVE MANDATORY NICKLE ALLERGY TESTING BEFORE EVER BEING INSERTED. THEY ARE POISON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032328	CONCEPTUS	10/16/2013	10/22/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/30/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE PRODUCT. I HAD A CT SCAN SHOWING THEY ARE NOT PLACED PROPERLY IN THE TUBES WHICH IS CAUSING MY PAIN. I HAVE TO FOLLOW UP WITH MY GYNECOLOGIST. I HAVE CONSTANT BACK PAIN, CRAMPS, HEAVY PERIODS, BURNING ON MY LEFT SIDE, PRESSURE WHEN I SIT DOWN WHICH NEVER GOES AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032330	BAYER	10/16/2013	10/22/2013

Event Information:

Event Date (B3): 4/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 11/21/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED IN 2007. PREGNANCY RESULTED IN 2013. UNABLE TO GET CONFIRMATION FROM DOCTOR IF OTHER ADVERSE FEMALE ORGAN RELATED SYMPTOMS THE PAST YEAR ARE DUE TO ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032313		10/17/2013	10/22/2013

Event Information:

Event Date (B3): 4/23/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305-R1; ESS305
Catalog # (E4):
Lot #(E4): 627298; 12385371

Single Use:
Implant Date (E6): 4/23/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER BEING PREGNANT A LOT AND ONLY HAVING THREE LIVE BABIES, I WANTED TO BECOME FIXED. SO I GOT THE ESSURE. THE DOCTOR NEVER REALLY TOLD ME A LOT ABOUT IT, BUT THAT IT WAS IN AND OUT AND COULD WALK RIGHT AFTERWARDS. WHICH I NEEDED BEING THAT I HAD THREE BABIES AT HOME AND A HUSBAND THAT WAS IN THE MILITARY AND GONE A LOT. I GOT IT DONE IN (B)(6) 2009 AND CAN'T WALK HALF THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032319	BAYER	10/17/2013	10/22/2013

Event Information:

Event Date (B3): 9/18/2008 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/18/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED (B)(6) 2008, IMMEDIATELY EXPERIENCED PAIN AND DISCOMFORT. HSG TEST WAS DONE (B)(6) 2008 WAS TOLD MY TUBES WERE 100% BLOCKED. I CONTACTED THE DOCTOR WHOM DID THE PLACEMENT HE BLEW ME OFF. MY SYMPTOMS INCLUDE IRON DEFICIENCY, ANXIETY AND PANIC ATTACKS, ACNE AND SKIN RASHES, BACK PAIN, FAINTING, BLURRY VISION, CHEST PAIN, FORGETFULNESS, CONFUSION, SPOTTING, CONSTANT SWEATING, CRAMPING, DIZZINESS, DRY SKIN, DRY HAIR, EAR ACHES, FACIAL PAIN, FATIGUE, HAIR LOSS, HEADACHES, HEAVY BLEEDING AND CLOTTING DURING PERIODS, ALLERGIC REACTIONS/IRRITATIONS, HIP PAIN, HYPOTHYROIDISMS, INSOMNIA, IRREGULAR PERIODS, MOOD SWINGS, IRRITABILITY, NIGHT SWEATS, PREGNANCY, STABBING PAINS IN SIDES, SORE THROAT, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032321	BAYER	10/17/2013	10/22/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 2020563

Single Use:
Implant Date (E6): 11/6/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED (B)(6) 2009. EVER SINCE I THEN HAVE HAD A NUMBER OF PROBLEMS, HEAVY BLEEDING, PAINFUL CRAMPS, BAD LOWER BACK PAIN, NAUSEA, HEADACHES, SHARP PAINS, RASH, NEVER ENDING PERIODS, UTI'S, FATIGUE, INSOMNIA, PANIC ATTACKS, BLOOD CLOTS, BLURRY VISION, BODY ACHES, BOWEL ISSUES, BREAST PAIN, FORGETFULNESS, CONSTANT SWEATING, DISCHARGE, DIZZINESS, EAR ACHES, WEIGHT GAIN, FIBROIDS, HAIR LOSS, HEART PALPITATIONS, IRREGULAR PERIODS, MOOD SWINGS, NICKEL TASTE, NUMBNESS IN HANDS, PAINFUL INTERCOURSE, PAINFUL OVULATION, AND SEVERE BLOATING. I NEVER HAD ANY OF THESE PROBLEMS BEFORE THE ESSURE AND I KNOW 100% IN MY HEART THESE ARE THE REASON FOR EVERYTHING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032348	CONCEPTUS	10/21/2013	10/24/2013

Event Information:

Event Date (B3): 3/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 628445

Single Use:
Implant Date (E6): 3/17/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A FEW MONTHS AFTER I HAD THE ESSURE COILS INSERTED AND HAD MY HSG TEST I STARTED NOTICING LOTS OF JOINT PAINS, HEAVY MENSTRUAL CYCLES PRODUCING BASEBALL SIZED CLOTS AND GOING THROUGH SUPER PLUS TAMPONS AND SUPER PADS EVERY 30 MINUTES TO HOUR, EXTREME FATIGUE, CHRONIC MIGRAINES, NUMBNESS AND TINGLING IN MY EXTREMITIES, INSOMNIA, ANXIETY DISORDER, FREQUENT URINATION, BACK AND HIP PAIN, LOSS OF SEX DRIVE, WEIGHT GAIN. FEELING BLOATED ALL THE TIME, CONSTIPATION, PAIN IN MY ABDOMEN, SEVERE CRAMPING IN MY ABDOMEN, IRREGULAR PERIODS, PRESSURE AS IF I AM ABOUT TO GIVE BIRTH, SEVERE ALLERGIES EVERYDAY ALL DAY LONG, GOUT IN MY RIGHT TOE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032349		10/21/2013	10/24/2013

Event Information:

Event Date (B3): 8/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DONE LAST YEAR AND SINCE THEN I HAVE HEAVY BLEEDING SIDE PAIN AND JOINT PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032362	BAYER	10/21/2013	10/25/2013

Event Information:

Event Date (B3): 8/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PROCEDURE DONE, HAVE HAD CONSTANT LRQ PAIN AND PRESSURE, LOWER BACK PAIN, BLADDER ISSUES INCLUDING INCONTINENCE AS WELL AS BOWEL PROBLEMS, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032364		10/21/2013	10/25/2013

Event Information:

Event Date (B3): 10/23/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PROCEDURE
Device Type (E2): ESSURE PROCEDURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/23/2007
Explant Date (E7): 8/16/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(4) 2007, AFTER I HAD MY THIRD CHILD. IN 2010 I STARTED HAVING PAIN WITH PERIODS THAT WERE SEVERE PAIN DURING MY CYCLE. I WAS LED TO BELIEVE IT WAS CRAMPS. IN (B)(6) OF 2012, I WAS HOSPITALIZED WITH SEVERE PAIN, THEY LOOKED AT MY APPENDIX AND FOUND NOTHING. I WAS STILL HAVING PAIN AND HAD ANOTHER DOCTOR LOOK AT IT IN THE STATE OF (B)(6). THAT'S WHEN IN (B)(6) OF 2012, THEY WENT IN TO DO EXPLORATORY SURGERY TO FIND THAT THE COIL HAD WRAPPED AROUND MY VEINS. I HAD TO HAVE MY RIGHT FALLOPIAN TUBE REMOVED BECAUSE OF IT. NOW I AM HAVING PAIN ON MY LEFT SIDE AND HAVE PAIN EVERY NOW AND THEN ON MY RIGHT SIDE AFTER THE SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032365		10/21/2013	10/25/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/12/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SHAR, SHOOTING PAINS IN OVARIES, BACK PAIN, PAINFUL SEX, HIVES, HEADACHES, LARGER BLOOD CLOTS, LOW SEX DRIVE, LOSS OF INTEREST, TIRED ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032370	CONCEPTUS	10/21/2013	10/25/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD MANY ISSUES WITH THE ESSURE. I'VE HAD BURNING WHERE MY TUBES ARE. NERVE PAIN SHOOTING DOWN MY LEGS. UNEXPLAINED SWEATING AND BACK PAIN. I'VE HAD AT LEAST TWO CHEMICAL PREGNANCIES. I'VE HAD HEADACHES ON A REGULAR BASIS, WHICH I NEVER USED TO GET. I'M EXHAUSTED ALL OF THE TIME. I'VE EVEN DEVELOPED ALOPECIA SINCE GETTING THE ESSURE. I NOW HAVE TO DRIVE 4 HOURS AND PAY (B)(4) TO HAVE A DOCTOR GET THE COILS OUT. UNFORTUNATELY, MOST DOCTORS DON'T KNOW HOW TO REMOVE THEM, WHICH IS VERY SCARY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032371	BAYER	10/21/2013	10/25/2013

Event Information:

Event Date (B3): 6/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626909

Single Use:
Implant Date (E6): 10/15/2008
Explant Date (E7): 4/28/2019
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HYSTERECTOMY, BILATERAL OOPHORECTOMY, AND LEFT OOPHORECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032372		10/21/2013	10/25/2013

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/31/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS. THESE ARE THINGS/SYMPTOMS. I HAVE EXPERIENCED SINCE MY ESSURE COILS WERE PLACED INSIDE ME. HEAVY BLEEDING, CRAMPING, JOINT PAIN, DIZZINESS, NAUSEA, FATIGUE/COMPLETE LOSS OF ENERGY, SHARP STABBING PAINS, BACK PAIN, MIGRAINES, PARESTHESIA, BLOATING LEG PAINS, HAIR CHANGES, NERVE PAIN, PROBABLE COMPLEX OVARIAN CYST, VITAMIN D DEFICIENCY, MULTIPLE PROBLEMS WITH MY TEETH, CLOUDINESS, FORGETFULNESS, ANXIETY AND PANIC ATTACKS, ACNE, BOILS, NECK AND SPINE PAIN, HOT FLASHES, NIGHTMARES, RASHES. I'VE DEAL WITH A LOT. I'M HOPING I HAVE NOT LEFT ANYTHING OUT. I BELIEVE MY COILS ARE OUT OF PLACE AND I AM SCHEDULING AN APPOINTMENT TO INVESTIGATE THAT MATTER FURTHER, HOWEVER, DID NOT WANT TO WAIT TO SUBMIT. ALSO, I DID NOT RECEIVE A PREGNANCY TEST OR A NICKEL ALLERGY TEST BEFORE MY PROCEDURE. I STARTED HAVING THESE ISSUES APPROX 2 TO 3 MONTHS AFTER MY PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032373	BAYER/CONCEPTUS	10/21/2013	10/25/2013

Event Information:

Event Date (B3): 1/12/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/12/2004
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2004 AND HAVE EXPERIENCED MULTIPLE ISSUES EVER SINCE. IT STARTED OFF SIMPLY ENOUGH WITH WHAT I THOUGHT WERE MENSTRUAL CRAMPS DESPITE NOT HAVING THEM PRIOR TO SURGERY. THE NEXT THING THEN I WAS PASSING GIANT BLOOD CLOTS AND THE CRAMPING WORSENED. I BEGAN GETTING RECURRENT URINARY TRACT INFECTIONS, WHICH I HAD NO HISTORY OF PRIOR TO THE PROCEDURE. I BEGAN HAVING PREGNANCY LIKE SYMPTOMS AND A PREGNANCY TEST INDICATED I WAS PREGNANT. I WENT TO MY OB/GYN TO LEARN I WAS NOT PREGNANT, BUT MIGHT HAVE CANCER AND NEEDED TESTING. I WAS DEVASTATED. TEST RESULTS DETERMINED THAT I DID NOT HAVE CANCER, BUT I DID HAVE NINE OVARIAN CYSTS WHICH WERE NOT PRESENT PRIOR TO THE ESSURE PROCEDURE. THERE IS NO HISTORY OF OVARIAN CYSTS ON EITHER SIDE OF MY FAMILY; I AM NOT GENETICALLY PREDISPOSED TO DEVELOPING THEM AND AGAIN HAD NO HISTORY OF THEM MYSELF PRIOR TO THE PROCEDURE. SOON AFTER, I BEGAN EXHIBITING SYMPTOMS SIMILAR TO MS OR A BRAIN TUMOR. NO ONE COULD FIGURE OUT, BUT FINALLY DECIDED THAT IT MIGHT BE MIGRAINES. THIS OCCURRED OVER ABOUT A THREE YEAR PERIOD OF TIME. CURRENTLY, I EXPERIENCE FREQUENTLY DEBILITATING CRAMPING BEFORE AND DURING MY PERIOD, BRINGING ME TO YEARS AND KEEPING ME PRISONER. MY PERIODS ARE NOW HIGHLY IRREGULAR SOMETIMES ENDING ONLY TO BEGIN AGAIN THE NEXT DAY, SOMETIMES NOT COMING AT ALL, AND SOMETIMES LASTING ONLY A SHORT TIME, BUT ALWAYS REQUIRING MULTIPLE SUPER ABSORBENCY TAMPONS EACH DAY AND OFTEN CAUSING EMBARRASSMENT FROM SEVERE LEAKAGE NONE OF WHICH OCCURRED PRIOR TO THE ESSURE IMPLANTS. SIGNIFICANT WEIGHT GAIN AND DIFFICULTY LOSING WEIGHT, CONSTANT BLOATING, ANXIETY, IRREGULAR HEARTBEAT, CHRONIC URINARY TRACT INFECTIONS, INSOMNIA, FATIGUE, LETHARGY, SEVERE MOOD SWINGS, GENERAL DECLINE IN HEALTH, SEIZURE-LIKE BRAIN ACTIVITY, INHIBITED SEROTONIN,

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DEPRESSION, FREQUENT DIARRHEA, GERD, EXCRUCIATING MIGRAINES, AND OTHER SYMPTOMS MANIFESTED SUBSEQUENT TO THE ESSURE PROCEDURE WITHOUT GENETICALLY ORGANIC CAUSATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032374	CONCEPTUS, INC	10/21/2013	10/25/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL DEVICE IMPLANTED IN 2010. SINCE I HAD THIS PROCEDURE DONE I HAVE HAD NOTHING BUT PROBLEMS. IT STARTED WITH SEVERE MIGRAINES, BACK PAIN, FATIGUE AND ANXIETY. IT HAD NOW ESCALATED TO SEVERE PELVIC PAIN WHERE THE COILS WERE PLACED, BOWL TROUBLE I HAVE HAD SEVERAL UTI INFECTIONS, BLOATING, NUMBNESS DURING INTERCOURSE, BREAST PAIN AND NOW CHRONIC NECK PAIN. I AM CURRENTLY NOW ON 3 DIFFERENT OVER THE COUNTER MEDICATION TWO OF WHICH ARE FOR PAIN. THE DOCTORS ARE TRYING TO FIGURE OUT WHY I AM HAVING SO MUCH PAIN. I WANT THESE THINGS OUT. I LOST MY SEX DRIVE ALMOST IMMEDIATELY AFTER THIS WAS DONE. I HAD THIS DONE SO I WOULD BE ABLE TO LIVE LIFE WITHOUT WORRYING ABOUT GETTING PREGNANT WITH ANOTHER CHILD THAT I COULD NOT AFFORD AT THE TIME. I WAS TOLD THERE WOULD BE NO SIDE EFFECTS AND I BELIEVE I WAS LIED TO. TO TOP IT OFF NOW THE ONLY WAY TO GET THEM OUT IS TO HAVE THE SURGERY THAT I WAS TRYING TO AVOID.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032375	CONCEPTUS, INC	10/21/2013	10/25/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN 2008. HAD THREE MONTH DYE TEST AND EVERYTHING LOOKED OK. AFTER THAT MY PERIODS HAVE BEEN 7-10 DAYS (AT LEAST 3 DAYS LONGER THAN BEFORE ESSURE). CONSTANT HORRID GIVING BIRTH PAIN FOR AT LEAST 3 DAYS CONSTANT MAKING ME ALMOST UNABLE TO MOVE LET ALONE TAKE CARE OF MY KIDS. A 2-3 INCH THICK CLOTS FOR 7-10 DAYS, HORRIBLE CONSTANT MIGRAINES. LOWER BACK NUMBNESS AS WELL AS FEELING DELIRIOUS AT TIMES. THIS IS EVERY MONTH!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032376	BAYER	10/21/2013	10/25/2013

Event Information:

Event Date (B3): 10/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/18/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE PROCEDURE DONE TO ME IN 2010. I GOT A PID INFECTION AND PAIN IN LEFT SIDE, AS THINGS WENT ON, I STARTED FAINTING AND MY PERIOD IS NOW EVERY TWO WEEKS. IT HAS BEEN LIKE THIS THE LAST 3 YEARS. I FEEL WEAK AND SICK ALL THE TIME. MY PERIODS ARE SO HEAVY I CANNOT STAND AND I SOAK PADS THROUGH TO MY PANTS AT TIMES. I CANNOT TAKE CARE OF MY LITTLE BOY ON SOME DAYS BECAUSE THE BLEEDING AND CRAMPS ARE SO BAD. I HAVE HAD VERY SCIENTIFIC TEST DONE TO ME SHOWING THAT THERE IS NOTHING WRONG. I NEVER HAD FEMALE PROBLEMS IN MY ENTIRE LIFE AND I AM (B)(6) UNTIL I HAD THE ESSURE PROCEDURE DONE. I AM TRYING TO GET THEM REMOVED. ALL OF MY LAB TEST SHOW THIS IS NOTHING WRONG WITH ME HORMONALLY, AND I DON'T HAVE ANY INFECTIONS, GROWTHS OR CANCERS. SCIENTIFICALLY THERE IS NOTHING WRONG WITH MY BODY. ALL OF THE PROBLEMS STARTED HAPPENING AFTER THE ESSURE PLACEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032377	BAYER/CONCEPTUS	10/21/2013	10/25/2013

Event Information:

Event Date (B3): 4/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 10/30/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) OF 2012. I HAD THE COILS REMOVED (B)(6) 2012. I HAD A HYSTERECTOMY (B)(6) 2013, ONLY KEEPING OVARIES. PROCEDURE WENT FINE. INSERTION WENT FINE. I WATCHED IT ALL ON THE SCREEN. TWO WEEKS LATER I PASSED OUT. WENT TO THE DOCTOR NOTHING WRONG A COUPLE MONTHS PASSED I WAS PERFECTLY FINE. THEN I WAS IN THE GROCERY STORE WITH MY 1 YEAR OLD IN THE CART AND PASSED OUT AGAIN. WENT TO THE DOCTOR NOTHING WRONG. THEN I BECAME CONSTANTLY DIZZY, HEADACHES, UNBEARABLE PAIN IN BACK LEGS AND STOMACH, ABS, YOU NAME IT I HAD IT. FINALLY CONNECTED IT TO WHEN IT ALL STARTED WHEN I HAD ESSURE PLACED. TO THIS DAY I AM STILL NOT ABLE TO LEAVE MY HOUSE OR DRIVE OR TAKE CARE OF MY KIDS ALONE BECAUSE OF WHATEVER PERMANENT DAMAGE THIS DEVICE CAUSED PHYSICAL AND NEURO. IT HAD ROBBED ME FROM LIFE AND MY KIDS FROM A MOM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032382	CONCEPTUS (BAYER)	10/21/2013	10/25/2013

Event Information:

Event Date (B3): 4/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 740669

Single Use:
Implant Date (E6): 7/14/2010
Explant Date (E7): 4/26/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DUE TO THE ESSURE BIRTH CONTROL DEVICE THAT I HAD IMPLANTED IN (B)(6) 2010, I STARTED TO HAVE MANY SIDE EFFECTS BELIEVE TO BE FROM A NICKEL ALLERGY, HAD PAIN, CRAMPING, SEVERE BLEEDING, CYSTS, INFECTIONS, HEADACHES, DIZZINESS, FOGGINESS, PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE, RASHES, BLOATING, WEIGHT GAIN AND ADENOMYOSIS. I WAS NOT TOLD PRIOR TO RECEIVING ESSURE THAT IT CONTAINED NICKEL. SIDE EFFECT STARTED SHOWING UP AROUND A YEAR AND A HALF AFTER IMPLANTING AND PROGRESSIVELY GOT WORSE UNTIL UNBEARABLE. HYSTERECTOMY OF UTERUS AND TUBES WAS DONE ON (B)(6) 2013 TO REMOVE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032383	BAYER	10/21/2013	10/25/2013

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 794899

Single Use:
Implant Date (E6): 6/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(6) 2011. AFTER I RECEIVED ESSURE I HAVE HAD SERIOUS PROBLEMS EVER SINCE. I'VE BEEN TO THE DOCTOR TO RULE OUT ALL OTHER THINGS AND IT KEEPS COMING BACK TO ESSURE. I HAVE BACK PAIN, HIP PAIN, LOTS OF UTI'S, ANXIETY, CYSTS, METALLIC SMELL, URGENCY TO PEE, BODY ACHES, JOINT PAIN, BREAST PAIN, CRAMPS ALL MONTH LONG, EXTRA DISCHARGE, FATIGUE, MIGRAINES OR HEADACHES EVERY SINGLE DAY, MY CYCLE IS DIFFERENT 8-9 DAYS LONG NIGHT SWEATS TENDER SPOTS ALL OVER BODY. NOW I'M BECOMING ALLERGIC TO SOAPS AND SOME FOODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032384	BAYER	10/21/2013	10/25/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE INSERTS
Device Type (E2): ESSURE INSERTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS PUT IN 2005 AND HAVE GOTTEN WORSE STEADILY WORSE OVER THE YEARS TO THE POINT THAT NOW I HAVE HEAVY BLEEDING, MIGRAINE HEADACHE, DIZZY SPELLS, WEIGHT GAIN, DEPRESSION, AND MANY MORE PROBLEMS HOW MANY WOMEN HAVE TO SUFFER OR DIE BEFORE YOU TAKE THE STEPS TO SHUT DOWN ESSURE PROCEDURE AND HOLD THE MANUFACTURE RESPONSIBLE FOR THEIR EXTREMELY DEFECTIVE PRODUCT (ESSURE).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032385	CONCEPTUS	10/21/2013	10/25/2013

Event Information:

Event Date (B3): 7/25/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/25/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) OF 2013. ALMOST IMMEDIATELY AFTER PLACEMENT, I DEVELOPED SEVERE LOWER BACK PAIN. AS THE WEEKS WENT ON, I DEVELOPED SEVERE BLOATING IN MY ABDOMEN AND ALMOST CONSISTENT GAS. I HAVE FREQUENT HEADACHES WHICH NEITHER TYLENOL NOR IBUPROFEN CAN RELIEVE. I HAVE STABBING PAINS IN THE SIDES OF MY ABDOMEN AND FREQUENT CRAMPING. IF I HOLD MY URINE FOR A LENGTH OF TIME, I HAVE SEVERE PAIN IN THE SIDES OF MY STOMACH THAT HURT FOR HOURS. I MENSTRUATE EVERY TWO WEEKS, WHICH MEANS I HAVE PMS EVERY OTHER WEEK. THIS LEAVES ME EVERY MOODY AND DEPRESSED. I AM VERY TIRED AND SORE AND IT IS ONLY GETTING WORSE. SOMETIMES, IT FEELS AT TIMES LIKE I HAVE BRUISES ON THE SIDES OF MY HIPS AS IF SOMEBODY HAD PUNCHED ME REPEATEDLY. I AM MISERABLE. I WOULD GLADLY HAVE A HYSTERECTOMY THAN LIVE WITH WHAT I AM LIVING WITH. I AM CARING FOR A NEWBORN WHILE I AM DEPRESSED, TIRED, AND UNCOMFORTABLY BLOATED AND IN PAIN. THE LOWER BACK PAIN IS THE WORST. I FEAR I WILL HAVE NEW SYMPTOMS POPPING UP BECAUSE THAT IS HOW IT HAS BEEN GOING. I WAS NOT TOLD THAT ANY OF THIS WAS EVEN A POTENTIAL SIDE EFFECT. I SPECIFICALLY ASKED ABOUT WEIGHT GAIN AND I WAS TOLD NO. I AM ALSO BLOATED AND GASSY ALL OF THE TIME, I LOOK LIKE I AM 7 MONTHS PREGNANT AND IF IS GETTING WORSE. I WAS NEVER TOLD THAT A NICKEL ALLERGY MIGHT BE PROBLEMATIC. I HAVE A NICKEL ALLERGY. IF I WEAR CHEAP JEWELRY, MY SKIN GETS RED, PUFFY, AND I HAVE TERRIBLE ITCHING. ESSURE HAS PROVED TO BE ONE OF MY BIGGEST REGRETS. AND TO MAKE MATTERS WORSE, IT DOESN'T APPEAR THAT THERE IS A WAY OUT. MOST DOCTORS WILL NOT DO REMOVAL AND WILL NOT DISCUSS A HYSTERECTOMY SERIOUSLY. EVEN IF THEY DID, I AM NOT SURE THAT INSURANCE WILL PAY FOR IT AS NO OBVIOUS PROBLEM IS SEEN.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	10/22/2013	11/1/2013

Event Information:

Event Date (B3): 9/24/2013 **Report Date (B4): 10/22/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): B27984

Single Use:
Implant Date (E6): 9/24/2013
Explant Date (E7): 9/24/2013
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEEL IN APPLICATOR WAS TURNED TOWARDS DOCTOR, BUT DEVICE MALFUNCTIONED & SLEEVE WASN'T SEEN. JUST SEEING COILS IN PROXIMAL AREA. DIDN'T SEE IT DEPLOYED CORRECTLY, TRIED TO MOVE DEVICE IN & OUT OF FALLOPIAN TUBE. NOTHING HAPPENED. RESISTANCE NOTED. WAS ABLE TO DEPLOY DEVICE AS SUPPOSE TO-TURN WHEEL TOWARD DOCTOR, PRESS-RELEASE BUTTON, INNER AREA INSIDE COIL WAS INSIDE UTERINE CAVITY. APPLICATOR WAS THEN ABLE TO BE REMOVED. HYSTEROSCOPE GRASPER WAS PLACED IN TO REMOVE PIECES OF DEVICE FROM FALLOPIAN TUBE. USED NEW DEVICE SUCCESSFUL. TOOK PICTURE AND SAW PIECES OF MALFUNCTIONED COIL INSIDE UTERINE CAVITY, WHICH WAS REMOVED W/HYTOSCOPE GRASPER. PATIENT TOLERATED PROCEDURE WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033557	BAYER	10/22/2013	12/24/2013

Event Information:

Event Date (B3): 5/19/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/19/2011
Explant Date (E7): 7/16/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2011, I HAD THE ESSURE IMPLANT PROCEDURE DONE. IT HAS BEEN NOTHING BUT PURE PAIN EVERY DAY. I STARTED BLEEDING HEAVILY FROM THE TIME I GOT IT FOR TWO MONTHS. I START GROWING CYSTS AND FIBROIDS. NOT TO MENTION PLENTY OF INFECTIONS. MY VISION HAS CHANGED AND I HAD FELT LIKE I WAS DYING. I LOST MY HAIR AND I GOT A FULL WORK UP AND HAD NO ISSUES UNTIL THAT DEVICE WAS INTRODUCED INTO MY BODY. IT'S NOT SAFE. I LOST MY LIFE. THE HEADACHES WERE DANGEROUS, AND THE HEAD PAINS, STOMACH PAINS/SHARP JAGGED PAIN, I WAS ON MY KNEES SOMETIMES IN PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033558	CONCEPTUS	10/22/2013	12/24/2013

Event Information:

Event Date (B3): 9/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/29/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2012 I CONSULTED MY DOCTOR ABOUT A TUBAL LIGATION AND WAS ADVISED TO GET THE ESSURE PROCEDURE. AFTER CHECKING THE MFR'S WEBSITE I DECIDED TO PROCEED WITH THE DOCTOR'S ADVISE. AFTER EXPERIENCING A LARGE NUMBER OF SIDE EFFECTS (WHICH I WILL LIST AT THE END) I DISCOVERED THAT THE ESSURE COILS THAT HAD BEEN IMPLANTED IN ME WERE MADE OF NICKEL. I HAD SEEN NO WARNING ON THEIR SITE THAT WAS CLEAR ENOUGH FOR ME TO NOTICE IT. I KNEW THAT I HAVE METAL ALLERGIES AND WOULD NOT HAVE PURSUED IT OTHERWISE, AND MY DOCTOR SEEMED UNCLEAR THAT PROBLEMS COULD ARISE FROM THE POTENTIAL OF NICKEL PROBLEMS. I WAS GIVEN NO TEST OR WARNING TO SEE IF I WAS ALLERGIC BEFORE HAND, DESPITE MY KNOWLEDGE OF MY PREDISPOSITION TO ALLERGIES, SPECIFICALLY METAL ALLERGIES. I FEEL LIKE I CAN'T TAKE CARE OF MY FAMILY AND I AM LETTING MY FAMILY DOWN. THE SYMPTOMS HAVE BECOME MORE SEVERE AND QUANTITATIVE OVER TIME AND INCLUDE: NAUSEA, VOMITING, WEIGHT GAIN, HAIR LOSS, DENTAL PROBLEMS, FREQUENT PERIODS (EVERY 2 WEEKS, WHEN I WAS REGULAR AT ONCE MONTHLY BEFORE), HEAVY PERIODS, FEVER, HEADACHES, VAGINAL DISCHARGE, EXTREME FOOD ALLERGIES, INCREASED GENERAL ALLERGIES, BLURRED VISION, UTI, BURNING, BACK PAIN, ACNE, DIZZINESS AND BLACKING OUT BLADDER PROBLEMS AND URGENT URINATION, PAINFUL INTERCOURSE AND BLEEDING AFTER SEX, BODY ACHES, BREAST PAIN, BRAIN FOG, CONFUSION, FORGETFULNESS, CRAMPING, HOT FLASHES, HEARTBURN, FATIGUE JOINT PAIN, MOOD SWINGS, MUSCLE SPASMS, BLOATING AND SHARP CHRONIC PAINS TO THE POINT THAT I'M ON MY KNEES UNABLE TO MOVE LASTING SOMETIMES FOR HOURS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033561	BAYER	10/22/2013	12/24/2013

Event Information:

Event Date (B3): 4/7/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/7/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE BACK IN (B)(6) OF 2008 AND EVER SINCE THEN I'VE BEEN HAVING VERY HEAVY DEBILITATING PERIODS THAT INCLUDE SEVERE MIGRAINES, VERY PAINFUL CRAMPING AND I HAVE TO BE ON BED REST FOR THE WHOLE WEEK THAT I'M ON MY PERIOD. I ALSO HAD THE FIRST OF MY PANIC ATTACKS STARTING IN (B)(6) OF 2008 (I GET THOSE ABOUT TWICE A MONTH EVERY MONTH), I HAVE HAD OVER FIFTY POUNDS OF WEIGHT GAIN, I'M EXHAUSTED ALWAYS AND I HAVE TO DEAL WITH BODY PAIN ON A DAILY BASIS. I JUST WANT MY LIFE BACK AND ESSURE STOLE IT FOR ME AND MY ONLY OPTION IS TO GET A HYSTERECTOMY AND I'M ONLY (B)(6)! ANOTHER VERY SERIOUS PROBLEM WAS THAT I WAS NOT INFORMED ABOUT THE DEVICE HAVING NICKEL IN IT AND I'M ALLERGIC TO NICKEL! I WANT WHOEVER IS RESPONSIBLE FOR POISONING US WOMAN WITH THIS EVIL DEVICE TO BE HELD ACCOUNTABLE! (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032430		10/23/2013	10/30/2013

Event Information:

Event Date (B3): 12/23/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893009

Single Use:
Implant Date (E6): 12/23/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011 I HAD THE PERMANENT BIRTH CONTROL ESSURE IMPLANTED INTO MY BODY. AFTER ABOUT A YEAR, I STARTED TO NOTICE CONSTANT CRAMPING, VERY HEAVY MENSTRUAL CYCLES AND SEVERE SHARP PAINS THAT WILL COME AND GO IN MY LOWER ABDOMEN. I DO NOT HAVE THE ENERGY THAT I USED TO HAVE, I ALWAYS FEEL AS IF I DON'T GET ENOUGH SLEEP. I HAVE VERY BAD NIGHT SWEATS, I WILL WAKE UP AND MY SHIRT WILL BE SOAKING WET. EVEN THOUGH I WORKOUT AND DIET, I CAN NOT SEEM TO LOSE THE WEIGHT IN MY LOWER ABDOMEN. I HAVE NEVER EXPERIENCED ANY OF THESE SYMPTOMS BEFORE I HAD ESSURE. I AM CURRENTLY WORKING WITH MY DOCTORS TO DETERMINE WHY I AM EXPERIENCING THIS. IN (B)(6) OF THIS YEAR, I WAS SENT TO THE EMERGENCY ROOM FOR SEVERE ABDOMINAL PAIN AND DEHYDRATION. I WAS DIAGNOSED WITH A BACTERIAL INFECTION(?). I BELIEVE THAT THIS IS ALL RELATED TO THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032433	CONCEPTUS	10/23/2013	10/30/2013

Event Information:

Event Date (B3): 2/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/18/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6). I HAD ESSURE PROCEDURE DONE 2010. I WANTED MY TUBES TIED AND THIS IS WHAT I GOT. I HAVE BEEN IN PAIN EVER SINCE THEN. I COULDN'T GET ANY HELP FROM THE GYN WHO PUT THEM IN. I WAS IN AND OUT THE HOSPITAL NUMEROUS TIMES FOR: SHARP ABDOMEN PAINS, HOT FLASHES, MOOD SWINGS, PRESSURE ON MY PELVIS LIKE I'M IN LABOR, METAL TASTE IN MY MOUTH, NUMBNESS OF FINGERS AND TOES, TINGLING IN MY BODY, NO SEX DRIVE CAUSE I'M IN SUCH PAIN, CYST HAS FORMED, CAN'T GO IN PUBLIC CAUSE I JERK SO BAD SOMETIMES FROM THE SHARP PAIN. FEELS LIKE A MACHETE SPINNING. THE NEW GYN HAD A VAGINAL ULTRASOUND DONE THAT SAYS MY COILS, WELL ONE, IS IN MY UTERUS BUT THE OTHER IS MISSING. I CAN'T GET IN TO SEE SPECIALIST UNTIL (B)(6) TO SCHEDULE HYSTERECTOMY. AFTER ALL THIS I'VE GOT TO STILL WAIT IN PAIN. I SCARE PEOPLE FROM JUMPING AND OUCHING AND SCREAMING FROM THE PAIN. MY NEW GYN SAID IT'S NOTHING ELSE SHE CAN DO, SHE DOESN'T EVEN DO THIS PROCEDURE CAUSE SHE SAID IT WAS TOO NEW. ALL I WANTED WAS MY TUBES TIED AND I GOT THE NIGHTMARE OF MY LIFE THAT IS NEVERENDING. I KNOW FOR SURE I DID NOT SIGN UP TO HAVE TO GET A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032436	CONCEPTUS	10/23/2013	10/30/2013

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS 306
Catalog # (E4):
Lot #(E4): 731586

Single Use:
Implant Date (E6): 7/1/2010
Explant Date (E7): 11/28/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTED THAT SHE HAD AN ESSURE IMPLANTED IN (B)(6) 2010. IMMEDIATELY AFTER THE SURGERY SHE BEGAN HAVING THE FOLLOWING SYMPTOMS: PAIN, MIGRAINES, NAUSEA, WEIGHT FLUCTUATIONS, INFLAMMATION, SWELLING, FREQUENT INFECTIONS, IRREGULAR UTERINE BLEEDING, ACNE, RASHES, AND CYST FORMATION IN THE FALLOPIAN TUBE. SHE STATED THAT SHE WAS IN A CAR ACCIDENT ON (B)(6) 2010 WHERE SHE TOTALLED HER CAR BECAUSE SHE PASSED OUT WHILE DRIVING DUE TO THE EXTREME PAIN. ABOUT 11 MONTHS LATER SHE REPORTED SEEING A DOCTOR WHO ASKED HER IF SHE WAS GIVEN AN ALLERGY TEST BEFORE THE IMPLANTATION OF THE DEVICE. SHE FOUND OUT THAT INDEED SHE WAS ALLERGIC TO THE NICKEL IN THE ESSURE. SHE ALLEGED THAT SHE NEARLY DIED AND THEY HAD TO GIVE HER EMERGENCY SURGERY TO REMOVE THE DEVICE ON (B)(6) 2011. SHE REPORTED THAT A PHYSICIAN TOLD HER THAT IT TAKES ABOUT A YEAR FOR THE NICKEL TO DETOX OUT OF THE BODY BUT PT STATED THAT SHE CONTINUES TO HAVE ALL OF THE SYMPTOMS SHE HAD PRIOR TO THE ESSURE'S REMOVAL BUT THEY ARE NOT AS BAD AS BEFORE. PT REPORTED BEING TOLD BY HER DOCTOR PRIOR TO THE IMPLANTATION OF THE ESSURE THAT IT WAS A REVERSIBLE PROCEDURE. SHE IS NOW EXTREMELY UPSET BECAUSE SHE CAN NO LONGER HAVE THE CHILDREN SHE PLANNED TO HAVE IN THE FUTURE. PT IS REQUESTING INFO ABOUT A REPORT THAT WAS FILED ON HER BEHALF BY THE MANUFACTURER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032392	BAYER	10/24/2013	10/30/2013

Event Information:

Event Date (B3): 9/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/12/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY DOCTORS RECOMMENDED ESSURE. I TOLD THAM I WAS ALLERGIC TO NICKEL AND THEY ALL SAID THERE WAS NOT ENOUGH IN THE COILS TO BOTHER ME. I HAD THE ESSURE PROCEDURE ON (B)(6) 2013, IT DID NOT GO SMOOTHLY. THE DOCTOR HAD PROBLEMS GETTING THE COIL IN THE LEFT FALLOPIAN TUBE, IT TOOK A LOT OF PUSHING AND WIGGLING, A LONG TIME. I WAS VERY UNCOMFORTABLE AND IN QUITE A LOT OF PAIN. AFTER A WHILE HE SAID HE MAY HAVE TO ABORT THE PROCEDURE, BUT ENDED UP GETTING IT IN. AFTER IT WAS DONE I WAS IN A LOT OF PAIN FOR SEVERAL DAYS. SINCE THEN, SIX WEEKS LATER, I HAVE HAD CRAMPS 24/7, SOMETIMES PRETTY BAD. ALSO DAILY SHARP PAINS IN THE TUBAL AREA, LOW SHARP BACK PAIN ON THE LEFT SIDE, AND ITCHING ACROSS MY ABDOMEN, LOW BACK, AND MY HANDS HAVE BROKE OUT - SIGNS OF NICKEL ALLERGY. I HAVE FELT BAD EVERY DAY SINCE THEN, THE CRAMPING KEEPS ME FROM DOING EVEN MORE THAN I USUALLY CAN DO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032395	BAYER	10/24/2013	10/30/2013

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN APPROXIMATELY (B)(6) 2012 AFTER MY DAUGHTER WAS BORN ((B)(6) 2012). MY DOCTOR GUARANTEED ME THAT THIS DEVICE WAS 99%+ EFFECTIVE AND SAID IT WAS NON-REVERSABLE. I WANTED TO HAVE MY TUBES CUT AND TIED BUT HE SAID THIS WAS A LESS PAINFUL PROCEDURE AND INFORMED ME I COULD NOT HAVE MY TUBES TIED UNLESS I HAD A C-SECTION DURING THE DELIVERY. ESSURE WAS MY ONLY OPTION. I AGREED TO DO THE PROCEDURE AND WAS GIVEN A LIST OF MEDICATIONS TO TAKE STARTING A COUPLE DAYS BEFORE AND FOLLOWING A FEW DAYS AFTER THE PROCEDURE. FIRST OFF, THIS WAS THE WORST PAIN I EVER FELT IN MY LIFE. AFTER THE PROCEDURE I BLED FOR MONTHS, WHEN I CALLED MY GYN HE TOLD ME THE BLEEDING WILL STOP. THE BLEEDING WAS NOT THE ONLY PROBLEM AT THAT TIME, I ALSO INFORMED HIM THAT I HAD HORRIBLE ABDOMINAL PAIN AND WAS TAKING THE VICODIN AS HE PRESCRIBED BUT IT WAS NOT HELPING. SINCE THE ESSURE WAS PLACED I HAVE HAD SEVERE ABDOMINAL PAIN, CRAMPING, EXTREMELY HEAVY PERIODS AND HEADACHES. THESE PAINS ARE NOT PAINS THAT COULD BE CONTROLLED BY TYLENOL OR IBUPROFEN, I WAS BED-RIDDEN WHEN THE PAIN STARTED UNTIL IT WENT AWAY 100% DAYS LATER. I WAS ON (B)(6) AT THE TIME OF PLACEMENT AND SINCE THEY ONLY COVER YOU FOR 6 WEEKS AFTER THE BIRTH I WAS UNABLE TO HAVE THE "DYE-TEST" DONE. I ASKED MY GYN TO DO THE TEST A LITTLE SOONER BEFORE THE (B)(6) RAN OUT SINCE I WOULD NO LONGER HAVE INSURANCE TO COVER THE TEST AND I WAS TOLD TO FILE FOR ANOTHER FORM ON (B)(6) TO JUST PAY FOR THE TEST. THE (B)(6) OFFICE PRETTY MUCH LAUGHED AT ME. I CALLED MY GYN BACK AND HE SAID I WOULD NEED TO PAY CASH FOR IT. WHEN I ASKED AGAIN WHY HE COULD NOT JUST TIE MY TUBES INSTEAD OF DOING THIS PROCEDURE HE SAID IT WAS IMPOSSIBLE SINCE I HAD A VAGINAL DELIVERY. I AM NOW 6 WEEKS 2 DAYS PREGNANT AND THOUGH WE ARE EXCITED GOD HAS GIVEN US A GIFT IT IS DANGEROUS. THERE ARE MANY LIKE ME THAT ARE HAVING HORRIBLE SIDE

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EFFECTS TO THIS AND SOMEONE NEEDS TO LOOK INTO IT. THE PAIN IS WORSE THAN CHILD BIRTH AND IT PUTS BIG STRAINS ON US FINANCIALLY AS I HAVE HAD TO LEAVE WORK SEVERAL TIMES DUE TO THE PAIN AND BLEEDING. THE BLEEDING WAS HEAVY ENOUGH TO SOAK THROUGH THE THICKEST PAD, AND A EXTRA SUPER (I THINK IT WHAT IT IS CALLED) TAMPON AS WELL AS MY CLOTHES, IN WHICH I WAS WEARING 2 PAIRS OF PANTS. I WAS ALSO APPARENTLY SUPPOSED TO GET A CARD WITH LOT NUMBER AND OTHER INFORMATION ON IT AND I NEVER RECEIVED IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032440	CONCEPTUS	10/25/2013	10/31/2013

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE FOR BIRTH CONTROL 3 YEARS AGO. SINCE THAT TIME I HAVE EXPERIENCED LIFE CHANGING SIDE EFFECTS. THE WORST BEING HORRIBLE STABBING PAIN IN MY PELVIC AREA. THIS DEVICE SHOULD BE RECALLED OR AT THE VERY LEAST COME WITH A SERIOUS WARNING TO ANY WOMAN CONSIDERING IT AS IT COULD POTENTIALLY RUIN THEIR LIFE. I DO NOT KNOW THE EXACT DATE BELOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032441	BAYER HEALTHCARE	10/25/2013	10/31/2013

Event Information:

Event Date (B3): 10/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE TUBAL LIGATION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/7/2012
Explant Date (E7): 10/22/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD ESSURE IMPLANTED ON (B)(6) 2012. FOLLOWING THE PROCEDURE PT EXPERIENCED PELVIC PAIN, DYSMENORRHEA AND DYSPAREUNIA. AN ULTRASOUND WAS DONE ON (B)(6) 2013 AND SHOWED THE RIGHT SIDED ESSURE HAD DISPLACED INTO CAVITY. APPROX 8-10 RINGS OF ESSURE WERE VISUALIZED AS WELL AS THE INSERT STILL ATTACHED INSIDE THE COIL. PT TAKEN TO OPERATING ROOM ON (B)(6) 2013, FOR HYSTEROSCOPY WITH REMOVAL OF ESSURE USING FORCEPS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032450	CONCEPTUS	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 11/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): A33565
Lot #(E4):

Single Use:
Implant Date (E6): 11/30/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DONE (B)(6) 2012. WHEN THE DOCTORS OFFICE CALLED FOR MY POST PROCEDURE CHECK I TOLD THEM I COULD FEEL THE COILS BUT ASKED IF IT WAS ALL IN MY HEAD. THEN BY (B)(6) 2013, I WAS CERTAIN THAT ALMOST EVERY DAY BURNING IN THE AREA IS MY FALLOPIAN TUBES COULD NOT BE NORMAL. MY LEFT TUBE FEELS LIKE THERE ARE ADHESIONS PULLING AT IT, MY RIGHT TUBE FEELS LIKE IT STABS ME EVERY NOW AND THEN. THE RIGHT TUBE ACTUALLY FEELS LIKE A NEEDLE POKES ME. I HAD NORMAL PERIOD CRAMPING ON OCCASION BEFORE ESSURE. THE CRAMPING NOW AT TIMES I'VE ALMOST GONE TO THE EMERGENCY ROOM BECAUSE OF THE INTENSE PAIN I'VE ALWAYS HAD ALLERGIES. I ASKED THE DR IF THAT MATTERED AND HE SAID IT WOULD NOT. MY BODY SEEMS TO BE BEGINNING HYPER SENSITIVE AND I'M BREAKING OUT IN HIVES ALL THE TIME. MY DR SAID IT SOUNDS LIKE I NEED TO HAVE THE COILS REMOVED. I'VE NOT HAD THEM REMOVED YET, I'M STILL PAYING OFF THE (B)(4) TEST TO SHOW I WAS FULLY STERILE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032451	BAYER	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 1/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL DEVICE IMPLANTED IN ME IN (B)(6) 2013. I HAVE HAD BLEEDING AND EXTREME PAIN IN MY ABDOMEN. I HAVE DEVELOPED HIVES AND RASHES. I HAVE ALSO HAD EXTREME HEADACHES AND HAIR LOSS. I PLAN TO HAVE THE ESSURE CLAMPS REMOVED WITH THE NEXT FEW WEEKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032452	CONCEPTUS	10/28/2013	11/1/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/9/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CHOSE ESSURE IMPLANT DUE TO NON-INVASIVE AND LOW DOWN TIME. PROCEDURE PERFORMED (B)(6) 2009, SEVERAL MONTHS AFTERWARDS MY PERIODS BECAME UNBEARABLE WITH PAIN AND EXTREME BLEEDING, HUGE BLOOD CLOTS (PRIOR TO ESSURE PERIODS WERE SHORT AND LIGHT FLOW NO PAIN WHATSOEVER). HAD ABLATION IN (B)(6) 2012, AGAIN, DUE TO LOW DOWN TIME AND NON-INVASIVE PROCEDURE. LOW BACK AND HIP PAIN AND STIFFNESS REMAINS CONSTANT, PAINFUL PERIODS HAVE RETURNED, AS WELL AS THE FEELING OF BEING IN LABOR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032455	BAYER	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 9/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/17/2009
Explant Date (E7): 9/5/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2009, I HAD THE ESSURE PROCEDURE DONE. THE REASON FOR THE ESSURE WAS BECAUSE IT WAS TOLD TO ME THAT IT WAS THE SAFE EFFECTIVE FORM OF BIRTH CONTROL FOR ME. AT THE TIME IT SEEMED THE RIGHT CHOICE, HOWEVER, AFTER THE THREE MONTH TEST THAT WAS DONE TO MAKE SURE THAT THE TUBES WERE BLOCKED I STARTED NOTICING CHANGES WITHIN MY BODY. MY PERIODS BECAME HEAVIER AND MORE INTENSE. THIS HAS GONE ON FOR THE LAST FOUR YEARS AND WAS TO THE POINT THAT I WAS LITERALLY LAID UP FOR TWO TO THREE DAYS BECAUSE THE BLEEDING WAS SO HEAVY AND THE PAIN WAS COMPLETELY UNBEARABLE. EARLIER THIS YEAR I FINALLY HAD ENOUGH AND SOUGHT A NEW DOCTOR TO FIND OUT WHAT COULD BE DONE TO HELP WITH THE PROBLEM. THE DOCTOR SUGGESTED NOVASURE BUT WOULD NEED TO GET AN ULTRASOUND DONE FIRST. THE ULTRASOUND SHOWED THAT I HAD TWO COILS ON THE RIGHT SIDE ONE OF WHICH WAS HANGING IN MY UTERUS AND THE LEFT SIDE SEEMED TO BE IN PLACE. I WAS LEFT WITH REALLY NO OPTION BUT TO HAVE A HYSTERECTOMY DONE. TO FIND OUT THAT ALL OF THE ISSUES THAT I WAS HAVING WAS A DIRECT RESULT OF THE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032457	CONCEPTUS	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 7/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/2/2013
Explant Date (E7): 11/13/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT THE ESSURE PERMANENT BIRTH CONTROL THAT HAS GIVEN ME SHARP PAINS IN LOWER ABDOMINAL AREA, MIGRAINES, BLOATING, BACK PAIN, TOOTH SENSITIVITIES, MOOD SWINGS, BLADDER INFECTIONS, FATIGUE/NO ENERGY, NOW I'M GOING TO HAVE TO HAVE A PARTIAL HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032458	CONCEPTUS	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 1/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): (R) 863581; (L) 919038

Single Use:
Implant Date (E6): 1/10/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RECEIVED ESSURE BIRTH CONTROL IMPLANTS (B)(6) 2012, I IMMEDIATELY STARTED EXPERIENCING A UNCOMFORTABLE VIBRATION FEELING IN MY VAGINA AND ABDOMINAL AREA WHICH WENT AWAY ABOUT 8 MONTHS LATER. MY PERIODS SINCE ESSURE IMPLANTS ARE HEAVY NOW, LAST LONGER, I HAVE ABDOMINAL CRAMPS AND BACK PAIN THAT I NEVER HAD BEFORE THAT REQUIRE PAIN KILLERS. MY MID SECTION IS SWOLLEN, AND I'M DEPRESSED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032459	BAYER	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 10/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER RECEIVING THE ESSURE PROCEDURE IMPLANTED, I STARTED TO EXPERIENCE ABDOMINAL PULLING AND PAIN WITH A FEELING OF SOMETHING MOVING AROUND. I HAD EXAMS, ABDOMINAL ULTRASOUND AND THEY COULD NOT FIND THE PROBLEM. I HAVE HEAVY BLEEDING NOW, AS WELL AS I WAS EXPERIENCING HIVES ALL OVER MY BODY WHICH I SOUGHT OUT AN ALLERGIST. MY STOMACH IS THREE TIMES IN SIZE SINCE I HAD THE PROCEDURE DONE. I HAVE BEEN ON SO MANY DIFFERENT MEDICATIONS SINCE THEN. I DON'T KNOW WHAT TO DO NEXT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032460	CONCEPTUS	10/28/2013	11/1/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2007, I HAD THE ESSURE PUT IN. MY SIDE EFFECTS ARE TO DATE NUMBNESS IN MY FINGERS, BAD HEADACHES, MEMORY ISSUES, GERD, CYSTS, EXTREME PAIN IN MY JOINTS, BACK PAIN SOMETIMES SO BAD I CAN'T STAND, NUMEROUS KIDNEY INFECTIONS, BAD STOMACH PAINS. I HAVE BEEN TO LOTS OF DOCTORS THAT DON'T FIND ANYTHING REALLY SERIOUS WRONG WITH ME BUT I KNOW THERE IS, MY BODY FEELS LIKE I'M 80 WHEN I'M NOT EVEN 40 YET. I HAVE THIS IN MY BODY FOR 6 YEARS NOW AND AM FINALLY SCHEDULED TO HAVE A HYSTERECTOMY TO HAVE THEM REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032461	CONCEPTUS	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 12/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/7/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) OF 2011. AT FIRST, ALL SEEMED TO BE FINE. ABOUT 6 MONTHS AFTER HAVING THE PROCEDURE DONE, I BEGAN BLEEDING, WHICH I THOUGHT WAS MY PERIOD COMING BACK AFTER YEARS OF BEING ON THE DEPO-PROVERA SHOT. AFTER 2 WEEKS OF SEVERE BLEEDING AND CLOTTING AND SEVERE LEFT TUBAL PAIN, I CONTACTED THE DOCTOR THAT DID THE PROCEDURE, AND THEY EXPLAINED TO ME THAT I SHOULD NOT BE CONCERNED. "IT WAS JUST MY BODY ADJUSTING TO THE IMPLANTS". I BELIEVE THAT THE ESSURE THAT WAS PUT INTO MY BODY IS DEFECTIVE AND DANGEROUS, AND SHOULD BE RECALLED DUE TO THE NUMEROUS COMPLAINTS THAT HAVE BEEN DOCUMENTED ON THIS DEVICE. I WISH THAT I WOULD HAVE NEVER GOTTEN IT DONE, AS (ALMOST 2 YEARS LATER) I AM STILL SUFFERING FROM SEVERE HEMORRHAGING AND SEVERE PAIN ASSOCIATED WITH THE DEVICES THAT WERE IMPLANTED IN MY TUBES. MY CURRENT DOCTOR (NOT THE ONE THAT DID THE PROCEDURE...I WILL NEVER GO BACK THERE) HAS SUGGESTED THAT IF I CONTINUE WITH THE PAIN AND BLEEDING, THE NEXT STEP WILL BE TO DO A COMPLETE HYSTERECTOMY. SINCERELY, I CONCERNED FRUSTRATED PT OF ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032462	BAYER	10/28/2013	11/1/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE COILS AS A FORM OF PERMANENT BIRTH CONTROL IN 2011. WITHIN LESS THAN A YEAR, I DEVELOPED HEAVY ABNORMAL BLEEDING. MY GYRO FOUND AN ABNORMALLY LARGE OVARIAN CYST THAT REQUIRED SURGERY. IN THE FEW MONTHS, IT TOOK TO GET ME SET UP, I STARTED HAVING LOWER ABDOMINAL PAIN WHICH WAS THEN ATTRIBUTED TO THE CYSTS AND HAD A COUPLE OF FAINTS. IN (B)(6) OF 2012, I UNDERWENT SURGERY AND TESTS SHOWED THE REMOVED CYST WAS BENIGN. THE PAIN STARTED UP AGAIN A MONTH LATER, THE ABNORMAL HEAVY BLEEDING FOR WEEKS CONTINUED AND OTHER HEALTH ISSUES BEGAN SHOWING THEMSELVES. HOWEVER, HEALTH INSURANCE RAN OUT AND I'VE SINCE SUFFERED WITH EXTREME PAIN, LOSS OF SEX DRIVE, VAGINAL DISCOMFORT, HEAVY BLEEDING, DIZZY SPELLS, COLLAPSING, MINI STROKE LIKE SYMPTOMS, WEIRD TINGLING SENSATIONS IN HANDS AND FEET (PARTICULARLY THE RIGHT SIDE), SLEEP PROBLEMS EITHER EXTREMELY TIRED DESPITE SLEEPING A TON OR CAN'T SLEEP, CONSTANTLY DEPRESSED, LACK OF MOTIVATION, TERRIBLY FORGETFUL, BLURRED VISION, UNPREDICTABLE EXTREME BLOATING, NAUSEOUS, HIVES ON ARMS AND LEGS, RECENTLY, CANNOT WEAR MY EARRINGS AS MY EARS START SWELLING AND ITCHING FIERCELY, COULD NOT FIGURE OUT WHAT COULD BE WRONG WITH ME UNTIL I FOUND A (B)(4) GROUP LAST YEAR THAT WAS FULL OF WOMEN SUFFERING LIKE ME. NOW I BELIEVE FIRMLY THAT I AM SUFFERING FROM SIDE EFFECTS FROM ESSURE THAT WERE NEVER BROUGHT TO MY ATTENTION. I WAS TOLD THIS WAS BASICALLY SIDE EFFECT AND PAIN FREE. I INTEND UPON GETTING A HYSTERECTOMY TO REMOVE THESE BUT INSTEAD OF A CHOICE, I FEEL FORCED IN ABLE TO LIVE A NORMAL LIFE AGAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032464	BAYER	10/28/2013	11/1/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) OF 2011 AND EVER SINCE HAVE NOTICED SIGNS OF JOINT PAIN, BACK PAIN, INTERCOURSE PAIN, PELVIC PAIN, TIREDNESS, MEMORY LOSS, BLURRED VISION AND HEADACHE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032479	BAYER	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 7/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/8/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THIS PROCEDURE PERFORMED IN 2011, WAS PERFECTLY HEALTHY NOW. MY HEALTH IS SLOWLY DETERIORATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032480	BAYER	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 1/8/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/8/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PRODUCT. CAUSING BLOATING, RASHES, ITCHY SKIN, HEADACHES, BODY ACHES, AND DIAGNOSED WITH LYMPHOMA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032481	CONCEPTUS	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 6/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/13/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CAUSING SEVERE ABDOMINAL PAIN, AND HEAVY PERIODS AND PAINFUL OVULATION. WILL BE HAVING FALLOPIAN TUBES REMOVED TO FIX PROBLEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032484	BAYER	10/28/2013	11/1/2013

Event Information:

Event Date (B3): 8/31/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 8/31/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE (B)(6) 2009, ABOUT ONE YEAR LATER, I STARTED HAVING PAIN. MY HAIR STARTED FALLING OUT, I BEGAN WAKING UP TASTING METAL. I AM HAVING VERY IRREGULAR MENSTRUAL CYCLES. HEADACHES I CAN'T GET RID OF.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032487	CONCEPTUS	10/29/2013	11/4/2013

Event Information:

Event Date (B3): 5/11/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/11/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6) AND IN (B)(6) OF 2011, I HAD THE ESSURE PROCEDURE DONE. AFTER THE PROCEDURE I STARTED HAVING EXCESSIVE BLEEDING, UNK RASH, SWELLING OF THE ANKLES, JOINT PAIN, AND ABDOMINAL PAIN. I TALKED TO DOCTOR ABOUT IT AND THE TWO OPTIONS SHE GAVE ME WAS TO START DEPO OR GET A HYSTERECTOMY. I'M TOO YOUNG TO BE GOING THROUGH THESE COMPLICATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032492	CONCEPTUS	10/29/2013	11/4/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE IMPLANTED I HAVE A LONG LIST OF HEALTH PROBLEMS THAT BEGAN ALMOST INSTANTLY, AND HAVE WORSENED THROUGH THE YEARS. THE TOP SYMPTOMS ARE DIZZY SPELLS, HEAVY BLEEDING AND BLOOD CLOTS, BREAK OUT IN HIVES, SEVERE ABDOMINAL PAIN AND BLOATING, MIGRAINES, BLACK SPOTS IN FRONT OF MY EYES, PASS OUT, PROJECTILE VOMITING. FEVER, AND RASH. SHOOTING PAIN FROM ABDOMEN DOWN MY LEG. MY LEFT LEG GOES NUMB ALONG WITH MY FOOT. CONSTANT SHOOTING PAIN DOWN MY LEFT LEG. THE LIST GOES ON, BUT THAT IS A LIST OF THE WORST SYMPTOMS. I HAVE BEEN TO THE EMERGENCY ROOM SEVERAL TIMES, SEEN A DR SEVERAL TIMES. HAD A FEW COLONOSCOPIES SINCE I HAVE DEVELOPED SIGNS AND SYMPTOMS OF CROHN'S DISEASE. NO ONE CAN FIGURE OUT THAT IS WRONG WITH ME. I KNOW ITS A REACTION TO ESSURE. I ALSO HAD 3 MISCARRIAGES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032493	CONCEPTUS	10/29/2013	11/4/2013

Event Information:

Event Date (B3): 10/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/15/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS PLACED IN 2010 INTO BOTH TUBES WITH NO PROBLEM. ON (B)(6) 2013 I STARTED HAVING PAIN IN MY LOWER STOMACH AND WAS ADMITTED INTO THE HOSPITAL. THE ESSURE ON MY RIGHT SIDE WAS COMING OUT AND A PIECE BROKE OFF. I HAD INFECTION IN MY TUBE AN UTERUS. THE ESSURE HAD TO BE PLACED BACK IN CORRECTLY AND THE PIECE WAS REMOVED FROM MY UTERUS. TWO DAYS IN THE HOSPITAL AND MUCH PAIN WAS INCURRED NOT INCLUDING ALL THE MEDICAL BILLS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032494	CONCEPTUS	10/29/2013	11/4/2013

Event Information:

Event Date (B3): 12/27/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/27/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2011. I AM HAVING SEVERE ABDOMINAL PAIN. IT FEELS AS IF SOMETHING LEANING ON MY BLADDER. I HAVE REPORTED IT TO MY OB-GYN DOCTOR ON MONDAY, (B)(6) 2013 AND CALLED HER AGAIN THIS MORNING. I ALSO REPORTED ABDOMINAL PAIN TO MY INTERNAL MEDICINE DOCTOR ON MONDAY, (B)(6) 2013. HE ASKED ME TO FOLLOW UP WITH MY OB-GYN AND I HAVE. I AM WAITING TO TALK TO HER TO SEE WHAT MY OPTIONS ARE. I DO BELIEVE I AM HAVING THESE PROBLEMS FROM THE ESSURE PROCEDURE AND WANTED TO BRING IT TO THE ATTENTION OF THE FDA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032495	BAYER	10/29/2013	11/4/2013

Event Information:

Event Date (B3): 4/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN 2010. I CARRIED A FULL TERM PREGNANCY AND DELIVERED (B)(6) 2013. I DID HAVE AN HSG TEST TO CONFIRM BLOCKAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032508	BAYER	10/30/2013	11/7/2013

Event Information:

Event Date (B3): 4/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/17/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE (B)(6) 2013, I HAVE HAD EXCRUCIATING PELVIC PAIN. I HAD ULTRASOUNDS AND EXAMS DONE FROM (B)(6) 2013. I HAVE HAD 3 DOCTORS TELL ME THAT THE ESSURE DEVICE WAS CAUSE TO MY PELVIC PAIN. NONE OF THE DOCTORS WANT TO DO ANYTHING TO ALLEVIATE MY PAIN DUE TO THE FACT THAT THEY DON'T KNOW WHAT THE DEVICE IS OR HOW TO REMOVE IT. ON (B)(6) 2013, I WENT TO URGENT CARE AGAIN FOR THE PELVIC PAIN THAT DOESN'T SEEM TO GO AWAY. THE DOCTOR PERFORMED A CT SCAN AND CANNOT FIND ANY RELEVANT INFO TO MY PELVIC PAIN. I WENT BACK TO MY PCP AND SHE REFERRED ME TO AN OB/GYN. THE OB/GYN THEN TOLD ME THAT I NEEDED TO GO TO THE DOCTOR THAT PLACED THE ESSURE DEVICE. I HAVE YET TO BE RELIEVED OF THE PAIN AND NO ANSWERS FROM ANYONE. I HAVE MAJOR BLOATING AND REOCCURRING BACTERIAL INFECTIONS DUE TO THE DEVICE. I HAVE CONSISTENT CONTRACTIONS OF THE UTERUS TRYING TO EXPEL THE DEVICE. I HAVE HAD NO PRIOR MEDICAL PROBLEMS BEFORE ESSURE DEVICE. ALL LAB TEST AND RESULTS SEEM TO BE NORMAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032511	CONCEPTUS	10/30/2013	11/7/2013

Event Information:

Event Date (B3): 10/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/6/2013
Explant Date (E7): 11/6/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS IN MY FALLOPIAN TUBES. ONE SIDE NEVER SCARRED OVER AND AFTER MY RADIOLOGY APPOINTMENT TO SEE IF IT SCARRED I HAVE BEEN HAVING DEBILITATING PAINS. I AM HAVING SURGERY TO HAVE THE COIL REMOVED AND POSSIBLY A HYSTERECTOMY DUE TO WERE IT IS IN THE UTERINE LINING ON (B)(6). I PUT IN THE DATE OF THE RADIOLOGY APPOINTMENT THAT THE PAIN STARTED AT FOR THE DATE OF THE EVENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032512	CONCEPTUS	10/30/2013	11/7/2013

Event Information:

Event Date (B3): 10/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/5/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE CHRONIC BACK PAIN, HAIR LOSS, ABDOMINAL PAIN AND SKIN IRRITATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032523	BAYER	10/31/2013	11/7/2013

Event Information:

Event Date (B3): 10/20/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/20/2011
Explant Date (E7): 2/2/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2011, I HAD THE ESSURE PROCEDURE DONE IN MY GYN OFFICE - (B)(6) 2012, I WENT IN FOR THE HSG TEST TO CONFIRM THE ESSURE IMPLANTS WERE IN PLACE AND SCAR TISSUE WAS BLOCKING MY FALLOPIAN TUBES. MUCH TO MY SURPRISE BOTH IMPLANTS WERE EXPELLED FROM MY TUBES AND WERE NOW IN MY PELVIS. WENT BACK TO MY GYN OFFICE AND WAS GIVEN THE OPTIONS OF WHAT TO DO NEXT AND BEING TOLD THAT I WAS THE FIRST PERSON OUT OF THOUSANDS THAT BOTH IMPLANTS CAME OUT! MY OPTIONS WERE AS FOLLOWS - HAVE THE USUAL TUBAL DONE BY ITSELF AND LEAVE THE IMPLANTS WHERE THEY WERE BECAUSE MY DOCTOR CALLED THE ESSURE COMPANY AND THEY TOLD HIM IT WAS NOT NECESSARY TO REMOVE THEM OR GO IN AND DO THE TUBAL AND REMOVE THE IMPLANTS. MY HUSBAND AND I OPTED FOR THE TUBAL AND REMOVAL OF IMPLANTS AND THAT TOOK PLACE IN (B)(6) 2012. IT IS NOW (B)(6) 2013, AND I HAD SEVERE LOWER BACK PAIN FOR 2 WEEKS AND WENT TO THE HOSPITAL ON (B)(6) 2013 TO FIND OUT WHAT MY PROBLEM WAS. THEY TOOK AN X-RAY OF MY BACK WHILE I WAS IN THE ER AND TOLD ME I HAVE METAL INSIDE OF ME AND IT WAS SHOWING UP ON THE X-RAY!! I CALLED MY DOCTOR AND TOLD THEM ABOUT THE FINDINGS AND JUST LIKE EVERYONE ELSE, HE SAID IT COULD NOT BE POSSIBLE - HE REMEMBERED TAKING BOTH INSERTS OUT AND EVEN WENT BACK INTO THE REPORT. NOW I STILL HAVE METAL INSIDE OF ME AND AM CONTINUING TO HAVE PAIN WITH NO RELIEF. I HAVE NO CLUE AND FEAR THAT IF I WERE EVER TO HAVE AN MRI, I WOULD EVEN MAKE IT THROUGH THE PROCESS WITHOUT POSSIBLY BEING KILLED DURING THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032524	CONCEPTUS	10/31/2013	11/7/2013

Event Information:

Event Date (B3): 2/27/2013 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/27/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD AN ESSURE IMPLANT IN (B)(6) 2013. HAD AN HSG IN (B)(6) AND ONE TUBE HAD NOT CLOSED OFF. HAD ANOTHER HSG TODAY ((B)(6) 2013) AND FOUND THAT THE DEVICE HSG "FAILED" ACCORDING TO MY OB/GYN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032525	CONCEPTUS	10/31/2013	11/7/2013

Event Information:

Event Date (B3): 7/13/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627735

Single Use:
Implant Date (E6): 7/13/2009
Explant Date (E7): 7/23/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE RPTR HAS COMPLAINTS OF: CONSTANT PELVIC PAIN, TORN FALLOPIAN TUBES, DEVICE MIGRATION, HEAVY CLOTTING AND CRAMPING, LOW POTASSIUM AND MAGNESIUM, NUMBNESS IN EXTREMITIES, SEVERE BLOATING, EXACERBATED DEPRESSION ANXIETY PTSD AND ENVIRONMENTAL ALLERGIES, BRAIN FOG, BLACKOUTS, JOINT STIFFNESS, HEART PALPATIONS, MEMORY LOSS, HAIR LOSS, DEVICE EMBEDDED IN SURROUNDING TISSUES/ORGANS, HEADACHES, FATIGUE, AUTOIMMUNE DIAGNOSIS, SWELLING FEET AND LEGS, HIP PAIN, TINGLING SENSATIONS, URGENCY TO URINATE, BLURRED VISION, CHRONIC ILLNESS, FRAGILE NAILS, WEIGHT GAIN, DIGESTIVE ISSUES, MUSCLE SPASMS, TEETH ISSUES, ITCHY SKIN, VIBRATING SENSATION IN ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032549		11/1/2013	11/7/2013

Event Information:

Event Date (B3): 10/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use:
Implant Date (E6): 10/15/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE AS A PERMANENT BIRTH CONTROL PROCEDURE. I TRUSTED MY DOCTOR WHEN HE SAID THERE WERE NO SIDE EFFECTS, AND NOT TO BELIEVE WHAT I HAVE READ ON THE INTERNET. I HAD THE PROCEDURE ON (B)(6) 2013. I WAS SEDATED FOR THE PROCEDURE. WHEN I CAME THROUGH, I WAS NAUSEOUS, DIZZY, THREW UP NASTY YELLOW BITTER THINGS THREE TIMES. I WAS TOLD THAT EVERYTHING WENT WELL. WHEN I GOT HOME, DRANK SOME APPLE JUICE, TOOK SOME PAIN KILLERS AND WENT TO SLEEP. WOKE UP AND FELT MUCH BETTER. HOWEVER, ON SUNDAY EVENING OF (B)(6) 2013 AS I WAS WASHING MY PRIVATE AREA IN THE SHOWER, I FELT SOMETHING FUNNY IN MY HAND. I WAS ALSO ON MY MENSTRUAL CYCLE, I HELD IT UP, RINSED IT OUT (EXCUSE ME FOR MY GRAPHIC DETAIL), TOOK A GOOD LOOK AT IT AND KNEW SOMETHING WAS NOT RIGHT. I IMMEDIATELY THOUGHT OF THE ESSURE. I GOT OUT OF THE SHOWER, PLACED IT IN A ZIPLOC BAG, WENT TO MY LAPTOP AND GOOGLED "ESSURE IMAGES". HERE IT WAS, THE EXACT REPLICA OF WHAT I WAS HOLDING. I WAS PANICKING BUT COULD NOT DO ANYTHING SINCE IT WAS LATE AND THE DR'S OFFICE WAS CLOSED. THE FOLLOWING MORNING I TOOK IT TO THE DR'S OFFICE. HE WAS NOT IN BUT I WAS ABLE TO GET AN APPOINTMENT LATER THE SAME DAY. I MET WITH THE DR., HE BASICALLY TOLD ME TO LIVE MY LIFE WITH THE OTHER ONE, AND TO BE SURE TO USE BIRTH CONTROL. HE THREW IT IN THE TRASH, ASKED ME TO MAKE A FOLLOW UP APPOINTMENT IN 3 MONTHS. I AM NOW WORRIED, FRUSTRATED AND MOST OF ALL REGRETFUL OF THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032550	BAYER	11/1/2013	11/7/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/6/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN (B)(6) 2012. SINCE THEN I HAVE HAD SEVERE ABDOMINAL SWELLING TO THE EXTREMITIES OF LOOKING 6-7 MONTHS PREGNANT. NATURALLY, I AM A PETITE (B)(6) FRAME. I AM HAVING ABDOMINAL PAINS AND CRAMPS AND ALSO SENSATIONS THAT FEEL LIKE CONTRACTIONS. I HAVE EXTREME FATIGUE SINCE HAVING THE ESSURE COILS INSERTED AND I FEEL SICK. ALSO WEIGHT GAIN AND EVEN HAIR LOSS HAVE OCCURRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00020	BAYER HEALTHCARE LLC	11/1/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): 893037, 12533513

Single Use: Y
Implant Date (E6): 4/22/2013
Explant Date (E7): 9/17/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT ESSURE WAS INSERTED IN A PT ON (B)(6) 2013. THERE WERE NO ISSUES AT THE TIME OF PLACEMENT. THE PT PRESENTED BACK WITH PERSISTENT ABDOMINAL PAIN. ON (B)(6) 2013 ESSURE WAS REMOVED VIA LAPAROSCOPY. THERE WAS NO SIGN OF DEVICE PERFORATION THROUGH THE TUBE UPON INSPECTION. THE PHYSICIAN REPORTED HE ALSO FOUND ADHESIONS AND WAS UNSURE IF THE PT'S SYMPTOMS WERE RELATED TO ESSURE. THE PT WAS FEELING FINE AT FIRST VISIT AFTER SURGERY. THE PHYSICIAN WAS UNSURE IF THE PT'S SYMPTOMS WERE RELATED TO ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00021	BAYER HEALTHCARE LLC	11/1/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): 50717071

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A HEALTH PROFESSIONAL REPORTS A PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PLACEMENT OF ESSURE REPORTEDLY 'WORKED,' BUT 'SECONDARY SURGERY' WAS NEEDED TO REMOVE A 'PLACE THAT BROKE OFF.'

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00022	BAYER HEALTHCARE LLC	11/1/2013	11/18/2013

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/4/2010
Explant Date (E7): 8/17/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A (B)(6) FEMALE CONSUMER REPORTED HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. SHE HAD A HISTORY OF BEING UNABLE TO WEAR METAL JEWELRY. IN (B)(6) 2010, SHE EXPERIENCED ABDOMINAL PAIN, ANXIETY, LOWERED IMMUNE SYSTEM, PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE , CHEST PAIN, HOT FLASHES, NIGHT SWEATS, JOINT PAIN AND SWELLING, TINGLING IN HANDS AND FEET, BODY TREMORS, HEART PALPITATIONS, EXTREME VERTIGO AND AN INFLAMED UTERUS. SHE WAS PRESENTED WITH THREE TREATMENT OPTIONS BY HER PHYSICIAN: TREATMENT WITH ANTIBIOTICS, LAPAROSCOPY FOR A PURPOSE UNK TO THE CONSUMER, OR HYSTERECTOMY. SHE WAS INITIALLY TREATED WITH AN UNSPECIFIED ANTIBIOTIC ON AN UNSPECIFIED DATE. ON 08/17/2013, HYSTERECTOMY AND REMOVAL OF HER FALLOPIAN TUBES WAS PERFORMED AND HER SYMPTOMS RESOLVED THE SAME DAY. PATHOLOGY EXAM POST HYSTERECTOMY WAS NORMAL. HEAVY METAL TOXIC PANEL WAS ALSO PERFORMED (ON BLOOD) WITH RESULTS PENDING. CONSUMER REPORTED THAT HER PHYSICIAN DID NOT BELIEVE THAT HER SYMPTOMS WERE RELATED TO ESSURE. ADDITIONAL INFO RECEIVED FROM THE PHYSICIAN WHO REPORTED THE PT COMPLAINED OF PAIN WITH A TENDER UTERUS AND WAS TREATED WITH ANTIBIOTICS. A HYSTERECTOMY WAS PERFORMED AND ESSURE WAS REMOVED, WHICH "CURED" HER PAIN. NO PATHOLOGY WAS FOUND. THE PHYSICIAN CANNOT DETERMINE IF THE PT'S EVENTS WERE RELATED TO ESSURE AND CANNOT CONFIRM THE PT'S ALLEGATION OF A NICKEL ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032573	BAYER	11/4/2013	11/7/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY DAUGHTER HAS THE ESSURE. SHE SEEMS TO BE GETTING WORSE EVERY DAY. PLEASE INFORM ME OF ANY DOCTORS THAT WILL REMOVE THIS ASAP. (B)(6). WE CANNOT AFFORD AN EXPENSIVE PROCEDURE. (B)(6) HAS THE (B)(6) INSURANCE. I HOPE TO HEAR FROM YOU SOON. THIS IS URGENT AND EVIDENCE OF MANY WHO ARE HAVING PROBLEMS SO THIS SHOULD NOT BE IGNORED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032552	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 5/19/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626626

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ABLATION AND ESSURE IMPLANTED IN 2008. I NOW HAVE ABDOMINAL PAIN, SHARP STABBING PAIN IN MY ABDOMEN WHEN I SIT STRAIGHT UP IN A CHAIR, CRAMPING ALL THROUGH THE MONTH, CONSTIPATION, HAIR LOSS, FATIGUE, TERRIBLE HEADACHES, JOINT PAIN, STOMACH BLOATING, PASSING LARGE BLOOD CLOTS, INCONTINENCE AND FREQUENT URINATION, DISCHARGE, NIGHT SWEATS. I CANNOT BE SURE THAT THIS IS NOT OLD AGE BECAUSE I AM 49 YEARS BUT I HAVE MANY FRIENDS WHO FEEL MUCH BETTER THAN I DO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032553		11/4/2013	11/8/2013

Event Information:

Event Date (B3): 7/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/13/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT THOUGHT ESSURE WAS GOING TO BE SAFE, BUT EVER SINCE I GOT IT I HAVE BEEN IN A TREMENDOUS AMOUNT OF PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032555	BAYER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 8/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM HAVING SIDE EFFECTS OF THE ESSURE PRODUCT FROM BAYER THAT INCLUDE, SEVERE HAIR LOSS, PELVIC PAIN, HIP PAIN, LOWER BACK PAIN FEELINGS OF BEING SHOCKED IN MY ABDOMEN, DIZZINESS, VISION PROBLEMS, YEAST INFECTIONS WEIGHT GAIN (SEVERE BLOATING), HEADACHES BRAN FOG, JOINT PAIN. ECT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032556	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 11/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305A27191
Catalog # (E4): ESS305A27191
Lot #(E4):

Single Use:
Implant Date (E6): 11/21/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT DEVICE PUT IN (B)(6) 2012, FOLLOWING AFTER THE PROCEDURE I HAD HEAVY BLEEDING CONSTANTLY WITH A WEEK IN BETWEEN. PAIN CONSTANTLY IN MY LOWER ABDOMEN LIKE SEVER CRAMPS. I HAVE SUFFERED FROM MIGRAINES PRIOR BUT THEY WENT FROM 4 A MONTH TO A DAILY MIGRAINE 6 OUT OF 7 DAYS A WEEK. CONSTANT FATIGUE, HAIR LOSS BY THE HANDFUL, I AM NOW VITAMIN D, B-12, B-6 DEFICIENT. IA HAVE NOT BEEN ABLE TO LOSE WEIGHT BY ANY FOR SINCE THIS PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032557	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 8/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE INSERT, I HAVE EXPERIENCED NO CYCLES, INCREASE FATIGUE, DAILY PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032558	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/7/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT ESSURE IMPLANTED IN (B)(6) 2013; I BEEN HAVING REALLY BAD PELVIC PAIN FOR FOUR MONTHS NOW, REALLY BAD HEADACHE AND MUCH MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032562	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 8/25/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/25/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED MY ESSURE IMPLANT IN 2005 AFTER THE BIRTH OF MY LAST CHILD. I HAVE SINCE HAD SEVERE PELVIC PAIN, MIGRAINE HEADACHES, WEAKNESS IN MY LEGS (ESPECIALLY AFTER EXERCISE), FATIGUED EASILY, SEVERE LOWER BACK PAIN (THIS HAPPENS ALL THE TIME, BUT ESPECIALLY WHEN IT IS TIME FOR MY MENSTRUAL PERIOD TO BEING AND THROUGHOUT MY PERIOD), SEVERE ABDOMINAL PAIN WHEN STRETCHING OR MOVING IN DIFFERENT DIRECTIONS, AND VERY HEAVY MENSTRUAL CYCLES. ALL OF THESE SYMPTOMS USUALLY HAPPEN ON A DAILY BASIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032563	CONCEPTUS/BAYER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE INSERTED ON (B)(6) 2006 AND REMOVED BY SALPINGECTOMY ON (B)(6) 2012. IN OFFICE PROCEDURE, SEVERE PAIN DURING INSERTION. BEGAN GETTING RANDOM INFECTIONS SHORTLY AFTER THAT KEPT GETTING WORSE. DEVELOPED SEVERE SWELLING IN 2009 AND DESPITE MAY TESTS DOCTORS COULD NOT FIND CAUSE. HOSPITALIZED FOR ANTIBIOTIC TREATMENT BUT CONTINUED INFECTIONS. SIDE EFFECTS INCLUDED WEIGHT GAIN, FATIGUE, PAIN DURING INTERCOURSE, IRREGULAR MENSES AND STABBING PAIN. ON (B)(6) AND TO HAVE FULL THYROIDECTOMY DUE TO MULTIPLE NODULES, THYROID SWELLED QUICKLY TO POINT I COULD NOT SWALLOW. CONTINUED GETTING SINUS AND EAR INFECTIONS THAT ANTIBIOTICS AND STEROIDS COULD NOT GET RID OF. LEGS STARTED POPPING OUT OF JOINT. REAR ENDED IN (B)(6) 2012, STABBING PAIN ON LEFT SIDE BECAME SO SEVERE. SIX DOCTORS COULD NOT FIND CAUSE AFTER MANY TESTS. I FOUND THE SIDE EFFECTS OF PET FIBERS WHICH INCLUDED ENDOCRINE ISSUES. GYNECOLOGIST GROUP REFUSED TO ACKNOWLEDGE COILS AS A PROBLEM DESPITE ONLY ONE COIL WAS VISUALIZED ON ULTRASOUND. THEY TOLD ME MY ONLY OPTION WAS HYSTERECTOMY AND I REFUSED SINCE I WAS ONLY (B)(6) AT THE TIME. WENT IN TO HAVE COILS REMOVED, WHICH I HAD TO PAY FOR OUT OF POCKET, WITH SINUS INFECTION ON WEEK 9. SINCE THE DAY MY COILS WERE REMOVED, I HAVE NOT HAD ANY OTHER SIDE EFFECTS SINCE AND MY SINUS INFECTION WHICH HAD BEEN THROUGH 3 TREATMENTS WENT AWAY IN THE SAME WEEK. IT HAS BEEN ONE YEAR AND ALL OF MY PROBLEMS ARE GONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032564	CONCEPTUS/BAYER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 11/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/2/2012
Explant Date (E7): 2/13/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED (B)(6) 2012. I BLED ALMOST NONSTOP FROM (B)(6) 2012 TO (B)(6) 2013. I HAD SEVERE PAIN IN MY LOWER ABDOMEN TO THE POINT IT FELT LIKE I WAS IN LABOR (B)(6). I WAS UNABLE TO HOLD MY NEWBORN SON BECAUSE OF THE PAIN IN MY ABDOMEN AND BACK. I HAD TERRIBLE MIGRAINES ALONG WITH FATIGUE AND SHOOTING PAINS UP AND DOWN MY RIGHT LEG. AFTER 2 TRIPS TO THE EMERGENCY ROOM AND 2 VISITS WITH MY IMPLANTING DOCTOR/ OB GYN. NO ONE COULD EXPLAIN WHY I WAS HAVING THESE ISSUES AND MY DOCTOR PERFORMED A BILATERAL SALPINGECTOMY ON (B)(6) 2013 AND ALL MY ISSUES DISAPPEARED AFTER SURGERY. I'M NO DOCTOR BUT NEVER HAD THESE PROBLEMS UNTIL ESSURE AND THEY'RE GONE AFTER REMOVAL, SO SOMETHING MUST BE WRONG WITH THIS PRODUCT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032565	BAYER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 11/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/20/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE BIRTH CONTROL WAS INSERTED IN (B)(6) 2011. A FEW DAYS FOLLOWING INSERTION, HEAVY BLEEDING WITH LARGE CLOTS WAS EXPERIENCED. SINCE THAT TIME, HAVE EXPERIENCED ABNORMAL PERIODS WITH ABDOMINAL PAIN. AT OTHER TIMES HAD SEVERE ABDOMINAL DISCOMFORT, NAUSEA/VOMITING/DIARRHEA, SEVERE FATIGUE, AND HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032566	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 3/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 927076

Single Use:
Implant Date (E6): 3/23/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(6) 2012. I EXPERIENCED MAJOR CRAMPS, ABNORMAL BLEEDING, BACK PAN, NUMBNESS IS ARM WHICH WAS NOT RELIEVED BY NEUROLOGIST OR CHIROPRACTIC CARE, HEADACHES, VISION PROBLEMS, AND MANY OTHER SIDE EFFECTS THAT I BELIEVE ESSURE HAS CAUSED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032567	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 9/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 9/25/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD PAIN ON LEFT SIDE FOR OVER 6 MONTHS. OTHER SYMPTOMS INCLUDED JOINT PAIN, INSOMNIA, AGITATION / IRRITABILITY, CRAMPING, MUSCLE SPASM, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032568	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 6/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/10/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PROBLEMS ARE BLOATING, TIREDNESS, WEIGHT GAIN, IRREGULAR CYCLES, BLEEDING AFTER SEX, PAINFUL SEX, MAJOR LOWER LEFT BACK PAIN AND I FEEL SPACY. IN (B)(6) 2013, I BEGAN BLEEDING, NONSTOP, WITH WORSE LOWER LEFT BACK PAIN. HAD TWO LARGE BLOOD CLOTS (SIZE OF SMALL APPLE) OR WAS THIS A MISCARRIAGE (HAVE PICTURES). OBGYN DID A VAGINAL SONOGRAM AND SAID I HAD CYSTS ON MY OVARIES, BUT WAS NOT WORRIED ABOUT THOSE AND I HAD THICKENING OF THE UTERUS WALL. OBGYN TOOK 5 BIOPSIES AND THEY CAME BACK NORMAL. HAD D&C ON (B)(6) 2013. OB REMOVED A POLYP FROM UTERUS AND SAID THAT THESE CAN CAUSE ISSUES. HAD A PERIOD 2 WEEKS AFTER D&C (NORMAL). DID NOT HAVE A PERIOD AGAIN UNTIL (B)(6) 2013. I HAVE HAD A WATERY DISCHARGE FOR A WHILE AND IT HAS AN ODOR. HAVE HAD BLEEDING FOR PAST TWO WEEKS (FROM (B)(6) 2013) AFTER I EXERCISE. I HAVE SYMPTOMS LIKE HERPES (B)(6). I GET THESE SYMPTOMS AFTER SEX EVERY TIME. WENT TO DOCTOR (B)(6) 2013 TO BE TESTED FOR (B)(6). TESTS CAME BACK NEGATIVE. HAD SONOGRAM ON (B)(6). DOCTOR SAID EVERYTHING LOOKED FINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032574	BAUER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 12/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE PROCEDURE DONE I HAVE EXPERIENCED SEVERE PAIN AND EXTREMELY HEAVY PERIODS. I ALSO GET STRANGE, ITCHY RASHES ON MY ABDOMINAL AREA THAT NO ONE HAS BEEN ABLE TO FIGURE OUT. HAVE DISCUSSED MY PROBLEMS WITH THE DOCTOR WHO IMPLANTED THE COILS AND HE REFUSES TO LISTEN TO MY CONCERNS AND HAS TOLD ME MY ONLY OPTIONS ARE TO DEAL WITH IT, GO ON BIRTH CONTROL PILLS, HAVE AN IUD PUT IN, OR A HYSTERECTOMY. HE WON'T EVEN LOOK INTO WHY I'M HAVING THE PROBLEMS THAT I'M HAVING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032575	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 11/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 936683

Single Use:
Implant Date (E6): 5/14/2012
Explant Date (E7): 11/4/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COMPLICATIONS. PAIN EVERY DAY BECAUSE OF ESSURE. MADE MANY TRIPS TO MY GYM BECAUSE OF ESSURE RELATED PROBLEMS. HAVE TO GET COILS REMOVED DUE TO ESSURE RELATED COMPLICATIONS. GOT ESSURE IN (B)(6) 2012, NOW IT'S 2013 AND I NEED A HYSTERECTOMY. I'M ONLY (B)(6). I JUST WANTED TO HAVE PERMANENT BIRTH CONTROL, NOT TO LIVE IN CONSTANT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032576	CONCEPTUS	11/4/2013	11/8/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/22/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE PLACED IN LATE (B)(6) OF 2013. SINCE THEN, I HAVE HAD VERY HEAVY BLEEDING, INCLUDING CLOTS AS BIG AS MY HAND. THE BLEEDING HAS ONLY STOPPED FOR A WEEK AT A TIME. ONCE IN (B)(6). I'VE BEEN TO THE ER 3 TIMES FOR SEVERE ABDOMINAL PAIN. I'VE FOLLOWED UP WITH MY DOCTOR AND AM NOW TAKING PAINKILLERS AND MUSCLE RELAXERS AND AM SUPPOSED TO START THE PILL AND TRY TO CONTROL THE BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032577	BAYER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 9/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305-R1; ESS305
Catalog # (E4):
Lot #(E4): A36524; 12533513

Single Use:
Implant Date (E6): 9/3/2013
Explant Date (E7): 10/11/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE STERILIZATION DONE AT THE BEGINNING OF (B)(6) 2013. I HAD PAIN, BLOATING, AND BLEEDING CONTINUOUSLY FROM THE TIME THE PROCEDURE WAS DONE UNTIL THE TIME I HAD TO HAVE BOTH OF THE COILS REMOVED IN (B)(6) 2013. ONE OF THE COILS HAD BENT AND IMBEDDED ITSELF INTO MY UTERUS. THE OTHER COIL MOVED OUT OF THE OTHER FALLOPIAN TUBE AND WAS TANGLED IN THE OMENTUM IN MY ABDOMEN. I EXPERIENCED BLEEDING, BLOATING, AND PAIN THE ENTIRE TIME THE ESSURE COILS WERE IN PLACE. I HAD TO UNDERGO SURGERY TO HAVE BOTH COILS REMOVED, AND AM STILL EXPERIENCING PAIN AND BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032578		11/4/2013	11/8/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/2/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEADACHES, JOINT PAIN, SEVERE BLOATING, BRAIN SHOCKS, GLUTEN SENSITIVE, ACNE, NIGHT SWEATS, LOW VITAMIN D, PELVIS PAIN, RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032579	BAYER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY PROCEDURE DONE IN (B)(6) 2010, IN MY DOCTOR'S OFFICE. SINCE THEN, I HAVE EXPERIENCED A HUGE NUMBER OF STRANGE, PERSISTENT SYMPTOMS. IT STARTED WITH DEBILITATING HEADACHES. MY EYES ACHE AND BURN AND IT FEELS AS THOUGH MY HEAD IS GOING TO EXPLODE. AT ITS WORSE, I AM DISORIENTED AND EXPERIENCE AUDITORY DISTORTIONS. I HAVE CONSTANT ABDOMINAL PAIN AND CRAMPING. IT IS AGONIZING AND HAS CAUSED SEVERE HEMORRHOIDS. ALONG WITH THE ABDOMINAL CRAMPING, I HAVE EXPERIENCED SEVERE BACK AND HIP PAIN, RADIATING DOWN MY THIGHS AND CALVES. MY MENSTRUAL CYCLE HAS GOTTEN EXCRUCIATING, WITH HEAVY BLEEDING, BLOOD CLOTS AND DEBILITATING CRAMPS. I HAVE CONSTANT MUSCLE SPASMS, HYPERTONIC REFLEXES, AND BURNING MUSCLE PAIN. I'VE RECEIVED 6 STEROID INJECTIONS TO MY NECK AND UPPER BACK IN AN ATTEMPT TO RELEASE THE MUSCLES THAT ARE NOW FROZEN. DUE TO THE SPASMS, I HAVE DEVELOPED DEGENERATIVE DISC DISEASE TO MY CERVICAL SPINE AND LOWER BACK. SEVERAL DISKS IN MY LUMBAR SPINE HAVE HERNIATED UNDER THE STRAIN OF CONSTANT HIP, BUTTOCK AND HAMSTRING SPASMS. I HAVE CHRONIC FATIGUE, WHICH AGAIN CAN BE ATTRIBUTED TO NEUROLOGICAL IRRITATION, POOR QUALITY OF SLEEP, AND CHRONIC IMMUNE SYSTEM RESPONSE. I HAVE HAD THREE SERIOUS NEUROLOGICAL EPISODES INVOLVING PARALYSIS TO MY LEFT SIDE. I'VE BEGUN DEVELOPING TINY NONSPECIFIC LESIONS ON MY BRAIN THOUGHT TO BE RELATED TO THE SEVERE HEADACHES I'VE BEEN HAVING. I HAVE BEEN HOSPITALIZED TWICE AND HAVE MADE DOZENS OF TRIPS TO THE EMERGENCY ROOM. MY HAIR HAS BEEN STEADILY THINNING AND FALLING OUT AND THE SKIN ON MY FACE IS OFTEN FLUSHED OR PEELING. I HAVE A KNOWN NICKEL ALLERGY, HISTORY, MY DOCTOR DID NOT DETERMINE THIS A REASON TO AVOID THIS PROCEDURE. THE INSERTION OF THE PROCEDURE ITSELF WAS REMARKABLE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032586	CONCEPTUS INC.	11/4/2013	11/8/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT STOMACH PAINS, VERY IRREGULAR PERIODS, WITH HEAVY BLEEDING AND CLOTS, SKIN RASHES, DIZZY SPELLS, WEIGHT PROBLEMS, NAUSEA, VOMITING, CONSTANT INFECTIONS AND BATHROOM TRIPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032587	BAYER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 7/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/8/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE IN 2010, I HAVE EXTREMELY BAD JOINT PAIN, MUSCLE PAIN, SWELLING OF HANDS, LEGS, ANKLES. MY STOMACH IS BLOATED AND BAD CRAMPING. HEADACHES ARE STARTING TO BE MORE FREQUENT AND MORE POWERFUL. I HAVE ALWAYS BEEN ENERGETIC AND NOW I HAVE NO ENERGY! I FEEL LIKE A (B)(6) YEAR OLD AND I'M ONLY (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032588	CONCEPTUS, INC.	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SIX YEARS AGO I HAD THE ESSURE PROCEDURE DONE. I HAVE HAD EXCRUCIATING PAIN SINCE. I HAVE IRREGULAR PERIODS SINCE, I HAVE STARTED PRE MENOPAUSE DUE TO THE PROCEDURE. THE LAST DOCTOR I SAW ABOUT IT REFUSES TO TAKE IT OUT. I WANT IT OUT! I WANT THIS PRODUCT OFF THE SHELVES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032589	BAYER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 11/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WITHIN A WEEK OF HAVING THE ESSURE IMPLANTS PLACED, I STARTED GETTING HIVES ALL OVER MY BODY THAT NEVER SEEMED TO GO AWAY, VAGINAL BLEEDING STARTED DIRECTLY AFTER THE PROCEDURE AS WELL AND DID NOT STOP UNTIL 5 MONTHS LATER. THE HIVES GOT SO BAD MY LIPS AND EYES SWELLED SHUT AND I STARTED HAVING SHORTNESS OF BREATH, I HAD TO BE RUSHED TO THE HOSPITAL AND GET SHOTS OF BENADRYL AND STEROIDS. APPARENTLY I AM ALLERGIC TO THE NICKEL IN THE COILS, MY DOCTOR NEVER INFORMED ME THE COILS HAD A SMALL AMOUNT OF NICKEL IN THEM. I HAVE CONSTANT PAIN IM MY LOWER ABDOMEN, AND STILL GET HIVES DAILY. I AM WAITING TO GET THE DATE TO HAVE MY COILS, UTERUS AND CERVIX REMOVED, AS A DIRECT RESULT FROM HAVING THE ESSURE IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032590	BAYER	11/4/2013	11/8/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 880438

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN AND THE TOOL USED TO PLACE THE ESSURE WOULDN'T RELEASE SO PART OF THE TOOL WAS LEFT IN MY TUBE AND THE OTHER COIL FELL OUT OF MY TUBE AND IS IN MY UTERUS. I HAVE PAIN AT ALL TIMES AND AT TIMES IT IS VERY BAD. CONSTIPATION AND DIARRHEA PROBLEMS, ALSO PAINFUL URINATING. ANXIETY, SOME DEPRESSION AND WEIGHT GAIN OF OVER 30 PLUS POUNDS, HAIR GROWING ON MY FACE AND BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032591	CONCEPTUS INC.	11/4/2013	11/8/2013

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 846833

Single Use:
Implant Date (E6): 8/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN 2011. SINCE THEN, I HAVE CONTINUOUS BLEEDING OFF AND ON AND MODERATE TO SEVERE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032620	CONCEPTUS, INC	11/5/2013	11/13/2013

Event Information:

Event Date (B3): 8/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/4/2010
Explant Date (E7): 10/1/2010
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LET JUST MAKE SURE THAT YOU KNOW THAT I NEVER HAD PAIN BEFORE I WENT IN FOR ESSURE COILS ON (B)(6) 2010. WITH PROLONGED PAIN, AND ULTRA SOUND WAS DONE AND ONE COIL HAD FALLEN INTO MY UTERUS. THIS WAS OCTOBER. THEY REMOVED THAT COIL. WITH CONTINUED PAIN AND NO ONE BELIEVING ME, I INSISTED ON ANOTHER ULTRASOUND. I WAS LOSING WEIGHT BECAUSE I WAS SO SICK. MY BODY WAS SHUTTING DOWN. I WAS RUNNING FEVERS, VOMITING, CHRONIC DIARRHEA. THE DOCTORS KEPT TELLING ME I WAS FINE. FINALLY, I CONVINCED THEM TO DO THE ULTRASOUND. IT SHOWED THAT THE COIL WAS STUCK 15 PERCENT IN THE TUBE AND 85 PERCENT IN THE UTERUS AND WAS BENT AT 90 DEGREES ANGLE. I LEFT WITH PERCOCET AND A HYSTERECTOMY SCHEDULED FOR DECEMBER. I HAD A FULL HYSTERECTOMY ON (B)(6) 2010. AFTER THAT THE PAIN HAS PERSISTED AND I SUFFER FROM CHRONIC PAIN AND A MANY CONTINUING ILLNESS THAT HAVE BEEN AN EFFECT OF CHRONIC INFLAMMATION. I AM IN PAIN 24/7 AND WITH THE STIMULATOR RELY ON PAIN MANAGEMENT TO GET THROUGH EACH AND EVERY DAY. THESE COILS HAVE TAKEN A PART OF MY LIFE. SUFFERING FROM CHRONIC PAIN IS A FULL TIME JOB AND EFFECTS EVERYONE AROUND YOU. THESE COILS ARE HORRIFIC. THEY NEED TO BE TAKEN OFF THE MARKET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032623	CONCEPTUS INCORPORATED	11/5/2013	11/13/2013

Event Information:

Event Date (B3): 7/13/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 12270995

Single Use:
Implant Date (E6): 7/13/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2006, I HAD THE ESSURE PROCEDURE DONE. SINCE THE PROCEDURE, I HAVE HAD EXTREME BLEEDING AND CRAMPING. A UTERINE ABLATION WAS SCHEDULED FOR (B)(6) 2013, BUT NOT COMPLETED DUE TO THE ESSURE. ONLY A HYSTEROSCOPY AND D&C WERE COMPLETED. THE SURGERY HELPED THE BLEEDING BUT THE CRAMPING IS STILL CONSTANT. THE ESSURE PROCEDURE WAS PERFORMED AT (B)(6), LOT REF ESS205, LOT 12270995.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032628	CONCEPTUS	11/5/2013	11/13/2013

Event Information:

Event Date (B3): 4/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/25/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AFTER MY 3RD CHILD IN (B)(6) OF 2012. SINCE THEN I'VE HAD ISSUES WITH SEVERE BACK PAIN, INFECTIONS WHEN I BEGIN MY CYCLE, A HEAVIER THAN EVER CYCLE AND ERRATIC CYCLES. THE BACK PAIN IS THE WORST AND THE PAIN WHEN MY CYCLE DOES HIT IS EXCRUCIATING AND LITERALLY MAKES ME SICK FOR DAYS. I NEVER HAD THE ISSUE WITH MY CYCLES UNTIL AFTER THE PROCEDURE AND WHILE I HAD MILD BACK PAIN BEFORE THE PROCEDURE, THE PAIN IS WORSE AND ONLY IS TOLERABLE WITH THE USE OF PAIN MEDICATION PRESCRIBED BY MY DOCTOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032629	BAYER	11/5/2013	11/13/2013

Event Information:

Event Date (B3): 12/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 11/4/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE IMPLANTATION OF ESSURE I HAVE HAD CHEST PAIN, HEART PALPITATIONS, FATIGUE, CRAMPING, BLOOD CLOTS, BETWEEN PERIOD BLEEDING, DIZZINESS, AND NUMBNESS IN EXTREMITIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00035	BAYER HEALTHCARE LLC	11/5/2013	2/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A RADIOLOGIST REPORTED A PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION. THREE MONTHS AFTER ESSURE INSERTION HYSTEROSALPINGOGRAM SHOWED AN UNUSUAL APPEARANCE, LIKE IT WAS PULLED APART. THE EVENT HAD NOT RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00024	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): 5/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7): 5/28/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED TWO MONTHS POSTPARTUM. SHE REPORTED THAT SHE SWELLED UP, DEVELOPED INFLAMED TUBES AND UTERUS AND RASHES (RASH FROM HEAD TO TOE), SWELLING IN HER UTERUS THAT WAS, ACCORDING TO HER DOCTORS, THE SIZE OF A (B)(6). SHE ALSO EXPERIENCED HEADACHES, PAIN (TWINGES) ON BOTH SIDES WHERE ESSURE WAS IN HER TUBES, HEAVY MENSTRUAL BLEEDING WITH CLOTS, WATER RETENTION THAT CAUSED HER TO LOSE 27 POUNDS AFTER ESSURE WAS REMOVED. THESE EVENTS WERE TREATED WITH PREDNISONE FOR A TIME. THE CONSUMER HAD HER TUBES REMOVED AND A PARTIAL HYSTERECTOMY WITH THE REMOVAL OF ESSURE ON (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00025	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 11/20/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED IN 2012. IMMEDIATELY AFTER INSERTION HER BODY REJECTED THE PROCEDURE. SHE FELT LIKE LITTLE GREMLINS WERE JUST TRYING TO CLAW THEIR WAY OUT, HER LEGS STARTED TO TREMOR AND SHE THREW UP A COUPLE OF TIMES. SHE THEN STARTED HAVING INFECTION AFTER INFECTION HAVING TO DO WITH HER FEMALE ORGANS AND CONSTANT LOWER ABDOMINAL PAIN. SHE HAD ESSURE IMPLANTS REMOVED, BUT THAT DID NOT END HER PAIN. IN 2013, HER OB PAIN SPECIALIST SUGGESTED AN X-RAY BE COMPARED WITH AN EARLIER CT SCAN WHICH VERIFIED THAT WHEN HER DOCTOR REMOVED ESSURE LAPAROSCOPICALLY, THE DEVICE BROKE AND PIECES WERE LEFT INSIDE. SHE HAD A HYSTERECTOMY IN 2013. ADDITIONALLY SHE PROVIDED OTHER SIDE EFFECTS, SOME STILL TRYING TO RESOLVE: ACNE AROUND HER NECKLINE AND CHEST, DIGESTIVE ISSUES, FOOD ALLERGIES/SENSITIVITIES, FATIGUE WORSENED, SEASONAL ALLERGIES, ABDOMINAL BLOATING, INCREASE ANXIETY, BLURRED VISION ON OCCASION, LOSS OF MOTIVATION FOR DAILY/SOCIAL/OTHER ACTIVITIES, 3 BROKEN TEETH (WHILE FLOSSING).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00026	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A (B)(6) YR-OLD CONSUMER REPORTED HAVING ESSURE IMPLANTED. SHE STATED THAT SHE EXPERIENCED CONSTANT PAIN/HORRIBLE PAIN AND WHEN SHE SITS DOWN WOULD FEEL LIKE SOMETHING WAS POKING HER STOMACH. HER DOCTOR FOUND ONE OF THE COILS HAD PARTIALLY MIGRATED OUT OF HER FALLOPIAN TUBE. HYSTERECTOMY PERFORMED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00027	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): 9/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): B27983

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A (B)(6) FEMALE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT BIRTH CONTROL ON (B)(6) 2013. ON (B)(6) 2013, THE PT CAME IN BECAUSE OF PAIN. ESSURE PERFORATION WAS CONFIRMED ON SONOGRAM. ON (B)(6) 2013, THE PT HAD SURGERY FOR REMOVAL OF ESSURE AND TUBAL LIGATION ON (B)(6) 2013 AND RECOVERED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00028	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/30/2006
Explant Date (E7): 8/5/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A MANAGER REPORTS ON OF A PHYSICIAN THAT ON (B)(6) 2006 A PT HAD ESSURE IMPLANTED FOR STERILIZATION BY ANOTHER PHYSICIAN. ON AN UNSPECIFIED DATE THE PT HAD AN ECTOPIC PREGNANCY. ON (B)(6) 2013, A LAPAROTOMY WAS PERFORMED AND THE PT RECOVERED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00029	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): DM11662

Single Use: Y
Implant Date (E6): 9/20/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A REP FROM THE PHYSICIAN OFFICE REPORTED A FEMALE PT HAD ESSURE IMPLANTED ON (B)(6) 2013. THE RPTR STATED THAT THEY HAD TROUBLE DEPLOYING THE COIL. AFTER ESSURE INSERTION, THE PROCEDURE WAS CHECKED AND IT APPEARED TO BE SUCCESSFUL. HOWEVER, THE PT DEVELOPED AN ABSCESS (QUITE ILL) AND THE COIL WAS THROUGH THE TUBE. THE PT UNDERWENT A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00030	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): 7/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/18/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A PT HAD ESSURE INSERTED FOR BIRTH CONTROL ON (B)(6) 2013. THERE WERE THREE RIGHT AND ONE LEFT TRAILING COILS AT THE TIME OF PLACEMENT. ON (B)(6) 2013, HYSTEROSALPINGOGRAM WAS PERFORMED AND THE PHYSICIAN REC'D A REPORT OF PT TUBE. AFTER LOOKING AT THE FILMS, THE PHYSICIAN DETERMINED THAT THE RIGHT DEVICE WAS NOT IN THE TUBE. THE PT WAS HAVING PAIN SO A TUBAL LIGATION WAS SCHEDULED AND POSSIBLE REMOVAL OF ESSURE ON THE RIGHT SIDE IF THE DEVICE COULD BE SEEN. ON (B)(6) 2013, THE PHYSICIAN PERFORMED THE TUBAL LIGATION AND ESSURE REMOVAL. THE DEVICE ON THE RIGHT SIDE WAS SEEN PERFORATING THE TUBE AND WAS REMOVED W/O INCIDENT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00031	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): UNK

Single Use: Y
Implant Date (E6): 5/1/2013
Explant Date (E7): 10/2/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL IN MAY 2013. IT WAS REPORTED THAT (DATE NOT SPECIFIED) THE INSERTS PERFORATED THE FALLOPIAN TUBES AND EMBEDDED ON THE RIGHT SIDE AND THE COIL FRACTURED. ON (B)(6) 2013 SHE HAD TO HAVE A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00032	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893037

Single Use: Y
Implant Date (E6): 6/1/2012
Explant Date (E7): 9/18/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CUSTOMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN JUNE 2012. IN JULY 2012 HER RIGHT LEG WENT COMPLETELY NUMB. TWO DAYS LATER FEELING IN LEG CAME BACK, EXCEPT FOR IN RIGHT FOOT FROM MIDDLE TOE TO PINKY TOE AND HER HEEL, WHICH STAYED NUMB FOR 2 MORE WEEKS. SHE ALSO EXPERIENCED MAJOR CRAMPS IN LOWER PELVIC AREA, NON-STOP HURTING, AND EXCESSIVE BLEEDING WITH EVERY PERIOD. AFTER A FEW MONTHS SHE NOTICED THAT HER HAIR WAS FALLING OUT COMPLETELY. SHE WENT TO 3 DIFFERENT EMERGENCY ROOMS, HER LAST ONE DUE TO SEVERE PAIN. ON (B)(6) 2013, A PARTIAL HYSTERECTOMY (REMOVED UTERUS AND TUBES) WAS PERFORMED. SHE ALSO REMOVED THE ESSURE INSERTS. IT WAS REPORTED THAT A HYSTEROSALPINGOGRAM CONFIRMATION TEST WAS NEVER DONE. SHE REPORTED SHE RECOVERED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00033	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON AN UNSPECIFIED DATE, A CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER STATED THAT SHE SUFFERED FROM ESSURE SIDE EFFECTS FOR FIVE YEARS BECAUSE THE COILS BROKE AFTER BEING IMPLANTED. A HYSTERECTOMY WAS PERFORMED AND THE OUTSIDE WAS COVERED BY SCAR TISSUE. IT WAS NOT SURE IF ESSURE PERFORATED OR IF IT WAS BROKEN INSIDE THE TUBE.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 22-JAN-2014: NEW REPORTER ADDED. THE CONSUMER HAD ESSURE IMPLANTED WHEN SHE WAS (B)(6), AFTER HER THIRD CHILD WAS BORN, AND SUFFERED THROUGH A PERFORATED UTERUS FROM A BROKEN ESSURE COIL, RESULTING IN A HYSTERECTOMY AT (B

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00034	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED INSERTING ESSURE INTO A POSTPARTUM FEMALE PT. FIVE WEEKS LATER, SHE WAS HAVING HEAVY BLEEDING. AS A RESULT, THE PHYSICIAN URGED THE PT TO COME IN FOR AN X-RAY WHEREUPON A 'METALLIC THING' WAS FOUND IN A BLOOD CLOT (ONE EXPELLED ESSURE IN VAGINA). HYSTEROSCOPY WAS DONE BECAUSE OF THE BLEEDING AND 'NO MAJOR ISSUES' WERE FOUND, ONLY MINOR ABRASIONS. DILATATION AND CURETTAGE WAS ALSO DONE BECAUSE THE ENDOMETRIUM WAS 'FLUFFY.' THE PT OPTED FOR A BILATERAL TUBAL LIGATION WHICH WENT WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00036	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED THAT A PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THAT PT REQUESTED REMOVAL OF THE ESSURE DEVICES COMPLAINING OF MENORRHAGIA AND SHOOTING LEG PAIN AFTER THE PROCEDURE. PHYSICIAN REQUESTED AN EARLY HYSTEROSALPINGOGRAM TO CONFIRM PLACEMENT OF THE DEVICES. THE PHYSICIAN STATED THAT THE BLEEDING WAS LIKELY DUE TO THE DEPO PROVERA THAT SHE WAS USING AT THE TIME OF THE PROCEDURE. SHE HAD A HISTORY OF FIBROIDS, SO THE PHYSICIAN DID A HYSTERECTOMY. THE PAIN RESOLVED AFTER HER SURGERY. PHYSICIAN STATED THERE WAS NOTHING UNUSUAL ABOUT THE DEVICES (I.E. PERFORATION, SCARRING) UPON EXAMINING DURING THE SURGERY. THE OUTCOME OF THE EVENTS WAS RECOVERED / RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00037	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): 9/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/9/2013
Explant Date (E7): 10/4/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED A 3 HR PROCEDURE TO HAVE ESSURE INSERTED ON (B)(6) 2013. ALMOST IMMEDIATELY AFTER INSERTION SHE EXPERIENCED FEVER UP TO 104 (WITH CHILLS AND SHAKING), EXCESSIVE BLEEDING WITH LARGE CLOTS AND FEELING LIKE A KNIFE WAS STABBING INSIDE HER. ABOUT 5 DAYS AFTER INSERTION, SHE WENT TO THE ER AND WAS TOLD SHE HAD A URINARY TRACT INFECTION. SHE WENT BACK TO HER PHYSICIAN (2 WEEKS POST OP.) AND HE TOLD HER SHE SHOULD NOT HAVE ESSURE IMPLANTED BECAUSE SHE IS AN AUTOIMMUNE PT. A PHYSICIAN CONFIRMED THE REMOVAL OF ESSURE VIA LAPAROSCOPY. HE ALSO STATED THAT HE CANNOT CONFIRM ANYTHING ELSE HAVING TO DO WITH THE CASE. HE STATED THAT THE PT WAS "ADAMANT TO HAVE" ESSURE REMOVED. REPORTING DOCTOR FEELS THAT ESSURE WAS REMOVED TOO SOON. HE WAS AWARE OF (BUT COULD NOT IDENTIFY) ANOTHER DOCTOR URGING THE PT TO HAVE ESSURE REMOVED AS, IN THIS MD'S VIEW, THE PT' EVENTS WERE RELATED TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00038	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): 919038

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A NURSE REPORTED A PT WAS TO HAVE THE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL ON (B)(6) 2013. SHE REPORTED THE DEVICE, WHEN READY TO RELEASE, WAS LOCKING AND DID NOT RELEASE. THEN, THE DEVICE BROKE INTO PIECES INSIDE THE PT AND THE PHYSICIAN HAD TO GO AND RIP THE PIECES OUT OF CERVIX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00039	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. PT IS REQUESTING REMOVAL OF THE ESSURE DEVICES AFTER VISITING PHYSICIAN ON ANOTHER ISSUE. PT DID NOT HAVE SPECIFIC COMPLAINTS/SYMPTOMS FOR REQUESTING THE REMOVAL OF THE DEVICES. HOWEVER, A RECENT ULTRASOUND SHOWED THAT SHE HAD HYDROSALPINX AND SHE IS REQUESTING A HYSTERECTOMY. THE SURGERY HAS NOT BEEN PERFORMED YET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00040	BAYER HEALTHCARE LLC	11/6/2013	11/13/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. SHE DESCRIBED THAT HER CRAMPING GRADUALLY PROGRESSED, AND IT KEPT GETTING WORSE. IT WAS LIKE HAVING A DAILY PERIOD OR PREPARING FOR LABOR (THE CONTRACTIONS OF LABOR PAINS). SHE ALSO SAID THAT ANY PHYSICAL MOVEMENT MADE CRAMPING WORSE. SHE COULDN'T LOSE BABY WEIGHT AND EXPERIENCED STRESS. SHE REPORTED THE PROCEDURE WENT FINE, EVEN THOUGH SHE WAS IN EXTREME PAIN. THE PHYSICIAN WAS NOT ABLE TO FULLY UNDERSTAND WHAT WAS GOING ON WITH HER UNTIL (B)(6) 2013, WHEN SHE DECIDED TO HAVE A HYSTERECTOMY. DURING THE HYSTERECTOMY, THE COIL WAS REMOVED. SHE SAID DOCTORS DISCOVERED THAT A MISSHAPE IN HER FALLOPIAN TUBE CAUSED ONE OF THE COILS TO SHOOT INTO HER UTERINE WALL. THE CONSUMER WAS NOT RECOVERED AFTER THE SURGERY, BUT SHE SAYS THE ENTIRE PROCESS CAUSED A YEAR OF PAIN, SUFFERING AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032636	BAYER	11/6/2013	11/14/2013

Event Information:

Event Date (B3): 1/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/22/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE BEING IMPLANTED WITH ESSURE, I'VE HAD NUMEROUS SIDE EFFECTS. I WAS A HEALTHY INDIVIDUAL PRIOR TO GETTING THIS PROCEDURE DONE. I NOW SUFFER FROM EXTREME JOINT PAIN, HEAVY BLEEDING (FOR 3 WEEKS AT A TIME), MIGRAINES (THAT LAST FOR DAYS), BLURRED VISION (FLOATERS), DIZZINESS, MEMORY LOSS, PELVIC PAIN, RINGING IN MY EAR, CHRONIC INFLAMMATION IN MY C2/C3 (SO SEVERE THAT IT IS NOTICEABLE IN X-RAYS), LOWER BACK PAIN, SHOULDER PAIN, BLOATING, HAIR LOSS, AND STABBING PAIN ON THE LEFT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032637	BAYER	11/6/2013	11/14/2013

Event Information:

Event Date (B3): 10/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/22/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE COIL WENT THROUGH MY FALLOPIAN TUBE AND IS NOW FLOATING AROUND MY STOMACH CAVITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032638	BAYER	11/6/2013	11/14/2013

Event Information:

Event Date (B3): 11/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/21/2012
Explant Date (E7): 10/24/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED 2012 - CAUSED WEIGHT GAIN, HAIR LOSS, PAIN, AND PREGNANCY EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032640		11/6/2013	11/14/2013

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/15/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN ABOUT THREE YRS AGO. I'VE EXPERIENCED SEVERE BLOATING IN THE ABDOMINAL AREA AND SEVERE LOWER BACK PAIN. PCP HAS EVALUATED LOWER BACK, BUT CAN FIND NO REASON FOR PAIN. DIFFICULTY LIFTING LEGS TO PUT ON PANTS AND NIGHT TIME PAIN WHILE IN BED TO THE POINT OF EXCRUCIATING PAIN WHEN TRYING TO TURN. STENTS FOR TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032645	BAYER (WAS CONCEPTUS)	11/6/2013	11/14/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 846835

Single Use:
Implant Date (E6): 10/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE DONE SINCE, I HAVE HAD HORRIBLE PELVIC PAIN, CRAMPS, ACHES, DIZZINESS, LOW BLOOD PRESSURE, ACNE, SWEATS, NICKEL ALLERGY CRASHES FOR 3 YRS. I CAN NO LONGER DO ANY WORK INVOLVING AB MUSCLES AND HAVE SINCE HAD HORRIBLE DENTAL PROBLEMS. I WAS ASKED IF I HAD AN ALLERGY TO NICKEL, TOLD THEM I DID NOT KNOWN AND THEY NEVER TESTED. NOW I HAVE CONSTANT RASHES THAT NEVER GO AWAY. HAVING SERIOUS SIDE EFFECTS AND CANNOT AFFORD TO GO TO THE DOCTOR/HOSPITAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032648	BAYER	11/6/2013	11/14/2013

Event Information:

Event Date (B3): 7/13/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 624000

Single Use:
Implant Date (E6): 7/13/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RECEIVED THE ESSURE IMPLANTS IN JULY 2007. I HAVE BEEN HAVING CONSTANT CRAMPING, EXCESSIVE BLEEDING, BACK PAIN, PAIN RADIATION DOWN MY LEGS, BURNING SENSATION AT IMPLANT SITE, PINS AND NEEDLES FEELING, A CONSTANT DISCOMFORT AND TENDER ABDOMINAL AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032649	BAYER/CONCEPTUS	11/6/2013	11/14/2013

Event Information:

Event Date (B3): 5/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/15/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN 2010 AND IN (B)(6) OF THIS YEAR (2013) I FOUND OUT I WAS PREGNANT, I AM NOW 27 WEEKS PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032650	CONCEPTUS	11/6/2013	11/14/2013

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2010. EVER SINCE I'VE BEEN ADMITTED TO HOSPITAL ON SEVERAL OCCASIONS. I'VE HAD ABDOMINAL PAINS, THROWING UP, LOW GRADE FEVER, HEAVY PERIODS, KIDNEY STONES, HIVES, NECK SHOULDER, AND LOWER BACK PAIN. I AM SEVERALLY ANEMIC, AND HAVE VITAMIN D DEFICIENCY. I HAVE LOST 20LBS. I ALWAYS GET BLOATED AND CAN'T FINISH MY FOOD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032651	CONCEPTUS	11/6/2013	11/14/2013

Event Information:

Event Date (B3): 2/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 689929

Single Use:
Implant Date (E6): 2/17/2010
Explant Date (E7): 3/18/2010
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PRODUCTS IN (B)(6) 2010. THE LEFT SIDE WENT IN FINE. THE RIGHT SIDE HURT WHEN IT WAS INSERTED. EIGHT DAYS LATER, I AWOKE WITH RIGHT UPPER QUADRANT PAIN. AFTER AN ENDOSCOPY AND NEGATIVE SCANS, A MONTH LATER - (B)(6) 2010, I HAD MY RIGHT FALLOPIAN TUBE REMOVED LAPAROSCOPICALLY BECAUSE IT WAS INFLAMED. MY SED RATE HAD GOTTEN UP TO 60, I WAS IN PAIN. I RETURNED TO WORK FOR TWO WEEKS AND THEN THE PAIN CAME BACK IN (B)(6) OF 2010. FOR THE PAST 3 AND 1/2 YEARS. I HAVE HAD SCANS, TRIGGER POINT INJECTIONS, AND HAVE LOST 35 POUNDS. I WENT FROM 145 POUNDS TO 110 POUNDS. IT HURTS TO EAT. I CAN NO LONGER WORK AS A TEACHER. BEING ON MY FEET FOR A LONG TIME HURTS. I CAN'T DO THINGS WITH MY DAUGHTERS LIKE I USED TO. I HAVE TRIED NEURONTIN, LYRICA, NORTRIPTYLINE. I HAVE HAD MY GALLBLADDER REMOVED AND I HAD A HYSTERECTOMY IN (B)(6) OF 2013, WHICH HAS NOT HELPED. I HAVE WORKED WITH THE (B)(6). I HAVE NOT RESPONDED TO ANY DRUGS WHICH BAFFLES DOCTORS. SOME DOCTORS QUESTION WHETHER THE TRIGGER IS STILL THERE. I AM CURRENTLY USING A 50 MCG PATCH OF FENTANYL EVERY 48 HRS. TO TAKE THE EDGE OF THE PAIN, I 1ST PRESENTED WITH PAIN IN UPPER RIGHT QUADRANT AFTER THE PROCEDURE, WHICH BAFFLED DOCTORS. I HAD A PELVIC PROCEDURE. I DID HAVE ADHESIONS WHEN THEY REMOVED THE INFLAMED RIGHT FALLOPIAN TUBE. MY LIFE CHANGED IN (B)(6) 2010. I WAS A PERFECTLY HEALTHY WOMEN WHO WAS ONE OF THOSE LUCKY PEOPLE WHO NEVER THOUGH ABOUT THEIR BODY. I HAVE NOW ENTERED THE WORLD OF CHRONIC PAIN. I HAVE READ A LOT ABOUT CHRONIC PAIN AND UNDERSTAND THAT IN SOME PEOPLE THE NERVES ENTER A STATE OF HYPEREXCITABILITY AFTER A TRAUMA. IT LOOKS LIKE THE COIL WAS INJECTED INTO THE SIDE OF THE FALLOPIAN TUBE INSTEAD OF THE LUMEN. I HAVE PICTURES OF THE INFLAMED RIGHT

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FALLOPIAN TUBE. EVERY PHYSICAL THERAPIST THAT I WORKS WITH CANNOT UNDERSTAND HOW MY BODY HAS BECOME SO TIGHT. THEY CAN FEEL THE TIGHTNESS ALL ALONG THE RIGHT SIDE OF MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032652	BAYER	11/6/2013	11/14/2013

Event Information:

Event Date (B3): 5/18/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/11/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE COILS IMPLANTED IN 2007, EVER SINCE HAVE HAD HEAVY BLEEDING/CLOTTING, CHRONIC MIGRAINES, FATIGUE, WEIGHT GAIN/BLOATING AND YEAST INFECTIONS, CRAMPING AND SWELLING, WENT INTO THE EMERGENCY ROOM WITH CYSTS ALTHOUGH NEVER HAD ANY ISSUES BEFORE. MAY HAVE A NICKEL ALLERGY. BREAST TENDERNESS, WAS OFFERED A HYSTERECTOMY BUT DECLINED DUE TO SIDE EFFECTS FROM THAT (VAGINAL WALLS COLLAPSING/ INCONTINENCE).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032630	BAYER	11/7/2013	11/13/2013

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER REPORTS THAT SINCE SHE HAD ESSURE IMPLANTED IN 2008, SHE HAS BEEN EXPERIENCING EXCRUCIATING PAIN, CRAMPING, HEAVY PERIODS AND PAINFUL SEX. SHE NOW HAS TO UNDERGO A HYSTERECTOMY AND ALSO HAVE HER FALLOPIAN TUBES REMOVED. SHE VISITED MORE THAN 3 GYNECOLOGISTS WHO WERE COMPLETELY UNKNOWLEDGEABLE ABOUT THE ADVERSE EFFECTS OF ESSURE. SHE WAS ABLE TO UNDERSTAND ALL HER ADVERSE EFFECTS ARE FROM ESSURE AFTER SHE JOINED AN ORGANIZATION OF MORE THAN 3000 WOMEN SUFFERING FROM THE SAME EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032665	CONCEPTUS INC.	11/7/2013	11/14/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PROCEDURE DONE IN 2011 AND SINCE I'VE HAD HORRIBLE PAINS ON MY RIGHT SIDE WORSE THAN LABOR PAINS, PULMONARY EMBOLISM, HEAVY PERIODS, BLOOD CLOTS IN PERIOD BLOOD, WEIGHT GAIN (80 LBS OR MORE), FATIGUE, BUCKLE ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032666	BAYER	11/7/2013	11/14/2013

Event Information:

Event Date (B3): 1/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/9/2013
Explant Date (E7): 11/4/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS IMPLANTED WITH ESSURE PERMANENT BIRTH CONTROL AT AGE (B)(6) DESPITE THE SAFETY WARNINGS THAT SAFETY AND EFFECTIVENESS OF PRODUCT HAS NOT BEEN PROVEN IN WOMEN 45 YEARS OF AGE AND OLDER. BEGAN HAVING CHRONIC PAIN WITHIN A WEEK OF INSERTION. ULTRASOUND TAKEN 3 WEEKS AFTER INSERTION SHOWED THAT THE RIGHT COIL HAD ALREADY MIGRATED 4 CM INTO THE UTERUS. EXPERIENCED CHRONIC HEAVY BLEEDING FOR MONTHS THAT PROHIBITED ME FROM GETTING THE HSG AT THE 90 DAY MARK TO ENSURE DEVICES WERE IN PLACE. WHEN I HAD THE HSG IN (B)(6), RESULTS SHOWED THE RIGHT COIL HAD MIGRATED AND WAS MISSING. LEFT COIL CONTINUED TO CAUSE CHRONIC PAIN, WEIGHT GAIN AND HEAVY BLEEDING. X-RAY INDICATED THAT I PASSED THE RIGHT COIL. AS A RESULT, I HAD A VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY ON (B)(6) 2013, TO REMOVE REMAINING ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032667	CONCEPTUS	11/7/2013	11/14/2013

Event Information:

Event Date (B3): 11/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 11/18/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2008, I HAD ESSURE DONE AS MY PERMANENT BIRTH CONTROL. I'VE LIVED WITH SEVERE CRAMPING, PAIN, EDEMA, AND IRREGULAR PERIODS FOR THE PAST FIVE YEARS. NOW I'M SUFFERING FROM EXTREME PAIN AND AFTER HAVING CT SCAN AND ULTRASOUND IT HAS BEEN DETERMINED I MUST HAVE A HYSTERECTOMY TO BE RID OF THE PAIN. THIS IS DUE TO THE ESSURE DEVICE SHIFTING FROM THE FALLOPIAN TUBE TO LOW IN MY UTERINE WALL. THIS PRODUCT SHOULD BE PULLED AND THE MAKERS HELD RESPONSIBLE. NEVER IN MY LIFE DID I THINK I'D BE OUT (B)(4) DOLLARS FOR SOMETHING THAT WAS SUPPOSED TO MAKE MY LIFE EASIER. I NEARLY FORGOT TOO MENTION, I'M ONLY (B)(6) AND LOOKING AT POSSIBLY GOING THROUGH MENOPAUSE DUE TO THIS HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032668	BAYER/CONCEPTUS	11/7/2013	11/14/2013

Event Information:

Event Date (B3): 7/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/17/2009
Explant Date (E7): 3/21/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS IMPLANTED IN ME IN (B)(6) 2009. I DEVELOPED AN ALLERGY TO THE NICKEL IN THE IMPLANT AND SUFFERED EXCESSIVE WEIGHT GAIN, BLISTERING RASHES, HIVES, NEUROLOGICAL CONDITIONS, ADHD, ANXIETY, DEPRESSION, CHRONIC INFLAMMATION, FOGGY THINKING AND EXTREME FATIGUE. MY DOCTOR RECOMMENDED REMOVING THE DEVICES AND I HAD SURGERY, A DOUBLE SALPINGECTOMY, TO REMOVE THEM IN (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032669	CONCEPTUS/BAYER	11/7/2013	11/14/2013

Event Information:

Event Date (B3): 1/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/11/2010
Explant Date (E7): 6/10/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATE SKIN RASH, CONSTANT ABDOMINAL, BACK AND JOINT PAIN, FATIGUE, FOOD INTOLERANCES DEVELOPED. PROCEDURES NEEDED TO REMOVE ADHESIONS, ENDOMETRIOSIS, FIBROIDS. NONE OF WHICH I HAD PRIOR TO INSERTION OF THE ESSURE IMPLANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032670	CONCEPTUS	11/7/2013	11/14/2013

Event Information:

Event Date (B3): 12/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MIGRATED AND PUNCTURED MY LEFT FALLOPIAN TUBE WHICH CAUSED ME TO HAVE A HYSTERECTOMY. I HAD HEAVY BLEEDING AND HORRIBLE PAIN AND FATIGUE WHICH LEAD UP TO THE COILS BEING REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032672	CONCEPTUS INC	11/7/2013	11/14/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/16/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IMPLANT IN (B)(4) OF 2010. SINCE RECEIVING IT I HAVE MILD TO MODERATE PAIN ON MY LEFT LOWER ABDOMEN, CHRONIC FATIGUE AND RUN FEVERS ALMOST DAILY FOR NO REASON. I HAVE ALSO HAD SEVERAL NON HEALING ABSCESSES AND CYSTS ON AND AROUND MY GROIN AND NECK. I HAVE BEEN TO THE DOCTORS SEVERAL TIMES WITHOUT BEING ABLE TO FIND A CAUSE FOR THEM. I ALSO BEGAN SEEING A DARK ALMOST BLACK FLUID COMING FROM MY NIPPLES AFTER IMPLANTATION. I HAVE BEEN CHECKED AND RECHECKED THREE TIMES BY ONCOLOGY AND THEY CAN NOT FIND A REASON IT'S HAPPENING EITHER. I BELIEVE THAT I AM SUFFERING FROM A NICKLE ALLERGY DUE TO THE ESSURE DEVICE. NO ONE INFORMED ME THAT IT WAS MADE OF (B)(4) WHEN I RECEIVED THEM. I BELIEVE THIS ALLERGY IS THE CAUSE OF MY SYMPTOMS AND I BELIEVE I SHOULD HAVE BEEN INFORMED BEFORE HAND ABOUT WHAT THE ESSURE COILS WERE MADE OF, I WOULD HAVE NEVER CONSENTED HAD I KNOWN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032673	BAYER/CONCEPTUS	11/7/2013	11/14/2013

Event Information:

Event Date (B3): 11/6/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/6/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PERMANENT BIRTH CONTROL DONE IN (B)(6) 2011. IT'S CAUSED ME UNCONTROLLABLE BLEEDING CHRONIC BACK AND PELVIC PAIN, SEVERE ABDOMINAL PAIN, TINGLING IN BOTH LEGS MAKE IT DIFFICULT TO WALK AND DO DAILY ACTIVITIES. EXTREME BLOATING AND HEADACHES AND PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032674	CONCEPTUS/BAYER	11/7/2013	11/14/2013

Event Information:

Event Date (B3): 5/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 810881

Single Use:
Implant Date (E6): 5/12/2011
Explant Date (E7): 9/12/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011, I HAD THE ESSURE BIRTH CONTROL DEVICE IMPLANTED IN ME IN (B)(6). WITHIN A FEW MONTHS I STARTED BREAKING OUT IN A RASH. THIS QUICKLY SPREAD TO MY ENTIRE BODY. THIS WENT ON FOR ALMOST A YEAR AND A HALF. AT FIRST, THE RASH WAS SO BAD I WAS TREATED WITH STEROIDS. THE RASH WAS IN MY THROAT AND DOCTORS FEARED IT WAS CLOSING MY THROAT. IN THE YEAR AFTER THE PROCEDURE, MY BODY COMPLETELY FELL APART. HERE IS A LIST OF MY SYMPTOMS: EAR PAIN (DEEP STABBING), NECK ARTHRITIS, DRY MOUTH, DRY EYES, DRY SKIN, FACIAL REDNESS/ROSACEA, SCALY RED BODY RASH - BODY ITCHY, FATIGUE, DERMATOGRAPHIC URTICARIA, CHRONIC URTICARIA, HEAT INDUCED URTICARIA, JOINT PAIN, SHOULDERS, AND ANKLES, HAIR LOSS, SWELLING OF HANDS AND FEET, LARGE WEIGHT LOSS, LOSS OF APPETITE, LOSS OF SEXUAL DRIVE, BRUISING, SLOW HEALING CUTS, CHRONIC CONSTIPATION WITH OVERFLOW, FOLLOWED BY FULL CONSTIPATION, ULCERS IN MOUTH, NAUSEA. I WAS A HEALTHY (B)(6) YEAR OLD WOMAN WHEN THIS WAS DONE. I ENDED UP HAVING A HYSTERECTOMY IN (B)(6) 2013 REMOVING MY UTERUS, AND TUBES CONTAINING COILS. I AM NOW SYMPTOM FREE AND HAVE NO HIVES. I LOST SEVERAL JOBS AND MUCH TIME WITH MY FAMILY DUE TO THIS PRODUCT. I WAS NEVER TOLD IT CONTAINED NICKEL. I WAS NEVER TOLD ABOUT THIS POSSIBLE COMPLICATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032675	CONCEPTUS INC	11/7/2013	11/14/2013

Event Information:

Event Date (B3): 3/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN BACK IN 2011, EVERYTHING WAS FINE FOR A WHILE. BUT BY (B)(6) 2012, I WAS IN CONTINUOUS PAIN ON THE REGULAR BASIS IN MY LOWER ABDOMINAL AREA. I BEGIN GETTING PRESCRIPTIONS FOR PAIN FROM MY OB/GYN. I COULD NOT TAKE THE PAIN ANYMORE SO I ASKED MY DR TO REMOVE THEM IN FEAR OF HURTING MORE. SHE TOOK PICTURES BEFORE REMOVING THE COILS AND IT HAD SHIFTED. SINCE HAVING THEM REMOVED NOW GET EXTREME MIGRAINES TO THE POINT I CAN HARDLY SEE OR THINK AND MEDS THAT CAN HELP I CAN'T TAKE BECAUSE, IT COUNTERACTS WITH MY ASTHMA. SO MY PAIN LEFT ONE AREA AND MOVED ELSEWHERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032678	BAYER	11/7/2013	11/14/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): L2843
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) OF 2012. SINCE THEN, I HAVE HAD NUMEROUS SIDE EFFECTS, TO INCLUDE: WEIGHT GAIN, NIGHT AND DAY SWEATS, VERTIGO, EXHAUSTION, CHRONIC INFLAMMATION, CLOTTY IRREGULAR PERIODS, SEVERE BLOATING, LACK OF MENTAL CLARITY, FORGETFULNESS, CONFUSION, ANXIETY, DEPRESSION, PMS, MOOD SWINGS, NUMBNESS IN EXTREMITIES, SEVERE LOWER BACK PAIN, INSOMNIA, LOW LIBIDO, METALLIC TASTE IN MOUTH. SEEKING REMOVAL OF ESSURE DEVICES. IMPLANTING DOCTOR REFERRED ME TO ANOTHER DOCTOR. MY APPOINTMENT IS MONDAY, (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032597	CONCEPTUS	11/7/2013	1/13/2014

Event Information:

Event Date (B3): 8/27/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

COMPLETE EXPULSION OF RIGHT COIL INTO UTERUS. COIL EMBEDDED IN UTERINE WALL. PARTIAL EXPULSION OF LEFT COIL INTO UTERUS, AND TWISTED UP ON ITSELF.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032594	CONCEPTUS	11/7/2013	1/14/2014

Event Information:

Event Date (B3): 9/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I IMMEDIATELY HAD SEVERE CRAMPING AND BLEEDING AFTER THE PROCEDURE. I CONTINUED TO BLEED FOR 4 MONTHS, SOMETIMES LIGHT AND SOMETIMES CLOTS SO BIG AND FLOW SO HEAVY I WAS SCARED. I CALLED MY DOCTOR 3 TIMES DURING THOSE 4 MONTHS TO SEE WHY IT WAS HAPPENING. SINCE THEN, I HAVE HAD VARIOUS SYMPTOMS INCLUDING ACNE, FLOATERS IN MY EYES, CONFUSION, FORGETFULNESS, BACTERIAL VAGINOSIS, BACKACHE, SPASMS, HEADACHES, SEVERE BLOATING AND WEIGHT GAIN, HEAVY PERIODS, LABOR-LIKE CRAMPING AND IRRITABILITY, JUST TO NAME A FEW!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032595	CONCEPTUS	11/7/2013	1/14/2014

Event Information:

Event Date (B3): 2/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BAD CRAMPS, HEAVY BLEEDING, BLOOD CLOTS, LOWER BACK PAIN, SEVERE BLOATING, SWELLING IN FEET AND FACE, SWOLLEN LYMPH NODES IN NECK, PANIC ATTACKS, BODY ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032596	CONCEPTUS	11/7/2013	1/14/2014

Event Information:

Event Date (B3): 8/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED (B)(6) 2011, I RECENTLY SUBMITTED ON (B)(6), A FOLLOW UP TO A EMAIL I SENT IN ON (B)(6). MY ACCESS # IS (B)(4). I AM ONCE AGAIN UPDATING. I HAVE RECENTLY UNDERGONE A HEAVY METALS HAIR TESTING DUE TO MY ALLERGY TO NICKEL, I WANTED TO SEE WHAT IT WAS BEFORE MY SURGERY. AS YOU CAN SEE IN PICTURE I PROVIDED, NOT GOOD AT ALL. MY PRE OP IN (B)(6), SURGERY IS SET FOR (B)(6), I WILL UNDERGO A HYSTERECTOMY, AND TUBES, AND COILS WILL BE REMOVED. THANK YOU ALL FOR REMOVING THE NICKEL WARNING, OFF THE LABEL NOT ENOUGH TO HARM SOMEONE WITH A NICKEL ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032598	CONCEPTUS	11/7/2013	1/14/2014

Event Information:

Event Date (B3): 5/13/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATE CRAMPING AND SEVERE PELVIC PAIN, NAUSEA, ADVERSE REACTION TO FOOD MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032599	CONCEPTUS	11/7/2013	1/14/2014

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED (B)(6) 2010. FOR THE PAST 4 MONTHS HAVE FOLLOWING SYMPTOMS: CONSTANT CRAMPING ON PELVIC RIGHT SIDE, CONSTANT BREAST TENDERNESS, FATIGUE, MENTAL FOG, TINGLING IN LEFT ARM. ALSO AM STARTING MENOPAUSE AT AGE IF (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032718	BAYER	11/8/2013	11/15/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE IMPLANTATION OF THIS DEVICE 2009, PATIENT HAS BEEN HAVING SEVERE ABDOMINAL, LOWER BACK AND PELVIC PAIN. SHE HAS BEEN ON PAIN PILLS SINCE IMPLANTATION OF DEVICE. SHE'S ALSO EXPERIENCING VAGINAL BLEEDING THAT GETS WORSE DURING MENSTRUATION. SHE HAS NO SEXUAL LIFE. PATIENT ALSO HAS AN ALLERGIC REACTION TO THE DEVICE CAUSING ITCHING, BUMPS, AND FLAKING SKIN, FOR WHICH HER DOCTOR ADMINISTERED A HYDROCORTISONE SHOT TO ALLEVIATE SYMPTOMS. HER OB/GYN PLANS FOR HER TO HAVE A HYSTERECTOMY AND FOR DEVICE TO BE EXPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032727	BAYER	11/8/2013	11/15/2013

Event Information:

Event Date (B3): 11/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/21/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PRODUCT INSERTED IN (B)(6) 2012. THE PRODUCT MALFUNCTIONED/MISFIRED. I CONTINUED TO BLEED DAILY. HSG TEST SHOWED FULL BLOCKAGE AT 6 MONTHS. I CONTINUED TO BLEED DAILY. I GAINED 15 LBS. IN (B)(6) 2013, VAGINAL ULTRASOUND SHOWED COIL IN MY UTERUS. I WILL HAVE TO HAVE HYSTERECTOMY IN ORDER TO REMOVE DEVICE. I HAVE CONTINUED TO BLEED DAILY. I DO NOT WANT A HYSTERECTOMY, I FEAR THE SIDE EFFECTS OF A HYSTERECTOMY AND YET I NOW AM LEFT WITH NO CHOICE. I WOULD NOT REQUIRE A HYSTERECTOMY BUT FOR THE ESSURE DEVICE AND ITS MALFUNCTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032728	BAYER	11/8/2013	11/15/2013

Event Information:

Event Date (B3): 12/6/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/6/2011
Explant Date (E7): 9/30/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MENSTRUAL CHANGES BEGAN ALMOST IMMEDIATELY AFTER IMPLANTATION. CYCLE INITIALLY MOVED FROM ONCE EVERY 4 WEEKS, TO ONCE EVERY 3 WEEKS, EVENTUALLY ENDING WITH PERIODS IN ONE MONTH AT TIME OF HYSTERECTOMY, WITH NO MORE THAN 2 DAYS BETWEEN BLEEDING. BLEEDING BECAME UNNATURALLY HEAVY (LEAKING THROUGH A SUPER PLUS TAMPON IN LESS THAN AN HOUR), AND WAS ACCOMPANIED BY LARGE CLOTS. NEW PMS SYMPTOMS DEVELOPED: EXTREME BREAST TENDERNESS (LIKE ENGORGEMENT PAIN WHEN NURSING), NIPPLE DISCHARGE, MOOD SWINGS WITH WEEPING AND RAGE, AND MIGRAINES. ADDITIONAL ISSUES INCLUDE BLURRED VISION, MEMORY PROBLEMS, INABILITY TO CONCENTRATE, SEVERE FATIGUE, STABBING PAINS IN PELVIC AREA, MIGRAINES, JOINT PAIN (UNABLE TO MAKE A FIST), HEAT FLASHES, CONSTANT NAUSEA, CONSTANT LOWER BACK PAIN (LIKE BACK LABOR), CONSTANT ITCHINESS ALL OVER BODY AND CONCENTRATED IN THE ARMPITS, PAIN DOWN LEFT HIP AREA, RASH ON BACKS OF THIGHS. ON 3 OCCASIONS I EXPERIENCED SUCH SEVERE ABDOMINAL AND RECTAL PAIN THAT I WAS UNABLE TO WALK/SIT/URINATE/DEFECATE, WAS VOMITING AND SWEATING PROFUSELY, THESE EPISODES LASTED FOR 2 DAYS ON 2 OF THE OCCASIONS AND ALL 3 OCCURRED FOLLOWING ORGASM. HYSTERECTOMY (CERVIX, UTERUS AND TUBES) PERFORMED ON (B)(6) 2013. ALL SYMPTOMS HAVE EITHER LESSENED OR COMPLETELY RESOLVED ONCE THE ESSURE PRODUCT WAS REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032729	CONCEPTUS	11/8/2013	11/15/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CHRONIC SEVERE PELVIC AND LOWER BACK PAIN, EXTREME FATIGUE, EXCESSIVE WEIGHT GAIN, HEADACHES, HAIR LOSS, DEPRESSION, MOOD SWINGS, ETC SINCE ESSURE IMPLANTS. APPARENTLY I HAVE TO REPORT THIS QUICKLY BECAUSE YOUR SITE HAS A TIME LIMIT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032765	BAYER	11/8/2013	11/15/2013

Event Information:

Event Date (B3): 9/22/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/22/2009
Explant Date (E7): 10/29/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I CANNOT EXPRESS THE FEELING I HAVE ABOUT MY RECENT DISCOVERY. I AM NOW 9 DAYS POST OP FROM MY LAVH DONE ON (B)(6). I FOLLOWED UP WITH MY OB/GYN YESTERDAY AND DISCOVERED FROM THE PATHOLOGY REPORT THAT A "INTRAUTERINE DEVICE" WAS EMBEDDED IN MY UTERUS. OBVIOUSLY, SINCE I HAVE NEVER HAD AN IUD, THIS IS AN ESSURE COIL DESPITE THE FACT THAT I HAD A POSITIVE HSG TEST IN 2010 THAT THERE WAS A COIL IN EACH FALLOPIAN TUBE. NO WONDER THE PAIN I HAD FOR SO LONG SINCE IMPLANTED IN 2009, WAS SUDDENLY GONE. THE HEAVINESS IN MY PELVIC AREA, MY BLADDER, EVEN POST OP - I COULD FEEL A DIFFERENCE. NOW, THAT I LEARNED MY ESSURE WAS EMBEDDED IN MY UTERUS, THE REPORT IS NOT CLEAR TO ME WHERE THE SECOND COIL MIGHT BE. I AM BEING VIGILANT ABOUT LOOKING FOR THE OTHER COIL. IF BOTH WERE IN MY UTERUS, IT IS NOT CLEAR TO ME, NOR MY DOCTOR'S OFFICE AS THERE WAS NOTHING NOTED IN THE REPORT OF THE FALLOPIAN TUBES AS TO FINDING ANY COIL. I AM PRAYING THAT IT HAS NOT EMBEDDED SOMEWHERE ELSE IN MY ABDOMINAL CAVITY - SUCH AS MY COLON. I AM WAITING TO GET ORDERS FOR AN X-RAY OR OTHER TYPE OF DIAGNOSTIC TO GIVE ME PEACE OF MIND ONCE AND FOR ALL. I ALSO HAVE INFLAMMATORY BOWEL DISEASE - ULCERATIVE COLITIS, AND HAVE EXPERIENCED CONTINUOUS FLARE UPS SINCE LATE 2009 - RIGHT AFTER GETTING THE ESSURE IMPLANTS. THOSE SYMPTOMS ARE STILL FLARING AND SINCE IN AM NOT RESPONDING TO MEDICATION, MY GI DOCTOR IS RECOMMENDING A COMPLETE COLECTOMY - REMOVAL OF MY ENTIRE LARGE INTESTINE. I AM PRAYING THAT SINCE DISCOVERING THE COIL IN MY UTERUS, THAT MAYBE MY BODY WILL CALM DOWN ONCE AND FOR ALL AND BEGIN TO FINALLY HEAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032766	BAYER	11/8/2013	11/15/2013

Event Information:

Event Date (B3): 9/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 11/16/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM EXPERIENCING A NICKEL ALLERGY SINCE HAVING ESSURE TUBAL IMPLANTS PUT IN. I AM EXPERIENCING ABNORMAL CRAMPING AND BLOATING, ITCHING, AND A RASH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032769	CONCEPTUS / BAYER	11/8/2013	11/15/2013

Event Information:

Event Date (B3): 10/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 761437

Single Use:
Implant Date (E6): 10/20/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2010. I WAS IN GOOD HEALTH BEFORE THE PROCEDURE. ABOUT 1 YEAR AGO, I STARTED TO HAVE SYMPTOMS WHICH INCLUDE DAILY PELVIC PAIN, BAD MENSTRUAL PERIODS, MIGRAINES, NAUSEA, BRAIN FOG, EXTREME MOOD SWINGS, JOINT PAIN. I HAVE NEVER BEEN IN A CONSTANT STATE OF PAIN UNTIL I HAD THIS PROCEDURE. THE SYMPTOMS GET PROGRESSIVELY WORSE AS TIME GOES ON. PLEASE, PLEASE, PLEASE LISTEN TO THE HUNDREDS / THOUSANDS OF COMPLAINTS THAT ARE COMING AND HELP US WOMEN OUT!!! WE NEED THIS PRODUCT RECALLED!!!! NO QUALITY OF LIFE FOR OURSELVES AND OUR FAMILIES ARE SUFFERING BECAUSE OF IT TOO. THANK YOU.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032618	CONCEPTUS	11/8/2013	1/13/2014

Event Information:

Event Date (B3): 10/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE ESSURE INSERTION PROCEDURE, MY BODY TREMORED AND I THREW UP A FEW TIMES. AFTERWARDS, I HAD SEVERAL INFECTIONS, BLOATING AND LOWER ABDOMINAL PAIN. I HAD THEM REMOVED ON (B)(6) 2012; HOWEVER, I FOUND OUT IN (B)(6) 2013, VIA X-RAY AND CT SCAN THAT METAL PIECES WERE LEFT BEHIND IN MY BODY DURING SURGERY. I CONTINUE TO HAVE LOWER ABDOMINAL PAIN, BLOATING, DIGESTION ISSUES, FOOD SENSITIVITIES, ACNE AROUND THE BASE OF MY NECK, BLURRED EYE-SIGHT, FATIGUE AND SO FORTH. THE ONLY WAY TO FULLY REMOVE THE REST OF THE BROKEN COIL PIECES AT THIS POINT IN ORDER TO HEAL MY BODY AND PREVENT FURTHER DAMAGE (ABNORMAL GROWTHS, COILS POKING OTHER ORGANS OR ATTACHING TO OTHER ORGANS, ETC) IS VIA HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032617	CONCEPTUS	11/8/2013	1/14/2014

Event Information:

Event Date (B3): 5/22/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE OF THE COILS PENETRATED THROUGH MY FALLOPIAN TUBE CAUSING IT TO GO INTO THE MUSCLE I HAD TO HAVE A CT SCAN PERFORMED AND MY DOCTOR RECOMMENDED SURGERY TO REMOVE THE COILS. I WAS IN EXCRUCIATING PAIN SEVERE BACKACHE HORRENDOUS CRAMPING PAIN IN MY PELVIC BONE AND SHOOTING PAIN DOWN MY LEG. WHAT WAS SUPPOSED TO BE TWO DAYS OFF OF WORK HAS NOW TURNED INTO ALMOST A MONTH. I HAD SURGERY ON (B)(6) TO REMOVE THE COILS. I WOKE UP FEELING 100 BETTER THAN WHEN I HAD THE ESSURE IMPLANTED. THERE'S SOMETHING WRONG WITH THOSE ESSURE "NOTHING SHOULD" THAT MUCH PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032777		11/11/2013	11/14/2013

Event Information:

Event Date (B3): 11/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED MY ESSURE IN 2011 AND SOON EXPERIENCED ABNORMAL MENSTRUAL CYCLES RESULTING IN EXTREME BLEEDING. I ALSO HAVE HYPERSENSITIVITY IN MY RIGHT LEG AS WELL AS SEVERE INCREASE OF HEADACHES, MOOD SWINGS AND A LARGE WEIGHT GAIN. AFTER BEING TOLD I WAS 100 PERCENT BLOCKED, I BECAME PREGNANT IN 2012 WHICH RESULTED IN A MISCARRIAGE AT 13 WEEKS DUE TO A COIL PERFORATING MY UTERUS AND UNBORN CHILD. I RECENTLY HAVE HAD AN ULTRASOUND THAT SHOWS ONE COIL COMPLETELY IN UTERUS AND OTHER NO WHERE TO BE FOUND. UNFORTUNATELY I WAS GIVEN THE CHOICE TO HAVE A HYSTERECTOMY AND DUE TO MY AGE I REFUSED AS I DO NOT WANT TO BE FORCED INTO SOMETHING SO EXTREME DUE TO SOMEONE NEGLIGENCE, I WILL BE PAYING TO HAVE THESE REMOVED. I WAS ALSO NEVER INFORMED OF A NICKEL ALLERGY OR GIVEN A TEST TO VERIFY THIS ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032716	CONCEPTUS	11/11/2013	11/15/2013

Event Information:

Event Date (B3): 9/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/17/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I GOT ESSURE, I AM IN PAIN, I HAVE TWO ENLARGED OVARIES AND CYSTS THAT COVER THEM BOTH. I NOW HAVE TO GET A HYSTERECTOMY TO CORRECT THE PROBLEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032717	CONCEPTUS	11/11/2013	11/15/2013

Event Information:

Event Date (B3): 6/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/10/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2012 I HAD ESSURE DONE. IN (B)(6) 2013 WE WERE TOLD WE ARE PREGNANT. NOW IT IS (B)(6) AND NOT ONLY ARE WE PREGNANT, WE ARE PREGNANT WITH TWINS. OUR TWINS ARE DUE (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032719	CONCEPTUS	11/11/2013	11/15/2013

Event Information:

Event Date (B3): 11/6/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 623215

Single Use:
Implant Date (E6): 12/9/2009
Explant Date (E7): 11/6/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2009: I HAD ESSURE IMPLANTED BY MY GYNECOLOGIST IN THE OFFICE. IMMEDIATELY AFTER PLACEMENT, I STARTED TO HAVE SEVERE ABDOMINAL PAIN. THE PAIN WAS UNBEARABLE AND I WAS NOT ABLE TO FUNCTION UNTIL THE PAIN PASSED. THIS HAPPENED FOR 3/4 MONTHS SPORADICALLY. ON (B)(6) 2010, I WENT TO HAVE MY HSG TEST DONE. IT WAS DISCOVERED THAT THE RIGHT COIL WAS NOT IN MY TUBE. IT WAS IN MY UTERUS. THE LEFT COIL WAS PARTIALLY IN MY TUBE BUT A PIECE HAD BROKEN OFF FROM MY COIL AND THERE WAS A SMALL FRAGMENT IN MY UTERUS. ON (B)(6) 2010 I HAD SURGERY. I HAD LAPAROSCOPIC SURGERY TO LOCATE THE RIGHT COIL. IT WAS FOUND ON TOP LEFT MID SIDE OF MY UTERUS ATTACHED TO MY UTERINE WALL. THEN ALSO HAVE A TUBAL LIGATION AT THE SAME TIME. THE LEFT COIL WAS LEFT IN PLACE, IN MY TUBE. IT WAS NOT REMOVED. IN 2011, I STARTED TO HAVE SEVERE BLOATING, PELVIC PAIN, PELVIC PRESSURE, PELVIC INFLAMMATION, LARGE MENSTRUAL CLOTS, HEAVY PERIODS, EXTREME FATIGUE, MIGRAINES, MID SECTION WEIGHT GAIN, INFLAMMATION PAINFUL INTERCOURSE EXTREME PAIN, SHARP STABBING PAINS ON SIDES OF ABDOMINAL. IN 2012, I HAD BLOOD WORK DONE, NOTHING UNUSUAL BUT LOW VITAMIN D. IN 2013, I HAD PELVIC ULTRASOUND. IT SHOWED I HAD RIGHT OVARIAN CYSTS. THESE CYSTS EVENTUALLY RESOLVED. IN (B)(6) 2013, I HAD PELVIC ULTRASOUND; LEFT COIL WAS NOT SEEN. ON (B)(6) 2013, I HAD PELVIC X-RAY. IT WAS DISCOVERED THAT THE LEFT COIL HAD MIGRATED TO MY RIGHT SIDE ABDOMEN. I ALSO HAD A SMALL FRAGMENT STILL ON MY LEFT SIDE NEAR MY BLADDER. ON (B)(6) 2013 I HAD SURGERY. I HAD DIAGNOSTIC LAPAROSCOPY AND A LEFT SALPINGECTOMY DUE TO THE PELVIC PAIN I WAS HAVING. DURING SURGERY, MY DOCTOR MANAGED TO LOCATE THE COIL; IT HAD ATTACHED TO MY APPENDIX. IT WAS REMOVED. THE SMALL FRAGMENT ON MY LEFT WAS FOUND PIERCING MY UTERUS. I ALSO HAD MY LEFT FALLOPIAN TUBE REMOVED. I AM RECOVERING AT HOME FROM SURGERY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032720	BAYER	11/11/2013	11/15/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/21/2010
Explant Date (E7): 12/17/2010
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE COILS PLACED (B)(6) 2010 AND HAD CAUSED CONSTANT SEVERE PELVIC PAIN, CYSTS ON OVARY SEVERE BLOATING AND MIGRAINES. REQUIRED TOTAL HYSTERECTOMY IN (B)(6) 2010.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032721	BAYER	11/11/2013	11/15/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 822374

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2011, I DECIDED TO HAVE THE ESSURE DEVICE IMPLANTED AS A WAY TO PREVENT PREGNANCY UNDER THE ADVICE OF MY OBGYN. AFTER A COUPLE OF MONTHS, I EXPERIENCED DAILY SEVERE CRAMPING, BACK PAIN, RAPID WEIGHT GAIN, SWELLING. AFTER LESS THAN ONE YEAR, I WAS TAKEN TO THE EMERGENCY ROOM TO BE DIAGNOSED WITH LOW THYROID GRAVES DISEASE. TWO MONTHS AFTER THAT, I LOST VOLUNTARY MUSCLE CONTROL AND WAS DIAGNOSED WITH MYASTHENIA GRAVIS AND HASHI MOTOS DISEASE. I NOW SUFFER FROM MUSCLE WEAKNESS, FATIGUE, DEPRESSION, ANXIETY, BLURRED AND DOUBLE VISION. CONSTANT PAIN, NAUSEA AND SEVERE HAIR LOSS TO THE POINT OF HAVING TO WEAR A WIG, CONSTANT DRY MOUTH, FREQUENT URINATION AND ANEMIA. I WAS A PERFECTLY HEALTHY, ACTIVE, STRONG MOTHER OF THREE PRIOR TO THE IMPLANTATION OF THIS DEVICE. SINCE THE IMPLANTATION, I HAVE BEEN REDUCED TO A DEPENDENT PERSON WHO CAN BARELY LIFT A GALLON OF MILK. I NOW HAVE A MEDI PORT DEVICE IMPLANTED FOR THE ADMINISTRATION OF REQUIRED IV TREATMENTS FOR THE MYASTHENIA GRAVIS THAT I HAVE DEVELOPED, AND AM ON A REGIMEN OF 28 PILLS PER DAY JUST FOR DAILY FUNCTIONALITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032722	CONCEPTUS	11/11/2013	11/15/2013

Event Information:

Event Date (B3): 11/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE PLACEMENT AT (B)(6). PROGRESSIVELY, MY HEALTH HAS DECLINED OVER THE YEARS. I AM NOW (B)(6) AND THE PAIN, NAUSEA, VOMITING, HEADACHES AND ILLNESS IS DEBILITATING. I CANNOT GO TO WORK DURING MENSES. I CANNOT WALK FOR FEAR OF ACCIDENTS AND THE PAIN DOES NOT DISSIPATE EVEN WITH HEAVY PRESCRIPTION MEDICATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032723	BAYER	11/11/2013	11/15/2013

Event Information:

Event Date (B3): 11/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/9/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CRAMPING, HEAVY BLEEDING, NAUSEA, SEVERE HEADACHES, CLOTTING, FATIGUE, JOINT PAIN, INCREASE IN ACNE, HAIR LOSS, UTI INCREASE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032724	BAYER	11/11/2013	11/15/2013

Event Information:

Event Date (B3): 8/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE COIL
Model # (E4): E205
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/19/2007
Explant Date (E7): 1/2/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN EXPERIENCING PELVIC PAIN, SEVERE BACK PAIN AND BLOATING FOR YEARS AFTER HAVING THE ESSURE PROCEDURE. HOWEVER, IN (B)(6) 2012, IT BECAME MUCH WORSE, SOMETIMES CAUSING ME NOT TO BE ABLE TO SLEEP. SINCE THEN, I HAVE HAD TWO TRANSVAG ULTRASOUNDS WHICH SHOWED INFLAMMATION OF MY CERVIX AND VARIOUS CYSTS. I ALSO WANTED TO ENSURE THAT MY COILS WERE IN PLACE, AND I SEE THAT THEY BOTH HAVE THE ENDS BROKEN OFF. I LIVE IN AN AREA WHERE NO ONE IS FAMILIAR WITH ESSURE AND MEDICAL CARE IS LIMITED. CURRENTLY, MY GYNECOLOGIST IS "RESEARCHING" BROKEN COILS. AFTER A MONTH AND A HALF OF TWO DIFFERENT ANTIBIOTICS FOR THE INFLAMMATION ON MY CERVIX, I AM STILL IN PAIN. I AM AFRAID THAT THE METAL HAS EMBEDDED SOMEWHERE BEYOND MY TUBES AND IS CAUSING INFECTIONS. I WAS NEVER TESTED FOR A NICKEL ALLERGY. ORIGINALLY, I HAD PLANNED TO HAVE MY TUBES TIED IMMEDIATELY AFTER THE BIRTH OF MY LAST CHILD, BUT WAS TOLD THE SURGERY TEAM AT THE HOSPITAL WAS TOO BUSY. THE NURSE WAS SENT DOWN TO SUGGEST THAT I DO ESSURE. PRIOR TO THAT, I HAD JUST SEEN THE POSTER IN THE MIDWIFE'S OFFICE. LATER, I HAD THE HER OPTION PROCEDURE FOR HEAVY BLEEDING IN 2009 OR 2010. THE PHYSICIAN IN (B)(6) SAID THERE WOULD BE NO PROBLEM HAVING IT AFTER THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032750	BAYER	11/11/2013	11/15/2013

Event Information:

Event Date (B3): 2/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 774372

Single Use:
Implant Date (E6): 2/2/2012
Explant Date (E7): 2/8/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS IMPLANTED WITH ESSURE ON (B)(6) 2012; RIGHT AWAY STARTED TO HAVE REACTION. HAD STOMACH SWELLING, PAIN IN ABDOMINAL AREA, MIGRAINES GOT WORSE TO THE POINT THEY THOUGHT I WAS HAVING A STROKE, EXTREME VAGINAL BLEEDING AT PERIOD TIME, SEVERE CRAMPS, LARGE BLOOD CLOTS, SEVERE FATIGUE TO WHOLE BODY, HAIR LOSS, EXTREME WEIGHT GAIN, RASHES, LONG LIST OF SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032753	BAYER	11/11/2013	11/15/2013

Event Information:

Event Date (B3): 11/18/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/18/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IMPLANTED IN 2009, I IMMEDIATELY HAD SEVERE CRAMPING AND A HEAVY CYCLE THAT LASTED WEEKS. I GOT THE HSG TEST AND IT CONFIRMED BLOCKED. MY CYCLES CONTINUED TO LAST 3 WEEKS OR MORE AND THE CRAMPING, DULL PAIN WAS CONTINUOUSLY, ESPECIALLY IF I SAT OR WALKED FOR LONG PERIOD OF TIME. I DIDN'T KNOW THAT WAS HAPPENING TO ME. I STARTED GETTING A RASH ON BOTH MY INNER THIGHS THAT JUST WON'T GO AWAY AFTER USING NUMEROUS PRESCRIBED CREAMS. I AM CURRENTLY IN A LOT OF PAIN. I GO TO THE ER AND OBGYN ALMOST EVERY OTHER WEEK. I FEEL MYSELF STARTING TO GET WORSE. MY STOMACH LOOKS AS IF I AM 7 MONTHS PREGNANT AND MY LAST CHILD WAS BORN 2007. I AM CURRENTLY WORKING TO GET THE ESSURE REMOVED, BECAUSE IT'S KILLING ME FROM THE INSIDE. MY UTERUS AND PELVIC AREA IS FILLED WITH SCAR TISSUE THAT CONTINUES TO GROW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032754	BAYER	11/11/2013	11/15/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE IMPLANTED, I STARTED HAVING SEVERE PAIN AND NAUSEA. I WAS DIAGNOSED WITH ENDOMETRIOSIS. THE FATIGUE AND NAUSEA HAS BEEN DEBILITATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032755		11/11/2013	11/15/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/9/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED ESSURE COILS IN (B)(6) 2009, 4 MONTHS OR SO LATER, I STARTED TO COMPLAIN ABOUT HORRIBLE ABDOMINAL PAIN WHERE THE COILS WERE PLACED. MY DOCTOR HAD ME COME IN AND I STATED TO HIM I WAS IN PERFECT HEALTH BEFORE THIS PROCEDURE. HE PRESCRIBED ME IBUPROFEN 800. I TOOK THEM FOR A WHILE AND STOPPED BECAUSE I DIDN'T WANT THE MEDS TO BECOME IMMUNE TO MY BODY AND I WILL HAVE TO GO TO A STRONGER MEDICATION. I CONTINUED TO COMPLAIN AND MY OB SET UP AN ULTRASOUND VISIT. THE TECH SAID SHE DIDN'T SEE ANYTHING ABNORMAL. I WENT BACK TO MY DOCTOR AND HE SAID ONLY THING HE CAN DO IS A HYSTERECTOMY. I WENT TO SEE MY PRIMARY DOCTOR AND HE TOLD ME THAT SINCE IT'S A FOREIGN OBJECT IN MY BODY, MY BODY IS TRYING TO REJECT IT, SO THAT'S WHY I'M EXPERIENCING SO MUCH PAIN. I WENT BACK TO MY OB AND HE BASICALLY SAID IT'S NOTHING HE CAN DO. MY PAIN LASTS FOR 30 MIN TO HOURS AT A TIME. I CAN'T WALK, WORK, CARE FOR MY FAMILY OR THINK WHEN THE PAIN IS GOING ON. IT'S VERY DANGEROUS FOR ME TO DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032756		11/11/2013	11/15/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/10/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IN 2012, AND HAVE SINCE GAINED 30 POUNDS DESPITE A HEALTHY LIFESTYLE, EXPERIENCED EXTREME ABDOMINAL PAIN, EXTREME BLEEDING WORSE THAN AFTER CHILDBIRTH, HORRIBLE MIGRAINES. I'M CURRENTLY WAITING FOR AN HSG TO CHECK COIL PLACEMENT 1, AND TRYING TO HAVE THEM REMOVED. THIS DEVICE HAS TAKEN MY LIFE AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032758	BAYER / CONCEPTUS	11/11/2013	11/15/2013

Event Information:

Event Date (B3): 11/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A06689

Single Use:
Implant Date (E6): 6/10/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE IMPLANTED (B)(6) 2013. SINCE THEN, HAVE HAD LEG AND NOW ARM WEAKNESS, PANIC ATTACKS, MISSED WORK DUE TO EXTREME FATIGUE AND WEAKNESS. MRI REPORTS THAT SHOW A NEUROLOGICAL CHANGE IN THE MYELIN OF MY SPINAL CORD AT T11-T12. THE IMPLANT ON MY LEFT SIDE HAS BEEN REJECTED BY MY BODY AND I AM NO LONGER PROTECTED AGAINST PREGNANCY. EXTREME PAIN WITH INTERCOURSE. DIFFICULTY WITH CRAMPING AND PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032759		11/11/2013	11/15/2013

Event Information:

Event Date (B3): 11/9/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/31/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IMPLANTED IN ME, (B)(6) 2012. SINCE THEN, I HAVE HAD EXTREME BLOATING IN MY ABDOMEN AREA. MY STOMACH SWELLS UP TO WHERE I LOOK 7-8 MONTHS PREGNANT. IT LITERALLY FEELS EXACTLY SIMILAR TO A BABY PUSHING ON MY RIB CAGE SO HARD THAT ITS DIFFICULT TO BREATH. WHICH IN ADDITION, CAUSES DIZZINESS, HEADACHES, BLURRED VISION, AND FEELING LIKE I AM ABOUT TO BLACKOUT. THE BLOATING CAN LAST ANYWHERE FROM 1 DAY TO A WEEK AND THEN MY ABDOMEN AREA WILL JUST GO COMPLETELY FLAT UNTIL IT COMES BACK AGAIN. THIS HAS HAPPENED EVERY WEEK SINCE I HAVE RECEIVED THE ESSURE. I HAVE NEVER HAD ANY ABNORMAL MEDICAL PROBLEMS UNTIL I RECEIVED ESSURE. I GOT THE ESSURE SO I WOULD NOT HAVE TO EXPERIENCE THE SYMPTOMS OF PREGNANCY EVER AGAIN AND THE RESULT HAS BEEN THE COMPLETE OPPOSITE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032751	CONCEPTUS	11/11/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/10/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTS IN (B)(6) 2009 AND HAVE HAD UNEXPLAINED SYMPTOMS EVER SINCE THE PROCEDURE. SYMPTOMS INCLUDE ABDOMINAL / BACK PAIN IRREGULAR PERIODS AND CONSTANT REOCCURRING INFECTIONS. THESE PROBLEMS DID NOT START UNTIL A FEW MONTHS AFTER PROCEDURE WAS DONE. I HAVE BEEN TO THE DOCTOR SEVERAL TIMES ABOUT THE PAIN AND DISCHARGE THAT SEEM TO HAVE BEEN CONSTANT SINCE THE COILS WERE PUT IN PLACE. MY DOCTOR SAYS IT CAN NOT BE CAUSED FROM THAT BUT THOUSANDS OF WOMEN ARE REPORTING THE SAME KIND OF PROBLEMS THAT I HAVE BEEN EXPERIENCING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032752	BAYER	11/11/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT OVER FIVE YEARS AGO AND HAVE BEEN IN EXCRUCIATING PAIN, DEVELOPED A NICKEL ALLERGY. BEEN SUFFERING FROM HEADACHES AND UNEXPLAINED WEIGHT GAIN, DIZZINESS AND FATIGUE. THE PAIN HAS GOTTEN SO BAD THAT NOW I AM BEING TOLD I NEED A HYSTERECTOMY BECAUSE DOCTORS DO NOT KNOW ANY OTHER WAY TO REMOVE THE IMPLANT AND I DO NOT HAVE (B)(6) TO PAY TO GET IT TAKEN OUT BY (B)(6). PLEASE HELP ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032757	CONCEPTUS / BAYER	11/11/2013	11/18/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS FITTED WITH ESSURE DEVICE IN YEAR 2000 AS A TRIAL RECEIPT. HAVE SUFFERED SIDE EFFECTS SUCH AS BLOATING, EXCESSIVE WEIGHT GAIN, DESPITE HEALTHY DIET, REGULAR EXERCISE, DEPRESSION, ANXIETY, MILD HAIR LOSS AND OVARIAN CYSTS. DESPITE DYE TEST CONFIRMING FULL BLOCKAGE, RECENT ULTRA SOUNDS, CT SCANS AND X-RAYS HAVE CONFIRMED OVARIAN CYST, KIDNEY CYST (LEFT SIDE). SCARRING ON RIGHT KIDNEY. COIL ON RIGHT SIDE WAS NOT PICKED UP ON SAID SCAN. PRESUMED MISSING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032866	CONCEPTUS INC.	11/11/2013	11/18/2013

Event Information:

Event Date (B3): 4/10/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/10/2012
Explant Date (E7): 10/12/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALMOST IMMEDIATELY AFTER HAVING ESSURE IMPLANTED, I STARTED TO EXPERIENCE SEVERE PAIN IN MY ABDOMEN. TROUBLE AND PAIN WHEN URINATING. SEVERE PAIN DURING AND AFTER INTERCOURSE. EXTREME WEIGHT GAIN (60 LBS IN TWO MONTHS).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032867	CONCEPTUS INC	11/11/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE: LOTS OF PAIN EVEN AFTER A YEAR. DOCTOR PERFORATED MY CERVIX AND PUNCTURED MY BLADDER. TOO MANY PROBLEMS WITH THIS PRODUCT, CAN'T AFFORD TO HAVE REMOVED OR I WOULD. SOMETHING NEEDS TO BE DONE WITH THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032868	CONCEPTUS, INC.	11/11/2013	11/18/2013

Event Information:

Event Date (B3): 12/17/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(4) 2012, I HAD THE ESSURE PROCEDURE DONE WHICH THE DOCTOR INFORMED ME THAT I CANNOT GET PREGNANT BUT SIX MONTHS LATER HERE I AM PREGNANT AGAIN AND MY LIFE HAS BEEN IN UTTER PAIN EVER SINCE, ABDOMEN PAIN, HEADACHES, STOMACH PAIN, CAN NOT MOVE; SOMETIMES HAD TO BE HOSPITALIZED FOR FOUR DAYS BUT DOCTOR COULD NOT TELL ME ANYTHING DUE TO ME BEING PREGNANT. I REALLY FEEL THAT THIS SITUATION NEEDS TO BE HANDLE BECAUSE I AM NOT THE ONLY ONE IN THIS SITUATION OBVIOUSLY. MAJOR CORPORATIONS ARE NOT TELLING PTS THE SERIOUS SIDE EFFECTS OF THIS PROCEDURE AND IT'S VERY MISLEADING. PLEASE TAKE IT OFF THE MARKET BEFORE DEATH BECOMES A FACTOR. THANK YOU.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032869	CONCEPTUS	11/11/2013	11/18/2013

Event Information:

Event Date (B3): 9/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 948836

Single Use:
Implant Date (E6): 5/21/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONCE I RECEIVED ESSURE, I STARTED TO LOSE MY HAIR. I DEVELOPED ANXIETY, PELVIC PAIN; HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032870	CONCEPTUS, INC.	11/11/2013	11/18/2013

Event Information:

Event Date (B3): 11/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I HAD THE ESSURE PLACED I HAVE HAD ABDOMINAL SPASMS/TWITCHING/KICKING SENSATIONS, ANXIETY, BACK PAIN, BLEEDING, SPOTTING AFTER SEX, BLOOD CLOTS, BODY ACHES AND PAINS, BREAST PAIN, BRUISING (UNEXPLAINED/EASILY), YEAST INFECTIONS, CHEST PAINS, DIZZINESS, PAINFUL PERIODS, PAINFUL INTERCOURSE, FATIGUE, GASTROINTESTINAL ISSUES, LOSS OF LIBIDO, EXCESSIVE BLEEDING DURING PERIODS, MIGRAINES/HEADACHES, MUSCLE SPASMS, NAUSEA, PELVIC PAIN, SEVERE BLOATING WEIGHT GAIN, AND HAIR LOSS. I NEVER HAD ANY OF THESE ISSUES BEFORE I HAD THE ESSURE PROCEDURE DONE. NO DOCTORS WOULD EVEN CONSIDER ESSURE AS THE ISSUE. I HAVE BEEN IN THE HOSPITAL WITH PAIN, I ALMOST FELT I WAS DYING THE PAIN WAS SO HORRIBLE AT ONE POINT AND I HAD BLOODY STOOLS FOR 3 WEEKS. MY GUESS IS THAT ONE OF THE COILS HAS DAMAGES MY INSIDES AND IT MOVED AND PUNCTURED SOMETHING. WILL BE GETTING TESTS DONE TO PROVE. HAD PROCEDURE ON (B)(6) 2010.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00041	BAYER HEALTHCARE LLC	11/12/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION ()
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON AN UNSPECIFIED DATE A CONSUMER HAD ESSURE INSERTED. CONSUMER REPORTED THAT 18 MONTHS AFTER HAVING THE PROCEDURE DONE, SHE EXPERIENCED HORRIBLE PAIN AND AN INFLAMMATORY SYSTEMIC CASCADE. SHE HAD TO HAVE A HYSTERECTOMY TO REMOVE THE INSERTS, ONE OF WHICH HAD PERFORATED HER UTERUS.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# F

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032832	BAYER	11/12/2013	11/18/2013

Event Information:

Event Date (B3): 7/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/24/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTATION IN 2009. NOW SUFFER EXTREME BLOATING, ABDOMINAL AND SIDE WALL PAIN THAT MAKES IT DIFFICULT TO WALK, EXCESS SCAR TISSUE ATTACHING TO OTHER ORGANS, EXCESSIVE BLEEDING, NAUSEA SOME DAYS AND BOWEL ISSUES, PELVIC INFLAMMATION, VITAMIN DEFICIENCIES DUE TO NICKEL TOXICITY (WHICH (B)(6) STATES NICKEL CAUSES CANCER AND BIRTH DEFECTS), NO ALLERGY TEST PERFORMED - NOR WAS I TOLD THAT NICKEL IN UNDER (B)(6). TEETH ARE LOOSENING, EXTREME FATIGUE, DEPRESSION, MEMORY ISSUES, HIP AND THIGH NUMBNESS, FLU-LIKE SYMPTOMS THAT DO NOT GO AWAY FOR A YEAR. AND NOW CLOSE TO LOSING ALL MY FEMALE ORGANS DUE TO ESSURE IMPLANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032836	BAYER	11/12/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/10/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I GOT THE ESSURE, I HAVE HAD SO MANY SYMPTOMS FROM BLEEDING (2-3 PERIODS A MONTH FOR A YEAR) TO CRAMPING (FEELS LIKE LABOR PAINS). I AM GETTING A HYSTERECTOMY ON (B)(6) 2013 DUE TO THE ESSURE. I AM ONLY (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032837	BAYER	11/12/2013	11/18/2013

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/23/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PAIN UTERUS AREA, BACK PAIN, HOT FLASHES, NAUSEA. I CAN'T AFFORD THE MEDICAL TREATMENT. GOING IN 2 YEARS WITH ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032838	CONCEPTUS, INC.	11/12/2013	11/18/2013

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/11/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED IN 2011. SINCE THEN I'VE HAD SEVERE PAIN IN THE PELVIC AREA, MIGRAINE HEADACHES, BACK PAIN, ONE INFECTION AFTER ANOTHER (YEAST), HEAVY PAINFUL PERIODS WITH HUGE CLOTS, PAINFUL SEXUAL INTERCOURSE, RASHES THAT CAN'T BE EXPLAINED, JUST CONSTANT SEVERE PAIN THAT AFFECTS MY DAILY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032839	CONCEPTUS, INC.	11/12/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/14/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE A LOT OF PAIN IN MY LEFT HIP. I HAVE BEEN TO AN ORTHOPEDIC AND A CHIROPRACTOR AND BOTH SAID NOTHING CAME BACK ON XRAYS BUT A LOT OF INFLAMMATION. NEVER HAD THIS PAIN UNTIL I GOT ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032840	CONCEPTUS, INC.	11/12/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/5/2009
Explant Date (E7): 8/5/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS PREGNANT WITH TWINS; THEY SAID I HAD A MISCARRIAGE AND THEN DISCOVERED I HAD A TUBAL. AFTER THEY DID SURGERY, BECAUSE OF THE TUBAL, THE DOCTORS TALKED ME INTO THE ESSURE PROGRAM SAYING I WAS TOO YOUNG FOR A HYSTERECTOMY AND THAT IF I GOT PREGNANT AGAIN IT COULD HURT ME. SO I DECIDED TO LET THEM DO THE PROCEDURE. NO ONE CHECKED MY PROCEDURE. ABOUT A YEAR AND A HALF AFTER THE PROCEDURE I GOT PREGNANT AGAIN AND ANOTHER TUBAL. THIS TIME THEY REMOVED MY TUBES. I STILL HAVE PAIN DOWN IN THAT REGION ON BOTH SIDES. MY FIRST TUBAL WAS ON THE LEFT SIDE AND THEY ONLY IMPLANTED ON THE RIGHT SIDE. WHY TALK ME INTO THIS PROCEDURE THEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032842	CONCEPTUS, INC.	11/12/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE PAIN ON MY RIGHT SIDE ALL THE TIME SINCE IT HAS HEALED BUT DOCTOR WON'T LISTEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032843	CONCEPTUS, INC.	11/12/2013	11/18/2013

Event Information:

Event Date (B3): 9/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/17/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED (B)(6) 2010 WITH THERM ABLATION. I HAVE NOTHING BUT CONSTANT ABDOMINAL PAIN, SPOTTING, PAINFUL SEX. SOMETIME I AM UNABLE TO GET OUT OF BED BECAUSE THE PAIN IS SO DEBILITATING. I DON'T HAVE INSURANCE TO BE ABLE TO GET THE PROPER CARE I NEED. SO I TRY TO GET THROUGH THE BEST I CAN. I DON'T KNOW IF THIS IS WHAT IS CAUSING ME TO HAVE EXTREME PAIN FUL SENSITIVITY TO MY NIPPLES, BUT IT STARTED A COUPLE WEEKS AFTER I GOT MY PROCEDURE DONE, AND HAS GOTTEN WORSE OVER TIME. GETTING ESSURE WAS THE WORSE DECISION I'VE EVER MADE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032844	CONCEPTUS, INC.	11/12/2013	11/18/2013

Event Information:

Event Date (B3): 8/12/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A96182

Single Use:
Implant Date (E6): 8/12/2013
Explant Date (E7): 11/6/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I OPTED FOR THE ESSURE PROCEDURE. I WAS IN CONSTANT PAIN AND DISCOMFORT. I HAD SHARP STABBING SHOOTING PAIN THROUGH MY VAGINAL AND PELVIC AREA EVERYDAY! I OPTED FOR THIS BECAUSE I HAVE 3 KIDS AND DIDN'T WANT ANY MORE. WITH THIS PROCEDURE THERE'S NO DOWNTIME-YEAH RIGHT, I WAS OUT OF WORK 3 WEEKS AND DID I MENTION I'M A MOM? AND WHEN I DID GO BACK I WAS STILL IN EXCRUCIATING PAIN. AFTER NUMEROUS DOCTOR VISITS AND MRI'S AND TESTS TRYING TO FIGURE OUT WHAT WAS WRONG, I ENDED UP HAVING A HYSTERECTOMY ON (B)(4) 2013, TO GET THESE (B)(4) COILS OUT OF MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032845	CONCEPTUS, INC.	11/12/2013	11/18/2013

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/12/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE SEVERE LEFT ABDOMEN PAIN DUE TO ESSURE. MY DOCTOR SAID REMOVAL IS NOT AN OPTION EXCEPT BY HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032846	BAYER	11/12/2013	11/18/2013

Event Information:

Event Date (B3): 7/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 646514

Single Use:
Implant Date (E6): 7/1/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN I GOT THE ESSURE, I STARTED GETTING HORRIBLE MIGRAINES ALMOST ON A DAILY BASIS, LOWER AND MID REGION STOMACH PAIN ON AVERAGE THREE WEEKS OUT OF THE MONTH, NO MATTER HOW MUCH REST I GET. I AM ALWAYS TIRED, I GET VERY DIZZY AND STOMACH IS ALMOST ALWAYS UP SET. I ALSO GET VERY SHAKY AND GET VERY WEAK IN THE KNEES WHEN THIS HAPPENS. I HAVE TO STOP WHATEVER I AM DOING AND JUST REST BECAUSE IT FEELS LIKE IF I DON'T JUST LAY DOWN I WILL JUST PASS OUT AT ANY MOMENT. THERE HAVE BEEN TIMES WHEN I WAS DRIVING THAT THIS HAS HAPPENED AND I HAVE HAD TO PULL OVER AND WAIT UNTIL IT PASSES. SINCE I HAVE HAD THE ESSURE I HAVE MAYBE ONE WEEK OUT OF THE MONTH WITHOUT THESE SYMPTOMS. THE ESSURE HAS STOLE MY LIFE AND SERIOUSLY AFFECTED ITS QUALITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032854		11/12/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE COILS WERE PUT IN, I HAVE HAD CRAMPING, EXTREME BLEEDING, BLOATING, WEIGHT GAIN, HAIR LOSS, ACNE. WHEN THEY WERE PUT IN, I BLED EXCESSIVELY FOR FOUR MONTHS AND NOW GET MULTIPLE PERIODS A MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032855	BAYER	11/12/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/8/2011
Explant Date (E7): 6/22/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS (B)(6) YEARS OF AGE WHEN I HAD THE ESSURE PLACED IN ME. IT IS A FORM OF PERMANENT BIRTH CONTROL, AND I HAD REALLY BAD SIDE EFFECTS FROM IT. NO SEX DRIVE, PAINFUL SEX. PROLONGED PERIODS UNNATURAL BLEEDING. DEPRESSION "FIGATIVE" I LOST MY LIFE FOR THOSE YEARS THE ESSURE WAS PLACED IN ME AND I AM STILL NOT FULLY BACK TO MY NORMAL SELF.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032856	CONCEPTUS	11/12/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/17/2013
Explant Date (E7): 1/2/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC/LOWER BACK PAIN, HEADACHES, PAIN DURING/AFTER SEX, SKIN IRRITATIONS, WEIGHT GAIN (30 LBS) HAVE HAD TO LEAVE WORK ON SEVERAL OCCASIONS DUE TO PAIN. SEX LIFE HAS SUFFERED DUE TO NOT BEING ABLE TO UNLESS I WISH MY PAIN TO BE 100X WORSE WHICH I DO NOT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032857		11/12/2013	11/18/2013

Event Information:

Event Date (B3): 7/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 632032

Single Use:
Implant Date (E6): 7/15/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE PUT IN, I'VE HAD SEVERE ANXIETY, DEPRESSION, HEADACHES, EXTREMELY HEAVY PAINFUL PERIODS, MOOD SWINGS, NIGHT SWEATS, CAN'T SLEEP, EXTREME FATIGUE, GAINED 40 POUNDS, CAN'T LOSE WEIGHT, BLOATING, SHOOTING PAINS WHERE THE COILS ARE PLACED AND YES I CAN FEEL THEM. LEG PAIN, DIZZINESS, LIGHT HEADED, BLURRED VISION, HEARTBURN/ACID REFLEX, OILY SKIN, ACNE PROBLEMS THAT I'VE NEVER HAD IN MY LIFE AND NOW HAVE AT (B)(6). AND MORE I'M SURE I AM FORGETTING TO MENTION, OH YEAH, FORGETFULNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032858	BAYER	11/12/2013	11/18/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD ESSURE SINCE (B)(6) 2013 AND I HAVE HAD EXCRUCIATING PAIN SINCE DAY ONE. I FEEL LIKE THERE IS A BLENDER INSIDE OF MY VAGINA JUST TEARING EVERYTHING UP. IF I HAVE AN ORGASM I CAN FEEL MY COILS MOVING, IF I STRETCH I CAN FEEL THEM, AND I HAVE BAD INFLAMMATION. I AM CONSTANTLY BLOATED AND CAN BARELY MAINTAIN AN OK DIET. I CRAMP SO BAD THAT I AM IN CONSTANT TEARS AND WHEN MY "PERIOD" COMES, IT IS ALWAYS OFF SCHEDULE AND 2-3 WEEKS AT A TIME. I HAVE ASKED MY DOCTOR AND HE SAYS THERE ARE NO SIDE AFFECTS. I ALSO HAD A D&C WITH MY PROCEDURE WHICH I WAS NOT AWARE OF UNTIL AFTER THE FACT. I ALSO WAS NOT AWARE THAT IT WAS ACTUALLY SURGERY, MY DOCTOR TOLD ME THAT IT WAS DONE IN THE OFFICE WITH NO PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032859	CONCEPTUS / BAYER	11/12/2013	11/18/2013

Event Information:

Event Date (B3): 9/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 683283

Single Use:
Implant Date (E6): 9/3/2010
Explant Date (E7): 9/4/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) OF 2010. MY SIDE EFFECTS BEGAN ALMOST IMMEDIATELY WITH HEAVY AND IRREGULAR MENSTRUAL BLEEDING, SEVERE PELVIC PAIN, DIZZY SPELLS, SKIN RASHES, WIDESPREAD CHRONIC INFLAMMATION, WIDE SPREAD CHRONIC PAIN, WEIGHT GAIN, SEVERE BLOATING AND MIGRAINES. I WAS DIAGNOSED WITH FIBROMYALGIA IN (B)(6) OF 2012. DUE TO THE SEVERE PELVIC PAIN MY GYNECOLOGIST PERFORMED A TOTAL HYSTERECTOMY ON (B)(6) OF 2013. AT THE AGE OF (B)(6), I HAD MY HYSTERECTOMY TO REMOVE THE ESSURE COILS. STARTING THE NIGHT AFTER SURGERY, MY SYMPTOMS BEGAN TO DISAPPEAR. I AM NOW COMPLETELY SYMPTOM FREE AND I NEVER HAD FIBROMYALGIA. MY SYMPTOMS HAVE BEEN ATTRIBUTED TO AM ALLERGY TO NICKEL. I WAS NEVER ALLERGIC TO NICKEL BEFORE HAVING THE ESSURE PLACED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032860	CONCEPTUS	11/12/2013	11/18/2013

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/21/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM A (B)(4) YEAR OLD FEMALE. I HAVE 6 CHILDREN. AFTER THE BIRTH OF MY LAST CHILD (BORN (B)(6) 2013) I HAD ESSURE IMPLANTED IN ME ON (B)(6) 2013. SINCE RECOVERY AFTER THE PROCEDURE, I HAVE BEEN HAVING MANY PROBLEMS. WHICH I TOOK UP WITH MY OB/GYN. HE GAVE ME A SAMPLE OF BIRTH CONTROL PILLS TO TAKE TO CONTROL MY VERY HEAVY BLEEDING DURING MENSTRUATION. HE STATED THAT IF MY HEAVY BLEEDING CONTINUES THAT HE WILL PERFORM A D&C. I HAVE SEVERAL SMALL OVARIAN CYSTS ON MY OVARIES. ALL THESE ISSUES, I HAVE NEVER HAD. THAT IS UNTIL ESSURE WAS IMPLANTED IN ME. MY MENSTRUAL CYCLES HAVE ALWAYS BEEN MODERATE. SINCE ESSURE THEY HAVE BEEN VERY HEAVY AND SOMETIMES LAST UP TO TWO WEEKS. I'M ALWAYS BLOATED ON MY LOWER ABDOMINAL AREA. PEOPLE ALWAYS ASK, IF I'M PREGNANT. I'M USUALLY VERY GOOD ABOUT LOSING MY BABY WEIGHT. I'M THIN ELSEWHERE EXCEPT MY PELVIC AREA. I HAVE PAIN WHERE THE COILS ARE. I FEEL PREGNANT MOST OF THE TIME AND SICK. AND I BELIEVE ALL THIS COMES DOWN TO ESSURE. BEFORE ESSURE I WAS HEALTHY AND I NEVER HAD ANY KIND OF MEDICAL OR GYNECOLOGICAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032861		11/12/2013	11/18/2013

Event Information:

Event Date (B3): 5/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/4/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED IN 2011 AND HAVE NOTHING BUT CHRONIC PAIN, BLOATING, METALLIC TASTE, MIGRAINES AND MANY MORE TO LIST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032863		11/12/2013	11/18/2013

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A20063

Single Use:
Implant Date (E6): 10/25/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE COILS IMPLANTED (B)(6) 2012, IMMEDIATELY EXPERIENCED BACK PAIN. WHEN I TOLD THE DOCTOR ABOUT BACK PAIN ONE WEEK POST OP, I WAS TOLD IT WAS FROM MY BODY GETTING USED TO THE COILS. BACK PAIN HAS CONTINUED TO GET WORSE, SOME DAYS I AM UNABLE TO WALK. OVER TIME I HAVE EXPERIENCED PELVIC PAIN, NOW ON A DAILY BASIS, HAIR LOSS, BLOATING, GASTROINTESTINAL ISSUES, JOINT PAIN, DEPRESSION, WEIGHT GAIN, SWELLING OF THE FEET AND ANKLES. WAS TOLD AFTER ULTRASOUND THAT I HAVE AN INVERTED UTERUS. IN 2011 WAS DIAGNOSED WITH HEMOCHROMATOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032619	CONCEPTUS	11/12/2013	1/14/2014

Event Information:

Event Date (B3): 9/19/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2008. APPROXIMATELY A YEAR AFTER I BEGAN TO GET DEBILITATING MIGRAINES, RIGHT SIDE STOMACH PAIN, RASHES AND CHRONIC FATIGUE AND BY 2 YEARS AFTER IMPLANTS MY HEALTH DECLINED DRAMATICALLY. I HAD A BLADDER INFECTION AT LEAST EVERY 2 MONTHS, SHARP PAIN DOWN MY RIGHT LEG, FINGERS AND TOES STARTED TO GO NUMB, CONSTANT HEARTBURN, BRAIN CLOUDINESS/FORGETFUL, BAD BOILS ALL OVER, SEVERELY BLOATED, GAINED 75+ LBS OVER 2 YEARS, ALOT OF DENTAL ISSUES, MOOD SWINGS, NIGHT SWEATS, HEART PALPITATIONS, PERIODS GOT HEAVIER EVERY MONTH, SEVERE CRAMPING, BACK PAIN, I WOULD LEAK FLUID RANDOMLY (NOT URINE) AND I WAS LOSING HAIR AT AN ALARMING RATE. I NEVER HAD ANY HEALTH ISSUES IN MY LIFE! ALL OF THESE CAME ABOUT AFTER ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032880	BAYER	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 4/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE TUBAL OCCLUSION
Device Type (E2): ESSURE TUBAL OCCLUSION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2011
Explant Date (E7): 4/25/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE (B)(6) YEAR OLD FEMALE, WHO PRESENTED WITH A HISTORY OF IRREGULAR BLEEDING AND PELVIC PAIN. PT STATED THAT SHE HAD AN ESSURE TUBAL OCCLUSION PROCEDURE DONE IN (B)(6) 2011 BY A PROVIDER IN A DIFFERENT CITY. SHE STATED THAT SHE TOLD HER DOCTOR THAT SHE WAS ALLERGIC TO MOST METALS AND HER DOCTOR SAID THAT THERE WAS NOT ENOUGH NICKEL IN THE COILS TO CAUSE A REACTION. PT STATED THAT SINCE HAVING THAT PROCEDURE SHE HAD BEEN HAVING PELVIC PAIN, CRAMPING IN NATURE. STATED THAT OVER THE PAST FEW MONTHS IT HAD GOTTEN WORSE AND BECOME ALMOST A CONSTANT, SEVERE CRAMPING PAIN IN HER PELVIS. HAD ALSO BEEN HAVING IRREGULAR BLEEDING SINCE THE ESSURE WAS PLACED. WAS PUT ON DEPO-PROVERA TO TRY TO CONTROL THE BLEEDING. STATED THIS DID NOT HELP. PT TAKEN TO SURGERY ON (B)(6) 2013, FOR LAPAROSCOPIC BILATERAL SALPINGECTOMY AND ESSURE COIL REMOVAL. DURING SURGERY IT WAS FOUND THAT THE ESSURE COIL INSERTION DEVICE (NOT JUST THE COILS) HAD BEEN LEFT IN THE PT'S BILATERAL FALLOPIAN TUBES. THERE WAS EVIDENCE OF CHRONIC INFLAMMATION. BOTH TUBES AND ALL FOREIGN BODIES WERE COMPLETELY REMOVED. SINCE THEN PT HAS HAD PROBLEMS WITH RECURRENT INFECTIONS AND CHRONIC PAIN AND IS LIKELY GOING TO NEED A HYSTERECTOMY. I DO NOT HAVE AVAILABLE THE PRODUCT, LOT, EXPIRATION DATE, ETC. ADDITIONAL INFO: DIAGNOSIS OR REASON FOR USE: PERMANENT STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032889	CONCEPTUS, INC.	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD ESSURE SINCE 2008. I HAVE BEEN IN AND OUT OF THE HOSPITAL WITH UTI INFECTIONS, I HAVE VERY BAD ABDOMINAL PAIN, SEVERE HEADACHES. I HAVE GONE TO THE HOSPITAL AND THEY TOLD ME ONE OF MY KIDNEYS IS SMALLER THAN THE OTHER. I HAVE NEVER HAD SO MANY MEDICAL PROBLEMS SINCE I HAVE GOTTEN THIS ESSURE PUT IN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032890	CONCEPTUS	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 9/19/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/19/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE ESSURE I'VE HAD A LOT OF PROBLEMS INCLUDING EXCRUCIATING CRAMPS WHILE NOT ON MENSTRUAL CYCLE, HORRIBLE MIGRAINES, HAIR LOSS, MOOD SWINGS, WEIGHT GAIN, AND BAD BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032891	CONCEPTUS	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 6/6/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 623826

Single Use:
Implant Date (E6): 6/7/2007
Explant Date (E7): 1/16/2008
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS FOR BIRTH CONTROL ON (B)(6) 2007. AFTER THAT CONSTANT PAIN, BLEEDING, DISCHARGE, NUMEROUS DOCTOR VISITS AND MEDICATIONS USED FOR IT. NONE HELPED. AFTER 7 MONTHS I HAD TO HAVE A HYSTERECTOMY TO HAVE THEM REMOVED. THE DOCTOR THAT PUT THEM IN WOULD NOT TAKE THEM OUT SO I HAD TO BEG NUMEROUS DOCTORS TO SEE ME TO TRY TO GET THEM OUT TO STOP THE EXCRUCIATING PAIN. THE COMPANY THAT MADE THEM WOULD NOT ACKNOWLEDGE THERE WAS A PROBLEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032892	CONCEPTUS	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 8/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/24/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THIS MEDICAL DEVICE ON (B)(6) 2011. THE ACTUAL IMPLANT PROCEDURE WENT SMOOTH. I WAS IN AND OUT OF THE DOCTOR'S OFFICE WITHIN AN HOUR. THREE MONTHS LATER, I WENT FOR MY HSG TEST AND BLOCKAGE OF OVARIES WAS CONFIRMED. APPROXIMATELY THREE MONTHS LATER, I BEGAN TO EXPERIENCE THE FOLLOWING SYMPTOMS: HEADACHES, HEAVY BLEEDING DURING MENSTRUAL CYCLE, EXTREME PELVIC PAIN, LOWER BACK PAIN, STABBING PAIN ON SIDES, HAIR LOSS, BRAIN FOG, MOOD SWINGS, FATIGUE, ANXIETY, AND DEPRESSION. I RECENTLY FOUND OUT THAT I WASN'T SUPPOSED TO HAVE THIS PROCEDURE DONE AS I ALSO SUFFER FROM AN AUTOIMMUNE DISORDER AND HAVE A TILTED UTERUS. MY DOCTOR NEVER ADVISED AGAINST GETTING THIS DONE. A LOT OF MY SYMPTOMS CAN BE ATTRIBUTED TO MY AUTOIMMUNE DISORDER, HOWEVER, ACCORDING TO MY RHEUMATOLOGIST, MY LAB WORK COMES OUT FINE AND IT APPEARS THAT IT'S UNDER CONTROL. IT'S ONLY AFTER HAVING THIS MEDICAL DEVICE IMPLANTED THAT I BEGAN TO FEEL LIKE MY LIFE IS FALLING APART AND I AM CONVINCED IT'S ESSURE RELATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032893	CONCEPTUS	11/13/2013	11/19/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2009. SINCE THEN I HAVE HAD CRAMPING THAT HAS WORSENED OVER THE YEARS TO THE POINT WHERE NOW, FOUR YEARS LATER I AM IN CONSTANT PAIN 95% OF THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032894	CONCEPTUS	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 7/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/31/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED (B)(6) 2013. WHEN I WENT IN FOR MY DYE TEST ON (B)(6) TO CHECK FOR BLOCKAGE, THE LEFT COIL WAS NOT IN THE FALLOPIAN TUBE ANYMORE BUT SOMEWHERE IN MY UTERUS. THE RIGHT TUBE IS BLOCKED BUT I HAVE BEEN EXPERIENCING LOWER ABDOMINAL PAIN IN THAT AREA FOR OVER A MONTH NOW. I HAVE ALSO BEEN EXPERIENCING ALL OVER JOINT PAIN SINCE THE IMPLANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032895	CONCEPTUS	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 6/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/10/2011
Explant Date (E7): 2/5/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

JUNE 2011 I HAD THE ESSURE PERMANENT BIRTH CONTROL DEVICE IMPLANTED IN BOTH FALLOPIAN TUBES. PRIOR TO ESSURE, I RECEIVED ANNUAL PHYSICALS WITH NO REPORT OF ANY HEALTH ISSUES/CONCERNS. SINCE (B)6) 2011, I HAVE EXPERIENCED SEVERE MIGRAINES, PELVIC PAIN, ABDOMINAL PAIN, MUSCLE AND JOINT PAIN, BLURRED VISION, BLACK OUTS WITH NO RECOLLECTION OF OCCURENCE, LOWER AND UPPER BACK PAIN, FATIGUE, CONSTANT METAL TASTE IN MY MOUTH AND ELECTRIC SHOCK WHEN I TOUCHED ANYTHING. I WAS DIAGNOSED WITH A HYPERACTIVE THYROID, HIGH BLOOD PRESSURE, DEPRESSION, THERE IS CURRENTLY A HOLE IN MY HEART AND I HAVE MANY BLOOD CLOTS IN MY BODY RESULTING IN HAVING TO TAKE BLOOD THINNERS FOR THE REST OF MY LIFE. AFTER A YEAR AND A HALF OF UNBEARABLE PAIN, I HAD AN ALLERGY TEST AND IT WAS DETERMINED I WAS ALLERGIC TO NICKEL AND MY BODY WAS HAVING A TOXIC REACTION TO THE ALLERGY. ON (B)(6) 2013, I HAD A HYSTERECTOMY TO HAVE THE METAL COILS REMOVED. I CURRENTLY HAVE MIGRAINE HEADACHES, DIGESTIVE PROBLEMS, BLURRED VISION, MUSCLE AND JOINT PAIN, BLOOD CLOTS AND A HEART CONDITION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032898	CONCEPTUS	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 7/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/30/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6) 2012. I WAS TOLD BY MY DOCTOR THAT THE SYMPTOMS AFTER THE PROCEDURE WOULD BE MILD CRAMPING THAT SHOULD GO AWAY. AFTER HAVING THE ESSURE PROCEDURE DONE I HAVE HAD CONTINUOUS SPORADIC ON THE SIDES WHERE MY OVARIES ARE. I HAVE MENTIONED THIS TO MY DOCTOR BUT THEY HAVE NOT CONCLUDED THAT IT IS THE ESSURE IMPLANT. I AM GETTING A SECOND OPINION NEXT MONTH WHEN MY INSURANCE IS EFFECTIVE. THE SYMPTOMS I AM HAVING ARE EXTREME SHOOTING PAIN SPORADICALLY THAT HITS THE AREA WHERE MY OVARIES/FALLOPIAN TUBES ARE, INCREDIBLY HEAVY MENSTRUAL CYCLES THAT LAST LONGER THAN THEY DID PRIOR TO THE IMPLANT, DIZZINESS, AND THE INABILITY TO LOSE WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032902	CONCEPTUS	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 12/15/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/15/2007
Explant Date (E7): 3/15/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS AND THE PAIN CONTINUALLY GOT WORSE OVER THE FIVE YEARS I HAD THEM. I VISITED DOCTORS AND FINALLY HAD THEM SURGICALLY REMOVED. MY PERIODS BECAME IRREGULAR AND I HAVE GAINED 30+ POUNDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032903	BAYER	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 6/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/7/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE. SINCE THIS PROCEDURE I HAVE HAD CONSTANT PAIN IN LOWER BACK, ABDOMEN PAIN AND PELVIS PAIN IN ADDITION TO MIGRAINE AND CHRONIC FATIGUE. I DID NOT HAVE THESE ISSUES UNTIL AFTER HAVING THE ESSURE PROCEDURE. ALSO SINCE ESSURE PROCEDURES, I HAVE HAD TO DEAL WITH REALLY BAD AND PERSISTANT FEMININE ODOR THAT I'VE NEVER HAD OR EXPERIENCED BEFORE HAVING THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032904	CONCEPTUS	11/13/2013	11/19/2013

Event Information:

Event Date (B3): 9/6/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/6/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN SEPT OF 2006, I HAD ESSURE IMPLANTED AS A FORM OF PERMANENT BIRTH CONTROL. I GOT PREGNANT LESS THAN A YEAR OF HAVING IT DONE AND HAD MY DAUGHTER (B)(6) OF 2007. AFTER I HAD HER, I HAD THE ESSURE TESTED THEY SAID EVERYTHING WAS GOOD TO GO. I GOT PREGNANT A SECOND TIME AFTER HAVING IT TESTED, MY SON WAS BORN (B)(6) OF 2009. AFTER THAT I HAD MY TUBE TIED AGAIN ALSO LEAVING IN THE ESSURE COILS AS WELL. I ALSO HAVE SIDE EFFECTS FROM THE ESSURE RANGING FROM SHARP PAINS ON MY RIGHT SIDE, HEADACHES, HOT FLASHES, LEG CRAMPS, ALWAYS TIRED, CAN'T LOOSE WEIGHT, TASTE OF METAL, LIGAMENT PAIN. CRAMPS IN MY FEET AND HANDS, MY LEGS ALWAYS TINGLE AND FALL ASLEEP AS WELL. I ALSO HAVE INSOMNIA IN DAYS THAT I'M SO TIRED OR IN SO MUCH PAIN I CAN'T MOVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00042	BAYER HEALTHCARE LLC	11/13/2013	11/21/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/29/2012
Explant Date (E7): 4/16/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED ON (B)(6) 2012. IT CAUSED SEVERE SIDE EFFECTS FOR 11 MONTHS UNTIL SHE HAD IT REMOVED BY HYSTERECTOMY ON (B)(6) 2013. THE SIDE EFFECTS INCLUDED SEVERE CRAMPING, BACK PAINS, MASSACRE BLEEDING FOR WEEKS AT A TIME AND FATIGUED ALL THE TIME. THREE ATTEMPTS WERE MADE TO OBTAIN FOLLOW-UP WITH NO RESPONSE TO DATE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00043	BAYER HEALTHCARE, LLC	11/13/2013	11/21/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2003
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED SHE HAD ESSURE INSERTED IN (B)(6) 2003. TWO YEARS AFTER THE INSERTION (2005), SHE BEGAN TO FEEL DIZZY AND SHE WAS SEEN BY PHYSICIAN AND WAS CONFIRMED THAT SHE WAS PREGNANT. SHE DID NOT HAVE ANY COMPLICATION DURING GESTATION AND THE BABY WAS FINE. AFTER THE DELIVERY SHE HAD A LOT OF ABDOMINAL PAIN. HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED WHICH SHOWED A TOTAL TUBAL OCCLUSION. THE CONSUMER REPORTED THAT EVERY MENSTRUAL CYCLE WAS VERY PAINFUL AND WITH VERY LARGE BLOOD CLOTS. SHE ALSO DESCRIBED THAT DURING ONE OF MENSTRUAL CYCLE, LARGE BLOOD CLOTS CAME OUT. DUE TO THIS, A BLOOD PREGNANCY TEST WAS PERFORMED AND IT WAS POSITIVE. THIS WAS CONFIRMED TO BE A TUBAL ABORTION. THE CONSUMER WAS CONVINCED THAT FROM 2005 TO 2006 (1 YEAR TIME SPAN) SHE WAS HAVING MONTHLY MISCARRIAGES (NOT MEDICALLY CONFIRMED). SHE STARTED ORAL CONTRACEPTION. SHE DID NOT REMEMBER THE BRAND NAME, BUT SHE BECAME PREGNANT AGAIN IN (B)(6) 2008. THIS WAS CONFIRMED TO BE A BLIGHTED OVUM AND DILATATION AND CURETTAGE PROCEDURE WAS PERFORMED. HSG WAS PERFORMED AND IT SHOWED A TOTAL OCCLUSION. THE CONSUMER ALSO REPORTED THAT ONE OF THE ESSURE'S COIL (COULD NOT REMEMBER WHICH ONE) APPEARED TO BE SLIGHTLY OUT OF PLACE. NO TREATMENT WAS RECEIVED. THE CONSUMER STATED THAT AT SOME POINT (DATE NOT SPECIFIED) SHE DEVELOPED STOMACH PAIN (DESCRIBED AS UPPER ABDOMEN) AND PAIN THAT FELT LIKE ESSURE WAS IN HER BLADDER. SHE ALSO WAS HAVING URINE THAT SMELLED METALLIC. SHE UNDERWENT COMPUTERIZED TOMOGRAPHY WHERE ONE ESSURE WAS FOUND ON HER STOMACH AND THE OTHER ON HER BLADDER. NO PHYSICIAN WANTED TO REMOVE THEM. AT THE TIME OF THIS REPORT, SHE STILL HAS THEM BOTH. SHE STILL SUFFERS FROM PAIN IN HER STOMACH AND BLADDER. IN (B)(6) 2013, IT WAS CONFIRMED THAT SHE WAS PREGNANT AGAIN AND ELECTIVE ABORTION WAS PERFORMED.

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Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	11/13/2013	11/22/2013

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4): 11/13/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): *
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): M418ESS3051Q
Lot #(E4): A78083

Single Use:
Implant Date (E6): 11/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WAS INSERTED INTO THE UTERUS/FALLOPIAN TUBE AS DIRECTED. THE THUMBWHEEL WAS TURNED/RETRACTED TO A STOP. THE BUTTON WAS PRESSED TO DISENGAGE THE SHEATH/GUIDEWIRE FROM THE IMPLANTABLE ESSURE, AND DID NOT AUDIBLY CLICK AS USUAL. WHEN THE THUMBWHEEL WAS TURNED/RETRACTED A SECOND TIME TO REMOVE THE STEALTH/GUIDEWIRE, THE PATIENT WAS NOTABLY IN DISCOMFORT AND RETRACTION WAS STOPPED. VISUALIZATION OF THE FIELD SAW THE GUIDEWIRE STILL ATTACHED. AN INSTRUMENT WAS USED TO REMOVED AS MUCH WIRE AND INDETERMINED GREEN-COLORED SUBSTANCE. UPON INSPECTION OF A NEW DEVICE, THE GREEN COLORED MATERIAL IS APPARENTLY FROM THE SHEATH. RESIDUAL SHEATH MATERIAL AND GUIDEWIRE ARE SUSPECTED TO REMAIN IN THE PATIENT. LAPAROSCOPY PROCEDURE TO BE FOLLOWED UP TO VIEW THE AREA, AND TO COMPLETE THE STERILIZATION PROCEDURE VIA LAPAROSCOPE.
THE MFR REPRESENTATIVE HAS BEEN ON SITE. RISK MANAGEMENT HAS AUTHORIZED RELEASE OF THE PRODUCT TO BAYER FOR EVALUATION. PHOTOS WERE TAKEN OF ALL MATERIALS AND PACKAGING. THE GREEN SHEATH MATERIAL COMPOSITION WILL BE PROVIDED. ALL OF LOT NUMBER A78083 HAVE BEEN PULLED FROM STOCK AND WILL BE REPLACED BY A NEW LOT NUMBER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032657	CONCEPTUS	11/13/2013	1/13/2014

Event Information:

Event Date (B3): 6/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM A (B)(6) REGISTERED NURSE WHO DESIRES TO FOCUS ON MY CAREER INSTEAD OF HAVING MORE CHILDREN. I WAS ON ORTHO- TRICYCLEN LOW FOR APPROXIMATELY 12 YEARS AND AT THE AGE OF (B)(6) I WANTED A MORE PERMANENT FORM OF BIRTH CONTROL. MY STORY BEGINS WITH MY 2012 YEARLY PAP SMEAR APPOINTMENT, THE OBGYN AND I DISCUSSED THIS " EASY" IN OFFICE PROCEDURE THAT WOULD ALLOW ME TO RETURN TO WORK IMMEDIATELY. I DECIDED TO HAVE THIS PROCEDURE DONE WITHIN A MATTER OF WEEKS. THE MORNING OF THE IN OFFICE PROCEDURE, I WAS GIVEN SEVERAL MEDICATIONS INCLUDING A SEDATIVE AND NARCOTIC MEDICATIONS TO MAKE ME COMFORTABLE DURING THE PROCEDURE. THE PHYSICIAN WAS EXTREMELY COMFORTING DURING THE PROCEDURE, HOWEVER, THE PROCEDURE LASTED LONGER THAN THE ADVERTISED 10 MINUTES DUE TO BEING UNABLE TO GET THE COIL INTO MY LEFT FALLOPIAN TUBE. I LAID ON THE EXAM TABLE WITH TEARS AND PAIN AS I FELT I WAS BEING MUTILATED. DUE TO THE EXTREME PAIN FOLLOWING THE INSERTION MY BLOOD PRESSURE WAS ELEVATED AND I CONTINUED TO BE MONITORED IN THE OFFICE UNTIL IT CAME DOWN. THE PAIN PASSED ONCE I GOT HOME AND I HAD SOME SLIGHT CRAMPING AND BLEEDING, BUT IT WAS TOLERABLE. WITHIN TWO WEEKS OF THE COIL INSERTION, I BEGAN TO EXPERIENCE NUMBNESS AND TINGLING IN MY UPPER EXTREMITIES, TO THE POINT THAT BOTH HANDS WERE GOING NUMB. I NOTIFIED THE PHYSICIAN'S OFFICE AND THE NURSE REPORTED THAT THIS COULD NOT BE RELATED TO THE PRODUCT. I WAS NEVER ASKED IF I HAD A NICKEL ALLERGY PRIOR TO INSERTION. SEVERAL WEEKS LATER, THE LOW BACK PAIN WAS SO SEVERE THAT IT MADE IT DIFFICULT TO GET OUT OF BED AND THIS HAS CONTINUED FOR A YEAR. A YEAR LATER, THE LOW BACK PAIN IS UNBEARABLE, THE PAIN IN MY LOWER ABDOMEN IS SEVERE AND CAUSES ME NAUSEA, THE NUMBNESS CONTINUES AND ALL LABS COME BACK NORMAL, YET IT WAS DIAGNOSED WITH NEUROPATHY. MY ABDOMEN SWELLS TO THE POINT I AM

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UNABLE TO ZIP MY DRESS PANTS FOR WORK. I HAVE ENDED UP IN THE E.R. MULTIPLE TIMES AND VISITED SEVERAL DIFFERENT PHYSICIANS TRYING TO FIND OUT WHY I'M EXPERIENCING THESE SYMPTOMS AFTER PLACEMENT OF ESSURE. I HAVE ALWAYS BEEN A HEALTHY INDIVIDUAL WHO WORKS OUT 3-4 DAYS A WEEK AND ONLY VISITED THE DOCTOR FOR WELL CHECKS. IN ONE YEAR, MY INSURANCE HAS BEEN BILLED NEARLY $ 17,000 IN DOCTOR BILLS SEARCHING FOR AN ANSWER TO MY SYMPTOMS. THIS PRODUCT IS RUINING HEALTHY WOMEN'S LIVES! THE DEBILITATING PAIN AND SUFFERING IS BEYOND WHAT I IMAGINED THIS PRODUCT TO BE. THIS PRODUCT NEEDS TO BE TAKEN OFF THE MARKET AS IT HAS NOT BEEN EVALUATED PROPERLY, ADVERSE EVENTS ARE NOT BEING REPORTED PROPERLY, AND THE FDA HAS NOT DONE THEIR JOB WITH REGARDS TO THIS MASS STERILIZATION BEING DONE TO WOMEN. I AM (B)(6) AND SINCE PLACEMENT, MY EVERYDAY LIFE HAS BECOME A CHALLENGE PHYSICALLY. I AM NOW FACING A FULL HYSTERECTOMY ONCE I FIND A PHYSICIAN THAT WILL AGREE TO DO IT. THIS PRODUCT HAS RUINED MY QUALITY OF LIFE, AND MANY OTHER WOMEN'S! TAKE IT OFF THE MARKET INSTEAD OF ALLOWING WOMEN TO SUFFER!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032659	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 9/9/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS NOT TOLD ABOUT THE NICKEL IN THE DEVICE. I DO NOT REACT WELL TO NICKEL. I HAVE VERY PAINFUL CRAMPS. POSSIBLE CYSTS BUT NOT FOUND. ACHY BODY. HEADACHES. FOGGY MEMORY. PAINFUL INTERCOURSE. ALL OF A SUDDEN REACTING TO TAMPONS. EVERY MONTH I GET ITCHY SKIN DOWN THERE. PAINFUL JOINTS. BUMPS ON MY FACE. BAD CRAMPS. WEIRD PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032660	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CHRONIC PELVIC PAIN, CRAMPING, LOW VITAMIN D, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032663	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 1/7/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LOWER ABDOMINAL PAIN, HEAVY BLEEDING WITH LARGE BLOOD CLOTS GOLF BALL SIZE AND LARGER. HEADACHES, FEELING OF EXHAUSTION, BLISTERS ON FEET, COMPLETE BODY ACHING IN JOINTS, A LOT OF BLOATING, INCREASED DEPRESSION, IRRITABILITY. SWELLING, SHARP SHOOTING PAINS IN THE VAGINAL AREA, PAINFUL WHEN HAVING SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032680	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE HEADACHE, ITCHING, BUMPS UNDER THE ARM PITS, INNER THIGH AND PELVIC AREA. BLURRED VISION, MOOD CHANGE, NO SEX DRIVE, TIREDNESS, WEIGHT GAIN,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032681	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 10/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

3 MONTHS AFTER HAVING THE ESSURE PLACED I BEGAN TO GET SYMPTOMS. IT STARTED WITH 3 PERIODS IN ONE MONTH AND THEN MISSING 2 CYCLES. I HAVE SEVERE ABDOMINAL PAIN, AND CRAMPING, HAVE HAD MULTIPLE YEAST INFECTIONS AS WELL AS BACTERIAL VAGINOSIS, MIGRAINES, VERTIGO, MUSCLE PAIN, NAUSEA AND VOMITING, HAIR LOSS, ANXIETY AND PANIC ATTACKS, CLEAR FLUID LEAKAGE, HIVES ON THE INNER BUTTOCKS AND VAGINAL LIPS, WHICH CAUSES EXTREME ITCHING WHICH HAS CAUSED THE SKIN TO PEEL AND THIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032682	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 6/5/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE IN (B)(6) 2009. I WAS GIVEN PAIN MEDS TO TAKE A FEW HOURS BEFORE HAND. DURING THE PROCEDURE IT WAS SLIGHTLY UNCOMFORTABLE BUT NOT MUCH PAIN. THE DR SAID ONE SIDE DIDN'T TAKE RIGHT SO HE HAD TO INSERT AND EXTRA COIL. THE OTHER TUBE ONLY HAS ONE. I RETURNED 3 MONTHS LATER FOR THE HSG TEST AND WAS CONFIRMED BLOCKED. IN 2012 I HAD A CYST BURST ON MY OVARY. HAD TO HAVE ULTRASOUND AND THE TECH COULD ONLY SEE ONE COIL. I NEVER THOUGHT MUCH ABOUT IT WHEN A FEW MONTHS LATER I HAD A COIL...POSSIBLY COILS FROM THE SIDE THAT HAD 2 STICKING TO MY TAMPON. SINCE THE PROCEDURE MY PERIODS ARE HEAVY AND I CLOT. THEY ARE ALSO MORE PAINFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032683	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 3/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A TVT SLING AND ESSURE PLACED AT THE SAME TIME UNDER GENERAL ANESTHESIA. I HAVE ELECTRICAL STIMULATION THROUGHOUT HANDS, FINGERS, FEET, TOES. I HAVE BURNING IN MY LOWER BACK, SHARP PAIN SHOOTING DOWN FROM MY LOWER BACK DOWN MY LEG. EXTREMELY FATIGUED ALL THE TIME, HAIR IS FALLING OUT, AND I HAVE PELVIC PAIN AND CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032684	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 1/23/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I HAD ESSURE I HAVE SUFFERED FROM MIGRAINES, BACK PAIN, PELVIC PAIN, HEAVY PERIODS WITH BLOOD CLOTS AND EXTREME CRAMPS TO THE POINT THAT THE CRAMPS FEEL LIKE LABOR PAINS, DEPRESSION, ANXIETY, PANIC ATTACKS, UNEXPLAINED FATIGUE, HIVES ON KNEES AND FACE, ALSO TOOTH LOSS. I HAVE BEEN DIAGNOSED WITH PID, AND ENDOMETRIOSIS ON (B)(6) 2013 AND WILL BE GETTING A HYSTERECTOMY IN (B)(6) 2013 TO GET THE ESSURE COILS OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032685	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 4/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED AND IMMEDIATELY STARTED HAVING IRREGULAR BLEEDING THAT WOULDN'T STOP. SEVERE PELVIC PAIN THAT DEBILITATED EVERY DAY ACTIVITIES, HEADACHES, JOINT PAIN, EXTREME FORGETFULNESS, BRAIN FOG, CLOTTING, AND SEVERAL OTHER SIDE EFFECTS. (B)(6) 2013, I HAD MY TUBES WITH ESSURE REMOVED DUE TO INFLAMMATION AND ALLERGY TO NICKLE DURING A EXPLORATORY DIAGNOSIS SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032686	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 9/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAD ESSURE PROCEDURE, I HAVE HAD VAGINAL PAIN, DURING INTERCOURSE, SHARP ABDOMINAL PAIN, SEVERE HEADACHES, DIZZINESS, BLOATING IN STOMACH, LOWER BACK PAIN,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032687	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 8/31/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING BAD PAIN IN MY LEFT SIDE. I WAKE UP TASTING METAL. I'M LOSING HAIR. BLOATING AND NAUSEATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032688	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING A LOT MORE PAIN THAN USUAL STARTED GOING TO THE DOCTOR FOR EXTREME PELVIC PAIN, HEMORRHAGE DURING CYCLES, MORE THAN ONE CYCLE A MONTH, HEADACHE, FATIGUE, JOINT PAIN, WEIGHT GAIN, DIZZINESS, OVALUATION PAIN, ETC...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032689	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 9/23/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED IN (B)(6) 2010 . I WAS NOT UNDER ANESTHESIA AND PLACEMENT ON THE LEFT SIDE WAS EXTREMELY DIFFICULT AND PAINFUL, ANOTHER DR WAS CALLED IN TO ASSIST. PROCEDURE TOOK NEARLY AN HOUR. I IMMEDIATELY DEVELOPED PMDD AND WAS PRESCRIBED PROZAC WHICH DID SUBSIDE SOME OF THE PAIN. SLOWLY I STARTED DEVELOPING OTHER ISSUES THAT COULD NOT BE EXPLAINED. CHRONIC FATIGUE, EXTREME JOINT PAIN, CONSTANT PRESSURE IN RECTUM AND GROIN, STABBING ABDOMINAL PAINS, KIDNEY INFECTIONS, YEAST INFECTIONS AND BLADDER PROBLEMS. DURING THIS TIME I HAD NUMEROUS BLOOD TESTS, CT SCANS, BLADDER SCANS, CYSTOSCOPY AND MANY PHYSICIAN VISITS. ALL TESTS WERE NORMAL. I EXPERIENCED SEVERE BRAIN FOG. THE BEST DESCRIPTION FOR THOSE THREE YEARS WAS MENTALLY AND PHYSICALLY LIVING AS AN 80 YEAR OLD WOMAN. EVERYDAY WAS A STRUGGLE. DURING A CYSTOSCOPY MY UROLOGIST NOTICED SOMETHING THAT WANTED ME TO REFER BACK TO MY OB. I MADE A VISIT AND FOUND THAT I HAD DEVELOPED OVARIAN CYSTS. IT WAS AT THIS TIME I BEGAN RESEARCHING MY ISSUES AND MADE THE CORRELATION BETWEEN ESSURE AND MY SYMPTOMS. ON (B)(6) I HAD A HYSTERECTOMY AND BILATERAL SALPINGECTOMY. WHEN I WOKE, ALL OF MY PREVIOUS SYMPTOMS WERE GONE. MY PATHOLOGY REPORT SHOWED LESIONS ON MY BLADDER AND BOWEL AND CHRONIC INFLAMMATION INTERNALLY. I MADE A WRITTEN REQUEST TO TEXT ALL TISSUE REMOVED FOR NICKEL AND THE REPORT CAME BACK POSITIVE FOR NICKEL SERUM. I AM NOW THREE WEEKS POST OP AND CANNOT BELIEVE I HAVE REGAINED MY LIFE AND AM COMPLETELY SYMPTOM FREE, I AM NOW TRYING TO DETERMINE HOW TO RID MYSELF OF THE NICKEL AND THE POSSIBLE LONG TERM EFFECTS I MAY HAVE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032690	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 3/6/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MASSIVE PAIN IN LOWER RIGHT ABDOMEN, BLOATING, JOINT PAIN, IRREGULAR MENSTRUAL CYCLE, FREQUENT HEADACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032691	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE COILS (B)(6) 2012. THE SAME DAY OF IMPLANTING THE DEVICES, ONE FELL OUT AFTER I GOT HOME AND WAS ON MY TOILET PAPER AFTER URINATING. I CALLED MY DOCTOR AND EVENTUALLY GOT ANOTHER ESSURE COIL PUT BACK IN MY FALLOPIAN TUBE. I RECEIVED THE DEPO SHOT, FOR THE FIRST TIME, AT MY FIRST IMPLANTING APPOINTMENT. (B)(6), WHILE WAITING FOR A MRI, I HAD MY BACK TOOTH BREAK OFF. (B)(6) 2012, I BLED ALMOST EVERYDAY AND HAD HORRIBLE JOINT PAIN ESPECIALLY IN MY HIPS. THE BEGINNING OF (B)(6) 2013, MY BLEEDING STOPPED BUT MY PAIN DID NOT. I HAD WHAT I THOUGHT WAS MY FIRST PERIOD IN (B)(6) BUT WASN'T REGULAR FOR MY USUAL PERIODS. I BLED AGAIN AT THE END OF (B)(6), BEGINNING OF (B)(6) WHICH STARTED TWO WEEKS AFTER WHAT I THOUGHT WAS MY FIRST. (B)(6) 2013 I HAD MY HSG TEST DONE WHICH CONFIRMED THAT MY TUBES WERE COMPLETELY BLOCKED. (B)(6) I HAD TWO "PERIODS" AND (B)(6) I HAD NOTHING. MY JOINT PAIN CONTINUED WHICH MADE IT TOO PAINFUL TO SLEEP ON EITHER SIDE OF MY BODY AT NIGHT. BY THE END OF (B)(6), I WAS HAVING ABDOMINAL PAIN, BLOATING, AND PAINFUL INTERCOURSE. (B)(6), I STARTED BLEEDING AFTER INTERCOURSE, WHICH WAS STILL PAINFUL. I SAW MY IMPLANTING DOCTOR (B)(6) 2013 BECAUSE THE PAIN WAS SO SEVERE. AT MY APPOINTMENT, HE DIDN'T FINISH MY PELVIC EXAM BECAUSE HE SAID HE COULD TELL I WAS IN TOO MUCH PAIN, WHICH I WAS. HE DIDN'T HAVE ANY OTHER ANSWERS TO ANY QUESTIONS ABOUT WHY I WAS EXPERIENCING WHAT I WAS OTHER THAN IT MIGHT STILL BE THE DEPO SHOT I WAS GIVEN 7 MONTHS PRIOR AND THOUGHT I HAD A CYST ON MY LEFT OVARY. MOST OF MY PAIN WAS ON THE RIGHT SIDE. HE DIDN'T FEEL THE NEED FOR FURTHER TESTS AND TOLD ME TO CALL IN 3-4 MONTHS IF I WAS STILL HAVING PAIN. I COULD HARDLY MOVE FOR A COUPLE OF DAYS BECAUSE THE PAIN WAS SO BAD. MY SON HAD AN APPOINTMENT WITH OUR FAMILY DOCTOR THAT SAME WEEK. I EXPLAINED TO HIM EVERYTHING I HAD BEEN EXPERIENCING AND ASKED WHAT HE

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THOUGHT I SHOULD DO AND IF HE THOUGHT IT WAS NORMAL. HE DIDN'T THINK WHAT I WAS EXPERIENCING WAS NORMAL, TOLD ME HE WOULD REFER ME TO ANYONE I WANTED, AND SCHEDULED ME FOR AN ULTRASOUND. THE ULTRASOUND REVEALED EVIDENCE OF A RECENTLY BURST CYST ON MY RIGHT OVARY AND AN ADDITIONAL CYST STILL ON MY RIGHT OVARY. (B)(6), I EXPERIENCED SEVERE BLOATING AND MULTIPLE ALLERGIC REACTIONS TO PRODUCTS I'VE USED MANY TIMES BEFORE WITH NO PROBLEMS PRIOR TO THE ESSURE IMPLANTS. SUCH AS MY SHAMPOO, ALEVE, AND MY SUNSCREEN. I GOT AN APPOINTMENT WITH A NEW GYNECOLOGIST SCHEDULED FOR (B)(6) 2013. BY (B)(6), I COULDN'T WEAR SOME OF MY EARRINGS I'VE WORN FOR YEARS BECAUSE MY EARS WOULD SWELL UP, GET BRIGHT RED, AND ITCHY. I ALSO GOT A METALLIC TASTE FOR ABOUT TWO WEEKS AND EVERYTHING I ATE MADE IT WORSE. I LOST MY APPETITE AND CONSTANTLY FELT NAUSEOUS FOR WEEKS. AUGUST (B)(6), I WEIGHED MYSELF AND I WAS DOWN TO (B)(6). WHEN I WAS IMPLANTED (B)(6) 2012, I WEIGHED (B)(6). I LOOKED AND FELT AS THOUGH I WOULD WAS DYING. I NEVER HAD ANY REPRODUCTIVE ISSUES PRIOR TO ESSURE, EXCEPT FOR WHEN I HAD THE MIRENA. ONCE THAT WAS REMOVED, I WAS FINE AGAIN. CYSTS WERE NEVER A PROBLEM, ABDOMINAL PAIN, OR THE CRAMPING I EXPERIENCED WITH ESSURE IN MY BODY. THERE WERE MULTIPLE TIMES I REALLY THOUGHT I WAS PREGNANT DO TO ALL THE PREGNANCY SYMPTOMS I WAS HAVING. ALL THE PREGNANCY TESTS I TOOK WERE NEGATIVE BUT MY BODY ACTED AS THOUGH I WAS PREGNANT. I BOUGHT MORE PREGNANCY TESTS IN 11 MONTHS THAN I DID THE LAST 11 YEARS. I HAD HORRIBLE ACNE THAT LOOKED LIKE I WAS GOING THROUGH PUBERTY AGAIN. I WOULD HAVE SWEAT DRIP FROM MY ARM PITS EVEN WHEN I WASN'T HOT, SKIN JUST FLAKING OFF MY LEGS (LOTION DID NOT HELP), HORRIBLE LOW BACK PAIN, I HAD EXCESSIVE HAIR GROWTH ON MY FACE (EVEN THOUGH I HAD LASER HAIR REMOVAL ON MY FACE '06-'07), AND I HAD NO ENERGY WHATSOEVER. AT MY FIRST APPOINTMENT WITH MY NEW GYNECOLOGIST, SHE LISTENED, DID A PELVIC EXAM, TALKED ABOUT MY OPTIONS, AND I SCHEDULED MY HYSTERECTOMY. I NEVER WANTED A HYSTERECTOMY BUT DIDN'T FEEL I REALLY HAD A CHOICE UNLESS I WANTED TO LIFE THE WAY I HAD BEEN FOR THE LAST 10-11 MONTHS. MY HYSTERECTOMY WAS DONE (B)(6) 2013. MY MAJOR SYMPTOMS VANISHED WITH REMOVAL. I WAS ON PAIN MEDS FOR ONE DAY FOLLOWING MY SURGERY. THE SECOND NIGHT AFTER MY SURGERY, I COULD SLEEP ON MY SIDE AGAIN WITH NO PAIN. MY SMALLER SYMPTOMS ARE SUBSIDING. I BELIEVE I HAVE HEAVY METAL POISONING AND MY BODY IS WORKING THEM OUT. MY BODY SEEMS TO BE DOING BETTER EVERY WEEK THAT GOES BY. MENTALLY I HAVE BECAME SOMEWHAT DEPRESSED DUE TO NEVER WANTING TO HAVE MY REPRODUCTIVE ORGANS TAKEN FROM ME. WHEN I GOT ESSURE, I CONSENTED TO BLOCKING MY TUBES, NOT LOSING MY TUBES, UTERUS, AND CERVIX. I AM ONLY (B)(6). NO ONE SHOULD HAVE TO EVER GO THROUGH THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032692	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 10/3/2011	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2011. AFTER ABOUT SIX WEEKS IS WHEN I STARTED NOTICING THE FIRST SIDE EFFECT! ALL OF MY SIDE EFFECTS TO DATE ARE HEAVY PERIODS, SEVERE CRAMPING IN PELVIC AND ABDOMINAL AREA NOT JUST DURING MENSTRUATION, VERY PAINFUL INTERCOURSE, BACK PAIN, DEBILITATING MIGRAINES, AND DIZZINESS, AND FORGETFULNESS. I HAVE RECENTLY SEEN A DOCTOR, AND WAS SUGGESTED I UNDERGO A HYSTERECTOMY! I AM ONLY (B)(6)!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032693	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 8/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN (B)(6). THE IMPLANTING DOCTOR COULD ONLY PLACE 1 OUT OF 2 COILS AS HE SAID THERE SEEMED TO BE BLOCKAGE IN MY RIGHT FALLOPIAN TUBE. THE PROCEDURE ITSELF WAS NOT THAT BAD, INITIALLY, WHAT HAS COME AFTER IS WHAT'S BOTHERSOME. THE DOCTOR SAID I WOULD HAVE LIGHT BLEEDING FOR A DAY OR 2, WHICH DID HAPPEN BUT THEN 4-5 DAYS LATER I STARTED BLEEDING AGAIN, HEAVIER, WHICH LASTED ALMOST 5 WEEKS. SO, ONLY THE LEFT COIL WAS PLACED AND THE DOCTOR SENT ME ON MY WAY AND SAID WAIT 3 MONTHS TO HAVE HSG TEST DONE TO CONFIRM IF THE LEFT COIL PLACED AND SCARRED OVER PROPERLY, HE SAID WE'LL GO FROM THERE REGARDING MY RIGHT TUBE. I HAVE BEEN CONTINUING TO TAKE MY BIRTH CONTROL BECAUSE I WAS NOT FULLY "ESSURED". BACK TO THE DOCTOR NOT BEING ABLE TO PLACE THE 2ND COIL, I FELT LIKE IT WAS NO BIG DEAL TO HIM THAT THERE WAS SOMETHING GOING ON WITH MY RIGHT SIDE SO I WENT TO SEE MY PRIMARY CARE PHYSICIAN AND ASKED IF WE COULD RUN SOME TESTS AND BECAUSE I HAD BEEN BLEEDING SINCE THE PROCEDURE. SHE SENT ME FOR A PELVIC US AND ENDOVAGINAL US ON (B)(6) 2013. THE FINDINGS CAME BACK THAT THERE SEEMED TO BE A COIL IN MY UTERUS. NO RESULTS AS TO WHAT WAS HAPPENING WITH TUBE. THE RADIOLOGIST RECOMMENDED I HAVE THE HSG DONE ASAP TO CONFIRM COIL PLACEMENT. I HAD THE HSG TEST ON (B)(6) 2013 AND INDEED HAVE A COIL IN MY UTERUS WITH BLOCKAGE TO BOTH OF MY FALLOPIAN TUBES NOW, NOT JUST ONE. SINCE HAVING THE PROCEDURE DONE AND FINDING OUT THE COIL IS NOT IN MY TUBE, I HAVE HAD MANY ISSUES, DIZZINESS, DIARRHEA, ERRATIC BLEEDING FOR UPWARDS OF A MONTH AT A TIME, PAINFUL INTERCOURSE WITH SPOTTING AFTERWARD, EASY BRUISING, SKIN RASHES/ITCHINESS, SEVERE CRAMPING WITH/WITHOUT BLEEDING THAT WAKES ME FROM SLEEP, BLOATING, BLADDER LEAKAGE, FATIGUE, BACK PAIN AND SWEATING. I AM CURRENTLY WAITING FOR MY PRE-OP APPT ON (B)(6) TO SET UP SURGERY DATE TO HAVE A

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LAPAROSCOPIC HYSTERECTOMY AND TUBE REMOVAL ALREADY APPROVED THROUGH TRICARE, MY INSURANCE. I TRUSTED MY DOCTOR WHEN HE RECOMMENDED ESSURE TO ME. I DID NOT EXPECT TO HAVE THIS PROCEDURE DONE, WHICH CLEARLY DID NOT WORK FROM THE BEGINNING WHEN HE COULDN'T PLACE BOTH COILS TO ULTIMATELY HAVING TO UNDERGO A HYSTERECTOMY TO FIX THIS AND THE PROBLEMS I'VE BEEN HAVING FROM IT. PLEASE TAKE IT OFF THE MARKET!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032695	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 7/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT WAS EXTREMELY PAINFUL AND TO THIS DAY HAS CONTINUED TO GIVE ME PROBLEMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032696	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 3/22/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN EXPERIENCING EXTREME PAIN IN MY LOWER STOMACH, BLEEDING AFTER INTERCOURSE, HAIR FALLING OUT, WEIGHT GAIN AND BOLTING, HEADACHES, BODY RASH AND ITCHY, NAUSEA AND VOMITING

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032697	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 11/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SYMPTOMS/SIDE EFFECTS: PERIOD FROM (B)(6) 2011 - (B)(6) 2012 ((B)(6)...IT WAS MIA FOR A YEAR AND 5 MONTHS. IT STARTED AGAIN (B)(6) 2013). WEIGHT GAIN/BLOATING; ABDOMINAL PAIN/CRAMPING (ESPECIALLY IN THE LEFT SIDE - FEELS LIKE A KNIFE); ACHING/TINGLING IN THE LIMBS; NUMBNESS IN FEET; HOT FLASHES; PAIN IN LEFT HIP (TO THE POINT OF LIMPING); FATIGUE (NO MATTER HOW MUCH I SLEEP); DIFFICULTY SLEEPING (MAINLY AT NIGHT...I FEEL LIKE MY BODY HAS MY DAYS AND NIGHTS MIXED UP); HEADACHES/MIGRAINES (HAVE GOTTEN WORSE...I'VE HAD HEADACHES IN THE PAST, BUT NOT EVERY DAY!); ACNE; GROWING/SORE BREASTS; PAINFUL INTERCOURSE (PAIN CONTINUES FOR A DAY OR TWO AFTER - DEVELOP ITCHING AROUND THE VAGINAL AREA AFTER INTERCOURSE); EXCESS VAGINAL DISCHARGE; MOOD SWINGS (FEEL LIKE I'M PMSING 24/7/365); METALLIC TASTE IN MOUTH; HEARTBURN/INDIGESTION; FREQUENT URINATION (SOMETIMES I FEEL LIKE I CAN 'T GET THE STREAM STARTED OR LIKE I GET IT ALL OUT); BOWEL PROBLEMS (IF I EAT A MEAL, 30 MINUTES OR SO LATER, I HAVE EXTREME STOMACH/BOWEL CRAMPS UNTIL I PASS A LOOSE STOOL). SHORT-TERM MEMORY; AT TIMES A SWEAR MY TUBES ARE TWITCHING; TWITCHING MUSCLES THROUGHOUT BODY; DISCOMFORT IN MY UPPER ABDOMEN ; DECREASED APPETITE (IT HURTS TO EAT, I ALWAYS FEEL FULL AND FOOD MAKES ME NAUSEOUS); TIMELINE: (B)(6) 2011 - HAD ESSURE PROCEDURE AT (B)(6) HOSPITAL BY DR (B)(6) (B)(6) 2011 - PERIOD BEGAN (B)(6) 2012 (JUST BEFORE MY PERIOD STOPPED) - HAD CHECK UP VISIT WITH DR (B)(6). EXPRESSED CONCERN THAT I WAS STILL ON MY PERIOD. WAS TOLD IT WAS NORMAL BUT THAT IF BLEEDING HAD NOT STOPPED IN A FEW MORE WEEKS WE WOULD HAVE TO CONSIDER A HORMONE BASED PILL. (B)(6) 2012 - PERIOD FINALLY STOPS (AFTER 8 WEEKS) (B)(6) 2012 (A DAY OR TWO AFTER PERIOD STOPPED) - HAD HSG TEST AT (B)(6) REGIONAL TO CONFIRM SUCCESS OF ESSURE PROCEDURE. PROCEDURE WAS RULED A SUCCESS AND I WAS RELEASED WITH NO FURTHER FOLLOW UP NECESSARY. (B)(6)

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2012 (END OF THE MONTH) - CONTACTED DR. (B)(6) OFFICE WITH CONCERN THAT I HAD MISSED TWO PERIODS AND WAS GAINING WEIGHT AS WELL AS HAD SORE BREASTS. HAD TAKEN HOME PREGNANCY TEST WHICH CAME BACK NEGATIVE. WAS TOLD THAT EVERY LADIES BODY IS DIFFERENT AND THAT DUE TO SUCH A LONG PERIOD BEFORE IT WAS NORMAL FOR ME TO MISS A MONTH OR TWO. (B)(6) 2012 (END OF THE MONTH) - AFTER MISSING PERIOD FOR A THIRD MONTH, CONTACTED MY REGULAR OB CLINIC ((B)(6)) FOR A SECOND OPINION. TOOK A HOME PREGNANCY TEST WHICH WAS NEGATIVE. DOCTOR ORDERED PREGNANCY TEST WHICH WAS NEGATIVE. DOCTOR SAID HE WANTS TO HAVE A FULL PELVIC ULTRASOUND DONE. (B)(6) 2012 - CONTACTED (B)(6) HOSPITAL FINANCE OFFICE TO GET FINANCIAL ASSISTANCE PAPERS, SO I CAN SCHEDULE ULTRASOUND. (B)(6) 2012 (SECOND OR THIRD WEEK) - SENT IN FINANCIAL ASSISTANCE PAPERWORK TO (B)(6) HOSPITAL. (B)(6) 2012 - NURSE AT (B)(6) OFFICE DOES AN ULTRASOUND TO MAKE SURE I AM NOT GETTING A FALSE NEGATIVE ON PREGNANCY TESTS. UTERUS WAS CORRECT SIZE/NO PREGNANCY. (B)(6) 2012 - CONTACTED (B)(6) FINANCE OFFICE TO CHECK ON PAPERWORK. (B)(6) 2012 - RELIEVED TO FIND OTHER WOMEN WHO ARE EXPERIENCING THE SAME SYMPTOMS AS ME! (B)(6) 2012 - STOPPED BY MY REGULAR (B)(6) OFFICE AND TALKED TO THE NURSE ABOUT MY SYMPTOMS AND FINANCIAL OPTIONS FOR MOVING FORWARD. (B)(6) 2012 - CONTACTED ANOTHER BRANCH OF (B)(6) THAT SEES UNINSURED WOMEN, BUT THEY SAID THEY ARE NOT CURRENTLY ACCEPTING NEW PATIENTS. CONTACTED (B)(6) OFFICE TO SET UP APPOINTMENT AND SET UP PAYMENTS. CANCELLED APPOINTMENT BECAUSE OF AMOUNT NEEDED UP FRONT. CONTACTED PHYSICIANS BILLING AT (B)(6) HOSPITAL. WAS TOLD THAT APPLICATION MAY HAVE BEEN LOST IN THE SHUFFLE AND NEW ONE WAS SENT OUT. CONTACTED DR (B)(6) OFFICE ((B)(6) OB/GYN) TO DISCUSS ALL MY NEW SYMPTOMS AND IN HOPES TO TALK TO DR (B)(6) OR HER NURSE. EXPLAIN THAT I DO NOT HAVE MONEY TO BE SEEN BY THE DOCTOR. (B)(6) 2012 - RECEIVED NEW FINANCIAL ASSISTANCE APPLICATION IN THE MAIL. TOOK HOME PREGNANCY TEST AGAIN WHICH CAME BACK NEGATIVE. RECEIVE VOICEMAIL FROM DR (B)(6) NURSE STATING THE THEY UNDERSTAND THAT I DO NOT HAVE MONEY TO BE SEEN BUT I STILL NEED TO MAKE AN APPOINTMENT, SO THE DOCTOR CAN SEE ME AND MAKE A DIAGNOSIS. ALREADY WORKING ON SCHEDULING AN APPOINTMENT WITH MY REGULAR OB/GYN. (B)(6) 2012 - FAXED FINANCIAL ASSISTANCE APPLICATION TO (B)(6) IN PHYSICIANS BILLING AT(B)(6) HOSPITAL. TALKED TO (B)(6) (WORKS WITH UNINSURED PATIENTS) AND EXPLAINED I WAS A PATIENT AT ANOTHER CLINIC. HAD BLOOD DRAWN AT (B)(6) FOR HORMONE AND THYROID TESTING. SCHEDULED APPOINTMENT TO SEE DR TO DISCUSS SYMPTOMS AND SCHEDULE PELVIC ULTRASOUND...ALSO PLAN TO ASK FOR A CT SCAN OR HSG. AFTER (B)(6), I CAN TELL YOU WHAT TESTS I'VE HAD DONE, BUT I'M UNSURE OF THE DATES. I CAN TELL YOU THAT ALL VISITS AND TESTS WERE BETWEEN (B)(6) 2012 AND "(B)(6) 1013." ALL OF MY BLOOD WORK FOR HORMONE TESTING AND THYROID CAME BACK NORMAL. PREGNANCY TEST CAME BACK NEGATIVE. THE MIDWIFE I SAW SUGGESTED I MAY HAVE PCOS AND STARTED ME ON THE PROGESTERONE CHALLENGE. NOTHING HAPPENED. I HAD A FULL PELVIC/TRANSVAGINAL ULTRASOUND. THE DOCTOR SAID EVERYTHING WAS NORMAL. HE STATED THAT WITH LACK OF CYSTS I PROBABLY DON'T HAVE PCOS. HE QUITE LITERALLY LOOKED AT ME AND SAID HE DIDN'T KNOW WHAT TO DO NEXT BECAUSE EVERYTHING WAS COMING BACK NORMAL. HE DECIDED TO HAVE ME DO THE SECOND STAGE OF THE PROGESTERONE CHALLENGE. NOTHING HAPPENED. SCHEDULED AN APPOINTMENT WITH A DIFFERENT DOCTOR IN THE SAME OFFICE. HE DID A PELVIC EXAM AND SAID NOT TO WRITE OFF PCOS. I MAY STILL HAVE IT EVEN THOUGH NO CYSTS WERE SEEN ON THE ULTRASOUND. I BEGGED HIM FOR ANOTHER HSG. AN HSG WAS SCHEDULED. BEFORE I COULD HAVE THE HSG, I WAS IN SO MUCH PAIN THAT I WENT TO MY LOCAL HOSPITAL ER. I REPORTED A MAJOR MIGRAINE, CHEST PAIN AND LOWER PELVIC PAIN. I TOLD THEM ABOUT ESSURE. I HAD TO EXPLAIN TO EVERYONE I SAW WHAT ESSURE IS. THE DOCTOR ORDERED A CT SCAN. AGAIN, BEFORE HAVING THE SCAN, I HAD TO EXPLAIN WHAT ESSURE IS. THE RADIOLOGIST SENT A REPORT SAYING THAT EVERYTHING LOOKED FINE ASIDE FOR SOME MINOR GRAVEL IN MY GALLBLADDER. THEY FOUND A DOCTOR IN THE ER WHO KNEW ABOUT ESSURE BECAUSE HIS WIFE WAS AN OB/GYN. HE CAME IN AND TALKED TO ME, BUT SAID ALL HE COULD DO FOR ME (BECAUSE ALL TESTS WERE COMING BACK NORMAL) WAS TO GIVE ME PAIN MEDS TO MANAGE THE PAIN. HE CHECKED TO BE SURE THAT I WAS NOT EXPERIENCING IN PAIN DUE TO THE GRAVEL IN MY GALLBLADDER. I HAVE HAD SEVERE PAIN

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SINCE THEN BUT HAVE NOT RETURNED TO THE ER BECAUSE I KNOW I NEED SOMETHING MORE THAN JUST PAIN MEDS AT THIS POINT. I DON'T WANT OR NEED A BANDAID. I NEED THE CAUSE OF MY ISSUES TREATED, NOT THE SYMPTOMS. I REPORTED FOR MY HSG AS SCHEDULED. BECAUSE I HAD JUST HAD A CT SCAN, THE RADIOLOGIST CONTACTED THE HOSPITAL I HAD WENT TO AND OBTAINED THE WRITTEN REPORT. SINCE THE REPORT STATED THAT EVERYTHING LOOKED NORMAL THEY REFUSED TO THE HSG. I WENT BACK TO MY DOCTOR. HE STATED THAT AT THAT POINT WE WOULD NO LONGER CONSIDER ESSURE WHEN ADDRESSING MY ISSUES. HE SIMPLY WANTED TO MAKE SURE THAT PAIN WAS MANAGED AND THAT MY PERIOD RETURNED. HE GAVE ME A PRESCRIPTION FOR BIRTH CONTROL PILLS AND TOLD ME TO SCHEDULE ANOTHER APPOINTMENT IN (B)(6) TO CHECK UP ON MY PROGRESS. HE ALSO REFERRED ME TO A GASTROENTEROLOGIST FOR MY BOWEL ISSUES. I TOOK ONE MONTH OF THE BIRTH CONTROL PILLS. MY PAIN WAS WORSE THAN EVER AND IT WAS MESSING WITH MY HORMONE LEVELS. I CALLED THE DOCTOR AND TOLD HIM THAT I WOULD NO LONGER BE TAKING THEM. THAT WAS IN FEBRUARY. AS OF (B)(6) 2013, MY PERIOD HAS RETURNED. HOWEVER, OVULATION AND MY CYCLE ARE BOTH EXTREMELY PAINFUL. I SPEND MOST OF THAT WEEK WITH A HEATING PAD. I TAKE BAYER ADVANCED EXTRA STRENGTH TO TRY TO MANAGE THE PAIN. IT TAKES THE EDGE OFF, BUT NEVER REALLY TAKES THE PAIN AWAY. MY CYCLE IS LIGHTER THAN IT EVER HAS BEEN. IT DOES NOT MAKE SENSE THAT I AM HARDLY BLEEDING AND YET I DOUBLED OVER IN TEARS WITH PAIN. AS FOR THE GASTRO DOCTOR, I HAD TO CANCEL THE APPOINTMENT BECAUSE OF FINANCES. I HAVE ALSO BEEN TO THE ER AT (B)(6) HOSPITAL FOR BLADDER ISSUES. I COULD NOT URINATE. THE DOCTOR SAID THAT MY BLADDER WAS SAGGING, MY RECTUM IS DESCENDED AND THAT I HAD A BAD BLADDER INFECTION. I TOOK AN ANTIBIOTIC THAT THEY PRESCRIBED TO CLEAR UP THE INFECTION. MY MAIN CONCERN (OTHER THAN THE PAIN I ENDURE EVERY DAY) IS THAT OVER TIME MY COILS WILL MIGRATE OR MOVE. I WAS TOLD BY A MEDICAL PROFESSIONAL WHEN I WENT TO THE ER, THE FIRST TIME THAT ANY DOCTOR THAT TRIED TO TELL ME THAT ESSURE CANNOT MOVE ONCE OCCLUDED IS LYING. EVERY DEVICE, NO MATTER WHAT THE TYPE OR FORM, HAS THE ABILITY TO MOVE. IT IS A FOREIGN OBJECT IN THE BODY. I WAS ALSO TOLD THAT NO MATTER HOW LONG YOU HAVE HAD A DEVICE, YOUR BODY CAN DECIDE TO REJECT IT AT ANY TIME. YOU MIGHT HAVE HAD IT FOR YEARS WITH NO ISSUES, BUT THE BODY CAN STILL REJECT IT. WHEN I ASKED IF IT WAS POSSIBLE THAT MY BODY WAS REJECTING ESSURE, I WAS TOLD THAT WAS ALWAYS A POSSIBILITY. HOWEVER, WHEN I FOLLOW UP WITH MY OB/GYN THEY DO NOT WANT TO CONSIDER ESSURE AS A CAUSE FOR ANY OF MY ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032699	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD TO HAVE LAPAROSCOPIC BILATERAL "SALPINGECTOMY" (B)(6) 2013. COIL MIGRATED AND WAS COMING THROUGH UTERUS. DEBILITATING MIGRAINE HEADACHES. EXTREME PELVIC PAIN. BLOATING. WEIGHT GAIN (20 LBS IN 2 YEARS). DAILY NAUSEA. FATIGUE. SHORTNESS OF BREATH. HEART PROBLEMS (DIAGNOSED WITH POTS). ANXIETY. BRAIN FOG / FORGETFULNESS. HEAVY PERIODS (ABNORMAL AND CLOTS AFTER DEVICE INSERTION). EXTREME BREAST TENDERNESS. PAIN RADIATING FROM OVARIES DOWN MY LEGS. RESTLESS LEG SYNDROME. PAIN AND SWELLING IN LEGS, ANKLES, FEET. EXTREME LOWER BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032701	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 9/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LEFT COIL FELL OUT INTO UTERUS AFTER BEING IN THERE ALMOST 3 MONTHS!! I HAVE NOTHING BUT BLOATING AND ALL OVER BODY PAIN SINCE I HAVE HAS THESE THINGS. DEPRESSION AND ANXIETY HAVE ALSO INCREASED BY OVER 90%.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032702	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 6/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NON STOP BLEEDING FOR 3 MONTHS CRAMPING, DIZZINESS, NAUSEA, WEAKNESS, ALWAYS TIRED , NUMBNESS IN VAGINAL AREA AND IN LEGS, ENTIRE BODY ACHES FEEL LIKE I HAVE THE FLU BUT I DONT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032703	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 2/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY FOLLOWING THE PROCEDURE, I HAVE HAD CONSTANT ABDOMINAL PAIN, ESPECIALLY ON MY RIGHT SIDE (PARTICULARLY IN THE AREA OF MY FALLOPIAN TUBES. EXTREMELY BAD CRAMPS AND HEAVY PERIODS, EVEN THOUGH I WAS TO HAVE AN ABLATION PROCEDURE DONE AT THE SAME TIME. I HAVE EXPRESSED CONCERN TO SEVERAL DOCTORS I BELIEVE ALL OF THESE MEDICAL ISSUES ARE DUE TO THE ESSURE PROCEDURE. I HAVE RECENTLY BEEN INFORMED I MAY HAVE A TEAR IN MY ABDOMINAL WALL. AND PLAN ON HAVING A HYSTERECTOMY TO REMOVE THE ESSURE COILS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032704	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 11/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HI, MY NAME IS (B)(6) AND I AM (B)(6) YEARS OLD. I HAVE BEEN MARRIED FOR 21 YEARS TO A WONDERFUL MAN (IN THE US MARINE CORPS). WE HAVE 3 CHILDREN, AGES (B)(6). OH, AND 2 DOGS. MY FAMILY IS HUGE INTO SOCCER, ALL 3 KIDS PLAY, MY HUSBAND COACHES ALL OF THE SELECT TEAMS AND I MANAGE THEM. WE ARE EXTREMELY ACTIVE AND ALWAYS ON THE GO. IN 2011, I STARTED SEEING A NEW GYNECOLOGIST AND SHE RECOMMENDED I GO OFF OF THE BIRTH CONTROL PILL. SHE TOLD ME ABOUT A PROCEDURE THAT WAS "VERY EASY TO DO" AND "HAD NO SIDE EFFECTS". I READ UP ON IT A BIT, AND DECIDED TO TAKE HER ADVICE AND HAVE THE ESSURE PROCEDURE DONE. THIS WAS APPROXIMATELY (B)(6) 2011. THE PROCEDURE ITSELF WAS PRETTY UNEVENTFUL. WE HAD ANTICIPATED THAT AN ABLATION MAY NEED TO BE DONE AFTER THE ESSURE PROCEDURE BECAUSE I HAD ALWAYS HAD SOME HEAVY, ERRATIC BLEEDING. ABOUT A MONTH LATER, WE HAD THE ABLATION DONE. WHILE WE EXPECTED THE ABLATION TO REDUCE THE AMOUNT OF BLEEDING, IT DIDN'T CHANGE IT MUCH AT ALL AND IF ANYTHING, AT TIMES IT HAD INCREASED. AFTER TALKING WITH MY GYNECOLOGIST AGAIN, SHE RECOMMENDED THAT I HAVE A PARTIAL HYSTERECTOMY. IN THE SPRING OF 2012, I HAD THE HYSTERECTOMY. IT WAS DONE BY THE DIVINCI ROBOT. I ENDED UP STAYING IN THE HOSPITAL FOR 2 NIGHTS BECAUSE I JUST DIDN'T "FEEL" RIGHT. WHEN I WAS SENT HOME I BLED LONGER THAN USUAL AND CRAMPED LONGER AS WELL. I WOULD GO BACK TO SEE MY GYNECOLOGIST REGARDING THE CRAMPING AND SHE JUST KEPT SAYING IT WOULD GET BETTER. THIS WENT ON FOR WEEKS. FINALLY I WENT TO SEE MY FAMILY PRACTICE DOCTOR AND HE REFERRED ME TO ANOTHER GYNECOLOGIST. AFTER SEEING HER SHE WAS ABLE TO DETERMINE I HAD A SMALL INFECTION GOING ON, PUT ME ON ANTIBIOTICS AND THAT PRETTY MUCH FIXED IT. FOR THE REST OF THE SPRING, SUMMER AND FALL OF 2012, MY HUSBAND SWEARS I WAS NOT THE SAME. SLEPT A LOT, STILL CRAMPED, HEADACHES ETC. FINALLY IN (B)(6) OF 2012 THE WORST STARTED. I WAS

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SITTING ON MY SOFA AND FELT A TINGLING AND NUMBING IN MY LEFT ARM. AFTER GOING BACK AND FORTH FOR A BIT WITH MY HUSBAND, WE WENT TO THE ER. THEY KEPT ME FOR A COUPLE HOURS AND THEN SENT ME HOME. A FEW HOURS LATER, I WAS SO DIZZY, MY HEAD WAS SPINNING, I COULD BARELY WALK. I CALLED MY MOM'S CARDIOLOGIST AND SHE SAID TO GO BACK IT. SHE WANTED ME ADMITTED. I WAS IN THE HOSPITAL FOR 5 DAYS. SO DIZZY, MY HEAD WAS IN A FOG - THEY HAD AN ALARM ON MY HOSPITAL BED SO I WOULD GET UP. WHEN I GOT OUT, MY CARDIOLOGIST WANTED ME TO SEE AN ENDOCRINOLOGIST. 3 DAYS LATER I SAW HER AND PASSED OUT IN HER OFFICE. BACK TO THE HOSPITAL AND ADMITTED FOR 3 MORE DAYS. THE ENDOCRINOLOGIST DETERMINED THAT MY NUMBERS WERE ALL WHACKED OUT AND SHE PUT ME ON TONS OF MEDICINE, INCLUDING STEROIDS. JUMP AHEAD ABOUT A MONTH OF ME FEELING MISERABLE ALL THE TIME. I END UP DRIVING AND ALMOST PASSING OUT SO BACK TO THE HOSPITAL FOR 7 MORE DAYS. BACK ON THE BED ALARM. AT THE END OF THE 7 DAYS, THEY DETERMINED THAT I HAVE POTS OR POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME. ESSENTIALLY, MY HEART RATE RACES WHEN I STAND UP, THE BLOOD GOES TO MY FEET AND I FEEL LIKE I WILL PASS OUT. THEY SEND ME 4 HOURS AWAY TO THE (B)(6). ONCE AT THE (B)(6) THEY DETERMINED THAT I HAVE SOME SORT OF ADRENAL INSUFFICIENCY, POTS AND DYSAUTONOMIA OR AUTONOMIC DYSFUNCTION (BASICALLY ANYTHING MY BODY DOES AUTOMATICALLY - IT WON'T DO.), AND CARDIOMYOPATHY (MY HEART NOW FUNCTIONS AT 40%). I STARTED SEEING CARDIOLOGISTS, NEUROLOGISTS AND ENDOCRINOLOGISTS. THE CARDIOLOGIST AND NEUROLOGIST ARE TWO OF THE LEADERS OF THE POTS CLINIC AT (B)(6). THE FIRST THING THEY SAY IS: "HAVE YOU HAD SOME SORT OF SURGERY OR HORMONAL CHANGE OR STRESSOR LIKE THAT?" APPARENTLY, THAT IS WHAT THEY BELIEVE TO BE THE CAUSE OF POTS AND DYSAUTONOMIA. I TOLD THEM ABOUT THE ESSURE, ABLATION AND HYSTERECTOMY. OF COURSE, NONE OF US WERE AWARE OF THE CONTROVERSY SURROUNDING ESSURE. SO, JUMPING WAY AHEAD, I HAVE HAD A FEW MORE HOSPITAL STAYS, GO TO THE (B)(6) ALMOST BI-WEEKLY, HAVE GAINED 30+ LBS BECAUSE OF MEDICINES AND EFFECTS OF THE SURGERIES, SLEEP ALL THE TIME AND CAN NO LONGER SUBSTITUTE TEACH AS I FEEL SO AWFUL ALL THE TIME. WE HAVE PAID COUNTLESS DOLLARS IN HOSPITAL BILLS, NEW CLOTHES WHEELCHAIRS AND WALKERS FOR WHEN I AM JUST TOO DIZZY ETC. I NOW STRONGLY FEEL THAT THE ESSURE PROCEDURE IS THE STRESSOR OR HORMONAL CHANGE THAT TRIGGERED ALL OF THIS. OF COURSE THERE IS SO MUCH MORE TO TELL, BUT THAT'S THE START. I WOULD DO ANYTHING TO FELL BETTER AND IF THIS IS CAUSED MY ESSURE, I WANT IT STOPPED. THANK YOU FOR TAKING THE TIME TO READ ALL OF THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032705	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 11/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY QUALITY OF LIFE HAS DETERIORATED FROM THIS PROCEDURE. I WENT IN THINKING THIS HAS GOT TO BE THE EASIEST FORM OF BIRTH CONTROL...AND IT WAS, IF I ONLY KNEW WHAT ALL THE SIDE EFFECTS WERE AND WHAT DAMAGE IT WAS GOING TO DO TO MY BODY. THERE ARE NO WORDS FOR WHAT THE TYPE OF STABBING PAINS I GET IN MY ABDOMEN/RECTUM. UNEXPLAINED SKIN REACTIONS, COMPLETE PHYSICAL/EMOTIONAL EXHAUSTION, CHEST PAINS, JOINT PAINS, HEADACHES, TINGLING IN YOUR HANDS/LEGS/FEET, BURNING FROM THE INSIDE OUT, UNBELIEVABLE LEG CRAMPS, NECK/SHOULDER PAIN DISCOMFORT, INTENSE HEADACHES, SHARP BREAST PAINS, NIPPLES ITCHING, NIPPLE DISCHARGE, MUCUS STOOLS, DISCHARGE, EXTREME BLEEDING AFTER SEXUAL INTERCOURSE, UNEXPLAINED HIP/KNEE/SPINAL PAINS - THE LIST COULD STILL GO ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032706	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 9/27/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED ON THAT DATE AND I HAVE HAD PROBLEMS EVERY SINGLE DAY EVER SINCE. I BLED FOR ALMOST CONSTANTLY FOR AN ENTIRE YEAR, I HAVE HORRIBLE MIGRAINES AND BACKACHES, I AM BLOATED AND RAPIDLY GAINING WEIGHT, OFTEN FEEL FATIGUED AND DEPRESSED, HAVE HAD SKIN RASHES AS WELL AS ALLERGIC REACTIONS TO METALS IN JEWELRY THAT NEVER BOTHERED ME BEFORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032707	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 4/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEPRESSION, MIGRAINES, CRAMPING, SPOTTING/BLEEDING BETWEEN PERIODS, OVARY PAIN, PAIN IN FEMALE AREA, FIBROMYALGIA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032708	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 12/16/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE IMPLANT INITIALLY FELT FINE AFTER THE THIRD DAY OF BEING INSERTED. THE FIRST ISSUE CAME UP ABOUT ONE MONTH AFTER THE IMPLANT. DURING INTERCOURSE I HAD SEVERE CRAMPING AND MY UTERUS FELT LIKE IT WAS RIPPING. OVER THE COURSE OF THE YEARS NEW COMPLICATIONS HAVE SPRUNG UP. IN ADDITION TO THE PAINFUL INTERCOURSE I NOW DEAL WITH CRAMPING AND PULLING OF THE UTERUS, LOWER BACK PAIN, BLOATED APPEARANCE ON A DAILY BASIS. WHILE ON MY PERIOD, I HAVE EVEN MORE PAINFUL CRAMPS AND PASS QUARTER SIZE OR LARGER CLOTS OF BLOOD. MASSIVE AMOUNTS OF BLOOD IS LOST, WHICH IS NOT HOW IT WAS BEFORE ESSURE. I ALSO WAS NOT GIVEN I NICKLE ALLERGY TEST BEFORE INSERTION OR TOLD THE COILS CONTAINED NICKLE OR I WOULD NOT HAVE HAD THE PROCEDURE. I HAVE NICKLE SENSITIVITY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032709	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE CAUSED SO MUCH PELVIC PAIN, I BLED FOR A TOTAL OF 100 DAYS, LIVING WITH PAIN ALL THIS TIME, JUST RECENTLY HAD SURGERY TO REMOVE THE ESSURE COILS, HAD HEADACHES, BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032710	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 11/14/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE PROCEDURE DONE IN LATE 2008, I'M UNSURE OF THE EXACT DATE, BUT IT WAS AFTER MY DAUGHTER'S BIRTH IN 2008. THE PROCEDURE WAS DONE AT (B)(6) BY MY OB/GYN, DR (B)(6). I WAS "PUT UNDER" FOR THE PROCEDURE AND HAD SOME MILD CRAMPING AFTERWARD. MY REAL ISSUES DIDN'T START UNTIL ROUGHLY 6 MONTHS LATER AND HAVE BEEN GETTING WORSE WITH EACH PASSING YEAR. I BECAME DEPRESSED, STARTED HAVING ANXIETY ATTACKS, MY PERIODS HAVE GOTTEN HEAVIER AND THE CRAMPING IS SO BAD THAT I AM OFTEN DOUBLED OVER IN PAIN. BEFORE ESSURE, I RARELY EVER HAD CRAMPS. NOW MY PERIODS ARE SO HEAVY DURING THE FIRST 4 OR 5 DAYS OF MY PERIOD THAT I AM FLOODING A SUPER PLUS TAMPON WITHIN 15 MINUTES TIME WHILE SITTING DOWN! IF I AM STANDING OR MOVING AROUND, IT'S MUCH SOONER THAN THAT. THE PAST FEW MONTHS I HAVE BEEN PASSING BLOOD CLOTS 3-4 INCHES IN DIAMETER. THIS IS NOT NORMAL FOR ME. SINCE GETTING ESSURE, I HAVE MIGRAINES THAT WILL LAST FOR DAYS AND THAT HURT SO BADLY I END UP THROWING UP. I GET AT LEAST 3 OR 4 OF THEM PER MONTH. I SUFFER FROM DEPRESSION, ANXIETY, CHRONIC PAIN IN MY HIP AND WAS DIAGNOSED ABOUT A YEAR AGO WITH FIBROMYALGIA. MY QUALITY OF LIFE IS VERY LOW. I AM IN CONSTANT PAIN, HAVE BOUTS OF INSOMNIA AND HAVE PUT ON OVER 100 LBS SINCE ESSURE WAS IMPLANTED. I DO NOT CURRENTLY HAVE HEALTH INSURANCE SO I AM UNABLE TO GO TO THE DR OR ER. SOMETIMES WHEN WALKING OR SITTING I GET SHARP PAINS IN MY ABDOMEN, LIKE SOMETHING IN THERE IS STABBING ME, AND I'M AFRAID IT IS ONE OF MY COILS. OVER THE PAST 6 MONTHS (WHEN I STILL HAD INSURANCE) I HAD XRAYS, A CT SCAN AND 2 MRI'S TO TRY TO FIND THE SOURCE OF MY HIP PAIN THAT HAS BEEN PLAGUING ME SINCE I HAD THE ESSURE COILS PLACED. ALL OF THOSE TEST HAVE LEFT THE DOCTORS BAFFLED BECAUSE THEY SHOW THAT NOTHING IS WRONG. BUT MY INABILITY TO WALK, BEND OVER, CONSTANT PAIN, AND NUMBNESS TELLS ME SOMETHING IS WRONG. SOMETHING IS TERRIBLY

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WRONG. I AM (B)(6) AND MY (B)(6) MOTHER IN LAW CAN PLAY WITH MY DAUGHTER AND GET AROUND BETTER THAN ME. SOMETHING IS WRONG! NONE OF THESE THINGS HAPPENED TO ME UNTIL AFTER ESSURE. I FINALLY GOT FED UP ABOUT A YEAR AGO AND STARTED LOOKING FOR ANSWERS ONLINE AND HAVE CONNECTED WITH GROUPS OF WOMEN WHO ALL HAVE VERY SIMILAR SYMPTOMS AND ONE COMMON FACTOR...WE ALL HAVE ESSURE!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032712	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2010, I DECIDED TO GET ESSURE SINCE I ALREADY HAD 3 CHILDREN. THE DOCTOR INFORMED ME THAT THERE WASN'T GOING TO BE MUCH PAIN AND THAT IT WOULD BE AN EASY PROCESS. IT SOUNDED LIKE THE PERFECT WAY TO GO, THEY SAID WITHIN A DAY I WOULD BE BACK TO NORMAL DOING REGULAR ACTIVITIES, AND THERE WOULD BE LIGHT BLEEDING. I CAN HANDLE PAIN, BUT THE PAIN I FELT AFTER GETTING ESSURE HAD ME IN TEARS. I HAD A HEAVY MENSTRUAL CYCLE FOR 3 MONTHS STRAIGHT. WHEN I CONTACTED MY OBGYN, HE INFORMED ME THAT IT WAS NORMAL. I HAD HORRIBLE BACK, ABDOMEN, AND HIP PAIN. THERE WERE DAYS I COULD NOT WALK, IN TEARS WHILE MY HUSBAND WOULD HAVE TO PICK ME UP TO STAND UP FROM THE COUCH. I CAN'T EVEN STAND UP STRAIGHT SOME DAYS OR DO SIMPLE THINGS LIKE TIE MY SHOES. MY HIPS AND ABDOMEN ACHE, LIKE NOTHING I HAVE EVER FELT BEFORE. AFTER HAVING MY 3RD CHILD, I BOUNCED BACK TO MY NORMAL (B)(6) POUNDS, SINCE ESSURE, I HAVE GAINED 25 POUNDS, I HAVE TRIED DIETING. I HAVE HORRIBLE MIGRAINES THAT I NEVER EXPERIENCED. MY (B)(6) OBGYN SAID THAT HE DOESN'T KNOW OF ANY DR'S IN TOWN THAT ARE ABLE TO DO A REVERSAL. FDA, PLEASE TAKE THESE COMPLAINTS SERIOUSLY, THIS IS THE WORST DECISION I HAVE EVER MADE. 3 YEARS LATER AND I AM STILL IN PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032715	CONCEPTUS	11/13/2013	1/14/2014

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THREE MONTHS AFTER HAVING THE PROCEDURE, I DEVELOPED A RASH COVERING THE MAJORITY OF MY BODY, I'VE BEEN TREATED FROM SCABIES AND PSORIASIS WITH NO MAJOR IMPROVEMENT. I ALSO STARTED GETTING HEADACHES A FEW WEEKS AFTER THE PROCEDURE THAT ARE CONSTANTLY REOCCURRING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032694	CONCEPTUS	11/13/2013	1/15/2014

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THIS PROCEDURE DONE BACK IN 2008, AFTER MY THIRD CHILD WAS BORN. IMMEDIATELY I COULD FEEL THE FOREIGN DEVICE. I WENT HOME IN TEARS, ALTHOUGH ON PAIN MEDS I COULD STILL FEEL IT. AFTER 3 DAYS RECOVERY AND BEING IN STRONG PAIN MEDS MY PELVIC PAIN WAS EXCRUCIATING! THE PAIN IS STILL THERE. I HAVE HORRIBLE CRAMPING DURING MY PERIOD ACCOMPANIED WITH BACK PAIN. BREAST TENDERNESS, IRREGULAR PERIODS, CYSTS, LOSS OF HAIR, LACK OF LIBIDO, PAIN DURING INTERCOURSE, HOT FLASHES, NIGHT SWEATS, CLOUDED MEMORY, TINGLING IN ALL EXTREMITIES. I AM ALLERGIC TO NICKEL, DOCTOR DIDN'T TELL ME IT HAD NICKEL!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032700	CONCEPTUS	11/13/2013	1/15/2014

Event Information:

Event Date (B3): 12/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER BEING TALKED INTO THIS PROCEDURE AS A SAFE ONE, IT HAS AFFECTED ME IN THE WRONG WAYS. I HAVE CHRONIC HEADACHES, ALONG WITH CHRONIC ABDOMEN PAIN, AND LOWER BACK PAIN, EMOTIONAL ROLLER COASTER, FREQUENT BLEEDING, AND HEAVY PERIODS, AND LACK OF CONCENTRATION ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032711	CONCEPTUS	11/13/2013	1/15/2014

Event Information:

Event Date (B3): 8/11/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALCOHOL INTOLERANCE-SICK FROM, ANXIETY, ACNE, BACKPAIN, BLURRING OF VISION AND FLOATERS, DISCHARGE (NO ODOR), BODY ACHES/HURTS/STIFFENS, BOWEL ISSUES-CONSTIPATION, BRUISES, CLOUDY BRAIN FOG, FORGETFULNESS, CRAMPING, DEPRESSION, DEHYDRATION, DIZZINESS, DRY EYES/SKIN/HAIR, EATING DISORDER-LOSS OR INCREASED APPETITE, FATIGUE-LOSS OF ENERGY, FEVER, HAIR GROWTH, HAIR LOSS, HEADACHES/MIGRAINES, HEAVY BLEEDING/CLOTTING DURING PERIOD, HIP PAIN, HOT FLASHES, INSOMNIA, MOOD SWINGS, NAUSEA, PAINFUL INTERCOURSE, PAINFUL OVULATION, PELVIC PAIN, SEVERE BLOATING, SHARP STABBING PAINS,TEETH ISSUES, WEIGHT GAIN, WEIGHT LOSS, FEELS LIKE YOUR BOTTOM IS GOING TO FALL OUT, HURTS TO WALK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032713	CONCEPTUS	11/13/2013	1/15/2014

Event Information:

Event Date (B3): 2/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I HAD THE ESSURE PRODUCT IMPLANTED IN (B)(6) 2010 MY LIFE CHANGED FOR THE WORSE AND I WOULD NEVER BE THE SAME. MY GYNECOLOGIST HIGHLY RECOMMENDED ESSURE STATING THE PROCEDURE WAS DONE IN THE OFFICE, NO SURGERY AND I COULD RETURN TO WORK THE NEXT DAY. I WAS IN CONSTANT PAIN FOR THE NEXT 2 1/2 YRS AND STILL AM IN PAIN TODAY. ESSURE HAS LEFT ME WITH SEVERE ADVERSE AFFECTS OR "AFTERMATH" AS I REFER TO IT. THIS HAS NOT ONLY EFFECTED ME BUT MY ENTIRE FAMILY. SHORTLY AFTER THE PROCEDURE MY HUSBAND AND MYSELF MADE SEVERAL CALLS TO MY DR STATING I WAS STILL IN A LOT OF PAIN. HE SAID THERE WAS NO WAY IT WAS FROM THE ESSURE. I WAS NEVER TOLD ABOUT, NOR WAS I EVER TESTED FOR, A POSSIBLE NICKEL ALLERGY, NEVER TOLD ABOUT NOR EVER GIVEN AN ESSURE CARD (WITH THE COILS LOT #/INFO) AND WAS NEVER TOLD ABOUT NOR GIVEN A HSG TEST TO THIS VERY DAY. THE ONLY THING MY DR DID FOR ME WAS GAVE ME PRESCRIPTIONS FOR PAIN MEDICATION. FROM THE DAY I WAS IMPLANTED UNTIL (B)(6) 2012 I SUFFERED WITH THE FOLLOWING SYMPTOMS: SEVERE WEIGHT GAIN AND BLOATING, BLURRED VISION, MEMORY LOSS, LOSS OF BALANCE, EXCRUCIATING PAIN RADIATING DOWN FROM MY LOWER BACK, INTO MY BUTTOCKS AND DOWN BOTH LEGS BACK AND FRONT, MIGRAINES AND LOW GRADE FEVERS DAILY, BLEEDING GUMS, EXTREME FATIGUE AND MANY MANY MORE SYMPTOMS. I SAW EVERY SPECIALIST KNOWN TO MANKIND, SUCH AS A NEUROLOGIST, ORTHOPEDIC, INFECTIOUS DISEASE SPECIALIST, SPINE DR, OPHTHALMOLOGIST AND RHEUMATOLOGIST, TO NAME A FEW...MANY TRIPS TO THE ER, CT SCANS, X-RAYS, MRI'S AND TONS OF BLOOD WORK. I WAS TESTED FOR AND DIAGNOSED/MISDIAGNOSED WITH LUPUS, MS, VITAMIN DEFICIENCIES, FIBROMYALGIA, LYME DISEASE, ADD, HIGH BLOOD PRESSURE, SCIATICA, DEPRESSION, ANXIETY AND; DIABETES TO NAME A FEW. I HAD ABNORMALLY HIGH LEVELS OF PRESSURE IN BOTH EYES, CONSTANT TASTE OF METAL IN MY MOUTH, COULDN'T FOCUS OR CONCENTRATE AND SEVERE

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MEMORY LOSS. I HAD A GREAT CAREER AS A BANK MANAGER AND COULD NO LONGER WORK, TAKE CARE OF MY KIDS AND WAS UNABLE TO DO COMMON HOUSEHOLD CHORES. I WAS IN BED FOR DAYS AT A TIME FROM THE PAIN. I SUFFERED FROM INSOMNIA AT TIMES ANDA OTHER TIMES I WOULD SLEEP FOR DAYS ON END. I WAS PUT ON AND TAKEN OFF DOZENS OF MEDS, NONE OF WHICH HELPED. IN (B)(6) 2012 MY HUSBAND TOOK ME TO THE ER FOR THE THIRD TIME IN A MONTH AND A HALF BECAUSE I COULD NOT WALK. THE LEFT SIDE OF MY FACE WAS "PARALYSED" AND I HAD SEVERE PAIN GOING DOWN MY SPINE, BACK AND LEGS. THEY TOOK X-RAYS AND DID A CT SCAN AND REFERRED ME TO A SPINE DR. THE NEXT DAY WHEN MAKING THE APPT WITH THE SPINE DR THE NURSE TOLD ME SHE WOULD ACCESS MY MEDICAL RECORDS THROUGH HER COMPUTER SO THE DR COULD LOOK THEM OVER BEFORE MY APPT. TEN MINUTES LATER SHE CALLED ME BACK AND SAID "(B)(6), DO YOU HAVE AN IUD BECAUSE THE CT SCAN REPORT STATES PORTIONS OF A METALLIC OBJECT HAVE MIGRATED INTO YOUR PELVIC REGION." THAT WAS THE FIRST TIME IN 2 1/2 YRS IT HIT ME...ESSURE! SHE INSTRUCTED ME TO SEE A GYNECOLOGIST IMMEDIATELY AND BY THAT AFTERNOON MY NEW GYNECOLOGIST SENT ME FOR MORE BLOOD WORK AND A VAGINAL ULTRA SOUND ONLY TO FIND OUT THAT THERE WAS A METAL CLIP INSIDE ME AND THE ESSURE COILS WERE SCATTERED THROUGHOUT MY PELVIC AREA. ONE WEEK LATER I WAS ADMITTED INTO THE HOSPITAL FOR A TOTAL ABDOMINAL HYSTERECTOMY (LEAVING THE OVARIES). THE COIL IN THE RIGHT FALLOPIAN TUBE PROTRUDED THROUGH THE MIDDLE OF THE TUBE AND WAS SCREWING ITSELF INTO MY UTERUS SO BADLY THAT MY UTERUS WAS UPSIDE DOWN. THREE QUARTERS OF THE COIL IN THE LEFT FALLOPIAN TUBE HAD SHATTERED AND MIGRATED THROUGHOUT MY PELVIC AREA. WITHIN HOURS OF MY SURGERY I FELT LIKE A COMPLETELY DIFFERENT PERSON. I HADN'T FELT THAT GOOD SINCE THE ESSURE WAS IMPLANTED. I HAD A VERY GOOD RECOVERY AND WAS FEELING BETTER AND BETTER EACH WEEK UNTIL (B)(6) 2012. I WAS HAVING SHARP ABDOMINAL AND LOWER BACK PAIN AND WAS TAKEN TO THE ER. THROUGH MORE ULTRA SOUNDS AND CT SCAN THEY FOUND CYSTS ON MY OVARIES THAT WERE OF CONCERN AND INSTRUCTED ME TO SEE MY GYNECOLOGIST WHO TOLD ME I HAD LARGE ABNORMAL COMPLEX OVARIAN CYSTS AND SAID HE COULD NOT HELP ME AND REFERRED ME TO GYN ONCOLOGIST. AFTER MEETING WITH THE ONCOLOGIST HE PUT ME ON BIRTH CONTROL, SENT ME FOR A VAGINAL ULTRA SOUND AND MRI. HE SAID HE WANTED TO WATCH THE CYSTS TO SEE IF THEY WOULD GROW BUT PUTTING ME ON BIRTH CONTROL MIGHT PREVENT THE CYSTS FROM GROWING AND THAT EVERY 2 MONTHS I WOULD HAVE TO GO FOR VAGINAL ULTRA SOUNDS AND MRI'S TO WATCH THE PROGRESSION. EVERY 2 MONTHS THE RESULTS WERE THAT DESPITE BEING ON THE BIRTH CONTROL THE CYSTS CONTINUED TO GROW AND EVENTUALLY BECOME SEPTATED. NOT KNOWING IF THIS WAS OVARIAN CANCER OR NOT IN (B)(6) 2013 I HAD TO HAVE MY OVARIES REMOVED. I THANKFULLY DID ONLY HAVE CANCER AND MADE A FULL RECOVERY. THE GYNECOLOGIST THAT PERFORMED MY HYSTERECTOMY TOLD ME SHE NO LONGER DOES THE ESSURE PROCEDURE DUE TO SEVERAL OF HER PATIENTS HAVING SIMILAR ISSUES. AS OF WRITING THIS ON (B)(6) 2013 I STILL SUFFER WITH PAIN AND FATIGUE, HEADACHES AND BRAIN FOG AND STILL AM UNABLE TO WORK. THERE ARE THOUSANDS OF WOMEN SUFFERING WITH STORIES SUCH AS MINE WHOSE LIVES HAVE BEEN SEVERELY AFFECTED. ESSURE NEEDS TO BE TAKEN OFF THE MARKET SO NO OTHER WOMEN NEED TO SUFFER THE WAY I HAVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032714	CONCEPTUS	11/13/2013	1/15/2014

Event Information:

Event Date (B3): 2/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I HAD THE ESSURE PRODUCT IMPLANTED IN (B)(6) 2010 MY LIFE CHANGED FOR THE WORST AND; WOULD NEVER BE THE SAME. MY GYNECOLOGIST HIGHLY RECOMMENDED ESSURE STATING THE PROCEDURE WAS DONE IN THE OFFICE, NO SURGERY AND; COULD RETURN TO WORK THE NEXT DAY. I WAS IN CONSTANT PAIN FOR THE NEXT 2 1/2 YRS AND STILL AM IN PAIN TODAY. ESSURE HAS LEFT ME WITH SEVERE ADVERSE AFFECTS OR "AFTER MATH" AS I REFER TO IT. THIS HAS NOT ONLY EFFECTED ME BUT MY ENTIRE FAMILY. SHORTLY AFTER THE PROCEDURE MY HUSBAND AND; MYSELF MADE SEVERAL CALLS TO MY DR STATING I WAS STILL IN A LOT OF PAIN. HE SAID THERE WAS NO WAY IT WAS FROM THE ESSURE. I WAS NEVER TOLD ABOUT NOR WAS I EVER TESTED FOR A POSSIBLE NICKEL ALLERGY, NEVER TOLD ABOUT NOR EVER GIVEN AN ESSURE CARD (WITH THE COILS LOT #/INFO) AND; WAS NEVER TOLD ABOUT NOR GIVEN A HSG TEST TO THIS VERY DAY. THE ONLY THING MY DR DID FOR ME WAS GAVE ME PRESCRIPTIONS FOR PAIN MEDICATION. FROM THE DAY I WAS IMPLANTED UNTIL (B)(6) 2012 I SUFFERED WITH THE FOLLOWING SYMPTOMS: SEVERE WEIGHT GAIN AND; BLOATING, BLURRED VISION, MEMORY LOSS, LOSS OF BALANCE, EXCRUCIATING PAIN RADIATING DOWN FROM MY LOWER BACK, INTO MY BUTTOCKS AND; DOWN BOTH LEGS BACK AND; FRONT, MIGRAINES AND; LOW GRADE FEVERS DAILY, BLEEDING GUMS, EXTREME FATIGUE AND; MANY MANY MORE SYMPTOMS. I SAW EVERY SPECIALIST KNOWN TO MANKIND SUCH AS A NEUROLOGIST, ORTHOPEDIC, INFECTIOUS DISEASE SPECIALIST, SPINE DR, OPHTHALMOLOGIST AND; RHEUMATOLOGIST TO NAME A FEW...MANY TRIPS TO THE ER, CT SCANS, X-RAYS, MRI'S AND; TONS OF BLOOD WORK. I WAS TESTED FOR AND; DIAGNOSED/MISDIAGNOSED WITH LUPUS, MS, VITAMIN DEFICIENCIES, FIBROMYALGIA, LYME DISEASE, ADD, HIGH BLOOD PRESSURE, SCIATICA, DEPRESSION, ANXIETY AND; DIABETES TO NAME A FEW. I HAD A ABNORMALLY HIGH LEVELS OF PRESSURE IN BOTH EYES, CONSTANT TASTE OF METAL IN MY MOUTH, COULDN'T FOCUS OR CONCENTRATE AND; SEVERE

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MEMORY LOSS. I HAD A GREAT CAREER AS A (B)(6) AND; COULD NO LONGER WORK, TAKE CARE OF MY KIDS AND; WAS UNABLE TO DO COMMON HOUSEHOLD CHORES. I WAS IN BED FOR DAYS AT A TIME FROM THE PAIN. I SUFFERED FROM INSOMNIA AT TIMES AND; OTHER TIMES I WOULD SLEEP FOR DAYS ON END. I WAS PUT ON AND; TAKEN OFF DOZENS OF MEDS, NONE OF WHICH HELPED. IN (B)(6) 2012 MY HUSBAND TOOK ME TO THE ER FOR THE THIRD TIME IN A MONTH AND A HALF BECAUSE I COULD NOT WALK. THE LEFT SIDE OF MY FACE WAS "PARALYSED" AND; HAD SEVERE PAIN GOING DOWN MY SPINE, BACK AND; LEGS. THEY TOOK X-RAYS AND; DID A CT SCAN AND; REFERRED ME TO A SPINE DR. THE NEXT DAY WHEN MAKING THE APPT WITH THE SPINE DR THE NURSE TOLD ME SHE WOULD ACCESS MY MEDICAL RECORDS THROUGH HER COMPUTER SO THE DR COULD LOOK THEM OVER BEFORE MY APPT. TEN MINUTES LATER SHE CALLED ME BACK AND; SAID "(B)(6), DO YOU HAVE AN IUD BECAUSE THE CT SCAN REPORT STATES PORTIONS OF A METALLIC OBJECT HAVE MIGRATED INTO YOUR PELVIC REGION". THAT WAS THE FIRST TIME IN 2 1/2 YRS IT HIT ME...ESSURE! SHE INSTRUCTED ME TO SEE A GYNECOLOGIST IMMEDIATELY AND; BY THAT AFTERNOON MY NEW GYNECOLOGIST SENT ME FOR MORE BLOOD WORK AND; A VAGINAL ULTRA SOUND ONLY TO FIND OUT THAT THERE WAS A METAL CLIP INSIDE ME AND; THE ESSURE COILS WERE SCATTERED THROUGHOUT MY PELVIC AREA. ONE WEEK LATER I WAS ADMITTED INTO THE HOSPITAL FOR A TOTAL ABDOMINAL HYSTERECTOMY (LEAVING THE OVARIES). THE COIL IN THE RIGHT FALLOPIAN TUBE PROTRUDED THROUGH THE MIDDLE OF THE TUBE AND; WAS SCREWING ITSELF INTO MY UTERUS SO BADLY THAT MY UTERUS WAS UPSIDE DOWN. 3/4 OF THE COIL IN THE LEFT FALLOPIAN TUBE HAD SHATTERED AND; MIGRATED THROUGHOUT MY PELVIC AREA. WITHIN HOURS OF MY SURGERY I FELT LIKE A COMPLETELY DIFFERENT PERSON. I HADN'T FELT THAT GOOD SINCE THE ESSURE WAS IMPLANTED. I HAD A VERY GOOD RECOVERY AND; WAS FEELING BETTER AND; BETTER EACH WEEK UNTIL (B)(6) 2012. I WAS HAVING SHARP ABDOMINAL AND; LOWER BACK PAIN AND; WAS TAKEN TO THE ER. THROUGH MORE ULTRA SOUNDS AND; CT SCAN THEY FOUND CYSTS ON MY OVARIES THAT WERE OF CONCERN AND; INSTRUCTED ME TO SEE MY GYNECOLOGIST WHO TOLD ME I HAD LARGE ABNORMAL COMPLEX OVARIAN CYSTS AND; SAID HE COULD NOT HELP ME AND; REFERRED ME TO GYN ONCOLOGIST. AFTER MEETING WITH THE ONCOLOGIST HE PUT ME ON BIRTH CONTROL, SENT ME FOR A VAGINAL ULTRA SOUND AND; MRI. HE SAID HE WANTED TO WATCH THE CYSTS TO SEE IF THEY WOULD GROW BUT PUTTING ME ON BIRTH CONTROL MIGHT PREVENT THE CYSTS FROM GROWING AND; THAT EVERY 2 MONTHS I WOULD HAVE TO GO FOR VAGINAL ULTRA SOUNDS AND; MRI'S TO WATCH THE PROGRESSION. EVERY 2 MONTHS THE RESULTS WERE THAT DESPITE BEING ON THE BIRTH CONTROL THE CYSTS CONTINUED TO GROW AND; EVENTUALLY BECOME SEPTATED. NOT KNOWING IF THIS WAS OVARIAN CANCER OR NOT IN (B)(6) OF 2013 I HAD TO HAVE MY OVARIES REMOVED. I THANKFULLY DID ONLY HAVE CANCER AND; MADE A FULL RECOVERY. THE GYNECOLOGIST THAT PERFORMED MY HYSTERECTOMY TOLD ME SHE NO LONGER DOES THE ESSURE PROCEDURE DUE TO SEVERAL OF HER PATIENTS HAVING SIMILAR ISSUES. AS OF WRITING THIS ON (B)(6) 2013 I STILL SUFFER WITH PAIN AND; FATIGUE, HEADACHES AND; BRAIN FOG AND; STILL AM UNABLE TO WORK. THERE ARE THOUSANDS OF WOMEN SUFFERING WITH STORIES SUCH AS MINE WHO'S LIVES HAVE BEEN SEVERELY EFFECTED. ESSURE NEEDS TO BE TAKEN OFF THE MARKET SO NO OTHER WOMEN NEED TO SUFFER THE WAY I HAVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032827	CONCEPTUS	11/14/2013	11/18/2013

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT STATED THAT HER DAUGHTER WAS BORN BOW LEGGED AND HAS MULTIPLE FOOD AND METAL ALLERGIES. SHE BELIEVES THAT BECAUSE OF THE USER OF ESSURE AND HER ALLERGIES TO NICKEL DURING PREGNANCY, HER DAUGHTER HAS DEVELOPED ALTERED BONE GROWTH AND HAS BEEN UNABLE TO HAVE VARIOUS IMMUNIZATIONS BECAUSE OF A DAIRY ALLERGY. HER DAUGHTER HAS EXPERIENCED DIARRHEA, HIVES AND ANAPHYLAXIS. MOTHER STATES THAT THE PEDIATRICIAN BELIEVES THAT DURING THE ESSURE USAGE, HER NICKEL ALLERGY CROSSED THE PLACENTAL BARRIER AND AFFECTED THE UNBORN CHILD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032829	CONCEPTUS	11/14/2013	11/18/2013

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2008
Explant Date (E7): 5/17/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT STATED THAT SHE HAD THE ESSURE IMPLANTED IN (B)(6) 2008 AND SHE BECAME PREGNANT IN 2009. POST-DELIVERY IT WAS DISCOVERED THAT SHE HAD RIGHT AND LEFT PUNCTURED FALLOPIAN TUBES. PT HAS EXPERIENCED INFLAMMATION, OPEN ULCERS, FAINTING, CYSTS AND MULTIPLE UTI'S. SHE HAS HOSPITALIZED IN 2012 AND SHE LOST 3 UNITS OF BLOOD. SPOTS HAVE BEEN FOUND ON HER LUNGS AND LIVER DURING A CT SCAN. SHE ALSO HAS EXPERIENCED HELICOBACTER PYLORI WHICH TOOK APPROXIMATELY A YEAR TO RESOLVE. SHE HAS HAD TO HAVE HER UTERUS AND FALLOPIAN TUBES REMOVED. PT IS ALLERGIC TO NICKEL AND THE H PYLORI AND ULCERS RESOLVED AFTER EXPLANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032934		11/14/2013	11/20/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 50667569

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SWELLING HANDS AND FEET, RASH AND HIVES, PAINS IN STOMACH, MOOD CHANGES, SLEEP PROBLEMS, HEADACHES, LIGHT-HEADED, BLOATED BELLY, PAIN IN LEGS AND BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032935	CONCEPTUS, INC	11/14/2013	11/20/2013

Event Information:

Event Date (B3): 11/12/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 12261233

Single Use:
Implant Date (E6): 11/12/2004
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED ON (B)(6) 2004, AND HERE ARE ALL THE SYMPTOMS I HAVE HAD OVER THE PAST 9 YEARS. STARTED WITH PAIN IN MY LOWER BACK AND DOWN TO MY TAIL BONE, PAIN IN MY HIPS, MY KNEES, MY HANDS, MY ELBOW. I HAVE SUFFERED WITH SEVERE HEADACHES, PROBLEMS WITH MY VISION, PROBLEMS SLEEPING DUE TO THE PAIN. I HAVE BEEN VERY TIRED, HAVE HAD SHARP PAIN IN MY VAGINA. ALSO VAGINAL ITCHING WITH NO INFECTION. I HAVE GONE TO SEVERAL DOCTORS TO HEAR THAT THEY COULD NOT FIND THE SOURCE OF MY PAIN. TO FEEL THE PAIN I FELT AND KNOW THE DOCTORS CAN NOT FIGURE IT OUT CAUSED SOME DEPRESSION. THIS HAS TAKEN TIME AWAY FROM MY FAMILY THAT I CAN NEVER GET BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032936		11/14/2013	11/20/2013

Event Information:

Event Date (B3): 3/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE IN (B)(6) 2012 AND I HAVE PAIN ON MY RIGHT SIDE WITH A KNOT. REASON FOR USE: GOT IT SO I DON'T GET PREGNANT AGAIN AFTER I LOST MY DAUGHTER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032937	BAYER/CONCEPTUS	11/14/2013	11/20/2013

Event Information:

Event Date (B3): 9/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/24/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING PAIN ON LOWER BACK, RIGHT LOWER ABDOMEN, PERIOD LASTING FOR 5 WEEKS, BLOOD CLOTS IN MENSTRUATION. LIMITED ACTIVITY RELATED TO PAIN, EASY FATIGABILITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032938		11/14/2013	11/20/2013

Event Information:

Event Date (B3): 10/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/12/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD THE ESSURE FOR 4 YEARS AND SINCE I'VE HAD THIS DEVICE, I HAVE LOWER BACK PAINS TO WHERE I CAN'T MOVE. ALSO ABDOMINAL PAIN. GOING TO THE HOSP IS NO HELP FOR ME BECAUSE OF THE AWARENESS OF THIS DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032939		11/14/2013	11/20/2013

Event Information:

Event Date (B3): 12/29/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/29/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE PERFORMED (B)(6) 2005. I HAVE HAD SO MANY PROBLEMS SINCE, BACK PAIN, PELVIC PAIN, BLEEDING, LONGER AND PAINFUL PERIODS, WEIGHT GAIN, DISCHARGE AND RASHES, PAINFUL INTERCOURSE, BREAST TENDERNESS, BLOOD CLOTS, BODY ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032940	BAYER	11/14/2013	11/20/2013

Event Information:

Event Date (B3): 7/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED LAST (B)(6) AND I HAVE BEEN IN PAIN EVERY DAY OF MY LIFE EVER SINCE. CRAMPS, HORRIBLE BACK PAIN, NAUSEA, HEMORRHAGING ON MY MENSTRUAL CYCLE, AND PAIN DAILY. I HAVE THOUGHT IT WAS JUST SOMETHING I HAD TO DEAL WITH UNTIL I SAW THE OTHER (B)(6) WOMEN WHO SUFFER FROM THIS AS WELL. IF I WOULD HAVE KNOWN THERE WAS NICKEL ON IT I WOULDN'T HAVE IT DONE. I AM VERY SENSITIVE TO NICKEL. I JUST WANT THEM OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032941		11/14/2013	11/20/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 699884

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE BEEN HAVING LOTS OF PAIN IN LOWER RIGHT ABDOMEN SINCE ESSURE PROCEDURE WAS DONE. (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032942		11/14/2013	11/20/2013

Event Information:

Event Date (B3): 4/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/23/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED IN TUBES ON (B)(6) 2013. HAD HSG TEST (B)(6) 2013. RIGHT TUBE BLOCKED AND FINE. LEFT TUBE COIL NOT IN PLACE AND EITHER IN UTERUS OR PERFORATED UTERUS. UNK IF IT WAS PLACEMENT ERROR OR JUST MIGRATED OUT OF TUBE. HAD 2ND HSG (B)(6), TOLD THAT ESSURE "RECOMMENDS" LEAVING COIL IN BODY BECAUSE RISK OF REMOVAL IS TOO HIGH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032943		11/14/2013	11/20/2013

Event Information:

Event Date (B3): 8/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ENSURE
Device Type (E2): ENSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'M IN SERIOUS PAIN ALL THE TIME ON MY LOWER ABDOMEN, LOSS OF HAIR BAD MIGRAINES DUE TO THE FACT AFTER THE PLACEMENT. I HAVE HAD THESE PROBLEMS CONSTANT URINARY TRACT INFECTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032944		11/14/2013	11/20/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSUER
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN (B)(6) 2012. SINCE THEN I HAVE HAD RASHES, INTENSE SWELLING IN THE ABDOMEN AREA WITH A LOT OF PAIN. I ALSO HAVE VERY HEAVY MENSTRUAL BLEEDING WITH HORRIFIC PAIN. I CAN FEEL THE COILS SPRING UP AND IT'S LIKE A SHOCK GOING THROUGH MY WAIST. LOTS OF LEG PAIN, SOMETIMES CAN'T EVEN WALK. PAIN STARTS BY MY OVARIES AND SHOOTS DOWN TO MY THIGHS AND LEGS. ALSO GET FEVERS AT LEAST 3 TO 6 TIMES A MONTH DURING MY PERIOD. (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032945	BAYER	11/14/2013	11/20/2013

Event Information:

Event Date (B3): 2/17/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/17/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED AS A FORM OF PERMANENT BIRTH CONTROL IN (B)(6) 2012. I WAS NOT ASKED ABOUT NICKEL ALLERGIES BEFORE HAVING THE PROCEDURE. I DO HAVE NICKEL ALLERGIES. I CANNOT WEAR EARRINGS MADE OF NICKEL OR MY EARS BREAK OUT IN SORES AND BURN BADLY. I FELT FINE FOR A FEW MONTHS AFTER THE PROCEDURE. THEN I STARTED HAVING CONSTANT LOW BACK PAIN AND SHOOTING PAINS IN MY UTERUS. MY PERIODS ARE HEAVIER AND I AM NOW ANEMIC AND HAVE TO TAKE PRESCRIPTION IRON. I HAVE DANDRUFF THAT WON'T GO AWAY. NEVER HAD BEFORE. I FEEL LIKE I AM SICK ALL THE TIME. LIKE MY IMMUNE SYSTEM IS LOW. I GET NAUSEATED AND GAG. I HAVE LOST 18 LBS WITHOUT DIET OR EXERCISE CHANGE. MY WEIGHT WENT FROM (B)(6), THE SKINNIEST I'VE EVER BEEN. I JUST DON'T FEEL RIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032779	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 1/27/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD SLIGHT CRAMPING THE EVENING I HAD THE ESSURE IMPLANTED AT A HOSPITAL UNDER SEDATION. BY THE NEXT DAY, I BEGAN HAVE A LOW GRADE FEVER, WHICH HAS COME AND GONE EVER SINCE. I THEN BEGAN HAVE UNPREDICTABLE PERIODS BOTH IN WHEN THEY WOULD COME AND THE LENGTH AND SEVERITY. I BEGAN HAVING PERIODS THAT WOULD INCLUDE WORSE CRAMPING, BLEEDING AND CLOTTING AND AT TIMES PERIODS THAT ENDED UP LATE AND SUPER LIGHT TO THE POINT I WOULD WONDER IF I WAS PREGNANT. I STARTED HAVING PROBLEMS WITH NUMBNESS AND TINGLING IN MY LEFT CALF STARTING ABOUT 4-5 MONTHS AFTER IMPLANTATION. THE NUMBNESS AND TINGLING HAS NOW SPREAD TO THE REST OF MY SIDE FROM MY FOOT UP TO MY FACE AND SMALL AREAS ON MY RIGHT LEG AND ARM. I HAVE HAD EXTREME FATIGUE, GI ISSUES, MEMORY ISSUES, PELVIC PAIN NOT ASSOCIATED WITH MY MONTHLY PERIOD, BACK AND HIP PAIN THAT RADIATES FROM THE PELVIC PAIN, JOINT PAIN, MUSCLE WEAKNESS, MUSCLE SPASMS, VISION ISSUES, AND A PLETHORA OF OTHER SMALLER ISSUES. I HAVE HAD NUMEROUS TESTS COMPLETED WITH NORMAL RESULTS. THE ONLY DIAGNOSED ISSUE I HAVE (ALTHOUGH I HAVE HAD BLOOD WORK AND VARIOUS TESTS COMPLETED) IS VARIOUS LEVELS OF BACK ARTHRITIS IN L4 AND L5 THAT HAS PRESENTED SINCE AN XRAY DONE IN (B)(6) 2011. MOST RECENTLY, BEGAN HAVING MORE INTENSE PAIN IN MY PELVIC AREA COMBINED WITH CONTRACTION LIKE MUSCLE SPASMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032781	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 7/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

TO WHOM THIS MAY CONCERN: I'M WRITING YOU TODAY TO INFORM YOU ABOUT THE AMOUNT OF PAIN, MENTAL ANGUISH, AND STRESS MY HUSBAND AND I HAVE UNFORTUNATELY EXPERIENCED WITH THE PERMANENT BIRTH CONTROL CALLED ESSURE. I WAS ADVISED BY MY OBGYN, DR (B)(6) AT (B)(6) THAT IT WOULD BE DONE IN THE OFFICE WITH LITTLE TO NO BLEEDING AND WOULD TAKE 10 - 15 MINUTES. I NOT ONLY BLED FOR A MONTH, THE PROCEDURE ALSO LASTED FOR ABOUT AN HOUR AS WELL. I CURRENTLY LOOK AND FEEL 4 TO 5 MONTHS PREGNANT, INCLUDING SHARP, SEVERE PELVIC, ABDOMINAL, CHEST, JOINT, AND HIP PAIN. I HAVE RASHES ALL OVER MY STOMACH, RANDOM BRUISING, ACNE, WEIGHT GAIN ALONG WITH SEVERE BLOATING, FORGETFULNESS, DEPRESSION, DISCHARGE, PAINFUL/ LEAKY BREAST (AND I DON'T BREAST FEED!), BLEEDING AFTER SEX, FATIGUE, NUMBNESS IN MY HANDS AND FEET, MIGRAINES, AND I EVEN FEEL VIBRATION IN MY ABDOMEN WHERE I BELIEVE MY TUBES ARE LOCATED. I OFTEN GET ANXIETY AND PANIC ATTACKS AND LATELY WHEN I BEND OVER OR STRETCH, I FEEL TUGGING ON THE INSIDE OF MY STOMACH. THE LIST GOES ON AND ON AND I NEVER HAD THESE PROBLEMS BEFORE ESSURE. I'M (B)(6), MARRIED, AND A STAY AT HOME MOM WITH FOUR BOYS. I FEEL LIKE MY LIFE IS OVER SINCE I HAD THIS PROCEDURE DONE DUE TO MY DOCTOR'S ADVICE. I'M NOT ABLE TO PLAY WITH MY KIDS LIKE I WANT TO OR BE INTIMATE WITH MY HUSBAND BECAUSE IT'S SO PAINFUL TO WALK, SIT, OR EVEN GET UP TO DO ANYTHING. I'M ANGRY/DEPRESSED, AND CONSTANTLY YELLING AND SCREAMING AT MY HUSBAND AND KIDS...I'M EVEN OUT OF BREATH FROM JUST CLEANING THE HOUSE. I STRONGLY BELIEVE YOU SHOULD TAKE ESSURE OFF THE MARKET OR AT LEAST EDUCATE DOCTORS ABOUT THIS PRODUCT. MAYBE, JUST MAYBE, WHEN DOCTORS DECIDE TO STOP WORRYING ABOUT HOW MUCH IS IN THEIR POCKET AND MORE ABOUT THE HEALTH OF THEIR PATIENTS, IT WON'T HAVE TO GET THIS FAR TO PROVE A POINT. I AM NOW LOOKING FOR INSURANCE SINCE (B)(6) PAYS TO HAVE IT

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IMPLANTED AND NOT REMOVED. ESSURE SHOULD BE TAKEN OFF THE MARKET AND EVERY WOMAN WHO HAS BEEN IMPLANTED AND SUFFERED FROM IT (INCLUDING MYSELF!) SHOULD HAVE THE OPTION OF REMOVING THIS BIRTH CONTROL. NO MATTER WHAT INSURANCE OR HOW MUCH MONEY THEY HAVE IN THEIR POCKETS...NO QUESTIONS ASKED!. MY HUSBAND AND I HAVE PACKED ON SO MUCH STRESS BEHIND ESSURE. THE EXCRUCIATING PAIN IS UNBEARABLE AND I JUST WANT MY LIFE BACK AND TO WAKE UP FROM THIS HORRIBLE NIGHTMARE CALLED ESSURE THANK YOU FOR YOUR TIME, (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032783	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 1/4/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I FIRST BEGAN TO EXPERIENCE DIFFUSE JOINT PAIN AND INFLAMMATION WITH NEGATIVE SERIAL SEROLOGICAL TESTING FOR AUTOIMMUNE DISEASES. OVER THE LAST 5-6 YEARS, I'VE HAD INCREASING PELVIC PAIN AND IRREGULAR MENSES WITH HEAVY BLEEDING. THIS BECAME LITTLE TO NO BLEEDING AT ALL WITH PERIODS. I WAS EXAMINED BY A GYN WHO HAD TO DILATE MY CERVIX AS IT HAD STENOSED. SHE HAD NO EXPLANATION FOR THIS OTHER THAN IT WAS PROBABLY DUE TO THE ESSURE PROCEDURE. THIS WAS NOT THE GYN WHO PUT THE COILS IN. PAIN IN PELVIS CONTINUED, I SAW MY GYN LAST YEAR WHO TOLD ME TO TAKE IBUPROFEN, ALSO DIAGNOSED A LARGE UTERINE FIBROID. CONTINUED IRREGULAR BLEEDING WITH MENSES AND INCREASED PELVIC PAIN. UNDERWENT REEXAMINATION BY GYN TWO WEEKS AGO WHO SAID MY CERVIX WAS STENOSED (SCARRING HAD BUILT UP).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032784	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 5/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD SEVERE ABDOMINAL PAIN, SEVERE BACK PAIN, GAINED 80 LBS, MIGRAINES PULMONARY EMBOLISM BRAIN FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032788	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 1/4/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THIS PROCEDURE DONE, I WAS IN A LOT OF PAIN AND BLEED WITH CRAMPING AND EXTREME BLEEDING FOR 12 WEEKS AND WAS SEEN ON AT LEAST THREE DIFFERENT OCCASIONS BY THE DOCTOR. I HAVE PAIN WHEN I MOVE ON MY LEFT SIDE AND WHEN I GET MY PERIOD I HAVE CRAMPS AND MAJOR SWELLING ON MY LEFT SIDE. I HAVE CLEAR DISCHARGE IN MASSIVE AMOUNTS ON AND OFF REGULARLY. SINCE THIS WAS OUT IN I HAVE HOT FLASHES, HAIR LOSS, WEIGHT GAIN, RANDOM DISCHARGE, SWELLING BACK PAIN AND DISCOMFORT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032789	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING A LOT MORE PAIN THAN USUAL STARTED GOING TO THE DOCTOR FOR EXTREME PELVIC PAIN, HEMORRHAGE DURING CYCLES, MORE THAN ONE CYCLE A MONTH, HEADACHE, FATIGUE, JOINT PAIN, WEIGHT GAIN, DIZZINESS, OVULATION PAIN, ETC...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032797	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PELVIC PAIN, HAIR LOSS, BLOATING, PAINFUL/IRREGULAR PERIODS, ACNE, BODY PAIN, PAIN IN BREATHS, AND SOME BRAIN FOG, ALLERGIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032799	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 2/26/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD SERIOUS PELVIC PAINS AND MY RIGHT SIDE HURTS ALL THE TIME GOES ALL THE WAY DOWN MY LEGS SOMETIMES WITH NUMBNESS. LEFT SIDE HURTS SOMETIMES BUT ALL THE TIME. I HAVE BEEN TOLD I HAVE CYSTS WHICH I NEVER HAD BEFORE ESSURE. I HAVE BAD MIGRAINES, METAL TASTE, NO ENERGY AND IRREGULAR PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032800	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 10/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WENT TO MY DOCTOR TO GET MY TUBES TIDE, SINCE I CANT TAKE HORMONE BIRTH CONTROL, BECAUSE OF MY HIGH BLOOD PRESSURE. AT THE CONVERSATION HE TOLD ME THAT ESSURE WOULD BE THE BEST FOR ME, BECAUSE OF MY BUSY LIFE STYLE AND THERE IS ALMOST NO SIDE EFFECT AND I COULD GO ON MY LIFE WITHOUT ANY PROBLEMS THE NEXT DAY. HE GAVE ME A BROCHURE FROM ESSURE THAT WAS PRINTED 2006. THIS SAYS THERE IS NICKEL IN ESSURE AND I CALLED HIM BACK AND TOLD HIM, THAT I HAVE A CRAZY NICKEL ALLERGY AND I REALLY DON'T WANT TO GET THIS THEN AND WANT TO HAVE MY TUBES TIDE INSTEAD. SO AT THE PRE SURGERY CONVERSATION, HE TOLD ME THAT FDA TOOK THE NICKEL ALLERGY WARNING OUT AND THAT IS NO NICKEL IN THERE, WHAT WILL CAUSE ME ANY PROBLEM AND I WILL BE FINE AND HE REALLY THINKS ESSURE WILL BE THE BEST FOR ME. SO I AGREED AND TRUSTED HIM. MY PROBLEM STARTED ON THE FIRST DAY, BUT I THOUGHT, ALRIGHT IT'S FRESH AND IT NEEDS TIME. I TOOK A COUPLE DAYS OFF TO NOT OVERDUE IT. BUT IT GOT WORSE. EVERY DAY SINCE THEN I AM IN HORRIBLE PAIN, EVEN THE PRESCRIPTION PAIN RELIEF IS NOT CUTTING IT OUT. WITH ACTIVITY IT EVEN GETS WORSE. I HAVE CRAMPING AND MY BELLY IS BLOATED LIKE 6 MONTHS PREGNANT. IF I BEND THE PAIN IS SO SHARP, LIKE A KNIFE IS STABBING ME. I'M GETTING NAUSEATED. I HAVE CONTRACTIONS COMPARED TO CHILDBIRTH, WHAT IS BREATH TAKING. MY SKIN IS HORRIBLE. I HAVE ACNE AND MY HAIR IS SO DRY. I DID NOT HAVE ANYTHING LIKE THIS BEFORE. AFTER X RAY AND ULTRA SOUND THE DOC DECIDED THAT MY BODY IS REJECTING THOSE IMPLANTS AND I'M HAVING AN ALLERGIC REACTION. SO I'M GETTING ON (B)(6) MY TUBES INCLUDING ESSURE TAKING OUT. SO KNOW I HAVE TO GET A MUCH BIGGER SURGERY AND MAYBE A HYSTERECTOMY IF MY UTERUS HAS DAMAGE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032801	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 1/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE IMPLANTED, I HAVE EXPERIENCED UNEXPLAINED SKIN RASHES, DAILY HEADACHES/MIGRAINES, FATIGUE, JOINT PAIN, SEVERE INFLAMMATION IN THE NECK (C2/C3), HEAVY BLEEDING, PELVIC PAIN, FLOATERS IN VISION, MEMORY LOSS, SEVERE MOOD SWINGS, HAIR LOSS, BLOATING, PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032809	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 10/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING, CRAMPING, PAIN IN LOWER BACK AND STOMACH, MIGRAINES, SKIN BREAKING OUT , TERRIBLE BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032811	CONCEPTUS	11/14/2013	1/14/2014

Event Information:

Event Date (B3): 7/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6), 2012 I WAS IN SEVERE PAIN AFTER THE PROCEDURE. I CALLED THE DOCTOR, HE CLAIMED IT WAS NORMAL. I FINALLY WAS ABLE TO SEE THE DOCTOR AROUND THE (B)(6) AND HE TOLD ME THAT NONE OF MY SYMPTOMS WERE RELATED TO THE ESSURE. HE TOLD ME I HAS POST PARTUM DEPRESSION, AND PUT ME ON PAXIL. ON (B)(6), POST ESSURE IN 2012 I WAS HOSPITALIZED FOR MENINGITIS. POST HOSPITAL DISCHARGE, I SUFFERED WITH SEVERE MIGRAINES DAILY, MUSCLE SPASMS, DIZZINESS, FAINTING, SEIZURE LIKE ACTIVITY, TINGLING IN ARMS, HANDS, RIGHT LEG. SEVERE ABDOMINAL PAIN, FATIGUE, VISION DISTURBANCES, METALLIC TASTE, MEMORY LOSS, TROUBLE CONCENTRATING, DEPRESSION (FROM BEING SO SICK AND NOTHING WAS HELPING), BLOOD CLOTS, MENORRHAGIA, BRAIN SHOCKS, MUSCLE WEAKNESS, URINARY TRACT/KIDNEY INFECTION, CANCEROUS CELLULAR CHANGE-DYSPLASIA, SPEECH PROBLEMS, INSOMNIA, CONFUSION, STOMACH PAIN, SEVERE PAIN-LOWER BACK, SEVERE PAIN-LEFT OVARY, COMPLETE HYSTERECTOMY ON (B)(6), 2013. ON (B)(6), 2013 I SUFFERED A VAGINAL DEHISCENCE THAT REQUIRED EMERGENT REPARATIVE SURGERY. TO THIS DAY, I CANNOT CONSUME ANY FOODS CONTAINING NICKEL, DAILY HEADACHE (MILD), DIZZINESS, WEAKNESS, OCCASIONAL FATIGUE, MILD MUSCLE SPASMS AND OCCASIONAL BRAIN SHOCKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032778	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 8/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM THE TIME I RECEIVED MY IMPLANTS, I BEGAN HAVING INCREASED BACK PAIN AND FOOD SENSITIVITIES, A COMMON SIDE EFFECT OF THE ESSURE IMPLANTS. HAVING RECENTLY GIVEN BIRTH AND IN NEED OF LOSING MY "BABY WEIGHT", I KEPT IGNORING MY SYMPTOMS. IT WASN'T UNTIL MY PERIODS RETURNED WHEN MY CHILD BEGAN TO WEAN ONTO SOME SOLID FOODS IN JANUARY OF 2012 THAT I BEGAN TO NOTICE INCREASING SYMPTOMS. WHEN MY PERIODS RETURNED, THEY WERE INCREASING WITH SEVERITY OF BLEEDING AND PAIN. I HAVE DIFFICULTY USING TAMPONS BECAUSE OF THE PAIN. I SUFFER FROM CHRONIC YEAST AND BLADDER/URINARY TRACT INFECTIONS, NEITHER WHICH I HAD BEFORE ESSURE. THE LONGER I GO, THE WORSE THE PAIN GETS. I HAVE PAIN WITH OVULATION THAT PUTS ME IN BED FOR DAYS. I HAVE TROUBLE LOSING WEIGHT, I HAVE PAINFUL BLOATING IN MY BELLY. I HAVE A CHRONIC METAL TASTE IN MY MOUTH AND NO AMOUNT OF GUM OR BREATH MINTS CURES IT. MY PERIOD THIS PAST MONTH PUT ME IN BED FOR FOUR DAYS. A TRANSVAGINAL ULTRASOUND REVEALED THAT MY IMPLANTS ARE STILL IN MY PELVIC AREA, HOWEVER MY UTERUS IS SHOWING SIGNS OF ADENOMYOSIS. MY NEW OB/GYN IS MEETING WITH ME NEXT MONTH TO CONSULT WITH ME TO SCHEDULE A PARTIAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032780	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 7/23/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ONLY MEDICAL CONDITIONS I HAVE ARE HISTORY OF (B)(6) AND ECZEMA...SINCE THE PROCEDURE MY ECZEMA IS WORSE, I HAVE HEADACHES, SWEATS, ONE STAPH INFECTION ON MY RIGHT SIDE, RASH IN THE CENTER OF MY BACK, ONE SEVERE YEAST INFECTION THAT TRAVEL OUTSIDE OF THE VAGINAL AREA, NAUSEA, SOFT STOOL, METAL TASTE IN MY MOUTH EVERYDAY ESPECIALLY IN THE MORNING, FEEL WEAK FROM TIME TO TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032782	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 9/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAVE HAD THE ESSURE DONE MY PERIODS HAVE BECOME VERY IRREGULAR AND EXTREMELY HEAVY WITH VERY LARGE BLOOD CLOTS. THE PAIN THAT I HAVE EXPERIENCED SINCE THE PLACEMENT OF THE ESSURE HAS BEEN HORRIBLE TO THE POINT WHERE I CAN'T MOVE OFF OF THE COUCH. I HAVE BEEN FEELING SICK SINCE THE PROCEDURE AND AN OVER ALL FEELING OF DEPRESSION. MY DOCTOR HAS DONE THE NOVASURE TO HELP OUT WITH THE PAIN AND BLEEDING BUT THAT DIDN'T HELP AT ALL WITH THE EXCEPTION OF THE BLEEDING. I WAS THEN PUT THROUGH A DIAGNOSTIC LAPAROSCOPE TO SEE IF THERE WAS A PROBLEM. I AM NOW SCHEDULED TO HAVE A TOTAL HYSTERECTOMY DONE. THE PAIN IS JUST SO BAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032785	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 10/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXHAUSTION, SWELLING, HEADACHES, DIZZY SPELLS, LOWER ABDOMINAL AND BACK PAIN, SHARP SHOOTING PAIN IN RIGHT SIDE, NAUSEA, NUMBNESS IN ARMS AND HANDS, BLURRED VISION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032786	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 1/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM A DIABETIC AND HAVE BEEN AT THE TIME I HAD THE ESSURE COILS PUT IN BACK IN 2009. I HAVE AT TIME FELT PREGNANT, SEVERE CRAMPS, AND HEAVING BLEEDING. THIS YEAR I HAVE EXPERIENCED SEVERE PAIN IN MY RIGHT PELVIC AREA AROUND MY TUBE. THIS IS A PULSATING PAIN THAT HAS GRADUALLY BECOME MORE FREQUENT. THE PAIN WORSENS WITH INTERCOURSE AND I CAN FEEL THE RIGHT COIL MOVING. MY DOCTOR SAW SIGNS OF AN INFECTION DURING AN INTERNAL EXAM AND I WAS PUT ON ANTIBIOTICS. I AM SCHEDULED FOR A LAPAROSCOPIC PROCEDURE IN (B)(6). I HAVE ALSO BEEN TO THE ER A TOTAL OF 4 TIMES THIS YEAR DUE TO THIS PAIN. THE HOSPITAL DID CAT SCANS, X-RAYS, ULTRASOUNDS, TRANS VAGINAL ULTRA SOUNDS THEY CLAIM THESE TEST REVEALED NOTHING. I HAVE HAD U.T.I.'S WITH BLOOD IN MY URINE. I ALSO HAVE UTERINE PAIN, AT TIMES IT FEELS LIKE MY UTERUS IS SEIZING UP. AT THIS POINT MY PAIN FEELS CONSTANT AND INTERFERES WITH MY EVERYDAY LIFE AND WAKES ME OUT OF MY SLEEP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032787	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 12/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABNORMAL UTERINE BLEEDING, CHRONIC PELVIC PAIN, JOINT PAIN, AUTOIMMUNE DISEASE (HASHIMOTO'S), CONSISTENT ABDOMINAL BLOATING, INCREASED URGENCY TO URINATE, CONSTIPATION, LOSS OF APPETITE, ANXIETY, INSOMNIA.....ALL STARTED APPROX. 3 MOS POST PLACEMENT OF ESSURE COILS. SCHEDULED FOR TOTAL HYSTERECTOMY ON (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032790	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 4/2/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT CRAMPING IN LOWER ABDOM, AND UPPER WEIGHT AND WATER GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032791	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 10/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY PROCEDURE DONE IN 2010. SINCE THEN, I HAVE EXPERIENCED A HUGE NUMBER OF STRANGE, PERSISTENT SYMPTOMS. I HAVE SOUGHT THE CARE OF NUMEROUS SPECIALISTS, ALL OF WHICH CAN'T SEEM TO MAKE A PICTURE OUT OF THIS STRANGE PUZZLE. IT STARTED WITH DEBILITATING HEADACHES. MY EYES ACHE AND BURN AND IT FEELS AS THOUGH MY HEAD IS GOING TO EXPLODE. THE PRESSURE IS SO INTENSE THAT IT REMINDS ME OF BEING UNABLE TO SWALLOW ON AN AIRPLANE. ONLY THE PRESSURE IS ALL OVER. NOT JUST MY EAR DRUMS. AT IT'S WORST, I AM DISORIENTED AND EXPERIENCE AUDITORY DISTORTIONS. IN (B)(6) 2011, AFTER SEVERAL TRIPS TO THE GP AND THE ER, WE DID A LUMBAR PUNCTURE ONLY TO DISCOVER I HAD VIRAL MENINGITIS. I HAVE CONSTANT ABDOMINAL PAIN AND CRAMPING. AT THE LEAST, IT FEELS AS THOUGH I MAY HAVE EATEN SOMETHING THAT DIDN'T AGREE WITH ME. AT MOST, IT FEELS AS THOUGH I HAVE SOME SORT OF FOOD POISONING. IT IS AGONIZING AND HAS CAUSED SEVERE HEMORRHOIDS. ALONG WITH THE ABDOMINAL CRAMPING, I HAVE EXPERIENCED SEVERE BACK AND HIP PAIN, RADIATING DOWN MY THIGHS AND CALVES. MY MENSTRUAL CYCLE HAS GOTTEN EXCRUCIATING, WITH HEAVY BLEEDING AND DEBILITATING CRAMPS. I HAVE CONSTANT MUSCLE SPASMS, HYPERTONIC REFLEXES, AND BURNING MUSCLE PAIN. I'VE RECEIVED 6 STEROID INJECTIONS TO MY NECK AND UPPER BACK IN AN ATTEMPT TO RELEASE THE MUSCLES THAT ARE NOW FROZEN. DUE TO THE SPASMS, I HAVE DEVELOPED DEGENERATIVE DISC DISEASE TO MY CERVICAL SPINE AND LOWER BACK. SEVERAL DISKS IN MY LUMBAR SPINE HAVE HERNIATED UNDER THE STRAIN OF CONSTANT HIP, BUTTOCK AND HAMSTRING SPASMS. AT TIMES, I CAN BARELY LIFT OUR TODDLERS INTO THEIR CAR SEATS OR BUCKLE THE STRAPS. I HAVE CHRONIC FATIGUE, WHICH AGAIN CAN BE ATTRIBUTED TO NEUROLOGICAL IRRITATION, POOR QUALITY OF SLEEP, AND CHRONIC IMMUNE SYSTEM RESPONSE. MY PHYSICAL THERAPIST DESCRIBED IT TO ME LIKE THIS, IF YOUR MUSCLES ARE EXTREMELY TIGHT IT TAKES A LOT MORE

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ENERGY TO GET THEM TO REACH, STRETCH OR MOVE. IMAGINE A TIGHT EXERCISE BAND VERSUS A LOSER ONE. IT TAKES WAY MORE STRENGTH TO GET IT TO STRETCH. TO MY HUSBAND, WE'VE ACTUALLY STOPPED SLEEPING IN THE SAME BED. I AM CONSTANTLY TOSSING AND TURNING AND TWITCHING AND MOANING... I HAVE HAD THREE SERIOUS NEUROLOGICAL EPISODES INVOLVING PARALYSIS TO MY LEFT SIDE. I'VE BEGAN DEVELOPING TINY NONSPECIFIC LESIONS ON MY BRAIN THOUGHT TO BE RELATED TO THE SEVERE HEADACHES I'VE;VE BEEN HAVING. I HAVE BEEN HOSPITALIZED TWICE AND HAVE MADE DOZENS OF TRIPS TO THE EMERGENCY ROOM. MY HAIR HAS BEEN STEADILY THINNING AND FALLING OUT AND THE SKIN ON MY FACE IS OFTEN FLUSHED OR PEALING. MY FACE, SHOULDERS, ARMS, AND LEGS OFTEN FEEL LIKE ICE WATER IS BEING SPLASHED ON THEM OR AS IF AN INSECT IS BITING ME. I OFTEN FEEL AS THOUGH BUGS ARE CRAWLING UP MY EXTREMITIES. I HAVE SPENT (B)(6) IN HOSPITALIZATIONS, SPECIALISTS, TESTING, MEDICATIONS AND PROCEDURES TO ADDRESS MY SYMPTOMS. THE PROBLEM IS THAT WE NEVER GET TO THE ROOT OF WHAT IS CAUSING THIS. I HAVE A NICKEL ALLERGY. I WAS TOLD THAT THESE COILS WERE SAFE AND HAD AN EXTREMELY LOW LIKELIHOOD OF CAUSING ADVERSE REACTIONS. WHILE THIS MAY BE THE CASE, I AM HAVING AN EXTREMELY HARD TIME GETTING ANY DOCTORS TO ACKNOWLEDGE THAT I MAY FALL INTO THE MINORITY OF PATIENTS WITH ADVERSE REACTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032792	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2011. IT WAS A VERY PAINFUL EXPERIENCE. I STARTED HAVING SIDE EFFECTS ABOUT 4 MONTHS LATTER WHICH INCLUDE: SEVERE PAIN, HEAVY BLEEDING, PERIODS LASTING 2-3 WEEKS WITH USUALLY ONLY A 3-5 DAY BREAK BETWEEN, DIZZINESS, NAUSEA, FAINTING, HEADACHES, EXTREME WEIGHT LOSS, SEASONAL ALLERGIES, ENDOMETRIOSIS, CONTINUAL UTERINE INFECTIONS, HEAVY DISCHARGE, LOW SEX DRIVE. I HAD MY FALLOPIAN TUBES ALONG WITH COILS REMOVED IN (B)(6) 2013, WHEN EXAMINING THE COILS DOCTOR FOUND THAT IMPLANTING DOCTOR LEFT IMPLANTATION TOOLS IN MY FALLOPIAN TUBES ALSO. I FELT FINE FOR ABOUT 6 MONTHS AFTER THE REMOVAL BUT NOW HAVE ALL THE SAME SYMPTOMS BACK. I HAVE TO TAKE BIRTH CONTROL PILLS, PAIN PILLS, AND ALLERGY MEDICATION DAILY AND HAVE BEEN HOSPITALIZED DUE TO RECURING UTERINE INFECTIONS. MY DOCTOR SUGGESTED I HAVE A HYSTERECTOMY BUT CANNOT AFFORD IT DUE TO NO INSURANCE, SO I HAVE TO LIVE EVERY DAY BEING IN EXTREME LABOR LIKE PAINS AND CONSTANTLY SICK DUE TO INFECTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032793	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 9/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

VERY PAINFUL AND MY STOMACH STAYED BLOATED FOR WEEKS, I HAVE BEEN BLEEDING ON A REGULAR BASIS SINCE. NO EXPLANATION OR RHYME OR REASON. MENTAL STRESS FROM THE CONSTANT CRAMPING AND STABBING PAINS IN MY OVARIES AND TUBES. I NOW SUFFER FROM MAJOR DEPRESSION, DUE TO THE FACT MY CHILDREN HAVE SUFFERED AND SO HAS MY MARRIAGE. I HAVE HAD MULTIPLE BLOOD TESTS DONE AND PAPS TO TRY AND EXPLAIN THE BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032794	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 6/15/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NOT REALLY SURE ABOUT THE MONTH BUT THE YEAR WAS 2005. HAD THIS DEVICE IMPLANTED BUT WAS TOLD VERY LITTLE ABOUT IT AS IT WAS FAIRLY NEW AND THERE WAS NOT MUCH INFORMATION ABOUT IT THEN. I HAD NO PROBLEMS THAT I WAS AWARE OF UNTIL (B)(6) OF 2012. I HAD A PAIN IN MY LEFT SIDE THAT I HAD BEEN HAVING OFF AND ON FOR YEARS BUT THIS DAY IT ESCALATED AND I WENT TO THE ER. ONCE THERE THEY PERFORMED TEST AFTER TEST BUT FOUND NOTHING. WHILE THERE I RECEIVED A SHOT FOR PAIN AND MY LEFT THIGH WENT NUMB. I WENT TO MY REGULAR DR. A FEW DAYS LATER AND SHE DID TESTS ALSO..NOTHING. THE NUMBNESS IN MY THIGH GAVE SLIGHTLY TO PAIN WHICH HAD ME UNABLE TO MOVE AROUND MUCH OR WORK. I WENT TO SPECIALIST AFTER SPECIALIST. NOTHING. I FINALLY STARTED RESEARCHING BECAUSE I FELT A POKING IN MY ABDOMEN AND WONDERED IF IT WAS ESSURE. I WENT TO GYNECOLOGIST AND SHE PERFORMED AN ULTRASOUND BUT FOUND NOTHING. SHE SUGGESTED EXPLORATORY SURGERY TO FIND THE ANSWER TO MY PAIN. I HAD IT DONE ON (B)(6), 2013. SHE HAD TO DO A HYSTERECTOMY DUE TO ALL OF THE SCARRING FOUND INSIDE MY UTERUS. AS OF TODAY (B)(6), 2013, A YEAR TO THE DAY OF THE INITIAL PAIN...THE PAIN IS GONE. I FOUND A GROUP AFTER RESEARCHING PROBLEMS FROM ESSURE AND FOUND MANY SIDE EFFECT..MOST OF WHICH I HAVE EXPERIENCED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032795	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 3/8/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACE IN (B)(6) 2005, THEY WERE UNABLE TO DO THE FOLLOW UP TESTING BECAUSE MY BODY WOULD NOT ALLOW THE INSTRUMENTS TO ENTER THE AREA. I STARTED FEELING A CHRONIC DULL ACHY LEFT SIDED PELVIC PAIN THAT WOULD BECOME SEVERE IF PRESSURE WAS APPLIED IN THE AREA. IN (B)(6) 2006 I STARTED HAVING DEBILITATING MIGRAINES, SEVERE LOWER BACK PAIN AND JOINT PAIN. SINCE THE ESSURES WERE PLACED IN (B)(6) 2005 MY HEALTH HAS BEEN DECLINING. I HAVE BEEN DIAGNOSED WITH HYPERTENSION, FIBROMYALGIA, CHRONIC DAILY MIGRAINES W/ AND W/OUT AURA, OSTEOARTHRITIS, LICHENS SCLEROSIS, ACHALASIA AND OCCIPITAL NEURALGIA ALL WITHIN A YEAR OF GETTING ESSURE. I ALSO GAINED OVER 50 POUNDS RATHER QUICKLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032796	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 11/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVER PELVIC PAIN. HEAVY BLEEDING. AUTO IMMUNE DISORDER (PSORIASIS AND; PSORIATIC ARTHRITIS) SEVERE HAIR LOSS. WEIGHT GAIN. INFLAMMATION WIDESPREAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032798	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 11/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS ESSURE IMPLANT HAS CAUSED A LOT OF STRESS DUE TO SIDE EFFECTS. SHARP PAINS IN MY LEFT SIDE WHERE THE IMPLANT WAS PLACED. HAD PAIN RUNNING DOWN TO BEGINNING OF MY THIGH SOMETIMES. I HAVE ALSO GONE THROUGH MENOPAUSAL SYMPTOMS WHICH INCLUDE NIGHT SWEATS, MOOD SWINGS, AND SLEEP APNEA. I HAVE ALSO HAD DIZZY SPELLS AT HOME AND WORK. I HAVE NOT HAD A REGULAR MONTHLY PERIOD IN MONTHS. I HAVE ALSO PUT ON A LOT OF WEIGHT SINCE AND SEX DRIVE IS NON EXISTENT NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032802	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 1/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT STARTED WITH A MIGRAINE AND SEVERE PMS (CRAMPING/STABBING PAIN, BREAST PAIN (MUCH MORE THAN TENDERNESS), IRRITABILITY, FATIGUE. ONCE MY PERIOD STARTED, I HAD VERY HEAVY BLEEDING(SUPER TAMPON PER HOUR FOR AN ENTIRE DAY. DAY TWO HEAVY (SUPER TAMPON EVERY 3HRS). DAY 3 IS REGULAR FLOW. NEXT 7-10 DAYS I HAD SPOTTING. THIS IS RECURRING EVERY MONTH. THROUGHOUT THE MONTH I HAVE EXTREME ANXIETY, DEPRESSION, BLOATING, LOWER BACK PAIN, NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032803	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 1/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE PUT IN A LITTLE AFTER I HAD MY LAST BABY. THE DOCTOR DIDN'T TELL ME THERE WAS NICKEL PARTS ON THE DEVICE NOR DID HE BOTHER TO ASK ME IF I HAD ANY ALLERGIC REACTIONS TO IT. IMMEDIATELY AFTER THE IMPLANT, I HAD SEVERE UTERUS PAIN. I THOUGHT IT WAS NORMAL SO I GAVE IT A COUPLE OF DAYS. AFTER A FEW WEEKS, THE PAIN WAS STILL THERE. I WAS HAVING PAINFUL MENSTRUATION, PAINFUL SEX, HOT FLASHES, FEVERS, MY STOMACH WAS BLOATED, ALL THE SYMPTOMS ASSOCIATED WITH THE ESSURE DEVICE. IT WAS A NIGHTMARE! I WAS IN AND OUT OF ER'S WITH THE SAME COMPLAINT BUT THEY ALL JUST THOUGHT I WAS A PAIN MED ADDICT. ONE NURSE EVEN ASKED IF I HAD AN ADDICTION PROBLEM! THAT WAS SOOOOO EMBARRASSING! THIS WENT ON FOR ALMOST A YEAR UNTIL I SWITCHED OB/GYN AND AFTER RUNNING SEVERAL TESTS, TOLD ME THAT IT MAYBE DUE TO THE ESSURE, THEREFORE HE REFERRED ME TO ANOTHER DOCTOR WHO CAN REMOVE IT. I MADE AN APPOINTMENT WITH THIS NEW DOC AND AFTER A FEW VISITS WITH HIM AND SEVERAL PAIN MEDICATIONS LATER, I FINALLY HAD IT REMOVED. DURING MY POST OP VISIT, HE TOLD ME EVERYTHING WENT FINE AND THAT I HAD ANOTHER FORM OF ENDOMETRIOSIS AND THE REASON WHY IT DIDN'T SHOW UP IN ANY TESTS OR BIOPSY WAS BECAUSE IT WAS INSIDE MY UTERUS. HOWEVER, ALMOST IMMEDIATELY AFTER THAT SURGERY, AFTER I WAS RELEASED TO GO HOME, I FELT SHARP, STABBING PAINS IN MY GROIN AREA. I FELT THE NEED TO PEE BUT I COULDN'T. WENT BACK TO THE HOSPITAL WHERE I HAD MY HYSTERECTOMY DONE, THEY RAN SOME TESTS AND SAID IT WAS NOTHING AND SENT ME ON MY WAY HOME. LITTLE DID I KNOW, MY NIGHTMARE WASN'T OVER. A WHOLE NEW PROBLEM STARTED. THEY REMOVED THE ESSURE DEVICE BUT NOW MY LIFE WAS AT STAKE. AGAIN, IN AND OUT OF ERS' AND BEING TREATED LIKE AN ADDICT, GIVEN LITTLE PAIN MEDS THEN SENT HOME. I COULDN'T SLEEP, EAT, PEE NOR POO. I COULDN'T DO ANYTHING! I WAS BED RIDDEN, WEAK AND IN PAIN. MY KIDNEYS HURT SO THE

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DOCTORS ALL THOUGHT I HAD KIDNEY STONES. AFTER ALMOST 7 MONTHS OF NON STOP PAIN, NOT BEING ABLE TO PEE, POO, EAT NOR SLEEP, I HAD ENOUGH AND SWITCHED ERS. THE ER DOCTOR ORDERED A CT WITH CONTRAST THAT NIGHT. HE LATER CAME IN AND TOLD ME THE CONTRAST I DRANK EARLIER JUST LEAKED ALL OVER MY PELVIC FLOOR AND THAT I NEEDED TO BE KEPT INPATIENT IMMEDIATELY! HE THEN TOLD ME THAT IF I HAD WAITED ANOTHER DAY, I'D HAVE DIED FROM ALL MY BODY WASTES' JUST RECIRCULATING ALL OVER ON THE INSIDE OF MY BODY! HE ASKED IF I HAVE HAD ANY SURGERIES AND I TOLD HIM YES, ESSURE REMOVAL/PARTIAL HYSTERECTOMY. HE TOLD ME THAT DURING THE PROCEDURE, THE DOCTOR MAY HAVE KNOCKED A PART OF MY URETHRA/URETER. A UROLOGIST CAME EARLY THE NEXT MORNING AT THE HOSPITAL AND EXPLAINED THE SAME THING THE ER DOC TOLD ME AND THE PROCEDURE THAT NEEDED TO BE DONE. I NEEDED A STENT PLACED IN AND THE EARLIEST HE CAN PUT IT IN WAS THE NEXT MORNING. I AGREED AND SIGNED THE NECESSARY PAPER WORKS. AFTER THE STENT WAS IN, I FELT IMMEDIATE RELIEF. I WAS KEPT THERE AT THE HOSPITAL FOR ALMOST A WEEK. AFTER 4 FAILED STENTS, THE UROLOGIST FINALLY TOLD ME I NEEDED TO JUST HAVE SURGERY YET AGAIN TO FIX MY URETER. I BARELY HAD THAT SURGERY DONE EARLIER THIS YEAR AND I'M DOING OK EXCEPT PAIN ON MY LEFT GROIN AREA. OH, AND AFTER ALL THAT PAIN MEDICATIONS I WAS ON, I HAD TO GO ON A METHADONE TREATMENT PROGRAM TO GET ME OFF OF NARCOTICS SUCCESSFULLY. I STARTED AT 30MGS OF METHADONE, WENT UP TO 70MGS, STAYED AT 70 FOR QUITE A LONG TIME, AND NOW I'M DETERMINED TO GET OFF OF METHADONE AS WELL. I'M CURRENTLY AT 18MGS. ALL THIS PROBLEMS STARTED WITH ONE LITTLE BIRTH CONTROL DEVICE. ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032804	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 8/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM (B)(6) ON, MY HEALTH HAS SLOWLY DECLINED. MY WORK PERFORMANCE IS LACKING. I NOW TAKE SEVERAL MEDS. NEVER HAD ONE PRIOR. QUALITY OF LIFE SEVERLY ALTERED AFTER IMPLANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032805	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 12/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THREE MONTHS AFTER HAVING ESSURE PLACED I RETURNED TO HAVE MY HSG TEST DONE. MY TUBES WERE NOT CLOSED FROM THE ESSURE. THE RIGHT COIL WAS NOT IN MY TUBE AT ALL. IT WAS IN MY UTERUS. MY LEFT COIL WAS PARTIALLY IN MY TUBE BUT A FRAGMENT FROM THE COIL HAD ALSO BROKEN OFF AND WAS IN MY UTERUS. TWO WEEKS AFTER THAT ON (B)(6) 2010 I HAD SURGERY, A TUBAL LIGATION AND ALSO TO FIND THE COIL IN MY UTERUS TO HAVE IT REMOVED. IT HAD MIGRATED FROM THE RIGHT SIDE OF MY UTERUS TO THE MID LEFT OF MY UTERUS AND ATTACHED ITSELF TO MY UTERUS. DURING THAT 3 MONTH PERIOD I HAD EXCRUCIATING ABDOMINAL PAIN. I COULD NOT CARE FOR MY CHILDREN. THE PAIN WAS WORSE THAN GIVING BIRTH. I WOULD CURL UP IN AGONY WAITING FOR THE PAIN TO SUBSIDE. AFTER THE COIL WAS REMOVED...THIS PAIN SUBSIDED. THE LEFT COIL WAS KEPT IN MY TUBE. IT WAS NOT REMOVED. I SLOWLY STARTED HAVING SOME PROBLEMS AND HEALTH ISSUES. I HAD SEVERE BLOATING, SEVERE PELVIC PAIN, SEVERE PELVIC PRESSURE, SEVERE PELVIC INFLAMMATION, SEVERE BACK PAIN, HEAVY MENSTRUAL CLOTTING, PAINFUL INTERCOURSE, EXTREME FATIGUE, JOINT SWELLING. I CONTINUED TO HAVE THESE SYMPTOMS AND PAIN. THREE PLUS YEARS LATER I FINALLY INSISTED TO MY DOCTOR THAT SOMETHING IS NOT RIGHT. THESE ARE NOT JUST SYMPTOMS OF MENSTRUATION, OVULATION. I HAD A PELVIC ULTRASOUND....THE LEFT COIL WAS NOT SEEN ON THE ULTRASOUND. I INSISTED THAT I GET AN X-RAY TO SEE WHERE THE COIL IS. ON THE X-RAY IT WAS DISCOVERED THAT THE LEFT COIL AD MIGRATED OUT OF MY FALLOPIAN TUBE TO SOMEWHERE ON THE RIGHT SIDE OF MY ABDOMEN. THERE WAS A FRAGMENT OF THE COIL ON MY LEFT AREA NEAR MY BLADDER. ON (B)(6) 2013 I HAD SURGERY. I HAD A LEFT SALPINGECTOMY AND DIAGNOSTIC LAPAROSCOPY. IT WAS DISCOVERED THAT THE LEFT COIL HAD MADE ITS WAY OVER TO MY RIGHT

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SIDE AND ATTACHED ITSELF TO MY APPENDIX. THE COIL WAS REMOVED. THE FRAGMENT ON MY LEFT SIDE WAS DISCOVERED PIERCING MY UTERINE WALL. THAT WAS ALSO REMOVED. MY LEFT FALLOPIAN TUBE WAS ALSO REMOVED DUE TO THE PAIN I CONSISTENTLY HAD ON MY LEFT SIDE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032806	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 6/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE HSG TEST TO CONFIRM MY FALLOPIAN TUBES WERE BLOCKED. ONE OF MY TUBES WAS BLOCKED BY THE ESSURE COIL HOWEVER THE OTHER COIL DID NOT EMBED ON MY TUBE BUT RATHER IN MY MUSCLE. I NOW HAVE TO HAVE MY FALLOPIAN TUBES REMOVED SINCE ESSURE FAILED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032807	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 11/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL/PELVIC PAIN, METAL TASTE IN MY MOUTH, DIFFICULTY HAVING SEX, AND SIGNIFICANTLY POSITIVE ALLERGY TO NICKEL VIA PATCH TEST (B)(6) 2013.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032808	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 3/12/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED IN (B)(6) 2007, MY FIRST PROBLEMS OCCURRED IN (B)(6) 2007. I STARTED BLEEDING FOR 3 1/2 MONTHS AND WENT TO THE DR. I ASKED HIM IF HE THOUGHT MAYBE I WAS HAVING SOME KIND OF REACTION TO MY ESSURE. HIS WORDS WERE NO IT WASN'T THE PROBLEM. I OFTEN WANDERED WHY I WOULD HAVE HAD A PROBLEM LIKE THAT. AFTER THAT I STARTED TO HAVE PROBLEMS WITH MY MENSTRUAL CYCLES, THEY WOULD COME ON VERY HEAVY AND LAST FOR DAYS. THEN IN (B)(6) 2010, I STARTED MY CYCLE AND IT WAS EXTREMELY HEAVY WITH LOTS OF BLOOD CLOTTING, AND SO VERY HEAVY IT WOULD RUN OUT OF ME AS IF I WERE PEEING IN MY PANTS. I WAS GOING ON MY 14TH DAY WHEN MY HUSBAND RUSHED ME TO THE ER, AND ONCE THERE THEY ENDED UP HAVING TO GIVE ME A BLOOD TRANSFUSION AND THEN A C WAS DONE LATER ON THAT DAY. THE DR. TOLD MY HUSBAND I WAS ON THE VERGE OF DEATH BECAUSE OF SO MUCH BLOOD LOSS. I HAVE JUST RECENTLY GONE BACK TO THE ER AGAIN IN (B)(6) 2013 BECAUSE OF BLACKING OUT WHILE ON MY OVERLY HEAVY CYCLE ONCE AGAIN. I HAVE HAD ESSURE FOR ALMOST 7 YEARS AND IT HAS BEEN NOTHING BUT PURE HELL AND MISERY. MY CYCLES ARE EXTREMELY MISERABLE AND CAN NOT BEAR TO EVEN GET A MONTHLY ANYMORE. I HAVE AWFUL MIGRAINES, LEFT HIP AND LOWER BACK PAIN. I HAVE BRAIN ZAPS AND CAN BARELY REMEMBER WHAT I WAS SAYING OR DOING 5 MINUTES BEFORE. IT IS EMBARRASSING AT TIMES TO EVEN HAVE A CONVERSATION WITH SOMEONE, BECAUSE OF FORGETTING WHAT I WAS EVEN SAYING. I AM A VERY MOODY PERSON NOW. I AM EXTREMELY FATIGUED, AND HAVE NO ENERGY IT'S ALL I CAN DO TO GET THROUGH MY DAILY ROUTINE. I AM SHORT OF BREATH AND FEEL VERY HEAVY CHESTED. MY LEGS TEND TO GET REALLY WEAK AND SHAKY FEELING WHEN I AM UP DOING MY CHORES FOR TO LONG AND I HAVE TO STOP AND RELAX A FEW MINUTES. I HAVE EXTREME BLOATING AND CRAMPING EVERYDAY AND IT TENDS TO GET WORSE THE MORE I'M ON MY FEET. COULD YOU IMAGINE BEING BLOATED WITH CRAMPS

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EVERYDAY OF YOUR LIFE. I HAVE GAINED SO MUCH WEIGHT IN THE PAST YEARS SINCE BEING ON ESSURE, AND IT IS IMPOSSIBLE TO LOSE ANY OF IT. MY HUSBAND AND I RARELY HAVE INTERCOURSE DUE TO THE BLOATING AND CRAMPING THAT I DEAL WITH. WHEN WE TRY IT ENDS UP BEING VERY PAINFUL. I AM BLESSED THAT I HAVE A VERY LOVING AND CARING HUSBAND THAT WORRIES ABOUT MY HEALTH. SOME MEN WILL WALK OUT. I WAS ALWAYS BLESSED WITH GOOD HEALTH AND NEVER HAD ANY ISSUES, UNTIL I WAS IMPLANTED WITH ESSURE IN 2007. SINCE THEN I HAVE HAD NOTHING BUT HEALTH ISSUES. I AM ONLY (B)(6) YEARS OLD AND FEEL SO MUCH OLDER WITH SO MANY ACHES AND PAINS. BEFORE ESSURE I WAS VERY ACTIVE AND FELT GREAT EVERYDAY. THAT'S HOW I WANT TO FEEL AGAIN. I AM SO TIRED OF THIS THING DRAINING THE LIFE OUT OF ME. I WISH TO MY GOD I WOULD HAVE JUST GONE ON WITH DOING THE TUBAL LIGATION AND NOT WENT WITH THE DRS. AND NURSE'S ADVICE AND HAVE THIS NIGHTMARE IMPLANTED IN ME. SINCE THIS LAST ER VISIT I HAVE BEEN FEELING A LOT WORSE AND DON'T KNOW WHAT TO DO, AND I CAN'T CONVINCE THE DR. THAT ESSURE IS WHAT'S CAUSING MY PROBLEMS. I KNOW MY BODY AND HOW I FELT BEFORE AND AFTER ESSURE. I AM SO TIRED OF BEING SICK. I JUST WANT MY LIFE BACK!!!!! I AM SO TIRED OF GRINNING AND BEARING THIS PAIN. I WANT THIS EVIL DEVICE OUT OF ME!!!!!!!! PLEASE TAKE OUR EXPERIENCES AND LIFE STORIES ABOUT THIS METHOD OF BIRTH CONTROL SERIOUS. YOU KNOW THAT SOMETHING HAS TO BE WRONG WITH IT IF THERE ARE MORE AND MORE WOMEN SPEAKING UP ABOUT THEIR HEALTH ISSUES AND WERE NOT ALL CRAZY EITHER. HOW CAN SO MANY WOMEN SUFFER FROM THE SAME ISSUES AND SOME MORE THAN OTHERS. PLEASE ADVISE ANY OF THE WOMEN YOU KNOW OR LOVE TO PLEASE NOT HAVE THIS PROCEDURE DONE. IT WILL TAKE YOUR LIFE FROM YOU.. THE BEST THING CONCEPTUS COULD HAVE DONE WAS TO NEVER MAKE THIS DEVICE. IT HAS DONE NOTHING BUT MAKE A MANY OF WOMEN SUFFER...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032810	CONCEPTUS	11/14/2013	1/15/2014

Event Information:

Event Date (B3): 4/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALWAYS IN PAIN AND GETTING INFECTIONS, BEEN IN ER FOR INFLAMMATORY PELVIC DISEASE AND MY BODY ACHES A LOT. MY BODY IS NOT THE SAME AS BEFORE, I REGRET GETTING IT, NEVER HAD INFECTION OR NOTHING TILL ESSURE, ALMOST BEEN HOSPITALIZED FOR INFECTION DOWN THERE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00044	BAYER HEALTHCARE LLC	11/15/2013	11/22/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON AN UNSPECIFIED DATE THE PT HAD ESSURE INSERTED. ON (B)(6) 2012, A SURGERY WAS PERFORMED WHERE THE MIGRATION OF ESSURE WAS NOTED. ONE DEVICE MIGRATED INTO THE BOWEL AND THE OTHER THROUGH THE TUBE ITSELF. THE SURGICAL IMAGES OF THIS PT WERE RECEIVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00045	BAYER HEALTHCARE LLC	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/11/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A (B)(6) CONSUMER HAD ESSURE INSERTED ON (B)(6) 2010. NO CONFIRMATION TEST PERFORMED. INSERTION TOOK AT LEAST AN HOUR AND DURING PROCEDURE, THE HCP TOLD HER SHE HAD A POLYP THAT WOULD NEED TO BE REMOVED. ALMOST IMMEDIATELY AFTER INSERTION, SHE EXPERIENCED PAIN (BACK AND JOINT). ON (B)(6) 2011, SHE HAD A CT PERFORMED BECAUSE OF THE PAIN. SHE LOOKED AT THE IMAGING AND COULD SEE "THE COILS WERE BROKEN." HER HCP WHO TOLD HER THESE WERE THE GALLBLADDER CLIPS THAT WERE INSERTED IN 1994. SHORTLY AFTER INSERTION, SHE HAD SEVERE BLEEDING FROM THE TIME OF OVULATION UNTIL AFTER PERIOD ENDED EVERY MONTH, WHICH SHE DESCRIBED AS 'CONSTANT AND HEAVY.' SHE HAD NUMEROUS TRIPS TO THE EMERGENCY ROOM FOR SEVERE CRAMPING AND PAIN, INCLUDING LEG PAIN - THE FIRST TRIP WAS LESS THAN A MONTH FROM THE TIME OF INSERTION. SHE ALSO HAD ADHESIONS OF THE BOWEL TO THE OMENTUM. HER UTERUS WAS ADHERED TO ABDOMINAL WALL. THERE WERE ADHESIONS FROM THE FALLOPIAN TUBES TO OVARIES TO ADNEXAL TO OMENTUM. SHE REPORTED: ADHESIONS TO THE ANTERIOR FUNDAL ASPECT OF THE UTERUS, ADHESIONS OF THE FALLOPIAN TUBES TO THE OVARIES, BILATERALLY AND ADHESIONS OF THE OMENTUM AND INTO THE LEFT ADNEXAL STRUCTURES. SHE ALSO REPORTED BLADDER ADHESIONS, A FIXED OF THE CORPUS OF THE UTERUS. STATED THAT "SEEDS WERE PLACED SO THE ADHESIONS WOULD NOT ADHERE, BUT THEY DID." CONSUMER WAS DIAGNOSED WITH ENDOMETRIOSIS AND ADENOMYOSIS. ON (B)(6) 2013, SHE HAD A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00046	BAYER HEALTHCARE LLC	11/15/2013	11/22/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 509015

Single Use: Y
Implant Date (E6): 5/5/2006
Explant Date (E7): 9/6/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2006 THE CONSUMER HAD ESSURE INSERTED FOR PERMANENT BIRTH CONTROL. SHE HAD A NUMBER OF ISSUES OVER THE PAST YEAR THAT WERE CAUSED BY ESSURE: HYPOTHYROIDISM, HIGH BLOOD PRESSURE, UNEXPLAINED RAPID WEIGHT GAIN, BURNING SENSATION IN LOWER BACK, KIDNEY AND BLADDER INFECTIONS, INCREASED ALLERGIES TO THE POINT SHE WAS CARRYING AN EPI-PEN, MOST OF THE TIME SHE FELT SICK, TIRED, WEAK, HEADACHE, METAL TASTE IN HER MOUTH. THE CONSUMER INSISTED ON A PELVIC ULTRASOUND AND FOUND THAT THE ESSURE INSERTS WERE PROTRUDING FROM THE FALLOPIAN TUBES AND REQUIRE A HYSTERECTOMY TO BE DONE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00047	BAYER HEALTHCARE LLC	11/15/2013	11/22/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT FROM THE MOMENT SHE CAME OUT OF SURGERY (ESSURE INSERTION PROCEDURE) SHE WAS IN TREMENDOUS PAIN AND SHE WAS CRYING BECAUSE SHE WAS IN SO MUCH PAIN. HER LEGS HURT. THEY WERE CRAMPING. IT ONLY GOT WORSE, SO BAD THAT SHE COULD NOT EVEN CARE FOR HER TWO YOUNG CHILDREN. SHE HAD TO USE A WALKER BECAUSE SHE COULD NOT WALK ON HER OWN. SHE ALSO HAD TO HOLD ONTO SOMETHING BECAUSE THE BACK PAIN AND PELVIC PAIN WERE SO BAD. HER DOCTORS COULD NOT FIGURE OUT WHAT WAS CAUSING THE PROBLEM. EVENTUALLY THE DOCTOR WHO INSERTED THE COILS REMOVED THEM AND DID A TUBAL LIGATION. CONSUMER STATED THAT ALMOST IMMEDIATELY HER HEALTH IMPROVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032953	BAYER	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 3/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/8/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE (B)(6) 2010 AFTER HAVING MY THIRD CHILD. I ASKED MY PHYSICIAN FOR A TUBAL LIGATION AND SHE TOLD ME THAT THEY NO LONGER DID THOSE BECAUSE THEY FOUND THEM NO LONGER EFFECTIVE AND THAT THEY HAVE A NEW PROCEDURE THAT WAS NON SURGICAL AND WAS 99.999% EFFECTIVE. SHE SAID THEY WERE T-SHAPED PLASTIC RODS THAT HAD SPRINGS INSIDE. NOT ONCE WAS I INFORMED THAT THESE WERE METAL COILS THAT HAD NICKEL IN THEM (WHICH I HAVE A NICKEL ALLERGY TO). SO I GOT IT DONE SINCE I DIDN'T WANT ANY MORE KIDS. NOW FOR THE LAST TWO YEARS I HAVE BEEN SEEING A PHYSICIAN FOR BACK AND KNEE PAIN WHICH GETS WORSE EVERYDAY TO THE POINT THAT I CAN'T WALK. I AM ONLY (B)(6) AND HAD BEEN IN GOOD HEALTH. I NOW HAVE SINUS INFECTIONS AND HEAD ACHES ALL THE TIME, ALONG WITH UTI'S (WHICH I NEVER USE TO GET). I HAVE PERIODS TWO TIMES A MONTH THAT ARE EXTREMELY PAINFUL AND IRREGULAR. I AM MOODY AND VERY IRRITABLE ALL THE TIME. MY STOMACH HURTS ALL THE TIME NOW AND I HAVE BAD PAIN WHERE MY TUBES ARE. I AM ON PAIN KILLERS TO HELP WITH THE PAIN AMONGST OTHER MEDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032954	BAYER	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 9/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/14/2012
Explant Date (E7): 10/29/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED ON (B)(6) 2012, THE PROCEDURE ITSELF DIDN'T CAUSE MUCH PAIN OTHER THAN WHEN INSERTING THE RIGHT SIDE OF THE ESSURE COIL IT TOOK LONGER THAN THE LEFT SIDE AND IT HURT MORE. I TOOK IT EASY FOR A FEW DAYS AND WENT SWIMMING ON (B)(6) 2012 AND HAD SHARP PAINS IN BOTH SIDES AS I WAS WALKING UP AND DOWN THE SWIMMING POOL. I CONTINUED TO HAVE CRAMPS ALL NIGHT. STARTING ON (B)(6) 2012, I STARTED TO HAVE SEVERE BLOATING AND CRAMPING WHICH WAS MADE WORSE BY STANDING. I HAD A VIBRATING/TINGLING FEELING THROUGHOUT MY BODY THAT WAS CONSTANT AND NEVER WENT AWAY NO MATTER WHAT I DID. I CALLED MY DOCTOR AND SHE GOT ME IN ON (B)(6) 2012, SHE CHECKED ME AND SAID MY CERVIX WAS CLOSED AND SOFT. SHE TOLD ME NOT TO WORRY IT WAS MY BODY GETTING USED TO THE PROCEDURE AND SENT ME ON MY WAY. ON (B)(6) 2012 I STARTED MY PERIOD WHICH WAS EXTREMELY HEAVING AND FULL OF BLOOD CLOTS WHICH WAS NOT THE NORM FOR ME. I CONTINUED TO BLEED AND CRAMP AND WAS BLOATED UNTIL (B)(6) 2012. ON (B)(6) 2012 I WAS WALKING IN A STORE AND STARTED GETTING SHARP PAINS DOWN TO MY HEELS AND TREMENDOUS BACK PAIN THAT COULD BE COMPARED TO LABOR PAINS ALONG WITH IT. I CALLED THE NURSE AGAIN ON (B)(6) 2012 AND SHE TOLD ME THE CRAMPS WERE STILL NORMAL AND TO TAKE SOME TYLENOL. WHILE ON THE PHONE WITH HER, I ASKED ABOUT REMOVAL OF THE DEVICES, SHE TOLD ME THE DOCTOR DOES NOT REMOVE THEM BUT WOULD ASK DOCTOR ABOUT THE PAIN AND CALL ME TOMORROW. I HAD ANXIETY SINCE DAY 4 OF INSERTION OF THIS DEVICE. THE PAINS AND HEADACHES AND BLOATING AND LOWER BACK PAIN NEVER WENT AWAY. MY DOCTOR SENT ME FOR A TRANSVAGINAL ULTRASOUND ON (B)(6) 2012 TO MAKE SURE THEY WERE IN PLACE, THEY SAID THEY WERE. I CALLED OVER 30 DOCTORS IN (B)(6) TO

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TRY TO FIND SOMEONE TO REMOVAL, NO ONE IN (B)(6) HAD ANY IDEAS HOW TO REMOVE THEM. MY DOCTOR SAID SHE WOULD CALL THE COMPANY AND GET BACK TO ME AND SHE NEVER DID. I FINALLY FLEW TO (B)(6) FOR REMOVAL ON (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032959	BAYER	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 4/17/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/17/2006
Explant Date (E7): 10/9/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE IMPLANTED IN (B)(6) 2006, I BEGAN TO EXPERIENCE VERY BAD SIDE EFFECTS ALMOST IMMEDIATELY AND THOSE CONTINUED FOR SEVERAL YEARS UNTIL I HAD AN ESSURE REVERSAL ON (B)(6) 2013. MY SIDE EFFECTS WERE: PAINFUL OVULATION, HIP / JOINT PAIN, HOT FLASHES, MUSCLE SPASMS, NAUSEA, PELVIC / SHARP STABBING PAINS, BACK PAIN, CHRONIC BOWEL ISSUES (DIARRHEA), EASY BRUISING, CRAMPING, DIZZINESS, FATIGUE, HAIR LOSS AND UNWANTED HAIR GROWTH. I WAS NEVER ABLE TO CONNECT MY SYMPTOMS TO ESSURE UNTIL RECENTLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032960	BAYER/CONCEPTUS	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 4/25/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 4/24/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN 2006. MY PROCEDURE WAS THE FIRST ONE MY DR. HAD PERFORMED IN HIS OFFICE ON A PT NOT UNDER ANESTHESIA. THE PROCEDURE WAS EXTREMELY PAINFUL AND WAS TO TAKE 20 MINS, START TO FINISH. AFTER ABOUT AN HOUR OF NOT BEING ABLE TO INSERT THE ESSURE COILS, HE SAID WE MAY NEED TO STOP AND RESCHEDULE THIS UNDER ANESTHESIA IN THE HOSP. HE FINALLY WAS ABLE TO INSERT THE ESSURE COILS IN THE OFFICE. I WAS IN EXTREME PAIN FOR DAYS. THERE WERE SEVERAL ESSURE REPS IN THE ROOM DURING THE PROCEDURE BECAUSE IT WAS THE FIRST HE HAD PERFORMED IN THE OFFICE (THAT IS WHAT I WAS TOLD). SINCE HAVING THE ESSURE COILS IMPLANTED, I HAD MY FIRST MENSTRUAL CRAMP IN MY LIFE. I HAVE A DAILY PINCHING FEELING IN MY FALLOPIAN TUBE AREA, CONSTANT ACHING AND TENDERNESS IN EACH SIDE, EXTREME CRAMPING AND PELVIC PAIN 2 PLUS WEEKS A MONTH, SHOOTING PAINS DOWN MY CERVIX AND DOWN THE BACK OF MY LEGS, LOWER BACK PAIN, JOINT PAIN IN MY LEFT HIP, FATIGUE, HEAVY MENSTRUAL CYCLES AND MASSIVE CLOTTING, ITCHY SKIN, AND UNEXPLAINED RASH AND BOILS THAT APPEAR ON MY FACE AND LEGS. I WAS A HEALTHY (B)(6) OLD WOMAN WITH NO HEALTH ISSUES, I DID NOT TAKE OVER THE COUNTER PAIN MEDICATION BUT TWICE A YEAR AND NEVER HAD PAINFUL OR ABNORMAL MENSTRUAL CYCLES UNTIL AFTER HAVING ESSURE. I HAD MY FIRST MIGRAINE AFTER ESSURE AS WELL. THE PAIN IS SO INTENSE AT TIME THAT I HAVE TROUBLE FINISHING A BREATH AND CANNOT MOVE. WHEN I OVULATE, THE PAIN IS SO EXCRUCIATING I HAVE HAD TO MISS WORK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032961	BAYER	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 5/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/12/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2012. SINCE HAVING IT PLACED, I HAVE EXPERIENCED TERRIBLE PAIN RANGING FROM SHARP STABBING PAIN TO UNBEARABLE ACHES IN LOWER ABDOMEN. I ALSO HAVE RECENTLY BEEN DIAGNOSED WITH HIGH BLOOD PRESSURE WHICH, OTHER THAN BEING PREGNANT, I HAVE NEVER HAD AN ISSUE WITH. I AM NOW ALMOST (B)(6) AND ON BLOOD PRESSURE MEDICINE. I HAVE JOINT PAIN ALL THE TIME. I AM ALWAYS EXHAUSTED AND NEVER FEEL LIKE I SLEEP ENOUGH. MY MENSTRUAL CYCLE HAS ALWAYS BEEN ON TIME UP UNTIL OCTOBER WHEN I COMPLETELY SKIPPED A PERIOD. AFTER A MONTH OF BEING LATE, I FINALLY STARTED AND FOR 2 DAYS, HAD UNBEARABLE CRAMPS AND HEAVY BLEEDING. I HAVE ALSO STARTED HAVING CYSTS WHICH I HAVE NEVER HAD A PROBLEM WITH BEFORE EXCEPT ONCE DURING ONE OF MY FOUR PREGNANCIES. I HAVE HEADACHES A LOT AND NAUSEA THAT DOESN'T SEEM TO GO AWAY. I ALSO EXPERIENCE LOW BACK PAIN ALMOST LIKE ARTHRITIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032962	BAYER	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 6/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/3/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PELVIC PAIN, SEVERE BLEEDING, MIGRAINES, BACK ACHES, BLOATING, BLURRED VISION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032964	BAYER	11/15/2013	11/22/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 794900

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I NEVER PUT IT TOGETHER UNTIL NOW. MY MENSTRUAL CYCLE IS HEAVIER AND MORE PAINFUL. I HAVE CONTINUED BLOATING I ALWAYS HAD A FLAT STOMACH NOT ANY MORE. MY FINGERS AND TOES TINGLE AND GET NUMB. MY KNEES ACHE TO THE POINT I CAN'T BEND AT TIMES. LOW VITAMIN D, FATIGUE, DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032967	CONCEPTUS/BAYER	11/15/2013	11/22/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627732

Single Use:
Implant Date (E6): 8/2/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2010 I WAS IMPLANTED WITH ESSURE AS A FORM OF PERMANENT BIRTH CONTROL. I WAS NOT INFORMED IT HAS NICKEL, I WAS TOLD IT WAS PLATED WITH TITANIUM. SINCE HAVING IT IMPLANTED I HAVE BEEN IN THE EMERGENCY ROOM AT LEAST 10 TIMES FOR SEVERE CHRONIC PELVIC PAIN, MIGRAINES, AND CONSTANT VAGINAL BLEEDING. I HAD A MIGRAINE SO INTENSE THEY THOUGHT I WAS HAVING A STROKE. I HAD NOT HAD A MIGRAINE PREVIOUS TO ESSURE BEING IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032968	BAYER	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 7/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/2/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE COIL PUT IN (B)(6) OF 2013, STARTED HAVING SEVERE PAIN DAYS AFTER. I ENDED UP IN THE EMERGENCY ROOM ON (B)(6) 22 BECAUSE OF SEVERE PAIN. THE NEXT DAY I HAD AN EMERGENCY SURGERY. THE DOCTOR FOUND THAT THE COIL BROKE AND PUNCTURED MY UTERUS. THE DOCTOR HAD TO REMOVE MY TUBE AND NOW I HAVE A COIL IN MY UTERUS BECAUSE IT WAS TOO DANGEROUS TO TAKE OUT AS IT WAS CAUSING INTERNAL BLEEDING. I'M STILL IN SEVERE PAIN DAILY AND MY DOCTOR WANTS ME TO HAVE A HYSTERECTOMY BUT THE INSURANCE WON'T COVER IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032969	CONCEPTUS	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 8/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/8/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN 2008 AFTER MY 3RD CHILD GOT THE HSG TEST TO CONFIRM BLOCKAGE AND WAS TOLD 100% BLOCKED. I BECAME PREGNANT IN 2011 AND WAS WATCHED CLOSELY THROUGHOUT MY PREGNANCY DUE TO ESSURE STILL BEING IN PLACE. I DELIVERED FULL TERM (B)(6) 2011 AND GOT MY TUBES TIED IN (B)(6) 2012. DURING MY TUBAL LIGATION MY DOCTOR COULDN'T FIND THE OTHER COIL. SHE WAS ABLE TO LOCATE ONE OF THE COILS THAT IS EMBEDDED IN MY UTERUS. THE OTHER COIL IS STILL IN PLACE AND I AM TERRIFIED THAT IT WILL COME LOOSE AND PUNCTURE ANOTHER ONE OF MY ORGANS. I AM NOW EXTREMELY BLOATED, CAN'T LOOSE WEIGHT, HAVE SEVERE HIP AND BACK PAIN AND HAVE PANIC ATTACKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032970	BAYER/CONCEPTUS	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 11/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4): 12241584

Single Use:
Implant Date (E6): 12/15/2003
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOR THE LAST 8 YEARS I HAVE EXPERIENCED SEVERE LOWER LEFT QUADRANT PAIN SO SEVERE AT TIMES THAT IT IMPEDED WALKING, SITTING, OR STANDING. DIZZINESS, NUMBNESS IN EXTREMITIES, MIGRAINES, NAUSEA, FATIGUE, LETHARGY, IRREGULAR PERIODS (NOT COMING, LASTING ONLY THREE DAYS, COMING AT DIFFERENT TIMES EACH MONTH, ENDING JUST TO BEGIN AGAIN A DAY OR TWO LATER, LASTING FOR UP TO TWO WEEKS, ETC), EXCRUCIATING CRAMPING WITH NO HISTORY OF CRAMPS AT ALL, LARGE CLOTS RESEMBLING RASPBERRY JAM, POSITIVE PREGNANCY TEST WHEN NOT PREGNANT, FOOT AND LEG SWELLING, EXTREME WEIGHT GAIN ((B)(6) POUNDS 6 WEEKS AFTER GIVING BIRTH TO (B)(6) LBS. CURRENTLY) RESISTANT TO LOSS EFFORTS, BLOATING, TOOTH LOSS AND DECAY, WILD AND UNCONTROLLABLE MOOD SWINGS, HAIR LOSS, HEART PALPITATIONS, URINARY INCONTINENCE, GERD, AND ACNE. NONE OF THESE SYMPTOMS WERE PRESENT PRIOR TO IMPLANTATION. SYMPTOMS OCCURRED GRADUALLY. WILL NEED REMOVAL SURGERY AS LT COIL MIGRATED, RT COIL MISSING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032975	BAYER	11/15/2013	11/22/2013

Event Information:

Event Date (B3): 8/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 689940

Single Use:
Implant Date (E6): 9/2/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6) 2010. OVER A PERIOD OF A YEAR, I NOTICED EXTREME FATIGUE, WEIGHT GAIN, METAL TASTE IN MOUTH, LOW GRADE FEVERS AND UNEXPLAINED RASHES. IN (B)(6) 2013, I WAS TAKEN TO THE ER WITH EXTREME ABDOMINAL PAIN. THE DEVICES HAVE BOTH MOVED WITH ONE MIGRATING OUT OF MY FALLOPIAN TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032976		11/15/2013	11/22/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2009, I HAD THE "ESSURE" SURGERY TO PREVENT GETTING PREGNANT. IN (B)(6) OF SAME YEAR, I HAD AN UNWANTED PREGNANCY. AFTER BIRTH, I HAD MY TUBES REMOVED AND AT THE TIME THOUGHT THE ESSURE DEVICE. OVER THE NEXT 2 YEARS, I HAD SEVERE PAIN IN MY SIDE, CLOTS, HEAVY BLEEDING, AND HEADACHES. FINALLY, THIS YEAR IN 2013, I HAD A HYSTERECTOMY AND REMOVED THE ESSURE DEVICE. SINCE THEN, ALL MY SYMPTOMS HAVE GONE AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032977		11/15/2013	11/22/2013

Event Information:

Event Date (B3): 6/24/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/24/2004
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVING SEVERE CRAMPS. VERY BAD BACK ACHES. WHEN ON MY PERIOD, THE CRAMPS GET EVEN WORSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032828	CONCEPTUS	11/15/2013	1/14/2014

Event Information:

Event Date (B3): 11/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLEEDING FOLLOWING SURGERY CONTINUED FOR 3 MONTHS AND EVERY OTHER MONTH FOR 3 YEARS. BLOATING AND PAIN THAT COULDN'T BE DETERMINED WHY...MIGRAINES ON A REGULAR BASIS. PAIN DURING INTERCOURSE. SWELLING I'M MY LYMPH NODES UNDER MY ARMS. IRRITABLE MOOD SWINGS, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032812	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 9/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING, HORRIBLE PAIN IN MY PELVIC AREA, SWELLING IN THE STOMACH AREA, HORRIBLE MIGRAINES, BRAIN FOG, REALLY BAD FATIGUE, PAIN/ STIFFNESS IN BONES/JOINTS TO THE POINT OF NOT BEING ABLE TO MOVE, PAINFUL INTERCOURSE, MOOD SWINGS, WEIGHT GAIN ECT...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032813	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 2/10/2005	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE BACK PAIN, SHARP PELVIC PAIN COMES AND GO. ITCHING, PAINFUL INTERCOURSE. SENSITIVE STOMACH HAVE TO BE CAREFUL WHAT I EAT AND SMALL AMOUNTS, JUST ABOUT ANYTHING GIVES ME BAD GAS. BEEN DEALING WITH SEVERE CONSTIPATION. STOMACH SWELLS, AS I'VE AGED, PROBLEMS HAVE GOTTEN WORSE. HAD HSG TEST DID SAY BLOCKED. SCARED THEY HAVE MOVED. HOPING TO GET REMOVED NEXT YEAR. WOULD NOT RECOMMEND. NOT SURE OF THE EXACT DATE PLACED. LOT#L2138. PRAYING ONLY ONE SET USED. PLEASE DISCONTINUE PLACEMENT LONG TERM SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032814	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 2/13/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOOD MORNING. I HAVE TO SAY... I HAVE HAD "THE COILS" AS I CALL THEM, FOR 7 YEARS. NOT A DAY GOES BY WHEN THE PAIN IS NOT THERE. WHEN ON MY CYCLE... NOW EXTREMELY RANDOM... THE PAIN IS SO BAD I CAN BARELY MOVE AND IT BRINGS ME TO TEARS FOR THE ENTIRE CYCLE, ESPECIALLY WHEN I OVULATE. ALL OF THE DOCTORS I WENT TO TOLD ME THAT THERE WAS NOTHING I COULD DO AND I WOULD HAVE TO LIVE WITH IT FOR THE REST OF MY LIFE, THEN THEY TELL ME THAT TYLENOL, ALEVE AND MIDOL WILL KILL THE PAIN. THEY WERE WRONG. FOR YEARS I SELF MEDICATED DAILY THROUGH ALCOHOL BECAUSE THAT WAS THE ONLY WAY I COULD GET THE PAIN TO STOP. AFTER GOING THROUGH REHAB A YEAR AGO FOR ALCOHOLISM, I AM NOW SOBER BUT BACK IN PAIN CONSTANTLY. I AM ACTUALLY AFRAID TO DRIVE NOW BECAUSE THE PAIN CAN GET SO BAD SO FAST THAT IT FEELS LIKE I AM GOING TO PASS OUT AT ANY MOMENT WITH NO WARNING. NOT A GOOD POSITION TO BE IN WHEN YOU ARE DRIVING 4 KIDS AROUND. THEN THERE IS THE WEIGHT GAIN. SINCE I HAD THE COILS INSERTED I HAVE GAINED 40 POUNDS. NO AMOUNT OF DIET OR EXERCISE WILL WORK. MY SKIN HAS CHANGED STARTING FROM DAY ONE. IT IS NOW EXTREMELY FLAKY AND RASHY FROM HEAD TO TOE AND AT RANDOM PLACES IN BETWEEN. MY HAIR ACTUALLY BEGAN TO FALL OUT WITHIN A MONTH OR TWO OF THE PROCEDURE AND HAS BECOME SO FINE AND THIN AT THE AGE OF (B)(6) THAT I HAVE LESS HAIR ON MY HEAD THAN MY (B)(6) FATHER! MY ENERGY HAS DECLINED TO THE POINT THAT I HAVE TO WORK JUST GET DINNER DONE BUT I CANNOT SLEEP BECAUSE OF THE PAIN. MY BACK AND NECK HAVE BEEN IN CONSTANT PAIN AND TO LIFT ANYTHING MORE THAN 15 POUNDS SEND CRIPPLING PAIN FROM MY PELVIC REGION THROUGH MY ENTIRE BODY. KEEPING IN MIND THAT I GOT THE IMPLANTS WHEN MY YOUNGEST CHILD WAS (B)(6), CAN YOU IMAGINE NOT BEING ABLE TO PICK UP YOUR OWN CHILD WHEN THEY ARE SAD, SCARED, OR HURT BECAUSE IF YOU DO, YOU ARE IN SO MUCH PAIN THAT YOU FALL TO YOUR KNEES? WELL, THAT IS WHAT

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

I HAVE HAD TO ENDURE. SEX...HA! IT IS SO PAINFUL THAT, WELL, THANK GOD MY HUSBAND LOVES ME. I HAVE CALLED THE MANUFACTURER AND THE ONLY RESPONSE I HAVE RECEIVED WAS THAT MY COMPLAINT WAS NOTED AND TO HAVE A GOOD DAY OR THAT MY DOCTOR MUST HAVE INSTALLED IT WRONG. WHEN I HAVE TRIED TO GET IT REMOVED THROUGH INSURANCE, THEY ALWAYS SAY NO BECAUSE THERE ARE NO VITAL ORGANS EFFECTED... PAIN IS NOT GOOD ENOUGH FOR (B)(6) APPARENTLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032815	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 12/31/1969 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME BLEEDING, PAIN, CHRONIC HIVES, FIBROIDS. HAD ABLATION IN (B)(6) 2013, AND WHEN THAT DIDN'T WORK, HAD HYSTERECTOMY ON (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032816	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 2/5/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE IMPLANTED ON (B)(6) 2009. DEVELOPED CONSTANT ITCHY SKIN AND OCCASIONAL HIVES BETWEEN 2009-2013. ALSO DEVELOPED MIGRAINES AND HASHIMOTO'S THYROIDITIS DURING THIS TIME PERIOD. DURING 2013, SKIN ITCHINESS INCREASED AND I WAS NO LONGER ABLE TO CONTROL IT WITH OVER THE COUNTER ALLERGY MEDICINE (EVEN WITH TAKING FOUR ZYRTECS A DAY). SAW MY ALLERGIST AND HE PERFORMED A PATCH TEST AND FOUND OUT I WAS ALLERGIC TO NICKEL. WHEN HE FOUND OUT THAT I HAD THE ESSURE DEVICE, HE RECOMMENDED THAT I HAVE THEM REMOVED. SCHEDULED AN APPOINTMENT WITH MY OBGYN, WHO ALSO IMPLANTED ESSURE IN 2009, AND DECIDED THAT THEY NEEDED TO BE REMOVED. NOW I HAVE A HYSTERECTOMY SCHEDULED FOR (B)(6) 2013. IF NICKEL ALLERGY TESTING WOULD HAVE BEEN REQUIRED PRIOR TO GETTING ESSURE, I WOULDN'T HAVE HAD TO GO THROUGH ALL OF THIS. NOW I HAVE THYROID DISEASE THAT I WILL HAVE THE REST OF MY LIFE AND WILL HAVE TO HAVE A HYSTERECTOMY THAT COULD HAVE EASILY BEEN PREVENTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032817	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE IMPLANTED ON (B)(6) 2012 I HAD A KIDNEY STONE ATTACK ON (B)(6) 2013 AND HAD TO HAVE IT SURGICALLY REMOVED. IN (B)(6) OF 2013 I WAS DIAGNOSED WITH SLEEP APNEA AND NOW HAVE TO USE A CPAP. JUST RECENTLY I HAVE STARTED HAVING SEVERE HEADACHES AND MIGRAINES TO THE POINT OF EXHAUSTION COUPLED WITH EXTREME JOINT PAIN AND PAIN BETWEEN MY SHOULDER BLADES THAT RADIATE UP TO MY NECK AND HEAD. PRESSURE IN MY PELVIC AREA AND BLOATING ALONG WITH STABBING PAINS IN MOSTLY MY LEFT SIDE BUT ALSO ON THE RIGHT SIDE. PERIODS HAVE BEEN HEAVY WITH CLOTTING WHICH I NEVER HAD BEFORE. I HAVE HAD 3 YEAST INFECTIONS IN THE LAST 2 MONTHS WHICH I HAVE ONLY HAD 1 BEFORE THIS AND I AM 32. THERE IS ALWAYS A DISTINCT ODOR DOWN THERE NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032818	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ENDOMETRIOSIS, WEIGHT GAIN, SWOLLEN LYMPH NODES, BACK, LEG, AND PELVIC PAIN, FATIGUE, DIARRHEA, SEVERE CRAMPING, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032819	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 11/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABNORMAL PAIN, HEADACHES, BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032820	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 5/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD SEVERE PELVIC PAIN TO THE POINT WHERE I COULD BARLEY GET OUT OF BED FROM THE DAY IT WAS PUT IN UNTIL I HAD IT REMOVED, (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032821	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 5/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I GOT THE ESSURE PROCEDURE DONE, I HAVE HAD MANY SIDE EFFECTS THAT AFTER GOING TO THE DOCTOR, THEY HAVEN'T FOUND A REASON. MY GUESS IS THEY HAVE TO DO WITH ESSURE SINCE I DIDN'T HAVE THESE BEFORE. I GET HEART PALPITATIONS, ANXIETY, A WEIRD FEELING IN MY HEAD THAT FEELS LIKE I'M GETTING SHOCKS IN THE BRAIN, AND AT TIMES WHEN I GET THAT FEELING, MY LIPS FEEL NUMB AS WELL. I CONSTANTLY HAVE A PAIN IN THE RIGHT SIDE, WHERE I'M ASSUMING MY OVARY IS. THIS IS THE SAME SIDE THAT THE DOCTOR HAD A HARD TIME GETTING THE COIL IN. ON A GOOD DAY, THE PAIN IS DULL AND CONSTANT. ON A BAD DAY, I'M ALMOST IN TEARS. THE PAIN RADIATES DOWN MY GROIN INTO MY LEG AND IT'S HARD TO EVEN WALK. I GET HEADACHES ALL THE TIME, ALMOST DAILY. I DO SUFFER FROM MIGRAINES, BUT I CAN TELL YOU THE DIFFERENCE BETWEEN THE TWO. ALSO, I GET EPISODES OF BLOATING THAT ARE SO UNCOMFORTABLE, AND MY STOMACH GETS SO SWOLLEN, I LOOK AT LEAST 5 MONTHS PREGNANT. I ALSO GET NAUSEOUS OFTEN, NO VOMITING, JUST THE FEELING. ANOTHER THING IS THAT I FREQUENCY URINATE, ALMOST LIKE A UTI. WHEN I HAD INSURANCE, I WOULD GO IN THINKING IT WAS A UTI, AND THE DOCTOR WOULD ORDER ANTIBIOTICS FOR ME TO START ON, AND WOULD DO LABS. A COUPLE OF DAYS LATER, HE WOULD CALL AND SAY THE TESTS CAME BACK NORMAL AND DISCONTINUE THE MEDICATION. THIS STILL GOES ON, BUT I JUST LET IT GO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032822	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 5/6/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE SEVERE BACK PAIN AND ABDOMINAL PAIN, SOMETIMES WHEN I WALK I CAN FEEL THE COIL ON MY LEFT SIDE AS IF ITS RUBBING AGAINST SOMETHING ITS UNCOMFORTABLE TO LAY ON MY SIDE BECAUSE I GET SHARP TUGGING PAINS. I HAVE REALLY BAD HEADACHES, I ALSO HAVE BECOME VERY TENDER AND BRUISE EASILY. I ALWAYS HAVE FATIGUE, AND I CANNOT LOOSE ANY WEIGHT PLUS I'VE GAINED WEIGHT THAT I'VE LOST POST PARTUM. I EVEN HAVE MEMORY ISSUES I SEEM TO FORGET THINGS FAIRLY EASY AND I WHAT SEX LIFE I DO HAVE ANYMORE HAS BECOME PAINFUL AND AFTERWARDS I FEEL LIKE IM HAVING REALLY BAD CONTRACTIONS. WHEN I DID MY HSG TEST THE PAIN IN MY BACK AND ABDOMEN HAVE BEEN TEN TIMES WORSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032823	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 10/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PROCEDURE WAS EXTREMELY PAINFUL! I FELT ALL 4 INJECTIONS TO NUMB THE CERVIX AND UTERUS AND I FELT THE PROCEDURE ITSELF. LOTS OF PAIN AND PRESSURE. I VOMITED DURING THE PROCEDURE. ONE COIL WOULD NOT DISENGAGE PROPERLY AND THE OTHER DID NOT GO IN VERY EASILY. I HAVE HAD NOTHING BUT CONSTANT PAIN AND PRESSURE WHERE MY TUBES ARE SINCE. I AM TAKING PAIN MEDS AROUND THE CLOCK NOW JUST TO FUNCTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032824	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 3/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING, BLOOD CLOTS, SEVERE LOWER BACK PAIN, CRAMPS THAT FEEL LIKE LABOR PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032826	CONCEPTUS	11/15/2013	1/15/2014

Event Information:

Event Date (B3): 1/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AROUND (B)(6) 2012 AND HAVE EXPERIENCED PAIN FROM DAY ONE. ABDOMINAL AND RIGHT SIDE PAIN. I THOUGHT IT WAS NORMAL AND I ASKED MY DOCTOR AND HE SAID IT WAS NORMAL AS WELL WHEN I FIRST HAD THIS DONE. IT'S NOW ALMOST 2 YEARS LATER AND I STILL HAVE THIS CONSTANT PAIN. I'M BEGINNING TO GET REALLY SCARED NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032825	CONCEPTUS	11/15/2013	6/24/2014

Event Information:

Event Date (B3): 12/30/2011 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED BECAUSE MY DR SAID IT WAS 100% EFFECTIVE WITH NO KNOWN SIDE EFFECTS. ONE YEAR AND A HALF I GOT PREGNANT AND THE PREGNANCY WAS ECTOPIC. I WENT TO THE EMERGENCY ROOM BECAUSE MY LIFE WAS AT RISK. I NOW SUFFER HEAVY BLEEDING, MIGRAINES, BLOATING, NAUSEA, MOOD SWINGS, HAIR LOSS. I JUST FOUND OUT THAT MY RIGHT COIL IS IN PLACE AND THE LEFT COIL IS NOT. NOW AT (B)(6) I'M FACING HYSTERECTOMY. IT'S BEEN A NIGHTMARE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032992		11/18/2013	11/22/2013

Event Information:

Event Date (B3): 1/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 898935

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2012, I HAD THE ESSURE PROCEDURE DONE. FEW HOURS LATER, I HAD SEVERE SWELLING THROUGHOUT MY BODY, EYES SWOLLEN SHUT, HIVES, EXTREME BLOATING AND SHARP SEVERE ABDOMINAL PAIN. AS OF TODAY ((B)(6) 2013) I STILL BREAK OUT IN HIVES, SEVERE SWELLING TO MY FACE, SEVERE CRAMPING, BLOATING AND HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032993	CONCEPTUS	11/18/2013	11/22/2013

Event Information:

Event Date (B3): 4/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): 20227514
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD THE ESSURE PUT IN ON (B)(6) 2010 AND I'VE BEEN HAVING SHARP EXCRUCIATING PAIN, IT'S SO PAINFUL TO WHERE I'M DOUBLE OVER IN PAIN. I CAN BE JUST SITTING HERE AS I AM NOW AND IN MY LEFT FALLOPIAN TUBE I'M HAVING EXTREME PAIN. HELP, WHAT DO I DO?

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032996	BAYER	11/18/2013	11/22/2013

Event Information:

Event Date (B3): 10/21/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627312

Single Use:
Implant Date (E6): 10/21/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2008. SINCE THE PROCEDURE, I HAVE HAD SEVERAL HEALTH ISSUES WHICH I BELIEVE TO BE DIRECTLY RELATED TO THE ESSURE COILS. IMMEDIATELY FOLLOWING THE PROCEDURE, I HAD HORRIBLE CRAMPING AND PAIN WHICH STARTED IN MY PELVIC AREA AND HAS NOW TAKEN OVER MY ENTIRE BODY. I HAD VERY HEAVY BLEEDING WHICH MY DOCTOR TREATED WITH ANOTHER PROCEDURE (H.T.A.) I HAVE DEVELOPED A HORRIBLE RASH THAT WILL NOT GO AWAY AND IS GETTING WORSE DAY BY DAY. I HAVE BEEN GIVEN SEVERAL MEDICATIONS BY THE DERMATOLOGIST NONE OF THEM WORK. I WAS NEVER TESTED FOR A NICKEL ALLERGY PRIOR TO HAVING THE ESSURE PUT IN. ON MY 3 MONTH CHECK POST PROCEDURE, THE DOCTOR SHOWED ME THE ULTRASOUND AND COULD CLEARLY SEE THAT ONE OF THE COILS HAD MIGRATED AND WAS NOT WHERE IT SHOULD BE. I HAVE HAD AN INCREASE IN MIGRAINE HEADACHES AND MUSCLE PAIN AND WEAKNESS. I HAVE ALSO DEVELOPED SEVERE DEPRESSION AND ANXIETY SINCE HAVING THE ESSURE PROCEDURE. THERE HAVE BEEN WEEKS THAT I WAS UNABLE TO GET OUT OF BED TO TAKE CARE OF MY FAMILY BECAUSE THE PELVIC PAIN WAS SO BAD. I HAVE ALSO HAD VERY BAD SWELLING THROUGHOUT MY BODY AND OFTEN GET A BURNING PAIN IN MY LOWER BACK AND LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032998	CONCEPTUS, INC.	11/18/2013	11/22/2013

Event Information:

Event Date (B3): 10/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use:
Implant Date (E6): 10/7/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE DEVICE IMPLANTED, AND HAVE BEEN IN SERIOUS PAIN SINCE, HAVE HAD A CONSTANT HEADACHE, SEVERE LOWER BACK PAIN, EXTREME PAIN IN LOWER ABDOMEN, NON-STOP BLEEDING, SINCE GETTING ESSURE DEVICE. MY DOCTOR NEVER TESTED ME FOR NICKEL ALLERGY (AND I WAS NEVER TESTED FOR NICKEL ALLERGY, LITTLE LESS ASKED). I AM CURRENTLY TRYING TO FIGURE OUT WHAT TO DO ABOUT THIS, SINCE MY DOCTOR JUST KEEPS TELLING ME TO "WAIT AND SEE".

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033001	CONCEPTUS	11/18/2013	11/22/2013

Event Information:

Event Date (B3): 8/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B09711

Single Use:
Implant Date (E6): 8/15/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED (B)(6) 15 DURING IMPLANTATION, ONE COIL FAILED TO RELEASE SO THE DOCTOR OPENED A NEW KIT AND USED ANOTHER. SINCE THAT TIME I HAVE BEEN HAVING HEAVY BLEEDING AND OR SPOTTING ALL THE TIME AND PAIN IN MY ABDOMEN. I HAD MY HSG TEST DONE YESTERDAY AND FOUND OUT THAT I HAVE TWO ESSURE COILS IN MY LEFT TUBE. I ALSO ONLY HAVE ONE STICKER WITH THE LOT NUMBER INSTEAD OF TWO SINCE TWO KITS WHERE USED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033003	BAUER/CONCEPTUS	11/18/2013	11/22/2013

Event Information:

Event Date (B3): 11/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 787229

Single Use:
Implant Date (E6): 3/4/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAD ESSURE IMPLANTED IN 2011 I HAVE HAD CONSTANT BLEEDING. I HAVE VAGINAL BLEEDING 25-28 DAYS PER MONTH EVERY MONTH. I HAVE BAD CRAMPING, CYSTS, PAIN WALKING, WEIGHT GAIN I CANNOT GET RID OF DIZZINESS, LIGHT HEADEDNESS, HEADACHES, BACK PAIN. ALL OF WHICH I NEVER HAD BEFORE ESSURE. I NOW HAVE TO TAKE IRON SUPPLEMENTS FROM THE BLOOD LOSS AND HAVE BEEN DIAGNOSED WITH PCOS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033005	CONCEPTUS	11/18/2013	11/22/2013

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 4/14/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE NAUSEA, VOMITING, PAIN THAT VARIED IN LOCATION, TYPE, DURATION AND INTENSITY. LACK OF STRENGTH AND ENERGY REQUIRING FREQUENT REST, DEPRESSION, ANXIETY, SHORTNESS OF BREATH, BAD HEAD-ACHES, BLOATING, ABDOMINAL TIGHTNESS AND SWELLING, DULL ACHES, DISCOMFORT AND WEAKNESS IN LIMBS, BODY ACHES, MIGRATING DULL ACHE RIGHT HIP AND BACK OF THIGH, INABILITY TO WORK AND ENJOY A NORMAL LIFE DUE TO DAILY SYMPTOMS OF POOR HEALTH. DIAGNOSED WITH TWO OVARIAN CYSTS AND MIGRATION OF ESSURE COIL (RIGHT SIDE) ON (B)(6) 2013. E.R. VISIT BASED ON CT SCAN DONE (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032911	CONCEPTUS	11/18/2013	1/14/2014

Event Information:

Event Date (B3): 5/14/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE PLACED I HAVE EXPERIENCED BLOATING, FATIGUE, HEADACHES, SEVERE MENSTRUAL CRAMPING, HEAVIER MENSTRUAL CYCLES, MOOD SWINGS. DIAGNOSED WITH FIBROMYALGIA IN 2001. DIAGNOSED WITH ANXIETY IN 2001. LEFT TUBE, OVARY AND DERMOID TUMOR REMOVED IN 2005. ALLERGY TO METAL AND NICKEL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032912	CONCEPTUS	11/18/2013	1/14/2014

Event Information:

Event Date (B3): 10/31/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

UPON HAVING THE ESSURE COILS IMPLANTED, I HAVE HAD SEVERE LOWER BACK PAIN, WEIGHT GAIN OF 50 LBS, BLOATING, JOINT PAIN, HEAVY MENSTRUATION, SEVERE HEADACHES, SHARP PAINS IN FALLOPIAN TUBE AREA, EXTREME FATIGUE. I AM CURRENTLY LOOKING INTO A HYSTERECTOMY IN ORDER TO HAVE THE ESSURE COILS REMOVED. ALL OF MY SYMPTOMS HAVE OCCURRED WITHIN A COUPLE OF MONTH FROM THE DATE ESSURE WAS IMPLANTED. ESSURE SHOULD BE TAKEN OFF OF THE MARKET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032909	CONCEPTUS	11/18/2013	1/15/2014

Event Information:

Event Date (B3): 3/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXCESSIVE BLEEDING THAT WOULD LAST FOR 3 WEEKS, OUT OF A MONTH. NUMBNESS IN RIGHT HAND, EXTREME BLOATING, HEADACHES, BACKACHES, INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032910	CONCEPTUS	11/18/2013	1/15/2014

Event Information:

Event Date (B3): 4/17/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED WITH ABDOMINAL PAIN, HEAVY UNCONTROLLABLE BLEEDING AND FREQUENT PERIODS EVERY 2-3 WEEKS; I GOT RED SPOTS ON MY FEET AND LEGS ALL THE WAY UP TO MY PELVIS; I HAVE HAD AN APPENDECTOMY (THEY THOUGHT IT MIGHT BE MY APPENDIX), THEN I HAD A PARTIAL HYSTERECTOMY LEAVING IN MY RIGHT OVARY AND TUBE SO I WOULD NOT GO THROUGH MENOPAUSE AT THE AGE OF (B)(6) (THE DOCTOR TOLD ME HE COULDN'T REMOVE THE COIL WITHOUT REMOVING MY OVARY TOO); I HAVE HAD THIS WEIRD METALLIC TASTE IN MY MOUTH FOR YEARS; I GET NAUSEOUS WITH SEVERE BLOATING...I GET SO BLOATED I LOOK LIKE I'M 8-9 MONTHS ALONG IN A PREGNANCY YET I HAVE SEVERE DIARRHEA AT THE SAME TIME; I HAVE SEVERE LEG, HIP AND KNEE PAIN; I HAVE GAINED A BUNCH OF WEIGHT YET I HAVE NO APPETITE; I WAKE UP CRYING AT NIGHT DUE TO THE ABDOMINAL PAINS; I HAVE HAD HAIR LOSS; MY TEETH ARE BRITTLE AND CONSTANTLY BREAKING; I HAVE "BLACKOUTS" WHERE I BLACKOUT AND FALL TO THE GROUND LOSING CONSCIOUSNESS; I AM NOT SUPPOSED TO DRIVE, BE LEFT ALONE OR EVEN GO UP AND DOWN STAIRS WITHOUT SOMEONE TO HELP ME; I AM A MOM OF 6 CHILDREN INCLUDING MY YOUNGEST WHO WAS 2 1/2 MONTHS OLD WHEN I HAD THIS DEVICE PUT IN, AND I AM A TEACHER...SO I HAVE ALSO HAD TO SHUT DOWN MY DAYCARE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032913	CONCEPTUS	11/18/2013	1/15/2014

Event Information:

Event Date (B3): 8/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN BEING IMPLANTED, THE DOCTOR SAID ONE OF THE COILS FAILED TO RELEASE SO SHE TOOK IT OUT TO PUT A NEW ONE IN. SINCE MY IMPLANTATION, I HAVE BEEN HAVING PAIN, BLEED OR SPOTTING. HEAD AND BODY ACES, FEVERS. I HAD MY HSG TEST DONE YESTERDAY AND FOUND OUT I HAVE TWO COILS IN ONE TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032914	CONCEPTUS	11/18/2013	1/15/2014

Event Information:

Event Date (B3): 1/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DONE IN (B)(6) 2008. BABY BORN ON (B)(6) 2009. I HAVE HAD HOT FLASHES, MOOD SWINGS, FEEL THE LEFT SIDE PAINS. I HAD COMPLICATIONS DURING PROCESS. TWO COILS PUT ON MY RIGHT SIDE BECAUSE DR. SAID THE FIRST ONE DID NOT TAKE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032915	CONCEPTUS	11/18/2013	1/15/2014

Event Information:

Event Date (B3): 9/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAD THE PROCEDURE DONE IN (B)(6), I HAVE SUFFERED FROM WEIGHT GAIN, NAUSEA, HAIR LOSS, SENSITIVE TEETH, JOINT PAIN, HIP PAIN, CRAMPING, BACK PAIN AND MORE... I HAVE BEEN MISERABLE FOR MONTHS AND I AM WORKING ON GETTING SURGERY SCHEDULED TO GET THEM REMOVED. THE CONSTANT ACHING HAS MADE ME SO IRRITABLE. I WANT MY LIFE BACK!!!

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00048	BAYER HEALTHCARE LLC	11/19/2013	12/4/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/15/2006
Explant Date (E7): 5/22/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSUMER REPORTED SHE HAD ESSURE INSERTED ON (B)(6) 2006. ON AN UNSPECIFIED DATE THE CONSUMER BEGAN TO EXPERIENCE MASSIVE VERY HEAVY AND FREQUENT MENSTRUAL PERIOD, SHARP PAINS, HEADACHES, HAIR LOSS, SHE HAD HER GALLBLADDER REMOVED, SHE WAS MOODY AND HAD NAUSEA. IN 2013 SHE HAD AN EXPLORATORY SURGERY AND ONE SPRING WAS ALMOST ALL THE WAY OUT OF TUBE AND ONE WAS HALF WAY OUT. THE PHYSICIAN REMOVED BOTH DEVICES. THE CONSUMER HAD ENDOMETRIOSIS, CYSTS AND FIXED BOWELS. SINCE REMOVAL OF ESSURE ALL THE SYMPTOMS HAD BEEN GONE. THE MENSTRUAL PERIOD HAD OCCURRED ONCE A MONTH, AT MOST 5 DAYS LONG AND LIGHT WITH BARELY ANY PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00049	BAYER HEALTHCARE LLC	11/19/2013	12/4/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM THE JOURNAL OF CLINICAL ULTRASOUND, A PHYSICIAN REPORTED IN AN ARTICLE ENTITLED "MIGRATED ESSURE PERMANENT BIRTH CONTROL DEVICE: SONOGRAPHIC FINDINGS". A PT UNDERWENT HYSTEROSCOPIC BILATERAL TUBAL OCCLUSION WITH ESSURE. THE PROCEDURE WAS COMPLICATED BY TUBAL SPASM BILATERALLY, SO PROMINENT AND PERSISTENT ON THE RIGHT THAT A PREEXISTING TUBAL OCCLUSION WAS CONSIDERED. NEVERTHELESS, THE ESSURE MICROINSERTS WERE DEPLOYED BILATERALLY WITH EIGHT TRAILING COILS NOTED IN THE UTERINE CAVITY ON THE LEFT AND 17 TRAILING COILS ON THE RIGHT. FOLLOWING THE PROCEDURE, CONTINUED BLEEDING FROM THE RIGHT TENACULUM SITE REQUIRED PLACEMENT OF TWO STITCHES. HYSTEROSALPINGOGRAM (HSG) PERFORMED 3 MONTHS LATER REPORTED AS NORMAL WITH NO EVIDENCE OF SPILLAGE BILATERALLY AND THE PT WAS TOLD THAT SHE COULD STOP USING ORAL CONTRACEPTIVE. REVIEW OF THE SCOUT FLUOROSCOPIC SPOT VIEW FROM THE HSG THOUGH DOES DEMONSTRATE SOME ASYMMETRY OF THE ESSURE DEVICES WITH THE RIGHT ONE BEING MORE PROXIMALLY POSITIONED. THE PT RETURNED TO HER PHYSICIAN 7 YEARS LATER FOR EVAL OF RIGHT-SIDED PELVIC PAIN AND CONSTANT BURNING THAT IMPROVED WITH RECUMBENT POSITIONING AND WORSENED WITH MOVEMENT. SHE ALSO REPORTED HEAVY AND PAINFUL MENSES CAUSING LIGHTHEADEDNESS AND DIZZINESS AND OCCASIONAL METRORRHAGIA AND AT PHYSICAL EXAMINATION HAD MILD RIGHT ADNEXAL TENDERNESS. AS A RESULT, THE PT UNDERWENT A TRANSABDOMINAL AND TRANSVAGINAL PELVIC ULTRASOUND EXAMINATION, WHICH REVEALED MIGRATION OF THE RIGHT ESSURE DEVICE. CONVENTIONAL PELVIC ULTRASOUND SHOWED THAT THE RIGHT COIL WAS ABNORMALLY POSITIONED, ALMOST ENTIRELY WITHIN THE UTERINE CAVITY. THIS WAS CONFIRMED AND BETTER VISUALIZED ON THE CORONAL RECONSTRUCTED VIEW OF THE 3D ULTRASOUND EXAMINATION OF THE UTERUS. THE PT ELECTED TO HAVE THE RIGHT ESSURE DEVICE REMOVED AND THIS

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WAS PERFORMED HYSTEROSCOPICALLY. THE FOLLOWING DAY THE PT UNDERWENT HSG THAT REVEALED BILATERAL TUBAL OCCLUSION. DESPITE THE TUBAL OCCLUSION DEMONSTRATED ON HSG, THE PT OPTED TO PROCEED WITH BILATERAL TUBAL LIGATION. AT A F/U VISIT 2 MONTHS LATER, THE PT REPORTED THAT HER PAIN HAD RESOLVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033031	CONCEPTUS	11/20/2013	11/27/2013

Event Information:

Event Date (B3): 8/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 710399

Single Use:
Implant Date (E6): 3/24/2010
Explant Date (E7): 8/5/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE CONTRACEPTIVE COILS INSERTED IN (B)(6) 2010 WITHOUT INCIDENT. HAD HSG IN JUNE 2010 AND CONFIRMED THAT TUBES WERE 100% BLOCKED. IN (B)(6) 2013 DISCOVERED THAT I WAS PREGNANT, AND THAT THE COIL FROM MY RIGHT TUBE WAS NOW IN MY CERVIX. HAD D AND C ABORTION AND REMOVED RIGHT COIL ON (B)(6) 2013. LEFT COIL REMAINS IN PLACE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032948	CONCEPTUS	11/20/2013	1/15/2014

Event Information:

Event Date (B3): 3/10/2009	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE PROCEDURE, MY PERIODS BECAME VERY HEAVY, WITH CRAMPING THAT I DIDN'T EXPERIENCE BEFORE. SHARP STABBING PAINS IN OVARY AREA. VERY PAINFUL PELVIC PAIN DURING SEX WHICH I NEVER EXPERIENCED UNTIL ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032949	CONCEPTUS	11/20/2013	1/15/2014

Event Information:

Event Date (B3): 12/6/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I HAD THE PROCEDURE DONE I WENT HOME. I HAD VOMITING, DIZZINESS, PAIN, AND CRAMPING. AS THE YEARS HAVE GONE ON, I HAVE EXPERIENCED SIDE EFFECTS SUCH AS: IRREGULAR BLEEDING, BLEEDING DURING AND AFTER SEX, BLOATING, CRAMPING BUT THESE CRAMPS WERE SEVER, DEPRESSION, SEVERE MOOD SWINGS, SHARP JABBING PAIN IN MY LOWER ABDOMINAL RIGHT SIDE, PELVIC PAIN, PAIN IN MY LOWER BACK, VOMITING, MY PERIODS STOP FOR 6 MONTHS, HOT FLASHES(BUT I'M NOT MENOPAUSAL) WEIGHT GAIN, I HAVE DEVELOPED BOTH FOOD AND IRREGULAR ALLERGIES, MY VAGINA BURNS WHEN I HAVE WALK TO MUCH OR FOR TO LONG, I CAN'T SIT LONG, NOR STAND LONG, SHORTNESS OF BREATH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032950	CONCEPTUS	11/20/2013	1/15/2014

Event Information:

Event Date (B3): 11/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEADACHES, ABDOMINAL PAIN, HEAVY PAINFUL PERIODS, LOSS OF ENERGY, FATIGUE, WEIGHT GAIN, PAINFUL INTERCOURSE, HAIR LOSS, LEG PAIN, BACK PAIN, MEMORY LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032951	CONCEPTUS	11/20/2013	1/15/2014

Event Information:

Event Date (B3): 11/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER COIL PLACEMENT, I HAD HIP AND LOWER BACK PAIN THAT WOULD PREVENT ME FROM BENDING OVER. CONSTANT PAIN LASTED UP UNTIL THE DAY I HAD THE COILS REMOVED WITH A TOTAL VAGINAL HYSTERECTOMY. JOINT PAIN IN HAND, WHICH PREVENTED ME FROM GRIPPING OBJECTS SUCH AS DEODORANT. NO PERIOD FOR 10 MONTHS, THEN DAILY, HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5032952	CONCEPTUS	11/20/2013	1/15/2014

Event Information:

Event Date (B3): 11/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY IMPLANT DONE 5 YEARS AGO IN (B)(6) AND ALL TESTED SHOWED TO BE STERILE, BUT (B)(6) 2012 GOT VERY SICK AND THE DR PROCEEDED IN TELLING ME I WAS PREGNANT AND WAS DUE IN (B)(6) 2013. I HAVE HORRIBLE MIGRAINES, CRAMPS, DIZZINESS, AND LOOSE CLUMPS OF HAIR DAILY, I HAVE ALSO BEEN HAVING VERY SHARP PAINS IN MY ABDOMEN AND BLOATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033078	CONCEPTUS INC	11/22/2013	11/27/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): A20055
Lot #(E4):

Single Use:
Implant Date (E6): 10/12/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT COMPLAINED OF PAIN IN FALLOPIAN TUBES, DIZZINESS, HIVES BETWEEN FINGERS AND TOES, SLEEP DISTURBANCES, DECREASED APPETITE, NAUSEA, HEADACHES, SEVERE MENSTRUAL BLEEDING, BLOATING, SEVERE LOWER BACK PAIN, CRAMPING. DEVICE WAS IMPLANTED FOR CONTRACEPTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033090	CONCEPTUS	11/22/2013	11/29/2013

Event Information:

Event Date (B3): 10/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/24/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE BIRTH CONTROL IN 2011, EXPERIENCING CONSTANT PAIN ABDOMEN AND BACK, FATIGUE, BLOTTING, REALLY HEAVY PERIODS, ETC.. SEEMS TO HAVE GOTTEN WORSE OVER TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033102	CONCEPTUS	11/22/2013	11/29/2013

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628432

Single Use:
Implant Date (E6): 6/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE PROCEDURE I HAVE HAD NUMEROUS REPRODUCTIVE SYSTEM PROBLEMS SUCH AS HEAVY BLEEDING THAT REQUIRED HORMONAL TREATMENT TO CONTROL, SEVERE TIREDNESS, MOOD SWINGS, LETHARGY, AND JUST A GENERAL FEELING OF NOT FEELING QUITE RIGHT. I HAVE SEVERE LABOR TYPE CRAMPING ON A REGULAR BASIS TO THE POINT I HAVE TO MISS WORK AND HIRE CHILDCARE FOR MY CHILDREN BECAUSE I AM UNABLE TO FUNCTION IN SO MUCH PAIN. I HAVE ALSO EXPERIENCED OUTRAGEOUS WEIGHT GAIN. REASON FOR USE: BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033104	BAYER	11/22/2013	11/29/2013

Event Information:

Event Date (B3): 11/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE IMPLANT
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 919039

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IN (B)(6) 2012. I BEGAN TO HAVE SEVERE PELVIC AND BACK PAIN WITHIN TWO WEEKS. DOCTORS COULDN'T TELL ME WHAT IT WAS, AND IT HAS GOTTEN WORSE EVERYDAY ALONG WITH MANY OTHER SYMPTOMS. I HAVE HAD SEVERE HEADACHES, DIZZINESS, MOMENTS OF MENTAL BLUR AND BLACKOUTS, UNEXPLAINED RASH THAT IS CONSTANTLY COMING AND GOING (DOCTORS COULDN'T EXPLAIN IT) MY STOMACH FELT AT TIMES LIKE THERE WAS A BABY KICKING, I HAVE GAINED WEIGHT EVER SINCE (BUT ONLY IN MY STOMACH) DESPITE THE FACT THAT I EAT RIGHT AND EXERCISE DAILY, MY EMOTIONS ARE UP AND DOWN LIKE A ROLLER COASTER, SEX HAS BECOME VERY UNCOMFORTABLE IT FEELS LIKE MY INSIDES ARE BRUISED, MY ENERGY LEVEL IS SO DOWN NOW THAT I FIND MYSELF STRUGGLING TO DO ANYTHING AND I'M A VERY ACTIVE PERSON. MY PERIODS HAVE GOTTEN REALLY BAD, I BLEED HEAVIER THAN I EVER HAVE AND PASS BLOOD CLOTS BIGGER THAN A HALF DOLLAR, I HAVE ACNE ALL OF A SUDDEN, IT WASN'T EVEN THIS BAD WHEN I WAS A TEENAGER. I HAVE AN UNUSUAL AMOUNT OF DISCHARGE ALL OF A SUDDEN, MY HAIR IS FALLING OUT EVERY TIME I WASH IT. THESE ARE ALL THINGS I NEVER DEALT WITH BEFORE THE ESSURE. I KNOW MY BODY AND EVER SINCE I HAD THIS PROCEDURE, MY BODY HAS BEEN WREAKING HAVOC. IT HAS RUINED MY QUALITY OF LIFE AND EVERYONE AROUND ME. I JUST WANT MY BODY AND MY LIFE BACK TO NORMAL. THESE ARE ALL SIDE EFFECTS THAT MY DOCTOR ASSURED ME COULDN'T BE POSSIBLE. IT IS VERY MISLEADING TO WOMEN AND EVERY ONE OF THESE SIDE EFFECTS SHOULD BE LISTED AND THEY'RE NOT. I NEVER WOULD HAVE HAD THE PROCEDURE HAD I KNOWN. NOW I JUST WANT THEM OUT OF ME. MY INSURANCE DROPPED ME RIGHT AFTER THE PROCEDURE WAS DONE SO I DON'T HAVE THE MONEY FOR THE SURGERY. THIS WHOLE EXPERIENCE HAS BEEN HORRIBLE FOR ME AND AS SOON AS I CAN AFFORD IT, THEY WILL BE OUT OF ME. THIS PRODUCT IS HURTING SO MANY WOMEN AND IT NEEDS TO BE DEALT WITH. I DON'T SEE HOW SOMEONE CAN

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KNOWINGLY LET MILLIONS OF WOMEN GET THIS EVERYDAY AND NOT LET THEM KNOW WHAT CAN HAPPEN TO THEM. THERE ARE WOMEN SUFFERING AND EVEN DYING AND EVERYONE IS TOO BUSY DENYING IT TO FIX THE PROBLEM. I, LIKE OTHER WOMEN, JUST WANT MY LIFE BACK. I'M TOO YOUNG TO BE FEELING AS OLD AS I DO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033105	BAYER	11/22/2013	11/29/2013

Event Information:

Event Date (B3): 12/18/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/18/2008
Explant Date (E7): 11/12/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY ESSURE IMPLANTS PLACED ON (B)(6) 2008. SOON AFTER THE PROCEDURE, I STARTED EXPERIENCING UNUSUAL THINGS. MY LEG BEGAN TO SWELL, SEVERE LEG, LOWER BACK, AND HIP PAIN. I ALSO STARTED TO EXPERIENCE ALLERGIES AND BECAUSE OF THIS I DEVELOPED ALLERGY INDUCED ASTHMA. MY HAIR BEGAN TO FALL OUT, STARTED TO HAVE PANIC ATTACKS, DEPRESSION, RESTLESS LEGS SYNDROME, AND VISION PROBLEMS. ONE OF THE MOST SCARY ISSUE WAS MY MEMORY. I HAVE ALWAYS HAD A VERY GOOD MEMORY, KNOWN WELL IN MY FAMILY AS THE GO TO PERSON TO REMEMBER THINGS AND EVENTS. BUT I WAS EXPERIENCING SHORT TERMS MEMORY LOSS. THIS BEGAN TO EFFECT MY WORK AND MY PERSONAL LIFE. I WAS GETTING SICK ALL THE TIME AND JUST DID NOT UNDERSTAND WHAT WAS GOING ON, I WAS ONLY IN MY (B)(6). ONE DAY, I GOOGLED "PROBLEMS WITH ESSURE" AND WOW THERE I WAS. I WAS NOT GOING CRAZY OR GROW OLD BEFORE MY TIME. I FOUGHT FOR YEARS TO HAVE ESSURE REMOVED BUT MOST DOCTORS DID NOT BELIEVE ESSURE WAS THE CAUSE. I DEVELOPED A FIBROID TUMOR AND THAT IS HOW I GOT A HYSTERECTOMY. TWO DAYS AFTER SURGERY, MY PAIN IS GOING, MY BRAIN FOG/MEMORY IS BETTER, MY VISION IS BETTER, AND I FELL GREAT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00050	BAYER HEALTHCARE LLC	11/22/2013	12/4/2013

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/22/2012
Explant Date (E7): 4/9/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED BY HER OBSTETRICIAN FOR PERMANENT BIRTH CONTROL. NOT EVEN A WEEK AFTER IMPLANTATION, CONSUMER WAS DOUBLED OVER IN PAIN, COULD NOT MOVE AND COULD NOT TAKE CARE OF HER KIDS. WHEN SHE WENT TO THE DOCTOR SHE WAS TOLD IT WAS NORMAL CRAMPING, PRESCRIBED PAIN MEDS (MEDICATIONS) AND WAS SENT ON HER WAY. SHE WAS STILL BLEEDING TWO WEEKS LATER AND WAS TOLD BY HER DOCTOR THAT THIS WAS NORMAL ALSO. THEN THE RASHES BEGAN ALL OVER HER FACE AND IN HER PRIVATES. SHE ALSO BEGAN HAVING PAIN IN HER LEG, SWELLING, NUMBNESS AND TINGLING IN HER EXTREMITIES UNEXPLAINED. TWO DAYS AFTER THAT, SHE TRIED HAVING SEX WITH HER BOYFRIEND AND IT HURT AND SHE BLED FOR TWO DAYS. SHE WENT AND SAW HER OB (OBSTETRICIAN) WHO IMPLANTED HER, AND SHE RAN TESTS, DID A PAP AND CONSUMER BLED ON HER HAND WHEN SHE SWABBED HER CERVIX. ALL BLOOD TESTS AND PAP SMEAR CAME BACK NEGATIVE SO SHE SCHEDULED CONSUMER FOR A HYSTERECTOMY FOR 2013. CONSUMER SPENT THE NIGHT IN THE HOSPITAL AND THE NEXT DAY SHE WAS UP AND WALKING AROUND WITH NO ISSUES WHAT SO EVER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00051	BAYER HEALTHCARE, LLC	11/22/2013	12/4/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2000
Explant Date (E7): 4/9/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD THE STOP DEVICE, (NOW MARKETED AS ESSURE 205) IMPLANTED IN 2000. SHE WAS PART OF THE STUDY GROUP WHEN SHE HAD THE STOP DEVICE IMPLANTED AND WHILE INVOLVED IN THE STUDY COMPLAINED OF PAIN AND OTHER ISSUES. THESE ISSUES (NOS) WERE DISMISSED BY THE STUDY STAFF AND CONSUMER WAS TOLD THAT SHE MUST HAVE ANOTHER HEALTH ISSUE AND THAT HER COMPLAINTS WERE NOT RELATED TO THE DEVICE. NOW, 13 YEARS LATER, AND AFTER NUMEROUS SPECIALISTS AND TESTS, SHE WAS HAVING A HYSTERECTOMY TO REMOVE THE IMPLANTS. SHE SUFFERS FROM WILDLY ERRATIC, IRREGULAR PERIODS, NEARLY CONSTANT PELVIC PAIN AND SHARP STABBING PAINS IN THE PELVIS REGION, HEADACHES, SYMPTOMS OF SEVERE ALLERGIC REACTIONS (PRESUMABLY FROM NICKEL AND-OR PET FIBERS), WIDESPREAD SEVERE SWELLING, EXTREME FATIGUE, MUSCLE PAIN, WEAKNESS, MUSCLE SPASMS, AND TREMORS. THE CONSUMER REPORTED THAT WHILE ON ESSURE, SHE HAD NO QUALITY OF LIFE, HAD BLACKOUT PERIODS AND WAS ALWAYS IN PAIN. SHE MENTIONED SHE WAS FORCED TO UNDERGO A HYSTERECTOMY TO REMOVE COILS DUE TO ALL COMPLICATIONS SHE BELIEVED THE COILS WERE CAUSING. NINE DAYS AFTER THE REMOVAL, SHE STATED SHE NEVER FELT BETTER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00052	BAYER HEALTHCARE LLC	11/22/2013	12/4/2013

Event Information:

Event Date (B3): 11/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2006
Explant Date (E7): 7/23/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSUMER HAD ESSURE (ESS205) INSERTED ON (B)(6) 2006. NEITHER AN HSG TEST WAS PERFORMED OR FOLLOW-UP WITH THE PHYSICIAN WHO IMPLANTED THE ESSURE BECAUSE SHE MOVED TO OTHER STATE. AFTER IMPLANTATION HER HAIR FELL OUT, SHE HAD LABOR LIKE PAINS, PERIODS LASTING 7-10 DAYS EVERY TWO WEEKS, WEIGHT GAIN (70 LBS), NAUSEA, CONSTANT CRAMPS, JOINT PAIN, IRRITABILITY, BRAIN FOG, HEARING LOSS, INABILITY TO HEAL PROPERLY, CHRONIC AND ACUTE INFLAMMATION OF MY UTERUS AND CERVIX, SHE DEVELOPED ENDOMETRIOSIS, ADENOMYOSIS, POLYCYSTIC OVARIAN SYNDROME, HAD NO ENERGY AND NO SEX DRIVE. SINCE ESSURE, SHE BECAME ALLERGIC TO PERCOCET AND BACTRIM. SHE ALSO EXPERIENCED DEPRESSION AND MOOD SWINGS WHICH STARTED ONE MONTH AFTER ESSURE WAS INSERTED. SHE HAD HEAVY BLEEDING FOR 3 MONTHS AFTER ESSURE PLACEMENT AND IT WAS TREATED WITH HORMONES. IN LATE 2011 OR EARLY 2012 (STATES HER MEMORY HAS BEEN POOR SINCE ESSURE) SHE ALSO HAD A MIRENA INSERTED FOR THE HEAVY BLEEDING. FEW WEEKS AFTER MIRENA INSERTION, SHE HAD ABDOMINAL PAIN. DUE TO THIS A PELVIC ULTRASOUND SHOWED A SEPTATED OVARIAN CYST AND THE MIRENA WAS REMOVED. IN (B)(6) 2013, SHE UNDERWENT A TOTAL ABDOMINAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY AND OOPHORECTOMY. SHE STATED THE PATHOLOGY REPORT SHOWED MULTIPLE DIFFERENT TYPES OF CYSTS IN THE UTERUS, INFLAMMATION OF THE CERVIX AND TUBES WERE LAYING PATENT. AFTER REMOVED, ALL SYMPTOMS DISAPPEARED.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 19-OCT-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033116	BAYER	11/25/2013	12/2/2013

Event Information:

Event Date (B3): 1/20/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/20/2006
Explant Date (E7): 1/16/2009
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2006, I HAD THE ESSURE PROCEDURE DONE FOR PERMANENT BIRTH CONTROL. I HAD THE DYE TEST DONE 3 MONTHS LATER AND WAS TOLD THAT BOTH OF MY TUBES WERE TOTALLY BLOCKED. (B)(6) 2008, I DISCOVERED I WAS PREGNANT. IN FACT, I WAS ABOUT 8 WEEKS ALONG. MY BABY DIED 2 WEEKS LATER. I HAD A D&C TO REMOVE MY BABY. I HAVE BEEN TREATED FOR DEPRESSION EVER SINCE. MY DOCTOR SUGGESTED THAT I HAVE MY TUBES CLAMPED OFF. I HAD THAT DONE IN (B)(6) 2009. HE DID AN EXPLORATORY ALSO TO FIND MY RIGHT COIL. IT WAS IMBEDDED IN MY BOWEL. HE REMOVED THAT AND CLAMPED MY TUBES OFF. MY LEFT COIL WAS STARTING TO COME OUT OF MY TUBE AT THAT TIME. HE LEFT IT WHERE IT WAS. I STARTED TO HAVE EXTREMELY BAD MENSTRUAL CYCLES AFTER THE MISCARRIAGE. IN (B)(6) 2009, I HAD HYDRO THERMAL ABLATION DONE. THAT PROCEDURE PRETTY MUCH STOPPED THE BLEEDING BUT I STILL HAVE EXTREME MENSTRUAL CRAMPS. MY DOCTOR SAID SHE COULD REMOVE MY UTERUS. I CAN'T AFFORD TO TAKE THE TIME OFF OF WORK FOR THIS. I AM EXTREMELY ANGRY THAT I HAD THE ESSURE PROCEDURE DONE IN THE FIRST PLACE. MY DEPRESSION HAS BEEN VERY BAD OVER THE LAST 5 YEARS. I TRIED TO KILL MYSELF IN (B)(6) 2010 BECAUSE IT WAS SO BAD. I WAS AN OTHERWISE HEALTHY WOMAN UNTIL I HAD THIS PROCEDURE DONE. I MISS WORK FOR MY MENSTRUAL CRAMPS BECAUSE THEY ARE SO SEVERE. THIS PRODUCT NEEDS TO BE TAKEN OFF OF THE MARKET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033124	CONCEPTUS	11/25/2013	12/2/2013

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A FEW YEARS AGO I DECIDED AFTER SPEAKING WITH MY OB/GYN TO ELECT TO HAVE THE ESSURE PROCEDURE. THE SURGERY DID NOT GO WELL AND WAS NOT SUCCESSFUL ON THE RIGHT SIDE. MY FALLOPIAN TUBE SPASM ON THE RIGHT SIDE BUT ESSURE WAS SUCCESSFUL ON THE LEFT SIDE. ANOTHER SURGERY DATE WAS SCHEDULE TO INSERT ESSURE ON THE RIGHT FALLOPIAN TUBE AGAIN, IT WAS NOT SUCCESSFUL DUE TO SPASM. MY OB/GYN STATED THAT I WAS AT RISK OF GETTING PREGNANT AND TO TRY ANOTHER METHOD WHICH IS NOT PERMANENT BUT LASTS UP TO FIVE YEARS AND HAS LOW DOSAGE OF HORMONES. SO FOR THE LAST 6 YEARS I'VE USED BOTH DEVICES SIMULTANEOUSLY. MY LEFT SIDE ALWAYS HAS PAIN AND I CAN FEEL THE DEVICE ON MY LEFT SIDE WHICH HAS OFTEN CAUSED ME NUMBNESS IN MY LEGS AND HANDS, BACK ACHES, HEADACHES, BLOATING AND SPOTTING. USING THESE DEVICES TOGETHER COULD NOT BE SAFE. I FEEL LIKE I'M SICK ALL THE TIME. I'VE BECOME IRRITABLE AND NAUSEOUS. MY FINGERS TINGLE AS WELL AS MY TOES TINGLE. I JUST WANT TO BE HEALTHY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033125	CONCEPTUS	11/25/2013	12/2/2013

Event Information:

Event Date (B3): 8/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/7/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IN 2006 AND AS THE YEARS GONE BY I'M IN MORE AND MORE PAIN. I HAVE DEVELOPED OVARIAN CYSTS ONE WHICH RUPTURED AND HAD ME SICK AND OUT OF WORK FOR ALMOST A MONTH. I HAVE GAINED TREMENDOUS AMOUNT OF WEIGHT IN MY ABDOMEN AREA WHICH APPEARS LOPSIDED AT TIMES. I HAVE EXTREME NAUSEA, MIGRAINES, TINGLING IN MY FINGERS, MUSCLE PAIN AND WEAKNESS. I ALSO EXPERIENCE EXTREME STABBING PAIN IN MY SIDE AS WELL AS NAVEL AREA. I BLEED BETWEEN MY CYCLES. I DON'T HAVE ADEQUATE HEALTH INSURANCE TO HAVE THE ESSURE REMOVED. AT TIMES, I WENT TO CUT IT OUT MYSELF. I HAVE NEVER HAD THESE ISSUES BEFORE THE ESSURE AND HAVE NO SUCH FAMILY HISTORY OF THIS. I HAVE COMPLAINED TO MY DOCTOR IN THE PAST WHICH I WAS TOLD IT WOULD PASS. I HAVE LOOKED INTO HAVING IT REMOVED BUT IT'S NOT OPTIONAL WITHOUT INSURANCE. PLEASE HELP I RATHER HAVE 500 KIDS THAN TO EXPERIENCE THE PAIN I FEEL ON A DAILY / MONTHLY BASES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033126	CONCEPTUS INC.	11/25/2013	12/2/2013

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE PERMANENT BIRTH, CONTROL. I HAVE HAD IT SINCE (B)(6) 2011. I HAVE NOTICED MY MENSTRUAL CYCLE HAS BEEN OFF AND I HAVE HAD PELVIC PAIN MORE OFTEN THAN I EVER HAD BEFORE. MY PAIN IS MAINLY ON MY LEFT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033127	BAYER	11/25/2013	12/2/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/12/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6) 2012 AFTER THE BIRTH OF MY THIRD CHILD. THAT'S WHEN METAL COILS ARE PUT IN YOUR TUBES TO FORM SCARE TISSUE SO THAT SPERM CAN'T PASS THROUGH TO THE OVARIES. THIS IS A BIRTH CONTROL. EVER SINCE MY PROCEDURE, I'VE GONE TO MY OB/GYN SIX TIMES WITH CONSTANT PAIN IN MY LEFT SIDE AND MY BACK. INTERCOURSE IS SO PAINFUL I CAN'T STAND IT ANYMORE. I CRAMP VERY BADLY WHEN IT'S TIME FOR MY CYCLE. I HAVE TERRIBLE HEADACHES. I'VE DONE RESEARCH ON THIS DEVICE AND OTHER WOMEN ARE IN THE SAME BOAT AS I AM AND WORST. WENT TO ANOTHER DOCTOR AND HE SAID I HAVE IBS. THE ONLY WAY TO REVERSE. THIS BIRTH CONTROL IS TO HAVE HYSTERECTOMY. THIS IS THE WORST FEELING IN THE WORLD. PLEASE HELP OTHER WOMEN BEFORE THEY MAKE THE BIGGEST MISTAKE OF THEIR LIVES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033128	BAYER	11/25/2013	12/2/2013

Event Information:

Event Date (B3): 1/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/11/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WILL BE HAVING A HYSTERECTOMY ON (B)(6) 2013 DUE TO MY CHOICE OF HAVING THE ESSURE IMPLANTED IN (B)(6) 2011. I HAVE HAD NOTHING BUT PROBLEMS SINCE RECEIVING THIS DEVICE. I HAVE HAD EXTREME LOWER BACK PAIN, CONSTANT PELVIC PAIN, LOSS OF HAIR, SWOLLEN ANKLES, DEPRESSION, FATIGUE, LARGE AMOUNTS OF FLUID IN THE UTERUS THAT I HAVE TO GET DRAINED EVERY 3 MONTHS, NUMBNESS OF HANDS AND FEET, INSOMNIA, HEADACHES, MOODINESS AND SWOLLEN ABDOMEN, I AM MISERABLE, BUT SHOULD HOPEFULLY GET SOME RELIEF SOON. THE ENTIRE REASON FOR GETTING THE ESSURE WAS TO AVOID SURGERY AND DOWNTIME. NOW I HAVE TO GO IN FOR A HYSTERECTOMY AND I AM ONLY (B)(6) OLD. ALSO, MY RIGHT COIL HAS MIGRATED SOME PLACE ELSE. LETS HOPE MY DOCTOR CAN FIND IT DURING SURGERY. MY QUALITY OF LIFE IS RIDICULOUS. MY FAMILY HAS SUFFERED!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033130	BAYER	11/25/2013	12/2/2013

Event Information:

Event Date (B3): 6/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN, IN (B)(6)2013. I HAVE HAD TERRIBLE PAINS, IRREGULAR BLEEDING, HEADACHES, HAD THE HSG TEST DONE AND THE LEFT COIL HAS TURN AND WENT INTO MY OVARY. I AM HAVING A HYSTERECTOMY ON (B)(6) 2014 TO REMOVE EVERYTHING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033142	CONCEPTUS	11/25/2013	12/2/2013

Event Information:

Event Date (B3): 3/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A73754

Single Use:
Implant Date (E6): 3/20/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SIX AND A HALF WEEKS AFTER MY CAESAREAN, I HAD THE ESSURE PROCEDURE. THE PROCEDURE ITSELF WAS PAINFUL BUT THAT I THOUGHT WAS TO BE EXPECTED. FOR A WEEK OR SO AFTERWARDS, THE PAIN WAS EXCRUCIATING. IT GRADUALLY LESSENED BUT THE PAIN HAS NEVER YET GONE AWAY. I HAD THE PROCEDURE ON (B)(6) 2013. I FEEL CONSTANT PAIN ON MY INSIDES. THE PAIN IS IN MY TUBES AND SURROUNDING AREA. IT IS ALL DAY, EVERY DAY. I ALSO HAVE DAILY HEADACHES WHICH I'M SURE IS MY BODY'S STRESS REACTION TO THE PAIN. SOMETIMES I HAVE BURSTS OF PAIN THAT FEEL LIKE MY TUBES AND OVARIES ARE BEING STRETCHED AND PULLED AND CUT. I LEAK DAILY A CLEARISH LIQUID THAT I THINK IS DUE TO TUBAL INFECTION. I FEEL LIKE MY HEART IS MISFIRING WHICH SCARES ME A GREAT DEAL. I HAVE ALSO BEEN UNABLE TO LOSE A SINGLE POUND SINCE ESSURE. OTHER SIDE EFFECTS ARE DECREASED SEX DRIVE, CHRONIC LOWER BACK PAIN AND ABDOMINAL SWELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033145		11/25/2013	12/2/2013

Event Information:

Event Date (B3): 9/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/15/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT MY ESSURE PUT IN (B)(6) 2010. THE BLEEDING AND CRAMPING LASTED 4 WEEKS AS THE CRAMPING HAS NEVER STOPPED. I GET DIZZY SPELLS AT ANY GIVEN TIME AND I'M NAUSEATED ALL THE TIME. I HAVE HAD MY GALL BLADDER REMOVED I HAVE HAD 2 RADIATION TESTS DONE ON ME. I HAVE SEEN A CARDIOLOGIST AND I HAVE HAD A CAMERA DOWN MY THROAT TO SEE MY INTESTINES AND MORE BLOOD TESTS YOU CAN THINK OF WHICH TO ALL OF THEM, TESTS HAVE COME BACK NORMAL. I'M A SINGLE MOM OF 2 KIDS AND IT MAKES MY DAYS VERY HARD WHEN I CAN'T CARE FOR MY KIDS THE WAY I WANT TO BECAUSE OF THE PAIN I'M IN. THE DOCTOR NEVER TOLD ME ABOUT ANY OF THE POSSIBLE SIDE AFFECTS I COULD GET AND HE TOLD ME THAT NO ONE HAS EVER HAD ANY PROBLEMS. I'M ONLY (B)(6) AND HAVE MY WHOLE LIFE AHEAD OF ME AND I WANT TO LIVE IT TO THE FULLEST BUT IT'S HARD TO DO WHEN I'M RESTRICTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033146		11/25/2013	12/2/2013

Event Information:

Event Date (B3): 7/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/11/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) 2011. HAVE EXPERIENCED PELVIC PAIN, CHRONIC INFECTIONS, BACK PAIN, HEADACHES, PROLONGED AND HEAVY MENSTRUATIONS, WEIGHT GAIN AND GYN SAYS DEVICE IS NOT RESPONSIBLE BUT I AM CONVINCED AFTER ALL THE NEWS REPORTS THAT THERE IS A PROBLEM WITH THIS DEVICE AND IT IS DAMAGING MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033054	CONCEPTUS	11/25/2013	1/14/2014

Event Information:

Event Date (B3): 11/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ONGOING AND ESCALATING ISSUES SINCE MY IMPLANTATION NEARLY 7 YEARS AGO. IT STARTED WITH STABBING PAIN AND BLOATING IN MY LOWER ABDOMEN. IT ALSO NOW INCLUDES CRUSHING FATIGUE, WEIGHT GAIN, MIGRAINE HEADACHES, AND GI ISSUES. I WAS CONCERNED I HAD OVARIAN CANCER, BUT THAT HAS BEEN RULED OUT VIA VAGINAL ULTRASOUND. I ATTRIBUTE ALL MY ISSUES TO ESSURE SINCE I HAD NONE OF THEM PRIOR TO IMPLANTATION - EXCEPT THE MIGRAINES, WHICH HAVE GOTTEN MUCH MORE FREQUENT AND INTENSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033055	CONCEPTUS	11/25/2013	1/14/2014

Event Information:

Event Date (B3): 1/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SOON AFTER I RECEIVED THE IMPLANTS, I STARTED HAVING MIGRAINES, UNEXPLAINED UTI, PELVIC PAIN, DEPRESSION, NUMBNESS AND TINGLING IN MY HANDS AND FEET. BREAKING OUT IN RASHES, BLOATING STOMACH, WEIGHT GAIN. I HAD BEEN GOING TO DOCTORS FOR UP TO 3 YEARS TRYING TO FIGURE OUT WHAT WAS WRONG. MANY XRAYS, BLOOD WORK, CT SCANS, ULTRASOUNDS, MRI'S, COLONOSCOPY, BIOPSIES AND ETC. SO MANY THINGS I CANT NAME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033057	BAYER	11/25/2013	1/14/2014

Event Information:

Event Date (B3): 3/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MIGRAINES, HEAVY MENSTRUAL PERIODS WITH LARGE CLOTS, PELVIC PAIN, HIP PAIN, DIZZINESS, ANXIETY/ PANIC ATTACKS,SKIN PROBLEMS, BACK PAIN, BLEEDING AFTER SEX, PAINFUL SEX, BODY ACHES, JOINT PAIN, BOWEL ISSUES, CHEST PAINS, BRAIN FOG, CRAMPING, LONGER PERIODS,DISCHARGE,DIZZINESS, DRY SKIN, FATIGUE, HIP PAIN, MOOD SWINGS, MUSCLE SPASMS, NECK PAIN, BLOATING, TEETH ISSUES, VIBRATING SENSATION IN LOWER ABDOMEN, NUMBNESS IN EXTREMITIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033059	CONCEPTUS	11/25/2013	1/14/2014

Event Information:

Event Date (B3): 6/6/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PUT IN 2004 AND IN THE PAST 3 YEARS, MY HEALTH HAS WENT DOWN HILL. I WENT IN WEIGHING (B)(6). AND NOW BETWEEN THE WEIGHT GAIN, HEADACHES, SEVER CRAMPING, MOODINESS, BEING AN EMOTIONAL WRECK, SHARP PAINS, THE HIT OR MISS PERIODS, FORGETFULNESS, BLURRED VISION, BACK AND NECK PAIN, SHARP PAINS ON THE LEFT SIDE WHEN BENDING DOWN, SUCH BAD BACK PAIN I COME TO TEARS TYING MY SHOES, TIREDNESS ALL THE TIME, DEPRESSED, SWELLING OF FEET AND LOWER LEGS, HAD TO HAVE TEETH PULLED IN 2011 BECAUSE FILLINGS WERE FALLING OUT AND NEW CAVITY WERE FORMING NO MATTER WHAT THEY WOULD DO AND NOT TO MENTION ABSOLUTELY NO SEX DRIVE. THESE ARE THE ONES THAT COME TO MIND WHILE FILING THIS OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033062	CONCEPTUS	11/25/2013	1/14/2014

Event Information:

Event Date (B3): 6/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CRAMPS, HEAVY BLEEDING ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033063	CONCEPTUS	11/25/2013	1/14/2014

Event Information:

Event Date (B3): 10/3/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE DIZZINESS, MULTIPLE MENSTRUAL CYCLES IN 1 MONTH, PAINFUL INTERCOURSE, HEAVY BLEEDING, HOT FLASHES, PAINFUL OVULATION, ACNE, BOILS, DEPRESSION, WEIGHT GAIN, DENTAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033056	BAYER	11/25/2013	1/15/2014

Event Information:

Event Date (B3): 5/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I FELT LIKE I HAD NO ENERGY LIKE THERE WAS SOMETHING DRAINED OUT OF ME. WENT TO ER, THEY SAID THEY DIDN'T SEE WHAT WAS WRONG. I SUFFER NOW FROM HEADACHES, NAUSEA, FATIGUE, PAIN ALL OVER MY BODY. WEAKNESS BLURRED VISION, SWELLING IN MY HANDS AND FEET. GURGLING OR WEIRD SOUNDS FROM INSIDE MY BODY AND STABBING PAIN IN AROUND MY UTERUS AREA. FOUL ORDER WHEN I URINATE, PAIN DURING SEX AND AFTER. LOSS OF SEX DRIVE. FORGETFULNESS. METALLIC TASTE IN MY MOUTH. NOW I HAVE DEVELOPED (B)(6).. HEARTBURN WORSE NOW...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033058	CONCEPTUS	11/25/2013	1/15/2014

Event Information:

Event Date (B3): 5/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE DEVICE IN (B)(6) BY MY GYNECOLOGIST. WITHIN 6 MONTHS OF IMPLANTATION, I WAS IN A LOT OF PAIN ON MY LOWER ABDOMEN, ON MY LEFT SIDE. I CALLED MY DOCTOR AND SHE ORDERED ULTRASOUNDS. WHEN SHE SHOWED ME THE RESULTS, SHE SAID EVERYTHING LOOKED FINE, EVEN THOUGH I NOTICED THAT THE COILS LOOK BENT AND TWISTED. AFTER 2 YEARS, I AM STILL IN A LOT OF PAIN DOWN THERE. AND NOW THE PAIN HAS MIGRATED DOWN TO MY LEG, THE RIGHT SIDE IS FINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033060	CONCEPTUS	11/25/2013	1/15/2014

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD NOT GOTTEN MY MONTHLY CYCLE FOR 2 MONTHS. I HAD ESSURE PLACED ON (B)(6) 2013 AND HAD NORMAL CYCLES UNTIL NOW. I FINALLY GOT IT ON (B)(6) 2013 AND IT HAD BEEN 2 MONTHS LATE. I HAVE CONSTANT BLOOD CLOTS, LOWER PELVIC PAIN ON BOTH SIDES, PAIN IN MY BACK, CONSTANT BLOATING, AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033061	CONCEPTUS	11/25/2013	1/15/2014

Event Information:

Event Date (B3): 10/23/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABNORMAL BLEEDING, SEVERE CRAMPING, HEADACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033064	CONCEPTUS	11/25/2013	1/15/2014

Event Information:

Event Date (B3): 1/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD CYST, CRAMPING, LONG PERIODS LASTING MORE THE 4 DAYS AS THEY USE TO. LASTING UP TO 7-8 DAYS. PAIN FROM MY WAIST DOWN CRAMPING. SHOOTING PAIN IN VAGINA AREA. HOT FLASHES, WEAK, TIRED, NOT HAVING ANY ENERGY. NOT ABLE TO SLEEP. CELLULITIS, CHEST PAINS, PANIC ATTACKS., HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00053	BAYER HEALTHCARE LLC	11/26/2013	12/4/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/17/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON AN UNSPECIFIED DATE, THE CONSUMER EXPERIENCED FREQUENT UTI (URINARY TRACT INFECTION), EXTREME FATIGUE, DEPRESSION, MOOD SWINGS, SEVERE ABDOMINAL BLOATING, EXTREMELY HEAVY MENSTRUAL BLEEDING WITH GOLF BALL SIZED CLOTS, IRREGULAR MENSES, BV (BACTERIAL VAGINOSIS)INFECTIONS, VERTIGO, FORGETFULNESS, MIGRAINES, JOINT PAIN, NUMBNESS IN EXTREMITIES, MISSING A PERIOD, MY BODY IS HAVING A REACTION TO THE METALS AND CHEMICALS IN THE PETS FIBER, I WAS IN SO MUCH PAIN, AND ABDOMINAL SWELLING. ON AN UNSPECIFIED DATE THE CONSUMER UNDERWENT A HYSTERECTOMY ((B)(6)) DUE TO REMOVAL OF ESSURE. ALL SYMPTOMS HAVE DIMINISHED SINCE REMOVING THE ESSURE.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2014: PTC RESULT UPDATED. FINAL ASSESSMENT: ADDITIONAL LOT NUMBERS RECEIVED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00054	BAYER HEALTHCARE LLC	11/26/2013	12/4/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/12/2012
Explant Date (E7): 10/30/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PT COMPLAINED OF A LOT PAIN DURING PLACEMENT OF ESSURE UNITS ON (B)(6) 2012, BUT HEALTHCARE PROFESSIONAL THOUGHT THE PROCEDURE WENT WELL. AT PLACEMENT, THE TRAILING COILS LOOKED CORRECT. SHE HAD THE MODIFIED HYSTEROSALPINGOGRAM ON TIME ((B)(6) 2012) AND THE TRAILING COILS LOOKED CORRECT AT THAT TIME. PT FELT OKAY FOR A WHILE BUT CAME BACK WITH COMPLAINT OF PAIN ON RIGHT SIDE. PT RECEIVED PAIN MEDICATIONS (PT HAS BEEN ON PAIN MEDICATIONS FOR OTHER PROBLEMS ALSO). ON (B)(6) 2013, HYSTERECTOMY WAS PERFORMED FOR TREATMENT, AND THE RIGHT ESSURE HAD PERFORATED THE RIGHT TUBE AND WAS ATTACHED TO THE BOWEL AND OMENTUM. ESSURE WAS REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033183	BAYER	11/26/2013	12/4/2013

Event Information:

Event Date (B3): 1/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305

Single Use:
Implant Date (E6): 1/18/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2013. SINCE HAVING ESSURE I HAVE HAD CONSTANT PELVIC AND BACK PAIN. I GET FREQUENT MIGRAINES AND CONSTANTLY FEEL TIRED. MY MENSTRUAL CYCLES ARE HEAVIER AND I HAVE HAD LOTS OF CLOTTING AND SEVERE PAIN. THEY ALSO LAST LONGER AND I SPOT IN BETWEEN. WHEN NOT BLEEDING I HAVE A CLEAR ODORLESS DISCHARGE WHICH IS HEAVY AND I USUALLY HAVE TO WEAR A PANTY LINER. I CONSTANTLY HAVE SHARP PAINS WHERE THE COILS ARE AND IT FEELS LIKE THEY ARE STABBING ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033184	CONCEPTUS INC.	11/26/2013	12/4/2013

Event Information:

Event Date (B3): 5/6/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/5/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE PLACED I HAVE HAD PAIN ON MY LEFT SIDE THAT HAS PUT ME IN THE EMERGENCY ROOM SEVERAL TIMES IN 4 YEARS. I HAVE HAD WEIGHT GAIN, BLOATING, SWELLING OF MY HANDS AND FEET, OVARIAN CYSTS AND IRREGULAR PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033187	CONCEPTUS	11/26/2013	12/4/2013

Event Information:

Event Date (B3): 3/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/18/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ENSURE IMPLANT (B)(6). IN ABOUT A YEAR AND HALF I STARTED HAVING NEW ALLERGIES. GI ISSUES, WEIGHT GAIN, JOINT PAIN, MUSCLE PAIN, SEVERE HEADACHES, BACK PAIN AND HIP PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033188	CONCEPTUS	11/26/2013	12/4/2013

Event Information:

Event Date (B3): 10/6/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/12/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PROCEDURE ON (B)(6) 2012, AS OF TODAY I AM 11 WEEKS PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033189	CONCEPTUS	11/26/2013	12/4/2013

Event Information:

Event Date (B3): 11/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/18/2009
Explant Date (E7): 11/12/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT HAD SCHEDULED AN ABDOMINOPLASTY FOR (B)(6) 2009 TO CORRECT EXTREME AND VERY UNSIGHTLY STRETCHING OF MY ABDOMINAL SKIN FOLLOWING TWO LARGE PREGNANCIES THAT COULD NOT BE EXERCISED AWAY. THE PLASTIC SURGEON TOLD ME THAT I WOULD NEED TO CHOOSE A PERMANENT CONTRACEPTION METHOD TO AVOID THE RISK OF FUTURE PREGNANCY. SHE PUT ME IN TOUCH WITH A GYN/OB I HAD NOT PREVIOUSLY KNOWN, AND I MET WITH HIM TO DISCUSS MY OPTIONS. HE TOLD ME THE SEMI-PERMANENT OPTIONS I WANTED WOULD NOT BE A POSSIBILITY AND ESSURE WAS THE WAY TO GO. I HAD NOT HEARD OF ESSURE AND I ASKED WHY IT WOULD BE PREFERABLE TO THE TRADITION TUBAL LIGATION PROCEDURE. HE GAVE ME A DVD TO WATCH AND SAID IT WOULD BE MORE RELIABLE AND IT WOULD BE DONE QUICKLY, AT THE SAME TIME AS THE ABDOMINOPLASTY. TRUSTING HIM, I SCHEDULED HAD THE ESSURE COILS IMPLANTED IN (B)(6) 2009. ONCE THE ESSURE COILS WERE IMPLANTED, MY MENSTRUAL PERIODS GRADUALLY BEGAN INCREASING IN LENGTH FROM 7 DAYS TO 11-12 DAYS AND MY BLOOD FLOW BECAME A LOT HEAVIER. MY CRAMPS ALSO BECAME MORE INTENSE. AND I NOTICED MY WEIGHT BEGAN TO CLIMB - ABOUT 25 POUNDS IN TOTAL. THEN IN (B)(6) 2012, MY PERIOD ESSENTIALLY NEVER ENDED. IT CONTINUED NONSTOP FOR THE NEXT THREE MONTHS IN THE FORM OF "SPOTTING" INTERMIXED WITH FULL BLOWN PERIODS. MY OB/GYN (SAME AS WHO IMPLANTED ESSURE) PERFORMED AN ENDOMETRIAL ABLATION IN (B)(6) 2012, BELIEVING IT WOULD FIX THE PROBLEM. IT HAD ABSOLUTELY NO EFFECT AND THE NONSTOP SPOTTING/HEAVING BLEEDING CONTINUED WITH TREMENDOUS DISCOMFORT. MY OB/GYN SAID A TOTAL HYSTERECTOMY - REMOVAL OF MY UTERUS, CERVIX AND BOTH FALLOPIAN TUBES - WAS THE ONLY LIKELY CURE BECAUSE HE SAID HE SUSPECTED THE BLEEDING MIGHT BE COMING FROM AN AREA IN ONE OF THE "HORNS" OF MY UTERUS WHICH WASN'T ACCESSIBLE DURING THE ABLATION. HE WAS RATHER INSISTENT THAT MY FALLOPIAN TUBES

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BE REMOVED. I DIDN'T REALLY UNDERSTAND WHY MY FALLOPIAN TUBES NEEDED TO BE TAKEN AND I WAS WORRIED THAT DOING SO WOULD JEOPARDIZE MY ABILITY TO KEEP MY OVARIES. BUT HE ASSURED ME, THAT BARRING ANY "SURPRISES", I WOULD BE ABLE TO KEEP MY OVARIES. I CONSULTED A SECOND GYNECOLOGIST AND THEN A THIRD. ALL THREE DOCTORS EXAMINED ME AND RAN THE USUAL TESTS ON ME AND AGREED I HAD UNEXPLAINED BLEEDING AND HYSTERECTOMY WOULD BE THE MOST LIKELY CURE. SO I RELUCTANTLY HAD THE TOTAL HYSTERECTOMY PERFORMED IN (B)(6) 2012. I WAS ABLE TO KEEP MY OVARIES, THANKFULLY. MY MOTHER HAD TO LEAVE MY FATHER, WHO IS COMPLETELY DISABLED, IN (B)(6) TO COME TO (B)(6) TO HELP ME AFTER THE SURGERY AND TAKE CARE OF MY CHILDREN WHILE I BEGAN MY RECOVER. A WEEK AFTER MY MOTHER LEFT, I EXPERIENCED A HEMORRHAGE AND HAD TO SPEND THE NIGHT TO THE ER AND TAKE OFF MORE TIME FROM WORK. MY RECOVERY AFTER THAT WAS SLOW BUT STEADY. I HAVE NOT BEEN ABLE TO LOSE THE WEIGHT. I INITIALLY PUT ON AFTER THE COILS WERE IMPLANTED. I SUFFERED A LOT OF PHYSICAL PAIN AND EMOTIONAL DISTRESS AS THE RESULT OF THE HEAVIER PERIODS, THE CONTINUED SPOTTING AND THE MORE INTENSE CRAMPS. I NOW HAVE VERY NOTICEABLE, UPPER-ABDOMINAL SCARS FROM THE LAPAROSCOPE. I MISSED MORE THAN FOUR WEEKS OF WORK AND I AM STILL PAYING THE HOSPITAL BILLS (WHICH HAVE ALREADY BEEN SENT TO "COLLECTIONS" AND HAVE ADVERSELY AFFECTED MY CREDIT SCORE). IT'S BEEN ROUGH; I WAS ONLY (B)(6) WHEN THIS ORDEAL BEGAN AND (B)(6) WHEN I HAD THE HYSTERECTOMY. I AM EMBARRASSED TO TALK ABOUT WHAT HAPPENED TO FRIENDS AS NO ONE CAN RELATE. I FEEL SO STUPID FOR ALLOWING MY DOCTOR TO IMPLANT THE ESSURE COILS IN MY BODY; HE JUST SEEMED SO SURE THEY WERE THE "LATEST AND GREATER". THEY WEREN'T. I HAVE NO DOUBT IN MY MIND THAT THE ESSURE COILS CAUSED ME TO NEED TO HAVE A HYSTERECTOMY. I HAD NEVER HAD ANY GYNECOLOGICAL PROBLEM PRIOR TO GETTING ESSURE AND ALL REASONABLE CAUSES FOR THE SPOTTING HAD BEEN RULED OUT -- NO FIBROIDS, NO ENDOMETRIOSIS, NO CANCER, NOT STIS. NO ONE COULD TELL ME WHY I WAS SPOTTING CONTINUALLY FOR SEVEN MONTHS OR WHY MY PERIODS ALMOST DOUBLED IN LENGTH. I BELIEVE ONE OF THE COILS MIGRATED AND WAS CAUSING THE SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033220	BAYER	11/27/2013	12/6/2013

Event Information:

Event Date (B3): 8/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B21581

Single Use:
Implant Date (E6): 8/9/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED ESSURE IN (B)(6) 2013. BEFORE MY PROCEDURE, I WAS TOLD I NEEDED TO BE ON BIRTH CONTROL AND WAS TOLD DEPO SHOT WOULD THIN THE LINING OF MY UTERUS, ULTIMATELY MAKING THE PROCEDURE EASIER. I GOT THE DEPO SHOT IN BEGINNING OF (B)(6). DAY OF PROCEDURE, I WAS GIVING VICODINE AND XANAX AND SAT IN THE FILLED WAITING ROOM FOR THE DRUGS TO KICK IN 30 MIN LATER IT WAS MY TURN. THE MEDS WERE NOT WORKING, THERE WAS A ESSURE REPRESENTATIVE IN THE ROOM, AND THE PROCEDURE WAS ALMOST AS PAINFUL AS CHILD BIRTH. OVER ALL MY EXPERIENCE WAS OFF TO A BAD START. AFTER THE PROCEDURE, I WAS BLEEDING AND CONTINUED TO BLEED, FOR THREE MONTHS. DURING THIS TIME, I WENT THROUGH A SUPER + TAMPON EVERY HOUR, THE PAIN GOT SO BAD I COULD NOT USE TAMPONS AND SWITCH TO PADS. I STOP BLEEDING FOR TWO WEEKS JUST TO START AGAIN, STILL WITH HEAVY BLEEDING AND GOLF BALL SIZE BLOOD CLOTS. I AM CURRENTLY, STILL ON MY PERIOD. BESIDES ALL THE MENSTRUATION ISSUES, MY HAIR BEGAN TO FALL OUT, I WOULD SAY I HAVE LOST 25% VOLUME OF MY HAIR SINCE (B)(6). MY SCALP BURNS AND ITCHES. I AM FATIGUED ALL THE TIME, IN CONSTANT STOMACH PAIN, I SWEAR IT FEELS LIKE SOMETHING IS STABBING ME ON THE INSIDE IN MY LOWER STOMACH. IT HURTS DURING AND AFTER INTERCOURSE. I HAD MY PROCEDURE DONE AT (B)(6), WHEN I TOLD THEM ABOUT MY ISSUES, THEY ASSURED ME IT WAS NOT ESSURE RELATED BUT THEY THINK IT IS DEPO SHOT SIDE EFFECTS. MY PLAN (B)(6) ONLY COVERED THE PROCEDURE AND THE HSG TEST, BUT WILL NOT COVER ANY F/U APPOINTMENTS IN CASE OF ISSUES. SO I CAN'T AFFORD TO GO SEE A DOCTOR UNTIL I GET ON AN (B)(6) PLAN. PLEASE HELP ME. I FEEL LIKE THEY PUT THESE THINGS IN ME AND THEN I AM JUST LEFT HERE WITH ALL THESE PROBLEMS. SINCE I GOT THESE COILS, I HAVE NOT BEEN THE SAME. THE SYMPTOMS KEEP

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GETTING WORSE. I FEEL SICKER AND SICKER. I DID GO TO THE EMERGENCY ROOM, HAD ULTRA SOUNDS AND X-RAYS IN (B)(6). THEY DREW BLOOD AS WELL AND SAID THEY DON'T SEE ANYTHING ELSE THAT COULD BE CAUSING MY SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033243	BAYER/CONCEPTUS	11/27/2013	12/6/2013

Event Information:

Event Date (B3): 1/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 787230

Single Use:
Implant Date (E6): 1/14/2011
Explant Date (E7): 11/8/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2011, AND SOON AFTER I BEGAN HAVING PELVIC PAIN. OVER THE NEXT FEW MONTHS, I STARTED HAVING HEAVIER PERIODS, CRAMPING, BLOATING, BACK PAIN, PAIN DURING INTERCOURSE, PAIN DURING OVULATION, HAIR LOSS, EXTREME FATIGUE, STIFFNESS/PAIN IN CALVES, NUMBNESS IN HANDS AND FEET AND THE PELVIC PAIN CONTINUED TO GET WORSE, SOMETIMES A DULL PAIN AND SOMETIMES A SHOOTING PAIN. I HAD A COMPLETE HYSTERECTOMY (B)(6) 2013 WITH ESSURE REMOVAL. I AM ANGRY THAT I NEEDED A HYSTERECTOMY TO GET MY OLD SELF BACK ESPECIALLY SINCE GETTING ESSURE IS SUPPOSE TO AVOID HAVING A SURGERY. PATHOLOGY REPORTED THEY FOUND ADENOMYOSIS AND CERVICITIS. I NO LONGER HAVE ANY PELVIC, BACK OR CALF PAIN. I NO LONGER HAVE BLOATING, FATIGUE OR NUMBNESS IN HANDS AND FEET. ESSURE HAS COMPLETELY TAKEN MY QUALITY OF LIFE FOR CLOSE TO 3 YEARS AND THE TIME LOSS TO PAIN, I WILL NEVER BE ABLE TO GET BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033250		11/27/2013	12/6/2013

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PROCEDURE DONE. SOON AFTER HAVING IT DONE PAIN ON THE LEFT SIDE, EXTREME LOWER BACK PAIN, PAIN DURING INTERCOURSE, ACNE, WEIGHT GAIN, HAIR LOSS, DEPRESSION, FEELING LIKE I AM LIVING IN A FOG, AND EXTREME HEADACHES. PERIODS ARE HEAVIER THAN NORMAL. I CAN'T WEAR TAMPONS ANYMORE DUE TO THE BLEEDING AMOUNT LITERALLY 20 MINS AFTER PUTTING IT IN, I HAVE TO TAKE IT OUT. I HAVE HAD MY THYROIDS TESTED TWICE, AND HAVE BEEN DIAGNOSED WITH BI-POLAR "NEGATE" MY DOCTOR COULDN'T FIGURE OUT WHAT WAS WRONG WITH ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033251		11/27/2013	12/6/2013

Event Information:

Event Date (B3): 9/20/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/20/2013
Explant Date (E7): 10/30/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE DONE ON (B)(6) 2013 AND BLEED EVERY DAY UNTIL (B)(6) 2013 WHEN MY DOCTOR PERFORMED A TOTAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033252	BAYER	11/27/2013	12/6/2013

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/7/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD SEVERE PELVIC PAIN FOR SIX YRS SINCE THE ESSURE WAS IMPLANTED AND RECENTLY FOUND OUT THAT I HAVE A SEVERE NICKEL ALLERGY. I AM NOW FACING A HYSTERECTOMY AS A RESULT OF THE ESSURE, PAIN AND MY OVARIES ARE ENLARGED. I ALSO HAVE SIGNIFICANT WEIGHT GAIN AND FATIGUE AND HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033253		11/27/2013	12/6/2013

Event Information:

Event Date (B3): 12/31/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/31/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE UNDER THE MISCONCEPTION THAT THERE REALLY WERE NO SIDE EFFECTS. SINCE IMPLANTATION, I HAVE HAD CONSTANT PAIN, WEIGHT GAIN, NAUSEA, AND NICKEL REACTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033254	CONCEPTUS	11/27/2013	12/6/2013

Event Information:

Event Date (B3): 11/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20182548

Single Use:
Implant Date (E6): 4/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE PELVIC PAIN, HEAVY BLEEDING, PASSING BLOOD CLOTS, BACK PAIN, AND HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033255		11/27/2013	12/6/2013

Event Information:

Event Date (B3): 2/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED (B)(6) 2012 AND STARTED HAVING SEVERE PAINS IN MY ABDOMEN IN (B)(6) 2012 AND SO I WENT BACK TO OB/GYN TO HAVE THE DEVICE CHECK AND DOC CONFIRMED ITS STILL IN PROPER PLACE. SO I CONTINUED TO HAVE PAIN AND WENT TO GASTRO DOCTOR FOR COLONOSCOPY, WHICH WAS PERFECTLY FINE THEN STILL HAVING PAIN SO WENT TO HOSPITAL FOR MRI ALL THIS COST OVER (B)(4)HEALTH INSURANCE WON'T PAY. SO NOW I HAVE GONE TO GET ANOTHER OPINION ABOUT ESSURE IMPLANTS AND THE 2ND OB/GYN HAS CONFIRMED IT IS THE DEVICES THAT ARE CAUSING THE PAIN, SO I WILL NEED TO HAVE TUBAL REMOVAL SURGERY THAT WILL COST ANOTHER (B)(4) ALL BECAUSE THIS DEVICE IS HIGHLY PAINFUL AND THE ADVERSE EFFECTS ARE NOT CLEARLY EXPRESSED BY THE MANUFACTURE OF ESSURE TO THE DOCTOR OR THE PT IF I HAD KNOWN THIS UPFRONT I WOULDN'T HAVE HAD THE DEVICE IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033256	CONCEPTUS INC	11/27/2013	12/6/2013

Event Information:

Event Date (B3): 1/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 678818

Single Use:
Implant Date (E6): 1/9/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN 2009. EVER SINCE THEN, I HAVE GAINED APPROX 40 LBS, HAVE SEVERE CONSTANT CRAMPING AND PAIN IN MY ABDOMEN, ITCHY FEET, INTERNAL TEMP CHANGES (HOT FLASHES), CONSTANT SWEATING, AND RASHES ALONG MY INNER THIGHS, UNDER MY BREASTS AND IN MY BUTT CRACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033216	CONCEPTUS INC	12/2/2013	12/6/2013

Event Information:

Event Date (B3): 8/6/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/6/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2009, I HAD ESSURE PERMANENT BIRTH CONTROL IMPLANTED WITHIN ONE YEAR OF GETTING THE ESSURE PRODUCT, I STARTED EXPERIENCING TERRIBLE CHANGES IN MY BODY. SHARP PAINS IN MY STOMACH WITH BOWEL MOVEMENTS WHERE MY TUBES ARE. SEVERE BACK PAIN, DIZZINESS, WEIGHT GAIN OF OVER 40 LBS, SEVERE FATIGUE, BLOATING TO THE POINT I LOOK 6 MONTHS PREGNANT, METAL TASTE IN MY MOUTH, HAIR LOSS, RINGING IN MY EARS AND FLOATERS ALL THESE SYMPTOMS STARTED AFTER HAVING ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033217	BAYER	12/2/2013	12/6/2013

Event Information:

Event Date (B3): 10/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/20/2009
Explant Date (E7): 11/21/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD DRASTIC CHANGES IN MY HEALTH STARTING AFTER THE ESSURE DEVICES WERE IMPLANTED IN 2009, CLEARLY SHOWN IN A DEFINITE TIMELINE OF MY MEDICAL RECORDS WITH MY PRIMARY CARE DOCTOR AND PRIOR GYNECOLOGIST. I WENT FROM HAVING A FEW SYMPTOMS TO EACH ADD'L SYMPTOM OVER TIME HAPPENING FASTER AS TIME HAS GONE ON. IN THE BEGINNING I HAD LOW BACK PAIN THAT RADIATED INTO MY LEGS AFTER BEING ON FEET DOING ACTIVITIES FOR LONG PERIODS OF TIME, BRAIN CLOUDINESS, BRAIN FOG, TROUBLE CONCENTRATING, FORGETFULNESS, WEIGHT GAIN OF APPROX 15-20 POUNDS WITHIN THE FIRST TWO MONTHS AFTER ESSURE WAS IMPLANTED, AND NO MATTER WHAT I DID, COULD NOT LOSE IT. SYMPTOMS ALSO OF HEAVY BLEEDING/MENSES EXPELLING LARGE BLOOD CLOTS/SEVERE PELVIC PAIN, BLURRED VISION, FORGETFULNESS, FATIGUE, TROUBLE BREATHING, UNBELIEVABLE JOINT AND MUSCLE PAIN THAT TURNED OVER TIME TO SEVERE BURNING IN MUSCLES AND JOINTS WITH HARDLY ANY EXERTION, SEVERE HEADACHES, CHEST PAINS, HEART PALPITATIONS AND SKIPPING BEATS/SVT/RAPID HEART RATE, NAUSEA, (ER VISIT IN 2012 DUE TO TINGLING IN HANDS, FEET, NOSE AND LIPS, BLACKING OUT WITH PAIN RADIATING UP INTO MY BACK AND INTO MY HEAD, LIMBS TURNING BLUE, INABILITY TO BREATHE), CONSTIPATION, LOSS OF TASTE AND SMELL/METALLIC TASTE, HAIR LOSS AND PAINFUL SCALP ACNE WITH SEVERE HEADACHES WHEN ACNE BREAKS OUT, INCREASED SEVERITY IN PRIOR SYMPTOMS OF DEPRESSION AND ANXIETY, INSOMNIA, NEW ALLERGY/SENSITIVITIES I'VE NEVER HAD BEFORE TO SEVERAL FOODS AND PLANTS, SKIN REDDENED AND SOMETIMES SPLOTCHY AND PURPLISH ON BACKS OF UPPER ARMS ABOVE ELBOWS, UNEXPLAINED FEVERS, BREAST PAIN, POSSIBLE ENDOMETRIOSIS OR ADENOMYOSIS WITH PELVIC PAIN/SHOOTING AT TIME DOWN INTO MY LEGS, WHITE VAGINAL DISCHARGE SOMETIMES CLEAR BUT NEVER ANY SMELL, DIZZINESS ON EXERTION, GENERAL SKIN/BODY ACHE RESEMBLING FLU SYMPTOMS WITH SWOLLEN FEELING THROUGHOUT

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BODY, RAYNAUD'S DISEASE AND SYMPTOMS OF MULTIPLE SCLEROSIS/AUTOIMMUNE PROBLEMS, AND RECENTLY IN THE LAST THREE MONTHS, I STARTED HAVING ESSENTIAL TREMORS WITH STUTTERING WHEN TRYING TO TALK OFF AND ON WITH HEADACHES TURNING TO MIGRAINE INTENSITY. I FINALLY HAD THE ESSURE COILS REMOVED A WEEK AGO, (B)(6) 2013. MY GYNECOLOGIST DID A LAPAROSCOPIC ASSISTED HYSTERECTOMY, AND SAID HE DID NOT SEE THE COILS BECAUSE HE TOOK MY UTERUS AND FALLOPIAN TUBES OUT IN ONE PIECE. I HAVE MY POSTOPERATIVE F/U APPOINTMENT NEXT WEEK WITH HIM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033258	ESSURE	12/2/2013	12/6/2013

Event Information:

Event Date (B3): 8/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/28/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE ON (B)(6) 2013, AS PROMISED AFTER THE PROCEDURE, I WAS ABLE TO GO ABOUT MY REGULAR ROUTINE. TWO MONTHS LATER AND NOW, THE SEVERE PROBLEMS HAVE STARTED. I AM HAVING SEVERE SHOOTING PAINS, I AM BLEEDING HEAVILY EVERY OTHER WEEK TO THE POINT I AM CHANGING SANITARY PADS EVERY HR. I CURRENTLY HAVE NO INSURANCE TILL (B)(6) OTHERWISE I WOULD HEAD TO THE HOSPITAL. I FEEL DRAINED OF ENERGY AND IT IS RUINING MY LIFE! PLEASE TELL ME WHAT TO DO. MY DOCTOR SAID THIS WAS THE SAFEST PROCEDURE AND LESS DOWNTIME, BUT NOW THE SIDE EFFECTS ARE CAUSING ME DOWNTIME. PLEASE HELP!!! PLEASE CALL ME AT ANYTIME (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033259	CONCEPTUS	12/2/2013	12/6/2013

Event Information:

Event Date (B3): 9/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 975395

Single Use:
Implant Date (E6): 9/17/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I GOT ESSURE, I HAVE BEEN HAVING CRAMPS AND HEADACHES AND BACK PAIN. JUST ROUND OUT THAT I HAVE A BUNCH OF OVARIAN CYSTS AND ENLARGED OVARIES. NOW ON (B)(6), I GOT TO HAVE A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033260	BAYER	12/2/2013	12/6/2013

Event Information:

Event Date (B3): 6/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'M HAVING LOTS OF PAIN, BURNING, REALLY BAD SHARP PAINS, HURTS WHEN HAVING SEX, HAVING REALLY BAD HEADACHES, HAVE DEPRESSING PROBLEMS, PUTTING ON MORE WEIGHT, ALL WITH THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033262	BAYER	12/2/2013	12/6/2013

Event Information:

Event Date (B3): 2/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/28/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WANTED TO GET THE NOVASURE AND MY DOCTOR STATED THAT I WOULD NEED TO GET ESSURE DONE ALONG WITH NOVASURE TO PREVENT COMPLICATIONS WITH PREGNANCY. THE ESSURE WAS IMPLANTED LATE (B)(6) 2013 AND THE NOVASURE WAS DONE LATE (B)(6) 2013. NOTICEABLE SIDE EFFECTS STARTED TO BECOME NOTICEABLE IN (B)(6) THAT INCLUDED PANIC ATTACKS, PELVIC PAIN, AND HAD HEADACHES THAT HAPPENED AT MY PERIOD. I DIDN'T CALL MY OB UNTIL THE FOLLOWING MONTH WHEN THE SYMPTOMS OCCURRED AGAIN AT THE SAME TIME; AT MY PERIOD. SINCE THEN MY SYMPTOMS HAVE GOTTEN MORE ACUTE AND REGULAR. I HAVE OTHER ONSET OF SYMPTOMS AS WELL, WORSEN JOINT PAIN, HEADACHES STILL, PELVIC PAIN (CAN FEEL PAIN ALONG SIDE UTERUS THAT SHOULD BE THE AREA OF MY TUBES), PELVIC PAIN DURING ORGASM, FATIGUE, CHEST PAINS, NIPPLES ARE ALWAYS SORE, WEIGHT GAIN, WORSENING MY PTSD, MY IBS IS UNCONTROLLABLE WITH DIET ALONE NOW, LEG NUMBNESS JUST SITTING, MOODINESS, AND INSOMNIA/RESTFUL SLEEP ISSUES. I ALSO HAVE HSV2 AND I RARELY HAD OUTBREAKS. I HAVE THEM EVERY MONTH NOW SINCE (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033266	BAYER	12/2/2013	12/6/2013

Event Information:

Event Date (B3): 6/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAS THIS DONE BACK IN (B)(6) OF 2013 SINCE THEN I'M IN A LOT OF PAIN CONSTANTLY CAN'T PLAY WITH MY KIDS LIKE I USED TO AND I BLEED NON STOP. I HAVEN'T STOPPED BLEEDING SINCE I HAD THE ESSURE PROCEDURE DONE. THIS NEEDS TO BE TAKEN OFF THE MARKET. I'M GOING BACK TO DOCTOR TOMORROW TO SEE IF IT'S DONE ANY MAJOR DAMAGE TO MY UTERUS OR TUBES BUT THIS ISN'T DOING ITS JOB. IT'S UNCOMFORTABLE AND I STAY IN PAIN 20 OUT OF THE 24 HOURS IN A DAY. I WAKE UP WITH SHARP, STINGING, STABBING PAINS IN MY STOMACH AND VAGINA AREA. I CAN'T HANDLE THIS ANYMORE AND DON'T WANT TO SEE ANYONE ELSE SUFFER LIKE I AM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033152	CONCEPTUS	12/2/2013	1/14/2014

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NAUSEA, TIREDNESS, BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033156	CONCEPTUS	12/2/2013	1/14/2014

Event Information:

Event Date (B3): 3/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GETTING ESSURE DONE I BLED FOR 5 MONTHS STRAIGHT. DOCTOR GAVE ME HORMONES TO STOP THE BLEEDING WHICH DIDN'T HELP. AFTER I STOPPED BLEEDING I STARTED TO HAVE 2 PERIODS A MONTH. ONE VERY HEAVY AND ONE LIGHT, WHICH BEFORE THIS I WAS ON TIME EVERY MONTH SINCE I STARTED WHEN I WAS 11. I NOW HAVE PAINFUL PERIODS THAT ARE IRREGULAR, BLOOD CLOTS, CRAMPING, BAD BREAST PAIN, HEAVY BLEEDING AND PAINFUL OVULATIONS. THEN THE PAST 2 YEARS I HAVE BEEN SEEING MY PRIMARY DOCTOR DUE TO VERY BAD LOWER BACK PAIN, NERVE PAIN THAT RUNS FROM LOWER BACK DOWN RIGHT LEG DOWN TO KNEE, MY KNEES ALSO HURT NON STOP AND SOME DAYS I HAVE A HARD TIME WALKING, BODY STIFFNESS AND JOINT PAIN. MY DOCTOR DID A MRI, XRAY, AND BLOOD WORK ALL TO SHOW NO CAUSE OF WHY I AM IN HORRIBLE PAIN. I HAVE SEEN A PHYSICAL THERAPIST (WHICH DIDN'T HELP) AND A CHIROPRACTOR AND MASSAGE THERAPIST (WHICH DIDN'T HELP EITHER). NOW FOR THE PAST YEAR I HAVE HAD NUMEROUS UTI'S WITH URGENCY TO URINATE WHICH I GET EVER OTHER MONTH. I KEEP GETTING INFECTIONS FOR UNKNOWN REASONS AND HAVE BEEN ON ANTIBIOTICS FOR ALMOST A YEAR NOW DUE TO THEM. I HAVE FATIGUE, HEADACHES, HORRIBLE MOODS SWINGS WERE NO ONE WANTS TO BE AROUND ME, IRRITABLE ALMOST ALL THE TIME, MUSCLE SPASMS, NAUSEA, PELVIC PAIN, SHARP STABBING PAINS (TO THE POINT I THINK SOMEONE HAS ACTUALLY STABBED ME IN MY BACK, SIDE OR LEG), I HAVE TINGLING SENSATIONS IN MY ARMS AND LEGS, NUMBNESS IN RIGHT THIGH, I BRUISE EASILY AND IF I GET CUT IT IS HARD TO HEAL (SOMETIMES IT TAKES 2-3 MONTHS TO HEAL), HAIR LOSS, ALLERGIES HAVE GOTTEN WORSE WITH A LOT OF SINUS INFECTIONS, TEETH PROBLEMS, AND HIP PAIN.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033147	BAYER	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 11/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY SYMPTOMS ARE BLOATING, WEIGHT GAIN, SKIN RASH ON MY HANDS AND I GET WATER BLISTERS ON MY HANDS, BOILS, BACK PAIN, DIZZINESS, BLEEDING AFTER SEX, PAIN DURING SEX, STIFFNESS, CONSTIPATION, SWEATING MY FACE AND PITS SOMETIMES (A LOT), SEVERE CRAMPING, DISCHARGE, NO ENERGY, HOT FLASHES, CAN'T SLEEP, AND MY TATTOOS ARE ITCHY AND RAISED. I TASTE A WEIRD TASTE SOMETIMES, I DON'T KNOW WHAT IT IS. I ALSO HAD AN ABLATION (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033148	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 4/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE IMPLANTING OF THIS PRODUCT MY PERIODS HAVE BECOME SO HEAVY I CAN NOT LEAVE THE HOUSE, ALONG WITH LARGE BLOOD CLOTS AND EXTREME CRAMPING. I WAS ALLERGIC TO NICKEL PRIOR, AND ASKED MY DOCTOR, AS WELL AS READ ALL THE INFORMATION I COULD ON THIS PRODUCT, THERE WAS NO MENTION OF NICKEL IN THE PRODUCT. WITHIN A DAY OF GETTING THIS IMPLANTED MY BODY STARTED HAVING A "REACTION" TO TOUCH. MY CLOTHING WE BE TO CLOSE TO MY BODY AND I WOULD BREAK OUT IN A RED, BUMPY RASH THAT ITCHED INTENSELY. SOMETIMES IT JUST HAPPENS WHEN I HAVEN'T TOUCHED ANYTHING. I AM AFRAID TO ALLOW MY CHILDREN OR SPOUSE TO HUG ME BECAUSE I WILL BREAK OUT IN THIS RASH. MY BODY ALSO REJECTED PIERCINGS I HAD FOR A DECADE PRIOR WITHIN A FEW DAYS OF GETTING THIS IMPLANT. THIS HAS CAUSED A MAJOR IMPACT TO MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033149	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 2/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT WAS VERY PAINFUL. I STILL HAVE SEVERE PELVIC PAIN, HEAVY PERIODS, FATIGUE, NAUSEA, HEADACHES, ON GOING INFECTION THROUGH OUT ORGANS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033150	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 8/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2012 IMPLANTED. ISSUES STARTED AS EARLY AS (B)(6). EXHAUSTED WAS FIRST NOTICEABLE. I STOPPED NURSING BECAUSE I THOUGHT (B)(6) WAS TAKING IT ALL OUT OF ME. IN THE LAST YEAR EVERYTHING HAS SHOWED ITSELF. 20LBS LOST. LARGE AMOUNT HAIR LOSS, ITCHING, BUGS UNDER SKIN, MAJOR PERSONALITY CHANGE SO MUCH I HAVE EMPLOYEES WRITING SOMETHING FOR ME TOO. ALL HAVE SEEN A SIGNIFICANT CHANGE IN ME. PANIC ATTACKS, DIAGNOSED HYPOTHYROID, VITAMIN D DEFICIENCY. HAVE PRESCRIPTION FOR INSOMNIA. TURNED DOWN THREE OTHER PRESCRIPTION OFFERS. THREE I HAVE IS PLENTY. BROKE TWO BONES THIS YEAR. THEY WON'T HEAL. LATEST IS DEMENTIA / DYSLEXIA HUGE CHANGES WITH THESE TWO JUST LATELY. BOSS SAT ME DOWN AND CUT HOURS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033151	BAYER	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 3/12/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MUSCLE PAIN, LEG CRAMPING, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033153	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 8/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANTLY SICK AT MY STOMACH. BRAIN FOG, PANIC ATTACKS, DIZZINESS, FLOATERS IN VISION, IRRITABLE, DIGESTION PROBLEMS, NO SEX DRIVE, BACTERIAL INFECTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033154	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 7/27/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD SEVERE BLEEDING DURING MY PERIODS, LOTS OF BACK PAIN EVERY DAY WORST THIS WEEK I CAN'T EVEN WALK. AND I AM 11 DAYS LATE IN MY PERIOD I THINK I MIGHT BE PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033155	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 10/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THIS PROCEDURE PLACED IN (B)(6) 2010 AND WAS NEVER TOLD THAT IT CONTAINED NICKEL, NOR WAS I GIVEN THE SKIN TEST. I WOULD HAVE NEVER HAD IT DONE IF I HAD KNOWN. SINCE HAVING THE ESSURE PROCEDURE DONE, I HAVE EXPERIENCED MULTIPLE ISSUES THAT HAVE IMPACTED MY DAILY LIFE AND CAUSED ME TO HAVE ADDITIONAL SURGERIES. I FEAR IT WILL NOT BE OVER UNTIL I HAVE HAD A COMPLETE HYSTERECTOMY. FROM THE START, I HAD HEAVY BLEEDING, IRREGULAR PERIODS (I BLEED FOR 7 MONTHS STRAIGHT AFTER I HAD THEM INSERTED) CRAMPING, SHARP STABBING PAINS, BACK PAIN, JOINT PAIN, PAINFUL INTERCOURSE, CHRONIC FATIGUE (SO BAD IT'S HARD TO GET OUT OF THE BED SOME DAYS) LOSS OF ENERGY, INCREASING SEVERE MIGRAINES, NAUSEA, DIZZINESS, NIGHT SWEATS, CLOUDY THOUGHTS, CONFUSION, MOOD SWINGS, SEXUAL DYSFUNCTION (LOSS OF INTEREST), WEIGHT GAIN, SEVERE BLOATING, HAIR LOSS, SKIN RASHES. SOME DEVELOPED OVER TIME. TINGLING SENSATIONS, NUMBNESS IN EXTREMITIES (HANDS AND FEET), NERVE PAIN, MUSCLE SPASMS, MUSCLE WEAKNESS, TEMPORARY FACIAL PARALYSIS, STROKE LIKE SYMPTOMS, URGENCY TO URINATE, CYSTS/BOILS, BLEEDING AFTER SEX, ANEMIA, VITAMIN D DEFICIENCY, ISSUES WITH MY TEETH, BLURRING OF VISION AND FLOATERS, DEPRESSION, WEIGHT LOSS, PERFORATED FALLOPIAN TUBE (ONE COIL IS STILL MISSING INSIDE ME AND CANT BE LOCATED VIA XRAY, CT SCAN OR ULTRASOUND, BUT THEY WERE BOTH SHOWN IN PROPER PLACE 4 MONTHS AFTER PLACEMENT, WHEN I WENT IN DUE TO A POSITIVE PREGNANCY TEST), CHRONIC UTI'S (I AM HAVING A PROCEDURE DONE NEXT MONTH TO CHECK FOR MISSING COIL), I HAVE HAD 10 OR MORE IN THE PAST 1.5 YEARS AND EVEN MANAGED TO GET THEM ON A DAILY ANTIBIOTIC. I RECENTLY HAD MY TUBES AND ONE COIL REMOVED. ALTHOUGH IT HAS LESSENED THE SYMPTOMS, THE REMAINING LOST COIL STILL CONTINUES TO RUIN MY

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LIFE ON A DAILY BASIS AND ROB MY CHILDREN OF THEIR MOTHER, BECAUSE I NEVER FEEL LIKE DOING ANYTHING. I HAVE (B)(6) TWINS AND THIS WAS PLACED SHORTLY AFTER THEY WERE BORN, SO IN FACT, I FEEL LIKE THEY HAVE NEVER HAD A REAL MOM THANKS TO THIS PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033157	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 10/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CRAMPING , BLEEDING, AND CLOTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033158	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 10/4/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IN SEVERE PAIN ON THE RIGHT SIDE WHERE MY RIGHT OVARY AND MY RIGHT TUBE IS AND IT SHOT DOWN MY LEG. I HAD SUCH SEVERE PAIN THAT I COULD NOT WALK BY THE END OF THE NIGHT AND I WOULD HAVE A BURNING PAIN IN MY HIP THAT WOULD KEEP ME UP MOST NIGHTS. ON (B)(6), MY DR FINALLY REMOVED MY TUBES AND COILS AND RIGHT WHEN I WOKE UP AFTER SURGERY, I KNEW THAT THE PAIN WAS GONE. ESSURE IS NOT SOMETHING THAT I WOULD RECOMMEND TO ANYONE!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033159	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 4/24/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE DEVICE IN PLACE, I STARTED HAVING REALLY BAD CRAMPS, HEAVY BLEEDING WITH CLOTS, BAD HEADACHES, BACK PAINS, MOOD SWINGS AND LOW SEX DRIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033160	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 5/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PAIN IN MY LEFT SIDE, HIP, LEG AND OVARIES . I'M IN PAIN 24/7, SOMETIMES I'M A 5 UP TO A 10.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033161	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 7/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SHARP STABBING, PAINS, HEAVY PERIODS, LOWER BACK ACHES, SPOTS IN MY EYES, HEADACHES, MOODINESS, LOSS OF HAIR, PINCHING IN THE PELVIC AREA, SPASMS IN THE PELVIC AREA, CONSTANT CYST, FATIGUE, FOGGING OF THE BRAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033162	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 3/1/2007	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING, MIGRAINES, SEVERE LOWER BACK CRAMPING, HEAVY MENSTRUAL BLEEDING, LOWER ABDOMEN CRAMPS, FORGETFULNESS, JOINT PAIN, MOODINESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033163	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 11/30/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE REPORTED OTHER SIDE EFFECTS PREVIOUSLY. AS OF THIS DATE ABOVE STATED FACE HAS NOW BROKE OUT IN HIVES. ITCHINESS HAS SPREAD TO FACE. EYES VERY ITCHY. HAVE NEVER HAD THIS IN MY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033164	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 11/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SWELLING IN FINGER, TOOK X-RAY NO BRAKEAGE OR FRACTURES. RIGHT PINKY FINGER WAS SWOLLEN FOR 4 MONTHS AND WENT DOWN, A RE-OCCURENCE OF OTHER FINGERS STARTED TO SWELL FOR MONTHS AT A TIME. SHOULDER PAIN AND LOWER BACK PAIN. NOW JOINT AND HAND PAIN LIKE CARPAL TUNNEL. METAL TASTE IN MOUTH ALONG WITH HEAVY BLEEDING AND MISSED PERIODS. NOW KNEE AND SWELLING IN LEGS. HEADACHES, ALONG WITH ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033165	CONCEPTUS	12/2/2013	1/15/2014

Event Information:

Event Date (B3): 11/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ABOVE DATE MENTIONED, (B)(6) 2013, ESSURE WAS IMPLANTED AT 2:00 PM. BY 6:00 PM, I FELT THE COIL MOVE ON MY RIGHT PELVIC REGION. AS IT MOVED, IT WAS ACCOMPANIED BY A SHARP, PIERCING LIKE PAIN. STILL UNDER THE EFFECTS OF THE LONG LASTING PAIN INJECTION I WAS GIVEN AT THE TIME OF THE PROCEDURE, I DID NOT TAKE ANYTHING ELSE FOR PAIN. HALF AN HOUR LATER, I FELT MY BOWELS MOVE AND EXPERIENCED EXCRUCIATING SHARP PAIN AGAIN ON MY RIGHT PELVIC REGION. I WENT TO HAVE A "BM" AND IT HURT VERY MUCH. NOT CONSTIPATION, THE PAIN STILL IN THE AREA PREVIOUSLY MENTIONED. (B)(6) 2013 - EXPERIENCING SEVERE HEADACHES, SWOLLEN THROAT/SORE, AND BLOATING. I DO HAVE THE NORMAL CRAMPING THAT IS EXPECTED POST OP FOR A PROCEDURE SUCH AS THIS, WHICH IS NOT TOO BOTHERSOME TO ME. (B)(6) 2013 - HEADACHES, BLOATING, CRAMPING, SAME SHARP PAIN, NOT CONSTANT BUT OFTEN, NOW HAVING METAL TASTE IN MOUTH, NAUSEA, AND ITCHING ON NECK AND CHEST. (B)(6) 2011 - SAME SYMPTOMS STATED PREVIOUSLY WITH SOME VOMITING AND NOW RASH HAS DEVELOPED. (B)(6) 2013 - NO CHANGE. (B)(6) 2013 - DOCTOR'S APPOINTMENT, PRESCRIBED AN ANTI-INFLAMMATORY. (B)(6) 2013 - NO CHANGE. (B)(6) 2013 - DOCTOR'S APPOINTMENT, DOCTOR PRESCRIBED BENADRYL FOR ITCHING/RASH. ALSO ORDERED X-RAY. (B)(6) 2013 - CT SCAN. I AM A VERY HEALTHY, (B)(6) FEMALE. I HAVE NO KNOWN ALLERGIES AND HAVE NO ILLNESSES, BIRTH DEFECTS, OR MEDICAL CONDITIONS. I AM VERY ACTIVE AND EAT WELL. NEVER HAVE I HAD ANY SYMPTOMS SUCH AS THESE ALL AT ONCE, IN SUCH A SHORT PERIOD OF TIME. AS OF TODAY'S DATE, (B)(6) 2013, I AM NOT FEELING WELL. I HAVE BEEN GETTING A BIT ABSENT MINDED, WHICH IS NOT NORMAL FOR ME, AND I AM IN A LOT OF PAIN. I STILL AM NOT TAKING ANY PRESCRIBED MEDICATIONS, I HAVE NOT TAKEN THE MICRONOR PRESCRIBED TO ME ONE (1) WEEK BEFORE PROCEDURE. IT WAS AFFECTING MY MILK SUPPLY, SO THE DAY BEFORE THE PROCEDURE, I STOPPED. HAVE BEEN ABSTINENT FOR MONTHS

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AND AM CONTINUING WITH THIS FORM OF BIRTH CONTROL. I DO NOT TAKE MEDICATIONS. NOT COLD MEDICINES OR PAIN MEDICATIONS, SUCH AS TYLENOL. I DRINK ONLY WATER, CRANBERRY JUICE, AND MILK. I HAVE NEVER SMOKED, NO DRUGS, NO ALCOHOL. I AM A VERY HEALTHY INDIVIDUAL AND TO BE EXPERIENCING ALL OF THIS RIGHT AFTER ESSURE IMPLANTS, I KNOW MY BODY IS HAVING A REACTION. I HAVE MY X-RAYS AND CT SCANS ON CD, SHOWING THE PLACEMENT OF THE ESSURE. AWAITING DOCTOR'S PHONE CALL AT THIS TIME (I READ HORSE XRAYS, SO I AM LAYMAN WHEN IT COMES TO HUMAN ANATOMY, BUT MY OPINION, IT SHOWS THE END OF THE COIL CURVING WAY UP INTO WHAT APPEARS TO BE MY BOWEL, ON THE RIGHT PELVIC REGION EXACTLY WHERE I AM FEELING THE SHARP POKING PAIN AND WHERE IT HURTS WHEN MY BOWELS MOVE). I WILL UPDATE FURTHER WHEN I RECEIVE RESULTS ON THESE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00056	BAYER HEALTHCARE LLC	12/3/2013	12/9/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED VIA A TELEVISION PROGRAM SHE HAD ESSURE INSERTED. ON UNSPECIFIED DATES SHE EXPERIENCED HIP PAIN AND BACK PAIN. SHE HAD A HYSTERECTOMY PERFORMED AND FELT NORMAL AFTER THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00057	BAYER HEALTHCARE LLC	12/3/2013	12/9/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED VIA TELEVISION SHE HAD ESSURE INSERTED FOR PERMANENT BIRTH CONTROL. ON AN UNSPECIFIED DATE, RIGHT AFTER INSERTION, THE CONSUMER EXPERIENCED PAINFUL SYMPTOMS: IT HURT TO SIT, TO STAND, TO LIE DOWN. HER ANXIETY WAS SO SEVERE. ONCE SHE REALIZED THE DEBILITATING PAIN COULD BE LINKED TO ESSURE, SHE LOOKED INTO HAVING IT REMOVED. HER GYNECOLOGIST SAID THE ONLY WAY TO REMOVE THE ESSURE WAS BY HYSTERECTOMY. WITH THAT SURGERY, EVERY SYMPTOM SHE HAD WAS GONE JUST THREE MONTHS LATER. UNABLE TO F/U WITH CONSUMER FOR FURTHER INFO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033271	CONCEPTUS	12/3/2013	12/9/2013

Event Information:

Event Date (B3): 7/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/5/2013
Explant Date (E7): 11/26/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM WRITING ON BEHALF OF THE ESSURE PERMANENT BIRTH CONTROL. I HAD MY COILS IMPLANTED ON (B)(6) 2013. MY DOCTOR USED LOCAL ANESTHESIA AND DID THE PROCEDURE IN HIS OFFICE. I WAS ENCOURAGED TO GET THIS DONE RATHER THAN A TUBAL LIGATION BECAUSE OF THE MINIMAL RECOVERY TIME AND THE PRICE POINT WITH INSURANCE. THE WHOLE PROCEDURE WAS EXTREMELY PAINFUL, I WILL NEVER FORGET THE FEELING AND THE CLICKING SOUND OF THE COILS BEING SCREWED INTO MY FALLOPIAN TUBES. THREE MONTHS LATER ON MONDAY, (B)(6) 2013 I HAD MY RADIOLOGY TEST AT THE HOSPITAL TO MAKE SURE THAT THE SCAR TISSUE WAS FORMED AND MY TUBES WERE BLOCKED. MY DOCTOR DID NOT TELL ME THAT THE TEST WOULD BE JUST AS PAINFUL AS THE PROCEDURE ITSELF. I WAS IN EXCRUCIATING PAIN LEAVING THE HOSPITAL AFTER THE TEST WAS DONE. I HOWEVER WAS PLEASED THAT THEY TOLD ME THAT IT WORKED AND I WAS GOOD TO GO. THE FRIDAY (B)(6) 2013, I RECEIVED A CALL FROM MY DOCTOR WHILE ON MY WAY TO WORK. HE INFORMED ME THAT HE RECEIVED A CALL FROM THE RADIOLOGIST THE DAY BEFORE AND SHE INFORMED HIM THAT SHE THOUGHT SOMETHING WAS WRONG. HE TOLD ME THAT HE WAS GOING TO MEET WITH A REPRESENTATIVE FROM THE COMPANY AND THEY WERE GOING TO LOOK AT THE PICTURES FROM THE TEST AND GET BACK WITH ME EARLY THE FOLLOWING WEEK AND LET ME KNOW WHAT THEY DECIDE. THE NEXT WEDNESDAY, I RECEIVED A CALL FROM MY DOCTOR STATING THAT THE COIL HAD PUNCTURED MY FALLOPIAN TUBE AND THE COMPANY OFFERED TO GIVE ME A NEW ONE TO INSERT BEHIND IT "AT NO COST TO ME." AFTER THESE COILS ARE PUT IN PLACE, DOCTORS REFUSE TO TAKE THEM OUT IF THERE ARE ISSUES. AFTER TALKING IT OVER WITH MY HUSBAND AND FAMILY MEMBERS, I DECIDED I WANTED MY ENTIRE LEFT FALLOPIAN TUBE REMOVED. I WAS ABSOLUTELY UNCOMFORTABLE LEAVING IT IN HALF HANGING OUT WITH THE POSSIBILITY THAT IT WOULD CAUSE ISSUES IN THE FUTURE. I AM NOW RECOVERING FROM A

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FALLOPIAN TUBE REMOVAL SURGERY AND I AM EXTREMELY UNHAPPY. I URGE YOU TO PLEASE TAKE THIS HORRIBLE BIRTH CONTROL OPTION OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033272	BAYER	12/3/2013	12/9/2013

Event Information:

Event Date (B3): 9/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20208778/664435

Single Use:
Implant Date (E6): 9/8/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE VERY BAD PERIODS, HORRIBLE DEPRESSION, HORRIBLE MOOD SWINGS, BAD PAIN WHERE INSERTS ARE MISCARRIAGES. THIS IS ALL DUE TO ESSURE. BROKEN TEETH PAIN ALL OVER BODY HAIR LOSS, PAIN DURING INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033273	BAYER	12/3/2013	12/9/2013

Event Information:

Event Date (B3): 3/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A63339

Single Use:
Implant Date (E6): 3/22/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(6) 2013. SINCE THEN I HAVE HAD ABNORMAL PERIODS THAT ARE VERY HEAVY, SEVERE CRAMPING, SEVER BACKACHES, EXTREMELY TIRED YET HAVE INSOMNIA, ACHY FROM HEAD TO TOES, MOODY, TINGLING IN FINGERS, MUSCLE WEAKNESS, NO ENERGY, WEIGHT GAIN, SEVERE BLOATING, SYMPTOMS OF PREGNANCY CONSTANTLY. I AM COMPLETELY MISERABLE SINCE ESSURE AND HAVE HAD NEVER HAD ANY OF THE ABOVE SYMPTOMS PRIOR TO HAVING ESSURE IMPLANTED. I CHOSE ESSURE SO I DIDN'T HAVE TO BE SEDATED, SO I COULD HAVE AN OUT PT, IN OFFICE PROCEDURE. LITTLE DID I KNOW THAT MY LIFE WOULD CHANGE IN A MILLION HORRIBLE WAYS SINCE THEN. NOW I WILL HAVE TO BE SEDATED AND GO UNDER THE KNIFE TO HOPEFULLY GET MY LIFE BACK. PLEASE TAKE THIS OFF THE MARKET SO OTHER WOMEN DO NOT HAVE TO SUFFER LIKE THOUSANDS OF US ARE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033274	CONCEPTUS	12/3/2013	12/9/2013

Event Information:

Event Date (B3): 3/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 685785

Single Use:
Implant Date (E6): 3/13/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2010, I WAS IMPLANTED WITH THE ESSURE BIRTH CONTROL DEVICE BY DR. (B)(6), THE OB GYN CENTER, (B)(6). I HAVE EXPERIENCED SEVERE PELVIC, BACK AND LEG PAIN, SEVERE BLEEDING WHEN MENSTRUATING WITH BLOOD CLOTS, MULTIPLE OVARIAN CYSTS. I DEVELOPED MUSCLE TREMORS AND NERVE PAIN, MIGRAINES, PSORIASIS, GASTROINTESTINAL PROBLEMS, FATIGUE, NAUSEA, DEPRESSION, ANXIETY AND SEVERE MEDICATION SENSITIVITY AND NOW I'M TOLD I HAVE A SUSPECTED AUTOIMMUNE DISEASE THAT NEEDS FURTHER TESTING. I HAVE REPORTS FROM 3 DIFFERENT NEUROLOGISTS, DR. (B)(6), A GASTROENTEROLOGIST DR. (B)(6), MY PCP DR. (B)(6), A NERVE DOCTOR DR. (B)(6), A WELLNESS DOCTOR DR. (B)(6), MY CURRENT OB/GYN DR. (B)(6). AFTER NUMEROUS TESTS I'M HAVING A HYSTERECTOMY ON (B)(6) 2014 TO REMOVE THIS ESSURE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033301	BAYER	12/4/2013	12/11/2013

Event Information:

Event Date (B3): 12/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/16/2013
Explant Date (E7): 12/2/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS INSERTED IN (B)(6) 2013. DURING MY 3 MONTH FOLLOW UP X-RAY ONE OF THE COILS WAS SITTING AT THE BOTTOM OF MY PELVIC FLOOR INSTEAD OF IN MY FALLOPIAN TUBE. SURGERY WAS SCHEDULED FOR (B)(6) TO RETRIEVE THE COIL. ONCE IN SURGERY THE DOCTOR SAW THE COIL WAS BROKEN INTO 4 PIECES. HE REMOVED THE BROKEN COIL AND BOTH FALLOPIAN TUBES TO REMOVE OTHER COIL IN CASE, BOTH WERE DEFECTIVE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/4/2013	12/19/2013

Event Information:

Event Date (B3): 12/3/2013 **Report Date (B4): 12/4/2013** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): B53550

Single Use:
Implant Date (E6): 12/3/2013
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WHILE ATTEMPTING TO PLACE THE ESSURE SYSTEM INTO THE FALLOPIAN TUBES BILATERALLY, THERE WERE PROBLEMS DEPLOYING THE COILS INTO THE TUBES AND A PIECE OF ONE OF THE CATHETERS BROKE OFF WHILE TRYING TO REMOVE THE CATHETER FROM THE PATIENT. THE PIECE WAS RETRIEVED BY THE PHYSICIAN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033299	CONCEPTUS	12/5/2013	12/11/2013

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL COIL
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2004
Explant Date (E7): 11/1/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CALLED TO REPORT ON ESSURE PERMANENT BIRTH CONTROL. SHE STATED SHE BEGAN EXPERIENCING PROBLEMS IN (B)(6) 2011. HER SYMPTOMS INCLUDE: PROBLEMS DIGESTING FOOD, PROBLEMS SWALLOWING FOOD, BLOATING, SHARP PAIN, CRAMPING AND BACK PAIN. SHE SAID SHE HAD AN ENDOSCOPY, COLONOSCOPY, ULTRASOUND AND A CAT SCAN TO TRY AND FIND THE CAUSE TO HER HEALTH ISSUES, BUT ALL TESTS SEEMED TO BE FINE. IN (B)(6) 2013, SHE STATED SHE HAD A HYSTERECTOMY AND THE DOCTOR FOUND THAT THE LEFT COIL HAD PERFORATED THE FALLOPIAN TUBE. PT SAID SINCE HER HYSTERECTOMY, SHE NO LONGER HAS PAIN OR ANY OF THE ABOVE HEALTH ISSUES. SHE SAID HER DOCTOR URGED HER TO CALL AND FILE A REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033366	CONCEPTUS	12/5/2013	12/16/2013

Event Information:

Event Date (B3): 1/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 919013

Single Use:
Implant Date (E6): 1/5/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2012. WITHIN SEVERAL DAYS, AFTER THE PROCEDURE, I HAD EXTREME PAIN ON MY LEFT LOWER SIDE. I CALLED THE IMPLANTING DOCTOR AND WAS ADVISED TO HAVE AN ULTRASOUND. THE ULTRASOUND REVEALED THAT I HAD PID FROM ESSURE. I HAD TO TAKE ANTIBIOTICS. I STILL HAVE PAIN ON THE LEFT SIDE AND NOW IMPACTS HOW I WALK. IT HAS GRADUALLY GOTTEN WORSE. IN ADDITION TO THE HIP/SIDE PAIN, I ALSO HAVE CHRONIC LOWER BACK PAIN. IN (B)(6) OF THIS YEAR I HAD AN EPISODE OF SEVERE DIZZINESS. I HAD ANOTHER EPISODE IN (B)(6). I WENT TO AN ENT. THE DOCTOR BELIEVES I NOW HAVE AN AUTO-IMMUNE DISEASE CALLED MINIERE'S DISEASE. I MENTIONED THIS BECAUSE I BELIEVE IT IS LINKED TO THE COILS IN MY BODY. PRIOR TO ESSURE, I NEVER HAD ISSUES. FINALLY, I LOOK AS THOUGH I AM 6 MONTHS PREGNANT. I HAD MY LAST CHILD IN (B)(6) 2011. MY STOMACH STAYS BLOATED. I EAT HEALTHY AND EXERCISE; HOWEVER, MY STOMACH REMAINS UNCHANGED. AGAIN, I BELIEVE THIS IS DUE TO THE ESSURE. I WAS TOLD THAT THE ONLY WAY TO REMOVE THE COILS IS A HYSTERECTOMY AND/OR TUBES REMOVED. I AM (B)(6) YEARS OLD AND DO NOT WANT THAT. ESSURE WAS PITCHED TO ME AS A LESS INVASIVE ALTERNATIVE TO TUBAL LIGATION. I HAD A C-SECTION AND DID NOT WANT TO RUN THE RISK OF COMPLICATIONS SO I OPTED FOR THE ESSURE. HAD I BEEN MADE AWARE OF ALL THE POSSIBLE SIDE EFFECTS I WOULD NOT HAVE CHOSE THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033368		12/5/2013	12/16/2013

Event Information:

Event Date (B3): 7/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): 452503
Catalog # (E4):
Lot #(E4): 635027

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS IMPLANTED AND I HAVE NOT HAD A REGULAR PERIOD SINCE. I HAVE PERIODS TWO OR MORE TIMES A MONTH WITH EXCESSIVE BLEEDING AND EVEN CLOTTING. THERE IS ABNORMAL PAIN THAT OCCURS ON BOTH SIDES OF MY ABDOMEN AND EXCESSIVE BLOATING WITH EVERY PERIOD. I CAN ALSO FEEL THE ESSURE IMPLANT INSIDE OF MY BODY. WHEN I MOVE I HAVE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033369	BAYER	12/5/2013	12/16/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2013. I HAVE HAD EXTREME ABDOMINAL PAIN, VERY NOTICEABLE BLOATING, SHOOTING PAINS DOWN MY LEGS AND VERY HEAVY PERIODS. I AM TOO YOUNG TO GET A HYSTERECTOMY. IT HAS MADE TAKING CARE OF MY FAMILY HARDER FOR ME, SEX IS EXTREMELY PAINFUL AND EVEN THE SMALLEST TASKS SEEM HARD TO DO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033370	ESSURE	12/5/2013	12/16/2013

Event Information:

Event Date (B3): 12/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4): 4324329422
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE HAS GIVEN ME STOMACH RASHES AND BACK KILLS ME; FEELS LIKE REALLY SHARP PAIN ON LEGS AND BACK GETS REALLY BAD MIGRAINES AND GET PAIN IN STOMACH THAT MAKES ME DROP TO MY KNEES AND THERE ARE DAYS I CAN'T GET OUT OF BED DUE TO HORRIBLE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033208	CONCEPTUS	12/5/2013	1/15/2014

Event Information:

Event Date (B3): 7/15/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN STARTED IN (B)(6). SEVERE ABDOMINAL PAIN, HEADACHES, FATIGUE, JOINT PAIN, INSOMNIA, BAD PERIODS, RASHES. ON (B)(6) 2013 HAD APPENDIX REMOVED BECAUSE OF SEVERE ABDOMINAL PAIN. IT'S (B)(6) 2013 AND I STILL HAVE ALL OF THESE SYMPTOMS. I'VE HAD CT SCANS, BLOOD WORK, ULTRASOUNDS, PELVIC EXAMS, XRAYS, AND URINALYSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033209	CONCEPTUS	12/5/2013	1/15/2014

Event Information:

Event Date (B3): 11/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I MISSED MY PERIOD AND HAD A BUNCH OF PREGNANCY SYMPTOMS, SO I TOOK A PREGNANCY TEST FRIDAY WHICH CAME BACK POSITIVE WAS EXCITED NEEDLES TO SAY I REGRET THIS ESSURE SO MUCH. WELL I WOKE UP SUNDAY LATE MORNING W/ PAIN IN MY STOMACH AND HAD SPOTTING. MY HUSBAND CALLED MY OB THIS MORNING AND THEY HAD ME GO IN FOR BLOOD WORK, WHICH WE ALSO ASKED THE NURSE IF THEY WERE HAVING MANY PEOPLE W/ PROBLEMS; SHE LOOKED AT ME LIKE I WAS COMPLETELY RETARDED OR MAKING THIS ALL UP AND SAID NO YOU'RE THE ONLY ONE I'VE HEARD OF, THEY FINALLY CALLED ME BACK AND SAID EVERYTHING WAS NEGATIVE, IT WAS PROBABLY AN OLD TEST. I HAD ONLY HAD THE TEST FOR MAY BE A MONTH NOT LONG. BUT SHE HASN'T HEARD OF ANYONE HAVING PROBLEMS FROM THE ESSURE OR THATS WHAT SHE TOLD ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033210	CONCEPTUS	12/5/2013	1/15/2014

Event Information:

Event Date (B3): 10/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CURRENTLY 5 WEEKS PREGNANT. ESSURE DONE (B)(6) 2013 AND CONFIRMATION HYSTEROSALPINGOGRAM DONE (B)(6) 2013 CONFIRMING CLOSURE OF TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033212	CONCEPTUS	12/5/2013	1/15/2014

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE WAS PLACED AND IMMEDIATELY I HAD SEVERE PAIN IN THE RIGHT TUBE. MY STOMACH WAS SWOLLEN AND PAINFUL. EVENTUALLY, THE PAIN REDUCED BUT, EACH MONTH I WOULD GET SEVERE PAIN ABOUT THE TIME I WOULD BE OVULATING FOR ABOUT 2 DAYS ALMOST UNBEARABLE. I CONTINUED WITH THAT TYPE OF PAIN FOR ABOUT 2 YEARS THEN, THE PAIN BECAME WORSE AND LONGER. ABOUT 10 DAYS OF THE MONTH VERY SHARP PAIN. MY PERIOD HAD REDUCED TO ABOUT 24 HOURS FROM 5-7 FULL DAYS. THE PAIN LEVEL WHEN THE DOCTOR PLACED THE DEVICE WAS 20 ON A SCALE OF 0-10.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033213	CONCEPTUS	12/5/2013	1/15/2014

Event Information:

Event Date (B3): 7/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I MUST SAY THAT BEFORE THIS PROCEDURE I NEVER HAD ANY OF THESE PROBLEMS AND FOR THE MOST PART I WAS QUITE A HEALTHY INDIVIDUAL. THE ISSUES BEGAN TO OCCUR ABOUT A MONTH AND A HALF AFTER IMPLANTATION. IT STARTED OF WITH MOOD SWINGS, NIGHT SWEATS, HOT FLASHES, AND JOINT PAIN. NOW HERE WE ARE 7 MONTHS AFTER IMPLANTATION AND NOT ONLY HAVE THOSE SYMPTOMS GOTTEN WORSE BUT I HAVE HAD EVEN MORE COME UP SINCE. MY SYMPTOMS ARE AS FOLLOWS: ANXIETY, ACNE, RASHES, BACK PAIN, BLADDER PROBLEMS, BLEEDING AFTER SEX, BLURRING OF VISION, BODY ACHES AND STIFFNESS, CHEST PAINS, BRAIN FOG, CONFUSION, UNEXPLAINED SPOTTING, COUGHING UP MUCUS, CRAMPING, DEHYDRATION, DISCHARGE, DIZZINESS, FATIGUE, FEVERS, HAIR LOSS, HEADACHES, HIP PAIN, HOT FLASHES, INSOMNIA, ITCHING, JOINT PAIN, MOOD SWINGS, MUSCLE SPASMS, NAUSEA, NECK PAIN, NIGHT SWEATS, NUMBNESS IN LIMBS, PAINFUL INTERCOURSE, PELVIC PAIN, BLOATING, SHARP STABBING PAINS IN THE OVARY AREA, TINGLING SENSATIONS IN MY FINGERS AND TOES, SHAKINESS, AND WEIGHT GAIN. I HAVE NO OTHER ONGOING ILLNESSES, I WAS A PRETTY HEALTHY (B)(6) UP UNTIL NOW. I HAVE SEEN MY IMPLANTING DOCTOR AND SHE DID A PELVIC EXAM AND DETERMINED THAT I WAS INFLAMED AND TOOK SOME SWABS TO SEND OUT FOR TESTING. SHE THEN DIAGNOSED ME WITH PELVIC INFLAMMATORY DISEASE. SHE SUBSCRIBED ME THE PROPER MEDICINE TO TREAT THIS AND I WAS TO RETURN TO HER OFFICE 2 WEEKS LATER FOR A FOLLOW UP. I WENT TO THE 2 WEEK APPOINTMENT AND ALL THE SWABS SHE TOOK AND SENT OUT FOR TESTING CAME BACK NEGATIVE FOR STD'S AND ANY TYPE OF BACTERIAL INFECTIONS. SHE IS NOW SENDING ME (B)(6) 2014 FOR AN ULTRASOUND.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033214	CONCEPTUS	12/5/2013	1/15/2014

Event Information:

Event Date (B3): 11/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT HAS CAUSED SERIOUS PAIN IN MY STOMACH AND BACK CONSTANTLY HAVING HEADACHES IRREGULAR PERIODS LAST MONTH I HAD A ONE DAY PERIOD AND I FATIGUE FEEL LIKE I HAVE THE FLU ALMOST EVERY DAY AND NONE OF THE DR OUT HERE KNOW ANYTHING ONE DR TOLD ME TO GET A HYSTERECTOMY AND I DON'T WANT THAT I WAS NOT WARNED IT HAD NICKLE IN IT I'M ALWAYS SICK BEFORE I HAD IT I WAS FINE. I'VE BEEN LIVING LIKE THIS FOR 4 YEARS TRYING TO FIGURE OUT WHAT IS GOING ON WITH MY BODY AND MY INSURANCE DOSE. NOT COVER TO GET IT TAKEN OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033336	BAYER	12/6/2013	12/16/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS IMPLANTED BACK IN 2007. I HAVE BEGUN HAVE MAJOR SYMPTOMS THAT I BELIEVE ARE DIRECTLY CAUSED BY THESE IMPLANTS. I AM SUFFERING FROM EXTREME ABDOMINAL PAIN. AT TIMES, I FEEL AS IF SOMETHING IS TRYING TO STAB THROUGH MY BODY. I SUFFER FROM EXTREME FATIGUE AND NAUSEA THAT LASTS ALL DAY LONG EVERY DAY. I SUFFER FROM HEADACHES AND EXTREMELY PAINFUL BACKACHES. I HAVE PROBLEMS WITH TASTING METAL IN MY MOUTH. I AM CURRENTLY IN THE PROCESS WITH CHECKING WITH MY GYN TO SEE WHAT I NEED TO DO TO HAVE THESE COILS PERMANENTLY REMOVED FROM MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033328	BAYER	12/9/2013	12/16/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT PREGNANT AFTER HAVING ESSURE. ALSO, ONE OF THE TWO COILS ON MY LEFT SIDE BROKE IN HALF AND 1/2 WAS FOUND IN MY COLON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033331		12/9/2013	12/16/2013

Event Information:

Event Date (B3): 12/2/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/2/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY ESSURE IMPLANTED THE END OF 2008. MY FIRST ANXIETY ATTACK WAS LESS THAN A MONTH LATER. I HAVE SUFFERED WITH REGULAR ANXIETY ATTACKS, HEART PALPITATIONS, CHEST PAIN, JOINT AND BODY PAIN. MY STOMACH IS CONSTANTLY BLOATED AND PAINFUL AND MY BACK IS ALWAYS SORE. I NOW GET PAINFUL HEADACHES AND MY HANDS AND FEET ALWAYS FEEL NUMB. I WAS COMPLETELY HEALTHY BEFORE I HAD THE ESSURE. I HAD AN ENDOMETRIOSIS BIOPSY THAT CAME BACK NORMAL. AN ULTRASOUND DID FIND ADENOMYOSIS. I HAVE A HYSTERECTOMY SCHEDULED FOR (B)(6) 2013. I AM (B)(6) YRS OLD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033332	CONCEPTUS INCORPORATED	12/9/2013	12/16/2013

Event Information:

Event Date (B3): 12/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 952104

Single Use:
Implant Date (E6): 8/26/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACE IN (B)(6) 2013 FOUND OUT (B)(6) 2013 WHEN I HAD HSG TEST DONE, I HAD A PERFORATED LEFT FALLOPIAN TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033409	ESSURE	12/11/2013	12/17/2013

Event Information:

Event Date (B3): 2/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/20/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2013, I HAD ESSURE PLACED. DOCTOR HAD A HARD TIME GETTING COIL PLACED IN LEFT TUBE. AFTER AN HOUR OF PAIN, THE PROCEDURE WAS DONE. I WENT IN A WEEK LATER FOR AN XRAY TO MAKE SURE COIL WAS STILL IN PLACE. IN (B)(6), I WENT BACK FOR THE DYE TEST AND EVERYTHING WAS PLUGGED. SINCE NOW GETTING MY PERIOD IN MAY, I HAVE BEGUN TO SUFFER WITH MIGRAINES FROM HELL, LOW BACK PAIN ALMOST LIKE LABOR, BLURRY VISION, NAUSEA, CRAMPING, CLOTTING, NO SEX DRIVE, PAIN DURING SEX, PAIN UP MY BACK NECK PAIN, ODOR AND DISCHARGE, HAIR GROWTH BOILS AND ALWAYS VERY TIRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033410		12/11/2013	12/17/2013

Event Information:

Event Date (B3): 2/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/20/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE DAY ONE I HAVE BEEN IN EXCRUCIATING PAIN, ALL OVER MY BODY, DEPRESSION, ANXIETY, SUICIDAL, MOOD SWINGS, REPEATED URINARY TRACT INFECTIONS, IMMUNE SYSTEM DETERIORATING, DOCTORS CONTINUE TO TELL ME IT IS ALL IN MY HEAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033413	BAYER	12/11/2013	12/17/2013

Event Information:

Event Date (B3): 8/10/2009 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/10/2009
Explant Date (E7): 8/15/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE COILS IMPLANTED AT THE SAME TIME AS THE NOVASURE ABLATION APPROX 4 YEARS AGO TO HELP WITH PAINFUL PERIODS. NOVASURE DONE TO STOP THE PERIODS AND CRAMPING AND ESSURE TO MAKE SURE I DID NOT GET PREGNANT AFTER THE ABLATION. SHORTLY AFTER PROCEDURE, MY MONTHLY PAIN BEGAN INCREASING WORSE THAN BEFORE PROCEDURES. PAIN BECAME INTENSE TO WHERE IT WAS CONSTANT ALL MONTH, RADIATING INTO BACK, BUTTOCKS, AND DOWN LEGS. FELT LIKE I WAS IN FULL BLOWN BACK LABOR CONSTANTLY TO THE POINT WHERE I COULD NOT GET OUT OF BED SOME DAYS, GO TO WORK, OR CARE FOR MY FAMILY. MULTIPLE TESTS DONE AND TRIED OTHER OPTIONS TO HELP WITH PAIN CONTROL SUCH AS LUPRON, DIFFERENT PAIN MEDS, YET NOTHING WORKED. SWITCHED DOCTORS AND FOUND OUT THAT THE SEVERE BACK AND SCIATIC PAIN AND CRAMPING WAS CAUSED FROM MY BODY TRYING TO EXPEL THE COILS. MY DOCTOR SAID IT WAS LIKE I WAS IN CONSTANT LABOR BECAUSE MY BODY WAS TRYING TO EXPEL A FOREIGN BODY AND THEY NEEDED TO COME OUT. NEVER WAS TESTED FOR NICKEL ALLERGIES PRIOR AND DO HAVE REACTIONS TO CHEAP JEWELRY. HAIR THINNED, HAD MULTIPLE HEALTH PROBLEMS AFTER INSERTION THAT I NEVER HAD PRIOR, INCLUDING A FIBROMYALGIA DIAGNOSES TO NAME ONE. HAD TO HAVE A HYSTERECTOMY IN (B)(6) 2013 AND HAVE NOT HAD ANY SYMPTOMS SINCE REMOVAL IN (B)(6). THE WHOLE POINT OF ME HAVING THE ABLATION WITH ESSURE WAS TO AVOID HYSTERECTOMY AND HELP PAIN, CAUSED ME HORRIFIC PAIN FOR 4 YEARS AND A HYSTERECTOMY IN THE END. HAD TO DEAL WITH CHRONIC PAIN DAILY WHILE I HAVE A HUSBAND WITH STAGE 4 COLON CANCER TO ALSO CARE FOR WAS NEARLY IMPOSSIBLE AND CAUSED MORE STRESS ON OUR FAMILY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033414	BAYER	12/11/2013	12/17/2013

Event Information:

Event Date (B3): 3/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/20/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD MY ESSURE PROCEDURE DONE IN (B)(6) 2013 AND HSG TEST IN (B)(6) 2013. ALL WENT WELL AND 100 PERCENT BLOCKED. MY CYCLES NOW COME ONCE A MONTH BUT VARY FROM 30 TO 42 DAYS. BEFORE ESSURE, CYCLES WERE NORMAL, 28 TO 32 DAYS. MILD CRAMPING IS NOW AN EVERYDAY OCCURRENCES BUT I EXPERIENCE MODERATE TO SEVERE PAIN DURING OVULATION. ALSO DURING OVULATION, I EXPERIENCE A SOMEWHAT HEAVY DISCHARGE. I CAN NOW ADD MIGRAINES (DIAGNOSED (B)(6) 2013) TO MY LIST OF PROBLEMS AFTER THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033415	CONCEPTUS	12/11/2013	12/17/2013

Event Information:

Event Date (B3): 7/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/11/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DUE TO SIDE EFFECTS OF ESSURE STERILIZATION PROCEDURE, INCLUDING SEVERE PELVIC AND BACK PAIN, LEG PAIN AND WEAKNESS, HEADACHES THAT RESULTED IN A TRIP TO THE EMERGENCY, ADRENAL AND THYROID DYSFUNCTION, METALLIC TASTE IN MY MOUTH, BURNING AND ITCHING OF MY SKIN, AND PANIC ATTACKS, I'M HAVING SURGERY TO HAVE BOTH COILS AND TUBES REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033416	BAYER/CONCEPTUS	12/11/2013	12/17/2013

Event Information:

Event Date (B3): 9/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/20/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN 2011. I HAVE HAD PROBLEMS EVER SINCE THE FIRST DAY AND THEY CONTINUE TO WORSEN EVERY DAY. I HAVE SEVERE PAIN EVERY DAY, FEELS LIKE I'M BEING STABBED WITH A KNIFE OR SOMETIMES LIKE THERE'S A MILLION NEEDLES POKING ME FROM THE INSIDE. MY HAIR STARTED FALLING OUT 1 WEEK AFTER THE PROCEDURE. I HAVE NAUSEA AND SEVERE HEADACHES ALMOST EVERY DAY. MY ABDOMEN IN BLOATED AND SORE, I LOOK LIKE I'M ABOUT 6 MONTHS PREGNANT. THE ESSURE IS CAUSING SEVERE TIREDNESS AND WEAKNESS. INTERCOURSE IS VERY PAINFUL. I AM A MOTHER OF 5 CHILDREN, I DO NOT WANT ANY MORE. I JUST WANT THESE COILS OUT OF MY BODY SO I CAN LIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033417		12/11/2013	12/17/2013

Event Information:

Event Date (B3): 12/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/7/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXPERIENCED VARIOUS SIDE EFFECTS UPON THE IMPLANTATION OF ESSURE INCLUDING: TENDER BELLY/PAIN IN ABDOMEN. BLOATING AND UNEXPLAINED WEIGHT IN BELLY/STOMACH AREA. LOWER BACK PAINS/SPASMS. CONSISTENT HEADACHES AND MIGRAINE ALMOST ON A DAILY BASIS. IRRITABILITY, MOOD SWINGS, CHILLS/SWEATS AND INSOMNIA. VERY HEAVY BLEEDING, SOMETIMES TWICE A MONTH WITH CLOTTING. PAIN DURING SEX AND URINATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033418	BAYER	12/11/2013	12/17/2013

Event Information:

Event Date (B3): 12/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PROCEDURE
Device Type (E2): ESSURE PROCEDURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/22/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE PROCEDURE DONE IN (B)(6) 2013. I HAVE BEEN IN PAIN IN MY LOWER STOMACH, LEFT HIP, MY BACK HAS BEEN IN SEVERE PAIN, BLOATING AND I GET CONSTANT HEADACHES. I TOLD MY GYNO ABOUT IT SHE SAID THERE IS SOMETHING ELSE WRONG WITH ME AND NOT MY ESSURE. REFUSED TO GIVE ME ANY REAL ANSWERS OR HELP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033419		12/11/2013	12/17/2013

Event Information:

Event Date (B3): 12/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/15/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2010, AFTER GETTING THE ESSURE DONE I BEGAN TO EXPERIENCE EXTREME PAIN IN THE LOWER ABDOMEN, HEAVY PERIODS AND SOMETIME MISSING PERIODS. WHEN I HAVE PAIN, I USUALLY HAVE TO GO INTO THE EMERGENCY ROOM BECAUSE IT BECOMES UNBEARABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033420	CONCEPTUS/BAYER	12/11/2013	12/17/2013

Event Information:

Event Date (B3): 8/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/27/2012
Explant Date (E7): 10/31/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6) 2012 AND AT FIRST I THOUGHT I HAD PROBLEMS DUE TO MY BODY CHANGING AFTER PREGNANCY, HOWEVER AS THE SYMPTOMS LASTED THAT WAS NOT THE CASE. I HAD ESSURE IMPLANTED 6 WEEKS AFTER GIVING BIRTH. I HAD SYMPTOMS WHICH INCLUDED EYE TWITCHES, MIND FOG, HEAVY CRAMPING, HEAVY BLEEDING ASSOCIATED WITH MENSTRUAL CYCLE, LONGER MENSTRUAL CYCLE, PAINFUL SEX, LONG TERM CRAMPING, BODY ACHES THROUGHOUT THE DAY AND FATIGUE. I ALSO WAS UNABLE TO WEAR MANY OF MY JEWELRY PIECES DUE TO A DEVELOPED ALLERGY. LOW AND BEHOLD THAT'S NOT EVEN THE END. I FOUND OUT I WAS PREGNANT IN (B)(6), I HAD A ROLLER COASTER PREGNANCY, WITH MANY INFECTIONS, PRETERM LABOR. (B)(6) ARRIVED ON (B)(6) 2013 WEIGHING IN AT (B)(6). I HAD TO MAKE NUMEROUS TRIPS TO DIFFERENT HOSPITALS TO HAVE ULTRASOUNDS THROUGHOUT MY PREGNANCY. (B)(6) HAD AN ECHOGENIC BOWEL WHICH WAS OF SOME CONCERN TO THE DOCTORS. I HAVE SINCE HAD SURGERY TO REMOVE THE COILS AND THE FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033452	BAYER	12/12/2013	12/18/2013

Event Information:

Event Date (B3): 10/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/2/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE IMPLANTED (B)(6) 2013, SINCE THE PROCEDURE, I HAVE HAD CONSTANT PELVIC PAIN, EXTREME JOINT, KNEE, AND BACK PAIN, A CONSTANT METALLIC TASTE IN MY MOUTH, HEADACHES, CONSTANT DIZZINESS AND AFTER BEING ABLE TO WALK/JOG 6 MILES A DAY, I CAN BARELY WALK ONE MILE. I HAVE EXCESSIVE WEIGHT GAIN AND EXTREME FATIGUE AS WELL AS UNEXPLAINED RASHES. MY BODY IS TRYING TO REJECT A DEVICE THAT MOST DOCTORS WANT TO REMOVE. I NOW AM LEFT WITH SAVING FOR A PROCEDURE THAT IS MORE THAN (B)(6). AT THE RATE I AM SAVING, I WILL HAVE TO DEAL WITH THESE HORRIBLE SIDE EFFECTS FOR YEARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033453	BAYER	12/12/2013	12/18/2013

Event Information:

Event Date (B3): 12/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/3/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIRTY SIX MONTHS AGO I HAD THE BAYER ESSURE BIRTH CONTROL COILS IMPLANTED. (I HAD A THIRD-PARTY EXAMINATION THAT SHOWED THAT THEY WERE IMPLANTED CORRECTLY.) SINCE THE WEEK THEY WERE IMPLANTED I HAVE HAD SO MANY ISSUES THAT I NEVER EXPERIENCED BEFORE, INCLUDING STABBING PAIN IN MY HIPS AND PELVIC AREAS, CRAMPS, HIGHLY IRREGULAR PERIODS, DIZZINESS, REALLY PAINFUL HEADACHES. I AM (B)(6), A NON-SMOKER, A NON-DRINKER, I EXERCISE WHEN I CAN, AND DOCTORS SAY I HAVE NO OTHER HEALTH ISSUES. BUT SINCE THE ESSURE, MY BODY IS FULL OF PAIN AND I AM VERY DISAPPOINTED THAT I WAS NOT WARNED OF THESE COMPLICATIONS BEFOREHAND!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033454	BAYER	12/12/2013	12/18/2013

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ES305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/21/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED (B)(6) 2007 WITH ESSURE COILS. I HAVE HAD MANY HEALTH PROBLEMS SINCE THEN WHICH I BELIEVE ARE RELATED TO ESSURE. APPENDIX REMOVAL, GALLBLADDER REMOVAL, VITAMIN DEFICIENCIES, BACK AND NECK PAIN ALL THE TIME, BLURRING OF VISION AND FLOATERS, BODY HURTS, STIFFENS AND ACHES, BOWEL ISSUES AND EXCESSIVE AMOUNTS, BURNING IN THIGHS, BRUISE EASILY, BREAST PAINS, CHEST PAINS, HEARTBURN, SWEATING ALL THE TIME, PELVIC PAIN ALL THE TIME WORSE DURING PERIODS, BLEED AFTER SEX (MILD), BLOOD IN URINE FOR NO REASON, SPINE PAIN, BOILS, ANXIETY/PANIC ATTACKS, CYSTS ON OVARIES, TEETH ISSUE, FEELING DEHYDRATED ALL THE TIME, URGENCY TO URINATE, DISCHARGE WITH NO ODOR, DIZZINESS, DRY EYES , HAIR AND SKIN, PAINFUL OVULATION, EARS FEEL INFECTED ALL THE TIME, PAINFUL PERIODS, VERY BAD CRAMPING, LOSS OF ENERGY, NIGHT SWEATS , HOT FLASHES DAY AND NIGHT, SEVERE BLOATING, HAIR LOSS AND HAIR UNDERGROWTH, WEIGHT GAIN, DIAGNOSED WITH FIBROMYALGIA, FAST TRACT DIGESTIVE SYSTEM, LOW SEX DRIVE, SHARP STABBING PAIN IN STOMACH AREA, PAIN ALL OVER MAY BODY, HEAD ACHES, BRAIN FOG, IBS, HEAVY PERIODS WITH CLOTS, FATIGUE, HIP PAIN IS OUTRAGEOUS, JOINT PAIN, SWELLING HANDS AND FEET WHICH HURT BAD AND ARE ALWAYS COLD, NICKEL TASTE, NAUSEA, HIVES FROM EXPOSURE TO NICKEL AND PAIN IS SO BAD HAVE HAD TO GO TO ER. I HAD 5 CHILDREN AND WAS COMPLETELY HEALTHY. I HAD TWINS IN 2004 FULL TERM BECAUSE I WAS SO HEALTHY. THEN 2007, HEALTH WENT DOWNHILL. I WAS NOT WARNED OF ANY OF THESE SIDE EFFECTS FROM ESSURE AND THROUGH ALL THESE ILLNESSES HAVE NEVER BEEN TOLD IT WAS BECAUSE OF ESSURE. I AM SURE THAT WHEN THE COILS DISAPPEAR, SO WILL THE SIDE EFFECTS. SCHEDULED TO HAVE HYSTERECTOMY TO REMOVE COILS.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033433	BAYER	12/12/2013	12/19/2013

Event Information:

Event Date (B3): 8/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/11/2011
Explant Date (E7): 8/16/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACES, LESS THAN 24 HOURS LATER WAS VERY SICK, ABDOMINAL PAIN, VOMITING, COULD NOT EAT OR SLEEP AND HAD A NEW BORN BABY TO CARE FOR. HAD THE SHAKES AND RASH, HIGH BLOOD PRESSURE. WENT TO THE ER THEN THE ORIGINAL ON DR WHO PLACED THEM SAID HE WOULD REMOVE THEM BUT I HAD TO ENDURE HAVING THEM IN AN ENTIRE WEEKEND PLUS ONE MORE NIGHT, SO HE COULD OPEN HIS SCHEDULE TO DO THE SURGERY ON A TUESDAY, AND DO A REGULAR TUBAL LIGATION. HIS PATHOLOGY REPORT WAS WRONG HE SAID HE TOOK 2 CM OF TUBE AND REMOVED A TANGLED ESSURE DEVICE. I LATER WENT FOR A TUBAL REVERSAL TO FIND I WAS MISSING 6 CM OF TUBE ON EACH SIDE. VARICOSE VEINS AROUND ORIGINAL FALLOPIAN TUBE HOLES. WHICH WERE RICH IN BLOOD AND COMPLETELY SCARED SHUT WITH FLAPS OF FALLOPIAN TUBES HANGING. THE DR WHO ORIGINALLY PLACED THE ESSURE DID NOT TEST ME FOR A NICKEL ALLERGY WHICH I BELIEVE IS WHY I BECAME SO SICK. HE TOOK MY HEALTH AND FERTILITY COMPLETELY FROM ME. "HE HAS HORRIBLE MENSTRUAL CYCLES AFTER HE REMOVED THE ESSURE AND DID A PARKLAND TUBAL LIGATION." THIS WHOLE PROCESS HAS RUINED MY LIFE AND MY HEALTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033309	BAYER	12/12/2013	1/13/2014

Event Information:

Event Date (B3): 9/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5033309 (B)(4). I HAVE BEEN UNABLE TO WORK SINCE 2 MONTHS AFTER ESSURE IMPLANT PROCEDURE DUE TO EXTREME PAIN, BLEEDING, WEAKNESS, EXHAUSTION, HEADACHES. I NOW HAVE A NICKEL ALLERGY THAT I DID NOT PREVIOUSLY HAVE. ONE COIL IN UTERUS, ONE PERFORATED FALLOPIAN TUBE. COMPLETE ABDOMINAL HYSTERECTOMY REQUIRED SND WILL BE DONE NEXT MONTH
LOT #789028.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033310	CONCEPTUS	12/12/2013	1/13/2014

Event Information:

Event Date (B3): 12/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVEN'T HAD MY MENSTRUAL CYCLE IN OVER TWO MONTHS BUT I AM DEFINITELY NOT PREGNANT. I CAN FEEL WHERE THE COILS ARE. I HAVE SHARP PAINS IN MY ABDOMEN AREA, AS WELL AS SHARP PAINS SHOOTING THROUGH MY HIP. BEFORE THE ESSURE, I HAD A NORMAL MENSTRUAL CYCLE, GOING 30 DAYS BETWEEN CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033313	CONCEPTUS	12/12/2013	1/13/2014

Event Information:

Event Date (B3): 12/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE ON (B)(6) 2008. I'M AN ATHLETE AND KNOW MY BODY VERY WELL WHEN I FIRST NOTICED THE FATIGUE SETTING IN THEN THE BODY ACHES. THEN THE JOINT PAIN STARTED, THE LOWER BACK PAINS AND PAIN IN HIPS AND AFFECTING MY SCIATIC NERVE TO MY RIGHT LEG. I WAS KICK BOXING AND HAD TO QUIT DUE TO NOT HAVING THE STAMINA TO TRAIN AND THE JOINT PAIN AND SEVERE MUSCLE FATIGUE I WAS EXPERIENCING. DURING THIS WHOLE TIME, I WAS GETTING SEVERE UI INFECTIONS THAT HAS LEAD TO SOME INCONTINENCE ISSUES. TODAY ON A DAILY BASIS, I EXPERIENCE ALL THIS PLUS THESE OTHER AILMENTS: CHRONIC FATIGUE, BODY ACHES, ACHY JOINTS, IRREGULAR CYCLES, ABDOMINAL BLOATING, ABDOMINAL PAINS, KIDNEY PAIN, BLADDER INFECTIONS, HEART FLUTTERS, LOWER BACK PAINS, HEADACHES DAILY SOMETIMES MIGRAINES, NECK PAIN, SPINAL PAIN, SCIATIC NERVE IN LEGS PAIN, JAW AND TEETH PAIN, THYROID ISSUES, HEAVY BLEEDING SOMETIMES GUSHING, BLOOD CLOTS DURING CYCLE, SEVERE JOINT PAIN AND MUSCLE FATIGUE, METAL TASTE IN MOUTH AND BLOOD, EAR ACHES W/NO INFECTION WHEN HAVING JAW PAIN, DISCHARGE AND ODOR, INCONTINENCE ISSUES, TINGLING IN LEFT HAND WITH CRAMPING OF FINGERS. LIGHT HEADED, BRAIN FOG, ASTHMA ATTACKS, CRAWLING SKIN, NIGHT SWEATS, BLEEDING AFTER SEX, SPOTTING IN BETWEEN HEAVY FLOWS, HIP PAIN, NAUSEA. IT IS ALMOST IMPOSSIBLE TO BE PHYSICAL DUE TO FATIGUE AND LOSS OF MUSCLE STRENGTH. I USED TO BE A SKI RACER AND NOW I AM LUCKY IF I CAN GO 100 YARDS WITHOUT MY LEG MUSCLES SCREAMING IN SEVER PAIN!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033308	CONCEPTUS	12/12/2013	1/14/2014

Event Information:

Event Date (B3): 11/15/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING PELVIC PAIN ESPECIALLY ON MY RIGHT SIDE. I THOUGHT IT WAS MY APPENDIX. I GOT IT ALL CHECKED OUT IN THE ER WITH CT SCAN AND IT TURNED OUT OK. THEY TOLD ME TO FOLLOW UP WITH MY GYNECOLOGIST. I MADE AN APPOINTMENT THE NEXT WEEK AND HAD A PELVIC ULTRASOUND DONE ON NOVEMBER 22, 2013. THEY FOUND CYSTS AND FLUID IN MY FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033311	CONCEPTUS	12/12/2013	1/14/2014

Event Information:

Event Date (B3): 11/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PELVIC PAIN, SEPSIS, HAIR LOSS, WEIGHT GAIN, INSOMNIA, BRITTLE TEETH, RASH/HIVES, DEBILITATING CRAMPS, HEAVY BLEEDING, EXCRUCIATING MIGRAINES, ANXIETY, DEPRESSION, FATIGUE, BLOATING, PREGNANCY, HEAVY METAL POISONING (NICKEL), HEART PALPITATIONS, FAINTING SPELLS, NUMBNESS/TINGLING IN ARMS HAND AND LEGS, BACKACHES, RESPIRATORY ISSUES, IMMUNE DEFICIENCIES, CHRONIC ILLNESSES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033312	CONCEPTUS	12/12/2013	1/14/2014

Event Information:

Event Date (B3): 7/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT MY ESSURE PROCEDURE DONE THAT DAY WAS TOLD ONLY SIDE EFFECTS REPORTED WERE MILD CRAMPING.BUT AFTER THE DEPO SHOT WORE OFF I STARTED TO GET MILD TO SEVERE CRAMPING.THEN WHEN I GOT MY PERIOD WHICH NEVER HAPPENED BEFORE I HAD ESSURE I NOW GET SEVERE CRAMPING A WEEK OR 2 BEFORE MY ACTUAL PERIOD.THE PAST FEW MONTH I HAVE NOT REALLY BEEN BLEEDING IT HAS JUST BEEN BLOOD CLOTS. I HAVE BREAST PAIN,BURNING AND ITCHING. I HAD A RASH FOR 3 DAYS I COULDNT EXPLAIN WITH SEVERE ITCHING. MY HAIR FALLS OUT IN CLUMPS THANK GOD I HAVE THICK HAIR. MY TEETH FEEL LIKE THEY ARE FALLING APART. I FEEL LIKE I AM GONNA THROW UP OFTEN. I HAVE HEADACHES WHICH I NEVER HAD VERY OFTEN NOW THEY ARE LIKE ALMOST EVERYDAY. I HAVE LOWER BACK PAIN, HIP PAIN, KNEE PAIN. I CANT SLEEP BECAUSE I WAKE UP WITH PAIN IN MY LOWER ABDOMEN AND HAVE TO SWITCH SIDES .I GET DIZZY SPELLS, DEPRESSION. SOME DAYS I CANT FUNCTION BECAUSE I AM IN SO MUCH PAIN OR DEPRESSED FOR WHATEVER REASON AND CAN'T FUNCTION. I AM MEAN AND LASH OUT TO THE ONES I LOVE. I JUST HAVE SO MANY MORE THINGS TO MENTION THAT ESSURE HAS RUINED MY LIFE. HOPING MY NEW OBGYN I GO TO FRIDAY CAN OFFER ME SOME RELIEF.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033467	ESSURE	12/13/2013	12/19/2013

Event Information:

Event Date (B3): 12/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B66015

Single Use:
Implant Date (E6): 12/6/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FOLLOWING PLACEMENT OF BILATERAL ESSURE IMPLANTS, A SMALL FIBROID WAS EXCISED FROM THE UTERINE CAVITY. AFTER EXCISION OF FIBROID, A PORTION OF THE DISTAL END OF THE METAL ESSURE IMPLANT WAS FOUND FLOATING IN THE UTERINE CAVITY. REASON FOR USE: UNDESIRED FERTILITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033482	BAYER	12/13/2013	12/19/2013

Event Information:

Event Date (B3): 12/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/9/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE ON (B)(6) 2013. ON (B)(6) 2013, I HAD MY F/U HSG TO SEE IF THE TUBES WERE BLOCKED. THIS REVEALED THAT ONE COIL HAS NOT FOLLOWED THE PATH OF A SEEMINGLY NORMAL FALLOPIAN TUBE; THE COIL APPEARS TO HAVE PERFORATED THE FALLOPIAN TUBE. MORE CONSULTATION/TESTING IS TO COME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033490	BAYER	12/16/2013	12/20/2013

Event Information:

Event Date (B3): 12/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/8/2013
Explant Date (E7): 12/9/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED (B)(6) 2013. ALMOST IMMEDIATELY I BEGAN HAVING MIGRAINES DAILY, FATIGUE, FORGETFULNESS, BLOATING, SPOTTING FOR 2 WEEKS AFTER MY PERIOD, ACNE, NEUTROPENIA, BRUISING, ALTERED TASTE AND SMELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033500	CONCEPTIS INC	12/16/2013	12/20/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN 2006. I HAVE HAD NOTHING BUT MEDICAL PROBLEMS EVER SINCE. THE LAST 2 YEARS IT'S JUST GOTTEN WORSE AND WORSE. I HAVE HEADACHES CONSTANTLY. ANXIETY, DEPRESSION, HIGH BLOOD PRESSURE, PAINS IN MY HIPS ANKLES FEET LEGS AND ARMS. I CAN'T WALK OR STAND FOR LONG. I CAN'T GO TO THE STORE BY MYSELF ANYMORE BECAUSE OF THE ANXIETY AND BECAUSE I GET DIZZY SO MUCH LIKE I'M GOING TO BLACK OUT. I HAVE PROBLEMS WITH MY VISION NOW. I AM IN CONSTANT PAIN SOMEWHERE IN MY BODY AT ALL TIMES. MOSTLY MY STOMACH AND ABDOMINAL AREA. WHEN I HAVE MY PERIOD, IT'S VERY HEAVY AND I HURT SO BAD I CAN'T EVEN GET OFF THE COUCH. MY KIDS DESERVE THEIR MOM BACK. MY HUSBAND DESERVES HIS WIFE. I CAN'T CLEAN HOUSE OR COOK OR ANYTHING. I JUST HURT TOO BAD. I WAS NOT GIVEN A CHOICE ON GETTING THIS DEVICE. I DIDN'T GET THE ESSURE CARD THAT I JUST FOUND OUT I WAS SUPPOSE TO GET. I DIDN'T EVEN KNOW THE NAME OF THE PRODUCT UNTIL RECENTLY. MY DOCTOR SAID NOTHING ABOUT COMING BACK TO HAVE IT CHECKED AFTER INSERTION, WHICH WAS NOT DONE IN THE DOCTORS OFFICE. IT WAS DONE IN THE HOSPITAL, IN AN OPERATING ROOM WHILE I WAS PUT TO SLEEP. ESSURE REPORTS SHOW THAT IT'S DONE WITH "GENERAL" ANESTHESIA AND INSIDE YOUR DOCTORS OFFICE. I WAS ABLE TO FIND A SIDE EFFECTS LIST AND I HAVE 76 OF THE SIDE EFFECTS THAT I KNOW OF. NOT COUNTING THE ONES THAT I DON'T HAVE THE MONEY TO GO TO THE DOCTOR AND HAVE CHECKED OUT. PLEASE TAKE THESE THINGS OFF THE MARKET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033502		12/16/2013	12/20/2013

Event Information:

Event Date (B3): 6/24/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/16/2013
Explant Date (E7): 6/24/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS INSERTED. UPON INSERTION ONE OF THE COILS PUNCTURED MY FALLOPIAN TUBE. I HAD TO HAVE SURGERY TO CLOSE TJ TUBE UP, BUT IT ENDED HAVING TO BE CAUTERIZED DUE TO THE DAMGE TO THE TUBE. I STILL HAVE ONE TUBE INSERTED. SINCE HAVING THE PROCEDURE I HAVE A HORRIBLE PERIOD EVERY 2 WEEKS FOR APPROX 6-7 DAYS. I LOST TREMENDOUS "OUBYS" OF BLOOD. I AM GOING TO HAVE TO HAVE ANOTHER SURGERY (ENDOMETRIAL ABLATION) DONE IN APPROX A WEEK TO HELP WITH ALL THE BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033503	CONCEPTUS, INC.	12/16/2013	12/20/2013

Event Information:

Event Date (B3): 1/6/2003 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/6/2003
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE BEEN IMPLANTED WITH ESSURE SINCE 2003. I'VE BEEN SUFFERING FROM ALL KINDS OF SIDE EFFECTS, AND PROBLEMS EVER SINCE. I AM IN CONSTANT PAIN, I SUFFER FROM CYSTS, SKIN IRRITATIONS, BLEEDING, AND STRONG ODORS. I BELIEVE I'M ALLERGIC TO THE NICKEL THAT THEY ARE MADE OF. IT'S HARD TO GET A REAL DIAGNOSIS, SINCE WHERE I LIVE NOW STILL REALLY HAVEN'T EVEN HEARD OF THIS PRODUCT. I HAVE PAIN AND BLEEDING DURING SEX. I'VE HAD MY VITAMIN K BECOME SO LOW THAT I'VE ALMOST DIED. I HAVE SEVER HEADACHES WHICH RUN FROM THE BASE OF MY NECK ON MY RIGHT SIDE. EVERYTIME I SAY COULD THIS PRODUCT BE DOING THIS TO ME, THEY SAY NO, YET THEY DON'T EVEN KNOW WHAT IT IS. IT HAS AFFECTED ME PHYSICALLY, MENTALLY, AND SOCIALLY. I HAVE PAIN IN MY LOWER BACK AND ABDOMEN. I HAVE PERMANENT SCARS FROM RASHES THAT I HAVE SUSTAINED FROM THIS PRODUCT. I CAN'T AFFORD HEALTHCARE TO GET THEM REMOVED, NOT THAT ANYONE IN THE AREA WHERE I LIVE WOULD KNOW HOW. WHEN I WAS APPROACHED WITH THE OPTION OF GETTING THIS PROCEDURE, I WANTED TO GET MY TUBES TIED, BUT THE DOCTOR TOLD ME THAT SINCE I ALMOST DIED WITH THE LAST CHILD THAT ESSURE WOULD BE A BETTER CHOICE. I BEG THE DIFFER. I HAVEN'T BEEN THE SAME IN TEN YEARS AND IT SEEMS TO GET WORSE AS THE YEARS GO BY. I BELIEVE THAT THEY HAVE MOVED INSIDE ME BECAUSE MY MATE SOMETIMES FEEL THAT SOMETHING IS THERE DURING INTERCOURSE. I REALLY REGRET GETTING THIS DONE TO ME, BUT WHAT REALLY HURTS IS HOW THE PEOPLE THAT PUT IT OUT THERE ACT LIKE IT'S NOT HAPPENING TO US.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033504	CONCEPTUS, INC	12/16/2013	12/20/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/18/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2013. I WAS ADMITTED INTO (B)(6) HOSPITAL DUE TO ANIMA. MY BLOOD WAS VERY LOW AND WAS ADMITTED BECAUSE I NEED A BLOOD TRANSFUSION. WHEN I WAS DISCHARGED FORM THE HOSPITAL I WAS TOLD TO FOLLOW UP WITH MY DOCTOR. I WENT TO BY GYN DOCTOR. DUE TO MY HEAVY BLEEDING DURING MY PERIOD EACH MONTH. HE SENT ME FOR A SONO AND I WAS TOLD THAT I HAVE AN ENLARGE UTERUS AND ADENOMYOSIS. I NEVER IN MY LIFE HAD THIS ISSUES. I FEEL ITS THE ESSURE DEVICE. I'M BLOATED AND IN PAIN. ON (B)(6) 2013, I HAD A BOWEL MOVEMENT WHICH HAD SMALL GRAYISH SILVERISH FRAGMENTS IN THE TOILETS WATER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033521	BAYER	12/17/2013	12/23/2013

Event Information:

Event Date (B3): 10/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893029

Single Use:
Implant Date (E6): 10/25/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2012, I HAD THE ESSURE PROCEDURE DONE AND IMMEDIATELY AFTER I STARTED BLEEDING AND HAVING MAJOR CRAMPS THAT RADIATED TO MY LOWER BACK. AS TIME WENT ON, I ALSO HAD NIGHT SWEATS, SEVERE HEADACHES, LIGHT HEADEDNESS. I BLED FOR 4 MONTHS UNTIL MY DOCTOR PUT ME ON BIRTH CONTROL TO STOP THE BLEEDING. I HAVE CONSTANT FEELING OF MENSTRUAL CRAMPS ALL MONTH LONG. MAJOR HEADACHES. SHARP PAINS THAT START FROM IMPLANT AREA AND SHOOT DOWN MY THIGHS TO MY KNEES AND ALSO WRAP AROUND TO MY LOWER BACK. MY PERIODS ARE VERY HEAVY AND I PASS CLOTS OF BLOOD THAT ARE AS BIG AS A SILVER DOLLAR. I ALSO HAVE HAD A BREAKOUT TO NICKEL AND AM PENDING TESTS FROM AN ALLERGIST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033524		12/17/2013	12/23/2013

Event Information:

Event Date (B3): 3/7/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE DONE IN (B)(6) 2012, EVER SINCE THEN I HAVE HAD SEVERE PELVIC PAIN ON THE LEFT SIDE. I DIDN'T GET MY PERIOD FOR THE FIRST 2 MONTHS AFTER THE PROCEDURE THEN I STARTED TO BLEED VERY HEAVY FOR A WEEK OF EACH MONTH. TO THIS DAY, I HAVE THE PELVIC PAIN AND THE HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033525	ESSURE	12/17/2013	12/23/2013

Event Information:

Event Date (B3): 7/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/29/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN THE ESSURE COIL WAS IMPLANTED, THERE WAS A MISFIRE AND A SIMPLE OFFICE PROCEDURE TURNED INTO A 3 HOUR PROCESS AS THE DOCTOR, THOUGH SHE HAD REMOVED THE COIL THAT MISFIRED. NOW MONTHS LATER, I HAVE BEEN HAVING PELVIC PAIN. CT SCAN SHOWED THE ESSURE THAT MISFIRED IS SOMEWHERE IN MY PELVIC CAVITY AND I AM SCHEDULED FOR EXPLORATORY LAPAROSCOPIC SURGERY TO FIND AND REMOVE IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033583	BAYER	12/18/2013	12/26/2013

Event Information:

Event Date (B3): 6/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 6/28/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I CHOSE TO GET THE ESSURE AS MY BIRTH CONTROL OF (B)(6) 2010, I'VE BEEN HAVING PROBLEMS FOR THE LAST 2 YEARS CONSISTING WITH PAIN ON MY RIGHT PELVIC AREA, CYST ON MY RIGHT OVARY THAT I HAD TO DO OUT-PATIENT SURGERY IN 2012. ABNORMAL PERIOD, HEAVY BLOOD CLOTS, I WAS TOLD I WOULD NOT HAVE ANY SIDE EFFECTS WHEN I GOT THIS PERMANENT FOR AS MY BIRTH CONTROL, BUT AM ALWAYS IN PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033584	CONCEPTUS, INC.	12/18/2013	12/26/2013

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2013
Explant Date (E7): 5/1/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL IMPLANTS. I HAD SEVERE PAIN ON THE FLOOR DOUBLED OVER CRYING. MY DOCTOR TRIED A FEW FIXES HE HAD HOPED WOULD WORK BUT IN THE END MY TUBES HAD TO BE REMOVED. I WAS LIKE MYSELF AGAIN NO MORE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033586	BAYER	12/18/2013	12/26/2013

Event Information:

Event Date (B3): 3/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/27/2013
Explant Date (E7): 12/16/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED ON (B)(6) 2013. I STARTED HAVING SYMPTOMS WITHIN A WEEK OF IMPLANTATION. SINCE MY PROCEDURE, I HAVE HAD CONSTANT CRAMPING IN MY LOWER ABDOMEN. PAINFUL SHARP STABBING PAINS TO MY RIGHT SIDE AND THEN THEY STOPPED (THAT DEVICE HAD MIGRATED INTO MY UTERUS). I HAVE HAD VERY PAINFUL SEX WHERE MY UTERUS HAS PAINFULLY CONTRACTED FOR AT LEAST 30 MINUTES AFTER INTERCOURSE. I HAVE EXPERIENCED MASSIVE HAIR LOSS, CONSTANT TASTE OF METAL IN MY MOUTH AND A LOT OF PAIN IN MY TEETH. I HAVE ALSO HAD WEIGHT GAIN THAT DAILY HIGH INTENSITY EXERCISE AND PROPER NUTRITION HAVE NOT AFFECTED. I NOW SUFFER FROM DEPRESSION WHEN I NEVER DID. I SUFFER FROM FATIGUE, BRAIN FOG, SHORT TERM MEMORY LOSS, BLURRED VISION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033588	BAYER	12/18/2013	12/26/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD ESSURE SINCE 2008. SINCE THEN I HAVE A LOT OF LOWER STOMACH PAIN, HEADACHES, HEAVIER PERIODS, BLEEDING AFTER SEX, WEIGHT GAIN AND DIZZINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033589	BAYER	12/18/2013	12/26/2013

Event Information:

Event Date (B3): 11/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PAIN IN LOWER RIGHT PELVIC AREA, HEADACHES, SWELLING IN FEET AND LEGS, BLOATING, FEELING AS THOUGH INSIDES ARE GOING TO DROP OUT, BLEEDING, PRESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033591		12/18/2013	12/26/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2011, I CHOSE ESSURE BECAUSE I DIDN'T WANT TO BE TAKING BIRTH CONTROL ANYMORE AND I DIDN'T WANT TO HAVE SURGERY TO TIE MY TUBES. NOW I HAVE TO TAKE BIRTH CONTROL PILLS BECAUSE MY PERIODS ARE EXTREMELY PAINFUL AND HEAVY. I CHANGE MY TAMPONS AND PADS EVERY HOUR OR TWO. THIS MONTH, (B)(6) 2013, I STARTED MY PERIOD ON (B)(6) THEN AGAIN (B)(6). I HAD A SONOGRAM AND MY DOCTOR TOLD ME I HAVE POLYPS INSIDE MY UTERUS WHICH WEREN'T THERE BEFORE MY ESSURE. IN (B)(6), I WILL HAVE SURGERY TO REMOVE THE POLYPS. IF THIS DOESN'T HELP THEN I WILL HAVE TO HAVE A HYSTERECTOMY. I HAVE HEADACHES ALL THE TIME. BACK AND ABDOMINAL PAIN. NAUSEA ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00058	BAYER HEALTHCARE LLC	12/18/2013	12/31/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2013
Explant Date (E7): 10/9/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED, A CONFIRMATION TEST SHOWING HER TUBES WERE NOT BLOCKED AND THE INSERTS RUPTURED HER FALLOPIAN TUBES. SHE HAD SURGERY TO HAVE THE DEVICES AND HER FALLOPIAN TUBES REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00059	BAYER HEALTHCARE LLC	12/18/2013	12/31/2013

Event Information:

Event Date (B3): 1/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 5/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ENSURE INSERTED. IN 2007, THE CONSUMER HAD EXCESSIVE BLEEDING CONSTANTLY SINCE INSERTION AND PELVIC PAIN. IN 2010, SHE HAD CONTINUOUS PELVIC PAIN, BACK PAIN, AND BLEEDING. SHE STATED THAT SHE COULD FEEL THE COILS GETTING HOTTER AND MOVING. IN (B)(6) 2010, SHE HAD A MICRODISCECTOMY AT L4, L5, AND S1. SHE WAS TOLD THAT METAL COILS RELEASED TOXINS AND CAUSED DAMAGED TO DISC. SHE RECEIVED STEROIDS AND A LOT OF ANTIBIOTICS. HER BLEEDING, PELVIC AND ABDOMINAL PAINS WERE CONSTANT. IN (B)(6) 2012, EVERY TIME SHE STOOD UP, SHE HAD BLEEDING AND PASSED OUT. SHE ALSO LOST A TOTAL OF 5 BACK MOLARS. SHE WAS SEEN BY A RHEUMATOLOGIST AND WAS TOLD SHE HAD ALL THE SYMPTOMS OF AUTOIMMUNE DISEASES. SHE WAS WEAK, COULD NOT EAT AND ALSO EXPERIENCED RASH ON HER FACE. SHE WAS ANEMIC AND HER HEMOGLOBIN WAS 5-7. SHE HAD B12 DEFICIENCY ANEMIA AND TOOK SHOTS FOR IT. IN (B)(6) 2013, SHE HAD A ABDOMINAL HYSTERECTOMY DUE TO EXCESSIVE BLEEDING AND NEEDED 2 UNITS OF BLOOD.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 16-SEP-2015 FROM CONSUMER (ONLINE POSTING): CONSUMER PROVIDED A COLLECTION OF PICTURES SHOWING SOME EVENTS SHE EXPERIENCED, INCLUDING A PICTURE OF HER FEET DURING ESSURE AND AFTER ITS REMOVAL (NO FURTHER WRITTEN DETAILS W

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033577	CONCEPTUS, INC.	12/19/2013	12/26/2013

Event Information:

Event Date (B3): 10/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/21/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011 I HAD ESSURE IMPLANTED. THE PROCEDURE WAS UNCOMFORTABLE BUT SEEMED TO FEEL OK AFTER A COUPLE DAYS. OVER THE COURSE OF A FEW MONTHS, MY BLOOD PRESSURE BEGAN TO RISE. MY HSG WAS DONE (B)(6) 2012 CONFIRMING THE TUBES WERE BLOCKED. ON (B)(6) 2012 I WENT TO THE ER BECAUSE OF MY HIGH BLOOD PRESSURE AND RACING HEART. THE ER RAN BLOOD WORK WITH EVERYTHING COMING BACK NORMAL EXCEPT MY POTASSIUM WAS SLIGHTLY LOW. THEY GAVE ME MEDS TO LOWER MY BLOOD PRESSURE AND ADVISED TO SEE MY FAMILY DOCTOR. DOCTOR RAN LABS AND COULD NOT TELL WHAT CAUSED THE SUDDEN BLOOD PRESSURE ISSUES. MY DOCTOR PUT ME ON BLOOD PRESSURE MEDS AND I STILL TAKE THEM TO THIS DAY. I HAVE HAD A WIDE RANGE OF HEALTH ISSUES SINCE GETTING ESSURE. I HAVE CONSTANT HEADACHES, BREAK OUT IN RASHES, HOT FLASHES, SEVERE PELVIC, ABDOMINAL AND BACK PAIN. MY HEART RACES, I HAVE FLUTTERING IN MY STOMACH, BLOOD CLOTS, I CANNOT SIT DOWN WITHOUT PAIN, MY SKIN IS VERY DRY AND ITCHY. I GET DIZZY AND HAVE BLURRED VISION OFTEN, I CONSTANTLY HAVE THE TASTE OF METAL IN MY MOUTH. I GET A BURNING FEELING NEAR WHERE MY TUBES ARE. I TWITCH OFTEN. AFTER BEING IMPLANTED, SYMPTOMS SLOWLY STARTED HAPPENING AND CONTINUE TO GET WORSE AND WORSE. I'M AT THE POINT NOW THAT I CANNOT LIFT MY TWO YEAR OLD SON WITHOUT IT BRING ME TO TEARS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033579	BAYER	12/19/2013	12/26/2013

Event Information:

Event Date (B3): 3/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/8/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IMPLANTED IN (B)(6) 2013. ONLY ONE SIDE WAS ABLE TO BE IMPLANTED SO I CAME BACK A WEEK LATER TO IMPLANT THE OTHER SIDE. ABOUT THREE WEEKS LATER, I HAD SEVERE CRAMPING AND ALMOST WENT TO THE ER WHEN I FELT A GUSH AND RAN TO THE BATHROOM. ONE OF THE IMPLANTS HAD FALLEN OUT. THE CRAMPING IMMEDIATELY CEASED AND I FELT A LOT BETTER, FOR A WHILE. NOW I HAVE SEVERE BACK PAIN ON MY LEFT SIDE. I'M SURE IT'S THE OTHER COIL THAT POSSIBLY MIGRATED AND IS PUNCTURING SOMETHING. MY DOCTOR SEEMS TO THINK IT'S NOTHING. FUNNY THAT THIS PAIN ONLY STARTED AFTER I HAD THE ESSURE IMPLANTED. I WOULD LOVE TO HAVE THE OTHER COIL REMOVED. I HAD A TUBAL AND AN ABLATION IN (B)(6) 2013 AND ASKED IF THE DOCTOR COULD FIND THE OTHER COIL. SHE SAID SHE DIDN'T SEE IT. SHOULDN'T SHE HAVE SEEN IT WHEN SHE CUT THE TUBE? I'M CONCERNED THAT IT'S JUST FLOATING AROUND SOMEWHERE AND CAUSING MY PAIN. I'M SURE THERE ARE INSTANCES OF THIS PROCEDURE GOING EXACTLY AS PLANNED BUT I FEEL THAT THERE ARE ENOUGH OF US OUT THERE THAT YOU NEED TO AT LEAST PAUSE THIS PROCEDURE FOR A WHILE AND TAKE A LOOK. PLEASE INVESTIGATE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033580	BAYER	12/19/2013	12/26/2013

Event Information:

Event Date (B3): 12/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/6/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE PROCEDURE WAS DONE ON ME ON (B)(6) 2013. SINCE THEN, I HAVE HAD MULTIPLE SIDE EFFECTS THAT I HAVE NEVER HAD BEFORE, INCLUDING SHARP PAINS, BLOATING, DIZZINESS, ANXIETY, HEART PALPITATIONS, MISSED MENSTRUAL CYCLES, HEAVY MENSTRUAL CYCLES, SEVERE CRAMPS, DEPRESSION, NAUSEA, VOMITING, HEADACHES, SHARP PAINS IN MY HIPS AND MY BACK, SEVERE EXHAUSTION, AND SEVERE WEIGHT GAIN. THAT'S NOT INCLUDING THAT I HAVE ALLERGIC REACTIONS TO NICKEL, I TOLD THE DOCTOR THAT I WAS ALLERGIC TO NICKEL, AND WAS TOLD THAT I WOULD HAVE NO EFFECTS FROM IT, ALTHOUGH I DO HAVE SYMPTOMS NOW. AFTER INFORMING THE DOCTOR WHO PERFORMED THE PROCEDURE, I WAS TOLD THAT "EVERYTHING LOOKS NORMAL" ON MY ULTRASOUND. YET, I AM STILL FEELING ALL OF THIS PAIN. THE ESSURE IS SAID TO HAVE "NO KNOWN SIDE EFFECTS," YET I HAVE SIDE EFFECTS. THE ONLY THING THAT I SEE THAT CAN BE DONE NOW IS A HYSTERECTOMY, WHICH IS A SURGERY THAT I AVOIDED IN THE FIRST PLACE BY GETTING THE ESSURE PLACEMENT. THIS IS NOT ACCEPTABLE. ESSURE NEEDS TO BE TAKEN OFF OF THE MARKET UNTIL MORE RESEARCH ON THE PRODUCT CAN BE COMPLETED. WOMEN SHOULD NOT HAVE TO GO THROUGH ALL OF THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033581	BAYER	12/19/2013	12/26/2013

Event Information:

Event Date (B3): 10/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A33561

Single Use:
Implant Date (E6): 10/5/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I HAD THE ESSURE PROCEDURE IMPLANTED, I HAVE HAD SEVERE ABDOMINAL PAIN, HEAVY LONG LASTING PERIODS, EXTREME PRESSURE DURING CYCLE ALMOST LIKE LABOR PAINS. I WANT THESE OUT AND EVERY WOMAN TO KNOW ALL THE POSSIBLE SIDE EFFECTS BEFORE MAKING THE CHOICE. I DIDN'T HAVE THIS INFORMATION MADE AVAILABLE BY THE DOCTOR NOR DID HE TELL ME ANY NEGATIVE EFFECTS. I EVEN WENT BACK IN A MONTH DUE TO THE PAIN AND HE TOOK AN X-RAY (WHICH I DIDN'T GET TO SEE) AND SAID EVERYTHING IS FINE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033582	BAYER	12/19/2013	12/26/2013

Event Information:

Event Date (B3): 7/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/19/2013
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM HAVING RE-OCCURRING ALLERGY SYMPTOMS. I HAVE OUTBREAKS OF RASHES, HIVES, AND BLISTERING SENSATIONS, AND MY TASTEBUDS SEEM TO GET AFFECTED TO HOT AND SOUR FOODS. I HAVE UNEXPLAINABLE BAD PAINS OFF AND ON, AND HEADACHES, INCLUDING THE TOP AND THE LOWER TWO SIDES OF MY HEAD, THEY PULSATE AND FEEL VERY TENDER, I GET MAJOR CRAMPING AS WELL AS SWELLING. DOSE OR AMOUNT: 3 DIFFERENT ONE TIME DAILY. FREQUENCY: ONCE DAILY. ROUTE: TAKEN BY MOUTH. DIAGNOSIS OR REASON FOR USE: FOR ANXIETY DUE TO ITCHING AND TENSION. EVENT REAPPEARED AFTER REINTRODUCTION: YES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033605	CONCEPTUS	12/20/2013	12/30/2013

Event Information:

Event Date (B3): 7/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/16/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2010, I HAD THE ESSURE PROCEDURE DONE. SINCE (B)(6) 2010, I HAVE BEEN DIAGNOSED WITH PCOS, I HAVE HAD TO SEE A RHEUMATOLOGIST FOR LUPUS (WHICH TURNED OUT I DID NOT HAVE, JUST HAVE THE SYMPTOMS OF IT), I HAVE BEEN DIAGNOSED WITH ARTHRITIS, AND CONTINUE TO HAVE HORRIBLE PAINS IN MY ABDOMEN THAT ARE CONSTANTLY THERE AND TERRIBLE, HEAVY PERIODS, THAT THANKFULLY ONLY LAST 2-3 DAYS. ALMOST IMMEDIATELY AFTER (B)(6) 2010, I BEGAN TO DEVELOP SEVERE, CYSTIC FACIAL ACNE AND FACIAL HAIR. I WENT TO SEE A FEW DERMATOLOGISTS AND FINALLY MY ENDOCRINOLOGIST (WHO I SEE FOR MY THYROID DISEASE THAT I WAS DIAGNOSED WITH IN 2004) DIAGNOSED ME WITH PCOS AND PUT ME ON BCP. IT DID HELP A LITTLE BUT HAD OTHER SIDE EFFECTS THAT I DIDN'T LIKE SO I STOPPED TAKING IT IN (B)(6) YEAR. IN 2011, I BEGAN TO SUFFER FROM A LOT OF JOINT PAIN AND SWELLING. I BEGAN TO SUFFER FROM MIGRAINES WITH ONE PER MONTH THEN IT GOT TO TWO PER MONTH. I WAS GIVEN AN MRI AND A PITUITARY TUMOR WAS FOUND. IN (B)(6) OF THIS YEAR MY LYMPH NODES BEGAN TO SWELL STARTING IN MY GROIN AND THEY MOVED UP MY BODY. I HAVE SWOLLEN LYMPH NODES IN MY GROIN, ARMPITS, COLLARBONE, UNDER MY CHIN, BEHIND MY EAR, AND ON THE BACK OF MY NECK. I WAS SENT TO DR AFTER DR TO TRY AND FIGURE OUT WHY THEY WERE SWOLLEN. I HAVE FINALLY BEEN TOLD THAT MY BODY IS TRYING TO FIGHT THE ESSURE COILS OFF AS IF THEY ARE AN INFECTION SINCE THEY ARE NOT IN THE CORRECT LOCATION. AROUND (B)(6) OF THIS YEAR I ALSO BEGAN TO ITCH LIKE CRAZY. ALL OVER MY BODY. I GOT HIVES AND MY SKIN ITCHED. FROM (B)(6) TO NOW I HAVE LOST A TOTAL OF 32 LBS WITHOUT TRYING TOO HARD. IT HAS ALWAYS BEEN VERY HARD FOR ME TO LOSE WEIGHT AND ALL OF A SUDDEN IT'S MELTING OFF OF ME. MY HAIR BEGAN TO FALL OUT IN CLUMPS BEGINNING IN (B)(6) OF THIS YEAR. ON

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TUESDAY, (B)(6) 2013, I HAD A TRANSVAGINAL ULTRASOUND DONE WHICH SHOWED ONE ESSURE COIL HAS PERFORATED MY TUBE AND IS PARTIALLY IN MY TUBE THE OTHER COIL IS COMPLETELY IN MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00060	BAYER HEALTHCARE LLC	12/20/2013	12/31/2013

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626220

Single Use: Y
Implant Date (E6): 3/6/2008
Explant Date (E7): 3/26/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED FOR PERMANENT BIRTH CONTROL. SIX MONTHS TO 1 YEAR POST IMPLANT, SHE STARTED DEVELOPING THYROID PROBLEMS, WEIGHT GAIN, DEPRESSION; SEVERE PELVIC PAIN, PAIN WITH SEX, POLY-CYSTIC OVARY SYNDROME, IRREGULAR MENSTRUAL CYCLE, SEVERE BACK PAIN, HAIR LOSS, JOINT PAIN, CHOLECYSTECTOMY DUE TO GALLSTONES, IBS (IRRITABLE-BOWEL SYNDROME), FLOATERS IN EYES, DAY/NIGHT SWEATS, INSOMNIA, PTSD (POST TRAUMA STRESS DISORDER), DISCHARGE, FATIGUE, LOSS OF ENERGY, MOOD SWINGS, ENLARGED UTERUS. PRIOR TO UNDERGOING A HYSTERECTOMY, SHE WAS DIAGNOSED WITH PCOS IN (B)(6) 2012. CONSUMER UNDERWENT A LAPAROSCOPIC HYSTERECTOMY DUE TO "PELVIC PAIN" WITH REMOVAL OF UTERUS, CERVIX, OVARIES AND TUBES ON (B)(6) 2013. CONSUMER REPORTED ALL SYMPTOMS (NOT SPECIFIED) SUBSIDED WITHIN ONE WEEK AFTER SURGERY. AT TIME OF THIS REPORT, CONSUMER WAS STILL BEING TREATED WITH A GENERIC FORM OF SYNTHROID FOR HER THYROID DISEASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00061	BAYER HEALTHCARE LLC	12/20/2013	1/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/8/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED. ABOUT (B)(6) 2011, SHE BEGAN TO EXPERIENCE PELVIC AND BACK PAIN. SHE ALSO REPORTED THAT ESSURE MADE HER BODY GO HAYWIRE AND SHE HAD MIGRAINES UP TO 20 A MONTH. ESSURE WAS REMOVED THROUGH FULL HYSTERECTOMY AND THE EVENTS OUTCOME IS RECOVERED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00062	BAYER HEALTHCARE LLC	12/20/2013	1/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2012
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED FOR CONTRACEPTION. AFTER IMPLANTATION, SHE EXPERIENCED MIGRAINES, PELVIC PAIN, CRAMPING, SEVERE INFLAMMATION AND NO PERIOD (AMENORRHEA) FOR FIRST 6 MONTHS AFTER INSERTION. INSTEAD SHE HAD A VAGINAL DISCHARGE THAT WAS A COPPER COLORED. SHE HAD TO USE A TAMPON FOR THE DISCHARGE. THEN AFTER 6 TO 7 MONTHS SHE STARTED TO BLEED AND BLED NON-STOP FOR 6 TO 7 WEEKS. AFTER THE BLEEDING STOPPED SHE AGAIN HAD A COPPER COLORED VAGINAL DISCHARGE. SHE ALSO EXPERIENCED HAIR LOSS JUST FALLING OUT, DIAGNOSED WITH HASHIMOTO'S DISEASE, LOST THYROID FUNCTION, HOT FLASHES, NIGHT SWEATS, TOTAL LOSS OF LIBIDO, HORRIBLE JOINT PAIN THROUGHOUT ENTIRE BODY, INSOMNIA, DIGESTIVE ISSUES, CHRONIC CONSTIPATION, INCREASED URINARY URGENCY THAT EVEN WAKE HER UP AT NIGHT BUT DID NOT GO VERY MUCH, ANXIETY THAT SHE DID NOT HAVE A HISTORY OF PRIOR TO ESSURE INSERTION. SHE ALSO THINKS SHE WAS ALLERGIC TO THE NICKEL IN THE COIL. AN HSG WAS NEVER DONE AFTER THE PROCEDURE, BUT IN LATE (B)(6) 2013 OR BEGINNING OF (B)(6) 2013, SHE HAD AN ULTRASOUND AND X-RAY TO CHECK PLACEMENT OF COILS. THE ULTRASOUND REPORT SAID POSSIBLE ESSURE VISUALIZED BY CORNUA, BUT NOT SURE. THE RADIOLOGY REPORT SAID ESSURE COILS IDENTIFIED IN ASPECT OF PELVIC CAVITY ON LEFT SIDE AND ONE COIL RESIDED TO THE RIGHT MIDLINE. ON THE VIEW IT APPEARED THAT ONE OF THE UNITS WAS SIGNIFICANTLY BENT. SHE WAS TREATED ARMOUR THYROID 1/2 GRAIN, SYNTHROID NOW 50 MCG DAILY, SEEN BY A FEW DIFFERENT PHYSICIANS FOR JOINT PAIN AND ANXIETY. SHE STATED SHE WAS FORCED TO HAVE A HYSTERECTOMY (EXCEPT OVARIES). SHE HAS THE COILS THAT WERE REMOVED AND THEY ARE COMPRESSED. THE COILS NEVER EXPANDED. SINCE REMOVAL OF ESSURE, JOINT PAIN IS GONE, PELVIC PAIN GONE. HER HYSTERECTOMY WAS AN EASIER RECOVERY THAN ESSURE INSERTION, HAIR LOSS DECREASED, AND SHE FEELS BETTER THAN SHE HAS IN A LONG TIME.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00063	BAYER HEALTHCARE LLC	12/20/2013	1/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AN ATTORNEY REPORTED ON BEHALF OF A PLAINTIFF/PLAINTIFF'S FAMILY THAT A FEMALE CONSUMER HAD ESSURE INSERTED. ON (B)(6) 2013, THE PT WAS SUBMITTED TO A ROBOTIC HYSTERECTOMY. ON AN UNSPECIFIED DATE THE PT EXPERIENCED SMALL PIECE OF COIL FOUND ON MRI FROM PREVIOUS PROCEDURES TO REMOVE THE COILS, WEAKNESS IN THE LEFT SIDE, NUMBNESS IN THE LEFT SIDE, SUBJECTIVE ABDOMINAL PAIN, BACK PAIN, FREQUENCY OF URINATION, PAIN, BLOATING, RASH, PELVIC DENSE ADHESION IN THE ANTERIOR AND POSTERIOR CUL-DE-SAC AREAS AND COMPLICATION OF DEVICE REMOVAL. THE OUTCOME OF THE EVENT RASH WAS RECOVERED / RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00064	BAYER HEALTHCARE LLC	12/20/2013	1/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2011
Explant Date (E7): 11/11/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A MEDICAL DOCTOR REFERRED TO A FEMALE PT WHO HAD ESSURE INSERTED. THE PT HAD CHRONIC RIGHT LOWER QUADRANT PAIN SINCE (B)(6) 2011 FOLLOWING AN ESSURE PLACEMENT. OPERATIVE NOTE DOCUMENTED THAT THE INITIAL PLACEMENT OF THE ESSURE DEVICE ON THE RIGHT SIDE NEEDED TO BE RE-DONE. THE PT'S MENSES ARE MONTHLY, LASTING TWO TO THREE DAYS AND ARE HEAVY. SHE HAS RIGHT LOWER QUADRANT PAIN EVERY DAY, BUT IT INCREASES WITH HER MENSES. HER RIGHT LOWER QUADRANT PAIN ALSO INCREASES AFTER HAVING A BOWEL MOVEMENT, WITH AND AFTER INTERCOURSE, AND WITH MOVEMENT, PARTICULARLY TORSION OF THE BODY. THE PT HAS HYPOTHYROIDISM DUE TO HASHIMOTO'S DISEASE, WHICH HAS BEEN CORRECTED WITH LEVOTHYROXINE 150 MCG A DAY. THE PT ALSO HAD CONSULTED WITH ANOTHER PHYSICIAN AND ONE MONTH DEPO-LUPROFL WAS GIVEN WITHOUT CHANGE. A TRIAL OF PHYSICAL THERAPY WAS NOT HELPFUL. THE PT WAS THEN ON TRAMADOL 100 MG FOR TREATMENT OF HER RIGHT LOWER QUADRANT PAIN. ON (B)(6) 2013, THE PT HAD LAPAROSCOPY WITH TOTAL ABDOMINAL HYSTERECTOMY, RIGHT SALPINGO-OOPHORECTOMY AND LEFT SALPINGECTOMY. THE FINAL DIAGNOSIS OF THE SPECIMEN INQUIRY WAS: UTERUS WITH RIGHT OVARY AND BILATERAL FALLOPIAN TUBES (TOTAL HYSTERECTOMY WITH RIGHT SALPINGO-OOPHORECTOMY AND LEFT SALPINGECTOMY): EIGHTY GRAM UTERUS SHOWING SECRETORY ENDOMETRIUM WITH ADENOMYOSIS. MILD CHRONIC CERVICITIS AND NABOTHIAN CYSTS. RIGHT OVARY WITH HEMORRHAGIC CORPUS LUTEUM CYST. FOCAL FIBROSIS AND DEPOSITION OF NON-POLARIZABLE FOREIGN MATERIAL NOTED IN BILATERAL FALLOPIAN TUBES. SEGMENTS OF COIL CONSISTENT WITH ESSURE DEVICES IDENTIFIED IN PROXIMAL ASPECT OF EACH FALLOPIAN TUBE. NO EVIDENCE OF MALIGNANCY. THE PT WAS DISCHARGED ON (B)(6) 2013.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033505	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 11/19/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALWAYS IN PAIN, UNABLE TO WORK, HIGH NICKEL, UNABLE TO FOCUS, MIGRAINES THAT WON'T GO AWAY, NICKEL TASTE WON'T GO A WAY, ALWAYS TIRED, UNABLE TO THINK CLEARLY, SHOCKING FEELING THROUGH THE HEAD AND LEGS, NUMBING FEELING THOUGH LEGS, NICKEL IN BREAST MILK, ISSUES WITH SINUS, MISCARRIAGE AFTER BEING 100%, COIL IN BETWEEN SKIN LAYERS OF THE TUBE, HAD HYSTERECTOMY TO REMOVE ESSURE AND ITS PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033506	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD MIGRAINES FOR YEARS BUT NEVER REALIZED THAT THEY MAY BE RELATED TO ESSURE UNTIL RECENTLY. HAVE NOW HAD SEVERE ABDOMINAL PAIN FOR 8 MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033507	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 10/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PELVIC AND BACK PAIN, VOMITING AND NAUSEA, HEADACHES, PAIN DURING AND AFTER INTERCOURSE, SEVERE BLOATING, AND FATIGUE JUST TO NAME A FEW. HAVE HAD THE BLOATING OFF AND ON WITH NAUSEA FOR 7 YEARS WITH A DIFFERENT POSSIBLE DIAGNOSIS EVERY TIME. IT HAS BEEN CONSISTENT WITH SEVERE PAIN FOR 2 1/2 MONTHS NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033508	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 9/26/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BLOOD FROM DAY ONE FOR ALMOST A YEAR AND HAD A CONTRACTUAL LIKE CRAMPS ALL THE TIME. THE FEW SELECT DAYS THAT I DIDN'T BLEED IF IT WENT PAST 3 DAYS I BLED HORRIBLY TO WHERE I COULDN'T STAND FOR MORE THAN 20, 30 MINUTES WITHOUT BLEEDING ALL OVER MYSELF. I WAS ALWAYS BLOATED, LOOKING LIKE I WAS PREGNANT. I ALWAYS HAD BACK PAIN AND JOINT PAIN. I ENDED UP HAVING TO HAVE A HYSTERECTOMY BECAUSE ONE OF THE COILS CAME OUT OF MY FALLOPIAN TUBE IN MY UTERUS, THA'S WHY I WAS BLEEDING. ON TOP OF THAT I ALWAYS HAD MIGRAINES. I WAS ALWAYS DEPRESSED. I AM ONLY (B)(6) AND HEALTHY I SHOULD NOT HAD TO HAVE A HYSTERECTOMY SO YOUNG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033509	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLED FOR THE FIRST 10 MONTHS STRAIGHT, SEVERE SHARP STABBING PAINS IN THE STOMACH AND RECTUM AND PELVIS, LOWER BACK PAIN, TINGLING IN THE HANDS AND FEET MUSCLE SPASMS IN THE NECK, SEVERE MIGRAINES, PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE, BLEEDING FROM THE RECTUM, PAIN WHEN WALKING AND SITTING, NAUSEA AND VOMITING, METAL TASTE IN THE MOUTH, UNCONTROLLABLE MOOD SWINGS, DEPRESSION AND ANXIETY, VITAMIN D DEFICIENCY, BLURRED VISION, RANDOM PAINS IN MY HEAD AND AROUND MY EYES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033531	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE A KNOT INSIDE OF ME, I VOMIT EVERYWHERE, MY PRIVATE PART HURT ONGOING. THIS ESSURE IS CAUTION MY BODY TO ACH 24 7 DAYS AND NIGHTS. IT HURT WHEN I BREATH OR COUGH. I AM CONTINUE UP ALL NIGHT WITH THIS PAIN FROM THE ESSURE. SOMETHING IS STICK ME FROM THE INSIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033533	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 11/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

COILS WERE PLACED (B)(6) 2009. THE RIGHT COIL HAD PERFORATED COMPLETELY THROUGH. I HAD A PREGNANCY IN 2010 WITH VERY BAD ISSUES WITH WEIGHT LOSS AND MIGRAINES AND MORNING SICKNESS. HAD UTERUS TAKEN OUT FROM SEVERE BLEEDING. THE RIGHT COIL WAS NOT ABLE TO BE LOCATED UNTIL (B)(6) 2013. AFTER SEVERAL ATTEMPTS IT WAS LOCATED IN FRAGMENTS NEAR/ON MY ASCENDING COLON. I HAD SURGERY (B)(6) 2013 TO HAVE BOTH TUBES AND COILS REMOVED. THE LEFT TUBE WAS ALSO BEING PERFORATED. I DO NOT BELIEVE THE ENTIRE COIL WAS RETRIEVED AND THE RIGHT WAS AGAIN UNABLE TO BE LOCATED SO IT WAS NOT REMOVED. I ALSO SUFFER FROM EXTREME PAIN FROM THE FRAGMENTS, SEVERE MIGRAINES, VERTIGO, NAUSEA, RASHES,VERY BAD PAIN IN MY LEGS AND BACK AND HAIR LOSS. I AM IN A VERY DANGEROUS SITUATION WITH THE COILS BEING IN FRAGMENTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033534	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE PROCEDURE I HAVE BEEN IN CONSTANT PAIN THAT IS ONLY GETTING WORSE EACH DAY. I HAVE CRAMPING IN MY UTERUS AND ENTIRE PELVIC REGION THROUGH MY BACK AND SOMETIMES DOWN MY LEGS. THE PAIN IS EVEN MORE EXTREME DURING OVULATION AND MY MONTHLY CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033535	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 11/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED TO NOTICE A RASH FROM A PIECE IF JEWELRY WHICH TURNED OUT TO BE A NICKEL ALLERGY. NOW I HAVE A NICKEL RASH IN MY LOWER BACK AND CHEST THAT IS PAINFUL AND ITCHY COMES AND GOES BUT SOME OF IT IS ALWAYS THERE. I HAVE HEAVY ERUPTS ONE THAT LASTED 32 DAYS AND ONLY STOPPED BECAUSE OF HORMONES THE DR GAVE ME. CONSTANT CRAMPING AND PAIN SINCE DAY ONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033536	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS WERE IMPLANTED (B)(6) 2011; HSG PERFORMED (B)(6) 2011; SYMPTOMS BEGAN APPROXIMATELY (B)(6) 2011. I BEGAN EXPERIENCING SEVERE CRAMPING, IRREGULAR MENSTRUAL PERIODS AND IRREGULAR MENSTRUAL FLOW W/ BLOOD CLOTTING FROM HEAVY FLOW TO LIGHT FLOW W/ LONGER DURATION OF CYCLE. DEPRESSION WORSENED W/ MEMORY LOSS, LOSS OF CONCENTRATION AND FOCUS. TINGLING, NUMBNESS, BURNING SENSATION IN BOTH LEGS PARTICULARLY THE RIGHT LEG. HAD PROBLEMS WITH PELVIC PAIN ON BOTH SIDES. SEXUAL INTERCOURSE WAS PAINFUL. I BEGIN TO HAVE UNEXPLAINED RASHES WHICH SPREAD ON MY NECK, SHOULDERS, AND UPPER PART OF MY CHEST THAT WOULD NOT CLEAR UP. I HAD SEVERE BLOATING AND EXCESSIVE BELLY PROTRUSION WITH NO SUCCESSFUL WEIGHT LOSS. I HAVE SUFFERED WITH HIP PAIN, BACK PAIN, MUSCLE AND JOINT ACHES. I HAD PROBLEMS STANDING FOR PERIODS OF TIME AND WALKING DUE TO PACK PAIN, LEG PAIN, AND PELVIC PAIN. MY FECES HAD AN ODD METALLIC ODOR SMELL THAT I NOTICED A FEW MONTHS AFTER ESSURE WAS IMPLANTED. CONSTIPATION HAD WORSENED. MENSTRUAL CYCLE WOULD COME ONE MONTH, MISS THE NEXT, THEN COME TWO TIMES IN ONE MONTH. THE WORST PART ABOUT THIS WHOLE EVENT IS THAT THE PHYSICIAN NEVER CONDUCTED A NICKEL ALLERGY FOR ME OR ASKED IF I WAS ALLERGIC. I WANTED A TUBAL LIGATION AND WAS TALKED INTO ESSURE BECAUSE "WE DON'T DO TUBAL LIGATIONS ANYMORE UNLESS YOU HAVE HAD A BABY." I FELT THAT WAS MY ONLY OPTION SINCE I NO LONGER WANTED TO HAVE CHILDREN. TODAY, I AM ONE WEEK HYSTERECTOMY POST-OP WHICH WAS THE BEST MEDICAL DECISION I HAVE MADE IN A WHILE COMPLIMENTARY OF ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033537	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 9/23/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE ON (B)(6) 2013. THE DOCTOR DID NOT GIVE ME A CHOICE HE SAID I NEEDED TO HAVE THIS DONE IN ORDER TO START THE IV PROCEDURE. I HAVE FIBROID THAT BLOCKED MY TUBES AND HE SAID THIS WAS NECESSARY SO THE FLUIDS WILL NOT DRIP INTO MY UTERUS. NOW I HAVE BEEN BLEEDING SINCE SUNDAY (B)(6) 2013 (26 DAYS STRAIGHT WITH NO BREAKS). MY DOCTOR SAID HE THINKS IT'S BECAUSE OF THE FIBROID BUT I NEVER BLED LIKE THIS WITH THE FIBROIDS. THEY NEVER BOTHERED ME. I ONLY HAD THIS SINCE THE ESSURE DEVICE WAS INSERTED. I AM (B)(6) OLD WITH NO KIDS AND I DO NOT WANT A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033538	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 7/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BECAME PREGNANT DESPITE BEING TOLD MY TUBES WERE CLOSED AND DENIED BIRTH CONTROL PILLS AS A BACK UP. I HAVE CONTINUED TO HAVE SEVERE STABBING PAINS THAT WERE NOT PRESENT PRIOR TO HAVING ESSURE PLACED. I ALSO STRUGGLE WITH HIVES AS WELL SINCE HAVING HAD THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033539	CONCEPTUS	12/20/2013	1/15/2014

Event Information:

Event Date (B3): 4/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I OFTEN HAVE SHARP PAINS IN PELVIC REGION. I CAN NO LONGER LAY ON STOMACH AS I WILL GET STABBING PAINS IF I DO. I HAVE CONSTANT ABDOMINAL BLOAT AND A TIGHT STOMACH. I HAVE A SMELLY GREENISH TINT VAGINAL DISCHARGE AND MY CYCLE IS NOT LONGEST CONSTANT. I OFTEN WILL HAVE 2 A MONTH WITH THEM LASTING 7-10 DAYS WITH A FLOW THAT IS BEYOND HEAVY WITH CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033532	CONCEPTUS	12/20/2013	1/29/2014

Event Information:

Event Date (B3): 11/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEBILITATING PELVIC PAIN. COULD NOT FUNCTION WITHOUT PAIN MEDS AND COULD NOT FUNCTION ON PAIN MEDS. MY LIFE AS I KNEW IT CHANGED DRASTICALLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033940	BAYER	12/23/2013	1/27/2014

Event Information:

Event Date (B3): 11/21/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE IN 2007. I'VE BEEN TO THE DR NOT KNOWING WHAT WAS WRONG. "IT HAS COME TO MY ATTENTION ESSURE ALL THE SYMPTOMS ARE THERE AND IT ALL MAKES SENSE." I AM A PERFECTLY HEALTHY (B)(6) WITH 3 KIDS. I HAVE SEVERE HEADACHES LOW BACK PAIN. I CAN'T HAVE SEX WITH MY HUSBAND WITHOUT BEING IN TEARS. MY UTERUS IS BACKWARDS. MY HAIR IS THINNING AND I AM TIRED ALL THE TIME AND JUST FEEL LIKE I NEED TO LAY DOWN. I BLEED AND THEN WILL BLEED AGAIN. "SOMETIME, I FEEL AS IF I AM MISCARRIAGE." I HAVE TO LAY DOWN AND PROP MY LEGS UP, SOMETIMES WHEN I AM BLEEDING SO BADLY. THIS IS NOT FAIR TO ME, MY HUSBAND OR 3 KIDS. THEY WANT THEIR MOMMY BACK AND SO DO I. I HAVE HOT FLASHES OR WAKE UP SWEATING MANY NIGHTS. THIS IS RIPPING MY 10 YEARS MARRIAGE APART. PLEASE DO SOMETHING, I CAN'T AT THE MOMENT. I HAVE NO INSURANCE. THIS IS NOT FAIR, SOMETHING MUST BE DONE. REASON FOR USE: 5 KIDS ALTOGETHER DON'T WANT ANYMORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033942	CONCEPTUS/BAYER	12/23/2013	1/27/2014

Event Information:

Event Date (B3): 8/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/31/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED ESSURE ON (B)(6) 2011. ALTHOUGH THE LITERATURE INFORMED ME THAT IT WOULD BE A QUICK, IN-OFFICE PROCEDURE, MY DOCTOR (LISTED ON ESSURE'S WEBSITE AS BEING TRAINED IN THE PROCEDURE) SENT ME TO THE SAME DAY SURGERY CENTER AT THE HOSPITAL, AND I WAS PUT COMPLETELY UNDER. THE LITERATURE ALSO STATES THAT THE SAFETY AND EFFECTIVENESS OF ESSURE IS NOT PROVEN FOR THOSE UNDER SIX WEEKS POSTPARTUM, BUT I RECEIVED MINE JUST SHY OF 5 WEEKS. MY DEVICES WERE IMPLANTED WITH 2 SHOWING ON ONE SIDE, AND 0 ON THE OTHER - BOTH TOO HIGH. SINCE THE PROCEDURE, PMS AND MY PERIODS HAVE GOTTEN INCREASINGLY WORSE. I AM NOW AT THE POINT WHERE I EXPERIENCE PAINFUL CRAMPS AND BACK ACHES SEVERAL TIMES WEEKLY ALL THROUGHOUT MY CYCLE. PMS WEEK HAS BECOME SO PAINFUL I AM BEDRIDDEN, AND I CONSISTENTLY EXPERIENCE ISSUES WITH PAINFUL CLOTS, AND EXTREMELY HEAVY FLOW (GOING THROUGH SUPER-PLUS TAMPONS IN AN HOUR). I HAVE BEEN DIAGNOSED WITH PMDD, WHICH I BELIEVE TO BE A DIRECT RESULT OF THE ESSURE. I AM ALLERGIC TO NICKEL, TO THE POINT WHERE I CANNOT WEAR JEWELRY CONTAINING IT, AND SELF-PERFORMED NICKEL TESTS HAVE LEFT MY SKIN ITCHY AND BRUISED FOR DAYS. I WAS INFORMED BY CONCEPTUS, MY DOCTOR AND THE FDA THAT THE NICKEL CONTRAINDICATION HAD BEEN REMOVED, SO I WAS SAFE. OBVIOUSLY, THIS WAS NOT THE CASE. MY DOCTOR KNEW MY UTERUS TO BE TILTED, HAVING MENTIONED THE PROBLEMS DETECTING MY BABIES' HEARTBEATS DURING PREGNANCY BOTH TIMES, YET NEVER MENTIONED THAT ESSURE IS NOT RECOMMENDED FOR WOMEN WITH A TILTED UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033943	BAYER	12/23/2013	1/27/2014

Event Information:

Event Date (B3): 10/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE MENSTRUAL CRAMPING, INCLUDING CRAMPING DOWN INTO THE VAGINA AND LEGS. HEADACHES. IRREGULARLY HEAVY PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033944	BAYER	12/23/2013	1/27/2014

Event Information:

Event Date (B3): 9/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/7/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2009 AND SINCE THEN, I HAVE HAD HEAVY BLEEDING, MENSTRUAL CRAMPS, AND SEVERE ABDOMINAL PAIN SINCE I'VE HAD IT. MY GYNECOLOGIST HAS TRIED EVERYTHING INCLUDING BIRTH CONTROL BECAUSE WE THOUGHT IT WAS HORMONAL. WE'VE DONE PAIN MEDS AND THE LAST STRAW WAS DOING A POSSIBLE SCOPE. I HAVE WANTED TO TAKE THEM OUT BUT IT IS A PROCEDURE THAT I DON'T HAVE INSURANCE FOR SO I HAVE TO SUFFER WITH THIS IMPLANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033946	BAYER	12/23/2013	1/27/2014

Event Information:

Event Date (B3): 12/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/21/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL DISLODGED FROM MY TUBES, RESULTING IN PREGNANCY IN 2009. NOW IN 2013, THE COIL THAT WAS IN PLACE IN RT TUBE HAS NOW PERFORATED THE TUBE. RESULTING IN ME HAVING TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	12/24/2013	12/31/2013

Event Information:

Event Date (B3): 9/16/2013 **Report Date (B4): 12/24/2013** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B26269

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/16/2013

Event Description (B5):

ESSURE DEVICE HAD PREMATURE UNCOILING. IT WAS REMOVED IN ITS ENTIRETY AND A NEW DEVICE WAS OBTAINED AND SUCCESSFULLY USED.
==========
MANUFACTURER RESPONSE FOR BIRTH CONTROL COILS, ESSURE (PER SITE REPORTER).
==========
REP TOOK DEVICE AS REP WAS PRESENT DURING PROCEDURE AND NOTED DEVICE FAILURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033629	BAYER	12/24/2013	12/31/2013

Event Information:

Event Date (B3): 12/11/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/17/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS NOT FULLY TOLD, ABOUT ALL OF THE SIDE EFFECTS OF ESSURE. IT WAS IMPLANTED (B)(6) 2011 AND SINCE THEN I HAVE ON AND OFF PROBLEMS, INCLUDING PAIN, BLOATING, BLEEDING, SWOLLEN OVARIES, VISION PROBLEMS, HAIR LOSS, CONSTIPATION, AND SHARP STABBING PAINS IN MY STOMACH. I HAVE HAD SEVERAL ULTRASOUNDS THAT HAVE CLEARLY SHOWED, THAT MY ESSURE IMPLANTS ARE NOT IN THE CORRECT POSITION, BUT I'M UNABLE TO AFFORD TO HAVE IT REVERSED, OR TO PAY FOR A "HYSTO". WE WOMEN WHO ARE SUFFERING ARE LEFT TO DEAL WITH THIS HORRIBLE DEVICE FOR YEARS UNTIL WE ARE ABLE TO PAY TO GET RID OF IT. I AM A (B)(6) FEMALE WHO IS NOT INTERESTED IN HAVING A "HYSTO", BUT BECAUSE OF ESSURE, IT MAY BE MY ONLY CHOICE. I SPEND MOST OF MY DAYS IN BED, HURTING TOO BAD TO EVEN FEED MY OWN CHILDREN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033625	BAYER	12/24/2013	1/2/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/29/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2011. SINCE THEN I HAVE EXPERIENCED SEVERE ABDOMINAL AND PELVIC PAIN, SEVERE HEADACHES AT LEAST FIVE DAYS A WEEK, THERE IS ALWAYS A METALLIC TASTE IN MY MOUTH, I AM ALWAYS TIRED, MY WEIGHT FLUCTUATES AND I HAVE VERY HEAVY AND IRREGULAR PERIODS. INTERCOURSE IS PRETTY MUCH NON EXISTENT BECAUSE OF THE PAIN. AFTER BEING ABLE TO WALK 3 MILES A DAY, PRIOR TO THE SURGERY, I CAN NOT EVEN FINISH 2 MILES, IF I SIT LONGER THAN 30 MINS OR TRY TO NAP, I GET UP FEELING AS IF I'M IN PAIN. I AM ONLY (B)(6) AND LIFE WAS SUCH A JOY BEFORE THIS PROCEDURE. I TAKE MULTIVITAMINS DAILY TO TRY AND HELP ME FEEL BETTER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033627	BAYER	12/24/2013	1/2/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE. I DID THE DYE TEST AND WAS TOLD I WAS STERILE. A YEAR LATER, I BECAME PREGNANT. THAT PREGNANCY ENDED IN C SECTION. DR COULDN'T FIND THE COIL IN MY TUBE. I HAVE HAD PAIN AND HAVE NOW HAD TO GET AN X-RAY AND AN MRI TO FIND THE LOCATION OF THE COILS. NOW I WILL NEED TO HAVE SURGERY TO HAVE THEM REMOVED FROM MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033628	BAYER	12/24/2013	1/2/2014

Event Information:

Event Date (B3): 6/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 919017

Single Use:
Implant Date (E6): 6/28/2012
Explant Date (E7): 11/7/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER TWO MISCARRIAGES WITHIN 18 MONTHS, I HAD THE ESSURE PERMANENT BIRTH CONTROL DEVICE IMPLANTED IN A SURGICAL DAY CARE FACILITY UNDER ANESTHESIA ON (B)(6) 2012. (REFERENCE #(B)(4), LOT #919017). I HAD PLANNED ON HAVING A STANDARD TUBAL LIGATION TO PREVENT PREGNANCY. HOWEVER, I OPTED FOR ESSURE AFTER LEARNING ABOUT THE MINIMAL DOWN TIME THAT IT OFFERED AND MY DOCTOR'S TESTIMONIAL OF ITS SUCCESS. I EXPRESSED MY CONCERN ABOUT NICKEL BEING IN THE DEVICE BECAUSE I HAVE NEVER BEEN ABLE TO WEAR COSTUME JEWELRY AND SUSPECTED A NICKEL ALLERGY. I WAS TOLD THAT THE NICKEL WARNING HAD BEEN REMOVED FROM THE PRODUCT BECAUSE THERE WAS SUCH A LOW AMOUNT OF IT IN THE DEVICE. AFTER A SUCCESSFUL AND UNREMARKABLE ESSURE IMPLANTATION, I HAD THE EXPECTED SIDE EFFECTS OF PELVIC PAIN AND CRAMPING. HOWEVER, THOSE SIDE EFFECTS NEVER WENT AWAY AND MANY OTHER EFFECTS BEGAN TO SURFACE IMMEDIATELY AFTER IMPLANTATION. (I HAD THE MANDATORY HSG DYE TEST 3 MONTHS AFTER IMPLANTATION WHICH SHOWED PERFECT PLACEMENT OF THE ESSURE COILS AND COMPLETE BLOCKAGE OF THE TUBES.) I BEGAN BLEEDING (LIKE A MENSTRUAL CYCLE) IMMEDIATELY AFTER IMPLANTATION AND IT CONTINUED FOR 3 MONTHS STRAIGHT. I ALWAYS HAD A LIGHT CYCLE EVERY 28-30 DAYS LIKE CLOCKWORK BEFORE ESSURE. IN THE 16 MONTHS POST-ESSURE, MY PERIODS WERE HEAVY WITH INCREDIBLE CLOTTING, SEVERE CRAMPS, AND OCCURRED EVERY TWO TO THREE WEEKS. I COULD NOT WEAR TAMPONS DUE TO PAIN AND CLOTTING. I HAD CONSTANT ABDOMINAL PAIN, CRAMPING, AND BLOATING THAT NEVER WENT AWAY FOR THE 16 MONTHS THAT ESSURE WAS IN MY BODY. I LOOKED PREGNANT, AND PEOPLE COMMENTED ON IT. I HAD CONSTANT EXCRUCIATING LOWER BACK PAIN, STABBING ABDOMINAL PAINS (ALTERNATING SIDES, VERY DISTINCT STABBING

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FEELING), SEVERE JOINT INFLAMMATION TO THE POINT WHERE I WAS VIRTUALLY UNABLE TO WALK AFTER 15 MONTHS, CONSTANT FATIGUE/LOSS OF ENERGY, CONSTANT NAGGING HEADACHES AND AN INCREASE IN THE INCIDENCE AND SEVERITY OF MIGRAINE HEADACHES, THE FEELING OF BEING STABBED WHEN I SAT DOWN AND A FEELING OF TEARING WHEN I STOOD UP - ALL THE TIME, HAIR LOSS TO THE POINT WHERE I CUT MY HAIR EXTREMELY SHORT TO HIDE THE FACT A SAVE MY PLUMBING, AN INCREASE IN CYSTIC ACNE, HOT FLASHES, INSOMNIA, MOOD SWINGS/IRRITABILITY, METAL TASTE IN MY MOUTH, SWELLING OF HANDS AND FEET, DENTAL ISSUES WHERE I WAS LOSING SILVER FILLINGS, WEIGHT GAIN, VISUAL ACUITY DECLINED DRAMATICALLY WITHIN 1 MONTH OF ESSURE AND REQUIRES ME TO WEAR GLASSES ALL OF THE TIME NOW, OCCIPITAL NEURALGIA, FORGETFULNESS/BRAIN FOG/CLOUDINESS SHORT-TERM MEMORY LOSS/CONFUSION, DIZZINESS WITH AND WITHOUT NAUSEA, HEARTBURN, AND DEPRESSION FROM ALWAYS BEING SICK, FEELING LOUSY, HAVING MY HEALTH DETERIORATE, AND NOT BEING ABLE TO DO THE THINGS THAT I WAS ALWAYS ABLE TO DO BEFORE ESSURE. IN (B)(6) 2013, I LOST VISION IN MY RIGHT EYE. I WAS DIAGNOSED WITH OPTIC NEURITIS AND MULTIPLE SCLEROSIS. IT IS VERY UNUSUAL TO BE DIAGNOSED WITH MS AT (B)(6). IN (B)(6) 2013, I HAD A FORMAL NICKEL ALLERGY TEST THAT CONFIRMED A SEVERE NICKEL ALLERGY. MY ALLERGIST RECOMMENDED THAT THE COILS BE REMOVED IMMEDIATELY. ON (B)(6) 2013, I HAD A LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY WITH REMOVAL OF THE FALLOPIAN TUBES - THUS REMOVAL OF THE ESSURE DEVICE. IN THE PAST 16 MONTHS, I HAVE SPENT AN INCREDIBLE AMOUNT OF MONEY ON SANITARY CARE PRODUCTS, PAIN MEDICATIONS AND PRESCRIPTIONS, DOCTOR AND SPECIALIST VISIT CO-PAYS, A (B)(6) INSURANCE CO-PAY TO HAVE SURGERY TO HAVE THE PRODUCT REMOVED, EYE GLASSES, DRAIN CLEANERS BECAUSE OF MY HAIR LOSS, AND DENTAL CARE. I FEEL INCREDIBLE NOW 8 WEEKS AFTER HAVING ESSURE REMOVED! ALTHOUGH MOST OF MY SYMPTOMS HAVE VANISHED, I AM STILL DIAGNOSED WITH MULTIPLE SCLEROSIS (AN INFLAMMATORY DISEASE THAT IN MY CASE IS SUSPECTED TO BE CAUSED BY CONSTANT EXPOSURE TO THE PET FIBERS IN THE ESSURE DEVICE) AND LOSS OF VISUAL ACUITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00065	BAYER HEALTHCARE LLC	12/30/2013	1/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/22/2011
Explant Date (E7): 4/23/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A FEMALE PT HAD ESSURE INSERTED FOR PERMANENT BIRTH CONTROL. INSERTION WAS DONE UNDER LOCAL ANESTHESIA IN AN OUTPATIENT SURGERY AT A MEDICAL CENTER. THE PT REC'D THE FOLLOWING CONCOMITANT MEDICATION: DEPO-PROVERA (MEDROXYPROGESTERONE ACETATE) AND ORAL CONTRACEPTIVE (UNSPECIFIED) FOR CONTRACEPTION. THE PHYSICIAN REPORTED THE PT STATED SHE HAD A NICKEL ALLERGY THAT WAS NOT RECOGNIZED AT THE TIME OF HER SURGERY AND THAT SHE COMPLAINED OF PAIN POSTOPERATIVELY. THE PT UNDERWENT A LAPAROSCOPIC PARTIAL SALPINGECTOMY ON (B)(6) 2013 AND IT STATED THAT THE INSERTION DEVICES NORMALLY REMOVED DURING THE PLACEMENT WERE NOT REMOVED. THE HCP (HEALTHCARE PROFESSIONAL) EXPLAINED THAT WHEN SHE INSERTED ESSURE ON THIS PT SHE SAW THREE COILS TRAILING WITHIN THE ENDOMETRIAL CAVITY ON BOTH SIDES, AND ACCORDING TO HER HYSTEROSCOPIC OPERATIVE NOTE SHE HAD DICTATED, BOTH DEVICES WERE DEPLOYED EASILY. A LAWYER CLAIMED SHE LEFT INSERTION TOOLS INSIDE. SHE DID NOT UNDERSTAND HOW THEY CAME TO THAT CONCLUSION. PT HAD ONE POSTOPERATIVE VISIT WHERE SHE COMPLAINED OF IRREGULAR BLEEDING AND SOME PELVIC CRAMPING. SHE HAD REC'D A PREOPERATIVE DOSE OF DEPOT-PROVERA IM (INTRAMUSCULARLY) AND AT HER POSTOPERATIVE VISIT PHYSICIAN HAD HER TAKING AN ORAL CONTRACEPTIVE. PT NEVER HAD HER POSTOPERATIVE HSG (HYSTEROSALPINGOGRAM), THOUGH IT WAS SCHEDULED TWICE. PHYSICIAN HAD NOT TALKED TO PT SINCE HER FIFTH WEEK POSTOP VISIT. THE OUTCOME OF THE EVENTS WAS UNK.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00066	BAYER HEALTHCARE LLC	12/30/2013	1/7/2014

Event Information:

Event Date (B3): 10/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 10/19/2012
Explant Date (E7): 12/17/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR BIRTH CONTROL. SHE STATED THE PROCEDURE WAS DONE IN HER DOCTOR'S OFFICE WITH CERVICAL BLOCK AND SOME PAIN MEDS (MEDICATIONS) TAKEN BEFORE THE APPOINTMENT. THE PROCEDURE WAS ONE OF THE MOST PAINFUL EXPERIENCES OF HER LIFE AND SHE HAD TWO VAGINAL BIRTHS. HER UTERUS WAS VERY RETROVERTED AND ONE COIL WAS VERY DIFFICULT TO PLACE. AFTER SEVERAL TRIES, THE DOCTOR FINALLY WAS ABLE TO PLACE IT. SHE SPENT THE REST OF THE DAY IN BED RESTING. THE NEXT DAY, SHE BEGAN TO HAVE LABOR LIKE CRAMPING AND VERY HEAVY MENSTRUAL BLEEDING. SHE CALLED HER DOCTOR AND THEY ASKED HER TO KEEP THEM POSTED. AFTER A COUPLE OF WEEKS OF PROGRESSIVELY WORSE BLEEDING, CRAMPING, FOLLOWED WITH MIGRAINES, HORRID BACK PAIN, AND EXTREME FATIGUE, HER DOCTOR ORDERED AN X-RAY TO RULE OUT PERFORATION. THE X-RAY SHOWED THAT THE COILS WERE EXACTLY WHERE THEY WERE SUPPOSED TO BE. HER SYMPTOMS GOT WORSE AND GOT MORE COMPLICATED. HAIR LOSS, MEMORY LOSS, CONFUSION, JOINT AND MUSCLE PAIN, INSOMNIA AND CHRONIC INFECTIONS FOLLOWED. SHE JUST WANTED BIRTH CONTROL, BUT GOT WAY MORE THAN WHAT SHE WAS EXPECTING. SHE WAS FORTUNATE THAT HER IMPLANTING DOCTOR WANTED TO SCHEDULE A HYSTERECTOMY IMMEDIATELY. HER DOCTOR SAID SHE WAS HAVING A BAD REACTION TO ESSURE. HE HAD NEVER SEEN IT BEFORE, BUT TOOK HER SERIOUSLY IMMEDIATELY. SHE HAD ONE VISIT TO EMERGENCY ROOM DUE TO FAINTING SPELLS. SHE HAS A NICKEL ALLERGY AND SHARED THAT WITH HER DOCTOR BEFORE IMPLANTATION AND HE SAID THAT NICKEL HAD BEEN REMOVED FROM THE LIST OF CONTRA-INDICATIONS. SHE HAD THE ESSURE COILS IN FOR ONLY 10 WEEKS, BUT IT WAS 10 WEEKS OF TOTAL (UNSPECIFIED). SHE STARTED FEELING BETTER WITHIN

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HRS AFTER HER HYSTERECTOMY AND MOST OF HER SYMPTOMS WERE GONE WITHIN A FEW WEEKS. SHE NEVER THOUGHT SHE WOULD HAVE TO HAVE SUCH AN EXTREME SURGERY AT THE AGE OF (UNSPECIFIED). SHE HAD TO TAKE THREE WEEKS OFF FROM WORK DURING (UNSPECIFIED).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033676	CONCEPTUS, INC.	12/30/2013	1/7/2014

Event Information:

Event Date (B3): 12/28/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/23/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN (B)(6) 2013 BUT SINCE THEN I HAVE HAD SEVERE PAIN IN MY LOWER BACK WHICH I HAVE EVERY DAY, AND OTHER PAINS, AND HEADACHES FROM IT AND I FEEL ITS JEOPARDIZING MY HEALTH AND I CAN'T HAVE THAT SINCE I AM A SINGLE MOM RAISING MY 2 SONS ALONE. I WOULD LIKE TO BE REMOVED BUT ALSO WANT TO MAKE SURE MY TUBES ARE OKAY IN CASE I WANT TO GET PREGNANT AGAIN SINCE GETTING REMARRIED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033677	CONCEPTUS, INC.	12/30/2013	1/7/2014

Event Information:

Event Date (B3): 12/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/14/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I'VE HAD ESSURE, I HAVE HAD PROBLEMS. MY BACK HURTS; MY SIDE HURTS AND I CAN HARDLY MOVE MY LEGS. I USED TO ENJOY WORKING OUT. NOW I CAN HARDLY MOVE MY LEGS; MY HIPS HURT. I FEEL SICK ALL THE TIME WITH HEADACHES. METAL TASTE IN MY MOUTH THAT WON'T GO AWAY. I HAVE ABOUT 10 DOCTOR'S APPOINTMENTS A MONTH RELATED TO ESSURE. I'VE HAD CYST, POLYPS, ARTHRITIS AND SCOLIOSIS. I'VE BEEN GIVEN 12 DIFFERENT MEDICATIONS MANAGEMENT AND PHYSICAL THERAPY. I CAN'T BEND OVER. IT HURTS TO WIPE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033699	CONCEPTUS INC	12/30/2013	1/7/2014

Event Information:

Event Date (B3): 9/11/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 863566

Single Use:
Implant Date (E6): 9/11/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACEMENT (B)(6), 2013. FOLLOW UP HSG (B)(6), 2013 SHOWED ONE TUBE BLOCKED, ONE COIL EMBEDDED IN UTERUS. DOCTOR SAYS IT WON'T CAUSE ME ANY PROBLEMS WHERE IT IS, AND WANTS TO PUT A FILSHIE CLIP ON THE UNBLOCKED TUBE. DOCTOR DOESN'T KNOW WHETHER COIL IN QUESTION MIGRATED OUT OF FALLOPIAN TUBE OR WAS PLACED INCORRECTLY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2013-00067	BAYER HEALTHCARE LLC	12/30/2013	1/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/20/2011
Explant Date (E7): 1/21/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE REPORTED FEELING DIZZY/ LIGHTHEADEDNESS AND PAIN/ACHE IN PELVIC AREA BY 2011. ALSO IN 2011, SHE WENT TO URGENT CARE FOR CHEST PAINS AND SHORTNESS OF BREATH. SHE ALSO HAS HAD WORSENING LIGHTHEADEDNESS, BRAIN FOG, LACK OF FOCUS, EXTREME FATIGUE, MOOD SWINGS/ IRRITABILITY (FELT AS IF HER BLOOD WAS ON FIRE), BLOATED, SWELLING, CONSTANT ACHE ON HER LEFT SIDE WITH OCCASIONAL SHOOTING PAINS. SHE WAS TESTED FOR THYROID AND OTHER AT HER GENERAL CHECKUP. FOUND THYROID LOW AND RECEIVED MEDS WHICH HELPED WITH SHORTNESS OF BREATH. ALL OTHER SYMPTOMS BECAME WORSE AND ADDED JOINT PAIN IN HER HANDS, HIPS, KNEES AND ANKLES. MORE TESTING AND SPECIALIST REFERRAL FOR LUPUS, FIBROMYALGIA AND RHEUMATOID ARTHRITIS, BUT ALL TESTS CAME BACK NEGATIVE EXCEPT ELEVATED PANEL VALUES INDICATING INFLAMMATION. SHE WAS GIVEN ANTI-INFLAMMATORY FOR ABOUT 10 DAYS AND FELT BETTER, BUT SYMPTOMS RETURNED AFTER MEDICATION THERAPY WAS COMPLETE. ON (B)(6) 2013, THE CONSUMER HAD ESSURE REMOVED VIA LAPAROSCOPY. SHE IMMEDIATELY FELT THAT ACHE/PAIN IN PELVIC AREA WAS GONE. AFTER ABOUT A MONTH, SHE HAD NO BRAIN FOG, HAD ENERGY BACK, COULD FOCUS/ CONCENTRATE AND WORK AGAIN. SHE NO LONGER HAD JOINT PAIN IN HER HANDS, HIPS OR KNEES AND THE SWELLING HAS COME DOWN. SHE NO LONGER FELT THAT SHE WAS ON FIRE OR A GENERAL UNWELL FEELING. HER PANEL BLOOD VALUES WERE COMING DOWN AS OF LAST TESTING. THE CONSUMER WAS FEELING SO MUCH BETTER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033661	CONCEPTUS/BAYER	12/31/2013	1/6/2014

Event Information:

Event Date (B3): 12/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DAUGHTER IS A PRODUCT OF A FAILED MEDICAL DEVICE (ESSURE). I BELIEVE HER HEALTH PROBLEMS MAY BE LINKED TO ESSURE. OUT OF ALL MY KIDS, SHE HAS HAD UPPER RESPIRATORY INFECTIONS AND BEING SICK (COLDS/FEVERS). I BELIEVE MAY BE LINKED TO ESSURE WITH A NICKEL ALLERGY. WHILE PREGNANT WITH HER EVERY TEST POPPED RED FLAG AND HAD TO SEE AN ECHOCARDIOLOGIST OFTEN TO MAKE SURE HER HEART WAS FINE SINCE THEY RED FLAGGED THAT TOO. SHE JUST TURNED (B)(6). I MUST REPORT SINCE THERE ARE NO STUDIES ON ESSURE BABIES AND THE COMPANY WILL NOT GIVE ANY ANSWERS SINCE THEY CLAIM NO BABIES HAVE BEEN REPORTED. I KNOW OF AT LEAST 30 BABIES AND 1 DEATH FROM AN ESSURE GROUP OF 4000 THAT I BELONG TO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033685		12/31/2013	1/7/2014

Event Information:

Event Date (B3): 3/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/25/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE BIRTH CONTROL DEVICE. I HAVE SEVERE PAIN DAILY WITH ABDOMINAL BLEEDING FOR ALMOST 3 YEARS. MY PAIN IS IN MY RIGHT SIDE PELVIC AREAS THAT HAS SPREAD TO MY RIGHT HIP AND LOWER BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033686		12/31/2013	1/7/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/19/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATE ERRATIC PERIODS. SEVERE PELVIC PAIN, SEVERE BLOATING, ITCHY SKIN, BACK PAIN, UTIS, OVARIAN CYST, ADRENAL PROBLEMS, WEIGHT GAIN, VITAMIN D DEFICIENCY, METALLIC TASTE IN MOUTH, MIGRAINES, FATIGUE, INSOMNIA, LOSS OF LIBIDO, GASTROINTESTINAL ISSUE - CONSTIPATION, HAIR LOSS. COMPLETELY HEALTHY AND HAPPY BEFORE THESE IMPLANTS. IT'S LAWFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033687	BAYER	12/31/2013	1/7/2014

Event Information:

Event Date (B3): 10/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/1/2003
Explant Date (E7): 12/30/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED 10 YEARS AGO. MY OB/GYN, DR. (B)(6), WAS ONLY ABLE TO IMPLANT THE COIL ON MY LEFT SIDE. I STARTED HAVING DEBILITATING MIGRAINES ABOUT 1.5 YEARS AGO AND EVERY PAIN ON MY LEFT SIDE ABOUT 7 MONTHS AGO. I MADE AN APPT. WITH MY OB/GYN AND HE ORDERED AN ULTRASOUND. THE TEST SHOWED THE COIL HAD MIGRATED. I HAD A COMPLETE HYSTERECTOMY ON (B)(6) 2013. MY MIGRAINES ARE GONE BUT I STILL HAVE THE PAIN IN MY LEFT SIDE. I HAD A CT SCAN AND IT SHOWED NO ISSUES. I HAVE BEEN TO DR. (B)(6), AN UROLOGIST AND A PAIN SPECIALIST AND NO ONE CAN EXPLAIN WHY I HAVE THE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033688	BAYER	12/31/2013	1/7/2014

Event Information:

Event Date (B3): 12/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/16/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD THE ESSURE DEVICE IMPLANTED AND IT IS THE WORST CHOICE THAT I HAVE EVER DONE. I HAVE CONSTANT PAIN AND HEADACHES ALL THE TIME AND FEEL LIKE I AM GOING THROUGH LIFE LIKE A ZOMBIE, JUST GOING THROUGH THEORIZING OF LIFE. I CHOSE THIS AFTER MY FOURTH CHILD BECAUSE OF THE FAST RECOVERY TIME BUT IT HAS FOREVER CHANGED MY LIFE. I HAVE GAINED SO MUCH WEIGHT WITH IT; I LOOK AND FEEL LIKE I'M 8 MONTHS PREGNANT AND IT IS VERY DEPRESSING. I REALLY WISH I COULD HAVE KNOWN WHAT I KNOW NOW ABOUT ESSURE AND I WOULD HAVE NEVER GOTTEN IT AND TAKEN MY CHANCES WITH A REGULAR TUBAL. I AM REALLY PRAYING THAT 2014, I WILL BE ABLE TO GET THESE THINGS OUT OF ME AND GET MY LIFE BACK. IT REALLY IS THE WORST THING EVER TO LIVE IN CONSTANT PAIN AND DEPRESSION, MY KIDS DESERVE THEIR MOTHER BACK, NOT THIS PERSON THAT I HAVE BECOME DUE TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033689	CONCEPTUS	12/31/2013	1/7/2014

Event Information:

Event Date (B3): 11/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/12/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

APPROX 30-60 DAYS FOLLOWING ESSURE IMPLANT IN (B)(6) 2009, I BEGAN HAVING NUMBNESS AND TINGLING ON MY LEFT SIDE SPREADING FROM FEET TO FACE. MOST SIGNIFICANTLY UPPER ARM AND LEFT SIDE. THIS CONSTANT ISSUE CREATES A GENERAL PAIN/WEAK FEELING IN MY BODY. ON OCCASION MY LEFT BREAST/NIPPLE IS ALSO VERY TENDER. I DEVELOPED TIGHTNESS IN MY NECK (LEFT SIDE) THAT KEPT IT TILTED TO SIDE. I HAD NEUROLOGY CONSULTS, 2 MRI'S AND HAD NO DIAGNOSED CONDITION. A FEW WEEKS LATER, IN ADDITION TO THOSE SYMPTOMS, I LOST MY VOICE. AN ENT PROCEDURE WAS ORDERED FOR THIS WITH NO OUTCOME. I GOT VOICE BACK WITHIN A WEEK, BUT SINCE HAVE PERIODIC ISSUES WITH VERY DRY AND SORE THROAT AND DRY MOUTH. I WAS IN ER, URGENT CARE AND CLINIC SEVERAL TIMES, OTHER THAN REALIZING I HAD HIGH BLOOD PRESSURE, NONE OF THIS WAS EVER DIAGNOSED. I DECIDED TO LIVE WITH THE MISERY AS I COULD NOT AFFORD ADDITIONAL TESTING AND THERE WAS NO CLUE AS TO WHAT WAS GOING ON NOR A CONNECTION TO THE ESSURE. AS THE MONTHS WENT ON, I BEGAN HAVING EXTREMELY INTENSE MENSTRUAL CRAMPS AND PELVIC PAIN THAT FELT LIKE I WAS PERIODICALLY GETTING STABBED (WORSE ON THE L). BLEEDING LASTS 2-3 DAYS, BUT PRODUCES VERY LARGE CLOTS, IT FELT LIKE MY INSIDES WERE FALLING OUT. I ALSO HAVE WHITE/YELLOW DISCHARGE THROUGHOUT THE MOUTH. SINCE IMPLANT, EVERY TIME I HAVE INTERCOURSE I BLEED, THIS LASTS FOR A FEW HOURS AFTERWARD. AT 30-60 DAYS POST IMPLANT THROUGH TODAY, I HAVE EXTREME SWELLING IN MY ANKLES AND FEET, OFTEN PRODUCING SMALL FLESHY/WHITE BUMPS AROUND THE BASE OF MY FOOT. THIS OCCURS AFTER ONLY MINUTES OF WALKING. I CANNOT SIT ON HIGH STOOLS IF MY FEET DANGLE OR THE SWELLING BECOMES VERY INTENSE. IF I DRIVE MORE THAN AN HOUR, I HAVE TO WEAR COMPRESSION SOCKS. MY HANDS ALSO SWELL IF I GO FOR A WALK OR AT OTHER SOMEWHAT RANDOM TIMES. I HAVE DEVELOPED SEBORRHEIC KERATOSIS ON MY SCALP. I HAVE GAINED APPROX 40 LBS

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WHICH PRIMARILY WAS PUT ON THE YEAR FOLLOWING IMPLANT WITH A FEW ADDITIONAL POUNDS IN SUBSEQUENT YEARS. IN ADDITION, I HAVE SEVERE INFLAMMATION/BLOTTING IN MY ABDOMINAL AREA, OFTEN CANNOT GET PANTS BUTTONED. I PREVIOUSLY ONLY HAD WEIGHT ISSUES IN MY LOWER HALF AND HAD A SMALL WAIST, NOW I HAVE A VERY PROMINENT ABDOMINAL AREA UP TO BREASTS, SIMILAR TO WHEN I WAS PREGNANT. CANNOT GET THIS MID SECTION WEIGHT OFF. I HAVE A SHARP PAIN IN MY LEFT BUTT CHEEK, COMES AND GOES. AND SORE SPONGY NOODLES ON RIBCAGE THAT COME AND GO. MY HAIR HAS BECOME VERY DRY AND BRITTLE AND GROWS SLOWLY. AS HAVE MY EYELASHES AND EYEBROWS. I BEGAN TAKING BIOTIN AND B12 ALONG WITH A MULTIVITAMIN ABOUT 2 YEARS POST IMPLANT AND THEY HAVE NOT CHANGED ANYTHING. I HAVE CONSTANT FATIGUE DESPITE SLEEPING A FULL NIGHT. ALSO GET INSOMNIA AT TIMES. THROUGHOUT THE YEARS, I HAVE ALSO DEVELOPED SEASONAL ALLERGIES WHICH I TAKE ZYRTEC FOR. CURRENTLY, I NEED TO TAKE THIS EVERY DAY/YEAR ROUND. I HAVE FELT AN INCREASED SENSE OF ANXIETY, WHICH PROMPTED ME TO LEAVE A JOB I HAD FOR 17 YEARS (AS I THOUGHT IT WAS GETTING TOO STRESSFUL FOR ME). HOWEVER, DESPITE CHANGING JOBS, I CONTINUE TO HAVE THIS HEIGHTENED ANXIETY LEVEL. I ALSO OFTEN FEEL LIKE I CANNOT REMEMBER THINGS I USED TO AND THAT I HAVE A BIT OF A BRAIN FOG - BECAME EVIDENT WHEN I WAS TRAINING FOR NEW JOB. I NOTICE THIS ALSO WHEN I AM DRIVING, THAT I AM JUST GENERALLY DISTRACTED AND NOT AS AWARE OF SURROUNDINGS. I RECENTLY (OVER THE LAST 2-3 MONTHS) BEGAN TO EXPERIENCE PERIODIC CHEST HEAVINESS, DIFFICULTY BREATHING AND A RAPID HEART RATE. THIS CAN OCCUR ANY TIME I GET UP FROM SITTING, TAKE STAIRS AS WELL AS SOMETIMES WHEN I AM JUST SITTING - IT IS RANDOM. IT FEELS LIKE AN ASTHMATIC TYPE SITUATION. THIS PROMPTED ME TO RECENTLY SEEK MEDICAL ATTENTION AS WELL AS DO SOME RESEARCH TO TRULY FIND OUT WHY MY BODY JUST SEEMS TO BE FALLING APART. THIS IS WHEN I CAME ACROSS OTHER WOMEN WITH SIMILAR SYMPTOMS THAT HAD ALL HAD THE ESSURE IMPLANT. I AM CURRENTLY GOING THROUGH SOME MD VISITS AND TESTS THAT MAY LINK MY SYMPTOMS TO ESSURE, IT DOES MAKES THE MOST SENSE AS ALL SYMPTOMS BEGAN FOLLOWING IMPLANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033690	BAYER	12/31/2013	1/7/2014

Event Information:

Event Date (B3): 3/11/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/11/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL DEVICE INSERTED. THE DOCTOR FAILED TO TELL ME I NEEDED TO GET AN X-RAY TO MAKE SURE IT WORKED. MORE THAN 6 MONTHS LATER I LEARNED FROM MY DOCTOR FOR THE FIRST TIME THAT I NEEDED TO HAVE AN X-RAY TO MAKE SURE THE DEVICE WAS "INSTALLED" PROPERLY. WHEN I HAD AN X-RAY IT SHOWED THAT ONE OF THE TUBES HAD FLOATED RIGHT THROUGH MY FALLOPIAN TUBE. I THEN HAD A TUBAL LIGATION AND THE DOCTORS TRIED TO REMOVE ESSURE BUT COULD NOT GET TO IT. DEVICE "LAST" INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033715	ESSURE	1/2/2014	1/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GETTING THE ESSURE, I HAVE THE FOLLOWING SYMPTOMS: HEAVY BLEEDING, CRAMPING, FEVERS, SHARP STABBING PAINS, BACK PAIN, JOINT PAIN, CHEST PAIN, FATIGUE/LOSS OF ENERGY, HEADACHES OR MIGRAINES, NAUSEA METALLIC TASTE IN MOUTH, DIZZINESS, TINGLING, SENSATIONS NUMBNESS, WEIGHT GAIN, SEVERE BLOATING, SWELLING OF LEGS OR FEET, LEG PAINS, HAIR LOSS OR CHANGES, HAIR GROWTH IN NEW PLACES, DEPRESSION, SUICIDAL THOUGHTS, ABNORMAL MENSES, TEETH ISSUES, HEARTBURN, CLOUDINESS, FORGETFULNESS, UTI'S, BLADDER INFECTIONS, INSOMNIA, HEART PALPITATIONS, FLUTTERING FEELING OR SPASMS, ANXIETY PANIC ATTACK, BACTERIAL VAGINOSIS, CONSTANT SPOTTING FOUL SMELL OR DISCHARGE, MOOD SWINGS, CANDIDA OR YEAST INFECTIONS, BREAST PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	1/2/2014	1/8/2014

Event Information:

Event Date (B3): 12/27/2013 **Report Date (B4): 1/2/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B53030

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 12/27/2013

Event Description (B5):

ESSURE DEVICE WAS PASSED THROUGH THE SCOPE WHEN THE TIP WAS FOUND TO BE BENT. A SECOND DEVICE WAS OPENED AND INTRODUCED THROUGH THE SCOPE INTO THE TUBE AND IT BECAME DEFORMED IN USE. A THIRD DEVICE WAS PULLED TO BE USED WHEN THE PATIENT'S TUBE WAS IN SPASM AND COULD NOT BE COMPLETED DUE TO ITS CONDITION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033723	CONCEPTUS INC.	1/2/2014	1/8/2014

Event Information:

Event Date (B3): 12/27/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ES8305
Catalog # (E4):
Lot #(E4): B34803; B27054

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE DIDN'T DEPLOY. THE SPRING COIL DIDN'T RELEASE. THREE BOXES OF TWO DEVICES HAD TO BE OPENED TO COMPLETE THE CASE. THE DEVICE LOT NUMBER NOTED DID NOT DEPLOY. ALSO, A SECOND DEVICE WITH LOT NUMBER B34803 ALSO DID NOT DEPLOY. THE LAST DEVICE ATTEMPTED, LOT B27984 DID FUNCTION PROPERLY. OUR MARGUETTE GENERAL REPORTING NUMBER FOR THIS REPORT IN 2013 IS: (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033724	CONCEPTUS, INC.	1/2/2014	1/8/2014

Event Information:

Event Date (B3): 3/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50700145

Single Use:
Implant Date (E6): 3/27/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2013, SINCE THEN I HAVE SEVERE ALLERGIES THAT DOES NOT RESPOND TO ANY OVER THE COUNTER MEDICATIONS, SEVERE HEADACHES THAT DOES NOT RESPOND TO REGULAR OVER THE COUNTER MEDICINE, PAIN THE LOWER ABDOMEN, SHARP PAIN WHEN I STRETCH IN CERTAIN DIRECTIONS, SEVERE LOWER BACK PAIN, FATIGUE, CONSTIPATION, AND WEIGHT GAIN EVEN WITH DIET AND EXERCISE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033730	BAYER	1/2/2014	1/8/2014

Event Information:

Event Date (B3): 5/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLOATING, WEIGHT GAIN, PELVIC PAIN, JOINT PAIN AND SWELLING, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033731		1/2/2014	1/8/2014

Event Information:

Event Date (B3): 12/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 685787

Single Use:
Implant Date (E6): 8/6/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE PROCEDURE FOR ESSURE DONE IN 2010. ABOUT 5 MONTHS AFTER THE PROCEDURE I BEGAN TO DEVELOP PROBLEMS. I DISCLOSED AT MY PRE OP APPOINTMENT THAT I HAD AN ALLERGY TO METALS AND WAS NOT AWARE UNTIL I RECEIVED MY ID CARD THAT THE ESSURE COILS WERE MADE FROM NICKEL MY ID CARD THAT THE ESSURE COILS WERE MADE FROM NICKEL TITANIUM ALLOY. SINCE THEN I HAVE BEGAN TO PRODUCE OVARIAN CYSTS, PAINFUL AND IRREGULAR MENSTRUAL CYCLES, HEADACHES AND NUMEROUS OTHER SIDE EFFECTS. I HAVE HAD ULTRASOUNDS AND MANY OTHER VISITS WITH MY PHYSICIAN ABOUT THE POSSIBILITY OF ESSURE BEING THE ISSUE WITH NO LUCK. I INTEND ON GETTING A SECOND OPINION (B)(6) 2014. I DID NOT HAVE ANY PROBLEMS BEFORE WITH THESE SYMPTOMS UNTIL AFTER ESSURE WAS INSERTED AND ALL I WANT NOW IS FOR THEM TO BE OUT OF ME SO I CAN CONTINUE MY LIFE HEALTHY WITH MY YOUNG CHILDREN. I'M ONLY (B)(6) AND AM PRAYING THAT A PARTIAL HYSTERECTOMY WILL BE ONE OF MY OPTIONS TO HEAD IN THE LIFE DIRECTION I WANT TO SO THAT I CAN ONCE AGAIN ENJOY LIFE WITHOUT BEING IN CONSTANT PAIN. THANK YOU, (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033732	BAYER	1/2/2014	1/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE SUFFERED ONGOING AND SOMETIMES EXTREMELY SEVERE PAIN SINCE THE INSERTION OF ESSURE BIRTH CONTROL COILS IN 2008. I NOW HAVE MULTIPLE MENSTRUAL CYCLES IN ONE MONTH, VERY HEAVY BLEEDING, AND DIGESTIVE TRACT ISSUES, WHERE PAIN IS MARKEDLY INCREASED IN EXACT SAME SPOT. I CAN ONLY SLEEP IF I APPLY PRESSURE TO MY ABDOMEN OVER THE AREA. PAIN SOMETIMES RADIATES INTO MY BACK AND HIP. NEVER HAD A NICKEL ALLERGY BEFORE BUT SEEM TO NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033743	CONCEPTUS INC	1/2/2014	1/9/2014

Event Information:

Event Date (B3): 12/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING SEX, I DISCOVERED A SMALL PIECE OF METAL ON MY HUSBAND. I LATER DISCOVERED THAT IT WAS MY ESSURE IMPLANT. IT CAUSED SOME HEMORRHAGING, BUT NOTHING SEVERE. I WENT TO MY OBGYN DOCTOR AND WAS TOLD IT WAS NO BIG DEAL. I WAS DIRECTED TO HAVE A DYE TEST DONE, WHICH I DID. I WAS TOLD MY TUBES WERE CLOSED. THEY DIDN'T INSERT A NEW IMPLANT AND IN (B)(6) 2009, I DISCOVERED I WAS PREGNANT. I HAD A MEDICAL ABORTION DUE TO THIS PROBLEM. I AM IN PAIN EVERY MONTH. I HAVE TO TAKE BIRTH CONTROL WHICH CAUSES EXTREME PAIN ON MY RIGHT SIDE WHERE THE IMPLANT IS LOCATED. I HAVE NEVER BEEN DIAGNOSED WITH A METAL ALLERGY, BUT I CAN'T WEAR EARRINGS IN ONE EAR AND HAVE HAD SEVERAL PROBLEMS WITH METAL BEFORE. I HAD A CESAREAN AND MY TUBES SHOULD HAVE BEEN DONE THEN, BUT THE DOCTOR INSISTED THE ESSURE WAS "BETTER." AFTER I WAS PREGNANT, MY DOCTOR OF MANY YRS ONLY SAID TO ME, "SORRY, I'M PRO LIFE!" JUST FOR AN ADDED NOTE. I HAVE CHANGED MY DOCTOR AND IT SEEMS THAT NO ONE HAS INFO OR IS WILLING TO REMOVE THIS IMPLANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033638	BAYER	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 12/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS A HEALTHY WOMEN UNTIL I GOT THE ESSURE IN 2010. EVER SINCE I HAVE HAD THE ESSURE I SUFFERED FROM SEVERE PAIN TO STOMACH AND LOST OVER 160 LBS. COULDN'T EVEN HANDLE SEXUAL INTERCOURSE. I COULDN'T EAT BECAUSE PAIN WAS TOO BAD AND WAS VERY WEAK. AS OF (B)(6) 2013 I HAD TO GET A HYSTERECTOMY TO GET COILS REMOVED. THIS PRODUCT NEEDS TO BE TAKEN OFF THE MARKET, AS YOUNG WOMEN DON'T DESERVE TO BE LIED TO AND SECOND PAIN AND SUFFERING. TRYING TO LIVE LIFE IS RIDICULOUS. THE WHOLE COMPANY SHOULD BE SHUT DOWN AND SUED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033639	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 11/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN I GOT THE PROCEDURE DONE EVERYTHING WENT FINE. THE DOCTOR EXPLAINED THAT I WOULD CRAMP AND BLEED FOR A FEW DAYS. AFTER 2 WEEKS OF EXCRUCIATING PAIN AND SICKNESS MY DOCTOR AGREED TO SEE ME. HE DECIDED I HAD A MINOR INFECTION AND PRESCRIBED AN ANTIBIOTIC AND A PAIN PILL. THE INFECTION WENT AWAY AFTER 3 WEEKS OF ANTIBIOTICS. THE PAIN HAS NEVER GONE AWAY. IT FEELS LIKE I AM BEING STABBED IN THE PELVIC AREA EVERY TIME I TRY TO EXERCISE OR HAVE SEX. MY STOMACH LOOKS LIKE I AM 6 MONTHS PREGNANT AND MY PERIODS ARE TERRIBLE. I AM HAVING 2 PERIODS A MONTH AND THEY ARE EXTREMELY HEAVY! I CAN FEEL THE COILS ALL THE TIME AND I THINK IT IS BECAUSE OF MY NICKEL ALLERGY. I HAVE DEVELOPED HYPERTHYROIDISM. I LOSE HAIR ALL THE TIME AND I AM CONSTANTLY TIRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033640	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAKING UP OUT OF A DEAD SLEEP, SCRATCHING MYSELF TO THE POINT WHERE I WAS GIVING MYSELF BRUISES THE SIZE OF SOFTBALLS, AND THEN IT GOT SO BAD, I WAS MAKING SORES ON MY BODY. FEELS LIKE MY SKIN IS ON FIRE, AND I'M ALSO BURNING FROM THE INSIDE OF MY BODY, OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033641	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 7/5/2011	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PROCEDURE WAS DONE IN THE OFFICE AND IT WAS VERY PAINFUL. FOLLOWING THAT PROCEDURE HAD CONSTANT PAIN IN MY LOWER LEFT PELVIC AREA. AT 3 MONTHS HAD THE X-DAY DONE TO LEARN THAT MY LEFT TUBE WAS NOT BLOCKED. AFTER 1.5 YEARS OF CHRONIC PAIN, SAW A NEW DOCTOR WHO REMOVED MY TUBES. AFTER DISSECTION WE LEARNED THE COILS WERE NOT THERE. JUST HAD A CAT SCAN SHOW MY COILS ARE IN MY UTERINE WALL. HAVE AN APPOINTMENT TO DISCUSS A HYSTERECTOMY TO RID MY BODY OF THESE COILS AND MY PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033642	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 7/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED WITH NUMBNESS IN JAW JUST 3 WEEKS AFTER PROCEDURE, CONSTANT NAUSEA, DIZZINESS, BODY ACHES, HEADACHES, NECK PAIN, CRAMPING, HEAVY CYCLE- SOMETIMES MORE THAN 1X PER MONTH, DISCHARGE, CONSTANT DIARRHEA, GALLSTONES, GALLBLADDER REMOVAL, INFLAMED INTESTINES, EAR ACHES, WORSE ALLERGIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033643	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 8/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PUT IN WOKE UP IN HORRIFIC PAIN THAT HAS YET TO GO AWAY. ALSO NOW SUFFER FROM INSANE NIGHT SWEATS AND HOT FLASHES ASSOCIATED WITH MY MENSTRUAL CYCLE. ALSO TERRIBLE MOOD SWINGS AROUND MY CYCLE. STILL SEEKING TREATMENT FOR ALL THESE AND OTHER SYMPTOMS. HAVE HAD BLOOD WORK THYROID TESTS URINE ANALYSIS ULTRA SOUND AND MULTIPLE OBGYN VISITS. HAVE BEEN TREATED FOR UTI AND PELVIC INFRACTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033644	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 8/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PUT IN, WOKE UP IN HORRIFIC PAIN THAT HAS YET TO GO AWAY. ALSO NOW SUFFER FROM INSANE NIGHT SWEATS AND HOT FLASHES ASSOCIATED WITH MY MENSTRUAL CYCLE. ALSO TERRIBLE MOOD SWINGS AROUND MY CYCLE. STILL SEEKING TREATMENT FOR ALL THESE AND OTHER SYMPTOMS. HAVE HAD BLOOD WORK, THYROID TESTS, URINANALYSIS, ULTRA SOUND AND MULTIPLE OB-GYN VISITS. HAVE BEEN TREATED FOR UTI AND PELVIC INFECTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033645	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 9/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

VERY HEAVY BLEEDING WITH PERIOD, SEVERE CRAMPING. EVERY MONTH NOW IT'S REALLY PAINFUL AND HEAVY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033646	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 11/13/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE IMPLANTED, I HAVE HAD LOWER PELVIC AND LOWER BACK PAIN , SHOOTING PAIN ON MY LOWER LEFT SIDE ALONG WITH HEAVY IRREGULAR PERIODS (SOMETIMES 2 TO 3 IN A MONTH), PAIN DURING AND AFTER SEX WHICH HAVE PROGRESSIVELY GOTTEN WORSE OVER THE LAST YEAR AND A HALF. I HAVE ALSO HAD HAIR LOSS, MAJOR FATIGUE, CRAMPING THAT FEELS LIKE FULL ON LABOR PAINS, WEIGHT GAIN PROGRESSIVELY SINCE HAVING ESSURE. I WEIGHED (B)(6) WHEN I GOT ESSURE, I NOW WEIGH (B)(6). I HAVE HAD A PELVIC ULTRASOUND AND THEN AN EXPLORATORY LAPAROSCOPY/HYSTEROSCOPY PLUS D AND C. THE RESULTS CAME BACK STATING MY RIGHT COIL COULD BE EMBEDDED IN MY UTERUS AND I HAVE ABNORMAL CELL GROWTH IN THE LINING OF MY UTERUS. MY DOCTOR THEN RECOMMENDED I HAVE A HYSTERECTOMY WHICH I'M SCHEDULED FOR (B)(6) 2013. I HAVE TO PAY OVER (B)(6) BEFORE THE HYSTERECTOMY CAN BE PERFORMED. I HAD NONE OF THESE ISSUES BEFORE ESSURE AND HAVING THIS DONE HAS CAUSED ME SO MUCH PAIN AND SUFFERING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033647	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 2/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE PELVIC PAIN AND BACK PAIN TO THE POINT WHERE IT HURTS TO SIT, STAND, AND WALK AND I GET TO THE POINT WHEN I SIT FOR MORE THAN 5 MINUTES AND THEN GET UP MY BACK IS SO STIFF AND IT HURT 10 TIME WORSE, I KEEP GETTING UTI WHEN I HAVEN'T DRINK SODA IN ALMOST 2 YEARS, REAL BAD HEADACHES, IT HURTS TO HAVE INTERCOURSE. IT GETS SO BAD THAT I CRY. I BEEN GOING THRU THIS FOR 7 YEARS AND I CANT TAKE ANY MORE, I HAVE LOST MY ENERGY AND I AM TOO TIRED TO DO ANYTHING BECAUSE OF THE PAIN THAT I LIVE WITH FOR THE PAST 7 YEARS. I HAVE GOTTEN PREGNANT A YEAR AND A HALF AFTER HAVING THE ESSURE PROCEDURE DONE. WHEN I CALLED THE ESSURE COMPANY THEY TOLD ME THAT I WAS THE FIRST TO GET PREGNANT WITH THE ESSURE BUT THEN OTHER WOMEN TELL ME THAT THEY HAVE GOTTEN PREGNANT TOO AND SOME HAVE MISCARRIED AND THE ESSURE COMPANY TELLS THEM THE SAME THING. SOMETHING IS RIGHT HERE AND THIS PROBLEM NEEDS TO BE FIXED BECAUSE I AM TIRED OF BEING IN THIS PAIN. PLEASE TAKE THIS ESSURE PRODUCT OFF THE MARKET SO THAT OTHER WOMEN WILL NOT SUFFER LIKE THE REST OF US. THANK YOU.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033648	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 9/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALLERGIC REACTION TO ESSURE, HAD TO HAVE HYSTERECTOMY, AND GALLBLADDER, AND APPENDIX REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033657	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM THE TIME THE DEVICE WAS INSERTED UNTIL PRESENT DAY, I HAVE EXPERIENCED CONSTANT NAUSEA, PAIN IN MY PELVIS, EXCRUCIATING OVULATION, MENSTRUAL CYCLES THAT ARE VERY PAINFUL AND HEAVY WITH TONS OF CLOTS, RASHES, AN ALLERGY TO JEWELRY AND A SENSE OF MENTAL FOG. RECENTLY, IN THE LAST 12 MONTHS, MY SENSE OF MENTAL FOG HAS TURNED INTO ANXIETY AND ANGER. MY SYMPTOMS HAVE GONE FROM BAD TO WORSE! MY IMPLANTS HAVE MIGRATED! I NOW HAVE SEVERE INFLAMMATION IN MY JOINTS, INCLUDING BUT NOT LIMITED TO MY HIPS. I AM CONSTANTLY HAVING PREGNANCY SYMPTOMS. MY MENSTRUAL CYCLES ARE OUT OF WHACK. FINDING A DOCTOR THAT WILL TAKE THIS SERIOUSLY HAS BEEN NEARLY IMPOSSIBLE. NOT ONE DOCTOR HAS DONE ANY LAB TESTS TO CONFIRM OR DENY THAT ESSURE IS/ISN'T THE PROBLEM! I WAS ALSO DIAGNOSED WITH CHRONIC PANCREATITIS(NOT RELATED TO ALCOHOL OR DIET) AND ANXIETY DISORDER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033658	CONCEPTUS	1/2/2014	1/15/2014

Event Information:

Event Date (B3): 3/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE BECAUSE I WAS TOLD IT WAS A GOOD PRODUCT WITH LOW SIDE EFFECTS AND I WAS SCARED TO BE PUT TO SLEEP. SINCE I HAVE HAD ESSURE DONE IN (B)(6) 2010, I HAVE HAD PROBLEMS... CRAMPING, SHARP STABBING PAINS IN MY HIP AND BELLY, CHEST PAIN, FATIGUE, LOSS OF ENERGY, HEADACHES, METALLIC TASTE IN MOUTH, DIZZINESS, MOOD SWINGS, HOT FLASHES, HEART FLUTTERING, BAD PMS, I NEVER HAD THESE PROBLEMS BEFORE I GOT THE ESSURE. I CAN'T STAND LIVING THIS WAY. I WANT TO HAVE IT REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033748	BAYER	1/3/2014	1/9/2014

Event Information:

Event Date (B3): 8/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/11/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE PROCEDURE IN 2011, I HAVE SINCE EXPERIENCED SEVERE PAIN, CONTINUOUS BLEEDING DAILY REQUIRING CONSTANT USE OF FEMININE PRODUCTS AND EMOTIONAL DISTRESS. AFTER HAVING AN ULTRASOUND, IT WAS DETERMINED THE ESSURE SPRING HAS MOVED AND LODGED ITSELF INTO MY UTERUS. THE PRODUCT HAS BEEN TRAVELING THROUGH MY UTERINE MUSCLE FOR TWO YRS NOW. THE DOCTOR WOULD LIKE TO PERFORM A HYSTERECTOMY, BUT, DUE TO ECONOMY AND MY CURRENT LAPSE OF INSURANCE, I AM UNABLE TO HAVE THE PROCEDURE. I AM (B)(6) YRS OF AGE, TO DATE. I HAVE ALWAYS BEEN HEALTHY WITH NO HEALTH CONDITIONS. I DO NOT SMOKE, DRINK OR USE DRUGS AT ALL. THIS PRODUCT HAS CAUSED ME INDESCRIBABLE PAIN, MY INTIMATE LIFE WITH MY SPOUSE IS NONEXISTENT, I HAVE TO LIMIT PLAY WITH MY CHILDREN AND TAKE FREQUENT BREAKS AT WORK DUE TO PAIN AND BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033751	BAYER	1/3/2014	1/9/2014

Event Information:

Event Date (B3): 8/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/8/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS INSERTED INTO MY FALLOPIAN TUBES (B)(6) OF 2012 AND HAVE HAD MANY SIDE AFFECTS THAT HAVE GONE UNEXPLAINED. I HAVE SEVERE PAINS IN MY LOWER ABDOMEN THAT MAY BEGIN AS A PIERCING, STABBING PAIN AND THEN TURN INTO STABBING PAINS SEVERAL TIMES A MONTH. I HAVE A LOT OF FATIGUE AND BRAIN FOG. I ALSO HAVE A DISTENDED ABDOMEN IN WHICH I LOOK AS IF I AM 6 MONTHS PREGNANT. DURING MY PERIOD, I HAVE AT LEAST A WEEK'S WORTH OF VERY HEAVY BLEEDING WITH QUARTER SIZE OR LARGER CLOTS. ALL OF MY SYMPTOMS GET PROGRESSIVELY WORSE INSTEAD OF BETTER AS TIME GOES BY. I ALSO SUFFER FROM MIGRAINES THAT MY USUAL MIGRAINES MEDICINE CANNOT HELP WITH ANY LONGER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033766	CONCEPTUS, INC. / BAYER	1/6/2014	1/13/2014

Event Information:

Event Date (B3): 5/30/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): ESSURE SYSTEM
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A96180

Single Use:
Implant Date (E6): 5/30/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE "EHELL" IN (B)(6) 2013, SINCE I HAVE HAD HORRIBLE/ SEVERE PROBLEMS SINCE THEY HAVE BEEN PLACED. I'M A (B)(6) HEALTHY ACTIVE WOMAN BUT SINCE IMPLANTATION, I HAVE BEEN HAVING SO MANY HEALTH ISSUES. I HAVE BLOATING, PAIN, SEVERE BLEEDING (WHICH SENT ME TO EMERGENCY ROOM TO END UP BEING PUT ON HORMONE PILLS TO STOP BLEEDING) AND THEN GOT SENT HOME MASKING UP MY PROBLEM! I HAVE HAD HAIR LOSS, ACNE, HORRIBLE PERIODS, MOODY, EXHAUSTED DAILY, WEIGHT GAIN, RASHES WITH WEARING MY WEDDING BAND AND ANOTHER JEWELRY, I FEEL VIBRATING/PULSATING WHERE THE COILS ARE, BACK AND STOMACH PAIN. ALL I WANT IS TO HAVE THESE REMOVED AND BE HEALTHY AGAIN!. I WANT THESE OFF THE MARKET SO OTHER WOMEN DON'T END UP LIKE ME! I HAVE MISSED WORK AND MISSED TIME WITH MY HUSBAND AND KIDS DUE TO MY SUFFERING!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033769	CONCEPTUS	1/6/2014	1/13/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/7/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE 2006 AND 7 YEARS LATER, I HAVE EXPERIENCING EXCRUCIATING PAIN DURING MY CYCLE. MY PAIN STARTED A FEW YEARS AGO AND MY CURRENT DOCTOR COULDN'T EXPLAIN WHY. I'VE HAD 2 ULTRASOUNDS DONE, IN WHICH THEY SHOW MY UTERUS IS NOW THE SIZE OF A 3 MONTH PREGNANT WOMAN. AFTER DOING MY OWN RESEARCH, I STRONGLY FEEL THAT ESSURE IS THE REASON FOR MY PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033775	CONCEPTUS/BAYER	1/6/2014	1/13/2014

Event Information:

Event Date (B3): 12/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/7/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2011, I HAD THE ESSURE DEVICE INSERTED. IN (B)(6) 2011 I HAD THE TEST TO FIND OUT IF DEVICE WAS PLACED CORRECTLY, IT WAS. BETWEEN (B)(6) 2011 AND (B)(6) 2013, THE DEVICE HAD COME OUT OF A FALLOPIAN TUBE AND MIGRATED INTO MY UTERUS. AFTER LIVING IN PAIN AND CONSTANT BLEEDING, HEADACHES, AND LOWER PELVIC PAIN, I RETURNED TO DR. HE ORDERED AN INTERNAL ULTRASOUND AND DISCOVERED THE ESSURE SPRING MIGRATED TO SOMEWHERE IT WASN'T SUPPOSED TO BE. MY DOCTOR WANTS ME TO HAVE A COMPLETE HYSTERECTOMY TO REMOVE THEM. I AM AGREEING TO THIS PROCEDURE SO THAT IT DOES NOT HAPPEN AGAIN ON THE OTHER SIDE. I AM IN A LOT OF PAIN, FEEL DEPRESSED AND HAVE NO ENERGY WHAT SO EVER ALONG WITH A LIST OF OTHER SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033734	CONCEPTUS	1/7/2014	1/14/2014

Event Information:

Event Date (B3): 12/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

YELLOWISH-GREEN DISCHARGE, CONSTANT SINUS INFECTIONS, PELVIC PAIN AND LOWER BACK PAIN. PAIN DURING SEX AND AFTER. NAUSEA AND SHOOTING PAIN IN LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033736	CONCEPTUS	1/7/2014	1/14/2014

Event Information:

Event Date (B3): 9/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLOATING, WEIGHT GAIN, CONSTANT PAIN, FLUTTERS, MIGRAINES, NERVE PAIN, BACK PAIN, ACNE, MOODY, DEPRESSED, HEAVY BLEEDING, PINCHING IN HIPS, BOWEL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033787	BAYER	1/7/2014	1/14/2014

Event Information:

Event Date (B3): 7/11/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/11/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM EXPERIENCING ABNORMAL CHRONIC ABDOMINAL PAIN SINCE THE IMPLANTATION OF THE ESSURE STERILIZATION STENTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033735	CONCEPTUS	1/7/2014	1/15/2014

Event Information:

Event Date (B3): 12/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD A HORRIBLE ONGOING HEADACHE, RASH ON MY BODY, HEAVY PERIODS, BACK PAIN, STOMACH PAIN THAT RADIATES DOWN MY LEG AND MAKES MY LEFT SIDE NUMB, THYROID IN MY THROAT FROM ESSURE, MENSTRUAL PERIOD IS HEAVY!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033737	CONCEPTUS	1/7/2014	1/15/2014

Event Information:

Event Date (B3): 10/13/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS "SOLD" TO ME AS A QUICK AND CONVENIENT METHOD OF PERM BIRTH CONTROL. IT HAS CAUSED MANY ADVERSE REACTIONS IN MY BODY. TO PROVIDE A CONDENSED LIST . . SYMPTOMS RANGE FROM SEVERE DIZZINESS, MULTIPLE CYCLES PER MONTH, EXTREME DERMATOLOGY ISSUES RESULTING IN MEDICATION, PAINFUL OVULATION, SEVERE BLOATING AND WEIGHT FLUCTUATION JUST TO NAME A FEW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033738	CONCEPTUS	1/7/2014	1/15/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AS OF (B)(6) 2013, I WAS TRAINING FOR A HALF MARATHON, BUT AFTER COMPLETING IT, I NOTICED I WAS HAVING EXTREME FATIGUE, NO ENERGY, HAIR LOSS, DEPRESSION, FORGETFULNESS, BRAIN FOG, A LITTLE ANXIETY AND FELT VERY MOODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033739	CONCEPTUS	1/7/2014	1/15/2014

Event Information:

Event Date (B3): 12/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DUE TO SEVERE NICKEL ALLERGY RESULTING IN CHRONIC SEVERE LOWER ABDOMINAL/PELVIC PAIN, I HAD TO HAVE A HYSTERECTOMY REMOVING ESSURE DEVICES FROM MY BODY, ALONG WITH MY FALLOPIAN TUBES, UTERUS, AND CERVIX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033740	CONCEPTUS	1/7/2014	1/15/2014

Event Information:

Event Date (B3): 12/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS FOUND THAT MEASURE DEVICE HAS MIGRATED TO MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033832	CONCEPTUS INC.	1/9/2014	1/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALMOST TWO YEARS AGO, I HAD THE ESSURE BIRTH CONTROL IMPLANTED. I WAS NEVER QUESTIONED ABOUT A NICKEL ALLERGY, OR WAS WARNED OF SERIOUS SIDE EFFECTS, IN FACT I WAS TOLD HOW MUCH SAFER, HEALTHIER AND PAINLESS THE ESSURE WOULD BE INSTEAD OF HAVING MY TUBES TIED OR A HYSTERECTOMY. AFTER THE IMPLANTS, VOMITING PERIODICALLY BEGAN, SEVERE SWEATING, POUNDING HEADACHES, IT FELT LIKE MY BRAIN WAS SPINNING OUT OF CONTROL THEN BACK PAIN SO SEVERE I COULD BARELY WALK. I WENT TO MY LOCAL EMERGENCY ROOM THIS PAST SUMMER BEGGING FOR ANSWERS, I BEGGED TO HAVE THE STENTS CHECKED, THEY TREATED ME LIKE A PAIN MEDICINE JUNKIE EVEN AFTER I REFUSED ANY PAIN MEDICINE. I WAS A JOKE, I WENT HOME, CRAMPS IN MY STOMACH HURT SO BAD I CRIED MYSELF TO SLEEP CURLED UP IN A BALL SHAKING, WOKE TO SWEATS, BRAIN SPINNING, THE WORLD IN MY EYES. I FAINTED BUSTING MY CHIN OPEN. LATER RIGHT BREAST BECAME SWOLLEN, ITCHY, I WENT TO SEE MY PRIMARY CARE PHYSICIAN FOR THE SEVERE BREAST PAIN. I INFORMED HER OF MY ESSURE IMPLANT; HOWEVER, SHE HAD NEVER HEARD OF IT, SHE IS A PRIMARY CARE PHYSICIAN IN (B)(6). MY IMPLANTS WERE DONE BY AN OB-GYN IN (B)(6). SHE DIAGNOSED ME WITH TIETZE SYNDROME AND PUT ME ON TRAMADOL, WHICH JUST MADE MY HEAD WORSE, I BLOAT RANDOMLY, THE CRAMPS ARE CONSTANT, THE PAIN FROM THE BOTTOM OF MY SPINE TO THE BASE OF MY NECK IS CONSTANT. INTERCOURSE IS NEARLY IMPOSSIBLE DUE TO PAIN AND BLEEDING. WHEN THE PAIN RESTRICTS MY ABILITY TO WALK OR FUNCTION, HOW AM I TO RAISE MY CHILDREN? I HAVE BECOME INCREASINGLY MORE DEPRESSED AND I HAVE FITS OF SELF-RAGE FEELING SO USELESS! I WAS NEVER WARNED OF THESE SIDE EFFECTS! MY LIST COULD GO ON FOR MILES TO INCLUDE ACNE! THIS PRODUCT HAS BEEN SLOWLY DESTROYING MY LIFE AND THE DOCTORS DENYING MY

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FEELINGS THAT THE ESSURE WAS THE CAUSE AND THE EMERGENCY ROOM TEAM TURNING A BLIND EYE HAS LEFT ME TO SHUT OUT THE WORLD, BELIEVING NO ONE COULD HEAR MY PAIN UNTIL NOW! I KNOW I AM NOT ALONE IN THE NIGHTMARE OF ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00001	BAYER HEALTHCARE LLC	1/9/2014	1/23/2014

Event Information:

Event Date (B3): 11/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 8/6/2007
Explant Date (E7): 11/30/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A FEMALE CONSUMER HAD ESSURE ((B)(4)) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED THAT AFTER THE INSERTION PROCEDURE, SHE HAD SEVERE PAIN IN RIGHT ABDOMEN. SHE WENT TO THE DOCTOR WHO PERFORMED SURGERY OVER AND OVER. WAS TOLD PAIN WAS NOT RELATED WITH ESSURE IMPLANTS. THE PAIN GOT WORSE IN 2009. THE RIGHT COIL HAD MIGRATED FROM THE TUBE AND A LAPAROSCOPIC SUPRACERVICAL HYSTERECTOMY WAS PERFORMED TO REMOVE THE COILS AND TUBES. THE PHYSICIAN FOUND THE COIL HAD ATTACHED ITSELF TO THE SMALL BOWEL. ESSURE REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00002	BAYER HEALTHCARE LLC	1/9/2014	1/23/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 6/16/2013
Explant Date (E7): 10/3/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A FEMALE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. IT WAS REPORTED THAT ONE COIL MIGRATED INTO CONSUMER'S BOWEL AND PIERCED IT. ACCORDING TO THE REPORTER, IF ESSURE HAD NOT BEEN SURGICALLY REMOVED ON (B)(6), 2013, SHE WOULD HAVE HAD MAJOR DAMAGE. AT TIME OF REPORT, SHE WAS EXPERIENCING TONS OF PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00003	BAYER HEALTHCARE LLC	1/9/2014	1/23/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. SHE STATED SHE WAS IN A LOT OF PAIN. SHE CAME HOME AND THE PAIN CONTINUED. SHE ALSO REPORTED BLEEDING A LOT. THE PAIN GOT WORSE OVER THE NEXT FIVE YEARS. SHE IS ALLERGIC TO NICKEL. IN (B)(6), HER PAIN WAS SO BAD THAT SHE COULD NOT STAND UP. SHE SUFFERED CHRONIC PELVIC PAIN WITH A POSSIBLE MISPLACED ESSURE. SHE HAD A HYSTERECTOMY (THE ONLY OPTION HER PHYSICIAN GAVE HER). SHE WAS TOLD THAT THE ESSURE DEVICE HAD PERFORATED HER UTERUS AND WAS LOOSE IN HER ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033847	BAYER	1/10/2014	1/16/2014

Event Information:

Event Date (B3): 2/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/8/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD THE BIRTH CONTROL ESSURE FOR ABOUT 4 YRS, EVERYTHING SEEMED FINE FOR AWHILE THEN I STARTED HAVING WEIRD UNEXPLAINED STOMACH PROBLEMS THAT INCLUDE SHARP PAINS IN MY ABDOMEN THAT AT TIMES LEAD TO SEVERE VOMITING, DIARRHEA, CONSTANT BLOATING, AND UNEXPLAINED PAIN. AT TIMES, IT FEELS LIKE THERE'S SOMETHING IN THE LOWER PART OF MY VAGINA ON THE INSIDE (LIKE A SMALL TAMPON) THAT'S BEEN WRONGLY INSERTED. REALLY ODD FEELING LIKE THERE IS SOMETHING THERE, OR OUT OF PLACE. I RECENTLY SKIPPED A PERIOD FOR THE FIRST TIME EVER UNLESS I WAS PREGNANT. MY PERIODS HAVE ALWAYS BEEN LIKE CLOCK WORK. I AM PREGNANT. I GET UNEXPLAINED LEG PAINS/CRAMPS, STOMACH CRAMPS, TERRIBLE HOT SPELLS, BACK ACHES OUT OT NO-WHERE THAT LAST FOR HRS. MY STOMACH PROBLEMS, AND ABDOMEN PAINS SEEM TO BE THE MOST PART OF UNEXPLAINED ISSUES. I HAD AN UPPER GI AND COLONOSCOPY DONE WHICH DID NOT DETECT THE CAUSE OF ISSUES I HAVE. I HAVE AN APPOINTMENT WITH MY OBGYN NEXT WEEK TO HOPEFULLY GET SOME ANSWERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033848	CONCEPTUS	1/10/2014	1/16/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 509798

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RIGHT SIDE PAIN RADIATING TOWARDS BOTH KNEES, BACK AND LEG PAIN SEVERE, SEVERE BLEEDING AND CRAMPS DURING MENSTRUAL CYCLE, UNABLE TO MOVE, CONSTANT PAIN EVERYDAY, WEIGHT GAIN, NO ABLE TO WALK OR EXERCISE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033849	BAYER	1/10/2014	1/16/2014

Event Information:

Event Date (B3): 2/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2012
Explant Date (E7): 12/13/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED (B)(6) 2012, REMOVAL OF FALLOPIAN TUBES WITH COILS ON (B)(6) 2013 BECAUSE OF ALL THE SICKNESS THAT HAS OCCURRED SINCE THEY WERE PLACED. STILL IN SEVERE PAIN AND HAVING TO GO BACK FOR A TOTAL HYSTERECTOMY NOW.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	1/10/2014	1/30/2014

Event Information:

Event Date (B3): 1/8/2014 **Report Date (B4): 1/10/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): A57108

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL WOULD NOT RELEASE FROM CANNULA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033794	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 9/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABNORMAL BLEEDING PL, PELVIC PAIN, LOST OF HAIR, LOST INTEREST IN SEX, ALLERGIES FOR LONG PERIOD, BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033795	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 9/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I POSTED EARLIER BUT FORGOT TO GIVE A FULL LIST OF THE ADVERSE SYMPTOMS THAT I HAVE EXPERIENCED SINCE I HAD THE ESSURE DONE ON (B)(6) 2009. I HAD NONE OF THESE SYMPTOMS UNTIL AFTER I HAD THE ESSURE PROCEDURE DONE. THE FULL LIST INCLUDES: WEIGHT GAIN, TROUBLE LOSING WEIGHT, SEVERE HAIR LOSS, RINGING IN EARS, DEPRESSION, SUICIDAL THOUGHTS, VITAMIN B-12 DEFICIENT, VOMITING DURING PERIOD, HEAVY PERIODS, SEVERE PELVIC PAIN/STABBING PAIN (ESPECIALLY IN RIGHT SIDE), BRAIN FOG (SHOCKS), LONGER PERIODS, STABBING SENSATION IN VAGINA, PAINFUL INTERCOURSE, MIGRAINES, DISCHARGE, METALLIC TASTE IN MOUTH (HUSBAND CAN EVEN TASTE IT WHEN HE KISSES ME), FATIGUE, LOSS OF ENERGY, ACNE, VISION PROBLEMS SUCH AS FLOATERS, BLURRED VISION, LOSS OF PERIPHERAL VISION, MOOD DISORDERS, INSOMNIA, SEVERE BLOATING, JOINT PAIN, DIZZINESS, BREAST PAIN, BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033797	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 1/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM (B)(6). I WAS TALKED INTO GETTING THE ESSURE PROCEDURE DONE BY MY DOCTOR, AFTER ASKING FOR A TUBAL LIGATION. SHE ACTED LIKE I WAS CRAZY FOR WANTING THE TUBAL BECAUSE THE ESSURE WAS SO MUCH EASIER AND AN IN AND OUT PROCEDURE, WITH NO DOWN TIME. I HAD MY PROCEDURE DONE (B)(6) 2013, IT TOOK HER ABOUT 45MIN TO 1HOUR TO PLACE THE COILS. ONE SIDE SHE HAD TROUBLE ON, SO GAVE IT A REST AND SWITCHED TO THE OTHER, THEN CAME BACK AND FINALLY GOT IT PLACED. AFTER THE PROCEDURE I HAD NON-STOP BLEEDING, BACK PAIN, CRAMPING, BLOATING, AND SHARP PAINS IN ABDOMEN. NOW, (9 MONTHS LATER) AFTER CALLING AND COMPLAINING CONSTANTLY, SHE HAD ME DO A TRANSVAGINAL ULTRASOUND THAT FOUND THAT ONE COIL HAD MIGRATED INTO MY UTERUS. LONG STORY SHORT, MY DOCTOR WILL BE GIVING ME A PARTIAL HYSTERECTOMY, TAKING OUT BOTH FALLOPIAN TUBES AND UTERUS. I WOULD DEFINITELY ADVISE AGAINST GETTING THIS DONE. I AM SO UPSET I AM HAVING TO GET A PARTIAL HYSTERECTOMY AT THE AGE OF 25. I WILL NEVER AGAIN LISTEN TO A DOCTOR WITHOUT DOING A LOT OF RESEARCH ON A PRODUCT FIRST!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033799	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 3/10/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM DAY 1 I WOULD HAVE A PERIOD THAT WOULDN'T STOP . I BLED FOR NEARLY 15 MONTHS BEFORE HAVING MY UTERUS AND CERVIX REMOVED. SINCE 2007 I HAVE HAD CONSTANT PAIN IN MY BACK, HIPS , LEGS. I CAN'T HAVE SEX WITH MY HUSBAND WITHOUT SEVERE PAIN AND USUALLY END UP IN TEARS . I HAVE A METAL TASTE IN MY MOUTH 24/7. I AM BLOATED TO LOOK LIKE I AM 9 MONTHS PREGNANT ON MOST DAYS. I HAVE ONLY GAINED WEIGHT, I CAN NOT LOSE. HEADACHES , BLURRED VISION, DIZZY SPELLS. I HAVE MOOD SWINGS AND ANXIETY. HAVING THE ESSURE PROCEDURE WAS THE WORST DECISION OF MY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033800	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 1/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN MY RIGHT OVARY, MOSTLY THROBBING WITH PANGS OF SHARP PAINS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033801	BAYER	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 3/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP 1 #FDA MW5033801 #(B)(4). TODAY IS (B)(6) 2014 AND IT'S BEEN SLIGHTLY OVER 9 MONTHS SINCE MY INITIAL ADVERSE REPORT WAS FILED AND APPROVED ON (B)(6) 2014. MY SYMPTOMS SINCE MY SURGERY ON (B)(6) 2014 (WHICH REMOVED THE COILS AND MY TUBES ONLY) HAVE NOT ALL DISSIPATED. AS A MATTER OF FACT SOME HAVE GOTTEN WORSE AND I HAVE NEW ADVERSE SYMPTOMS AS WELL. I AM NOW ABOUT TO HAVE A TOTAL HYSTERECTOMY TO REMOVE MY UTERUS AND CERVIX TO HOPEFULLY RID MY BODY OF THE CONTAMINATED TOXINS/POISONS THAT THE INGREDIENTS TO THIS DEVICE CONTAINS. PRIMARILY THE PET FIBERS IN THE CENTER OF THE DEVICE SINCE I NOW UNDERSTAND THROUGH MY OWN RESEARCH THAT IT'S INTENTIONAL PURPOSE IS TO CAUSE INFLAMMATION. I AM STILL SUFFERING FROM CHRONIC INFLAMMATION IN MY ABDOMEN DAILY. MY ABDOMEN IS SO DISTENDED FROM CHRONIC BLOATING THAT I DEFINITELY LOOK LIKE I'M ABOUT TO GIVE BIRTH TO A BABY. IT RESEMBLES THAT OF A MALNUTRITION-ED PERSON. IT HAS CAUSED PRETTY SEVERE DEPRESSION AND ANXIETY TO MY PSYCHOLOGICAL WELL-BEING. I WAS A VERY AVID ACTIVE PERSON BEFORE ESSURE. MY JOINTS ARE STILL ACHY AND SWOLLEN AND VISIBLY YOU CAN SEE THE EDEMA IN THEM. I HAVE AND CONTINUE TO GAIN UNEXPLAINED WEIGHT ON A WEEKLY BASIS. TODAY I WEIGH (B)(6) POUNDS WITH A TOTAL WEIGHT GAIN OF 26 LBS. SINCE INITIAL ESSURE IMPLANTATION ON (B)(6) 2013. I HAVE NEVER WEIGHED THIS MUCH IN MY ENTIRE LIFE! THE MOST I HAVE EVER WEIGHED WAS (B)(6). AND THAT WAS WHEN I WAS PREGNANT WITH MY SON. MY DIET IS EXTREMELY HEALTHY. THERE IS NO REASON OTHER THAN THE OBVIOUS REASON THAT ESSURE IT THE SOLE CAUSE OF WEIGHT GAIN. I FEEL AS IF I HAVE NO CONTROL OVER MY BODIES BEHAVIORS. I FEEL VIOLATED AND DECEIVED. THERE WAS NO DISCLOSURE OF SUCH SIDE EFFECTS AT THE TIME I WAS IMPLANTED. THIS DEVICE IS ADVERTISED AS A SAFE ALTERNATIVE TO A TUBAL LIGATION WHICH INCLUDES NO DOWN TIME, NO INVASIVE SURGERY, DONE IN

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AN OFFICE SETTING WITHOUT THE USE OF ANESTHESIA. I FIND IT AWFULLY HORRIFIC AND DECEPTIVE THAT WOMEN ARE HAVING NO CHOICE BUT TO UNDERGO A HYSTERECTOMY IN ORDER TO SEEK RELIEF FROM THE ON-GOING AND EXCRUCIATING, LIFE ALTERING, SERIOUS ILL SIDE-EFFECTS THAT THIS DEVICE CAUSES. I AM ACTUALLY LOOKING FORWARD TO MY HYSTERECTOMY BECAUSE I AM SO SICK AND TIRED OF BEING PLAGUED WITH THE HELL I FACE ON A DAILY BASIS. MY BODY HAS BEEN SEVERELY INJURED BY THIS PRODUCT AND THOUSANDS UPON THOUSANDS OF OTHER WOMEN ARE ALSO SUFFERING SINCE THE ESSURE PROCEDURE WAS PERFORMED ON THEM AS WELL. WE DID NOT SIGN UP FOR TORTURE! WE CHOSE TO BE RESPONSIBLE WOMEN AND CHOSE WHAT WE THOUGHT WAS A SAFE METHOD TO PREVENT FUTURE PREGNANCIES. THIS IS UNIMAGINABLE AND A DISGRACE THAT THIS PRODUCT IS STILL AVAILABLE TO WOMEN TODAY. I HAVE NEVER BEEN SO DETERMINED IN MY ENTIRE LIFE TO CREATE THE LOUDEST VOICE TO SPREAD AWARENESS OF THE DANGERS OF THIS PRODUCT. I LOST MY LIFE AS I KNEW IT THE DAY I CHOSE TO BE PERSUADED INTO A STRING OF LIES. THIS IS TOTALLY UNACCEPTABLE THAT THIS AMOUNT OF REPORTS FILED ON ESSURE HAS NOT CAUSED THE FDA TO THOROUGHLY RE-INVESTIGATE IT'S SAFETY. IT IS UNFAIR TO THE MANY WOMEN WHO ARE NOW UNDER-GOING THIS PROCEDURE IMPROPERLY INFORMED. IT IS UNJUST. THE DESTRUCTION THAT NOT ONLY WOMEN HAVE TO UNKNOWINGLY GO THROUGH AND THEIR FAMILIES IS JUST PURELY UNCALLED FOR! PLEASE RECONSIDER ALL THE ADVERSE REPORTS FILED AGAINST ESSURE AND ACT PROMPTLY AND ACCORDINGLY. THANK YOU.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033802	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 3/10/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM DAY 1 I WOULD HAVE A PERIOD THAT WOULDN'T STOP . I BLED FOR NEARLY 15 MONTHS BEFORE HAVING MY UTERUS AND CERVIX REMOVED. SINCE 2007 I HAVE HAD CONSTANT PAIN IN MY BACK, HIPS , LEGS. I CAN'T HAVE SEX WITH MY HUSBAND WITHOUT SEVERE PAIN AND USUALLY END UP IN TEARS . I HAVE A METAL TASTE IN MY MOUTH 24/7. I AM BLOATED TO LOOK LIKE I AM 9 MONTHS PREGNANT ON MOST DAYS. I HAVE ONLY GAINED WEIGHT I CAN NOT LOSE. HEADACHES , BLURRED VISION, DIZZY SPELLS. I HAVE MOOD SWINGS AND ANXIETY. HAVING THE ESSURE PROCEDURE WAS THE WORST DECISION OF MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033803	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CRAMPING AND BLOATING TO THE POINT I CAN NOT WALK , SEVERE MIGRAINES, FEEL TIRED ALL THE TIME, BACK ACHES AND LOTS OF BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033804	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 1/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FATIGUE, HEADACHES, BLOATING, DEPRESSION, HEAVY BLEEDING, IRREGULAR PERIODS. NOW AT (B)(6) I HAVE TO HAVE A HYSTERECTOMY. BECAUSE OF THE DAMAGE CAUSED TO MY UTERUS. ALSO I HAVE A NICKEL ALLERGY. THAT IS ONE REASON WHY MY DOCTORS AGREED TO LOOK INTO REMOVING THE DEVICES. I WAS NOT TOLD AND OR TESTED FOR NICKEL ALLERGY BEFORE I WAS IMPLANTED. I WAS (B)(6) WHEN I GOT ESSURE IMPLANTED. FROM WHAT I KNOW YOU AREN'T ALLOWED TO HAVE STERILIZATION BEFORE AGE (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033806	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 1/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I PREVIOUSLY REPORTED MY ONSET SYMPTOMS. MY RECENT SYMPTOMS ARE DAILY HEADACHES, CRAMPING, SHARP PAIN IN RIGHT OVARY AREA, TEETH SENSITIVITY, LOWER BACK PAIN, STABBING HIP PAIN, METAL TASTE IN MY MOUTH, LEGS GO TO SLEEP OFTEN, COLD FEET, OVERLY FATIGUE, AND DEPRESSION. LISTENING TO MY DOCTOR AND GETTING THE ESSURE PROCEDURE WAS THE BIGGEST MISTAKE OF MY LIFE. I WANT PERMANENT BIRTH CONTROL BUT THESE SIDE EFFECTS ARE HORRIBLE AND RUINING MY LIFE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033808	CONCEPTUS	1/13/2014	1/13/2014

Event Information:

Event Date (B3): 10/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LOWER BACK PAIN, HEADACHES, PELVIC PAIN, BLEEDING FOR 3 WEEKS, TIRED, INTERCOURSE LOST INTERCOURSE PAIN ONLY ONE POSITION SAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033805	CONCEPTUS	1/13/2014	1/14/2014

Event Information:

Event Date (B3): 12/3/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CHEST PAINS, HEADACHES, BACK PAINS, STOMACH PROBLEMS, WEIGHT GAIN, BLOATING, FATIGUE, NIGHT SWEATS ,PANIC ATTACKS, HOT FLASHES, LOSS OF SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033807	CONCEPTUS	1/13/2014	1/14/2014

Event Information:

Event Date (B3): 7/17/2012	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE, I HAVE HAD CONSTANT PELVIC PRESSURE , MIGRAINES, WEIGHT GAIN , EXTREME BLOATING, BACK PAIN, PAINFUL SEX, BREAK OUTS, INFLAMMATION, SO BAD IT CAUSES CHRONIC HEARTBURN. THIS DEVICE HAS BEEN NOTHING BUT A LIVING HELL! IT NEEDS OFF THE MARKET ASAP!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033792	CONCEPTUS	1/13/2014	1/15/2014

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THIS DEVICE PUT INTO ME, I HAVE SUFFERED FROM THE FOLLOWING SYMPTOMS THAT I HAVE NEVER SUFFERED FROM BEFORE: SEVERE ABDOMINAL CRAMPING, MISSED MENSTRUAL CYCLE, HEAVY MENSTRUAL CYCLE, FATIGUE, ANXIETY, SEVERE BLOATING, WEIGHT GAIN, UNABLE TO LOSE WEIGHT (I HAVE ALWAYS BEEN TALL AND SKINNY UNTIL NOW,) ITCHY SKIN, SHARP PAINS IN BACK, PAIN DURING INTERCOURSE, HAIR LOSS, EYE SIGHT CHANGES, DIZZINESS, AND LOSS OF INTEREST IN SEX. THE BLOATING IS SO BAD THAT I FEEL LIKE I AM ABOUT TO BURST ON SOME DAYS. I CONSTANTLY HAVE SHARP PAINS LIKE I CAN FEEL WHERE THE COILS ARE, BUT MY LEFT SIDE IS WORSE. IT EVEN HURTS TO BEND, RIDE IN A CAR, AND EVEN LIFT MY CHILDREN. THE SYMPTOMS HAVE MADE ME DEPRESSED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033793	BAYER	1/13/2014	1/15/2014

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING VERY BAD MIGRAINES AT THIS TIME. OVER THE NEXT 6 YEARS, UNTIL NOW, MY MIGRAINES HAVE GOTTEN WORSE, I HAVE CONTINUALLY HAD A CLEAR, SOMETIMES MILKY, ODORLESS VAGINAL DISCHARGE, A 50LB WEIGHT GAIN AND ABDOMINAL CRAMPS. IN ADDITION TO THOSE SIDE-EFFECTS, MORE RECENTLY, WITHIN THE PAST 6 MONTHS, I HAVE HAD BLURRY VISION, BRAIN FOG, SHORT TERM MEMORY LOSS, DIZZINESS, THINNING HAIR, BACK PAIN, JOINT PAIN, LOSS OF ENERGY, TINGLING IN MY ARMS, LEGS, AND FACE, SWELLING IN MY LEGS/FEET, MOOD SWINGS, AND HOT FLASHES. I WAS SENSITIVE TO METALS BEFORE GETTING THE ESSURE IMPLANTATION, BUT WAS NEVER ASKED ABOUT A SENSITIVITY, AS WELL AS NEVER HAVING BEEN TESTED FOR AN ALLERGY TO NICKEL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033796	CONCEPTUS	1/13/2014	1/15/2014

Event Information:

Event Date (B3): 9/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVERY SINCE THE DAY I HAD ESSURE DONE I HAVE HAD NOTHING BUT PROBLEMS. I WASN'T GIVEN ANY MEDICATION BEFORE, DURING, OR AFTER THE PROCEDURE TO HELP WITH THE PAIN CAUSED BY THE ESSURE. THEY HAD TROUBLE PLACING MY RIGHT COIL SO THEY HAD TO USE A SECOND DEVICE TO PUT INTO MY RIGHT TUBE. I WAS IN SO MUCH PAIN DURING THE PROCEDURE THAT I ALMOST TOLD THEM TO STOP, BUT THEY KEPT ASSURING ME THAT THE PAIN WAS NORMAL. I FOUND OUT THAT MY INSURANCE WOULDN'T COVER THE DYE TEST AND I COULDN'T AFFORD TO PAY FOR IT SO I NEVER HAD IT DONE. ABOUT TWO MONTHS AFTER THE PROCEDURE I NOTICED THAT THEY PAIN WAS NOT GOING AWAY IN MY ABDOMEN, AND THAT MY MENSTRUAL CYCLE BECAME A LIVING HELL, WITH EXTREME CRAMPING AND HEAVY BLEEDING. I ALSO NOTICED THAT I WAS LOSING HAIR LIKE CRAZY, AND GAINING A LOT OF WEIGHT, I NEVER RELATED IT TO ESSURE, SO I WENT TO THE DOCTOR TO HAVE MY THYROID CHECKED AND EVERYTHING CAME BACK NORMAL, BUT I KNEW SOMETHING WAS WRONG. I WAS ALSO HAVING SEVERE MIGRAINES THAT WOULD OCCUR AT LEAST 4 TIMES OR MORE A WEEK. I WENT TO THE EYE DOCTOR TO SEE IF IT WAS MY VISION, AND THEY TOLD ME THAT I HAS PSEUDOTUMOR CEREBRI, WHICH BASICALLY MEANS "FAKE TUMOR" AND THEY SENT ME TO A NEUROLOGIST AND FROM THERE MANY SCANS AND TESTS AND LOTS OF MONEY THAT I DIDN'T HAVE BECAUSE AT THIS TIME, I HAD NO INSURANCE. I HAD A MRI WITH AND WITHOUT CONTRAST, I HAD AN MRV WITH AND WITHOUT CONTRAST. I HAD TO HAVE A SPINAL TAP BECAUSE MY SPINAL PRESSURE WAS ALMOST 40, WHICH IS CONSIDERED LETHAL, THEY DRAINED SPINAL FLUID TO MAKE MY PRESSURES GO DOWN. THEN I WAS SENT HOME, BUT HAD TO GO BACK A WEEK LATER TO GET A BLOOD PATCH BECAUSE THE MIGRAINES WERE WORSE AFTER THE SPINAL TAP, AND I HAD TO STAY LAYING DOWN OR IT WOULD FEEL LIKE MY HEAD WAS GOING TO EXPLODE. I WAS PUT ON A COUPLE MEDICATIONS THAT WOULD HELP WITH MY MIGRAINES AND TO HELP

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REGULATE MY SPINAL PRESSURES, BUT AFTER A FEW MONTHS OF TAKING THEM THEY WERE MAKING MY MIGRAINES WORSE, SO I STOPPED TAKING THEM. THEN I FINALLY GOT THE RESULTS BACK FROM MY NEUROSURGEON SAYING THAT MY MRV RESULTS SHOWED THAT I HAD UNDER DEVELOPED VEINS IN THE RIGHT SIDE OF MY SKULL. THEN THE DEPRESSION HIT AND THE SUICIDAL THOUGHTS RAGED THROUGH MY HEAD BECAUSE I KNEW MY BODY AND I KNEW IT WASN'T UNDER DEVELOPED VEINS THAT WAS CAUSING ALL MY PROBLEMS. THEN I FOUND THE (B)(6), "ESSURE PROBLEMS" AND STARTED READING OTHER WOMEN'S STORIES AND IT FELT LIKE I WAS READING A STORY OF MY LIFE. THAT'S WHEN I STARTED FOLLOWING THE REAL STORY TO THE DEVISE, AND GOT IN CONTACT WITH THE OB/GYN THAT DID MY ESSURE AND LOW AND BEHOLD, HE IS NO LONGER PRACTICING. SO I CALLED THE OB/GYN THAT DELIVERED MY GIRLS AND HE TOLD ME THAT I NEEDED A HYSTERECTOMY AS SOON AS POSSIBLE. SO I'M COVERING ALL MY BASES AND TRYING TO GET INSURANCE TO HAVE THE ESSURE REMOVED. HOPEFULLY IT WILL HAPPEN SOON, SO I CAN GET MY LIFE BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033798	CONCEPTUS	1/13/2014	1/15/2014

Event Information:

Event Date (B3): 1/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WENT IN FOR MY HSG TEST AND FOUND THAT BOTH ESSURE IMPLANTS HAD MIGRATED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033866	BAYER	1/13/2014	1/22/2014

Event Information:

Event Date (B3): 1/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/23/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2011 WHEN I TURNED (B)(6). TWO WEEKS AFTER I HAD THE IMPLANTS PLACED, I BEGAN EXPERIENCING SEVERE ABDOMINAL PAIN THAT WOULD SHOOT DOWN TO MY LEG. I CAN BARELY SIT UP OR WALK SOMETIMES. THEN IN 2012, I ALSO BECAME PREGNANT WITH THE ESSURE IMPLANTS IN-PLACE. NOW AFTER LABOR, I AM IN WORSE PAIN THAN EVER BEFORE. I CAN HARDLY BREASTFEED MY CHILD BECAUSE OF THE AMOUNT OF PAIN I'M IN. NOT TO MENTION THAT MY PARTNER AND I OPTED FOR PERMANENT BIRTH CONTROL BECAUSE WE CAN NOT AFFORD THE 4 CHILDREN WE HAD ALREADY. ESSURE HAS DESTROYED MY LIFE IN EVERY WAY POSSIBLE. IT HAS TAKEN ME AWAY FROM MY CAREER AND NOW I HAVE ANOTHER CHILD TO CARE FOR BECAUSE I THOUGHT THAT I WAS SAFE. AFTER SPEAKING WITH MY PROVIDER, IT HAS BEEN EXPLAINED THAT INSURANCE DOES NOT COVER THE REVERSAL OF THE ESSURE AND MANY TIMES THE REVERSAL REQUIRES A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033875	CONCEPTUS INC.	1/13/2014	1/22/2014

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): E55 305
Lot #(E4): A78081

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLINDING HEADACHES, HEADACHES WILL NOT GO AWAY FOR DAYS AT A TIME, LOW GRADE FRYERS NO CAUSE FOR THEM DAYS ON END. FATIGUE, DEPRESSION SWELLING LIKE I AM ABOUT 5 MONTH PREGNANT (I AM NOT) GAINED WEIGHT DESPITE EATING PROPERLY. LACK OF DESIRE OR DRIVE TO DO ANY DAILY TASK OR ROUTINE. CRAMPING PAINS ON DURING AND AFTER MY CYCLE AM/PM WHEN EVER. NO MED; NO HEAT PAD CAN HELP. ODD FLUTTER LIKE TICKLE IN ABDOMEN (ODD) WRIST JOINTS ACHE, AWFUL LIKE SPRAINED WHEN NOT ON CYCLE. ON CYCLE IT GOES AWAY. LOW BACK SPASM. I AM BACK ON BIRTH CONTROL PILL. I DO NOT TRUST THIS PRODUCT!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033878	CONCEPTUS OR BAYER	1/13/2014	1/22/2014

Event Information:

Event Date (B3): 3/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/29/2012
Explant Date (E7): 4/24/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER PCP FAILED TO RUN PREGNANCY TEST, LESS THAN 24 HOURS LATER, I EXPERIENCED A RUPTURED ECTOPIC PREGNANCY, LOST OVER 2 LITERS OF BLOOD, CODED TWICE. I HAD THE MIRENA IUD AT THE TIME WHICH THE SURGEONS LEFT IN PLACE. TWO DAYS LATER, I REQUESTED IT BE REMOVED BEFORE MY HOSPITAL DISCHARGE AS IT HAD OBVIOUSLY FAILED. I WAS TERRIFIED, IN PAIN, ON MANY MEDICATIONS AND 8 WEEKS LATER HAD THE ESSURE COIL IMPLANTED IN MY REMAINING FALLOPIAN TUBE. RECENTLY, I HAVE DISCOVERED THAT PER THE ESSURE IFU, IT IS NOT RECOMMENDED TO HAVE ESSURE PLACEMENT UNILATERALLY, HOWEVER, THE OB/GYN PLACED IT REGARDLESS. WITHIN 3 WEEKS OF HAVING THE ESSURE COIL PLACED, I HAD CONTINUED CRAMPING, BLEEDING, EXCRUCIATING PAIN, NAUSEA, WEIGHT LOSS, LOWER LEFT PELVIC PAIN, DIZZINESS, EXTREME FATIGUE. IT FELT LIKE MY BODY WAS REJECTING THE COIL AND I COULD PINPOINT THE EXACT LOCATION OF THE COIL DUE TO THE PAIN. I HAD TO FORCE TREATMENT AS SEVERAL DOCTORS TOLD ME IT WAS ALL IN MY HEAD, THAT THEY HAD CONSULTED SEVERAL COWORKERS AS WELL AS THE MFR OF ESSURE, ALL OF WHOM STATED MY SYMPTOMS AND COMPLAINTS COULD IN NO WAY BE RELATED TO THEIR COIL. FINALLY, THE OB/GYN PERFORMED EXPLORATORY SURGERY TO VERIFY THE LOCATION OF THE COILS - FROM VAGINAL ENTRY WITH CAMERA THE COILS WERE UNABLE TO BE LOCATED. THE SURGEON THEN HAD TO GO IN LAPAROSCOPICALLY THROUGH ABDOMEN, REMOVED THE LEFT FALLOPIAN TUBE, AND LOCATED "FOREIGN OBJECT" AKA ESSURE COIL IN MY TUBE. THE SURGEON PERFORMED A HYSTERECTOMY. I HAD NEVER HAD MEDICAL ISSUES PRIOR TO THESE EVENTS. THE LARGEST PART OF MY MEDICAL HISTORY WAS MY PREGNANCY IN 2010. SINCE (B)(6) 2012, I HAVE BEEN TO DOCTOR'S APPOINTMENTS IN EXCESS OF 150 TIMES IN A 2 YEAR PERIOD. MY IMMUNE SYSTEM HAS NOT BEEN WORKING, DIZZINESS, EXTREME FATIGUE, DEPRESSION, WEIGHT GAIN, ABSCESSES ON ARMS, TACHYCARDIA, HEART PALPITATIONS, MIGRAINES ARE ALL SYMPTOMS AND

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MEDICAL PROBLEMS I HAVE BEEN LIVING WITH AND CANNOT EXPLAIN WITH ANY OTHER EXPLANATION, OTHER THAN THE RUPTURE HEMORRHAGE, ESSURE COIL, AND IT'S MIGRATION AND NEGLIGENCE OF THE DOCTORS. I HAVE READ THE RECENT REVIEWS ABOUT THE FINDINGS THAT THESE REPORTED ADVERSE REACTIONS DON'T IMPACT THE FDA'S POSITION REGARDING ESSURE. HOW CAN THE ESSURE PRODUCT BE REMOVED FROM THE CA PRE-EMPTIVE LAW AS IT IS NOT A LIFE SAVING DEVICE AND SHOULD NOT BE EXEMPT FROM LIABILITY. THERE ARE SEVERAL WEBSITES AND GROUPS WITH NO HUNDREDS, BUT THOUSANDS OF WOMEN WHO ALL HAVE THE SAME PROBLEMS, ALL OF WHICH DID NOT BEGIN UNTIL ESSURE PLACEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033881		1/13/2014	1/22/2014

Event Information:

Event Date (B3): 1/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 1/9/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WAS IMPLANTED IN ME AT THE AGE OF (B)(6), I AM (B)(6) NOW AND, JUST HAD SURGERY ON (B)(6) 2014 TO REMOVE IT. SHORTLY AFTER IMPLANTATION, I STARTED TO SUFFER SEVERE SIDE EFFECTS. SEARING PAIN TO THE POINT OF IMMOBILITY, HEAVY PERIODS, HEADACHES, BACK PAIN, AND MORE. THE PAIN WAS SO SERIOUS, THAT I ENDED UP IN THE HOSPITAL WITH THEM THINKING I HAD AN APPENDIX RUPTURE. IT WAS NOT MY APPENDIX, IT WAS THE ESSURE THAT HAD MIGRATED AND WAS STABBING THROUGH MY UTERINE WALL INTO MY MUSCLE. IT TOOK ME A YEAR TO SAVE UP AND FIND A DOCTOR TO REMOVE THE ESSURE FROM MY BODY. THE SURGERY WAS SUPPOSED TO TAKE 2 HOURS BUT LASTED ALMOST 5 HOURS BECAUSE THE ESSURE KEPT BREAKING AND GETTING STUCK IN MY MUSCLE. IT LEFT ME WITH SEVERE PAIN AND DAMAGE. I AM THANKFUL THAT THE HORRIBLE DEVICE THE FDA APPROVED IS OUT OF ME BUT, IT NEEDS TO BE REMOVED FROM THE MARKET. THE MANY WOMEN EFFECTED BY ESSURE IS CRIMINAL. I CAN'T BELIEVE A PRODUCT THAT WAS MINIMALLY TESTED AND HAS GIVEN WOMEN SUCH HORRIBLE SIDE EFFECT IS PROTECTED BY THE FDA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033882	BAYER	1/13/2014	1/22/2014

Event Information:

Event Date (B3): 10/3/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/3/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACED IN (B)(6) 2006. FROM THAT TIME UNTIL (B)(6) 2008, I HAD A MENSTRUAL CYCLE THAT WOULD NOT STOP. IN (B)(6) 2008, I HAD MY UTERUS AND CERVIX REMOVED. THE BLEEDING STOPPED BUT SINCE THEN I HAVE HAD BLEEDING GUMS, PULSE SOUND IN MY RIGHT EAR NON STOP, FATIGUE, ANXIETY, SEVERE BLOATING, FREQUENT URINATION, BLADDER INFECTIONS, YEAST INFECTIONS, JOINT PAIN, KNEE PAIN, PAINFUL INTERCOURSE, WEIGHT GAIN, SLEEP PROBLEMS, SKIN PROBLEMS, METAL TASTE IN MY MOUTH, DENTAL PROBLEMS, SWOLLEN HANDS AND FEET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033883		1/13/2014	1/22/2014

Event Information:

Event Date (B3): 5/26/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERFORATED MY TUBES, CAUSED SCAR TISSUE, WHICH CAUSED ORGANS TO FUSE TOGETHER. HAD TO HAVE TOTAL ABDOMINAL HYSTERECTOMY WITH REMOVAL OF TUBES AND ONE OVARY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033888	BAYER	1/13/2014	1/22/2014

Event Information:

Event Date (B3): 3/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/27/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6), 2012, I WAS STERILIZED WITH THE ESSURE PRODUCT. ESSURE WAS IMPLANTED IN MY FALLOPIAN TUBES W/O MY CONSENT AT (B)(6) IN (B)(6) BY (B)(6) FROM 2AM-4AM. I WAS RELEASED ON (B)(6), 2012. SINCE THEN, I HAVE HAD A SEVERE ALLERGIC REACTION- SWELLING OF WRISTS, ANKLES, LEGS, REDNESS OF THE EYES, SNEEZING. ALSO, I HAVE HAD PELVIC PAIN; ABDOMINAL PAIN AND BLOATING; AND UNEXPLAINED WEIGHT GAIN FROM (B)(6) LBS AT THE TIME OF IMPLANT TO (B)(6) LBS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033890	BAYER	1/14/2014	1/22/2014

Event Information:

Event Date (B3): 8/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/21/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN AFTER ESSURE WAS PLACED. PAIN DURING AND AFTER SEX WITH HEAVY BLEEDING, HEADACHES, PREGNANCY LIKE SYMPTOMS. PERIODIC PAIN ON ONE OR BOTH SIDE WHERE IMPLANT IS PLACED. PAIN MEDICATION REQUIRED TO RELIEVE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033892	CONCEPTUS/BAYER	1/14/2014	1/22/2014

Event Information:

Event Date (B3): 2/8/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 621676

Single Use:
Implant Date (E6): 2/8/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2007. SUBSEQUENTLY, I HAVE HAD SEVERAL SIDE EFFECTS INCLUDING: SURGERY IN 2012 TO REMOVE MIGRATED COIL; INTENSE BACK PAIN; HIP PAIN; URINARY TRACT ISSUES; BOWEL ISSUES; PELVIC PAIN; LOSS OF LIBIDO; SEXUAL DYSFUNCTION; WEIGHT GAIN; MOOD ISSUES; HAIR LOSS; MUSCLE SPASMS; HEADACHES; BRAIN-FOG; DIFFICULTY FOCUSING; POOR SHORT-TERM MEMORY; PERSISTANT FATIGUE; VAGINAL SWELLING; BLOATING; BLEEDING AFTER SEX; DYSFUNCTIONAL UTERINE BLEEDING; ANXIETY; NIGHT SWEATS; INCREASE IN BREAST SIZE; INCONTINENCE. SYMPTOMS MAGNIFIED 4-YRS AFTER IMPLANTATION. INTERFERING WITH RELATIONSHIPS, WORK PERFORMANCE, FINANCIAL BURDENS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033893	BAYER	1/14/2014	1/22/2014

Event Information:

Event Date (B3): 11/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 623191

Single Use:
Implant Date (E6): 4/3/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING SEVERE PELVIC PAIN (B)(6). I WAS SEEN BY MY GENERAL PRACTITIONER ON (B)(6). SHE DID A URINALYSIS. THERE WAS BLOOD IN MY URINE. SHE DIAGNOSED A UTI AND PRESCRIBED ME AN ANTIBIOTIC. I SAW HER AGAIN ON (B)(6), AND THE PAIN WAS GETTING WORSE. SHE DID ANOTHER URINALYSIS. ONCE AGAIN THERE WAS BLOOD IN MY URINE. SHE DIAGNOSED A UTI AND PRESCRIBED ME ANOTHER ANTIBIOTIC. THE PAIN CONTINUED, SO ON (B)(6), I WAS IN TERRIBLE PAIN. I COULD FEEL A POKING/STABBING SENSATION ON THE INSIDE OF MY PELVIS. I WENT TO (B)(6). I HAD A CT SCAN AND AN INTERNAL/EXTERNAL ULTRASOUND. THE RESULTS WHERE AN ENLARGED UTERUS AND SOME DISTURBING UTERINE CHANGES. THEY SENT MET TO MY OB/GYN THE NEXT MORNING WHO CONTRADICTED THOSE RESULTS AND TOLD ME MY UTERUS WAS NORMAL. SHE TOOK SOME SWABS AND SENT ME FOR BLOOD WORK. THIS WHOLE TIME I'M TAKING TRAMADOL FOR PAIN. SHE ALSO PRESCRIBED TWO DIFFERENT ANTIBIOTICS AS WELL AS ANTI NAUSEA MEDICINE. I SCHEDULED A F/U VISIT FOR (B)(6). ON (B)(6), SHE AGREED THAT THIS WAS MORE THAN LIKELY ESSURE RELATED AND SENT ME FOR MORE BLOOD WORK AND AN MRI ON (B)(6). THE MRI RESULTS WERE INCONCLUSIVE. BUT THE MRI REPORT DID GIVE A MENTION OF FURTHER TESTING THROUGH A FLAT PLATE X-RAY. SO TODAY, I WENT BACK TO MY GENERAL PRACTITIONER TO GET MY MRI RESULTS REVIEWED. MY DR DID DECIDE TO GIVE ME A FLAT PLATE X-RAY AS WAS RECOMMENDED. MY DEVICE HAS COMPLETELY MIGRATED ON MY LEFT SIDE AND EVEN THE RIGHT SIDE LOOKS DAMAGED AS WELL. I'VE BEEN IN EXCRUCIATING PAIN THIS ENTIRE TIME. I FIND IT VERY DIFFICULT TO DO THE MOST SIMPLE DAILY CHORES. THE DISHES, LAUNDRY, EVEN CARING FOR MYSELF AND SHAVING MY LEGS HAS BECOME UNBEARABLE. THE PAIN IS ALWAYS THERE AND NEVER GOES AWAY.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033894		1/14/2014	1/22/2014

Event Information:

Event Date (B3): 12/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/16/2009
Explant Date (E7): 12/9/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL INJURED ME AS FAR AS PAIN AND MENTALLY AS WELL. "IN THE END I HAD TO HAVE TO HAVE MY TUBES REMOVED. (B)(6), 2013. I WAS SICK FOR FOUR AN A HALF YRS. SUFFERING."

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033895	CONCEPTUS/BAYER	1/14/2014	1/22/2014

Event Information:

Event Date (B3): 8/29/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/15/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE COIL PLACEMENT, I HAVE HAD MIGRAINES, EXTREME LOWER BACK PAINS, ABDOMEN CRAMPS THAT IS WORSE BEFORE, DURING AND AFTER MY MENSTRUAL CYCLE. HUGE BLOOD CLOTS ALONG WITH UNRELIABLE PERIODS THAT CAN LAST BETWEEN FOUR AND EIGHT DAYS EVERY THREE WEEKS. I CONSTANTLY HAVE A DISCHARGE AND I HAVE A LACK OF SEX DRIVE AND INTERCOURSE IS VERY PAINFUL. I HAVE MAJOR WEIGHT GAIN THAT I CAN NOT LOSE EVEN WITH EXERCISE. I HAVE DENTAL PROBLEMS AND A METALLIC TASTE IN MY MOUTH. I AM CONSTANTLY TIRED AND HAVE TROUBLE SLEEPING. I HAVE DRY SKIN NOW WHEN IT WAS ALWAYS OILY AND MY HAIR IS NOW FALLING OUT. I HAVE SEVERE BLOATING WHERE I LOOK AS IF I AM ABOUT SIX MONTHS PREGNANT. I HAVE NERVE PAIN THAT I HAVE SEEN A DOCTOR FOR AN JOINT PAINS. ON A SCALE OF 1-10, I AM A CONSTANT 8 IN EVERYDAY PAIN AND IT GOES UP TO 10+ DURING MY CYCLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033896	BAYER	1/14/2014	1/22/2014

Event Information:

Event Date (B3): 8/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BEEN TO ER FOR PELVIC PAIN AND ALSO HAVE SKIN RASHES ON MY BODY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00006	BAYER HEALTHCARE LLC	1/14/2014	1/30/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/9/2013
Explant Date (E7): 10/4/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED. THE ESSURE PROCEDURE TOOK 3 HOURS DUE TO HER UTERUS BEING TILTED AND A LOT OF FLUID. ON AN UNSPECIFIED DATE, CONSUMER STARTED RUNNING A FEVER OF 104, BLEEDING EXCESSIVELY AND IN A MAJOR AMOUNT OF PAIN. SHE STATED THAT HER BODY REJECTED ESSURE INSERTS BECAUSE SHE IS AN AUTOIMMUNE CONSUMER, WHO HAS BEEN ON STEROIDS DAILY FOR 3 MONTHS AND INSERTS HAD TO BE REMOVED. SHE ALSO STATED THAT AN INTERVENTION WAS REQUIRED (BUT IT WAS NOT SPECIFIED).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00007	BAYER HEALTHCARE LLC	1/14/2014	1/30/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A64626

Single Use: Y
Implant Date (E6): 3/11/2013
Explant Date (E7): 9/15/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SINCE THEN, SHE HAD PAIN WHERE IMPLANTED, CRAMPING (INTENSITY OF 7-8 ON A SCALE OF 1-10), BACK PAIN AND HEADACHES. SHE HAS SEEN HER GYNECOLOGIST AND 2 DIFFERENT ONES FOR A SECOND AND THIRD OPTION. SINCE GETTING ESSURE INSERTED, SHE EXPERIENCED NOTHING BUT STABBING PAIN IN HER LEFT SIDE AND CRAMPING EVERY DAY. SHE REPORTED THAT SHE JUST WANTED TO HAVE IT REMOVED, BUT HAS ALSO REPORTED THAT ESSURE WAS REMOVED ON (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00004	BAYER HEALTHCARE LLC	1/14/2014	2/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): 623217

Single Use: Y
Implant Date (E6): 5/19/2009
Explant Date (E7): 2/6/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ACCORDING TO HER EVERYTHING WENT SMOOTH FOR THE FIRST SEVERAL MONTHS TO A YEAR. AFTER THAT SHE HAD MANY ADVERSE SIDE EFFECTS. SHE DEVELOPED SKIN ALLERGIES TO CLEANING SUPPLIES. SHE ALSO DEVELOPED MANY CAVITIES AFTER A LIFE OF HEALTHY TEETH AND HAD TO HAVE ONE ROOT CANAL (ONE NEEDS TO BE SCHEDULED YET). SHE FREQUENTLY DEVELOPS BOILS ON HER BUTTOCKS, VAGINAL AREA AND FACE; HER DOCTOR COULD NOT FIND A SOURCE OF THE BOILS. SHE EXPERIENCED AN UNEXPLAINED RAPID WEIGHT GAIN WHILE EATING A STRICT DIET AND EXERCISING AND HER ENERGY LEVEL PLUMMETED. SHE HAD INTENSE PAIN IN HER ABDOMEN FOR OVER 2 HOURS AND WENT TO HER GYNECOLOGIST WHEN SHE COULD NOT TAKE THE PAIN ANY LONGER. BOTH COILS HAD COME OUT OF HER TUBES: ONE PERFORATED THROUGH HER UTERUS AND THE OTHER HAD BECOME FUSED INTO HER UTERINE WALL. SHE WAS SCHEDULED FOR AN EMERGENCY HYSTERECTOMY WITHIN THE SAME WEEK AND HAD THE DEVICES REMOVED ON (B)(6) 2013 (SHE KEPT ONLY HER OVARIES). SINCE THE SURGERY, SHE HAS GAINED EVEN MORE WEIGHT AND IS CONSTANTLY BLOATED. HER BLADDER HURTS CONSTANTLY AND SHE HAS EXTREMELY PAINFUL GAS AND BOWEL MOVEMENTS. SHE REPORTED THAT SHE HAD NONE OF THOSE ISSUES PRIOR TO HAVING THE ESSURE COILS INSERTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00005	BAYER HEALTHCARE LLC	1/14/2014	2/7/2014

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/10/2008
Explant Date (E7): 10/30/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED. SHE REPORTED THAT IMMEDIATELY AFTER ESSURE PLACEMENT SHE EXPERIENCED PAIN, HEADACHES, FOUL ODOR AND CONSTANT BLEEDING. SHE WENT FOR HER X-RAYS AFTER THE THREE MONTHS AND WAS TOLD BY THE TECHNICIAN THAT IT APPEARED THAT THE COILS HAD PUNCTURED THE FALLOPIAN TUBES AND ONE OF THE COILS WAS BROKEN. HER DOCTOR DISAGREED WITH THE TECH'S STATEMENTS AND BLAMED HER PROBLEMS ON ENDOMETRIOSIS. IN 2008, SHE HAD A HYSTERECTOMY; AFTER THE SURGERY, THE PHYSICIAN FINALLY ADMITTED THAT HER TUBES HAD BEEN PUNCTURED. SHE EXPERIENCED MENOPAUSAL SYMPTOMS SINCE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033917	BAYER	1/15/2014	1/24/2014

Event Information:

Event Date (B3): 1/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): B60754

Single Use:
Implant Date (E6): 12/20/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE BEEN EXPERIENCING SEVERE PAIN ON MY LEFT SIDE EVERYDAY AND WORSE PAIN DURING BLEEDING. I HAVE HAD 4 PERIODS SINCE IMPLANTATION THREE WEEKS AGO. I HAVE HAD SEVERE HEADACHES ON A DAILY BASIS REQUIRING PRESCRIPTIONS. NAUSEA IS ALSO A HUGE PROBLEM SINCE IMPLANTATION. I HAVE NEVER HAD SYMPTOMS LIKE THIS BEFORE OR ANYTHING THAT LASTED 3 WEEKS NON-STOP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033919	BAYER	1/15/2014	1/24/2014

Event Information:

Event Date (B3): 1/14/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE RECENTLY BEEN FEELING ALL THESE SYMPTOMS SINCE I WENT IN FOR MY SURGERY WHICH IS ESSURE PERMANENT BIRTH CONTROL, BACK IN 2010; VERY FATIGUE, WEIGHT GAIN, HEAVY PERIODS, BLOATING, SHORTNESS OF BREATH, SEVERE BACK AND FRONT ABDOMINAL PAIN, HEADACHES, OVARIAN CYST, RECENTLY UTERINE FIBROID, STRONG VAGINAL ODOR, BACTERIAL VAGINITIS (BV) URINARY TRACT INFECTIONS, BLACK BLOOD, BROWN BLOOD OFTEN BRIGHT RED BLOOD THAT OFTEN IS HEAVY BLEEDING, IRREGULAR PERIODS LAST MORE THAN A WEEK, SEVERE CRAMPS, DISCHARGE, SHORTNESS OF BREATH, CONSTIPATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033921	CONCEPTUS/BAYER	1/15/2014	1/24/2014

Event Information:

Event Date (B3): 1/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/26/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2006. SINCE THEN I HAVE HAD INCREASINGLY BAD MIGRAINE TYPE HEADACHES, THAT NO MEDICATION HELPS. I ALSO HAVE A PAIN IN MY RIGHT OVARY AREA THAT GETS A STABBING LIKE PAIN WHEN I COUGH, SNEEZE OR STAND UP TOO FAST. I HAVE RECENTLY WITHIN THE PAST YEAR, STARTED TO GET A BRAIN FOG AND WEIGHT GAIN (EVEN WITH DIET AND EXERCISE). MY PERIODS HAVE BECOME MUCH MUCH HEAVIER AND A LOT MORE PAINFUL. I ALSO GET BLOOD CLOTS ABOUT THE SIZE OF A GOLF BALL, ALL THROUGHOUT MY PERIOD. I HAVE STOMACH PROBLEMS INCLUDING HEARTBURN DAILY, AND I AM FATIGUED ALL THE TIME. MY FACE AND MY BACK BREAK OUT AND IT NEVER DID BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033924	BAYER	1/15/2014	1/24/2014

Event Information:

Event Date (B3): 8/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE DEVICE IMPLANTED (B)(6) 2013 IN A DOCTOR'S OFFICE. SHE IMPLANTED KNOWING I HAVE LUPUS AND HISTORY OF ENDOMETRIOSIS AND BLOCKED TUBE. DAY SHE IMPLANTED WAS TAKEN TO E.R. BY HER. NOW I HAVE A ESSURE COIL BUNCHED UP AND BROKEN INTO UTERINE WALL ON LEFT TUBE. HAIR FALLING OUT, WEIGHT GAIN, DEPRESSION, NUMBNESS HANDS AND FEET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033902	BAYER	1/16/2014	1/24/2014

Event Information:

Event Date (B3): 11/6/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/10/2012
Explant Date (E7): 11/6/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE PERMANENT BIRTH CONTROL (B)(6) 2012. IN THE FIRST FEW DAYS FOLLOWING I HAD BRIEF SHARP SHOOTING PAINS ON MY RIGHT SIDE SPECIALLY WHEN I TURNED CERTAIN WAYS. THIS SUBSIDED AND ONLY CAME BACK RANDOMLY STARTING IN (B)(6) 2013 WITH IT WORSENING IN (B)(6) 2013. MY FIRST HSG TEST ON (B)(6) 2012, SHOWED PT TUBE ON RIGHT SIDE WITH APPARENT MALPOSITION OF COIL. MY DOCTOR WANTED ME TO HAVE ANOTHER HSG TEST 6-9 MONTHS LATER TO GIVE IT MORE TIME TO CLOSE. I DID HAVE THAT SECOND HSG TEST ON (B)(6) 2013, WITH THE HEAD OF THE OBGYN DEPARTMENT PRESENT AS WELL. I DEVELOPED A YEAST INFECTION RIGHT BEFORE THIS TEST BUT WAS TOLD THE TEST COULD STILL BE DONE. RESULT OF THE SECOND TEST READ MY TUBES WERE SEALED AND I WAS STERILIZED. ON (B)(6) 2013, I HAD WHAT I THOUGHT WAS THE WORST AND HEAVIEST PERIOD OF MY LIFE. THE PAIN SUBSIDED THAT EVENING WITH PAIN KILLERS. I WOKE TO LIGHT PAIN WITH THE PASSING OF AN EMBRYO (B)(6) 2013. THE NEXT DAY (B)(6) 2013, MY BIRTHDAY, IT WAS CONFIRMED PREGNANCY TISSUE. MY SYMPTOMS WORSENED FROM HERE WITH VAGINAL YEAST NOT BEING CONTROLLED WITH MULTIPLE ATTEMPTS OF HIGH DOSAGE DRUGS. I HAD LOWER BACK PAIN AND RIGHT SIDE BODY ACHES. MY JOINTS AND MUSCLES FELT WEAK WHERE I COULD NOT HOLD A PHONE UP TO MY EAR WITHOUT SHAKING, WALKING DOWN STAIRS MY LEGS FELT WOBBLY, I DEVELOPED HEADACHES ON A REGULAR BASIS, I COULD FEEL A PRESSURE IN MY PELVIC AREA AND NEAR MY PUBIC BONE. IT FELT LIKE MY CERVIX WAS OPENING AT NIGHTS WHEN I WOULD LAY DOWN FOR BED. I TOSSED AND TURNED AT NIGHT BECAUSE I COULD NOT FIND A COMFORTABLE POSITION TO LAY. I WOULD WAKE WITH PAIN IN MY BACK AND HAD A HARD TIME WALKING RIGHT AWAY IN THE MORNING. I SUFFERED FROM FATIGUE, LOSS OF ENERGY, HIP PAIN, CHRONIC PELVIC PAIN, PAINFUL SEX, LOSS OF LIBIDO, COPIOUS AMOUNTS OF VAGINAL DISCHARGE (7 YEAST INFECTIONS TOTAL IN 4 MONTHS) UTERINE INFLAMMATION AND GI

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ISSUES. RUNNING BACKWARDS WHILE PLAYING WITH MY DAUGHTER I COULD FEEL PAIN AND PRESSURE ON MY RIGHT SIDE. LAYING ON MY BACK READING TO MY KIDS I FELT A "SPRINGY VIBRATION" COMING FROM MY RIGHT PELVIC AREA. AT TIMES I WOULD FEEL A THROBBING, STINGING SENSATION AT WORK SITTING IN MY CHAIR. THESE PAINS EVENTUALLY STARTED TO TRAVEL DOWN MY RIGHT LEG AS WELL. ON (B)(6) 2013, I SOUGHT A SECOND OPINION BECAUSE I WAS NOT GETTING CLEAR ANSWERS FROM MY IMPLANTING CLINIC. I WAS TOLD THE COILS NEEDED TO COME OUT AND HE SAID IT WOULD BE DIFFICULT TO FIND. I WENT ON (B)(6) 2013 TO THE HOSPITAL FOR A SCHEDULED LAPAROSCOPIC ASSISTED SUPRA CERVICAL HYSTERECTOMY. MY COILS, TUBES AND UTERUS ALL CAME OUT THAT DAY. AFTER SURGERY I FOUND OUT I HAD AN ADHESION TO MY LIVER THAT WAS STARTING TO GET INFECTED AND MY UTERUS WAS PERFORATED FROM THE RIGHT COIL. IT'S BEEN 2.5 MONTHS SINCE SURGERY AND I FEEL LIKE A STORM WAS QUIETED IN MY BODY! I AM HAPPY TO BE ON THIS ROAD TO RECOVERY AND HOPE SOMEDAY ESSURE WILL BE NO LONGER BE ON THE MARKET AND HARM MORE WOMEN. THIS WAS A TRAUMATIC EXPERIENCE FOR MYSELF AND MY FAMILY. MODEL NUMBER WAS NOT GIVEN TO ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033906	BAYER/CONCEPTUS	1/16/2014	1/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE MICRO INSERT
Device Type (E2): ESSURE MICRO INSERT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/15/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXCESSIVE EXCRUCIATING PELVIC PAIN WITH INFLAMMATION DIZZINESS, LOSS OF BALANCE, IMPAIRED VISION, NAUSEA, RASHES, SWELLING MIGRAINES, FEVERS, INSOMNIA, NIGHT SWEATS, ASTHMA SYMPTOM, JOINT PAIN, DENTAL HEALTH DECLINE, TOTAL BODY ITCHING, PERSISTENT VAGINAL DISCHARGE, CHRONIC FATIGUE, LOSS OF SEX DRIVE, PAINFUL BLOATING SUSPECTED NICKEL ALLERGY, STABBING PAIN WHERE FALLOPIAN TUBES ARE LOCATED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033907	BAYER	1/16/2014	1/24/2014

Event Information:

Event Date (B3): 8/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/5/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL PUT IN 2010 AND SINCE HAVE HAD HAIR LOSS, LOSS OF ENERGY, HEAVY BLEEDING, NO SEX DRIVE AND SEVERE MOOD SWINGS. DUE TO ALL OF MY ISSUES, I WILL BE HAVING A HYSTERECTOMY IN (B)(6) 2014. WITH TWO CHILDREN AND A FULL TIME JOB, LIFE HAS BEEN VERY DIFFICULT DUE TO THE SIDE EFFECTS. I AM ALSO MALIGNANT HYPERTHERMIA WHICH MEANS A HYSTERECTOMY IS NOT AN IN AND OUT SURGERY FOR ME. I WILL NEED TO STAY LONGER IN THE HOSPITAL AND HAVE A SPECIAL ANESTHESIOLOGIST THERE AT ALL TIMES. A PRODUCT LIKE THIS SHOULD NOT BE ALLOWED TO BE PUT INTO WOMEN WITH NO SUCH WARNINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033973	CONCEPTUS INC	1/17/2014	1/30/2014

Event Information:

Event Date (B3): 3/16/2004 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS205
Catalog # (E4): 12244149
Lot #(E4):

Single Use:
Implant Date (E6): 3/16/2004
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE AS A TUBAL LIGATION IN 2004 WHEN I WAS (B)(6). MY DOCTOR WAS (B)(6). THE PROCEDURE ITSELF WAS RELATIVELY PAINLESS, AS I WAS UNDER ANESTHESIA, WITH A SHORT RECOVERY TIME. HOWEVER, SHORTLY AFTER THE PROCEDURE (WHICH I WAS TALKED INTO BY MY OBGYN WHO TOLD ME VERY LITTLE ABOUT THE PROCEDURE AND WHO DIDN'T TELL ME ANY RISKS INVOLVED), MY BODY BEGAN TO DETERIORATE. I'VE HAD A VERY BAD ADVERSE REACTION TO THE IMPLANTS. THEY CAUSE IMMENSE PAIN AND I DO NOT DOUBT, ONE BIT, THAT THEY HAVE BEEN THE CAUSE OF MY CURRENT AILMENTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5033992	BAYER	1/17/2014	1/30/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/22/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN (B)(6) 2010. SINCE THEN I HAVE HAD BAD MENSTRUAL CRAMPS WHERE BEFORE I HAD VERY FEW. MY PERIODS COME FOR A COUPLE OF MONTHS THEN GO AWAY FOR MONTHS. THE DOCTOR CHECKED AND COULD NOT EXPLAIN WHY THIS IS HAPPENING. I HAVE STARTED DEVELOPING LARGE CYSTS ON MY OVARIES WHERE I HAVE NEVER HAD ANY PROBLEMS LIKE THIS BEFORE. I HAVE NAUSEA CONSTANTLY. ALL THIS STARTED RIGHT AFTER I HAD THE PROCEDURE. AT FIRST, WE THOUGHT IT WAS BECAUSE OF THE DEPO SHOT THE DOCTOR GAVE ME, BUT IT IS STILL HAPPENING AND GETTING WORSE. I HAVE SHARP PAINS EVERY MONTH IN MY RIGHT OVARY WHETHER I START OR NOT. I DO NOT KNOW IF THIS CAN BE REMOVED (I WAS TOLD THEY CAN NOT) BUT MY INSURANCE WILL NOT PAY FOR ANY PROCEDURE. NOW AFTER THE REPORTS I WORRY CONSTANTLY. I AM STARTING TO HAVE PAIN WHEN INTIMATE IN MY SIDES AND THE DOCTOR SAYS HE SEES NO PROBLEM AT MY LAST VISIT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034019	BAYER	1/23/2014	1/31/2014

Event Information:

Event Date (B3): 1/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/19/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED (B)(6) 2012, HAVE HAD RANDOM DISCHARGE, BELIEVED TO BE FROM NICKEL ALLERGY CAUSED BY COILS. MILD TO VERY UNCOMFORTABLE CRAMPS WITH OR WITHOUT MENSTRUAL CYCLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034022	CONCEPTUS INC.	1/23/2014	1/31/2014

Event Information:

Event Date (B3): 12/17/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): A46107
Lot #(E4):

Single Use:
Implant Date (E6): 12/17/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE (B)(6) 2012. (B)(6) TOLD ME IT WOULD BE VERY EASY RECOVERY AND I WOULD BE IN AND OUT QUICKLY WITH NO OPEN WOUNDS RATHER THAN INVASIVE PROCEDURE, TUBAL LIGATION. I AGREED, THOUGHT IT WOULD BE THE BEST PROCEDURE. THEY ASKED IF I WAS ALLERGIC TO ANY MEDICATION, I SAID YES, CECLOR. I WAS NOT AWARE THE SPRING CONTAINED NICKEL. I CAN NOT WEAR FAKE EARRINGS, MY EARS SWELL. I NEVER THOUGHT ABOUT IT CONSIDERING I AM NOT THE SURGEON JUST A PT WHO WANTED PERMANENT BIRTH CONTROL AT AGE (B)(6). SO WHEN I WENT TO FOLLOW UP TO SEE IF THE PROCEDURE WAS SUCCESSFUL IT WAS. I ASKED IF IT WAS NORMAL TO HAVE PAINS IN MY SIDES AND BAD CRAMPING. I WAS TOLD YES, IT WILL SUBSIDE, IT'S FROM THE SCARRING OF THE DEVICE IN MY TUBES. NOW, A YEAR LATER I FEEL LIKE I AM GOING THROUGH MENOPAUSE. HOT FLASHES, NAUSEA ALMOST EVERY DAY, HEADACHES 3-4 DAYS A WEEK, EVERY TIME I BEND, COUGH OR USE STOMACH MUSCLES I HAVE PAIN. EVEN PAINFUL INTERCOURSE AND AFTER I SOMETIMES LAY IN VERY BAD PAIN. THE LIST GOES ON AND ON. I THOUGHT I WAS GOING CRAZY. I JUST A FEW DAYS AGO HAD DARK BROWN MUCOUS LIKE DISCHARGE FOLLOWED BY LIGHT RED BLOOD IN PAD. EVERY TIME I PEE, CLOTS COME OUT. I HAVE HEMORRHAGED SEVERAL TIMES IN THE PAST AND I AM VERY SCARED. I CALLED (B)(6) TODAY AND REQUESTED TO SEE THE SURGEON AND THE NURSE SAID SEE FAMILY DOCTOR FIRST FOR TESTING, IT COULD BE SOMETHING ELSE? OMG, REALLY?!! SO SHE SCHEDULED ME IN FOR (B)(6). I ALREADY HAVE AN APPOINTMENT WITH FAMILY DOCTOR NEXT WEEK. I PRAY I CAN SAFELY HAVE THESE SPRINGS REMOVED IN A TIMELY FASHION WITHOUT ANY MORE ISSUES WITH (B)(6). EVERY TIME I GET MY PERIOD NOW, I FEEL FLUSHED, I GET ACHY ALL OVER, LOW FEVER AND FEEL LIKE HELL. THAT'S HOW I KNOW WHEN I WAKE UP THE NEXT DAY I HAVE MY PERIOD. I

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CAN'T DO THIS ANYMORE, I WANT IT OUT. I AM NOW (B)(6) AND FEEL 99. HELP. DON'T LET THIS CONTINUE. TOO MANY NAIVE WOMEN LIKE MYSELF FALL FOR THE "EASY TUBAL". LIKE THEY SAY. THE EASY WAY ISN'T ALWAYS THE BEST WAY. I LIVE AND I LEARN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034024	CONCEPTUS	1/23/2014	1/31/2014

Event Information:

Event Date (B3): 1/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/25/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED IN (B)(6) 2009 AND IN (B)(6) 2009 I WAS IN SO MUCH PAIN IN MY LEFT LEG TO THE VERGE OF TEARS. WENT TO DOCTOR AND WAS INFORMED OF BEING VITAMIN D DEFICIENT. AS TIME PASSED I STARTED SUFFERING FROM DEBILITATING MIGRAINES INCLUDING OCULAR MIGRAINES THAT I WAS SENT TO SEE AN EYE DOCTOR THAT SPECIALIZES IN PROBLEMS WITH THE RETINA. I HAVE ON SEVERAL OCCASIONS HAVE HAD TO GO TO THE DOCTOR OR HOSPITAL FOR WHAT FEELS LIKE A HEART ATTACK OR STROKE. THE LEFT SIDE OF MY BODY INCLUDING FACE STARTS GOING NUMB I BREAK OUT INTO A SWEAT AND HAVE TROUBLE BREATHING MY HAND STARTS TINGLING AND I HAVE A HEADACHE THAT FEELS LIKE SOMEONE HIT ME WITH A HAMMER. TEST RESULTS FROM THOSE INCIDENTS COME BACK NORMAL. AS A RESULT INSTEAD I WAS DIAGNOSED WITH VERTIGO AND PARASTHESIA. I STARTED SUFFERING FROM HORRIBLE PANIC/ANXIETY ATTACKS. I HAVE BEEN SENT TO DIFFERENT SPECIALISTS FOR DIFFERENT TESTS THAT ALWAYS COME BACK NORMAL. I HAVE BEEN PRESCRIBED DIFFERENT TYPES OF MEDICATION FOR MY MIGRAINES AND VERTIGO. I HAVE TAKEN A VERY HIGH DOSE OF VITAMIN D. I HAVE BEEN DIAGNOSED WITH VERY LOW HDL LEVELS. I SUFFER FROM BACK, LEG, AND JOINT PAIN THAT HAS ME SOME DAYS JUST PRAYING FOR RELIEF. I GAINED A RIDICULOUS AMOUNT OF WEIGHT AFTER IMPLANTATION AND MY SKIN IS SO DRY AND ITCHY. I GET RED BUMPS AFTER I SHAVE THAT ITCH SO BAD I'M SCRATCHING ALL THE TIME LIKE A DOG WITH FLEAS WOULD. I HAVE RECENTLY ALSO BEEN DIAGNOSED WITH A.D.D. AND AM NOW ON VYVANSE WHICH HAS ALLEVIATED THE MIGRAINES BUT I STILL HAVE DULL HEADACHES. MY PERIODS ARE EXTREMELY PAINFUL AND HEAVY TO THE POINT WHERE I HAVE TO USE BOTH A TAMPON AND PAD. I SUFFER FROM EXTREME AND PAINFUL STOMACH BLOATING TO THE POINT WHERE I HAVE TRIED TO CUT OUT ANY TYPE OF FOOD THAT I FEEL WILL GIVE ME ISSUES. I GET SHARP STABBING PAINS IN MY BELLY BUTTON AREA AND IN MY VAGINAL/RECTUM AREA. IT IS PAINFUL TO

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HAVE INTERCOURSE. I HAVE MAJOR MOOD SWINGS THAT ARE AFFECTING MY MARRIAGE. I FEEL AT (B)(6) THAT I HAVE THE BODY OF AN 80 YEAR OLD. I'M IN CONSTANT PAIN AND I NEED TO FIND RELIEF.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034026	CONCEPTUS	1/23/2014	1/31/2014

Event Information:

Event Date (B3): 1/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 12/31/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD THE ESSURE METHOD PUT IN (B)(6), 2008 AND HAVE HAD NOTHING BUT PROBLEMS WITH MY MENSTRUAL FLOW. I HAVE HAD BAD MENSTRUAL CRAMPS SINCE. I HAD TO GET "D & C" AND THERMAL ABLATION, DUE TO THE FACT I COULDN'T STOP BLEEDING. I STILL GOT MY PERIOD BACK, I'VE BEEN HAVING PROBLEMS WITH MY PERIOD SINCE. IT HURTS IN MY LOWER ABDOMEN WHEN I HAVE SEX IT FEELS LIKE SOMEONE IS STABBING ME. I HAVE REALLY BAD PMS NOW. MY PERIODS LAST LONGER THAN NORMAL. HAS ONLY GOTTEN WORSE SINCE, I'VE BEEN PASSING LARGE CLOTS. I GET BAD HEADACHES WITH MY PERIOD. MY PERIOD CAN LAST 7-14 DAYS WHERE AS BEFORE IT ONLY LASTED 3-5 DAYS AND I HARDLY NOTICED IT CAME. NOTHING HAS BEEN RIGHT WITH ME SINCE. I WAS NORMAL BEFORE THOSE. I'VE ASKED SEVERAL GYNECOLOGISTS INCLUDING THE ONE WHO PUT THEM IN ABOUT THE COILS AND COULD THIS BE CAUSING MY PROBLEMS. NATURALLY I GET TOLD NO BUT NO TESTS ARE DONE TO PROVE IT'S NOT FROM THE COILS. I'M TELLING YOU I DIDN'T HAVE PROBLEMS UNTIL ESSURE. I AM NOW LOOKING AT A HYSTERECTOMY, I DON'T WANT ONE. I'M ONLY (B)(6). I REALLY JUST WISH A DOCTOR WOULD TAKE THE COILS OUT AND SEE IF MY SYMPTOMS GO AWAY. I WILL GET SECOND AND THIRD OPINIONS BEFORE I GET A HYSTERECTOMY. PLEASE INVESTIGATE THESE COILS FURTHER. OH ALSO LAST TIME I CHECKED INTO THESE COILS MINE WOULD HAVE BEEN MADE OF NICKEL AND AN ALLERGY TEST SHOULD HAVE BEEN DONE BEFORE PLACING THE COILS AND WASN'T. I KNOW I CAN'T WEAR CHEAP JEWELRY. I KNOW NOW THEY DON'T USE NICKEL ANYMORE. ALL I WANT IS THESE THINGS TOOK OUT AND TO TRY THAT AND NO ONE WILL LISTEN. SO TIRED OF HEARING NO IT CAN'T BE THAT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034027	BAYER	1/23/2014	1/31/2014

Event Information:

Event Date (B3): 1/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305 901342

Single Use:
Implant Date (E6): 1/18/2012
Explant Date (E7): 11/20/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICES IMPLANTED IN (B)(6) OF 2012. I WAS COMPLETE IN MY FAMILY. I STARTED HAVING ISSUES RIGHT AWAY, SEVERE BLEEDING, PASSING BLOOD CLOTS THE SIZE OF PLUMS, HEADACHES, BACKACHES, LOWER PELVIC PAIN, SEEN IN (B)(6) 2013 AND TOLD HIM ALL ABOUT MY ISSUES. AT FIRST I THOUGHT IT WAS MY BODY GETTING BACK TO NORMAL AFTER GOING OFF MY DEPO SHOT. HE DECIDED TO DO A NOVASURE ABLATION THAT WOULD HELP WITH THE BLEEDING. IT DID FOR THE MOST PART BUT NONE OF MY OTHER ISSUES WENT AWAY. SEEN HIM SEVERAL TIMES DURING 2013 AND AT MY FINAL APT IN (B)(6) HE DECIDED TO DO AN ULTRASOUND. IT SHOWED THAT I HAD POST ABLATION SYNDROME. NOW I MUST TELL YOU THAT I NEVER HAD ANY ISSUES PRIOR TO HAVING ESSURE. IN (B)(6) OF 2013 I HAD TO HAVE A HYSTERECTOMY DUE TO ALL THE PAIN AND ISSUES. ONCE DOCTOR WAS IN THERE HE ADVISED US THAT I HAD ENDOMETRIOSIS AND ALSO ADENOMYOSIS. NEITHER WERE SEEN WHEN ESSURE WAS BEING PUT IN! I HAVE TO SAY THAT WITH NOT HAVING ANY FEMALE ISSUES AT ALL BEFORE ESSURE, THAT I'M CONVINCED THAT THE PET FIBERS IN THE DEVICE CAUSED ALL THESE ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034032	CONCEPTUS	1/23/2014	1/31/2014

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/8/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GETTING ESSURE IMPLANTED I HAVE DEVELOPED AN UNEXPLAINED FULL BODY RASH, MIGRAINES, DIZZY SPELLS, AND CONSTANT PAIN IN MY LEFT LOWER ABDOMEN. NONE OF THIS WAS PRESENT BEFORE THE IMPLANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034034	BAYER	1/23/2014	1/31/2014

Event Information:

Event Date (B3): 3/25/2010 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 681140

Single Use:
Implant Date (E6): 3/25/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I 'CHOOSE' ESSURE AS MY BIRTH CONTROL METHOD. SINCE BEING IMPLANTED, I HAVE HUGE MENSTRUAL BLOOD CLOTS, HEAVY MENSTRUAL FLOW (SOAKING THROUGH A SUPER MEGA TAMPON AND PAD IN UNDER 2 HOURS), EXTREME FATIGUE, MOOD SWINGS, SHARP PIERCING PELVIC PAIN, HAIR LOSS, METALLIC TASTE, MIGRAINES, WEIGHT GAIN (EVEN EATING RIGHT AND EXERCISING). THE LIST GOES ON AND ON. WHEN I PRESENTED TO MY DR. HE IMMEDIATELY OFFERED TO DO AN ABLATION OR HYSTERECTOMY. THOSE SIMPLY ARE NOT CHOICES YET. I AM LOOKING AT HAVING THESE COILS EITHER REMOVED, OR THE ENTIRE PROCEDURE REVERSED, AT THE OUT OF POCKET EXPENSE OF NEARLY (B)(6) TO AVOID THINGS LIKE PERFORATED TUBES, LESIONS, CYSTS, OR THE COILS MIGRATING ON THEIR OWN ACCORD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034035	BAYER	1/23/2014	1/31/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/20/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DIZZINESS, ABDOMINAL PAIN AND CRAMPING, EXCESSIVE VAGINAL DISCHARGE, EXTREMELY PAINFUL MENSTRUAL CYCLES, HEAVY MENSTRUAL CYCLES, PAIN, NUMBNESS, AND TINGLING IN FEET, MIGRAINE HEADACHES, JOINT PAIN AND DETERIORATION, TENDONITIS, ARTHRITIS, SKIN RASHES AND INFECTIONS, DRY EYE AND SKIN, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034060		1/23/2014	1/31/2014

Event Information:

Event Date (B3): 9/19/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN 2011, AND I HAVE HAD SO MUCH PAIN, BLOATING, FATIGUE, HEADACHES, MEMORY LOSS, BLURRED VISION, INSOMNIA, AND THE LIST GOES ON AND ON. I CANNOT LIVE DAILY IN SO MUCH PAIN. THE PHYSICIAN WHO PERFORMED THE SURGERY USED 2 PACKS, I HAVE THREE ESSURE COILS IN MY BODY, ONE HAS EMBEDDED INTO MY UTERUS WALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034070	CONCEPTUS BAYER	1/23/2014	1/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/18/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE IMPLANT IN (B)(6) 2010. IN (B)(6) 2013, BEGAN EXPERIENCING PERSISTENT NAUSEA ON A MONTHLY BASIS, USUALLY AROUND TIME OF MENSTRUATION. PERSISTENT NAUSEA MIMICS MORNING SICKNESS AND USUALLY LASTS ANYWHERE FROM A DAY TO TWO WEEKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034071	BAYER	1/23/2014	1/31/2014

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED (B)(6) 2013. I NOW SUFFER FROM CHRONIC FATIGUE, MIGRAINES, HEAVY BLEEDING, BLOOD CLOTS, BLEEDING FOR WEEKS ON END, BACK PAIN, BLURRED VISION, NO SEX DRIVE, CONSTANT PAIN IN MY JOINTS, BACK AND STOMACH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034031	CONCEPTUS, INC.	1/23/2014	2/3/2014

Event Information:

Event Date (B3): 1/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANT SURGERY IN (B)(6) 2012. I HAD A CONFIRMATION TEST COMPLETED 4 MONTHS AFTER THE PROCEDURE. I HAVE EXPERIENCED CONTINUOUS PAIN WITH ONE OF THE IMPLANTS, BUT MORE IMPORTANTLY I JUST FOUND OUT THAT I AM PREGNANT. AFTER SIGNING MULTIPLE DOCUMENTS ACKNOWLEDGING THAT I UNDERSTOOD I WOULD BE STERILE AND UNABLE TO HAVE ANY MORE CHILDREN, IT IS SHOCKING TO FIND OUT THAT I AM PREGNANT A YEAR LATER. AT THIS POINT, THE RISK TO MYSELF AND FETUS IS UNCLEAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034048	CONCEPTUS, INC.	1/24/2014	1/31/2014

Event Information:

Event Date (B3): 8/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/23/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS IMPLANTED IN (B)(6) 2013. ABOUT A MONTH AND A HALF I STARTED EXPERIENCING PAINFUL CRAMPING AND THEN JOINT PAIN, I KEPT GOING TO MY DOCTOR TELLING HER MY HANDS, WRIST AND KNEES WERE HURTING HORRIBLY. AFTER 3 MONTHS SHE RAN THE BLOOD WORK AND DIAGNOSED ME WITH RHEUMATOID ARTHRITIS AND SENT ME TO A RHEUMATOLOGIST NOW AFTER SEEING THIS DR. AND NOT BE ABLE TO WALK AT THIS POINT SHE SAID SOMETHING ELSE HAS TO BE WRONG SINCE I HAVE GOTTEN SO BAD SO FAST AND NO RELIEF WITH MEDICATION. SO AFTER DOING SOME RESEARCH MY BOYFRIEND FOUND OUT I COULD BE HAVING AN ALLERGIC REACTION TO MY COILS. I WENT TO GET BLOOD TEST DONE TO SEE IF I WAS ALLERGIC TO NICKEL. RIGHT NOW I CURRENTLY LOOKING FOR A DR TO REMOVE MY ESSURE COILS SEEING HOW THEY ARE THE BLAME FOR ALL THIS PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034052	CONCEPTUS, INC.	1/24/2014	1/31/2014

Event Information:

Event Date (B3): 6/21/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/21/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY YOUNGEST CHILD IN (B)(6) 2013. I WAS DONE HAVING CHILDREN AND WANTED TO GET TUBES TIED, BURNED SNIPPED DID NOT CARE IF THEY TOOK EVERYTHING. I JUST DIDN'T WANT ANY MORE CHILDREN. I HAVE 4. SO I WENT FOR MY 6 WEEK POSTPARTUM CHECK UP. THE DOCTOR, (B)(6), SUGGESTED THE ESSURE PROCEDURE. IT WAS SUPPOSED TO BE AN IN OFFICE PROCEDURE WITH A QUICKER RECOVERY TIME THAN A MAN GETTING A VASECTOMY, WAS TOLD THERE WERE NO SIDE EFFECTS. HEY I AM ALL FOR THAT WITH HAVING 4 KIDS AT HOME AND MY PARENTS LIVING OUT OF STATE BEING ABLE TO BE BACK ON MY FEET AND DOING MY MOMMY DUTIES QUICK WAS A BLESSING. SO ON (B)(6) 2013 I WENT INTO THE OFFICE WITH MY HUSBAND HAD THE PROCEDURE DONE AND WENT HOME IN A STATE OF HIGHNESS FROM THE PAIN KILLERS I WAS GIVEN IN OFFICE AND BEFORE PROCEDURE. IMMEDIATELY AFTER THE PAIN MEDICATION WORE OFF I NOTICED THAT I WAS STILL CRAMPING. I CALLED MY DOCTORS OFFICE AND WAS TOLD THAT IT WAS NORMAL. SO AFTER A MONTH OF THE SAME CRAMPING EVERYDAY I CONTACTED MY DOCTOR AGAIN, STILL BEING TOLD EVERYTHING WAS NORMAL AND I HAD TWO MORE WEEKS TO GO UNTIL MY HSG TEST WAS TO BE PERFORMED. TEST WAS DONE (B)(6) CONFIRMED TUBES WERE BLOCKED. STILL HAVING CRAMPS AND THE OTHER PROBLEMS, SO DOCTOR HAD ME COME IN FOR AN ULTRASOUND WHICH SHOWED A 1MM CYST. NOT ENOUGH TO DO ANYTHING BY TECHNICIAN OR NURSES TELLING ME. I NEVER HAD ANY PROBLEMS BEFORE THIS PROCEDURE AND MY DOCTOR ISN'T LISTENING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034014	BAYER	1/27/2014	1/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 654831

Single Use:
Implant Date (E6): 11/6/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE YEAR AFTER ESSURE IMPLANTED, CARDIOVASCULAR AND NEUROLOGIC SYMPTOMS BEGAN FOLLOWED BY SEVERE DERMATITIS CONDITIONS. ALL REQUIRING MULTIPLE DIAGNOSTIC TEST AND DOCTOR VISITS. CURRENTLY AWAITING SURGERY TO REMOVE IMPLANT FOR RELIEF OF SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034015		1/27/2014	1/31/2014

Event Information:

Event Date (B3): 3/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/1/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2006. SINCE THAT TIME I HAVE EXPERIENCED SEVERE ABDOMINAL PAIN WHICH IS LOCATED IN THE LEFT QUADRANT AND WILL QUITE OFTEN RADIATE TO MY BACK. I ALSO HAVE HAD VERY IRREGULAR MENSTRUAL CYCLES THAT DID NOT BEGIN UNTIL AFTER HAVING THE PROCEDURE. SOMETIMES THEY WOULD BE 2 WEEKS EARLY OR SOMETIMES I WOULD BE A WEEK LATE. I HAVE ALSO JUST RECENTLY BEGAN BREAKING OUT INTO HIVES WITH NO REASON. I USUALLY HAVE TO TAKE SEVERAL DOSES OF BENADRYL TO GET RID OF THEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034075	CONCEPTUS	1/27/2014	1/31/2014

Event Information:

Event Date (B3): 1/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/12/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONGOING PROBLEMS THAT STARTED AFTER ESSURE WAS INSERTED. INCREASED BP, ALLERGIC REACTIONS HAD TO GO TO THE ER TWICE, HAD STRESS TESTS, ULTRASOUNDS, HEAVY BLEEDING WITH MENES, FEELINGS OF EXHAUSTION AND JOINT PAIN, CHEST PAINS, AND COSTOCHONDRITIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034078	BAYER / CONCEPTUS	1/27/2014	1/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WITHIN MONTHS OF MY ESSURE IMPLANT I BEGAN CONSTANT VOMITING TO THE POINT OF REMOVING MY GALLBLADDER, WHICH DID NOT HELP, CONSTANT HOT FLASHED, CONSTANT CRAMPING AND SHARP PAINS, DIAGNOSED WITH FIBROMYALGIA, ANXIETY, AND PTSD TO THE POINT OF BEING ADMITTED TO A NEUROLOGICAL CENTER. I WAKE EVERY MORNING WITH "MORNING SICKNESS" AND CONSTANT PAINS THROUGHOUT MY ENTIRE BODY, MY JOINTS AND MUSCLES CONSTANTLY ACHE AND THE TOUCH OF ANYTHING ON MY SKIN IS SO SENSITIVE AND HEIGHTENED TO THE POINT I CAN'T HAVE ANYONE TOUCH ME. I, AT RANDOM POINTS, GET AN ODD METALLIC TASTE IN MY MOUTH THAT WON'T GO AWAY NO MATTER HOW MUCH I BRUSH MY TEETH OR USE MOUTHWASH. WITHIN A WEEK AFTER MY IMPLANTS I GOT MY VERY FIRST EVER MIGRAINE; THE MIGRAINES HAVE GOTTEN SO FREQUENT I FIND MYSELF BATTLING THEM WEEKLY SOMETIMES LASTING TWO OR THREE DAYS. I GET SO DIZZY AND LIGHT HEADED, FOR WHAT SEEMS TO BE NO APPARENT REASON, TO THE POINT I HAVE PASSED OUT. THIS PAST (B)(6), I GOT DIZZY AND PASSED OUT FALLING DOWN A FLIGHT OF STAIRS SHATTERING MY DOMINATE HAND. I HAD TO HAVE FOUR SCREWS AND A PLATE PUT IN AND AFTER FOUR LONG MONTHS OF THERAPY, I WILL NEVER HAVE FULL FUNCTION OF MY HAND AGAIN. I HAD TESTS RAN ON MY BRAIN, MY HEART AND BLOOD PRESSURE AND THERE IS NO EXPLANATION SO FAR AS TO WHY THIS ALL HAS BEEN HAPPENING. COINCIDENTALLY, EVERY PROBLEM THAT I HAVE HAD BEGAN WITHIN MONTHS OF MY ESSURE IMPLANTS AND BEFORE THESE THINGS WHERE PUT IN MY BODY I WAS ALWAYS HEALTHY. I WAS ALSO ACTIVE AND HAPPY, AND NOW I SHELTER MYSELF. I AM SCARED AND TOO HURT TO FUNCTION AND BE THE MOTHER AND HAPPY PERSON I WAS BEFORE THE IMPLANTS THAT I WAS ASSURED BY THE DOCTOR WAS "A MUCH SAFER ALTERNATIVE TO TUBAL LIGATION WITH PRACTICALLY NO SIDE EFFECT" HIS IDEA OF NO SIDE EFFECTS TURNED OUT TO BE THE WORST DECISION OF MY LIFE. I AM NOT MYSELF AND I KNOW IT'S

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BECAUSE OF THIS DEVICE. ESSURE IMPLANT, TWO COILS THAT ARE NOT REMOVABLE. THEY ARE PERMANENT. DOSE OR AMOUNT: 2 COILS; ROUTE: VAGINA. DATES OF USE: (B)(6) 2008. DIAGNOSIS OR REASON FOR USE: BIRTH CONTROL DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034101	CONCEPTUS INCORPORATED	1/28/2014	2/3/2014

Event Information:

Event Date (B3): 1/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 689939

Single Use:
Implant Date (E6): 9/30/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AND SINCE HAVE EXPERIENCED PINPOINTED SHARP STOMACH PAINS AND CRAMPS ON MY LOWER LEFT SIDE OF MY STOMACH, MIGRAINES, EXTREME LOWER BACK PAIN, AND BLEEDING WHEN I AM NOT SUPPOSED TO HAVE MY PERIOD AND EXTREMELY EXCESSIVE BLEEDING WHEN I DO, TO THE POINT OF BLEEDING THROUGH A SUPER TAMPON AND PAD AND UNDERWEAR AND CLOTHING REGARDLESS OF HOW MUCH I CHANGE FEMININE PRODUCTS. CAN LITERALLY STAND AND HAVE BLOOD GUSH OUT OF ME DURING MY PERIOD AS OPPOSED TO A NORMAL PERIOD FLOW. I WAS TRULY UPSET AND DISTRAUGHT THE OTHER DAY WHEN I WAS AT WORK AND PULLED DOWN MY PANTS TO GO TO THE BATHROOM AND CHANGE A TAMPON AND AS I DID THIS BLOOD LITERALLY WAS FALLING OUT OF ME INTO AND ALL OVER THE TOILET, THE TOP OF THE TOILET SIDES AND FLOOR ALL AROUND IT COULDN'T EVEN WIPE OR CONTROL IT FAST ENOUGH, WHEN I FINALLY WAS ABLE TO POSITION TO PULL THE TAMPON OUT BLOOD LITERALLY GUSHED OUT OF ME AND SPLATTERED EVERYWHERE INCLUDING EVEN ON THE BATHROOM WALL NEXT TO ME. THIS WAS HORRIBLE TO HAVE HAPPEN TO ME AT WORK, AND TRY TO BE IN THE BATHROOM CLEANING SO NO ONE KNOWS ABOUT IT BEFORE THE NEXT PERSON COMES IN! THIS IS SOMETHING I HAVE NEVER EXPERIENCED IN MY LIFE AND IT SEEMS TO HAVE GOTTEN WORSE AS TIMES GOES ON FROM HAVING HAD THE ESSURE PROCEDURE DONE. I HAVE SAT AT MY CHILD'S FOOTBALL GAMES AND BLED THROUGH EVERYTHING AND HAD TO GET UP WITH A BLANKET WRAPPED AROUND ME TO WALK TO THE CAR. I AM (B)(6). I KNOW MY BODY WELL AND I NEVER HAD ISSUES LIKE THIS BEFORE THIS ESSURE. I FIND MYSELF IN PAIN AND DISCOMFORT AT LEAST TWO WEEKS OUT OF EVERY MONTH, DURING SEX WITH MY HUSBAND, IT CAN BE PAINFUL OR UNCOMFORTABLE AT TIMES ALSO AND I BLEED ALMOST EVERY TIME WHICH NEVER HAPPENED PRIOR TO THE SURGERY.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034102	BAYER	1/28/2014	2/3/2014

Event Information:

Event Date (B3): 1/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): REF: ESS305
Catalog # (E4):
Lot #(E4): B04952

Single Use:
Implant Date (E6): 1/7/2014
Explant Date (E7): 1/14/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HELLO, I GOT MY RIGHT TUBE IMPLANTED WITH ESSURE ON (B)(6) 2014. INSTANTLY BEGAN TO HURT AND IT GOT WORSE DURING THE WEEK. THE SIDE EFFECTS WERE: ABDOMINAL PAIN, BACKPAIN, SHARP PAIN ON THE RIGHT SIDE, BLEEDING, DIZZY SPELLS, FEVER. EXACTLY ONE WEEK AFTER IMPLANT, THE COIL WAS REMOVED. AND ALL PAINS THAT I HAD WERE GONE. TO ME ESSURE SEEMED TO BE A GOOD OPTION BECAUSE THE BROCHURE WAS VERY POSITIVE AND I WOULDN'T NEED ANESTHESIA. A PAINLESS, 10 MINUTES PROCEDURE AND YOU CAN GO BACK TO WORK THE NEXT DAY. THAT IS MISLEADING! FOR MOST WOMEN THAT MAY BE THE CASE BUT FOR THOUSANDS IT ISN'T. I FIND IT DISTURBING THAT SO MANY WOMEN HAVE HAD TO GET HYSTERECTOMIES AT YOUNG AGES. THAT IS NOT WHAT THEY SIGNED UP FOR!! I WAS "LUCKY". BUT MY POINT IS THAT THE RISK SHOULD BE INVESTIGATED RATHER THAN TO BE DISMISSED SO HARSHLY AND DIRECT. IT'S YOUR JOB TO INVESTIGATE AND IF FOUND WITH DANGER, TAKING ESSURE OFF THE MARKET, OR AT LEAST INDICATE IT AT A LOWER LEVEL SO THAT BAYER CAN BE SUED FOR MALPRACTICE. I WISH YOU LOTS OF WISDOM IN YOUR NEXT ACTIONS. THIS IS A SERIOUS MATTER TO THOUSANDS OF WOMEN AND THEIR FAMILIES (WHOM BY THE WAY ARE ALSO DEALING WITH PREGNANCIES EVEN WHILE ON ESSURE) PARDON MY SPELLING, BUT I AM FROM THE (B)(6), I THANK YOU FOR YOUR TIME AND I EXPECT TO BE TAKEN SERIOUSLY. SINCERELY, (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034109	BAYER	1/28/2014	2/3/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED ABOUT 6 MONTHS AGO. I HAVE HAD EXTREME PAIN EVER SINCE, TYPICALLY AROUND THE TIME OF OVULATION. I HAVE ALSO NOTICED BACK PAIN, ACHINESS, FATIGUE, AND NAUSEA. I HAD THE CONFORMATION TEST DONE, CONFIRMING THAT THE IMPLANTS WERE PLACED IN THE CORRECT POSITION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034045	CONCEPTUS	1/29/2014	1/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4): 12367144

Single Use:
Implant Date (E6):
Explant Date (E7): 12/13/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE WAS IMPLANTED IN 2009 FOR BIRTH CONTROL AND IT CAUSED PATIENT TO SUFFER FROM HEAVY MENSTRUAL BLEEDING, PAINFUL MENSTRUAL BLEEDING, PAINFUL MENSTRUATION, BLOATING, INDIGESTION AND WEAKNESS. PATIENT WAS TOLD BY HER DOCTOR THAT SHE WAS HAVING A REACTION TO THE DEVICE. IT WAS REMOVED ON (B)(6) 2013 AND PATIENT ALSO HAD A PARTIAL HYSTERECTOMY. ALL SYMPTOMS RESOLVED FOLLOWING REMOVAL OF DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034123	BAYER	1/29/2014	2/4/2014

Event Information:

Event Date (B3): 8/20/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/20/2013
Explant Date (E7): 11/5/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2013, I HAD THE ESSURE PROCEDURE DONE BY DR (B)(6). I HAD CHOSEN THIS PROCEDURE UNDER THE RECOMMENDATION OF MY DOCTORS AND FRIENDS WHO HAVE HAD IT DONE AND BECAUSE I WOULD HAVE NO "DOWN TIME"; THIS WAS IMPORTANT TO ME, AS I HAVE TWO YOUNG CHILDREN TO CARE FOR. THE PROCEDURE WENT SMOOTHLY AND I EXPECTED TO BE "BACK TO NORMAL" THE NEXT DAY. HOWEVER, I HAD CHRONIC PAIN, CRAMPING, AND BLEEDING THAT LASTED FOR DAYS. I CALLED THE DOCTOR'S OFFICE (B)(6) AND WAS TOLD TO CALL BACK THE NEXT WEEK IF I WAS STILL HAVING ISSUES. I WAS, INCLUDING DEVELOPING A UTI, AND HAD AN ULTRASOUND DONE ON (B)(6). THE ULTRASOUND SHOWED THE COILS WERE IN PLACE AND NOTHING SEEMED OUT OF THE ORDINARY. THE PAIN, LOCATED IN MY ABDOMEN AND LOWER BACK, CONTINUED, SOMETIMES SEVERE, ALONG WITH THE CRAMPING AND SPORADIC BLEEDING. I HAD SORENESS IN THE AREA THE COILS WERE PLACED AND DEVELOPED AN UNUSUAL IRRITATION IN MY MOUTH. DUE TO THE MOUTH IRRITATION, THE PAIN, AND THE STRESS AND ANXIETY OF NOT KNOWING WHAT WAS CAUSING MY ISSUES, I HAD LITTLE APPETITE AND LOST 8-10 POUNDS IN A MONTH. MY DOCTOR, ALONG WITH OTHERS IN HER PRACTICE, WERE NOT SURE WHAT WAS WRONG AND HAD NOT SEEN ISSUES LIKE MINE AFTER ESSURE. THEY WEREN'T SURE IF THEY COULD DO ANYTHING TO RELIEVE MY SYMPTOMS. I WAS TAKING 600-800 MG OF IBUPROFEN EVERY FOUR HOURS DURING THE DAY AND TOOK PRESCRIBED PAINKILLERS AT NIGHT (THE DOCTOR GAVE ME PERCOCET AND VICODIN, WHICH I COULD NOT TAKE DURING THE DAY, AS I WAS HOME WITH MY SMALL CHILDREN). ON (B)(6), MY DOCTOR WAS ABLE TO REMOVE ONE COIL THROUGH HYSTEROSCOPY; THE OTHER COIL HAD MOVED INTO MY TUBE AND COULD NOT BE REMOVED THIS WAY. MY DOCTOR STATED THE COIL WAS REMOVED WITH EASE. WE WAITED SOME TIME TO SEE IF MY SYMPTOMS WERE RELIEVED BY THE REMOVAL OF ONE COIL. MY SYMPTOMS DID IMPROVE, BUT DID NOT GO AWAY. I WAS THEN SCHEDULED FOR A

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LAPAROSCOPIC SURGERY TO CUT THE TUBE TO REMOVE THE REMAINING COIL. THIS PROCEDURE WAS DONE ON (B)(6) 2013. MY DOCTOR REPORTED THAT THE COIL REMOVED VERY EASILY. SINCE THE REMOVAL OF BOTH COILS, THE PAIN HAS SUBSIDED, WITH ONLY SOME MOUTH IRRITATION REMAINING. OBVIOUSLY, MY BODY DID NOT LIKE THE COILS. SINCE THEY REMOVED WITH EASE, LIKE THEY HAD NO SCAR TISSUE SECURING THEM, I FEEL MY BODY WAS REJECTING THEM FROM THE START. I AM NOT SURE WHY MY BODY DID NOT REACT WELL TO THE COILS. BEFORE THE ESSURE PROCEDURE, I WAS ASKED A SERIES OF QUESTIONS, ONE BEING "ARE YOU ALLERGIC TO NICKEL?" I HONESTLY ANSWERED "I DON'T KNOW". I DON'T KNOW IF A NICKEL ALLERGY WAS AN ISSUE, BUT IF IT IS IMPORTANT ENOUGH TO BE ASKED BEFORE THE PROCEDURE, SHOULDN'T FURTHER ACTION BE TAKEN, LIKE A NICKEL TEST BEFORE SURGERY? I ENDURED CHRONIC PHYSICAL PAIN, AS WELL AS EMOTIONAL DISTRESS, INCLUDING THE STRESS OF DEALING WITH MY INSURANCE COMPANY TO SEE IF THEY WOULD COVER THE COST OF REMOVAL OF THE COILS. MY DAILY LIFE AND ACTIVITIES WERE NEGATIVELY AFFECTED. I WAS TRYING TO AVOID AN INVASIVE SURGERY BY HAVING THE ESSURE PRODUCT DONE AND ENDED UP HAVING 2 SURGERIES AFTER ESSURE. I KNOW MY ESSURE EXPERIENCE IS NOT COMMON BUT I DON'T THINK I AM THE ONLY ONE TO HAVE A NEGATIVE EXPERIENCE. IF SOMETHING CAN BE DONE, LIKE PRE-PROCEDURE TESTING, TO PREVENT AN EXPERIENCE LIKE MINE, I FEEL SOMETHING SHOULD BE DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034135		1/29/2014	2/4/2014

Event Information:

Event Date (B3): 11/30/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): HYSTEROSCOPIC STERILIZATION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/11/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT CONCEIVED APPROXIMATELY 7 MONTHS AFTER HAVING ESSURE PLACED. OF NOTE, SHE DID NOT GET THE CONFIRMATORY HSG TEST DONE. SHE INITIALLY HAD DMPA AFTER THE PROCEDURE AND THEN STARTED ORAL CONTRACEPTIVE PILLS BUT STOPPED THEM DUE TO SIDE EFFECTS. INSERTED PER NORMAL PROCEDURES. PT HAD A PREGNANCY TERMINATION ON (B)(6) 2014 DUE TO PATENT. TUBES/DEVICE FAILURE (LIKELY EXPULSION).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00013	BAYER HEALTHCARE LLC	1/29/2014	2/6/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/9/2007
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSUMER HAD ESSURE INSERTED ABOUT 7 WEEKS AFTER DELIVERING HER SECOND SON. NUVA RING WAS USED AS BACK-UP CONTRACEPTION BEFORE TOTAL OCCLUSION CONFIRMATION. ON UNSPECIFIED DATE, HYSTEROSALPINGOGRAM TEST WAS PERFORMED AND SHOWED BOTH TUBES COMPLETELY OCCLUDED. LEFT ABDOMINAL PAIN AND FATIGUE WERE PRETTY MUCH INSTANT AFTER THE INSERTION. THE PAIN DURING INTERCOURSE STARTED APPROXIMATELY 1 YEAR AFTER INSERTION. THE HIGH BLOOD PRESSURE, LACTOSE INTOLERANCE, GLUTEN SENSITIVITY AND HIGH CHOLESTEROL STARTED 1 YEAR AGO, FROM THIS REPORT. THE CONSUMER ADDED CHRONIC UTI'S AS AN EVENT DURING ESSURE TREATMENT. ON (B)(6) 2013, SHE HAD AN EXPLORATORY LAPAROSCOPY. SHE WENT TO HER PHYSICIAN WITH UNBEARABLE PAIN ON A THURSDAY AND HAD THE SURGERY ON THAT FRIDAY, THE DAY AFTER. SHE HAD A HYSTERECTOMY; HOWEVER, HER OVARIES ARE STILL IN PLACE. THE RIGHT ESSURE WAS REMOVED SOMETIME AFTER (B)(6) 2013. ESSURE WAS REMOVED BY LAPAROTOMY AND HYSTERECTOMY. SHE WAS TOLD THAT ONE OF THE ESSURES PERFORATED ONE OF FALLOPIAN TUBES. THEY ALSO IDENTIFIED A HUGE FIBROID TUMOR IN HER UTERUS. ALL THE EVENTS STOPPED IMMEDIATELY AFTER ESSURE WAS REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00008	BAYER HEALTHCARE LLC	1/29/2014	2/7/2014

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/6/2013
Explant Date (E7): 11/6/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED. ORTHO-CYCLEN PILLS WERE USED AS BACK-UP CONTRACEPTION AFTER INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. SHE HAD TWO HSG (HYSTEROSALPINGOGRAM) TESTS PERFORMED. FIRST HSG AT 3 MONTHS POST INSERTION, SECOND IN (B)(6) 2013 TO SEE IF LEFT SIDE TUBE WAS BLOCKED. BOTH TESTS SHOWED THAT THE RIGHT SIDE TUBE WAS BLOCKED, BUT THE LEFT SIDE NEVER BLOCKED. SHE EXPERIENCED HORRIBLE PAIN ON THE LEFT SIDE AFTER SECOND HSG DONE IN (B)(6) 2013. SHE RECEIVED PAIN MEDICATIONS. SHE WAS NOT HOSPITALIZED; SHE JUST WENT TO THE EMERGENCY ROOM FOUR TIMES, WAS IN AND OUT THE SAME DAY. BETWEEN (B)(6) 2013, CT (COMPUTED TOMOGRAPHY) SCAN WAS PERFORMED, BUT RESULTS WERE NOT PROVIDED. SHE HAD A SALPINGECTOMY TO REMOVE ESSURE AND BELIEVED THE REMOVAL WAS MEDICALLY NECESSARY SINCE THE LEFT SIDE NEVER BLOCKED AND HER DOCTOR RECOMMENDED REMOVAL BEING AFRAID OF IT MIGRATING. IT WAS REPORTED THAT BOTH COILS WERE FOUND IN PLACE, THE LEFT SIDE NEVER CLOSED AND NOTHING BROKE OFF. PAIN WENT AWAY ALMOST IMMEDIATELY ONCE ESSURE WAS REMOVED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 29-AUG-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00009	BAYER HEALTHCARE LLC	1/29/2014	2/7/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2009
Explant Date (E7): 7/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED SHE RECEIVED THE ESSURE COIL IMPLANTS AND SUFFERED COMPLICATIONS (NOT OTHERWISE SPECIFIED) AND HORRIBLE PAIN OVER A SPAN OF TWO YEARS THAT EVENTUALLY LED TO A HYSTERECTOMY WITH REMOVAL OF ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00010	BAYER HEALTHCARE LLC	1/29/2014	2/7/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 731586

Single Use: Y
Implant Date (E6): 7/1/2010
Explant Date (E7): 11/28/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSUMER REPORTED SHE HAD ESSURE IMPLANTED. IMMEDIATELY AFTER THE SURGERY SHE HAD THE FOLLOWING SYMPTOMS: PAIN, MIGRAINES, NAUSEA, WEIGHT FLUCTUATIONS, INFLAMMATION, SWELLING, FREQUENT INFECTIONS, IRREGULAR UTERINE BLEEDING, ACNE, RASHES, AND CYST FORMATION IN THE FALLOPIAN TUBE. SHE STATED THAT SHE WAS IN A CAR ACCIDENT IN 2010 WHERE SHE TOTALED HER CAR BECAUSE SHE PASSED OUT WHILE DRIVING DUE TO THE EXTREME PAIN. ABOUT 11 MONTHS LATER, SHE REPORTED SEEING A DOCTOR WHO ASKED IF SHE WAS GIVEN AN ALLERGY TEST BEFORE THE IMPLANTATION OF THE DEVICE. SHE FOUND OUT THAT INDEED SHE WAS ALLERGIC TO THE NICKEL IN THE ESSURE. SHE ALLEGED THAT SHE NEARLY DIED AND THEY HAD TO GIVE HER EMERGENCY SURGERY TO REMOVE THE DEVICE. SHE REPORTED THAT A PHYSICIAN TOLD HER IT TAKES ABOUT A YEAR FOR THE NICKEL TO DETOX OUT OF THE BODY, BUT SHE CONTINUES TO HAVE ALL OF THE SYMPTOMS SHE HAD PRIOR TO THE ESSURE'S REMOVAL- BUT THEY ARE NOT AS BAD AS BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00011	BAYER HEALTHCARE LLC	1/29/2014	2/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A08087

Single Use: Y
Implant Date (E6): 3/22/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A NON-HEALTHCARE PROFESSIONAL REPORTED A CONSUMER HAD ESSURE INSERTED. SHE EXPERIENCED MIGRATION OF THE COIL INTO THE PELVIS, PELVIC PAIN AND NICKEL ALLERGY (ALLERGIC RASH ALL OVER BODY). LAPAROSCOPIC REMOVAL OF ESSURE COIL FROM LEFT SIDE AND LAPAROSCOPIC LINEAR LEFT SALPINGOSTOMY PERFORMED ON (B)(6) 2013. THE RIGHT SIDE WAS NOT REMOVED. OUTCOME OF THE REPORTED EVENTS WAS RECOVERED.

Manufacturer Narrative (H10):

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This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00012	BAYER HEALTHCARE LLC	1/29/2014	2/7/2014

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 9/18/2004
Explant Date (E7): 10/28/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSUMER REPORTED THAT ESSURE WAS INSERTED 30 MONTHS AFTER PREGNANCY. SHE USED CONDOMS AS BACK UP CONTRACEPTION AFTER INSERTION, BEFORE TOTAL OCCLUSION CONFIRMATION. HYSTEROSALPINGOGRAM WAS PERFORMED AT 3 MONTHS AND IT WAS NORMAL OR OCCLUDED. SHE BEGAN HAVING PELVIC PAIN IN 2006. IT WAS INTERMITTENT PAIN FOR 5 YEARS AND CONSTANT FOR THE LAST 2 YEARS. THE PAIN WAS SO DISTRACTING SHE HADN'T WORKED SINCE (B)(6) OF 2011. AN ULTRASOUND, BLOOD TESTS AND SHE THOUGHT A PELVIC SONOGRAM, WAS PERFORMED IN 2013, BUT SHE COULD NOT RECALL. SHE DID NOT HAVE THE PATHOLOGY RESULTS. BASED ON HER SYMPTOMS SHE WAS TOLD SHE DEVELOPED NICKEL ALLERGY POST PLACEMENT. SHE SAW HER DOCTOR AGAIN IN (B)(6) 2013 AND HE SAID IT WAS THEORETICALLY NOT POSSIBLE FOR HER PAIN TO BE A PROBLEM AND THAT THE PROBLEM WAS HER AGE. HYSTERECTOMY, BILATERAL SALPINGECTOMY AND LAPAROSCOPIC ESSURE REMOVAL OCCURRED ON (B)(6) 2013. CONSUMER ALSO MENTIONED THAT ONE ESSURE WAS PRESSING ON HER FALLOPIAN TUBE MAKING IT VERY, VERY THIN. THE OTHER HAD MIGRATED INTO THE UTERUS AND WAS DESCRIBED AS LOOKING LIKE A TANGLED WEB. THE CONSUMER FELT MUCH BETTER AFTER ESSURE REMOVAL AND ALSO CONSIDERED HER CONDITION AS RELATED TO ESSURE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00014	BAYER HEALTHCARE LLC	1/29/2014	2/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 12/30/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A PATIENT HAD ESSURE IMPLANTED IN 2009. PHYSICIAN REPORTED THAT, ON (B)(6) 2013 AND ON (B)(6) 2013, SONOGRAPHIES WERE PERFORMED SHOWING ESSURE'S INCORRECT POSITION. NO PERFORATIONS WERE FOUND, BUT PATIENT WAS PRESENTING WITH DYSMENORRHEA AND MENORRHAGIA. PATIENT WAS CONCERNED ABOUT BEING PREGNANT AND, BECAUSE OF THAT, ON (B)(6) 2013 ESSURE WAS REMOVED VIA HYSTEROSCOPY. DURING SURGERY IT WAS NOTED THAT THE RIGHT DEVICE WAS WHOLE IN THE ENDOMETRIUM AND THE LEFT DEVICE WAS PARTIALLY IN THE ENDOMETRIUM. PHYSICIAN SUSPECTS THAT THE INTRAUTERINE POSITION OF THE DEVICE CAUSED THE PAIN AND BLEEDING. AFTER REMOVAL OF THE RIGHT SIDED DEVICE BEING COMPLETED, THE LEFT SIDED WAS ALSO REMOVED. PATHOLOGY RESULTS ARE PENDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034141		1/30/2014	2/5/2014

Event Information:

Event Date (B3): 5/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE COIL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/28/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2013 FOUR PIECES BROKE OFF ESSURE COIL DURING DEPLOYMENT IN RIGHT REMAINING TUBE. WAS TOLD AND IT WAS WRITTEN IN MY OPERATING REPORT BY THE DOCTOR AND ESSURE REP THAT THIS HAPPENED TO PATIENTS BEFORE WITH NO EFFECT ON HSG CONFIRMING OCCLUSION. HAD SEVERE ABDOMINAL PAIN FOR A MONTH AFTERWARDS. ON (B)(6) 2013 FOLLOW UP HSG SHOWED THAT THE COIL HAD MIGRATED NEAR THE END OF THE TUBE NEAREST THE OVARY AND NO OCCLUSION HAD TAKEN PLACE. ON (B)(6) 2013 DOCTOR STATED THE ONLY WAY TO KNOW IF COIL HAS PERFORATED THE TUBE, IS BY HAVING SURGERY. STILL HAVE MODERATE-SEVERE PAIN ON RIGHT SIDE IN LOCATION OF COIL, ESPECIALLY DURING OVULATION, AFTER INTERCOURSE AND EXERCISE. HAVE DEVELOPED SEVERE PSORIASIS ON SCALP, WHICH I NEVER HAD PRIOR TO ESSURE. I WAS NEVER TESTED FOR A NICKEL ALLERGY PRIOR TO PROCEDURE, WHICH I'VE FOUND OUT AFTERWARDS SHOULD HAVE BEEN DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034142		1/30/2014	2/5/2014

Event Information:

Event Date (B3): 4/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 689933

Single Use:
Implant Date (E6): 4/22/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE ESSURE WAS PUT IN, I HAVE HAD HEALTH ISSUES. FIRST THE BLEEDING AND CRAMPING WAS SO BAD I NEEDED AN ABLATION, THEN I SUDDENLY WAS LEAKING URINE AND SO HAD SURGERY FOR BLADDER MESH. IT TURNED OUT I DIDN'T REALLY NEED THE MESH OR AT LEAST AS TIGHT AS IT WAS SO I COULDN'T URINATE ON MY OWN FOR OVER NINE WEEKS. I THEN HAD A SURGERY TO RELEASE THE MESH. BLED VERY BADLY AFTER SURGERY, THEN THE MESH CAME THROUGH THE VAGINAL WALL AND I HAD TO HAVE SURGERY TO HAVE THAT REMOVED, THEN THE MESH WAS IN THE WRONG PLACE, SO I NEEDED ANOTHER SURGERY TO REMOVE AS MUCH OF THE MESH AS POSSIBLE, AND THEN BLED VERY BADLY AGAIN AND IT HAS CHANGED ME FOREVER. ALL THE WHILE I HAVE BEEN IN PAIN, I THOUGHT MAYBE IT WAS THE MESH BUT I SIT HERE AFTER HAVING IT REMOVED AND I AM IN CHRONIC PAIN. I'VE HAD ABOUT EVERY TEST KNOWN TO MAN KIND AND THEY CAN'T FIND A CAUSE. I HAVE, SINCE ESSURE, VERY BAD HEADACHES, BACK PAIN, EXTREME PELVIC AND LOWER STOMACH PAIN, BEEN TOLD I HAVE AN AUTO IMMUNE DISORDER, CONSTANT URINARY TRACT INFECTIONS, VITAMIN D DEFICIENCY, AND ALL THESE THINGS CAME AFTER ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034146	CONCEPTUS INC. USA	1/30/2014	2/5/2014

Event Information:

Event Date (B3): 5/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 789025; 761438

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM THE MOMENT I WAS IMPLANTED I HAD DAILY CRAMPING AND BACKACHES AND OVER THE 2 PLUS YEARS IT CONTINUALLY WORSENED TO THE POINT THAT I COULDN'T FUNCTION. ALSO I HAD SEVERE MIGRAINES, WEIGHT GAIN, EXTREME FATIGUE, DEPRESSION, PAIN DURING SEX, RANDOM NUMBNESS IN MY FEET, AND IRREGULAR PERIODS. ALL OF THESE SYMPTOMS ARE GONE SINCE HAVING THE ESSURE REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00015	BAYER HEALTHCARE LLC	1/30/2014	2/14/2014

Event Information:

Event Date (B3): 12/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 12/31/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

WHILE INSERTING THE DEVICE IN THE FALLOPIAN TUBE, THE REPORTING PHYSICIAN USED THE BUTTON AND IT DID NOT RELEASE COMPLETELY. PART OF THE DEVICE WAS IN THE FALLOPIAN TUBE AND THE REST OF THE COILS UNRAVELED. HE COULD NOT REMOVE THE DEVICE AND HE PUSHED THE UNRAVELED COILS BACK IN THE PATIENT'S UTERUS. HE WAS TAKING HER TO THE OPERATION ROOM FOR A TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00016	BAYER HEALTHCARE LLC	1/30/2014	3/4/2014

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/23/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED. IN 2010, SHE EXPERIENCE PAIN WITH HER PERIODS WHICH SHE BELIEVED WERE CRAMPS. IN 2012, SHE WAS HOSPITALIZED WITH SEVERE PAIN. THEY LOOKED AT HER APPENDIX, BUT NOTHING WAS FOUND. SHE WAS STILL HAVING PAIN AND SAW ANOTHER PHYSICIAN. AN EXPLORATORY SURGERY WAS PERFORMED AND A COIL WAS FOUND WRAPPED AROUND HER VEINS. SHE HAD HER RIGHT FALLOPIAN TUBE REMOVED ON (B)(6) 2012. NOW SHE IS HAVING PAIN ON HER LEFT SIDE AND EVERY NOW AND THEN, PAIN ON HER RIGHT SIDE AFTER THE SURGERY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00017	BAYER HEALTHCARE LLC	1/30/2014	3/4/2014

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS#05
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2011
Explant Date (E7): 11/7/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED BY A PHYSICIAN. NO BACK-UP CONTRACEPTION WAS USED AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION BECAUSE THE CONSUMER WAITED TO HAVE SEX UNTIL HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AFTER THE THREE MONTH PERIOD. SINCE INSERTION SHE HAS HAD BURNING WHERE HER TUBES ARE, NERVE PAIN SHOOTING DOWN HER LEGS, UNEXPLAINED SWEATING AND BACK PAIN. SHE HAS HAD HEADACHES ON A REGULAR BASIS, WHICH SHE NEVER USED TO GET. SHE IS EXHAUSTED ALL OF THE TIME. SHE HAD EVEN DEVELOPED ALOPECIA SINCE GETTING ESSURE. SHE REPORTED AT LEAST TWO CHEMICAL PREGNANCIES, NOT CONFIRMED BY A PHYSICIAN. FOR THE FIRST CHEMICAL PREGNANCY, MENSTRUAL PERIOD HAD BEEN TWO DAYS LATE AND SHE HAD THREE POSITIVE HME TESTS IN (B)(6) 2012. WHEN SHE WENT TO THE PHYSICIAN, THE TEST WAS NEGATIVE BY THEN. FOR THE FIRST CHEMICAL PREGNANCY SHE HAD AN ULTRASOUND PERFORMED WHICH DETECTED NO PREGNANCY. SHE HAD TWO POSITIVE HOME TESTS IN THE BEGINNING 2013 FOR THE SECOND CHEMICAL PREGNANCY, BUT NEVER WENT TO THE PHYSICIAN. SHE JUST KNEW SHE WAS NOT PREGNANT ANYMORE, BECAUSE OF HER FIRST EXPERIENCE. SHE DID NOT REMEMBER THE EXACT DATES. ESSURE WAS REMOVED DUE TO ALL HER SYMPTOMS. SHE HAD A HSG RIGHT BEFORE THE SURGERY JUST TO CONFIRM THAT THE DEVICES WERE IN PLACE AND THEY WERE. CONSUMER REPORTED AS FOR REMOVAL OF THE ESSURE SHE HAD AN ABDOMINAL INCISION LIKE A C-SECTION AND THEY WENT IN AND UNATTACHED HER FALLOPIAN TUBES FROM THE UTERUS AND REMOVED THE ESSURES AND THEN REATTACHED THE TUBES TO HER UTERUS, HYSTERECTOMY OR SALPINGECTOMY WERE NOT DONE, SHE STATED SHE GOT TO KEEP ALL HER PARTS. CONSUMER DOES NOT KNOW OF PATHOLOGY RESULTS. DURING SURGERY, THE RIGHT ESSURE WAS IN PLACE AND THERE WERE NO SEEN ISSUES. THE LEFT WAS SHOWN TO HAVE PERFORATED THE FALLOPIAN TUBE, NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS

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AFFECTED. CONSUMER STATED THE PERFORATION DID NOT OCCUR DURING THE INSERTION PROCEDURE. THE SYMPTOMS/PAIN RESOLVED AFTER SURGERY, EXCEPT WHILE SHE HAD THE ESSURE, SHE HAD GAINED 20 LBS (POUNDS) AND SHE STILL HAS THEM.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00018	BAYER HEALTHCARE LLC	1/30/2014	3/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 740669

Single Use: Y
Implant Date (E6): 7/14/2010
Explant Date (E7): 4/26/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED AND STARTED TO HAVE MANY SIDE EFFECTS WHICH SHE BELIEVED WERE RELATED TO A NICKLE ALLERGY. SHE WAS NOT TOLD PRIOR TO INSERTION THAT ESSURE CONTAINED NICKEL. SHE EXPERIENCED PAIN, CRAMPING, SEVERE BLEEDING, CYSTS, INFECTIONS, HEADACHES, DIZZINESS, PAINFUL INTERCOURSE, FOGGINESS, BLEEDING AFTER INTERCOURSE, RASHES, BLOATING, WEIGHT GAIN AND ADENOMYOSIS. HER SYMPTOMS STARTED SHOWING UP AROUND A YEAR AND A HALF AFTER THE INSERTION AND PROGRESSIVELY GOT WORSE UNTIL THEY BECAME UNBEARABLE. SHE HAD A HYSTERECTOMY AND HER TUBES WERE ALSO REMOVED IN ORDER TO REMOVE ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00023	BAYER HEALTHCARE LLC	1/30/2014	3/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 810881

Single Use: Y
Implant Date (E6): 12/1/2011
Explant Date (E7): 9/12/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED FOR BIRTH CONTROL. HER HUSBAND HAD A VASECTOMY, SO NO OTHER BACK-UP CONTRACEPTION WAS NECESSARY. NO HSG WAS PERFORMED. WITHIN A FEW MONTHS SHE STARTED BREAKING OUT IN A RASH THAT STARTED AS A COUPLE OF BUMPS AND THEN SPREAD TO HER WHOLE BODY. SHE WENT TO A NEW OB/GYN AND A DERMATOLOGIST CONCERNING THESE SYMPTOMS AND NO PARTICULAR DIAGNOSIS WAS GIVEN. SHE WAS TREATED WITH STEROIDS FOR WHOLE BODY HIVES, AND GAINED 60 POUNDS DUE TO THE STEROIDS. THE RASH WAS IN HER THROAT AND DOCTORS FEARED IT WAS CLOSING HER THROAT. SHE EXPERIENCED EAR PAIN (DEEP STABBING), NECK ARTHRITIS, DRY MOUTH, DRY EYES, DRY SKIN, FACIAL REDNESS/ROSACEA, SCALEY RED BODY RASH - BODY ITCHY, FATIGUE, DERMATOGRAPHIC URTICARIA, CHRONIC URTICARIA, HEAT INDUCED URTICARIA, JOINT PAIN OF SHOULDERS AND ANKLES, HAIR LOSS, SWELLING OF HANDS AND FEET, LARGE WEIGHT LOSS, LOSS OF APPETITE, LOSS OF SEXUAL DRIVE, BRUISING, SLOW HEALING CUTS, CHRONIC CONSTIPATION WITH OVERFLOW FOLLOWED BY FULL CONSTIPATION, ULCERS IN MOUTH, AND NAUSEA. SHE ENDED UP HAVING A HYSTERECTOMY REMOVING HER UTERUS AND TUBES CONTAINING THE COILS. SHE IS NOW SYMPTOM FREE AND HAS NO HIVES.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 11-NOV-2013: UPON INTERNAL REVIEW, IT WAS NOTED THAT TWO CASES HAVE BEEN CREATED FOR THE SAME PATIENT. THIS CASE WAS UPDATED WITH THE INFORMATION FROM THE DUPLICATE CASE (B)(4). FUP INFORMATION RECEIVED ON 27-NOV-2013: NO NEW CLINICA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034173		1/31/2014	2/6/2014

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 7/1/2010
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT PROCEDURE DONE IN (B)(6) 2009. I STARTED EXPERIENCING EXCRUCIATING ABDOMINAL PAIN IN (B)(6) 2010. I ALSO HAD HEADACHES. I ENDED UP HAVING A PARTIAL HYSTERECTOMY TO HAVE THE IMPLANTS REMOVED ON (B)(6) 2010. I HAD NUMEROUS EMERGENCY ROOM VISITS TO SEE WHAT WAS CAUSING THE ISSUE AND THERE WAS NEVER A GOOD ANSWER. ONCE THE IMPLANTS WERE REMOVED I HAVE HAD NO FURTHER MEDICAL PROBLEMS. I WAS ONLY (B)(6) WHEN THIS OCCURRED AND NEVER IMAGINED HAVING TO HAVE A HYSTERECTOMY AT THIS EARLY OF AN AGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034191		2/3/2014	2/7/2014

Event Information:

Event Date (B3): 5/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/9/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY WIFE HAD THE ESSURE PROCEDURE DONE THREE YEARS AGO. SHE HAD MANY OF THE PAIN SYSTEMS OTHER WOMEN HAVE COMPLAINED ABOUT. IN LATE (B)(6) OF 2013, WE DISCOVERED SHE WAS PREGNANT. THE REASON MY WIFE HAD THE PROCEDURE DONE WAS HER FIRST TWO CHILDREN WERE PREMATURE AND OUR LAST CHILD SHE WAS ABLE TO CARRY FULL TERM BUT IT TOOK A TOLL ON HER BODY. NOW FINDING OUT THAT SHE WAS 7 MONTHS PREGNANT SHE WAS NOT ABLE TO TAKE CARE OF HERSELF PROPERLY. DOCTORS DISMISSED ANY CHANCE OF PREGNANCY, KNOWING SHE HAD THE ESSURE PROCEDURE DONE, SHE WAS TREATED FOR OTHER POSSIBLE PROBLEMS AND GIVEN DRUGS THAT WOULD NOT BE GIVEN TO A PREGNANT WOMAN. WE WENT ON OUR OWN AND BOUGHT A HOME TEST AFTER SHE STARTED LACTATING, THEN FOLLOWED UP WITH HER DOCTOR. AFTER SHE HAD HER ULTRASOUND DONE IT WAS DISCOVERED THAT HER PLACENTA IS SITTING ON HER CERVIX. DUE TO THIS SHE MUST NOW BE EXTRA CAUTIOUS FOR IF SHE GOES INTO LABOR EARLY WITHOUT PROPER MEDICAL PERSONNEL AND EQUIPMENT NEAR BY, SHE CAN BLEED TO DEATH. ALONG WITH A C-SECTION, SHE MUST NOW BE HOSPITALIZED, FOR YET ANOTHER BIRTH CONTROL PROCEDURE, THIS TIME A MORE TRADITIONAL TUBAL, SHE REQUIRES THE DOCTORS TO CUT HER TUBES AND MAKE SURE THAT THE ESSURE SPRINGS ARE REMOVED AND NO LONGER POSE ANY HEALTH RISK TO HER, DUE TO THE COMPLICATIONS OF THE UNWANTED AND UNPLANNED PREGNANCY HER LIFE IS NOW IN DANGER. SHE IS DUE NOW AT THE END OF (B)(6), 2014, WE PRAY THAT ALL GOES WELL FOR BOTH HER AND OUR UNEXPECTED CHILD. WE FEEL VERY LUCKY THAT THE EGG WAS NOT FERTILIZED IN HER TUBES AND THAT MY WIFE, EVEN THOUGH SHE DID MANY THINGS A PERSON DOES THAT IS NOT PREGNANT, DOES TAKE GOOD CARE FOR HER HEALTH AND DOES NOT DRINK OR SMOKE. WE STILL WORRY

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ABOUT THE BABY'S HEALTH AND ANY LONG TERM DAMAGE THE PRESCRIPTION DRUGS MY WIFE IS ON MAY HAVE. SHE WAS ON CYCLOBENZAPRINE AND NAPROXEN FOR BACK PROBLEMS AS WELL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034195		2/3/2014	2/7/2014

Event Information:

Event Date (B3): 1/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/7/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2012. SINCE (B)(6) 2013, HAVE HAD INCREASING PAIN IN LEFT PELVIC AREA. INCREASED MENSTRUAL BLEEDING WITH METALLIC SMELL. INCREASINGLY PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE, METALLIC SMELL WITH BLEEDING AND DISCHARGE AFTER INTERCOURSE. RECENTLY HAVE STARTED HAVING CHEST PAIN AND DIZZINESS WITH A NEGATIVE CARDIAC WORK-UP. TINGLING SENSATION IN ARMS AND FEET. INCREASED FREQUENCY OF HOT FLASHES. DECREASED ENERGY WITH WEIGHT GAIN. INABILITY TO LOSE WEIGHT WITH DIETING AND EXERCISE. UNABLE TO WEAR JEWELRY I HAVE WORN FOR YEARS DUE TO ITCHING AND REDNESS IN AREA OR SKIN TURNING GREEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034211	CONCEPTUS, INC	2/4/2014	2/10/2014

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

REC'D ESSURE (B)(6) 2013. I HAVE NEVER EXPERIENCED THESE SYMPTOMS UNTIL AFTER HAVING THE DEVICE IMPLANTED. I GET SEVERE ABDOMINAL CRAMPING ESPECIALLY ON THE LEFT SIDE. EXCESSIVE BLOATING TO THE POINT I LOOK PREGNANT, BODY AND MUSCLES ACHES, HAIR LOSS, PAIN DURING SEX, BAD HEADACHES ALMOST EVERYDAY, SEVERE FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034213	CONCEPTUS	2/4/2014	2/10/2014

Event Information:

Event Date (B3): 12/6/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 621684

Single Use:
Implant Date (E6): 12/6/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2006, I HAD ESSURE COILS INSERTED. I WAS EXPERIENCING SEVERE MENORRHAGIA AND WAS TOLD BY MY DOCTOR (WHO DID NOT FURTHER WORK-UP TO DETERMINE THE CAUSE) THAT THE ONLY SOLUTION TO THE MENORRHAGIA WAS UTERINE ABLATION AND THAT I WOULD HAVE TO BE STERILIZED PRIOR. I TOLD MY MD THAT I AM NICKLE ALLERGIC AND HE ADVISED THAT IT WOULD NOT MATTER AND IN FACT WOULD HELP PROMOTE SCAR TISSUE GROWTH TO OCCLUDE THE TUBES FASTER. HE ADVISED MY HUSBAND AND ME THAT ESSURE WAS THE BEST WAY TO DO THIS AND MADE ME FEEL AS IF I WERE MAKING A BAD DECISION IF I DIDN'T DO IT. IMMEDIATELY AFTER SURGERY, I HAD TO HAVE MORPHINE TWICE AND WAS SENT HOME WITH PAIN MEDS. THREE DAYS POST-OP, I DEVELOPED FEVER OF 102 AND SIGNIFICANT LOWER RIGHT QUADRANT PAIN. I CALLED THE MD'S OFFICE AND THE NURSE RETURNED MY CALL. SHE ADVISED THAT MY BODY WAS PROBABLY TRYING TO REJECT THE COILS AND CALLED IN AN ANTIBIOTIC AND VICOPROFEN FOR PAIN. SINCE THE ESSURE, I HAVE DEVELOPED SEVERE ATYPICAL MIGRAINES WITH STROKE LIKE SYMPTOMS, SEVERE DEPRESSION / ANXIETY AND NOW BIPOLAR DISORDER, I ONLY HAVE A PERIOD WHEN IT'S INDUCED BY MEDICATION, I HAVE GAINED A TREMENDOUS AMOUNT OF WEIGHT, I AM SEVERELY VITAMIN D DEFICIENT, I'M CONSTANTLY FATIGUED, I FALL ASLEEP WITH NO WARNING, I HAVE NO LIBIDO, I HAVE HAD ACNE TO THE POINT OF NEEDING MEDICATION (NEVER HAVE I EVER HAD ACNE BEFORE), I HAVE BEEN DIAGNOSED WITH PCOS, CYSTS ON MY OVARIES, AND CONSTANT PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034214	BAYER	2/4/2014	2/10/2014

Event Information:

Event Date (B3): 12/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): 5028694
Catalog # (E4):
Lot #(E4): 0000206785

Single Use:
Implant Date (E6): 12/28/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE HAS TAKEN OVER MY LIFE SINCE (B)(6) 2011 DAILY SEVER PAIN, LOSS OF SMELL, BLOATING, SEVER MEMORY LOSS, BACK PAIN, PELVIC PAIN, SEVERE DEPRESSION, ALWAYS HAVING LOW GRADE FEVER, DIZZINESS, EYE SITE ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034219	BAYER	2/4/2014	2/10/2014

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): CONCEPTUS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

AS A PREVIOUSLY VERY HEALTHY PERSON WITHIN MONTHS OF HAVING ESSURE IMPLANTED I HAD TO HAVE MY GALLBLADDER REMOVED, FOLLOWED BY MANY KIDNEY ISSUES, CONSTANT PELVIC PAIN TO THE POINT I CAN'T MOVE, HEART TROUBLE, CHEST PAIN, SEVERE ANXIETY ISSUES, BLACKING/PASSING OUT; THE MOST RECENT "BLACKOUT" I FELL DOWN A FLIGHT OF STAIRS SHATTERING MY DOMINANT HAND REQUIRING SURGERY AND LEFT WITH A PARTIALLY FUNCTIONAL HAND, SUICIDAL THOUGHTS, AND PROBLEMS WITH PTSD, UNEXPLAINABLE SKIN RASHES AND UNCONTROLLABLE ITCHING. THESE ARE A FEW OF THE BIGGER PROBLEMS I SUFFER FROM DAILY AND WAS NOT WARNED ABOUT AS SIDE EFFECTS TO MY ESSURE IMPLANTS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00019	BAYER HEALTHCARE LLC	2/4/2014	2/12/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 977933

Single Use: Y
Implant Date (E6): 3/25/2013
Explant Date (E7): 12/16/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PHYSICIAN USED CERVICAL DILATION, TORADOL, ATROPINE AND CARBOCAINE 1% TO PERFORM THE INSERTION OF ESSURE. IT WAS UNSURE IF THE INSERTION WAS EASY OR DIFFICULT. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY AND THE FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. CONDOMS WERE REPORTED AS THE BACK-UP CONTRACEPTION USED AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. ON (B)(6), 2013 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED LEFT TUBE "WIDELY OPEN", ESSURE DEVICE IN PERITONEAL CAVITY. ALTHOUGH THE PATIENT WAS ASYMPTOMATIC, THE REMOVAL OF DEVICE WAS MEDICALLY NECESSARY AND WAS REQUESTED. ON (B)(6), 2013, ESSURE WAS LAPAROSCOPICALLY REMOVED. HYSTERECTOMY OR SALPINGECTOMY WAS NOT NECESSARY. DURING THE SURGERY, ESSURE WAS FOUND IN THE LEFT FIMBRIATED END OF THE TUBE, HALF OUT, AND IT PULLED OUT EASILY. THE PATIENT NEEDED A TUBAL (LIGATION).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00020	BAYER HEALTHCARE LLC	2/4/2014	2/12/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 10/1/2008
Explant Date (E7): 8/5/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS INSERTED IN (B)(6) 2008 (ALSO REPORTED (B)(6) 2008) AFTER HER DAUGHTER WAS BORN ON (B)(6), 2008, CONSUMER WAS (B)(6) AT THAT TIME. AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION TEST, CONDOMS WERE USED FOR CONTRACEPTION. A HSG (HYSTEROSALPINGOGRAM) TEST WAS NOT PERFORMED BECAUSE CONSUMER'S INSURANCE WOULD NOT COVER IT. IN (B)(6) 2013, THE SYMPTOMS STARTED. SHE SAW A DOCTOR AS SHE HAD TERRIBLE HIVES ALL OVER HER AND LIVED ON BENADRYL (DIPHENHYDRAMINE) AND AN EPI PEN (EPINEPHRINE). THIS WAS BECAUSE SHE HAD AN ALLERGY TO NICKEL. SHE HAD MIGRAINES, HER STOMACH WAS BLOATED AND SHE LIKE SHE WAS FIVE MONTHS PREGNANT AND SHE HAD PAIN IN HER RIGHT SIDE NEAR WHERE HER OVARY WAS. EVERYTHING STOPPED RIGHT AFTER THE COILS AND FALLOPIAN TUBES WERE REMOVED BY LAPAROSCOPIC BILATERAL SALPINGECTOMY ON (B)(6) 2013. THE PROCEDURE WAS PERFORMED OUTPATIENT. THE CONSUMER REPORTS SHE IS 100 PERCENT BETTER AND RECOVERED FROM THE SYMPTOMS AND THE PROCEDURE. THE CONSUMER HAD A PATHOLOGY REPORT, BUT HAD NOT READ IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034218	BAYER	2/5/2014	2/10/2014

Event Information:

Event Date (B3): 2/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL PUT IN 2006. I HAVE HAD NOTHING BUT ISSUES WITH THIS. FROM SEVERAL ISSUES WITH BLEEDING, PAINFUL SEXUAL INTERCOURSE, HAIR FALLING OUT, BLOATING. I LOOK LIKE I'M 6 MONTH'S PREGNANT. WEIGHT HAS GONE UP SO MUCH AND BACK DOWN AND BACK UP. NOW I GOT TO HAVE ALL MY LADY PARTS TAKEN OUT BECAUSE ONE OF THE DEVICES HAS TORN THRU AND HAS MANAGED TO GO TO ANOTHER BODY PART WHERE IT SHOULD NOT BE. MY MOOD SWINGS HAVE BEEN HORRIBLE. HAS GOT TO THE POINT WHERE I HAVE THOUGHT ABOUT ENDING MY LIFE. THE PAIN IS HORRIBLE. THIS NEEDS TO COME OFF THE MARKET. IT IS DESTROYING PEOPLE'S FAMILIES AND WOMAN'S LIVES. DOCTORS SHOULD BE EDUCATED ON HOW BAD THESE ARE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034227	BAYER	2/5/2014	2/11/2014

Event Information:

Event Date (B3): 7/7/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/7/2005
Explant Date (E7): 8/28/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED IN (B)(6) 2005, JUST WEEKS SHY OF MY (B)(6) BIRTHDAY. I AM THE PROUD MOTHER OF TWO CHILDREN THAT WERE (B)(6) AT THE TIME. MY OB/GYN THAT I TRUSTED AND DELIVERED BOTH OF MY CHILDREN HIGHLY RECOMMENDED ESSURE STERILIZATION WHEN I TOLD HIM I WANTED TO HAVE MY TUBES TIED. ALL OTHER BIRTH CONTROL I TRIED (I.E. PILLS, DEPO) WREAKED HAVOC ON MY HORMONES AND BODY. MY DOCTOR ENCOURAGED ESSURE AS IT HAD LITTLE TO NO DOWN TIME AND WAS A QUICK OUTPATIENT SURGERY. HE STATED THAT THE ONLY SIDE EFFECTS WERE NEVER BEING ABLE TO HAVE CHILDREN AGAIN (UNLESS I USED IVF) AND I MAY HAVE SOME MILD CRAMPING AND BLEEDING FOR A LITTLE BIT AFTER THE INITIAL SURGERY. IN 2007 I HAVE DOCUMENTATION VIA MY MEDICAL RECORDS THAT I COMPLAINED ABOUT THE INFLAMMATION AND PAIN IN MY PELVIC REGION, AS WELL AS WEIGHT GAIN. MY DOCTOR DID NOTHING ABOUT MY CONCERNS FOR MY PAIN AND AS FAR AS THE WEIGHT WENT, HE SUGGESTED I TRY A DIET CALLED (B)(6) THAT HIS WIFE WAS CONVENIENTLY A SPOKES PERSON FOR. COMPLETELY DISAPPOINTED IN THIS DOCTOR THAT WAS THE LAST TIME I EVER SAW HIM. FAST FORWARD OF (B)(6) 2013 AND A FEW DOCTOR VISITS AND ULTRA SOUNDS LATER ALL TO NO AVAIL. THE PAIN HAD GOTTEN SO SEVERE IT FELT AS THOUGH MY COILS WERE NOT ONLY GOING TO PUNCTURE THROUGH MY TUBES AND SKIN, BUT THAT THEY WERE RADIATING HEAT LIKE THERE ARE TWO MINIATURE CURLING IRONS IN MY TUBES THAT WERE ON FIRE. MY BELLY WAS CONSTANTLY DISTENDED AND INFLAMED AND IN PAIN. ANY EXERCISE ONLY EXASPERATED THE ISSUES. MY PERIODS WERE AT AN ALL TIME HEAVY FLOW, LONGEST DURATION, EXTREMELY PAINFUL, AND QUITE FRANKLY SO WAS INTERCOURSE. I HAVE BEEN TESTED FOR RHEUMATOID ARTHRITIS BECAUSE I WAS HAVING MAJOR JOINT PAINS THROUGHOUT MY ENTIRE BODY. IT CAME BACK NEGATIVE. I DID TEST POSITIVE FOR EBSTEIN-BARR, HOWEVER, WHICH IS COMPLETELY BIZARRE. MY EXHAUSTION HAS BEEN ONGOING FROM DAY ONE BUT GOT WORSE OVER THE YEARS. IT

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FELT AS THOUGH MY BODY WAS FILLED WITH LEAD. MY HORMONES TESTED AT ALMOST MENOPAUSAL, I WAS ONLY (B)(6) AT THE TIME OF THAT TEST. I AM NOW VITAMIN B12 DEFICIENT AS WELL AS VITAMIN D DEFICIENT. I HAVE NO PREVIOUS HEALTH ISSUES. I HAD BEEN TO PHYSICIANS, EMERGENCY ROOMS INCLUDED BECAUSE OF THE GUT WRENCHING PAIN I WAS IN AND HAD ULTRASOUNDS AND XRAYS THAT ALL SUGGESTED MY COILS WERE PROPERLY PLACED, IT TURNED OUT THAT THEY WERE WRONG. I FOUND A DOCTOR THAT AGREED TO REMOVE MY TUBES ALONG WITH THE COILS. I HAD A BILATERAL SALPINGECTOMY ON (B)(6) 2013. ALMOST ALL OF MY PAIN WENT AWAY WITH EXCEPTION TO SOME INFLAMMATION AND TWINGES OF PAIN. I HAD A FEW TESTS DONE THAT SHOWED FRAGMENTS BROKE OFF INSIDE MY UTERUS ON EACH SIDE. THE ONLY WAY TO REMOVE THEM WAS TO REMOVE MY UTERUS. ON (B)(6) 2014 I HAD A LAPAROSCOPIC SUPRACERVICAL HYSTERECTOMY. NOW I AM DEALING WITH AN ABSCESS AS A COMPLICATION. ESSURE HAS RUINED MY BODY. I ALSO WOULD LIKE TO NOTE THAT, THE PET FIBERS THAT WERE SUPPOSED TO BE IN MY DEVICE WERE ALMOST NON-EXISTENT AT REMOVAL, WHICH I BELIEVE TO BE SERIOUSLY DISTURBING AS THE LAST THING I WANT IS MY BODY ABSORBING THEM , AND I WAS GIVEN A CARD FROM MY IMPLANTING DOCTOR BUT IT DOES NOT HAVE ANY LOT OR MODEL NUMBERS ON IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034236	CONCEPTUS	2/10/2014	2/11/2014

Event Information:

Event Date (B3): 7/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT LIGHTHEADED, SHORT OF BREATH, SWEATY, AND A HEADACHE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034237	CONCEPTUS	2/10/2014	2/11/2014

Event Information:

Event Date (B3): 9/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD INCREASED PAIN IN MY NECK, BACK, AND LEGS, HEADACHES, INCREASED FATIGUE, BLOATING, EXTREMELY PAINFUL UTERINE CRAMPING, INCREASE IN THE AMOUNT OF BLOOD LOST DURING PERIODS, STABBING PAIN ON MY LEFT SIDE (WHERE MY ESSURE IS) UNDER MY RIBCAGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034238	CONCEPTUS	2/10/2014	2/11/2014

Event Information:

Event Date (B3): 9/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE A RETROVERTED UTERUS. IN 2010, MY OB/GYN REMOVED MY RIGHT TUBE AND OVARY DUE TO A DERMOID TERATOMA. I HAD ESSURE IMPLANTED IN MY LEFT TUBE ON (B)(6) 2013. I BLED HEAVILY FOR SEVERAL DAYS FOLLOWING THE PROCEDURE AND HAD INTENSE CRAMPING. SINCE THAT TIME, I HAVE HAD HEADACHES, INCREASED TROUBLE WITH MY VISION, INCREASED PAIN, STIFFNESS, AND SPASMS IN MY NECK, BACK, HIPS, AND FINGERS I BLEED MORE IN ONE DAY THAN I USED TO IN FOUR OR FIVE PERIODS, INTENSE UTERINE CRAMPING (THIS HAPPENS WHEN I AM ON MY PERIOD AND WHEN I AM NOT), INCREASED FATIGUE, SHARP/STABBING PAINS IN MY LEFT SIDE BELOW MY RIBCAGE. I MET WITH MY FAMILY DOCTOR ON (B)(6) 2013 TO DISCUSS MY SYMPTOMS BECAUSE AT THE TIME I DID NOT BELIEVE THEY WERE RELATED TO THE ESSURE. SHE RAN SOME LABS (VITAMIN B12, RHEUMATOID FACTOR, ANTINUCLEAR ANTIBODIES DIRECT, AND C-REACTIVE PROTEIN). ALL OF THESE TESTS CAME BACK NORMAL. I WAS REFERRED TO A NEUROLOGIST TO RULE OUT MS. I SAW THE NEUROLOGIST ON (B)(6) 2013. SHE RAN LABS. I WAS TESTED FOR ANTIBODY, ASSAY TRIIODOTHYRONINE, ASSAY THYROID STIM HORMONE, THRYOXINE, FREE,RIA, ANGIOTENSIN ENZYME. I WILL HAVE THE RESULTS OF THOSE TESTS AT MY FOLLOWUP VISIT ON (B)(6) 2014. SHE RAN AN MRI OF MY BRAIN AND THORACIC SPINE. THE REPORT DOES NOT INDICATE THE PRESENCE OF LESIONS OF DEMYELINATION. IT DID INDICATE SMALL HEMANGIOMAS WITHIN T9 AND T10. THESE HEMANGIOMAS WERE NOT PRESENT ON MY (B)(6) 2013 MYELOGRAM. SHE ALSO RAN A VISUAL EVOKED POTENTIAL TEST. I WILL HAVE THE RESULTS OF THAT TEST AT MY FOLLOWUP VISIT ON (B)(6) 2014. AFTER DOING SOME RESEARCH, I FOUND THAT ESSURE IS NOT RECOMMENDED FOR WOMEN WHO HAVE A RETROVERTED UTERUS, ONLY ONE TUBE, OR A NICKEL ALLERGY. MY OB/GYN HAS BEEN SEEING ME FOR OVER 13 YEARS. HE WAS/IS AWARE THAT I HAVE A RETROVERTED UTERUS, ONLY ONE TUBE (AS HE IS THE ONE THAT REMOVED IT), AND A COUPLE YEARS AGO, PRESCRIBED MEDICATION FOR A

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RASH ON MY STOMACH THAT STARTED BECAUSE THE METAL FROM MY BELT BUCKLE CAME INTO CONTACT WITH MY SKIN (THE BUCKLE IS NICKLE PLATED). I AM ANGRY WITH MYSELF FOR THINKING THAT THIS PRODUCT WAS SAFE, EFFECTIVE, AND HAD RARE/MINIMAL SIDE EFFECTS. I HAVE JOINED THE ESSURE PROBLEMS FACEBOOK GROUP AND FOUND MANY WOMEN, LIKE ME THAT ARE SUFFERING AFTER HAVING THIS HARMFUL PRODUCT PLACED IN OUR BODIES. I NOW DO NOT BELIEVE THIS PRODUCT IS SAFE, EFFECTIVE, OR THAT THE RISK OF SIDE EFFECTS IS MINIMAL. I FULLY SUPPORT HAVE THIS PRODUCT REMOVED FROM THE MARKET AND THE PMA LABEL REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034239	CONCEPTUS	2/10/2014	2/12/2014

Event Information:

Event Date (B3): 9/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PRIOR TO GETTING ESSURE, I HAD MY RIGHT TUBE AND OVARY REMOVED (2010) DUE TO A DERMOID TERATOMA. I HAVE SEVERAL ISSUES WITH MY SPINE ESPECIALLY THE LUMBAR AREA. DUE TO NERVE IMPINGEMENT, I HAVE WEAKNESS, DROP FOOT, NUMBNESS, ETC. IN MY RIGHT LEG. I HAD A MYELOGRAM AND CT OF MY ENTIRE SPINE ON (B)(6) 2013. THE RESULTS SHOWED ARTHRITIS IN MY NECK WITH POSSIBLY A BONE SPUR RESTING ON THE THECAL SAC, BONE SPURS IN MY THORACIC SPINE, A GRADE I SLIP AT L5-S1 WITH HARDWARE FROM FUSION ((B)(6) 2012, BULGING DISCS AT L3-S1. I HAD ESSURE PLACED IN MY LEFT TUBE ON (B)(6) 2013. SINCE THAT DATE, I HAVE EXPERIENCED INTENSE UTERINE CRAMPING (EVEN WHEN I AM NOT ON MY PERIOD), HEAVY BLEEDING DURING EXTENDED PERIODS, INCREASED FATIGUE, INCREASED MUSCULAR PAIN AND SPASMS (ALL OVER BODY), INCREASED JOINT PAIN/STIFFNESS (ESPECIALLY FINGERS, KNEES, AND ENTIRE SPINE), DECREASED VISION, DIZZINESS, STABBING PAIN ON MY LEFT SIDE (ABDOMEN TO SIDE UNDER RIBCAGE AROUND WHERE THE OVARY WOULD BE). MY PERIODS WERE NEVER REGULAR (MY FIRST WAS AT AGE (B)(6)) BUT WERE ALWAYS VERY LIGHT AND ONLY LASTED TWO DAYS WITHOUT CRAMPING. EACH TIME I HAVE BLED SINCE ESSURE, I BLEED FOR FOUR TO FIVE DAYS AND BLEED MORE IN ONE DAY THAN I USED TO IN FOUR TO FIVE PERIODS. IN LATE (B)(6) 2013, THE ISSUES WITH MY SPINE AND RIGHT LEG PROGRESSED TO THE POINT, I STARTED USING A CANE WHEN WALKING. I SAW MY PRIMARY CARE PHYSICIAN ON (B)(6) 2013 COMPLAINING ABOUT ALL THESE SYMPTOMS EXCEPT THE BLEEDING/CRAMPING. SHE RAN LABS FOR B12 AND AMP; FOLATE, RA FACTOR, ANA DIRECT, AND C-REACTIVE PROTEIN. ALL OF THESE TESTS CAME BACK WITHIN THE NORMAL RANGE. SHE REFERRED ME TO A NEUROLOGIST TO RULE OUT MS. I MET WITH THE NEUROLOGIST ON (B)(6) 2013. SHE DID A BASIC EXAM, SENT ME FOR LABS AND SCHEDULED A BRAIN MRI, A THORACIC SPINE MRI, AND A VISUAL EVOKED POTENTIAL TEST. SHE RAN LABS FOR ANTIBODY, T-3, FT-4, THYROID STIM

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HORMONE, AND ANGIOTENSIS ENZYME. I WILL FIND OUT THE RESULTS OF THE LABS AND THE EVOKED POTENTIAL TEST AT MY FOLLOWUP APPOINTMENT ON (B)(6) 2014. THE RESULTS OF MY MRI DO NOT INDICATE ANY LESIONS IN THE BRAIN OR DEMYELINATION (AS BEST AS I CAN TELL WITHOUT A MEDICAL EXPERT EXPLAINING THE REPORT TO ME). THE THORACIC SPINE MRI INDICATED A RETROVERTED UTERUS (KNOWN TO MY OB/GYN FOR OVER 13 YEARS) AND SMALL HYMANGIOMAS WITHIN T9 AND T10 WHICH WERE NOT PRESENT ON THE MYELOGRAM OR CT FROM SEPTEMBER. I HAVE A NICKEL ALLERGY TEST SCHEDULED FOR (B)(6) 2014 BECAUSE I BELIEVE I MAY HAVE A NICKEL ALLERGY. I HAVE ALWAYS HAD IRRITATION FROM CHEAP JEWELRY AND MY STOMACH HAS BROKEN OUT IN A RASH FOR THE LAST 16 YEARS WHEN THE BELT BUCKLE ON THE BELTS SUPPLIED BY MY EMPLOYER TOUCHED MY SKIN (THE BUCKLE IS NICKEL PLATED). MY OB/GYN GAVE ME SOME OINTMENT A FEW YEARS BACK TO TREAT IT, BUT IT ALWAYS CAME BACK. SINCE (B)(6) 2013, MY QUALITY OF LIFE HAS STEADILY DECLINED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034425	BAYER	2/10/2014	2/18/2014

Event Information:

Event Date (B3): 2/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 806702

Single Use:
Implant Date (E6): 2/4/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE IMPLANTS PUT IN I BROKE OUT INTO A RASH ALL OVER MY BODY AND WAS TREATED IN THE ER, HAVE ONGOING HEADACHES AND HAVE HAD AN UNEXPLAINED RASH FOR OVER 6 MONTHS AND WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034431	CONCEPTUS INCORPORATED	2/10/2014	2/18/2014

Event Information:

Event Date (B3): 8/28/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893037

Single Use:
Implant Date (E6): 7/13/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IMPLANTS IN (B)(6) 2012, THREE MONTHS AFTER GIVING BIRTH TO MY SECOND CHILD. THE DOCTOR WHO PLACED THE ESSURE WAS DR (B)(6) WITH (B)(6). I RECEIVED THE NECESSARY CONTRAST X-RAY TO CONFIRM BLOCKED TUBES (B)(6) 2013. THIS WAS PERFORMED AT (B)(6) DUE TO OUR FAMILY MOVING OUT OF (B)(6). THE HSG WAS ORDERED BY MY NEW OBGYN, (B)(6) WITH (B)(6). THE RADIOLOGIST CONFIRMED THAT MY TUBES WERE COMPLETELY BLOCKED. IN (B)(6) 2013, I HAD A POSITIVE HOME PREGNANCY TEST. AFTER GOING TO MY DOCTOR OUT OF SHOCK SHE CONFIRMED THE PREGNANCY VIA ULTRASOUND. I WAS 6 WEEKS PREGNANT. I AM CURRENTLY 29 WEEKS PREGNANT AND SEEING BOTH MY OBGYN, AS WELL AS A MATERNAL FETAL MEDICINE SPECIALIST DUE TO THE HIGH RISK NATURE OF AN ESSURE PREGNANT, COMBINED WITH GESTATIONAL DIABETES AND HIGH BLOOD PRESSURE. MY MATERNAL FETAL MEDICINE SPECIALIST IS DR (B)(6) WITH THE(B)(6). HE CONTACTED THE MAKERS OF ESSURE TO OBTAIN WHAT INFORMATION HE COULD REGARDING THE RISKS OR PRECAUTIONS DURING PREGNANCY AFTER THE ESSURE IMPLANTS. HE NEVER RECEIVED ANY INFO BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034432		2/10/2014	2/18/2014

Event Information:

Event Date (B3): 12/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/15/2011
Explant Date (E7): 5/8/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AFTER A MISCARRIAGE MY OBGYN (B)(6) WITH (B)(6) SUGGESTED THE ESSURE OVER HAVING MY TUBES TIED. AFTER THE PROCEDURE WAS COMPLETED, I GAINED 35 LBS, AND WAS SO SICK. ONE DAY I WOKE UP SCREAMING IN SEVERE PAIN, WAS RUSH TO THE EMERGENCY ROOM. WHILE THEY EXAMINED ME AT THE EMERGENCY ROOM THEY REALIZED A BARRIER WAS BLOCKING ME FROM HAVING MY MONTHLY PERIOD. ONE OF THE COILS HAD NOT STAYED IN PLACE AND CUT ME INSIDE CREATING A BARRIER SO MY PERIODS WERE STAYING INSIDE. AFTER THEY REALIZED WHAT HAD HAPPENED MY OBGYN, WHOM PERFORMED THE PROCEDURE, EXPLAINED I WOULD HAVE TO HAVE A HYSTERECTOMY, IN ORDER TO CORRECT THE PROBLEM HE CREATED. THE HYSTERECTOMY WAS PERFORMED BY (B)(6) WITH THE "LA DAVINCI" ROBOTIC LASER MACHINE. I HAD MORE PROBLEMS ARISE. THIS HAS BEEN AN ON GOING HORRIBLE PROBLEM FOR THE LAST 3 YEARS AND HAVE NO IDEA WHAT TO DO OR HOW TO GET MY LIFE BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034433		2/10/2014	2/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): 2108012799
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANT, I HAVE HAD THE ESSURE IMPLANT FOR 6 MONTHS. I HAVE HAD A TREMENDOUS AMOUNT OF PAIN AND BLOATING SINCE. AN INFECTION THAT KEEPS COMING BACK IRREGULAR PAINFUL PERIODS. AND A NON STOP ALLERGIC REACTION. I WAS IN PERFECT HEALTH BEFORE ESSURE. AND EVER SINCE I HAVE BEEN MISERABLE. THERE IS NO DOUBT MY MIND THAT ESSURE HAS NO PLACE IN THE MARKET AND IT IS A TOTALLY IRRESPONSIBLE PRODUCT. I REQUESTED TO HAVE MY PROCEDURE DONE THE OLD FASHION WAY. AND MY DOCTOR TALKED ME INTO ESSURE. HE NEVER WARNED ME ABOUT THE POSSIBILITY OF AN ALLERGIC REACTION AND NEVER TESTED ME FOR SENSITIVITY. I CAN'T BELIEVE WITH ALL THE UPROAR PERTAINING TO THIS PRODUCT NOTHING HAS BEEN DONE YET. KNOW THAT EVERY DAY THIS THING IS BEING OFFERED SOME ONE ELSE'S LIFE IS BEING RUINED. I HAVE NOTHING ELSE TO SAY. I COULD SPIT FIRE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034484	CONCEPTUS, INC.	2/10/2014	2/18/2014

Event Information:

Event Date (B3): 1/8/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): REF ESS305
Catalog # (E4):
Lot #(E4): 66014

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MISFIRED WHILE IN THE TRIPLE LUMEN SCOPE. NO ONE AND NOTHING TOUCHED THE ESSURE. THERE WAS NO PT HARM. A NEW ESSURE TRAY WAS OPENED AND THE PROCEDURE WAS COMPLETED WITHOUT INCIDENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034487	BAYER	2/10/2014	2/18/2014

Event Information:

Event Date (B3): 6/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 6/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER BEING IMPLANTED WITH THE PERMANENT BIRTH CONTROL DEVICE CALLED ESSURE, I STARTED HAVING ADVERSE EFFECTS 6 MONTHS LATER. THE PROBLEMS HAVE INCREASED EVER SINCE. I NOW SUFFER FROM A REOCCURRING STABBING PAIN IN MY BELLY BUTTON THAT LASTS FOR 10 DAYS EACH MONTH, EAR RINGING, FATIGUE, SWOLLEN/SOR TOES, SWIMMY HEAD, BLOATED, VITAMIN DEFICIENCY, THYROID, CONSTIPATION, NUMBNESS IN FINGERS, HEADACHES, BRAIN FATIGUE AND EYE WEAKNESS. SOME OF THESE SYMPTOMS COME AND GO, OTHERS ARE CONSTANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034488	BAYER	2/10/2014	2/18/2014

Event Information:

Event Date (B3): 2/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 871972

Single Use:
Implant Date (E6): 9/11/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE SINCE (B)(6) 2011. NOW HAVING TO HAVE A HYSTERECTOMY DUE TO COMPLICATIONS OF THE ESSURE DEVICE. MY TUBE AND UTERUS COLLAPSED WHEN THE DOCTOR PUT IT IN AND SHE WASN'T SUPPOSE TO DO IT BLINDLY THAT WHERE IT ALL BEGAN (I HAD NO CLUED THEY GIVE YOU LITTLE INFORMATION ABOUT THIS PROCEDURE) I SPENT LAST SUNDAY IN THE HOSPITAL DUE TO PELVIC PAIN AND HAD TO EXPLAIN TO TWO NURSES, ONE DOCTOR AND ULTRASOUND TECH AND A MED-TECH WHAT ESSURE WAS THAT JUST PROVES TO ME THAT DOCTOR, NEED MORE INFORMATION. I AM NOW HAVING A HYSTERECTOMY DUE TO PAIN, NAUSEA, LONG HEAVY PERIODS, BACK PAINS, AND LOSS OF LIMB AND SEX HURTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034489	CONCEPTUS	2/10/2014	2/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I MADE THE DECISION ON TRYING ESSURE BIRTH CONTROL COILS IN 2012. EVER SINCE THEN I HAVE HEAVY PERIODS, ABNORMAL BLEEDING, BLOATING, LOWER BACK PAIN, LEG PAIN, ABDOMINAL PAIN AND TIREDNESS. I WANT THESE OUT, SAD THING IS I DON'T HAVE THE MONEY. I DON'T RECOMMEND ESSURE TO ANYONE! THEY SHOULD NOT BE APPROVED TO ANYONE!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034490	CONCEPTUS	2/10/2014	2/18/2014

Event Information:

Event Date (B3): 2/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/31/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6), 2012. SINCE THEN I HAVE HAD SERIOUS SIDE EFFECTS. ANXIETY, PANIC ATTACKS, LOWER-BACK PAIN AND THE BIGGEST SYMPTOM OF ALL SWELLING/BLOATING OF MY ABDOMEN. THE SWELLING IS VERY PAINFUL. IT CAN LAST ANYWHERE FROM A FEW HOURS TO A WEEK AT A TIME. THEN IT GOES AWAY. AND RANDOMLY RETURNS. IT IS SO EXTREME THAT MY STOMACH GOES FROM FLAT TO LOOKING AT LEAST 6 MONTHS PREGNANT IN SUCH A SHORT PERIOD OF TIME. I CANNOT SEE MY FEET WHEN THIS HAPPENS! PEOPLE ASK ME IF I'M PREGNANT. WHEN THIS SWELLING/BLOATING HAPPENS I BECOME TIRED, FATIGUED AND SHORT OF BREATH. EXACTLY LIKE THE FEELING WHEN YOU ARE PREGNANT AND THE BABY IS PUSHING UP ON YOUR RIBS AND ITS HARD TO BREATH, THAT'S THE ONLY WAY I CAN EXPLAIN IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034255	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 1/2/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, HOT BURNING FEET AND HANDS, BUTTERFLY, MIGRAINES, HIP PAIN, BACK PAIN, HEAVING BLEEDING, SEVERE JOINT PAINT, MUSCLE PAIN, MUSCLE SPASMS, MUSCLE STIFFNESS, RESTLESS LEG SYNDROME, TACHYCARDIA, HEART PALPITATIONS, TMJ, VITAMIN D DEF, LOSS OF BLADDER CONTROL, INSOMNIA, THYROID LEVELS ERRATIC, IRRITABLE BOWEL SYNDROME, FIBROMYALGIA, HAIR GROWTH IN UNWANTED PLACES, HAIR LOSS ON SCALP, NUMBNESS IN HANDS AND FEET, LEGS AND ARMS, BRAIN SHOCKS, AUTO IMMUNE TESTS SHOWING POSITIVE, THEN NEGATIVE, POS ANA TEST, PAINFUL INTERCOURSE, HEART BURN, ACID REFLUX,COULDN'T SEE DRIVING AT NIGHT, OILY HAIR, VISION CHANGES HALO'S, HEMORRHOIDS, STABBING PAINS IN VAGINA AND RECTUM, OVARIAN CYSTS,, METAL TASTE IN MOUTH, FOUL VAGINAL DISCHARGE, DENTAL ISSUES, CRACKING TEETH, SHORT TERM MEMORY LOSS, FREQUENT URINATION, SKIN BOILS ON HEAD AND LEGS, SORES ON SCALP, NO SEX DRIVE, DRY SKIN AND EYES, NAUSEA, SEVERE BLOATING, ANXIETY, DEPRESSION, PANIC ATTACKS, CHRONIC FATIGUE SYNDROME, COUGHING ALL THE TIME, MOOD SWINGS, DIZZY, NO APPETITE, ARTHRITIS, EASY BRUISING, HEEL PAIN, COLD INTOLERANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034256	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 1/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT SEVERE HEADACHES. OFF AND ON PAIN ON THE RIGHT SIDE. VERY HEAVY BLEEDING WITH BLOOD CLOTS DURING MY CYCLE. JOINT PAIN. BACK AND HIP PAIN. MOOD SWINGS. PAIN AFTER SEX. BLOATING AND SEVERE WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034257	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 6/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING PAIN IN MY SIDES AND ABDOMEN. HAS BEEN INCREASING IN INTENSITY AND FREQUENCY, NOW BEING DAILY. EXTREME FATIGUE SOME DAYS. INCREASED HEADACHES. WHOLE BODY HURTS. AFFECTING DAILY LIFE AND ACTIVITIES. PAIN WITH SEX. PAINFUL PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034260	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 1/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2012 I HAD THE ESSURE DEVICE IMPLANTED. ABDOMINAL PAIN,EXTREME BLOATING, AND WEIGHT GAIN SINCE DAY ONE OF INSERTION. SKIN IRRITATION, LOTS OF ITCHING THROUGHOUT MY BODY. (B)(6) ANDAMP; (B)(6) 2012 - NO MENSTRUAL CYCLE, ABDOMINAL PAIN AND BLOATING CONTINUED. (B)(6) - EXTREMELY HEAVY PERIOD, LASTED ABOUT 10 DAYS, HEAVY BLEEDING, LOTS OF BLOOD CLOTS, STRINGY SUBSTANCE THAT LOOKED LIKE TISSUE. AFTER 10 DAYS OF HEAVY BLEEDING, CONTINUED SPOTTING EVERYDAY FROM (B)(6) 2011. (B)(6) - WENT TO GET THE DYE TEST AND TECHNICIAN SAID COILS WERE IN PLACE. DEVELOPED A SEVERE RASH AND VAGINAL INFECTION. BOUGHT OVER THE COUNTER MEDICATION AND CREAMS. SPOTTING CONTINUED TILL (B)(6) 2011. SCHEDULED AN APPOINTMENT WITH THE OBGYN. SAW HIM IN (B)(6) 2011, TOLD HIM MY SYMPTOMS. HE SAID THE SYMPTOMS WERE NOT A CONCERN, HE PRESCRIBED ME BIRTH CONTROL PILLS TO HELP WITH THE BLEEDING. I NEVER TOOK THE PILLS HOPING THE BLEEDING WOULD STOP ON ITS OWN. (B)(6) 2011 - PRESENT - HEAVY PERIOD, AND CONTINUED WITH ALL THE OTHER SYMPTOMS ALONG WITH NOW A LOT OF HAIR LOSS, NEW RED MOLES ON MY BODY, ESPECIALLY IN MY STOMACH, START AS SMALL AS A PIN DROP AND ARE GROWING AT A RAPID PACE. I NOW HAVE ANXIETY DUE TO ALL OF THESE HEALTH COMPLICATIONS, I CANNOT WEAR CHEAP EARRINGS AS THESE NOW CAUSE MY EYES TO GET INFLAMED, MY EARS SEEM TO ALWAYS BE ITCHY AS WELL. I'VE DEVELOPED ALLERGIES NOW, NOSE ITCH, EYE ITCH, ALL OF WHICH I NEVER HAD BEFORE. ALSO HAVE LEG PAIN, STARTS FROM MY ABDOMEN DOWN MY HIPS AND DOWN MY LEGS, TO THE POINT WHERE THERE ARE DAYS I CANNOT WALK PROPERLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034265	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 1/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED NOTICING THAT MY HAIR WAS COMING OUT IN HANDFULS, AND THAT I HAD TERRIBLE BREAST PAIN (I WAS NOT NURSING) MY EYELASHES WERE COMING OUT, ACNE WAS GETTING BAD, GETTING FACIAL HAIR, VAGINAL BOILS, THICK CLEAR VAGINAL DISCHARGE, UPPER PART OF MY BACK HURTS MORE, CONSTIPATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034268	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 8/18/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD ESSURE PLACED IN (B)(6) OF 2009. SHORTLY AFTER I STARTED HAVING SEVER CRAMPS, HEAVY BLEEDING, NUMBNESS IN MY LOWER BACK, PAIN IN MY LOWER BACK, DOUBLED OVER IN PAIN IT WAS SO BAD. THIS AND MANY OTHER SYMPTOMS WENT ON FOR YEARS. A FEW MONTHS AGO IN (B)(6)OF 2013 I HAD A COMPLETE HYSTERECTOMY. PATHOLOGY REPORT SHOWED ENLARGED UTERUS WHICH CAN CAUSE PAIN IN LOWER BACK, EVEN TODAY I HAVE BACK PROBLEMS AND AM ON MEDICATION TO HELP DEAL WITH IT. MY HYPOTHYROIDISM MY MEDICATION HAS TRIPLED SINCE HAVING ESSURE PLACED. THERE ARE JUST WAY TO MANY PROBLEMS TO LIST SINCE HAVING ESSURE PLACED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034269	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 1/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS WERE MY CHOICE HIGHLY RECOMMENDED BY MY DR. I WANTED A TUBAL LIGATION AND HE SAID THIS IS SAFE AND NEW WAY. NO DOWN TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034273	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2012, I HAD ESSURE INSERTED BECAUSE WE WERE DONE HAVING CHILDREN AND I WAS TOLD BY MY OB/GYN THAT ESSURE WAS SAFE EVEN AFTER I TOLD HIM OF MY NICKEL ALLERGY, AND I WAS NOT LOOKING TO HAVE SURGERY AND MISS ANY TIME FROM WORK. AS SOON AS THE ESSURE WAS PLACED, I HAD ABDOMINAL PAIN AND CRAMPING BUT THOUGHT IT WAS MY BODY'S WAY OF GETTING ACCUSTOMED TO THE ESSURE. AT THE BIG TESTING, IT SHOWED I WAS COMPLETELY BLOCKED AND I EXPRESSED MY CONCERNS ON ABDOMINAL PAIN, DIZZINESS, JOINT PAIN AND CRAMPING WITH HEAVY MENSTRUAL PERIODS THAT LASTED FOR OVER A WEEK WHEN MY NORMAL WAS HARDLY ANY BLEEDING, NO CRAMPS AND WOULD LAST MAYBE 3 DAYS. MY DOCTOR DISMISSED IT AND SAID EVERYTHING IS OKAY AND ITS MY BODY'S WAY OF GETTING ACCUSTOMED TO THE ESSURE. I STARTED HAVING MORE SIDE EFFECTS TO THE POINT THAT I HAD TO CHANGE DOCTORS, AS MINE WOULDN'T LISTEN, AND WAS TOLD I MAY BE HAVING SEIZURES AND POSSIBLY A HEART CONDITION, HAD TO LEAVE MY JOB IN (B)(6) 2012 AND WAS ABLE TO RETURN IN LATE (B)(6) 2013 AFTER ESSURE WAS REMOVED AND MOST OF MY SYMPTOMS WENT AWAY. MY ESSURE REMOVAL WAS ON (B)(6) 2013 AND WAS DONE BY HAVING TO HAVE A PARTIAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034274	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 11/16/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CHRONIC PELVIC PAINS, BLOATING , IRREGULAR WEIGHT GAIN, NON-STOP HEADACHES, MONTHS TO A YEAR WITH NO PERIOD, MEMORY LOSS, HAIR LOSS, NON-STOP BLEEDING,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034275	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 12/19/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD CRAMPING FROM DAY ONE OF ESSURE! I ALSO HAVE HAD 2 PERIODS PER MONTH FOR THE PAST 6 MONTHS AND ALSO HEADACHES, TIRED AND LOSS OF ENERGY!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034276	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 11/16/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE GOTTEN MY TUBES REMOVED IN (B)(6) OF 2013 AND NOW I AM GETTING MY UTERUS REMOVED TOMORROW (B)(6) 2014 FOR NON-STOP BLEEDING. MY TUBES WERE SEVERELY SWOLLEN AND SCARRED. CAUSED A LOT OF SCAR TISSUE TO BUILD UP INSIDE CAUSING MORE PELVIC PAIN. MY BLADDER UTERUS AND ALONG WITH A FEW OTHER ORGAN/INTESTINES TO BE STUCK TOGETHER. CAUSING MY UTERUS TO SHIFT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034277	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PAIN IN MY LOWER ABDOMEN, HEADACHES, MEMORY LOSS, BRAIN FOG, SEVERE FATIGUE, PAIN DURING INTERCOURSE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034280	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 6/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GETTING ESSURE I EXPERIENCED MIGRAINES, NIGHT SWEATS, TENDER SPOTS ALL OVER MY BODY, MONTHLY CYCLE CHANGED, HEADACHES EVERYDAY, ALLERGIES TO SOAPS AND FOOD, BACK PAIN, HIP PAIN, JOINT PAIN, LOTS OF UTI'S, CYSTS, METALLIC SMELL, URGENCY TO PEE ALL THE TIME, BODY ACHES, BREAST PAIN, CRAMPS ALL MONTH, EXTRA DISCHARGE, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034282	BAYER	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE ESSURE WAS PLACED I HAVE HAD 2 ROOT CANALS, 2 TEETH EXTRACTED, PITTING EDEMA IN MY LEGS AND FEET DAILY, CHRONIC YEAST INFECTIONS, HEAVY MENSTRUAL BLEEDING THAT INCLUDES CLOTS, MY UTERINE LINING IS 21MM (NORMAL IS 5MM-8MM), I HAVE HAD A HYSTEROSCOPY WITH D AND C WHICH SHOWED NOTHING, I HAVE HAD A UTERINE BIOPSY THAT WAS NORMAL, I BROKE OUT IN A BLISTERED RASH (ALL LAB TESTS SHOWED NOTHING ABNORMAL), I HAVE GAINED 40 POUNDS, MY HIPS ACHE SO BAD SOMETIMES I CAN'T SLEEP OR SIT, AND I GET SPASMS IN MY LOWER ABDOMEN (UTERUS AREA) EVERY DAY, BLOATING AND BACTERIAL VAGINOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034284	BAYER	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

VERY HEAVY BLEEDING DURING PERIODS NOW (HAD LIGHT PERIODS BEFORE ESSURE DEVICE WAS PLACED) CRAMPING, HEADACHES, WEIGHT GAIN, DIZZINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034285	BAYER	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 7/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN ME FOR 9 YEARS. ON (B)(6) I STARTED EXPERIENCING TERRIBLE PAIN IN MY LOWER LEFT BACK, A LITTLE MORE TO THE LEFT SIDE THEN THE SPINE, AND THE LEFT FRONT SIDE OF MY LOWER ABDOMEN WITH A THROBBING SENSATION (PAIN TO THE BONE) IN MY LEFT THIGH. I DIDN'T SLEEP FOR 7 MONTHS! I HAD AN MRI THAT SHOWED NOTHING ABNORMAL IN MY SPINE. THEN MY DOCTOR HAD ME GET AN ULTRASOUND OF MY ABDOMEN AREA. THOSE RESULTS ALSO SHOWED NOTHING ABNORMAL. THEN I CHOSE TO HAVE AN X-RAY OF MY LOWER ABDOMEN TO SEE MY COILS. THE LEFT COIL LOOKED TO BE MUCH HIGHER THAN MY RIGHT ONE. THE RIGHT ONE LOOKED JUST LIKE A FISH HOOK. MY OB/GYN THAT IMPLANTED THEM 9 YEARS AGO SAID THAT THEY DIDN'T LOOK RIGHT. I HAD SURGERY TO REMOVE THEM ON (B)(6) 2013. IT TURNS OUT THE LEFT COIL WAS DEEP INTO MY UTERUS. THE DOCTOR WAS ABLE TO GET IT OUT OF MY UTERUS THEN CAUTERIZED IT. SHE THOUGHT THAT MAY HAVE BEEN THE CAUSE OF MY PAIN. SHE TOOK OUT MY TUBES AND OVARIES. ONE MONTH LATER, I'VE STILL BEEN EXPERIENCING THE SAME BURNING/INFLAMED PAIN ON MY LEFT BACK BUT THE FRONT PAIN HAS GONE AWAY SINCE REMOVING THE EMBEDDED COIL. I OPENED THE CONTAINERS AND REALIZED THAT ONLY MY INNER COILS WERE GIVEN TO ME BY PATHOLOGY. I ASKED MY DOCTOR WHERE WERE THE OUTER COILS? AFTER ASKING MY DOCTOR, SHE REVIEWED THE PATHOLOGY REPORT AND IT READ THAT THERE WAS METAL IN THE RIGHT FALLOPIAN TUBE, APPARENTLY IT WAS THE OUTER COIL, BUT NO MENTION OF THE LEFT OUTER COIL. SO NOW I HAVE AN X-RAY SCHEDULED, BY MY DOCTOR, TOMORROW TO SEE IF IT IS EMBEDDED SOMEWHERE THAT IS CAUSING MY CONSTANT PAIN. IT HAS BEEN A PHYSICALLY AND EMOTIONALLY EXHAUSTING 7 MONTHS!! NOW I COME TO FIND OUT THAT THESE COILS HAVE TOXIC MATERIALS IN THE PET FIBERS AND ARE STERILIZED IN A TOXIC SOLUTION IS MORE THAN I CAN TAKE. THEY MUST BE TAKEN OFF THE MARKET BEFORE THEY HURT MORE WOMEN THEN IT ALREADY HAS.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034287	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 9/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NEW ISSUES SINCE ESSURE: EXTREME, CHRONIC FATIGUE (THIS OCCURRED IMMEDIATELY. I HAVE FELT LIKE I HAD THE FLU SINCE THAT DAY. SORE JOINTS, RAW THROAT AND SINUS PASSAGES EVERY SINGLE DAY SINCE); EXTREME BLOATING; HYSTERECTOMY; LABOR-LIKE MENSTRUAL PAIN ; HEAVY POST-LABOR-LIKE MENTRUAL BLEEDING WITH LARGE CLOTS; RANDOM CRAMPING EVEN WHEN NOT ON PERIOD; INCREASED SYSTEMIC TENSION DUE TO THIS AGGRAVATION; FEEL ANEMIC DURING CYCLE; LOWER BACK PAIN; OCCASIONAL HOT FLASHES; NIGHT SWEATS EVERY NIGHT; EXCESSIVE SWEATING DURING EVERYDAY ACTIVITIES; JOINT PAIN; INSOMNIA; SHARP PELVIC PAINS; INCREASED HORMONAL ACNE/CYSTS; DEPRESSION CAUSED BY DEALING WITH THESE SYMPTOMS. I HAD ESSURE IMPLANTED (B)(6) 2012. THIS PRODUCT HAS DECREASED MY QUALITY OF LIFE SIGNIFICANTLY DUE TO THE SYMPTOMS LISTED ABOVE. I RESEARCHED WITH DUE DILIGENCE WITH INFORMATION AVAILABLE AT THE TIME. MY DOCTOR SAID THERE WERE NO SIDE EFFECTS. RIGHT AFTER THE PROCEDURE, I WAS RUSHED OUT OF THE OFFICE WHILE STILL CRAMPING AND BLEEDING AND HANDED A CARD. I HAD NO IDEA THAT I WOULD GET A CARD THAT I WOULD HAVE TO PACK AROUND THE REST OF MY LIFE. A FEW DAYS AND WEEKS LATER I REPORT PROBLEMS TO THE IMPLANTING DOCTOR WHO MINIMIZES THEM. AFTER ENOUGH COMPLAINING, SHE OFFERED A HYSTERECTOMY. NATURALLY, THIS WAS VERY UPSETTING. I DIDN'T WANT A HYSTERECTOMY. I DIDN'T EVEN WANT A TUBAL LIGATION TO BEGIN WITH. FINALLY SHE OFFERED TO REMOVE THE TUBES. I DECIDED TO TAKE HER PA'S ADVICE TO "IGNORE THE PAIN AND IT WILL GO AWAY" BUT THAT HAS NOT WORKED. I FOUND OUT THE DEVICE HAS NICKEL IN IT, WHICH I HAVE ALWAYS REACTED TO. OUT OF FRUSTRATION, I WENT TO SEE AN ALLERGIST FOR A NICKEL TEST. I THINK THIS WAS (B)(6) 2012 AFTER BEING IMPLANTED IN (B)(6). I WAS FOUND TO BE HYPERSENSITIVE TO NICKEL - WITH A BIG PATCH OF BLISTERS DOWN MY BACK THAT TOOK A FEW WEEKS TO HEAL. LAST MONTH I SAW

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ANOTHER OB WHO AGREED THAT ESSURE IS CAUSING INFLAMMATION THAT IS CAUSING MY SYMPTOMS. HE ADMITTED THAT HE COULDN'T HELP ME UNLESS I WOULD DO A HYSTERECTOMY BECAUSE OF THE DIFFICULTY IN REMOVING THE DEVICE. HE ADVISED ME THAT IF I COULD FIND A TUBAL REVERSAL DOCTOR/MICROSURGEON WHO COULD REMOVE ALL THE METAL THAT WOULD BE MY BEST BET SHORT OF HYSTERECTOMY. IN ADDITION, I ALSO HAD TO EXPLAIN TO THIS OB THAT THE DEVICE CONTAINED NICKEL. ONE OF THE MOST APPALLING THINGS TO ME IS THAT BOTH OB'S I SAW TRIED TO TELL ME THAT THE DEVICE CONTAINS NO NICKEL. I HAD TO EXPLAIN THIS. THE IMPLANTING DOCTORS HAVE NO IDEA WHAT THIS DEVICE CONTAINS AND THAT IT IS DESIGNED TO CAUSE INFLAMMATION. OVER THE LAST YEAR, I HAVE CONTACTED THE MANUFACTURER FOR HELP A FEW TIMES. DURING THE LAST PHONE CALL, THE REPRESENTATIVE (WHO SOMETIMES REFERRED TO MIRENA EVEN AFTER BEING REMINDED THAT THIS WAS ESSURE, NOT MIRENA) WOULD ALWAYS REPLY "ESSURE IS PERMANENT," WHICH WAS COMPLETELY UNHELPFUL. WHEN I ASKED FOR A REMEDY, I WAS REFERRED TO A WEBSITE THAT DID NOT WORK TO FILE A CLAIM FOR THE HSG CONFIRMATION TEST FEE. THE REMEDY I WANTED IS TO HAVE THE DEVICE REMOVED AND MY ANATOMY RESTORED TO WHERE I FELT OKAY. WHEN I ASKED IF THEY COULD HELP ME FIND A DOCTOR TO REMOVE IT, THEY REFERRED ME TO THEIR WEBSITE FOR DOCTORS THAT IMPLANT ESSURE. I TOLD THEM THAT WON'T WORK BECAUSE THOSE DOCTORS CAN'T REMOVE, ONLY IMPLANT. THEN THE REP ADMITTED THAT THEY DON'T KNOW DOCTORS THAT CAN REMOVE ESSURE. THAT IS NOT GOOD AT ALL AND COMPLETELY UNHELPFUL TO THOSE HAVING ISSUES WITH THE PRODUCT. NOTHING WORKS FOR EVERYONE, THERE ARE ALWAYS ISSUES- BUT IT IS CLEAR TO ME THAT THE MANUFACTURER MADE NO PREPARATIONS FOR WORST CASE SCENARIO AND HAS JUST ABANDONED PEOPLE LIKE ME WITH PROBLEMS FROM THE DEVICE. AFTER SOME RESEARCH, I HAVE FOUND A COUPLE DOCTORS WILLING TO REVERSE THE DEVICE BUT THE COST IS $6800.00-7500.00 PLUS. MY FAMILY CANNOT AFFORD THIS. SO I AM IN A REALLY BAD POSITION WHERE I NEED TO TAKE CARE OF MY HEALTH TO THE DETRIMENT OF PROVIDING FOR MY FAMILY. IF I LEAVE ALL THIS INFLAMMATION IN MY BODY, WILL THIS CONTRIBUTE TO HEART DISEASE? WHAT ELSE? I'M SCARED OF WHAT THIS IS DOING TO ME AND HAVE NO OPTION TO REMOVE IT. AT THE VERY LEAST, I AM ASKING THE FDA TO REQUIRE THAT HYSTERECTOMY IS A VERY REAL RISK IN BIG, BOLD LETTERS RIGHT ON THE ESSURE LITERATURE. ALSO THAT THE HYSTERECTOMY STATISTICS BE PROVIDED NEXT TO THAT. PRIOR TO ESSURE, I WAS NOT INFORMED THAT HYSTERECTOMY WAS A RISK. I CAN TELL YOU UNEQUIVOCALLY THAT I WOULD NOT HAVE AGREED TO ESSURE HAD THAT BEEN ON THERE. THE BROCHURE SAID "MAJOR SURGERY," WHICH I TOOK TO MEAN LAPAROSCOPY TO REMOVE THE COILS. I DID ASK MY DOCTOR ABOUT THAT, AND THE DOCTOR WAVED HER HAND AND SAID THERE WOULDN'T BE A PROBLEM -THAT NO ONE HAD EVER HAD A PROBLEM. IN SUMMARY I'M ASKING: CORRECT MANUFACTURER LITERATURE FOR RISK OF HYSTERECTOMY, NOT JUST "MAJOR SURGERY." FULLY TEACH DOCTORS ABOUT WHAT THE DEVICE IS MADE OF AND WHAT IT DOES. THEN IN TURN THE DOCTOR MUST INFORM THE PATIENTS OF THIS PLUS THE RISKS. REQUIRE DOCTORS WHO IMPLANT TO RECOGNIZE THE RISKS BOTH AS PART OF THEIR TRAINING AND THEIR DIALOG WITH PATIENTS. REQUIRE DOCTORS TO INFORM PATIENTS OF ANY ISSUES WITH INSERTION, SUCH AS PERFORATION. MY DOCTOR DID NOT TELL ME. I FOUND OUT BY GETTING THE OP NOTE. REQUIRE THE MANUFACTURER TO REMEDY PATIENTS WHO WERE NOT INFORMED OF RISKS DUE TO NICKEL ALLERGY OR ANYTHING ELSE. AS AN ENGINEER, WE TAKE PRECAUTIONS FOR WORST-CASE SCENARIO AND PROVIDE DISASTER RECOVERY SOLUTIONS. AS A PATIENT, IT IS SADLY APPARENT THAT THERE IS A REAL LACK OF EXCELLENCE AND ADVANCEMENT IN THE MEDICAL FIELD TODAY. WHY? IS IT BECAUSE OF MONEY, POLITICS, FEAR OF BEING SUED? I AM ASKING THE FDA AND MEDICAL INDUSTRY TO PUSH ASIDE BARRIERS AND STRIVE FOR EXCELLENCE IN MEDICINE. DON'T BE AFRAID OF THE PROBLEM, INSTEAD GET TO THE ROOT OF THE PROBLEM SO THAT YOU CAN SOLVE THE SOLVABLE ONES. I'M APPALLED THAT THIS DEVICE GOT APPROVED BY THE FDA WITHOUT A LONG TERM STUDY WHERE UTERUSES HAD NOT BEEN REMOVED (AND LOSING THE LONG-TERM INFO THAT COULD HAVE BEEN GLEANED FROM THOSE SUBJECTS).

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034289	CONCEPTUS	2/11/2014	2/11/2014

Event Information:

Event Date (B3): 2/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED TO HAVE SEVERE PANIC ATTACKS, BACK PAIN STARTED, AND MY HIPS WERE HURTING AS WELL. I HAVE SERIOUS TROUBLE SLEEPING AND NO ENERGY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034258	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN THE TUBE AREA, BLOATING, BACK PAIN, DEPRESSION AND HEADACHES, AND LACK OF ENERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034259	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 5/20/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

OVARIAN CYSTS, EXTREME HEAVY PERIODS, CONSTANT MIGRAINES, STABBING PAINS, MIGRATING OF COILS, I HAVE A NICKEL ALLERGY,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034261	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BEGAN HAVING ISSUES WITH ESSURE SHORTLY AFTER PLACEMENT WHICH WAS (B)(6) 2013. PAIN, CRAMPING, FOUL DISCHARGE, HEAVY PERIODS, PAINFUL INTERCOURSE, RASH, BLADDER INFECTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034262	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 9/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT UTERINE CRAMPS, PAIN IN MY UPPER RIGHT SIDE OF BACK, FATIGUE, JOINT PAIN, MORE THAN NORMAL BLOOD WITH MY PERIOD AND LARGE CLOTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034263	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 1/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PERIODS WERE MIA !!! MY UTERUS WAS FULL OF ADENOMYOSIS , BLOATED , GAIN 50 SOMETHING POUNDS , SWELLING , BAD HEAD ACHES , SHRAP PAINS ON MY RIGHT SIDE ! COULD NOT PICK UP ANYTHING WITH PAIN ! AND A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034264	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 11/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEADACHES, IRREGULAR AND PAINFUL MENSTRUAL CYCLES, SHARP PAINS IN UTERINE AREA, BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034266	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 3/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN HIPS AND BACK. PAINFUL MENSTRUATION. LARGE CLOTS AND HEAVY BLEEDING. MIGRAINES. ANXIETY. HAIR LOSS AND BREAKING. ALL OF THESE SYMPTOMS HAVE CONTINUED AND BECOME WORSE AS TIME GOES ON. DURING MY PERIOD THERE ARE DAYS THAT I AM UNABLE TO FUNCTION BECAUSE THE PAIN IS SO TERRIBLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034267	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 5/20/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2008. THE FIRST DAY THE PAIN WAS EXTREME, I CALLED THE DOCTOR THE FOLLOWING DAY AND WAS TOLD IT IS COMMON. MY MENSTRUAL CYCLE HAS NOT BEEN THE SAME SINCE HAVING ESSURE. THE FIRST CYCLE AFTER IMPLANTS WAS VERY HEAVY AND LONG. BEFORE ESSURE I WOULD HAVE A CYCLE THAT WOULD LAST 3-4 DAYS THE MOST. I WAS IMPLANTED 6 1/2 YEARS AFTER THE BIRTH OF MY TWINS. SINCE THEN UNTIL TODAY MY CYCLES HAVE BEEN EXTREMELY PAINFUL, HUMONGOUS BLOOD CLOTS AND TISSUE COME OUT. I WENT BACK TO IMPLANTING DOCTOR AND WAS TOLD THAT MY NEW COMPLAINTS HAD NOTHING TO DO WITH ESSURE AND THAT IT WAS COMMON FOR MY AGE FOR MY BODY TO CHANGE. CYCLES WOULD LAST ANYWHERE FROM 7-14 DAYS, CURRENTLY, I HAVE CYCLES THAT LAST 7-14 DAYS, SPOTTING IN BETWEEN AND CYCLES COME EVERY 20 DAYS SOMETIMES 23 DAYS. SEVERE LOWER ABDOMINAL AND BACK PAIN. SINCE INSERTION OF ESSURE I AM CONTINUOUSLY INFLAMED AND HAVE TO RELY ON IBUPROFEN WHICH HAS CONTRIBUTED TO A REALLY BAD STOMACH PROBLEM MOST DAYS I HAVE DIARRHEA. I DID NOT DO THE HSG DUE TO BEING A FULL TIME GRADUATE STUDENT, FULL TIME EMPLOYED, SET OF TWINS AND ANOTHER CHILD, IT WAS VERY COMPLICATED GETTING TO SCHEDULE THE HSG SINCE IT HAD TO BE CERTAIN DAYS OF THE MONTH. WHEN MY COMPLAINTS WERE IGNORED BY THE DOCTOR I STOPPED GOING BACK. I HAVE A SEVERE MUCOUS SINUS PROBLEM, BACK PROBLEM AND PELVIC DISCOMFORT DAILY. I AM UNABLE TO ENJOY OR HAVE SEX, I BLEED AFTERWARDS AND VERY DISCOMFORTING DURING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034270	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 1/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE AS BIRTH CONTROL WAS TOLD THE NEW WAY SAFER THAN TUBALS AND WANTED MY TUBES TIED, I HAVE HAD PAIN SINCE DAY OF THE IMPLANTS THINKING IT WAS NEW AND GIVE TIME , ALSO STARTED WITH OTHER HEALTH ISSUES SOON AFTER ALL DOCUMENTED AT MY DOCTORS OFFICE. I WAS DIAGNOSED WITH FIBROMALASIA! I HAVE MIGRAINE HEADACHES , NUMB HANDS FEET SWELLING HANDS FEET, MEMORY LOSS HAIR LOSS , WEIGHT GAIN NO MATTER WHAT DIET EXERCISE I TRY WEIGHT WONT BUDGE, PERIODS ARE NOT NORMAL HUGE CLOTS PASS , SEVERE ALL OVER BODY ACHES SWELLING OF JOINTS, PAINFUL INTERCOURSE! TO NAME THE WORST ONES NEW ONES SEEM TO KEEP DEVELOPING LIKE RASHES FOR NO REASON .

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034271	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AT FIRST, IT WAS LOTS OF BACK PAIN, SHARP INTENSE ABDOMINAL PAIN, THEN IT WAS BLOOD CLOTS DURING MY CYCLE, VERY HEAVY CYCLE, CYCLE OFF SCHEDULE, NECK PAIN, NERVE PROBLEMS (SHOOTING PAINS THRU OUT MY HIPS AND LEGS) SHOOTING PAIN AND PRESSURE IN MY PELVIC, NO SEX DRIVE, STRESS, DEPRESSION, ANXIETY, HEADACHES. THEN I HAD THEM REMOVED AND MY CYCLE WENT BACK TO NORMAL, NO MORE PAIN IN MY ABS AND PELVIC AND WEIGHT GAIN. TO THIS DAY, I HAVE DEGENERATIVE DISC AND DEGENERATIVE JOINT DISEASE, BILATERAL FORMATION, PINCHED NERVES IN BACK AND NECK, BULGING DISC, HEMORRHAGIC CYST, KIDNEY CYST, BONE SPURS, OSTEOPENIA. I WAS VERY MUCH IN SHAPE AND HEALTHY BEFORE I GOT THESE IN ME, NOW MY DAYS ARE PAINFUL, STRESSFUL AND CAN'T DO ANYTHING FOR MY KIDS, NOR PLAY WITH MY KIDS. AND I HAVE A HUGE FEAR OF MEDICINES AND EMERGENCY ROOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034272	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 4/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AS SOON AS I WOKE UP FROM SURGERY, SEARING HOT PAIN IN RIGHT SIDE, KEPT GETTING WORSE EVERY DAY. MADE APPOINTMENT TO GO TO DR. BECAUSE OF PAIN, AND THEN HE GAVE PAIN MEDS, STILL DIDN'T HELP, CAME BACK TO THE DR. AND DECIDED THE ESSURE NEEDED TO COME OUT. AND WOULD HAVE TO PERFORM A HYSTERECTOMY. I HAD PAIN FOR ALMOST 2 MONTHS BEFORE IT WAS TAKEN OUT. MY TUBES WERE VERY SWOLLEN AND INFLAMED BECAUSE I HAD AN ALLERGIC REACTION TO THE NICKLE IN THE ESSURE COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034278	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 10/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ADENOMYOSIS. UTI'S. BACK PAIN. BACTERIAL VAGINOSIS. CLOTS. BLURRY VISION. BODY ACHES. BREAST PAIN. YEAST INFECTIONS. CHEST PAIN. HEARTBURN. CRAMPING. DISCHARGE. DIZZINESS. DRY SKIN HAIR. WEIGHT GAIN. LEG PAINS\RESTLESS LEGS. FATIGUE. HAIR GROWTH. MIGRAINES. HEAVY BLEEDING. HIP PAIN. STOMACH PAIN. SHARP STABBING PAIN. IRREGULAR PERIODS. MUSCLE SPASMS. NECK PAIN. PAINFUL INTERCOURSE. LOW SEX DRIVE. BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034279	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 10/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACED IN (B)(6) 2012. I DID NOT HAVE TOO MUCH LOCALIZED PAIN IMMEDIATELY FOLLOWING PROCEDURE. TWO MONTHS AFTER THE PROCEDURE I ALSO HAD A VERY HEAVY PERIOD WHICH INCLUDED BLOOD CLOTS WITH HEAVY CRAMPING AND BACKACHE. AT THIS TIME I ALSO STARTED EXPERIENCING SOME UNUSUAL SYMPTOMS AND THESE SYMPTOMS PROGRESSED OVER THE COURSE OF THE LAST YEAR. MY PERIODS ARE EVERY THREE WEEKS, WITH RANDOM BLEEDING IN BETWEEN CYCLES. I HAVE PERIODS OF HOT FLASHES, NIGHT SWEATS, AND MOOD SWINGS, ANXIETY, AND LOSS OF LIBIDO. I HAVE SEVERE JOINT AND MUSCLE PAIN ESPECIALLY IN MY FEET, HANDS, AND LOWER CALVES; AND TINGEING/NUMBNESS IN EXTREMITIES. I HAVE SEVERE LOWER BACKACHES THAT INTERFERE WITH MY ABILITY TO SLEEP; I ALSO HAVE PRESSURE AND CRAMPING IN LOWER ABDOMEN AREA. (THESE PAINS FLUCTUATE BUT ARE VERY TROUBLESOME ABOUT 3 WEEKS PER MONTH.) I HAVE FREQUENT HEADACHES AND DIZZINESS, SEIZURE-LIKE BRAIN ACTIVITY. I HAD A SEIZURE ON (B)(6) 2013, WITH NO HISTORY OF PRIOR SEIZURES. I ALSO DEVELOPED HEARTBURN (WHICH I NEVER HAD A PROBLEM WITH PRIOR). I HAVE SKIN PROBLEMS INCLUDING ACNE, ITCHING, AND RASHES. I HAVE PROBLEMS WITH VAGINAL IRRITATION/ITCHING, ODOR, DISCHARGE (BV) (WITH NO YEAST INFECTION, BUT FREQUENT UTIS). MY HSG TEST REVEALED THAT ONLY ONE TUBE WAS BLOCKED, SO PROCEDURE DID NOT WORK AS IT WAS INTENDED. I HAVE GASTROINTESTINAL PROBLEMS WHICH INCLUDE FREQUENT PROBLEMS WITH LOOSE BOWELS, NAUSEA, AND BLOATING. I HAVE HAD FIBROMYALGIA FOR 23 YEARS, AND THE SYMPTOMS OF MY CONDITION, INCLUDING MUSCLE PAIN AND FATIGUE HAVE BEEN EXACERBATED. MANY OF THESE SYMPTOMS ARE NOT PART OF MY CONDITION (SUCH AS JOINT PAIN AND PAIN IN FEET). IN THE LAST SEVERAL MONTHS, MY FUNCTIONING LEVEL HAS STEADILY DECREASED. ADDITIONALLY, I WAS NOT AWARE THAT ESSURE COILS CONTAINED NICKEL WHEN I HAD THEM PLACED. I HAD REACTIVITY TESTING BY (B)(6) OF 2003 WHICH

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REVEALED THAT I AM HIGHLY REACTIVE TO NICKEL. IT WAS AFTER I STARTED EXPERIENCING SYMPTOMS THAT I DISCOVERED ESSURE COILS CONTAINED NICKEL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034281	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2010, MY PERIODS HAVE BECOME IRREGULAR. ALSO I DEVELOPED ACNE LIKE A TEENAGER ALL OVER MY CHEEKS THAT TOOK MONTHS TO GO AWAY. I ALSO BECOME REALLY SICK BY (B)(6) AND NEEDED ANTIBIOTICS FOR AN UNKNOWN INFECTION THAT LASTED 3 MONTHS AND WAS DEBILITATING TO WHERE I COULD NOT MOVE MY JOINTS OR DO SIMPLE THINGS SUCH AS ZIP A COAT OR BUTTON ANYTHING. I ALSO HAD NOTICED MY LEGS FALL ASLEEP VERY OFTEN AT THIS TIME AND CERTAIN POSITIONS OR BENDS I DO OR MAKE SEND A SHARP PAIN THROUGH MY LOWER ABS WHERE MY COILS ARE LOCATED. ALSO HAVING SEX HAS CHANGED. I CANNOT HAVE ROUGH SEX OR BE PENETRATED IN A DEEP MAN OR WITHOUT FEELING LIKE MY COILS ARE GOING TO BE SHOT OUT WHICH IS VERY PAINFUL ALMOST LIKE A FUNNY BONE FEELING THROUGHOUT MY FEMALE ORGAN REGION . I WAS TOLD BY MY DOCTOR THAT A PENIS CANNOT COME IN CONTACT WITH THE DEVICE BUT I'M SURE IT HAS AND MY HUSBAND HAS FELT THEM HIMSELF AND ASKED WHAT HE WAS POSSIBLY HITTING. ALSO I HAVE MAJOR CRAMPS WHERE I AM IN BED FOR DAYS AFTER NORMAL SEX AND SOFT SEXUAL INTERCOURSE. I HAVE ALSO BLED AFTER INTERCOURSE TO THE EXTENT THAT MY SHEETS AND MATTRESS HAD BEEN RUINED AND I WAS NOT ON MY OR CLOSE TO MY MENSTRUAL CYCLE. WITHIN THE FIRST YEAR I HAD NOTICED I HAVE LOST A LOT MORE HAIR DURING BRUSHING. TO THIS DAY MY HAIR IS THINNING AND HAS BECOME A LOT SHORTER WITH OUT THE NEED OF BEING CUT. I'VE HAD TO PULL MY HAIR TO THE SIDE JUST TO MAKE IT LOOK LIKE IT IS FULLER BUT IS NOT. IN (B)(6) 2012 I STARTED MISSING MY PERIODS OR BECOME A FEW WEEKS LATE AT A TIME. SOME PERIODS ARE HEAVY SOME ARE REALLY LIGHT. I NEVER KNOW WHAT OR WHEN IT WILL HAPPEN NEXT. I WENT TO MY GYN AND WAS TOLD I HAVE DEVELOPED PCOS AND HAD CYST ON MY LEFT OVARY OF WHICH I NEVER HAD FEMALE ISSUES IN MY LIFE. I WAS ALSO TOLD THE WEIGHT GAIN I HAVE SINCE AFTER MY LAST BIRTH MIGHT BE PART OF THE PROBLEM BUT ALSO MAY NOT

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BE THE PROBLEM. MY DOCTOR HAD ALSO SCREENED ME FOR PRE MENOPAUSE AT AGE (B)(6) AND CAME BACK NEGATIVE. EVEN WITH THE CHANGE IN FOOD AND EXERCISE I AM STILL DEALING WITH THESE ISSUES. ALSO SINCE PLACEMENT OF ESSURE MY VAGINA AROUND DURING AND AFTER PERIODS FEEL AT TIMES LIKE SOMEONE HAS KICKED ME IN THE CROTCH AND FROM THE OUTSIDE I LOOK INFLAMED AS IF SWOLLEN AND ALL I WANT TO DO IS SIT IN A REALLY HOT OR COLD BATH OR HAVE A COMPRESS AGAINST MYSELF. THE FEELING FEELS LIKE I HAD JUST PUSHED OUT A BABY AND NEED ICE PACKS. MY WHOLE BODY HURTS. I'M NOT SURE IF I AM ALLERGIC TO NICKEL I DON'T RECALL EVER BEING GIVEN THAT TEST. MY JOINTS HURT. SOMETIMES I GET SHARP PAINS OUT OF THE BLUE IN MY LOWER ABDOMEN. AND MY BELLY AROUND PERIOD TIME BLOATS VERY BIG TO WHERE PEOPLE ASK ME IF I'M PREGNANT BUT AM NOT . THOUGH WHILE I AM OFF MY CYCLE I HAVE LITTLE BLOAT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034283	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NAUSEA, BLOATING, FATIGUE, NECK PAIN, SHOULDER PAIN, PELVIC PAIN, LIGHT HEADEDNESS, HOT FLASHES, SWEATING, ACNE, SEVERE HEADACHES, VEIN PAIN (IN FOREARMS), WEIGHT GAIN, SHORTNESS OF BREATH, WORSENING VISION, EASY BRUISING, SLOW HEALING OF CUTS/SORES, DEPRESSION, SUICIDAL THOUGHTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034286	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 1/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SHORTLY AFTER BEING IMPLANTED WITH ESSURE, I STARTED TO HAVE LOWER BACK PAIN. AS TIME WENT ON, MY LEGS STARTED TO HURT AND AT THIS POINT THEY HURT ALL THE TIME. MY ENERGY LEVEL HAS DROPPED SIGNIFICANTLY AND I FEEL TIRED ALL THE TIME. I WAS A VERY ACTIVE PERSON AND STILL TRY TO BE, BUT ITS BEEN DIFFICULT. I HAVE BEEN TO SEVERAL DOCTORS(CHIROPRACTOR, RHEUMATOLOGIST, ORTHOPEDIC, ENDOCRINOLOGIST, AND PRIMARY CARE) DONE COUNTLESS BLOOD LABS AND THEY HAVE RULED OUT OTHER MEDICAL CONDITIONS. I HAVE HAD TO HAVE TWO NERVE BLOCKS BECAUSE OF THE PAIN. SOME LESS SERIOUS REACTIONS ARE CONSTIPATION, HAIR THINNING, BODY ACHES, HEADACHES, MEMORY LOSS(BRAIN FOG), CAN'T LOSE WEIGHT, INSOMNIA AND 2 CRACKED TEETH FROM DECREASED VITAMIN D LEVELS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034288	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 11/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY ESSURE WAS PLACED IN (B)(6) 2012. (B)(6) 2013 WAS MY FLUOROSCOPY X-RAY TO CONFIRM PLACEMENT WHICH WENT NORMALLY. FOLLOWING THE PLACEMENT CONFIRMATION, I CONTINUED TO HAVE LEFT LOWER ABDOMINAL PAINS, THEY WERE RANDOM AND FELT STABBING. I CALLED MY PHYSICIANS OFFICE AND WAS TOLD THIS WAS COMMON BUT SHOULD GO AWAY. OVER THE NEXT FEW MONTHS THE PAIN CONTINUED AND WORSENED WITH EACH PERIOD. ON NOVEMBER 23, 2013, I PASSED OUT DUE TO LOW BLOOD PRESSURE AND WAS TAKEN TO THE ER WITH SEVERE ABDOMINAL PAIN (I WAS HAVING MY SECOND PERIOD FOR THE MONTH). THE LAB RESULTS SHOWED I HAD AN INFECTION (WBC- 18) AND A CT SCAN OF ABDOMEN AND PELVIS WITH CONTRAST SHOWED THAT MY LEFT ESSURE DEVICE WAS OUT OF MY FALLOPIAN TUBE, THROUGH MY UTERINE WALL AND INTO MY PELVIC TISSUE. AFTER MULTIPLE ANTIBIOTICS, I HAD A FULL HYSTERECTOMY ON DECEMBER 12, 2013 AND WAS HOSPITALIZED FOR A DAY. I WAS UNABLE TO WORK FROM (B)(6) UNTIL (B)(6) AS A RESULT OF THIS EVENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034290	CONCEPTUS	2/11/2014	2/12/2014

Event Information:

Event Date (B3): 12/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALL OF A SUDDEN I HAVE ALL KINDS OF PROBLEMS. I BLOATING, PELVIC PAIN, HEAVY PERIODS, DEPRESSED, FATIGUE, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034520	CONCEPTUS, INC.	2/11/2014	2/20/2014

Event Information:

Event Date (B3): 2/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): L2843
Catalog # (E4):
Lot #(E4): A06689

Single Use:
Implant Date (E6): 1/10/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAD THE ESSURE IMPLANTED I'VE HAD NOTHING BUT PROBLEMS, MY PAINS ARE UNBEARABLE AND MY PERIODS ARE 100 TIMES WORSE WITH HEAVY BLEEDING, CRAMPING AND BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034521	CONCEPTUS, INC.	2/11/2014	2/20/2014

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 869756

Single Use:
Implant Date (E6): 10/21/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DEVICES PLACED IN (B)(6) OF 2011. BY THE FOLLOWING SUMMER I WAS EXPERIENCING RIGHT SIDE ABDOMINAL PAIN, NAUSEA, AND BLOOD IN MY URINE. A CYSTOSCOPY, TWO CT'S, AND A URETEROSCOPY SHOWED NO SIGNS OF PROBLEMS. A GYN EVAL ALSO SHOWED NO OTHER EXPLANATION FOR MY ISSUES, WHICH STILL PERSIST TO DATE. I HAVE HAD TO ABANDON MY PREVIOUSLY ACTIVE LIFESTYLE BECAUSE OF THE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034529	BAYER	2/11/2014	2/20/2014

Event Information:

Event Date (B3): 10/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS306
Catalog # (E4):
Lot #(E4): A46116

Single Use:
Implant Date (E6): 10/25/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE BIRTH CONTROL DEVICE IMPLANTED IN (B)(6) 2012. IN (B)(6) OF 2013 MY HEALTH BEGAN TO DECLINE. I HAVE SEVERE ABDOMINAL CRAMPS, LOWER BACK PAIN, JOINT PAIN, DIAGNOSED WITH FIBROMYALGIA, NEUROPATHY, PASS EXTREMELY LARGE BLOOD CLOTS, PAIN AND BLEEDING DURING SEX, SEVERE FATIGUE, CAN NOT FUNCTION WELL DAY TO DAY, AND NOW I AM ON A BUNCH OF MEDICATIONS THAT DO NOTHING. I SEE A RHEUMATOLOGIST AND NEUROLOGIST. I HAVE HAD NUMEROUS TESTS DONE AND NO ANSWERS. MY NEUROLOGIST POINTED ME IN THE DIRECTION OF REACTION TO ESSURE AND AFTER READING THE OVER 8000 OTHER WOMEN'S STORIES THE TIME FRAME IS RIGHT FOR THE PROBLEMS I HAVE BEEN DEALING WITH. I WANT MY LIFE BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034530	CONCEPTUS, INC.	2/11/2014	2/20/2014

Event Information:

Event Date (B3): 6/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED AFTER MY SON WAS BORN IN 2010... I HAVE HAD NOTHING BUT PROBLEMS SINCE. I NEEDED A HYSTERECTOMY LAST YEAR ACCORDING TO MY GYNECOLOGIST. SHE IS THE SAME DOCTOR THAT PUT THEM IN PLACE. I DID NOT HAVE (B)(6) TO PAY AND I STILL DONT HAVE THE MONEY. I HAVE INSURANCE THROUGH WORK BUT THAT'S HOW MUCH I HAVE TO PAY UPFRONT. I HAD X-RAYS DONE LAST WEEK. AND ONE HAS MIGRATED WAY UP. NOW I WILL HAVE TO SEE ANOTHER DOCTOR. I NEED THESE ITEMS OUT AND THEY SHOULD NOT BE ON THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034531	CONCEPTUS, INC.	2/11/2014	2/20/2014

Event Information:

Event Date (B3): 3/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/21/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE PUT IN ABOUT 3 YEARS AGO I WAS FORCED BY THE DOCTOR THAT DID THE SURGERY TO DO IT BECAUSE OF HIM BEING THE ONLY DOCTOR IN TOWN THAT I COULD HAVE WENT TO BUT ANYWAYS BACK TO WHAT HAPPENED I HAVE HAD NO PROBLEMS WITH THE DEVICE UNTIL I MISSED MY PERIOD AND I DISCOVERED THAT I WAS PREGNANT AND STILL AM ABOUT 6 MONTHS ALONG. WHEN THE DOCTORS DID THE ULTRASOUND TO FIND OUT HOW FAR ALONG I WAS THEY DISCOVERED THAT THE COIL WAS/IS NEXT TO THE BABY SO NOW I AM HIGH RISK. I WOULD LIKE SOMETHING DONE ABOUT THIS PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034533	BAYER	2/11/2014	2/20/2014

Event Information:

Event Date (B3): 12/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 1/17/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE MONTH AFTER I HAD ESSURE IMPLANTED, I HAD MY FIRST SYMPTOM OF RA. THESE SYMPTOMS CONTINUED AND A YEAR LATER I WAS DIAGNOSED WITH RA. I ALSO HAVE A NICKEL ALLERGY THAT I NEVER HAD BEFORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034534	CONCEPTUS	2/11/2014	2/20/2014

Event Information:

Event Date (B3): 9/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/25/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE ON (B)(6) 2013, SINCE THEN HAVE HAD SEVERE BLEEDING THAT HAS NOT STOPPED TO THIS DAY. HEADACHES, DIZZINESS, BACK PAIN, CRAMPING, HAIR LOSS, VAGINAL DISCHARGE, FOUL SMELL, PELVIC PAIN, JOINT PAIN. I AM 5 MONTHS INTO HAVING ESSURE AND PROBLEMS JUST KEEP COMING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034535	BAYER	2/11/2014	2/20/2014

Event Information:

Event Date (B3): 7/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 959210

Single Use:
Implant Date (E6): 7/23/2012
Explant Date (E7): 1/28/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD BOTH MY FALLOPIAN TUBES REMOVED BECAUSE DEVICE HAD MIGRATED TO MY ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00021	BAYER HEALTHCARE LLC	2/11/2014	2/25/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A69943

Single Use: Y
Implant Date (E6): 7/3/2013
Explant Date (E7): 10/9/2013
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/28/2014

Event Description (B5):

A PATIENT HAD ESSURE INSERTED. SHE WAS SEEN IN THE HOSPITAL 3 MONTHS AFTER ESSURE FITTING FOR ABDOMINAL PAIN. ESSURE HAD PERFORATED UTERINE TUBE AND WAS IN OMENTUM. DEVICE WAS WITHDRAWN BY COELIOSCOPY. THE OUTCOME WAS UNKNOWN. THE REPORTER DID NOT PROVIDE FURTHER INFORMATION DESPITE SEVERAL FOLLOW-UP ATTEMPTS.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-SEP-2014: FINAL ASSESSMENT: THE CASE IS REOPENED TO ADD AE AND UPDATE ASSESSMENT STATEMENT ONLY. NO NEW ADDITIONAL INFORMATION FOR INVESTIGATION. SINCE PRODUCT WAS RETUR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00022	BAYER HEALTHCARE LLC	2/11/2014	3/4/2014

Event Information:

Event Date (B3): 7/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 7/2/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED INTO LEFT FALLOPIAN TUBE FOR CONTRACEPTION, AS RIGHT FALLOPIAN TUBE WAS PREVIOUSLY REMOVED. SHE STARTED HAVING SEVERE PAIN DAYS AFTER INSERTION. SHE WENT TO THE EMERGENCY ROOM BECAUSE OF THE PAIN AND HAD EMERGENCY SURGERY. THE DOCTORS FOUND THE COIL BROKEN AND PUNCTURED IN THE UTERUS. HER (LEFT) FALLOPIAN TUBE WAS REMOVED, BUT A COIL WAS STILL SEEN IN HER UTERUS AND CAUSING INTERNAL BLEEDING. SHE IS STILL HAVING SEVERE PAIN AND THE DOCTOR WANTS TO PERFORM A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00024	BAYER HEALTHCARE LLC.	2/11/2014	3/4/2014

Event Information:

Event Date (B3): 9/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 12533513

Single Use: Y
Implant Date (E6): 9/3/2013
Explant Date (E7): 10/11/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED FOR STERILIZATION. SHE HAD PAIN, BLOATING, AND BLEEDING CONTINUOUSLY FROM THE TIME THE PROCEDURE WAS DONE UNTIL THE TIME SHE HAD TO HAVE BOTH COILS REMOVED. ONE OF THE COILS HAD BENT AND EMBEDDED ITSELF INTO HER UTERUS. THE OTHER COIL MOVED OUT OF THE OTHER FALLOPIAN TUBE AND WAS TANGLED IN THE OMENTUM IN HER ABDOMEN. SHE HAD SURGERY PERFORMED TO HAVE BOTH COILS REMOVED AND IS STILL EXPERIENCING PAIN AND BLOATING. FOLLOW-UP ATTEMPTED WITHOUT SUCCESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034291	BAYER	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 6/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #(B)(4). IMPLANT DATE WAS (B)(6) 2010. HSG TEST WAS ON (B)(6) 2010. ON (B)(6) 2011, I HAVE DNC WHERE DOCTOR HAD FOUND COIL HAD FLIPPED AROUND AND WAS HANGING OUT OF MY FALLOPIAN TUBE SO DOCTOR PULLED IT OUT. I HAD A REPEAT HSG TEST DONE ON (B)(6) 2011 THAT CONFIRMED I WAS 100% BLOCKED FOR THE SECOND TIME. ON (B)(6) 2012, I HAD MY 1ST ULTRASOUND THAT CONFIRMED PREGNANCY. MY CHILD WAS BORN (B)(6) 2012. AFTER DELIVERY I HEMORHAAGED SO BAD I PASSED OUT. ON (B)(6) 2014, I WENT TO MY DOCTOR BECAUSE MY SYMPTOMS OF DAILY HEADACHES, IRREGULAR BLEEDING, LOWER BACK PAIN, FATIGUE, PAINFUL INTERCOURSE, AND LOWER RIGHT QUADRANT PAIN HAD RETURNED AND WAS BECOMING UNMANAGEABLE WITH OVER THE COUNTER MEDICATIONS. I HAD A HYSTEROSCOPY AND DNC. DURING THIS PROCEDURE MY DOCTOR FOUND ADHESIONS ON MY RIGHT SIDE FROM MY INTESTINES TO MY ABDOMINAL WALL. ON (B)(6) 2014, I HAD A BILATERAL SALPINGECTOMY TO REMOVE MY OTHER COIL BECAUSE MY DOCTOR BELIEVED THE SYMPTOMS I HAS HAVING WAS DUE TO DEVELOPING A NICKEL ALLERGY. DURING THIS PROCEDURE MY DOCTOR FOUND THE ADHESIONS HAD GROWN BACK IN THE SAME SPOT IN 7 WEEKS AND THAT PART OF MY INTESTINES WAS INFLAMED. MY DOCTOR ALSO FOUND A CYST ON MY RIGHT OVARY THAT HAD TO BE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034292	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 7/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2012, RIGHT AFTER I HAD A GOOD AMOUNT OF PAIN AND HEAVY BLEEDING. SHORTLY AFTER I BEGAN HAVING PELVIC PAIN RANDOMLY AND MY PERIOD WAS COMING EVERY 2 WEEKS AND I WAS ALSO HAVING GI ISSUES WITH EVERYTHING I ATE OR DRANK. LOTS OF BACK PAIN AND HIP PAIN SHORTLY FOLLOWED. I WENT TO THE DRS IN (B)(6) BECAUSE I WASN'T FEELING WELL AND WAS BECOMING VERY SHAKY, SO WITH MY FAMILY'S HISTORY OF DIABETES I WANTED TO GET EVERYTHING CHECKED OUT. SHORTLY AFTER ARRIVING AT THE DR'S OFFICE AND HAVING URINE TESTS DONE THE DR INFORMED ME THAT EVEN THOUGH IT WASN'T SUPPOSED TO BE POSSIBLE I WAS PREGNANT. MY OB TOLD ME THAT SHE COULDN'T GUARANTEE HOW SAFE MY PREGNANCY WOULD BE BUT SHE WOULD KEEP A CLOSE EYE ON ME AND MAKE SURE EVERYTHING WAS OK. I AM 23 YEARS OLD AND ALREADY HAVE 2 KIDS WHO ARE ONLY (B)(6) SO I WAS EXTREMELY SHOCKED TO FIND OUT I WOULD HAVE TO START OVER AND RAISE ANOTHER BABY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034293	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 7/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BEGAN HEAVY MENSTRUAL BLEEDING AND CRAMPING I HAD NEVER EXPERIENCED BEFORE. BEGAN BEING CONSTANTLY TIRED, NO ENERGY, SLURRED SPEECH, VISION PROBLEMS, OVARIAN CYSTS WHICH I'VE NEVER HAD BEFORE, PAIN ALL OVER MY BODY, VIBRATION INSIDE MY ORGANS, ITCHY DRY SKIN, NAUSEA, LOSS OF APPETITE, INSOMNIA, PAIN AND BLEEDING DURING AND AFTER INTERCOURSE, LOSS OF LIBIDO, UNABLE TO ACHIEVE ORGASM, FOUL ORDER FROM VAGINAL SECRETIONS, INCREASE IN DISCHARGE, MOOD INSTABILITY, BLOATING, SWELLING AND FOUL SMELLING GAS. THE TOLL ON MY MARRIAGE IS MAKING ME SUFFER DEPRESSION AND THOUGHTS OF SUICIDE HAVE CROSSED MY MIND. FORTUNATELY ALTHOUGH IT'S TAKING A TOLL ON MY MARRIAGE MY HUSBAND IS SUPPORTIVE AND REMAINS MY STRENGTH. HE UNDERSTANDS THAT IT'S NOT MY FAULT WHAT IS HAPPENING TO US.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034294	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT IS A CONSTANT PAIN IN MY ABDOMINAL AREA(ESPECIALLY DURING MENSTRUAL), CONSTANT BACK PAIN(NATURAL CHILD BIRTHER HERE), DISCOMFORT DURING SEX REOCCURRING HEADACHES AND MOOD SWINGS. THIS METHOD OF BIRTH CONTROL WASN'T JUST A RECOMMENDATION FROM MY OB/GYN BUT MORE, MY DR'S ONLY RECOMMENDATION.....I JUST WANT THEM GONE!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034295	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEADACHES, BLOATING / SWELLING, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034296	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE FAILURE. COILS IMPLANTED (B)(6) 2010. 100% BLOCKAGE HSG CONFIRMED (B)(6) 2010. CONFIRMED VIABLE PREGNANCY (B)(6) 2011. BABY BOY BORN (B)(6) 2011, DUE DATE WAS (B)(6) 2011. BABY FINE, MOTHER NOT SO LUCKY. I AM FILING A SEPARATE REPORT CONCERNING THE MOTHERS POST DELIVERY, NEAR FATAL, COMPLICATIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034297	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE FAILURE. COILS IMPLANTED (B)(6) 2010. 100% BLOCKAGE HSG CONFIRMED (B)(6) 2010. CONFIRMED VIABLE PREGNANCY (B)(6) 2011. BABY BOY BORN (B)(6) 2011, DUE DATE WAS (B)(6) 2011. BABY FINE, MOTHER NOT SO LUCKY. I AM FILING A SEPARATE REPORT CONCERNING THE MOTHER'S POST DELIVERY, NEAR FATAL, COMPLICATIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034298	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WE WERE "STEERED" TO ESSSURE PROCEDURE (REQUESTED TUBAL LIGATION) IN (B)(6) 2010. A 100% BLOCKAGE HSG TEST IN (B)(6) 2010. CONFIRMED VIABLE PREGNANCY (B)(6) 2011. DUE DATE (B)(6) 2011. BABY BOY BORN (B)(6) 2011, WATER BROKE EARLY, I BELIEVE FROM BEING PUNCTURED BY ESSURE COIL. EXTRA MONITORING AND TESTING DURING PREGNANCY BECAUSE WE ARE CONSIDERED "OLD" FOR CHILD BEARING. DELIVERY WENT NORMAL. BABY BOY IS FINE. MOTHER HAD POST DELIVERY BLEEDING THAT COULD NOT BE LOCATED. EMERGENCY DNC, AND EMERGENCY "HYSTERECTOMY ATTEMPT" WITHIN 12 HOURS OF DELIVERY. NEAR FATAL BLEEDING FROM ABDOMINAL TEAR. BLOOD TRANSFUSIONS. ICU.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034299	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 11/13/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECENTLY HAD THIS PROCEDURE DONE, AND BEEN HAVING A LOT OF SIDE EFFECTS FROM IT. SUCH AS REALLY BAD HEAD ACHES, SEVER ABDOMINAL PAIN, LEG PAIN, ALL OVER BODY/ JOINT PAIN, MEMORY LOSE AS WELL AS HAIR LOSS. I WOULD NOT RECOMMEND ANY WOMAN TO HAVE THIS PROCEDURE DONE. I WILL BE SEEING MY DOCTOR TO HAVE IT REMOVED AS SOON AS POSSIBLE BEFORE IT CAUSES ANY MORE PAIN AND SUFFERING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034300	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 10/27/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS HAVING PELVIC PAIN, PAINFUL INTERCOURSE, HEADACHES, HIP ANDAMP; JOINT PAIN, LEG PAIN. I ENDED UP WITH A VIT D AND B12 DEFICIENCY, I ALSO FOUND WHEN I HAD THEM REMOVED THAT ONE OF THE COILS HAD BEEN POKING MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034301	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FATIGUE/LOSS OF ENERGY, NO SEX DRIVE, HARD TO LOSE WEIGHT, HAIR THINNING, DEPRESSION, CLOUDINESS, FORGETFULNESS, TROUBLE SLEEPING, HEAVIER PERIODS, INFLAMMATION (FERRATIN), ANXIETY, MOOD SWINGS, INTOLERANCE TO ALCOHOL, NIGHT SWEATS, BREAK OUT WORSE, HIP PAIN, HAND PAIN, STARTED BLEEDING AFTER SEX, EYESIGHT SEEMS TO HAVE GOTTEN WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034302	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVEN'T HAD ANY ISSUES WITH MY HEALTH UNTIL RECENTLY. ABOUT 6 MONTHS AGO ((B)(6) 2013) I STARTED TO DEVELOP A RASH ON MY REAR END. IT THEN SPREAD TO MY BACK ARMS AND FEET. WHEN I HAD MY PHYSICAL IN (B)(6) 2013 MY DOCTOR DIAGNOSED ME AS HAVING DRY SKIN BECAUSE THE WEATHER WAS CHANGING. SHE ADVISED ME TO USE LOTION EVERYDAY AND NOT TAKE HOT SHOWERS, IN WHICH I DID. I CHANGED MY BODY WASH AND LAUNDRY SOAP TO A NON-HYPOALLERGENIC SOAP AND USE LOTION EVERYDAY. IN (B)(6) 2014, MY BACK WAS HURTING. I WENT TO THE DOCTORS BECAUSE I THOUGHT I HAD PULLED MY SCIATIC NERVE AND IT WAS PAINFUL. I STILL HAD THE RASH IT WAS NOW ITCHY AND NOW A METALLIC TASTE IN MY MOUTH. AT THAT APPOINTMENT THE DOCTOR PRESCRIBED ME PREDNISONE AND SOME MUSCLE RELAXERS FROM MY BACK. I HAD A REACTION TO THE PREDNISONE. I EXPERIENCED HEADACHES WHILE TAKING THE PREDNISONE EVERYDAY. WE'LL ONE DAY I WAS WORKING AND I JUST DIDN'T FEEL RIGHT, I HAD A HEADACHE, MY HANDS, TONGUE AND MOUTH FELT NUMB AND LIKE THEY WERE SWELLING UP. I NEED UP GOING BACK TO THE DOCTOR WHO ADVISED ME TO STOP TAKING THE PREDNISONE, THAT I WAS HAVING SOME SORT OF REACH TO IT. IN THE MEANTIME, I WAS WATCHING TV AND SAW A NEWS STORY ABOUT THESE 2 WOMEN WHO HAD THE ESSURE PROCEDURE DONE AND THEY WERE EXPERIENCING SYMPTOMS THAT REFLECTED FROM HAVING THE ESSURE IMPLANTED IN THEIR BODY. THEY GAVE THE NAME TO A FACEBOOK PAGE OF THOUSANDS OF WOMEN SHARING THEIR STORIES AND SYMPTOMS. ONE OF THE SYMPTOMS THAT CAUGHT MY EYE WAS, WOMEN EXPERIENCING AN ITCHY RASH. NEVER BEING ALLERGIC TO ANYTHING IN MY LIFE, AFTER HEARING AND READING THESE WOMEN'S STORIES I REALIZED THIS ITCHY RASH AND OTHER SYMPTOMS COULD BE FROM HAVING THE ESSURE IMPLANTS, IN THE PAST I HAVE EXPERIENCED HEAVY PERIODS, LARGE BLOOD CLOTS DURING MY PERIOD, OCCASIONAL BLEEDING AFTER INTERCOURSE, BACKACHES, DIARRHEA, PAIN

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IN MY GROIN AREA WHEN STANDING AFTER SITTING FOR A LONG TIME, CRAMPING, METALLIC TASTE IN MY MOUTH, TINGLING FEELING IN MY HANDS AND LIPS AND MOST RECENTLY THE ITCHY RASH OVER MY BODY. BACK WHEN I HAD MY PHYSICAL IN (B)(6) 2013, THE DOCTOR ORDERED BLOOD WORK, IN WHICH MY LIVER COUNT WAS ELEVATED ALONG WITH OTHER COUNTS THAT WERE OUT OF WHACK. THROUGH MY ENTIRE LIVE I HAVE ALWAYS BEEN EXCEPTIONALLY HEALTHY EXCEPT FOR BEING OVERWEIGHT. BEING OVERWEIGHT IS THE ONLY ISSUE THAT I HAVE STRUGGLED WITH THROUGHOUT MY LIFE AND NOW ALL OF A SUDDEN MY HEALTH SEEMS TO BE DETERIORATED. IN (B)(6) 2014 I HAVE SCHEDULED A GYNECOLOGIST APPOINTMENT WHERE I AM GOING TO INQUIRE WITH MY DOCTOR ABOUT THESES SYMPTOMS I AM TOO EXPERIENCING AND FEEL IN MY GUT IT'S FROM THE ESSURE IMPLANTS I HAD A FEW YEARS AGO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034303	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 3/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN, HEADACHE, MISCARRIAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034304	BAYER	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 8/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IT STARTED OUT AT A HORRIBLE STABBING PAIN IN MY SIDE SHORTLY AFTER IMPLANTATION, THEN I WAS TESTED FOR SEVERAL AUTOIMMUNE DISEASES BUT THE ONLY THING THEY COULD FIGURE WAS FIBROMYALGIA AND TENDONITIS FOR MY JOINT PAIN. OVER THE YEARS, IT HAS GROWN CONSISTENTLY WORSE AND NOW I'M TO THE POINT I CAN'T EVEN STAND UP STRAIGHT BECAUSE OF THE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034305	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 1/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A BILATERAL SALPINGECTOMY TO REMOVE ESSURE AND HOPEFULLY ABATE ONGOING SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034306	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 11/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WENT TO THE ER WITH LOWER RIGHT QUADRANT PAIN. I THOUGHT IT WAS MY APPENDIX. UPON DOING A CT SCAN THEY DETERMINED MY APPENDIX WAS OK. THEY DIAGNOSED ME WITH PELVIC CONGESTION AND SAID I NEED TO FOLLOW UP WITH MY GYNECOLOGIST. I HAD AN ULTRASOUND DONE THROUGH MY GYNO AND THEY DETERMINED I HAVE FLUID AND CYSTS IN MY FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034307	BAYER	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 2/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE SUFFERED EVERY MONTH WITH HEAVY BLEEDING/PERIODS THAT WOULD LAST 7-10 DAYS WITH SOME MENSTRUAL CYCLES COMING TWICE A MONTH, PASSING A NUMBER OF BLOOD CLOTS, SEVERE CRAMPING THAT AT TIMES I HAVE HAD TO GO TO THE ER, SEVER PELVIC PAIN, BACK PAIN AND EVEN HEADACHES ALONG WITH SOME CRAMPING IN MY LEGS. LET'S NOT FORGET TO MENTION THE UNEXPLAINED RASHES AT TIMES. I'VE HAD MY SURGERY (B)(6) 2013 AND HAD MY FALLOPIAN TUBES REMOVED WITH THE COILS, NOVASURE ABLATION WITH A D AND C DONE. SINCE SURGERY I HAVE BEEN TO DOCTOR TWICE, THE ER ONCE, AND NOW THE ENDING STATUS IS, MY FEMALE INSIDES ARE GONE DUE TO ESSURE AND NOW IT'S TIME FOR FULL HYSTERECTOMY HERE IN (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034308	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 10/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BEEN EXTREMELY EXHAUSTED. I HAVE BEEN BLEEDING THE ENTIRE TIME THAT I HAVE HAD IT. I STARTED PRODUCING MILK. I HAVE BEEN VERY MOODY. MY NECK STARTED HURTING A COUPLE WEEKS AGO. I KEEP HAVING HORRIBLE HEADACHES. MY STOMACH KEEPS SWELLING. I KEEP GETTING NAUSEOUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034309	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 1/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WOKE UP IN THE MIDDLE OF THE NIGHT WITH A SEVERE BACK PAIN. COULDN'T EVEN SLEEP TRIED TAKING ADVIL DID NOT HELP. I'VE ALSO BEEN HAVING TERRIBLE STOMACH ACHES AND PAINS, BAD RASHES AND PIMPLES ALL OVER MY CHEST AND BACK AREA. I WENT TO THE DR AND THEY TOLD ME I HAVE A VAGINAL BACTERIAL INFECTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034310	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN AND BLEEDING. I JUST THOUGHT I WAS GETTING HEAVIER PERIODS BECAUSE I WAS MARRIED IN ()B)(6) OF 2012 AND MY BODY WAS RE-ADJUSTING TO HAVING SEX AGAIN. I WENT TO MY OBGYN FOR BLOOD WORK AND WAS TOLD I HAD LOW PROGESTERONE BUT EVERYTHING ELSE WAS FINE. THE PAIN CONTINUED ON AND BECAME WORSE SUDDENLY IN (B)(6) OF 2013. ON (B)(6), 2013, I WENT TO (B)(6) FOR AN HSG. MY RIGHT COIL HAS MIGRATED OUT OF THE FALLOPIAN TUBE AND IT EXTENDS THROUGH THE CORNUA THROUGH THE FUNDUS OF MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034311	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MILD CRAMPING DURING THE PROCEDURE WHICH CONTINUED FOR SEVERAL DAYS AFTER. I STARTED SPOTTING SOON AFTER THE PROCEDURE AS WELL. THE SPOTTING TURNED INTO A HEAVY FLOW WITHIN A WEEK OR SO AND CONTINUED FOR 4 MONTHS. I BLED FOR 4 MONTHS STRAIGHT! IT VARIED FROM LIGHT FLOW TO CLOTS SO LARGE THAT I CALLED MY IMPLANTING DOCTOR'S OFFICE SEVERAL TIMES TO MAKE SURE I WAS OK. AFTER THE 2ND OR 3RD CALL, THEY HAD ME COME IN AND I WAS TOLD THIS WAS NORMAL, ALTHOUGH IT WAS NOT DISCUSSED PRIOR TO THE PROCEDURE THAT THIS MAY OCCUR. I EVENTUALLY STOPPED BLEEDING DAILY, BUT THEN WAS ON A CYCLE OF HAVING A PERIOD EVERY 24 DAYS AND MY HEAVY DAYS WERE SO HEAVY THAT I SOAKED SUPER PLUS TAMPONS IN UNDER 2 HOURS FOR 2-3 DAYS AT A TIME. I STARTED CRAMPING SEVERELY AS WELL. I NEVER SUFFERED FROM MENSTRUAL CRAMPS BEFORE HAVING ESSURE PLACED, OCCASIONALLY OVULATION CRAMPS WHICH WERE VERY MILD. THE CRAMPING I EXPERIENCED FROM ESSURE WAS SO DEBILITATING, I COULD HARDLY FUNCTION. I FELT LIKE I WAS IN LABOR. I ALSO GAINED AN EXCESSIVE AMOUNT OF WEIGHT. IN ALL, I PUT ON NEARLY 60 POUNDS, EVEN THOUGH MY DIET HAD NOT CHANGED AND I STARTED WORKING OUT DUE TO THE WEIGHT GAIN TO NO AVAIL. I EVENTUALLY STARTED HAVING CONSTANT BACTERIAL INFECTIONS (BACTERIAL VAGINOSIS). I WAS FATIGUED SO SEVERELY THAT I COULD FALL ASLEEP SITTING UP. I ALSO EXPERIENCED BACK PAIN, EXCESSIVE SWEATING, BRAIN FOG, FLOATERS IN MY EYES, ITCHY LEGS, DEVELOPED UTERINE FIBROIDS, NICKEL SENSITIVITY, URGENCY TO URINATE, LEG PARASTHESIA, DENTAL ISSUES, CHRONIC PELVIC PAIN, MOOD CHANGES, PAINFUL INTERCOURSE, HOT FLASHES, DRY SKIN, HIP PAINS, AND ABDOMINAL PAIN AND SOMETIMES FLUTTERING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034312	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 6/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS IMPLANTED IN (B)(6) 2009 WITHOUT INCIDENT. SEVERAL MONTHS AFTER THAT I BEGAN EXPERIENCING SEVERE DEPRESSION AND PERIODS OF EXTREME IRRITABILITY, CRYING FOR NO APPARENT REASON, SUICIDAL THOUGHTS AND HORRIBLY PAINFUL AND UNUSUAL PERIODS. I'D NEVER IN MY LIFE EXPERIENCED ANY OF THESE BEFORE SO I SCHEDULED AN APPOINTMENT WITH MY DR WHO DIAGNOSED IT AS PMDD AND PRESCRIBED A MEDICATION FOR DEPRESSION. THE SYMPTOMS HAVE CONTINUED SINCE BUT KNOWING THERE WAS A REASON, I JUST LEARNED TO LIVE WITH IT. OVER THE LAST FEW YEARS I HAVE BEGUN TO EXPERIENCE CHRONIC LOWER BACK AND HIP PAIN, ABDOMINAL BLOATING, FREQUENT YEAST INFECTIONS, INSOMNIA, DECREASED CIRCULATION IN MY LEGS AND FEET, TINGLING IN MY ARMS AND HANDS, ANXIETY, HIGH BLOOD PRESSURE AND SEVERAL OTHER AILMENTS I NEVER ATTRIBUTED TO A COMMON CAUSE. IN (B)(6) 2013 I DEVELOPED A SUDDEN EXTREMELY SEVERE HEADACHE THAT HAS NOW BEEN PRESENT AND UNCONTROLLED FOR 143 DAYS ACCOMPANIED BY MEMORY LOSS, FOGGINESS AND A DECREASED LEVEL OF FUNCTION. I HAVE BEEN HOSPITALIZED, UNDER THE CARE OF A NEUROLOGIST AND TO DATE A CAUSE HAS NOT BEEN DETERMINED. AN MRI SHOWS ISCHEMIC CHANGES TO THE LEFT FRONTAL LOBE OF MY BRAIN AND MY NEUROLOGIST BELIEVES THAT HAS BEEN CAUSED BY THE SEVERITY OF THE HEADACHE AND COULD BE PERMANENT. SHE SAYS I'M ALSO AT RISK OF HAVING A STROKE EVERY DAY I CONTINUE TO HAVE THIS HEADACHE AT THIS PAIN LEVEL OF 10 OUT OF 10 AND SHE CAN'T FIND ANY AMOUNT OF MEDICATION THAT WILL STOP IT ALTHOUGH SHE'S TRYING HER HARDEST. NOW HAVING FINALLY HAD A CHANCE TO REVIEW ALL OF THE FINE PRINT ASSOCIATED WITH ESSURE, I BELIEVE EVERY ONE OF THESE SYMPTOMS CAN BE ATTRIBUTED TO THIS DEVICE AS I EXPERIENCED NONE OF THESE ISSUES IN THE 33 YEARS PRIOR TO BEING IMPLANTED AND THEY JUST CONTINUE TO RAPIDLY GET WORSE WITHOUT ANY RELIEF OR MEDICAL EXPLANATION.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034313	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 10/16/2013 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IRREGULAR MENSES...ELEVATED TEMPS....NAUSEA.... ABDOMINAL PAIN NOT WNL....BLOOD CLOTS...HEADACHES MORE FREQUENT... TINGLING TO BILATERAL LEGS AND LEFT ARM... URINARY DISCOMFORT... CONSTIPATION NOT WNL

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034314	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 4/24/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE DEVICE PLACED I BEGAN SUFFERING FROM PAIN IN MY ABDOMINAL AND PELVIC AREA. THIS PAIN BECAME MUCH MORE PROMINENT NEAR THE BEGINNING OF MY MENSTRUAL CYCLE. MY MENSTRUAL CYCLE BECAME HEAVIER, I SUFFERED PMS SYMPTOMS I HAD PREVIOUSLY NOT HAD AND IT INCREASED IN LENGTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034315	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 3/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CHRONIC LOWER BACK PAIN, SEVERE CRAMPING IN LOWER ABDOMINAL AREA ON OR OFF MENSTRUAL CYCLE, HEADACHES, VERTIGO, MEMORY PROBLEMS. NEVER HAD ANY OF THESE PROBLEMS PRIOR TO ESSURE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034316	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) OF 2010, FOR THE REASON OF BEING SATISFIED WITH MY FAMILY AND NOT WANTING TO ADD ANYMORE. IN (B)(6) OF 2013 I STARTED GETTING DAILY MIGRAINES, SEVERE BLOATING WITH PERIODS TO THE POINT OF NOT FITTING INTO MY JEANS, AND LEFT LOWER PELVIC PAIN. WHEN I PRESENTED MY DOCTOR WITH THESE EFFECTS I WAS TOLD ESSURE WAS NOT RELATED. I AM CURRENTLY STILL BATTLING THESE EFFECTS AND THE MIGRAINES ARE WORSE. ESSURE PAIN IS NOT TOLERABLE AND EFFECTS MY DAILY LIFE. I CAN'T HAVE SEX WITHOUT PAIN AND BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034317	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 5/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME PELVIC PAIN, BLOATING, FATIGUE, HEAVY PERIODS, PASSING LARGE BLOOD CLOTS, DEPRESSION, ANXIETY, WEIGHT GAIN, PAINFUL INTERCOURSE, BODY ACHES, ABDOMINAL INFLAMMATION, ULCERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034318	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 7/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN VAGINA WHEN HAVING SEX, SCRATCHING FEELING, BLEEDING, HEADACHES EVERYDAY, WEAK AT TIMES TO THE POINT I CANT GET OUT OF BED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034319	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 1/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FIRST OF ALL, NO ONE TOLD ME THIS HAD NICKEL IN IT AND I AM ALLERGIC TO NICKEL! FROM THE SECOND ESSURE WAS INSERTED INTO MY TUBES, I HAD HORRIBLE CRAMPING, THAT HAS NOW TURNED INTO HORRIBLE PELVIC PAIN THAT HAS ONLY GOTTEN WORSE WITH EACH PASSING DAY. I JUST RECENTLY ((B)(6)) HAD A THREE WEEK PERIOD, I'M ALWAYS TIRED AS I ALWAYS FEEL SICK. I WAS A VERY ACTIVE WOMAN WHEN I HAD THESE PLACED, THEY HAVE TAKEN MY LIFE AWAY. I'VE BEEN ON NUMEROUS DEPRESSION MEDS, NONE OF WHICH HAS HELPED OVER THE LAST FEW MONTHS. I'M HAVING SEVERE PAIN, THAT NORCO IS NOT RELIEVING AND I WAS JUST TOLD, IF I WANT THE PAIN TO GO AWAY, I HAVE TO HAVE A HYSTERECTOMY- SERIOUSLY?!!! THIS LAST YEAR HAS BEEN THE WORSE YEAR OF MY LIFE! THERE IS SOMETHING WRONG WITH THIS PRODUCT!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034320	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 12/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ULTRASOUND FOR CONSTANT ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034321	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 8/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IN (B)(4). RIGHT AFTER SURGERY I PASSED OUT COMING OUT OF ANESTHESIA...I'VE HAD SEVERAL SURGERIES IN THE PAST HAVE NEVER HAD THAT ISSUE BEFORE (SURGERIES INCLUDE PAIN IN MY COLLAR BONE, LAP BAND, WISDOM TEETH). I DIDN'T THINK ANYTHING OF IT PROBABLY UNTIL ALL THESE OTHER FACTORS CAME INTO PLACE I WOULD NOT HAVE EITHER. NEVERTHELESS, I BLED FOR ABOUT THE FIRST 3 MONTHS STRAIGHT. I WAS TOLD IT SHOULD LAST A COUPLE OF WEEKS BUT THAT DIDN'T HAPPEN. I FINALLY STOPPED BLEEDING. SHORTLY AFTER I STARTED HAVING NIGHT SWEATS WHICH I THOUGHT WAS COMPLETELY ODD BECAUSE I ALWAYS HAVE A BLANKET NO MATTER WHAT DEGREE IT IS OUTSIDE, I LIVE IN (B)(6) WHERE IT'S HOTTER THAN HOT. I DIDN'T REALLY DO ANYTHING ABOUT IT JUST THOUGHT IT WAS A FLUKE. I'M GOING TO BE TURNING (B)(6) THIS YEAR JUST THOUGHT IT WAS THAT. I HAVE NEVER HAD HEALTH PROBLEMS IN MY LIFE BESIDES BEING OVERWEIGHT WHICH I HAD LAP BAND SURGERY OVER 9 YEARS AGO AND HAVE KEPT OFF OVER 100 POUNDS SO I HAVE ALWAYS BEEN REALLY HEALTHY. I THEN STARTED HAVING SHARP PAINS IN MY VAGINA FOR NO REASON. I WOULD TELL MY HUSBAND BUT AGAIN, DIDN'T THINK ANYTHING OF IT. I STARTED HAVING ISSUES WITH INTERCOURSE AS IT HURTS FOR ME TO BE IN THE ACT OF. EXTREMELY PAINFUL. I'VE BEEN WITH MY HUSBAND FOR 10 YEARS AND THIS BY FAR HAS NEVER BEEN A PROBLEM. I THEN REALIZED MY CHEST WAS BREAKING OUT WITH PIMPLES EVERYWHERE. MY HUSBAND WOULD INSPECT MY BODY. I FINALLY DECIDED ONE DAY TO GOOGLE THESE SIDE AFFECTS AS THEY DON'T MAKE SINCE. WHILE I WAS GOOGLING I HAD TERRIBLE STOMACH PAINS WHICH CONTINUED FOR DAYS AND FINALLY WENT AWAY. I FINALLY FOUND A FACEBOOK WEBSITE CALLED ESSURE PROBLEMS. NEVER DID I THINK THIS COULD BE THE PROBLEM; HOWEVER, IT'S THE ONLY ANSWER. SINCE THEN I HAVE HAD SEVERE STOMACH

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PAINS, BACTERIAL VAGINOSIS (NOT SURE ON SPELLING) BV, EXTREME BACK PAIN, HEADACHES AND ALL DAY EVERY DAY I EXPERIENCE THESE ISSUES. I WISH I WOULD HAVE NEVER HAD THESE PLACED IN ME ESPECIALLY SINCE I NEVER HAD HEALTH PROBLEMS UNTIL NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034322	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 5/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD PAIN IN MY LOWER BACK, RIGHT SIDE WHERE IMPLANT IS, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034323	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 8/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREMELY HEAVY MENSTRUAL CYCLE, SHARP STABBING PAINS IN MY LOWER ABDOMEN. DAILY HEADACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034324	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 1/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PAINS CONTINUE ON LEFT SIDE, ALWAYS HAVE HEADACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034325	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 7/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I IMMEDIATELY HAD PAIN WITH THE INSERTION OF THE ESSURE COILS. I BEGAN TO HAVE TERRIBLE ABDOMINAL PAINS AND EXPERIENCED VOMITING. BETWEEN 2010 AND 2013 I WAS DIAGNOSED WITH ARTHRITIS, PRURITUS, SWOLLEN LYMPH NODES, MIGRAINES, AND PCOS. I WAS TESTED FOR LUPUS, MY HAIR BEGAN TO FALL OUT, I DEVELOPED BRUISES FOR AN UNKNOWN REASONS, I WAS PUT ON MEDICATION FOR MY DEBILITATING MIGRAINES, A PITUITARY TUMOR WAS FOUND IN 2012, AND I LIVED WITH DAILY SHARP STABBING PAINS IN MY ABDOMEN AND LOWER BACK. IN 2013, I WAS SENT FOR AN ULTRASOUND OF MY ABDOMEN AND IT WAS FOUND THAT BOTH COILS HAD MIGRATED DOWN MY TUNES AND PERFORATED MY TUBES. IT WAS ALSO FOUND THAT I WAS SUFFERING FROM AN ALLERGIC REACTION TO THE NICKEL. MY LYMPH NODES WERE SWOLLEN DUE TO MY BODY REJECTING THE HORRIBLE FOREIGN OBJECT IN MY BODY. MY LIFE AND HEALTH WAS COMPLETELY DETERIORATING. I HAD SURGERY TO REMOVE THE MIGRATED COILS ON (B)(6) 2014. THE LEFT COIL WAS FOUND TO HAVE NOT "RELEASED" IN MY TUBE THE WAY IT SHOULD HAVE. IT WAS VERY TINY AND NOT A LONG COIL LIKE IN MY RIGHT TUBE. THERE WERE NO COILS SHOWING WHERE MY TUBE AND UTERUS MEET LIKE STATED IN MY MEDICAL REPORT FROM THE DR. WHO PLACED THEM. THIS DEVICE SHOULD NOT BE ALLOWED IN ANYMORE WOMEN. IT IS DANGEROUS. BY (B)(6) 2014 BY JOINT PAIN WAS GONE, THE MAJORITY OF MY LYMPH NODES ARE NOT SWOLLEN ANYMORE AND MY ABDOMINAL AND BACK PAIN IS GONE. THAT IS PROOF RIGHT THERE THAT THE ESSURE COILS ARE POISONOUS TO A PERSON'S BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034326	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 9/22/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2008. SHORTLY AFTER THE PROCEDURE I BECAME NAUSEATED AND HAD A SEVERE HEADACHE. WITHIN WEEKS I HAD STRANGE RASHES ON MY ARMS AND OCCASIONALLY HAD A METALLIC TASTE IN MY MOUTH. I HAD ALWAYS HAD NORMAL CYCLES UNTIL THE PROCEDURE. I BEGAN TO EXPERIENCE LONGER PERIODS THAT WERE MUCH HEAVIER WITH HUGE CLOTS. AFTER I STOPPED BREAST FEEDING MY SON, MY RIGHT BREAST CONTINUED TO PRODUCE SMALL AMOUNTS OF MILK THAT WOULD NOT GO AWAY. MY PHYSICIAN TOLD ME MY ISSUES WERE NOT ESSURE RELATED AND RECOMMENDED BIRTH CONTROL. I GOT ESSURE SO I DIDN'T HAVE TO TAKE HORMONES, BUT STILL I TRIED IT AND IT DIDN'T HELP. I CONTINUED TO HAVE NAUSEA TO THE POINT THAT I WOULD VOMIT. I WENT TO MY INTERNAL MEDICINE DOCTOR WHO COULD NOT FIND ANYTHING ABNORMAL IN MY BLOOD WORK AND EVENTUALLY INSISTED IT WAS BECAUSE I WAS OVERWEIGHT AND/OR PSYCHOLOGICAL. I SOUGHT HELP FROM AN ACUPUNCTURIST IN 2011 WHO ON MORE THAN ONE OCCASION HAD TO GIVE ME HERBAL REMEDIES TO STOP THE BLEEDING. I RECEIVED SOME RELIEF FROM THE PAIN WITH ACUPUNCTURE, BUT NONE OF MY SIDE EFFECTS EVER WENT AWAY. AS THE YEARS PASSED, I ADDED NEW SYMPTOMS LIKE THE INABILITY TO LOSE WEIGHT WITH PROPER DIET AND EXERCISE (WITH A NUTRITIONIST), JOINT SWELLING, PAINFUL INTERCOURSE, BLEEDING WITH INTERCOURSE, SEVERE AND CONSTANT PELVIC PAIN, CONSTIPATION, BLOATING, AND BLEEDING BETWEEN PERIODS. IN (B)(6) 2012 I HAD EXPLORATORY LAPAROSCOPIC SURGERY TO SEE WHAT WAS CAUSING THE PAIN. THE DOCTOR WAS CERTAIN IT WAS ENDOMETRIOSIS. THE SURGERY FOUND NO ENDOMETRIOSIS, JUST A SPONGY UTERUS WHICH WAS EXPECTED TO BE ADENOMYOSIS. BECAUSE I WAS IN MY EARLY (B)(6) I DIDN'T WANT TO HAVE A HYSTERECTOMY SO I TRIED BIRTH CONTROL. I WAS UNABLE TO CONTINUE THE BIRTH CONTROL DUE TO EXTREME HEADACHE WITH VISUAL DISTURBANCES. IN (B)(6) 2013 I SOUGHT A SECOND OPINION BECAUSE THE

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PAIN WAS UNBEARABLE. A PELVIC ULTRASOUND AND PELVIC MRI CONFIRMED THE COILS WERE IN PLACE PROPERLY AND THAT ADENOMYOSIS AND POLYPS WERE MY ISSUE. I AGREED TO HAVE A HYSTERECTOMY. I HAD MY HYSTERECTOMY ON (B)(6) 2013. MOST OF MY SYMPTOMS WENT AWAY WITHIN DAYS. THE PATHOLOGY REPORT CONFIRMED ONE OF MY COILS WAS IMBEDDED IN THE UTERINE WALL. I WAS TOLD THIS IS COMMON WHEN INSERTING ESSURE IN WOMEN WITH A RETROVERTED UTERUS BUT I AM NOT SURE. THE WHOLE EXPERIENCE HAS BEEN A NIGHTMARE. I WOULD STRONGLY SUGGEST THAT IF THIS PRODUCT IS KEPT ON THE MARKET, WOMEN ARE PROPERLY INFORMED OF ALL THE SIDE EFFECTS SO THEY CAN MAKE AN EDUCATED DECISION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034327	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 4/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN (B)(6) 2013 AND ABOUT A MONTH LATER I STARTED HAVE PAIN IN MY JOINTS AND REGULAR CRAMPING. I THOUGHT THE CRAMPING WAS DUE TO THE TUBES BUILDING SCAR TISSUE. AFTER A COUPLE MONTHS OF THE JOINT PAIN I FINALLY WENT TO THE DR'S THE DR COULDN'T UNDERSTAND WHY I WAS HAVING JOINT PAIN ALL OF A SUDDEN AFTER BEING HEALTHY SO AT FIRST SHE THOUGHT I HAD TENDINITIS BUT AS THE PAIN GOT WORST AND TRAVELED FROM MY HANDS TO MY LEGS I WENT BACK TO THE DR'S SHE THEN DID BLOOD WORK FOR RHEUMATOID ARTHRITIS AND X RAYS THE BLOOD WORK CAME BACK POSITIVE BUT X RAYS DIDN'T SHOW ANY SIGN OF ARTHRITIS, BUT TO BE SAFE THEY HAD ME SEE A RHEUMATOLOGIST NOW THEY HAVE PUT ME ON 3 DIFFERENT MEDICATIONS AND NOTHING IS GETTING IN FACT I'M GETTING WORST. SO MY RHEUMATOLOGIST HAS SUGGESTED TO GET A NICKEL ALLERGY TEST DONE SINCE ALL THESE SYMPTOMS STARTED AFTER THE ESSURE WAS PUT IN. I AM GOING IN TODAY FOR THE TEST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034328	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER A YEAR OF HAVING ESSURE IMPLANTED IN MY TUBES, I STARTED LOSING PATCHES OF HAIR ON MY HEAD. I WENT TO THE DOCTOR AND WAS TESTED POSITIVE FOR LUPUS. A FEW MONTHS LATER AS PAIN STARTED TO SET IN MY ENTIRE BODY I WAS ALSO DIAGNOSED WITH FIBROMYALGIA. I HAVE BEEN FIGHTING RANDOM RASHES, BLOATING, HAIR LOSS, PAIN IN MY ENTIRE BODY, BRAIN FOG, INSOMNIA, AND MANY MORE SYMPTOMS. IT IS ALL SAID TO BE BECAUSE I DEVELOPED AN ALLERGY TO THE NICKEL WHICH CAUSES AUTOIMMUNE PROBLEMS TO BEGIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034329	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 1/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IRREGULAR PERIODS. SEVERE CRAMPING. BLOOD CLOTS. BLEEDING AFTER INTERCOURSE. SPOTTING BETWEEN PERIODS. CRAMPING/PAIN DURING INTERCOURSE. PAIN/CRAMPING WHILE EXERCISING. METALLIC TASTE MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034330	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 8/28/2013 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD 104 DEGREE TEMPERATURE, WAS DIZZY, HAD MIGRAINES, BACK PAIN, COULD NOT WALK WITHOUT COLLAPSING,AND WAS THROWING UP ALL DAY. MIGRAINES, DIZZINESS, FATIGUE, BACK PAIN, NAUSEA, DENTAL TOOTH PAIN AND GUM INFECTIONS, BRUISING ALL OVER BODY, RED BOIL LIKE MARKS ALL OVER BODY, CONTINUOUS ACNE ALL OVER BODY, ABDOMINAL PAIN, BRAIN FOG, FORGETFULNESS, EMOTIONAL ISSUES- UNCONTROLLABLY CRYING, ANGER ECT...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034331	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 4/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT ESSURE DONE IN 2010, 6 MONTHS AFTER STARTED HAVING PAIN AND NOW 4 YEARS LATER STILL IN PAIN AND TRYING TO GET IT REMOVED! HAVE SO MANY PROBLEMS NOW, SHOOTING PAIN ON BOTH SIDES, MEMORY LOSS REALLY BAD, ALLERGIC TO NICKEL AND DOCTOR NEVER ASKED ME IF I WAS ALLERGIC! BURNING SENSATIONS IN STOMACH, HEAVY HEAVY MENSTRUAL CYCLES, HAIR LOSS, TEETH HURTING, VERY FORGETFUL ...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034343	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE GETTING ESSURE COILS IMPLANTED I HAVE BEEN SUFFERING FROM SHARP/SHOOTING ABDOMINAL AREA PAINS, MIGRAINES, CONFUSION, FORGETFULNESS, MEMORY PROBLEMS, HAIR LOSS, WEIGHT GAIN, VAGINAL AND ANAL ITCHING, IRREGULAR PERIODS, NAUSEA, VOMITING, DIARRHEA, JOINT PAIN, MUSCLE PAIN, FOOT PAIN, SHINGLES, HIVES, DERMATITIS, STAPH INFECTIONS, FOLLICULITIS, EXTREME EXHAUSTION, FATIGUE, SLEEPING PROBLEMS, DEPRESSION, ANXIETY, BLOOD SUGAR ISSUES, LACK OF APPETITE, LACK OF ABILITY TO TASTE, DEVELOPED NEW AUTOIMMUNE TYPE ALLERGIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034349	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BEGAN HAVING PELVIC PAIN REOCCURRING TRACT INFECTIONS YEAST INFECTIONS I AM ALLERGIC TO NICKLE I GOT REALLY BAD ACNE STARTED LOSING HAIR I HAVE NO ENERGY SLEEPLESS NIGHTS AND I NOW HAVE TO GET A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034350	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 11/4/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE GETTING THE ESSURE I HAVE BEEN IN PAIN. I EXPERIENCE THE PAIN OFTEN IN MY ABDOMEN, LEGS, HEAVY PERIODS LASTING FOR MORE 5 DAYS, VERY BAD HEADACHES, LOTS OF UNBEARABLE PELVIC PAIN, AND SHARP PAINS IN MY GROIN AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034353	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 12/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NAUSEA, PAIN, MIGRAINE, VERTIGO, RIGHT PAIN LEG, MENSTRUATION WITH BLOOD CLOTTED, BACKACHE AND MORE...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034355	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 5/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN ON MY PERIOD SINCE THEY'VE BEEN PLACED. CRAMPING, CLOTTING, BROWN BLOOD, HEADACHES, CONSTANTLY TIRED, WEIGHT GAIN SO FAR 15 LBS, NAUSEA, DEPRESSION, AND I'M SURE I'VE GOT MORE THAT HAVEN'T BEEN DISCOVERED

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034356	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 3/3/2009 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LOWER BACK PAIN THAT IS IN MY B***, CONTINUOUSLY DOWN MY LEG GOES NUMB, BURNING, STABBING, UNABLE TO POOP, PAINFUL SEX. DOESN'T HAVE ENERGY. HAIR FALLING OUT. RASHES ON MY FINGERS WITH MY RINGS IS THAT IN CONSTANT ABDOMINAL PAIN ESPECIALLY ON THE RIGHT SIDE NOW ON THE LEFT SIDE BUT MORE THE RIGHT SIDE AND EVER SINCE I GOT THESE THINGS AND I'VE NEVER HAD BACK PROBLEMS. I SLEEP SOMETIMES NOT AT ALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034357	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 2/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABDOMINAL PAIN VOMITING -MISTY MESENTERY - (B)(6) 2012- ER ABDOMINAL PAIN, (B)(6) 2012-ER FLANK PAIN, (B)(6) 2012-GALLBLADDER SURGERY, (B)(6) 2013 FLANK PAIN, (B)(6) 2013-BACK FLANK PAIN, (B)(6) 2013 CHRONIC GASTRIS, MULTIPLE TRIPS TO PCP- CHRONIC DIARRHEA, HEAVING BLEEDING, SPOTTING, SERVER FATIGUE, PAIN-JOINT MUSCLE, CRAMPING, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034358	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 5/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, BACK PAIN, ABD PAIN, HEADACHES, IRREGULAR BLEEDING. I WAS WORKING FULL TIME AND GOING TO SCHOOL AND THOUGHT IT WAS STRESS. DIARRHEA 3 DAYS WENT TO DR. CT SCAN SHOWED OVARIAN CYST. MEDICATION SHRUNK CYST. SYMPTOMS PERSIST, D AND C, SYMPTOMS PERSIST. SYMPTOMS WORSENING AS TIME GOES ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034359	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

INFLAMMATORY RESPONSE, JOINT PAIN MAINLY IN HIPS AND KNEES. HIVES IN (B)(6) 2013. WIDESPREAD, DAILY. PELVIC INFLAMMATION IN (B)(6) 2013 WITH BLADDER INVOLVEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034360	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 7/28/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CRAMPING, BLOATING, NAUSEA, DIARRHEA, DIZZINESS, FAINTING, HEAVY BLEEDING DURING PERIODS, PAIN DURING AND AFTER INTERCOURSE, CONSTANT PAIN EVERYWHERE, JOINT PAIN, BACK PAIN, BLOOD CLOTS, LOWER ABDOMINAL PAIN CONSTANT, ESPECIALLY ON RIGHT SIDE, I'M ALWAYS IN PAIN, DEPRESSION, ANXIETY, NO ENERGY AT ALL, MUSCLE WEAKNESS, SHAKINESS. MY KIDS ARE EFFECTED BY THIS AND SO IS MY FIANCE. MY SEX LIFE IS NO FUN AT ALL IT HURTS TOO BAD. IT'S HORRIBLE, NO WOMAN SHOULD HAVE TO SUFFER THIS MUCH FROM SOMETHING THAT'S PUT IN OUR BODY. I WANT MINE REMOVED AS SOON AS POSSIBLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034361	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THIS METHOD OF BIRTHCONTROL, ON THIS DAY AFTER MY PROCEDURE, I WAS BLEEDING VERY BAD ON (B)(6) WHEN I CHANGED DR. HE DID A D AND C AND TOLD ME THAT SHOULD STOP THE BLEEDING. WELL IT DID NOT STOP, THEN IN (B)(6) I WENT INTO ANOTHER PROCEDURE ABLATION AND FINALLY THE BLEEDING WAS GONE TOTALLY BUT NOW EVERYTIME I HAVE SEX MY HUSBAND GETS THIS CUTS ALL AROUND HIS PENIS AND VERY ITCHY AND I GET VERY ITCHY ON MY VAGINA. IT IS LIKE MY (SECREATION) BURN HIM AND I FEEL VERY BAD FOR MEN TO GO THROUGH THIS AFTER ALL THAT WE WENT THROUGH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034362	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I NOTICED THAT MY STOMACH AND PELVIC AREA WAS VERY ITCHY. ALSO I HAVE MIGRAINE BRAIN FOG,NUMBNESS AND TINGLING IN ARMS AND HANDS. I JUST RECENTLY NOTICED A METAL TASTE IN MOUTH IT SEEMS EACH MONTH I'M GETTING WORSE AND NO MATTER WHAT I DO NOTHING IS GETTING BETTER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034363	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 8/16/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED TO EXPERIENCE HEAVY PERIODS AND EVENTUALLY BEGAN HAVING SHARP, STABBING PAIN ON MY LOWER LEFT ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034364	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 9/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) OF 2010 ALMOST A MONTH AFTER I STARTED TO HAVE EXCESSIVE BLEEDING, LARGE CLOTS, AND SEVERE PELVIC PAIN. THE PELVIC PAIN WOULD BE SO SEVERE THAT I COULDN'T NOT FUNCTION ON A DAY TO DAY BASIS ON THE LEFT SIDE OF MY ABDOMEN! FOLLOWING THAT I STARTED TO HAVE SEVERE DEBILITATING FATIGUE THAT WOULD REQUIRE ME TO SLEEP FOR 12+ HOURS AT A TIME AND STILL NOT FEEL LIKE I HAD ANY ENERGY. I HAD DAILY MIGRAINES THAT NO MEDICATION WOULD TOUCH. I STARTED HAVING DAILY CONSTIPATION SO SEVERE THAT NOTHING WOULD MAKE ME GO TO THE BATHROOM OTHER THAN A ENEMA- I BEGAN TO EXPERIENCE LOSS OF APPETITE AND SEVERE NAUSEA AND VOMITING WHICH I HAD TO BE PUT ON MEDICATION TO STOP THROWING UP ! MY STOMACH BECAME SO BLOATED THAT I LOOKED LIKE I WAS 6-7 MONTHS PREGNANT BUT I HADN'T GAINED ANY WEIGHT! PRIOR TO ESSURE I WAS 100% HEALTHY AND HAD NO ISSUES OUTSIDE OF PREGNANCY. MY DOCTOR SAW THAT I HAD BEEN THROUGH ENOUGH WITH MY PAIN AND SYMPTOMS SO I HAD A TOTAL HYSTERECTOMY AND REMOVAL OF TUBES AND ESSURE AND SINCE THEN ALL MY SYMPTOMS HAVE DISAPPEARED THAT I HAD AFTER I GOT ESSURE!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034365	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 7/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING PAIN IN MY RIGHT BACK/HIP AREA WITH BURNING IN MY PELVIC AREA. I THOUGHT I HAD HURT MY BACK. AT TIMES IT WAS SO BAD I COULDN'T WALK. MY NEIGHBOR HAS HAD TO COME AND GET ME OFF OF THE FLOOR. MY MUSCLES THEN STARTED TO SPASM SOMETHING TERRIBLE. I WENT TO MY PCP AND HE PUT ME IN ANTI-INFLAMMATORY AND STEROIDS. I WAS FINE AS LONG AS I WAS ON THE MEDICATION BUT AS SOON AS IT WAS OUT OF MY SYSTEM IT WAS BACK. I STARTED TO GAIN WEIGHT LIKE CRAZY. TO BE HONEST I FELT PREGNANT AND STILL DO. MY BACK PAIN IS STILL HORRIBLE. THE ONLY THING I HAD DONE DIFFERENT IN MY LIFE WAS HAVE THE ESSURE DEVICE IMPLANTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034366	CONCEPTUS	2/12/2014	2/12/2014

Event Information:

Event Date (B3): 3/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER PLACEMENT OF DEVICE, SEVERE PAIN IN LOWER ABDOMEN, SHARP STABBING PAINS DURING SEX, SWELLING OF MY STOMACH MIMICKING 6 MONTHS PREGNANT. NIGHT SWEATS. FATIGUE. ULTIMATE RESULTING IN A TOTAL HYSTERECTOMY IN (B)(6) OF 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034555	CONCEPTUS INC	2/12/2014	2/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(6) OF 2008-2009 AND ABOUT 6 MONTHS AFTER I HAD IT DONE, I STARTED TO NOTICE PROBLEMS SUCH AS A LOT OF VERY BAD PAIN IN MY LOWER ABDOMEN AREA AND IN MY BACK, I HAVE VERY BAD HEADACHES AT TIMES AND NOTHING HELPS. I ALSO HAVE MONTHS WHERE I HAVE A PERIOD ALL MONTH LONG AND SOME MONTHS I DON'T HAVE ONE AT ALL. I HAVE HAD SOME SWELLING AND BLOATING THAT I HAD NEVER HAD BEFORE THE PROCEDURE AND I HAVE DIZZY FEELINGS IT JUST COMES AND GOES. I HAVE BEEN TO THE DOCTORS AND THEY DON'T KNOW WHY I HAVE ALL THE SYMPTOMS I HAVE. I HAVE EVEN BEEN TO THE HEALTH DEPARTMENT AND STILL NO ANSWER. THIS ESSURE IS THE ONLY THING THAT HAS CHANGED IN MY LIFE THAT COULD BE CAUSING MY PROBLEMS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00031	BAYER HEALTHCARE LLC	2/12/2014	2/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE YEAR PRIOR TO DIFFICULTIES, A WOMAN HAD HYSTEROSCOPIC STERILIZATION WITH ESSURE MICROINSERTS. AFTER NORMAL FINDINGS AT DIAGNOSTIC HYSTEROSCOPY AND A NORMAL HISTOLOGY IN AN ENDOMETRIAL BIOPSY, SHE HAD AN ENDOMETRIAL ABLATION BY UTERINE BALLOON THERAPY. THE ENDOMETRIAL ABLATION WAS UNEVENTFUL. HER SYMPTOMS STARTED SHORTLY AFTER THE ABLATION AND HAD GRADUALLY WORSENED. SHE PRESENTED WITH PREDOMINANTLY RIGHT-SIDED LOWER ABDOMINAL PAIN AND FEVER OF SEVERAL WEEKS' DURATION. THE PAIN WAS DESCRIBED AS A CONTINUOUS PAIN RADIATING TO THE BACK AND INSIDE OF THE RIGHT LEG. FURTHERMORE, SHE REPORTED NAUSEA AND DYSURIA. SHE HAD BEEN TAKING ANTIBIOTICS FOR 1.5 WEEKS AFTER A SUSPECTED URINARY TRACT INFECTION. EXAMINATION REVEALED A TENDER LOWER ABDOMEN WITHOUT GUARDING OR REBOUND TENDERNESS, AN ABNORMAL VAGINAL DISCHARGE, A TENDER UTERUS AND A PAINFUL AND IMMOBILE SWELLING OF APPROXIMATELY 5 CM IN THE RIGHT ILIAC FOSSA. THE SWELLING THAT HAD BEEN PALPATED WAS VISIBLE ON ULTRASOUND BETWEEN UTERUS AND BLADDER AND HAD A HOMOGENEOUS ECHOGENIC ASPECT. THERE WAS A SMALL AMOUNT OF FREE FLUID IN THE POUCH OF DOUGLAS. WITH A DIAGNOSIS OF TUBAL OVARIAN ABSCESS, SHE WAS ADMITTED FOR INTRAVENOUS TREATMENT WITH DOXYCYCLINE AND METRONIDAZOLE. LAPAROSCOPY SHOWED THE PELVIS DENSELY COVERED WITH OMENTUM AND BOWEL, AND A CONVERSION TO LAPAROTOMY WAS PERFORMED. DURING LAPAROTOMY, THE UTERUS APPEARED COVERED WITH OMENTUM, COLON, AND ILEUM. THE APPENDIX WAS NORMAL AND NOT ADHERENT TO THE ABSCESS. AFTER EXTENSIVE ADHESIOLYSIS, THE UTERUS AND ADNEXA BECAME VISIBLE. IN BOTH INTRAMURAL PARTS OF THE TUBES EXTENDING TO THE CORNUA OF THE UTERUS, AN ABSCESS WITH NECROSIS WAS PRESENT. THE WALL OF THE TUBE AND CORNUA SURROUNDING THE ESSURE MICROINSERTS HAD BEEN DESTROYED BY NECROSIS. IN BOTH ABSCESSES, THE

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ESSURE MICROINSERTS WERE LOCATED EXACTLY IN THE CENTER. THEY WERE REMOVED TOGETHER WITH NECROTIC TISSUE. FURTHERMORE, BOTH FALLOPIAN TUBES WERE REMOVED, AS WELL AS THE APPARENTLY NORMAL APPENDIX BECAUSE IT WAS LYING WITH ITS TIP IN THE INFECTED PROCESS. POSTOPERATIVE RECOVERY WAS QUICK AND UNEVENTFUL; TEMPERATURE NORMALIZED WITHIN 3 DAYS, ANTIBIOTICS CONTINUED ORALLY FOR 3 WEEKS AND THE INFLAMMATORY PARAMETERS NORMALIZED SLOWLY. SIX WEEKS AFTER THE OPERATION, SHE WAS FREE OF PAIN WITH NO PALPABLE OR VISIBLE ABNORMALITIES. AUTHOR'S COMMENT: POSSIBLY, ASYMPTOMATIC ENDOMETRITIS, DUE TO THE FOREIGN BODIES OF THE ESSURE MICROINSERTS, WAS EXACERBATED AFTER THE ENDOMETRIAL ABLATION AND CAUSED THE ABSCESSES. OR ENDOMETRITIS AFTER THE ENDOMETRIAL ABLATION COULD HAVE CAUSED ABSCESSES TO FORM ON THE SITE OF THE FOREIGN BODIES-THE ESSURE MICROINSERTS. FOR THIS REASON, SUGGESTION OF ADMINISTERING PROPHYLACTIC ANTIBIOTICS BEFORE ENDOMETRIAL ABLATION IN WOMEN WITH ESSURE MICROINSERTS IN SITU.

Manufacturer Narrative (H10):

FU RECEIVED ON 07-MAY-2014. THE CASE WAS CREATED FROM REFERENCE # (B)(4) FROM THE ARTICLE TITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW". NO NEW INFORMATION WAS RECEIVED. FOLLOW-UP 27 MAY 2014

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00025	BAYER HEALTHCARE LLC	2/12/2014	2/26/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2011
Explant Date (E7): 4/25/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A PATIENT HAD ESSURE IMPLANTED FOR PERMANENT STERILIZATION IN A DIFFERENT CITY. PATIENT STATED THAT SINCE HAVING THAT PROCEDURE DONE SHE HAD BEEN HAVING PELVIC PAIN, CRAMPING IN NATURE. SHE STATED OVER THE PAST FEW MONTHS IT HAD GOTTEN WORSE AND BECAME ALMOST A CONSTANT, SEVERE CRAMPING PAIN IN HER PELVIS. SHE ALSO HAD BEEN HAVING IRREGULAR BLEEDING SINCE ESSURE WAS PLACED. SHE WAS PUT ON DEPRO-PROVERA (MEDROXYPROGESTERONE) TO TRY TO CONTROL THE BLEEDING. SHE STATED THIS DID NOT HELP. PATIENT WAS TAKEN TO SURGERY FOR LAPAROSCOPIC BILATERAL SALPINGECTOMY AND ESSURE COIL REMOVAL. DURING SURGERY IT WAS FOUND THAT THE ESSURE COIL INSERTION DEVICE (NOT JUST THE COILS) HAD BEEN LEFT IN THE CONSUMER'S BILATERAL FALLOPIAN TUBES. THERE WAS EVIDENCE OF CHRONIC INFLAMMATION. BOTH TUBES AND ALL FOREIGN BODIES WERE COMPLETELY REMOVED. SINCE THEN THE PATIENT HAS HAD PROBLEMS WITH RECURRENT INFECTIONS AND CHRONIC PAIN AND IS LIKELY GOING TO NEED A HYSTERECTOMY. THE REMOVAL OF ESSURE WAS MEDICALLY NECESSARY. COMPLETE CROSS SECTIONS OF TUBES AND FIMBRIATED ENDS AND COILS WERE SIGNS AND SYMPTOMS OF INFECTION. THE PATIENT'S SYMPTOMS RESOLVED BRIEFLY AFTER SURGERY, BUT SHE CONTINUED TO HAVE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00026	BAYER HEALTHCARE LLC	2/12/2014	2/26/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 12261233

Single Use: Y
Implant Date (E6): 11/12/2004
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED. NO BACK-UP CONTRACEPTION WAS USED AFTER THE INSERTION AND BEFORE TOTAL OCCLUSION WAS CONFIRMED. ACCORDING TO HER, SHE STARTED EXPERIENCING PAIN IN TAIL BONE 6 MONTH AFTER ESSURE INSERTION ((B)(6) 2005). SHE ALSO EXPERIENCED PAIN IN HER LOWER BACK BONE, HIP AND KNEES, PAIN IN HANDS, PAIN IN ELBOW, SEVERE HEADACHES, PROBLEMS WITH VISION, PROBLEMS SLEEPING DUE TO THE PAIN, TIRED, SHARP PAIN IN HER VAGINA, VAGINAL ITCHING WITH NO INFECTION, PAIN AND DEPRESSION. OVER THE YEARS SEVERAL DOCTORS WERE SEEN, BUT NO EXPLANATION HAD BEEN GIVEN TO HER SYMPTOMS. SHE WAS TREATED WITH MUSCLE RELAXERS AND WAS REFERRED TO A CHIROPRACTOR. DUE TO THE SYMPTOMS, ESSURE WAS LAPAROSCOPICALLY REMOVED ALONG WITH HER UTERUS. THE REPORTING CONSUMER FELT PRETTY GOOD AFTER THE DEVICE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00028	BAYER HEALTHCARE LLC	2/12/2014	2/26/2014

Event Information:

Event Date (B3): 8/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/19/2013
Explant Date (E7): 11/29/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED. DEPOPROVERA WAS INJECTED ONE WEEK BEFORE INSERTION. HYSTEROSALPINGOGRAM WAS NOT PERFORMED BECAUSE SHE WAS IN LOT OF PAIN. SHE STATED THAT SHE EXPERIENCED PAIN ALL OVER HER BODY AND BACK DAILY. SHE VISITED A DOCTOR AND THE DIAGNOSIS WAS THAT SHE WAS IN CHRONIC PAIN, BUT WAS NOT HOSPITALIZED. THE PATIENT WAS TREATED WITH IBUPROFEN AND OXYCONTIN. ON AN UNSPECIFIED DATE AN ULTRASOUND WAS DONE AND SHOWED THAT THE COILS WERE IN THE TUBES AND THAT THERE WAS A BLOOD POCKET IN THE TUBES. ESSURE WAS REMOVED DUE TO THE PAIN BY LAPAROSCOPIC SALPINGECTOMY. DURING THE SURGERY, IT WAS NOTED THAT THE COILS WERE TOO HIGH AND THAT WAS CAUSING THE PAIN. PATHOLOGY ANALYSIS WAS DONE, BUT RESULT WAS NOT AVAILABLE. THE OUTCOME OF THE EVENTS WAS RECOVERED/RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00030	BAYER HEALTHCARE LLC	2/12/2014	2/26/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/9/2013
Explant Date (E7): 11/4/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED FOR PERMANENT BIRTH CONTROL. SHE BEGAN HAVING CHRONIC PAIN WITHIN A WEEK OF INSERTION. ULTRASOUND, 3 WEEKS AFTER INSERTION, SHOWED THAT THE RIGHT COIL HAD ALREADY MIGRATED 4 CM INTO THE UTERUS. SHE EXPERIENCED CHRONIC HEAVY BLEEDING FOR MONTHS THAT DELAYED HER FROM GETTING THE HYSTEROSALPINGOGRAPHY AT THE 90 DAY MARK, BUT ULTIMATELY SHOWED THE RIGHT COIL HAD MIGRATED AND WAS MISSING. THE LEFT COIL CONTINUED TO CAUSE CHRONIC PAIN, WEIGHT GAIN AND HEAVY BLEEDING. X-RAY INDICATED THAT SHE PASSED THE RIGHT COIL. AS A RESULT, SHE UNDERWENT VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY TO REMOVE REMAINING ESSURE DEVICE. FOLLOW-UPS ATTEMPTED WITHOUT RESPONSE.

Manufacturer Narrative (H10):

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This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00033	BAYER HEALTHCARE LLC	2/12/2014	2/26/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 8/5/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED AFTER A TUBAL PREGNANCY AND MISCARRIAGE OF TWINS. SHE DID NOT USE BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. HSG (HYSTEROSALPINGOGRAM) TEST WAS NOT PERFORMED. HER LAST MENSTRUAL CYCLE WAS AROUND (B)(6) 2012. ON (B)(6) 2012 SHE WENT TO THE EMERGENCY ROOM WITH COMPLAINTS OF PAIN. A POSITIVE URINE PREGNANCY TEST AND ULTRASOUND CONFIRMED A TUBAL PREGNANCY WHICH LED TO A THERAPEUTIC ABORTION. ESSURE AND BOTH TUBES WERE REMOVED. AS CONSUMER WAS UNIDENTIFIABLE TO HEALTH CARE PROFESSIONAL, ATTEMPTS AT FOLLOW-UP WERE UNSUCCESSFUL.

Manufacturer Narrative (H10):

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This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00027	BAYER HEALTHCARE LLC	2/12/2014	3/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/10/2013
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED. SINCE INSERTION SHE'S HAD SO MANY SYMPTOMS FROM BLEEDING (2-3 PERIODS A MONTH FOR A YEAR) AND CRAMPING (FEELS LIKE LABOR PAINS). SHE ALSO REPORTED THAT IN 2013 SHE HAD A HYSTERECTOMY DUE TO ESSURE. FOLLOW-UPS ATTEMPTED WITH NO RESPONSE.

Manufacturer Narrative (H10):

FOLLOW-UP 19-FEB-2014: CONSUMER REPORTED ON COMPANY INTERNET SITE SHE WAS (B)(6) AND NOW HAS TO GET A HYSTERECTOMY BECAUSE OF ESSURE. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014 FROM SOCIAL MEDIA: THE CONSUMER REPORTED THAT SHE WAS GETTING HYSTERECTOMY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00029	BAYER HEALTHCARE LLC	2/12/2014	3/4/2014

Event Information:

Event Date (B3): 11/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/2/2012
Explant Date (E7): 2/13/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED. SHE REPORTED SHE BLED ALMOST NONSTOP FROM (B)(6) 2012 TO 2013. SHE HAD SEVERE PAIN IN HER LOWER ABDOMEN TO THE POINT WHERE IT FELT LIKE SHE WAS IN LABOR. SHE WAS UNABLE TO HOLD HER NEWBORN SON BECAUSE OF THE PAIN IN HER ABDOMEN AND BACK. SHE HAD TERRIBLE MIGRAINES ALONG WITH FATIGUE AND SHOOTING PAINS UP AND DOWN HER RIGHT LEG. AFTER TWO TRIPS TO THE EMERGENCY ROOM AND TWO VISITS WITH HER IMPLANTING DOCTOR/OB GYN, NO ONE COULD EXPLAIN WHY SHE WAS HAVING THESE ISSUES. HER DOCTOR PERFORMED A BILATERAL SALPINGECTOMY AND ALL HER ISSUES DISAPPEARED AFTER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00032	BAYER HEALTHCARE LLC	2/12/2014	3/4/2014

Event Information:

Event Date (B3): 2/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/17/2011
Explant Date (E7): 12/30/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED IN HER GYNECOLOGIST'S OFFICE. DEPO SHOT SINCE 1996 WAS REPORTED AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. RIGHT AFTER ESSURE PROCEDURE, SHE EXPERIENCED STABBING PAIN IN LOWER ABDOMEN NEAR OVARIES. HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND SHOWED BOTH IMPLANTS WERE MIGRATED INTO PELVIC AREA (OMENTUM). SHE OPTED FOR THE TUBAL AND REMOVAL OF IMPLANTS. THE REMOVAL WAS MEDICALLY NECESSARY SINCE IT WAS NOT IN THE CORRECT PLACE. DURING SURGERY, BOTH COILS WERE FOUND MIGRATED TO THE PELVIC AREA. ONLY ONE WAS REMOVED AND WAS REPORTED TO BE IN TWO PIECES. NO HOSPITALIZATION WAS REQUIRED. SHE DID NOT HAVE A DATE FOR REMOVAL OF THE SECOND COIL. THE SYMPTOMS/PAIN RESOLVED AFTER SURGERY FOR A TIME, BUT THAT SHE EXPERIENCED BACK PAIN AGAIN. THE 20 MONTHS LATER ((B)(6) 2013), SHE WAS HAVING BACK PAIN AND HAD AN X-RAY SHOWED A COIL STILL IN THE PELVIC AREA. FOLLOW-UP ATTEMPTS WERE UNSUCCESSFUL.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# F

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00034	BAYER HEALTHCARE LLC	2/12/2014	3/4/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A96182

Single Use: Y
Implant Date (E6): 8/12/2013
Explant Date (E7): 11/6/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED. SHE WAS IN CONSTANT PAIN AND DISCOMFORT DAILY DESCRIBED AS SHARP, STABBING, SHOOTING PAIN THROUGH HER VAGINAL AND PELVIC AREA. IT WAS REPORTED THAT SHE WAS HOSPITALIZED BECAUSE OF THE EVENTS. AFTER NUMEROUS DOCTORS, SHE HAD A HYSTERECTOMY TO REMOVE ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00035	BAYER HEALTHCARE LLC	2/12/2014	3/4/2014

Event Information:

Event Date (B3): 12/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 623215

Single Use: Y
Implant Date (E6): 12/9/2009
Explant Date (E7): 11/6/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED. IMMEDIATELY AFTER PLACEMENT, SHE STARTED HAVING SEVERE ABDOMINAL PAIN. THIS HAPPENED FOR 3/4 MONTHS SPORADICALLY. DURING HYSTEROSALPINGOGRAM, THE RIGHT COIL WAS NOT FOUND IN THE TUBE, BUT IN THE UTERUS. THE LEFT COIL WAS PARTIALLY IN THE TUBE, BUT A PIECE HAD BROKEN OFF AND THERE WAS A SMALL FRAGMENT IN THE UTERUS. SHE HAD LAPAROSCOPIC SURGERY WHICH LOCATED THE RIGHT COIL ON THE TOP LEFT SIDE OF THE UTERUS ATTACHED TO UTERINE WALL. SHE HAD A TUBAL LIGATION AT THE SAME TIME. THE LEFT COIL WAS LEFT IN PLACE IN THE TUBE. IN 2011, SHE HAD SEVERE BLOATING, PELVIC PAIN, PELVIC PRESSURE, PELVIC INFLAMMATION, LARGE MENSTRUAL CLOTS, HEAVY PERIODS, EXTREME FATIGUE, MIGRAINES, MID- SECTION WEIGHT GAIN, INFLAMMATION, PAINFUL INTERCOURSE, EXTREME, SHARP, STABBING PAINS ON THE SIDES OF HER ABDOMEN. THE LEFT COIL HAD MIGRATED TO THE RIGHT SIDE OF ABDOMEN. SHE ALSO HAD A SMALL FRAGMENT STILL ON THE LEFT SIDE NEAR THE BLADDER. LAPAROSCOPY AND LEFT SALPINGECTOMY PERFORMED DUE TO PELVIC PAIN. THE LEFT FALLOPIAN TUBE WAS REMOVED. DURING SURGERY, THE COIL WAS LOCATED ATTACHED TO THE APPENDIX. IT WAS REMOVED. THE SMALL FRAGMENT ON THE LEFT WAS FOUND PIERCING THE UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034354	CONCEPTUS	2/12/2014	6/24/2014

Event Information:

Event Date (B3): 9/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABDOMINAL PAIN SEVERE, FATIGUE, ABDOMINAL DISTENTION, WEIGHT GAIN, BRAIN FOG, DIZZINESS, PAINFUL INTERCOURSE, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034367	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 1/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I HAVE BEEN SUFFERING FROM CHRONIC PELVIC AND ABDOMINAL PAIN, SEVERE HEADACHES, RASHES, DIZZINESS, U T INFECTIONS, BRUISING, TINGLING IN HANDS AND LEGS, BURNING IN LEGS, NAUSEA, BLURRY VISION, DRY EYE SOCKETS, HOT FLASHES, MUSCLE WEAKNESS, BROWN SPOTS UNDER BREAST, HEAVY BLEEDING AND LOWER BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034368	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 12/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING REALLY BAD PELVIC PAINS AFTER GETTING THE ESSURE PUT IN. IT PERSISTED EVERYDAY UNTIL I GOT THEM REMOVED. I ALSO EXPERIENCED MIGRAINES, DEPRESSION, AND OVARIAN CYST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034370	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 1/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERAL SYMPTOMS FROM ESSURE INCLUDING CRAMPING, PAIN, FOUL DISCHARGE, HEAVY PERIODS, PAINFUL INTERCOURSE, HAIR LOSS, BLOATING, BLADDER INFECTION. SYMPTOMS RESOLVED AFTER PARTIAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY TO REMOVE DEVICES AND INFLAMED UTERINE TISSUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034371	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 1/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY AND PAINFUL BLEEDING AND CLOTTING THE SIZE OF GOLF BALLS, HEADACHES, WEIGHT GAIN, BLOATING, INFLAMMATION, PAIN IN LOWER STOMACH AND BACK, FATIGUE, LOSING HAIR, ANXIETY, DEPRESSION. ALL THIS HAS BEEN A NIGHTMARE SINCE THESE DEVICES WERE IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034372	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AT FIRST IT WAS LOTS OF BACK PAIN; SHARP INTENSE ABDOMINAL PAIN; THEN IT WAS BLOOD CLOTS DURING MY CYCLE; VERY, VERY HEAVY CYCLE; CYCLE OFF SCHEDULE; NECK PAIN; NERVE PROBLEMS (SHOOTING PAINS THROUGHOUT MY HIPS AND LEGS); SHOOTING PAIN AND PRESSURE IN MY PELVIS; NO SEX DRIVE; STRESS; DEPRESSION; ANXIETY; HEADACHES. THEN I HAD THEM REMOVED AND MY CYCLE WENT BACK TO NORMAL, NO MORE PAIN IN MY ABS AND PELVIS AND WEIGHT GAIN. TO THIS DAY I HAVE DEGENERATIVE DISC AND DEGENERATIVE JOINT DISEASE, BILATERAL FORMATION, PINCHED NERVES IN BACK AND NECK, BULGING DISC, HEMORRHAGIC CYST, KIDNEY CYST, BONE SPURS, OSTEOPENIA. I WAS VERY IN-SHAPE AND HEALTHY BEFORE I GOT THESE IN ME NOW MY DAYS ARE PAINFUL, STRESSFUL AND CANT DO FOR MY KIDS, PLAY WITH MY KIDS. AND I HAVE A HUGE FEAR OF MEDICINES AND EMERGENCY ROOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034373	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 12/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING CORRECTIVE 2ND NOVASURE UTERINE ABLATION MANDATORILY, IMPLANTED ESSURE. FOUR MONTHS LATER I DEVELOPED AURA MIGRAINES AND WAS HOSPITALIZED FOR 3 DAYS. IN 2013 SEVERE STOMACH BLOATING AND TENDERNESS IN PELVIC REGION. PAINFUL PELVIC CRAMPS WHEN BLADDER IS FULL ESPECIALLY AT NIGHT (AWAKEN FROM PAIN), AFTER RELIEF PELVIC REGION REMAINS IN PAIN. SUFFERER FROM HEART PALPITATIONS, IRON TASTE IN MOUTH AND FATIGUE. LATTER 2013 SUFFER FROM INCONTINENCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034374	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN MY DAUGHTER WAS 6 MONTHS OLD MY HUSBAND AND I DECIDED THAT OUR FAMILY WAS COMPLETE. I WENT TO MY DOCTOR ASKING TO HAVE MY TUBES TIED. I WAS HANDED A PAMPHLET AND TOLD, "THIS IS HOW WE DO IT NOW." I TRUSTED MY DOCTOR AND THOUGHT ESSURE WAS THE BEST FOR ME. I WAS TOLD THERE WAS NO DOWN TIME AND EASY TO RECOVER FROM AND NO SIDE AFFECTS. I HAD ESSURE IMPLANTED (B)(6) 2011 THE NEXT DAY I STARTED WITH FLU LIKE SYMPTOMS AND HEAVY BLEEDING FOR 10 DAYS. THEN ALL THE SIDE AFFECTS STARTED ABOUT A YEAR LATER PELVIC PAIN MOSTLY ON MY LEFT SIDE, NO ENERGY, JOINT PAIN, PAIN DURING AND AFTER INTERCOURSE CONSTANT UTI, SIX IN ONE YEAR, ALL OF WHICH I NEVER HAD BEFORE ESSURE. I WENT BACK AND FORTH WITH MY GYN FOR OVER A YEAR SHE TOLD ME ESSURE CAN NOT BE CAUSING ALL MY PROBLEMS. I FOUND A DOCTOR THAT DID BELIEVE ME AND ON (B)(6) 2014 I HAD TO HAVE LAPAROSCOPIC SURGERY TO REMOVE MY TUBES AND ESSURE ALL TOGETHER. ITS BEEN 3 WEEKS AND I FEEL GREAT ALL MY SYMPTOMS ARE GONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034375	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 10/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DAY I HAD THE ESSURE COILS PLACED I IMMEDIATELY FELT ILL. I WAS SHAKING TO THE POINT I FELT I WAS GOING TO DIE. A FEW DAYS LATER IS WHEN EVERYTHING BEGAN. I SUDDENLY HAD ANXIETY, DEPRESSION, MOOD DISORDERS, MINI STOKE WHICH HOSPITALIZED ME FOR A WEEK, AND STOMACH ISSUES. ALL THESE SYMPTOMS HAD CARRIED ON ALL THESE YEARS. THEN I STARTED TO BECOME EXTREMELY ILL TO THE POINT I WAS UNABLE TO WORK, GO TO SCHOOL, OR CARE FOR MY FAMILY. I WAS ALWAYS AGITATED, FOGGY BRAIN, STOMACH PROBLEMS, LYMPH NODES WERE ALWAYS SWOLLEN, PROBLEMS SWALLOWING, EXCESSIVE DRY SKIN, ACNE ISSUES, BRITTLE NAILS THAT PEELED OFF IN LAYERS, HAIR LOSS, LOSS OF FEELING IN MY LEFT LEG AND ARM, TINGLING SENSATION THROUGHOUT BODY, TEETH STARTED BECOMING LOOSE AND BREAKING OFF, AND SUDDENLY BECAME ALLERGIC TO 27 FOODS, ALL MY HEALTH AND BEAUTY PRODUCTS, AND CLEANING SUPPLIES ALL OF WHICH I HAVE USED OR EATEN ALL MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034376	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 4/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BACK PAIN, UNEXPLAINABLE PELVIC PAIN, JOINT PAIN, MIGRAINES EVERY MORNING, AND MY OBGYN TRIED EXPLORATION SURGERY AND COULDN'T FIND ANYTHING WRONG, AND I GOT WITH A GROUP OF WOMEN WHO HAVE THESE SAME SYMPTOMS. I THINK IT SHOULD BE ON RECALL. I DON'T THINK ANY WOMEN SHOULD GET THIS. I HAVE 3-5 MENSTRUAL CYCLES A MONTH AND BLEED RIDICULOUSLY BAD. I WANT THIS NOT TO BE AN OPTION AND OUT OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034377	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 8/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD EXTREME WEIGHT GAIN (CURRENTLY THE HEAVIEST I HAVE EVER BEEN), SEVERE CRAMPING, HEADACHES/ MIGRAINES WEEKLY, HAIR LOSS, MY SKIN IS SO DIFFERENT (BREAKING OUT/RASHES/BLISTERING UNDER JEWELRY), DEPRESSION, SUICIDAL THOUGHTS, EXHAUSTED DAILY, CAN'T SLEEP, HARD TO FOCUS (IN A FOG/DIZZY), SPASMS, EMOTIONAL, EXTREMELY BLOATED, BACK PAINS, STABBING PAINS IN MY ABDOMINAL AREA, SEVERE DRY SKIN, DIARRHEA CONSTANTLY. I HAVE MISSED WORK, LOST JOBS, LOST TIME WITH MY HUSBAND AND CHILDREN DEALING WITH ALL OF THIS. I HAVE FELT THAT THERE IS NO OTHER CHOICE THEN TO TAKE MY OWN LIFE BECAUSE THERE ARE DAYS THAT I JUST DON'T WANT TO GET OUT OF BED, BECAUSE NO ONE KNOWS THE HELL I FEEL ON AN EVERYDAY BASIS, NO ONE KNOWS MY BODY BETTER THAN I DO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034378	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 10/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABDOMINAL PAIN AND CRAMPING WAS MY MAJOR SYMPTOM. AFTER THE ESSURE IMPLANT WAS PLACED I THOUGHT THE CRAMPING WAS MORE INTENSE THAN USUAL. THEN IT JUST CONTINUED TO GET WORSE. I HAVE A HIGH TOLERANCE FOR PAIN SO I DIDN'T THINK ABOUT GOING TO SEE A DOCTOR UNTIL ABOUT (B)(6). I HAVE PAIN WHEN URINATING AS WELL AS BLOATING. THE METAL TASTE IN MY MOUTH IS AWFUL. I CAN BRUSH MY TEETH AND IN 10 MINUTES I FEEL LIKE I SHOULD DO IT AGAIN. I HAVE SEEN 7 DOCTORS TO TRY AND RESOLVE THE SYMPTOMS AND THEY HAVE AGREED IT MUST BE THE ESSURE IMPLANTS. I HAVE TO HAVE A HYSTERECTOMY TO REMOVE THEM NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034379	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 3/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AS SOON AS I LEFT THE DR OFFICE I BEGAN HAVING CHEST PAIN, DIFFICULTY BREATHING, CONTRACTION LIKE SPASMS IN MY ABDOMEN. I WAS IN EXCRUCIATING PAIN. I COULD BARELY MOVE WITHOUT BEING IN PAIN. I WAS GIVEN MORPHINE AT THE ER AND WAS STILL IN PAIN. FOR SEVERAL MONTHS AFTER THE IMPLANT OF ESSURE I COULD FEEL THE COILS AND WOULD HAVE SHARP AND AT TIMES SEVERE PAIN WITH SHARP AND SEVERE CRAMPING, AND LOWER BACK PAIN. MY MENSTRUAL CYCLE HAS INCREASED TO 10 DAYS WHEN IT USED TO BE LESS THAN A WEEK, I HAVE HEAVY, CRAMPY BLEEDING. THIS IS THE FIRST TIME IN MY LIFE THAT I HAVE HAD PERIOD PROBLEMS. THE PMS IS WORSE, AND SO IS POST MENSTRUAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034380	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 5/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE IMPLANTATION OF THE ESSURE DEVICES, I HAVE HAD UNCONTROLLABLE BLOATING, PAIN, AND HEAVY PERIODS. BEGINNING IN (B)(6), I STARTED TO NOTICE THAT MY BELLY WAS BLOATING EVERY COUPLE OF WEEKS FOR A FEW DAYS. IN TANDEM WITH THE BLOATING, I HAVE HAD PAIN, TENDERNESS, AND WHAT FEELS LIKE MUSCLE SPASMS ALL OVER MY BELLY. ALSO, SINCE THAT TIME, I HAVE NOTICED MY PERIODS GETTING INCREASINGLY HEAVIER, LAST MONTH BEING THE WORST YET AS I SOAKED THROUGH A SUPER-PLUS TAMPON AND BACKUP PAD EVERY TWO HOURS FOR THREE DAYS. THIS IS NOT NORMAL FOR ME. I HAVE ALSO RECENTLY FOUND OUT THAT THE HORRIBLY SHARP PAINS I HAVE IN THE SIDES OF MY HEAD FOR THE LAST 6 MONTHS ARE CALLED "ICE PICK HEADACHES." I HAD NEVER EXPERIENCED THIS BEFORE AND THOUGHT I WAS HAVING A STROKE OR ANEURISM. ALONG WITH SEVERAL MIGRAINES, WHICH I HAD ALSO NEVER EXPERIENCED, I THOUGHT FOR SURE THAT I WAS DYING. I CONTINUE TO HAVE ALL OF THESE SYMPTOMS, BUT I CANNOT SEE A DOCTOR BECAUSE I HAVE NO HEALTH INSURANCE AND I AM WAITING ON (B)(6) TO COME THROUGH. I SINCERELY HOPE THE FDA/(B)(4) WILL RECONSIDER ALLOWING THIS DEVICE TO REMAIN ON THE MARKET. I CAN ONLY IMAGINE WHAT HAVOC IS BEING WREAKED INSIDE MY BODY RIGHT NOW, AND I CAN'T EVEN DO ANYTHING ABOUT IT. I'M SCARED. I HAVE CHILDREN AND I DON'T WANT TO DIE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034381	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 5/26/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WELL AFTER ESSURE I HAD BAD CRAMPS, BUT I THOUGHT IT WAS NORMAL, THEN HEADACHES, ACNE, WEIGHT GAIN, PAIN LIKE IF SOMEONE WAS STABBING ME, IT HURTS TO EVEN MOVE, CAN'T SLEEP BECAUSE OF THE PAIN, DIZZINESS, AND NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034383	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 1/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BEFORE ESSURE MY ONLY HEALTH ISSUE WAS BEING OVERWEIGHT. AFTER ABOUT A YEAR OF GETTING THE ESSURE I STARTED HAVING HEAVY PERIODS WITH BIG CLOTS. I STARTED GETTING UNGODLY PAINS IN MY UTERUS AND OVARY AREAS. BAD PAINS IN MY LOWER BACK THAT WOULD SHOOT DOWN MY LEFT LEG. SITTING TO GO TO THE BATHROOM IS TO LONG IN ONE POSITION BECAUSE MY FEET GO NUMB. I STARTED TO GET DOUBLE PERIODS EACH MONTH. I FEEL LIFE HAS BEEN HELL SINCE THE IMPLANT OF THESE THINGS AND WANT THEM OUT!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034391	CONCEPTUS	2/13/2014	2/13/2014

Event Information:

Event Date (B3): 7/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I GOT ESSURE I HAVE HAD LABOR PAINS. MY ABDOMEN SWELLS UP LOOKING PREGNANT. MY LOWER BACK HURTS ALL THE TIME. I AM GASSY AND BM MORE THEN EVER. I CAN'T HAVE INTERCOURSE WITH MY HUSBAND. IT HURTS LIKE MY INSIDES ARE COMING OUT. I BLEED FOR WEEKS AT A TIME, STOP FOR A COUPLE DAYS, AND START ALL OVER AGAIN. I HAVE A NEW NICKEL ALLERGY TO MY WEDDING BAND. I'M TIRED ALL THE TIME. WEIGHT GAIN AND MIGRAINES...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034369	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 1/15/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CRAMPING, HEADACHES, DIZZINESS, BLEEDING TO THE POINT I CAN'T GET OUT OF BED, PAIN SEVERE, WEIGHT LOST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034382	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 5/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE EXPERIENCED LEFT SIDED PELVIC PAIN, INTERMITTENT DIZZINESS, TINGLING IN ARMS AND HANDS, CHEST PAIN, IRREGULAR PERIODS LASTING 10-16 DAYS WITH HEAVY BLEEDING AND CRAMPING, ACID SMELLING DISCHARGE, BURNING SENSATION IN VAGINAL AREA WITH DISCHARGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034384	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 11/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED GETTING DAILY MIGRAINES WITH EXTREME FATIGUE AND INSOMNIA. FOLLOWED BY PELVIC AND LOWER BACK PAIN. I WAS SEEN IN THE ER FOR MIGRAINES AND TREATED WITH IMITREX AS WELL AS TORIDAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034385	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 5/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED FEELING NUMBNESS IN MY RIGHT ARM THAT TRAVELS TO MY HANDS AND FINGER. IT COMES AND GOES, BUT I'VE NEVER HAD THIS PROBLEM BEFORE. EVERY TIME BEFORE AND DURING MY MENSTRUAL, I FEEL NAUSEATED, TENDER BREAST AND VERY HEAVY PERIODS. I'VE NEVER HAD THIS PROBLEM AND I HAVE TWO CHILDREN. DURING SEX THERE'S PAIN AND DISCOMFORT AND A LOT OF TIMES, SEX IS THE LAST THING THAT'S ON MY MIND. I FEEL LIKE A WOMAN IN HER 90'S AND I'M (B)(6) YEARS OLD. STARTING ABOUT 3 MONTHS AGO, THERE'S THIS METAL TASTE IN MY MOUTH, SEEN THE DENTIST AND TOLD ME THAT EVERYTHING WAS OKAY WITH MY GUMS AND TEETH. MY MEMORY IS SO FOGGY I FEEL LIKE I HAVE A PIECE OF MY BRAIN BEING CHIPPED AWAY DAILY AND IT'S NOT A VERY GOOD FEELING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034386	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 7/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2012. SEVERAL WEEKS AFTERWARDS, I EXPERIENCED EXTREME HEADACHES. I WENT TO MY REGULAR FAMILY DOC AND HE SAID HE HADN'T HEARD OF ESSURE AND IT WAS PROBABLY DUE TO STRESS. WOULD TAKE PAIN KILLERS DAILY, DIDN'T ALWAYS WORK. PERIOD IS SO IRREGULAR, I USUALLY START FOR A DAY, THEN STOP FOR TWO, THEN START BACK UP FOR A WEEK... VERY HEAVY... PAIN IN LOWER BACK AND ABS... ODD TASTE IN MOUTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034387	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 6/19/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PELVIC PAIN, SEVERE BOATING (50 MONTH PREGNANCY BELLY), HEAVIER PERIODS THAN EVER (SAME IMPLANTING DOCTOR PERFORMED THE NOVASURE ABLATION THE FOLLOWING YEAR), RINGING IN EARS, WEIGHT GAIN (OVER 40 POUNDS!), FOOD ALLERGIES THAT NEVER EXISTED BEFORE, ALLERGY TO WHITE GOLD, GASTROINTESTINAL ISSUES, FATIGUE, ADRENAL ISSUES, BRAIN FOG, PAINFUL OVULATION, SPOTTING BETWEEN PERIODS AND AFTER INTERCOURSE, NAUSEA, VERTIGO, SEVERE HEADACHES, ACNE, INSOMNIA, FLUSHING IN CHEST AND EARS, AND RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034388	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 12/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS COMPLETELY HEALTHY WHEN I GOT ESSURE. AFTER GETTING ESSURE DONE, I BECAME SO SICK. I STARTED HAVING PAIN ALL OVER MY BODY. MY MUSCLES AND JOINTS HAVE BEEN AFFECTED FROM IT. I HAVE BEEN DIAGNOSED WITH BI-POLAR, DEPRESSION, ANXIETY, RESTLESS LEG, IRRITABLE BOWEL, FIBROMYALGIA, CHRONIC PAIN, CHRONIC FATIGUE, AND CHRONIC MUSCLE FATIGUE. MY HANDS DRAW UP. MY LEGS GO NUMB. I HAVE TO TAKE FLUID PILLS BECAUSE I RETAIN SO MUCH FLUID. I HAVE MIGRAINES. IT'S HARD FOR ME TO WALK OR DRIVE. EVERY DAY TASKS ARE A CHALLENGE NOW. I HAVE PELVIC PAIN, I STAY BLOATED, SEX IS NO LONGER ENJOYABLE, IT HURTS. SINCE HAVING IT DONE, I HAVE HAD TO HAVE MY TONSILS REMOVED AS WELL AS MY GALLBLADDER. I FIGHT WITH ACNE ALL THE TIME. I CAN BE SITTING AROUND AND IT FEELS LIKE I'M GETTING SHOCKED. MY RIGHT LEG GETS 2 1/2 INCHES BIGGER THAN MY LEFT LEG. MY LEGS TURN PURPLE. I CAN NOT WRITE FOR A LONG TIME NOW FOR MY HANDS DRAWLING UP. THIS HAS AFFECTED NOT ONLY MY LIFE BUT MY CHILDREN'S AND HUSBAND'S AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034389	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 10/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FIRST OF ALL, THE INITIAL TIME, THE DOCTOR COULDN'T PLACE THE BOTH COILS IN. I CAME BACK (B)(6) FOR THE SECOND COIL TO BE PLACED. THERE WAS A LOT OF CRAMPING AND PAIN. APPARENTLY SHE NEEDED A LONGER SCOPE FOR MY ONE SIDE. I DO HAVE A TILTED UTERUS, WHICH I DON'T KNOW IF THAT WAS WHY SHE COULDN'T PLACE THE SECOND ONE IN. OVER THE PAST 3 YEARS I HAVE HAD YEAST INFECTIONS, BACTERIAL INFECTIONS, BLADDER INFECTIONS, HAIR LOSS, VERY BAD PERIODS, STABBING PAIN, BLOATING AND NOW RED BLOOD SHOT EYES. I WOULD GET AN INFECTIONS ALL THE TIME AND WAS ON ANTIBIOTICS CONSTANTLY. MY PERIODS WERE SO BAD I COULD NOT FUNCTION FOR 3 DAYS BECAUSE IT WOULD JUST POUR OUT OF ME. I GOT A DNC DONE AND THAT DIDN'T HELP, MY BLOOD COUNTS WERE DOWN BECAUSE MY BODY COULD NOT KEEP UP WITH THE BLOOD LOSS. I THEN GOT THE NOVASURE DONE AND THAT DEFINITELY HELPED WITH ME NOT REALLY HAVING MY PERIOD ANYMORE. INSTEAD, NOW I HAVE A STABBING PAIN FOR 3 DAYS AND IT FEELS LIKE A KNIFE IS STABBING ME. I RECENTLY HAVE HAD BLOOD SHOT EYES SINCE (B)(6) AND I THOUGHT IT WAS DRY EYE AND HAVE BEEN USING EYE DROPS AND HAVE TO USE VISINE TO TAKE THE RED OUT OF MY EYES. I COME TO FIND OUT THAT THE BLOOD SHOT EYES IS A SIGN OF CHRONIC INFLAMMATION. THIS IS PROBABLY FROM MY STOMACH BECAUSE IT JUST SEEMS TO BE GETTING BIGGER AND BIGGER AND I THINK IT IS BECAUSE I AM SWOLLEN INSIDE. I EAT VERY WELL, ALL VEGGIES, FRUIT, FISH AND CHICKEN, SO IT ISN'T LIKE I EAT JUNK. IT IS SO FRUSTRATING. I ALSO JUST FOUND OUT I HAVE A VITAMIN D DEFICIENCY. THE LIST JUST KEEPS GETTING LONGER AND LONGER. I AM NOW IN THE PROCESS OF GETTING A CT SCAN AND ULTRA SOUND AND HOPEFULLY I AM ON MY WAY OF GETTING THESE THINGS OUT OF ME AND GETTING ON WITH MY LIFE. THIS EXPERIENCE HAS BEEN TERRIBLE AND THE DOCTORS MAKE YOU FEEL LIKE YOU ARE CRAZY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034390	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 3/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE ESSURE WAS IMPLANTED MY WHOLE LIFE CHANGED. I'VE BEEN HAVING SUPER HEAVY BLEEDING. I'VE BEEN HAVING LOTS OF PELVIC PAIN, FATIGUE, SWELLING ON FEET AND FACE, LOTS OF PAIN WHEN IN PERIOD AND SOMETIMES MY PERIOD LASTS 2 MONTHS NON-STOP, BLOOD CLOTS, TIREDNESS HEADACHES. AT TIMES IT FEELS LIKE MY OVARIES VIBRATE AND IT FEELS LIKE A BABY MOVES INSIDE ME. LOWER PAIN. I FEEL LIKE ANTS WALK ALL OVER MY LEGS N ABDOMEN. FEEL LIKE CONTRACTIONS AT TIMES. VERY SLEEPY. I GET FEVERS EVERY OTHER DAY WITH CHILLS AND NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034392	BAYER	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 11/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE, I HAVE BECOME SICK ALMOST DAILY. I GET HEADACHES, NAUSEA, PELVIC PAIN, ANXIETY ATTACKS, AND HAVE HEAVY BLEEDING DURING PERIODS. I HAVE ALSO MISSED PERIODS, PAINFUL INTERCOURSE, VAGINAL INFECTIONS, BLEEDING IN BETWEEN PERIODS AND PAINFUL CRAMPS. STABBING/SHARP PAINS IN PELVIC AREA WHERE MY FALLOPIAN TUBES ARE LOCATED. I HAVE LOST ALMOST 30 LBS SINCE HAVING ESSURE DUE TO THE FACT I HAVE A HARD TIME "READING" BECAUSE OF THE NAUSEA. I ALSO FEEL LIKE MY QUALITY OF LIFE HAD DRASTICALLY CHANGED FOR THE WORST AS I CAN NO LONGER GET OUT AND PLAY WITH MY THREE CHILDREN. I HAVE "SLASH" BEEN DIAGNOSED WITH HIGH BLOOD PRESSURE SINCE HAVING ESSURE. I WAS HEALTHY BEFORE HAVING THIS PROCEDURE AND NOW I WAKE UP EVERY DAY FEELING LIKE I AM LITERALLY KNOCKING ON DEATH'S DOOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034393	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 3/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON-GOING SHARP PAIN IN MY PELVIC AREA LIKE IF A PIECE OF METAL IS PUNCTURING ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034394	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 3/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE ESSURE WAS IMPLANTED MY WHOLE LIFE CHANGED. I'VE BEEN HAVING SUPER HEAVY BLEEDING. I'VE BEEN HAVING LOTS OF PELVIC PAIN, FATIGUE, SWELLING ON FEET AND FACE, LOTS OF PAIN WHEN IN PERIOD AND SOMETIMES MY PERIOD LASTS 2 MONTHS NON-STOP, BLOOD CLOTS, TIREDNESS HEADACHES. AT TIMES IT FEELS LIKE MY OVARIES VIBRATE AND IT FEELS LIKE A BABY MOVES INSIDE ME. LOWER PAIN. I FEEL LIKE ANTS WALK ALL OVER MY LEGS AND ABDOMEN. FEEL LIKE CONTRACTIONS AT TIMES. VERY SLEEPY. I GET FEVERS EVERY OTHER DAY WITH CHILLS AND NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034395	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PERIODS STARTED TO CHANGE ALMOST IMMEDIATELY. I HAVE ALWAYS HAD VERY EASY PERIODS WITH ALMOST NO PAIN AND WOULD LAST FOR THE MOST 4 DAYS, SINCE INSERTION OF ESSURE I NOW GET 2 PERIODS A MONTH, LASTS FROM 4-9 DAYS, THE CRAMPING PAINS IS HORRENDOUS, SMELLY DISCHARGE, WEAK BLADDER, SEVERE PELVIC PAIN OFTEN, BLOATING, WEIGHT GAIN, FATIGUE, LOSS OF MEMORY, HOT FLASHES, CYSTS WHICH I HAVE NO HISTORY OF, GAS PAINS, DEPRESSION, LOWER BACK PAIN, AND WEAK IMMUNE SYSTEM. I DO HAVE ALLERGIC REACTIONS TO NICKEL AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034396	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 1/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOR THE FIRST 6 MONTHS AFTER GETTING ESSURE IMPLANTED I BLEED VERY HEAVILY. I WAS SERIOUSLY SICK. WHITE AS A GHOST AND WAS SO VERY WEAK I COULDN'T GET OUT OF MY BED. I WAS IN EMERGENCY ROOMS AND DR APPOINTMENT AND EVERYONE SAID I WAS FINE AND NORMAL. I LOST ALL CONTROL OF MY BODY AND WASN'T ABLE TO BE A MOTHER TO MY BEAUTIFUL CHILDREN AND PLAY WITH THEM. AFTER THE BLEEDING HAD STOPPED I'VE GAINED NUMEROUS POUNDS OF WEIGHT AND NOTHING EXPLAINS WHY. MY HEALTHY DIETS HAVE NEVER CHANGED OR ANYTHING. I HAVE HAD SEVERE MIGRAINES FROM THE DAY I HAVE HAD ESSURE IMPLANTED AND WITH TON OF MEDICAL BILLS AND NO DRS HELP, I SELF MEDICATED BY IBUPROFEN AND HAD CAUSED KIDNEY DAMAGE. MY BACK AND BODY ALSO HURTS WITH SO MUCH PAIN THAT NOT EVEN A SCOLDING HOT BATH WILL HELP. ALSO EVERY MONTH I HAVE MOOD SWINGS LIKE I'M GOING THROUGH MENOPAUSE. ONE WEEK I'LL BE CRYING, ANOTHER I'LL BE SO CRABBY AND WANT TO CUT PEOPLES' HEADS OFF, ANOTHER I'M IN SO MUCH PAIN I JUST WANT TO BE LEFT ALONE. ON TOP OF, MY PARTNER HAS SUFFERED FROM ESSURE AS WELL BECAUSE MY SEX DRIVE HAS GONE OUT THE WINDOW AND IM (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034397	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 8/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN DURING SEX, CRAMPING, FEELING LIKE TUBES ARE GOING TO EXPLODE; TIREDNESS FATIGUE REASON I ENDED UP WITH A HYSTERECTOMY; MOOD SWINGS, NAUSEA, PREGNANCY SYMPTOMS, I'VE LOST 5 YEARS OF MY LIFE WITH MY HUSBAND AND WITHIN MYSELF TRYING TO FIGURE OUT WHAT IS CAUSING THIS. I HAVE FINALLY FOUND MY ANSWER YET AGAIN, IT CALLS FOR ANOTHER SURGERY TO HAVE TUBES REMOVED SO THAT I CAN BE PAIN FREE AND FINALLY GET BACK TO FEELING LIKE MYSELF.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034398	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 12/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAIR IS FALLING OUT IN CHUNKS NOW, NO ENERGY, ACNE, ALWAYS BLOATED, HEAVY PAINFUL PERIODS, BAD TASTE IN MOUTH, VERY MOODY, LOW SEX DRIVE, CONTINUOUS PAIN IN KIDNEY AND OVARIES AREA, CONSTANT HEAD ACHES NEVER HAS THIS STUFF BEFORE MY ESSURE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034399	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 2/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THREE YEARS AGO IS WHEN ALL THIS STARTED. THE DAY I GOT HOME. I WAS IN A LOT OF PAIN..THE NEXT DAY MRE PAIN AND FROM THAT DAY ON HAS GOT NOTHING BUT WORSE. SEVERE PAIN IN PELVIC AREA. STABBING PAIN WHEN I BEND OVER. BLOOD CLOTS, PERIODS IRREGULAR. RECURRING UTI SYMPTOMS WITHOUT UTI PRESENT. PAIN THROUGHOUT JOINTS. BELLY PAIN, JOLTS IN STOMACH, HAIR LOSS, MENTAL PROBLEMS, FATIGUE, PROBLEMS SLEEPING, TINGLING AND ITCHING SENSATIONS IN VAGINA. STRANGE DISCHARGE WITH NO UNKNOWN CAUSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034400	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 8/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER 2 WEEKS HAVING ESSURE, I STARTED TO BLEED A LOT, AND SO MUCH PELVIC PAIN, WENT BACK TO PLANNED PARENTHOOD. THE PLACE WERE I GOT IT DONE TELLING THEM I WAS BLEEDING A LOT AND THE PAIN DID NOT STOP. THEY SAID IT WAS NORMAL, THEN ON (B)(6) I WENT TO A DIFFERENT DR, WHO PERFORMED A D AND C ON (B)(6), AFTER THAT I WAS STILL BLEEDING, SO HE PERFORMED AN ABLATION, WHEN ALL MY PROBLEMS WERE RESOLVED IS WHEN THEY REALLY STARTED. I STARTED HAVING SEX WITH MY HUSBAND AFTER ALMOST 8 MONTHS OF NOTHING BECAUSE OF THE BLEEDING, MY HUSBAND STARTED TO GET A RASH, CUTS, SWELLING, BURNING AND PAIN ON HIS PENIS AFTER SEX, AND I HAD TERRIBLE IRRITATION AND BURNING AND ITCHING ON MY VAGINAL. IS LIKE SOMETHING THAT I WAS RELEASING FROM MY BODY WAS CAUSING US GETTING SICK, WE WENT TO THE DR. THEY SAID WE HAD (B)(6) AND WE GOT CHECKED FOR ALL YOU CAN BELIEVE, ALL WAS NEGATIVE!!! BUT WE NEVER GOT CHECKED IF WE WERE ALLERGIC TO NICKEL! AND THAT IS WHEN WE FOUND OUT WHAT WAS THE CAUSE OF ALL THIS PROBLEMS....ESSURE HAS NICKEL AND ME AND MY HUSBAND ARE ALLERGIC TO IT....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034401	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 11/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD EXTREMELY BAD BODY ACHES AND JOINT PAIN, HEADACHES,HEAVY BLEEDING WHEN ON MY MENSTRUAL CYCLE AND CRAMPING WHICH IS NOT NORMAL FOR ME. I AM VERY FATIGUED AND MOODY WITH IS UNLIKE ME. I HAD TO HAVE ESSURE PLACED TWICE ON MY LEFT SIDE TUBE BECAUSE ONE WAS LOST. THE COIL WAS NO WHERE TO BE FOUND. THE FIRST PLACEMENT WAS ON (B)(6) 2013 AND THE SECOND WAS IN (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034402	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 1/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HORRIBLE BACK PAIN, NAUSEA, HEADACHE, STOMACH PAIN, PRISM VISION, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034403	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 4/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, LOWER BACK PAIN, FATIGUE, JOINT PAIN, DEPRESSION, ANXIETY, WEIGHT GAIN, DETERIORATING TEETH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034404	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 4/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, LOWER BACK PAIN, FATIGUE, JOINT PAIN, DEPRESSION, ANXIETY, WEIGHT GAIN, DETERIORATING TEETH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034405	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 2/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN LOWER LEFT ABDOMINAL AREA, NUMBNESS IN LIMBS, CONSTANT HEADACHES, HEAVY BLEEDING, CYSTS ON OVARIES, RINGING IN EARS, TROUBLE GETTING WORDS OUT - BRAIN FOG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034406	BAYER	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 8/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS PUT UNDER FOR THE ESSURE PLACEMENT. THE DEVICES WERE PLACED WITH 0 COILS SHOWING IN MY RIGHT TUBE AND 0 SHOWING IN MY LEFT (SLIGHTLY TOO HIGH). I WAS NEVER GIVEN AN HSG - MY OBGYN DID A QUICK KUB X-RAY, WHICH SHOWED ONE TO BE STRAIGHT, AND HOW I HAD SEEN THEM IN PRODUCT INFORMATION, AND ONE LOOKING LIKE A BACKWARDS C. HE PRONOUNCED THEM PERFECT AND MOVED ON. I WAS ONLY 5 WEEKS POSTPARTUM, I HAVE A TILTED UTERUS, AND I HAVE A NICKEL ALLERGY. NONE OF THESE WERE EXPLAINED TO ME AS CONTRAINDICATIONS. PLACING A NICKEL (CONTAINING (B)(4) NICKEL) ON MY ANKLE FOR 24 HOURS LEAVES MY SKIN BRUISED AND ITCHY FOR DAYS AFTERWARD. STARTING THE FIRST PERIOD AFTER ESSURE, I BLED EXTREMELY HEAVILY THE FIRST FEW DAYS OF EACH CYCLE (SOAKING THROUGH SUPER PLUS TAMPONS IN AN HOUR). I DEVELOPED PMDD. PERIODS WERE PAINFUL. THEN PMS BECAME PAINFUL. THEN OVULATION BECAME PAINFUL. FOR THE PAST FEW MONTHS, I HAVE FELT STABBING PAINS CONSTANTLY. OVULATION AND PMS WEEKS HAVE ME IN CRYING AND WRITHING IN BED, AND I AM BACK IN BED THE FIRST CYCLE DAY. I WAS ABLE TO ATTEND WORK 2 DAYS THE PAST WEEK, AND WAS USELESS THE ENTIRE TIME. TWO SEPARATE DOCTORS REFUSED TO BELIEVE ANYTHING WAS WRONG (NOTHING LIKE HAVING A MALE DOCTOR TELL YOU THAT YOU JUST DON'T KNOW WHAT A REAL PERIOD FEELS LIKE). THEY STATED THAT THE COILS DO NOT MOVE AFTER PLACEMENT (VERY FALSE - I'VE SEEN THE PICTURES OF ALL THE EMBEDDED ORGANS). I FINALLY FOUND A DOCTOR WHO WILL BE DOING EXPLORATORY SURGERY AT THE END OF THE MONTH. I WILL BE (B)(6) IN A FEW WEEKS, AND AM FACING A PARTIAL HYSTERECTOMY AT LEAST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034407	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 1/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED WITH TIRED, JOINTS HURTING THOUGHT SOME TYPE OF ARTHRITIS. WENT TO MANY DR APPOINTMENTS IN 2012 AND HAD TONS OF LABORATORY WORK DONE AND X-RAYS. NEVER BEING DIAGNOSED WITH ANYTHING. CONTINUED BLOATING AND HEADACHES, PELVIC PAIN, METALLIC TASTE IN MOUTH, PAIN DURING INTERCOURSE, LOWER BACK PAIN. RECENTLY HAD A MISCARRIAGE AND WASN'T SUPPOSED TO GET PREGNANT. MENTALLY I AM FOGGY AT TIMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034408	CONCEPTUS	2/13/2014	2/14/2014

Event Information:

Event Date (B3): 8/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HEAVY PERIODS WITH HUGE BLOOD CLOTS. MIGRAINES, HAIR LOSS, LOWER BACK PAIN, ITCHY SKIN ALL THE TIME, HORRIBLE MOOD SWINGS, WEIGHT GAIN, BAD CRAMPS, TIRED ALL THE TIME, NO SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034420	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 12/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THREE DAYS AFTER PULLING FEELING IN MY STOMACH, HEADACHES, BLURRED VISION, MEMORY LOSS, HAIR LOSS, ANXIETY, PIMPLES LIKE CYSTS, METAL TASTE, DENTAL PROBLEMS, BACK HURTS, CRAMPS, PAIN IN FLANK AREA, DIARRHEA, CONSTIPATION, DIVERTICULITIS, HEAVY PERIOD, BLOOD CLOTS, BLEEDING EVERY 15-18 DAYS, BLACK BLOOD, HIPS HURT. I'VE HAD CT, MRI, KUB, ULTRA SOUND, 2 X-RAY, COLONOSCOPY, LAPAROSCOPY, "HISTOROCPY" AND I'VE TRIED LOTS OF MEDICATION, PHYSICAL THERAPY, PAIN MANAGEMENT, BIRTH CONTROL PILLS X2, 60+ DR VISITS AND ER VISIT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034421	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 10/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL AND PELVIC PAIN, BACK PAIN, HEAVY PERIODS, HAD TO BE REMOVED IN (B)(6) 2012 DUE TO ABCESSES FORMED AROUND THE TUBULES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034423	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 8/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

VERY PAINFUL CRAMPING EACH MONTH ASSOCIATED WITH CYCLE, BLOATING TO THE POINT CLOTHES DON'T FIT AND LOOK PREGNANT, HEAVY CYCLE WHERE I USE SEVERAL OVERNIGHT PADS TO CONTROL, LARGE CLOTS, AT TIMES NO CYCLE FOR MONTHS, THEN CYCLE APPEARS FOR SEVERAL WEEKS AT A TIME AND IS VERY PAINFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034424	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 5/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE PUT IN, CHRONIC PELVIC PAIN (WORSE DURING MENSTRUAL CYCLE AND OVULATION).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034429	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 8/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DEVICES PLACED IN (B)(6) OF 2011, SINCE THE IMPLANTATION OF THE ESSURE, I HAVE HAD UNCONTROLLABLE BLOATING PAIN, AND HEAVY PERIODS WITH CLOTTING AND HORRIBLE CRAMPS. SOME MONTHS THE PAIN IS SO STRONG I HAVE DIARRHEA AND VOMITING. I HAVE HAD PAIN, TENDERNESS, AND WHAT FEELS LIKE MUSCLE SPASMS ALL OVER MY BELLY SINCE THE PROCEDURE. SOMETIMES IT GETS FIRM AND REMINDS ME OF CONTRACTIONS LIKE WHEN I AM PREGNANT. I HAVE NOTICED MY PERIODS INCREASINGLY HEAVIER, LAST MONTH I SOAKED THROUGH A SUPER-PLUS TAMPON AND BACKUP PAD EVERY 1-2 HOURS PLUS LARGE CLOTS. SEVERAL TIMES I HAVE JUST CHANGED AND HAVE A SUDDEN GUSH OF BLOOD AND I AM NOT ABLE TO MAKE IT TO THE BATHROOM WITHOUT A BIG MESS. I NEVER HAD HEAVY PERIODS UNTIL ESSURE. DOCTORS SAID I WAS LUCKY TO HAVE BABIES BECAUSE MY PERIODS WERE SO LIGHT AND ONLY LASTED A FEW DAYS. I ALSO CONTINUE TO SUFFER FROM MANY OTHER SYMPTOMS SUCH AS SEVERE HEADACHES/MIGRAINES, PELVIC PAIN, LOWER BACK PAIN, THYROID PROBLEMS, GASTRO PROBLEMS (JUST HAD AN EXPLORATORY SURGERY), ADRENAL PROBLEMS, INTERCOURSE IS PAINFUL DURING AND AFTER. I HAVE HAD 2 YEAST INFECTIONS, 2 BACTERIAL INFECTIONS, AND 2 BLADDER INFECTIONS IN THE LAST SEVERAL WEEKS, HAIR LOSS, VERY BAD PERIODS, STABBING PAIN, BLOATING (LOOK LIKE I AM PREGNANT), MY STOMACH SEEMS TO BE GETTING BIGGER AND BIGGER AND I THINK IT IS BECAUSE I AM SWOLLEN INSIDE. I HAVE ALSO WOKE UP SEVERAL NIGHTS CRYING OUT BECAUSE OF HORRIFIC CHEST PAIN. (I WAS SO NERVOUS I WAS HAVING A HEART-ATTACK OR WOULD NOT WAKE UP THE NEXT MORNING). I USED TO PLAY SOCCER AND BE ABLE TO LIFT WEIGHTS AND WORK OUT EVERYDAY. I CAN NO LONGER WORKOUT OR PLAY WITH MY KIDS. I DON'T GET TO DO ANY OF THE THINGS I USED TO LOVE DOING WITH MY FAMILY. I STRUGGLE TO EVEN GET OUT OF BED IN THE MORNING TO GET MY KIDS BREAKFAST AND HELP GET THEM READY FOR THE DAY. I AM SO TIRED AND

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FATIGUED ALL THE TIME NO MATTER HOW MANY HOURS OF SLEEP I GET. IT IS SO FRUSTRATING... THE LIST JUST KEEPS GETTING LONGER AND LONGER.. I HAVE GONE TO SEVERAL DOCTORS AND HAVE BEEN TOLD BY ALL OF THEM THAT THESE SYMPTOMS ARE NOT FROM ESSURE. I AM SICK OF DOCTORS NOT BELIEVING ME AND THINKING I AM CRAZY. I AM SCHEDULED TO SEE ANOTHER DOCTOR IN 2 WEEKS AND HOPEFULLY I AM ON MY WAY OF GETTING THESE THINGS OUT OF ME AND GETTING ON WITH MY LIFE .. THIS EXPERIENCE HAS BEEN TERRIBLE. MY FAMILY AND I HAVE SUFFERED FOR 2 1/2 YEARS AND STILL NO RELIEF. I HAVE SPENT SO MUCH TIME AND MONEY TRYING TO GET HELP AND STILL DO NOT HAVE HELP TO THIS DAY. I DO NOT CARE ABOUT THE MONEY BUT I AM SICK OF BEING IN CONSTANT PAIN. I WANT THE DOCTORS TO BE INFORMED. JUST LIKE SOME PRESCRIPTIONS DO NOT WORK FOR SOME I BELIEVE ESSURE IS THE SAME. I DO KNOW THAT IT WAS NOT RIGHT FOR ME AND MY BODY. THE DOCTORS WHO PLACE THE COILS NEED TO BE AWARE THAT IT IS NOT RIGHT FOR SOME WOMEN AND NEED TO BE EDUCATED ON HOW TO REMOVE THE COILS. IT IS TIME THAT WE ADMIT THAT THEIR IS A PROBLEM WITH ESSURE AND STOP DENYING THE SIDE EFFECTS THAT OCCUR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034430	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 7/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DIAGNOSED WITH FIBROMYALGIA, PSORIASIS, ITCHY SKIN AND SCALP, NAUSEA AND VOMITING, HAIR LOSS, MEMORY LOSS AND HARD TIME CONCENTRATING, CONSTANT HEADACHES, BLURRED VISION, FACE PAINS, BACK PAINS, BODY AND JOINT PAINS, BODY TINGLING AND NUMBNESS, INFLAMMATION, CHEST PAINS, LOSS OF BREATH, HEAVY AND PAINFUL PERIODS, BIG CLOTS DURING PERIODS, CONSTANT BLEEDING, SWELLING OF FEET, FATIGUE AND WEAKNESS, ANXIETY AND DEPRESSION, HURT TO TOUCH SKIN, PELVIC PAIN, HIP PAIN, BLOATING OF STOMACH, WEIGHT GAIN, MOODINESS, LOSS OF SEX DRIVE, HARD TO LOSE WEIGHT, BRUISE EASILY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034435	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 12/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE PLACED, I HAVE EXPERIENCE COUNTLESS ADVERSE REACTIONS. I HAVE HAD CONSISTENT HEAVY, PAINFUL, AND IRREGULAR MENSTRUATION CYCLES. THERE HAS BEEN A DRASTIC INCREASE IN MIGRAINE EPISODES. I HAVE DEVELOPED PERSISTANT LOWER BACK AND PELVIC PAIN, BLOATING, GASTROINTESTINAL ISSUES, BRAIN FOG, AND MOOD SWINGS. I ABSOLUTELY BELIEVE THAT THESE ARE RELATED TO THE ESSURE PLACEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034436	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY DOCTOR URGED ME FOR 3 YEARS TO GET THEM AND FINALLY I CAVED. I HAVE ALWAYS HAD CERVICAL ISSUES AND AFTER 4 CHILDREN, I WAS MOST DEFINITELY FINISHED HAVING CHILDREN SO MY DOCTOR KEPT URGING ME TO GET THE ESSURE BECAUSE IT WAS "QUICK AND EASY AND SAFE." BIRTH CONTROL PILLS NEVER WORKED FOR ME, I GOT PREGNANT ON THE PILL, IT ALWAYS GAVE ME HIGH BLOOD PRESSURE AND HORRIBLE UTI'S. PLUS, I HAVE THYROID ISSUES AND THIS WAS A NON-HORMONAL WAY FOR ME TO END MY CHILD BEARING YEARS SO IT REALLY SEEMED LIKE THE ANSWER TO MY PRAYERS. WELL, MY DOCTOR GOT THE FIRST ONE IN PRETTY EASILY, AFTER 5 MINUTES HE SAID "WE'RE HALFWAY THERE (B)(6)!" BUT 40 MINUTES LATER WITH ME LITERALLY SCREAMING AND CRYING HE GAVE UP AND SAID I NEEDED TO COME BACK IN 2 WEEKS AND HE'D TRY AGAIN TO GET THE 2ND ONE IN. HE ONLY TRIED FOR SO LONG AT MY URGING. HE WANTED TO STOP AFTER 20 MINUTES BUT I BEGGED HIM TO KEEP TRYING BECAUSE I DIDN'T WANT TO DO IT ALL OVER AGAIN. YOU'RE ALREADY THERE, I'M ALREADY IN PAIN - JUST FINISH IT! FORTY MINUTES LATER, NO SUCH LUCK AND HE INSISTED ON STOPPING. I SPENT 2 DAYS IN BED IN IMMENSE PAIN. HONESTLY, THE CLOSEST THING I COULD COMPARE IT TO IS CONTRACTIONS. I REALLY FELT LIKE I WAS HAVING CONTRACTIONS EVERY 10-15 MINUTES. IT WAS AWFUL BUT HE SAID THAT I HAD TO FOLLOW THROUGH AND GET THE SECOND ONE INSERTED OR THE WHOLE THING WAS A WASTE OF TIME. WE TALKED A LOT ABOUT IT AND HE SAID HE WOULD GIVE ME STRONGER MEDS BEFOREHAND AND WOULD GO ABOUT IT DIFFERENTLY AND NOT TO WORRY, HE WOULD TAKE CARE OF ME. I LOVE MY DOCTOR SO I TRUSTED HIM AND IT WASN'T REALLY BAD AT ALL. THE SECOND TIME AROUND HE GAVE ME MORE PAIN MEDS BEFORE HAND AND A STRONGER XANEX AND HE GOT IT IN AFTER 10-15 MINUTES, IT WASN'T EASY FOR HIM TO GET IT IN BUT HE SPOKE TO OTHER DOCTORS WHO HAD SIMILAR PROBLEMS AND WENT ABOUT IT DIFFERENTLY. THERE WERE NO TEARS, NO MAJOR PAIN

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AFTERWARDS. I WAS FINE. 3 MONTHS LATER I HAD THE ULTRASOUND AND BOTH TUBES WERE CLOSED SO I WAS HAPPY. MY FRIEND (WHO WORKS FOR AN OB) WAS NOT PLEASED WITH ME AND SAID WITH MY HISTORY, I SHOULD NOT BE MESSING AROUND AND THAT WE SHOULD HAVE JUST USED CONDOMS UNTIL I HIT MENOPAUSE BUT IT WAS JUST SO ANNOYING AND THIS SEEMED SO MUCH EASIER! WELL, HERE WE ARE ALMOST A YEAR LATER. I HAVE THIS BELLY NOW, THAT I NEVER HAD BEFORE AND I JUST ATTRIBUTED IT TO ME BEING STRESSED (CARING FOR MY PARENTS NOW AS WELL AS BEING THE BREADWINNER OF MY FAMILY OF 6) BUT NOW I HAVE MY PERIOD AND I'M ON DAY 6 HERE AND STILL THE HEAVIEST FLOW I CAN DESCRIBE IN ADDITION TO BLOATING SINCE INSERTION AND CONSTANT BACK PAIN

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034437	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE MENSTRUAL CRAMPING, HEADACHES, SEVERE DEPRESSION, WEIGHT GAIN, BLOATING, CYSTIC ACNE, HAIR LOSS AND THINNING, HIP BURNING SENSATION, NECK PAIN, LEFT SIDE OF BODY PAIN, METAL TASTE IN MOUTH, HEAVY MENSTRUAL BLEEDING THAT LASTS 8-9 DAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034438	BAYER	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 1/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STILL HAVE NOT HAD A HYSTERECTOMY TO HAVE ESSURE REMOVED. RECENTLY WAS SEEN BY THE DOCTOR BECAUSE MY BLEEDING HAS GOTTEN HEAVIER AND I AM NOW PASSING BOUNCY BALL SIZED CLOTS. DOCTORS HAVE PLACED ME ON BIRTH CONTROL TO TRY AND CONTROL THE BLEEDING. THE PAIN IN MY LEFT SIDE IS GETTING WORSE TO THE POINT WHERE I AM UNABLE TO FUNCTION FOR DAYS AT A TIME AND THIS OCCURS MOSTLY WHEN I AM ON MY PERIOD. MY BLOATING HAS INCREASED AND MY CRAMPS DURING MY MONTHLY CYCLE HAVE ALSO INCREASED. I NOW ALSO HAVE A RASH THAT COMES AND GO DAILY WHICH OCCURS ON MY ABDOMEN, LEGS, AND ARMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034439	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 1/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN BLEEDING LIGHT TO MEDIUM FLOW FOR 4 WEEKS, SINCE THE DAY I HAD THE ESSURE PROCEDURE. MY BELLY LOOKS AND FEELS LARGER AND BLOATED. I FEEL IRRITATED IN AND OUTSIDE OF VAGINA FROM THE PROLONG BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034440	BAYER	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 3/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY EXPERIENCE WITH ESSURE IS MISERABLE. I HAVE BEEN EXPERIENCING VERY BAD HEADACHES, FATIGUE, BACK PAIN, PELVIC PAIN, AND BLOATING. I HAVE BEEN EXPERIENCING THESE PROBLEMS STARTING IN (B)(6) 2013. I AM VERY UNHAPPY WITH THIS DEVISE, THE DR THAT PLACED MY ESSURE HAD PROBLEMS PLACING MY LEFT ONE FOR IT GOT STUCK AND HAD PROBLEMS PLACING IT . IT WAS VERY PAINFUL. MY MEDICAL PROBLEMS ARE: SVT AND I WAS BORN WITHOUT A SPLEEN. MY ALLERGIES ARE: IODINE AND LATEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034441	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 9/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE MY ESSURE WAS PLACED I HAVE BEEN BLEEDING AND HAS NOT STOPPED. CRAMPING, BACK PAIN, DIZZINESS, HAIR LOSS, SHARP STABBING PAINS IN LOWER ABDOMINAL AREA, FATIGUE, LOW ENERGY, LOW-NO SEX DRIVE, HEAVY BLEEDING AFTER SEX, HEAVY DISCHARGE, FOUL SMELL, SEVERE HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034442	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 4/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM THE MOMENT I HAD ESSURE PUT IN ME, I HAD CONSTANT LOWER ABDOMEN PAIN AND CRAMPING. IF I TRIED TO WALK OR MOVE AROUND MUCH IT WOULD AGITATE IT EVEN WORSE. MY LOWER BELLY FELT BLOATED BUT I JUST ASSUMED IT WAS FROM THE PROCEDURE. NONE OF IT EVER WENT AWAY UNTIL I HAD IT REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034443	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 2/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT MY ESSURE IMPLANTS IN (B)(6) 2010 (I ALSO HAD MY GALL BLADDER REMOVED RIGHT BEFORE THIS) AT FIRST I THOUGHT MY PAIN WAS FROM HAVING A FOREIGN OBJECT PUT INTO MY BODY. SIX MONTHS LATER I AM STILL HAVING THE SAME PAINS, I THOUGHT THAT MY SURGERY FROM MY GALL BLADDER WAS INFECTED SO I WENT BACK TO THE DOCTOR TO CHECK FOR INFECTIONS, GOT THE ALL CLEAR. SO NOW I HAVE DEALT WITH THIS PAIN FOR 2 YEARS AND NOW IT SEEMS TO BE GETTING WORSE. (B)(6) 2013 I THOUGHT I COULD POSSIBLY HAVE CANCER SO I WENT TO THE DOCTOR AND HAD THEM TEST ME FOR EVERYTHING UNDER THE SUN, STILL ALL CLEAR. SO NOW HERE I AM 3 1/2 YEARS LATER AND STILL HAVE ALL THESE PAINS (HAIR LOSS, ALWAYS TIRED, IF I SIT THE WRONG WAY MY LEGS GO NUMB, TINGLY FEELING IN MY LIMBS, EAR ACHES, HEADACHE WHICH I THOUGHT WAS MY EYES ITS NOT, CONSTANT SHARP PAIN WHERE MY OVARIES AND TUBES ARE, OVARIAN CYSTS THAT I HAVE NEVER HAD BEFORE HAVING ESSURE WHICH WHEN THOSE BURST THE PAIN IS UNBEARABLE, THE CONSTANT BLOATED FEELING AND LOOKING LIKE I AM 8 MONTHS PREGNANT ALL THE TIME). I AM AT THE POINT WHERE I AM TYING A ROPE AND HANGING ON. I HAVE BEEN TO DOCTORS AND NOBODY SEEMS TO HAVE ANSWERS FOR MY UNEXPLAINED PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034444	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FATIGUE, WEIGHT GAIN,DEPRESSION, ACHES AND PAINS, CONTINUOUS HEADACHE, NIGHT SWEATS, HOT FLASHES, MEMORY PROBLEMS, GAS,BLOATING, IRREGULAR PERIODS, CRAMPING(LEGS AND ABDOMEN), NUMBNESS AND TINGLING IN LIMBS, BREAST TENDERNESS, NO "SEX DRIVE", FEELING SICK(WHEN NOT). ALL LABS ARE NORMAL!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034445	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 1/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'M IN CONSTANT PAIN ON THE LEFT SIDE, HEAVY PERIODS, I CAN FEEL THE COIL DURING SEX WHICH IS TOO PAINFUL SO I DO NOT HAVE SEX AT ALL. I HAVE ITCHY RASHES OFF AND ON. I HAVE A LOT OF JOINT PAIN AND INFLAMMATION ALL THE TIME FROM THE NICKEL AND PET I THINK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034446	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 3/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BEGAN TO DEVELOP NICKEL ALLERGY, ADRENAL FATIGUE. SUFFERED FROM SEVERE ABDOMINAL PAIN, UNUSUAL MOOD SWINGS, HEADACHES, BACK PAIN, CYSTIC ACNE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034447	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED PASSING BLOOD CLOTS WITH STOOLS AT THIS TIME. I SUFFER FROM CHRONIC FATIGUE AND CONSTANT HEADACHES. I ALSO HAVE SWOLLEN LYMPH NODES DUE TO AN ALLERGIC REACTION WITH THE ESSURE IMPLANTS. I GOT A SPOTTY SKIN RASH THAT COMES AND GOES. I HAVE A CONSTANT STABBING PAIN IN MY ABDOMINAL AREA. I CAN NO LONGER HOLD A JOB BECAUSE I SEEM TO BARELY FUNCTION ON A DAILY BASIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034448	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 10/29/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE IMPLANTS INSERTED, I AM HAVING HAIR LOSS, DIZZINESS, FATIGUE, PAINFUL INTERCOURSE, 3 PERIODS IN A MONTH, NO PERIOD IN A MONTH AT ALL, RASHES IN BOTH SIDES OF MY BELLY WHERE MY OVARIES ARE, MOOD SWINGS, NIGHT SWEATS, HOT FLASHES, SICK, FEEL LIKE I AM DYING, PINCHING AND PAIN IN MY BELLY AND BACK, NUMBNESS IN LEGS FEET AND HANDS, AND I'M IN CONSTANT PAIN. MY PERIODS ARE WORSE THEN EVER AND HEAVIER. I HAVE CERVICAL CANCER NOW. I HAD AN CYST 5CM BIG ON MY LEFT OVARY LIKE ONE YEAR AGO. I JUST WANT THESE OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034449	BAYER	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

STABBING PAIN IN BELLY BUTTON LASTING 10 DAYS PER MONTH CONTINUOUSLY, FATIGUE, SWIMMY HEAD, BLOATED, VITAMIN DEFICIENCY, THYROID, CONSTIPATION, NUMBNESS IN DIGITS, HEADACHES, BRAIN FOG, EYE WEAKNESS, SWOLLEN/SORE TOES, EAR RINGING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034450	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2012 I STARTED TO EXPERIENCE TWINGES OF PAIN IN MY LOWER RIGHT ABDOMINAL AREA ACCOMPANIED BY NAUSEA. I ALSO STARTED HAVING VISIBLE BLOOD IN MY URINE AFTER RUNNING OR HIKING. I WAS REFERRED TO A UROLOGIST WHO BEGAN A SERIES OF PROCEDURES - A CYSTOSCOPY, TWO CT'S, AND A URETEROSCOPY. NONE OF THESE PROCEDURES RESULTED IN AN EXPLANATION FOR THE PAIN OR CONSTANT MICROSCOPIC BLOOD IN MY URINE. MY GYNECOLOGIST DID A BATTERY OF TESTS FOR STD'S (ALL NEGATIVE) AND AN ULTRASOUND TO CHECK THE PLACEMENT OF THE ESSURE DEVICES AND THEY APPEAR TO BE WHERE THEY SHOULD BE. I AM STILL HAVING PAIN ON THE RARE OCCASIONS THAT I RUN OR HIKE AND EXPERIENCE CONSTANT FATIGUE. I HAVE ALSO STARTED GAINING WEIGHT BECAUSE I CAN NOT LEAD THE ACTIVE LIFESTYLE I ONCE DID.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034451	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 10/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED ITCHING. AT FIRST, IT WAS JUST ITCHING HERE, AND THEN GOT MORE PROGRESSIVE, AND THEN STARTED GETTING HIVES ALL OVER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034452	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CRAMPING, PAIN, HEADACHES, IRREGULAR AND VERY HEAVY MENSTRUATION BLOATING JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034453	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 12/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN MY PELVIC AREA AND THE PAIN RUNS DOWN MY LEG. I HAVE METAL TASTE IN MY MOUTH. I ONLY HAVE THE ESSURE ON MY RIGHT SIDE AND THAT'S WHERE I HAVE THE PAIN. MY STOMACH IS BLOATED MOST OF THE TIME I LOOK PREGNANT. WHEN IM SITTING DOWN OR BENDING THE RIGHT SIDE OF MY PELVIC AREA HURTS WORST. I CAN'T WEAR JEANS BECAUSE IT HURTS ANY PRESSURE I PUT ON IT. IT HURTS. I ONLY HAVE THE ESSURE ON MY RIGHT BECAUSE THE DOCTOR WAS HURTING ME DURING THE PROCEDURE AND I ASKED HER TO STOP. THE WEEK AFTER THAT SHE TIED MY TUBS. SINCE THEN I HAVEN'T STOPPED SPOTTING AND HAVE NOT HAD A PERIOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034454	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 7/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SHARP PAIN IN LOWER BACK AND STOMACH, PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034455	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 7/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SHARP PAIN IN LOWER BACK AND STOMACH, PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034456	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT ABDOMINAL PAIN AND CRAMPING, GALLBLADDER FAILED AND REMOVED IN (B)(6) 2013, GI ISSUES (CONSTIPATION, DIARRHEA, IRREGULAR), H PYLORI, DAILY NAUSEA AND INDIGESTION, DAILY EXTREME BLOATING THAT CONTINUES TO GET WORSE AS TIME GOES BY, EXTREMELY HEAVY PERIODS LASTING FOR ABOUT 5 DAYS, THEN CONTINUING FOR ABOUT 4 MORE DAYS AS LIGHT (PINK AND BROWN). CHRONIC FATIGUE AND MUSCLE ACHES. DUE TO TAKING MOTRIN REGULARLY FOR THE ABDOMINAL PAIN AND MUSCLE ACHES, I HAVE DEVELOPED STOMACH ULCERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034457	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 8/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2012, I WENT IN FOR MY HSG TEST (DYE TEST THAT CONFIRMS COILS ARE IN PLACE AND FALLOPIAN TUBES ARE BLOCKED). I WAS TOLD BY THE NURSE ADMINISTRATING THE TEST THAT EVERYTHING LOOKED GREAT AND THAT THE COILS WERE WHERE THEY WERE SUPPOSED TO BE. EXACTLY ONE MONTH LATER, I WAS GETTING READY FOR WORK AND HAD A SUDDEN PAIN IN MY SIDE DEVELOPED. EVENTUALLY, I HAD TO CALL INTO WORK BECAUSE THE PAIN BECAME SO BAD THAT I WAS NOT ABLE TO MOVE AND I LAID IN BED FOR THE REST OF THE MORNING. I FELT DIZZY AND WHEN I ATTEMPTED TO USE THE RESTROOM, I FAINTED. MY HUSBAND HEARD ME HIT MY HEAD ON OUR SHOWER DOOR. LATER THAT AFTERNOON, HE TRIED TO WALK ME TO THE CAR TO TAKE ME TO THE HOSPITAL BECAUSE THE PAIN WAS INCREASING. I FAINTED TWO TIMES BEFORE WE EVEN GOT TO THE FRONT DOOR. WE CALLED 911 AND THE AMBULANCE TOOK ME TO THE ER. IT WAS THERE THAT WE DISCOVERED I HAD SUFFERED AN ECTOPIC PREGNANCY THAT HAD RUPTURED AND FOR THE PAST 12 HOURS I HAD BEEN INTERNALLY BLEEDING. I HAD TO HAVE AN EMERGENCY SURGERY TO REMOVE THE COILS (BOTH OF WHICH HAD MOVED AND PUNCTURED MY UTERUS). MY DR HAD TO COMPLETELY REMOVE MY RIGHT FALLOPIAN TUBE BECAUSE IT WAS BADLY DAMAGED FROM THE ECTOPIC PREGNANCY, AND HE BURNED OFF THE LEFT FALLOPIAN TUBE. BECAUSE I HAD LOST SO MUCH BLOOD DUE TO THE INTERNAL BLEEDING, I HAD TO HAVE A TRANSFUSION TO HAVE THE LOST BLOOD REPLACED. I WAS HOSPITALIZED, MY TWO YOUNG CHILDREN ALMOST LOST THEIR MOTHER AND I LOST A PREGNANCY. ON TOP OF THAT EMOTIONAL ROLLERCOASTER, WE WERE THEN FACED WITH MOUNTING MEDICAL BILLS. I HAVE ALL MY MEDICAL RECORDS FROM WHEN I FIRST HAD ESSURE IMPLANTED, MY TEST RESULTS FROM MY HSG TEST, EVEN MY DR'S NOTES FROM MY EMERGENCY SURGERY STATING THAT ESSURE WAS INEFFECTIVE AND HAD MOVED, PUNCTURING MY UTERUS AND CAUSING MY ECTOPIC PREGNANCY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034458	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 3/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN ME (B)(6) 2013 SINCE THAT DAY I HAVE HAD CRAMPING, STABBING PAIN IN LEFT SIDE WHERE ESSURE WAS IMPLANTED, PAINFUL INTERCOURSE, HEADACHES, BACK ACHES, INFLAMMATION BECAUSE I'M ALLERGIC TO NICKEL AND ESSURE HAS NICKEL IN IT. I HAVE GAINED 50 POUNDS SINCE ESSURE HAS BEEN PLACED IN ME. I DO GO TO THE GYM AND CAN'T LOOSE ANY WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034459	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 10/22/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS TOLD THIS WOULD BE THE OPTION FOR ME INSTEAD OF GETTING MY TUBES TIDE. SINCE THEY HAVE BEEN INSERTED, I HAVE HAD SEVER ABDOMINAL PAIN EVERY DAY, MY PERIODS ARE MORE PAINFUL, I HAVE GAINED ABOUT 40 LBS, I HAVE HAD SPOTS OF ENDOMETRIOSIS REMOVED, I SUFFER WITH MIGRAINE HEADACHES EVERYDAY, ALWAYS FEEL COLD, ALWAYS FEEL TIRED, I JUST RECENTLY RECEIVED THE 2ND LUPRON DEPO SHOT DUE TO THE ENDOMETRIOSIS THAT CAUSES EVEN MORE BAD SIDE EFFECTS AND DON'T UNDERSTAND HOW THIS SHOT WAS EVEN PASSED BY THE FDA BECAUSE OF ALL THE HORRIBLE THINGS IT CAUSES. I AM GOING ON (B)(6) 2014 TO GET AN ULTRASOUND DONE BECAUSE 2 WEEKS AFTER RECEIVING THE 1ST SHOT I DEVELOPED A SWOLLEN THROAT/ NECK ON THE LEFT SIDE WITH SOME KIND OF MASS THAT FEELS KIND OF SPONGY IF YOU PUSH ON IT. HAVING THE ESSURE PROCEDURE DONE IN THE FIRST PLACE IS WHEN ALL OF THESE SYMPTOMS STARTED. I REGRET EVER HAVING IT DONE. IF I HAD IT TO DO ALL OVER AGAIN I WOULD NOT EVEN THINK ABOUT IT. THESE IMPLANTS ARE COSTING LOTS OF WOMEN ALL OVER THE WORLD THERE LIVES AND DOCTORS DON'T SEEM TO EVEN CARE. I BELIEVE THAT THEY SHOULD BE TAKEN OFF THE MARKET NOT TOMORROW, OR A MONTH, OR A YEAR OR TWO FROM NOW, BUT RIGHT NOW, TODAY!!!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034460	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

INITIALLY THERE WAS AN ENORMOUS AMOUNT OF WEIGHT ACCUMULATED ONLY IN THE STOMACH AREA. MY WEIGHT WENT FROM (B)(6). EVEN WITH DAILY EXERCISE, THE STOMACH AREA STAYED BLOATED FOR WEEKS AT A TIME. IT LOOK AS IF I WERE 6 MONTHS PREGNANT. THERE HAVE BEEN AT LEAST 5 TIMES PER YEAR SINCE THE IMPLANT THAT I WILL EXPERIENCE DAYS OF NAUSEA, DIARRHEA, VOMITING AND THEN MIGRAINES. AT THE END OF THAT WEEK, I COULD NOT WALK AND WAS ADMITTED TO THE EMERGENCY ROOM IN THE LOCAL HOSPITAL. THE BLOATING STILL PERSISTS AT LEAST EVERY OTHER WEEK. THE MIGRAINES HAPPEN AT LEAST ONCE EVERY THREE WEEKS. I NOW ENDURE SHARP PAINS IN MY LOWER ABDOMEN. THIS PAIN IS SHARP AND PAINFUL TO THE POINT THAT I CANNOT WALK OR MOVE. EVERY MORNING I EXPERIENCE NAUSEA AND SOME VOMITING. MY MENSTRUAL CYCLES ARE PAINFUL WITH AN ENORMOUS AMOUNT OF THICK BLOOD CLOTS THAT LITERALLY DROP FROM MY VAGINA. I HAVE AN ALLERGY TO NICKEL. SO MUCH SO THAT I CONSTANTLY BREAK OUT IN HIVES, BLOTCHY AND ITCHY SKIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034461	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CRAMPS, HEAVY BLEEDING, HEADACHES, BODY ACHES, SICK TO STOMACH, HAIR LOSS, CONSTIPATION AND NOW IBS. MAJOR FATIGUE, TINGLING IN LEGS. FEELING UNWELL. LOSS OF COIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034462	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 11/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM THE MOMENT OF IMPLANTATION, ON (B)(6) 2013, I HAVE HAD LOWER BACK PAIN, HEADACHES, SHARP PAINS IN OVARY AREA AND EVERY DAY BLEEDING. AT THE END OF (B)(6) 2014, I PASSED A PIECE OF BROKEN COIL FROM MY VAGINA. MY LOWER BACK PAIN GOT WORSE AND I GOT UPPER LEG PAIN TOO. I WENT TO SEE MY DOCTOR AND HE DID AN ABDOMINAL X-RAY AND SAID MY COILS WERE IN PLACE AND IT IS NO BIG DEAL. HE TOOK ME OFF THE PILL AND PUT ME ON ESTROGEN SUPPLEMENTS FOR THE DAILY BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034463	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 11/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HEADACHE EVERYDAY, I HAVE GAINED 30 POUNDS, I FEEL LIKE I HAVE BOBBED-WIRE IN ME, MY PERIODS ARE CRAZY, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034464	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 6/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HEAVY BLEEDING THAT LASTS FOR 8 DAYS, I HAVE SEVERE BLOOD CLOGS, BAD CRAMPING, PAIN IN MY LOWER BACK, HAIR LOSS MIGRAINES, FATIGUE, WEIGHT GAIN, BLOATING,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034465	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 12/23/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE STABBING PAIN IN BOTH TUBE'S CURRENTLY AND SINCE I HAD THEM PUT IN, RASH ON LEGS A COUPLE OF TIMES IN 2012 AND 2013, VERY TO HARD TO CLIMAX AND PAIN DURING INTERCOURSE, MIGRAINE HEADACHES STARTED WHEN I HAD ESSURE IMPLANTED AND CURRENTLY, DEPRESSION STARTED ABOUT 10 MONTHS AFTER IMPLANTED, HAIR LOSS STARTED IN 2012 TO CURRENT, ANKLE AND KNEE JOINT PAIN STARTED IN 2013 CURRENTLY ALL MY JOINTS HURT WHEN I TAKE A SHOWER AND THE WATER HITS MY BACK IT FEELS LIKE MY BACK IS GOING TO CRACK, FEELING OF POISON THROUGH MY LEGS, DIZZY SPELLS, NAUSEA, FATIGUE, NEAT PASSING OUT EPISODES WITH RINGING OF EARS AND SEEING SPOTS, EXTREME PMS SYMPTOMS, EXTREME BLOATING, FOGGY HEADED, PROBLEM WITH MEMORY, BACK PAIN, ALLERGIC REACTION TO MEDICATIONS, PELVIC PAIN , P.I.D WITH NO UTI OR STD. (B)(6) 2014 AT (B)(6) HOSPITAL, (B)(6) WAS ADMITTED FOR PASSING OUT FROM SHOT CEFTRIAXONE, ANXIETY,PROBLEMS SLEEPING, SHORTNESS OF BREATH IF WALKING OR MOVING TOO FAST, HEART PAIN, 2 POSITIVE PREGNANCY TEST AND 2 NEGATIVE (NOT PREGNANT), PREGNANCY SYMPTOMS, I AM (B)(6) OLD BUT WAKE UP DIZZY AND ACHING FEELING LIKE 80 YRS OLD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034466	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 10/4/2000 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

VERY HEALTHY FEMALE WITH THREE CHILDREN, NORMAL VAGINAL BIRTHS. PARTICIPANT IN STOP CLINICAL TRIAL LATER TO BE NAMED ESSURE. CONSCIOUS SEDATION USED DURING PROCEDURE. NO COMPLICATIONS DURING PROCEDURE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034467	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 3/5/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN DURING SEX, PAINFUL AND VERY HEAVY PERIODS. SHARP PAINS ON RIGHT SIDE INNER HIP AREA, SHARP PAINS IN VAGINAL AREA INSIDE, LOSS OF HAIR, FATIGUE, SKIN RASHES, CONSTANT DISCHARGE, CRAMPING AND BLOATING 24-7.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034468	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 4/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT ALL STARTED IN (B)(6) 2013. I WENT TO THE DOCTOR ASKING ABOUT ADIANA BECAUSE A FRIEND OF MINE HAD IT DONE AND SHE WAS BACK TO WORK THE NEXT DAY WITH NO PROBLEMS. MY HUSBAND AND I HAD DECIDED WE DEFINITELY DIDN'T WANT ANY MORE CHILDREN AND WERE LOOKING FOR A PERMANENT STERILIZATION THAT WOULD BE NON-INVASIVE AND I WOULD NOT MISS WORK. I HAD ONLY BEEN AT MY CURRENT JOB 7 MONTHS, SO IT WAS VERY IMPORTANT TO US THAT I DIDN'T MISS MUCH WORK. MY DOCTOR DETERRED ME FROM ADIANA AND ENCOURAGED ME TO TRY ESSURE INSTEAD. I READ THE PAMPHLET AND TALKED TO MY HUSBAND AND SINCE IT'S A SIMILAR PROCEDURE, WE AGREED TO DO IT AND SCHEDULED THE APPOINTMENT TO GET ESSURE PLACED. MY ESSURE PROCEDURE WAS DONE ON (B)(6) 2013. FROM THE MOMENT I WOKE UP I HAD PAIN. THE VERY DAY I HAD MY PROCEDURE MY FATHER WENT INTO THE HOSPITAL. SO A WEEK GOES BY AND I'M IN PAIN BUT I FIGURE IT'S BECAUSE I HAVE YET TO LET MY BODY REALLY REST SINCE I HAD BEEN GOING BACK AND FORTH TO THE HOSPITAL. I HAD CONSTANT CRAMPING WITH THE LEFT SIDE BEING MORE PAINFUL THAN THE OTHER. I KEEP TELLING MYSELF I'VE JUST BEEN OVER DOING IT. I FELT LIKE I WAS HAVING BRAXTON HICKS CONTRACTIONS 24/7 AND IF I MOVED AROUND TOO MUCH THE PAIN RADIATED TO MY BACK AND IT FELT LIKE BACK LABOR. I WAS SO CONVINCED THAT IT WAS LIKE LABOR PAINS I EVEN TOOK A PREGNANCY TEST TO MAKE SURE I WAS NOT PREGNANT. THE ONLY THING THAT HELPED THE PAIN WAS TO LAY FLAT ON MY BACK. MY KIDS WOULD HAVE TO COME LAY IN THE BED TO SPEND ANY TIME WITH ME. I TRIED TO GO TO THE MOVIES WITH MY HUSBAND AND CRIED SO HARD BECAUSE IT HURT TO SIT THAT NEITHER ONE OF US COULD EVEN ENJOY THE MOVIE. ON (B)(6) 2013 I FINALLY WENT TO THE ER BECAUSE I WAS SO TIRED OF BEING IN PAIN. THEY GAVE ME PAIN MEDICINE AND TOLD ME TO CALL THE DOCTORS OFFICE FIRST THING IN THE MORNING. I CALLED THE OFFICE AND THEY TOLD ME TO COME IN AT 2PM. ABOUT 1PM I GOT A

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PHONE CALL FROM MY DOCTORS NURSE TELLING ME THE DOCTOR SAID TO JUST NOT WORRY ABOUT COMING IN AND GIVE MY BODY A FEW MORE DAYS ON THE PAIN PILLS TO SEE IF IT CALMS DOWN. AROUND 5PM WE GOT A CALL FROM THE DOCTORS OFFICE ASKING WHY I WAS A NO SHOW AFTER HAVING BEEN IN THE ER THE NIGHT BEFORE. CLEARLY MY HUSBAND AND I WERE LIVID AND AT THE DOCTORS OFFICE FIRST THING THE NEXT MORNING. AT THE OFFICE THAT MORNING HEADS WERE ROLLING AND MY DOCTOR FINALLY SHOWED UP TO SEE ME. I SAW MY DOCTOR AND SHE SAID IT'S PROBABLY JUST SOME SMALL INFECTION THAT IS CAUSING ME SUCH DISCOMFORT. ANTIBIOTICS WERE PRESCRIBED AND SHE TOLD ME TO COME BACK IN TWO WEEKS. IN THE MEANTIME I'M MISSING OUT OF MY LIFE BECAUSE THE ONLY WAY TO AVOID THE CRAMPING IS TO LAY STILL ON MY BACK. I COULDN'T STAY AT HORSE SHOWS THAT I HAD WANTED TO ATTEND OR TRAIL RIDES THAT I HAD PLANNED WITH FRIENDS. I HAD TO CANCEL A PLANNED TRIP TO (B)(6) THAT MY CHILDREN WERE REALLY LOOKING FORWARD TO. FAMILY AND FRIENDS WOULD COME BY AND JUST SIT ON MY BED TO KEEP ME COMPANY. I DID MAKE IT IN TO WORK EVERY COUPLE OF DAYS BUT I WOULD SIT THERE IN PAIN AND BREAKING OUT IN A SWEAT TILL THEY JUST TOLD ME TO GO HOME BECAUSE I LOOKED SO BAD. TWO WEEKS PASSED AND I WENT AND SAW THE DOCTOR ON (B)(6) 2013. I TOLD HER NOTHING HAD CHANGED MY PAIN WAS UNBEARABLE AND I WANTED THOSE COILS OUT. IT CONSTANTLY FELT LIKE I HAD TWO COILS IN MY SIDES WHICH I THOUGHT WE WEREN'T SUPPOSED TO FEEL A THING. IT FELT LIKE I COULD ACTUALLY PUT MY FINGERS WHERE THE COILS WERE IN MY BODY. MY BODY WAS CLEARLY REJECTING THEM AND I WAS DONE. SHE AGREED AND SET UP SURGERY TO TAKE OUT THE COILS AND MY FALLOPIAN TUBES THE FOLLOWING MONDAY. (B)(6) 2013, I HAD MY ESSURE REMOVAL. WE WERE GOING TO REMOVE THE COILS AND MY FALLOPIAN TUBES. IT WAS A BITTER SWEET DAY BECAUSE MY BEST FRIEND WAS HAVING HER BABY VIA C-SECTION THAT DAY IN THE SAME HOSPITAL BUT I COULDN'T BE THERE, BECAUSE GETTING THIS POISON OUT OF ME WAS SO IMPORTANT. THE SURGERY TOOK LONGER THAN IT SHOULD HAVE. THE DOCTOR WAS SICK. A PIECE OF EQUIPMENT BROKE AND THEY HAD TO FIND ANOTHER ONE TO FINISH THE SURGERY. THE LEFT COIL HAD MOVED UP MY TUBE AND SHE COULD NOT FIND IT WITHOUT REALLY DIGGING AROUND INSIDE OF ME. WHEN I GOT HOME MY LEFT SIDE LOOKED LIKE IT HAD A GUNSHOT WOUND. I WAS IN SUCH TERRIBLE PAIN I COULDN'T EVEN ENJOY THE COILS BEING GONE. MY AUNT PASSED AWAY AND I WAS HOPING THAT I COULD MAKE IT TO THE FUNERAL BUT THAT WAS NOT GOING TO HAPPEN. I WAS BEDRIDDEN FOR YET ANOTHER WEEK. MY HUSBAND HAD TO TAKE MORE TIME OFF WORK TO CARE FOR ME. I COULDN'T GET UP OUT OF BED BY MYSELF OR ANYTHING. THIS WAS LAPAROSCOPIC SURGERY. I'VE HAD MY GALL BLADDER TAKEN OUT AND I EXPECTED A SIMILAR EASY RECOVERY. BY THE END OF THAT WEEK, MY FRIEND THAT HAD HAD THE C-SECTION WAS MOVING AROUND BETTER THAN ME. AT THAT POINT, I KNEW MY NIGHTMARE REALLY WAS NOT OVER. I CALLED THE ER AND THEY CONTINUED MY PAIN MEDS OVER THE PHONE. THEY TALKED LIKE MAY BE I WAS JUST BEING A WIMP. THEY EVEN HAD ME THINKING MAY BE I WAS JUST OVERLY WEAK IN MY OLD AGE AND DON'T BOUNCE BACK AS WELL LIKE I USED TO. I WAS SUPPOSED TO GO BACK TO WORK THAT FOLLOWING MONDAY. I SUCKED IT UP, DOUBLED UP ON PAIN MEDS AND WITH GREAT AGONY GOT READY FOR WORK AND CLIMBED INTO MY CAR. THAT'S AS FAR AS I GOT. THE PAIN WAS SO INTENSE THAT JUST SITTING I COULDN'T EVEN LEAN OVER AND CLOSE THE CAR DOOR. I HAD TO CALL MY HUSBAND FROM THE CAR BAWLING LIKE A BABY JUST STUCK WAITING THERE FOR HIM TO COME GET ME. STUCK IN MY OWN CAR, IN MY OWN DRIVEWAY. THAT'S WHEN I KNEW THIS WAS NOT ME BEING WEAK, BUT VERY SICK. HUBBY GOT ME TO THE ER. THE ER DOCTOR WAS GETTING FRUSTRATED BECAUSE MY DOCTOR WOULDN'T CALL HIM BACK TO DISCUSS MY CASE. AT THAT POINT, I KNEW I WAS DONE WITH THIS DOCTOR. AFTER A VERY PAINFUL MRI, IT SEEMS MY INTESTINES WERE INFLAMED FROM A TRAUMATIC SURGERY. THAT'S HOW THE ER DOCTOR EXPLAINED IT TO US. SO MORE PAIN MEDICINE AND MORE ANTIBIOTICS WERE PRESCRIBED. A WEEK LATER, I GO BACK AND SEE A NEW OB DOCTOR IN THE SAME FACILITY. HE SAID HE'S NOT SURE IF IT WAS INFLAMED INTESTINES OR A POSSIBLE HEMATOMA UP UNDERNEATH EVERYTHING. HE WAS VERY CARING AND CONCERNED ABOUT MY WELL-BEING. HE TOLD ME TO GIVE A FEW MORE WEEKS AND IF THAT PAIN DIDN'T GO AWAY TO CALL HIM DIRECTLY. A FEW WEEKS LATER, I STARTED HAVING WHAT LOOKED LIKE A CONTINUOUS STITCH COME OUT OF MY LEFT INCISION. I KEPT

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PULLING IT OUT FOR A WEEK UNTIL MY CO-WORKERS INSISTED I TELL THE DOCTOR. I GO BACK TO THE NEW DOCTOR AND HE AGREED IT WAS PROBABLY STITCHING AND TO ONLY PULL IT, IF IT PROTRUDES OUT OF MY BODY. I STOPPED PICKING AT IT BUT YOU CAN SEE IT BUNCHED UP UNDER MY SCAR AND THERE IS A SHARP PAIN IF YOU TOUCH UNDER MY SCAR. I ALSO HAVE A MASS OR SOMETHING UNDER MY RIGHT RIB. IT'S BEEN THERE EVER SINCE THE SURGERY BUT SINCE IT DOESN'T HURT UNLESS I LAY DIRECTLY ON IT, I HAVE NOT BEEN COMPLAINING. THERE'S A POINT WHERE YOU ARE JUST SICK OF DOCTORS AND DON'T WANT TO KEEP GETTING THINGS FIXED. I DO PLAN ON HAVING THIS LOOKED AT THIS SPRING. IT'S JUST RIDICULOUS THAT IF I HAD NEVER STARTED WITH THE ESSURE I WOULDN'T HAVE THESE OTHER HEALTH ISSUES. SO THAT'S MY ONGOING STORY. IT HAS BEEN A TRUE NIGHTMARE. THE SAD THING IS, I AM ONE OF THE LUCKY ONES. (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034469	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 9/20/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED TO PREVENT PREGNANCY AND HAD A TERRIBLE REACTION TO IT. MY ALLERGIES GOT WAY WORSE, I WAS BECOMING ALLERGIC TO THINGS THAT NEVER BOTHERED ME BEFORE. SOME OF THOSE THINGS INCLUDE POTATOES, AVOCADOS, CARROTS, DOGS, AIR OUTSIDE, AND MANY OTHER THINGS. I WAS INCREDIBLY WEAK AND TIRED. I COULDN'T TAKE CARE OF MY FAMILY OR MY HOUSE. I BRUISED REALLY EASILY, I WAS PUKING CONSTANTLY, I WAS PALE, HAD TERRIBLE PELVIC PAIN, WAS DEPRESSED, THOUGHT MY FAMILY WOULD BE BETTER WITHOUT ME ALIVE BECAUSE I COULDN'T TAKE CARE OF THEM AND WAS VERY GRUMPY AND IRRITABLE. I WAS SO WEAK SOME DAYS I WOULD ONLY MOVE OFF THE COUCH TO GO TO THE BATHROOM. I HAVE NEVER BEEN THAT SICK IN MY LIFE. I WOULD GO TO BED AT NIGHTS AND LITERALY THOUGHT I WASN'T GOING TO WAKE UP IN THE MORNING. I THOUGHT MY HUSBAND WOULD FIND ME DEAD. IT DIDN'T START OUT THAT BAD. IT STARTED WITH EXCRUTIATING PELVIC PAIN, FATIGUE AND VERY HEAVY PERIODS, PUKING WHILE ON PERIOD, HEADACHES AND A FEW OTHERS BUT I WAS STILL ABLE TO FUNCTION FOR THE MOST PART BUT EVENTUALLY IT GOT TO THE POINT I TRULY THOUGHT I WAS GOING TO DIE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034470	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 6/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE ESSURE IMPLANTATION, I HAVE HAD MANY SIDE EFFECTS. CLUSTER MIGRAINES, BLOATING, WEIGHT GAIN, PELVIC AND ABDOMINAL PAIN, TINGLING IN MY LEGS, EXTREMELY HEAVY BLEEDING AND CLOTTING (SO MUCH I HAVE HAD TO RESORT TO WEARING DEPENDS), LOW IRON (WAS A REGULAR PLASMA DONOR AND AS TIME PROGRESSES WITH THE ESSURE MY IRON IS GETTING LOWER THAT DONATION IS NOT AN OPTION ANYMORE), MOOD SWINGS, DEPRESSION...THE LIST GOES ON AND ON...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034471	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN LEGS, BLOATING, MIGRAINES, LOSS OF MEMORY, HAIR LOSS. AND MORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034472	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 5/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PALPITATIONS, SHORTNESS OF BREATH, TINGLING DOWN THE ENTIRE LEFT SIDE OF MY BODY, EYES EXTREMELY HEAVY, EXHAUSTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034473	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING FOR MONTHS, CRAMPS SO BAD I COULD BARELY MOVE, MIGRAINES THAT HAVE BEEN PERSISTENT, LOWER BACK PAIN AND PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034474	BAYER	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 2/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOUR DAYS AFTER IMPLANT OF ESSURE I HEMORRHAGED EXCESSIVELY. I ENDED UP GOING TO THE HOSPITAL. MY OB SAID THAT HAD NEVER HAPPENED BEFORE. I THEN BLED FOR 10 MONTHS. SUMMER OF 2011, IRON WAS VERY LOW AND I WOULD PASS OUT DURING EXERCISE CLASSES. SINCE THEN I NOW HAVE JOINT INFLAMMATION, HIP PAIN, BRAIN FOG (LOSS OF MEMORY), I HAD A SPELL OF NUMBNESS AND TINGLING IN MY RIGHT SIDE OF BODY IN (B)(6) 2013, VITAMIN D VERY LOW, AS WELL AS VITIMINS B1, B6, B12 AND IRON AS OF (B)(6) 2013, VERTIGO, ITCHY THROUGHOUT BODY ALL THE TIME (SOMETIMES FEELS LIKE BURNING), MAY BE SENSITIVE TO GLUTEN, VERY IRREGULAR PERIODS AND BLEEDING IN BETWEEN PERIODS, IRREGULAR BOWELS. I WAS A VERY HEALTHY WOMAN BEFORE ESSURE! EVERYTHING WENT DOWNHILL AFTERWARDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034475	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 10/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A COUPLE OF WEEKS AFTER HAVING ESSURE I STARED DEVELOPING A METAL TASTE IN MY MOUTH, THE HIVES IN DIFFERENT AREAS OF MY BODY (BACK, ARMS, BELLY, CHEST, LEGS) , THEN WITHIN A COUPLE OF MONTHS I STARTED WITH A SEVERE PINK EYE INFECTION THAT TOOK ME TO THE HOSPITAL AND URGENT CARE FOLLOWED BY THE OPHTHALMOLOGIST FOR 2 MONTHS. IN MY ROUTINE LAB TEST I SHOW DEFICIENCY ON VITAMIN D, THEN I STARED EXPERIENCING TINGLING IN BOTH ARMS, HANDS AND LEGS (NOT NECESSARILY AT THE SAME TIME), BRAIN FOGS, HEART PALPITATION, MIGRAINES, DIZZINESS, PELVIC PAIN, PRESSURE IN MY RIGHT EYE, PANIC ATTACKS, TIREDNESS, JOIN PAIN AND SO MANY MORE SYMPTOMS THAT ARE MAKING ME FEEL DEPRESSED .

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034476	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 2/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SERIOUS PAIN, HEAVY BLEEDING, HEADACHES, FATIGUE, CLOTTING, SEVERE WEIGH GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034477	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 12/2/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING NONSTOP BLEEDING. ENDED WITH HAVING A HYSTERECTOMY IN 2009. A COIL CAME OUT AND IMBEDDED IN THE LINING OF MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034478	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 5/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED AFTER MY 3 CHILD WAS BORN DUE TO THE FACT THAT MY BODY WAS "WORE OUT." I HAVE 3 HEALTHY CHILDREN BUT HAVE ALSO HAD 2 MISCARRIAGES AND AN ECTOPIC PREGNANCY. WHEN I DISCUSSED MY OPTIONS WITH THE DOCTOR HE SAID THE ESSURE WAS THE BEST OPTION. THE FIRST THING I ASKED HIM WAS ABOUT SIDE EFFECTS DUE TO THE FACT THE I HAD A MIRENA ALSO AT ONE TIME WHICH ALSO GAVE ME MANY PROBLEMS AND HAD TO BE REMOVED. SO THE IDEA OF HAVING SOMETHING ELSE IMPLANTED INSIDE ME WAS VERY SCARY. HE ASSURED ME THAT IS WAS EVERY SAFE AND VERY FEW REPORTS OF SIDE EFFECTS OR PROBLEMS (THIS TURNED OUT TO BE A LIE). IT WAS ONLY. THREE DAYS AFTER I HAD THE ESSURE IMPLANTED THAT I EXPERIENCED MAJOR PAIN AND BLEEDING. I BLEED HEAVY FOR 3 MONTHS STRAIGHT AFTER IT WAS IMPLANTED. AND THE PAIN IS UNBEARABLE. I'M UNABLE TO EAT MUCH DUE TO FACT THAT IT CAUSES ME SEVERE LOWER ABDOMINAL PAIN, CRAMPING, VOMITING AND NAUSEA. I STARTED OUT WEIGHING (B)(6) LBS WHEN IT WAS FIRST PUT IN. AND MY CURRENT WEIGHT IS (B)(6). THE PAIN GETS MORE SEVERE WITH TIME. THE WEIGHT KEEPS FALLING AND MY ABILITY TO KEEP UP WITH 3 KIDS IS DIMINISHING DUE TO THE FACT THE I HAVE STRENGTH AND AM TIRED AND FATIGUE CONSTANTLY. I EVEN HAVE MONEYS WHEN I GET SUPER LIGHT HEADED AND THE ROOM STARTS SPINNING AND I FEEL LIKE I NEED TO PASS OUT. I GET SHAKES AND I'M WEAK, TAKES ME A WHILE TO RECOVER WHEN THIS HAPPENS. IT HAS ALSO MESSED WITH MY HORMONES, I CRY A LOT OVER NOTHING. I CAN BE WALKING DOWN THE AISLE AT THE GROCERY STORE AND START CRYING. MY MOODS CHANGE RAPIDLY. THIS IS AN AWFUL DEVICE AND SHOULD BE REMOVED FROM THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034479	CONCEPTUS	2/14/2014	2/14/2014

Event Information:

Event Date (B3): 3/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ONE ESSURE IMPLANT PLACED ON (B)(6) 2008. THEY COULD ONLY PLACE THE RIGHT SIDE DUE TO ABNORMALITIES IN MY LEFT FALLOPIAN TUBE. I HAD PRE-CONSENTED TO TUBAL LIGATION IN THE EVENT ESSURE WAS NOT POSSIBLE, SO THAT PROCEDURE WAS DONE THE SAME DAY. APPROX 18 MONTHS LATER, IN (B)(6) 2011 I BEGAN EXPERIENCING SHARP STABBING PAINS IN MY LOWER RIGHT ABDOMEN. THESE WERE NOT NORMAL PREMENSTRUAL CRAMPS AND WERE NOT RELATED TO MY CYCLE IN ANY WAY. THE PAIN WAS INTENSE AND DEBILITATING AND THE FIRST TIME I EXPERIENCED IT, THE PAIN LASTED FOR ABOUT 30 MINUTES WHERE I WAS UNABLE TO MOVE OR BARELY BREATH. AFTER THE PAIN SUBSIDED, THERE WAS A RESIDUAL BRUISED FEELING IN THAT AREA THE REST OF THE DAY. I CONTINUE TO EXPERIENCE THESE PAINS AT RANDOM INTERVALS WITH NO CORRELATION TO ACTIVITY, MENSTRUAL CYCLE, OR OTHER ILLNESS. TWO ULTRASOUNDS AND A FULL BLOOD WORKUP HAVE NOT REVEALED ANY OTHER POSSIBLE CAUSE FOR THIS PAIN. I CAN ONLY DESCRIBE IT AS A STABBING PAIN, AS IF SOMEONE HAS TAKEN A DULL KNIFE AND JAMMED IT INTO MY ABDOMEN AND TWISTED IT REPEATEDLY. SOMETIMES IF FEELS AS IF THE STABBING IS COMING FROM THE INSIDE. ON A FEW OCCASIONS, THE PAIN HAS BEEN LOCALIZED IN MY PELVIC AREA AS IF THE KNIFE HAS BEEN INSERTED INTO MY VAGINA. MOST TIMES, THE PAIN CAUSES ME TO STOP IN MY TRACKS AND STRUGGLE FOR BREATH. MY PERIOD HAS ALWAYS BEEN HEAVY, BUT SINCE HAVING THE ESSURE DEVICE IMPLANTED, THERE IS MORE CLOTTING AND THE FLOW IS HEAVIER FOR LONGER DURATION. I HAVE ALSO RECENTLY DEVELOPED UNEXPLAINED BLOATING AND THE TENDERNESS AROUND MY RIGHT TUBE AND OVARY HAS INCREASED. I FEAR THE DEVICE HAS EITHER MIGRATED OR PERFORATED SOMETHING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034610	BAYER	2/18/2014	2/24/2014

Event Information:

Event Date (B3): 1/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): ESSURE SYSTEM
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A96180

Single Use:
Implant Date (E6): 5/30/2013
Explant Date (E7): 1/30/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ALWAYS BEEN A HEALTHY (B)(6) OLD FEMALE, TAKING NO MEDICATION ON A DAILY BASIS EVER, BUT I FELT MY HEALTH GETTING WORSE FOR THE LAST 8 PLUS MONTHS. I HAVE HAD THE FOLLOWING SYMPTOMS AND PAIN SINCE THE PLACEMENT OF ESSURE ON (B)(6) 2013. I FEEL I WAS MISLEAD WITH ESSURE; THERE ARE MORE SIDE EFFECTS THAN BENEFITS OF THIS DEVICE. THESE COILS HAVE ABSORBED A STERILIZING AGENT, ETHYLENE OXIDE, (LISTED ON THE BACK OF ESSURE PACKAGE) DOESN'T DISSIPATE AND AN SEEP INTO YOUR BODY VIA THE COILS. THE STERILIZING AGENT IS A KNOWN CARCINOGEN AND CAN BE ABSORBED INTO PET FIBERS IN THE COILS AND WHEN PET FIBERS COME INTO CONTACT WITH SALT OR SALINE SOLUTION THIS CARCINOGEN AGENT CAN BE RELEASED EVEN FURTHER INTO THE BODY. I HAVE HAD WEIGHT GAIN (CURRENTLY THE HEAVIEST I HAVE EVER BEEN), HEAVY/SEVERE BLEEDING AND CLOTTING WHICH HAS SENT ME TO THE ER TO THEN BE PLACED ON HORMONES FOR 10 DAYS TO STOP/CONTROL THE BLEEDING, SEVERE CRAMPING, HEADACHES/MIGRAINES WEEKLY, HAIR LOSS, MY SKIN IS SO DIFFERENT (BREAKING OUT/RASHES/BLISTERING UNDER JEWELRY), MOODY, EXHAUSTED DAILY, CAN'T SLEEP, HARD TO FOCUS (IN A FOG/DIZZY), SPASMS/VIBRATING (WHERE COILS ARE, ALMOST LIKE I HAVE MY CELL PHONE ON ME), EMOTIONAL, EXTREMELY BLOATED, STABBING PAINS IN MY ABDOMINAL AREA, DIARRHEA CONSTANTLY. I HAVE MISSED WORK, TIME WITH MY HUSBAND AND CHILDREN DEALING WITH ALL OF THIS. NO ONE KNOWS MY BODY BETTER THAN I DO, SO I ASKED MY DR TO TAKE THE NEXT STEP IN REMOVING THESE COILS FROM MY BODY. WHICH ENDED UP WITH ME HAVING MY FALLOPIAN TUBES, COILS AND UTERUS REMOVED AT THE YOUNG AGE OF (B)(6) ON (B)(6) 2014. I FELT THAT I WAS SLOWING BEING POISONED AND THAT IF I WANTED TO LIVE AND LIVE HEALTHILY THIS WAS MY ONLY CHANCE. NOW 2 WEEKS POST OP ALL MY SYMPTOMS ARE GONE, DOWN 8 PDS TOO!! I FEEL LIKE ME AGAIN. SADLY IF I WANTED TO DO A REVERSAL TO BECOME PREGNANT AGAIN I SADLY CAN NOT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034536	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIS PAIN BLOATING, HEADACHES, HEAVY PERIODS, LONG LASTING PAIN, PREGNANCY SIGN, TIREDNESS, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034537	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 10/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE DONE. I DO NOT RECALL BEING ASKED TO TEST FOR ANY ALLERGIES TO NICKEL. THE PROCEDURE WAS DONE IN THE DOCTORS OFFICE. I ONLY TOOK A MILD SEDATIVE AND SEEMS LIKE PROCEDURE TOOK NO LONGER THAN 30 MINUTES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034538	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 12/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BEGIN FEELING NAUSEOUS (ALMOST FLU LIKE SYMPTOMS), HAVING PELVIC PAIN / PRESSURE, HEADACHES, BLACK OUT EPISODES, HOT FLASH, MASSIVE BLEEDING (WEARING A TAMPON/PAD, CHANGING EVERY HOUR), LARGE CLOTS, FATIGUE, DRY SKIN, BLOATED ABDOMEN, ABDOMEN PAIN ON BOTH RIGHT AND LEFT SIDE, ABDOMEN WARM TO THE TOUCH, HIP PAIN, LEFT LOWER BACK PAIN, DIZZY, BECAME VITAMIN D DEFICIENT ((B)(6) 2013), LEG CRAMPS, SHARP ABDOMEN PAIN WHEN EXERCISING, AND NAUSEATED AFTER WORKING OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034539	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN SUFFERING FROM CHRONIC PELVIC PAIN, HEAVY BLEEDING, ABDOMINAL PAIN, RASHES, DIZZINESS, UT INFECTIONS, HEADACHES, BRUISING, TINGLING IN HANDS AND LEGS, ITCHING EVERY WHERE, NAUSEA, BLURRY VISION, DRY EYE SOCKET, HOT FLASHES, MUSCLE WEAKNESS, BROWN SPOTS UNDER BREST AND ON ARMS, LOWER BACK PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034540	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 1/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE MONTH AFTER I GOT STARTED HAVING BAD ANXIETY, PANIC ATTACKS, WIND IN MY BRAIN, DEPRESSION, NEVER THOUGHT IS WAS ESSURE. MY "NO" JUST PASSED AND THOUGHT I WAS JUST GOING THROUGH IT. WELL THEN I HAVE SEVERE PAIN EVERYWHERE FIRST STARTED IN MY HIPS WHEN LAYING ON MY SIDE THEN THE PAIN WENT DOWN MY LEGS TO MY TOES. MY EYE SIGHT HAS GOTTEN WAY WORSE. I HAVE NO ENERGY, ITS GONE, I CAN BARELY WALK ANYMORE. I'M ONLY (B)(6) AND HAVE 5 KIDS TO CARE FOR. IT'S JUST GETTING WORSE. I FEEL LIKE I'M SLOWLY DYING. THEN I STARTED GETTING THESE LABOR LIKE PAINS THAT FEEL LIKE SOMEONE IS STABBING ME. I'M TO YOUNG FOR THIS. PLEASE HELP. AND MY HAIR IS FALLING OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034541	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 7/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING INSERTION, COIL TORE FALLOPIAN TUBE AND EMBEDDED IN UTERUS. FOLLOW UP SURGERY TO ASSESS AND REPAIR DAMAGE WAS REQUIRED. ONGOING SEVERE ABDOMINAL PAIN, CONSTANT BLEEDING, AND POST TUBAL LIGATION SYNDROME HAVE FOLLOWED. SCHEDULED FOR HYSTERECTOMY AND TUBE REMOVED (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034542	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 3/15/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING MIGRAINES , EXTREME HIP PAIN THAT MADE MOVEMENT PAINFUL, IRREGULAR PERIODS, HEAVY PERIODS, PAIN IN LEGS, TREMOR AND MUSCLE SPASMS, HOT FLASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034543	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 1/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THREE MONTHS AFTER I GOT ESSURE I WAS TOLD I HAD FIBROMYALGIA, SINCE THEN I HAVE HAD PELVIC CRAMPING AND PERIODS THAT LAST AS LONG AS 8 DAYS, USUAL LAST 4 DAYS. I HAVE MY LUPUS ISSUES TIMES TWO. AFTER I GOTTEN ESSURE I HAD GOTTEN "CELLULATUS".

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034544	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 11/12/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WEIGHT GAIN, BLOATING, PELVIC PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034545	CONCEPTUS	2/19/2014	2/19/2014

Event Information:

Event Date (B3): 2/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ONGOING PAIN IN MY LEFT SIDE, I HAVE DEVELOPED A NICKEL ALLERGY WITH RASHES, THE COIL FROM MY LEFT TUBE HAS MIGRATED, MY MENSTRUAL PERIODS HAVE CHANGED SEVERELY SINCE HAVING ESSURE I HAVE MULTIPLE PERIODS PER MONTH WITH BAD CRAMPS AND CLOTS, MY BLOOD PRESSURE IS HIGH, MY CHOLESTEROL IS VERY LOW, MY VITAMIN D IS VERY LOW, AND I HAVE BEEN PUT ON HORMONE PILLS AS WELL AS OTHER MEDICATIONS TO TRY AND REGULATE MY ISSUES AND NOTHING IS HELPING. I HAVE DEVELOPED "BRAIN FOG" I CAN'T REMEMBER SIMPLE TERMS AND NAMES, I HAVE CONSTANT BACK PAIN, DEVELOPED A METALLIC TASTE IN MY MOUTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034630	BAYER	2/19/2014	2/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE 4 YEARS AGO AND HAVE NOTICED SYMPTOMS PROGRESSING AND HAVE NOW LINKED IT TO ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034632	BAYER	2/19/2014	2/25/2014

Event Information:

Event Date (B3): 8/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE PERMANENT BIRTH CONTROL IN 2012. I HAVE HAD SEVERE CRAMPS SINCE (B)(6) 2013 AND AT THE END OF SUMMER I NOTICED MORE AND MORE PELVIC PAIN. NOW MY LEFT LEG GOES NUMB, GROIN PAIN THAT IS SHARP AND CONSISTENTLY THERE THAT RADIATES DOWN MY LEG TO MY FEET EVEN MY TOES, IT HAS BECOME ALMOST IMPOSSIBLE TO HAVE SEX AND IF I'M LUCKY ENOUGH TO FINISH I AM IN EXCRUCIATING PAIN FOR HOURS TO DAYS AFTER. I ALSO HAVE BLOOD CLOTS AND BLEEDING AFTER. THE PAIN MAKES ME FEEL LIKE I AM IN LABOR AFTER. I ALSO HAVE PAIN IN MY BUTTOCK AREA ON MY LEFT. MY DOCTOR INITIALLY BELIEVED IT WAS BACK PAIN BUT AFTER TESTS AND X-RAYS THAT WAS RULED OUT. I'M DEPRESSED, GAINED WEIGHT, AND OVERALL MISERABLE. I AM A NURSE SO TAKING PAIN MEDICATIONS IS NOT AN OPTION SO I AM IN THE PROCESS OF FIGURING OUT HOW TO MAKE THINGS BETTER. I NOW ALSO HAVE CYSTS, FIBROIDS, AND FOLLICLES AND WAITING TO SEE IF I HAVE ENDOMETRIOSIS. I KNOW THESE CANNOT BE RELATED BUT I NEVER HAD ISSUES PRIOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034634	ESSURE	2/19/2014	2/25/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LOWER "ENABLING" PELVIC PAIN, HEAVY BLEEDING MONTH TO MONTH, TWO BLOOD TRANSFUSIONS IN TWO MONTHS. HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034635	CONCEPTUS	2/19/2014	2/25/2014

Event Information:

Event Date (B3): 6/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50686226

Single Use:
Implant Date (E6): 6/3/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED ON (B)(6) 2013. I WAS NOT TOLD THAT THE DEVICE HAS NICKEL IN IT (I AM ALLERGIC). I STARTED HAVING SIDE-EFFECTS WITHIN DAYS. MY HAIR AND EYEBROWS STARTED FALLING OUT, I DEVELOPED MYSTERY RASHES AND HIVES, DEPRESSION, SEVERE ABDOMINAL PAIN, I'VE BEEN ON MY PERIOD SINCE THEN (TODAY IS (B)(6) 2014) WITH THE EXCEPTION OF 4-6 NON CONSECUTIVE DAYS A MONTH, MIGRAINES, WEIGHT GAIN 40 POUNDS AND COUNTING), BLOATING, NIGHT SWEATS, ANXIETY, LEG CRAMPS, IRREGULAR HEARTBEATS AND PAIN IN THE CHEST, SHAKES IN HANDS AND FEET, ALL-OVER SWELLING, INSOMNIA BUT I'M ALWAYS TIRED, LACK OF ENERGY, MOOD SWINGS, BACK PAIN, JOINT PAIN, OCCASIONAL SIGHT PROBLEMS, CONSTANT METALLIC TASTE IN MOUTH, JUST TO NAME A FEW. I WENT FOR MY DYE TEST IN (B)(6) AND THE DOCTOR ADVISED ME THAT THE COIL ON MY LEFT SIDE SUCCESSFULLY BLOCKED MY FALLOPIAN TUBE BUT ON MY RIGHT SIDE IT WAS MISSING AND HE SAID THAT I MUST HAVE PASSED IT BECAUSE THERE WAS NO SIGN OF IT. FROM THAT DAY UNTIL (B)(6) I HAD EVEN MORE SEVERE CRAMPING COMPARABLE TO CHILD BIRTH, SEVERE BLEEDING, SWEATS, FEVERS, I WAS BEDRIDDEN MOST TIMES BECAUSE I WAS IN SO MUCH PAIN. THEN I WENT TO USE THE WASHROOM AND DISCOVERED THAT I HAD PASSED THE "MISSING" COIL. SOME OF THE SYMPTOMS WERE LESS INTENSE AFTER THIS BUT THEY ARE STILL THERE AND I HAVE TO LIVE WITH THEM EACH AND EVERY DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034637	BAYER	2/19/2014	2/25/2014

Event Information:

Event Date (B3): 10/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/15/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2009. SINCE THEN I HAVE SUFFERED EXTREME LOWER ABDOMEN PAIN, CONSTANT MIGRAINES, SEVERE MEMORY LOSS, AND JUST RECENTLY WAS DIAGNOSED WITH FIBROMYALGIA AS A LAST RESORT DIAGNOSIS FOR MY SYMPTOMS. I WAS A HEALTHY WOMAN UNTIL THIS PROCEDURE. NOW I ALSO HAVE LIVER PROBLEMS AND PELVIC INFLAMMATORY DISEASE. I HAVE TROUBLE WALKING WITHOUT HELP. I CAN'T MAKE ANY FAST MOVES OR I FEEL A SHARP STABBING PAIN FROM MY PELVIC BONE TO MY BELLY BUTTON. I AM ONLY (B)(6) AND I CAN'T TAKE MY CHILDREN OUT TO PLAY OR EVEN LIFT MY YOUNGEST ANYMORE. MY LIFE HAS BEEN RUINED DUE TO MY POOR RESEARCH ON THIS HORRIBLE PRODUCT. NOW I AM FINDING IT ALMOST IMPOSSIBLE TO FIND A DOCTOR TO REMOVE THE COILS, AND CONTINUE TO SUFFER. THE PAIN IS WORSE DAILY. I HAVE BEEN MARRIED ONLY 5 MONTHS AND I CAN NO LONGER HAVE INTERCOURSE WITH MY HUSBAND. I WANTED A REVERSAL BUT DUE TO THE EXTREME PAIN INCREASE I JUST WANT THE TUBES OUT OR A COMPLETE HYSTERECTOMY. MY FAMILY IS SUFFERING AND IT'S ALL MY FAULT. I HAVE RESEARCHED MY SYMPTOMS AND FOUND THOUSANDS OF WOMEN HAVE THE SAME SYMPTOMS AND THEY DISAPPEARED AFTER THE COILS WERE REMOVED. I NEED MY LIFE BACK. MY CHILDREN NEED THEIR MOTHER BACK. MY HUSBAND NEEDS HIS WIFE BACK. I HAVE LOST MULTIPLE JOBS DUE TO PAIN. MY HUSBAND IS OFF WORK DUE TO AN AMPUTATION AT HIS JOB. I NEED TO GET MY HEALTH BACK! I NEED MY LIFE BACK. IT'S NOT RIGHT THAT I JUST TURNED (B)(6) A COUPLE OF WEEKS AGO AND I CAN'T WALK WITHOUT ASSISTANCE. I USED TO RUN EVERY DAY. WITH THE THOUSANDS AND THOUSANDS OF WOMEN SUFFERING FROM THIS PRODUCT I DON'T UNDERSTAND HOW IT IS STILL BEING USED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034641	CONCEPTUS	2/19/2014	2/25/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 789026

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN, UNABLE TO FUNCTION IN DAILY ACTIVITIES. I HAVE NAUSEA, WEIGHT GAIN AND CONSTANT PROBLEMS WITH MY STOMACH FROM PAIN TO SWELLING. I HAVE MANY TESTS DONE AND EVERYONE THINKS I AM CRAZY. I WAS NORMAL BEFORE I HAD THE ESSURE AND EVER SINCE I HAVE HAD THE DEVICE MY HEALTH AND QUALITY OF LIFE HAVE HANGED FOR THE WORSE. I WAS NOT TOLD OF SO MANY THINGS THAT WOULD HAPPEN TO ME AFTER THE INSERTS WERE DONE. I NOW TAKE IT ONE DAY AT A TIME AND AM EVEN UNABLE TO WORK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034645	BAYER	2/19/2014	2/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN THE MIDDLE OF 2013. I WENT IN FOR HSG SCANS TO FIND OUT THE TUBES WERE NOT BLOCKED. I WENT FOR THIS PROCEDURE IN ORDER TO HAVE A NONINVASIVE AND NON HORMONAL WAY OF BEING FIXED. I WAS ALSO NOT ASKED NOR TESTED FOR A NICKEL ALLERGY. I AM NOW HAVING TO HAVE A TUBAL LIGATION NOW AS WELL AS AM HAVING SIDE EFFECTS OF BLURRED VISION AND LIGHT HEADED MESS AS WELL AS BLOATING AND STOMACH PAIN. HAD I KNOWN WHAT WAS GOING TO COME OUT OF THIS I WOULDN'T HAVE DONE IT AND IT'S ONLY THE BEGINNING HOPEFULLY NO MORE PROBLEMS ARISE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034649	BAYER	2/19/2014	2/25/2014

Event Information:

Event Date (B3): 2/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B06103

Single Use:
Implant Date (E6): 7/17/2013
Explant Date (E7): 2/4/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD GOTTEN THE ESSURE PROCEDURE DONE AND HAVE ISSUES SUCH AS MOOD SWINGS. I GOT EAR INFECTIONS OUT OF THE BLUE, PAIN EVERYWHERE, HEADACHES, NO SEX DRIVE, PAIN IN LIMBS, PAIN IN VAGINAL AREA DURING SEX, BOWEL ISSUES AND STOMACH, COULD NOT TAKE CARE OF MY KIDS WITHOUT HELP, COULD HOLD MY BABY, I COULD NOT DO ANYTHING WITHOUT HAVING PAIN WITH IT AND RECENTLY HAD A HYSTERECTOMY DUE TO IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00036	BAYER HEALTHCARE LLC	2/19/2014	2/26/2014

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/17/2011
Explant Date (E7): 1/17/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED 10 MONTHS AFTER HER LAST DELIVERY. FOUR MONTHS LATER SHE HAD A HYSTEROSALPINGOGRAM TEST PERFORMED. BEFORE TOTAL OCCLUSION CONFIRMATION SHE DID NOT HAVE INTERCOURSE. SHE STARTED EXPERIENCING HEAVY VAGINAL BLEEDING, RASH UNDER ARMS, UP AT NIGHT TO URINATE 10 TIMES AND DURING THE DAY UP TO 40 TIMES AND TIREDNESS. IN (B)(6) 2013, THE PAIN GOT SO BAD SHE COULD NOT WORK OR TAKE CARE OF HER CHILDREN. SHE HAD ULTRASOUNDS, MAGNETIC RESONANCE IMAGES AND X-RAYS AND WAS TOLD THAT ALL LOOKED FINE. IN (B)(6) 2012, HER CHIROPRACTOR DID AN X-RAY OF HER BACK AND NOTED THAT THE COILS WERE SIDEWAYS AND CROOKED ON ONE SIDE. ON THE OTHER SIDE THE COIL WAS BENT OUT OF SHAPE. ANOTHER X-RAY IN (B)(6) 2013 SHOWED THE COILS WERE WORSE THAN BEFORE. SHE WENT TO THE DOCTOR BECAUSE OF THESE EVENTS AND WAS TOLD NOTHING WAS WRONG. NO TREATMENT WAS GIVEN UNTIL SHE HAD A HYSTERECTOMY, SALPINGECTOMY AND ESSURE REMOVED. SHE REQUESTED THE REMOVAL. AFTER THE PROCEDURE SHE HAD PAIN FROM THE INCISION, BUT NO FEVER OR REDNESS ON HER ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00038	BAYER HEALTHCARE LLC	2/19/2014	2/26/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/17/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTS ESSURE WAS EASILY INSERTED AND CERVICAL DILATION, SOUNDING AND CONSCIOUS SEDATION PARA CERVICAL WERE PERFORMED DURING INSERTION. THE CONFIRMATION OF ESSURE PLACEMENT WAS PERFORMED ONLY VISUALLY. CONDOMS WERE USED AS BACK-UP CONTRACEPTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. A HYSTEROSALPINGOGRAM SHOWED OBSTRUCTED RIGHT FALLOPIAN TUBE AND PATENT LEFT FALLOPIAN TUBE, ESSURE WAS ADJACENT TO LEFT TUBE. THE PT SUFFERED FROM PELVIC PAIN. THE PERFORATION DID NOT OCCUR DURING SOUNDING, CERVICAL DILATION, HYSTEROSCOPY, BEFORE DEPLOYMENTS OR WITH COIL AFTER DEPLOYMENT. ON (B)(6) 2013, THE PT HAD LEFT ESSURE REMOVED VIA LAPAROSCOPIC LEFT SALPINGECTOMY. IT WAS MEDICALLY NECESSARY. AFTER SURGERY THE EVENTS WERE RESOLVED AND PT RECOVERED WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00040	BAYER HEALTHCARE LLC	2/19/2014	2/26/2014

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 7/2/2013
Explant Date (E7): 11/20/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED SHE HAD ESSURE INSERTED 6 WEEKS POSTPARTUM. SHE USED A PATCH FOR BACK-UP CONTRACEPTION WHOSE NAME SHE COULD NOT RECALL. A HYSTEROSALPINGOGRAM WAS NOT PERFORMED. A FEW DAYS AFTER INSERTION, SHE BEGAN TO EXPERIENCE HEAVY BLEEDING WITH HER PERIODS. NO HOSPITALIZATION WAS REQUIRED, BUT SHE HAD BEEN TO THE EMERGENCY ROOM COUPLE OF TIMES FOR ABDOMINAL PAIN, SHARP PAINS AND BLADDER INFECTIONS WHICH WERE TREATED WITH ANTIBIOTICS. IN (B)(6) 2013, BLOOD TESTS WERE PERFORMED AND THE RESULTS WERE NORMAL. ON (B)(6) 2013, A HYSTERECTOMY WAS PERFORMED AND ESSURE WAS REMOVED BY LAPAROSCOPIC PROCEDURE. HER DOCTOR THOUGHT IT WAS MEDICALLY NECESSARY SINCE SHE WAS LOSING TOO MUCH BLOOD. THE PATHOLOGY RESULTS WERE NOT REPORTED. DURING SURGERY, THE COILS WERE OBSERVED STILL IN PLACE. ALL SYMPTOMS WENT AWAY AFTER SHE GOT THE HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00041	BAYER HEALTHCARE LLC	2/19/2014	2/26/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

EINARSSON JI, MOULDER J. LAPAROSCOPIC APPROACH TO ESSURE IMPLANT REMOVAL. GYNECOLOGICAL SURGERY, VOL 10 (SUPL. 1) S129, 2013. A PHYSICIAN REPORTED A PT HAD INTERMITTENT PELVIC PAIN AND SYMPTOMATIC NICKEL ALLERGY FOLLOWING ESSURE STERILIZATION. SHE DESIRED CONTINUED STERILIZATION WITH COMPLETE REMOVAL OF ESSURE MICRO-INSERTS. GIVEN THE PLACEMENT OF THE ESSURE MICRO-INSERTS ACROSS THE UTEROTUBAL JUNCTION, A CORNEAL RESECTION AND SALPINGECTOMY BILATERALLY WAS PERFORMED TO ASSURE COMPLETE MICRO-INSERT REMOVAL AND CONTINUED STERILIZATION. CAREFUL INSPECTION REVEALED NO MICRO-INSERT PERFORATION. DISSECTION OF THE PELVIC SIDEWALL WAS PERFORMED TO IDENTIFY THE UTERINE ARTERY AT ITS ORIGIN. IN ORDER TO MINIMIZE BLOOD LOSS, TEMPORARY BILATERAL OCCLUSION OR THE UTERINE ARTERIES WAS PERFORMED USING VASCULAR CLIPS, PRIOR TO CORNUAL RESECTION. THE UTERINE CORNUA WERE INFILTRATED WITH DILUTE VASOPRESSIN TO FURTHER MINIMIZE BLOOD LOSS. COMPLETE CORNEAL RESECTION WAS PERFORMED BILATERALLY, AND THE HYSTEROTOMY SITES WERE CLOSED USING 0 PDO QUILL SUTURE. EXAMINATION OF THE SPECIMENS REVEALED COMPLETE REMOVAL OF THE ESSURE MICRO-INSERTS. CONTINUED PERMANENT STERILIZATION WAS ACHIEVED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 22-AUG-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (INCIDENT REPORT). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00037	BAYER HEALTHCARE LLC	2/19/2014	2/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/9/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PHYSICIAN REPORTED A PATIENT HAD ESSURE INSERTED, BUT DID NOT HAVE CONFIRMATION HYSTEROSALPINGOGRAM. SHE SUBSEQUENTLY BECAME PREGNANT AND DELIVERED HER CHILD. AFTER THE DELIVER, HYSTEROSALPINGOGRAM WAS PERFORMED AND SHOWED A PATIENT RIGHT TUBE WITH THE DEVICE IN RIGHT UPPER PELVIS. THE PATIENT UNDERWENT LAPAROSCOPIC REMOVAL OF THE DEVICE FROM THE SMALL BOWELS EPIPLOIA. ADDITIONAL FOLLOW UP ATTEMPTS WERE UNSUCCESSFUL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00039	BAYER HEALTHCARE LLC	2/19/2014	2/28/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS#05
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 6/17/2011
Explant Date (E7): 11/6/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED SHE HAD ESSURE INSERTED 2 YEARS AFTER HER LAST DELIVERY. AFTER INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION, SHE USED CONDOMS. HYSTEROSALPINGOGRAM SHOWED BOTH TUBES WERE BLOCKED. IN (B)(6) 2013, SHE STARTED EXPERIENCING SYMPTOMS. ON AN UNSPECIFIED DATE SHE WENT TO DOCTOR'S OFFICE AND THE PHYSICIAN STATED THAT ESSURE COILS WERE COMING OUT AND THAT THEY NEEDED TO BE REMOVED. IN (B)(6) 2013, SHE WENT TO EMERGENCY ROOM DUE TO ABDOMINAL AND PELVIC PAIN. SHE WAS TREATED WITH PAIN MEDICATIONS. TOMOGRAPHY AND ABDOMINAL ULTRASOUND SHOWED THAT EVERYTHING WAS NORMAL. ON (B)(6), 2013, SHE HAD AN UNSPECIFIED LAPAROSCOPIC PROCEDURE TO REMOVE ESSURE AND PART OF HER TUBES BECAUSE OF THE PAIN. SHE RECOVERED FROM THE REMOVAL AND FROM ALL EVENTS REPORTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00042	BAYER HEALTHCARE LLC	2/19/2014	2/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

SIMON M, UBEDA A, CUSIDO MT. PELVIC PAIN AFTER TRANSCERVICAL TUBAL OCCLUSION: A CASE REPORT. GYNECOLOGICAL SURGERY 10 (SUPPL. 1): S39-S40 (2013), 22ND ANNUAL CONGRESS OF THE EUROPEAN SOCIETY OF GYNAECOLOGICAL ENDOSCOPY (ESGE), OCTOBER 16-19, 2013, BERLIN. A PATIENT UNDERWENT TRANSCERVICAL TUBAL OCCLUSION IN 2008. AFTER AN UNEXPECTED PREGNANCY IN 2010, SHE UNDERWENT AN UNEVENTFUL LAPAROSCOPIC BILATERAL TUBAL BINDING (BTB). IN OCTOBER 2010, SHE COMPLAINED OF A TWO YEARS CHRONIC PAIN. ULTRASOUND SHOWED THE ABSENCE OF THE INTRAMURAL PORTION OF THE DEVICE. SHE WAS SUGGESTED TO UNDERGO A DIAGNOSTIC LAPAROSCOPY. DURING SURGERY BOTH DEVICES WERE FOUND TO BE SUBSEROUS AT THE LEVEL OF BOTH UTERINE CORNUAL REGIONS. THEY WERE BOTH EASILY REMOVED. SEE SCANNED PAGE.

Manufacturer Narrative (H10):

(B)(6)-2014: SEVERAL ATTEMPTS TO CONTACT AUTHOR, WHO REFUSED TO PROVIDE FURTHER INFORMATION. CASE CLOSED. PTC RESULTS WERE RECEIVED ON 22-AUG-2014, A NEW DEVICE SIMILAR CASE LISTING WAS GENERATED AND THIS CASE WAS RE-DISTRIBUTED AS A FINAL REPORT. THIS AD

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00043	BAYER HEALTHCARE LLC	2/19/2014	2/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2009
Explant Date (E7): 4/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2009, THE CONSUMER HAD ESSURE IMPLANTED. SHE EXPERIENCED HEAVY MENSTRUAL BLEEDING, BACK PAIN, CLOTS, ANXIETY AND BONE PROBLEMS. SHE ALSO SUFFERED FROM LOW BONE DENSITY, BONE DISEASE IN THE LOWER BACK AND JOINT PROBLEMS. EVERYTHING STARTED IN HER LOWER BACK. SHE ALSO HAD ARTHRITIS, CYSTS AND SHARP PAIN. ONCE SHE GOT THE ESSURE AND HER TUBES REMOVED IN (B)(6) 2012, EVERYTHING WENT BACK TO NORMAL EXCEPT FOR THE BONE PROBLEMS. SHE GAINED TWENTY POUNDS WITHIN A YEAR AFTER THE ESSURE INSERTION. DUE TO LACK OF CONSUMER OR PHYSICIAN CONTACT INFORMATION PROVIDED, NO FOLLOW-UP IS OBTAINABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00044	BAYER HEALTHCARE LLC	2/19/2014	2/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2009
Explant Date (E7): 1/9/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED FOR PREVENTION OF PREGNANCY. IN 2011, SHE HAD SEVERE LEFT SIDE PAIN. SHE WENT TO MULTIPLE GYNECOLOGISTS AND NO ONE WOULD LISTEN TO HER. THREE DOCTORS DID AN ULTRASOUND AND A CT (COMPUTED TOMOGRAPHY) SCAN. THE COIL ON LEFT SIDE MIGRATED DOWN INTO UTERUS AND THROUGH THE WALL AND INTO ABDOMINAL WALL. BOTH COILS WERE REMOVED ON (B)(6), 2014. MASSIVE RECONSTRUCTIVE SURGERY WAS DONE. THE COIL BROKE APART IN THE ABDOMINAL WALL. SURGERY WAS FIVE HOURS LONG. SHE HAS LOSS OF FEELING ON LEFT INNER THIGH. NO FURTHER DETAILS WERE REPORTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00045	BAYER HEALTHCARE LLC.	2/19/2014	3/4/2014

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSIVE, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/15/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED 6 YEARS AFTER HER LAST DELIVERY. SHE USED CONDOMS AS BACK-UP CONTRACEPTION. THREE MONTHS AFTER INSERTION, HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND SHOWED BOTH TUBES WERE OCCLUDED. IN OR ABOUT (B)(6) 2013, SHE STARTED EXPERIENCING BLEEDING, PAIN AND CRAMPS. IN (B)(6) 2013, TWO ULTRASOUNDS WERE DONE - ONE, WITH SALINE INJECTED VAGINALLY AND OTHER PROCEDURE (NOS). ULTRASOUND REVEALED BOTH COILS CAME OUT OF UTERUS AND DID NOT CLOSE THE TUBES AS IT WAS SUPPOSED TO. COMPLETE OR PARTIAL PERFORATION/EMBEDMENT DID NOT OCCUR AND NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS AFFECTED. SHE HAD TWO AN INITIAL EXPLORATORY PROCEDURE TO SEE IF THE COILS IN THE UTERUS WERE EMBEDDED OR NOT AND THEN THE SURGEON PERFORMED A HYSTEROSCOPIC PROCEDURE TO REMOVE THE ESSURE COILS AND BOTH TUBES. SALPINGECTOMY WITH ESSURE REMOVAL WAS PERFORMED. SHE RECOVERED FROM THE REMOVAL PROCEDURE AND ALL THE SYMPTOMS WENT AWAY AFTER REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034677	CONCEPTUS	2/20/2014	2/26/2014

Event Information:

Event Date (B3): 1/23/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): L2843
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/23/2007
Explant Date (E7): 11/21/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE BY CONCEPTUS PERMANENT BIRTH CONTROL MICRO INSERTS IN MY FALLOPIAN TUBES IN (B)(6) 2007. A YEAR LATER I WAS SUFFERING WITH A NUMBER OF PAINFUL SYMPTOMS: MIGRAINES, BACK PAIN, HEAVY MENSES, BLOOD CLOTS, PELVIC PAIN, SHARP STABBING PAIN ON MY LEFT SIDE OF MY PELVIC AREA. I HAD A NUMBER OF INFECTIONS THROUGH OUT THE YEARS FROM YEAST INFECTIONS, VAGINOSIS AND PID. I WAS ALSO DIAGNOSED WITH ENDOMETRIOSIS, PELVIC CONGESTION SYNDROME FROM ALL THE INFLAMMATION IN MY LOWER ABDOMEN, AND SEVERAL CYSTS ON MY LEFT OVARY. I HAD TO HAVE A HYSTERECTOMY TO FINALLY REMOVE COILS AND FEMALE ORGANS WAS ONLY LEFT WITH MY RIGHT OVARY. MY PROCEDURE WAS DONE (B)(6), 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034695	BAYER	2/21/2014	2/27/2014

Event Information:

Event Date (B3): 6/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 5/29/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LEFT FALLOPIAN TUBE SEIZED AND EXPELLED ESSURE DEVICE INTO ABDOMEN. SEVERE PAIN AND SEVERE DISCOMFORT FOR 2 WEEKS AFTER IMPLANTATION. SPORADIC SHARP PAIN IN ABDOMEN, FALLOPIAN TUBES, UTERUS AND VAGINA CONTINUE. SEVERE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034701	CONCEPTUS, INC	2/21/2014	2/27/2014

Event Information:

Event Date (B3): 12/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/26/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2010, HAD AN ENDOMETRIAL ABLATION FOR HEAVY MENSTRUAL BLEEDING TO PREVENT ANEMIA. UNDER ADVISE FROM MY DOCTOR, RECOMMENDED STERILIZATION TO PREVENT A PREGNANCY AFTER THE ABLATION PROCEDURE. HE RECOMMENDED THE ESSURE CONTRACEPTIVE. ONE OF THE COILS RUPTURED FALLOPIAN TUBE AND ONE OF MY BLOOD ARTERIES OR VEINS DOCTOR REPAIRED DURING A 4 HOUR SURGERY. NOW, HAVING SEVERE HEADACHES, PAIN IN PRESSURE IN MY BACK AND ABDOMEN, HEAVY MENSTRUAL CYCLE EVEN AFTER THE ABLATION, BLOATING. WILL HAVE TO UNDERGO ANOTHER SURGERY LAPAROSCOPY IN THE FUTURE TO DETERMINE IF I HAVE ANOTHER UNDERLYING PROBLEM IF THE ESSURE CONTRACEPTIVE COIL HAS BECOME DISPLACED OR SOME OTHER COMPLICATION. I HAVE BEEN TESTED FOR MS, HAD MRI'S AND CAT SCANS TO DETERMINE ROOT CAUSES OF THE SEVERE HEADACHES. ALL TESTS HAVE BEEN NEGATIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034723	BAYER	2/24/2014	2/28/2014

Event Information:

Event Date (B3): 2/23/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/10/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE DEVICE PUT IN BACK IN 2011. I HAVE HAD NOTHING BUT PROBLEMS SINCE THEN. I HAVE HAD EXTREME BLEEDING. EXTREME PAIN THAT HAS KEPT ME FROM WORKING. PLUS MUCH MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034725		2/24/2014	2/28/2014

Event Information:

Event Date (B3): 4/17/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305-R1; ESS305
Catalog # (E4):
Lot #(E4): 927075

Single Use:
Implant Date (E6): 4/17/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE NOT BEEN TO THE DOCTOR SINCE I RECEIVED THE ESSURE PROCEDURE IN (B)(6) OF 2012. FOR THE LEFT SIDE REF ESS305, LOT 927075, RIGHT SIDE (BECAUSE THE ORIGINAL ONE WOULD NOT GO IN PROPERLY) REF ESS305-R1, LOT 124755788. THE WHOLE PROCEDURE WAS HORRIBLE, PAINFUL, I EXPERIENCED A LOT OF CONSTANT BLEEDING FOR THREE MONTHS AFTER THE PROCEDURE WAS DONE. MY PERIODS HAVE GOTTEN EXTREMELY HEAVIER, AND VERY PAINFUL ALMOST RENDERING ME INCAPABLE OF MOVING AND LAST ABOUT 3 DAYS LONGER THAN NORMAL WITH A CONSTANT AND HEAVY FLOW. I AM EXPERIENCING MAJOR LOWER PACK PAIN THAT SHOOTS DOWN MY SPINE AND INTO MY HIPS. IT IS A CHRONIC PAIN THAT WORSENS THE LONGER I STAND. I WORK STANDING 8 TO 10.5 HOURS A DAY, SO IT HAS BEEN MAKING WORK VERY DIFFICULT TO COMPLETE AND MY ATTENDANCE HAS TAKEN AT TOLL DUE TO THE PAIN I'VE BEEN IN. ALSO, INCAPACITATING MIGRAINES ARE FREQUENT AND MAJOR HAIR LOSS. IT FALLS OUT IN HAND FULLS AT TIMES. IT'S BEEN A HORRIBLE EXPERIENCE, AND THAT WAS RECOMMENDED BY MY GYNECOLOGIST AND I REGRET IT EVERYDAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034750	BAYER	2/25/2014	3/4/2014

Event Information:

Event Date (B3): 2/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/12/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE COILS IMPLANTED IN (B)(6) OF 2010. SINCE THEN, MY PERIODS HAVE GROWN HEAVIER, MY CRAMPS ARE INTOLERABLE, AND THE PAIN IS ABSOLUTELY UNBEARABLE DURING MY MENSTRUAL CYCLE. I PASS LARGE BLOOD CLOTS AND OVERALL REGRET THE DECISION. I HAVE EXPERIENCED NEARLY EVERY NEGATIVE SIDE EFFECT LISTED FOR THE PRODUCT AND I JUST WANT THE PAIN TO STOP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034755	CONCEPTUS/BAYER	2/26/2014	3/5/2014

Event Information:

Event Date (B3): 2/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS005
Catalog # (E4):
Lot #(E4): 12241584

Single Use:
Implant Date (E6): 12/15/2003
Explant Date (E7): 2/10/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEE PREVIOUS REPORT FOR LIST OF SYMPTOMS. ON (B)(6) 2014 I UNDERWENT A LAVH (LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY) WITH BILATERAL SALPINGECTOMY AND REMOVAL OF THE CERVIX DUE TO ESSURE. PATHOLOGY CONFIRMED ADENOMYOSIS, CERVICITIS, ENDOCERVICITIS, HEMORRHAGE OF THE LEFT FALLOPIAN TUBE, AND SCARRING OF THE INTESTINE DUE TO INFLAMMATION CAUSED BY ESSURE WAS VISUALIZED AND PARTIALLY REMOVED. SINCE THAT TIME ALL OF MY SYMPTOMS WHICH DEVELOPED DURING THE DECADE IN WHICH I PLAYED HOST TO ESSURE RESOLVED. PLACEMENT (B)(6) 2003.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00047	BAYER HEALTHCARE LLC	2/26/2014	3/12/2014

Event Information:

Event Date (B3): 2/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/13/2012
Explant Date (E7): 12/13/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED FOR PERMANENT STERILIZATION. HER PROBLEMS STARTED RIGHT AFTER INSERTION. THE PROCEDURE WAS REALLY PAINFUL, ESPECIALLY THE LEFT SIDE. SHE HAD BAD CRAMPING AND BLEEDING THAT WENT "ON AND ON". SHE SAID SHE HAD BAD BLEEDING FOR THREE MONTHS STRAIGHT. SHE BEGAN HAVING TWO PERIODS EACH MONTH. SHE HAD BLOOD CLOTS. SHE ALSO HAD BACK PAIN AND HEADACHES. SHE WENT TO THE DOCTOR BUT "THEY COULD NOT FIND A SOURCE." IN (B)(6) 2013, HER SYMPTOMS WERE REALLY BAD AND HER PHYSICIAN SAID THE INSERTS HAD TO COME OUT. ESSURE WAS REMOVED BY DAVINCI LAPAROSCOPY AND VAGINAL HYSTERECTOMY. DURING SURGERY IT WAS NOTED THAT LEFT ESSURE WAS BROKEN IN PIECES AND A PIECE WAS SOMEWHERE ELSE, WHILE THE RIGHT DEVICE WAS FOUND IN PLACE. AFTER REMOVAL, SHE DEVELOPED AN INFECTION WITH TWO ABSCESSES WHICH WERE DRAINED. ALL THE OTHER EVENTS RESOLVED AFTER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00046	BAYER HEALTHCARE LLC	2/26/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/11/2011
Explant Date (E7): 11/18/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED SHE HAD ESSURE IMPLANTED AND SINCE THEN SHE HAS HAD SEVERE PAIN IN THE PELVIC AREA, CRAMPING, MIGRAINE HEADACHES, BACK PAIN, ONE INFECTION AFTER ANOTHER (YEAST), HEAVY PAINFUL PERIODS WITH HUGE CLOTS, PAINFUL SEXUAL INTERCOURSE AND RASHES THAT CANNOT BE EXPLAINED. SHE WENT TO THE ER SEVERAL TIMES FOR CHRONIC PAIN AND THEY THOUGHT IT COULD BE DUE TO HER PANCREAS OR APPENDIX, BUT ALL TESTS CAME BACK NORMAL. HER FALLOPIAN TUBES WERE SWOLLEN UP; HER UTERUS WAS SWOLLEN AND INFLAMED. ESSURE WAS REMOVED BY LAPAROSCOPIC PROCEDURE AT CONSUMER'S REQUEST. SHE ALSO REPORTED THAT BOTH FALLOPIAN TUBES WERE DAMAGED AND THEREFORE ALSO REMOVED. THE REMOVAL WAS EASY AND ONE OF THEM MIGHT HAVE TURNED AND BENT; THERE WAS NO PERFORATIONS AND WERE NOWHERE CLOSE TO THE UTERUS. HER SYMPTOMS DISAPPEARED A COUPLE OF WEEKS AFTER ESSURE WAS REMOVED. PHYSICIAN WHO PERFORMED ESSURE REMOVAL THOUGH IT WAS ESSURE THAT CAUSED HER SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034797	BAYER	2/27/2014	3/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): B21579

Single Use:
Implant Date (E6): 11/5/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE (LOT #B21579, (B)(4)) IMPLANTED ON (B)(6) 2013. WHEN I HAD MY HSG TEST DONE IN (B)(6) 2014 IT SHOWED NOT ONLY THAT THE PROCEDURE HAD FAILED, BUT THE COIL HAD PERFORATED MY UTERUS, MISSING THE FALLOPIAN TUBE ENTIRELY. THE PLACEMENT PROCEDURE WAS EXTREMELY PAINFUL. I HAD CONSTANT PAIN AFTERWARDS. I REPORTED THIS TO MY DOCTOR, HAD AN ULTRASOUND DONE AND WAS TOLD AT THAT TIME THAT THE COIL WAS IN PLACE AND THERE WAS NO WAY IT WAS CAUSING PAIN. (B)(6) HSG CONFIRMED OTHERWISE. I STILL HAVE CONSTANT PAIN AND WAS TOLD THAT THE COIL WOULD NOT CAUSE ANY PROBLEMS. I AM NOT ABLE TO BELIEVE THAT A FOREIGN BODY IN MY ABDOMINAL CAVITY COULD NOT AND IS NOT CAUSING THIS CONSTANT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034798	CONCEPTUS	2/27/2014	3/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20192094

Single Use:
Implant Date (E6): 9/22/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN 2010. THE PROCEDURE ITSELF LIVED UP TO ITS CLAIMS OF BEING FAST, EASY AND RELATIVELY PAINLESS. HOWEVER, IN THE FOUR YEARS SINCE THE ESSURE COILS WERE PLACED IN MY BODY, I'VE BEEN CHALLENGED WITH A NUMBER OF HEALTH PROBLEMS I NEVER EXPERIENCED BEFORE ESSURE. THESE PROBLEMS INCLUDE: SPORADIC SEVERE LOWER ABDOMINAL PAIN, BLEEDING IN BETWEEN PERIODS, HEADACHES, NAUSEA, FEELINGS OF HOPELESSNESS, ANXIETY, PRONENESS TO URINARY TRACT INFECTIONS (NEVER HAD ONE BEFORE ESSURE), DISCHARGE FROM NIPPLE, SEVERE SENSITIVITY TO EARRINGS (EARS BECOME VERY RED AND ITCHY IF I WEAR EARRINGS FOR ONE EVENING, AND I WEAR ONLY HYPOALLERGENIC EARRINGS), RANDOM RASHES AND ITCHINESS. MY MAIN LIFE GOAL HAS BECOME SAVING UP ENOUGH MONEY TO HAVE THESE COILS REMOVED SO I CAN GO BACK TO THE BEING CHEERFUL, PAIN-FREE, HEALTHY WOMAN I WAS BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034799	CONCEPTUS INC.	2/27/2014	3/6/2014

Event Information:

Event Date (B3): 8/16/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTS
Device Type (E2): ESSURE IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/16/2004
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2004 I HAD THE ESSURE IMPLANTS PUT IN. SINCE THIS DAY I HAVE HAD EXTREME PAIN ABDOMINAL CRAMPING AND NUMBNESS OF MY LEGS AND FEET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034821	BAYER	3/4/2014	3/7/2014

Event Information:

Event Date (B3): 2/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/30/2013
Explant Date (E7): 2/24/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED ON (B)(6) 2013 AND IMMEDIATELY STARTED HAVING SHARP, SHOOTING PAIN IN MY OVARY AREA. I BROKE OUT IN A CHRONIC RASH, GAINED 10 LBS WITHOUT CHANGING DIET AND EVEN AFTER STARTING YOGA 5 DAYS A WEEK. HAD CHRONIC HIP AND KNEE ACHES/PAINS AND KEPT FEELING WORSE AND WORSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034830	BAYER	3/4/2014	3/10/2014

Event Information:

Event Date (B3): 11/9/2006 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 508295

Single Use:
Implant Date (E6): 11/16/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTING WITH OVER 75 LBS. OF WEIGHT GAIN, DEPRESSION, HAIR LOSS, HEAVY BLEEDING AND CLOTTING, FLU LIKE SYMPTOM, BODY PAIN, BACK PAIN, PELVIC PAIN, ABDOMINAL PAIN, CRAMPING, ALLERGIC REACTION TO THE NICKEL, HIVES, RASHES, ITCHINESS THROUGHOUT THE BODY, JOINT PAIN, FATIGUE, LOSS OF ENERGY, HEADACHES/MIGRAINES, NAUSEA, METAL TASTE IN MOUTH, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, WEIGHT GAIN, SEVERE BLOATING, WATER RETENTION, SWELLING OF LEGS, HANDS AND FEET, LEG PAINS, CHEST PAIN, BREAST PAIN, BURNING SENSATION THROUGHOUT BODY, DEPRESSION, SUICIDAL THOUGHTS, BRAIN SHOCKS, ABNORMAL MENSES, PERIOD STOPS NERVE PAIN, TEETH ISSUES, TEETH HAVE FALLEN OR BROKEN, HEARTBURN, CLOUDINESS, FORGETFULNESS, INSOMNIA, HEART PALPITATIONS, FLUTTERING FEELING, SPASMS, ANXIETY, PANIC ATTACK, CONSTANT SPOTTING, FOUL SMELL, DISCHARGE, MOOD SWINGS, BOWEL ISSUES, CONSTIPATION, MISCARRIAGE, BOILS, CYSTIC ACNE, HOT FLASHES, NECK PAIN, SPINE PAIN, HYPOTHYROIDISM, BLURRY VISION, IT ALL HAPPENED AFTER ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034871	BAYER HEALTHCARE LLC (CONCEPTUS, INC)	3/4/2014	3/12/2014

Event Information:

Event Date (B3): 2/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE STERILIZATION DEVICE-PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE STERILIZATION DEVICE-PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B61388; B59454

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/4/2014

Event Description (B5):

ESSURE STERILIZATION DEVICE/PERMANENT BIRTH CONTROL PRODUCT LOT B59454, ATTEMPTING TO DEPLOY DEVICE #1 INTO RIGHT FALLOPIAN TUBE. IT WAS NOTED THAT IT HAD A TINY BEND IN THE OUTER INTRODUCER SHEATH. THE COILED DEVICE ONLY PARTIALLY DEPLOYED, LEAVING APPROX 5-7 COILS OUTSIDE THE TUBE. IT DIDN'T FEEL LIKE IT DEPLOYED CORRECTLY, SO IT WAS REMOVED, 2ND DEVICE WAS OPENED TO USE ON THE LEFT FALLOPIAN TUBE, BUT IT HAD A TINY BEND IN THE OUTER INTRODUCER SHEATH, MUCH LIKE DEVICE #1, SO IT WAS NOT USED. PRODUCT LOT B61388, A 3RD DEVICE WAS OPENED AND ATTEMPTED, BUT WAS NOTED TO HAVE A BEND AT THE TIP OF THE DELIVERY WIRE. A 4TH DEVICE WAS ATTEMPTED, BUT ABLE TO INSERT D/T ANATOMY OF TUBE, NO NOTED DEFECTS. SURGICAL PROCEDURE HAD TO BE ABORTED. COMPANY NOTIFIED OF INCIDENT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034849	BAYER	3/5/2014	3/11/2014

Event Information:

Event Date (B3): 8/6/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/6/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE COILS IMPLANTED IN 2007 AND EVER SINCE I HAVE PELVIC PAIN, BACK PAIN, NEUROPATHY AND FEEL TIRED ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034850	CONCEPTUS, INC.	3/5/2014	3/11/2014

Event Information:

Event Date (B3): 1/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 787226

Single Use:
Implant Date (E6): 8/30/2012
Explant Date (E7): 1/30/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL RUPTURED MY TUBE AND THE COIL EMBEDDED ITSELF IN THE SOFT TISSUE OF MY BOWEL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034853		3/5/2014	3/11/2014

Event Information:

Event Date (B3): 9/20/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): A96187
Lot #(E4):

Single Use:
Implant Date (E6): 9/20/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY THIRD CHILD AND DECIDED I WAS DONE HAVING KIDS. I TOLD MY DOCTOR I WANTED MY TUBES TIED. HE STATED THAT THEY REALLY DON'T DO THAT VERY OFTEN ANY MORE AND THEY DO WHAT IS ESSURE IN THE OFFICE. EVER SINCE I HAD ESSURE I HAVE HORRIBLE CRAMPS AND BLOATING EVERYDAY. I FEEL LIKE I AM ON MY CYCLE EACH AND EVERYDAY. I HAVE SHARP PAINS IN MY HIP AND LOWER BACK REGION. ALSO MY BACK NOW CATCHES EVERY ONCE IN A WHILE AND I CAN NOT MOVE TILL IT RELEASES. I HAVE ALSO GAINED ALMOST 20 POUNDS SINCE HAVING ESSURE DONE - NOT CHANGING ANYTHING I WAS DOING PREVIOUSLY. I WENT FOR MY 3 MONTH CHECK AFTER BEING IMPLANTED AND ONE SIDE WAS NOT STOPPING OR BLOCKING ANY DYE ON THE TEST. I GO BACK AGAIN FOR ANOTHER TEST (B)(6), 2014 FOR ANOTHER DYE TEST TO SEE IF IT IS WORKING. I FEEL LIKE THIS PRODUCT HAS RUINED MY BODY. IT HURTS DAILY SINCE (B)(6), 2013. I JUST WANT MY LIFE BACK AND NOT LIVE IN PAIN AND FEAR THAT I MAY BECOME PREGNANT AGAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00048	BAYER HEALTHCARE LLC	3/5/2014	3/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2009, A CONSUMER HAD ESSURE IMPLANTED TO PREVENT GETTING PREGNANT. HER HYSTEROSALPINGOGRAM SHOWED HER TUBES WERE BLOCKED, BUT SHE BECAME PREGNANT. SHE EXPERIENCED CRAMPING AND A PAIN IN HER SIDE DURING THE PREGNANCY. IN (B)(6) 2010, AFTER THE BIRTH, SHE HAD HER TUBES REMOVED. OVER THE NEXT TWO YEARS SHE HAD SEVERE PAIN IN HER SIDE, IRREGULAR PERIODS, CLOTS, HEAVY BLEEDING, AND HEADACHES. SHE NEEDED A HEATING PAD EVERY DAY FOR PAIN AS IT WAS HURTING TO WALK AND BEND OVER AND SHE HAD TO TAKE A LOT OF MOTRIN. SHE WAS PASSING HEAVY CLOTS OF BLOOD ABOUT A GOLF BALL SIZE ON AND OFF. SINCE REPORTED FEELING MISERABLE SINCE ESSURE INSERTION AND EVEN AFTER HAVING HER TUBES REMOVED. IN (B)(6) 2013, SHE HAD A HYSTERECTOMY. PICTURES OF HER UTERUS SHOWED 2 PIECES OF COIL INSIDE THE UTERUS, ONE ON EACH SIDE. HER UTERUS WAS ALSO EXTREMELY ENLARGED - IT WAS SUPPOSED TO BE 60, BUT IT WAS 130 (UNITS NOT SPECIFIED). ALL SYMPTOMS RESOLVED IMMEDIATELY AFTER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00049	BAYER HEALTHCARE LLC	3/5/2014	3/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/10/2009
Explant Date (E7): 8/15/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED A THE SAME TIME AS THE NOVASURE ABLATION WAS DONE TO HELP WITH PAINFUL PERIODS. SHORTLY AFTER INSERTION, HER MONTHLY PAIN BECAME WORSE THAN BEFORE THE PROCEDURES. IT WAS CONSTANT ALL MONTH, RADIATING INTO HER BACK, BUTTOCKS AND DOWN HER LEGS. SHE WAS FEELING LIKE SHE WAS IN FULL BLOWN BACK LABOR. MULTIPLE TESTS WERE DONE AND SHE TRIED OTHER OPTIONS TO HELP WITH PAIN CONTROL, SUCH AS LUPRON AND DIFFERENT PAIN MEDS, YET NOTHING WORKED. THE SEVERE BACK AND SCIATIC PAIN AND CRAMPING WERE CAUSED FROM HER BODY TRYING TO EXPEL THE COILS. IT WAS LIKE SHE WAS IN CONSTANT LABOR BECAUSE HER BODY WAS TRYING TO EXPEL A FOREIGN BODY AND THEY NEEDED TO COME OUT. SHE HAD REACTIONS TO CHEAP JEWELRY, HER HAIR THINNED, AND SHE HAD MULTIPLE HEALTH PROBLEMS AFTER INSERTION THAT SHE NEVER HAD PRIOR, INCLUDING A FIBROMYALGIA TO NAME ONE. SHE HAD A HYSTERECTOMY ON (B)(6), 2013 AND SHE HAS NOT HAD ANY SYMPTOMS SINCE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00050	BAYER HEALTHCARE LLC	3/5/2014	3/13/2014

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 710399

Single Use: Y
Implant Date (E6): 3/24/2010
Explant Date (E7): 8/5/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED WITHOUT INCIDENT. SHE DEVELOPED PAIN IN THE PELVIC, VAGINAL AND LOWER ABDOMINAL AREA. IN (B)(6) 2013 AN ULTRASOUND SHOWED SHE WAS PREGNANT. HER LAST MENSTRUAL PRIOR WAS ON (B)(6), 2013. IT ALSO SHOWED THE RIGHT INSERT WAS IN HER CERVIX. ALONG WITH A DILATION AND CURETTAGE ABORTION PERFORMED ON (B)(6), 2013, THE CONSUMER REQUESTED THE INSERT BE REMOVED. UPON DILATION OF THE CERVIX, THE RIGHT COIL, WHICH WAS WEDGED INTO HER CERVIX, CAME OUT EASILY. THE LEFT COIL REMAINS IN PLACE. PAIN RESOLVED AFTER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00051	BAYER HEALTHCARE	3/5/2014	3/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 919013

Single Use: Y
Implant Date (E6): 1/5/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED WITHIN SEVERAL DAYS, AFTER HAVING ESSURE INSERTED, SHE EXPERIENCED EXTREME PAIN ON HER LEFT LOWER SIDE. AN ULTRASOUND REVEALED SHE HAD PID FROM ESSURE. SHE TOOK ANTIBIOTICS, BUT STILL HAS PAIN ON THE LEFT SIDE THAT IMPACTS HOW SHE WALKS. IT HAS GRADUALLY GOTTEN WORSE. IN ADDITION TO THE HIP AND SIDE PAIN, SHE ALSO HAS CHRONIC LOWER BACK PAIN. THIS YEAR, SHE HAD TWO EPISODES OF SEVERE DIZZINESS. THE DOCTOR BELIEVES SHE NOW HAS AN AUTO-IMMUNE DISEASE CALLED MINIERE'S DISEASE. FINALLY, SHE STATED THAT SHE LOOKS AS THOUGH SHE IS 6 MONTHS PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034879		3/6/2014	3/12/2014

Event Information:

Event Date (B3): 5/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 623640

Single Use:
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACEMENT. HAD SEVERAL PROBLEMS SINCE ESSURE PLACEMENT (B)(6) 2007: WEIGHT GAIN, EASY BRUISING, FACIAL HAIR GROWTH, HAIR LOSS, SWOLLEN GLANDS, RINGING IN THE EARS, HIGH BLOOD PRESSURE, NUMBNESS IN HANDS FEET AND THIGHS, NAUSEA, BLOATING, DRY SKIN, ACNE, GASTRO ISSUES, BACK PAIN, ANEMIA, MIGRAINES, HEADACHES, PAINFUL OVULATION, SHARP PELVIC PAIN, LONG MENSTRUAL CYCLES, EXCESSIVE PAINFUL BLEEDING, CHRONIC PELVIC PAIN, DISCHARGE, OVARIAN CYST, AND BREAST CYST. EACH TIME I WENT TO THE DOCTOR I WAS JUST PUT BACK ON BIRTH CONTROL TO MANAGE THE SYMPTOMS, BUT NOT ACCURATELY TAKING CARE OF THE PROBLEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034881		3/6/2014	3/12/2014

Event Information:

Event Date (B3): 3/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2009 I GOT ESSURE BIRTH CONTROL PLACED INSIDE MY FALLOPIAN TUBES, SINCE THEN I HAVE HAD PELVIC PAIN AND ABNORMAL PERIODS AS WELL AS BEING DIAGNOSED WITH FIBROMYALGIA. NOW THE ESSURE COILS HAVE RUPTURED THROUGH MY FALLOPIAN TUBES AND ARE NOW IN MY UTERUS. MY DR HAS TOLD ME THE ONLY WAY TO FIX THIS IS TO GET A HYSTERECTOMY. THERE'S NO OTHER REASON FOR ME TO HAVE A HYSTERECTOMY EXCEPT THAT ESSURE FAILED. NOW I HAVE TO GET A MAJOR SURGERY THAT WILL CHANGE MY LIFE FOREVER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034883	BAYER	3/6/2014	3/12/2014

Event Information:

Event Date (B3): 2/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/11/2014
Explant Date (E7): 2/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WENT TO HAVE THE ESSURE PRODUCT IMPLANTED. THE DEVICE MALFUNCTIONED WHEN THE DOCTOR WAS PUTTING IT IN AND THE DEVICE WOULD NOT FULLY RELEASE THE ESSURE COIL. AS THE DOCTOR RETRACTED THE CAMERA THAT IMPLANTS THE DEVICE, THE COIL CAME OUT 1/2 WAY WITH THE CAMERA. I THEN HAD TO WAIT A FULL WEEK TO GET IN TO THE OUTPATIENT OPERATING ROOM WHERE THE DOCTOR HAD TO REMOVE THE DEVICE WITH A HISTOSCOPY. DURING THE WEEK PRIOR TO THE REMOVAL I WAS HAVING CONTINUED SHARP PAIN IN MY ABDOMEN AND UTERINE AREA AND CONTINUED HEAVY VAGINAL BLEEDING. THE DEVICE WAS FOUND IN MY UTERUS NOT IN MY TUBE. I NOW HAVE MINOR SCARRING IN MY UTERUS AND IN MY ONE TUBE THAT IT WAS IMPLANTED IN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00052	BAYER HEALTHCARE LLC	3/6/2014	3/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 735709

Single Use: Y
Implant Date (E6): 8/3/2010
Explant Date (E7): 11/26/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS EASILY INSERTED 7 MONTHS POST-PARTUM. CONDOMS WERE USED AS BACK-UP CONTRACEPTION BEFORE TOTALLY OCCLUSION CONFIRMATION. ON (B)(6) 2010, ULTRASOUND WAS USED TO CONFIRM PLACEMENT. HEAVY MENSTRUAL CYCLES, SEVERE HEADACHES, BACK ACHES, NAUSEA, LIGHT HEADEDNESS, DIZZINESS, SEVERE CRAMPING WHERE THE COILS ARE LOCATED, FATIGUE, SOME INSTANCES OF FAINTING AND BACTERIAL INFECTIONS APPEARED AFTER INSERTION. SHE WENT TO A DOCTOR CONCERNING THE SYMPTOMS, BUT NO PARTICULAR DIAGNOSIS WAS PROVIDED. SHE WENT TO THE EMERGENCY ROOM, BUT NO DIAGNOSIS WAS PROVIDED. SHE WAS TREATED WITH PAIN RELIEVERS, MOTRIN 800MG, METRONIDAZOLE AND CLINDAMYCIN, FOR BACTERIAL INFECTION VAGINOSIS. ON (B)(6) 2013, HOSPITALIZATION FOR REMOVAL OCCURRED (PER PATIENT'S REQUEST DUE TO PAIN) VIA LAPAROSCOPY AND HYSTEROSCOPY. A BILATERAL SALPINGECTOMY WAS PERFORMED. PATHOLOGY RESULTS INCLUDED: RIGHT CHRONIC SALPINGITIS, HYDRO AND HEMATOSALPINX AND POSSIBLE ENDOMETRIOSIS. LEFT SIDE WAS NORMAL, BUT THERE WAS A MILD CHRONIC INFLAMMATION. NORMAL PLACEMENT WAS FOUND AND NO PERFORATION. ON THE LEFT, TWO COILS IN THE CAVITY. ON THE RIGHT, NO COILS IN UTERUS, PLACED IN TUBE AND NO PERFORATION. PATIENT RECOVERED FROM EVENTS AFTER SURGERY. PHYSICIAN CONSIDERED ENDOMETRIOSIS AS POSSIBLE ALTERNATIVE EXPLANTATION FOR EVENTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00053	BAYER HEALTHCARE LLC	3/6/2014	3/13/2014

Event Information:

Event Date (B3): 12/15/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/15/2007
Explant Date (E7): 3/15/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSUMER HAD ESSURE INSERTED 3 MONTHS AFTER HER LAST DELIVER. DEPO-SHOT WAS USED AS CONTRACEPTION BEFORE TOTAL OCCLUSION CONFIRMATION. ACCORDING TO THE CONSUMER, PAIN BEGAN IMMEDIATELY. PERCOCET WAS PRESCRIBED AND OVER TIME THE PAIN BECAME LESS BUT IT WAS STILL THERE. THE IRREGULAR PERIODS AND WEIGHT GAIN FOLLOWED THAT FOR THE NEXT 5 YEARS. ON (B)(6) 2013 ESSURE WAS REMOVED BY LAPAROTOMY (HYSTERECTOMY OR SALPINGECTOMY WERE NOT NECESSARY). SHE WAS NOT HOSPITALIZED. AFTER REMOVAL, SHE USED PERCOCET AGAIN FOR THE PAIN. SHE STATED THAT THERE WERE SIGNS OF INFLAMMATION. DURING SURGERY, THE LEFT COIL WAS FOUND CROOKED AND HAD PUNCTURED THE TUBE. THE RIGHT WAS IN PLACE. SHE RECOVERED FROM THE ESSURE REMOVAL PROCEDURE. ON (B)(6) 2013 THE EVENTS STOPPED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00055	BAYER HEALTHCARE LLC	3/6/2014	3/13/2014

Event Information:

Event Date (B3): 1/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/14/2014
Explant Date (E7): 2/12/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED IN THE HOSPITAL UNDER ANESTHESIA FOR CONTRACEPTION. PAIN STARTED RIGHT AFTER SHE WOKE UP FROM THE PROCEDURE. IT WAS A VERY STRONG PAIN AND THEY GAVE HER MORE MEDICATION TO PUT HER TO SLEEP. SHE ALSO EXPERIENCED BLEEDING FOR TWO WEEKS STRAIGHT ON AND OFF. SHE WENT TO A DOCTOR CONCERNING THESE SYMPTOMS AND THE DIAGNOSIS GIVEN WAS A POSSIBLE ALLERGIC REACTION TO THE NICKEL IN THE DEVICE. HER HCP (HEALTHCARE PROFESSIONAL) STARTED HER ON ANTIBIOTICS AND SHE WAS GIVEN AN INJECTED (CEFTRIAXONE) AND TABLETS (AZITHROMYCIN) FOR AN INFECTION AND TYLENOL AND IBUPROFEN FOR THE PAIN. SHE ALSO WAS EXPERIENCING BACK PAIN AND WHEN CARRYING THE FIVE MONTH OLD BABY SHE GOT A SHOCKING, POKING PAIN IN THE LOWER PELVIC AREA. ESSURE WAS REMOVED LAPAROSCOPICALLY. BOTH FALLOPIAN TUBES WERE REMOVED ALONG WITH THE COILS. SHE IS STILL RECOVERING FROM THE REMOVAL PROCEDURE AND SHE FEELS A LOT BETTER AFTER THE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00056	BAYER HEALTHCARE LLC	3/6/2014	3/13/2014

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2004
Explant Date (E7): 11/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED FOR PERMANENT BIRTH CONTROL. SHE BEGAN EXPERIENCING PROBLEMS ON (B)(6) 2011. HER SYMPTOMS INCLUDE PROBLEMS DIGESTING AND SWALLOWING FOOD, BLOATING, SHARP PAIN, CRAMPING AND BACK PAIN. SHE SAID SHE HAD AN ENDOSCOPY, COLONOSCOPY, ULTRASOUND AND A CAT (COMPUTER ASSISTED TOMOGRAPHY) SCAN TO TRY AND FIND THE CAUSE TO HER HEALTH ISSUES, BUT ALL TESTS SEEMED TO BE FINE. IN 2013, SHE HAD A HYSTERECTOMY AND THE DOCTOR FOUND THE LEFT COIL HAD PERFORATED THE FALLOPIAN TUBE. ESSURE WAS EXPLANTED AND SHE NO LONGER HAS PAIN OR ANY OF THE ABOVE HEALTH ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00057	BAYER HEALTHCARE LLC	3/6/2014	3/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/16/2013
Explant Date (E7): 12/2/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED 6 MONTHS AFTER HER LAST DELIVER ON (B)(6) 2013. AS BACK UP CONTRACEPTION SHE WAS ABSTINENT. ABOUT A WEEK AFTER INSERTION SHE STARTED EXPERIENCING CRAMPING. SHE WENT TO THE DOCTOR AND NO PARTICULAR DIAGNOSIS WAS PROVIDED. ON (B)(6) 2013, 3 MONTHS AFTER INSERTION, A HYSTEROSALPINGOGRAM SHOWED THAT THE COIL WAS BROKEN INTO 4-5 PIECES. ONE PIECE WAS STUCK ON HER UTERUS AND ONE WAS SITTING AT THE BOTTOM OF THE PELVIC FLOOR. NO RELATED DIAGNOSTIC TESTS WERE PERFORMED. ESSURE WAS REMOVED LAPAROSCOPICALLY ALONG WITH HER FALLOPIAN TUBES, BUT SHE KEPT HER UTERUS. HER DOCTOR TOLD HER IT WAS MEDICALLY NECESSARY AS IT COULD HAVE PERFORATED AND AFFECTED ORGANS LIKE THE BOWEL AND BLADDER SINCE IT WAS NEARBY. DURING SURGERY BROKEN PIECES OF COIL WERE FOUND INSIDE FALLOPIAN TUBES, UTERUS AND PELVIC FLOOR. NO COMPLETE OR PARTIAL PERFORATION OR EMBEDMENT OCCURRED AND NO SIGNS OF INFECTION. SHE IS RECOVERED FROM THE ESSURE REMOVAL PROCEDURE WITH ALL HER SYMPTOMS RESOLVING AFTER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00058	BAYER HEALTHCARE LLC	3/6/2014	3/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED. FOAM AND EVERYTHING SHE COULD POSSIBLY USE WAS BACK-UP CONTRACEPTION BEFORE TOTAL OCCLUSION CONFIRMATION. IN (B)(6) 2008, AN ULTRASOUND WAS PERFORMED AND SHOWED PREGNANCY, CONFIRMED BY URINE AND BLOOD TEST. ON (B)(6) 2009, SHE HAD A FULL TERM VAGINAL DELIVERY WITHOUT COMPLICATION DURING PREGNANCY OR DELIVERY. ON (B)(6) 2014, ESSURE WAS REMOVED BY LAPAROSCOPY AND SALPINGECTOMY AS SHE WAS HAVING JABBING PAIN. SHE REPORTED THAT THE REMOVAL WAS MEDICALLY NECESSARY DUE TO THE ISSUES SHE WAS HAVING. HER TUBES WERE REMOVED. THEY FOUND THE COIL BROKEN IN HALF. ONE HALF WAS LODGED IN HER COLON. SHE RECOVERED FROM THE REMOVAL PROCEDURE AND THE SYMPTOMS RESOLVED AFTER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00059	BAYER HEALTHCARE LLC	3/6/2014	3/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B02269

Single Use: Y
Implant Date (E6):
Explant Date (E7): 12/30/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ACCORDING TO THE PHYSICIAN, ESSURE WAS EASILY INSERTED. CERVICAL DILATION AND SOUNDING WERE APPLIED DURING INSERTION, AS WELL AS ANALGESIA WITH TORADOL, VALIUM AND VICODIN. AS BACK-UP CONTRACEPTION, THE PATIENT WAS TOLD TO USE PROGESTERONE - ONLY PILL FOR ONE MONTH AND THEN CONDOMS. AFTER INSERTION SHE WAS TESTED AND A NICKEL ALLERGY DETECTED. THE PATIENT REQUESTED TO HAVE ESSURE REMOVED AS A RESULT. SHE WAS ALSO HAVING PAIN. ESSURE WAS REMOVED VIA LAPAROSCOPY AND SALPINGECTOMY WAS ALSO NECESSARY. THE LOCATION AND CONDITION OF THE DEVICES WAS GOOD. THE PATIENT'S SYMPTOMS AND PAIN RESOLVED AFTER SURGERY. THE PHYSICIAN WAS UNSURE WHETHER THE CONDITION WAS CAUSED BY ESSURE DEVICE AND STATED THE PATIENT HAD STRONG NICKEL ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00054	BAYER HEALTHCARE LLC	3/6/2014	4/2/2014

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893028

Single Use: Y
Implant Date (E6): 9/14/2012
Explant Date (E7): 10/29/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTED THAT THE INSERTION WAS EASY AFTER TISSUE WAS REMOVED TO EXPOSE THE OSTIA. ON (B)(6) 2012, AN ULTRASOUND WAS PERFORMED. NO RESULTS PROVIDED. PHYSICIAN REPORTED THAT THE PT COMPLAINED OF PERSISTENT PAIN. ESSURE DEVICES WERE REMOVED. RECOVERED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034903		3/7/2014	3/13/2014

Event Information:

Event Date (B3): 7/17/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2008, I WAS GIVEN THE OPTION OF ESSURE FOR PERMANENT BIRTH CONTROL. AFTER IMPLANTATION MY PERIODS BECAME IRREGULAR AND I BEGAN TO GAIN WEIGHT. APPROX 2 YEARS LATER MY PERIODS BEGAN TO INCREASE IN LENGTH (FROM 5 DAYS TO 7-10 DAYS) AND BECAME HEAVY WITH LARGE CLOTS. I BEGAN TO LOSE ENERGY. MY BREAST WOULD BECOME PAINFUL AND TENDER FOR 3 WEEKS OUT OF THE MONTH. I ALSO STARTED GETTING ABDOMINAL PAIN AND SEVERE MIGRAINES. IN (B)(6) OF 2013 I HAD A PARTIAL HYSTERECTOMY, REMOVING MY UTERUS AND FALLOPIAN TUBES AS WELL AS THE ESSURE DEVICES. MY POST OP REPORT INDICATED I HAD A SMALL CYST ON MY TUBE, MY UTERUS WAS ENLARGED, AND I WAS DIAGNOSED WITH ADENOMYOSIS. I WAS HEALTHY AND HAD NO FEMALE ISSUES PRIOR TO THIS DEVICE BEING IMPLANTED. I WAS NOT NOTIFIED PRIOR TO IMPLANTATION THAT THE DEVICE HAD NICKEL. I DO HAVE AN ALLERGY TO NICKEL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034911	CONCEPTUS	3/10/2014	3/14/2014

Event Information:

Event Date (B3): 7/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/25/2013
Explant Date (E7): 9/16/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2013, I HAD ESSURE DEVICES PUT IN PLACE. I WAS TOLD BY MY DOCTOR THAT THEY NOW PREFER ESSURE OVER A TUBAL LIGATION, SO I AGREED, BECAUSE I DID NOT WANT TO HAVE SURGERY ANYWAYS. I WAS EXPERIENCING A LOT OF PAIN ON ONE SIDE. WHEN I HAD MY X-RAY/ DYE TEST WE DISCOVERED THAT ONE OF THE DEVICES HAD BECOME DISLODGED AND WAS NOW IN MY UTERUS AND THAT WAS THE SOURCE OF MY PAIN. I HAD TO HAVE SURGERY TO HAVE IT REMOVED AND MY TUBE TIED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034931		3/11/2014	3/18/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN AFTER MY DAUGHTER WAS BORN IN 2010, 6 MONTHS AFTER IT WAS PUT IN HAD SEVERE STOMACH PAIN TO THE POINT I HAD TO HAVE A PARTIAL HYSTERECTOMY AND EVERY NOW AND THEN I STILL FEEL THE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034932		3/11/2014	3/18/2014

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 731587

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER 2010 THAT I HAD THE PLACEMENT OF ESSURE I STARTED LOSING HAIR DRASTICALLY; HOWEVER, I WAS TOLD THAT IT IS NORMAL AFTER HAVING A BABY. TODAY, I HAD A 60% HAIR LOSS. ALSO EXCRUCIATING PELVIC PAIN, INCLUDING INTERCOURSE AND MENSTRUAL CYCLE. I AM CONSIDERING A HYSTERECTOMY TO REMOVE THESE DEVICES. I WANT TO REGAIN MY LIFE AND YOUTH THAT ESSURE STOLE AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034943	CONCEPTUS	3/11/2014	3/18/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS DONE IN 2010, AS A PERFECT CANDIDATE. PROCEDURE DONE SUCCESSFULLY. CRAMPING ASSESSED AS NORMAL. AFTER THAT, PAIN AND BLOATING HAS NOT STOPPED. MANY EPISODES OF CHRONIC AND ACUTE LOW ABDOMEN PAIN AND BLOATING, AS WELL AS LOWER BACK PAIN. THE OBGYN THAT DID PROCEDURE STATES IT HAS NOTHING TO DO WITH PROCEDURE, YET I NEVER HAD THIS BEFORE PROCEDURE. HE DISMISSED IT AS OVARIAN CYSTS, CONSIDERS IT NORMAL. I AM SURE THE PINCHING PAIN AND INFLAMMATION IS NOT NORMAL. IT HAS BEEN 4 YEARS OF MISERY, AND REMOVAL REQUIRES A HYSTERECTOMY, WHICH I THINK IS BARBARIC. IF I KNEW THIS PAIN WOULD BE THIS BAD, I WOULD HAVE CHOSEN MY TUBES TO BE CUT INSTEAD. REMOVE THIS PRODUCT FROM THE MARKET, IT MAKES PTS SICK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00063	BAYER HEALTHCARE LLC	3/12/2014	3/19/2014

Event Information:

Event Date (B3): 1/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A57123

Single Use: Y
Implant Date (E6): 1/16/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS INSERTED 1 YEAR AND 4 MONTHS AFTER LAST DELIVERY. SHE USED DEPO PROVERA ABOUT A MONTH BEFORE INSERTION AND BIRTH CONTROL PILLS FOR A MONTH UNTIL CONFIRMATION OF BLOCKAGE. THE DAY AFTER ESSURE INSERTION PROCEDURE, SHE WOKE UP WITH SEVERE PAIN. THE LEFT COIL HAD PUNCTURED THE TUBE, WAS FLOATING IN ABDOMEN AND HAD DAMAGED THE TUBE. ON (B)(6) 2013, SHE HAD EMERGENCY LAPAROSCOPIC SURGERY. IT WAS A 15 MINUTE PROCEDURE, BUT TUBE COULD NOT BE REPAIRED AND HAD TO BE CAUTERIZED. THE RIGHT SIDE WAS BLOCKED AND WAS NOT REMOVED. SHE CONTINUED TO HAVE SEVERE PAIN, HORRIBLE CRAMPING AND BLEEDING WERE BLOOD CLOTS WOULD FALL OUT. TO RELIEVE THE BLEEDING AND PAIN SHE HAD A CERVICAL ABLATION ON (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034949	BAYER	3/12/2014	3/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): A33567

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM IN THE BEGINNING STAGES OF TESTING FOR PROBLEMS RELATED TO ESSURE. EXTREME PAIN IN LOWER ABDOMEN AND BACK. ULTRASOUND SHOWED NO MASSES ON OVARIES, OR OTHER ORGANS. HEAVY BLEEDING SOMETIMES TWO TIMES A MONTH. HEADACHES, NAUSEA, RASH, FATIGUE, AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034959		3/12/2014	3/21/2014

Event Information:

Event Date (B3): 2/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM NO LONGER ABLE TO WORK CAUSE IT IS HARD FOR ME TO FUNCTION WITH THE PAIN I AM IN BECAUSE MY ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034960	BAYER	3/12/2014	3/21/2014

Event Information:

Event Date (B3): 9/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/27/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2010 SINCE THEN IT HAS BEEN HELL! WEIGHT GAIN, SEVERE BLEEDING, PAIN DURING INTERCOURSE, FATIGUE, SHARP SHOOTING PAINS IN OVARY, LOWER BACK PAIN. JUST ALWAYS IN CHRONIC PAIN AND THE LOSS OF BLOOD I LOSE EVERY MONTH HAS MADE ME VERY WEAK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00060	BAYER HEALTHCARE LLC	3/12/2014	3/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/16/2013
Explant Date (E7): 1/7/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PATIENT UNDERWENT ESSURE INSERTION COMPLICATED BY PLACEMENT OF TWO COILS ON THE LEFT AS THE FIRST COIL WAS THOUGHT TO HAVE NOT DEPLOYED INITIALLY. THE PROCEDURE WAS OTHERWISE UNCOMPLICATED. THE PATIENT COMPLAINED OF NAUSEA, EMESIS AND PELVIC PAIN FOLLOWING THE PROCEDURE. SHE ATTRIBUTED THESE TO NICKEL ALLERGY AND PLACEMENT OF TWO COILS ON THE LEFT. SHE ULTIMATELY UNDERWENT HYSTEROSCOPY AND LAPAROSCOPY BILATERAL SALPINGECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00064	BAYER HEALTHCARE LLC	3/12/2014	3/28/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2010
Explant Date (E7): 10/9/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSUMER ALSO HAD A LOT OF PELVIC PAIN AND A LOT OF PRESSURE BELOW. SHE WAS ALWAYS IN A FOG, VERY FORGETFUL. BY NOON EVERY DAY, SHE WAS JUST EXHAUSTED. AFTER THREE YEARS OF PROBLEMS, SHE ASSOCIATES WITH THE DEVICE, SHE HAD A COMPLETE HYSTERECTOMY IN 2013 TO REMOVE IT. SHE IMMEDIATELY WAS RELIEVED OF ALL PREVIOUS SYMPTOMS.

Manufacturer Narrative (H10):

FOLLOW-UP IDENTIFIED ON 19-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00065	BAYER HEALTHCARE LLC	3/12/2014	3/28/2014

Event Information:

Event Date (B3): 11/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53033

Single Use: Y
Implant Date (E6): 10/2/2013
Explant Date (E7): 11/9/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO WEEKS AFTER INSERTION, PATIENT SEEN FOR CHECK-UP. SHE REPORTED ABDOMINAL CRAMPING AND SPOTTING. ON (B)(6) 2013, THE PATIENT WENT TO ER (EMERGENCY ROOM) WITH SYMPTOMS OF MILD-STERNAL CHEST PAIN AT LEVEL OF XIPHOID PROCESS RADIATING UP INTO HER CHEST, DIZZINESS, ARM TINGLING, NAUSEA AND DIAPHORESIS. SHE WAS TREATED FOR MILD PANCREATITIS AND THEN DISCHARGED. ON (B)(6) 2013, SHE WAS BACK TO EMERGENCY ROOM WITH VOMITING AND ABDOMINAL PAIN. A TOMOGRAPHY SHOWED ESSURE WAS OUT OF PLACE. ON (B)(6) 2013, PATIENT WAS TAKEN TO SURGERY. SHE HAD AN EXPLORATORY LAPAROTOMY FOR LYSIS OF ADHESIONS, MANAGEMENT OF OBSTRUCTION, APPENDECTOMY AND REMOVAL OF MICRO-INSERT. THE REPORTER DID NOT THINK ESSURE CAUSED IT, BUT WAS INVOLVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00061	BAYER HEALTHCARE LLC	3/12/2014	4/2/2014

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 919017

Single Use: Y
Implant Date (E6): 6/28/2012
Explant Date (E7): 11/7/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS INSERTED UNDER ANESTHESIA. AFTER A SUCCESSFUL AND UNREMARKABLE ESSURE IMPLANTATION SHE HAD THE EXPECTED SIDE EFFECTS OF PELVIC PAIN AND CRAMPING, WHICH NEVER WENT AWAY. SHE BEGAN BLEEDING LIKE A MENSTRUAL CYCLE IMMEDIATELY AFTER IMPLANTATION AND IT CONTINUED FOR 3 MONTHS STRAIGHT. SHE ALWAYS HAD A LIGHT CYCLE EVERY 28-30 DAYS LIKE CLOCKWORK BEFORE ESSURE. HYSTEROSALPINGOGRAM (HSG) DYE TEST WAS PERFORMED 3 MONTHS AFTER IMPLANTATION AND IT SHOWED PERFECT PLACEMENT OF THE ESSURE COILS AND COMPLETE BLOCKAGE OF THE TUBES. IN THE 16 MONTHS POST-ESSURE, HER PERIODS WERE HEAVY WITH INCREDIBLE CLOTTING, SEVERE CRAMPS AND OCCURRED EVERY TWO TO THREE WEEKS. SHE COULD NOT WEAR TAMPONS DUE TO PAIN AND CLOTTING. SHE HAD CONSTANT ABDOMINAL PAIN, CRAMPING, AND BLOATING THAT NEVER WENT AWAY FOR THE 16 MONTHS THAT ESSURE WAS IN HER BODY. SHE LOOKED PREGNANT, AND PEOPLE COMMENTED ON IT. SHE HAD CONSTANT EXCRUCIATING LOWER BACK PAIN, STABBING ABDOMINAL PAINS (ALTERNATING SIDES, VERY DISTINCT STABBING FEELING), SEVERE JOINT INFLAMMATION TO THE POINT WHERE SHE WAS VIRTUALLY UNABLE TO WALK AFTER 15 MONTHS, CONSTANT FATIGUE/LOSS OF ENERGY, CONSTANT NAGGING HEADACHES AND AN INCREASE IN THE INCIDENCE AND SEVERITY OF MIGRAINE HEADACHES, THE FEELING OF BEING STABBED WHEN SHE SAT DOWN AND A FEELING OF TEARING WHEN SHE STOOD UP - ALL THE TIME, HAIR LOSS TO THE POINT WHERE SHE CUT HER HAIR EXTREMELY SHORT TO HIDE IT, AN INCREASE IN CYSTIC ACNE, HOT FLASHES, INSOMNIA, MOOD SWINGS/IRRITABILITY, METAL TASTE IN HER MOUTH, SWELLING OF HANDS AND FEET, DENTAL ISSUES WHERE SHE WAS LOSING SILVER FILLINGS, WEIGHT GAIN, VISUAL ACUITY DECLINED DRAMATICALLY WITHIN 1 MONTH OF ESSURE AND REQUIRED HER TO WEAR GLASSES ALL OF THE TIME NOW, OCCIPITAL NEURALGIA, FORGETFULNESS/BRIAN FOG/CLOUDINESS, SHORT-TERM MEMORY LOSS/CONFUSION, DIZZINESS WITH AND

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WITHOUT NAUSEA, HEARTBURN AND DEPRESSION FROM ALWAYS BEING SICK, FEELING LOUSY, HAVING HEALTH DETERIORATE, AND NOT BEING ABLE TO DO THE THINGS THAT SHE WAS ALWAYS ABLE TO DO BEFORE ESSURE. SHE LOST VISION IN HER RIGHT EYE AND WAS DIAGNOSED WITH OPTIC NEURITIS AND MULTIPLE SCLEROSIS. SHE HAD A LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY WITH REMOVAL OF THE FALLOPIAN TUBES, AND ESSURE. CONSUMER STATED SHE FEELS INCREDIBLE 8 WEEKS AFTER HAVING ESSURE REMOVED. ALTHOUGH MOST OF HER SYMPTOMS HAD VANISHED, SHE WAS STILL DIAGNOSED WITH MULTIPLE SCLEROSIS AND LOSS OF VISUAL ACUITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00062	BAYER HEALTHCARE LLC	3/12/2014	4/2/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 4/1/2013
Explant Date (E7): 5/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE CONSUMER HAD SEVERE PAIN, ON THE FLOOR DOUBLED OVER CRYING. HER DOCTOR TRIED A FEW FIXES HE HOPED WOULD WORK BUT IN THE END, CONSUMER'S TUBES HAD TO BE REMOVED. SHE WAS LIKE HERSELF AGAIN, NO MORE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034970	CONCEPTUS	3/13/2014	3/21/2014

Event Information:

Event Date (B3): 8/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B34597

Single Use:
Implant Date (E6): 8/22/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE HAS CAUSED ME MANY PROBLEMS. I AM TIRED ALL THE TIME AND I USED TO HAVE ENERGY. I HAVE TO TAKE IBUPROFEN IN HIGH DOSES EVERY MORNING JUST TO BE ABLE TO GET THROUGH MY DAY AS MY PELVIC AREA HURTS SO MUCH I CAN BARELY WALK SOME DAYS. I STAY BLOATED AND HAVE STARTED TO GAIN WEIGHT. IT MESSES WITH MY PERIOD EVERY MONTH. I WENT SEVERAL MONTHS WITHOUT ONE AFTER THE PROCEDURE WAS DONE. I BLEED EVERY TIME I TRY TO HAVE SEX IF I CAN EVEN GET THAT FAR INTO THE ACT. MY HAIR FALLS OUT AT A CRAZY RATE. EVER SINCE ESSURE WAS IMPLANTED I HAVE TO GO TO THE BATHROOM JUST LIKE A PREGNANT LADY, IE EVERY HALF HOUR AND IF I TRY TO HOLD IT I GET IN SO MUCH PAIN ITS UNBEARABLE. I HAVE SHOOTING PAINS THROUGH OUT MY PELVIC AREA ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034973	BAYER	3/13/2014	3/21/2014

Event Information:

Event Date (B3): 6/23/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/23/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD COILS INSERTED (B)(6) 2005 IN (B)(6). WAS TOLD THEY WERE MADE FROM SURGICAL STAINLESS STEEL AND FROM THE START HAD PROBLEMS - DIZZINESS, CRAMPING ABDOMINAL PAIN. SYMPTOMS PROGRESSED AS TIME PASSED. MASSIVE WEIGHT GAIN AND I WAS USUALLY AVERAGE WEIGHT (B)(6) LBS FOR BEING (B)(6). I WAS NEVER GIVEN THE SERIAL NUMBER CARD THAT WAS SUPPOSED TO BE GIVEN TO ME EITHER. IN 2012 I MOVED TO (B)(6) AND FOUND A GYNECOLOGIST AND FOUND OUT THEY WERE MADE OF NICKEL AND FOUND OUT I HAD A SERIOUS UTERINE INFECTION THANKS TO A DR WHO UNDERSTOOD AND KNEW ABOUT THE CONS OF ESSURE. PLUS PCOS AMONG OTHER THINGS LIKE BEING PRE MENOPAUSAL AT (B)(6). WAS GIVEN THE OPPORTUNITY TO GET A HYSTERECTOMY IN (B)(6) TIL (B)(6) WAS TAKEN FROM ME SO STILL LIVING WITH THESE (B)(6) THINGS IN ME AND IT SUCKS. JOINED THE ESSURE PROBLEMS ON FACEBOOK FOR SUPPORT AND WHAT OTHER WOMEN WERE GOING THROUGH ONLY TO SEE THAT I WAS NOT THE ONLY ONE DEALING WITH THESE ISSUES. SEEN WOMEN GETTING THEIR X-RAYS AND DECIDED TO GET MINE. AND IMAGINE TO MY SURPRISE THAT THE COILS THAT ARE SUPPOSED TO BE IN MY FALLOPIAN TUBES WERE NOT, ONE IS IN DEAD CENTER OF MY UTERUS AND THE OTHER IS JUST SOMEWHERE. ONCE I GET MY MEDICAL I PLAN ON GETTING ANOTHER XRAY BECAUSE THOSE X-RAYS WERE FROM (B)(6) 2012 SO WHO KNOWS WERE THEY ARE LOCATED NOW AND I'M TIRED OF LIVING IN PAIN AND NOT BEING ABLE TO BE MYSELF. ITS A BUNCH OF (B)(6) AND IT HAS TAKEN OVER MY LIFE. I AM TIRED OF (B)(6) AND WANT THESE (B)(6) OUT OF ME.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC.	3/13/2014	5/15/2014

Event Information:

Event Date (B3): 3/12/2014 **Report Date (B4): 3/13/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B61394

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WHILE PERFORMING A STERILIZATION PROCEDURE, A BEND OCCURRED IN THE ESSURE DEVICE DURING INSERTION, RENDERING IT UNUSABLE. THE SURGEON FEELS IT IS A DEVICE FAILURE, BUT ANOTHER DEVICE WAS OPENED AND THE PROCEDURE WAS SUCCESSFULLY COMPLETED. THERE WAS NO HARM TO THE PATIENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035030	BAYER	3/14/2014	3/21/2014

Event Information:

Event Date (B3): 1/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN AND I HAVE HAD NOTHING BUT PAIN ON MY RIGHT SIDE SINCE IT HAS BEEN PUT IN. I HAVE BEEN BLEEDING SINCE AND MY HAIR IS FALLING OUT LIKE CRAZY. I FEEL LIKE SOMETHING IS IN THERE LITERALLY POKING ME LIKE CRAZY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035031		3/14/2014	3/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/23/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2009, I INFORMED MY OB/GYN THAT I WANTED MY TUBES TIED. HE INFORMED ME THAT THEY RARELY DO THAT ANYMORE AND THAT I SHOULD LOOK INTO HAVING THE ESSURE DONE. I WAS ONLY (B)(6). I DID NOT WANT ANYMORE CHILDREN, SO I FIGURED SURE WHY NOT. EVERYTHING WENT OK WITH THE PROCEDURE. THE 3 MONTHS LATER I HAD MY FIRST HSG DONE. I DON'T KNOW WHAT THE RADIOLOGIST AND THE DOCTOR DID, BUT IT HURT. I HAD NEVER BEEN IS SO MUCH PAIN IN MY LIFE. IT TURNS OUT THAT I ENDED UP NEEDING A SECOND HSG DONE BECAUSE THEY COULD NOT TELL IF THE COILS WERE PROPERLY PLACED. I WAS SO SCARED OF GOING IN FOR THE SECOND HSG BECAUSE OF THE AMOUNT OF PAIN I HAD THAT I PUT OFF SCHEDULING IT FOR ABOUT 3 OR SO MONTHS. I FINALLY WENT BACK AND HAD IT DONE. IT STILL WAS AS PAINFUL AS IT WAS THE 1ST TIME I HAD IT DONE. AFTER ABOUT A YEAR - (B)(6) OF 2010 - I STARTED HEAVY BLEEDING. I WOULD ONLY LAST ABOUT A WEEK OR SO. IN (B)(6) 2010, THE HEAVY BLEEDING STARTED AGAIN, AND DIDN'T STOP UNTIL (B)(6) 2010. I WENT TO MY GYN AND HE SUGGESTED THAT I HAVE A THERMAL ABLATION DONE. SINCE THE BLEEDING HAD STOPPED I DECIDED THAT MAYBE IT WAS A ONE TIME THING AND DIDN'T HAVE THE ABLATION DONE. UNTIL (B)(6) 2011, 3 MONTHS AFTER THE FIRST TIME THE HEAVY BLEEDING STARTED. THE EXTREMELY HEAVY BLEEDING HAD STARTED AGAIN, AND I COULDN'T DEAL WITH IT ANYMORE. I COULD NOT LEAVE MY HOUSE, I COULD NOT MOVE WITHOUT SOME SORT "MESS" BECAUSE OF ALL THE BLOOD. I FINALLY SCHEDULED THE THERMAL ABLATION AND HAD IT DONE IN (B)(6) 2011. THAT WENT OK. IN (B)(6) 2011, I STARTED HAVING SEVERE CRAMPING ISSUES. THE DOCTOR SAID THAT NOTHING WAS WRONG. THIS WENT ON UNTIL 2013. I'D START HAVING CRAMPS FOR ABOUT 3 WEEKS, THEN I'D BLEED FOR ABOUT A MONTH. THIS WENT ON FOR ABOUT TWO YEARS. THE DOCTOR SAYING NOTHING WAS WRONG. I USED TO LOVE MY OB/GYN, AND NOW I'LL NEVER GO BACK. ANOTHER GYN THAT I WENT TO ACTUALLY TOLD ME THAT HE WOULD

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HAVE NEVER IMPLANTED ESSURE INTO SOMEONE SO YOUNG. AT (B)(6), THAT ISN'T A DECISION I SHOULD NOT HAVE BEEN ABLE TO MAKE. SINCE GETTING ESSURE DONE, I'VE GAINED OVER 80 LBS, AND FOR THE LAST 6 MONTHS I HAVE BEEN FIGHTING TO GET IF OFF. NOTHING HELPS. MY FACE HAS SUFFERED, I BREAK OUT WITH SEVERE CYSTIC ACNE. I AM CONSTANTLY TIRED. I HAVE HAD SEVERAL LABS OF BLOODWORK DONE, ALL SHOWING THAT EVERYTHING IS NORMAL AND NOTHING IS WRONG. BUT I KNOW THIS IS ALL FROM THE ESSURE. I DID NOT SUFFER ANY OF THIS UNTIL I HAD THE ESSURE DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035032	CONCEPTUS	3/14/2014	3/21/2014

Event Information:

Event Date (B3): 7/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BECAME PREGNANT AFTER CONFIRMED 100% BLOCKED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035033	BAYER	3/14/2014	3/21/2014

Event Information:

Event Date (B3): 1/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED, HAVE CONSTANT PAIN, HEAVY BLEEDING. I WAS TOLD I WAS TOO HEAVY TO HAVE HYSTERECTOMY SO I HAD A GASTRIC SLEEVE. LOST OVER 100 LBS AND STILL HAVE ALL THE ADVERSE SYMPTOMS. I HAVE EVEN GONE TO EMERGENCY ROOM FOR BLEEDING THAT WOULD NOT STOP. HEADACHES, MOOD SWINGS, BLEEDING, PAIN, CYSTS ON OVARIES, I HAD TO HAVE XRAY AND FOUND THAT ONE COIL IS MISSING, I WILL HAVE A HYSTERECTOMY IN THE SUMMER TO REMOVE EVERYTHING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035025	CONCEPTUS	3/18/2014	3/20/2014

Event Information:

Event Date (B3): 2/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2008
Explant Date (E7): 12/20/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2008, AND HAD THE HSG 3 MONTHS LATER CONFIRMING 100% OCCLUSION. I HAD CONSTANT DULL, ABDOMINAL PAIN COMBINED WITH EXCRUCIATING CRAMPING DURING PERIODS SINCE IMPLANTING. I EXPERIENCED EXTREME FATIGUE AND BRAIN FOG STARTING IN 2009, WHICH RENDERED ME UNABLE TO WORK. I DEVELOPED ALLERGIC REACTIONS TO ALL METALS THAT TOUCHED MY SKIN, INCLUDING GOLD, SILVER, STAINLESS STEEL, AND ALL ZIPPERS AND BUTTONS ON CLOTHING. I BEGAN HAVING RASHES AND SWELLING ON MY ARMS AND LEGS. MY VAGINAL FLUIDS CAUSED BURNING, SWELLING, AND RASHES ANYWHERE THEY TOUCHED MY HUSBAND. MY ABDOMEN WOULD BLOAT AND SWELL SEVERELY THROUGHOUT THE COURSE OF A DAY. I WOULD GAIN 3 CLOTHING SIZES WITHIN 6 HOURS. I VISITED THE ER SEVERAL TIMES FOR THE EXTREME PAIN, ONLY TO BE TOLD EVERYTHING WAS FINE. IN 2013, I BECAME PREGNANT IN (B)(6) AND MISCARRIED IN (B)(6). AFTER THAT, THE FATIGUE AND PAIN INTENSIFIED UNTIL I HAD THE ESSURE COILS SURGICALLY REMOVED IN (B)(6) 2013. ALL SYMPTOMS GONE WITHIN 48 HOURS OF SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035055		3/18/2014	3/24/2014

Event Information:

Event Date (B3): 3/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD ESSURE SINCE 2006. I'VE BEEN EXPERIENCING HORRIBLE HEALTH PROBLEMS THAT MIMIC FIBROMYALGIA. ALSO HAVE EXCRUCIATING PELVIC AND LOW BACK PAIN, HIPS AND GROIN. BOWELS ARE INCONSISTENT. I HAVE HAD NOTHING BUT HEALTH PROBLEMS SINCE MY IMPLANTING AND I WAS ONCE A HEALTHY ADULT WITH NO HISTORY OF HEALTH PROBLEMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035056		3/18/2014	3/24/2014

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE COIL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/8/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS IMPLANTED (B)(6) 2013, HAVE HAD CONSTANT CRAMPING IN PELVIC AREA SINCE THE IMPLANT DAY, VERY HEAVY PERIODS WITH CLOTS, FREQUENT HEADACHES, HAIR LOSS, BLOATING IN LOWER STOMACH, ANXIETY/DEPRESSION, DEVELOPED CYST ON RIGHT OVARY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035058	BAYER	3/18/2014	3/24/2014

Event Information:

Event Date (B3): 3/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/6/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SIX MONTHS AFTER HAVING THE ESSURE PLACED ON MY FALLOPIAN TUBES I BEGAN HAVING PELVIC PAIN ALONG WITH PAIN AND BLEEDING DURING INTERCOURSE. OVER TIME THE SYMPTOMS HAVE GOTTEN WORSE. THE PELVIC PAIN IS DAILY CAN BE DEBILITATING. AT THIS TIME THERE IS CURRENTLY ANOTHER APPOINTMENT WITH MY DOCTOR TO DISCUSS TREATMENT OPTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035062	BAYER	3/18/2014	3/24/2014

Event Information:

Event Date (B3): 3/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT ESSURE DONE IN 2011. I AM NOW (B)(6). IT HAS BEEN GIVING ME PROBLEMS SINCE, SUCH AS SEVERE ABDOMEN PAIN, ABNORMAL PERIODS EITHER LASTING FOR MONTHS OR NOT COMING AT ALL OR JUST SPOTTING, BACKACHES, HEADACHES, LOSS OF APPETITE, MOOD SWINGS. I HAVE GOTTEN ALL THE PROPER TESTS DONE AND NOTHING SHOWED UP BUT I HAD NO HEALTH PROBLEMS BEFORE I GO THIS DONE. MY MEDICAL PAID FOR IT IN MY STATE, DOCTOR TO DO IT, BUT NO STATE DOCTOR WILL REVERSE WHICH CAN BE DONE, AND PAID FOR BY INSURANCE. SOMETHING NEEDED TO BE DONE. I'M IN CONSTANT PAIN EVERYDAY. I HAVE 3 CHILDREN. I CANNOT TAKE CARE OF BECAUSE OF MY PAIN, CAN'T WORK LONG HOURS WITHOUT DOUBLING OVER. PLEASE HELP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035073	BAYER	3/18/2014	3/24/2014

Event Information:

Event Date (B3): 11/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 774376

Single Use:
Implant Date (E6): 11/18/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED AND JUST FOUND OUT I AM SEVERELY ALLERGIC TO NICKEL. NOW I HAVE TO HAVE A HYSTERECTOMY ON (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035074	CONCEPTUS INC, BAYER	3/18/2014	3/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626278

Single Use:
Implant Date (E6): 3/1/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE CONTRACEPTIVE DEVICE WAS IMPLANTED IN (B)(6) 2008. THREE MONTHS AFTER IMPLANTATION, A HYSTEROSALPINGOGRAM DETERMINED FALLOPIAN TUBES WERE BLOCKED. AT THAT TIME, CEASED ORAL CONTRACEPTIVES. WITHIN ONE YEAR, DEVELOPED CYSTIC ACNE. DOCTOR PRESCRIBED SPIRONOLACTONE. WITHIN MONTHS OF DEVELOPING CYSTIC ACNE, DEVELOPED MENORRHAGIA (HEAVY, LENGTHY PERIODS). DOCTOR PRESCRIBED ORAL CONTRACEPTIVES. BEGAN EXPERIENCING A SIGNIFICANT HAIR LOSS FROM SCALP AND EYEBROWS (2009). PRE MENSTRUAL SYNDROME INTENSIFIED FOLLOWING IMPLANTATION. WITHIN THREE YEARS OF IMPLANTATION, PAINFUL, NIGHTTIME, UNEXPLAINED TOE AND FOOT CRAMPS BEGAN (2010). DOCTOR UNABLE TO DIAGNOSE FOLLOWING ELECTROLYTE AND BLOOD TESTING. DEVELOPED GALLSTONES REQUIRING REMOVAL OF GALLBLADDER (2012). STARTED EXPERIENCING MIGRAINES DURING MENSTRUATION LASTING THREE DAYS. DOCTOR PROSCRIBED ESTROGEN TO TAKE DURING MENSTRUAL CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034963	CONCEPTUS	3/19/2014	3/19/2014

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ALWAYS HAD A REGULAR PREDICTABLE CYCLE. TWO NORMAL PREGNANCIES AND DELIVERIES. I HAVE HAD NO MAJOR HEALTH PROBLEMS. MY DR SOLD ME ON ESSURE. DEVICE PLACEMENT IN (B)(6) OF 2013 WENT AS EXPECTED. CAME HOME GROGGY FROM DR'S OFFICE. FELT BAD PERIOD CRAMPS WITHIN THE HR AND HAD LIGHT SPOTTING. LIGHT SPOTTING RESIDED WITHIN A FEW DAYS AND AFTER A WEEK OR SO THE CRAMPING REDUCED TO A 2/10 PAIN SCALE. OVER THE NEXT 6 MONTHS OF MY BUSY LIFE WITH TWO CHILDREN AND HOLIDAYS I DEALT WITH THE 2-4/10 CRAMPING/BURNING IN MY PELVIC AREA. IT ALMOST FELT LIKE A BLADDER INFECTION BUT AS A NURSE I COULD LOOK AT MY URINE AND TELL THAT IT WAS NOT. STRANGELY I COULD FEEL THIS PAIN IN TWO ISOLATED AREAS. ONE HIGH IN THE LLQ AND ONE LOW IN MY RLQ. IMMEDIATELY AFTER THE HOLIDAYS I WAS ABLE TO HAVE MY HSG WHICH SHOWED THE RIGHT COIL TO BE IN MY PELVIC FLOOR. AT THE TIME I WAS ALSO BEING WORKED UP TO HAVE MY GALLBLADDER REMOVED HAVING HAD CHRONIC PAIN FOR 3+ WEEKS THAT RELATED TO FOOD AND POLYPS WERE FOUND. SURG WAS ON (B)(6) 2014- L COIL AND TUBE REMOVED. 2 STABLES AND A SMALL "MILLIMETERS" OF THE COIL REMAINS. THE R COIL TOOK HER 1.5 HRS TO FIND. THE COIL WAS FOUND , USING X-RAY, BETWEEN MY PELVIC WALL AND MY R OVARY. THE OVARY AND PELVIC WALL, AFTER BEING RUBBED RAW, HAD ADHERED TOGETHER. IT TOOK HER OVER AN HR TO REMOVE THIS COIL BECAUSE THEY STRETCH AND FRAGMENT. I'M 3 WEEKS POST OP. MY WOUNDS HAVE HEALED BUT I HURT WORSE THAN BEFORE THE SURGERY. I HAVEN'T BEEN ABLE TO PICK UP MY (B)(6) IN 3 WEEKS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034964	CONCEPTUS	3/19/2014	3/19/2014

Event Information:

Event Date (B3): 2/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE PROCEDURE, I HAVE HAD ON AND OFF NAUSEA, PAIN WHEN HAVING A BOWEL MOVEMENT, HEAVY BLEEDING WITH LARGE PIECES OF TISSUE, GAS PAIN BEHIND THE BELLY BUTTON, CHANGES IN APPETITE, CRAMPING WHICH TRAVELS DOWN THE LEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034965	BAYER	3/19/2014	3/19/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDA MW5034965 #(B)(4). I WAS DIAGNOSED WITH FIBROMYALGIA SEVERAL YEARS BEFORE BEING IMPLANTED WITH ESSURE AND NOW SYMPTOMS ARE WORSE. CHRONIC FATIGUE IS WORSE THERE ARE DAYS THAT IT IS TOO HARD TO GET OUT OF BED. I WAS IMPLANTED IN 2013 MY DR KNEW I ONLY HAD ONE TUBE BECAUSE OF A RUPTURED ECTOPIC PREGNANCY IN 2004, HOWEVER THE DR INSERTED A COIL IN THE SCAR TISSUE ON THAT SIDE. I WAS NEVER TOLD ESSURE CONTAINS NICKEL, I HAVE NEVER BEEN ABLE TO WEAR JEWELRY THAT CONTAINS NICKEL AS EARS WOULD SWELL AND ANY OTHER AREAS THAT JEWELRY CONTAINING NICKEL WOULD DEVELOP A RASH. HEADACHES ARE STILL ALMOST DAILY TO THE POINT OF NOT BEING ABLE TO FUNCTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034966	CONCEPTUS	3/19/2014	3/19/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, THE FEELING OF INFLAMMATION IN LOWER ABDOMINAL REGION, SEVERE BLOATING, PAINFUL OVULATION, MIGRAINES, SHARP SHOOTING PAINS LEFT OVARY MORE OFTEN THAN RIGHT, CRAMPING, GENERAL TIREDNESS, RASH (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034986	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN ALL THE TIME, NO MOTIVATION, ENDOMETRIOSIS, INFLAMED TUBES, PAINFUL AND IRREGULAR PERIODS, HEADACHES FREQUENTLY, MOOD SWINGS, ABDOMINAL CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034987	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 4/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HORRIBLE ABDOMEN PAIN, BLEEDING, WEIGHT GAIN SWELLING IN STOMACH MISSED PERIODS FOR MONTHS THEN BLEED FOR MONTHS, FATIGUE, DEPRESSION, AND HEADACHES. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034988	BAYER	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 2/16/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP 1 #FDA MW5034988 #(B)(4). I HAVE HAD MY HYSTERECTOMY AND THEY ONLY FOUND ONE COIL, SO I HAD XRAYS TO FIND THE OTHER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034989	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 10/5/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING LOWER PAIN AFTER IMPLANTATION. ABOUT TWO MONTHS AGO STARTED HAVING SEVER ABDOMINAL PAIN, EVEN MY HIPS HURT. MY PERIODS WENT FROM 4 DAYS TO TWO WEEKS WITH A LOT OF SPOTTING. MY LEFT LOWER SIDE RIGHT ABOVE OF MY PELVIC BONE BULGES OCCASIONALLY AND HURTS CONSTANTLY. I ALSO GAINED 10LBS IN A MONTH AND HAVE BEEN EXERCISING DAILY AND CAN'T LOOSE ANYTHING.
(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034990	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 4/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL MIGRATED. I EXPERIENCED BACK PAIN, RANDOM SHOOTING PAINS IN SIDE AND PELVIC AREA, CHEST PAINS, FATIGUE, WEIGHT GAIN, SLEEP APENA, GI ISSUES, BRAIN FOG, MOOD SWINGS, UTI, HAIR LOSS ETC. GATHERING LAB DATA. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034991	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 4/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL MIGRATED. I EXPERIENCED BACK PAIN, RANDOM SHOOTING PAINS IN SIDE AND PELVIC AREA, CHEST PAINS, FATIGUE, WEIGHT GAIN, SLEEP APNEA, GI ISSUES, BRAIN FOG, MOOD SWINGS, UTI, HAIR LOSS ETC. GATHERING LAB DATA. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034992	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 12/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, PAINFUL SEXUAL INTERCOURSE, BLOATING, MIGRAINES, VERTIGO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034993	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN EXPERIENCING DIZZINESS,NAUSEA, BACK/LEG/HIP/JOINT PAINS, SEVERE MIGRAINES, FATIGUE, VERY LARGE CLOTS WHEN I HAVE MY PERIOD, DRY VAGINAL ITCHING, WEIGHT GAIN. ON OCCASION I CAN TASTE METAL IN MY MOUTH FOR NO APPARENT REASON. I HAVE CRAMPS EVERY SINGLE DAY!! SOME DAYS ARE MODERATE SOME DAYS THEY ARE SEVERE. MOST DAYS I FEEL LIKE I'M HAVING PREGNANCY SYMPTOMS. I HAD MY ESSURE IMPLANTED IN (B)(6) 2012. THE FIRST TWO MONTHS I BARELY HAD A PERIOD BUT OVER THE NEXT COUPLE MONTHS I STARTED EXPERIENCING A LOT OF CRAMPING TO THE POINT IT WAS DOUBLING ME OVER AND VERY LARGE BLOOD CLOTS THAT I COULD LITERALLY FEEL COMING OUT OF MY BODY. MY BODY ACHES CONSTANTLY NOW, EVEN MY TEETH HURT SOMETIMES. I HAVE HEADACHES EVERYDAY AND SOME WEEKS I HAVE AT LEAST 2 MIGRAINES. I HAVE GAINED ABOUT 40 LBS SINCE I HAVE HAD ESSURE DESPITE MY WEIGHT LOSS EFFORTS. I ALSO HAVE VAGINAL ITCHING THAT I HAVE HAD TESTS DONE TO CONFIRM THAT IT WASN'T SOME SORT OF INFECTION. I ALSO HAVE MILK IN MY BREASTS AGAIN. I HAVE TAKEN SEVERAL PREGNANCY TESTS AND I AM NOT PREGNANT!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034994	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 3/26/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THIS PROCEDURE I HAVE EXPERIENCED BLOATING, HIVES, CHRONIC BACK PAIN, CHRONIC JOINT PAIN, ABNORMAL WEIGHT GAIN, UTERINE PROLAPSE, RECTAL PROLAPSE, MENORRHAGIA, DYSMENORRHEA, ADENOMYOSIS, PELVIC PAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034995	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DECIDED ON HAVING THE ESSURE IMPLANTED BECAUSE I HAVE 3 KIDS AND FEEL THAT OUR FAMILY IS COMPLETE. IN (B)(6) 2012 I HAD THE PROCEDURE. IT WAS INCREDIBLY PAINFUL AND THE DOCTOR WAS ONLY ABLE TO IMPLANT 1 COIL ON MY RIGHT TUBE, HE SAID MY LEFT TUBE WAS NOT WORKING. DUE TO THE FACT THAT HE WAS UNABLE TO DO BOTH SIDES I THEN HAD TO FIND A DIFFERENT FORM OF BIRTH CONTROL. A FEW MONTHS LATER I BEGAN SHOWING SYMPTOMS WHICH INCLUDE DEPRESSION, ANXIETY, HEAVY BLEEDING, CRAMPS SO BAD I COULDN'T MOVE, LARGE BLOOD CLOTS, FATIGUE AND SKIN ISSUES SUCH AS RASHES AND BOILS. I HAD TO HAVE A HYSTERECTOMY TO REMOVE THE COIL. UPON REMOVAL THE DOCTOR NOTED THAT THE ESSURE COIL WAS NOT IN MY TUBE, IT WAS COMPLETELY EMBEDDED IN MY UTERUS. THIS DEVICE HAS CAUSED ME SO MUCH PAIN AND COSTLY MEDICAL BILLS. I AM ONLY (B)(6) AND NOW HAVE NO REPRODUCTIVE ORGANS. I FEEL THIS DEVICE SHOULD NOT BE ON THE MARKET WHATSOEVER!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034996	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 2/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RUPTURING OF OVARIAN CYSTS.... DUE TO EGGS NOT BEING PROPERLY RELEASED. I HAVE HAD THIS BIRTH CONTROL FOR 5 YEARS AND HAVE HAD MANY, MANY MORE BAD REACTIONS INCLUDED BUT NOT LIMITED TO VERY HEAVY PERIODS THAT LAST A MONTH AT A TIME AND HAD TO BE STOPPED BY MEDICATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034997	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 5/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONGOING FEELING OF MENSTRUAL CRAMPING AND CONSTANT LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034998	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE PROCEDURE DONE IN 2009 I HAVE HAD SOME PROBLEMS BUT IN THE LAST YEAR, THEY HAVE GOTTEN WORSE. MIGRAINES, EYES BLUR, EXTREME BACK PAIN, BAD CRAMPS ALL THE TIME, PELVIC PAIN, FATIGUE, WEIGHT GAIN IN THE PAST FEW MONTHS. I HAVE GOTTEN A RASH THAT COMES AND GOES, AND OFTEN FORGETTING THINGS THAT I NEVER DID BEFORE. MY PERIODS ARE ALL OUT OF WHACK, COULD BE REALLY LIGHT FOR A DAY OR TWO AND THEN SO HEAVY .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5034999	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 1/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SHARP/PIERCING LOWER ABDOMEN PAIN. SHARP AND SHOOTING DOWN MY LEG MAKING IT DIFFICULT TO WALK AT TIMES. BLOATING OR INFLAMMATION AND ABDOMEN TO THE POINT THAT I LOOK 7 MONTHS PREGNANT. MIGRAINES DEBILITATING BECAUSE I AM NOT ABLE TO GO OUTSIDE OR EVEN LEAVE MY ROOM, EVERY NOISE HURTS MY WHOLE BODY. LOSS OF APPETITE BECAUSE OF NAUSEA IN PREGNANCY LIKE SYMPTOMS. LOWER BACK PAIN. PAIN IN MY SHOULDERS AND NECK. BRAIN FOG TO THE POINT THAT I'M NOT ABLE TO GET ANYTHING ACCOMPLISHED AND SOME SHORT TERM MEMORY LOSS. I DON'T KNOW WHAT ELSE I'M SUPPOSED TO DO BECAUSE ALL OF MY TESTS COME BACK THAT I AM HEALTHY ALTHOUGH I FEEL LIKE MY LIFE IS SLOWLY SLIPPING AWAY FROM ME AND THERE IS NOT ONE THING I CAN DO ABOUT IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035000	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WELL, THE PROCEDURE ITSELF WENT FINE. BUT IT WASN'T A COUPLE OF MONTHS AND THE FIRST OF THE SYMPTOMS STARTED AND HAVEN'T STOPPED YET. I STARTED HAVING REALLY BAD CHEST PAINS, ACID REFLUX (THAT HAD CAUSED PRECANCEROUS CELLS AND HAVE TO TAKE MEDS TO CONTROL IT AND HAVE TO GET IT CHECKED EVERY YEAR), WEIGHT LOSS, BRUISING EVERYWHERE, HAVING LIVER FUNCTION PROBLEMS, STOMACH PAINS, VERY BAD BACK AND HIP PAIN, CONSTANT NOSE SORES, SKIN RASHES, BLISTERS ON HANDS AND LOWER ABDOMINAL AREA, VERY SHARP ABDOMINAL PAIN, EXTREME FATIGUE AT TIMES, VERY BAD HEADACHES, I JUST NOW HAVE BEEN DIAGNOSED WITH AN AUTOIMMUNE DISEASE. I DONT THINK IT IS A COINCIDENCE THAT I HAD NONE OF THESE SYMPTOMS BEFORE ESSURE AND NOW 3 YEARS LATER I FEEL LIKE I AM LITERALLY FALLING APART. I AM ONLY (B)(6) YEARS OLD AND I FEEL LIKE AN (B)(6) YEAR OLD. IF ALL OF THESE THINGS HAVE HAPPENED IN 3 YEARS I DONT KNOW WHAT IT WILL BE LIKE IF I KEEP THEM COILS IN ME LONGER. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035001	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 1/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER ESSURE I HAVE BEEN IN EXTREME PELVIC PAIN; BACK PAIN, FATIGUE, BLEEDING, SPOTTING, BLOATING, HAVE TO TAKE PAIN MEDICATION JUST TO GET THROUGH EACH DAY. I CRAMP ALL OF THE TIME. I HAVE PELVIC PAIN ALL OF THE TIME. IT HAS IMPACTED EVERY ASPECT OF MY LIFE.
(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035002	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 1/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BAD HEADACHES, SEVERE ABDOMINAL PAIN, HEAVY PERIODS, MISSED PERIODS, 2 IN ONE MONTH, INSOMNIA, BLOATING, BACK ACHES, CYSTS. OVERALL ALWAYS FEELING BAD AND WEAK. IN THE END, HAD HYSTERECTOMY (B)(6) 2014. ALREADY FEELING BETTER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035003	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 1/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONCE I HAD THE ESSURE PUT IN, I STARTED HAVING VERY BAD PERIODS, WITH MAJOR CRAMPING TO WHERE I WAS TAKING PRESCRIBED PAIN PILLS, HEAVY BLEEDING, ALWAYS FEELING SICK TO MY STOMACH, DEALT WITH DEPRESSION, ANXIETY AND NERVOUSNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035004	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 11/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD SEVERE CRAMPING WITH BLEEDING AND BLOOD CLOTS SINCE (B)(6) OF 2013. I NOW HAVE A UTERINE BACTERIAL INFECTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035005	BAYER	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 11/30/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE COILS PLACED (B)(6) 2006 AND HAVE HAD MIGRAINES, SEVERE CRAMPING, SEVERE MOOD SWINGS AND DEPRESSION (TO THE POINT OF HAVING TO BE PUT ON MEDICATIONS), WEIGHT GAIN OF 50+ POUNDS, I GET BOILS ON MY SKIN NOW (NEVER DID BEFORE), THERE ARE TIMES I HAVE BLEEDING OR SPOTTING AFTER SEX, PROBLEMS WITH MY BLADDER THAT WAS NEVER THERE BEFORE, PAIN IN MY BREASTS AT TIMES, CONSTANT HEARTBURN IF I AM NOT ON MY MEDICATION, I CONSTANTLY HAVE DISCHARGE, DRY SKIN AND HAIR, AN EXTREME LOSS OF ENERGY, I HAVE HOT FLASHES (BOTH DAY AND NIGHT), I WAKE UP IN THE MIDDLE OF THE NIGHT SOAKED IN SWEAT. (I SHOW ALL BUT A COUPLE SIGNS OF PRE-MENOPAUSE STARTING AT AGE (B)(6), I AM NOW (B)(6)). I HAVE IRREGULAR PERIODS, JOINT PAIN, MUSCLE SPASMS, NAUSEA, NERVE PAIN, AND GET A METAL TASTE IN MY MOUTH. I GET NUMBNESS IN MY HANDS ON A CONSTANT BASIS, EXTREMELY PAINFUL PERIODS, AND PAINFUL OVULATION, PELVIC PAIN, RINGING IN MY EARS, SKIN ITCHINESS, SHARP STABBING PAINS, TINGLING SENSATIONS IN THE BACK OF MY HEAD, URGENCY TO URINATE, AND FREQUENT VIBRATING SENSATIONS IN MY LOWER ABDOMEN. ALL OF THESE SYMPTOMS STARTED APPROXIMATELY A MONTH AFTER THE COILS WERE PLACED. I WAS DIAGNOSED WITH HIGH BLOOD PRESSURE IN 2005 AND IT IS VERY WELL CONTROLLED WITH MY MEDICATIONS. I WAS NOT PUT ON DEPRESSION MEDS UNTIL APPROXIMATELY 2010. I HAD TO BE PUT ON TOPAMAX AS A MIGRAINE PREVENTATIVE BECAUSE NO OTHER MIGRAINE MEDICATION WOULD WORK AT THE ONSET OF A MIGRAINE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035006	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 9/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I SPENT 8 DAYS IN THE HOSPITAL DUE TO SEVERE HEADACHES. NO ONE EVER DECIDED THE CAUSE. I HAVE HAD SEVERE ANXIETY AND A SUICIDE ATTEMPT. I WAS DIAGNOSED WITH AN AUTO-IMMUNE RESPONSE, POSSIBLE WEGNERS GRANULOMATOSIS. I STARTED HAVING SEVERE THYROID ISSUES AND WEIGHT INSTABILITY AND HAD TO HAVE HALF OF MY THYROID REMOVED. I STARTED HAVING SEVERE PELVIC AND ABDOMINAL PAIN AND WAS IN THE HOSPITAL FOR 4 DAYS DUE TO A SEVERELY INFLAMED BOWEL. I HAVE DEBILITATING JOINT PAIN DAILY. I HAVE WENT FROM WORKING FULL TIME AS AN ACTIVE FUN PRESCHOOL TEACHER IN 2008 TO BE UNABLE TO WORK EVEN PART TIME IN 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035007	BAYER	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 1/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

DECREASED LIBIDO, PELVIC PAIN, FATIGUE, HAIR LOSS, WEIGHT GAIN, DEPRESSION, RECURRING BACTERIA IN URINE, ETC. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035008	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT PREGNANT WITH ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035009	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 3/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE RIGHT COIL KEPT HURTING ME, FOR FOUR YEARS STRAIGHT. THE LEFT COIL HURT IN THE BEGINNING, BUT THE PAIN SUBSIDED LATER. DURING THE OPERATION FOR REMOVAL OF BOTH COILS IT TURNED OUT THAT THE LEFT COIL HAD CAUSED INFLAMMATION AND ENDOMETRIOSIS AND THE LEFT FALLOPIAN TUBE HAD GROWN ATTACHED TO MY ABDOMINAL WALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035010	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 12/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD CONSTANT SKIN ISSUES SUCH AS HIVES, AND ABDOMINAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035011	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 3/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN ABDOMEN, FATIGUE, HAIR-LOSS, NUMBNESS ON LEGS, INFLAMMATION, POKING PAIN ON RIGHT AND LEFT SIDE OF ABDOMEN, CRAMPING, HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035012	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 2/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY MENSTRUAL BLEEDING WITH CLOTS FOR 3 WEEKS NOW, SEVERE LOWER ABDOMINAL PAIN, PELVIC PAIN SHOOTING INTO HIPS AND THIGHS, DAILY MIGRAINES, EXTREME LIGHTHEADEDNESS WITH WAVES OF NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035013	BAYER	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 4/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

LEFT PAIN, CYST ON OVARIES, PELVIC PAIN, MIGRAINES, LOWER BACK PAIN, 2 OR 3 PERIODS A MONTH, TIRED ALL THE TIME, MISCARRIAGE. UPDATE ON (B)(6) 2014: HEAVY BLEEDING AND CLOTTING; MY PERIODS ARE AWFUL NOW AND HURT SO BAD. BEFORE ESSURE I DIDN'T EVEN KNOW WHAT A PERIOD CRAMP WAS; RASHES; DIZZINESS AND MIGRAINES - SOMETIMES WHEN I'M DIZZY I BLACK OUT. I KNOW MY BP IS GOOD AND MY BLOOD SUGARS BECAUSE I CHECK THEM RIGHT AFTER IT HAPPENS! METALLIC TASTE IN MOUTH; SHARP STABBING PAINS; BACK PAIN; KIDNEY AND UTI INFECTIONS; FATIGUE/LOSS OF ENERGY; TINGLING SENSATIONS; WEIGHT GAIN IN MY STOMACH (SEVERE BLOATING) PEOPLE ALWAYS ASKING WHEN IM DUE TO HAVE MY BABY; CHEST PAINS; BRAIN SHOCKS (ESSURE "DUMBNESS"); THERE HAS BEEN 3 DIFFERENT MONTHS WHERE I DIDN'T GET A PERIOD AND WILL HAVE PREGNANCY SYMPTOMS, BUT NEGATIVE PG TEST; OVARIAN CYST- VERY PAINFUL; FALLOPIAN TUBE CYSTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035014	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 7/24/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY WIFE WAS IMPLANTED WITH THE ESSURE DEVICE (B)(6) OF 2012. SOON AFTER THE DEVICE WAS IMPLANTED WE RESUMED SEXUAL INTERCOURSE. FOR THE ENTIRE TIME SHE WAS IMPLANTED WITH ESSURE EVERY SINGLE TIME WE HAD INTERCOURSE WE BOTH BECAME VERY ILL. I HAD A RASH AND RAISED BUMPS ON MY PENIS AFTER INTERCOURSE. THERE WAS A TIME THAT THE BUMPS JUST STAYED AND DID NOT GO AWAY. SHE AND I EXPERIENCED VOMITING AND DIARRHEA IMMEDIATELY FOLLOWING INTERCOURSE. THE RASH I EXPERIENCED WAS IRRITATED, BURNED, AND ITCHED. WE BOTH WENT TO THE DOCTOR COUNTLESS TIMES. WE WERE TESTED FOR EVERY STD YOU CAN THINK OF. ALL BEING NEGATIVE. AFTER HER HYSTERECTOMY AND REMOVAL OF ESSURE DEVICE WE HAVE NOT HAD A PROBLEM WITH RASHES, BUMPS, OR ILLNESS FOLLOWING INTERCOURSE. SHE HAS BEEN ESSURE FREE SINCE (B)(6) OF 2013. I PURPOSELY WAITED ALMOST A YEAR BEFORE FILING TO MAKE SURE THAT THESE EFFECTS WOULD NOT RESURFACE. AS THEY HAVE NOT IT LEADS ME TO BELIEVE THAT THIS WAS A SERIES OF ISOLATED EVENTS CAUSED BY ESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035015	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 3/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN ABDOMEN, FATIGUE, HAIR-LOSS, NUMBNESS ON LEGS, INFLAMMATION, POKING PAIN ON RIGHT AND LEFT SIDE OF ABDOMEN, CRAMPING, HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035016	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RASH ALL OVER MY BODY, SHOOTING PAIN IN MY HEAD, WENT TO ER, THEY PUT ME ON NARCOTICS. SHOOTING PAIN IN PELVIC AREA ON RIGHT SIDE, UP AND DOWN LEG, MADE IT HARD TO MOVE. TEST AND SURGERY PROVED MY IMPLANT MIGRATED DEEP INTO WALL OF UTERUS, DR TOLD ME I WOULD NEED MY UTERUS REMOVED. MY OVERALL HEALTH IS WORST, THYROID AND SUGAR LEVEL OFF AND I GAINED 65 POUNDS WITHIN THREE MONTHS OF GETTING MY IMPLANT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035017	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 4/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING IMPLANTING THERE WAS GREAT PAIN IN THE LEFT SIDE AS WELL AS CRAMPS. THESE SYMPTOMS CONTINUED WITH ADDED SYMPTOMS OF MIGRAINES ANXIETY SEVERE BACK PAIN PELVIC PAIN BLADDER INFECTION NICKEL ALLERGY TIRED UPDATE ON (B)(6) 2014: MY SURGERY DATE WAS (B)(6) 2013! I HAD A PERFORATION ON MY UTERUS ON MY LEFT SIDE AND ALSO MY COIL ON MY RIGHT COIL IT PERFORATED THROUGH THE RIGHT SIDE OF MY FALLOPIAN TUBE! MY LEFT SIDE WASN'T BLOCKED AND WASN'T IN MY UTERUS AT ALL! I WAS IN SO MUCH PAIN!!! PREGNANCIES PRIOR TO IMPLANTING: 5, PREGNANCIES POST IMPLANTING: 0, HSG PERFORMED? YES. WHAT DID IT SHOW? NOT BLOCKED ON LEFT SIDE BUT BLOCKED IN RIGHT. FORM OF CONTRACEPTION BETWEEN IMPLANT AND HSG CONFIRMATION? ABSTINENCE. ANY GYN ISSUES PRIOR TO ESSURE? HAD AN 8 WEEK EARLY BABY ON (B)(6) AND THEN A D AND C ON (B)(6), HAD A BAD INFECTION AND WAS ON ANTIBIOTICS DUE TO THE LED PLACENTA. ANY GYN POST? YES, IN (B)(6) 2014 BEFORE SURGERY CALENDAR OF SYMPTOMS. PAINFUL LEFT OVARY! GOT MY TUBES REMOVED AND COILS. WHEN DID I GET IT? (B)(6) 2014 PATHOLOGY. WAS IT DEEMED ELECTIVE OR MEDICALLY NECESSARY? IT'S POSTED NOT SURE MEDICALLY BECAUSE OF COIL PERFORATION! ALSO PERFORATION IN UTERUS ON LEFT SIDE! REMOVE COILS? YES. ANY NOTICEABLE IMPACT ON SURROUNDING ORGANS? PERFORATION IN UTERUS AND PERFORATION IN FALLOPIAN TUBE. LOT A73753. (B)(6) ALSO HAD YOU HAD COMPLICATIONS FROM SURGERY TOO. ALSO ON PATHOLOGY REPORT I HAD A FEW CYSTS!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035018	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 11/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN FROM ESSURE. MAJOR BLEEDING ON PERIODS AND HAVE FULL COPIES OF RECORDS OF LABS AND REPORTS OF THIS HORRIBLE DEVICE I THOUGHT WAS GOOD FOR ME. NO ONE ASKED OR TESTED TO SEE IF I WAS ALLERGIC TO WHAT WAS IN IT. I LOST OVER 143 LBS ON ESSURE. COULDN'T EAT, THAT'S HOW BAD PAIN WAS. COULDN'T ENJOY SEXUAL ENCOUNTER EITHER...SO I ENDED UP WITH FULL HYSTERECTOMY ON (B)(6) 2013, AND ALSO THEY FOUND ENDEMEOTRIOS DURING SURGERY WHICH I HAVE NEVER HAD BEFORE. MAJOR, MAJOR PELVIC PAIN, HEADACHES, ALWAYS DIZZY, SICK. IT WAS TERRIBLE..... I'M GLAD I GOT THEM REMOVED. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035019	CONCEPTUS	3/19/2014	3/20/2014

Event Information:

Event Date (B3): 2/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I UNDERWENT A HYSTERECTOMY DUE TO ESSURE. I HAD SEVERE NECK, BACK, PELVIC AND ABDOMINAL PAIN AS WELL AS BLEEDING -BAD CLOTTING AND PINCHING SENSATIONS WITH EXTREME HIP PAIN. I HAVE NEUROPATHY IN MY RIGHT INNER THIGH AND KNEE --CONSTANTLY NUMB AND KNEE IS SWOLLEN TO THE POINT WHERE I HAVE DIFFICULTY BENDING IT. SEVERE ANXIETY AS WELL AS DEPRESSION TO THE POINT I WANTED TO END MY LIFE MORE THAN ONCE. THE ONLY THING THAT KEPT ME ALIVE AND GOT ME OUT OF BED EVERYDAY WAS THE THOUGHT OF MY CHILDREN BEING RAISED WITHOUT ME. I'M A WEEK POST OP FROM HAVING A HYSTERECTOMY AND I FEEL MENTALLY WONDERFUL. (BORED FROM BEING HOME RECOVERING AND SOME PAIN WHERE THE INCISIONS ARE). I ASKED MY HUSBAND, HIS THOUGHT...HOW DO YOU SEE ME NOW? DO I STILL SEEM DEPRESSED OR ANXIOUS? HE SAID I HAVE SEEN MY WIFE 100% BETTER SINCE GETTING THE COILS OUT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035090	CONCEPTUS, INC.	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 1/20/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THREE YEARS AGO I HAD THE ESSURE COILS INSERTED INTO BILATERAL FALLOPIAN TUBES. SINCE THEN I HAVE DEVELOPED SEVERE ABDOMINAL AND LOWER BACK PAIN, MORE ON THE RIGHT POWER SIDE. ABNORMAL BLEEDING AND IRREGULAR PERIODS WITH LARGE BLOOD CLOTS. UNKNOWN SKIN RASHES, IRREGULAR HEART RHYTHM, FLUID RETENTION, DENTAL PROBLEMS, VISUAL PROBLEMS, FATIGUE, FLU LIKE SYMPTOMS, BODY ACHES, FINGER AND TOES GOING NUMB, URINARY INCONTINENCE, SEVERE CONSTIPATION, CHRONIC BACTERIAL VANITIES, ABD. BLOATING, WEIGHT GAIN, "MELASTHMA", MEMORY LOSS, VERTIGO, EXPRESSIVE APHASIA, INABILITY TO PRONOUNCE WORDS, HOH, NAUSEA, SEVERE MOOD CHANGES, ABDOMINAL BEHAVIOR, I HAVE LOST MORE THAN HALF MY HAIR, MIGRAINES, SINUS AND ALLERGIES ENHANCEMENT. I DID NOT HAD THESE SYMPTOMS PRIOR TO THE INSERTION OF THESE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035094	BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 5/6/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/6/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED ON (B)(6) 2013. SIDE EFFECTS NOTICED AS OF AS OF (B)(6) 2013 - UNEXPLAINED INSULIN RESISTANCE AND EXTREMELY HIGH BLOOD SUGARS, EXTREMELY HIGH HEART RATE, ABNORMAL EKG ((B)(6) 2014), VAGINAL DRYNESS, UNCOMFORTABLE/PAINFUL INTERCOURSE, TAMPON USE IRRITATION, VITAMIN B12 DEFICIENT, VITAMIN D DEFICIENT, CRAMPING ALLERGIC REACTIONS TO THE NICKEL CHEMICAL AND FOOD SENSITIVITIES, HIVES, RASHES, ITCHING, METALLIC TASTE IN MOUTH, RECURRING YEAST INFECTIONS, FATIGUE/LOSS OF ENERGY, HEADACHES OR MIGRAINES, POSSIBLE ENDOMETRIOSIS, NAUSEA, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, EXTREME WEIGHT LOSS, SWELLING OF LEGS OR FEET, LEG PAINS, HAIR LOSS OR CHANGES, ABNORMAL MENSES - DYSFUNCTIONAL UTERINE BLEEDING PERIOD STOPS, PTSD, VITAMIN D DEFICIENT TEETH ISSUES - SORE, ITCHY GUMS, BLEEDING GUMS, SORE TEETH, ITCHY TONGUE HEARTBURN - INDIGESTION, CLOUDINESS, FORGETFULNESS, INSOMNIA, HEART PALPITATIONS, FLUTTERING FEELING OR SPASMS, ANXIETY, PANIC ATTACK, CONSTANT SPOTTING, FOUL SMELL OR DISCHARGE, MOOD SWINGS, AND HOT FLASHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035103	BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 11/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/13/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED ON (B)(6), 2012 AND HAVE BEEN SUFFERING EVER SINCE. CHRONIC LOWER BACK PAIN, NECK PAIN, BUTTOCK PAIN, ABDOMINAL PAIN, SIDE AND HIP PAIN, MUSCLE CRAMPS IN BACK, LEGS, BUTTOCKS AND ABDOMEN, CHRONIC FATIGUE, DEPRESSION, ANXIETY, MUSCLE ACHES AND PAINS, MOOD SWINGS, EXCESSIVE GAS AND BLOATING, NAUSEA, VOMITING, INDIGESTION, LOSS OF APPETITE, HEAD ACHES, JOINT PAIN, LOSS OF CONCENTRATION, MIND FOG, MISSED PERIODS, PAINFUL PERIODS, NIGHT SWEATS, INSOMNIA, RASHES, SENSITIVITY TO SUNLIGHT, SKIN IS TENDER TO THE TOUCH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035104	CONCEPTUS	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 10/2/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/2/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2008 I HAD ESSURE IMPLANTED AS PERMANENT STERILIZATION. (B)(6) 2012 BEGAN EXPERIENCING HEAVY VAGINAL BLEEDING, CLOTTING ALONG WITH EXCRUCIATING LOWER BACK AND ABDOMINAL PAIN. BY (B)(6) 2012 LOWER BACK AND ABDOMINAL PAIN BECAME DEBILITATING AT TIMES AND THE VAGINAL BLEEDING BECAME EXCESSIVE. I HAVE ALSO EXPERIENCED SOME HAIR LOSS AND WEIGHT GAIN IN THE PROCESS. ULTRASOUND IN (B)(6) 2012 REVEALED ONE OF THE THREE ESSURE COILS EMBEDDED INTO MY UTERINE WALL, NOT IT'S ORIGINAL LOCATION. THE MOST RECENT ISSUE WITH ESSURE HAS CAUSED VAGINAL BLEEDING SINCE (B)(6), 2014 THROUGH TODAY'S POSTING, NON-STOP. DUE TO LOSS OF JOB AND INSURANCE IN 2012 UNABLE TO AFFORD TO HAVE COILS REMOVED. NOW THAT NEW INSURANCE IS IN PLACE, HYSTERECTOMY IS SCHEDULED FOR (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035105	BEYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 3/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/15/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2012, I WAS IMPLANTED WITH ESSURE AS A PERMANENT FORM OF BIRTH CONTROL. I THOUGHT IT WAS GOING TO BE THE BEST OPTION. I WAS WRONG. I HAVE BEEN HAVING VERY PAINFUL PERIODS MONTHLY, TO THE POINT THAT MY DOCTOR PRESCRIBED ME ESTROGEN TO TAKE EVERY MONTH DURING MY CYCLE. MY CYCLE NOW LASTS 10-15 DAYS DURING THE MONTH. I HAVE NEVER HAD THEM TO BE THAT WAY. I ALSO HAVE HAD SEVERE HIP AND MUSCLE PAIN TO THE POINT THAT IT IS DIFFICULT TO MOVE. I FIND MYSELF ALWAYS EXHAUSTED, WHICH HAS BEEN HARD TO HANDLE ESPECIALLY WITH A BABY UNDER THE AGE OF 2. I HAVE BEEN HAVING CONSTANT PAIN IN MY LOWER ABDOMEN. MY PAIN LEVEL AVERAGES BETWEEN A 3 OR 4 IN THE MORNINGS, THEN BY THE TIME I GO TO BED IT IS CLOSE TO AND 8 OR 9. I JUST WANT ALL OF THE PAIN TO STOP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035106	CONCEPTUS, INC	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 3/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 761437

Single Use:
Implant Date (E6): 10/28/2013
Explant Date (E7): 1/21/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL DEVICE IMPLANTED (B)(6) 2010. APPROXIMATELY 2 YEARS LATER, I EXPERIENCED EXTREMELY BAD PERIODS, NAUSEA, DIZZINESS, BRAIN FOG, MEMORY LOSS, DAILY BLOATED, WEIGHT GAIN, EXTREMELY PAINFUL OVULATION, DAILY PELVIC PAIN, MIGRAINES, JOINT PAIN, DAILY IRRITABILITY, HAIR LOSS, EXTREME FATIGUE, LOSS OF INTEREST IN DAILY ACTIVITIES, BLURRY VISION, HOT FLASHES, CONSTANT SINUS ISSUES, HEART PALPITATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035107	BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVING SIDE EFFECTS FROM THE ESSURE PROCEDURE. HORRIBLE METAL TASTE, CRAMPING, FATIGUE, CLOUDY BRAIN, AND HEADACHES. FEEL LIKE I'M BEING POISONED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035128	BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 9/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/23/2013
Explant Date (E7): 2/12/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE ON (B)(6) 2013. THE INITIAL PROCEDURE WENT WELL. I HAD BLEEDING AFTERWARDS AND HEAVY BLEEDING THAT CONTINUED FOR 2 MONTHS SOLID THEN I WOULD STOP BLEEDING FOR A COUPLE OF DAYS THEN CONTINUE WITH HEAVY BLEEDING FOR A COUPLE OF WEEKS THEN STOP BLEEDING FOR A COUPLE OF DAYS AND THIS CONTINUED. I ALSO HAD SEVERE PELVIC PAINS THAT WOULD COME OFF AND ON. I ENDED UP BEING SEVERELY ANEMIC FROM THE BLOOD LOSS. I HAD LOTS OF HAIR FALLING OUT AND BRUISES ALL OVER MY BODY. I ALSO HAD LOWER BACK PAIN AFTER HAVING THEM INSERTED. I CALLED MY DOCTOR WHO IMPLANTED THEM AND THEY TOLD ME THEY NEVER HAD ANY PATIENTS WITH THESE SYMPTOMS. I TOLD THEM I WANTED THEM OUT OF ME BECAUSE I'VE BEEN BLEEDING AND IN PAIN SINCE HAVING THEM IN. THEY DECIDED NOT TO DO THE HSG TEST BECAUSE I WANTED THEM OUT. MY OTHER DOCTOR DECIDED REMOVING THEM WOULD BE BEST. I HAD A HYSTERECTOMY ON (B)(6) 2014 LEAVING OVARIES. THE BLEEDING, PAIN, BRUISING, AND HAIR LOSS HAVE ALL STOPPED AND I FEEL A LOT BETTER NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035130		3/19/2014	3/25/2014

Event Information:

Event Date (B3): 3/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/10/2010
Explant Date (E7): 2/26/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE DEVICE IN 2010 AND EVER SINCE THEN I HAVE BEEN IN PAIN, BLOATED, FELT LIKE SOMETHING WAS STABBING ME. I HAVE HAD JOINT PAINS THAT STARTED AFTER PLACEMENT. THEN A COUPLE WEEKS AGO THEY THOUGHT MY ESSURE WAS GOING INTO MY UTERUS. SO THEY DID A REMOVAL AND TIED MY TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035131	BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 8/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/14/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED (B)(6) 2009. BEGAN EXPERIENCING SEVERE AND HEAVY BLEEDING FOR EXTENDED TIME PERIODS. DOCTOR KEPT DIAGNOSING AS OVARIAN CYSTS THAT WERE CYCLICAL WITH MENSTRUATION. DOCTOR PRESCRIBED BIRTH CONTROL PILLS. BEGAN HAVING PELVIC AND BACK PAINS (MILD) THAT WERE DISMISSED. CHANGED MEDICAL PRACTICES. A HYDRO-ABLATION WAS PERFORMED TO DECREASE THE AMOUNT OF BLEEDING. SYMPTOMS OF LETHARGY, HAIR LOSS, WEIGHT GAIN, JOINT PAINS, MIGRAINES, AND OTHER ISSUES BEGAN INCREASING WITH THE PELVIC PAIN AND BACK PAIN CONTINUING. MY BLOOD PRESSURE BEGAN INCREASING WITH NO APPARENT CAUSE. ON (B)(6) 2013 I WAS TAKEN TO THE EMERGENCY ROOM WITH A MIGRAINE AND DIZZINESS. A CT SCAN AND LUMBAR PUNCTURE WERE PERFORMED. THE RESULTS SHOWED NO BRAIN BLEEDS BUT NO APPARENT CAUSE FOR THE PAIN. THE DOCTOR THAT PERFORMED THE ABLATION HAD SINCE LEFT THE PRACTICE SO I SAW ANOTHER DOCTOR IN THE SAME PRACTICE. DOCTOR ORIGINALLY THOUGHT I WAS HAVING A UTERINE INFECTION AS A RESULT OF THE ABLATION (WHICH WAS PERFORMED OVER A YEAR EARLIER, (B)(6)2012). AN ANTIBIOTIC WAS PRESCRIBED TO WHICH I HAD AN ALLERGIC REACTION. BLOOD TESTS AND AN ULTRASOUND WERE PERFORMED. BLOOD RESULTS SHOWED SLIGHTLY DECREASED LEVELS OF PROGESTERONE LEVELS BUT ALL OTHER HORMONES WERE FINE. ULTRASOUND FOUND MY UTERUS TO BE QUITE INFLAMED. DOCTOR PRESCRIBED A PROGESTERONE CREAM. I HAVE BEEN ON THE PROGESTERONE NOW FOR A MONTH AND NONE OF THE ORIGINAL SYMPTOMS HAVE CHANGED. I ASKED THE DOCTOR ABOUT THE POSSIBILITY OF ESSURE BEING THE CAUSE AND SHE WAS NOT RECEPTIVE TO LOOKING INTO ESSURE AS BEING THE ROOT CAUSE FOR ANY OF MY UNEXPLAINED SYMPTOMS.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035132	BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 8/13/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627283

Single Use:
Implant Date (E6): 8/13/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2008 I WAS IMPLANTED WITH ESSURE SIX WEEKS AFTER THE BIRTH OF OUR SECOND CHILD. MY HSG WAS DONE FOUR MONTHS LATER (MY CYCLE DID NOT MATCH UP WITH AVAILABLE APPOINTMENTS AT THE THREE MONTH MARK AS RECOMMENDED) AND I WAS TOLD I WAS 100% OCCLUDED AND COULD DISCONTINUE ORAL BIRTH CONTROL. (B)(6) 2010 I WAS EVALUATED BY A NEW OB/GYN FOR CLOTTY, HEAVY, HEMORRHAGIC (AT TIMES) BLEEDING DURING MY PERIODS. I EXPRESSED MY CONCERN THAT ESSURE WAS THE CAUSE AS THAT WAS THE ONLY NEW THING I HAD DONE. THE DOCTOR DISMISSED MY CONCERN SAYING "ESSURE IS NON-HORMONAL AND HAS NO EFFECT ON YOUR BLEEDING." SHE PUT ME ON ORAL BIRTH CONTROL AFTER DOING AN ENDOMETRIAL BIOPSY. (B)(6) 2011 I DISCONTINUED THE ORAL BC AS MY BLEEDING HAD STARTED PRIOR TO THE END OF THE HORMONAL PILLS IN THE PACK. THE PILLS HAD NOT HELPED MY BLEEDING WHATSOEVER ANYWAY, IT WAS STILL HEAVY AND VERY CLOTTY. (B)(6) 2011 I DID NOT HAVE A PERIOD. I HAD BEEN WORKING OUT A LOT AND WATCHING MY DIET AND HAD LOST 35 LBS. I THOUGHT MY BODY WAS ADJUSTING TO THE WEIGHT LOSS AND COMING OFF OF THE HORMONES. (B)(6) I DID NOT HAVE A PERIOD. (B)(6) 2011 I RETURNED TO MY OB/GYN AND THEY TOLD ME I WAS 13 WEEKS PREGNANT. MY PREGNANCY PROGRESSED NORMALLY, I WAS BEING OBSERVED WITH WEEKLY ULTRASOUNDS FOR MILD POLYHYDRAMNIOS AND HAD TWICE WEEKLY NON-STRESS TESTS DUE TO MY WEIGHT. MY BABY WAS BORN (B)(6) 2012. I UNDERWENT A LAPAROSCOPIC TUBAL LIGATION AND HERNIA REPAIR (B)(6) 2012. MY OB/GYN FOUND THAT MY LEFT ESSURE COIL HAD COMPLETELY MIGRATED OUT OF THE FALLOPIAN TUBE AND WAS SCARRED INTO MY ABDOMINAL WALL. THE RIGHT ESSURE COIL HAD ALSO PERFORATED AND WAS PARTIALLY IN THE TUBE STILL, WITH THE FREE END MAKING CONTACT WITH MY COLON. SHE ELECTED TO

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REMOVE THAT ONE BUT DECIDED TO LEAVE THE LEFT COIL IN MY ABDOMEN. SINCE MY PARTIAL REMOVAL I STILL HAVE HEAVY, HEMORRHAGIC, CLOTTY PERIODS. I HAVE SINCE BEEN DIAGNOSED WITH MULTIPLE FIBROIDS, WHICH I DID NOT HAVE PRIOR TO ESSURE IMPLANTATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035133		3/19/2014	3/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN AFTER MY 4TH CHILD IN 2009 NOW I GET REAL BAD PAINS, HEADACHES AND BIG BLOOD CLOTS WHEN I GET MY PERIOD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035134	BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 3/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/16/2008
Explant Date (E7): 3/10/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER BEING IMPLANTED WITH ESSURE I BEGAN HAVING HEALTH ISSUES. WAS DIAGNOSED WITH AUTO IMMUNE DISEASE AND HAD SEVERE HEADACHES, LOW BACK PAIN, SEVERE ABDOMINAL PAIN, SEVERE PELVIC PAIN ETC. I WAS HOSPITALIZED ON SEVERAL OCCASIONS DUE TO ESSURE. I BECAME ANEMIC FROM THE HEAVY BLEEDING. IT ENDED UP I HAVE TO HAVE A HYSTERECTOMY WHERE THE DOCTOR FOUND THAT MY UTERUS AND BLADDER HAD GROWN TOGETHER AND ATTACHED TO MY ABDOMINAL WALL. I HAD A TREMENDOUS AMOUNT OF ADHESIONS AND MY UTERUS WAS FULL OF BLOOD AND HAD SET UP LIKE CONCRETE AND PART OF MY UTERUS WAS STRETCHED OUT AND JUST DANGLING. THERE IS MUCH MORE I HAVE BEEN THROUGH SINCE HAVING ESSURE IT HAS REALLY BEEN A VERY BAD PRODUCT AND I WOULD NEVER RECOMMEND IT TO ANYONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035135		3/19/2014	3/25/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE DONE. IN 2008, STARTED HAVING PELVIC PAIN IN (B)(6), STABBING, BURNING, PULSING PAIN ALSO TIMES WHEN URINATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035136	CONCEPTUS/BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 2/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B61388

Single Use:
Implant Date (E6): 12/13/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SIX WEEKS AFTER HAVING ESSURE INSERTED I WOKE UP WITH HORRIBLE LOWER BACK PAIN. IT HASN'T GONE AWAY. I'M ALSO DEALING WITH CHRONIC FATIGUE, AND STABBING PAINS IN MY PELVIC AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035137	BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): 7/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/28/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY ESSURE PROCEDURE DONE IN (B)(6) 2011. APPROX 6 MONTHS AFTER THE PROCEDURE ((B)(6) 2011) I BEGAN TO GAIN WEIGHT. OVER THE NEXT YEAR, I HAD GAINED 45 LBS. MY DIET AND EXERCISE 5-6 DAYS A WEEK HAD NOT CHANGED. I NOW HAVE CYSTS AT THE VAGINAL OPENING, FACIAL HAIR GROWTH, OCCASIONAL SWOLLEN GLANDS W/ NO EXPLANATION, RINGING AND ACHES IN EARS W/ NO INFECTIONS, OCCASIONAL NUMBNESS IN MY THIGHS, FOREARMS, FINGERS, WRISTS AND FEET. I WAS DIAGNOSED WITH RAYNAUDS PHENOMENON IN (B)(6) 2011 AND SUFFER FROM NERVE PAIN WHEN I HAVE AN ATTACK, METAL TASTE IN MOUTH, LONGER LASTING, PAINFUL MENSTRUAL CYCLES (DYSMENORRHEA), OCCASIONAL BLEEDING BETWEEN CYCLES, OVARIAN CYSTS. I AM ANEMIC SINCE 2000; HOWEVER, AFTER THE PROCEDURE IT IS MUCH HARDER TO MAINTAIN HEALTHY IRON LEVELS DUE TO THE AMOUNT OF MENORRHAGIA I EXPERIENCE DURING MY CYCLES AND I TEND TO PASS LARGE BLOOD CLOTS. A FEW DAYS BEFORE AND A FEW DAYS AFTER MY CYCLE, I HAVE DISCHARGE WITH ODOR. I NOW SUFFER WITH MIGRAINES, OCCASIONAL MUSCLE SPASMS, SIGNIFICANT FATIGUE, FOGGY BRAIN WITH SHORT TERM MEMORY LOSS. I AM MOODY, AND SUFFER FROM INSOMNIA. INTERCOURSE IS PAINFUL AND TO THE POINT I AM IN TEARS DURING AND/OR AFTERWARDS, AS WELL AS ACCOMPANIED WITH LIGHT BLEEDING. I GET CONSTIPATED FAR MORE FREQUENTLY AND ON TOP OF EATING A HIGH IN FIBER DIET, I ALSO HAVE TO TAKE FIBER SUPPLEMENTS AND ADD IN A FIBER POWDER TO MEALS/DRINKS. MY HAIR IS THINNING, I HAVE LOWER BACK AND HIP PAIN. MY ABDOMEN SWELLS AND REMAINS SWOLLEN FOR DAYS AT A TIME ACCOMPANIED WITH STABBING PAINS AND PELVIC PAINS AND ABDOMINAL SPASMS. ABOUT 1 WK BEFORE MY CYCLE, MY BREASTS BECOMING EXTREMELY PAINFUL AND INCREDIBLY SENSITIVE. ASIDE FROM THE ANEMIA, WHICH HAS NOW WORSENED, I DID NOT START

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ANY OF THIS UNTIL APPROX 6 MO AFTER MY ESSURE WAS IMPLANTED. IT HAS TAKEN A TOLL ON MY LIFE AS WELL AS MY FAMILY'S LIVES. I HAVE 4 CHILDREN WHO NEED THEIR MOTHER TO BE 100% AT ALL TIMES, AND I AM NOT ANYMORE. THAT IS NOT FAIR TO THEM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035138	CONCEPTUS / BAYER	3/19/2014	3/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE MICRO INSERTS
Device Type (E2): ESSURE MICRO INSERTS
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626159

Single Use:
Implant Date (E6):
Explant Date (E7): 3/8/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2008 MY DOCTOR RECOMMENDED AND IMPLANTED ESSURE MICRO-INSERTS REF NUMBER ESS305 LOT NUMBER 626159. FROM THE VERY MOMENT OF HAVING THE IMPLANTS I HAVE EXPERIENCED EXCRUCIATING PAIN, DEBILITATING PAIN THAT STAYED AND BECAME CHRONIC. AFTER SOME TIME WENT BY, I HAD DAYS THAT THE PAIN WOULD SUBSIDE FROM DEBILITATING TO MANAGEABLE CRAMPS, THEN BACK TO DEBILITATING PAINS DURING MENSTRUATION TIMES. I WOULD BE BED RIDDEN THE WEEK PRIOR TO MY MENSTRUAL CYCLE, THE WEEK OF MY MENSTRUAL CYCLE, AND A FEW DAYS AFTER MENSTRUAL CYCLE THE PAINS WOULD START TO SUBSIDE A LITTLE ENOUGH THAT I COULD MOVE AROUND A LITTLE BETTER. THE PAINS NEVER TOTALLY GO AWAY. DURING MENSTRUAL CYCLE THE PAINS WERE SO STRONG AND STABBING THAT I WOULD HAVE BOUTS OF VOMITING, AND CRYING, COULD NOT TAKE CARE OF MYSELF AND MY CHILDREN. FAMILY MEMBERS HAD TO TAKE OVER THE CHORES AND DAILY FUNCTIONS THAT I WOULD NORMALLY DO. MY LIFE HAD CHANGED AND I BECAME MORE AND MORE UNABLE TO PERFORM DAILY LIVING TASKS. I RELIED MORE AND MORE ON THE HELP OF OTHERS. I WENT TO SEVERAL DOCTORS AND EMERGENCY ROOM VISITS. DOCTORS COULD NOT EXPLAIN WHAT WAS WRONG WITH ME, THEY PRESCRIBED PAIN KILLERS AND SENT ME HOME. I HAVE SUFFERED WITH THIS AFFLICTION FOR MANY YEARS SINCE BEING IMPLANTED WITH THE ESSURE MICRO INSERTS. IT FINALLY DRAINED MY MARRIAGE AND AS A RESULT MY HUSBAND DIVORCED ME IN 2011. AS I KEPT GETTING WORSE AND SUFFERING TO THE POINT I THOUGHT I WAS GOING TO DIE, FINALLY FOUND A DOCTOR TO DO AN MRI AND RUN MORE TESTS. THE RESULTS: LESIONS, INFLAMED OVARIES AND UTERUS, CYST SO BIG AND FLUID FILLED THAT IT TOTALLY TOOK OVER MY LEFT OVARY, PRESSED ON MY BLADDER CAUSING INCONTINENCE, AND PUSHING ON MY ABDOMEN CAUSING ADDITIONAL PAINS AND BLOATING, THE RIGHT OVARY WAS INFLAMED AND WITH FLUID FILLED CYSTS. THE INSERTS RUINED MY LIFE. IN 2013 MY DOCTOR

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SAID SHE COULD NOT REMOVE THE ESSURE. THE ONLY WAY TO GET THEM OUT OF ME WAS TO PERFORM A HYSTERECTOMY. I HAD A HYSTERECTOMY ON (B)(6) 2013 TO REMOVE THE ESSURE COILS. SINCE THE REMOVAL, THE CHRONIC PAIN HAS GONE. BUT AS A RESULT OF GETTING THE COILS OUT OF ME, I HAVE HAD TO HAVE MY HEALTHY UTERUS AND OVARY AND TUBES REMOVED. MY OTHER SYMPTOMS DURING THE TIME THE ESSURE WERE IN ME: PAINS, DIZZY, METAL TASTE, MOOD SWINGS, HAIR LOSS, STABBING PAIN, TEETH AND GYMS SENSITIVE, SKIN CHANGED, HIVES AND RASHES, ITCHY BURNING SKIN, ODD PERIODS, FORGETFULNESS, SHARP PAINS IN BACK, HIP AND LEG. INSOMNIA, CHRONIC FATIGUE, BLOATED, WEIGHT GAIN, NAUSEA, MIGRAINES, BLEEDING, SPOTTING, UMBILICAL HERNIA, TO NAME JUST SOME OF MY ILLNESSES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035020	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 12/6/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DAY I WAS SCHEDULED TO HAVE THE PROCEDURE, I WAS GIVEN A PAIN PILL ALONG WITH A NERVE PILL. WHEN THE DOCTOR CAME IN, HE PLACED MY LEFT SIDE FIRST AND THEN MY RIGHT. I HAD MORE PAIN IN MY RIGHT SIDE BECAUSE, HE SAID THAT SIDE SEEMED HARDER TO PLACE. I CRAMPED AND BLED IMMEDIATELY AFTER PROCEDURE. THE CRAMPING GOT WORSE, I WAS HAVING SEVERE MOOD SWINGS, SEVERE LOWER BACK PAIN, AND PAIN IN MY LEGS. I FELT VERY SICK TO MY STOMACH SEVERAL DAYS AFTER. THE BLEEDING GOT WORSE AS THE DAYS WENT ON. I CALLED MY DOCTOR'S OFFICE SEVERAL TIMES AND WAS TOLD I NEEDED TO LET MY BODY ADJUST TO THE CHANGES OF THE ESSURE. ABOUT 1 MONTH AFTER THE PROCEDURE, MY HUSBAND AND I WERE SLEEPING AND HE WOKE ME UP IN THE MIDDLE OF THE NIGHT BECAUSE, I HAD BLED OUT ON MY BED, MYSELF, AND MY HUSBAND. IT WAS SO BAD THAT THE BLOOD WENT THROUGH THE PADDING ON OUR BED AND SOAKED INTO OUR MATTRESS. THE ER TOLD ME THAT WAS NORMAL. BEFORE THIS I HAD BEEN TO THE DOCTOR'S OFFICE TO HAVE PAP SMEARS DONE AND ALL I WAS TOLD WAS THAT THEY WERE IRREGULAR AND WOULD NEED ANOTHER. THEY WOULD NOT TELL ME WHAT THE PROBLEM WAS ITSELF. I THEN CHOSE NOT TO GO BACK TO THE DOCTOR BECAUSE, IT BECAME APPARENT THEY WERE NOT GOING TO HELP ME. I FELT AS THOUGH I WAS GOING INSANE. IT WAS HARD FOR ME TO CARRY ON MY DAILY TASK WITH MY CHILDREN. AS SOON AS MY HUSBAND WOULD COME HOME FROM WORK, I WOULD HAVE TO GO LAY DOWN. I WAS FATIGUED BADLY WITH MULTIPLE HEADACHES ALONG WITH THE PELVIC PAIN THAT NEVER GOES AWAY. TO THIS DAY, I STILL HAVE ALL THESE PROBLEMS BESIDES BLEEDING OUT, THAT WAS A ONE TIME DEAL BUT, SCARY. MY PERIODS NOW ARE STILL HORRID. I BLEED FOR ALMOST TWO WEEKS NOW WITH HUGE CLOTS THAT ARE VERY PAINFUL. MY PELVIC PAIN INCREASES DURING MY MONTHLY. I GO THROUGH ALMOST THREE AND A HALF PACKAGES OF PADS. MY HEADACHES HAVE NOW TURNED INTO MIGRAINES WHICH MAKE ME

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VIOLENTLY SICK. I DON'T GET TO SPEND TIME WITH MY CHILDREN LIKE I SHOULD BE ABLE TO. I AM (B)(6) YEARS OLD AND I SHOULD BE FEELING GREAT. ESSURE HAS RUINED MY LIFE AND ALMOST BROKE UP MY MARRIAGE BECAUSE, MY HUSBAND COULDN'T BELIEVE HOW MUCH I HAD CHANGED DUE TO ESSURE. HE COULDN'T HANDLE THE PRESSURE OF ME ALWAYS BEING IN PAIN WHICH RESULTED IN ME BEING MOODY. IT IS A HORRIBLE THING TO GO THROUGH. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035021	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A YEAR AFTER I RECEIVED THE ESSURE DEVICE I STARTED CRAMPING VERY BADLY EACH MONTH DURING MY PERIOD WHICH WAS MY FIRST SIDE EFFECT. MY SECOND SIDE EFFECT WAS DURING MY PERIOD I WAS PASSING VERY LARGE CLOTS (WHICH HAS NEVER HAPPENED). THE THIRD SIDE EFFECT IS SUDDEN SHARP, STABBING PAINS WOULD COME AND GO ON THE LOWER LEFT SIDE OF MY STOMACH AND THE PAIN WOULD START IN MY LOWER LEFT PELVIC AREA AND MOVE UPWARD JUST UNDER MY RIB CAGE BUT THE MOST SEVERE PAIN IS IN MY LOWER LEFT PELVIC AREA WITH SUDDEN BOUTS OF NAUSEA AND VOMITING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035022	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED TO EXPERIENCE CRAMPING, WORSE JOINT PAIN, MAJOR WEIGHT GAIN, SEVERE LOWER BACK, MAJOR STOMACH BLOATING, FATIGUE, AND BAD BRAIN FOG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035023	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/2/2012
Explant Date (E7): 2/26/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MIGRAINES,PELVIC PAIN, PAIN WITH SEXUAL INTERCOURSE, DIZZINESS, PAIN DOWN LEGS, NAUSEA, BLOATING,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035024	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 6/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CRAMPING, LOSS OF MENSTRUATION, PELVIC PAIN, A LOT OF VAGINAL MUCUS AND GRAY AND WHITE TISSUE COMING OUT, A MISCARRIAGE AFTER PLACEMENT 8 WEEKS IN, SEVERE ABDOMINAL SWELLING, VAGINAL SWELLING, RASH ON LOWER HIP AREA, HAIR LOSS, WEIGHT GAIN, FATIGUE, NAUSEA, VOMITING, HEADACHES, HEAVY PULSATING FEELING IN STOMACH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035036	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 7/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT A RASH ON MY ARMS. I WAS BLOATED AND AT FIRST THOUGHT IT WAS ATTRIBUTED TO JUST HAVING A BABY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035044	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 7/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT A RASH ON MY ARMS. I WAS BLOATED AND AT FIRST THOUGHT IT WAS ATTRIBUTED TO JUST HAVING A BABY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035045	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 2/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER TWO YEARS OF HAVING THE ESSURE IN ONE OF MY FALLOPIAN TUBES THE DOCTOR SUGGESTED I HAVE ULTRASOUND OR THE DYE PROCEDURE AGAIN. IT WAS NOTED THAT THE DEVICE WAS NO LONGER IN MY TUBE. NOW THE DR WANT TO REMOVE THE DEVICE. I'M SCHEDULE TO SEE DR ON THE (B)(6) TO SEE WHAT ARE MY OPTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035048	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 1/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALLERGIC REACTION, SEVERE PELVIC PAIN, HEADACHES, DIZZYNESS, NAUSEA, CONSTANT BLEEDING, MUSCLE SPASMS,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035049	BAYER	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 2/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY AFTER WAKING UP FROM THE PROCEDURE I WAS EXPERIENCING SEVERE HEADACHE, DIZZINESS, CRAMPING LIKE THOSE FELT DURING MENSTRUATION, PAIN IN MY RIGHT LEG, STABBING PAINS IN MY LOWER BACK, FORGETFULNESS, DEPRESSION. THESE SYMPTOMS AFTER 5 WEEKS HAVE NOT GONE AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035050	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEADACHES, MUSCLE SPASMS, BAD CRAMPS, MOOD SWINGS, BACKACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035051	CONCEPTUS	3/20/2014	3/20/2014

Event Information:

Event Date (B3): 3/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NOT LONG AFTER THE PLACEMENT OF ESSURE I STARTED HAVING ISSUES. LOWER BACK PAIN, FORGETFULNESS, HORRIBLE HEADACHES, TINGLING IN MY LEGS AND FEET, RIDICULOUS PERIODS... COMING AND GOING AS THEY PLEASE. SOMETIMES 3 DAYS SOMETIMES 7. SOME MONTHS ON TIME SOME MONTHS 2 OR 3 PERIODS. EXCRUCIATING PELVIC PAIN ON BOTH SIDES. AND THE LIST GOES ON AND ON. I WORK FULL TIME AND HAVE 3 CHILDREN. NOT MUCH TIME FOR ME TO SIT IN A DR OFFICE SO I TOOK IT AS I WAS FEELING "OLD".... THE PAINS GOT SO BAD RECENTLY I FOUND MYSELF IN SO MUCH PAIN IN THE MIDDLE OF THE NIGHT I GOT UP TO CALL EMS. INSTEAD I WOKE UP ON THE COUCH NOT KNOWING WHAT WAS GOING ON..... I HAD PASSED OUT FROM THE AMOUNT OF PAIN. I SAW THE DR WHO INSERTED ESSURE IMMEDIATELY. HE DID ULTRA SOUNDS AND WITHIN A WEEK I HAD A HYSTERECTOMY.... AT THE AGE OF (B)(6).... (WAY TOO YOUNG MAY I ADD) I AM NOW 2 WEEKS POST OP AND ON MY 2ND WEEK OF BED REST. NOT ONLY AM I PROBABLY LOSING MY JOB BECAUSE OF BEING OFF WORK, MY HUSBAND HAD TO TAKE A WEEK OFF TO TAKE CARE OF ME AND WITH THE COST OF THIS SURGERY MY WHOLE FAMILY WILL PROBABLY BE SUFFERING FOR MONTHS TO COME..... THE ESSURE WAS THE WORST MISTAKE I HAVE EVER MADE AND IN NO WAY CAN I UNDERSTAND HOW THE FDA CAN SAY THIS DEVICE IS SAFE FOR ANY WOMAN!!! THE LAST 8 YEARS OF MY LIFE HAVE BEEN MADE HELL BY THIS DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035052	BAYER	3/20/2014	3/21/2014

Event Information:

Event Date (B3): 5/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE PROCEDURE TO IMPLANT THE ESSURE COILS THERE WAS SOME TYPE OF PROBLEM DURING INSERTION AND ONE COIL BROKE SO MY GYN HAD TO OPEN A SECOND KIT TO FINISH IMPLANTING. AFTER IT WAS OVER I HAD CRAMPING, BLEEDING, AND DISCOMFORT AS MY DOCTOR HAD WARNED ME OF. EVERYTHING SEEMED FINE AND THEN TWO WEEKS LATER I STARTED MY REGULAR PERIOD. IT LASTED 6 MONTHS. I CONTACTED MY GYN, AND SHE WANTED ME TO TAKE BIRTH CONTROL PILLS TO GET MY PERIOD BACK ON TRACK BUT WHEN I WENT TO MY APPOINTMENT I COULD NOT TAKE THE PILL BECAUSE FOR THE FIRST TIME IN MY LIFE I HAD HIGH BLOOD PRESSURE. SHORTLY AFTER THAT VISIT MY PERIOD STOPPED. A MONTH LATER MY PERIOD STARTED AGAIN AND LASTED MY NORMAL 5 DAYS. HOWEVER WITH THAT PERIOD AND EVERY PERIOD SINCE (THAT WAS IN (B)(6) OF 2012) ON MY SECOND DAY OF MY PERIOD I BLEED HORRIBLY. I HAVE TO USE 2 TAMPONS AND A (B)(4) PAD AT A TIME. I WILL STILL BLEED THROUGH THAT WITHIN AN HOUR AND HAVE HUGE GUSHES OF BLOOD THAT ACCOMPANIED BY LARGE CLOTS COVER MY CLOTHES DOWN MID-THIGH. SINCE IMPLANTING I HAVE ALSO HAD MANY OTHER SIDE EFFECTS THAT I DIDN'T THINK WERE ESSURE RELATED UNTIL DOING SOME RESEARCH ONLINE AND MADE THE CONNECTION BETWEEN THEM. MY OTHER SYMPTOMS ARE AS FOLLOWS: WEIGHT GAIN (45 LBS.) THAT I CAN NOT LOSE, NUMBNESS IN MY UPPER LIP, MUSCLE SPASMS, METALLIC TASTE IN MY MOUTH, FATIGUE, LOSS OF ENERGY, CONSTANT BRAIN FOG, BOILS, PAINFUL OVULATION, UNEXPLAINED BRUISING, MOODINESS, HEART PALPITATIONS, NAUSEA, SPOTTING AFTER SEX, EXCESSIVE CRAMPING DURING MY PERIOD, SEVERE BLOATING, JOINT PAIN, NUMBNESS AND TINGLING IN MY HANDS AND FEET, SHARP STABBING PAINS IN MY PELVIS, BREAST PAIN AND TENDERNESS, ABDOMINAL SPASMS, TWITCHING AND A FEELING OF A FLUTTER, CHRONIC LOWER BACK

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PAIN. YESTERDAY I WAS FINALLY ABLE TO HAVE MY HSG CONFORMATION TEST ONLY FOR IT TO BE DISCOVERED THAT THE COIL THAT IS SUPPOSED TO BE IN MY RIGHT FALLOPIAN TUBE IS IN MY ABDOMEN. I AM NOT STERILE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035181	CONCEPTUS BAYER	3/20/2014	3/26/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/1/2010
Explant Date (E7): 2/5/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY FOLLOWING IMPLANTATION WITH THE ESSURE DEVICE I DEVELOPED A SIGNIFICANT AMOUNT OF MEDICAL CONDITIONS/SYMPTOMS, IE FATIGUE, UNINTENDED ABNORMAL WEIGHTLOSS (82LBS IN 6 MONTHS), ACUTE SINUSITIS, THYROIDITIS, ADRENAL DISORDERS, ADRENAL INSUFFICIENCY, INSULIN DYSREGULATION, ALLERGIC REACTION, ADENOMYOSIS, PARATUBAL CYSTS, CHRONIC ENDOCERVICITIS WITH SQUAMOUS METAPLASIA, TREMOR (ON EXAM), NEUROLOGICAL SYMPTOMS, DEPRESSION, DRY EYE SYNDROME, HYPOGLYCEMIA, DYSHIDROTIC ECZEMA, HYPERGLYCEMIA, ARTHRALGIAS IN MULTIPLE SITES, DIPLOPIA WORSENS WITH FATIGUE, ANEMIA, ABDOMINAL PAIN (SYMPTOM), PERIPHERAL NEUROPATHY, NONTOXIC SOLITARY THYROID NODULE, BREAST LUMP (FIBROADENOMA), REPEATED URINARY TRACT AND KIDNEY INFECTIONS, FOLIC ACID DEFICIENCY, MYALGIA AND MYOSITIS, CELLULITIS, SKIN: A RASH (SYMPTOM), CHRONIC INTERSTITIAL CYSTITIS, VITAMIN B12 DEFICIENCY, HYPERACTIVITY OF THE BLADDER, EASY BRUISING TENDENCY, STOMACH ULCERS, GASTRITIS, MALABSORPTION, DEFICIENCIES OF SODIUM, POTASSIUM, MAGNESIUM, AND MORE. MY DOCTORS DESPERATELY TRIED TO LOCATE THE CAUSE OF MY DECLINE AND IT IS BELIEVED THAT MY ISSUES ARE CAUSED BY ESSURE. I WAS PREVIOUSLY A HEALTHY MOM OF THREE AND NOW I CANNOT WORK, TAKE CARE OF MY SPECIAL NEEDS CHILDREN, AND WILL NEVER HAVE A NORMAL LIFE DUE TO THIS PRODUCT. I HAVE HAD THREE SURGERIES SINCE I RECEIVED THIS DEVICE AND HAD NEVER HAD SURGERY BEFORE. I HAVE ALSO HAD LENGTHY HOSPITALIZATIONS DUE TO COMPLICATIONS POSTOPERATIVELY AND NEARLY DIED. MY FIRST SURGERY WAS THE REMOVAL OF A LYMPH NODE WHICH PATHOLOGISTS FOUND SMALL HYPERPLASTIC FOLLICLES, FEW PARACORTICAL NODULES, AND SINUS HISTIOCYTES. SOME OF THE HISTIOCYTES CONTAIN BROWN-BLACK PIGMENT AND SHORT, REFRACTILE NEEDLES, SUSPICIOUS FOR AMALGAM OR OTHER METAL DEBRIS, YET I HAVE NO OTHER METAL EVER IN MY BODY OR TEETH. THE ONLY PLACE THEY COULD

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HAVE COME FROM IS THE ESSURE. I RECEIVED A HYSTERECTOMY ON (B)(6) 2014. I WAS DISCHARGED TWO DAYS LATER FOR 15 HOURS BEFORE BEING ADMITTED AGAIN FOR BOERHAAVE SYNDROME (ESOPHAGEAL RUPTURE DUE TO VOMITING) I BARELY AVOIDED CARDIO THORACIC SURGERY AND SPENT 12 DAYS IN THE HOSPITAL. I AM STILL RECOVERING FROM SURGERY AND COMPLICATIONS DUE TO THE MANY CONDITIONS THIS DEVICE HAS CAUSED ME, YET, I HAVE MANY SYMPTOMS THAT ARE ALREADY GONE. SADLY THE DAMAGE IS DONE TO MY BODY AND MANY OF THE DEVELOPED CONDITIONS WILL REMAIN FOR LIFE. WITH NON FUNCTIONING ADRENAL GLANDS, AND NOW BEING STEROID DEPENDENT AT (B)(6), I WILL LIKELY DIE ONE DAY FROM THIS DEVICE DUE TO THE DAMAGE IT HAS CAUSED SYSTEMICALLY. IN THE LAST THREE YEARS I HAVE ACCRUED WELL OVER (B)(6) IN MEDICAL BILLS, AND THE COST OF MY CURRENT HEALTH REQUIREMENTS HAVE BEEN CATASTROPHIC.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00066	BAYER HEALTHCARE LLC	3/20/2014	3/31/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/10/2012
Explant Date (E7): 11/6/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED VIA FDA (CASE # (B)(4)) THAT SHE HAD ESSURE INSERTED ON (B)(6) 2012. SOMETIME IN 2013, SHE HAD THE WORST PERIOD OF HER LIFE WHEN SHE REPORTEDLY PASSED PREGNANCY TISSUE. AFTER THAT, HER SYMPTOMS WORSENED. SHE HAD LOWER BACK PAIN AND RIGHT SIDE BODY ACHES. SHE COULD FEEL PRESSURE IN HER PELVIC AREA AND NEAR HER PUBIC BONE; PAINFUL SEX, COPIOUS AMOUNTS OF VAGINAL DISCHARGE AND UTERINE INFLAMMATION WERE ALSO REPORTED. PAIN BEGAN TRAVELLING DOWN HER RIGHT LEG. ESSURE WAS REMOVED VIA LAPAROSCOPY ON (B)(6) 2013 AND IT WAS REPORTED THAT SHE HAD AN ADHESION TO HER LIVER THAT WAS STARTING TO GET INFECTED. HER UTERUS WAS REPORTEDLY PERFORATED BY THE COIL ON THE RIGHT SIDE. TWO AND A HALF MONTHS AFTER ESSURE REMOVAL, SHE REPORTS BEING "ON THIS ROAD TO RECOVERY".

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00068	BAYER HEALTHCARE LLC	3/20/2014	3/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBUAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 6213191

Single Use: Y
Implant Date (E6): 4/1/2007
Explant Date (E7): 1/23/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTS THAT SHE HAD ESSURE INSERTED IN (B)(6) 2007 AND STARTED EXPERIENCING A PERIOD THAT "LASTED FOR A YEAR". AFTER THAT, SHE PRESENTED WITH PELVIC PAIN FROM THEN ON. SHE REPORTS TAKING "NARCO 10 MG" Q4H FOR PAIN. IN (B)(6) 2013, SHE EXPERIENCED SEVERE ABDOMINAL PAIN THAT FELT LIKE STABBING, POKING INSIDE HER PELVIC REGION. ESSURE WAS REMOVED ON (B)(6) 2014 AT THE SAME TIME AS A HYSTEROSALPINGECTOMY. REPORTEDLY, 99% OF HER SYMPTOMS WENT AWAY AFTER REMOVAL OF ESSURE. (NOTE - REPORT WAS ALSO RECEIVED FROM FDA ON THE SAME DAY AS THE CONSUMER REPORTED TO (B)(4)).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00079	BAYER HEALTHCARE LLC	3/20/2014	3/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH--DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 12241584

Single Use: Y
Implant Date (E6): 1/14/2004
Explant Date (E7): 2/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED ON (B)(6) 2004, SIX WEEKS POSTPARTUM, AND SUBSEQUENTLY BEGAN EXPERIENCING MENSTRUAL-TYPE CRAMPS, LIKE LABOR PAIN. SHE REPORTS PASSING "GIANT BLOOD CLOTS" VAGINALLY THAT LOOKED LIKE RASPBERRY JAM, WITH WORSENING CRAMPS. SHE ALSO STARTED HAVING URINARY TRACT INFECTIONS, WHICH SHE STATES SHE HAS NO PRIOR HISTORY OF. SIX MONTHS AFTER INSERTION, SHE EXPERIENCED FOOT DROP AND TINGLING IN EXTREMITIES. SHE WENT TO HER PHYSICIAN AND WAS DIAGNOSED WITH NINE OVARIAN CYSTS. OVER A THREE-YEAR PERIOD (UNSPECIFIED) SHE BEGAN EXPERIENCING MIGRAINE-LIKE EVENTS. HER CRAMPING WORSENED, ESPECIALLY AROUND THE TIME OF HER MONTHLY PERIOD, WHICH BECAME HIGHLY IRREGULAR. HER ALSO EXPERIENCED SIGNIFICANT WEIGHT GAIN, CONSTANT BLOATING, FOOT AND LEG SWELLING, ANXIETY , PALPITATIONS, ACNE, INSOMNIA, FATIGUE, LETHARGY, "WILD AND UNCONTROLLABLE" MOOD SWINGS, SEIZURE-LIKE BRAIN ACTIVITY, "INHIBITED SEROTONIN" DEPRESSION, FREQUENT DIARRHEA, AND GERD. IN (B)(6) 2014, SHE WAS DIAGNOSED WITH ADENOMYOSIS AND A NICKEL ALLERGY. A HYSTERECTOMY WAS PERFORMED ON (B)(6) 2014, AND REPORTEDLY HER SYMPTOMS HAVE RESOLVED. (NOTE - THE CONSUMER ALSO REPORTED DIRECTLY TO FDA, CASE (B)(4)).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00080	BAYER HEALTHCARE LLC	3/20/2014	3/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): 689940

Single Use: Y
Implant Date (E6): 9/2/2010
Explant Date (E7): 12/13/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED ON (B)(6) 2010 AND SUBSEQUENTLY EXPERIENCED EXTREME FATIGUE, WEIGHT GAIN, METAL TASTE IN MOUTH, LOW-GRADE FEVERS, AND RASHES. SHE WAS TAKEN TO THE ER WITH SEVERE ABDOMINAL PAIN. TREATMENT WAS NOT REPORTED. AT AN UNSPECIFIED TIME, THE CONSUMER EXPERIENCED MULTIPLE INFECTIONS (UNSPECIFIED), YEAST INFECTION, BACTERIAL VAGINOSIS AND UTIS. ON (B)(6) 2013, SHE WENT TO THE ER AGAIN, AND WAS DIAGNOSED WITH KIDNEY STONES. A CT SCAN SHOWED THAT ESSURE HAD MIGRATED, PERFORATING THE FALLOPIAN TUBE, AND WAS LOCATED NEAR HER LEFT HIP BONE. THE RIGHT COIL HAD ALSO MIGRATED, BUT WAS STILL WITHIN THE FALLOPIAN TUBE. ON (B)(6) 2013, THE ESSURE COILS WERE REMOVED VIA LAPAROSCOPY. A SALPINGECTOMY WAS PERFORMED. THE CONSUMER SUBSEQUENTLY RECOVERED. (NOTE - CONSUMER ALSO REPORTED DIRECTLY TO FDA, CASE (B)(4).)

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00081	BAYER HEALTHCARE LLC	3/20/2014	3/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 685785

Single Use: Y
Implant Date (E6): 4/17/2010
Explant Date (E7): 1/15/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTS THAT SHE HAD ESSURE INSERTED ON (B)(6) 2010 AND FOR TWO WEEKS HAD CRAMPING AND BLOATING. SUBSEQUENTLY, SHE EXPERIENCED SEVERE PELVIC PAIN, BACK PAIN, LEG PAIN, BLEEDING DURING MENSES WITH CLOTS, MULTIPLE OVARIAN CYSTS, MUSCLE TREMORS, NERVE PAIN, MIGRAINES, PSORIASIS, GASTROINTESTINAL PROBLEMS, FATIGUE, NAUSEA, DEPRESSION, ANXIETY, SEVERE MEDICATION SENSITIVITY, AND SUSPECTED AUTOIMMUNE DISEASE. SOMETIME IN 2011, SHE STARTED EXPERIENCING LEFT EYE DROOPING, BLURRED VISION, CHRONIC ALLERGIC CONJUNCTIVITIS, LEFT HAND TREMOR (DIAGNOSED AS DYSTONIA), INVOLUNTARY MUSCLE SPASMS, TINGLING AND NUMBNESS IN HER FACE, BRAIN FOG, LOSS OF COORDINATION, SLURRED SPEECH, RAPID HEARTBEAT, EXTREME FATIGUE, SEVERE NERVE PAIN, CONSTANT NAUSEA, UPPER ABDOMINAL PAIN, HEARTBURN, MULTIPLE PERIODS EACH MONTH, AND CHRONIC HEADACHES. A HYSTERECTOMY WAS PERFORMED ON (B)(6) 2014 DURING WHICH THE ESSURE COILS WERE FOUND INTACT IN THE FALLOPIAN TUBES; THE TUBES WERE SEVERELY INFLAMED. ENDOMETRIOSIS AND DYSTONIA (LEFT HAND TREMOR) WERE DIAGNOSED AT THAT TIME. REPORTEDLY, THE CONSUMER WAS FEELING A LOT BETTER AFTER RECOVERING FROM HER SURGERY. (NOTE - CONSUMER ALSO REPORTED DIRECTLY TO FDA, (B)(4))

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00067	BAYER HEALTHCARE LLC	3/20/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSUE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): A63339

Single Use: Y
Implant Date (E6): 3/22/2013
Explant Date (E7): 1/28/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE WAS INITIALLY RECEIVED VIA FDA (CASE # (B)(4)) AND INVOLVES A CONSUME WHO HAD ESSURE INSERTED ON (B)(6) 2013. STARTING ABOUT 3-4 MONTHS LATER, SHE BEGAN EXPERIENCING VERY HEAVY PERIODS (3 WEEKS OUT OF A MONTH), SEVERE CRAMPING AND BACKACHES, FEELING EXTREMELY TIRED, WITH MUSCLE WEAKNESS, WEIGHT GAIN AND BLOATING. SHE ALSO REPORTED THAT SHE LOOKED LIKE SHE WAS 6 MONTHS PREGNANT. SHE TRIED MUSCLE RELAXERS, TYLENOL AND PHYSICAL THERAPY FOR HER LOW BACK PAIN. LATE IN 2013, SHE SAW HER PRIMARY PHYSICIAN DUE TO BACK PAIN TRAVELING DOWN HER LEG. HER PHYSICIAN WASN'T SURE IF THE PAIN WAS RELATED TO ESSURE. A PARTIAL HYSTERECTOMY (OVARIES WERE SPARED) ON (B)(6) 2014. CONSUMER REPORTS THAT HER SYMPTOMS HAVE RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00070	BAYER HEALTHCARE LLC	3/20/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED VIA (B)(4) THAT SHE HAD ESSURE INSERTED AND THAT SHE HAD TO UNDERGO A FULL HYSTERECTOMY AFTER ESSURE "TORE THROUGH HER INTERNAL ORGANS, ABSCESSED AND CAUSED SEPSIS."

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00071	BAYER HEALTHCARE LLC	3/20/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 1/2/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTS VIA (B)(4) THAT SHE HAD ESSURE INSERTED IN 2007 AND SUBSEQUENTLY EXPERIENCED UNBEARABLE PELVIC PAIN. REPORTEDLY, THE LEFT COIL WAS EMBEDDED DEEPLY IN HER UTERUS. THE CONSUMER UNDERWENT A HYSTERECTOMY ON (B)(6) 2014 AND WHEN THE COILS WERE REMOVED, THEY WERE "LITERALLY BLACK."

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00072	BAYER HEALTHCARE LLC	3/20/2014	4/2/2014

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 5/20/2013
Explant Date (E7): 1/30/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED ON (B)(6) 2013 AND ABOUT TWO MONTHS LATER BEGAN EXPERIENCING LOSING HAIR, MIGRAINES, GAINING 30 LBS, AND HORRIBLE BLEEDING. SHE WENT TO THE EMERGENCY ROOM AND WAS PLACED ON AN UNSPECIFIED HORMONE TO STOP THE BLEEDING. A SONOGRAM AND PELVIC X-RAY REVEALED ONE COIL EMBEDDED IN HER UTERUS AND THE OTHER COIL EMBEDDED IN A FALLOPIAN TUBE. A HYSTERECTOMY WAS PERFORMED ON (B)(6) 2014, WHICH ALSO REMOVED ESSURE. CONSUMER STATES THAT SHE HAS SINCE LOST 8 LBS AND HER MIGRAINES HAVE RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00073	BAYER HEALTHCARE LLC	3/20/2014	4/2/2014

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 3/1/2011
Explant Date (E7): 12/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED IN (B)(6) 2011. SHE REPORTS THAT SHE HAD BLEEDING FOR 100 DAYS WITHIN MONTHS OF INSERTION. SHE BECAME PREGNANT ON AN UNSPECIFIED DATE AND SUBSEQUENTLY EXPERIENCED A MISCARRIAGE. ESSURE WAS REMOVED IN (B)(6) 2013, AND HER "TUBES WERE CUT OUT". REPORTEDLY, HER PHYSICIAN FOUND ONE MICRO-INSERT NEAR THE CERVIX AND THE OTHER PERFORATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00074	BAYER HEALTHCARE LLC	3/20/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED VIA (B)(4) THAT SHE HAD ESSURE INSERTED AND THAT SHE SUBSEQUENTLY HAD BOWEL DAMAGE. REPORTEDLY, ESSURE HAD TO BE "CUT FROM HER BOWEL", AND THAT IT HAD BEEN "PERFORATING MULTIPLE ORGANS". SHE ALSO REPORTS, RASHES, ALLERGIES, PAIN AND THAT SHE ATE PALEO DUE TO HER BOWEL DAMAGE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00075	BAYER HEALTHCARE LLC	3/20/2014	4/2/2014

Event Information:

Event Date (B3): 4/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 4/29/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED VIA FDA (B)(4) THAT SHE HAD ESSURE INSERTED AND THAT SINCE THAT TIME SHE HAS HAD HORRIBLE BLEEDING, CLOTTING, AND SEVERE PAIN. REPORTEDLY, SHE "HAD NO OTHER OPTION EXCEPT HYSTERECTOMY".

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00077	BAYER HEALTHCARE LLC	3/20/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/29/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED VIA EMAIL THAT SHE HAD ESSURE INSERTED ON (B)(6) 2012 AND THAT SHE SUBSEQUENTLY EXPERIENCED NUMEROUS EVENTS: DIZZINESS, BLACKING OUT, HEIGHTENED ALLERGIC REACTIONS TO ANYTHING CONTAINING NICKEL (INCLUDING FOODS WITH SOY, HAMBURGERS, DRINKS, AND MOST FRUITS AND VEGETABLES), EXTREME PAIN, SHARP CHRONIC PAIN, BODY ACHES (SOMETIMES TO THE POINT WHERE SHE CAN BARELY MOVE), HEADACHES, GETTING SICK FREQUENTLY, NAUSEA, BOWEL ISSUES, VOMITING, WEIGHT GAIN, HAIR LOSS, DENTAL PROBLEMS, HEAVY AND FREQUENT PERIODS (EVERY 2 WEEKS), FEVER, VAGINAL DISCHARGE, BLURRED VISION, UTI-LIKE BURNING, ACNE, BLADDER PROBLEMS, PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE, BREAST PAIN, BRAIN FOG, CONFUSION, FORGETFULNESS, CRAMPING, BLOATING, HOT FLASHES, HEARTBURN, MOOD SWINGS, AND MUSCLE SPASMS. SHE UNDERWENT A HYSTERECTOMY AND "FINALLY GOT HER LIFE BACK". (NOTE - CONSUMER ALSO REPORTED TO FDA VIA CASE #(B)(4).)

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CASE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00078	BAYER HEALTHCARE LLC	3/20/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/29/2011
Explant Date (E7): 1/31/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PHYSICIAN REPORTS THAT A PATIENT HAD ESSURE INSERTED ON (B)(6), 2011. SUBSEQUENTLY, THE PATIENT EXPERIENCED PAIN AND ESSURE WAS REMOVED ON (B)(6), 2014 DURING A LAPAROSCOPIC BILATERAL SALPINGECTOMY. THE DEVICES WERE IN THE CORRECT PLACE AND NO OBVIOUS ABNORMALITIES WERE OBSERVED. AFTER THE HYSTERECTOMY AND ESSURE REMOVAL, THE PATIENT'S SYMPTOMS RESOLVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035197		3/21/2014	3/27/2014

Event Information:

Event Date (B3): 3/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/30/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2008, ABOUT A YEAR LATER I STARTED EXPERIENCING A LOT OF PAIN TO THE POINT I COULD NOT MOVE EXCEPT TO CURL UP IN A BALL. I HAVE SEEN A FEW DOCTORS, BEEN TO A FEW HOSPITALS AND EACH PLACE TELLS ME IT IS SOMETHING DIFFERENT. I HAVE BEEN TOLD ANYTHING FROM CANCER TO JUST SIMPLE ABDOMINAL PAIN BUT WHEN I GET TESTS RUN EVERYTHING COMES BACK CLEAN AND LOOKS GOOD. I NEVER HAD A MEDICAL PROBLEM UNTIL I HAD THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035199	BAYER	3/21/2014	3/27/2014

Event Information:

Event Date (B3): 12/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/2/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PELVIC PAIN, BACK PAIN, BLEEDING, ALLERGIC TO NICKEL AND WAS NOT TESTED TO IT PRIOR TO BEING IMPLANTED. UTERINE FIBROIDS AND "ENDOMETERIOUS" RESULTING IN POSSIBLE HYSTERECTOMY AT THE AGE OF (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035147	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

REACTION TO NICKEL IN COILS RESULTING IN RASH, REDNESS AND SWELLING ALONG WITH BLISTERS ON FEET. PELVIC PAIN AND LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035148	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 11/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH COILS (B)(6), 2013. MID (B)(6) STARTED WITH INTENSE BACK AND PELVIC PAIN, HEADACHES, NAUSEA, NUMBNESS IN FINGERS AND TOES, DIZZINESS, HAIR LOSS, WEIGHT GAIN, BLOATED ABDOMEN, RASH ON STOMACH, ACNE, MOOD SWINGS, BRAIN FOG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035149	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 1/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I CONTINUED TO CRAMP EVEN AFTER THE DR SAID I SHOULD HAVE BEEN OK. AT TIMES THE CRAMPING FELT LIKE LABOR PAINS. THEN AT THE END OF FEBRUARY I GOT VERY TENDER DOWN INTO MY VAGINAL AREA INCLUDING INFLAMMATION. UPON VISITING MY DR HE SAID EVERYTHING WAS FINE WITH MY MUCOUS BUT THE COILS NEEDED REMOVED ASAP.

(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035150	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 1/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN ON (B)(6) 2014, I AWOKE TO SHARP CUTTING PAIN AT ABOUT 4AM. I FELT LIKE I WAS BEING CUT AND SOMETHING WAS TRYING TO GO THROUGH MY TUBES OR UTERUS. I LAID IN BED THINKING MY BODY IS JUST TRYING TO REJECT THE COILS AND DEALT WITH THE PAIN FOR ALMOST 30 MINUTES. I TOOK PAIN KILLERS AND WENT TO SLEEP ONLY TO HAVE THIS PAIN ADVANCE TO PAIN, VOMITING AND FEVER OVER THE NEXT FEW DAYS. I WENT TO MY OB/GYN ON (B)(6) 2014. AFTER AN ULTRASOUND IT APPEARED THE RIGHT COIL WAS PROTRUDING THROUGH MY UTERUS AND THERE WAS A LARGE BLOOD CLOT FORMED ON THE OUTSIDE OF THE UTERINE WALL. I WAS GIVEN ANTIBIOTICS IN OFFICE AND SENT TO SURGERY ON (B)(6) 2014. IT WAS CONFIRMED THE RIGHT COIL HAD COME OUT OF THE FALLOPIAN TUBE AND TRAVELED THROUGH THE UTERUS, PERFORATED THE UTERUS AND WAS NOTED THAT THE COIL HAD UNCOILED SOME. MY COILS WERE REMOVED AND THE PERFORATED UTERUS WAS REPAIRED AND BLOOD CLOT REMOVED OR DRAINED. I ALSO HAD A TRADITIONAL TUBAL LIGATION DONE AT THE TIME. I CAME HOME AND WITHIN TWO DAYS I WAS VOMITING WITH FEVER AND ABDOMINAL PAIN. I WENT TO THE ER ONCE THE FEVERS HIT 103 AGAIN. IN THE ER, I WAS GIVEN MORPHINE AND ANOTHER PAIN MED FOR THE EXTREME PAIN I WAS IN. ONE OF MY OB DOCS WAS CALLED IN AND REQUESTED AN MRI, WHICH SHOWED I HAD A LARGE BLOOD CLOT IN MY DEEP VEIN. I WAS GIVEN MULTIPLE BLOOD TEST AND SHOWED TO BE SEPSIS. I WAS FULL OF INFECTION. I AM ALLERGIC TO PENICILLIN, I WAS PUT ON 3 DIFFERENT ANTIBIOTICS AND NOT GETTING ANY BETTER. I COULD NOT KEEP ANYTHING DOWN, CONSTANT VOMITING, PAIN AND FEVER PERSISTED WHILE IN THE ICU IN THE HOSPITAL. I WAS GIVEN 4 UNITS OF BLOOD FOR LOW IRON AND I WAS IN THE ICU FOR 8 DAYS. ANOTHER SCAN ORDERED SHOWED MULTIPLE CLOTS (SO MANY THAT THERE IS NO TEXT BOOK CASE TO REFER TO). I WAS THEN PUT ON THE COUSIN DRUG TO PENICILLIN-ROCEFIN AND THEN MY INFECTION RATE STARTED TO LOWER SLOWLY. MY

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CONDITION BEGAN TO IMPROVE. GENETICS TESTING WAS ORDERED BY THE HEMATOLOGIST WHO FOLLOWED ME, WHICH SHOWED NO GENETIC PREDISPOSITION FOR CLOTTING ISSUES OR BLEEDING DISORDERS. MY INFECTIOUS BLOOD DOCTOR PUT ME ON IV ANTIBIOTICS UPON LEAVING THE HOSPITAL ON DAY 12 ((B)(6) 2014). I STILL HAVE THE PICC LINE IN MY ARM WHICH IS HOW I GET THE ROCEFIN AT HOME. I HAVE A NURSE COME ONCE A WEEK TO TAKE BLOOD AND CHANGE BANDAGES AND MY SISTER, COUSIN AND MOTHER ADMINISTER MY MEDS DAILY. I AM ALSO TAKING XERALTO DAILY TO THIN MY BLOOD AND CONTROL GETTING NEW CLOTS. I WAS TOLD I'LL BE ON THIS MEDICINE FOR AT LEAST A YEAR. I AM UNABLE TO WORK AT THIS TIME. I CAN NOT RETURN UNTIL THE PICC LINE IS OUT OF MY ARM. I HAVE OFFICIALLY BEEN DIAGNOSED WITH DEEP VEIN THROMBOSIS. I HAD NO MEDICAL CONDITIONS AT THE TIME OF THE SURGERIES. I WAS NOT ON ANY MEDICATION. I HAVE FOUR CHILDREN ALL DELIVERED NATURALLY INCLUDING A SET OF TWINS. THE ONLY SURGERY I EVER HAD WAS TO REMOVE A HERNIA ON THE LEFT SIDE WHEN I WAS (B)(6). I AM (B)(6) YEARS OLD, I DON'T SMOKE OR DRINK. I'M BEING FOLLOWED BY THREE DOCTORS NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035151	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 12/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING EXTREME FATIGUE CRAMPING WITH CYCLE AND NOW HAVE A HIGH EOS COUNT FOR THE LAST 3 BLOOD DRAWS THE DOCTORS HAVE PREFORMED. AM NOW WAITING TO FIND OUT MORE OF WHAT'S GOING ON BUT THE EXTREME FATIGUE HAS BEEN THE WORST OF ALL WHEN I CAN'T EVEN GET OUT OF BED MOST DAYS TO TAKE CARE OF MY 3 CHILDREN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035152	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN IMMEDIATELY AFTER PLACEMENT. PELVIC PAIN BECAME WORSE DURING OVULATION AND MENSTRUAL CYCLE. SYMPTOMS ARE AS FOLLOWS THAT WERE NOT PRESENT BEFORE ESSURE PLACEMENT: CHRONIC FATIGUE, HAIR LOSS, ACNE, MOOD SWINGS, DEPRESSION, ANXIETY, LOSS OF LIBIDO, WEIGHT FLUCTUATIONS DESPITE STRICT DIETS AND EXERCISE. ABDOMINAL SWELLING AND/OR BLOATING. A YEAR AND A HALF AFTER PLACEMENT I STARTED STRUGGLING WITH MULTIPLE UTIS OR UTI SYMPTOMS THAT DID TEST POSITIVE. URINE FREQUENCY, BURNING DURING URINATION. TWO CASES OF VB. NAUSEA, LOWER BACK PAIN, ACHING JOINTS, SHOTS OF PAIN FROM HIP TO KNEE, SEVERE PELVIC STABBING PAIN. I HAD TWO OVARIAN CYSTS REMOVED (B)(6) 2013. PAIN GOT WORSE. NAUSEA GOT WORSE. DEPRESSION GOT WORSE. HAD ELEVATED LIVER ENZYMES-SAW GI. LABS CAME OUT NORMAL. HAD SMALL AMOUNT OF BLOOD IN URINE-UROLOGIST WAS NOT CONCERNED OR ADVISED ANY FURTHER TESTING. HAD ESSURE COILS REMOVED VIA BILATERAL SALPINGECTOMY (B)(6), 2014. BRAIN FOG GONE! DEPRESSION GONE! FATIGUE GONE! STABBING PAIN DECREASED BY 70%. BACK PAIN DECREASED BY 20%. JOINTS ON RIGHT SIDE COMPLETELY GONE. JOINT PAIN ON LEFT INCREASING, CRAMPING AND BACK PAIN STILL PRESENT. WENT TO POST OP AND HAD ULTRASOUND. TECHNICIAN FOUND A FRAGMENT ABOUT 2CM IN LENGTH ON LEFT SIDE UTERINE CAVITY. I WILL NOW HAVE A PARTIAL VAGINAL HYSTERECTOMY IN THE COMING WEEKS TO REMOVE THE REMAINING ESSURE COIL FRAGMENT AT THE AGE OF (B)(6). (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035153	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 6/14/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE PROCEDURE IN (B)(6) 2005. JUST TWO WEEKS LATER I BEGAN HAVING HORRIBLE PELVIC PAIN. THE TYPE OF PAIN THAT KNOCKS YOU TO YOUR KNEES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035154	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 11/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN MY LEFT SIDE, NICKEL ALLERGY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035155	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 7/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE NOVASURE ABLATION IN EARLY 2008. MY DOCTOR SAID THAT I NEEDED PERMANENT BIRTH CONTROL DUE TO THE RISKS TO MOM AND BABY IF I EVER GOT PREGNANT AFTER I HAD THE NOVASURE DONE. HE RECOMMENDED THE ESSURE. SINCE I HAD THE ESSURE I HAVE GAINED OVER 80 POUNDS, DIFFICULTY CONCENTRATING, PELVIC PAIN RADIATING FROM MY PELVIC AREA TO MY HIP AND LOWER BACK, INCONTINENCE, FREQUENT UTI'S OR URINARY SENSITIVITY,RASHES, SEVERE HEADACHES, DENTAL ISSUES, METALLIC TASTE IN MY MOUTH, CHRONIC FATIGUE, INSOMNIA, LOSS OF LIBIDO, PAINFUL INTERCOURSE, INCREASE IN GI ISSUES, JOINT PAIN, DIZZINESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035156	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 6/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2012 I HAD ESSURE PUT IN. THE DAY AFTER SURGERY I WAS IN TERRIBLE PAIN, I CALLED MY DOCTOR EVERYDAY FOR 2 WEEKS..FINALLY I WAS GIVEN AN PELVIC ULTRASOUND, NOTHING FOUND. I CONTINUED TO HAVE PAIN MORE FOCUSED ON THE RIGHT SIDE OF MY STOMACH, VERY BAD STABBING CRAMPING PAIN, HEAVY MENSTRUAL PERIODS. ON (B)(6) 2012 I HAD MY HCG TEST AND IT SHOWED THAT BOTH OF THE ESSURE COILS WERE NOT IN MY TUBES. ON (B)(6) 2012 I HAD SURGERY AGAIN FOR TUBAL LIGATION AND TO HAVE BOTH COILS REMOVED. AFTER LOOKING THROUGH MY MEDICAL RECORDS IT ONLY STATES THAT ONE COIL WAS REMOVED. I HAVE A MENSTRUAL CYCLE EVERY 2 WEEKS, WITH VERY HEAVY BLEEDING TERRIBLE CRAMPING. I AM NOW TRYING TO FIND A DOCTOR THAT CAN TELL ME WHERE THE OTHER COIL IS IN MY BODY AND TO SEE WHY I AM HAVING A MENSTRUAL CYCLE EVERY 2 WEEKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035157	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE TINGLING/NUMB FEELING IN MY HANDS AND FEET, BLOATING, WEIGHT GAIN, HEADACHES, ITCHING, MISSED MENSTRUAL CYCLES, LOWER BACK PAIN AND CRAMPING AND PAINS IN MY LOWER ABDOMEN CONSTANTLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035158	CONCEPTUS	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 8/13/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED SIX WEEKS AFTER THE BIRTH OF OUR SECOND CHILD. I WAS CONFIRMED BLOCKED FOUR MONTHS LATER BY HSG. I HAVE EXPERIENCED HEAVY, HEMORRHAGIC, CLOTTY PERIODS. I HAVE BEEN PUT ON ORAL BC TWICE TO HELP WITH THE BLEEDING AND IT DID NOT HELP. THREE YEARS AFTER IMPLANTATION I FOUND OUT I WAS 13 WEEKS PREGNANT. AFTER DELIVERY I HAD A LAPAROSCOPIC TUBAL AND THE DOCTORS SAW BOTH OF MY COILS MIGRATED INTO MY ABDOMEN, NEARLY PERFORATING MY COLON. I HAVE ALSO BEEN DIAGNOSED WITH FIBROIDS WHICH I DID NOT HAVE PRIOR TO ESSURE. I STILL HAVE HEMORRHAGIC, CLOTTY PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035162	BAYER	3/24/2014	3/24/2014

Event Information:

Event Date (B3): 4/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY ESSURE IMPLANTED APPROX 2 YEARS AGO. THE PROCEDURE IS SUPPOSED TO TAKE 10 MINUTES THE OB/GYN THAT INSERTED THEM BUT MINE ENDED UP TAKING OVER AN HOUR AND WAS EXCRUCIATING. I COULDN'T EVEN WALK AFTERWARDS AND HAD TO HAVE MY HUSBAND PICK ME UP BECAUSE I WAS IN TOO MUCH PAIN TO DRIVE, EVEN TOUGH I WAS TOLD IT WAS SIMPLE AND I WOULDN'T NEED A DRIVER OR ANYONE TO COME WITH ME TO THE APPOINTMENT. I STARTED TO DEVELOP DERMATITIS ON MY RIGHT EYELID IN (B)(6) OF 2013. OVER THE NEXT FEW MONTHS IT KEPT SPREADING TO OTHER AREAS ON MY FACE AND THEN ON THE FRONT AND BACK OF MY NECK. I WENT TO MY DERMATOLOGIST TWICE AND WAS GIVEN PRESCRIPTION CREAMS TO USE, WHICH DIDN'T HELP. IT BECAME SO BAD THAT I COULDN'T GO TO WORK SOME DAYS NOR DO SOME OF MY REGULAR ACTIVITIES BECAUSE MY EYELIDS AND FACE WERE SO RED AND RAW. IT ALSO HURT TO WEAR SCARVES AND CLOTHING THAT WOULD RUB UP AGAINST MY NECK. I ENDED UP GOING TO AN ALLERGIST WHERE I WAS GIVEN A PATCH TEST ON MY BACK. TURNS OUT I HAVE A NICKEL ALLERGY. I'VE SINCE HAD TO CUT OUT ALL FOOD AND DRINKS WITH NICKEL IN THEM, WHICH IS A TON OF ITEMS, AND A COMPLETE LIFE CHANGE. I CAN'T WEAR JEWELRY BECAUSE MY SKIN REACTS BADLY AND TURNS RED AND ITCHES. I CAN'T WEAR ANYTHING THAT HAS METAL ON IT THAT WILL TOUCH MY SKIN, TOUCH MONEY, OR A PLETHORA OF OTHER ITEMS THAT ARE METAL BASED. SO FAR ALL PRESCRIPTION AND OTC ALLERGY MEDICATIONS, LOTIONS AND CREAMS DO NOT HELP SO I SUFFER ON A WEEKLY BASIS FROM THIS ALLERGY. I HAD TO HAVE SURGERY ON (B)(6) BY AN OB/GYN TO HAVE MY FALLOPIAN TUBES AND ESSURE IMPLANTS REMOVED. IT'S BEEN ALMOST 3 WEEKS AND NON OF MY NICKEL SYMPTOMS HAVE SUBSIDED SO I'VE NOW BEEN REFERRED TO (B)(6) TO BE SEEN BY THEIR DERMATOLOGY DEPARTMENT FOR MORE

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DETAILED TESTING. I ALSO TESTED POSITIVE FOR DOG, SHELLFISH, BACITRACIN AND CARBA MIX ALLERGIES AS WELL AS THE NICKEL ALLERGY. I'VE NEVER HAD ISSUES WITH ALLERGIES BEFORE THIS ALL STARTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035159	CONCEPTUS	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 12/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE IMPLANTS OF ESSURE, I HAVE HAD PAIN IN THE PELVIC AREA/STOMACH AREA. THE PAIN WOULD COME AND GO WITH SOME MONTHS BEING WORSE THAN OTHERS. FOR THE PAST COUPLE OF YEARS, THE PAIN HAS GOTTEN WORSE ALONG WITH NEW SYMPTOMS APPEARING. FOR INSTANCE, PAINFUL INTERCOURSE, SPOTTING IN BETWEEN PERIODS, HAIR LOSS, MUSCLE TWITCHING, BURNING TONGUE, METALLIC TASTE IN MOUTH, SORE MUSCLES, LACK OF LIBIDO, HEADACHES, FEELING BLOATED CONSTANTLY, DEVELOPMENT OF FIBROIDS, FATIGUE, SWELLING OF HANDS, NUMBNESS IN LIPS, RINGING AND PRESSURE IN EARS, EAR ACHES, NUMBNESS IN THIGH, STABBING PAINS IN VAGINAL AREA, HEIGHTENED ALLERGIES, VISION FLOATERS, NIGHT SWEATS, DRY SKIN AND EYES, BLEEDING AFTER INTERCOURSE, BREAST PAIN, BACK PAIN, AND HIP PAIN. (B)(6) OF 2012, MY DOCTOR IMPLANTED THE MIRENA TO HELP WITH SYMPTOMS. THIS BACKFIRED BY INCREASING SYMPTOMS AND HAD TO BE REMOVED 4.5 MONTHS LATER. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035160	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 3/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE DONE AND BLED FOR 7.5 WEEKS NON STOP HEAVY BLEEDING WHICH CAUSED OTHER SYMPTOMS LIKE DIZZINESS, FATIGUE, BACK PAIN, CRAMPS. ONCE BLEEDING STOPPED IT NEVER CAME BACK BUT HAVE CONSTANT DISCOMFORT AND SOMETIMES FELT BAD PAIN ON LEFT SIDE. AFTER THREE MONTHS I HAD HSG AND THEY TOLD ME MY LEFT SIDE MIGRATED NEAR UTERUS AND TUBE WAS PATENT. THEY SAID COME BACK IN ANOTHER THREE MONTHS TO SEE IF IT HEALED. AFTER TWO TRIED THEY WERE NOT ABLE TO INSERT TUBE WITH DYE TO CHECK MY TUBES BECAUSE THEY SAID MY CERVIX WAS POSSIBLY SCARRED. SO NOW I HAVE NO WAY OF KNOWING IF THE LEFT SIDE HEALED CLOSED OR NOT. STILL HAVE A CONSTANT DISCOMFORT ON LEFT, FEELS LIKE SOMETHING IS STICKING IN THERE (KIND OF LIKE A LARGE OVARIAN CYST WHICH I KNOW I DON'T HAVE) AND DURING SEX IF IT GOES TOO DEEP I FEEL A LOT OF PAIN WHERE BEFORE PROCEDURE I DID NOT FEEL ANY PAIN.

(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035163	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 7/4/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BECAME PREGANANT AFTER BEING CONFIRMED 100% BLOCKED VIA HSG.

(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035164	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 12/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS PLACED (B)(6) 2012. STARTED TO FEEL ABDOMINAL PAINS THAT WERE SHARP, STABBING PAINS THAT WOULD COME AND GO, BUT WOULD GET WORSE OVER TIME. OTHER THINGS STARTED HAPPENING LIKE DIZZINESS, HEAD ACHES, WEIRD JITTERY FEELING, FORGETFULNESS, BLOATING, ACNE (INCREASED), PELVIC PAIN, IRREGULAR PERIODS, HEAVY BLEEDING, VERY BIG BLOOD CLOTS (RANGING IN SIZE FROM DIME TO HALF DOLLAR SIZE CLOTS). ALL OF THESE SYMPTOMS STARTED RIGHT ABOUT THE TIME I WAS SCHEDULED TO HAVE MY HSG TEST TO CONFIRM TUBES WERE BLOCKED, WHICH WAS (B)(6) 2012. THAT HSG TEST CONFIRMED THAT ONLY ONE TUBE WAS BLOCKED, THE OTHER ONE WAS NOT. THESE SYMPTOMS SINCE THEN HAVE GOTTEN EXTREMELY WORSE OVER THE LAST YEAR. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035165	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 11/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2011. SIX MONTHS LATER I STARTED HAVING SEVERE HEAVY BLEEDING DURING MY PERIODS. MY STOMACH LOOKS BLOATED ALL THE TIME. LACK OF APPETITE. CHRONIC PELVIC PAIN, ABNORMAL UTERINE BLEEDING, BODY ACHES. I HAVE GAINED OVER 40 POUNDS AND CAN NOT LOSE A SINGLE POUND NO MATTER WHAT I DO. LOWER BACK PAIN, I CAN NOT SIT OR STAND FOR MORE THAN 3 HOURS. PAINFUL TO HAVE SEX WITH MY HUSBAND. MY PAIN IS INCREASING AS TIME GOES ON. EXHAUSTED CONSTANTLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035166	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY FOURTH CHILD IN (B)(6) 2013. I HAD THIS PROCEDURE DONE IN (B)(6) 2013. IT WAS THE WORST PAIN THAT I THINK I HAVE EVER BEEN IN. MY DOCTOR SOLD THIS PROCEDURE TO MY HUSBAND LIKE IT WAS A PIECE OF CANDY WHILE I WAS RECOVERING FROM A C-SECTION. IS IT TRUE THAT DOCTORS GET THREE TIMES MORE MONEY FOR PERFORMING THIS PROCEDURE THAN HAVING TUBES TIED?? HMMMMMM. I TRUSTED MY DOCTOR AND DIDN'T RESEARCH THIS. I WAS ALWAYS COMING DOWN THE STAIRS TELLING MY HUSBAND THAT I FEEL LIKE MY UTERUS IS FALLING OUT. I HAVE TERRIBLE HEADACHES, BACKACHES, NIGHT SWEATS, MY ARMS AND LEGS ARE NUMB AT NIGHT WHEN I LAY DOWN. I SWITCHED BLOOD PRESSURE MEDICATIONS THREE TIMES BECAUSE I THOUGHT IT WAS THAT. NOTHING WORKS AT TIMES TO CONTROL MY PRESSURE. I FEEL LIKE I AM HAVING A STROKE OFTEN IN THE MIDDLE OF THE NIGHT. I HAVE SO MUCH ANXIETY THAT IT IS HARD TO TAKE CARE OF MY HOUSE AND MY FOUR CHILDREN. MY HANDS ARE SWOLLEN BEYOND BELIEF. I LOOK 6 MONTHS PREGNANT. I DID TWO DIETS AND A JUICE CLEANSE AND COULDN'T LOSE A POUND!!! I CAN'T BELIEVE THAT THIS WAS APPROVED. I AM EDUCATING MYSELF MORE EACH DAY. I AM FURIOUS THAT I MADE THE DECISION TO HAVE THIS DONE AND WILL NEVER BUY ANOTHER PRODUCT THAT BAYER MAKES EVER AGAIN. I HOPE THEY GO BANKRUPT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035167	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 4/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CHRONIC PELVIC PAIN, ABNORMAL UTERINE BLEEDING, BODY ACHES, NUMBNESS, TINGLING, BURNING, SEVERE SHARP PAINS, HIP PAIN, LEG PAIN, HEADACHES, DIZZINESS, CHRONIC FATIGUE, NAUSEA, LOSS OF MOTIVATION, SEVERE ANXIETY, PANIC ATTACKS, DEPRESSION, CRAMPS, BLURRED VISION, PASSING OUT, METAL TASTE, CHANGE IN APPETITE, PAIN DURING INTERCOURSE, FREQUENT URINATION, CONSTIPATION, SEVERE ABDOMINAL BLOATING, CHANGES IN SKIN AS WELL AS HAIR LOSS AND ALSO VERY PAINFUL MENSTRUAL CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035168	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BEGAN GAINING WEIGHT EVEN THOUGH I WORK OUT 6 DAYS A WEEK AND EAT VERY HEALTHY. BLOOD PRESSURE WAS RISING EVEN THOUGH MY MEDICINE (BEFORE THE ESSURE) HAD CONTROLLED IT VERY WELL. BEGAN TO HAVE MORE HEART PALPITATIONS. BEGAN LOSING HAIR. INABILITY TO FALL ASLEEP FOR HOURS, AND THEN WHEN I FINALLY WOULD, I WOULD SLEEP FOR 8 HOURS AND THEN STILL NEED A NAP IN THE AFTERNOON. DRY SKIN. DIAGNOSED WITH HYPOTHYROIDISM THREE MONTHS AFTER IMPLANTATION OF ESSURE. NEVER HAD ANY ISSUES WITH MY THYROID BEFORE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035169	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 8/30/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IT CAUSES MANY PROBLEMS. MY PERIODS ARE UNPREDICTABLE IF THEY COME AT ALL. MISSED PERIODS. BLOATING. FREQUENT URINATION. PAIN WHEN HAVING INTERCOURSE AND BLEEDING. EXTREME FATIGUE, I WAS A HAPPY HEALTHY ACTIVE PERSON PRIOR TO ESSURE, NOW I'M SO TIRED IF I SIT DOWN I FALL ASLEEP AND THAT'S SO UNCOOL WITH AN ACTIVE (B)(6). PAIN, I TAKE HIGH DOSES OF IBUPROFEN EVERY MORNING JUST TO GET THROUGH MY DAD. MY HAIR FALLS OUT A LOT MORE THAN IT USED TO. MY SKIN HAS CHANGED, IT LOOKED HORRIBLE NOW AND I HAD GREAT SKIN BEFORE NOT ONE BLEMISH AND NOW I HAVE THEM ALL THE TIME. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035170	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 7/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BECAME PREGANANT AFTER BEING CONFIRMED 100% BLOCKED VIA HSG.

(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035171	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 6/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP 1 #FDA MW5035171 #(B)(4). SINCE (B)(6) OF 2014 I HAVE BEEN WORKING CLOSELY WITH MY OBGYN TRYING TO FIND THE CAUSE OF MY HEAVY PAINFUL PERIODS PAINFUL SEX SWOLLEN OVARY AND JABBING SIDE PAIN ON THE LEFT SIDE, ON (B)(6) 2015 MY DOCTOR DECIDED TO DO AN EXPLORATORY SURGERY TO SEE IF HE COULD FIGURE OUT WHAT WAS GOING ON, INSIDE HE FOUND THAT MY ESSURE DEVICE HAD PENETRATED THROUGH MY LEFT FALLOPIAN TUBE AND WAS STABBING INTO MY LEFT OVARY, WITH THIS PROBLEM AND THE REST OF MY FEMALE PROBLEMS MY DOCTOR AND I HAD DISCUSSED BEFORE HAND IF HE FOUND ANY PROBLEMS HE WOULD TAKE CARE OF THEM WHILE I WAS ALREADY PUT TO SLEEP SO THAT I WOULD NOT HAVE TO GO THROUGH THAT TWICE. I ENDED UP LEAVING THE HOSPITAL WITH MY RIGHT OVARY EVERYTHING ELSE WAS REMOVED DUE TO PROBLEMS WITH THE ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035172	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 3/26/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, BLOATING, PAINFUL INTERCOURSE. POSTOPERATIVE. DIAGNOSES: MENORRHAGIA. CHRONIC PELVIC PAIN. WITH THE ADDITION OF A LEFT HEMORRHAGIC OVARIAN CYST. PROCEDURE: LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY AND LEFT OOPHORECTOMY AND CYSTOSCOPY FINDINGS: NORMAL UTERUS AND RIGHT TUBE. DILATED LEFT TUBE. BOTH TUBE ADHESIONS TO PELVIC SIDEWALL AND OVARY, MORE ON THE LEFT. LEFT HEMORRHAGIC OVARIAN CYST APPROXIMATELY 5 CM IN SIZE. THERE WAS NOT A SIGNIFICANT AMOUNT OF ADHESIONS TO THE UTERUS. HOWEVER, BOTH FALLOPIAN TUBES WERE ADHERENT TO THE OVERLYING OVARIES, AND THE LEFT OVARY WAS ENLARGED WITH A HEMORRHAGIC CYST. THE RIGHT OVARY APPEARED WITHIN NORMAL LIMITS. AFTER SURGERY ALL SIDE AFFECTS ARE NOW GONE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035173	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 3/14/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

POTENTIAL MISCARRIAGE, MIGRAINES, BLOATING, WEIGHT GAIN, LEFT SIDED PELVIC PAIN (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035174	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED (B)(6) 2012, SINCE THEN I HAVE BEEN GAINING WEIGHT, HAVE HEADACHES, AM TIRED ALL THE TIME, MY MENSTRUAL CYCLES ARE HEAVIER, WITH SOME BLOOD CLOTS, I HAVE PAIN IN MY HIPS, I'M BLOATED, CURRENTLY I LOOK PREGNANT AND I'M MOODY. UPDATE ON (B)(6) 2014: I WANTED TO ADD A FEW THINGS THAT I FORGOT. MY BREASTS ARE LEAKING AND I HAVE JOINT PAIN. I HAD ESSURE PLACED JUST 2 MONTHS AFTER HAVING A BABY, PRIOR TO THE PREGNANCY MY WEIGHT WAS (B)(6) LBS, AFTER HAVING THE BABY I WAS AT (B)(6), WHEN I HAD ESSURE PLACED MY WEIGHT WAS AT (B)(6). SINCE THEN MY WEIGHT HAS BEEN INCREASING. CURRENTLY MT WEIGHT IS (B)(6) LBS. I HAVE NEVER BEEN THIS HEAVY, I'M TOO TIRED TO DO ANYTHING, I CANT SLEEP, I HAVE HEADACHES EVERYDAY AND I'M VERY IRRITABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035175	BAYER	3/24/2014	3/25/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAIR STARTED FALLING OUT BY THE HAND FUL, DEPRESSION, MOOD SWINGS, ANXIETY, CRAMPS, HEAVY PERIODS, RASHES, BLOOD CLOTS, REACTION TO FOOD AND ALCOHOL, ACNE, BACK/JOINT PAIN, PLUS MORE ALL STARTED SOON AFTER THESE WERE PLACED. WORST DECISION EVER TO GET IT IN. (B)(4). UPDATE ON 2014-(B)(6): AFTER YEARS OF PAIN. I FINALLY FOUND A DR TO HELP ME. I AM ONLY (B)(6), BUT HAVE HAD MY UTERUS, CERVIX, TUBES, AND ESSURE YESTERDAY. I AM FINALLY FREE OF THE NIGHTMARE. PLEASE AVOID THIS PRODUCT IT IS HORRIBLE AND RUINS WOMEN'S LIVES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035236	CONCEPTUS	3/24/2014	3/28/2014

Event Information:

Event Date (B3): 3/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/19/2010
Explant Date (E7): 7/5/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2010. I BEGUN TO EXPERIENCE LOST OF ENERGY AND FEELING VERY TIRED. I ALSO START TO HAVE GASTROINTESTINAL PROBLEMS DEVELOPING DIARRHEA FEW TIMES A WEEK. AS TIME WENT BY I DEVELOPED MORE SYMPTOMS SUCH AS HOT FLASHES, NAUSEA, DIZZINESS, SHARP STABBING PELVIC PAIN, MOOD CHANGES, WEIGHT GAIN, FORGETFULNESS, SEBACEOUS CYST WHICH HAD TO BE SURGICALLY REMOVED. I ALSO BEGUN TO EXPERIENCE SHORTNESS OF BREATH, TIGHTNESS IN CHEST FOR WHICH I HAD TO BE REFERRED TO SEE A PULMONARY SPECIALIST. I BEGUN TO GAIN WEIGHT, AND DEVELOPED WRIST PAIN FOR WHICH I HAD AND EMG / NCV COMBO NEURO AND IT SHOWED THAT I HAD DEVELOPED CARPAL TUNNEL SYNDROME. I WAS REFERRED TO SEE AN ORTHOPEDIC DOCTOR AND HE CONFIRM THAT I HAD CTS, SYNOVITIS OF WRIST AND GANGLION ON MY LEFT WRIST. I HAD TO USE HAND SPLINTS EVERY NIGHT AND SOME TIME DURING THE DAY. I ALSO EXPERIENCE VERY PAINFUL INTERCOURSE AND BLEEDING AFTER SEX. MY PERIODS WERE HEAVY AND I HAD BIG BLOOD CLOTS DURING MY PERIODS. I ALSO HAD THE SEVERE BLOATING, BLACK OUT SPELLS AND BLEEDING DURING PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035242	BAYER	3/24/2014	3/28/2014

Event Information:

Event Date (B3): 3/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A73752

Single Use:
Implant Date (E6): 3/28/2013
Explant Date (E7): 11/25/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE (B)(6) 2013, HAD EXTREMELY BAD SIDE EFFECTS WITH THIS DEVICE. EXCESSIVE BLOATING, WEIGHT GAIN, EXTREMELY PAINFUL STABBING PAINS IN UTERUS (SO BAD I WAS UNABLE TO WALK AT TIMES), HAIR LOSS, DIZZINESS, HEADACHES, MOOD SWIGS, HEAVY UNPREDICTABLE PERIODS. HAD ESSURE REMOVED (B)(6) BY BILATERAL SALPINGECTOMY (REMOVED COILS AND BOTH FALLOPIAN TUBES). DOCTOR SAID ONE COIL WAS FURTHER IN MY UTERUS CAUSING THE PAIN. SINCE REMOVAL, ALL THE ABOVE SYMPTOMS HAVE DISAPPEARED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035249	BAYER	3/24/2014	3/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 774396

Single Use:
Implant Date (E6): 5/19/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED ON (B)(6) 2011. SINCE IMPLANTED WITH THIS ESSURE DEVICE, MY PERIODS HAVE BECOME INCREASING IN FLOW WITH LARGE CLOTS AND SEVERE PAIN, SO BAD THAT I AM UNABLE TO WORK ON MOST DAYS OF MY PERIOD. I HAVE SPENT THE DAY IN THE EMERGENCY ROOM GETTING IV FLUIDS AND TESTS DONE TO HELP DETERMINE THE CAUSE OF THE EXCESSIVE BLEEDING; NONE OF THE RESULTS HAVE CONCLUDED TO ANY CAUSES. I SEE AURAS FOR 10 MIN TO LITTLE OVER AN HOUR. FOLLOWING AURAS I DO NOT ALWAYS GET HEADACHES, MOST I DO NOT. JUST ABOVE EVERY DAY I HAVE AT LEAST ONE MILD EPISODE, BUT A COUPLE DAYS BEFORE AND DURING MY PERIODS, THEY ARE VERY INTENSE AND OFTEN. THE AURAS ARE SO BAD MOST OF THE TIME THAT I CANNOT SEE. DOCTORS ARE SAYING THAT THESE ARE MIGRAINES. I GET THE SHAKES AFTER AN AURA EPISODE, WHERE MY BODY SHAKES UNCONTROLLABLY AND I CANNOT STOP IT. THESE SEEMS TO GO OFF OF THE INTENSITY OF THE AURA EPISODE. IF THE AURA WAS SEVERE AND LASTS ON THE LONGER SIDE, THE SHAKES ALSO LAST LONGER AND ARE MORE NOTICEABLE BY OTHERS. I GET VERY NAUSEOUS DURING AND AFTER THE AURA EPISODES. AT TIMES I HAVE VOMITED. I HAVE DAYS OF DULL, CONSTANT HEADACHES. I HAVE HORRIBLE CRAMPING DURING MY PERIODS; CRAMPING SO BAD THAT I CANNOT FUNCTION. EVERY PERIOD I HAVE SUCH BAD CRAMPING, THE CRAMPING HAS INCREASED WITH EVERY PERIOD I HAVE HAD SINCE ESSURE. LARGE BLOOD CLOTS DURING MY PERIODS, CLOTS LARGER THAN HALF DOLLARS AND NOT JUST ONE OR TWO LARGE ONES BUT 10 PLUS A DAY. VERY HEAVY FLOW OF BLOOD FOR 2-3 DAYS OF MY 4-5 DAY PERIODS. HORRIBLE SUDDEN STABBING PAIN IN LOWER ABDOMEN, MORE ON MY RIGHT SIDE THAN LEFT, BUT PRESENT IN BOTH SIDES - DURING AND NOT DURING MY PERIODS. CONSTANT PELVIC PAIN AND PRESSURE. CHRONIC LOWER BACK PAIN. RANDOM RASH THAT POPS UP ON MY BACK, SHOULDERS AND STOMACH. LACK OF APPETITE FOR DAYS DUE TO NAUSEA AND FATIGUE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035294		3/25/2014	3/31/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/28/2011
Explant Date (E7): 3/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE IN (B)(6) 2011 AND SINCE THEN I'VE BEEN TO MY PCP A LOT TO TRY TO FIGURE OUT WHY MY HEALTH WAS FAILING. SINCE I GOT IMPLANTED, I'VE HAD HEAVY BLEEDING, HUGE BLOOD CLOTS, CRAMPING, SHARP STABBING PAINS IN MY ABDOMEN, BACK PAIN, JOINT PAIN, CHEST PAIN, SEVERE FATIGUE, HEADACHES, NAUSEA AFTER EATING, METALLIC TASTE IN MY MOUTH, DIZZINESS, TINGLING SENSATIONS IN MY LIMBS, NUMBNESS, LEG PAIN, HAIR LOSS, DEPRESSION, B12 DEFICIENCY, TEETH ISSUES, HEART BURN, BRAIN FOG, FORGETFULNESS, 11 UTI'S, INSOMNIA, HEART PALPITATIONS, ANXIETY, PANIC ATTACKS, BACTERIAL VAGINOSIS (6 TIMES), FOUL SMELLING DISCHARGE, MOOD SWINGS, BOWL ISSUES, HOT FLASHES, BREAST PAIN, SPINE PAIN, LOW PLATELET COUNT, SHARP PAIN IN RECTUM, VISION IS GETTING WORSE, GUSHING BLOOD DURING SEX, PAIN DURING SEX, NO SEX DRIVE, ACNE, LOSS OF CONCENTRATION, LOSS OF HOPE, START CRYING FOR NO REASON, EYE TWITCHING, ITCHY SCALP, FEELS LIKE A BRUISE ON MY SCALP, CRAWLING SKIN, BUMPS THAT FEEL LIKE MOSQUITO BITES, WEAKNESS IN LIMBS, DIAGNOSED WITH ITP. MY DOCTOR AND I HAVE DONE EVERY TEST KNOWN TO MAN. I HAD A HYSTERECTOMY ON (B)(6) 2014, THEY REMOVED MY UTERUS, TUBES, CERVIX, AND ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035296	BAYER	3/25/2014	3/31/2014

Event Information:

Event Date (B3): 4/23/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 663256

Single Use:
Implant Date (E6): 4/23/2010
Explant Date (E7): 1/23/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE BIRTH CONTROL IN (B)(6) 2010. NOT LONG AFTER, MY HEALTH STARTED TO DECLINE. HEAVIER MENSTRUAL CYCLES, CRAMPING, FATIGUE, MOOD SWINGS WITH ANGER, LOOS OF MEMORY AND FOGGINESS, JOINT PAIN, DIZZINESS, MIGRAINE HEADACHES, METAL TASTE IN MOUTH, NUMBNESS TO EXTREMITIES AND WEIGHT GAIN THAT WOULD NOT GO AWAY WITH CHANGE OF DIET AND EXERCISE. (B)(6) 2011, I WAS HOSPITALIZED FOR CHEST PAIN AND FACE NUMBNESS. ALL TEST CAME BACK NORMAL. LIVED AND DEALT WITH ISSUES UNTIL (B)(6) 2012 WHEN THE PAIN BECAME TOO MUCH TO HANDLE. AFTER ULTRASOUNDS AND A PAP, IT WAS DETERMINED I HAD A MASS AND INFECTION IN MY UTERUS. (B)(6) 2013, I HAD A PARTIAL HYSTERECTOMY LEAVING ONLY OVARIES AND REMOVING THE ESSURE DEVICE. ALMOST IMMEDIATELY MY HEALTH ISSUES STARTED TO DISAPPEAR. NO MORE HEADACHES, NO MORE PAINS, NO MORE FOGGINESS OR DIZZINESS. ENERGY LEVEL IS UP AND WEIGHT IS DOWN. THERE IS STILL SLIGHT NUMBNESS IN THE FACE THAT COMES AND GOES BUT IS NO LONGER CONSTANT. MOOD SWINGS ARE GONE AND THE ANGER HAS SUBSIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035297	BAYER	3/25/2014	3/31/2014

Event Information:

Event Date (B3): 5/20/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MAY 2008, I HAD ESSURE PLACED TO KEEP FROM HAVING ANY MORE KIDS. SHORTLY AFTER HAVING IT PLACED, I STARTED HAVING BACK PAINS, JOINT PAINS, MUSCLE PAIN, ETC. IT TOOK ME YEARS TO FIGURE IT OUT IT WAS ESSURE AFTER GOING TO SEVERAL DIFFERENT DOCTORS AND ALL TESTS CAME BACK NEGATIVE TO REALIZE IT WAS ESSURE, SO I DID RESEARCH AND FOUND A SITE THAT DESCRIBED ALL THE SYMPTOMS OF ESSURE AND I HAD THEM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035298	BAYER	3/25/2014	3/31/2014

Event Information:

Event Date (B3): 3/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RECEIVED THE ESSURE PROCEDURE ON ONLY 1 SIDE IN (B)(6) OF LAST YEAR AND EVER SINCE I GET A STABBING PAIN IN THE ESSURE AREA, ONLY ON THE SIDE THAT HAS THE IMPLANT. I HAVE TALKED TO MY DOCTOR AND SHE SAID IT WOULD BE HIGHLY INVASIVE TO REMOVE THE ESSURE COIL SINCE THE TISSUE HAS ALREADY GONE AROUND IT. IT ISN'T A CONSTANT PAIN BUT WHEN IT DOES HIT ME IT'S HORRIBLE AND I AM UNABLE TO DO NORMAL DAILY ACTIVITIES. I AM VERY UPSET AT THIS PRODUCT AND THE FDA AND EVERYONE AND EVERYTHING ASSURED THE PATIENT THAT THERE WAS LIMITED SIDE EFFECTS AND THAT I WOULDN'T FEEL IT AFTER IT WAS IN, WHAT A LIE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035302	CONCEPTUS, INC.	3/25/2014	3/31/2014

Event Information:

Event Date (B3): 12/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/28/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE HAVING ESSURE PLACED IN 2013 I HAVE HAD EXCRUCIATING PAIN DURING MY CYCLES AS WELL AS PASSING CLOTS THE SIZE OF SILVER DOLLARS. I FREQUENTLY EXPERIENCE PAIN IN MY SIDES, BLOATING AND WEIGHT GAIN. I FOR THE MOST PART HAVE JUST BEEN FEELING ALL AROUND UNWELL. I HAVE HAD GLANDS SWELLING WITHOUT REASON AFTER BLOOD TESTS SHOW NO CAUSE. I HAVE BROKEN OUT IN RASHES WHICH HAVE LASTED MONTHS AROUND MY CHIN AND BELLY. I AM HOPING THAT I CAN SOMEHOW HAVE THE DEVICES REMOVED AND GET BACK TO MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00082	BAYER HEALTHCARE, LLC	3/25/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 761437

Single Use: Y
Implant Date (E6): 10/20/2010
Explant Date (E7): 1/21/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED ON (B)(6) 2010, FOUR MONTHS POSTPARTUM. FULL BLOCKAGE WAS CONFIRMED IN (B)(6) 2011. SHE REPORTS THAT NAUSEA AND BRAIN FOG STARTED TWO MONTHS POST-INSERTION, AND WORSENED AS TIME WENT ON. SHE ALSO REPORTS EXPERIENCING A GRADUAL INCREASE IN PELVIC PAIN ABOUT TWO YEARS POST-INSERTION. IN (B)(6) 2013, SHE WAS DIAGNOSED WITH ENDOMETRIOSIS. OTHER SYMPTOMS (UNKNOWN START DATE) INCLUDED BAD MENSTRUAL PERIODS, MIGRAINES, EXTREME MOOD SWINGS AND JOINT PAIN. ON (B)(6) 2014, SHE UNDERWENT A PARTIAL HYSTERECTOMY (HER OVARIES WERE PRESERVED). HER UTERUS WAS FOUND TO BE SPONGY AND INFLAMED. REPORTEDLY, ESSURE WAS FOUND TO BE INTACT IN BOTH TUBES DURING SURGERY. SHE RECOVERED POST-HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00083	BAYER HEALTHCARE LLC	3/25/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/10/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS REPORT WAS GENERATED FROM (B)(4). THE CONSUMER REPORTED HAVING ESSURE INSERTED. SHE HAD TWO SURGERIES TO HAVE ESSURE REMOVED AND THERE IS STILL A PIECE EMBEDDED IN HER UTERUS, WHICH WOULD REQUIRE A THIRD SURGERY. ESSURE WAS THE REASON SHE HAD TO GET A TUBAL. FOLLOW UP CANNOT BE DONE.

Manufacturer Narrative (H10):

CONSUMER: SHE REPORTED VIA SOCIAL MEDIA THAT ON (B)(6) 2014 WAS 5 YEARS THAT SHE HAD ESSURE PROCEDURE DONE. SHE STATED SHE HAD 3 SURGERIES BECAUSE OF ESSURE AND THE TUBAL LIGATION WAS DONE BECAUSE ESSURE DID NOT WORK; AND THE COILS ENDED UP PERFORATING AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00084	BAYER HEALTHCARE LLC	3/25/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS REPORT IS GENERATED FROM ESSURE (B)(4). A CONSUMER REPORTED HAVING ESSURE INSERTED AFTER HER LAST BABY. THREE YEARS AFTER INSERTION THE CONSUMER HAD TO HAVE BOTH TUBES REMOVED, HALF OF HER UTERUS, AND MOST HER OVARIES BECAUSE BOTH OF THE ESSURE HAD PERFORATED THE TUBES. WHEN THEY DID THE REMOVAL, THEY ALSO FOUND A 14 WEEK FETUS TRAPPED INSIDE ONE OF THE ESSURE. FOLLOW UP CANNOT BE DONE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00085	BAYER HEALTHCARE LLC	3/25/2014	4/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 922603

Single Use: Y
Implant Date (E6): 3/29/2012
Explant Date (E7): 4/24/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

EIGHT WEEKS AFTER ECTOPIC PREGNANCY WITH MIRENA, CONSUMER HAD ESSURE IMPLANTED IN HER REMAINING FALLOPIAN TUBE. WITHIN 3 WEEKS OF PLACEMENT, SHE HAD CONTINUED CRAMPING, BLEEDING, EXCRUCIATING PAIN, NAUSEA, WEIGHT LOSS. LOWER LEFT PELVIC PAIN, DIZZINESS, EXTREME FATIGUE. IT FELT LIKE HER BODY WAS REJECTING THE COIL AND SHE COULD PINPOINT THE EXACT LOCATION OF THE COIL DUE TO THE PAIN. SHE HAD TO FORCE TREATMENT AS SEVERAL DOCTORS TOLD HER IT WAS ALL IN HER HEAD. THEY HAD CONSULTED SEVERAL COWORKERS AS WELL AS THE MFR OF ESSURE, ALL OF WHOM STATE HER SYMPTOMS AND COMPLAINTS COULD IN NO WAY BE RELATED TO THEIR COIL. HER DOCTOR WAS SEEN. ESSURE MIGRATION WITH NO PERFORATION, PID, PARTIAL BOWEL OBSTRUCTION WERE ALL MENTIONED BY DOCTOR, BUT NEVER DIAGNOSED. FINALLY, THE PHYSICIAN PERFORMED EXPLORATORY SURGERY TO VERIFY THE LOCATION OF THE COILS- FROM VAGINAL ENTRY WITH CAMERA THE COILS WERE UNABLE TO BE LOCATED. THE SURGEON THEN HAD TO GO IN LAPAROSCOPICALLY THROUGH ABDOMEN, REMOVED THE LEFT FALLOPIAN TUBE, AND LOCATED "FOREIGN OBJECT" (ESSURE COIL) IN HER TUBE.

Manufacturer Narrative (H10):

THE EVENT "ABSCESSES ON ARMS" WAS RECODED TO (B)(4) "ABSCESSES OF SKIN". FOLLOW-UP INFORMATION RECEIVED ON 01-APR-2014: THIS CASE IS NOW POTENTIAL LEGAL. MENTAL AND EMOTIONAL DISTRESS, INJURIES/INJURED BY MIRENA/TORTIOUS INJURIES WERE REPORTED. THE CONSUM

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00086	BAYER HEALTHCARE LLC	3/25/2014	4/2/2014

Event Information:

Event Date (B3): 5/26/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE IMPLANTED. ON (B)(6) 2011, ESSURE PERFORATED TUBE, CAUSED SCAR TISSUE, WHICH CAUSED ORGANS TO FUSE TOGETHER. CONSUMER HAD TO HAVE TOTAL ABDOMINAL HYSTERECTOMY WITH REMOVAL OF TUBES AND ONE OVARY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	3/26/2014	3/31/2014

Event Information:

Event Date (B3): 3/24/2014 **Report Date (B4): 3/26/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): B82481

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE MISFIRED THE IMPLANT. THE IMPLANT WAS COILED AND STUCK AT THE END OF THE DEVICE. A NEW DEVICE WITH NEW IMPLANT WAS USED SUCCESSFULLY WITHOUT ANY ADVERSE EFFECTS TO THE PATIENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035337	BAYER	3/26/2014	4/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTS
Device Type (E2): ESSURE IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4): 20222098

Single Use:
Implant Date (E6): 4/16/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IMPLANTS (B)(6) 2010. SINCE BEING IMPLANTED I HAVE HAD CHRONIC AND PERSISTANT PELVIC PAIN, HEMORRHAGING WITH MENSTRUAL CYCLES, HAIR LOSS, SWELLING OF THE ABDOMEN, SEVERE HIP AND LOWER BACK PAIN, HEADACHES, VISION CHANGES, TERRIBLE PERSISTENT HEARTBURN, RECURRING YEAST AND BLADDER INFECTIONS, KIDNEY PROBLEMS, SERIOUS WEIGHT GAIN, MOODINESS, IRRITABILITY, DEPRESSION REQUIRING DAILY MEDICATION, LOSE OF LIBIDO, AND PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035228	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 5/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I GOT THE ESSURE PROCEDURE DONE I HAVE HAD MANY SIDE EFFECTS THAT AFTER GOING TO THE DOCTOR THEY HAVEN'T FOUND TO HAVE A REASON. MY GUESS IS THEY HAVE TO DO WITH ESSURE SINCE I DIDN'T HAVE THESE BEFORE. I GET HEART PALPITATIONS, ANXIETY, A WEIRD FEELING IN MY HEAD THAT FEELS LIKE I'M GETTING SHOCKS IN THE BRAIN AND AT TIMES WHEN I GET THAT FEELING MY LIPS FEEL NUMB AS WELL. I CONSTANTLY HAVE A PAIN IN THE RIGHT SIDE, WHERE I'M ASSUMING MY OVARY IS. THIS IS THE SAME SIDE THAT THE DOCTOR HAD A HARD TIME GETTING THE COIL IN. ON A GOOD DAY THE PAIN IS DULL AND CONSTANT. ON A BAD DAY I'M ALMOST IN TEARS. THE PAIN RADIATES DOWN MY GROIN INTO MY LEG AND ITS HARD TO EVEN WALK. I GET HEADACHES ALL THE TIME, ALMOST DAILY. I DO SUFFER FROM MIGRAINES, BUT I CAN TELL YOU THE DIFFERENCE BETWEEN THE TWO. ALSO I GET EPISODES OF BLOATING THAT ARE SO UNCOMFORTABLE AND MY STOMACH GETS SO SWOLLEN I LOOK AT LEAST 5 MONTHS PREGNANT. I ALSO GET NAUSEOUS OFTEN, NO VOMITING JUST THE FEELING. ANOTHER THING IS THAT I GET FREQUENCY TO URINATE, ALMOST LIKE A UTI. WHEN I HAD INSURANCE I WOULD GO IN, THINKING IT WAS A UTI AND THE DOCTOR WOULD ORDER ANTIBIOTICS FOR ME TO START ON AND WOULD DO LABS. A COUPLE OF DAYS LATER HE WOULD CALL AND SAY THE TESTS CAME BACK NORMAL AND DISCONTINUE THE MEDICATION. THIS STILL GOES ON BUT I JUST LET IT GO. UPDATE ON (B)(6) 2014: I FORGOT TO MENTION THAT SEX HAS BEEN PAINFUL BUT OVER TIME IT HAS GOTTEN A LOT WORSE, TO THE POINT IT MAKES ME CRY AND I BLEED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035239	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 11/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM THE MOMENT OF IMPLANTATION, ON (B)(6) 2013, I HAVE HAD LOWER BACK PAIN, HEADACHES, SHARP PAINS IN OVARY AREA AND EVERY DAY BLEEDING. AT THE END OF (B)(6) 2014, I PASSED A PIECE OF BROKEN COIL FROM MY VAGINA. MY LOWER BACK PAIN GOT WORSE AND I GOT UPPER LEG PAIN TOO. I WENT TO SEE MY DOCTOR AND HE DID AN ABDOMINAL X-RAY AND SAID MY COILS WERE IN PLACE AND IT IS NO BIG DEAL. HE TOOK ME OFF THE PILL AND PUT ME ON ESTROGEN SUPPLEMENTS FOR THE DAILY BLEEDING. UPDATE ON (B)(6) 2014: ON (B)(6) 2014 I HAD MY DYE TEST DONE. IT WAS CONFIRMED MY TUBES WERE BLOCKED AND I WAS STERILE. DURING MY CONSULTATION MY DOCTOR DISMISSED MY BACK PAIN, LEG PAIN, AND SHOOTING PAINS IN MY SIDES. HE SAID THE PROCEDURE WORKED, DON'T WORRY ABOUT IT AND SAID IT IS NOT ESSURE RELATED. I BROUGHT UP THE PART OF THE COIL THAT CAME OUT OF MY VAGINA AND HE SAID HE DIDN'T KNOW WHY THAT HAPPENED BUT DON'T WORRY BECAUSE THE PROCEDURE WORKED. MORE SYMPTOMS HAVE OCCURRED. ON THIS DATE, (B)(6) 2014, I AM HAVING SEVERE RIGHT SHOULDER PAIN THAT RADIATES DOWN MY ENTIRE ARM TO MY HANDS. MY ARM PAIN WAKES ME UP AT NIGHT IT IS SO SEVERE. MY LOWER BACK PAIN IS STILL HAPPENING. I HAVE KNOTS ON MY FACE ESPECIALLY IN THE CHIN AREA. THEY ARE PAINFUL, AND LIKE PIMPLES, BUT THEY NEVER SURFACE. IN THE PAST FEW WEEKS I HAVE HAD TINGLING IN MY FINGERS AND HANDS. I HAVE HAD A HARD TIME GRASPING, TYPING, TEXTING, AND PICKING UP OBJECTS LIKE MY MAKEUP BRUSHES. I HAVE ALSO BEEN EXPERIENCING DIARRHEA DAILY, AND HAVE TO TAKE SOMETHING TO STOP IT SO I CAN GO TO WORK. FINALLY, UPON WAKING UP EVERY MORNING I ACHE SO BAD, IT TAKES AT LEAST AN HOUR TO BE ABLE TO FUNCTION.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035240	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 5/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE EXPERIENCED LEFT SIDED PELVIC PAIN, INTERMITTENT DIZZINESS, TINGLING IN ARMS AND HANDS, CHEST PAIN, IRREGULAR PERIODS LASTING 10-16 DAYS WITH HEAVY BLEEDING AND CRAMPING, ACID SMELLING DISCHARGE, BURNING SENSATION IN VAGINAL AREA WITH DISCHARGE. UPDATE ON (B)(6) 2014: HYSTERECTOMY WITH REMOVAL OF COILS ON (B)(6) 2014 WITH RESOLUTION OF PELVIC PAIN, DISCHARGE, ODOR, DIZZINESS. NOW WITH MINIMAL CHEST PAIN AND SIGNIFICANT REDUCTION IN ARTHRITIC PAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035241	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 8/10/2012 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER 2 WEEKS HAVING ESSURE I STARTED TO BLEED A LOT AND SO MUCH PELVIC PAIN. I WENT BACK TO (B)(6) THE PLACE WERE I GOT IT DONE TELLING THEM I WAS BLEEDING A LOT AND THE PAIN DID NOT STOP THEY SAID IT WAS NORMAL. THEN ON (B)(6) I WENT TO A DIFFERENT DR WHO PERFORMED A D AND C ON (B)(6) AFTER THAT I WAS STILL BLEEDING SO HE PERFORMED AN ABLATION. WHEN "I THAT ALL MY PROBLEMS" WERE RESOLVED IS WHEN THEY REALLY STARTED. I STARTED HAVING SEX WITH MY HUSBAND AFTER ALMOST 8 MONTHS OF NOTHING BECAUSE OF THE BLEEDING. MY HUSBAND STARTED TO GET A RASH, CUTS, SWELLING, BURNING AND PAIN ON HIS PENIS AFTER SEX, AND I HAD TERRIBLE IRRITATION AND BURNING AND ITCHING ON MY VAGINA, LIKE SOMETHING THAT I WAS RELEASING FROM MY BODY WAS CAUSING US TO GET SICK. WE WENT TO THE DR. THEY SAID WE HAD AN STD AND WE GOT CHECKED FOR ALL. CAN YOU BELIEVE ALL WAS NEGATIVE! BUT WE NEVER GOT CHECKED IF WE WERE ALLERGIC TO NICKEL! AND THAT IS WHEN WE FOUND OUT WHAT WAS THE CAUSE OF ALL THESE PROBLEMS....ESSURE HAS NICKEL AND ME AND MY HUSBAND ARE ALLERGIC TO IT.... UPDATE ON (B)(6) 2014: ON (B)(6) 2014 MY PELVIC PAIN WAS SO BAD I ENDED UP IN THE ER. THEY SENT ME TO HAVE A VAGINAL ULTRASOUND. THEY FOUND THE COILS ON MY UTERUS. ON (B)(6) 2014 I HAD A HYSTERECTOMY. I LOST MY UTERUS, MY CERVIX, AND TUBES, AND SO MANY MORE THINGS, MONEY, TIME OFF WORK, DEPRESSION, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035251	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 10/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE DONE. I DO NOT RECALL BEING ASKED TO TEST FOR ANY ALLERGIES TO NICKEL. THE PROCEDURE WAS DONE IN THE DOCTOR'S OFFICE. I ONLY TOOK A MILD SEDATIVE AND SEEMS LIKE PROCEDURE TOOK NO LONGER THAN 30 MINUTES. UPDATE ON (B)(6) 2014: I WOULD LIKE TO POST WHAT I FEEL ARE SIDE EFFECTS TO THIS DEVICE: PAINFUL CRAMPING, PASSING BLOOD CLOTS DURING PERIODS, WEIGHT GAIN, BRAIN FOG, JOINT STIFFNESS, CHRONIC FATIGUE, FLU LIKE SYMPTOMS, BLOATED FEELING, DEPRESSION, MUSCLE STIFFNESS, BACK PAIN, ARTHRITIS LIKE SYMPTOMS, NECK SHOULDER PAIN, FIBROMYALGIA SYMPTOMS, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035252	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 1/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME CRAMPING. PERSISTENT BLEEDING. VOMITING. NAUSEA. HAIR LOSS. HEADACHE. DIZZY SPELLS. BODY RASH (PAINFUL AND ITCHY) EXTREME PELVIC PAIN. BLOATING. FATIGUE. WEIGHT LOSS. JOINT PAIN. BODY STIFFNESS. NECK/BACK/ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035253	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 5/24/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2010. FROM THE DAY OF INSERTION I HAD SEVERE PELVIC PAIN. I WAS ASSURED BY MY DOCTOR THAT THIS PAIN WOULD GO AWAY AND EVERYTHING WOULD BE BETTER AFTER A FEW WEEKS. UNFORTUNATELY THE PAIN NEVER WENT AWAY. THE PELVIC PAIN GOT WORSE AND I BEGUN BLEEDING HEAVILY AGAIN, DESPITE HAVING THE ENDOMETRIAL ABLATION DONE. IN (B)(6) 2011 I ENDED UP HAVING A HYSTERECTOMY (REMOVAL OF UTERUS AND CERVIX) TO HOPEFULLY CONTROL THE BLEEDING AND THE PAIN. THE BLEEDING STOPPED BUT THE PAIN DID NOT LESSEN ANY. I HAVE HAD MANY GYNECOLOGICAL APPOINTMENTS FOR THE PAIN AS WELL AS ALL OVER ITCHING (PRURITUS), SEVERE LOWER BACK PAIN, CONSTANT HEADACHES, NIGHT SWEATS, NIGHT TERRORS, HOT FLASHES, AND JOINT PAIN. I AM A (B)(6) MOTHER AND I HAVE NOT BEEN ABLE TO LIVE MY LIFE IN THE MANNER I WAS ABLE TO BEFORE HAVING ESSURE IMPLANTED. I HAVE HAD NUMEROUS EMERGENCY DEPARTMENT VISITS ALL RESULTING IN INCONCLUSIVE ANSWERS. I HAVE ALSO DEVELOPED KIDNEY STONES SINCE HAVING ESSURE IMPLANTED, SOMETHING I NEVER HAD TO DEAL WITH BEFORE. IN (B)(6) 2014 I FINALLY FOUND A DOCTOR WHO WAS WILLING TO LISTEN TO ME ABOUT MY CONCERNS WITH ESSURE AND HE ORDERED AN X-RAY TO CHECK PLACEMENT. THE X-RAY SHOWED ONE ESSURE COIL ON THE LEFT SIDE AND WHAT APPEARED TO BE A SURGICAL CLIP ON THE LEFT SIDE. HOWEVER, THERE WAS NO ESSURE COIL PRESENT ON THE RIGHT SIDE OF THE X-RAY. IN (B)(6) 2014, MY GYNECOLOGIST AGREED TO REMOVE MY TUBES AND LOOK FOR THE RIGHT ESSURE COIL. AFTER REMOVING MUCH SCAR TISSUE BELIEVED TO BE CAUSED BY THE INFLAMMATION FROM ESSURE, HE STILL COULD NOT LOCATE THE RIGHT COIL. IT IS BELIEVED THAT IT WAS EITHER EXPELLED AND I DID NOT NOTICE IT OR THAT IT HAS MIGRATED INTO MY INTESTINES OR COLON. WHILE ESSURE WAS IMPLANTED MY ANA TITERS WERE FOUR TIMES HIGHER THAN THEY SHOULD HAVE BEEN AND I AM NOW BEING TESTED FOR SLE AND MIXED CONNECTIVE TISSUE DISEASE. NO ONE

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IN MY IMMEDIATE FAMILY HAS THIS. SLE IS CAUSED BY INFLAMMATION IN THE BODY AND IT IS MY BELIEF THAT HAVING ESSURE IMPLANTED FOR SO LONG HAS CAUSED ME TO BE AT RISK FOR AUTOIMMUNE DISORDERS BECAUSE OF THE CONSTANT INFLAMMATION ESSURE CAUSES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035254	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 11/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY I STARTED EXPERIENCING TERRIBLE PAIN AND SWELLING IN MY LEGS, MUSCLES AND JOINTS IN MY BODY, AND BLEEDING EVERYDAY. NOT BEING ABLE TO TELL ONE PERIOD FROM ANOTHER DUE TO CONSTANT BLEEDING. AND MIGRAINES. AND SWELLING THROUGH OUT MY BODY, AS WELL AS MY FINGERS AND HANDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035255	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 5/24/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD HSG SOME TIME THIS MONTH AND I WAS BLOCKED BUT ONE COIL DID MIGRATE UP FROM WHERE IT WAS PLACED WHERE I HAD TO HAVE ANOTHER SURGERY TO HAVE MY TUBES BURNT TO PREVENT POSSIBLE PREGNANCY AND OR ETOPIC PREGNANCY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035256	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 7/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABOUT A YEAR AFTER ESSURE WAS IMPLANTED I BEGAN HAVING VERY SHARP PAINS IN MY RIGHT SIDE EQUALLY AT THE BEING OF MY CYCLE. BACK PAIN , HIP PAIN, THAT WOULD USUALLY GET A LITTLE BETTER AFTER MY PERIOD ENDED. I ALSO GET A LOT OF HEADACHES. ABOUT 3-4 WEEKS AGO IT STARTED GETTING A LOT WORSE. NECK PAIN, HEADACHES, AND THE WHOLE RIGHT SIDE OF MY BODY HURT WENT TO ER. DID CT SCAN. SAID THEY WEREN'T SURE WHAT WAS GOING ON. THEN FOLLOWED UP WITH MY OBGYN WHO SAID THAT THIS SOUNDS ESSURE RELATED AND WANTED TO DO TESTS. I HAD AN INTERNAL ULTRASOUND WHERE IT WAS FOUND THAT I HAVE 2 COMPLEX CYSTS ON MY RIGHT OVARY. I ENDED UP BACK IN THE ER AGAIN A FEW DAYS LATER BECAUSE OF PAIN. ANOTHER CT SCAN WAS DONE AND TOLD TO FOLLOW UP WITH OBGYN. OBGYN IS DISCUSSING REMOVING THE COIL BUT NOT SURE YET IF WE HAVE TO JUST REMOVE TUBE OR FULL HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035257	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 10/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT BLEEDING FROM THE TIME OF IMPLANT, NAUSEA, WEIGHT GAIN, BLOATING, MEMORY LOSS, BLURRED VISION, DISCOLORATION ON THE FACE, HAIR LOSS, ANXIETY, MOOD SWINGS, NON EXISTENT LIBIDO, CONSTANT FATIGUE, JOINT PAIN, NIGHT SWEATS, ARTHRITIS, HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035258	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN (B)(6) 2012. STARTED HAVING ISSUES 4-5 MONTHS, ATTRIBUTED THEM TO NOT BEING ON TOP OF MY EATING HABITS AND GETTING OLDER. HOWEVER ENDED UP IN ER ON (B)(6) 2014 DUE TO PELVIC PAIN AND SEVERE HEADACHE. THEY DID AN U/S AND I'VE DEVELOPED FIBROIDS AND HAVE AN UNKNOWN MASS ON ONE TUBE. MY LEFT COIL IS ALMOST COMPLETELY INSIDE MY UTERINE CAVITY AS WELL. OVER THE PAST YEAR AND A HALF I'VE HAD CHRONIC UTI'S, PAINFUL STABBING LIKE PAINS IN MY PELVIC AREA, 30% OF WEIGHT GAIN, NIGHTSWEATS, NUMBNESS, TINGLING IN MY LEFT BREAST, SEVERE HEADACHES, ANXIETY, THROAT INFECTIONS, PNEUMONIA, DIZZINESS, ABNORMAL PAP RESULTS FOR THE FIRST TIME IN 17 YEARS (ON THE 1ST AND ONLY TEST DONE SINCE ESSURE WAS INSERTED), FIBROIDS, UNKNOWN MASS ON A TUBE, SHORTER CYCLES, RANDOM CRAMPING, ODOR, HEARTBURN, CRAZY MOOD SWINGS, RASHES ON MY LEFT ARM, EXCESSIVE PEEING, HEAD FUZZINESS AND RINGING IN MY EARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035259	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 2/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN I FIRST GOT THE DEVICE I NOTICED I LOST MY SEX DRIVE, MY PERIODS WERE NON-EXISTENT TO SPOTTING TO HEAVY BLEEDING TO WHERE I AM HAVING THEM 2 OR 3 TIMES A MONTH AND THEY ARE LASTING A COUPLE OF WEEKS WITH THE PASSING OF BLOOD CLOTS. I HAVE ALSO HAD NUMBNESS IN MY HANDS AND LEGS AND PAIN IN MY LEGS. VERY FATIGUED, DEPRESSED, NO ENERGY. I'VE HAD SHARP PAINS ON BOTH MY SIDES. I GET HEADACHES A LOT AND HAVE HAD HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035261	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 11/25/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THE FIRST SYMPTOM I QUESTIONED AS ESSURE RELATED WAS MY LEFT FOOT/ANKLE/LOWER LEG SWELLING. I HAD A SLEW OF TESTS RUN AND NO DIAGNOSIS OR CURE- I HAVE DEALT WITH/LIVED WITH THIS SINCE! SINCE THEN, I HAVE HAD A MIRIAD OF ISSUES THAT NO DR CAN FIND THE REASON FOR. I HAVE HAD MS LIKE SYMPTOMS OFF AND ON, CAUSING THE DRS TO CHECK FOR MS TWICE EVEN SO FAR AS ORDERING A SPINAL TAP! I HAVE HAD SHINGLES AT THE VERY YOUNG AGE OF 35, MY EYE DR THOUGHT I HAD OPTIC NEURITIS, I HAVE DEALT WITH WORSENING DEPRESSION, MOOD SWINGS, IRREGULAR PERIODS, HEAVY BLEEDING/BLOOD CLOTS, HEADACHES, A CHRONIC LEFT BACK/HIP PAIN, TIREDNESS, FORGETFULNESS, AND AN INABILITY TO BE THE ENERGETIC MOM TO MY KIDS AND WIFE TO MY HUSBAND THAT I USED TO BE. I HAVE GAINED WEIGHT THAT NO DIETING OR EXERCISE WILL TAKE OFF AND THE BLOATING IS RIDICULOUS!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035262	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 4/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS WAS THE ONSET OF THE FIRST PROBLEM AND SYMPTOM OF ESSURE. I WAS DIAGNOSED WITH LEUKEMIA WHICH IS A CANCER OF THE WHITE BLOOD CELLS WHICH FIGHT OFF INFECTION. I HAVE TO HAVE BLOOD WORK DONE EVERY MONTH. I HAVE HAD ULTRASOUNDS DONE AND RECENTLY THEY FOUND A CYST. I HAVE MANY PROBLEMS INCLUDING CONSTANT CONSTIPATION, BLOATING LIKE I AM PREGNANT, PAIN IN THE ABDOMEN, VERY GASSY, TERRIBLE PAIN DURING PERIODS AND QUARTER SIZE CLOTTING. I HAVE BEEN GETTING SPOTTING IN BETWEEN PERIODS OVER THE LAST THREE MONTHS, I HAVE BEEN HOSPITALIZED FOR MIGRAINES THREE TIMES, I HAVE MILD HEADACHES EVERY DAY, PAIN IN MY HIPS AND OTHER JOINTS. I AM FATIGUED ALL THE TIME AND WEAK. I HAVE HEART PALPITATIONS AND HAVE HAD AN EKG TEST DONE TO CHECK ON THAT BUT IT DIDN'T HAPPEN DURING THE TEST. I SOMETIMES GET SHARP PAINS IN MY VAGINAL OPENING AND JUST ON THE INSIDE AND IRRITATING LEAKAGE AND DISCHARGE. BEFORE I GOT THIS I DID HAVE A METAL ALLERGY TO CERTAIN JEWELRY. WITH ALL OF THESE PROBLEMS THIS PRODUCT SHOULD BE BANNED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035263	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 3/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I FORGOT TO ADD THIS INTO MY INITIAL REPORT. I WAS IMPLANTED IN (B)(6) 2008. I HAVE STARTED TO GAIN WEIGHT AND I CANNOT LOSE IT. I HAVEN'T CHANGED MY DIET AS FAR AS PORTIONS AND HAVE BEEN GOING TO THE GYM TO LOSE WEIGHT AND I AM STILL STEADILY BUT SLOWLY GAINING. I HAVE EVEN STARTED EATING HEALTHIER. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035264	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 12/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS VOMITING BEFORE I HIT THE PARKING LOT. BY THE TIME I GOT HOME, I HONESTLY FELT LIKE I WAS GOING TO DIE. THE PAIN WAS WORST THAN GIVING BIRTH. MY HUSBAND CONTACTED THE DRS OFFICE AND THEY PRESCRIBED STRONGER PAIN MEDS AND ANTI NAUSEOUS MEDS. I WAS ABLE TO FINALLY GET SOME REST. AS TIME CONTINUED, I STARTED TO NOTICE NUMEROUS THINGS. FOR EXAMPLE SHORTNESS OF BREATHE, RAPID HEART PALPITATIONS, DEBILITATING MIGRAINES, BLURRY VISION, PAIN DURING AND AFTER SEX, NO DESIRE TO HAVE SEX, LOSS OF HAIR, ACNE BREAK OUT, INSOMNIA, LITTLE ENERGY, BLOATED STOMACH, SEVERE CRAMPING, STOMACH WAS TENDER TO THE TOUCH. THIS IS JUST TO NAME A FEW. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035265	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 1/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PAIN, DEPRESSION, MOOD SWINGS, ITCHY SKIN, EXHAUSTION. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035266	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 9/12/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME PAIN AND BLEEDING DURING PROCEDURE. EXTREME PAIN AND BLEEDING AFTER PROCEDURE. REQUIRED TWO IRON INFUSIONS DUE TO BLOOD LOSS. I DIDN'T HAVE A PERIOD FOR SEVERAL MONTHS AFTER INITIAL BLEEDING ENDED. WAS GIVEN HORMONES TO START PERIOD. I NOW HAVE AVERAGE TWO PERIODS A MONTH. I HAD A 45 DAY PERIOD SUMMER 2013. I HAD A 40 DAY PERIOD WINTER 2014. CONTINUED SEVERE PELVIC PAIN, UTERINE PAIN, BREAST PAIN AND TENDERNESS. OCCASIONAL SEVERE HEADACHES AND LOW BACK PAIN. DEVELOPED RASH ON MY FACE. SUDDEN ALLERGIC REACTION TO POISON IVY. BRAIN FOG. DEPRESSION. WEIGHT GAIN. I AM SCHEDULED FOR A HYSTERECTOMY (B)(6) 2014 TO REMOVE ESSURE, FALLOPIAN TUBES, CERVIX, AND UTERUS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035268	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 9/17/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FIRST OFF PRIOR TO IMPLANTATION, I WAS ALREADY DIAGNOSED WITH A AUTOIMMUNE DISORDER. NEVER ONCE DID MY IMPLANT, DOCTOR SAID THERE WOULD BE AN ISSUE IF I HAD THIS PUT IN ME. I ALSO ASKED IF IT WOULD BE AND WAS TOLD NO. HER BIGGEST CONCERN WAS MY WEIGHT, WHICH IS THE REASON SHE PUSHED FOR ESSURE. AFTER IMPLANTATION, I HAVE BEEN SUFFERING FROM SHARP SHOOTING PAIN ON MY SIDES. IT PARTICULARLY HITS ME WHEN DOING ACTIVITIES OR FAST MOVEMENTS. FREQUENT BLEEDING AND ABNORMAL PERIODS. I HAD TO TAKE STEROIDS AND BACK ON THE PILL DUE TO THIS. I AM FREQUENTLY LATE ON AVERAGE 5 TO 8 DAYS LATE. ONCE I GET MY PERIOD, I AM BLEEDING FOR 10 TO 20 DAYS STRAIGHT. IT WILL STOP ONLY TO COME BACK A WEEK LATER. I HAD TO HAVE A PELVIC EXAM, MOST PAINFUL THING I HAD EVER DONE. I AM EXTREMELY SWOLLEN, IT HURTS DURING INTERCOURSE. I AM NOW LOOKING AT A HYSTERECTOMY TO GET THESE THINGS OUT. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035269	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED ITCHING IN RANDOM PLACES FOR NO APPARENT REASON AROUND THE SAME TIME THE DEVICE WAS INSERTED. I HAD NO REASON TO THINK IT WAS THE ESSURE BECAUSE I WASN'T MADE AWARE THERE WAS NICKEL IN THE DEVICE, WHICH I AM ALLERGIC TO. LATER I STARTED HAVING ISSUES WITH PAIN, DEPRESSION, SLEEPING A LOT MORE THAN NORMAL, IRRITABILITY, VERY ABNORMAL PERIODS - I BLEED ENOUGH TO HAVE TO CHANGE A SUPER PLUS TAMPON EVERY HALF AN HOUR DURING THE HEAVIEST POINT OF MY PERIOD. IT HAS NEVER EVER BEEN LIKE THIS BEFORE. I ALSO HAVE A SCRAPING/BURNING PAIN SENSATION THAT'S ALMOST CONSTANT IN MY ABDOMEN. IT FEELS LIKE SOMEONE IS SCRAPING MY INSIDES WITH A HOT KNIFE, WITH STABBING PAINS THAT SHOOT ALL OVER FROM MY ABDOMEN OCCASIONALLY. AFTER GOING TO AN ALLERGIST, I WAS DIAGNOSED WITH NICKEL ALLERGY, COBALT (WHICH IS FOUND FREQUENTLY USED WITH NICKEL, AND IN STAINLESS STEEL), AND A COUPLE OTHER NON-RELATED ALLERGIES. I'M EXTREMELY WORRIED ABOUT MY SURGERY TO REMOVE THIS DEVICE (WHICH WILL BE SCHEDULED FOR (B)(6)), AS I AM ALLERGIC TO EVERY ANTIBIOTIC I'VE TAKEN. I DON'T KNOW WHAT WILL HAPPEN IF I DEVELOP AN INFECTION POST-OP. AND A PARTIAL OR FULL HYSTERECTOMY IS THE ONLY WAY I CAN GET THIS REMOVED. I'M ONLY (B)(6). I HAVE HAD TO GO THE ER A FEW TIMES FOR THE PROBLEMS I NOW ATTRIBUTE TO ESSURE (AFTER FINDING OUT ABOUT THE NICKEL). THIS NEEDS TO STOP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035270	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING EVER SINCE ESSURE IMPLANTED. IRREGULAR CYCLES. BLEED EVERYDAY. EXTREME CRAMPING LOWER BACK AND PELVIC AREA. YELLOW PURE LIQUID RUNNY DISCHARGE THAT COMES OUT LIKE PEE BUT DIFFERENT CONSISTENCY FROM VAGINA. ICY COLD RUSH SENSATION UP AND DOWN LEGS. EXTREME WEAKNESS IN ARMS AND HANDS. NO GRIP. KNEES POPPING. JOINTS BURN AND FEEL ON FIRE AND HURT. FEEL ICY COLD ALL THE TIME. FEEL CHILLED TO THE BONE. LEGS AND FEET SWOLLEN AND HURT. HARD TO STAND OR WALK. HIPS HURT. NECK HURTS. LOSS OF APPETITE. FEEL PRESSURE ON MY PELVIC FLOOR AND BLADDER. BURNING COLD PAIN WHERE MY COILS ARE. CAN FEEL THEM SQUEEZING MY TUBES. MAINLY MY RIGHT SIDE BUT BOTH ARE BAD. MY WHOLE BODY HURTS. STABBING PELVIC AND BACK PAIN. EXTREME FATIGUE. NAUSEA, MIGRAINE HEADACHES. DIZZINESS. COLD CHILLS. HOT FLASHES. INSOMNIA. NIGHT SWEATS. CHEST PAINS. HAVE TO WORK HARDER TO BREATHE. SHALLOW BREATHS. INCREASED HEARTRATE. HAIR FALLING OUT FAST, STOMACH TORE UP, SHAKES. EXTREMELY EMOTIONAL. MUSCLE WEAKNESS. NO STRENGTH . TOXIC LEVEL OF NICKEL IN MY BLOOD? INTENSE LEG AND ARM HEAVINESS. CAN'T STAND LONG. FEELS WEIGHED DOWN. SORE. LIKE I HAVE TO DRAG MY LEGS AROUND. HARD TO LIFT MY LEGS AND ARMS. ACNE. INTENSE PELVIC PAIN. AND KILLER LOWER BACK PAIN. METALLIC TASTE IN MY MOUTH. CERVIX FEELS LIKE IT'S ON FIRE CONSTANTLY. SWOLLEN LEGS AND FEET. NUMBNESS AND TINGLING IN HANDS. HARD TO CONCENTRATE OR REMEMBER. BRAIN FOG. MY TUBES ARE ON FIRE CONSTANTLY. PAINFUL SEX. BLEEDING DURING AND AFTER SEX. CHUNKS OF BLOODY TISSUE COMES OUT OF VAGINALLY WHEN PEE. I BLEED VAGINALLY EVERY TIME I PEE OR POOP. FEELS LIKE SOMETHING CONSTANTLY CRAWLING INSIDE MY BODY WANTING TO PUSH OUT.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035271	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 8/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BEGAN HAVING LOTS OF UNEXPLAINED PAIN AND EVERY WAY POSSIBLE I HAD PELVIC PAIN, HIP PAIN, DIZZINESS, FATIGUE, MISTLETOE AND JOINT PAIN. HEAVY BLEEDING AND PAINFUL PERIODS. I HAD BLOOD CLOTS DURING PERIOD. INFLAMED UTERUS AND CERVIX BLEEDING AND PAIN DURING SEX. HEADACHES. BLADDER PROBLEMS. VITAMIN D DEFICIENT. DEPRESSION. SEVERE HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035274	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 3/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SURGERY SCHEDULED FOR HYSTERECTOMY, NO DATE YET, DUE TO A NICKEL ALLERGY AND INFLAMED UTERUS, AND REMOVAL OF ESSURE, AND A POSSIBLE PUNCTURED UTERUS FROM THE COIL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035275	BAYER	3/27/2014	3/27/2014

Event Information:

Event Date (B3): 2/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHILE HAVING SEX GOT SHARP CRAMP LIKE PAIN IN MY LEFT SIDE THAT TOOK MY BREATH AWAY. FOLLOWED BY 2 1/2 DAYS OF VAGINAL BLEEDING/SEVERE LEFT SIDE/ABDOMINAL CRAMPING. FOLLOWED BY A MONTH OF DULL ACHY FEELING IN MY ABDOMEN/LEFT SIDE. THEN ON (B)(6) PAIN DOWN LOWER LEFT BACK/FRONT ABDOMEN THAT FLOWED DOWN THROUGH MY PELVIS/BUTTOCK INTO MY LEFT LEG ON BACK THIGH AND KNEE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035273	BAYER	3/27/2014	3/28/2014

Event Information:

Event Date (B3): 7/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED BY DR. (B)(6) ON (B)(6)-2012 APPROXIMATELY 3 WEEKS LATER I DEVELOPED A RASH ACROSS UPPER BACK. WENT TO PRIMARY CARE CLINIC AND WAS TREATED FOR CONTACT DERMATITIS WITH BENADRYL AND CREAM. RASH CLEARED UP TEMPORARILY. ABOUT 10 DAYS LATER RASH REAPPEARED ON UPPER BACK AND DOWN THE FRONT OF BOTH THIGHS. CONTINUED TO TREAT WITH BENADRYL AND CREAM FOR A COUPLE WEEKS. RASH DID NOT CLEAR UP. I BEGAN TO DEVELOP SEVERE AND CRIPPLING CHEST PAINS AT RANDOM TIMES THROUGHOUT DAY AND NIGHT. IT WAS AT THIS POINT I NOTICED I WAS PUTTING ON A WEIGHT. I WENT BACK TO PRIMARY DOCTOR FOR RASH AND CHEST PAINS. MY BLOOD PRESSURE WAS HIGH AND WAS ONCE AGAIN DIAGNOSED WITH CONTACT DERMATITIS. WITHIN A COUPLE WEEKS I HAD GAINED MORE WEIGHT SPECIFICALLY IN ABDOMEN AREA, RASHES CONTINUED AND NOW WERE UNDER ARMS AS WELL. CHEST PAINS AND RACING HEART CONTINUED ALONG WITH OTHER NEW SYMPTOMS, I NOW SUFFERED FROM NUMBNESS IN HANDS, FORGETFULNESS LIKE I WAS LIVING IN A FOG, HAIR LOSS, AND BLEEDING GUMS. AS WELL I SEEMED TO STOP HAVING MENSTRUAL CYCLES AS WELL. THESE SYMPTOMS CONTINUED AND WELL AS DOCTOR VISITS TO PRIMARY. I KNEW SOMETHING WAS WRONG MY MOTHER ASKED WHEN I HAD ESSURE PLACED. THIS WAS A DEFINING MOMENT AT THIS POINT I WAS ABLE TO FIND A POSSIBLE CAUSE OF THESE SYMPTOMS I HAD NEVER DEALT WITH BEFORE. I RETURNED TO IMPLANTING DOCTOR (B)(6) HE SAID HE DOES NOT BELIEVE IT IS ESSURE HAS NEVER HEARD OF ANYONE HAVING ISSUES WITH ESSURE. I WENT TO ANOTHER OBGYN DR. (B)(6) WITH MY CONCERNS AND WAS TOLD HE THOUGHT ESSURE COULD NOT CAUSE MY ISSUES AND TO SEE A PSYCHOLOGIST. MY SYMPTOMS CONTINUED I CONTINUED TO FOLLOW UP WITH PRIMARY AND EVEN ENDED UP IN ER WITH CRIPPLING CHEST PAINS WITH EXTREMELY HIGH BLOOD PRESSURE. FINALLY WAS REFERRED TO DERMATOLOGIST DR. (B)(6). WHERE A SKIN PATCH TEST WAS DONE ON BACK. THIS SHOWED

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A POSITIVE REACTION FOR SODIUM THIOSULFATE (GOLD). WE WERE BOTH STUMPED BY THIS BECAUSE THE AREA OF RASHES WAS NOT CONSISTENT WITH AREAS JEWELRY IS WORN. I DECIDED TO LOOK MORE INTO THE BIRTH CONTROL DEVICE. I CONTACTED MANUFACTURE AND WAS PROVIDED A LIST OF INGREDIENTS AND THERE WAS MY CONFIRMATION GOLD WAS IN THE DEVICE. I RETURNED TO DR. (B)(6) WITH LIST OF INGREDIENTS IN ESSURE DEVICE AND ALLERGY CONFORMATION. HE AGREED TO REMOVE ESSURE DEVICES. ON (B)(6)-2013 I WAS ADMITTED INTO (B)(6) FOR LAPAROSCOPIC SURGERY TO REMOVE DEVICES. DR. (B)(6) REMOVED ESSURE COILS VIA CUTTING ENDS OF FALLOPIAN TUBES, PULLING OUT COILS, AND PERFORMING A TUBAL LIGATION. AT THIS POINT MOST OF MY SYMPTOMS CLEARED UP. RASHES WERE GONE WITHIN 24 HOURS CHEST PAIN STOPPED, GUMS STOPPED BLEEDING, MY HAIR WAS NOT COMING OUT NEARLY AS MUCH AND WITHIN A MONTH I BEGAN TO MENSTRUATE AGAIN. SADLY THE NUMBNESS IN HANDS AND BRAIN FOG CONTINUED. APPROXIMATELY 2 MONTHS AFTER SURGERY I STARTED HAVING SEVERE PELVIC PAIN AND PELVIC PRESSURE. I DECIDED I WAS NOT GOING BACK TO DR. (B)(6) BECAUSE I KNEW SOMETHING WAS WRONG. I CALLED SEVERAL OB/GYNS IN MY AREA AND NO ONE WAS WILLING TO SEE ME DUE TO ISSUES WITH ESSURE DEVICE. IN APPROXIMATELY (B)(6) OF 2013 I WAS ABLE TO GET IN AT (B)(6). THE PA THAT SAW ME ORDERED A PELVIC ULTRA SOUND. ON (B)(6)-2013 I WAS SEEN AT (B)(6) FOR PELVIC ULTRA SOUND. DURING ULTRA SOUND FRAGMENTS OF ESSURE DEVICE WERE FOUND IN UTERINE CAVITY AND CONFIRM VIA X-RAY. I WAS THEN REFERED BACK TO PLANNED (B)(6). DUE TO LACK OF RESOURCES IN THEIR OFFICE I WAS THEN REFERED TO DR. (B)(6). AFTER CONSULTATION WITH HIM IT WAS DETERMINED THAT I WOULD NEED A HYSTERECTOMY. ON (B)(6)-2014 I HAD A HYSTERECTOMY WERE MY UTERUS, CERVIX AND LEFT OVARY WAS REMOVED. MY LEVEL OF PAIN IMPROVED GREATLY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00087	BAYER HEALTHCARE LLC	3/27/2014	4/8/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 5/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE WAS RECEIVED FROM THE HEALTH AUTHORITIES IN (B)(6) (B)(4) AND DESCRIBES THE OCCURRENCE OF ECTOPIC PREGNANCY IN A FEMALE PT WHO HAD ESSURE INSERTED AND DID NOT USE CONTRACEPTION FOR THE THREE MONTHS FOLLOWING FITTING. SHE UNDERWENT SALPINGECTOMY.

Manufacturer Narrative (H10):

CASE CORRECTION AFTER INTERNAL REVIEW ON 23-JUL-2014. IN 2013, THE PATIENT EXPERIENCED ECTOPIC PREGNANCY. PTC INVESTIGATION RESULT WAS RECEIVED ON 24-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). T(B)(4). FINAL ASS

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035260	BAYER	3/27/2014	6/24/2014

Event Information:

Event Date (B3): 1/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT MY ESSURE ON (B)(6) 2009, WITHIN A WEEK OR 2 OF HAVING THEM I GOT A KIDNEY STONE THAT HAD TO BE SURGICALLY REMOVED. BACK PAIN, NECK PAIN, NUMBING/TINGLING DOWN MY SIDES IN MY HIPS, FEET, HANDS, ARMS, LEGS., SHARP INTENSE PAINS IN MY LOWER ABS, PAINS IN MY KNEES, HEAVY BLEEDING DURING MENSTRUAL (1 PAD EVERY 15 MINS), BLOOD CLOTS, SHOOTINGS PAINS IN MY PELVIC, PRESSURE IN MY VAGINA, PAINS IN HIPS AND BUTTOCKS, NO SEX DRIVE, STRESS, DEPRESSION, PAIN AND ANXIETY, HEADACHES. IN AND OUT OF DRS AND ERS. IN (B)(6) 2012, I HAD AN HSG DONE AND IT CAME BACK AS NORMAL. I WOKE UP ONE MORNING AND COULDN'T WALK, MY MOM TOOK ME TO THE ER AND THEY FOUND DEGENERATIVE DISC DISEASE, DEGENERATIVE JOINT DISEASE, ARTHRITIS, DISC BULGE, 2 PINCHED NERVES, BILATERAL FORMATION IN MY LOWER BACK. ALSO DID ULTRA SOUNDS AND FOUND CYSTS ON MY OVARIES, CYST ON MY KIDNEY, BROKEN PELVIC, BLOOD IN URINE, ENDOMETRIOSIS. SOON AFTER ON (B)(6) 2012, I HAD THEM REMOVED. I SUFFER NOW FROM VIT D DEFICIENCY, OSTEOPENIA, JOINT DISEASE IN ALL JOINTS, BONE SPURS, DEGENERATIVE DISC DISEASE, ARTHRITIS, NERVE DAMAGE, HIGH SUGAR, MUSCLE SPASMS, ANXIETY AND VERY HIGH FEAR OF MEDICINE. I AM FORCED TO TAKE FORTEO JUST SO MAYBE MY BONES WILL GROW. I TAKE VIT D SUPPLEMENTS AND GLUCOSAMINE RELIEF FOR PAIN. MY LIFE ISN'T THE SAME ANYMORE, I'M IN CONSTANT PAIN STILL, I HAVEN'T HAD ANYMORE KIDNEY STONES, CYST ON MY OVARIES, ENDOMETRIOSIS, OR PELVIC AND AB PAIN. ALL MY TESTS AND EXAMS I HAVE BLOODWORK, MRI AND XRAYS, ULTRA SOUNDS. I AM STILL GOING FOR TESTING, THIS INST THE END OF MY STORY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035276	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 2/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AS SOON AS I WOKE UP FROM HAVE ESSURE DONE I HAD PAIN IN LOWER LEFT PELVIC AND OVER A MONTH LATER STILL HAVE IT. BLOATING STOMACH PAIN. PELVIC PAIN. BACK AND HIP PAIN. BURNING MOUTH. RASH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035277	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE JOINT PAIN AND INFLAMMATION. MISSED AND LATE PERIODS. HORRIBLE CRAMPS. HEAVY BLEEDING DURING MENSTRUATION. SEVERE PAINS ON BOTH SIDES OF MY LOWER PELVIC REGION. MUSCLE SPASMS AND QUIVERS ON BOTH SIDES OF MY PELVIC REGION WHERE MY OVARIES ARE LOCATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035278	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PERIODS WERE HEAVIER AND MORE PAINFUL THAN NORMAL. STABBING PAIN THAT LASTS ALL MONTH. WAS TOLD MY HSG WAS BLOCKED ON ONE SIDE BUT NOT THE OTHER AND TO CONTINUE TAKING BC. "GUN" WROTE FOR 3 MONTH'S WORTH THEN REFUSED TO REFILL STATING HE HAD NEVER HEARD OF ANYONE NOT BEING BLOCKED AFTER THAT AMOUNT OF TIME. I ENDED UP GETTING PREGNANT A FEW MONTHS LATER. MY PREGNANCY WAS RIDDLED WITH COMPLICATIONS AND ULTIMATELY MY DAUGHTER WAS DELIVERED VIA EMERGENCY C-SECTION DUE TO ALMOST LOOSING HER. I REMAIN IN PAIN WITH CHRONIC INFLAMMATION ISSUES GROWING WITH EACH YEAR THAT PASSES. I NOW HAVE TO TAKE BC PILLS (NEW DR) TO HELP WITH PAIN. IF THEY DON'T HELP WITHIN THE NEXT 4 MONTHS, I'VE BEEN TOLD I'LL NEED A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035279	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 3/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD MIGRAINE HEADACHES CONTINUOUSLY EVER SINCE THE PROCEDURE WAS DONE ALONG WITH LOWER BACK PAIN AND LEG PAIN WITH NUMBNESS. I HAVE ABDOMINAL PAIN AT LEAST TWICE A WEEK WITH CRAZY IRREGULAR PERIODS. NOW I HAVE THIS SHARP PINCHING PAIN IN MY VAGINA, KINDA FEELS LIKE SOMETHING IS POKING ME INTERNALLY. I NEVER HAD ANY PROBLEMS BEFORE THIS PROCEDURE. I HATE ESSURE AND WHAT ITS DONE TO MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035308	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THIS DEVICE IMPLANTED. I HAVE EXPERIENCED WEIGHT GAIN, PELVIC PAIN, FATIGUE, MUSCLE SPASMS, SEVERE BLOATING, BACK AND HIP PAIN, LEG NUMBNESS AND LOSS OF LIBIDO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035309	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 1/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SCLERODERMA, MIXED CONNECTIVE TISSUE DISEASE, ABDOMINAL PAIN, IRREGULAR HEAVY BLEEDING, OTHER AUTO IMMUNE DISEASES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035310	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 11/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN (B)(6) 2009. IN (B)(6) 2009 I STARTED LOSING FEELING IN MY HANDS AND FEET. IN (B)(6) 2010 I HAD A LYMPH NODE IN MY NECK THAT REQUIRED SURGERY TO REMOVE AND BE TESTED FOR CANCER. IN THE PAST FOUR YEARS I HAVE SEEN COUNTLESS DOCTORS. HAVE BEEN TESTED FOR EVERY AUTOIMMUNE DISEASE OUT THERE. I HAVE UNDERGONE CANCER TESTING THAT ALWAYS COMES BACK FINE EVERY SIX MONTHS, I HAVE SWELLING PAIN AND TENDERNESS IN THE BREASTS, SHOOTING PAIN THROUGHOUT MY BODY. WENT WITHOUT A PERIOD FOR 7 MONTHS OR BETTER AND HAVE LITTLE TO NONE NOW. HAVE NO APPETITE AND FEEL NAUSEOUS AFTER ONLY EATING A LITTLE BIT. HAVE MIGRAINES THAT LAST FOR DAYS WITH NO EXPLANATION OF WHY. I HAVE SPENT THE LAST FOUR YEARS TRYING TO FIGURE OUT WHAT IS WRONG WITH ME AND THE COUNTLESS DOCTORS AND SPECIALIST I HAVE SEEN CAN'T FIGURE IT OUT. THE ONLY THING THAT APPEARS TO BE THE PROBLEM IS THAT IT ALL STARTED AFTER HAVING THE ESSURE PUT IN. MY LIFE HAS BEEN NOTHING BUT MISERABLE AND PAINFUL SINCE HAVING IT PUT IN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035311	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 1/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE BECAUSE IT WAS CHEAPER AND LESS TIME DOWN AFTER GETTING IT THAN ANYTHING ELSE "PERMANENT". I HAD DIFFICULT PREGNANCIES SO I CHOSE THIS DEVICE BECAUSE IT ALLOWED ME TO GET BACK TO MY LIFE AS EASY AND AS FAST AS POSSIBLE. UNFORTUNATELY THOUGH IT WAS NOT THAT EASY I HAD LOTS OF TESTS DONE AND NO ONE STILL BELIEVED ME THAT I WAS VERY MISERABLE. I FINALLY FOUND A DR WHO LISTEN AND WHEN HE GOT IN THERE FOR EXPLORATORY SURGERY FOUND ENDOMETRIOSIS AND MY RIGHT SIDE FALLOPIAN TUBE WAS REALLY INFLAMED. SO IN THE PROCESSES I WAS ALWAYS CONSTIPATED AND STILL AM AFTER GETTING THEM OUT. I HAVE TERRIBLE STOMACH ISSUES I CAN'T AFFORD TO GO BACK TO SEE WHAT ELSE IT CAUSE FOR ME TO HAVE TO DEAL WITH. SO I'M STILL DEALING WITH ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035312	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 3/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD ESSURE SINCE 2009 I STARTING HAVING ISSUES WITH IRREGULAR PERIODS, PAIN IN MY OVARIES, BACK PAIN, PAIN DURING SEX, SPOTTING WHILE NOT ON MY PERIOD, I CAN NOT MOVE TOO FAST WHILE SITTING DOWN BECAUSE IF I DO IT HURTS IN MY MID SECTION (LOWER BELLY), AND HAIR LOSS. MY SEX LIFE IS BAD, THERE ARE TIMES I CAN'T EVEN HAVE INTERCOURSE BECAUSE IT HURTS TOO MUCH, NOT TO MENTION THAT I NEVER KNOW WHEN MY PARTNER IS GOING TO END UP WITH BLOOD ALL OVER HIM. THIS MAKES ME FEEL VERY UNCOMFORTABLE AND EMBARRASSED. (B)(4)

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035313	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DAY ESSURE WAS PLACED ((B)(6) 2011), I EXPERIENCED HEAVY CRAMPING DURING THE PROCEDURE. IMMEDIATELY FOLLOWING THE PROCEDURE, I WAS NAUSEATED AND FATIGUED FOR THE ENTIRE DAY. I HAD TO RECEIVE 2 FOLLOW-UP HSG TESTS AND DURING BOTH I SUFFERED FROM SEVERE CRAMPING. IN (B)(6) 2012, I BEGAN TO EXPERIENCE ANXIETY ALONG WITH PELVIC PAIN. SINCE THIS ONSET OF SYMPTOMS, I HAVE EXPERIENCED THE FOLLOWING: EXTREME MOOD SWINGS, PELVIC PAIN, SEVERE CRAMPING DURING MENSTRUATION, NUMBNESS AND TINGLING IN THE EXTREMITIES, INCREASE IN ACNE (HAD TO BEGIN USING (B)(6)), ONSET OF ENVIRONMENTAL ALLERGIES, DRY/BRITTLE HAIR, INCREASE IN HAIR GROWTH, SEVERE YEAST INFECTION, SHARP PAINS DURING INTERCOURSE, JOINT PAINS, FATIGUE, MEMORY LAPSES AND BRAIN FOG, CHANGES IN MENSTRUAL CYCLE, FOOD SENSITIVITIES, RECURRING ULCERS ON THE TONGUE, ACID REFLUX, AND CHRONIC RHINITIS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035314	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

INCREASED NAUSEA AND ABDOMINAL PAIN FOR AT LEAST A WEEK EVERY MONTH SINCE ABOUT 6 MONTHS AFTER INSERTION. HEAVY AND PAINFUL MENSTRUATION THAT IS UNPREDICTABLE/INCONSISTENT ON HOW LONG IN BETWEEN PERIODS WHEN WAS COMPLETELY REGULAR 28 DAYS FOR OVER 10 YEARS. THIS HAS AFFECTED MY WORK AND HOME LIFE BECAUSE OF THE LACK OF ENERGY AND PAIN THAT IS ASSOCIATED WITH MOVEMENT DURING MENSES. SIGNIFICANT NAUSEA FOR 1 WEEK A MONTH THE WEEK BEFORE MENSES AND ABDOMINAL PAIN AND PAINFUL INTERCOURSE FOR AT LEAST 2 WEEKS EVERY MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035315	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT PAIN AND BLEEDING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035316	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT PAIN AND BLEEDING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035317	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 6/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXCESSIVE BLEEDING, BLOOD CLOTS, BLOATING, UNBEARABLE INTERCOURSE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035318	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 11/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HSG AT THREE MONTHS TO CONFIRM BLOCKAGE OF TUBE I BEGAN TO HAVE DAILY CRAMPING AND RANDOM LIGHT SPOTTING. THE SPOTTING AND CRAMPING BECAME WORSE AND WORSE. I WENT TO THE DOCTOR AND GOT AN ULTRASOUND AND X RAY. THERE ARE TWO COILS IN THE RIGHT TUBE ONLY. SCHEDULED FOR HYSTERECTOMY (B)(6). (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035319	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT PAIN, PRESSURE, BLADDER PROBLEMS, CONSTANT BLEEDING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035320	BAYER	3/28/2014	3/28/2014

Event Information:

Event Date (B3): 11/14/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE IN (B)(6) 2007 AFTER MY SON WAS BORN. ABOUT TWO MONTHS AFTER, I STARTED HAVING EXTREME CRAMPING AND SHARP STABBING PAINS ON MY RIGHT SIDE. SO BAD THAT I WOULD ALMOST FALL TO THE FLOOR IN PAIN. HEAVY BLEEDING AND CLOTTING DURING MY PERIOD ALONG WITH THE CRAMPING. SOMETIMES, THE PAIN IS ALL ACROSS MY STOMACH AND OTHER TIMES JUST ON THE RIGHT SIDE. THEN ABOUT 3 YRS AGO (2011), I STARTED HAVING A PROBLEM WITH CERTAIN FOODS, MAINLY PORK OR PRODUCTS WITH PORK IN THEM. NEVER HAD A PROBLEM WITH THAT BEFORE. AND AT THE SAME TIME, I STARTED HAVING DIZZY SPELLS AGAIN ONLY AROUND THE TIME OF MY PERIOD, BUT SOME SO BAD I WOULD FALL ON THE FLOOR WHEN I TRIED TO STAND UP OR IF I ROLLED OVER IN BED IT WAS SO BAD I WOULD ALMOST BLACK OUT. WITH IN THE LAST YEAR, MY GLANDS IN THE BACK OF MY NECK HAVE BEEN SWOLLEN AND I ITCH ALL THE TIME. I ALSO HAVE BEEN GETTING LEG CRAMPS IN BOTH THE BACK OF MY LEG AND THE FRONT. SOMETIMES, EVEN IN MY FOOT. I USE TO GET MIGRAINES ALL THE TIME BEFORE I HAD MY SECOND CHILD AND THEN THEY WENT AWAY AND NOW THEY ARE BACK AND SOME ARE ALMOST WORSE THEN ANY I HAVE HAD IN THE PAST. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035463	BAYER	3/28/2014	4/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 508837

Single Use:
Implant Date (E6): 4/4/2006
Explant Date (E7): 7/15/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2006, I DELIVERED MY FIFTH CHILD BY C-SECTION AND I WAS HIGH RISK PREGNANCY DUE TO GESTATIONAL DIABETES. AFTER THE BABY WAS BORN I WANTED TO TIE MY TUBES BUT MY GYN DOCTOR ADVISED ME THAT WOULD BE AN UNSAFE PROCEDURE BECAUSE I WOULD NEED FURTHER SURGERY. SHE THEN PROCEEDED TO TELL ME ABOUT A NEW PROCEDURE THAT HAS NO SIDE EFFECTS IN A FIVE YEAR STUDY. SHE CONVINCED ME IT WOULD BE SAFE, NO DOWN TIME, NO INCISIONS, AND NO HORMONES. I WAS ON BOARD, AFTER ALL SHE HAD DELIVERED TWO OF MY CHILDREN BY HIGH RISK C-SECTION. I TRUSTED HER COMPLETELY. AT THIS POINT I WAS A HEALTHY (B)(6) WHO WALKED 4 HOURS A NIGHT AND STOOD AT A GATE DIRECTING TRAFFIC FOR 2 HOURS EVERY MORNING. I WAS VERY HEALTHY WITH NO PRIOR BACK INJURIES OR HEALTH PROBLEMS. IN (B)(6) 2006, I WAS IMPLANTED WITH THE ESSURE COILS UNDER ANESTHESIA. WHEN I AWOKE I WAS A DIFFERENT WOMAN. I NOTICED SYMPTOMS INSTANTLY. WHEN I RETURNED BACK TO WORK, MY LEGS AND LOWER BACK WOULD BURN AS I STOOD AT THE GATE. FROM THERE I BECAME VERY ILL. FLU LIKE SYMPTOMS. BY (B)(6) 2006, I HAD TO RESIGN MY POSITION OF (B)(6) DUE TO BEING SICK AND USING UP ALL MY TIME OFF (PTO). THIS PUT ME INTO A DEPRESSION. SO I DECIDED TO FIND A POSITION THAT WOULDN'T BE SO DEMANDING. I THEN BEGAN NOTICING AND TELLING MY CO-WORKERS THAT MY WRIST AND ANKLES ARE ACHING/BURNING. THIS WAS WHEN MY HEALTH STARTED GOING ON A DOWNWARD SPIRAL. I STARTED HAVING PERIODS THAT WERE VERY HEAVY. I WOULD TAKE SHOWERS AND LOOK IN THE BOTTOM OF TUB AND SEE BLOOD CLOTS THE SIZE OF QUARTERS. I HAD X-RAYS ON MY WRIST, MRI ON MY BACK, BACK INJECTIONS FOR LOWER BACK BURN, PHYSICAL THERAPY FOR MY WRIST AND BACK. I BECAME VERY HEAVY, I GAINED (B)(6) AND MY STOMACH WAS EXTENDED AS IF I WAS 7/8 MONTHS PREGNANT. I BECAME DIABETIC. DIAGNOSED WITH DIABETIC NEUROPATHY. AND SENT ON MY WAY WITH METFORMIN, CYMBALTA AND VICODIN. I LOST MY

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HAIR. LOST THIS NEXT POSITION AFTER 2 YEARS BECAUSE I COULDN'T TOLERATE THE PAIN OR BLOOD. I WORKED THIRD SHIFT BUT MY BODY BECAME PHYSICALLY WEAK. I FELT LIKE AN 80 YEAR OLD WOMEN AND I COULD BARELY CLIMB STAIRS. I HAD A BIOPSY ON CLOTS, PAP SMEARS, XRAYS, MRIS, CT SCANS, BACK INJECTIONS, CHECK FOR MS AND LYME. BUT ALL BLOOD WORK NORMAL. I STAYED ALONE IN SILENCE AND PAIN, DEPRESSION FOR YEARS. IN 2013 I FOUND A SUPPORT GROUP THAT WAS SPREADING AWARENESS OF THE SIDE EFFECTS OF THE ESSURE COILS. HELLO. I HAD BEEN SAVED. I IMMEDIATELY INFORMED MY PERSONAL CARE DOCTOR AND MY GYN DOCTOR OF WHAT ALL MY SYMPTOMS WERE. MY PCP DOCTOR RAN A KIND OF BLOODTEST. INCLUDING NICKEL, COPPER AND LEAD. ALL NORMAL. DIABETES WENT AWAY TOO AT THIS POINT I WEIGHED (B)(6). I WAS VERY ILL, IN PAIN. MY DOCTOR THEN DIAGNOSED ME WITH FIBROMYALGIA. AND THEN I WENT TO SEE MY GYN WHO ORDERED ULTRASOUND OF MY ESSURE COILS THAT LOOKED TO BE THAT ONE OF THE COILS DIDN'T EXTEND ON IMPLANT. HE ORDERED A HYSTERECTOMY DATE FOR (B)(6) 2013. I WAS HURTING SO BAD AT THIS POINT THAT I DIDN'T THINK I COULD MAKE IT MUCH LONGER. MY THUMBS STARTED BURNING AND I MADE MY DOCTOR AWARE THAT WAS MY LAST SYMPTOM BEFORE MY ABDOMINAL SURGERY TO REMOVE ESSURE COILS. WHEN THE DOCTOR REMOVED COILS HE STATED THAT HE COULD TELL THAT I WOULD GET INSTANT RELIEF. I HAD ENDOMETRIOSIS, ADENOMYOSIS, FIBROIDS, CYST ON FALLOPIAN TUBES AND LOTS OF SCAR TISSUE. TODAY I FELL 80 PERCENT BETTER NO BURNING IN HANDS, WRISTS, FINGERS. NO BLOOD AND NO PAIN OF THE ESSURE COILS. I GAVE UP ALL MEDICATION AND STARTED SELF MEDICATING WITH MARIJUANA FOR EXTREME PAIN IN JOINTS MUSCLES AND HEADACHES. TODAY AFTER REMOVAL, I DO NOT HAVE THE HEADACHES, JOINT PAIN IN WRIST/HANDS/FINGERS. ALL BLOOD GONE. I AM STARTING TO FEEL LIKE MY OLD SELF. ALTHOUGH I STILL HAVE LOWER BACK ACHES AND LEG MUSCLE PAIN. ALL OTHER SYMPTOMS ARE GONE COMPLETELY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035321	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 4/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HORRIBLE PAIN IN ABDOMEN, CRAMPS, GI ISSUES, MIGRAINES, ANXIETY, DEPRESSION, JOINT PAIN, UNBEARABLE SEX, PASSING OUT FOR NO REASON, BLURRED VISON, FLOATERS IN EYES. I HAD THE ESSURE REMOVED THEN 6 MONTHS LATER A HYSTERECTOMY. I HAVEN'T BEEN ABLE TO DRIVE OR EVEN LEAVE MY HOUSE IN OVER A YEAR AFTER HYSTERECTOMY DUE TO BLURRED VISION AND SEEING SPOTS, PASSING OUT AND EXTREME ANXIETY THAT NO MEDS TOUCH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035322	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 4/14/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE WAS IMPLANTED (B)(6), 2008. ON OR AROUND THE (B)(6), BEGAN THE MIGRAINE TYPE HEADACHES AND SEVERE HEMORRHAGING. THEREAFTER CAME THE SEVERE BLOATING, SHARP RIGHT AND LEFT-SIDED STABBING PAINS, HAIR LOSS, ACNE ISSUES, MULTIPLE UTIS AND BLADDER INFECTIONS, LOSS OF SEX DRIVE, PAIN DURING FOREPLAY AND ONSET OF SEX, BLEEDING AFTER INTERCOURSE, GLUTEN INTOLERANCE, BOWEL ISSUES, MASSIVE WEIGHT GAIN, ETC. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035323	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 9/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CHRONIC HEADACHES, WEIGHT GAIN, DEPRESSION AND MOOD SWINGS WHICH THE DOCTOR THEN PUT ME ON ZOLOFT FOR (FIRST TIME I HAVE EVER HAD TO TAKE AN ANTI-DEPRESSANT), ABSENTMINDED, LOWER BACK PAIN, CONTINUOUS STOMACH BLOAT. THEN ON (B)(6) 2014 I WAS HAVING SEVERE LOWER ABDOMEN PAINS AND NOT ABLE TO HOLD DOWN ANY FOOD. ON (B)(6) 2014 I WENT TO THE EMERGENCY ROOM BECAUSE THE ABDOMEN PAIN WAS SO INTENSE AND I WAS NOT FEELING LIKE MYSELF ON ANY LEVEL. THE EMERGENCY ROOM DOCTOR INFORMED ME THAT THE CT SCAN SHOWED THE COILS HAD MOVED AND ONE HAD PUNCTURED INTO MY UTERUS. UPDATE ON (B)(6) 2014: DOCTOR HAS AGREED THAT A LAPAROSCOPIC VAGINAL HYSTERECTOMY IS WHAT IS BEST FOR ME TO REMOVE THE ESSURE COILS FROM MY BODY. THE FOLLOWING ARE ALL OF THE ISSUES I HAVE HAD SINCE THE COILS WERE IMPLANTED IN ME: LEAKING LEFT BREAST (LIKE COLOSTRUM), CONSTANT SEVERE HEADACHES, NECK AND BACK OF HEAD PAIN, CONSTANT/SEVERE BLOATING, DEPRESSION/MOOD SWINGS, INCREDIBLE CRAMPS/VERY HEAVY BLEEDING AND CLOTTING, PERIODS ON AND OFF FOR 10-15 DAYS, PNEUMONIA 2 TIMES EVEN AFTER HAVE THE PNEUMONIA SHOT, LOWER BACK PAIN, SEVERE PELVIC AND ABDOMINAL PAIN, WEIGHT GAIN THAT I CAN'T GET RID OF NO MATTER HOW MUCH EXERCISING AND DIETING I DO, EXCESSIVE FATIGUE, DIMINISHED BRAIN FUNCTION (BRAIN FOG/CONFUSION/CLOUDY/ FORGETFULNESS/SHORT TERM MEMORY LOSS), VITAMIN D DEFICIENCY, FAINTING, CONSTANT DRY MOUTH, NIGHT SWEATS, ALL OVER ITCHINESS, HEARTBURN, HIP PAIN, EXTREME IRRITABILITY. ALL OF THESE ISSUES HAVE PUT MY LIFE INTO A COMPLETE DOWNWARD TAILSPIN, I WAS ALWAYS A HAPPY AND VERY SOCIAL PERSON SO FULL OF LIFE AND ALWAYS COORDINATING EVENTS AND FUN THINGS WITH FAMILY AND FRIENDS AND WITHIN THE LAST 6-9

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MONTHS WHEN ALL THESE SYMPTOMS HAVE REALLY PICKED UP AND GOTTEN WORSE I HAVE HARDLY SEEN ANYONE OR DONE MUCH, IF ANY, SOCIALIZING BECAUSE I AM ALWAYS IN PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035324	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 3/31/2001 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS TOLD I HAD PELVIC INFLAMMATORY DISEASE, MAJOR DEPRESSION AND CLUSTER HEADACHES. I ALSO HAVE SLEEP APNEA, WEIGHT ISSUES, HAIR GROWTH, RINGING IN EARS, VOMITING, YEAST INFECTIONS, DENTAL ISSUES, CHRONIC PELVIC PAIN, FATIGUE, BRAIN FOG, FREQUENT URINATION, PAINFUL OVULATION, INSOMNIA, CHEST PAINS, NECK PAIN, BACK PAIN, PAINFUL INTERCOURSE, GASTROINTESTINAL ISSUES, HAIR LOSS, NAUSEA, PAINFUL PERIODS, HIP PAIN, SEVERE BLOATING, JOINT PAIN, BREAST PAIN AND ALL OVER BODY ACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035325	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 3/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NUMBNESS IN LEGS AND FEET. ACUTE PELVIC PAIN. NO PERIOD ONCE A MONTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035326	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 3/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS AN UPDATE TO A PREVIOUS REPORT # (B)(4). ON (B)(6) 2014, I HAD SURGERY. I HAD TO HAVE MY UTERUS, CERVIX, BOTH FALLOPIAN TUBES, AND LEFT OVARY REMOVED DUE TO DEVICE FRAGMENTS OF ESSURE LEFT BEHIND FROM A PREVIOUS IMPROPER ESSURE REMOVAL (FROM MY UTERUS) IN 2011. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035327	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 5/3/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING A PERIOD MORE THEN ONCE A MONTH UP TO 2 TO 3 TIMES A MONTH WITH VERY HEAVY BLEEDING WHERE I AM SOAKING THROUGH A PAD IN LESS THEN A HOUR AND VERY SEVERE BACK PAIN EVERY DAY AND VERY BAD CRAMPING IN MY ABDOMINAL AREA TO WHERE IT HURTS TO DO ANYTHING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035328	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 1/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING SERIOUS JOINT PAIN AND HEADACHES. HAVE HAD TO HAVE NUMEROUS MAMMOGRAMS DUE TO BREAST PAIN. HAVE BECOME VERY DEPRESSED AND PUT ON MEDICATION FOR THAT. I HAVE MY PERIOD FOR 1 DAY AND PASS CLOTS THE SIZE OF GOLF BALLS. MY CRAMPS ARE DEBILITATING AND SOMETIMES ITS HARD FOR ME TO MOVE. HAVE SHARP PAINS IN MY RIGHT SIDE AND NO ENERGY AT ALL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035329	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 7/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BEGAN TO FEEL VERY WEAK AND TIRED WITH NO RELIEF EVEN AFTER REST IT SLEEP. EVERY SINGLE DAY, I WOULD HAVE A HEADACHE THAT WAS NOT RELIEVED BY ANY TYPE OF OTC MEDICINE. WEIGHT GAIN BECAME A CONSTANT ISSUE WITH GAINS OF 10 POUNDS A WEEK AT TIMES. ON TOP OF THESE ISSUES, I ALSO STARTED TO BATTLE WITH SEVERE DEPRESSION, ANXIETY, AND PANIC ATTACKS THAT COULD NOT BE MANAGED BY PRESCRIPTION MEDS. AFTER BATTLING ALL OF THE SYMPTOMS WHILE TRYING TO CONTINUE TO WORK FULL TIME AND CARE FOR MY FAMILY, I HAD TO QUIT MY JOB. THE FATIGUE HAS GOTTEN SO HORRIBLE THAT I HAVE TO REST AFTER JUST ONE LOAD OF LAUNDRY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035330	BAYER	3/31/2014	3/31/2014

Event Information:

Event Date (B3): 6/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM WRITING TO UPDATE REPORT NUMBER (B)(4). I HAD OBSERVATORY SURGERY (B)(6) 2013 . THE DR HAD REMOVED ESSURE THAT WAS PERFORATED THROUGH MY TUBES. I WAS FEELING BETTER BUT BEGAN FEELING ILL AGAIN AROUND THE END OF (B)(6) 2013. I HAVE HAD AN X RAY SHOWING FRAGMENTS IN MY ABDOMEN. I AM FEELING FATIGUE, ABDOMINAL PAIN, HAIR LOSS, MUSCLE AND JOINT PAIN AMONGST OTHER THINGS. I AM GOING TO BE SEEING ANOTHER GYN. I WILL MOST LIKELY NEED ANOTHER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035347	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 9/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY AFTER HAVING THIS ESSURE IMPLANT IN ME I STARTED HAVING MIGRAINES, STOMACH CRAMPS, MEMORY LOSS, NO ENERGY AT ALL, SOMETIMES NO PERIODS, OTHER TIMES HEAVY BLEEDING, THE LIST CAN GO ON FOREVER. I AM NOT THE SAME PERSON I USED TO BE AND I DONT LIKE IT AT ALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035349	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AT FIRST I EXPERIENCED HIVES AND ACNE ON MY FACE, NECK AND HEAD DURING MY CYCLE EACH MONTH EVEN THOUGH THERE WAS LITTLE NO KNOW BLEEDING. PELVIC AND BACK PAIN STARTED OFF MILD BUT OVER THE MONTHS BECAME INCREASINGLY SEVERE, ONLY ON MY LEFT SIDE, WORSE DURING MY CYCLE AND OVULATION. THE PAIN HAS GOTTEN SO SEVERE THAT IT INHIBITS MY QUALITY OF LIFE PREVENTING ME FROM DOING MY DAILY ROUTINE, EXERCISING, AND EVEN WORKING AT TIMES. I BEGAN TO BLEED HEAVILY WITH CLOTS, AND I DEVELOPED MODERATE STOMACH BLOATING. I ALSO SUFFER FROM NIGHT SWEATS, LEG PAIN AND WEAKNESS, ESPECIALLY WHEN RUNNING. PRIOR TO ESSURE I RAN MY FIRST 5K; AS MY SYMPTOMS GOT WORSE, I AM NO LONGER ABLE TO COMPLETE EVEN ONE MILE WITHOUT PELVIC AND LEG PAIN STOPPING ME. I'VE ALSO SUFFERED FROM OCCASIONAL BOUTS OF DIZZINESS, ESPECIALLY IN THE MORNING. I AM SCHEDULED FOR A TOTAL HYSTERECTOMY TO REMOVE MY TUBES, UTERUS, AND CERVIX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035350	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 10/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD NOTHING BUT ISSUES WITH THIS PRODUCT. CONSTANT CRAMPING (ALMOST LIKE ACTIVE LABOR CONTRACTIONS), SNAPPING LIKE FEELING AND SOUNDS IN MY RIGHT SIDE OF MY UTERUS, ALLERGIC TO MY WEDDING RING AND ENGAGEMENT BAND (WHICH HAS NEVER HAPPENED UNTIL NOW), AND MY MENSTRUAL CYCLE IS ALL OUT OF WACK (MEANING ONE MONTH I WILL HAVE A REGULAR PERIOD FOR 7 DAYS OUT OF THE MONTH, THE MONTH AFTER I WILL HAVE A PERIOD FOR 14 DAYS OUT OF THE MONTH AND THE LAST 45 DAYS I HAVE NOT BLED AND FEAR A POSSIBLE PREGNANCY)!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035351	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 3/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS MY ADVERSE EVENT REPORT THAT I SUBMITTED WITH THE FDA IN (B)(6) 2013: SINCE HAVING ESSURE PLACED, I HAVE HAD MANY HEALTH PROBLEMS. THESE PROBLEMS ARE: BACK PAIN (SEVERE, LOWER BACK), HIP PAIN (BOTH HIPS), HEAVY PERIODS (SOAKING AN OVER NIGHT PAD IN 1 HOUR), BLOOD CLOTS DURING PERIOD, PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE, CONSTIPATION (BOWEL MOVEMENTS SOMETIMES 3 DAYS APART), BRAIN SHOCKS (DIAGNOSED AS TRIGEMINAL NEURALGIA), CHEST PAINS (BOTH SIDES, RADIATES INTO SHOULDER), SPOTTING BETWEEN PERIODS, DISCHARGE (BETWEEN PERIODS), YELLOWISH GREEN COLOR, NO INFECTIONS FOUND, DIZZINESS, SPOTS/FLOATERS IN VISION, WEIGHT LOSS (UNEXPLAINED), HAIR LOSS (FALLING OUT 10-15 STRANDS AT A TIME), LOSS OF ENERGY (EVEN AFTER FULL NIGHTS SLEEP), HEART PALPITATIONS, NICKEL TASTE IN MOUTH, NUMBNESS/SWELLING IN HANDS (BOTH), OVARIAN CYSTS, PRESSURE IN BUTTOCKS WHEN SITTING, CAVITIES IN TEETH (ORAL HYGIENE DID NOT CHANGE AFTER IMPLANTATION), VIBRATING SENSATION IN LOWER ABDOMEN. I HAD A HYSTERECTOMY ON (B)(6) 2013. MY CERVIX, UTERUS, TUBES AND COILS WERE REMOVED. SINCE HAVING THE SURGERY, I HAVE GOTTEN MY ENERGY BACK, MY HAIR DOES NOT FALL OUT QUITE AS MUCH, MY VISION NO LONGER HAS FLOATERS, I AM NO LONGER DIZZY AND I HAVE STOPPED LOOSING WEIGHT WITHOUT TRYING TO. ALSO, MY HANDS DON'T SWELL AS OFTEN ANYMORE AND I HAVEN'T HAD ANY RASHES/HIVES SINCE SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035352	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 7/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WITHIN SEVERAL MONTHS OF HAVING ESSURE IMPLANTED, I DEVELOPED ITCHY RASH ON MY "FEEL" WITH OCCASIONAL BULLA, JOINT PAIN, ABDOMINAL AND PELVIC PAIN, AND FATIGUE. I HAD A KNOWN ALLERGY TO NICKEL BEFORE INSERTION, BUT WAS TOLD NOT TO WORRY ABOUT IT. MY SYMPTOMS HAVE NEARLY ALL RESOLVED (SOME FATIGUE REMAINS) SINCE I HAD THE ESSURE REMOVED (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035353	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 4/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN OR AROUND (B)(6) 2005, I BEGAN TO EXPERIENCE SEVERE DEPRESSION AND MOOD SWINGS. ABOUT THIS TIME, I ALSO BEGAN TO EXPERIENCE DIZZINESS AND PULSATING SOUNDS IN MY LEFT EAR, WHICH I AM STILL EXPERIENCING TODAY. AROUND 2007, I BEGAN TO HAVE ISSUES WITH MY VISION - DRY EYES, SEVERE TEARING, REDNESS, AS WELL AS SEVERE BACK PAIN, PELVIC PAIN, LIMITED MOBILITY, AND IRREGULAR PERIODS. IN (B)(6) 2010, I HAD TWO EPISODES OF HEAVY BLEEDING, PAIN, AND PASSAGE OF CLOTS, THEN MY PERIODS CONTINUED TO BE IRREGULAR. IN (B)(6) 2012, I BEGAN TO EXPERIENCE LEG PAIN AND SOME HIP PAIN, CONTINUED BACK PAIN. IN (B)(6) 2012, I HAD MY FIRST INDICATION OF GALLSTONES AND FOR ALMOST AN ENTIRE YEAR, I EXPERIENCED BILIARY COLIC, WHICH INCLUDED SEVERE ABDOMINAL PAIN, NAUSEA, AND VOMITING. IN 2013, MY HIP PAIN BECAME SO BAD, I HAVE NOT BEEN ABLE TO SIT OR STAND FOR LONG PERIODS OF TIME. I STILL EXPERIENCE ABDOMINAL, LEG, HIP, PELVIC, AND BACK PAIN, TINGLING, VIBRATIONS IN MY FEET, SEVERE FATIGUE, AND INFLAMMATION. ALL OF THESE HAVE AFFECTED MY QUALITY OF LIFE AS WELL AS MY SEX LIFE, MY PERSONAL LIFE (EXERCISING, SOCIALIZING), AND ATTENDANCE AT WORK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035354	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THEM PLACED IN (B)(6) 2007. IN OF 2011 MY THYROID WAS FOUND TO HAVE MULTIPLE GOITERS, IN 2013 BECAUSE OF INCREASED SIZE, HAD IT COMPLETELY REMOVED, NOW ON THYROID MEDICATION FOR REST OF MY LIFE. IN (B)(6) 2012 STARTED WITH SEVERE PAIN ON MY LEFT SIDE (PELVIC, HIP AND BUTT, INCREASE BLOATING). IT INCREASES WHEN I START MY CYCLE. I HAVE BEEN LIVING ON PAIN PILLS AND IBUPROFEN, BEEN TO MULTIPLE DOCTORS INCLUDING MY PRIMARY CARE, CHIROPRACTOR, GYNECOLOGIST, UROLOGIST. THEY ALL REFERRED ME BACK TO GYN SINCE THEY DIDN'T FIND ANYTHING. I NOW HAVE A CYST AND FIBROIDS, PERIODS LASTING 3 WEEKS AT A TIME AND NOW UNPREDICTABLE TIMING AS TO WHEN IT STARTS. THE PAIN IS TO THE POINT I CAN'T SIT, STAND, LOOSE FOCUS TO DO MY JOB. I'M PACING TO WORK THROUGH IT. I FEEL AS THOUGH I HAVE BEEN IN HELL FOR 21 MONTHS FINALLY GYN IS LISTENING ABOUT THE PAIN IN THE PELVIC AREA AND THE CHAIN REACTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035355	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 11/13/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVING REALLY BAD CRAMPING, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035356	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 2/1/2008 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2008, AND THE HSG TEST 3 MONTHS LATER CONFIRMING 100% OCCLUSION. I HAD CONSTANT DULL ABDOMINAL PAIN COMBINED WITH EXCRUCIATING CRAMPING DURING PERIODS SINCE IMPLANTING. I EXPERIENCED EXTREME FATIGUE AND BRAIN FOG STARTING IN 2009, WHICH RENDERED MY UNABLE TO WORK. I DEVELOPED ALLERGIC REACTIONS TO ALL METALS THAT TOUCHED MY SKIN, INCLUDING GOLD, SILVER, STAINLESS STEEL, AND ALL ZIPPERS AND BUTTONS ON CLOTHING. I BEGAN HAVING RASHES AND SWELLING ON MY ARMS AND LEGS. MY HUSBAND GOT BURNING, SWELLING AND RASHES ANYWHERE MY VAGINAL FLUIDS TOUCHED HIM. MY ABDOMEN WOULD BLOAT AND SWELL SEVERELY THROUGHOUT THE COURSE OF A DAY- I WOULD GAIN 3 CLOTHING SIZES WITHIN 6 HOURS. I VISITED THE ER SEVERAL TIMES FOR THE EXTREME PAIN, ONLY TO BE TOLD EVERYTHING WAS FINE. IN 2013, I BECAME PREGNANT IN (B)(6) AND MISCARRIED IN (B)(6). AFTER THAT, THE FATIGUE AND PAIN INTENSIFIED UNTIL I HAD THE ESSURE COILS SURGICALLY REMOVED IN (B)(6) 2013. ALL SYMPTOMS GONE WITHIN 48 HOURS OF SURGERY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035357	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 3/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS INSERTED ON (B)(6) 2014 AND ON THE EVENING OF (B)(6) 2014 I WAS RUSHED TO THE ER FOR EXTREME CHEST PAINS AND TROUBLE TAKING A DEEP BREATH. MY BLOOD PRESSURE WAS LOW, MY MAGNESIUM LEVELS WERE LOW. THEY THOUGHT THE CHEST PAINS WERE CAUSED BY INDIGESTION AND I WAS SENT HOME WITH A SCRIPT FOR PEPCID. I BEGAN SPOTTING THAT SUNDAY AND TO THIS DAY I STILL CONTINUE TO BLEED, I'M HAVING SHARP SHOOTING PAINS IN MY PELVIC AREA, STILL HAVING TROUBLE TAKING A DEEP BREATH, BLOATED, DIZZY SPELLS, NAUSEA AND EXTREMELY WINDED ALL THE TIME. I HAD AN HSG XRAY DONE ON (B)(6) 2014 TO SEE THAT THE COILS WERE IN THE CORRECT SPOT (WHICH THEY WERE). HAVE TO GO BACK ON (B)(6) 2014 TO HAVE A BIOPSY DONE ON MY CERVIX AS I RECENTLY HAD AN ABNORMAL PAP. I HAVE ENDOMETRIOSIS, PCOS AND CERVICAL DYSPLASIA. ESSURE SHOULD HAVE NEVER BEEN SUGGESTED TO ME WITH ALL MY OTHER PROBLEMS. I'M GOING TO DISCUSS WITH MY DR WHAT MY OPTIONS ARE TO HAVE THEM REMOVED, EITHER JUST THE COILS OR A PARTIAL HYSTERECTOMY. I'M (B)(6) YEARS OLD WITH 2 BABIES. THIS WAS NOT WHAT I WAS ASKING FOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035359	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 1/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAVE HAD THIS PLACED I HAVE HAD UNCONTROLLABLE BLEEDING FROM (B)(6)2013- (B)(6) 2013 I HAD BLEED NON STOP ONLY TO BE GIVEN BIRTH CONTROL PILLS TO STOP THE BLEEDING WHICH DID NOT WORK, SINCE (B)(6) TO DATE I STILL HAVE ABNORMAL PERIODS I CAN BLEED FOR 2-3 WEEKS AND STOP FOR A COUPLE DAYS AND THEN IT WILL START OVER AGAIN. ALONG WITH THE BLEEDING I HAVE SHARP PAINS ON MY LEFT SIDE, IT FEELS LIKE LABOR PAINS OR A KNIFE BEING TWISTED INSIDE. I HAVE A HARD TIME HAVING BOWEL MOVEMENTS AS WELL AS URINATING AT TIMES IT FEELS LIKE MY INSIDES ARE ON FIRE. I HAVE NUMBNESS SPELLS THAT COME AND GOES FROM MY ARM TO MY FINGERS OR MY LEGS. I HAVE A SHORT ATTENTION SPAN AND IT IS REALLY HARD FOR ME TO CONCENTRATE OR REMEMBER CERTAIN THINGS. I HAVE MIGRAINES EVERY DAY. MY ANXIETY IS REALLY BAD ESPECIALLY WHEN I AM IN PAIN. WHICH IS AN EVERYDAY OCCURRENCE. I GET REALLY BAD CHEST PAINS/ HEARTBURN ALMOST EVERYDAY. MY KNEES AND HIPS GET REALLY BAD PAINS IN THEM. SOMETIMES IT FEELS LIKE I SOMETHING SITTING ON MY BLADDER AND OTHER TIMES IT FEELS LIKE SOMETHING IS TRYING TO CRAWL OUT IT HURTS SO BAD. I HAVE A ABNORMAL AMOUNT OF HAIR LOSS. I HAVE BEEN TO TWO DIFFERENT DOCTORS AND KEEP GETTING THE SAME RESULT OF JUST BEING PRESCRIBED BIRTH CONTROL PAINS FOR THE BLEEDING AND PAIN. I HAVE FINALLY BEEN APPROVED BY MY DOCTOR TO HAVE A HYSTERECTOMY TO HAVE THIS DEVICE TAKEN OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035360	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 12/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED WITH MY FIRST UTI, THAT NEVER WENT AWAY COMPLETELY. THEN STARTED HAVING ABDOMINAL PAINS BELOW BELLY BUTTON ON LEFT SIDE. WENT TO THE ER SEVERAL TIMES. NO REAL DIAGNOSIS. HAD CT SCAN AND COIL DIDN'T SHOW UP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035361	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 4/11/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT STARTED WITH THE EXPECTED CRAMPS AND BLEEDING BUT MY CYCLE GOT LONGER. I WAS ASSURED IT WOULD STOP BUT I WENT FROM A 3 DAY CYCLE TO A 7 DAY CYCLE. SIX MONTHS LATER, I START DEVELOPING MENOPAUSAL SYMPTOMS, HOT/COLD FLASHES, SWEATS, IRRITABILITY,MIGRAINES, TOOTH DECAY, DEPRESSION, AND NAUSEA. IT IS NOW ALMOST 7 YRS LATER AND THESE SYMPTOMS HAVE INCREASED OVER THE YEARS, I NOW SOMETIMES GET 2 CYCLES IN ONE MONTH, DEBILITATING CRAMPS, STOMACH SWELLS UNTIL I APPEAR 5 MONTHS PREGNANT, TOES AND FEET ARE CONSTANTLY COLD AND/OR NUMB, NAUSEA AND VOMITING, ANGER FITS, ANXIETY, WEIGHT GAIN, CYST THAT RANDOMLY APPEAR ON MY SCALP (CAUSED MY HAIR TO FALL OUT) OR OVARIES, LEFT SIDE NUMBNESS, MIGRAINES, MORE TOOTH DECAY, INEXPLICABLE RASHES/BRUISES/BUMPS, CONFUSION, DIZZY SPELLS, LETHARGIC, DIFFICULTY REGULATING MY BODY TEMPERATURE, VIBRATING SENSATION FROM IMPLANT (ASSUMED) LOCATIONS, RANDOM PAINS THAT MIMIC LABOR PAINS WITH ADDED PRESSURE AS IF THE INFANT'S HEAD IS ABOUT TO CROWN, MEMORY LOSS, BLACK OUTS, UTI'S/YEAST, INSOMNIA, CONFUSION, AND A TENDENCY TO RANDOMLY STOP BREATHING..

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035362	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 3/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS INSERTED ON (B)(6). I STARTED MY PERIOD THAT MORNING BUT THE OB/GYN SAID WE COULD GO AHEAD WITH THE PROCEDURE. THE PROCESS WAS VERY PAINFUL AND MUCH LONGER BECAUSE OF THE ONSET OF MY PERIOD. ON (B)(6) I STARTED TO EXPERIENCE EXTREME CRAMPING IN THE LOWER ABDOMINAL AREA. CALLED OB/GYN OFFICE AND THEY PRESCRIBED NORCO. THIS DID NOT HELP THE PAIN. MANAGED UNTIL (B)(6) AND WENT TO ER TO HAVE CT SCAN DONE. CT SCAN SHOWED COILS WERE CORRECTLY PLACED BUT PAIN CONTINUES TO THIS DAY ((B)(6)).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035363	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 9/14/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WATCH WHAT I EAT AND MY INTAKE AMOUNT AND MY STOMACH STILL LOOKS AS IF I'M ABOUT 4 MONTHS PREGNANT. I HAVE SHARP PAINS IN MY ABDOMEN AREA, I GET LIKE A MORNING SICKNESS, AND MY BOOBS HAVE BEEN HURTING AS IF THEY NEED TO BE PUMPED. I HAVE BEEN HAVING STIFF KNEES AND BAD HEADACHES. NONE HAVE THIS HAS STARTED TILL THE ADVERSE DATE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035364	BAYER	3/31/2014	4/1/2014

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT YEAST INFECTIONS; DYSPAREUNIA; EXCESSIVE VAGINAL DISCHARGE; PAINFUL CRAMPS DURING MENSTRUATION; DARKNESS OF FACE AND NECK; DECREASED LIBIDO; SOMETIMES UP TO 3 PERIODS IN A MONTH; SOMETIMES HEAVY AND SOMETIMES LIGHT PERIODS; SUDDENLY SHOCK-LIKE ABDOMINAL PAINS;WEIGHT GAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035381	CONCEPTUS INC	3/31/2014	4/2/2014

Event Information:

Event Date (B3): 5/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER REPORTS THAT SHE WAS IMPLANTED WITH ESSURE LESS THAN A YEAR AGO AND HAS BEEN HAVING DIZZY SPELLS, ITCHING ALL OVER HER BODY, HEAVY BLEEDING DURING HER MENSTRUAL CYCLE. SOME TIMES SHE HAS TO CHANGE TAMPONS EVERY 30 MINUTES. SHE ALSO EXPERIENCES EXCRUCIATING PAIN ESPECIALLY AROUND HER RIGHT OVARIES AND HAS GAINED MORE THAN 20LBS SINCE SHE HAD THE TUBES IMPLANTED. HER QUALITY OF LIFE HAS BEEN DRASTICALLY AFFECTED AND NOW SHE IS DUE A HYSTERECTOMY IN 2 WEEKS TO REMOVE THE COILS HOPING ALL THE ADVERSE EFFECTS. SHE PLEADS WITH THE FDA TO LOOK INTO THIS ISSUE SERIOUSLY AND GET THE PRODUCT OFF THE MARKET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035366	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 12/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD PROCEDURE ON (B)(6) 2013. SHORTLY THEREAFTER, I BEGAN EXPERIENCING THE FOLLOWING SYMPTOMS: HEAVY BLEEDING WITH CYCLE (WHICH WAS NEVER AN ISSUE PREVIOUSLY) SEVERE NIGHT SWEATS (DRENCHED), HAND NUMBNESS (PARTICULARLY IN MY RIGHT HAND), GAINED 15 POUNDS IN LESS THAN A MONTH, FOGGY BRAIN (ALMOST LIKE MY BODY IS THERE BUT MY BRAIN IS BLANK), CONTINUOUS CLOTTING (NEVER HAD A PROBLEM WITH THAT BEFORE), FOUL VAGINAL ODOR (NOT ATTRIBUTED TO BV OR A YEAST INFECTION), CONTINUOUS DULL PAIN IN MY LOWER ABDOMEN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035367	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN THE WERE DOING THE PROCEDURE I FELT LIKE MY HEAD WAS GOING TO EXPLODE THEY SAID IT WAS PROBABLY A ALLERGIC REACTION. SINCE I HAVE HAD THESE I HAVE ONLY HAD ONE PERIOD. MY MOOD HAS COMPLETELY CHANGED TO WHERE I AM ON KLONOPINS FOR. I CONSTANTLY CRAMP HAVE VERY EXCRUCIATING PAIN IN MY LEFT SIDE I CRAMP CONSTANTLY MY LOWER BACK HURTS WHEN I HAVE SEX I CAN BARELY TAKE IT AND I BLEED AFTERWARDS. I'VE BEEN HAVING YELLOW GREEN DISCHARGE THAT IS VERY THICK THAT U CAN LITERALLY ROLL IN A BALL. I AM CONSTANTLY TIRED FEEL LIKE I HAVE NO ENERGY AT ALL. SOMETIMES I FEEL LIKE I CANT BREATH. I GET EMOTIONALLY DEPRESSED CONSTANTLY. RECENT MEDICAL CONDITIONS FIBROMYALGIA PSORIASIS AND SPONDYLITIS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035368	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 6/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEADACHE, PELVIC PAIN, ABDOMINAL PAIN, BACK PAIN, JOINT PAIN, BLEEDING FOR MONTHS, FOGGED MIND, IRRITABLE, BLOATING IN MY STOMACH. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035370	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 4/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING BAD PAINS IN MY FEMALE PARTS. HEAVY PERIODS, FEELS LIKE IM IN LABOR. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035371	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 11/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABDOMINAL PAIN, HAIR LOSS, BLEEDING, VAGINAL DISCHARGE, MOOD SWINGS, HEADACHES, NERVE ISSUES, BACKACHE, FEELING OF TIREDNESS, LABIA PAIN, PAIN DURING SEXUAL INTERCOURSE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035372	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE FIRST SYMPTOMS TO APPEAR WAS IRREGULAR MENSTRUAL CYCLES AND SEVERE PAIN WITH THEM. ALSO I STARTED EXPERIENCING PMS SEVERELY. MY STOMACH WOULD SWELL AND BE HARD. I WOULD HAVE PELVIC PAIN, WEIGHT GAIN, PAIN SHOOTING DOWN BOTH LEGS. SEVERE CRAMPS BEFORE AND DURING MY PERIOD. HEAVY BLEEDING. ALONG WITH MOOD CHANGES AND DEPRESSION. THEN MY JOINTS WOULD HURT AND STIFFEN UP, ALL OF MY JOINTS. MY PRIMARY DOCTOR DID X-RAYS AND BONE DENSITY TEST. WHICH BOTH TEST WERE NORMAL. THEN HE DID A CRP BLOOD TEST WHICH HAD SHOWN VERY HIGH INFLAMMATION. MY DOCTOR THOUGHT I MAY HAVE LUPUS. SINCE 2011 MY JOINT AND MUSCLE PAIN HAS WORSENED AND IT EFFECTS MY DAILY LIFE. IT HURTS TO GET OUT OF BED. I GET SICK VERY EASILY AND SUFFER EXTREME EXHAUSTION. MY BODY HAD HAD WEIRD RASHES SUCH AS ON MY BACK, MY CHEST AND UNDER MY BREAST. ABOUT (B)(6) 2013 I DEVELOPED AN OVARIAN CYST WHICH WAS EXTREMELY PAINFUL, BEEN TO THE ER A FEW TIMES FOR THAT UNTIL IT FINALLY BURST. I HAVE BEEN IN AND OUT OF THE ER 8 TIMES IN THE PAST YEAR DUE TO SEVERE PELVIC PAIN. RECENTLY I WAS PUT ON VICODIN, TRAMADOL FOR THE PAIN OF THE JOINTS AND PELVIC PAIN. WHEN THE PAIN MEDS FAILED, MY DOCTOR PUT ME ON PREDNISONE WHICH HELPED BUT CAUSED ADVERSE REACTIONS. SO I WENT TO THE ER AND THE DOCTOR STOPPED THE PREDNISONE AND HAD ME TAKE ATIVAN. THE LAST 2 YEARS I HAVE BEEN TAKING MELOXICAM FOR INFLAMMATION. THE PAST 3 MONTHS VICODIN AND TRAMADOL FOR PAIN. ZOFRAN FOR NAUSEA. I FOUND A GYN DR THAT SAID THE ESSURE COILS ARE MAKING ME SICK, THAT MY BODY IS REJECTING THEM AND MAY HAVE DEVELOPED AN NICKLE ALLERGY, WHICH IS IN THE COILS. I WILL BE HAVING SURGERY (B)(6) 2014 TO HAVE THE COILS REMOVED ALONG WITH MY FALLOPIAN TUBES.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035373	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 12/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE FITTED ON (B)(6) 2013, SINCE THEN I HAVE HAD INSOMNIA AND HAVE SLEPT 3HRS PER NIGHT. ON MY RIGHT SIDE ACROSS FROM MY HIP IS EXTREMELY PAINFUL WHICH CONTINUES DOWN BOTH MY LEGS. FEELS LIKE REALLY BAD CRAMP EVERYDAY. I PASS HUGE CLOTS ON DAILY BASIS WHICH I HAVE NEVER HAD BEFORE IT LOOKS LIKE LUMPS OF LIVER. DISGUSTING! MY HAIR IS FALLING OUT, MY STOMACH IS BLOATED AND PAINFUL, MY SKIN IS COVERED IN SPOTS. I NEED TO URINATE EVERY 30MINS WHICH IS NOT PRACTICAL WITH WORK ETC! EXTREME FATIGUE AND MOODY! THIS IS THE WORST DEVICE EVER MADE, ITS CONTROLLING MY LIFE! (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035374	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FIRST MY PERIODS STARTED TO GET REALLY HEAVY WITH BLOOD CLOTS, WENT FROM 3-5 DAY PERIODS TO 7-14 DAY PERIODS WITH ABDOMINAL BLOATING/CRAMPS, AND BACK PAIN.(PREVIOUS TO THAT MY PERIODS WERE MILD WITH CRAVINGS OF CHOCOLATE ONLY) I THEN WOKE UP ONE MORNING WITH HIP/GROIN PAIN. IT HAS PROGRESSED TO CHRONIC PELVIC PAIN, LOWER BACK PAIN ALL ON THE RIGHT SIDE WHERE MY COIL IS LOCATED. I ALSO HAVE JOINT PAIN, HEART PALPITATIONS, BREAST PAIN/TENDERNESS, CYSTS IN VAGINAL OPENING, A LOT OF VAGINAL DISCHARGE WITH NO ODOR, NIGHT SWEATS, EXTREME FATIGUE, FLATULENCE, VAGINAL GAS, ABDOMINAL BLOATING BETWEEN 4-8 INCHES EVERY TIME I EAT, INSOMNIA, MUSCLE SPASMS, BLEEDING AND PAIN DURING INTERCOURSE, WEIGHT GAIN, I CAN NOT STAND OR SIT FOR MORE THAN 15-20 MINUTES WITHOUT SEVERE BACK AND HIP PAIN. BENDING IS PAINFUL. I AM UNABLE TO CARRY MY (B)(6) FOR MORE THAN A FEW MINUTES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035375	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 4/19/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

VOMITING, PAIN, CLOTTING...LOWER BACK PAIN, LOTS OF BLEEDING WHEN HAVING INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035377	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 2/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAD THE ESSURE PROCEDURE IMPLANTED IN ME ON (B)(6) 2013 I HAVE BEEN HAVING MANY ISSUES UP UNTIL NOW. PRESENT. I HAVE BLOAT, SWELLING, VERY HEAVY BLEEDING, OVATION CYSTS, PAIN AND TENDERNESS IN MY PELVIC REGION, PAIN THAT'S CONSISTENT ON MY RIGHT SIDE WHERE ONE OF THE COILS WAS IMPLANTED. LIGHTHEADED, DIZZINESS, MIGRAINE HEADACHES, PAIN DURING INTERCOURSE, SEVERE ACNE, BREAST TENDERNESS, BOWELS MOVEMENTS HAVE CHANGED DRASTICALLY SINCE ESSURE HAS BEEN IMPLANTED IN ME. I'M ALWAYS CONSTIPATED. BEFORE ESSURE I HAD NONE OF THESE ONGOING SYMPTOMS. I HAVE ALWAYS BEEN HEALTHY EXCEPT FOR A PREVIOUS ILLNESS EPILEPSY AS A CHILD. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035380	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 1/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE SEVERE PELVIC PAIN FROM DAY ONE! THE PAIN GOT WORSE AND WORSE OVER TIME. IN (B)(6) OF 2013, I STARTED A PERIOD THAT DID NOT END FOR 3 WEEKS. THEN A WEEK AFTER I STOP I START AGAIN AND BLED UNTIL (B)(6). I AGAIN START A FEW DAYS LATER AND BLED UNTIL THE DAY BEFORE MY HYSTERECTOMY (B)(6), 2014. MY GYN STATED ESSURE WAS THE CAUSE OF ALL MY PAIN AND ISSUES AS IT WAS MOSTLY IN MY UTERUS! SO I HAD TO HAVE A HYSTERECTOMY DUE TO THE PAIN FROM ESSURE!! AND DR LIE ON HIS ADVERSE REPORT! MY PROCEDURE WAS DONE IN THE HOSPITAL AND I WASN'T AWARE OF ANY ISSUES! I HAVE ESSURE (B)(4). (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035383	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 3/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SCALPINGECTOMY LEFT SIDE (B)(6) 2013, HYSTERECTOMY (B)(6) 2014, SCALPINGECTOMY RIGHT SIDE (B)(6) 2014. SINCE I GOT THE ESSURE (B)(6) 2013, I HAVE HAD PELVIC PAIN, BACK PAIN, AND HIP PAIN. AND NOW I HAVE ENDOMETRIOSIS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035385	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 6/18/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDA MW5035385, #(B)(4). SINCE MY INITIAL REPORT I HAVE DEVELOPED HYPERGLYCEMIA AND PSORIASIS ON MY FACE, NECK AND INNER EAR. I HAD A HYSTERECTOMY, LEAVING THE OVARIES IN (B)(6) OF 2014. MANY OF THE EARLIER SYMPTOMS DISAPPEARED IMMEDIATELY AFTER THE HYSTERECTOMY, BUT I AM STILL LEFT WITH OCCASIONAL CHRONIC PAIN, PRE-HYPERTENSION, COGNITIVE ISSUES (BRAIN FOG, FORGETFULNESS), IRRITABLE BOWEL, AND LOW VITAMIN B12 AND D WHICH REQUIRE DAILY SUPPLEMENTS. ALL WHICH ARE ISSUES I NEVER HAD BEFORE ESSURE WAS PUT IN MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035387	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 11/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE INSERTS PLACED IN (B)(6) 2008 AND BY (B)(6) 2008 I SOUGHT HELP FOR FATIGUE AND DIZZINESS WHICH I HAD EXPERIENCED FOR MONTHS. I WENT TO AN EAR SPECIALIST TO GET TESTS DONE ON MY HEARING AND EQUILIBRIUM. MY LAST VISIT WAS IN (B)(6) 2013 AND NO RESOLVE. I CONTINUE TO FEEL FATIGUED AND BECOME DIZZY MORE OFTEN THAN NOT. IN 2009, I BEGAN TO FEEL NUMBNESS IN BOTH HANDS AND FOUND A HAND SPECIALIST. I WORE BRACES ON BOTH HANDS DURING THE NIGHT FOR A FEW YEARS AND BY LAST YEAR I RETIRED THEM. MY NUMBNESS HAD ADVANCED UP TO MY ELBOWS. THIS SENSATION OCCURS NIGHTLY AND THE BRACES FOR MY WRISTS ARE NO LONGER HELPING THAT ISSUE. IN (B)(6) 2010, MY RIGHT KNEE BEGAN TO MAKE A POPPING SOUND AND THEN WEEKS LATER IT DECIDED TO JUST GIVE OUT ON ME. THE PAIN WAS HORRIBLE. I HAVE NO HISTORY OF KNEE PROBLEMS NOR ANY INJURIES. I WENT THROUGH THERAPY TO RECOVER AND STILL FEEL THE PAIN IN THAT JOINT AT TIMES. JUST A FEW WEEKS AGO, I FELT MY LEFT KNEE READY TO DO THE SAME TO ME. I AM NOT SURE OF THE EXACT DATE THAT I BEGAN TO FEEL ALL OF THE PELVIC PAIN, LOWER BACK PAIN, AND THE ABDOMINAL PAIN, BUT IT HAS BEEN AT LEAST THE LAST 3 YEARS. NOT ONLY DO I EXPERIENCE PELVIC AND LOWER BACK PAIN, THE PAIN MOVED INTO MY HIPS AND THE HIP BONES. THE LAST FEW YEARS, I HAVE HAD MULTIPLE TESTS DONE ON MY UTERUS AND HIPS INCLUDING ULTRASOUNDS AND X-RAYS. IN (B)(6) 2013, I HAD A HIP X-RAY AND WAS PLACED ON MEDICATION FOR A SHORT TIME. IN (B)(6) 2013, AN ULTRASOUND FOUND MY UTERUS WAS ENLARGED. IN (B)(6) 2013, DUE TO THE SEVERE ABDOMINAL PAIN AND ANUS PAIN, I HAD AN ENDOSCOPY AND COLONOSCOPY PERFORMED. I HAVE AN ELONGATED COLON. IN (B)(6) 2014, I WENT TO A RHEUMATOLOGIST FOR ALL OF THE JOINT PAIN IN MY LEFT HAND, MY KNEES AND MORE IMPORTANTLY FOR THE PAIN IN MY HIPS, PELVIS, AND LOWER BACK. I HAD BLOOD WORK, AN X-RAY OF MY LEFT HIP, AND A FULL-BODY 3-PHASE BONE SCAN. THE BODY SCAN IDENTIFIED AN

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ABNORMAL AREA UNDER MY LEFT 8TH RIB, SO I WAS SENT FOR AN X-RAY OF MY LEFT SIDE. THE X-RAY SHOWS SOMETHING VERY SMALL IN SIZE. I AM NOW SEEKING SECOND OPINIONS. MY BLOOD WORK RESULTS INDICATE LOW VITAMIN D AND B-12. AT TIMES I DO EXPERIENCE CHEST PAINS ON MY LEFT SIDE AND MY MENSTRUAL CYCLE IS BRUTAL EVERY MONTH FOR THE WEEK LEADING UP TO MY CYCLE AND THE WHOLE TIME DURING MY CYCLE. IN THE PAST MONTHS, I HAVE ALSO EXPERIENCED FULL-BODY NUMBNESS NOT LONG AFTER I FALL ASLEEP. I FEEL AS THOUGH I AM HAVING A STROKE OR A HEART ATTACK. I BECOME ALERT AND COLLAPSE TO THE FLOOR AS I TRY TO GET OUT OF BED ON LIFELESS LEGS AND FEET. THESE EPISODES ARE VERY SCARY AND MY HEART IS RACING OUT OF MY CHEST. I PLAN TO SEE A NEUROLOGIST THIS MAY. I TEND TO HAVE HEADACHES AND CAN'T SLEEP DUE TO THE JOINT, LOWER BACK, HIP, AND PELVIC PAIN. ALL OF MY SYMPTOMS ARE PROGRESSIVELY GETTING WORSE AND MOST HAVE BECOME CHRONIC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035388	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 11/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PROCEDURE WAS DONE AT THE DR (B)(6) OFFICE AND I WAS ABLE TO FEEL THE PAIN AND WATCH AS THE DR WAS INSERTING THESE COILS IN MY TUBES. THE PAIN WAS HORRIBLE AS I WAS TOLD THE PAIN WAS MINIMAL. I WAS INFORMED I WOULD BE FINE TO DO WHAT I HAD TO DO RIGHT AFTERWARDS. I PRACTICALLY WAS IN BED IN PAIN FOR ABOUT 2 WEEKS. THE PAIN IN MY LOWER BODY WAS HORRIBLE THAT AT TIMES I WOULD CRY. I WOULD TAKE TYLENOL TO CALM DOWN MY PAIN. AFTER ABOUT 6 MONTHS PAST THE PROCEDURE I STARTED GETTING HEADACHES THAT I HAD NEVER REALLY HAD BEFORE I HAD MY PROCEDURE DONE. MORNING SICKNESS AND BLOATING AROUND THE TIME OF MY MENSTRUAL CYCLE, CRAMPS WERE HORRIBLE TO THE POINT WHERE I JUST WANTED TO STAY IN BED AND NOT DO ANYTHING. LITTLE BY LITTLE MY LIFE HAS BEEN TAKEN AWAY WITH THIS PROCEDURE. I NO LONGER WANTED TO HANG OUT WITH FRIENDS, FAMILY, MY KIDDOS WANTED TO GO TO THE PARK AND I WAS JUST IN NO MOOD TO GO DUE TO PAIN. BACK PAIN, LOWER ABDOMINAL PAIN, HEADACHES, ALWAYS FEELING SICK. I'M ALWAYS SLEEPY, TIRED, HAVING HEADACHES, BACK PAIN, HORRIBLE CRAMPING WHEN MENSTRUAL CYCLE IS AROUND, BIG BLOOD CLOTS THAT I NEVER AND I MEAN NEVER HAD EXPERIENCED BEFORE I GOT PROCEDURE. I'VE THOUGHT TIME AFTER TIME I AM PREGNANT JUST BECAUSE I GET ALL THE SYSTEMS OF BEING PREGNANT,I 'M UNABLE TO LOOSE WEIGHT, I GET BLOATED TO WHERE I LOOK LIKE IM PREGNANT AND DAYS AFTER MY MENSTRUAL CYCLE IS OVER IT GOES DOWN KEEP IN MIND I NEVER EXPERIENCED THIS BEFORE I RECEIVED PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035389	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 8/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAIR LOSS, GIGANTIC BLOOD CLOTS, TREMENDOUS WEIGHT LOSS, ABDOMINAL PAIN, HEAVY MENSTRUAL, ABNORMAL BLEEDING, HEAD ACHES, LOSS OF APPETITE DUE TO PAIN, AND HEADACHE NUMBNESS IN MY HANDS LEGS AND FEET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035390	BAYER	4/1/2014	4/1/2014

Event Information:

Event Date (B3): 3/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT STARTING WITH A SLIGHT GROIN PAIN ON MY RIGHT SIDE. SOON THE PAIN INCREASED TO MY RIGHT HIP AND BEGAN TO FEEL LIKE BONE ON BONE CRUSHING PAIN. I WAS FIRST SENT TO A PT AND AFTER TWO LONG PAINFUL MONTHS NOT WAS DID THE PAIN GO AWAY BUT IT HAD NOW MOVED INTO MY PELVIS. I WAS THEN SENT TO AN ORTHO. I HAD A MRI AND I FOR THE FIRST TIME IN 13 YRS WAS UNABLE TO FINISH THAT BECAUSE OF THE VIBRATION. I HAD A HIP X-RAY, BLOOD WORK AND NOTHING CAME BACK. BY THIS TIME I WAS USING AN ARM CRUTCH TO WALK. FOUR MORE MRI'S WERE ORDERED, I NOW WAS SEEING MY PCP/URO/OB/GYN/NEURO TO PICK THIS APART. MY URETHRA FELT LIKE IT WAS IN CONSTANT SPASMS; MY HIPS FELT LIKE THEY WERE GOING TO EXPLODE. IN EARLY 2014 2 OF THE 4 THE MRI'S WERE DONE, HIP/LUMBAR UNDER SEDATION. THOSE CAME BACK SHOWING NOTHING. I STILL WENT INTO MY PCP AND WOULD NOT BACK DOWN AND THEN MOVED MY CASE INTO URO. THERE WE DID A HYDO/CYSTO THINKING IT MIGHT HAVE BEEN THE INTERSTITIAL CYSTITIS. BECAUSE OF ALL OF THE INTENSE PAIN I WAS IN MY OB/GYN CAME IN AND DID A PELVIC ON ME WHILE I WAS UNDER SEDATION AS WELL. AFTER A PAINFUL DAY SURGERY IT TURNED OUT NOT TO BE THE CASE. MEANING THE IC WAS NOT CAUSING MY URETHRA TO BE IN SO MUCH DISCOMFORT. MY LAST OPTION WAS THE OB/GYN. SHE NOTED DURING MY EXAM UNDER SEDATION SHE COULD FEEL HOW "TIGHT MY MUSCLES" WERE. SHE LOOKED AT ONE OF MRI'S AND FOUND THAT THE RIGHT IMPLANT WAS SITTING SIDEWAYS AND ALSO BOTH OF MY FALLOPIAN TUBES WERE FILLED WITH FLUID. SHE ALSO FOUND A SMALL CYST. ON (B)(6) 2014 WE REMOVED MY FALLOPIAN TUBES, THE IMPLANTS AND THE CYST. BUT SHE FOUND STAGE III ENDOMETRIOSIS. SHE BURNED OFF ALL THAT SHE COULD FIND AND WE ARE NOW TREATING IT WITH BC. FOR NEARLY 9 MONTHS I HAVE SPENT LIVING IN PURE HELL. I HAVE BEEN "NON-RESPONSIVE" TO MOST PAIN MEDS AND I HAD TO GO TO THE ER TWICE FOR SOME RELIEF. I CAN CLEARLY REMEMBER TELLING

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ANESTHESIA ON TWO OCCASIONS THAT I WAS AT A LEVEL "10" AND I HAVE BEEN A CHRONIC PAIN PATIENT FOR 16 YEARS. I HAVE NEVER SAID 10. I HAVE ALMOST PASSED OUT FROM THE PAIN WALKING THROUGH STORES. I PUT TOGETHER MY LIVING WILL BECAUSE OF THIS. THE IMPLANTS ARE OUT BUT MY HIPS STILL HURT AND THE PAIN IS STILL IN MY GROIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00088	BAYER HEALTHCARE LLC	4/1/2014	4/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/21/2008
Explant Date (E7): 1/21/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE IMPLANTED. A HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED IN (B)(6) 2009, BOTH COILS WERE IN PLACE AND BOTH TUBES WERE BLOCKED. LEFT COIL WAS OUT AND IN UTERUS, EMBEDDED ALL THE WAY THROUGH UTERUS, ONLY THIN LAYER WAS LEFT OUT FOR IT TO GO OUT INTO ABDOMINAL CAVITY. AS FOR RIGHT COIL, INITIALLY WITH HG TEST THEY SAID RIGHT COIL WAS IN PLACE. THEN CT WITH CONTRAST COULD NOT LOCATE COIL, THEY SAID IT PERFORATED TUE AND BACK INTO UTERUS. NO ORGANS OR INTRA-ABDOMINAL STRUCTURES WERE AFFECTED. THE PERFORATION HAD NOT OCCURRED DURING INSERTION. CT SCAN WITH CONTRAST, BLOOD TESTS, URINE TESTS, MOST RECENT PAP (PAPANICOLAOU) SMEAR IN (B)(6)-2013 CAME BACK NORMAL, IT SHOWED EXTREME INFLAMMATION. GYNECOLOGIST PERFORMED HYSTERECTOMY AND STATED THERE WAS PARTIALLY RIGHT SIDED COIL IN THE TUE. CONSUMER WAS NOT 100 PERCENT SURE, AND DOES NOT KNOW WHERE IT IS IN THE TUBE, THE UTERUS. SHE HAD ONLY ONE POST-FOLLOW UP VISIT SO FAR. HER DOCTOR DISSECTED THE UTERUS TO MAKE SURE SHE GOT BOTH COILS, SHE SAID SHE GOT ALL THE PIECES OF COIL OUT. CONSUMER HAS NOT TOTALLY RECOVERED AT TIME OF REPORTING. OTHER SYMPTOMS/PAIN RESOLVED AFTER SURGERY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00090	BAYER HEALTHCARE LLC	4/1/2014	4/9/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/28/2013
Explant Date (E7): 1/27/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PT WAS 3 MONTHS POSTPARTUM AT TIME OF ESSURE INSERTION. THREE MONTH HSG WAS PERFORMED AND CONFIRMED TUBAL PERFORATION. SHE EXPERIENCED UNILATERAL, LEFT TUBAL AND CORNUA OS TUBE PERFORATION. THE PHYSICIAN CONFIRMED THAT UTERUS AND TUBE WERE PERFORATED. THE PERFORATION DID NOT OCCUR DURING SOUNDING, CERVICAL DILATATION OR HYSTEROSCOPY PRIOR ESSURE INSERTION NOR BEFORE DEPLOYMENT. IT OCCURRED WITH COIL AFTER DEPLOYMENT. THERE WERE NO SYMPTOMS OF INFECTION, BUT SHE EXPERIENCED MENORRHAGIA AND LOW BACK PAIN. SHE HAD A VAGINAL HYSTERECTOMY AND ESSURE WAS REMOVED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 28-OCT-2015 FROM PATIENT: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00099	BAYER HEALTHCARE LLC	4/1/2014	4/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED. SHE WAS IN PAIN ALL THE TIME. THERE NEVER WAS A DAY WITHOUT PAIN. HER PERIODS WERE HORRIBLE AND SHE HAD TO HAVE A HYSTERECTOMY AT (B)(6).

Manufacturer Narrative (H10):

FOLLOW-UP FROM 19-JUN-2014: FOLLOW-UP CANNOT BE COMPLETED DUE TO LACK OF PRIMARY REPORTER CONTACT INFORMATION. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 12-AUG-2014: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00092	BAYER HEALTHCARE LLC	4/2/2014	4/9/2014

Event Information:

Event Date (B3): 8/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/11/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED FOR PERMANENT BIRTH CONTROL. SHE HAD BLED CONTINUOUSLY EVERY DAY SINCE ESSURE WAS PLACED. SHE HAD EMOTIONAL DISTRESS AND SEVERE PAIN. SHE WAS UNABLE TO HAVE AN INTIMATE LIFE WITH HER HUSBAND, PLAY WITH HER CHILDREN, AN HAD TO TAKE FREQUENT BREAKS AT WORK. APPROXIMATELY TWO WEEKS AFTER INSERTION, CONSUMER WENT TO THE BATHROOM, AND A FEW COILS CAME OUT. SHE ALSO HAD CRAMPING. THE HEALTHCARE PROFESSIONAL HAD PLACED HER ON AN UNK ORAL CONTRACEPTIVE FOR THE CRAMPING AND BLEEDING, AND THEY DID NOT WORK. APPROXIMATELY SIX MONTHS LATER IN 2012 SHE HAD A TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00094	BAYER HEALTHCARE LLC	4/2/2014	4/9/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/7/2007
Explant Date (E7): 5/7/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED IN THE DOCTOR'S OFFICE. SHE WAS NOT ADVISED OF THE NICKEL, NOR DID SHE RECEIVE A PELVIC EXAM OR TEST FOR CERTAIN DISEASES PRIOR TO THE PROCEDURE. SHE ALSO REPORTED THAT SHE HAD ALL OF HER DOCTOR'S NOTES AND A URINE PREGNANCY TEST WAS NOT PERFORMED ON THE INSERTION DATE - IT WAS ONLY PERFORMED IN 2008. AFTER INSERTION, SHE PRESENTED TO THE DOCTOR'S OFFICE IN EXCRUCIATING PAIN, BLEEDING, CRAMPING AND BLOATING. SHE WAS TOLD BY HER DOCTOR THAT HER BODY WAS ADJUSTING, BUT SHE WENT BACK TO THE OFFICE 7 MORE TIMES WITH THE SAME COMPLAINT. HER DOCTOR INFORMED HER THAT IT COULD NOT BE ESSURE AND THAT SHE MIGHT HAVE A CYST ON HER OVARIES OR UTERUS OR FIBROIDS. HER DOCTOR WANTED TO PLACE HER ON BIRTH CONTROL, BUT SHE REFUSED. SHE ALSO REFUSED LAPAROSCOPIC SURGERY, ABLATION AND DILATION AND CURETTAGE. SHE DECIDED TO SEARCH FOR ANOTHER DOCTOR BECAUSE HER CURRENT ONE INSISTED THAT IT WAS NOT ESSURE THAT WAS CAUSING HER SYMPTOMS. OVER THE COURSE OF 5 YEARS SHE HAS BEEN VERY SICK, ANEMIC, AND FATIGUED DUE TO EXCESSIVE BLOOD CLOTS. SHE ALSO EXPERIENCED UNEXPLAINED FEVER, RASH, HEARING PROBLEMS, VISION PROBLEMS, TASTE PROBLEMS, LOSS OF CONCENTRATION, LOSS OF BALANCE, WEIGHT GAIN, SEVER WEIGHT LOSS, IRRITABLE BOWEL SYNDROME, ANXIETY, HIGH BLOOD PRESSURE, PANIC ATTACKS, NAUSEA, DIARRHEA, MAJOR PAIN ON RIGHT SIDE AS SHE COULD ACTUALLY FEEL THE ESSURE COILS, HEADACHES, MIGRAINES, ALLERGIES, NERVOUSNESS, DIZZINESS, LEG PAIN, BACK PAIN , NECK PAIN, BLISTERS IN HER NOSE AND MOUTH, BOWLS ON HER LEGS, INSOMNIA, CRYING, SADNESS, ANGER AND FEELING MISERABLE. IN 2010 OR 2012 SHE VISITED ANOTHER GYNECOLOGIST WHO TOLD HER THAT HER COILS WERE MAKING HER SICK. SHE TOLD HIM THAT SHE WAS ALLERGIC TO NICKEL AND HE

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TOLD HER THAT HER BODY WAS IN CHRONIC INFLAMMATORY STATE FOR A LONG TIME. SHE HAD HYSTERECTOMY PERFORMED AND HER TUBES WERE REMOVED ALONG WITH ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00095	BAYER HEALTHCARE LLC	4/2/2014	4/9/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/20/2013
Explant Date (E7): 11/5/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE CONSUMER HAD ESSURE INSERTED. THE PROCEDURE WENT SMOOTHLY AND SHE EXPECTED TO BE BACK TO NORMAL THE NEXT DAY, BUT SHE EXPERIENCED CHRONIC PAIN, CRAMPING, AND BLEEDING THAT LASTED FOR DAYS. SHE CONTACTED HER DOCTOR AND WAS TOLD TO CALL BACK IN ONE WEEK IF SHE STILL HAD ISSUES. SHE THEN DEVELOPED AN URINARY TRACT INFECTION AND HAD AN ULTRASOUND DONE. THE ULTRASOUND SHOWED THAT THE COILS WERE IN PLACE AND NOTHING SEEMED OUT OF THE ORDINARY. THE PAIN LOCATED IN HER ABDOMEN AND LOWER BACK CONTINUED (SOMETIMES IT WAS SEVER), AS WELL AS THE CRAMPING AND SPORADIC BLEEDING. SHE HAD SORENESS IN THE AREA THE COILS WERE PLACED AND DEVELOPED AN UNUSUAL IRRITATION IN HER MOUTH. DUE TO THE IRRITATION, PAIN, STRESS, AND ANXIETY OF NOT KNOWING WHAT WAS HAPPENING, SHE HAD LITTLE APPETITE AND LOST 8-10 POUNDS IN A MONTH. SHE WAS ALSO TAKING 600-800 MG OF IBUPROFEN EVERY FOUR HOURS AS WELL AS PERCOCET AND VICODIN AT NIGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00096	BAYER HEALTHCARE LLC	4/2/2014	4/9/2014

Event Information:

Event Date (B3): 1/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): B04952

Single Use: Y
Implant Date (E6): 1/7/2014
Explant Date (E7): 1/14/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER HAD ESSURE INSERTED IN HER RIGHT TUBE. SHE INSTANTLY BEGAN TO HURT AND IT GOT WORSE DURING THE WEEK. SHE REPORTED HER SIDE EFFECTS WERE ABDOMINAL PAIN, BACK PAIN, SHARP PAIN ON HER RIGHT SIDE, BLEEDING, DIZZY SPELLS AND FEVER. EXACTLY ONE WEEK AFTER IMPLANTATION, THE COIL WAS REMOVED AND ALL PAINS THAT SHE HAD WERE GONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00097	BAYER HEALTHCARE LLC	4/2/2014	4/9/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20183879

Single Use: Y
Implant Date (E6): 6/22/2010
Explant Date (E7): 12/18/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS IMPLANTED 3 MONTHS AFTER THE CONSUMER'S LAST DELIVERY. MONTHS AFTER INSERTION, SHE STARTED EXPERIENCING EXTREME LOWER BACK PAIN, CONSTANT PELVIC PAIN, LOSS OF HAIR, SWOLLEN ANKLES, DEPRESSION, FATIGUE, LARGE AMOUNTS OF FLUID IN THE UTERUS, NUMBNESS OF HANDS AND FEET, INSOMNIA, HEADACHES, MOODINESS, AND SWOLLEN ABDOMEN. HER UTERUS KEPT FILLING UP WITH FLUID AND SHE HAD TO HAVE IT DRAINED EVERY 3 MONTHS HER PHYSICIAN EXPLAINED THIS AS ACTIVE CHRONIC ENDOCERVICITIS WITH SQUAMOUS METAPLASIA, UTERUS WAS SOMEWHAT BOGGY, LEFT OVARY HAD SOME CYSTS AND PELVIC PAIN PARTICULARLY ON LEFT SIDE FOR SEVERAL MONTHS. ON (B)(6) 2013 THE PT WAS HOSPITALIZED FOR HYSTERECTOMY AND SALPINGECTOMY. ESSURE REMOVAL WAS MEDICALLY NECESSARY. DURING SURGERY, ESSURE WAS FOUND IN THE TUBES AND IT WAS INTACT. PATHOLOGY RESULTS SHOWED THAT THE TUBES WERE SEVERLY INFLAMED AND HER UTERUS HAD ADENOMYOSIS. ALL SYMPTOMS WENT AWAY AFTER SHE RECOVERED FROM THE HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00098	BAYER HEALTHCARE LLC	4/2/2014	4/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B61398

Single Use: Y
Implant Date (E6): 1/27/2014
Explant Date (E7): 2/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A PT HAD ESSURE INSERTED BY THE REPORTING PHYSICIAN WITH NO PROBLEMS. SHE COMPLAINED OF PAIN ON BOTH SIDES WHICH WAS NOT GETTING BETTER. THE PT WANTED THEM REMOVED. REPORTING DOCTOR PERFORMED A LAPAROSCOPIC LINEAR SALPINGECTOMY ON BOTH TUBES TO REMOVE ESSURE COILS. ON THE RIGHT SIDE HE NOTICED A LOT OF INFECTION OF THE TUBE WITH (MILKY FLUID) AND ON THE LEFT SIDE THE COIL HAD GOT KINKED UP INSIDE THE TUBE. DOCTOR REMOVED THE COILS WITH NO PROBLEMS AND THE PT'S PAIN WENT AWAY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00093	BAYER HEALTHCARE LLC	4/2/2014	4/10/2014

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/20/2013
Explant Date (E7): 2/6/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PATIENT WAS SEVEN MONTHS POSTPARTUM AT TIME OF ESSURE INSERTION AND BREASTFEEDING. INSERTION WAS EASY ON LEFT SIDE, BUT IT WAS DIFFICULT ON THE RIGHT. THERE WAS TUBE SPASM AND THE PHYSICIAN WAS UNABLE TO DEPLOY ESSURE WITH OPTIMAL PLACEMENT (10 COILS WERE VISIBLE ON DEPLOYMENT). ON (B)(6), 2014, PELVIC ULTRASOUND SHOWED RIGHT ESSURE COIL EXTENDED INTO ENDOMETRIUM. PATIENT REQUESTED REMOVAL. THE CONSUMER STATED THAT PART OF THE RIGHT COIL WAS SUPPOSED TO BE 3-4 STRINGS IN UTERUS, BUT SHE HAD 8 STRINGS WHICH CAUSED LOW BACK PAIN, CHRONIC PELVIC PAIN, BLOATING, AND CRAMPING. LAPAROSCOPIC BILATERAL SALPINGECTOMY AND HYSTEROSCOPY WERE DONE. COILS WERE REMOVED WITH HYSTEROSCOPE GRASPER, THEN LIGATURE WAS DONE, PATIENT WAS NOT HOSPITALIZED. ON (B)(6), 2014, PATHOLOGY RESULTS SHOWED UNREMARKABLE FALLOPIAN TUBES. ESSURE COILS WERE WITHIN FALLOPIAN TUBES, NOT PERFORATED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00091	BAYER HEALTHCARE LLC	4/2/2014	4/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED IN 2005 FOR STERILIZATION. IN 2007 SHE HAD DOCUMENTATION VIA HER MEDICAL RECORDS THAT SHE COMPLAINED ABOUT THE INFLAMMATION AND PAIN IN HER PELVIC REGION, AS WELL AS WEIGHT GAIN. HER DOCTOR DID NOTHING ABOUT HER CONCERNS FOR HER PAIN AND AS FAR AS THE WEIGHT WENT, HE SUGGESTED SHE TRY A DIET. SHE HAD ULTRASOUNDS PERFORMED (RESULTS UNAVAILABLE). THE PAIN HAD GOTTEN SO SEVERE IT FELT AS THOUGH HER COILS WERE NOT ONLY GOING TO PUNCTURE THROUGH HER TUBES AND SKIN, BUT THAT THEY WERE RADIATING HEAT LIKE THERE WERE SKIN, BUT THAT THEY WERE RADIATING HEAT LIKE THERE WERE TWO MINIATURE CURLING IRONS IN HER TUBES THAT WERE ON FIRE. HER BELLY WAS CONSTANTLY DISTENDED AND INFLAMED AND IN PAIN. ANY EXERCISE ONLY EXASPERATED THE ISSUES. HER PERIODS WERE AT AN ALL-TIME HEAVY FLOW, LONGEST DURATION, EXTREMELY PAINFUL, AND QUITE FRANKLY SO WAS INTERCOURSE. SHE HAD BEEN TESTED FOR RHEUMATOID ARTHRITIS BECAUSE SHE WAS HAVING MAJOR JOINT PAINS THROUGHOUT HER ENTIRE BODY. IT CAME BACK NEGATIVE. SHE ALSO TESTED POSITIVE FOR EPSTEIN-BARR VIRUS. HER EXHAUSTION HAS BEEN ONGOING FROM DAY ONE, BUT GOT WORSE OVER THE YEARS AND FELT AS THOUGH HER BODY WAS FILLED WITH LEAD. HER HORMONES TESTED AT ALMOST MENOPAUSAL. SHE WAS VITAMIN B12 AND VITAMIN D DEFICIENT. CONSUMER HAD BEEN TO PHYSICIANS AND EMERGENCY ROOMS DUE TO THE PAIN SHE WAS IN AND HAD ULTRASOUNDS AND X-RAYS THAT ALL SUGGESTED HER COILS WERE PROPERLY PLACED, IT TURNED OUT THAT THEY WERE WRONG. CONSUMER FOUND A DOCTOR THAT AGREED TO REMOVE HER TUBES ALONG WITH THE COILS. SHE HAD A BILATERAL SALPINGECTOMY IN 2013. ALMOST ALL OF HER PAIN WENT AWAY WITH EXCEPTION TO SOME INFLAMMATION AND TWINGES OF PAIN. CONSUMER HAD A FEW TESTS DONE THAT SHOWED FRAGMENTS BROKE OFF INSIDE HER UTERUS ON EACH SIDE. THE ONLY WAY TO REMOVE THEM

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WAS TO REMOVE HER UTERUS. IN 2014 SHE HAD A LAPAROSCOPIC SUPRACERVICAL HYSTERECTOMY. NOW SHE WAS DEALING WITH AN ABSCESS AS A COMPLICATION. SHE ALSO WOULD LIKE TO NOTE THAT, THE PET FIBERS THAT WERE SUPPOSED TO BE IN HER DEVICE WERE ALMOST NON-EXISTENT AT REMOVAL. CONSUMER DECLINED FURTHER CONTACT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035490	CONCEPTUS/BAYER	4/3/2014	4/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 855622

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE (B)(6) 2011. HAD DYE TEST DONE TO SHOW PLACEMENT AND TOLD 100 PERCENT BLOCKAGE (B)(6) 2012. IN (B)(6) 2012 FOUND OUT I WAS PREGNANT WITH MY BABY THAT I HAD IN (B)(6) 2013. AFTER HAVING ANOTHER DYE TEST (B)(6) 2013 DONE TO ENSURE THAT THIS DEVICE WAS STILL DOING WHAT IT WAS SUPPOSED TO IT SHOWED PLACEMENT GOOD AND AGAIN 100 PERCENT BLOCKAGE AND AGAIN IN (B)(6) 2013 I WOULD FIND OUT I WAS PREGNANT AGAIN WITH THIS BABY DUE IN (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00100	BAYER HEALTHCARE LLC	4/3/2014	4/10/2014

Event Information:

Event Date (B3): 8/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): A02555

Single Use: Y
Implant Date (E6): 8/8/2012
Explant Date (E7): 8/8/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED FOR BIRTH CONTROL. SHE REPORTED HAVING MEDICAL PROBLEMS FROM THE DAY IT WAS PUT IN. PAIN WAS VERY TERRIBLE WHEN SHE WOKE UP AFTER THE PROCEDURE. THE DOCTOR TOLD SHE COULD GO TO WORK RIGHT AWAY, BUT SHE WAS IN BED FOR A WEEK. SHE EXPERIENCED PAIN EVERY DAY, PAIN TO URINATE, FEELING LIKE SHE HAD TO PEE EVERY 5 MINUTES, HAD TO PEE CONSTANTLY, URINARY TRACT INFECTIONS, SHARP SHOOTING PAIN TO TOES DURING LAST 2 MONTHS BEFORE REMOVAL OF ESSURE, NIGHT SWEATS, CONSTANT FEVER, CONSTANT RASH AND ITCHING SIMILAR TO DIAPER RASH IN VAGINAL AREA AND SWELLING IN STOMACH. SHE WAS GIVEN PRESCRIPTION OF GABAPENTIN FOR NERVE DAMAGE, NORTRYPTILINE, FLAGYL, DOXYCYCLINE, HYDROCODONE, FLEXERIL, CIPROFLOXACIN AND PAIN MEDICATIONS WHICH NEVER HELPED. SHE ENDED UP HAVING HYSTERECTOMY BY LAPAROSCOPIC PROCEDURE. DURING SURGERY ESSURE COILS WERE IN FALLOPIAN WHERE THEY WERE SUPPOSED TO BE. RASH WENT AWAY 2 WEEKS AFTER ESSURE REMOVAL. ALL SYMPTOMS WENT AWAY AFTER HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035529	CONCEPTUS	4/4/2014	4/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 632032

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS INSERTED IN 2009 AND FOR THE PAST 4 YEARS MY MENSTRUAL CYCLE IS VERY HEAVY WITH CLOTS BIGGER THAN A QUARTER, I HAVE EXPERIENCED UNEXPLAINABLE RASHES ON MY BODY THAT COME AND GO, HEADACHES EVERY MONTH, ABDOMINAL CRAPS EVEN WHEN NOT ON CYCLE AND SPOTTING BETWEEN PERIODS. I'VE ALSO EXPERIENCED LOW SEX DRIVE AND SOMETIMES PAINFUL, A PINCHING FEELING IN MY LOWER ABDOMINAL AREA ESPECIALLY WHEN I'M ON MY PERIOD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035574	BAYER	4/4/2014	4/11/2014

Event Information:

Event Date (B3): 3/24/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IMPLANT 6 YEARS AGO. RECENTLY DIAGNOSED WITH PIECE OF COIL DISLODGED FROM FALLOPIAN TUBE AND IS IN MY UTERUS. ALSO A "LESION" WAS DISCOVERED ON MY BLADDER. I AM A (B)(6) PERFECTLY HEALTHY WOMEN NOW NEEDING SURGERY TO REMOVE THE COIL FOUND IN MY UTERUS AND THE LESION ON MY BLADDER. SUBSEQUENTLY, I HAVE READ ABOUT NUMEROUS STORIES LIKE MINE DESCRIBING EFFECTS OF THE ESSURE IMPLANT. THE FDA NEEDED TO LOOK INTO THE ESSURE IMPLANT TO DETERMINE ITS LONG TERM SAFETY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035576	BAYER	4/6/2014	4/11/2014

Event Information:

Event Date (B3): 12/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL IMPLANT IN (B)(6) OF 2013. I WAS TOLD IT WOULD CAUSE MILD PAIN OR CRAMPING. IT WAS EXTREME PAIN AND HAS CONTINUED TO BE EXTREME PAIN FOR OVER 3 MONTHS. THE PAIN IS SO BAD I CAN'T FUNCTION TO DO MY REGULAR DAILY ROUTINE. I BLEED CONSTANTLY VERY HEAVILY AND IT IS UNBEARABLE. I FEEL THAT THIS PERMANENT BIRTH CONTROL IS HORRIBLE AND HAS CAUSED ME MORE PROBLEMS THAN GOOD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035577		4/6/2014	4/11/2014

Event Information:

Event Date (B3): 3/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/28/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLEEDING AND ABDOMINAL PAIN AFTER 1 MONTH OF HAVING ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035583	CONCEPTUS	4/8/2014	4/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20210352

Single Use:
Implant Date (E6): 12/15/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

OVER THE LAST FEW YEARS I'VE BEEN EXPERIENCING UNEXPLAINED DIZZINESS, PAIN IN MY LEFT SIDE AROUND MY OVARY/TUBE, SEVERE CRAMPING AND MENSTRUAL BLEEDING (WORSE THAN BEFORE WITH A LOT MORE CLOTTING), WEIGHT FLUCTUATIONS, SEVERE HOT FLASHES (TO THE POINT I NEARLY PASS OUT AND HAVE TO LAY DOWN) AND OTHER PROBLEMS THAT DOCTORS SAY ARE NOTHING AND TO GO HOME AND TAKE IBUPROFEN AND SEE A COUNSELOR. I'VE BEEN CHECKED FOR THYROID PROBLEMS, DIABETES, MENOPAUSE, ABDOMINAL PAIN, AND VARIOUS OTHER PROBLEMS JUST TO BE SENT HOME SAYING THAT I'M MAKING IT UP AND IT'S ALL IN MY HEAD. IT JUST KEEPS GETTING WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035584	BAYER	4/8/2014	4/15/2014

Event Information:

Event Date (B3): 4/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/25/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ACUTE ALLERGIC REACTION TO THE NICKEL IN ESSURE, CAUSED SWELLING OF THE LIPS, FEET AND EYES. BLED PROFUSELY VAGINALLY FOR ALMOST 6 MONTHS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035594	BAYER	4/8/2014	4/15/2014

Event Information:

Event Date (B3): 4/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESSURE
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/20/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(4) 2012 SHORTLY AFTER HAVING MY SON IN (B)(4). I'VE BEEN HAVING STOMACH PAINS, LEG PAINS, CRAMPING, FEVERS, HOT FLASHES, ABDOMINAL PAIN LIKE SHARP SHOOTING PAINS DOWN MY LEGS AND UP MY STOMACH. I'VE HAD VAGINAL BLEEDING THAT I WENT TO THE EMERGENCY ROOM OVER LIKE 2 STRAIGHT WEEKS OF BLEEDING. THE EMERGENCY ROOM GAVE ME MEDICINE TO STOP THE UTERINE BLEEDING. I HAD X-RAYS DONE AT THE TIME OF THE BLEEDING AND THE COILS WERE STILL IN PLACE. THEN I HAD THE HSG TEST DONE AND THEY PUT IN THE DYE AND SAID I WAS BLOCKED. I'VE HAD PAINS EVER SINCE I TRIED GOING BACK TO MY DOCTOR AND THEY TOLD ME THAT THEY DIDN'T DO IT THERE ANYMORE, THAT I'D HAVE TO GO TO THE HOSPITAL FOR ANYTHING. NOW I CAN'T EVEN HAVE SEX; IT HURTS MY SIDES AND LOWER BACK. I'VE HAD BLOOD CLOTS ABOUT 2 CM LONG AND 1 CM WIDE EVERYTIME I USE THE RESTROOM ON MY PERIOD AND I HAVE ANEMIA. I CAN'T KEEP IRON. I DO NOT USE ANY OTHER MEDICATION. I TAKE MIDOL FOR ALL OF THE CRAMPING BUT IT DOES NOT WORK. SO I STOPPED TAKING IT. FATIGUE IS THE WORST. I HAVE 3 KIDS AND ONE IS AUTISTIC WHICH TAKES UP A LOT OF MY TIME AND SINCE I'VE HAD ESSURE I'VE BEEN IN PAIN AND JUST FLAT TIRED (JUST WANT TO SLEEP). I HAD ESSURE IMPLANTED BECAUSE OF THE CHILDREN I ALREADY HAVE AS WELL AS IT WAS EASIER THAN TYING MY TUBES BUT I WISHED I WOULD HAVE WENT WITH THAT. I HAVE PAIN IN MY SIDES LAYING DOWN, SITTING A CERTAIN WAY, CAN'T GET TO THE RESTROOM FAST ENOUGH, USING THE RESTROOM, EVEN STANDING UP FOR LONG PERIODS OR BENDING TO PICK UP SOMETHING OR JUST TO TIE MY SHOES. I HAVE REALLY BAD MIGRAINES THAT I TAKE EXCEDRIN FOR. I HAVE DULL BACK ACHES THAT JUST SIT AND FEELS LIKE A SORE MUSCLE THAT JUST ACHES. SOMETIMES I FEEL LIKE I CAN'T GET ALL OF MY PEE OUT WHEN I USE THE RESTROOM. SOMETIMES WHEN I USE THE RESTROOM, I SIT THERE BECAUSE MY STOMACH ACHES IN MY SIDES. IT'S CRAMPED SO HARD IN MY SIDES THAT MY ACTUAL

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VAGINA HURTS AND FEELS LIKE IT'S GOING TO FALL OUT. THE DOCTOR SAID I HAD A SMALL ANATOMY SO I'M CONCERNED IF THE COILS HAVE SHIFTED BECAUSE I FEEL STABBING PAINS AT TIMES WHEN I BEND.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035506	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 5/14/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED (B)(6) 2013. ON (B)(6) 2013 I HAS SEVERE PELVIC PAIN AND BLEEDING. WAS IN ER 3XS WITHIN THE WEEK OF BEING IMPLANTED. SYMPTOMS INCLUDED: SEVERE PAIN, BLEEDING, UNABLE TO EAT OR DRINK, SUICIDAL THOUGHTS, EXTREME NAUSEA DIZZINESS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035507	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 1/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WENT TO THE HOSPITAL WITH LOWER ABDOMINAL PAIN, VAGINAL PRESSURE AND ANAL PRESSURE. AFTER A CAT SCAN AND OTHER TEST, I WAS TOLD I HAD A BLADDER, KIDNEY AND WAS SEPTIC. I ALSO HAD 2 ABDOMINAL STAPH ABSCESSES. AFTER 6 DAYS IN THE HOSPITAL, I WENT HOME ON IV ANTIBIOTIC FOR 15 DAY THEN HAD A PARTIAL HYSTERECTOMY. THE RESULTS WHERE THAT THE STAPH INFECTION STARTED IN MY FALLOPIAN TUBE WHERE ESSURE WAS PLACED. I AM NOW SCHEDULED FOR A FULL HYSTERECTOMY NEXT TUESDAY DUE TO SEVERE PAIN ON MY OTHER SIDE AND BACK. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035508	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOUND OUT I WAS PREGNANT AFTER HAVING ESSURE IMPLANTED IN (B)(6) 2011. I ALSO HAD MY HSG IN (B)(6) OF 2012 THAT CONFIRMED 100% BLOCKAGE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035509	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 2/16/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED TO HAVE SHARP PAINS ON MY RIGHT PELVIC AREA , HEAVY PERIODS FOR 7 DAY SOMETIMES TWICE A MONTH, TINGLY HANDS, JOINT PAIN , HAIR LOSS , WEIGHT GAIN , BLOATING, FEEL DIZZY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035510	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 2/4/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED WITH BACK PAIN WHEN I WOKE UP. AFTER IBUPROFEN AND TIME MOVING AROUND IT WOULD EASE. NOW I'M TAKING NORCO AND SKELAXIN ON TOP OF IBUPROFEN TO TRY TO CONTROL WHAT HAS BECOME CONSTANT SOMETIMES UNBEARABLE PAIN. I HAVE CRAMPS IN MY CALF MUSCLES. I HAVE GAINED 20 POUNDS. I AM TIRED ALL THE TIME AND HAVE ZERO SEX DRIVE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035511	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD A HYSTERECTOMY AT AGE (B)(6) BECAUSE OF PAIN, BLOATING, EXCESSIVE BLEEDING, AFTER HAVING ESSURE PUT IN 2 YEARS BEFORE AND HAD BEEN DEALING WITH THE PAIN THAT LONG. AFTER NORMAL; PAINS FROM HYSTERECTOMY STOPPED. HAD NO MORE PAINS FROM THE HYSTERECTOMY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035512	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 10/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED ON (B)(6) 2012. I HAD CONTINUOUS BLEEDING FOR TWO OR THREE MONTHS, SO MY DOCTOR PRESCRIBED ESTROGEN. IN (B)(6) 2013, I WENT BACK TO MY DOCTOR DUE TO CHRONIC RIGHT SIDED PAIN AND HE DIAGNOSED ME WITH A UTERINE INFECTION AND PUT ME ON DOXYCYLINE AND GAVE ME AN INJECTION OF ROCEPHIN. I WENT BACK TO THE DOCTOR (B)(6) 2013 WITH THE SAME SIDE EFFECTS. I WAS PUT ON ANOTHER ORAL ANTIBIOTIC AND GIVEN ANOTHER INJECTION. I ASKED THE DOCTOR WHAT WOULD KEEP CAUSING UTERINE INFECTIONS AND HE DID NOT KNOW. IN (B)(6) 2013, I STARTED HAVING JOINT PAIN IN MY LEFT SHOULDER AND AFTER A COUPLE OF MONTHS WENT TO SEE A ORTHOPEDIC DOCTOR, HE PUT ME ON VOLTAREN FOR MY PAIN AND DIAGNOSED ME WITH SHOULDER IMPINGEMENT BUT I WAS UNABLE TO TAKE MEDS DUE TO STOMACH UPSET. THE PAIN IN MY RIGHT SHOULDER JOINT STOPPED HURTING A COUPLE OF MONTHS LATER. MY RIGHT SHOULDER STARTED HURTING NOT LONG AFTER AND STILL CONTINUES TO HURT UNTIL THIS DAY. I HAVE TROUBLE SLEEPING DUE TO THE PAIN. I BELIEVE THIS IS DUE TO THE INFLAMMATION CAUSED BY ESSURE. I NEVER HAD A PROBLEM WITH THIS BEFORE. I ALSO HAVE HAD A LOT OF WEIGHT GAIN AND BLOATING ALL IN MY ABDOMINAL AREA. I HAVE BEEN SEEING A CHIROPRACTOR DUE TO CHRONIC LOWER BACK AND RIGHT LEG PAIN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035513	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE ON (B)(6), 2013. I HAD AN HSG TEST DONE 3 MONTHS LATER TO CONFIRM 100% BLOCKAGE. SINCE (B)(6) 2013 I HAVE EXPERIENCED EXTREME STABBING PAINS IN MY LEFT FALLOPIAN TUBE, TERRIBLE MOOD SWINGS, EXTREME ANXIETY AND DEPRESSION IN WHICH I NEEDED TO SEEK COUNSELING AND A PRESCRIPTION OF XANAX. I ALSO HAVE EXPERIENCED ON A DAILY BASIS, BLADDER ISSUES. I HAVE PROBLEMS GOING TO THE BATHROOM, PROBLEMS EMPTYING MY BLADDER, LEAKAGE, AND PAIN WHILE URINATING. I AM CONSTANTLY TIRED. I AM CONSTANTLY BATTLING HEADACHES AND SINUS INFECTIONS. MY BODY IS SORE LIKE IT'S FIGHTING OFF AN ILLNESS EVERY SINGLE DAY. MY MENSTRUAL CRAMPS ARE EXTREMELY PAINFUL AS WELL. THESE SYMPTOMS ARE AFFECTING MY LIFE AS A MOTHER AND WIFE. I REGRET EVER GETTING THIS PRODUCT IMPLANTED IN MY BODY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035514	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BEGAN HAVING CONSTANT PELVIC PAINS. SOME DEBILITATING. THE PAINS WOULD GO FROM THE PELVIS TO MY BACK. ABNORMAL BLEEDING WOULD GET MENSTRUAL PERIODS TWICE A MONTH, BLEED THROUGH TAMPONS AND PADS. SOMETIMES, WOULD NOT GET PERIODS. CONSTANT BLOATING. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035515	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 3/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2010. THE SAME DAY I HAD THE PROCEDURE, I NOTICED SOME BLEEDING, THE BLEEDING KEPT GETTING WORSE AND WAS VERY HEAVY, IT LASTED FOR 5 MONTHS STRAIGHT UNTIL MY OB/GYN PRESCRIBED ME SOME MEDICATION TO HELP WITH THE BLEEDING AND DUE TO THE CONSTANT BLEEDING I AM NOW ANEMIC. I STARTED HAVING SEVERE STOMACH CRAMPING AFTER THE BLEEDING STOPPED, IT'D GET SO BAD I WOULD LITERALLY BE IN THE FETAL POSITION ON THE FLOOR CRYING IN PAIN. I'VE HAD PROBLEMS WITH MY MENSTRUAL CYCLE EVER SINCE. BEFORE ESSURE, MY PERIODS CAME ON TIME AND WERE MODERATELY HEAVY, AFTER ESSURE, MY PERIODS HAVE BEEN EXTREMELY HEAVY WITH A LOT OF CLOTTING AND ON THE HEAVIEST DAYS, I WILL GO THROUGH AN ESTIMATED 3-4 OVER NIGHT PADS IN 1 HOURS TIME, THIS IS EVERY HOUR! IT WASN'T UNTIL (B)(6) 2013 THAT THE PAIN REALLY STARTED TO SET IN AND KEEPS GETTING CONSTANT WITHOUT STOPPING. ON A DAILY BASIS, I HAVE PELVIC PAIN WHERE THE COILS ARE IMPLANTED, SHARP PAINS BEHIND MY BELLY BUTTON AND ON THE LEFT SIDE OF MY BELLY BUTTON THAT GET SO INTENSE I CAN'T GO ANYWHERE OR DO ANYTHING EXCEPT LAY DOWN. I STAY BLOATED, I RUN RANDOM FEVERS FOR NO REASON, I HAVE ABDOMINAL SPASMS AND TWITCHING, I HAVE DIZZY SPELLS, NAUSEA, INSOMNIA, DAILY HEADACHES, MUSCLE SPASMS, NUMBNESS IN MY ARMS AND LEGS, HAIR LOSS, MOOD SWINGS, FORGETFULNESS, BRUISE EASILY, CONSTANT DIARRHEA/CONSTIPATION, I HAVE HEAVY VAGINAL DISCHARGE THAT IS CONSTANT WHICH I NEVER HAD BEFORE ESSURE, AND I HAVE FREQUENT PANIC ATTACKS WITH ANXIETY. I WAS NEVER TESTED FOR A NICKLE ALLERGY, MY DOCTOR AT THE TIME NEVER MENTIONED ANY RISKS OF HAVING AN ALLERGIC REACTION TO NICKLE. I AM HIGHLY ALLERGIC TO JEWELRY AND CERTAIN METALS! I STAY FATIGUE ON A DAILY BASIS WITH LITTLE TO NO ENERGY AT ALL, I USE TO BE VERY ACTIVE AND WAS ALWAYS ON THE GO, BUT NOW MY ENERGY LEVEL IS SO LOW I'M LUCKY IF I GET OUT OF THE HOUSE 3 TIMES A

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MONTH. SINCE MY ESSURE PROCEDURE WAS DONE, I HAVE NOTICED A LOT OF NEGATIVE CHANGES WITH MY BODY. IT SEEMS AS THOUGH THE MORE TIME THAT PASSES WITH THESE COILS INSIDE OF ME, THE WORSE MY SYMPTOMS BECOME. I USE TO BE AN ACTIVE, HEALTHY WOMAN WHO LOVED LIFE, BUT NOW EVERY THING HAS CHANGED. I BLAME ESSURE BECAUSE BEFORE ESSURE I WAS ABSOLUTELY FINE. LIFE AFTER ESSURE HAS BEEN ONE DEVASTATING EVENT AFTER ANOTHER. I'M TIRED OF LIVING IN PAIN EVERY DAY AND FEELING THE CHRONIC PAINS IN MY PELVIC AREA. THIS IS NOT NORMAL AND SHOULD NOT BE TAKEN LIGHTLY.(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035516	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 12/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DAY OF THE IMPLANT, MY STOMACH SWELLED UP LIKE I WAS SEVEN MONTHS PREGNANT. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035517	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 11/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE ON (B)(6), 2012. AFTERWARDS I EXPERIENCED SEVERE CRAMPING AND VERY HEAVY BLEEDING. THE CRAMPING FINALLY SUBSIDED BUT I CONTINUED TO HAVE EPISODES OF SEVERE STABBING PAIN IN MY RIGHT LOWER QUADRANT. FINALLY ON (B)(6), 2014 THE PAIN BECAME UNMANAGEABLE AND I WENT TO THE HOSPITAL. THEY WEREN'T ABLE TO FIND ANYTHING WRONG EXCEPT THE ESSURE. THE PAIN HAS NOT LET UP AND I'M IN CONSTANT DEBILITATING PAIN. MY OBGYN HAS AGREED TO GIVE ME A HYSTERECTOMY TO REMOVE THE ESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035518	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 3/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLOATED, HEAVY PERIODS, PELVIC PAIN, ABDOMINAL PAIN, JOINT PAIN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035519	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 4/29/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NOT TOO LONG AFTER MY IMPLANTATION ((B)(6) 2009) I STARTED TO EXPERIENCE PAIN IN MY PELVIC REGION. I WOULD SIT DOWN AND COULD FEEL AS IF THERE WAS POKING FROM THE INSIDE OF MY BODY. I LET MY DR KNOW ABOUT THIS AND HE SAID ITS NOT THE ESSURE AND HE COULDN'T FEEL IT. FROM THAT POINT THERE WAS A MONTH I BLED FOR TWO WEEKS. THIS HAS NEVER HAPPENED EVER UNTIL ESSURE. VISIT TO IMPLANTING DR AND HE SAID PROBABLY HORMONES BUT NEVER CHECKED MY BLOOD FOR IT. I HAD MY CR SALPINGO HYSTEROSALP W INJ ON (B)(6) 2009 COMPLETE OCCLUSION OF BILATERAL FALLOPIAN TUBES NOTED. ER VISIT ON (B)(6) 2009 FOR EXTREME NAUSEA AND DISORIENTATION. HAD WHITE SPOTS INSIDE MOUTH AND CHEEKS. I HAD TWO SMALL GLASSES OF WINE AND FELT EXTREMELY DRUNK. THIS HAS NEVER HAPPENED BEFORE EITHER OFF OF TWO GLASSES OF WINE. (COME TO FIND OUT I AM SEVERELY ALLERGIC TO NICKEL TEST CONFIRMED (B)(6) 2013 AND THIS IS A PROBABLE CAUSE "ALCOHOL INTOLERANCE" LIVER WORKING OVERTIME TO EXPEL THE NICKEL AND ALCOHOL). HAD STARTED HAVING ABDOMINAL PAINS AND PROBLEMS WITH FOOD FEELING LIKE IT WAS STUCK UNDER MY STERNUM, SO PCP REFERRED ME TO HAVE A CR UPPER GI UGI SERIES STOMACH AND US ABD LIMITED ON (B)(6) 2010 EVERYTHING NORMAL. THEN I WAS REFERRED TO DR (B)(6) FOR AN ESOPHAGOGASTRODUODENOSCOPY WITH BIOPSY ON (B)(6) 2010, NO FINDINGS OF ANYTHING ABNORMAL(STILL CONTINUE TO HAVE ISSUES TO PRESENT DATE). STILL HAVING PAIN IN MY ABDOMEN AND LEFT SIDE AND PAINS THAT SHOOT DOWN MY LEFT LEG. IN BETWEEN THESE DATES I HAD BEEN EXPERIENCING BRAIN ZAPS AS I CALL THEM. FEELS LIKE ELECTRICITY SHOOTING FROM TOP OF MY HEAD DOWN AN INCH OR TWO INTO MY BRAIN. I HAD ALSO GONE TO DR FOR LOSS OF PERIPHERAL VISION FOR A PERIOD OF 45 MINS 2 TIMES WITHIN 2 MONTHS AND CONTINUING OF BLURRED VISION. NO FINDINGS OF CAUSE THERE EITHER. ON (B)(6) 2012 I HAD XRAYS OF BOTH FEET BECAUSE OF UNBEARABLE PAIN AND BURNING ON BOTH

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BOTTOMS OF MY FEET. THIS LASTED FOR ALMOST 2 WEEKS. I COULD BARELY WALK. NOTHING FOUND ON XRAY. I ALSO HAD BEEN EXPERIENCING JOINT PAIN IN ANKLES, KNEES, WRIST AND HANDS. ON (B)(6) 2012 I HAD AN ER VISIT FOR THE SAME LEFT SIDE ABDOMINAL PAIN THAT HAD BEEN AT AN UNBEARABLE LEVEL FOR ALMOST A MONTH. NOTHING OUT OF ORDINARY WAS FOUND. I HAD A CT ABDOMEN WITH CONTRAST. THE ONLY THING THAT WAS ABNORMAL WAS A PROBABLE 1.8CM HEPATIC HEMANGIOMA ON MY LIVER SEGMENT 6. ALL ALONG I STILL HAD BEEN HAVING HEAVY MENSTRUATION AND LARGE BLOOD CLOTS. I HAVE ALSO BEEN EXPERIENCING EXTREME FATIGUE, SEVERE MOOD SWINGS AND IN PAST ONE AND A HALF YEARS BRAIN FOG AND MEMORY LOSS. I HAVE ALSO NOTICED MY HAIR LINE RECEDING. I HAVE ALSO HAD RAPID TOOTH DECAY AND GUM ISSUES. I FINALLY BEGGED MY NEW OB/GYN TO REFER ME TO AN ALLERGIST BECAUSE WITH ALL THESE SYMPTOMS I WAS PIECING TOGETHER LOOKED AS IF I WAS ALLERGIC TO NICKEL. I HAD SEEN THE ALLERGIST AND HE AGREED THAT ALL MY SYMPTOMS COULD BE FROM ALLERGIC REACTION TO NICKEL. HE TESTED ME AND THE FINDINGS WERE I HAVE ++ STRONG REACTION TO NICKEL. HE SAID THAT I SHOULD NOT HAVE ANY DEVICE IN ME THAT CONTAINS ANY AMOUNT OF NICKEL IN IT. I HAVE ALSO HAD EXTREMELY COLD HANDS AND FEET THAT WILL TURN PURPLE AT TIMES. THINKING THIS IS BECAUSE OF MY NICKEL OVERLOAD FROM ESSURE. I ALSO HAVE BEEN EXPERIENCING TACHYCARDIA.. I WILL BE HAVING ESSURE REMOVAL AT SOME POINT IN TIME IN THE NEXT MONTH OR SO. I AM NOT SURE IF I WILL BE ABLE TO KEEP MY UTERUS UNTIL THE DR GOES IN AND SEES THE DAMAGE THE COILS HAVE CAUSED. I WILL BE FILING ANOTHER REPORT AFTER REMOVAL. THANK YOU

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035520	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 1/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEART PALPITATIONS. HIGH BLOOD PRESSURE. INSOMNIA. CRAMPING / PERIODIC HEAVY BLEEDING. EYE TWITCHING. DIZZINESS. RINGING IN EARS. NUMBNESS. CHEST PAIN. NIGHT SWEATS. ACNE. UNEXPLAINED ALLERGIC REACTIONS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035522	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 6/7/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2007. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMERLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2007. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE ~ DAILY CONSTANT MIGRAINES; SEVERE PELVIC PAIN; SHARP SHOOTING PAINS AROUND ESSURE AREA; SHOOTING PAINS IN UTERUS, CERVIX, DOWN THRU VAGINA AND INTO LEGS; MOOD SWINGS; DEPRESSION; ANXIETY; LOSS OF FOCUS; WEIGHT GAIN 40 LBS+; TROUBLE WITH VISION; MEMORY LOSS; BLOATING; INFLAMMATION; EXTREME FATIGUE; EXCESSIVE BLEEDING; ABNORMAL PERIODS; LOWER BACK PAIN; JOINT PAIN; LOW GRADE FEVERS; CRAMPING; OVARIAN CYSTS; CERVICAL CYSTS; HOT FLASHES; MUSCLE ACHES; INSOMNIA; FEELING "FLU LIKE" ALL THE TIME; PAIN DURING INTERCOURSE; BLOOD CLOTS; SHARP STABBING PAINS; ABNORMAL MENSES; VITAMIN D DEFICIENT; RECURRING YEAST INFECTIONS AND BACTERIAL INFECTIONS; NAUSEA, DIZZINESS; HEARTBURN; CHEST PAIN; CLOUDINESS; FORGETFULNESS; HEART PALPITATIONS; FOUL SMELL AND DISCHARGE; POLYPS; SCAR TISSUE BETWEEN UTERUS, GALL BLADDER AND BOWELS. ALL WERE ATTACHED. I HAVE BEEN SEEN BY 2 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS. THE DEVICE HAS BEEN REMOVED ON (B)(6) 2014. THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035539	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 4/29/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE JUST FELT REALLY BAD SINCE HAVING ESSURE PLACEMENT. I FEEL TIRED, SORE AND JUST DRAINED SINCE HAVING ESSURE. I BLEED ALL THE TIME AND HAVE REALLY BAD CRAMPS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035540	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 4/11/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED ON (B)(6), 2005. I COULD FEEL THE COILS IN MY TUBES. THIS WAS PAINFUL FOR ME ESPECIALLY DURING INTERCOURSE. I ALSO STARTED HAVING LONGER AND STRONGER PERIODS. HEAVY BLEEDING WITH BLOOD CLOTS FOR MANY YEARS UNTIL I HAD A FULL HYSTERECTOMY ON (B)(6), 2013. DUE TO HAVING TO HAVE A HYSTERECTOMY, I CAN NO LONGER HAVE SEX DUE TO COMPLICATIONS. I HAVE PAIN EVERYDAY DUE TO MY BLADDER DROPPING AFTER MY HYSTERECTOMY. CRYING IS A DAILY OCCURRENCE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035541	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 12/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DONE IN 2008. WHILE IN THE BEGINNING I THOUGHT THINGS HAD GONE SMOOTHLY HOWEVER THAT WAS NOT THE CASE. ONE SIDE WAS CLOSED IN 3 MONTHS IT TOOK THE OTHER SIDE 1 YEAR FOR IT TO BE CLOSED THROUGH THE HSG TEST. I WAS NEVER ONE TO HAVE HEAVY PERIODS OR HAVE ANY CRAMPING OF ANY KIND. HOWEVER AFTER THE PROCEDURE I WOULD HAVE HEAVY PERIOD AND WOULD HAVE SEVERE CRAMPS. MY REGULAR CYCLE WOULD BE 3 DAYS, IT TURNED TO 5-7 DAYS. I STARTED GAINING WEIGHT, STARTED GETTING ANXIETY, SHORT TEMPER, I HAVE SHARP PAINS CONSTANTLY WHERE MY COILS ARE, I HAVE HAD 2 ESSURE PREGNANCIES AND GAVE BIRTH TO 2 BABIES. MY PREGNANCIES WERE HARD AND I HAD CERVICAL CANCER A YEAR AFTER GETTING THE PROCEDURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035542	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 2/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2013....I HAVE REPORTED SEVERAL SIDE EFFECTS ON HERE AND THEY NEVER SHOW UP SO I CANT GO IN AND MODIFY. I HAVE HAD SEVERE STOMACH PAINS CONSTANTLY, BV, I AM IN MENOPAUSE AT (B)(6), I HAVE HOT FLASHES CONSTANTLY. I LOOK PREGNANT AND I'VE NEVER BEEN PREGNANT DUE TO BLOATING! CONSTANTLY TIRED AND I BREAK OUT WITH LITTLE PIMPLES EVERYWHERE. NEVER HAD ANY PROBLEMS UNTIL AFTER ESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035543	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 2/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE IN (B)(6) 2010, CANT REMEMBER THE DAY BUT IT WAS (B)(6) 2010. I WENT IN TO MY DOCTORS OFFICE AND MY DOCTOR PUT IT IN. I WASN'T PUT TO SLEEP. EVERYTHING WENT WELL. I STARTED TO HAVE PAIN A FEW MONTHS TO A YEAR LATER, PAIN IN MY FEMALE PARTS, HIP, BACK, LEGS, CHEST, HEAD. I STILL HAVE ALL OF THESE. I ALSO HAVE OTHER PROBLEMS SUCH AS FORGETTING A LOT OF THINGS AND MORE. MY (B)(6) WAS CUT OUT AROUND THE MONTH OF (B)(6). I HAVE NOT BEEN ABLE TO GO TO THE DOCTOR MUCH OTHER THE ER A FEW TIMES FOR PAIN IN MY BACK. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035544	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 4/16/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, RASH OUTBREAKS, BLOATING. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035545	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 6/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DAY AFTER ESSURE WAS IMPLANTED I STARTED GETTING PELVIC PAIN, ABDOMINAL PAIN, CHEST TIGHTNESS, FOGGED MIND, BLEEDING FOR MONTHS AT A TIME, HAIR LOSS IN LARGE AMOUNTS, STOMACH BLOATING LOOKING LIKE I WAS NINE MONTHS PREGNANT, HEADACHES, JOINT PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035546	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NICKEL SENSITIVITY, NAUSEA, FEVER, BLOATING, IRREGULAR PERIODS, HEAVY BLEEDING, WEIGHT GAIN, DIZZINESS, ACNE, LOWER BACK PAIN, SEVERE CRAMPING, FATIGUE, JOINT PAIN, HIVES AND HYSTERECTOMY REMOVING TUBES, DEVICES, UTERUS AND CERVIX. (B)(6) 2013. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035547	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 5/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. I HAVE MY ESSURE CARD BUT IT DOES NOT CONTAIN THE LOT NUMBER OR MODEL NUMBER AS IT SHOULD. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON THE DAY OF IMPLANTATION, (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: MIGRAINES, LOWER BACK PAIN (CONSTANT), PELVIC PAIN, PAINFUL OVULATION RESULTING IN AN INABILITY TO PERFORM NORMAL DAILY TASKS DUE TO THE AMOUNT OF PAIN, GI UPSET (VOMITING AND DIARRHEA), CONSTANT SPOTTING, HIVE LIKE RASH COVERING NECK, BACK, TORSO, PELVIC REGION WHICH BEGAN HOURS AFTER IMPLANTATION AND DID NOT GO AWAY UNTIL I HAD THE DEVICE REMOVED IN (B)(6) 2013, CERVICAL DYSPLASIA (ABNORMAL CELLS ON THE CERVIX WHICH RESULTED IN TWO SURGICAL PROCEDURES SO FAR, AS OF TODAY (B)(6) 2014. THERE IS NO HPV, NO HISTORY OF HPV AND NEVER HAD AN ABNORMAL PAP IN MY ENTIRE LIFE UNTIL AFTER ESSURE. MY PAP SMEAR IMMEDIATELY BEFORE ESSURE WAS IMPLANTED WAS NORMAL, 16 MONTHS LATER, IT'S PRE-CANCEROUS ((B)(6) 2013) I HAVE BEEN SEEN BY 3 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: ALLERGIC REACTION TO ESSURE DEVICE, CERVICAL DYSPLASIA. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: COLPOSCOPY, LEEP, REMOVAL OF ESSURE AND PART OF BOTH FALLOPIAN TUBES WITH TUBAL ANASTOMOSIS. THE DEVICE HAS BEEN REMOVED AS OF NOVEMBER (B)(6) 2013. THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER. THE DEVICE WAS IN MY POSSESSION AND HAS BEEN SENT TO A LAB FOR METAL TESTING. (B)(4).

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035548	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 10/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING LEFT LOWER ABDOMEN PAIN FOR ABOUT TWO MONTHS ALMOST CRAMPING LIKE AFTER TWO MONTHS IT MOVED DOWN TO THE LOWER QUADRANT OF THE ABDOMEN THE CREASE BETWEEN THIGH AND ABDOMEN AND NOW FEELS LIKE THE PAIN IS IN MY HIPS. IT HURTS TO WALK AND EVEN JUST SIT AROUND THE PAIN IS CONSTANT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035549	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 12/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED PRESENTING RADON UNKNOWN RASHES ON MY LOWER BACK AND BELLY. WITHIN A FEW WEEKS I STARTED HAVING HIVES ON ARMS, INNER LEGS, LOWER BACK; CRAMPING WHEN GETTING MY PERIOD; A GREENISH DISCHARGE OUT OF MY VAGINA THAT ALWAYS TESTS NEGATIVE; HEAVY BLEEDING; DEVELOPED A NASTY METAL TASTE IN MY MOUTH ESPECIALLY WHEN HAVING A GLASS OF WINE AND WHEN EATING FISH; THEN I DEVELOPED SWOLLEN JELLY LOOKING ON THE CONJUNCTIVA OF THE EYE WHICH AFTER BEING IN THE ER TWICE THE URGENT CARE AND OPHTHALMOLOGIST 5 TIMES IN A PERIOD OF 3 MONTH THEY SAID IT LOOKED LIKE CONJUNCTIVITIS BUT NOT ONE MEDICINE PRESCRIBED BROUGHT ANY COMFORT OR RELIEF FOR 3 SOLID MONTHS. THEN WHEN I WENT TO MY REGULAR DOCTOR HE FOUND MY VITAMIN D BEING IN AN ALARMING 8. THEN I STARTED DEVELOPING MINOR CLOUDINESS, DIZZINESS, NUMBNESS IN MY LEGS, FEET, HANDS AND ARMS; LEG PAIN; MASSIVE TEETH ISSUES - MOST OF MY MOLARS STARTED CHIPPING. I STARTED GETTING TERRIBLE CAVITIES THAT WERE DETERIORATING MY TEETH REALLY FAST; JOIN PAIN, FLU-LIKE SYMPTOMS VERY OFTEN WITH NO FEVER PRESENT. THEN DEPRESSION KICKED IN; INSOMNIA. WITHIN A FEW MONTHS OF FEELING A BIT BETTER I STARTED HAVING CHEST PAINS, HEADACHES AND MIGRAINES WHICH I HAD NEVER IN MY LIFE EXPERIENCED, HEART PALPITATIONS, ANXIETY, PANIC ATTACKS, STARTED HAVING BLOOD CLOTS WHEN HAVING PERIOD, FATIGUE EVERY DAY, SHARP STABBING PAIN ESPECIALLY ON MY RIGHT SIDE OF MY ABDOMEN, VERY PAINFUL OVULATION THAT WILL TOTALLY DISABLE ME, INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035550	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 8/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMERLY BY CONCEPTUS INC. MY LOT NUMBER IS 893038 MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. WEIGHT LOSS; PELVIC AND VAGINAL PAIN; IRREGULAR AND ABNORMAL MENSES; ABDOMINAL PAIN; FLANK PAIN; PAIN IN LIMBS; CHEST PAIN; HEART PALPITATIONS; DIZZINESS; NUMBNESS AND/OR TINGLING IN LIMBS AND FACE; RASH; METALLIC TASTE IN MOUTH; DIFFICULTY WITH MEMORY; SWELLING AND INFLAMMATION OF VEINS; (B)(6); WEAKNESS; SHORTNESS OF BREATH; IRRITATED AND DRY EYES; SORES IN EYES, NOSE, MOUTH; FEVER THAT COMES AND GOES; CHILLS; PAIN IN LYMPH NODES; MUSCLE ACHE; JOINT PAIN; BONE PAIN; PAINFUL INTERCOURSE; DIGESTIVE PROBLEMS. I HAVE BEEN SEEN BY 6 DOCTORS. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: SALPINGECTOMY. THE DEVICE HAS BEEN REMOVED (B)(6) 2012. I DO NOT KNOW IF THE DEVICE WAS RETURNED TO THE MANUFACTURER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035551	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE CALLED ESSURE ON (B)(6) 2011. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMERLY BY CONCEPTUS INC. MY LOT NUMBER IS 844600. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER, I DO NOT HAVE THE EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN (B)(6) 2011. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: MODERATE/CYSTIC ACNE, DIZZINESS, CHRONIC MIGRAINES, CHRONIC PELVIC PAIN, LOWER BACK PAIN, PAINFUL PERIODS, BREAK-THROUGH PERIODS, BLOATING, LOSS OF ENERGY, FIBROID MASS IN MY UTERUS, CYSTS IN MY OVARIES, AND THICKENING OF MY UTERINE LINING. I HAVE BEEN SEEN BY MY PCP AND REFERRED TO A GYNECOLOGIST. I HAVE BEEN DIAGNOSED WITH MIGRAINES, WHICH I AM CURRENTLY TAKING PROCHLORPERAZINE FOR. DYSMENORRHEA AND MENORRHAGIA HAVE BEEN ADDED TO MY LIST OF SYMPTOMS. I AM SCHEDULED FOR A HYSTERECTOMY ON (B)(6) 2014. THE DEVICE IS CURRENTLY STILL INSIDE ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035552	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 11/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I HAD PROCEDURE I HAVE BEEN IN THE WORST PAIN IT WAS DONE IN (B)(6) AND EVERY DR I SPOKE TO SAID IT WAS NOTHING ALSO SAID EVERYTHING WAS IN PLACE I RECENTLY FOUND OUT I AM 9 WEEKS PREGNANT AND EXCRUCIATING PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035553	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 8/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS IMPLANTED WITH THE ESSURE DEVICE. HAS CONTINUOUS BLEEDING FOR 7 MONTHS AND MUCH PAIN AND DISCOMFORT AND IN (B)(6) 2012 FOUND OUT I WAS PREGNANT. CURRENTLY STILL HAVE A MIGRATED COIL SOMEWHERE IN MY BODY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035554	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 3/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER MONTHS (YEARS) OF INCREASINGLY TROUBLESOME ABNORMAL UTERINE BLEEDING, PAIN, PAINFUL INTERCOURSE, ETC. A NEW GYN PROVIDER REQUESTED A TRANSVAGINAL ULTRASOUND. THE RESULTS SHOW THAT BOTH ESSURE DEVICES ARE EXTENDED INTO MY UTERUS, CAUSING THE SYMPTOMS I MENTION ABOVE. I AM TOLD THAT WHILE IN EVERY OTHER REGARD I AM HEALTHY WITH NO FIBROIDS OR CYSTS, A HYSTERECTOMY IS REQUIRED TO REMOVE THE ESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035555	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 3/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE SYMPTOMS: HEADACHES THAT LAST FOR 5-10 DAYS - I'VE HAD A HEADACHE EVERY DAY FOR OVER A YEAR, DAYS WITHOUT ONE ARE RARE. CHEST PAINS THAT HAPPEN EVERY OTHER DAY. CRUNCHING IN THROAT WHEN SWALLOWING. DIARRHEA THE WHOLE DAY BEFORE I START MY PERIOD, LIKE CLOCKWORK FOR THE LAST YEAR. HORRIBLE MENSTRUAL PAIN. BLOOD CLOTS THE SIZE OF GOLF BALLS AND AS LONG AS A SHARPIE. PERIOD ENDS - OFF FOR TWO OR THREE DAYS, 4TH DAY PERIOD STARTS AGAIN, BY MID-DAY TO NIGHT TIME BLOOD IS DARK BROWN, OLD. DEBILITATING BACK PAIN. SHARP PAINS IN AREA OF COILS, BOTH SIDES. POPPING SENSATION WHEN BENDING OVER. FEELS LIKE RIPPING MUSCLES WHEN ON MY STOMACH ASLEEP AND ATTEMPTING TO ROLL OVER AND ALSO WHEN SITTING AND LAYING BACK, THEN TRY AND SIT UP QUICKLY. FEELS LIKE WHEN I WAS 9 MONTHS PREGNANT AND MY STOMACH MUSCLES WERE STRETCHED OUT AND I WOULD TRY TO SIT UP AND IT WAS LIKE A CHARLIE HORSE IN MY WHOLE ABDOMEN. THESE HAPPEN EVERY SINGLE DAY AND EVERY SINGLE NIGHT. BOILS ON MY INSIDE GROIN AREA THAT COME AND GO. BEEN HAPPENING FOR ABOUT TWO YEARS NOW. SMALL BUMPS, NOT LIKE A PIMPLE BUT LIKE A CALLUS THAT ITCH LIKE CRAZY. ONLY ON MY HANDS FOR ABOUT THREE YEARS UNTIL NOW ((B)(6) 2013) THEY HAVE STARTED ON MY FEET. LEFT FOOT TO BE EXACT. ON BOTTOM AND IN BETWEEN TOES. PIMPLE LIKE BUMPS ON MY CHEST AND ARMS THAT DON'T SEEM TO BE PIMPLES. JUST BUMPS THAT LAST FOR WEEKS AND THEN SCAR. HAIR HAS FALLEN OUT IN HANDFULS. IT HAS BROKEN TWO VACUUM CLEANERS AND I DAILY PULL HAIR BALLS OUT OF ALL THE LAUNDRY. I CLEAN MY HAIRBRUSH OUT ONCE A WEEK BECAUSE IT IS COMPLETELY FULL. MY HAIR WAS SO THICK AT ONE TIME I COULD ONLY PUT A SCRUNCHEE AROUND ONE TIME. NOW I CAN WRAP ONE AROUND THREE TIMES AND IT'S STILL LOOSE. I GET A FEELING OF A BABY KICKING. THIS HAS BEEN GOING ON FOR 2 1/2 YEARS. I FEEL A PAIN THAT SEEMS CONNECTED FROM THE INSIDE OF MY BELLY BUTTON TO MY VAGINA. IT

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MAKES ME FEEL LIKE I HAVE TO SLUMP OVER BECAUSE IF I SIT STRAIGHT UP IT PULLS AND HURTS UNCONTROLLABLY LIKE IT'S CONNECTED. THIS HAPPENS ABOUT 4-6 TIMES A MONTH. MY HEARTBEAT BECOMES IRREGULAR, VERY RAPID, IT TAKES MY BREATH AWAY AND MY FACE FEELS NUMB (FAT LIKE WHEN YOU LOSE CIRCULATION TO A FINGER) I CAN FEEL THE TIPS OF MY LIPS AND MY NOSE. TO STOP THIS I TAKE A DEEP BREATH IN, BUT IT'S WITH GREAT PRESSURE, A RESISTANCE. ITS HARD TO TAKE A DEEP BREATH BUT IT ALWAYS STOPS IT. EXCEPT ONCE. IT HAPPENED AT BEDTIME ONE NIGHT WHILE I WAS SAYING MY PRAYERS. I TOOK A DEEP BREATH AND FOR THE FIRST TIME IT DIDN'T STOP IT AND IT HURT (THE BREATH ITSELF). THIS HAPPENS 4 OR 5 TIMES A WEEK NOW. A DEEP THROBBING PAIN DEEP INSIDE MY EARS. THIS ONLY STARTED SINCE (B)(6) 2013. IT HAPPENS ALL THE TIME. NOT ENOUGH OF TO REALLY HURT BAD BUT A THROBBING PAIN LIKE A HEARTBEAT. NOT CONSTANT BUT WILL OCCUR MAYBE FOR ABOUT AN HOUR OR TWO AND THEN NOTHING UNTIL THE SEVERAL HOURS LATER OR SOMETIMES THE NEXT DAY. EXTREME WEIGHT GAIN. USED TO BE ABOUT (B)(6) NOW I WEIGH CLOSE TO (B)(6). VERY SWOLLEN ABDOMEN. LOOKS LIKE I'M PREGNANT. EXERCISE DOESN'T HELP. I'VE BEEN LIKE THIS FOR 2 YEARS. TODAY, (B)(6) 2013, I WAKE UP AND HAVE A LARGE LIGHT BROWN RASH ON MY LEFT CHEST EXTENDING DOWN TO MY BREAST. I THOUGHT MAYBE IT WAS BECAUSE I HAD JUST WOKEN UP AND WOULD GO AWAY. IT IS NOW NEARLY TEN AT NIGHT AND STILL THE SAME. DOESN'T ITCH, BURN OR ANYTHING. I WASHED IT. DIDN'T COME OFF. NOT STRETCHMARKS. DR KNEW I WAS HIGHLY ALLERGIC TO NICKEL, STAINLESS AND SURGICAL STEEL, AND EVERYTHING ELSE EXCEPT 24 KT GOLD. I CAN'T REALLY WEAR ANY JEWELRY BECAUSE OF THIS. I ASKED WHAT THIS WOULD DO INSIDE MY BODY, WAS TOLD I WOULD BE FINE. DIZZINESS, NAUSEATED, GET TOO HOT ALL THE TIME, CONSTANT CONSTIPATION, STOMACH HURTS SO BAD I WANT TO CRY, STOMACH HURTS ON THE RIGHT SIDE DIRECTLY AROUND THE BELLY BUTTON WHEN MY BLADDER IS EMPTYING (B)(6) 2013, RASH LIKE BUMPS ON THIGHS/ BOTTOM (B)(6) 2013, CYSTS ON LEGS AND WRISTS (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035556	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 8/29/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ABNORMAL PAINFUL PERIODS,HEAVY BLEEDING .CONSTANT SHARP PAINFUL STABBING PAINS. ALWAYS FEEL SICK AND NAUSEA. FEELS LIKE MY INSIDES ARE ON FIRE. PAINFUL INTERCOURSE. LOW TO NO ENERGY. EXTREME MOOD SWINGS. CONSTANT CRAMPING. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035557	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 6/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BROKE OUT WITH A RASH ON MY STOMACH SHORTLY AFTER IMPLANTATION. NOW I AM PREGNANT. I HAVE ALSO HAD A TREMENDOUS AMOUNT OF PAIN AND CRAMPING SINCE I HAVE HAD THIS DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035558	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 7/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL PAIN, MIGRAINES EVERYDAY CAUSING BLURRY VISION IT GETS SO BAD, FOUL SMELL FROM VAGINAL AREA, SEVERE PERIOD WHEN BEFORE I GOT ESSURE IT WAS VERY MANAGEABLE NOT I AM STUCK HOME FOR A WEEK IT IS SO BAD, CYST TYPE ACNE ON FACE, BACK, NECK, SCALP AND CHEST, NUMBNESS IN ARMS AND HANDS, DECREASE IN MOUTH HEALTH IT JUST CONFUSES MY DENTIST. MORE CAVITIES THAN I HAVE EVER HAD IN MY LIFE IN THE LAST YEAR SINCE ESSURE ALONG WITH MOUTH AND GUM SORES AND ISSUES, FORGETFULNESS, BRAIN FOG, LOSS OF MEMORY, LOSS OF SEX DRIVE, WEIGHT GAIN, HAIR LOSS, NO HAIR GROWTH AT ALL, TASTE IN MY MOUTH METALLIC, NO ENERGY WHAT SO EVER CAN'T EVEN SPEND TIME WITH MY CHILDREN, BLOATING, HOT FLASHES, JOINT PAIN,THE LIST GOES ON I COULD BE HERE ALL DAY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035563	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 4/2/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE IMPLANT FAILED AND DURING MY 3 MONTHS POST-PROCEDURE APPOINTMENT THE DOCTOR COULD STILL SEE DYE COMING OUT OF THE UTERINE TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035564	BAYER	4/9/2014	4/9/2014

Event Information:

Event Date (B3): 7/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD A TIA, WAS ADMITTED TO HOSPITAL FOR 4-5 DAYS. PAIN IN LOWER ABDOMINAL REGION ON AND OFF FOR 3 YEARS. HAD SEVERAL ULTRASOUNDS AND CAMERAS SENT DOWN TO STOMACH TO LOOK FOR PROBLEMS. MAJOR MOOD PROBLEMS, WEIGHT GAIN AND MIGRAINES THROUGHOUT THE LAST 3 YEARS. DIAGNOSED WITH HYPOTHYROIDISM (B)(6) 2013. DIAGNOSED WITH UTERINE FIBROIDS AND POLYCYSTIC OVARIAN SYNDROME (B)(6) 2014. EXCESSIVE PAIN AND DISCOMFORT IN 2013 AND 2014 IN PELVIC, LOWER ABDOMINAL REGION. MY GYNECOLOGIST IS DOING A HYSTERECTOMY DUE TO ALL MY PROBLEMS, REMOVING MY UTERUS, FALLOPIAN TUBES (ESSURE), AND CERVIX. SHE'S TRYING TO SAVE MY OVARIES EVEN WITH THE POLYCYSTIC OVARIAN SYNDROME. (I HAVE BIPOLAR DISORDER AND HAVE BEEN GETTING REGULAR TREATMENT SINCE 2002 WHICH IS NOT RELATED).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035599	BAYER	4/9/2014	4/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IS HORRIBLE. I GET PELVIC PAIN, HEAVIER/MORE PAINFUL PERIODS, HEADACHES, BACK PAIN, AND TIRED A LOT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00102	CONCEPTUS, INC.	4/9/2014	4/22/2014

Event Information:

Event Date (B3): 10/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/15/2012
Explant Date (E7): 3/3/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2012 THE PATIENT HAD ESSURE INSERTED. SHE WAS SEEN ON (B)(6) 2013 FOR THE PELVIC PAIN AND AGAIN ON (B)(6) 2013, WHEN THE PAIN WAS LABELED CHRONIC. SURGERY WAS DONE ON (B)(6) 2013 BY LAPAROTOMY AND USING WIRE CUTTERS TO REMOVE THE ESSURE BILATERALLY AND REMOVE PARTS OF BOTH FALLOPIAN TUBES FOR STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00104	BAYER HEALTHCARE LLC	4/9/2014	4/23/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76532

Single Use: Y
Implant Date (E6): 3/11/2014
Explant Date (E7): 3/14/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2014, ESSURE INSERTION WAS ATTEMPTED. THE PHYSICIAN WAS ATTEMPTING TO DO THE RIGHT SIDE AND ESSURE DID NOT RELEASE. HE HAD TO CUT THE DEVICE. ON (B)(6) 2014, LAPAROSCOPIC TUBAL LIGATION AND REMOVAL OF ESSURE (RIGHT SIDE) WERE PERFORMED. IT WAS REPORTED THAT THE REMOVAL WAS MEDICALLY NECESSARY. HYSTEROSCOPE WAS USED FOR THE ESSURE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00101	BAYER HEALTHCARE LLC	4/9/2014	4/24/2014

Event Information:

Event Date (B3): 2/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53550

Single Use: Y
Implant Date (E6): 10/14/2013
Explant Date (E7): 3/7/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2014 HYSTEROSALPINGOGRAM WAS PERFORMED. RIGHT DEVICE WAS IN CORRECT POSITION AND THE TUBE WAS OBSTRUCTED. LEFT IMPLANT WAS IN PERITONEAL CAVITY WITH NO EVIDENCE OF DAMAGE TO FALLOPIAN TUBE. LEFT FALLOPIAN TUBE WAS PATENT. PERFORATION WAS DENIED DURING INSERTION AND AFTER PROCEDURE. ON (B)(6) 2014 ESSURE WAS REMOVED BY LAPAROSCOPY (FLUOROSCOPY PRIOR TO LAPAROSCOPY INTRA-OPERATIVELY); IT WAS MEDICALLY NECESSARY. SIGNS AND SYMPTOMS OF INFECTION WERE NOT FOUND. DURING SURGERY, THE LEFT IMPLANT WAS IN THE PERITONEAL CAVITY ADHERED TO RECTOSIGMOID COLON. A TUBAL LIGATION WAS DONE VIA LAPAROSCOPY. ACCORDING TO THE PHYSICIAN, THERE WAS NO DAMAGE TO THE FALLOPIAN TUBE TO SUGGEST PERFORATION; MOST LIKELY EXPULSION OUT OF THE TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00103	BAYER HEALTHCARE LLC	4/9/2014	4/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2010 ESSURE WAS INSERTED APPROX 5 WEEKS AFTER LAST PREGNANCY. ON UNSPECIFIED DATE, SHE STARTED EXPERIENCING EXTREME BLOATING, PAIN IMMEDIATELY AFTER INSERTION, REALLY BAD EXTREME ABDOMINAL PAIN ON LEFT SIDE, EXTREME FATIGUE, MIGRAINE HEADACHE, VAGINAL INFECTIONS BACTERIAL-VAGINOSIS TO YEAST INFECTIONS CONSTANTLY, REALLY HEAVY ABNORMAL BLEEDING THAT WOULD NEVER GO AWAY, AND LARGE CLOTS WITH BLEEDING. THE DRS NEVER UNDERSTOOD WHY SHE WAS HAVING THOSE PROBLEMS, BUT HER NEW OB/GYN DR LINKED IT TO ESSURE. SHE REC'D MULTIPLE TREATMENTS. SHE WAS HOSPITALIZED MULTIPLE TIMES. A LAPAROSCOPIC VAGINAL HYSTERECTOMY WAS PERFORMED AND ESSURE DEVICES WERE REMOVED. BOTH COILS WERE STUCK IN THE UTERUS, DID NOT KNOW IF IT WAS ON BOTH SIDES OF THE UTERUS. IT WAS REPORTED THAT SHE THINKS THERE WAS PERFORATED FALLOPIAN TUBE ON LEFT SIDE. ALL HER REPRODUCTIVE ORGANS WERE REMOVED (UTERUS, FALLOPIAN TUBES, CERVIX, ALONG WITH ESSURE COILS). HER OVARIES WERE KEPT. HER SYMPTOMS/PAIN RESOLVED AFTER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00105	BAYER HEALTHCARE LLC	4/9/2014	4/25/2014

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 901342

Single Use: Y
Implant Date (E6): 1/18/2012
Explant Date (E7): 11/20/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

A CONSUMER REPORTED HAVING ESSURE INSERTED. THREE MONTHS AFTER INSERTION, SHE STARTED EXPERIENCING HORRIBLE PAIN IN PELVIC AREA, UNCONTROLLABLE BLEEDING FOR 8-9 DAYS, HEADACHES EVERY SINGLE DAY, BACKACHE, LOW PELVIC AND HIP PAIN, THYROID LEVEL - ONE HIGHER THAN NORMAL, ENDOMETRIOSIS, AND ADENOMYOSIS. DOCTOR DECIDED TO DO A NOVASURE ABLATION THAT WOULD HELP WITH THE BLEEDING. IT DID FOR THE MOST PART BUT NONE OF OTHER ISSUES WENT AWAY. AFTER AN ULTRASOUND SHE WAS TOLD SHE HAD POST ABLATION SYNDROME. ADMITTED TO THE HOSPITAL FOR LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY OVERNIGHT. SHE WENT FOR COMPLETE HYSTERECTOMY SO SHE DID NOT HAVE ANY FRAGMENTS OF COIL LEFT IN. SHE KEPT HER OVARIES. PATHOLOGY RESULTS SHOWED CYSTS ON RIGHT FALLOPIAN TUBE, FOCAL DYSTROPHIC CALCIFICATION OF THE RIGHT FALLOPIAN TUBE. SHE WAS NOT SURE IF IT PERFORATED HER TUBE OR NOT, THAT'S WHERE SHE HAD MOST PAIN ISSUES ON THE RIGHT SIDE. SHE RECOVERED FROM ESSURE REMOVAL PROCEDURE. THE CONSUMER STATED THAT HER PHYSICIAN DOES NOT THINK IT WAS DUE TO ESSURE. HE NEVER GAVE HER A DIAGNOSIS. HE SAID IT MAY BE HER THYROID, SINCE LEVEL WAS ONE POINT HIGHER THAN NORMAL, BUT SHE NEVER HAD THYROID PROBLEM BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035607	BAYER	4/10/2014	4/16/2014

Event Information:

Event Date (B3): 12/13/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/17/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HOSPITALIZED FOR 3 DAYS DUE TO DOUBLE KIDNEY INFECTION CAUSED BY CHRONIC CONSTIPATION WHICH WAS CAUSED BY METAL COILS. SHARP STABBING PAINS IN BOTH SIDES. MIGRAINES, SEVERE CRAMPING AND HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035654	CONCEPTUS	4/14/2014	4/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2013 ONE COIL WENT MISSING. HAD A SECOND PROCEDURE DONE (B)(6) 2013. STARTED HAVING SEVERE CRAMPING, BLEEDING, CLOTTING, HAIR LOSS TO THE POINT OF HAVING TO WEAR A WIG, TINGLING AND LEG CRAMPING PAIN, HEADACHES, MAJOR FATIGUE TO THE POINT I COULD NO LONGER DO DAILY NORMAL THINGS, MOOD SWINGS, IN SO MUCH PAIN I JUST WANTED TO DIE, SUICIDE THOUGHTS, COULD NOT HAVE SEX BECAUSE OF PAIN, UNUSUAL RASHES, ANXIETY AND PANIC ATTACKS, VOMITING, SICK TO MY STOMACH EVERYDAY, CONSTIPATION OR DIARRHEA, BOWEL PROBLEMS, HIP AND JOINT AND MAJOR MUSCLE PAIN. I HAD TO HAVE A HYSTERECTOMY AND THEN ALSO DIAGNOSED WITH ENDOMETRIOSIS WHICH I NEVER HAD BEFORE ESSURE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035671	BAYER	4/14/2014	4/18/2014

Event Information:

Event Date (B3): 5/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/3/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2012, I HAD THE ESSURE PROCEDURE DONE. I CHOSE THIS OPTION BECAUSE I WAS A WORKING MOTHER OF TWO AND THERE WAS LITTLE DOWN TIME. AFTER HAVING THE PROCEDURE, I STARTED HAVING SEVERE CRAMPING, ABDOMINAL PAIN, HEADACHES SOMETIMES TURNING INTO MIGRAINES, AND VERY HEAVY PERIODS (WITH CLOTS). I HAVE SINCE HAD ULTRASOUNDS, MRI FOR THE MIGRAINES, AND PLACED ON A NUMBER OF MEDICINES. I'M STILL GOING TO THE OBGYN TO TRY TO GET MY PAIN UNDER CONTROL AND HAVE NOW ALSO BEEN PUT ON BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035672	BAYER	4/14/2014	4/18/2014

Event Information:

Event Date (B3): 10/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305-R1
Catalog # (E4): CS0002F
Lot #(E4): B04950

Single Use:
Implant Date (E6): 10/14/2013
Explant Date (E7): 4/8/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE IMPLANTATION OF THE DEVICE ON (B)(6) 2013, MY LEFT TUBE DID NOT ACCEPT THE ESSURE COIL AND THE DEVICE WAS NOT IMPLANTED. I BEGAN HAVING SHARP PAINS IN MY LEFT SIDE, HIP AND LOWER BACK AND ABDOMEN PAIN. I BEGAN HAVING MIGRAINES, EXTREME STOMACH PAIN, BURNING, ITCHY SKIN AND RASH, EXTREME MOOD FLUCTUATIONS, EXTREME HAIR LOSS, DIZZINESS AND INSOMNIA. I WENT TO THE DOCTOR, THEY PERFORMED A ULTRASOUND, THEY CONFIRMED THE LEFT COIL WAS IN THE RIGHT PLACE, THEY GIVE ME THE OPTION TO CONSIDER SURGERY BECAUSE IT SEEMED THAT MY BODY WAS REJECTING THE COIL. ON (B)(6) 2014, I HAD A HYSTERECTOMY BY LAPAROSCOPIC SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035673	BAYER	4/14/2014	4/18/2014

Event Information:

Event Date (B3): 3/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/16/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6), 2012 AND THE F/U HSG DONE ON (B)(6) 2013 WHICH CONFIRMED CORRECT PLACEMENTS AND BLOCKAGE OF MY TUBES. FOUND OUT IN (B)(6) 2014, ONE YR POST ESSURE, THAT I AM PREGNANT WITH MY 4TH CHILD. THIS PRODUCT WAS NOT EFFECTIVE IN PROVIDING PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035674	BAYER	4/14/2014	4/18/2014

Event Information:

Event Date (B3): 11/14/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 626400

Single Use:
Implant Date (E6): 11/14/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BACK IN 2008, I HAD THE ESSURE COIL PUT IN MY TUBES TO PREVENT PREGNANCY. EVER SINCE THEN, MY PERIODS HAVE BEEN EXTREMELY HEAVY AND THE PAIN I GO THROUGH EACH MONTH IS GETTING WORSE. I AM (B)(6) AND HAVE HAD 3 CHILDREN. I THOUGHT THIS PRODUCT WOULD BE GOOD BUT DIDN'T REALIZE THE SIDE EFFECTS. I SPOT 3-4 DAYS BEFORE MY PERIOD WITH MILD ACHING PAIN, THEN WHEN MY PERIOD STARTS I HAVE TO WEAR SUPER TAMPONS AND A PAD AND CHANGE IT EVERY 1 1/2 HRS. THE PAIN CAN'T BE CONTROLLED. NOW I WILL HAVE TO GET A HYSTERECTOMY TO HAVE THIS REMOVED AND FOR THE PAIN TO STOP. BEFORE THIS MY PERIODS WERE NORMAL AND CRAMPS WERE NONE TO MILD. SOON AS I HAD THIS DONE, IT HAS BECOME WORSE EVERY MONTH AND YR SINCE THEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035731	CONCEPTUS, INC	4/16/2014	4/24/2014

Event Information:

Event Date (B3): 10/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/13/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2011, AFTER MY DAUGHTER WAS BORN, I HAD A PROCEDURE DONE CALLED "ESSURE" PROCEDURE AND RIGHT AFTER IT WAS DONE I HAD CRAMPING AND BLED THROUGH TOWEL AFTER TOWEL. EVER SINCE I HAVE HAD IT MY HEAD HURTS, CRAMPING IN MY STOMACH, HEAVY BLEEDING WHILE ON MY PERIOD, MISSING MY PERIOD. I HAVE HOT FLASHES ALL THE TIME. I CAN'T REMEMBER ANYTHING THAT I DO WHILE OR AFTER I COMPLETE SOMETHING. MY BODY IS JUST DIFFERENT. IN 2013, I WENT THROUGH THE PROCESS OF BECOMING A SURROGATE MOTHER WHEN I WAS TOLD SOME DEVASTATING NEWS THAT I WAS NOT A GOOD CANDIDATE TO BE A SURROGATE BECAUSE THE COILS THAT ARE INSIDE OF ME ARE BENT AND POKING INTO MY BODY. I DID GO TO THE DR ONCE SINCE I HAD THE PROCEDURE AND DR TOLD ME I WOULD NEED TO GET A HYSTERECTOMY AND I RAN OUT OF HER OFFICE AND HAVE NOT BEEN BACK SINCE BECAUSE I AM SCARED TO FIND OUT IF SOMETHING ELSE IS WRONG. I'M AFRAID TO GO TO THE GYNO BECAUSE OF WHAT I HAVE BEEN PUT THROUGH. ESSURE IS AWFUL AND EVERYONE SHOULD NOT HOW HORRIBLE IT REALLY IS - ESSURE WILL RUIN YOUR LIFE AS YOU KNOW IT. THERE ARE SO MANY THINGS WRONG WITH MY BODY THAT I DIDN'T HAVE BEFORE THE PROCEDURE. THANK YOU.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035732	BAYER/CONCEPTUS	4/16/2014	4/24/2014

Event Information:

Event Date (B3): 11/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/23/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED IN 2007 AND HAD A BABY IN 2012. THROUGH DIAGNOSTIC TESTS CONFIRMED THAT THERE IS NO ESSURE IMPLANT IN RIGHT FALLOPIAN TUBE (MIGRATED/LOST).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00110	BAYER HEALTHCARE INC.	4/16/2014	4/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/5/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PATIENT DID NOT HAVE ANY PREVIOUS GYNECOLOGICAL INTERVENTION. IN 2011 SHE HAD ABNORMAL PAP. SHE IS G (GRAVIDA) 0. THE PATIENT WAS NOT POSTPARTUM AT TIME OF ESSURE INSERTION. CERVICAL DILATATION, ANALGESIA AND GENERAL ANESTHESIA WERE APPLIED DURING INSERTION. THE PATIENT WAS NOT PREGNANT. THE INSERTION AND THE VISUALIZATION OF THE TUBAL OSTIUM WERE EASY. THE FLUID LOSS DURING HYSTEROSCOPY WAS NOT MORE THAN 1500 CC AND DID NOT TAKE MORE THAN 20 MINUTES. CONDOMS WERE USED AS BACK-UP CONTRACEPTION. ON UNSPECIFIED DATE THE PATIENT EXPERIENCED PAIN ON LEFT. ON (B)(6) 2013 ULTRASOUND AND CT (COMPUTERIZED TOMOGRAPHY) WERE PERFORMED TO CONFIRM ESSURE PLACEMENT AND SUGGESTED PERFORATION ON LEFT. ON (B)(6) 2013 LEFT SALPINGECTOMY WAS PERFORMED BY LAPAROSCOPY. DURING SURGERY NO PERFORATION WAS SEEN. THE COIL WAS SEEN PUSHING AGAINST TUBE LUMEN AND WAS REMOVED. NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WERE SEEN PERFORATED ON LAPAROSCOPY. NO PERFORATION OCCURRED DURING SOUNDING, CERVICAL DILATATION OR HYSTEROSCOPY PRIOR ESSURE INSERTION. THERE WERE NO SIGNS AND SYMPTOMS OF INFECTION. THE PATIENT RECOVERED FROM ESSURE REMOVAL PROCEDURE. ON UNKNOWN DATE, PHYSICIAN STATED THAT PATIENT STILL HAVE A PATENT RIGHT TUBE WITH ESSURE IN PLACE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00111	BAYER HEALTHCARE LLC	4/16/2014	4/29/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014, WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6)/AOL AND EXPERIENCED AWFUL PERIODS, REMOVED FALLOPIAN TUBES WITH ESSURE TUBAL COILS AND MY UTERUS, TIRED AFTER SURGERY, GAS HURTS, AND SORE AFTER SURGERY. STUDY DESCRIPTION: ESSURE GENERIC ACTIVE ONLINE LISTENING. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT SHE HAD HER SURGERY. SHE REPORTED THAT SHE HAD HER FALLOPIAN TUBES REMOVED WITH ESSURE COILS AND HER UTERUS. SHE KEPT HER OVARIES AND CERVIX. SHE WAS JUST TIRED AND SORE, SHE FELT LIKE HAVE TO PASS GAS BUT ONLY LITTLE BURPS WANT TO COME OUT. SHE STATED THAT THE GAS HURT MORE THAN THE PAIN FROM SURGERY. CONSUMER STATED THAT SHE WAS READY TO LIVE NOT RULED BY AWFUL PERIODS. NO FURTHER INFORMATION PROVIDED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN AWFUL PERIODS, REMOVED FALLOPIAN TUBES WITH ESSURE TUBAL COILS AND MY UTERUS, TIRED AFTER SURGERY, GAS HURTS, AND SORE AFTER SURGERY AND ESSURE WAS NOT REPORTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00107	BAYER HEALTHCARE LLC	4/16/2014	5/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B06103

Single Use: Y
Implant Date (E6): 7/17/2013
Explant Date (E7): 2/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA (B)(4) IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MOOD SWINGS, EAR INFECTIONS, PAIN EVERYWHERE, HEADACHES, NO SEX DRIVE, PAIN IN LIMBS, PAIN IN VAGINAL AREA DURING SEX, AND BOWEL ISSUES AND STOMACH. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B06103. ON UNSPECIFIED DATE THE CONSUMER EXPERIENCED PAIN EVERYWHERE, PAIN IN LIMBS, MOOD SWINGS, EAR INFECTIONS, HEADACHES, NO SEX DRIVE, PAIN IN VAGINAL AREA DURING SEX, AND BOWEL ISSUES AND STOMACH. SHE COULD NOT DO ANYTHING WITHOUT HAVING PAIN WITH ESSURE AND ON (B)(6) 2014 SHE HAD A HYSTERECTOMY DUE TO IT. THE OUTCOME OF THE EVENTS WAS UNKNOWN. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS NOT REPORTED. FOLLOW UP INFORMATION WAS RECEIVED FROM THE CONSUMER ON (B)(6) 2014: THE CONSUMER'S BMI (BODY MASS INDEX) WAS (B)(6). SHE DENIED PREVIOUS GYNECOLOGICAL PROBLEMS, RELEVANT MEDICAL HISTORY, OR CONCURRENT CONDITIONS. ON (B)(6) 2013, THE CONSUMER DELIVERED A BABY AND ON (B)(6) 2013 SHE HAD ESSURE, MODEL ESS305 INSERTED. AFTER THE INSERTION SHE RECEIVED A SHOT OF DEPO PROVERA AS BACK-UP CONTRACEPTION. IN (B)(6) 2013 HYSTEROSALPINGOGRAPHY WAS PERFORMED AND BOTH SIDES WERE BLOCKED. THE CONSUMER CONFIRMED THE PREVIOUS EVENTS REPORTED. SHE ALSO REPORTED THAT SHE THE PAIN AND BLEEDING GOT WORSE/STARTED IN (B)(6) 2013, AT THE TIME OF HER PERIODS. SHE DESCRIBED THAT SHE USED TO CRY BECAUSE OF A SEVERE CRAMPING SINCE HER STOMACH HURT SO BAD. SHE ALSO HAD MORE HEADACHES. THE

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CONSUMER WENT TO THE DOCTOR WHO PERFORMED ESSURE PROCEDURE BECAUSE OF PAIN, SHE WAITED FOR 2 HOURS AND ENDED UP GOING TO THE HOSPITAL BECAUSE OF PAIN. TESTS WERE PERFORMED, BUT THE PHYSICIAN DID NOT KNOW WHAT WAS CAUSING PAIN. OTHER DOCTOR SAID THAT ESSURE WAS CAUSING ALL PROBLEMS. ACCORDING TO THE CONSUMER AT HOSPITAL COMPUTERIZED TOMOGRAPHY SCAN OF ABDOMEN WAS PERFORMED. IT SHOWED ONE INCH CYST OVER THE OVARY. ULTRASOUND ABDOMEN WAS PERFORMED AND THE CYST WAS NOT FOUND. SHE STAYED AT THE EMERGENCY ROOM BECAUSE OF STOMACH PAIN AND OTHER STUFF STARTED SHOWING UP LIKE EAR INFECTIONS. ON (B)(6) 2014 THE CONSUMER WAS ADMITTED IN THE HOSPITAL DURING ONE DAY FOR HYSTERECTOMY (FALLOPIAN TUBES WERE REMOVED). THE SYMPTOMS RESOLVED AFTER THE PROCEDURE. DURING THE SURGERY THE DEVICES WERE FOUND IN THE TUBES. THE CONSUMER DID NOT KNOW PATHOLOGY RESULTS. THE CONSUMER HAS RECOVERED, SYMPTOMS/PAIN WERE RESOLVED AFTER SURGERY. HOWEVER, SHE DESCRIBED THAT SHE HAD BLEEDING FROM THE STITCHES AND SINCE IT WAS MOIST AND SHE HAD A BACTERIAL INFECTION. STITCHES HAD NOT HEALED YET. THE CONSUMER BELIEVED THE CONDITION WAS CAUSED BY THE ESSURE DEVICES. SHE ALSO DESCRIBED THAT COULD HAVE UNDERGONE A TUBAL LIGATION INSTEAD OF UNDERGOING A MAJOR SURGERY AND HAVING HER UTERUS REMOVED. THE CONSUMER ALSO ASKED FOR COMPENSATION AND THREATENED TO GET A LAWYER TO RECEIVE IT. FURTHER FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER ON (B)(6) 2014: THE NON-PREGNANT CONSUMER HAD ESSURE INSERTED FOR STERILIZATION ON (B)(6) 2013. SHE DID NOT WORRY FOR THE FIRST MONTH AFTER THE PROCEDURE BECAUSE SHE WAS HAVING PAIN AND SHE WAS TOLD THAT SHE WOULD HAVE PAIN. AFTER THAT, AND CONTINUING THROUGH (B)(6) 2013, SHE WAS BLEEDING FOR TWO WEEKS DURATION. BLEEDING WAS WORSE THAN HER PERIODS PRIOR TO ESSURE. HER PERIODS USED TO LAST FIVE DAYS. DURING THAT SAME TIME, SHE ALSO HAD SEVERE STOMACH PAIN AND WAS UNABLE TO DO ANYTHING. SHE HAD BEEN TO THE ER (EMERGENCY ROOM) FOR STOMACH PAIN AT LEAST TWO OR THREE TIMES. SHE HAD A CAT SCAN TO SEE WHAT WAS WRONG WITH HER STOMACH. SHE ADDED THAT SHE EXPERIENCED RANDOM MIGRAINES, EAR INFECTION WITHOUT HAVING A COLD, NO SEX DRIVE, MOOD SWINGS AND FEELING DEPRESSED A COUPLE OF TIMES. ER SENT HER TO OB (OBSTETRICIAN) DOCTOR WHO DID ULTRASOUND AND CONFIRMATION X-RAY. ALL OF THIS WAS DURING (B)(6) 2013. TESTS SHOWED HER FALLOPIAN TUBES WERE CLOSED BUT THE INSERTS COULD BE CAUSING HER STOMACH AND OTHER PROBLEMS BECAUSE SHE SAID THEY COULD NOT SEE THE INSERTS. SHE HAD A HYSTERECTOMY AT THE HOSPITAL ON (B)(6) 2014. CONSUMER SAID TESTS SHOWED HER STOMACH WAS FINE AND HER HEALTH PROBLEMS WERE CAUSED BY ESSURE. HE HAD NO PRIOR HISTORY, SHE SAID, INCLUDING STOMACH PROBLEMS OR STOMACH PAIN. STOMACH PAIN IS GONE AND SHE IS FEELING BETTER. CONSUMER SAID SHE WOULD HAVE HAD A TUBAL LIGATION IF SHE HAD KNOWN THAT ESSURE WOULD CAUSE HER PROBLEMS. AT TIME OF REPORTING, AFTER THE HYSTERECTOMY, SHE IS GOING THROUGH EARLY MENOPAUSE. SHE IS UNHAPPY AND SHE SAID IT IS NOT FAIR. SHE WILL CONTINUE WITH HER BEDREST FOR A COUPLE OF MORE WEEKS.

Manufacturer Narrative (H10):

FOLLOW UP FROM (B)(4) 2014: NO FURTHER INFORMATION IS EXPECTED. CASE CLOSED. F/U INFO RECEIVED ON (B)(4) 2014: THE REPORTER STATED THAT IT WAS NOT POSSIBLE TO CONTACT THE PT. NO FURTHER INFO PROVIDED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00106	BAYER HEALTHCARE LLC.	4/16/2014	5/15/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/23/2007
Explant Date (E7): 11/21/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

CASE STATUS: SERIOUS - UNLISTED - RELATED - INCIDENT. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (MW5034677) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE ((B)(4)) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC CONGESTION SYNDROME, MIGRAINES, BACK PAIN, HEAVY MENSES, BLOOD CLOTS, PELVIC PAIN, SHARP STABBING PAIN ON MY LEFT SIDE OF MY PELVIC AREA. ENDOMETRIOSIS, YEAST INFECTIONS, VAGINOSIS, PID, INFLAMMATION IN MY LOWER ABDOMEN, AND SEVERAL CYSTS ON MY LEFT OVARY. NO INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2007 THE CONSUMER HAD ESSURE ((B)(4)) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AT UNK. IT WAS UNK WHETHER ESSURE ((B)(4)) WAS USED PREVIOUSLY. SHE WAS IMPLANTED WITH ESSURE BIRTH CONTROL IN HER FALLOPIAN TUBES IN 2007. A YEAR LATER SHE WAS SUFFERING WITH A NUMBER OF PAINFUL SYMPTOMS: MIGRAINES, BACK PAIN, HEAVY MENSES, BLOOD CLOTS, PELVIC PAIN, SHARP STABBING PAIN ON MY LEFT SIDE OF MY PELVIC AREA. I HAD A NUMBER OF INFECTIONS THROUGH OUT THE YEARS FROM YEAST INFECTIONS, VAGINOSIS AND PID. I WAS ALSO DIAGNOSED WITH ENDOMETRIOSIS, PELVIC CONGESTION SYNDROME FROM ALL THE INFLAMMATION IN MY LOWER ABDOMEN, AND SEVERAL CYSTS ON MY LEFT OVARY. SHE HAD TO HAVE A HYSTERECTOMY TO FINALLY REMOVE COILS AND FEMALE ORGANS. WAS ONLY LEFT WITH HER RIGHT OVARY. HER PROCEDURE WAS DONE ON (B)(6) 2013.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00108	BAYER HEALTHCARE LLC	4/16/2014	5/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON (B)(4) 2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER (B)(4), RECEIVED AT FDA ON (B)(4) 2014). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED LOWER 'ENABLING' PELVIC PAIN, HEAVY BLEEDING MONTH TO MONTH. ON FDA FORM REPORTED REPORT TYPE WAS 'INJURY', OUTCOME OF EVENTS WAS 'OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)'. NO INFO WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. CONSUMER REPORTED SHE EXPERIENCED LOWER 'ENABLING' PELVIC PAIN, HEAVY BLEEDING MONTH TO MONTH, TWO BLOOD TRANSFUSIONS IN TWO MONTHS, HYSTERECTOMY (DATE NOT SPECIFIED).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00109	BAYER HEALTHCARE LLC	4/16/2014	5/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): A96180

Single Use: Y
Implant Date (E6): 5/30/2013
Explant Date (E7): 1/30/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON (B)(4) 2014 FROM THE SAME CONSUMER VIA (B)(4) NEW CASE NUMBER (B)(4), RECEIVED AT FDA ON (B)(4) 2014). THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE HAD ESSURE (ESS305, FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER A96180, IMPLANTED. FDA FORM REPORTED REPORT TYPE WAS 'INJURY', AND OUTCOME OF EVENTS WAS NEWLY REPORTED AS 'REQUIRED INTERVENTION'. CONSUMER REPORT SHE HAD SYMPTOMS AND PAIN SINCE THE PLACEMENT OF ESSURE ON (B)(6) 2013. SHE FEELS SHE WAS MISLEAD WITH ESSURE, THERE ARE MORE SIDE EFFECTS THAN BENEFITS OF THIS DEVICE. THESE COILS HAVE ABSORBED A STERILIZING AGENT, ETHYLENE OXIDE (LISTED ON THE BACK OF ESSURE PACKAGE) DOES NOT DISSIPATE AND AN SEEP INTO YOUR BODY VIA THE COILS. THE STERILIZING AGENT IS A KNOWN CARCINOGEN AND CAN BE ABSORBED INTO PET FIBERS IN THE COILS AND WHEN PET FIBERS COME INTO CONTACT WITH SALT OR SALINE SOLUTION THIS CARCINOGEN AGENT CAN BE RELEASED EVEN FURTHER INTO THE BODY. CONSUMER HAS HAD WEIGHT GAIN (AT TIME OF REPORTING THE HEAVIEST SHE HAS EVER BEEN), HEAVY/SEVERE BLEEDING AND CLOTTING WHICH HAS SENT HER TO THE ER (EMERGENCY ROOM) TO THEN BE PLACED ON HORMONES FOR TEN DAYS TO STOP/CONTROL THE BLEEDING, SEVERE CRAMPING, HEADACHES/MIGRAINES WEEKLY, HAIR LOSS, SKIN SO DIFFERENT (BREAKING OUT/RASHES/BLISTERING UNDER JEWELRY), MOODY, EXHAUSTED DAILY, CANNOT SLEEP, HARD TO FOCUS (IN A FOG/DIZZY), SPASMS/VIBRATING (WHERE THE COILS ARE, ALMOST LIKE SHE HAS HER CELL PHONE ON HER), EMOTIONAL, EXTREMELY BLOATED, STABBING PAINS IN HER ABDOMINAL AREA, DIARRHEA CONSTANTLY. CONSUMER ASKED HER DOCTOR TO REMOVE THE COILS FROM HER BODY. ON (B)(6) 2014, CONSUMER HAD HER FALLOPIAN TUBES, COILS AND UTERUS REMOVED. SHE FELT THAT SHE WAS SLOWLY BEING POISED AND THAT IF SHE WANTED TO LIVE HEALTHY THIS WAS HER ONLY CHANCE. AT THE TIME OF REPORTING, TWO WEEKS AFTER THE

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OPERATION, ALL HER SYMPTOMS WERE GONE, DOWN 9 POUNDS, TOO. SHE FEELS LIKE HERSELF AGAIN. SADLY, IF SHE WANTED TO DO A REVERSAL TO BECOME PREGNANT AGAIN SADLY SHE CANNOT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035632	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 12/31/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WENT TO A NEW GYN TO GET MY TUBES TIED AND SHE RECOMMENDED I GET ESSURE BECAUSE IT WAS EASIER THAN GETTING MY TUBES TIED. SHE STATED THAT IT WAS NICKLE COILS THAT WILL CAUSE SCAR TISSUE TO BLOCK THE TUBES, NO SIDE EFFECTS AND NO SURGERY NEEDED AND YOU CAN GO BACK TO WORK THE NEXT DAY. SOUNDED GOOD BEING I WAS A SINGLE MOM TO 3 KIDS (I PLAYED EVERY SPORT IMAGINABLE) AND HAD A FULL TIME JOB AND A LOT OF OVER TIME. MADE AN APPOINTMENT HAD IT DONE (B)(6) 2009, WORST MISTAKE OF MY LIFE. FIRST I STARTED HAVING REALLY BAD BACK PAIN I HAD TO LEAVE WORK TO GO TO THE DR BECAUSE I WAS FEELING SICK, WEAK AND WHITE AS A GHOST. THAT'S WHEN THE SHARP PAIN STARTED ON MY LEFT SIDE. I WAS TOLD I HAD A KIDNEY STONE AND I SHOULD PASS IT. WENT IN FOR A CHECK UP, NO MORE SHARP PAINS IN MY BACK, SO THE DR SAID I PROBABLY PASSED IT. I STILL HAD SOME PAIN IN MY BACK IT WASN'T THE SAME. MY MOM AND I WENT SHOPPING A FEW DAYS LATER AND MY BACK STARTED HURTING AND IT WAS STARTING ALL OVER BUT THIS TIME IT WAS INTENSE IT MADE ME SIT ON THE FLOOR IN (B)(6) STORE. MY MOM TOOK ME TO THE ER AND THE ER DOCTOR TOLD ME I HAD A HUGE KIDNEY STONE AND HE ADMITTED ME TO THE HOSPITAL AND TOLD ME THEY WERE DOING SURGERY IN THE MORNING TO REMOVE IT. I TOLD HIM THEY COULDN'T BECAUSE I WASN'T COMPLETELY HEALED FROM GETTING THE ESSURE PUT IN. BUT IT HAD TO BE DONE. THEY GAVE ME AN IV WITH SOMETHING THAT GAVE ME A RASH AND THE NURSE SAID IT WAS OK, I MADE HER TAKE IT OUT OF ME. ABOUT A MONTH AFTER THAT MY CYCLE STARTED TO GET HEAVY AND OFF TRACK. MY BACK WAS GETTING WORSE. IN 2010-2011, I WAS IN AND OUT OF THE ER AND GYNS. THEY ALL JUST WANTED TO GIVE ME PAIN MEDS AND SOME DID EXAMS AND TOLD ME I WAS FINE NOTHING WAS WRONG AND THAT IT WAS NORMAL AT MY AGE (I WAS (B)(6) OF 2010) THAT I WAS BLEEDING HEAVY AND HAVE BACK PAINS. I HAD A FEW GYNS TELL ME I HAD ENDOMETRIOSIS AND NEEDED A HYSTERECTOMY. ALL

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THIS TIME I JUST WANTED THE COILS OUT (JUST TUBES AND COILS). I WAS GETTING WORSE SHARP PAINS IN ABS ON LEFT SIDE WAY WORSE, NAUSEA, NO SEX DRIVE, NO ENERGY, DEPRESSED, ANXIOUS, ANGRY, BLOOD CLOTS, PRESSURE IN MY PELVIS, I GAINED (B)(6) IN LESS THAN A YR. FINALLY IN (B)(6) OF 2012, I WOKE UP AND COULD BARELY MOVE, I CALLED MY MOM TO TAKE ME TO A HOSPITAL IN ANOTHER TOWN, ON HER WAY OVER I WORKED ON GETTING UP. THEY TOOK XRAYS AND MRIS AND FOUND DEGENERATIVE JOINT DISEASE AND DEGENERATIVE DISC DISEASE, DISC BULGE, PINCHED NERVES, ARTHRITIS AND PROTRUSION. I CHECKED UP WITH A NEW FAMILY DR AND I TOLD HIM WHAT WAS GOING ON AND HE CALLED A GYN AND TOLD HIM AND HE AGREED TO REMOVE THEM. MY CYCLES HAVE WENT BACK TO NORMAL, NO MORE PAIN IN MY ABS. MY BACK I KNEW WAS MESSED UP. I STILL HAD NUMBING AND TINGLING, SHARP PAINS IN MY BACK, HIPS, KNEES, NECK, AND FEET. I RECENTLY FOUND OUT WHAT THE ESSURE MATERIALS CAN DO TO YOU AND TOLD MY DOCTOR AND SINCE I HAVE FOUND A LOT MORE EFFECTS IT PUT ON MY BODY. I HAVE A VIT. D DEFICIENCY, OSTEOPENIA, JOINT DISEASE IN MY NECK, BACK, ELBOWS, KNEES, HIGH SUGAR, BONE SPURS. I JUST GOT MORE BLOOD WORK AND AN EMG DONE ON MY ARM AND LEG ON MY LEFT SIDE. IM RECENTLY FIGHTING FOR SSD BECAUSE MY BONES, JOINTS AND NERVES ARE SO BAD. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035634	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 4/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ISSUES WITH MY BOWEL MOVEMENTS. MY PERIODS ARE ALOT STRONGER. THEY ALSO LAST LONGER AND I HAVE 2 EVERY MONTH. I HAVE ACHES AND PAINS IN MY JOINTS NOW WHERE AS I NEVER DID BEFORE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035635	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 1/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING LOW BACK PAIN, CONTINUAL BLOATING AND SWELLING THEN BEGAN TO HAVE CRAMPING WHILE NOT ON MY CYCLE. WITHIN A YEAR MY PERIODS WERE BEGINNING TO GET HEAVIER AND HEAVIER. BY 2013 IT BEGAN TO BE UNBEARABLE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035636	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 9/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTING IN (B)(6) AND STILL CONTINUING, I HAVE BEEN DEALING WITH PELVIC PAIN, FATIGUE, NAUSEA, AND MALAISE. I HAVE A VERY WEAK IMMUNE SYSTEM. I ALSO HAVE SIGNS OF AN ALLERGIC REACTION, INCLUDING HIVES AND RASHES. I HAVE BEEN DIAGNOSED WITH CELIAC, WITH NO FAMILY HISTORY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035637	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN SUFFERING FROM SIGNIFICANT PAIN, MUSCLE SPASMS, NUMBNESS, CHRONIC FATIGUE, SIGNIFICANT WEIGHT GAIN, DRASTIC FOOD ALLERGIES ACCOMPANIED BY ECZEMA. I HAVE SUFFERED FROM DEPRESSION AND ANXIETY AS A RESULT OF THESE SYMPTOMS AND THEIR LIMITING AFFECT ON MY DAILY LIFE. ALL DAILY LIFE ACTIVITIES ARE SIGNIFICANTLY IMPACTED AND I FREQUENTLY HAVE TO WALK WITH A CANE DUE TO PAIN AND MUSCLE SPASMS. MONTHLY MENSTRUAL CRAMPS ARE ALSO DEBILITATING. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035638	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 3/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONFIRMED PREGNANCY, CYST ON THE OVARY, SEVER CRAMPING, FATIGUE, NAUSEA. SEVERE CHEST PAINS ON RIGHT SIDE, WITH ACHE AND NUMBING IN THE ARM. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035639	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 3/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LET'S SEE.. I'M IN CONSTANT PAIN SINCE I HAVE HAD IT.. SEX NOW HURTS.. I TOLD THEM I WAS ALLERGIC TO NICKEL BEFORE THEY IMPLANTED ME WITH IT AND THEY TOLD ME I WOULD BE FINE.. WELL I NOW ITCH ALL OVER ALL THE TIME.. I HAD NO HEALTH ISSUES TILL I HAD ESSURE.. I NOW HAVE AN AUTO IMMUNE DISEASE.. WHICH IS LUPUS.. REALLY. DON'T RUN IN MY FAMILY.. MY PERIOD IS OFF WACK.. I NOW HAVE PAINFUL HEAVY PERIODS.. MIGRAINES ALL THE TIME. PELVIC PAIN ALL THE TIME.. SEX HURTS TERRIBLY. MY VISION GOES BLURRY NOW FOR NO REASON.. THERE IS A LOT MORE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035640	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WELL FROM THE MOMENT THEY PUT ESSURE IN ON (B)(6) 2012 I HAVE HAD BACK AND PELVIC PAIN JOINT PAIN HAIR LOSS AND BLOATING.... AROUND (B)(6) 2013 I DEVELOPED A RASH ALL OVER MY LOWER HALF OF MY BODY AND VAGINAL AREA DUE TO RASH AND PAIN, LOSS OF SEXUAL ACTIVITY WITH HUSBAND. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035641	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 2/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING VERY BAD CRAMPS, AND STARTED TO PUT WEIGHT BACK ON THAT I WAS LOSING SINCE THE BIRTH OF MY DAUGHTER 4 MONTHS BEFORE, ALSO STARTED TO LOSE MILK SUPPLY.. A FEW MONTHS AFTER THAT MY HAIR STARTED TO FALL OUT.. OUT OF NO WHERE I WOULD GET VERY PAINFUL STABBING FEELING.. IT ALSO 2 MONTHS AFTER HAVING ESSURE PLACED, MY MS PAIN GOT WORSE WITH NO CHANGE IN BRAIN OR SPINE (USE OF MRI TO CHECK).. ALSO (B)(6) 2013 I FOUND OUT I WAS PREGNANT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035642	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 7/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MOMMY FOUND OUT SHE WAS PREGNANT WITH ME. SHE WAS IN SUCH PAIN THE WHOLE TIME SHE WAS PREGNANT WITH ME. IT WAS SUCH A ROUGH TIME FOR HER AND FOR MY BIG BROTHER AND SISTER ALONG WITH MY DADDY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035643	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 1/5/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A COUPLE MONTHS AFTER HAVING ESSURE PLACED I STARTED HAVING SEVERE PELVIC PAIN. STABBING PAIN IN LOWER RIGHT ABDOMEN. LOWER BACK PAIN THAT HAS PROGRESSED OVER THE YEARS INTO DEBILITATING BACK PAIN. HAVE HAD MANY INFECTIONS IN MY INTESTINES. MY INTERNALS HAVE REMAINED SWOLLEN FOR THE PAST FOUR YEARS. EXPERIENCE SEVERE BLOATING ON A DAILY BASIS. GAINED WEIGHT THAT I CAN NOT SEEM TO LOOSE AT ANY ATTEMPT. WEAKNESSES IN BODY ALONG WITH SEVERE FATIGUE. BRAIN FOG DAILY. MEMORY LOSS. NUMBNESS IN MY ARMS AND LEGS. RANDOM AND FREQUENT VOMITING. PAINFUL INTERCOURSE. LOSS OF SEXUAL DRIVE. HEAVY PAINFUL PERIODS. SEVERE MOOD SWINGS. SEVERE DEPRESSION DUE TO ALL THESE ISSUES. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035644	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 2/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE IMPLANTATION OF THE DEVICE ON (B)(6) 2014 MY RIGHT TUBE "SPASMED" CAUSING THE DEVICE TO MISFIRE AND ONLY PART OF THE DEVICE WAS IMPLANTED, BUT MY DOCTOR INFORMED ME THAT WE WOULD JUST KEEP AN EYE ON IT. THEN, A FEW WEEKS LATER, AROUND (B)(6) 2013, I BEGAN HAVING SHARP PAINS IN MY RIGHT SIDE, HIP AND LOWER BACK. MY DOCTOR DID AN ULTRASOUND THAT SHOWED IT BEING IN THE RIGHT PLACE AND INSTRUCTED ME TO GIVE IT A FEW MORE WEEKS AND COME BACK IF THE PAIN DIDN'T GO AWAY. THE PAIN ONLY GOT WORSE AND SPREAD TO MY WHOLE LOWER ABDOMEN. I BEGAN HAVING MIGRAINES, EXTREME STOMACH PAIN, BURNING, ITCHY SKIN AND RASH ON MY UPPER LEGS AND LOWER ABDOMEN, EXTREME MOOD FLUCTUATIONS, EXTREME HAIR LOSS, DIZZINESS AND INSOMNIA. I WENT BACK TO THE DOCTOR AND SHE AGAIN CONFIRMED THE COILS WERE IN THE RIGHT PLACE AND SHE THEN GAVE ME THE OPTION TO CONSIDER SURGERY BECAUSE IT SEEMED THAT MY BODY WAS REJECTING THE COILS. WE SET A DATE FOR SURGERY FOR (B)(6) TO HAVE MY TUBES REMOVED BY LAPAROSCOPIC SURGERY. SHORTLY AFTER THE PROCEDURE I WENT TO THE ER DUE TO UNBEARABLE STOMACH PAINS AND INABILITY TO BEND OVER (I HAVE 3 CHILDREN (B)(6)) SO NEEDLESS TO SAY NOT BEING ABLE TO BEND OVER IS A HUGE HANDICAP IN MY HOME. THE DOCTORS RAN TESTS, DID X-RAYS, MORE ULTRASOUNDS AND STILL NOTHING WAS FOUND TO BE WRONG. I'VE NEVER HAD ANY ISSUES SUCH AS THIS BEFORE THE ESSURE, SO HOPEFULLY I WILL SEE IMPROVEMENT AFTER THEY ARE REMOVED ON FRIDAY!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035645	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 9/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVIER/LONGER PERIODS, CRAMPING, SHARP PAINS IN MY SIDE, HEADACHES, FATIGUE, BACK/LEG PAIN. WAS TESTED FOR NICKEL ALLERGY AND TESTED POSITIVE. WAS TESTED FOR MS TO RULE OUT; THAT WAS NEGATIVE. WAS TESTED FOR LYME; THAT WAS POSITIVE. WITH ONLY ONE TUBE, I SHOULD NOT HAVE BEEN IMPLANTED (ACCORDING TO THE MANUFACTURER). THE NICKEL WARNING WAS NOT REQUIRED AT THE TIME OF IMPLANTATION SO I WAS NOT TESTED UNTIL AFTER HAVING ESSURE FOR A FEW MONTHS. ALSO, I HAVE SINCE LEARNED THAT NICKEL CAN MAKE THE SYMPTOMS OF LYME WORSE. I HAD A LAPAROSCOPIC SUPRACERVICAL HYSTERECTOMY ON (B)(6) 2014 TO REMOVE MY UTERUS AS WELL AS MY LEFT TUBE (WITH COIL INTACT). (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035646	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 7/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE PROCEDURE I HAVE HAD REOCCURRING VAGINAL INFECTIONS CONSTANT SEVERE PAIN IN LOWER ABDOMINAL AREA AND BACK. HEAVY PERIODS WITH HUGE BLOOD CLOTS TO THE POINT I AM UNABLE TO LEAVE MY HOME WITHOUT EXTRA CLOTHES. SEVERE MIGRAINES, HAIR LOSS, AND WEIGHT GAIN. I AM ALWAYS BLOATED EVEN BEFORE AND AFTER MENSTRUAL CYCLE. SINCE THE PROCEDURE MY BREAST STAY SORE AND ENGORGED WITH CLEAR DISCHARGE THAT COMES OUT OF BOTH BREASTS. THIS IS THE WORST DECISION I HAVE MADE IN MY LIFE AND NOBODY WILL HELP. PLEASE RECALL THIS PRODUCT SO NO OTHER WOMAN HAVE TO ENDURE THE CONSEQUENCES OF THIS PROCEDURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035647	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 4/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MIGRAINES/HEADACHES; TIREDNESS (ALL THE TIME); CRAMPS IN ABDOMEN THAT WRAPS AROUND TO MY BACK; IRREGULAR PERIODS (EVERY 2 WEEKS); ITCHY SKIN; TREMENDOUS HAIR LOSS; LOSS OF WEIGHT WITH NO DIETING OR EXERCISING; EYE DRYNESS, THROBBING PAIN, AND BLOOD SHOTS IN EYES (WENT TO EYE DOCTOR, EYE EXAMS AND X-RAY CAME OUT NORMAL); SHORTNESS OF BREATH; ANXIETY; INSOMNIA; LOSS OF APPETITE; JOINT/BACK/SHOULDER/NECK PAINS; NUMBNESS ON LEFT CHEEK/JAW; LOSS OF ENERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035648	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 2/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE PROCEDURE I HAVE EXPERIENCED HEAVY BLEEDING, CONSTANT, SOMETIMES EXTREME PAIN, SEVERE BLOATING. I HAVE GAINED (B)(6) AND HAVE BLOTCHY RED FACE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035651	BAYER	4/17/2014	4/17/2014

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I'VE HAD ESSURE IMPLANTED I BLEED SUPER HEAVY WHEN IM ON MY PERIOD. I CRAMP UP EVERYDAY AND WHEN IM ABOUT TO START MY PERIOD A WEEK BEFORE I START GETTING PAINS LIKE I AM GOING INTO LABOR IT'S TERRIBLE. I AM CONSTANTLY BLOATED, MY ABDOMEN SWELLS A LOT TOO. MY BREAST HURT TERRIBLY. I SPOT THROUGHOUT THE MONTH. WHEN I STRETCH MY FALLOPIAN TUBES HURT IF THAT MAKES ANY SENSE. TERRIBLE BACK PAIN AND HEADACHES. LEGS HURT ALL THE TIME. JUST ALWAYS IN A LOT OF ABDOMEN PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035705	BAYER	4/17/2014	4/22/2014

Event Information:

Event Date (B3): 4/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER HAD ESSURE PROCEDURE DONE ABOUT TWO MONTHS AGO. ON (B)(6) 2014, THE COIL DETACHED AND FELL OUT OF HER. SINCE THEN SHE'S BEEN EXPERIENCING PAIN, CRAMPING WITH HEAVY BLEEDING. CONTACTED HER DOCTOR WHO SCHEDULE AN X-RAY AFTER WHICH WILL DETERMINE THE NEXT COURSE OF ACTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00112	BAYER HEALTHCARE, LLC	4/17/2014	4/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B30426

Single Use: Y
Implant Date (E6): 3/18/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A HOSPITAL NURSE AT A GYNECOLOGIST/OBSTETRICIAN DEPARTMENT IN THE UNITED STATES ON (B)(6) 2014. THE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHILE INSERTION WAS ATTEMPTED THE FILAMENTS IN THE COIL SEPARATED AND METAL CLIP WAS ATTACHED TO THE SPRING INSTEAD OF THE COIL. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2014 THE PATIENT WAS TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B30426 (EXPIRATION DATE MAY-2016) INSERTED. ON (B)(6) 2014, THE HCP (HEALTHCARE PROFESSIONAL) PLACED ESSURE BILATERALLY. THE FILAMENTS IN THE COIL SEPARATED AND THE METAL CLIP WAS ATTACHED TO THE SPRING INSTEAD OF THE COIL. IT WAS ASKED IF HCP NEEDED TO DO ANYTHING TO FOLLOW-UP THIS OTHER THAN THE THREE-MONTH HSG (HYSTEROSALPINGOGRAM). NO FURTHER DETAILS WERE REPORTED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00114	BAYER HEALTHCARE LLC	4/17/2014	4/24/2014

Event Information:

Event Date (B3): 3/20/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THREE COILS OF ONE DEVICE BROKE OFF. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION RECEIVED. ON (B)(6) 2014 THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, AND THREE COILS OF ONE DEVICE BROKE OFF. THE DOCTOR WENT IN A GRASPING TOOL, AND AS HE WAS BRINGING THE PIECE THROUGH THE CERVIX AND INTO THE VAGINA WHEN IT DISAPPEARED AND HE LOST SIGHT OF IT. THE PT HAD AN X-RAY OF HER ABDOMEN AND OF A BAG OF TRASH TO SEE IF THE COILS COULD BE FOUND AND THERE WAS NO FOREIGN BODY IN THE UTERUS OR VAGINA. NO OUTCOME WAS PROVIDED. NO CAUSALITY ASSESSMENT WAS GIVEN. FOLLOW-UP RECEIVED ON (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00115	BAYER HEALTHCARE LLC	4/17/2014	4/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DISTAL MICRO INSERT TIP BROKEN AND FOUND IN THE UTERUS DURING INSERTION. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B42237. IT WAS STATED THAT DURING THE ESSURE PLACEMENT, DISTAL MICRO INSERT TIP BROKEN AND WAS FOUND IN THE UTERUS. NO CLINICAL CONSEQUENCES OBSERVED. ACTION TAKEN: VIGILANCE ON THE CONCERNED BATCH. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00116	BAYER HEALTHCARE LLC	4/17/2014	4/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B40025

Single Use: N
Implant Date (E6): 3/5/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BAD DEVICE RELEASE ON THE LEFT. DEVICE REMAINED ATTACHED TO THE INTRODUCER, THE COIL STRETCHED UNTIL BREAKAGE, AND THE COIL WAS CUT FLUSH TO THE LEFT OSTIUM, AND BILATERAL PLACEMENT WAS NOT PERFORMED. NO INFO GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AT OPERATING ROOM, LOT NUMBER B40025, AT UNK. DURING PLACEMENT, BAD DEVICE RELEASE WAS OBSERVED ON THE LEFT, DEVICE REMAINED ATTACHED TO THE INTRODUCER. THE COIL STRETCHED UNTIL BREAKAGE. THE DEVICE COULD NOT BE PULLED OUT, DISTENDED AS A RESULT OF PULLING, SMALL PIECES WERE WITHDRAWN SUCCESSIVELY. FOR THE REMAINING PART OF DEVICE STILL IN TUBE, THE COIL WAS CUT FLUSH TO LEFT OSTIUM. NO ANATOMIC REASON COULD EXPLAIN THE ANOMALY. PROCEDURE ON THE RIGHT WAS UNEVENTFUL, 3 TRAILING COILS. BILATERAL PLACEMENT WAS NOT PERFORMED. MEDICAL DEVICE VIGILANCE PROCEDURE WAS DONE WITHIN THE HOSPITAL, NO DECLARATION TO HEALTH AUTHORITIES IN (B)(6). THE DEVICE WAS KEPT IN THE HOSPITAL. NO OTHER INFO AVAILABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00113	BAYER HEALTHCARE LLC	4/17/2014	6/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): B63564

Single Use: Y
Implant Date (E6): 3/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN THE UNITED STATES ON (B)(6) 2014 WITH REQUEST FOR REPLACEMENT OF ONE DEVICE. THE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE BROKE OFF AFTER INSERTION AND HAD TO BE REMOVED. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B63564, INSERTED. ON (B)(6) 2014, ESSURE BROKE OFF AFTER INSERTION AND HAD TO BE REMOVED, ANOTHER WAS INSERTED SUCCESSFULLY. THE PATIENT HAD NO INJURY. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	CONCEPTUS, INC	4/18/2014	4/22/2014

Event Information:

Event Date (B3): 11/20/2013 **Report Date (B4): 4/18/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B59458

Single Use:
Implant Date (E6): 11/20/2013
Explant Date (E7): 11/26/2013
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/7/2014

Event Description (B5):

DURING PLACEMENT OF THE PERMANENT BIRTH CONTROL DEVICE, THE SHEATH DID NOT RETRACT AS THE DEVICE IS INTENDED. THE PHYSICIAN ATTEMPTED TO REMOVE THE DEVICE AND A COIL BROKE OFF IN THE LEFT FALLOPIAN TUBE. THE PATIENT REQUIRED A RETURN TO THE OR TO REMOVE THE COIL AND REPLACE THE ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035747	BAYER	4/21/2014	4/23/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/1/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035759	BAYER	4/21/2014	4/25/2014

Event Information:

Event Date (B3): 6/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/8/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN (B)(6) OF 2011. I HAVE SINCE HAD LOTS OF LOWER ABDOMINAL PAIN AND SHARP, SHOOTING, LOWER VAGINAL PAIN. I HAVE LOWER BACK PAIN THAT NEVER GOES AWAY. I ALSO HAVE A HEADACHE THAT IS ALWAYS THERE. I HAVE NUMBNESS IN MY ARMS AND LEGS AND I HAVE FOGGY MIND MOST OF THE TIME. CYCLES THAT HAVE LASTED 8 AND 9 DAYS AND HAVING 2 A MONTH. THESE ARE THINGS THAT I NEVER HAD BEFORE THE PLACEMENT OF THIS PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035761	CONCEPTUS, INC.	4/21/2014	4/25/2014

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL PROCEDURE OVER A YEAR AGO. I WAS TOLD IT WAS FAST AND FOR THE MOST PART PAIN FREE. MY DOCTOR EVEN WENT AS FAR AS TO SAY "WOMEN HAVE BEEN KNOWN TO COME IN AND HAVE IT DONE ON THEIR LUNCH BREAK" HA! I CAME IN AND HAD THE PROCEDURE DONE. WHILE IN THE MIDDLE OF GETTING THE ESSURE I NEARLY PASSED OUT AND I VOMITED. THE PAIN WAS UNLIKE ANYTHING I HAD EVER FELT. AN HOUR LATER, ON MY DRIVE HOME, "WHICH IS PERHAPS 1/2 MILE" I WAS HIT WITH SUCH EXCRUCIATING PAIN THAT I ALMOST DROVE INTO ONCOMING TRAFFIC. I HAD TO PULL OVER. I VOMITED MANY MORE TIMES AND CRIED FOR ABOUT A HALF HOUR BEFORE I COULD CONTINUE HOME. I CALLED THE DOCTOR WHO SAID IT WAS NORMAL. THE SAME DOCTOR THAT TOLD ME IT IS SO EASY AND PAIN FREE, NOW THIS PAIN IS NORMAL AND TO BE EXPECTED. DAYS LATER WITH ZERO IMPROVEMENT I CALLED HER AGAIN. SHE SAID I WOULD JUST HAVE TO WAIT UNTIL THE APPOINTMENT WHERE THEY INJECT THE DYE TO SEE IF THE PROCEDURE WORKED. AT THAT APPOINTMENT SHE SAID ALL WAS PERFECT. FOR SEVERAL MONTHS I WAS ALMOST BED RIDDEN. IN A CONSTANT STATE OF PAIN. TO THIS DAY I, AT TIMES, FEEL LIKE THERE IS A COIL PIERCING THROUGH MY STOMACH. I STILL SUFFER FROM WHAT I HAVE BEEN TOLD ARE FALLOPIAN TUBE SPASMS ALMOST DAILY. THE NIGHTMARE HAS NEVER ENDED BUT THE DOCTOR REFUSES TO ADDRESS THE FACT THAT THESE SYMPTOMS ARE A DIRECT RESULT OF THE ESSURE. OF COURSE THEY ARE! I AM ONLY (B)(6) AND I HAVE ASKED MY NEW DOCTOR FOR A HYSTERECTOMY OR ANYTHING TO GET THESE THINGS OUT OF ME. BECAUSE OF MY AGE AND MY POOR INSURANCE THIS OPTION IS NOT AVAILABLE TO ME. GETTING ESSURE WAS THE BIGGEST MISTAKE OF MY LIFE. I FEEL LIKE MY LIFE HAS BEEN STRIPPED AWAY FROM ME. I CAN NO LONGER DO NORMAL ACTIVITIES WITHOUT THE PAIN. I AM CONSTANTLY GRUMPY BECAUSE OF THE PAIN. I GAINED A DANGEROUS AMOUNT OF WEIGHT BECAUSE I CAN NO

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LONGER BE AS ACTIVE AS I WAS BEFORE. I BELIEVE I HAD SENT IN A COMPLAINT A YEAR OR SO AGO BUT I NEVER HEARD BACK SO I AM DOING IT ONLINE THIS TIME. I DO NOT HAVE THE EXACT DATES BUT I CAN GET THEM IF NEED BE. I AM GUESSING IT WAS CLOSE TO 2 YEARS AGO NOW. I JUST WANT HELP. I WANT SOMEONE TO COVER THE COST OF HAVING THESE THINGS REMOVED. I HAVE BEEN TOLD THAT ESSURE IS PROTECTED BY THE FDA SO A LAWSUIT WOULD BE A WASTE OF MY TIME AND MONEY BUT AT THIS POINT I HAVE NOTHING TO LOSE. I KNOW MANY OF MY COMPLAINTS WERE DIRECTED AT MY DOCTOR BUT I HAVE LOOKED AT THE ESSURE WEBSITE AND BROCHURES AND THEY ARE SO GROSSLY MISLEADING. THE THINGS THAT ARE LISTED AS PRO'S ARE NOT AT ALL TRUE. I HAVE SINCE COMMUNICATED WITH OVER 2000 WOMEN WHO HAVE HAD THE SAME ISSUES AS ME OR EVEN WORSE. SOMETHING HAS TO BE DONE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00120	BAYER HEALTHCARE LLC	4/21/2014	4/29/2014

Event Information:

Event Date (B3): 3/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(6) 2014. THE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERT AND EXPERIENCED DEVELOPED SYMPTOMS OF NICKEL ALLERGY. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT DRUGS AND CONCURRENT CONDITIONS. CONSUMER WAS NOT PREGNANT. ON (B)(6) 2014, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. ON (B)(6) 2014, THE CONSUMER DEVELOPED SYMPTOMS OF NICKEL ALLERGY AND WAS IN THE HOSPITAL FOR ONE NIGHT. REPORTER CAUSALITY ASSESSMENT: CONSUMER WANTS TO HAVE THE ESSURE REMOVED AND HER HCP (HEALTHCARE PROFESSIONAL) SAID HE COULD REMOVE IT IN THE OFFICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00117	BAYER HEALTHCARE LLC	4/21/2014	5/1/2014

Event Information:

Event Date (B3): 2/28/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 3/17/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LEFT SIDE DEVICE PERFORATED THE FALLOPIAN TUBE. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014, THE PT HAD AN ATTEMPT TO PLACE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AT UNK, BUT ONLY THE LEFT SIDE WAS INSERTED. THE RIGHT SIDE INSERTION WAS NOT COMPLETED, AND THE LEFT SIDE DEVICE PERFORATED THE FALLOPIAN TUBE. THE PT WAS SEEN IN THE EMERGENCY ROOM LAST EVENING WITH COMPLAINTS OF ABDOMEN AND BACK PAIN. SHE IS SCHEDULED TO HAVE THE DEVICE REMOVED ON THE DAY OF THIS REPORT. IT WAS REPORTED THAT PHYSICIAN IS TAKING THE PT TO THE OPERATING ROOM TO REMOVE A PERFORATED ESSURE DEVICE. THE OUTCOME OF THE EVENT LEFT SIDE DEVICE PERFORATED THE FALLOPIAN TUBE WAS UNK. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN LEFT SIDE DEVICE PERFORATED THE FALLOPIAN TUBE AND ESSURE IS NOT REPORTED. FURTHER INFO RECEIVED ON (B)(6) 2014: ESSURE REMOVAL WAS MEDICALLY NECESSARY (REMOVED LAPAROSCOPICALLY) ON (B)(6) 2014. A CT SCAN SHOWED PERFORATION OF UTERUS AND COIL HUGGING FUNDUS, PERFORATED LEFT CORNUA. NO HYSTERECTOMY OR SALPINGECTOMY NEEDED. INFLAMED UTERINE SURFACE WAS NOTED. PT WAS RECOVERED FROM ESSURE REMOVAL PROCEDURE. HOWEVER, SHE PRESENTED SEVERE PAIN DURING AND AFTER PROCEDURE. FOLLOW-UP INFO RECEIVED ON (B)(6) 2014: NEW REPORTER WAS ADDED. FOLLOW-UP INFO RECEIVED ON (B)(4) 2014: CASE CLOSED. FOLLOW-UP INFO WAS RECEIVED ON (B)(4) 2014: PT'S DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) YEARS OLD FEMALE PT. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL

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PROBLEMS OR PROCEDURES. ON (B)(6) 2012, ESSURE WAS EASILY IMPLANTED. SHE WAS POSTPARTUM AT THE TIME OF INSERTION (DELIVERED ON (B)(6) 2011). PARACERVICAL BLOCK, TORADOL WAS APPLIED DURING INSERTION. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. ON (B)(6) 2012, HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED TO CONFIRM ESSURE PLACEMENT. DEPO PROVERA WAS USED AS BACK-UP CONTRACEPTION. ON (B)(6) 2014, BLOOD TEST WAS PERFORMED AND CONFIRMED PREGNANCY, ECTOPIC PREGNANCY WAS REPORTED. ESSURE WAS NOT REMOVED AND REMOVAL WAS NOT PLANNED. NO FURTHER INFO WAS PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00122	BAYER HEALTHCARE LLC	4/21/2014	5/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IS THE UNITED STATES AND DETECTED ON (B)(6) 2014 VIA AN ESSURE GENERIC AOL/ACTIVE ONLINE LISTENING ACTIVITY. THE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. REPORT STATED 'ONE GIRL ON HERE HAD TO GET HER FALLOPIAN TUBES REMOVED BECAUSE OF IT'. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR BIRTH CONTROL. REPORTER STATED SHE HAS BEEN TOLD BY A LOT OF PEOPLE TO STAY AWAY FROM ESSURE, ONE GIRL ON HERE HAD TO GET HER FALLOPIAN TUBES REMOVED BECAUSE OF IT. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00123	BAYER HEALTHCARE LLC	4/21/2014	5/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B8S138

Single Use: Y
Implant Date (E6): 3/28/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/10/2014

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS REC'D FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THAT DEFECTIVE ESSURE BROKE, 5 SPIRALS FROM THE TOP AND COMPLICATION OF DEVICE INSERTION. NO INFO GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT DRUGS AND CONCURRENT CONDITIONS. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH LOT NUMBER B8S138 (EXPIRATION DATE OCT-2016). ON (B)(6) 2014 DURING PLACEMENT, THE DEFECTIVE ESSURE BROKE, 5 SPIRALS FROM THE TOP. THERE WAS NO ANATOMICAL CAUSE TO EXPLAIN THE ABNORMALITY. THE DEFECT WAS ON THE INSERT ITSELF. THE BILATERAL PLACEMENT WAS PERFORMED, WITH THE INSERT CONCERNED. THE OUTCOME OF EVENT WAS NOT REPORTED.

Manufacturer Narrative (H10):

THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EFFECTS AND PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 25-JUL-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIK

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00119	BAYER HEALTHCARE LLC	4/21/2014	5/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A85496

Single Use: Y
Implant Date (E6): 3/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM OTHER HEALTH PROFESSIONAL IN UNITED STATES IN (B)(6) 2014, WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND THE RIGHT ESSURE BROKE OFF DURING. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. PATIENT WAS NOT PREGNANT. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PATIENT HAD LEFT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER A85496 (EXPIRATION DATE JANUARY 2016). HEALTH CARE PROFESSIONAL INSERTED ESSURE ON THE LEFT SIDE AND IT WENT FINE. WHEN THE RIGHT ESSURE WAS INSERTED, IT BROKE OFF AND THE BROKEN PART WENT INTO THE PATIENT'S BODY. THE PIECE WAS RETRIEVED AND IT IS AVAILABLE FOR RETURN. ANOTHER ESSURE WAS REPLACED SUCCESSFULLY ON (B)(6) 2014. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN RIGHT INSERT BROKE OFF AND THE BROKEN PART WENT INTO THE PATIENT'S BODY AND ESSURE IS NOT REPORTED. FOLLOW-UP ON (B)(6) 2014: NO NEW INFORMATION WAS PROVIDED DESPITE OF SOME REQUESTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00118	BAYER HEALTHCARE LLC	4/21/2014	5/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON (B)(6) 2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5034701, RECEIVED AT FDA ON 02/21/2014). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND ONE OF THE COILS RUPTURED FALLOPIAN TUBE AND ONE OF HER BLOOD ARTERIES OR VEINS, SHE EXPERIENCES SEVERE HEADACHES, PAIN AND PRESSURE IN HER BACK AND ABDOMEN, HEAVY MENSTRUAL CYCLE, BLOATING. ON FDA FORM REPORTED, REPORT TYPE WAS "INJURY", OUTCOME OF EVENTS WAS "OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)." NO INFO WAS GIVEN ON PAST DRUGS, CONCOMITANT MEDICATION. CONSUMER'S HISTORY/CONCURRENT CONDITIONS INCLUDED ENDOMETRIAL ABLATION IN 2010 FOR HEAVY MENSTRUAL BLEEDING TO PREVENT ANEMIA. UNDER ADVISE OF HER DOCTOR, STERILIZATION WAS RECOMMENDED TO PREVENT PREGNANCY AFTER THE ABLATION PROCEDURE. ON (B)(6) 2010, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR STERILIZATION.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON (B)(6) 2014 WITH NO NEW CLINICAL INFO. FOLLOW UP (B)(6) 2014: FOLLOW-UP INFO RECEIVED FROM THE CONSUMER. CONSUMER'S DATE OF BIRTH WAS ADDED TO CASE AND HER AGE, (B)(6) AND BMI 24.885. CONSUMER HAD 2 PREGNANCIES WITH 2 LIVE BIRTHS, LA

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00121	BAYER HEALTHCARE LLC	4/21/2014	5/20/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/24/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHO WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4), AND EXPERIENCED THE COIL THAT WAS SUPPOSED TO BE IN MY LEFT TUBE COMING OUT THE TOP OF MY UTERUS, THE COIL SCRAPPED MY INTESTINE AND WAS 0.5 INCH FROM PUNCTURING MY APPENDIX, PAIN/PELVIC PAIN, MY LEFT SIDE WAS COMPLETELY OPEN AND I HAVE YET TO HAVE A PERIOD. STUDY DESCRIPTION: ESSURES GENERIC ACTIVE ONLINE LISTENING. THE CUSTOMER HAD 3 CHILDREN. NO INFO WAS PROVIDED ON HER DRUG HISTORY, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATIONS. ON (B)(6) 2013 SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AFTER THE PROCEDURE SHE WAS FINE, EXCEPT FOR A FEW PAINS HERE AND THERE. AFTER ABOUT A MONTH, THE PAIN WORSENED AND GOT TO THE POINT THAT SHE COULD NOT WALK. SHE HAD HER 3-MONTH SCAN PERFORMED AND IT SHOWED THAT HER RIGHT SIDE WAS CLOSED AND THAT THE LEFT ONE WAS COMPLETELY OPEN. SHE RECEIVED A DEPO SHOT AND WAS TOLD TO WAIT 3 MORE MONTHS. DURING THIS TIME SHE STILL HAD PAIN AND WAS UNABLE TO WORK; SHE ALSO REPORTED THAT SHE TOOK ADVIL AND IT DID NOT WORK. AN ULTRASOUND WAS THEN PERFORMED AND SHOWED THAT HER TUBE WAS STILL OPEN; AT THAT TIME, THE DEVICE COULD NOT BE SEEN. SHE HAD A SURGERY PERFORMED ON (B)(6) 2014 WHERE IT WAS DISCOVERED THAT THE COIL THAT WAS SUPPOSED TO BE IN HER LEFT TUBE WAS ACTUALLY COMING OUT THE TOP OF HER UTERUS. SHE CONSIDERED. SHE CONSIDERED THAT THE DOCTOR WHO PERFORMED THE INSERTION PLACED THE COIL IN THE UTERINE WALL AND IT MIGRATED UP AND OUT DUE HER LINE OF WORK, WHICH INCLUDED A LOT OF BENDING AND LIFTING. THE COIL HAD SCRAPPED HER LARGE INTESTINE AND WAS 0.5 INCH FOR PUNCTURING HER APPENDIX. THE PHYSICIAN REMOVED THE COIL FROM HER UTERUS AND REMOVED HER RIGHT TUBE (EVEN THOUGH THE INSERTION HAD BEEN DONE

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CORRECTLY ON THAT SIDE) AND WITH HER LEFT TUBE. SHE REPORTED THAT SHE HAS YET TO HAVE A PERIOD AND STILL EXPERIENCES PAINFUL PELVIC PAIN EVERY DAY. THE REPORTER'S CAUSALITY WAS NOT PROVIDED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035765		4/22/2014	4/28/2014

Event Information:

Event Date (B3): 7/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BORN TO A MOTHER USING ESSURE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	4/22/2014	5/6/2014

Event Information:

Event Date (B3): 9/3/2013 **Report Date (B4): 4/22/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): 50713475

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN PREPARING FOR INSERTION, THE ESSURE MISFIRED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035766		4/23/2014	4/29/2014

Event Information:

Event Date (B3): 8/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/13/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE BIRTH CONTROL IN (B)(6) 2013. DURING THE PROCEDURE, WHEN INSERTING THE LEFT COIL, IT BROKE OFF SEVERAL DIFFERENT TIMES. MY DOCTOR TRIED TO TAKE IT OUT, BUT IT KEPT BREAKING. SHE ADVISED ME TO GO RIGHT TO SURGERY. ANOTHER DOCTOR CAME TO ASSIST HER, AND AFTER SOME DEBATING, THEY DECIDED TO JUST LEAVE IT ALONE AND IF ALL ELSE FAILS I WOULD HAVE TO HAVE MY TUBES TIED IF THE DYE WOULD PASS THROUGH WHEN I GET TESTED IN 3 MONTHS. SHE INSERTED THE RIGHT SIDE WITH NO ISSUES. THAT DAY WAS TERRIBLE, LOTS OF CRAMPING AND I BLED FOR SEVERAL WEEKS. I REPORTED THIS TO MY DOCTOR AND SAID DUE THE TRAUMA WITH INSERTION IT WAS MORE THAN LIKELY VERY IRRITATED. I HAD BAD HEADACHES, CRAMPING, AND WEIGHT GAIN ALMOST INSTANTLY. ABOUT 8 WEEKS AFTER MY PROCEDURE, I WENT TO THE REST ROOM AND THERE IN MY PANTIES WAS A WHOLE COIL! I WAS BLEEDING AND CRAMPING BAD. I RETURNED TO THE DOCTOR WITHIN A COUPLE HOURS. AN X-RAY SHOWED THAT THE RIGHT COIL WAS NO LONGER THERE. I KEPT THE COIL AND STILL HAVE IT. SO TO THIS DAY I ONLY HAVE A PARTIAL COIL ON THE LEFT SIDE (UNSURE HOW MUCH) AS THAT ONE KEPT BREAKING DURING INSERTION. I NEVER DID REACH THE 3 MONTHS TO HAVE THE DYE RUN THROUGH TO SEE IF THEY WERE BLOCKED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035772	CONCEPTUS INC	4/23/2014	4/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/2/2005
Explant Date (E7): 7/6/2005
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN AT MY OBGYN OFFICE. I WAS PUT UNDER AND OUT OF THE OFFICE IN A MATTER OF A FEW HOURS. I HAD CRAMPING AND A LITTLE SPOTTING FOR A FEW DAYS AND WAS TOLD TO TAKE IBUPROFEN. THE NEXT DAY I WAS HAVING A HARD TIME BREATHING AND CALLED THE OB. SHE SAID TO GO TO THE HOSPITAL AND WOULD SEE ME THERE. MY GALLBLADDER HAD TO BE REMOVED RIGHT AWAY BECAUSE IT WAS INFLAMED SO I HAD TO BE PUT UNDER AGAIN. SURGERY WENT FINE, AFTER A FEW DAYS OF NORMAL PAINS OF SURGERY I HAD TO RETURN TO DO THE 'CONFORMATION" TEST. THEY SAID THE OB WOULD CONTACT ME IN A FEW DAYS WHEN TESTS WERE READ. MY DOCTOR'S OFFICE CALLED AND SAID TO IMMEDIATELY COME IN AND GET ON A DIFFERENT FORM OF BIRTH CONTROL BECAUSE THE DYE SHOWED WENT THROUGH AND ESSURE DIDN'T WORK. I TOOK THE TEST AGAIN AND THIS TIME THEY ASSURED ME IT HAD WORKED THERE WERE NO PROBLEMS AND MY ESSURE WAS COMPLETELY EFFECTIVE. I BEGAN IN THE NEXT MONTHS TO BLEED A LOT AROUND MY MENSTRUAL CYCLE TIME. VERY HEAVY AND PAINFUL. MY DOCTOR DID AN ABLATION NOVA SURE. THAT WAS THREE SURGERIES IN A MONTH OR TWO TIME. FOR TWO YEARS OR A LITTLE LESS, I HAD NO PROBLEMS. THEN IT STARTED. I BEGAN BLEEDING HEAVILY AGAIN OUT OF NOWHERE. I THOUGHT I WAS HAVING A BABY RIGHT THERE WHERE I STOOD DOING DISHES BECAUSE I STARTED CRAMPING SO BAD. I THOUGHT IT WAS CONTRACTIONS AND I WAS HAVING A BABY. I RUSHED TO EMERGENCY ROOM WHERE THEY RAN TONS OF TESTS TRYING TO FIND THE PROBLEM. I WAS RELEASED WITH PAIN PILLS AND TOLD IT WAS MY PERIOD AND I HAD CRAMPS. THIS CONTINUED FOR 8 MONTHS. SEVERE CRAMPING/CONTRACTING, TONS OF DOCTORS TRYING TO FIND PROBLEMS. ONE DOCTOR DID A EXPLORATORY SURGERY WHICH I HAD TO BE PUT UNDER AGAIN. SHE FOUND A LITTLE BLEEDING AND SAID EVERYTHING LOOKED OK. SHE SUGGESTED BIRTH CONTROL AS DID EVERY OB. AFTER FOUR-FIVE OB'S, ONE FINALLY SAID IT WAS A BULKY UTERUS AND SCAR TISSUE

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CAUSING PAIN AND I NEEDED A HYSTERECTOMY. I WANTED IT ALL OUT, WAS TIRED OF THE PAIN. TERRIBLE ON MY RIGHT SIDE THAT LEFT ME UNABLE TO MOVE WHEREVER I WAS, IT JUST CAME FROM NOWHERE. CRYING, SCREAMING, IN COMPLETE PAIN WITH 5 KIDS AND UNABLE TO MOVE, FOCUS, DO ANYTHING. THE HYSTERECTOMY WENT WELL. THE DOCTOR SAID THERE WAS A VERY LOT OF BLEEDING AND THE OVARIES STAYED IN. SHE ALSO SAID MY ESSURE HAD COME ALL THE WAY THROUGH MY TUBE. AND THAT MY OVARIES HAD A LOT OF CYSTS THAT SHE REMOVED. I KNOW THE PROBLEM WAS ESSURE, I FEEL IT. AS DO HUNDREDS OF OTHER WOMEN I'VE SPOKEN TO WITH SAME PROBLEMS. STILL HAVING PROBLEMS SUCH AS TENDERNESS OF BREASTS AND LITTLE THINGS THAT SEEM TO LEAD BACK TO ESSURE. PLEASE HELP WOMEN FROM HAVING TO GO THROUGH WHAT I DID.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035775	CONCEPTUS	4/23/2014	4/29/2014

Event Information:

Event Date (B3): 2/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/9/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD THE ESSURE PERMANENT BIRTH CONTROL DEVICE SINCE (B)(6) 2012 AND HAVE SINCE HAD ISSUES WITH BLEEDING WEIGHT GAIN. CRAMPING SEVERE ABDOMINAL PELVIC AND BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035802	BAYER	4/24/2014	4/30/2014

Event Information:

Event Date (B3): 9/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628043

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE AFTER HAVING MY THIRD CHILD, I BELIEVE IT WAS ONE YEAR LATER IN 2009. I AM WAITING ON MY MEDICAL RECORDS NOW. SINCE THEN I HAVE HAD SEVERE PAIN WHEN HAVING INTERCOURSE AND ALSO RANDOMLY THROUGHOUT THE DAY AND NIGHT. I'VE ALSO EXPERIENCED LOWER BACK PAIN. MY MENSTRUAL CYCLE CHANGED DRAMATICALLY AFTER ESSURE. I NOW HAVE HUGE BLOOD CLOTS, A SHORTER CYCLE, AND ALSO RANDOM PERIODS. I ALSO HAVE MAJOR ANXIETY AND A GENERAL FEELINGS OF SICKNESS. I AM CONSTANTLY TIRED EVEN IF I SLEEP SO MUCH. THIS HAS REALLY RUINED MY QUALITY OF LIFE. BEFORE ESSURE I WAS ENERGETIC, SHARP AND ALWAYS READY FOR MY DAY. NOW I LIVE MY LIFE IN A CONSTANT FOG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035878	BAYER	4/28/2014	5/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 675112

Single Use:
Implant Date (E6): 1/27/2010
Explant Date (E7): 2/24/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER MY 4TH CHILD I DECIDED I WAS DONE HAVING CHILDREN. I SPOKE TO MY DOCTOR ABOUT MY OPTIONS AND I CHOSE TO HAVE THE ESSURE PROCEDURE PERFORMED IN EARLY 2010. IT WAS A QUICK, PAINLESS PROCEDURE. THINGS WERE OK FOR A MONTH OR SO BUT THEN I BEGAN HAVING SEVERE CRAMPING, HEAVIER THAN NORMAL BLEEDING WHILE PASSING VERY LARGE CLOTS, MOOD SWINGS, FATIGUE, LOSS OF BALANCE, AND HEADACHES. THE BLEEDING WAS SO HEAVY AT TIMES THAT I COULDN'T LEAVE MY HOUSE. I WOULD SPEND HOURS JUST SITTING ON THE TOILET WAITING FOR IT TO PASS. I MADE TRIPS TO THE E.R. AND LEFT WITHOUT KNOWING WHAT THE PROBLEM WAS. I HAD VISITS TO MY DOCTOR. HE EVEN PUT ME ON THE BIRTH CONTROL PILL TO TRY TO REGULATE MY MENSTRUAL CYCLE. AS THE MONTHS WENT ON AND NOTHING WAS WORKING I HAD A FULL HYSTERECTOMY LEAVING ONLY 1 OVARY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035879	BAYER	4/28/2014	5/6/2014

Event Information:

Event Date (B3): 4/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 5/1/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CHRONIC ABDOMINAL AND PELVIC PAIN SINCE THE PROCEDURE IN 2007. CHRONIC BV.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035882	BAYER HEALTH	4/28/2014	5/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS ABOUT 7 YEARS AGO. SINCE THEN I HAVE DEVELOPED AN ARRAY OF COMPLICATIONS. I EXPERIENCE FREQUENT HEADACHES, JOINT PAIN, EXTREME TIREDNESS AND FATIGUE, THE OIL IN MY SKIN HAS A METALLIC SMELL, FREQUENT DIZZINESS, NAUSEA, NUMBNESS OF TOES, ABDOMINAL BLOATING, EDEMA AND THE WORST PROBLEM IS LOWER RIGHT ABDOMINAL PAIN AND PELVIC CRAMPING. IN (B)(6) 2012 I STARTED EXPERIENCING SEVERE LOWER RIGHT ABDOMINAL PAIN WHILE ON VACATION. WHEN I RETURNED HOME I WENT TO THE LOCAL URGENT CARE THINKING I MIGHT HAVE APPENDICITIS. AFTER BLOODWORK AND CT WITH CONTRAST THE DOCTORS COULDN'T DETERMINE THE CAUSE OF MY PAIN. THE FOLLOWING APRIL THE PAIN STARTED BECOMING UNBEARABLE SO I ENDED UP AT THE E.R. ONE SUNDAY AFTERNOON ONCE AGAIN THINKING IT COULD BE APPENDICITIS. THE DOCTOR DID BLOODWORK AND A CT AND TOLD ME THERE WAS NO CAUSE FOR THE PAIN I DESCRIBED. A FEW DAYS LATER, WHILE GETTING READING FOR WORK, THE PAIN WAS EXCRUCIATING SO I CALLED MY GYN, WHO IS NOT THE ONE THAT DID THE ESSURE PROCEDURE, AND WAS TOLD TO COME IN TO SEE A DOCTOR. I WAS IN SO MUCH PAIN I WAS ALMOST UNABLE TO DRIVE. I WAS SOBBING DUE TO THE EXCRUCIATING PAIN. THE DOCTOR DID A VAGINAL ULTRASOUND AND SAID THE COILS WERE IN PLACE AND SHE HAD TROUBLE BELIEVING I WAS IN THAT MUCH PAIN. I LEFT AND CALLED MY PRIMARY CARE DOCTOR AND WAS TOLD TO GO STRAIGHT TO THE E.R. FOR A CT WITH CONTRAST. THE E.R. DOCTOR ALSO DID VARIOUS BLOODWORK. THE CT AND ALL BLOODWORK WAS NORMAL AND I WAS ONCE AGAIN TOLD THEY SAW NO REASON FOR THE PAIN I EXPLAINED. WHEN TELLING THE E.R. DOCTOR AND NURSE ABOUT THE ESSURE, THEY HAD NEVER HEARD OF IT. IT IS TIME FOR MY YEARLY GYN APPOINTMENT AND WILL DISCUSS MY SYMPTOMS FURTHER WITH THIS BEING A NEW DOCTOR THAT I WILL BE SEEING. PLEASE TAKE THE COMPLAINTS AND CONCERNS OF WOMEN WITH ESSURE SERIOUSLY. WE SUFFER EVERYDAY AND CAN'T

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SEEM FIND ANYONE THAT WILL LISTEN! I DON'T WANT A REVERSAL. I AM (B)(6) SO I HAVE NO DESIRE TO HAVE ANOTHER CHILD. I WOULD LIKE THE OPTION FOR REMOVAL OF ESSURE THAT WILL BE COVERED BY INSURANCE DUE TO THE CONSTANT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035883	BAYER/CONCEPTUS	4/28/2014	5/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/18/2013
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2013. SINCE THEN I HAVE HAD UNBEARABLE ABDOMEN PAIN NUMBNESS IN MY LEGS, DEBILITATING MIGRAINES. IT'S TERRIBLE. IT TAKES AWAY FROM MY CHILDREN AND CAUSES DR. CIVETS WHICH I CANNOT AFFORD. STOP ESSURE IT'S A TERRIBLE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00127	BAYER HEALTHCARE LLC	4/29/2014	5/5/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: N
Implant Date (E6): 4/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM ANOTHER HEALTH PROFESSIONAL VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PRURITUS ON FACE AND NECK, HOLE WITH PAPULES PRURIGO, AND LESIONS SCRATCHING. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. IN (B)(6) 2012, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PATIENT EXPERIENCED SKIN PRURITUS ON FACE AND NECK ON (B)(6) 2012, HOLE WITH PAPULES PRURIGO AND LESIONS SCRATCHING. SHE HAD A SUSPICION OF CONTACT ALLERGY AND STANDARD SERIES OF TESTS (UNSPECIFIED) WERE DONE IN (B)(6) 2013 AND SHOWED NICKEL ++. NON-SERIOUS CASE ACCORDING TO THE REPORTER. NO FURTHER INFORMATION AVAILABLE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00128	BAYER HEALTHCARE LLC	4/29/2014	5/5/2014

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): EES305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 2/21/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT WAS ADMITTED INPATIENT ON (B)(6) 2014. PATIENT WAS ADMITTED FOR HYPOKALEMIA, LEUKOCYTOSIS, MILD THROMBOCYTOPENIA, CONSTIPATION, ABDOMINAL AND FLANK PAIN, NAUSEA, VOMITING, AND SEPSIS WITH SYSTEMIC INFLAMMATORY RESPONSE SYNDROME SECONDARY TO PID VERSUS PYELONEPHRITIS. SHE WAS GIVEN IV ANTIBIOTIC TREATMENT. SHE UNDERWENT ADRENAL ULTRASOUND, MORE LABS AND WATCHED HER IN THE HOSPITAL. THE REPORTED DID NOT KNOW THE OUTCOME OF THE EVENTS, DISCHARGE DATE, NOT SURE HOW MANY DAYS PATIENT WAS AT THE HOSPITAL.

Manufacturer Narrative (H10):

PHYSICIAN'S OFFICE CONFIRMED THE PATIENT HAS A CONFIRMATORY DIAGNOSIS OF PELVIC INFLAMMATORY DISEASE. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. SHE WAS NOT PREGNANT. SHE HAD ESSURE PLACED IN (B)(6) 2014 OR (B)(6) 2014 AND HAS NOT HAD A HSG (HYSTE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00125	BAYER HEALTHCARE LLC	4/29/2014	5/6/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B72580

Single Use: Y
Implant Date (E6): 3/27/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014. THE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS DISCHARGED WITHOUT PROBLEM BUT IT WENT TO KINK, DURING REMOVAL ATTEMPT THE DEVICE EXPANDED AND BROKE AND COMPLICATION OF DEVICE INSERTION. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2014, THE PATIENT WAS TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B72580, INSERTED BY PHYSICIAN FOR STERILIZATION. THE IMPLANT WAS DISCHARGED WITHOUT PROBLEM BUT IT WENT TO KINK. DURING REMOVAL ATTEMPT IT EXPANDED AND BROKE. ULTRASOUND SHOWED PART OF THE IMPLANT IN SITU IN RIGHT CORNU. ALSO X-RAY SHOWED A PART OF THE IMPLANT IN RIGHT CORNU (TWO MARK POINTS VISIBLE). FURTHER PLAN WAS TO PERFORM LAPAROSCOPIC STERILISATION. REPORTER DID NOT ACCESS DEVICE-EVENT RELATIONSHIP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035860	BAYER	4/29/2014	5/6/2014

Event Information:

Event Date (B3): 12/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE INSERTED AND SINCE HAD TO HAVE THE HYSTERECTOMY. I HAD EXTREME PAIN AND BLOATING. I ALSO DEVELOPED ACHES AND PAIN IN MY JOINTS AND EXCESSIVE DAYTIME SLEEPINESS WHICH I STILL SUFFER FROM. A PULMONARY DOCTOR PUT ME ON STIMULANTS AND THEN A NEUROLOGIST INCREASED THEM. I THEN GRINDED MY TEETH AT NIGHT AND CHIPPED 2 AND BROKE ONE. I HAVE SINCE STOPPED ALL THE STIMULANTS BUT NOW I HAVE TO GO GET MY TEETH FIXED. I HAVE A HARD TIME WORKING FULL TIME AND FLEW TO (B)(6) TO BE DIAGNOSED WITH IDIOPATHIC HYPERSOMNIA AFTER 3 SLEEP STUDIES. I ALSO SUFFER FROM TMJ FROM THE TENSION THE STIMULANTS CAUSED. I TOLD MY GYNO THAT IT STARTED AFTER THE ESSURE BUT WAS TOLD THAT COULD NOT BE THE CASE. I HAVE ALSO BEEN TO AN INTERNIST, DIETICIAN, AND ENDOCRINOLOGIST TO TRY TO FIND OUT WHY I CANNOT STAY AWAKE. THEY RULED OUR APNEA, IRON, THYROID, LYME DISEASE, ADDISON, GLUTEN, ETC. I AM LOSING MY QUALITY OF LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035861	BAYER	4/29/2014	5/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/16/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(6) OF 2010, AT THE TIME I WAS NEVER GIVEN A CARD IDENTIFYING THE PRODUCT SERIAL NUMBER, BATCH NUMBER, NOTHING. AT FIRST THE PAIN AND DISCOMFORT WASN'T TOO MUCH TO BEAR, SO I JUST DEALT WITH IT, BUT WITHIN THE LAST YEAR IT HAS BECOME WORSE. I HAVE VERY HEAVY BLEEDING DURING MY PERIODS, PAINFUL CRAMPS, AND JOINT PAINS AND STIFFNESS. THESE ARE JUST THE SMALL ISSUES UNFORTUNATELY. I WENT IN FOR MY ANNUAL IN (B)(6) OF THIS YEAR, WHICH CAME BACK ABNORMAL, I THEN WENT IN FOR A COLPOSCOPY. WHEN MEETING WITH MY DOCTOR AFTER THE COLP TEST, HE WAS SHOCKED IT WAS NOT FOUND SOONER. THE AMOUNT OF ABNORMAL CELLS MADE IT SEEM AS THOUGH IT HAD BEEN THERE FOR AT LEAST 3+ YEARS. NONE OF THIS HAD BEEN FOUND PREVIOUSLY THOUGH. HE THEN REFERRED ME TO A SPECIALIST WHO INFORMED ME THAT I HAVE PRECANCEROUS CELLS IN MY CERVIX AND I WILL BE GOING IN ON THE (B)(6) TO MAKE SURE THERE IS NO CANCER DEEPER. AFTER THIS, I STARTED LOOKING INTO THESE ISSUES AND FOUND MORE INFO ON ESSURE. ALL THE SIDE EFFECTS IT CAN CAUSE, HEAVIER THAN NORMAL BLEEDING, WEIGHT GAIN, CRAMPS, JOINT PAINS, PAIN DURING INTERCOURSE AND EVEN CERVICAL CANCER. I HAVE ALL OF THE SIDE EFFECTS I LISTED, SOME MORE SEVERE THAN OTHERS. I AM REQUESTING MY SPECIALIST TO REMOVE THE ESSURE COMPLETELY BY HYSTERECTOMY IF NECESSARY AS SOON AS POSSIBLE. I WANT TO FEEL WELL AGAIN, AND BE HEALTHY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035863	CONCEPTUS INC.	4/29/2014	5/6/2014

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 919034

Single Use:
Implant Date (E6): 2/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2012, SINCE THEN MY PERIODS HAVE BECOME MORE PAINFUL WITH EACH CYCLE. ALSO, I HAVE BEEN PASSING VERY LARGE BLOOD CLOTS. MY LAST CYCLE HAD TWO THAT WERE BETWEEN ORANGE AND GRAPEFRUIT SIZE. I DID NOT HAVE A PROBLEM WITH THIS BEFORE HAVING THIS PROCEDURE. MY PERIODS HAVE ALSO BECOME MORE PAINFUL WITH INTENSE UTERUS CRAMPING AND A MUCH HEAVIER FLOW. AFTER TALKING WITH A FRIEND WHO ALSO HAD THIS PROCEDURE DONE, SHE STARTED EXPLAINING HER SYMPTOMS AND THEY WERE THE EXACT SAME AS MINE. AT FIRST I THOUGHT THIS MADE ME FEEL BETTER BUT AFTER THINKING ABOUT IT I BECAME EVEN MORE CONCERNED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035876	CONCEPTUS (BOUGHT OUT BY BAYER)	4/29/2014	5/6/2014

Event Information:

Event Date (B3): 2/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 754913

Single Use:
Implant Date (E6): 2/10/2011
Explant Date (E7): 4/7/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2011, I HAD ESSURE IMPLANTS (LOT 754913) PLACED IN MY FALLOPIAN TUBES BILATERALLY. IN (B)(6) 2011, I BEGAN EXPERIENCING NEUROLOGIC SYMPTOMS CONSISTING OF MODERATE PARESTHESIAS IN BOTH ARMS AND LEGS, DIZZINESS, AND PROBLEMS WITH BALANCE AND COORDINATION. IN (B)(6), I SAW A NEUROLOGIST WHO DIAGNOSED ME WITH A SEVERE VITAMIN B12 DEFICIENCY, WITH SERUM B12 LEVEL OF 150. I WAS IMMEDIATELY PLACED ON DAILY VITAMIN B12 1000 MCG INJECTIONS AND DAILY ORAL VITAMIN B12 1000 MCG SUPPLEMENTS JUST TO MAINTAIN MY SERUM VITAMIN B12 LEVEL WITHIN NORMAL RANGE. IN (B)(6) 2011, I BEGAN EXPERIENCING CONTINUOUS CARDIAC PALPITATIONS AND CHEST PAIN. I SAW A CARDIOLOGIST WHO DIAGNOSED ME WITH PREMATURE ATRIAL CONTRACTIONS, SOMETIMES BIGEMINAL. I WAS MAINTAINED ON A BETA BLOCKER MEDICATION TO CONTROL MY CARDIAC SYMPTOMS. IN (B)(6) 2012, I BEGAN DEVELOPING SPONTANEOUS FEVERS OF 102-103 THAT WOULD LAST SEVERAL DAYS AT A TIME. I DEVELOPED EPISODES OF SPONTANEOUS SWELLING, EXTREME REDNESS AND PAIN IN MY NOSE AND ALTERNATING BETWEEN BOTH OF MY EARS, EACH LASTING WEEK TO 10 DAYS AT A TIME. I SAW A RHEUMATOLOGIST WHO DIAGNOSED ME WITH RELAPSING POLYCHONDRITIS. I CONTINUED TO HAVE INTERMITTENT FEVERS, FATIGUE, JOINT AND MUSCLE PAIN. IN (B)(6) 2013, MY FLARES WERE SO FREQUENT, THEY WERE NOT BEING EFFECTIVELY CONTROLLED WITH PREDNISONE. MY RHEUMATOLOGIST SAID THE NEXT STEP WOULD BE TO PLACE ME ON IMMUNE SYSTEM SUPPRESSANT MEDICATIONS. I ASKED MY RHEUMATOLOGIST IF SHE BELIEVED MY AUTOIMMUNE DISORDER AND OTHER PREVIOUS SYMPTOMS COULD HAVE BEEN CAUSED BY THE IMPLANTATIONS OF MY ESSURE DEVICES, SINCE I HAD NO HEALTH PROBLEMS PRIOR TO THEM BEING IMPLANTED. SHE SAID SHE THOUGHT IT WAS VERY SUSPICIOUS AND REQUIRED FURTHER

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INVESTIGATION. SHE SAID THE IMPLANTS MAY HAVE CAUSED A SYSTEMIC INFLAMMATORY RESPONSE IN MY BODY, OR I MAY BE REACTING TO THE COMPONENTS THE DEVICE IS MADE OF, SUCH AS THE NICKEL. I WAS NOT TESTED FOR A NICKEL ALLERGY PRIOR TO IMPLANTATION, AS THE FDA DROPPED THAT REQUIREMENT. IN (B)(6) 2014, I VISITED MY GYNECOLOGIST TO DISCUSS MY SYMPTOMS AND REQUEST TO HAVE THE ESSURE IMPLANTS REMOVED. I DID NOT WANT A COMPLETE HYSTERECTOMY, SO HE REFERRED ME TO A SPECIALTY GYNECOLOGIC SURGEON WHO COULD REMOVE ONLY THE ESSURE DEVICES, FALLOPIAN TUBES AND BILATERAL CORNUA OF THE UTERUS. IN (B)(6) 2014, I HAD A PELVIC CT SCAN TO CONFIRM CURRENT PLACEMENT OF BOTH COILS. BOTH COILS HAD MIGRATED DISTALLY IN THE FALLOPIAN TUBES, THE LEFT PRACTICALLY EXITING THE FALLOPIAN TUBE NEAR THE OVARY. ON (B)(6) 2014, I HAD LAPAROSCOPIC PELVIC SURGERY TO PERFORM REMOVAL OF BILATERAL ESSURE COILS, BILATERAL SALPINGECTOMY, AND BILATERAL CORNEAL RESECTION OF THE UTERUS. I AM CONVINCED THAT THE ESSURE DEVICES ARE WHAT HAVE BEEN CAUSING MY HEALTH PROBLEMS AND DECLINE SINCE (B)(6) 2011 WHEN THEY WERE IMPLANTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00124	BAYER HEALTHCARE LLC	4/29/2014	5/7/2014

Event Information:

Event Date (B3): 8/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/19/2013
Explant Date (E7): 3/14/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2013, ESSURE 305 WAS INSERTED. INSERTION WAS DIFFICULT (NARROW CERVICAL CHANNEL). TUBAL OS WAS EASILY VISUALIZED. THERE WERE NO ABNORMAL FINDINGS PRIOR TO INSERTION. THERE WERE NO COMPLAINTS IMMEDIATELY AFTER INSERTION. ON (B)(6) 2013, PERFORATION (UNILATERAL RIGHT) WAS DIAGNOSED VIA ULTRASOUND. IT WAS STATED PERFORATION OCCURRED BEFORE DEPLOYMENT. PT WAS EXPERIENCING ABDOMINAL PAIN. NO ESSURE CONFIRMATION TEST WAS PERFORMED. ESSURE WAS REMOVED ON THE LEFT SIDE. ON (B)(6) 2014, ESSURE WAS REMOVED ON THE RIGHT SIDE. IT WAS NOT MEDICALLY NECESSARY TO REMOVE ESSURE. REMOVAL WAS PERFORMED LAPAROSCOPICALLY. PT WAS RECOVERED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON (B)(4) 2014: IT WAS REPORTED THAT PERFORATION OCCURRED ON THE RIGHT FALLOPIAN TUBE. WITH THE FIRST SURGICAL PROCEDURE ON (B)(6) 2013, DEVICE WAS NOT FOUND IN THE ABDOMEN AND THE PATIENT REQUESTED REMOVAL OF ESSURE ON THE LEFT TUBE. O

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00130	BAYER HEALTHCARE LLC	4/29/2014	5/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): TU00

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF ECTOPIC PREGNANCY 2 YEARS AFTER SUCCESSFUL CONFIRMATION TEST AND DEVICE INEFFECTIVE IN A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PT RECEIVED ANY CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER TU00, FOR STERILIZATION. ON AN UNSPECIFIED DATE THE PT EXPERIENCED ECTOPIC PREGNANCY 2 YEARS AFTER SUCCESSFUL CONFIRMATION TEST. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE IS NOT REPORTED. F/U RECEIVED ON (B)(6) 2014: F/U ATTEMPTS WERE DONE WITHOUT SUCCESS AND CASE CLOSED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00132	BAYER HEALTHCARE LLC	4/29/2014	5/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: N
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(4) 2014 WITH REQUEST FOR REPLACEMENT OF ONE DEVICE. THE REPORT REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND TOO MUCH WINDINGS WERE VISIBLE IN CAVUM AND DURING ATTEMPT OF REMOVAL 2-3 WINDINGS OF ESSURE BROKE. NO INFO WAS GIVEN ON PT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON AN UNSPECIFIED DATE, AFTER INSERTION OF ONE ESSURE, TOO MANY WINDINGS WERE SEEN IN THE CAVUM, EXACT NUMBER OF WINDINGS WERE NOT KNOWN BY REPORTER. PHYSICIAN DECIDED TO REMOVE THE ESSURE AFTER ONE WEEK. THE SECOND ESSURE WAS WELL INSERTED. DURING ATTEMPT OF REMOVAL 2-3 WINDINGS OF ESSURE BROKE. PHYSICIAN DECIDED TO LET THE PARTS THAT WERE LEFT OVER REMAIN. THERE WERE NO SIGNS OF PERFORATION. PT WILL COME AFTER 3 MONTHS FOR ECHO (ULTRASOUND) AND PHYSICIAN HAS PREPARED HER FOR A POSSIBLE HSG (HYSTEROSALPINGOGRAM). PHYSICIAN MENTIONED THAT IN THE PAST HE REMOVED ESSURES OFTEN, EVEN FOR TIMEFRAMES LONGER THAN ONE WEEK.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00133	BAYER HEALTHCARE LLC	4/29/2014	5/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE #MW5034903) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED "MY PERIODS BECAME IRREGULAR, BEGAN TO GAIN WEIGHT, PERIODS BEGAN TO INCREASE IN LENGTH FROM 5 TO 7-10 DAYS AND BECAME HEAVY WITH LARGE CLOTS, BEGAN TO LOSE ENERGY, BREAST WOULD BECOME TENDER FOR 3 WEEKS OUT OF THE MONTH, ABDOMINAL PAIN, SEVERE MIGRAINES, SMALL CYST ON MY TUBE, UTERUS WAS ENLARGED, AND DIAGNOSED WITH ADENOMYOSIS." NO INFO GIVEN ON CONSUMER'S MEDICAL HISTORY AND ON CONSUMER'S DRUG HISTORY. THE CONSUMER'S CONCURRENT CONDITION INCLUDED NICKEL ALLERGY. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. IN 2008, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AFTER IMPLANTATION HER PERIODS BECAME IRREGULAR AND SHE BEGAN TO GAIN WEIGHT. ABOUT TWO YEARS LATER HER PERIODS BEGAN TO INCREASE IN LENGTH, FROM FIVE DAYS TO SEVEN-TEN DAYS, AND BECAME HEAVY WITH CLOTS. SHE BEGAN TO LOOSE ENERGY. HER BREAST WOULD BECOME PAINFUL AND TENDER FOR THREE WEEKS OUT OF THE MONTH. SHE ALSO STARTED GETTING ABDOMINAL PAIN AND SEVERE MIGRAINES. IN 2013, SHE HAD A PARTIAL HYSTERECTOMY, REMOVING HER UTERUS AND FALLOPIAN TUBES AS WELL AS THE ESSURE. HER POST OPERATIVE REPORT INDICATED THAT SHE HAD A SMALL CYST ON HER TUBE, HER UTERUS WAS ENLARGED AND SHE WAS DIAGNOSED WITH ADENOMYOSIS. SHE WAS HEALTHY AND HAD NO FEMALE ISSUES PRIOR TO ESSURE BEING IMPLANTED. SHE WAS NOT NOTIFIED PRIOR TO IMPLANTATION THAT ESSURE HAD NICKEL. F/U RECEIVED ON 04/16/2014: AFTER THREE F/U ATTEMPTS, NO RESPONSE HAS BEEN RECEIVED.

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Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00129	BAYER HEALTHCARE LLC	4/29/2014	5/9/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF ECTOPIC PREGNANCY AND DEVICE INEFFECTIVE IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION. PATIENT HAD A CONFIRMED HSG (HYSTEROSALPINGOGRAM) ON UNSPECIFIED DATE. ON AN UNSPECIFIED DATE THE PATIENT EXPERIENCED ECTOPIC PREGNANCY AND DEVICE INEFFECTIVE. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP INFO RECEIVED ON (B)(6) 2014. AFTER THREE FOLLOW-UP ATTEMPTS, NO RESPONSE RECEIVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00126	BAYER HEALTHCARE LLC	4/29/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50741327

Single Use: N
Implant Date (E6): 3/25/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABLATION OF THE GUIDE (RESISTANCE AND THE METAL END WAS DISCONNECTED). NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ESSURE LOT NUMBER WAS 50741327. ON (B)(6) 2014 ON ABLATION OF THE GUIDE THERE WAS A RESISTANCE AND THE METAL END WAS DISCONNECTED. NO FURTHER INFORMATION WAS PROVIDED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN ABLATION OF THE GUIDE (RESISTANCE AND THE METAL END WAS DISCONNECTED) AND ESSURE IS NOT REPORTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00131	BAYER HEALTHCARE LLC	4/29/2014	6/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): B85139

Single Use: Y
Implant Date (E6): 4/3/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM "A OTHER" IN (B)(6) ON 03-APRIL-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE WOUND DOWN INSERT WAS RELEASED IN THE FALLOPIAN TUBE BUT THE DELIVERY CATHETER DIDN'T COME OFF AND COMPLICATION OF DEVICE INSERTION. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B85139, INSERTED. THE WOUND DOWN INSERT WAS RELEASED IN THE FALLOPIAN TUBE BUT DELIVERY CATHETER DID NOT COME OFF. CATHETER GUIDE WAS CUT IN THE UTERUS. FOLLOW-UP INFORMATION RECEIVED FROM THE PHYSICIAN ON (B)(6) 2014. PALIN ABDOMEN X-RAY AS WELL AS ULTRASOUNDS WAS TO BE DONE AND THEN PATIENT WAS TO UNDERGO HYSTEROSCOPY TO WELL IDENTIFY THE PROBLEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035815	BAYER	4/30/2014	4/30/2014

Event Information:

Event Date (B3): 12/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT PROCEDURE IN (B)(6) 2012. SINCE THAT TIME, I HAVE EXPERIENCED NUMEROUS COMPLICATIONS INCLUDING: LONG TERM, POST SURGERY PROJECTILE BLEEDING, ONE YEAR OF IRREGULAR PERIODS, LOSS OF PERIOD, DISCHARGE OF OLD BLOOD, PERSISTENT PAIN IN OVARIES, INCREASED ACNE/CYSTS, INCREASED PAIN DURING OVULATION, RECURRING BACTERIAL VAGINOSIS/PID. #MEDWATCHER #MW156157.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035817	BAYER	4/30/2014	4/30/2014

Event Information:

Event Date (B3): 3/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY ESSURE PLACED ON (B)(6) AND MY DOCTOR HAD TO PUT ONE SET IN AND REMOVE THEM AND THEN PLACE ANOTHER SET. THE FIRST SET BROKE OFF INSIDE WHICH SHE DID NOT KNOW AND WHEN SHE PLACED THE SECOND SET IT PIERCED THROUGH MY FALLOPIAN TUBE AND HIT A FAT POCKET ALMOST PERFORATING MY BOWEL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035812	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN 2008. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN (B)(6) 2009. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. EXTREME AND CHRONIC ABDOMINAL PAINS, IRREGULAR PERIODS, BLEEDING, SPOTTING, INFLAMMATION LEADING TO CONSTIPATION AND HEMORRHOIDS. NUMEROUS VISITS TO THE ER, A COLORECTAL SURGERY DUE TO ABSCESS, HEADACHES, EXTREME FATIGUE, CONFUSION, LACK OF CLARITY AND CONCENTRATION, DEPRESSION, WEIGHT GAIN, INABILITY TO LOSE WEIGHT AND MIGRAINES. I HAVE BEEN SEEN BY AT LEAST 7 DIFFERENT NUMBER OF DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS IBS, RLS, OVARIAN CYSTS, DEPRESSION AND MIGRAINES. THE DEVICE IS STILL INSIDE OF ME. THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035813	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN A VERY HEALTHY ACTIVE MOM OF THREE. NO OTHER MEDS OR KNOWN ILLNESS. I STARTED WAKING UP WITH TINGLING IN MY HANDS. IT LATER SPREAD DOWN TO INTO MY HIPS AND LOWER BACK. SEX HAS BECOME UNBEARABLE! MY PERIODS ARE NOT NORMAL, MY PERIODS ARE BROWNISH IN COLOR AND VERY CLOTTY. MY HIPS AND BACK HURT CONSTANT AND OFTEN IS DEBILITATING. I HAVE MISSED WORK AND MY KIDS ACTIVITIES. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035814	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN 2010, 2 MONTHS AFTER THE BIRTH OF MY 4TH CHILD. SINCE THE IMPLANTATION, I HAVE HAD EXCRUCIATING CRAMPS, HEAVY BLEEDING DURING MY PERIODS, AND PAINFUL INTERCOURSE TO LIST A FEW. I HAD LOST MY WILL TO CONTINUE BEING THE FUN LOVING SELF I ONCE WAS. I NEVER HAD ANY ENERGY AND SPENT MOST OF MY TIME IN BED. IF I DID GO OUT IT WAS LIKE I WAS HAVING AN OUT OF BODY EXPERIENCE LIKE I WAS ALWAYS IN A DAZE THAT I COULD NOT GET OUT OF AND SEEING EVERYTHING FROM THE OUTSIDE IN. I FELT LIKE I WAS LITERALLY GOING TO DIE EVERY MONTH DURING MY CYCLE. I HAD NEVER HAD THIS MUCH PAIN NOT EVEN DURING OR AFTER CHILDBIRTH. I ALWAYS FELT A SHARP PAIN IN MY SIDES THAT I LEARNED TO LIVE WITH IT SINCE I DIDN'T KNOW ANY BETTER I THOUGHT THIS WAS JUST THE NORMAL FEELING THAT I WAS GOING TO HAVE FOR THE REST OF MY LIFE. MY HUSBAND TRIED HIS BEST TO CONSOLE ME AND TRY TO UNDERSTAND MY PAIN. THE BEST WAY THAT I COULD EVER EXPLAIN IT TO HIM WAS LIKE IF I GOT THE SHARPEST KNIFE IN THE KITCHEN AND WAS CONSTANTLY STABBING MY FALLOPIAN TUBES, THAT IS THE BEST WAY TO HAVE HIM UNDERSTAND MY PAIN. I THANK GOD THAT I FOUND THE ANSWER TO MY PAIN. ON (B)(6), I UNDERWENT A VAGINAL HYSTERECTOMY WITH THE REMOVAL OF MY UTERUS, BOTH FALLOPIAN TUBES(WITH ESSURE), AND CERVIX. MY DOCTOR OPTED TO HAVE ME STAY WITH MY OVARIES TO AVOID HAVING TO BE ON HORMONES SINCE I AM ONLY (B)(6) YEARS OLD. I NEVER IN MY WILDEST DREAMS WOULD HAVE IMAGINED THAT I WOULD HAVE MY WOMANHOOD TAKEN FROM ME AT SUCH A YOUNG AGE. I HAVE TO ADMIT THAT THE PAIN FROM HAVING MY FEMALE ORGANS REMOVED DID NOT EVEN COME CLOSE TO THE PAIN THAT I SUFFERED ON A DAILY BASIS WITH ESSURE. I RETURNED TO WORK A WEEK AFTER MY SURGERY AND HAD NEVER FELT SO ALIVE. I AM NOW 19 DAYS POST OP AND I'M SO BLESSED TO SAY THAT MY CHILDREN HAVE THEIR MOM BACK AND MY HUSBAND HIS WIFE. IT IS STILL AN ONGOING PROCESSES THAT I

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HAVE TO ALLOW MYSELF TO COME TO TERMS WITH. I AT TIMES GET SO EMOTIONAL OVER THE FACT THAT IT HAD TO COME TO THIS EXTREME TO FEEL BETTER. IF SOMEONE WOULD HAVE TOLD ME AND WARNED ME ABOUT EVERYTHING I WAS GOING TO FEEL AND GO THROUGH BACK IN 2010, I WOULD NEVER HAVE HAD THIS DEVICE IMPLANTED!! I SELECTED PERMANENT DAMAGE SINCE I WILL NEVER GET MY ORGANS BACK! (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035816	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A WEEK AFTER INSERTED WITH ESSURE I WENT TO DR. WITH PAIN AND WAS CONFIRMED TO HAVE A UTI. THIS WAS THE FIRST OF MANY. 10 DAYS AFTER INSERT I AWOKE WITH WHAT I THOUGHT WAS A BLOODY NOSE ONLY TO FIND OUT IT WAS AN ENORMOUS AMOUNT IF CLEAR FLUID. I DID NOT HAVE ALLERGIES/COLD. SINCE THAT TIME I AWAKE EVERYDAY FEELING LIKE I HAVE BEEN HIT IN THE BACK OF MY HEAD WITH A BASEBALL BAT. I HAVE IRREGULAR BLEEDING AND PERIODS THAT RANGE FROM LIGHT OR SKIPPED TO EXTREMELY HEAVY. I HAVE HAD TEXT BOOK PERIODS MY WHOLE LIFE. INTERCOURSE IS EXTREMELY PAINFUL. THE PAIN IS MOSTLY ON MY RIGHT SIDE AND RIGHT HIP. DAYS BEFORE MY PERIOD I HAVE A HARD TIME WALKING DUE TO PAIN. RECENTLY I WENT TO DR. FOR SEVERE PAIN ON MY RIGHT SIDE. THEY DID SEVERAL TESTS THINKING IT WAS A KIDNEY STONE. TURNS OUT I HAD AN ECOLI INFECTION FOUND BY TAKING A CULTURE OF MY URINE. IT IS BECAUSE OF THIS ECOLI THAT I BEGAN TO RESEARCH ESSURE. I AM READING THAT IT CAN PUNCTURE THE BOWELS. I WILL HAVE MORE TESTS DONE SOON TO FIND OUT WHAT'S GOING ON. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035818	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 7/17/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I FOUND I WAS 5 WEEKS PREGNANT AND ONE OF THE COILS MIGRATED. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035819	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 3/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SERVER ABDOMINAL CRAMPING, WEIGHT GAIN, HEADACHES, SKIN CHANGE, MOOD CHANGE, PAIN DURING INTERCOURSE, RASHES OFF AND ON, HEAVY HEAVY BLEEDING, IRREGULAR PERIODS, PERIODS 3 TIMES A MONTH THAT LASTED A WEEK A PIECE, AND BACK PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035820	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 3/16/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I GOT IMPLANTED, MY CYCLES BECAME MUCH HEAVIER, VERY PAINFUL, AND VERY IRREGULAR..I WOULD SOMETIMES HAVE GOLF BALL SIZED CLOTS DURING MY PERIODS...SOMETIME'S I WOULD HAVE 2 IN 1 MONTH OR MISS A WHOLE MONTH ALL TOGETHER..ABOUT 1 YEAR LATER, I STARTED HAVING METALLIC TASTE IN MY MOUTH, AND SHARP STABBING PAINS IN MY LOWER ABDOMEN..IN (B)(6) OF 2010, I FOUND OUT I WAS PREGNANT, AND 2 WEEKS LATER FOR A FOLLOW-UP ULTRASOUND VISIT, I WAS TOLD I MISCARRIED AT (B)(6)..THEN AGAIN IN (B)(6) OF 2013, I FOUND OUT I WAS PREGNANT AGAIN AND WAS ALREADY (B)(6) ALONG {DUE TO IRREGULAR PERIODS, I HAD NO IDEA I WAS PREGNANT}.. I WAS VERY WORRIED ABOUT THE PREGNANCY..MY DR HAD NO IDEA WHAT COULD HAPPEN TO ME OR THE BABY..SHE WAS BORN (B)(6) 2014..I HAD MY TUBES TIED AFTER THE BIRTH.. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035821	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 7/27/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOUND OUT I WAS PREGNANT AFTER FOUR YEAR OF HAVING ESSURE DELIVERED A BABY BOY (B)(6), 2014. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035822	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 8/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY CONTINUOUS BLEEDING THAT LEAD TO ANEMIA AND IRON DEFICIENCY. FATIGUE, JOINT PAIN, VISION PROBLEMS, ANXIETY ATTACKS, DEPRESSION, LOWER BACK PAIN, ABDOMEN PAIN, HIGH BLOOD PRESSURE. #MEDWATCHER #MW156149.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035823	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 7/10/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE OF THE DEVICE MIGRATED OUT OF MY BODY AND THE FOLLOWING WEEK FOUND OUT I WAS EXPECTING 5 WEEKS ALREADY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035825	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 8/27/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4): ESS205
Lot #(E4): 624476

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PROBLEMS STARTED WHEN THE DOCTOR WAS PUTTING IN THE COILS/DEVICES FROM ESSURE. SHE HAD A HARD TIME SEEING WHAT SHE WAS DOING AND WHEN SHE WAS TRYING TO PUT THE ESSURE COIL IN MY LEFT FALLOPIAN TUBE, SHE PERFORATED IT. THAT WAS WHEN THE SHARP, PIERCING PAIN STARTED ON MY LEFT SIDE. THE PELVIC PAIN WAS EXTREME. I STARTED GETTING SKIN RASHES, HIVES, BARTHOLIN'S CYSTS AND OTHER CYSTS AND SEVERE ACNE. I STARTED HAVING ISSUES WITH HIVES AFTER I ATE. I ORIGINALLY BELIEVED IT TO BE FROM GLUTEN, BUT EVEN WHEN I AVOIDED GLUTEN I STILL HAD HIVES. MY DOCTOR DID ALLERGY TESTING AND IT CAME BACK I HAD NO ALLERGIES. BUT, I WAS STILL FULL OF HIVES. I DEVELOPED A CONTINUAL CASE OF BACTERIAL VAGINOSIS AFTER GETTING ESSURE. I HAD EXTENSIVE AND CONTINUAL VAGINAL DISCHARGE, BOTH WITH AND WITHOUT ODOR. I HAD BLOOD CLOTS DURING MY PERIOD THAT WOULD BE BETWEEN THE SIZE OF A TENNIS BALL AND A BASEBALL. THE BLEEDING WAS EXTREMELY HEAVY DURING MY PERIOD. I COULD NOT USE TAMPONS BECAUSE THE FLOW WAS TOO HEAVY AND THE CLOTS WERE TOO BIG THAT THE TAMPONS WOULD GET PUSHED OUT BY THIS. MY PERIODS COULD LAST ANYWHERE FROM 6 DAYS TO OVER 20 DAYS AT A TIME. I NEVER KNEW WHEN IT WOULD STOP OR HOW LONG IT WOULD BE BEFORE I WOULD START BLEEDING AGAIN. THE CRAMPING WOULD BE SEVERE AT TIMES AND I NEVER WOULD KNOW WHAT WAS TRIGGERING IT. I STARTED GETTING ABNORMAL PAP SMEARS. I HAD TO HAVE MORE THAN ONE COLPOSCOPY AND ONE CRYOSURGERY AFTER GETTING ESSURE. I STARTED TO GET A LOT PHLEGM/MUCUS IN MY THROAT. I NEVER FELT I COULD CLEAR MY THROAT OF IT. I GOT A CONTINUAL TASTE OF METAL IN MY MOUTH. I NEVER HAD DENTAL ISSUES BEFORE I GOT ESSURE AND NEEDED TO GET 2 CROWNS ON MY TEETH. I LOST APPROXIMATELY 75% OF MY HAIR. I AM A HAIRSTYLIST AND I HAVE TO WEAR WIGS/HAIRPIECES AND/ OR HAVE EXTENSIVE SCALP PRODUCTS TO TRY TO HIDE/COVER UP MY BALDNESS. THAT HAS BEEN EXTREMELY DIFFICULT. MY

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EYES BECAME EXTREMELY DRY. MY EYE DOCTOR DID NOT UNDERSTAND WHY THEY BECAME SO DRY. MY SKIN BECAME EXTREMELY DRY ALSO. I STARTED TO GET UNEXPLAINED BOUTS OF DIZZINESS. I STARTED GETTING EXTREME FATIGUE AND LOSS OF ENERGY. I DEVELOPED INSOMNIA. I WOULD GET A VIBRATING SENSATION IN THE AREA OF MY FALLOPIAN TUBES, I WOULD ALSO GET WHAT I CAN ONLY DESCRIBE AS A ZAPPING FEELING IN THAT AREA ALSO. I WOULD GET THE SENSATION OF WHAT FELT LIKE TO ME A BABY MOVING IN MY ABDOMEN. I DEVELOPED EXTREME GAS. I GAINED WEIGHT, ESPECIALLY IN MY ABDOMEN AREA, AND I COULD NOT LOSE IT NO MATTER HOW HARD I TRIED TO LOSE IT. I HAD TESTING FOR LOW THYROID AND ALL OF THE TESTS FOR THAT CAME IN THE NORMAL RANGE. IN MY HSG IMAGE AT 90 DAYS PAST WHEN I HAD ESSURE PUT IN. IN THE HSG IMAGING CRITERIA OF POSITION MY COILS AND IMAGE SHOWED THAT IT WAS A GRADE 3. THE COILS HAD MIGRATED UP MY TUBES AND THERE WERE NO COILS TRAILING IN MY UTERUS. WHEN MY PROCEDURE WAS DONE, HAD I HAD 3 COILS TRAILING IN MY UTERUS ON MY RIGHT SIDE AND 2 COILS TRAILING ON MY LEFT SIDE. BY THE FIRST 90 DAYS, AT MY HSG CHECKUP, IT DID NOT SHOW THAT, IT ONLY SHOWED MIGRATION. IT ALSO SHOWED SPILLAGE FROM WHERE MY FALLOPIAN TUBE WAS PERFORATED. I WAS TOLD AFTER MY HSG THAT THIS WAS SUCCESSFULLY PLACED. IT WASN'T. I HAD MY COILS AND FALLOPIAN TUBES REMOVED ON (B)(6) 2014. I THEN FOUND OUT THAT I HAD DEVELOPED FALLOPIAN TUBE CYSTS. SINCE MY REMOVAL, I AM STARTING TO SEE SOME OF THE SIDE EFFECTS DISSIPATING. I AM HOPING THAT THEY ALL GO AWAY. I DON'T KNOW HOW TO PROVIDE LAB DATA? (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035826	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 4/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE SUFFERED MULTIPLE STRANGE SYMPTOMS THAT REACT LIKE AN AUTOIMMUNE DISEASE. I HAVE ALSO SUFFERED A GOITER WITH NODULES AND SOME THYROIDITIS SINCE IMPLANTED IN 2011. I AM NOW EXPERIENCING HAIR LOSS, SEVERE PELVIC PAIN, INCREASED MENSTRUATION, HEADACHES, WEIGHT GAIN, RASHES, EDEMA, DECREASED LIBIDO, MOOD SWINGS, IBS LIKE BOWEL CHANGES, DIZZINESS, WHICH LED ME FROM DOCTOR TO DOCTOR TILL FINALLY LANDING IN MY OBGYN OFFICE WHO FOUND AN OVARIAN CYST FOR THE FIRST TIME IN MY LIFE AND THE RIGHT SIDE ESSURE COIL SEEMS TO BE "HANGING INSIDE THE UTERUS" MEANING ITS BEING "EXPELLED". MY DOCTOR SAYS THE ONLY HOPE TO FIX THIS IS A HYSTERECTOMY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035827	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 7/31/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, FIBROIDS, ADENOMYOSIS, INFLAMMATION, REQUIRED FULL HYSTERECTOMY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035829	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 1/15/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MIGRAINES AT LEAST 3X A WEEK. SEVERE BLOATING, LEG CRAMPING AND SPASMS. MUSCLE WEAKNESS IN ARMS AND LEGS. SPASMS IN ARMS. HEAVY PERIODS AND ACHING BODY DURING PERIOD. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035830	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 11/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THIS DEVICE PROCEDURE FOR STERILIZATION. PRIOR TO THIS MY MENSES WERE NORMAL. AFTER THE DEVICE WAS PLACED IN MY BODY I BEGAN TO EXPERIENCE UNUSUAL MENSES. VERY HEAVY AT TIMES WITH SEVERE CRAMPING. I THEN WOULD HAVE MENSES EVERY TWO WEEKS. I EXPERIENCE CRAMPING IN THE PELVIC AREA AND INTO MY LOWER BACK. THESE ARE INTENSE AT TIMES AND FEEL LIKE LABOR. I WENT TO THE GYN AND HE STATED MAYBE PERIMENOPAUSE BUT NO EVIDENCE OF THAT. I WENT ON THE EXPERIENCE ALL THESE SYMPTOMS ON TOP OF DEPRESSION, WEIGHT GAIN, BLOATING, JOINT PAIN THROUGHOUT MY BODY, HEADACHES, AND TIREDNESS. I CHANGED GYN DOCTORS DUE TO INSURANCE CHANGES. I BEGAN TO HAVE NO MENSES FOR FIVE MONTHS. AFTER THAT I HAD ONE WHICH WAS VERY ABNORMAL. MY FAMILY DOCTOR ALSO HAS NOT ADDRESSED ALL OF THESE SYMPTOMS AS IT IS NOT IN HER LINE OF CARE. AFTER MANY TESTS NOTHING ELSE HAS BEEN IDENTIFIED. I AM GOING FOR YET ANOTHER OPINION TO SEE WHY. I AM ALSO GOING TO UNDERGO ALLERGY TESTING TO SEE IF IT IS THE NICKEL/METAL COMPONENT. THIS DEVICE HAS CHANGED MY LIFE FOR THE WORSE. IT IS IN NO MEAN WHAT I THOUGHT IT WOULD BE AFTER CONSULTING MY DOCTOR IN THE BEGINNING. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035831	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 1/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED BLEEDING PROFUSELY. I WOULD OVERFLOW A SUPER NIGHT PAD ABOUT EVERY THIRTY MINUTES. THIS LASTED FOR A LITTLE OVER THREE WEEKS. SINCE THEN I HAD 1 PERIOD WHICH WAS IN (B)(6) 2013. I AM NO LONGER HAVING PERIODS BUT STILL HAVE MAJOR SYMPTOMS ASSOCIATED WITH OVULATION. I NOW BLEED DURING INTERCOURSE. I HAVE SEVERE PELVIC PAIN THAT RADIATES TO MY LOWER BACK CAUSING EXTREME PAIN. MY FEET AND LEGS SWELL TO THE POINT I BUY BIGGER SHOES TO ALLOW FOR THE SWELLING. MY LEGS HURT SO BAD I CAN BARELY STAND AT TIMES. I STAY EXTREMELY TIRED AND HAVE EVEN BEEN UNABLE TO WORK AT TIMES. I HAVE CONSTANT HEADACHES. I HAVE MAJOR MOOD SWINGS THAT INTERFERE WITH RELATIONSHIPS. MY VISION CHANGES CONSTANTLY. I AM VERY SENSITIVE TO LIGHT. I OFTEN FIND MYSELF FEELING OFF BALANCE AND HAVE FELL SEVERAL TIMES. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035832	BAYER	4/30/2014	5/1/2014

Event Information:

Event Date (B3): 10/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHAT THE FDA IS GOING TO DO ABOUT ESSURE? THOUSAND YOUNG WOMAN ARE ENDING LIKE ME, HAVING HYSTERECTOMY BECAUSE ESSURE.!!!!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035904	BAYER	4/30/2014	5/7/2014

Event Information:

Event Date (B3): 7/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/1/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED APPROX IN 2005. BEGAN HAVING FATIGUE AND LOWER BACK/HIP PAIN. BY 2010, ALSO HAVE CONSTANT, DAILY NAUSEA. AS OF TODAY, I HAVE SURGERY PLANNED NEXT WEEK TO REMOVE MY FALLOPIAN TUBES DUE TO THE PAIN AS WELL AS SEVERELY DILATED FALLOPIAN TUBE. THE BACK/HIP PAIN AND FATIGUE IS SEVERE ENOUGH THAT IT AFFECTS MY ABILITY TO WORK APPROX 1 OF EVERY 3 DAYS I'M SCHEDULED TO WORK AT MY PART TIME JOB AND I HAVE TO USE A WHEELCHAIR 3-5 DAYS A WEEK TO GET AROUND. I DO NOT HAVE COPIES OF ANY RECORDS, SO DATES LISTED HERE ARE APPROXIMATE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035907	BAYER	4/30/2014	5/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2010. I NOW SUFFER FROM HEADACHE, BLURRED VISION, ABDOMINAL PAIN, HIP PAIN, BACK PAIN, DEPRESSION. I WAS DIAGNOSED WITH INFLAMMATION OF THE CERVIX AND OVARIES A WEEK AGO, AND AN NOW ON 2-500MG ANTIBIOTICS TWICE A DAY PLUS HYDROCODONE FOR PAIN. I GO BACK TO MY OB-GYN AT THE END OF THE MONTH FOR MORE TESTS. I HAVE NOT HAD ANY PREVIOUS MEDICAL ISSUES. I USED TO BE ABLE TO ENJOY HIKING AND MANY OTHER OUTDOOR ACTIVITIES AND NOW HAVE TO FORCE MYSELF OUT OF BED EVERY MORNING BECAUSE I AM SO FATIGUED. I HAVE NO CYSTS AND WAS NOT ON BIRTH CONTROL PRIOR TO HAVING THE PROCEDURE DONE. I WILL BE MORE THAN HAPPY TO PROVIDE MY F/U APPOINTMENT FINDINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035824	BAYER	4/30/2014	5/12/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING, PERIOD CYCLE EVERY TWO WEEKS, SHARP STABBING CRAMPING IN LOWER ABDOMINAL REGION, MASSIVE HEADACHES, SKIN TEXTURE CHANGES, WEIGHT GAIN, HAIR LOSS, FATIGUE, ABDOMINAL SWELLING, WATER RETENTION, METALLIC TASTE, IRRITABLE (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036043	BAYER	4/30/2014	5/14/2014

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): PRODUCT #20182548

Single Use:
Implant Date (E6): 12/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD PAIN INTERMITTENT IN MY RIGHT TUBE. PAIN HURTS A LOT OF TIMES AND MAKES ME BEND OVER IN PAIN. NOW THAT IT IS 2014 I HAVE IT CONSISTENTLY. IT HURTS TO SNEEZE, COUGH AND NOW IT HURTS TO EVEN LAUGH. I FEEL IT PULLING INSIDE RIPPING SOMETHING. THIS HURTS. ALSO I AM STARTING TO GET PAIN IN MY LOWER BACK TAIL BONE AREA AND MY HIPS. PAIN WITH SEX TOO. ONCE INSERTED THE PAIN WAS ALWAYS THERE. HEALTH PROBLEM IN PAIN MOST OF THE TIME. PELVIC PAIN AND TUBES ARE IN PAIN. ONCE INSERTED THE PAIN WAS ALWAYS THERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036042	BAYER	5/1/2014	5/14/2014

Event Information:

Event Date (B3): 4/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 12/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN (B)(6) 2011 AND HAVE NEVER BEEN THE SAME. I HAVE EXPERIENCED SEVERE NON-STOP BLOATING, BOWEL ISSUES, SEVERE FATIGUE, DEPRESSION AND NON-STOP HEARTBURN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035937	BAYER	5/2/2014	5/8/2014

Event Information:

Event Date (B3): 9/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6), 2011 I HAVE ESSURE IMPLANTED AS I WAS DONE HAVING KIDS. I STARTED TO HAVE PELVIC PAIN, PAINFUL INTERCOURSE AND I WAS BLEEDING ALL THE TIME INCLUDING CLOTS THE SIZE OF HALF DOLLARS OR LARGER. AFTER RETURNING TO DOCTOR AND BEING PUT ON BC PILLS TO HELP WITH THE BLEEDING AND THAT FAILING. I HAD TO HAVE A COMPLETE HYSTERECTOMY ON (B)(6), 2012 LEAVING JUST THE OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035948	CONCEPTUS	5/5/2014	5/12/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/31/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE COILS LAST YEAR. SINCE THAT DAY, I CRAMP (WHICH BECOMES SEVERE PAIN DURING MY MENSTRUAL PERIOD) AND THE INFLAMMATION IS SO SEVERE, THAT I PREFER NOT TO GO OUT MANY DAYS. I CALLED MANY, MANY TIMES THE DOCTOR WHO PERFORMED THE PROCEDURE. WHEN SHE FINALLY GOT ME IN, IT WAS TOO LATE TO REMOVE THE COILS. CONSULTED ANOTHER DOCTOR SINCE THEN. EVEN THOUGH THE ULTRASOUND SHOWS MY TISSUE IS "NORMAL", I DON'T FEEL THIS SUFFERING IS "NORMAL" AT ALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035951	BAYER	5/5/2014	5/12/2014

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2012, I HAD THE ESSURE IMPLANTED IN MY FALLOPIAN TUBES. EVER SINCE THEN I HAVE EXPERIENCED EXTREME FATIGUE, "PINCHING" ON BOTH SIDES OF MY ABDOMEN, ABDOMINAL CRAMPING, IRREGULAR PERIODS, HEADACHES, DEPRESSION, RIGHT LEG PAIN AND BACKACHE. AFTER CONSULTING WITH MY THERAPIST AND MY GYNECOLOGIST, IT IS RECOMMENDED I HAVE A HYSTERECTOMY. I AM SCHEDULED FOR SURGERY ON (B)(6) 2014. IF I WOULD HAVE BEEN MADE AWARE OF THESE SIDE EFFECTS, I WOULD NOT HAVE OPTED FOR THIS KIND OF BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035953	BAYER	5/5/2014	5/12/2014

Event Information:

Event Date (B3): 12/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/16/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED ON (B)(6) 2010. SINCE THE PROCEDURE DATE, I HAVE HAD TREMENDOUS PAIN IN THE COIL PLACEMENT AREAS WHEN GOING FROM A SITTING TO STANDING POSITION. VERY PAINFUL, FEELS LIKE SHARP/STABBING AND LITERALLY MAKES ME DOUBLE OVER IN PAIN. IT HAPPENS DAILY. INTENSE BLOATING, HEADACHE, VISION PROBLEMS THAT COME AND GO (SEEING FLOATING BLACK SPECKS), MEMORY LOSS, MIXING WORDS WHEN I SPEAK, ITCHING LIKE I HAVE A RASH BUT I DON'T, NUMBNESS/LOSS OF FEELING IN LEGS, SEVERE PAIN AT TIME OF OVULATION AND INTENSE PAIN PRIOR TO MENSTRUAL CYCLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035955	BAYER / CONCEPTUS	5/5/2014	5/12/2014

Event Information:

Event Date (B3): 4/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): 626222

Single Use:
Implant Date (E6): 3/19/2008
Explant Date (E7): 4/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE DEVICE ESSURE IMPLANTED IN (B)(6) 2008. THE IMPLANTATION OF THE DEVICE WENT SMOOTHLY WITH NO COMPLICATIONS AND VERY MINIMAL DISCOMFORT. I WAS AWAKE FOR THE PROCEDURE AND THERE WAS A REPRESENTATIVE FROM CONCEPTUS PRESENT. BOTH DOCTOR AND CONCEPTUS REP WERE VERY PLEASED WITH THE IMPLANTATION AND SAID EVERYTHING WENT WELL. I WAS VERY SATISFIED WITH THE ESSURE FOR THE FIRST 3 YEARS OF IMPLANTATION. IN (B)(6) 2011, I STARTED EXPERIENCING SHARP PAINS IN MY LEFT PELVIC AREA. THE PAIN FELT LIKE A TWISTING STABBING PAIN THAT RADIATED TO MY HIP AND LOWER BACK. THAT SAME MONTH MY PERIODS BECAME EXTREMELY HEAVY WITH VERY HEAVY CLOTTING. I WENT TO SEE MY GYN. HE DID MY YEARLY PAP ALONG WITH AN ULTRASOUND AND ALL SEEMED "NORMAL". THAT SAME YEAR 2011, I WENT BACK ON 4 SEPARATE OCCASIONS TO SEE THE GYN. ALL WITH COMPLAINTS OF PELVIC PAIN, HEAVY BLEEDING, AND WHAT FELT LIKE UTI'S. AGAIN HE DID SONOGRAMS AND ALL SEEMED "NORMAL". IN 2012, I STARTED EXPERIENCING EXTREME FATIGUE ALONG WITH SEVERE PELVIC INFLAMMATION. I ALSO CONTINUED EXPERIENCING WHAT FELT LIKE UTI'S. I STARTED SEEING MY PRIMARY DOCTOR THINKING MAYBE HE COULD FIGURE OUT WHAT WAS WRONG. AFTER HAVING BLOOD WORK DONE, MY RESULTS CAME BACK THAT MY THYROID WAS OVERACTIVE. THAT EXPLAINED THE FATIGUE BUT NOT THE PAIN AND INFLAMMATION. HE THEN SENT ME TO SEE A ENDOCRINOLOGIST, A UROLOGIST, A GASTROENTEROLOGIST. ALL RAN TEST BUT ALL CAME BACK NORMAL! IN 2013, THE PAIN, INFLAMMATION AND PRESSURE REACHED A WHOLE NEW LEVEL. THE CONSTANT INFLAMMATION HAD NOW PUT PRESSURE ON MY BLADDER AND I STARTED LEAKING URINE. FINALLY I DECIDED TO CHANGE GYN'S AND GET A SECOND OPINION. THE NEW DOCTOR DID A SONOGRAM WHICH LOOKED "NORMAL". HE SENT ME TO A NEW UROLOGIST WHO SENT ME FOR A CT SCAN OF MY BLADDER. ON THE CT SCAN, IT SHOWED THE ESSURE IMPLANT LOOKED "NORMAL". I HAD A SMALL

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LESION ON MY KIDNEY SO THEY SENT ME FOR AN MRI. AGAIN ESSURE LOOKED "NORMAL". AFTER TAKING ALL TEST RESULTS BACK TO MY NEW GYN AND HE COULD NOT EXPLAIN THE PAIN AND INFLAMMATION WE AGREED TO DO A LAPAROSCOPIC SALPINGECTOMY TO REMOVE THE ESSURE DEVICE. ON (B)(6) 2014, THREE YEARS AFTER I STARTED EXPERIENCING PAIN AND INFLAMMATION AND SIX YEARS AFTER IMPLANTING THE ESSURE, I HAD A BILATERAL SALPINGECTOMY. WHEN THE DOCTOR REMOVED THE TUBES WITH COILS, HE NOTED THAT THE COIL IN THE LEFT FALLOPIAN TUBED WAS TWISTED AND KINKED UP. THE CONSTANT PAIN AND PRESSURE I HAD BEEN FEELING IN MY LEFT PELVIC REGION WERE ALLEVIATED AS SOON AS THE ESSURE DEVICE WAS REMOVED. THE CONSTANT PRESSURE IN MY BLADDER IS NOW ALSO GONE! I CHOOSE TO USE ESSURE AS A PERMANENT FORM OF BIRTH CONTROL TO AVOID HAVING THE SURGERY NECESSARY WITH A TUBAL LIGATION AND ENDED UP HAVING A BIGGER SURGERY JUST TO HAVE THEM REMOVED. NOT TO MENTION THE YEARS OF PAIN AND MONEY SPENT ON DOCTORS VISITS JUST TO RECEIVE A PROPER DIAGNOSIS. THE BIGGEST PROBLEM WITH THE ESSURE DEVICE IS THE DIFFICULTY IN DIAGNOSING A PROBLEM WITH THE DEVICE. UNLESS THE DEVICE HAD ACTUAL MIGRATED FROM THE PROPER POSITION, THERE IS NO WAY OF TELLING IF THE DEVICE IS CAUSING HARM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035956	BAYER	5/5/2014	5/12/2014

Event Information:

Event Date (B3): 4/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 810880

Single Use:
Implant Date (E6): 1/27/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MULTIPLE ENDOCRINE NEOPLASIA LEVEL 2A AT AGE (B)(6). THYROID CANCER WITH REMOVAL, LEFT AND RIGHT ADRENAL GLANDS SURGICALLY REMOVED, PHEOCHROMOCYTOMAS SURGICALLY REMOVED. HISTORY OF RARE ENDOCRINE TUMOR CONDITION. MEDICATIONS: SYNTHROID 175 MCG, FLUDROCORTISONE 0.1 MG, PREDNISONE 5 MG. AFTER IMPLANTATION, MY PERIODS INCREASED TO 14 DAYS OF BLEEDING WITH 3 DAYS OF HEAVY BLEEDING. I DEVELOPED DAILY SEVERE HEADACHES AND SIGNIFICANT CONSTANT PELVIC AND BACK PAIN. MY VISION BECAME BLURRY WITH WHITE FLASHES, AND CONFUSION FOR BRIEF SECONDS. IN (B)(6) 2013, I HAD A RAPID ONSET OF CRUSHING CHEST PAIN ALONG WITH SHORTNESS OF BREATH, WHITE FLASHES IN MY EYES AND A PINCHED NERVE FEELING ON THE SIDE OF MY NECK. I WAS SEEN IN THE EMERGENCY ROOM. THE CRUSHING CHEST PAIN AND SHORTNESS OF BREATH NEVER WENT AWAY. IN (B)(6) 2013, I BEGAN TO SUFFER FROM CHRONIC YEAST INFECTIONS WHICH I NEVER HAD BEFORE. I GET THEM ALMOST EVERY MONTH NOW. ALSO THIS IS WHEN THE SEVERE BLOATING OCCURRED CAUSING MY STOMACH TO EXTEND SIMILAR TO WHEN I WAS SEVEN MONTHS PREGNANT. I WAS SEEN IN THE EMERGENCY ROOM. MY SEXUAL DESIRE IS ALMOST NON-EXISTENT DUE TO THE CHRONIC PELVIC PAIN, PAIN DURING INTERCOURSE, AND RECURRING YEAST INFECTIONS. IN (B)(6) 2013, MY VISION IS WORSENING AND MY CONFUSION EPISODES ARE LASTING LONGER. THE HEADACHES ARE INCREASING IN INTENSITY REQUIRING MORE MOTRIN INTAKE. IN (B)(6) 2013, WHILE WALKING, I EXPERIENCED A SHARP STABBING ICE PICK CENTRALIZED PAIN ON MY LEFT SIDE, FOLLOWED BY WHITE FLASHES IN MY EYES, BLURRED VISION, AND CONFUSION WHICH BROUGHT ME TO MY KNEES. IN (B)(6) 2013, MY INNER LEFT KNEE BEGINS TO SWELL AND HURT. I BOUGHT A DRUGSTORE BRACE TO HELP WITH THE PAIN FROM WALKING AND DOING EVERY DAY TASKS. THE INTAKE OF MOTRIN INCREASED TO DEAL WITH THE KNEE PAIN, BACK PAIN, HEADACHES, AND PELVIC PAIN. IN (B)(6) 2013, I CAN NO LONGER

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WALK FOR LONG PERIODS OF TIME WITHOUT SHORTNESS OF BREATH AND SIGNIFICANT PAIN. THE BLOATING INCREASED AND NOW IS DIFFICULT AND PAINFUL TO SLEEP. MY VISION HAS WORSENED WITH INCREASED WHITE FLASHES, CONFUSION EPISODES ARE LASTING LONGER AND NOW THE SAME PAIN THAT IS IN MY KNEE IS NOW IN MY RIGHT ELBOW. IN (B)(6) 2014, I BEGIN GROWING DARK SIDEBURNS ON MY FACE ALONG WITH INCREASED WHITE FACIAL HAIR ON MY CHEEKS AND NECK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035887	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 2/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN WITH INTERCOURSE, CONSTANT PELVIC PAIN, BLOATING, HAIR LOSS, CONSTANT BLEEDING, VERY PAINFUL MENSTRUATION CYCLES. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035888	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 11/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AS OF (B)(6) I HAD A HYSTERECTOMY REMOVING MY UTERUS, OVARIES AND TUBES. SINCE SURGERY I HAVE ENERGY BACK, MY BLOATING HAS GONE DOWN. THE PAIN FROM REMOVAL IS LESS THEN ANY PAIN FELT WHILE ESSURE WAS IN MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035889	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD SEVERE ABDOMINAL STABBING PAIN, NAUSEA, DIZZY SPELLS, HOT FLASHES, THE LEFT ESSURE COIL IS NOW NO WHERE TO BE FOUND. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035890	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 3/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONGOING ILLNESS, YEAST INFECTION FROM THE TIME IT WAS INSERTED. CONSTANT SPOTTING, SEVERE PAIN IN BREAST AND BURNING SENSATION ON BOTH SIDES OF PELVIS AREA. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035891	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 12/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING LOTS OF PELVIC PAIN IN (B)(6) AND JOINT PAIN IN MY KNEES. SINCE THEN I'VE EXPERIENCED MORE AND MORE SYMPTOMS SUCH AS: FATIGUE, NAUSEA, MEMORY LOSS (CONFUSION), WEIGHT GAIN, BLURRED VISION, BLEEDING FOR 56 DAYS PLUS, STOMACH PAIN, METAL TASTE IN MY MOUTH, HEADACHES, BLOATING, PAIN WITH INTERCOURSE, SHOOTING VAGINAL PAINS, DIZZINESS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035892	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 3/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'M HAVING AN ALLERGIC REACTION TO THE NICKEL IN THE COILS. I HAVE ITCHING ALL OVER MY BODY, SEVERE HEADACHES, NAUSEA AN VOMITING, BLOATING, PELVIC PAIN, CONSTANT VAGINAL BLEEDING, CHEST PAINS WITH INCREASED HEART RATE, FATIGUE, NIGHT SWEATS, AND DIZZINESS. I PASSED OUT A WEEK AFTER ESSURE BEING PLACED DUE TO THE REACTION. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035893	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 2/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I FIGHT BLACK OUT SPELLS, MEMORY PROBLEMS, PAIN, PROLONGED PERIODS, STOMACH BLOATING, SEVERE BLEEDING DURING PERIODS, HEAVING CRAMPING, CHEST PAINS, BLOOD IN URINE DONE AT MY PCP'S OFFICE AS OF (B)(6) 2014 AND IT WAS PRESENT WHILE I WAS PREGNANT, PREGNANCY ((B)(6) 2013), PRETERM LABOR, PAIN IN PELVIC AREA THAT WAS STABBING, NUMBNESS IN LEGS AND FEET, LOSS OR GAIN OF APPETITE FATIGUE,INSOMNIA, BACK PAIN, PELVIC PRESSURE,PAINFUL INTERCOURSE, NAUSEA, BODY ACHES, METAL ALLERGIES TO NICKEL. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035894	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVERY TIME I OVULATE I FEEL LIKE MY TUBE IS ON FIRE. IT'S JUST AS PAINFUL AS MY NATURAL BIRTH. WHEN I GET MY MONTHLY VISIT I LOSE SO MUCH BLOOD I BECOME WEAK, DIZZY, AND LIGHT HEADED. NOT TO MENTION THE SEVERE (ON A SCALE OF 1-10, 10!) ACHES AND PAINS, AS WELL AS HEAD SPLITTING MIGRAINES. I'VE NEVER HAD ANYTHING MORE THAN A FEW CRAMPS UNTIL ESSURE. I'M PHYSICALLY MISERABLE. IT HURTS TO MOVE AND LIFT MY CHILDREN. ALL I CAN DO IS CURL UP IN A BALL AND CRY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035895	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 10/14/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE IMPLANTATION OF THE ESSURE DEVICE ON (B)(6) 2013 I BEGAN HAVING SHARP PAIN IN MY LEFT SIDE, HIP AND LOWER BACK AND ABDOMEN PAIN, I WAS ALSO HAVING SUDDEN BRUISES ALL OVER MY BODY AND I WAS HAVING "NONESS" LEGS. I BECAME HAVING MIGRAINES, EXTREME STOMACH PAIN, BURNING, ITCHING SKIN AND RASH, FATIGUE, EXTREME MOOD FLUCTUATIONS, EXTREME HAIR LOSS, DIZZINESS AND INSOMNIA, BRAIN FOG, BLEEDING, INFLAMMATION SEX PAIN. I WENT TO THE DOCTOR, AND THEY SEND ME A HSG ULTRASOUND. (PATENT LEFT FALLOPIAN TUBE. LEFT TUBAL OCCLUSION DEVICE NOT WITHIN THE LEFT FALLOPIAN TUBE). I END ON HYSTERECTOMY SURGERY. (B)(4). UPDATE ON (B)(6) 2014: WE ARE WAITING FOR THE FDA TO STOP BAYER!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035896	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HODGKIN'S LYMPHOMA, CHRONIC PELVIC PAIN, SEVERE ALLERGY TO NICKEL AND SEVERAL CHEMICAL PRESERVATIVES DEVELOPED. PRIOR TO HAVING A SALPINGECTOMY AND HYSTERECTOMY I HAD PAINFUL HEAVY PERIODS. I ALSO EXPERIENCED ANEMIA FROM HEAVY BLEEDING AND IT REQUIRED IRON INFUSIONS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035897	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 6/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLACKED OUT. HAVE HORRIBLE PAIN THAT RADIATES DOWN MY LEG GOITER IN MY THROAT BLOATING AND CRAMPING AS WE'LL AS HEADACHES THAT ARE UNBEARABLE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035898	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM NOW PREGNANT!!!!! I GOT THIS PROCEDURE DONE TO P R E V E N T PREGNANCY AS I HAVE 3 CHILDREN ALREADY AND HAD TO HAVE A LEEP PROCEDURE DONE! NOW I AM HIGH RISK AND HAVE TO DRIVE OVER AN HR TO SEE A DR AT (B)(6) AND I HAD TO QUIT MY JOB! I HAVE NO INCOME TO SUPPORT MY CHILDREN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035906	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HORRIBLE MENSTRUAL PAINS, HEAVY BLEEDING, ALMOST CONSTANT JOINT PAIN, HEADACHES, EXTREME MOOD SWINGS. AND MY SEX DRIVE IS ALMOST GONE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035914	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RASH ALL OVER MY CHEST EVERY TIME I GO IN SUNLIGHT. MENSTRUAL BLEEDING 20-23 DAYS A MONTH, MIGRAINES, MUSCLE CRAMPS, ANXIETY, DEPRESSION, IBS, SEVERE STABBING PAIN IN SIDE, BACK PAIN, JOINT PAIN. DR SAYS I NEED HYSTERECTOMY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035915	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 10/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE WAS PLACED (B)(6) 2011. DURING INSERTION ,THERE WAS AN EVENT HAVE GREAT DISCOMFORT DURING PLACEMENT, BUT THE PROCEDURE WAS COMPLETED. PAIN AND BLEEDING CONTINUED TO INTENSIFY OVER THE NEXT COUPLE OF DAYS. THE SITUATION AND MY HEALTH CONTINUED TO DETERIORATE OVER THE MONTHS. BLEEDING WAS VERY HEAVY WITH LARGE CLOTS. I BLED FOR OVER 7 1/2 MONTHS STRAIGHT. CRAMPING, PELVIC PAIN WAS COMPARABLE TO CHILD LABOR. PAIN MOVED INTO MY BACK JUST AS VICIOUSLY. JOINT PAIN, ESPECIALLY IN THE HIPS, DOWN MY LEGS CAUSING TINGLING IN MY FEET. IT HURT TO WALK, TO MOVE, THERE WERE TIMES I COULD NOT MOVE. ACHY ALL OVER. CHEST PAIN. I WAS EXPERIENCING VERTIGO, HEADACHES, INTERMITTENT ELEVATED TEMPERATURES WITH SWEATS AND CHILLS, EXTENSIVE BLOATING AND WEIGHT GAIN. DEPRESSION, MOOD SWINGS, ANXIETY, INCREDIBLE FATIGUE, EXTREME DRY EYES AND TWITCHING OF THEM. I FELT I WAS DYING A SLOW DEATH. AFTER MANY DOCTOR VISITS AND TESTING, THE DEVICES WERE REMOVED VIA A DOUBLE SALPINGECTOMY ON (B)(6) 2012. SYMPTOMS BEGAN DISAPPEARING IN AS SOON AS DAYS FOLLOWING REMOVAL. STILL UNKNOWN IF THE REMOVAL WAS 100% CURE AS OF NOW BUT IT CERTAINLY HELPED ME GAIN MY LIFE BACK FOR A SOME TIME. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035916	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 7/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABOUT A YEAR AND A HALF (GIVE OR TAKE A FEW MONTHS) AFTER ESSURE WAS IMPLANTED, MY PERIODS CHANGED. I WENT FROM A NORMAL 5 DAYS AND LIGHT BLEEDING TO 8 TO 10 DAYS AND VERY HEAVY BLEEDING AND CLOTS. ALSO, I WAS TIRED ALL THE TIME AND I WAS GETTING BACK PAIN AND PELVIC PAIN TO WHERE IT WAS BECOMING REALLY DIFFICULT TO FUNCTION DAILY. I HAVE DEVELOPED ALLERGIES TO THINGS SUCH AS BANDAIDS SINCE ALONG WITH OTHER THINGS. I GET HEADACHES OFTEN AND THEY LAST FOR DAYS. MY WHOLE BODY ITCHES AND SOME PARTS OF MY BODY FEEL INFLAMED AND HURTS TO TOUCH. I DON'T HAVE MUCH OF A SEX DRIVE ANYMORE. I HAVE GONE TO SEE A DOCTOR SEVERAL TIMES DURING THE LAST 3 YEARS TO FIGURE OUT WHAT IS WRONG AND WHY I FEEL THE WAY I DO. MY BLOOD PRESSURE AND ALL THAT IS NORMAL AND THEY CAN'T FIGURE OUT WHY AND TRY TO PUT ME ON ANXIETY MEDS WHICH I DON'T NEED. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035917	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NUMBNESS ON LEFT SIDE AND LUPUS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035918	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVELOP AUTO IMMUNE DISEASE, PHOTOSENSITIVITY, HAIR LOSS, MEMORY LOSS. HIVES AND RASHES. JOINT PAIN, REOCCURRING UTI'S. NO OTHER MEDICAL CONDITIONS PRIOR TO THIS OR DURING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035919	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 2/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE (B)(6) OF 2013, I HAVE EXPERIENCE THE FOLLOWING SIDE EFFECTS AND SYMPTOMS DUE TO ESSURE. CHEST PAINS, HEART PALPITATIONS, ANXIETY, DEPRESSION, FORGETFULNESS, MOOD DISORDERS, EXCESSIVE SWEATING, DIZZINESS, SEVERE MIGRAINES, PAINFUL MENSTRUAL CYCLE (WHEN I HAVE A MENSTRUAL CYCLE), LACK OF MENSTRUAL CYCLE (FOR 3-4 MONTHS A TIME), PELVIC CHRONIC PAIN, LOWER BACK PAIN, HIP PAIN, BLOATING, CONSTIPATION AND DIARRHEA, AND NIGHT SWEATS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035920	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER FOR THE LEFT SIDE IS #686083 AND THE LOT NUMBER FOR THE RIGHT SIDE IS #12407573. MY MODEL NUMBER FOR THE RIGHT SIDE IS ESS305-R1 AND THE MODEL NUMBER FOR THE LEFT SIDE IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINTS STARTED IN (B)(6) 2011. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. NO MENSUS FOR 14 MONTHS AND WHEN IT RETURNED, IT WAS EXTREMELY HEAVY WITH SEVERE CRAMPING AND CLOTTING. GYNO PUT ME ON BIRTH CONTROL TO REGULATE MY CYCLE TO 4X PER YEAR, HOWEVER, MY BODY WILL NOT WAIT THE FULL 12 WEEKS TO MENSTRUATE. I HAVE BREAK THROUGH BLEEDING A LOT. CHRONIC FATIGUE, SEVERE MIGRAINE HEADACHES, 35LB WEIGHT GAIN, MEMORY LOSS, BRAIN FOG AND CONFUSION AT TIMES, CONSTANT LOSS OF HAIR, NO ENERGY, BLOATING FROM JUST UNDER MY BREASTS ALL THE WAY DOWN TO MY HIPS (I LOOK 7 MO PREG), PELVIC PAIN THAT COME AND GOES, JOINT/MUSCLE PAIN, URINARY INCONTINENCE AND CONSTANT PRESSURE ON MY BLADDER THAT I HAVE TO WEAR A MAXI PAD EVERYDAY-ALL DAY, MY DEPRESSION AND ANXIETY HAVE INCREASED SIGNIFICANTLY THAT MY MEDS HAVE BEEN INCREASED, NIGHT SWEATS/HOT FLASHES, RASHES, 4 DIFFERENT BARTHOLIN CYSTS, LOWER BACK PAIN THAT FEELS LIKE LABOR, LEG/FOOT CRAMPS, DIZZINESS, SPOTTING AFTER SEXUAL INTERCOURSE. I HAVE RECENTLY BEEN SEEN BY ONE DOCTOR TO DISCUSS MY ISSUES. WE ARE LOOKING AT SCHEDULING A HYSTERECTOMY IN THE NEAR FUTURE. THE DEVICE IS STILL INSIDE OF ME. I JUST WANT MY LIFE BACK. I HAVE NOT FELT LIKE MYSELF FOR OVER 3 YEARS NOW. I HAVE TRULY BEEN MISERABLE AND MY FAMILY HAS HAD TO WATCH ME SUFFER. (B)(4).

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035921	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS HAS BEEN ONGOING SINCE ABOUT 6 MONTHS AFTER GETTING ESSURE. FATIGUE AND LOSS OF ENERGY, ZERO SEX DRIVE, FOGGY BRAIN ALL THE TIME AND MEMORY ISSUE, EYE SITE PROBLEMS, HIP ISSUES, CONSTANT POKING FEELING AND VERY PAINFUL SEX, ANXIETY, CAN'T SLEEP. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035923	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 7/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY FIRST EXPERIENCE WITH SIDE EFFECTS STARTED ON THIS DATE BUT HAS CONTINUED TO THE PRESENT. ANXIETY/PANIC ATTACK SYMPTOMS. DIGESTIVE ISSUES INCLUDING ACUTE ESOPHAGITIS AND AN ABNORMAL AMOUNT OF BILE, NAUSEA, DIARRHEA, JOINT PAIN ,SEVERE MUSCLE PAIN, NERVE PAIN (DIAGNOSED WITH FIBROMYALGIA AND ARTHRITIS) HEADACHES, DIZZINESS, TINGLING SENSATIONS, CHEST PAIN (DIAGNOSED WITH PERICARDITIS), VISION ISSUES, BRAIN FOG, HOT FLASHES, NIGHT SWEATS, NEW FOOD ALLERGIES, ABNORMAL PERIODS (LASTING A MONTH OR TWO OR NOTHING FOR 2-3 MONTHS) HEAVY BLEEDING W/ LARGE CLOTS, CAN NO LONGER DYE HAIR (BURNING SENSATION OF SCALP), HAIR DEVELOPS A GREEN TINT, PAINFUL SEX AND SHARP PAINS IN RIGHT FALLOPIAN TUBE AREA (HAVE COIL AND NO OVARY ON RIGHT SO PAIN CAN NOT BE DUE TO OVULATION). I BELIEVE THIS TO BE ALL. SINCE THE PLACEMENT ((B)(6) OF 2010) I HAVE BEEN IN THE ER 7 TIMES WITH 5 HOSPITAL STAYS. I DID NOT HAVE THESE ISSUES BEFORE THE PLACEMENT OF ESSURE. #MEDWATCHER #MW156187.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035924	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT PREGNANT AND IT "SPOUSE" NOT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035925	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT PREGNANT AND IT "SPOUSE" NOT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035926	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 3/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WENT TO PCP FOR BLURRY VISION AND SEVERE HEADACHE . DIAGNOSED WITH SEVERE MIGRAINES AND PRESCRIBED EPILEPTIC MEDICATION TO TAKE DAILY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035927	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HSG TESTING SHOWED A DEFECTIVE COIL IN THE LEFT FALLOPIAN TUBE THAT WAS BROKEN AND NOT SEALING OFF THE LEFT TUBE. HAD DIZZY SPELLS WHILE DRIVING AND SOMETIMES STANDING. NAUSEA FEELING FOR MONTHS THAT CAME AND WENT ALL DAY LONG. SEVERE MEMORY LOSS AND BLACK OUTS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035928	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 10/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN AND SWELLING IN UTERUS. NAUSEA. HAVE BLED FOR 5 MONTHS STRAIGHT. STARTED LACTATING. EXTREMELY SLEEPY AND MOODY. EYES GET VERY DRY AND BLURRY. I GET MIGRAINES . NOW HAVING TO HAVE A HYSTERECTOMY TO GET THIS DEVICE OUT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035929	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED (B)(6) OF 2010. I STARTED HAVING HEAVY PERIODS RIGHT AWAY, SOMETIMES TWICE A MONTH. AROUND (B)(6) 2012 I HAVE CRAMPING ALL DAY EVERYDAY. I NOW HAVE LOWER BACK PAIN, HIP PAIN, CHRONIC PELVIC PAIN, WEIGHT GAIN, DEPRESSION, IRREGULAR BLEEDING, BURNING FEELING IN VAGINAL AREA, SHARP STABBING ON MY LEFT SIDE, MIGRAINE HEADACHES (DAILY), HOT FLASHES, ANXIETY, NAUSEA (DAILY), NUMBNESS IN HANDS AND IN THE LAST MONTH ((B)(6) 2014) THE DR FOUND A LARGE CYST ON MY RIGHT OVARY AND CERVICAL DYSPLASIA. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035930	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4): 20182548

Single Use:
Implant Date (E6): 12/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD PAIN INTERMITTENTLY IN MY RIGHT TUBE. PAIN HURTS A LOT OF TIMES AND MAKES ME BEND OVER IN PAIN. NOW THAT IT IS 2014 I HAVE IT CONSISTENTLY. IT HURTS TO SNEEZE, COUGH AND NOW IT HURTS TO EVEN LAUGH. I FEEL IT PULLING INSIDE RIPPING SOMETHING. THIS HURTS. ALSO I AM STARTING TO GET PAIN LOWER BACK TAIL BONE AREA AND MY HIPS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035931	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 4/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WENT TO ER WITH ABDOMINAL PAIN, FOLLOWED UP WITH OB-GYN ON (B)(6) 2014, DIAGNOSED WITH INFLAMMATION OF CERVIX AND OVARIES, FOLLOW UP ON (B)(6) 2014. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035932	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 12/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN EVERY WHERE, SICK, MOOD SWINGS, "PELIV IMMFLORY" DISEASE, BACK, ABDOMINAL PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035933	BAYER	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SIX MONTHS AFTER RECEIVING ESSURE I EXPERIENCED HEAVY BLEEDING, RANDOM STABBING PAINS IN MY ABDOMEN, DIFFICULTY AT TIMES HAVING INTERCOURSE, BLOATING, TIREDNESS AND FATIGUE, HOT FLASHES, AND DEPRESSION AND MOOD CHANGES, IN 2012 I WAS ALSO DIAGNOSED WITH ANA. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035934	CONCEPTUS	5/6/2014	5/6/2014

Event Information:

Event Date (B3): 9/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD INCREASED PAIN IN MY NECK, BACK, AND LEGS, HEADACHES, INCREASED FATIGUE, BLOATING, EXTREMELY PAINFUL UTERINE CRAMPING, INCREASE IN THE AMOUNT OF BLOOD LOST DURING PERIODS, STABBING PAIN ON MY LEFT SIDE (WHERE MY ESSURE IS) UNDER MY RIBCAGE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035935	BAYER	5/6/2014	5/7/2014

Event Information:

Event Date (B3): 4/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 3 WEEKS: I HAVE VISITED THE ER AND DOCTORS 10 TIMES. CONTINUE TO HAVE DULL PAIN CONSTANTLY, IRREGULAR SHARP PAINS, BLOATING, PANIC ATTACKS, MIGRAINES, NAUSEOUS AND VOMITING, COMPLEX OVARIAN CYST, TIREDNESS, LONG/ SHORT TIME MEMORY LOSS, NIGHT SWEATS, EMOTIONS OF ANY KIND MAKES ME SWEAT, HEART RACING, SHORTNESS OF BREATH, JOINTS, HIP AND BACK PAIN, INSOMNIA. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00143	BAYER HEALTHCARE LLC	5/6/2014	5/12/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/16/2008
Explant Date (E7): 3/10/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5053134) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ENSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FOUND THAT MY UTERUS AND BLADDER HAD GROWN TOGETHER AND ATTACHED TO MY ABDOMINAL WALL, AUTO IMMUNE DISEASE, SEVERE HEADACHES, LOW PACK PAIN, SEVERE ABDOMINAL PAIN, SEVERE PELVIC PAIN, ANEMIC, HEAVY BLEEDING, TREMENDOUS AMOUNT OF ADHESIONS, UTERUS WAS FULL OF BLOOD AND HAD SET UP LIKE CONCRETE, AND PART OF MY UTERUS WAS STRETCHED OUT AND JUST DANGLING. NO INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2008 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AFTER INSERTION WITH ESSURE DIAGNOSED WITH AUTO IMMUNE DISEASE AND HAD SEVERE HEADACHES, LOW BACK PAIN, SEVERE ABDOMINAL PAIN, SEVERE PELVIC PAIN ETC, SHE WAS HOSPITALIZED ON SEVERAL OCCASIONS DUE TO ESSURE. SHE BECAME ANEMIC FROM THE HEAVY BLEEDING. SHE HAD HYSTERECTOMY WHERE THE DOCTOR FOUND THAT HER UTERUS AND BLADDER HAD GROWN TOGETHER AND ATTACHED TO HER ABDOMINAL WALL. SHE HAD TREMENDOUS AMOUNT OF ADHESIONS, HER UTERUS WAS FULL OF BLOOD, HAD SET UP LIKE CONCRETE AND PART OF HER UTERUS WAS STRETCHED OUT AND JUST DANGLING. THERE IS MUCH MORE SHE HAS BEEN THROUGH SINCE HAVING ESSURE. ESSURE WAS REMOVED ON (B)(6) 2014. REPORTED CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS NOT REPORTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036015		5/6/2014	5/13/2014

Event Information:

Event Date (B3): 2/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/17/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE COILS PLACED IN (B)(6) 2010. I HAVE BEEN EXPERIENCING SIDE EFFECTS SUCH AS SEVERE PAIN IN MY LOWER ABDOMEN, MORE FREQUENT, IRREGULAR, HEAVY PERIODS, EXHAUSTION AND HEADACHES. I DID NOT HAVE ISSUES WITH THIS PRIOR TO HAVING THE COILS INSERTED. THE SIDE EFFECTS CONTINUE TO GET WORSE. SO FAR MY DOCTORS HAVE SAID IT COULDN'T BE THE ESSURE GIVING ME THE ISSUES BUT I HAVEN'T HAD ANY TESTS DONE TO BE SURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036017	BAYER	5/6/2014	5/13/2014

Event Information:

Event Date (B3): 2/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESURE TUBAL IMPLANT
Device Type (E2): TUBAL IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/10/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS PLACE IN (B)(6) 2011. I NEVER PUT TWO AND TWO AND TWO TOGETHER THAT THESE MAY BE CAUSING ANY PROBLEMS. EVEN AFTER AN XRAY TO MAKE SURE THEY WERE IN PROPER POSITION MY IMPLANTS MIGRATED AND PUNCTURED MY UTERUS. I HAVE TO HAVE THEM REMOVED (B)(6) 2014 ALONG WITH MY UTERUS. I'M (B)(6) YEARS OLD AND HAVE TO HAVE A FULL HYSTERECTOMY DUE TO ESSURE IMPLANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00135	BAYER HEALTHCARE LLC	5/6/2014	5/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 789025 / 761438

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5034146) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DAILY CRAMPING, BACKACHES, SEVERE MIGRAINES, WEIGHT GAIN, EXTREME FATIGUE, DEPRESSION, PAIN DURING SEX, RANDOM NUMBNESS IN MY FEET, AND IRREGULAR PERIODS. NO INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED LOT NUMBER 789025 / 761438 (EXPIRATION DATE 11-NOVEMBER-2005). FROM THE MOMENT ESSURE WAS IMPLANTED, PT STARTED EXPERIENCING DAILY CRAMPING AND BACKACHES AND OVER THE 2 PLUS YEARS CONTINUALLY WORSENED TO THE POINT THAT SHE COULD NOT FUNCTION. ALSO SHE HAD SEVERE MIGRAINES, WEIGHT GAIN, EXTREME FATIGUE, DEPRESSION, PAIN DURING SEX, RANDOM NUMBNESS IN FEET AND IRREGULAR PERIODS. ALL OF THE EVENTS WERE GONE AFTER ESSURE REMOVAL.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 22-SEP-2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE. TO DATE, THERE HAS BEEN NO RESPONSE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

ADDITIONAL INFORMATION RECEIVED ON 24-SEP-2014:

LOT NUMBER 789025, THE MANUFACTURE DATE IS OCT-2010 AND EXPIRATION DATE IS O

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00137	BAYER HEALTCARE LLC	5/6/2014	5/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED FAILED RIGHT SIDE, DEVICE TIP BENT/BROKE, AND COMPLICATION OF DEVICE INSERTION. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITION AND CONCOMITANT MEDICATION RECEIVED. ON (B)(6), 2013 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER A95862. ON (B)(6) 2013 THE PATIENT EXPERIENCED FAILED RIGHT SIDE, DEVICE TIP BENT/BROKE, AND COMPLICATION OF DEVICE INSERTION. PATIENT FOLLOWED WITH A TUBAL. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00138	BAYER HEALTHCARE LLC	5/6/2014	5/14/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B11728

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/28/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT'S INITIALS AND BIRTHDATE WERE INFORMED. SHE WAS (B)(6) AT THE TIME OF EVENT ONSET, WITH (B)(6) . THE PT WAS NOT PREGNANT. THE PT DID NOT HAVE PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES, ANY OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. SHE WAS GRAVIDA I, PARA I, NO ABORTION AND NO ECTOPIC PREGNANCIES. THE PT HAD ESSURE (ESS305) EASILY INSERTED (LOT NUMBER WAS B11728). THE INSERTION WAS NOT PERFORMED POST-PARTUM, W/O CERVICAL DILATION OR GENERAL ANESTHESIA, AND WITH SOUNDING, PARACERVICAL BLOCK, VICODIN, MOTRIN, PHENERGAN AND XANAX. THE TUBAL OSTIUM WAS EASILY VISUALIZED, THE FLUID LOSS WAS NOT GREATER THEN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. THE BACK-UP CONTRACEPTION WAS DEPOPROVERA. THE PERFORATION DID NOT OCCUR DURING SOUNDING, CERVICAL DILATION, HYSTEROSCOPY PRIOR TO ESSURE INSERTION OR BEFORE ESSURE DEPLOYMENT. ON (B)(6) 2013, THE HYSTEROSALPINGOGRAPHY SHOWED LEFT TUBE OCCLUDED WITH NORMAL ESSURE PLACEMENT AND RIGHT ESSURE COIL DISPLACED INTO PERITONEAL CAVITY. THERE WAS...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00140	BAYER HEALTHCARE LLC	5/6/2014	5/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/10/2010
Explant Date (E7): 2/26/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON (B)(6) 2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE #MW5035130). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PAIN, BLOATED, FELT LIKE SOMETHING WAS STABBING HER, JOINT PAINS, THEY THOUGHT HER ESSURE WAS GOING INTO HER UTERUS. ON FDA FORM REPORTED REPORT TYPE WAS "INJURY", OUTCOME OF EVENTS WAS "REQUIRED INTERVENTION". NO INFO WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2010, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. CONSUMER REPORTED EVER SINCE IMPLANTATION SHE HAD BEEN IN PAIN, BLOATED, FELT LIKE SOMETHING WAS STABBING HER. SHE HAD HER JOINT PAINS THAT STARTED AFTER PLACEMENT. THEN A COUPLE OF WEEKS BEFORE TIME OF REPORTING THEY THOUGHT HER ESSURE WAS GOING INTO HER UTERUS, SO THEY DID A REMOVAL ON (B)(6) 2014 AND TIED HER TUBES. NO FURTHER DETAILS WERE REPORTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00141	BAYER HEALTHCARE LLC	5/6/2014	5/14/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/30/2013
Explant Date (E7): 2/24/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5034821) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP SHOOTING PAIN IN MY OVARY AREA, BROKE OUT IN A CHRONIC RASH, GAINED 10 LBS, AND CHRONIC HIP AND KNEES ACHES/PAINS. NO INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IMMEDIATELY AFTER ESSURE INSERTION, PT STARTED TO EXPERIENCE SHARP, SHOOTING PAIN IN OVARY AREA. SHE BROKE OUT IN CHRONIC RASH, GAINED 10 LBS WITHOUT CHARGING DIET AND EVEN AFTER STARTING YOGA 5 DAYS A WEEK. SHE HAD CHRONIC HIP AND KNEE ACHES/PAIN AND KEPT FEELING WORSE AND WORSE. ESSURE WAS DISCONTINUED ON (B)(6) 2014. CONSUMER DID NOT RESPOND TO F/U ATTEMPTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00146	BAYER HEALTHCARE LLC	5/6/2014	5/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 787227

Single Use: Y
Implant Date (E6): 2/1/2013
Explant Date (E7): 5/15/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVE FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SLIGHT PAIN, CRAMPING, SLIGHT BLEEDING, AND ONE OF THE SPRINGS WAS NOT IN THE CORRECT PLACE, IT WAS UP AGAINST MY COLON. NO INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION. THE REPORTED LOT NUMBERS WERE, 787227 AND 922605. ON (B)(6) 2013 IMMEDIATELY AFTER INSERTION THE CONSUMER EXPERIENCED SLIGHT PAIN, CRAMPING AND SLIGHT BLEEDING. SHE STATED WHEN SHE WAS BENDING OVER, SHE FELT LIKE A SPLINTER INSIDE HER ON RIGHT SIDE. ON UNSPECIFIED DATE HSG (HYSTEROSALPINGOGRAM) SHOWED ONE OF THE SPRINGS WAS UP AGAINST COLON, SHE DID NOT KNOW WHICH SIDE. ESSURE WAS REMOVED ON (B)(6) 2013 AND THAT TIME CLIPS WERE REPLACED ON BOTH TUBES, AS BIRTH CONTROL. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENT AND ESSURE IS NOT PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00147	BAYER HEALTHCARE LLC	5/6/2014	5/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ESSURE WAS OUTSIDE OF UTERINE CAVITY AND PARALLEL TO THE FALLOPIAN TUBE AND UNABLE TO DO ONE INSERT. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS UNK WHETHER THE PT RECEIVED ANY CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION. AT TIME OF INSERTION, THE DOCTOR WAS UNABLE TO INSERT ONE DEVICE. LAPAROSCOPIC SURGERY WAS PERFORMED IN (B)(6) 2014. THE ESSURE WAS OUTSIDE OF THE UTERINE CAVITY AND PARALLEL TO THE FALLOPIAN TUBE. IT WAS UNK IF THE DEVICE WAS REMOVED. THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE WAS NOT REPORTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00139	BAYER HEALTHCARE LLC	5/6/2014	5/30/2014

Event Information:

Event Date (B3): 9/17/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 975395

Single Use: Y
Implant Date (E6): 9/17/2012
Explant Date (E7): 12/30/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON UNSPECIFIED DATES PT PERFORMED A COMPUTED TOMOGRAPHY SCAN AND PELVIC ULTRASOUND THAT SHOWED ENLARGED CYSTS, OVER ENLARGED UTERUS, OVARIES WERE ENLARGED AND CYSTS COVERING BOTH OF THE OVARIES. ON (B)(6) 2014, PT HAD HYSTERECTOMY ALONG WITH ESSURE REMOVAL. IT WAS A LAPAROSCOPIC PROCEDURE. SHE ALSO HAD HER FALLOPIAN TUBES REMOVED AND ONLY HER OVARIES WERE LEFT. DURING SURGERY, PART OF ONE COIL WAS FOUND IN THE TUBE AND PART OF THE OTHER ONE WAS IN UTERUS. PT DOES NOT KNOW IF COMPLETE OR PARTIAL PERFORATION OCCURRED. SHE IS RECOVERED FROM THE ESSURE REMOVAL PROCEDURE AND ALL HER OTHER SYMPTOMS/PAIN RESOLVED AFTER SURGERY. SHE BELIEVES THAT ESSURE CAUSED HER CONDITION BECAUSE SHE HED ALL OF HER SYMPTOM AFTER ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00136	BAYER HEALTHCARE LLC	5/7/2014	5/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE CONSUMER VIA REGULATORY AUTHORITY IN UNITED STATES (MW5034141) ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED 4 PIECES BROKE OFF ESSURE COIL DURING DEPLOYMENT IN RIGHT REMAINING TUBE, COMPLICATION OF DEVICE INSERTION, SEVERE ABDOMINAL PAIN FOR A MONTH AFTERWARDS, HSG SHOWED COIL HAD MIGRATED NEAR END OF TUBE NEAREST THE OVARY, ON OCCLUSION HAD TAKEN PLACE, MODERATE-SEVERE PAIN ON RIGHT SIDE IN LOCATION OF COIL ESPECIALLY DURING OVULATION, PAIN AFTER INTERBOURSE AND EXERCISE AND SEVERE PSORIASIS ON SCALP. NO INFO WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2013, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THAT PIECES BROKE OFF ESSURE COIL DURING DEPLOYMENT IN RIGHT TUBE. IT WAS WRITTEN IN HER OPERATING REPORT. SHE EXPERIENCED SEVERE ABDOMINAL PAIN FOR A MONTH AFTERWARDS, IN 2013, A HYSTEROSALPINGOGRAM WAS PERFORMED AND SHOWED THAT COIL HAD MIGRATED NEAR END OF TUBE NEAREST THE OVARY AND NO OCCLUSION HAD TAKEN PLACE. THE DOCTOR STATED THAT THE ONLY WAY TO KNOW IF COIL HAS PERFORATED THE TUBE WAS BY HAVING SURGERY. SHE IS STILL HAVING MODERATE-SEVERE PAIN ON RIGHT SIDE IN LOCATION OF COIL ESPECIALLY DURING OVULATION AND AFTER INTERCOURSE AND EXERCISE. SHE ALSO DEVELOPED SEVERE PSORIASIS ON SCALP, WHICH SHE NEVER HAD PRIOR ESSURE AND SHE WAS NEVER TESTED FOR A NICKEL ALLERGY TO THE PROCEDURE. THE OUTCOME OF THE EVENTS WAS UNK. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS NOT REPORTED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00134	BAYER HEALTHCARE LLC	5/7/2014	5/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/6/2012
Explant Date (E7): 3/5/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2013 BY CONCEPTUS IN THE UNITED STATES AND TRANSMITTED TO BAYER (B)(6) ON (B)(6) 2014. THE REPORT REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THREE MONTHS AFTER INSERTION IT WAS FOUND THAT THE DEVICES WERE ASYMMETRIC AND VERY DISTANT FROM EACH OTHER, FOUR YEARS LATER, IT WAS FOUND RIGHT AND LEFT INSERT HAD MIGRATED - PROBABLY DOUBLE PERFORATION, AND PT GOT PREGNANT (DEVICE INEFFECTIVE). NO INFO WAS GIVEN ON PT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. IN JULY 2009, THE PT HAD BEEN FITTED WITH ESSURE. BATCH NUMBER WAS UNK BY REPORTER. AFTER FITTING WITHOUT DIFFICULTY, THE SURGEON PERFORMED CONTROL X-RAY THREE MONTHS AFTER INSERTION (OCTOBER 2009) THAT HE CONSIDERED AS GOOD. ON THE RADIOGRAPH, LEFT INSERT WAS STRAIGHT, FOURTH MARKER WAS IN ABNORMAL POSITION, THE TWO INSERT'S SHAPE WAS NOT SYMMETRIC, AND DISTANCE BETWEEN THE TWO PROXIMAL PARTS WAS ABOVE ONE INSERT'S SIZE (SIZE OF ONE IMPLANT 4 CM, THAT IS AVERAGE UTERUS SIZE). THE PT WAS SEEN FOUR YEARS LATER, PREGNANT. A NEW RADIOGRAPH PERFORMED AT THE TIME OF PREGNANCY SHOWED RIGHT INSERT HAD MIGRATED BECAUSE IT WAS NOT IN A CORRECT POSITION, AND LEFT INSERT HAD ALSO MIGRATED AS IT WAS NOT IN PLACE, IT PROBABLY WAS A DOUBLE PERFORATION THAT SHOULD HAVE BEEN SEEN AT THREE MONTHS CONTROL X-RAY. NO OTHER INFO WAS AVAILABLE. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP. FOLLOW-UP INFO RECEIVED ON 04/07/2014: PT'S INFO WAS ADDED. THE PT HAD 2 PREVIOUS PREGNANCIES. SHE DID NOT HAVE ECTOPIC PREGNANCY, ELECTIVE ABORTION, C-SECTION AND PREVIOUS GYNAECOLOGICAL INTERVENTION. SHE IS GRAVIDA 2 AND PARA 2, BUT SPONTANEOUS ABORTION WAS REPORTED AS HISTORICAL CONDITION. THERE WAS NO UTERINE ANOMALY PRIOR TO INSERTION. ON

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(B)(6) 2012, ESSURE WAS INSERTED. INSERTION WAS PERFORMED DURING FOLLICULAR PHASE. THE VISUALIZATION OF TUBAL OS WAS DIFFICULT; OSTIUM WAS NOT SEEN. IT WAS A LITTLE BIT DIFFICULT ON THE LEFT SIDE. FLUID LOSS DURING HYSTEROSCOPY WAS NOT MORE THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MIN. THE PT COMPLAINT AFTER THE PLACEMENT OF ESSURE. SHE EXPERIENCED ABDOMINO-PELVIC PAIN FOR 3 WEEKS AND SHE RECEIVED SEDATIVE THE NEXT DAY. IDENTIFICATION AT THE TIME OF ESSURE CONFIRMATION TEST WAS DONE. THERE WAS WORK STOPPAGE FOR 3 WEEKS. ON (B)(6) 2013, INCORRECT ESSURE POSITION WAS DIAGNOSED ON ULTRASOUND, X-RAY AND LAPAROSCOPY. PERFORATION WAS BILATERAL. NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS PERFORATED. PERFORATION OCCURRED WITH COIL AFTER DEPLOYMENT. IF LEFT TUBE OCCURRED COMPLETE PERFORATION, ESSURE WAS BETWEEN UTERINE HORN AND CAECUM. ON (B)(6) 2013, ESSURE CONFIRMATION TEST WAS DONE BY X-RAY AND ULTRASOUND. THE FIRST CONFIRMATION TEST DID NOT CONFIRM TUBAL OCCLUSION. THE PT WAS ADVISED ABOUT ESSURE EFFECTIVENESS BASED ON THE RESULT OF CONFIRMATION TEST. ON (B)(6) 2013, ESSURE WAS REMOVED VIA LAPAROSCOPY. ESSURE WAS NOT REMOVED BECAUSE OF PT REQUEST. IT WAS MEDICALLY NECESSARY. NO PATHOLOGY RESULTS, SIGNS OF INFECTION AND INFLAMMATION WERE REPORTED. THE PT RECOVERED. NO FURTHER INFO WILL BE AVAILABLE. CASE CLOSED.

Manufacturer Narrative (H10):

DATA CORRECTION OF 15-APR-2014: FOLLOWING INTERNAL REVIEW, IT WAS NOTICED THAT INITIAL NARRATIVE'S HEADER IS INCORRECT. THE CONCEPTUS UNIT WHICH FORWARDED THE CASE WAS FROM (B)(6). INTERNAL CORRECTION FROM 15-APR-2014 FOLLOWING CASE REVIEW: THE EVENT DEVI

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00142	BAYER HEALTHCARE LLC	5/7/2014	6/10/2014

Event Information:

Event Date (B3): 2/1/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 2/11/2014
Explant Date (E7): 2/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 09-APR-2014 REFERRING TO HERSELF. THE FEMALE CONSUMER OF UNSPECIFIED AGE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEVICE MALFUNCTIONED AND WOULD NOT FULLY RELEASE THE COIL, CONTINUED SHARP PAIN IN MY ABDOMEN, CONTINUED SHARP PAIN IN MY UTERINE AREA, CONTINUED HEAVY VAGINAL BLEEDING, DEVICE WAS FOUND IN MY UTERUS, MINOR SCARRING IN MY UTERUS AND MINOR SCARRING IN MY TUBE THAT IT WAS IMPLANTED IN. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAS DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION RECEIVED. ON (B)(6) 2014, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE DEVICE MALFUNCTIONED WHEN THE DOCTOR WAS PUTTING IN AND IT WOULD NOT FULLY RELEASE THE COIL. AS THE DOCTOR RETRACTED THE CAMERA THAT IMPLANTS THE DEVICE. THE COIL CAME OUT HALF WAY WITH THE CAMERA. THE CONSUMER HAD TO WAIT A FULL WEEK TO HAVE THE DEVICE REMOVED VIA HYSTEROSCOPY ON (B)(6) 2014. DURING THE WEEK PRIOR TO REMOVAL, THE CONSUMER EXPERIENCED CONTINUED SHARP PAIN IN MY ABDOMEN, CONTINUED SHARP PAIN IN MY UTERINE AREA AND CONTINUED HEAVY VAGINAL BLEEDING. THE DEVICE WAS FOUND IN HER UTERUS. IT WAS MENTIONED THAT SHE NOW HAD A MINOR SCARRING IN HER UTERUS AND IN HER TUBE THAT IT WAS IMPLANTED IN. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00144	BAYER HEALTHCARE LLC	5/7/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/23/2013
Explant Date (E7): 2/12/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED BLEEDING/HEAVY BLEEDING, SEVERE PELVIC PAIN, SEVERELY ANEMIC, HAIR FALLING OUT, BRUISING ALL OVER MY BODY, LOWER BACK PAIN, AND PAIN. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AT UNK IMPLANTED. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED BLEEDING AFTERWARDS AND HEAVY BLEEDING THAT CONTINUED FOR 2 MONTHS SOLID THEN STOPPED FOR A COUPLE OF DAYS AND THEN CONTINUE WITH HEAVY BLEEDING FOR A COUPLE OF WEEKS THEN STOP BLEEDING FOR A COUPLE OF DAYS AND THAT CONTINUED. SHE ALSO EXPERIENCED SEVERE PELVIC PAIN THAT WOULD COME OFF AND ON. SHE ENDED UP BEING SEVERELY ANEMIC FROM THE BLOOD LOSS. SHE HAD LOTS OF HAIR FALLING OUT AND BRUISES ALL OVER HER BODY. SHE ALSO HAD LOWER BACK PAIN AFTER HAVING THEM INSERTED. SHE CALLED HER DOCTOR WHO IMPLANTED THEM AND THEY TOLD HER THEY NEVER HAD ANY PATIENTS WITH THOSE SYMPTOMS. SHE TOLD THEM SHE WANTED THEM OUT OF HER BECAUSE SHE HAS BEEN BLEEDING AND IN PAIN SINCE HAVING THEM IN. THEY DECIDED NOT TO DO THE HSG TEST BECAUSE SHE WANTED THEM OUT. HER OTHER DOCTOR DECIDED REMOVING THEM WOULD BE BEST. ON (B)(6) 2014 A HYSTERECTOMY WAS PERFORMED LEAVING OVARIES. THE BLEEDING, PAIN, BRUISING AND HAIR LOSS HAVE ALL STOPPED AND SHE WAS FEELING A LOT BETTER. THE OUTCOME OF THE EVENTS BLEEDING/HEAVY BLEEDING, SEVERE PELVIC PAIN, SEVERELY ANEMIC, HAIR FALLING OUT, BRUISING ALL OVER MY BODY, LOWER BACK PAIN, AND PAIN WAS UNKNOWN. REPORTER CAUSALITY: THE RELATIONSHIP

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BETWEEN BLEEDING/HEAVY BLEEDING, SEVERE PELVIC PAIN, SEVERELY ANEMIC, HAIR FALLING OUT, BRUISING ALL OVER MY BODY, LOWER BACK PAIN, AND PAIN AND ESSURE IS RELATED. AFTER 3 FOLLOW-UP ATTEMPTS, NO RESPONSE WAS RECEIVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00145	BAYER HEALTHCARE LLC	5/7/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626159

Single Use: Y
Implant Date (E6):
Explant Date (E7): 3/8/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN THE UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING PAIN / DEBILITATING PAIN THAT STAYED AND BECAME CHRONIC / STABBING PAIN, DEBILITATING TO MANAGEABLE CRAMPS, DEBILITATING DURING MENSTRUATION, PAINS PRIOR MENSTRUAL CYCLE, BOUTS OF VOMITING, CRYING, LESIONS, RIGHT INFLAMED OVARIES, LESIONS OF UTERUS, INFLAMED UTERUS, CYST SO BIG AND FLUID FILLED THAT IT TOTALLY TOOK OVER MY LEFT OVARY/ RIGHT OVARY WITH FLUID FILLED CYSTS, IN CONTINENCE, BLOATING, DIZZY, METAL TASTE, MOOD SWINGS, HAIR LOSS, TEETH AND GUMS SENSITIVE, SKIN CHANGED, HIVES, RASHES, ITCHY BURNING SKIN, ODD PERIODS, FORGETFULNESS, SHARP PAINS IN BACK, SHARP PAINS IN HIP, SHARP PAIN IN LEG, INSOMNIA, CHRONIC FATIGUE, WEIGHT GAIN, NAUSEA, MIGRAINES, BLEEDING / SPOTTING, AND UMBILICAL HERNIA. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. IN 2008, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH LOT NUMBER 626159. IN 2008 SINCE HAVING ESSURE INSERTED, THE CONSUMER EXPERIENCED EXCRUCIATING PAIN, DEBILITATING PAIN THAT STAYED AND BECAME CHRONIC. AFTER SOME TIME WENT BY, SHE HAD DAYS THAT THE PAIN WOULD SUBSIDE FROM DEBILITATING TO MANAGEABLE CRAMPS, THEN BACK TO DEBILITATING PAINS DURING MENSTRUATION TIMES. SHE WAS BED RIDDEN THE WEEK PRIOR TO HER MENSTRUAL CYCLE, THE WEEK OF MENSTRUAL CYCLE AND A FEW DAYS AFTER MENSTRUAL CYCLE, THE PAINS STARTED TO SUBSIDE A LITTLE ENOUGH THAT SHE COULD MOVE AROUND A LITTLE BETTER. THE PAINS NEVER TOTALLY GO AWAY. DURING MENSTRUAL CYCLE THE PAIN WAS SO STRONG AND

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STABBING THAT SHE WOULD HAVE BOUTS OF VOMITING, AND CRYING. HER LIFE HAD CHANGED AND SHE BECAME MORE AND MORE UNABLE TO PERFORM DAILY LIVING TASKS. SHE WENT TOT SEVERAL DOCTORS AND EMERGENCY ROOM VISITS. DOCTORS COULD NOT EXPLAIN WHAT WAS WRONG WITH HER, THEY PRESCRIBED PAIN KILLERS AND SENT HER HOME. SHE HAD SUFFERED WITH THIS AFFLICTION FOR MANY YEARS SINCE BEING IMPLANTED WITH THE ESSURE MICRO INSERTS. AS I KEPT GETTING WORSE AND SUFFERING TO THE POINT I THOUGHT I WAS GOING TO DIE, FINALLY FOUND A DOCTOR TO DO AN MRI (MAGNETIC RESONANCE IMAGE) AND RUN MORE TESTS. THE RESULTS WERE LESIONS, INFLAMED OVARIES AND UTERUS, CYST SO BIG AND FLUID FILLED THAT IT TOTALLY TOOK OVER HER LEFT OVARY, PRESSED ON HER BLADDER CAUSING INCONTINENCE AND PUSHING ON HER ABDOMEN CAUSING ADDITIONAL PAINS AND BLOATING; THE RIGHT OVARY WAS INFLAMED AND WITH FLUID FILLED CYSTS. IN 2013 THE DOCTOR SAID SHE COULD NOT REMOVE ESSURE. THE ONLY WAY TO GET THEM OUT WAS TO PERFORM A HYSTERECTOMY. SHE HAD A HYSTERECTOMY ON (B)(6) 2013 TO REMOVE THE ESSURE COILS. SINCE THE REMOVAL, THE CHRONIC PAIN HAS GONE. BUT AS A RESULT OF GETTING THE COILS OUT OF HER, SHE HAS HAD TO HAVE HER HEALTHY UTERUS AND OVARY AND TUBES REMOVED. THE OTHER SYMPTOMS DURING THE TIME THE ESSURE IN WERE PAINS, DIZZY, METAL TASTE, MOOD SWINGS, HAIR LOSS, STABBING PAIN, TEETH AND GUMS SENSITIVE, SKIN CHANGED, HIVES AND RASHES, ITCHY BURNING SKIN, ODD PERIODS, FORGETFULNESS, SHARP PAINS IN BACK, HIP AND LEG, INSOMNIA, CHRONIC FATIGUE, BLOATED, WEIGHT GAIN, NAUSEA, MIGRAINES, BLEEDING, SPOTTING, UMBILICAL HERNIA. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS NOT REPORTED. DESPITE SEVERAL FOLLOW-UP ATTEMPTS NO NEW INFORMATION COULD BE OBTAINED.

Manufacturer Narrative (H10):

DEVICE IS AN INSTRUMENT AND IS NOT IMPLANTED/EXPLANTED. THE INSTRUMENT WAS RETURNED TO LIFE TECHNOLOGIES CORP AND REPAIRED BY REPLACING POWER AMPLIFIER & DAMPER. AFTER REPAIR, THE INSTRUMENT PASSED ALL THE CALIBRATION, FINAL TESTS, PERFORMANCE SPECIFICATI

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00148	BAYER HEALTHCARE LLC	5/7/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/25/2013
Explant Date (E7): 9/16/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN UNITED STATES ON (B)(4) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ONE OF THE DEVICES HAD BECOME DISLODGED AND WAS NOW IN MY UTERUS. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT SHE WAS EXPERIENCING A LOT OF PAIN ON ONE SIDE. X-RAY/DYE TEST WAS PERFORMED AND SHOWED THAT DEVICES HAD BECOME DISLODGED AND WERE IN HER UTERUS. SHE SAID IT WAS THE SOURCE OF HER PAIN. SHE WAS SUBMITTED TO A SURGERY TO REMOVE IT AND TO TIE HER TUBES. ESSURE WAS REMOVED ON (B)(6) 2013. NO FOLLOW UP INFORMATION IS EXPECTED. CASE CLOSED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036064	BAYER	5/8/2014	5/14/2014

Event Information:

Event Date (B3): 4/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED AND THE DR. TORE MY UTERUS AND THEN SINCE THEN I HAVE HAD ON-GOING PAIN, HEADACHES, BLEEDING WITH CLOTS, MY UTERUS IS ENLARGED. IT HAS BEEN A NIGHTMARE SINCE THE DAY IT WAS IMPLANTED. I AM NOT MYSELF AND IN PAIN EVERY DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035966	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 10/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY TUBES NEVER OCCLUDED. RIGHT COIL PERFORATED MY FALLOPIAN TUBE. LEFT COIL MIGRATED OUT OF MY VAGINA ON (B)(6) 2014. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035967	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 6/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE VERY BAD HEADACHES, STOMACH PAIN AND CRAMPING BAD BLOATING AND THEY CANNOT FIND MY LEFT COIL WHICH IS A RECENT DISCOVERY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035968	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 10/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I'VE HAD THE ESSURE DEVICE PUT IN I'VE HAD HEADACHES AT LEAST 3X A WEEK, CRAMPS EVERY DAY, SEVERE BLOATING, LOWER BACK PAIN, DEPRESSION, PAINFUL INTERCOURSE, FATIGUE, SHARP SHOOTING PAIN IN LOWER ABDOMEN, AND SOME DAYS I CAN FEEL THE SPRING IN MY TUBES. PAINFUL. I ALSO LOST MY BOYFRIEND OF 2.5 YEARS BECAUSE I DIDN'T WANT TO HAVE INTERCOURSE BECAUSE OF THE PAIN. OUR RELATIONSHIP WENT DOWNHILL FAST. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035969	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE NIGHT OF THE ESSURE PROCEDURE (B)(6) 2008 I HAD PROBLEMS; BEFORE IMPLANTATION DR. TOLD ME IT WAS MADE OF STAINLESS STEEL, SO THERE SHOULD BE NO SIDE EFFECTS. (YEAH OK EDUCATE THE DR (B)(6) BEFORE LETTING THEM DO PROCEDURES.). THAT NIGHT (B)(6) 2008, I WAS PUKING AND HAD HIGH FEVER CALLED THE HOSPITAL NUMBER THEY GAVE ME IF I HAD ANY PROBLEMS AND THEY TOLD ME IT WOULD BE OK AND THIS IS NORMAL, TAKE THE PAIN MEDS THEY GAVE ME, IT WILL HELP ME. INSTEAD IT MADE IT WORSE FOR ME, THIS CONTINUED FOR 2 DAYS AND THEY WOULDN'T SEE ME IN THE OFFICE DUE TO MY MEDICAID RAN OUT, SO I WAS STUCK. COUPLE WEEKS LATER, NOTICED MORE PROBLEMS AND FOR ME THIS WAS A BIG DEAL BECAUSE I HAD ALWAYS BEEN VERY HEALTHY ALL MY LIFE AND NO COMPLICATIONS DURING ANY PREGNANCY. TO CUT THIS SHORT, I HAD BEEN THROUGH ABOUT EVERY ER IN (B)(6). ALL SYMPTOMS ARE CONSTANT ABDOMINAL PAIN,NAUSEA, METALLIC TASTE IN MOUTH, PAINFUL INTERCOURSE TO WERE IT'S CAUSING PROBLEMS IN MY MARRIAGE. BLOATING, FATIGUE, WEIGHT GAIN, WATER RETENTION, HEADACHES, SHARP PELVIC PAINS (STABBING AND SHOCKING FEELINGS), HAVING BOWEL PROBLEMS TO WHERE I DO NOT GO ON MY OWN WITHOUT A LAXATIVE, UTERINE INFECTION, SEVERE ACNE, VAGINAL DISCHARGE 98 PERCENT OF THE TIME, THINNING HAIR, HAIR LOSS, GREYING OG HAIR IM ONLY (B)(6) (NO IT IS NOT HEREDITARY), EXTREMELY DRY SKIN EVEN WITH CONSTANT MOISTURIZING, IN XRAYS I HAVE THE COILS DO NOT LOOK TO BE IN THE RIGHT SPOTS WHERE THEY SHOULD BE, DIAGNOSED WITH PCOS AND PTLS, LOSS OF CONCENTRATION, HAVE BEEN SUGGESTED TO HAVE A HYSTERECTOMY UNTIL ONCE AGAIN MEDICAID WAS TAKEN FROM ME. TIL THIS DAY, I AM STILL IN PAIN AND EVERYTHING IS STARTING TO BECOME WORSE FOR ME AND I DON'T THINK ANY OTHER WOMEN SHOULD HAVE TO DEAL WITH

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

THIS AT ALL. ENOUGH IS ENOUGH AND IT NEEDS TO BE TAKEN OFF THE MARKET. THIS THING CAUSES PERMANENT DAMAGE ESPECIALLY WHEN YOUNG WOMEN HAVE TO HAVE HYSTERECTOMIES CAUSE OF IT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035970	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 2/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

EXCRUCIATING PAIN IN TAILBONE WHEN SITTING ERECT. PAIN SUBSIDES WHEN STANDING. MY JOB REQUIRES COMPUTER WORK AND OCCASIONAL TRAVEL WHICH POSES PROBLEMS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035971	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 3/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I MISSED MY PERIOD AND TOOK A PREGNANCY TEST. FOUND OUT I WAS PREGNANT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035972	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 3/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE 32 SYMPTOMS ! NAUSEA, DIZZINESS, CRAMPS, HORRIBLE STOMACH PROBLEMS, BOWEL MOVEMENTS PROBLEMS, INSOMNIA, DEPRESSION, ANXIETY, CRAMPS, BACK PAIN, RASH, BLADDER INFECTIONS, NECK PAIN, RASH, JOINT PAIN, HOT FLASHES, WEIGHT GAIN, HAIR LOSS, HEADACHES, ETC. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035973	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS HAVING HORRIBLE ABDOMINAL PAIN, NAUSEA, PELVIC PAIN, HOT FLASHES, MIGRAINES, INSOMNIA, EXTREMELY HEAVY AND LONG MENSTRUAL CYCLES... (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035974	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CRAMPS, HEADACHES, BACK PAINS, BLOATED, DEPRESSION, SHARP LOWER ABDOMEN PAIN, BRAIN SHOCKS, SUDDEN MOVEMENT IN STOMACH, KICKING SENSATION, LOTS OF URINE INFECTION, VAGINAL INFECTIONS, LOSS OF HAIR, IRRITABILITY, AND SWELLING OF THE HANDS AND FEET, AND WEIGHT GAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035975	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GAVE BIRTH TO MY 4TH CHILD (B)(6) AND HAD THE DEPO SHOT THE DAY AFTER, I HAD A LIGHT PERIOD SINCE THE DAY SHE WAS BORN AND WHILE THEY PLACED ESSURE WEEKS LATER WHICH IS NORMAL FOR ME AFTER GIVING BIRTH. AFTER ESSURE WAS PLACED I HAD HEAVIER BLEEDING FOR ALMOST 6 MONTHS AND VERY PAINFUL CRAMPING, WHICH MY OB PRESCRIBED PREMARIN TO STOP THE BLEEDING. AFTER A VAGINAL ULTRASOUND I WAS TOLD I HAD ADENOMYOSIS. I HAVE NEVER HAD PROBLEMS WITH DEPO SHOTS AND I'VE HAD THEM AFTER EACH OF MY CHILDREN FOR 2 DOSES. MY OB TOLD ME I WILL NEED A HYSTERECTOMY AND I AM ONLY (B)(6). I AM EXTREMELY TIRED AS SOON AS I WAKE UP AND HAVE TO FIGHT TO STAY AWAKE ALL DAY TO CARE FOR MY 4 CHILDREN, MY OVARIES ARE TWITCHING CONSTANTLY, FEELING LIKE A CHILD MOVING AROUND IN THERE AND PREGNANCY TESTS ALL COME BACK NEGATIVE. I'VE TAKEN A FEW THAT CAME BACK WITH A FAINT BUT VISIBLE POSITIVE LINE THEN NEGATIVE A FEW WEEKS LATER. I GOT ESSURE BECAUSE I HAD NO ONE TO HELP ME WHILE I RECOVERED FROM GETTING MY TUBES TIED AND NOW I HAVE TO HAVE SOMEONE HELP KEEP ME AWAKE DURING THE DAY. MY OB IMMEDIATELY SAID IT WAS NOT ESSURE RELATED BUT ONLY DID AN ULTRASOUND AND NO OTHER TESTS AND I WAS NOT HAVING ANY OF THESE PROBLEMS UNTIL AFTER ESSURE WAS PLACED. I NOW HAVE A PERIOD EVERY 2-3 WEEKS AND THE CRAMPING IS SO BAD I CANT GET OUT OF BED AND GET EXTREMELY NAUSEOUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035976	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 7/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN PELVIC AREA, HEAVY BLEEDING AND CLOTTING, PAIN WHILE HAVING SEX, HEADACHES, BLOATING, SWELLING, WEIGHT GAIN, MOODINESS, ACHES AND PAINS IN CHEST, LEGS AND ARMS. GALLBLADDER ISSUES CAUSING REMOVAL OF MY GALLBLADDER. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035977	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 3/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I NOTICE A LOT OF BODY CHANGES IN MY BODY AFTER PLACING ESSURE PERMANENT BIRTH CONTROL. THE MENSTRUAL CYCLE HAS CHANGE SIGNIFICANTLY. I NEVER USED TO GET SEVERE CRAMPS, PROLONG MENSTRUAL, AND BLOOD CLOT. NOW I GET ALL THOSE ON WHEN I GET MY PERIOD. THE OTHER SYMPTOMS ARE: ABDOMINAL PAIN, EXTREME BLOATING, HEADACHES, PELVIC PAIN, FAINTING EPISODES, NAUSEA, LOW AND UPPER BACK PAIN, FATIGUE, ANXIETY, AGAIN CHANGES IN MENSTRUAL CYCLE, PANIC ATTACK, PANIC SHARP PAIN IN MY LOWER ABDOMEN (LEFT AND RIGHT SIDE), BOWELS CHANGES, CHRONIC JOINT PAIN, FLU LIKE SYMPTOMS, NECK PAIN,LACK OF ENERGY, LOSS OF APPETITE, HAIR LOSS/THINNING HAIR. BEFORE ESSURE I WAS PERFECTLY HEALTHY AND VERY ENERGETIC. ULTRASOUND, X-RAY, AND NUMEROUS OF OTHER BLOOD WORK, AND URINE TESTS HAS BEEN DONE AND ALL CAME OUT NORMAL. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035978	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 10/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE ON (B)(6) 2006. MY LOT NUMBER 620744. MODEL NUMBER ESS205. THE ONSET OF MY COMPLICATIONS WAS (B)(6) 2010 WITH UNEXPLAINED ABDOMINAL PAIN WHICH LED TO TWO TRIPS TO THE ER. THIS IS A LIST OF MY SIDE EFFECTS DUE TO ESSURE: MIGRAINES, BACK AND NECK PAIN, FATIGUE, NAUSEA, GERD, ANXIETY, HEART PALPITATIONS, NIGHT SWEATS, SWOLLEN GLANDS, SORE THROAT, IRREGULAR MENSTRUAL CYCLE, HEAVY PERIODS, PELVIC PAIN. I HAVE BEEN DIAGNOSED WITH CHRONIC FATIGUE SYNDROME. I HAVE SEEN 6 DOCTORS. THE DEVICE IS STILL INSIDE ME. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035979	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 3/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PELVIC CRAMPS DAILY, BACK AND HIP PAIN, FATIGUE, WEIGHT GAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035980	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 11/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP 1, #FDA MW5035980, #(B)(4). I THINK THE PAIN WILL KILL ME. I HAVE NO INSURANCE, MEDICAID NOT AVAILABLE IN (B)(4). NO RELIEF IN SIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035981	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 1/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LOWER BACK PAIN ON MY RIGHT SIDE, MOSTLY IN THE MORNINGS, MAKING IT HARD TO DO EVERYDAY LIFE ACTIVITIES. DID HAVE AN X-RAY SHOWING A COIL HAD MOVED FROM ORIGINAL LOCATION. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035982	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 5/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY 3RD CHILD BY EMERGENCY C SECTION AND FOUND OUT I HAD A SOFT SPOT IN MY UTERUS AND I DECIDED TO GET THE ESSURE PROCEDURE. I GOT THE ESSURE DONE (B)(6) 2012. THE DOCTOR STARTED ON THE RIGHT SIDE AND AFTER GOING THROUGH 2 KITS THAT DIDN'T DEPLOY THEY TOOK A BREAK BECAUSE I WAS IN SO MUCH PAIN WENT TO THE LEFT SIDE WITH THE 3RD KIT AND IT DEPLOYED RIGHT AWAY AFTER THAT THE RIGHT DEPLOYED WITH THE 3RD KIT. I HAVE HAD CRAMPING PAIN IN MY ABDOMEN MOSTLY ON RIGHT SIDE, HEAVY BLEEDING WITH GOLF BALL SIZE CLOTS, PAIN AFTER INTERCOURSE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035983	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 5/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LOTS OF CRAMPING IN PELVIC AREA, MUSCLE PAIN, SEVERE FATIGUE, NECK PAIN, LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035984	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 5/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME PAIN FROM IMPLANTS, WEIGHT GAIN, DEPRESSION, HEAVIER PERIODS, ANXIETY, TIRED ALL THE TIME, GENERAL DETERIORATION IN HEALTH. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035985	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 3/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE PLACEMENT I WENT THE FIRST YEAR WITHOUT A MENSTRUAL CYCLE THEN WHEN I DID MY PERIODS HAVE BEEN IRREGULAR AND HEAVY. I GO TEN DAYS LATE TO FIVE DAYS EARLY AND I NEVER KNOW WHEN IT WILL HIT ME. I HAVE CONSTANT PAIN IN MY SIDES AND LOWER ABDOMEN. PAINFUL SEX AND PAIN THE DAY AFTER IS HORRIBLE. I HAVE NO DESIRE FOR SEX ANYMORE. I HAVE MIGRAINES THAT HAVE ONLY GOTTEN WORSE AS TIME GOES BY. METAL TASTE IN MY MOUTH THAT HURTS MY TEETH. MY MEMORY IS HORRIBLE. I CALL FOR ONE OF MY KIDS THEY COME AND I HAD ALREADY FORGOT THAT I CALLED FOR THEM. I'M VERY TIRED ALL THE TIME AND VERY MOODY. MY RIGHT BREAST HURTS ALL THE TIME AND HAS GOTTEN SO BAD I CAN'T WEAR A BRA. I HAVE GAINED 60 POUNDS AND I LOOK LIKE IM SIX-NINE MONTHS PREGNANT. NO AMOUNT OF EXERCISE HAS RELIEVED IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035986	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 9/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BECAME PREGNANT AFTER HAVING THE ESSURE PROCEDURE. ALONG WITH HEAVIER PERIODS SEVERE CRAMPS WITH MY MENSTRUAL AS WELL AS SHARP PAINS IN MY ABDOMEN WHERE MY TUBES ARE AT. I HAVE HAD SEVERE HEADACHES AND LOWER BACK PAIN, AND PAIN DURING SEXUAL INTERCOURSE. I HAVE HAD RECURRING BV AND NO EXPLANATION AS TO HOW. I'M IN CHRONIC PAIN ALL THE TIME AND NO ANSWER AS TO WHY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035987	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 12/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PUTTING IT IN WAS A PAINFUL AND I HAD CRAMPING BUT WAS FINE THE SAME DAY. HAD MY PERIOD IN (B)(6) OF 2014, IN (B)(6) I BLED ALL MONTH, THAN IN (B)(6) NOTHING AND IN (B)(6) I SPOTTED FOR A DAY. I AM A HEALTHY PERSON BUT NOW I HAVE HEADACHES ALMOST EVERYDAY, PAINS IN LEFT SIDE INTO BACK, CRAMPS, PINS AND NEEDLES IN MY FOOT AND HAND ON LEFT SIDE. I AM LOOSING MY HAIR AND I AM TIRED ALL THE TIME. I HAVE BAD MOODSWINGS. #MEDWATCHER #MW156229.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035988	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 8/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DOCTOR THAT IMPLANTED MY ESSURE STOPPED TAKING MY INSURANCE ONE WEEK AFTER I GOT IT. I HAD TO GO TO ANOTHER DOCTOR IN THE SAME OFFICE FOR MY 2 WKS AFTER THE PROCEDURE SO THEY COULD MAKE SURE IT WAS PLACED RIGHT THROUGH ULTRASOUND. NEEDLESS TO SAY THAT NEVER HAPPENED. EVER SINCE I GOT THE IMPLANTS I HAVE BEEN HAVING REALLY SEVERE PAIN ON MY LEFT SIDE TO THE POINT WHERE I CAN NOT MOVE, LOWER BACK PAINS, PAINFUL INTERCOURSE, PELVIC PAIN, HEADACHES, FATIGUE, HEAVY PERIODS AND NO SEXUAL URGES. I BROUGHT THIS TO MY DOCTORS ATTENTION AND HE PRESCRIBES ME IBUPROFEN. I INFORMED HIM THAT THE PAIN NEVER GOES AWAY IT IS CONSTANT AND HE DOES NOTHING. #MEDWATCHER #MW156230.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035989	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 7/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PROBLEMS BEGAN SOON AFTER IMPLANTATION WITH ABDOMINAL PAIN. I HAD PAID FOR THE DEVICE MYSELF AND DID NOT THINK THERE WAS A WAY TO REMOVE THEM, SO I LEARNED TO DEAL WITH THE PAIN. THE SEVERITY OF MY ABDOMINAL PAIN HAS FLUCTUATED OVER THE YEARS WITH THE LAST SIX MONTHS BECOMING QUITE SEVERE. ALONG THE WAY, I HAD BOUTS OF EXTREME FATIGUE WHICH MY DOCTOR COULD FIND NO CAUSE. THE LAST TWO YEARS MY SYMPTOMS HAVE BECOME WORSE. AS I STATED BEFORE, MY ABDOMINAL PAIN HAS GOTTEN WORSE. I HAVE ALSO EXPERIENCED SIGNS OF PERI-MENOPAUSE EVEN THOUGH MY DOCTORS TELL ME I AM TOO YOUNG FOR THAT. I BREAK OUT IN HIVES FROM TIME TO TIME, SEEMINGLY FOR NO REASON. I ALSO HAVE BOWEL ISSUES AND SEVERE ABDOMINAL BLOATING. I THINK MY MOST DEVASTATING SYMPTOM HAS BEEN CHRONIC JOINT PAIN WHICH HAS KEPT ME FROM DOING THINGS I LOVE, LIKE KNITTING. AS WITH MANY OF THE VICTIMS OF THIS DEVICE, IT DIDN'T OCCUR TO ME THAT MY PROBLEMS COULD BE CAUSED BY ESSURE. WHEN MY ABDOMINAL PAIN BECAME WORSE, I DID SOME RESEARCH TO SEE IF IT COULD BE ESSURE. I WAS AMAZED (AND RELIEVED) TO FINALLY HAVE ANSWERS. NOT ONLY COULD MY ABDOMINAL PAIN BE CAUSED BY THIS DEVICE, BUT ALL MY SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035990	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 4/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL FELL OUT AND ENDED UP COMING ALL THE WAY OUT AND CAUSED BLEEDING FOR TWO PLUS WEEKS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035991	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN THE TIME THAT I HAVE HAD THE ESSURE DEVICE I HAVE HAD PELVIC PAIN, ABDOMINAL PAIN, THAT ARE VERY SEVERE. I HAVE HAD SEVERELY PAINFUL HEADACHES, SEVERE FATIGUE, ABDOMINAL SWELLING, PERIOD LASTING FOUR MONTHS, NAUSEA AND THINNING HAIR. THE FEELING OF SOMETHING STABBING ME IN MY LOWER LEFT SIDE ALSO. I WANT THE ESSURE REMOVED BUT MY DOCTOR DENIES THAT THIS CAN BE DONE. I KNOW THAT IT CAN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035992	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 10/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STABBING CONTRACTION CONSTANT PAIN IN PELVIC AREA AND LOWER BACK, MEMORY FOG, CONSTANT HIGH PITCHED RINGING IN BOTH EARS, NEUROLOGICAL PROBLEMS - PERIPHERAL NEUROPATHY, INABILITY TO TYPE, NUMBNESS IN LEGS, MULTIPLE FALLS, RADICULOPATHY, FIBROMYALGIA, ACUTE HYPONATREMIA ON SEVERAL OCCASIONS INCLUDING SEVERAL OVERNIGHT STAYS IN HOSPITAL, HYPOMAGNESEMIA, ADENOMYOSIS, HYPOKALEMIA, INTRAPERITONEAL ABCESS, PELVIC ABCESS, RECTOCELE, POSTMENOPAUSAL ATROPHIC VAGINITIS, INCONTINENCE WITHOUT SENSORY AWARENESS, INTRINSIC SPHINCTER DEFICIENCY, MIXED INCONTINENCE URGE AND STRESS, OTHER CHRONIC CYSTITIS, MULTIPLE UTI'S, SLOWING URINARY STREAM, URINARY URGENCY, VOIDING DIFFICULTIES, RETENTION OF URINE, PELVIC MASS, GRANULATION OF TISSUE IN VAGINAL VAULT, FEMALE STRESS INCONTINENCE, DEPRESSION, GAD, PTSD, PLANTAR FASCIITIS, EXCESSIVE THIRST, HIGH BLOOD PRESSURE, SEVERAL HOSPITALIZATIONS WHILE ESSURE WAS IN PLACE, PROBLEMATIC HYSTERECTOMY REQUIRING BLOOD TRANSFUSION - 4 UNITS - DEVELOPMENT OF 3 HEMATOMAS IN THE PELVIC AREA RESULTING IN A DRAIN INSERTED THRU THE VAGINAL WALL THRU SURGERY FOR 2 WEEKS TO DRAIN, PAIN MANAGEMENT FIRST SET OF CORTISONE INJECTIONS, RISING AST LEVEL, FORGETFULNESS, TROUBLE WITH WORD RECALL, 30% LOSS OF HEARING IN BOTH EARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035993	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 2/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RASH AROUND MY NECK AND ON MY CHEST. MY CRAMPS GOT WORSE. SEE AND I GOT PREGNANT WITH ESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035994	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 10/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

EXCRUCIATING PAIN ON THE RIGHT SIDE OF MY LOWER ABDOMEN. (B)(4). UPDATE ON (B)(6) 2014: THIS PAIN IS OFF AND ON ALL OF THE TIME NOW. WHEN IT STARTED IT WAS ACUTE FOR OVER TWO MONTHS. I WENT TO MY DR TO URGENT CARE AND THE HOSPITAL AND HAD NUMEROUS TESTS RUN. EVERYTHING CAME BACK NEGATIVE. I'M STILL IN PAIN, ALTHOUGH NOT ACUTE ANY LONGER. I HAVE NEVER HAD PAIN LIKE THIS BEFORE AND I AM CERTAIN IT IS RELATED TO THE ESSURE COIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035995	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAINFUL, HEAVY CLOTTING PERIODS, RINGING IN EARS, DEPRESSION AND ANXIETY, LOW BACK PAIN, FATIGUE, PAINFUL SEX, PELVIC PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035996	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 8/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME PAIN, EXTREME CRAMPING AND BLEEDING. HAD A ABLATION DONE AND STILL HAVING THE PROBLEM. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035997	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 6/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2006, I STARTED HAVING A RASH ON MY ARMS AND THEN I STARTED HAVING SEVERE MENSTRUAL CRAMPS. I ALSO STARTED HAVING SEVERE INTESTINAL CRAMPS, THAT WOULD CAUSE MY FACE AND EYES TO TURN BLOOD RED. THIS USUALLY CAME AROUND TIME FOR MY MONTHLY CYCLE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035998	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 3/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SHARP STABBING PAIN IN MY UTERUS. HEAVY MENSTRUAL PERIODS. SEVERE CRAMPS. WEIGHT GAIN. HIGH BLOOD PRESSURE. LOWER BACK PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5035999	BAYER	5/12/2014	5/12/2014

Event Information:

Event Date (B3): 2/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GOING TO MY PCP, DERMATOLOGIST, OB/GYN AND AN ALLERGIST, IT WAS DETERMINED I HAD AN ALLERGIC REACTION TO THE NICKEL, IN THE ESSURE THAT INCLUDED HIVES, EXHAUSTION, WEIGHT GAIN, BLOATING, PELVIC PAIN AND HEAVY BLEEDING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036102		5/12/2014	5/19/2014

Event Information:

Event Date (B3): 5/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2014 AT THE IMAGING CENTER. ON (B)(6) 2014, I FOUND OUT I HAVE A ESSURE IMPLANT DISLODGED AFTER 5 YEARS IMPLANT WAS DONE ON (B)(6) 2009 NOW NOT SURE WHAT WILL HAPPEN. HAVE TO SEE A OB-GYN. WENT AND RESEARCHED ONLINE AND LOOKS LIKE I'LL BE DOING A HYSTERECTOMY BECAUSE OF THIS. VERY UPSET WAS NOT TOLD THIS COULD HAPPEN. MEANWHILE OVER THE PAST YEARS I'VE HAD ALL KINDS OF HEALTH ISSUES NOT SURE IF IT RELATED. I GET VERY BAD CRAMPS AND HAVE OVER THE PAST FEW YEARS. ON (B)(6) 2014, I STARTED BLEEDING. AFTER THE ESSURE IMPLANT I STOP BLEEDING. IT'S BEEN 5 YEARS SO WHEN I STARTED TO BLEED I WENT TO THE DOCTOR THE TESTING STARTED ONLY TO FIND OUT IT'S DISLODGED. (B)(6) 2014 - VAGINAL ULTRASOUND/PELVIC ULTRASOUND.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036110	ESSURE	5/12/2014	5/19/2014

Event Information:

Event Date (B3): 12/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/5/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

UTERINE D AND C AND ABLATION TO HELP RESOLVE PROBLEMS CAUSED BY ESSURE SURGICALLY DIAGNOSED WITH ENDOMETRIOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00149	BAYER HEALTHCARE LLC	5/12/2014	6/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT REC'D FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED COILS STRETCHED AND BROKE OFF, FAILED INSERTION, AND ESSURE DID NOT RELEASE. NO INFO GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION REC'D. ON AN UNSPECIFIED DATE THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN HAD A FAILED ESSURE PROCEDURE. AGAIN THE ESSURE DID NOT RELEASED AND SHE PULLED IT DUE TO WHICH THE COILS WERE STRETCHED AND BROKE OFF. PHYSICIAN REMOVED THE REMAINING COILS WITH A TANG, BUT SHE WAS NOT SURE SHE REMOVED THEM ALL. THE PATIENT WOULD COME BACK FOR REPLACEMENT. NO FURTHER INFO WAS PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00152	BAYER HEALTHCARE LLC	5/14/2014	5/22/2014

Event Information:

Event Date (B3): 4/8/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B26271

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT REC'D FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A (B)(6) OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MIGRATION OF ONE DEVICE IN THE ABDOMINAL CAVITY AND PART OF THE SPRING WAS MISSING ON THIS EXPLANTED DEVICE. NO INFO WAS GIVEN ON THE PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2013 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED; THE LOT NUMBER B26271 WAS PROVIDED. SHE PRESENTED WITH ABDOMINAL PAIN AND ON (B)(6) 2014, THE RIGHT DEVICE WAS FOUND TO HAVE MIGRATED INTO THE ABDOMINAL CAVITY (IT WAS PLACED ON THE SIGMOID OPPOSITE TO THE UTERUS - A RISK OF RECTUM PERFORATION WAS REPORTED BY THE SURGEON). BOTH DEVICES WERE REMOVED, THE ABDOMINAL CAVITY WAS EXTENSIVELY WASHED AND A BILATERAL SALPINGECTOMY WAS PERFORMED. THE SURGEON NOTICED THAT THERE WAS A PART OF THE COIL MISSING IN THE EXPLANTED DEVICE. THERE WERE NO CLINICAL CONSEQUENCES TO THE PATIENT AND SHE HAD NO COMPLICATIONS POSTOPERATIVELY. THE REPORTER'S CAUSALITY WAS NOT PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00153	BAYER HEALTHCARE LLC	5/14/2014	5/22/2014

Event Information:

Event Date (B3): 4/7/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50750351

Single Use: Y
Implant Date (E6): 4/7/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CAE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND IT WAS IMPOSSIBLE TO RELEASE THE DEVICE: BROKEN CATHETER AND IMPOSSIBLE WITHDRAWAL AND THE DELIVERY WAS NOT BILATERAL. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PT HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION, LOT NUMBER 50750351. THE REPORTER STATED THAT, ALTHOUGH CONDITIONS OF THE PLACEMENT WERE EXCELLENT, DURING DEVICE PLACEMENT THE COILS DEVICE WAS NOT RELEASED AND IT WAS IMPOSSIBLE TO REMOVE THE CATHETER (BROKEN CATHETER AND IMPOSSIBLE WITHDRAWAL). THE DELIVERY WAS NOT BILATERAL AND A CELIOSCOPY TO REMOVE DEVICE WAS REQUIRED. THE DEVICE WAS KEPT IN THE HOSPITAL. THE CRITERION OF SERIOUSNESS WAS BY THE REPORTER AS A SERIOUS RISK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00154	BAYER HEALTHCARE	5/14/2014	5/22/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INVALID DATA	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B 42 240

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE DELIVERY CATHETER CAME OUT AND WAS TWISTED AT THE EXTREMITY, PLASTIC ELEMENT FOUND IN THE UTERINE CAVITY, AND FEELING OF BLOCKAGE IN OPERATOR CANAL WHEN THE SECOND ESSURE SYSTEM WAS INSERTED ON THE RIGHT SIDE. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B 42 240. INSERTION OF ESSURE SYSTEM ON THE LEFT SIDE WAS SATISFACTORY. DURING THE SECOND MICRO-INSERT INSERTION THERE WAS A FEELING OF BLOCKAGE IN OPERATOR CANAL ON THE RIGHT SIDE. IN THE UTERINE CAVITY, THE DELIVERY CATHETER CAME OUT AND WAS TWISTED AT THE EXTREMITY. ESSURE SYSTEM WAS RELEASED. PLASTIC ELEMENT WAS SEEN IN THE UTERINE CAVITY AND WAS LATER REMOVED AT THE END OF THE PROCEDURE. A THIRD ESSURE SYSTEM WAS INSERTED ON THE RIGHT SIDE; GOOD TUBAL INSERTION AND THEN WHEN ESSURE WAS RELEASED NO COIL DEVELOPMENT, THE DEVICE COMPLETELY CAME OUT OF THE FALLOPIAN TUBE. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS NOT REPORTED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014 FROM PHARMACIST: THE PATIENT WAS FINE BUT THE REPORTER DID NOT HAVE FURTHER INFORMATION BECAUSE HE DID NOT PLACE MIRENA. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00150	BAYER HEALTHCARE LLC	5/14/2014	6/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B60754

Single Use: Y
Implant Date (E6): 12/20/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN UNITED STATES ON (B)(6) 2014 REFERRING TO HERSELF. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN ON LEFT SIDE EVERYDAY, BLEEDING, HAVE HAD 4 PERIOD SINCE IMPLANTATION, SEVERE HEADACHES ON A DAILY BASIS, AND NAUSEA. NO INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT DRUGS AND CONCURRENT CONDITIONS. ON (B)(6) 2014 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH LOT NUMBER B60754. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED BLEEDING, SEVERE PAIN ON LEFT SIDE EVERYDAY, HAVE HAD 4 PERIODS SINCE IMPLANTATION, SEVERE HEADACHES ON A DAILY BASIS, WHICH REQUIRED UNSPECIFIED PRESCRIPTIONS AND NAUSEA SINCE INSERTION. SHE HAS NEVER HAD EVENTS LIKE THESE BEFORE. IT WAS NOT REPORTED IF ESSURE WAS REMOVED AFTER EVENTS. CONSUMER'S OUTCOME WAS NOT REPORTED. NO ASSESSMENT WAS GIVEN.

Manufacturer Narrative (H10):

FOLLOW-UP INFO WAS RECEIVED ON (B)(4) 2014: CASE UPGRADED TO INCIDENT. SHE HAS NO RELEVANT MED HISTORY. AN ULTRASOUND WAS DONE WITHIN 3 WEEKS OF ESSURE IMPLANTATION UP UNTIL HYSTERECTOMY WHICH SHOWED CORRECT PLACEMENT. X-RAY WAS INCONCLUSIVE, DIAGNOSTIC L

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00151	BAYER HEALTHCARE LLC	5/14/2014	6/17/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INVALID DATA	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/5/2008
Explant Date (E7): 6/22/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT REC'D ON (B)(6) 2014 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (B)(4) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PERIODS WERE GETTING HEAVIER AND HEAVIER, PHYSICALLY EXHAUSTED, AND EMOTIONALLY STRESSING. NO INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2008 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER STATED THAT IN 2010 HER PERIODS WERE BECOMING COMPLETELY UNMANAGEABLE; EVERY MONTH THEY WERE GETTING HEAVIER AND HEAVIER CAUSING HER TO BE PHYSICALLY EXHAUSTED, EMOTIONALLY STRESSED AND ISOLATING HER TO HER BATHROOM FOR DAYS ON END. DUE TO THE EVENT SHE WOULD MISS WORK AND IT SEVERELY IMPACTED HER LIFE. IN 2011, CONSUMER WAS GIVEN MEDICATION TO CONTROL THE BLEEDING AND IN THE SAME YEAR SHE UNDERWENT A HYSTERECTOMY. ESSURE MICRO-INSERT WAS REMOVED ON (B)(6) 2011. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS NOT REPORTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036144	BAYER	5/15/2014	5/21/2014

Event Information:

Event Date (B3): 2/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/12/2014
Explant Date (E7): 3/7/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS WERE PLACED IN (B)(6) 2014 WITHOUT MY CONSENT. DOCTOR WAS SUPPOSED TO DO A TRADITIONAL TUBAL, AND I WOKE UP WITH COILS. AFTER TALKING TO HIM REGARDING THE REMOVAL, I WAS UNHAPPY WITH HIS APPROACH AND FOUND ANOTHER DOCTOR THAT WOULD REMOVE THE COILS A SAFE WAY. FROM THE MOMENT I WOKE UP FROM PLACEMENT, I HAD A MIGRAINE, BLOATING, CRAMPING, BLEEDING, DEPRESSION, HAIR LOSS, AND 2 WEEKS MY LEFT LEG FROM THE HIP TO ANKLE ACHED. AFTER REMOVAL, ALL THE SYMPTOMS DISAPPEARED EXCEPT MY HAIR LOSS. REMOVAL WAS DONE ON (B)(6) 2014. I HAD MY TUBES AND COILS REMOVED VIA DAVINCI.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036155	BAYER	5/15/2014	5/21/2014

Event Information:

Event Date (B3): 11/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/25/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE DEVICE PLACED, I STARTED HAVING SEVERE HEADACHES. OTHER SYMPTOMS WERE DIZZINESS, VISUAL DISTURBANCES TO WHERE I WAS SEEING BLACK SPOTS, FEELING FAINT AND A FOGGY HEAD. THEN I STARTED HAVING WEAKNESS AND HAVING TROUBLE REMEMBERING WHAT I HAD DONE. I CURRENTLY HAVE AN 11 MONTH OLD AND FIXED A BOTTLE TWICE. I WENT AND HAD SOME TESTS DONE AND REPORTS SHOWED THAT AI ONLY HAD 2% OF MY SHORT TERM MEMORY LEFT. I HAVE ALSO HAD HEAVY METAL TESTS DONE THAT REVEALED LOW LEVELS OF ARSENIC IN MY BLOOD AS WELL AS LOW POTASSIUM LEVELS AND VITAMIN B12 LEVELS WERE SO LOW THAT I AM NOW TAKING SHOTS TO GET MY LEVEL BACK UP. I WAS NEVER TOLD THAT THE DEVICE HAD NICKEL IN THE DEVICE AND I HAVE NEVER BEEN ABLE TO WEAR NICKEL EARRINGS DUE TO AN ALLERGY TO IT. I HAVE ALSO HAD ABDOMINAL CRAMPING, HEAVY BLEEDING FOR WEEKS AFTER IT WAS PLACED. ALSO, I HAVE HAD LOW GRADE FEVERS EVER SINCE I HAVE HAD THIS DEVICE PLACED INSIDE OF ME. I HAVE HAD A PSYCHOANALYSIS TEST PERFORMED ALONG WITH MRI'S, CAT SCANS AND EEG TESTING. THE PSYCHOANALYSIS THAT WAS PERFORMED ALSO SHOWED THAT MY THINKING LEVEL IS AT A SIXTH TO EIGHTH GRADE LEVEL. I AM CURRENTLY A NURSE AND UNABLE TO WORK AT THIS TIME. I WAS ALWAYS AN A/B STUDENT AND MADE THE DEAN'S LIST IN SCHOOL. THE ANALYSIS REVEALED THAT I HAD TOXIC ENCEPHALOPATHY WHICH COULD POSSIBLY BE COMING FROM A FOREIGN OBJECT IN MY BODY. MY OB-GYN TOLD ME THAT THESE SYMPTOMS COULD NOT BE COMING FROM THE ESSURE PRODUCT, BUT I WAS A COMPLETELY HEALTHY NORMAL PERSON PRIOR TO ITS PLACEMENT. I HAVE READ OTHER'S STORIES THAT HAVE HAD THIS DEVICE PLACED AND HAVE NUMEROUS SYMPTOMS AS THEY DID.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE, LLC.	5/16/2014	5/20/2014

Event Information:

Event Date (B3): 5/5/2014 **Report Date (B4): 5/16/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): B26272

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE WAS INSERTED THROUGH THE OPERATING CHANNEL OF THE HYSTEROSCOPE. THE LEFT OSTIA WAS VISUALIZED AND BASED ON MANUFACTURER RECOMMENDATIONS, THE DEVICE WAS DEPLOYED. IN A SIMILAR FASHION, THE RIGHT OSTIA WAS VISUALIZED AND BASED ON MANUFACTURER RECOMMENDATIONS, THE DEVICE WAS DEPLOYED. THE DEVICE DID NOT DEPLOY AS EXPECTED; HOWEVER THE COILS INSERTED WERE WITHIN THE NORMAL PARAMETERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036177	BAYER	5/16/2014	5/23/2014

Event Information:

Event Date (B3): 9/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/7/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2009. SINCE THEN I HAVE HAD SERIOUS HEALTH PROBLEMS. I HAD GAINED 80LBS IN TWO WEEKS AFTER THE INSERTION OF THE DEVICE. I ALSO DEVELOPED SUGAR PROBLEMS WHICH WERE NOT EVIDENT BEFORE THE DEVICE WAS IMPLANTED. I ALSO HAD 2 YEARS OF CONTINUOUS BLEEDING FOLLOWED BY 2 YEARS OF NO PERIOD AND THEN FINALLY GOT MY PERIOD ONLY TO HAVE IT LAST 10 DAYS AND BE HEAVY AND PAINFUL. I ALSO SUFFER FROM JOINT AND MUSCLE PAIN. I HAVE A TREMENDOUS AMOUNT OF EXTRA HAIR GROWTH. I ALSO HAVE PAIN IN MY ABDOMEN AND FREQUENTLY FEEL A STABBING PAIN WHEN I STAND UP TOO QUICK. I NOW SUFFER FROM SLEEP APNEA WHICH WAS NEVER A PROBLEM BEFORE. I HAVE BOUTS OF DEPRESSION AND ANXIETY. ALL OF THIS HAPPENED SHORTLY AFTER THE DEVICE WAS IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036182	BAYER	5/16/2014	5/23/2014

Event Information:

Event Date (B3): 6/26/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/26/2009
Explant Date (E7): 8/31/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS TOLD THAT ESSURE WAS THE BEST ROUTE TO GO FOR PREVENTION OF PREGNANCY. NEVER KNEW I COULDN'T GET THEM TAKEN OUT AND PLAN ANOTHER PREGNANCY DOWN THE ROAD. AFTER THE IMPLANT OF ESSURE ((B)(6) 2009), I STARTED EXPERIENCING ENORMOUS AMOUNTS OF INFLAMMATION, WHICH CAUSED EXTREME PAIN. I COMPLAINED TO MY GYNO ABOUT THIS NUMEROUS TIMES, SHE PUT ME ON NON-INFLAMMATORY. THE PAIN CONTINUED THE WHOLE TIME I HAD THESE COILS IN ME. THEN, I STARTED HAVING HUGE CYSTS ON MY OVARIES, WHICH I HAD ULTRASOUNDS FOR. ALSO WENT TO THE EMERGENCY ROOM FOR THE EXTREME PAIN OF A CYST ON MY OVARY. FINALLY, ON (B)(6) 2011 I WENT UNDER SURGERY TO GET THEM REMOVED. LITTLE DID I KNOW UNTIL A FEW MINUTES BEFORE SURGERY, THEY ARE TAKING MY WHOLE TUBE OUT. THUS, PREVENTING ME FROM EVER BEING ABLE TO BE A MOTHER TO ANOTHER CHILD AGAIN, CRUSHING MY DREAMS AND HOPES, AND LEFT ME FEELING LESS OF A WOMAN. NOTE THAT I NEVER HAD ANY OF THESE PROBLEMS BEFORE HAVING ESSURE. SINCE ESSURE WAS INTRODUCED INTO MY LIFE, I WAS DIAGNOSED WITH FIBROMYALGIA AND I HAVE BEEN DEALING WITH (B)(6) AND LEEP PROCEDURES SINCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036183	BAYER	5/16/2014	5/23/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/17/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FIVE MONTHS AFTER HAVING ESSURE PLACED I DEVELOPED FIBROMYALGIA. CHRONIC PAIN DAILY, AND INSOMNIA. ALMOST A YEAR AFTER I AM NOW DIAGNOSED WITH REYNOLDS SYNDROME. ALSO SUFFER FROM VITAMIN DEFICIENCY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036190	CONCEPTUS, INC.	5/19/2014	5/27/2014

Event Information:

Event Date (B3): 9/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/25/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE LEFT PROCEDURE FAILED AND NOW THERE IS NO TRACE OF ENSURE COIL WHAT SO EVER. WAS TOLD BY DR (B)(6) OB/GYN OF (B)(6), THAT HE WOULD HAVE TO GET IN CONTACT WITH MFR FOR A REPLACEMENT. THE DEVICE ON THE OTHER HAND HAS ATTACHED ITSELF TO MY UTERUS WALL AND NOW I AM EXPERIENCING SEVERE ABDOMINAL PAINS. I AM CURRENTLY BEING TOLD THAT AN AUTHORIZATION IS IN PROCESS FOR A REPLACEMENT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00156	BAYER HEALTHCARE LLC	5/19/2014	6/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT REC'D FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE DISCOMFORT, FATIGUE, GENERALLY FEELING AWFUL, DEBILITATING CONDITIONS, BACK, JOINT AND PELVIC PAIN, BLEEDING, EXTREME LETHARGY, HEADACHES, MENSTRUAL IRREGULARITIES, AND WEIGHT FLUCTUATION. NO INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER REC'D AMU CONCOMITANT MEDICATION. IN (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON AN UNSPECIFIED DATE THE CONSUMER WAS SUFFERING FROM DEBILITATING CONDITIONS ON ESSURE. THE TROUBLES REPORTED BY HER AND OTHER PATIENTS (UNSPECIFIED) INCLUDES BACK, JOINT AND PELVIC PAIN, BLEEDING, EXTREME LETHARGY, HEADACHES, MENSTRUAL IRREGULARITIES, AND WEIGHT FLUCTUATION. SHE ALSO EXPERIENCED SEVERE DISCOMFORT, FATIGUE AND IS GENERALLY FEELING AWFUL. CONSUMER UNDERWENT A SURGICAL REMOVAL OF HER FALLOPIAN TUBES, UTERUS AND CERVIX. REPORT CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE IS NOT REPORTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00155	BAYER HEALTHCARE CORP	5/19/2014	6/27/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED HALF OF ESSURE REMOVED. NO INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICA. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER CALLED TO ASK INFO ON WHO WAS QUALIFIED TO REMOVE THE ESSURE BEING THAT SHE HAD HALF OF IT REMOVED. NO FURTHER INFO PROVIDED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN HALF OF ESSURE REMOVED AND ESSURE WAS NOT REPORTED. FOLLOW-UP INFO RECEIVED ON 04/29/2014: DESPITE FOLLOW-UP ATTEMPTS, NO CONTACT WAS OBTAINED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 12-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIG

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036225		5/21/2014	5/28/2014

Event Information:

Event Date (B3): 4/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) 2012. I HAD THE CONFORMATION TEST DONE IN (B)(6) 2013 WHICH SHOWS MY TUBES WERE IN PLACE AND CLOSED. I FOUND OUT I WAS PREGNANT IN (B)(6) 2014. NO COIL WAS FOUND IN MY LEFT TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036264	CONCEPTUS	5/21/2014	5/29/2014

Event Information:

Event Date (B3): 3/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT WITH ESSURE INSERTED 2008, TOLD HER FOLLOW-UP HSG SHOWED BILATERAL TUBAL OCCLUSION. PT HAD PREGNANCY IN 2009, AND AGAIN IN 2014. DATE OF USE: INSERTED 2008, COILS STILL IN. DIAGNOSIS OR REASON FOR USE: PERMANENT CONTRACEPTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036292	BAYER HEALTH	5/21/2014	5/29/2014

Event Information:

Event Date (B3): 5/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 634989

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAVE HAD THE SPRINGS PLACED I HAVE SEEN NUMEROUS DOCTORS ABOUT THIS IMMOBILIZING PAIN IN MY LOWER ABDOMEN, AS WELL AS HAIR LOSS, AND CONSTANT LETHARGY. DOCTORS STATE THAT SINCE THE SPRINGS ARE IN THE PROPER PLACE, I AM EXPERIENCING PHANTOM PAINS. I DO NOT WANT TO BE ON PAIN MEDS FOR THE REST OF MY LIFE BECAUSE OF A PRODUCT/DEVICE THAT WAS NOT PROPERLY RESEARCHED BEFORE BEING FDA APPROVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00157	BAYER HEALTHCARE LLC	5/21/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A73752

Single Use: Y
Implant Date (E6): 3/28/2013
Explant Date (E7): 11/25/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN THE UNITED STATES ON (B)(4) 2014, WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE BLOATING, WEIGHT GAIN, EXTREMELY PAINFUL STABBING PAINS IN UTERUS, HAIR LOSS, DIZZINESS, HEADACHES, MOOD SWINGS, HEAVY UNPREDICTABLE PERIODS AND ONE COIL WAS FURTHER IN MY UTERUS. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2013, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH LOT NUMBER A73752. ON AN UNSPECIFIED DATE, THE PATIENT STATED EXPERIENCING EXCESSIVE BLOATING, WEIGHT GAIN, EXTREMELY PAINFUL STABBING PAINS IN UTERUS (SO BAD THAT SHE WAS UNABLE TO WALK AT TIMES), HAIR LOSS, DIZZINESS, HEADACHES, MOOD SWINGS AND HEAVY UNPREDICTABLE PERIODS. ON (B)(6) 2013, ESSURE WAS REMOVED BY BILATERAL SALPINGECTOMY; REMOVED COILS AND BOTH FALLOPIAN TUBES. HER DOCTOR SAID THAT ONE COIL WAS FURTHER IN HER UTERUS CAUSING THE PAIN. THE OUTCOME OF THE EVENTS WAS RECOVERED / RESOLVED. ACCORDING TO HER, SINCE THE REMOVAL, ALL SYMPTOMS HAVE DISAPPEARED. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS ASSESSED AS RELATED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00158	BAYER HEALTHCARE LLP	5/21/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/28/2011
Explant Date (E7): 3/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING, HUGE BLOOD CLOTS, CRAMPING, SHARP STABBING PAINS TO MY ABDOMEN, BACK PAIN, JOINT PAIN, CHEST PAIN, HEADACHES, NAUSEA AFTER EATING, METALLIC TASTE IN MY MOUTH, DIZZINESS, LEG PAIN, HAIR LOSS, DEPRESSION, B12 DEFICIENCY, TEETH ISSUES, HEART BURN, 11 UTI'S, ANXIETY, BACTERIAL VAGINOSIS (6 TIMES), BOWL ISSUES, HOT FLASHES, BREAST PAIN, SPINE PAIN, VISION IS GETTING WORSE, GUSHING BLOOD DURING SEX, PAIN DURING SEX, ACNE, EYE TWITCHING, ITCHY SCALP, FEELS LIKE A BRUISE ON MY SCALP, CRAWLING SKIN, BUMPS THAT FEEL LIKE MOSQUITO BITES, AND DIAGNOSED WITH ITP. NO INFO WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2011, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON AN UNSPECIFIED DATE THE CONSUMER STARTED EXPERIENCING HEAVY BLEEDING, 11 UTI'S, DIAGNOSED WITH ITP, HUGE BLOOD CLOTS, CRAMPING/SHARP STABBING PAINS IN MY ABDOMEN, BACK PAIN, JOINT PAIN, CHEST PAIN, SEVERE FATIGUE, HEADACHES, NAUSEA AFTER EATING, METALLIC TASTE IN MY MOUTH, DIZZINESS, TINGLING SENSATIONS IN MY LIMBS, NUMBNESS, LEG PAIN, HAIR LOSS, DEPRESSION, B12 DEFICIENCY, TEETH ISSUES, HEART BURN, BRAIN FOG, FORGETFULNESS, INSOMNIA, HEART PALPITATIONS, ANXIETY, PANIC ATTACKS, BACTERIAL VAGINOSIS (6 TIMES, FOUL SMELLING DISCHARGE, MOOD SWINGS, BOWL ISSUES, HOT FLASHES, BREAST PAIN, SPINE PAIN, LOW PLATELET COUNT, SHARP PAIN IN RECTUM, VISION IS GETTING WORSE, GUSHING BLOOD DURING SEX, PAIN DURING SEX, NO SEX DRIVE, ACNE, LOSS OF CONCENTRATION, LOSS OF HOPE, START CRYING FOR NO REASON, EYE TWITCHING, ITCHY SCALP, FEELS LIKE A BRUISE ON MY SCALP, CRAWLING SKIN, BUMPS THAT FEEL LIKE MOSQUITO BITES AND WEAKNESS IN LIMBS.

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SEVERAL TESTS WERE DONE (RESULTS NOT REPORTED). ON (B)(6) 2014, HYSTERECTOMY WAS PERFORMED (ESSURE AND FALLOPIAN TUBES WERE REMOVED). THE OUTCOME OF THE EVENTS WAS UNK. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS NOT REPORTED. F/U ON (B)(6) 2014: NO F/U INFO WAS RECEIVED FROM CONSUMER UP TO DATE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00159	BAYER HEALTHCARE LLC	5/21/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 663256

Single Use: Y
Implant Date (E6): 4/23/2010
Explant Date (E7): 1/23/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE #MW5035296) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVIER MENSTRUAL CYCLES, CRAMPING, FATIGUE, MOOD SWINGS WITH ANGER, LOSS OF MEMORY, FOGGINESS, JOINT PAIN, DIZZINESS, MIGRAINE HEADACHES, METAL TASTE IN MOUTH, NUMBNESS IN EXTREMITIES, WEIGHT GAIN, CHEST PAIN, FACE NUMBNESS, PAIN, MASS IN MY UTERUS, AND INFECTION IN UTERUS. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2010, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER 663256 (EXPIRATION DATE 10/10/2011) FOR BIRTH CONTROL. NOT LONG AFTER THE INSERTION, THE HEALTH OF PT STARTED TO DECLINE. SHE STARTED EXPERIENCING HEAVIER MENSTRUAL CYCLES, CRAMPING, FATIGUE, MOOD SWINGS WITH ANGER, LOSS OF MEMORY AND FOGGINESS, JOINT PAIN, DIZZINESS, MIGRAINE HEADACHES, METAL TASTE IN MOUTH, NUMBNESS TO EXTREMITIES AND WEIGHT GAIN THAT WOULD NOT GO AWAY WITH CHANGE OF DIET AND EXERCISE. IN 2011, SHE WAS HOSPITALIZED FOR CHEST PAIN AND FACE NUMBNESS. ALL TESTS CAME BACK NORMAL. IN 2012, THE PAIN BECAME TOO MUCH TO HANDLE. AFTER AN ULTRASOUND AND A PAP SMEAR, IT WAS DETERMINED SHE HAD A MASS AND AN INFECTION IN THE UTERUS. IN 2013, SHE HAD A PARTIAL HYSTERECTOMY, LEAVING ONLY HER OVARIES, AND REMOVING THE ESSURE DEVICE. ALMOST IMMEDIATELY HER HEALTH ISSUES STARTED TO DISAPPEAR. SHE HAS NO MORE HEADACHES, NO MORE PAINS, NO MORE FOGGINESS OR DIZZINESS, ENERGY LEVEL IS UP AND WEIGHT IS DOWN. THERE IS STILL SLIGHT NUMBNESS IN THE FACE THAT COMES AND GOES, BUT IT

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IS NO LONGER CONSTANT. MOOD SWINGS ARE GONE AND THE ANGER HAS SUBSIDED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS ESSURE IS NOT REPORTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00160	BAYER HEALTHCARE LLC	5/21/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 787224

Single Use: Y
Implant Date (E6): 12/15/2010
Explant Date (E7): 4/14/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT REC'D FROM A ADULT FEMALE CONSUMER IN UNITED STATES ON (B)(4) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING, BLOATING, PELVIS PAIN, HAIR LOSS, METALLIC TASTE IN MY MOUTH, AND LEFT LEG NUMBNESS. FOLLOW-UPS REC'D ON (B)(4) 2014 (ALSO VIA COMPANY INTERNET SITE), (B)(4) 2014 (PHONE) AND (B)(4) 2014 (QUESTIONNAIRE ANSWERED BY CONSUMER). THE NON-PREGNANT CONSUMER (AT TIME OF REPORTING (B)(6) OLD). CONSUMER WAS GRAVIDA II, PARA II, NO ABORTIONS, STILLBIRTHS. SHE REPORTED SHE HAS NO RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITION, OTHER THAN GETTING HER GALL BLADDER OUT AFTER SECOND BABY, SHE WAS COMPLETELY HEALTHY, USED TO RUN, NEVER RAN IN FOUR YRS AT TIME OF REPORTING. ON (B)(6) 2010, CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 787224, INSERTED FOR STERILIZATION. MODEL NUMBER WAS ESS305, ESS205, SHE HAS BOTH LISTED. ESSURE WAS INSERTED SIX WEEKS AFTER LAST DELIVERY. CONSUMER HAD NO SEX BETWEEN INSERTION AND HSG (HYSTEROSALPINGOGRAM) CONFIRMATION TEST. HSG TEST WAS NOT DONE BECAUSE HER INSURANCE RAN OUT. ON (B)(6) 2010, ON DAY OF INSERTION, EVENTS STARTED. CONSUMER REPORTED SHE HAS HAD PAIN FOR THE LAST THREE AND ONE-HALF YRS AND SHE WAS TOLD TO CONSIDER HAVING A HYSTERECTOMY. CONSUMER SAID SHE HAS TWO INSERTS ON THE RIGHT SIDE AND ONE INSERT ON THE LEFT SIDE. THE LEFT COIL TWISTED UP, RIGHT COIL WAS IN UTERUS, SHE EXPERIENCED MEMORY LOSS, HIP PAIN, LEG PAIN, ABDOMINAL PAIN, SOMETIMES SHE CANNOT GET OUT OF BED. ALL SYMPTOMS ARE GOING ON EVERY DAY. SHE HAS SEEN DOCTOR CONCERNING THESE SYMPTOMS. DIAGNOSIS WAS REPORTED AS 'ESSURE CAUSING ALL PROBLEMS.' THE ONLY WAY TO TREAT IT IS TO TAKE ESSURE OUT. SHE HAD BEEN TO ER (EMERGENCY ROOM) FOR ABDOMINAL PAIN, DOES NOT REMEMBER IF SHE WAS ADMITTED OR NOT. ON (B)(6) 2014, CONSUMER FOUND OUT THAT ESSURE

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WAS IN AN INCORRECT POSITION. SHE HAD TO REQUEST AN X-RAY. LEFT COIL TWISTED UP, RIGHT COIL IN UTERUS. CONSUMER GOT THE X-RAY RESULT AND HAS NOT SEEN THE DOCTOR. CONSUMER CONSIDERED ESSURE CAUSED THE CONDITION 100 PER CENT. IT CAUSED THE HIP PAIN, LEG PAIN, ABDOMINAL PAIN, METALLIC TASTE IN MOUTH AND IT HAS CAUSED EVERYTHING. ESSURE IS SLOWLY KILLING ALL, SHE HAS TO PAY TO HAVE IT TAKEN OUT. F/U (B)(4) 2014: F/U INFO REC'D FROM THE CONSUMER. ESSURE REMOVAL WAS DONE ON (B)(6) 2014. THIS REMOVAL WAS MEDICALLY NECESSARY AND ALSO A REQUEST FROM CONSUMER BECAUSE OF ALL THE PROBLEMS SHE HAD WITH IT. SHE REALLY WANTED IT REMOVED BUT HER INSURANCE DID NOT PAY FOR IT. SHE HAD OVER (B)(6) DOLLARS IN BILLS FOR THIS. CONSUMER REPORTED THAT AN X-RAY WAS DONE BEFORE HER HYSTERECTOMY (NOT SURE OF THE DATE) AND IT SHOWED THE ESSURE COILS WERE NOT IN THE TUBES. DAVINCI LAPAROSCOPIC WAS PERFORMED TO REMOVE CONSUMER'S UTERUS, TUBES AND CERVIX. CONSUMER REPORTED THAT SHE HAS NOT SEEN ANY PATHOLOGY RESULTS AND SHE DID NOT KNOW IF THERE WERE SIGNS AND SYMPTOMS OF INFECTION LIKE REDNESS, INFLAMMATION ETC. DURING SURGERY, THE RIGHT ESSURE WAS FOUND PERFORATING HER UTERUS. THE LEFT WAS BUNCHED UP BESIDE HER OVARY. CONSUMER THOUGHT IT WAS BROKEN IN PIECES THERE. HER OVARIES WERE SWOLLEN AND HEAVY. THEY HAD TO BE SUTURED TO THE WALLS OF HER ABDOMEN TO KEEP THEM IN PLACE. SHE HAS BEEN IN AND OUT OF THE HOSPITAL WITH ALLERGIES TO MEDICATIONS. CONSUMER STATED THAT SHE WAS FEELING BETTER BUT IT WAS ONLY A WEEK AGO. SHE HAD SUTURES INSIDE THAT WERE DISSOLVABLE AND WAS BONDED WITH GLUE ON THE OUTSIDE. THE SWELLING IN HER ABDOMEN HAS GONE DOWN. HER BONES AND JOINTS WERE NOT PAINFUL ANYMORE. HER LEFT HIP AND LEG WERE FINE, HAIR LOSS WAS LESS. THE METAL TASTE WAS GONE FROM HER MOUTH AS SOON AS SHE WOKE UP FROM SURGERY. CONSUMER CONSIDERED THAT ESSURE IT CAUSED ALL THE PROBLEMS SHE HAD AND SHE WOULD NEVER RECOMMEND IT TO ANYONE. IT SHOULD BE PULLED FROM THE MARKET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00161	BAYER HEALTHCARE LLC	5/21/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/11/2014
Explant Date (E7): 3/26/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN THE UNITED STATES ON (B)(6)2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED DIFFICULTY BREATHING. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATIONS. ON (B)(6) 2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AT UNK IMPLANTED FOR CONTRACEPTION. IN (B)(6) 2014 THE PATIENT WAS ADMITTED TO THE HOSPITAL WITH COMPLAINTS OF DIFFICULTY BREATHING. AT THE TIME OF THIS REPORT SHE WAS STILL IN THE HOSPITAL. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN DIFFICULTY BREATHING AND ESSURE IS NOT REPORTED. FOLLOW-UP ON (B)(6) 2014, PHYSICIAN RESPONDED TO FOLLOW-UP CALL. THEY STATED PATIENT'S INITIALS WERE WRONG, CORRECT INITIALS ARE (B)(6). REPORTER STATED AS FAR AS HE REMEMBERS PATIENT HAS TO CONCURRENT CONDITIONS NOR RECEIVED ANY CONCURRENT MEDICATION. ON (B)(6) 2014, PATIENT HAD ESSURE INSERTED. SHE HAD SOME THROAT SWELLING. PATIENT WENT TO THE ER (EMERGENCY ROOM) IN A HOSPITAL WHERE REPORTING PHYSICIAN IS NOT A STAFF MEMBER. PATIENT GOT ADMITTED IN THE HOSPITAL FOR A POSSIBLE ALLERGIC REACTION TO ESSURE. SHE HAD SOME DIFFICULTY BREATHING, SHORTNESS OF BREATH, POOR DENTITION. SHE WAS TREATED WITH EPINEPHRINE INJECTIONS, STEROIDS FOR SWELLING OF FACE. SHE HAD OTHER SCANS DONE AND IN HOSPITAL SHOWED NO ISSUE AND CAME BACK NEGATIVE FOR ABSCESS. REPORTER DOES NOT HAVE THOSE RESULTS. PATIENT WENT BACK TO REPORTER FOR FOLLOW-UP AND WAS STILL HAVING VAGINAL BLEEDING AND FOUND TO BE HAVING A FIBROID. SHE MAY OR MAY NOT BE HAVING A NICKEL WITH BILATERAL SALPINGECTOMY ALONG WITH ESSURE REMOVAL ON (B)(6) 2014. SHE CAME FOR POSTOPERATIVE FOLLOW-UP ON (B)(6) 2014 AND HAS HAD NO ISSUES.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00166	BAYER HEALTHCARE LLC	5/22/2014	6/2/2014

Event Information:

Event Date (B3): 4/18/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 4/18/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A SURGEON, (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED IMPLANT DID NOT WANT TO FALL INTO PLACE AND STUCK IN DELIVERY SYSTEM, IMPLANT WAS NOT CORRECTLY PLACED, POSSIBLE LESION INSIDE OF FALLOPIAN TUBE, AND POSSIBLE LESION INSIDE OF UTERUS. NO INFO GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR INDICATION NOT REPORTED. PHYSICIAN REPORTED THAT AT THE TIME OF THE ESSURE RELEASE, IMPLANT DID NOT WANT TO FALL INTO PLACE AND STUCK IN DELIVERY SYSTEM. IMPLANT WAS NOT CORRECTLY PLACED. IMMEDIATE ACTION: IMPLANT WAS REMOVED WITH GRASPING FORCEPS FROM UROLOGY. PHYSICIAN REPORTED POSSIBLE LESION INSIDE OF FALLOPIAN TUBE AND UTERUS AND CONSIDERED IT AS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. A NEW IMPLANT WAS FITTED WITHOUT APPARENT PROBLEM. REPORTER CAUSALITY: PHYSICIAN DID NOT REPORT THE RELATIONSHIP BETWEEN ALL THE EVENTS INITIALLY REPORTED AND ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00168	BAYER HEALTHCARE LLC	5/22/2014	6/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B93872

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT (UNSPECIFIED AGE) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE INNER CATHETER DID NOT RELEASE THE COIL PROPERLY WITH ROLL BACK IT STRETCHED AND EVENTUALLY UNRAVELED AND SNAPPED OFF AT GREEN SHEATING, HE DEPLOYED THE COIL AND THE INNER COIL CAME BACK OUT WITH WIRE AND IS LOOSE IN TOP OF UTERUS AND MD REPORTED COIL WAS IN THE PT WITH ABOUT 1/2 COIL TRAILING. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON (B)(6) 2014, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN DEPLOYED THE COIL AND THE INNER COIL CAME BACK OUT WITH WIRE AND IS LOOSE IN TOP OF UTERUS. THE OUTER COIL STAYED IN TUBE. IT APPEARS THE INNER CATHETER DID NOT RELEASE, THE COIL PROPERLY AND WITH ROLL BACK, IT STRETCHED AND EVENTUALLY UNRAVELED AND SNAPPED OFF AT THE GREEN SHEATHING. THE PHYSICIAN REPORTED COIL WAS IN THE PT, WITH ABOUT 1/2 COIL TRAILING. THE PHYSICIAN WILL CHECK IT IN THE 3 MONTHS HYSTEROSALPINGOGRAPHY. REPORTER CAUSALITY: NO ASSESSMENT WAS GIVEN. FOLLOW-UP INFO RECEIVED ON 05/08/2014: THIS CASE REFERS TO A (B)(6) PT. ESSURE LOT NUMBER WAS B93872 (EXPIRATION DATE 11/2016). ESSURE WAS INSERTED 9 WEEKS POST-PARTUM. PREVIOUS GYNECOLOGICAL INTERVENTIONS WERE DENIED. THE INSERTION WAS CONSIDERED EASY, XYLOCAINE WAS USED AS ANALGESIC. TUBAL SPASM OCCURED. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. THE FLUID LOSS DURING HYSTEROSCOPY WAS NOT MORE THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. NO IMAGING TESTS OR HSG WERE PERFORMED YET. DPV (INTERPRETED AS DEPO PROVERA) WAS USED AS BACK-UP CONTRACEPTION. IT WAS

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MENTIONED THAT ONE COIL APPEARED IN PLACE, BUT THE OTHER ESSURE WAS NOT VISUALIZED IN TUBE. A NEW ATTEMPT TO VISUALIZE THE COIL WOULD BE PERFORMED IN THE FOLLOWING DAY. THE REPORTED CONSIDERED THE CONDITIONS CAUSED BY THE ESSURE DEVICES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036351		5/22/2014	6/2/2014

Event Information:

Event Date (B3): 3/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 744391

Single Use:
Implant Date (E6): 3/3/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE RECEIVING ESSURE IMPLANTS, I'VE EXPERIENCED EXTREME CRAMPING AND EXCESSIVE BLEEDING. LONGER AND MORE FREQUENT MENSTRUAL CYCLES RESULTED IN AN ENDOMETRIAL ABLATION PROCEDURE TO CORRECT. THE BLEEDING STOPPED, BUT THE PAIN DID NOT. FREQUENT SHARP/STABBING PAIN ON THE RIGHT SIDE. USUAL DEVELOPMENT OF CYSTS ON LEFT OVARY, RIGHT OVARY, BREAST, CERVIX, AND KIDNEY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00163	BAYER HEALTHCARE LLC	5/22/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B02261

Single Use: Y
Implant Date (E6): 5/29/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) YEARS OLD FEMALE CONSUMER IN UNITED STATES ON (B)(4) 2014. SHE HAD MIRENA (LEVONORGESTREL) INSERTED AND HAD ONLY 3 PERIODS WHILE ON MIRENA. AFTER THAT SHE HAD HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DIZZY SPELLS, ITCHING EVERYWHERE "HEAD TO TOE", CONSTANT PELVIC PAIN, RIGHT OVARY WAS CONSTANTLY PAINFUL, SHE HAS NOT HAD A NORMAL PERIOD SINCE ESSURE INSERTED, EXTREMELY HEAVY BLEEDING DURING PERIOD/BLEEDING LIKE SHE WAS DELIVERING A CHILD AND THAT SHE MIGHT BE ALLERGIC TO NICKEL. ADD'L INFO RECEIVED ON (B)(4) 2014. ON INFO GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. IN (B)(6) 2008, THE CONSUMER HAD MIRENA (LEVONORGESTREL) INSERTED AT 20MCG/24 HR CONTINUOUS INTRAUTERINE. IT WAS NOT CLEAR WHETHER MIRENA WAS USED PREVIOUSLY OR NOT. SHE REPORTED THAT SHE HAD ONLY 3 PERIODS WHILE ON MIRENA. THE IUS WAS REMOVED ON (B)(6) 2013. ON (B)(6) 2013, SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION WITH LOT NUMBER B02261. ABOUT 2 MONTHS AFTER PROCEDURE, SHE STARTED EXPERIENCING DIZZY SPELLS IN PARTICULAR WHEN SHE GOT OUT OF BED; SHE HAD TO HOLD ON BECAUSE SHE FELT LIKE SHE WAS GOING TO FALL. SHE ALSO STATED THAT SHE STARTED ITCHING EVERYWHERE FROM HEAD TO TOE; SHE WOULD WAKE UP AND BE BLEEDING BECAUSE SHE SCRATCHED SO MUCH. SHE WAS IN CONSTANT PELVIC PAIN AND HER RIGHT OVARY WAS CONSTANTLY PAINFUL. SHE HAS NOT HAD A NORMAL PERIOD SINCE ESSURE WAS INSERTED AND COMPLAINED OF EXTREMELY HEAVY BLEEDING DURING PERIOD, CHANGING PADS AND CLOTHES MULTIPLE TIME A DAY, AND STATED THAT SHE WAS BLEEDING LIKE SHE WAS DELIVERING A CHILD. SHE CONSIDERED THAT MIGHT BE ALLERGIC TO NICKEL AND HAD NO PREVIOUS DIAGNOSIS OF NICKEL ALLERGY. SHE WILL HAVE A HYSTERECTOMY TO HAVE ESSURE REMOVED. THE

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REPORTER'S CAUSALITY WAS NOT PROVIDED. F/U INFO WAS RECEIVED ON (B)(4) 2014. CASE HAS BEEN UPGRADED TO INCIDENT DUE TO A HYSTERECTOMY. IN (B)(6) 2013, AN ULTRASOUND AND HSG (HYSTEROSALPINGOGRAM) WERE PERFORMED AND SHOWED THE COILS WERE IN PLACE. ON (B)(6) 2014, SHE HAD A TOTAL VAGINAL HYSTERECTOMY WHICH WAS MEDICALLY NECESSARY BECAUSE OF ALL THE PROBLEMS SHE WAS HAVING. TVAH WAS REPORTED AS THE PROCEDURE USED FOR THE ESSURE REMOVAL. SHE WAS TOLD THAT THE COILS WERE STICKING OUT OF THE TUBES AND PUNCTURING UTERUS. THERE WERE NO SIGNS AND SYMPTOMS OF INFECTION. AFTER ESSURE REMOVAL PROCEDURE, THE LOW BACK PAIN AND DIZZINESS RESOLVED. SHE WAS FEELING A LOT BETTER. IT WAS REPORTED THAT THE EVENTS WERE CAUSED BY THE ESSURE DEVICES BECAUSE SHE WAS FEELING SO MUCH BETTER EVEN THOUGH SHE DOES NOT HAVE SOME OF HER ORGANS ANYMORE, THE OUTCOME WAS RESOLVING. NO FURTHER INFO WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00165	BAYER HEALTHCARE LLC	5/22/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN THE UNITED STATES ON (B)(6) 2014. THE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED GI (GASTROINTESTINAL) SYMPTOMS AND PAIN POST ESSURE PLACEMENT, SALPINGITIS WAS DIAGNOSED. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PATIENT REPORTED GI SYMPTOMS (GASTROINTESTINAL) AND PAIN POST ESSURE PLACEMENT. IN THE WEEK BEFORE TIME OF REPORTING, A COUPLE OF WEEKS AFTER ESSURE PLACEMENT, THE PATIENT WAS HOSPITALIZED FOR SALPINGITIS. PATIENT RECOVERED. THE INSERTS WERE NOT REMOVED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2014: THEY ARE UNABLE TO COMPLETE THE FAX RECEIVED SINCE THERE WERE NO PATIENT IDENTIFIERS. MESSAGE LEFT WITH RECEPTIONIST IF SHE COULD CHECK WITH PHYSICIAN TO SEE IF SHE COULD RECALL WHO THE PATIENT WAS AND COMPLETE THE FORMS. NO RESPONSE TO DATE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00167	BAYER HEALTHCARE LLC	5/22/2014	6/10/2014

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/18/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY UNK IF IN UTERUS, POSSIBLE ECTOPIC AND DEVICE INEFFECTIVE IN A (B)(6) YEAR OLD FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE PT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AT UNK FOR PERMANENT STERILIZATION. ON (B)(6) 2014 REPORTER STATED THAT PREGNANCY WAS DIAGNOSED HOWEVER IT WAS UNK IF IN UTERUS, POSSIBLE ECTOPIC. REPORTER WAS ALSO UNK HOW FAR ALONG THE PREGNANCY WAS. FURTHER PT TESTING WAS IN PROGRESS. ON (B)(6) 2013, A CONFIRMATION TEST WAS POSITIVE. ESSURE WAS NOT REMOVED AND OUTCOME OF EVENTS WAS ONGOING. REPORTER CAUSALITY WAS NOT REPORTED. FOLLOW UP INFO RECEIVED ON (B)(4) 2014: NO LOT NUMBER PROVIDED AND NO DEVICE RETURNED. FOLLOW UP INFO RECEIVED ON (B)(4) 2014: PHYSICIAN'S OFFICE CONFIRMED THEY RECEIVED QUESTIONNAIRE AND WILL ANSWER AS SOON AS POSSIBLE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00164	BAYER HEALTHCARE LLC	5/22/2014	6/30/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B93880

Single Use: Y
Implant Date (E6): 4/17/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT REC'D FROM A NURSE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO REC'D ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED DOCTOR REMOVED COILS BUT SAW COILS STILL IN TUBE WITH SCOPE, COIL DID NOT RELEASE FROM THE INTRODUCER, HCP PULLED BACK AND STRETCHED COILS, COMPLICATION DURING DEVICE INSERTION, AND HCP STOPPED PROCEDURE AND DID NOT ATTEMPT TO PLACE SECOND ESSURE. NO INFO GIVEN ON PATIENT'S HISTORY, PAST DRUGS ANC CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT REC'D ANY CONCOMITANT MEDICATION. ON (B)(6) 2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B93880 FOR STERILIZATION. DURING THE INSERTION PROCEDURE, PHYSICIAN WENT TO PLACE FIRST COIL IN TUBE AND WHEN PHYSICIAN WENT TO CLICK THE WHEEL BACK, THE COIL DID NOT RELEASE FROM THE INTRODUCER. HCP PULLED BACK AND STRETCHED COILS, HE THOUGHT COIL WAS OUT OF TUBE. PHYSICIAN THEN WENT IN WITH GRASPERS AND REMOVED COIL; THEN OPENED (NEW) SECOND COIL, AND WANTED TO PLACE IT IN THE SAME TUBE. PHYSICIAN STARTED PROCEDURE WITH SCOPE, THE DOCTOR SAW COILS STILL IN TUBE. PHYSICIAN DID NOT KNOW IF INSERT BROKE, HE STOPPED PROCEDURE AND DID NOT ATTEMPT TO PLACE SECOND COIL. CALLER SAID PATIENT WAS OKAY. NO FURTHER INFO PROVIDED. REPORTER CAUSALITY WAS NOT REPORTED. F/U FROM (B)(4) 2014: NO RESPONSE TO DATE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00162	BAYER HEALTHCARE LLC	5/22/2014	8/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7): 4/9/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM CONSUMER VIA REGULATOR AUTHORITY (B)(4) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RIGHT SIDE PAIN RADIATING TOWARDS BOTH KNEES, BACK PAIN, LEG PAIN SEVERE, SEVERE BLEEDING DURING MENSTRUAL CYCLE, CRAMPS DURING MENSTRUAL CYCLE, UNABLE TO MOVE, CONSTANT PAIN EVERYDAY, WEIGHT GAIN, AND NOT ABLE TO WALK OR EXERCISE. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER 509798. ON AN UNSPECIFIED DATE, THE CONSUMER EXPERIENCED RIGHT SIDE PAIN RADIATING TOWARDS BOTH KNEES, BACK AND LEG PAIN SEVERE, SEVERE BLEEDING AND CRAMPS DURING MENSTRUAL CYCLE, WAS UNABLE TO MOVE, HAD CONSTANT PAIN EVERYDAY, WEIGHT GAIN, WAS NOT ABLE TO WALK OR EXERCISE. THE CONSUMER REQUIRED INTERVENTION (UNSPECIFIED). REPORTER CAUSALITY: THE RELATIONSHIP WAS NOT REPORTED. FOLLOW-UP INFORMATION WAS RECEIVED ON 01-APR-2014: CONSUMER STATED SHE WAS GOING TO HAVE A SURGERY CORNUAL RESECTION OF THE UTERUS ALONG WITH REMOVAL OF FALLOPIAN TUBES AND ESSURE COILS REMOVAL ON (B)(6) 2014. IT WAS REPORTED THAT ESSURE PROCEDURE WAS PERFORMED 8 YEARS BACK AND SHE HAS THE MEDICAL RECORDS WITH HER. CONSUMER DOES NOT ALLOW CONTACT WITH PHYSICIAN. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 23-APR-2014: CONSUMER ANSWERED ON PHONE TO FOLLOW-UP QUESTIONS. AS FOR DIAGNOSTIC TESTS CONSUMER STATED SHE HAD TO GET A LOT OF ULTRASOUNDS AND CT SCANS FOR THE PAST EIGHT YEARS TO KNOW WHAT WAS GOING ON. SHE WAS STILL NOT SURE IF IT WAS STILL OF HER BODY, SHE STILL HAS TO GET A CT SCAN TO MAKE SURE. ON (B)(6)

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2014, ESSURE WAS REMOVED VIA LAPAROSCOPY. DOCTOR TOOK ONE OF HER TUBES BY LAPAROSCOPIC METHOD, PART OF THE UTERUS, PART OF THE TUBE ON THE OTHER SIDE AND SUTURED IT. CONSUMER DOES NOT KNOW EXACTLY WHICH SIDE THEY REMOVED COMPLETELY AND THE OTHER SIDE PART OF IT. A CORNUAL RESECTION WAS DONE ON (B)(6) 2014. CONSUMER HAS NOT GOT PATHOLOGIC RESULT, SHE WILL GET IT IN THE WEEK FOLLOWING TIME OF REPORTING WHEN SHE GOES FOR HER POST-OPERATION APPOINTMENT. DOCTOR TOLD HER THAT ONE OF THE DEVICES WAS BENT. THEY EXPLAINED IT TO HER HUSBAND WHILE SHE WAS GETTING OPERATED. SHE STILL HAS TO TALK TO HER DOCTOR. CONSUMER HAS NOT YET RECOVERED FROM THE REMOVAL PROCEDURE. AFTER HER SURGERY, HER BACK PAIN HAS GONE AWAY, LOT OF THINGS WENT AWAY, HER NERVES USUALLY GET SWOLLEN, THAT HAS DRASTICALLY GONE DOWN. BLOATING WENT AWAY. BUT SHE STILL HAS TO WAIT FOR HER MENSTRUAL CYCLE THAT IS THE REAL TEST TO HER. CONSUMER STATED THE EVENTS WERE CAUSED BY ESSURE. SHE SUFFERED FOR EIGHT YEARS WITH IT. SHE HAD TERRIBLE, UNBEARABLE PAIN DURING EVERY MENSTRUAL CYCLE FOR 25 DAYS (MORE PAIN THAN WHEN SHE WENT THROUGH DURING DELIVERY), HAD LOW BACK PAIN, LOWER PELVIC PAIN, BECAME ALLERGIC TO MOST OF THE FOODS. SHE HAD NICKEL ALLERGY. THEY DID NOT TEST HER BEFORE FOR THAT. SHE WAS VERY UPSET. SHE HAD TRUSTED HER DOCTORS. THE PRODUCT WAS DEADLY, IT TOTALLY SCREWED UP AND RUINED HER LIFE. SHE WAS REALLY MAD. CONSUMER HAD TO UNDERGO 4-5 HOURS OF SURGERY BECAUSE OF ALL THAT. SHE NEVER HAD ANY PROBLEMS BEFORE. HER CYCLES WERE NORMAL AND SHE HAD TWO NORMAL DELIVERIES. SHE HAD TO QUIT HER JOB ALSO DUE TO THAT. FOLLOW-UP 09-MAY-2014. NO FOLLOW-UP RESPONSE WAS RECEIVED UP TO DATE. CASE CONSIDERED CLOSED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036333	BAYER	5/23/2014	6/2/2014

Event Information:

Event Date (B3): 5/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN 2007, AFTER MY LAST CHILD WAS BORN. I HAVE NOT BEEN MYSELF EVER SINCE. I HAVE EXPERIENCED ABDOMINAL PAINS, MY TUBES ARE SORE, AND I CAN FEEL THEM MOVE WHEN I MOVE AROUND, I HAVE HAD WEIGHT GAIN, BACK PAIN, HEAVY IRREGULAR PERIODS, AND MANY HEADACHES. I HAVE EXPERIENCED A METAL TASTE IN MY MOUTH, FATIGUE, TINGLING AND TWITCHING IN FINGERS AND SOME HAIR LOSS. THIS BEGAN IN 2007.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036227	BAYER	5/27/2014	5/28/2014

Event Information:

Event Date (B3): 3/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DID A LOT OF RESEARCH PRIOR TO THIS PROCEDURE AND COULD NOT FIND ANYTHING NEGATIVE REGARDING THE ESSURE DEVICE NOR DID I FIND ANYTHING ABOUT ANY NICKEL ALLERGY WARNING. I RECEIVED THE ESSURE IN (B)(6) 2012 AS A MEANS OF PERMANENT STERILIZATION. THE PROCEDURE ITSELF WENT RELATIVELY WELL. THE IMPLANTING DOCTOR HAD A LITTLE TROUBLE GETTING THE DEVICE INTO THE LEFT FALLOPIAN TUBE. TOOK ABOUT 20-30 MINUTES. I STARTED TO FEEL LIGHTHEADED AND DIAPHORETIC TOWARD THE END OF THE PROCEDURE AND THOUGHT I MIGHT PASS OUT. THE NURSE HAD ME LAY THERE FOR A FEW MINUTES AND BROUGHT ME A (B)(6) TO DRINK. I WENT HOME AND SLEPT FOR A FEW HOURS AND FELT PRETTY GOOD AFTERWARD. I HAD SOME VAGINAL SPOTTING OFF AND ON FOR THE NEXT 3 MONTHS WHEN I WENT IN FOR MY CONFIRMATION HSG. MY LEFT TUBE WAS NOT CLOSED AT THAT TIME, THE RIGHT SIDE WAS OCCLUDED. THIS TEST WAS FAR MORE PAINFUL THAN THE IMPLANTATION OF THE ESSURE AND AGAIN I ALMOST PASSED OUT. I WENT HOME TO THINK ABOUT WHAT I WANTED TO DO IN THE MEANTIME REGARDING BIRTH CONTROL SINCE THE LEFT TUBE WAS STILL OPEN. I CONTINUED TO HAVE VAGINAL BLEEDING AND SPOTTING OFF AND ON UNTIL (B)(6) 2012 (7 MONTHS AFTER I WAS IMPLANTED WITH ESSURE). I NEVER HAD ANY TYPE OF GYN PROBLEMS PRIOR TO ESSURE. I WAS NOT ON ANY TYPE OF BIRTH CONTROL FOR AT LEAST 3-4 YEARS PRIOR TO BEING IMPLANTED WITH ESSURE. I FINALLY WENT BACK TO THE DOCTOR TO INQUIRE ABOUT THE BLEEDING AND SPOTTING. IT WAS AN OLD BROWN BLOODY DISCHARGE THAT I WAS EXPERIENCING. MY DOCTOR THOUGHT THAT THE ESSURE MAY HAVE PERFORATED THE FALLOPIAN TUBE SO HE WANTED TO DO SURGERY TO FIND OUT WHAT WAS GOING ON. ON (B)(6) 2012 I HAD A DIAGNOSTIC LAPAROSCOPY, BILATERAL TUBAL LIGATION (SINCE MY LEFT TUBE WASN'T BLOCKED HE WENT AHEAD AND DID BOTH SIDES WHILE HE WAS THERE), D AND C; AND A ROLLERBALL ABLATION. MY PATHOLOGY CAME BACK AS PROBABLE ADENOMYOSIS. I

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RECOVERED FROM THAT PROCEDURE AND THOUGHT ALL WAS WELL. OVER THE NEXT YEAR AND A HALF I NOTICED THAT I WAS BLOATED A LOT, HAD A LOT OF JOINT PAIN AND PELVIC PAIN. I ALSO NOTICED BEING VERY TIRED, DIZZY AND HAD VISUAL CHANGES AS WELL. IN ADDITION, I GAINED ABOUT 25 POUNDS WITHOUT HAVING ANY CHANGES TO MY ACTIVITY OR DIET. ONCE AGAIN, I NEVER HAD ANY OF THIS PRIOR TO HAVING ESSURE. I TRIED DIET CHANGES, INCREASING MY EXERCISE, STRETCHING FOR THE JOINT PAIN AND LOTS OF IBUPROFEN. TOWARD (B)(6) 2013 I NOTICED AN INCREDIBLE INCREASE IN THE PELVIC PAIN AND BLOATING THAT I WAS HAVING. IT WOULD LAST ABOUT 3 WEEKS OUT OF THE MONTH. THE JOINT PAIN WAS INCREASING AS WELL. I ALSO HAD MY PHYSICAL EXAM AT THE END OF (B)(6) 2013 AND MY VITAMIN D WAS LOW FOR THE FIRST TIME IN MY LIFE. THIS WAS AT THE END OF SUMMER AFTER HAVING SPENT A MAJORITY OF MY TIME IN THE SUN AT THE NEIGHBORHOOD POOL. I WENT TO MY DOCTOR IN (B)(6) 2014 DUE TO THE WEIGHT GAIN, PELVIC PAIN AND BLOATING. HE PERFORMED A VAGINAL ULTRASOUND AND EVERYTHING APPEARED TO BE NORMAL. HE WAS ABLE TO VISUALIZE THE LEFT ESSURE COIL BUT NOT THE RIGHT. HE SAID THE ONLY THING LEFT TO DO AT THIS POINT WAS TO REMOVE THINGS. I CHOSE TO HAVE A COMPLETE HYSTERECTOMY WITH BILATERAL REMOVAL OF FALLOPIAN TUBES AND ESSURE COILS. HE ALSO REMOVED MY RIGHT OVARY DUE TO A VERY LARGE CYST. THIS WAS PERFORMED ON (B)(6) 2014. I WAS IN THE HOSPITAL OVERNIGHT AND HAD TO MISS 4 WEEKS OF WORK, WHICH I DID NOT HAVE ENOUGH PTO TO COVER THE TIME OFF. DURING MY SURGERY, MY DOCTOR NOTED THAT MY FALLOPIAN TUBES HAD ALMOST DISINTEGRATED BEYOND WHERE THE ESSURE WAS PLACED. MY DOCTOR BELIEVES THAT I WAS ALLERGIC TO THE NICKEL IN THE ESSURE. I AM UNABLE TO WEAR ANY TYPE OF JEWELRY WITH NICKEL, ESPECIALLY EARRINGS. I WAS UNAWARE OF THE NICKEL IN THE PRODUCT PRIOR TO PLACEMENT. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036228	BAYER	5/27/2014	5/28/2014

Event Information:

Event Date (B3): 7/3/2011	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AT FIRST EVERYTHING SEEMED OK. THEN ABOUT 2 MONTHS AFTER GETTING ESSURE, I BEGAN GETTING HORRIBLE HEADACHES, EXTREME FATIGUE, AND MOOD SWINGS, HORRIBLE CRAMPING WHICH I NEVER HAD BEFORE, PERIODS PASSING HUGE CLOTS. ABOUT 6 MONTHS AFTER I BEGAN DRASTICALLY LOSING WEIGHT TO THE POINT I WEIGHED (B)(6). AS A MOTHER OF 5 CHILDREN THIS IS NOT ACCEPTABLE. I WENT TO DR AFTER DR AFTER DR, HAD VITAMIN DEFICIENCY TESTS, TESTS FOR LEUKEMIA, ETC...THEY COULD FIND NO REASON FOR THE EXTREME WEIGHT LOSS. MY HAIR BEGAN TO FALL OUT, MY IMMUNE SYSTEM WAS LOW. I WAS HOSPITALIZED IN (B)(6) 2014 FOR LACK OF KIDNEY FUNCTION. I BECAME EXTREMELY ANEMIC. DEVELOPED ADENOMYOSIS AND ENDOMETRIOSIS, EXTREME BACK PAIN, COMPLETE LOSS OF ENERGY. AGAIN THE DOCTORS COULD FIND NO REASON FOR ALL OF THIS. FINALLY I HAD NO CHOICE OTHER THAN A HYSTERECTOMY WITH COMPLETE TUBE REMOVAL INCLUDING THE ESSURE ON (B)(6) 2014. MOST OF MY SYMPTOMS HAVE BEGUN TO GO AWAY AND SINCE THE ESSURE REMOVAL I HAVE BEGUN TO GAIN WEIGHT. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036229	BAYER	5/27/2014	5/28/2014

Event Information:

Event Date (B3): 1/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL CRAMPS AND SHARP SHOOTING PAIN IN MY RIGHT SIDE. EXTREME BACKACHES, MIGRAINES, PAIN IN GROIN AREA, JOINT PAIN, PAINFUL INTERCOURSE, ENDOMETRIOSIS AND HEAVY CLOTTING BLEEDING. I BLED FOR 16 MONTHS AFTER HAVING THE IMPLANTS PLACED. I HAD TO HAVE MY GALLBLADDER REMOVED, I HAD A SEVERE CASE OF PANCREATITIS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036230	BAYER	5/27/2014	5/28/2014

Event Information:

Event Date (B3): 4/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DIAGNOSED WITH MULTIPLE ENDOCRINE NEOPLASIA LEVEL 2A AGE (B)(6). THYROID CANCER WITH REMOVAL, LEFT AND RIGHT ADRENAL GLANDS SURGICALLY REMOVED, TWO SEPARATE PHEOCHROMOCYTOMAS SURGICALLY REMOVED PRIOR TO IMPLANT. HISTORY OF RARE ENDOCRINE TUMOR DISORDER. AFTER IMPLANTATION, MY PERIODS INCREASED TO 14 DAYS OF BLEEDING WITH 3 DAYS OF HEAVY BLEEDING. I DEVELOPED DAILY SEVERE HEADACHES AND SIGNIFICANT CONSTANT PELVIC AND BACK PAIN. MY VISION BECAME BLURRY WITH WHITE FLASHES, AND CONFUSION FOR BRIEF SECONDS. IN (B)(6) 2013, I HAD A RAPID ONSET OF CRUSHING CHEST PAIN ALONG WITH SHORTNESS OF BREATH, WHITE FLASHES IN MY EYES AND A PINCHED NERVE FEELING ON THE SIDE OF MY NECK. I WAS SEEN IN THE EMERGENCY ROOM. THE CRUSHING CHEST PAIN AND SHORTNESS OF BREATH NEVER WENT AWAY. IN (B)(6) 2013, I BEGAN TO SUFFER FROM CHRONIC YEAST INFECTIONS WHICH I NEVER HAD BEFORE. I GET THEM ALMOST EVERY MONTH NOW. ALSO THIS IS WHEN THE SEVERE BLOATING OCCURRED CAUSING MY STOMACH TO EXTEND SIMILAR TO WHEN I WAS SEVEN MONTHS PREGNANT. I WAS SEEN IN THE EMERGENCY ROOM. MY SEXUAL DESIRE IS ALMOST NON-EXISTENT DUE TO THE CHRONIC PELVIC PAIN, PAIN DURING INTERCOURSE, AND RECURRING YEAST INFECTIONS. IN (B)(6) 2013, MY VISION IS WORSENING AND MY CONFUSION EPISODES ARE LASTING LONGER. THE HEADACHES ARE INCREASING IN INTENSITY REQUIRING MORE MOTRIN INTAKE. IN (B)(6) 2013, WHILE WALKING, I EXPERIENCED A SHARP STABBING ICE PICK CENTRALIZED PAIN ON MY LEFT SIDE, FOLLOWED BY WHITE FLASHES IN MY EYES, BLURRED VISION, AND CONFUSION WHICH BROUGHT ME TO MY KNEES. IN (B)(6) 2013, MY INNER LEFT KNEE BEGAN TO SWELL AND HURT. I BOUGHT A DRUGSTORE BRACE TO HELP WITH THE PAIN FROM WALKING AND DOING EVERY DAY TASK. THE INTAKE OF MOTRIN INCREASES TO DEAL WITH THE KNEE PAIN, BACK PAIN, HEADACHES, AND PELVIC PAIN. IN (B)(6) 2013, I CAN NO LONGER WALK FOR LONG PERIODS OF TIME WITHOUT

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SHORTNESS OF BREATH AND SIGNIFICANT PAIN. THE BLOATING INCREASED AND NOW IS DIFFICULT AND PAINFUL TO SLEEP. MY VISION HAS WORSENED WITH INCREASED WHITE FLASHES, CONFUSION EPISODES ARE LASTING LONGER AND NOW THE SAME PAIN THAT IS IN MY KNEE IS NOW IN MY RIGHT ELBOW. IN (B)(6) 2014, I BEGAN GROWING DARK SIDEBURNS ON MY FACE ALONG WITH INCREASED WHITE FACIAL HAIR ON MY CHEEKS AND NECK. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036231	BAYER	5/27/2014	5/28/2014

Event Information:

Event Date (B3): 11/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BEGAN GAINING WEIGHT EVEN THOUGH I WORK OUT 6 DAYS A WEEK AND EAT VERY HEALTHY. BLOOD PRESSURE WAS RISING EVEN THOUGH MY MEDICINE (BEFORE THE ESSURE) HAD CONTROLLED IT VERY WELL. BEGAN TO HAVE MORE HEART PALPITATIONS. BEGAN LOSING HAIR. INABILITY TO FALL ASLEEP FOR HOURS, AND THEN WHEN I FINALLY WOULD, I WOULD SLEEP FOR 8 HOURS AND THEN STILL NEED A NAP IN THE AFTERNOON. DRY SKIN. DIAGNOSED WITH HYPOTHYROIDISM THREE MONTHS AFTER IMPLANTATION OF ESSURE. NEVER HAD ANY ISSUES WITH MY THYROID BEFORE. (B)(4) UPDATE ON (B)(6) 2014: HAD SURGICAL REMOVAL OF BOTH COILS AND TUBES ON (B)(6) 2014. IT'S ONLY BEEN A COUPLE OF DAYS, BUT I HAVE NOT HAD ANY HEART PALPITATIONS. SWELLING/PUFFINESS AROUND BELLY HAS SUBSIDED DRAMATICALLY, ALTHOUGH I'M STILL SWOLLEN WHERE MY INCISION WAS MADE. NO LONGER LOOK 5 MONTHS PREGNANT. STILL HAVING SOME TROUBLE FALLING ASLEEP. DOCTOR WANTS ME TO GO OFF THYROID MEDICINE FOR 4-6 WEEKS AND THEN RECHECK TO SEE IF LEVELS RETURN TO NORMAL NOW THAT ESSURE IMPLANTS HAVE BEEN REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036232	BAYER	5/27/2014	5/28/2014

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THIS PROCEDURE DONE BACK IN 2008, AFTER MY THIRD CHILD WAS BORN. IMMEDIATELY I COULD FEEL THE FOREIGN DEVISE. I WENT HOME IN TEARS, ALTHOUGH ON PAIN MEDS I COULD STILL FEEL IT. AFTER 3 DAYS RECOVERY AND BEING IN STRONG PAIN MEDS MY PELVIC PAIN WAS EXCRUCIATING! THE PAIN IS STILL THERE. I HAVE HORRIBLE CRAMPING DURING MY PERIOD ACCOMPANIED WITH BACK PAIN. BREAST TENDERNESS, IRREGULAR PERIODS, CYSTS, LOSS OF HAIR, LACK OF LIBIDO, PAIN DURING INTERCOURSE, HOT FLASHES, NIGHT SWEATS, CLOUDED MEMORY, TINGLING IN ALL EXTREMITIES. I AM ALLERGIC TO NICKEL, DOCTOR DIDN'T TELL ME IT HAD NICKEL! (B)(4). MW5032694 UPDATE ON (B)(6) 2014: ON (B)(6) 2014 I HAD TO HAVE A PARTIAL HYSTERECTOMY AT THE AGE OF (B)(6) TO REMOVE THE ESSURE DEVICE. SINCE THE SURGERY, MY ADVERSE REACTIONS OR COMPLICATIONS I HAVE HAD IN THE PAST ARE NOW GONE! MY BACK PAIN IS GONE, I DON'T HAVE ANY BREAST TENDERNESS, MY LIBIDO IS BACK, NO HOT FLASHES, NO NIGHT SWEATS, NO MORE CLOUDY BRAIN, NO MORE TINGLING, NO MORE BRAIN ZAPS, MY HAIR IS GROWING, MY NAILS ARE GROWING, I HAVE A TON OF ENERGY, I HAVEN'T HAD TO USE A SLEEP AID TO FALL ASLEEP LIKE I HAVE HAD TO DO EVERY NIGHT FOR THE LAST FIVE YEARS. I AM SO GLAD TO BE FREE OF ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036233	BAYER	5/27/2014	5/28/2014

Event Information:

Event Date (B3): 7/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2012. SEVERAL WEEKS AFTERWARDS, I EXPERIENCED EXTREME HEADACHES. I WENT TO MY REGULAR FAMILY DOC AND HE SAID HE HADN'T HEARD OF ESSURE AND IT WAS PROBABLY DUE TO STRESS. WOULD TAKE PAIN KILLERS DAILY, DIDN'T ALWAYS WORK. PERIOD IS SO IRREGULAR, I USUALLY START FOR A DAY, THEN STOP FOR TWO, THEN START BACK UP FOR A WEEK. VERY HEAVY. PAIN IN LOWER BACK AND ABS. ODD TASTE IN MOUTH. (B)(4). MW5034386 UPDATE ON (B)(6) 2014: ON (B)(6) 2014, I HAD THE ESSURE COILS REMOVED BY DR (B)(6). I HAD A PRE-OP APPOINTMENT PLUS MY SURGERY WHICH CONSISTED OF QUITE A DRIVE TO (B)(6), BUT SO WORTH IT. THE DOCTOR SAID SHE FOUND SOME ENDOMETRIOSIS DURING SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036371		5/27/2014	6/3/2014

Event Information:

Event Date (B3): 3/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/4/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACE AFTER THE BIRTH OF MY 4TH CHILD IN 2011, SINCE HAVING THE COILS PLACED I HAVE HAD SIGNIFICANT PELVIC PAINS, SEVERE MENSTRUAL CRAMPS, WEIGHT GAIN, RECURRENT PELVIC INFECTIONS, SWELLING AND INFLAMMATION IN MY PELVIC AREA AND ABDOMEN. I AM CURRENTLY IN THE PROCESS OF FINDING A OBGYN TO REMOVE THE ESSURE COILS AND ASSESS THE DAMAGE TO MY PELVIC REGION. I HAVE HAD 2 ULTRASOUNDS AND A CAT SCAN ALL DUE TO PELVIC PAIN. THIS DEVICE HAS COST ME THOUSANDS OF DOLLARS IN OFFICE VISITS, AND HAS GREATLY NEGATIVELY AFFECTED MY QUALITY OF LIFE. I HAVE PAIN DAILY, MY MARRIAGE HAS SUFFERED AS SEXUAL INTERCOURSE IS VERY PAINFUL, AND MY DESIRE FOR SEX HAS DROPPED DRAMATICALLY. I HAVE HAD TO CHANGE MY DIET TO HELP ALLEVIATE SOME OF THE INFLAMMATION BUT NOTHING TRULY RIDS ME OF THE PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00169	BAYER HEALTHCARE LLC	5/27/2014	6/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): 758631

Single Use:
Implant Date (E6): 1/14/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5031543) IN UNITED STATES ON (B)(6) 2013 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED STABBING PAIN IN HER UTERUS, HEAVY CRAMPS, LOWER BACK PAIN, DIZZINESS, HEADACHES, NAUSEA, MOOD SWINGS, AND FATIGUE. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2011, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AT UNK. REPORTED LOT NUMBER: 758631/787224. IT WAS NOT REPORTED WHETHER ESSURE WAS USED PREVIOUSLY. CONSUMER STATED THAT SHE HAD THE ESSURE IMPLANT PLACED IN HER TUBES IN 2011. SINCE THEN SHE HAS PRESENTING SEVERE SIDE EFFECTS WHICH ARE HEAVY CRAMPS OR STABBING PAIN IN HER UTERUS, LOWER BACK PAIN, DIZZINESS, HEADACHES, NAUSEA, MOOD SWINGS, FATIGUE. SHE HAS HAD SEVERAL BLOOD TESTS DONE TO REVIEW WHAT IS CAUSING THE ISSUE AND THEY COME BACK NORMAL. DISABILITY OR PERMANENT DAMAGE WAS REPORTED AS EVENT OUTCOME (SERIOUS CRITERIA) BY HEALTH AUTHORITY. NO ASSESSMENT WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: ESSURE WAS INSERTED IN 2010 AND REMOVED IN 2013. THE CONSUMER ALSO EXPERIENCED MEMORY LOSS AND SHE WAS IN SO MUCH PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

ADDITIONAL LOT # 787224.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00170	BAYER HEALTHCARE LLC	5/27/2014	6/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B21581

Single Use: Y
Implant Date (E6): 7/24/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED SATES ON (B)(4) 2013 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BOTH SIDES WERE PERFORATED. NO INFORMATION WAS GIVEN ON PT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2013 THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION. LOT NUMBER WAS B21581. IT WAS REPORTED THAT THE HSG TEST WAS DONE TOO SOON (DATE NOT SPECIFIED) AND SHOWED THAT BOTH SIDES WERE PERFORATED. AN ULTRASOUND WILL BE DONE. THE RELATIONSHIP BETWEEN BOTH SIDES WERE PERFORATED AND HSG TEST WAS DONE TOO SOON AND ESSURE WAS NOT REPORTED. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2013: PT INITIALS AND DATE OF BIRTH WERE ADDED. THE HSG TEST WAS PERFORMED ON (B)(6) 2013. FOLLOW-UP RECEIVED ON (B)(4) 2013: PT IS SCHEDULED FOR BILATERAL TUBAL LIGATION ON (B)(6) 2013. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2014. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS AND RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. SHE HAD 02 PREGNANCIES AND 02 LIVE BIRTHS. ON (B)(6) 2013 ESSURE WAS EASILY IMPLANTED UNDER GENERAL ANESTHESIA. SHE WAS 6 WEEKS POSTPARTUM. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. SHE RECEIVED DEPO ON THE SAME DAY OF ESSURE INSERTION AS BACK-UP CONTRACEPTION. THREE MONTHS HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND SHOWED BILATERAL PATENCY. COMPLETE BILATERAL TUBAL PERFORATION. THE PT WAS ASYMPTOMATIC. ON UNSPECIFIED DATE ESSURE WAS REMOVED. SINCE IT WASN'T WORKING FOR HER, PT REQUESTED ESSURE REMOVAL. THEY DID ANOTHER HYSTEROSCOPY, GOT ESSURE OUT OF RIGHT SIDE. BUT ON THE LEFT SIDE, COULDN'T SEE THE ESSURE AND PT REQUESTED FOR

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A HYSTERECTOMY BECAUSE SHE WANTED BOTH COILS OUT. SHE UNDERWENT REMOVAL OF UTERUS ALONG WITH BILATERAL FALLOPIAN TUBE REMOVAL AND ESSURE COIL REMOVAL. THEY WERE INSIDE THE UTERUS, DIDN'T GO THROUGH THE UTERUS, ASSUMING WAS IN THE MYOMETRIUM. IT WAS NOT IN THE ABDOMINAL CAVITY. THE PT RECOVERED FROM THE ESSURE REMOVAL PROCEDURE. SHE WAS DOING GREAT. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00171	BAYER HEALTHCARE LLC	5/27/2014	6/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B44009

Single Use: Y
Implant Date (E6): 12/3/2013
Explant Date (E7): 4/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ESSURE MIGRATED IN INTRAPERITONEAL PART AND WAS FOUND IN MESOCOLON AREA. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B44009, INSERTED AT UNK FOR STERILIZATION. INSERTION WAS SUCCESSFUL. ON (B)(6) 2014, ESSURE ON THE LEFT SIDE WAS EXTRAUTERINE AND MIGRATED IN INTRAPERITONEAL PART SEEN ON REPEAT PLAIN ABDOMEN X-RAY, ULTRASOUND AND CT-SCAN PERFORMED 3 MONTHS AFTER THE INSERTION. CLINICAL CONSEQUENCES OBSERVED: INFECTIOUS AND HEMORRHAGIC RISKS. REMOVAL OF ESSURE WAS PERFORMED VIAL CELIOSCOPY ON (B)(6) 2014. ESSURE WAS FOUND IN MESOCOLON AREA. ESSURE WAS NOT KEPT. CASE MEDICALLY SIGNIFICANT ACCORDING TO THE REPORTER. THE OUTCOME OF THE EVENT ESSURE MIGRATED IN INTRAPERITONEAL PART AND WAS FOUND IN MESOCOLON AREA WAS UNKNOWN. REPORTER CAUSALITY WAS NOT REPORTED. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00172	BAYER HEALTHCARE LLC	5/27/2014	6/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS REC'D FROM A PHYSICIAN IN THE UNITED STATES ON (B)(6) 2014. THE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND NEVER DID A HSG (HYSTEROSALPINGOGRAM), SHE EXPERIENCED PAIN AND BILATERAL PERFORATION WAS FOUND, REPORTER BELIEVES IT WAS HALF IN AND HALF OUT, AFTER HYSTERECTOMY PATHOLOGY COILS WERE NOT FOUND. NO INFO WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THEY NEVER DID A HSG (HYSTEROSALPINGOGRAM). ON AN UNSPECIFIED DATE, SIX MONTHS AFTER ESSURE PLACEMENT, THE PATIENT EXPERIENCED BILATERAL COMPLAINTS OF PAIN. A PELVIC ULTRASOUND WAS ORDERED AND FOUND BILATERAL PERFORATION. REPORTER BELIEVED IT WAS HALF IN AND HALF OUT. THEY DID A HYSTERECTOMY (DATE UNSPECIFIED). ON PATHOLOGY EVALUATION THEY COULD NOT FIND ANY COILS AT ALL. THEY DID NOT X-RAY THE UTERUS AFTER REMOVAL, BUT REPORTER IS SURE THE COILS WERE NOT THERE. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP. F/U (B)(4) 2014: NO FURTHER INFO COULD BE OBTAINED FROM PHYSICIAN UP TO DATE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036234	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 9/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVER CHRONIC HEADACHES, WEIGHT GAIN, DEPRESSION AND MOOD SWINGS WHICH THE DOCTOR THEN PUT ME ON ZOLOFT FOR (FIRST TIME I HAVE EVER HAD TO TAKE AN ANTI-DEPRESSANT), ABSENTMINDED, LOWER BACK PAIN, CONTINUOUS STOMACH BLOAT. THEN ON (B)(6) 2014, I WAS HAVING SEVERE LOWER ABDOMEN PAINS AND NOT ABLE TO HOLD DOWN ANY FOOD. ON (B)(6) 2014, I WENT TO THE EMERGENCY ROOM BECAUSE THE ABDOMEN PAIN WAS SO INTENSE AND I WAS NOT FEELING LIKE MYSELF ON ANY LEVEL. THE EMERGENCY ROOM DOCTOR INFORMED ME THAT THE CT SCAN SHOWED THE COILS HAD MOVED AND ONE HAD PUNCTURED INTO MY UTERUS. (B)(4) - UPDATE ON (B)(6) 2014: DOCTOR HAS AGREED THAT A LAPAROSCOPIC VAGINAL HYSTERECTOMY IS WHAT IS BEST FOR ME TO REMOVE THE ESSURE COILS FROM MY BODY. THE FOLLOWING ARE ALL OF THE ISSUES I HAVE HAD SINCE THE COILS WERE IMPLANTED IN ME: LEAKING LEFT BREAST (LIKE COLOSTRUM), CONSTANT SEVERE HEADACHES, NECK AND BACK OF HEAD PAIN, CONSTANT/SEVERE BLOATING, DEPRESSION/MOOD SWINGS, INCREDIBLE CRAMPS/VERY HEAVY BLEEDING AND CLOTTING, PERIODS ON AND OFF FOR 10-15 DAYS, PNEUMONIA 2 TIMES EVEN AFTER HAVE THE PNEUMONIA SHOT, LOWER BACK PAIN, SEVERE PELVIC AND ABDOMINAL PAIN, WEIGHT GAIN THAT I CAN'T GET RID OF NO MATTER HOW MUCH EXERCISING AND DIETING I DO, EXCESSIVE FATIGUE, DIMINISHED BRAIN FUNCTION (BRAINFOG/CONFUSION/CLOUDY/ FORGETFULNESS/SHORT TERM MEMORY LOSS), VITAMIN D DEFICIENCY, FAINTING, CONSTANT DRY MOUTH, NIGHT SWEATS ALL OVER ITCHINESS HEARTBURN, HIP PAIN, EXTREME IRRITABILITY. ALL OF THESE ISSUES HAVE PUT MY LIFE INTO A COMPLETE DOWNWARD TAILSPIN, I WAS ALWAYS A HAPPY AND VERY SOCIAL PERSON SO FULL OF LIFE AND ALWAYS COORDINATING EVENTS AND FUN THINGS WITH FAMILY AND FRIENDS AND WITHIN THE LAST 6-9 MONTHS WHEN ALL THESE SYMPTOMS HAVE REALLY PICKED UP AND GOTTEN WORSE, I HAVE HARDLY SEEN ANYONE OR

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DONE MUCH IF ANY OF SOCIALIZING BECAUSE I AM ALWAYS IN PAIN. (B)(4) - UPDATE ON (B)(6) 2014: HAD MY HYSTERECTOMY ON (B)(6) 2014, THEY REMOVED MY UTERUS, FALLOPIAN TUBES WITH ESSURE COILS AND MY CERVIX. THE COILS HAD NOT MIGRATED AT ALL BUT MY FALLOPIAN TUBES WERE IRRITATED. SINCE HAVING THE SURGERY, THE DAILY CHRONIC HEADACHES ARE GONE, EXTREME ABDOMINAL PAIN AND BLOATING ARE GONE, NO MORE LOWER BACK PAIN, NO HIP PAIN, NO DEPRESSION OR CRAZY MOOD SWINGS, NO MORE EXCESSIVE FATIGUE OR INTENSE DRY MOUTH, THE ALL OVER ITCHINESS SEEMS TO BE GONE AND MY PLANTAR FASCIITIS HASN'T BEEN AN ISSUES AT ALL SINCE. I CAN EXIST ON A DAILY BASIS LIKE A NORMAL PERSON NOW AND MY HUSBAND AND KIDS DON'T RUN FORM ME ANYMORE BECAUSE I AM NOT SO EXTREMELY MOODY LIKE I WAS BEFORE. (B)(4) - UPDATE ON (B)(6) 2014: PATHOLOGY REPORT FROM HYSTERECTOMY SHOWS EXTENSIVE ADENOMYOSIS WITHIN THE UTERUS, ENDOCERVIX - NABOTHIAN CYSTS, LEFT FALLOPIAN TUBE - PARATUBAL CYSTS. THE UTERUS AND CERVIX WEIGHED 332 GRAMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036235	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 10/22/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS TOLD THIS WOULD BE THE OPTION FOR ME INSTEAD OF GETTING MY TUBES TIED. SINCE THEY HAVE BEEN INSERTED I HAVE HAD SEVERE ABDOMINAL PAIN EVERY DAY, MY PERIODS ARE MORE PAINFUL, I HAVE GAINED ABOUT 40 LBS, I HAVE HAD SPOTS OF ENDOMETRIOSIS REMOVED, I SUFFER WITH MIGRAINE HEADACHES EVERYDAY, ALWAYS FEEL COLD, ALWAYS FEEL TIRED, I JUST RECENTLY RECEIVED THE 2ND LUPRON DEPO SHOT DUE TO THE ENDOMETRIOSIS THAT CAUSES EVEN MORE BAD SIDE EFFECTS AND DON'T UNDERSTAND HOW THIS SHOT WAS EVEN PASSED BY THE FDA BECAUSE OF ALL THE HORRIBLE THINGS IT CAUSES. I AM GOING ON (B)(6) 2014 TO GET AN ULTRASOUND DONE BECAUSE 2 WEEKS AFTER RECEIVING THE 1ST SHOT I DEVELOPED A SWOLLEN THROAT/ NECK ON THE LEFT SIDE WITH SOME KIND OF MASS THAT FEELS KIND OF SPONGY IF YOU PUSH ON IT. HAVING THE ESSURE PROCEDURE DONE IN THE FIRST PLACE IS WHEN ALL OF THESE SYMPTOMS STARTED. I REGRET EVER HAVING IT DONE. IF I HAD IT TO DO ALL OVER AGAIN I WOULD NOT EVEN THINK ABOUT IT. THESE IMPLANTS ARE COSTING LOTS OF WOMEN ALL OVER THE WORLD THEIR LIVES AND DOCTORS DON'T SEEM TO EVEN CARE. I BELIEVE THAT THEY SHOULD BE TAKEN OFF THE MARKET NOT TOMORROW, OR A MONTH OR A YEAR OR TWO FROM NOW, BUT RIGHT NOW TODAY!!!! (B)(4).MW5034459 UPDATE ON (B)(6) 2014: ON (B)(6) 2014 I FINALLY GOT THE HYSTERECTOMY THAT I SO BADLY NEEDED AND I AM NOW 4 WEEKS POST OP AND DOING GREAT. ALL THE HEADACHES HAVE STOPPED, ALL THE BODY ACHES ARE GONE, AND I NO LONGER HAVE ANY ABDOMINAL PAIN. I WILL START TO WORK ON LOOSING THE WEIGHT THAT THE ESSURE CAUSED ME TO GAIN AS SOON AS I AM CLEARED WITH THE DOCTOR TO EXERCISE. I AM FINALLY GETTING MY LIFE BACK TO THE WAY IT WAS BEFORE ESSURE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036236	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 12/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE ON (B)(6) 2008. I'M AN ATHLETE AND KNOW MY BODY VERY WELL WHEN I FIRST NOTICED THE FATIGUE SETTING IN THEN THE BODY ACHES. THEN THE JOINT PAIN STARTED, THE LOWER BACK PAINS AND PAIN IN HIPS AND AFFECTING MY SCIATIC NERVE TO MY RIGHT LEG. I WAS KICK BOXING AND HAD TO QUIT DUE TO NOT HAVING THE STAMINA TO TRAIN AND THE JOINT PAIN AND SEVERE MUSCLE FATIGUE I WAS EXPERIENCING. DURING THIS WHOLE TIME I WAS GETTING SEVERE UI INFECTIONS THAT HAS LEAD TO SOME INCONTINENCE ISSUES. TODAY ON A DAILY BASIS I EXPERIENCE ALL THIS PLUS THESE OTHER AILMENTS: CHRONIC FATIGUE, BODY ACHES, ACHY JOINTS, IRREGULAR CYCLES, ABDOMINAL BLOATING, ABDOMINAL PAINS, KIDNEY PAIN, BLADDER INFECTIONS, HEART FLUTTERS, LOWER BACK PAINS, HEADACHES DAILY SOMETIMES MIGRAINES, NECK PAIN, SPINAL PAIN, SCIATIC NERVE IN LEGS PAIN, JAW AND TEETH PAIN, THYROID ISSUES, HEAVY BLEEDING SOMETIMES GUSHING, BLOOD CLOTS DURING CYCLE, SEVERE JOINT PAIN AND MUSCLE FATIGUE, METAL TASTE IN MOUTH AND BLOOD, EAR ACHES W/NO INFECTION WHEN HAVING JAW PAIN, DISCHARGE AND ODOR, INCONTINENCE ISSUES, TINGLING IN LEFT HAND WITH CRAMPING OF FINGERS. LIGHT HEADED, BRAIN FOG, ASTHMA ATTACKS, CRAWLING SKIN, NIGHT SWEATS, BLEEDING AFTER SEX, SPOTTING IN BETWEEN HEAVY FLOWS, HIP PAIN, NAUSEA. IT IS ALMOST IMPOSSIBLE TO BE PHYSICAL DUE TO FATIGUE AND LOSS OF MUSCLE STRENGTH. I USED TO BE A SKI RACER AND NOW I AM LUCKY IF I CAN GO 100 YARDS WITHOUT MY LEG MUSCLES SCREAMING IN SEVERE PAIN! (B)(4) MW5033313 UPDATE ON (B)(6) 2014: SURGERY WAS (B)(6) 2014, LAVH. I WANTED TO KEEP MY OVARIES BUT THEY WERE DAMAGED TOO MUCH TO KEEP. MY OVARIES, TUBES AND UTERUS WERE FUSED TO MY COLON. MY DOCTOR NEEDED TO CALL IN THE GENERAL SURGEON TO SEPARATE MY ORGANS IN ORDER TO SAVE MY COLON. I HAVE MANY OLD CYSTS AND NEW ONES. FILLED WITH ENDOMETRIOSIS FUSING MY ORGANS. I HAD LARGE FIBROIDS IN THE UTERUS AND

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CHOCOLATE POCKETS (?) FILLED WITH OLD BLOOD THAT WOULD NOT SLOUGH OFF DURING MY CYCLE. I HAD A UTI TREATED PRIOR TO SURGERY AND HAVE HAD ANOTHER SINCE SURGERY. I NEVER HAD UTI'S PRIOR TO ESSURE! I FELT REALLY GOOD AFTER SURGERY, NO HEADACHES, BODY ACHES, FATIGUE. I THEN HAD A PATCH TEST DONE WITH SOME OF THE ESSURE MATERIALS AND TWO HOURS AFTER THE PATCH WAS APPLIED I HAD A MAJOR HEADACHE THEN WOKE UP WITH THE BODY ACHES AND FATIGUE. THE PATCH WAS REMOVED AFTER 48 HOURS AND THE SYMPTOMS REMAINED ANOTHER 24 HOURS, THEN DISAPPEARED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036237	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 2/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AS SOON AS I WOKE UP FROM HAVE ESSURE DONE I HAD PAIN IN LOWER LEFT PELVIC AND OVER A MONTH LATER, STILL HAVE IT. BLOATING STOMACH PAIN. PELVIC PAIN. BACK AND HIP PAIN. BURNING MOUTH. RASH. (B)(4) - UPDATE ON (B)(6) 2014: I HAD A HYSTERECTOMY (B)(6) 2014 BECAUSE RIGHT ESSURE COIL MIGRATED FROM MY TUBE AND WAS PIERCED INTO THE TOP OF MY UTERUS. REMOVED UTERUS, CERVIX, AND BOTH TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036238	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 6/7/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2007. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2007. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE~ DAILY CONSTANT MIGRAINES, SEVERE PELVIC PAIN, SHARP SHOOTING PAINS AROUND ESSURE AREA, SHOOTING PAINS IN UTERUS, CERVIX, DOWN THRU VAGINA AND INTO LEGS. MOOD SWINGS, DEPRESSION, ANXIETY, LOSS OF FOCUS. WEIGHT GAIN 40 LBS+, TROUBLE WITH VISION, MEMORY LOSS, BLOATING, INFLAMMATION, EXTREME FATIGUE, EXCESSIVE BLEEDING, ABNORMAL PERIODS, LOWER BACK PAIN, JOINT PAIN, LOW GRADE FEVERS, CRAMPING, OVARIAN CYSTS, CERVICAL CYSTS, HOT FLASHES, MUSCLE ACHES, INSOMNIA, FEELING "FLU LIKE" ALL THE TIME, PAIN DURING INTERCOURSE, BLOOD CLOTS, SHARP STABBING PAINS, ABNORMAL MENSES, VITAMIN D DEFICIENT, RECURRING YEAST INFECTIONS AND BACTERIAL INFECTIONS, NAUSEA, DIZZINESS, HEARTBURN, CHEST PAIN, CLOUDINESS, FORGETFULNESS, HEART PALPITATIONS, FOUL SMELL AND DISCHARGE, POLYPS, SCAR TISSUE BETWEEN UTERUS, GALL BLADDER AND BOWELS. ALL WERE ATTACHED. I HAVE BEEN SEEN BY 2 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS. THE DEVICE HAS BEEN REMOVED ON (B)(6) 2014 THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER. (B)(4). MW5035522 UPDATE ON (B)(6) 2014: I HAVE COME TO REALIZE I HAD A FEW MORE ISSUES RELATED TO HAVE HAD ESSURE: PELVIC INFLAMMATORY DISEASE. CHRONIC PELVIC CONGESTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036239	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 11/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AT THE TIME OF PLACEMENT I A HAD CONSISTENT MONTHLY CYCLE FOR THE PAST 3 YEARS SINCE THE BIRTH OF MY CHILD IN 2009. IT WAS 3-4 DAYS EVERY 26-29 DAYS, AVERAGE BLEEDING AND LIGHT CRAMPING. AFTER PLACEMENT MY CYCLE BECAME ERRATIC, HEAVY, EXTREMELY PAINFUL AND CONTINUED TO GET WORSE AS THE MONTHS WENT BY. I STARTED HAVING SEVERE LOWER BACK PAIN, SHARP SHOOTING PAIN IN MY ABDOMEN WHEN ROLLING OVER WHILE SLEEPING. I COULDN'T RUN ANYMORE, EXHAUSTION SET IN, I BEGAN HAVING CHRONIC MIGRAINES AND STOMACH ISSUES. I GAINED OVER 30 POUNDS WITH MOST OF THE WEIGHT BEING IN MY STOMACH. I LOOKED AS IF I WAS PREGNANT. IT HAS AFFECTED ME MENTALLY AND EMOTIONALLY AS WELL AS MY RELATIONSHIP WITH MY HUSBAND AND CHILDREN. (B)(4). MW5035888 UPDATE ON (B)(6) 2014: AS OF (B)(6) I HAD A HYSTERECTOMY REMOVING MY UTERUS, OVARIES AND TUBES. SINCE SURGERY I HAVE ENERGY BACK, MY BLOATING HAS GONE DOWN. THE PAIN FROM REMOVAL IS LESS THEN ANY PAIN FELT WHILE ESSURE WAS IN MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036240	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 4/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN (B)(6) 2013 AND ABOUT A MONTH LATER I STARTED TO HAVE PAIN IN MY JOINTS AND REGULAR CRAMPING. I THOUGHT THE CRAMPING WAS DUE TO THE TUBES BUILDING SCAR TISSUE. AFTER A COUPLE MONTHS OF THE JOINT PAIN I FINALLY WENT TO THE DR'S. THE DR COULDN'T UNDERSTAND WHY I WAS HAVING JOINT PAIN ALL OF A SUDDEN AFTER BEING HEALTHY, SO AT FIRST SHE THOUGHT I HAD TENDINITIS BUT AS THE PAIN GOT WORSE AND TRAVELED FROM MY HANDS TO MY LEGS I WENT BACK TO THE DR'S. SHE THEN DID BLOOD WORK FOR RHEUMATOID ARTHRITIS AND X RAYS THE BLOOD WORK CAME BACK POSITIVE BUT X RAYS DIDN'T SHOW ANY SIGN OF ARTHRITIS, BUT TO BE SAFE THEY HAD ME SEE A RHEUMATOLOGIST. NOW THEY HAVE PUT ME ON 3 DIFFERENT MEDICATIONS AND NOTHING IS GETTING BETTER IN FACT I'M GETTING WORSE. SO MY RHEUMATOLOGIST HAS SUGGESTED TO GET A NICKEL ALLERGY TEST DONE SINCE ALL THESE SYMPTOMS STARTED AFTER THE ESSURE WAS PUT IN. I AM GOING IN TODAY FOR THE TEST. (B)(4). MW5034327 UPDATE ON (B)(6) 2014: I HAVE GOTTEN WORSE TO THE POINT I CAN'T WALK NOW. HAVING EXTREME HAIR LOSS, SORES ON MY BODY. I HAVE NOW BEEN SCHEDULED FOR A TOTAL HYSTERECTOMY (B)(6) TO GET THE ESSURE COILS REMOVED. MW5034327 UPDATE ON (B)(6) 2014: I WANTED TO LET YOU GUYS KNOW I HAD A TOTAL HYSTERECTOMY ON (B)(6) 2014 AND AS OF TODAY 5 DAYS POST OP ALMOST ALL MY SYSTEMS HAVE GONE AWAY. I AM ABLE TO WALK PAIN FREE AS WELL AS SWELLING HAS WENT AWAY AND THERE ARE NO MORE RASH MARKS ON MY BODY. EACH DAY I HAVE BEEN ABLE TO WALK MORE AND I WAS ABLE TO CLIMB MY 10 STAIRS THAT I HAVEN'T BEEN ABLE TO CLIMB IN OVER 4 MONTHS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036241	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 9/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CHRONIC HEADACHES, WEIGHT GAIN, DEPRESSION AND MOOD SWINGS WHICH THE DOCTOR THEN PUT ME ON ZOLOFT FOR (FIRST TIME I HAVE EVER HAD TO TAKE AN ANTI-DEPRESSANT), ABSENTMINDED, LOWER BACK PAIN, CONTINUOUS STOMACH BLOAT. THEN ON (B)(6) 2014 I WAS HAVING SEVERE LOWER ABDOMEN PAINS AND NOT ABLE TO HOLD DOWN ANY FOOD. ON (B)(6) 2014 I WENT TO THE EMERGENCY ROOM BECAUSE THE ABDOMEN PAIN WAS SO INTENSE AND I WAS NOT FEELING LIKE MYSELF ON ANY LEVEL. THE EMERGENCY ROOM DOCTOR INFORMED ME THAT THE CT SCAN SHOWED THE COILS HAD MOVED AND ONE HAD PUNCTURED INTO MY UTERUS. (B)(4). MW5035323 UPDATE ON (B)(6) 2014: DOCTOR HAS AGREED THAT A LAPAROSCOPIC VAGINAL HYSTERECTOMY IS WHAT IS BEST FOR ME TO REMOVE THE ESSURE COILS FROM MY BODY. THE FOLLOWING ARE ALL OF THE ISSUES I HAVE HAD SINCE THE COILS WERE IMPLANTED IN ME: LEAKING LEFT BREAST (LIKE COLOSTRUM); CONSTANT SEVERE HEADACHES; NECK AND BACK OF HEAD PAIN; CONSTANT/SEVERE BLOATING; DEPRESSION/MOOD SWINGS; INCREDIBLE CRAMPS/VERY HEAVY BLEEDING AND CLOTTING; PERIODS ON AND OFF FOR 10-15 DAYS; PNEUMONIA 2 TIMES EVEN AFTER HAVE THE PNEUMONIA SHOT; LOWER BACK PAIN; SEVERE PELVIC AND ABDOMINAL PAIN; WEIGHT GAIN THAT I CAN'T GET RID OF NO MATTER HOW MUCH EXERCISING AND DIETING I DO, EXCESSIVE FATIGUE; DIMINISHED BRAIN FUNCTION (BRAINFOG/CONFUSION/CLOUDY/ FORGETFULNESS/SHORT TERM MEMORY LOSS); VITAMIN D DEFICIENCY; FAINTING; CONSTANT DRY MOUTH; NIGHT SWEATS; ALL OVER ITCHINESS; HEARTBURN; HIP PAIN; EXTREME IRRITABILITY. ALL OF THESE ISSUES HAVE PUT MY LIFE INTO A COMPLETE DOWNWARD TAILSPIN, I WAS ALWAYS A HAPPY AND VERY SOCIAL PERSON SO FULL OF LIFE AND ALWAYS COORDINATING EVENTS AND FUN THINGS WITH FAMILY AND FRIENDS AND WITHIN THE LAST 6-9 MONTHS WHEN ALL THESE SYMPTOMS HAVE REALLY PICKED UP AND GOTTEN WORSE I HAVE HARDLY SEEN ANYONE OR

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DONE MUCH IF ANY SOCIALIZING BECAUSE I AM ALWAYS IN PAIN. MW5035323 UPDATE ON (B)(6) 2014: HAD MY HYSTERECTOMY ON (B)(6) 2014, THEY REMOVED MY UTERUS, FALLOPIAN TUBES WITH ESSURE COILS AND MY CERVIX. THE COILS HAD NOT MIGRATED AT ALL BUT MY FALLOPIAN TUBES WERE IRRITATED. SINCE HAVING THE SURGERY THE DAILY CHRONIC HEADACHES ARE GONE, EXTREME ABDOMINAL PAIN AND BLOATING ARE GONE, NO MORE LOWER BACK PAIN, NO HIP PAIN, NO DEPRESSION OR CRAZY MOOD SWINGS, NO MORE EXCESSIVE FATIGUE OR INTENSE DRY MOUTH, THE ALL OVER ITCHINESS SEEMS TO BE GONE AND MY PLANTAR FASCIITIS HASN'T BEEN AN ISSUE AT ALL SINCE. I CAN EXIST ON A DAILY BASIS LIKE A NORMAL PERSON NOW AND MY HUSBAND AND KIDS DON'T RUN FROM ME ANYMORE BECAUSE I AM NOT SO EXTREMELY MOODY LIKE I WAS BEFORE. MW5035323 UPDATE ON (B)(6) 2014: PATHOLOGY REPORT FROM HYSTERECTOMY SHOWS EXTENSIVE ADENOMYOSIS WITHIN THE UTERUS, ENDOCERVIX - NABOTHIAN CYSTS, LEFT FALLOPIAN TUBE - PARATUBAL CYSTS. THE UTERUS AND CERVIX WEIGHED 332 GRAMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036242	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

6 MONTHS AFTER RECEIVING ESSURE, I EXPERIENCED HEAVY BLEEDING, RANDOM STABBING PAINS IN MY ABDOMEN, DIFFICULTY AT TIMES HAVING INTERCOURSE, BLOATING, TIREDNESS AND FATIGUE, HOT FLASHES, AND DEPRESSION AND MOOD CHANGES, IN 2012 I WAS ALSO DIAGNOSED WITH ANA. (B)(4) - UPDATE ON (B)(6) 2014: SCHEDULED TO HAVE A HYSTERECTOMY ON JUNE (B)(6) 2014...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036243	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 2/28/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2013....I HAVE REPORTED SEVERAL SIDE EFFECTS ON HERE AND THEY NEVER SHOW UP, SO I CANT GO IN AND MODIFY. I HAVE HAD SEVERE STOMACH PAINS CONSTANTLY, BV, I AM IN MENOPAUSE AT (B)(6), I HAVE HOT FLASHES CONSTANTLY. I LOOK PREGNANT AND I'VE NEVER BEEN PREGNANT DUE TO BLOATING! CONSTANTLY TIRED AND I BREAK OUT WITH LITTLE PIMPLES EVERYWHERE. NEVER HAD ANY PROBLEMS UNTIL AFTER ESSURE. (B)(4) UPDATE ON (B)(6) 2014: I'VE HAD A HYSTERECTOMY ON (B)(6) 2014 ALMOST 1 WEEK POST OP AND MY SYMPTOMS OF WEIGHT GAIN (LOST 16 LBS FIRST WEEK), BLOATING WENT AWAY (EVEN WITH A HYSTO), DAILY STABBING PAIN PELVIC AREA ... GONE! SO GLAD ESSURE WAS REMOVED FROM ME!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036244	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 1/7/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LOWER ABDOMINAL PAIN, HEAVY BLEEDING WITH LARGE BLOOD CLOTS GOLF BALL SIZE AND LARGER. HEADACHES FEELING OF EXHAUSTION BLISTERS ON FEET COMPLETE BODY ACHING IN JOINTS A LOT BLOATING INCREASED DEPRESSION, IRRITABILITY. SWELLING SHARP SHOOTING PAINS IN THE VAGINAL AREA PAINFUL WHEN HAVING SEX. (B)(4) UPDATE ON (B)(6) 2014: I STILL HAVE NO ENERGY ALWAYS IRRITABLE. I HAD A DNC ENDOMETRIAL ABLATION AND CERVICAL BIOPSY IN (B)(6) 2013 BLEEDING HASN'T STOPPED, IT DID SLOW DOWN BUT IT INCREASINGLY GETTING HEAVY AGAIN. DEPRESSION IS GETTING WORSE AND ABSOLUTELY NO SEXUAL INTEREST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036245	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE ON (B)(6) 2013. I HAD AN HSG TEST DONE 3 MONTHS LATER TO CONFIRM 100% BLOCKAGE. SINCE (B)(6) 2013 I HAVE EXPERIENCED EXTREME STABBING PAINS IN MY LEFT FALLOPIAN TUBE, TERRIBLE MOOD SWINGS, EXTREME ANXIETY AND DEPRESSION IN WHICH I NEEDED TO SEEK COUNSELING AND A PRESCRIPTION OF XANAX. I ALSO HAVE EXPERIENCED ON A DAILY BASIS BLADDER ISSUES. I HAVE PROBLEMS GOING TO THE BATHROOM, PROBLEMS EMPTYING MY BLADDER, LEAKAGE, AND PAIN WHILE URINATING. I AM CONSTANTLY TIRED. I AM CONSTANTLY BATTLING HEADACHES AND SINUS INFECTIONS. MY BODY IS SORE LIKE IT'S FIGHTING OFF AN ILLNESS EVERY SINGLE DAY. MY MENSTRUAL CRAMPS ARE EXTREMELY PAINFUL AS WELL. THESE SYMPTOMS ARE AFFECTING MY LIFE AS A MOTHER AND WIFE. I REGRET EVER GETTING THIS PRODUCT IMPLANTED IN MY BODY. (B)(4). MW5035513 UPDATE ON (B)(6) 2014: AS OF (B)(6) 2014, AFTER SEEKING A NEW OB-GYN I WAS SENT FOR AN ULTRASOUND AND MAMMOGRAM OF MY LEFT BREAST AND MY LYMPH NODES ARE INFLAMED. MY BODY IS FIGHTING OFF THE FOREIGN BODY OF ESSURE. I HAVE TO HAVE A HYSTERECTOMY IN (B)(6) 2014 TO REMOVE THEM. AT THE AGE OF (B)(6) I SHOULD NOT HAVE TO GO THROUGH THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036246	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I'VE HAD ESSURE IMPLANTED I BLEED SUPER HEAVY WHEN I'M ON MY PERIOD. I CRAMP UP EVERYDAY AND WHEN I'M ABOUT TO START MY PERIOD A WEEK BEFORE I START GETTING PAINS LIKE I AM GOING INTO LABOR, IT'S TERRIBLE. I AM CONSTANTLY BLOATED, MY ABDOMEN SWELLS A LOT TOO. MY BREASTS HURT TERRIBLY. I SPOT THROUGHOUT THE MONTH. WHEN I STRETCH MY FALLOPIAN TUBES HURT, IF THAT MAKES ANY SENSE. TERRIBLE BACK PAIN AND HEADACHES. LEGS HURT ALL THE TIME. JUST ALWAYS IN A LOT OF ABDOMEN PAIN. (B)(4). MW5035651 UPDATE ON (B)(6) 2014: I FORGOT TO MENTION THAT AFTER I HAD THE ESSURE PROCEDURE DONE I BLED FOR 6 MONTHS STRAIGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036247	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WE'LL FROM THE MOMENT THEY PUT ESSURE IN ON (B)(6) 2012, I HAVE HAD BACK AND PELVIC PAIN JOINT PAIN HAIR LOSS AND BLOATING.... AROUND (B)(6) 2013, I DEVELOPED A RASH ALL OVER MY LOWER HALF OF MY BODY AND VAGINAL AREA DUE TO RASH AND PAIN LOSS OF SEXUAL ACTIVITY WITH HUSBAND. (B)(4) UPDATE ON (B)(6) 2014: WILL GO IN FOR A LAVH ON THE (B)(6), LEAVING MY OVARIES HOPING TO TAKE CARE OF THE PELVIC PAIN, THE PAINFUL INTERCOURSE, THE JOINT PAIN, AND THE HAIR LOSS AMONG MANY OTHER THINGS WILL SUBMIT ANOTHER UPDATE AFTER SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036248	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DAY ESSURE WAS PLACED ((B)(6) 2011), I EXPERIENCED HEAVY CRAMPING DURING THE PROCEDURE. IMMEDIATELY FOLLOWING THE PROCEDURE, I WAS NAUSEATED AND FATIGUED FOR THE ENTIRE DAY. I HAD TO RECEIVE 2 FOLLOW-UP HSG TESTS AND DURING BOTH I SUFFERED FROM SEVERE CRAMPING. IN (B)(6) 2012, I BEGAN TO EXPERIENCE ANXIETY ALONG WITH PELVIC PAIN. SINCE THIS ONSET OF SYMPTOMS, I HAVE EXPERIENCED THE FOLLOWING: EXTREME MOOD SWINGS, PELVIC PAIN, SEVERE CRAMPING DURING MENSTRUATION, NUMBNESS AND TINGLING IN THE EXTREMITIES, INCREASE IN ACNE (HAD TO BEGIN USING (B)(6)), ONSET OF ENVIRONMENTAL ALLERGIES, DRY/BRITTLE HAIR, INCREASE IN HAIR GROWTH, SEVERE YEAST INFECTION, SHARP PAINS DURING INTERCOURSE, JOINT PAINS, FATIGUE, MEMORY LAPSES AND BRAIN FOG, CHANGES IN MENSTRUAL CYCLE, FOOD SENSITIVITIES, RECURRING ULCERS ON THE TONGUE, ACID REFLUX, AND CHRONIC RHINITIS. (B)(4). MW5035313 UPDATE ON (B)(6) 2014: AFTER UNDERGOING SEVERAL BLOOD TESTS AND PHYSICAL EXAMINATIONS TO RULE OUT OTHER CONDITIONS, ALL OF WHICH CAME BACK NEGATIVE, IT WAS CONCLUDED THAT I WAS EXPERIENCING A REACTION TO THE ESSURE DEVICE. I UNDERWENT A LAPAROSCOPIC SUPRACERVICAL HYSTERECTOMY ON MAY 7, 2014 WITH A MINI ABDOMINAL INCISION. DURING SURGERY, THE PHYSICIAN REMOVED ENDOMETRIOSIS, OVARIAN CYSTS, AND MY UTERUS AND FALLOPIAN TUBES IN TACT THROUGH THE PELVIC INCISION. THE PATHOLOGY REPORT FINDINGS INCLUDED - UTERUS, BILATERAL FALLOPIAN TUBES, AND ESSURE COILS SUPRACERVICAL HYSTERECTOMY: SUPRACERVICAL UTERUS: 42 G; ESSURE COILS IDENTIFIED (GROSS EXAMINATION); ADENOMYOSIS OF THE LEFT TUBOUTERINE JUNCTION IS IDENTIFIED; BENIGN PROLIFERATIVE ENDOMETRIUM; BENIGN RIGHT AND LEFT FALLOPIAN TUBES WITH BILATERAL PARATUBAL CYSTS; ENDOSALPINGIOSIS OF LEFT PARATUBAL SOFT TISSUE; INTRALUMINAL STROMAL WITH CALCIFICATION INVOLVING THE RIGHT TUBE; NO DYSPLASIA, HYPERPLASIA, OR MALIGNANCY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

IDENTIFIED. LEFT OVARIAN CYST: BENIGN CYST WITH FEATURES SUGGESTIVE OF A HEMORRHAGIC CORPUS LUTEUM CYST; NO DYSPLASIA OR MALIGNANCY IDENTIFIED. DURING MY POST-OPERATIVE VISIT, THE PHYSICIAN INFORMED ME THAT ENDOMETRIOSIS WAS STILL PRESENT ALONG MY URETERS AND BLADDER. SHE REQUESTED TO TREAT IT WITH DEPOT LUPRON FOR 6 MONTHS AND I DENIED TREATMENT. I WILL RECEIVE TREATMENT IF I BECOME SYMPTOMATIC IN THE FUTURE AND I AM TO FOLLOW-UP AT MY ANNUAL VISIT IN (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036251	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 5/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ONGOING ECZEMA AND/OR PRURITIS AS WELL AS BLURRED VISION AND ABDOMINAL BLOATING FOR A FEW YEARS. MOST RECENTLY, I DISCOVERED THAT I HAVE BLOOD IN MY URINE AND AN UMBILICAL HERNIA. THE HERNIA IS MOST LIKELY NOT RELATED, BUT THE OTHER SYMPTOMS ARE CONSISTENT WITH OTHERS WHO HAVE UNDERGONE THE ESSURE PROCEDURE. I HAVE TRIED CHANGES IN MY DIET AND ENVIRONMENT TO DEAL WITH THE EVER PRESENT SKIN ISSUES; I AM EXPERIENCING BURNING AND ITCHING ON NUMEROUS AREAS NOW. I LOOK SEVERAL MONTHS PREGNANT DESPITE ALL THE EXERCISE I DO EVERY DAY AND I HAVE ABDOMINAL PAIN PRETTY CONSISTENTLY AS WELL. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036256	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE MIGRAINES, CYST ON OVARIES, SHARP PAINFUL LOWER ABDOMINAL PAIN, LOWER BACK PAIN, DIZZINESS, PAIN DURING INTERCOURSE, SHARP NUMBING PAIN IN RIGHT LEG, MOOD SWINGS, REAL HEAVY IRREGULAR PERIODS, NONE OF WHICH I HAVE HAD BEFORE ESSURE. (B)(4). UPDATE ON (B)(6) 2014: WEIGHT GAIN, AND BLOATING NO MATTER WHAT I DO/TRY I CAN NOT GET IT TO STOP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036257	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 4/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLEEDING PROFUSELY WITH GOLF BALL SIZED BLOOD CLOTS CHANGING PADS 2 TIMES PER HOUR WITH PERIODS LASTING OVER 10 DAYS AND REOCCURRING AFTER 2 WEEKS. CRAMPS WERE EXTREMELY PAINFUL CAUSING MISSED WORK DAYS AND NOT ABLE TO GET OUT OF BED. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036261	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 5/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAD THE DEVICE PLACED, I HAVE HAD MANY ADVERSE SIDE EFFECTS. I HAVE EXPERIENCED EXTREME FATIGUE, WEIGHT LOSS, MOUTH SORES, HEADACHES, EXTREME ABDOMINAL PAIN DURING PERIODS, VERY HEAVY, BRIGHT RED, BLEEDING WITH SIGNIFICANT CLOTTING DURING PERIODS. I ALSO HAVE JOINT PAIN, TINGLING AND NUMBNESS IN LIMBS, MAINLY ARMS. FURTHER, IT SEEMS THAT THIS HAS INTERFERED WITH MY IMMUNE SYSTEM, AS I HAVE HAD A VERY DIFFICULT TIME FIGHTING OFF INFECTIONS, AND BECOMING ILL ON A MUCH MORE CONSISTENT BASIS THAN EVER BEFORE IN MY LIFE. I AM GENERALLY HEALTHY, AND HAVE MAINTAINED A HEALTHY LIFESTYLE AND WEIGHT. I HAVE HAD NUMEROUS BLOOD TESTS TO RULE OUT OTHER ILLNESSES, AND THERE IS SIMPLY NO OTHER EXPLANATION FOR THE SYMPTOMS THAT I AM EXPERIENCING, OTHER THAN ESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036268	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 4/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS INJECTED WITH ESSURE ON (B)(6) 2013 AT THE IN OFFICE DOCTORS VISIT. I HAD EXCRUCIATING PAIN THAT SHOT THROUGH MY ORGANS. I WAS CRYING AND THEN LAUGHING TO TRY AND STOP THE PAIN BECAUSE I WAS BEING TOLD RELAX JUST BREATH! I STARTED BLEEDING THAT NIGHT... AND DID NOT STOP BLEEDING UNTIL (B)(6) 2013 (THREE DAYS AFTER MY BILATERAL SALPINGECTOMY) I GAINED 40 POUNDS, I WAS EXTREMELY FATIGUED, I COULD NOT MOVE WITHOUT SHOOTING STABBING PAINS IN MY OVARY AREAS. I HAD SEVERE HEADACHES, HAIR LOSS, I CALLED OFF WORK DUE TO THE DEBILITATING PAIN ALL THE TIME. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036273	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WEIGHT ISSUES (LOSS/ GAIN); RINGING IN EARS (PULSATILE TINNITUS) /EAR ACHE (FEELS LIKE AN INFECTION), DEPRESSION (SADNESS/SUICIDAL THOUGHTS), HIGH BLOOD PRESSURE, ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE (VULVODYNIA), UTI/ BLADDER INFECTIONS, SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN (PARESTHESIA), YEAST INFECTIONS (CANDIDA), BACTERIAL VAGINOSIS SWELLING OF LEGS/FEET DISCHARGE (ODOR/NO ODOR), MUSCLE SPASMS, DENTAL ISSUES, METALLIC TASTE IN MOUTH, FATIGUE/LOSS OF ENERGY/CHRONIC FATIGUE SYNDROME, DIMINISHED BRAIN FUNCTION (BRAINFOG/CONFUSION/CLOUDY/ FORGETFULNESS/SHORT TERM MEMORY LOSS), PAINFUL OVULATION (MITTELSCHMERZ), VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION), EXCESSIVE SWEATING, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), SKIN IRRITATION/ITCHING, MOOD DISORDERS, INSOMNIA, NIGHT SWEATS, CHEST PAINS/HEART PALPITATIONS, NECK/SPINE PAIN, HOT FLASHES, GASTROINTESTINAL ISSUES (CONSTIPATION, DIARRHEA, HEARTBURN, GAS), HAIR LOSS, DRY SKIN/HAIR/EYES, NAUSEA, HIP PAIN, SEVERE BLOATING, JOINT PAIN, NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), ANXIETY/PANIC ATTACKS, SHARP/STABBING PELVIC PAIN, DIZZINESS, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, BACK PAIN, ALL OVER BODY ACHES/PAIN, INABILITY TO MAINTAIN BLOOD SUGARS (HYPOGLYCEMIA, TREMORS/SHAKY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036280	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 5/9/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LOW BACK PAIN WEIGHT GAIN, PERIODS EARLIER AND EARLIER EVERY MONTH.

(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036283	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 3/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE FAILED AND I HAD A TUBAL PREGNANCY. I AM ALSO EXPERIENCING SWELLING IN MY ABDOMEN AND ALL OVER JOINT PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036288	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 10/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED SWELLING AND HAVING FREQUENT TRIPS TO THE ER. DRY HEAVING,CONSTANT INFECTIONS,ABDOMINAL PAIN, AND SPOTTING AFTER PERIODS. RESTLESS, GROGGY, GROUCHY, AND REALLY BAD HEADACHES. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036293	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 11/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ANEMIA,FATIGUE, UNEXPLAINED BLOOD LOSS,STOMACH PAIN,BODY ACHES UNCONTROLLED, WEIGHT LOSS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036294	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 4/28/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HORRIBLE CRAMPING AND PAIN WITH MUSCLE SPASMS AROUND COILS IN TUBES FOR OVER A YEAR. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036297	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 9/21/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BAD STOMACH PAIN, BLEEDING 3 WKS OUT OF A MONTH, BACK AND LEG PAIN, WEAKNESS AND DEPRESSION. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036298	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 10/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEIZURES, CHRONIC FATIGUE, MIGRAINES, BIG EYE FLOATERS, NO SEX DRIVE, BODY ACHES,CONSTANT BACTERIAL VAGINOSIS, HOT FLASHES, MUSCLE SPASMS,DIZZINESS, FORGETFULNESS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036299	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 10/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS PERFECTLY HEALTHY. I DECIDED WITH MY HUSBAND THAT WE WOULD NOT HAVE ANYMORE CHILDREN BUT BEING THAT I HAD A C-SECTION WITH MY 1ST AND A VBACS WITH MY 2ND CHILD... WE DID NOT WANT TO HAVE ME UNDER THE KNIFE AGAIN. ESSURE SEEMED LIKE THE BEST SOLUTION. IT WAS QUICK AND EASY, OR SO IT SEEMED. I WENT IN A WEEK LATER AND THEN A MONTH AFTER AND ALL WAS WELL EXCEPT FOR CRAMPING WHICH I WAS TOLD WAS NORMAL. THE CRAMPING I FELT HAS YET TO GO AWAY. I GET WEAKNESS IN MY LEGS , I'VE GAINED OVER 100LBS I GET SHARP PIERCING PAINS ON MY RIGHT SIDE WHERE MY OVARY AND FALLOPIAN TUBES HAVE BEEN POINTED OUT IN X-RAYS. I FEEL SLUGGISH. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036300	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 1/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LESS THAN A MONTH AFTER MY HSG TO CONFIRM BLOCKAGE, I STARTED HAVING SEVERE PELVIC PAIN, MIGRAINES, NUMBING IN MY LEGS, SEVERE MONTHLY BLEEDING, WEIGHT GAIN, GI ISSUES(LED TO REMOVAL OF GALLBLADDER), EXTREME FATIGUE, METALLIC TASTE IN MOUTH, SEVERE SWELLING IN LEFT PELVIC AREA, BLOATING AND SWELLING, RASH THAT COMES AND GOES (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036301	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 9/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE GETTING THE ESSURE BIRTH CONTROL, I HAVE EXPERIENCED MANY SIDE AFFECTS. HEAVY BLEEDING DURING PERIODS. PERIODS LASTING FOR TWO WEEKS AT A TIME. BLOOD CLOTS THE SIZE OF GOLF BALLS. EXTREME PAIN IN MY LOWER STOMACH AREA. CONSTANT BREAST PAIN. CYST ALWAYS APPEARING, I TAKE CARE OF IT AND THEN A NEW ONE APPEARS. SINCE HAVING ESSURE, I HAVE BECOME VERY DEPRESSED TO THE POINT OF ATTEMPTING TO COMMITTED SUICIDE AND RESULTED IN MY CHILDREN BEING TAKEN OUT OF MY CARE. I'M NOW HAVING TO BE ON MEDICATION. I ALWAYS HAVE HEADACHES ALONG WILL ENTIRE BODY ACHES. I HAVE GAIN A LOT OF WEIGHT SINCE HAVING ESSURE AND CAN NOT LOOSE WEIGHT NO MATTER HOW HARD I TRY. ESSURE HAS DEFINITELY RUINED MY LIFE IN MANY WAYS. I HAD TO HIRE A LAWYER TO GET BACK MY KIDS AND NOW GOING ON TWO YEARS WITHOUT MY BABY'S. NOW AS OF (B)(6), HAVE NOT HAD A PERIOD STILL ACHY EVERYWHERE, NOT SURE IF I AM PREGNANT OR NOT. THIS DEFINITELY NEEDS TO BE TAKEN OFF THE MARKET. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036302	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 12/5/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS IMPLANTED (B)(6) 2009. SEVERAL WEEKS AFTER BEING IMPLANTED WITH ESSURE I STARTED EXPERIENCING EXCRUCIATING PAIN IN MY LEFT LEG AND KNEE. SO MUCH SO THAT I WENT TO THE DR WHERE I WAS TOLD I WAS VIT D DEFICIENT. I WAS PRESCRIBED A HIGH DOSE OF VIT D AND THAT HELPED FOR A WHILE. THE PAIN WOULD COME AND GO AND I WOULDN'T THINK MUCH OF IT UNTIL I WAS IN PAIN WHERE I WOULD UP MY VIT D. I STAYED IN PAIN IN MY LOWER BACK AS WELL. I COULDN'T EVEN JUST BEND DOWN TO PICK SOMETHING UP WITHOUT HOLDING ON TO SOMETHING. I WOULD SOMETIMES NOT EVEN BE ABLE TO WALK BECAUSE THE BACK PAIN WAS UNBEARABLE. I WOULD BE EXTREMELY DIZZY I WAS DIAGNOSED WITH VERTIGO. I WENT TO DRS AND HOSPITAL MORE TIMES THAN I SHOULD HAVE FOR WHAT I THOUGHT WAS A STROKE OR HEART ATTACK. I BEGAN HAVING MANY PANIC/ANXIETY ATTACKS. I BEGAN FEELING SUCH DEPRESSION THAT I COULD NOT BE MOTIVATED TO DO ANYTHING. I MISSED A GOOD AMOUNT OF DAYS FOR DISCOMFORT IN MY STOMACH. IT WAS NOT QUITE A STOMACH BUG BUT GAS THAT WAS TRAPPED IN THERE AND MY STOMACH WOULD BLOW UP AND BE SO HARD THAT I STARTED OMITTING ANYTHING THAT I THOUGHT WOULD CAUSE BLOATING/GAS FROM MY DIET. THE MIGRAINES WERE BECOMING VERY SCARY. I THOUGHT FOR SURE MY HEAD WOULD ONE DAY JUST EXPLODE OR THAT I HAD TO HAVE A TUMOR BECAUSE THAT KIND OF PAIN COULD NOT BE NORMAL. I WAS SENT TO AN EYE DR THAT SPECIALIZED IN ISSUES OF THE RETINA. AND I WAS SENT TO A NEUROLOGIST AS WELL. THE LEFT SIDE OF MY BODY STAYED FEELING NUMB AND TINGLY. I ALWAYS FELT AS THOUGH MY BODY WAS GOING TO HAVE A SEIZURE OR THAT IT WAS NOT RIGHT. I KEPT FEELING "OFF" I WOULD BE TALKING AND IF I DIDN'T COMPLETELY FORGET WHAT I WAS TALKING ABOUT I FELT LIKE I COULD JUST NOT FORM COMPLETE SENTENCES AT TIMES. I HAD SHARP PAINS IN MY PELVIC AREA AND BELLY BUTTON AREA. I WOULD HAVE SUCH BAD MENSTRUAL CYCLES I HAD MANY

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ACCIDENTS AT WORK BECAUSE EVEN THOUGH I WOULD HAVE TO DOUBLE UP WITH A PAD AND TAMPON I WOULD STILL BLEED THROUGH. THE CRAMPING WAS THE WORST I HAD EVER FELT THAT I WOULD PRAY THAT MY PERIOD WOULD BEGIN ON A WEEKEND DAY SO I WOULDN'T SUFFER SO MUCH AT WORK. ON SEVERAL OCCASIONS I REMEMBER THINKING THAT MY UTERUS FELT AS THOUGH IT WAS GETTING READY TO PUSH OUT A BABY. I WOULD FEEL VERY TENDER DOWN THERE AND SINCE I WAS BLEEDING I WOULD TRY TO PUT ON A TAMPON THINKING IT WAS MY PERIOD AND IT WAS EXTREMELY PAINFUL TO INSERT ONE. I CAN ONLY THINK THAT I WAS POSSIBLY HAVING MISCARRIAGES ON THOSE OCCASIONS. I FEEL THAT ESSURE WAS AT LEAST KEEPING ITS WORD ABOUT BEING BIRTH CONTROL BECAUSE MY HUSBAND AND I WERE UNABLE TO HAVE INTERCOURSE AT TIMES DUE TO HOW MUCH IN PAIN I WAS. I COULD FEEL MY FALLOPIAN TUBES HURTING SO MUCH THAT I COULD NOT EVEN HAVE RELATIONS WITH MY HUSBAND. I HAD SO MANY OTHER ISSUES THAT I WENT TO MY IMPLANTING DR WITH MY ISSUES. AFTER HE DISMISSED ALL MY ISSUES I KNEW THAT IT WAS TIME TO CHANGE TO A DIFFERENT GYNO. I FOUND A WOMAN GYNO AND TOLD HER ABOUT ALL OF MY ISSUES AND SHE KNEW THAT THE ONLY WAY TO HELP ME GET RELIEF WAS TO HAVE A HYSTERECTOMY. I CAN SAY THAT THE MONTH BEFORE I HAD MY HYSTERECTOMY (SURGERY DATE (B)(6) 2014) WAS THE WORST THAT I HAD EVER FELT IN THE 4 YEARS I HAD THE COILS IMPLANTED. I FELT AS THOUGH I HAD A HOT IRON ON THE UPPER LEFT PART OF MY BACK AND I COULDN'T LAY DOWN ON MY BACK TO SLEEP OR EVEN SIT BACK AS I WAS IN A LOT OF PAIN AND DISCOMFORT. I ALSO FELT BRUISING ON THE INSIDE OF MY SKIN THAT I COULDN'T SEE VISIBLY ON MY SKIN. I AM NOW 12 WEEKS POST OP AND I AM STILL STRUGGLING WITH ISSUES. I HAVE STARTED SEEING A CLINICAL KINESIOLOGIST AND HE FOUND ME TO BE ESTROGEN DOMINANT, MY LIVER IS NOT FUNCTIONING PROPERLY AND SOMETHING IN MY BODY IS DEPLETING MY ZINC AS MY LEVELS ARE VERY LOW. I AM TRYING TO FEEL "NORMAL" AND IT SEEMS THAT THE COILS HAVE LEFT A MESS IN MY BODY. I WAS ONCE A RATHER HEALTHY WOMAN AND NOW I JUST WANT TO FEEL AT LEAST 80% BACK TO NORMAL. I CAN SAY THOUGH THAT THE PAIN THAT I FELT IN MY LEFT LEG AND LOWER BACK PAIN SINCE IMPLANTATION WAS GONE IMMEDIATELY AFTER MY HYSTERECTOMY. I HAD SUBMITTED AN ADVERSE REPORT BACK IN JANUARY THIS IS MY UPDATED ONE. MY ACCESS NUMBER IS: MW5034024. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036303	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 11/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NONE STOP SINUS INFECTION, EAR ACHES, BREAST TENDERNESS AND SWOLLEN, WEIGHT GAIN, PELVIC PAIN, BACK PAIN, HEAVY MENSTRUAL CYCLE OR LATE MENSTRUAL CYCLE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036304	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 4/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE. I WAS AWAKE AT THE TIME, GIVEN A VICODIN PRIOR TO THE PROCEDURE. THE PROCEDURE BEGAN WITH LOTS OF PRESSURE AND PAIN. AFTERWARDS I WAS TOLD I WOULD SPOT BLEED AND BE IN A LITTLE PAIN FOR A OF COUPLE DAYS. AFTER 1 WEEK I WAS STILL BLEEDING HEAVILY AND IN A LOT OF PAIN. I CALLED THE DOCTOR AND WAS TOLD THIS IS NORMAL. END OF WEEK 2 COMES STILL BLEEDING AND LOTS OF PAIN. WEEK 3 FINALLY GET AN APPT AND LABS DRAWN. WAS TOLD AFTER I GET THE DEPOSIT SHOT THEN THE BLEEDING WILL STOP. WELL THAT DIDN'T HAPPEN. GOT THE SHOT HEAVY BLEEDING AND STILL IN EXCRUCIATING PAIN. I HAVE COMPLETELY LOST INTEREST IN SEX. I CONTINUED TO BEG THE DOCTOR TO DO SOMETHING. HE SAYS THERE IS NOTHING HE CAN DO. SO FOR MONTHS IN AND OUT THE BLEEDING AND PAIN CONTINUE. I GO OVER 6 MONTHS OF CONTINUOUS BLEEDING SO BAD IT'S HUGE CLOTS AND PAIN. THE DOCTOR DOES NOTHING. I WAKE UP 1 MORNING AND FEEL VERY WEAK AND LIGHT HEADED, ALMOST PASS OUT. I GO TO THE ER AND THEY RUN TESTS. I'M SEVERELY ANEMIC AND WAS TOLD POSSIBLY GOING TO BE ADMITTED. BUT THEY GOT ME AN APPT FOR A GYN DOCTOR AT THE CLINIC. I GO VISIT HER AND SHE WAS AMAZED AT THE BLOOD LOSS. SHE REFERRED ME TO A SPECIALIST. THE MEAN TIME STILL BLEEDING AND IN PAIN, NO SEX DRIVE AT ALL. DID LOTS OF ULTRASOUNDS AND HSG AND THE ESSURE IS MISSING OUT OF ONE TUBE AND THEIR IS LEAKAGE AFTER HAVING THEM IN NOW OVER A YEAR. STILL IN PAIN. BLEEDING BETTER. STILL NO SEX DRIVE, SEX IS VERY PAINFUL. THIS DEVICE HAS CAUSED ME PAIN THIS WHOLE TIME. IT'S BEEN 2YRS AND I'M STILL IN EXCRUCIATING PAIN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036305	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 4/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAIR LOSS, PAINFUL INTERCOURSE, HURTS TO SIT DOWN BECAUSE I'M TOO SWOLLEN, SHARP PAINS, UTERUS LINING THICKENING, LOW SEX DRIVE, LOW ENERGY, MIGRAINE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036306	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 12/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

BEGINNING IN (B)(6) WERE THE SEVERE UTERINE CRAMPS (SO SEVERE I WOULD DOUBLE OVER). THE LAST WEEK OF (B)(6), MY EYES BEGAN TO HAVE A SKIN REACTION. I ENDED UP GOING TO URGENT CARE IN (B)(6), FOLLOWING THE HSG TEST WITH EYE IRRITATION AND SKIN ITCHING. I HAVE SINCE BEEN TO MY FAMILY DOCTOR AND AN ALLERGIST. I WAS NOT PREVIOUSLY ALLERGIC TO THE MATERIALS I CURRENTLY AM AND STILL HAVE THE PAIN, CHRONIC FATIGUE AND HAVE BEGUN ALLERGY SHOTS. PATCH TESTING SHOWS ALLERGIES TO SEVERAL MATERIALS IN THE COILS. (B)(4). UPDATE ON (B)(6) 201421: LOT # 30-257-DK, EXPIRATION JUNE 1, 2015. HAVE SINCE BEEN TO MY OB/GYN AND WILL BE HAVING A HYSTERECTOMY AND FALLOPIAN TUBES REMOVED (B)(6). I CONTINUE TO HAVE DEBILITATING CRAMPS, ALLERGY ISSUES AND CHRONIC FATIGUE. ALSO WANTING TO NOTE THAT BOTH PLACEMENT AND HSG TESTING WERE DONE WHILE UNDER NO ANESTHESIA RESULTING IN EXTREME DISCOMFORT AND PAIN DURING BOTH PROCEDURES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036307	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 2/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING, SPOTTING, ERRATIC MENSTRUAL CYCLES (COULD NOT BE CONTROLLED OR LESSENED BY BIRTH CONTROL PILLS), PASSING LARGE CLOTS, MIGRAINES, HAIR LOSS, JOINT PAIN, BACKACHES, FATIGUE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036308	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 5/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AS SOON AS I GOT THE PROCEDURE, I STARTED HAVING PROBLEMS, PAIN, BLEEDING FOR FIVE MONTHS, HEADACHES, ABDOMINAL CRAMPING, BLOATING AND A LOT OF HAIR LOSS. YESTERDAY MORNING, I WENT TO USE THE BATHROOM AND NOTICED A PIECE OF THE SPRING ON MY TOILET PAPER AFTER I WIPED. THAT WHOLE DAY, I HAD HORRIBLE BLEEDING AND CRAMPING. I WENT TO THE E.R AND THEY DID BLOOD WORK AND X RAY'S. WHEN MY RESULTS CAME BACK, THEY SHOWED THAT BOTH SPRINGS ARE OUT OF PLACE. ONE IS HIGH ABOVE ONE TUBE AND THE OTHER IS BROKEN INTO TWO PIECES INSIDE MY UTERUS... NOT INCLUDING THE PIECE THAT ALREADY CAME OUT. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036309	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HORRIBLE HEADACHES, HORRIBLE BLEEDING DURING CYCLE! I HAVE HORRIBLE ITCHING IN EARS! HAVE RECENTLY HAD BAD INFECTIONS IN EARS. HAVE OCCASIONAL ABDOMINAL PAINS! LOWER BACK PAINS! ALL ITEMS NOT AT ONCE, BUT OVER THE 5YRS I HAVE HAD ESSURE! (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036310	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

BEGAN HAVING NEW ALLERGIC REACTIONS TO FOODS, VITAMIN D DEFICIENCY, TACHYCARDIA, NIGHT SWEATS, WEIGHT GAIN, ANXIETY, PELVIC PAIN, BACK PAIN, AND PALPITATIONS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036311	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 8/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN PELVIC, ALLERGIES TO NICKLE, HEADACHES/MIGRAINES, MESSED UP MENSTRUAL CYCLE, SUDDEN FOOD ALLERGIES, PAINFUL SEX. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036312	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 6/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE GETTING IMPLANTED WITH ESSURE I HAVE HAD ERRATIC PERIODS, SEVERE PMS, HEAVY BLEEDING, PAIN WHILE OVULATING (SO BAD I CANNOT SIT DOWN WITHOUT FEELING LIKE MY UTERUS IS A HUGE BALLOON AND TEARING THROUGH MY ENTIRE BODY) I HAVE EXTREME FATIGUE, UNEXPLAINED RASHES, PAIN AT ALL TIMES ESPECIALLY OVULATION UP TO MY PERIOD WHERE I HAVE EXTREME ROUND LIGAMENT PAINS. THE PAIN IS SOMETIMES SO BAD I MISS OUT ON TIME BEING A MOM AND HAVING TO MISS WORK. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036313	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 4/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT HURT BAD WHEN THE ESSURE COIL WAS PLACED IN MY RIGHT FALLOPIAN TUBE. EVER SINCE PLACEMENT, I HAVE BEEN EXPERIENCING SHARP, STABBING PAINS ON MY RIGHT SIDE AND CONSTANT CRAMPING WITH LOWER BACK PAIN IN MY RIGHT SIDE. I HAD A CT SCAN AND X-RAY(HSG) TO DETERMINE IF THE COIL HAD MIGRATED. MY RIGHT COIL DID MIGRATE UP TOO FAR INTO MY FALLOPIAN TUBE. NOW I AM HAVING BOTH (R AND L) FALLOPIAN TUBES AND THE ESSURE REMOVED COMPLETELY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036314	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 12/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE EXPERIENCED SO MANY PROBLEMS SINCE HAVING THIS PROCEDURE DONE. DIZZINESS, FATIGUE, TEETH FALLING OUT AND ROTTEN, LIGHT HEAD, TRYING TO FAINT, STOMACH AND ABDOMEN PAIN, NOT TO MENTION ALWAYS BEING SICK IN STOMACH SAYS ITS IRRITABLE BOWEL SYNDROME, AND MANY MORE VARIOUS PROBLEMS. DOCTORS DON'T EVEN THINK ITS THAT OR THEY DON'T EVEN KNOW WHAT IT IS. I HAVE NO INSURANCE SO HAVE A LOT OF EMERGENCY BILLS SINCE HAVING THIS DONE FOR VARIOUS REASONS LISTED ABOVE. THIS HAS AFFECTED MY DAILY LIFE SO MUCH CAN'T GO OUT BECAUSE OF STOMACH NEVER KNOW WHEN I WILL HAVE THESE PAINS AND GET SICK. MISSING ON SO MUCH WITH MY 4 KIDS AND SCHOOL EVENT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036315	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 11/6/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DIZZINESS, FATIGUE, TEETH FALLING OUT AND ROTTEN, LIGHT HEADED, FAINTING SPELLS RESULTING IN SERIOUS INJURIES AND SURGERY. HEAVY BLEEDING, SPOTTING, ERRATIC MENSTRUAL CYCLES (COULD NOT BE CONTROLLED OR LESSENED BY BIRTH CONTROL PILLS), PASSING LARGE CLOTS, MIGRAINES, HAIR LOSS, JOINT PAIN, BACKACHES, FATIGUE, STABBING PAIN IN PELVIC AREA AND LOWER BACK, CONSTANT SHARP PAIN FROM R BUTTOCK THROUGH R HIP, LEG, FOOT TO TOES, NUMBNESS IN LEGS, FEET, MEMORY FOG, HIGH PITCHED RINGING IN BOTH EARS, NEUROLOGICAL PROBLEMS, INABILITY TO TYPE, NUMBNESS IN LEGS, MULTIPLE FALLS, FIBROMYALGIA, STRESS, URINARY URGENCY, VOIDING DIFFICULTIES, RETENTION OF URINE, PELVIC MASS, SEVERE DEPRESSION, EXCESSIVE THIRST, FORGETFULNESS, TROUBLE WORD RECALL, STOMACH AND ABDOMEN PAIN, NOT TO MENTION ALWAYS NAUSEOUS, AND MANY MORE VARIOUS PROBLEMS. DOCTORS DON'T EVEN KNOW WHAT IT IS. I HAVE NO INSURANCE, SO HAVE A LOT OF EMERGENCY BILLS SINCE HAVING THIS DONE FOR VARIOUS REASONS LISTED ABOVE. THIS HAS AFFECTED MY DAILY LIFE SO MUCH, CAN'T WORK, SOCIALIZE, OR GO OUT BECAUSE I NEVER KNOW WHEN I WILL HAVE THESE PAINS AND GET SICK. MISSING SO MUCH WITH MY 3 KIDS, FAMILY, FRIENDS, JUST MISSING LIFE. I WANT THESE THINGS OUT AND CANNOT EVEN GET THAT DONE! LATELY I'VE HAD TROUBLE BREATHING AND DIFFICULTY SWALLOWING. BENADRYL HELPS, SO I GUESS MY ONLY CHOICE IS TO PRAY THE COILS AREN'T CAUSING THAT ALLERGIC REACTION. MY DISABILITY WAS DENIED AS THE SSA DOESN'T SEE WHY I CAN'T FUNCTION AND WORK. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036316	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PERIODS ARE BADLY MESSED UP, EXTREME STOMACH PAINS, SEX BOUT KILLS ME, FATIGUE, NAUSEATED ALL THE TIME; DOCS TELL ME I HAVE IRRITABLE BOWEL SYNDROME. DIZZY NEAR FAINTING. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036317	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 3/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE PROCEDURE, I HAVE GAINED ALMOST 60 PDS. I HAVE DEVELOPED COMPLICATED MIGRAINES HAVING SHARP STABBING PAIN IN STOMACH. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036318	BAYER	5/28/2014	5/28/2014

Event Information:

Event Date (B3): 10/20/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS HAVING SEVERE CRAMPS, ITCHING, AND BURNING FOR THE ENTIRE MOUTH, SO MY DOCTOR ORDERED AN ULTRASOUND; WHEN I WENT IN, MY DOCTOR PRESCRIBED ME 5 MG NORETHINDRONE; IT HELPED THE CRAMPS BUT STILL HAD ITCHING AND BURNING, SO I FOUND THAT IT GOT WORSE DURING INTERCOURSE, SO WE STARTED USING CONDOMS WHICH HELPED SOME BUT STILL GOING ON AND MY CRAMPS ARE NOT WHAT THEY WERE BUT THEY'RE COMING MORE OFTEN AND IT FEELS LIKE MY INSIDES ARE BEING PINCHED (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036428	BAYER	5/28/2014	6/4/2014

Event Information:

Event Date (B3): 5/31/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/31/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN 2009. SINCE THEN I HAVE EXPERIENCED SYMPTOMS AND PROBLEMS FROM THE DAY I GOT OUT OF THE PROCEDURE. I AM LIGHT HEADED, DIZZY, VOMITING, DIARRHEA, MENSTRUAL IRREGULARITIES, INCONTINENCE, MIGRAINES, TEETH PROBLEMS, VISION PROBLEMS, FATIGUE, MUSCLE AND BODY ACHES, DIABETES TYPE II, HIGH BLOOD PRESSURE, MOOD CHANGES, MEMORY LOSS, DIFFICULTY CONCENTRATING, IRRITABILITY, SLEEP APNEA AND FINALLY TACHYCARDIA AND BRADYCARDIA. MY HEART ACTUALLY HAS STOPPED DURING A TEST FOR 10 SECONDS. ISN'T THAT CONSIDERED LEGALLY DEAD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036403	CONCEPTS, INC.	5/29/2014	6/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED ON (B)(6) 2010 AND HAVE HAD SERIOUS SIDE EFFECTS EVER SINCE. I DO NOT HAVE THE MONEY TO RUN TO THE DOCTOR. I HAVE VERY HEAVY MENSTRUAL CYCLES. I PASS BLOOD CLOTS BIGGER THAN GOLF BALLS EVERY MONTH. I HAVE BEEN SERIOUSLY DEPRESSED FOR OVER THREE YEARS NOW. I HAVE GAINED ABOUT 45 POUNDS. I HAVE SEVERE PAIN IN MY ABDOMEN ALL THE TIME. I HAVE THE PAIN EVEN WHEN I AM NOT ON MY MENSTRUAL CYCLE. I USE TAMPONS AND PADS TOGETHER BECAUSE I BLEED SO SEVERELY. I HAVE HEADACHES SO SEVERE THAT I GO TO MY ROOM SHUT THE DOOR AND CRY WHEN THEY AREN'T MAKING THROW UP BECAUSE THEY HURT SO BADLY. I AM HAVING BAD VISION PROBLEMS. I STAY REALLY TIRED ALL THE TIME. SOME DAYS I AM SO TIRED I DO NOT WANT TO GET OUT OF THE BED BECAUSE I FEEL SO HORRIBLE. THE PAIN FROM THIS DEVICE IS UNBEARABLE AT TIMES. THERE ARE DAYS THAT I FEEL LIKE I HAVE BEEN HIT BY A TRAIN. I AM (B)(6) YEARS OLD AND I WOULD LOVE TO HAVE A HYSTERECTOMY DONE BECAUSE THIS DEVICE HAS ME IN SO MUCH PAIN BUT CANNOT AFFORD TO GO TO THE DOCTOR BECAUSE I DON'T HAVE THE MONEY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00178	BAYER HEALTHCARE LLC	5/29/2014	6/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

UNDERDEVELOPED LUNGS IN PREMATURE BABY [IMMATURE RESPIRATORY SYSTEM] PREMATURE BABY (B)(6) [PREMATURE BABY 26 TO 32 WEEKS]. CASE DESCRIPTION: SERIOUS, RELATED, UNLISTED (INCIDENT, UNANTICIPATED). THIS SPONTANEOUS CASE REPORT WAS REC'D FROM A CONSUMER IN THE UNITED STATES ON (B)(6) 2014 VIA INTERNET. THE REPORT REFERS TO THE PREMATURELY ((B)(6) WEEK) BORN MALE BABY WHOSE MOTHER OF UNSPECIFIED AGE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PREGNANCY WITH ESSURE, ESSURE FAILED, AND ERRANT COIL PERFORATED THE AMNIOTIC SAC CAUSING HER WATER TO BREAK, AND MOTHER WENT INTO PREMATURE LABOR AT (B)(6) WEEKS. BABY'S UNDER-DEVELOPED LUNGS COULD NOT SUSTAIN HIM AND HE DIED ON THE DAY HE WAS BORN. MOTHER'S CASE WAS REPORTED AT BAYER CASE NUMBER (B)(6). NO INFO WAS GIVEN ON MOTHER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE MOTHER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. ON AN UNSPECIFIED DATE, THE MOTHER EXPERIENCED PREGNANCY WITH ESSURE, ESSURE FAILED, AND MOTHER WENT INTO PREMATURE LABOR AT (B)(6) WEEKS AFTER AN ERRANT COIL PERFORATED THE AMNIOTIC SAC CAUSING HER WATER TO BREAK. MALE BABY WAS BORN ALIVE, AND HIS UNDER-DEVELOPED LUNGS COULD NOT SUSTAIN HIM AND HE DIED ON THE DAY HE WAS BORN. REPORTER ASSESSED THE EVENTS WERE RELATED TO ESSURE. F/U -PTC INVESTIGATION RESULT WAS REC'D ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PYC GLOBAL NUMBER (B)(6). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE

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MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFO AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. F/U (B)(6) 2014: REPORTER DENIES FURTHER CONTACT. COMPANY CAUSALITY COMMENT: A SPONTANEOUS CASE OF PREMATURE BABY (B)(6) WEEKS AND UNDERDEVELOPED LUNGS IN PREMATURE BABY IN A MALE BABY, WHOSE MOTHER WENT INTO PREMATURE LABOR AT (B)(6) WEEKS AFTER ERRANT COIL PERFORATED THE AMNIOTIC SAC CAUSING HER WATER TO BREAK IN ASSOCIATION WITH MOTHER;S ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) USE WAS REPORTED BY A CONSUMER. THE MALE BABY DIED ON THE DAY HE WAS BORN. THIS CASE WAS NOT MEDICALLY CONFIRMED. PREMATURE BABY (B)(6) WEEKS AND ITS COMPLICATION UNDERDEVELOPED LUNGS IN PREMATURE BABY WERE REGARDED SERIOUS DUE TO FATAL AND UNLISTED FOR ESSURE IN THE REFERENCE SAFETY INFO. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP A CONTRIBUTIVE EFFECT OF DISLOCATED ESSURE IN BABY'S MOTHER TO THE OCCURRENCE OF THE EVENTS IN THE BABY CANNOT BE EXCLUDED (RELATED). BOTH EVENTS WERE REGARDED AS INCIDENTS. ACCORDING TO THE REC'D PTC (PRODUCT TECHNICAL COMPLAINT) ANALYSIS THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00174	BAYER HEALTHCARE LLC	5/29/2014	6/10/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE (ESS205)
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

EVENT VERBATIM (LOWER LEVEL TERM) (RELATED SYMPTOMS IF ANY SEPARATED BY COMMAS). EXCRUCIATINGLY PAINFUL ESSURE INSERTION AND PAIN FOR AROUND TWO WEEKS AFTER THE PROCEDURE (PROCEDURAL PAIN). CONSTANT AND EXTREME ABDOMINAL PAIN (CHRONIC ABDOMINAL PAIN). THE OTHER SIDE THE DEVICE WAS IN PIECES (DEVICE BREAKAGE). PSYRICES ON HER SCALP (SCALP DISORDER). VAGINAL DISCHARGE (VAGINAL DISCHARGE). LARGE PIECE OF PLASTIC STICKING INTO HER UTERUS (LOOKED LIKE PART OF THE INSERTION CATHETER) (EMBEDDED DEVICE). CASE DESCRIPTION: SERIOUS, LISTED RELATED (INCIDENT). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(4) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION CONTINUED IN ADDITIONAL INFO SECTION INSERT) INSERTED AND EXPERIENCED EXCRUCIATINGLY PAINFUL ESSURE INSERTION AND PAIN FOR AROUND TWO WEEKS AFTER THE PROCEDURE, DIZZINESS, NAUSEA, DIARRHOEA, VOMITING, COLD SWEATS, METAL TASTE IN HER MOUTH. NUMBNESS AROUND THE LIPS, NUMBNESS FACE AND HANDS, CONSTANT AND EXTREME ABDOMINAL PAIN, MIGRAINES, CONFUSION, VAGUENESS, INSOMNIA, LOOSING HAIR, PSYRICES ON HER SCALP, VAGINAL DISCHARGE, JOINT PAIN, CONTACT DERMATITIS, GALL STONES, HANDS AND FEET WOULD SWELL, HER STOMACH WOULD EXPAND TO LOOK LIKE SHE WAS 8 MONTHS PREGNANT, STOMACH WAS HARD AS A ROCK OF HER VISITS TO HER GENERAL PRACTITIONER ABOUT HER ABDOMINAL PAIN, IT WAS IN HER HEAD, LARGE PIECE OF PLASTIC STICKING INTO HER UTERUS (LOOKED LIKE PART OF THE INSERTION CATHETER), AND THE OTHER SIDE OF THE DEVICE WAS IN PIECES. THE CONSUMER'S MEDICAL HISTORY INCLUDED PARITY 3. THE CONSUMER'S CONCURRENT CONDITION INCLUDED GALLBLADDER REMOVED AND NICKEL ALLERGY. NO INFORMATION GIVEN ON CONSUMER'S DRUG HISTORY AND CONCOMITANT MEDICATION. IN 2008 THE CONSUMER HAD ESSURE

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(ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. CLINICAL EVENT INFORMATION: AFTER THE BIRTH OF THIRD CONSUMER'S SON, SHE WANTED A PERMANENT BIRTH CONTROL AND SHE WAS REFERRED TO A HOSPITAL IN 2008 FOR TUBAL LIGATION (TUBES TIED). THE DOCTOR SAID TO HER THAT THERE WAS A RELATIVELY NEW DEVICE THAT WAS IN (B)(6) AND IT HAD BEEN USED FOR 10 YEARS IN THE USA AND HAD BEEN USED IN (B)(6) FOR AROUND 2 YEARS WITH NO SIDE EFFECTS AND WAS LESS INVASIVE THAN TUBAL LIGATION, DONE IN DAY SURGERY, NO HEALING TIME AND IT WOULD TAKE ABOUT 20 MINS TO DO. CONSUMER HAD THE PROCEDURE DONE IT WAS EXCRUCIATINGLY PAINFUL. SHE WAS ONLY GIVEN A LOCAL ANAESTHETIC WHICH DID NOTHING AND WAS IN PAIN FOR AROUND TWO WEEKS AFTER THE PROCEDURE. AFTER ABOUT 6 WEEKS, SHE STARTED GETTING BOUTS OF DIZZINESS, NAUSEA, DIARRHEA, VOMITING, COLD SWEATS, NIGHT SWEATS, METAL TASTE IN HER MOUTH, NUMBNESS AROUND THE LIPS, FACE AND HANDS. THIS HAPPENED EVERY TIME SHE OVULATED AND EVERY TIME SHE HAD A PERIOD AND WOULD LAST FOR AROUND A WEEK EACH TIME. SHE ALSO HAD CONSTANT ABDOMINAL PAIN. SHE WENT SEVERAL TIMES TO THE EMERGENCY WHO RAN BLOOD TEST EVERYTHING CAME BACK WITHIN NORMAL RANGE. CONSUMER KEPT TELLING THEM THERE WAS SOMETHING WRONG WITH THE IMPLANTS AND FINALLY SHE WENT BACK TO THE DOCTOR WHO IMPLANTED ESSURE IN THE CONSUMER AND THIS DOCTOR SAID TO HER IT COULD NOT BE ESSURE AND REFERRED HER TO MENTAL HEALTH AND SAID IT WAS IN HER HEAD. SHE SPENT 2 YEARS ON ANTI-DEPRESSANTS BUT THE SYMPTOMS PERSISTED AND SHE GAINED SOME NEW ONES. SHE HAD EXTREME ABDOMINAL PAIN, MIGRAINES, CONFUSION, VAGUENESS AND INSOMNIA. SHE STARTED LOSING A LOT OF HAIR PSYRICES ON HER SCALP, VAGINAL DISCHARGED THAT WOULD BLEACH HER UNDERWEAR, JOINT PAIN, BLISTERS ON HER HANDS AND FEET THAT HER GENERAL PRACTITIONER DIAGNOSED AS CONTACT DERMATITIS. CONSUMER GOT GALL STONES AND HAD HER GALLBLADDER REMOVED, ENDOSCOPY AND COLONOSCOPY FOR THE NAUSEA, DIARRHEA AND VOMITING AGAIN FINDING NOTHING. CONSUMER'S HANDS AND FEET WOULD SWELL, HER STOMACH WOULD EXPAND TO LOOK LIKE SHE WAS 8 MONTHS PREGNANT AND WAS HARD AS A ROCK ONE OF HER VISITS TO HER GENERAL PRACTITIONER ABOUT HER ABDOMINAL PAIN AND HE SENT HER FOR AN X-RAY BECAUSE HE THOUGHT SHE MIGHT HAVE HAD A BLOCKED BOWL. THERE WAS NOTHING THERE WHEN SHE WAS LOOKING AT THE X-RAY. SHE NOTICED THAT ONE OF THE ESSURE DEVICES LOOKED TO HAVE 2 BROKEN BITS. SHE GOT A REFERRAL TO ANOTHER DOCTOR WHO SAID NO IT LOOKED NORMAL BUT SAID THE ONLY WAY THEY COULD GET IT OUT WAS HYSTERECTOMY. SHE DIDN'T WANT THAT PROCEDURE SHE JUST WANTED HER TUBES REMOVED AND THEM TO CUT OUT THE PART OF THE DEVICE THAT PROTRUDES INTO THE CERVIX. THE DOCTOR REFUSED TO DO IT AND SUGGESTED AN ABLATION. CONSUMER DECIDED TO GET A SECOND OPINION FROM ANOTHER DOCTOR THAT HAD REMOVED THE DEVICE FROM OTHER WOMEN USING THIS METHOD AT A DIFFERENT HOSPITAL SHE PERFORMED THE SURGERY AND FOUND ONE SIDE THE TUBE HAD A LARGE PIECE OF PLASTIC STICKING INTO HER UTERUS AND THE OTHER SIDE, THE DEVICE WAS IN PIECES. SHE HAD PICTURES AND DOCTOR'S REPORT OF THE SURGERY SHOWED THAT THE PLASTIC IT LOOKED LIKE PART OF THE INSERTION CATHETER. THE PATHOLOGY REPORT MADE NO MENTION OF THE PLASTIC NOR THE BROKEN DEVICE AND WAS DESTROYED BEFORE SHE COULD REQUEST IT. CONSUMER HAD NO IDEA HOW A DEVICE COULD BE USED IN A PERSON WITHOUT THE DEVICE BEING APPROVED BY THE TGA AS APPROVAL FOR THE DEVICE WASN'T GIVEN UNTIL 2010, 2 YEARS AFTER SHE WAS IMPLANTED. AT NO TIME, SHE WAS TOLD THAT THE DEVICE HADN'T HAD TGA APPROVAL NOR WAS SHE IN ANY TRIAL. SHE WAS NOT GIVEN THE DEVICE CARD WITH THE BATCH NUMBER ON IT THE DOCTOR ASKED HER IF SHE HAD AN ALLERGY TO NICKEL SHE SAID YES SHE COULDN'T WEAR CHEAP EARRINGS AND THE DOCTOR SAID IT WAS NOT THE SAME AS THAT THEY USED THIS MATERIAL IN HEART PATIENTS. SHE WAS NEVER TOLD IT CONTAINED PET FIBRES THAT WHAT CAUSES THE TUBES TO SCAR CLOSED WITH INFLAMMATION WHICH CONTAIN A WHOLE RANGE OF CARCINOGENS. REPORTER CAUSALITY: CONSUMER DID NOT PROVIDE THE RELATIONSHIP BETWEEN ALL THE EVENTS INITIALLY REPORTED AND ESSURE.

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Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2014: FINAL ASSESSMENT: WHEN A TERM LIKE "BREAKAGE" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLA

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00175	BAYER HEALTHCARE LLC	5/29/2014	6/10/2014

Event Information:

Event Date (B3): 3/10/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B42244

Single Use: Y
Implant Date (E6): 3/10/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPOSSIBLE TO REMOVE IMPLANT AS SPRING BROKE [DEVICE REMOVAL FAILED] PART OF IMPLANT WAS STILL IN FALLOPIAN TUBE [DEVICE BREAKAGE] SPRING BROKE [DEVICE BREAKAGE]. CASE DESCRIPTION: CASE SUMMARY: SERIOUS, UNLISTED, RELATED (NEAR-INCIDENT). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE#(B)(4)) IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED IMPOSSIBLE TO REMOVE IMPLANT AS SPRING BROKE, SPRING BROKE, AND PART OF IMPLANT WAS STILL IN FALLOPIAN TUBE. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE PT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B42244, AT UNK IMPLANTED. DURING IMPLANT INSERTION, IT WAS DECIDED TO REMOVE IMPLANT BEFORE IT HAD BEEN FITTED, BUT IT WAS IMPOSSIBLE TO REMOVE THE IMPLANT AS SPRING BROKE. A PART OF THE IMPLANT REMAINED IN THE FALLOPIAN TUBE. THE SURGEON WAS NOT ABLE TO REMOVE IT. SURGICAL TRADE-IN WAS PLANNED IN THE FOLLOWING WEEKS TO TRY TO REMOVE THE REST OF THE IMPLANT. CASE WAS CONSIDERED AS SERIOUS BY REPORTER. NO ASSESSMENT WAS GIVEN. FRANCE BDP LOCAL DRUG SAFETY DEPARTMENT ASSESSED THE CAUSAL RELATIONSHIP WITH ESSURE AS INCIDENT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM REGULATORY AUTHORITY IN FRANCE AND REFERS TO A FEMALE PT OF NOT REPORTED AGE WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED IMPOSSIBLE TO REMOVE IMPLANT AS SPRING BROKE, SPRING BROKE, AND PART OF IMPLANT WAS STILL IN FALLOPIAN TUBE. A SURGERY IS PLANNED FOR REMOVAL OF THE REMAINING PIECE OF INSERT. IMPOSSIBLE TO REMOVE IMPLANT AS SPRING BROKE IS LISTED IN THE REFERENCE SAFETY INFO FOR ESSURE. SPRING BROKE AND PART OF IMPLANT

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WAS STILL IN FALLOPIAN TUBE ARE UNLISTED. ALL REPORTED EVENTS ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND REGARDED AS NEAR-INCIDENT DUE TO DEVICE BREAKAGE. DURING DIFFICULT INSERTION OR REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE SURGEON DECIDED TO REMOVE THE INSERT BEFORE IT HAS BEEN FITTED. IT IS NOT CLEAR WHETHER THE DEVICE BREAKAGE OCCURRED DURING INSERTION OR ATTEMPT OF REMOVAL. AS TEMPORAL RELATIONSHIP BETWEEN REPORTED EVENTS AND ESSURE USE IS POSITIVE, CAUSALITY IS ASSESSED AS RELATED. AS THIS CASE WAS RECEIVED VIA REGULATORY AUTHORITY, NO FURTHER INFO IS EXPECTED.

Manufacturer Narrative (H10):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM REGULATORY AUTHORITY IN (B)(6) AND REFERS TO A FEMALE PT OF NOT REPORTED AGE WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED IMPOSSIBLE TO REMOVE IMPLANT AS SPRING BROKE, SPRING BROK

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00176	BAYER HEALTHCARE LLC	5/29/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

COLON RESECTION DUE TO THE BUILDUP OF SCAR TISSUE [INTESTINAL FIBROSIS] INTESTINES FUSING TO THE RECTUM [INTESTINAL ADHESIONS]. ESSURE COIL SETTLED IN COLON [DEVICE DISLOCATION INTO ABDOMINAL CAVITY]. CASE DESCRIPTION: SERIOUS, RELATED, UNLISTED (INCIDENT, UNANTICIPATED). THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(6) 2014 VIA INTERNET. THE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COIL SETTLED IN HER COLON, COLON RESECTION WAS DONE DUE TO THE BUILDUP OF SCAR TISSUE, AND HER INTESTINES FUSING TO THE RECTUM. NO INFO WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. THE CONSUMER HAD AN ESSURE COIL SETTLE IN HER COLON WHICH LED TO A COLON RESECTION DUE TO THE BUILDUP OF SCAR TISSUE AND HER INTESTINES FUSING TO THE RECTUM. CONSUMER WAS PUT AT RISK OF WEARING A COLOSTOMY BAG. REPORTER ASSESSED THE EVENTS WERE RELATED TO ESSURE. F/U INFO RECEIVED ON (B)(4) 2014: PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED. PTC GLOBAL NUMBER (B)(4). F/U (B)(4) 2014: WHEN RECEIVING QUESTIONNAIRE, CONSUMER REFUSED TO ANSWER MORE QUESTIONS. COMPANY CAUSALITY COMMENT: A SPONTANEOUS CASE OF ESSURE COIL SETTLED IN HER COLON, COLON RESECTION WAS DONE DUE TO BUILDUP OF SCAR TISSUE, AND HER INTESTINES FUSING TO THE RECTUM IN A FEMALE CONSUMER OF UNSPECIFIED AGE IN ASSOCIATION WITH ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS REPORTED BY A CONSUMER. THIS CASE WAS NOT MEDICALLY CONFIRMED. ALL REPORTED EVENTS WERE REGARDED AS SERIOUS INJURY DUE TO A REQUIRED INTERVENTION (COLON RESECTION). ESSURE COIL SETTLED IN HER COLON IS LISTED FOR ESSURE IN THE

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REFERENCE SAFETY INFO, WHEREAS ITS COMPLICATIONS BUILDUP OF SCAR TISSUE AND HER INTESTINES FUSING TO THE RECTUM ARE UNLISTED. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE USE WAS REGARDED RELATED, AS NO ALTERNATIVE EXPLANATION HAS BEEN PROVIDED AND AS SUCH CONSIDERED AS INCIDENTS. ACCORDING TO PTC FINAL ASSESSMENT THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

EVAL SUMMARY: FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: MEDICAL ASSESS

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00177	BAYER HEALTHCARE, LLC	5/29/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ERRANT COIL PERFORATED THE AMNIOTIC SAC CAUSING HER WATER TO BREAK [DEVICE DISLOCATION]. WENT INTO PREMATURE LABOR AT 26 WEEKS [PREMATURE LABOR]. ESSURE FAILED [DEVICE INEFFECTIVE]. ERRANT COIL PERFORATED THE AMNIOTIC SAC CAUSING HER WATER TO BREAK [PREMATURE RUPTURE OF MEMBRANES]. PREGNANT WITH ESSURE [PREGNANCY WITH CONTRACEPTIVE DEVICE]. CASE DESCRIPTION: SERIOUS, RELATED, UNLISTED (INCIDENT, UNANTICIPATED). THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(6) 2014 VIA INTERNET. IT DESCRIBES THE OCCURRENCE OF PREGNANCY WITH ESSURE, ESSURE FAILED, IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ERRANT COIL PERFORATED THE AMNIOTIC SAC CAUSING HER WATER TO BREAK, AND SHE WENT INTO PREMATURE LABOR AT 26 WEEKS. MALE BABY WAS BORN WITH UNDER-DEVELOPED LUNGS AND DIED ON DAY OF BIRTH, CASE WAS REPORTED AT BAYER CASE NUMBER (B)(4). NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. REPORTER ASSESSED THE EVENTS WERE RELATED TO ESSURE. FOLLOW-UP - PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON (B)(4) 2014 (GLOBAL COMPANY PTC NUMBER (B)(4)). FOLLOW UP (B)(4) 2014: CONSUMER REFUSED TO ANSWER MORE QUESTIONS.

Manufacturer Narrative (H10):

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EVALUATION SUMMARY: FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE MEDI

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00179	BAYER HEALTHCARE LLC	5/29/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/5/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DISTAL COIL MARKER IS NOT CONTINUOUS WITH THE REST OF THE COIL, LIKE IT BROKE OFF [DEVICE BREAKAGE]. LEFT HAS CONTRAST SPILLING [DEVICE INEFFECTIVE]. CASE DESCRIPTION: NON-SERIOUS, RELATED, UNLISTED AND NEAR-INCIDENT. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014, WHICH REFERS TO A (B)(6) Y/O FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DISTAL COIL MARKER IS NOT CONTIGUOUS WITH THE REST OF THE COIL, LIKE IT BROKE OFF AND LEFT HAS CONTRAST SPILLING. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION RECEIVED. IN (B)(6) 2013, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014, HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED LEFT HAD CONTRAST SPILLING AND THE RIGHT SIDE WHICH WAS BLOCKED SHOWED DISTAL COIL MARKER NOT CONTIGUOUS WITH THE REST OF THE COIL, LIKE IT BROKE OFF. NO FURTHER INFO WAS PROVIDED. F/U INFO RECEIVED ON (B)(6) 2014 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: 2014(B)(6). F/U INFO WAS RECEIVED ON (B)(6) 2014. PT'S WEIGHT AND HEIGHT WERE PROVIDED. ON (B)(6) 2013, ESSURE WAS EASILY IMPLANTED. CERVICAL DILATATION, SOUNDING AND GENERAL ANESTHESIA WERE APPLIED DURING INSERTION. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. DEPO PROVERA WAS USED AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. VASECTOMY WAS ALSO REPORTED. HSG TEST WAS PERFORMED (PICTURES WERE TAKEN AFTER PLACEMENT). THE PHYSICIAN MEDICALLY CONFIRMED THE EVENTS. NO FURTHER INFO WAS PROVIDED.

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Manufacturer Narrative (H10):

MEDICAL ASSESSMENT: THIS CASE REPORTED BREAKAGE (BASED ON HSG REVIEW) AS WELL AS DEVICE INEFFECTIVE (HSG DYE SPILLAGE). THESE EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. ADDITIONALLY, LACK OF EFFECTIVENESS MAY OCCUR WITH THE USE OF ANY PROD

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00181	BAYER HEALTHCARE LLC	5/29/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B61389

Single Use: Y
Implant Date (E6): 4/29/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

COMPLICATION OF DEVICE INSERTION [COMPLICATION OF DEVICE INSERTION]. THE WHEEL DID NOT WHEEL BACK ON THE SECOND WHEEL BACK/INSERTER HAD DIFFICULTY DEPLOYING [DEVICE DEPLOYMENT ISSUE]. HALF OF THE DISTAL DEVICE REMAINING IN RIGHT TUBE AND PROXIMAL END OF THE INNER COIL AND PROXIMAL END ARE MISSING [DEVICE BREAKAGE]. CASE DESCRIPTION: CASE SUMMARY: NON-SERIOUS, RELATED, UNLISTED, NEAR-INCIDENT. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6), 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED IT STRETCHED CAUSING INNER ROD TO STRETCH OUT IN UTERINE CAVITY, HALF OF THE DISTAL DEVICE REMAINING IN RIGHT TUBE AND PROXIMAL END OF THE INNER COIL AND PROXIMAL END ARE MISSING, COMPLICATION OF DEVICE INSERTION, AND THE WHEEL DID NOT WHEEL BACK ON THE SECOND WHEEL BACK/INSERTER HAD DIFFICULTY DEPLOYING. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6), 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH LOT NUMBER B61389 (EXPIRATION DATE AUGUST 2016). IT WAS NOT REPORTED WHETHER ESSURE WAS USED PREVIOUSLY. DURING ESSURE INSERTION, THE WHEEL DID NOT GO BACK ON THE SECOND WHEEL BACK. THE INSERTER HAD DIFFICULTY WITH DEPLOYING AND IT STRETCHED CAUSING THE INNER ROD TO STRETCH OUT IN THE UTERINE CAVITY. THEY REMOVED THE INNER ROD THAT WAS HANGING IN THE UTERUS. THE DOCTOR GOT A FLAT PLATE OF ABDOMEN AND IT SHOWED THAT HALF OF THE DISTAL DEVICE REMAINING IN THE RIGHT TUBE. HSG WAS DONE ON (B)(6) 2014 AND SHOWED THE DISTAL END OF THE OUTER COIL AND DISTAL END OF INNER WERE IN THE CORRECT PLACE. THE PROXIMAL END OF THE INNER COIL AND PROXIMAL END WERE MISSING UNDER FLUOROSCOPY BECAUSE OF

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DETACHMENT DIFFICULTY. THE OUTCOME OF THE EVENTS WAS UNKNOWN. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS NOT REPORTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON MAY 06, 2014: PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED: PTC GLOBAL NUMBER (B)(4). FOLLOW-UP RECEIVED ON (B)(6), 2014. THE PATIENT WEIGHT WAS (B)(6). THE PATIENT HAD NO CONCURRENT CONDITIONS. IT WAS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00185	BAYER HEALTHCARE LLC	5/29/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSTION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE COILS WERE WELL IMBEDDED IN THE ILEUM [DEVICE DISLOCATION INTO ABDOMINAL CAVITY] INTRA-ABDOMINAL BREAKAGE OF A TUBAL OCCLUSION DEVICE [DEVICE BREAKAGE] RIGHT ESSURE COIL WAS FOUND TO BE PERFORATED THROUGH THE UTERUS [UTERINE PERFORATION] ([DEVICE DISLOCATION]). CASE DESCRIPTION: SERIOUS, RELATED, LISTED, INCIDENT. THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 05/01/2014, ARTICLE ENTITLED "ESSURE PERFORATION WITH INTRA-ABDOMINAL BREAKAGE". IT REFERS TO A (B)(6) -YEAR-OLD FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION AND EXPERIENCED RIGHT ESSURE COIL WAS FOUND TO BE PERFORATED THROUGH THE UTERUS, THE COILS WERE WELL IMBEDDED IN THE ILEUM, AND INTRA-ABDOMINAL BREAKAGE OF THE TUBAL OCCLUSION DEVICE. PT HAD BEEN PREVIOUSLY ON MEDROXYPROGESTERONE ACETATE FOR 12 YEARS, BUT DUE TO DEXA SCANS THAT REVEALED OSTEOPENIA (LUMBAR SPINE T-SCORE -1.1) SHE WAS ENCOURAGED TO SEEK AN ALTERNATIVE METHOD. SHE WAS COUNSELED FOR AN ESSURE PERMANENT STERILIZATION PROCEDURE AND WAS SUBSEQUENTLY SET-UP FOR AN OFFICE PROCEDURE. A NORMAL INTRAUTERINE CAVITY WAS NOTED AND BILATERAL OSTIA WERE VISUALIZED. BOTH FALLOPIAN TUBES WERE OCCLUDED WITH ESSURE DEVICE. NO COMPLICATIONS WERE NOTED AND THE PT TOLERATED THE PROCEDURE WELL. A CONFIRMATORY HYSTEROSALPINGOGRAM (HSG) SHOWED THE LEFT ESSURE COILS WAS FOUND TO BE IN AN ANATOMICALLY CORRECT POSITION WITH SUBSEQUENT BLOCKAGE OF FLUOROSCOPIC DYE OF THE LEFT FALLOPIAN TUBE. THE RIGHT ESSURE COIL, HOWEVER, APPEARED TO BE MALPOSITIONED AND IN TWO LOCATIONS. A PORTION OF THE RIGHT COIL WAS IMBEDDED IN THE RIGHT CORNUAL ASPECT OF THE UTERUS WITH A SECOND PORTION IN AN UNSPECIFIED AREA IN THE PELVIC CAVITY. A LAPAROSCOPIC TUBAL FULGURATION PROTRUDING THROUGH THE RIGHT UTERINE CORNUA. THE SECOND PART

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OF THE RIGHT ESSURE COIL WAS FOUND TO BE PERFORATED THROUGH THE UTERUS AND ATTACHED IN A PARALLEL FASHION TO THE SEROSA OF THE BOWEL. THE COILS WERE WELL IMBEDDED IN THE ILEUM WITHOUT EVIDENCE OF PERFORATION, ERYTHEMA, BOWEL DILATATION, OR STRANGULATION. THERE WAS NO BLOOD IN THE ABDOMINAL OR PELVIC CAVITY AND THE REMAINDER OF THE BOWEL WAS GROSSLY NORMAL. THE SPECIMEN WAS RETAINED IN THE PELVIS WITH NO FURTHER SURGERY. THE AUTHORS CONCLUDED THAT HIS CASE STUDY SHOWS THE POSSIBILITY OF HYSTEROSCOPIC PERFORATION AND INTRA-ABDOMINAL BREAKAGE OF A TUBAL OCCLUSION DEVICE AND SHOW THE IMPORTANCE OF POST OPERATIVE HSG AFTER ESSURE TUBAL OCCLUSION DEVICE. THIS MEDICAL LITERATURE CASE REPORT REFERS TO A (B)(6)-YEAR-OLD PT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RIGHT ESSURE COIL WAS FOUND TO BE PERFORATED THROUGH THE UTERUS, THE COILS WERE WELL IMBEDDED IN THE ILEUM, AND INTRA-ABDOMINAL BREAKAGE OF A TUBAL OCCLUSION DEVICE. THE FIRST TWO EVENTS WERE CONSIDERED SERIOUS, AS MEDICALLY SIGNIFICANT AND ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFO FOR ESSURE. THE EVENT INTRA-ABDOMINAL BREAKAGE OF A TUBAL OCCLUSION DEVICE WAS REGARDED AS NON-SERIOUS AND IS UNLISTED. UTERINE PERFORATION MAY HAPPEN WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE INCLUDING ESSURE THERAPY; IN WHICH IT OCCURS MOST OFTEN DURING INSERTION. OWING TO THE ANATOMICAL RELATIONSHIP BETWEEN BOWEL AND UTERUS, THE BOWEL MAY BE PERFORATED DUE TO ESSURE DEVICE MIGRATION OR DURING THE PLACEMENT PROCEDURE. ALSO, IN CASES OF DIFFICULT REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE IT WAS REPORTED THAT AT HYSTEROSALPINGOGRAPHY, THE RIGHT ESSURE COIL WAS MALPOSITIONED; A LAPAROSCOPY WAS PERFORMED AND CONFIRMED THAT ONE PORTION OF ESSURE WAS PERFORATING THE UTERUS AND A SECOND PORTION WAS IN THE PELVIC CAVITY (EMBEDDED IN ILEUM, HOWEVER, WITHOUT BOWEL PERFORATION), THE AUTHOR CONCLUDED ON AN INTRA-ABDOMINAL BREAKAGE OF ESSURE. CONSIDERING THE ABOVE MENTION INFO AND THE EVENTS CHARACTERISTICS, THEY WERE CONSIDERED AS RELATED TO ESSURE THERAPY AND DUE TO THE REQUIRED INTERVENTION REGARDED AS INCIDENTS.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 22-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BRE

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00188	BAYER HEALTHCARE, LLC	5/29/2014	6/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLEEDING FOR NEARLY 8 MONTHS [GENITAL BLEEDING]. CASE DESCRIPTION: SERIOUS, LISTED AND RELATED (INCIDENT). THIS IS SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES VIA SOCIAL MEDIA ON (B)(6) 2014 REFERRING TO HERSELF. THE FEMALE CONSUMER OF UNSPECIFIED AGE WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4)/AOL (STUDY DESCRIPTION: ESSURE GENERIC ACTIVE ONLINE LISTENING) AND EXPERIENCED BLEEDING FOR NEARLY 8 MONTHS. PAST DRUGS INCLUDED IUD (INTRA-UTERINE DEVICE). NO INFO GIVEN ON CONSUMER'S HISTORY, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION RECEIVED. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER EXPERIENCED BLEEDING FOR NEARLY 8 MONTHS AFTER SHE HAD HER IUD OUT AND HER ESSURE IMPLANTS PLACED. SHE WAS GIVEN HORMONAL TREATMENT TO STOP THE BLEEDING, BUT IT DID NOT WORK - SHE TRIED FOR 6 MONTHS, BUT THE BLEEDING GOT WORSE. THE TREATMENT LEFT HER WITH SOME HORMONE ISSUES SHE WAS STILL DEALING WITH. THE CONSUMER THEN WENT WITH HYSTERECTOMY AND HAD HER UTERUS, CERVIX AND FALLOPIAN TUBES REMOVED. SHE WAS ONLY IN THE HOSPITAL OVERNIGHT AND THE SURGERY GAVE HER ALMOST INSTANT RELIEF. NO FURTHER INFO WAS PROVIDED. FOLLOW UP INFO RECEIVED ON (B)(4) 2014. NO FURTHER INFO AVAILABLE. CONTACT INFO OF REPORTER INCOMPLETE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA REFERRING TO HERSELF. THE FEMALE CONSUMER OF UNSPECIFIED AGE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING FOR NEARLY 8 MONTHS. BLEEDING FOR NEARLY 8 MONTHS IS SERIOUS AS MEDICALLY SIGNIFICANT AND LISTED EVENT ACCORDING TO REF. SAFETY

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INFO FOR ESSURE. TEMPORAL RELATIONSHIP BETWEEN EVENT AND ESSURE THERAPY IS PLAUSIBLE AND AN ALTERNATIVE EXPLANATION IS NOT AVAILABLE. A CAUSAL RELATIONSHIP BETWEEN THEM CANNOT BE EXCLUDED (RELATED). BLEEDING FOR NEARLY 8 MONTHS IS REGARDED AS INCIDENT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00182	BAYER HEALTHCARE LLC	5/29/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): FSSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 787226, 806702, 787226

Single Use: Y
Implant Date (E6): 9/15/2011
Explant Date (E7): 1/30/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN HE WAS INSERTING THE COILS, TUBES WERE SPASMING [DEVICE INSERTION DIFFICULT] R DIFFICULTY THREADING BUT IT DID NOT BREAK [DEVICE DIFFICULT TO USE] RUPTURED MY TUBE [FALLOPIAN TUBE PERFORATION] (PAIN, ABDOMINAL PAIN LOCALISED). IT WAS PIERCING WHEN BOWELS WOULD BE FULL AND THATS WHERE COIL WAS EMBEDDED (TRAUMATIC INTESTINAL PERFORATION). WHEN HE WAS INSERTING THE COILS, TUBES WERE SPASMING (FALLOPIAN TUBE SPASM). RLQ (RIGHT LOWER QUADRANT) PAIN (RIGHT LOWER QUADRANT PAIN) THE COIL EMBEDDED ITSELF IN THE SOFT TISSUE OF MY BOWEL (DEVICE DISLOCATION INTO ABDOMINAL CAVITY) COIL WAS BROKEN (DEVICE BREAKAGE). CASE DESCRIPTION: SERIOUS, RELATED, UNLISTED (INCIDENT). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2014 REFERRING TO HERSELF. THE FEMALE CONSUMER OF UNSPECIFIED AGE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RUPTURED MY TUBE AND THE COIL EMBEDDED ITSELF IN THE SOFT TISSUE OF MY BOWEL. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION RECEIVED. ON (B)(6) 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER 787226. ON AN UNSPECIFIED DATE, THE CONSUMER STATED THAT ESSURE RUPTURED HER TUBE AND THE COIL EMBEDDED ITSELF IN THE SOFT TISSUE OF HER BOWEL. ESSURE WAS REMOVED ON (B)(6) 2014 (REMOVAL METHOD NOT PROVIDED). NO FURTHER INFORMATION WAS GIVEN.

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Manufacturer Narrative (H10):

NO FURTHER INFORMATION WAS GIVEN. FOLLOW-UP (B)(4) 2014: CONSUMER ANSWERED TO QUESTIONNAIRE. CONSUMER IS (B)(6) YEARS OLD, BODY MASS INDEX (B)(6). CONSUMER HAD NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES, AND NO OTHER MEDICAL HISTORY OR CONCURRENT CO

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00183	BAYER HEALTHCARE LLC	5/29/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): B60760

Single Use: Y
Implant Date (E6): 4/17/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT WAS HAVING PAIN DURING PROCEDURE [PROCEDURAL PAIN]. HAD TO TERMINATE THE PROCEDURE [DEVICE INSERTION FAILED]. LEFT THE PLASTIC IN THE UTERUS [COMPLICATION OF DEVICE INSERTION]. WHEN HE ROLLED IT BACK TO RELEASE COIL GOT STUCK ON THE INSERTER CATHETER, INNER CATHETER HAS UNCOILED [DEVICE DEPLOYMENT ISSUE]. LEFT THE PLASTIC IN THE UTERUS [DEVICE BREAKAGE]. ROLLED THE WHEEL BACK AND IT LOCKED, HAD DIFFICULTY PRESSING THE BUTTON. [DEVICE DEPLOYMENT ISSUE]. CASE DESCRIPTION: CASE SUMMARY: NON-SERIOUS, RELATED, UNLISTED, NEAR-INCIDENT. THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A HEALTH PROFESSIONAL (HCP) IN THE UNITED STATES ON (B)(6) 2014. THE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHEN HCP ROLLED THE WHEEL BACK AND IT LOCKED, HCP HAD DIFFICULTY PRESSING THE BUTTON, WHEN HE ROLLED IT BACK TO RELEASE COIL GOT STUCK ON THE INSERTER CATHETER AND LEFT THE PLASTIC IN THE UTERUS, HCP HAD TO TERMINATE THE PROCEDURE. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2014, THE PATIENT WAS TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B60760 (EXPIRATION DATE AUGUST-2016) INSERTED. ON (B)(6) 2014, HCP WAS IN THE OR (OPERATING ROOM) AND HAD TO TERMINATE THE PROCEDURE. HCP REPORTED HE PASSED THE COIL UP TO THE BLACK MARK AND THEN ROLLED THE WHEEL BACK AND IT LOCK AND HAD DIFFICULTY PRESSING THE BUTTON. WHEN HE ROLLED IT BACK TO RELEASE THE COIL, IT GOT STUCK ON THE INSERTER CATHETER AND LEFT THE PLASTIC IN THE UTERUS. NO FURTHER DETAILS WERE REPORTED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: ESSURE PROCEDURE WENT WELL. BUTTON WAS HARD TO DEPRESS, FINALLY DEPRESSED ROLL WHEEL, WHEN WENT TO WITHDRAW TWEEZED IT

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OUT. THE INNER CATHETER HAD UNCOILED. BUT 2-3 CM OF PLASTIC SHEATH WAS LEFT IN PLACE. PATIENT WAS HAVING PAIN SO THE PROCEDURE WAS TERMINATED. THE PHYSICIAN BELIEVED THE INSERT HAD DEPLOYED CORRECTLY. HE PLANNED TO REMOVE THE GREEN CATHETER SHEATH AND WOULD INSERT ANOTHER COIL IN THE OTHER TUBE, AS HE DID NOT DO THIS ON THE FIRST PROCEDURE.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2014: PTC GLOBAL NUMBER: (B)(4). EVALUATION SUMMARY - FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00186	BAYER HEALTHCARE LLC	5/29/2014	6/17/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 4/1/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE COIL MIGRATED AND BROKE OFF AND WAS IN THE OMENTUM [DEVICE BREAKAGE]. PELVIC PAIN [PELVIC PAIN]. ESSURE COILS WERE POKING THROUGH THE FUNDUS OF UTERUS [EMBEDDED DEVICE]. ONE COIL MIGRATED AND BROKE OFF AND WAS IN THE OMENTUM [DEVICE DISLOCATION INTO ABDOMINAL CAVITY]. NICKEL ALLERGIES [NICKEL SENSITIVITY]. FATIGUE [FATIGUE]. BECAME PREGNANT [PREGNANCY WITH CONTRACEPTIVE DEVICE]. DEVICE INEFFECTIVE [DEVICE INEFFECTIVE]. ESSURE COILS WERE POKING THROUGH THE FUNDUS OF UTERUS [PARTIAL EXPULSION OF DEVICE]. ONE SIDE ERODING THROUGH THE TUBE [EMBEDDED DEVICE]. CASE DESCRIPTION: CASE SUMMARY: SERIOUS, LISTED, RELATED (INCIDENT). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014. IT DESCRIBES THE OCCURRENCE OF BECAME PREGNANT, DEVICE INEFFECTIVE, PELVIC PAIN, FATIGUE, ESSURE COILS WERE POKING THROUGH THE FUNDUS OF UTERUS, ESSURE COILS WERE POKING THROUGH THE FUNDUS OF UTERUS, ONE SIDE ERODING THROUGH THE TUBE, ONE COIL MIGRATED AND BROKE OFF AND WAS IN THE OMENTUM, ONE COIL MIGRATED AND BROKE OFF AND WAS IN THE OMENTUM, AND NICKEL ALLERGIES IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) . NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. IN 2008, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. IT WAS UNKNOWN WHETHER ESSURE WAS USED PREVIOUSLY. ON UNSPECIFIED DATE, THE 3 MONTHS HSG (HYSTEROSALPINGOGRAPHY) WAS CONFIRMED. AFTER PROCEDURE THE PATIENT BECAME PREGNANT AND HAD A BABY (BORN IN 2008). THE PATIENT WAS EXPERIENCING PELVIC PAIN AND FATIGUE, THE PHYSICIAN PERFORMED A LAPAROSCOPY IN 2010 AND SAW ESSURE COILS WERE POKING THROUGH THE FUNDUS OF UTERUS AND ONE SIDE ERODING THROUGH TUBE.

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PHYSICIAN OFFERED TO REMOVE THE ESSURE DEVICE AND DO AN HYSTERECTOMY BUT THE PATIENT WANTED TO WAIT. ON (B)(6) 2014, PHYSICIAN HAD A HYSTERECTOMY PERFORMED. ONE OF THE ESSURE COILS MIGRATED AND BROKE OFF AND WAS IN THE OMENTUM. PHYSICIAN ALSO MENTIONED THAT THE PATIENT COMPLAINT OF NICKEL ALLERGIES 1-2 YEARS AGO (FROM TIME OF REPORT). REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE WAS NOT REPORTED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED. PTC GLOBAL NUMBER IS (B)(4). FOLLOW-UP (B)(4) 2014: REPORTER DID NOT ANSWER TO FOLLOW-UP REQUESTS UP TO DATE.

Manufacturer Narrative (H10):

EVALUATION SUMMARY: FINAL ASSESSMENT: WHEN THE TERMS "BREAK," "BREAKAGE," "BROKE," "BROKEN," "FALLING APART," OR "SPLIT" ARE USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALON

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00187	BAYER HEALTHCARE LLC	5/29/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B82481

Single Use: Y
Implant Date (E6): 4/29/2014
Explant Date (E7): 4/29/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEPLOYED SPONTANEOUSLY [DEVICE DEPLOYMENT ISSUE] RIGHT SEVERE FALLOPIAN SPASM DURING INSERTION [COMPLICATION OF DEVICE INSERTION]. SOME OF THE METAL MIGHT BE IN THE RIGHT TUBE [DEVICE BREAKAGE]. RIGHT SEVERE FALLOPIAN SPASM DURING INSERTION [FALLOPIAN TUBE SPASM]. UNABLE IF ESSURE WAS PLACED IN LEFT TUBE [DEVICE INSERTION FAILED]. CASE DESCRIPTION: CASE STATUS: NON-SERIOUS- UNLISTED - RELATED - NEAR-INCIDENT. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NON-HEALTH PROFESSIONAL IN UNITED STATES ON (B)(6) 2014. REFERS TO A (B)(6) FEMALE PATIENT WHO HAD D ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RIGHT SEVERE FALLOPIAN SPASM DURING INSERTION, ESSURE DEPLOYED SPONTANEOUSLY, COMPLICATION OF DEVICE INSERTION, SOME OF THE METAL MIGHT BE IN THE RIGHT TUBE AND UNSURE IF ESSURE WAS PLACED IN LEFT TUBE. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED PERMANENT CONTRACEPTION WITH LOT NUMBER # B82481 (EXPIRATION DATE 10/2016). IT WAS REPORTED THAT WHEN PHYSICIAN WAS DOING THE INSERTION OF ESSURE ON RIGHT SIDE, THE PATIENT EXPERIENCED RIGHT SEVERE FALLOPIAN SPASM AND ESSURE DEPLOYED SPONTANEOUSLY. PHYSICIAN WAS UNSURE IF ESSURE WAS PLACED IN THE LEFT TUBE, BUT POSSIBLY SOME METAL MIGHT BE IN THE RIGHT TUBE. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS NOT REPORTED. FOLLOW UP RECEIVED ON (B)(6) 2014 WITH THE FINAL PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4).

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Manufacturer Narrative (H10):

FINAL ASSESSMENT: WHEN THE TERMS "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", OR "SPLIT" ARE USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00173	BAYER HEALTHCARE LLC	5/29/2014	6/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B09698

Single Use: Y
Implant Date (E6): 1/8/2014
Explant Date (E7): 4/22/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DISTAL END HAD PARTIALLY PERFORATED RIGHT TUBE, ADHERED TO OVARIAN FOSSA, BOAD LIGAMENT AND MESENTERY (FALLOPIAN TUBE PERFORATION] CASE DESCRIPTION: SERIOUS, RELATED, LISTED (INCIDENT) THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RIGHT SIDE OCCLUDED BUT ESSURE EXPELLED INTO PERITONEAL CAVITY. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. IN (B)(6)-2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION. INSERTION WAS UNCONPRIVATED, THE HSG (HYSTEROSALPINGOGRAM) WAS DONE IN (B)(6)-2014 AND SHOWED LEFT SIDE OCCLUDED, RIGHT SIDE OCCLUDED BUT ESSURE EXPELLED INTO PERITONEAL CAVITY. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN RIGHT SIDE OCCLUDED BUT ESSURE EXPELLED INTO PERITONEAL CAVITY AND ESSURE WAS NOT REPORTED. FOLLOW-UP RECEIVED ON (B)(6)-2014 NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. FOLLOW-UP (B)(6)-2014: HEALTHCARE PROFESSIONAL QUESTIONNAIRE WAS RETURNED. THE (B)(6), WAS GRAVIDA 4, PARA 2, TWO ELECTIVE ABORTIONS, NO SPONTANEOUS NOR THERAPEUTIC ABORTIONS, NO ECTOPIC PREGNANCIES. PATIENT HAD A PREVIOUS GYNECOLOGICAL INTERVENTION (DATE UNSPECIFIED), HSC D AND C (HYSTEROSCOPIC DILATION AND CURETTAGE) WITH AN UTERINE PERFORATION. OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS INCLUDE RHEUMATOID ARTHRITIS TREATED WITH PLAQUENIL (HYDROXYCHLOROQUINE). ON (B)(6)-2014, PATIENT HAD ESSURE (ESS305, LOT NUMBER 809698) INSERTED. PATIENT WAS NOT POSTPARTUM AND WAS NOT PREGNANT. CERVICAL DILATATION, SOUNDING, GENERAL ANESTHESIA WERE DONE. INSERTION WAS EASY. VISUALIZATION OF BOTH TUBAL OSTIA WAS EASY.

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THERE WAS NO FLUID LOSS DURING HYSTEROSCOPY OF MORE THAN 1500CC. PROCEDURE TOOK 5-7 MINUTES. DEPO PROVERA (MEDROXYPROGESTERONE) WAS USED FOR BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED ON (B)(6)-2014, WHICH SHOWED R (RIGHT) TUBE DISPLACED, RIGHT PARTIAL PERFORATION. PATIENT DID NOT PRESENT SYMPTOMS. PERFORATION DID NOT OCCUR DURING SOUNDING, CERVICAL DILATION, HYSTEROSCOPY, BEFORE DEPLOYMENT BEFORE ESSURE INSERTION, IT OCCURRED AFTER DEPLOYMENT. NO DIAGNOSTIC TESTS WERE PERFORMED (ULTRASOUND, FLAT PLATE X-RAY, MRI, CAT-SCAN, RELEVANT BLOOD TESTS OR ALLERGY TESTS ETC). OUTCOME WAS ADVERSE, AN UNPLANNED LAPAROSCOPY AND RIGHT SALPINGECTOMY WERE MEDICALLY NECESSARY. ON (B)(6)-2014, ESSURE WAS REMOVED. PATHOLOGY RESULTS ARE PENDING. DURING SURGERY IT WAS FOUND THAT THE DISTAL END HAD PERFORATED THE TUBE, ADHERED TO OVARIAN FOSSA, BEAD LIGAMENT AND MESENTERY. PATIENT HAS RECOVERED FROM THE ESSURE REMOVAL PROCEDURE. REPORTER ASSESSED THE CONDITION AS CAUSED BY ESSURE DEVICES. PTC FINAL INVESTIGATION RECEIVED ON (B)(6)-2014: FINAL ASSESSMENT LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE MEDICAL EVENT REPORTED IS A POSSIBLE UNDESIRABLE EVENT WITH THE USE OF ESSURE AND NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER 809698. NO BATCH SIGNAL CAN BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

EVALUATION SUMMARY: FINAL ASSESSMENT LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE MEDICAL EVE

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00180	BAYER HEALTHCARE LLC	5/29/2014	6/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE OCCLUSION, TUBAL CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): B76537

Single Use: Y
Implant Date (E6): 4/29/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

OUTER COIL BROKE OFF AT ABOUT 5 COILS PROXIMAL WHEN STARTED SECOND ROLLBACK OF RELEASING DEVICE [DEVICE BREAKAGE] COMPLICATION OF DEVICE INSERTION [COMPLICATION OF DEVICE INSERTION] CASE DESCRIPTION: NON-SERIOUS,RELATED,UNLISTED AND NEAR-INCIDENT. THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN THE UNITED STATES ON (B)(6) 2014. THE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND OUTER COIL BROKE OFF AT ABOUT 5 COILS PROXIMAL WHEN DOCTOR STARTED SECOND ROLLBACK OF RELEASING DEVICE. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2014, THE PATIENT WAS TO HAVE ESSURE (ESS305, FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B76537, INSERTED. ON (B)(6) 2014, THE OUTER COIL BROKE OFF AT ABOUT 5 COILS PROXIMAL WHEN DOCTOR PUSHED THE BUTTON AND STARTED THE SECOND ROLL BACK OF RELEASING THE DEVICE. THE OTHER OUTER COILS AND INNER COIL WERE INTACT. PHYSICIAN LEFT THE DEVICE AND REMOVED THE BROKEN PIECE WITH GRASPERS. BILATERAL PLACEMENT WAS SUCCESSFUL. THERE WAS NO INJURY. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP.

Manufacturer Narrative (H10):

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DESPITE OUR REPEATED REQUESTS, FOLLOW-UP INFORMATION COULD NOT BE OBTAINED UNTIL (B)(4)2014. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00184	BAYER HEALTHCARE, LLC	5/29/2014	6/18/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

SUSPECTED ALLERGIC REACTION [HYPERSENSITIVITY]; ABDOMINAL PAIN [ABDOMINAL PAIN]; MILD DYSPNOEA [DYSPNOEA]. CASE DESCRIPTION: CASE SUMMARY: SERIOUS, RELATED, UNLISTED. (INCIDENT). THIS CASE REPORT FROM GREAT BRITAIN WAS DERIVED FROM MEDICAL LITERATURE ON 01-MAY-2014, ARTICLE ENTITLED ""I WANT THEM OUT DOC!". LAPAROSCOPIC EXCISION OF ESSURE MICRO-INSERTS". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN, MILD DYSPNOEA, AND SUSPECTED ALLERGIC REACTION. THE REPORTED TRADE NAME IS ESSURE. CASE REPORT AND AUTHORS COMMENT: A CASE OF LAPAROSCOPIC REMOVAL OF DEVICES WITH SUBSEQUENT BILATERAL SALPINGECTOMY. THE PATIENT REPORTED ABDOMINAL PAIN AND MILD DYSPNEA TWO WEEKS FOLLOWING INSERTION OF THE DEVICES. THE DEVICES WERE INSERTED WITHOUT COMPLICATION, UNDER GENERAL ANESTHESIA. THE PATIENT HAD A KNOWN HISTORY OF NICKEL ALLERGY, PROVEN BY A PREVIOUS SKIN PATCH TEST. THE ESSURE MICRO-INSERT'S OUTER CORE IS MADE OF A NITINOL (NICKEL-TITANIUM ALLOY) THAT RAISED A CONCERN ABOUT ALLERGIC REACTION. CRP, WCC AND EOSINOPHIL'S WERE WITHIN NORMAL RANGE REDUCING LIKELIHOOD OF ALLERGY AND PERFORATION. HISTOPATHOLOGY DEMONSTRATED NO SPECIFIC FEATURES OF AN ALLERGIC RESPONSE. DISCUSSION WILL CENTRE ON ESSURE COMPLICATIONS AND IDEAL MODES OF REMOVAL.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 22-AUG-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: A NEW DEVICE SIMILAR CASE LISTING WAS GENERATED AND THIS CASE WAS RE-DISTRIBUTED AS A FINAL REPORT. THIS ADVERSE EVENT REPORT IS RELATED TO A

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036439	CONCEPTUS INC.	5/30/2014	6/6/2014

Event Information:

Event Date (B3): 8/27/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626603

Single Use:
Implant Date (E6): 8/27/2008
Explant Date (E7): 8/12/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED ESSURE COIL IMPLANTS IN (B)(6) OF 2008. IMMEDIATELY AFTER THE COILS WERE PLACED, I HAD PAIN, TENDERNESS, AND CRAMPING THAT CONTINUED FOR THE BETTER PART OF 5 YEARS. THIS FINALLY STOPPED AFTER GOING THROUGH VARIOUS OB/GYN DOCTORS AND FINALLY FINDING ONE TO GIVE ME A HYSTERECTOMY. I WAS ONLY (B)(6) YEARS OLD WHEN I GOT THE HYSTERECTOMY. BUT I NOW HAVE NO SYMPTOMS (CRAMPING, PAIN, BLOATING, TENDERNESS, ETC.) THAT I HAD ENDURED WHEN I HAD THE COILS. IN ADDITION TO THIS, MOST OF THE OB'S THAT I WENT TO TOLD ME THAT "I WAS EXAGGERATING", "I WAS CRAZY" OR "I WAS SEEKING PAIN MEDS" AND BLEW ME OFF COMPLETELY. I WAS TOLD (SEVERAL TIMES) BEFORE GETTING THE COILS THAT I HAD ABSOLUTELY NOTHING TO WORRY ABOUT REGARDING SIDE EFFECTS. I WAS MISERABLE AND NOW HAVE A SEVERE DISTRUST FOR DOCTORS AFTER NO ONE HELPED ME UNTIL ABOUT 5 YEARS LATER. THE ONLY REASON I FINALLY GOT THE HYSTERECTOMY WAS BECAUSE AN X-RAY REVEALED THAT ONE COIL WAS BROKEN. ALSO, I SWITCHED TO A NEW PROVIDER THAT FINALLY LISTENED TO ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036440		5/30/2014	6/6/2014

Event Information:

Event Date (B3): 5/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/13/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD MANY ISSUES SINCE HAVING ESSURE PROCEDURE DONE NEARLY FIVE YEARS AGO. I'VE NEVER HAD TO GO TO ER LIKE THIS BEFORE. NO MATTER THAT ISSUE I GO IN FOR, INFECTION IS ALWAYS ONE PROBLEM. ANY KIND OF INFECTION POSSIBLE I HAVE HAD SINCE THEN. NOT TO MENTION THE PAIN EVERY DAY ALL DAY. HEADACHES THAT STAY FOR WEEKS WITH NOTHING SLACKING THEM EVEN A LITTLE. WENT IN FOR THAT AND (B)(6) DR SAID I MUST HAVE HIT MY HEAD! WHEN IT HURTS REALLY BAD, THERE IS A "CAVE IN" ON MY HEAD. CAN FEEL IT! OH BY THE WAY, IN SO MUCH PAIN ALL THE TIME DOWN AROUND BLADDER AREA THAT SOMETIMES IT EVEN BUCKLES ME. ONE WHO HAS THREE KIDS AND CAN NORMALLY JUST DEAL WITH ANYTHING. SINCE HAVING ESSURE PUT IN SEX IS NOT WHAT ONCE WAS. IT'S PAINFUL. HAD I KNOWN EXACTLY THE ISSUES WITH THIS DONE, I'D NEVER HAD IT DONE. MY CYCLE NOW COMES TWICE A MONTH, MOST OF THE TIME. LASTING 7 TO 10 DAYS. NEVER IN MY LIFE HAS MY CYCLE LASTED MORE THAN 5 DAYS EVER. SO IN A MONTH I'M LUCKY IF I GET 14 DAYS WITH NO PERIOD. IT'S HEAVIER TOO. MY HAIR IS COMING OUT LIKE CRAZY, BY THE TIME I'M (B)(6) I'LL BE BALD I'M SURE. SINCE THE PROCEDURE, I'M ALWAYS BLOATED. CAN'T LOOSE WEIGHT AT ALL. THIS HAS RUINED MY LIFE. ALL PARTS OF IT. I'M SICK AND IN PAIN ALL THE TIME. HAVE TO PUSH MYSELF TO EVEN GET UP. MISSED ALL KINDS OF WORK, WHICH I HAVE DID BEFORE AND THIS PROCEDURE HAS RUINED MY SEX LIFE WITH MY HUSBAND. I WANT THIS OUT OF ME ASAP.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE	5/30/2014	6/18/2014

Event Information:

Event Date (B3): 5/20/2014 **Report Date (B4): 5/30/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B93871

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE DEPLOYMENT OF THE ESSURE, THE DEVICE WAS NOTED TO HAVE A MALFUNCTION AND THE ENTIRE ESSURE DEVICE WAS REMOVED FROM THE OSTIUM. THE SPECIFICS OF THE MALFUNCTION ARE UNKNOWN. THIS OCCURRED WITH THE LEFT FALLOPIAN TUBE. NO INJURIES OCCURRED TO THE PATIENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036524	BAYER	6/2/2014	6/12/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2007 I HAD THE ESSURE PROCEDURE DONE ON ME. AFTER A WHILE MY PERIODS HAVE GOTTEN WORSE BY THE MINUTE. I GOT BLOOD CLOTS THE SIZE OF GOLF BALLS, LOW IRON LEVELS, WEAKNESS, NAUSEA, CRAMPING BAD, AND DIZZINESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036526	BAYER	6/2/2014	6/12/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/26/2013
Explant Date (E7): 6/27/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) OF 2013. IT WAS REMOVED IN (B)(6) OF 2013 DUE TO EXTREME PAIN, BLOATING, AND EXCESSIVE BLEEDING. I HAVE SINCE BEEN DIAGNOSED WITH (B)(6), AND IMMUNODEFICIENCIES. THE PAIN HAS SINCE INCREASED AND I HAVE A HYSTERECTOMY SCHEDULED FOR (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036522	BAYER	6/2/2014	6/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'M IN CHRONIC PAIN DUE TO ESSURE. I GET HIVES, RASHES, VOMITING, ABDOMINAL SWELLING, DYSMENORRHEA, VITAMIN D DEFICIENCY, CHRONIC HEADACHES, AND MUSCLE PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00190	BAYER HEALTHCARE LLC	6/4/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B26272

Single Use: Y
Implant Date (E6): 5/5/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

COMPLICATION OF DEVICE INSERTION. [COMPLICATION OF DEVICE INSERTION] COIL BROKE INSIDE THE PATIENT/ DOCTOR PULLED BACK CATHETER AND THE LAST FIVE COILS BROKE OFF [DEVICE BREAKAGE]. CASE DESCRIPTION: CASE SUMMARY: NON-SERIOUS, RELATED, UNLISTED, NEAR-INCIDENT. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED COIL BROKE INSIDE THE PATIENT/ DOCTOR PULLED BACK ON CATHETER AND THE LAST FIVE COILS BROKE OFF AND COMPLICATION OF DEVICE INSERTION. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION RECEIVED. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B26272 (EXPIRATION DATE 2015) FOR STERILIZATION. DURING INSERTION, THE COIL BROKE INSIDE THE PATIENT/ DOCTOR PULLED BACK ON CATHETER AND THE LAST FIVE COILS BROKE OFF (COMPLICATION OF DEVICE INSERTION). THE DOCTOR LEFT BROKEN COIL IN PLACE AND WOULD DO A HSG (HYSTEROSALPINGOGRAPHY) IN THREE MONTHS. DOCTOR COULD SEE INNER COIL AT THE OS. THERE WERE OUTER COILS AT THE OS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014- PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). MEDICAL ASSESSMENT: THIS CASE REPORTED DEVICE SPECIFIC EVENTS OF COMPLICATION OF INSERTION DUE TO BREAKAGE (LAST FIVE COILS BROKE OFF WHILE PULLING BACK CATHETER) BUT THESE EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. FIVE (5) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER (B)(4) BUT ONLY TWO (2) OF THESE CASES REFERS TO A COMPLICATION OF DEVICE INSERTION BUT IN A DIFFERENT SITUATION. NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE

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PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT, BASED ON DESCRIPTION OF THE REPORTED BREAKAGE, CONCLUDED THAT THE BREAKAGE REFLECTS A DEVICE FAILURE THAT IS WELL UNDERSTOOD. AT TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT- BUT PLAUSIBLE" WITH A FINAL RISK CATEGORY ILL, WHICH POSES NOT A SIGNIFICANT HAZARD TO HEALTH AS THE SEVERING OF THE COILS OCCURS INSIDE THE CATHETER AND DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PATIENT. ACCORDING TO THE TECHNICAL ASSESSMENT A QUALITY DEFECT WAS PLAUSIBLE AND BASED ON THE PROVIDED INFORMATION THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING (B)(4) DEVICE BREAKAGE. IN SUMMARY, A CAUSAL RELATIONSHIP CAN NOT BE EXCLUDED BASED ON THE AVAILABLE INFORMATION IN REGARD TO THE EVENT OF DEVICE BREAKAGE AND A PRODUCT DEFECT. FINAL ASSESSMENT: WHEN THE TERMS "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", OR "SPLIT" ARE USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, OR IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN". SINCE NO PRODUCT WAS RETURNED TO US TOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE CANNOT CONFIRM THIS QUALITY COMPLAINT; HOWEVER, BASED ON THE COMPLAINT DESCRIPTION PROVIDED, WE ARE ABLE TO CONCLUDE THAT A QUALITY ISSUE IS PLAUSIBLE. IT IS POSSIBLE DURING THE MANUFACTURING ASSEMBLY PROCESS A SMALL GAP WAS LEFT BETWEEN THE INNER COIL AND INNER CATHETER (THEY SHOULD BE BUTTED TOGETHER DURING ASSEMBLY). WHEN THE OUTER COIL OF THE MICRO-INSERT IS WOUND DOWN A SMALL PORTION OF THE COIL CAN BECOME TRAPPED IN THE GAP. IF A DEVICE HAS THIS ISSUE, WHEN THE PHYSICIAN PRESSES THE BUTTON TO RELEASE THE MICRO-INSERT, THE OUTER COIL MAY SEVER ITSELF AS IT IS BEING DEPLOYED FROM THE CATHETER. IN TYPICAL SITUATIONS, THE PROXIMAL 3-6 OUTER COILS AND PLATINUM HALF-BAND ARE SEPARATED FROM THE REMAINDER OF THE MICRO-INSERT. THE SEVERING OF THE COILS OCCURS INSIDE THE CATHETER AND DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PATIENT. FOLLOW-UP FROM (B)(6) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING INSERTION PROCEDURE COIL BROKE INSIDE THE PATIENT/ DOCTOR PULLED BACK ON CATHETER AND THE LAST FIVE COILS BROKE OFF (COMPLICATION OF DEVICE INSERTION). ALL REPORTED EVENTS ARE NON-SERIOUS. THE EVENT COIL BROKE INSIDE THE PATIENT/ DOCTOR PULLED BACK ON CATHETER AND THE LAST FIVE COILS BROKE OFF IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS A NEAR-INCIDENT DUE TO DEVICE BREAKAGE. THE REMAINING EVENT IS LISTED AND REGARDED AS NON-INCIDENT. DURING DIFFICULT INSERTION, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE COIL BROKE INSIDE THE PATIENT DURING INSERTION PROCEDURE. THE PHYSICIAN PULLED BACK THE DELIVERY CATHETER AND THE LAST FIVE COILS BROKE OFF. AS TEMPORAL RELATIONSHIP BETWEEN REPORTED EVENTS AND ESSURE INSERTION IS POSITIVE, CAUSALITY CANNOT BE EXCLUDED. ACCORDING TO PTC REPORT, NO COMPLAINT SAMPLE WAS PROVIDED AND THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. THE TECHNICAL INVESTIGATION CONCLUDED

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"UNCONFIRMED QUALITY DEFECT- BUT PLAUSIBLE". IN SUMMARY, A CAUSAL RELATIONSHIP CAN NOT BE EXCLUDED BASED ON THE AVAILABLE INFORMATION IN REGARD TO THE EVENT OF DEVICE BREAKAGE AND A PRODUCT DEFECT.

Manufacturer Narrative (H10):

MEDICAL ASSESSMENT: THIS CASE REPORTED DEVICE SPECIFIC EVENTS OF COMPLICATION OF INSERTION DUE TO BREAKAGE (LAST FIVE COILS BROKE OFF WHILE PULLING BACK CATHETER) BUT THESE EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. FIVE (5) ADDITIONAL AE

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00192	BAYER HEALTHCARE LLC	6/4/2014	6/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B59462

Single Use: Y
Implant Date (E6): 1/10/2014
Explant Date (E7): 4/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MICRO INSERT WAS IN THE ABDOMEN (ESSURE MIGRATION), ONE TUBE PATENT [DEVICE DISLOCATION INTO ABDOMINAL CAVITY] CASE DESCRIPTION: CASE DESCRIPTION: SERIOUS, RELATED, LISTED (INCIDENT) THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN THE UNITED STATES ON (B)(6)-2014. THE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE MICRO INSERT WAS FOUND IN THE ABDOMEN (ESSURE MIGRATION), ONE TUBE WAS PATENT. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6)-2014, THE PATIENT STARTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B59462, IMPLANTED FOR CONTRACEPTION. GYNECOLOGIST/OBSTETRICIAN STATED THAT ON (B)(6)-2014, HE COMPLETED ALTO (LAPAROSCOPIC TUBAL LIGATION) ON ONE SIDE OF PATIENT'S TUBAL ANATOMY WHICH PROVED TO BE PATENT AFTER ESSURE CONFIRMATION TEST. A FLAT SCAN X-RAY INDICATED THAT THE MICRO INSERT WAS IN THE ABDOMEN. DOCTOR REMOVED THE MICRO INSERT FROM THE OMENTUM. THE OUTCOME OF THE EVENT WAS NOT REPORTED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON (B)(6)-2014: PTC INVESTIGATION. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSP

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00189	BAYER HEALTHCARE LLC	6/4/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/29/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PTC: PERSISTENCE OF STEEL THREADS AND PLASTIC PART AFTER INSERTION OF THE IMPLANT [DEVICE BREAKAGE]. CASE DESCRIPTION: CASE SUMMARY: NON-SERIOUS, UNLISTED, RELATED (NEAR-INCIDENT). THIS IS A SPONTANEOUS CASE REPORT REC'D FROM A PHYSICIAN IN (B)(6) ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PTC: PERSISTENCE OF STEEL THREADS AND PLASTIC PART AFTER INSERTION OF THE IMPLANT. NO INFO GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. IT WAS NOT CONTINUED IN ADD'L INFO SECTION REPORTED IF THE PATIENT WAS PREGNANT OR NOT, OR IF IT WAS UNKNOWN. ON (B)(6) 2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THAT THERE WAS A PERSISTENCE OF STEEL THREADS AND A PLASTIC PART AFTER IMPLANT INSERTION. THOSE 2 ELEMENTS WERE REMOVED WITH IMPLANT. THE RELATIONSHIP BETWEEN PTC: PERSISTENCE OF STEEL THREADS AND PLASTIC PART AFTER INSERTION OF THE IMPLANT AND ESSURE WAS NOT REPORTED. NO FURTHER INFO WAS PROVIDED. F/U INFO REC'D ON (B)(4) 2014 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). MEDICAL ASSESSMENT: THIS CASE REPORTED BREAKAGE (PRESENCE OF WIRE AND PLASTIC) WITH THE INSERTION OF THE IMPLANT BUT THIS EVENT IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. ONE (1) ADD'L AE CASE REPORT HAS BEEN REC'D TO DATE IN RELATION TO BATCH NUMBER B85139 BUT THIS CASE DOES NOT REFER TO A SIMILAR TYPE OF BREAKAGE EVENT. NO BATCH SIGNAL CAN BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT." BASED ON THE INFO AVAILABLE, THERE IS NO

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REASON TO SUSPECT A QUALITY DEFECT. FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AS OF (B)(4) 2014, NO DEVICE WAS RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF NOR REPORTED AGE WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED PTC: PERSISTENCE OF STEEL THREADS AND PLASTIC PART AFTER INSERTION OF THE IMPLANT. THIS CASE IS MEDICALLY CONFIRMED. PTC: PERSISTENCE OF STEEL THREADS AND PLASTIC PART AFTER INSERTION OF THE IMPLANT IS UNLISTED IIN THE REFERENCE SAFETY INFO FOR ESSURE AND CONSIDERED NON-SERIOUS. THIS CASE WAS REGARDED AS NEAR-INCIDENT DUE TO DEVICE BREAKAGE. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, DEVICE BREAKAGE HAD OCCURRED DURING INSERTION. AS TEMPORAL RELATIONSHIP REPORTED EVENT AND ESSURE INSERTION IS POSITIVE, CAUSALITY IS ASSESSED AS RELATED. ACCORDING TO PTC FINAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT."

Manufacturer Narrative (H10):

EVALUATION SUMMARY: MEDICAL ASSESSMENT: THIS CASE REPORTED BREAKAGE (PRESENCE OF WIRE AND PLASTIC) WITH THE INSERTION OF THE IMPLANT BUT THIS EVENT IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. ONE (1) ADDITION AE CASE REPORT HAS BEEN REC'D TO DATE I

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00191	BAYER HEALTHCARE LLC	6/4/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE (ESS205)
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 508837

Single Use: Y
Implant Date (E6): 4/6/2006
Explant Date (E7): 7/15/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WRIST AND ANKLES ARE ACHING/BURNING [PAINFUL JOINTS]. ADENOMYOSIS [ADENOMYOSIS]. CYST ON FALLOPIAN TUBES [FALLOPIAN TUBE CYST]. PAIN OF THE ESSURE COILS [MEDICAL DEVICE PAIN]. BECAME VERY HEAVY [WEIGHT INCREASED]. STOMACH WAS EXTENDED AS IF I WAS 7/8 MONTHS PREGNANT [ABDOMINAL BLOATING]. I COULD BARELY CLIMB STAIRS [WEAKNESS]. MY LEG AND BACK WOULD BURN AS I STOOD [BURNING SENSATION]. FLU LIKE SYMPTOMS [FLU LIKE SYMPTOMS]. ONE COIL DID NOT EXTEND ON IMPLANT [DEVICE DEPLOYMENT ISSUE]. LOTS OF SCAR TISSUE [SCAR]. LOWER BACK ACHES [LOW BACK PAIN]. HEADACHES [HEADACHE]. DIABETIC [DIABETIC]. THUMBS STARTED BURNING/ BURNING IN HANDS, WRISTS, FINGERS [BURNING FINGER]. PAIN IN JOINTS MUSCLES [ARTHROMYALGIA]. DEPRESSION [DEPRESSION]. DIABETIC NEUROPATHY [DIABETIC NEUROPATHY]. PAIN [PAIN]. BODY BECAME PHYSICALLY WEAK [WEAKNESS GENERALISED]. VERY ILL /SICK [MALAISE]. LOST MY HAIR [ALOPECIA]. FIBROMYALGIA [FIBROMYALGIA]. ENDOMETRIOSIS [ENDOMETRIOSIS]. PERIODS THAT WERE VERY HEAVY [HEAVY PERIODS]. FIBROIDS [FIBROIDS]. CASE DESCRIPTION: CASE STATUS: SERIOUS - LISTED-RELATED-INCIDENT. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ENDOMETRIOSIS, MY LEG AND BACK WOULD BURN AS I STOOD, VERY ILL/ SICK, FLU LIKE SYMPTOMS, DEPRESSION, WRIST AND ANKLES ARE ACHING/BURNING, PERIODS THAT WERE VERY HEAVY, BECAME VERY HEAVY, STOMACH WAS EXTENDED AS IF I WAS 7/8 MONTHS PREGNANT, DIABETIC, DIABETIC NEUROPATHY, LOST MY HAIR, PAIN, BODY BECAME PHYSICALLY WEAK, I COULD BARELY CLIMB STAIRS, FIBROMYALGIA, ONE COIL DID NOT EXTEND ON IMPLANT, THUMBS STARTED BURNING/ BURNING IN HANDS, WRISTS, FINGERS, ADENOMYOSIS, FIBROIDS, CYST ON FALLOPIAN TUBES, LOTS OF SCAR

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TISSUE, PAIN IN JOINTS MUSCLES, PAIN OF THE ESSURE COILS, HEADACHES, AND LOWER BACK ACHES. THE CONSUMER'S MEDICAL HISTORY INCLUDED C-SECTIONS, PARITY 5, GESTATIONAL DIABETES, AND ANESTHESIA. THE CONSUMER'S INTERCURRENT CONDITION INCLUDED MARIJUANA USE. THE CONSUMER CONSIDERED HERSELF HEALTHY. NO INFO GIVEN ON CONSUMER'S DRUG HISTORY AND CONCOMITANT MEDICATION. ON (B)(6) 2006 THE CONSUMER HAD ESSURE (ESS205) INSERTED WITH ANESTHESIA (LOT NUMBER # 508837). WHEN SHE AWOKE SHE WAS A DIFFERENT WOMAN. SHE NOTICED SYMPTOMS INSTANTLY. WHEN SHE RETURNED BACK TO WORK HER LEGS AND LOWER BACK STARTED BURNING AS SHE STOOD AT THE GATE. FROM THERE SHE BECAME VERY ILL, WITH FLU-LIKE SYMPTOMS. BY 2006, SHE HAD TO RESIGN HER POSITION OF DUE TO BEING SICK AND USING UP ALL HER TIME OFF. THIS PUT HER INTO A DEPRESSION. SO SHE DECIDED TO FIND A POSITION THAT WOULDN'T BE SO DEMANDING. SHE THEN BEGAN NOTICING AND TELLING HER CO-WORKERS THAT HER WRIST AND ANKLES ARE ACHING/BURNING. THIS WAS WHEN HER HEALTH STARTED GOING ON A DOWNWARD SPIRAL. SHE STARTED HAVING PERIODS THAT WERE VERY HEAVY. SHE WOULD TAKE SHOWERS AND LOOK IN THE BOTTOM OF TUB AND SEE BLOOD CLOTS THE SIZE OF QUARTERS. SHE HAD X-RAYS ON HER WRIST, MRI ON HER BACK, BACK INJECTIONS FOR LOWER BACK BURN, PHYSICAL THERAPY FOR HER WRIST AND BACK. SHE BECAME VERY HEAVY, SHE GAINED WEIGHT AND HER STOMACH WAS EXTENDED AS IF SHE WAS 7/8 MONTHS PREGNANT. SHE BECAME DIABETIC AND WAS DIAGNOSED WITH DIABETIC NEUROPATHY AND TREATED WITH METFORMIN, CYMBALTA AND VICODIN. SHE LOST HER HAIR AND LOST THIS NEXT POSITION AFTER 2 YEAR BECAUSE SHE COULDN'T TOLERATE THE PAIN OR BLOOD. SHE WORKED THIRD SHIFT BUT HER BODY BECAME PHYSICALLY WEAK. SHE FELT LIKE AN 80 YEAR OLD WOMEN AND SHE COULD BARELY CLIMB STAIRS. SHE HAD A BIOPSY ON CLOTS, PAP SMEARS, X-RAYS, MRIS, CT SCANS, BACK INJECTIONS, CHECK FOR MS (MULTIPLE SCLEROSIS) AND LYME, BUT ALL BLOOD WORK WAS NORMAL. SHE STAYED ALONE IN SILENCE AND PAIN, DEPRESSION FOR YEARS. IN 2013, SHE INFORMED HER PERSONAL CARE DOCTOR AND HER GYNECOLOGIST DOCTOR OF WHAT ALL HER SYMPTOMS WERE. HER DOCTOR RAN A KIND OF BLOOD TEST, INCLUDING NICKEL, COPPER AND LEAD BUT ALL WAS NORMAL. DIABETES WENT AWAY TOO AT THAT PINT TO. SHE WAS VERY ILL, IN PAIN. HER DOCTOR THEN DIAGNOSED HER WITH FIBROMYALGIA. THEN SHE WENT TO SEE HER GYNECOLOGIST WHO ORDERED ULTRASOUND OF HER ESSURE COILS AND IT LOOKED THAT ONE OF THE OILS DIDN'T EXTEND ON IMPLANT. A HYSTERECTOMY WAS SCHEDULED. HER THUMBS STARTED BURNING AND SHE MADE HER DOCTOR AWARE THAT WAS HER LAST SYMPTOM BEFORE HER ABDOMINAL SURGERY TO REMOVE ESSURE COILS. WHEN THE DOCTOR REMOVED COILS ON (B)(6) 2013, HE STATED THAT HE COULD TELL THAT SHE WOULD GET INSTANT RELIEF. SHE HAD ENDOMETRIOSIS, ADENOMYOSIS, FIBROIDS, CYST ON FALLOPIAN TUBES AND LOTS OF SCAR TISSUE. THE CONSUMER WAS NO LONGER FELLING BURNING IN HANDS, WRISTS, FINGERS. SHE WAS NOT HAVING BLOOD AND PAIN OF THE ESSURE COILS. SHE GAVE UP ALL MEDICATION AND STARTED SELF-MEDICATING WITH MARIJUANA FOR EXTREME PAIN IN JOINTS MUSCLES AND HEADACHES. AT TIME OF REPORT THE CONSUMER HAS IMPROVED AND ALTHOUGH SHE CONTINUED HAVING LOWER BACK ACHES AND LEG MUSCLE PAIN, ALL OTHER SYMPTOMS WERE GONE COMPLETELY. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS RELATED. FOLLOW-UP ON (B)(4) 2014. CONSUMER WAS CONTACTED AND ANSWERED TO QUESTIONS ON PHONE. CONSUMER, (B)(6) YEAR OLD, HAD (B)(6) LBS, HEIGHT 62 INCHES. ESSURE WAS INSERTED ON (B)(6) 2006 AT A HOSPITAL BY A PHYSICIAN WHO CONSUMER THINKS IS NOT THERE ANYMORE. CONSUMER SEES AN OTHER DOCTOR AT HOSPITAL WHO PERFORMED HYSTERECTOMY AND TOOK ESSURE OUT ON 07/15/2013. CONSUMER STATED SHE HAS THE LOT NUMBER AND EXPIRATION DATE AND WILL PROVIDE IT LATER. AT TIME OF REPORTING, SHE WAS IN A STORE. NO FURTHER DETAILS WERE REPORTED. FOLLOW UP INFO RECEIVED ON (B)(6) 2014: PTC INVESTIGATION. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THEN HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MFG DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MFG BATCH RECORD AND

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CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THIS CASE ALSO REPORTED A DEPLOYMENT ISSUE (COIL DID NOT EXTEND IN FALLOPIAN TUBE) WHICH ALSO IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. SIX (6) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER # 508837 BUT NONE OF THESE CASES REFERS TO ANY SIMILAR TYPE OF MEDICAL EVENT AND ALTHOUGH THREE (3) OF THESE CASES REFER TO A DEPLOYMENT ISSUE IT WAS NOT A SIMILAR EVENT OF THE COIL DID NOT EXTEND (IN FALLOPIAN TUBE). NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL ASSESSMENT, THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFO AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP RECEIVED ON (B)(4) 2014: NO RESPONSE RECEIVED. CASE CONSIDERED TO BE CLOSED.

Manufacturer Narrative (H10):

EVAL SUMMARY: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATH

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE	6/4/2014	6/24/2014

Event Information:

Event Date (B3): 5/23/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): CS000312; B71770; B53030

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DONE ON RIGHT SIDE WITHOUT DIFFICULTY. ON TO LEFT SIDE: ESSURE TIP APPEARED BAD OUT OF THE PACKAGE; BENT DURING THE CASE- LOT # B53030; ANOTHER DEVICE OBTAINED FROM ANOTHER LOT NUMBER AND THIS DEVICE TIP BENT WHEN TRYING TO INSERT-LOT #B71770. A THIRD DEVICE FROM ANOTHER LOT NUMBER OBTAINED; THIS DEVICE DEPLOYED AFTER INSERTION WAS COMPLETE BUT THE RELEASE BUTTON HAD NOT BEEN HIT-LOT #CS0003R; CAUSING SIGNIFICANT DELAY IN CASE.
FROM PHYSICIAN NOTE REGARDING LEFT SIDE: "MULTIPLE ATTEMPTS TO PASS ESSURE COILS WERE UNDERWENT. THE FIRST ESSURE APPARATUS WAS NOTED TO BE BENT DUE TO THE ANGLE AND MULTIPLE DIFFERENT ANGLES WERE ATTEMPTED. FOUR DIFFERENT ESSURE APPARATUSES WERE ATTEMPTED AND A DECISION WAS MADE TO ABORT THE PROCEDURE AT THIS TIME WITH THE SUSPICION OF TUBAL OCCLUSION ON THE PATIENT'S LEFT SIDE VERSUS PATHOLOGIC TUBAL ANATOMY. AT THIS TIME, VIEW OF THE ESSURE COIL ON THE RIGHT SIDE YIELDED COMPLETE EXPULSION OF THE ESSURE COILS INTO THE UTERINE CAVITIES. THE ESSURE COILS WERE REMOVED FROM THE CAVITY. AT THIS TIME, THE DECISION WAS MADE TO USE THE MYOSURE APPARATUS TO REMOVE THE ENDOMETRIAL MASS. THIS WAS UNDERWENT WITHOUT DIFFICULTY."

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00195	BAYER HEALTHCARE LLC	6/6/2014	6/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON MAY 7, 2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED LEFT ECTOPIC PREGNANCY WITH ESSURE (DEVICE INEFFECTIVE) AND RUPTURED LEFT ECTOPIC PREGNANCY WITH ESSURE. ESSURE WAS REPORTED AS THE TRADE NAME. CASE REPORT: THIS FEMALE PATIENT WITH TUBAL RUPTURE, UNDERWENT AN EMERGENCY EXPLORATORY LAPAROTOMY, WITH IDENTIFICATION OF A LEFT ECTOPIC PREGNANCY, AND FINDINGS OF APPROPRIATELY PLACED MICRO-INSERTS. SHE HAD PREVIOUSLY UNDERGONE A HSG (HYSTEROSALPINGOGRAM), WHICH CONFIRMED BILATERAL TUBAL OCCLUSION. REPEAT HSG 3 MONTHS AFTER THE RUPTURED ECTOPIC PREGNANCY SHOWED RIGHT TUBAL PATENCY. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTIONS, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: THIS IS THE CASE REPORT OF ECTOPIC PREGNANCY WITH ESSURE, RESULTING IN RUPTURE. RELATED CASE: (B)(4). FOLLOW-UP RECEIVED ON (B)(4) 2014: THIS CASE REPORT IS FROM THE LITERATURE ARTICLE WHICH WAS PUBLISHED IN ANNALS OF EMERGENCY MEDICINE, TITLE AS "RUPTURED ECTOPIC PREGNANCY AFTER PREVIOUSLY CONFIRMED TUBAL OCCLUSION BY THE ESSURE PROCEDURE" AND AUTHORED BY BJORNSSON

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HM, GRAFFEO CS, DAVIS SS. CASE REPORT: THIS 43-YEAR-OLD BLACK WOMAN GRAVIDA 1 PARA 1 PRESENTED TO THE EMERGENCY DEPARTMENT (ED), COMPLAINING OF SEVERE LOWER ABDOMINAL PAIN THAT HAD BEGUN EARLY THAT SAME MORNING. THIS WAS ACCOMPANIED BY NAUSEA AND DIZZINESS BUT NO OTHER ASSOCIATED SYMPTOMS. THE PATIENT STATED THAT SHE HAD A HISTORY OF AN ESSURE PROCEDURE. ON ARRIVAL IN THE ED, THE PATIENT WAS IN HYPOVOLEMIC SHOCK. A URINE PREGNANCY TEST RESULT WAS POSITIVE, AND FREE FLUID WAS OBSERVED IN THE ABDOMEN ON BESIDE EMERGENCY ULTRASONOGRAPHY. RUPTURED ECTOPIC PREGNANCY WAS SUSPECTED, AND SHE UNDERWENT AN EMERGENCY EXPLORATORY LAPAROTOMY. AN ECTOPIC PREGNANCY WAS IDENTIFIED IN THE LEFT FALLOPIAN TUBE, BUT THE ESSURE DEVICES APPEARED TO BE CORRECTLY PLACED IN BOTH TUBES. THE PATIENT HAD AN UNEVENTFUL HOSPITAL COURSE AND WAS DISCHARGED HOME ON POSTOPERATIVE DAY 2. A REVIEW OF HER OUTPATIENT MEDICAL RECORDS CONFIRMED THAT TUBAL OCCLUSION HAD BEEN OBSERVED ON A HYSTEROSALPINGOGRAM 3 MONTHS AFTER THE ESSURE PROCEDURE BUT THE LEFT DEVICE MAY HAVE BEEN SLIGHTLY MORE DISTAL THAN THE IDEAL RECOMMENDED PLACEMENT. ON A REPEATED HYSTEROSALPINGOGRAM CONDUCTED 3 MONTHS AFTER HER RUPTURED ECTOPIC PREGNANCY, THE RIGHT FALLOPIAN TUBE THAT WAS OCCLUDED ON THE PREVIOUS HYSTEROSALPINGOGRAM WAS FOUND TO BE PATIENT. AUTHOR'S COMMENT: THIS IS A CASE OF RUPTURED ECTOPIC PREGNANCY WITH HEMORRHAGIC SHOCK IN A WOMAN WHO HAD PREVIOUSLY UNDERGONE HYSTEROSCOPIC STERILIZATION BY THE ESSURE PROCEDURE AND CONFIRMATION OF TUBAL OBSTRUCTION BY HYSTEROSALPINGOGRAM. THIS IS THE FIRST REPORT OF SUCH A CASE, ALTHOUGH PREGNANCY HAS BEEN REPORTED AFTER FAILURE OF THIS PROCEDURE. EMERGENCY PHYSICIANS SHOULD BE AWARE OF THE POTENTIAL FOR ECTOPIC PREGNANCY IN WOMEN WHO HAVE HAD AN ESSURE PROCEDURE DESPITE CONFIRMED TUBAL OCCLUSION.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 31-MAY-2014: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN T

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036543	BAYER	6/6/2014	6/13/2014

Event Information:

Event Date (B3): 6/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/3/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2014, I HAD THE ESSURE PROCEDURE DONE. WHAT WAS SUPPOSED TO BE A 10 MINUTE PROCEDURE TURNED INTO 2 HOURS AND A DAY SURGERY APPOINTMENT THE NEXT DAY. MY DOCTOR WENT TO INSERT THE FIRST COIL INTO MY RIGHT FALLOPIAN TUBE. WHEN HE HIT RELEASE THE COIL DID NOT RELEASE. HE HIT RELEASE SEVERAL MORE TIMES BEFORE GETTING A NEW DEVICE. BY THIS TIME I WAS IN IMMENSE, SHOOTING PAIN. HE THEN INSERTED THE NEW COIL WITHOUT ANY TROUBLE, BUT THIS CONTINUED TO CAUSE EVEN GREATER PAIN. HE INSERTED THE COIL IN THE LEFT TUBE WITHOUT ANY DIFFICULTY. AFTER THE PROCEDURE HE LOOKED AT THE DEVICE AND REALIZED THAT THE FIRST DEVICE DID IN FACT RELEASE A COIL INTO MY FALLOPIAN TUBE, SO I HAD TWO COILS IN ONE TUBE DUE TO A FAULTY DEVICE AND NEGLIGENCE ON MY DOCTORS PART. SINCE THEN I HAVE HAD IMMENSE CRAMPING IN MY RIGHT SIDE THAT FEELS LIKE IT'S BURNING, AND IS RADIATING INTO MY THIGH AND ACROSS MY LOWER BACK. I WAKE UP SEVERAL TIMES DURING THE NIGHT FROM PAIN. THE DAY AFTER THE INITIAL PROCEDURE, I WENT TO THE SURGICAL CENTER TO GO UNDER GENERAL ANESTHESIA AND HAVE THE 2ND COIL IN MY RIGHT FALLOPIAN TUBE REMOVED. THE DOCTOR PULLED IT OUT, EVEN THOUGH THE ESSURE INSERT SAYS NOT TO DO THIS, AND THE DEVICE WAS BENT ON THE FRONT AND LOOKS TO BE MISSING COILS FROM THE PHOTOS. THE ORIGINAL FAULTY DEVICE IS STILL IN MY TUBE, I HAVE NOT HAD ANY IMAGING TO CONFIRM ITS PLACEMENT OR THAT IT IS NOT BROKEN, SINCE THE INSERTION DEVICE USED WAS FAULTY. THERE ARE NO COILS IN MY CERVIX BECAUSE THE DEVICE IS TOO FAR IN. WHAT WAS SUPPOSED TO BE A ONE DAY PROCEDURE HAS PUT ME OUT OF WORK FOR SEVERAL DAYS AND PROBABLY MORE, SEVERE MENTAL ANGUISH, AND EXTREME PAIN. I HAVE BEEN BLEEDING SINCE, AND I AM NOT SURE IF IT IS MY PERIOD OR A SIDE EFFECT.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036550	BAYER	6/6/2014	6/13/2014

Event Information:

Event Date (B3): 11/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/6/2013
Explant Date (E7): 5/2/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY DOCTOR WOULDN'T TAKE NO FOR AN ANSWER WITH THE ESSURE PERMANENT BIRTH CONTROL SO I GOT IT PLACED IN ONE TUBE, THE OTHER TUBE HE COULDN'T GET IT PLACED IN. SO HE DIDN'T BECAUSE HE WAS THINKING THAT ONE TUBE WAS BLOCKED ALREADY. I GOT THE HSG DONE 3 MONTHS LATER AND IT WASN'T BLOCKED. SO FOR 6 MONTHS I WAS ON THE NUVARING WITH THAT ONE ESSURE PLACEMENT TO PREVENT PREGNANCY. I WAS CONSTANTLY IN PAIN AND DEVELOPED A NICKEL ALLERGY. I THEN HAD TO HAVE MY TUBES REMOVED AND ALL THE SYMPTOMS THAT I WAS HAVING SUDDENLY DISAPPEARED. MIGHT I ADD THAT THE ESSURE I HAD IT FOR ONLY 6 MONTHS AND THERE WERE A LOT OF LEFT OVER PARTICLES IN MY UTERUS. I HAVE PICTURES TO PROVE IT. I FEEL LIKE DOCTORS DON'T LISTEN TO THEIR PATIENTS ANYMORE AND JUST WANT TO TAKE THE EASY WAY OUT (OF COURSE ESSURE IS SO MUCH EASIER TO DO THEN TIE TUBES THE OLD FASHION WAY). NO CUTS, NOTHING. AND IN SO I HAD TO GO THROUGH MORE PAIN AND SUFFERING JUST LIKE MILLIONS OF OTHER WOMEN OUT HERE. IT IS SUPPOSED TO BE A MORE "EFFECTIVE" BIRTH CONTROL THAN AN ACTUAL TUBAL LIGATION SO THEY SAY, BUT TO TELL YOU THE TRUTH I HAVEN'T KNOWN OF ANYONE GETTING PREGNANT WITH A TUBAL. BUT ON THE OTHER HAND I SEE PEOPLE WITH ESSURE EVERYDAY POPPING UP PREGNANT. IN ALL REALITY DO THE MATH, THIS PRODUCT NEEDS TO BE OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00208	BAYER HEALTHCARE LLC	6/6/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 07-MAY-2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED ESSURE MALPOSITION/DISLOCATION. ESSURE WAS REPORTED AS THE TRADE NAME. CASE REPORT: IN THIS FEMALE PT'S CASE, IN PARTICULAR THERE WERE MULTIPLE UNSUCCESSFUL ATTEMPTS AT REMOVING THE MALPOSITIONED/DISLOCATED DEVICE WITH GRASPERS, AND FAILURE TO CUT THE TRAILING METAL COILS WITH SCISSORS. ALSO TRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: HYSTEROSCOPIC RETRIEVAL OF ESSURE IS GENERALLY DESCRIBED AS BEING SIMPLE AND NOT REQUIRING EXCESSIVE TRACTION, HOWEVER IN THIS CASE THERE MULTIPLE UNSUCCESSFUL ATTEMPTS AT REMOVING THE DEVICE WITH GRASPERS, AND FAILURE TO CUT THE TRAILING METAL COILS WITH SCISSORS. RELATED CASE: (B)(4). "FOLLOW-UP RECEIVED ON 15-MAY-2014: THIS CASE REPORT IS FROM THE LITERATURE ARTICLE WHICH WAS PUBLISHED IN JOURNAL OF ULTRASOUND IN MEDICINE: OFFICIAL JOURNAL OF THE AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE, TITLED AS "AN UNUSUAL COMPLICATION OF HYSTEROSCOPIC STERILIZATION" AND AUTHORED BY BROWN WW, 3RD. CASE REPORT: THIS (B)(6)

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OLD WOMAN PRESENTED WITH A REQUEST FOR PERMANENT STERILIZATION. HER MEDICAL HISTORY WAS NOTABLE FOR MULTIPLE ABDOMINAL SURGERIES SUBSEQUENT TO CHILDHOOD INJURIES SUSTAINED IN AN AUTOMOBILE COLLISION. AFTER PROPER COUNSELING, SHE ELECTED TO PROCEED WITH THE ESSURE MICROINSERT (CONCEPTUS INC, MOUNTAIN VIEW, CA) TRANSCERVICAL STERILIZATION PROCEDURE. AFTER HYSTEROSCOPIC PLACEMENT OF THE FIRST MICROINSERT INTO THE RIGHT FALLOPIAN TUBE AND EXPANSION OF THE OUTER COIL, IT BECAME EVIDENT THAT THE DELIVERY WIRE WOULD NOT AUTOMATICALLY RELEASE THE DEVICE DESPITE PROPER BACKWARD THUMBWHEEL ROTATION ON THE HANDLE WHICH RESULTED IN UNRAVELING OF LARGE PORTIONS OF PRIMARILY THE INNER COIL INTO THE UTERINE CAVITY. ONCE THE DELIVERY WIRE DID FINALLY DISCHARGE FROM THE DEVICE, CLOSE INSPECTION AT THE TUBAL OS REVEALED THAT POLYESTER FIBERS SURROUNDING THE INNER COIL WERE POSITIONED AT THE APPROPRIATE LOCATION WITHIN THE PROXIMAL TUBE. THUS, DESPITE THE COMPLICATED DEPLOYMENT, IT WAS PERCEIVED THAT THE FUNCTIONAL END RESULT WOULD STILL BE TUBAL OCCLUSION, AND THE DECISION WAS MADE TO PROCEED WITH PLACEMENT OF A SECOND DEVICE ON THE CONTRALATERAL SIDE. UNFORTUNATELY, THERE WAS RELEASE FAILURE AGAIN ON THE LEFT, AND THE OUTCOME WAS ALSO UNRAVELING AND PARTIAL DISLODGMENT OF THIS MICROINSERT INTO THE ENDOMETRIAL CAVITY. THE SECOND DELIVERY WIRE DID FINALLY DETACH AFTER CONTINUED TRACTION ON THE DEVICE AND HANDLE MANIPULATION. ATTEMPTS TO REMOVE THE SURPRISINGLY WELL ANCHORED IMPLANTS ENTIRELY FROM THE TUBES USING GRASPING FORCEPS WERE UNSUCCESSFUL, AND EFFORTS TO CUT THE TRAILING METAL COILS WITH SCISSORS FAILED. THE PROCEDURE WAS ABANDONED AT THIS POINT, LEAVING UNRAVELED DEVICE COILS SCATTERED THROUGHOUT THE UTERINE CAVITY, AND AN ABDOMINAL MINI LAPAROTOMY WITH BILATERAL TUBAL LIGATION WAS SUCCESSFULLY ACCOMPLISHED. APPROX 5 MONTHS AFTER THE PROCEDURE, THE PT WAS SEEN BY HER PRIMARY CARE PROVIDER, WHO ORDERED PELVIC SONOGRAPHY FOR PAINLESS UTERINE BLEEDING. AT THE TIME, THE INTERPRETING PHYSICIANS WERE COMPLETELY UNAWARE OF THE PREVIOUS DIFFICULTIES ENCOUNTERED DURING SURGICAL HYSTEROSCOPY, AND THE FINAL ULTRASOUND REPORT ONLY MENTIONED A BIZARRELY SHAPED FOREIGN BODY OF UNK ORIGIN WITHIN THE UTERUS. LATER, AFTER 3-DIMENSIONAL RECONSTRUCTED CORONAL VIEWS OF THE UTERUS WERE MADE AVAILABLE, SOME OF THE MORE COMMON WELL DESCRIBED IMAGING APPEARANCES OF ESSURE IMPLANTS COULD BE APPRECIATED. AUTHOR'S COMMENT: THIS CASE HIGHLIGHTS AN UNEXPECTED AND PREVIOUSLY UNREPORTED COMPLICATION INVOLVING ESSURE DEVICE DEPLOYMENT, WITH THE BIZARRE HYSTEROSCOPIC RESULTS YIELDING MOSTLY UNRECOGNIZABLE SONOGRAPHIC IMAGES OF AN INTRAUTERINE FOREIGN BODY. THE MENTRUAL IRREGULARITIES PROMPTING SONOGRAPHY IN THIS PT WERE THOUGHT TO RESULT FROM THE LINGERING EFFECTS OF PREPROCEDURAL DEPOMEDROXYPROGESTERONE ENDOMETRIAL SUPPRESSION. FINALLY, THE PRESENCE OF THIS FOREIGN BODY DISPERSED IRREGULARLY THROUGHOUT THE UTERINE CAVITY MAY POSE DIFFICULTIES LATER IN LIFE SHOULD THERE ARISE A CLINICAL INDICATION FOR ENDOMETRIAL EVAL. ANY ATTEMPT AT BLIND BIOPSY, OR EVEN SALINE INFUSION SONOHYSTEROGRAPHY, MAY BE DIFFICULT OR IMPOSSIBLE AND SHOULD BE REPLACED BY DIRECT HYSTEROSCOPIC VISUALIZATION AND TARGETED SAMPLING. RELATED CASE: (B)(4).

Manufacturer Narrative (H10):

REPORT SOURCE LITERATURE DESCRIPTION. JOURNAL: JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY. AUTHOR: ADELMAN MR, DASSEL MW, SHARP HT. TITLE: MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW. VOLUME: XX YEAR:

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00210	BAYER HEALTHCARE LLC	6/6/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCE PERSISTENT CHRONIC ABDOMINAL PAIN. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: A PT EXPERIENCED PERSISTANT PAIN, FOLLOWING THE INSERTION OF MICRO INSERT. SHE HAD A NORMAL X RAY, THE MICRO-INSERTS WERE CORRECTLY PLACED. THE CHRONIC ABDOMINAL PAIN DID NOT RESOLVE AFTER LAPAROSCOPY SALPINGECTOMY AND APPENDECTOMY. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: EIGHT CASES OF PERSISTANT PAIN WERE IDENTIFIED. THERE WERE A TOTAL OF 4 NORMAL ULTRASOUNDS, 3 NORMAL HYSTEROSCOPIES, AND 1 NORMAL X RAY. ALL OF THE PTS UNDERWENT BILATERAL MICRO-INSERT REMOVAL, WITH EITHER A HYSTEROSCOPIC OR LAPAROSCOPIC APPROACH. RELATED CASE: (B)(4).

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Manufacturer Narrative (H10):

(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00214	BAYER HEALTHCARE LLC	6/6/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 05/07/2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED CORNUAL PERFORATION WITH SUBSEROSAL PLACEMENT OF THE MICRO-INSERT. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: A PT EXPERIENCED CORNUAL PERFORATION WITH SUBSEROSAL PLACEMENT. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: CORNUAL PERFORATION WITH SUBSEROSAL PLACEMENT OF THE MICRO-INSERT WAS NOTED IN 3 CASES, TWO OF WHICH SPECIFICALLY CITED A DIFFICULT INSERTION. A CORNUAL PERFORATION IS DEMONSTRATED LAPAROSCOPICALLY. ONE OF THE DEVICES WAS REMOVED HYSTEROSCOPICALLY, ONE WAS REMOVED LAPAROSCOPICALLY BY UNROOFING THE SEROSA AND TEASING THE DEVICE OUT WITH GENTLE TRACTION, AND THE THIRD WAS DISCOVERED AT THE TIME OF HYSTERECTOMY. RELATED CASES: OTHER CASES FOR CORNUAL PERFORATION REPORTED IN SAME REVIEW ARTICLE ARE: (B)(4). SIGNIFICANT F/U (FULL TEXT ARTICLE FOR REFERENCE NUMBER 30) RECEIVED ON 05/14/2014: CASE REPORT: THIS CASE REFERS TO (B)(6) WOMAN G4P2 WHO PRESENTED WITH CHRONIC PELVIC PAIN FOR 1 YEAR. THE PAIN STARTED AFTER UNCOMPLICATED

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HYSTEROSCOPIC STERILIZATION WITH ESSURE BY HER PRIMARY GYNECOLOGIST. THE PT DENIED ANY HISTORY OF PELVIC PAIN BEFORE ESSURE PLACEMENT. SHE HAD BEEN ON ORAL CONTRACEPTIVES (OCPS) FOR 10 YEARS BEFORE ESSURE PLACEMENT BUT DECIDED TO STOP OCPS AFTER A NEW DIAGNOSIS OF FACTOR V LEIDEN DEFICIENCY. HSG AT 3 MONTHS AFTER ESSURE PLACEMENT CONFIRMED SUCCESSFUL TUBAL OCCLUSION. THE PT COMPLAINED OF LEFT LOWER QUADRANT PAIN RADIATING TO THE BACK. SHE DESCRIBED THE PAIN AS A SHARP, PULLING PAIN, MAKING IT DIFFICULT FOR HER TO LIE ON HER LEFT SIDE. THE PAIN WAS CONSTANT, NOT RELATED TO HER MENSES, AND SHE DENIED DYSMENORRHEA OR DYSPAREUNIA. THE PT ALSO COMPLAINED OF IRREGULAR, HEAVY VAGINAL BLEEDING THAT DID NOT RESPOND TO MEDICAL MANAGEMENT. THE PT UNDERWENT A TOTAL LAPAROSCOPIC HYSTERECTOMY WITH BILATERAL SALPINGECTOMY FOR DEFINITIVE MANAGEMENT OF HER CHRONIC PELVIC PAIN AND MENOMETRORRHAGIA. AT THE TIME OF LAPAROSCOPY, THE LEFT ESSURE COIL WAS NOTED TO HAVE PERFORATED THE LEFT CORNUA AND APPEARED AS A SUBSEROSAL ELLIPTICAL COIL OVERLYING THE LEFT FALLOPIAN TUBE AT THE UTEROTUBAL JUNCTION. THERE WAS NO EVIDENCE OF ENDOMETRIOSIS AT THE TIME OF LAPAROSCOPY. PATHOLOGIC EXAMINATION SHOWED EVIDENCE OF ADENOMYOSIS. ON REVIEWING THE IMAGES OF THE HSG, IT WAS NOTED THAT, ALTHOUGH TUBAL OCCLUSION WAS CONFIRMED, THE LEFT ESSURE COIL APPEARED TWISTED IN AN ABNORMAL CONFIGURATION AND DID NOT SEEM TO FOLLOW THE EXPECTED ANATOMIC TRAJECTORY OF THE FALLOPIAN TUBE. INSTEAD, IT APPEARED CURVED ON ITSELF IN AN ELLIPTICAL FASHION, A CONFIGURATION THAT IS CONSISTENT WITH THE FINDINGS SEEN AT THE TIME OF LAPAROSCOPY. AUTHORS' COMMENT: IN THIS CASE, DESPITE THE PATHOLOGIC FINDING OF ADENOMYOSIS, WE BELIEVE THAT THE PT'S CONSTANT, LOCALIZED, POSITIONAL PULLING PAIN IN HER LEFT LOWER QUADRANT, WHICH ONLY STARTED AFTER ESSURE PLACEMENT AND IS NOT ASSOCIATED WITH DYSMENORRHEA OR DYSPAREUNIA, IS MOST LIKELY RELATED TO THE PERFORATED ESSURE RATHER THAN ADENOMYOSIS. THE ABNORMAL BLEEDING, ON THE OTHER HAND, IS DIFFICULT TO ATTRIBUTE TO ONE FACTOR OR ANOTHER, BECAUSE THE PT WAS ON OCPS FOR SEVERAL YEARS BEFORE ESSURE PLACEMENT. RELATED CASE FROM THE SAME ARTICLE: (B)(4).

Manufacturer Narrative (H10):

REPORT SOURCE LITERATURE DESCRIPTION; JOURNAL: JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY; AUTHOR: ADELMAN MR, DASSEL MW, SHARP HT; TITLE: MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMIC REVIEW. VOLUME: XX YEAR: 2

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00201	BAYER HEALTHCARE LLC	6/6/2014	7/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(4) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED LESION IN MY BLADDER, PIECE OF COIL DISLODGED FROM FALLOPIAN TUBE AND PIECE OF COIL IS IN UTERUS. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. IN 2008 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. ON (B)(6) 2014, THE CONSUMER WAS DIAGNOSED WITH PIECE OF COIL DISLODGED FROM FALLOPIAN TUBE AND WAS IN HER UTERUS. ALSO A LESION WAS DISCOVERED ON HER BLADDER AND SHE WOULD NEED A SURGERY TO REMOVE THE COIL FOUND IN HER UTERUS AND THE LESION ON HER BLADDER. NO ASSESSMENT WAS GIVEN.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON (B)(4) 2014: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC) - NEAR INCIDENT REPORT. THE BAYER REFERENCE NUMBER FOR THE PTC REP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00196	BAYER HEALTHCARE LLC	6/7/2014	6/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON MAY 7, 2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED MALPOSITIONED DEVICE IN PERITONEAL CAVITY AND SEVERAL PIECES OF MICRO INSERT FOUND IN PERITONEAL CAVITY. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: A MALPOSITION OF THE MICRO-INSERT WAS IDENTIFIED. THE PATIENT EXPERIENCED 4 YEARS OF PAIN, 1 LAPAROSCOPY, AND 3 LAPAROTOMIES BEFORE SEVERAL PIECES OF THE MICRO-INSERT WERE IDENTIFIED ON CT SCAN, AND REMOVED VIA LAPAROTOMY WITH INTRAOPERATIVE FLUOROSCOPY. THE PATIENT EXPERIENCED RESOLUTION OF PAIN POSTOPERATIVELY. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEN FDA APPROVED IN THE UNITED STATED SINCE 2002. COMPLICATIONS ASSOCIATED WITH ENSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATION, COMPOUND BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: THERE WERE 2 PATIENTS WHO EXPERIENCED PROLONGED PERIODS OF PAIN, WITH LENGTHY EVALUATION, BOTH OF WHICH ULTIMATELY REQUIRED REMOVAL OF THE DEVICES FROM THE PERITONEAL CAVITY. A PATIENT EXPERIENCED 4 YEARS OF PAIN, 1 LAPAROSCOPY, AND 3 LAPAROTOMIES BEFORE SEVERAL PIECES OF THE MICRO-INSERT WERE IDENTIFIED ON CT SCAN, AND REMOVED VIA LAPAROTOMY WITH INTRAOPERATIVE FLUOROSCOPY. ALL PATIENTS WITH PAIN AND MALPOSITIONED DEVICES

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EXPERIENCED RESOLUTION OF THEIR PAIN POSTOPERATIVELY. RELATED CASE: 2014-068089. FOLLOW UP RECEIVED ON MAY 14, 2014: THIS CASE REPORT IS FROM AN ARTICLE ENTITLED, "USE OF INTRAOPERATIVE FLUOROSCOPY DURING LAPAROTOMY TO IDENTIFY FRAGMENTS OF RETAINED ESSURE MICRO INSERTS CASE REPORT." AUTHORED BY HOWARD DL, CHRISTENSON PJ, STRICKLAND JL. CASE REPORT: THE PATIENT, A (B)(6) YEAR-OLD WOMAN, GRAVIDA 6 PARA 5, HAD UNDERGONE AN UNCOMPLICATED ESSURE PROCEDURE 4 YEARS EARLIER. THE MEDICAL HISTORY WAS NOTABLE FOR MIGRAINE HEADACHES, BIPOLAR DISORDER, AND RENAL FAILURE IN A PREVIOUS PREGNANCY. BOTH OSTIA WERE VISUALIZED ADEQUATELY. THERE WERE 13 TRAILING COILS AFTER PLACEMENT OF THE ESSURE MICRO INSERT IN THE LEFT FALLOPIAN TUBE, AND 9 TRAILING COILS AFTER PLACEMENT OF THE ESSURE MICROINSERT IN THE RIGHT FALLOPIAN TUBE. AT FOLLOW-UP HYSTEROSALPINGOGRAPHY (HSG) , THE LEFT FALLOPIAN TUBE WAS OCCLUDED, INDICATING THAT THE LEFT MICROINSERT WAS IN PLACE. THE RIGHT FALLOPIAN TUBE WAS PATENT, AND THE RIGHT MICROINSERT WAS VISUALIZED IN THE ABDOMINAL CAVITY, AND UTERINE PERFORATION SECONDARY TO MIGRATION OF THE RIGHT ESSURE MICROINSERT WAS SUSPECTED. THE PATIENT HAD NO SYMPTOMS, AND FINDINGS AT POST-HSG ABDOMINAL EXAMINATION WERE COMPLETELY BENIGN, WITH NORMAL VITAL SIGNS. TWO MONTHS LATER, THE PATIENT UNDERWENT LAPAROSCOPY, AND RIGHT-SIDED ESSURE MICROINSERT WAS NOTED TO BE PERFORATING THROUGH THE UTERINE FUNDUS. THIS MICROINSERT WAS REMOVED, AND RIGHT-SIDED UNILATERAL TUBAL LIGATION WAS CARRIED OUT VIA BIPOLAR COAGULATION. ALTHOUGH THERE WAS A VISUAL ATTEMPT TO ENSURE COMPLETE REMOVAL OF THE PERFORATING MICROINSERT DURING THIS LAPAROSCOPIC PROCEDURE, NO INTRAOPERATIVE RADIOGRAPHIC EXAMINATION WAS PERFORMED TO CONFIRM THAT NO FOREIGN MATERIAL REMAINED. SIX MONTHS AFTER LAPAROSCOPIC RETRIEVAL OF THE RIGHT-SIDED ESSURE MICROINSERT, THE PATIENT WENT TO ANOTHER EMERGENCY ROOM BECAUSE OF SEVERE ABDOMINAL PAIN. HER TEMPERATURE WAS 99.7 DEGREE F; PULSE, 130 BEATS PER MINUTE; AND BLOOD PRESSURE, 113/78 MM HG. THE WHITE BLOOD CELL COUNT WAS ELEVATED AT 13, 200, AND HEMOGLOBIN WAS 12.9 G/DL. THE ABDOMINAL PAIN HAD WORSENED SUBSTANTIALLY DURING HER STAY IN THE EMERGENCY ROOM, AND ABDOMINAL EXAMINATION REVEALED EXTREME GUARDING WITH PERITONEAL SIGNS. A COMPUTED TOMOGRAPHY (CT) SCAN OBTAINED WHILE THE PATIENT WAS IN THE EMERGENCY ROOM SHOWED A LINEAR METALLIC DENSITY EXTENDING FROM THE CENTRAL UTERINE CANAL THOUGH THE MYOMETRIUM INTO THE PERIUTERINE FAT. TRANSVAGINAL ULTRASOUND WAS SUBSEQUENTLY PERFORMED, AND AN ECHOGENIC FOREIGN BODY WAS OBSERVED, EXPLORATORY LAPAROTOMY AND TOTAL ABDOMINAL HYSTERECTOMY. INTRAOPERATIVELY, THE SURGEON COLD PALPATE A WIRELIKE TUBULAR STRUCTURE ALONG THE LEFT CORNUAL REGION OF THE UTERUS THAT WAS COVERED BY VISCERAL PERITONEUM AND WHICH EXTENDED TO THE MIDPORTION OF THE LEFT FALLOPIAN TUBE. THE OVARIES WERE VISUALIZED, AND WERE NOTE TO BE NORMAL BILATERALLY AND WERE LEFT IN PLACE. THE APPENDIX WAS NORMAL IN APPEARANCE AND WAS NOT REMOVED. NO OTHER INTRA-ABDOMINAL ABNORMALITIES WERE NOTED. THE POSTOPERATIVE COURSE WAS UNREMARKABLE. THE FINAL PATHOLOGY REPORT CONFIRMED A ROUND DENSE FOREIGN BODY (MEASURING 0.2 CM) WITHIN THE MIDPORTION OF THE LEFT FALLOPIAN TUBE AND A SYNTHETIC WIRE DEVICE EMBEDDED IN THE LEFT CORNUA OF THE UTERUS. THREE MONTHS AFTER UNDERGOING THE HYSTERECTOMY, THE PATIENT HAD RIGHT LOWER QUADRANT PAIN. TRANSVAGINAL ULTRASOUND SHOWED A COMPLEX RIGHT OVARIAN CYST THAT MEASURED 6CM IN ITS WIDEST DIMENSION. SUBSEQUENTLY, THE PATIENT UNDERWENT EXPLORATORY LAPAROTOMY, WITH RIGHT SALPINGO-OOPHORECTOMY AND LEFT OVARIAN CYSTOTOMY. THERE WERE EXTENSIVE ADHESIONS AT THE OMENTUM OVER THE BILATERAL ADNEXA AND OVER THE BLADDER, AS WELL AS TO THE PELVIC SIDEWALL, AND THE COLON WAS AFFIXED TO THE BLADDER AND THE OMENTUM. ALSO OF NOTE, A WALLED-OFF AREA FULL OF SEROUS FLUID WAS NOTED ADJACENT TO THE RIGHT FALLOPIAN TUBE AND SEPARATE FROM THE RIGHT OVARY. FINAL PATHOLOGIC ANALYSIS DEMONSTRATED MULTIPLE HEMORRHAGIC CYSTS WITHIN THE RIGHT OVARY. TWO YEARS AFTER THE HYSTERECTOMY, DURING WHICH TIME THE PATIENT HAD UNDERGONE SURGICAL REMOVAL OF THE RIGHT ADNEXA, SHE AGAIN REPORTED PERSISTENT PELVIC PAIN THAT WAS NOT RESPONDING TO MEDICAL MANAGEMENT. TRANSVAGINAL ULTRASOUND REVEALED

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A 5-CM COMPLEX LEFT OVARIAN CYST. AT PHYSICAL EXAMINATION, VITAL SIGNS WERE NORMAL; HOWEVER, THERE WAS LOWER QUADRANT TENDERNESS, AND AT PELVIC EXAMINATION, THERE WAS LEFT ADNEXAL TENDERNESS. THE PATIENT SUBSEQUENTLY UNDERWENT A THIRD EXPLORATORY LAPAROTOMY, WITH LEFT OOPHORECTOMY. INTRAOPERATIVELY, EXTENSIVE ADHESIONS WERE NOTED BETWEEN THE OMENTUM AND ABDOMINAL WALL AND BETWEEN THE BOWEL AND PELVIS. THE FINAL PATHOLOGIC REPORT FROM THIS SURGERY INDICATED A HEMORRHAGIC CORPUS LUTEUM CYST ALONG WITH SEVERAL SMALL SIMPLE FOLLICULAR CYSTS. ONE YEAR AFTER THE EXPLORATORY LAPAROTOMY AND LEFT OOPHORECTOMY, THE PATIENT CONTINUED TO HAVE WORSENING RIGHT LOWER QUADRANT PAIN, AND SHE WAS AGAIN ADMITTED. VITAL SIGNS WERE WITHIN NORMAL LIMITS, AND ABDOMINAL EXAMINATION WAS NOTABLE ONLY FOR MILD RIGHT LOWER QUADRANT TENDERNESS; THERE WERE NO PERITONEAL DURING THIS HOSPITALIZATION, THE PATIENT UNDERWENT CT, WHICH REVEALED A LINEAR FOREIGN BODY PROJECTING FROM ABOVE THE URINARY BLADDER AND EXTENDING INTO THE RIGHT ADNEXA, CONSISTENT WITH A RETAINED ESSURE MICROINSERT. A UROLOGIST WAS CONSULTED, AND AT OPEN LAPAROTOMY, A FIRM LINEAR OBJECT WITH THE CT FINDINGS WAS PALPATED IN TISSUE ADJACENT TO THE BLADDER. THE TISSUE WAS RESECTED, AND FLUOROSCOPY OF THE TISSUE DEMONSTRATED A LINEAR METALLIC MATERIAL. HOWEVER, FLUOROSCOPY OF THE ABDOMEN DEMONSTRATED A SECOND METALLIC FOREIGN BODY THAT HAD BEEN INCORPORATED INTO THE OMENTUM. THIS WAS ALSO RESECTED, AND FURTHER FLUOROSCOPY OF THE ABDOMEN DEMONSTRATED NO FURTHER METALLIC DENSITIES. THE FINAL PATHOLOGIC REPORT FROM THIS SURGERY INDICATED MULTIPLE IRREGULAR TAN SOFT-TISSUE FRAGMENTS MEASURING 3.0X0.1X0.1 CM. THE PATIENT EXPERIENCED AN UNREMARKABLE POSTOPERATIVE COURSE, WITH COMPLETE RESOLUTION OF THE PELVIC PAIN WITHOUT RECURRENCE.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON MAY 20, 2014: PTC NUMBER PROVIDED: (B)(4). FOLLOW UP MAY 21, 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE.

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00193	BAYER HEALTHCARE LLC	6/7/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

TUBAL PERFORATION BY ESSURE: THREE DIFFERENT CLINICAL PRESENTATIONS. OBJECTIVE: TO ASSESS THE CONVENIENCE AND SAFETY OF ESSURE STERILIZATION IN AN OUTPATIENT SETTING AND THE USE OF ULTRASOUND AS DIAGNOSTIC TOOL FOR VERIFICATION OF PROPER PLACEMENT FOR THE 3-MONTH FOLLOW- UP. DESIGN: PROSPECTIVE COHORT STUDY. SETTING: TEACHING HOSPITAL DEPARTMENT OF OBSTETRICS AND GYNECOLOGY. PATIENT(S): FEMALE PATIENTS WITH A REQUEST FOR PERMANENT TUBAL STERILIZATION. INTERVENTION(S): ESSURE STERILIZATION. MAIN OUTCOME MEASURE(S): BILATERAL TUBAL OCCLUSION AFTER ESSURE STERILIZATION AND COMPLICATION RATE. RESULT(S): A TOTAL OF 149 PATIENTS WERE SCHEDULED FOR ESSURE STERILIZATION. MICROINSERT PLACEMENT WAS ATTEMPTED IN 143 PATIENTS. BILATERAL PLACEMENT OF THE DEVICE WAS SUCCESSFUL IN 95% (95% CONFIDENCE INTERVAL [CI] 92%-99%). SEVEN ATTEMPTS WERE UNSUCCESSFUL. THE COMPLICATION RATE WAS 2% (N 1/4 3), AND ALL INVOLVED A PERFORATION. THESE THREE CASES ARE DISCUSSED IN DETAIL. VAGINAL ULTRASOUND WAS CONCLUSIVE IN 91.7% (95% CI 87%-96%); TWO PERFORATIONS WERE NOT RECOGNIZED ON THE ULTRASOUND. CONCLUSION(S): ESSURE STERILIZATION IS A SAFE AND RELIABLE STERILIZATION METHOD IN AN OUTPATIENT SETTING. PERFORATION OF THE DEVICE IS THE MOST FREQUENT COMPLICATION. VAGINAL ULTRASOUND IS RELIABLE FOR VERIFICATION AFTER AN UNCOMPLICATED PROCEDURE. WHEN THE PROCEDURE IS DIFFICULT (E.G., HIGHER RESISTANCE, MORE PAIN THAN AVERAGE, MORE TIME OR MORE THAN TWO DEVICES NEEDED), A HYSTEROSALPINGOGRAM SHOULD BE PERFORMED. (FERTIL STERIL 2008;90:2011.E5-E10. 2008 BY AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE.) CASE REPORT: A (B)(6) MULTIPAROUS WOMAN VISITED OUR DEPARTMENT FOR TUBAL STERILIZATION. SHE HAD A LEVONORGESTREL INTRA-UTERINE DEVICE (IUD), BUT BECAUSE OF VAGINAL DISCHARGE SHE ASKED FOR A TUBAL STERILIZATION AND REMOVAL OF THE IUD.

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[ADDENDUM <(B)(4) 2010>: THIS CASE WAS CONVERTED FROM THE (B)(4) DATABASE INTO ARGUS. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED.] SIGNIFICANT FOLLOW UP (FULL TEXT ARTICLE) RECEIVED ON (B)(4) 2014. THE INITIAL 2008 ARTICLE HAS NOW BEEN REFERENCED IN A 2014 REVIEW ARTICLE FOR ESSURE. ADDITIONAL INFORMATION IS ADDED TO THIS CASE FOR ESSURE, WHICH IS NOW A BAYER COMPANY PRODUCT. CASE REPORT: (B)(6) MULTIPAROUS WOMAN VISITED OUR DEPARTMENT FOR TUBAL STERILIZATION. SHE HAD A LEVONORGESTREL INTRAUTERINE DEVICE (IUD), BUT BECAUSE OF VAGINAL DISCHARGE SHE ASKED FOR A TUBAL STERILIZATION AND REMOVAL OF THE IUD. AFTER INFORMATION ABOUT LAPAROSCOPIC STERILIZATION AND HYSTEROSCOPIC ESSURE STERILIZATION, THE PATIENT OPTED FOR THE ESSURE PROCEDURE. WITH THE VAGINOSCOPIC APPROACH WE EASILY GOT ACCESS TO THE UTERINE CAVITY. EXPLORATION OF THE CAVITY SHOWED A NORMAL CAVITY, AND BOTH TUBAL OSTIA WERE EASILY IDENTIFIED. AT THE RIGHT SIDE THE ESSURE DEVICE WAS PLACED INTO THE TUBE WITHOUT ANY PROBLEMS, AND 5 COILS WERE VISIBLE. AT THE LEFT SIDE ONE ATTEMPT WAS DONE, BUT EXPULSION OF THE INNER COIL THROUGH THE OUTER COIL WAS SEEN AND THE DEVICE WAS IMMEDIATELY REMOVED. IN THE SAME SETTING, A NEW DEVICE WAS PLACED AT THE LEFT SIDE. THE PLACEMENT WAS WITH HIGHER RESISTANCE OF THE TUBE THAN NORMALLY EXPERIENCED. WITH 4 COILS VISIBLE OUT OF THE LEFT TUBE, THE PROCEDURE WAS CONSIDERED TO BE SUCCESSFUL. THE WHOLE PROCEDURE TOOK 8 MIN AND HER VAS SCORE FOR PAIN WAS 7. THE PATIENT USED ORAL CONTRACEPTIVE FOR 3 MONTHS. VAGINAL ULTRASOUND EXAMINATION FOLLOWED AFTER 3 MONTHS AND BOTH DEVICES WERE SEEN IN APPROPRIATE PLACE. THE PATIENT WAS ADVISED TO STOP USING THE ORAL CONTRACEPTIVES. SEVEN MONTHS AFTER PLACEMENT, THIS PATIENT HAD A POSITIVE PREGNANCY TEST. ULTRASOUND SHOWED AN INTRAUTERINE PREGNANCY OF 6 WEEKS AMENORRHEA AND BOTH OF THE ESSURE DEVICES WERE STILL SEEN. BECAUSE THE PREGNANCY WAS NOT PLANNED, AN ABORTION WAS INDUCED USING PROSTAGLANDINS. AFTER ONE NORMAL MENSTRUAL PERIOD, AN HSG WAS PERFORMED. THE HSG REVEALED TUBAL OCCLUSION ON THE RIGHT SIDE,WITH CORRECT LOCATION OF THE DEVICE AND A PATENT TUBE ON THE LEFT SIDE. THE LEFT DEVICE WAS TWISTED IN AN ABNORMAL CONFIGURATION. THE PATIENT UNDERWENT LAPAROSCOPIC STERILIZATION USING FILSHI CLIPS. THE ESSURE DEVICE ON THE LEFT SIDE COULD NOT BE SEEN BUT COULD BE FELT UNDER THE SEROSA, WHICH CONFIRMED A PERFORATION OF THE DEVICE. THE DEVICE ON THE RIGHT SIDE COULD BE VISUALIZED IN A PERFECT PLACE IN THE TUBE. BOTH DEVICES WERE LEFT IN SITU. AN INTERNAL REVIEW ON (B)(4) 2014 IDENTIFIED THAT THE CASE (B)(4) IS A DUPLICATE OF THIS CASE. THE CASE (B)(4) WAS MARKED FOR DELETION. ALL INFORMATION WAS ALREADY TRANSFERRED TO THIS CASE IN THE FOLLOW-UP FROM (B)(4) 2014. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM THE MEDICAL LITERATURE AND REFERS TO A (B)(6) FEMALE PATIENT WHO HAD A MIRENA (LEVONORGESTREL) AND THEN AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR HYSTEROSCOPIC STERILIZATION AND DURING INSERTION, LEFT SIDE INSERT INNER COIL EXPULSION THROUGH THE OUTER COIL DURING INSERTION (DEVICE BREAKAGE). LATER, MICRO INSERT FELT UNDER THE SEROSA, CONFIRMED A PERFORATION OF THE DEVICE. LEFT SIDE INSERT INNER COIL EXPULSION THROUGH THE OUTER COIL DURING INSERTION (DEVICE BREAKAGE) IS NON-SERIOUS AND UNLISTED EVENT ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE IS RELATED TO ESSURE AND REGARDED AS NEAR-INCIDENT AS IT COULD LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH UNDER LESS FORTUNATE CIRCUMSTANCES OR WITHOUT INTERVENTION OF HEALTHCARE PROFESSIONAL. MICRO INSERT FELT UNDER THE SEROSA,CONFIRMED A PERFORATION OF THE DEVICE IS SERIOUS AND LISTED EVENT FOR ESSURE. DUE TO THE NATURE OF EVENT, IT IS CONSIDERED RELATED TO ESSURE AND REGARDED AS NON-INCIDENT. ADDITIONALLY, THE NON-SERIOUS EVENTS LEFT SIDE INSERT INNER COIL EXPULSION THROUGH THE OUTER COIL DURING INSERTION (COMPLICATION OF DEVICE INSERTION), PREGNANT WITH ESSURE MICRO-INSERT AND THE LEFT MICRO INSERT WAS TWISTED IN AN ABNORMAL CONFIGURATION. VAGINAL DISCHARGE WHILE ON LEVONORGESTREL INTRAUTERINE DEVICE WAS ALSO REPORTED.

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Manufacturer Narrative (H10):

(B)(4).

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00204	BAYER HEALTHCARE LLC	6/7/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON MAY 07, 2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED ALLERGY TO NICKEL (URTICARIA AND ERYTHEMA). THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: FEMALE PATIENT HAVING UNDERGONE SUCCESSFUL MICRO-INSERT PLACEMENT, ALLERGY TO NICKEL WAS NOTED. PATIENT EXPERIENCING URTICARIA AND ERYTHEMA SHORTLY AFTER THE PROCEDURE. SYMPTOMS RESOLVED AFTER REMOVAL OF DEVICES. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATION AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. FOLLOW UP RECEIVED ON MAY 14, 2014. FULL TEXT RECEIVED, TITLED COMPLICATIONS OF HYSTEROSCOPIC ESSURE STERILISATION: REPORT ON 4306 PROCEDURES PERFORMED IN A SINGLE CENTRE. CASE REPORT: A WOMAN WITH A HISTORY OF ATOPY, WHO PRESENTED SHORTLY AFTER THE PROCEDURE WITH PAPULAR URTICARIA AND ERYTHEMA, AND IN WHOM THE SYMPTOMS DISAPPEARED AFTER THE SUBSEQUENT REMOVAL OF DEVICES. CORRECTION ON MAY 14, 2014: FOLLOWING COMPANY INTERNAL REVIEW THE COUNTRY OF CASE ORIGIN WAS AMENDED TO SPAIN.

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Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00207	BAYER HEALTHCARE LLC	6/7/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6) 2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED CHRONIC ABDOMINAL PAIN. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: THIS CASE IN WHOM THE MICRO-INSERTS WERE PLACED, CHRONIC ABDOMINAL PAIN LAPAROSCOPIC SALPINGECTOMY AND REFERS TO FEMALE PATIENT THOUGHT TO BE CORRECTLY DID NOT RESOLVE AFTER APPENDECTOMY. PATIENT UNDERWENT BILATERAL MICRO-INSERT REMOVAL. WHEN COMPLETED LAPAROSCOPICALLY, SALPINGECTOMY WAS FAVORED. AUTHOR'S COMMENT: THIS FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION HAD CHRONIC ABDOMINAL PAIN. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. OTHER RELATED CASE: (B)(4). FOLLOW UP RECEIVED ON (B)(6) 2014. NEW INFORMATION REGARDING THE REPORTER WAS RECEIVED. THE COUNTRY OF INCIDENCE OF THIS CASE WAS (B)(6), AS CONFIRMED BY THE ORIGINAL PUBLICATION. (B)(4). COMPLICATIONS ASSOCIATED WITH ESSURE DEVICE: ANALYSIS AFTER 4000 PROCEDURES. GYNECOLOGICAL SURGERY 2010 (SUPPL 7) 889. THIS PATIENT WAS INCLUDED IN A RETROSPECTIVE STUDY, THE

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FEMALE PATIENT OF UNSPECIFIED AGE HAD A FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION HAD CHRONIC ABDOMINAL PAIN THAT HAS NOT IMPROVED AFTER LAPAROSCOPIC SALPINGECTOMY AND APPENDECTOMY. ABSTRACT: OBJECTIVES: TO ANALYZE THE COMPLICATIONS AT SHORT, MEDIUM AND LONG TERM, REGISTERED IN PATIENTS THAT UNDERWENT HYSTEROSCOPIC TUBAL STERILIZATION WITH ESSURE DEVICE. MATERIALS AND METHODS: RETROSPECTIVE COHORT STUDY OF 4000 CONSECUTIVE PATIENTS WITH THE PROCEDURE PERFORMED BETWEEN 2003 TILL 2010. ALL DATA ARE REGISTERED IN THE DATABASE OF THE OFFICE HYSTEROSCOPY UNIT OF AUTHORS' HOSPITAL. THE TELEPHONE NUMBER IS GIVEN TO ALL PATIENTS TO COMMUNICATE ALL KIND OF PROBLEMS. FOLLOW UP OF PATIENTS INCLUDES FROM 3 MONTHS TILL 8 YEARS. RESULTS: THE GLOBAL RATE OF COMPLICATIONS IS 1.8% (73 CASES). THE MOST FREQUENT COMPLICATION IS VASOVAGAL SYNCOPE AFTER PROCEDURE (1.07%, 43 CASES}, FOLLOWED BY EXPULSION OF ONE OF THE DEVICES (0.47%, 19 CASES). NO SYNCOPE REQUIRED HOSPITALIZATION AND THEY WERE CURED WITH RECOVERY. THE EXPULSIONS WERE MOST OF THEM IN THE THREE MONTHS AFTER PLACEMENT, 2 WERE AFTER 5 MONTHS, 1 WAS AFTER 1 YEAR, AND 2 AFTER 2 YEARS. OTHER COMPLICATIONS ARE RARE: 2 MIGRATIONS TO CAVITY THAT DID NOT REQUIRE SURGERY; 3 INTRA MYOMETRIAL PLACEMENTS, AND 2 IPD THAT WERE CURED WITH ANTIBIOTICS; 1 TUBAL PERFORATION THAT REQUIRED A LAPAROSCOPIC SALPINGECTOMY; 1 ABDOMINAL PAIN THAT HAS NOT IMPROVED AFTER LAPAROSCOPIC SALPINGECTOMY AND APPENDECTOMY; AND 2 NICKEL ALLERGIES WITHOUT PREVIOUS DIAGNOSES THAT REQUIRED A LAPAROSCOPIC SALPINGECTOMY AFTER ESSAY AN HYSTEROSCOPIC APPROACH. THE DEVICES HAVE BEEN PLACED IN 25 KNOWN NICKEL ALLERGIES WITHOUT SIDE EFFECTS. CONCLUSIONS: THE PERMANENT BIRTH CONTROL WITH ESSURE DEVICE HAS DEMONSTRATED TO BE A SAFE METHOD, WITH A LOW RATE OF COMPLICATIONS, WHICH ITS SECURITY PERSIST AFTER 8 YEARS FOLLOW UP. THAT MEANS THAT ESSURE METHOD SHOULD BE THE REFERENCE METHOD IN WHAT IS TO DO WITH DEFINITIVE CONTRACEPTION. OTHER BAYER CASE NUMBERS FROM THIS STUDY (B)(4).

Manufacturer Narrative (H10):

REPORT SOURCE LITERATURE DESCRIPTION. JOURNAL: JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY. AUTHOR: ADELMAN MR, DASSEL MW, SHARP HT. TITLE: MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW. VOLUME: XX YEAR:

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00209	BAYER HEALTHCARE LLC	6/7/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 07-MAY-2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED MALPOSITIONED DEVICE IN PERITONEAL CAVITY. THE TRADENAME WAS REPORTED TO BE ESSURE. CASE REPORT: ONE PATIENT EXPERIENCED 3 YEARS OF PAIN AND UNDERWENT A LAPAROSCOPY BEFORE THE MICRO-INSERT WAS EVENTUALLY IDENTIFIED ON CT SCAN, AND UNDERWENT SUBSEQUENT REMOVAL VIA LAPAROSCOPY WITH INTRAOPERATIVE FLUOROSCOPY. THE PATIENT EXPERIENCED RESOLUTION OF PA2N POSTOPERATIVELY. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: THERE WERE 2 PATIENTS WHO EXPERIENCED PROLONGED PERIODS OF PAIN, WITH LENGTHY EVALUATIONS, BOTH OF WHICH ULTIMATELY REQUIRED REMOVAL OF THE DEVICES FROM THE PERITONEAL CAVITY. ONE PATIENT EXPERIENCED 3 YEARS OF PAIN AND UNDERWENT A LAPAROSCOPY BEFORE THE MICRO-INSERT WAS EVENTUALLY IDENTIFIED ON CT SCAN, AND UNDERWENT SUBSEQUENT REMOVAL VIA LAPAROSCOPY WITH INTRAOPERATIVE FLUOROSCOPY. ALL PATIENTS WITH PAIN AND MALPOSITIONED DEVICES EXPERIENCED RESOLUTION OF THEIR PAIN POSTOPERATIVELY.

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RELATED CASE:(B)(4). FOLLOW UP RECEIVED ON (B)(4)2014. THIS CASE REPORT IS FROM A LITERATURE ARTICLE TITLED "COMPLICATION OF THE ESSURE IMPLANT STERILIZATION PROCEDURE: A CASE REPORT" AUTHORED BY PYKE R, BLACKWOOD LR. CASE REPORT: A (B)(6) PRESENTED WITH A 3-YEAR HISTORY OF LEFT LOWER QUADRANT PAIN. THE PAIN WAS INTERMITTENT, OCCURRING IN THE MID-PORTION OF THE LEFT SIDE OF THE ABDOMEN AND LEFT LOWER QUADRANT. THE PAIN WAS RELIEVED BY LYING DOWN AND EXACERBATED BY STANDING UP. THE PAIN WAS NOT WORSE DURING INTERCOURSE OR VIGOROUS EXERCISE. THE EPISODES BECAME PROGRESSIVELY WORSE OVER THE COURSE OF 1.5 YEARS. SHE DENIED NAUSEA AND VOMITING, AND EATING HAD NO EFFECT ON THE PAIN. SHE DENIED DIARRHEA OR CONSTIPATION, AND THE PAIN WAS NOT RELATED TO BOWEL MOVEMENTS. SHE LOST 15 POUNDS OVER SEVERAL MONTHS, AND THE PAIN WOKE HER UP AT NIGHT. THE PATIENT HAD ESSURE IMPLANTS FOR PERMANENT STERILIZATION PLACED IN (B)(6) 2004. THE MARKER ON THE ESSURE IMPLANT PLACED IN THE RIGHT TUBE WAS DIFFICULT TO VISUALIZE. ACCORDING TO THE SURGEON, THE BLACKENED MARKER WAS UNABLE TO BE VISUALIZED AND THERE WERE NO TRAILING COILS WITHIN THE UTERINE CAVITY. THE PROCEDURE WAS CONTINUED ON THE LEFT SIDE AND THREE TRAILING COILS WERE IDENTIFIED IN THE UTERINE CAVITY. THE IMPLANT SHEATH WAS COMPARED AND THOUGHT TO BE IDENTICAL. THE SURGEON DETERMINED THE RIGHT MICRO-INSERT HAD BEEN DEPLOYED CORRECTLY BUT HIGHER IN THE TUBAL CANAL. AS PER PROCEDURE, A HYSTEROSALPINGOGRAM REVEALED THE OCCLUSION OF THE RIGHT FALLOPIAN TUBE BUT FREE SPILLAGE OF THE DYE IN THE LEFT FALLOPIAN TUBE. THE LEFT ESSURE IMPLANT WAS AT THE LEVEL OF THE ILIAC CREST OUTSIDE THE TUBAL OSTIA WITH THE PATENCY OF THE LEFT TUBAL SEGMENT. THE PATIENT WAS COUNSELED THAT THE DISPLACEMENT OF THE IMPLANT WAS PROBABLY DUE TO TUBAL CRAMPING. FOLLOWING THIS PROCEDURE, THE PATIENT BEGAN EXPERIENCING THE ABOVE SYMPTOMS. INFORMED CONSENT WAS OBTAINED FOR AN EXPLORATORY LAPAROSCOPY AND BILATERAL TUBAL COAGULATION. ALTHOUGH THE PATIENT PREFERRED TO HAVE A REPEAT PLACEMENT OF THE ESSURE IMPLANT ON THE LEFT, HER INSURANCE COMPANY WOULD NOT APPROVE IT. SHE WAS COUNSELED OF THE RISKS, BENEFITS, AND ALTERNATIVES TO INSPECT THE PELVIS AND ABDOMEN TO FIND THE ESSURE IMPLANT, KNOWING THE LIKELIHOOD WAS THEY WOULD NOT FIND JT. A LAPAROSCOPY WAS PERFORMED TO COMPLETE THE STERILIZATION PROCESS. EXPLORATION OF THE ABDOMEN WAS PERFORMED, WHICH FAILED TO LOCATE THE IMPLANT. THE DISTAL PORTION OF THE RIGHT ESSURE IMPLANT WAS IDENTIFIED. THE UPPER ABDOMEN, LIVER EDGES, GALLBLADDER, AND SPLENIC AREAS WERE INSPECTED, BUT THERE WAS NO EVIDENCE OF THE IMPLANT. BOTH FALLOPIAN TUBES WERE COAGULATED BY USING THE KLEPPINGER FORCEPS. THE LEFT TUBE WAS COAGULATED IN THE MID- AMPULLARY PORTION OF THE LEFT TUBE IN THREE SEQUENTIAL AREAS. THE PROCEDURE WAS REPEATED ON THE RIGHT SIDE, BUT INFERIOR TO THE AREA OF THE IMPLANT, SO AS NOT TO COAGULATE THE IMPLANT ITSELF. THE PELVIS WAS AGAIN INSPECTED, AND THERE WAS NO EVIDENCE OF THE DISPLACED IMPLANT. SHE CONTINUED TO HAVE PAIN AND BEGAN HAVING A WORK-UP OF OTHER ORGAN SYSTEMS. SHE HAD A URINALYSIS FOR HEMATURIA AND WAS TREATED WITH ANTIBIOTICS. A WORK-UP FOR KIDNEY INFECTION WAS PERFORMED AND WAS NEGATIVE. MRI WAS PERFORMED TO EVALUATE THE SPINE, AND THERE WAS NO EVIDENCE OF NERVE-ROOT IMPINGEMENT. THE THORACIC SPINE WAS ESSENTIALLY NORMAL AS WELL. AN INTRAVENOUS PYELOGRAM EVALUATION WAS NEGATIVE AND RULED OUT EVIDENCE OF DILATATION OR OBSTRUCTION OF THE URETER. A SUMMARY PLAN DESCRIPTION SCAN OF THE ABDOMEN WAS CONSISTENT WITH ADENOPATHY AND NEGATIVE FOR A FOREIGN BODY. A COMPUTED TOMOGRAPHY (CT) SCAN OF THE PELVIS REVEALED A METALLIC STRUCTURE IN THE LEFT ASPECT OF THE PELVIS AND ADJACENT TO THE ANTERIOR PORTION OF THE COLON. IN 2007, THE PATIENT WAS EVALUATED BY A SECOND OBSTETRICIAN OR GYNECOLOGIST. AN ULTRASOUND OF THE ABDOMEN SHOWED NORMAL LIVER, GALLBLADDER, AND KIDNEYS. A PELVIC ULTRASOUND WAS CONSISTENT WITH A NORMAL-SIZE UTERUS AND NORMAL-APPEARING OVARIES. SHE HAD A FIRST-DEGREE UTERINE PROLAPSE AND A PESSARY WAS INSERTED, BUT THERE WAS NO IMPROVEMENT IN HER SYMPTOMS. SHE WAS REFERRED TO A GASTROENTEROLOGIST AND A COLONOSCOPY WAS SCHEDULED. THEY WERE NOT CONVINCED THE PAIN WAS ASSOCIATED WITH THE BOWELS, BUT SUGGESTED THE COLONOSCOPY, BECAUSE OF A FAMILY HISTORY OF POLYPS. HOWEVER,

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SHE DEVELOPED A SEVERE EPISODE OF LEFT LOWER QUADRANT PAIN ASSOCIATED WITH VOMITING AND WAS EVALUATED IN THE EMERGENCY ROOM. HER WHITE BLOOD COUNT WAS 5700. ONE (1) MONTH PRIOR TO ADMISSION, HER HEMATOCRIT WAS 42.2 AND HEMOGLOBIN WAS 14.8. (B)(6) CULTURES WERE (B)(6). CT SCAN WAS PERFORMED. SHE WAS PLACED IN THE SUPINE POSITION FOR THE FIRST STUDY AND THEN PRONE IN THE SECOND STUDY. THE ESSURE IMPLANT WAS NOT VISUALIZED IN THE SUPINE POSITION BUT WAS SEEN IN THE PRONE POSITION ON THE LEFT LATERAL SIDE OF THE LOWER PELVIS ADJACENT TO THE DESCENDING COLON. THERE WAS NO EVIDENCE OF FREE AIR OR FREE FLUID IN THE PELVIS. THIS SUGGESTED THAT THE ESSURE IMPLANT WAS FREELY MOBILE WITHIN THE PERITONEAL CAVITY. AN EXPLORATORY LAPAROSCOPY PROCEDURE WAS PERFORMED WITH FLUOROSCOPY AFTER THE INSERTION OF A 10-MM PORT THROUGH AN UMBILICAL INCISION AND TWO 5-MM PORTS WERE PLACED IN EACH LOWER QUADRANT OF THE ABDOMEN. FLUOROSCOPY WAS USED TO VISUALIZE THE ENTIRE ABDOMEN,AND THE ESSURE IMPLANT WAS LOCATED ADJACENT TO THE LEFT LOBE OF THE LIVER. A LONG PROBE WAS USED TO IDENTIFY THE IMPLANT WITH THE AID OF THE FLUOROSCOPY. IT WAS DETERMINED TO BE LOCATED IN A PORTION OF OMENTUM, WHICH WAS IN THE LEFT UPPER QUADRANT ON THE ABDOMEN UNDER THE LIVER. THE OMENTUM WAS GRASPED AND MOVED TO A MORE ACCESSIBLE REGION OF THE PELVIS. ALTHOUGH THE IMPLANT COULD NOT BE VISUALIZED IN THE OMENTUM BY LAPAROSCOPY YET, THE FLUOROSCOPY CONFIRMED THE IMPLANT MOVED WITH THE INFERIOR PORTION OF THE OMENTUM. THE COIL WAS FINALLY IDENTIFIED BY USING FLUOROSCOPY AND LAPAROSCOPIC GRASPERS. THE IMPLANT WAS REMOVED WITH A PORTION OF THE OMENTUM AND SENT TO PATHOLOGY. THE COLON WAS FREE OF DIVERTICULA OR EVIDENCE OF INFLAMMATION. THE PELVIS WAS INSPECTED AND FOUND TO BE CONSISTENT WITH A DEFECT IN BOTH FALLOPIAN TUBES FROM THE COAGULATION. THE UTERUS HAD A SMOOTH SURFACE, WITH NO EVIDENCE OF ENDOMETRIOSIS OF ADHESIONS. BOTH OVARIES WERE NORMAL IN SIZE AND APPEARANCE. PATHOLOGY WAS CONSISTENT WITH THE GROSS IMPLANT, WHICH WAS INTACT WITH ATTACHED FRAGMENTS OF BENIGN FIBRO-FATTY CONNECTIVE TISSUE. POSTOPERATIVELY, THE PATIENT DID VERY WELL. SHE NO LONGER COMPLAINED OF THE PAIN. AUTHOR'S COMMENT: THIS IS A CASE REPORT ILLUSTRATING A PATIENT WHO HAD THE INSERTION OF THE ESSURE IMPLANT WITH A PERFORATION INTO THE PERITONEAL CAVITY (PREVIOUSLY MENTIONED AS MALPOSITIONED DEVICE IN PERITONEAL CAVITY) AND ENTRAPMENT INTO THE OMENTUM, CAUSING CHRONIC PAIN. IT ILLUSTRATES HOW THIS SMALL IMPLANT CAN CAUSE MORBIDITY, AND THE USE OF FLUOROSCOPY CAN AID IN LOCATING THE TINY MICRO-INSERT IF IT IS DISLODGED INTO THE ABDOMINAL CAVITY. OTHER CASES FROM THIS ARTICLE: (B)(4). FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: PTC NUMBER PROVIDED (B)(4). FOLLOW-UP RECEIVED ON (B)(4) 2014: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC)- INCIDENT REPORT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. ADDITIONALLY, THE CASE REPORTED DISLOCATION OF DEVICE AND COMPLICATION OF INSERTION DUE TO A MEDICAL EVENT. THESE EVENTS ARE ALSO NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00200	BAYER HEALTHCARE LLC	6/7/2014	6/18/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 9/4/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN THE UNITED STATES ON 08-MAY-2014. THE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PREGNANCY WITH ESSURE {DEVICE INEFFECTIVE), NO COILS IN TUBES WERE NOTED IN TUBES, COILS SEEN IN PELVIC REGION PER KUB TEST, MAY HAVE COME OUT OF THE END OF THE TUBES. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2012, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. LOT NUMBER WAS NOT REPORTED. ON (B)(6) 2013, THE PATIENT CALLED HCP (HEALTHCARE PROFESSIONAL), SHE HAD A POSITIVE PREGNANCY TEST. ON (B)(6) 2014, PATIENT DELIVERED FULL TERM. POSTPARTUM, HCP DID BILATERAL SALPINGECTOMIES, ONE DAY AFTER DELIVERY. HCP NOTED NO COILS IN TUBES. PATIENT ASSUMED COILS CAME OUT. PATIENT SEEN BY PRIMARY DOCTOR WHO PERFORMED KUB (KIDNEYS, URETERS, AND BLADDER X-RAY). COILS WERE SEEN IN PELVIC REGION. HCP DENIES PERFORATION BECAUSE TUBES WERE OCCLUDED. HCP THINKS COILS MAY HAVE COME OUT OF THE END OF THE TUBES AND WANTS TO KNOW ABOUT REMOVAL OF COILS IF PATIENT IS ASYMPTOMATIC. TREATMENT FOR EVENT WAS REPORTED AS 'UNKNOWN'. EVENT WAS ONGOING, THE ESSURE COILS WERE NOT REMOVED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2014 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). MEDICAL ASSESSMENT: LACK OF EFFECTIVENESS MAY OCCUR WITH THE USE OF ANY PRODUCT AND PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. THIS CASE ALSO REPOR

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00202	BAYER HEALTHCARE LLC	6/7/2014	6/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 07-MAY-2014 , ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED DELAYED HYPERSENSITIVITY TO NICKEL AND BABOON SYNDROME. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: A (B)(6) WOMAN PRESENTED WITH SEVERE ANOGENITAL PRURITUS APPEARED 3 WEEKS BEFORE. CLINICAL EXAMINATION DISCLOSED A GENERALIZED ERYTHEMATOUS MACULOPAPULAR ERUPTION PREDOMINANTLY DISTRIBUTED IN THE GENITAL AND FLEXURAL AREAS (BABOON SYNDROME). TOPICAL CORTICOSTEROIDS, ORAL ANTIHISTAMINES, AND SYSTEMIC CORTICOSTEROIDS PROVIDED NO RELIEF. THREE MONTHS BEFORE THE ONSET OF SKIN LESIONS, SHE UNDERWENT A PERMANENT INTRATUBAL STERILIZATION WITH NITINOL METALLIC IMPLANTS ESSURE SYSTEM. UPON QUESTIONING, SHE DESCRIBED INTOLERANCE OF JEWELRY METALS SINCE ADOLESCENCE. THE PATCH TESTS PERFORMED WITH THE STANDARD SERIES WERE POSITIVE TO NICKEL SULFATE (1+). A SYSTEMIC CONTACT DERMATITIS TO NICKEL WAS SUSPECTED, AND THE IMPLANTS WERE REMOVED BY SALPINGECTOMY. WHEREAS NO TREATMENT HAD BEEN PREVIOUSLY EFFECTIVE, 3 DAYS AFTER IMPLANTS REMOVAL, SKIN LESIONS WERE IMPROVING WITH COMPLETE RESOLUTION IN 3 MONTHS. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF

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ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: SYSTEMIC CONTACT DERMATITIS REPRESENTS A DELAYED HYPERSENSITIVITY REACTION TO SYSTEMIC ADMINISTRATION OF AN ANTIGEN IN A SUBJECT WHO IS ALREADY SENSITIZED TO THE SAME ANTIGEN. INITIALLY DESCRIBED AS THE BABOON SYNDROME, IT MANIFESTS AS AN ACUTE ERYTHEMATOUS ERUPTION ELECTIVELY DISTRIBUTED IN THE FOLDS AND GENITAL REGIONS. THE AUTHORS POSTULATE THAT THE SYSTEMIC REACTION TO THE IMPLANTS COULD BE EXPLAINED BY CORROSION OF THE NITINOL AFTER IMPLANTATION, RESULTING IN THE RELEASE OF NICKEL INTO THE BLOOD, AS HAS BEEN OBSERVED WITH OTHER NITINOL-CONTAINING IMPLANTABLE DEVICES. RELATED CASE:(B)(4).

Manufacturer Narrative (H10):

REPORT SOURCE LITERATURE DESCRIPTION: JOURNAL: DERMATITIS. AUTHOR: BIBAS N, LASSERE J, PAUL C, AQUILINA C, GIORDANO-LABADIE F; TITLE: NICKEL-INDUCED SYSTEMIC CONTACT DERMATITIS AND INTRATUBAL IMPLANTS: THE BABOON SYNDROME REVISITED. VOLUME: 24 (1) YEAR: 2

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00206	BAYER HEALTHCARE LLC	6/7/2014	6/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 07-MAY-2014 , ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND MALPOSITION. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: A MALPOSITION WAS REPORTED FOR A FEMALE PATIENT INCLUDED WITH CORNUAL RESECTION. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. FOLLOW UP RECEIVED ON (B)(4) 2014: FULL TEXT RECEIVED. THE COUNTRY OF INCIDENCE WAS (B)(6) AND THE STUDY WAS AN INTERVENTIONAL STUDY. CASE REPORT: THIS IS A CASE OF FEMALE PATIENT IN WHICH PERFORATION WAS DIAGNOSED AFTER 2 YEARS OF MICRO-INSERT PLACEMENT. THIS WOMAN REQUESTED THAT HER MICRO- INSERTS BE REMOVED FOLLOWING A 6-MONTH HISTORY OF PAIN. THE PAIN WAS DESCRIBED AS A SCRATCHY IRRITATING PAIN IN THE PELVIC REGION ON THE RIGHT SIDE, WHICH WAS NOT ASSOCIATED WITH ANY SYSTEMIC UPSET OR CHANGE IN BLOOD PICTURE NORMALITY. THE SURGEON INVOLVED PERFORMED A SMALL TRANSVERSE SUPRAPUBIC LAPAROTOMY INCISION AND CONFIRMED A PARTIAL PERFORATION WHERE ONE-THIRD OF THE MICRO-INSERT WAS COILED UNDER THE PERITONEUM JUST BELOW THE RIGHT UTEROTUBAL JUNCTION. THERE

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WAS NO EVIDENCE OF IN-AMMATION OR ADHESION FORMATION. A BILATERAL CORNUAL RESECTION CONTAINING EACH MICROINSERT WAS PERFORMED. THE PAIN SETTLED POST-OPERATIVELY AND THE WOMAN HAS REMAINED PAIN-FREE FOLLOWING 18 MONTHS OF FOLLOWUP. HISTOLOGICAL EVALUATION REVEALED THAT THE DEVICE HAD PERFORATED THE TUBE HALF WAY ALONG ITS INTRAMURAL SEGMENT AND CONTINUED PARALLEL TO THE UNDERSIDE OF THE PERITONEUM ADJACENT TO THE UTEROTUBAL JUNCTION. THERE WAS NO EVIDENCE OF ANY INFECTION PRESENT.

Manufacturer Narrative (H10):

REPORT SOURCE LITERATURE DESCRIPTION: JOURNAL: JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY; AUTHOR: ADELMAN MR, DASSEL MW, SHARP HT; TITLE: MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW. VOLUME: XX YEAR:

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00212	BAYER HEALTHCARE LLC	6/7/2014	6/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED CORNUAL PERFORATION WITH SUBSEROSAL PLACEMENT OF THE MICRO-INSERT AND DIFFICULT INSERTION OF MICRO INSERT. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: A PATIENT EXPERIENCED CORNUAL PERFORATION WITH SUBSEROSAL PLACEMENT AND DIFFICULT INSERTION OF MICRO INSERT. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDER REPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: THERE WERE 2 PATIENTS WHO EXPERIENCED PROLONGED PERIODS OF PAIN, WITH LENGTHY EVALUATIONS, BOTH OF WHICH ULTIMATELY REQUIRED REMOVAL OF THE DEVICES FROM THE PERITONEAL CAVITY. A PATIENT EXPERIENCED 4 YEARS OF PAIN, 1 LAPAROSCOPY AND 3 LAPAROTOMIES BEFORE SEVERAL PIECES OF THE MICRO-INSERT WERE IDENTIFIED ON CT SCAN, AND REMOVED VIA LAPAROTOMY WITH INTRAOPERATIVE FLUOROSCOPY. ALL PATIENTS WITH PAIN AND MALPOSITIONED DEVICES EXPERIENCED RESOLUTION OF THEIR PAIN POSTOPERATIVELY. RELATED CASE: (B)(4). SIGNIFICANT FOLLOW UP RECEIVED ON (B)(4) 2014 (FULL TEXT FOR REFERENCE (B)(4) RECEIVED). CASE REPORT: A (B)(6) WOMAN, GRAVIDA 2, PARA 2, WAS SEEN FOR

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ELECTIVE STERILIZATION WITH THE ESSURE DEVICE. HER SECOND INFANT WAS BORN VAGINALLY 6 YEARS BEFORE PRESENTATION. SHE HAD NO PREVIOUS MEDICAL PROBLEMS AND NO PREVIOUS SURGERIES. RESULTS OF HER GYNECOLOGIC EXAMINATION WERE NORMAL. THE PATIENT WAS COUNSELED ABOUT THE BENEFITS, RISKS, AND ALTERNATIVES OF THE PROCEDURE; THEN SHE ELECTED TO HAVE THE ESSURE DEVICE UNDER LOCAL ANESTHESIA. AS RECOMMENDED BY THE COMPANY, SHE RECEIVED PREMEDICATION WITH ORAL PROGESTIN (P) FOR 1 MONTH BEFORE THE SCHEDULED PROCEDURE. DURING THE PROCEDURE, THERE WAS ENDOMETRIAL TISSUE OBSCURING BOTH FALLOPIAN TUBE OSTIA, AND A HYSTEROSCOPIC FORCEPS WAS USED TO HELP MOVE THAT TISSUE AWAY TO VISUALIZE THE OSTIA ON BOTH SIDES. THE ESSURE DEVICE WAS THEN INTRODUCED EASILY IN THE RIGHT FALLOPIAN TUBE. MILD TO MODERATE RESISTANCE WAS ENCOUNTERED ON THE LEFT SIDE, BUT THE DEVICE WAS PLACED SUCCESSFULLY WITH THE TIP OF THE DEVICE VISUALIZED PROTRUDING FROM THE FALLOPIAN TUBE AS RECOMMENDED. THE PATIENT TOLERATED THE PROCEDURE WELL AND WENT HOME THE DAY OF THE PROCEDURE. SHE HAD NO SYMPTOMS AT THE 1-WEEK FOLLOW-UP VISIT. SHE ELECTED TO RECEIVE MEDROXYPROGESTERONE ACETATE INJECTION AFTER THE PROCEDURE FOR CONTRACEPTION. THREE MONTHS LATER, SHE WAS SEEN FOR HER FOLLOW-UP HSG, WHICH SHOWED PATENCY OF THE LEFT FALLOPIAN TUBE WITH THE ESSURE DEVICE CURLED IN THE PROXIMITY OF THE PROXIMAL LEFT FALLOPIAN TUBE. THE RIGHT FALLOPIAN TUBE WAS OCCLUDED ON HSG. THE PATIENT HAD NO SYMPTOMS AT THAT TIME, AND THE FINDINGS WERE DISCUSSED WITH HER. SHE WAS COUNSELED ABOUT HAVING AN IMMEDIATE LAPAROSCOPIC EXPLORATION WITH REMOVAL OF THE ESSURE DEVICE AND LEFT TUBAL LIGATION-RESECTION, BUT SHE DEFERRED AND ELECTED EXPECTANT MANAGEMENT WITH ANOTHER MEDROXYPROGESTERONE ACETATE INJECTION AND A REPEAT HSG IN 3 MONTHS. SHE WAS SEEN 1 MONTH LATER COMPLAINING OF OCCASIONAL EPISODES OF SHARP LEFT LOWER QUADRANT PAIN DESCRIBED AS "STABBING" WITH A MAXIMUM INTENSITY OF 8/10. A PELVIC ULTRASOUND EXAMINATION WAS PERFORMED AND SHOWED NORMAL UTERINE CAVITY AND OVARIES WITH THE ESSURE DEVICES VISUALIZED ON BOTH SIDES. A PLAIN ROENTGENOGRAM OF THE ABDOMEN AND PELVIS IN UPRIGHT AND SUPINE POSITIONS SHOWED THAT THE OCCLUSIVE DEVICES WERE STILL IN THE SAME PLACE COMPARED WITH THE PREVIOUS HSG PERFORMED. THE PATIENT AGREED ON HAVING AN EXPLORATORY LAPAROSCOPY, WHICH SHOWED THAT THE ESSURE DEVICE WAS MISPLACED IN A CURLED FASHION UNDERNEATH THE LEFT CORNUAL SEROSA AWAY FROM THE LEFT FALLOPIAN TUBE TRACT AND THE RIGHT FALLOPIAN TUBE LOOKED NORMAL. A LAPAROSCOPIC NEEDLE CONNECTED TO MONOPOLAR ENERGY WAS USED TO UNROOF THE SEROSAL TUNNEL CONTAINING THE DEVICE, WHICH WAS REMOVED COMPLETELY AND EASILY BY GENTLY TEASING IT OFF THE TUNNEL; THEN THE TUNNEL WAS SEALED WITH USE OF THE HARMONIC SCALPEL POWER, AND LEFT SALPINGECTOMY WAS PERFORMED. CHROMOTUBATION CONFIRMED OCCLUSION OF THE LEFT CORNEUM AND THE RIGHT FALLOPIAN TUBE AT THE END OF THE SURGERY. THE PATIENT WENT HOME AFTER THE PROCEDURE AND HAD AN UNEVENTFUL FOLLOW-UP. AUTHOR'S COMMENT: IN THIS CASE, THERE WAS DIFFICULTY VISUALIZING THE FALLOPIAN TUBE OSTIA ON ENTRY TO THE UTERINE CAVITY BY HYSTEROSCOPY DESPITE APPROPRIATE PREPARATION OF THE ENDOMETRIUM WITH P. THE RESISTANCE TO INTRODUCING THE DEVICE ON THE LEFT SIDE MIGHT HAVE BEEN DUE TO TUBAL SPASM THAT COULD HAVE PROVOKED THE CREATION OF A FALSE TUNNEL. COMPARED WITH THE CASES DESCRIBED IN THE LITERATURE,THE PATIENT'S SYMPTOMS STARTED 4 MONTHS AFTER THE ESSURE PLACEMENT, AND THERE WAS A SUBSEROSAL DISPLACEMENT OF THE ESSURE DEVICE. NEITHER PHASE II NOR PHASE III STUDIES ON ESSURE REPORT PAIN WITH SUCH A LATE ONSET AFTER ESSURE PLACEMENT. THIS CASE REINFORCES BESIDES AN UNUSUAL LOCATION OF A MISPLACED ESSURE DEVICE THAT LATE-ONSET (UP TO 4 MONTHS) PELVIC PAIN SHOULD ALERT THE PHYSICIAN TO SUCH A COMPLICATION. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2014: PTC NUMBER PROVIDED PTC ID (B)(4). FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2014- PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). MEDICAL ASSESSMENT: THE MEDICAL EVENT REPORTED AS WELL AS THE REPORTED TECHNICAL ISSUE OF DIFFICULT TO USE (INSERTION) ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE AND NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH

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NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT, THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT." BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME.

Manufacturer Narrative (H10):

(B)(4). AUTHOR: ADELMAN MR, DASSEL MW, SHARP HT. TITLE: MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW. VOLUME: XX YEAR: 2014 PAGES: XX JOURNAL: FERTILITY AND STERILITY. AUTHOR: MAHMOUD, MOHAMAD S., FR

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00213	BAYER HEALTHCARE LLC	6/7/2014	6/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): KSS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 07-MAY-2014 , ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO RECEIVED FALLOPIAN TUBE OCCLUSION INSERT FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED ECTOPIC PREGNANCY (DEVICE INEFFECTIVE). ESSURE WAS REPORTED AS THE TRADE NAME. CASE REPORT : IN A RETROSPECTIVE SURVEY OF PREGNANCIES REPORTED TO PHYSICIANS IN FRANCE, THIS FEMALE PATIENT WAS REPORTED WITH ECTOPIC PREGNANCY. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: THIS IS THE CASE REPORT OF ECTOPIC PREGNANCY WITH ESSURE. RELATED CASE : (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

F/U RECEIVED ON (B)(4) 2014: NEW REPORTER WAS ADDED. FULL TEXT RECEIVED WITH NO NEW INFORMATION. FOLLOW-UP RECEIVED ON (B)(4) 2014: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00197	BAYER HEALTHCARE LLC	6/7/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 05/07/2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW.". IT REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND HAD BOWEL OBSTRUCTION. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: A FEMALE PT PRESENTED WITH PROGRESSIVE PAIN, NAUSEA, VOMITING, AND ABDOMINAL DISTENSION. RADIOLOGIC IMAGING WAS SUSPICIOUS FOR A SMALL BOWEL OBSTRUCTION, AND LATER REVIEW REVEALED THAT THE MICRO-INSERTS WERE MALPOSITIONED, OR ABSENT FROM THEIR EXPECTED LOCATION. IN THIS CASE, A PT A LAPAROTOMY WAS PERFORMED, AND A METAL WIRE WAS OBSERVED TO TRAVERSE THE MESENTERY, ENSNARING A LOOP OF TERMINAL ILEUM. THE WIRE WAS IDENTIFIED AS A STRETCHED ESSURE DEVICE, RESULTING IN A LOCAL PERFORATION OF THE BOWEL WALL. THE STRANGULATING COIL WAS REMOVED, AND AN ILEOCECAL RESECTION WAS PERFORMED. THE RIGHT ESSURE DEVICE WAS NOTED TO BE ABSENT FROM THE FALLOPIAN TUBE, AND CLIPS WERE APPLIED TO THE FALLOPIAN TUBES BILATERALLY. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WERE DATA ALLOW. FOLLOW UP RECEIVED ON 05/14/2014: FULL TEXT RECEIVED. CASE REPORT: (B)(6) OLD WOMAN, GRAVIDA 1, PARA 1, WITH NO NOTABLE PAST MEDICAL OR SURGICAL HISTORY

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UNDERWENT AN OPERATIVE HYSTEROSCOPY, IUD REMOVAL, ENDOMETRIAL POLYPECTOMY, UTERINE CURETTAGE, AND PLACEMENT OF ESSURE INTRATUBAL MICROINSERTS WITHOUT DIFFICULTY. AT THE END OF THE ESSURE MICROINSERT PLACEMENT, TWO COILS WERE VISUALIZED AT THE FIGHT OSTIA AND FIVE AT THE LEFT. THE PROCEDURE WAS UNEVENTFUL AND WAS COMPLETED IN 18 MINUTES. ONE MONTH AFTER SHE HAD UNDERGONE ESSURE MICROINSERT PLACEMENT, THIS PT WAS EVALUATED TWICE IN THE EMERGENCY DEPARTMENT OF ANOTHER HOSPITAL FOR VAGINAL SPOTTING AND THE SUDDEN ONSET OF LEFT LOWER QUADRANT PAIN AFTER INTERCOURSE. ON HER SECOND VISIT, THE PT NOTED WORSENING PAIN, WITH ASSOCIATED NAUSEA AND VOMITING. DESPITE A COMPUTED TOMOGRAPHY (CT) SCAN OF HER ABDOMEN AND PELVIS THAT SUGGESTED THAT ONE OF THE ESSURE MICROINSERTS WAS NOT PROPERLY LOCATED IN THE FALLOPIAN TUBE, SHE WAS TREATED CONSERVATIVELY AND DISCHARGED HOME. ON PRESENTATION TO OUR HOSPITAL, SHE CONTINUED TO EXHIBIT PERSISTENT PELVIC PAIN, NAUSEA, AND VOMITING. REVIEW OF SYSTEMS AS WELL AS HER PAST MEDICAL, SOCIAL, AND FAMILY HISTORIES WERE UNREMARKABLE. ON PHYSICAL EXAMINATION, SHE WAS ALERT, ORIENTED, AND NOTICEABLY UNCOMFORTABLE. HER BLOOD PRESSURE WAS 145/80MMHG, PULSE 75 BEATS/MINUTE, RESPIRATORY RATE 20/MINUTE, AND TEMPERATURE 36.7 C. SHE WAS DIFFUSELY TENDER IN THE LOWER ABDOMEN WITH NO GUARDING OR REBOUND. THE PELVIC EXAMINATION WAS NOTABLE FOR PELVIC AND CERVICAL MOTION TENDERNESS WITH MINIMAL VAGINAL BLEEDING. A PREGNANCY TEST AND URINE ANALYSIS WERE NEGATIVE EXCEPT FOR TRACE BLOOD, TRACE PROTEIN, AND 30 KETONES. A PRESUMPTIVE DIAGNOSIS OF ENDOMETRITIS WITH A SUSPICION OF UTERINE PERFORATION UNDIAGNOSED AT THE TIME OF ESSURE MICROINSERT PLACEMENT WAS MADE, AND THE PT WAS ADMITTED. SHE WAS STATED ON PARENTERAL ANTIBIOTICS, ANTIEMETICS, AND PAIN MEDICATION. ALTHOUGH SHE INITIALLY IMPROVED, BY DAY 2 OF ADMISSION HER SYMPTOMS WORSENED. A FLAT PLATE AND UPRIGHT ABDOMINAL X-RAY REVEALED DILATED SMALL BOWEL LOOPS WITH AIR-FLUID LEVELS, CONSISTENT WITH A LOCALIZED SBO. A NASOGASTRIC TUBE WAS PLACED, AND THE GENERAL SURGERY DEPARTMENT WAS CONSULTED. A CT SCAN OF THE ABDOMEN AND PELVIS CONFIRMED THE X-RAY FINDINGS A TRANSITION POINT WAS APPRECIATED AT THE DISTAL ILEUM, CONSISTENT WITH EARLY COMPLETE SBO. AT SUBSEQUENT OPERATIVE LAPAROSCOPY, IT BECAME APPARENT THAT THE DISTAL ILEUM WAS COLLAPSED. THE ILEOCECAL JUNCTION WAS IDENTIFIED, AND THE SMALL BOWEL WAS RUN TO A LEVEL OF PROXIMAL DILATATION. THE COILED ASPECT OF THE ESSURE DEVICE WAS SEEN ADHERENT TO THE LATERAL ASPECT OF THE MID-ILEUM, WHICH WAS THE FOCAL POINT OF OBSTRUCTION DUE TO INFLAMMATION AND ADHESIONS. THERE WAS A BAND OF ADHESIONS ATTACHED TO THE COIL, WHICH TRAVERSED ACROSS THE RIGHT LOWER QUADRANT. UNDERNEATH THIS BAND, A LOOP OF JEJUNUM WAS ENSNARED, CAUSING A CLOSED LOOP OBSTRUCTION. THE BAND OF ADHESIONS WAS TRACKED DISTALLY AND WAS FOUND IMBEDDED INTO THE DISTAL TIP OF THE APPENDIX. THE DISTAL TIP OF THE APPENDIX WAS RED AND INFLAMED. THE UTERUS AND THE FALLOPIAN TUBES WERE GROSSLY NORMAL, AND NO SIGNS OF PERFORATION WERE IDENTIFIED. THE PT UNDERWENT LYSIS OF ADHESIONS, LEFT SALPINGECTOMY, APPENDECTOMY, AND REMOVAL OF THE MIGRATED ESSURE MICROINSERT. IN THIS CASE, WE CONSIDERED IT PRUDENT TO ASSUME THAT THE LEFT FALLOPIAN TUBE WAS STILL PT; THUS, A LEFT SALPINGECTOMY WAS PERFORMED TO ENSURE TUBAL OCCLUSION. THE PT'S POSTOPERATIVE COURSE WAS UNCOMPLICATED, AND SHE HAS REMAINED WELL. HYSTEROSALPINGOGRAPHY PERFORMED 3 MONTHS AFTER HER OPERATION CONFIRMED THE PROPER PLACEMENT OF THE RIGHT MICROINSERT AND BILATERAL TUBAL OCCLUSION. AUTHORS' COMMENT: PERFORATION AFTER ESSURE MICROINSERT PLACEMENT IS AN UNCOMMON COMPLICATION BUT MAY OCCUR WHEN AN EXCESSIVE AMOUNT OF FORCE IS APPLIED DURING THE PROCEDURE TO OVERCOME RESISTANCE. DEVICE PERFORATION OR MIGRATION OF THE ESSURE MICROINSERT DOES NOT CAUSE SERIOUS ADVERSE EVENTS IN PTS. THE EVENT ESSURE WAS OBSERVED TO TRAVERSE THE MESENTERY WAS UPDATE TO ESSURE WAS SEEN ADHERENT TO THE LATERAL ASPECT OF THE MID-ILEUM AND THE EVENT BOWEL OBSTRUCTION TO SMALL BOWEL OBSTRUCTION.

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Manufacturer Narrative (H10):

REPORT SOURCE LITERATURE DESCRIPTION: JOURNAL: JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY. AUTHOR: ADELMAN MR, DASSEL MW, SHARP HT. TITLE: MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW. VOLUME: XX. YEAR

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00198	BAYER HEALTHCARE LLC	6/7/2014	6/19/2014

Event Information:

Event Date (B3): 5/11/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B40021/B53031

Single Use: Y
Implant Date (E6): 5/7/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FORM A NURSE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALES PT OF UNSPECIFIED AGE WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED TWO COILS-BOTH FAILED TO DO IT'S JOB, SPRINGS CAME APART AND PT HAS COIL IN ONLY ONE SIDE AND DEVICE INSERTION COMPLICATION. NO INFORMATION GIVEN ON PT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B53031 AND B40021, FOR STERILIZATION. PHYSICIAN REPORTED THAT THE ESSURE LOT B40021 BROKE, THE SPRINGS CAME APART. NO FURTHER INFORMATION WAS PROVIDED. IT WAS ALSO REPORTED THAT THE ESSURE LOT B53031, HAD TWO COILS FAILED TO DO IT'S JOB. REPORTER THINKS THAT THE PT HAS ESSURE INSERTED IN ONLY ONE SIDE. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN TWO COILS-BOTH FAILED TO DO IT'S JOB, SPRINGS CAME APART AND PT HAS COIL IN ONLY ONE SIDE AND ESSURE WAS NOT REPORTED. FOLLOW-UP RECEIVED ON 05/16/2014: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PT WHO HAS NO PREVIOUS GYNECOLOGICAL INTERVENTION, PROBLEMS NOR PROCEDURES AND DOES NOT HAVE ANY MEDICAL HISTORY OR CONCURRENT CONDITIONS; HAD ESSURE INSERTED ON (B)(6) 2014. PT WAS NOT POST-PARTUM AT THE TIME OF INSERTION AND NO CERVICAL DILATATION OR SOUNDING WERE APPLIED DURING INSERTION. PHYSICIAN REFERS THAT A GENERAL ANESTHESIA AS WELL AS ANALGESIA WITH TORADOL WERE APPLIED DURING PROCEDURE. HEALTH CARE PROFESSIONAL ALSO INFORMED THAT THE INSERTION IN THE LEFT SIDE WAS EASY; HOWEVER THE RIGHT SIDE PRESENTED DIFFICULTY, PHYSICIAN INFORMED THAT THE FIRST ESSURE BENT 90 DEGREES, THE SECOND ONE BENT 180 DEGREES, THE THIRD ONE PRESENTED SPLINTERED END AND THE FOURTH ONE BROKE INTO THREE PIECES. IN ADDITION A

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PHYSICIAN REPORTED THAT ONLY ONE SIDE WAS EASILY VISUALIZED AND STATES THAT THERE WAS ALSO PROBLEM WITH HYSTEROSCOPY (PRIOR VISUALIZATION). THERE WAS NO FLUID LOSS MORE THAN 1500 CC AND PROCEDURE TOOK ONE AND A HALF HOURS. ON (B)(6) 2014, PT VISITED EMERGENCY ROOM FOR ENDOMETRITIS AND WAS TREATED WITH ANTIBIOTICS (OUTPATIENT). ON THE SAME DAY AN ABDOMEN/PELVIS COMPUTERIZED TOMOGRAPHY WAS PERFORMED TO CONFIRM ESSURE PLACEMENT (LEFT TUBE WITH MICRO-INSERT). THERE WERE NO PATHOLOGY RESULTS AND NO HOSPITALIZATION OCCURRED. ALSO ACCORDING TO PHYSICIAN, PT IMPLORED FOR ANTIBIOTICS AND PAIN MEDICATIONS. HEALTH CARE PROFESSIONAL BELIEVES THAT THE CONDITION WAS CAUSED BY ESSURE DEVICES AND ALSO DUE TO DIFFICULT VISUALIZATION FROM HYSTEROSCOPY AND THE DEVICES DEFECTS. AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION PT USED CONDOMS. NO HYSTEROSALPINGOGRAM WAS PERFORMED. THE REMOVAL OF ESSURE DEVICES WAS NOT PERFORMED NEITHER IS PLANNED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00199	BAYER HEALTHCARE LLC	6/7/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/3/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN THE UNITED STATES ON (B)(6) 2014. THE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN, ESSURE ON RIGHT TUBE WAS OUT OF PLACE, DOCTOR HAD TO RESECT TO GET THE COIL OUT OF MYOMETRIUM OR WHOLE METRIUM. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. PATIENT WAS NOT PREGNANT. ON (B)(6) 2010, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THREE YEARS AFTER IMPLANTATION, PATIENT WAS ON VACATION AND STARTED HAVING SEVERE PAIN. PATIENT HAD AN ULTRASOUND DONE, NOTHING WAS SEEN SO SHE HAD TO HAVE A CT (COMPUTED TOMOGRAM) WITH CONTRAST. THEY FOUND THE ESSURE ON THE RIGHT TUBE OUT OF PLACE. THE DOCTOR TOLD HE DID NOT KNOW WHEN THE PATIENT CAME IN, THE DOCTOR DOES NOT HAVE THAT INFORMATION. THE DOCTOR HAD TO GO IN AND RESECT TO GET THE COIL OUT OF THE MYOMETRIUM OR THE WHOLE METRIUM. REPORTER WENT AHEAD AND CHECKED THE LEFT TUBE AND THAT COIL WAS IN THE RIGHT POSITION. OUTCOME WAS NOT REPORTED. REPORTER DID NOT ASSESS DEVICE - EVENT RELATIONSHIP. FOLLOW-UP RECEIVED ON (B)(4) 2014: PTC GLOBAL AND LOCAL NUMBER WERE RECEIVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4) . FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE

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DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW UP (B)(4) , 2014: ESSURE-UTERINE/TUBAL PERFORATION QUESTIONNAIRE RECEIVED FROM THE PHYSICIAN WHO DID NOT PERFORM THE ESSURE INSERTION. PATIENT'S DATA WAS UPDATED. PATIENT'S MEDICAL CONDITION INCLUDES MENORRHAGIA, 2 PREGNANCIES WITH 2 LIVE BIRTHS. THIS REPORTER PHYSICIAN DID NOT HAVE INFORMATION REGARDING THE ESSURE INSERTION AND PERFORMED THE HSG (HYSTEROSALPINGOGRAM) ON (B)(6) 2010 WHICH SHOWED OBSTRUCTION ESSURE DEVICE B. ON (B)(6) 2014 A CT SCAN WAS PERFORMED AND SHOWED NO PERFORATION, THE TUBE WAS INTACT. IT APPEARED THE COIL WAS EXPELLED FROM THE LATERAL ASPECT OF THE TUBE ON THE RIGHT. COIL WAS EMBEDDED ON THE OMENTUM REQUIRING SURGICAL REMOVAL WHICH WAS PERFORMED ON (B)(6) 2014. PATIENT ALSO EXPERIENCED PAIN, NAUSEA AND VOMITING. NO INTRA-ABDOMINAL PERFORATION. THE TESTS, HSG, CT SCAN WERE PERFORMED AN OUTSIDE HOSPITAL. BRIEFLY WITH CONTRAST AND REVEALED FOREIGN OBJECT CONSISTENT WITH THE COIL SITTING JUST ANTERIOR TO THE ASCENDING COLON. NO COIL WAS SEEN IN THE RIGHT TUBE. ESSURE WAS REMOVED LAPAROSCOPICALLY. THE SYMPTOMS RESOLVED AFTER SURGERY. PATIENT WAS DOING WELL AFTER ESSURE REMOVAL. PHYSICIAN CONSIDERED ALL THE EVENTS AS RELATED TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00203	BAYER HEALTHCARE LLC	6/7/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

JOURNAL: JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY. AUTHOR: ADELMAN MR, DASSEL MW, SHARP HT. TITLE: MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW. VOLUME: XX YEAR: 2014 PAGES: XX. JOURNAL: OBSTET GYNECOL. AUTHOR: AL-SAFI Z, SHAVELL VI, KATZ LE AND BERMAN JM. TITLE: NICKEL HYPERSENSITIVITY ASSOCIATED WITH AN INTRATUBAL MICROINSERT SYSTEM. VOLUME: 117 (2) YEAR: 2011 PAGES: 461-2. THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6) 2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OLLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED HYPERSENSITIVITY TO NICKEL. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: THE AUTHOR DESCRIBES ABOUT A FEMALE PATIENT WHO DEVELOPED GENERALIZED PRURITUS IN THE ABSENCE OF A VISIBLE RASH, THREE DAYS AFTER AN UNCOMPLICATED HYSTEROSCOPIC STERILIZATION. SHE WAS REFERRED FOR SKIN PATCH TESTING, AND WAS FOUND TO HAVE HYPERSENSITIVITY TO NICKEL AND NITINOL. SHE UNDERWENT HYSTEROSCOPIC REMOVAL WITHOUT DIFFICULTY 8 DAYS AFTER THE INITIAL PROCEDURE, AND HER SYMPTOMS IMPROVED. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDER REPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHOR'S COMMENT:

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THE AUTHORS POSTULATE THAT THE SYSTEMIC REACTION TO THE IMPLANTS COULD BE EXPLAINED BY CORROSION OF THE NITINOL AFTER IMPLANTATION, RESULTING IN THE RELEASE OF NICKEL INTO THE BLOOD, AS HAS BEEN OBSERVED WITH OTHER NITINOL-CONTAINING IMPLANTABLE DEVICES.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00205	BAYER HEALTHCARE LLC	6/7/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

JOURNAL:JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY. AUTHOR: ADELMAN MR, DASSEL MW, SHART HT. TITLE: MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW. VOLUME: XX: 2014 PAGES: XX. JOURNAL: FERTILITY CONTROL. AUTHOR: POVEDANO B, ARJONA JE, VELASCO E, MONSERRRAT JA, LORENTE J, CASTELO-BRANCO C. TITLE: COMPLICATIONS OF HYSTEROSCOPIC ESSURE STERILIZATION: REPORT ON 4306 PROCEDURES PERFORMED IN A SINGLE CENTRE. YEAR: 2012. THIS CASE REPORT FROM THE UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED ALLERGY TO NICKEL (PERSISTENT GENERALIZED PRURITIS). THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: FEMALE PATIENT HAVING UNDERGONE SUCCESSFUL MICRO-INSERT PLACEMENT, ALLERGY TO NICKEL WAS NOTED. PATIENT EXPERIENCING PERSISTENT GENERALIZED PRURITUS 1 YEAR AFTER INSERTION. SYMPTOMS RESOLVED AFTER REMOVAL OF DEVICES. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES TREATMENT OPTIONS WHERE DATA ALLOW. FOLLOW UP RECEIVED ON (B)(4) 2014. PUBLICATION TITLE: COMPLICATIONS OF HYSTEROSCOPIC ESSURE STERILIZATION: REPORT ON 4306 PROCEDURES PERFORMED IN A SINGLE CENTRE RECEIVED. CASE REPORT: A WOMAN REFERRED WITH A HISTORY OF

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PERSISTENT GENITAL PRURITUS 1 YEAR AFTER THE PLACEMENT WHO DECIDED TO REMOVE THE DEVICES. CORRECTION ON (B)(4) 2014: FOLLOWING COMPANY INTERNAL REVIEW THE COUNTRY OF CASE ORIGIN WAS AMENDED TO (B)(6).

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 31-MAY-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00211	BAYER HEALTHCARE LLC	6/7/2014	6/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 07-MAY-2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED ECTOPIC PREGNANCY OF UNDETERMINED LOCATION, GREATER THAN 50% OF THE COILS WITHIN ENDOMETRIAL CAVITY AND LEFT-SIDED TUBAL PERFORATION. ESSURE WAS REPORTED AS THE TRADE NAME. CASE REPORT: THIS FEMALE PATIENT PRESENTED WITH A PREGNANCY OF UNDETERMINED LOCATION 4 YEARS AFTER HYSTEROSCOPIC TUBAL STERILIZATION. A POSTOPERATIVE HSG HAD CONFIRMED BILATERAL TUBAL OCCLUSION, ALTHOUGH THERE WERE GREATER THAN 50% OF THE COILS WITHIN THE ENDOMETRIAL CAVITY, WHICH DOES NOT MEET THE CRITERIA SET FORTH BY THE MANUFACTURER FOR SATISFACTORY LOCATION. SHE UNDERWENT A D&C AND LAPAROSCOPIC BILATERAL SALPINGECTOMY, AS THE PATIENT DID NOT DESIRE FERTILITY. ON LAPAROSCOPY, THERE WAS NO OBVIOUS TUBAL OR ADNEXAL PATHOLOGY, ALTHOUGH A LEFT-SIDED TUBAL PERFORATION WAS APPARENT. THERE WERE NO CHORIONIC VILLI OR AN IMPLANT SITE IDENTIFIED IN THE PATHOLOGY SPECIMEN. WHEN HER BETA-HCG CONTINUED TO RISE POSTOPERATIVELY, SHE WAS SUCCESSFULLY TREATED WITH METHOTREXATE. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS

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TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: THIS IS THE CASE REPORT OF ECTOPIC PREGNANCY WITH ESSURE, WITHOUT BEING DEFINITIVELY LOCALIZED. RELATED CASE: (B)(4). FOLLOW-UP RECEIVED ON 15-MAY-2014: THIS CASE REPORT IS FROM THE LITERATURE ARTICLE WHICH WAS PUBLISHED IN THE JOURNAL OF REPRODUCTIVE MEDICINE, TITLED AS "ECTOPIC PREGNANCY AFTER HYSTEROSCOPIC TUBAL OCCLUSION CONFIRMED BY HYSTEROSALPINGOGRAM: A CASE REPORT." AND AUTHORED BY HUGUELET P. CASE REPORT: THIS (B)(6), MULTIGRAVID WOMAN PRESENTED TO THE EMERGENCY DEPARTMENT COMPLAINING OF CRAMPING PELVIC PAIN AND A POSITIVE PREGNANCY TEST. HER SURGICAL HISTORY WAS SIGNIFICANT FOR HYSTEROSCOPIC ESSURE TUBAL STERILIZATION 4 YEARS PRIOR. SHE REPORTED THAT BILATERAL TUBAL OCCLUSION HAD BEEN CONFIRMED BY 3-MONTH FOLLOW-UP HSG. SERUM BETA-HCG WAS 354 MLU, AND PELVIC ULTRASONOGRAPHY REVEALED AN ENDOMETRIAL STRIPE OF 6 ROM WITH A QUESTIONABLE 3.3-CM LEFT ADNEXAL MASS. GIVEN HEMODYNAMIC STABILITY AND UNCLEAR ETIOLOGY OF THE MASS, SHE WAS INSTRUCTED TO FOLLOW-UP IN 48 HOURS. SHE THEN PRESENTED 36 HOURS LATER WITH WORSENING PELVIC CRAMPING AND NEW ONSET VAGINAL SPOTTING. REPEAT SERUM BETA-HCG WAS 373 MIU. REPEAT ULTRASOUND NO LONGER DEMONSTRATED AN ADNEXAL MASS, BUT THERE WAS STILL NO INTRAUTERINE PREGNANCY. SHE WAS THEREFORE TAKEN TO THE OPERATING ROOM FOR A DILATION AND CURETTAGE. SHE ALSO UNDERWENT LAPAROSCOPIC BILATERAL SALPINGECTOMY SINCE SHE NO LONG DESIRED FERTILITY. DURING LAPAROSCOPY NO ADNEXAL OR TUBAL PATHOLOGY WAS FOUND. HOWEVER, THE LEFT-SIDED ESSURE MICRO- INSERT WAS NOTED TO BE PERFORATING THROUGH THE UTERINE CORNUA. THE RIGHT SIDE APPEARED NORMAL. SALPINGECTOMY WAS THEREFORE PERFORMED TO ENSURE STERILIZATION AND TO ALLOW FOR A THOROUGH PATHOLOGIC EVALUATION FOR CHORIONIC VILLI. FINAL PATHOLOGIC EXAMINATION OF THE ENDOMETRIAL CURETTINGS AND FALLOPIAN TUBES DID NOT SHOW EVIDENCE OF CHORIONIC VILLI OR IMPLANTATION SITE. THE PATIENT WAS THEN FOLLOWED WITH SERIAL BETA-HCG LEVEL TESTING. HER FIRST BETA-HCG, OBTAINED 8 DAYS AFTER SURGERY, WAS 625 MIU. GIVEN HER RISING BETA-HCG AND PERSISTENT PELVIC PAIN, SHE WAS COUNSELED THAT SHE LIKELY HAD AN ECTOPIC PREGNANCY OF UNKNOWN LOCATION, AND METHOTREXATE WAS ADMINISTERED AT A DOSE OF 50 MG/M2. HER BETA-HCG LEVEL DECREASED APPROPRIATELY TO 107 ON DAY 4 AND TO 8 ON DAY 7 AND SUBSEQUENTLY WAS UNDETECTABLE. THE PATIENT'S PREVIOUS RECORDS REVEALED THAT SHE UNDERWENT MICRO-INSERT STERILIZATION WITHOUT COMPLICATION. FINDINGS AT THE TIME OF HYSTEROSCOPY INCLUDED A NORMAL ENDOMETRIAL CAVITY AND TUBAL OSTIA. AFTER ESSURE COIL DEPLOYMENT, 3 COILS WERE VISIBLE ON THE RIGHT AND 9 COILS WERE VISIBLE ON THE LEFT. HSG WAS THEN PERFORMED 12 WEEKS LATER. REVIEW OF HER HSG REVEALED THAT ON THE RIGHT SIDE THE PROXIMAL MARKER WAS APPROPRIATELY LOCATED AT THE CORNUAL-TUBAL JUNCTION. ON THE LEFT SIDE, HOWEVER, MORE THAN 50% OF THE INNER COIL WAS LYING WITHIN THE ENDOMETRIAL CAVITY. NO CONTRAST FLOWED INTO EITHER FALLOPIAN TUBE. AUTHOR'S COMMENT: PREGNANCY AFTER HYSTEROSCOPIC STERILIZATION IS A RARE EVENT. TO DATE, NO PREGNANCY HAS BEEN REPORTED IN THE LITERATURE IN PATIENTS AFTER ADEQUATE INTERIM CONTRACEPTION, PROPERLY POSITIONED DEVICES, AND CONFIRMED TUBAL OCCLUSION BY 3-MONTH FOLLOW-UP HSG. IN THIS CASE, INCORRECT PROXIMAL PLACEMENT OF THE ESSURE MICRO-INSERT STILL RESULTED IN THE APPEARANCE OF BILATERAL TUBAL OCCLUSION ON FOLLOW-UP HSG. ULTIMATELY, THIS FALSE-POSITIVE RESULT LED TO MISGUIDED REASSURANCE FOR THE PATIENT. THIS APPEARS TO BE THE FIRST CASE REPORTED IN WHICH PROXIMAL PLACEMENT ULTIMATELY RESULTED IN ECTOPIC PREGNANCY. UPON REVIEW OF THE PATIENT'S RECORDS, 2 POTENTIAL FINDINGS MAY HAVE LED TO A DIFFERENT COURSE OF ACTION. AT THE TIME OF PLACEMENT, 9 COILS WERE VISUALIZED ON THE LEFT SIDE. THE MANUFACTURER RECOMMENDS ONLY 3-8 TRAILING COILS FOR IDEAL PLACEMENT. ALTHOUGH THE PRESENCE OF 9 COILS MAY BE ACCEPTABLE, THIS SHOULD HAVE PROMPTED CLOSER EVALUATION DURING THE FOLLOW-UP HSG. SECONDLY, THE LOCATION OF THE MICRO-INSERT WITHIN THE FALLOPIAN TUBE WAS CLEARLY MALPOSITIONED. CONCEPTUS PROVIDES AN ESSURE CONFIRMATION TEST CHECKLIST FOR PHYSICIANS, TO CONFIRM WHETHER THE PATIENT CAN RELY ON ESSURE FOR ADEQUATE STERILIZATION. THE HSG MUST DEMONSTRATE BOTH SATISFACTORY BILATERAL TUBAL OCCLUSION AND PROPER POSITION OF THE MICRO-INSERT WITHIN

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THE FALLOPIAN TUBE. THE MICRO-INSERT MUST BE< 30 MM FROM THE PROXIMAL END OF THE INNER COIL TO THE CONTRAST FILL IN THE CORNUA, WITH <50% OF THE LENGTH OF THE INNER COIL TRAILING INTO THE UTERINE CAVITY. ACCURATE MICRO-INSERT PLACEMENT IN THE NARROW DIAMETER OF THE INTRAMURAL PORTION OF THE FALLOPIAN TUBE AND SUBSEQUENT FIBROUS TISSUE IN-GROWTH ARE NECESSARY TO PROMOTE FIRM ANCHORING OF THE MICRO-INSERT. THIS CASE ILLUSTRATES AN ECTOPIC PREGNANCY AFTER ESSURE STERILIZATION DESPITE APPARENT TUBAL OCCLUSION. IT DEMONSTRATES THE ABSOLUTE NECESSITY OF ESTABLISHING BOTH ABSENCE OF DYE SPILL AND CORRECT MICRO-INSERT LOCATION IN ORDER TO GUARANTEE STERILIZATION. THE ABSENCE OF DYE SPILL ALONE ON HYSTEROSALPINGOGRAM DOES NOT CONFIRM STERILIZATION. HYSTEROSCOPIC STERILIZATION OFFERS A UNIQUE ADVANTAGE IN THAT IT CAN BE PERFORMED IN AN OUTPATIENT SETTING UNDER LOCAL ANESTHESIA. IN ORDER TO GUARANTEE ITS CONTINUED SUCCESS, CAREFUL ATTENTION MUST BE PAID TO THE FOLLOW-UP PROCESS. FOLLOW-UP INFORMATION RECEIVED ON 20-MAY-2014: PTC NUMBER PROVIDED: PTC ID (B)(4). FOLLOW UP 21-MAY-2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY IV. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE AND NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. ADDITIONALLY, PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00194	BAYER HEALTHCARE LLC	6/7/2014	7/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A95863

Single Use: Y
Implant Date (E6): 4/4/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN THE UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE COIL AND SHEATH GOT CAUGHT IN THE FALLOPIAN TUBE AND THE COIL FELL APART (DEVICE INSERTION FAILED, COMPLICATION OF DEVICE INSERTION). NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATIONS. ON (B)(6) 2014 THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER A95863. THE COIL AND SHEATH GOT CAUGHT IN THE FALLOPIAN TUBE AND THE COIL FELL APART (COMPLICATION OF DEVICE INSERTION). BILATERAL PLACEMENT WAS NOT ACHIEVED (DEVICE INSERTION FAILED). PT WAS FINE. NO FURTHER INFO WAS PROVIDED. ADDENDUM (B)(6) 2014: DESPITE SEVERAL FOLLOW-UP ATTEMPTS NO NEW INFO COULD BE OBTAINED. FOLLOW-UP PTC FINAL RESULT RECEIVED ON (B)(6) 2014: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THIS CASE REPORTED DEVICE BREAKAGE DUE TO COMPLICATION OF INSERTION AND DIFFICULT TO USE DUE TO BILATERAL PLACEMENT NOT BEING ACHIEVED. THESE REPORTED EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THREE (3) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER (B)(4) AND THESE CASES REFER TO EVENTS OF DIFFICULT TO USE AND COMPLICATION OF INSERTION (ALL DUE TO TUBAL SPASM) BUT NONE OF THESE CASES REFERS TO DEVICE BREAKAGE. NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL

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INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFO AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP ON (B)(6) 2014: HEALTHCARE PROFESSIONAL QUESTIONNAIRE WAS RETURNED. THE (B)(6) YEAR OLD PT, HEIGHT 5 FEET 5 INCHES, WEIGHT (B)(6), HAD NO GYNECOLOGICAL INTERVENTIONS (A CERVICAL CONIZATION, CURETTAGE, PREVIOUS IUS/IUD (INTRAUTERINE SYSTEM OR DEVICE), MYOMECTOMY, ADNEXAL SURGERY) IN THE PAST, AND NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES, AND NO OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. PT WAS TO HAVE ESSURE (ESS305, LOT NUMBER A95863, EXPIRATION DATE ON 01/2016) INSERTED WHEN SHE WAS NOT POSTPARTUM. CERVICAL DILATATION WAS PERFORMED, BUT NO SOUNDING, AND NO GENERAL ANESTHESIA WERE DONE. ANALGESIA WAS PERFORMED WITH ORAL TORADOL (KETOROLAC TROMETHAMINE) 10MG, ORAL VALIUM (DIAZEPAM) 10 MG. INSERTION WAS DIFFICULT, THE SHEATH OF DEVICE DID NOT RELEASE AND COIL STRETCHED AND DEFORMED. THERE WAS NO FLUID LOSS DURING HYSTEROSCOPY OF MORE THAN 1500CC. PROCEDURE TOOK LONGER THAN 20 MINUTES, 49 MINUTES EXACTLY. VISUALIZATION OF TUBAL OSTIA WAS EASY. IT WAS ALSO REPORTED PROCEDURE WAS ABORTED DUE TO POOR HYSTEROSCOPIC VISUALIZATION AND PT DISCOMFORT. PT LEFT WITHOUT ESSURE. NO TREATMENT WAS REQUIRED FOR REPORTED EVENTS, NO DIAGNOSTIC TESTS PERFORMED, NOT PATHOLOGICAL RESULTS, NO HOSPITALIZATION OCCURRED. REPORTER STATED THE CONDITION WAS CAUSED BY ESSURE DEVICES, THE SHEATH DID NOT RELEASE AND COIL WAS DEFORMED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. NO NEW INFO. CORRECTION ON (B)(6) 2014 WITH INFO RECEIVED ON (B)(6) 2014: THE CASE INCIDENT CATEGORY, PREVIOUSLY DOWNGRADED FROM NEAR-INCIDENT TO NON-INCIDENT ON (B)(6) 2014, WAS AFTER A COMPANY INTERNAL REVIEW AMENDED TO NEAR-INCIDENT. ALSO, AFTER THE REVIEW OF THE PTC RESULT THE EVENT: THE COIL AND SHEATH GOT CAUGHT IN THE FALLOPIAN TUBE AND THE COIL FELL APART WAS CONSIDERED AS ANTICIPATED AND THUS, LISTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036559		6/9/2014	6/16/2014

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE (B)(6) 2013. SUFFERED FROM HEAVY BLEEDING AND PELVIC PAIN. HAD A D7C AND TOTAL VAGINAL HYSTERECTOMY WHICH REMOVED ONE COIL. ONE MONTH LATER HAD BOTH TUBES REMOVED. SECOND COIL HAS MIGRATED BEHIND MY BLADDER AND COULD NOT BE RETRIEVED WITHOUT THE HELP OF A SPECIALIST. THIS DEVICE HAS IMPACTED, MY LIFE AND HEALTH, AND I STILL NEED ANOTHER SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036564	BAYER	6/9/2014	6/16/2014

Event Information:

Event Date (B3): 4/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/30/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE WEEK AFTER HAVING ESSURE IMPLANTED I STARTED TO HAVE HORRIBLE PAIN IN MY RIGHT QUADRANT AFTER FEELING A POP AND A STAB DURING MY SHOWER. THIS WAS BAD ENOUGH THAT I MISSED 3 DAYS OF WORK AND HAVE HAD SERIOUS PAIN IN MY ABDOMEN AND WHOLE BACK. I CONTINUE TO HAVE THIS PAIN ON AN ONGOING BASIS AND NOT A DAY GOES BY THAT I HAVEN'T HAD THIS PAIN. IT IS MORE TOLERABLE NOW AND OCCASIONALLY I HAVE EPISODES OF WORSE PAIN TO THE POINT I FEEL AS IF I AM IN LABOR. THE ULTRASOUND WAS DONE ONE MONTH FROM THE PROCEDURE. IT SHOWED THE RIGHT COIL WAS EMBEDDED IN MY UTERINE WALL, MY RIGHT TUBE WAS INFLAMED AND THE COIL WAS NO LONGER IN THE PROPER PLACE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036566	CONCEPTUS	6/9/2014	6/16/2014

Event Information:

Event Date (B3): 10/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): 869762
Catalog # (E4):
Lot #(E4): ESS305

Single Use:
Implant Date (E6): 10/25/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE (B)(6) 2011 AND HAVE HAD PAIN IN MY SIDES, NAUSEA, CRAMPING, PELVIC PAIN, NIGHT SWEATS, LONG MENSTRUAL CYCLES, METALLIC TASTE IN MOUTH, HEARTBURN, DIZZINESS, AND WEIGHT ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036567	CONCEPTUS INCORPORATED	6/9/2014	6/16/2014

Event Information:

Event Date (B3): 10/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/15/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HIGH BLOOD PRESSURE AFTER GETTING THE ESSURE PLACED IN 2010. I GET HEADACHES ALL THE TIME AND DIZZY SPELLS. I ONLY SPOT WHEN ON MY PERIOD AND IT ONLY LAST FOR A DAY. I AM SLEEPY ALL THE TIME AND I HAVE A REACTIVE LYMPH NODE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036596	BAYER	6/10/2014	6/17/2014

Event Information:

Event Date (B3): 9/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/9/2009
Explant Date (E7): 12/31/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE (B)(6) OF 2009, I HAVE HAD NOTHING BUT PROBLEMS. AFTER THE IMPLANTATION OF THE ESSURE DEVICE, I BLED FOR 47 DAYS STRAIGHT. IRON LEVELS FELL AND I WAS GIVEN A SPECIAL DIET AND IRON PILLS. AFTER THE BLEEDING STOPPED I NOTICED A NAGGING PAIN ON THE RIGHT SIDE AND THEN IN MY LOWER BACK. I WOULD TELL MY GYN ABOUT IT AND HE JUST SNUBBED ME OFF. I FEEL LIKE I WAS BULLIED INTO THIS BECAUSE HE WAS SUPPOSED TO TIE AND CUT MY TUBES AFTER I GAVE BIRTH. HE DECIDED TO WAIT UNTIL MY 6 WEEK APPOINTMENT. I MEAN NO PROBLEMS AND I WOULD HAVE 3 CHILD NATURAL WITHOUT AN EPIDURAL BUT I GOT IT SO THAT MY TUBES COULD BE TIED. WELL AT THE END OF (B)(6) OF 2009 MY CYCLE BEGAN, BLEEDING PROFUSELY, AND PAINFULLY. IT LASTED ABOUT A FULL WEEK AND APPROXIMATELY 12 DAYS LATER IT CAME BACK. I THOUGHT I WAS CRAZY. FROM 2009 TO (B)(6) 2014, I HAVE HAD 2 PERIODS A MONTH THAT KEEP ME FROM DOING NORMAL ACTIVITIES. I HAVE EXTREME FATIGUE, LOWER ABDOMINAL PAIN, LOWER BACK PAIN, HEADACHES, NAUSEA, PAIN IN THE SAME SPOT ON THE RIGHT SIDE AFTER IMPLANTATION, SHOOTING PAINS UP AND DOWN MY LEGS, STABBING PAINS ON THE RIGHT SIDE OF MY LOWER STOMACH, SWELLING THAT HAS PLAGUED ME SINCE 2009, JUST PAIN. IN 2012. I CHANGED DOCTORS, THIS GYN TOLD MY DOCTORS ARE PAID FOR NEW DEVICES AND I MAYBE A VICTIM OF A DOCTOR JUST WANTING TO GET PAID. THIS DOCTOR GAVE ME A SONOGRAM IN WHICH HE SAID THE ESSURE WERE STILL IN PLACE BUT SEEMED LOW. IN (B)(6) OF THIS YEAR 2014, I WAS FED UP AND WENT BACK TO MY NEW DOCTOR SINCE 2012 AND DISCOVERED I HAD POLYPS ALL AROUND THE OPENINGS OF MY FALLOPIAN TUBES. SO I HAD AN EMERGENCY (SKIPPED A LOT OF PEOPLE) D AND C DONE TO REMOVE ALL OF THEM AND A HYSTEROSCOPY AND THE REASON HE SUGGESTED THIS IS BECAUSE I HAD BEEN BLEEDING FROM (B)(6) UNTIL THE SECOND WEEK IN (B)(6). CLOTS THE SIZE OF A LARGE PRUNE. SO POST D AND C, I STILL HAVE 2 PERIODS A MONTH IN BETWEEN BLEEDING, SO HEAVY I BLEED ON

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MYSELF SOMETIMES AT WORK. SUPER PLUS TAMPONS ALONG WITH OVERNIGHT PADS EVERY 25 TO 30 MINUTES MUST BE CHANGED. THE FATIGUE IS BACK WITH A VENGEANCE. I HAVE A CYST ON MY LEFT OVARY, I NOW HAVE THE PAINS SHOOTING UP AND DOWN MY LEGS ON BOTH SIDES WITH THAT STABBING PAIN FROM MY RIGHT NOW ON THE LEFT IN THE FRONT AND THE BACK OF MY STOMACH AND LOWER BACK. HEADACHES, REPEATED NAUSEA ETC. I GO BACK (B)(6) FOR ANOTHER SONOGRAM TO SEE WHY AFTER 5 YEARS I'M STILL HURTING AND IN PAIN. IT'S HARD TO KEEP UP WITH THE EXPENSE OF ALL THESE UNSUCCESSFUL PROCEDURES BUT I FEEL LIKE I'M DYING IT'S SO BAD. SEEMS LIKE I CAN ALMOST TELL WHEN I OVULATE AS WELL. I FEEL THIS STABBING PAIN IN BETWEEN PERIODS THAT ALMOST BRINGS ME TO MY KNEES, AND EVERY MONTH IT SWAPS SIDES. NOW I DON'T KNOW IF YOU OVULATE FROM EACH OVARY EVERY OTHER MONTH OR NOT, BUT BECAUSE I HAVE 2 PERIODS A MONTH I GET THAT PAIN ON EITHER SIDE TWICE A MONTH EVERY MONTH. I HAVE BLED INTO THE SEAT OF CARS 20 MINUTES AFTER I LEFT FOR WORK, FELT FAINT AND NO ONE UNDERSTANDS THIS ALL STARTED AFTER ESSURE. I BLEED SO BAD THAT EVEN WITH A TAMPON, THE SECOND I PULL MY PANTS DOWN I'M BLEEDING ALL OVER THE FLOOR, TOILET SEAT AND ALL BEFORE I EVEN SIT DOWN. IN TURN I MUST CHANGE CLOTHES AT HOME OR WORK, CLEAN MYSELF AND THE TOILET. OH LORD PLEASE HELP ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036597		6/10/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/16/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE IMPLANTED LAST (B)(6) PER MY DOCTOR'S REQUEST INSTEAD OF LITIGATION. I LET HIM KNOW I'M ALLERGIC TO METAL AND HE SAID IT'D BE FINE. BY (B)(6), I'D BEEN TO THE HOSPITAL 3 TIMES FOR CHRONIC HIVES. I'D SEEN MY DOCTOR THAT WEEK. MY BLOOD PRESSURE WAS 80/40, AND I ENDED UP IN THE EMERGENCY ROOM 2 STATES FROM HOME. MY HEART CONTINUED TO RACE, AND AS I STABILIZED AFTER THEY CHECKED MY EKG, THEY WOULDN'T LET ME GO FOR HOURS BECAUSE IT WOULDN'T CALM DOWN EVEN WHEN I WAS ASLEEP. IN THE LAST YEAR I'VE HAD CHRONIC HIVES AT LEAST 130 DAYS OF THE LAST YEAR. I HAVE PAIN ALL OVER. MY HANDS AND FEET ARE NUMB. I'VE GAINED 80 POUNDS. AND I'VE BEEN CALLED CRAZY BY MANY DOCTORS; PRETTY SURE THEY STILL THINK I'M CRAZY. WHEN I LEFT MY NETWORK OF DOCTORS FRIDAY THE ONE I GOT BY CHANCE TESTED ALL THE NORMAL THINGS THAT WOULD CAUSE ALLERGIC REACTION IN LABS. THE ONLY THING HE COULD BRING IT BACK TO IS THE ESSURE. I SHOULD HAVE THOUGHT OF IT, IT WAS THE SAME TIMELINE. I NEVER EXPECTED TO FEEL SO TERRIBLE A YEAR LATER. I HAVE NEVER, EVER FELT THIS BAD IN MY ENTIRE LIFE. I'M PRETTY SURE I NOW HAVE TO SPEND TIME FIGHTING TO GET IT REMOVED. THE DOCTOR WHO DID IT IS NO LONGER AROUND, AND IT'S NOT COMMON IN (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036570	CONCEPTUS INC	6/11/2014	6/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE STERILIZATION COILS. SINCE THE PROCEDURE I HAVE HAD NUMBEROUS ADVERSE SYMPTOMS. FIRST IS THAT I HAVE HAD RIGHT SIDE WEAKNESS AND PAIN IN MY HIP, SI JOINT AND OVARIES. THIS INCLUDES SHARP SEARING PAIN THAT SHOOTS DOWN MY LEG. I ALSO FEEL LIKE THERE IS A BABY IN MY BELLY AND THERE ISN'T. MY BELLY LITERALLY DISPLAYS KICKING SENSATIONS AS IF A BABY IS KICKING. THIS HAS GONE ON FOR YEARS NOW. I HAVE INCREASED SWELLING IN MY ABDOMEN AND AT TIMES LOOK PREGNANT. EVER SINCE I HAVE GOTTEN THE ESSURE MY WEIGHT HAS STEADILY INCREASED DESPITE DIET AND EXERCISE. I NOW HAVE TO TAKE PROGESTERONE AND I HAVE WEIRD INFLAMMATION IN MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036641	BAYER	6/12/2014	6/18/2014

Event Information:

Event Date (B3): 7/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AS SOON AS I WOKE UP FROM HAVING THE ESSURE COILS IMPLANTED, I WAS IN EXTREME PAIN. I WAS TOLD THE PAIN WOULD PASS IN 24 HOURS AND EVERYTHING WAS OK. I WAS SENT HOME ON PAIN MEDICATION TO RECOVER. THE PAIN NEVER SUBSIDED AND IT WORSENED. I SPENT THE NEXT FEW MONTHS GOING BACK AND FORTH WITH MY GYN, ABOUT THE EXCRUCIATING PAIN I WAS EXPERIENCING. IT FELT LIKE HOT POKERS WERE BEING JAMMED INTO MY PELVIS. I COULD ACTUALLY FEEL THE ESSURE COILS WERE IMPLANTED. I WAS SO MISERABLE. I WAS UNABLE TO CARE FOR MY TWO YOUNG CHILDREN AND SPENT MANY WEEKS FEELING GUILTY. I WAS TOLD BY MY GYN THAT I WAS ONE IN A MILLION WHO EVER HAD PROBLEMS WITH THE DEVICES AND SHE WAS BAFFLED I WAS IN SO MUCH PAIN. SHE PRESCRIBED ME PAIN MEDICINE THAT I TOOK AROUND THE CLOCK AND IT JUST DULLED THE PAIN, AND DID NOT TAKE IT AWAY. MY GYN OFFERED TO REMOVE THE COILS BUT CAUTIONED ME THAT SHE HAD NEVER DONE IT BEFORE. THIS WAS VERY CONCERNING TO ME. I KNEW THAT HAVING THE COILS REMOVED WAS MY ONLY OPTION, BUT DID NOT WANT TO HAVE SOMEONE OPERATE ON ME WHO WAS NOT EXPERIENCED. I HAD TO FIND A PHYSICIAN WHO HAD DONE THIS TYPE OF SURGERY BEFORE. THE DOCTOR I FOUND WAS WONDERFUL BUT NOT COVERED UNDER MY INSURANCE. I ULTIMATELY HAD THE SURGERY AND PAID THE EXTRA FEES TO HAVE THE EXPERIENCED DOCTOR PERFORM THE SURGERY. THE SURGERY ALSO INCLUDED A TUBAL LIGATION TO PREVENT PREGNANCY. WHEN I WOKE UP FROM THE REMOVAL, THE PAIN THAT I HAD BEEN EXPERIENCING WAS GONE. I COULD NOT BELIEVE HOW QUICKLY RELIEF HAD COME. SO, THE ESSURE PROCEDURE ULTIMATELY COST ME A SMALL FORTUNE TO HAVE IMPLANTED AND THEN QUICKLY REMOVED. THE SURGERY, THE MEDICATIONS, TIME WITH MY HUSBAND, HAD TO TAKE OFF WORK, AND THE VALUABLE TIME I MISSED WITH MY INFANT DAUGHTER THAT I WILL NEVER GET BACK.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00215	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): OTHER	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B42237

Single Use: Y
Implant Date (E6): 4/1/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BREAKAGE OF THE IMPLANT HOLDER AND COMPLICATION OF THE DEVICE INSERTION. ADDITIONAL INFORMATION RECEIVED ON (B)(4) 2014. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B42237. DURING RELEASE OF THE IMPLANT, THE IMPLANT HOLDER BROKE AND REMAINED IN PLACE IN THE IMPLANT, WHICH ITSELF WAS POSITIONED IN THE TUBE. IMPLANT AND BROKEN INTRODUCER WERE REMOVED. BILATERAL INSERTION WAS PERFORMED, WITH ANOTHER DEVICE. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE IS NOT REPORTED.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2014. FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AS OF (B)(4) 2014, NO DEVICE WAS RETURNED; THEREFORE, NO DEVIC

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00216	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** PO

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH, DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM THE MEDICAL LITERATURE ON (B)(4) 2014 FROM A REVIEW ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO RECEIVED FALLOPIAN TUBE OCCLUSION INSERT (ESSURE) FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED PERSISTENT PAIN AFTER INSERTION OF ESSURE. THIS CASE REFERS TO ONE OF EIGHT FEMALES WHO EXPERIENCED PERSISTENT PAIN AFTER INSERTION OF ESSURE WHICH WERE WITHOUT EVIDENCE OF PERFORATION. THE OUTCOME OF THIS PATIENT WAS UNKNOWN. FURTHER INFORMATION IS EXPECTED FROM THE PRIMARY ARTICLE WHICH WAS REFERRED TO AS REFERENCE 22 IN THE REVIEW ARTICLE: CORREIA L, MACHADO A, DELGADO E, FARELO A: HYSTEROSCOPIC STERILIZATION. ESSURE: 4 YEARS OF EXPERIENCE. EUROPEAN JOURNAL OF CONTRACEPTION AND REPRODUCTIVE HEALTH CARE, 2010;15:199-200. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDERREPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHOR'S COMMENT: THE AUTHORS REPORTED COMPLICATIONS ASSOCIATED WITH ESSURE.

Manufacturer Narrative (H10):

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FOLLOW-UP (B)(4). THE PRIMARY ARTICLE BY CORREIA L ET AL. PRESENTS A RETROSPECTIVE STUDY OF FORTY-NINE WOMEN ELECTED FOR STERILIZATION BY HYSTEROSCOPIC METHOD BETWEEN (B)(6) 2005 AND (B)(6) 2009. HYSTEROSCOPIC STERILIZATION CONSISTED IN THE PLACEMENT OF E

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00217	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6) 2014, ARTICLE ENTITLED "COMPLICATION OF THE ESSURE IMPLANT STERILIZATION PROCEDURE: A CASE REPORT." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION AND EXPERIENCED PERFORATION OF DEVICE THROUGH THE FALLOPIAN TUBE. CASE REPORT: ONE CASE OF PERFORATION WAS DIAGNOSED 2 YEARS AFTER THE PLACEMENT OF THE MICRO-INSERT. THEY WERE REMOVED AFTER A 6-MONTH HISTORY OF SCRATCHY IRRITATING PAIN IN THE PELVIC REGION ON THE RIGHT SIDE, WHICH WAS NOT ASSOCIATED WITH ANY SYSTEMIC SYMPTOMS. THE INSERTS WERE REMOVED BY LAPAROTOMY AND SHE HAS REMAINED PAIN FREE FOR 18 MONTHS OF FOLLOW-UP. HISTOLOGIC EVALUATION REVEALED PERFORATION OF THE DEVICE THROUGH THE TUBE HALFWAY ALONG ITS INTRAMURAL SEGMENT AND CONTINUED PARALLEL TO THE UNDERSIDE OF THE PERITONEUM ADJACENT TO THE UTEROTUBAL JUNCTION. THERE WAS NO EVIDENCE OF INFECTION. AUTHOR'S COMMENT: ALTHOUGH THIS IMPLANT IS VERY SMALL, IT HAS THE POTENTIAL FOR SIGNIFICANT MORBIDITY. THE AUTHORS REPORT A CASE OF PERFORATION, WHICH WAS DIAGNOSED 2 YEARS AFTER THE PLACEMENT OF THE MICRO-INSERT. OTHER CASES FROM THIS ARTICLE: (B)(4).

Manufacturer Narrative (H10):

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FOLLOW UP RECEIVED ON (B)(6) 2014. FULL TEXT RECEIVED. THE COUNTRY OF INCIDENCE WAS (B)(6) AND THE STUDY WAS AN INTERVENTIONAL STUDY. CASE REPORT: ONE CASE OF PERFORATION WAS DIAGNOSED AFTER 2 YEARS OF MICRO-INSERT PLACEMENT. THIS WOMAN REQUESTED THAT HER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00218	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6) 2014, ARTICLE ENTITLED "COMPLICATIONS ASSOCIATED WITH ESSURE DEVICE: ANALYSIS AFTER 4000 PROCEDURES". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO RECEIVED FALLOPIAN TUBE OCCLUSION INSERT FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED TUBAL PERFORATION. CASE REPORT: THIS CASE REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT PLACED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED TUBAL PERFORATION THAT REQUIRED A LAPAROSCOPIC SALPINGECTOMY. AUTHOR'S COMMENT: THIS CASE REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT PLACED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED TUBAL PERFORATION. ABSTRACT: OBJECTIVES: TO ANALYSE THE COMPLICATIONS AT SHORT, MEDIUM, AND LONG TERM, REGISTERED IN PATIENTS THAT UNDERWENT HYSTEROSCOPIC TUBAL STERILIZATION WITH ESSURE DEVICE. MATERIALS AND METHODS: RETROSPECTIVE COHORT STUDY OF 4000 CONSECUTIVE PATIENTS WITH THE PROCEDURE PERFORMED BETWEEN 2003 TILL 2010. ALL DATA ARE REGISTERED IN THE DATABASE OF THE OFFICE HYSTEROSCOPY UNIT OF (B)(4) HOSPITAL. THE TELEPHONE NUMBER IS GIVEN TO ALL PATIENTS TO COMMUNICATE ALL KIND OF PROBLEMS. FOLLOW UP OF PATIENTS INCLUDES FROM 3 MONTHS TILL 8 YEARS. RESULTS: THE GLOBAL RATE OF COMPLICATIONS IS (B)(4) ((B)(4)CASES). THE MOST FREQUENT COMPLICATION IS VASOVAGAL SYNCOPE AFTER PROCEDURE ((B)(4), (B)(4) CASES), FOLLOWED BY EXPULSION OF ONE OF THE DEVICES ((B)(4), (B)(4) CASES). NO SYNCOPE REQUIRED HOSPITALIZATION AND THEY WERE CURED WITH RECOVERY. THE EXPULSIONS WERE MOST OF THEM IN THE THREE MONTHS AFTER PLACEMENT, 2 MIGRATIONS TO CAVITY THAT DID NOT REQUIRE SURGERY, 3 INTRAMYOMETRIAL PLACEMENTS, AND 2 IPD THAT WERE CURED WITH ANTIBIOTICS; 1 TUBAL PERFORATION THAT REQUIRED A LAPAROSCOPIC

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SALPINGECTOMY, 1 ABDOMINAL PAIN THAT HAS NOT IMPROVED AFTER LAPAROSCOPIC SALPINGECTOMY AND APPENDECTOMY; AND 2 NICKEL ALLERGIES WITHOUT PREVIOUS DIAGNOSES THAT REQUIRED A LAPAROSCOPIC SALPINGECTOMY AFTER ESSAY AN HYSTEROSCOPIC APPROACH. THE DEVICES HAVE BEEN PLACED IN (B)(4) KNOWN NICKEL ALLERGIES WITHOUT SIDE EFFECTS. CONCLUSIONS: THE PERMANENT BIRTH CONTROL WITH ESSURE DEVICE HAS DEMONSTRATED TO BE A SAFE METHOD, WITH A LOW RATE OF COMPLICATIONS, WHICH ITS SECURITY PERSIST AFTER 8 YEARS FOLLOW UP. THAT MEANS THAT ESSURE METHOD SHOULD BE THE REFERENCE METHOD IN WHAT IS TO DO WITH DEFINITIVE CONTRACEPTION. OTHER (B)(6) CASE NUMBERS FROM THIS STUDY 2014-(B)(4), 2014-(B)(4).

Manufacturer Narrative (H10):

COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE. ARTICLE ENTITLED: COMPLICATIONS ASSOCIATED WITH ESSURE DEVICE: ANALYSIS AFTER 4000 PROCEDURES. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSU

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Report Type: MANUFACTURER **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00219	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVIE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 10/30/2012
Explant Date (E7): 3/20/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN. NO INFORMATION GIVEN ON PATIENT HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON (B)(6) 2012 PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION. REPORTER WAS NOT ABLE TO INFORM ITS LOT NUMBER AND EXPIRATION DATE. PATIENT HAD BEEN EXPERIENCING CHRONIC PELVIC PAIN SINCE (B)(6)-2013. SHE DID NOT RECEIVE ANY TREATMENT FOR THE EVENT. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENT AND ESSURE WAS NOT REPORTED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM PHYSICIAN: THE PATIENT WEIGHT AND HEIGHT WERE PROVIDED. IT WAS STATED THAT CERVICAL DILATATION AND GENERAL ANESTHESIA WERE APPLIED DURING INSERTION. ESSURE WAS EASILY INSERTED. DEPO-PROVERA WAS USED AS BACK-UP CONTRACEPTION. ON (B)(6) 2014, A PELVIC ULTRASOUND WAS PERFORMED AND IT WAS NORMAL. ON (B)(6) 2013, HSG WAS PERFORMED AND BOTH TUBES WERE BLOCKED. ESSURE DEVICES WERE IN POSITION. ON (B)(6) 2014, ESSURE WAS REMOVED (IT WAS MEDICALLY NECESSARY). PATIENT WAS EXPERIENCING PAIN. LAPAROSCOPIC SUPRACERVICAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY WERE PERFORMED TO REMOVE ESSURE. PATHOLOGY RESULT WAS NORMAL WITH NO INFLAMMATION. NORMAL LOCATION AND CONDITION OF DEVICES. PATIENT RECOVERED FROM PAIN AFTER SURGERY.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2014: PTC GLOBAL NUMBER: 2014-(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00220	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 07-MAY-2014, ARTICLE ENTITLED "MANAGEMENT OF COMPLICATIONS ENCOUNTERED WITH ESSURE HYSTEROSCOPIC STERILIZATION: A SYSTEMATIC REVIEW." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD FALLOPIAN TUBE OCCLUSION INSERT INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED INTERMITTENT ABDOMINAL PAIN AFTER REMOVAL OF THE THE MICRO-INSERT. THE TRADE NAME WAS REPORTED TO BE ESSURE. CASE REPORT: THE PATIENT EXPERIENCED IMPROVEMENT IN PROGRESSIVE DAILY PAIN AFTER THE REMOVAL OF THE MICRO-INSERT, BUT WITH CONTINUED INTERMITTENT ABDOMINAL PAIN. ABSTRACT: ESSURE HYSTEROSCOPIC STERILIZATION HAS BEEN FDA APPROVED IN THE UNITED STATES SINCE 2002. COMPLICATIONS ASSOCIATED WITH ESSURE INCLUDE IMPROPER PLACEMENT (MALPOSITIONING), UNINTENDED PREGNANCY, PAIN, INFECTION, AND NICKEL ALLERGY. THE RARITY OF COMPLICATIONS, COMPOUNDED BY UNDER REPORTING, MAKES IT DIFFICULT TO DETERMINE BEST PRACTICES WITH REGARDS TO MANAGEMENT. THIS SYSTEMATIC REVIEW SYNTHESIZES THE NATIONAL AND GLOBAL EXPERIENCE WITH MANAGEMENT OF ESSURE-RELATED COMPLICATIONS, AND SUGGESTS TREATMENT OPTIONS WHERE DATA ALLOW. AUTHORS COMMENT: THE PATIENT EXPERIENCED IMPROVEMENT IN PROGRESSIVE DAILY PAIN AFTER THE REMOVAL OF THE MICRO-INSERT, BUT WITH CONTINUED INTERMITTENT ABDOMINAL PAIN. RELATED CASE: (B)(4).

Manufacturer Narrative (H10):

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SIGNIFICANT FOLLOW UP (FULL TEXT OF (B)(4)) RECEIVED ON (B)(4) 2014. CASE REPORT: A (B)(6) WOMAN WHO HAD COMPLETED HER FAMILY WAS REFERRED BY HER PHYSICIAN FOR CONSIDERATION OF LAPAROSCOPIC STERILIZATION. SHE HAD HAD TWO CHILDREN BY VAGINAL DELIVERIES AND

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00221	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B27984

Single Use: Y
Implant Date (E6): 12/30/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LEFT ESSURE GUIDE WIRE IN WHICH THE TIP HAS DETACHED FROM CENTRAL WIRE - THERE ARE TWO SEPARATE PIECES IN THE FALLOPIAN TUBE. NO INFORMATION WAS GIVEN ON THE PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2013, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. AT HER TWELVE WEEK MARK, THE HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND IT SHOWED THAT LEFT TUBE WAS NOT YET BLOCKED. THE PHYSICIAN DECIDED TO WAIT A LITTLE LONGER AND SHE HAD ANOTHER HSG PERFORMED IN (B)(6) 2014. ACCORDING TO THE RADIOLOGIST, THERE WAS A MALFUNCTION IN ESSURE SINCE THE LEFT ESSURE GUIDE WIRE IN WHICH THE TIP WAS HAD DETACHED FROM CENTRAL WIRE - THERE WERE TWO SEPARATE PIECES IN THE FALLOPIAN TUBE. THE PHYSICIAN QUESTIONED IF IT WOULD SCAR OVER THE WAY IT IS OR IF THEY WOULD NEED TO INSERT A NEW DEVICE. THE REPORTER'S CAUSALITY AS NOT PROVIDED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2014. FIRST REPORT SHOWED SATISFACTORY POSITION OF RIGHT DEVICE AND OCCLUSION. DISTAL PLACEMENT OF THE LEFT DEVICE, WITH SOME CONTRAST AT THE DEVICE EXTENDING TO ITS DISTAL EXTENT AND SHOWING PERSISTANT POOLING

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00222	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): LNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 05/14/2014, ARTICLE ENTITLED "SUBSEROSAL MISPLACEMENT OF ESSURE DEVICE MANIFESTED BY LATE-ONSET ACUTE PELVIC PAIN". (RELATED CASE: (B)(4)). THIS CASE REFERS TO REFERENCE ARTICLE: "PERSISTENT PAIN AFTER HYSTEROSCOPIC STERILIZATION WITH MICROINSERTS." IT REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO RECEIVED FALLOPIAN TUBE OCCLUSION INSERT (FALLOPIAN TUBE OCCLUSION INSERT) FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED BILATERAL POKING PELVIC PAIN. CASE REPORT: THIS CASE REFERS TO A PT WHO EXPERIENCE BILATERAL "POKING" PELVIC PAIN THAT STARTED 2 DAYS AFTER THE ESSURE PLACEMENT AND LASTED FOR 10 WEEKS. WAS RESISTANT TO NONSTEROIDAL ANTI-INFLAMMATORY DRUGS, AND EVENTUALLY REQUIRED A DIAGNOSTIC LAPAROSCOPY, BUT ON THE PT'S REQUEST REMOVAL OF THE IMPLANTS AND BILATERAL SALPINGECTOMY WERE PERFORMED, AND SHE WAS FREE OF PAIN AFTERWARD. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE AND REFERS TO A FEMALE PT WHO HAD FALLOPIAN TUBE OCCLUSION INSERT (ESSURE) INSERTED AND EXPERIENCED BILATERAL POKING PELVIC PAIN THAT STARTED 2 DAYS AFTER THE ESSURE PLACEMENT AND LASTED FOR 10 WEEKS, WAS RESISTANT TO NON-STEROIDAL ANTI-INFLAMMATORY DRUGS, AND EVENTUALLY REQUIRED A DIAGNOSTIC LAPAROSCOPY. THERE WAS NO APPARENT ESSURE MISPLACEMENT DURING LAPAROSCOPY, BUT ON THE PT'S REQUEST REMOVAL OF THE IMPLANTS AND BILATERAL SALPINGECTOMY WERE PERFORMED, AND SHE WAS FREE OF PAIN AFTERWARD. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFO OF ESSURE. IN THIS PARTICULAR CASE, 2 DAYS AFTER ESSURE PLACEMENT, THE PT DEVELOPED POKING PELVIC PAIN AND WAS RESISTANT TO NON-STEROIDAL ANTI-INFLAMMATORY DRUGS. REMOVAL OF THE IMPLANTS AND BILATERAL SALPINGECTOMY WERE PERFORMED

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AND THE PT WAS FREE OF PAIN AFTERWARD. THE POSITIVE TEMPORAL RELATIONSHIP AND THE POSITIVE DECHALLENGE CAUSALITY BETWEEN THE REPORTED PELVIC PAIN AND THE SUSPECT INSERT CANNOT BE EXCLUDED, AND THIS EVENT WAS THEREFORE, REGARDED AS IN INCIDENT DUE TO THE REQUIRED ESSURE REMOVAL BY LAPAROSCOPY AND BILATERAL SALPINGECTOMY. PTC IN PROCESS.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00223	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 14-MAY-2014, ARTICLE ENTITLED "SUBSEROSAL MISPLACEMENT OF ESSURE DEVICE MANIFESTED BY LATE-ONSET ACUTE PELVIC PAIN". IT REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED FOR ELECTIVE STERILIZATION AND EXPERIENCED PAIN STARTING IMMEDIATELY AFTER THE ESSURE PLACEMENT. CASE REPORT: THIS CASE REFERS TO A HYSTEROSCOPIC AND LAPAROSCOPIC REMOVAL OF ESSURE DEVICES IN A PT WHO PRESENTED WITH PERSISTENT ABDONIMAL PAIN LASTING MORE THAN 6 WEEKS. THE PAIN STARTED IMMEDIATELY AFTER THE PROCEDURE AND NO APPARENT PELVIC PATHOLOGIC CONDITION WAS DIAGNOSED. THE PAIN WAS GONE AFTER ESSURE DEVICE REMOVAL. RELATED CASE FROM THE SAME ARTICLE: (B)(4).

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2014. PTC NUMBER PROVIDED: (B)(4). FOLLOW UP (B)(4) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO USE FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00224	BAYER HEALTHCARE LLC	6/12/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 14-MAY-2014, ARTICLE ENTITLED "SUBSEROSAL MISPLACEMENT OF ESSURE DEVICE MANIFESTED BY LATE-ONSET ACUTE PELVIC PAIN". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO REC'D FALLOPIAN TUBE OCCLUSION INSERT (FALLOPIAN TUBE OCCLUSION INSERT) FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED PAIN STARTED IMMEDIATELY AFTER THE ESSURE PLACEMENT. CASE REPORT: THIS CASE REFERS TO A PATIENT WHO EXPERIENCED PERSISTENT ABDOMINAL PAIN 2 WEEKS AFTER ESSURE PLACEMENT LASTING FOR MORE THAN 6 WEEKS. NO APPARENT PELVIC PATHOLOGIC CONDITION WAS DIAGNOSED, AND THE PAIN WAS GONE AFTER ESSURE DEVICE REMOVAL. RELATED CASE FROM THE SAME ARTICLE: (B)(4). COMPANY CAUSALITY COMMENT: A CASE OF PAIN STARTED 2 WEEKS AFTER THE ESSURE PLACEMENT IN A FEMALE PATIENT OF UNSPECIFIED AGE IN ASSOCIATION OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS DERIVED FROM THE MEDICAL LITERATURE. ESSURE WAS REMOVED APPROXIMATELY TWO MONTHS AFTER INSERTION. PAIN STARTED 2 WEEKS AFTER THE ESSURE PLACEMENT WAS REGARDED SERIOUS (INTERVENTION PERFORMED FOR ESSURE REMOVAL) AND LISTED FOR ESSURE IN THE REFERENCE SAFETY INFO. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND THE LACK OF AN ALTERNATIVE EXPLANATION PAIN STARTED 2 WEEKS AFTER THE ESSURE PLACEMENT WAS REGARDED RELATED TO ESSURE USE AND AS AN INCIDENT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036653	BAYER	6/13/2014	6/19/2014

Event Information:

Event Date (B3): 6/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I HAD MY FOURTH CHILD IN 2009, I WENT FOR MY 6 WEEK CHECK AND AT THAT APPOINTMENT MY DOCTOR AND I TALKED ABOUT PERMANENT STERILIZATION (TUBES TIED) EVEN THOUGH MY HUSBAND HAD ALREADY BEEN FIXED. I CHOSE TO HAVE TUBES TIED, MY DOCTOR TOLD ME ABOUT ESSURE. SHE TOLD ME THAT THERE WERE NO SIDE EFFECTS AND COILS WERE INSERTED INTO MY TUBES AND IN THREE MONTHS THE TUBES CLOSED. NO SURGERY, 10 MINS IN AND OUT, GONE SHOPPING. SHE WAS RIGHT BUT WHAT I DID NOT KNOW IS THAT A YEAR LATER MY BODY WOULD BE SO ITCHY EVERYDAY. MY PERIODS WOULD BE SO IRREGULAR TO ALMOST NONE EXISTENCE. HEADACHES ALMOST EVERYDAY WHERE I HAVE ONLY EVER HAD ONE BEFORE IN MY LIFE. EXTREMELY GASSY TO THE POINT EVERY STEP I TAKE I (B)(4) AND IT'S NOT PLEASANT SMELLING. I HAVE EXTREME BLOATING WHERE I TAKE TUMS EVERY NIGHT. WEIGHT GAIN AND TIRED ALL THE TIME, HAVE GAINED OVER 70 LBS, DIZZINESS AND FAINTNESS. I HAVE ANXIETY DISORDER AND ON MEDICATION SO THAT I CAN SLEEP. I TAKE TYLENOL FOR PAIN IN MY STOMACH AND SOMETIMES IN MY LOWER ABDOMINAL AREA. I HAVE MAJOR LOWER BACK PAIN DAILY, ALSO NECK PAIN DAILY. JOINT PAIN AND NUMBNESS IN EXTREMITIES. MY FEET AND HANDS ARE EXTREMELY TENDER. MY SYMPTOMS ALL STARTED AFTER I GOT ESSURE. I WAS TO DOCTORS TO FIND OUT WHAT WAS WRONG, ALL THEY WOULD SAY IS I'M AS HEALTHY AS A HORSE. I WOULD ASK IF YOU MEANT A DYING HORSE. FINALLY GOT A DOCTOR TO SEEK INTO MORE OF MY MEDICAL ISSUES. SHE SENT ME FOR ULTRASOUNDS AND FOUND NOTHING, WRONG, BUT I AM AS OF RIGHT AWAITING FOR A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036654	BAYER	6/13/2014	6/19/2014

Event Information:

Event Date (B3): 5/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/3/2011
Explant Date (E7): 5/28/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE CAUSED ADENOMYOSIS AND GIANT CELL TUMORS. I HAD A D&C, ABLATION AND MOST RECENTLY A HYSTERECTOMY. TRIGGERED AN AUTOIMMUNE REACTION WHICH CAUSED DISCOID ECZEMA, MIGRAINES, DEPRESSION, ANXIETY AND ELEVATED SUGAR LEVELS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036655	BAYER	6/13/2014	6/19/2014

Event Information:

Event Date (B3): 7/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/28/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS PLACED (B)(6) 2010. VOMITING DURING PROCEDURE BECAUSE THE PAIN WAS SO EXTREME. AFTERWARDS, MY PERIODS WERE EXTREMELY HEAVY, VERY PAINFUL. HORRID CRAMPS AND BACK PAIN SO SEVERE, I COULD NOT GET OUT OF BED, PICK UP AND CARE FOR MY CHILDREN LIKE NORMAL MOMS WOULD DO. DURING MY DYE CONFIRMATION TEST IN (B)(6), IT WAS FOUND THAT ONE OF THE COILS PERFORATED A TUBE. SURGERY WAS SCHEDULED TO REMOVE COILS AND OBTAIN THE COILS. DURING SURGERY, ONE COIL WAS CUT FROM TUBE AND TUBE WAS BURNED. THE PERFORATED COIL COULD NOT BE LOCATED. AT THIS TIME, IT WAS BELIEVED COIL HAD EMBEDDED ITSELF IN SCAR TISSUE FROM A PERVIOUS C-SECTION. DR CONSULTED REPS FROM MFR AND THEY CONCLUDED THERE SHOULD BE NO MORE PROBLEMS. MY BACK PAIN, HEAVY AND PAINFUL PERIODS CONTINUED. HAD NUMBNESS IN FEET, WEIGHT GAIN, ACNE DEVELOPED, HEADACHES, PAINFUL INTERCOURSE, STABBING PAINS IN ABDOMEN, EXTREME HAIR LOSS, DEPRESSION, BOWEL ISSUES, ANXIETY. AFTER SUFFERING TO THE POINT, I HAD WITHDRAWN FROM MY FAMILY, DR AGREED HYSTERECTOMY WOULD BE A GOOD IDEA TO REMOVE COIL AND TO GAIN RELIEF FROM THE SYMPTOMS. HYSTERECTOMY WAS DONE IN (B)(6) 2013. ESSURE COIL COULD NOT BE LOCATED AND WAS SAID TO HAVE TRAVELED OUTSIDE UTERUS. HAD A LONGER HOSPITAL STAY DUE TO BLOOD LOSS AND PAIN CONTROL. COMPANY REPS THEN SAID IT WOULD NOT CAUSE ANY ISSUES OR DAMAGE. THE ONLY RELIEF I GAINED FROM THE HYSTERECTOMY WAS HEAVY AND PAINFUL PERIODS. ALL OTHER SYMPTOMS REMAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036656	BAYER	6/13/2014	6/19/2014

Event Information:

Event Date (B3): 12/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/12/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WENT INTO HAVE THE ESSURE PUT IN (B)(6) 2012, THE SECOND HE PUT THOSE IN I WAS IN PAIN, AND MY DOCTOR SAID IT WAS NORMAL. THE NEXT DAY, MY EARS FILLED WITH FLUID, WITH RINGING IN MY EARS (THEY STILL RING EVERYDAY ALL DAY). THE NEXT MONTH, I STARTED TO GET PAIN ON MY RIGHT SIDE, UNDER MY RIB. GALLBLADDER WAS INFLAMED,(B)(6) 2013 IT WAS REMOVED. AFTER THAT I WENT INTO MY OB'S OFFICE AND TOLD HIM THAT I HAVE PAINS IN MY SIDES AND BACK TO WHERE I WAS ABOUT TO PASS OUT, HE SAID IT HAD NOTHING TO DO WITH THE ESSURE. THE NEXT VISIT WAS TO GO FOR THE DYE TO SEE IF THE SCAR TISSUE WAS THERE. IT WAS FINE BUT I ASKED HIM AGAIN ABOUT THE PAIN AND TOLD HIM THAT IT WAS NOT LIKE THAT BEFORE. HE AGAIN SAID NOPE, NOT THE ESSURE. SO I CAME HOME LOOKED INTO IT AND SEE OTHERS WERE HAVING THE SAME PROBLEM AND AGAIN I WENT IN TO THE OB'S OFFICE AND HE HOLD ME I WAS CRAZY AND THAT ALL THOSE PEOPLE WERE FAKE PEOPLE THAT WERE REPORTING THESE ISSUES. A FEW MONTHS AGO MY HAIR STARTED TO FALL OUT AND SUPER DRY HAIR TOO. THEN I FOUND A LUMP IN THE RIGHT SIDE OF MY THYROID, I HAVE 2 NODULES, THAT THEY ARE WATCHING FOR 6 MONTHS, NOW I HAVE PAIN ALL THE TIME AND IT'S GONE TO MY WRISTS, I HAVE TO HAVE PHYSICAL THERAPY 3X A WEEK. MY FEET STARTED TO HURT SO BAD THAT I HAD TO GO TO A FOOT DOCTOR. I NOW HAVE PLANTAR FASCITIS. I ALSO HAVE NIGHT SWEATS BAD AND DON'T SLEEP ANYMORE. I ALSO GET VERY BAD VAGINAL INFECTIONS, AND CYSTS IN MY LEFT BREAST. NUMBING AND TINGLING IN HANDS AND FEET. THE ESSURE SHOULD BE OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00225	BAYER HEALTHCARE LLC	6/13/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/23/2011
Explant Date (E7): 5/9/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY WITH ESSURE, DEVICE INEFFECTIVE AND THE COIL FOUNDS ITS WAY OUT OF TUBE IN A (B)(6)-YEAR OLD FEMALE PT WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS). NO INFO GIVEN ON PT MEDICAL HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON (B)(6) 2011, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED FOR PERMANENT STERILIZATION. REPORTER WAS NOT ABLE TO INFORM ITS LOT NUMBER AND EXPIRATION DATE. PHYSICIAN REPORTED THAT THE COIL FOUND ITS WAY OUT OF TUBE. HE REMOVED THE COIL, BUT AFTER GOING BACK OVER THE RECORDS, HE NOTED THAT PT WAS PREGNANT ON (B)(6) 2013. SHE WAS (B)(6) PREGNANT AT THAT TIME ON (B)(6) 2014, PT HAD A FULL-TERM DELIVERY (WITH COIL STILL IN BODY, BUT OUT OF FALLOPIAN TUBE). ON (B)(6) 2014, PHYSICIAN WENT IN SURGICALLY AND REMOVED THE COIL. SURGERY WENT FINE. IT WAS NOT REPORTED IF ONE COIL WAS LEFT IN PT. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE ADVERSE EVENTS AND ESSURE (B)(4) AND LOCAL (B)(4)NUMBERS WERE RECEIVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6) 2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN (B)(4)". MEDICAL ASSESSMENT: LACK

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OF EFFECTIVENESS MAY OCCUR WITH THE USE OF ANY PRODUCT. ADDITIONALLY, PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. THESE EVENTS, ALONG WITH DISLOCATION OF DEVICE, ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE. AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVAL IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFO AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW UP FROM (B)(6) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE WITH NO RESPONSE TO DATE. CASE CLOSED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00226	BAYER HEALTHCARE LLC	6/13/2014	6/25/2014

Event Information:

Event Date (B3): 5/8/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BILATERAL SALPINGECTOMY. NO INFORMATION GIVEN ON PATIENT MEDICAL HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED FOR PERMANENT BIRTH CONTROL. REPORTER DID NOT INFORM ITS LOT NUMBER AND EXPIRATION DATE. NURSE REPORTED THAT ON (B)(6) 2014, THE PHYSICIAN DID A BILATERAL SALPINGECTOMY ON A PATIENT WHO HAD ESSURE PLACED. NO ADDITIONAL INFORMATION WAS PROVIDED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENT AND ESSURE WAS NOT REPORTED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6) 2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN (B)(4)." MEDICAL ASSESSMENT: THE MEDICAL EVENT REPORTED IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE

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TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. THE PTC GLOBAL NUMBER IS (B)(4). FOLLOW-UP RECEIVED ON (B)(6) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00227	BAYER HEALTHCARE LLC	6/13/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED ISSUES RELATED TO NICKEL ALLERGY, COMPLAINED OF ITCHING, AND TRIED TO REMOVE ESSURE IN THE OFFICE BUT WAS UNSUCCESSFUL. NO INFO GIVEN ON PT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PT RECEIVED ANY CONCOMITANT MEDICATION. THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. IT WAS REPORTED THAT THE PT HAS ESSURE WITHIN THE PAST 2 YEARS. ON AN UNSPECIFIED DATE, THE PT EXPERIENCED ISSUES RELATING TO NICKEL ALLERGY. SHE COMPLAINED OF ITCHING, WENT TO ANOTHER HCP TO HAVE ESSURE REMOVED. HE TRIED TO REMOVE ESSURE IN OFFICE BUT WAS UNSUCCESSFUL. PHYSICIAN TOOK THE PT TO SURGERY AND REMOVED ESSURE AND ONE OF HER TUBES BUT SHE WAS STILL COMPLAINING OF ISSUES. NO FURTHER INFO PROVIDED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EXPERIENCING ISSUES RELATING TO NICKEL ALLERGY, COMPLAINED OF ITCHING, AND TRIED TO REMOVE ESSURE IN THE OFFICE BUT WAS UNSUCCESSFUL AND ESSURE WAS NOT REPORTED.

Manufacturer Narrative (H10):

(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNT

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00228	BAYER HEALTHCARE LLC	6/13/2014	6/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** NL

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH- DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/5/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INNER COIL STAYED BEHIND IN LEFT TUBA AND OUTER COIL DID NOT AND COIL DID NOT RELEASE WELL. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2013, THE INNER COIL STAYED BEHIND WITH THE INSERTION. THEY FOUND THIS OUT WHEN THE PATIENT CAME AGAIN FOR AN INSERTION ON (B)(6) AND THIS DID NOT SUCCEED. ON (B)(6), A HYSTEROSALPINGOGRAM WAS PERFORMED AND THEN IT BECAME CLEAR THAT THE INNER COIL STAYED BEHIND AND HAS GROWN TOGETHER. SO ON (B)(6), NOT EVERYTHING HAS COME OUT. THE OUTER COIL DID, BUT NOT THE INNER COIL. THE INSERTION IN THE RIGHT TUBE WENT WELL ON (B)(6), BUT NOT IN THE LEFT ONE. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE IS NOT REPORTED.

Manufacturer Narrative (H10):

FOLLOW UP RECEIVED ON (B)(4) 2014: PRODUCT TECHNICAL GLOBAL ((B)(4)) AND LOCAL (B)(4) NUMBERS WERE RECEIVED. CASE CONSIDERED TO BE CLOSED. FOLLOW-UP RECEIVED ON (B)(4) 2014: NO NEW CLINICAL INFORMATION. CASE CONSIDERED TO BE CLOSED. CORRECTION(B)(4) 2014

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00229	BAYER HEALTHCARE LLC	6/13/2014	6/25/2014

Event Information:

Event Date (B3): 5/5/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ENH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76528, CS0003V

Single Use: Y
Implant Date (E6): 5/5/2014
Explant Date (E7): 5/5/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED GIGANTIC CRUMBLED MESS AT ENTRANCE OF LEFT FALLOPIAN TUBE, FIRST ESSURE DID NOT DEPLOY, WENT TO RIGHT SIDE TO INSERT TIP BENDED AND KEPT BENDING ON ITSELF, PHYSICIAN CHECKED LEFT SIDE AGAIN AND JUST A PIECE OF ESSURE WAS THERE (COMPLICATION OF DEVICE INSERTION) AND TRIED TO REMOVE THE ESSURE AND IT DID NOT UNATTACH. INFO GIVEN ON PT MEDICAL HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON (B)(6) 2014, THE PT HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBERS B76528 AND CS0003V, FOR STERILIZATION. REPORTER WAS NOT ABLE TO INFORM ITS EXPIRATION DATS. ON (B)(6) 2014, THE PHYSICIAN WENT TO INSERT THE FIRST ESSURE MICRO-INSERT ON THE FIRST TUBE AND AT IT DID NOT DEPLOY. THE PHYSICIAN RETRIED IT AND NOTICE THAT THERE WAS A GIGANTIC CRUMBLED MESS AT ENTRANCE OF LEFT FALLOPIAN TUBE. THEN, SHE WENT TO THE RIGHT SIDE AND TRIED TO INSERT, BUT THE TIP BENDED AND IT KEPT BENDING ON ITSELF. SHE REMOVED IT AND THE SAME THING KEPT OCCURRING. THE PHYSICIAN CHECKED ON THE LEFT SIDE AGAIN AND NOTICED THAT JUST A PIECE OF IT WAS THERE, SO SHE TRIED TO REMOVE IT AND IT DID NOT UNATTACH. ON (B)(6) 2014, 4 DAYS AFTER ESSURE ATTEMPTED INSERTION, THE PT HAD TO GO TO SURGERY. SHE HAD A BILATERAL TUBAL LIGATION AND THE CRUMBLED MESS WAS REMOVED ON THE LEFT SIDE. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE ADVERSE EVENTS AND ESSURE WAS NOT REPORTED. FOLLOW-UP RECEIVED ON 05/16/2014: PRODUCT TECHNICAL COMPLAINT GLOBAL (B)(4) AND LOCAL (B)(4) NUMBERS WERE RECEIVED.

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Manufacturer Narrative (H10):

COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE FIRST ESSURE DID NOT DEPLOY, GIGANTIC CRUMBLED MESS AT ENTRA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036608	BAYER	6/16/2014	6/16/2014

Event Information:

Event Date (B3): 10/6/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, ACNE, JOINT AND MUSCLE PAIN, METALLIC TASTE IN MOUTH, PAINFUL INTERCOURSE, HEAVY PERIODS WITH CLOTS (UTERINE ABLATION WAS DONE), PAINFUL PERIODS,FIBROMYALGIA, PLANTAR FASCIITIS REQUIRING 2 SURGERIES, HIVES, RASHES, VAGINAL ITCHING(NO DISCHARGE), BACK PAIN, FEVERS, WEIGHT DRAIN, FATIGUE, NAUSEA, DIZZINESS ,BLOATING,SWELLING IN EXTREMITIES , CHEST PALPITATIONS, DEPRESSION, ANXIETY, TREMORS, HAIR THINNING, MEMORY LOSS, LOW VITAMIN D, MOUTH SORES, INSOMNIA , HEART BURN, PANIC ATTACKS,MOOD SWINGS, CYSTS, BREAST PAIN AND CYSTS, NECK AND SPINE PAIN. C-REACTIVE PROTEIN ELEVATED 9-80. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036610	BAYER	6/16/2014	6/16/2014

Event Information:

Event Date (B3): 4/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY LAST AND FINAL BABY ON (B)(6). SHE WAS AN OOPS BABY. I ONLY HAD 1 TUBE AND OVARY THE WAY IT WAS. I HAD BEEN ASKING MY DOCTOR FOR A HYSTERECTOMY FOR YEARS DUE TO SEVERAL OVARIAN CYST SURGERIES. HE REFUSED AND I ENDED UP PREGNANT WITH MY LAST CHILD. I HAD A VAGINAL DELIVERY, SO HE SAID HE WANTED TO DO THE ESSURE AT A LATER DATE. FAST FORWARD TO (B)(6). I HAD MY IN OFFICE PROCEDURE DONE. HE ENDED UP PUTTING COILS IN BOTH SIDES BECAUSE HE SAID I STILL HAD A STUMP ON THE RIGHT SIDE, NO OVARY, BUT STILL A STUMP FROM THE TUBE REMOVAL YEARS PRIOR. I IMMEDIATELY STARTED NOTICING THINGS CHANGING WITH MY BODY. I BLED THE ENTIRE TIME. I HAD SEVERE PELVIC PAIN, WHICH I THOUGHT WAS JUST NORMAL FROM THE SCAR TISSUE STARTING TO FORM. MY ABDOMEN BECAME SO SENSITIVE TO TOUCH THAT I COULDN'T HOLD MY BABY FOR FEAR OF HER KICKING ME. I HAD FLANK PAIN ON BOTH SIDES SO BAD, THE ONLY WAY TO DESCRIBE THE PAIN WAS IF YOU ATE OR DRANK SOMETHING THEN WENT RUNNING OR SWIMMING TOO SOON. IT FELT AS THOUGH SOMEONE WAS SQUEEZING MY ACTUAL STOMACH ORGAN. I WAS HAVING DIZZY SPELLS. I COULDN'T TAKE A DEEP BREATHE WITHOUT IT HURTING. I WENT TO MY POST-OP APPOINTMENT LAST FRIDAY. I TOLD MY DOCTOR I WAS IN PAIN. HE DID AN ULTRASOUND TO MAKE SURE THE COILS WERE IN THE CORRECT PLACES STILL. ACCORDING TO HIM, THEY WERE. SO I SUFFERED ALL LAST WEEKEND. ON MONDAY, I COULD NOT TAKE IT ANYMORE. I GOT ONLINE AND STARTED DOING MY RESEARCH AND FOUND THE (B)(6) PAGE WITH SO MANY WOMEN GOING THROUGH THE SAME THINGS I WAS. ONLY A LOT OF THEM HAD BEEN GOING THROUGH IT FOR YEARS. I CALLED MY DOCTOR THAT DAY AND MADE MY APPOINTMENT. I DEMANDED THEY BE REMOVED. I PRINTED OUT ALL OF THE PAGES OF TESTIMONIALS AND MADE HIM LOOK AT THEM. HE SWEARS THEY REMOVED THE CONTRAINDICATION OF NICKEL IN THEM. I AM HIGHLY ALLERGIC TO NICKEL. I CANNOT WEAR A WATCH, CHEAP EARRINGS OR EVEN THE BACK

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OF MY JEANS BUTTON WILL RASH MY STOMACH OUT. SO ON THURSDAY, I UNDERWENT THE DAVINCHI ROBOT SURGERY. THE PLAN WAS TO REMOVE THE COILS AND THE TUBE AND STUMP, BUT I HAD TO SIGN PAPERS THAT I UNDERSTOOD THAT IT MAY BE NECESSARY TO REMOVE MY UTERUS AS WELL. I SAID WHATEVER YOU HAVE TO DO TO GET THESE (B)(6) THINGS OUT OF ME, JUST DO IT. ACCORDING TO MY DOCTOR, ONE COIL HAD COME LOOSE, PUNCTURED A "FATTY PAD" AND WAS NOW LODGED IN MY UTERUS. THEY OTHER COIL WAS COMPLETELY BENT. I WAS FULL OF INFECTION. THANKFULLY, I WAS ABLE TO KEEP MY UTERUS, BUT I HAVE NO TUBES AT ALL NOW AND ONLY 1 OVARY. MY DOCTOR SAID I HAD EVERY REASON TO BE HURTING. HE HAS PICTURES AND SHOWED MY MOTHER, WHO WAS THERE AT THE HOSPITAL WITH ME. WHEN I GO FOR MY POST-OP APPOINTMENT ON WEDNESDAY, I WANT COPIES OF MY PICS. I HAVE TO BE ON ANTIBIOTICS FOR 2 WEEKS NOW TO GET THE INFECTION UNDER CONTROL INSIDE OF MY ABDOMEN. WE HAVE TO GET THESE (B)(6) THINGS OFF THE MARKET. LET ME KNOW HOW I CAN HELP IN ANYWAY POSSIBLE!! (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036614	BAYER	6/16/2014	6/16/2014

Event Information:

Event Date (B3): 3/19/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

A FEW MONTHS AFTER GETTING ESSURE, I STARTING HAVING BAD HEADACHES AND MUSCLES ACHES. NOT LONG AFTER I ALSO STARTED BLEEDING REALLY BAD. I HAVE ALWAYS BEEN ON TIME WITH MY PERIODS UNTIL I GOT ESSURE. I NOW WILL BLEED FOR TWO TO THREE MONTHS AT A TIME AND IT IS SO HEAVY THAT I WILL HAVE TO WEAR PADS AND TAMPONS. I WAS A LITTLE OVER (B)(6) WHEN I GOT THE DEVICES AND NOW I AM WELL OVER (B)(6). I EAT HEALTHY AND EXERCISE AND STILL KEEP GAINING WEIGHT. I STAY EXTREMELY FATIGUE WHICH I NEVER USED TO AND I ALSO HAVE SO MUCH PAIN IN MY LOWER ABDOMINAL AREA THAT IT INTERFERES WITH MY DAILY ROUTINES. WHEN I BLEED, IT CONSTANTLY SMELLS LIKE A METALLIC SMELL AND I GET A METALLIC TASTE IN MY MOUTH. I WAS RECENTLY DIAGNOSED WITH PCOS AFTER CONSTANTLY HAVING TO GO TO THE DR OVER THESE SYMPTOMS. TRUTHFULLY, I DO NOT BELIEVE THAT I DO HAVE IT AND EVERYTHING THAT HAS BEEN HAPPENING IS DUE TO ESSURE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036609	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 5/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVING SEVERE PELVIC PAINS. WAS TOLD ONE OF MY COILS IS MISSING. STILL IN PAIN. NO EXPLANATION OF THE PAIN OR ANYTHING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036611	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 11/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED GETTING A PINCHING OR POKING FEELING WHERE MY RIGHT OVARY IS. IT HAPPENS ESPECIALLY WHEN I AM SITTING CROSSED LEGGED AND SLEEPING ON MY LEFT. I HAD MODERATE SWELLING IN MY RIGHT KIDNEY THAT WAS UNEXPLAINED AND WENT AWAY ON IT'S OWN. I HAVE EXTREMELY HEAVY PERIODS THAT I NEVER USED TO HAVE. ALSO HAVE OVARIAN CYSTS THAT I NEVER HAD BEFORE THE ESSURE. #MEDWATCHER #MW156312.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036612	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 10/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS TOLD PROCEDURE WOULD TAKE 15 MINUTES BUT TOOK 4 HOURS. I WAS IN SO MUCH PAIN AND KEPT CALLING DR WHO IGNORED ME. CALLED ANOTHER DR AND HE HAD ME COME IN FOR SURGERY IMMEDIATELY TO REMOVE COILS. COULDN'T FIND THEM SINCE THEY MIGRATED AFTER 2 MONTHS. HAD TO HAVE TUBES REMOVED. FOUND FERTILIZED EGG AND THREE COILS. DR WHO DID ESSURE LIED IN HIS REPORT AS SAID HE INSERTED TWO. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036613	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 5/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HI I AM (B)(6) YEARS OLD AND HAVE A FACTOR 5 CLOTTING DISORDER SO ESSURE SEEMED TO BE A GOOD OPINION. HAD THE PROCEDURE DONE ON (B)(6) REALLY SIMPLE PROCEDURE NO COMPLICATION. WAS IN A LITTLE PAIN BUT RETURNED TO WORK THE NEXT DAY. HOWEVER, ON TUESDAY (B)(6), I HAD A FEVER OF 103.4 AND WAS NOT FEELING GOOD. CALLED MY OBGYN WHO SAID TO GO TO THE ER. WHEN I ARRIVED, BLOOD PRESSURE WAS 162/124 TEMP 104.0 AND O2 LEVEL 89. DID EKG IT WAS FINE CHEST X-RAY WAS CLEAR THEN HAD CAT SCAN THERE WAS FLUID IN MY FALLOPIAN TUBS AND UTERUS. WAS TRANSPORTED TO THE HOSPITAL WHERE OBGYN WAS AT. THEY GAVE ME FOUR ROUNDS OF I.V ANTIBIOTIC BY THIS TIME I WAS LETHARGIC. INFECT WAS BEGINNING TO SHOW UP IN MY BLOOD STREAM. THE DOCTOR CAME IN AND SAID I HAD TO HAVE A EMERGENCY HYSTERECTOMY AND TUBES REMOVED OR I WILL DIE. SURGERY WAS THREE HOURS AND LEFT ME ONLY ONE OVARY. WAS STILL IN ICU FOR THREE DAYS FIGHTING THE INFECTION. CAME HOME SUNDAY (B)(6) AND TRYING TO RECOVER FROM EVERYTHING. STILL CONFUSED WHAT HAPPEN AND WHY. I HAVE TOLD ALL MY FRIENDS NOT TO SO THIS PROCEDURE. SO SAD I DIDN'T WANT TO HAVE ANY MORE KIDS BUT DON'T KNOW HOW TO FEEL. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036615	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

WELL I DON'T REALLY KNOW WHERE TO BEGIN. MY HUSBAND AND I HAD OUR FIRST CHILD 21YRS AGO. 18 YRS LATER WE WERE SURPRISED TO HEAR THAT OUR OLDEST SON WAS GOING TO HAVE A SIBLING. I HAD MY SECOND CHILD WHEN I WAS (B)(6) YRS OLD. HE WAS BORN IN SEPT OF 2010. ESSURE WAS INTRODUCED TO ME BY MY OB-GYN IN (B)(6) OF THAT SAME YEAR. I DID MY RESEARCH AT THAT TIME AND THERE WAS NOT MUCH OUT THERE AT THE TIME ABOUT COMPLICATIONS. I AGREED TO HAVE IT DONE. IT WAS DONE IN (B)(6) 2010. AFTER THE PROCEDURE WAS DONE, MY DOC TOLD ME THAT ONE WAS SUCCESSFULLY IMPLANTED AND THE OTHER WAS NOT. (I COULD NOT REMEMBER ABOUT WHETHER IT WAS LEFT OR RIGHT). I ASKED WHAT WE COULD DO ABOUT IT AT THAT TIME AND SHE STATED NOTHING. SHE SCHEDULED FOR ME TO HAVE LAPAROSCOPIC TUBAL LIGATION A FEW MONTHS LATER AND IT WAS DONE. EVER SINCE (B)(6) 2010, I HAD BEEN EXPERIENCING BAD ABDOMINAL CRAMPS, ESPECIALLY AROUND MY CYCLE TIMES. BEFORE ESSURE, I RARELY EVER HAS A MENSTRUAL CRAMP. MY CYCLES POST ESSURE WERE ALSO CLOTTY. I HAVE A HIGH PAIN TOLERANCE, SO I JUST MANAGED TO LIVE LIFE WITH THE PAIN. UNFORTUNATELY, MY PAIN KEPT GETTING WORSE INSTEAD OF BETTER. I STARTED REQUIRING TO HAVE TO TAKE PAIN MEDS DURING MY CYCLES. THIS PROGRESSED TO PAIN MEDICATION NEEDING TO BE TAKEN MORE OFTEN (NOT JUST AROUND CYCLE TIMES) BECAUSE MY PELVIC/ABDOMINAL PAIN KEPT INCREASING. MY PAIN PROGRESSED TO WHERE I REQUIRED BED REST A LOT IN THE EVENINGS AFTER WORKING BECAUSE MY PAIN KEPT GETTING WORSE. (THANK GOD FOR A SISTER WHO WAS ABLE TO WATCH MY LITTLE ONE.) I PROGRESSED TO HAVING TO TAKE OXYCODONE AROUND MY CYCLES TIMES TO PAIN MEDICATION NEEDED DAILY DUE TO MY PAIN. FAST FORWARD TO PRESENT DAY, MY LAST THREE CYCLES HAD BEEN EXTREMELY PAINFUL WITH ONGOING PELVIC PAIN THAT HAS NOT CEASED. MY LEFT SIDE HAS ALWAYS BEEN MORE PAINFUL THAN MY RIGHT, BUT MY RIGHT SIDE IS DEFINITELY PAINFUL TOO. I'VE

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ALSO HAD LEFT LEG PAIN FROM MY THIGH TO MY ANKLE. RECENTLY, AFTER MY LEFT THIGH STARTED TO SWELL, I FINALLY GOOGLED TO SEE IF THERE HAD BEEN ANY COMPLAINTS ABOUT ESSURE, AND I FOUND THIS SIGHT. I IMMEDIATELY CALLED THE OB-GYN AND SHE WAS ABLE TO SEE ME THE SAME DAY. I TOLD HER ABOUT ALL OF MY PAIN, INCLUDING MY LEG PAIN AND SWELLING AND SHE STATED THAT SHE DIDN'T THINK THAT THE LEG PAIN WAS RELATED. I TOLD HER THAT I THOUGHT IT WAS RELATED BECAUSE EVERY TIME THAT MY PELVIC PAIN THROBS, IT RADIATES TO MY THIGH. THEY DID AN ULTRA-SOUND AND SAW THAT THE RIGHT COIL WAS IN PLACE AND THE LEFT COIL COULD NOT BE SEEN. I HAVE BEEN SCHEDULED FOR SOME PRE-OP WORKUP ON THE (B)(6) AND WILL HAVE SURGERY ON (B)(6). JUST WANTED TO SHARE MY EXPERIENCE. (B)(4). UPDATE ON (B)(6) 2014: I HAD MY SECOND CHILD AT (B)(6) YEARS OLD, NOT (B)(6). OTHER SIDE EFFECTS TO LIST: INTERMITTENT BLURRY VISION, BLOATEDNESS, INTERMITTENT NUMBNESS/TINGLENESS IN ARMS, FINGERS OFTEN SWELL OVERNIGHT UPDATE ON (B)(6) 2014: I ALSO WANT TO ADD MEMORY LOSS AS A SIDE EFFECT. I'VE HAD PROBLEMS WITH BEING IN A FAMILIAR PLACE (FOR EXAMPLE....THE ELEVATOR OF MY JOB). I CAN'T GET OFF THE ELEVATOR AND FOR A BRIEF MOMENT, NOTHING LOOKS FAMILIAR TO ME. THIS HAS ALSO HAPPENED WHILE I AM DRIVING AND IN PARKING LOTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036616	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 5/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STIFFNESS/PAIN IN BOTH HANDS, SEVERAL FINGERS, WRIST, AND BOTH KNEES. AT TIMES, IT WAS VERY IMPOSSIBLE TO BEND WITH OUT BEING IN SEVER PAIN! STARTED WAKING UP WITH MIGRAINES THAT WOULD COME AND GO AS WELL DURING THE DAY. HAVE STARTED EXPERIENCING BAD MEMORY, A LOT OF FATIGUE, LOSS OF APPETITE, WEIGHT GAIN WITH NO CHANGE OF DIET, SEVERE PELVIC PAIN, CONTINUOUS BLOATING, PAIN DURING AS WELL AS AFTER INTERCOURSE, AND AS WELL AS DEPRESSION. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036617	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 6/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE LOW PELVIC PAIN ON LEFT SIDE, MIGRAINES, HAD MULTIPLE SURGERIES FOR PELVIC PAIN DIDN'T HELP HAD TO HAVE TUBES REMOVED AND THEY TOOK THE DEVISE OUT WITH TUBES I FEEL BETTER SINCE REMOVED. LOST MULTIPLE JOBS BECAUSE OF MISSING TIME AND NOT BEING ABLE TO STAND FOR LONG PERIOD OF TIME THE ESSURE HAS TAKING YEARS AWAY FROM ME AND MY FAMILY I COULDN'T ENJOY LIFE FOR YEARS BECAUSE OF PAIN. #MEDWATCHER #MW156327.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036618	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ASKED MY DR. TO CUT AND TIE MY TUBES, WHICH I THOUGHT THAT'S WHAT THEY STILL DO. SHE SAID THAT THEY NO LONGER TIE TUBES UNLESS YOU ARE ALREADY HAVING A CESAREAN, IN WHICH CASE YOU ARE ALREADY CUT OPEN. SHE THEN BEGAN TO DISCUSS WITH ME MY OPTIONS AND HANDED ME A PAMPHLET THAT EXPLAINED ESSURE. THE WAY SHE EXPLAINED, IT WAS LIKE THIS WAS MY LAST RESORT AND MADE IT SOUND LIKE A PIECE OF CAKE, THIS IS THE NEW THING. SO I HAD MY TRUST IN HER AND SAID YES. I KNEW I WAS GETTING INTO A PERMANENT PROCEDURE THAT COULD NOT BE REVERSED AND HAD SOME SIDE EFFECTS THAT SHE SAID AFFECTS ABOUT 1% OF PEOPLE. MAKING IT SOUND MINIMAL. I WAS OK WITH POSSIBLY DEALING WITH OCCASIONAL DISCOMFORT IF ANY. HOWEVER, THAT IS NOT THE CASE. I AM IN CONSTANT PAIN WHICH CONSISTS OF ACHING, CRAMPING(MORE SEVERE DURING MENSTRUAL CYCLE), SHARP PAIN/STABBING, CONSTANT HEARTBURN, FATIGUE, MOOD SWINGS, GAINED WEIGHT, BLOATING (MORE SEVERE AT NIGHT), HEART PALPITATIONS/ACHE/TIGHTENING, BONES ACHE, AND VITAMIN D DEFICIENCY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036619	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 10/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LIGHT HEADED, DIZZINESS, NAUSEA, CHANGE IN BOWEL HABITS, MILD CRAMPING, ABNORMAL BLEEDING, ABSENCE OF MENSTRUATION, PELVIC PAIN, URINARY TRACT INFECTION, AND VITAMIN D DEFICIENCY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036620	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 5/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I FOUND OUT THAT I HAVE INSULIN RESISTANCE AND AM BORDER LINE TYPE 2 DIABETES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036621	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

TACHY/BRADY HEART SYNDROME, DIABETES TYPE II, CONSTANT BODY ACHES AND FATIGUE, FEET, LEG, ANKLE SWELLING, FLUID BUILD UP IN FEET AND ANKLES, CHRONIC ABDOMINAL PAIN, CHRONIC LOWER BACK PAIN INCONTINENCE, YEAST INFECTIONS, TOE AND FINGER NAIL FUNGUS, SLEEP APNEA, ABNORMALLY HEAVY MENSTRUAL CYCLES, BLOOD CLOTS, BLOOD PRESSURE ISSUES, MOOD SWINGS, PTSD SYMPTOMS, MEMORY LOSS, GENERAL MENTAL CONFUSION, VAGINAL DISCHARGE, HOT FLASHES, NIGHT SWEATS, BLEEDING/SPOTTING AFTER SEX, URGENT/FREQUENT URINATION, BREAST PAIN/TENDERNESS, HEADACHES, MIGRAINES, DIZZINESS, TINGLING SENSATIONS, ANXIETY/PANIC ATTACKS, STROKE SYMPTOMS, DEPRESSION, RINGING IN EARS, TREMORS/SHAKINESS, BLOOD CLOTS, UNEXPLAINED/EASILY BRUISING, SILVER METAL ALLERGIES, HIVES/RASHES, CYSTS, BOILS, ACNE, SKIN IRRITATION/ITCHING, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, BOWEL ISSUES, HEARTBURN, HAIR LOSS, DENTAL ISSUES, INSOMNIA, WEIGHT ISSUES, VISION PROBLEMS, DRY SKIN AND EYES. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036622	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 12/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2011. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2011. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. WEIGHT GAIN, FATIGUE, ADRENAL PROBLEMS, VERY PAINFUL INTERCOURSE, CRAMPING, HEAVY PERIODS, THYROID PROBLEMS, GLUTEN SENSITIVITY, FOOD ALLERGIES, PAINFUL CRAMPING MAKING ME THINK I HAD APPENDICITIS, ANXIETY, DEPRESSION. I HAVE HAD A NUMBER OF BLOOD TESTS SHOWING I NOW HAVE A SLOW WORKING THYROID, AND ADRENALS THAT ARE NOT WORKING PROPERLY. I HAVE BEEN SEEN BY NINE DOCTORS. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ENSURE, UPCOMING HYSTERECTOMY, (B)(6) 2014. THE DEVICE IS STILL INSIDE OF ME/ OR HAS BEEN REMOVED (B)(6) 2014. THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER. THE DEVICE IS IN MY POSSESSION. I HAVE FILED A PREVIOUS ADVERSE EVENT REPORT AND HERE IS MY REFERENCE NUMBER #(B)(4) #MEDWATCHER #MW156334.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036623	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 11/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN THEY PUT THE ESSURE IN 2010, THE DOCTOR DID NOT WARN ME ABOUT THE SIDE EFFECTS WHICH BEGAN LIKE 6 MONTH AFTER. I DID NOT KNOW WHAT WAS WRONG WITH ME, WHEN I ASKED TO THE CLINIC THEY SAID IT WAS NORMAL. I FEEL A SHARP PAIN ON MY LOWER LEFT ABDOMEN, LIKE ELECTRIC SHOCKS RUNNING TO MY LOWER BACK, HAS BECOME SO UNBEARABLE THAT I HAVE NOT BEEN ABLE TO GET OUT OF BED, MY LEGS HURT, MY HANDS ARE NUMB AN MY LEFT LEG. I HAVE TERRIBLE HEADACHES, WHICH LED ME TO THE EMERGENCY ROOM, THEY HAVE DONE 2 MRI AND EVERYTHING WENT WELL. THE RIGHT SIDE HURTS SLIGHTLY, I'M WITH MENSTRUAL PAINS ALL THE TIME, PELVIC PAINS, MY PERIOD COMES TWICE A MONTH, I HAVE PAINFUL INTERCOURSE, GAIN WEIGHT, THE ESSURE REMOVE THE JOY OF MY LIFE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036624	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 1/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/17/2014
Explant Date (E7): 6/23/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DEVELOPED A RASH THAT ITCHES REALLY BAD I HAVE BEEN BLEEDING NON STOP AND PASSING HEAVY BLOOD CLOTS MY FEET HAVE BEEN SWELLING I HAVE BEEN HAVING SHARP PAIN ON MY RIGHT SIDE THAT FEELS LIKE SOMETHING IS STABBING ME ON THE INSIDE NEAR MY UTERUS AND OVARIES I HAVE PAIN DURING SEX I CAN'T STAND IT. #MEDWATCHER #MW156337.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036625	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 5/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DO NOT HAVE ANY ONGOING ILLNESSES, I DO NOT TAKE ANY MEDICATIONS. I GOT THE ESSURE IN EARLY TO MID (B)(6) 2014. I HAVE BEEN HAVING A MILD TO SEVERE PAIN IN MY LOWER ABDOMEN FOR THE PAST 3 WEEKS, I HAVE BEEN HAVING HORRIBLE HEADACHES SINCE I HAVE GOTTEN THE ESSURE AS WELL AS SHARP PAINS SOMETIMES IN MY LEGS AND OTHER TIMES IN MY SIDE. IVE GAINED AT LEAST 10 POUNDS IN THE PAST MONTH. I DO HAVE A NICKEL ALLERGY AND WAS NOT TOLD THAT ESSURE HAS NICKEL IN IT OR ELSE I WOULD HAVE WENT A DIFFERENT ROUTE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036626	BAYER	6/16/2014	6/17/2014

Event Information:

Event Date (B3): 2/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING SEVERE PELVIC PAIN, BACK PAIN, NAUSEA, SWOLLEN HANDS , I FEEL LIKE IF I STRETCH I CAN FEEL THEM MOVE. RASH ON MY ABDOMEN. PAINFUL INTERCOURSE. BLOOD DISCHARGED. #MEDWATCHER #MW156330.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036692		6/16/2014	6/23/2014

Event Information:

Event Date (B3): 12/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HORRIBLE PAIN IN MY STOMACH. I DON'T FEEL LIKE GETTING OUT OF BED, VERY HEAVY PERIODS AND I GET BAD HEADACHES. IT IS PAINFUL TO HAVE SEX, MY STOMACH SWELLS EVERY NIGHT. I LOOK LIKE I'M 6 MONTHS PREGNANT. I GAINED WEIGHT AND I CAN'T GET RID OF THE WEIGHT. I'VE GAINED ABOUT 60 POUNDS SINCE ESSURE. THE WORST MISTAKE MADE. MY FAMILY HAS LOST VALUABLE TIME WITH ME BECAUSE I'M IN SO MUCH PAIN. I CAN'T GET UP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036698	CONCEPTUS, INC.	6/16/2014	6/23/2014

Event Information:

Event Date (B3): 6/13/2014 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/26/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I CHOOSE ESSURE AS A CONTRACEPTIVE METHOD. I GOT 2 METAL COILS INSERTED IN MY TUBES IN 2012. THREE MONTHS AFTER THE PROCEDURE WAS DONE, I WENT FOR A CONTRAST TEST. THE TEST SHOWED THAT MY RIGHT TUBE WAS STILL OPENED EVEN THOUGH THE COIL WAS INSERTED CORRECTLY. I WAS TOLD TO COME BACK IN 6 MONTHS JUST TO BE SURE THAT IT WAS COMPLETELY SEALED. I WENT BACK A YEAR AND HALF LATER FOR ANOTHER CONTRAST TEST, ONLY TO FIND OUT THAT RIGHT SIDE IS STILL NOT CLOSED. WHAT ARE MY OPTIONS AT THIS POINT? THIS IS A PAINFUL AND COSTLY PROCEDURE! I DON'T WANT TO SPEND MORE MONEY ON THIS. THANKS!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036700	CONCEPTUS	6/16/2014	6/23/2014

Event Information:

Event Date (B3): 3/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A25165

Single Use:
Implant Date (E6): 4/17/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY ESSURE IMPLANTS HAS MADE MY UTERUS SWOLLEN AND INFLAMED. HYSTERECTOMY WAS RECOMMENDED AS SOON AS POSSIBLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036702	CONCEPTUS, INC.	6/16/2014	6/23/2014

Event Information:

Event Date (B3): 12/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/10/2010
Explant Date (E7): 5/13/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE COILS INSERTED (B)(6) 2010. I IMMEDIATELY VOMITED AND EXPERIENCED LOW BLOOD PRESSURE. FOR APPROXIMATELY 4 DAYS AFTER THE INSERTION, I WAS IN SUCH TERRIBLE PAIN THAT I COULD NOT WALK UPRIGHT OR SLEEP. WITHIN A MONTH OF THE PLACEMENT, I DEVELOPED PAINFUL BLOATING, WEIGHT GAIN AND CONTINUAL ABDOMINAL CRAMPING. MY LIFELONG ECZEMA TROUBLES SKYROCKETED AND I DEVELOPED IBS. SIX MONTHS AFTER HAVING THEM PLACED, I HAD TO HAVE A FULL HYSTERECTOMY TO REMOVE THEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036705	CONCEPTUS, INC.	6/16/2014	6/23/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'M FROM (B)(6), AND IN 2009 I HAD THE ESSURE COIL IMPLANTS WHICH WAS NEW AT THE TIME AND I WISH I HADN'T. WHEN I HAD THE PROCEDURE, I HAD A PELVIC PAIN BUT I THOUGHT I WAS TO BE EXPECTED, THEN AFTER A COUPLE OF WEEKS, I HEMORRHAGED AND HAD BLOOD CLOTS. THE PELVIC PAIN GOT WORSE OVER THE MONTHS BUT AGAIN I THOUGHT IT WAS BODY FORMING TISSUE AROUND THE IMPLANTS AS TO BLOCK THE FALLOPIAN TUBES. MY PERIODS GOT HEAVIER AND THE PAIN GOT WORSE. I THEN THOUGHT I WAS PRE-MENOPAUSAL AS I HAD HOT FLUSHES, NAUSEA, MY HAIR STARTED TO THIN AND I WAS SUFFERING FROM SEVERE BLOATING, I WENT TO MY DOCTORS AND HAD A BLOOD TEST TO CHECK MY HORMONE LEVELS AND THAT CAME BACK NORMAL. I HAD A SCAN TO CHECK TO SEE IF MY OVARIES HAD SHRUNK AND THEY WERE NORMAL. I WAS (B)(6) AND TOLD I WAS TOO YOUNG TO BE GOING THROUGH THE MENOPAUSE. I WAS SUFFERING FROM CONSTANT NAUSEA AND I HAD AN ENDOSCOPY AND THAT CAME BACK NORMAL. I HAVE AT TIMES FELT LIKE I WAS PREGNANT, BUT THAT IS A IMPOSSIBILITY AS MY HUSBAND HAS HAD A VASECTOMY. OVER THE YEARS MY SYMPTOMS HAVE GOT WORSE, TO HAVING MIGRAINES AND MY PERIODS HAVE GONE BIZARRE, I AM HAVING TWO PERIODS CONSECUTIVELY, ONE AFTER ANOTHER IN A COURSE OF 8 DAYS. THE NAUSEA IS CONSTANT EVERYDAY AND THIS IS AFFECTING ALL ASPECTS OF MY LIFE. I HAVE RECENTLY HAD AN INTERNAL VAGINAL SCAN WHICH SHOWED SCAR TISSUE AND IS VERY PAINFUL, MORE THAN USUAL FREE FLUID OR ASCITES. MY BUTTOCKS AND MY LOWER LIMBS ARE CONSTANTLY COLD. I GET PAIN AND NUMBNESS IN MY LEGS. I SOMETIMES CANNOT STAND UP DUE TO PELVIC PAIN. I AM TELLING YOU TO HIGHLIGHT IT IS NOT JUST THE WOMEN IN AMERICA WHO ARE EXPERIENCING THESE CHRONIC PROBLEMS WITH THE ESSURE IMPLANTS, BUT WE TOO IN THE (B)(6) WHO HAVE HAD THE IMPLANTS FOR A FEW YEARS ARE EXPERIENCING LONG TERM PROBLEMS TOO.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036707	CONCEPTUS, INC.	6/16/2014	6/23/2014

Event Information:

Event Date (B3): 6/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/13/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IRREGULAR PERIODS SOME LIGHT PERIODS OTHER HEAVY BLEEDING ACCOMPANIED BY BLOOD CLOTS. MY MENSTRUAL CYCLE HAVE BEEN LONGER OR SHORTER, SOME SKIPPED PERIODS. HOT FLASHES WITH TROUBLE SLEEPING INSOMNIA ALONG WITH HEADACHES AND FATIGUE. EMOTIONAL CHANGES: MOOD SWINGS, AGGRESSIVENESS, DEPRESSED, OR ANXIETY. FEELING THAT MY HEART IS BEATING TOO FAST OR UNEVENLY PALPITATIONS. PROBLEMS WITH REMEMBERING OR THINKING CLEARLY, DIFFICULTY CONCENTRATING. VAGINAL DRYNESS AND DISCOMFORT DURING SEX. URINE LEAKAGE WHEN COUGHING OR SNEEZING AND URINARY URGENCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036708	BAYER	6/16/2014	6/23/2014

Event Information:

Event Date (B3): 2/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS IMPLANTED AND IT HAS CAUSED SYSTEMATIC INFLAMMATION, CHRONIC PELVIC PAIN, HEAVY BLEEDING DURING MENSES, PAIN BEFORE, DURING AND AFTER MENSES. PAIN DURING AND AFTER SEX. DEPRESSION ENSURING FROM NOT BEING ABLE TO GET UP AND DO THINGS LIKE I USED TO BEFORE ESSURE. HEAVY METAL POISONING. NICKEL IS LEAKING FROM THE DEVICE INTO MY BODY MORE AND MORE. BREAKING OUT IN HIVES AND ESSURE IS THE ONLY KNOWN CAUSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036709	BAYER	6/16/2014	6/23/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE BIRTH CONTROL DEVICE IMPLANTED. HAVE HAD SEVERE LOWER ABDOMINAL CRAMPING THAT HAS SENT ME TO THE E.R. HAIR LOSS, DEPRESSION, ANXIETY, WEIGHT GAIN, UNABLE TO LOSE WEIGHT, DECREASED SEXUAL ACTIVITY, INSOMNIA, NIGHT SWEATS, UNCONTROLLED MOOD SWINGS. I HAD THIS IMPLANTED IN 2011 AFTER THE BIRTH OF MY DAUGHTER. I WAS TOLD IT WAS A SAFE ALTERNATIVE FROM TUBAL LIGATION. I WAS TOLD IT WAS NOT A SURGERY BUT A PROCEDURE. I WAS NEVER TOLD OF ANY SIDE EFFECTS. I WAS TOLD THAT IT WAS NICKEL AND THAT WAS IT I WAS NOT TOLD OF THE PET FIBERS THAT IT CONTAINED. I AM IN PAIN ALMOST EVERY DAY SINCE THESE HAVE BEEN IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036711	CONCEPTUS, INC.	6/16/2014	6/23/2014

Event Information:

Event Date (B3): 3/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE DEVICES A LITTLE OVER 4 YEARS AGO. MY LIFE HAS CHANGED. I CRAMP EVERY SINGLE DAY I FEEL THROBBING IN MY FALLOPIAN TUBES. I NOW HAVE BAD HEADACHES; MY STOMACH BLOWS UP LIKE A BALLOON; PEOPLE ASK ME IF I'M PREGNANT A LOT. MY PERIODS ARE VERY HEAVY; NOW MY MOODS HAVE CHANGED A LITTLE; I'M DEPRESSED A LOT MORE CAUSE I CAN'T DO THINGS WITH MY FAMILY LIKE I WANT TO. I KEEP GETTING TOLD LIES AFTER LIES FROM DOCTORS ETC THESE THINGS ARE THE DEVIL! THESE THINGS NEED TO BE TAKEN OFF THE MARKET. I SUFFER EVERY DAY AND IT'S NOT FUN AT ALL. MY SEX LIFE HAS CHANGED FROM THE PAIN FROM THESE THINGS ALSO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00276	BAYER HEALTHCARE LLC	6/16/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/10/2011
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT: RECEIVED FROM A CONSUMER IS PHYSICIAN (CASE # MW5036017) IN THE UNITED STATES ON 16-JUN-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE INSERTED ON (B)(6) 2011 AND EXPERIENCED THE FOLLOWING ADVERSE EVENTS. AN X-RAY WAS PERFORMED AND SHOWED THAT IMPLANTS MIGRATED AND PUNCTURED HER UTERUS. IN 2014, ESSURE WAS REMOVED WHICH HER UTERUS (FULL HYSTERECTOMY PERFORMED). NO FURTHER INFO WAS PROVIDED. OTHER SERIOUS MEDICAL EVENT WAS ASSESSED BY CONSUMER; HOWEVER, NO FURTHER INFO WAS PROVIDED.

Manufacturer Narrative (H10):

FOLLOW-UP INFO RECEIVED ON 18-JUN-2014: THE PTC GLOBAL NUMBER WAS ADDED AS (B)(4). PTC INVESTIGATION RESULT WAS RECEIVED ON 03-JUL-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUC

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036660	BAYER	6/18/2014	6/18/2014

Event Information:

Event Date (B3): 6/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS TOLD THAT IT WAS SHOWN ON THE XRAY THAT MY LEFT SIDE COIL HAD RIPPED THROUGH MY FALLOPIAN TUBE AND IS LODGED HALF IN AND HALF OUT OF MY UTERUS. SINCE HAVING THE ESSURE INSERTED I GET FREQUENT HEADACHES (WHICH I USED TO RARELY GET) AND AT TIMES I HAVE MEASURING FROM MILD, TO INTENSE CRAMPS/PAIN ON THE LEFT SIDE AROUND MY MENSTRUAL CYCLE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036661	BAYER	6/18/2014	6/18/2014

Event Information:

Event Date (B3): 5/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE I'VE HAD EXTREME PERIODS. MISSING PERIODS. FIBROIDS, POLYPS, CYSTS, AND NOW ENDOMETRIAL HYPERPLASIA. WHICH WILL RESULT IN A HYSTERECTOMY SCHEDULED FOR (B)(6), 2014. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036662	BAYER	6/18/2014	6/18/2014

Event Information:

Event Date (B3): 5/12/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN RADIATING DOWN LEGS; ABDOMINAL PAIN; SEVERE CRAMPING; EXCESSIVE BLEEDING; FATIGUE; MIGRAINES; ANXIETY; JOINT PAIN; CHEMICAL SENSITIVITY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036663	BAYER	6/18/2014	6/18/2014

Event Information:

Event Date (B3): 5/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CHRONIC PELVIC PAIN AND BURNING, CRAMPING SENSATIONS. SENSITIVITY TO METALS. SENSITIVITY TO SUPPLEMENTS, MEDICATIONS, HYGIENE PRODUCTS AND FOODS WHICH I COULD PREVIOUSLY TOLERATE. FREQUENT SYMPTOMS OF UTI, BUT OFTEN NO INFECTION DIAGNOSED. SHARP STABBING PAINS IN PELVIC AREA, ON RIGHT AND LEFT SIDES, WORSE WHEN SITTING, WORST WHEN DRIVING. ANXIETY AND DEPRESSION. REDNESS AND INFLAMMATION IN PELVIC AREA. CHRONIC ABDOMINAL BLOATING, RESEMBLING PREGNANCY. SHOOTING PAINS DOWN LEGS, CHRONIC BURNING SENSATION IN SOLES OF FEET. OVARIAN CYST. PAINS IN VULVAR AREA. CYSTS IN VULVAR AREA. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036664	BAYER	6/18/2014	6/18/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME SCRATCHING ALL OVER BODY, MAINLY HEAD, EXTREMELY VIVID NIGHTMARES, RASHES, OVARIAN CYSTS, PAIN IN HANDS, AND LEGS, SWOLLEN ABDOMEN, FREQUENT URINATION, NIGHT SWEATS, HOT FLASHES, BRUISING, MIGRAINES, FIBROIDS IN UTERUS, CONSTANT PAIN IN RIGHT ABDOMEN, CONSTANT DISCOMFORT IN ABDOMEN, AND LEGS, SHOOTING PAIN IN LEGS, HEART RACING, MOOD SWINGS, FOUL SMELLING DISCHARGE, WEIGHT GAIN, SWELLING IN LEGS AND ANKLES, ACNE, PAIN DURING INTERCOURSE, ANXIETY, BACK PAIN, PAIN IN RIGHT SIDE UNDER RIBS, PUCKERING ON BREASTS, PAIN IN CHEST, AND ARMPITS, SMALL CYSTS IN ARMPITS, SHOOTING PAIN FROM CHEST TO ARMPITS, HEAVY PERIODS, BLOOD CLOTS, EXTREME CRAMPING CONSTANTLY, DIZZINESS, FATIGUE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036665	BAYER	6/18/2014	6/18/2014

Event Information:

Event Date (B3): 7/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING MAJOR CRAMPING IN MY SIDES SO BAD THAT I HAVE TO SIT DOWN TO CALM THEM DOWN. IT SEEMS LIKE IT STARTED NOT TO LONG AFTER I HAD THEM BUT IT HAS INTENSIFIED THE LONGER I HAVE HAD ESSURE. IT IS GETTING TO THE POINT I DON'T KNOW IF I WILL BE ABLE TO WORK. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036666	BAYER	6/18/2014	6/18/2014

Event Information:

Event Date (B3): 1/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE BLEEDING AND CRAMPING DURING CYCLE INCLUDING CLUMPS OF BLOOD. CONSTANT PAIN IN THE OVARY AREA, SHARP STABBING PAINS IN THE OVARY AREA AND VAGINAL AREA, STOMACH PAIN,DIZZY, LOW BACK PAIN. RASH, JOINT PAIN, NAUSEA. SICK DURING CYCLE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036667	BAYER	6/18/2014	6/18/2014

Event Information:

Event Date (B3): 4/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PROCEDURE COMPLETED IN (B)(6) OF 2011. ABOUT 6 MO. LATER BEGAN HAVING HORRIBLE BACK PAIN AND RIGHT HIP PAIN. EACH PERIOD REQUIRED CHANGE OF TAMPON HOURLY IF NOT SOONER DUE TO BLOODFLOW. JOINTS IN MY BODY HURT MORE THAN NORMAL AND PAIN BEGAN IN MY RIGHT UPPER ARM. I BEGAN GAINING WEIGHT AND ATTENDED (B)(6) TO TRY TO LOSE IT, RESULTING IN GAIN OF WEIGHING MORE THAN WHEN STARTED. I CONSULTED WITH MY OB-GYN AND WAS TOLD THE ESSURE DIDN'T CAUSE IT AND CAN NOT BE REMOVED BECAUSE ITS PERMANENT. SHE ADVISED AN ABLATION INSTEAD. I'VE BEEN TREATED FOR MENTAL HEALTH ISSUES MANY YEARS PRIOR TO PROCEDURE, DURING, AND CURRENTLY AS THAT HAS NOTHING TO DO WITH THESE SYMPTOMS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036782	BAYER	6/18/2014	6/26/2014

Event Information:

Event Date (B3): 12/23/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE IMPLANTED 2006 IS CAUSING, TO MYSELF, SEVERAL HEALTH CONDITIONS. EXTREME MENSTRUAL CYCLES WITH CRAMPS, GETTING LOW RANGE IN THE HEMOGLOBIN. UNBELIEVABLE PAINS ALL AROUND MY BODY ESPECIALLY THE ABDOMEN AND THE BACK, CHRONIC MIGRAINES, FIBROMYALGIA, INFLAMMATORY ARTHRITIS, LOSS OF HAIR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036670	BAYER	6/19/2014	6/19/2014

Event Information:

Event Date (B3): 4/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MOODINESS, DEPRESSION, SUICIDAL THOUGHTS, BLOATING, ALLERGIES, HEADACHES, FATIGUE, CHRONIC ABDOMINAL CRAMPING, HEAVY PERIODS, IRREGULAR PERIODS, PAIN ON RIGHT SIDE OF ABDOMEN, MIGRATION OF ESSURE COIL, ESSURE COIL PROTRUDING THROUGH RIGHT FALLOPIAN TUBE, RASH, ITCHING, HYSTERECTOMY ON (B)(6) 2014, FRAGMENT SURGERY ON (B)(6) 2014. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036671	BAYER	6/19/2014	6/19/2014

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOW UP1, #FDA MW5036671 #(B)(4). I GAINED APPROX 50 LBS SINCE I HAVE HAD THE IMPLANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036672	BAYER	6/19/2014	6/19/2014

Event Information:

Event Date (B3): 10/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON THIS DAY I EXPERIENCED MY FIRST OF MANY MIGRAINES. SINCE THEN ITS BEEN A CONSTANT BATTLE WITH WEIGHT GAIN AND SWELLING, TINGLING FINGERS, IRREGULAR HEARTBEAT, HAIR LOSS, PAIN IN MY ABDOMEN AND LOWER BACK, UNEXPLAINED BRUISING, DIZZINESS AND NAUSEA, DEPRESSION, EXTREME FATIGUE, LOSS OF LIBIDO AND PAINFUL INTERCOURSE THAT IS USUALLY FOLLOWED BY BLEEDING, RASHES, ABNORMAL BOWEL MOVEMENTS, AND GAS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036674	BAYER	6/19/2014	6/19/2014

Event Information:

Event Date (B3): 3/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT STARTED WHEN I HAD IT INSERTED IN (B)(6), WITH AN EXCRUCIATING INSERTION OF THE ESSURE. EVEN MY DOCTOR SAID IT WAS UNCOMMON THAT IT HURT SO BAD. THE CRAMPING AND SHARP PAIN CONTINUED THROUGH THE WEEKS, GETTING WORSE AND WORSE. MY HSG TEST CONFIRMED THAT I WAS NOT IN FACT STERILE, NOR WERE THE IMPLANTS IN PLACE. AT THIS TIME THROUGH NOW, I HAVE LOST AN ABUNDANCE OF HAIR, HAVE ITCHINESS ALL OVER MY BODY, MAINLY MY FACE, AND AM IN CONSTANT PAIN. THE PAIN LEVELS COME AND GO, TO WHERE SOME DAYS IT IS MILD CRAMPING, TO PAIN THAT KEEPS ME IN BED HALF THE DAY. I HAVE BEEN SCHEDULED FOR A HYSTERECTOMY WITH MY NEW DOCTOR FOR TWO WEEKS FROM NOW. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036675	BAYER	6/19/2014	6/19/2014

Event Information:

Event Date (B3): 1/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THERE WAS EXTREME PAIN WHEN THE HSG TO CONFIRM BLOCKAGE WAS DONE. THIS PAIN WAS ONLY THE BEGINNING. SINCE ESSURE PLACEMENT, I'VE DEVELOPED A MULTITUDE OF SYMPTOMS. THESE SYMPTOMS INCLUDE.... CRAMPING, HOT FLASHES, LOSS OF LIBIDO, SPOTTING AFTER SEX, PAINFUL PERIODS, PAINFUL INTERCOURSE, BLEEDING BETWEEN PERIODS, LONG MENSTRUAL CYCLE, UNABLE TO ORGASM, URGENT AND FREQUENT URINATION, URINARY TRACT INFECTION, ITCHING AND STINGING OF VAGINAL ENTRANCE, BREAST PAIN, ABDOMINAL SPASMS/TWITCHING, BACK PAIN, JOINT PAIN, NECK PAIN, SPINE PAIN, SEVERE BLOATING, MIGRAINES, DIMINISHED BRAIN FUNCTION (CONFUSION, BRAIN FOG, SHORT TERM MEMORY LOSS), MOOD SWINGS, WORSENING OF DEPRESSION, RINGING IN EARS, SENSATION OF BURNING, STINGING, OR PRICKLING OF SKIN, HIGH BLOOD PRESSURE, ALLERGIC REACTIONS, HIVES/RASHES, ABCESS CYSTS, SKIN IRRITATION/ITCHING, SWELLING OF FEET, HAIR LOSS, INFLAMED/BLEEDING GUMS, LOOSE TEETH, INSOMNIA. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036676	BAYER	6/19/2014	6/20/2014

Event Information:

Event Date (B3): 2/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

FOR THE FIRST FEW WEEKS AFTER THE IMPLANTATIONS, I FELT FINE...BUT OVER TIME, I HAVE HAD TROUBLES WITH DEPRESSION, BLOATING LOSS OF LIBIDO...I HAVE NICKEL SENSITIVITY AND TOLD THE DR ABOUT THIS WHEN HE DESCRIBED THE COILS. HE TOLD ME I WOULD BE FINE. I HAVE HAD RANDOM SERIOUS ALLERGIC REACTIONS TO FOODS, TO THINGS I NEVER HAD REACTIONS TO BEFORE. I HAVE BEEN TO THE EMERGENCY ROOM SEVERAL TIMES FOR TREATMENTS TO ALLERGIC REACTIONS THAT NO REASON COULD BE FOUND FOR. I SUFFER FROM CRAMPING IN MY PELVIC AREA. BLOATING TO THE POINT I LOOK PREGNANT. THE DOCTOR DID AN ABLATION WHILE HE WAS IN THERE...SO MY PERIODS HAVE ALL BUT STOPPED, BUT AFTER MY FIANCÉ AND I HAVE INTERCOURSE, I BLEED. SPOTS, CLOTS THAT HAVE SOME SUBSTANCE TO THEM. I HAVE RANDOM DISCHARGES THAT RANGE IN COLOR FROM OFF WHITE TO A RUDDY BROWN. IT HURTS TO HAVE SEX. IT NEVER DID BEFORE WITH MY FIANCE....HE BY THE WAY FEELS I NO LONGER WANT RELATIONS WITH HIM....MY DRIVE HAS PLUMMETED. IT DOESN'T FEEL AS GOOD....LIKE A DYSFUNCTION HAS HAPPENED. WHEN I NEED TO URINATE, ITS LIKE AN URGENT NEED TO GO..I GET RANDOM ABDOMINAL SPASMS, TWITCHES AND A FEELING OF FLUTTERING.....BACK PAIN, LEG, NECK AND HIP PAIN. I GET SEVER BLOATING...TO THE POINT IT'S DIFFICULT TO GET UP AND DOWN. THE HEARTBURN I GET NOW IS TERRIBLE. I GET TINGLING SENSATIONS IN MY HANDS AND TOES. MY MOOD SWINGS ARE QUITE FRIGHTENING--TO ME. I CAN ONLY IMAGINE HOW MY FIANCE FEELS ABOUT THEM. MY BLOOD PRESSURE WENT DOWN AFTER I HAD THE PROCEDURE DONE. BUT OVER THE LAST TWO YEARS, IT HAS CREPT BACK UP...THE STRESS AND WORRY ABOUT WHAT IS GOING ON INSIDE MY BODY..MAKES IT HARD TO STAY CALM. THE ALLERGIC REACTIONS I HAVE SEEM TO GET WORSE EVERY TIME I HAVE ONE...BUT OTHER THAN THE COILS INSIDE ME, I DON'T KNOW WHAT THE REACTIONS ARE COMING FROM. MY HANDS ARE CURRENTLY SUFFERING NOW WITH A RASH THAT I HAVE HAD SINCE (B)(6) OF 2014. I

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

WENT TO SEE A DERMATOLOGIST. HE DOES NOT KNOW WHAT CAUSED IT, OR HOW TO MAKE IT GO AWAY..HE GIVES ME CREAMS AND OINTMENTS TO KEEP MY HANDS SORT OF STABLE. I ASKED IF HE THINKS THEY WILL EVER HEAL, HE SAYS HE HOPES SO. I GET ACNE TYPE BREAKOUTS THAT LOOK LIKE CYSTS... I HAVE GAINED WEIGHT...AND HAVE SWELLING OF THE LEGS AND FEET. THE PELVIC AND ALLERGIC REACTIONS ARE BECOMING UNBEARABLE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036677	BAYER	6/19/2014	6/20/2014

Event Information:

Event Date (B3): 11/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABDOMINAL PAIN, PERIODS STARTED BECOMING IRREGULAR, HEAVY, AND PAINFUL, CHRONIC FATIGUE, HEADACHES, SOME JOINT PAIN AND HEAVY BLEEDING DURING SEX. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036678	BAYER	6/19/2014	6/20/2014

Event Information:

Event Date (B3): 8/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GUESS ON THE DATE. IMPLANTED (B)(6) 2013. ABOUT THE END OF (B)(6), I BEGAN HAVING PAINS ON MY LEFT SIDE. THEY FEEL AS IF THEY ARE CONTRACTIONS IN THE ARE OF MY TUBES. CONTINUOUS PAIN. BODY ACHES NIGHT SWEATS. ALSO CAUSING DEPRESSION BECAUSE OF INABILITY TO PERFORM DAILY TASKS. HEAVY BLEEDING THAT IS CONSTANT. A MONTH OR MORE AT A TIME. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE	6/19/2014	6/24/2014

Event Information:

Event Date (B3): 6/10/2014 **Report Date (B4): 6/19/2014** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): *

Single Use:
Implant Date (E6): 5/20/2014
Explant Date (E7): 6/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT UNDERWENT ESSURE PLACEMENT AT OUTSIDE FACILITY ABOUT A MONTH AGO. PATIENT REPORTED RIGHT SIDED PELVIC PAIN SINCE PLACEMENT. TRANSVAGINAL ULTRASOUND PERFORMED AT AN OUTSIDE FACILITY SHOWED RIGHT ESSURE COIL WITHIN MYOMETRIUM AND DEVICES IN PELVIS. ABOUT THREE WEEKS LATER, AT THIS FACILITY, PATIENT UNDERWENT AN OPERATIVE LAPAROSCOPY, BILATERAL SALPINGECTOMY, AND EXCISION OF ESSURE DEVICES AS WELL AS A LAPAROSCOPIC ILEOCECECTOMY DUE TO A FULL-THICKNESS PERFORATION OF BOTH WALLS OF THE TERMINAL ILEUM DUE TO MIGRATION OF AN ESSURE COIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036690	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 6/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE SIDE EFFECTS STARTED (B)(6) DAY OF IMPLANT . (B)(6) DAY ONE: HEAVY BLEEDING, CRAMPING. (B)(6) DAY TWO: SLIGHT CRAMPING, HEAVY BLEEDING. (B)(6) DAY THREE: PAIN IN LOWER BACK, ABDOMEN, HEAVY BLEEDING, CRAMPING, HEADACHE, FEEL BLOATED. (B)(6) DAY FOUR: PAIN IN LOWER BACK, ABDOMEN, HEAVY BLEEDING, CRAMPING, HEADACHE, FEEL BLOATED. (B)(6) DAY FIVE: PAIN IN LOWER BACK, ABDOMEN, HEAVY BLEEDING, CRAMPING, SHOOTING PAINS IN ABDOMEN, PAINS IN SHOULDER THAT GOES TO ELBOW, PAIN THAT SHOOTS FROM PELVIC AREA DOWN MY LEGS, HEADACHE, FEEL BLOATED. (B)(6) DAY SIX: STOMACH PAIN, LEG PAIN, CRAMPING, HEADACHE. #MEDWATCHER #MW156368.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036694	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 5/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

UTI, HAIR LOSS, LACK OF ENERGY, ACHY MUSCLES, NON STOP BLEEDING, PELVIC PAIN, THE LIST GOES ON! #MEDWATCHER #MW156369.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036695	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 5/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

UTI, HAIR LOSS, LACK OF ENERGY, ACHY MUSCLES, NON STOP BLEEDING, PELVIC PAIN, THE LIST GOES ON! (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036701	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 6/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LOWER ABDOMEN PAIN, BACK PAIN, HIP PAIN, PERIODS ARE ALL MESSED UP. I RECENTLY HAD ENDOMETRIOSIS AND A GROWTH IN MY UTERUS NOW IM HAVING A HYSTERECTOMY ON MONDAY (B)(6) 2013. I HAVE CHRONIC MIGRAINES FATIGUE BLOATING PAINFUL SEX. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036706	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 6/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MISSED PERIODS, EXCESSIVE CRAMPING, CYST ON OVARIES, BLOATING, HEADACHES, MIGRAINES, DIZZINESS, IRRITABILITY, MOOD SWINGS, JOINT PAIN, CRACKING AND POPPING BONES. #MEDWATCHER #MW156371.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036712	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 1/9/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE BACK PAIN, ABDOMINAL CRAMPS, BURNING PAIN IN LEFT BACK AND LEFT ABDOMEN, PAIN DURING INTERCOURSE, NAUSEA, FATIGUE, RASH, AND MIGRAINES. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036713	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 1/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE BACK PAIN, ABDOMINAL CRAMPS, BURNING PAIN IN LEFT BACK AND LEFT ABDOMEN, PAIN DURING INTERCOURSE, NAUSEA, FATIGUE, RASH, AND MIGRAINES. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036714	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 9/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE MOMENT THOSE ESSURE COILS WENT INTO MY BODY, I HAD EXTREME ABDOMINAL PAIN. I STAYED IN THE DR.'S OFFICE FOR 4 HOURS WITH THEM PUMPING ME FULL OF PAIN PILLS TO HELP, BUT TO NO AVAIL. THE PAIN DIDN'T END UNTIL I HAD A PARTIAL HYSTERECTOMY TO REMOVE THE COILS, AT WHICH POINT THE PAIN WAS GONE. PAIN THE SECOND ESSURE WAS PUT IN MY BODY AND FULL RELIEF THE SECOND ESSURE WAS TAKEN OUT OF MY BODY. NO DOUBT IN THE WORLD, THAT IT WAS ESSURE THAT CAUSED MY TWO MONTHS OF HELL! I HAD AN ULTRASOUND OF THE AREA ONE WEEK AFTER THE COILS WERE INSERTED AND THE DR. COULD SEE THAT ONE OF THE COILS WAS ALREADY MOVED FROM ITS INSERTION POINT, MY BODY'S WAY OF TRYING TO FORCE IT OUT. I WENT THROUGH 2 MONTHS OF EXTREME AND CONSTANT ABDOMINAL PAIN. ALWAYS STRONG, SOMETIMES SHOOTING PAIN. ABDOMINAL SWELLING ENOUGH TO MAKE ME LOOK SEVERAL MONTHS PREGNANT. WEIGHT GAIN. BARELY ABLE TO WALK AT MOMENTS DUE TO SEVERE PAIN. INABILITY TO HAVE INTERCOURSE AS IT INCREASED THE PAIN, WHICH I DIDN'T THINK IT WAS EVEN POSSIBLE TO HAVE WORSE PAIN. BACK PAIN. MOOD SWINGS. LACK OF ENERGY. DAYS OF MISSED WORK. UNBEARABLE 2 MONTHS OF MY LIFE. THEN, HAD TO GO UNDERGO A MAJOR AND EXPENSIVE SURGERY, A PARTIAL HYSTERECTOMY, TO REMOVE THE ESSURE COILS. THE DR. TOOK PHOTOS, DURING AND POST SURGERY, AND YOU CAN SEE HOW THEY DEFORMED INSIDE MY BODY. UNBELIEVABLE. I HAVE A NON BLOOD RELATED STEPSISTER WHO HAS HER OWN HORROR STORY AND HAD TO HAVE A FULL HYSTERECTOMY TO REMOVE HER ESSURE COILS. NEVER, EVER PUT THIS PRODUCT INTO YOUR BODY! #MEDWATCHER #MW156373.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036715	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 8/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED FEELING FATIGUED, CONTINUED THROUGHOUT THE YEARS AS WEIGHT GAIN, BLOATING, INABILITY FOR MY BODY TO ABSORB VITAMINS/MINERALS, INABILITY TO MANAGE BLOOD SUGAR LEVELS, IRREGULAR MENSES, LOW LIBIDO, NEW HAIR GROWTH ON FACE, SWELLING OF LEGS AND FEET. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036716	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL CRAMPING, URGENCY TO HAVE BOWL MOVEMENTS, DIARRHEA. SINCE JUNE OF 2011 I HAVE EXPERIENCED PAIN THAT COMES IN WAVES. SOMETIMES, IT FEELS LIKE MY OVARIES ARE WANTING TO EXPLODE. MY STOMACH FEELS LIKE ITS HAVE SPASMS NEAR MY FALLOPIAN TUBES. AT TIMES, IT ALSO CAN FEEL LIKE SOMETHING SHARP IS SLOWLY COMING DOWN MY UTERUS. FROM THE TIME THESE SYMPTOMS STARTED I HAVE BEEN DIAGNOSED WITH H. PYLORI, POSSIBLE IBS TO JUST NOW I AM DEVELOPING ENDOMETRIOUS. I IMMEDIATELY KNEW THAT ESSURE WAS THE CAUSE OF MY PROBLEM. I HAVE NEVEE HAD TO VISIT AN EMERGENCY OR SEE A DOCTOR SO OFTEN UNTIL THIS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036717	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 12/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY FOLLOWING PROCEDURE, SEVERE CHRONIC PELVIC PAIN, HEAVY IRREGULAR BLEEDING, MIGRAINES, ANXIETY, DEPRESSION, RASHES, HIVES, NICKEL ALLERGY, DIZZINESS, NAUSEA, PAIN AND BLEEDING WITH INTERCOURSE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036718	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 9/3/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED GAINING A LOT OF WEIGHT AROUND THE 9TH MONTH AFTER PLACEMENT OF THE ESSURE. I ALSO EXPERIENCED MY FIRST ANXIETY ATTACK (REQUIRING ANTI-ANXIETY MEDICATION SINCE) SHORTLY AFTER HAVING THE ESSURE PLACED. I'VE HAD CHRONIC SKIN ISSUES (REDNESS AND HIVE LIKE RAISED BUMPS AND RANDOM AREAS OF RASHES). CHRONIC FATIGUE FOR THE PAST 7 YEARS. TERRIBLE PELVIC PAIN. PAINFUL PERIODS. AND NEW BLADDER INCONTINENCE FOR THE LAST YEAR. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036719	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN IN THE PELVIC REGION, MORE SEVERE ON ONE SIDE. HEAVY ERRATIC BLEEDING ALL MONTH, EVERY MONTH. SUDDEN SHARP SEVERE PELVIC PAIN WITH SUDDEN MOVEMENTS THAT WILL DROP ME ON THE SPOT. #MEDWATCHER #MW156381.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036720	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 7/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAIR LOSS, MIGRAINES, ABDOMINAL PAIN, DIZZINESS, NAUSEOUS, MOOD SWINGS, FATIGUE, TEETH PAIN, MULTIPLE UTI'S, SMELLY DISCHARGE WITH NOTHING WRONG. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036721	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 10/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PERIODS HAVE BEEN HORRIBLE SINCE HAVING THE PROCEDURE DONE INCLUDING; HEAVY BLEEDING, CLOTTING, ABDOMINAL PAIN, FATIGUE AND SOMETIMES I HAVING TWO A MONTH. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036722	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 6/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD ESSURE SINCE 2010 AND HAD PROBLEMS SINCE DAY 1 I CRAMP SO BAD I CAN'T MOVE, MY BACK AND SIDES HURT MY PERIODS ARE VERY HEAVY I'M ALWAYS TIRED AND IN SO MUCH PAIN. I DON'T FEEL LIKE DOING ANYTHING. I HAVE A DISCHARGE WHITISH, NO ODER. MY HAIR IS FALLING OUT. ALWAYS MOODY MY BLOTTED, BLEED WITH INTERCOURSE. MY HANDS GO NUMB, THERE'S MORE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036723	BAYER	6/20/2014	6/20/2014

Event Information:

Event Date (B3): 7/1/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CHRONIC ABDOMINAL PAIN, BLOATING, EXCESSIVE BLEEDING, HAIR LOSS, PAINFUL SEX. #MEDWATCHER #MW156382.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036724	BAYER	6/20/2014	6/23/2014

Event Information:

Event Date (B3): 1/21/2010 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY COILS PUT IN (B)(6) 2009 ON SUGGESTION FROM MY DR. AS WELL AS AN ABLATION. WITHIN A MONTH OF THESE COILS BEING PLACED IN MY TUBES, I HAD NOTHING BUT PROBLEMS. I STARTED EXPERIENCING DEBILITATING PAIN IN MY LOWER ABDOMEN CLOSE TO MY OVARIES AND BACK. IT WOULD COME AND GO AT FIRST AND I THOUGHT MY BODY WAS RECOVERING FROM SURGERY. THEN THE PAIN BECAME CONSTANT.. ALL THE TIME. I CALLED MY DR. ON (B)(6) 2010. WENT IN AND HAD AN ULTRASOUND DONE. THE TECH LEFT THE ROOM IN A PANIC AND PUT ME IN A DIFFERENT ROOM TO WAIT FOR THE DOCTOR. I HEARD NURSES DISCUSSING ME OUT IN THE HALL SAYING THAT I HAD A FOREIGN BODY SOMEWHERE IN MY UTERUS AND THEY WERE ALL MAKING FUN OF ME. THE DR. CAME IN AND SAID THAT THE COIL "MAY" HAVE DISLODGED A BIT BECAUSE THEY COULDN'T SEE IT ON THE ULTRASOUND BUT THAT EVERYTHING ELSE LOOKED GOOD, IT COULD BE HIDING IN A SHADOW AND I WAS FINE. I TOLD THE DR. I WAS BEYOND UNCOMFORTABLE WITH PAIN, COULDN'T HAVE SEX, HAD SOME BLEEDING ON AND OFF (NEVER KNEW WHEN THAT WOULD STRIKE), SEVERE BACK PAIN, HEADACHES, CRAMPING, AND NO ENERGY. SOMETIMES I WAS IN BED ALL DAY! I WENT TO SEE A DIFFERENT DOCTOR LATER IN 2010. SHE DISCOVERED THAT THE ESSURE COIL HAD DISLODGED ITSELF AND PERFORATED MY UTERUS. SHE WAS PRETTY SURE THIS WAS THE CAUSE OF ALL OF MY PAIN. UNDER ADVISE FROM THE NEW DOCTOR THAT FINALLY FIGURED OUT WHAT THE PROBLEM WAS, I ENDED UP HAVING A PARTIAL HYSTERECTOMY IN (B)(6) 2011. THE NEW DR. THAT PERFORMED THIS PROCEDURE MADE SURE PATHOLOGY FOUND BOTH COILS BECAUSE DURING SURGERY, SHE COULDN'T FIND BOTH OF THEM. #MEDWATCHER #(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036798	BAYER	6/20/2014	6/26/2014

Event Information:

Event Date (B3): 3/18/2013 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/21/2011
Explant Date (E7): 3/18/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE DEVICE (B)(6) OF 2011. I BECAME PREGNANT IN 2012. ON (B)(6) 2013, I HAD TO DELIVER MY SON (B)(6), BUT HE HAD ALREADY DIED IN UTERO THREE TO FOUR DAYS PRIOR. ON (B)(6) 2013, I WENT BACK IN FOR SURGERY TO HAVE MY FALLOPIAN TUBES REMOVED. UPON AWAKENING I WAS INFORMED THE ESSURE ON ONE SIDE HAD MIGRATED AND PERFORATED MY UTERUS WITH A POSSIBILITY OF LATER PUNCTURING MY BOWEL. THEREFORE, I NEEDED A HYSTERECTOMY. ON (B)(6), I WENT BACK UNDER TO HAVE THE HYSTERECTOMY; HOWEVER, LEAVING MY OVARIES. THREE DAYS LATER I WAS BACK IN THE HOSPITAL WITH A FEVER OF 103. NOTHING CAME OF THE FEVER BUT NOW I AM MISSING MY SON AND A BODY PART.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036805	CONCEPTUS, INC.	6/20/2014	6/27/2014

Event Information:

Event Date (B3): 2/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE INVERTED 2012 HAVE HAD 6 INPATIENT HOSPITALIZATIONS, ABDOMINAL PAIN, NAUSEA, VOMITING, INCREASED MENSTRUAL BLEEDING. DEVELOPED A RASH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036806	BAYER HEALTHCARE PHARMACEUTICALS	6/20/2014	6/27/2014

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 4/17/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER ESSURE COILS WERE INSERTED, I HAVE EXPERIENCED VAGINAL DRYNESS, PROBLEMS LUBRICATING AND LOWERED SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036871	CONCEPTUS	6/23/2014	7/1/2014

Event Information:

Event Date (B3): 7/31/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/31/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTS FEELING SICK IMMEDIATELY AFTER IMPLANT OF ESSURE. PT EXPERIENCED PROFUSE BLEEDING, HAIR LOSS, MEMORY LOSS, NAUSEA, VOMITING, MUSCLE PAIN, SEVER ABDOMINAL PAIN, BLOATING, CONFUSION, HIGH BLOOD PRESSURE, VISION PROBLEMS, TEETH AND GUM PROBLEMS, AND LETHARGY. "I FEEL LIKE AN 80 YEAR OLD LADY". PT ALSO REPORTS HAVING STABBING PAIN AND BURNING SENSATION BUT SUBSIDED A LITTLE AFTER 1CM OF ESSURE WAS EXPLANTED BY PHYSICIAN ON (B)(6) 2013. DURING THE EXPLANT PHYSICIAN WAS ONLY ABLE TO GET 1CM OUT OF THE 4CM IMPLANTED THIS WAS DUE TO DEVICE FRAGMENTATION. A 3CM OF DEVICE HAS MIGRATED TO PT'S RIBS AND HIPS. EXPLANTING PHYSICIAN ALSO REALIZED THE IMPLANTING PHYSICIAN PERFORMED A TUBAL AS WELL AND HER FALLOPIAN TUBES WERE PERFORATED AS A RESULT OF THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036883	BAYER	6/23/2014	7/1/2014

Event Information:

Event Date (B3): 4/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 664659

Single Use:
Implant Date (E6): 2/16/2010
Explant Date (E7): 4/8/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6), 2014, I REPORTED TO THE LOCAL EMERGENCY ROOM WITH PAINS IN MY ABDOMEN, FOUR POSITIVE PREGNANCY TESTS, AND ALSO HAVE THE ESSURE COILS. THEY DID AN ULTRASOUND AND SAID IT WAS POSS ECTOPIC, SO THEY WERE GOING TO DO SURGERY TO REMOVE THE RIGHT TUBE, COIL AND FETUS LAPAROSCOPICALLY. HE TRIED BUT THERE WAS TOO MUCH SCAR TISSUE SO THEY HAD TO OPEN MY OLD C-SECTION SCAR. WHEN HE GOT IN HE LOCATED THE LEFT TUBE COIL AND OVARY INTACT AND THE RIGHT HE REMOVED ALONG WITH THE FETUS. THE COIL HAD COME ALL THE WAY OUT AND WAS STUCK IN MY UTERUS WHICH HE ALSO REMOVED ALONG WITH 100ML OF BLOOD CLOTS FROM THE OTHER END OF THE COIL, SCRAPING AROUND INSIDE ME. I HAVE HAD THREE PREVIOUS VISITS TO THE EMERGENCY ROOM WITH EXCRUCIATING PAIN AND THE CT'S SHOWED NOTHING THERE. I WAS TOLD THE ESSURE COULD NOT BE MY PROBLEM SO I'VE LEARNED TO DEAL WITH THE PAIN AT HOME SINCE THE EMERGENCY SAYS THERE'S NOTHING THERE. THE DOCTOR THAT REMOVED THE COIL SAYS THAT WAS PROBABLY WHAT WAS CAUSING IT. I HAD THE ESSURE PLACED IN 2010 AND KNEW THE RIGHT SIDE WAS OUT SOME BUT WASN'T ALL THE WAY OUT EVERY CT OR ULTRASOUND SHOWED IT WAS STILL IN THERE AND IN PLACE JUST STICKING OUT OF THE TUBE A LITTLE. YES, PAIN IS A SIDE AFFECT NOTED IN THE BROCHURE, BUT NOT CONSTANT PAIN! I HAVE ALSO HAD DEPRESSION AND WEIGHT GAIN OF ABOUT 40 IBS. THIS SHOULD BE TAKEN OFF THE MARKET. IT IS TAKING BABY'S LIVES AND COULD TAKE THE MOTHERS ALSO. I ALMOST DIED FROM THIS AND MY PAIN WAS ALMOST ALWAYS ON THE RIGHT SIDE BUT SINCE THE REMOVAL IT'S SWITCHED TO THE LEFT SIDE, AND I HAVEN'T HURT ON THE RIGHT SIDE SINCE REMOVAL. SO I KNOW WHAT THE PROBLEM WAS FOR SURE, I JUST WISH HE WOULD HAVE TAKEN OUT THE OTHER COIL SO I COULD HAVE MY LIFE BACK!

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036743	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 1/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I NOTICED AFTER HAD THE DEVICE IMPLANTED, I WOULD HAVE A DARK GLUEY DISCHARGE TWO WEEKS AFTER MY CYCLE WHICH WOULD LAST FOR A WEEK. I WOULD HAVE ABDOMINAL PAINS AND SOMETIMES FEEL LIKE A STICKING INSIDE MY ABDOMEN. I ALSO HAVE BLOATING AND DOES NOT MATTER THE ABDOMINAL EXERCISES I DO MY TUMMY JUST KEEPS ON GROWING. I NEVER HAD PROBLEMS WITH MY TUMMY BEING THIS BIG BEFORE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036744	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 3/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 958703 MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED THE DAY AFTER I WAS IMPLANTED BUT BECAME EXTREMELY WORSE ABOUT 6 MONTHS LATER. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. I HAVE LOWER BACK PAIN, SEVERE CHRONIC PELVIC PAIN, MANY UTI'S YEAST INFECTIONS AND OTHER UTERINE INFECTIONS, CHRONIC UTERINE INFLAMMATION, HEAVY IRREGULAR BLEEDING, MIGRAINES, RASHES, HIVES, NICKEL ALLERGY, DIZZINESS, NAUSEA, PAIN AND BLEEDING WITH INTERCOURSE. WORST OF ALL...I AM NOW 23 WEEKS PREGNANT. ONE COIL STILL IN PLACE AND THE OTHER IN MY UTERUS WITH BABY MAKING ME VERY HIGH RISK. I HAVE BEEN SEEN BY 3 DOCTORS. THE DEVICE IS STILL INSIDE OF ME BUT I WILL BE HAVING A FULL HYSTERECTOMY 6 WEEKS AFTER MY BABY IS BORN DUE TO ALL MY COMPLICATIONS AND THE MIGRATED COIL. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036745	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 10/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED SEEING STARS IN MY VISION. DOUBLE VISION, HEADACHES. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036746	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 3/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE 2012, I HAVE HAD VERY BAD ABNORMAL BLEEDING. I ONLY GO ABOUT 10 TO 15 DAYS WITHOUT BLEEDING. MY BLEEDING IS VERY HEAVY TO THE POINT OF SOFT BALL SIZE BLOOD CLOTS. ALSO VERY BAD PAIN IN THE LOWER PELVIC ARE WHERE THE ESSURE IS LOCATED. IF I MOVE OR STRETCH MY PELVIC AREA THE WRONG WAY I AM ON THE GROUND IN A BALL. MY HUSBAND AND I CANT EVEN HAVE INTERCOURSE, BECAUSE IT IS TOO PAINFUL FOR ME. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036747	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 3/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2013. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. MIGRAINES; BODY ACHES/CRAMPS; PAIN DURING SEX; ABNORMAL PERIODS/HEAVY BLEEDING; MISCARRIAGE; WEIGHT GAIN/BLOATING; DECREASE IN BONE STRENGTH; I HAVE BEEN SEEN BY 4 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: MIGRAINES; I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE; TOTAL ABDOMINAL HYSTERECTOMY; OPEN REDUCTION INTERNAL FIXATION ANKLE; THE DEVICE HAS BEEN REMOVED AS OF (B)(6) 2014; THE DEVICE WAS/WAS NOT RETURNED TO THE MANUFACTURER. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036748	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 3/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MISCARRIAGES, WEIGHT GAIN, PAIN, HEAVY BLEEDING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036749	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 8/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME PAIN...FEELING OF MY FEMALE PARTS FALLING OUT....HEMORRHAGING....NICKLE ALLERGY...HEART PALPITATIONS, DEPRESSION, ANXIETY, BLOOD PRESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036750	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 11/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DAY THEY IMPLANTED ME WITH ESSURE IT WAS HORRIBLE. IT TOOK LIKE TWO MINUTES BUT FELT LIKE TWO YEARS. IT WAS VERY PAINFUL THAT THE NURSE HAD TO HOLD ME DOWN AND ALL I CAN THINK OF WAS THAT I WAS IN PAIN. I TOLD THE DOCTOR THAT I WAS HURTING REALLY BAD AND HE SAID THAT IT'LL LAST A FEW DAYS BUT PRESCRIBED ME MEDS FOR THE PAIN HYDROCODONES 10/500S SINCE THEN ITS AN ON GOING PAIN, BLEEDING DOWN MY LEGS, HURTS WHILE INTERCOURSE, ABNORMAL PERIODS, TIRED ALL THE TIME AND I WOULD NEVER BE THE SAME. I HAVE GONE THROUGH LOTS OF TEST. NO CANCER. NO OTHER PROBLEMS. BUT I AM GOING TO HAVE A HYSTERECTOMY TO REMOVE THE DEVICE IN ABOUT A WEEK. AND I HAVE HAD SEVERAL MISCARRIAGES. HOW CAN YOU ALL HAVE SUCH A THING LIKE THIS FOR WOMEN WITH ALL THE COMPLICATIONS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036751	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 2/23/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD NO HEALTH ISSUES OR CONDITIONS PRIOR TO GETTING ESSURE IN (B)(6) 2004. I HAD AN IMMEDIATE ADVERSE REACTION TO THE COILS. I WAS SICK FOR 5 YEARS WITH CHRONIC INFLAMMATION, SEVERE ALLERGIES TO FOOD AND COMMON CHEMICALS AND PROLONGED AND INTENSE FATIGUE. I HAVE MEDICAL REPORTS TO SUBSTANTIATE ELEVATED INFLAMMATION LEVELS THAT DIMINISHED JUST A FEW MONTHS AFTER REMOVAL. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036752	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 5/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DR. STILL REFUSES TO ADMIT THAT IT COULD POSSIBLY BE THE ESSURE. IN FACT IN MY PRE-OP NOTES SHE STATED BASICALLY THAT MORE THEN LIKELY IT WASN'T AND I UNDERSTOOD I WOULD PROBABLY BE IN PAIN AFTER WHICH WASN'T THE CASE. I TOLD HER REPEATEDLY I KNEW FOR SURE IT WAS THE ESSURE AND NOW THAT IT IS OUT I CAN CONFIRM IT. I WAS ALSO EXTREMELY UPSET THAT SHE TRIED TO BLAME THE PAIN ON OTHER PERSONAL THINGS THAT MADE ABSOLUTELY NO SENSE. REGARDLESS 3 DAYS POST OP AND I AM ALREADY FEELING 100% BETTER THEN MY ESSURE DAYS!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036753	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 4/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AS SOON AS ESSURE WAS IMPLANTED ON (B)(6) 2013, IT WAS IMMENSELY PAINFUL. THE BLEEDING AND PAIN CONTINUED TO WORSEN INSTEAD OF IMPROVE. ON (B)(6) 2013 I HAD A BILATERAL SALPINGOSTOMY, ESSURE REMOVAL, AND TUBAL LIGATION. PAIN RETURNED AND WORSENED. HEALTH WORSENED AND WAS DIAGNOSED WITH AN AUTOIMMUNE DISORDER, PCOS, CHRONIC PAIN, CHRONIC FATIGUE, AND (B)(6). WENT ON PROMETRIUM THERAPY, AN ANTI-INFLAMMATORY DIET, GLUTATHIONE, NALTREXONE, ACYCLOVIR, PROZAC, ZYRTEC, PROAIR, SYMBICORT, FLONASE, ZYFLAMMEND, WOBENZYME, ANTIOXIDANTS, LIVER DETOX. WAS DIAGNOSED WITH A NICKEL ALLERGY IN (B)(6) OF 2014. ON (B)(6) 2014 HAD A TOTAL VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY. PATHOLOGY REPORT ON (B)(6) 2014 FOUND CYSTS INSIDE THE FALLOPIAN TUBES. MRI SCAN ON (B)(6) 2014 FOUND ADENOMYOSIS, AND METAL FRAGMENTS EMBEDDED IN MY UTERUS NEAR OR IN MY CESAREAN SCAR. THE MRI WAS COMPARED TO A PELVIC CT SCAN ON FILE FROM 2011. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036754	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE BACK PAIN, ABDOMINAL CRAMPS, BURNING PAIN IN LEFT BACK AND LEFT ABDOMEN, PAIN DURING INTERCOURSE, HIVES, SWELLING, NAUSEOUS, DIZZY, FAINT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036755	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 1/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABOUT 3 MONTHS AFTER HAVING THE ESSURE PROCEDURE I STARTED HAVING SEVERE LOWER BACK PAIN, ABDOMINAL CRAMPING, NAUSEA, CHEST PAIN, RESTLESS LEG SYNDROME, WEIGHT GAIN, HEADACHES, HEART PALPITATIONS AND ANXIETY RESULTING IN FACIAL TWITCHING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036756	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 11/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NEEDED SURGERY IN (B)(6) OF 2014 TO REMOVE MY ESSURE COILS AND FALLOPIAN TUBES BECAUSE OF SEVERE PELVIC PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036757	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 8/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING, LONGER PERIODS (MINE USE TO BE 3 DAYS AND NOW 7-18 DAYS), PELVIC PAIN, TIRED ALL THE TIME, HAIR LOSS, RASH ON HANDS, VERY BAD CRAMPING, VERY BAD BLOATING THAT WILL NOT GO AWAY, BOWEL MOVEMENT ISSUES, VERY BAD DISCHARGE, PAINFUL SEXUAL INTERCOURSE, HOT FLASHES, DIZZINESS, ACID REFLEX (LIKE I HAD WHEN I WAS PREGNANT) VERY BAD HEAD PAINS. I HAVE NEVER EVER HAD ISSUES LIKE THIS UNTIL THE ESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036758	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 2/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ONCE IMPLANTED, I BEGAN TO GET MY MENSTRUAL EVERYDAY FOR ABOUT 9 MONTHS CAUSING ME TO HAVE TO GET ON DEPO PROVERA TO CONTROL. DURING THIS TIME THE HSG WAS COMPLETED AND THE LEFT TUBE WAS NOT BLOCKED. THE COIL WAS REMOVED AND BOTH TUBES WERE CLAMPED. SINCE THEN I'VE HAD TO TAKE FMLA FOR THE SHARP CHEST PAINS. SINCE THEN I'VE DEVELOPED MANY OTHER SYMPTOMS. (B)(4). UPDATE ON (B)(6) 2014: THE FOLLOWING HAVE BEEN MY MANY SYMPTOMS: VAGINAL ODOR, CRAMPING HANDS, LOWER BACK PAIN, PAIN IN MY THIGHS, SHARP CHEST PAINS, SHARP RIGHT SIDE PAINS, MIGRAINES, FATIGUE, HAIR LOSS, BRAIN FOG (MEMORY ISSUES), MUSCLE SPASM IN THIGH/HIP, MUSCLE SPASM IN FEET NEAR TOES, BLOATING, HOT FLASHES. HAD SURGERY (B)(6) 2014, TO HAVE MY FALLOPIAN TUBES REMOVED AND THE MIGRATED COIL AS WELL. THE MIGRATED RIGHT COIL WAS NEAR THE RIGHT ABDOMINAL WALL AND COLON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036759	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 1/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS AT WORK WHEN ALL OF A SUDDEN MY BODY STARTED TO ACHE SO BAD. I DIDN'T KNOW WHAT WAS GOING ON, I JUST KNEW THAT ALL OF A SUDDEN I COULD BARELY WALK, MY WHOLE BODY FELT LIKE IT WAS ON FIRE. MY DAUGHTER CAME TO PICK ME UP FROM WORK AND TOOK ME DIRECTLY TO ER. THEY COULD NOT FIND ANYTHING WRONG, ALL THEY DID WAS PAIN CONTROL. SINCE THEN MY PAIN IN MY ENTIRE BODY IS CONSTANT. I HAVE PAIN SHOOTING UP AND DOWN MY BACK, I HAVE CONSTANT MIGRAINES, MY ARMS AND LEGS GO NUMB VERY EASILY. I AM UNABLE TO KEEP A JOB DUE TO ALWAYS GOING OUT OF WORK DUE TO NOT FEELING WELL. I HAVE BEEN HOSPITALIZED ONCE DUE TO SYMPTOMS OF STROKE, BUT IT WAS DETERMINED NOT TO BE. I BELIEVE THAT ESSURE MAY BE THE CAUSE OF ALL OF THIS HAPPENING TO MY BODY. MY LIFE IS SLOWLY GOING DOWNHILL, I HAVE PUT MY FAMILY IN FINANCIAL STRAIGHTS DUE TO THIS ILLNESS. PLEASE HELP US. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036760	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

WEIGHT GAIN, MIGRAINES, CRAMPING IN LOWER ABDOMEN, IRREGULAR MENSTRUAL CYCLES, PRESSURE CONSTANTLY IN LOWER ABDOMEN, FREQUENT SHARP PAIN NEAR HIPS, NAUSEA, SKIN RASH, DRY SKIN. FATIGUE, LOSS OF LIBIDO, STOMACH CRAMPING. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036761	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 2/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO DAYS AFTER THE PROCEDURE, I STARTED BLEEDING FOR TWELVE DAYS. AROUND THE THIRD WEEK OF (B)(6), I BEGAN HAVING SEVERE HEADACHES AND CHRONIC FATIGUE. (B)(6), I STARTED MY PERIOD WITH QUARTER SIZE BLOOD CLOTS AND EXCESSIVE BLEEDING FOR TWENTY ONE DAYS. AFTER THIS PERIOD, I BEGAN HAVING SEVERE ABDOMINAL PAIN AND SEVERE LEFT SIDE FLANK PAIN. I BEGAN GETTING VERY CONFUSED AND COULD NOT CONCENTRATE AS NORMAL. THIS HAS CONTINUED ON UP UNTIL NOW. I WAS ADMITTED INTO THE HOSPITAL ON (B)(6) DUE TO THE EXCESSIVE SEVERE PAIN AND NONSTOP BLEEDING SINCE (B)(6). (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036762	BAYER/CONCEPTUS	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 12/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH COTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626906

Single Use:
Implant Date (E6): 12/5/2008
Explant Date (E7): 3/17/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE ON (B)(6) 2008. I'M AN ATHLETE AND KNOW MY BODY VERY WELL WHEN I FIRST NOTICED THE FATIGUE SETTING IN THEN THE BODY ACHES. THEN THE JOINT PAIN STARTED, THE LOWER BACK PAINS AND PAIN IN HIPS AND AFFECTING MY SCIATIC NERVE TO MY RIGHT LEG. I WAS KICK BOXING AND HAD TO QUIT DUE TO NOT HAVING THE STAMINA TO TRAIN AND THE JOINT PAIN AND SEVERE MUSCLE FATIGUE I WAS EXPERIENCING. DURING THIS WHOLE TIME, I WAS GETTING SEVERE UTI INFECTIONS THAT HAS LEAD TO SOME INCONTINENCE ISSUES. TODAY ON A DAILY BASIS I EXPERIENCE ALL THIS PLUS THESE OTHER AILMENTS: CHRONIC FATIGUE, BODY ACHES, ACHY JOINTS, IRREGULAR CYCLES, ABDOMINAL BLOATING, ABDOMINAL PAINS, KIDNEY PAIN, BLADDER INFECTIONS, HEART FLUTTERS, LOWER BACK PAINS, HEADACHES DAILY SOMETIMES MIGRAINES, NECK PAIN, SPINAL PAIN, SCIATIC NERVE IN LEGS PAIN, JAW AND TEETH PAIN, THYROID ISSUES, HEAVY BLEEDING SOMETIMES GUSHING, BLOOD CLOTS DURING CYCLE, SEVERE JOINT PAIN AND MUSCLE FATIGUE, METAL TASTE IN MOUTH AND BLOOD, EAR ACHES W/NO INFECTION WHEN HAVING JAW PAIN, DISCHARGE AND ODOR, INCONTINENCE ISSUES, TINGLING IN LEFT HAND WITH CRAMPING OF FINGERS. LIGHT HEADED, BRAIN FOG, ASTHMA ATTACKS, CRAWLING SKIN, NIGHT SWEATS, BLEEDING AFTER SEX, SPOTTING IN BETWEEN HEAVY FLOWS, HIP PAIN, NAUSEA. BAD PAP SMEARS THAT NEED TREATMENT FOR CANCER CELLS. SKIN CANCER REQUIRING MAJOR SURGERY. IT IS ALMOST IMPOSSIBLE TO BE PHYSICAL DUE TO FATIGUE AND LOSS OF MUSCLE STRENGTH. I USED TO BE A SKI RACER AND NOW I AM LUCKY IF I CAN GO 100 YARDS WITHOUT MY LEG MUSCLES SCREAMING IN SEVERE PAIN! (B)(4) UPDATE ON (B)(4) 2014: SURGERY WAS (B)(6) 2014, LAVH. I WANTED TO KEEP MY OVARIES BUT THEY WERE DAMAGED TOO MUCH TO KEEP. MY OVARIES, TUBES AND UTERUS WERE FUSED TO MY COLON. MY DOCTOR NEEDED TO CALL IN THE GENERAL SURGEON TO SEPARATE MY ORGANS IN ORDER TO SAVE MY COLON. I HAVE MANY OLD CYSTS AND NEW ONES. FILLED

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WITH ENDOMETRIOSIS FUSING MY ORGANS. I HAD LARGE FIBROIDS IN THE UTERUS AND CHOCOLATE POCKETS (?) FILLED WITH OLD BLOOD THAT WOULD NOT SLOUGH OFF DURING MY CYCLE. I HAD A UTI TREATED PRIOR TO SURGERY AND HAVE HAD ANOTHER SINCE SURGERY. I NEVER HAD UTI'S PRIOR TO ESSURE! I FELT REALLY GOOD AFTER SURGERY, NO HEADACHES, BODY ACHES, FATIGUE. I THEN HAD A PATCH TEST DONE WITH SOME OF THE ESSURE MATERIALS AND TWO HOURS AFTER THE PATCH WAS APPLIED I HAD A MAJOR HEADACHE THEN WOKE UP WITH THE BODY ACHES AND FATIGUE. THE PATCH WAS REMOVED AFTER 48 HOURS AND THE SYMPTOMS REMAINED ANOTHER 24 HOURS, THEN DISAPPEARED. THREE MONTHS POST OP AND I STILL GET SEVERE KIDNEY INFECTIONS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036763	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 8/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE ON (B)(6) 2012. TWO DAYS LATER I AWOKE WITH NECK/SHOULDER PAIN, WHICH RESULTED IN AN EMERGENCY ROOM VISIT ON (B)(6) 2012 WHERE THEY FOUND NO CAUSE FOR MY PAIN BUT TREATED IT. SINCE THEN I HAVE LIVED WITH CHRONIC NECK/SHOULDER PAIN. I HAVE HAD AN MRI AND X-RAYS THAT REVEALED ONLY A MUSCLE SPASM WITH NO KNOWN CAUSE. I HAVE BEEN TO PHYSICAL THERAPY, PAIN MANAGEMENT, A CHIROPRACTOR AND A MASSAGE THERAPIST. ALL OF WHICH CAN FIND NO CAUSE TO MY PAIN AND HAVE FAILED TO MAKE IT DISSIPATE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036764	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 9/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED (B)(6)2013. I HAD HEAVY BLEEDING (WOULD FILL A PAD WITHIN A HOUR). HAD TO HAVE HYSTERECTOMY (B)(6) 2013 JUST TO STOP THE BLEEDING, (B)(6) 2014 HAD FALLOPIAN TUBE'S AS WELL AS ESSURE REMOVED AND LEFT OVARIAN CYSTS DRAINED. DUE TO THE ESSURE I DEVELOPED BLOOD CLOTS IN ARM AND NOW HAVE TO BE ON WARFIN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036765	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 5/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE BLOATING, TWO PERIODS A MONTH, BLOOD CLOTS VERY HEAVY, PELVIC PAIN, WEIGHT LOSS, HEADACHES, NO ENERGY, SHARP STOMACH PAINS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036766	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2010, APPROXIMATELY 13 MONTHS AFTER HAVING ESSURE PUT IN, I STARTED BLEEDING HEAVILY AND SEVERE CRAMPING. THIS LASTED FOR ABOUT 5 MONTHS. AFTER 5 MONTHS OF GOING TO MY GYN REPEATEDLY, HE FINALLY OFFERED A THERMAL ABLATION AS A SOLUTION. EVERY FEW MONTHS, I STILL BLEED AND HAVE SEVERE CRAMPING. THE BLEEDING LASTS ANYWHERE FROM ABOUT 7 TO 28 DAYS. IT IS CONSTANT HEAVY BLEEDING THAT INTERRUPTS MY DAILY ROUTINES SUCH AS WORK AND RAISING MY DAUGHTER. THE CRAMPING IS UNCONTROLLABLE. I JUST BARELY MAKE IT THROUGH MY DAYS EVEN WITH PRESCRIPTION NAPROXEN THAT MY GYN PRESCRIBED TO ME. I HAVE ALSO GAINED A LOT OF WEIGHT THAT I CAN NOT LOSE. I HAVE HORRIBLE ACNE AT (B)(6). I AM LOSING MY HAIR IN HANDFULS EVERY DAY. I USED TO HAVE THICK HAIR AND NOW IT IS THIN AND BRITTLE. I GET HORRIBLE SKIN RASHES AND BUMPS THAT LAST ANYWHERE FROM 3 TO 10 DAYS. THE BUMPS AND RASHES ARE SO SORE THAT I CAN BARELY WEAR JEANS/PANTS. I ALSO HAVE A HIGH IRON LEVEL THAT MY PRIMARY AND A HEMATOLOGIST CAN NOT DIAGNOSE. I CURRENTLY AS OF TODAY ((B)(6) 2014) HAVE 4 OF THESE BUMPS. THE SIZES RANGE FROM ANYWHERE BETWEEN DIME SIZED TO ABOUT 3 INCHES IN DIAMETER. THESE BUMPS HAVE CAUSED MAJOR SCARRING WHEREVER THEY ARE AND QUITE A BIT OF EMBARRASSMENT. I DO NOT WEAR SHORTS OR BATHING SUITS AND REFUSE TO HAVE ANY SORT OF INTIMATE RELATIONSHIP BECAUSE OF THESE DARK PURPLE HOLES, RED BUMPS AND THE TUNNELING THAT IT HAS CAUSED ON MY LEGS, THIGHS AND STOMACH. I HAVE BEEN IN THE HOSPITAL APPROXIMATELY 5 TIMES DUE TO BLEEDING. I HAVE BEEN TO MY GYN APPROXIMATELY 10 TIMES. I HAVE ALSO BEEN TO A DERMATOLOGIST, A HEMATOLOGIST AND MY PRIMARY DOCTOR COUNTLESS TIMES DUE TO THE SIDE EFFECTS FROM ESSURE. BEFORE I HAD ESSURE, I HAD NO PROBLEMS WHAT SO EVER. NOW AS A FACTOR OF SEVERAL OF MY SIDE EFFECTS, I HAVE HIGH CHOLESTEROL AND AM BEING TREATED FOR DIABETES BECAUSE I CAN NOT LOSE THE WEIGHT I

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GAINED WHILE HAVING ESSURE. I AM ONLY (B)(6), A SINGLE MOM AND I WORK FULL TIME. I DO NOT RECEIVE ANY HELP FROM MY CHILD'S FATHER, SO TAKING OFF WORK DUE TO THE SEVERITY OF THESE EFFECTS IS OUT OF THE QUESTION. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036767	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 6/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6)2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. I WAS NOT GIVEN MY LOT NUMBERS. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED (B)(6)2014. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. ITCHING, METAL TASTE IN MY MOUTH, SWOLLEN HEAD, NECK, BACK N SHOULDERS, LEADING TO SWELLING OF THE GLAND IN THE THROAT MAKING IT HARD TO BREATHE, DIZZY, CONFUSION, VOMITING, MIGRAINES. I HAVE BEEN SEEN BY DOCTORS AT (B)(6) HOSPITAL. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS ANAPHYLACTIC REACTION TO NICKLE/ ESSURE. THE DEVICE IS STILL INSIDE OF ME. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036768	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 6/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING, EXTREME PAIN IN PELVIC REGION, RASH, FATIGUE, BLOATING. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036769	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS UNABLE TO FIND THE LINK TO UPDATE MY REPORT BUT SINCE THEN I HAVE BEEN DIAGNOSED WITH RA. LUPUS ANTIBODY?.... THIS DISEASE DOES NOT RUN IN MY FAMILY! I HAVE NOW HAD A HYSTERECTOMY TO REMOVE THE ESSURE COILS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036770	BAYER	6/24/2014	6/24/2014

Event Information:

Event Date (B3): 6/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY FIRST FEELING PAIN I THINK WAS IN (B)(6) 2012 I WAS HAVING BACK PAIN AND ABDOMINAL PAIN RUNNING FEVER. I WENT TO THE ER AND THEY FINALLY TOLD ME THAT I HAD A BAD BLADDER INFECTION AND MY WHITE CELL COUNT WAS LOW. WHEN I HAVE MY CYCLE I BLEED HEAVY AND CLOT BAD. I STILL HAVE ABDOMINAL AND BACK PAIN IN THE REGULAR. SINCE I GOT ESSURE MY URINE SMELL AWFUL. (B)(4).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00243	BAYER HEALTHCARE LLC	6/24/2014	7/1/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B04950

Single Use: Y
Implant Date (E6): 10/14/2013
Explant Date (E7): 4/8/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP PAINS IN LEFT SIDE, HIP PAIN, LOWER BACK PAIN, ABDOMEN PAIN, MIGRAINES, STOMACH PAIN, BURNING SKIN, ITCHY SKIN, RASH, MOOD FLUCTUATIONS, HAIR LOSS, DIZZINESS, AND INSOMNIA. ON (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED (LOT NUMBER B04950). CONSUMER REPORTED THAT DURING THE IMPLANTATION OF THE DEVICE IN 2013 HER LEFT TUBE DID NOT ACCEPT THE ESSURE COIL AND THE DEVICE WAS NOT IMPLANTED. SHE BEGAN HAVING SHARP PAINS IN HER LEFT SIDE, HIP AND LOWER BACK AND ABDOMEN PAIN. SHE ALSO BEGAN HAVING MIGRAINES, EXTREME STOMACH PAIN, BURNING, ITCHY SKIN AND RASH, EXTREME MOOD FLUCTUATIONS, EXTREME HAIR LOSS, DIZZINESS AND INSOMNIA. CONSUMER WENT TO THE DOCTOR AND THE DOCTOR PERFORMED AN ULTRASOUND WHICH CONFIRMED THE LEFT COIL WAS IN THE RIGHT PLACE AND GAVE HER THE OPTION TO CONSIDER SURGERY BECAUSE IT SEEMED THAT HER BODY WAS REJECTING THE COIL ON (B)(6) 2014, SHE HAD A HYSTERECTOMY BY LAPAROSCOPIC SURGERY. CONSUMER DID NOT PROVIDE THE RELATIONSHIP BETWEEN ALL EVENTS INITIALLY REPORTED AND ESSURE.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2014. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00246	BAYER HEALTHCARE LLC	6/24/2014	7/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97492

Single Use: Y
Implant Date (E6): 5/28/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN THE UNITED STATES ON (B)(6)-2014 WITH ADDITIONAL INFORMATION RECEIVED ON (B)(6)-2014. REPORTER ASKED FOR A DEVICE REPLACEMENT. THE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BUTTON DID NOT WORK/SHEATH WOULD NOT RELEASE/NEVER SAW THE GOLD BAND; THE ENTIRE OUTER COIL UNRAVELED, COIL BROKE OFF AT THE GREEN SLEEVE, GREEN SHEATH WAS PARTIALLY STUCK IN THE OSTIA, HE HAD TO CUT THE OUTER COIL/CUT SOME OF THE COIL FROM THE HYSTEROSCOPE, AND TRIED TO GRASP THE PARTS THAT WERE LEFT IN BUT COULD NOT GET IT ALL OUT. ON (B)(6)-2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B97492 (EXPIRATION DATE NOV-2016) FOR PERMANENT CONTRACEPTION. INSERTION OF LEFT COIL WAS FINE. ON THE RIGHT SIDE, ESSURE COIL ADVANCED FINE AND WHEN HE HIT THE BUTTON SECOND TIME TO RETRACTING SHEATH WOULD NOT RELEASE THE SLEEVE. HE FELT AN UNUSUAL SNAP DURING SECOND ROLL BACK AND THE DEVICE WAS STUCK WHEN HE DID THE ROLL BACK, THE BUTTON DID NOT WORK. THE SLEEVE WAS STUCK IN THE OSTIA. PULLED BACK ON THE HAND PIECE THE OUTER COIL UNRAVELED, IT BROKE OFF AT THE GREEN SLEEVE. HE STOPPED THE PROCEDURE AND WHEN REMOVING THE HYSTEROSCOPE THE ENTIRE OUTER COIL UNRAVELED AND THE GREEN SHEATH WAS PARTIALLY STUCK AND HE HAD TO CUT THE OUTER COIL THAT WAS EXTENDING OUT OF TUBE AND IN PART OF BODY. HE TRIED TO REMOVE AS MUCH OF THE GREEN SLEEVE AS POSSIBLE. HE TRIED TO GRASP THE PARTS THAT WERE LEFT IN WITH A FORCEPS BUT COULD NOT GET IT ALL OUT. HE HAD TO CUT SOME OF THE COIL FROM THE HYSTEROSCOPE AND NEVER SAW THE GOLD BAND. ESSURE WAS NOT REMOVED AND DOCTOR HAS SCHEDULED PATIENT FOR A HYSTERECTOMY AS THE PATIENT DOES NOT WANT TO WAIT FOR HSG (HYSTEROSALPINGOGRAM). REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 30-JUL-2014. (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00247	BAYER HEALTHCARE LLC	6/24/2014	7/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER IN THE UNITED STATES, ON BEHALF OF A PLAINTIFF/PLAINTIFF'S IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING ADVERSE EVENTS: IN (B)(6)-2008, CONSUMER WENT TO THE IMPLANTING PHYSICIAN TO HAVE ESSURE IMPLANTED IN HER FALLOPIAN TUBES FOR BIRTH CONTROL. THE IMPLANTING PHYSICIAN ATTEMPTED TO INSERT THE DEVICE ON HIS OWN WITH THE DELIVERY SYSTEM AND HYSTEROSCOPIC EQUIPMENT. AFTER SEVERAL ATTEMPTS, THE IT WAS UNABLE TO PLACE THE DEVICE. AFTER ONE MONTH, CONSUMER RETURNED TO THE IMPLANTING PHYSICIAN, WHO ATTEMPTED TO PLACE THE DEVICE. WITHOUT BAYER'S REPRESENTATIVE PRESENT, THE IMPLANTING PHYSICIAN ATTEMPTED TO PLACE THE DEVICE SEVERAL TIMES. FINALLY, THE MICRO-INSERTS WERE PLACED. AFTER TWO YEARS, SHE WAS THEN HOSPITALIZED FOUR TIMES DUE TO SEVERE PAIN, FEVER, AND FAINTING SPELLS. EVENTUALLY A CT SCAN REVEALED THAT ONE OF THE MICRO- INSERTS HAD MIGRATED FROM THE FALLOPIAN TUBE AND BECAME LODGED IN OR BEHIND HER COLON. IT WAS ALSO DISCOVERED THAT THERE WERE THREE MICRO-INSERTS INSIDE OF CONSUMER, INSTEAD OF TWO. IN (B)(6)-2013, AS A RESULT OF ESSURE, CONSUMER UNDERWENT A COMPLETE HYSTERECTOMY AND AN ADDITIONAL SURGERY TO REMOVE THE COIL LODGED IN HER COLON. SHE NOW SUFFERS FROM SEVERAL AUTOIMMUNE AND ADHESION DISORDERS. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

LEGAL COMPLAINT RECEIVED ON (B)(6) 2015: IT WAS REPORTED THAT THE CONSUMER'S ESSURE DEVICE MIGRATED FROM FALLOPIAN TUBES TO HER UTERUS/RECTUM RESULTING IN FIVE HOSPITALIZATIONS AND HYSTERECTOMY ON (B)(6) 2013. CONSUMER ALSO SUFFERED FROM PELVIC PAIN, NIGH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00248	BAYER HEALTHCARE LLC	6/24/2014	7/1/2014

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A78083

Single Use: Y
Implant Date (E6): 11/1/2013
Explant Date (E7): 11/1/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2013. THE REPORT AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MISPLACEMENT ON ONE ESSURE UNIT, TIP BROKE OFF AND IS STILL IN PATIENT (DEVICE ACHIEVED. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2013, THE PATIENT HAD ESSURE INSERTED FOR CONTRACEPTION. ON (B)(6) 2013, HCP (HEALTHCARE PROFESSIONAL) STATED SHE ENCOUNTERED SOME SORT OF MISPLACEMENT ON ONE ESSURE UNIT, THE TIP BROKE OFF AND IS STILL IN PATIENT (DEVICE INSERTION COMPLICATION). ONLY UNILATERAL PLACEMENT WAS ACHIEVED (RIGHT OR LEFT WAS NOT REPORTED). THE EVENT WAS ONGOING, TREATMENT WAS NOT REPORTED. ESSURE ON ONE SIDE WAS CONTINUED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2013. THE PTC GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COUL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036874	BAYOR	6/24/2014	7/1/2014

Event Information:

Event Date (B3): 6/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/11/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS CONTRACEPTIVE DEVICE PLACED IN 2009. EVER SINCE THAT I HAVE HAD CHRONIC PELVIC PAIN, IBS RELATING TO THIS AND NICKEL ALLERGY. MY ULTRASOUNDS SHOW LEFT COIL NOT IN FALLOPIAN TUBE AND ON X-RAY SHOWS BOTH THERE BUT ONE IS VERTICAL AND THE OTHER HORIZONTALLY. I AM SEEKING MEDICAL ADVICE NOW AND I HAVEN'T BEEN OFFERED ANY RELIEF WITH THIS AS OF YET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00245	BAYER HEALTHCARE LLC	6/24/2014	7/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A95855

Single Use: Y
Implant Date (E6): 3/28/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A (B)(6) AND EXPERIENCED ESSURE TIP VISIBLY BENT AND BROKEN DURING THE PROCEDURE (COMPLICATION OF DEVICE INSERTION). STUDY DESCRIPTION: (B)(6). NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT DRUGS AND CONCURRENT CONDITIONS. ON (B)(6) 2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH LOT NUMBER A95855; AND THE ESSURE TIP VISIBLY BENT AND BROKEN DURING THE PROCEDURE. THE OUTCOME OF EVENTS WERE NOT PROVIDED. NO ASSESSMENT WAS GIVEN.

Manufacturer Narrative (H10):

COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE SUBJECT WHO WAS INVOLVED IN A (B)(6). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE TIP VISIBLY BENT AND BROKEN DURING THE PROCEDURE (COMP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00244	BAYER HEALTHCARE LLC	6/24/2014	7/14/2014

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSIO, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 5/23/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF BABY CONCEIVED IN 2012, DEVICE INEFFECTIVE, STATED ON NEAR 30 DAY HOSPITAL CONFINEMENT DUE TO PREGNANCY COMPLICATIONS, AND BABY BORN PREMATURE IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2007, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD A BABY CONCEIVED IN 2012 AFTER ESSURE PLACEMENT IN 2007. SHE STATED THAT ON NEAR 30 DAY HOSPITAL CONFINEMENT DUE TO PREGNANCY COMPLICATIONS AND BABY BORN PREMATURE, CORD WRAPPED AROUND NECK AFTER BIRTH AND ESSURE BABY WAS ADMITTED INTO HOSPITAL AS ABDOMEN WAS SWOLLEN WITH FLUID. REPORTER CAUSALITY: CONSUMER DID NOT PROVIDE THE RELATIONSHIP BETWEEN ALL THE EVENTS INITIALLY REPORTED AND ESSURE. LINKED CASE FOR THE BABY: (B)(4).

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED (B)(6) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. CASE CLOSED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2014. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00249	BAYER HEALTHCARE LLC	6/25/2014	7/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53031

Single Use:
Implant Date (E6): 5/7/2014
Explant Date (E7): 5/7/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENT. ON (B)(6)-2014, ESSURE WAS INSERTED FOR PERMANENT BIRTH CONTROL, LOT NUMBER B53031. THE PHYSICIAN NOTICED THAT WAS A SMALL PIECE OF METAL AT THE TIP THAT LOOKED LATERAL TO THE TUBE ON ONE COIL. PHYSICIAN BENT THE OTHER COIL SOMEHOW. PHYSICIAN REPORTED THAT BILATERAL PLACEMENT WAS NOT SUCCESSFUL, AND THAT THE PIECES WERE RETRIEVED. SHE REPORTED THAT THE PATIENT HAD NO INJURIES. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

THIS MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND EXPERIENCED "PROVIDER NOTICED THERE WAS A SMALL PIECE OF METAL AT THE TIP THAT LOOKED LATER TO THE T

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036915	BAYER	6/25/2014	7/2/2014

Event Information:

Event Date (B3): 5/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/3/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IMPLANT IN (B)(6) 2012, WITHIN A MONTH OF HAVING THIS IMPLANT, I STARTED EXPERIENCING VERY SHARP ABDOMINAL PAIN ON BOTH THE LOWER RIGHT AND LEFT SIDES. AT FIRST, IT WAS A FEW TIMES DURING THE DAY AND NOW IT IS SO CONSTANT THAT IT HAS BECOME A "NORMAL" CHRONIC PAIN I DEAL WITH DAILY. IN THE SUMMER OF 2013, I BEGAN TO HAVE EXCRUCIATING LOWER BACK PAIN SIMILAR TO WHEN I HAD BACK LABOR DURING MY PREGNANCY. THE PAIN WAS SO DEBILITATING, I THOUGHT I HAD A BAD KIDNEY INFECTION OR KIDNEY STONES. I WENT TO THE DOCTOR WHO RAN TESTS ONLY TO HAVE THE TESTS COME BACK WITH A SLIGHT UTI, BUT NOTHING THAT WOULD CAUSE SUCH HORRIBLE PAINS. AFTER THAT, THE BACK PAIN HAS CONTINUED TO BE A CONSTANT AGGRAVATION AND ALTHOUGH ONCE A MONTH, IT IS ALMOST UNBEARABLE, THE OTHER DAYS IT IS JUST LIKE THE PAINS THAT SHOOT THROUGH MY ABDOMEN BEARABLE BUT ALWAYS THERE. I TAKE IBUPROFEN DAILY SEVERAL TIMES JUST TO TOLERATE THE PAIN. IN (B)(6) 2013 I STOPPED HAVING A MONTHLY CYCLE UNTIL (B)(6) 2014 AT WHICH POINT I BLED UNTIL (B)(6). THE WEEK OF (B)(6), I TRIED TO DO SOME GARDENING AND WAS STOPPED IN THE PROCESS FROM THE EXCRUCIATING PAIN THAT SHOT THROUGH MY LOWER BACK AND DOWN MY LEGS. AT FIRST, I THOUGHT IT WAS JUST BEING INACTIVE BUT THE PAIN GREW AND BECAME MORE INTENSE AND LASTED FOR SEVERAL WEEKS, IT WAS THE SAME HORRIBLE PAIN I EXPERIENCED EVERY MONTH ONLY WORSE. IT TOOK MY BREATH AWAY AND I FELT I MAY BE PASSING A KIDNEY STONE OR HAD A SLIPPED DISC IN MY SPINE. THAT'S HOW BAD THIS PAIN FEELS. TWO WEEKS PRIOR TO (B)(6), I EXPERIENCED HORRIBLE CRAMPING AND JOINT PAIN. IT INTENSIFIED WITH EACH DAY AND ON (B)(6), I FINALLY HAD ANOTHER PERIOD AND THE PAIN HAS NOT STOPPED. I'VE TRIED HEATING PADS, COLD COMPRESSES EVERYTHING I CAN THINK OF AND NOTHING STOPS THIS EVER PRESENT PAIN I DEAL WITH DAILY. MY QUALITY OF LIFE IS SLOWLY DECLINING AND IN SUCH A SHORT TIME I'M NOT A

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PERSON WHO LIKES TO COMPLAIN AND I TRY HARD TO DEAL WITH MY PAIN, BUT ENOUGH IS ENOUGH, I CAN'T STAND THE FEELING EVERYDAY LIKE I AM FALLING APART AND IN PAIN. NOTHING SEEMS TO BE GOING AWAY. I'VE ALSO HAD DENTAL PROBLEMS THIS YEAR WITH AN ABSCESSED TOOTH AND GROWING SENSITIVITY. I'M ONLY (B)(6) YEARS OLD AND BEFORE I HAD THE ESSURE IMPLANTS, I REMEMBER FEELING WONDERFUL AND EXCITED ABOUT MY LIFE, NOW I AM IN CONSTANT PAIN AND FEEL MY BODY IS FALLING APART AND I DON'T HAVE ANY OTHER EXPLANATION BUT ESSURE. ALL OF MY TESTS COME BACK NEGATIVE, YET THIS IS NOT NORMAL TO FEEL THIS BAD EVERY DAY ALL DAY! IT'S NOT NORMAL. I AM COMPLETELY EMOTIONALLY EXHAUSTED FROM DEALING WITH THE PAIN AND DISCOMFORT. THERE IS NO OTHER EXPLANATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036916	CONCEPTUS, INC.	6/25/2014	7/2/2014

Event Information:

Event Date (B3): 11/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/5/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) 2008 AND HAVE HAD SEVERAL MEDICAL PROBLEMS SINCE THEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036919	BAYER	6/25/2014	7/2/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 694961

Single Use:
Implant Date (E6): 4/17/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN 2012. IT WAS PLACED UNDER GENERAL ANESTHESIA IN THE OPERATION ROOM. INITIALLY, I HAD MINIMAL DISCOMFORT THAT WAS RESOLVED WITHIN A WEEK. MY FOLLOW UP WAS UNREMARKABLE. I HAD MY HSG PERFORMED 3 MONTHS FOLLOWING. ONLY ONE TUBE WAS BLOCKED BUT BOTH COILS REMAINED IN PROPER PLACEMENT. I WAS TOLD THAT I WOULD NEED ANOTHER HSG TO ENSURE THAT I WAS EITHER BLOCKED COMPLETELY OR WOULD NEED TO HAVE ANOTHER SURGERY. AROUND (B)(6) 2013 BEGAN HAVING PREGNANCY SYMPTOMS. WEIGHT GAIN, MOOD SWINGS, MORNING SICKNESS, MY AREOLA DARKENED, AND I STARTED LACTATING. I WENT TO THE DOCTOR AND MY PREGNANCY TEST WAS NEGATIVE. AT THAT POINT I UNDERWENT ANOTHER HSG TO DETERMINE IF I WAS BLOCKED. THEY ENSURED ME THAT I WAS COMPLETELY BLOCKED IN BOTH TUBES. I BEGAN HAVING DEBILITATING PAIN IN MY ABDOMEN. INTERMITTENT AT FIRST THEN PROGRESSIVELY BECAME MORE CONSISTENT. AT TIMES IT FELT LIKE I WAS BEING STABBED. RADIATING PAIN FROM MY FLANK TO UMBILICUS WITH NO SOURCE OF RELIEF. WHEN I'M NOT HAVING BOUTS OF SHARP PAIN THERE IS A CONSTANT ACHE THROBBING IN MY ABDOMEN BILATERALLY. MY PERIODS BECAME IRREGULAR. THERE WERE TIMES WHEN I WOULD GO MONTHS WITHOUT A PERIOD AND MONTHS THAT I WOULD CONSTANTLY BLEED. I TALKED TO MY PHYSICIAN AND WAS TOLD IF IT CONTINUED I WOULD NEED AN ABLATION (CONTRAINDICATED WITH ESSURE). AS TIME PASSED I KNEW SOMETHING WASN'T RIGHT. I WAS A COMPLETELY HEALTHY WOMAN THAT WAS NOW STRUGGLING TO GET OUT OF BED BECAUSE OF PAIN, NAUSEA, AND FATIGUE. I WENT BACK TO MY DOCTOR AND SHE TOLD ME I WAS CONSTIPATED. GAVE ME MEDICATION TO HELP WITH THE VOMITING AND LOOSEN MY STOOL. AFTER FOLLOWING HER INSTRUCTIONS, NOTHING CHANGED. SO I FOUND A NEW DOCTOR. I HAD MY ANNUAL PAP AND WAS SCHEDULED FOR AN INTERNAL/EXTERNAL ULTRASOUND. WITHIN A FEW DAYS I RECEIVED A PHONE CALL TELLING

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ME THAT ONE OF MY COILS WAS IN MY UTERUS AND NOT MY TUBE. I AM SCHEDULED FOR SURGERY IN (B)(6). WHERE AT THE AGE OF (B)(6) WILL HAVE TO UNDERGO A HYSTERECTOMY. I'M STILL UNSURE AS TO WHAT MORE INTERNAL AND PERMANENT DAMAGE THEY WILL FIND. UNTIL THEN I WILL CONTINUE TO SUFFER FROM PAIN, NAUSEA, DAILY VOMITING, EXTREME BLOATING, AND FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036920	BAYER	6/25/2014	7/2/2014

Event Information:

Event Date (B3): 11/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/22/2013
Explant Date (E7): 1/24/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED AT THE DOCTOR OFFICE. IT WAS THE ABSOLUTE WORST PAIN DURING THE IMPLANTATION. I ACTUALLY CRIED DURING THE PROCEDURE. WHEN I LEFT THE OFFICE, I TOLD MY BOYFRIEND THAT I WOULD NEVER HAVE GONE THROUGH THIS IF I KNEW IT WOULD HURT SO BAD. THE PAIN JUST KEPT GETTING WORSE EACH DAY FROM THE IMPLANTATION. I WENT BACK TO THE IMPLANTATION DOCTOR WITHIN A WEEK. I ASKED HER TO PLEASE TAKE THIS PRODUCT OUT OF ME. THE IMPLANTATION DOCTOR ASSURED ME THE PAIN WOULD GET BETTER. HOWEVER, THE PAIN DID NOT STOP. THE PAIN IN MY BACK AND STOMACH WAS SO BAD THAT IT WAS HARD TO WORK, WALK, AND ENJOY THE SIMPLE THINGS LIKE TAKING A BIKE RIDE WITH MY CHILDREN. MY HAIR STARTED TO THIN AND FALL OUT. I STARTED TO GAIN WEIGHT. I CRIED ALL THE TIME BECAUSE SOMETHING THAT WAS PROMISED TO BE SO EASY, TURNED INTO A NIGHTMARE. THE ONLY THING THAT STOPPED THE PAIN WAS HAVING TO HAVE A HYSTERECTOMY. I AM (B)(6) AND HAD TO HAVE A HYSTERECTOMY. I HAD TO TAKE TIME OFF FROM WORK TO RECOVER, I HAVE HAD TO SPEND SO MUCH MONEY ON DOCTOR BILLS. I CAN'T EVEN KEEP UP WITH ALL THE BILLS I HAVE BECAUSE OF THIS HORRIBLE PRODUCT. I NOW HAVE TWO HORRIBLE SCARS ON MY STOMACH ALL BECAUSE I CHOSE TO HAVE ESSURE IMPLANTED IN ME. IT WAS THE WORSE DECISION OF MY LIFE AND SHOULD BE TAKEN OFF THE MARKET IMMEDIATELY. I BELIEVE THE ESSURE HAS LED TO OTHER HEALTH PROBLEMS THAT I AM NOW FACING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036820	BAYER	6/26/2014	6/26/2014

Event Information:

Event Date (B3): 9/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS NOT TOLD ABOUT THE NICKEL IN THE DEVICE. I DO NOT REACT WELL TO NICKEL. I HAVE A VERY PAINFUL CRAMPS. POSSIBLE CYSTS BUT NOT FOUND. ACHY BODY. HEADACHES. FOGGY MEMORY. PAINFUL INTERCOURSE. ALL OF A SUDDEN REACTING TO TAMPONS. EVERY MONTH I GET ITCHY SKIN DOWN THERE. PAINFUL JOINTS. BUMPS ON MY FACE. BAD CRAMPS. WEIRD PERIODS. (B)(4). UPDATE ON (B)(4) 2014: MY DOCTOR ALSO DID AN ABLATION TO HELP WITH THE BLEEDING AND CRAMPS. THE BLEEDING STOPPED BUT STILL HAVE HORRIBLE CRAMPS. THOUGHT AN ABLATION WASN'T SUPPOSE TO BE DONE WHEN YOU HAVE ESSURE?

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036822	BAYER	6/26/2014	6/26/2014

Event Information:

Event Date (B3): 1/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WENT IN FOR MY HSG TEST AND FOUND THAT BOTH ESSURE IMPLANTS HAD MIGRATED. (B)(4). UPDATE ON (B)(6) 2014: IMPLANTED (B)(6) 2011 - MIGRATION - HSG TEST (B)(6) 2012 - TUBAL AND REMOVAL OF COILS SCHEDULED FOR (B)(6) 2012.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036824	BAYER	6/26/2014	6/26/2014

Event Information:

Event Date (B3): 12/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING CORRECTIVE 2ND NOVASURE UTERINE ABLATION MANDATORILY, IMPLANTED ESSURE. 4 MONTHS LATER I DEVELOPED AURA MIGRAINES AND WAS HOSPITALIZED FOR 3 DAYS . 2013 SEVERE STOMACH BLOATING AND TENDERNESS IN PELVIC REGION. PAINFUL PELVIC CRAMPS WHEN BLADDER IS FULL ESPECIALLY AT NIGHT (AWAKEN FROM PAIN) AFTER RELIEF PELVIC REGION REMAINS IN PAIN. SUFFERER FROM HEART PALPITATIONS IRON TASTE IN MOUTH AND FATIGUE. LATTER 2013 SUFFER FROM INCONTINENCE. (B)(4). UPDATE ON (B)(6) 2014: HOSPITAL RECORD NUMBER (B)(6) ON (B)(6) 2014 I WAS DIAGNOSED WITH 4 LARGE UTERINE FIBROIDS. ESSURE COILS NOT PRESENT IN FALLOPIAN TUBES AND ARE MISPLACED IN THE MYOMETRIUM AND ENDOMETRIUM, UTERUS. DEGENERATIVE BONE DISEASE LOWER SPINE L5 OSTEOARTHRITIS. ANXIETY GIVEN .5 LORAZEPAM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036825	BAYER	6/26/2014	6/26/2014

Event Information:

Event Date (B3): 12/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE IMPLANTS OF ESSURE, I HAVE HAD PAIN IN THE PELVIC AREA/STOMACH AREA. THE PAIN WOULD COME AND GO WITH SOME MONTHS BEING WORSE THAN OTHERS. FOR THE PAST COUPLE OF YEARS, THE PAIN HAS GOTTEN WORSE ALONG WITH NEW SYMPTOMS APPEARING. FOR INSTANCE, PAINFUL INTERCOURSE, SPOTTING IN BETWEEN PERIODS, HAIR LOSS, MUSCLE TWITCHING, BURNING TONGUE, METALLIC TASTE IN MOUTH, SORE MUSCLES, LACK OF LIBIDO, HEADACHES, FEELING BLOATED CONSTANTLY, DEVELOPMENT OF FIBROIDS, FATIGUE, SWELLING OF HANDS, NUMBNESS IN LIPS, RINGING AND PRESSURE IN EARS, EAR ACHES, NUMBNESS IN THIGH, STABBING PAINS IN VAGINAL AREA, HEIGHTENED ALLERGIES, VISION FLOATERS, NIGHT SWEATS, DRY SKIN AND EYES, BLEEDING AFTER INTERCOURSE, BREAST PAIN, BACK PAIN, AND HIP PAIN. DECEMBER OF 2012, MY DOCTOR IMPLANTED THE MIRENA TO HELP WITH SYMPTOMS. THIS BACKFIRED BY INCREASING SYMPTOMS AND HAD TO BE REMOVED 4.5 MONTHS LATER. (B)(4). UPDATE ON (B)(6) 2014: ON (B)(6), 2014 MY DOCTOR PERFORMED A HYSTERECTOMY TO REMOVE FALLOPIAN TUBES, COILS, UTERUS, AND CERVIX. HEADACHES, METAL TASTE, SORE MUSCLES, HEADACHES, BLOATED FEELING, EAR PRESSURE, EAR ACHES, NUMBNESS IN THIGH, STABBING PAINS, INCREASED ALLERGIES, BREAST PAIN, BACK PAIN ARE GONE. I AM STILL HOPEFUL THAT THE REST OF MY SYMPTOMS WILL DISAPPEAR. EVEN AFTER SURGERY, I HAVEN'T FELT THIS GOOD IN ALL THE YEARS WITH ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036835	BAYER	6/26/2014	6/26/2014

Event Information:

Event Date (B3): 1/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DEVELOPED A RASH THAT ITCHES REALLY BAD, I HAVE BEEN BLEEDING NON STOP AND PASSING HEAVY BLOOD CLOTS, MY FEET HAVE BEEN SWELLING, I HAVE BEEN HAVING SHARP PAIN ON MY RIGHT SIDE THAT FEELS LIKE SOMETHING IS STABBING ME ON THE INSIDE NEAR MY UTERUS AND OVARIES, I HAVE PAIN DURING SEX I CAN'T STAND IT. (B)(4) UPDATE ON (B)(4) 2014: NOW I AM HAVING A HYSTO ON MONDAY (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036908	CONCEPTUS/BAYER	6/26/2014	7/2/2014

Event Information:

Event Date (B3): 2/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 2/22/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2011, I HAD ESSURE IMPLANTED. SINCE THAT TIME, I HAVE NOTICED SEVERAL DIFFERENT SIDE EFFECTS. SEVERE ABDOMINAL CRAMPING, SHARP STABBING PELVIC PAIN, VAGINAL DISCHARGE, EXCESSIVE BLEEDING DURING MY MENSTRUAL CYCLE, PAINFUL MENSTRUATION, PAINFUL INTERCOURSE, INCONTINENCE, ABDOMINAL SPASM, BACK PAIN, SEVERE BLOATING, METALLIC TASTE, HEARTBURN, HEADACHES, SWELLING AND TINGLING OF HANDS AND FEET, MOOD SWINGS, FORGETFULNESS, HIGH BLOOD PRESSURE, ACNE, HAIR LOSS, TEETH DECAY AND LOSS, WEIGHT GAIN, AND EXCESSIVE SWEATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036909	CONCEPTUS INC	6/26/2014	7/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSUR
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 841859

Single Use:
Implant Date (E6): 2/10/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE DONE IN (B)(6) 2012. WITHIN WEEKS, I BEGAN TO HAVE SEVERE MIGRAINE HEADACHES, USUALLY HEAVY MENSTRUAL FLOW, SPOTTING BETWEEN MENSTRUAL CYCLES, AND FREQUENT UTI'S AND YEAST INFECTIONS. WITHIN 4 MONTHS OF HAVING THE DEVICES IMPLANTED, I GAINED 40 POUNDS WITHOUT HAVING CHANGED MY LIFESTYLE HABITS. THE SYMPTOMS GRADUALLY GOT WORSE: SHARP, STABBING PAINS AND CRAMPING IN MY ENTIRE PELVIC REGION; UNEXPLAINED HOT FLASHES (I AM ONLY IN MY EARLY (B)(6)) ; PAIN IN JOINTS THROUGHOUT MY BODY; SEVERE INSOMNIA; CHRONIC FATIGUE; HEART PALPITATIONS; DIZZINESS; MEMORY PROBLEMS; NUMBNESS AND TINGLING IN MY EXTREMITIES (PARTICULARLY MY FINGERTIPS AND TOES); LOWER PACK PAIN; CHES PAIN; PAIN IN MY LEFT SHOULDER AND ARM; AND RECURRING BOWEL PROBLEMS. I HAD NOT TIED, THE SYMPTOMS I HAD BEEN HAVING TO THE ESSURE IMPLANTS AT FIRST. I VISITED MY DOCTOR AND SHE ORDERED SOME LAB TESTS: ALL MY BLOOD WORK CAME BACK AS COMPLETELY NORMAL. I CONTINUED TO STRUGGLE WITH THESE "MYSTERIOUS" SYMPTOMS WITH NO RELIEVE AND NO ANSWERS FOR OVER TWO YEARS. ON (B)(6), I STUMBLED UPON A SUPPORT GROUP CALLED "ESSURE PROBLEMS" AND READ THAT THERE WERE SEVERAL WOMEN WHO WERE ALL EXPERIENCING THE SAME SYMPTOMS AS I WAS. I CONTINUED TO DO RESEARCH OVER THE NEXT FEW MONTHS AND I FOUND THAT THE PROBLEMS I WAS HAVING WERE ALL ADVERSE SIDE EFFECTS OF ESSURE. I PLAN TO VISIT MY OB/GYN AND DISCUSS POSSIBLE REMOVAL OF THE IMPLANTS, BECAUSE I FEEL I HAVE SUFFERED WITH THIS CHRONIC PAIN LONG ENOUGH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036837	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 2/24/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY HUSBAND AND I DECIDED TO FOLLOW THROUGH WITH THE ESSURE PROCEDURE AFTER LOOKING INTO MULTIPLE OPTIONS. EVERYTHING WE READ LOOKED AS IF THIS WOULD BE AN EASY PROCEDURE THAT WOULD NOT REQUIRE HOSPITALIZATION. I CALLED THE ESSURE HOTLINE AND THEY PROVIDED ME A LIST OF DOCTORS IN OUR ARE WHO PERFORM THE PROCEDURE AND ASKED ABOUT MY NICKEL ALLERGY. I WAS TOLD THAT I WOULD HAVE NO PROBLEM AS THIS DEVICE DOES NOT CONTAIN NICKEL. I THEN MADE A DOCTORS APPOINTMENT AND MY HUSBAND AND I HAD OUR CONSULT. WE ADDRESSED OUR CONCERNS MAINLY MY SEVERE ALLERGY TO NICKEL. I WAS AGAIN TOLD THE PRODUCT DOES NOT CONTAIN NICKEL. MY HUSBAND AND I DECIDED TO MAKE AN APPOINTMENT AND FOLLOW THROUGH WITH THE PROCEDURE. THE NIGHT THE PROCEDURE WAS PERFORMED I REMEMBER BLEEDING A LOT. I WAS IN SO MUCH PAIN I WAS THROWING UP. THE NEXT FEW DAYS I MADE CALLS TO BOTH THE DOCTOR AND ESSURE HOTLINE CONCERNED ABOUT THE BURNING SENSATION I WAS HAVING AND THE AMOUNT OF BLOOD I WAS STILL LOOSING. I WAS SOAKING THROUGH THICK PADS EVERY HOUR AND PASSING HUGE BLOOD CLOTS THE SIZE OF GUMBALLS. THE ESSURE HOTLINE ADVISED ME THIS WAS NOT NORMAL TO CONTACT MY DOCTOR AGAIN. THE DOCTORS OFFICE SAID TO KEEP AN EYE ON IT, IT WOULD GET BETTER. FOUR WEEKS OF SOAKING THROUGH PADS EVERY HOUR IT SEEMED TO GET A LITTLE BETTER. THE BURNING NEVER WENT AWAY. I GOT THE HSG TEST DONE AT 3 MONTHS THAT CONFIRMED BLOCKAGE. AFTER A FEW MONTHS MY ENERGY HAD DECREASED DRASTICALLY, I WAS SLEEPING CONSTANTLY. MY MIGRAINES GOT TO THE POINT I WAS UNABLE TO FUNCTION FOR DAYS ON END. I FELT AS IF I WAS LIVING IN A FOG. I COULDN'T LIFT ANYTHING HEAVY RUN AROUND WITH MY KIDS BE THE FUN LOVING MOTHER THAT I WAS JUST A FEW MONTHS PRIOR. I WENT TO WORK 3 DAYS A WEEK AND WOULD GO FROM THE BED TO THE COUCH. I HAD NO DESIRE TO DO ANYTHING AT ALL WHATSOEVER. MY PERIODS PRIOR TO

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ESSURE LASTED 3 DAYS AT MOST AND WERE SUPER LIGHT. NEVER HAD EMOTIONAL PERIODS, NEVER HAD ANY CRAMPING, BLOATING, FATIGUE DURING THEM. AFTER ESSURE THEY WOULD LAST ANYWHERE FROM 7-20 DAYS. THICK BLOOD CLOTS AND HEAVY BLEEDING SOAKING THROUGH SUPER PLUS TAMPONS AND PADS TOGETHER EVERY HOUR OR TWO. CRAMPING, BLOATING TO THE POINT I LOOKED PREGNANT. I WAS AN EMOTIONAL DISASTER, I WAS A CRYING SOBBING MESS WHICH IS JUST NOT WHO I AM!! THE BACKACHES AND TENDERNESS IN MY THIGHS, CRAMPING, BLOATING, HEADACHES, BLURRED VISION, "EYE GUNK", WEIGHT GAIN, CHRONIC FATIGUE, FOOT CRAMPS, MUSCLE TIGHTNESS AND TENDERNESS, RASH, BRAIN FOG, BOWEL ISSUES, DIGESTION ISSUES, MEMORY LOSS, FORGETFULNESS, LACK OF MOTIVATION AND THE LIST GOES ON AND ON. BASICALLY I QUICKLY BECAME THE WORLDS WORST MOM AND WIFE IN THE MATTER OF A YEAR. THE FUN LOVING, ACTIVE, ENERGETIC MOM AND WIFE HAD BECOME AN EMOTIONAL MESS WITH NO ENERGY OR DRIVE TO DO ANYTHING. I WENT IN FOR A CHECK UP AND FINALLY GOT MY DOCTOR TO LISTEN TO ME WHEN I SAID I WAS ABSOLUTELY MISERABLE, I WAS TOLD I WAS TOLD IT WAS DEPRESSION AND ADVISED I SHOULD BE MEDIATED (I REFUSED). ANOTHER YEAR WENT BY, I IGNORED THE ISSUES AND TRIED TO MOVE ON AS IF THIS IS JUST WHAT LIFE HAD BECOME AS THE DOCTORS DIDN'T BELIEVE ME ANYWAYS... MY YEARLY PAP CAME AROUND I TALKED WITH THE DOCTOR ABOUT THE PROTRUSION ON MY LEFT SIDE (YOU COULD SEE THE IRRITATION OUTSIDE OF MY SKIN WHERE MY FALLOPIAN TUBES WERE) THAT WAS GETTING WORSE AND MUCH MORE PAINFUL. THE BURNING AND STINGING CONSTANTLY WAS TO THE POINT I COULD HARDLY BEAR IT ANY LONGER. HE FINALLY SET UP AN ULTRASOUND. A FEW DAYS LATER I GOT A LETTER IN THE MAIL SAYING THEY FOUND ABNORMAL CELLS THAT WOULD REQUIRE FURTHER EXAMINATION. I HAD NEVER HAD AN ABNORMAL PAP. I WAS IN SHOCK! I RESCHEDULED MY ULTRASOUND AND WENT IN FOR A COLPOSCOPY INSTEAD. MISERABLE AND PAINFUL THE DOCTOR SENT AWAY THE CELLS TO BE BIOPSIED. TWO DAYS LATER WENT IN FOR MY ULTRASOUND. THE DOCTOR SAID HE HAD THE RESULTS OF MY COLPOSCOPY AND WOULD DISCUSS THEM AFTER THE ULTRASOUND. HE ADVISED THAT WITH ALL OF THE PAIN AND WITH THE RESULTS OF THE ABNORMAL CELLS I SHOULD HAVE A FULL HYSTERECTOMY CERVIX UTERUS AND FALLOPIAN TUBES ONLY LEAVING MY OVARIES. MY HEART SANK. I'M ONLY (B)(6), WHAT HAPPENED? I KEPT IT TOGETHER LONG ENOUGH TO FINISH MY ULTRASOUND AND LEAVE THE OFFICE. I LOST IT. I CALLED MY HUSBAND IN UTTER DISBELIEF. ESSURE RUINED MY LIFE AND BECAUSE OF IT I NOW HAVE TO UNDERGO MAJOR SURGERY AND LOOSE EVERY BIT OF WHAT MADE ME A WOMAN AND A MOTHER. I GOT A CALL FROM THE HOSPITAL SAYING THAT MY SURGERY WOULD BE IN LESS THAN A MONTH AS THE DOCTOR WANTED EVERYTHING OUT ASAP. THAT NIGHT DECIDED TO DO SOME RESEARCH.. TO MY SURPRISE NICKEL WAS TAKEN OFF OF THEIR LABELING... IN 2012. GO FIGURE. I WAS LIED TO, BY BAYER, BY ESSURE, BY MY DOCTOR. AS I TRIED TO COMPREHEND WHAT HAD HAPPENED OVER THE LAST 2 YEARS I FELL IN A RUT. IT AS A LONG FEW WEEKS... WAKING UP IN THE RECOVERY ROOM AFTER MY HYSTERECTOMY (I ONLY HAVE MY OVARIES) I CANNOT EXPLAIN HOW AMAZING I FELT. THE PAIN WAS UNREAL BUT I COULD SEE... CLEARLY AND WAS ABLE TO LISTEN AND FOCUS ON WHAT MY HUSBAND WAS TELLING ME, AND I REMEMBERED IT. THE BRAIN FOG WAS GONE! I FELT ALIVE AGAIN LIKE A BRAND NEW WOMAN. I KNEW I HAD A VERY LONG ROAD AHEAD OF ME, BUT I WAS BACK. SIX PLUS MONTHS LATER AND I AM FINALLY FEELING AS IF I AM GOING TO BE OK. THE ROAD TO RECOVERY HAS BEEN LONG! I HAD MAJOR DIGESTION AND BOWEL ISSUES THAT I AM STILL BATTLING. MY VISION IS STARTING TO CORRECT ITSELF. I HAVE ENERGY, I AM ACTIVELY INVOLVED AS A MOTHER AND WIFE LIKE I USED TO BE. I LOST ALL OF THE WEIGHT I HAD GAINED WITH ESSURE IN LESS THAT 2 WEEKS! BLOATING, FATIGUE, FORGETFULNESS, GONE! I STILL SUFFER WITH MIGRAINES AND MAJOR BREAKOUTS AS BY BODY IS STILL FIGHTING TO PUSH OUT THE NICKEL. I AM STILL DEALING WITH HORMONAL IMBALANCE ALONG WITH PERFUSE SWEATING. BUT I'M ON THE MEND. ESSURE STOLE PRECIOUS TIME AWAY FROM MY LOVED ONES, IT CAN NEVER BE REPLACED. I WILL NEVER BE ABLE TO RECREATE THE MEMORIES ALONG WITH THE ONES I AM UNABLE TO NOW REMEMBER DUE TO ESSURE. THIS HAS CHANGED MY LIFE IN WAYS NO ONE WILL EVER BE ABLE TO UNDERSTAND. I KNEW I WAS NEVER GOING TO HAVE ANOTHER CHILD WHEN WE CHOSE TO GET ESSURE, BUT BEING

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FORCED TO HAVE A HYSTERECTOMY DUE TO ESSURE IT STOLE A PIECE OF MY HEART THAT DAY. THE EMOTIONAL BAGGAGE THAT CAME ON THAT DAY IS A HARD PILL TO SWALLOW. I DON'T SEE HOW THIS PRODUCT IS STILL ON THE MARKET... (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036838	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE DONE IN (B)(6) 2014 FOR PERMANENT BIRTH CONTROL. SINCE (B)(6) 2014 I HAVEN'T GOTTEN A PERIOD, DOCTOR PUT ME ON PROVERA TO BRING ON PERIOD (NOTHING). NOW HE WANTS TO PUT ME ON BIRTH CONTROL TO TRY TO BRING ON PERIOD. I HAVE GAINED WEIGHT , AM FATIGUED, HAVE BODY RASH AND HAVE PAIN ON MY LOWER RIGHT SIDE. WANT TO HAVE THESE TAKEN OUT. VERY MISINFORMED. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036839	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 8/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I HAD ESSURE IMPLANTED I STARTED GAINING WEIGHT FOR NO REASON. I ALSO STARTED HAVING JOINT PAIN, SWELLING, TENDONITIS (ACHILLES, BOTH ELBOWS, AND A SHOULDER). I TORE TENDONS IN BOTH HIPS WHILE DOING NOTHING OUT OF THE ORDINARY. MY ACHILLES TENDONITIS CAUSED A BONE SPUR ON MY HEEL. I HAD YEAST INFECTIONS THAT WOULD NOT GO COMPLETELY AWAY. I STARTED TO HAVE LOW ENERGY, AND BRAIN FOG. I COULD ACCOMPLISH WHAT I DID PREVIOUSLY. I HAD SEVERELY ITCHY RASHES THAT WOULD KEEP ME AWAKE ALL NIGHT. I HAD SINUS PRESSURE WHICH CAUSED TOOTH PAIN. I WENT FROM BEING A VERY FIT AND HEALTHY MOTHER, TEACHER, TRIATHLETE, TO BEING IN CONSTANT PAIN, AND NOT ACCOMPLISHING MUCH. I RECENTLY HAD A HYSTERECTOMY AND WITHIN TWO DAYS, THE JOINT PAIN, TOOTH PAIN AND RASHES WERE GONE. I AM WAITING TO SEE IF THE TENDONITIS HEALS ON IT'S OWN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036840	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 4/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DAY I HAD ESSURE PLACED MY WHOLE BODY HURT AFTERWARDS, I COULDN'T EVEN LAUGH WITHOUT HURTING. IN THE NEXT 2 DAYS THE PAIN WENT AWAY BESIDES MY LEG PAIN. I STILL HAVE LEG PAIN TO THIS DAY A YEAR LATER. BLOATING IS HORRIBLE! I'VE NEVER BLOATED LIKE THIS IN MY ENTIRE LIFE. MY HAIR IS FALLING OUT LIKE CRAZY ALL OF A SUDDEN, I ALSO GAINED A LOT OF WEIGHT SINCE I HAD ESSURE PLACED. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036841	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 4/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED ON (B)(6) 2013 THEY WERE ONLY ABLE TO PLACE ONE COIL. THIS PLACEMENT TOOK OVER TWO HOURS, ON (B)(6) MY BODY EVICTED THE COIL. WHEN THIS HAPPENED IT CAUSED BLEEDING AND SERIOUS PAIN FOR 6 WEEKS. ON (B)(6) I HAD A TUBAL LIGATION DONE DUE TO THE FAILURE OF THE ESSURE I WOULD NEVER RECOMMEND THIS PRODUCT TO ANY WOMAN OR ANIMAL. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036842	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 4/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED ON (B)(6) 2013 THEY WERE ONLY ABLE TO PLACE ONE COIL. THIS PLACEMENT TOOK OVER TWO HOURS, ON (B)(6) MY BODY EVICTED THE COIL. WHEN THIS HAPPENED IT CAUSED BLEEDING AND SERIOUS PAIN FOR 6 WEEKS. ON (B)(6) I HAD A TUBAL LIGATION DONE DUE TO THE FAILURE OF THE ESSURE I WOULD NEVER RECOMMEND THIS PRODUCT TO ANY WOMAN OR ANIMAL. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036843	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 6/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING CHRONIC MIGRAINES , PELVIC PAIN, PAIN WHEN SITTING, STANDING. WEIGHT GAIN. IN PAIN SINCE DAY 1 OF THIS ESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036844	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 5/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALMOST IMMEDIATELY AFTER INSERTION I STARTED HAVING STABBING PAIN IN MY LEFT SIDE WHICH BECAME A CONSTANT NAGGING PAIN. I ALSO DEVELOPED RASHES ALL OVER MY BODY. I GAINED AN EXCESSIVE AMOUNT OF WEIGHT IN A VERY SHORT TIME, HAD CONSTANT ABDOMINAL BLOATING, AND PERIODS SO HEAVY THAT EVEN WITH A PAD AND TAMPON I WAS STILL HAVING TO CHANGE EVERY HOUR. I STARTED HAVING CHRONIC HEADACHES, SEVERE FATIGUE AND INSOMNIA (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036845	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOLLOW UP TO (B)(4). I STARTED OUT WITH A RASH/ HIVES. (THE RASH ON MY FACE HAS NEVER GONE AWAY COMPLETELY) THEN CAME THE INFECTIONS URINARY TRACT, KIDNEY INFECTIONS EVERY MONTH. PAINS IN MY STOMACH THAT WERE NEVER DIAGNOSED. CYSTS IN THE VAGINAL AREA THAT HAD TO BE SURGICAL REMOVED. HAD NUMEROUS TESTS THEY FOUND PALYPS IN MY INTESTINES. HEADACHES, MY MENSTRUAL CYCLE WHICH WASN'T PAINFUL WAS NOW EXTREMELY BLOODY AND UNBEARABLE!!!! NEXT CAME THE HORRIBLE ACHEY PAINS IN MY JOINTS AND EXTREME FATIGUE. I USED TO BE A COMPLETELY HEALTHY PERSON. I HAVE BEEN DIAGNOSED WITH RA AND SOMETHING LUPUS ANTIBODIES??? NOBODY ON EITHER SIDES OF MY FAMILY HAVE THIS DISEASE! I'VE HAD A HYSTERECTOMY SINCE, BUT MY SYMPTOMS REMAIN! (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036846	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 10/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DAILY PAIN ON MY RIGHT SIDE NAUSEA AND FEELING SICK EVERY DAY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036847	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 4/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING PAINFUL MENSTRUATION EVERY 2 WEEKS, WHEN I WAS REGULAR EVERY 28 DAYS BEFORE SURGERY. I WAS DIAGNOSED AS HAVING FIBROIDS, DIDN'T HAVE BEFORE PROCEDURE. I AM CONSTANTLY HAVING ABDOMINAL PAIN, TO THE POINT WHERE I CAN NOT BE SEXUALLY ACTIVE WITH MY PARTNER, WHICH HAS PUT A STRAIN ON OUR RELATIONSHIP. NOW AFTER HAVING THE ESSURE FOR 6 YEARS I AM NOW PREGNANT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036848	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 6/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DON'T HAVE A DATE THE PROCEDURE WAS DONE, BUT IT WAS IN 2008 ACCORDING TO MY CARD. IN 2009 I DEVELOPED CHRONIC PAIN, FATIGUE, NAUSEA, AND CONSTANT LOW LEVEL PAIN IN MY ABDOMEN. I'VE HAD CHRONIC UTIS IN THAT TIME, AS WELL AS MIGRAINES. MY PERIODS STOPPED COMPLETELY LAST YEAR. THE PATH TO DIAGNOSIS STOPPED WHEN I LOST MY INSURANCE ALONG WITH MY JOB THAT I WAS IN TOO MUCH PAIN TO WORK. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036849	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 6/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DON'T HAVE A DATE THE PROCEDURE WAS DONE, BUT IT WAS IN 2008 ACCORDING TO MY CARD. IN 2009 I DEVELOPED CHRONIC PAIN, FATIGUE, NAUSEA, AND CONSTANT LOW LEVEL PAIN IN MY ABDOMEN. I'VE HAD CHRONIC UTIS IN THAT TIME, AS WELL AS MIGRAINES. MY PERIODS STOPPED COMPLETELY LAST YEAR. THE PATH TO DIAGNOSIS STOPPED WHEN I LOST MY INSURANCE ALONG WITH MY JOB THAT I WAS IN TOO MUCH PAIN TO WORK. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036850	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 6/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING PAIN FOR TWO YEARS AND LAST NIGHT "SOMETHING" IN MY VAGINA CUT MY HUSBANDS PENIS. HE HAS AN INCH LONG CUT ON THE SHAFT OF HIS PENIS AND IT HAPPENED DURING SEX. THE ONLY SHARP OBJECT IN ME IS ESSURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036851	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 6/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NICKEL ALLERGY, PAIN IN LOWER BACK, PAIN IN LOWER ABDOMEN , SEVERE BLEEDING, SEVERE CRAMPING, DIAGNOSED WITH ENDOMETRIOSIS, ACNE, SWELLING ALL OVER, MOOD SWINGS, HEAD ACHES, FATIGUE, LOSS OF HAIR, BLOATING AND WEIGHT GAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036852	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 2/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE MY ESSURE WAS IMPLANTED IN (B)(6) 2013 I HAVE BEEN EXPERIENCING HORRIBLE PAIN ALL AROUND THE CENTER OF MY BODY. MOSTLY LOWER ABDOMEN AND BACK. I HAVE ALSO BEEN EXPERIENCING MAJOR HEADACHES AND SHOULDER AND KNEE PAIN ON THE LEFT SIDE OF MY BODY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036853	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 4/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON GOING DEBILITATING PAIN. CHRONIC FATIGUE, FIBROMYALGIA, SWOLLEN JOINTS, HAIR LOSS, SEVERE ABDOMINAL PAIN, ALLERGIES DEVELOPED FROM ALCOHOL TO NICKEL AND SEVERAL OTHERS. MIGRAINES, BLOATING THAT IS PAINFUL, TEETH DETERIORATION... ALSO WAS ELECTROCUTED AND ENHANCED BC OF ESSURE COILS. TACHYCARDIA. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036854	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 6/11/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

METAL-LIKE TASTE IN MOUTH, MUSCLE PAIN, MOODY, BRAIN FOG, ALLERGIES WORSENED, DIZZY UPON STANDING. (B)(4). UPDATE ON (B)(6) 2014: SENSITIVITY TO MILK AND MILK PRODUCTS...MAKE ME GASSY AND IRRITABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036855	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALMOST IMMEDIATELY AFTER HAVING ESSURE PLACED MY MENSTRUAL CYCLE BECAME VERY IRREGULAR, HEAVY, AND DOUBLED IN THE TIME. MY MONTHLY CYCLE LASTS AT LEAST 2 WEEKS IF NOT LONGER. THE LONGER THE COILS ARE IN THE MORE I NOTICE. I DEVELOPED FIBROMYALGIA DUE TO THE COILS. MY TEETH HAVE BEEN ROTTING AND BREAKING AND HAVE HAD MANY PULLED. MOOD SWINGS, IRRITABILITY, SEVERE ABDOMINAL CRAMPING WITH MENSTRUATION, ABNORMAL PAP. DEPRESSION. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036856	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 8/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MONTHLY CYCLES STARTED AND WOULD LASTED FOR 2 WEEKS AND REOCCUR A WEEK AND A HALF TO TWO WEEKS LATER. EXTREMELY PAINFUL IN THE CROTCH AND HEAVY HEAVY BLEEDING THE FIRST FEW DAYS. BLEEDING AND VERY PAINFUL EVERY TIME HAVE INTERCOURSE. CHRONIC PAIN IN RIGHT PELVIC BONE MAKING IT HARD TO WALK OR MOVE WHILE SLEEPING. PAINFUL OVULATION ON THE SIDE OVULATING AND BAD PAIN IN LOWER BACK. PAINFUL HEADACHES MAKING IT DIFFICULT TO WORK DUE TO SENSITIVITY TO NOISE AND LIGHT. SIDE EFFECTS SEEMED TO GET WORSE EACH DAY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036857	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 8/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MONTHLY CYCLES STARTED AND WOULD LASTED FOR 2 WEEKS AND REOCCUR A WEEK AND A HALF TO TWO WEEKS LATER. EXTREMELY PAINFUL IN THE CROTCH AND HEAVY HEAVY BLEEDING THE FIRST FEW DAYS. BLEEDING AND VERY PAINFUL EVERY TIME HAVE INTERCOURSE. CHRONIC PAIN IN RIGHT PELVIC BONE MAKING IT HARD TO WALK OR MOVE WHILE SLEEPING. PAINFUL OVULATION ON THE SIDE OVULATING AND BAD PAIN IN LOWER BACK. PAINFUL HEADACHES MAKING IT DIFFICULT TO WORK DUE TO SENSITIVITY TO NOISE AND LIGHT. SIDE EFFECTS SEEMED TO GET WORSE EACH DAY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036858	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 6/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS GOING TO GO GET A BALL THAT ROLLED PAST THE KIDS AND I WAS WALKING, GRASS WAS DRY, ALL OF A SUDDEN - MY BODY LITERALLY FROZE - I HAD NO CONTROL OVER ARMS, LEGS, NECK, HEAD AND I FELL VERY AWKWARDLY TO THE GROUND. TODAY I HURT ALL OVER. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036859	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 8/4/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME STOMACH PAIN, STIFFNESS OF LEGS, HOSPITALIZATION, EXTREME DISCOMFORT DURING SEX. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036860	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 6/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ALLERGIES, MIGRAINES, PAIN IN LOWER BACK, PAIN IN RIGHT SIDE OF THE ABDOMEN, HAIR LOSS, ACNE, GAIN WEIGHT, SWOLLEN FEET, MENSTRUAL PROBLEMS, DEPRESSION. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036861	BAYER	6/27/2014	6/27/2014

Event Information:

Event Date (B3): 4/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HORRIBLE CRAMPING, DEPRESSION, ABDOMINAL PAIN, BACK PAIN, CONTINUOUS BLEEDING, HAIR LOSS, GYNECOLOGICAL IRRITATIONS, UTI, YEAST INFECTIONS, BLADDER INFECTIONS, FATIGUE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037017	BAYER	6/27/2014	7/7/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE IMPLANTED 3 MONTHS AGO. I HAVE EXPERIENCED EXTREME FATIGUE, FREQUENT HEADACHES, NIGHT SWEATS, ABDOMINAL PAINS, CRAMPING, MUSCLE SPASMS, HAIR LOSS, AND CAN NOT REMEMBER TO COMPLETE TASKS. THIS DEVICE HAS DEFINITELY HAD SEVERE SIDE EFFECTS ON MY HEALTH AND OVER ALL WELL BEING. I CAN'T EVENT FUNCTION DAILY BETWEEN THE FATIGUE AND MEMORY LOSS I HAVE EXPERIENCED SINCE ABOUT 2 WEEKS POST PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037019	BAYER	6/27/2014	7/7/2014

Event Information:

Event Date (B3): 8/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/23/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED (B)(6) 2012. I HAVE EXPERIENCED RASH, HORRIBLE BACK PAIN WITH PAIN UNDER MY RIBS, LIGHTHEADEDNESS, MOOD SWINGS, FIBROIDS WHERE THE TUBE IS, ENDOMETRIOSIS. I NOW HAVE TO HAVE SURGERY NEXT MONTH TO REMOVE IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037020	CONCEPTUS	6/27/2014	7/7/2014

Event Information:

Event Date (B3): 2/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): NA
Lot #(E4): A64633

Single Use:
Implant Date (E6): 2/25/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PRODUCT IMPLANTED IN (B)(6) 2013. SINCE IMPLANTING, PERIODS HAVE BECOME SO HEAVY I HAVE HAD TO GO TO THE EMERGENCY ROOM NUMEROUS TIMES DUE TO FAINTING AND SERIOUS PAIN. I CONSTANTLY FEEL SEVERE CRAMPING, ESPECIALLY DURING SEX; WHICH IS NOW ALMOST IMPOSSIBLE AND NO LONGER ENJOYABLE. THERE HAVE BEEN DAYS I HAD TO LEAVE WORK EARLY BECAUSE OF THE PAIN. A LOT OF THE TIME IT FEELS LIKE A STABBING PAIN, ALMOST LIKE SOMEONE IS SHOVING A KNIFE THROUGH MY ABDOMEN AND TWISTING IT VIGOROUSLY. MIGRAINES HAVE STARTED AND SEEM TO GET WORSE AS TIME GOES ON. DID I MENTION THE CONSTANT PAIN. THERE IS ALSO A LOT OF ABDOMINAL SWELLING, SOME DAYS IT LOOKS AS THOUGH I AM 3 OR 4 MONTHS PREGNANT. THIS PRODUCT HAS CAUSED ME NOTHING BUT DISCOMFORT, PAIN, STRESS, ANGER, AND BORDERLINE DEPRESSION. HOW IN GOD'S NAME IT WAS ABLE TO BE CLASSIFIED AS A LIFESAVING DEVICE IS BEYOND ME. IT'S BIRTH CONTROL, OR STERILIZATION, THE ONLY THING IT HAS DONE IS RUINED MY LIFE. AND MY HUSBAND'S, AND MY CHILDREN'S, AND WHILE WE ARE AT IT, PROBABLY MY BOSS'S TOO SINCE I'M ALWAYS GONE FROM WORK. PLEASE RE-THINK THIS CLASSIFICATION SO THOSE OF US WHO HAVE SUFFERED CAN AT THE LEAST HAVE THE SURGERY EXPENSES COVERED TO REMOVE THESE PIECES FROM OUR BODIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037021		6/27/2014	7/7/2014

Event Information:

Event Date (B3): 5/6/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/6/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE TUBAL DONE ON (B)(6) 2011. SINCE THEN I HAVE HAD CHRONIC MIGRAINES, CHEST PAINS, WEIGHT GAIN, DEPRESSION, MULTIPLE UTI'S AND KIDNEY INFECTIONS, EXTREME FATIGUE, AND MASSIVE MONTHLY BLOOD LOSS. THE BEGINNING OF THIS YEAR I WENT INTO THE ER AND THEY ENDED UP NOT ONLY ADMITTING ME, BUT GIVING ME A BLOOD TRANSFUSION BECAUSE MY BLOOD CELL COUNT WAS HALF WHAT IT SHOULD BE. THE DOCTOR SAID I COULD'VE DIED HAD I NOT COME IN. THEY HAVE SINCE PUT ME ON IRON PILLS AND BIRTH CONTROL TO TRY AND STOP THE BLOOD LOSS AND GET MY BLOOD COUNT TO GO UP WHERE IT SHOULD BE. I WAS SUPPOSED TO GO BACK IN (B)(6) TO SEE IF IT WAS WORKING, BUT HAVE MOVED MY APPOINTMENT UP TO NEXT WEEK BECAUSE I HAVE BEEN BLEEDING FOR ALMOST 3 WEEKS NOW AND HAVING STABBING PAINS IN MY ABDOMEN. I AM BEING TOLD THE ESSURE DEVICE WILL HAVE TO BE REMOVED AND THEY ARE SAYING I MIGHT HAVE TO HAVE A HYSTERECTOMY AT (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037022	BAYER	6/27/2014	7/7/2014

Event Information:

Event Date (B3): 8/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS306
Catalog # (E4):
Lot #(E4): B30422

Single Use:
Implant Date (E6): 8/22/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS ESSURE IMPLANTED ON (B)(6) 2013. IMMEDIATELY FOLLOWING AND SINCE THEN, I HAVE HAD DEBILITATING SIDE EFFECTS. I DEAL WITH MIGRAINES, STABBING PAINS, CRAMPING, EXCESSIVE BLEEDING DURING "MONTHLY", NAUSEA, DIARRHEA, DIZZINESS, HEAD FOG, DEPRESSION, MOOD SWINGS, TINGLING IN HANDS AND FEET, JOINT PAIN, AND BLOATING. I AM ALLERGIC TO NICKEL AND WAS NOT TOLD THAT THIS PRODUCT CONTAINED NICKEL. I HAD MY HSG AND I HAVE A BROKEN COIL, MY COILS ARE TOO FAR INTO UTERUS, AND I NOW HAVE AN ANTEFLEXED UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037023	BAYER	6/27/2014	7/7/2014

Event Information:

Event Date (B3): 6/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/13/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LAST YEAR AROUND THIS TIME, ((B)(6)) I HAD MY SECOND CHILD. I TOLD MY DR THAT I WANTED A TUBAL LIGATION. I NEVER CHOSE THE TYPE OF PROCEDURE I WANTED. THEY JUST KIND OF GAVE IT TO ME. SO I HAD MY CHILD VIA C-SECTION AND THEY IMPLANTED ESSURE RIGHT AFTER I HAD GIVEN BIRTH. DURING THE C-SECTION, I KEEP TELLING THE DR THAT I FELT PAIN AND NOT PRESSURE. MY RIGHT SIDE WAS NOT COMPLETELY NUMB AS MY LEFT, PRIOR TO THE SURGERY. SO SHE UPPED THE DOSAGE UNTIL LATER SHE SAID SHE COULDN'T GIVE ME ANYMORE. FAST FORWARDING UNTIL NOW, EVERY MONTH, EITHER BEFORE OR DURING MY MENSTRUAL CYCLE, I WOULD HAVE THESE SHARP, STABBING, CONSTANT, AND INTERMITTENT PAINS ON THAT SAME RIGHT SIDE, IN THE SAME EXACT SPOT. LAST MONTH, MY MENSTRUAL CYCLE CAME ON TWICE WITH EVEN STRONGER PAINS IN THAT VERY SAME SPOT. THIS PAST MONDAY, I WAS IN EXTREME PAIN AND THE NEXT DAY, I WENT TO SEE AN URGENT CARE DR WHO HAD TO INFORM ME, AFTER A PELVIC EXAM, THAT I HAD A MASSIVE CYST ON MY RIGHT OVARY THAT BLED OUT. SINCE THE EXAM, THAT VERY SPOT HAS SINCE STILL BEEN VERY PAINFUL AND SORE TO THE TOUCH. TO ADD SOME MORE DETAILS: I HAD ANOTHER C-SECTION 3 YRS PRIOR TO THE BIRTH OF MY SECOND CHILD WITHOUT ANY PROBLEMS AND THAT PREGNANCY WAS A TWIN PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037024	BAYER	6/27/2014	7/7/2014

Event Information:

Event Date (B3): 4/11/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/11/2006
Explant Date (E7): 2/26/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN 2006 IN THE PHYSICIANS OFFICE. THERE WERE COMPLICATIONS DURING THE PROCEDURE FOR WHICH I WAS AWAKE. I BEGAN HAVING UNEXPLAINED PAIN AND SYMPTOMS INCLUDING, SEVERE, HEAVY BLEEDING AND CLOTTING DURING MY MENSTRUAL CYCLE, HORRIFIC ABDOMINAL AND LOWER BACK PAIN, CONSTANT STABBING IN MY TUBES, ICE PICK HEADACHES, ITCHING SKIN, RASHES, DEBILITATING JOINT PAIN (HIPS AND HANDS), TWITCHING, ACUTE VAGINAL PAIN, BODY ACHES, PAINFUL INTERCOURSE, IRREGULAR MENSTRUAL CYCLES, SEVERELY ANEMIC. I HAD A HYSTERECTOMY IN 2014 FOR THE PURPOSE OF REMOVING ESSURE AND THE MAJORITY OF THESE SYMPTOMS WENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037030	BAYER	6/27/2014	7/7/2014

Event Information:

Event Date (B3): 1/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/30/2008
Explant Date (E7): 1/7/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD SEVERE PELVIC PAIN. I HAD TO HAVE A HYSTERECTOMY TO REMOVE DEVICES SO PELVIC PAIN WOULD SUBSIDE. DEVICE ALSO CAUSED EXTREMELY HEAVY PERIODS ALONG WITH SEVERE HEADACHES AND CONSTANT OVARIAN CYSTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037035	BAYER	6/27/2014	7/7/2014

Event Information:

Event Date (B3): 6/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626626

Single Use:
Implant Date (E6): 7/21/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE SINCE 2006, REF (B)(4). LOT #626626 SINCE THEN I'VE HAD SEVERE LOWER BACK PAIN, SEVERE BLOATING, STOMACH PAIN, TEETH PROBLEMS, KIDNEY STONES, MULTIPLE EMERGENCY ROOM VISITS FOR ALL THESE PROBLEMS. SINCE (B)(6) 2013 MY SYMPTOMS HAVE BECOME WORSE. THEY ARE AS FOLLOWED: MINI STROKE, CONSTANT LIGHTHEADEDNESS, TINGLING IN MY CHEST UP INTO NECK, SEVERE BLOATING, PERIODS LASTING 25 DAYS, CHANGING PAD EVERY 1 1/2 HOURS, BLOOD CLOTTING, WEIGHT GAIN, MUSCLE SPASMS IN LEGS AND FEET, LOWER BACK PAIN, HIVES ON HEAD, ACNE ON BACK OF NECK, PELVIC PAIN, YEAST INFECTIONS, BRAIN FOG, ANEMIA, CYST ON OVARIES, RUPTURED CYSTS, LEAKING HEART VALVE, DEPRESSION, FATIGUE, FORGETFUL, IRRITABLE BOWEL SYNDROME, CHEST PAINS. SINCE THIS DEVICE HAS BEEN PUT INTO MY BODY MY QUALITY OF LIFE HAS NOT BEEN GOOD. THIS IS EFFECTING MY JOB AND TIME WITH MY FAMILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037036	BAYER	6/27/2014	7/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/31/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) OF 2008. SINCE HAVING THIS PLACED I HAVE EXPERIENCED VERY PAINFUL AND HEAVY PERIODS. THE LAST 4 YEARS IT HAS BECOME WORSE. I HAVE SEVERE ABDOMINAL PAIN, MAINLY THE RIGHT SIDE AND TAMPON AT THE SAME TIME AND HAVING TO CHANGE EVERY 10-15 MINUTES AS WELL AS CLOTHING) PASSING OF CLOTS RANGE FROM A QUARTER SIZE TO THE SIZE OF MY PALM. VERY PAINFUL! IT AFFECTS ME AT WORK AND HOME. IRREGULAR LONG LASTING PERIODS. BREAST TENDERNESS, AND AT TIMES LEAKING. LOTS OF HAIR LOSS. WAY MORE THAN NORMAL@ I HAVE BEEN TO THE EMERGENCY ROOM MANY TIMES WITH SEVERE ABDOMINAL PAIN AND VOMITING. HAD CT SCANS DONE AND ALL THAT EVER COMES ABOUT IT THEY GIVE ME PAIN PILLS AND SEND ME HOME. I HAVE NEVER HAD A PROBLEM WITH CYSTS UNTIL ESSURE. I HAVE NOW BEEN DIAGNOSED WITH POLYCYSTIC OVARIAN SYNDROME AND PELVIC INFLAMMATORY DISEASE. I HAVE NO ENERGY AND I AM A DIFFERENT PERSON. I HAVE GAINED QUITE A BIT OF WEIGHT AND I HAVE HEADACHES A LOT. SOME ARE MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037037	BAYER	6/27/2014	7/7/2014

Event Information:

Event Date (B3): 11/11/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626806

Single Use:
Implant Date (E6): 11/11/2008
Explant Date (E7): 12/3/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2008, I WAS IMPLANTED WITH THE ESSURE STERILIZATION DEVICE. IT TOOK ALMOST 3 HOURS TO COMPLETE A 10 MINUTE PROCEDURE. THEN I HAD TO HAVE A HSG TESTS DONE, BECAUSE THE DOCTORS DIDN'T RECORD THE CORRECT MEASUREMENTS ON THE FIRST TEST. I IMMEDIATELY BEGAN HAVING PROBLEMS, AND COMPLAINED OFTEN TO MY DOCTOR, WHO REPEATEDLY WROTE MY PROBLEMS OFF AS OTHER DIAGNOSES. I THOUGHT MAYBE HE WAS RIGHT, UNTIL AROUND (B)(6) OF 2013 WHEN I STARTED HAVING MY PERIOD EVERY TWO WEEKS WITH SEVERE BLEEDING AND MAJOR BLOOD CLOTS. I HAVE HAD CONSTANT HEADACHES, MOOD SWINGS, IRRITABILITY, SEVERE SKIN RASHES, HAIR LOSS, WEIGHT GAIN, FATIGUE, CHEST PAINS, NIGHTMARES, SEVERE PAIN DURING INTERCOURSE, AND ALMOST ALL OF MY TEETH HAVE BROKEN AND ARE FALLING OUT. I HAVE HAD DIZZINESS, WEAKNESS, BRAIN FOG, AND MANY OTHER SYMPTOMS. I LOST MY ABILITY TO INTERACT WITH MY CHILDREN AND MY HUSBAND PHYSICALLY AND MENTALLY. I DID NOT HAVE INSURANCE AT THE TIME, SO I SUFFERED FOR ABOUT HALF OF THE YEAR IN 2013, THEN STARTED GOING BACK TO MY OBGYN, WITH HIS HELP TO REDUCE MY BILL. AFTER EXAMS AND BLOOD TESTS, MY DOCTOR AGREED THAT I WAS POSSIBLE HAVING A REACTION TO THE ESSURE COILS AND WE SCHEDULED A HYSTERECTOMY FOR (B)(6) 2013. I LOST ALL OF MY REPRODUCTIVE PARTS EXCEPT FOR MY OVARIES, AND AM STILL HAVING SOME ISSUES, BUT AT LEAST I'M NOT BLEEDING SEVERELY ANYMORE. ESSURE HAS STOLEN MY LIFE AS I KNEW IT AWAY FROM ME, AND IT NEEDS TO BE TAKEN OFF THE MARKET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036889	BAYER	6/30/2014	7/1/2014

Event Information:

Event Date (B3): 10/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DIARRHEA, HEADACHES, HEMORRHOIDS, ANAL FISHERS, CHRONIC PAIN IN MY GUT (A STEADY PAIN LEVEL OF 5 WITH STABS OF PAIN WITH A LEVEL OF 7), CHRONIC PELVIC PAIN (STEADY PAIN LEVEL OF 6 WITH STABS OF PAIN FROM 7 TO 9), DURING MY PERIOD IT FEELS LIKE I AM HAVING CONTRACTIONS, SEVERE PELVIC PAIN AFTER INTERCOURSE, MY PERIOD WENT FROM 4 TO 5 DAYS BEFORE ESSURE NOW IT IS 10 TO 12 DAYS AND MUCH HEAVIER THAN IT USE TO BE, TINGLING AND NUMBNESS IN MY HANDS, ARMS, NECK AND HEAD, PROGRESSIVE PAIN FROM MY HANDS TO UP MY ARMS TO MY NECK AND UP AND OVER MY HEAD, SWELLING IN MY HANDS AND ARMS, LOTS OF YEAST INFECTIONS, VAGINAL DISCHARGE, HARDER TO ORGASM, LOWER SEX DRIVE, SPOTTING AFTER SEX, BODY EXHAUSTION, NO STAMINA, VISION HAS WORSENED, WAKING THROUGH OUT THE NIGHT, HICCUPS ALL THE TIME, HOT FLASHES, NIGHT SWEATS, SLOW HEALING CUTS, PAINFUL OVULATION, BREAST PAIN, MY SKIN ITCHES, ABDOMINAL SPASM AND TWITCHES, BLOATING, HEADACHES, DIZZINESS, BRAINFOG, MOOD SWINGS, RINGING IN EARS, EARS ITCH, DRY MOUTH, FORGETFULNESS, TREMORS AND SHAKINESS, INSOMNIA, I SWEAT A LOT, OCCASIONALLY MY HEART POUNDS HARD FOR NO REASON TO THE POINT THAT I HEAR IT. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036890	BAYER	6/30/2014	7/1/2014

Event Information:

Event Date (B3): 2/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT ABDOMINAL PAIN, SHARP PAINS UP SIDES, PAIN DURING SEXUAL INTERCOURSE, WEIGHT GAIN, HORRIBLE LONG PERIODS, DEPRESSION, AND RASHES.

(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036891	BAYER	6/30/2014	7/1/2014

Event Information:

Event Date (B3): 9/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE PRODUCT WAS IMPLANTED (B)(6) 2013 BY MY OB/GYN, DR. (B)(6). MY SYMPTOMS AND ADVERSE EVENTS BEGAN WITHIN A FEW DAYS OF THE PROCEDURE (AROUND (B)(6) 2013), AND HAVE BEEN NOTHING LIKE I HAVE EXPERIENCED BEFORE. RIGHT AWAY I SUSPECTED MY NEW SYMPTOMS WERE RELATED TO THE ESSURE. MY SYMPTOMS INCLUDE PELVIC PAIN (MORE SEVERE DURING CERTAIN TIMES OF MONTH), BACK PAIN, NERVE PAIN, AND HEADACHES. THE NERVE PAIN IS ALL OVER, BUT VERY PRONOUNCED ON LEFT SIDE OF NECK, WITH SHOOTING PAIN DOWN MY NECK, SHOULDER, ARM, AND LEG, AND NUMBNESS/TINGLING IN MY LEGS AND FEET. MOST DAYS MY LEGS ARE SORE AND FATIGUED LIKE I'VE RUN A MARATHON (WHICH I HAVE, SO I KNOW!). WITHIN A COUPLE OF WEEKS OF THE PROCEDURE, I RETURNED TO DR. (B)(6)'S OFFICE, TO DISCUSS MY UNUSUAL SYMPTOMS. I TRIED NOT TO PLACE BLAME AND TOOK A MORE SUBTLE APPROACH SAYING THINGS LIKE, AND "PERHAPS I OVERSTRAINED MY BODY DURING EXERCISE." SINCE I REALLY DID'T KNOW FOR CERTAIN, AND I DIDN'T WANT TO MAKE HER FEEL BADLY, I INITIALLY SPOKE FROM A PLACE OF COMPASSION. BECAUSE THE SYMPTOMS RESEMBLED THAT OF MS, I WAS REFERRED TO A NEUROLOGIST TO RULE OUT THIS AND OTHER ILLNESSES. TWO OFFICE VISITS AND THREE MRI'S WERE DONE IN (B)(6) OF 2013. NO DIAGNOSIS WAS MADE BY MY NEUROLOGIST BUT SHE DID PRESCRIBE A HIGH-STRENGTH B MULTIVITAMIN (WHICH IS GIVEN TO PEOPLE WITH DIABETES TO HELP WITH NERVE PAIN.) DURING THIS SAME PERIOD, I BEGAN RESEARCHING ESSURE AGAIN ON THE INTERNET. UNFORTUNATELY, THERE WAS NEW INFORMATION OUT THERE - WEBSITES AND DISCUSSION OF NEGATIVE SIDE EFFECTS THAT I DIDN'T SEE BEFORE DURING MY INITIAL RESEARCH IN (B)(6) 2013. I READ STORIES FROM LADIES ALL OVER, WHO WERE EXPERIENCING THE SAME SYMPTOMS. IT WAS SO UNBELIEVABLE AND SCARY. SINCE (B)(6) 2014, I HAVE BEEN ON THE HUNT FOR A DOCTOR TO REMOVE THE ESSURE, WITHOUT PERFORMING A HYSTERECTOMY. I HAVE HAD MORE DISCUSSIONS WITH

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THE OB/GYN WHO DID THE IMPLANT, BUT SHE WILL NOT REMOVE THE ESSURE, WITH TUBES ONLY. AFTER MONTHS OF RESEARCH, AND DISCUSSION WITH SEVERAL GYNECOLOGISTS, I AM SCHEDULED TO HAVE THE ESSURE REMOVED IN (B)(6) 2014. SHE WILL REMOVE MY TUBES AND PERFORM A CORNEAL RESECTION OF MY UTERUS (BUT LEAVE THE UTERUS AND OVARIES.) I AM LOOKING FORWARD TO BEING ESSURE FREE AND PAIN FREE. MY HISTORY INCLUDES LUPUS, AND UNDERACTIVE THYROID. BOTH CONDITIONS HAVE BEEN STABLE WITH MEDICATION. MY RHEUMATOLOGIST DOES NOT BELIEVE THE SYMPTOMS DESCRIBED ABOVE ARE LUPUS OR THYROID RELATED. MY ALLERGIES INCLUDE PENICILLIN AND SULFA ANTIBIOTICS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036892	BAYER	6/30/2014	7/1/2014

Event Information:

Event Date (B3): 11/6/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2009. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 20205262. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2008. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. CRAMPING, SHARP/STABBING PELVIC PAIN, MENORRHAGIA (EXCESSIVE BLEEDING), MITTELSCHMERZ (PAINFUL OVULATION), NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, SPOTTING AFTER SEX, PAINFUL PERIODS, PAINFUL INTERCOURSE, INCONTINENCE, SEXUAL DYSFUNCTION, URGENT/FREQUENT URINATION, VULVODYNIA (ITCHING, BURNING, STINGING, STABBING OF VAGINA ENTRANCE), BREAST TENDERNESS AND PAIN, ABDOMINAL SPASMS/TWITCHING/FLUTTERING, BACK, JOINT, LEG, BREAST, NECK, SPINE AND HIP PAIN, CHRONIC PELVIC PAIN, GAS, CONSTIPATION, SEVERE BLOATING, METALLIC TASTE IN MOUTH, BOWEL ISSUES, HEADACHES, MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN SHOCKS, NERVE PAIN, BRAIN FOG, MOOD SWINGS, DEPRESSION, RINGING IN EARS, BLACK OUT SPELLS/FAINTING, DIMINISHED BRAIN FUNCTION, NUMBNESS IN THIGHS, NUMBNESS/TINGLING IN EXTREMITIES, SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN, TREMORS/SHAKINESS, VITAMIN D DEFICIENCY, EASILY BRUISED, FIBROMYALGIA, SKIN IRRITATION, SWELLING OF LEGS AND FEET, INSOMNIA, WEIGHT ISSUES (LOSS/GAIN), TOOTH PAIN, SWOLLEN GLANDS, UNEXPLAINED FEVERS, MUSCLE SPASMS, VISION PROBLEMS (FLOATERS, BLURRED, DECREASED), EXCESSIVE SWEATING, DRY SKIN, HAIR AND EYES, SEVERE BLOATING. I HAVE NOT BEEN SEEN BY DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS, FIBROMYALGIA. THE DEVICE IS STILL INSIDE OF ME. (B)(4).

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037039	BAYER	6/30/2014	7/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE HAS CAUSED PELVIC PAIN AND BACK PAIN, A METALLIC TASE IN MY MOUTH AND VERY HEAVY MENSTRUAL CYCLE. NOW NEED TO HAVE A HYSTERECTOMY FOR REMOVAL THAT IS SCHEDULED FOR (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037042	BAYER/CONCEPTS INCORPORATED	6/30/2014	7/7/2014

Event Information:

Event Date (B3): 5/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): REF # ESS305
Catalog # (E4):
Lot #(E4): 789034

Single Use:
Implant Date (E6): 11/16/2011
Explant Date (E7): 9/18/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I REC'D THE ESSURE IN 2011 AND HAD TO HAVE A HYSTERECTOMY IN (B)(6) 2013. I HAD DEVELOPED EDEMATOUS, WHICH I NEVER HAD MAJOR STOMACH AND BACK PAIN. EVERY SINGLE DAY BACK PAIN WITH INTERCOURSE, MY LIFE WAS TERRIBLE. I BEG DOCTORS TO HELP ME UNTIL I FINALLY FOUND ONE AND HAD TO HAVE THEN REMOVED, THAN GOD SHE DID BECAUSE I HAD VERY BAD EDEMATOUS I LOST SO MUCH WEIGHT COULDN'T EAT OR EVEN SLEEP COMFORTABLE FATIGUE I AM NOT E-FREE BUT SUFFERING FROM NOT FEELING LIKE A NORMAL WOMAN ANYMORE AND DEPRESSED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037043	BAYER	6/30/2014	7/7/2014

Event Information:

Event Date (B3): 7/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/31/2013
Explant Date (E7): 6/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IMPLANTED ON (B)(6) 2013. THEY PLACED 3 COILS INTO MY FALLOPIAN TUBE. I HAD SOME DISCOMFORT FOR 2 MONTHS AFTER PROCEDURE WHERE THE COILS WERE PLACED AND FELT FATIGUED, HEAVY PERIODS, CRAMPING, AND INTENSE THROBBING PAIN WHERE COILS WERE PLACED THAT WOULD HURT AT RANDOM TIMES. IT DIDN'T MATTER IF I WAS SITTING, STANDING, LAYING DOWN OR EXERCISING. I HAD MY HSG TEST (B)(6) 2013 TO CONFIRM BLOCKAGE AND EVERYTHING WAS CORRECT ALL COILS IN PLACE. ON (B)(6) 2014 I STARTED EXPERIENCING ABNORMAL SYMPTOMS STARTING WITH A MISSED PERIOD, FREQUENT URINATION, BLADDER INFECTIONS, DIZZY SPELLS, NAUSEA, WEIGHT GAIN, SEVERE BLOATING WHERE I LOOKED 3 MONTHS PREGNANT, SEVERE CONSTIPATION, SEVERE ABDOMINAL CRAMPING LIKE MY INSIDES WERE BEING TWISTED AND TORN APART AS WELL AS CRAMPING IN PELVIC REGION LIKE MY UTERUS WAS STRETCHING. I WENT TO MY OBGYN (B)(6) 2014 AND SHE DID A VAGINAL EXAM AND URINE TEST AND CAME BACK NEGATIVE. SHE DIAGNOSED IT AS HORMONAL IMBALANCE. MY SYMPTOMS BECAME WORSE WITH SEVERE ABDOMINAL CRAMPING TO THE POINT WHERE I COULDN'T WALK, THROBBING PAIN IN PELVIC REGION WHERE COILS COULD HAVE BEEN PLACED AND 2" BELOW, AND SEVERE CONSTIPATION FOR 6 DAYS AND I WENT INTO AN URGENT CARE CLINIC (B)(6) 2014 AND THEY DIAGNOSED IT AS SEVERE CONSTIPATION AND BLOCKAGE IN MY INTESTINES AS WELL AS BLOOD IN MY STOOL, AND HIGH LEVELS OF PROTEIN. MY SYMPTOMS BECAME EVEN WORSE WITH ABDOMINAL PAIN, FLANK PAIN, UTI, AND PREVIOUS SYMPTOMS LISTED PRIOR. I WENT TO A DOCTOR (B)(6) 2014 AND SHE RAN A URINE TEST AS I STILL HAD NOT STARTED MY PERIOD AND SHE REQUESTED AN X-RAY AND DIAGNOSED ME WITH A UTI, AND THE X-RAY SHOWED I HAD BLOCKAGE IN MY INTESTINES AS WELL AS FOUND 3 COILS, 2 IN MY FALLOPIAN, ONE ON EITHER SIDE AND ONE BELOW FALLOPIAN TUBES BUT THOUGHT NOTHING OF IT WHEN WE LOOKED AT IT BECAUSE WE WERE FOCUSED ON THE BLOCKAGE IN

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MY INTESTINES. MY DOCTOR PRESCRIBED ME WITH SOME ANTIBIOTICS FOR MY UTI. MY SYMPTOMS STILL REMAINED ALL OF THEM LISTED PRIOR BUT THIS TIME HIGH FEVER. LESS THAN 24 HOURS LATER, LEAVING HER OFFICE, EXPERIENCED HIGH FEVER FOR 6 DAYS OF 101-103, SEVERE ABDOMINAL CRAMPING WHERE I COULDN'T MOVE, AND I BROKE OUT IN A RASH HEAD TO TOE AND MY SYMPTOMS BECAME WORSE AND I WOUND UP IN THE EMERGENCY ROOM (B)(6) 2014. I WENT TO THE EMERGENCY ROOM AND THEY LOOKED AT MY X RAY AND PERFORMED A CT SCAN AS WELL AS DID BLOOD WORK. MY DOCTORS CAME IN AND SAID THAT WHAT THEY COULD CONCLUDE FROM MY CT SCAN, X RAY, BLOOD TESTS AND URINE TESTS IS THE 3RD COIL HAD BROKEN OFF WHICH I WASN'T AWARE I HAD A THIRD COIL AND IT WAS PERFORATING MY UTERUS CAUSING ALL OF MY SYMPTOMS. MY DOCTORS TOLD ME TO CALL MY OBGYN RIGHT AWAY AND TO SCHEDULE SURGERY TO HAVE IT REMOVED IMMEDIATELY. ON (B)(6) 2014 I HAD MY BLOOD WORK DONE FOR PRE SURGERY. ON (B)(6) I HAD THE FAULTY COIL REMOVED USING LAPAROSCOPIC SURGERY. I REQUESTED TO SEE THE IMAGE AND THE COIL WAS BENT, ENTWINED, AND DAMAGED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037044	BAYER HEALTH	6/30/2014	7/7/2014

Event Information:

Event Date (B3): 6/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/16/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACED IN (B)(6) 2011 AND ALSO HAD THE DIE TEST DONE ABOUT 5 MONTHS LATER AND EVERYTHING HAS SEEMED OKAY UNTIL I STARTED TO PUT MY SYMPTOMS TO DATE. ALL WERE AFTER THE COILS WERE PLACED. I CURRENTLY STILL HAVE THE COILS IN PLACE BUT I AM TRYING TO FIND A DOCTOR THAT WILL REMOVE THEM. THE PROBLEMS I AM HAVING ARE SEVERE BLOATING TO THE POINT I LOOK PREGNANT, AND PAIN OCCASIONALLY, HEAVIER PERIODS THAN I HAVE EVER HAD, AND I WAS RECENTLY DIAGNOSED WITH IBS AND THAT IS SOMETHING I'VE NEVER HAD. THESE COILS NEED TO BE TAKEN OFF THE MARKET AND CURRENT PATIENTS WITH THEM SHOULD NOT HAVE SUCH A HARD TIME FINDING A DOCTOR TO GET THEM OUT! THESE ARE A NIGHTMARE AND IF I KNEW ALL OF THIS BEFORE I HAD THEM PLACED I WOULD NEVER HAVE GOTTEN THEM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037046	BAYER	6/30/2014	7/7/2014

Event Information:

Event Date (B3): 12/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): WASN'T GIVEN TO ME.
Catalog # (E4): WASN'T GIVEN TO ME.
Lot #(E4): WASN'T GIVEN TO ME.

Single Use:
Implant Date (E6): 12/4/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PERMANENT BIRTH CONTROL PLACED (B)(6) 2013. HAD HSG RADIOLOGICAL TEST COMPLETED (B)(6) 2014 TO TEST FOR BLOCKAGE OF FALLOPIAN TUBES. DURING HSG DYE FLUSHING, THE LEFT ESSURE COIL WAS FLUSHED COMPLETELY THROUGH MY FALLOPIAN TUBE AND INTO MY PERINEAL CAVITY. DOCTOR HAS SUGGESTED SURGERY TO HAVE MISPLACED COIL FOUND AND REMOVED. ALSO DURING SURGERY, I WOULD REQUIRE MY LEFT TUBE TO BE TIES TO PREVENT PREGNANCIES. DO NOT HAVE FINANCIAL ABILITY TO HAVE SURGERY AT CURRENT TIME. ALSO HAVE EXPERIENCED JOINT PAIN AND 30 LB UNEXPLAINED WEIGHT GAIN. SEVERE DEPRESSION RELATED TO COMPLICATIONS RELATED TO ESSURE DEVICE DISLODGEMENT AND PLACEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037055	CONCEPTUS INC	6/30/2014	7/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/27/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAIR LOSS, SWOLLEN ABDOMEN, SEVERE PAIN IN BACK, UTERUS AND HIPS, BLADDER WORSENING OF ECZEMA, PROLONGED BLEEDING DURING MONTHLY CYCLES, PASSING BLOOD CLOTS DURING CYCLE. AGONIZING HEADACHE LASTING WEEKS AT A TIME WORSENING OF DEPRESSION DUE TO UNBEARABLE AND CONSTANT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037056	CONCEPTUS, INC	6/30/2014	7/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE COILS FOR PERMANENT STERILIZATION IN 2005 AFTER THAT I HAVE DEVELOPED A LARGE DERMOID CYST ON MY RIGHT OVARY. HAVE AN ECTOPIC PREGNANCY, BAD CRAMPS, MISSED PERIOD, HEAVY BLEEDING AND MIGRAINES. LOSS OF FEELING IN PELVIC AREA (TINGLING SENSATIONS) LOSS OF SEX DRIVE. SWELLING IN ABDOMEN, HUGE BLOOD CLOTHS DURING PERIOD. DIZZINESS, LIGHT HEADED AND BALANCE PROBLEMS. REOCCURRING YEAST INFECTIONS, FREQUENT URINATION, MOOD SWINGS, DEPRESSION, NO ENERGY. IT HAS TAKEN AWAY THE QUALITY OF MY LIFE AND IM ONLY (B)(6)!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037057	BAYER	6/30/2014	7/7/2014

Event Information:

Event Date (B3): 6/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/18/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LAST WED ON THE (B)(6) I FOLLOWED MY DR'S OPINION AND ALLOWED HIM TO IMPLANT THE ESSURE, SIMPLY BECAUSE THEY STATED THERE WAS NO DOWN TIME, I WOULD BE ABLE TO RETURN TO WORK RIGHT AWAY, ITS OVER A WEEK LATER AND I HAVE BEEN BACK TO HIM ALMOST EVERY OTHER DAY, HE HAS MADE ME TAKE NUMBEROUS TESTS, PLACED ME ON VARIOUS ANTIBIOTICS AND I STILL FEEL HORRIBLE, MY BODY IS WEAK, I HAVE MIGRAINE HEADACHES WHICH I NEVER HAD BEFORE, MY KNEE STARTED HURTING YESTERDAY, MY LOWER BACK AND FRONT OF MY STOMACH IS IN SO MUCH PAIN THAT IT'S HARD FOR ME TO SIT, DRIVER AND LAY DOWN FLAT. YESTERDAY I WENT TO HIM PLEADING THAT SOMETHING IS WRONG WITH THE ESSURE BECAUSE I WAS HEALTHY BEFORE, HE STATED THAT HE NEEDED TO DO FURTHER TESTING BECAUSE THE SURGERY WENT WELL, AND ONLY OPTION I HAD WAS A HYSTERECTOMY, IM (B)(6) NOTHING IS WRONG WITH MY FEMALE ORGANS AND BECAUSE FOLLOWING HIS ADVICE I HAVE TO REMOVE THEM, I DID NOT GO IN HIS OFFICE FOR AN ESSURE, HE RECOMMENDED I TIE MY TUBES AND CHOSE THAT PROCEDURE.. CAN SOMEONE PLEASE HELP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037058	CONCEPTUS/BAYER	6/30/2014	7/7/2014

Event Information:

Event Date (B3): 1/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): 0909075-0523
Catalog # (E4):
Lot #(E4): A63347

Single Use:
Implant Date (E6): 1/10/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACE (B)(6) 2013, I HAVE HAD PROBLEMS FROM THE MOMENT I WOKE UP IN RECOVERY, STABBING PAIN IN SIDED, STILL CONTINUES TIL THIS DAY, DEPRESSION, BLOATING, TUGGING PAIN IN STOMACH, HEAVY BLEEDING, CRAMPING, PAIN IN OVARIES, STOMACH SOMETIMES FEELS LIKE SOMETHING HEAVY IN STOMACH, HEARING AND EYESIGHT HAVE CHANGED, BREASTS ALWAYS TENDER, BACTERIA IN GUMS, SOMETIMES ABSENCE OF MENSTRUAL CYCLE MAY GO 3 MONTHS WITHOUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036910	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 4/11/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD A HYSTERECTOMY (B)(6) 2014 FOR PURPOSE OF REMOVING ESSURE. SINCE REMOVAL SYMPTOMS SUCH AS SEVERE JOINT PAIN, HEADACHES, ABDOMINAL PAIN, ITCHING SKIN AND RASHES, HEADACHES, INVOLUNTARY MUSCLE SPASMS, LOSING MY BALANCE, VAGINAL PAIN, PAIN DURING INTERCOURSE, STABBING PAIN IN MY LOWER ABDOMEN HAVE DISAPPEARED. THE DAY OF MY HYSTERECTOMY THESE WERE ALL PRESENT AND HAD BEEN FOR 6 YEARS. THE MAJORITY OF THESE SYMPTOMS DISAPPEARED AFTER HAVING ESSURE REMOVED MOST NOTICEABLY WAS THE JOINT PAIN. I COULD NOT GRIP OR USE MY HANDS WITHOUT SEVERE PAIN OR WALK WITH WITHOUT SEVERE PAIN IN MY HIP. THOSE ARE BOTH GONE SINCE HAVING ESSURE REMOVED. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036911	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 6/24/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD EXTRA HEAVY CYCLES, PRE ESSURE THEY WERE LIGHT TO MEDIUM. I HAVE A CONSTANT PINCH/STABBING FEELING IN MY PELVIS MOSTLY ON THE LEFT BUT ALSO ON THE RIGHT. SWELLING A LOT, JOINT PAIN, DISCHARGE, HEADACHES. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036912	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS DONE IN 2008, SINCE THEN HAD HEALTH ISSUES, DEPRESSION, BACKPAIN, SEVERE FATIGUE, MORE SENSITIVE TEETH, PELVIC PAIN AT ARE OF IMPLANTS, MULTIPLE KIDNEY INFECTIONS, UTI'S, ANY MANY OTHER ISSUES. IN (B)(6) OF 2014, I HAD AN ULTRASOUND AND WAS DIAGNOSED WITH CHRONIC PELVIC CONGESTIVE SYNDROME, IN OTHER WORDS VARICOSE VEINS IN MY TUBES AROUND THE ESSURE IMPLANT SITE. A WEEK AFTER THAT I WAS SCHEDULED FOR A HYSTERECTOMY ONLY LEAVING MY OVARIES. I'M (B)(6), DIVORCED AND NOW HAVE NO HOPE OF EVER HAVING ANOTHER CHILD. NOW I WILL HAVE TO DEAL WITH WEIGHT GAIN AND THAT IS NOT FAIR. ESSURE HAS RUINED MY LIFE AND IT HAS TO BE TAKEN OFF THE MARKET. NO WOMAN SHOULD GO THROUGH WHAT I HAVE GONE THROUGH. SOME HAS GOT TO DO SOMETHING ABOUT THIS. PLEASE HELP. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036913	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 6/26/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY PAINFUL PERIODS, LOTS OF BLOOD CLOTS, HAIR FALLING OUT, REAL BAD HEADACHE, IT FEELS LIKE SOMETHING POKING ME ON MY SIDE. TEETH IS SENSITIVE, STOMACH HURTS ALL THE TIME. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036917	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 8/11/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE WEIGHT GAIN, DEPRESSION, BLOATING, CRAMPING, HYPOTHYROIDISM. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036918	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 3/15/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

LONGER MORE PAINFUL PERIODS. AWFUL PAINS A WEEK BEFORE MY PERIOD, BACK PAIN. SEVERE BLOATING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036925	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE SYMPTOMS. IMPLANTED (B)(6) 2012. CONF BLOCKED (B)(6) 2013. ABLATION (B)(6) 2013. 3 MONTH INFECTION. HAIR FALLING OUT. TUBAL PAIN ALWAYS AFTER SEX. SEVERE BLOATING. CHEST PAIN. HARD TO CATCH BREATH. CHEST POUNDING ANXIETY ATTACK. DIGESTIVE ISSUES. ACHY MUSCLES AND JOINTS. TIRED ALL OF THE TIME. HEART FEELS LIKE IT'S WORKING TOO HARD. SUDDEN SWOLLEN GLANDS UNDER ARMS AND NECK. SEVERE MOTION SICKNESS. MAJOR METAL ALLERGIES. KIDNEY BACK PAIN. BRAIN FOG. THINKING CLEARLY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036926	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 4/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD EXTREME WEIGHT GAIN IN SHORT TIME PERIOD THAT HAS LASTED 3+ MONTHS (STILL GOING), SEVERE CRAMPING, SEVERE BACK PAIN, DIZZINESS, RASHES, FATIGUE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036928	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 6/26/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE STOMACH SWELLING, CONSTANT HIP AND LOWER BACK PAIN, HAIR IS STARTING TO FALL OUT, HEADACHES, SEVERE PAIN SWELLING AND POPPING SOUND WHERE COILS SHOULD BE PLACED, OVULATE TWICE IN A 6 WEEK CYCLE RATHER THEN 8 WEEKS WHICH HAS RESULTED IN (NO NORMAL PERIODS) BLEEDING FOR UP TO 14 DAYS STRAIGHT. POKING AND THROBBING PAIN LOCATED IN AND THROUGH CERVIX. SEVERE PAIN DURING INTER COURSE, PERIODS CONTAIN A HUGE AMOUNT OF TISSUE, ALLERGIC TO WEDDING RINGS. CONSTANT THROBBING PAIN (24/7) IN VAGINAL AREA DOWN TO THIGHS. ALL OF THIS HAS OCCURED SINCE COILS HAVE BEEN PLACED. I FELT THE COIL COMING THROUGH MY CERVIX JUST LAST WEEK THOUGH. I HAVE HAD MY COILS SINCE (B)(6) 2011. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036930	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 4/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CLOSE TO THIS DATE I STARTED TO HAVE MILD TO SEVERE ABDOMINAL-PELVIC PAIN; SPOTTING BETWEEN PERIODS; BLOATING; THEN AROUND (B)(6) 2013 I STARTED HAVING PAINFUL INTERCOURSE TO THE POINT THAT I HAVE NOT BEEN ABLE TO DO MY "WIFE DUTIES" W/O HAVING PAIN WITH PENETRATION; ALSO AFTER HE WAS DONE MY VAGINA AREA WAS SO INFLAMED AND SORE THAT I JUST QUIT HAVING INTERCOURSE WITH MY HUSBAND, WHO BY THE WAY BELIEVES I AM CHEATING ON HIM WITH ANOTHER PERSON JUST BECAUSE I CAN'T HAVE SEX ANYMORE AND HE DOES NOT UNDERSTAND THE MISERY I AM LIVING. I AM ONE STEP AHEAD OF DIVORCE, AND I AM NOT SURE IF I AM ALLERGIC TO THE ESSURE COMPONENTS BECAUSE I HAVE NEVER BEEN TESTED FOR ALLERGIES. THEN TO COMPLETE MY STORY ON-ABOUT (B)(6) 2014 I WAS WORKING AND STARTED "SEATING" SO BAD HAD A TERRIBLE PELVIC PAIN AND STARTED BLEEDING SMALL AMOUNTS AT A TIME, BUT BECAUSE THE INSURANCE I HAVE RIGHT NOW WANTS ME TO PAY 100% OF ER VISITS I COULD NOT GO. I AM THE ONLY WORKING PERSON IN MY HOUSEHOLD, I HAVE THREE KIDS TO SUPPORT AND CAN'T STOP WORKING TO TAKE CARE OF MYSELF, BUT WHAT I KNOW FOR SURE IS THAT I NEVER FELT SO MISERABLE. NOT JUST BECAUSE OF THE SIDE EFFECTS I AM HAVING R/T ESSURE BUT TO THE FACT THAT I WAS SO IGNORANT AT THE TIME OF INSERTION (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036940	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 5/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2007, AFTER MY SON WAS BORN I DECIDED TO DO THE RESPONSIBLE THING AND HAVE THE ESSURE BIRTH CONTROL PLACED. THIS TURNED OUT TO BE THE WORST IDEA OF MY LIFE. AT THAT TIME, MY NOW EX HUSBAND AND I DECIDED, THAT TWO AND HEALTHY, CHILDREN WERE ENOUGH. I WAS TOLD THIS WAS AN EASY 10 TO 15 MINUTE PROCEDURE IN THE DOCTOR'S OFFICE. THAT IT WAS A PERMANENT BIRTH CONTROL, WITH MINIMAL SIDE EFFECTS. THE DOCTOR MADE IT SOUND LIKE A GREAT CHOICE, ESPECIALLY FOR A BUSY MOM OF TWO. I STARTED DEVELOPING HEALTH PROBLEMS ALMOST IMMEDIATELY, SUCH AS: HAIR LOSS, SEVER PELVIC PAIN, MEHORRHAGIA, ANEMIA, HEADACHES, MIGRAINES MEMORY PROBLEMS, JOINT PAIN, BACK PAIN, MOOD SWINGS, DISCHARGE, RANDOM SEVER SHARP LIKE STABBING PAIN OVER MY OVARIES, DENTAL PROBLEMS (DE-CALCIFICATION OF MY TEETH) AND ELEVATED COPPER LEVELS. AFTER YEARS OF PROBLEMS, A DIVORCE AND A CROSS COUNTRY MOVE, I DECIDED ENOUGH WAS ENOUGH. I CONSULTED WITH SEVERAL OBGYN'S DID LAB WORK AND ULTRASOUNDS AND WAS TOLD THE MOST DEVASTATING NEWS A (B)(6) WOMEN COULD EVER BE TOLD. THE CAUSE OF THESE PROBLEMS WERE DUE TO THE ESSURE BIRTH CONTROL I HAD PLACED AFTER MY SON WAS BORN; THE ONLY WAY TO TREAT ALL THESE PROBLEMS WAS BY HAVING TOTAL HYSTERECTOMY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036941	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 12/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

-2X PERIODS PER MONTH. -SHARP PAIN ON MY RIGHT SIDE WHERE THE IMPLANT IS AT. IT'S THE SAME PAIN AS THE DAY IT WENT IN. -MY HIPS AND KNEES HURT. -MY TEETH FEEL LIKE THEY ARE GOING TO EXPLODE. -MY ABDOMEN SWELLS. - I BLOAT VERY BAD AND IT'S HARD TO WEAR A WATCH OR RINGS. - THINNING HAIR. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036942	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, PRESSURE. SEVERE CRAMPING. PERIODS ARE MUCH WORSE. ABDOMINAL PAIN. FATIGUE. WEIGHT GAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036943	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 11/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PROCEDURE ALONE WAS PAINFUL AND I WAS AWAKE GIVEN MEDICINE FOR THE NIGHT BEFORE. AFTER THE PROCEDURE I WAS VERY SORE ON MY LEFT LOWER ABDOMEN. I COULDN'T TWIST OR MOVE AROUND MUCH FOR TWO WEEKS. I WAS IN PAIN, HAD SHARP PAINS , CRAMPS, HEADACHES, NAUSEA, A SCARY AMOUNT OF HAIR LOSS AND BLED FOR 6 1/2 MONTHS UNTIL ONE PIECE OF ONE COIL CAME OUT. SEX CAN BE VERY PAINFUL. SOMETIMES I FEEL LIKE I FEEL MOVING OR TWITCHING IN MY LOWER ABDOMEN. WHEN I WENT TO HOSPITAL I WAS TOLD THAT COILS MIGRATED TO MY UTERUS. IF I DIDN'T USE CONDOMS AS A BACKUP I WOULD DEFINITELY BE PREGNANT. ESSURE HAS BEEN A TOTAL FAILURE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036944	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 1/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2013.
THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC.
MY LOT NUMBER IS B66019. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE.

THE ONSET OF MY COMPLAINT STARTED WITH MY FIRST MENSTRUAL CYCLE IN JANUARY 2014.

THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE.
SHARP/STABBING PELVIC PAIN, SEVERE CRAMPING (ESPECIALLY DURING MY PERIOD), EXCESSIVE BLEEDING DURING PERIOD AND CONTINUOUS BLEEDING IN BETWEEN, HOT FLASHES (RESEMBLING FEVER, BUT NO ACTUAL FEVER), EXTREME FATIGUE, PAINFUL INTERCOURSE, WEIGHT GAIN AND TROUBLE LOSING WEIGHT, BREAST AND ABDOMINAL TENDERNESS, ABDOMINAL TWITCHES, BACK, HIP AND JOINT PAIN (ESPECIALLY LEGS AND FEET), METALLIC TASTE IN MOUTH, TINGLY FACE SENSATIONS (NUMB TEETH), MIGRAINES, DIZZINESS, BRAINFOG (A LOT OF FORGETFULNESS), MOOD SWINGS, BLOATING, DRY AND ITCHY SKIN, AND SWOLLEN HANDS AND FEET.

I HAVE BEEN SEEN BY THREE DOCTORS, INCLUDING ONE ER VISIT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS SINUSITIS, DEHYDRATION, AND UTERINE POLYP. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE, NUVASURE/HYSTEROSCOPY AND THE DEVICE IS STILL INSIDE OF ME.

(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036945	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 10/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2009. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 626504. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: CHRONIC SEVERE PAIN IN MY ABDOMEN THAT WOULD LAST FOR DAYS AT A TIME, ALL MONTH LONG, SHARP STABBING ABDOMINAL PAIN, ADVERSE REACTION TO NICKEL FROM ALLERGY (POSITIVE NICKEL ALLERGY TEST), CRAMPING, TINGLING, NUMBNESS, INSOMNIA FROM PAIN, SEVERE BLOATING, LOWER BACK PAIN, STABBING PAIN ESPECIALLY MY LEFT OVARY, UNUSUAL BLEEDING, A FUNNY VIBRATING FEELING IN THE AREA OF MY TUBES, FATIGUE, PAIN SO BAD I ALMOST FAINTED, DIZZINESS, A RASH, HEAVY PERIODS WITH CLOTTING, PAIN SO BAD I WOULD MISS WORK AND MOOD SWINGS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS NICKEL ALLERGY. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: REMOVAL OF THE ESSURE COILS. THE DEVICE HAS BEEN REMOVED ON (B)(6) 2013. THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036946	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 11/17/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE I DEVELOPED A LOT OF HEALTH ISSUES MOSTLY PELVIC PAIN, BLOATED STOMACH, CONSTANT HEADACHES, FATIGUE, STOMACH ISSUES, CONSTIPATION, PAINFUL INTERCOURSE, LOSS OF HAIR, MAJOR WEIGHT GAIN, DEPRESSION BECAUSE OF PAIN, MUSCLE AND JOINT PAIN, INFLAMMATION, PAINFUL PERIODS, MOOD SWINGS, EMOTIONALLY UNSTABLE, MEMORY LOSS, LOSS OF TEETH, AND ALSO HAD TO GET PARTIAL HYSTERECTOMY WHERE THEY REMOVED MY FALLOPIAN TUBES WITH ESSURE COILS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036947	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 6/5/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS THE DATE I HAD MY PROCEDURE DONE AND EVERYTHING WENT TO HELL. FROM THE MOMENT I GOT IT PLACED I WAS IN SEVERE PAIN VERY HEAVY PERIODS. I HAVE HAD SEVERE PAINS EVERY SINCE THAT BRINGS ME TO TEARS AND TO MY KNEES. I HAVE HAD SOME FALSE PREGNANCY AND A MISCARRIAGE DUE TO THE DEVICE AS WELL AND HAD TO HAVE SURGERY FOR THEM TO SEE AND MAKE SURE THERE WAS NO ERODING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036948	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 6/26/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING, SHARP PELVIC PAIN, LIGHTHEADEDNESS, HEART PALPITATIONS...CURRENTLY PREGNANT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036949	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 9/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT HEAVY PERIOD BLEEDING, CHRONIC PAIN THROUGHOUT MY ENTIRE BODY, MIGRAINES DAILY THAT I NOW TAKE PRESCRIPTION MEDICINE FOR, RESTLESS LEG SYNDROME, DECREASE IN ENERGY, WEIGHT GAIN. EVERYTIME I EAT IT NOW MAKES ME SICK TO MY STOMACHE.

(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036950	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 3/8/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PREGNANCY. DATE OF CONCEPTION (B)(6), 2014. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036951	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 11/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD TWO COILS PLACED IN ONE TUBE (RIGHT SIDE) WHICH HAS CAUSED PAIN ON THAT SIDE, ALSO THE OTHER SIDE (LEFT SIDE) WAS CONFIRMED STILL UNBLOCKED 7 MONTHS LATER BY HSG TEST. I'VE GONE THREE MONTHS WITH NO PERIOD AT ALL (WHICH I WAS PRESCRIBED MEDICATION TO START IT AGAIN) THEN I HAD FOUR PERIODS IN A TWO MONTH TIME FRAME. I'VE HAD SEVERE JOINT PAIN AND BACK PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036952	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 10/11/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLOATING, WEIGHT GAIN, HEAVY PERIODS, CRAMPING , HOT FLASHES, SKIPPED MENSTRUAL CYCLES. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036953	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN 2007. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS623822. MY MODEL NUMBER IS ESS205 . THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN 2011 THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. PANIC ATTACKS, HEART PALPITATIONS, BACK PAIN, CHEST PAIN(EVEN HAD HEART TESTS DONE), FORGETFULNESS, DIZZINESS, FATIGUE, UNEXPLAINED FEVER, HEADACHES, SHARP STABBING PAINS IN ABDOMEN, URGENCY TO URINATE, SPASMS IN LOWER ABDOMEN, CRAMPING, HOT FLASHES, PAINFUL OVULATION, LOSS OF LIBIDO, PAINFUL INTERCOURSE (DYSPAREUNIA) , BREAST PAIN, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, METAL ALLERGIES (NICKEL), HEIGHTENED ALLERGIES/ ALLERGIC REACTIONS , RASHES/HIVES, SEVERE ABDOMINAL TENDERNESS AND BLOATING, DENTAL ISSUES, INSOMNIA, MUSCLE SPASMS, HIP PAIN , MOOD SWINGS, RHEUMATOID ARTHRITIS. I HAD HEAVY PAINFUL PERIODS UNTIL 2010 WHEN I HAD NOVASURE ABLASION. I HAVE BEEN SEEN BY 3 DIFFERENT OF DOCTORS. THE DEVICE IS STILL INSIDE OF ME BUT I AM ON WAITING LIST FINALLY FOR REMOVAL (WHICH IS 12 MONTH LIST). (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036954	BAYER	7/1/2014	7/1/2014

Event Information:

Event Date (B3): 3/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANT RIGHT BY THAT TIME BECAUSE IT SUPPOSED TO BE THE BEST . BUT AFTER 3 MONTHS I STARTED NOTICED THAT MY PERIODS BECOME LONGER AND PAINFUL , HEAVY. AND I HAD LIKE THIS NIGHT SWEATS LIKE I WAS GOING THRU MENOPAUSE AND MOOD SWINGS, BACK PAIN VERY STRONG. MY KNEE HURTS WEIRD PAIN MY LEG, HEADACHES, PELVIC PAIN. OMG MY LIFE WAS CHANGING A LOT AND I DIDN'T KNOW WHAT WAS HAPPENING TO ME. SO I WENT BACK TO SEE MY OB GYN. AND UNTOLD HER SINCE I HAD ESSURE I'M BEEN HAVING THIS PROBLEMS I NOTICED THAT AND SHE TOLD ME NO I DON'T THINK SO, SO SHE SEND ME TO HAVE SOME HORMONES AND MENOPAUSE TEST, EVEN SHE SEND ME TO SEE A PHYCOLOGIST BECAUSE MY MOOD SWINGS AND JUST GOING CRAZY. SO IS BEEN A LONG RUN NO ONE BELIEVES HOW MY PAIN WAS AND HOW I TERRIBLE I WAS FEELING, PAIN AND DON'T KNOW HOW TO EXPLAIN. I RECENTLY HAD HYSTERECTOMY DONE I HAD MY ESSURE REMOVE FINALLY !! IM STILL AND RECOVERY (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036955	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 10/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2008. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 627290. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED AROUND (B)(6) 2008. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: RASH, FATIGUE, DRASTIC INCREASE IN BLOOD PRESSURE, METALLIC TASTE IN MOUTH, BLOATING, BOWEL ISSUES, NUMBNESS, BRAIN FOG, DEPRESSION, VITAMIN D DEFICIENCY, DEVELOPED FOOD AND ENVIRONMENTAL ALLERGIES AND SENSITIVITIES, TITANIUM ALLERGY, HYPOTHYROIDISM, HAIR LOSS, DENTAL ISSUES, CRAMPING, IRREGULAR BLEEDING, JOINT PAIN, INFLAMMATION AND ADRENAL PROBLEMS. I HAVE BEEN SEEN BY SEVERAL DOCTORS (PRIMARY CARE, ALLERGIST, DERMATOLOGIST, GYNECOLOGIST). I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: HIGH BLOOD PRESSURE, ALLERGIES, HYPOTHYROIDISM, ADENOMYOSIS AND DEPRESSION. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: SUPRACERVICAL HYSTERECTOMY. THE DEVICE HAS BEEN REMOVED AS OF (B)(6), 2014. THE DEVICE IS NOT IN MY POSSESSION. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036957	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 2/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE DEVICE INSERTED ON THE ABOVE DATE. I FELT OK FOR THE FIRST FEW MONTHS BY (B)(6) I STARTED GETTING ABDOMINAL PAIN ON THE LEFT SIDE ONLY LASTED A FEW HOURS. IN (B)(6), I GET THE PAIN AGAIN. EACH MONTH, THE PAIN WOULD GET STRONGER AND LAST A LITTLE LONGER. BY (B)(6) THAT YEAR, I STARTED NOTICING BRUISING AND HOW EASY IT WAS TO BRUISE. AND MY ANXIETY WAS GETTING WORSE. BY (B)(6) 2013 I WAS GETTING THE PAIN AND IT WAS LASTING A DAY OR SO. IN (B)(6), I ENDED UP HAVING TO LEAVE WORK ONE DAY CAUSE THE PAIN WAS UNBEARABLE AND I WENT TO THE ER. WHILE THERE, THEY PREFORMED MANY BLOOD TESTS AND AN ULTRASOUND AND EVERYTHING CAME BACK NORMAL. I WAS OFF WORK FOR A WEEK AND ON TORADOL AND NAPROXEN FOR PAIN. THE PAIN FINALLY WENT AWAY AFTER 5 DAYS. IN (B)(6) THE SAME THING WAS IN LOTS OF PAIN BUT HAD LEFT OVER NAPROXEN AND THAT SEEMED TO HELP. (B)(6) 2013 I WOKE UP WITH UNBEARABLE LEFT PELVIC PAIN. I WAS NAUSEAS FROM THE PAIN AND COULDN'T EVEN WALK THE PAIN WENT ALL THEY WAY DOWN MY LEG. MY HUSBAND RUSHED ME TO THE ER WHICH IS OVER AN HOUR AWAY. SAME THING, BLOOD TEST AFTER BLOOD TEST AND INTERNAL AND EXTERNAL ULTRASOUNDS AND STILL EVERYTHING CAME BACK NORMAL. I LEFT THE HOSPITAL WITH A PRESCRIPTION FOR OXYCODONE. THE PAINS LASTED ABOUT 5 DAYS AGAIN. IN (B)(6) THE SAME THING. I WENT TO THE DOC AND SAME THING ALL TESTS WERE NORMAL. SO I SUFFERED FOR A WEEK. BY (B)(6) I WAS SO DEPRESSED AND I WAS JUST SO TIRED ALL THE TIME I HAD TO QUIT MY JOB CAUSE THE PAIN WAS GETTING STRONGER IN INTENSITY AND LASTING OVER A WEEK. IN (B)(6) I GOT THE PAIN RIGHT ON SCHEDULE EVERY 28 DAYS OR SO AND IT WAS SO BAD I GOT IN TO SEE MY GYNO ASAP, HE THEN PRESCRIBED TRAMADOL FOR THE PAIN WHICH DIDN'T TAKE THE PAIN AWAY JUST MADE IT MORE BEARABLE AND WE DISCUSSED DOING A LAPAROSCOPY TO SEE WHAT HE COULD FIND. IN (B)(6) I WENT BACK TO SEE HIM CAUSE EVEN ON THE TRAMADOL THAT MONTH IT WAS

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TOO MUCH FOR ME TO HANDLE. SO HE DOUBLED THE DOSE AND WE TALKED ABOUT A HYSTERECTOMY. IN (B)(6) I WAS ON VACATION IN CALGARY ALBERTA AND I HAD THE PAIN SO BAD THAT EVEN ON THE TRAMADOL I COULDN'T MOVE THE PAIN WAS SO MUCH THAT IT WAS TAKING MY BREATHE AWAY, SO WE WENT TO THE ER AND YET AGAIN BLOOD TESTS AND BOTH ULTRASOUNDS DONE AND NOTHING WAS FOUND THAT COULD BE CAUSING THE PAIN. SO SENT ME HOME WITH PERCOCET. 36 HOURS LATER, I ENDED UP BACK IN THE ER NOTHING WAS HELPING WITH THE PAIN EVEN THE MORPHINE DIDN'T REALLY HELP. WELL THE WAIT LIST FOR MY GYN IS SO LONG THAT I HAD TO FIND A NEW DOC AND TRAVEL 6 HOURS AWAY FROM MY HOUSE. GOT IN TO SEE HIM ON (B)(6) 2013 I HAD A HYSTERECTOMY TO REMOVE THE COILS. MY DOC SAID THAT THERE WAS SO MUCH INFLAMMATION IN MY UTERUS THAT MY CERVIX HAD SEIZED SHUT. IT TOOK ME 6 WEEKS TO PHYSICALLY HEAL FROM THE SURGERY BUT MENTALLY IM STILL TRYING TO DEAL WITH THIS WHOLE SITUATION (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036958	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 6/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN 2008 AFTER MY THIRD BABY, WHILE DISCUSSING WITH MY DOCTOR WHAT WOULD BE THE BEST BIRTH CONTROL FOR ME, MY HUSBAND AND I DECIDED THAT WE DID NOT WANT ANY MORE CHILDREN. THE DOCTOR MENTIONS ESSURE AND ASSURED ME THAT IT WOULD BE THE EASIEST NO DOWN TIME NO HORMONE, SAFEST OPTION FOR ME, I THOUGHT GREAT! I WON'T EVEN NEED TO RECOVER FROM THIS SO NO TIME AWAY FROM MY CHILDREN. SHORTLY AFTER GETTING THE COILS THE CRAMPING WAS AWFUL, I WOULD SAY I REMEMBER THAT PAIN MORE THAN I REMEMBER HAVING ALL 3 OF MY CHILDREN. I VISIT MY DOCTOR THAT YEAR MULTIPLE TIMES WITH DIFFERENT SYMPTOMS, AT FIRST THE CRAMPING, BLEEDING, AND THE BLOATING, SOON CAME THE ANEMIA THAT WAS FOUND BY A NURSE IN ONE OF THOSE VISITS. ABOUT 2 YEARS AFTER GETTING ESSURE I HAD DEVELOPED LOTS OF DIFFERENT PROBLEMS AND SEEN MULTIPLE DOCTORS HOPING FOR AN ANSWER BUT NO ONE KNEW WHY I WAS SO SICK, BY THIS TIME I HAD THE MAJOR BLOATING, SUPER HEAVY BLEEDING, CRAMPING, ANEMIA, FATIGUE, JOINT PAIN, DIZZINESS, HAIR LOSS, MUSCLE ACHES, SKIN PROBLEMS, DIGESTIVE PROBLEMS, HEADACHES, MEMORY LOSS, EYE PROBLEM, UPPER STOMACH PAIN, DEPRESSION, PAIN DURING SEX, ALL OF THIS AT AGE 24. I THOUGHT I WAS GOING CRAZY, HOW CAN A 24 YEAR OLD SUFFER SO MANY PROBLEMS AND WITH NO ANSWER AS FOR WHY. AFTER MULTIPLE VISITS TO THE DOCTORS AND SPECIALIST MULTIPLE EXAMS, MRI, X-RAYS, CT SCANS, ULTRASOUNDS, UPPER SCOPE, COLONOSCOPY, BLOOD-WORK EVERYTHING WAS ALWAYS NEGATIVE, I WAS EVEN PUT ON A FEEDING TUBE TO RULE OUT FOOD ALLERGIES. BY THIS TIME MY GI DOCTOR WAS FRUSTRATED. HIS NEXT STEP WAS GOING TO BE A SURGERY BUT THAT WAS THE LAST THING HE WANTED TO DO BECAUSE OF THE RISKS, SO HE ASKED ME TO GO OVER MY MEDICAL HISTORY WITH HIM - ANY SURGERIES OR JUST ANYTHING I CAN THINK OF. I CAME ACROSS ESSURE, I EXPLAINED TO HIM THAT IT WAS A PERMANENT BIRTH CONTROL, HE ASKED IF IT RELEASES

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HORMONES I TOLD HIM IT DID NOT, HE SAID HE WOULD LOOK INTO IT AND WE WOULD TALK ABOUT IT NEXT TIME. I FOUND OUT THAT ESSURE HAS SOME NICKEL AND OTHER METALS, I KNEW THAT THERE WAS A CHANCE I COULD BE ALLERGIC TO NICKEL BECAUSE MY MOTHER IS AND SO THE DOCTOR ASKED ME TO GET TESTED FOR NICKEL AND TO GO VISIT MY OB/GYN TO RULE OUT ESSURE BEFORE HE DOES THE SURGERY. I VISITED WITH A NEW OB/GYN AND I EXPLAINED TO HER WHAT HAS BEEN GOING ON, BUT SHE TELLS ME RIGHT AWAY THAT THERE IS NO WAY THAT ESSURE HAS ANYTHING TO DO WITH THE PROBLEMS, I TELL HER THAT I'M NOT SAYING THAT ESSURE IS CAUSING ALL THIS PROBLEMS BUT I WANT TO BE 100% SURE THAT ITS NOT BEFORE I DO THE STOMACH SURGERY, SO SHE SAYS FINE BUT I WILL HAVE TO TALK TO A SURGEON FIRST. SOON LATER SHE COMES BACK IN WITH A BETTER ATTITUDE AND SAYS WELL I GUESS THE SURGEON HAS HAD TO REMOVE SOME ALREADY BECAUSE THEY HAVE AFFECTED SOME LADIES. AFTER TALKING TO THE SURGEON I WAS SCHEDULED TO GET A HYSTERECTOMY. I HAD THE HYSTERECTOMY DONE ALMOST 2 WEEKS AGO AND I CAN FEEL A CHANGE. I HAVE NOT HAD ANY HEADACHES, I HAVE NOTICED A HUGE CHANGE TO MY SKIN, NO MORE STOMACH OR DIGESTIVE PROBLEMS, MY BODY DOES NOT ACHE, I AM NOT AS FATIGUED EVEN AFTER SURGERY I HAVE MORE ENERGY. THINGS HAVE BEEN CHANGING AFTER THE REMOVAL OF ESSURE. I GOT THE COILS IN 2008 I HAD THEM FOR 6 YEARS AND FOR THE 6 YEARS I THOUGHT I WAS CRAZY, I THOUGHT I WOULD HAVE TO LIVE IN PAIN FOR THE REST OF MY LIFE. IT'S BEEN 2 WEEKS AND SOME OF MY HEALTH PROBLEMS HAVE GONE AWAY. I WON'T KNOW IF THEY ARE GONE FOR GOOD BUT I HAVE HOPE. I REMEMBER THE OB/GYN TELLING ME THAT THE AMOUNT OF WOMEN THAT HAVE HAD A BAD REACTION IS SMALL COMPARED TO THE SUCCESSFUL ONES, BUT THEN I ASKED WELL HOW MANY OF THEM MIGHT NOT EVEN KNOW THAT ESSURE IS THE CAUSE OF ANY HEALTH PROBLEMS, I WOULD HAVE NEVER KNOWN IT WAS CAUSING ME PROBLEMS IF MY GI DOCTOR HAD NOT BROUGHT IT UP. I NEVER IMAGINED THAT SOMETHING PLACED IN MY FALLOPIAN TUBES COULD BE CAUSING PROBLEMS ALL AROUND AND ALL I KNOW IS THAT WE ARE NOT ALL THE SAME AND I GUESS I WAS IN THE 1%. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036959	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 7/30/2009	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SOON AFTER THE PLACEMENT OF ESSURE-I STARTED TO NOTICE THAT I WAS LOSING MY HAIR. I THEN GOT DEATHLY ILL IN (B)(6) 2009 AND WAS DIAGNOSED WITH ULCERATIVE COLITIS. I RECEIVE REMICADE TREATMENTS EVERY 8 WEEKS. I CURRENTLY AM BEING TREATED FOR DEPRESSION. I SUFFER FROM BRAIN FOG-VERY FORGETFUL AND LOSE MY TRAIN OF THOUGHT. I HAVE BECOME HYPOGLYCEMIC AND SUFFER FROM SEVERE HOT FLASHES AND DIZZINESS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036960	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 2/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE DEVICE INSERTED ON THE ABOVE DATE. I FELT OK FOR THE FIRST FEW MONTHS BY (B)(6) I STARTED GETTING ABDOMINAL PAIN ON THE LEFT SIDE ONLY LASTED A FEW HOURS. IN (B)(6) I GET THE PAIN AGAIN. EACH MONTH THE PAIN WOULD GET STRONGER AND LAST A LITTLE LONGER. BY (B)(6) THAT YEAR I STARTED NOTICING BRUISING AND HOW EASY IT WAS TO BRUISE. AND MY ANXIETY WAS GETTING WORSE. BY (B)(6) 2013 I WAS GETTING THE PAIN AND IT WAS LASTING A DAY OR SO. IN (B)(6) I ENDED UP HAVING TO LEAVE WORK ONE DAY CAUSE THE PAIN WAS UNBEARABLE AND I WENT TO THE ER. WHILE THERE THEY PREFORMED MANY BLOOD TESTS AND AN ULTRASOUND AND EVERYTHING CAME BACK NORMAL. I WAS OFF WORK FOR A WEEK AND ON TORADOL AND NAPROXEN FOR PAIN. THE PAIN FINALLY WENT AWAY AFTER 5 DAYS. IN (B)(6) THE SAME THING WAS IN LOTS OF PAIN BUT HAD LEFT OVER NAPROXEN AND THAT SEEMED TO HELP. (B)(6) 2013 I WOKE UP WITH UNBEARABLE LEFT PELVIC PAIN. I WAS NAUSEOUS FROM THE PAIN AND COULDN'T EVEN WALK THE PAIN WENT ALL THEY WAY DOWN MY LEG. MY HUSBAND RUSHED ME TO THE ER WHICH IS OVER AN HOUR AWAY. SAME THING BLOOD TEST AFTER BLOOD TEST AND INTERNAL AND EXTERNAL ULTRASOUNDS AND STILL EVERYTHING CAME BACK NORMAL. I LEFT THE HOSPITAL WITH A PRESCRIPTION FOR OXYCODON. THE PAINS LASTED ABOUT 5 DAYS AGAIN. IN (B)(6) THE SAME THING. I WENT TO THE DOC AND SAME THING ALL TESTS WERE NORMAL. SO I SUFFERED FOR A WEEK. BY (B)(6) AND (B)(6) I WAS SO DEPRESSED AND I WAS JUST SO TIRED ALL THE TIME I HAD TO QUIT MY JOB CAUSE THE PAIN WAS GETTING STRONGER IN INTENSITY AND LASTING OVER A WEEK. IN (B)(6) I GOT THE PAIN RIGHT ON SCHEDULE EVERY 28 DAYS OR SO AND IT WAS SO BAD I GOT IN TO SEE MY GYNO ASAP HE THEN PRESCRIBED. TRAMODOL FOR THE PAIN WHICH DIDN'T TAKE THE PAIN AWAY JUST MADE IT MORE BARE ABLE AND WE DISCUSSED DOING A LAPAROSCOPY TO SEE WHAT HE COULD FIND. IN (B)(6) I WENT BACK TO SEE HIM CAUSE EVEN ON THE TRAMODOL THAT MONTH IT

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WAS TOO MUCH FOR ME TO HANDLE. SO HE DOUBLED THE DOSE AND WE TALKED ABOUT A HYSTERECTOMY. IN (B)(6) I WAS ON VACATION IN (B)(6) AND I HAD THE PAIN SO BAD THAT EVEN ON THE TRAMODOL I COULDN'T MOVE THE PAIN WAS SO MUCH THAT IT WAS TAKING MY BREATHE AWAY SO WE WENT TO THE ER AND YET AGAIN BLOOD TESTS AND BOTH ULTRASOUNDS DONE AND NOTHING WAS FOUND THAT COULD BE CAUSING THE PAIN. SO SENT ME HOME WITH PERCOCET. 36 HOURS LATER I ENDED UP BACK IN THE ER NOTHING WAS HELPING WITH THE PAIN EVEN THE MORPHINE DIDN'T REALLY HELP. WELL THE WAIT LIST FOR MY GYN IS SO LONG THAT I HAD TO FIND A NEW DOC AND TRAVEL 6 HOURS AWAY FROM MY HOUSE. GOT IN TO SEE HIM ON (B)(6) AND ON (B)(6) 2013 I HAD A HYSTERECTOMY TO REMOVE THE COILS. MY DOC SAID THAT THERE WAS SO MUCH INFLAMMATION IN MY UTERUS THAT MY CERVIX HAD SEIZED SHUT. IT TOOK ME 6 WEEKS TO PHYSICALLY HEAL FROM THE SURGERY BUT MENTALLY IM STILL TRYING TO DEAL WITH THIS WHOLE SITUATION. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036961	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 12/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC RIGHT SIDE PAIN LEADING TO BACK SOMETIMES PAIN GO TO THE BATHROOM, PAIN DURING SEX PAIN ALL THE TIME ITS A STABBING PAIN.

(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036962	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON APPROXIMATELY (B)(6) 2006. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY CONCEPTUS, INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I WAS NOT MADE AWARE OF THIS BY THE DOCTOR OR MANUFACTURING COMPANY AND DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON APPROXIMATELY (B)(6) 2009. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: CRAMPING; SHARP/STABBING PELVIC PAIN; DISCHARGE (WITH AND WITHOUT ODOR); BARTHOLIN'S CYST; PAINFUL PERIODS; MULTIPLE URINARY TRACT INFECTIONS; ABDOMINAL SPASMS; BLOATING; BOWEL ISSUES; HEIGHTENED ALLERGIES; FOOD ALLERGIES; NIGHT SWEATS; EXCESSIVE DRY SKIN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036963	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 4/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2012, THE PROCEDURE SEEMED TO GO WELL BUT WAS VERY PAINFUL AND I BLED FOR APPROX. 5 DAYS AND WAS EXTREMELY CRAMPY UNLIKE A FEW OF MY FRIENDS WHO HAD THE PROCEDURE AND FELT FINE WITH NO BLEEDING. I ALWAYS FELT LIKE I COULD FEEL WHERE THE COILS WERE AND THIS DISCOMFORT WAS ALWAYS AMPLIFIED WHEN I HAD MY PERIOD. I ALWAYS HAD LIGHT EASY PERIODS AND AFTER THE PROCEDURE MY PERIODS BECAME MUCH LONGER WITH HEAVING BLEEDING AND INTENSE CRAMPING. MY STOMACH ALWAYS FELT BLOATED AND INFLAMED ESPECIALLY AFTER INTERCOURSE. I DEVELOPED FREQUENT UTI'S AND YEAST INFECTIONS. WHEN I WENT BACK TO HAVE THE TEST TO MAKE SURE THE PROCEDURE TOOK THEY COULDN'T GET THE INSTRUMENT IN ME IT WAS SO PAINFUL THAT THEY STOPPED AND TOLD ME THEY COULDN'T DO PROCEDURE BECAUSE I WAS SO INFLAMED. I MADE NUMEROUS VISITS TO MY GYN AND PCP FOR A BUNCH OF VAGINAL AND STOMACH ISSUES, AND HAVING NO LUCK OR ANSWERS WITH THEM THEY PASSED ME ONTO GYNO/UROLOGIST WHO ALSO DID SEVERAL TESTS, BLOOD, BLADDER, ULTRASOUNDS ETC... PUTTING ME ON ESTROGEN, PHENAZOPYRIDINE AND NITROFLURANTOIN TO HELP SUBSIDE MY SYMPTOMS. THEY HELPED A LITTLE BUT I WAS STILL ALWAYS UNCOMFORTABLE. I THEN DEVELOPED SEVERE CONSTIPATION AN TROUBLE DIGESTING FOOD. THIS LED ME TO A GASTRO DOCTOR WHO DID A COLONOSCOPY AND ENDOSCOPY WHICH RESULTED IN MILD DIVERTICULITIS AND ULCERS IN MY ESOPHAGUS WHICH I DID NOT HAVE BEFORE THIS PROCEDURE. I HAD MILD CONSTIPATION BEFORE BUT NOT THIS EXTREME AND NEVER ANY DIGESTIVE OR ULCER ISSUES, THIS LEAD TO NOT BEING ABLE TO BEING EAT PROPERLY AND PUT ON PREVACID AND PRILOSEC. NEITHER MEDICATIONS HELPED AND I WAS NOT ABLE TO EAT REGULARLY OR DIGEST FOOD UNTIL THE COILS WERE TAKEN OUT (B)(6) 2014. IN SUMMARY BEFORE ESSURE I WAS A HEALTHY (B)(6) YEAR OLD WITH MILD FIBROMYALGIA, MILD BOWEL ISSUES NO STOMACH OR DIGESTION ISSUES AND

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SINCE THE IMPLANTS IN 2012 I HAVE BEEN DIAGNOSED WITH LUPUS AND MY FIBROMYALGIA IS THROUGH THE ROOF. I USED TO BE ABLE TO CONTROL WITH ALEVE OR MOTRIN AND EXERCISE. FOR THE PAST SIX MONTH I HAVE ALSO BEEN SEEING A RHEUMATOLOGIST TO TRY GET MY SEVERE JOINT/MUSCLE PAIN UNDER CONTROL AND HAVE TRIED SEVERAL MEDICATION WITH NO LUCK. ALL SYMPTOMS SINCE IMPLANTS ARE AS FOLLOWS: RANDOM PELVIC PAIN AND SHARP SHOOTING PAINS REGULARLY, DISCHARGE, HOT FLASHES, LONG PERIODS, EXCESSIVE BLEEDING DURING PERIODS, EXCESSIVE CRAMPING, PAINFUL INTERCOURSE, STOMACH PAIN AND BLOATING AFTER INTERCOURSE, SEVERE STOMACH BLOATING IN GENERAL, WAS TOLD I WAS GOING THROUGH EARLY MENOPAUSE, URGENT/FREQUENT URINATION, FREQUENT UTI INFECTIONS, ITCHING, BURNING, STABBING IN VAGINAL ENTRANCE, BREAST PAIN SWELLING AND TENDERNESS, CHRONIC JOINT AND MUSCLE PAIN, ALL OVER BODY ACHES AND PAINS, HEARTBURN, BOWEL ISSUES, NERVE PAIN, TINGLING SENSATIONS, NUMBNESS, ANXIETY (I NOW TAKE XANAX AS NEEDED) TREMORS/SHAKINESS, VERY ITCHY ON SKIN AND SCALP, EXTREME FATIGUE. I HAVE SINCE HAD THE COILS REMOVED ON (B)(6) 2014, I WAS TOLD THAT THE ONLY WAY TO BE RID OF ALL THESE AWFUL SYMPTOMS WAS TO HAVE A FULL HYSTERECTOMY AT THE AGE OF (B)(6) WHICH IS WHAT I HAD DONE WITH A PHYSICIAN OUT OF THE (B)(6), HE HAS DONE SEVERAL REMOVALS AND IN HIS EXPERIENCE THE WOMAN THAT DIDN'T HAVE A FULL HYSTO WERE BACK IN FOR ANOTHER SURGERY SO THIS IS WHY I OPTED TO HAVE A FULL. I MISSED 4 WEEKS OF WORK AND WENT BACK TOO EARLY BECAUSE I COULDN'T STAY OUT ANY LONGER SO I DEFINITELY WENT BACK TO WORK SOONER THAN I SHOULD HAVE. PRETTY MUCH MOST OF SYMPTOMS ARE GONE EXCEPT THE MUSCLE/JOINT PAIN WHICH I CAN'T GET UNDER CONTROL AND I STILL HAVE EXTREME FATIGUE. MY EXTREME DIGESTIVE AND BLOATING ISSUES WERE FIXED IMMEDIATELY ALTHOUGH I AM CURRENTLY 8 WEEKS POST OP AND STILL IN RECOVERY MODE SO I DON'T KNOW WHAT OTHER ISSUES I MAY STILL HAVE AND I HAVEN'T HAD MUCH INTERCOURSE. I STILL HAVE SOME CONSTIPATION ISSUES BUT NOT AS BAD. I HAVE NO PAIN WHERE THE COILS AND NO RANDOM STOMACH OR PELVIC PAIN. THIS PAST TWO YEARS HAS BEEN THE WORST EXPERIENCE OF MY LIFE. MY DOCTOR WHO IMPLANTED NEVER TOLD ME ABOUT ANY OF THE POSSIBLE SIDE EFFECTS AND COMPLICATIONS TO THIS PROCEDURE. IT WAS MARKED AS A LESS INVASIVE NON SURGICAL PROCEDURE AND IF I HAD TO DO IT AGAIN I WOULD GET MY TUBES TIED BECAUSE IN THE END I ENDED UP TO HAVE MAJOR SURGERY TO CORRECT ALL THE DAMAGE THE ESSURE HAS DONE TO MY BODY AND SOME OF THESE ISSUES MAY BE PERMANENT. (B)(4). UPDATE ON (B)(6) 2014: MY ESSURE REF # IS (B)(4) LOT #823472 MY DEVICE HAS A THREE YEAR SHELF LIFE ALTHOUGH I DO NOT HAVE THE EXPIRATION DATE. THE DEVISE IS NOW IN MY POSSESSION SINCE MY REMOVAL ON (B)(6) 2014. THE MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS, INC. UPDATE ON (B)(6) 2014: MY PATHOLOGY REPORT SHOWED AN ENLARGED UTERUS AND ADENOMYOSIS WHICH I HAD NO TRACES OR SYMPTOMS OF BEFORE ESSURE. I WAS TOLD BY PHYSICIAN THIS WAS MOST LIKELY THE CAUSE OF MY HEAVING BLEEDING AND PAIN DURING MY MENSTRUAL CYCLE WHICH AS I PREVIOUSLY STATED WAS NOT AN ISSUE BEFORE THE ESSURE IMPLANTS. I AM STILL HAVING DIFFICULTY WITH INTERCOURSE 8 WEEKS POST OPT FOR A HYSTO WHICH I HOPE IS NOT PERMANENT EITHER AS FOR THERE WERE NO ISSUES WITH INTERCOURSE BEFORE ESSURE. UPDATE ON (B)(6) 2014: MY PATHOLOGY REPORT SHOWED AN ENLARGED UTERUS AND ADENOMYOSIS WHICH I HAD NO TRACES OR SYMPTOMS OF BEFORE ESSURE. I WAS TOLD BY PHYSICIAN THIS WAS MOST LIKELY THE CAUSE OF MY HEAVING BLEEDING AND PAIN DURING MY MENSTRUAL CYCLE WHICH AS I PREVIOUSLY STATED WAS NOT AN ISSUE BEFORE THE ESSURE IMPLANTS. I AM STILL HAVING DIFFICULTY WITH INTERCOURSE 8 WEEKS POST OPT FOR A HYSTO WHICH I HOPE IS NOT PERMANENT EITHER AS FOR THERE WERE NO ISSUES WITH INTERCOURSE BEFORE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036964	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 2/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE IRREGULAR MENSES NOW, ABOUT EVERY TWO WEEKS. ON THE WEEKS THAT I AM NOT BLEEDING, I AM FEELING MY OVULATION CYCLE. EXCESSIVE SWEATING, BLOOD CLOTS, DRY MOUTH, PELVIC PAIN, HAIR LOSS, LEFT SIDE PAIN BY TUBES. I HAVE HAD THE NICKLE ALLERGY PATCH TEST DONE FOR NICKLE, GOLD, TITANIUM, AND SILVER. THIS CAME BACK NEGATIVE. I HAVE HAD A UTERINE BIOPSY WHICH WAS ALSO NEGATIVE. MULTIPLE ULTRASOUNDS AND TRANSVAGINAL ULTRASOUNDS. NO ANSWERS AS TO WHY I AM BLEEDING SO MUCH. IMPLANTING DOCTOR SAYS THAT MY COILS ARE EMBEDDED INTO UTERINE MUSCLE. I WAS ADVISED THAT THIS SHOULD NOT BE THE CASE. I HAVE GONE TO A SECOND OBGYN WHO I AM CURRENTLY UNDER HIS CARE FOR. THE OPTIONS I HAVE BEEN GIVEN ARE TO HAVE THE MIRENA PLACED AS WELL (WHICH I REFUSE TO DO. NOTHING ELSE IS BEING PLACED IN MY BODY!!) OR TO HAVE A HYSTERECTOMY. I WILL HAVE TO HAVE MY TUBES WITH COILS IN TACT REMOVED AS WELL AS MY UTERUS AND CERVIX. IF MY OVARIES HAVE TOO MANY CYSTS ON THEM, I WILL HAVE TO HAVE THEM REMOVED AS WELL. IF THAT HAPPENS, AS YOU KNOW, I WILL GO INTO EARLY MENOPAUSE. NOT WHAT I EXPECTED IN 2012 WHEN I STARTED TALKING TO MY DOCTOR ABOUT GETTING OFF BIRTH CONTROL PILLS BECAUSE OF FAMILY HISTORY OF BREAST CANCER. I MYSELF HAD TO HAVE A BREAST BIOPSY IN 2010 WHERE A TITANIUM CLIP WAS PLACED. I ALSO HAVE CONSTANT PAIN AT THAT SPOT AS WELL. I CHECKED THE OUTCOME AS PERMANENT DAMAGE AS I WILL HAVE TO HAVE THAT HYSTERECTOMY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036965	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 6/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE LEFT COIL HAS MIGRATED OUT OF MY TUBE AND HAS ADHERED TO THE WALL OF THE UTERUS. I WILL MOST LIKELY REQUIRE A HYSTERECTOMY AND I'M ONLY (B)(6).
(B)(4)

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036966	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 10/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PERIODS BECAME HEAVIER AND HEAVIER. CRAMPING WAS INTOLERABLE. WITHIN A FEW MONTHS, I BEGAN HAVING ISSUES WITH MY GALL BLADDER. THAT WAS REMOVED. PERIODS PROGRESSED TO THE POINT OF INCAPACITATION. THERMAL ABLATION WAS PERFORMED. CRAMPING CONTINUED AND ALSO RENDERED INCAPACITY. HYSTERECTOMY PERFORMED IN (B)(6) 2009. I ALSO SUFFERED WITH CONTINUOUS MIGRAINES THROUGHOUT THE YEARS THAT ESSURE WAS IMPLANTED. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036967	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BEGAN TO HAVE IRREGULAR BLEEDING, AND EXTREMELY LONG AND HEAVY MENSTRUAL CYCLES, HEAD ACHES AND DEBILITATING CRAMPS IN MY PELVIS AND LOWER BACK. I DEVELOPED A RASH ON MY INNER THIGHS AND THE SKIN DARKENED IN PATCHES. ON (B)(6) 2014, I TESTED POSITIVE FOR PREGNANCY BY BOTH BLOOD AND AN ULTRA SOUND. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036968	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE (B)(6) 2011. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED AROUND (B)(6) 2011. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. HEAVY PERIODS, FREQUENT MIGRAINES, MUSCLE SPASMS, NEUROPATHY IN HANDS AND FEET, HIVES, SKIN RASH, GLUTEN SENSITIVITY, FIBROMYALGIA, HYPERTENSION, INAPPROPRIATE SINUS TACHYCARDIA, IRRITABLE BLADDER, WATER RETENTION (UP TO 8 LBS IN A DAYS TIME), WEIGHT GAIN (55 LBS OVER 8 MONTHS), SEVERE FATIGUE, BRAIN FOG, DEPRESSION, AND INSOMNIA. I HAVE BEEN SEEN BY A 3 NEUROLOGISTS, A DERMATOLOGIST, AN ALLERGIST, A UROLOGIST, A NURSE PRACTITIONER, AND MY FAMILY PHYSICIAN. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: FIBROMYALGIA, HYPERTENSION, INAPPROPRIATE SINUS TACHYCARDIA, HEAVY MENSTRUAL PERIODS. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: BILATERAL SALPINGECTOMY, NOVASURE ABLATION. I HAVE ALSO HAD A SLEEP STUDY, MRI OF THE HEAD AND NECK, ABDOMINAL ULTRASOUND, AND ABDOMINAL SCAN. THE DEVICE WAS REMOVED (B)(6) 2013. MY SYMPTOMS IMPROVED SLIGHTLY BUT DID NOT COMPLETELY RESOLVE. I DO NOT KNOW IF THE DEVICE WAS RETURNED TO THE MANUFACTURER. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036969	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTING LOSING MY HAIR APPROXIMATELY 1 MONTH AFTER HAVING ESSURE PLACED. AS TIME PASSED I STARTED HAVING CONSTANT JOINT PAIN. IT HAS PROGRESSIVELY GOTTEN WORSE. I HAVE NO STOP PAIN IN MY LEGS AND JOINTS OF MY LEGS. I HAVE EXTREME MOOD SWINGS AS WELL AS FEELING ANXIOUS A LOT. MY TEETH HAVE STARTED TO CHIP AND BREAK. ALL THOUGH MY TEETH ARE NOT PAINFUL THEY HAVE BECOME PROBLEMATIC AS I HAVE HAD TO LIMIT WHAT I CAN AND CANT EAT IN FEAR THEY WILL CONTINUE TO BREAK AND CRACK. MY PERIODS HAVE BECOME MUCH SHORTER IN LENGTH BUT I HAVE HEAVY BLEEDING THE IS VERY UNUSUAL FOR ME. IT IS ALSO PAINFUL SINCE ESSURE TO USE TAMPONS. I HAVE A LOT OF BLOOD CLOTS AS WELL.

(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036970	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 3/1/2007 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED 2007, SIDE EFFECTS STARTED IMMEDIATELY AFTERWARDS. A WEEK BEFORE MENSTRUATING, I GO THROUGH ALL MY PREGNANCY SYMPTOMS, HEARTBURN, ENGORGED BOOBS, AT TIMES EVEN SOME LEAKAGE, FOOD CRAVINGS AND, NAUSEA. WHILE MENSTRUATING, THE VAGINA AREA IS EXTREMELY PAINFUL AND THROBBING. ANY OTHER RANDOM TIME THERE'S CRYING FOR NO REASON, BLOATING, LOWER BACK PAIN, NUMBNESS IN THE RIGHT SIDE OF ABDOMEN GOING DOWN THE RIGHT LEG/THIGH, NUMBNESS IN UPPER RIGHT SIDE OF THE BACK, ALWAYS FEELING BRUISED TO THE TOUCH, SHARP STABBING PAINS IN THE VAGINA REGION, CHRONIC PELVIC PAIN, PAINFUL INTERCOURSE, FLUTTERING SENSATION IN THE ABDOMEN, ALWAYS TIRED, RASH, HORRIBLE MOOD SWINGS, WEIGHT GAIN AND, THE INCREASE OF SWELLING IN MY KNEES DUE TO AN AUTOIMMUNE DISEASE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036971	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 8/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS IMPLANTED (B)(6) 2007, CONFIRMED BLOCKED. POST IMPLANT I HAVE HAD SEVERE BLEEDING WITH MENSES, PELVIC PAIN, DIAGNOSES OF FIBROMYALGIA, CELIAC DISEASE, HYPERTHYROIDISM, SEVERE JOINT PAIN AND FATIGUE. A HYSTERECTOMY TO REMOVE ESSURE ON (B)(6) IS SCHEDULED. OVARIES WILL REMAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036972	BAYER	7/1/2014	7/2/2014

Event Information:

Event Date (B3): 9/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAIR LOSS, DEVELOPED ANXIETY, PELVIC PAIN, HEAVY BLEEDING, DEVELOPED ADENOMYOSIS AND HAD TO HAVE A HYSTERECTOMY ... THIS IS AN UPDATE REPORT HAVE ONE ON FDA SITE (B)(4). (B)(4). UPDATE ON (B)(4) 2014: INCLUDE, HEART PAPULATION, BRAIN ZAPS, BLURRED VISION, WEIGHT GAIN, SERVER BLOATING...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037133	BAYER HEALTHCARE	7/1/2014	7/11/2014

Event Information:

Event Date (B3): 6/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97492

Single Use:
Implant Date (E6): 6/12/2014
Explant Date (E7): 6/12/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PT WAS SCHEDULED FOR ESSURE PROCEDURE. LEFT TUBAL OSTIA WAS IDENTIFIED AND THE ESSURE COIL DEVICE WAS INSERTED IN LEFT TUBAL OSTIA AND DEPLOYED WITHOUT COMPLICATION. THE RIGHT OSTIA WAS IDENTIFIED AND THE ESSURE DEVICE WAS INSERTED AND THE SURGEON ATTEMPTED TO DEPLOY THE COIL. HE REPORTED THAT IT FELT TIGHTER THAN NORMAL, WHEN HE DEPLOYED HE DID NOT HEAR THE CLICK ASSOCIATED WITH PRESSING THE BUTTON. HE FELT THAT THE SPRING DID NOT DEPLOY AND ATTEMPTED TO REMOVE THE ESSURE DEVICE FROM THE TUBE. AT THIS POINT, HE NOTED THE SPRING "UNRATTLEING" AND NOT COMING OUT OF THE TUBAL OSTIA. THERE WAS ALSO A STRAIGHT WIRE NOTED TO BE COMING THROUGH THE TUBAL OSTIA. HE REMOVED THE ESSURE INTRODUCER, HOWEVER, THE WIRE WAS COMING THROUGH. A GRASPER WAS UTILIZED IN ATTEMPT TO REMOVE THE REMAINING WIRE AND IT CONTINUED TO BREAK INTO SMALL PIECES. AT THAT POINT THE SURGEON DECIDED TO REMOVE THE RIGHT FALLOPIAN TUBE TRIGGERING THAT THE WIRE WOULD COME OUT WITH THE REMOVAL OF THE TUBE. MANUFACTURER WAS NOTIFIED BY SURGEON AND NURSE MANAGER OF FACILITY. NURSE MANAGER WAS DIRECTED TO KEEP PRODUCT AND THAT WE WOULD BE NOTIFIED IN 16 DAYS WITH ADDITIONAL DIRECTION. DEVICE PLACED IN BIOHAZARD BAG. STILL REMAINS ON SITE AND HAVE NOT HEARD FROM COMPANY ON NEXT STEP. MANAGER TO FOLLOW UP TODAY (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037136	BAYER	7/1/2014	7/11/2014

Event Information:

Event Date (B3): 6/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IN 2007 AND HAVE BEEN HAVING CHRONIC PELVIC PAIN EVER SINCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037138	BAYER	7/1/2014	7/11/2014

Event Information:

Event Date (B3): 2/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/22/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER RECEIVING THE ESSURE PROCEDURE, I BLED FOR TWO WEEKS STRAIGHT, FILLING A LONG/EXTRA ABSORBENT PAD EVERY 2 HOURS. THE PAIN HAS BEEN INCREASING IN INTENSITY AND DURATION SINCE THE PROCEDURE IN (B)(6) 2013 SO THAT NOW I AM SUFFERING DEBILITATING PAIN AROUND AND DURING MY PERIOD THAT PREVENTS ME FROM LIVING A NORMAL LIFE. I HAVE MODERATE PAIN AT ALL OTHER TIMES. I ALSO EXPERIENCE A SHARP, STABBING PAIN UPON AROUSAL. MY DOCTOR BELIEVES I MAY NEED TO UNDERGO SURGERY TO REMOVE THE DEVICE. MY PERIOD FLOW HAS ALSO INCREASED DRASTICALLY. I USED TO EMPTY MY DIVA CUP TWICE A DAY, AND IT WAS ONLY EVER HALF FULL. NOW, I HAVE TO EMPTY IT EVERY HOUR AND HALF SINCE THE PROCEDURE. A DIVA CUP HOLDS 30ML (1 OUNCE). AS A NORMAL PADS HOLDS 5ML OF FLUID, AND FILLING UP A PAD AN HOUR IS SEEN AS A BAD SIGN, I'LL LET YOU DO THE MATH. I HAVE ALSO GAINED 40 LBS, HAVE SWELLING AROUND MY ABDOMEN, AND HAVE BEEN UNABLE TO LOSE WEIGHT DESPITE DIETING AND EXERCISING. I'M (B)(6) AND FAR TOO YOUNG TO BE FACING EVEN A PARTIALLY HYSTERECTOMY. THE DYE TEST ALSO CAUSED EXTREMELY SEVERE PAIN AND LEFT ME BLEEDING FOR OVER A WEEK. I HAD BEEN LIED TO ABOUT THE PAIN I WOULD EXPERIENCE, BEING TOLD IT WOULD BE LIKE " A PERIOD CRAMP." I VOMITED AND COULD NOT MOVE. I HAD TO BE WHEELED OUT OF THE HOSPITAL AND CARRIED INTO MY HOUSE. THAT IS NOT A "PERIOD CRAMP."

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036973	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 6/6/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS EXPERIENCING PAIN ON MY LEFT SIDE; IT WAS SO BAD I WENT TO HOSPITAL. THEY DID AN MRI AND THE LEFT SIDE COIL PENETRATED THROUGH MY TUBE AND A MOTHER PIECE IS FLOATING IN MY UTERUS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036974	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 6/26/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD TO HAVE MY FALLOPIAN TUBES TAKEN OUT. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036975	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 9/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD PELVIC PAIN STARTED MOSTLY ON LEFT SIDE HAD BLOATING, NAUSEA, MENOPAUSAL SYMPTOMS, I HAD TO HAVE MY TUBES REMOVED BECAUSE THEY WERE DILATED AND ONE HAD FLUID IN IT AND THE OTHER HAD A CYST ON IT AND I GOT DONE WITH THAT OPERATION AND HEALED I THOUGHT EVERYTHING WAS GOING TO BE BACK TO NORMAL BUT NOW I HAVE NAUSEA, PALENESS, AND WEAKNESS, DURING MY PERIOD I AM SICK AND WEAK FOR ABOUT A WEEK OR TWO SO I GO BACK TO THE DOCTOR HE WANTS TO DO EXPLORATORY SURGERY THEN HE SAID WE MY HAVE TO DO A HYSTERECTOMY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036976	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 8/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STOMACH PAINS, NAUSEA, FATIGUE, PERIODS NOT CONSISTENT, BAD CRAMPING, HEAVY BLEEDING, SPOTTING IN BETWEEN PERIODS, FIBROIDS, CYST, LOSS OF HAIR, TEETH PAINFUL, SINUS AND THROAT INFECTIONS, MOOD SWINGS, DEPRESSION, LEG CRAMPS, BACK ACHES, SHARP PAINS IN PRIVATE AREAS, ANKLE SWELLING HAND SWELLING, FACE SWELLING, FEET CRAMPS, HAND NUMBNESS AND FEET NUMBNESS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036977	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 2/3/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD ESSURE SINCE 2003. FIRST NOTICED WEIGHT GAIN AND HAIR FALLING OUT. DR RAN TESTS AND I WAS ONLY DIAGNOSED WITH A SEVERE VITAMIN D DEFICIENCY. A COUPLE YEARS AGO I STARTED HAVING SEVERE STOMACH PAIN. I HAD MY GALLBLADDER REMOVED IN 2012. THE PAIN IS STILL THERE. I'VE HAD VERY HEAVY PERIODS THIS WHOLE TIME. LAST YEAR IN (B)(6) OF 2013 I NOTICED I FELT SOMETHING METAL WHEN INSERTING A TAMPON. THEN MY BOYFRIEND AND I STARTED TO GET INTIMATE. HE TOO FELT IT AND WAS HURT. HE COULD FEEL IT TOO. IT IS VERY PAINFUL. EVERY DOCTOR I'VE SEEN, 3 TOTAL IS UNABLE TO FEEL IT. BUT MYSELF AND BOYFRIEND FEELS IT TO THE POINT WERE BEING INTIMATE IS PAINFUL FOR US BOTH AND WE RARELY GET INTIMATE ANYMORE.

(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036978	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOR NEARLY A YEAR I WATCHED MY HEALTH DETERIORATE (FROM VERY ACTIVE AN PAIN FREE TO FEEBLE AND PAIN RIDDLED AT (B)(6)). PHYSICALLY EXPERIENCED WEIGHT GAIN, JOINT PAINT, SWOLLEN/CHRONICALLY INFLAMED UTERUS (FEELING OF BOWLING BALL STUCK IN MY UTERUS/CRAMPING/SHARP PAIN IN TUBES), BACK PAIN, MIGRAINES; AND MENTALLY EXPERIENCED BRAIN FOG, CHRONIC FATIGUE, MOOD DISORDERS/ANXIETY/DEPRESSION WHICH RESULTED IN A HYSTERECTOMY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036979	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 11/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NO MENSTRUAL, FATIGUE,WEIGHT GAIN, PELVIC PAIN, BACK PAIN, SWELLING IN LEGS AND FEET, HOT FLASHES, LIGHT HEADED. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036980	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 3/4/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NAUSEA, VOMITING, SHARP STABBING PAINS IN STOMACH, BLOATING, RASHES, PURPLE BRUISES, THREE WEEK MENSTRUAL CYCLE, SEX HURTING, MIGRAINES, LOWER BACK AND ABDOMINAL PAIN AS IF I'M IN LABOR. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036981	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 9/15/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT CRAMPING IN LOWER ABDOMEN THAT SHOOTS PAINS DOWN MY LEGS. BLOATED FEELING. NAUSEA. VAGINAL BLEEDING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036982	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 5/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT STARTED THIS DAY WITH A SHARP CRAMP IN MY LOWER ABDOMEN. OVER THE YEARS IT HAS COME TO CRAMPING, BLOATING BEFORE DURING, AFTER PERIODS. I HAVE HEAVY BLEEDING, AND MY PERIODS LAST 17+ DAYS. I ALSO HAVE THIS I DON'T KNOW WETHER TO CALL IT BLOOD OR DISCHARGE BUT ITS BROWN AND HAS A HORRIBLE SMELL. IT HURTS TO HAVE INTERCOURSE AND IF I ACTUALLY GET THERE I BLEED DURING. I GET SICK TWO TO THREE TIMES A WEEK. SO I LOSE A LOT OF WEIGHT IN THE LAST 2 MONTHS I WENT FROM 125 TO 101LBS. NOT SURE IF I AM ALLERGIC TO NICKEL. I HAVE A CYST ON MY OVARY. LAST MONTH IN A HALF BEEN IN HOSPITAL FOR UTI INFECTION THEY THOUGHT I HAD KIDNEY STONES. THREE WEEKS LATER BACK FOR SAME SYMPTOMS HAD PELVIC INFLAMMATORY DISEASE. FOR SOME REASON I AM PRODUCING EXCESS BILE. MY FEET SWELL. LOTS OF TIRED FEELING THE LIST CAN GO ON. (B)(4). UPDATE ON (B)(6) 2014: SCHEDULED A REMOVAL BUT MY INSURANCE DENIED ME SERVICES. SO JUST WAITING ON A JUMP THROUGH IF ANYONE KNOW WHERE I CAN GET A REVERSAL DONE CLOSE TO (B)(6) IT WILL HELP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036983	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS IMPLANTED WITH ESSURE (B)(6) 2006 I FOUND OUT I AM ALLERGIC TO NICKEL IN 2014, I HAVE HAD ON GOING PAIN IN JOINTS, KNEES, HIPS IN LAST YEAR. WEIGHT GAIN, CHRONIC FATIGUE, MEMORY LOSS, HEAVING PERIODS FOR YEARS 2006-2013 HAD TO HAVE HEAT/ WATER ABLATION TO STOP HEAVY PERIODS. BACK PAIN ON LEFT SIDE, BODY SWELLING AND BLOATING. HEAD ACHE AND ELEVATED LIVER TESTS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036984	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 1/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED DURING AN IN OFFICE VISIT ON (B)(6) 2014. THIS MEDICAL DEVICE IMPLANT IS MANUFACTURED BY BAYER, FORMERLY, CONCEPTUS INC. IMMEDIATE PAIN STARTED AS THE LEFT SIDE WAS HARD TO PLACE; SEVERE CRAMPING, AND GAS PAINS; BLOATING, SWOLLEN TUMMY; BLEEDING, PASSING BLOOD CLOTS AS LARGE AS GOLF BALLS; PERIOD/ BLEEDING THAT NEVER STOPPED FROM DAY IT WAS INSERTED; SMALL RED DOTTED RASH COVERING MY UPPER THIGHS, AND ARMS; CONSTANT HEADACHE AND ENERGY LOSS; JOINT PAIN AND LOWER BACK PAIN; HAIR LOSS. MY DOCTOR THAT IMPLANTED ESSURE DECIDED IT BEST TO REMOVE ESSURE THROUGH A HYSTERECTOMY. I AM NOW 8 WEEKS POST OP HYSTERECTOMY AND ALL MY SYMPTOMS LISTED ABOVE ARE COMPLETELY GONE. THE RED DOTTED RASH DISAPPEARED WITHIN THE FIRST FEW DAYS AFTER SURGERY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036985	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 6/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAINFUL INTERCOURSE, WATERY DISCHARGE, PELVIC DULL PAIN, FIBROIDS, HEAVY PERIODS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036989	BAYER	7/2/2014	7/2/2014

Event Information:

Event Date (B3): 10/5/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED HAVING LOWER PAIN AFTER IMPLANTATION. ABOUT TWO MONTHS AGO, STARTED HAVING SEVER ABDOMINAL PAIN, EVEN MY HIPS HURT. MY PERIODS WENT FROM 4 DAYS TO TWO WEEKS WITH A LOT OF SPOTTING. MY LEFT LOWER SIDE RIGHT ABOVE OF MY PELVIC BONE BULGES OCCASIONALLY AND HURTS CONSTANTLY. I ALSO GAINED 10LBS IN A MONTH AND HAVE BEEN EXERCISING DAILY AND CAN'T LOOSE ANYTHING. (B)(4) UPDATE ON 2014-06-30: (B)(6), I HAD BOTH COILS AND TUBES REMOVED BECAUSE THE ESSURE WAS EXPELLING ITSELF DUE TO THE FACT IT WAS NEVER IMPLANTED CORRECTLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036998	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 2/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE. THIS IS MANUFACTURED BY BAYER , FORMERLY CONCEPTUS. I HAVE SEEN DR. (B)(6) MY IMPLANTING DR. HE DOESN'T LISTEN TO MY COMPLAINTS . I AM LOOKING FOR ANOTHER DR. I HAVE HAD SEVERE WEIGHT GAIN. VITAMIN D DEFICIENCY, BLOATING IN THE ABDOMEN AND PELVIS AREA. I HAVE ABNORMAL SHARP PAINS IN THE AREA OF IMPLANT, PAINFUL INTERCOURSE, IRREGULAR PERIODS, IRREGULAR BOWEL MOVEMENTS, FLUTTERING MOVEMENTS IN THE AREA OF THE COILS. THIS HAS BEEN STEADY FOR THE PAST FEW YEARS, I STILL HAVE THE DEVICE INSIDE ME. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5036999	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 7/10/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BRAIN FOG, PELVIC PAINS THAT LOST ME JOBS AND KEEPS ME BED RIDDEN, MISCARRIAGE, MIGRAINES, MOOD SWINGS, HAIR FALLS OUT IN HAND FULLS AT A TIME, CHRONIC FATIGUE, ANEMIA, DKA, EXCESSIVE BLEEDING DURING PERIODS, LOWER BACK PAIN, SENSITIVITY TO TOUCH. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037000	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 7/10/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BRAIN FOG, PELVIC PAINS THAT LOST ME JOBS AND KEEPS ME BED RIDDEN, MISCARRIAGE, MIGRAINES, MOOD SWINGS, HAIR FALLS OUT IN HAND FULLS AT A TIME, CHRONIC FATIGUE, ANEMIA, DKA, EXCESSIVE BLEEDING DURING PERIODS, LOWER BACK PAIN, SENSITIVITY TO TOUCH. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037001	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 2/18/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IRREGULAR HEART RATE, IRREGULAR MENSTRUAL CYCLES, MIGRAINES, IRREGULAR BOWEL MOVEMENTS, SEVERE ABDOMINAL PAIN, LOWER BACK PAIN, SWOLLEN STOMACH, THROBBING PAIN IN VAGINA, STABBING PAIN IN VAGINA, PRESSURE IN THE VAGINA, MOOD SWINGS, LIGHT HEAD, DIZZY, NAUSEA, WEIGHT GAIN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037002	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GIVING BIRTH TO YOUNGEST SON, I WAS IMPLANTED WITH THE ESSURE DEVICE. (B)(6) 2007 WAS IMPLANT DATE BY DR (B)(6) AT (B)(6) HOSPITAL IN (B)(6). SINCE IMPLANTATION, I HAVE HAD SEVERE ABDOMINAL PAIN, CRAMPS, SEVERE SWELLING ALMOST TO THE POINT I LOOK PREGNANT. PAINFUL INTERCOURSE, EXCRUCIATING PAINS BEFORE AND DURING MENSTRUAL CYCLE. MIGRAINES AND DEVELOPED HIGH BLOOD PRESSURE AND PALPITATIONS. EXCESSIVE WEIGHT GAIN THAT CANNOT BE REASONED WITH DR AFTER KEEPING 30 DAY FOOD JOURNAL. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037003	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 3/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED IN THE OFFICE WITH TROUBLE IMPLANTING THE LEFT COIL. DEPO SHOT GIVEN AT SAME TIME FOR BIRTH CONTROL UNTIL SCARRING OCCURRED AND DEVICES WERE CONFIRMED IN CORRECT POSITION. PROBLEMS WITH ESSURE STARTED ALMOST IMMEDIATELY. WITH ABDOMINAL PAIN AND CONSTANT BLEEDING. THE DAY OF THE PROCEDURE, I HAD WHAT MY OB/GYN DESCRIBED AS NORMAL CRAMPING AND SLIGHT BLEEDING. A FEW DAYS LATER, I STARTED HAVING LARGE AMOUNT OF BLEEDING AND PAIN IN THE AREA WHERE THE COILS WERE PLACED. I WENT BACK AND FORTH TO THE DOCTOR MANY TIMES TO HAVE THE BLEEDING CHECKED AND TO SEE WHAT WAS HAPPENING, NOTHING WAS EVER FOUND. THERE WAS NEVER ANY LAB ABNORMALITY ASSOCIATED WITH THE COILS. THE COILS WERE CONFIRMED TO HAVE BEEN SCARED AND EVERYTHING WAS IN A GOOD SPOT WITH THE COILS. I WAS AT MY DESK ONE DAY AND ENDED UP DOUBLED OVER IN PAIN. FELT AS THOUGH I WAS BEING STABBED. I WAS TAKEN TO THE EMERGENCY ROOM AND WAS ADMITTED FOR A FEW DAYS WITH NO RESOLUTION IN WHAT WAS GOING ON. I WAS DISCHARGED AND TOOK MY SON TO THE MOVIES AND THE SAME PAIN RETURNED WHILE I WAS DRIVING. I WAS TAKEN BACK TO THE ER VIA AMBULANCE AND ONCE AGAIN NO RESOLUTION BESIDES PAIN MEDICATION AND NAUSEA MEDICATIONS. ONCE AGAIN A RETURN TO THE OB/GYN AND HE AGREED TO HAVE THE COILS REMOVED. IN (B)(6) MY OB/GYN DECIDED TO TAKE THE COILS OUT. AS WAS TOLD TO ME, I WAS HIS ONLY PATIENT THAT HAD PROBLEMS WITH THE COILS. I UNDERWENT A SALPINGECTOMY (B)(6) 2011. ALL OF THE PAIN, STOPPED ALMOST IMMEDIATELY. I CONTINUED TO HAVE HEAVY BLEEDING THAT WAS 3 YEARS LATER HANDLED WITH ANOTHER PROCEDURE. ALL OTHER SYMPTOMS, NAUSEA, VOMITING, WEIGHT GAIN, BLOATING, PAIN, EXTREME LETHARGY, EXTREME THRUST AND CRITICALLY LOW IRON ALL WERE

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CORRECTED WITHIN THE LAST 3 YEARS. THE EXTREME BLEEDING WAS TREATED WITH A UTERINE ABLATION IN (B)(6) 2014 AND 11 IRON INFUSIONS COMPLETED MY TREATMENT. ALL OF THE SYMPTOMS SEEM TO HAVE RESOLVED. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037004	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 2/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IN (B)(6) 2013 AFTER DOCTOR WOULDN'T DO A TUBAL LIGATION. HAD TEST DONE TO MAKE SURE BLOCKAGE WAS DONE. TUBES WERE BLOCKED. I HAD MY FIRST PERIOD IN (B)(4), IT WAS NORMAL, THEN WHEN I HAD ONE IN (B)(4) IT LASTED OVER 14 DAYS, AND I HAD HEAVY BLEEDING. EACH MONTH AFTER HAS BEEN HEAVY AND LASTING 14 PLUS DAYS. I HAVE SEVER PELVIC PAIN, MY MUSCLES HURTS, MY BACK HURTS. I FEEL EXTREMELY EXHAUSTED, MY CHEST FEELS HEAVY, AND SO MUCH MORE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037005	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 12/15/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, INCREASE IN ECZEMA, BLOATING,. NEW FOOD ALLERGIES, IBS, FATIGUE. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037006	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 6/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

TODAY I HAVE BEEN IN SEVERE PAIN BUT IT WOULDN'T LET ME PICK THE ACTUAL DAY THIS STARTED; THIS STARTED RIGHT AFTER I HAD ESSURE IMPLANTED INTO MY FALLOPIAN TUBES (B)(6) 2012; I WAS IN SEVERE STOMACH AND PELVIC PAIN AND A FEW DAYS LATER, I HAD A THICK AMOUNT OF SCAR TISSUE OR SOMETHING FALL OUT. I TOOK IT TO MY DOCTOR AND THEY SAID IT WASN'T A MISCARRIAGE, DUH I ALREADY KNEW THAT IT HAD TO BE SOMETHING FROM MY SURGERY. I HAVE DEVELOPED IBS FROM THIS DEVICE, HOT FLASHES AND SO MUCH STOMACH PAIN; I CAN'T TAKE IT SOMETIMES AND HAVE BEEN PUT INTO THE HOSPITAL AND I HAVE NO INJURY, CONSTANT ITCHING MY LEGS AND BODY, SEVERE HEADACHES AND LIGHTHEADEDNESS. THIS DEVICE NEEDS TO BE OFF THE MARKET, THE SIDE EFFECTS ARE BAD. I WILL COME BACK AND ADD ON MY LAB REPORTS AND HOSPITAL REPORTS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037007	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 4/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DAILY NAUSEA AND VOMITING WITH AN UNNECESSARY GALLBLADDER REMOVAL, DAILY PAINS IN MY PELVIC AND LOWER BACK SO BAD I CAN'T GET OUT OF BED MOST DAYS. MIGRAINES, FATIGUE, SUICIDAL THOUGHTS AND BEHAVIORS, STOMACH INFLAMMATION, JOINT PAIN, ONGOING HEART PROBLEMS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037008	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 8/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED EXPERIENCING EXCRUCIATING PAIN TO MY LEFT LOWER ABDOMEN AND PELVIC AREA. IT FELT LIKE SEVERE CRAMPS WHICH I HAVE NEVER IN MY ENTIRE LIFE HAD EXPERIENCED. I WAS ORDERED BLOOD WORK AND A ULTRASOUND WHICH REVEALED I HAD A HEMORRHAGIC CYST. I CONTINUED TO HAVE MORE PAIN THROUGHOUT THE MONTHS, FOLLOWED UP WITH MORE ULTRASOUNDS AND CT SCANS. THEN THE FIRST WEEK OF DECEMBER MY GYNECOLOGIST DID A HYSTEROSCOPE ON ME AND TOOK OUT ONE OF THE ESSURE COILS OUT OF ME VAGINALLY ON THE LEFT SIDE ONLY AND UNDER NO ANESTHESIA. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037009	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 6/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE CRAMPING ALL THE TIME EVER SINCE THE ESSURE WAS DONE IN 2012. HEADACHES, BLOATING, CRAMPING, BLEEDING, MISSED PERIODS, RASHES, DEPRESSION, CYST ON OVARIES, BRUISES FOR NO REASON, BACK PAIN ALL THE TIME, UTIS ALL THE TIME. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037010	BAYER	7/2/2014	7/3/2014

Event Information:

Event Date (B3): 6/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE PUT IN, I WAS BLEEDING FOR MONTH'S LATER ALONG WITH SEVERE PAINS. I WAS HAVING BLOOD CLOTS THE SIZE OF LEMONS. DIZZINESS, WEIGHT GAIN, LOSS OF SEX DRIVE, AND IN (B)(6) 2014 I HAD TO HAVE A FULL VAGINAL ASSIST HYSTO. (B)(4).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00256	BAYER HEALTHCARE LLC	7/2/2014	7/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626222

Single Use: Y
Implant Date (E6): 3/19/2008
Explant Date (E7): 4/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA (B)(6) (CASE# MW5035955) IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)) INSERTED AND EXPERIENCED ADVERSE EVENTS AS DESCRIBED BELOW. CONSUMER REPORTED THAT SHE HAD THE DEVICE ESSURE IMPLANTED ON (B)(6)-2008. THE IMPLANTATION OF THE DEVICE WENT SMOOTHLY WITHOUT COMPLICATIONS AND VERY MINIMAL DISCOMFORT. SHE WAS AWAKE FOR THE PROCEDURE AND THERE WAS A REPRESENTATIVE FROM CONCEPTUS PRESENT. BOTH DOCTOR AND CONCEPTUS REP WERE VERY PLEASED WITH THE IMPLANTATION AND SAID EVERYTHING WENT WELL. SHE WAS VERY SATISFIED WITH THE ESSURE FOR THE FIRST 3 YEARS OF IMPLANTATION. IN 2011, SHE STARTED EXPERIENCING SHARP PAINS IN HER LEFT PELVIC AREA AND THE PAIN FELT LIKE A TWISTING STABBING PAIN THAT RADIATED TO HER HIP AND LOWER BACK. THAT SAME MONTH HER PERIODS BECAME EXTREMELY HEAVY WITH VERY HEAVY CLOTTING. SHE WENT TO SEE HER GYNECOLOGIST AND HE DID HER YEARLY (2011) PAP ALONG WITH AN ULTRASOUND AND ALL SEEMED NORMAL. THAT SAME YEAR, 2011, CONSUMER WENT BACK ON 4 SEPARATE OCCASIONS TO SEE THE GYNECOLOGIST. ALL WITH COMPLAINTS OF PELVIC PAIN, HEAVY BLEEDING AND WHAT FELT LIKE UTIS (URINARY TRACT INFECTIONS). AGAIN, THE DOCTOR DID SONOGRAMS AND ALL SEEMED NORMAL. IN 2012, CONSUMER STARTED EXPERIENCING EXTREME FATIGUE ALONG WITH SEVERE PELVIC INFLAMMATION AND SHE ALSO CONTINUED EXPERIENCING WHAT FELT LIKE UTIS. SHE STARTED SEEING HER PRIMARY DOCTOR THINKING MAYBE HE COULD FIGURE OUT WHAT WAS WRONG. AFTER HAVING BLOOD WORK DONE, HER RESULTS CAME BACK THER HER THYROID WAS OVERACTIVE. THAT EXPLAINED THE FATIGUE BUT NOT THE PAIN AND INFLAMMATION. HE THEN SENT HER TO SEE AN ENDOCRINOLOGIST, A UROLOGIST AND A GASTROENTEROLOGIST. ALL RAN TESTS BUT ALL CAME

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BACK NORMAL. IN 2013, THE PAIN, INFLAMMATION AND PRESSURE REACHED A WHOLE NEW LEVEL. THE CONSTANT INFLAMMATION HAD PUT PRESSURE ON HER BLADDER AND SHE STARTED LEAKING URINE. FINALLY THE CONSUMER DECIDED TO CHANGE HER GYNECOLOGIST AND GET A SECOND OPINION. THE NEW DOCTOR DID A SONOGRAM WHICH LOOKED NORMAL. HE SENT HER TO A NEW UROLOGIST WHO SENT HER FOR A CT SCAN OF HER BLADDER AND THE CT SCAN SHOWED THE ESSURE IMPLANT LOOKED NORMAL. SHE HAD A SMALL LESION ON HER KIDNEY SO THEY SENT HER FOR MRI (MAGNETIC RESONANCE IMAGING). AGAIN ESSURE LOOKED NORMAL. AFTER TAKING ALL TEST RESULTS BACK TO HER NEW GYNECOLOGIST AND HE COULD NOT EXPLAIN THE PAIN AND INFLAMMATION WE AGREED TO DO A LAPAROSCOPIC SALPINGECTOMY TO REMOVE THE ESSURE DEVICE. ON (B)(6)-2014, THREE YEARS AFTER SHE STARTED EXPERIENCING PAIN AND INFLAMMATION AND SIX YEARS AFTER IMPLANTING THE ESSURE, SHE HAD A BILATERAL SALPINGECTOMY. WHEN THE DOCTOR REMOVED THE TUBES WITH COILS, HE NOTED THAT THE COIL IN THE LEFT FALLOPIAN TUBE WAS TWISTED AND KINKED UP. THE CONSTANT PAIN AND PRESSURE SHE HAD BEEN FEELING IN HER LEFT PELVIC REGION WERE ALLEVIATED AS SOON AS THE ESSURE DEVICE WAS REMOVED. THE CONSTANT PRESSURE IN HER BLADDER WAS ALSO GONE. CONSUMER CHOSE TO USE ESSURE AS A PERMANENT FORM OF BIRTH CONTROL TO AVOID HAVING THE SURGERY NECESSARY WITH A TUBAL LIGATION AND ENDED UP HAVING A BIGGER SURGERY JUST TO HAVE THEM REMOVED. CONSUMER MENTIONED THAT THE BIGGEST PROBLEM WITH THE ESSURE DEVICE WAS THE DIFFICULTY IN DIAGNOSING A PROBLEM WITH THE DEVICE. UNLESS THE DEVICE HAD ACTUALLY MIGRATED FROM THE PROPER POSITION, THERE WAS NO WAY OF TELLING IF THE DEVICE WAS CAUSING HARM. FOLLOW UP INFORMATION RECEIVED ON (B)(6)-2014: PTC GLOBAL NUMBER ADDED AS (B)(4). FOLLOW UP INFORMATION WAS RECEIVED ON (B)(6)-2014. NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW UP (B)(6)-2014. QUALITY DEPARTMENT PROVIDED RESULT OF PRODUCT TECHNICAL COMPLAINT ANALYSIS (COMPANY GLOBAL PTC NUMBER (B)(4)): BATCH NUMBER 626222.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 06-JUN-2014: PTC GLOBAL NUMBER ADDED AS (B)(4). FOLLOW UP INFORMATION WAS RECEIVED ON 10-JUN-2014. NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW UP 17-JUN-2014. QUALITY DEPARTMENT PROVIDED RESULT OF PRODUCT TECHNICAL C

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037124	BAYER	7/2/2014	7/11/2014

Event Information:

Event Date (B3): 12/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/18/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

TERRIBLE SIDE EFFECTS SINCE DEVICE WAS IMPLANTED, SEVERE PAIN, ALLERGY SYMPTOMS, HAIR LOSS, HEADACHES, EXTREME FATIGUE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00251	BAYER HEALTHCARE LLC	7/2/2014	7/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE INSERTED AND EXPERIENCED THE FOLLOWING ADVERSE EVENTS. ON (B)(6) 2005, ESSURE WAS INSERTED. CONSUMER PRESENTED CRAMPING AND A LITTLE SPOTTING FOR A FEW DAYS AND WAS TOLD TO TAKE IBUPROFEN. THE NEXT DAY, SHE WAS HAVING HARD TIME BREATHING. SHE WENT TO THE HOSPITAL AND HER GALLBLADDER HAD TO BE REMOVED RIGHT AWAY BECAUSE IT WAS INFLAMED. SURGERY WENT FINE, AFTER A FEW DAYS OF NORMAL PAINS OF SURGERY, THE CONFIRMATION TEST WAS PERFORMED AND THE DYE SHOWED WENT THROUGH AND ESSURE DIDN'T WORK. THE TEST WAS PERFORMED AGAIN AND THIS TIME, THEY ASSURED THE CONSUMER IT HAD WORKED AND THERE WERE NO PROBLEMS, THAT ESSURE WAS COMPLETELY EFFECTIVE. THE FOLLOWING MONTH, SHE STARTED TO BLEED A LOT AROUND HER MENSTRUAL CYCLE TIME. IT WAS VERY HEAVY AND PAINFUL. AN ABLATION NOVA SURE WAS PERFORMED. FOR TWO YEARS OR A LITTLE LESS, SHE HAD NO PROBLEMS. THEN SHE BEGAN BLEEDING HEAVILY AGAIN OUT OF NOWHERE. SHE PRESENTED CRAMPING AGAIN AND CONTRACTIONS. SHE WENT TO EMERGENCY ROOM AND UNSPECIFIED TEST WERE PERFORMED. SHE WAS GIVEN PAIN PILLS AND WAS TOLD IT WAS HER PERIOD. SHE CONTINUED FOR 8 MONTHS TO EXPERIENCE CRAMPING AND CONTRACTIONS. SHE WAS SUBMITTED TO AN EXPLORATORY SURGERY WHICH FOUND A LITTLE BLEEDING AND PHYSICIAN SAID EVERYTHING LOOKED OK. ANOTHER PHYSICIAN SAID IT WAS A BULKY UTERUS AND SCAR TISSUE CAUSING PAIN AND A HYSTERECTOMY WAS PERFORMED. THERE WAS A LOT OF BLEEDING, THE OVARIES STAYED IN BUT WITH A LOT OF CYSTS REMOVED, THE ESSURE HAD COME ALL THE WAY THROUGH HER TUBE. A DISCREPANT

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DATE WAS PROVIDED AS ESSURE REMOVAL ((B)(6) 2005). CONSUMER STATED THE PROBLEMS WERE RELATED TO ESSURE. SHE STILL PRESENTS PROBLEMS SUCH AS TENDERNESS OF BREASTS AND A LITTLE THINGS THAT SEEM TO LEAD BACK TO ESSURE. (B)(4).

Manufacturer Narrative (H10):

FOLLOW UP INFO RECEIVED ON (B)(4) 2014 (PTC) NUMBERS) AND (B)(4) 2014 (FROM CONSUMER). CONSUMER'S DEMOGRAPHIC INFO WAS PROVIDED. SHE HAD FOUR PREVIOUS PREGNANCIES AND A TOTAL OF FOUR BIRTHS. SHE HAS NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES OR ANY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00252	BAYER HEALTHCARE LLC	7/2/2014	7/14/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE #MW5035860) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. ON AN UNSPECIFIED DATE THE PT HAD ESSURE INSERTED AND THEN SHE STARTED EXPERIENCING EXTREME PAIN/ACHE, BLOATING, PAINS IN HER JOINTS AND EXCESSIVE DAYTIME SLEEPINESS. SHE RECEIVED STIMULANTS FROM PULMONARY AND NEUROLOGIST DOCTORS. THEN, SHE GRINDED HER TEETH AT NIGHT AND CHIPPED 2 AND BROKE ONE; SHE SUFFERED FROM TMJ (TEMPOROMANDIBULAR JOINT) FROM THE TENSION THAT THE STIMULANTS CAUSED. SHE WAS DIAGNOSED WITH IDIOPATHIC HYPERSOMNIA AFTER 3 SLEEP STUDIES. THE CONSUMER TOLD TO HER GYNECOLOGIST THAT ALL THE EVENTS STARTED AFTER ESSURE INSERTION, BUT WAS TOLD HER THAT ESSURE COULD NOT BE THE CASE. SHE WAS BENNY TO AN INTERNIST DIETICIAN AND VISITED AN ENDOCRINOLOGIST TO TRY TO FIND THE REASON THAT SHE CANNOT STAY AWAKE. THE DOCTORS RULED OUT APNEA, IRON, THYROID, LYME DISEASE, ADDISON AND GLUTEN. SHE SAID THAT SHE WAS LOSING HER QUALITY OF LIFE. ON AN UNSPECIFIED DATE, HYSTERECTOMY WAS PERFORMED. FOLLOW-UP INFO RECEIVED ON 06/16/2014. FOLLOW-UP ATTEMPTS WERE PERFORMED BUT NO RESPONSE HAS BEEN RECEIVED TO DATE. FOLLOW UP FROM 06/17/2014: PTC RESULT. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE ARE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT

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THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFO AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME PAIN/ACHE, BLOATING, PAINS IN MY JOINTS, EXCESSIVE DAYTIME SLEEPINESS, DIAGNOSED WITH IDIOPATHIC HYPERSOMNIA AFTER 3 SLEEP STUDIES AND TMJ (GRINDED TEETH AT NIGHT/CHIPPED 2 AND BROKE ONE). THIS CASE IS NOT MEDICALLY CONFIRMED. ALL THE EVENTS WERE CONSIDERED NON-SERIOUS. EXTREME PAIN/ACHE AND BLOATING ARE LISTED EVENTS ACCORDING TO REFERENCE SAFETY INFO FOR ESSURE WHILE THE REMAINING EVENTS WERE CONSIDERED UNLISTED. THE EVENTS PAINS IN MY JOINTS, EXCESSIVE DAYTIME SLEEPINESS, DIAGNOSED WITH IDIOPATHIC HYPERSOMNIA AFTER 3 SLEEP STUDIES AND TMJ (GRINDED TEETH AT NIGHT/CHIPPED 2 AND BROKE ONE) WERE CONSIDERED AS UNRELATED TO ESSURE THERAPY, GIVEN THE LOCAL ACTION OF ESSURE AT FALLOPIAN TUBES. IN THIS PARTICULAR CASE THE CONSUMER UNDERWENT HYSTERECTOMY, THE MAIN INDICATION OF SURGERY WAS NOT REPORTED, HOWEVER AS SHE SATED THAT HER SYMPTOMS STARTED AFTER ESSURE INSERTION, THE EVENTS EXTREME PAIN/ACHE AND BLOATING WERE CONSIDERED AS RELATED TO ESSURE THERAPY AND THUS INCIDENTS. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFO AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF THE PRODUCT. REFERENCE US/IMPORTER REPORT # MW5035860.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 03-NOV-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE FOR ESSURE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE ON

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00254	BAYER HEALTHCARE LLC	7/2/2014	7/14/2014

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 754913

Single Use: Y
Implant Date (E6): 2/10/2011
Explant Date (E7): 4/7/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY ((B)(4)) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE, LOT NUMBER 754913, INSERTED ON (B)(6) 2011 AND EXPERIENCED THE FOLLOWING ADVERSE EVENTS. IN 2011, CONSUMER STARTED EXPERIENCING NEUROLOGICAL SYMPTOMS CONSISTING OF MODERATE PARESTHESIA IN ARMS AND LEGS, DIZZINESS, AND PROBLEMS WITH BALANCE AND COORDINATION. SHE WAS DIAGNOSED WITH A SEVERE VITAMIN B12 DEFICIENCY, WITH SERUM B12 LEVEL OF 150. SHE WAS IMMEDIATELY PLACED ON DAILY VITAMIN B12 1000 MCG INJECTIONS AND DAILY ORAL VITAMIN B12 1000 MCG SUPPLEMENTS. SHE ALSO PRESENTED CONTINUOUS CARDIAC PALPITATIONS AND CHEST PAIN AND WAS DIAGNOSED WITH PREMATURE ATRIAL CONTRACTIONS, SOMETIMES BIGEMINAL. SHE WAS MAINTAINED ON A BETA BLOCKER MEDICATION. IN 2012, SHE STARTED DEVELOPING SPONTANEOUS FEVERS OF 102-103 THAT WOULD LAST SEVERAL DAYS AT A TIME. SHE ALSO DEVELOPED EPISODES OF SPONTANEOUS SWELLING, EXTREME REDNESS AND NOSE PAIN, ALTERNATING BETWEEN EARS, EACH LASTING WEEK TO 10 DAYS AT A TIME. SHE WAS DIAGNOSED WITH RELAPSING POLYCHONDRITIS. SHE CONTINUED TO HAVE INTERMITTENT FEVERS, FATIGUE, JOINT AND MUSCLE PAIN. IN 2013, HER FLARES WERE SO FREQUENT, THAT IT WAS NOT BEING EFFECTIVELY CONTROLLED WITH PREDNISONE. SHE SATED THAT HAD NO HEALTH PROBLEMS PRIOR TO ESSURE. PHYSICIAN TOLD CONSUMER THAT IT WAS VERY SUSPICIOUS AND THE IMPLANTS MAY HAVE CAUSED A SYSTEMIC INFLAMMATORY RESPONSE OR SHE MAY BE REACTING TO THE COMPONENTS THE DEVICE IS MADE OF, SUCH AS THE NICKEL. SHE WAS NOT TESTED FOR A NICKEL ALLERGY PRIOR TO IMPLANTATION. IN 2014, CONSUMER REQUESTED TO HAVE THE ESSURE REMOVED DUE TO HER SYMPTOMS. A PELVIC CT SCAN WAS PERFORMED AND SHOWED BOTH COILS HAD MIGRATED DISTALLY IN THE FALLOPIAN TUBES, THE LEFT

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PRACTICALLY EXITING THE FALLOPIAN TUBE NEAR THE OVARY. ON (B)(6) 2014, A LAPAROSCOPIC PELVIC SURGERY WAS PERFORMED TO REMOVE BOTH ESSURES, BILATERAL SALPINGECTOMY AND BILATERAL CORNEAL REACTION OF THE UTERUS WAS PERFORMED. SHE RELATED HER HEALTH PROBLEMS TO ESSURE.

Manufacturer Narrative (H10):

FOLLOW UP INFO RECEIVED ON (B)(4) 2014: PTC GLOBAL NUMBER ADDED AS (B)(4). FOLLOW-UP FROM (B)(4) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. FOLLOW-UP (B)(4) 2014: QUALITY DEPARTMENT PROVIDED RESULT OF PRODUCT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00255	BAYER HEALTHCARE LLC	7/2/2014	7/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE INSERTED IN 2011 AND EXPERIENCED THE FOLLOWING ADVERSE EVENTS. ON AN UNSPECIFIED DATE, SHE STARTED TO HAVE PELVIC PAIN, PAINFUL INTERCOURSE AND BLEEDING ALL THE TIME INCLUDING CLOTS THE SIZE OF HALF DOLLARS OR LARGER. SHE WAS PRESCRIBED BIRTH CONTROL PILLS TO HELP WITH THE BLEEDING AND THAT FAILED. IN 2012, SHE WAS SUBMITTED TO A COMPLETE HYSTERECTOMY, LEAVING JUST THE OVARIES. SHE STATED EVENT DATE WAS (B)(6) 2011, HOWEVER, NO FURTHER INFORMATION WAS PROVIDED REGARDING EACH EVENT SHE PRESENTED IN THAT DATE. NO FURTHER INFORMATION WAS PROVIDED. REFERENCE (B)(4).

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6) /2014. FOLLOW-UP ATTEMPTS WERE MADE, WITH NO RESPONSE TO DATE. FOLLOW-UP (B)(6) 2014. QUALITY DEPARTMENT PROVIDED RESULT OF PRODUCT TECHNICAL COMPLAINT ANALYSIS (COMPANY GLOBAL PTC NUMBER (B)(4)). FINAL ASSESSMENT:

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00257	BAYER HEALTHCARE LLC	7/2/2014	7/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 675112

Single Use: Y
Implant Date (E6): 1/27/2010
Explant Date (E7): 2/24/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE #MW5035878) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. CONSUMER REPORTED THAT AFTER HER 4TH CHILD SHE DECIDED SHE WAS DONE HAVING CHILDREN AND AFTER TALKING TO HER DOCTOR, SHE CHOSE FOR ESSURE WHICH WAS INSERTED ON (B)(6) 2010 WITH LOT NUMBER 675112. IT WAS A QUICK AND PAINLESS PROCEDURE. THINGS WERE OK FOR A MONTH OR SO BUT THEN SHE BEGAN HAVING SEVERE CRAMPING, HEAVIER THAN NORMAL BLEEDING WHILE PASSING VERY LARGE CLOTS, MOOD SWINGS, FATIGUE, LOSS OF BALANCE AND HEADACHES. THE BLEEDING WAS SO HEAVY AT TIMES THAT SHE COULDN'T LEAVE HER HOUSE. CONSUMER MENTIONED THAT SHE MADE TRIPS TO THE EMERGENCY ROOM AND LEFT WITHOUT KNOWING WHAT THE PROBLEM WAS. SHE HAD VISITS TO HER DOCTOR AND HE EVEN PUT HER ON THE BIRTH CONTROL PILL TO TRY TO REGULATE HER MENSTRUAL CYCLE. AS THE MONTHS WENT ON AND NOTHING WAS WORKING SHE HAD A FULL HYSTERECTOMY LEAVING ONLY 1 OVARY WITH ESSURE REMOVAL, ON (B)(6) 2014. FOLLOW-UP FROM (B)(6) 2014: QUALITY DEPARTMENT PROVIDED RESULT OF PRODUCT TECHNICAL COMPLAINT ANALYSIS (COMPANY GLOBAL PTC NUMBER (B)(4)): BATCH NUMBER 675112. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, IT WAS NOT POSSIBLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, ONE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, A REVIEW OF THE MANUFACTURING BATCH RECORD WAS CONDUCTED AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT

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MET ALL RELEASE REQUIREMENTS. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THREE (3) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER 675112 BUT NONE OF THESE CASES REFER TO ANY SIMILAR TYPE OF MEDICAL EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED 'UNCONFIRMED QUALITY DEFECT'. BASED ON THE INFO AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. REFERENCE: MW5035878.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00261	BAYER HEALTH CARE LLC	7/2/2014	7/14/2014

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF. SHE IS A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW: CONSUMER STATED THAT SHE HAD A PAST MEDICAL HISTORY OF DIVERTICULITIS. CONSUMER HAD ESSURE INSERTED APPROXIMATELY 8 MONTH AGO, IN (B)(6) 2013. SHE STATED THAT DURING INSERTION, THE HEALTH CARE PROFESSIONAL LOST SIGHT OF IT,AND SHE THOUGHT IT WENT CROOKED. CONSUMER HAS BEEN EXPERIENCING PAIN INSERTION. HER 3 MONTH HSG (HYSTEROSALPINGOGRAM) TESTING REVEALED THAT HER LEFT TUE WAS BLOCKED BUT THE RIGHT ONE THE DYE WENT THROUGH. SHE HAD A 6 MONTH TEST AND THE RIGHT TUBE REMAINED OPEN. CONSUMER HAD A LAPAROSCOPIC PROCEDURE LAST MONTH ((B)(6) 2014, AND HER HEALTH CARE PROFESSIONAL COULD NOT REMOVE THE INSERTS AND WAS TOLD HER INTESTINES WERE WRAPPED AROUND HER TUBES AND HE COULD NOT REACH THEM. DOCTOR REFUSED TO DO ANY MORE SURGERY AND WOULD NT TOUCH HER ANYMORE. CONSUMER STATED THAT SHE REMAINED IN PAIN AND WANTED TO THEM REMOVED. SHE HAD SEEN ON THE NEWS THA THIS HAS HAPPENED TO OTHER PEOPLE. FOLLOW-UP FROM (B)(6) 2014, (B)(6) 2014, AND (B)(6) 2014: QUALITY DEPARTMENT PROVIDED RESULT OF PRODUCT TECHNICAL COMPLAINT ANALYSIS (COMPANY GLOBAL PTC NUMBER (B)(4)): FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, IT WAS NOT POSSIBLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, ONE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, IT WAS NOT POSSIBLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. MEDICAL ASSESSMENT: THE MEDICAL EVENTS

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REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. LACK OF EFFECTIVENESS IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT AS IT MAY OCCUR WITH THE USE OF ANY PRODUCT. THIS CASE ALSO REPORTED DIFFICULT TO USE DUE TO LOST VISUALIZATION AND USE ERROR DUE TO BEING CROOKED AS WELL AS UNABLE TO REMOVE INSERTS BUT THESE EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE COMPANY PHARMACOVIGILANCE DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED 'UNCONFIRMED QUALITY DEFECT'. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. AFTER INTERNAL REVIEW, THE CONSUMER ALSO STATED THAT SHE WAS DIABETIC. THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN MADE WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00250	BAYER HEALTHCARE LLC	7/2/2014	8/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B60746

Single Use: Y
Implant Date (E6): 6/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE PROXIMAL 5 COILS BROKE OFF AND HAD TO BE REMOVED ALONG WITH ORIGINAL DEVICE. ON (B)(6) 2014, DURING THE INSERTION PROCEDURE, 5 COILS FROM PROXIMAL ESSURE BROKE OFF AND HAD TO BE REMOVED ALONG WITH THE ORIGINAL DEVICE. THE LOT USED WAS B60746. BILATERAL PLACEMENT WAS SUCCESSFUL. CASE CORRECTION ON (B)(6) 2014: AFTER INTERNAL REVIEW THIS CASE WAS UPGRADED TO NEAR-INCIDENT DUE TO DEVICE BREAKAGE. THE EVENT DEVICE FAILED INSERTION WAS ADDED TO THE CASE.

Manufacturer Narrative (H10):

FOLLOW-UP AND PTC INVESTIGATION RESULT RECEIVED ON 06/16/2014. NO RESPONSE WAS OBTAINED AFTER FOLLOW-UP ATTEMPTS. (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BROKE" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF TH

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00253	BAYER HEALTHCARE LLC	7/2/2014	8/25/2014

Event Information:

Event Date (B3): 11/20/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): B59458

Single Use: Y
Implant Date (E6): 11/20/2013
Explant Date (E7): 11/20/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL VIA REGULATORY AUTHORITY IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED THE FOLLOWING EVENT. PATIENT HAD NO PRE-EXISTING CHARACTERISTICS. THE PATIENT HAD A RECENT HISTORY OF COPPER IUD REMOVAL AND A DILATATION AND CURETTAGE PROCEDURE. ON (B)(6) 2013, DURING PLACEMENT OF PERMANENT BIRTH CONTROL DEVICE, THE SHEATH DID NOT RETRACT AS THE DEVICE WAS INTENDED. THE PHYSICIAN ATTEMPTED TO REMOVE THE DEVICE AND A COIL BROKE OFF IN THE LEFT FALLOPIAN TUBE. THE PATIENT REQUIRED A RETURN TO THE OPERATING ROOM TO REMOVE THE COIL AND REPLACE THE ESSURE DEVICE. THE DEVICE USE PROBLEM REPORTED WAS A FAILED DEVICE; DEVICE BROKE AND COULDN'T GET IT TO WORK OR STOPPED WORKING. THE EVENT OCCURRED IN THE HOSPITAL. THE PRODUCT LOT NUMBER USED WAS B5945B. SERIOUSNESS CRITERIA PROVIDED BY HEALTH AUTHORITY. FOLLOW UP INFORMATION RECEIVED ON 06/06/2014: PTC GLOBAL NUMBER ADDED AS (B)(4). FOLLOW UP INFORMATION RECEIVED ON 06/16/2014: FOLLOW-UP ATTEMPTS WERE DONE; NO RESPONSE HAS BEEN RECEIVED TO DATE. FOLLOW UP 06/16/2014: PTC INVESTIGATION RESULTS WERE PROVIDED.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION WAS RECEIVED ON 25-AUG-2014. ESSURE LOT NUMBER WAS CHANGED FROM B5945B TO B59458. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 09-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00258	BAYER HEALTHCARE LLC	7/2/2014	8/25/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): MALFUNCTION	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B72578

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/16/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 03 JUNE 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE IMPLANT WAS BROKEN BEFORE RELEASE (DURING THE PLACEMENT). IT WAS STATED THAT ANOMALY CONCERNING THE INSERT WAS OBSERVED IN OPERATING BLOCK DURING PLACEMENT AND THAT THERE WAS NO ANATOMICAL CAUSE THAT COULD EXPLAIN THE ANOMALY. BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER DEVICE. FRANCE BHP LOCAL DRUG SAFETY DEPT ASSESSED THE EVENT WITH ESSURE AS NEAR INCIDENT. NO FURTHER INFO WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 24 JUNE 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NEITHER PRODUCT WAS RETURNED FOR INSPECTION NOR DO WE HAVE A PHOTOGRAPH OF THE ACTUAL DEVICE, WE CANNOT DETERMINE EXACTLY WHAT THE FAILURE IS. BASED ON OUR EXPERIENCE WITH THE COMPLAINTS OF A SIMILAR NATURE, IT IS LIKELY THE REPORTER IS REFERRING TO AN EVENT IN WHICH THE MICRO-INSERT WAS BENT OR STRETCHED INTO A SHAPE WHICH RENDERED THE DEVICE TO BE UNUSABLE, AND HENCE, "BROKEN." SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE CANNOT CONFIRM THIS QUALITY COMPLAINT. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS CASE REPORTED COMPLICATION OF INSERTION DUE TO BREAKAGE WHICH OCCURRED BEFORE RELEASE. THE REPORTED EVENT IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER B72578.

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NO BATCH SIGNAL CAN BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND THAT REPORTED EVENT IS ANTICIPATED EVENT. BASED ON THE INFO AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO FEMALE PATIENT OF THE UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE IMPLANT BEING BROKEN BEFORE RELEASE (DURING THE PLACEMENT) AND COMPLICATION OF DEVICE INSERTION. UPON RECEIPT OF TECHNICAL INVESTIGATION, EVENT "THE IMPLANT WAS BROKEN BEFORE RELEASE (DURING PLACEMENT)," INTERPRETED AS A DEVICE BREAKAGE AND PREVIOUSLY CONSIDERED UNLISTED ACCORDING TO REFERENCE SAFETY INFO FOR ESSURE, WAS UPDATED TO LISTED (ANTICIPATED). ALL THESE EVENTS WERE CONSIDERED NON-SERIOUS. THE EVENT "THE EVENT WAS BROKEN BEFORE RELEASE (DURING PLACEMENT)" (ASSUMED AS DEVICE BREAKAGE) WAS REGARDED AS NEAR-INCIDENT DUE TO THE REPORTED BREAKAGE. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, IT WAS ONLY MENTIONED THAT THE IMPLANT WAS BROKEN BEFORE RELEASE (DURING THE PLACEMENT) WITHOUT DETAILS ABOUT THIS EVENT. THUS, CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED RELATED. PTC FINAL INVESTIGATION: AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND THAT REPORTED EVENT IS ANTICIPATED EVENT. BASED ON THE INFO AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 01-OCT-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE ABLE TO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00260	BAYER HEALTHCARE LLC	7/2/2014	8/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B94876

Single Use: Y
Implant Date (E6): 6/1/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. ESSURE INSERTION PROCEDURE WAS PERFORMED IN (B)(6) 2014 FOR CONTRACEPTION AND LOT NUMBER USED WAS B94876. PHYSICIAN REPORTED DETACHMENT ISSUE. THE DEVICE WOULD NOT DETACH FROM THE INSERTER AND THE DOCTOR HAD TO LEAVE THE PATIENT IN THE ROOM WHILE A STAFF MEMBER WENT TO THE HOSPITAL AND OBTAINED A PAIR OF HYSTEROSCOPIC SCISSORS. SHE WAS ABLE TO CUT THE INSERTION CATHETER WITH THE SCISSORS. PHYSICIAN DIDN'T HAVE ANY ADDITIONAL INFORMATION. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2014. PATIENT'S INITIALS, DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. CONCOMITANT CONDITION INCLUDED OBESITY (BMI (B)(6)). SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES, AND ANY RELEVANT MEDICAL HISTORY. SHE WAS NOT ON POSTPARTUM STATE AT THE TIME OF ESSURE INSERTION. LOCAL ANALGESIA WAS APPLIED DURING INSERTION. THE INSERTION WAS CONSIDERED INTERMEDIATE DIFFICULTY DUE TO TIGHT TUBAL OS. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. THE PHYSICIAN MEDICALLY CONFIRMED THE EVENTS. SHE WAS COMPLAINING OF DISCOMFORT. SHE WAS TAKEN TO OPERATING ROOM FOR HYSTEROSCOPY FOR EXCESS COIL REMOVAL. NO HOSPITALIZATION WAS REQUIRED. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SI

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00259	BAYER HEALTHCARE LLC	7/2/2014	8/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B61391

Single Use: Y
Implant Date (E6): 6/3/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW: PT'S LAST MENSTRUAL PERIOD BEFORE ESSURE INSERTION WAS ON (B)(6) 2014, SHE USED CONDOMS AS BIRTH CONTROL AND URINE PREGNANCY TEST PERFORMED BEFORE THE PROCEDURE WAS NEGATIVE. CONCOMITANT MEDICATIONS INCLUDED XANAX 1MG AND VICODIN. NO MEDICAL HISTORY. PT WAS A NONSMOKER, SEXUALLY ACTIVE AND HER GYNECOLOGICAL HISTORY INCLUDED GRAVIDA 2, PARITY 2 (2002 AND 2007), PERIODS EVERY 21 DAYS. HER LAST PAP SMEAR WAS IN 2012; SHE HAD AN ABNORMAL PAP SMEAR IN 1996 WITH HPV1/PRECANCEROUS CELLS. NO KNOWN DRUG ALLERGIES. PT HAD PENDING F/U OF BLOODY DIARRHEA, WHICH HAS RESOLVED. PHYSICIAN REPORTED THAT ESSURE WAS INSERTED ON (B)(6) 2014 WITH LOT NUMBER # B61391 (EXPIRATION DATE IN 08/2016) FOR FEMALE STERILIZATION. DURING THE PROCEDURE BLOOD PRESSURE WAS 128/88, PULSE 72, TEMPERATURE 37.01 CELSIUS DEGREE AND PT RECEIVED TORADOL, KETOROLAC 60MG INTRA-MUSCULAR AND VALIUM 10MG (ORAL). PARACERVICAL BLOCK WAS PERFORMED USING 22 GAUGE SPINAL NEEDLE AND 22CC OF FENTANYL/NAROPIN AND LIDOCAINE. DURING ESSURE INSERTION, THE LEFT TUBE WAS CANNULATED AND DEVICE DEPLOYED WITHOUT ISSUE. HOWEVER, ON THE RIGHT TUBE UPON DEPLOYMENT A PORTION OF THE IMPLANT WAS EJECTED. INITIALLY THOUGHT TO BE THE ENTIRE IMPLANT A SECOND IMPLANT WAS ATTEMPTED TO BE DEPLOYED AND THE TUBE WAS CANNULATED WITH SLIGHT RESISTANCE BUT UPON DEPLOYMENT THE ENTIRE IMPLANT EJECTED. PHYSICIAN REMOVED THE TWO IMPLANTS AND UPON FURTHER INVESTIGATION AND REMOVAL OF THE EJECTED MATERIAL, IT WAS NOTED THAT THE FIRST IMPLANT WAS ACTUALLY ONLY A PORTION OF THE DEVICE. UPON EXTRACORPOREAL INSPECTION IT WAS NOTED THE FIRST IMPLANT WAS

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FRACTURED AND ONLY APPROXIMATELY 5 COILS WERE NOTED COMPARED TO THE FULL LENGTH OF TH E SECOND DEVICE. AFTER THIS INSTIGATION, THE PHYSICIAN PERFORMED A FURTHER INSPECTION INTO THE OSTIA WITH FULL DISTENTION. AT THIS TIME IT WAS NOTED THAT 2 COILS WERE SEEN AND THE DEVICE WAS ACTUALLY IN PLACE WITH THE IMPLANT IN THE OSTIA. PHYSICIAN MENTIONED THAT THE PT WAS FULLY INFORMED AS THE PROCEDURE WAS UNDERWAY AND DID NOT BELIEVE SHE WAS HARMED IN ANY WAY AND BELIEVED THAT THE PARTIAL IMPLANT SHOULD FUNCTION AS ANTICIPATED AS ONLY 5 COILS WERE BROKEN AND 2 WERE SEEN IN THE OSTIA. PHYSICIAN LEFT 4 COILS ON THE LEFT AND 2 ON THE RIGHT. CIPRO 1 TABLET 500MG, ORALLY, EVERY 12 HRS, 3 DAYS WAS GIVEN DUE TO INCREASED INSTRUMENTATION. PT WOULD HAVE A FOLLOW UP VISIT FOR ESSURE TOTAL OCCLUSION CONFIRMATION VIA HSG (HYSTEROSALPINGOGRAM) IN 3 MONTHS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REF. NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE CANNOT CONFIRM THIS QUALITY COMPLAINT; HOWEVER, BASED ON THE COMPLAINT DESCRIPTION PROVIDED, WE ARE ABLE TO CONCLUDE THAT A QUALITY ISSUE IS PLAUSIBLE. IT IS POSSIBLE DURING THE MFG ASSEMBLY PROCESS A SMALL GAP WAS LEFT BETWEEN THE INNER COIL AND INNER CATHETER (THEY SHOULD BE BUTTED TOGETHER DURING ASSEMBLY). WHEN THE OUTER COIL OF THE MICRO-INSERT IS WOUND DOWN A SMALL PORTION OF THE COIL CAN BECOME TRAPPED IN THE GAP. IF A DEVICE HAS THIS ISSUE, WHEN THE PHYSICIAN PRESSES THE BUTTON TO RELEASE THE MICRO-INSERT, THE OUTER COIL MAY SEVER ITSELF AS IT IS BEING DEPLOYED FROM THE CATHETER. IN TYPICAL SITUATIONS, THIS SEVERING OCCURS INSIDE THE CATHETER PRIOR TO THE PIECES BEING DEPLOYED FROM THE CATHETER. THE SEVERING OF THE COILS INSIDE THE CATHETER DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PT. MEDICAL ASSESSMENT: ONE (1) ADDITIONAL AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER B61391 BUT THIS CASE DID NOT REFER TO A SIMILAR BREAKAGE EVENT OR DEPLOYMENT ISSUE. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. ACCORDING TO THE TECHNICAL ASSESSMENT A QUALITY DEFECT WAS PLAUSIBLE BASED ON THE COMPLAINT DESCRIPTION AND BASED ON THE PROVIDED INFO THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING MEDDRA LLT DEVICE BREAKAGE. AT TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT - BUT PLAUSIBLE" WITH A FINAL RISK CATEGORY IV, A DEFECT WHICH DOES NOT POSE A HAZARD TO PT'S HEALTH AS THE SEVERING OF THE COILS DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF TH E PT. IN SUMMARY, BASED ON THE AVAILABLE INFO OF THE DEVICE BREAKAGE AND A PRODUCT DEFECT, A CAUSAL RELATIONSHIP CAN NOT BE EXCLUDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE ON THE RIGHT TUBE UPON DEPLOYMENT A PORTION OF THE IMPLANT WAS EJECTED (FIRST IMPLANT); THE FIRST IMPLANT FRACTURED (APPROXIMATELY 5 COILS BROKEN)/ COMPLICATION OF DEVICE INSERTION; SECOND IMPLANT CANNULATED WITH SLIGHT RESISTANCE AN DUPON DEPLOYMENT THE ENTIRE IMPLANT EJECTED (SECOND IMPLANT). REPORTER CAUSALITY WAS NOT PROVIDED. ALL REPORTED EVENTS ARE NON-SERIOUS. THE EVENT THE FIRST IMPLANT FRACTURED (APPROX. 5 COILS BROKEN) INTERPRETED AS A DEVICE BREAKAGE; IS UNLISTED ON THE REFERENCE SAFETY INFO FOR ESSURE AND WAS CONSIDERED A NEAR-INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE REMAINING EVENTS ARE LISTED AND NON-INCIDENTS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES DURING RIGHT INSERT DEPLOYMENT (AT FIRST ATTEMPT HE BELIEVED THE ENTIRE INSERT WAS EJECTED AND TRIED TO PLACE ANOTHER ONE, WHICH WAS ALSO EJECTED. FURTHER, UPON EXTRACORPOREAL INSPECTION OF THE EJECTED INSERTS IT WAS SEEN THAT THE FIRST ONE WAS BROKEN (APPROXIMATELY 5 COILS); AND ITS REMAINING PORTION WAS ACTUALLY IN PLACE WITH 2 COILS VISUALIZED IN THE RIGHT TUBAL OSTIA. THE PHYSICIAN BELIEVED THAT NO HARM

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OCCURRED TO THE PT AND THAT THE SECOND DEVICE MALFUNCTIONED DUE TO THE PRESENCE OF THE FIRST ONE IN TUBE. AS THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, THEIR CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS, THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT - BUT PLAUSIBLE." IN SUMMARY, BASED ON THE AVAILABLE INFO OF THE DEVICE BREAKAGE AND A PRODUCT DEFECT A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037104	BAYER	7/3/2014	7/11/2014

Event Information:

Event Date (B3): 3/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WENT TO GYN ASKING TO GET "TUBES TIED" AND WAS TOLD ABOUT THE ESSURE PROCEDURE. IT WAS PRESENTED AS A NEW AND IMPROVED, LESS INVASIVE AND MORE EFFECTIVE VERSION OF GETTING "TUBES TIED" I WAS TOLD THAT THERE WAS A VERY SLIGHT CHANCE OF CHRONIC PAIN, BUT THAT IT WAS VERY RARE. I WAS TOLD THAT THE PROCEDURE WOULD BE DONE UNDER GENERAL ANESTHESIA AND THAT THE WORST OF THE RECOVERY WOULD BE JUST COMING OUT OF THE ANESTHESIA. I WAS TOLD THEY WERE SOFT, FLEXIBLE FIBER COILS, THERE WAS NEVER ANY MENTION THAT THE "FIBERS" INCLUDED ANY METALS AND ESPECIALLY NICKLE OR I THINK I WOULD HAVE SEEN THAT AS A RED FLAG. I WOKE FROM ANESTHESIA SURPRISED BY THE INTENSE CRAMPING AND WONDERING WHAT HAPPENED. SINCE THEN I HAVE HAD CRAMPING, SOMETIMES SO INTENSE IT'S HARD TO STAND UP STRAIGHT AND THAT CAUSES CRAMPING AND SHOOTING PAINS RADIATING DOWN MY INNER THIGHS. SOME DAYS THERE'S A STRONG BURNING AND PRESSURE LIKE A BALLOON IN MY ABDOMEN IS GOING TO EXPLODE. FREQUENTLY I HAVE PELVIC PAIN THAT FEELS LIKE MY PELVIC BONE IS BRUISED AND THAT MY INSIDES ARE GOING TO FALL OUT. THE ONLY OTHER TIMES I EVER HAD SIMILAR PAIN/SENSATIONS WAS WHEN I WAS IN MY LAST TRIMESTER OF MY PREGNANCIES AND ON MY FEET TOO LONG. ALTHOUGH I REALLY HAVEN'T HAD A PERIOD SINCE THIS PROCEDURE, I HAVE EXTREME PMS SYMPTOMS LIKE I AM 15 AGAIN WITH CRAMPING, BACK ACHES, HEADACHES, MOOD SWINGS, FOOD CRAVINGS. I ALSO HAVE HOT FLASHES AND NIGHT SWEATS SINCE THE PROCEDURE. I'VE ALSO HAD NOT JUST BREAST TENDERNESS THAT COMES AND GOES, BUT ALSO BREAST FULLNESS/FIRMNESS AND AT TIMES EVEN LUMPS THAT DISAPPEAR AFTER A FEW DAYS AND SHARP STABBING PAINS IN MY BREASTS AS WELL. SOMETIMES I GET STABBING PAINS (APPROXIMATELY WHERE THE COILS OR SCAR TISSUE WOULD BE) THAT ARE SO SHARP THAT AT THE SAME INSTANCES OF THE STABBING FEELING, I INSTANTLY FEEL LIKE I'M GOING TO FAINT FOLLOWED BY A WAVE OF NAUSEA.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037061	BAYER	7/7/2014	7/7/2014

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

RASHES APPEARING ALL OVER BODY, BLOATING, WEIGHT GAIN, PELVIC PAIN, HEAVY AND LONG PERIODS, LACK OF LIBIDO, PAINFUL INTERCOURSE, ANXIETY, FATIGUE.

(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037059	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 1/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS EXPERIENCING RECTAL BLEEDING AND HIGH PROTEIN LEVELS IN MY URINE. THAT EVENING I HAD EXTREME PAIN ON MY RIGHT SIDE AND VOMITING. I WENT TO THE ER AND THEY PERFORMED A CT SCAN AND US. BOTH REPORTS CAME BACK NORMAL. MY ER DR. STATED THAT I SHOULD FOLLOW UP WITH MY GYNO DUE TO MY ESSURE LOOKING VERY WEIRD AND COULD BE THE CAUSE OF MY PAIN. HE WAS WORRIED BECAUSE HIS WIFE HAD THEM ALSO AND NEVER KNEW THAT THEY COULD "MOVE". I FOLLOWED UP WITH MY DR. AND SHE SAID EVERYTHING WAS OK. I ASKED HER TO PERFORM A 4D ULTRA SOUND AND THAT'S WHEN SHE DISCOVERED THAT MY PLACEMENT WAS VERY WRONG. MY ESSURE WAS GOING THROUGH MY FALLOPIAN TUBE INTO THE SIDE OF MY UTERUS. SHE DECIDED TO PERFORM IMMEDIATE SURGERY BUT NEEDED TO CALL TO FIND OUT HOW TO REMOVE THE DEVICE SINCE SHE HAD NEVER SEEN THIS BEFORE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037060	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 10/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT DULL CRAMPS, BLOATED STOMACH, LOWER BACK PAIN, WEIGHT GAIN PROBABLY DUE TO SWELLING. I HAVE STARTED TO HAVE HEART PALPITATIONS, HIGH LEVELS OF ANXIETY AND NERVOUSNESS AND I CAN'T KEEP MY THOUGHTS IN ORDER. I ALSO HAVE HAD AN INCREASE IN OCULAR MIGRAINES AND FLOATERS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037062	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 8/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

SIDE EFFECTS: CRAMPS WEEK BEFORE PERIOD; PERIOD EVERY TWO WEEKS; HEADACHES PROBABLY 10 X'S A MONTH ALWAYS BEFORE PERIOD; EXTREME BACK PAIN 2 DAYS BEFORE; NO ENERGY MOST DAYS JUST WANT TO LAY AROUND; CAN'T LOOSE WEIGHT AND WORK OUT 6 DAYS A WEEK AND WORK WITH PERSONAL TRAINER 2XS A WEEK; MAY HAVE SEX 1 X A MONTH AND IN PAIN THE NEXT 2 DAYS AND BLEED; HOT FLASHES ALL THE TIME; HAIR RECENTLY JUST STOPPED FALLING OUT AND MORE 3 COLON INFECTION IN 3 MONTHS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037063	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD MANY TIMES OF OB AND ER VISITS DUE TO THE PAIN AND BEING TREATED FOR PELVIC PAIN AND SENT HOME NUMEROUS TIMES. I HAVE SHARP SHOOTING PAINS THAT MAKE YOU BODY JERK AND SHAKE FROM PAIN. I CAN TASTE METAL IN MY MOUTH AT TIMES. I HAVE SOME ER VISIT PAPERS THAT I HAVE SAVE UNSURE OF ALL THE DATES AND ALL THE VISITS TO OB HOWEVER I HAVE BEEN SO MANY TIMES, I AM TIRED OF GOING BUT DO NOT FUNCTION LIKE A NORMAL PERSON ANYMORE. LOST JOB BECAUSE OF PAIN AND NOT BEING ABLE TO WORK A WHOLE SHIFT OR CALLING IN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037064	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 6/24/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2014 I WAS HAVING EXTREME PELVIC PAIN IN MY LEFT SIDE. I WENT TO THE E.R. AND WAS TOLD I WAS PREGNANT AND ONE OF MY ESSURE E COILS IS IN MY MEMBRANE WALL AND COULD HARM MY BABY. (B)(4). UPDATE ON (B)(6) 2014: I HAD MY ESSURE E.COILS PUT IN ME ON/AROUND (B)(6) 2013. NOW I AM TOLD AFTER I HAVE MY BABY, I WILL HAVE TO UNDERGO FULL OR PARTIAL HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037065	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN TREATED FOR ABDOMINAL MUSCLE TEARS, POSSIBLE HERNIAS, OVARIAN CYSTS, DYSMENORRHEA, BACTERIAL INFECTIONS, AND IRRITABLE BOWEL SYNDROME SINCE I GOT THE IMPLANT. ALL OF THE DOCTORS REFER ME TO SOMEONE ELSE. I'VE NEVER HAD ABDOMINAL PAIN UNTIL I GOT THESE IMPLANTS. THE WORST PART ISN'T PAIN, IT'S THE HEAVY PERIODS. I NEED TO BE ON MY FEET AS A NURSE FOR 12-16 HOURS, BUT I HAVE TO RUN TO A BATHROOM EVERY HOUR TO CHANGE MY PAD OR TAMPON. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037066	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 7/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BLEED 10 MONTHS STRAIGHT TOOK ESTROGEN PILLS AND DEPO SHOT NOTHING STOPPED THE BLEEDING. HAD HEAD ACHES, LIGHT HEADED, PELVIC PAIN, SORES, WEIGHT GAIN, TIRED ALL THE TIME AND COULDN'T KEEP UP WITH MY CHILDREN CAUSE I DIDN'T FEEL RIGHT. HAD TO HAVE A HYSTERECTOMY AT (B)(6) DUE TO ESSURE AND COILS WERE IN PROPER PLACE.

(B)(4)

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037067	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 12/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLOATING, PELVIC PAIN, AND CRAMPING. ALL OF THESE THINGS BECAME INCREASINGLY PAINFUL AND CONSTANT AFTER THE COMPLETION OF MY PROCEDURE IN (B)(6) 2008. I HAD SPOKE WITH MY PCP AND OB/GYN THROUGH FOLLOW UP. ALL COMPLAINTS WERE PUT OFF. IN (B)(6) 2014 I DEMANDED THAT MEDICAL STAFF LOOK INTO THE PLACEMENT OF MY ESSURE. I UNDERWENT SPECIAL IMAGING, WHERE IT WAS FOUND THAT THE COIL IMPLANTED INTO MY LEFT TUBE WAS NOT BLOCKING AND STILL OPEN. MEANING I COULD STILL BECOME PREGNANT. I IMMEDIATELY FOLLOWED UP WITH MY OB/GYN AND WAS TOLD THERE IS NOTHING THAT CAN BE MADE RIGHT. THE IMPLANTS CAN NOT BE SAFELY REVERSED AND THAT I NEED TO BE CAREFUL DURING INTERCOURSE BECAUSE NOT ONLY DO I HAVE A CHANCE OF PREGNANCY, BUT GREATER CHANCES OF ECTOPIC PREGNANCY. NOT ONLY DID THIS PRODUCT AND PROCEDURE CAUSE ME PAIN, BUT IT IS INEFFECTIVE AS WELL. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037068	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MIGRAINES THAT I CAN RARELY TREAT BECAUSE I CAN'T TAKE MANY MEDICATIONS DUE TO SIDE EFFECTS, BREAST PAIN, PELVIC PAIN, PAIN DURING INTERCOURSE THAT MAKES IT UNBEARABLE AT TIMES CAUSING RELATIONSHIP PROBLEMS, METALLIC TASTE IN MOUTH AND SMELL, DIZZY, SICK TO STOMACH, BLOATING THAT MAKES ME LOOK 4 MONTHS PREGNANT, GAS, HORRIBLE DISCHARGE SMELL, NUMBNESS/TINGLES IN LIMBS. ALL THESE SYMPTOMS CAUSE ME TO HAVE ANXIETY AND IT'S HARD TO WORK WITH THAT AND TAKE CARE OF MY DISABLED 3 YR OLD. I HAVE HAD BLOOD DRAWN, STD TESTS, CT SCAN, EKG, ETC....MY ORGANS ARE FINE. THE ONLY THING WRONG WITH ME IS THESE COILS AND ALL THEIR HORRIBLE SIDE EFFECTS THAT I WAS NOT TOLD ABOUT. MY "CURRENT" HAS PUT ME ON A LOW DOSE BIRTH CONTROL PILL TO HELP WITH THE SYMPTOMS BUT NOTHING YET. WHY SHOULD I HAVE TO PAY EXTRA A MONTH FOR BIRTH CONTROL PILLS? IF I WANTED BIRTH CONTROL PILLS, I WOULD NEVER HAD THE ESSURE. WISHING I COULD PAY MY (B)(6) DEDUCTIBLE AND GET THESE COILS OUT. I WOULD RATHER BE TAKING THE BIRTH CONTROL PILLS INSTEAD OF THESE COILS. BIGGEST MISTAKE I'VE MADE WAS GETTING ESSURE. NEEDS TO BE OFF THE MARKET!!! (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037069	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 4/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #(B)(4). THE FOLLOWING IS A LIST OF SYMPTOMS I HAVE HAD SINCE BEING IMPLANTED WITH ESSURE: ACNE/BOILS/CYSTS/DRY SKIN, ANXIETY, BLOATING, FULL FEELING, BODY ACHES AND PAIN, "BRAIN FOG," DEPRESSION, DIMINISHED BRAIN FUNCTION, DIZZINESS, DYSMENORRHEA, FATIGUE, FREQUENT SICKNESSES INCLUDING PNEUMONIA AND BRONCHITIS, FOUL DISCHARGE, HAIR LOSS, HYPOTHYROIDISM, IMMUNE ISSUES, INSOMNIA, JOINT PAIN, LOSS OF LIBIDO, MEMORY LOSS/FORGETFULNESS, METRORRHAGIA, MOOD SWINGS, NAUSEA/VOMITING, NUMBNESS AND TINGLING IN MY EXTREMITIES, OVARIAN TORSION RESULTING IN REMOVAL OR RIGHT TUBE AND OVARY, PAINFUL INTERCOURSE, (DYSPAREUNIA), PAIN IN MY UTERUS, LIKE A BURNING/STABBING, PAINFUL OVULATION (MITTELSCHMERZ), SWELLING OF LEGS, FEET AND HANDS, SWOLLEN LYMPH NODES/GLANDS, THYROID ISSUES, URINARY URGENCY, FREQUENCY, INCONTINENCE, INABILITY TO EMPTY BLADDER, VERTIGO, VITAMIN D DEFICIENCY, WEIGHT GAIN, WHENEVER I DO ANYTHING STRENUOUS, SUCH AS AEROBIC EXERCISE OR YARD WORK, I HAVE FLU-LIKE SYMPTOMS FOR 1-2 WEEKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037070	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 3/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

UNCONTROLLABLE PAIN, JOINT PAIN, SEVERE BACK PAIN, CONSTANT HEADACHES, CONSTANT ABNORMAL DISCHARGE, ABNORMAL BLEEDING, BLURRED VISION, MEMORY ISSUES, SKIN RASHES, ACNE, BELLY BLOAT, DEPRESSION, CHRONIC FATIGUE, NARCOLEPSY,

(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037071	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 5/1/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PROCEDURE WAS VERY PAINFUL, I WAS HAVING BAD CRAMPS AND OTHER SYMPTOMS AND NOTHING WAS DONE. I HAVE GAINED EXCESSIVE WEIGHT, SEVERE BACK PAIN THAT WONT GO AWAY CAUSES ME TO HUNCH OVER, PAINFUL OVARIES, UTERUS FEELS INFLAMED, MY FACE IS FLUSHED, PAINFUL SEX, BLOATED, LEAKY BLADDER, PAINFUL PERIODS WISH I NEVER IN A MILLION YEARS GOT THIS AND I PRAY NO ONE ELSE DOES. YOUNG WOMEN ARE HAVING HYSTERECTOMIES BECAUSE OF IT. PLEASE DONT LET ANYONE GO THROUGH WHAT I AM. I WANT IT OUT AND THE PAINFUL BUMPS APPEARING ON MY STOMACH TO STOP. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037072	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

COIL HAD RUPTURED THROUGH ONE OF MY TUBES CAUSING INTENSE PAIN. IF I COUGHED, IT WOULD HAVE ME BUCKLED OVER AND IT FELT LIKE A KNOT. I WOULD HAVE TO RELAX AND WAIT FOR IT TO EASE UP TO STAND NORMAL AGAIN. ABNORMAL BLEEDING, EXTREME HAIR LOSS, UNCONTROLLABLE WEIGH GAIN, BLOATING THAT WOULD CAUSE PAIN. I HAD THEM REMOVED AND SINCE IT HAD PUNCTURED THROUGH THE TUBE IT'S VERY LIKELY THOSE PET FIBERS HAD SPREAD. DURING MY REMOVAL, MY DOCTOR TOLD ME THERE WAS MORE SCAR TISSUE THAN EXPECTED AND I MAY HAVE TO GO BACK IN THE FUTURE TO HAVE IT REMOVED. I FELT BETTER BUT THE PAIN HAS RETURNED. ACCORDING TO THE DR, THIS IS MOST LIKELY FROM ALL THE EXTRA SCAR TISSUE ESSURE CAUSED FROM PUNCTURING THROUGH MY TUBE. I AM NOT HAVING TO LOOK INTO HAVING A HYSTERECTOMY TO FULLY REMOVE THE EFFECTS ESSURE LEFT ON MY BODY. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037073	BAYER	7/7/2014	7/8/2014

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BLOATING, SWELLING, FATIGUE, WEIGHT GAIN, RASH, ACNE, PELVIC PAIN, BRAIN FOG, JOINT PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037143	BAYER	7/7/2014	7/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD PELVIC PAIN, HEAVY PERIODS, FIBROIDS, MEMORY LOSS, DIZZINESS, HEADACHES, HAIR LOSS, URINARY TRACT INFECTIONS, BLADDER INFECTIONS, WEIGHT GAIN, DEPRESSION, ANXIETY ATTACKS, SUICIDAL THOUGHTS, MOOD SWINGS, LOSS OF LIBIDO, JOINT PAIN, BACK PAIN, METALLIC TASTE IN MOUTH, SWOLLEN AND PAINFUL GLANDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037148	BAYER	7/7/2014	7/11/2014

Event Information:

Event Date (B3): 8/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/15/2013
Explant Date (E7): 2/12/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

APPROXIMATELY 6 WEEKS AFTER THE BIRTH OF MY SECOND DAUGHTER, I HAD ESSURE COILS PLACED IN MY FALLOPIAN TUBES DURING AN IN-OFFICE PROCEDURE AT MY OB/GYN'S OFFICE. THERE WERE NO COMPLICATIONS OR PROBLEMS DURING THE PROCEDURE. A MONTH LATER I STARTED HAVING ABDOMINAL CRAMPING, INCREASING VAGINAL DISCHARGE AND FEVERS. AFTER REPEATED TRIPS TO MY OB/GYN'S OFFICE, IT WAS FINALLY TIME FOR MY HYSTEROSALPINGOGRAM, WHICH WAS INITIALLY DELAYED DUE TO MY SYMPTOMS. THE HSG SHOWED THAT THE LET COIL HAD KINKED AND PERFORATED MY LEFT FALLOPIAN TUBE. I HAD TO HAE A PARTIAL HYSTERECTOMY TO REMOVE BOTH COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037149	CONCEPTUS, INC.	7/7/2014	7/11/2014

Event Information:

Event Date (B3): 4/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/25/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CYST ON OVARIES AND MANY HEALTH PROBLEMS AND CAN'T FIND A DOCTOR TO HELP FIX MY PROBLEM WITH ESSURE IMPLANTS. I'VE HAD SINCE 2009.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037151	CONCEPTUS, INC.	7/7/2014	7/11/2014

Event Information:

Event Date (B3): 7/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): 975391
Lot #(E4):

Single Use:
Implant Date (E6): 2/8/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS IMPLANT WITH ESSURE IN 2012 AND IT MIGRATED AND HAS PERFORATED MY UTERUS. I WILL NOW HAVE TO GET A HYSTERECTOMY AT (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037074	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 9/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I WAS IMPLANTED, I STARTED PRESSURE AND PAIN IN THE AREAS IMPLANTED. I WAS UNDER THE IMPRESSION ONLY ONE DEVICE WAS IMPLANTED SINCE I ONLY HAVE ON FALLOPIAN TUBE AND ONE OVARY, HOWEVER 2 AND A HALF YEARS LATER DISCOVERED THAT I WAS IMPLANTED WITH 2 DEVICES. I STARTED HAVING SHARP LIKE STABBING A LITTLE KNIFE LIKE FEELINGS IN MY LEFT AND ONLY FALLOPIAN TUBE TOGETHER WITH CONSTANT PRESSURE IN THERE PLUS IN THE RIGHT SIDE OF MY UTERUS . THESE PAINS , FEELINGS AND DISCOMFORT INCREASES AND TOWARDS THE 2 YEARS MARKED THE PAIN IN THE LEFT SIDE INCREASED AS WELL AS THE WHOLE ABDOMENS AREA DISCOMFORT. AROUND 3 MONTHS AFTER IMPLANTED, I EXPERIENCES ON AND OFF NUMBNESS IN MY EXTREMITIES, LEGS AND MOSTLY ARMS AND HANDS) IN OCCASIONS WHEN I WAS NOT EVEN LAYING OR MAKING PRESSURE OF ANY KIND ON THEM. AROUND 6 MONTHS INTO IT I NOTICED GAIN OF WEIGHT THAT NOTHING WAS WORKING TO TAKE OFF. CLOTHES I WORE 2-3 WEEKS AFTER DELIVERING MY SON IN (B)(6) 2011 WASN'T EVEN FITTING ANYMORE!. I WAS CONSTANTLY FEELING BLOATED IN MY BELLY . I ALSO EXPERIENCE OFTEN LIKE BRAIN FOGS ON AND OFF. I WAS ALSO BLEEDING ON AND OFF BEFORE AND AFTER MY PERIODS . HAVING INTIMATE RELATIONSHIPS , TURNED PAINFUL AND EXTREMELY UNCOMFORTABLE. I CONSTANTLY FELT TIRED, IT WAS ANNOYING AND OVERWHELMING. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037075	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 10/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL PAIN, JOINT PAIN, WEIGHT GAIN, CHRONIC FATIGUE, HEAVY PERIODS, CLOTS, THOUGHT WAS FROM CROHNS BUT NO FLARE WHEN IN E.R. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037076	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 7/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AROUND THE SUMMER OF 2006 I STARTED TO GET REALLY BAD HEADACHES, THAT I NEVER HAD BEFORE. I ALSO STARTED TO FORGET THINGS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037077	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 11/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE IMPLANTING ESSURE, I HAVE HAD EXTREMELY HEAVY BLEEDING, BLOOD CLOTS THE SIZE OF MY HAND, LOWER BACK PAIN, HIP PAIN, MOOD SWINGS, EXTREME WEIGHT GAIN, FATIGUE, PELVIC PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037078	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME PAIN AT LEAST 2 WEEKS OUT OF EVERY MONTH, HEAVIER PERIODS AND PASSING CLOTS AND/OR TISSUE, EXTREME BLOATING AND WEIGHT GAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037079	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 3/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM PREGNANT WITH TWINS 1 1/2 YEARS AFTER GETTING THE ESSURE PROCEDURE DONE. I HAD THE PROCEDURE DONE IN (B)(6) 2012 AND WENT BACK IN (B)(6) FOR THE 3 MONTH CHECK UP AND EVERYTHING WAS BLOCKED AND SUCCESSFUL. I HAVE THE PAPER STATING IT WAS SUCCESSFULLY DONE. IN (B)(6) OF 2014 I FOUND OUT I WAS 8.5 WEEKS PREGNANT WITH TWINS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037080	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 10/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS HEALTHY AND PAIN-FREE WITH NO MEDICATIONS BEFORE THE ESSURE IMPLANTS IN 2010 (REF # ESS305, LOT 686081). I WAS IN EXCRUCIATING PAIN DURING THE PLACEMENT OF THE DEVICES, AND THE PROCEDURE TOOK MORE THAN 30 MINUTES BECAUSE THE DOCTOR HAD TROUBLE GETTING THE DEVICES INTO PLACE. THE HSG WAS ALSO EXCRUCIATINGLY PAINFUL BECAUSE THE DOCTOR WAS UNABLE TO GET THE TUBES INTO CORRECT PLACEMENT ON THE FIRST TRY. THE AMOUNT OF PAIN WAS BEYOND WHAT SHOULD BE ALLOWED WITHOUT GENERAL ANESTHESIA. THE PAIN EASED UP SOMEWHAT AFTER A FEW DAYS OF PLACEMENT, BUT HAS FLARED UP REPEATEDLY AND HAS CAUSED MANY OTHER PROBLEMS, INCLUDING: SEVERE CRAMPING, SHARP AND STABBING PELVIC PAIN, BURNING PELVIC PAIN, IRREGULAR PERIODS, SPOTTING, DISCHARGE WITH ODOR, HOT FLASHES, NIGHT SWEATS, PAINFUL PERIODS, HEAVY PERIODS, LARGE BLOOD CLOTS, LOSS OF LIBIDO, UTIS, URGENT AND FREQUENT URINATION, BREAST PAIN, NIPPLE DISCHARGE, ABDOMINAL SPASMS/TWITCHES, JOINT PAIN, BODY ACHES AND PAINS, MUSCLE CRAMPS/SPASMS, TENDINITIS, FIBROMYALGIA, ARTHRITIS, FACIAL PAIN, NERVE PAIN, TMJ PAIN, TOOTH PAIN, NAUSEA, VOMITING, CONSTIPATION, SEVERE BLOATING, HEADACHES, CHRONIC FATIGUE, MIGRAINE WITH AURA, VERTIGO, CHRONIC DIZZINESS, TINGLING IN HANDS AND FEET, NUMBNESS IN HANDS AND FEET, RESTLESS LEG SYNDROME, ELECTRIC SHOCK FEELINGS THROUGHOUT BODY, BRAIN FOG, FORGETFULNESS, CONFUSION, DIFFICULTY CONCENTRATING, ANXIETY, PANIC ATTACKS, CHRONIC CHOKING FEELING, GLOBUS HYSTERICUS, MOOD SWINGS, DEPRESSION, TINNITUS, BODY TWITCHING, ITCHY SKIN, TREMORS, SHAKINESS, CHEMICAL SENSITIVITIES, SEASONAL ALLERGIES, DUST ALLERGIES, HIVES, SKIN RASHES, ACNE, COCHLEAR SENSITIVITY, SENSITIVE TEETH, GUM TISSUE WEARING AWAY, HAIR LOSS, DRY AND BRITTLE HAIR AND NAILS, DRY SKIN, INSOMNIA, WEIGHT GAIN, INABILITY TO LOSE WEIGHT WITH DIET AND EXERCISE, EYE FLOATERS, BLURRY VISION, DOUBLE VISION, METAL

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TASTE IN MOUTH, EXCESSIVE SWEATING, CHRONIC PHLEGM, CHRONIC SINUS CONGESTION, EAR FULLNESS, VITAMIN D DEFICIENCY, LOW FERRITIN LEVELS, ELEVATED LIVER ENZYMES, HEART PALPITATIONS, UNEXPLAINED BRUISING, FREQUENT NOSEBLEEDS. I HAVE HAD MULTIPLE MRIS, CT SCANS, BLOOD TESTS, AND DOCTOR VISITS SINCE ESSURE WAS PLACED, AND NO ONE CAN GIVE ME ANY OTHER EXPLANATION FOR ALL THE PAIN AND SIDE EFFECTS I'VE HAD OTHER THAN CHRONIC INFLAMMATION FROM ESSURE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037081	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 9/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED ON (B)(6) 2013. THAT EVENING I STARTED CRAMPING VERY BAD AND MAJOR PAINS THROUGH OUT MY BODY. STARTED GETTING MIGRAINES FROM THAT EVENING TO NOW THAT ARE SO SEVERE I VOMIT AND CAN'T KEEP FOOD DOWN OR BE AROUND LIGHT OR NOISE AND MY PAIN MEDICATION DOES NOT WORK. I CAN BARELY GO UP AND DOWN MY STAIRS AND THERE ARE DAYS I CAN NOT EVEN GET OUT OF BED DUE TO THE PAIN I HAVE. I HAVE A RASH OUT BREAK CAUSED FROM THE NICKLE AND CANT WEAR MY JEWELRY ANY MORE. I HAVE SWELLING ALL OVER MY BODY. I HAVE HAD MAJOR WEIGHT GAIN. OVER 64 POUNDS SINCE HAVE THE PROCEDURE DONE LESS THAN A YEAR AGO. I HAVE PAIN WITH BOWEL MOVEMENTS AND URINATION. HEAVY BLEEDING AND MAJOR CRAMPING WITH PERIODS THAT LAST A WEEK AND OCCUR EVERY 2 WEEKS. I AM EITHER CONSTIPATED OR HAVE DIARRHEA. HAVE DIZZY SPELLS AND FORGETFULNESS. I CAN NOT LONGER PLAY WITH MY KIDS ALL I CAN DO IS WATCH THEM. I HAVE TO HAVE CONSTANT HELP WITH MY YOUNGEST 2 WHO ARE 1 AND 4 BECAUSE I CAN NOT DO MUCH TO BE ABLE TO HELP TAKE CARE OF THEM. I HAVE JOINT PAIN AND CHRONIC BACK PAIN THAT MAKES IT HARD TO MOVE. I HAVE MAJOR MOOD SWINGS AND DEPRESSION NOW. I HAVE NO APPETITE TO EAT AND WHEN I DO EAT, IT IS HARD TO KEEP IT DOWN. I HAVE A BAD CASE OF ACID REFLUX THAT BURNS MY THROAT. I HAVE NO SEX DRIVE WHAT SO EVER AND HATE THE THOUGHT OF BEING TOUCHED. THIS DEVICE HAS RUINED SO MUCH FOR ME. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037082	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 1/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP 1. #FDA MW5037082, #(B)(4). I WAS ALSO DIAGNOSED WITH FIBROMYALGIA AFTER GETTING ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037083	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 11/20/2011 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABDOMEN SWELLING AND CRAMPS VERY PAINFUL. RASH ON STOMACH AND I'M ALLERGIC TO NICKEL THAT IS IN THE ESSURE. PAINFUL PERIODS. DIAGNOSED WITH LUPUS AND DIVERTICULITIS AFTER HAVING ESSURE DEVICE. FEEL SICK ALL THE TIME, TIRED. HAVEN'T HAD ANY ISSUES TILL THE ESSURE PROCEDURE WAS DONE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037086	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 6/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE DAY ONE I HAD ESSURE IMPLANTED I'VE BEEN EXPERIENCING REALLY BAD MIGRAINES AND ALL KINDS OF DIFFERENT ILLNESSES LIKE MIGRAINES, VERY BAD CRAMPING AND "BLEEDING" OF MY STOMACH AND HEAVY PERIODS. SOMETIMES I WOULD GET MY PERIOD NON STOP FOR 3 MOTHS IN A ROW ALSO WEAKNESS, WEIGHT GAIN AND SWOLLEN FEET AND PROBLEMS WITH MY EYES AND SHORT TERM MEMORY, LOOSE DEPRESSION AND ANXIETY ATTACKS. I ALSO DEVELOPED FACIAL PARALYSIS A COUPLE OF WEEKS AFTER ESSURE IMPLANTED. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037087	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 9/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DAILY PELVIC PAIN, RE OCCURING YEAST INFECTIONS, RASH, HYPERTENSION, METALLIC TASTE, PAINFUL AND IRREGULARLY HEAVY PERIODS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037088	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 3/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING THE PROCEDURE OF THE ESSURE COILS I FELT A LOT OF PAIN AND PRESSURE ON MY RIGHT SIDE. THE DOCTOR SAID IT WAS NORMAL IT WILL GO AWAY. SINCE I'VE HAD THE ESSURE COILS PLACED IN I'VE HAD NOTHING BUT PAIN ON MY RIGHT SIDE. BLOATING , NAUSEA, WEIGHT GAIN, FATIGUE, TASTE OF METAL, FEW PERIODS A MONTH, AND SHARP PAINS. IF I MOVE A CERTAIN WAY IT FEELS LIKE I'M BEING PINCHED. I HAVE A SHARP PAIN ON MY RIGHT SIDE THAT WILL SHOOT DOWN MY RIGHT LEG. I HAVE ON GOING SHARP PAINS TO WERE WHATEVER IT IS I'M DOING I HAVE TO STOP. I'VE HAD TO GO TO THE EMERGENCY ROOM FOR THE PAIN AND BLOATING. GOT DIAGNOSE WITH HAVING A INFECTION IN MY UTERUS. I'VE BECOME VERY LIMITED ON MY ACTIVITIES DO TO SHARP PAINS. I'VE NEVER BEEN TESTED TO SEE IF I WAS ALLERGIC TO NICKEL . IM GOING TO THE DOCTOR AT THIS TIME TO BE TESTED TO SEE IF I AM ALLERGIC TO NICKEL. THE ONLY OTHER HEALTH PROBLEM I HAVE IS ASTHMA . (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037089	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 6/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEBILITATING PAIN FROM THE TOP OF MY HEAD TO THE BOTTOM OF MY FEET 24 HOURS, 7 DAYS A WEEK FOR OVER A YEAR BEFORE I WAS DIAGNOSED WITH FIBROMYALGIA. HEAVY, OVERFLOWING, DEBILITATING, AND VERY PAINFUL MENSTRUAL CYCLES. DEPRESSION. HIGH BLOOD PRESSURE. TREMENDOUS WEIGHT GAIN. I AM ABOUT TO GO THROUGH A HYSTERECTOMY WITH MORE PAIN AND A 6 WEEK RECOVERY PERIOD. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037090	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 10/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN I HAD ESSURE IMPLANTED ON (B)(6), 2012 THEY HAD TROUBLE PUTTING THE RIGHT COIL IN. IT WAS SO PAINFUL THAT I CRIED. THEY FINALLY SUPPOSEDLY GOT IT IN. I HAD HEAVY BLEEDING FOR SEVERAL WEEKS THEN MY PERIODS WERE NOT NORMAL FOR AT LEAST A YEAR. SOMETIMES I WOULD HAVE 2 IN ONE MONTH. I HAVE HAD MEDICAL PROBLEMS AND SYMPTOMS SINCE I WAS IMPLANTED THAT I DID NOT HAVE BEFORE IMPLANTATION. I HAVE HAD IRREGULAR PERIODS, PAINFUL PERIODS, HUGE CLOTS WITH MY PERIOD, STIFFNESS WHEN STANDING, PAIN IN LOWER ABDOMEN, PELVIC PAIN, PAIN ON RIGHT SIDE, LOWER BACK PAIN, CRAMPING, TERRIBLE BLOATING LOOKING AS IF I WERE PREGNANT, SKIN BREAKOUTS ESPECIALLY ON FACE WITH CLEAR FLUID THAT LEAVES BAD SCARS, A OVERALL NAUSEA AND ILL FEELING, NAUSEA WHEN I EAT, MIGRAINES, LOSS OF LIBIDO AND SEXUAL DYSFUNCTION, BREAST TENDERNESS, ABDOMINAL SPASMS AND FLUTTERING FEELING, METABOLIC TASTE IN MOUTH AND FOOD JUST DOESN'T TASTED THE SAME, HEARTBURN, EXCESSIVE GAS, DIZZINESS, BRAIN FOG FORGETTING STUFF, FEELING SAD ALL THE TIME, DEPRESSION, MOOD SWINGS, ANXIETY, VITAMIN D DEFICIENCY, SKIN ITCHING, SWELLING ANKLES AND FEET, HAIR LOSS. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037091	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2009. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON OR AROUND (B)(6), 2011. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. UTERINE FIBROIDS, UTERINE INFLAMMATION, ENDOMETRIOSIS, WEIGH GAIN, SWOLLEN GLANDS, EAR ACHE, LACK OF MENSTRUAL CYCLE, UNEXPLAINED FEVERS, SWELLING OF LEGS AND FEET, MIGRAINE HEADACHES, CHRONIC PELVIC PAIN, FATIGUE, INTERSTITIAL CYSTITIS, IRRITABLE BOWEL SYNDROME, NIGHT SWEATS, JOINT PAIN, NAUSEA, PAINFUL PERIODS, HIP PAIN, SEVERE BLOATING, BACK PAIN. I HAVE BEEN SEEN BY SIX DIFFERENT DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS; IBS, AND IC. THE DEVICE IS STILL INSIDE OF ME. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037092	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 3/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

VERY PAINFUL PROCEDURE, GOT THE COILS IMPLANTED 2013 AND HAVE HAD PAIN IN MY LOWER ABDOMEN AND BLOATING, WEIGHT GAIN, FEELING ILL ALL THE TIME, MIGRAINES EVERY WEEK, VERY HEAVY PERIODS, ITCHY RASHES ON ABDOMEN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037093	BAYER	7/8/2014	7/8/2014

Event Information:

Event Date (B3): 4/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SHARP LOWER ABDOMINAL PAIN, HAIR LOSS, NAUSEA AND BRAIN FOG. I HAVE SHARP PAINS THAT COME AND GO IN MY LOWER ABDOMEN. THEY STARTED ABOUT A MONTH AND A HALF AFTER IMPLANTATION. I WENT TO THE ER AND WAS TOLD MY CERVIX WAS BRUISED AND UTERUS SEEMED INFLAMED. I WAS GIVEN LORTAB FOR THE PAIN AND TOLD TO FOLLOW UP WITH MY OB. THE INFLAMMATION WENT AWAY, BEFORE I WAS ABLE TO GET IN TO SEE MY OB (A MONTH) AND THE BRUISING WAS GONE. THE PAINS ARE STILL HAPPENING FROM TIME TO TIME. NOT AS FREQUENT, BUT THEY CERTAINLY HAVEN'T STOPPED. MY HAIR WAS SO THICK AND PRETTY, NOW IT IS THIN AND DULL. MY HAIR HAS ALWAYS HAD A SHINY REDDISH/AUBURN TINT TO IT AND IT IS NOW JUST A BLAND FLAT BROWN. THE SHINE IS TOTALLY GONE. IT'S BEEN FALLING OUT IN HAND FULLS. IT WAS MID BACK AND I CUT IT TO CHIN LENGTH, BECAUSE THE HAIR ALL OVER THE HOUSE WAS CLOGGING UP MY VACUUM CLEANER AND SHOWER DRAIN. PLUS, THAT IS JUST DISGUSTING. I ALWAYS HAVE A SLIGHTLY NAUSEATED FEELING. IT NEVER GOES AWAY COMPLETELY, BUT IT MUCH WORSE SOMETIMES. IT IS VERY MUCH LIKE MORNING SICKNESS WHILE PREGNANT. I HAVE NEVER HAD THIS PROBLEM, OUTSIDE OF PREGNANCY, UNTIL AFTER THE ESSURE WAS PLACED. I HAVE THE HARDEST TIME CONCENTRATING AND REMEMBERING WHAT I'M TRYING TO DO. THIS IS ALSO SOMETHING I HAVE NEVER HAD TROUBLE WITH UNTIL AFTER ESSURE. I HAVE ALWAYS BEEN A VERY "TOGETHER" PERSON; WELL ORGANIZED, GOOD MEMORY(SHORT TERM AND LONG TERM). NOW I AM CONSTANTLY FORGETTING WHY I WALKED INTO A ROOM, LOSE MY CAR KEYS, PHONE, ETC. ON A DAILY BASIS. IT IS UNEXPLAINABLE HOW DIFFICULT THESE PROBLEMS HAVE MADE MY LIFE. TO GO FROM A WELL ORGANIZED AND EASY GOING PERSON, TO A DISORGANIZED, STRESSED OUT AND FRAZZLED PERSON HAS MADE ME REALLY LOSE A LOT OF MY FEELING OF SELF WORTH AND DIGNITY. I HONESTLY DON'T FEEL LIKE I'M ME ANYMORE. I'VE BEEN MUCH SHORTER WITH EVERYONE IN MY LIFE. MY FUSE IS ALMOST

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NOTHING, BECAUSE I AM CONSTANTLY ON EDGE, DUE TO FEELING TERRIBLE AND MY BRAIN NOT WORKING HOW IT SHOULD. IT HAS BEEN TERRIBLE AND FROM WHAT I'VE READ, I HAVE IT BETTER THAN A LOT DO. (B)(4).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00262	BAYER HEALTHCARE LLC	7/9/2014	7/25/2014

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 922603

Single Use: Y
Implant Date (E6): 4/1/2012
Explant Date (E7): 6/3/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2014, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. IN 2012, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EVER SINCE STARTED EXPERIENCING EXTREME FATIGUE, PINCHING ON BOTH SIDES OF HER ABDOMEN, ABDOMINAL CRAMPING, IRREGULAR PERIODS, HEADACHES, DEPRESSION, RIGHT LEG PAIN AND BACKACHE. HOSPITALIZATION WAS DESCRIBED, HOWEVER, IT WAS NOT RELATED TO A SPECIFIED EVENT. AFTER CONSULTING WITH HER GYNECOLOGIST AND THERAPIST, HYSTERECTOMY WAS RECOMMENDED. SHE WAS SCHEDULED FOR THE SURGERY (WHICH WAS NOT PERFORMED UNTIL THE REPORT). SHE STATED THAT IF SHE WOULD HAVE BEEN MADE AWARE OF THESE SIDE EFFECTS, SHE WOULD NOT HAVE OPTED FOR ESSURE.

Manufacturer Narrative (H10):

FOLLOW-UP INFO RECEIVED ON (B)(6) 2014 FROM CONSUMER: CONSUMER'S INFO ADDED; INITIALS, AGE, WEIGHT AND HEIGHT. SHE REPORTED THAT HAD AN ECTOPIC PREGNANCY ON 1996. SHE WAS GRAVIDA 4 AND PAR 2, WITH ONE SPONTANEOUS ABORTION. NO OTHER RELEVANT HISTORY OR CON

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037163	BAYER	7/10/2014	7/10/2014

Event Information:

Event Date (B3): 7/5/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HOT FLASHES, SWELLING, TENDER BREASTS, ABDOMINAL PAIN, LOWER BACK PAIN, MOOD SWINGS. EXTREME TIREDNESS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037164	BAYER	7/10/2014	7/10/2014

Event Information:

Event Date (B3): 9/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ONGOING PAIN AS FAR A CRAMPING, STOMACH PAIN, HEAVY HEAVY BLEEDING, HUGE BLOODCLOTS, EXTREME NAUSEA, BLOATING, SKIN RASHES. BOTH COILS HUNG OUT OF MY FALLOPIAN TUBES ONE COIL MIGRATED INTO MY UTERUS. BOTH TUBES WERE REMOVED DO TO SEVERE PAIN. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037165	BAYER	7/10/2014	7/10/2014

Event Information:

Event Date (B3): 4/4/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE COILS IMPLANTED IN MY DOCTORS OFFICE IN (B)(6) 2007 TO PREVENT ME FROM HAVING ANYMORE BABIES. IN (B)(6) 2008 I STARTED TO HAVE HEAVY BLEEDING AND CRAMPS THINKING IT WAS JUST ASSOCIATED WITH MY PERIODS UNTIL (B)(6) 2012 WHEN I PASSED OUT AT HOME AND WAS TAKEN TO THE HOSPITAL WITH SEVER ABDOMINAL PAIN ON THE RIGHT SIDE I WAS IN AND OUT OF THE HOSPITAL WITH SEVERAL SURGERIES THEN IN (B)(6) 2012 WITH WHAT WAS JUST A COMMON EXPLORATORY SURGERY TO SEE WHAT THE PAIN WAS FOR THE SECOND TIME THEY FOUND THAT MY RIGHT COIL IN THE TUBE WAS BENT AND THE BLOOD VEINS WAS WRAPPED AROUND THE COIL AND THEY HAD TO REMOVE IT I STILL AM HAVING PAIN ON THE LEFT SIDE ALONG WITH RASHES EVERY NOW AND THEN, MIGRAINES NEVER HAD MIGRAINES UNTIL AFTER ESSURE, EXCESSIVE ITCHING OF THE SKIN, HEAVY BLEEDING DURING PERIODS, ABDOMINAL PAIN, AND ETC RELATED TO THE ESSURE I NEVER HAD ANY ISSUES UNTIL I HAD THE ESSURE PUT INTO MY BODY. KNOW I WISH THAT I NEVER HAD IT BECAUSE IT HAS TORN MY LIFE APART FROM NOT BEING ABLE TO PLAY WITH MY LIFE TO MY SEXUAL LIFE SINCE IT HURTS SOME TIMES TO HAVE SEX. I JUST WISH IT WOULD ALL GO AWAY BUT I CANT FIND A DOCTOR THAT WILL REMOVE THE SECOND COIL. THIS IS A NIGHTMARE IT HAS MESSED WITH MY JOBS AS WELL. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037166	BAYER	7/10/2014	7/10/2014

Event Information:

Event Date (B3): 9/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED ABOUT A MONTH AFTER GIVING BIRTH. THE PROCEDURE TOOK AN HOUR AND FORTY MINUTES TO COMPLETE, AND WAS VERY UNCOMFORTABLE. WITHIN A FEW WEEKS OF THE IMPLANT, I NOTICED STRANGE THINGS - VERY PAINFUL SEX, EXHAUSTION, SEVERE RASHES OF PERINEAL AREA, AND OTHERS ALL OVER BODY, BACTERIAL INFECTION, PAIN IN AREA OF OVARIES/UTERUS, HEAVY BLEEDING DURING MENSTRUATION AND LARGE BLOOD CLOTS, HAIR LOSS, WEIGHT GAIN, SEVERE BLOATING, "BRAIN FOG" WHICH, I ATTRIBUTED TO HAVING A NEWBORN, BUT A YEAR LATER I AM STILL SUFFERING, JOINT PAIN IN PLACES WHERE I DID NOT HAVE PAIN BEFORE, AND MUSCLE SPASMS AND CRAMPING, DRY, ITCHY EYES, RECEDING GUM-LINE - CRUMBLING TEETH (NEVER HAD CAVITIES BEFORE), MOODINESS, AND THINGS I PROBABLY HAVEN'T EVEN REALIZED YET! I AM PHYSICALLY DISABLED ALREADY AND AM TERRIFIED OF BECOMING PREGNANT AGAIN! (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037167	BAYER	7/10/2014	7/10/2014

Event Information:

Event Date (B3): 11/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FROM THE VERY BEGINNING I HAVE HAD VERY BAD PAIN ON MY LEFT SIDE FALLOPIAN TUBE AREA. THE PAIN HAS SPREAD TO MY WHOLE ABDOMINAL AREA AND MY BACK. I WILL HAVE PAIN IN MY LEFT HIP. I HAVE LIGHT HEADED DIZZY SPELLS, BRAIN FOG TROUBLE FOCUSING OR REMEMBERING. HEART PALPITATIONS. I HAVE BEEN TO THE ER ONCE FOR THE HEART PALPITATIONS. I HAVE TROUBLE SLEEPING BECAUSE OF THE PAIN AND OR HEART PALPATIONS. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037168	BAYER	7/10/2014	7/10/2014

Event Information:

Event Date (B3): 4/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SICK, LETHARGIC, ALLERGY SYMPTOMS, LOW BLOOD PRESSURE, SHAKES TREMORS, PASSING OUT, SHALLOW BREATHING, NIGHT SWEATS, SKIN RASHES.... LAB TEST; SPECIALIST APPOINTMENTS IN PROGRESS. (B)(4)

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037170	BAYER	7/10/2014	7/10/2014

Event Information:

Event Date (B3): 4/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT BLOATING, ABSENTMINDEDNESS, MY EYE SITE IS FOGGY, FREQUENT HEADACHES/MIGRAINE, PERIODS ARE WEIRD, REALLY HEAVY AND VERY DARK RED, CRAMPING 25 DAYS OUT OF 30 DAYS A MONTH...EVERY MONTH!!!, BLEEDING AFTER SEX...SOMETIMES FOR DAYS. UNEXPLAINED KIDNEY PAIN, PAIN WAS SO BAD I COULD GET UP FROM BED FOR HOURS. TESTS CAME BACK NEGATIVE FOR KIDNEY STONES OR UTI....DR'S DIDN'T KNOW WHY FOR THE PAIN. I GET SHOOTING PAINS IN MY BACK RANDOMLY ALL THE TIME NOW...THEY SUCK THE AIR OUT OF ME. MY FEET ARE SWOLLEN MOST ALL THE TIME! I GET DRY MOUTH OFTEN TOO...AM THIRSTY ALL THE TIME. I HAD AN ABNORMAL PAP AFTER PROCEDURE. I BLEED NON STOP FROM (B)(6) 2014 TIL (B)(6) 2013 AFTER PROCEDURE. I HAD AN UNEXPLAINED SKIN RASH IN (B)(6) 2014. ALWAYS BLOATED. ..ALWAYS! GAINED WEIGHT AND CAN NOT LOSE IT WITH ANYTHING! MY HAIR FALLS OUT IN CLUMPS AND HAVE HEARTBURN OFTEN....I ALSO FEEL NAUSEOUS ALL THE TIME! (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037171	BAYER	7/10/2014	7/10/2014

Event Information:

Event Date (B3): 5/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6), 2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6), 2014. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. CHRONIC BLEEDING (20 WEEKS), SHARP PAIN, BLOATING, WATER RETENTION, NAUSEA, HEADACHES, CRAMPING, BACTERIAL VAGINOSIS, HOT FLASHES, UTERINE INFLAMMATION, NIGHT SWEATS, ACNE, PERFORATION OF THE TUBES BY THE COILS, COIL MIGRATION, COILS BECOMING EMBEDDED IN OTHER TISSUES, SWELLING OF LEGS OR FEET, WEIGHT ISSUES, UNEXPLAINED/EASILY BRUISING, DIZZINESS. I WILL HAVE THE FOLLOWING SURGERIES DUE TO ESSURE: LEFT AND RIGHT SALPINGECTOMY, POTENTIALLY COMPLETE HYSTERECTOMY, ON (B)(6), 2014. THE DEVICE WILL BE REMOVED ON (B)(6), 2014. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037169	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 5/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABDOMINAL PAIN AND SWELLING, PROLONGED MENSTRUAL CYCLES ACCOMPANIED WITH SEVERE PAIN AND BLOATING. BLURRED VISION, HIGH BLOOD PRESSURE, MINI BLACK OUT SPELLS, NUMBNESS IN ARMS AND LEGS, HEADACHES.

(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037172	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 10/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED (B)(6) 2012. IN (B)(6) OF 2012, I STARTED HAVING MAJOR ALLERGIES, HIVES, RASHES AND PAINFUL ITCHING.

(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037173	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 5/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD WEIGHT LOSS SURGERY (B)(6) AND WAS TOLD I WOULD NEED TO FIND ANOTHER FORM OF BIRTH CONTROL BECAUSE I WAS CURRENTLY TAKING THE PILL. I HAD ONCE TRIED A IUD A FEW YEARS AGO AND HAD THIS PAIN IN MY RIGHT SIDE OF MY BREAST AND FELT LIKE I WAS GOING TO COME OUT SCREAMING OF MY SKIN. WHEN I TOLD MY DOCTOR THAT I HAD PAIN IN MY BREAST, HE SAID HE HAD NEVER HEARD OF THAT BUT HE WOULD TAKE IT OUT. ONCE OUT PAIN WENT AWAY. SO I ASKED TO GET MY TUBES TIED AND MY DOCTOR SAID THERE IS A PROCEDURE THAT IN THE OFFICE AND IT WAS PERMANENT FORM OF BIRTH CONTROL. I SAID GREAT LET'S DO IT. HE GAVE ME A BROCHURE AND I READ THROUGH IT AND SOUNDED TO BE OK. SO ON (B)(6) 2014 THE SECOND HE PUT THE FIRST COIL IN, I FELT THAT PAIN IN MY RIGHT BREAST AND IT SHOT UP THE SIDE OF MY BREAST JUST LIKE THE IUD. I MEAN IT WAS STRONG AND I GRABBED MY BOOB AND WAS TALKING TO THE NURSE ABOUT IT BECAUSE THE DOCTOR WAS CONCENTRATING ON THE SECOND ONE. RIGHT THEN I WAS SO UPSET THAT I HAD THAT PAIN AGAIN. I LEFT HOPING IT WOULD GO AWAY. THAT SAME DAY I HAD A MAMMOGRAM DONE AND SHE ASKED ANY PAINS AND I TOLD HER NOT UNTIL TODAY AND EXPLAINED WHAT HAD JUST HAPPENED. NOT SURE SHE DOCUMENTED WHAT I SAID. SO AFTER MY FIRST PERIOD, IT WAS REALLY REALLY HEAVY AND HAD BLOOD CLOTS COMING OUT WHICH I HAD NEVER HAD BEFORE AND MY BOOB HURT SO BAD THAT I WAS GETTING ANXIETY ABOUT IT AND JUST WANTED IT OUT. WENT TO THE DOCTOR AND HE TELLS ME IT IS IMPOSSIBLE TO HAVE PAIN IN MY BREAST FROM THIS AND THAT IT HAS TO BE A COINCIDENCE BUT I KNOW MY BODY AND KNOW FOR A FACT WHEN I TRIED THE IUD THAT THE SAME THING HAPPENED. ALSO, I HAD GONE TO THE GYM A WEEK AND SECOND WEEK AFTER MY WEIGHT LOSS SURGERY AND AFTER I HAD ESSURE PLACED IN ME I WAS SO FATIGUED AND HERE I THOUGHT IT WAS FROM MY SURGERY AND I DON'T THINK SO, I MEAN I CAME HOME AND JUST WANTED TO SLEEP. I AM EXTREMELY TIRED AND I HAD

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ENERGY BEFORE I HAD THIS DONE. I JUST DIDN'T KNOW ANY OF THE SIDE AFFECTS. I ONLY WISHED I HAD DONE MORE RESEARCH ON THIS BEFORE GETTING THIS DONE. I SAW ON THE BROCHURE NO HORMONES, SO I WAS THINKING NO WEIGHT GAIN AND HERE ONE OF THE SIDE AFFECTS IS WEIGHT GAIN AND HERE I JUST HAD WEIGHT LOSS SURGERY AND THE SCALE HASN'T MOVED IN ABOUT 5 WEEKS NOW. JUST UPSET AND WANT THESE THINGS OUT. (B)(4). UPDATE ON (B)(6) 2014: AFTER RESEARCH, I REALIZED THAT MY FATIGUE IS CAUSED BY ESSURE BECAUSE AFTER MY WEIGHT LOSS SURGERY, I WAS WALKING EVERY HOUR LIKE I WAS TOLD AND EVEN WENT TO THE GYM A COUPLE OF TIMES IN THE TWO WEEKS I HAD OFF TO RECOVERY. I FELT GREAT, THEN TOWARD THE END OF MY SECOND WEEK WAS WHEN I GOT ESSURE PLACED (THURSDAY MORNING), MONDAY MORNING I WENT BACK TO WORK AND I GOT HOME AND DIDN'T EVEN WANT TO GO UPSTAIRS TO TAKE A SHOWER OR GET MY PAJAMAS ON. IT TAKES EVERY THING I HAVE TO TRY TO GO TO THE GYM AND WALK. I AM SUPPOSE TO BE EXERCISING EVERY DAY BUT CAN'T BECAUSE I AM SO FATIGUED. I HAVE LOWER BACK PAIN AND DIDN'T EVEN THINK IT COULD BE FROM THIS AND IT IS. I HAVE BEEN IN LEFT FIELD WITH MY MIND, FORGETTING TO DO THINGS AT WORK, JUST FLAKY, I HAD BEEN BLAMING ALL THESE SYMPTOMS ON MY WEIGHT LOSS SURGERY AND NO ONE ELSE IN MY GROUP FOR SUPPORT WAS HAVING ANY OF THE SAME ISSUES. BUT I HAVE READ HOW WOMEN HAVE THE SAME ISSUES AS ME FROM THIS PROCEDURE. I WISHED THAT THERE WAS BETTER INFORMATION ON THE BROCHURE THAT I WAS GIVEN IN ORDER TO MAKE A DECISION LIKE THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037174	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 12/28/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS IMPLANTED WITH ESSURE ON (B)(6) 2012 SINCE THEN I HAVE INCONTROLLABLE WEIGHT GAIN. MIRGRAINES. ABDOMINAL PAIN THAT HAS CAUSED SEVERAL EMERGENCY ROOM VISITS. UNBEARABLE MENSTRUAL CYCLES THAT ARE SO PAINFUL I CANT EVEN GET OUT OF BED. METALLIC TASTE IN MY MOUTH THAT IS HORRIBLE. I HAVE HAD ER VISITS FOR SEVERE BLEEDING AND PAIN. MENSTRUAL CYCLES ARE NOT NORMAL SOMETIMES THEY LAST FOR TWO WEEKS. I HAVE UNEXPECTED BLEEDING THAT OCCURS. I LOST MY JOB DUE TO MISSING WORK BECAUSE OF ABDOMINAL PAIN THAT HAD ME DOUBLED OVER. OR LEAVING DUE TO UNEXPECTED BLEEDING AND MIGRIANES. NO ONE SHOULD GO THROUGH THE HELL THAT ESSURE CAUSES. ESSURE SHOULD BE TAKEN OFF THE MARKET IT IS NOT SAFE. ITS CAUSED ME TO HAVE MISCARRIAGES AND AFFECTED MY QUALITY OF LIFE THAT WAS GREAT BEFORE ESSURE NOW I DO GOOD TO HAVE ENOUGH ENERGY TO TAKE A SHOWER.

(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037175	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 11/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. FATIGUE; UNABLE TO LOSE WEIGHT; EXCESSIVE BLEEDING; IRREGULAR PERIODS; SEVERE CRAMPING; SEVERE BACK PAIN; NIGHT SWEATS; EXCESSIVE BLOATING; DENTAL PROBLEMS; ACNE; HEADACHES; DIZZINESS; BLOOD CLOTS; SPOTTING; SPOTTING AFTER INTERCOURSE; EXCESSIVE BLEEDING AFTER INTERCOURSE. I HAVE BEEN SEEN BY 2 DOCTORS. THE DEVICE IS STILL INSIDE OF ME. THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER. THE DEVICE IS IN MY POSSESSION. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037176	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 4/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD HORRIBLE CRAMPS AT FIRST I HAD NO PERIOD AND I GAINED 40 LBS SO I THOUGHT I WAS PREGNANT THE FIRST YEAR THEN I STARTED TO GET MY PERIOD FOR 2 WEEKS AT A TIME WITH HORRIBLE CRAMPS MIGRAINES HAIR LOSS FATIGUE SHARP PAINS AT THE BOTTOM OF MY STOMACH AND NOW I HAVE DIABETES TYPE 2 AND MY DOCTOR WHO PUT ESSURE IN DIDN'T DO THE HSG TEST 3 MONTHS AFTER PLACING ESSURE IN I DIDN'T FIND OUT I EVEN NEEDED A HSG TEST UNTIL 4 YEARS LATER I ALSO DEAL WITH NAUSEA. (B)(4). UPDATE ON (B)(6) 2014: ALSO STOMACH BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037177	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 2/27/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HELLO, FOLLOWING UP. I STARTED HAVING A LOT OF HAIR LOSS AND TEST MILDLY POSITIVE FOR LUPUS. HAD REALLY BAD RASHES THAT MY OB SAID IT WAS ALLERGIC REACTION DUE TO THE NICKLE IN ESSURE. I HAD SO MUCH INFLAMMATION I ALSO HAVE A CYST ON OVARY I HAD TO GET A HYSTERECTOMY ON (B)(6) 2014 TO REMOVE EVERYTHING BUT OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037178	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 4/29/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

INCREASED BLEEDING AND IRREGULAR MENSTRUAL CYCLES, SHARP LOWER ABDOMINAL PAIN, INCREASED MIGRAINES, BACTERIAL VAGINOSIS, INCREASED DEPRESSION, DAMAGE TO UTERUS.

#(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037179	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 11/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS VERY HEALTHY BEFORE THEN THREE MONTHS AFTER IMPLANTED I DEVELOPED MANY SYMPTOMS. PELVIC PAIN, COMPLETE NUMBNESS IN BOTH LEGS, BREATHING PROBLEMS, DIZZINESS, LIGHT HEADED, HEART PALP, BRAIN ZAPS AND WEIGHT GAIN. MANY TRIPS TO THE DOCTOR, ER AND URGENT CARE. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037180	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 4/26/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2010, I WAS IMPLANTED WITH ESSURE AS A FORM OF PERMANENT BIRTH CONTROL. AFTER MY PROCEDURE WAS COMPLETED I WAS TOLD THAT MILD CRAMPING WAS TO BE EXPECTED AND THAT IT WOULD GO AWAY WITH IN A FEW DAYS. IT HAS BEEN 4 YEARS 2MONTHS 7DAYS TO DATE THAT I WAS IMPLANTED WITH ESSURE AND THE CRAMPING THAT I FELT ON THAT VERY SAME DAY HAS NOT SUBSIDED, ONLY GOTTEN WORSE. ALONG WITH THE CRAMPING I HAVE BLOATING TO WHERE I AM ASKED A LOT WHEN I AM DUE, EVEN TO INCLUDE GOING TO THE EMERGENCY ROOM DUE TO BEING IN PAIN AND SO BLOATED THAT THEY EVEN WANTED TO PREP ME TO GO TO LABOR AND DELIVERY. I BRAKE OUT IN HIVES ON A DAILY BASIS SO I HAVE BEEN LEFT WITH NO CHOICE BUT TO TAKE BENADRYL DAILY TO EASE THE HIVES. EVERY MONTH DURING OVULATION I CAN FEEL MY LEFT COIL/FALLOPIAN TUBE MOVING. I ALSO HAVE HAD RANDOM NAUSEA/VOMITING FROM PAIN, RANDOM FEVERS WITHOUT BEING SICK, MY WHITE BLOOD CELL COUNT IS HIGH EVERY TIME IT IS CHECKED AND NO ONE CAN EXPLAIN WHY. I GO BACK AND FORTH FROM BEING FATIGUED TO HAVING INSOMNIA. LIFTING MORE THAN 10 LBS CAUSES ME EXTREME PAIN. STANDING FOR MORE THAN AN HOUR AT A TIME CAUSES ME TO GO FROM MILD CRAMPING TO SEVERE CRAMPING. MY CYCLES WENT FROM BEING NORMAL/MEDIUM FLOW TO EXTREME FLOW I.E.(CHANGING HEAVY PAD EVER 20 TO 30 MIN OR SUPER PLUS TAMPON EVERY 15 MIN). (B)(4). UPDATE ON 2014-(B)(6): I HAVE HEADACHES THAT LAST FOR DAYS, INTERCOURSE IS PAINFUL, HAIR LOSS, WEIGHT GAIN. (B)(6) 2013, I WAS DIAGNOSED WITH PID AND I HAVE HAD THE SAME SEXUAL PARTNER FOR 4 YEARS. I ALSO HAVE HOT FLASHES, NIGHT SWEATS, AND MOOD SWINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037181	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 2/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE BEEN DEALING WITH ANEMIA SINCE THE BIRTH OF SECOND CHILD OF (B)(6) 2007, THE (B)(6) 2008, I HAD THE ESSURE PLACEMENT. THE FOLLOWING YEAR FATIGUE AND HEADACHES WORSENED BECAUSE OF THE ANEMIA WORSENED. IN THE (B)(6) OF 2010, I STARTED HAVING SEVERE MIGRAINES. BY (B)(6) 2011, I COULD NOT GET OUT OF BED DUE TO EXTREME FATIGUE, MUSCLE WEAKNESS AND PAIN. I WAS DIAGNOSED WITH FIBROMYALGIA IN (B)(6) 2011. I AM CURRENTLY ON DISABILITY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037182	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 6/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HELLO, MY NAME IS (B)(6) AND I LIVE IN (B)(6). I AM USING MY SISTER (B)(6) AS A TOOL FOR COMMUNICATION AND FURTHER RESOURCE. I AM A (B)(6) YEARS OLD WOMAN MOTHER OF TWO BEAUTIFUL CHILDREN WHO DECIDED TO HAVE THE ESSURE PROCEDURE 7 MONTHS AGO AS PART OF FAMILY PLANNING. AFTER LONG CONVERSATIONS WITH THE OB- GYN AND MY HUSBAND, AND HAVING DISCUSSED WHAT WE THOUGHT WERE THE PROS AND CONS OF THE PROCEDURE, WE OPTED TO MOVE FORWARD WITH THIS METHOD AND DO IT. THE FIRST SET BACK WAS THAT ONE OF MY TUBES KEPT "REJECTING" THE IMPLANT OR SO I WAS TOLD. I HAVE TO GO BACK AND DO IT ALL OVER AGAIN TIMES 3, AT THAT TIME, THE PROCEDURE WAS LABELED AS A "SUCCESS". I EXPERIENCED FEW EPISODES OF MINIMAL BLEEDING AND PAIN. AS TIME PASSED, I KEEP TAKING ORAL CONTRACEPTIVES TO BE SURE THAT NO SURPRISES WILL DEVELOP DURING THE "WAITING" TIME. LITTLE THAT I KNOW, AS IT TODAY, I AM 5 WEEKS PREGNANT. ALTHOUGH HAVING A CHILD IS THE MOST WONDERFUL NEWS ONE CAN RECEIVED, MY CONCERNS ARE GROWING WITH THE BABY EVERY PASSING DAY. I FIRST NOTICED SOMETHING OUT OF THE ORDINARY ABOUT A WEEK AND 1/2 AGO. I DEVELOPED A SUDDEN, SHARP, AND DEBILITATING PAIN ON ONE OF MY SIDES. I THOUGHT MAY BE I AM OVULATING. I COULD NOT MOVE OR DO ANYTHING FOR THE REST OF THAT DAY. THE VERY NEXT DAY, I FELT THE URGENCY TO TAKE A PREGNANCY TEST, DO NOT QUITE KNOW WHY, MAY BE THE SIXTH "MOTHERLY" SENSE KICKED IN. TO OUR SURPRISE, IT CAME BACK KIND OF BLURRY, REASON WHY, WE WENT TO THE LOCAL LAB TO REQUEST A CERTIFIED TEST. THIS TIME, THE TEST CAME BACK POSITIVE. I IMMEDIATELY MADE THE APPOINTMENT TO SEE MY OB-GYN THINKING THAT IT COULD BE AN ECTOPIC PREGNANCY. MANY LABS AND ULTRASOUND WERE PERFORMED (I FELT LIKE A LAB RAT), A WEEK LATER, EVERYTHING SEEMS TO BE "NORMAL" INCLUDING THE BLOOD LEVELS, HORMONES, AND THE BABY'S GROWING PATTERNS ALONG WITH ITS LOCATION. GOOD

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NEWS RIGHT? THE PHYSICIAN LOOKED (DARE TO SAY) WORRIED BECAUSE SHE HAS NO KNOWLEDGE ON HOW THE MATERIAL OR IMPLANT CAN AFFECT MY BABY'S DEVELOPMENT OR EVEN MY HEALTH IN THE FUTURE AND NOW IT IS RECOMMENDING TO TERMINATE THE PREGNANCY. HOW IN THE NAME OF GOD, ONE CAN EVEN CONSIDER TO DO THAT? IT IS SO LITTLE AND WE WERE NOT EXPECTING THIS SURPRISE AT ALL, BUT STILL OUR BABY. I DO NOT UNDERSTAND IF IS SHOWING NORMALCY TERMS THEN, WHY THE RECOMMENDATION. WHAT IS BEHIND THE MANUFACTURING PROCESS OR THE INSIDE COMPONENTS THAT COULD BE SO DAMAGING TO CONSIDER THE SUGGESTION OF MAKING US CHOOSE BETWEEN LIFE AND DEATH? THIS WHOLE EXPERIENCE IS A NIGHTMARE. I COULD HAVE UNDERSTOOD THE RUSH OF MAKING A DECISION DUE TO THE COMPLICATIONS OF AN ECTOPIC PREGNANCY BUT, NOW THAT I KNOW THAT EVERYTHING LOOKS "NORMAL", HOW CAN I TERMINATE OUT OF FEARS OF THE UNKNOWN? I WAS TRYING TO PREVENT FUTURE PREGNANCIES NEVER IN MY LIFE HAVE CROSSED MY MIND ENDING ONE. IF YOU HAVE ANY INFORMATION OR PRECEDENTS OF SITUATIONS LIKE MINE ALONG WITH THEIR OUTCOMES, PLEASE FEEL FREE TO DISCUSS IT WITH MY SISTER WHO WILL PASS THE INFORMATION TO ME. I EVEN CONSIDERED MOVING IN WITH HER IN (B)(6) TO GET PROPER MEDICAL CARE IF NECESSARY. THANK YOU. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037183	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 1/28/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN THE DR WAS IMPLANTING THE DEVICE, HE WAS UNABLE TO IMPLANT MY RIGHT COIL DUE TO SEVERE PAIN. THE NEXT DAY I HAD A SLIGHTLY PROLAPSED UTERUS. SINCE IMPLANTATION, I HAVE HAD TO HAVE MY GALL BLADDER REMOVED, I HAVE SEVERE LOWER BACK PAIN, AND HIP PAIN. I ALSO HAVE SEVERE ABDOMINAL PAIN. DURING MY MENSTRUAL CYCLE, I BLEED HEAVILY. I WILL GO THROUGH A SUPER PLUS TAMPON AND SUPER PAD IN 30 MINUTES. I ALSO PASS EXTREMELY LARGE GRAY COLORED CLOTS. I HAVE ALSO BEEN LOSING A LOT OF HAIR. I AM ALWAYS EXHAUSTED BUT HAVE TROUBLE SLEEPING. I HAVE CHRONIC DIARRHEA. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037184	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 3/17/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN THE LAST FIVE MONTHS I HAVE EXPERIENCE CRAMPING AND STABBING PAINS , EXCESSIVE BLEEDING DURING PREGNANCY, NIGHT SWEAT, BLEEDING AFTER SEX, PAINFUL PERIODS, LEG PAINS, BLOATING , METALLIC TASTE IN MY MOUTH, HEAD ACHE, DIZZINESS, TINGLING SENSATION ON MY HANDS AND FEET, BRAIN FOG, MOOD SWINGS, DEPRESSION, BLACK OUT, FORGETFULNESS, NUMBNESS IN MY HANDS AND FEET, DIZZINESS, BRUISING, NICKLE ALLERGY, SKIN SENSITIVE, SKIN ITCHING AND IRRITITATION, INSOMNIA AND I ALSO GOT PREGNANT AFTER BEING ON THIS.

(B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037185	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 7/2/2007	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE CALLED ESSURE ON (B)(6), 2006. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 50918. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINTS STARTED IN 2007. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE.. PELVIC PAIN, LOWER BACK AND THIGH PAIN, WEIGHT GAIN, INSOMNIA, THYROID, VIT D, SWELLING FEET AND ANKLES, MUSCLE SPASMS, DENTAL ISSUES, BRAIN FOG, FORGETFULNESS, BLURRED VISION, UNEXPLAINED BRUISES, HEART PALPITATIONS, HAIR LOSS, DRY SKIN, SEVERE BLOATING, HEARTBURN, GALLBLADDER REMOVED AND HYSTERECTOMY. I HAVE BEEN SEEN BY DOCTORS AND HAD THE HYSTERECTOMY DUE TO ESSURE. THE DEVICE WAS REMOVED ON (B)(6), 2014 AND WAS NOT RETURNED TO THE MANUFACTURER. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037186	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 12/1/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SERIOUS WEIGHT GAIN , FATIGUE, STARTED MIGRAINES, DIAGNOSED WITH HYPOTHYROIDISM, HAIR LOSS, SHARP PAINS IN GROIN AT TIMES, ACNE, HAIR GROWTH IN AREAS NOT WANTED, HOT FLASHES, UNCONTROLLABLE SWEATING AT TIMES, CAN NO LONGER TOLERATE HEAT, DIZZINESS, MOODINESS, SWELLING ALL OVER, BLOATED BELLY, TENDER LOWER LEGS, EASILY BRUISE, UNDER ARM ODOR CHANGE, CHEST PAIN IN PAST, ALLERGIES STARTED. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037187	BAYER	7/10/2014	7/11/2014

Event Information:

Event Date (B3): 2/1/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

FIRST SYMPTOMS SHOWED UP VERY SHORTLY AFTER IMPLANTATION: HAIR LOSS BY THE HANDFULS, BLOATEDNESS, WEIGHT GAIN THAT WILL NOT GO AWAY, ITCHY SKIN, TATTOOS GET RAISED AND ITCHY, USED TO HAVE NO BLEEDING (JUST SPOTTING) WITH PERIODS DUE TO A PREVIOUS ABLATION, NOW I BLEED FOR 2-3 DAYS, HORRIBLE CRAMPING WITH PERIODS, MY PERIOD USED TO BE PREDICTABLY EVERY 28 DAYS NOW IT IS ANYWHERE FROM 21-24 DAYS APART AND THE PMS IS VERY INTENSE, RIGHT SIDED PELVIC PAIN RIGHT HIP PAIN, SOMETIMES I GET RANDOM HIVES AND RASHES AFTER EATING OR DRINKING EVEN WHEN IT IS SOMETHING I REGULARLY CONSUME. I HAVE DEEP ACNE THAT IS PAINFUL AND DOESN'T COME TO A HEAD ON MY FACE, NECK, AND BUTTOCKS THAT TAKE WEEKS TO GO AWAY, I HAVE HAIR GROWING IN NEW AND ODD PLACES AND LASER HAIR REMOVAL ISN'T REMOVING HAIR EVEN AFTER 20 TREATMENTS! I HAVE GAINED OVER 40 POUNDS ALL IN MY BELLY WHICH IS NOT NORMALLY HOW I GAIN THAT I CAN NOT LOOSE DESPITE WORKING OUT 6 DAYS A WEEK AND WATCHING WHAT I EAT. MY ANKLES AND FEET SWELL UP AND NEVER HAD BEFORE THIS. I HAD LASIK A FEW MONTHS AFTER MY ESSURE AND NOW I AM GETTING TIMES WHEN MY VISION BLURRY LIKE MY EYES ARE GREASY AND IT COMES AND GOES. LOTS OF FLOATERS AND A RECENT INCREASE IN THE NUMBER OF MIGRAINES I AM GETTING. SOME PAPS SHOW ASCUS AND SOME ARE NORMAL BUT MY LAST EXAM SHOWED AN ABNORMAL GROWTH AND SHE RECOMMENDED A COLPOSCOPY BECAUSE HE HAD NEVER SEEN ANYTHING LIKE IT (THAT PAP CAME BACK NORMAL AFTER THE ON 6 MONTHS BEFORE CAME BACK ASCUS). MY BREAST GET SO TENDER I HAVE TO SLEEP WITH A BRA ON AND THEY HURT TO THE POINT OF TEARS WHEN I TAKE IT OFF TO SHOWER (THIS LASTS FOR ABOUT A WEEK RIGHT AROUND PERIOD TIME ALTHOUGH THEY ARE TENDER ALL OF THE TIME JUST NOT TO THIS EXTENT). I GET GENERAL BODY ACHES, MILD NAUSEA, DIZZINESS FOR NO REASON, AND FATIGUE FAIRLY FREQUENTLY WITH MOOD SWINGS AND DEPRESSION. MY RIGHT EAR

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HAS BEEN RINGING LOW GRADE SINCE AFTER I HAD THE ESSURE PUT IN AND OCCASIONALLY I GET TINGLING SPOTS ON THE BOTTOM OF MY FEET. I HAVE NEVER HAD HIGH BLOOD PRESSURE BEFORE BUT FOR THE LAST THREE YEARS IT HAS BEEN HIGHER THAN NORMAL. IN THE LAST FEW MONTHS, MY FINGER JOINTS HAVE STARTED SWELLING AND ACHING PAINFUL. ESPECIALLY THE RING AND THUMB FINGERS OF MY RIGHT HAND. I AM ONLY (B)(6) AND HAVE HAD THIS SINCE EARLY 2010. I REGRET MY DECISION TO HAVE THIS DONE. RECENTLY I HEARD THE DOCTOR WAS SUPPOSED TO DO A NICKEL TEST PRIOR TO IMPLANT. THAT NEVER HAPPENED AND I CAN'T WEAR NICKEL JEWELRY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037249	CONCEPTIS, INC.	7/10/2014	7/16/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/12/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I REQUIRED SEVERAL TRIPS TO EMERGENCY ROOM FOR INTENSE HIP AND LOWER ABDOMINAL PAIN. BLEEDING SO HEAVY DURING CYCLE, I HAVE TO TAKE EXTRA IRON PILLS AND HAVE EXTREME CRAMPING AND BACK PAIN THAT OTC MEDS DON'T HELP. SEVERE MIGRAINES LASTING SEVERAL DAYS. PASS VERY LARGE BLOOD CLOTS DURING CYCLE. DEPRESSION AND MOOD SWINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037258	CONCEPTUS/BAYER	7/10/2014	7/16/2014

Event Information:

Event Date (B3): 10/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE PROCEDURE WAS RECOMMENDED BY MY OBGYN SINCE IT WAS MINIMALLY INVASIVE SO I HAD IT DONE IN THE FALL OF 2011. I WAS UNAWARE THE IMPLANT CONTAINED NICKEL OR IF AN ALLERGIC REACTION POSED A RISK. I'VE BEEN THROUGH A SERIES OF MEDICAL TESTING DUE TO PROGRESSIVE SYMPTOMS (NAUSEA, PAIN, CHRONIC FATIGUE, HEADACHES, DIZZINESS, TINNITUS, UTIS, ETC.) WITHOUT AN AFFIRMATIVE DIAGNOSIS. THE MAIN VARIABLE PRIOR TO THE START OF MY SYMPTOMS WAS THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037259	CONCEPTUS/BAYER	7/10/2014	7/16/2014

Event Information:

Event Date (B3): 9/18/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4): 641436 / 12401848

Single Use:
Implant Date (E6): 9/8/2009
Explant Date (E7): 7/4/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN 2009. OVER THE LAST 5 YEARS MY HEALTH HAS DECLINED STEADILY. IT STARTED WITH WEIGHT GAIN, PERIODS EVERY 11 TO 14 DAYS THAT WOULD LAST FOR 5 TO SEVEN DAYS EACH AND PELVIC PAIN AND PULLING IN LOWER PELVIC REGION. OVER TIME, I DEVELOPED A HIP PROBLEM THAT CAUSED GREAT DISCOMFORT AND PAIN. I EXPERIENCED ENLARGED LYMPH NODES ON MANY OCCASIONS AND CAUGHT EVERY VIRUS AND BUG THAT WAS AROUND. I HAVE BEEN SICK CONSTANTLY SINCE BEING IMPLANTED. I DEVELOPED ANXIETY AND I FELT AS IF MY BODY WAS NEVER ABLE TO RELAX. FATIGUE BECAME A PROBLEM IN THAT I WOULD TIRE EASILY AND I JUST WASN'T FEELING RIGHT OR WELL. I ALSO BEGAN TO SUFFER FROM WHAT I WOULD CONSIDER MIGRAINE HEADACHES IN WHICH I WOULD SEE AURAS, LIGHTENING FLASHES, BLACK SPOTS, FLOATER AND WOULD LOSE VISION ALONG WITH HAVING TO BE IN DUE TO THE TERRIBLE HEAD PAIN. I WOULD EXPERIENCE STRANGE MOMENTS OF HAND AND FEET ITCHING, REDNESS AND SWELLING. ALSO HAD THE FEELING THAT MY TEETH WERE BEING STRIPPED OF NUTRIENTS. I WOULD HAVE A HORRIBLE METALLIC TASTE IN MY MOUTH WHEN MY TEETH HURT. IN THE YEAR 2013-2014 MY HEALTH GREATLY DECLINED. I WAS SICK NONSTOP, I WAS BEGINNING TO HAVE TROUBLE WITH MEMORY AND WOULD INCREASINGLY CALL PEOPLE BY THE WRONG NAMES (INCLUDING MY OWN 3 CHILDREN AND HUSBAND). FATIGUE BEGAN TO BECOME UNBEARABLE IN WHICH I NO LONGER FELT I COULD KEEP UP WITH MY NORMAL LIFE, SCHEDULE AND MISSED MANY EVENTS AND FUNCTIONS. IT TOOK EVERYTHING I HAD TO MAKE IT THROUGH A WORK DAY. MY BELLY WAS OUT OF CONTROL. I HAVE ALWAYS BEEN A FIT PERSON AND I WAS FRUSTRATED AND STRUGGLING TO FIGURE OUT WHY MY STOMACH WOULD BE PRETTY FLAT ONE MOMENT AND OUT OF NO WHERE I WOULD EXPAND TO LOOK LIKE I WAS 8 MONTHS PREGNANT. THEN DEVASTATION AND DESPERATION TOOK PLACE WHEN MY BODY BEGAN TO BREAK DOWN AND THERE WAS NOTHING I OR ANYONE COULD DO ABOUT IT. I

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BEGAN TO SUFFER FROM HORRIBLE JOINT PAIN THROUGHOUT MY BODY. I HAD MUSCLE ACHES AND SPASMS ALONG WITH TREMORS. HAND AND FEET TINGLING ALONG WITH NUMBING AT TIMES. DIZZINESS AND LIGHT HEADED. SHOOTING PAINS THROUGHOUT BODY. HAIR BEGAN TO FALL OUT MORE THAN NORMAL. IT WOULD FILL A COMB EVERY MORNING. WEIRD RASHES ON MY BODY. HEAVY PERIODS. MY MEMORY PROBLEMS BEGAN TO GET WORSE AND I BEGAN TO HAVE SPEECH ISSUES. I AM A TEACHER AND MY STUDENTS AND COWORKERS BEGAN TO WORRY ABOUT ME AS I WAS DETERIORATING EVERYDAY WITH SPEECH, MEMORY, OVERALL HEALTH AND MY ABILITY TO WALK. I COLLAPSED AT WORK AND WAS NOT ABLE TO RETURN TO WORK DUE TO MY WORSENING HEALTH. I BEGAN WALKING WITH A GAIT AND WAS UNABLE TO DO NORMAL TASKS AT WORK DUE OR AT HOME WITH MY FAMILY. MENTALLY AND PHYSICAL I WAS COMPLETELY BROKEN. I'VE BEEN TO MANY DOCTORS, AND SPECIALIST, HAD MANY BLOOD TEST, SCANS. I HAD NONE OF THIS BEFORE GETTING ESSURE. I'VE BEEN A HEALTHY HARD WORKING WIFE, MOM, AND TEACH MOST OF MY LIFE BUT EVER SINCE IMPLANTING ESSURE I HAVE HAD A STEADY DECLINE IN MY HEALTH AND WELL BEING. AFTER SPEAKING TO MANY DOCTORS WE DETERMINED THAT I WAS EXPERIENCING INFLAMMATION OF MY NERVOUS SYSTEM. WE JUST DIDN'T KNOW WHY. WE THEN BEGAN LOOKING AT THE ONE FOREIGN THING IN MY BODY ESSURE IMPLANTS. AFTER EXAM WITH GYN DOCTOR WE DECIDED TO GO TROUGH WITH A HYSTERECTOMY DUE TO PELVIC PAIN, 2 PERIODS A MONTH, HEAVY PERIODS AND IN HOPES THAT WE COULD ALSO RID MYSELF OF THE METAL COILS TO SEE IF WE COULD SEE IMPROVEMENTS WITH ALL AROUND HEALTH. I AM 5 DAYS OUT OF SURGERY. IMPROVEMENTS BEING SEEN ALREADY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00263	BAYER HEALTHCARE LLC	7/10/2014	7/25/2014

Event Information:

Event Date (B3): 4/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50700145

Single Use: Y
Implant Date (E6): 4/8/2013
Explant Date (E7): 10/2/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA (B)(4) IN UNITED STATES ON (B)(4) 2013 REFERRING TO HERSELF. SHE IS A FEMALE CONSUMER OR UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LIKE ICE FIRE RUSHING THROUGH RIGHT SIDE EXCRUCIATING, LEFT SIDE VERY UNCOMFORTABLE, NOT THE SPOTTING THEY PREP YOU FOR BUT BLEEDING, CRAMPING, PINCHING STABBING PAIN ON MY RIGHT SIDE, VERY DULL BACK PAIN DOWN MY SPINE THAT IS CONSTANT, AND SEVERLY DEPRESSED. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS UNKNOWN WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, WITH LOT NUMBER 50700145. CONSUMER REPORTED THAT AFTER 3 CHILDREN, THREE SHORT MONTH AFTER DELIVERY IN 2013, SHE WENT TO HER GYNECOLOGIST WHO SOLD HER ON THIS BRAND NEW DEVICE ESSURE; NO SURGERY, VIRTUALLY NO PAIN AND WE WOULD BE IN AND OUT WITHIN 15-20 MINUTES. FOR MONTHS, CONSUMER DID COUNTLESS HOURS OF RESEARCH LOOKING FOR THE BAD ESSURE AND SHE COULD NOT FIND ANYTHING. SINCE IN THE SMALL OFFICE PROCEDURE ROOM SHE WAS LAID ON THE TABLE AND DOCTOR SAID ALL RIGHT LET'S BEGIN. AT TIME OF THE ESSURE INSERTION DOCTOR SAID TO THE CONSUMER THAT HER UTERUS WAS TILTED, AND SHE FELT A HORRIFIC PINCH, BUT AND STING HE HAD TO CLAMP HER CERVIX OPEN AND TILT HER UTERUS UP. CONSUMER TOOK 2 MOTRIN'S BEFORE THE VISIT BECAUSE SHE WAS TOLD IT WAS JUST SOME CRAMPING AND SHE WAS NOT PREPPED FOR WHAT CAME NEXT HE INSERTED THE CAMERA AND TOLD IT WAS JUST SOME CRAMPING AND SHE WS NOT PREPPED FOR WHAT CAME NEXT HE INSERTED THE CAMERA AND THE ESSURE PLACEMENT DEVICE AND SHE SCREAMED SO LOUDLY THAT HER HUSBAND WHO WAS IN THE WAITING ROOM ACROSS THE DOCTOR'S OFFICE COULD HEAR HER. SHE FELT LIKE A MILLION KNIVES STABBING

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HER OVER AND OVER LIKE ICE FIRE RUSHING THROUGH HER RIGHT SIDE. EXCRUCIATING. THE LEFT SIDE WAS A LITTLE BREEZIER NOT NEAR AS MUCH PAIN STILL VERY UNCOMFORTABLE. CONSUMER ALSO REPORTED THAT AFTER FINISHING THE ESSURE PROCEDURE INSERTION SHE IMMEDIATELY START BLEEDING NOT HT SPOTTING THEY PREP HER FOR BUT BLEEDING. NEXT FEW DAYS, SHE WAS CRAMPING AND REALLY SORE AND HAVING TO TAKE TYLENOL AND MOTRIN TOGETHER EVERY 30 TO 45 MINUTES. ON AN UNSPECIFIED DATE THE CONSUMER WAS STILL BLEEDING LIKE A PERIOD AND IT HAS NOT STOPPED AND EVERY TIME SHE MOVED SHE FELT A PINCHING STABBING PAIN ON HER RIGHT SIDE. CONSUMER ALSO HAS NOTICED A VERY DULL BACK PAIN DOWN HER SPINE THAT WAS CONSTANT NEVER LETTING UP AND SHE CALLED HER DOCTOR. THE NURSES ALWAYS TOLD HER THAT THE PAIN AND BLEEDING WERE NORMAL AND SHE WOULD GO BACK TO BEING HER IN A COUPLE OF WEEKS. CONSUMER WAS EITHER AT WORK OR HOME CURLED IN A BALL ON HER BED. CONSUMER DID NOT HAVE THE ENERGY, AND DID NOT HAVE THE STRENGTH, AND SHE HAS NOT STOPPED BLEEDING. SHE HAS LOT ALL SENSE OF HAPPINESS AND SEVERELY DEPRESSED, WHERE AS JUST A MONTH BEFORE SHE WAS OUTSIDE PLAYING WITH HER CHILDREN ENJOYING LIFE. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS NOT REPORTED.

Manufacturer Narrative (H10):

FOLLOW-UP ON (B)(4): THE INCIDENT CATEGORY WAS CHANGED FROM INCIDENT TO NON-INCIDENT FOLLOWING COMPANY REVIEW. INTERNAL CORRECTION ON NARRATIVE FROM F/U (B)(4) 2013: THE CASE WAS MAINTAINED AS INCIDENT UNTIL FURTHER FOLLOW-UP INFORMATION. FOLLOW-UP RECEIV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00267	BAYER HEALTHCARE LLC	7/10/2014	7/25/2014

Event Information:

Event Date (B3): 2/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ES305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2010
Explant Date (E7): 10/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATOR AUTHORITY (CASE# MW5029557) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. ON (B)(6) 2010 SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE STATED THAT SHE EXPERIENCED MANY ADVERSE REACTIONS SINCE THE DATE OF IMPLANT INCLUDING SEVERE PAIN, UTI'S, PELVIC PAIN, FEVERS, DIARRHEA, VOMITING, RASHES, NEPHROPATHY, HIGH BLOOD PRESSURE, WEIGHT GAIN, STREP THROAT, SEVERE INFECTION, CONSTANT MIGRAINES AND FIBROMYALGIA. SHE SAID SHE WAS NEVER TOLD THAT A HYSTERECTOMY WAS THE ONLY WAY OF REMOVAL OF THE DEVICE. SHE SAID SHE WAS IN PAIN MEDICATION AND ALSO HAD TO GO TO PAIN MANAGEMENT AND EXPERIENCED SEVERE ARTHRITIS. A PARTIAL HYSTERECTOMY WAS DONE IN 2012, WHICH REMOVED THE DEVICE AND SHE INSTANTLY FELT A LOT BETTER. SHE STATED THAT SINCE THE REMOVAL OF THE DEVICE, HER PAIN HAS DRASTICALLY IMPROVED AND HER BLOOD PRESSURE HAS GONE BACK DOWN. SHE WAS EXTREMELY UNHAPPY WITH DEVICE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REF NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIESES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE

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NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFO NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFO THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDE "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NOT MEDICALLY-CONFIRMED, SPONTANEOUS CASE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN, UTI'S AND STREP THROAT. THE REPORTED EVENTS WERE CONSIDERED SERIOUS, AS MEDICALLY SIGNIFICANT; THE FIRST IS LISTED WHILE THE REMAINING EVENTS ARE UNLISTED ACCORDING TO THE REF SAFETY INFO FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL, PELVIC, AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS PARTICULAR CASE, THE CONSUMER STATED THAT SHE EXPERIENCED SEVERE PAIN SINCE ESSURE INSERTION; WHICH IMPROVED AFTER THE DEVICE REMOVAL BY PARTIAL HYSTERECTOMY. ALTHOUGH THE REASON FOR THIS SURGICAL PROCEDURE WAS NOT PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED, AND DUE TO THE SURGICAL INTERVENTION IT WAS REGARDED AS IN INCIDENT. UTI PATHOGENESIS IN WOMEN BEGINS WITH COLONIZATION OF THE VAGINAL INTROITUS BY UROPATHOGENS FROM THE FECAL FLORA, FOLLOWED BY ASCENSION VIA THE URETHRA INTO THE BLADDER. IN THIS PARTICULAR CASE THE CONSUMER REPORTED UTI'S, NO FURTHER INFO WAS PROVIDED, GIVEN THE LIMITED DATA, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE CANNOT BE ASSESSED BY NOW, AND IT WAS THUS, REGARDED AS NON-INCIDENT. CONCERNING STREP THROAT (STREPTOCOCCAL SORE THROAT), IT IS A CONTAGIOUS INFECTION, WHICH SPREADS THROUGH CLOSE CONTACT WITH AN INFECTED INDIVIDUAL. GIVEN THIS INFO AND CONSIDERING ESSURE LOCAL ACTION AT FALLOPIAN TUBES, THE REPORTED EVENT WAS CONSIDERED AS UNRELATED TO ESSURE AND THUS NON-INCIDENT. IN ADDITION, THE NON-SERIOUS EVENTS PELVIC PAIN, DIARRHEA, VOMITING, RASHES, NEPHROPATHY, HIGH BLOOD PRESSURE, WEIGHT GAIN, SEVERE INFECTION, CONSTANT MIGRAINES, FIBROMYALGIA, AND SEVERE ARTHRITIS WERE REPORTED. NO FURTHER INFO IS EXPECTED (NO CONTACT INFO PROVIDED). ACCORDING TO THE PTC INVESTIGATION RESULT, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-AUG-2015: CONSUMER REPORTED NOW THAT ESSURE WAS INSERTED ON (B)(6) 2010 AND REMOVED ON (B)(6) 2012 (DISCREPANT WITH INFORMATION INITIALLY PROVIDED). COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00268	BAYER HEALTHCARE LLC	7/10/2014	7/25/2014

Event Information:

Event Date (B3): 6/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE HAD PERFORATED HER BOWEL. PHYSICIAN STATED THAT ON (B)(6) 2014 THE PT WENT TO THE MED CTR AND HAD SURGERY BECAUSE THE ESSURE HAD PERFORATED HER BOWEL. NO FURTHER INFO WAS PROVIDED. FOLLOW UP INFO FROM (B)(6) 2014: NO FURTHER INFO WAS PROVIDED. FOLLOW-UP INFO WAS RECEIVED ON (B)(6) 2014. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THE NAME OF THE PHYSICIAN WHO IS TAKING CARE OF THE PT WHO HAD SURGERY PERFORMED BY ANOTHER DOCTOR WAS PROVIDED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REF NUMBER FOR THE PT REPORTS IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENT IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFO NEITHER THE TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00269	BAYER HEALTHCARE LLC	7/10/2014	7/25/2014

Event Information:

Event Date (B3): 2/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRCEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/12/2014
Explant Date (E7): 3/7/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((CASE# MW5036144) IN UNITED STATES ON 06/13/2014, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED FOLLOWING EVENTS. ON (B)(6) 2104, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AT UNK INSERTED WITHOUT HER CONSENT. DOCTOR WAS SUPPOSED TO DO A TRADITIONAL TUBAL, AND SHE WOKE UP WITH COILS. FROM THE MOMENT SHE WOKE UP FROM PLACEMENT, SHE HAD A MIGRAINE, BLOATING, CRAMPING, BLEEDING, DEPRESSION, HAIR LOSS, AND HER LEFT LEG FROM THE HIP TO ANKLE ACHED FOR 2 WEEKS. ON (B)(6) 2014, SHE HAD HER TUBES AND COILS REMOVED VIA DAVINCI. AFTER REMOVAL, ALL THE SYMPTOMS DISAPPEARED EXCEPT HER HAIR LOSS. DISABILITY OR PERMANENT DAMAGE WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE IS RELATED.

Manufacturer Narrative (H10):

FOLLOW-UP INFO RECEIVED ON 06/16/2014: GLOBAL PTC NUMBER ADDED AS (B)(4). FOLLOW UP INFO RECEIVED ON 06/18/2014 FROM A (B)(6) FEMALE CONSUMER: IN (B)(6) 2014 PATIENT HAD ESSURE INSERTED. SHE STATED THAT WENT IN FOR A TUBAL LIGATION, SIGNED THE CONSENT FOR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00271	BAYER HEALTHCARE	7/10/2014	7/25/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SOLICITED CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(4) 2014 VIA (B)(4). THE REPORT REFERS TO REPORTER'S BABY, (B)(6) . IT WAS REPORTED THAT THE REPORTING CONSUMER HAD ESSURE INSERTED FOR BIRTH CONTROL AND IT FAILED. THE CONSUMER HAS A (B)(6). NO FURTHER IN FORMATION WAS PROVIDED. (B)(4). FOLLOW UP INFORMATION FROM (B)(4) 2014: NO FURTHER FOLLOW UP WILL BE ATTEMPTED FOR THIS CASE .

Manufacturer Narrative (H10):

FOLLOW UP (B)(4) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPEC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00272	BAYER HEALTHCARE LLC	7/10/2014	7/25/2014

Event Information:

Event Date (B3): 6/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97492

Single Use: Y
Implant Date (E6): 6/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A SURGERY CENTER IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. ESSURE WAS INSERTED ON (B)(6) 2014 FOR STERILIZATION 2: (LOT NUMBER WAS B97492). SURGERY CENTER CALLED TO REQUEST REPLACEMENT FOR ONE ESSURE DEVICE AND REPORTED THAT ESSURE DEVICE COMPLETELY UNCOILED INSIDE THE RIGHT FALLOPIAN TUBE. THE SURGEON REMOVED THE RIGHT FALLOPIAN TUBE AND THEY HAD THE DEVICE AVAILABLE FOR RETURN. THE LEFT INSERTION WAS FINE. PATIENT WAS ASLEEP .

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC) . (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00274	BAYER HEALTHCARE LLC	7/10/2014	7/25/2014

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/26/2009
Explant Date (E7): 8/31/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA (B)(4) IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED THE FOLLOWING EVENTS. ON (B)(6) 2009, ESSURE WAS INSERTED FOR CONTRACEPTION. CONSUMER REPORTED THAT AFTER THE IMPLANT OF ESSURE SHE STARTED TO EXPERIENCE ENORMOUS AMOUNTS OF INFLAMMATION, WHICH CAUSED EXTREME PAIN. SHE COMPLAINED TO HER PHYSICIAN NUMEROUS TIMES AND SHE PUT HER ON NON-INFLAMMATORY. THE PAIN CONTINUED THE WHOLE TIME HAD THE ESSURE INSIDE HER. THEN, SHE REPORTED, THAT SHE STARTED HAVING HUGE CYSTS ON HER OVARIES; SHE WAS DIAGNOSED BY ULTRASOUND. SHE WENT TO THE EMERGENCY ROOM FOR THE EXTREME PAIN OF CYST ON HER OVARY. ON (B)(6) 2011, SHE UNDERWENT A SURGERY TO REMOVE THE DEVICES; SHE ONLY KNEW THAT THEY WOULD REMOVE HER WHOLE TUBES OUT A LITTLE BEFORE THE SURGERY. CONSUMER STATED THAT PREVENTING HER FROM BEING A MOTHER AGAIN CRUSHED HER DREAMS AND HOPES AND LEFT HER FEELING LESS OF A WOMAN. CONSUMER ALSO STATED THAT SHE NEVER HAD THESE PROBLEMS BEFORE. SHE WAS DIAGNOSED WITH FIBROMYALGIA AND HAD TO DEAL WITH LEEP PROCEDURES SINCE ESSURE PLACEMENT.

Manufacturer Narrative (H10):

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FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2014: (B)(4). PTC INVESTIGATION RESULT WAS RECEIVED ON(B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00275	BAYER HEALTHCARE LLC	7/10/2014	7/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT IN UNITED STATES RECEIVED ON (B)(4) 2014 FROM TELEVISION CHANNEL WHO INTERVIEWED A CONSUMER WHO HAD ESSURE INSERTED AND THE REPORTER MENTIONED THE OCCURRENCE OF PREGNANCY, DEVICE BREAKAGE AND ESSURE COULD NOT BE REMOVED. INFORMATION WAS RECEIVED FROM THE REPORTER THAT ONE WOMAN GOT THE PROCEDURE, SHE ENDED UP GETTING PREGNANT. SHE COULDN'T HAVE IT REMOVED AND IN THE (B)(6) WEEK OF THE PREGNANCY, THE COIL BROKE. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2014: ANOTHER TELEVISION INTERVIEW WAS DONE AND IT WAS REPORTED THAT THE ONE WOMAN ENDED UP GETTING PREGNANT. SHE COULDN'T HAVE THE COIL REMOVED AND IN THE (B)(6) WEEK OF THE PREGNANCY ESSURE BROKE AND MIGRATED, PE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00270	BAYER HEALTHCARE LLC	7/10/2014	9/18/2014

Event Information:

Event Date (B3): 6/6/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C13144

Single Use: Y
Implant Date (E6): 6/6/2014
Explant Date (E7): 6/6/2014
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 8/5/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED THE FOLLOWING EVENTS. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014, PLACEMENT PROCEDURE OF ESSURE SYSTEM WAS UNDER LOCAL ANESTHESIA. THE OSTIUM WAS WELL VISIBLE. THE PLACEMENT WAS EASY. AT THE TIME TO RELEASE ESSURE SYSTEM, THE DELIVERY CATHETER WAS STILL LINKED TO THE ESSURE SYSTEM THAT WENT OUT OF THE FALLOPIAN TUBE WHICH REQUIRED REMOVING ALL THE SYSTEM. THIS WAS PERFORMED WITH DIFFICULTY . THE PATIENT EXPERIENCED SIGNIFICANT PAIN AND BLEEDING. DUE TO SIGNIFICANT PAIN AND BLEEDING, ANOTHER ESSURE SYSTEM WAS IMPOSSIBLE TO BE PLACED . THE OUTCOME OF THE EVENTS WAS UNKNOWN. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE WAS NOT REPORTED. FRENCH METHOD OF CAUSALITY: NOT APPLICABLE. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 07-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00273	BAYER HEALTHCARE LLC	7/10/2014	9/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B85129

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/30/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS LISTED BELOW . ANOMALY OCCURRED IN OPERATING BLOCK. IT WAS OBSERVED DURING INSERTION: THERE WAS NO IMPLANT RELEASE AND HANGING OF THE DELIVERY CATHETER IN HORN OSTIUM (WOUND). THERE WAS NO ANATOMIC REASON FOR THIS ANOMALY. IT WAS ON DELIVERY HANDLE, CATHETER AND IMPLANT . ANOMALY DESCRIPTION: INTRODUCTION OF CATHETER AND IMPLANT CLASSIC. AFTER THUMBWHEEL AND BUTTON MANIPULATION, THERE WAS NO IMPLANT RELEASE. IT WAS IMPOSSIBLE TO REMOVE CATHETER, IT REMAIN WEDGED IN HORN AND FINALLY BROKE IN THE HYSTEROSCOPE. CONDITIONS OF INSERTION WERE EXCELLENT. NEW ATTEMPT OF INSERTION WITH NEW KIT WAS WITHOUT DIFFICULT. INSERTION WAS BILATERAL WITH A NEW IMPLANT. NO FURTHER INFORMATION WAS PROVIDED. (B)(6) LOCAL DRUG SAFETY DEPARTMENT ASSESSED THE CAUSAL RELATIONSHIP WITH ESSURE AS NEAR INCIDENT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 22-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00266	BAYER HEALTHCARE LLC	7/10/2014	9/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B82475

Single Use: Y
Implant Date (E6): 6/11/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 AND EXPERIENCED THE ADVERSE EVENT LISTED BELOW . WHEN HEALTHCARE PROFESSIONAL REMOVED THE CATHETER FROM THE RIGHT, 5 OF THE OUTER COILS TORE AWAY FROM THE MICROINSERT. HCP REMOVED THE 5 COILS FROM THE UTERINE CAVITY. THEY COULD SEE THE PROXIMAL INNER COIL IN THE CORRECT LOCATION OF THE UTERO-TUBAL JUNCTION. SO IT WAS LEFT IN PLACE, AND WILL DO THE CONFIRMATION TEST IN 3 MONTHS. THE LEFT SIDE INSERTION WAS SUCCESSFUL. THE PT WAS FINE, NO DISCOMFORT, NO COMPLAINT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014: NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. SHE DENIED ANY RELEVANT MEDICAL HISTORY, CONCURRENT CONDITIONS, PREV

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037188	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 4/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HORRIBLE SIDE PAINS, WEIGHT PROBLEMS, PHYSICALLY DRAINED ALL THE TIME, TERRIBLE HEADACHES, ABNORMAL CLUMPS FALLING OUT OF BODY DURING MENSTRUAL CYCLE, SEVERE MOOD SWINGS, ABNORMAL PERIODS, I SWEAR ESSURE MAKES MY BODY BELIEVE IT IS PREGNANT AND I WILL MISS A MONTH AND I BLOW UP AND LOOK IT ALSO UNTIL MY MENSTRUAL CYCLE COMES. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037189	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 9/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABDOMINAL PAIN AND CRAMP, BACK PAIN, PREMENSTRUAL SYNDROME, HEADACHE, PELVIC LOWER ABDOMINAL PAIN, MENTAL CRAMP SEVERE, VAGINAL DISCHARGE AND INFECTIONS.. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037190	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 9/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2010 THAT I HAVE EXPERIENCED DUE TO ESSURE. SEVERE LOWER BACK PAIN-DAILY; MIGRAINES- 2-4 ON A WEEKLY BASIS; I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 731686. MY MODEL NUMBER IS (ESS305, ESS205) IF YOU KNOW IT. THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. EXCESSIVE PELVIC PAIN AND CRAMPING; SPOTTING A WEEK BEFORE MENSTRUAL CYCLE, 3 DAYS OF HEAVY BLEEDING/WITH CRAMPING FOLLOWED BY A WEEK OF LEAKING VAGINAL FLUID. VERY IRREGULAR MENSTRUAL CYCLE; DIARRHEA A WEEK PRIOR TO MENSTRUAL CYCLE; SWOLLEN ABDOMEN, SWOLLEN HANDS, AND FEET; EXCESSIVE CRAMPING POST SEXUAL INTERCOURSE; NUMBNESS IN LABIA; LOSS OF LIBIDO; EXTREME EMOTIONAL HIGHS AND LOWS; NIGHT SWEATS LOSS OF ENERGY; HAIR LOSS; I HAVE BEEN SEEN BY 2 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS DYSMENORRHEAL, SEVERE ABDOMINAL PAIN. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE HYSTERECTOMY SCHEDULED FOR (B)(6) 2014. THE DEVICE IS STILL INSIDE OF ME. THE LEFT COIL HAS MIGRATED THROUGH MY TUBE AND IS LODGED NEAR MY RIGHT KIDNEY. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037191	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 7/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACE (B)(6) 2012. I WANTED A BIRTH CONTROL METHOD THAT WAS PERMANENT, INEXPENSIVE, WITH A FAST HEALING TIME. INITIAL CRAMPING AND SPOTTING AT FIRST IS TO BE EXPECTED. I HAVE FELT PAIN EVER SINCE. I HAD SEVER PAIN AND NAUSEA AND MY APPENDIX WAS REMOVED (B)(6) 2012. I WAS TOLD THAT MY GALL BLADDER SHOULD REMOVED SOMETIME, I HAVE NOT HAD THIS COMPLETED YET. DUE TO POOR INSURANCE COVERAGE AND FINANCES. I HAD VERY SEVERE CRAMPING. MY "PERIODS" LAST FOR MONTHS. I HAVE BEEN PRESCRIBED HORMONES TO BALANCE MINE SINCE THEY HAVE BECOME VERY ABNORMAL. WAS GETTING DEPRESSED AND CRYING EASILY. SEX HURTS AND SEX DRIVE IS GONE. I AM (B)(6) AND THIN BUILD YET I HAVE GAINED WEIGHT AND HAVE A PROTRUDING BELLY THAT I NEVER HAVE HAD BEFORE. SUDDEN MOVEMENTS CAUSES A SHARP SHOOTING PAIN FROM THE LOWER QUADRANT OF MY MIDSECTION JUST INSIDE MY HIP BONES. THE PAIN RADIATES INTO MY LEGS. IT CAN BE BILATERAL OR ISOLATED TO RIGHT OR LEFT SIDE. I HAVE TRANSIENT PAIN IN MY LOWER BACK ALSO. I AM NOW ON HORMONE REPLACEMENT THERAPY GIVEN BY A NATUROPATHIC DOCTOR WHICH IS VERY EXPENSIVE. MY DOCTOR HAS REQUESTED I TRY THE HRT PRIOR TO HYSTERECTOMY TO LEVEL OUT HORMONES AND THEN DEAL WITH THE PAIN BY REMOVAL. I DON'T WANT TO HAVE A HYSTERECTOMY AT (B)(6) BUT SO FAR THAT WILL BE THE ONLY WAY TO DEAL WITH SEVERE PAIN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037192	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 2/1/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE EXPERIENCED HEADACHES AND PAIN IN MY STOMACH AREA AND NUMBNESS OF MY HANDS AND WEIGHT GAIN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037193	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 9/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT STARTED WITH PAIN RIGHT AFTER PLACEMENT THAT HAS NEVER WENT AWAY. SHARP STABBING PAIN IN BOTH SIDES OF MY PELVIC AREA. PAINFUL SEX, HIVES, HEADACHES, HEAVY PERIODS WITH LARGE BLOOD CLOTS AS WELL AS ON GOING BACK PAIN. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037194	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 7/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT HAS NOW BEEN A WEEK SINCE THE FEELING OF POSSIBLE PROLAPSE AND LEAKING. AS I AM WAITING FOR MY INSURANCE CARD, I CANNOT SEE A DOCTOR. I HAVE ALSO EXPERIENCED TWO OCCASIONS OF SUCH DEBILITATING PELVIC PAIN THAT LASTED ABOUT AN HOUR EACH OCCURRENCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037195	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING ACCOMPANIED BY HEAVY AND PAINFUL CRAMPING, ABNORMAL AND CONSISTENT BLOATING, WEIGHT GAIN, FATIGUE, ABNORMAL UTERINE ULTRASOUND RESULTING IN THICKENING OF UTERINE WALL (PENDING DATE FOR UTERINE BIOPSY), EXCESSIVE ACNE WHICH IVE NEVER HAD BEFORE, SPORADIC LOWER ABDOMINAL PAIN, AND VAGINAL DISCHARGE WITH NEGATIVE LAB RESULTS FOR INFECTION, BACK PAIN, DEPRESSION. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037196	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 12/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD BLOOD IN MY URINE, SWELLING IN STOMACH, IN LEGS, SCAR TISSUE, WEIGHT LOSS, DIZZINESS, BLACKOUT MOMENTS, CONSTANT BURNING IN VAG AREA, PANIC ATTACKS, NUMBNESS IN HANDS, BRAIN FOG, CHRONIC ABDOMINAL PAINS, METAL TASTE, HEADACHES, BACKACHES, MUSCLE PAIN, HAD VERY BAD PERIODS FOR WEEKS AT TIME, ALWAYS HURTING IN RIGHT SIDE, HAD OVARY CYST, HAD DNC SURGERY IN (B)(6) 2014, SCAR TISSUE, PELVIC INFLAMMATION. (B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037208	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 6/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CRAMPING. SHARP/STABBING PELVIC PAIN. UTERINE INFLAMMATION. ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING. BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP. CHRONIC PELVIC PAIN. NAUSEA. VOMITING. HEADACHES OR MIGRAINES. DIZZINESS. HIGH BLOOD PRESSURE. WEIGHT ISSUES (LOSS/ GAIN). KIDNEY INFECTION. (B)(6), 2011 IS THE DATE I WAS SENT HOME FROM A FIVE DAY HOSPITAL STAY AFTER IMPLANTATION OF ESSURE IN 2010. ABOVE IS THE ADVERSE EFFECTS I WAS EXPERIENCING AT THAT VISIT. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037221	BAYER	7/11/2014	7/11/2014

Event Information:

Event Date (B3): 9/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2013. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS A96184. LEFT SIDE WAS SAID TO BE DIFFICULT TO PUT IN. HAD A HSG ON (B)(6) 2013 TO CONFIRM TUBES WERE BLOCKED. LEFT TUBE WAS NOT BLOCKED AND COIL I WAS TOLD WAS NOT ANYWHERE TO BE SEEN FROM MY LEFT TUBE. I HAD A SECOND ATTEMPT TO PUT IN LEFT COIL ON (B)(6) 2012 THAT WAS UNSUCCESSFUL. LOT NUMBER WAS NEVER GIVE TO ME NOR PUT IN MY RECORDS. THIS DEVICE HAS A THREE YEAR SHELF LIFE. I HAVE THE EXPIRATION DATE OF FIRST COILS STATING 2/2016. I HOWEVER DO NOT HAVE INFORMATION ON THE SECOND SET OF COIL(S) FROM THE SECOND ATTEMPT. THE ONSET OF MY SIDE EFFECTS AND SYMPTOMS STARTED AROUND (B)(6) 2013. FIRST ATTEMPT AT COIL INSERTION LASTED AROUND 30MINUTES. NO PAIN DURING THAT EXAM. MY HSG CONFIRMATION TEST WAS A BIT MORE PAINFUL THAN A NORMAL PERIOD CRAMPING. MY SECOND ATTEMPT AT PUTTING THE COIL IN MY LEFT TUBE LASTED LONGER THAN 20 MINUTES. I WAS IN EXTREME PAIN. NO PAIN MEDS, LOCAL ECT WERE OFFERED EXCEPT FOR 800MG OF IBUPROFEN AND THAT WAS ONLY HALF WAY THROUGH THE PROCEDURE. PAIN WAS SO BAD I WAS IN TEARS. HAD ESSURE SALES PEOPLE IN ROOM WITH ME. PAIN WAS SO BAD THAT AFTERWARDS I COULD HARDLY WALK OUT OF THE CLINIC. PAIN CONTINUED TO WORSEN AFTER THAT ATTEMPT. I WAS BED BOUND DUE TO THE EXTREME PAIN. THIS IS A LIST OF SIDE EFFECTS AND SYMPTOMS I HAVE EXPERIENCED DUE TO ESSURE: BLEEDING/SPOTTING DURING AND AFTER INTERCOURSE; PAINFUL PERIODS; SEVERE BLOATING; ANXIETY/PANIC ATTACK INCREASE; SHARP AND STABBING PELVIC PAIN; DIZZINESS; ABDOMINAL SPASMS, TWITCHING AND FLUTTERING; BACK PAIN HAS WORSENED; INABILITY TO MAINTAIN BLOOD SUGARS HAS WORSENED; MIGRATED AND MISSING COILS; PID (PELVIC INFLAMMATORY DISEASE); WEIGHT GAIN; DEPRESSION/SUICIDAL THOUGHTS HAVE WORSENED;

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BLACK OUT AND FAINTING SPELLS; LONG MENSTRUAL CYCLES; SEXUAL DYSFUNCTION; BLEEDING BETWEEN PERIODS; DISCHARGE; YEAST INFECTIONS; CHRONIC PELVIC PAIN; FATIGUE AND LOSS OF ENERGY; FREQUENT URINATION; SKIN ACNE (CYSTS); EXCESSIVE SWEATING; UNEXPLAINED AND EASILY BRUISING; MOOD DISORDERS; INSOMNIA WORSENED; LOSS OF LIBIDO; PAINFUL INTERCOURSE; GASTROINTESTINAL ISSUES; NAUSEA; PELVIC PAIN AFTER INTERCOURSE. I HAVE BEEN SEEN BY THREE DIFFERENT DOCTORS TO SEE WHAT WAS CAUSING MY SYMPTOMS. MY REGULAR PHYSICIAN, MY OB AND A GASTROENTEROLOGIST. I WAS DIAGNOSED WITH PID ON (B)(6) 2014. STARTING IN (B)(6) 2013 MY DEPRESSION GOT EXTREMELY BAD TO THE POINT WHERE I WAS SUICIDAL. ANXIETY ATTACKS INCREASED TO WHERE I WAS PUT ON 10MG XANAX TWICE DAILY. IN (B)(6) 2013 I ALSO STARTED GAINING WEIGHT AT A FASTER RATE THAN NORMAL. I'VE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: ROBOTIC ASSISTED TOTAL LAPAROSCOPIC HYSTERECTOMY WITH BILATERAL SALPINGECTOMY ON (B)(6) 2014. THE DEVICE HAS BEEN REMOVED ON (B)(6) 2014. THE DEVICE AS FAR AS I KNOW WAS NOT RETURNED TO MANUFACTURER. (B)(4).

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE	7/11/2014	8/6/2014

Event Information:

Event Date (B3): 7/9/2014 **Report Date (B4): 7/11/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER DEPLOYMENT OF THE COILS INTO THE FALLOPIAN TUBE, THERE WAS A WIRE THAT REMAINED IN THE UTERINE CAVITY AND PROTRUDED OUT THE CERVIX. UPON TRYING TO REMOVE THE WIRE, THE PATIENT BEGAN TO HAVE INCREASED BLEEDING AND HER ABDOMEN BEGAN TO DISTEND. THE REPRESENTATIVE FROM THE COMPANY WAS CALLED. BLEEDING THEN OBSCURED THE HYSTEROSCOPIC FIELD. AN EXPLORATORY LAPAROSCOPY WAS PERFORMED TO RULE OUT TUBE RUPTURE OR OBVIOUS PERFORATION. A FILCHE CLIP TUBAL LIGATION WAS PERFORMED IN ORDER TO COMPLETE THE STERILIZATION. THE PATIENT HAD TO BE ADMITTED FOR OBSERVATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00265	BAYER HEALTHCARE LLC	7/11/2014	9/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2005
Explant Date (E7): 5/6/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5035904) IN UNITED STATES ON 06/02/2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE INSERTED ON (B)(6) 2005 AND PRESENTED THE FOLLOWING ADVERSE EVENTS. ON AN UNSPECIFIED DATE, SHE STARTED EXPERIENCING FATIGUE AND LOWER BACK/ HIP PAIN. BY 2010, ALSO HAVE CONSTANT, DAILY NAUSEA. AS OF THE TIME OF THIS REPORT, SHE HAS A SURGERY PLANNED TO REMOVE HER FALLOPIAN TUBES DUE TO THE PAIN AS WELL AS SEVERELY DILATED FALLOPIAN TUBE. THE BACK/ HIP PAIN AND FATIGUE IS SEVERE ENOUGH THAT IT AFFECTS HER ABILITY TO WORK APPROXIMATELY 1 OF EVERY 3 DAYS. SHE IS SUPPOSED TO WORK AT HER PART TIME JOB AND SHE HAS TO USE A WHEELCHAIR 3-5 DAYS A WEEK TO GET AROUND. CONSUMER ASSESSED OTHER MEDICALLY SIGNIFICANT AS SERIOUSNESS CRITERIA; HOWEVER, NO FURTHER INFO WAS PROVIDED.

Manufacturer Narrative (H10):

FOLLOW UP INFO RECEIVED ON 06/12/2014 FROM CONSUMER: PT'S MEDICAL HISTORY INCLUDED EPILEPSY AND SLEEP APNEA. IN 2006 (PREVIOUSLY REPORTED AS 2005), ESSURE WAS INSERTED. DEPO WAS USED AS BACK UP CONTRACEPTION. BEFORE THIS SHE HAD MIRENA AND IT DIDN'T WORK

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037291	ESSURE	7/14/2014	7/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EIGHT YEARS AGO, ESSURE WRECKED MY LIFE. I HAVE CONSTANT HEADACHES, BODY ACHES, HIP PAIN, AWFUL PERIODS WITH NASTY PAIN, RINGING IN EARS AND HUGE WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037300	ESSURE	7/14/2014	7/21/2014

Event Information:

Event Date (B3): 7/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/9/2013
Explant Date (E7): 1/9/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ABOUT 11 MONTHS AGO, I HAD A BIRTH CONTROL PROCEDURE (ESSURE). DR (B)(6) INFORMED ME THAT THE PROCEDURE WOULD BE SIMPLE WITH MINIMAL SIDE EFFECTS. I DECIDED TO HAVE THE PROCEDURE DONE. UNFORTUNATELY, FOR 11 MONTH I'VE HAD BACK AND PELVIC PAIN WHICH CONTINUES TO PLAQUE ME. MY DOCTORS HAVE MADE VARYING EFFORTS TO HELP ME, YET I STILL HAVE NO IDEA WHAT THE PROBLEM OR A DIAGNOSIS IS OR WHY I'M HAVING PAIN. AFTER THE PROCEDURE WAS COMPLETED, ALMOST IMMEDIATELY, I EXPERIENCED LOWER BACK PAIN. I CONTACTED THE NURSES, VIA PHONE WHO ASSURED ME THAT THE PAIN WOULD SUBSIDE. UNFORTUNATELY, THE PAIN DIDN'T GO AWAY. IT ONLY GOT WORSE. AFTER 2 MONTHS, THE BACK AND PELVIC PAIN BECAME SO EXTREME, I MISSED WORK DAYS AND TOOK PAIN MEDICATION DAILY. BY (B)(6) 2013, I VISITED OBGYN DR (B)(6); HE SUGGESTED REMOVING THE COILS (ESSURE) DEVICE. I AGREED. IN (B)(6) 2014, DR (B)(6) PERFORMED MY LAPAROSCOPIC SURGERY TO REMOVE THE DEVICE. THE SURGERY ALSO INCLUDED REMOVING MY FALLOPIAN TUBES. AFTER WEEKS OF RECOVERY AND TIME OFF WORK, I CONTINUED TO EXPERIENCE PELVIC AND BACK PAIN. I COMMUNICATED MY SYMPTOMS WITH SEVERAL DOCTORS, INCLUDING DR (B)(6) AND MY PRIMARY CARE PHYSICIAN, DR (B)(6) ON MANY OCCASIONS VIA E-MAIL, PHONE AND DOCTOR VISITS. WHILE I BELIEVE THE DOCTORS TRIED TO HELP WITH THE ISSUES, THERE ARE SOME KEY PROBLEMS. MY INITIAL OBGYN DOCTOR DR (B)(6), WHO COMPLETED THE ESSURE PROCEDURE WAS RELUCTANT TO DISCUSS MY CHRONIC PAIN. HE DISCUSSED THE LEGAL ISSUES WITH ESSURE AND THE "LAWYERS JUST WANTING MONEY." I THOUGH HIS STATEMENT WERE UNUSUAL, SINCE I DIDN'T INITIATE OR DISCUSS LEGAL ISSUES AT THE VISIT. HE CONTINUED TO BE UNPROFESSIONAL DURING THE VISIT, BY TELLING ME HE HAD A VASECTOMY. HE SAID IT CAUSED HIM SEVERE PAIN FOR A YEAR BUT EVENTUALLY THE PAIN WENT AWAY. HE IMPLIED THAT I SHOULD WAIT FOR THE PAIN TO SUBSIDE INSTEAD OF REMOVING THE COILS. HE EVENTUALLY

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SUGGESTED REMOVING THE ESSURE DEVICE AND OFFERED TO PERFORM THE PROCEDURE. AS A PT, I LOST TRUST IN HIS ABILITY TO COMPLETE THE PROCEDURE BECAUSE HE SEEMED MORE CONCERNED WITH ESSURE COMPLAINTS INSTEAD MY PT HEALTH. I DECIDED TO HAVE MY ORIGINAL OBGYN, DR (B)(6) REMOVE THE DEVICE. SHE WAS VERY HELPFUL WITH TRYING TO SET A TIME TO REMOVE THE DEVICE DUE TO MY PAIN. SADLY, MY SURGERY COULD NOT BE SCHEDULED UNTIL 1 MONTH LATER DUE TO (B)(6) BEING BOOKED FOR SURGERIES. AFTER DR (B)(6) COMPLETED THE SURGERY, I CONTINUED TO HAVE BACK AND PELVIC PAIN. DR (B)(6) TOLD ME THIS WAS NORMAL. AFTER 3 WEEKS OF CONTINUED PAIN, I CONTACTED DR (B)(6). SHE RELEASED ME TO WORK WITHOUT ADDRESSING MY PAIN ISSUES. I RECEIVED NO PAIN MANAGEMENT TREATMENT. I VISITED MY PRIMARY CARE DR (B)(6). SHE ADVISED ME TO ATTEND PHYSICAL THERAPY. I STARTED PHYSICAL THERAPY, AFTER SEVERAL SESSIONS YET MY PAIN CONTINUED. ALONG WITH THE PHYSICAL THERAPY, I COMPLETED PHYSICIAN ADVISED MASSAGE THERAPY, CHIROPRACTIC CARE, EPSON SALT BATHS, HEATING PADS AT WORK/HOME FOR SEVERAL MONTHS. AS A PT, I'M CONCERNED ABOUT MY HEALTH. I TRY TO BE PROACTIVE IN MY HEALTH. I WAS HEALTHY BEFORE THIS PROCESS BEGAN 11 MONTHS AGO. I TRIED TO FOLLOW THE DOCTORS' ORDERS. WHILE I RECOGNIZE THERE ARE NO GUARANTEES WITH MEDICAL PROCEDURES, MY CONCERNS ARE LISTED BELOW: I DO NOT BELIEVE MY DOCTORS AND MEDICAL STAFF HAVE COMMUNICATED WITH OTHERS EFFECTIVELY. I HAVE RECEIVED CONFLICTING ADVICE OR NO ANSWERS TO MY REQUEST. MY BACK AND SURROUNDING AREAS HAVE NOT RECEIVED A FULL EXAMINATION OR TEST BEFORE OR AFTER THE SURGERIES I'VE RECEIVED. I HAVE NOT RECEIVED PAIN MANAGEMENT TREATMENT. I DO NOT HAVE A DIAGNOSES OR REASON FOR THE CHRONIC PAIN. MY MOBILITY AND QUALITY OF LIFE ARE AFFECTED BY THIS CHRONIC PAIN. I HAVE NO REAL UNDERSTANDING OF WHAT OR WHY THIS PROBLEM PERSISTS. I CONTINUE TO TAKE TESTS, DO EVASIVE PROCEDURES, SPEND MONEY, AND MISS WORK TIME TO ADDRESS THIS ISSUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037485	BAXTER HEALTHCARE, LLC	7/14/2014	7/31/2014

Event Information:

Event Date (B3): 6/27/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): BAYER HEALTHCARE, LLC
Device Type (E2): ESSURE DEVICE
Model # (E4): ESS305
Catalog # (E4): 830
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANT WAS GETTING STUCK ON SHEATH OF HYSTEROSCOPE, BENDING THE IMPLANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037334	CONCEPTUS/BAYER	7/15/2014	7/23/2014

Event Information:

Event Date (B3): 5/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/3/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED IN (B)(6) 2010. CONFIRMED BLOCKED BY OB/GYN IN (B)(6) 2010. PREGNANCY CONFIRMED IN (B)(6) 2010. AFTER 3 D&C, I CONTINUED TO RETAIN TISSUE AND RECEIVE POSITIVE ON BLOOD AND URINE PREGNANCY TESTS. IN (B)(6) 2011, I WAS SUSPECTED TO HAVE AN INVASIVE MOLE (MOLAR PREGNANCY) AND REFERRED TO A GYN ONCOLOGIST. WATCHED CLOSELY BY ONCOLOGISTS AND GOT A SECOND OPINION AT THE MAYO CLINIC IN (B)(6) 2011. EVENTUALLY, IT CLEARED ON ITS OWN (NO NEED FOR HYSTERECTOMY, CHEMO, ETC) BUT CAUSED MUCH TURMOIL AND REGULAR CARE (MISSING WORK, INCURRING COSTS, ETC.) FOR OVER A YEAR. YEARS LATER NOW, MY PERIODS HAVE CHANGED AND COME MORE FREQUENTLY, I GET MORE FREQUENT UTI'S (BLOOD IS ALSO DETECTED IN MY URINE) AND YEAST INFECTIONS SO I TAKE ANTIBIOTICS PROPHYLACTICALLY, MY SKIN AND SCALP ARE DRY AND ITCHY, MY RIGHT LOWER LEG AND FOOT ARE TINGLY AND NUMB, AND I AM BLOATED IN MY STOMACH AREA SO I ALWAYS LOOK SLIGHTLY PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037319	BAYER HEALTHCARE U.S. HEADQUARTERS	7/15/2014	7/24/2014

Event Information:

Event Date (B3): 7/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL DEVICE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B93872

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE PERMANENT BIRTH CONTROL DEVICE FAILED TO DEPLOY. TWO DEVICES WERE IN THE BOX, ONE FAILED TO DEPLOY AND THE OTHER ONE WORKED. NO HARM TO THE PT. MFR: PLEASE NOTE THAT WE DO NOT SEND PRODUCTS TO THE MFR, BUT YOU MAY ARRANGE FOR PICK-UP BY CALLING (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037305	BAYER	7/16/2014	7/23/2014

Event Information:

Event Date (B3): 7/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAIR LOSS, RASH, LEG PAIN, BLOATING AND THE LIST GOES ON AND ON.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE	7/16/2014	8/5/2014

Event Information:

Event Date (B3): 6/23/2014 **Report Date (B4): 7/16/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B60749

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WAS FED INTO THE HYSTEROSCOPE AND THEN INTO THE LEFT TUBAL OSTIA UNTIL THE BLACK MARK WAS SEEN. THE BLACK MARK WAS FLUSHED WITH THE TUBAL OSTIA, THEN THE WHEEL WAS ROLLED BACK. HOWEVER, AT THE TIME OF DEPLOYING THE DEVICE, THERE WAS A MALFUNCTION AND THE DEVICE WAS NOT DEPLOYED. THE DEVICE AND SPRING WAS SLOWLY REMOVED WITH CONSTANT TENSION LEAVING NO RESIDUAL DEVICE IN THE PATIENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037309	BAYER	7/17/2014	7/23/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INVALID DATA	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4): A90483

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE A RASH ALL OVER MY BODY, WAS GIVEN ANTIBIOTICS AND THE RASH HASN'T IMPROVED, ABDOMINAL PAIN COMES AND GOES, AND TENSION HEADACHES, WENT TO EMERGENCY ROOM ONCE FOR A BOIL GROWING ON MY LOWER RIGHT ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037310	BAYER	7/17/2014	7/23/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/10/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN 2010 I WAS NOT TOLD OF ANY OF THE SIDE EFFECTS THAT I AM HAVING NOW. I HAVE MASSIVE PAIN THE LOWER LEFT SIDE OF MY ABDOMEN AREA. IT HAS SENT ME TO THE EMERGENCY ROOM MANY TIMES AND THE ONLY WAY THE DOCTORS COULD EVENT TALK TO ME WAS TO GIVE ME PAIN MEDS THROUGH IV. ALSO SINCE I HAVE HAD IT I GET THE WORST HEADACHES WHICH MAKE MY MOOD CHANGE BECAUSE OF THE PAIN. I HAVE TO GET PAIN MEDS FROM MY DOCTOR TO TAKE JUST TO KEEP ME OUT OF PAIN. HONESTLY MY MOODS ARE SO BAD DUE TO THE PAIN THAT I GET INTO MORE ARGUMENTS THAN EVER. MY FIANCÉ HAS HAD TO LEAVE WORK IN ORDER TO TAKE ME TO THE EMERGENCY ROOM BECAUSE OF THE PAIN AND NOT BEING ABLE TO WALK. I HAVE PAID OUT SO MUCH MONEY TO THE DOCTORS JUST BECAUSE I HAVE TO KEEP GOING BACK DUE TO THE PAIN THAT I AM HAVING THAT IN NEVER HAD UNTIL I GOT THE ESSURE PLACED. THIS I WOULD NOT RECOMMEND TO ANYONE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00290	BAYER HEALTHCARE LLC	7/17/2014	7/25/2014

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE,OCCLUSION,TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628441

Single Use: Y
Implant Date (E6): 11/24/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED THE FOLLOWING EVENTS. ESSURE DEVICES WERE INSERTED ON (B)(6)-2009; THE LOT NUMBER USED WAS 628441. CONSUMER REPORTED THAT ESSURE MIGRATED OUT OF HER FALLOPIAN TUBES ON BOTH SIDES. THE ESSURE OF LEFT SIDE WAS FOUND IN THE FATTY TISSUE OF THE ABDOMEN. ON (B)(6) 2013, SHE HAD A HYSTERECTOMY DONE BECAUSE OF PELVIC PAIN. THE LEFT COIL WAS DISCOVERED OUT OF PLACE BEFORE THE SURGERY. THE HYSTERECTOMY SHOWED ENDOMETRIOSIS AND VARICOSE VEINS ON HER UTERUS. AT THE TIME, THEY THOUGHT THAT THEY ALSO REMOVED THE RIGHT COIL. ON (B)(6)-2014, SHE WENT BACK TO HER PHYSICIAN DUE TO A BACK TROUBLE. AN X-RAY WAS DONE AND SHOWED A COIL IN THE UPPER QUADRANT, BY THE RIBS WHERE HER GALLBLADDER WAS. CONSUMER STATED THAT SHE WAS FEELING A ''PINCHING'' IN THE SIDE. CONSUMER ALSO REPORTED THAT IN 2012 SHE HAD HER GALLBLADDER REMOVED BECAUSE OF CONSTANT SIDE PAINS, AND IT SHOWED CHRONIC INFLAMMATION. SHE HAD A SCAN IN 2009 WHICH CAME UP AS ''FUNCTIONING''. NO FURTHER INFORMATION PROVIDED.

Manufacturer Narrative (H10):

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CORRECTION (B)(6)-2014 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT "CHRONIC INFLAMMATION OF GALLBLADDER" WAS RECODED TO MEDRA LLT "CHRONIC CHOLECYSTITIS". FOLLOW-UP FROM (B)(6)-2014: FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE. PTC

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00232	BAYER HEALTHCARE LLC	7/17/2014	7/28/2014

Event Information:

Event Date (B3): 5/9/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B82480

Single Use: Y
Implant Date (E6): 4/24/2014
Explant Date (E7): 5/15/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN, BLEEDING, AND RASH. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6)-2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B82480, FOR STERILIZATION. ON (B)(6)-2014, THE PATIENT SAW HER HEALTH CARE PROFESSIONAL FOR BLEEDING, ABDOMINAL PAIN, AND RASH. AN ULTRASOUND WAS DONE, RESULTS NOT REPORTED. ON (B)(6) 2014, ESSURE WAS REMOVED BILATERALLY AND BOTH FALLOPIAN TUBES. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN ABDOMINAL PAIN, BLEEDING, AND RASH AND ESSURE IS NOT REPORTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6)-2014: THIS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT. IT WAS REPORTED THAT PATIENT MEDICAL HISTORY INCLUDED A DELIVERY ON (B)(6)-2014. ESSURE, EXPIRATION DATE OCT-2016, WAS INSERTED 16 WEEKS POSTPARTUM. CERVICA

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00233	BAYER HEALTHCARE LLC	7/17/2014	7/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6) AND EXPERIENCED. STUDY DESCRIPTION: ESSURE GENERIC ACTIVE ONLINE LISTENING. NO INFO GIVEN ON CONSUMER MEDICAL HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED. NO LOT NUMBER AND EXPIRATION DATE WERE PROVIDED. PHYSICIAN REPORTED THAT CONSUMER HAD TO HAVE ESSURE REMOVED DUE TO CONFIRMED TITANIUM ALLERGY TO THE IMPLANTS. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENT AND ESSURE WAS POSSIBLY RELATED.

Manufacturer Narrative (H10):

COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONFIRMED TITANIUM ALLERGY TO THE IMPLANTS. CONFIRMED TITANIUM ALLERGY TO THE IMPLANTS WAS CONS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00234	BAYER HEALTHCARE LLC	7/17/2014	7/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT FROM A CONSUMER IN THE UNITED STATES WAS IDENTIFIED ON (B)(6) 2013 ON THE INTERNET PAGE OF A TV CHANNEL AFTER EMISSION. THE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE REPORTED SHE NEVER THOUGHT THAT SHE WOULD BE LOOKING AT A HYSTERECTOMY AT (B)(6). NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. CONSUMER STATED, SHE NEVER THOUGHT THAT SHE WOULD BE LOOKING AT A HYSTERECTOMY AT (B)(6). NO FURTHER DETAILS WERE REPORTED. IT WAS STATED CONSUMER BLAMES THE ESSURE PROCEDURE, A NON- SURGICAL, NON-HORMONAL FORM OF PERMANENT BIRTH CONTROL APPROVED BY THE FDA IN 2002.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 30-JUN-2014. NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 04 AUG 2014: CONSUMER REPORTED THAT HER PELVIC PAIN WAS GREATLY REDUCED SINCE HYSTERECTOMY. HER CHRONIC ILLNESS WAS STILL RAGING

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00235	BAYER HEALTHCARE LLC	7/17/2014	7/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ESSURE MICRO-INSERT THAT IS NOT IN THE UTERUS OR TUBE BUT EXPELLED INTO THE ABDOMEN. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ESSURE MICRO-INSERT WAS NOT IN THE UTERUS OR TUBE BUT EXPELLED INTO THE ABDOMEN. EVENT AND ESSURE TREATMENT WERE ONGOING. REPORTER CAUSALITY: THE RELATIONSHIP WAS NOT REPORTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. PATIENT'S INITIALS WERE PROVIDED. SHE WAS 6 WEEKS POSTPARTUM AT THE TIME OF ESSURE INSERTION. PARACERVICAL ANALGESIA WAS APPLIED DURING INSERTION. ESSURE INSERTION AND VISUALIZATION OF THE TUBAL OSTIUM WE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00238	BAYER HEALTHCARE LLC	7/17/2014	7/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 4/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(4)2014 . THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED BLEEDING, CRAMPING, AND FEELS SHE HAS A NICKEL ALLERGY. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. IN 2009, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. THE CONSUMER REPORTED SHE HAD EXPERIENCED SEVERE BLEEDING, CRAMPING, AND HAD BEEN TO THE ER (EMERGENCY ROOM). CONSUMER FEELS SHE HAS A NICKEL ALLERGY . SHE GETS GREEN COLOR WHEN SHE WEARS RINGS AND HER EAR LOBES GET ITCHES WITH CHEAP METALS . THE CONSUMER REPORTED HER DOCTOR SAID HE WOULD NOT REMOVE THE ESSURE AND CONSUMER WANTS TO HAVE THE COILS REMOVED WITHOUT HAVING A HYSTERECTOMY.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 31-JAN-2015: INFORMATION RECEIVED FROM CONSUMER STATES THAT DAMAGE TISSUE AND THE INFLAMMATION RESPONSE NEVER STOPS (FALLOPIAN TUBES AND LIVER). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00278	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/5/2011
Explant Date (E7): 4/8/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA HEALTH AUTHORITY FDA MAUDE (CASE# MW5036110) IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. CONSUMER REPORTED THAT ESSURE WAS INSERTED ON (B)(6) 2012 AND SHE UNDERWENT UTERINE DILATATION AND CURETTAGE AND ABLATION TO HELP RESOLVE PROBLEMS CAUSED BY ESSURE. SHE ALSO STATED THAT SHE WAS SURGICALLY DIAGNOSED WITH ENDOMETRIOSIS.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 29-AUG-2014. PHYSICIAN STATED THAT HE DID NOT PERFORM ESSURE INSERTION, HE DIDN'T FEEL THAT ANY OF CONSUMER'S SYMPTOMS WERE CAUSED BY THE DEVICE. HE DID PERFORM A HYSTERECTOMY AND FOUND PROPERLY PLACED DEVICES IN HER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00279	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/13/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. ON (B)(6) 2013 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. FORTY EIGHT HOURS AFTER THE PLACEMENT ((B)(6) 2013), THE PATIENT EXPERIENCED PAIN AND THEN RESOLVED. ONE MONTH LATER, ON (B)(6) 2014, SHE EXPERIENCED SIGNIFICANT PAIN. SMALL BOWEL OBSTRUCTION WAS DIAGNOSED. SURGERY WAS DONE AND OCCLUSIVE ADHESION WITH A METALLIC ASPECT AROUND SMALL BOWEL LOOP WITHOUT NECROSIS WAS NOTED.

Manufacturer Narrative (H10):

FOLLOW UP (B)(6) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPEC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00281	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRASEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 17-JUN-2014, ARTICLE ENTITLED "ESSURE AND CHRONIC PELVIC PAIN: A POPULATION-BASED COHORT". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE MICRO-INSERTS) INSERTED FOR HYSTEROSCOPIC STERILISATION AND EXPERIENCED MILD PROCEDURAL PAIN AND CHRONIC PELVIC PAIN. CASE REPORT: (B)(6) FEMALE PATIENT (CASE 1 FROM TABLE L) HAD STERILIZATION. THE SURGEON DESCRIBED THE PROCEDURE AS SATISFACTORY DEVICE PLACEMENT WITH 2 COILS IN RIGHT TUBE AND 3 COILS IN LEFT TUBE. PATIENT EXPERIENCED PROCEDURAL MILD VIA PAIN ASSESSMENT TOLERANCE. X-RAY WAS DONE AS A CONTROL TEST. CHRONIC PELVIC PAIN THAT STARTED IMMEDIATELY AFTER PLACEMENT INCREASED WITH TIME AND DID MICRO-INSERT REMOVAL. THE DEVICE WAS REMOVED BY LAPAROSCOPY, TIME BETWEEN MICRO-INSERT PLACEMENT AND REMOVAL WAS 22 MONTHS. THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR'S COMMENTS: THE PRESENT, VERY LARGE SAMPLE DEMONSTRATES THAT CHRONIC PELVIC PAIN IS A VERY RARE COMPLICATION WITH THE ESSURE SYSTEM. INDEED SIX OF THE SEVEN WOMEN REPORTED THAT THE ONSET OF SYMPTOMS STARTED IMMEDIATELY AFTER THE PROCEDURE AND DID NOT IMPROVE WITH THE INTAKE OF STANDARD ANALGESICS. IN THREE OF THESE PATIENTS, THE SURGEON DESCRIBED THE DEVICE PLACEMENT AS DIFFICULT, REQUIRING A HYSTEROSALPINGOGRAPHY AS A CONTROL TEST, SHOWING DEVICE OCCLUSION AS WELL AS DEVICE DISPOSAL. THIS FACT IS NOTEWORTHY, SINCE PELVIC PAIN MAY BE RELATED TO MALPOSITIONING OF A MICROINSERT. THREE OF THE SEVEN CASES DESCRIBED THE PAIN DURING THE PROCEDURE AS HIGH, WITH THIS PERCENTAGE BEING GREATER THAN THAT OBSERVED IN THE WHOLE COHORT. SERIES IS THE LARGEST TO DATE EVALUATING THE FEASIBILITY, SAFETY AND EFFECTIVENESS OF ESSURE HYSTEROSCOPIC STERILISATION, WITH THE INCIDENCE OF CHRONIC PP OBSERVED BEING EXTREMELY LOW. AUTHOR

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IDENTIFIED ALL WOMEN UNDERGOING THE PROCEDURE DURING THE STUDY PERIOD. THE CAUSES THAT MIGHT EXPLAIN CHRONIC PP IN WOMEN WITH ESSURE REMAIN UNKNOWN AND, CONSEQUENTLY, FURTHER STUDIES ARE WARRANTED. PUBLICATION ABSTRACT: THE AIM OF THIS STUDY WAS TO ASSESS THE INCIDENCE OF CHRONIC PELVIC PAIN IN WOMEN AFTER PLACEMENT OF ESSURE MICROINSERTS. THIS WAS A CASE SERIES STUDY AT THE HYSTEROSCOPY UNIT IN A TEACHING HOSPITAL. AUTHOR INCLUDED 4,274 PATIENTS UNDERGOING PERMANENT STERILIZATION WITH ESSURE MICROINSERTS FROM JANUARY 2005 TO DECEMBER 2011. ESSURE DEVICES WERE REMOVED IN ALL PATIENTS REPORTING PELVIC PAIN AFTER INSERTION. ALL DATA WERE COLLECTED FROM THE HYSTEROSCOPY UNIT DATABASE WITH LATER REVIEW OF MEDICAL RECORDS IN CASES OF CHRONIC PELVIC PAIN AND A TELEPHONE SURVEY AFTER MICROINSERT REMOVAL. MAIN OUTCOME MEASURES WERE: GRADE OF PROCEDURE DIFFICULTY PERCEIVED BY THE SURGEON; TOLERANCE DESCRIBED BY THE PATIENT AFTER PLACEMENT; THE NEED FOR ANALGESICS DURING OR IMMEDIATELY AFTER THE PROCEDURE; SIDE-EFFECTS; AVERAGE TIME BETWEEN DEVICE PLACEMENT AND THE ONSET OF SYMPTOMS; TIME BETWEEN DEVICE PLACEMENT AND REMOVAL; TECHNIQUE FOR DEVICE REMOVAL AND ANY SYMPTOMS THEREAFTER. A TOTAL OF SEVEN WOMEN (0.16%) PRESENTED WITH CHRONIC PELVIC PAIN REQUIRING MICROINSERT REMOVAL, WITH FOUR CLASSIFYING THE PAIN PERCEIVED DURING THE PROCEDURE AS MEDIUM HIGH. SIX PATIENTS DID NOT REQUIRE ANALGESICS AFTER THE PROCEDURE AND A VASOVAGAL SYNDROME REQUIRING ENDOVENOUS ANALGESIA AND MONITORING OCCURRED IN ONLY ONE CASE. SIX WOMEN REPORTED PAIN IMMEDIATELY AFTER THE PROCEDURE, WITH A MEAN TIME BETWEEN PLACEMENT AND REMOVAL OF 29.4 MONTHS. IN ALL CASES, THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR CONCLUDED THAT THE DEVELOPMENT OF CHRONIC PELVIC PAIN IS VERY UNCOMMON AFTER PLACEMENT OF ESSURE MICROINSERTS. REMOVAL OF THESE DEVICES USUALLY IMPROVES THE PAIN. OTHER CASES FROM THIS ARTICLE: 2014-092125, 2014-092126, 2014-092127, 2014-092128, 2014-092129, 2014-092130.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIG

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00282	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6)-2014, ARTICLE ENTITLED "ESSURE AND CHRONIC PELVIC PAIN: A POPULATION-BASED COHORT". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE MICRO-INSERTS) INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED MILD PROCEDURAL PAIN AND CHRONIC PELVIC PAIN. CASE REPORT: (B)(6) FEMALE PATIENT (CASE 2 FROM TABLE 1) HAD ESSURE MICRO-INSERT IMPLANTED FOR HYSTEROSCOPIC STERILIZATION. THE SURGEON DESCRIBED THE PROCEDURE AS LOW LEVEL OF DIFFICULTY. THE SURGEON REPORTED SATISFACTORY DEVICE PLACEMENT WITH 4 COILS IN RIGHT TUBAL AND 7 COILS IN LEFT TUBAL. PATIENT EXPERIENCED PROCEDURAL PAIN IMMEDIATELY AFTER PLACEMENT, IT WAS ASSESSED AS MILD VIA PAIN ASSESSMENT TOLERANCE. X-RAY WAS DONE AS A CONTROL TEST. CHRONIC PELVIC PAIN THAT STARTED IMMEDIATELY AFTER PLACEMENT INCREASED WITH TIME AND DID NOT DISAPPEAR USING STANDARD ANALGESIC DRUGS REQUIRING MICRO-INSERT REMOVAL. THE DEVICE WAS REMOVED BY LAPAROSCOPY, TIME BETWEEN MICRO INSERT PLACEMENT AND REMOVAL WAS 57 MONTHS. THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR'S COMMENTS: THE PRESENT, VERY LARGE SAMPLE DEMONSTRATES THAT CHRONIC PELVIC PAIN IS A VERY RARE COMPLICATION WITH THE ESSURE SYSTEM. INDEED SIX OF THE SEVEN WOMEN REPORTED THAT THE ONSET OF SYMPTOMS STARTED IMMEDIATELY AFTER THE PROCEDURE AND DID NOT IMPROVE WITH THE INTAKE OF STANDARD ANALGESICS. IN THREE OF THESE PATIENTS, THE SURGEON DESCRIBED THE DEVICE PLACEMENT AS DIFFICULT, REQUIRING A HYSTEROSALPINGOGRAPHY AS A CONTROL TEST, SHOWING DEVICE OCCLUSION AS WELL AS DEVICE DISPOSAL. THIS FACT IS NOTEWORTHY, SINCE PELVIC PAIN MAY BE RELATED TO MALPOSITIONING OF A MICROINSERT. THREE OF THE SEVEN CASES DESCRIBED THE PAIN DURING THE PROCEDURE AS HIGH, WITH THIS PERCENTAGE BEING GREATER THAN THAT OBSERVED IN THE WHOLE

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COHORT. SERIES IS THE LARGEST TO DATE EVALUATING THE FEASIBILITY, SAFETY AND EFFECTIVENESS OF ESSURE HYSTEROSCOPIC STERILISATION, WITH THE INCIDENCE OF CHRONIC PP OBSERVED BEING EXTREMELY LOW. AUTHOR IDENTIFIED ALL WOMEN UNDERGOING THE PROCEDURE DURING THE STUDY PERIOD. THE CAUSES THAT MIGHT EXPLAIN CHRONIC PP IN WOMEN WITH ESSURE REMAIN UNKNOWN AND, CONSEQUENTLY, FURTHER STUDIES ARE WARRANTED. PUBLICATION ABSTRACT: THE AIM OF THIS STUDY WAS TO ASSESS THE INCIDENCE OF CHRONIC PELVIC PAIN IN WOMEN AFTER PLACEMENT OF ESSURE MICROINSERTS. THIS WAS A CASE SERIES STUDY AT THE HYSTEROSCOPY UNIT IN A TEACHING HOSPITAL. AUTHOR INCLUDED 4,274 PATIENTS UNDERGOING PERMANENT STERILIZATION WITH ESSURE MICROINSERTS FROM JANUARY 2005 TO DECEMBER 2011. ESSURE DEVICES WERE REMOVED IN ALL PATIENTS REPORTING PELVIC PAIN AFTER INSERTION. ALL DATA WERE COLLECTED FROM THE HYSTEROSCOPY UNIT DATABASE WITH LATER REVIEW OF MEDICAL RECORDS IN CASES OF CHRONIC PELVIC PAIN AND A TELEPHONE SURVEY AFTER MICROINSERT REMOVAL. MAIN OUTCOME MEASURES WERE: GRADE OF PROCEDURE DIFFICULTY PERCEIVED BY THE SURGEON; TOLERANCE DESCRIBED BY THE PATIENT AFTER PLACEMENT; THE NEED FOR ANALGESICS DURING OR IMMEDIATELY AFTER THE PROCEDURE; SIDE-EFFECTS; AVERAGE TIME BETWEEN DEVICE PLACEMENT AND THE ONSET OF SYMPTOMS; TIME BETWEEN DEVICE PLACEMENT AND REMOVAL; TECHNIQUE FOR DEVICE REMOVAL AND ANY SYMPTOMS THEREAFTER. A TOTAL OF SEVEN WOMEN (0.16%) PRESENTED WITH CHRONIC PELVIC PAIN REQUIRING MICROINSERT REMOVAL, WITH FOUR CLASSIFYING THE PAIN PERCEIVED DURING THE PROCEDURE AS MEDIUM HIGH. SIX PATIENTS DID NOT REQUIRE ANALGESICS AFTER THE PROCEDURE AND A VASOVAGAL SYNDROME REQUIRING ENDOVENOUS ANALGESIA AND MONITORING OCCURRED IN ONLY ONE CASE. SIX WOMEN REPORTED PAIN IMMEDIATELY AFTER THE PROCEDURE, WITH A MEAN TIME BETWEEN PLACEMENT AND REMOVAL OF 29.4 MONTHS. IN ALL CASES, THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR CONCLUDED THAT THE DEVELOPMENT OF CHRONIC PELVIC PAIN IS VERY UNCOMMON AFTER PLACEMENT OF ESSURE MICROINSERTS. REMOVAL OF THESE DEVICES USUALLY IMPROVES THE PAIN. OTHER CASES FROM THIS ARTICLE: 2014-092124, 2014-092126, 2014-092127, 2014-092128, 2014-092129, 2014-092130.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 12-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIG

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00283	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRASEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6)-2014 , ARTICLE ENTITLED "ESSURE AND CHRONIC PELVIC PAIN: A POPULATION-BASED COHORT". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN-TUBE MICRO-INSERTS) IMPLANTED FOR HYSTEROSCOPIC STERILISATION AND EXPERIENCED SEVERE PROCEDURAL PAIN AND CHRONIC PELVIC PAIN. THE DEVICE WAS DIFFICULT TO INSERT, PLACEMENT RESULT WAS UNSATISFACTORY WITH 10 COILS IN RIGHT TUBAL AND 4 COILS IN LEFT TUBAL. CASE REPORT: (B)(6) FEMALE PATIENT (CASE 3 FROM TABLE 1) HAD ESSURE MICRO-INSERT IMPLANTED FOR HYSTEROSCOPIC STERILIZATION. THE SURGEON DESCRIBED THE PROCEDURE AS HIGH LEVEL OF DIFFICULTY DUE TO ANATOMICAL REASON. THE SURGEON REPORTED UNSATISFACTORY DEVICE PLACEMENT WITH 10 COILS IN RIGHT TUBAL AND 4 COILS IN LEFT TUBAL. PATIENT EXPERIENCED PROCEDURAL PAIN IMMEDIATELY AFTER PLACEMENT, IT WAS ASSESSED AS SEVERE VIA PAIN ASSESSMENT TOLERANCE. HSG (HYSTEROSALPINGOGRAM) WAS DONE AS A CONTROL TEST. CHRONIC PELVIC PAIN THAT STARTED IMMEDIATELY AFTER PLACEMENT INCREASED WITH TIME AND DID NOT DISAPPEAR USING STANDARD ANALGESIC DRUGS REQUIRING MICRO-INSERT REMOVAL. THE DEVICE WAS REMOVED BY HYSTEROSCOPY, TIME BETWEEN MICRO INSERT PLACEMENT AND REMOVAL WAS 55 MONTHS. THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR'S COMMENTS: THE PRESENT, VERY LARGE SAMPLE DEMONSTRATES THAT CHRONIC PELVIC PAIN IS A VERY RARE COMPLICATION WITH THE ESSURE SYSTEM. INDEED SIX OF THE SEVEN WOMEN REPORTED THAT THE ONSET OF SYMPTOMS STARTED IMMEDIATELY AFTER THE PROCEDURE AND DID NOT IMPROVE WITH THE INTAKE OF STANDARD ANALGESICS. IN THREE OF THESE PATIENTS, THE SURGEON DESCRIBED THE DEVICE PLACEMENT AS DIFFICULT, REQUIRING A HYSTEROSALPINGOGRAPHY AS A CONTROL TEST, SHOWING DEVICE OCCLUSION AS WELL AS DEVICE DISPOSAL. THIS FACT IS NOTEWORTHY, SINCE PELVIC

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PAIN MAY BE RELATED TO MALPOSITIONING OF A MICROINSERT. THREE OF THE SEVEN CASES DESCRIBED THE PAIN DURING THE PROCEDURE AS HIGH, WITH THIS PERCENTAGE BEING GREATER THAN THAT OBSERVED IN THE WHOLE COHORT. SERIES IS THE LARGEST TO DATE EVALUATING THE FEASIBILITY, SAFETY AND EFFECTIVENESS OF ESSURE HYSTEROSCOPIC STERILISATION, WITH THE INCIDENCE OF CHRONIC PP OBSERVED BEING EXTREMELY LOW. AUTHOR IDENTIFIED ALL WOMEN UNDERGOING THE PROCEDURE DURING THE STUDY PERIOD. THE CAUSES THAT MIGHT EXPLAIN CHRONIC PP IN WOMEN WITH ESSURE REMAIN UNKNOWN AND, CONSEQUENTLY, FURTHER STUDIES ARE WARRANTED. PUBLICATION ABSTRACT: THE AIM OF THIS STUDY WAS TO ASSESS THE INCIDENCE OF CHRONIC PELVIC PAIN IN WOMEN AFTER PLACEMENT OF ESSURE MICROINSERTS. THIS WAS A CASE SERIES STUDY AT THE HYSTEROSCOPY UNIT IN A TEACHING HOSPITAL. AUTHOR INCLUDED 4,274 PATIENTS UNDERGOING PERMANENT STERILISATION WITH ESSURE MICROINSERTS FROM JANUARY 2005 TO DECEMBER 2011. ESSURE DEVICES WERE REMOVED IN ALL PATIENTS REPORTING PELVIC PAIN AFTER INSERTION. ALL DATA WERE COLLECTED FROM THE HYSTEROSCOPY UNIT DATABASE WITH LATER REVIEW OF MEDICAL RECORDS IN CASES OF CHRONIC PELVIC PAIN AND A TELEPHONE SURVEY AFTER MICROINSERT REMOVAL. MAIN OUTCOME MEASURES WERE: GRADE OF PROCEDURE DIFFICULTY PERCEIVED BY THE SURGEON; TOLERANCE DESCRIBED BY THE PATIENT AFTER PLACEMENT; THE NEED FOR ANALGESICS DURING OR IMMEDIATELY AFTER THE PROCEDURE; SIDE-EFFECTS; AVERAGE TIME BETWEEN DEVICE PLACEMENT AND THE ONSET OF SYMPTOMS; TIME BETWEEN DEVICE PLACEMENT AND REMOVAL; TECHNIQUE FOR DEVICE REMOVAL AND ANY SYMPTOMS THEREAFTER. A TOTAL OF SEVEN WOMEN (0.16%) PRESENTED WITH CHRONIC PELVIC PAIN REQUIRING MICROINSERT REMOVAL, WITH FOUR CLASSIFYING THE PAIN PERCEIVED DURING THE PROCEDURE AS MEDIUM -HIGH. SIX PATIENTS DID NOT REQUIRE ANALGESICS AFTER THE PROCEDURE AND A VASOVAGAL SYNDROME REQUIRING ENDOVENOUS ANALGESIA AND MONITORING OCCURRED IN ONLY ONE CASE. SIX WOMEN REPORTED PAIN IMMEDIATELY AFTER THE PROCEDURE, WITH A MEAN TIME BETWEEN PLACEMENT AND REMOVAL OF 29.4 MONTHS. IN ALL CASES, THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR CONCLUDED THAT THE DEVELOPMENT OF CHRONIC PELVIC PAIN IS VERY UNCOMMON AFTER PLACEMENT OF ESSURE MICROINSERTS. REMOVAL OF THESE DEVICES USUALLY IMPROVES THE PAIN. OTHER CASES FROM THIS ARTICLE: 2014-092125, 2014-092124, 2014-092127, 2014-092128, 2014-092129, 2014-092130.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 11-AUG-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00284	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON JUNE 17, 2014, ARTICLE ENTITLED "ESSURE AND CHRONIC PELVIC PAIN: A POPULATION-BASED COHORT". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN-TUBE MICRO-INSERTS) IMPLANTED FOR HYSTEROSCOPIC STERILISATION AND EXPERIENCED MODERATE CHRONIC PELVIC PAIN STARTING ONE WEEK AFTER INSERTION. THE DEVICE WAS DIFFICULT TO INSERT. NUMBER OF DEVICES WAS 10 COILS IN RIGHT TUBAL AND 12 COILS IN LEFT TUBAL. CASE REPORT: (B)(6) FEMALE PATIENT (CASE 4 FROM TABLE 1) HAD ESSURE MICRO-INSERT IMPLANTED FOR HYSTEROSCOPIC STERILIZATION. THE SURGEON DESCRIBED THE PROCEDURE AS HIGH LEVEL OF DIFFICULTY DUE TO TUBAL OBSTRUCTION. THE SURGEON REPORTED SATISFACTORY DEVICE PLACEMENT. THERE WERE 10 COILS IN RIGHT TUBAL AND 12 COILS IN LEFT TUBAL. PATIENT EXPERIENCED PAIN ONE WEEK AFTER PLACEMENT, IT WAS ASSESSED AS MODERATE VIA PAIN ASSESSMENT TOLERANCE. HSG (HYSTEROSALPINGOGRAM) WAS DONE AS A CONTROL TEST. CHRONIC PELVIC PAIN THAT STARTED ONE WEEK AFTER PLACEMENT INCREASED WITH TIME AND DID NOT DISAPPEAR USING STANDARD ANALGESIC DRUGS REQUIRING MICRO-INSERT REMOVAL. THE DEVICE WAS REMOVED BY HYSTEROSCOPY, TIME BETWEEN MICRO-INSERT PLACEMENT AND REMOVAL WAS 12 MONTHS. THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR'S COMMENTS: THE PRESENT, VERY LARGE SAMPLE DEMONSTRATES THAT CHRONIC PELVIC PAIN IS A VERY RARE COMPLICATION WITH THE ESSURE SYSTEM. INDEED SIX OF THE SEVEN WOMEN REPORTED THAT THE ONSET OF SYMPTOMS STARTED IMMEDIATELY AFTER THE PROCEDURE AND DID NOT IMPROVE WITH THE INTAKE OF STANDARD ANALGESICS. IN THREE OF THESE PATIENTS, THE SURGEON DESCRIBED THE DEVICE PLACEMENT AS DIFFICULT, REQUIRING A HYSTEROSALPINGOGRAPHY AS A CONTROL TEST, SHOWING DEVICE OCCLUSION AS WELL AS DEVICE DISPOSAL. THIS FACT IS NOTEWORTHY, SINCE PELVIC

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON JULY 9, 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00285	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2014 , ARTICLE ENTITLED "ESSURE AND CHRONIC PELVIC PAIN: A POPULATION-BASED COHORT". IT REFERS TO A 32-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE MICRO-INSERTS) IMPLANTED FOR HYSTEROSCOPIC STERILISATION AND EXPERIENCED SEVERE DIFFICULT TO INSERT, UNSATISFACTORY DEVICE PLACEMENT WAS REPORTED. CASE REPORT: 32 YEARS OLD FEMALE PATIENT (CASE 5 FROM HYSTEROSCOPIC STERILIZATION). THE SURGEON DESCRIBED THE PROCEDURE AS HIGH LEVEL OF DIFFICULTY DUE TO ANATOMICAL REASON. THE SURGEON REPORTED UNSATISFACTORY DEVICE IN LEFT TUBAL. PATIENT EXPERIENCED PROCEDURAL PAIN IMMEDIATELY AFTER PLACEMENT, IT WAS ASSESSED AS SEVERE VIA PAIN ASSESSMENT TOLERANCE. HSG (HYSTEROSALPINGOGRAM) STARTED IMMEDIATELY AFTER PLACEMENT INCREASED WITH TIME REQUIRING MICRO-INSERT REMOVAL. THE DEVICE WAS REMOVED BY HYSTEROSCOPY, TIME BETWEEN MICRO INSERT PLACEMENT AND REMOVAL WAS 4 MONTHS. THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR'S COMMENTS: THE PRESENT, VERY LARGE SAMPLE DEMONSTRATES THAT CHRONIC PELVIC PAIN IS A VERY RARE COMPLICATION WITH THE ESSURE SYSTEM. INDEED SIX OF THE SEVEN WOMEN REPORTED THAT THE ONSET OF SYMPTOMS STARTED IMMEDIATELY AFTER THE PROCEDURE AND DID NOT IMPROVE WITH THE INTAKE OF STANDARD ANALGESICS. IN THREE OF THESE PATIENTS, THE SURGEON DESCRIBED THE DEVICE PLACEMENT AS DIFFICULT, REQUIRING A HYSTEROSALPINGOGRAPHY AS A CONTROL TEST, SHOWING DEVICE OCCLUSION AS WELL AS DEVICE DISPOSAL. THIS FACT IS NOTEWORTHY, SINCE PELVIC PAIN MAY BE RELATED TO MALPOSITIONING OF A MICROINSERT. THREE OF THE SEVEN CASES DESCRIBED THE PAIN DURING THE PROCEDURE AS HIGH, WITH THIS PERCENTAGE BEING GREATER THAN THAT OBSERVED IN THE WHOLE COHORT. SERIES IS THE LARGEST TO DATE EVALUATING THE FEASIBILITY, SAFETY AND EFFECTIVENESS OF

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ESSURE HYSTEROSCOPIC STERILISATION, WITH THE INCIDENCE OF CHRONIC PP OBSERVED BEING EXTREMELY LOW. AUTHOR IDENTIFIED ALL WOMEN UNDERGOING THE PROCEDURE DURING THE STUDY PERIOD. THE CAUSES THAT MIGHT EXPLAIN CHRONIC PP IN WOMEN WITH ESSURE REMAIN UNKNOWN AND, CONSEQUENTLY, FURTHER STUDIES ARE WARRANTED. PUBLICATION ABSTRACT: THE AIM OF THIS STUDY WAS TO ASSESS THE INCIDENCE OF CHRONIC PELVIC PAIN IN WOMEN AFTER PLACEMENT OF ESSURE MICROINSERTS. THIS WAS A CASE SERIES STUDY AT THE HYSTEROSCOPY UNIT IN A TEACHING HOSPITAL. AUTHOR INCLUDED 4,274 PATIENTS UNDERGOING PERMANENT STERILISATION WITH ESSURE MICROINSERTS FROM JANUARY 2005 TO DECEMBER 2011. ESSURE DEVICES WERE REMOVED IN ALL PATIENTS REPORTING PELVIC PAIN AFTER INSERTION. ALL DATA WERE COLLECTED FROM THE HYSTEROSCOPY UNIT DATABASE WITH LATER REVIEW OF MEDICAL RECORDS IN CASES OF CHRONIC PELVIC PAIN AND A TELEPHONE SURVEY AFTER MICROINSERT REMOVAL. MAIN OUTCOME MEASURES WERE: GRADE OF PROCEDURE DIFFICULTY PERCEIVED BY THE SURGEON; TOLERANCE DESCRIBED BY THE PATIENT AFTER PLACEMENT; THE NEED FOR ANALGESICS DURING OR IMMEDIATELY AFTER THE PROCEDURE; SIDE-EFFECTS; AVERAGE TIME BETWEEN DEVICE PLACEMENT AND THE ONSET OF SYMPTOMS; TIME BETWEEN DEVICE PLACEMENT AND REMOVAL; TECHNIQUE FOR DEVICE REMOVAL AND ANY SYMPTOMS THEREAFTER. A TOTAL OF SEVEN WOMEN (0.16%) PRESENTED WITH CHRONIC PELVIC PAIN REQUIRING MICROINSERT REMOVAL, WITH FOUR CLASSIFYING THE PAIN PERCEIVED DURING THE PROCEDURE AS MEDIUM- HIGH. SIX PATIENTS DID NOT REQUIRE ANALGESICS AFTER THE PROCEDURE AND A VASOVAGAL SYNDROME REQUIRING ENDOVENOUS ANALGESIA AND MONITORING OCCURRED IN ONLY ONE CASE. SIX WOMEN REPORTED PAIN IMMEDIATELY AFTER THE PROCEDURE, WITH A MEAN TIME BETWEEN PLACEMENT AND REMOVAL OF 29.4 MONTHS. IN ALL CASES, THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR CONCLUDED THAT THE DEVELOPMENT OF CHRONIC PELVIC PAIN IS VERY UNCOMMON AFTER PLACEMENT OF ESSURE MICROINSERTS. REMOVAL OF THESE DEVICES USUALLY IMPROVES THE PAIN. OTHER CASES FROM THIS ARTICLE: 2014-092125; 2014-092126;2014-092127; 2014-092124; 2014-092129; 2014-092130.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: USABILITY ISSUES (UIS) ARE NOT ASSOCIATED WITH TECHNICAL DEFECTS OR ADVERSE EVENTS. UIS ARE TYPICA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00286	BAYER HEALTHECARE LLP	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 17-JUN-2014, ARTICLE ENTITLED "ESSURE AND CHRONIC PELVIC PAIN: A POPULATION-BASED COHORT". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE MICRO-INSERTS) INSERTED FOR HYSTEROSCOPIC STERILISATION AND EXPERIENCED SEVERE PROCEDURAL PAIN AND CHRONIC PELVIC PAIN. CASE REPORT: (B)(6) FEMALE PATIENT (CASE 6 FROM TABLE 1) HAD ESSURE MICRO-INSERT IMPLANTED FOR HYSTEROSCOPIC STERILIZATION. THE SURGEON DESCRIBED THE PROCEDURE AS LOW LEVEL OF DIFFICULTY. THE SURGEON REPORTED SATISFACTORY DEVICE PLACEMENT WITH 3 COILS IN RIGHT TUBAL AND 3 COILS IN LEFT TUBAL. PATIENT EXPERIENCED PROCEDURAL PAIN IMMEDIATELY AFTER PLACEMENT; IT WAS ASSESSED AS SEVERE VIA PAIN ASSESSMENT TOLERANCE. X-RAY WAS DONE AS A CONTROL TEST. CHRONIC PELVIC PAIN THAT STARTED IMMEDIATELY AFTER PLACEMENT INCREASED WITH TIME AND DID NOT DISAPPEAR USING STANDARD ANALGESIC DRUGS REQUIRING MICRO-INSERT REMOVAL. THE DEVICE WAS REMOVED BY LAPAROSCOPY; TIME BETWEEN MICRO INSERT PLACEMENT AND REMOVAL WAS 44 MONTHS. THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR'S COMMENTS: THE PRESENT, VERY LARGE SAMPLE DEMONSTRATES THAT CHRONIC PELVIC PAIN IS A VERY RARE COMPLICATION WITH THE ESSURE SYSTEM. INDEED SIX OF THE SEVEN WOMEN REPORTED THAT THE ONSET OF SYMPTOMS STARTED IMMEDIATELY AFTER THE PROCEDURE AND DID NOT IMPROVE WITH THE INTAKE OF STANDARD ANALGESICS. IN THREE OF THESE PATIENTS, THE SURGEON DESCRIBED THE DEVICE PLACEMENT AS DIFFICULT, REQUIRING A HYSTEROSALPINGOGRAPHY AS A CONTROL TEST, SHOWING DEVICE OCCLUSION AS WELL AS DEVICE DISPOSAL. THIS FACT IS NOTEWORTHY, SINCE PELVIC PAIN MAY BE RELATED TO MALPOSITIONING OF A MICROINSERT. THREE OF THE SEVEN CASES DESCRIBED THE PAIN DURING THE PROCEDURE AS HIGH, WITH THIS PERCENTAGE BEING GREATER THAN THAT OBSERVED IN THE WHOLE

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COHORT. SERIES IS THE LARGEST TO DATE EVALUATING THE FEASIBILITY, SAFETY AND EFFECTIVENESS OF ESSURE HYSTEROSCOPIC STERILISATION, WITH THE INCIDENCE OF CHRONIC PP OBSERVED BEING EXTREMELY LOW. AUTHOR IDENTIFIED ALL WOMEN UNDERGOING THE PROCEDURE DURING THE STUDY PERIOD. THE CAUSES THAT MIGHT EXPLAIN CHRONIC PP IN WOMEN WITH ESSURE REMAIN UNKNOWN AND, CONSEQUENTLY, FURTHER STUDIES ARE WARRANTED. PUBLICATION ABSTRACT: THE AIM OF THIS STUDY WAS TO ASSESS THE INCIDENCE OF CHRONIC PELVIC PAIN IN WOMEN AFTER PLACEMENT OF ESSURE MICROINSERTS. THIS WAS A CASE SERIES STUDY AT THE HYSTEROSCOPY UNIT IN A TEACHING HOSPITAL. AUTHOR INCLUDED 4,274 PATIENTS UNDERGOING PERMANENT STERILISATION WITH ESSURE MICROINSERTS FROM (B)(6) 2005 TO (B)(6) 2011. ESSURE DEVICES WERE REMOVED IN ALL PATIENTS REPORTING PELVIC PAIN AFTER INSERTION. ALL DATA WERE COLLECTED FROM THE HYSTEROSCOPY UNIT DATABASE WITH LATER REVIEW OF MEDICAL RECORDS IN CASES OF CHRONIC PELVIC PAIN AND A TELEPHONE SURVEY AFTER MICROINSERT REMOVAL. MAIN OUTCOME MEASURES WERE: GRADE OF PROCEDURE DIFFICULTY PERCEIVED BY THE SURGEON; TOLERANCE DESCRIBED BY THE PATIENT AFTER PLACEMENT; THE NEED FOR ANALGESICS DURING OR IMMEDIATELY AFTER THE PROCEDURE; SIDE-EFFECTS; AVERAGE TIME BETWEEN DEVICE PLACEMENT AND THE ONSET OF SYMPTOMS; TIME BETWEEN DEVICE PLACEMENT AND REMOVAL; TECHNIQUE FOR DEVICE REMOVAL AND ANY SYMPTOMS THEREAFTER. A TOTAL OF SEVEN WOMEN (0.16%) PRESENTED WITH CHRONIC PELVIC PAIN REQUIRING MICROINSERT REMOVAL, WITH FOUR CLASSIFYING THE PAIN PERCEIVED DURING THE PROCEDURE AS MEDIUM- HIGH. SIX PATIENTS DID NOT REQUIRE ANALGESICS AFTER THE PROCEDURE AND A VASOVAGAL SYNDROME REQUIRING ENDOVENOUS ANALGESIA AND MONITORING OCCURRED IN ONLY ONE CASE. SIX WOMEN REPORTED PAIN IMMEDIATELY AFTER THE PROCEDURE, WITH A MEAN TIME BETWEEN PLACEMENT AND REMOVAL OF 29.4 MONTHS. IN ALL CASES, THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR CONCLUDED THAT THE DEVELOPMENT OF CHRONIC PELVIC PAIN IS VERY UNCOMMON AFTER PLACEMENT OF ESSURE MICROINSERTS. REMOVAL OF THESE DEVICES USUALLY IMPROVES THE PAIN. OTHER CASES FROM THIS ARTICLE: (B)(4).

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 12-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00287	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRASEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2014, ARTICLE ENTITLED "ESSURE AND CHRONIC PELVIC PAIN: A POPULATION-BASED COHORT". IT REFERS TO A 34-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE MICRO-INSERTS) FOR HYSTEROSCOPIC STERILISATION AND EXPERIENCED MILD PROCEDURAL PAIN AND CHRONIC PELVIC PAIN. CASE REPORT: 34 YEARS OLD FEMALE PATIENT (CASE 7 FROM TABLE 1) HAD ESSURE MICRO-INSERTS IMPLANTED FOR HYSTEROSCOPIC STERILIZATION. THE SURGEON DESCRIBED THE PROCEDURE AS LOW LEVEL OF DIFFICULTY. THE SURGEON REPORTED SATISFACTORY DEVICE PLACEMENT WITH 3 COILS IN RIGHT TUBAL AND 2 COILS IN LEFT TUBAL. PATIENT EXPERIENCED PROCEDURAL PAIN IMMEDIATELY AFTER PLACEMENT, IT WAS ASSESSED AS MILD VIA PAIN ASSESSMENT TOLERANCE. X-RAY WAS DONE AS A CONTROL TEST. CHRONIC PELVIC PAIN THAT STARTED IMMEDIATELY AFTER PLACEMENT INCREASED WITH TIME AND DID NOT DISAPPEAR USING STANDARD ANALGESIC DRUGS REQUIRING MICRO-INSERT REMOVAL. THE DEVICE WAS REMOVED BY LAPAROSCOPY, TIME BETWEEN MICRO INSERT PLACEMENT AND REMOVAL WAS 12 MONTHS. THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR'S COMMENTS: THE PRESENT, VERY LARGE SAMPLE DEMONSTRATES THAT CHRONIC PELVIC PAIN IS A VERY RARE COMPLICATION WITH THE ESSURE SYSTEM. INDEED SIX OF THE SEVEN WOMEN REPORTED THAT THE ONSET OF SYMPTOMS STARTED IMMEDIATELY AFTER THE PROCEDURE AND DID NOT IMPROVE WITH THE INTAKE OF STANDARD ANALGESICS. IN THREE OF THESE PATIENTS, THE SURGEON DESCRIBED THE DEVICE PLACEMENT AS DIFFICULT, REQUIRING A HYSTEROSALPINGOGRAPHY AS A CONTROL TEST, SHOWING DEVICE OCCLUSION AS WELL AS DEVICE DISPOSAL. THIS FACT IS NOTEWORTHY, SINCE PELVIC PAIN MAY BE RELATED TO MALPOSITIONING OF A MICROINSERT. THREE OF THE SEVEN CASES DESCRIBED THE PAIN DURING THE PROCEDURE AS HIGH, WITH THIS PERCENTAGE BEING GREATER THAN THAT OBSERVED IN THE WHOLE

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COHORT. SERIES IS THE LARGEST TO DATE EVALUATING THE FEASIBILITY, SAFETY AND EFFECTIVENESS OF ESSURE HYSTEROSCOPIC STERILISATION, WITH THE INCIDENCE OF CHRONIC PP OBSERVED BEING EXTREMELY LOW. AUTHOR IDENTIFIED ALL WOMEN UNDERGOING THE PROCEDURE DURING THE STUDY PERIOD. THE CAUSES THAT MIGHT EXPLAIN CHRONIC PP IN WOMEN WITH ESSURE REMAIN UNKNOWN AND, CONSEQUENTLY, FURTHER STUDIES ARE WARRANTED. PUBLICATION ABSTRACT: THE AIM OF THIS STUDY WAS TO ASSESS THE INCIDENCE OF CHRONIC PELVIC PAIN IN WOMEN AFTER PLACEMENT OF ESSURE MICROINSERTS. THIS WAS A CASE SERIES STUDY AT THE HYSTEROSCOPY UNIT IN A TEACHING HOSPITAL. AUTHOR INCLUDED 4,274 PATIENTS UNDERGOING PERMANENT STERILISATION WITH ESSURE MICROINSERTS FROM JANUARY 2005 TO DECEMBER 2011. ESSURE DEVICES WERE REMOVED IN ALL PATIENTS REPORTING PELVIC PAIN AFTER INSERTION. ALL DATA WERE COLLECTED FROM THE HYSTEROSCOPY UNIT DATABASE WITH LATER REVIEW OF MEDICAL RECORDS IN CASES OF CHRONIC PELVIC PAIN AND A TELEPHONE SURVEY AFTER MICROINSERT REMOVAL. MAIN OUTCOME MEASURES WERE: GRADE OF PROCEDURE DIFFICULTY PERCEIVED BY THE SURGEON; TOLERANCE DESCRIBED BY THE PATIENT AFTER PLACEMENT; THE NEED FOR ANALGESICS DURING OR IMMEDIATELY AFTER THE PROCEDURE; SIDE-EFFECTS; AVERAGE TIME BETWEEN DEVICE PLACEMENT AND THE ONSET OF SYMPTOMS; TIME BETWEEN DEVICE PLACEMENT AND REMOVAL; TECHNIQUE FOR DEVICE REMOVAL AND ANY SYMPTOMS THEREAFTER. A TOTAL OF SEVEN WOMEN (0.16%) PRESENTED WITH CHRONIC PELVIC PAIN REQUIRING MICROINSERT REMOVAL, WITH FOUR CLASSIFYING THE PAIN PERCEIVED DURING THE PROCEDURE AS MEDIUM- HIGH. SIX PATIENTS DID NOT REQUIRE ANALGESICS AFTER THE PROCEDURE AND A VASOVAGAL SYNDROME REQUIRING ENDOVENOUS ANALGESIA AND MONITORING OCCURRED IN ONLY ONE CASE. SIX WOMEN REPORTED PAIN IMMEDIATELY AFTER THE PROCEDURE, WITH A MEAN TIME BETWEEN PLACEMENT AND REMOVAL OF 29.4 MONTHS. IN ALL CASES, THE SYMPTOMS DISAPPEARED AFTER ESSURE REMOVAL. AUTHOR CONCLUDED THAT THE DEVELOPMENT OF CHRONIC PELVIC PAIN IS VERY UNCOMMON AFTER PLACEMENT OF ESSURE MICROINSERTS. REMOVAL OF THESE DEVICES USUALLY IMPROVES THE PAIN. OTHER CASES FROM THIS ARTICLE: 2014-092124, 2014-092125, 2014-092126, 2014-092127, 2014-092128, 2014-092129.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 12-AUG-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00288	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 17-JUN-2014 , ARTICLE ENTITLED "ESSURE AND CHRONIC PELVIC PAIN: A POPULATION-BASED COHORT". IT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR HYSTEROSCOPIC STERILISATION AND EXPERIENCED PELVIC PAIN IMMEDIATELY AFTER THE PROCEDURE. CASE REPORT: CASE 1 WAS A (B)(6) YEAR-OLD WOMAN WHO HAD THE ESSURE INSERTS PLACED 43 DAYS PREVIOUSLY. SHE COMPLAINED OF PELVIC PAIN IMMEDIATELY AFTER THE PROCEDURE. THE PAIN WAS DULL AND BILATERAL, AND DID NOT IMPROVE WITH EMPIRIC ANTIBIOTIC THERAPY. AN ULTRASOUND AND DIAGNOSTIC HYSTEROSCOPY CONFIRMED APPROPRIATE PLACEMENT OF THE INSERTS. BECAUSE OF THE PERSISTENT PAIN, SHE REQUESTED REMOVAL OF THE DEVICES AS WELL AS PERMANENT SURGICAL STERILIZATION. A 5-MM HYSTEROSCOPE WAS USED WITH GLYCINE DISTENTION MEDIA. GLYCINE WAS SELECTED IN CASE ELECTROCAUTERY WAS NEEDED DURING THE REMOVAL PROCESS. THE ESSURE COILS WERE CLEARLY SEEN EXTENDING FROM BOTH OF THE TUBAL OSTIA. THE HYSTEROSCOPIC FORCEPS WAS USED TO GENTLY EXTRACT BOTH COILS UNDER DIRECT VISUALIZATION. THE COILS WERE EASILY REMOVED INTACT. A LAPAROSCOPIC TUBAL LIGATION WITH ELECTROCAUTERY WAS THEN PERFORMED. TEN DAYS AFTER THE PROCEDURE, THE PATIENT'S INITIAL SYMPTOMS OF PELVIC PAIN HAD RESOLVED. AUTHOR'S COMMENTS: IN THIS CASE DESCRIBED, AUTHOR DEMONSTRATED SUCCESSFUL REMOVAL OF THE ESSURE DEVICE AFTER PERSISTENT PELVIC PAIN. PELVIC PAIN AFTER PLACEMENT OF THE ESSURE DEVICE IS USUALLY TRANSIENT. IT WAS UNABLE TO IDENTIFY ANY SPECIFIC ETIOLOGY OF THE PAIN, SUCH AS INFECTION OR IMPROPER PLACEMENT. IN THIS, THE SYMPTOMS COMPLETELY RESOLVED AFTER REMOVAL OF THE DEVICE. IN SUCH CASES, IT WAS DEMONSTRATED THAT THE DEVICE CAN BE REMOVED BY HYSTEROSCOPY WITH GENTLE TRACTION, OR BY LAPAROSCOPY IN CASES

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WHERE NO COILS ARE VISIBLE AT THE TUBAL OSTIA. THIS CASE INDICATE THAT FOR CASES OF PERSISTENT PAIN UP TO 6 WEEKS AFTER THE PROCEDURE, REMOVAL BY HYSTEROSCOPY OR LAPAROSCOPY IS POSSIBLE. PUBLICATION ABSTRACT: OBJECTIVE: TO PRESENT TWO CASE REPORTS OF TECHNIQUES FOR REMOVAL OF THE ESSURE (CONCEPTUS, INC., MOUNTAIN VIEW,CA) HYSTEROSCOPIC TUBAL OCCLUSION DEVICE. DESIGN: CASE REPORT. SETTING: UNIVERSITY-AFFILIATED TEACHING HOSPITAL. PATIENT(S): TWO WOMEN REQUESTING REMOVAL OF ESSURE DEVICES BECAUSE OF PERSISTENT PELVIC PAIN UP TO 6 WEEKS AFTER PLACEMENT. INTERVENTION(S): HYSTEROSCOPIC AND LAPAROSCOPIC REMOVAL OF THE ESSURE MICROINSERTS. NO INSTITUTIONAL REVIEW BOARD APPROVAL WAS OBTAINED BECAUSE THE PROCEDURES WERE NOT PART OF A STUDY PROTOCOL. MAIN OUTCOME MEASURE(S): EFFECTIVE REMOVAL OF THE ESSURE DEVICE AND RESOLUTION OF PELVIC PAIN SYMPTOMS. RESULT(S): SUCCESSFUL REMOVAL OF THE DEVICE WAS ACHIEVED IN BOTH PATIENTS. IN ONE CASE, THE PROCEDURE WAS PERFORMED ENTIRELY BY HYSTEROSCOPY. IN THE OTHER CASE, A LAPAROSCOPIC APPROACH WAS REQUIRED BECAUSE OF A LACK OF VISUALIZATION OF THE DEVICE. PAIN SYMPTOMS RESOLVED WITHIN 2 WEEKS OF REMOVAL IN BOTH PATIENTS. CONCLUSION(S): THESE ARE THE FIRST REPORTED CASES OF SUCCESSFUL REMOVAL OF THE ESSURE TUBAL OCCLUSION DEVICES UP TO 6 WEEKS AFTER PLACEMENT. THIS PROCEDURE CAN BE SAFELY PERFORMED WITH THE USE OF HYSTEROSCOPY IF THE INSERTS ARE CLEARLY VISUALIZED. LAPAROSCOPY IS AN ALTERNATIVE WHEN THE DEVICE IS COMPLETELY WITHIN THE FALLOPIAN TUBE. FURTHER STUDY IS NEEDED TO ASSESS THE FUNCTIONALITY OF THE TUBE AFTER THE PROCEDURE, AS WELL AS FEASIBILITY OF REMOVAL BEYOND 6 WEEKS. OTHER CASE FROM THIS ARTICLE: 2014-092737. CORRECTION ON 17-JUN- 2014: THE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) MODEL WAS AMENDED TO ES205.

Manufacturer Narrative (H10):

FOLLOW UP RECEIVED ON 24-JUN-2014: PTC GLOBAL NO ADDED PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-JUN-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00289	BAYER HEALTHCARE LLC	7/17/2014	7/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON JUNE 17, 2014, ARTICLE ENTITLED "ESSURE AND CHRONIC PELVIC PAIN: A POPULATION-BASED COHORT". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR HYSTEROSCOPIC STERILISATION AND EXPERIENCED BILATERAL, BURNING PELVIC PAIN RADIATING TO BACK AND LEGS. IT WAS REPORTED THAT THE DEVICE BROKE INTO TWO SEGMENTS DURING EXTRACTION WITH HYSTEROSCOPIC FORCEPS. CASE REPORT: A (B)(6) WOMAN WHO UNDERWENT THE ESSURE PROCEDURE 35 DAYS PREVIOUSLY. TWO WEEKS AFTER THE PROCEDURE, SHE REPORTED BILATERAL, BURNING PELVIC PAIN RADIATING TO HER BACK AND LEGS. A CLINICAL EXAMINATION, ULTRASOUND, AND LABORATORY STUDIES WERE WITHIN NORMAL LIMITS. SHE REQUESTED REMOVAL OF THE DEVICES AS WELL AS PERMANENT SURGICAL STERILIZATION. A 5-MM HYSTEROSCOPE WITH GLYCINE DISTENTION MEDIA WAS USED. DURING THE HYSTEROSCOPY, ONLY THE COIL OF THE LEFT-SIDED INSERT WAS SEEN EXTENDING FROM THE TUBAL OSTIA. DURING EXTRACTION WITH HYSTEROSCOPIC FORCEPS, THE DEVICE BROKE INTO TWO SEGMENTS. THE RESIDUAL FRAGMENT WAS GRASPED AND EASILY REMOVED. THE INSERT AT THE RIGHT FALLOPIAN TUBE WAS NOT VISUALIZED, AND AUTHOR'S ATTENTION TURNED TO A LAPAROSCOPIC APPROACH. THE ISTHMUS OF THE RIGHT FALLOPIAN TUBE WAS INJECTED WITH A SOLUTION OF BUPIVICAINE AND EPINEPHRINE. A NEEDLE-POINT BIPOLAR ELECTROCAUTERY DEVICE WAS USED TO MAKE A LINEAR INCISION ON ALONG THE MIDPORTION OF THE TUBE, JUST BEYOND THE END OF THE INSERT. THE CANAL WAS ENTERED, AND THE DISTAL TIP OF THE INSERT WAS VISUALIZED. A GRASPER WAS THEN USED TO EXTRACT THE COIL UNDER GENTLE TRACTION. THE COIL WAS REMOVED IN ITS ENTIRETY WITHOUT DIFFICULTY. A BILATERAL TUBAL LIGATION WAS THEN PERFORMED IN THE USUAL FASHION, WITH THE USE OF ELECTROCAUTERY OVER THE INCISED SEGMENT OF THE TUBE. TWO

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WEEKS AFTER THE PROCEDURE, THE PATIENT'S PAIN HAD RESOLVED. AUTHOR'S COMMENTS: IN THIS CASE DESCRIBED AUTHOR DEMONSTRATED SUCCESSFUL REMOVAL OF THE ESSURE DEVICE AFTER PERSISTENT PELVIC PAIN. PELVIC PAIN AFTER PLACEMENT OF THE ESSURE DEVICE IS USUALLY TRANSIENT. IT WAS UNABLE TO IDENTIFY ANY SPECIFIC ETIOLOGY OF THE PAIN, SUCH AS INFECTION OR IMPROPER PLACEMENT. IN THIS, THE SYMPTOMS COMPLETELY RESOLVED AFTER REMOVAL OF THE DEVICE. IN SUCH CASES, IT WAS DEMONSTRATED THAT THE DEVICE CAN BE REMOVED BY HYSTEROSCOPY WITH GENTLE TRACTION, OR BY LAPAROSCOPY IN CASES WHERE NO COILS ARE VISIBLE AT THE TUBAL OSTIA. THIS CASE INDICATE THAT FOR CASES OF PERSISTENT PAIN UP TO 6 WEEKS AFTER THE PROCEDURE, REMOVAL BY HYSTEROSCOPY OR LAPAROSCOPY IS POSSIBLE. PUBLICATION ABSTRACT: OBJECTIVE: TO PRESENT TWO CASE REPORTS OF TECHNIQUES FOR REMOVAL OF THE ESSURE (CONCEPTUS, INC., MOUNTAIN VIEW,CA) HYSTEROSCOPIC TUBAL OCCLUSION DEVICE. DESIGN: CASE REPORT. SETTING: UNIVERSITY-AFFILIATED TEACHING HOSPITAL. PATIENT(S): TWO WOMEN REQUESTING REMOVAL OF ESSURE DEVICES BECAUSE OF PERSISTENT PELVIC PAIN UP TO 6 WEEKS AFTER PLACEMENT. INTERVENTION(S): HYSTEROSCOPIC AND LAPAROSCOPIC REMOVAL OF THE ESSURE MICROINSERTION. NO INSTITUTIONAL REVIEW BOARD APPROVAL WAS OBTAINED BECAUSE THE PROCEDURES WERE NOT PART OF A STUDY PROTOCOL. MAIN OUTCOME MEASURE(S): EFFECTIVE REMOVAL OF THE ESSURE DEVICE AND RESOLUTION OF PELVIC PAIN SYMPTOMS. RESULT(S): SUCCESSFUL REMOVAL OF THE DEVICE WAS ACHIEVED IN BOTH PATIENTS. IN ONE CASE, THE PROCEDURE WAS PERFORMED ENTIRELY BY HYSTEROSCOPY. IN THE OTHER CASE, A LAPAROSCOPIC APPROACH WAS REQUIRED BECAUSE OF A LACK OF VISUALIZATION OF THE DEVICE. PAIN SYMPTOMS RESOLVED WITHIN 2 WEEKS OF REMOVAL IN BOTH PATIENTS. CONCLUSION(S): THESE ARE THE FIRST REPORTED CASES OF SUCCESSFUL REMOVAL OF THE ESSURE TUBAL OCCLUSION DEVICES UP TO 6 WEEKS AFTER PLACEMENT. THIS PROCEDURE CAN BE SAFELY PERFORMED WITH THE USE OF HYSTEROSCOPY IF THE INSERTS ARE CLEARLY VISUALIZED. LAPAROSCOPY IS AN ALTERNATIVE WHEN THE DEVICE IS COMPLETELY WITHIN THE FALLOPIAN TUBE. FURTHER STUDY IS NEEDED TO ASSESS THE FUNCTIONALITY OF THE TUBE AFTER THE PROCEDURE, AS WELL AS FEASIBILITY OF REMOVAL BEYOND 6 WEEKS. OTHER CASE FROM THIS ARTICLE: (B)(4).

Manufacturer Narrative (H10):

(B)(4). FINAL ASSESSMENT: IN THIS CASE, THE PHYSICIAN BROKE THE COILS DURING A SCHEDULED REMOVAL OF THE ESSURE DEVICES, HENCE ALSO LEADING TO A HANDLING ERROR WITH THE DEVICES WHILE REMOVING. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00231	BAYER HEALTHCARE LLC	7/17/2014	7/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C13148

Single Use: Y
Implant Date (E6): 4/24/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT REC'D FROM A PHARMACIST ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PART OF IMPLANT REMAINED IN FALLOPIAN TUBE AT THE TIME OF IMPLANT RELEASE (COMPLICATION OF DEVICE INSERTION). NO INFO WAS GIVEN ON THE PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AT THE TIME OF IMPLANT RELEASE, A PART REMAINED IN THE FALLOPIAN TUBE. THE REPORTER'S CAUSALITY WAS NOT PROVIDED.

Manufacturer Narrative (H10):

COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE PART OF IMPLANT REMAINED IN FALLOPIAN TUBE AT THE TIME OF IMPLANT RE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00236	BAYER HLTHCARE LLC	7/17/2014	8/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B93871

Single Use: Y
Implant Date (E6): 5/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE AND PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE WIRE APPLICATOR, PLASTIC SHEATH AND COIL OF ONE SIDE GOT STUCK IN THE TUBE AFTER FRAYING, INSERT DID NOT DEPLOY WHEN SHE PRESSED THE BUTTON, MAY HAVE PERFORATED THE TUBE DURING INSERTION PROCEDURE, INSERTER INNER CATHETER STRETCHED WHILE IT WAS ATTACHED TO THE DEVICE, AND STRETCHED OUT THIS COLI AND IT EVENTUALLY BROKE DUE TO THE TENSION / A PORTION OF THE INSERTION CATH IS STILL IN THE PATIENT. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. THE PATIENT WAS NOT PREGNANT. ON (B)(6) 2014, THE PATIENT HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION, LOT NUMBER B93871. THE NURSE CALLED REQUESTING IMMEDIATE ASSISTANCE REGARDING ESSURE PLACEMENT PROCEDURE THAT WAS TAKING PLACE DURING CALL THE WIRE APPLICATOR, PLASTIC SHEATH AND COIL OF ONE SIDE GOT STUCK IN THE TUBE AFTER FRAYING AND SNAPPING AND COULD NOT BE REMOVED WITH TENSION. THE PHYSICIAN HAD DIFFICULTY DEPLOYING ESSURE INSERT, AS THE INSERT DID NOT DEPLOY WHEN SHE PRESSED THE BUTTON. SHE ALSO BELIEVED THEY MAY HAVE PERFORATED THE TUBE. SHE TRIED TO PULL BACK ON THE INSERTER WAS UNABLE TO DETACH INSERT. SHE REMOVED THE HYSTEROSCOPE AND INSERTER. THIS STRETCHED THE INNER CATHETER OUT THE CERVIX AND THEN IT SNAPPED FREE. SHE SAID THAT THE GREEN SHEATH WAS STILL IN THE OSTIA AND THIS WIRE WAS STRETCHED TO THE CERVIX. A PICTURE WAS SENT AND IT APPEARED THAT INSERTER INNER CATHETER STRETCHED WHILE IT WAS ATTACHED TO THE DEVICE, AS PHYSICIAN REMOVED HYSTEROSCOPE IT STRETCHED OUT THIS COIL AND IT EVENTUALLY BROKE DUE TO THE TENSION. THE COIL WAS REMOVED VIA

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HYSTEROSCOPY, ALTHOUGH THEY WERE UNABLE TO CUT ESSURE, HAVING BROKEN TWO PAIRS OF SCISSORS. IT SEEMED THAT A PORTION OF THE INSERTION CATHETER WAS STILL IN THE PATIENT AS THE GREEN AND COILS FROM THE INNER CATHETER COULD BE SEEN. NO PERFORATION OR BLEEDING WAS CONFIRMED. REPORTER CAUSALITY: THE RELATIONSHIP WAS NOT REPORTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 20-MAY-2014. NO NEW CLINICAL INFORMATION PROVIDED. ADDENDUM 30-MAY-2014: DESPITE SEVERAL FOLLOW-UP ATTEMPTS NO NEW INFORMATION COULD BE OBTAINED. PTC INVESTIGATION RESULT RECEIVED ON 03-JUN-2014. PTC GLOBAL NUMBER: (B)(4). FINAL ASSE

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00237	BAYER HLTHCARE LLC	7/17/2014	8/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B40021

Single Use: Y
Implant Date (E6): 5/7/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UPON DEPLOYMENT, PROVIDER NOTICED THAT COIL WAS BROKEN INTO ABOUT 3 PIECES IN UTERUS AND BILATERAL PLACEMENT NOT SUCCESSFUL. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON (B)(6) 2014 THE PATIENT HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B40021. UPON DEPLOYMENT, PROVIDER NOTICED THAT COIL WAS BROKEN INTO ABOUT 3 PIECES IN UTERUS AND THEN, THE PIECES WERE RETRIEVED. BILATERAL PLACEMENT WAS NOT SUCCESSFUL. THE PRODUCT WILL NOT BE SENT BACK. REPORTER CAUSALITY: THE RELATIONSHIP WAS NOT REPORTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON (B)(4) 2014: THE REQUIRED NUMBERS OF FOLLOW-UP ATTEMPTS WERE DONE WITHOUT RESPONSE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENC

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00280	BAYER HEALTHCARE, LLC	7/17/2014	10/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/17/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) YEAR OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENT. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THAT DEVICE WAS PUT IN AND WHEN THE DEVICE WAS PULLED OUT, THE PLASTIC AROUND THE ESSURE STAYED INSIDE HER UTERUS (COMPLICATION OF DEVICE INSERTION). FOLLOW UP (B)(6) 2014: NO RESPONSE FROM THE REPORTER PHYSICIAN AFTER 3 FOLLOW UP ATTEMPTS. NO NEW INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 07/11/2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. FOLLOW-UP INFORMATION RECEIVED INDICATED A PORTION OF THE DELIVERY CATHETER BROKE AND WAS ATTACHED TO THE IMPLANT. DELIVERY CATHETER BREAKAGE IS ALSO AN

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ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED.

Manufacturer Narrative (H10):

MEDICAL ASSESSMENT: THIS CASE REPORTED COMPLICATION OF INSERTION DUE TO BREAKAGE BUT THE REPORTED EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THREE (3) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER B60750

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037347	BAYER	7/18/2014	7/24/2014

Event Information:

Event Date (B3): 7/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 7/16/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A HYSTERECTOMY TO REMOVE ESSURE. AFTER I HAD THE ESSURE PROCEDURE, I HAD THE FOLLOWING: SEVERE BACK PAIN, FOLLOWED BY DOCTOR VISITS, CORTISONE SHOTS, MRI'S AND THERAPY. BAD MIGRAINES, CRAMPING, EXCESSIVE BLEEDING, PELVIC PAIN, HAIR LOSS, WEIGHT GAIN, BRAIN FOG, BLOATING AND IRRITABLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037353		7/18/2014	7/24/2014

Event Information:

Event Date (B3): 3/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/9/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN (B)(6) 2012, SINCE THEN I HAVE HAD SEVERE PAIN IN PELVIC AREA, BLEEDING FOR WEEKS ON END HEAVILY HOT FLASHES, HEADACHES THAT WON'T GO AWAY, WEIGHT GAIN TENDERNESS TO BREAST, SLEEPINESS, IRRITABLE, MOODY, GET SICK EASILY, FEELING DEPRESSED ALOT FOR NO REASON. LOWER BACK PAIN, BLEEDING DURING AND AFTER SEX AND SHARP PELVIC PAIN DURING AND AFTER SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037354		7/18/2014	7/24/2014

Event Information:

Event Date (B3): 12/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/2/2007
Explant Date (E7): 12/6/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2002 AFTER I CONTINUALLY HAD SWELLING IN MY LEGS AND KNEE WITH GREAT PAIN GAINED AN EXTREME RHEUMATOLOGIST, AND NONE OF THEM COULD FIND ANYTHING WRONG - WENT TO GYNECOLOGIST AND SHE SAID LEFT GET THAT OUT AND DO A HYSTERECTOMY, BEST THING I EVER DID. I AM NOW (B)(6) POUNDS DOWN NO PAIN AND NO SWELLING. I FEEL THE BEST I HAVE IN A LONG TIME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00292	BAYER HEALTHCARE LLC	7/18/2014	7/25/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/7/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA SALES REPRESENTATIVE IN (B)(4) ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE INSERTED AND IT WAS FOUND IN ABDOMEN (PERFORATION). THE PATIENT WANTED ESSURE IMPLANT TO BE REMOVED. UNDER BRILLIANCE AMPLIFIER, THE PHYSICIAN SAW THAT THE IMPLANT WAS NOT WELL PLACED: IT WAS FOUND IN ABDOMEN. BUT WITH CELIOSCOPY, IMPLANT WAS NOT FOUND AND SO IT COULD NOT BE REMOVED. NO FURTHER INFORMATION WAS PROVIDED. (B)(4) BHP LOCAL DRUG SAFETY DEPARTMENT ASSESSED THE CAUSAL RELATIONSHIP WITH ESSURE AS NOT APPLICABLE ACCORDING TO THE (B)(4) METHOD OF CAUSALITY.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00294	BAYER HEALTHCARE LLC	7/18/2014	7/25/2014

Event Information:

Event Date (B3): 6/3/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 12566552

Single Use: Y
Implant Date (E6): 6/3/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. ESSURE INSERTION WAS DONE ON (B)(6) 2014 FOR STERILIZATION AND THE LOT NUMBER USED WAS 12566552. NURSE REPORTED THAT PHYSICIAN WAS DOING AN ESSURE PROCEDURE AND WHEN SHE WAS PUTTING THE CATHETER WITH THE COIL, IT WOULD NOT RELEASE. THE ESSURE COIL WAS STRETCHED. SHE HAD TO CALL THE SALES REPRESENTATIVE AND FIND OUT WHAT TO DO. SHE ENDED UP CUTTING THE ESSURE DEVICE THROUGH THE HYSTEROSCOPE. SINCE THEN, PATIENT HAS COMPLAINED OF PAIN AND BLEEDING. SHE CAME BACK TO OFFICE ON (B)(6) 2014 AND SHE WAS SCHEDULED FOR SURGERY TO CUT THE EXTRA COIL ON (B)(6) 2014. NURSE WOULD LIKE TO KNOW IF THIS HAS EVER HAPPENED BEFORE WITH THE ESSURE DEVICE. FOLLOW-UP FROM (B)(4) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 04-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DE

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00239	BAYER HEALTHCARE LLC	7/18/2014	7/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 12566552

Single Use: Y
Implant Date (E6): 5/19/2014
Explant Date (E7): 5/19/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED TIP OF INSERTER BROKE OFF (COMPLICATION OF DEVICE INSERTION) AND HCP REMOVED THE BROKEN OFF PART AND THE COIL CARNE OUT WITH THE GRASPER . NO INFORMATION GIVEN ON PATIENT'S HISTORY , PAST DRUGS AND CONCURRENT CONDITIONS . IT IS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION . ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER 12566552 (EXPIRATION DATE DEC-2015) FOR PERMANENT BIRTH CONTROL. IT WAS STATED THAT HEALTHCARE PROFESSIONAL INSERTED THE ESSURE INSERTER AND DEPLOYED AS USUAL . THE TIP OF THE INSERTER BROKE OFF AND WAS IN THE UTERUS . THE HEALTHCARE PROFESSIONAL USED A GRASPER AND REMOVED THE BROKEN OFF PART AND THE COIL CARNE OUT WITH THE GRASPER . IT WAS SUCCESSFULLY REPLACED WITH ANOTHER ESSURE IN THE SAME DAY . NO FURTHER INFORMATION PROVIDED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON (B)(4) 2014: THE REPORTER ASKED FOR A REPLACEMENT OF ESSURE . NO NEW CLINICAL INFORMATION. FOLLOW-UP FROM (B)(4) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. PTC INVESTIGATION RESULT RECEIV

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00240	CONCEPTUS, INC.	7/18/2014	7/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 9/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(4) 2014, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED, WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6) , AND EXPERIENCED BLEEDING, CHRONIC INFLAMMATION, PAIN, AND BLOATING. THIS REPORT INCLUDED INITIAL AND FOLLOW-UP REPORT OF (B)(6) 2014. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST OR CONCURRENT DRUGS AND CONCURRENT CONDITIONS. CONSUMER WAS NOT PREGNANT (SHE MENTIONED HER "NON-PREGO NON- #ESSURE BELLY EIGHT MONTHS POST OP"). ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE IMPLANTED. ON AN UNSPECIFIED DATE, THE CONSUMER EXPERIENCED BLEEDING, CHRONIC INFLAMMATION, AND PAIN. CONSUMER STILL SO BLOATED EIGHT MONTHS POST OPERATION . REPORTEDLY, A HYSTERECTOMY WAS NEEDED. ESSURE WAS REMOVED IN (B)(6) 2013. CONSUMER REPORTED THAT ESSURE WAS THE WORST PRODUCT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2014 . PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, W

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00241	BAYER HEALTHCARE LLC	7/18/2014	8/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B94873

Single Use: Y
Implant Date (E6): 5/21/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CATHETER DID NOT SEPARATE FROM THE DISTAL PORTION OF COIL AND COIL IN PLACE BUT CATHETER ALSO STILL IN PATIENT . NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON (B)(6) 2014, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION. ESSURE LOT NUMBER WAS B94873. PHYSICIAN HAD DEPLOYMENT ISSUE WITH ESSURE CATHETER. THE CATHETER DID NOT SEPARATE FROM THE DISTAL PORTION OF COIL. COIL WAS IN PLACE BUT CATHETER ALSO STILL IN PT. BILATERAL PLACEMENT OCCURRED BUT CATHETER WAS STILL ATTACHED TO COIL ON ONE UNIT. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN CATHETER DID NOT SEPARATE FROM THE DISTAL PORTION OF COIL AND COIL IN PLACE BUT CATHETER ALSO STILL IN PT AND ESSURE WAS NOT REPORTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFO WAS RECEIVED ON (B)(4) 2014: ON (B)(6) 2014, ESSURE DEVICE DID NOT RELEASE FROM CATHETER. WHEN DOCTOR TRIED TO REMOVE CATHETER, IT STRETCHED AND BROKE (PREVIOUSLY REPORTED AS COIL IN PLACE BUT CATHETER ALSO STILL IN PATIENT), LEAVING THE DI

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00242	BAYER HEALTHCARE LLC	7/18/2014	8/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/15/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT REC'D FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEVICE WOULD NOT DEPLOY COMPLETELY AND RELEASE CATHETER BROKE OFF IN SEVERAL PIECES. NO INFO GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION REC'D. ON (B)(6) 2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AT INSERTION PROCEDURE, THE DEVICE WOULD NOT DEPLOY COMPLETELY AND RELEASE CATHETER BROKE OFF IN SEVERAL PIECES. THERE WAS NO INJURY. BILATERAL PLACEMENT WAS ACHIEVED. NO CAUSALITY ASSESSMENT WAS GIVEN.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 22-JUL-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BROKE" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00295	BAYER HEALTHCARE LLC	7/18/2014	8/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. ON AN UNSPECIFIED DATE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT BIRTH CONTROL. PHYSICIAN STATED THAT DURING ATTEMPT OF ESSURE INSERTION, SHE WENT TO RELEASE IT, IT CLICKED, BUT ESSURE DID LET GO OF IT. WHEN SHE ATTEMPTED TO WITHDRAW, THE CTR PART OF THE ESSURE STRETCHED AND THE GOLD BAND WAS MISSING. THERE WERE ONLY TWO COILS TRAILING INTO THE UTERUS. COMPANY CAUSALITY COMMENT: A FEMALE PT OF UNSPECIFIED AGE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE GOLD BAND WAS MISSING WHEN THE PHYSICIAN ATTEMPTED TO WITHDRAW. THIS CASE IS MEDICALLY CONFIRMED. THE GOLD BAND WAS MISSING (CONSIDERED AS DEVICE BREAKAGE) IS NON-SERIOUS, UNLISTED EVENT FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFO AND REGARDED AS NEAR-INCIDENT. DURING DIFFICULT INSERTION/REMOVALS SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE DEVICE BREAKAGE OCCURRED DURING ATTEMPT OF ESSURE INSERTION. BASED ON THE INFO RECEIVED, COMPANY CONSIDERS THE REPORTED EVENT TO BE RELATED TO ESSURE. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: THE PHYSICIAN WENT TO RELEASE IT, IT CLICKED, BUT ESSURE DID LET GO OF IT; WHEN SHE ATTEMPTED TO WITHDRAW, THE CENTER PART OF THE ESSURE STRETCHED; THERE WERE ONLY TWO COILS TRAILING INTO THE UTERUS; COMPLICATION OF DEVICE INSERTION. FURTHER INFO WILL BE REQUESTED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 04-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00293	BAYER HEALTHCARE LLC	7/18/2014	8/19/2014

Event Information:

Event Date (B3): 8/13/2013 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/13/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 20-JUN-2014 WHICH REFERS TO HERSELF. SHE IS A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. CONSUMER REPORTED THAT SHE ESSURE FAILED DURING INSERTION ON THE LEFT SIDE. WHEN THE DOCTOR WAS INSERTING IT AND RELEASED IT FROM THE PROBE, IT DID NOT COMPLETELY RELEASE BECAUSE THE COILS BROKE OFF. SHE TRIED TO REMOVE IT THEN, THE REST OF IT, AND ALL THE COILS KEPT COMING OFF; EVERY LOOP WAS COMING OFF. THEY WERE GOING TO SEND THE CONSUMER TO SURGERY BUT THEY DECIDED NOT TO DO IT, SO THEY LEFT IT. CONSUMER DID NOT PUT ANOTHER ONE ON THAT SIDE. THE DOCTOR HAD TO OPEN ANOTHER PACK FOR THE PROBE OR THE INSTRUMENT ITSELF TO HELP GET IT OUT, BUT CONSUMER'S INSURANCE COMPANY ONLY COVERED ONE. THREE MONTHS LATER, IN (B)(6) 2013, THE RIGHT SIDE, THE GOOD SIDE THAT THEY HAD NO ISSUES WITH, FELL OUT. CONSUMER WENT TO THE BATHROOM AND THERE IT WAS. SHE WENT IN TO THE DOCTOR AFTER THE ESSURE ON THE RIGHT SIDE CAME OUT AND THEY DID X-RAYS AND THE X-RAY SHOWED THAT THE ONLY PART WAS THE BROKEN PIECE SEEN ON THE LEFT SIDE. THEY NEVER DID THE HSG (HYSTEROSALPINGOGRAM). HER DOCTOR REQUIRED FOUR-FIVE MONTHS TO DO THE HSG INSTEAD OF THE RECOMMENDED THREE. CONSUMER EXPERIENCED A LOT OF BLEEDING AND CRAMPING EVER SINCE THE ESSURE WAS PUT IN AND SHE CALLED THE DOCTOR A COUPLE OF TIMES AFTER THAT. THE DOCTOR SAID IT WAS BECAUSE IT WAS PROBABLY STILL IRRITATED BECAUSE OF THE COMPLICATIONS WITH THE INSERTION BUT SHE THOUGHT IT WAS NORMAL. EVENTUALLY IT DID SUBSIDE WHEN THE OTHER SIDE CAME OUT. CONSUMER BLED ALMOST THE WHOLE THREE MONTHS UNTIL THE OTHER SIDE CAME OUT;

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NOT A LOT, NOT HEAVY AND NOT EVERY DAY, BUT EVER SINCE THE ESSURE WAS PUT IN. AFTER THE ESSURE ON THE RIGHT SIDE CAME OUT CONSUMER HAD TONS AND TONS AND TONS OF SEVERE CRAMPING AND BLEEDING FOR THREE TO FOUR DAYS AND THEN IT STOPPED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION FROM 30-JUN-2014: PTC RESULT RECEIVED. (B)(4). ASSESSMENT: WHEN A TERM LIKE "BROKE" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITI

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00291	BAYER HEALTHCARE LLC	7/18/2014	8/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C13145

Single Use: Y
Implant Date (E6): 6/16/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE ON (B)(6) 2014 AND THE FOLLOWING ADVERSE EVENTS OCCURRED. THE PHYSICIAN WANTED TO REMOVE THE DEVICE FOLLOWING A RELEASE PROBLEM. THE COIL THAT WOULD HAVE UNCOILED AT DISTAL EXTREMITY BROKE IN TWO. THERE WAS STILL A PIECE OF THE COIL THAT COULD NOT BE REMOVED BY HYSTEROSCOPY OR BY CELIOSCOPY AT PATIENT'S UTERINE HORN LEVEL. FINALLY, THE DEVICE WAS NOT PLACED. NOVASURE PROCEDURE COULD NOT BE PERFORMED. THE DEVICE WAS KEPT AT THE HOSPITAL. NO FURTHER INFORMATION WAS PROVIDED. (B)(6) ASSESSED THE EVENT WITH ESSURE AS NEAR INCIDENT. CRITERION OF SERIOUSNESS: NOT APPLICABLE. CAUSAL RELATIONSHIP BETWEEN THE EVENT AND ESSURE: NOT APPLICABLE.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: AS OF (B)(4) 2014, NO PRODUCT

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00296	BAYER HEALTHCARE, LLC	7/18/2014	8/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/3/2014
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) YEAR OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENT. ON (B)(6) 2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR CONTRACEPTION. ON (B)(6) 2014 HYSTEROSALPINGOGRAM WAS DONE. ACCORDING TO THE REPORTER, HSG WAS A LITTLE UNCLEAR. THE PROXIMAL MARKER APPEARED TO HAVE SEPARATED APPROXIMATELY 4 MM FROM THE REST OF THE DEVICE. CONTRAST WAS SEEN WITHIN LEFT PROXIMAL TUBE TO MIDPOINT OF DEVICE, HOWEVER DID NOT EXTEND TO DISTAL PORTION OF DEVICE. SPILLAGES FROM EITHER TUBE WERE NOT SEEN. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. ON (B)(6) 2014 AN ESSURE WAS INSERTED. THE PHYSICIAN SAID THAT PROCEDURE WAS UNCOMPLICATED; SAW TRAILING COILS, NO RESISTANCE. ON (B)(6) 2014 HSG WAS PERFORMED AND SHOWED THAT 1 TUBE-DEVICE LOOKS NORMAL. OTHER SIDE DEVICE LOOKS LIKE A U SHAPE. THE RIGHT SIDE LOOKED OK AND HAD NO SPILLAGE. THE LEFT-PROX MARKER OF LEFT COIL DEVICE WAS SEPARATED BY THE REST OF THE DEVICE BY ABOUT 4 MM. SMALL AMOUNT OF CONTRAST WAS EXTENDED TO MID COIL NONE BEYOND THE DISTAL END OF THE COIL. THERE WAS NO EVIDENCE OF INTRAPERITONEAL SPILL FROM TUBE. SHE WAS CONCERNED OF A POTENTIAL PERFORATION. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 16-JUL-2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: IN MANY HSG IMAGES, ONLY THE RADIOPAQUE MARKERS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037368		7/21/2014	7/25/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE BIRTH CONTROL. PROBLEMS FROM THE BEGINNING. IN AFFECTIVE BC STILL GOT PREGNANT 1 1/2 YEARS LATER. I HAVE HAD SEVERE PAIN. THE COILS HAVE BEEN MISSING UNTIL RECENTLY AND I AM HAVING A TOTAL HYSTERECTOMY SOON. I HAVE HAD GASTRITIS THAT WILL NEVER END AND HEADACHES AND SKIN RASHES THAT I BLAME ALL ON THE NICKLE CONTENT AND THE FOREIGN IMPLANTATION OF THESE COILS. WHEN FOUND RECENTLY THEY WERE PROTRUDING THROUGH MY MYOMETRIUM OF MY UTERINE WALL. THE PAIN IS UNBEARABLE. MAJOR SURGERY TO CORRECT A MINIMAL PROCEDURE. PLEASE STOP THIS DEVICE FROM RUINING MORE LIVES!.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037375		7/21/2014	7/25/2014

Event Information:

Event Date (B3): 3/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): A20063

Single Use:
Implant Date (E6): 3/21/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2014 AND I HAVE BEEN HAVING HAIR LOSS, BACK ACHES, CRAMPING, INABILITY TO LOSE WEIGHT, INSOMNIA, MUSCLE WEAKNESS, AND NO SEX DRIVE. I AM SCHEDULED TO GET IT REMOVED (B)(6), 2014. ESSURE IS TOTAL HELL AND NEEDS TO BE TAKEN OFF THE MARKET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037376	CONCEPTUS / BAYER	7/21/2014	7/25/2014

Event Information:

Event Date (B3): 6/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 6/21/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) OF 2013 AND SINCE THIS PROCEDURE. I HAVE BEEN IN CONSTANT PAIN STEMMING FROM SEVERE, DEBILITATING PAIN ON MY LEFT HIP/PELVIC AREA, IRREGULAR PERIODS, DIZZINESS, CRAMPING, LOSS OF APPETITE AND BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037439		7/23/2014	7/29/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAVE HAD THE ESSURE IMPLANTED I'VE BEEN HAVING MAJOR HEADACHES, MOOD SWINGS AND PELVIC PAINS. MY PERIODS LAST ANYWHERE FROM 1 WEEK TO 3 WEEKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037442	BAYER	7/23/2014	7/29/2014

Event Information:

Event Date (B3): 7/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2008. DURING THE IMPLANTATION, ONE OF THE COILS BROKE, THE DOCTOR WAS ABLE TO RETRIEVE IT, AND INSERT ANOTHER ONE. IMMEDIATELY FOLLOWING THE PROCEDURE, I BECAME VERY LIGHTHEADED, ALMOST PASSED OUT, AND MY BLOOD PRESSURE SPIKED. SHORTLY AFTER, I STARTED HAVING LEFT SIDE PELVIC PAIN WHICH I REPORTED TO MY GYNECOLOGIST, AND WAS TOLD IT WAS NORMAL. PAIN HAS SINCE PROGRESSED INTO LEFT SIDE PELVIC PAIN, BACK PAIN, HIP PAIN, AND PAIN GOING DOWN MY LEFT LEG TO THE KNEE AND SOMETIMES FOOT. I EXPERIENCE CONSTANT MUSCLE SPASMS IN THESE AREAS AS WELL, CAUSING A SIGNIFICANT AMOUNT OF PAIN. SINCE HAVING THE IMPLANTS, I AM NORMALLY BLOATED AROUND THE MIDSECTION. THIS BLOATING CAN DISAPPEAR FOR A FEW DAYS, AND RETURN WITHIN A DAY SO IT'S NOT WEIGHT GAIN. MY PERIODS HAVE BEEN IRREGULAR, AND I HAVE EXPERIENCED FATIGUE DUE TO HYPOTHYROIDISM DIAGNOSED AFTER ESSURE COILS WERE IMPLANTED. I HAVE HAD SEVERAL IMAGING TESTS, NONE OF WHICH CAN PINPOINT A SOURCE OF THE PAIN. I HAVE HAD THREE CORTISONE SHOTS TO TRY TO DIAGNOSE AND RELIEVE PAIN, ALL UNSUCCESSFUL. I AM HAVING COILS REMOVED ON (B)(6), 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037444	BAYER	7/23/2014	7/29/2014

Event Information:

Event Date (B3): 11/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 11/15/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT WAS RECOMMENDED BY A DOCTOR AFTER GIVING BIRTH TO MY LAST SON, THAT I NEEDED A TUBAL LIGATION BECAUSE OF MY HEALTH ISSUES. I'VE HAD TWO BLADDER REPAIRS AND MY UTERUS WAS CLOSE TO RUPTURING DURING DELIVERY. THE DOCTOR TOLD ME I WASN'T ABLE TO HAVE ANY MORE CHILDREN. I HAD THE ESSURE PLACEMENT IN (B)(6) 2013, AND THE CONFIRMATION IN (B)(6) 2014. I AM CURRENTLY PREGNANT. IT WASN'T EVEN 3 MONTHS AFTER THE DOCTOR AND RADIOLOGIST BOTH CONFIRMED MY BLOCKAGE. I NOW HAVE TO GO TO (B)(6) FOR CLOSER OBSERVATION DUE TO BEING CONSIDERED HIGH RISK.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00264	BAYER HEALTHCARE LLC	7/23/2014	8/8/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A45104

Single Use: Y
Implant Date (E6): 12/14/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(6)2014 WITH REQUEST FOR SUPPORT TO REMOVE THE ESSURE. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED LOTS OF HEALTH PROBLEMS, THEY (ESSURE) ARE KILLING HER FROM THE INSIDE OUT. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. CONSUMER HAD NOT HAD AN ACCIDENT AND HAD NOT GOT HURT IN THE PAST. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. CONSUMER REPORTED SHE IS HAVING LOTS OF HEALTH PROBLEMS. HER DOCTORS KEEP ASKING HER IF SHE GOT IN AN ACCIDENT OR GOT HURT. NOTHING HAD HAPPENED TO HER EXCEPT BEING INSERTED WITH ESSURE. CONSUMER ASKED TO GET SUPPORT TO GET THE ESSURE OUT SINCE THEY ARE KILLING HER FROM THE INSIDE OUT. NO FURTHER DETAILS WERE REPORTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 24-DEC-2014. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOLLOW-UP COMPLAINT OPENED SINCE LOT NUMBER WAS RECEIVED. LOT NUMBER A45104 IS A VALID LOT NUMBER. MFR DATE: 08/2012 EXP DATE: 08/2015. BLEEDING IS THE PROCESS O

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037462	BAYER	7/24/2014	7/30/2014

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 10/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED ESSURE IMPLANT DEVICES IN MY FALLOPIAN TUBES IN (B)(6) 2012. I AM NOW EXPERIENCING SEVERE PELVIC PAIN AND INFLAMMATION IN THE EXACT LOCATION OF THE INSERTS, AND STABBING PELVIC PAIN ON THE LEFT SIDE. I WILL SEE MY GYNECOLOGIST ABOUT ESSURE REMOVAL ON (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037463	BAYER	7/24/2014	7/30/2014

Event Information:

Event Date (B3): 8/26/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/26/2009
Explant Date (E7): 6/24/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE SEVERAL YEARS AGO, AND FROM THE MOMENT I WOKE UP AFTER SURGERY I WAS IN PAIN. MY PELVIC/ABDOMINAL PAIN GREW WORSE AND WORSE. I ULTIMATELY HAD TO HAVE A HYSTERECTOMY, REMOVING BOTH FALLOPIAN TUBES THAT CONTAINED THE ESSURE COILS ON (B)(6) 2014 IN (B)(6). I HAD HORRIBLE PELVIC PAIN, ABDOMINAL CRAMPING, PAIN IN MY UPPER THIGHS, BACK PAIN, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00298	BAYER HEALTHCARE LLC	7/24/2014	8/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED DEBILITATING PAIN. IN 2008 THE CONSUMER HAD ESSURE INSERTED. CONSUMER STATED ON A TELEVISION PROGRAM THAT THE PAIN SHE WAS FEELING WAS DEBILITATING FOR THREE YEARS UNTIL SHE HAD A HYSTERECTOMY AND ESSURE HARDWARE WAS REMOVED. THE PAIN WREAKED HAVOC ON HER MARRIAGE AND STOPPED HER FROM RIDING HORSES COMPETITIVELY. SHE STATED THAT SHE NEVER FELT DISCRIMINATED AGAINST LIKE SHE HAD WITH THIS PROBLEMS WITH ESSURE. CONSUMER REPORTED THAT HER PHYSICIAN PRESSURED HER TO HAVE IT INSTALLED; WHEN SHE COMPLAINED ABOUT THE PAIN HE TOLD HER THAT SHE WAS SILLY LITTLE WOMAN, THAT SHE WAS HORMONAL. NO FURTHER INFORMATION PROVIDED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT TIS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PITC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNE

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Report Type: MANUFACTURER **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00299	BAYER HEALTHCARE LLC	7/24/2014	8/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FORM A SOCIAL MEDIA (WEBSITE) IN UNITED STATES ON (B)(6)-2104 WHICH REFERS TO A BABY OF UNSPECIFIED AGE WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERO AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. THE MOTHER HAD THE ESSURE PROCEDURE AND SHE ENDED UP GETTING PREGNANT. SHE COULDN'T HAVE ESSURE REMOVED AND IN THE 25TH WEEK OF THE PREGNANCY IT BROKE AND MIGRATED, PERFORATING THE AMNIOTIC FLUID. THE CHILD DIDN'T MAKE IT. THE LINKED MOTHER'S CASE IS (B)(4). PTC INVESTIGATION RESULTS WAS RECEIVED ON (B)(6)-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR THE INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. NO INFORMATION ABOUT THE EXACT CAUSE OF CHILD DEATH WAS

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PROVIDED (PREMATURITY, INFECTION); HOWEVER GIVEN THE GESTATION AGE AT EVENT OCCURRENCE A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THE REPORTED EVENT WAS, THEREFORE CONSIDERED AS RELATED TO THE SUSPECT INSERT. FOLLOW-UP INFORMATION CANNOT BE OBTAINED SINCE THIS IS A SOCIAL MEDIA CASE. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A SOCIAL MEDIA (WEBSITE) AND REFERS TO A BABY WHO HAD ESSURE MICRO-INSERT EXPOSURE IN UTERO AND IN THE 25TH WEEKS OF MOTHER'S PREGNANCY THE CHILD DIDN'T MAKE IT. REPORTER'S CAUSALITY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00300	BAYER HEALTHCARE LLC	7/24/2014	8/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 869756

Single Use: Y
Implant Date (E6): 12/19/2011
Explant Date (E7): 3/11/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(6)2014. THE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PELVIC PAIN AND FLUID AND CYSTS IN THE TUBE WERE FOUND. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. CONSUMER WAS NO PREGNANT. IN (B)(6) 2011, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 869756, IMPLANTED FOR CONTRACEPTION. CONSUMER REPORTED IN (B)(6) 2013 SHE STARTED HAVING PELVIC PAIN REALLY BAD. THEY THOUGHT IT MIGHT BE HER APPENDIX BUT THEY COULD NOT FIND ANYTHING SO THEY REFERRED HER BACK TO HER GYNECOLOGIST. HE SAID SHE HAD FLUID AND CYSTS IN HER TUBE AND HE TOLD HER SHE NEEDED TO HAVE HER TUBES AND COILS TAKEN OUT. HE MENTIONED USING CAUTERIZATION DURING THE REMOVAL PROCESS. REPORTED DID NOT ASSESS THE DEVICE-EVENT RELATIONSHIP.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION WAS RECEIVED ON (B)(4) 2014. CONSUMER HAS SCHEDULED SURGERY TO REMOVE THE ESSURE AND TUBES ON (B)(4) 2014. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP RECEIVED ON (B)(4) 2014: NEW REPORTERS ADDED. FOLLOW UP (B)(4) 2014: NO RESPONS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00303	BAYER HEALTHCARE LLC	7/24/2014	8/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B717262

Single Use: Y
Implant Date (E6): 3/14/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF (B)(6) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. GYNECOLOGIST REPORTED THAT ON (B)(6) 2014 SHE DID AN ESSURE INSERTION IN A PATIENT WITHOUT PROBLEMS DURING THE PROCEDURE AND THE COILS FILLED RIGHT IN. LAST WEEK, IN (B)(6) 2014 THE HSG (HYSTEROSALPINGOGRAM) SHOWED THE LEFT WAS OCCLUDED AND IN THE RIGHT LOCATION, THE RIGHT SHOWED THE SPRING WAS FLOATING IN THE LEFT UPPER QUADRANT OF PELVIS AND THERE WAS SPILLAGE. ON (B)(6) 2014 THE PHYSICIAN DID A LAPAROSCOPIC TUBAL AND COULD NOT FIND THE COIL BUT THE DOCTOR COULD NOT FIND IT WITH A LAPAROSCOPE. DOCTOR WOULD LIKE TO KNOW IF SHOULD DO ANYTHING ELSE. FOLLOW UP INFORMATION RECEIVED ON 27-JUN-2014: PHYSICIAN DID LAP ON RIGHT TUBE. PATIENT IS ASYMPTOMATIC. NO FURTHER INFORMATION PROVIDED. FOLLOW-UP FROM 09-JUNE-2014 AND 10-JUNE-2014: FOLLOW UP RECEIVED FROM SALES REPRESENTATIVE, BUT NO NEW INFORMATION WAS PROVIDED. NEW REPORTER WAS ADDED. THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF (B)(6) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE RIGHT SHOWED THE SPRING WAS FLOATING IN THE LEFT UPPER QUADRANT OF PELVIS AND I COULD NOT FIND THE COIL WITH THE LAPAROSCOPE. THE RIGHT SHOWED THE SPRING WAS FLOATING IN THE LEFT UPPER QUADRANT OF PELVIS IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENT IS CONSIDERED NON-SERIOUS. THE RIGHT SHOWED THE SPRING WAS FLOATING IN THE LEFT UPPER QUADRANT OF PELVIS

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ASSUMED AS DEVICE DISLOCATION CAN OCCUR AFTER INSERTION OF AN IUD. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT THE HSG (HYSTEROSALPINGOGRAM) SHOWED THE LEFT WAS OCCLUDED AND IN THE RIGHT LOCATION, THE RIGHT SHOWED THE SPRING WAS FLOATING IN THE LEFT UPPER QUADRANT OF PELVIS AND THERE WAS SPILLAGE. THE PHYSICIAN DID A LAPAROSCOPIC TUBAL AND COULD NOT FIND THE COIL. THEY HAD THE FLUOROSCOPY AND COULD SEE THE COIL BUT THE DOCTOR COULD NOT FIND IT WITH THE LAPAROSCOPE. DUE TO LAPAROSCOPIC PROCEDURE MADE THIS CASE WAS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION AND DUE TO LACK OF AN ALTERNATIVE EXPLANATION THE EVENTS WERE CONSIDERED RELATED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) THERAPY. PTC ANALYSIS WILL BE REQUEST.

Manufacturer Narrative (H10):

FOLLOW UP 21.JUL.2014: FOLLOW UP INFORMATION RECEIVED FROM THE PHYSICIAN. NO PREVIOUS GYNECOLOGICAL INTERVENTIONS OR PROBLEMS. NO OTHER RELEVANT MEDICAL HISTORY. PATIENT'S HISTORICAL CONDITIONS INCLUDED GRAVIDA 3, ONE SPONTANEOUS ABORTION, ONE ELECTIVE AB

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00306	BAYER HEALTHCARE LLC	7/24/2014	8/8/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FORM A CONSUMER IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE GENERIC ACTIVE ONLINE LISTENING. CONSUMER STATED THAT SHE WAS SUBMITTED TO A LAVH (INTERPRETED AS LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY) WITH TUBE REMOVAL ON (B)(6) (YEAR NOT PROVIDED) AND CAME HOME ON THE NEXT DAY. SHE PRESENTED CHRONIC PELVIS PAIN AND ESSURE CAUSED THE SURGERY. OVERALL SHE WAS FEELING FINE (SORE SOMEWHAT). NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT; REFERS TO A FEMALE SUBJECT WHO WAS INVOLVED IN ESSURE ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIS PAIN. THIS EVENT WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING OT THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT THE SUBJECT HAD CHRONIC PELVIS PAIN AND WAS SUBMITTED TO A HYSTERECTOMY WITH TUBE REMOVAL. SHE WAS FEELING FINE WITH SORE SOMEWHAT AFTER THIS SURGICAL PROCEDURE. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE; A CAUSAL RELATIONSHIP BETWEEN CHRONIC PELVIC PAIN AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE OT THE REQUIRED INTERVENTION THIS EVENT WAS REGARDED AS AN INCIDENT. IN ADDITION THE NON-SERIOUS EVENT SORE SOMEWHAT WAS REPORTED. NO FOLLOW UP WILL BE PURSUED SINCE THIS IS A SOCIAL MEDIA CASE. A PRODUCT TECHNICAL ANALYSIS WILL BE SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 12-AUG-2014: PTC RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPI

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00297	BAYER HEALTHCARE, LLC	7/24/2014	8/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B06097

Single Use: Y
Implant Date (E6): 2/14/2014
Explant Date (E7): 3/5/2014
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/14/2014

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2014, WHICH REFERS TO A FEMALE PATIENT OF AN UNSPECIFIED AGE, WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4), HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. ON (B)(6) 2014, IT WAS ALSO PROVIDED WITH THE INITIAL REPORT THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS PERFORMED ON (B)(6) 2014 (INITIAL COMPLAINT WAS A PTC ONLY) REGARDING THE ESSURE LOT NUMBER B06097 AND A SAMPLE OF THE ESSURE INVOLVED IN THIS COMPLAINT. STUDY DESCRIPTION: ESSURE GENERIC REIMBURSEMENT PROGRAM. ESSURE LOT NUMBER USED B06097. THIS GYNECOLOGIST ASKED FOR A REPLACING ESSURE BECAUSE THE ESSURE DID NOT UNBLOCK. GYNECOLOGIST EXPLAINED THAT HE THOUGHT THE ESSURE LET GO WHEN PRESSING THE BUTTON, BUT THIS WAS NOT THE CASE WHEN IT STRETCHED OUT AND BROKE OFF. A COUPLE COILS REMAINED BEHIND, BUT ACCORDING TO THE GYNECOLOGIST, THESE FELL OFF THE PATIENT ON ITS OWN. GYNECOLOGIST WAS NOT SURE, BUT ACCORDING TO HIM, REPLACEMENT HAS ALREADY BEEN PERFORMED BY ANOTHER PHYSICIAN. PTC - TECHNICAL ASSESSMENT: JUSTIFICATION: UNCONFIRMED QUALITY DEFECT. FINAL ASSESSMENT: INSPECTION RESULTS: LARGE TIGHT PITCH COIL WAS STRETCHED AND BROKEN. ALL IFU STEPS WERE COMPLETED. LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. FINAL RISK CLASSIFICATION: RISK CATEGORY IV. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE ESSURE DID NOT UNBLOCK AND STRETCHED OUT AND BROKE OFF AND A COUPLE REMAINED BEHIND AND FELL OFF THE PATIENT ON ITS OWN. REPORTER CAUSALITY WAS NOT PROVIDED. THE REPORTED

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EVENTS, INTERPRETED AS A DEPLOYMENT ISSUE, HANDLING ISSUE (STRETCHED), DEVICE BREAKAGE AND EXPULSION (COILS FELL OFF) ARE NON-SERIOUS, LISTED ON THE REFERENCE SAFE INFORMATION FOR ESSURE AND WERE CONSIDERED NON-INCIDENTS, WITH EXCEPTION OF THE REPORTED BREAKAGE WHICH IS UNLISTED AND WAS CONSIDERED A NEAR-INCIDENT, ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. SINGLE CASE OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES DURING THE INSERT DEPLOYMENT (IT DID NOT UNBLOCK), ESSURE STRETCHED OUT AND BROKE OFF; AND THE COILS THAT REMAINED, FELL OFF THE PATIENT. CONSIDERING THAT THESE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, THEIR CASAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. FOLLOW-UP INFORMATION IS BEING SOUGHT. A PRODUCT TECHNICAL COMPLAINT ANALYSIS WAS PREVIOUSLY PERFORMED (DUE TO INITIAL COMPLAINT OF PROBLEMS WITH INSERT AND INTRODUCER) AND WAS UNABLE TO CONFIRM THE COMPLAINT, FURTHER PTC ANALYSIS (TO ASSESS THE REPORTED EVENTS) IS BEING SOUGHT.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00302	BAYER HEALTHCARE LLC	7/24/2014	8/19/2014

Event Information:

Event Date (B3): 6/25/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26941; B85139

Single Use: Y
Implant Date (E6): 6/25/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014, WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED THE FOLLOWING EVENTS. NO INFORMATION GIVEN ON PT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014, THE PT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER C26941 AND B85139. DURING THAT INSERTION PROCEDURE, ON ONE SIDE, PLACEMENT OF ESSURE SYSTEM, LOT NUMBER (C26941) WAS DONE AND SYSTEM WAS RELEASED, BUT AFTER THE CONTROL, THE ESSURE SYSTEM CAME OUT OF THE FALLOPIAN TUBE. AT THE REMOVAL, THE PHYSICIAN SAW THAT ESSURE SYSTEM WAS BROKEN. HE USED A PLIER TO REMOVE THE MISSING PART OF ESSURE SYSTEM. THE PT EXPERIENCED PAIN AND BLEEDING. ANOTHER ESSURE SYSTEM WAS PLACED. ON THE SECOND SIDE, PLACEMENT OF ESSURE SYSTEM, LOT NUMBER (B85139), TUBAL OSTIUM WAS TORTUOUS AND THE ESSURE SYSTEM WAS TWISTED. THE SYSTEM WAS NOT RELEASED AND REMOVED. ANOTHER ESSURE SYSTEM WAS PLACED. AT THE END, FOLLOWING THESE 2 FAILURES, 2 ESSURE SYSTEMS WERE WELL PLACED. THE OUTCOME OF THE REPORTED EVENTS WAS UNK. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE WAS NOT REPORTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW-UP RECEIVED ON 22-JUL-2014: INTRODUCTION OF BETTOCCHI HYSTEROSCOPY WITHOUT PARTICULAR INCIDENT. UTERINE CAVITY WAS VERY THICK WITH FLAPS WHICH PREVENT FROM HAVING A GOOD VISUALIZATION. CIRCULAR HEMORRHAGE WAS OBSERVED (PREVIOUSLY REPORTED BLEEDING

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00304	BAYER HEALTHCARE LLC	7/24/2014	8/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26940

Single Use: Y
Implant Date (E6): 6/17/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/15/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH PROFESSIONAL IN (B)(6) ON (B)(6) 2014, WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ATTEMPTED AND EXPERIENCED BREAK OF THE COIL, THREAD NOT RELEASED, COMPLICATION OF DEVICE INSERTION, AND FAILED INSERTION. ON (B)(6) 2014, THE PRACTITIONER MET A PROBLEM AT THE TIME OF THE RELEASE AND THE REMOVAL OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT): BREAK OF THE COIL, THREAD NOT RELEASED AND SYSTEM REMOVED WITH BIOPSY PLIERS. USE OF A SECOND ESSURE SYSTEM.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 23-JUL-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK" IS US

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00305	BAYER HEALTHCARE LLC	7/24/2014	8/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B34603

Single Use: Y
Implant Date (E6): 1/14/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014, WHICH REFERS TO A FEMALE PT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HSG CONFIRMATION TEST SHOWED THAT ONE COIL HAD BROKEN INTO THREE DIFFERENT PIECES. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 07/07/2014: PT INFORMATION WAS UPDATED; DATE OF BIRTH, WEIGHT AND HEIGHT WERE ADDED. THE PT HAD NO PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES. PHYSICIAN REPORTED THAT THE PT HAD CHRONIC BACK PAIN/SCIATICA. ON (B)(6) 2014, ESSURE ESS305 WAS INSERTED; THE LOT NUMBER USED WAS B34603. THE PT WAS NOT POSTPARTUM AT TIME OF INSERTION. DURING THE INSERTION PROCEDURE, PHYSICIAN USED CERVICAL DILATATION, SOUNDING AND CONSCIOUS SEDATION (MAC). PHYSICIAN REPORTED THAT IT WAS DIFFICULT TO VISUALIZE THE LEFT OSTIA DUE TO ENDOMETRIUM AND CLOT; BUT ESSURE WAS INSERTED EASILY ONCE THE OSTIA IDENTIFIED. NO FLUID LOSS WAS OBSERVED AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. ON (B)(6) 2014, HSG WAS DONE AND SHOWED ABNORMAL APPEARING OF ESSURE COIL SUGGESTING SEPARATION OF COMPONENTS. THE LEFT FALLOPIAN TUBE WAS PATENT. NO PERFORATION WAS NOTED. PT WAS ON DEPO-PROVERA AS BACK-UP CONTRACEPTION; SHE WILL CONTINUE WITH TREATMENT UNTIL LAP TUBAL BE PERFORMED IF THE PT DESIRES. NO OTHER SYMPTOMS ASSOCIATED. NO OTHER RELATED DIAGNOSTIC TESTS WERE PERFORMED. NO HOSPITALIZATION WAS REQUIRED. PHYSICIAN RELATED THE EVENT WITH ESSURE DEVICES. AT THE TIME OF THE REPORT, ESSURE DEVICES WERE NOT REMOVED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 22-JUL-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: A HYSTEROSALPINGOGRAM (HSG) IS AN X-RAY TEST THA

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	7/24/2014	8/21/2014

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4): 7/24/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6): 7/1/2014
Explant Date (E7): 7/1/2014
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

COIL FAILED TO DEPLOY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037387	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 3/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONLY A COUPLE MONTHS OF HAVING ESSURE I STARTED DEALING WITH HEADACHES, DIZZINESS, FATIGUE, AND HEAVY BLEEDING. SINCE THEN THESE HEADACHES WON'T JUST GO AWAY THEY ARE CONSTANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037388	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 5/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WENT TO ER IN EXCRUCIATING PAIN. CT SCAN SHOWED MULTIPLE LARGE CYSTS AND FIBROIDS IN UTERUS. ESSURE COILS MISPLACED IN UTERUS. VISITED SURGEON AND HE FOUND A MASS AND BIOPSIED. I AM NOW DIAGNOSED WITH LARGE B CELL LYMPHOMA. IT HAS SOLELY HOUSED ITSELF IN MY UTERUS. CHEMOTHERAPY TREATMENT BEGINS ON (B)(6). 126 DAYS OF TREAT. COILS STILL MISPLACED IN UTERUS AND WILL BE ADDRESSED ONCE CANCER TREATMENT IS COMPLETE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037389	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 4/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INITIALLY AFTER PLACEMENT IN 2008 I EXPERIENCED MILD CRAMPING AND LIGHT BLEEDING THAT WENT AWAY. I WENT IN FOR 3 MONTH VERIFICATION OF SUCCESS CHECKUP AND THINGS WERE STILL A LITTLE ACHY BUT NOT TOO BAD. WITHIN THE NEXT 2/3 MONTHS, MY PERIODS CHANGED FROM 3 DAYS OF LIGHT BLEEDING TO 7/10 DAYS OF VERY HEAVY AND EXTREMELY PAINFUL ONES. IT WAS LIKE LABOR PAINS AS MY UTERUS WAS CONTRACTING EVERY 3/5 MINUTES FOR THE ENTIRE FIRST 36 HOURS OF MY PERIOD EVERY MONTH. I HAD NEVER EXPERIENCED PAIN AS SUCH OUTSIDE OF ACTUAL CHILDBIRTH HAVING MY THREE CHILDREN. MULTIPLE TRIPS TO OB/GYN AND THE ER I WAS PRESCRIBED NARCOTICS WITHOUT BEING TOLD WHAT THE PROBLEM WAS AND A FEW TIMES TOLD THAT IT WAS PID THOUGH ALL TESTS WERE NEGATIVE AND I HAD NOT BEEN SEXUALLY ACTIVE SINCE MONTHS PRIOR TO THE PLACEMENT OF THE ESSURE A YEAR PRIOR. IN 2010, I EVENTUALLY SAID ENOUGH IS ENOUGH AND SCHEDULED AN APPOINTMENT TO DISCUSS THE ESSURE POSSIBLY CAUSING ALL THE PAIN SINCE THERE WERE NO PREVIOUS ISSUES PRIOR TO PLACEMENT. AT THAT APPOINTMENT I WAS TOLD I HAD ENDOMETRIOSIS WITH WITHOUT TESTS, LAPAROSCOPIC CONFIRMATION, OR HISTORY OF ENDOMETRIOSIS. I WAS THEN TOLD I HAD TO EITHER CHOSE A TOTAL HYSTERECTOMY OR TRY HORMONE THERAPY TO TREAT THE PAIN. I CHOSE THE HORMONE THERAPY AS I WAS (B)(6) NEVER MARRIED AND DID NOT FEEL AS THOUGH A TOTAL HYSTERECTOMY WAS WARRANTED OR SHOULD HAVE BEEN DEEMED MY ONLY OPTION. WHILE ON THE HORMONE THERAPY, I WENT FROM (B)(6) LBS TO AN EXCESS OF (B)(6) LBS IN ABOUT 3 MONTHS. I WAS DEEPLY DEPRESSED AND UTTERLY DISGUISED WITH MY APPEARANCE AND MY BODY, EXCERISE AND DIETING DID NOTHING TO HELP. BEING ON ACTIVE DUTY, I EVEN FAILED THE PHYSICAL READINESS TEST WHICH DIRECTLY AFFECTS MY CAREER. I WAS DOWN AND OUT AND SCHEDULED ANOTHER APPOINTMENT TO DEMAND A LAPAROSCOPY TO VERIFY IF IN FACT I ACTUALLY HAD

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ENDOMETRIOSIS BEFORE I WOULD AGREE TO SUBJECTING MY BODY THROUGH ANY OTHER SERIES OF HORMONE THERAPY. THE LAPAROSCOPY WAS SCHEDULED AND WOULD YOU BELIEVE THAT EVERYTHING LOOKED PICTURE PERFECT AND NO SIGNS OF ENDOMETRIOSIS WERE FOUND ANYWHERE BUT THERE WERE TWO LARGE BLUE VEINS FOUND ON THE FRONT AND TOP OF THE UTERUS THAT WAS RATHER ODD. INSTEAD OF ADMITTING THAT THEY DID NOT KNOW HOW TO REMOVE THE ESSURE THAT HAD BEEN THE CAUSE OF ALL MY PAIN, THEY SAID THE ENDOMETRIOSIS WAS MORE THAN LIKELY MICROSCOPIC. I INFORMED THE PROVIDER THAT I RESEACHED SURGEONS THAT PERFORM ESSURE REMOVALS OUT IN TOWN DURING MT RECOVERY, HE IMMEDIATELY TOLD ME IF I WENT OUT IN TOWN AND HAD THEM REMOVED HE WOULD HAVE ME SENT TO CAPTAINS MAST FOR DISOBEYING A LAWFUL ORDER. I THEN TOLD HIM I WANTED A SECOND OPINION IN WHICH HE STATED HE WAS MY SECOND OPINION AND THAT WAS ALL THEY WERE GOING TO DO FOR ME AT THAT POINT UNLESS I WANTED A TOTAL HYSTERECTOMY. I LEFT FEELING OVERWHELMED, DEPRESSED AND DEFEATED. IN 2012, THE MOST AMAZING URO-GYNECOLOGIST BEGAN WORKING AT THAT SAME HOSPITAL AND DURING CASUAL CONVERSATION WITH ONE OF HIS SURGICAL TECHNOLOGIST AND DEAR FRIEND OF MINE, HE WAS MADE AWARE OF MY CASE. HE DECIDED TO TAKE A LOOK AT EVERYTHING AND WANTED TO TALK WITH ME TO GET A GOOD HISTORY OF EVERYTHING THAT HAD GONE ON. AFTER OUR CONVERSATION HE STATED HE WOULD LOOK AT THE MEDICAL DOCUMENTS AND IF HE FOUND ANYTHING HE WOULD LET ME KNOW AND IT MAY BE AT LEAST A MONTH BEFORE I HEARD ANYTHING BACK FROM HIM. I THANKED HIM FOR TAKING THE TIME OUT TO LISTEN AND LOOK INTO MY FILES. LESS THAN TWO WEEKS LATER, I RECEIVED A CALL FROM HIS NURSE STATING SHE WANTED TO SCHEDULE A APPOINTMENT FOR ME TO COME IN AS THE SURGEON WOULD LIKE TO SEE ME. AT MY APPOINTMENT, THE SURGEON CAME IN AND TOLD ME, IT WAS THE ESSURE THAT WAS CAUSING ALL THE PAIN AND HE WOULD LIKE TO REMOVE THEM; I WAS ECSTATIC! THREE WEEKS LATER USING THE DAVINCI ROBOT, HE REMOVED THE COILS, BILATERAL TUBES AND PERFORMED A PARTIAL UTERINE RESECTION DUE TO ONE OF THE COILS BEING IMBEDDED IN THE UTERINE WALL. AFTER RECOVERY, FIVE YEARS OF AGONIZING PAIN WAS OVER! NOT ONLY AM I ALLERGIC TO MORPHINE BUT I HAVE A ALLERGY TO NICKEL WHICH IS A METAL USED IN THE COILS THAT I WAS NEVER TESTED OR TOLD ABOUT BY THE OB/GYN SURGEON THAT PLACED THEM. ALL DOCUMENTS AND LABS ARE AVAILABLE UPON OFFICIAL REQUEST. THANK YOU AND I HOPE THIS ISSUE IS NOT TAKEN LIGHTLY AND MAY POSSIBLY BE USED TO HELP SOMEONE ELSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037390	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 11/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DURING ESSURE PLACEMENT MY BP ELEVATED TO 180/120 AND I DEVELOPED A RASH ACROSS MY CHEST. MY BP REMAINED ELEVATED FOR SEVERAL HOURS AFTER THE PROCEDURE. STARTING SHORTLY AFTER THE PROCEDURE I WOULD RANDOMLY BREAK OUT INTO THE SAME RASH THAT I DEVELOPED DURING THE PROCEDURE. I HAVE SINCE DEVELOPED MULTIPLE CHEMICAL SENSITIVITIES. I HAVE A NICKEL ALLERGY AND THIMERSOL ALLERGY. I ALSO NOW GET EXTREMELY BLOATED TO THE POINT OF LOOKING 5 OR 6 MONTHS PREGNANT. I HAD MODERATE PAIN ON MY LEFT SIDE AS WELL. I HAD THE ESSURE COILS REMOVED LAPAROSCOPICALLY ON (B)(6), 2014. SOME OF THE RASH HAS IMPROVED, BUT I AM LEFT WITH MULTIPLE SENSITIVITIES TO CHEMICALS AND FOODS. THE PAIN ON MY LEFT SIDE HAS IMPROVED AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037391	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING SEVERE SHARP PAINS IN MY PELVIC REGION, LOWER BACK PAIN, ALONG WITH DIZZINESS AND FATIGUE. I HAVE FINALLY HAD A DOCTOR WHO SENT ME FOR AN ULTRASOUND AND IT SHOWS THAT COILS HAVE MOVED AND ARE NO LONG IN THE CORRECT POSITION AND ARE THE REASON FOR THE ISSUES THAT I AM HAVING. I AM CURRENTLY WAITING FOR A SCHEDULE DATE FOR A SURGERY TO REMOVE THE COILS AND POSSIBLE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037392	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM A COMPLETELY DIFFERENT PERSON SINCE I HAD THE COILS PUT IN. I AM VERY MOODY HAVE NO MOTIVATION FOR ANYTHING. NO INTEREST IN SEXUAL INTERCOURSE. MY PERIODS ARE SUPER HEAVY FILLED WITH BLOOD CLOTS THE SIZE OF QUARTERS TO GOLF BALL SIZE. I CAN'T LOOSE WEIGHT. CONSTANT HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037393	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, BRAIN FOG, TOOTH AND GUM ISSUES, HAIR LOSS, EXCESSIVE SLEEPINESS, PAINFUL INTERCOURSE, LOSS OF SEXUAL DESIRE, JOINT PAIN, LOSS OF SENSATION IN HANDS AND FEET, METAL TASTE IN MOUTH, CONSTANT FEELING OF HAVING THE FLU, UTERINE SPASMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037394	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIC REACTIONS START TO INCREASE. I AM NOW ON 6 ANTIHISTAMINES A DAY AND A MED FOR BREAKTHROUGH ISSUES. I HAVE DEVELOPED HEAD TO TOE HIVES OF UNKNOWN ORIGIN.. THEY AT TIMES CAUSE WHEEZING... PROBLEM IS I'M ALLERGIC TO EPINEPHRINE, THE MED GIVEN FOR ANAPHYLAXIS. IF MY CONDITION GETS TO THAT POINT (WHICH IT RAPIDLY IS), I HAVE NO RECOURSE OR MED I CAN TAKE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037395	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 8/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE (B)(6) 2012 FOR A PERMANENT BIRTH CONTROL. I IMMEDIATELY HAD EXCESSIVE BLEEDING, CRAMPING, RASH, BLOOD CLOTS AND UNCOMFORTABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037396	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, SEVERE BACK PAIN, EXCESSIVE BLEEDING, NIGHT SWEATS, STABBING PAIN, HEADACHE, SEVERE MOOD SWINGS, INSOMNIA, NUMBNESS IN HANDS AND FEET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037398	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 2/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE IMPLANTED (B)(6) 2011. AS SOON AS I GOT HOME I WAS IN A LOT OF PAIN AND SOON AFTER I STARTED MY CYCLE AND THE PAIN BECAME WORSE. I WAS IN SO MUCH PAIN I COULD BARELY MOVE AND THERE WAS A LOT OF PRESSURE. I CALLED THE DOCTOR AND THEY SAID THE PAIN WAS NORMAL. WHEN I WENT BACK FOR THE CONFIRMATION TEST THE ESSURE PRODUCT ON MY LEFT SIDE WAS NOT COMPLETELY POSITION INTO MY TUBES AND WAS HANGING OUT IN SOMEWHAT A UPSIDE DOWN L-SHAPE. THE DOCTOR THEN CONFIRM THE REASON FOR PAIN AND TOLD ME IT WAS FINE AND TO TAKE PAIN MEDICATION WHEN I START TO FEEL ANY PAIN. I ASKED HOW LONG WILL I HAVE THE PAIN SHE COULD NOT SAY ANYTHING OTHER THAN TAKE PAIN MEDICATION. SINCE THEN MY CYCLE HAVE BEEN ABNORMAL AND EXTREMELY PAINFUL STARTED TO HAVE SOME NEUROLOGICAL PROBLEMS SUCH AS HEADACHES, PANIC/ANXIETY ATTACKS, TINGLING SENSATION IN ARMS, HANDS, LEGS AND FEET. I WAS THEN PUT BACK ON BIRTH CONTROL PILLS TO SEE IF THE SYMPTOMS WOULD LEAVE THEY DID NOT ONLY GOTTEN WORSE. I NOW HAVE ALONG WITH THE OTHER SYMPTOMS I HAVE SEVERE BLOATING, HEARTBURN, BACK , NECK, SPINE PAIN, PAINFUL INTERCOURSE AND SOMETIMES SPOTTING AFTER INTERCOURSE, MILD HIGH BLOOD PRESSURE, WEIGHT GAIN UNABLE TO LOSE WEIGHT, FATIGUE, DENTAL PROBLEMS AND THE LIST GOES ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037399	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 10/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER ESSURE WAS IMPLANTED I BECAME ILL WITH FLU SYMPTOMS 24 HOURS LATER. I HAVE BEEN BLEEDING EVERYDAY SINCE IMPLANTATION AND HAVING HEADACHES, NUMBNESS IN ARMS AND LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037400	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 6/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, HEAVY PERIODS, FALLOPIAN TUBE CYSTS, LONG PERIODS, PAINFUL SEX, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037401	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 7/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE IN 2012 I EXPERIENCE BACK AND STOMACH PAIN. STOMACH HAS BLOATED AND HAVE HAD SEVERE PAIN THT HAS BEEN REHABILITATING. WENT TO THE DR AFTER COILS WERE IMPLANTED BUT SHE SAID THEY BOTH LOOKED FINE EVEN THOUGH ONE WAS PLACED HIGHER AND HAD BLEEDING FOR 4 MONTHS. EXPERIENCE DAILY PAIN IN ABDOMEN AND BACK SINCE THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037402	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I GOT ESSURE DONE, I HAVE HAD THE FOLLOWING PROBLEMS/SIDE EFFECTS.... I HAVE EXTREMELY HEAVY PERIODS THAT LAST 7-8 DAYS WITH CLOTTING. BEFORE ESSURE, I HAD LIGHTER PERIODS LASTING 4-5 DAYS. I HAVE BAD HEADACHE'S LASTING DAYS, I NEVER HAD HEADACHES LIKE THIS BEFORE ESSURE. I HAVE EXTREME BLOATING TO THE POINT WHERE I THOUGHT I WAS PREGNANT. I OFTEN EXPERIENCE FATIGUE. I HAVE HAD TWO EPISODES WHERE I WOKE UP AT NIGHT IN HEAVY SWEATS AND NAUSEA AND THREW UP THEN I WAS FINE THE NEXT DAY. SINCE ESSURE, MY EMOTIONS AND OVERALL SELF HAVE BEEN SO OUT OF WACK, IM JUST NOT THE SAME. I HAVE EXTREME CRAMPING DURING MY PERIOD THAT GOES FROM MY LOWER BACK TO THE MIDDLE OF MY LEGS (DULL PAIN). I ALSO GET SHARP PAINS IN THE FRONT OF MY PELVIS, THESE ARE SPASTIC AND HAPPEN WHEN IN NOT ON MY PERIOD AS WELL AS WHEN I AM. I HAVE RECENTLY BEEN EXPERIENCING DIZZY SPELLS AND LIGHT HEADEDNESS. ALL OF THESE SYMPTOMS HAVE ACCUSED SINCE I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2011. THE DATE OF MY ADVERSE EFFECTS IS (B)(6) 2011.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037403	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 4/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #(B)(4). I HAVE NOW BEEN CONFIRMED BY AN ALLERGIST THAT I AM ALLERGIC TO NICKEL . I HAD A 2+ REACTION ON THE TEST AND ALSO ALLERGIC NOW TO 2-BROMO. I HAVE BEEN TESTED FOR IC OF THE BLADDER AND WAITING RESULTS. I AM SCHEDULED NOW FOR A LAVH HYSTERECTOMY LEAVING OVARIES FOR HORMONE PRODUCTION ON (B)(6) 2014. I WILL POST BACK WITH IC RESULTS SOON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037404	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE DEVICE WAS IMPLANTED IN BOTH TUBES WITHOUT INCIDENT. DYE CONFORMATION TEST WAS NOT PREFORMED DUE TO COST AND 14 MONTHS LATER I BECAME PREGNANT. ALSO HAVE NOTICED RANDOM HIVES OF HANDS AND FEET THAT HAVE NO CAUSE AND HAVE AT TIMES REQUIRED MEDICATION. AND INABILITY TO LOOSE WEIGHT DESPITE WORKING OUT, DIET RESTRICTIONS, AND LIFE STYLE CHANGES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037405	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 3/27/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED (B)(6) 2009, MY REF# ((B)(4)), LOT#(628432). EVERY SINCE I HAD COMPLICATIONS SEVERE PELVIC PAIN, SHARP SIDE PAIN, LOWER BACK PAIN, WEIGHT GAIN, SEVERE HEADACHES THAT I'M NOW ON MEDICINE FOR, I NOW HAVE HIGH BLOOD PRESSURE WHICH I'M ON MEDICINE FOR, DIZZINESS, MENSTRUAL HEAVY BLEEDING, BLOOD CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037406	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY, PANIC, MUSCLE SPASMS, BLURRY VISION, TINNITUS, HEART PROBLEMS, CHEST PAIN, BREAST PAIN, VAGINAL PAIN, HAIR LOSS, PAINFUL INTERCOURSE, DISCHARGE, HEAVY BLEEDING, BIG CLOTS, HIGH BLOOD PRESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037407	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 7/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5037407 #(B)(4). HYSTERECTOMY (TVH) PREFORMED (B)(6) 2015. CHRONIC ENDOMETRITIS, FIBROUS SCARRING, AND CHRONIC INFLAMMATION NOTED ON PATHOLOGY REPORT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037408	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 6/10/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEPRESSION, ANXIETY, JOINT PAIN, SUPERFICIAL ULCERS, HYPO-THYROID AUTO IMMUNE DISEASE ,GALLBLADDER, ABDOMINAL BLOATING, VERY PAINFUL OVULATION, CHRONIC PELVIC PAIN, HEADACHES, VERY HEAVY PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037409	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 12/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS SITTING DOWN AND I WENT TO LAY DOWN IN MY BED AND WHEN I STRETCHED I HAD A VERY SHARP PAIN IN THE LOWER RIGHT SIDE OF MY ABDOMEN NEAR MY OVARY. SINCE THIS FIRST TIME, I HAVE HAD THIS ONGOING PROBLEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037410	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 7/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY ESSURE REMOVED SATURDAY (B)(6). I JUST HAD IT PUT IN WEDNESDAY (B)(6) AND HAVE HAD SO MANY COMPLICATIONS. FIRST I HAD IT DONE IN OFFICE NOT UNDER ANESTHESIA. HE NUMBED MY CERVIX WITH LIDOCAINE AND THEN DILATED MY CERVIX, WHICH I FELT EVERY MINUTE OF. WHEN THE DOCTOR DID PROCEDURE, HE KEPT PUSHING FLUIDS THROUGH MY UTERUS TO OPEN IT UP AND FIND THE TUBES...THIS WAS THE WORST PAIN I'VE EVER FELT. THIS PROCEDURE WAS SUPPOSED TO BE A 20 MINUTE ORDEAL, WELL IT WENT ON FOR AN HOUR AND 15 MINUTES. I LEFT VOMITING AND CRYING UNCONTROLLABLY IT FELT AS THOSE I'D BEEN VIOLATED. WELL A FEW HOURS LATER, I FELT AS IF MY LUNGS WERE ON FIRE AND CALLED THE OFFICE, THEY TOLD ME TO GO TO EMERGENCY ROOM. I WAS THEN TAKEN IN AND WAITED THE NEXT 3 HOURS FOR THE ER DOCTOR TO DETERMINE WHICH KIND OF TEST TO PERFORM ON ME SINCE I ONLY HAVE ONE KIDNEY AND I AM ALLERGIC TO IODINE. THEY FINALLY OPTED TO PRE MEDICATE ME AND DO CTA. THIS SHOWED I HAD FLUID SURROUNDING THE LINING OF MY LUNGS AND MY RIGHT LUNG WAS COLLAPSED. THEY ADMITTED ME. I SEEN PULMONOLOGIST THE NEXT DAY AND SHE SAID I WAS INCONCLUSIVE FOR A BLOOD CLOT BUT SHE DIDN'T BELIEVE I THREW A CLOT. SHE SEND ME DOWN TO HAVE MY LUNGS DRAINED. THE RADIOLOGIST HAD TO INSERT A NEEDLE RIGHT BELOW MY SHOULDER BLADE AND ENTER INTO SPACE BESIDE LUNG. IT WAS EXCRUCIATING AND RADIOLOGIST APOLOGIZED CAUSE THE LINING WAS SO INFLAMED THE NUMBING MEDICINE DID NOTHING TO STOP THE PAIN INSIDE. I HAD AN X RAY AFTER THIS TO MAKE SURE MY LUNG DIDN'T GET HIT. THEY PULLED ALMOST 300MLS OFF MY LUNGS, WHICH TURNED OUT TO BE THE SAME AMOUNT "MISSING" FROM ESSURE PROCEDURE. MY GYN THAT DID PROCEDURE CAME IN AND SAID HE KNEW HE SHOULD HAVE STOPPED BUT HE DIDN'T WANT ME TO HAVE TO GO UNDER ANESTHESIA. THE PULMONOLOGIST LATER SAID SHE BELIEVES THE WATER HE PUT IN FROM PROCEDURE WENT PAST MY DIAPHRAGM AND WENT TO MY

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LUNGS. EARLY FRIDAY MORNING I WOKE UP IN TREMENDOUS AMOUNT OF PAIN IN MY RIGHT LOWER ABDOMEN. IT FELT LIKE MY INSIDES WERE COMING OUT. THE HOSPITAL RUSHED ME DOWN TO DO CT SCAN AND THEY CHECKED TUBES AND LUNGS, EVERYTHING APPEARED NORMAL. THE PULMONOLOGIST AND INTERNAL MD OVERSEEING ME DISCHARGED ME BUT I REQUESTED TO SEE SOMEONE FROM GYN OFFICE. THE DR THAT CAME IN WAS NOT THE DOCTOR THAT DID MY PROCEDURE NOR IS SHE ANYONE THAT I HAD EVER SEEN. SHE INSISTED THAT MY PAIN WAS NORMAL AND MY TUBES WERE JUST SPASMING. . SO I WENT TO ANOTHER HOSPITAL AND THEY REMOVED ESSURE ALONG WITH MY TUBES. WHEN I GOT HOME I CALLED THE HOSPITAL AND REQUESTED TO SPEAK WITH DOCTOR, SHE DIDN'T COME TO THE PHONE BUT RELAYED MESSAGES BETWEEN THE NURSE AND TOLD ME TO TAKE IBUPROFEN FOR THE PAIN. I TOLD HER I ONLY HAVE ONE KIDNEY AND I CAN'T TAKE IBUPROFEN. SHE SAID THEN SHE HAD NO OTHER ANSWER FOR ME. I MADE MY HUSBAND GET MY STUFF TOGETHER AND WE WENT TO ANOTHER HOSPITAL. THEY TOOK ME IN IMMEDIATELY AND STAYED PAIN MEDICATION AND DID ANOTHER CTA SCAN ON LUNGS AND TUBES. THE LUNGS CAME BACK FINE AS DID THE TUBES. WELL IN WALKS THE DOCTOR THAT DID THE ESSURE PROCEDURE IN THE FIRST PLACE AND SAID HE WAS GOING TO ADMIT ME. IN THE MORNING HE SAID HE WOULD GO IN AND REMOVE THE ESSURE DEVICE AND REMOVE MY TUBES WITH THEM, SO THAT I WILL BE STERILE AND I WILL HAVE THESE DEVICES OUT OF MY BODY. I AGREED. THE NEXT MORNING WHEN SURGERY WAS OVER HE SAID THE ESSURE TIP OF MY RIGHT SIDE WAS POKING INTO MY UTERUS WALL AND THE LEFT ONE WAS PLACED IMPROPERLY. HE ASKED HOW I FELT COMING OUT OF SURGERY EXPECTING ME TO SAY I WAS SORE, BUT INSTEAD I SAID I FELT WONDERFUL AND I DID! I NEVER FELT SO MUCH RELIEF FROM HAVING SOMETHING REMOVED. THESE WERE THE MOST HORRIFIC DAYS I HAVE EVER BEEN THROUGH. I HONESTLY TOLD MY HUSBAND MANY TIMES TO TELL MY KIDS HOW MUCH I LOVED THEM. I DIDN'T THINK I WOULD SEE THEM AGAIN. I WAS THEN READMITTED TO HOSPITAL DUE TO POSSIBLE INFECTION FOR 4 DAYS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037411	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 7/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY ESSURE REMOVED SATURDAY (B)(6). I JUST HAD IT PUT IN WEDNESDAY (B)(6) AND HAVE HAD SO MANY COMPLICATIONS. FIRST I HAD IT DONE IN OFFICE NOT UNDER ANESTHESIA. HE NUMBED MY CERVIX WITH LIDOCAINE AND THEN DILATED MY CERVIX, WHICH I FELT EVERY MINUTE OF. WHEN THE DOCTOR DID PROCEDURE HE KEPT PUSHING FLUIDS THROUGH MY UTERUS TO OPEN IT UP AND FIND THE TUBES...THIS WAS THE WORST PAIN I'VE EVER FELT. THIS PROCEDURE WAS SUPPOSED TO BE A 20 MINUTE ORDEAL, WELL IT WENT ON FOR AN HOUR AND 15 MINUTES. I LEFT VOMITING AND CRYING UNCONTROLLABLY IT FELT AS THOUGH I'D BEEN VIOLATED. WELL A FEW HOURS LATER I FELT AS IF MY LUNGS WERE ON FIRE AND CALLED THE OFFICE, THEY TOLD ME TO GO TO EMERGENCY ROOM. I WAS THEN TAKEN IN AND WAITED THE NEXT 3 HOURS FOR THE ER DOCTOR TO DETERMINE WHICH KIND OF TEST TO PERFORM ON ME SINCE I ONLY HAVE ONE KIDNEY AND I AM ALLERGIC TO IODINE. THEY FINALLY OPTED TO PRE MEDICATE ME AND DO CTA. THIS SHOWED I HAD FLUID SURROUNDING THE LINING OF MY LUNGS AND MY RIGHT LUNG WAS COLLAPSED. THEY ADMITTED ME. I SAW A PULMONOLOGIST THE NEXT DAY AND SHE SAID I WAS INCONCLUSIVE FOR A BLOOD CLOT BUT SHE DIDN'T BELIEVE I THREW A CLOT. SHE SENT ME DOWN TO HAVE MY LUNGS DRAINED. THE RADIOLOGIST HAD TO INSERT A NEEDLE RIGHT BELOW MY SHOULDER BLADE AND ENTER INTO SPACE BESIDE LUNG. IT WAS EXCRUCIATING AND RADIOLOGIST APOLOGIZED BECAUSE THE LINING WAS SO INFLAMED THE NUMBING MEDICINE DID NOTHING TO STOP THE PAIN INSIDE. I HAD AN X RAY AFTER THIS TO MAKE SURE MY LUNG DIDN'T GET HIT. THEY PULLED ALMOST 300MLS OFF MY LUNGS, WHICH TURNED OUT TO BE THE SAME AMOUNT "MISSING" FROM ESSURE PROCEDURE. MY GYN THAT DID PROCEDURE CAME IN AND SAID HE KNEW HE SHOULD HAVE STOPPED BUT HE DIDN'T WANT ME TO HAVE TO GO UNDER ANESTHESIA. THE PULMONOLOGIST LATER SAID SHE BELIEVES THE WATER HE PUT IN FROM PROCEDURE WENT PAST MY DIAPHRAGM AND WENT TO

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MY LUNGS. EARLY FRIDAY MORNING I WOKE UP IN TREMENDOUS AMOUNT OF PAIN IN MY RIGHT LOWER ABDOMEN. IT FELT LIKE MY INSIDES WERE COMING OUT. THE HOSPITAL RUSHED ME DOWN TO DO CT SCAN AND THEY CHECKED TUBES AND LUNGS, EVERYTHING APPEARED NORMAL. THE PULMONOLOGIST AND INTERNAL MD OVERSEEING ME DISCHARGED ME BUT I REQUESTED TO SEE SOMEONE FROM GYN OFFICE. THE DR THAT CAME IN WAS NOT THE DOCTOR THAT DID MY PROCEDURE NOR IS SHE ANYONE THAT I HAD EVER SEEN. SHE INSISTED THAT MY PAIN WAS NORMAL AND MY TUBES WERE JUST SPASMING. SO I WENT TO ANOTHER HOSPITAL AND THEY REMOVED ESSURE ALONG WITH MY TUBES. WHEN I GOT HOME I CALLED THE HOSPITAL AND REQUESTED TO SPEAK WITH THE DOCTOR SHE DIDN'T COME TO THE PHONE BUT RELAYED MESSAGES BETWEEN THE NURSE AND TOLD ME TO TAKE IBUPROFEN FOR THE PAIN. I TOLD HER I ONLY HAVE ONE KIDNEY AND I CAN'T TAKE IBUPROFEN. SHE SAID THEN SHE HAD NO OTHER ANSWER FOR ME. I MADE MY HUSBAND GET MY STUFF TOGETHER AND WE WENT TO ANOTHER HOSPITAL. THEY TOOK ME IN IMMEDIATELY AND STAYED PAIN MEDICATION AND DID ANOTHER CT SCAN ON LUNGS AND TUBES. THE LUNGS CAME BACK FINE AS DID THE TUBES. WELL, IN WALKS THE DOCTOR THAT DID THE ESSURE PROCEDURE IN THE FIRST PLACE AND SAID HE WAS GOING TO ADMIT ME. IN THE MORNING HE SAID HE WOULD GO IN AND REMOVE THE ESSURE DEVICE AND REMOVE MY TUBES WITH THEM SO THAT I WILL BE STERILE AND I WILL HAVE THESE DEVICES OUT OF MY BODY. I AGREED. THE NEXT MORNING WHEN SURGERY WAS OVER HE SAID THE ESSURE TIP OF MY RIGHT SIDE WAS POKING INTO MY UTERUS WALL AND THE LEFT ONE WAS PLACED IMPROPERLY. HE ASKED HOW I FELT COMING OUT OF SURGERY EXPECTING ME TO SAY I WAS SORE, BUT INSTEAD I SAID I FELT WONDERFUL AND I DID! I NEVER FELT SO MUCH RELIEF FROM HAVING SOMETHING REMOVED. THESE WERE THE MOST HORRIFIC DAYS I HAVE EVER BEEN THROUGH. I HONESTLY TOLD MY HUSBAND MANY TIMES TO TELL MY KIDS HOW MUCH I LOVED THEM. I DIDN'T THINK I WOULD SEE THEM AGAIN. I WAS THEN READMITTED TO HOSPITAL DUE TO POSSIBLE INFECTION FOR 4 DAYS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037412	BAYER	7/25/2014	7/25/2014

Event Information:

Event Date (B3): 12/30/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NEW ALLERGIES, CHRONIC JOINT PAIN, EXCESSIVE DRY SKIN AND HAIR LOSS, SLEEP DISTURBANCES, WEIGHT GAIN, SUDDEN (OVERNIGHT) HERNIATION OF DISCS IN NECK NOT CAUSED BY TRAUMA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037497	BAYER	7/25/2014	7/31/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS PUT IN PLACE. SEVERE BLEEDING AND PAINS, MIGRAINES, JOINT PAINS, VOMITING, NAUSEA.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	7/25/2014	8/7/2014

Event Information:

Event Date (B3): 6/27/2014 **Report Date (B4): 7/25/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B09705

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT WAS UNDER GENERAL ANESTHESIA FOR A HYSTEROSCOPY WITH ESSURE STERILIZATION. THE SURGERY INVOLVES PLACING AN ESSURE DEVICE IN THE RIGHT AND LEFT FALLOPIAN TUBES. THE HYSTEROSCOPY WAS IN PROGRESS AND THE FIRST STERILE ESSURE INSERT (REF # ESS305, LOT # B09705) WAS OPENED. WHEN THE SURGEON EXAMINED THE INSERT, SHE NOTED IT WAS BENT AT THE TIP. THE INSERT WAS REPLACED WITH A SECOND INSERT FROM THE SAME LOT NUMBER, OPENED, INSPECTED AND DEPLOYED WITHOUT INCIDENT. NO HARM TO THE PATIENT.
==========
MANUFACTURER RESPONSE FOR STERILIZATION, ESSURE (PER SITE REPORTER)
==========
N/A AS THE DEVICE HAS NOT BEEN RETURNED TO THE MANUFACTURER YET. THE PRODUCT REP IS SUPPOSED TO RETRIEVE THE DEVICE WITHIN THE NEXT WEEK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037514	BAYER	7/28/2014	8/4/2014

Event Information:

Event Date (B3): 7/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/30/2009
Explant Date (E7): 7/23/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE IMPLANTED IN 2009. STARTED HAVING SYMPTOMS IN 2010 THAT INCLUDED DAILY FATIGUE, A SEVERE MENSTRUAL CRAMPING, VOMITING, HIP PAIN, LEG PAIN, JOINT PAIN ON A DAILY BASES. VOMITING WAS A FEW TIMES A MONTH DURING MY CYCLE. PAIN WOULD BE SEVERE TO POINT OF NOT BEING ABLE TO CONTINUE REGULAR DAILY ACTIVITIES. COULD NO LONGER RUN, EXERCISE, OR PRACTICE YOGA. WHEN I SNEEZED OR COUGHED, THE INTERNAL PAIN IN MY LOWER ABDOMEN WAS EXCRUCIATING. BLOOD TESTS HAVE SHOWN THAT I HAD BECOME ANEMIC CAUSING ME TO BE COLD, SHAKY, AND EASILY BRUISED. HAD LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY (B)(6) 2014 TO REMOVE UTERUS AND FALLOPIAN TUBES TO ENSURE THAT COILS WERE REMOVED AND THERE WOULD BE NO FUTURE PROBLEMS. HAD CHRONIC INFLAMMATION OF THE UTERUS AND FALLOPIAN TUBES AND LIVER ADHESIONS, AS WELL. TWO DAYS POST OPERATION AND MY LEG, HIP, AND JOINT PAIN IS ALREADY GONE AND I AM NO LONGER FATIGUED. EVEN THOUGH I AM IN PAIN FROM THE SURGERY, I ALREADY FEEL 10 TIMES BETTER THAN BEFORE MY SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037517	BAYER	7/28/2014	8/4/2014

Event Information:

Event Date (B3): 4/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/9/2009
Explant Date (E7): 5/22/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2009 I HAD ESSURE IMPLANTED. IT WAS AN IN-OFFICE VISIT WITHOUT GENERAL ANESTHESIA. I WAS NEVER GIVEN AN IDENTIFICATION CARD WITH INFO ON IT REGARDING THE COILS THAT WERE IMPLANTED SO I HAVE NO SERIAL OR LOT NUMBERS OR ANYTHING. ONLY THE DATE OF IMPLANT. ON (B)(6) 2009 AND HSG SHOWED ONE COIL IN PLACE BUT NOT WORKING. THE LOCATION OF THE OTHER COIL COULDN'T FULLY BE DETERMINED. ANOTHER HSG WAS PERFORMED ON (B)(6) 2009 WITH BASICALLY THE SAME RESULTS. I HAD TO CHOOSE A DIFFERENT METHOD OF BIRTH CONTROL AFTER I'D GONE THROUGH THE INSERTION OF "PERMANENT" ESSURE BIRTH CONTROL. ABDOMINAL PAIN WAS ABUNDANT BUT TESTS REVEALED NO CAUSE. I HAD AN ABDOMINAL ULTRASOUND (B)(6) 2009, A CT SCAN (B)(6) 2009, AN ENDOSCOPY (B)(6) 2010. LATER THAT YEAR I DEVELOPED EXTREME FATIGUE, JOINT PAIN, MUSCLE WEAKNESS AND PAIN, SWOLLEN FEET AND ANKLES, DRY EYES AND DRY MOUTH, A RECURRING EYE RASH. MY LIFE ENDED AS I KNEW IT AND MOST DAYS I COULDN'T DRAG MYSELF OFF THE COUCH FOR ALL THE PAIN I WAS IN AND THE CRUSHING FATIGUE I FELT. I WAS UNABLE TO CARE FOR MY CHILDREN. UNABLE TO WORK/VOLUNTEER/PARTICIPATE IN ANY OF THE ACTIVITIES I WAS USED TO DOING. PRIOR TO THE ESSURE INSERTION I WAS A VERY HEALTHY, VERY ACTIVE PERSON. I SAW A RHEUMATOLOGIST (B)(6) 2011. GOT A SECOND OPINION (B)(6) 2011. HAD BEEN BLEEDING RECTALLY FOR A COUPLE MONTHS SO HAD A COLONOSCOPY THAT REVEALED INTERNAL HEMORRHOIDS. IT SEEMED MY ENTIRE BODY WAS INFLAMED. ON (B)(6) 2011 STARTED PLAQUENIL FOR TREATMENT OF THE AUTOIMMUNE DISEASE SJOGREN'S. ON (B)(6) 2012 HAD ANOTHER ENDOSCOPY FOR SEVERE ACID SYMPTOMS. THE ONLY ABNORMALITY IN ANY OF THESE TESTS AND PROCEDURES WAS A SLIGHTLY ELEVATED ANA AND MY INTERNAL HEMORRHOIDS. OTHERWISE, MY BLOOD WORK AND TESTS REVEALED THAT I WAS THE PICTURE OF HEALTH. BUT I WASN'T. IN (B)(6) 2014 MY BACK UP BIRTH CONTROL WAS REMOVED SO A THIRD AND FINAL HSG TEST

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WAS DONE TO DETERMINE THE POSITION OF THE ESSURE AFTER 5 YEARS. ONE COIL WAS STILL IN PLACE, BUT STILL NOT WORKING. THE OTHER COIL WAS EMBEDDED IN MY UTERUS. ON (B)(6) 2014 I UNDERWENT A HYSTERECTOMY AS THAT WAS THE ONLY SAFE WAY TO REMOVE THE ESSURE IMPLANTS FROM MY BODY. NOW THAT I AM 9 WEEKS POST OPERATION, MY SYMPTOMS ARE 90% RESOLVED. I AM WEANING OFF THE SJOGREN'S MEDS TO SEE HOW I DO. ALL OF MY ABDOMINAL PAIN/DISCOMFORT FROM THE ESSURE IS RESOLVED AND MOST OF MY SJOGREN'S SYMPTOMS ARE RESOLVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037506	BAYER	7/30/2014	7/30/2014

Event Information:

Event Date (B3): 10/30/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BLED THREE WEEKS OUT OF THE MONTH FOR A YEAR. CONSTANT BLOATING, PAIN IN MY JOINTS, SWELLING IN MY CALVES, ANKLES AND FEET, HEADACHES, PAIN IN MY ABDOMEN, HAIR LOSS, DEPRESSION, FATIGUE, NO SEX DRIVE, SMELLY VAGINAL DISCHARGE, STRONG BODY ODOR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037507	BAYER	7/30/2014	7/30/2014

Event Information:

Event Date (B3): 7/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE BEING IMPLANTED WITH ESSURE (B)(6), 2007 I'VE HAD CONSISTENTLY HEAVY MENSTRUAL CYCLES, MENSTRUAL CYCLES THAT LAST FOR MONTHS AT A TIME, SEVERE LOWER BACK PAIN, SEVERE CRAMPING, SEVERE PAIN IN ABDOMEN, BLOOD CLOTS DURING CYCLE. HEADACHES. UNABLE TO LOSE WEIGHT WHICH HAS LED TO TYPE 2 DIABETES. ALL OVER BODY ACHES. FATIGUE, DEPRESSION. SHARP STABBING PAIN IN ABDOMEN AND CERVIX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037508	BAYER	7/30/2014	7/30/2014

Event Information:

Event Date (B3): 1/19/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN HAVING HEAVY BLEEDING AND FEELING VERY TIRED ALL THE TIME. I FELT DEPRESSED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037509	BAYER	7/30/2014	7/30/2014

Event Information:

Event Date (B3): 8/20/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5037509 #(B)(4) I HAVE SINCE HAD TO HAVE A HYSTERECTOMY DUE TO ESSURE FOR REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037510	BAYER	7/30/2014	7/30/2014

Event Information:

Event Date (B3): 7/29/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD PAIN THAT HAS HOSPITALIZED ME FOR DAYS HAD ME IN ER A NUMBER OF TIMES AND I HAD EXPLORATORY SURGERY AND EVERY TEST RAN AND I AM A HEALTHY (B)(6) YET I HAVE FELT LIKE THIS 5 MONTHS AFTER IMPLANTED AND IT HAS NEVER QUIT ONLY GOT WORSE MY PERIODS ARE SO PAINFUL BEFORE AND DURING MORE THAN EVER. I HAVE MORE THAN NORMAL FATIGUE. THE PAIN IS SO HORRIBLE IT EFFECTS EVERYTHING AND EVERYONE I AM AROUND THERE IS A LOT OF THINGS THAT HAVE COMPLETELY CHANGED AFTER HAVING THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037546	BAYER HEALTH	7/30/2014	8/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I FEEL THE ESSURE PROCEDURE HAS CAUSED SEVERE SIDE EFFECTS THAT I WAS NOT WARNED ABOUT, INCLUDING SEVERE CRAMPING, PAIN, HEAVY BLEEDING, OVERALL TERRIBLE PERIODS THAT CAN MAKE ME SICK FOR UP TO A WEEK, AND BLOATING. I HAD THE PROCEDURE IN (B)(6) OF 2012. I DID NOT USE BIRTH CONTROL, SUCH AS THE PILL, PRIOR TO THIS SO I DON KNOW WHAT MY PERIODS WERE LIKE BEFORE ESSURE. IF I COULD HAVE IT REMOVED IT WOULD BE GONE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00310	BAYER HEALTHCARE LLC	7/30/2014	8/20/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# MW5036559) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. IN 2013 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED. IT WAS REPORTED THAT THE CONSUMER SUFFERED FROM HEAVY BLEEDING AND PELVIC PAIN. SHE HAD A DILATION AND CURETTAGE AND A TOTAL VAGINAL HYSTERECTOMY WHICH REMOVED ONE COIL. ONE MONTH LATER, SHE HAD BOTH TUBES REMOVED AND THE SECOND COIL HAD MIGRATED BEHIND HER BLADDER AND COULD NOT BE RETRIEVED WITHOUT THE HELP OF A SPECIALIST. ACCORDING TO HER, ESSURE HAD IMPACTED HER LIFE AND HEALTH. SHE STATED THAT ANOTHER SURGERY WILL BE DONE. AN INJURY (HOSPITALIZATION) WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW UP WILL BE REQUESTED.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 12-AUG-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM A

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00314	BAYER HEALTHCARE LLC	7/30/2014	8/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626603

Single Use: Y
Implant Date (E6): 8/27/2008
Explant Date (E7): 8/12/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(4) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. ON (B)(6) 2008, ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER # 626603. ACCORDING TO THE CONSUMER, IMMEDIATELY AFTER THE COILS WERE PLACED, SHE HAD PAIN, TENDERNESS AND CRAMPING THAT CONTINUED FOR THE BETTER PART OF 5 YEARS. THIS FINALLY STOPPED AFTER GOING THROUGH VARIOUS DOCTORS AND FINALLY FINDING ONE TO GIVE HER A HYSTERECTOMY. SHE STATED THAT THE ONLY REASON SHE FINALLY GOT THE HYSTERECTOMY WAS BECAUSE AN X-RAY REVEALED THAT ONE COIL WAS BROKEN. SHE HAD NO SYMPTOMS (CRAMPING, PAIN, BLOATING AND TENDERNESS) THAT SHE HAD ENDURED WHEN SHE HAD THE COILS. IN ADDITION TO THIS, MOST OF THE DOCTORS THAT SHE WENT, TOLD HER THAT SHE WAS EXAGGERATING, SHE WAS CRAZY OR SHE WAS SEEKING PAIN MEDS AND BLEW HER OFF COMPLETELY. SHE WAS TOLD (SEVERAL TIMES) BEFORE GETTING THE COILS THAT SHE HAD ABSOLUTELY NOTHING TO WORRY ABOUT REGARDING SIDE EFFECTS. SHE WAS MISERABLE AND HAD A SEVERE DISTRUST FOR DOCTORS AFTER NO ONE HELPED HER UNTIL ABOUT 5 YEARS LATER. ESSURE WAS REMOVED ON (B)(6) 2013. THE OUTCOME OF THE EVENTS PAIN, TENDERNESS, CRAMPING, BLOATING, AND X-RAY REVEALED THAT ONE COIL WAS BROKEN WAS RECOVERED / RESOLVED. AN INJURY (REQUIRED INTERVENTION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP WILL BE REQUESTED. CORRECTION ON (B)(4) 2014 BASED ON INFORMATION FROM (B)(4) 2014: THE EVENT XRAY REVEALED THAT ONE COIL WAS BROKEN WAS CONSIDERED SERIOUS.

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Manufacturer Narrative (H10):

(B)(4). CONSUMERS WEIGHT AND HEIGHT WERE PROVIDED. IN (B)(6) 2008, ESSURE LOT NUMBER # 626603 WAS INSERTED. ESSURE WAS NOT INSERTED AFTER A PREGNANCY. SHE EXPERIENCED CRAMPS AND SO MUCH PAIN IT HURT TO BREATHE. SHE RECEIVED MOTRIN FOR THE PAIN AND HEATING

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00311	BAYER HEALTHCARE LLC	7/30/2014	8/21/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CUSTOMER VIA SOCIAL MEDIA IN UNITED STATES ON (B)(6) 2014, WHICH REFERS TO HERSELF. SHE IS A (B)(6) YEAR OLD FEMALE CONSUMER WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4) HAD ESSURE INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. CONSUMER HAD 2 PREGNANCIES AND ALSO HAD HEAVY PERIOD. CONSUMER REPORTED THAT SHE WAS SO SICK BEING PREGNANT AND DID ESSURE PROCEDURES TO GET FIXED (DATE NOT REPORTED) AND AN ABLATION FOR HEAVY PERIOD. SHE HAD ABLATION ALONG WITH ESSURE FOR HEAVY PERIOD AND THIS ABLATION CAUSED A POST ABLATION TUBAL STERILIZATION SYNDROME WITH EXCRUCIATING PAIN FOR 3 YEARS. CONSUMER UNDERWENT HYSTERECTOMY AND STATED THAT SHE HAS ALREADY SEEN GOOD RESULTS WITH HER HYSTERECTOMY BECAUSE SHE HAD THE WORST SMELLING DISCHARGE FOR THE PAST 3 YEARS AND THE DOCTORS TREATED HER FOR INFECTIONS, BUT IT NEVER WENT AWAY AND SHE WAS HAPPY TO SAY IT RESOLVED AFTER HYSTERECTOMY. CONSUMER ALSO MENTIONED THAT AFTER HYSTERECTOMY SHE RECEIVED PAIN MEDICATIONS AS IBUPROFEN. SHE WAS DEPRESSED BECAUSE JEANS JUST HURT. SHE STATED THAT SHE HASN'T HAD ANY BLEEDING OR SPOTTING AND SURE HOPE IT WASN'T IN THERE GETTING AN INFECTION. SHE WOULD HAVE AN APPOINTMENT WITH HER DOCTOR.

Manufacturer Narrative (H10):

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THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 12-AUG-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00313	BAYER HEALTHCARE LLC	7/30/2014	8/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED THE EVENTS DESCRIBED BELOW. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED UNDER GENERAL ANESTHETIC DUE TO SEVERE PAIN AND CRAMPING. UPON WAKING SHE KNEW THAT SOMETHING WAS WRONG. SHE DISCOVERED THAT THE COILS WERE MADE OF NICKLE AND WAS WAITING FOR AN ALLERGY TEST TO CONFIRM. SHE EXPERIENCED SEVERE CRAMPING AND PAIN IN HER PELVIC REGION AND CONSTANT BLEEDING VERY HEAVY FOR MANY MONTHS FOLLOWING. SHE DIDN'T WANT TO HAVE THE HSG FOLLOW UP APPOINTMENT AS WAS A LOT OF PAIN AND COULDN'T LET ANY MORE PROCEDURES HAPPEN. SHE VISITED HER DOCTOR ON A NUMBER OF OCCASIONS WITH VARIOUS COMPLAINTS INCLUDING BLEEDING, PAIN, HEADACHES AND HIP PAIN. TWELVE MONTHS AFTER INSERTION SHE HAS HAD THE COILS SURGICALLY REMOVED AND A LOT OF HER SYMPTOMS HAVE GONE BUT SOME REMAIN. THE PATIENT IS AWAITING AN X-RAY TO SEE IF FRAGMENTS WERE LEFT BEHIND IN HER UTERUS AS SHE ONLY HAD HER FALLOPIAN TUBES AND COILS REMOVED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 7/17/2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00307	BAYER HEALTHCARE LLC	7/30/2014	9/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. ESSURE WAS INSERTED ON (B)(6) 2014. PHYSICIAN REPORTED THAT DURING CONTROL EXAMINATION AFTER 3 MONTHS WITH ESSURE, HE FOUND DESOLIDARISATION OF TEFLON MEMBRANE OF THE COIL. HE ALSO MENTIONED THAT THERE WAS NO PROBLEM DURING PLACEMENT. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: IT IS DIFFICULT TO DETERMINE T

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00308	BAYER HEALTHCARE LLC	7/30/2014	9/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76537

Single Use: Y
Implant Date (E6): 7/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT} INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. ESSURE INSERTION PROCEDURE WAS PERFORMED ON (B)(6) 2014 FOR BIRTH CONTROL WITH LOT NUMBER USED 876537. PHYSICIAN REPORTED DEPLOYMENT DIFFICULTY. THE INNER COIL WAS STRETCHED ACROSS THE UTERINE CAVITY AND THE DOCTOR TRIED TO REMOVE IT FOR 3 TIMES AND IT BROKE. SOME OF THE COIL WAS IN THE PATIENT AND SOME OUT. PATIENT WAS SCHEDULED FOR LAPAROSCOPIC PROCEDURE FOR REMOVAL OF DEVICE AND THEN TUBAL LIGATION.

Manufacturer Narrative (H10):

FOLLOW-UP FROM (B)(4) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. FOLLOW UP (B)(4) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00309	BAYER HEALTHCARE LLC	7/30/2014	9/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97499

Single Use: Y
Implant Date (E6): 6/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. ON AN UNSPECIFIED DATE ESSURE WAS INSERTED. IT WAS REPORTED THAT PATIENT WENT TO THE PHYSICIAN'S OFFICE BECAUSE SHE WAS IN PAIN. HCP WORRIED THAT PART OF DEVICE WAS STILL IN THERE. A DIAGNOSTIC PROCEDURE WAS DONE AND SHOWED THAT COILS WERE FLOATING IN CAVITY. PREVIOUS ESSURE WAS REMOVED AND ANOTHER ESSURE WAS PLACED IN TUBE (ON (B)(6) 2014). THE OUTCOME OF THE EVENTS COILS WERE FLOATING IN CAVITY AND HCP WORRIED THAT PART OF DEVICE STILL IN PATIENT WAS RECOVERED/RESOLVED. FOLLOW-UP INFORMATION WAS RECEIVED ON 07-JUL-2014. PATIENT'S INITIALS AND DATE OF BIRTH WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. ON (B)(6) 2014 ESSURE LOT NUMBER B97499 WAS INSERTED. NO FURTHER INFORMATION WAS PROVIDED. CORRECTION ON 10-JUL-2014 BASED ON INFORMATION RECEIVED ON 07-JUL-2014: IT WAS ALSO REPORTED DURING FOLLOW-UP THAT PATIENT COMPLAINED OF PAIN AND CAME IN FOR A FOLLOW UP ON (B)(6) 2014. AT THAT TIME ESSURE DEVICE WAS LOCATED FLOATING IN THE UTERUS AND REMOVED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "PART OF THE DEVICE STILL IN PATIENT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00312	BAYER HEALTHCARE, LLC	7/30/2014	9/9/2014

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50656873

Single Use: Y
Implant Date (E6): 10/3/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. THE CONSUMER'S CONCURRENT CONDITION INCLUDED NICKEL ALLERGY. ON (B)(6) 2012 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED CHRONIC PAIN IN THE LOWER BACK AND PELVIS AND HIPS, GROIN PAIN WITH SHOOTING PAINS DOWN LEGS, HIVES, ITCHING, DIFFICULTY WALKING, PAIN DURING AND AFTER SEX, SHARP STINGING PAINS, AND A RIPPING PAIN WHEN I TWIST SLIGHTLY OR ROLL OVER IN BED, VERY PAINFUL MENSTRUAL CRAMPS, VERY HEAVY MENSTRUAL PERIODS PASSING LARGE CLOTS (TENNIS BALL SIZE IN DIAMETER), INCREASINGLY SHORTENING MENSTRUAL CYCLE (AROUND 18-20 DAYS) INCREASINGLY IRREGULAR, SPOTTING OR BLEEDING BETWEEN MENSTRUAL PERIODS, FATIGUE, BURNING PAIN IN PELVIS AND CERVIX (NOT DURING URINATION), BLOATING, THYROID DISEASE DIFFICULT TO CONTROL, B12 DEFICIENCY AND BLOOD IN URINE (MICROSCOPIC). ACCORDING TO HER, SHE HAD LAPAROSCOPIC AND HYSTEROSCOPY SURGERY TO INVESTIGATE ISSUES. ONE OF THE ESSURE COILS/CLIPS HAD GONE INTO THE UTERUS; THE INNER STEEL ROD HAD COME AWAY FROM THE COILS AND WAS PERFORATING THE UTERUS. THE OTHER COIL WAS NOT VISIBLE SO IT SEEMED IT HAD MIGRATED. SHE STATED THAT SHE HAS ALLERGY TO NICKEL AND ESSURE SHOULD NOT HAVE BEEN IMPLANTED. SHE BELIEVED THAT SHE HAS BEEN INJURED BY THIS PRODUCT AND HAD TO TAKE MONTHS OFF WORK AS THE PAIN WAS CHRONIC. BILATERAL SALPINGECTOMY REMOVAL OF TUBES AND COILS AND HYSTERECTOMY WAS SCHEDULE TO (B)(6). ESSURE WAS NOT REMOVED YET. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS ASSESSED AS RELATED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00315	BAYER HEALTHCARE LLC	7/30/2014	9/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B06097

Single Use: Y
Implant Date (E6): 5/6/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/10/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6)2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAS ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER B06097 EXPIRATION DATE (B)(6) 2016 INSERTED ON (B)(6) 2014 AND THE FOLLOWING SITUATION WAS REPORTED. PHYSICIAN STATED THAT ONCE THE DEVICE WAS DEPLOYED AND FINAL ROLLED BACK THE CATHETER WILL NOT COME AWAY AND SEPARATE. THE BUTTON WAS PRESSED AGAIN AND WAITED FOR 3 MINUTES TO ALLOW TIME BUT NO LUCK. AFTER 5 MINUTES OF TOTAL WAIT AND THEN SLIGHT MOVEMENTS ON THE CATHETER STILL NO LUCK. PHYSICIAN THEN HAD TO PULL THE CATHETER TO SEPARATE IT FROM THE PATIENT. AS IT WAS DONE ESSURE ELONGATED TO MORE THAN 40 INCHES BUT THERE WAS SOME SORT OF DEVICE STILL IN THERE. NO FURTHER INFO WAS PROVIDED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 20-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00316	BAYER HEALTHCARE LLC	8/1/2014	8/26/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B26266

Single Use: Y
Implant Date (E6): 12/16/2013
Explant Date (E7): 7/8/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. ESSURE WAS INSERTED IN (B)(6) 2014. THE GYNECOLOGIST REPORTED THAT PATIENT EXPERIENCED MIGRATION OF ESSURE TO SMALL INTESTINE WHICH CAUSED PERFORATION. ON (B)(6) 2014 ESSURE WAS REMOVED BY THE DOCTOR. THE PATIENT WAS STILL HOSPITALIZED AT THE TIME OF THIS REPORT. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF (B)(6) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MIGRATION OF ESSURE TO SMALL INTESTINE WHICH CAUSED PERFORATION. MIGRATION OF ESSURE TO SMALL INTESTINE WHICH CAUSED PERFORATION IS SERIOUS DUE TO HOSPITALIZATION REPORTED AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THIS CASE WAS REGARDED AS AN INCIDENT CASE SINCE A INTERVENTION WAS PERFORMED TO REMOVE THE MICRO-INSERT. EXPERIENCED MIGRATION OF ESSURE TO SMALL INTESTINE WHICH CAUSED PERFORATION ASSUMED AS DEVICE DISLOCATION CAN OCCUR AFTER INSERTION OF AN (B)(6). INTERNAL ORGANS PERFORATION MAY OCCUR WITH ESSURE, DUE TO DEVICE MIGRATION. THE PERFORATION OF INTERNAL BODILY STRUCTURES OTHER THAN THE UTERUS AND FALLOPIAN TUBES (E.G. BOWEL, BLADDER, AND MAJOR BLOOD VESSELS) MAY OCCUR DURING HYSTEROSCOPY, AS WELL AS DURING DEVICE PLACEMENT; THIS RISK IS INHERENT WITH ANY HYSTEROSCOPIC PROCEDURE. DUE TO THE ANATOMICAL RELATIONSHIP BETWEEN BOWEL AND UTERUS, THE BOWEL IS THE MOST COMMONLY AFFECTED ORGAN. IN THIS PARTICULAR CASE, THE GYNECOLOGIST REPORTED THAT PATIENT EXPERIENCED MIGRATION OF ESSURE TO SMALL INTESTINE WHICH CAUSED PERFORATION. THE EXACT DATE AND THE MECHANISM OF PERFORATION ARE

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NOT KNOWN. A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE EVENT CANNOT BE EXCLUDED. FURTHER INFORMATION AND PTC ANALYSIS WILL BE REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM THE GYNECOLOGIST. PATIENT'S INITIALS, YEAR OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. HISTORICAL CONDITION INCLUDED GRAVIDA IV, PARA IV, 3 SPONTANEOUS MISCARRIAGES AND CURETTAGE. ON (B)(6) 2013 (PREVIOUSL

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	8/1/2014	9/12/2014

Event Information:

Event Date (B3): 5/5/2014 **Report Date (B4): 8/1/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE **(**KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): B71765

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

MD INSERTING ESSURE STERILIZATION COIL VIA HYSTEROSCOPY WHEN COIL DID NOT FULLY RELEASE INTO RIGHT FALLOPIAN TUBE. ONLY PART OF COIL WAS INSERTED. LEFT FALLOPIAN TUBE WENT WITHOUT PROBLEMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037638	CONCEPTUS	8/4/2014	8/8/2014

Event Information:

Event Date (B3): 8/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/15/2008
Explant Date (E7): 6/25/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS IMPLANTED IN (B)(6) 2008. WITHIN ONE MONTH, I BEGAN EXPERIENCING EXTREMELY HEAVY MENTRUAL BLEEDING, ABDOMINAL PAIN, SERIOUS CRYING SPELLS, DEPRESSION, MOOD SWINGS. AT THE TIME, I DID NOT ATTRIBUTE THE ISSUES TO ESSURE, BUT TO POSSIBLE PERIMENOPAUSAL SYMPTOMS. THE CRYING, DEPRESSION, MOOD SWINGS WERE VERY SEVERE AND REQUIRED PSYCHIATRIC ATTENTION. I WAS PLACED ON OVER TEN DIFFERENT MEDICATIONS, NON HELPED, SOME MADE SYMPTOMS WORSE. FOR SEVERAL YEARS, I LIVED WITH THE SYMPTOMS AND WENT TO VARIOUS MENTAL HEALTH PROFESSIONALS, GYN DOCTORS. NOTHING WAS EVER MENTIONED CONCERNING ESSURE. THE SYMPTOMS WERE SO BAD, I BECAME SUICIDAL. MY MOTHER BEGAN RESEARCHING THE ESSURE DEVICE AND FOUND THAT (B)(6). WERE PERFORMING LOADS OF ESSURE REMOVAL SURGERIES. IN 2013, I WAS SEEN BY (B)(6)AND PERFORMED MY ESSURE REMOVAL. DURING MY CONSULTATION WITH (B)(6), HE TOLD HE COULD HELP ME WITH THE SYMPTOMS I WAS EXPERIENCING. AFTER HAVING THE ESSURE COILS REMOVED, MY MOOD SWINGS WERE GONE, EPISODES OF RAGE, PHYSICAL SYMPTOMS, ABDOMINAL AND LEG PAIN, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037656	THERMACON, LLC	8/4/2014	8/11/2014

Event Information:

Event Date (B3): 7/31/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERM BIRTH CTL-SINGLE
Device Type (E2): ESSURE
Model # (E4): REF/3 ESS305
Catalog # (E4):
Lot #(E4): B93875

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING SURGERY (HYSTEROSCOPIC TUBAL OCCLUSION), THE ESSURE DEVICE DID NOT RELEASE THE COIL PROPERLY FOR THE LEFT FALLOPIAN TUBE. DR WAS ABLE TO REMOVE THE SHEATH COVERING THE COIL. THE ESSURE DEVICE RELEASED PROPERLY FOR THE RIGHT FALLOPIAN TUBE. NO INJURY TO THE PATIENT. LEFT FALLOPIAN TUBE - 10 COILS EXPOSED, RIGHT FALLOPIAN TUBE - 3 COILS EXPOSED. (B)(6) (ESSURE REP) WAS PRESENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037595	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 10/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD SEVERE MENSTRUAL BLEEDING 18 DAY PERIODS..NUMBNESS IN TOES. HEADACHES AND FATIGUE..RESULTING IN A PARTIAL HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037596	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 3/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5037596 #(B)(4). DURING MY IMPLANTATION, MY UTERUS WAS PUNCTURED BY THE HYSTEROSCOPE, AND MY PROCEDURE WAS TERMINATED WITH ONLY THE LEFT SIDE IMPLANTED AND THEY WERE UNABLE TO TELL IF IT WAS PLACED CORRECTLY AS A RESULT; 500 CC'S OF SALINE SOLUTION LEAKED IN TO MY ABDOMINAL CAVITY AS A RESULT OF THE PERFORATED UTERUS, AS STATED IN MY MEDICAL RECORD. I CHOSE NOT TO RETURN TO HAVE THE RIGHT SIDE PLACED DUE TO THE DIFFICULTY DURING IMPLANTATION OF MY LEFT COIL, I NEVER RECEIVED AN ID CARD WITH MY LOT/KIT NUMBER AFTER IMPLANTATION. I HAVE SINCE HAD A HYSTERECTOMY TO REMOVE THE COIL. ((B)(6), 2014) I THEN EXPERIENCED A VAGINAL CUFF DEHISCENCE DURING INTERCOURSE (B)(6), 2015 AND, AFTER A TRIP TO THE EMERGENCY ROOM, HAD EMERGENCY SURGERY TO FIX THE DEHISCENCE. (I HAD BEEN CLEARED TO RESUME ALL ACTIVITIES BY THE DOCTOR WHO PERFORMED THE HYSTERECTOMY AS OF (B)(6), 2015.)

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037597	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 6/6/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE SPRINGS WERE PLACED, I HAD CONSTANT CRAMPING/SHARP PAINS IN THE PELVIC AREA. I ALSO HAD CONSTANT BLEEDING. HAD A ABLATION AFTERWARDS AND STILL HAD THE PAIN. COME TO FIND OUT, ONE OF THE SPRINGS WAS PERFORATING MY UTERUS. ENDED WITH A HYSTERECTOMY. ALL I HAVE NOW IS AN OVARY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037598	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 2/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SHARP/STABBING PELVIC PAIN, BACTERIAL VAGINOSIS, CONSTANT SPOTTING, DISCHARGE, HOT FLASHES, EXCESSIVE BLEEDING DURING PERIOD, NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS, PAINFUL INTERCOURSE, BLEEDING BETWEEN PERIODS, INCONTINENCE, SEXUAL DYSFUNCTION, YEAST INFECTIONS, URGENT/FREQUENT URINATION, VAGINAL SWELLING/INFLAMMATION, ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, BACK/LEG/BREAST/NECK/SPINE/HIP PAIN, FACE PAIN, ALL OVER BODY ACHES/PAIN, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, MIGRAINES, TINGLING SENSATIONS, NUMBNESS, BRAIN FOG AND CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, SAD THOUGHTS, RINGING IN EARS ,BLACK OUT SPELLS/ FAINTING, NUMBNESS/TINGLING IN HANDS/FEET, SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN, SHAKINESS, DIZZINESS, HIGH BLOOD PRESSURE, VITAMIN D DEFICIENCY, UNEXPLAINED/EASILY BRUISING, HASHIMOTO'S DISEASE, CHEMICAL AND FOOD SENSITIVITIES, HEIGHTENED ALLERGIES/ ALLERGIC REACTIONS, GLUTEN SENSITIVITY, ALLERGIC REACTIONS, HIVES, RASHES, CYSTS, BOILS, ACNE, SKIN IRRITATION/ITCHING, SWELLING OF LEGS OR FEET, HAIR LOSS, DENTAL ISSUES, INSOMNIA, THYROID DISEASE (HYPOTHYROID), WEIGHT ISSUES (LOSS; GAIN), SLEEP APNEA, MUSCLE SPASMS, VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION), EXCESSIVE SWEATING, DRY SKIN/HAIR/EYES, SEVERE BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037599	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 1/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SURGERY DATES WERE WRONG IN THE FOLLOW UP. APPY WAS DONE ON (B)(6) 2013 AND HYSTERECTOMY WAS (B)(6) 2014. ALL OTHER INFORMATION IS CORRECT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037600	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 4/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I SUFFER FROM PAINFUL PERIODS, CYSTS ON MY OVARIES THAT CAUSE SERIOUS PAIN UNTIL THEY RUPTURE WHICH I CAN FEEL HAPPEN, PELVIC PAIN, PAIN ALL OVER MY STOMACH, TENDER BREASTS, MIGRAINES, FOUL TASTE IN MY MOUTH, HAIR THINNING, ANGER, SADNESS, LOTS OF MOOD SWINGS, ACNE, PAIN IN MY KIDNEYS, RESTLESS LEG SYNDROME, MEMORY FOG, TROUBLE CONCENTRATING, RINGING IN MY EARS, CONSTIPATION. AND I REALLY CAN'T STRESS ENOUGH ALL THE STOMACH PAIN I HAVE. I FEEL LIKE I'VE BEEN POISONED AND PAINS SHOOT THROUGHOUT MY WHOLE UPPER BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037601	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 8/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SIDE PAINS SINCE THE ESSURE WAS IMPLANTED. I HAVE BEEN DIAGNOSED WITH IBS, FIBROMYALGIA, SEVERE MIGRAINES, LOWER BACK PAINS, FREQUENT SKIN HIVES, SLEEP DISORDERS, PERICARDITIS, DIZZINESS, INTERSTITIAL CYSTITIS AND PELVIC FLOOR DISFUNCTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037602	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 8/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, ABNORMAL AND PAINFUL PERIODS, EXCESSIVE BLEEDING DURING PERIODS, CONSTANT SPOTTING, EXCESSIVE SWEATING, HOT FLASHES, HEADACHES, DIZZINESS, HAIR LOSS, WEIGHT GAIN, AND MOOD SWINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037603	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 8/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVEN'T STOP BLEEDING SINCE I HAD THE PROCEDURE BACK IN (B)(6), 2014. I THOUGHT THE CRAMPING AND PAIN AFTER THE FIRST 2 WEEKS WAS NORMAL. I GET STABBING PAIN IN MY UTERUS, I STILL BLEEDING , AM BLOATED AND I FEEL REALLY TIRED. I NOTICED THAT I GET ITCHING AND NUMBNESS IN THE BACK OF MY HEAD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037604	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 9/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING, SWELLING IN MY FEET, HOT FLASHES, HEAVY BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037605	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 11/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE GAINED 55 POUNDS IN JUST 7 MONTHS OR SO I HURT CONSTANTLY MY HEADACHES ARE SO BAD I PASS OUT I HAVE DEPRESSION ANXIETY MAJOR WEIGHT GAIN ABDOMINAL PAIN BACK PAIN BLOATING EVERY DAY DIZZY SPELLS NO SEX DRIVE AND THIS NEVER HAPPENED BEFORE ESSURE BEFORE THESE STUPID COILS I WAS HAPPY AND NOT A WORRY IN THE WORLD NOW YOU HAVE DEVELOPED ALL THESE THINGS AFTER ESSURE AND I WANT THEM TAKING OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037606	BAYER	8/6/2014	8/6/2014

Event Information:

Event Date (B3): 4/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE IN (B)(6) OF 2011 AND SINCE SPRING OF 2012 I HAVE BEEN HAVING PAIN, BROWN MUCUS, BIG BLOOD CLOTS DURING PERIODS, I HAVE FELT MY UTERUS CONTRACT FOR 45 MINUTES AFTER HAVING INTERCOURSE WITH MY HUSBAND. I HAVE HORRIBLE HEADACHES ALL THE TIME, BAD FATIGUE, I CAN'T STAND NOR SIT FOR LONG PERIODS OF TIME. I CAN'T LIFT ANYTHING WITHOUT FEELING PAIN ON LEFT AND RIGHT SIDE. I DIDN'T HAVE CYSTS BEFORE I GOT THE ESSURE AND NOW I DO. I HAVE NO ENERGY LIKE EVER. I HAVE HOT FLASHES BEFORE DURING AND AFTER MY PERIOD EVERY MTH. I NEVER HAD HOT FLASHES BEFORE I GOT ESSURE. BENDING OVER TO BATHE MY KIDS HURTS AND I HAVEN'T BEEN ABLE TO BEND OVER FOR OVER A MTH NOW. I CAN'T PUT ANY PRESSURE ON MY ABDOMEN AREA, IT HURTS REALLY BAD IF I DO. I CAN'T LAY ON MY STOMACH BECAUSE IT HURTS REAL BAD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037659	BAYER	8/7/2014	8/7/2014

Event Information:

Event Date (B3): 6/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD TO HAVE SURGERY DUE TO INFLAMMATION, RASHES, AND CONSTANT PAIN TO REMOVE BOTH OF MY TUBES AND UTERUS DUE TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037660	BAYER	8/7/2014	8/7/2014

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY SON IN (B)(6) 2011 AND THE ESSURE PROCEDURE DONE IN (B)(6) 2011. I STARTED GAINING WEIGHT ALMOST IMMEDIATELY. BEFORE I COULD EVEN GET MY HSG DONE I WAS HAVING A SECOND SURGERY WHICH I WAS TOLD WASN'T RELATED; IT WAS FOR MY GALL BLADDER. NEVER HAD A SINGLE ISSUE WITH IT UNTIL THE END OF (B)(6). BY (B)(6) I WAS HAVING ATTACKS SO BAD I HAD TO CRAWL ON THE FLOOR TO THE BATHROOM, TO MAKE BOTTLES FOR MY INFANT SON, TO HELP MY (B)(6) OLD, ETC. THAT SURGERY WAS (B)(6). BY THE END OF (B)(6), I WAS ALSO HAVING SEVERE PAIN AND TOTAL NUMBNESS IN MY WRISTS AND HANDS, IT WAS FIRST ASSUMED I HAD TENDONITIS SO I WAS GIVEN IBUPROFEN AND A BRACE. ONCE THAT DIDN'T HELP THEY SENT ME TO A UPPER EXTREMITY AND NERVE SPECIALIST. I HAD AN EMG DONE TO TEST FOR CARPAL TUNNEL WHICH WAS EXTREMELY PAINFUL AND TURNED UP NORMAL. THEY JUST TOLD ME TO REST MY ARMS (IMPOSSIBLE WITH TWO SMALL KIDS) AND LET IT GO. HAD MY HSG DONE IN (B)(6) OF THAT YEAR, IT SHOWED EVERYTHING WAS BLOCKED AND WAS FAIRLY PAINLESS. AROUND THIS TIME IS WHEN THE HEAVY, EXTREMELY PAINFUL PERIODS BEGAN. I IGNORED IT BECAUSE I WAS GOING THROUGH A LOT (HAD JUST GOTTEN MY YOUNGER BROTHER SOBER OFF OF OPIATES AND PUT HIM UP IN MY HOME AGAIN. HE HAD A BRAIN HEMORRHAGE AND WE FOUND HIM DEAD IN HIS ROOM) AND DIDN'T HAVE TIME TO HANDLE MY OWN ISSUES. AROUND (B)(6) 2012 THE PAIN WHEN MY PERIOD WASN'T DUE STARTED. EXCRUCIATING, STABBING, TAKE ME TO MY KNEES PAIN. MOSTLY ON THE RIGHT SIDE. THEN CAME THE SPOTTING, THEN THE FULL ON PERIODS WHENEVER. MY DOCTOR BRUSHED IT OFF, KEPT TRYING OTHER BIRTH CONTROLS FOR THE HORMONES. THE WHOLE REASON I GOT THIS DONE WAS TO NOT HAVE TO TAKE PILLS OR ANY OTHER FORM OF BIRTH CONTROL. SHORTLY AFTER THOSE THINGS BEGAN, SO DID WHAT I WOULD CONSIDER MIGRAINE HEADACHES AND SLEEPLESS NIGHTS. MY FAMILY DOCTOR BRUSHED IT OFF; TOLD ME I NEED MORE EXERCISE, LESS CAFFEINE ETC. THEY

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TOLD ME MY LACK OF WEIGHT LOSS WAS BECAUSE I WASN'T TRYING HARD ENOUGH. I WORKED OUT DAILY AND HAD BEEN WATCHING WHAT I ATE SINCE GALL BLADDER REMOVAL. MY MOOD SWINGS ARE OUT OF CONTROL, MY SEX DRIVE IS GONE. I AM CONSTANTLY FATIGUED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037715	BAYER/CONCEPTUS	8/7/2014	8/14/2014

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/30/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2013 AND SINCE MY PROCEDURE, I'VE HAD WORSENING SHARP, STABBING RELENTLESS PAIN IN MY PELVIC AREA EXTENDING INTO MY LEGS THAT DOES NOT ALLOW ME TO WALK WELL OR LIFT HEAVY OBJECTS, WEIGHT LOSS, HAIR LOSS, GENERAL MALAISE, BODY ACHES, INSOMNIA DUE TO PAIN, IRREGULAR BLEEDING, DISCHARGE, MIGRAINES AND LOSS OF APPETITE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00320	BAYER HEALTHCARE LLC	8/7/2014	9/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS. IN 2012 ESSURE WAS INSERTED. ON AN UNSPECIFIED DATE, HSG WAS DONE AND SHOWED THAT THE TUBES WERE OCCLUDED. IN 2013, THE CONSUMER EXPERIENCED PAIN AND DIZZINESS AND WAS TOLD THAT SHE WAS PREGNANT. SHE STATED IT WAS A DIFFICULT PREGNANCY, HAD TO GO TO THE HOSPITAL NUMEROUS TIMES AND WAS GIVEN AN UNKNOWN MEDICATION TO STOP THE CONTRACTIONS AND STEROIDS DUE TO PRE-TERM LABOR. ON AN UNSPECIFIED DATE, SHE DELIVERED A HEALTHY FEMALE BABY. SHE STATED THAT SHE HAD A SECOND HSG TEST AFTER THE PREGNANCY AND WAS TOLD THAT THE DEVICE WAS NOT IN HER TUBE, IT WAS SITTING OUTSIDE AND RIGHT NEXT TO THE TUBE. THE OUTCOME OF THE EVENT DIFFICULT PREGNANCY WITH ESSURE WAS RECOVERED I RESOLVED. CONSUMER REFUSED TO PROVIDE CONTACT INFORMATION.

Manufacturer Narrative (H10):

FOLLOW UP (B)(4) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPEC

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00319	BAYER HEALTHCARE LLC	8/7/2014	12/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76537

Single Use: Y
Implant Date (E6): 7/10/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER B76537 INSERTED ON (B)(6) 2014 AND FIVE COILS BROKE (IN ONE PIECE) DURING INSERTION. REPORTER STATED THAT EVERYTHING WAS FINE UNTIL HE CLICKED TO RELEASE (DEPLOY) INSERT. WHEN HE PULLED BACK, IT SEEMED FINE, THERE WAS NO TENSION BUT FIVE COILS BROKE (IN ONE PIECE) FROM INSERT. HE WAS ABLE TO REMOVE THE BROKEN PIECE WITH HYSTEROSCOPE. HE WILL AND DO AN HSG ON THIS PT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(6) . FINAL ASSESSMENT: WHEN A TERM LIKE "BROKE" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, OR IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN". SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MFG SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MFG BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE CANNOT CONFIRM THIS QUALITY COMPLAINT;

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HOWEVER, BASED ON THE COMPLAINT DESCRIPTION PROVIDED, WE ARE ABLE TO CONCLUDE THAT A QUALITY ISSUE IS PLAUSIBLE. IT IS POSSIBLE DURING THE MFG ASSEMBLY PROCESS A SMALL GAP WAS LEFT BETWEEN THE INNER COIL AND INNER CATHETER (THEY SHOULD BE BUTTED TOGETHER DURING ASSEMBLY). WHEN THE OUTER COIL OF THE MICRO-INSERT IS WOUND DOWN A SMALL PORTION OF THE COIL CAN BECOME TRAPPED IN THE GAP. IF A DEVICE HAS THIS ISSUE, WHEN THE PHYSICIAN PRESSES THE BUTTON TO RELEASE THE MICRO-INSERT, THE OUTER COIL MAY SEVER ITSELF AS IT IS BEING DEPLOYED FROM THE CATHETER. IN TYPICAL SITUATIONS, THIS SEVERING OCCURS INSIDE THE CATHETER PRIOR TO THE PIECES BEING DEPLOYED FROM THE CATHETER. THE SEVERING OF THE COILS INSIDE THE CATHETER DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PT. MEDICAL ASSESSMENT: THIS CASE REPORTED COMPLICATION OF INSERTION DUE TO BREAKAGE BUT THESE REPORTED EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THREE (3) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER B76537 BUT ONLY TWO (2) OF THESE CASES REFER TO A BREAKAGE EVENT AS WELL AS COMPLICATION OF INSERTION. NO UNUSUAL PATTERN CAN BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION BUT BASED ON THE COMPLAINT DESCRIPTION PROVIDED, THE RQU WAS ABLE TO CONCLUDE THAT A QUALITY ISSUE IS PLAUSIBLE DUE TO THE CAUSE OF THE DESCRIBED BREAKAGE HAS BEEN PREVIOUSLY INVESTIGATED AND IS WELL UNDERSTOOD. AT TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED" UNCONFIRMED QUALITY DEFECT - BUT PLAUSIBLE" WITH A FINAL RISK CATEGORY IV, A DEFECT WHICH DOES NOT POSE A HAZARD TO PT'S HEALTH AS THE SEVERING OF THE COILS DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PT. ACCORDING TO THE TECHNICAL ASSESSMENT A QUALITY DEFECT WAS PLAUSIBLE AND BASED ON THE PROVIDED INFO THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING MEDDRA LLT DEVICE BREAKAGE. IN SUMMARY, BASED ON THE AVAILABLE INFO A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED BETWEEN THE REPORTED DEVICE BREAKAGE AND A PRODUCT DEFECT. FOLLOW UP INFO RECEIVED ON 07/23/2014: ALL FOLLOW UP ATTEMPTS DONE WITH NO RESPONSE TO DATE. CASE CLOSED.

Manufacturer Narrative (H10):

COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE FIVE COILS BROKE (IN ONE PIECE) FROM INSERT (COMPLICA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037998	CONCEPTUS/BAYER	8/8/2014	9/4/2014

Event Information:

Event Date (B3): 4/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/11/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE PROCEDURE DONE ON (B)(6) 2014. I WENT FOR MY HSG TEST ON (B)(6) 2014 AND FOUND THAT THE RIGHT SIDE WAS COMPLETELY SEALED BUT THE LEFT SIDE WAS OPEN AND THE COIL WAS PIERCED THROUGH MY UTERUS. I HAVE BEEN HAVING BURNING, STABBING, THROBBING PAINS ALMOST CONSTANTLY ON MY LEFT SIDE AND OCCASIONALLY ON MY RIGHT. I AM SCARED TO MOVE TO QUICKLY OR PICK UP MY KIDS FOR FEAR IT WILL DISLODGE AND SEVERE SOMETHING VITAL. I VISITED A DIFFERENT OB AND HE TOLD ME MY ONLY OPTION WAS TO HAVE A HYSTERECTOMY. I COULD POSSIBLY DIE REMOVING IT BY BLEEDING TO DEATH. I AM HAVING ALMOST CONSTANT HEADACHES, CRAMPING AND BLOATING. I SHOULD NOT HAVE A HYSTERECTOMY AT AGE (B)(6). I AM A NURSING MOTHER AND NICKEL IS KNOWN TO LEAK INTO BREASTMILK. I WAS NOT TOLD THIS UPON GETTING IT IMPLANTED. I HAVE NO IDEA WHAT SORT OF DAMAGE THIS MAY BE DOING TO MY CHILD. MY DR TOLD ME THAT THIS WAS THE SAFEST MOST CONVENIENT OPTION. THIS IS NOT TRUE. IT HAS DONE NOTHING BUT CAUSE ME PROBLEM. THIS IS NOT SAFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037700	CONCEPTUS INC.	8/11/2014	8/13/2014

Event Information:

Event Date (B3): 1/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE - CONCEPTUS INC.
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/6/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL PAIN THAT RADIATES INTO LOWER BACK, PULSATING SENSATION AROUND FALLOPIAN TUBES, SPOTTING BETWEEN MENSTRUAL CYCLE, IRREGULAR MENSTRUAL CYCLE. SHOOTING PAIN IN LEGS, SEVERE CONSTIPATION. SUGGESTS PROBLEM COULD BE RELATED TO ESSURE. SEEN BY FAMILY PHYSICIAN, FOLLOWED BY AN ER VISIT LATER THAT NIGHT DUE TO SEVERITY OF SYMPTOMS. DIAGNOSIS OR REASON FOR USE: TO PREVENT PREGNANCY, STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037701		8/11/2014	8/13/2014

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): A63347

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE WAS DEPLOYED INTO FALLOPIAN TUBE. UPON REMOVAL OF THE INSERTION DEVICE, THE COIL WAS NOTED TO STILL BE PRESENT ON THE INSERTER, HAVING PULLED OUT OF THE FALLOPIAN TUBE INTACT. DIAGNOSIS OR REASON FOR USE: ELECTIVE STERILIZATION. MANUFACTURER NAME, CITY AND STATE: AR-MED LTD. (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037702		8/11/2014	8/13/2014

Event Information:

Event Date (B3): 8/1/2012	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE COILS PUT IN (B)(6) 2012. MANY INFECTIONS, ULTRASOUNDS DUE TO PAIN IN RIGHT SIDE. CHANGE OF BOWEL MOVEMENTS, DIZZINESS, NAUSEA CONSTANTLY. PAIN IN RIGHT SIDE IS CONSTANT, BEEN TO (B)(6) MANY TIMES. ULTRASOUNDS DONE. HAD INFECTION AFTER SURGERY, PAIN IMMEDIATELY FOLLOWED UP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037703		8/11/2014	8/13/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE IN 2001 AND STARTED HAVING PAIN SHORTLY AFTER. THE PAIN HAD LASTED FOR OVER 12 YEARS. IT HAS NOT ONLY TAKE ITS TOLL ON MY BODY BUT MY LIFE AS WELL. MY QUALITY OF LIFE HAS NOT BEEN THE SAME AND NOW I'M GOING TO GO THROUGH A SURGERY TO TRY AND STOP THIS HORRIBLE PAIN. I GET THE WORST CRAMPING THAT I CAN HARDLY MOVE. I FEEL LIKE THERE IS BARBED WIRE JUST TEARING MY INSIDES UP. NOT TO MENTION ALL THE OTHER SYMPTOMS LIKE THE MIGRAINE HEADACHES, BACK PAINS, INSOMNIA, DEPRESSION, LACK OF ENERGY, AND MANY MORE. THIS PRODUCT SHOULD NOT BE USED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037801	BAYER	8/11/2014	8/21/2014

Event Information:

Event Date (B3): 3/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4): ESS205
Lot #(E4): 12244149

Single Use:
Implant Date (E6): 3/8/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE STERILIZATION PROCEDURE DONE ON (B)(6) 2014. I HAVE BEEN GOING TO THE DOCTOR FOR SEVERAL SYMPTOMS SUCH AS: NAUSEA/VOMITING, DIARRHEA, MODERATE TO SEVERE PAIN IN LOWER ABDOMINAL AREA, TASTE OF METAL IN MOUTH, TINGLING IN LEGS, A LINGERING VAGINAL ODOR AND PERIODIC ITCHING IN VAGINAL AREA, USUAL TASTE IN MOUTH, AND PAINFUL INTERCOURSE. I HAVE GONE TO DOCTORS WITH NO RESOLVE. AFTER ADMINISTERING TESTS, THEY CANNOT FIND THE CAUSE. SO AT THIS POINT, I HAVE BEEN HAVING SYMPTOMS TREATED. IT DAWNED ON ME THAT PERHAPS THE PROCEDURE COULD BE THE ISSUE SO I ASKED MY GYN IF HE FELT THIS WAS POSSIBLE. JUST AS I ASSUMED, HE KNEW SO LITTLE ABOUT THE PRODUCT, AS WELL AS OTHERS. I AM SADDENED THAT DOCTORS ARE NOT INFORMED ON THIS PROCEDURE. THE TYPE OF WORK I DO MAKES IT VERY DIFFICULT FOR ME TO PERFORM AT 100%. IN FACT, I MUST HAVE TAKE ANTI-DIARRHEAL MEDS AND NAUSEA MEDICATIONS DAILY, SINCE THE GASTROINTESTINAL DOCTOR SAID HE SAW NO REASON WHY I SHOULD BE HAVING THESE SYMPTOMS (HE EVEN PRESCRIBED SOME MEDICATIONS FOR THE SYMPTOMS), BUT AGAIN TREATING A SYMPTOM WITHOUT KNOWING THE CAUSE. I STRONGLY FEEL THIS IMPLANT HAS TO BE THE UNDERLYING CAUSE OF THESE SYMPTOMS. I AM NOT A DOCTOR, BUT I HAVE INFORMED THEM ON EACH VISIT AND I ALSO PRESENT THE MEDICAL INFORMATION CARD THAT I WAS GIVEN AFTER THE PROCEDURE WAS PERFORMED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00324	BAYER HEALTHCARE LLC	8/12/2014	8/26/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B60747/ 12566552

Single Use: Y
Implant Date (E6): 7/14/2014
Explant Date (E7): 7/14/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. PREGNANCY WAS DENIED. ESSURE LOT NUMBER B60747, EXPIRATION DATE AUG-2016 WAS INSERTED FOR CONTRACEPTION. ESSURE COIL GOT STUCK AND WOULD NOT GO ANY FURTHER AND WHEN REMOVED FROM INTRODUCER THE TIP WAS BROKEN ON (B)(6) 2014 AND IT HAD BEEN INSIDE THE PATIENT. IT WAS NOT REMOVED. BILATERAL PLACEMENT WAS ACHIEVED WITH OTHER COILS. FOLLOW UP INFORMATION FROM (B)(6) 2014: NEW LOT NUMBER WAS PROVIDED. NURSE CALLED ASKING REPLACEMENT FOR ESSURE LOT NUMBER 12566552, EXPIRATION DATE DEC-2015 (DISCREPANT INFORMATION WAS PREVIOUSLY PROVIDED.) SHE ALSO INFORMED THAT ESSURE WAS REMOVED ON (B)(6) 2014 AND THAT BILATERAL PLACEMENT WAS ACHIEVED WITH DIFFERENT COILS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP FROM 01-AUG-2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE ESSURE COIL GOT STUCK AND WOULD NOT GO ANY FURTHER AND WHEN REMOVED FROM INTRODUCER THE TIP WAS BROKEN. REPORTER CAUSALITY WAS NOT PROVIDED. THESE EVENTS; INTERPRETED AS A DEVICE DEPLOYMENT ISSUE AND BREAKAGE, ARE NON-SERIOUS. THE REPORTED BREAKAGE IS UNLISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS CONSIDERED A NEAR-INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE DEPLOYMENT ISSUE IS LISTED AND NON-INCIDENT. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, A DEPLOYMENT

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ISSUE WAS REPORTED DURING ESSURE PLACEMENT PROCEDURE AND WHEN THE DEVICE WAS REMOVED FROM THE INTRODUCER ITS TIP WAS BROKEN. A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THE REPORTED EVENTS, HOWEVER CONSIDERING THAT THEY OCCURRED IN ASSOCIATION WITH ESSURE INSERTION, THEIR A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00322	BAYER HEALTHCARE LLC	8/12/2014	9/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B66025

Single Use: Y
Implant Date (E6): 2/26/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATED ON 03/07/2014 WHICH REFERS TO A (B)(6) YR OLD FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER B66025 (EXP DATE 09/2016). IT WAS REPORTED THAT THE COIL MISFIRED AND ONE COIL WENT IN AND SOME PARTS AND PIECES THAT FELL WITHIN THE CAVITY AND THE PHYSICIAN HAD TO GO FISHING FOR THE OTHER PIECES THAT FELL APART. THE DOCTOR HAD TO OPEN UP ANOTHER PACKAGE AND THE PLACEMENT WAS SUCCESSFUL.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 08-AUG-2014: NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION FROM 19-AUG-2014: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00323	BAYER HEALTHCARE LLC	8/13/2014	8/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/26/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. PHARMACIST REPORTED THAT ESSURE WAS INSERTED IN AN OPERATING ROOM ON (B)(6) 2014. ESSURE MATERIAL DEFECT: THUMBWHEEL RAN IDLE, NO CLIC SOUND AT RELEASE. ESSURE WAS PLACED AND DELIVERY CATHETER REMOVED WITHOUT USUAL PROTOCOL, MATERIAL WAS CHECKED AFTER SURGERY. THUMBWHEEL WHICH RAN IDLE FINALLY UNLOCKED. ESSURE SYSTEM WAS NOT AVAILABLE. BLOOD EXPOSURE ACCIDENT AND STITCHES FOR THE OPERATOR FOLLOWING THE CHECK OF THE MATERIAL. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. CORRECTION PERFORMED ON (B)(6) 2014 REGARDING THE INITIAL REPORT FROM (B)(4) 2014: THIS CASE REFERS TO A GYNECOLOGIST'S ASSISTANT (GENDER NOT REPORTED) WHO WAS EXPOSED TO ESSURE DURING INSERTION PROCEDURE IN A PATIENT AND EXPERIENCED THE ADVERSE EVENTS AS PREVIOUSLY DESCRIBED IN THE NARRATIVE. ALSO THE EVENT STITCHES FOR THE OPERATOR FOLLOWING THE CHECK OF THE MATERIAL (DURING ESSURE INSERTION) WAS AMENDED TO UNLISTED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: 1) ROLLBACK TO INITIAL HARD STOP. 2) DEPRESS BUTTON. 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE

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AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED; HOWEVER, THE OPERATOR WAS INJURED DUE TO THE HANDLING ERROR. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED AS WELL AS THE REPORTED TECHNICAL ISSUE ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT", STATED THAT MEDICAL EVENT REPORTED WAS DUE TO HANDLING ERROR AND THAT A DETACHMENT DIFFICULTY EVENT IS AN ANTICIPATED EVENT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A GYNECOLOGIST'S ASSISTANT WHO HAD BLOOD EXPOSURE ACCIDENT FOR THE OPERATOR FOLLOWING THE CHECK OF THE MATERIAL DURING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION IN A PATIENT AND RECEIVED STITCHES FOR THE OPERATOR FOLLOWING THE CHECK OF THE MATERIAL (DURING ESSURE INSERTION). ALSO AT THE PROCEDURE THERE WAS A MATERIAL DEFECT: THUMBWHEEL RAN IDLE, NO CLIC SOUND AT RELEASE. ALL THE REPORTED EVENTS ARE NON-SERIOUS. THE EVENT STITCHES FOR THE OPERATOR FOLLOWING THE CHECK OF THE MATERIAL (DURING ESSURE INSERTION); INTERPRETED AS AN OCCUPATIONAL INJURY TO THE ASSISTANT, WAS INITIALLY CONSIDERED LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND FURTHER AMENDED TO UNLISTED AFTER A COMPANY INTERNAL REVIEW. THIS EVENT WAS REGARDED AS NEAR-INCIDENT SINCE IT COULD HAVE LED TO SERIOUS INJURY. THE REMAINING EVENTS ARE LISTED. CONSIDERING THAT THE INJURY AND REPORTED MATERIAL DEFECT OCCURRED AT ESSURE INSERTION PROCEDURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE EVENT BLOOD EXPOSURE ACCIDENT FOR THE OPERATOR FOLLOWING THE CHECK OF THE MATERIAL (DURING ESSURE INSERTION), GIVEN ITS NATURE IT WAS CONSIDERED AS UNRELATED TO ESSURE. A PRODUCT TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT", STATED THAT MEDICAL EVENT REPORTED WAS DUE TO HANDLING ERROR AND THAT A DETACHMENT DIFFICULTY EVENT IS AN ANTICIPATED EVENT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION WAS RECEIVED FROM THE GYNECOLOGIST ON (B)(6)-2014. INITIALS, DATE OF BIRTH, WEIGHT AND HEIGHT CONCERNED THE PATIENT WHO HAD ESSURE EASILY INSERTED WAS PROVIDED. ULTRASOUND SHOWED THAT ESSURE WAS IN PLACE. PLAIN ABDOMEN X-RAY WAS REQU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00325	BAYER HEALTHCARE LLC	8/13/2014	8/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** GM

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM (B)(6) ON (B)(6)-2014 AND REGARDS TO A FEMALE CONSUMER OF UNSPECIFIED AGE FROM UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UTERUS BROKEN BY A COIL WAS PIERCED. A YOUNG WOMAN, WHO AFTER THE BIRTH OF HER THIRD CHILD HAD ESSURE INSERTED. HER UTERUS, ALLEGEDLY BROKEN BY A COIL, WAS PIERCED AND HAD TO BE COMPLETELY REMOVED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENT REPORTED IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4)-2014: THE (B)(4) WAS FOUND TO BE A DUPLICATE OF THIS CASE. ALL INFORMATION WAS TRANSFERRED TO THIS CASE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT RECEIVED FROM LAY PRESS REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UTERUS BROKEN BY A COIL WAS

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PIERCED. THIS EVENT WAS CONSIDERED SERIOUS AND INCIDENT SINCE IT LED TO SERIOUS INJURY AND REQUIRED A SURGICAL INTERVENTION (HYSTERECTOMY). IT IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE EXACT NATURE OF THE UTERINE INJURY WAS NOT CLEAR FROM THE REPORTED INFORMATION. REPORTED EVENT UTERUS BROKEN BY A COIL WAS PIERCED COULD REFER TO A UTERINE PERFORATION WHICH MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). THEREFORE, EVENT UTERUS BROKEN BY A COIL WAS PIERCED WAS CONSIDERED RELATED TO ESSURE. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037721	BAYER	8/13/2014	8/14/2014

Event Information:

Event Date (B3): 8/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT MY ESSURE 6 YEARS AGO; WITHIN MY FIRST YEAR, I STARTED GETTING REALLY BAD MIGRAINES AND PELVIC PAIN. THEN NO PERIOD. I HAVE CYST ON MY OVARIES NOW THAT I NEVER HAD BEFORE; A TILTED CERVIX THAT I NEVER HAD TIL ESSURE; I'VE HAD A MISCARRIAGE IN (B)(6) 2012 WASN'T THAT FAR ALONG. I HAVE NUMBNESS IN MY HANDS AND FEET, TIRED ALL THE TIME, BRAIN FOG, I GET INFECTION VERY EASILY NOW NEVER DID BEFORE ESSURE, I HAVE FATIGUE, MOODINESS, DEPRESSION, MY HAIR IS FALLING OUT, BLOATED (LOOKING 6 MONTHS PREGNANT AND I'M NOT), WEIGHT GAIN, I'M ALLERGIC TO NICKEL AND MY IMPLANTING DR. NEVER TOLD ME THEY HAD NICKEL PLATED, MY LEFT COIL IS EITHER UNRAVELED OR THERE'S TWO ON MY LEFT SIDE, CONSTANT PAIN THROUGH MY ENTIRE BODY EVERYDAY. GOING TO HAVE TO GET A HYSTERECTOMY TO REMOVE THEM AND I'M ONLY (B)(6) YEARS OLD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037722	BAYER	8/13/2014	8/14/2014

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT UNBEARABLE ABDOMINAL PAIN, HEADACHES, LOSS OF HAIR, BLOATING (NONSTOP) , ECT.....

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037723	BAYER	8/13/2014	8/14/2014

Event Information:

Event Date (B3): 5/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERFORATED LEFT FALLOPIAN TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00327	BAYER HEALTHCARE LLC	8/13/2014	8/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** GM

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT WAS A TRANSLATION OF (B)(6) WHICH WAS REGARDING WOMEN WHO HAD ESSURE INSERTED AND EXPERIENCED ADVERSE EVENTS IN UNITED STATES. IT WAS STATED THAT A PHOTO SHOWS AN UNBORN, ON WHOSE NECK A METAL ROD INFECTED, APPARENTLY PART OF A BROKEN COIL. NO FURTHER INFORMATION WAS PROVIDED. (B)(4). THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6)-2014:(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(6), BECAUSE AN INVESTIGATION OF THE SAME FAILURE MODE HAS ALREADY BEEN INITIATED. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE (B)(6) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, GOT PREGNANT AND A PHOTO SHOWS AN

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UNBORN ON WHOSE NECK A METAL ROD INFECTED. THIS CASE IS NOT MEDICALLY CONFIRMED. NECK METAL ROD INFECTED IS CONSIDERED A SERIOUS EVENT DUE TO MEDICAL IMPORTANCE AND IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THIS EVENT WAS NOT CONFIRMED. BUT ACCORDING TO INFORMATION PROVIDED A CAUSAL RELATIONSHIP BETWEEN THE REPORTED SERIOUS EVENT AND ESSURE CANNOT BE EXCLUDED. PTC FINAL ASSESSMENT; THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FURTHER INFORMATION CANNOT BE REQUESTED SINCE THIS CASE WAS DERIVED FROM LAY PRESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037778	BAYER	8/13/2014	8/21/2014

Event Information:

Event Date (B3): 8/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 4/22/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT ESSURE IN (B)(6) OF 2014 AND STARTED HAVING CHRONIC PELVIC PAIN, WEIGHT GAIN ((B)(6) LBS) IN THREE MONTHS, WORSENING ALC LEVELS, PAIN DURING INTERCOURSE, RASHES, NAUSEA, SEVERE BACK PAIN, PRESSURE IN PELVIS, DEPRESSION, ANXIETY, AND SWINGS. DIAGNOSED WITH PELVIC CONGESTION SYNDROME AND POLY CYSTIC OVARIAN SYNDROME. HAD TO HAVE MULTIPLE CT SCANS AND ULTRASOUNDS ALONG WITH MANY DR VISITS AND ER VISITS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00326	BAYER HEALTHCARE LLC	8/13/2014	8/27/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** GM

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS A TRANSLATION OF GERMAN LAY PRESS WHICH WAS RECEIVED ON (B)(6) 2014 REGARDING WOMEN WHO HAD ESSURE INSERTED AND EXPERIENCED ADVERSE EVENTS IN UNITED STATES. EVENTS OCCURRED WITH FETUS WAS REPORTED ON CASE (B)(4). THE REPORTER PROVIDED ULTRASOUND PHOTOS OF FETUSES, AND A PHOTO SHOWED AN UNBORN (PREGNANCY WITH ESSURE - DEVICE INEFFECTIVE), ON WHOSE NECK A METAL ROD INFECTED, APPARENTLY PART OF A BROKEN COIL. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BROKEN COIL" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN". FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE

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INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: LACK OF EFFECTIVENESS MAY OCCUR WITH THE USE OF ANY PRODUCT AND PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. BOTH OF THESE REPORTED EVENTS ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THIS CASE ALSO REPORTED BREAKAGE WHICH IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND NOTED THAT A BREAKAGE EVENT IS AN ANTICIPATED EVENT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED A PREGNANCY WITH ESSURE (DEVICE INEFFECTIVE); ALSO ULTRASOUND PHOTOS SHOWED APPARENTLY PART OF A BROKEN COIL ON THE NECK OF THE UNBORN. BROKEN COIL, REGARDED AS A DEVICE BREAKAGE, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND REGARDED AS A NEAR-INCIDENT AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THIS EVENT PREVIOUSLY CONSIDERED UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, WAS, UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) UPDATED TO LISTED (ANTICIPATED). THE REMAINING EVENTS ARE LISTED AND NON-INCIDENTS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS PARTICULAR CASE, IT WAS NOT REPORTED THE DATE OF INSERTION OF ESSURE AND THE DATE OF CONCEPTION OR GESTATIONAL AGE. THEREFORE A CAUSAL RELATIONSHIP BETWEEN THE REPORTED PREGNANCY AND ESSURE CANNOT BE ASSESSED. REGARDING THE REMAINING EVENT, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. FOR THIS CASE A DEVICE BREAKAGE WAS SUSPECTED IN ULTRASOUND PHOTOS, ALTHOUGH THIS EVENT WAS NOT CONFIRMED GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. A PTC ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF ESSURE. NO FURTHER INFORMATION IS EXPECTED SINCE THIS IS A LAY PRESS CASE (NEWS MEDIA).

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00328	BAYER HEALTHCARE LLC	8/13/2014	8/28/2014

Event Information:

Event Date (B3): 7/18/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B82476

Single Use: Y
Implant Date (E6): 7/18/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014, DURING THE INSERTION PROCEDURE OF ESSURE LOT B82476, THE INSERTER WHEEL WAS ROLLED BACK TO A HARD STOP. THE GOLD NOTCH COULD NOT BE VISUALIZED. DEVICE PLACEMENT WAS ADJUSTED TO FIND GOLD NOTCH. THE GOLD NOTCH WAS NOTICED, STILL UNDER THE SHEATH. SEVERAL ATTEMPTS WERE MADE TO SCROLL THE WHEEL FURTHER BUT WITHOUT SUCCESS. THE PHYSICIAN ATTEMPTED TO REMOVE DEVICE. THE DISTAL TIP OF THE ESSURE IMPLANT WAS STUCK, ALTHOUGH THE DELIVERY DEVICE WAS REMOVED. GRASPERS WERE USED TO RETRIEVE THE REMAINING IMPLANT, BUT THE NITINOL COIL BROKE SEVERAL TIMES, DURING THE RETRIEVAL. THE DISTAL END OF THE INNER AND OUTER COIL COULD NOT BE VISUALIZED AND WHERE LEFT IN THE OS. PATIENT HAD NO INJURIES AND BILATERAL PLACEMENT WAS NOT ACHIEVED. NO FURTHER INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: 1) ROLLBACK TO INITIAL HARD STOP 2) DEPRESS BUTTON 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO "DEPLOYMENT DIFFICULTY." SEVERAL FACTORS

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CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4) , "PROCESSING ESSURE CASES IN DEV@COM," BECAUSE AN ADEQUATE INVESTIGATION OF THE SAME FAILURE MODE HAS ALREADY BEEN CONDUCTED. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS ALSO AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS CASE REPORTED COMPLICATION OF INSERTION DUE TO A DEPLOYMENT ISSUES WHICH LED TO BREAKAGE AND DIFFICULTY IN USE. THESE REPORTED EVENTS, BREAKAGE AND TECHNICAL/USABILITY ISSUES, ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. TWO (2) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER B82476 BUT NONE OF THESE CASES REFER TO A SIMILAR TYPE OF BREAKAGE OR TECHNICAL EVENT. ALTHOUGH ONE (1) CASE REFERS TO A SIMILAR USABILITY ISSUE IN A DIFFERENT CONTEXT. NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND NOTED THAT A DEPLOYMENT ISSUE OR A BREAKAGE EVENT ARE BOTH ANTICIPATED EVENTS. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP (B)(6) 2014: NO RESPONSE AFTER THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS COMPLETED. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DISTAL TIP OF THE ESSURE IMPLANT WAS STUCK / THE NITINOL COIL BROKE SEVERAL TIMES, DISTAL END OF THE INNER AND OUTER COIL COULD NOT BE VISUALIZED AND WHERE LEFT IN THE OS, SEVERAL ATTEMPTS MADE TO SCROLL THE WHEEL BUT WITHOUT SUCCESS, COMPLICATION OF DIVIDE INSERTION AND DEVICE INSERTION FAILED. ALL REPORTED EVENTS ARE NON-SERIOUS EXCEPT FOR THE EVENT DISTAL TIP OF THE ESSURE IMPLANT WAS STUCK / THE NITINOL COIL BROKE SEVERAL TIMES INTERPRETED AS A DEVICE BREAKAGE; WHICH WAS CONSIDERED SERIOUS AND REGARDED AS A NEAR-INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THIS EVENT PREVIOUSLY CONSIDERED UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, WAS, UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) UPDATED TO LISTED (ANTICIPATED). THE REMAINING EVENTS ARE LISTED AND NON-INCIDENTS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, DURING THE INSERTION PROCEDURE, THE INSERTER WHEEL WAS ROLLED BACK TO A HARD STOP. SEVERAL ATTEMPTS WERE MADE TO SCROLL THE WHEEL FURTHER BUT WITHOUT SUCCESS. THEN, THE PHYSICIAN ATTEMPTED TO REMOVE THE DEVICE AND THE DISTAL TIP WAS STUCK, ALTHOUGH THE DELIVERY DEVICE WAS REMOVED. GRASPERS WERE USED TO RETRIEVE THE REMAINING IMPLANT, BUT THE NITINOL COIL BROKE SEVERAL TIMES, DURING THE

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RETRIEVAL AND THE DISTAL END OF THE INNER AND OUTER COIL COULD NOT BE VISUALIZED AND WHERE LEFT IN THE OS. PATIENT HAD NO INJURIES AND BILATERAL PLACEMENT WAS NOT ACHIEVED. GIVEN THE EVENT'S NATURE, CAUSALITY BETWEEN THE EVENTS AND ESSURE USE IS ASSESSED AS RELATED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00321	BAYER HEALTHCARE LLC	8/13/2014	9/9/2014

Event Information:

Event Date (B3): 6/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71770

Single Use: Y
Implant Date (E6): 6/17/2014
Explant Date (E7): 6/18/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED THE FOLLOWING EVENTS. ON (B)(6) 2014, THE PHYSICIAN TRIED TO INSERT ESSURE, LOT NUMBER B71770. DURING THE INSERTION TUBE/UTERUS PERFORATION OCCURRED. PERFORATION WAS CONFIRMED BY X-RAY. PHYSICIAN PERFORMED A HYSTERECTOMY AND THE PATIENT WAS DOING FINE. NO FURTHER INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014. FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS:

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00329	BAYER HEALTHCARE LLC	8/14/2014	8/28/2014

Event Information:

Event Date (B3): 7/15/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A33565

Single Use: Y
Implant Date (E6): 7/15/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE INSERTION (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER A33565 . IT WAS STATED THAT COIL APPEARED TO HAVE A PIECE OF METAL IN IT AND PHYSICIAN TRIED TO REMOVE BUT WAS UNSUCCESSFUL. SECOND SIDE WAS NOT VISIBLE DUE TO DENSE TISSUE. BILATERAL PLACEMENT WAS NOT ACHIEVED. IT OCCURRED ON (B)(6) 2014. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS REPORT REFERS TO A (B)(6) FEMALE WHO HAD AN ATTEMPT OF ESSURE PLACEMENT AND EXPERIENCED COIL APPEARED TO HAVE A PIECE OF METAL IN IT, COMPLICATION OF DEVICE INSERTION , DOCTOR TRIED TO REMOVE BUT WAS UNSUCCESSFUL AND SECOND SIDE NOT VISIBLE, THEN BILATERAL INSERTION WAS NOT ACHIEVED. ALL EVENTS ARE NON-SERIOUS EXCEPT THE EVENT COIL APPEARED TO HAVE A PIECE OF METAL IN IT INTERPRETED AS A DEVICE BREAKAGE .THIS EVENT IS UNLISTED WHILE THE REMAINING EVENTS ARE LISTED. THIS CASE WAS REGARDED AS A NEAR-INCIDENT SINCE A DEVICE BREAKAGE WAS REPORTED. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE WAS STATED THAT COIL APPEARED TO HAVE A PIECE OF METAL IN IT AND PHYSICIAN TRIED TO REMOVE BUT WAS UNSUCCESSFUL. SECOND SIDE WAS NOT VISIBLE DUE TO DENSE TISSUE. BILATERAL PLACEMENT WAS NOT ACHIEVED. PTC ANALYSIS WILL BE REQUEST.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION FROM (B)(4) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00330	BAYER HEALTHCARE LLC	8/15/2014	8/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH CARE PROFESSIONAL IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED URTICARIA (HIVES) AND PELVIC PAIN. ON AN UNSPECIFIED DATE, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. IT WAS REPORTED THAT THE PATIENT EXPERIENCED URTICARIA (HIVES). THE ESSURES WERE REMOVED BILATERALLY BY LAPAROSCOPY ON UNKNOWN DATE. THE URTICARIA RESOLVED AFTER ESSURE REMOVAL. REPORTER DID NOT KNOW THE INSERTION DATE BUT SHE REPORTED THAT ESSURE DEVICES WERE REMOVED ABOUT 6 MONTHS AFTER THEY WERE INSERTED. REPORTER STATED THAT THE PATIENT CONTINUED TO HAVE PELVIC PAIN. PATIENT WENT TO ANOTHER PHYSICIAN AND HAD A HYSTERECTOMY. PATIENT IS SUING THE HEALTH CARE PROFESSIONAL WHO INSERTED ESSURE. NO FURTHER INFORMATION WAS PROVIDED. CORRECTION PERFORMED ON (B)(6) 2014: DURING INTERNAL REVIEW OF THIS CASE IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE (B)(6) 2014 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS (B)(4) 2014. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2014. NO NEW CLINICAL INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT

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OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN (B)(4)," BECAUSE AN INVESTIGATION OF THE SAME FAILURE MODE HAS ALREADY BEEN INITIATED. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE AND NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE (B)(4) FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW UP 01-AUG-2014: NO RESPONSE FROM THE PHYSICIAN AFTER FOLLOW UP ATTEMPTS TO OBTAIN ADDITIONAL INFORMATION. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED URTICARIA (HIVES). THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE ESSURE REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE PATIENT HAD URTICARIAL (HIVES) AND THE EVENT RESOLVED WITH ESSURE REMOVAL (PER LAPAROSCOPY). THEREFORE, DECHALLENGE CAN BE CONSIDERED AS POSITIVE. GIVEN THE POSITIVE DECHALLENGE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED AND DUE THE REQUIRED INSERT REMOVAL THIS CASE WAS REGARDED AS AN INCIDENT. ADDITIONALLY NON-SERIOUS EVENT PELVIC PAIN WAS REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037794	BAYER/CONCEPTUS	8/15/2014	8/21/2014

Event Information:

Event Date (B3): 7/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 7/16/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2011. I BEGAN EXPERIENCING PROBLEMS NOT LONG AFTER. HORMONAL AND OTHERWISE. HAD EXTREME FLUCTUATIONS IN BEHAVIOR. ANGER AND ANXIETY BEING THE MOST NOTABLE. THEN BEGAN HAVING HORRIBLE CYST-LIKE ACNE ON MY FACE. THEN BEGAN HAVING THE SAME PAINFUL PIMPLES IN MY VAGINAL AREA (NOT PLACES WHERE THERE WOULD BE ANY HAIR FOLLICLES). DEVELOPED A DRY, ITCHY, INVISIBLE SPOT ON ONE SIDE OF MY VAGINA. (ALL STD TESTS AND BACTERIA AND YEAST TESTS WERE NEGATIVE). BEGAN HAVING PHANTOM PERIODS WHICH INCLUDED CRAMPING AND A CLEAR, STRANGE, SMELLY DISCHARGE (ALSO STUMPED THE DOCTORS). HAD ELEVATED COPPER LEVEL. REDUCED SEX DRIVE. IDIOPATHIC PERIPHERAL NEUROPATHY DEVELOPED IN 2012. PERIODS BECAME HEAVIER AND CLOTTY. DURING AND BEFORE PERIODS WOULD HAVE DIZZY SPELLS. HYSTERECTOMY TO REMOVE DEVICE ENTIRELY AND NOT RISK HAVING ANY PIECE LEFT AS PER THE CONCEPTUS INFO PAMPHLET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00331	BAYER HEALTHCARE LLC	8/15/2014	9/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 789029

Single Use: Y
Implant Date (E6): 3/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE) INSERTED. ON (B)(6) 2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER 789029. IT WAS REPORTED THAT COIL DID NOT COMPLETELY RELEASE AND THEN BROKE OFF IN TUBE. NO INJURY TO THE PATIENT. BILATERAL PLACEMENT ACHIEVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED COIL DID NOT COMPLETELY RELEASE, BROKE OFF IN TUBE AND COMPLICATION OF DEVICE INSERTION. ALL THE EVENTS ARE CONSIDERED NON-SERIOUS. BROKE OFF IN TUBE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE REMAINING EVENTS ARE LISTED. THE EVENT BROKE OFF IN TUBE (ASSUMED AS DEVICE BREAKAGE) WAS REGARDED AS OTHER REPORTABLE EVENT AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, WAS REPORTED THAT COIL DID NOT COMPLETELY RELEASE AND THEN BROKE OFF IN TUBE, WITHOUT FURTHER DETAILS. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION , CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED EXCEPT THE EVENT COIL DID NOT COMPLETELY RELEASE THAT WAS CONSIDERED UNRELATED .

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION WAS RECEIVED ON 18-AUG-2014. NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 22-AUG-2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00332	BAYER HEALTHCARE LLC	8/18/2014	8/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/31/2012
Explant Date (E7): 3/11/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2013 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED U/S (ULTRASOUND) SHOWS RIGHT SIDE SHOT UP IN THE FALLOPIAN TUBE, SHE DID NOT GET HER PERIOD ANYMORE, ITCHING ALL OVER, RASH ALL OVER, BLURRY VISION, WEIGHT GAIN OF 30 POUNDS, AND HEADACHES. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. IT WAS NOT REPORTED WHETHER ESSURE WAS USED PREVIOUSLY. ABOUT TWO WEEKS AFTER ESSURE INSERTION THE CONSUMER DEVELOPED PELVIC PAIN ALTERNATING LEFT AND RIGHT SIDES. IT WAS SO BAD THAT SHE WANTS THE ESSURE OUT. IN (B)(6) 2012, SHE WENT TO THE EMERGENCY ROOM FOR PAIN AND AN ULTRASOUND SHOWED THE LEFT COIL WAS IN CORRECT PLACEMENT, BUT THE RIGHT SIDE SHOT UP IN THE FALLOPIAN TUBE. ON AN UNSPECIFIED DATE, THE HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED BUT CONSUMER DID NOT KNOW THE RESULTS. OTHER STRANGE SYMPTOMS SHE WAS PRESENTING INCLUDED: DID NOT GET HER PERIOD ANYMORE, INTERMITTENT STABBING PAIN ON THE LEFT AND RIGHT PELVIC SIDES, ITCHING AND RASH ALL OVER (USED CREAMS BUT NO IMPROVEMENT), AND WORSE OF ALL BLURRY VISION WHEN HER PRE-ESSURE VISION WAS VERY GOOD, WEIGHT GAIN OF 30 LBS, AND HEADACHES. ESSURE WAS NOT REMOVED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN U/S (ULTRASOUND) SHOWS RIGHT SIDE SHOT UP IN THE FALLOPIAN TUBE, SHE DID NOT GET HER PERIOD ANYMORE, ITCHING ALL OVER, RASH ALL OVER, BLURRY VISION, WEIGHT GAIN OF 30 POUNDS, HEADACHES AND ESSURE WAS NOT REPORTED. FOLLOW UP INFORMATION RECEIVED ON 10-FEB-2014: CONSUMER HAD 2 EMERGENCY VISITS. ONE OF HER COILS BROKE APART IN HER TUBE AND THE

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OTHER BECAUSE SHE HAD THE FOLLOWING SYMPTOMS: MAJOR WEIGHT GAIN (25-30 POUNDS), SEVERE STOMACH BLOATING, INTENSE INTERMITTENT PAIN IN HER TUBE AREA, PERIODS 2- 3 TIMES A MONTH, SPOTTING ALL THROUGH THE MONTH, VISION PROBLEMS, HEADACHES, ABDOMINAL PAIN IN OTHER AREAS, INTENSE PAIN ESPECIALLY RIGHT SIDE OVARY (FALLOPIAN TUBE AREA WHERE THE COIL BROKE APART), RASH AND SEVERE SKIN ITCHING. CONSUMER REPORTED THAT SHE WANTS ESSURE REMOVAL. ESSURE WAS NOT REMOVED YET. FOLLOW-UP - PTC INVESTIGATION RESULT WAS RECEIVED ON 11-APR-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. ADDITIONALLY REPORTED EVENTS OF DEVICE DISLOCATION AND BREAKAGE ARE ALSO NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT BATCH NUMBER OR SAMPLE. AT THE TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP INFORMATION WAS RECEIVED ON 21-JUL-2014. CONSUMER STATED SHE HAD THE ESSURE PROCEDURE DONE. SHE HAD THE DEVICE MALFUNCTION INSIDE OF HER AND I HAD TO HAVE IT REMOVED. ONE OF THE COILS GOT BROKE ALL APART AND WAS PIERCING THROUGH DIFFERENT PARTS OF MY FALLOPIAN TUBE. THE LEFT SIDE WAS PERFECT, BUT THE OTHER SIDE WAS COMPLETELY MANGLED CAUSING HER PAIN AND BLEEDING, LIKE 27 DAYS OF THE MONTH. SHE HAS SIX KIDS. THE DOCTOR TOLD HER IT HAD MALFUNCTIONED AND IT NEEDED TO BE REMOVED AS SOON AS POSSIBLE. SHE HAD IT REMOVED IN (B)(6) 2014. HE GAVE THE COILS TO HER IN A JAR AND HE SHOWED HOW BAD IT WAS AND SAID, 'NO WONDER WHY; IT IS COMPLETE DEVICE MALFUNCTION. CASE WAS UPGRADED TO INCIDENT DUE TO ESSURE REMOVAL. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 21-JUL-2014: THIS IS A POTENTIAL LEGAL CASE. CONSUMER SENT A LETTER REQUESTING REIMBURSEMENT STATING THAT ESSURE WAS BROKEN/ MANGLED. SHE ALSO FORWARDED A LETTER FROM PHYSICIAN. THIS CASE IS MEDICALLY CONFIRMED. ESSURE WAS INSERTED ON (B)(6) 2012 (NOT ON (B)(6) 2013 AS PREVIOUSLY ADDED IN THE NARRATIVE) AND NO COIL COULD BE SEEN EXTRUDING FROM THE RIGHT TUBAL OSTIUM, BUT IT WAS CONFIRMED THAT IT HAD BEEN DEPLOYED FROM THE DEVICE. BOTH COILS WENT INTO THE TUBES EASILY WITH NO RESISTANCE THE INTRODUCER DID NOT SLIDE OUT EASILY ON THE RIGHT SIDE, AND THE TAIL OF THE COIL WAS NOT SEEN AFTER PLACEMENT. OTHERWISE IT WENT EASILY. SHE CALLED 3 DAYS LATER WITH LEFT SIDED DISCOMFORT THAT WAS NOT SEVERE, STOPPED HER MICRONOR AFTER THE PROCEDURE (NOT SEXUALLY ACTIVE), AND HAS HAD A FEW BLEEDING EPISODES SINCE, SOME BILATERAL PELVIC PAIN SINCE THE PROCEDURE, WHICH WAS BETTER AT THAT TIME. SHORTLY THEREAFTER, SHE PRESENTED RIGHT SIDED PAIN. A FOLLOW-UP ULTRASOUND SHOWED THAT BOTH COILS WERE PRESENT IN THE ADNEXAE, AND A PLAIN FILM SHOWED THAT THE RIGHT ESSURE COIL WAS FRACTURED. SINCE THAT PROCEDURE SHE HAS EXPERIENCED CHRONIC PELVIC PAIN THAT SHE HAS NOT BEEN ABLE TO CONTROL. SHE REPORTED TO PHYSICIAN THAT WHILE HER SYMPTOMS HAVE BEEN WORSE ON THE RIGHT, THEY HAVE PERSISTED ON BOTH SIDES. SHE THUS FELT STRONGLY THAT SHE WANTS TO HAVE BOTH ESSURE COILS REMOVED, IN THE HOPE THAT IT WOULD IMPROVE HER SYMPTOMS. SHE ADDITIONALLY STATED TO PHYSICIAN ABNORMAL UTERINE BLEEDING, FOR WHICH PHYSICIAN RECOMMENDED A FULL EVALUATION THAT SHE UNDERGO A DIAGNOSTIC LAPAROSCOPY TO EVALUATE HER ADNEXAE AND THE COILS (PARTICULARLY THE FRACTURED RIGHT SIDED COIL), REMOVAL OF THE COILS, AND ENDOMETRIAL EVALUATION WITH DILATION AND CURETTAGE AND HYSTEROSCOPY. PHYSICIAN BELIEVED THAT THOSE PROCEDURES WERE MEDICALLY NECESSARY FOR HER CHRONIC PAIN, DEVICE MALFUNCTION (WITH THE FRACTURED COIL) AND ABNORMAL UTERINE BLEEDING. ON (B)(6) 2012 CONSUMER WENT TO THE

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EMERGENCY DEPARTMENT FOR PAIN AND BLEEDING, THE ESSURE COILS APPEARED TO BE IN THE BILATERAL TUBES BY ULTRASOUND, AND KUB SHOWED NO SIGN OF OBSTRUCTION, AND A BREAK IN THE RIGHT SIDED ESSURE COIL, WHICH WAS PROXIMAL, WITH A SMALL END OF THE COIL SEPARATED FROM THE REST OF THE DEVICE, SITTING IN THE CORNUA. RADIOLOGY REPORT INCLUDED: NO EVIDENCE OF HIGH-GRADE BOWEL OBSTRUCTION, BILATERAL FALLOPIAN TUBE COILS WERE IN PLACE WITH FRAGMENTATION OF RIGHT-SIDED COIL (LINEAR ECHOGENICITY IN THE AREA OF THE FALLOPIAN TUBE AND EXTENDING INTO THE CORNUA CORRESPONDING TO ESSURE) AND RIGHT OVARIAN CYST. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND U/S SHOWS RIGHT COIL SHOT UP IN THE FALLOPIAN TUBE/ ONE OF THE COILS WAS PIERCING THROUGH DIFFERENT PARTS OF MY FALLOPIAN TUBE, SPOTTING ALL THROUGH THE MONTH/ BLEEDING LIKE 27 DAYS OF THE MONTH , ONE OF THE COILS BROKE APART IN MY TUBE/ WAS COMPLETELY MANGLED THE INTRODUCER DID NOT SLIDE OUT EASILY ON THE RIGHT SIDE AND ABNORMAL UTERINE BLEEDING. U/S SHOWS RIGHT COIL SHOT UP IN THE FALLOPIAN TUBE/ ONE OF THE COILS WAS PIERCING THROUGH DIFFERENT PARTS OF MY FALLOPIAN TUBE, SPOTTING ALL THROUGH THE MONTH AND ABNORMAL UTERINE BLEEDING WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT ONE OF THE COILS BROKE APART IN MY TUBE/ WAS COMPLETELY MANGLED WAS INITIALLY REPORTED AS ONE OF THE COILS BROKE APART IN MY TUBE AND CONSIDERED NON-SERIOUS, NEAR-INCIDENT, HOWEVER UPON RECEIPT OF FOLLOW-UP INFORMATION IT WAS REGARDED AS SERIOUS, SINCE THE CONSUMER STATED THAT ESSURE WAS REMOVED. ALTHOUGH THE EXACT REMOVAL PROCEDURE WAS NOT REPORTED, WHEN ESSURE REMOVAL IS NECESSARY IT WILL LIKELY REQUIRE SURGERY; THEREFORE ALL THE ABOVE REPORTED EVENTS WERE CONSIDERED AS INCIDENTS. BLEEDING MAY OCCUR AFTER ESSURE INSERTION .THERE IS ALSO A POSSIBILITY THAT PATIENT EXPERIENCED BLEEDING AFTER ESSURE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS PARTICULAR CASE WAS STATED THAT CONSUMER EXPERIENCED , SPOTTING ALL THROUGH THE MONTH/ BLEEDING LIKE 27 DAYS OF THE MONTH AND ABNORMAL UTERINE BLEEDING. IN THIS PARTICULAR CASE, A RIGHT SIDE ESSURE COIL BREAKAGE AND PERFORATION WERE REPORTED, THE EXACT DATE AND MECHANISM OF THESE EVENTS WERE NOT KNOWN, HOWEVER GIVEN THEIR NATURE THEY WERE, IN ADDITION TO THE REPORTED BLEEDING, CONSIDERED AS RELATED TO ESSURE THERAPY. ADDITIONALLY THE NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00333	BAYER HEALTHCARE LLC	8/18/2014	8/18/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B06101

Single Use: Y
Implant Date (E6): 8/24/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY AND DEVICE INEFFECTIVE IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B06101, AT UNK IMPLANTED. ON AN UNSPECIFIED DATE THE PATIENT EXPERIENCED PREGNANCY. AT THE TIME OF THIS REPORT THE PREGNANCY WAS ONGOING. THE PATIENT HAD HSG (HYSTEROSALPINGOGRAM) THAT WAS PROBABLY MISREAD. ESSURE WAS NOT REMOVED. NO ASSESSMENT WAS GIVEN. FOLLOW-UP RECEIVED ON (B)(6) 2014: NO NEW CLINICAL INFORMATION. CASE CONSIDERED TO BE CLOSED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 (ESSURE HEALTHCARE PROFESSIONAL QUESTIONNAIRE RECEIVED): PATIENT´S DEMOGRAPHIC INFORMATION WAS PROVIDED (THIS IS A (B)(6) FEMALE PATIENT). PATIENT´S MEDICAL HISTORY INCLUDED GRAVIDA 3 AND PARA 3. IT WAS DENIED HISTORY OF GYNECOLOGICAL PROBLEMS AND PROCEDURES OR OTHER RELEVANT MEDICAL HISTORY. HER CONCURRENT CONDITION INCLUDED OBESITY (BMI=(B)(6)). ON (B)(6) 2013, ESSURE WAS INSERTED WITH DIFFICULT (TUBES WERE LIKELY SCARRED, COILS EVENTUALLY ABLE TO BE DEPLOYED). SHE WAS NOT POST-PARTUM AT THE TIME OF INSERTION. TORADOL AND VERSED WERE USED DURING INSERTION. DEPO-PROVERA INJECTION WAS USED AS BACK-UP CONTRACEPTION. ON (B)(6) 2013, A HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND SHOWED BILATERAL TUBAL OCCLUSION. ON (B)(6) 2014, PREGNANCY WAS CONFIRMED WITH URINE AND BLOOD TESTS. AN ULTRASOUND WAS ALSO PERFORMED AND CONFIRMED PREGNANCY. PATIENT´S LAST MENSTRUAL PERIOD OCCURRED ON (B)(6) 2014. ECTOPIC PREGNANCY WAS REPORTED

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(PREVIOUSLY REPORTED AS PREGNANCY). NO FURTHER INFORMATION WAS PROVIDED. THE CASE WAS UPGRADED TO INCIDENT DUE TO THE REPORTED ECTOPIC PREGNANCY. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: PTC RESULT. PTC GLOBAL NUMBER: 2014-019414. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED MEDICAL EVENTS ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. ADDITIONALLY, LACK OF EFFECTIVENESS MAY OCCUR WITH THE USE OF ANY PRODUCT AND PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. FOUR (4) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER B06101 BUT NONE OF THESE CASES REFER TO A SIMILAR TYPE OF MEDICAL EVENT OR LACK OF EFFICACY. ALTHOUGH THREE (3) OF THESE CASES REFER TO A SIMILAR USABILITY ISSUE IT WAS NOT REPORTED IN THE SAME CONTEXT. NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (A DIFFICULT INSERTION OF ESSURE WAS REPORTED). LATER SHE EXPERIENCED AN ECTOPIC PREGNANCY (DEVICE INEFFECTIVE) WITH ESSURE. REPORTER CAUSALITY ASSESSMENT WAS NOT PROVIDED. ECTOPIC PREGNANCY WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE; IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS INCIDENT (AS ALTHOUGH NOT REPORTED, THIS EVENT USUALLY REQUIRES INTERVENTION). THE REMAINING EVENT (DIFFICULT INSERTION) IS LISTED AND NON-SERIOUS. ECTOPIC PREGNANCIES HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE THE INSERT IN PLACE. IN THIS PARTICULAR CASE, THE PHYSICIAN REPORTED THAT ESSURE INSERTION WAS DIFFICULT AS THE TUBES WERE LIKELY SCARRED, THIS SCAR TISSUE MIGHT BE AN ALTERNATIVE EXPLANATION FOR THE REPORTED ECTOPIC PREGNANCY; NEVERTHELESS CONSIDERING THIS EVENT NATURE A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00334	BAYER HEALTHCARE LLC	8/18/2014	8/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN ON (B)(6) 2014 WHICH REFERS TO AN ADULT ABOUT (B)(6) YEARS OLD) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. INSERTION HAD BEEN PAINFUL AND AFTER INSERTION SHE HAD HARD PAINS. LAPAROSCOPY SHOWED PERFORATION OF LEFT TUBE AND LEFT TUBE WAS REMOVED. PAINS STILL CONTINUED AND THE PATIENT ARRANGED AN APPOINTMENT WITH A PRIVATE GYNECOLOGIST (REPORTER). MRI SHOWED THAT IMPLANT IN RIGHT SIDE WAS WELL IN SITU. BASIC LABORATORY TEST TAKEN AND THESE WERE NORMAL. BECAUSE THE PATIENT WAS SO PAINFUL, GYNECOLOGIST SENT HER TO HOSPITAL. LATER PATIENT INFORMED THE GYNECOLOGIST THAT A NEW LAPAROSCOPY WAS PERFORMED IN HOSPITAL AND ALSO RIGHT TUBE WAS REMOVED. PAINS ARE RELIEVED, BUT STILL SHE HAD SOME PAIN FOR EXAMPLE AFTER EATING. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014: NO NEW CLINICAL INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE ADULT PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERFORATION OF LEFT TUBE, TUBE REMOVED AND RIGHT TUBE REMOVED. BOTH EVENTS ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PERFORATION OF LEFT TUBE, TUBE REMOVED WAS CONSIDERED INCIDENT AS IT LED TO SERIOUS INJURY (SALPINGECTOMY). UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, IT WAS ALSO REPORTED THAT THE PATIENT EXPERIENCED A PAINFUL INSERTION AND HARD PAINS AFTER INSERTION WHICH MAY SUGGEST THAT PERFORATION OF LEFT TUBE, TUBE REMOVED COULD HAVE HAPPENED

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DURING ESSURE INSERTION PROCEDURE. THEREFORE, PERFORATION OF LEFT TUBE, TUBE REMOVED WAS CONSIDERED RELATED TO ESSURE. SINCE THE INDICATION FOR RIGHT TUBE REMOVED WAS NOT REPORTED, ITS RELATIONSHIP WITH ESSURE COULD NOT BE ASSESSABLE. FOLLOW UP INFORMATION WAS REQUESTED FOR CLARIFICATION. THE PATIENT ALSO EXPERIENCED NON-SERIOUS EVENT PAIN AFTER EATING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00337	BAYER HEALTHCARE LLC	8/18/2014	8/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/6/2013
Explant Date (E7): 5/30/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA PHYSICIAN (CASE# MW5036550) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2013, CONSUMER GOT ESSURE PLACED IN ONE TUBE; THE OTHER TUBE PHYSICIAN COULDN'T GET IT PLACED IN; SO HE DIDN'T PUT IT BECAUSE HE WAS THINKING THAT ONE TUBE WAS BLOCKED ALREADY. THE HSG (HYSTEROSALPINGOGRAM) WAS DONE 3 MONTHS LATER (UNSPECIFIED DATE) AND SHOWED THAT IT WASN'T BLOCKED. SHE USED NUVARING FOR 6 MONTHS, WITH THAT ONE ESSURE PLACED TO PREVENT PREGNANCY. SHE STATED THAT SHE WAS CONSTANTLY IN PAIN AND DEVELOPED A NICKEL ALLERGY. ON (B)(6) 2014, SHE HAD TO HAVE HER TUBES REMOVED AND ALL THE SYMPTOMS THAT SHE WAS HAVING SUDDENLY DISAPPEARED. HOSPITALIZATION WAS REPORTED AS SERIOUS CRITERIA BY PATIENT, BUT NOT SPECIFIED AND NOT ASSIGNED TO ONE OF THE EVENTS. SHE REPORTED THAT SHE HAD ESSURE FOR ONLY 6 MONTHS AND THERE WERE A LOT OF LEFT OVER PARTICLES IN HER UTERUS. HER PHYSICIAN WANTED HER TO HAVE ESSURE PLACED AND SHE HAD TO GO THROUGH MORE PAIN AND SUFFERING JUST LIKE MILLIONS OF OTHER WOMEN OUT THERE. SHE STATED THAT ESSURE WAS SUPPOSED TO BE A MORE "EFFECTIVE" BIRTH CONTROL THAN AN ACTUAL TUBAL LIGATION, SHE HAVEN'T KNOWN OF ANYONE GETTING PREGNANT WITH A TUBAL; BUT ON THE OTHER HAND SHE SEES PEOPLE WITH ESSURE EVERYDAY POPPING UP PREGNANT. IN ALL REALITY DO THE MATH; THIS PRODUCT NEEDS TO BE OFF THE MARKET. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "LEFT OVER PARTICLES" IS USED WHEN DESCRIBING A DEVICE

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EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN". FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THIS CASE ALSO REPORTED A TECHNICAL/USABILITY ISSUE AS WELL AS A BREAKAGE EVENT BUT BOTH OF THESE EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND NOTED THAT THE BREAKAGE EVENT IS AN ANTICIPATED EVENT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. CONSUMER'S DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) CONSUMER. SHE DENIED ANY PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES OTHER THAN HER TWO KIDS. MEDICAL HISTORY INCLUDED SPINAL FUSION IN 2008. ON (B)(6) 2013 ESSURE WAS INSERTED 8 WEEKS AFTER LAST DELIVERY. NUVA-RING WAS USED AS BACK-UP CONTRACEPTION. SHE STATED THAT IMMEDIATELY AFTER ESSURE WAS IN THERE, THE VERY NEXT DAY, SHE WAS NOT ABLE TO WEAR WEDDING RINGS. SHE HAD A BIG RASH ON HER FINGER. INTERCOURSE WAS SO PAINFUL, THE LEFT SIDE FELT NUMB, IN PAIN EVERY DAY, ALLERGIC TO NICKEL. SHE WENT BACK TO THE DOCTOR AND HE GAVE PAIN PILLS. SHE HATED TAKING PAIN MEDICATION AND IT WAS NOT ACCEPTABLE TO HER. SO, SHE WENT TO ANOTHER DOCTOR IN (B)(6) 2014 AND SHE TOLD HER IT COULD BE AN INFECTION AND SHE GAVE HER MEDICINE THAT WOULD CLEAR IT UP. ALSO AN ULTRASOUND WAS DONE

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AND THE ONE COIL SHE HAD WAS IN PLACE. HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND SHOWED THAT THE RIGHT WAS NOT BLOCKED. THE DOCTOR WAS UNABLE TO PLACE ON THE RIGHT AND HE THOUGHT IT WAS NATURALLY BLOCKED FOR SOME REASON. ON (B)(6) 2014 SHE UNDERWENT A LAPAROSCOPIC REMOVAL OF BOTH TUBES AND ESSURE. DURING THE SIX MONTHS SHE HAD THE ESSURE THERE MUST HAVE BEEN FRAGMENTS IN HER UTERUS. SHE CLEANED OUT HER UTERUS AND FOUND SO MANY LEFTOVER FRAGMENTS LEFT IN HER UTERUS AND WHERE SHE CLEANED IT OUT THERE WERE NO FRAGMENTS. SHE WAS NOT HOSPITALIZED AND RECOVERED IN ABOUT 3 DAYS. SHE HAD PICTURES OF THE FRAGMENTS IN HER UTERUS. SHE BELIEVED THE CONDITION WAS CAUSED BY ESSURE BECAUSE SHE HAD ALL THE PROBLEMS WHILE SHE HAD IT AND THEY ALL WENT AWAY AFTER IT WAS REMOVED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP (B)(6) 2014: FOLLOW UP ATTEMPT WAS DONE WITH THE PHYSICIAN WHO REMOVED ESSURE BUT DIDN'T INSERT THEM. THIS PHYSICIAN CONFIRMED ALL THE EVENTS PREVIOUSLY REPORTED BY THE CONSUMER BUT DIDN'T PROVIDE NEW INFORMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UNILATERAL PLACEMENT-COULD NOT GET IT PLACED IN, CONSTANT PAIN , NICKEL ALLERGY LEFT OVER PARTICLES OF ESSURE IN UTERUS, BIG RASH ON MY FINGER , INTERCOURSE WAS PAINFUL AND LEFT SIDE FELT NUMB. ALL THE EVENTS ARE CONSIDERED NON-SERIOUS EXCEPT THE EVENT LEFT OVER PARTICLES OF ESSURE IN UTERUS THAT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE . UPON RECEIPT OF TECHNICAL INVESTIGATION, EVENT LEFT OVER PARTICLES OF ESSURE IN UTERUS, INTERPRETED AS A DEVICE BREAKAGE AND PREVIOUSLY CONSIDERED UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, WAS UPDATED TO LISTED (ANTICIPATED). THE REMAINING EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT LEFT OVER PARTICLES OF ESSURE IN UTERUS (ASSUMED AS DEVICE BREAKAGE) WAS REGARDED AS INCIDENT SINCE THE CONSUMER HAD TO HAVE HER TUBES REMOVED. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, IT WAS MENTIONED THAT SHE HAD ESSURE FOR ONLY 6 MONTHS AND THERE WERE A LOT OF LEFT OVER PARTICLES IN HER UTERUS. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION , CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED, EXCEPT THE EVENT UNILATERAL PLACEMENT-COULD NOT GET IT PLACED IN THAT WAS CONSIDERED UNRELATED TO ESSURE. ACCORDING THE PTC FINAL ANALYSIS THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND NOTED THAT THE BREAKAGE EVENT IS AN ANTICIPATED EVENT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FURTHER INFORMATION WILL BE REQUEST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037833	BAYER	8/18/2014	8/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD THE ESSURE COILS PLACED IN 2013. EVER SINCE THEN, I HAVE HAD MISCARRIAGES, EXCRUCIATING PELVIC PAIN, ABDOMINAL AND PELVIC PAIN (TO THE POINT OF CRYING AFTER INTERCOURSE), MIGRAINES EVERYDAY, AND EXCESSIVE ITCHING. I HAVE BEEN HOSPITALIZED FOUR TIMES BECAUSE OF PAIN IN MY PELVIS. IT FEELS LIKE A SHARP STAB OR PINCHED NERVE. I AM BLOATED ALL THE TIME AND FEEL NAUSEATED EVERYDAY. ESSURE HAS COMPLETELY RUINED MY AND MY CHILDREN'S LIVES BECAUSE EVER SINCE I GOT IT, MY HEALTH AND DAILY ACTIVITIES HAVE GONE DOWNHILL. I WAS NEVER WARNED BY ANY DOCTORS THAT THE IMPLANTS WERE NICKEL AND THAT'S SOMETHING I'M ALLERGIC TO. I HAVE HAD THREE MISCARRIAGES SINCE I HAD THE ESSURE COILS PLACED. ESSURE SHOULD HAVE NEVER BEEN ON THE MARKET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00335	BAYER HEALTHCARE LLC	8/18/2014	9/3/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26937

Single Use: Y
Implant Date (E6): 7/18/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/26/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY IN (B)(6) ON (B)(6)2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. ON (B)(6) 2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER C26937. DURING ESSURE PLACEMENT PROCEDURE, THE INSERTION OF THE SPRING IN THE LEFT OSTIUM WENT SMOOTHLY UNTIL THE DROPPING OF THE SPRING: A PART OF THE PLACEMENT UU CLAMP REMAINED WITH THE SPRING. ITS REMOVAL COULD NOT BE DONE TOTALLY BY HYSTEROSCOPY. A CONVERSION BY LAPAROSCOPY FOR LIGATING OF THE UTERINE TUBES WAS THEN ADVOCATED PER THE PHYSICIAN. THE LEFT TUBE WAS REMOVED WITHOUT THE DEVICE TO BE FOUND OUT. A THIRD TIME IN HYSTEROSCOPY DID NOT ALLOW FINDING THE DEVICE. THE OUTCOME OF THE EVENTS WAS UNKNOWN. THE INCRIMINATED DEVICE WAS KEPT AVAILABLE AT THE PHARMACY (DISCREPANT INFORMATION REPORTED), AS WELL AS THE SECOND DEVICE NOT USED OF THE SAME BOX. THE CRITERION OF SERIOUSNESS WAS NOT REPORTED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE WAS REPORTED AS NOT APPLICABLE. NO FURTHER INFORMATION WILL BE AVAILABLE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED A PART OF THE UU CLAMP REMAINED WITH THE SPRING , COMPLICATION OF ESSURE DEVICE INSERTION, DEVICE FAILED INSERTION, ITS REMOVAL COULD NOT BE DONE TOTALLY BY HYSTEROSCOPY AND DEVICE WAS NOT FOUND OUT. THE EVENT DEVICE WAS NOT FOUND OUT IS CONSIDERED SERIOUS. THE REMAINING EVENTS WERE CONSIDERED NON-SERIOUS. A PART OF THE UU CLAMP REMAINED WITH THE SPRING IS UNLISTED WHILE THE OTHER EVENTS ARE LISTED IN THE REFERENCE

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SAFETY INFORMATION FOR ESSURE. THE EVENT A PART OF THE UU CLAMP REMAINED WITH THE SPRING (ASSUMED AS DEVICE BREAKAGE) WAS REGARDED AS NEAR-INCIDENT DUE TO THE REPORTED BREAKAGE. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE THE INSERTION OF THE SPRING IN THE LEFT OSTIUM WENT SMOOTHLY UNTIL THE DROPPING OF THE SPRING: A PART OF THE PLACEMENT UU CLAMP REMAINED WITH THE SPRING. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY).IN THIS PARTICULAR CASE THE LEFT TUBE WAS REMOVED WITHOUT THE DEVICE TO BE FOUND OUT. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION , CAUSALITY BETWEEN THE EVENS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 30-JAN-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: (B)(4). FINAL ASSESSMENT: LOT NUMBER: C26937; EXPIRATION DATE: 28-FEB-2017; PRODUCTION DATE: 19-FEB-2014. SINCE PRODUCT WAS RETURNED TO US FOR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00336	BAYER HEALTHCARE LLC	8/18/2014	9/3/2014

Event Information:

Event Date (B3): 6/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/3/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA PHYSICIAN (CASE# MW5036543) IN UNITED STATES ON 21-JUL-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ESSURE WAS INSERTED ON (B)(6) 2014. CONSUMER STATED THAT PROCEDURE LASTED 2 HOURS AND HAD A DAY SURGERY APPOINTMENT THE NEXT DAY. HER PHYSICIAN TRIED TO INSERT THE FIRST COIL INTO HER RIGHT FALLOPIAN TUBE. WHEN HE HIT RELEASE THE COIL DID NOT RELEASE. HE REPEATED IT SEVERAL MORE TIMES BEFORE GETTING A NEW DEVICE. BY THIS TIME CONSUMER WAS IN IMMENSE, SHOOTING PAIN. PHYSICIAN THEN INSERTED THE NEW COIL WITHOUT ANY TROUBLE, BUT THIS CONTINUED TO CAUSE EVEN GREATER PAIN. A COIL WAS INSERTED IN THE LEFT TUBE WITHOUT ANY DIFFICULTY. AFTER THE PROCEDURE HE LOOKED AT THE DEVICE AND REALIZED THAT THE FIRST DEVICE DID IN FACT RELEASE A COIL INTO HER FALLOPIAN TUBE, SO SHE HAD TWO COILS IN ONE TUBE DUE TO A FAULTY DEVICE AND NEGLIGENCE ON HER PHYSICIAN´S PART. SINCE THEN SHE HAS HAD IMMENSE CRAMPING IN HER RIGHT SIDE THAT FEELS LIKE ITS BURNING, AND IS RADIATING INTO HER THIGH AND ACROSS LOWER BACK. SHE WOKE UP SEVERAL TIMES DURING THE NIGHT FROM PAIN. THE DAY AFTER THE INITIAL PROCEDURE, SHE WENT TO THE SURGICAL CENTER TO GO UNDER GENERAL ANESTHESIA AND REMOVE THE 2ND COIL OF HER RIGHT FALLOPIAN TUBE. PHYSICIAN PULLED IT OUT, AND THE DEVICE WAS BENT ON THE FRONT AND LOOKED TO BE MISSING COILS FROM THE PHOTOS. THE ORIGINAL FAULTY DEVICE WAS STILL IN HER TUBE. THERE WERE NO COILS IN HER CERVIX BECAUSE THE DEVICE WAS TOO FAR IN. SHE MISSED WORK FOR SEVERAL DAYS AND EXPERIENCED SEVERE MENTAL ANGUISH, AND EXTREME PAIN. SHE HAS BEEN ALSO BLEEDING SINCE, AND SHE WAS NOT SURE IF IT WAS HER PERIOD OR A SIDE EFFECT. FOLLOW-UP RECEIVED ON 30-JUL-2014: NEW REPORTER WAS ADDED. THE REPORTER STATED THAT THE CONSUMER WAS IN SURGERY TO GET

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BAYER PRODUCT REMOVED. SHE DID NOT WANT MORE CONTACT WITH COMPANY. PTC INVESTIGATION RESULT WAS RECEIVED ON 05-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "MISSING COILS" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN". SINCE NEITHER PRODUCT WAS RETURNED FOR INSPECTION NOR DO WE HAVE A PHOTOGRAPH OF THE ACTUAL DEVICE, WE CANNOT DETERMINE EXACTLY WHAT THE FAILURE IS. BASED ON OUR EXPERIENCE WITH DEVICE COMPLAINTS OF A SIMILAR NATURE, IT IS LIKELY THE REPORTER IS REFERRING TO AN EVENT IN WHICH THE MICRO-INSERT WAS BENT OR STRETCHED INTO A SHAPE WHICH RENDERED THE DEVICE TO BE UNUSABLE, AND HENCE, "BROKEN." SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THIS CASE REPORTED TECHNICAL ISSUES OF MALFUNCTION DUE TO DEPLOYMENT ISSUE WHERE DEVICE APPEARED NOT TO RELEASE BUT HAD RELEASED THE DEVICE RESULTING IN MISUSE. ADDITIONALLY REPORTED WAS OFF LABEL USE WITH ONE OF THE TWO COILS REMOVED NEXT DAY RESULTING IN COMPLICATION OF REMOVAL DUE TO USE ERROR (APPEARED BENT) AND APPARENT BREAKAGE. THESE REPORTED TECHNICAL AND USABILITY ISSUES ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND NOTED THAT A BREAKAGE EVENT IS AN ANTICIPATED EVENT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PHYSICIAN PULLED ESSURE OUT AND LOOKED TO BE MISSING COILS , DEVICE IS IN TOO FAR AND BLEEDING SINCE ESSURE PROCEDURE. EXPERIENCED PHYSICIAN PULLED ESSURE OUT AND LOOKED TO BE MISSING COILS IS CONSIDERED NON-SERIOUS, WHILE THE REMAINING EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ALL EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT EXPERIENCED PHYSICIAN PULLED ESSURE OUT AND LOOKED TO BE MISSING COILS (ASSUMED AS DEVICE BREAKAGE) WAS REGARDED AS NEAR-INCIDENT DUE TO THE REPORTED BREAKAGE. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE PHYSICIAN PULLED IT OUT, AND THE DEVICE WAS BENT ON THE FRONT AND LOOKED TO BE MISSING COILS FROM THE PHOTOS. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY).IN THIS PARTICULAR CASE THERE WERE NO COILS IN HER CERVIX BECAUSE THE DEVICE WAS TOO FAR IN, CONSIDERED A DEVICE DISLOCATION. THE EVENT BLEEDING SINCE ESSURE PROCEDURE WAS ASSUMED AS GENITAL HAEMORRHAGE WHICH MAY OCCUR AFTER ESSURE INSERTION; THIS EVENT WAS REGARDED AS NON-INCIDENT. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. UPON RECEIPT OF FOLLOW-UP INFORMATION A NEW REPORTER STATED

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THAT THE CONSUMER WAS IN SURGERY TO GET BAYER PRODUCT REMOVED, HOWEVER AS NO INFORMATION WAS PROVIDED ABOUT THE TYPE AND REASON FOR THIS PROCEDURE THE CASE WAS MAINTAINED AS NEAR-INCIDENT. FURTHER CONTACT WAS NOT ALLOWED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

AFTER INTERNAL REVIEW ON (B)(4) 2014, FURTHER CORRECTION WAS MADE REGARDING THE INFORMATION RECEIVED ON (B)(4) 2014: THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5036543). THE INCIDENT CATEGORY WAS AMENDED T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00338	BAYER HEALTHCARE LLC	8/19/2014	8/19/2014

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/10/2010
Explant Date (E7): 5/13/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5036702) IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO RECEIVED ESSURE ((B)(4)) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EVENTS. ON (B)(6)-2010 THE CONSUMER HAD ESSURE ((B)(4)) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR TUBAL OCCLUSION. THE CONSUMER HAD ESSURE COILS INSERTED AND IMMEDIATELY SHE VOMITED AND EXPERIENCED LOW BLOOD PRESSURE. FOR APPROXIMATELY 4 DAYS AFTER THE INSERTION, SHE WAS IN SUCH TERRIBLE PAIN THAT SHE COULD NOT WALK UPRIGHT OR SLEEP. WITHIN A MONTH OF THE PLACEMENT SHE DEVELOPED PAINFUL BLOATING, WEIGHT GAIN AND CONTINUAL ABDOMINAL CRAMPING. HER LIFELONG ECZEMA TROUBLES SKYROCKETED AND SHE DEVELOPED IRRITABLE BOWEL SYNDROME. SIX MONTHS AFTER HAVING THEM PLACED, SHE HAD TO HAVE A FULL HYSTERECTOMY TO REMOVE THEM ON (B)(6)-2011. INTERNAL CORRECTION FROM INITIAL CASE: CASE CORRECTED FROM INCIDENT (ANTICIPATED) TO INCIDENT (UNANTICIPATED). PTC INVESTIGATION RESULT RECEIVED ON (B)(6)-2014: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL

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BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP FROM (B)(6)-2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE INSERTED AND IMMEDIATELY AFTER INSERTION PROCEDURE, EXPERIENCED VOMIT AND LOW BLOOD PRESSURE. APPROXIMATELY 4 DAYS AFTER INSERTION, SHE EXPERIENCED TERRIBLE PAIN. WITHIN A MONTH OF THE PLACEMENT SHE DEVELOPED PAINFUL BLOATING, WEIGHT GAIN AND CONTINUAL ABDOMINAL CRAMPING. HER LIFELONG ECZEMA TROUBLES SKYROCKETED AND SHE DEVELOPED IRRITABLE BOWEL SYNDROME. IRRITABLE BOWEL SYNDROME AND ECZEMA TROUBLES SKYROCKETED WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THESE EVENTS WERE CONSIDERED INCIDENT (UNANTICIPATED) AS THEY LED TO A HYSTERECTOMY TO REMOVE ESSURE COILS. THE EVENTS VOMIT AND LOW BLOOD PRESSURE AFTER INSERTION PROCEDURE, TERRIBLE PAIN, PAINFUL BLOATING, WEIGHT GAIN, AND CONTINUAL ABDOMINAL CRAMPING WERE CONSIDERED NON-SERIOUS. IRRITABLE BOWEL SYNDROME (IBS) IS A FUNCTIONAL GI DISORDER CHARACTERIZED BY ABDOMINAL PAIN AND ALTERED BOWEL HABITS IN THE ABSENCE OF SPECIFIC AND UNIQUE ORGANIC PATHOLOGY. A COMPLEX COMBINATION OF ELEMENTS, INCLUDING PSYCHOLOGICAL STRESS, HORMONES, THE IMMUNE SYSTEM, AND NEUROTRANSMITTERS, APPEARS TO CAUSE ABNORMAL GI MUSCLE CONTRACTIONS OR SPASMS. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, CONSUMER HAD A LIFELONG HISTORY OF ECZEMA. HOWEVER, BASED ON POSITIVE TEMPORAL RELATIONSHIP, AND ALSO BASED ON THE INFORMATION THAT ESSURE CAN CAUSE OR AGGRAVATE HYPERSENSITIVITY REACTIONS, THE CAUSALITY BETWEEN ESSURE USE AND THESE EVENTS CANNOT BE TOTALLY EXCLUDED. THE PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00339	BAYER HEALTHCARE LLC	8/19/2014	8/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2012
Explant Date (E7): 8/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM LAY PRESS WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING AND PAIN. IN (B)(6) 2012 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED. THE FIRST THING SHE EXPERIENCED WAS THE BLEEDING AND THEN, THERE WAS A PAIN. SHE HAD TO STAY IN BED AND SAID THAT AT TIMES, SHE FELT LIKE SHE WAS IN LABOR. EVENTUALLY, AFTER CONSULTING WITH HER DOCTOR, SHE DECIDED HER ONLY OPTION WAS TO GET A HYSTERECTOMY AT (B)(6) OF AGE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED MEDICAL EVENTS ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON

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THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT RECEIVED FROM NEWS SEGMENT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN AND BLEEDING. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE. THEY WERE REGARDED AS INCIDENTS AS A HYSTERECTOMY WAS REPORTED (REQUIRED INTERVENTION). FOLLOWING THE ESSURE INSERTION PAIN AND BLEEDING OR SPOTTING MAY OCCUR. IN THIS PARTICULAR CASE, CONSIDERING THAT THE REPORTED EVENTS OCCURRED AFTER ESSURE PLACEMENT THEIR CAUSAL RELATION WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NO FURTHER INFORMATION IS EXPECTED SINCE THIS IS A LAY-PRESS CASE. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 07-JAN-2016 FROM CONSUMER, VIA SOCIAL MEDIA: AFTER LESS THAN A YEAR OF ESSURE INSERTION, THE CONSUMER HAD TO HAVE A HYSTERECTOMY IN (B)(6) 2013 AT (B)(6) BECAUSE ONE OF THE COILS MIGRATED AND EMBEDDED IN HER UTERUS. SHE H

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037867	BAYER	8/19/2014	8/25/2014

Event Information:

Event Date (B3): 8/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/6/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE ESSURE HAS BEEN IMPLANTED I'VE HAD A LOT OF HEADACHES, HEAVY PERIODS, BAD CRAMPING, DIZZINESS, AND EXTREME FATIGUE. I RECENTLY FOUND OUT I'M ALLERGIC TO NICKEL. THAT'S CAUSING MY SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037868	BAYER	8/19/2014	8/25/2014

Event Information:

Event Date (B3): 5/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/28/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED ON (B)(6) 2014. THE PROCEDURE TOOK AROUND TWENTY MINUTES, BECAUSE MY CERVIX HAD TO BE OPENED. SINCE THE PLACEMENT OF ESSURE, I HAVE BATTLED CHRONIC PELVIC PAIN. I HAVE TWO VERY SMALL CHILDREN, AND THIS HAS CAUSED A GREAT AMOUNT OF PROBLEMS. I AM NOW SCHEDULED FOR A HYSTERECTOMY ON (B)(6) 2014 TO HAVE THE COILS REMOVED. IN ORDER TO DO SO PROPERLY, MY FALLOPIAN TUBES AND UTERUS WILL NEED TO BE REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00340	BAYER HEALTHCARE LLC	8/20/2014	8/20/2014

Event Information:

Event Date (B3): 6/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/24/2014
Explant Date (E7): 7/11/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN, CONSTANT IN BILATERAL LOWER QUADRANTS AND LOWER BACK PAIN. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM PHYSICIAN: NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: PATIENT WAS NOT PREGNANT. ACHY WITH 6 OUT OF 10 ON PAIN SCALE. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM PHYSICIAN: AFTER SERIOUS INFORMATION RECEIVED ON FOLLOW-UP THIS CASE WAS UPGRADED TO SERIOUS AND CLASSIFIED AN INCIDENT DEVICE CASE. PATIENT INFORMATION WAS UPDATED; WEIGHT AND HEIGHT WERE ADDED, THE PATIENT WAS CONSIDERED OVERWEIGHT. SHE IS A NON-SMOKER. PHYSICIAN REPORTED THAT THE PATIENT HAS MULTIPLE DRUG ALLERGIES (DEMEROL, EPINEPHRINE, NORCO, VANCOMYCIN AND VICODIN). THE PATIENT WAS GRAVIDA 3 AND PARA 3; WITH 4 NORMAL SPONTANEOUS VAGINAL DELIVERIES. SHE HAD AN APPENDECTOMY, ARM SURGERY, CARDIAC CATH, CHOLECYSTECTOMY AND A JAW FRACTURE. SHE HAD NO PREVIOUS GYNECOLOGICAL INTERVENTIONS. SHE WAS USING ORTHO-CYCLEN BIRTH CONTROL PILLS. ON (B)(6) 2014, ESSURE WERE INSERTED. THE PATIENT WAS 6 WEEKS POST-PARTUM REQUESTING SURGICAL STERILIZATION. DURING THE INSERTION PROCEDURE CERVICAL DILATATION, SOUNDING AND GENERAL ANESTHESIA WERE NOT APPLIED. IV SEDATION WAS USED (NOS). PHYSICIAN CONSIDERED THE PROCEDURE AND THE TUBAL OSTIUM VISUALIZATION AS EASY. NO FLUID LOSS WAS OBSERVED AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. THE RIGHT SIDE ONE COIL WAS SEEN AT THE END OF THE TUBAL OPENING; ON THE LEFT SIDE 3 COILS WERE SEEN. PHYSICIAN REPORTED THAT THERE WAS BLEEDING NOTED FROM THE TENACULUM SITE; HEMOSTASIS WAS CREATED USING MONSEL SOLUTION AND THE VAGINA WAS PACKED WITH 1

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INCH VAGINAL PACKING WHICH WAS REMOVED IN THE DAY AFTER THE PROCEDURE. PHYSICIAN REPORTED THAT THE PATIENT TOLERATED THE PROCEDURE WELL AND WAS TRANSFERRED TO THE RECOVERY ROOM IN GOOD CONDITION. NO IMAGING TESTS WERE PERFORMED AFTER ESSURE INSERTION. THE PATIENT USED ORAL CONTRACEPTIVE PILLS AS BACK UP CONTRACEPTION BEFORE TOTAL OCCLUSION CONFIRMATION. THE HSG WAS ALSO NOT DONE. ON UNSPECIFIED DATE, THE PATIENT WAS ADMITTED FOR BRADYCARDIA OVERNIGHT AND WAS RELEASED THE NEXT DAY. SHE STATED THAT SHE HAD DISCOMFORT FOR A COUPLE OF DAYS, BUT THEN HAD NO PAIN UNTIL (B)(6) 2014. STARTING (B)(6) 2014, THE STATED THAT SHE HAD CONSTANT BILATERAL LOWER QUADRANT PAIN IN THE ADNEXAL REGIONS ON THE LEFT SIDE GREATER THAN RIGHT WITH SEPARATE LOW BACK PAIN. HER PAIN WAS DESCRIBED AS ACHY INTENSITY (B)(6). SHE WAS TAKING MOTRIN 800MG EVERY 6 HOURS AND TYLENOL 3 AT NIGHT. SHE STATED THAT SHE HAS NEVER HAD THIS PAIN BEFORE. SHE HAS NO GI PROBLEMS. SHE ALSO STATED THAT HER LAST MENSES LASTED ONE WEEK AND WAS HEAVY THE ENTIRE TIME; HER MENSES WERE ASSOCIATED WITH MODERATE CRAMPING. SHE STATED THAT HER PERIODS WERE HEAVY BEFORE SHE DELIVERED. THE PATIENT HAD BILATERAL ADNEXAL PAIN POST ESSURE PROCEDURE AND THOUGHT TO BE ASSOCIATED WITH LOW BACK PAIN. AFTER DISCUSSING OPTIONS WITH THE PATIENT, IT WAS AGREED TO REMOVE THE DEVICES VIA LAPAROSCOPY, AT THE SAME TIME, THE PATIENT WOULD UNDERGO BILATERAL CAUTERY OF THE TUBES WITH BIPOLAR CAUTERY. ON (B)(6) 2014, THE FOLLOWING ADMISSION PHYSICAL EXAMINATIONS WERE MADE: VITAL SIGNS: BLOOD PRESSURE WAS 118/72; RESPIRATORY RATE WAS 18; PULSE WAS 78 AND TEMPERATURE WAS 98.4. IN GENERAL, SHE HAD NO ACUTE DISTRESS. CARDIOVASCULAR, LUNGS, ABDOMEN, EXTREMITIES, PELVIC AND ULTRASOUND EXAMS WERE ALL NORMAL. ON (B)(6) 2014, ESSURE DEVICES WERE REMOVED. THE RIGHT COIL WAS REMOVED BY HYSTEROSCOPY AND THE LEFT LAPAROSCOPY (NO EVIDENCE OF PERFORATION WAS OBSERVED). SHE WAS DIAGNOSED PREOPERATIVE WITH PELVIC PAIN AND ABNORMAL UTERINE BLEEDING. PHYSICIAN REPORTED THAT IT WAS USED GENERAL ANESTHESIA FOR THE PROCEDURE. THE HYSTEROSCOPE WAS INTRODUCED TO THE FUNDUS OF THE UTERUS AND BOTH OSTIA WERE NOTED. THE PATIENT'S LEFT OSTIA SHOWED NO EVIDENCE OF ESSURE COIL BUT THE RIGHT OSTIA CLEARLY SHOWED THE ESSURE COIL AND A HYSTEROSCOPY GRASPER WAS USED IN ORDER TO GRAB THE COIL AND THE COIL WAS REMOVED WITHOUT DIFFICULTY. A LAPAROSCOPY WAS DONE AFTER; THE INSPECTION OF THE UTERUS REVEALED IT TO BE WITHIN NORMAL LIMITS AND THE RIGHT FALLOPIAN TUBE AND THE OVARY WERE WITHIN NORMAL LIMITS. THE LEFT OVARY AND TUBE WERE ALSO WITHIN NORMAL LIMITS. A TUBAL LIGATION WAS PERFORMED. THE LEFT FALLOPIAN TUBE WAS VISUALIZED; ESSURE WAS VISUALIZED AND REMOVED WITHOUT DIFFICULTY AND SENT TO PATHOLOGY. THERE WAS STILL SOME COIL MATERIAL THAT WAS EMBEDDED IN THE FALLOPIAN TUBE TISSUE THAT WAS REMOVED WITH DEBAKEYS. UNFORTUNATELY, HEMOSTASIS WAS NOT EXCELLENT. A TUBAL LIGATION ON THIS TUBE WAS ALSO DONE. DURING SOUNDING OF UTERUS, AT THE END OF THE PROCEDURE, A UTERINE PERFORATION WAS CONFIRMED USING HYSTEROSCOPY; THEREFORE THE ABLATION PROCEDURE WAS NOT DONE. PHYSICIAN STATED THAT HAVEN'T SEEN THE PATIENT AFTER SURGERY; HOWEVER SHE CALLED AND SAID THAT ALL CRAMPING HAS RESOLVED. FOLLOW UP (B)(6) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: WHEN A TERM LIKE "PIECES EMBEDDED" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN". FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL

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CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED MEDICAL EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THIS CASE ALSO REPORTED COMPLICATION OF REMOVAL (DURING TUBAL LIGATION PROCEDURE) DUE TO BREAKAGE BECAUSE OF DEVICE BEING EMBEDDED WITHIN THE FALLOPIAN TUBE. THESE EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND NOTED THAT THE BREAKAGE EVENT IS AN ANTICIPATED EVENT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABNORMAL UTERINE BLEEDING, THERE WAS BLEEDING NOTED FROM THE TENACULUM SITE, THERE WAS STILL SOME COIL MATERIAL THAT WAS EMBEDDED IN THE FALLOPIAN TUBE AND ESSURE WAS REMOVED BUT THERE WAS STILL SOME COIL MATERIAL IN FALLOPIAN TUBE AND CONSTANT BILATERAL PAIN IN LOWER QUADRANTS. ALL EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN WAS SO INTENSE THAT LED TO SURGICAL REMOVAL OF THE DEVICES, THEREFORE THE EVENT IS REGARDED AS INCIDENT, WHILE THE OTHER EVENTS ARE NON-INCIDENTS. IN THIS CASE, THE PHYSICIAN INFORMED THE ESSURE INSERTION PROCEDURE WAS EASY, WITHOUT COMPLAINTS, EXCEPT FOR SOME BLEEDING NOTED FROM TENACULUM SITE. 8 DAYS AFTER THE INSERTION, THE PATIENT STARTED TO EXPERIENCE PELVIC PAIN AND HEAVY UTERINE BLEEDING. THE PAIN WAS SO INTENSE THAT LED TO A HYSTEROSCOPY TO REMOVE THE DEVICES, NINE DAYS AFTER THE ONSET OF THE PAIN. DURING THE PROCEDURE, THE RIGHT OSTIA CLEARLY SHOWED THE ESSURE COIL AND A GRASPER WAS USED IN ORDER TO GRAB THE COIL AND REMOVE IT. ON THE LEFT SIDE, THE DEVICE WAS NOT VISUALIZED AND A LAPAROSCOPY WAS THEN PERFORMED. ESSURE WAS REMOVED WITHOUT DIFFICULTY AND SENT TO PATHOLOGY. THERE WAS STILL SOME COIL MATERIAL THAT WAS EMBEDDED IN THE FALLOPIAN TUBE TISSUE AND WAS REMOVED WITH DEBAKEYS. A TUBAL LIGATION ON BOTH TUBES WAS DONE. PHYSICIAN STATED THAT HAVEN'T SEEN THE PATIENT AFTER SURGERY; HOWEVER SHE CALLED AND SAID THAT ALL CRAMPING HAS RESOLVED. THEREFORE, DECHALLENGE REGARDING THE PELVIC PAIN IS CONSIDERED AS POSITIVE. GIVEN THE EVENT'S NATURE AND POSITIVE DECHALLENGE, CAUSALITY BETWEEN

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THE EVENTS AND ESSURE USE IS ASSESSED AS RELATED. ADDITIONALLY NON-SERIOUS EVENTS LOWER BACK PAIN, NO HSG DONE, DEVICE REMOVAL COMPLICATION, CRAMPING AND BRADYCARDIA WERE REPORTED. THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND NOTED THAT THE BREAKAGE EVENT IS AN ANTICIPATED EVENT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00341	BAYER HEALTHCARE LLC	8/20/2014	9/4/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C03091

Single Use: Y
Implant Date (E6): 7/23/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVICE COILED INSIDE THE TUBE AND FOLDED ON ITSELF AND THE HCP LEFT THE DEVICE IN PLACE AND WAS ABLE TO WITHDRAW THE GUIDE. THIS CASE INITIALLY PROCESSED AS NON-INCIDENT AND NON-SERIOUS, WAS UPON RECEIPT OF FOLLOW UP INFORMATION, UPGRADED TO NEAR-INCIDENT AND A COMPLETE NARRATIVE IS REQUIRED. ESSURE WAS INSERTED ON (B)(6) 2014 (LOT NUMBER C03091, EXPIRATION DATE DEC-2016). LEFT SIDE WAS SUCCESSFULLY INSERTED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM PHYSICIAN: PHYSICIAN WANTED TO SPEAK WITH A SPECIALIST BECAUSE WAS HAVING A HARD TIME GETTING THE DEVICE OUT AND THE GOLD BAND WAS IN THE UTERUS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM PHYSICIAN: THE PATIENT'S WEIGHT AND HEIGHT WERE ADDED; SHE WAS CONSIDERED OBESE (BMI > (B)(6)). PATIENT'S AGE WAS ALSO ADDED. THE PATIENT DID NOT HAVE ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS. SHE WAS NOT POST PARTUM AT TIME OF THE PROCEDURE. SHE HAD NO CONCURRENT CONDITIONS. PHYSICIAN REPORTED THAT THE INSERTION PROCEDURE WAS CONSIDERED EASY; CERVICAL DILATATION, SOUNDING AND IV SEDATION (NO GENERAL ANESTHESIA) WERE PERFORMED. THE TUBAL OSTIUM WAS EASILY VISUALIZED. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES AND NO FLUID LOSS WAS OBSERVED. NO IMAGING OR ANY RELATED TESTS WERE PERFORMED AFTER THE INSERTION. THE PATIENT STARTED DEPO PROVERA TREATMENT AFTER THE PROCEDURE AS BACK-UP CONTRACEPTION. THE PHYSICIAN CONFIRMED EVENTS DATES AND DETAILS. NO PERFORATION OCCURRED. NO HOSPITALIZATION WAS REQUIRED. PHYSICIAN CONSIDERED THE EVENTS RELATED TO ESSURE DEVICES. ESSURE DEVICES WERE NOT REMOVED AT TIME OF THE REPORT; NOR DID HAVE PLAN TO REMOVE.

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COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE DEVICE COILED INSIDE THE TUBE AND FOLDED ON ITSELF; HCP HAVING A HARD TIME GETTING THE DEVICE OUT; HE LEFT THE DEVICE IN PLACE AND WAS ABLE TO WITHDRAW THE GUIDE AND THE GOLD BAND IS IN THE UTERUS. REPORTER CAUSALITY WAS NOT PROVIDED. ALL REPORTED EVENTS ARE NON-SERIOUS. THE EVENT GOLD BAND IS IN THE UTERUS INTERPRETED AS A DEVICE BREAKAGE; IS UNLISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS CONSIDERED A NEAR-INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE REMAINING EVENTS ARE LISTED AND NON-INCIDENTS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES DURING THE INSERT DEPLOYMENT AND REPORTED THAT THE GOLD BAND (INTERPRETED AS PART OF THE DELIVERY CATHETER) WAS IN UTERUS. A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THE REPORTED EVENTS, HOWEVER CONSIDERING THAT THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, THEIR A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. FOLLOW-UP INFORMATION (FOR EVENTS CLARIFICATION) IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037816	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 4/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE IMPLANTED AND THE DEVICE FROM RIGHT SIDE PERFORATED MY FALLOPIAN TUBE THAT SAME EVENING. THIS WAS CONFIRMED BY THE REQUIRED DYE TEST AT 3 MONTHS POST SURGERY DATE. SECOND PROCEDURE WAS REQUIRED FOR A TUBAL LIGATION A MONTH LATER. COIL HAD FALLEN INTO MY ABDOMEN. CHRONIC PELVIC PAIN SINCE DAY OF ORIGINAL IMPLANT OF ESSURE. SOON TO HAVE A TUBE AND OVARY REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037817	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 10/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC BACK, PELVIC, JOINT, AND HIP PAIN; CHEMICAL, FOOD, AND METAL SENSITIVITY; ANXIETY, DEPRESSION, MOOD CHANGES, MEMORY LOSS, AND SUICIDAL THOUGHTS; UNEXPLAINED BRUISING; UTI'S, ACNE, EXCESSIVE SWEATING, AND HAIR LOSS; ABDOMINAL AND MUSCLE SPASMS; SEVERE MIGRAINES, DIZZY SPELLS, AND BLACK OUT SPELLS; DYSPAREUNIA, METRORRHAGIA, BLEEDING AFTER INTERCOURSE, PAINFUL OVULATION, SEXUAL DYSFUNCTION AND LOSS OF LIBIDO; NAUSEA, VOMITING, AND SEVERE ACID REFLUX; UNEXPLAINED FEVERS, ANEMIA, INSOMNIA, CHRONIC FATIGUE, AND METALLIC TASTE SEVERE WEIGHT LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037819	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 7/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, CHRONIC INFLAMMATION OF ALL BODY PARTS, CHRONIC FATIGUE, REPEATED YEAST INFECTIONS, FOGGINESS, BLOATING TO THE POINT OF LOOKING 8 MONTHS PREGNANT, WEIGHT GAIN IN A SMALL AMOUNT OF TIME AND NO WAY TO LOSE IT, CHANGE IN BEHAVIOR IE: MOODY, ANXIETY, DEPRESSION, FREQUENT MENSTRUAL PERIODS DURING THE MONTH OR JUST CONTINUED PERIODS FOR 35 DAYS AT A TIME, RLS, RASH WITH ITCH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037820	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 3/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, PAIN IN THE OVARIES, BACK PAIN, LEFT LEG AND GROIN PAIN. MOOD SWINGS, DEPRESSION, UNUSUAL PERIODS AND HORRIBLE CRAMPING WHEN PERIOD IS ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037821	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 3/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, PAIN IN THE OVARIES, BACK PAIN, LEFT LEG AND GROIN PAIN. MOOD SWINGS, DEPRESSION, UNUSUAL PERIODS AND HORRIBLE CRAMPING WHEN PERIOD IS ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037822	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 3/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5037822 (B)(4). DENTAL ISSUES HAVE ARISEN. SENSITIVE TEETH, RESEEDING GUMS, SOFTENED TEETH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037823	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 8/3/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WITH THIS DEVICE MY VISION IS NOW BLURRY. I HAVE IN EXPLAINABLE RASHES AND BRUISES OVER MY BODY. CHRONIC CRAMPING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037824	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE IMPLANT OF THE ESSURE I HAVE EXPERIENCED RAPID WEIGT GAIN, EXTREME BLOATING AND SWELLING, DIZZYNESS, FATIGUE, RASH ON MIDSECTION, NAUSEA, HEADACHES, MOOD SWINGS, JOINT ACHES

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037825	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 664591. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2010. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: DURING THE IMPLANTATION OF THE ESSURE COILS AND IMMEDIATELY FOLLOWING, I EXPERIENCED EXCRUCIATING STABBING PAIN IN MY LOWER LEFT ABDOMEN. THIS PAIN HAS NEVER STOPPED FOR MORE THAN A WEEK'S TIME. THE PAIN WILL OCCUR AT RANDOM TIMES, BUT IS HEIGHTENED BY LIFTING, SEXUAL ACTIVITY, OVULATION, AND NON STOP DURING MY MENSTRUAL CYCLE. THE BEST WAY TO DESCRIBE THE PAIN IS THAT SOMETHING IS RIPPING MY INSIDES APART. I HAVE ALSO BEEN EXPERIENCING HAIR LOSS, BACK PAIN, LEG PAIN, RED BLOTCHY SPOTS ON MY UPPER ABDOMEN, MIGRAINES, SEVERE ABDOMINAL CRAMPS, MOOD SWINGS, DEPRESSION, EXCESSIVE BLEEDING, EXCESSIVE BLOOD CLOTTING. THESE SYMPTOMS HAVE INCREASED IN FREQUENCY AND INTENSITY. I HAVE BEEN SEEN BY 2 EMERGENCY DOCTORS AND 1 GYNECOLOGISTS AND I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: PTS AND OVARIAN CYSTS. THE DEVICE IS STILL INSIDE OF ME. I HAVE BEEN IN THE EMERGENCY ROOM ON SEVERAL OCCASIONS FROM THE SEVERE ABDOMINAL CRAMPS, BLEEDING, AND CLOTTING. I HAVE BEEN TREATED FOR PTS AND OVARIAN CYSTS. OTHER THAN THOSE TWO DIAGNOSES, NO DOCTOR HAS BEEN ABLE TO GIVE ME AN EXPLANATION FOR MY SYMPTOMS AND DOES NOT ARGUE THE COILS COULD BE CAUSING THE PROBLEM.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037826	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN LOWER ABDOMEN. THAT SPREAD INTO MY BACK AND DOWN MY LEG. EXTREME MENSTRUAL PAIN. SLOWING OF MENSTRUAL CYCLE TO ONLY HALF A DAY OF BLEEDING. CHRONIC FATIGUE. DIZZINESS, MIGRAINES, WEIGHT GAIN. LOSS OF LIBIDO. EMOTIONAL CHANGES. MUSCLE SPASMS. SCIATIC NERVE PAIN. BOUTS OF UNEXPLAINED PAIN IN ABDOMEN RESULTING IN LOSS OF WAGES AT WORK. DENTAL ISSUES. MEMORY LOSS. SWELLING AND TINGLING IN HANDS AND FEET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037827	BAYER	8/21/2014	8/21/2014

Event Information:

Event Date (B3): 8/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, LOWER BACK PAIN, EXTREMELY HEAVY PERIODS DURING FIRST 4 DAYS OF CYCLE, WEIGHT GAIN, CONSTIPATION, LEG PAIN AND NUMBNESS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037898	BAYER	8/21/2014	8/27/2014

Event Information:

Event Date (B3): 3/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/13/2014
Explant Date (E7): 8/14/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PRODUCT WAS INSERTED IN (B)(6) 2014. UPON CHECKUP IN (B)(6) 2014, IT WAS DEEMED UNSUCCESSFUL BECAUSE IT WAS "BROKEN" AND NOT IN THE PROPER POSITION. WAITED A MONTH FOR SURGEON TO FIGURE OUT WHAT TO DO. ENDED UP HAVING ESSURE DEVICE AND TUBES REMOVED (B)(6) 2014. STILL RECOVERING AND STILL IN PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037899	BAYER	8/21/2014	8/27/2014

Event Information:

Event Date (B3): 1/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/2/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE FIRST YEAR I RECEIVED THE ESSURE I WAS FINE. GRADUALLY, AS THE MONTHS WENT ON, I STARTED TO HAVE DEBILITATING PELVIC PAIN ONLY ON ONE SIDE, AND IT IS THE LOWER PELVIC AREA, WHERE PAIN MEDICATION DOES NOT EVEN HELP I HAVE BEEN TO THE HOSPITAL SEVERAL TIMES WITH NO INFECTION OR ANY SPECIFIC REASON AS TO WHY I AM IN SO MUCH PAIN. I WENT TO (B)(6) THE ESSURE AND FOUND OTHERS HAD THE SAME PROBLEM I AM HAVING. SO I AM GOING TO SCHEDULE TO HAVE THEM REMOVED, SO I CAN HAVE MY LIFE BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037828	BAYER	8/22/2014	8/22/2014

Event Information:

Event Date (B3): 1/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BACK ACHES, MIGRAINES, CONSTANT CRAMPING, BLEEDING CONSTANTLY, ANXIETY, PANIC ATTACKS, FOGINESS, FATIGUE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037927		8/22/2014	9/2/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS FORCED TO HAVE MY UTERUS REMOVED DUE TO BEING ALLERGIC TO THE ESSURE DEVICE. THIS WAS SUPPOSED TO BE A NON SURGICAL PROCEDURE. I HAVE BEEN SCARRED FOREVER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037949		8/22/2014	9/2/2014

Event Information:

Event Date (B3): 6/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE PROCEDURE DONE IN 2006 AFTER MY SON WAS BORN. SINCE THEN I HAVE DEVELOPED (B)(6), GAINED 100 LBS EVEN WITH A STRICT DIET AND EXERCISE. MY HAIR HAS FALLEN OUT, MY THYROID IS OUT OF WHACK AND MY PERIODS ARE SO UNPREDICTABLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037956		8/22/2014	9/2/2014

Event Information:

Event Date (B3): 5/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/5/2013
Explant Date (E7): 6/11/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT PREGNANT AFTER ESSURE IMPLANT PLACED AND MY DAUGHTER WAS BORN AT 25 WEEKS DUE TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00342	BAYER HEALTHCARE LLC	8/25/2014	8/25/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM CONSUMER'S HUSBAND IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED THE FOLLOWING EVENTS. ON (B)(6) 2014, THE REPORTER'S WIFE HAD THE ESSURE DONE (INSERTED) FOR PERMANENT BIRTH CONTROL. HE REPORTED THAT ONE SIDE WENT WELL BUT HER PHYSICIAN HAD DROPPED THE OTHER INSIDE OF HER UTERUS BECAUSE HIS WIFE WENT INTO SPASM. THE PHYSICIAN SAID TO WAIT IF THE ESSURE WILL FALL OFF BY ITSELF, AND IF NOT, HE WILL REMOVE IT NEXT WEEK. THE REPORTER STATED THAT HIS WIFE WAS IN A LITTLE BIT OF PAIN, AND SHE'S HAVING LIGHT BLEEDING, MORE THAN SPOTTING. AT TIME OF REPORT, ESSURE WAS NOT REMOVED. NO FURTHER INFORMATION PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN

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AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: CONSUMER`S WEIGHT AND HEIGHT WERE ADDED. CONSUMER DID NOT HAVE ANY GYNECOLOGICAL PROBLEMS OR PROCEDURES. SHE DID NOT HAVE ANY OTHER RELEVANT MEDICAL HISTORY. ON (B)(6) 2014, ESSURE WAS INSERTED. THE INSERTION WAS PERFORMED 8 WEEKS AFTER LAST DELIVERY. CONSUMER USED DEPO-SHOT 6 WEEKS AFTER DELIVERY, BEFORE ESSURE WAS INSERTED. ON (B)(6) 2014, ON THE DAY OF THIS REPORT, CONSUMER WAS GETTING A X-RAY DONE, NO RESULT WAS PROVIDED. CONSUMER CONFIRMED ALL EVENTS THAT WERE PREVIOUSLY REPORTED. SHE REPORTED THAT WHEN THE PHYSICIAN WENT TO INSERT ESSURE, HER TUBES SPAMMED AND IT WAS NOT INSERTED PROPERLY, BUT IT WAS STILL IN RIGHT PLACE ON ONE SIDE. CONSUMER STATED THAT SHE HAD MODERATE BLEEDING AND SOME PRETTY BAD PAIN, LOT OF CRAMPING. SHE STATED THAT SHE WAS ON NARCO MEDICATION SO SHE WAS NOT FEELING WHERE EXACTLY THE PAIN WAS. THE SYMPTOMS STARTED RIGHT AFTER THE PROCEDURE AND IT IS ONGOING. SHE STATED THAT HER PHYSICIAN SAID THAT ESSURE MAY COME OUT BY ITSELF BECAUSE IT WAS NOT IN THE RIGHT PLACE. CONSUMER REPORTED THAT ESSURE CAUSED HER CONDITION; SHE DID NOT EXPERIENCE ANY OF THE SYMPTOMS BEFORE ESSURE. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM CONSUMER: SHE STATED THAT ESSURE WILL BE REMOVED ON (B)(6) 2014. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP (B)(6) 2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER WHO REPORTED LAPAROSCOPIC REMOVAL OF ESSURE WAS ATTEMPTED ON (B)(6) 2014. THE RIGHT WAS STILL IN PLACE BUT THE LEFT WAS NOT SEEN IN THE TUBE. HCP (HEALTH CARE PROFESSIONAL) SCRAPED THE UTERUS AND DID NOT FIND IT THERE EITHER. CONSUMER STATED THAT SHE WAS NOT RECOVERED AND HAD MORE PAIN THAN BEFORE IN HER LEFT SIDE (PREVIOUSLY REPORTED AS A LITTLE OF PAIN) . SHE WOULD HAVE A SECOND OPINION SCHEDULED FOR (B)(6) 2014. THE CASE WAS UPGRADED TO INCIDENT DUE TO REPORTED INTERVENTION. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. SHE DID NOT GET THE ESSURE REMOVED YET BECAUSE THE DOCTOR WANTED HER TO WAIT A COUPLE OF MONTHS. SHE WAS STILL IN PAIN AND STILL BLEEDING. SHE WOULD FOLLOW-UP AFTER THE NEXT APPOINTMENT IN (B)(6) 2014. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS HAVING LIGHT BLEEDING; THEN DURING AN ATTEMPT TO REMOVE ESSURE (BY LAPAROSCOPY) THE DEVICE ON LEFT WAS NOT SEEN, HCP SCRAPED THE UTERUS AND DID NOT FIND IT THERE EITHER. THE REPORTED EVENTS WERE CONSIDERED SERIOUS, AS MEDICALLY SIGNIFICANT AND ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. THESE EVENTS WERE REGARDED AS INCIDENTS DUE TO THE REPORTED SURGICAL INTERVENTION (LAPAROSCOPIC SURGERY). DURING AND IMMEDIATELY FOLLOWING ESSURE INSERTION GENITAL BLEEDING AND SPOTTING MAY OCCUR; ALSO THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, IT WAS REPORTED A DIFFICULT ESSURE INSERTION ON LEFT SIDE DUE TO TUBAL SPASM, AND CONSUMER STATED THAT HER PHYSICIAN SAID THE DEVICE MAY COME OUT BY ITSELF (DEVICE EXPULSION?); LATER AT LAPAROSCOPY THE LEFT DEVICE WAS NOT FOUND. GIVEN THESE EVENTS NATURE AND CONSIDERING THEIR CLOSE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT. DURING FOLLOW-UP ATTEMPT THE CONSUMER STATED THAT SHE IS STILL BLEEDING (CONSIDERED A SERIOUS EVENT) AND IN PAIN, ESSURE WAS NOT REMOVED YET, FURTHER FOLLOW-UP TO OBTAIN CONSUMER'S OUTCOME IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW UP INFORMATION RECEIVED ON 27-AUG-2015 FROM CONSUMER: THE CONSUMER MENTIONED THAT HSG (HYSTEROSALPINGOGRAM) TEST WAS NOT DONE. THE CONSUMER SAID ONE COIL TOOK PROPERLY AND THE OTHER COIL FELL OUT DURING THE PROCEDURE. THE ONLY THING THE DOCTOR TOLD

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00346	BAYER HEALTHCARE LLC	8/25/2014	8/25/2014

Event Information:

Event Date (B3): 7/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97494

Single Use: Y
Implant Date (E6): 7/29/2014
Explant Date (E7): 7/29/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014, ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT CONTRACEPTION WITH LOT NUMBER B97494. ACCORDING TO THE REPORTER, ESSURE COIL DID NOT DEPLOY IN LEFT TUBE. WHEN HCP ATTEMPTED TO REMOVE IT THE WIRE ON INSERTER BROKE OFF AND WAS STUCK IN UTERINE WALL. PATIENT WAS TAKEN TO OPERATING ROOM TO REMOVE WIRE. ESSURE WAS INSERTED SUCCESSFULLY IN THE RIGHT TUBE AND NOT ACHIEVED IN THE LEFT TUBE. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: THE PATIENT'S WEIGHT AND HEIGHT WERE ADDED; SHE WAS CONSIDERED OVERWEIGHT (BMI =(B)(6)). THE PATIENT HAD A CERVICAL CONIZATION AS MEDICAL HISTORY. ON (B)(6) 2014, SHE HAD (B)(6). SHE WAS NOT POST-PARTUM AT TIME OF THE PROCEDURE. THE PATIENT WAS GRAVIDA 4 AND PARA 4. SHE WAS EVERY DAY SMOKER AND SELDOM ALCOHOL USE. SHE HAD TWO EPISODES OF COMMUNITY-ACQUIRED PNEUMONIA REQUIRING ANTIBIOTICS AND HOSPITALIZATION IN ONE OCCASION. ON 2002, SHE UNDERWENT A LEEP PROCEDURE AND AT AGE (B)(6) SHE HAD GANGRENE OF BOWEL-BOWEL RESECTION. ON (B)(6) 2014, ESSURE PROCEDURE WAS MADE. PHYSICIAN REPORTED THAT THE INSERTION PROCEDURE WAS CONSIDERED EASY; CERVICAL DILATATION AND SOUNDING WERE NOT PERFORMED; INTRACERVICAL AND PARACERVICAL BLOCK WERE USED FOR ANALGESIA. THE TUBAL OSTIUM WAS EASILY VISUALIZED. IT WAS REPORTED THAT THE PATIENT HAD MINIMAL RESISTANCE. THE RIGHT SIDE WAS CORRECTLY PLACED. THE DEVICE WAS PLACED IN THE LEFT FALLOPIAN TUBE UNTIL BLACK MARK WAS VISUALIZED AT THE UTEROTUBAL JUNCTION. THE SHEATH WAS RETRACTED AND AN ATTEMPT WAS MADE TO DEPLOY THE COILS; THIS WAS UNSUCCESSFUL. PHYSICIAN MADE A DECISION TO REMOVE THE DEVICE; THE DEVICE WAS ROTATED (CLOCKWISE AND

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COUNTER-CLOCKWISE). THE DEVICE WAS GENTLY RETRACTED FROM FALLOPIAN TUBE BUT THE COILS PARTIALLY DEPLOYED AS THE DEVICE WAS BEING REMOVED. THE MICRO INSERT NEVER COMPLETELY DETACHED FROM APPLICATOR; THE OUTER COIL BECAME DISTENDED AND EVENTUALLY SEPARATED FROM APPLICATOR. GENTLE TRACTION OF THE DEVICE RESULTED IN BREAKAGE OF THE COIL; AGAIN TRACTION WAS PLACED ON THE DEVICE BUT IT COULD NOT BE COMPLETELY REMOVED. THE FRAGMENTS THAT HAD BEEN REMOVED WERE RETRIEVED FROM THE UTERUS. THE PATIENT BEGAN TO EXPERIENCE DISCOMFORT DURING THE REMOVAL PROCESS. THE PROCEDURE WAS TERMINATED AND A DECISION TO TAKE THE PATIENT TO THE OPERATING ROOM AND CONTINUE THE PROCEDURE UNDER GENERAL ANESTHESIA WAS MADE. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES AND NO FLUID LOSS WAS OBSERVED. NO IMAGING OR ANY RELATED TESTS WERE PERFORMED AFTER THE INSERTION. AN IMAGING TEST (NOS) WAS DONE AFTER THE PROCEDURE AND SHOWED CORRECT PLACEMENT OF RIGHT COIL AND INCORRECT OF LEFT COIL. ON THE SAME DAY, ESSURE WERE PARTIALLY REMOVED; PHYSICIAN STATED THAT THE DEVICE'S REMOVAL WAS NECESSARY. ESSURE WAS REMOVED BY HYSTEROSCOPY AND WITH GENERAL ENDOTRACHEAL ANESTHESIA. THE PRE-OPERATIVE DIAGNOSIS: IMMEDIATELY STATUS POST FAILED ESSURE STERILIZATION WITH INCORRECT DEPLOYMENT OF THE LEFT MICRO-INSERT; PORTIONS OF MICRO-INSERT WERE LODGED IN THE FALLOPIAN TUBE AND UTERINE CAVITY. OPERATIVE FINDINGS: NORMAL EXTERNAL FEMALE GENITALIA. THE CERVIX HAD SOME LIGHT BLEEDING CONSISTENT WITH RECENT PLACEMENT OF TENACULUM. THE ENDOCERVIX WAS GROSSLY NORMAL. THE UTERINE CAVITY HAD A NORMAL LEAD DEPLOYED AND CORRECTLY PLACED RIGHT ESSURE MICRO INSERT. THE OUTER COIL OF THE LEFT MICRO-INSERT WAS VISIBLE AS WELL AS THE INNER WIRE, BOTH COMING OUT FROM LEFT FALLOPIAN TUBE. A LONG PACKING OF FORCEPS WERE INSERTED INTO THE UTERINE CAVITY; THE INNER WIRE WAS ABLE TO BE GRASPED AND BROUGHT TO THE CERVIX, A GENTLE TRACTION REMOVED ALL VISIBLE PORTION OF INNER WIRE. A HYSTEROSCOPIC GRASPER WAS USED TO GRAB THE OUTER COIL; THE COIL WAS TURNED, FIRST CLOCKWISE AND THEN COUNTER-CLOCKWISE, A GENTLE TRACTION WAS USED AND AFTER APPROXIMATELY 10-15 ROTATIONS OF THE COIL, A PIECE FRAGMENTED WAS OFF AND WAS RETRIEVED. THE REMAINING PORTION WAS GRASPED AGAIN AND ROTATION WAS PERFORMED UNTIL MAJORITY OF THE COIL WAS REMOVED. THIS LARGE FRAGMENT APPEARED TO BE ESSENTIALLY THE NORMAL SIZE OF THE OUTER COIL. CAREFUL INSPECTION WITH THE HYSTEROSCOPE REVEALED NO EVIDENCE OF ANY OTHER FOREIGN BODIES IN THE UTERINE CAVITY. THE CORNEAL AREA AND UTERUS TUBAL JUNCTION WAS CAREFULLY INSPECTED. THERE WAS NO EVIDENCE OF ANY OUTER COIL OR INNER COIL THAT COULD BE SEEN. TWO FLAT PLATES X-RAY WERE PERFORMED AND APPEARED THAT SOME ESSURE DEVICE WAS STILL PRESENT DISTALLY IN THE FALLOPIAN TUBE. A CONTRAST IMAGING (FLUOROSCOPY) DEMONSTRATED THAT THE DEVICE IN RIGHT SIDE WAS APPROPRIATELY PLACED; AND THE LEFT DEVICE WAS STILL PRESENT DISTALLY IN THE LEFT SIDE, IT WAS NO EVIDENCE OF THE OUTER COIL BUT THE INNER. DURING THE PROCEDURE, PHYSICIAN NOTED A PURULENT DISCHARGE FROM THE ANTERIOR LIP OF CERVIX. A CAREFUL INSPECTION REVEALED THAT THERE WAS A PROBABLE NABOTHIAN ABSCESS IN THE ANTERIOR LIP OF CERVIX; PHYSICIAN DURING THE PROCEDURE, PHYSICIAN NOTED A PURULENT DISCHARGE FROM THE ANTERIOR LIP OF CERVIX. A CAREFUL INSPECTION REVEALED THAT THERE WAS A PROBABLE NABOTHIAN ABSCESS IN THE ANTERIOR LIP OF CERVIX; PHYSICIAN SQUEEZED WITH RING FORCEPS TO TRY EXPRESS AS MUCH PUS AS POSSIBLE; 2G OF ANCEF AND 500MG OF METRONIDAZOLE WERE GIVEN TO THE PATIENT AS INFECTION PROPHYLAXIS. THE PROCEDURE WAS ENDED AND THE REMAINED DEVICE WAS LEFT INSIDE THE FALLOPIAN TUBE. THE PATIENTS TOLERATED THE PROCEDURE WELL. PHYSICIAN CONSIDERED THE EVENTS RELATED TO ESSURE DEVICES, RELATED TO INCORRECT DEPLOYMENT OF COIL. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BROKE" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT

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OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, ALSO A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED IN THE CONTEXT OF A COMPLICATED INSERTION. HOWEVER, THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN (SEE TECHNICAL STATEMENT). ONE FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. (B)(4), BUT THIS CASE DOES NOT REFER TO A SIMILAR TECHNICAL TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH DID NOT GIVE ANY REASON TO SUSPECT A QUALITY DEFICIT (SEE TECHNICAL STATEMENT). IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO (B)(6) YEAR OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ESSURE IS STUCK IN UTERINE WALL(EMBEDDED /EXPULSION), THE WIRE ON INSERTER BROKE OFF (COMPLICATION OF DEVICE INSERTION), UNILATERAL PLACEMENT, ESSURE COIL DID NOT DEPLOY IN LEFT TUBE (DEPLOYMENT ISSUE), AN ATTEMPT WAS MADE IN THE OFFICE TO REMOVE THE DEVICE BUT THE DEVICE FRAGMENTED / LEFT DEVICE REMAINED DISTALLY IN THE FALLOPIAN TUBE AND DISCOMFORT DURING THE REMOVAL PROCEDURE. THE EVENT ESSURE IS STUCK IN UTERINE WALL IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE WHILE THE REMAINING EVENTS WERE CONSIDERED NON-SERIOUS. ALL THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT THE WIRE ON INSERTER BROKE OFF PREVIOUSLY CONSIDERED UNLISTED WAS AMENDED TO LISTED (ANTICIPATED) UPON RECEIPT OF PRODUCT TECHNICAL (PTC) ANALYSIS. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS

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MOVEMENT COULD BE AN EXPULSION (INTO UTERUS) OR DISLOCATION. IN THIS PARTICULAR WHEN HCP ATTEMPTED TO REMOVE IT THE WIRE ON INSERTER BROKE OFF AND WAS STUCK IN UTERINE WALL. AN ATTEMPT WAS MADE IN THE OFFICE TO REMOVE BUT THE DEVICE WAS FRAGMENTED. THIS EVENT WAS CONSIDERED AS RELATED TO ESSURE AND REGARDED AS INCIDENT SINCE THE PATIENT UNDERWENT A SURGICAL HYSTEROSCOPY TO REMOVE THE INSERT. THE EVENT THE WIRE ON INSERTER BROKE OFF WAS ASSUMED AS DEVICE BREAKAGE; SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE WHEN HCP ATTEMPTED TO REMOVE IT THE WIRE ON INSERTER BROKE OFF AND WAS STUCK IN UTERINE WALL. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED EXCEPT THE EVENT ESSURE COIL DID NOT DEPLOY IN LEFT TUBE THAT WAS CONSIDERED UNRELATED. THE PTC ANALYSIS CONCLUDED THAT THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW UP 22.AUG.2014: THIS CASE IS A POTENTIAL LEGAL CASE. LETTER WAS RECEIVED FROM THE CONSUMER'S LAWYER STATING THAT ESSURE ESS305, LOT NUMBER B97494 HAS BEEN RETURNED TO BAYER HEALTHCARE. THE LETTER WAS FORMAL NOTICE REQUESTING THAT THE DEVICE BE PRES

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00345	BAYER HEALTHCARE LLC	8/25/2014	9/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B63029

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON AN UNSPECIFIED DATE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT CONTRACEPTION WITH LOT NUMBER B63029 (EXPIRATION DATE JUL-2016). IT WAS REPORTED THAT THE PHYSICIAN WENT IN TO PLACE THE ESSURE AND THE TIP OF ESSURE CAME OFF IN THE UTERINE CAVITY, SO GRASPERS WERE TAKEN TO TAKE IT OUT (THE SIDE WAS NOT SPECIFIED). THERE WAS NO INJURY TO THE PATIENT. ANOTHER ESSURE COILS WAS PLACED. FOLLOW-UP INFORMATION RECEIVED ON 06-AUG-2014: ON (B)(6) 2014, TIP OF THE DEVICE BROKE OFF INSIDE UTERUS AFTER DEPLOYMENT (THE PREVIOUS REPORTED EVENT THE TIP OF THE ESSURE CAME OFF IN THE UTERINE CAVITY DURING PROCEDURE WAS AMENDED TO TIP OF THE DEVICE BROKE OFF INSIDE UTERUS AFTER DEPLOYMENT). THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 14: THE BAYER GLOBAL REFERENCE NUMBER FOR THE PTC REPORT WAS (B)(4). FINAL ASSESSMENT : WHEN A TERM LIKE "CAME OFF " IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS

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TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT : THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED IN THE CONTEXT OF A COMPLICATED INSERTION. HOWEVER, THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN (SEE TECHNICAL STATEMENT). NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B63029. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH DID NOT GIVE ANY REASON TO SUSPECT A QUALITY DEFICIT. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 15-AUG-2014: NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND TIP OF THE DEVICE BROKE OFF INSIDE UTERUS AFTER DEPLOYMENT (PREVIOUSLY REPORTED AS TIP OF THE ESSURE CAME OFF IN THE UTERINE CAVITY DURING PROCEDURE)/COMPLICATION OF DEVICE INSERTION. THE PATIENT HAD NO INJURY. REPORTER CAUSALITY WAS NOT PROVIDED. THE REPORTED EVENT, INTERPRETED AS A DEVICE BREAKAGE, IS NON-SERIOUS, UNLISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS CONSIDERED A OTHER REPORTABLE EVENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, CONSIDERING THAT DEVICE BREAKAGE OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS CONCLUDED THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH DID NOT GIVE ANY REASON TO SUSPECT A QUALITY DEFICIT. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00343	BAYER HEALTHCARE LLC	8/25/2014	9/9/2014

Event Information:

Event Date (B3): 7/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B85141

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/15/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER B86141. DURING THE INSERTION PROCEDURE, THE ESSURE DEVICE HAD A BAD RELEASE WHICH BROKE AT FOURTH TRAILING COIL AT INTRAUTERINE EXTREMITY. THE IMPLANT COULD NOT BE REMOVED, DESPITE TRACTION WITH PREHENSIVE PLIERS. PLACEMENT WAS PERFORMED WITHOUT ANY DIFFICULTY ON RIGHT SIDE. THE CRITERION OF SERIOUSNESS WAS CONSIDERED AS NON-SERIOUS BY THE REPORTER. NO FURTHER INFORMATION WAS PROVIDED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE WAS NOT REPORTED. ACCORDING TO THE FRENCH METHOD OF CAUSALITY THE ASSESSMENT OF THE CAUSAL RELATIONSHIP WITH ESSURE WAS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BAD RELEASE DEVICE WHICH BROKE AT FOURTH TRAILING COIL AT INTRAUTERINE EXTREMITY(DEVICE BREAKAGE/ DEVICE DEPLOYMENT ISSUE), IMPLANT COULD NOT BE REMOVED AND COMPLICATION OF DEVICE INSERTION. ALL EVENTS ARE CONSIDERED NON-SERIOUS.THE EVENT BAD RELEASE DEVICE WHICH BROKE AT FOURTH TRAILING COIL AT INTRAUTERINE EXTREMITY(DEVICE BREAKAGE) IS CONSIDERED UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. THE EVENT BAD RELEASE DEVICE WHICH BROKE AT FOURTH TRAILING COIL AT INTRAUTERINE EXTREMITY, ASSUMED AS DEVICE BREAKAGE, WAS REGARDED AS NEAR-INCIDENT DUE TO THE REPORTED BREAKAGE. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF

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ESSURE BREAKAGE. IN THIS PARTICULAR CASE, IT WAS MENTIONED THAT DURING THE INSERTION PROCEDURE, THE ESSURE DEVICE HAD A BAD RELEASE WHICH BROKE AT FOURTH TRAILING COIL AT INTRAUTERINE EXTREMITY. THE IMPLANT COULD NOT BE REMOVED, DESPITE TRACTION WITH PREHENSIVE PLIERS. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED. PTC ANALYSIS WILL BE REQUEST.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 18-JUN-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). THE PTC INVESTIGATION RESULT WAS UPDATED UPON COMPLAINT SAMPLE RECEIPT. FINAL ASSESSMENT SINCE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00344	BAYER HEALTHCARE LLC	8/25/2014	9/9/2014

Event Information:

Event Date (B3): 7/28/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/28/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED THE EVENTS DESCRIBED BELOW. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. IN THE MIDDLE OF AN ESSURE PROCEDURE THE DOCTOR WISHED TO SPEAK TO SOMEONE SINCE NEITHER SIDE LOOKED LIKE WHAT THEY WERE USED TO SEEING; BOTH SIDES LOOKED LIKE PART OF THE DEVICE WAS COMING OUT. THERE WAS A LONG THIN METALLIC PIECE. THERE WERE THREE COILS ON THE LEFT AND FIVE ON THE RIGHT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BROKE" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE

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FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, ALSO A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED IN THE CONTEXT OF A COMPLICATED INSERTION. HOWEVER, THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN (SEE TECHNICAL STATEMENT). NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THERE IS A LONG THIN METALIC PIECE, PART OF THE DEVICE IS COMING OUT AND COMPLICATION OF DEVICE INSERTION. THE EVENTS THERE IS A LONG THIN METALIC PIECE AND COMPLICATION OF DEVICE INSERTION ARE CONSIDERED NON-SERIOUS WHILE THE EVENT PART OF THE DEVICE IS COMING OUT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE .THE EVENT THERE IS A LONG THIN METALIC PIECE IS UNLISTED WHILE THE REMAINING EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT THERE IS A LONG THIN METALIC PIECE (ASSUMED AS DEVICE BREAKAGE) WAS REGARDED AS OTHER REPORTABLE EVENT SINCE THE REPORTER STATED A DEVICE BREAKAGE. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, IN THE MIDDLE OF AN ESSURE PROCEDURE THE DOCTOR WISHED TO SPEAK TO SOMEONE SINCE NEITHER SIDE LOOKED LIKE WHAT THEY WERE USED TO SEEING; BOTH SIDES LOOKED LIKE PART OF THE DEVICE WAS COMING OUT. THERE WAS A LONG THIN METALLIC PIECE. ACCORDING TO PTC FINAL ANALYSIS, BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00348	BAYER HEALTHCARE LLC	8/26/2014	8/26/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 664659

Single Use: Y
Implant Date (E6): 2/15/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2010, ESSURE WAS INSERTED (LOT NUMBER 664659) FOR TUBAL OCCLUSION. IN 2014, CONSUMER REPORTED TO THE LOCAL EMERGENCY ROOM WITH PAINS IN ABDOMEN AND FOUR POSITIVE PREGNANCY TESTS. AN ULTRASOUND WAS PERFORMED AND SHE WAS SAID IT WAS POSSIBLE ECTOPIC, SO THEY WERE GOING TO DO SURGERY TO REMOVE THE RIGHT TUBE, COIL AND FETUS LAPAROSCOPICALLY. ON (B)(6) 2014, ESSURE WAS REMOVED. AT FIRST, IT WAS TRIED BUT THERE WAS TOO MUCH SCAR TISSUE SO THEY HAD TO OPEN HER OLD C-SECTION SCAR. WHEN PHYSICIAN GOT IN, HE LOCATED THE LEFT TUBE COIL AND OVARY INTACT AND THE RIGHT HE REMOVED ALONG WITH THE FETUS. THE COIL HAD COME ALL THE WAY OUT AND WAS STUCK IN HER UTERUS WHICH HE ALSO REMOVED ALONG WITH 100ML OF BLOOD CLOTS FROM THE OTHER END OF THE COIL, SCRAPING AROUND INSIDE HER. SHE HAD THREE PREVIOUS VISITS TO THE EMERGENCY ROOM WITH EXCRUCIATING PAIN AND THE CTS SHOWED NOTHING THERE. SHE WAS TOLD THE ESSURE COULD NOT BE HER PROBLEM SO SHE LEARNED TO DEAL WITH THE PAIN AT HOME SINCE THE EMERGENCY SAID THERE WAS NOTHING THERE. THE DOCTOR THAT REMOVED THE COIL SAID TO HER THAT WAS PROBABLY WHAT WAS CAUSING IT. SHE STATED THAT KNEW THE RIGHT SIDE WAS OUT SOME BUT WASN'T ALL THE WAY OUT. EVERY CT OR ULTRASOUND SHOWED IT WAS STILL IN THERE AND IN PLACE JUST STICKING OUT OF THE TUBE A LITTLE. SHE ALSO PRESENTED DEPRESSION AND WEIGHT GAIN OF ABOUT 40 LBS. CONSUMER STATED THAT ALMOST DIED FROM ESSURE AND PAIN WAS ALMOST ALWAYS ON THE RIGHT SIDE BUT SINCE THE REMOVAL IT WAS SWITCHED TO THE LEFT SIDE, AND SHE HAS NOT HURT ON THE RIGHT SIDE SINCE REMOVAL. FOLLOW UP (B)(6) 2014: FOLLOW UP INFORMATION RECEIVED FROM THE

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CONSUMER. CONSUMER'S DATA WERE UPDATED, INCLUDING HER AGE, (B)(6) YEARS OLD AND BMI, (B)(6). NO PREVIOUS GYNECOLOGICAL PROBLEMS. CONCOMITANT DISEASES INCLUDES DIABETES AND HIGH BLOOD PRESSURE. CONSUMER REPORTED THAT ESSURE WAS INSERTED A YEAR AND A MONTH AFTER HER LAST DELIVERY WHICH OCCURRED IN (B)(6) 2009. CONSUMER USED CONDOMS AS CONTRACEPTIVE METHOD UNTIL ESSURE OCCLUSION CONFIRMATION. ON A DATE NOT REPORTED HYSTEROSALPINGOGRAM WAS PERFORMED AND SHOWED THAT ON THE LEFT SIDE, THE TUBE WASN'T CLOSED ALL THE WAY, THEY SAID IT WAS IN THERE BUT IT WAS HANGING OUT A LITTLE BIT. SHE CONFIRMED ALL THE EVENTS PREVIOUSLY REPORTED AND SAID THAT SHE HAS NOT RECOVERED FROM THEM AND MENTIONED IN ADDITION, PAIN ON THE RIGHT SIDE. CONSUMER STATED THAT RIGHT SIDED ECTOPIC PREGNANCY WAS REMOVED. THE ECTOPIC PREGNANCY WAS DIAGNOSED WITH 7 WEEKS OF GESTATION AND ON (B)(6) 2014, THEY TOOK OUT RUPTURED RIGHT SIDED ECTOPIC PREGNANCY. A RIGHT LAPAROSCOPY CONVERTED TO LAPAROTOMY SECONDARY TO OMENTAL ADHESIONS. RIGHT SALPINGECTOMY AND REMOVAL OF RIGHT ECTOPIC PREGNANCY AND REMOVAL OF RIGHT ESSURE DEVICE. THEY PULLED RIGHT ESSURE OUT OF HER UTERUS (IT WAS STUCK IN HER UTERUS). THE LEFT ESSURE HAS BEEN STILL THERE. UTERUS WAS INTACT. CONSUMER WAS HOSPITALIZED FOR 3 DAYS TO HAVE THESE PROCEDURES PERFORMED. SHE HAS NOT RECOVERED FROM THE OTHER SYMPTOMS. CONSUMER STATED THAT THERE WAS NO PLAN FOR ESSURE REMOVAL ON THE LEFT SIDE. CONSUMER CONSIDERED ALL THE EVENTS AS RELATED TO ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. LACK OF EFFECTIVENESS MAY OCCUR WITH THE USE OF ANY PRODUCT AND PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. BOTH OF THESE EVENTS ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. FIVE (5) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER (B)(4) BUT ONLY ONE (1) OF THESE CASES REFERS TO A SIMILAR MEDICAL EVENT BUT NONE OF THESE CASES REFER TO A LACK OF EFFICACY EVENT. NO UNUSUAL PATTERN COULD BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. THIS CASE IS NOW MEDICALLY CONFIRMED. PATIENT'S MIDDLE INITIAL WAS ADDED. SHE USED TO SMOKE (QUIT 7 YEARS PRIOR TO THIS REPORT). MEDICAL HISTORY INCLUDED DIABETES MELLITUS TYPE II, HYPERLIPIDEMIA, AND HYPERTENSION. PAST SURGICAL HISTORY INCLUDED CAESAREAN SECTION IN 2005, 2009 (FTP (INTERPRETED AS FAILURE TO PROGRESS), PREECLAMPSIA), TONSILLECTOMY (2002), AND HEMORRHOIDECTOMY (2013). HISTORICAL DRUG INCLUDED DEPO-PROVERA 150MG/ML, METFORMIN HCL 500MG XR 24H-TAB, LISINOPRIL 20 MG TAB, CLARITIN 10 MG AND GLYBURIDE 5 MG. CONCOMITANT DRUG INCLUDED GLYBURIDE 5 MG TABLET, IRON ORAL TABLET 325 MG (65MG IRON), LISINOPRIL-HYDROCHLOROTHIAZIDE ORAL TABLET 20-12.5MG, LOVASTATIN ORAL TABLET 20 MG, METFORMIN HCL 500MG XR 24H-TAB AND ZYRTEC ORAL TABLET 10MG. CONCOMITANT CONDITION INCLUDED ALLERGY TO HYDROCODONE-ACETAMINOPHEN (VOMITING WITH HIGH DOSAGES). CONCERNING FAMILY'S MEDICAL HISTORY, COLON CANCER WAS SUFFERED BY PATERNAL UNCLE; DIABETES MELLITUS WAS SUFFERED BY AUNT, BROTHER, FATHER, PATERNAL AND MATERNAL GRANDFATHER

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AND GRANDMOTHER, MOTHER, SISTER AND UNCLE; HEART ATTACK WAS SUFFERED BY HER AUNT, FATHER, MATERNAL GRANDFATHER AND GRANDMOTHER, PATERNAL GRANDMOTHER, MOTHER, UNCLE; HEART DISEASE BY HER AUNT, FATHER AND UNCLE; HIGH BLOOD PRESSURE BY AUNT, BROTHER, FATHER, PATERNAL AND MATERNAL GRANDFATHER AND GRANDMOTHER, MOTHER, SISTER AND UNCLE; OSTEOPOROSIS BY AUNT, PATERNAL GRANDMOTHER, MOTHER; STROKE WAS SUFFERED BY HER FATHER. SHE HAD 03 PREGNANCIES, 02 LIVE BIRTHS AND 01 SPONTANEOUS ABORTION. ON (B)(6) 2010, ESSURE LOT NUMBER 664659 WAS EASILY IMPLANTED. SOUNDING (8) WAS APPLIED DURING INSERTION. SHE WAS NOT ON POSTPARTUM STATE. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. HSG WAS PERFORMED. THE PHYSICIAN MEDICALLY CONFIRMED THE EVENTS. NO PERFORATION WAS NOTED AT THE TIME OF ESSURE INSERTION. ON (B)(6) 2010, HSG WAS PERFORMED AND SHOWED THAT RIGHT ESSURE WAS NOTED TO HAVE EXTRUDED FROM THE RIGHT FALLOPIAN TUBE AND WAS ADHERENT TO THE UTERUS ITSELF. RIGHT TUBE WAS PATENT AND THERE WAS FREE SPILL SEEN IN THE PERITONEUM ON THE RIGHT SIDE. HEMOSTASIS WAS NOTED. ON THE LEFT SIDE, THE PROXIMAL BAND OF THE INNER COIL WAS ABOUT 6-7MM FROM THE CORNU. THE LEFT FALLOPIAN TUBE WAS OCCLUDED AT THE CORNU. SHE COULD NOT GET SECOND DEPO SHOT AS THEY SHOWED SHE WAS STERILE. SHE SHOULD HAVE GOTTEN DEPO IN (B)(6). HER PERIOD STARTED ON (B)(6). ON (B)(6) 2014, SHE PRESENTED TO THE EMERGENCY ROOM WITH ONSET OF RIGHT LOWER QUADRANT PAIN. THE PATIENT WAS NOTED TO HAVE A POSITIVE QUANTITATIVE OF OVER 700. PELVIC ULTRASOUND WAS SUGGESTIVE OF A RUPTURED RIGHT ECTOPIC PREGNANCY. SHE UNDERWENT A DIAGNOSTIC LAPAROSCOPY CONVERTED TO LAPAROTOMY SECONDARY TO OMENTAL ADHESIONS, RIGHT SALPINGECTOMY AND REMOVAL OF ECTOPIC PREGNANCY, REMOVAL OF RIGHT ESSURE DEVICE. GENERAL ANESTHESIA WAS APPLIED. THE PATHOLOGY WAS NEGATIVE FOR MALIGNANCY. SHE REPORTED TENDERNESS TO FRONT OF ABDOMEN THAT SHE DEVELOPED 3 WEEKS PRIOR TO THIS REPORT. SHE DENIED DRAINAGE FROM THE INCISION SITE AND VAGINAL BLEEDING. SHE HAS NOTICED A SMELL FROM THE INCISION. SHE WAS TRANSFERRED TO THE PACU IN STABLE CONDITION. SHE DENIED BODY ACHES, NIGHT SWEATS, NAUSEA, VOMITING, DIARRHEA, CONSTIPATION, BLOOD IN STOOLS, GENITOURINARY URGENCY, FREQUENCY, DYSURIA AND INCONTINENCE, EASY BLEEDING, EASY BRUISING, LYMPH NODE ENLARGEMENT OR TENDERNESS. ON (B)(6) 2014, BP WAS 120/74 ON SITTING POSITION. ON PHYSICAL ABDOMINAL EXAMINATION IT WAS NOTED THAT ABDOMEN NONTENDER TO PALPATION, NORMAL BOWEL SOUNDS, TONE NORMAL WITHOUT RIGIDITY OR GUADING, NO MASSES PRESENT, RIGHT INCISIONAL AREA WITH YEAST AND SKIN OPEN, NO DRAINAGE. NO HERNIAS WERE PRESENT. NYSTATIN TOPICAL POWDER 3 TIMES PER DAY WAS PRESCRIBED AND SHE WAS INSTRUCTED TO NOT HAVE INTERCOURSE FOR 1-2 WEEKS, KEEP WOUND DRY AND RETURN TO NORMAL ACTIVITY. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEARS-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ECTOPIC PREGNANCY/RUPTURED RIGHT SIDE ECTOPIC PREGNANCY; ESSURE COIL HAD COME OUT ALL THE WAY AND WAS STUCK IN HER UTERUS; TUBE WAS NOT CLOSED ALL THE WAY, COIL HANGING OUT A LITTLE BIT ON THE LEFT SIDE. SHE WAS SUBMITTED TO RIGHT SALPINGECTOMY WITH REMOVAL OF RIGHT ECTOPIC PREGNANCY AND RIGHT ESSURE DEVICE; SHE CONSIDERED THE EVENTS AS RELATED TO ESSURE. THE REPORTED ECTOPIC PREGNANCY WAS CONSIDERED SERIOUS AND AN INCIDENT DUE TO HOSPITALIZATION AND REQUIRED INTERVENTION; THE REMAINING EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND NON-INCIDENTS. ALL EVENTS ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ECTOPIC PREGNANCIES HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE THE INSERT IN PLACE. IN THIS PARTICULAR CASE, CONSUMER STATED THAT RIGHT ESSURE INSERT WAS STACKED IN HER UTERUS AND SHE ALSO HAD AN RIGHT SIDE ECTOPIC PREGNANCY WHICH RUPTURED; CONSIDERING THESE EVENTS NATURE AND GIVEN THE POSITIVE TEMPORAL RELATIONSHIP A CAUSAL RELATION WITH THE SUSPECT INSERT

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CANNOT BE EXCLUDED. REGARDING THE EVENT TUBE WAS NOT CLOSED ALL THE WAY, COIL HANGING OUT A LITTLE BIT ON THE LEFT SIDE, IT WAS ALSO CONSIDERED AS RELATED TO THE SUSPECT INSERT SINCE IT WAS INTERPRETED AS A DEVICE DISLOCATION WHICH MAY OCCUR DURING ESSURE THERAPY. ADDITIONALLY OTHERS NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO THE RECEIVED PRODUCT TECHNICAL COMPLAINT ANALYSIS THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00349	BAYER HEALTHCARE LLC	8/26/2014	8/26/2014

Event Information:

Event Date (B3): 7/31/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/31/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5036871) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2008, ESSURE WAS INSERTED. CONSUMER STATED THAT FELT SICK IMMEDIATELY AFTER IMPLANT OF ESSURE. SHE EXPERIENCED PROFUSE BLEEDING, HAIR LOSS, MEMORY LOSS, NAUSEA, VOMITING, MUSCLE PAIN, SEVERE ABDOMINAL PAIN, BLOATING, CONFUSION, HIGH BLOOD PRESSURE, VISION PROBLEMS, TEETH AND GUM PROBLEMS, AND LETHARGY. SHE STATED THAT FELT LIKE AN 80 YEAR OLD LADY. SHE ALSO EXPERIENCED STABBING PAIN AND BURNING SENSATION BUT SUBSIDED A LITTLE AFTER 1CM OF ESSURE WAS EXPLANTED. DURING THE EXPLANT, PHYSICIAN WAS ONLY ABLE TO GET 1CM OUT OF THE 4CM IMPLANTED AND THIS WAS DUE TO DEVICE FRAGMENTATION. A 3CM OF DEVICE HAS MIGRATED TO CONSUMER´S RIBS AND HIPS. EXPLANTING PHYSICIAN ALSO REALIZED THE IMPLANTING PHYSICIAN PERFORMED A TUBAL AS WELL AND HER FALLOPIAN TUBES WERE PERFORATED AS A RESULT OF THE PROCEDURE. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014: NO RESPONSE TO DATE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6)2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT : WHEN A TERM LIKE "BROKE" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE

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INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED MEDICAL ASSESSMENT : THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE MAJORITY OF EVENTS WAS CONSIDERED AS UNRELATED OR NOT ASSESSABLE BY COMPANY AT THIS POINT IN TIME. IN THIS PARTICULAR CASE, ALSO A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED IN THE CONTEXT OF A COMPLICATED INSERTION. HOWEVER, THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN (SEE TECHNICAL STATEMENT). THE AE CASE REFERS ALSO TO A USABILITY ISSUE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PROFUSE BLEEDING, DEVICE FRAGMENTATION, 3 CM OF DEVICE MIGRATED TO HER HIPS AND RIBS AND FALLOPIAN TUBES WERE PERFORATED. ALL EVENTS WERE CONSIDERED SERIOUS, AS MEDICALLY SIGNIFICANT AND REGARDED AS INCIDENTS SINCE AN ATTEMPT TO EXPLANT ESSURE WAS REPORTED (REQUIRED INTERVENTION). THEY ARE LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR DEVICE FRAGMENTATION WHICH WAS INTERPRETED AS A DEVICE BREAKAGE AND CONSIDERED UNLISTED. FALLOPIAN TUBE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION, MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR RESULT OF PERFORATION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF ESSURE MIGRATION AND PERFORATION WERE NOT KNOWN, HOWEVER GIVEN THEIR NATURE THEY WERE CONSIDERED AS RELATED TO ESSURE THERAPY. THE SAME ASSESSMENT IS GIVEN FOR THE EVENT PROFUSE BLEEDING SINCE DURING AND IMMEDIATELY FOLLOWING ESSURE INSERTION GENITAL BLEEDING AND

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SPOTTING MAY HAPPEN. REGARDING THE BREAKAGE, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE; IN THIS CASE A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION; HOWEVER A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED BY NOW. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. PTC ANALYSIS CONCLUDED, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037968	BAYER	8/26/2014	9/2/2014

Event Information:

Event Date (B3): 6/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B82470

Single Use:
Implant Date (E6): 6/18/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED ON (B)(6) 2014. WITHIN 3 WEEKS SIDE EFFECTS. I STARTED EXPERIENCING SEVERE, CHRONIC MIGRAINES WHICH WERE DEBILITATING. THEN I STARTED GETTING JOINT PAIN, BACK ACHES, GENERAL FATIGUE, "BRAIN FOG", AND WAS EXPERIENCING SEVERE ABDOMINAL PAINS. I CONSULTED WITH MY DOCTOR SHE SENT ME FOR A CT SCAN. AND NOW I AM SCHEDULED FOR A COMPLETE HYSTERECTOMY (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00347	BAYER HEALTHCARE LLC	8/26/2014	9/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THAT DOCTOR PLACED FIRST INSERT IN LEFT TUBE AND 10 SECONDS AFTER DEPLOYMENT, DEVICE WAS EXPELLED. ANOTHER DEVICE WAS PLACED IN LEFT AND IT STAYED. PUT IN RIGHT TUBE AND IT STAYED TOO. INSERT BROKE WHEN PULLING OUT AND REMOVED FROM UTERUS (COMPLICATION OF DEVICE INSERTION). ON AN UNSPECIFIED DATE, HSG WAS DONE. ON THE LEFT SIDE, ESSURE WAS IN CORRECT LOCATION AND THE TUBE WAS OCCLUDED. ON THE RIGHT SIDE, THE TUBE WAS ALSO OCCLUDED BUT THE DEVICE WAS TOO CLOSE. PROXIMAL END OF THE OUTER COIL IS NOT FIXED TO THE INNER COIL. AND IS A SHORT DISTANCE TO THE REST OF THE INSERT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ON RIGHT SIDE AT HSG DEVICE IS TOO CLOSE AND INSERT BROKE WHEN PULLING OUT/PROX END OF THE OUTER COIL IS NOT FIXED TO THE INNER COIL. EVENT INSERT BROKE WHEN PULLING OUT/PROX END OF THE OUTER COIL IS NOT FIXED TO THE INNER COIL WAS CONSIDERED NON-SERIOUS, IT IS UNLISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE, AND WAS REGARDED AS OTHER REPORTABLE INCIDENTS, DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE; IN THIS CASE A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION; HOWEVER A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED BY NOW. REGARDING ON RIGHT SIDE AT HSG DEVICE IS TOO CLOSE, INTERPRETED AS DEVICE DISLOCATION, IT WAS CONSIDERED SERIOUS DUE TO MEDICAL

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SIGNIFICANCE, IT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS NON-INCIDENT. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE DISLOCATION WAS NOT REPORTED (DEVICE IS TOO CLOSE TO THE OSTIUM? TOO CLOSE TO THE CONTRALATERAL DEVICE AT HSG?), GIVEN THE NATURE OF THE EVENT IT WAS CONSIDERED RELATED TO ESSURE. ALSO, NON-SERIOUS EVENT COMPLICATION OF DEVICE INSERTION WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: WH

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038046	BAYER	8/27/2014	9/8/2014

Event Information:

Event Date (B3): 9/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/15/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) OF 2013 AND BECAME PREGNANT IN (B)(6) OF 2013. AFTER THREE COMPLETELY NORMAL PREGNANCIES THIS FOURTH PREGNANCY AFTER THE ESSURE IMPLANTS CAUSED MAJOR HEALTH PROBLEMS FOR MY UNBORN CHILD AND MYSELF. I EXPERIENCED INCREASED AMNIOTIC FLUID THAT LEAD TO MULTIPLE TRIPS TO THE HOSPITAL FOR CONTRACTIONS LEADING TO THE USE OF MEDICATIONS TO PREVENT EARLY DELIVERY. MY UNBORN CHILD DEVELOPED A CYSTIC HYGROMA, HEART DEFECTS AND KIDNEY ABNORMALITIES. AFTER BIRTH, HIS HEART CONDITIONS REMAIN, HOWEVER MILD HE EXPERIENCES TACHYPNEA, WHICH LEAD TO INTUBATION, AND A 40-DAY NICU STAY. HE IS UNABLE TO SWALLOW FULL FEEDS AT A RATE CONSIDERED AVERAGE FOR A CHILD OF HIS AGE REQUIRING A FEEDING TUBE FOR EIGHT WEEKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038049	BAYER HEALTH	8/27/2014	9/8/2014

Event Information:

Event Date (B3): 10/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/29/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2012, I HAD THE ESSURE IMPLANTED IN MY FALLOPIAN TUBES. SINCE THE TIME IT WAS IMPLANTED, I HAVE BEEN HAVING SEVERE MIGRAINES, 2-4 TIMES A WEEK, HOT FLASHES, NIGHT SWEATS, PELVIC PAIN, BACK PAIN, JOINT PAIN, FACIAL HAIR GROWTH, NAUSEA; I HAVE BEEN DIAGNOSED WITH RAYNAUD'S. I GET SHOOTING PAINS THROUGH MY HIPS AND DOWN MY LEGS, BREAST PAIN, AND CHEST PAIN AND WEIGHT LOSS. I ALSO HAVE UNEXPLAINED RASHES AND THE SKIN ON THE PALMS OF MY HANDS IS PEELING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00350	BAYER HEALTHCARE LLC	8/27/2014	9/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B85141

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN FRANCE ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B85141 (EXPIRATION DATE OCT-2016), INSERTED AND INFORMED THAT, DURING PLACEMENT, DEVICE BROKE IN TWO PARTS INTO HYSTEROSCOPE OPERATING CHANNEL. THE PHARMACIST REPORTED AN INCIDENT WHICH OCCURRED DURING PLACEMENT. ACCORDING TO REPORTER DEVICE BROKE IN TWO PARTS INTO HYSTEROSCOPE OPERATING CHANNEL. HEALTH CARE PROFESSIONAL DID NOT HAVE FURTHER INFORMATION BUT SHE KEPT THE DEVICE TO IDENTIFY THE PROBLEM. A NEW DEVICE WAS PLACED WITHOUT ANY PROBLEM. FRENCH IMPUTABILITY ASSESSMENT: FRANCE BHP LOCAL DRUG SAFETY DEPARTMENT ASSESSED THE CAUSAL RELATIONSHIP WITH ESSURE AS NOT APPLICABLE ACCORDING TO THE FRENCH METHOD OF CAUSALITY. NO FURTHER INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY

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ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. AS OF (B)(6) 2014, SINCE NEITHER PRODUCT WAS RETURNED FOR INSPECTION NOR DO WE HAVE A PHOTOGRAPH OF THE ACTUAL DEVICE, WE CANNOT DETERMINE EXACTLY WHAT THE FAILURE IS. BASED ON OUR EXPERIENCE WITH DEVICE COMPLAINTS OF A SIMILAR NATURE, IT IS LIKELY THE REPORTER IS REFERRING TO AN EVENT IN WHICH THE MICRO-INSERT WAS BENT OR STRETCHED INT OA SHAPE WHICH RENDERED THE DEVICE TO BE UNUSABLE, AND HENCE, "BROKEN." CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED EVENT IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE A TECHNICAL DEFECT (DEVICE BROKE IN TWO PARTS) WAS REPORTED. THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B85141. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH REVEALED NO REASON TO SUSPECT A QUALITY DEFICIT (SEE TECHNICAL STATEMENT). THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: THE PRODUCTION DATE OF DEVICES FOR LOT NUMBER B85141 IS (B)(6) 2013. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE, THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE RE-CODED LEGACY REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEVICE BROKE IN TWO PARTS INTO HYSTEROSCOPE OPERATING CHANNEL. THIS EVENT WAS CONSIDERED NON-SERIOUS AND OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND STATED THAT THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT

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BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN EVENT DEVICE BROKE IN TWO PARTS INTO HYSTEROSCOPE OPERATING CHANNEL AND ESSURE CANNOT BE EXCLUDED AND THE REPORTED EVENT WAS CONSIDERED ANTICIPATED (LISTED). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038038	ESSURE IMPALNTS	8/29/2014	9/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTS
Device Type (E2): ESSURE IMPLANTS
Model # (E4): 4783319075
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED AND EVER SINCE I'VE BEEN HAVING HORRIBLE HEAVY BLEEDING, MIGRAINES, BLURRY VISION, FORGETFUL, DIZZY SPELLS, THROWING UP, DIARRHEA, HORRIBLE CRAMPS, EVERYDAY MAJOR ABDOMINAL PAINS, AWFUL BACK PAINS LIKE IT'S BREAKING SWOLLEN FEET, HANDS AND FACE RED DOTS APPEARING ON MY BODY AND AWFUL TASTE IN MY MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038066	BAYER	8/29/2014	9/8/2014

Event Information:

Event Date (B3): 4/17/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/17/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE COILS, MADE BY BAYER, INSERTED INTO MY FALLOPIAN TUBES ON (B)(6) 2014. I WAS PUT UNDER ANESTHESIA FOR THE PROCEDURE. WHEN I CAME TO, I WAS IN TREMENDOUS PAIN. THEY SENT ME HOME WITH A RX FOR VICODIN. I HAVE HAD ABDOMINAL PAIN EVER SINCE. ON (B)(6) I WAS TAKEN TO THE ER BY AMBULANCE FOR SEVERE ABDOMINAL CRAMPING AND DIARRHEA. THEY PERFORMED SEVERAL TESTS, CT SCAN, BLOOD AND URINE TESTS. THEY DIDN'T KNOW WHAT WAS WRONG. THEY PUT ME ON 7 DIFFERENT MEDICATIONS, INCLUDING 2 ANTIBIOTICS AND REFERRED ME TO A GASTROENTEROLOGIST. I HAD A COLONOSCOPY, THEN AN ENDOSCOPY AND THEN A SPECIAL X-RAY TEST TO LOOK AT MY SMALL INTESTINE. TURNS OUT I HAD A C-DIFF INFECTION, A VERY SERIOUS ONE TOO. I AM STILL ON THE ROAD TO RECOVERY. I'VE BEEN BATTLING THIS INFECTION FOR 2 AND A HALF MONTHS NOW. BEFORE ESSURE, I WAS A HEALTHY, ACTIVE WOMAN. NOW I HAVE 2 PERIODS A MONTH, EXTREME ABDOMINAL PAINS DURING MENSES AND BAD ABDOMINAL PAIN ALL THE TIME. MY JOINTS AT MY HIPS HURT, I GET HEADACHES NOW, WHEREAS BEFORE I NEVER DID. I GET SHARP PAINS IN MY LEFT OVARY. I DO NOT HAVE CYSTS OR ENDOMETRIOSIS. NONE OF MY DOCTORS COULD EXPLAIN TO ME HOW I ENDED UP WITH A C-DIFF INFECTION. NONE OF MY DOCTORS CAN FIND WHY MY HEALTH HAS BEEN DECLINING. I KNOW WHY. EVER SINCE I HAD THE ESSURE PROCEDURE, MY WHOLE LIFE HAS CHANGED. IT'S NOT GETTING ANY BETTER EITHER. ONLY WORSE. I THINK THIS PRODUCT NEEDS TO BE PULLED OFF THE MARKET. I JOINED A GROUP OF LOCAL WOMEN HAVING THE SAME ISSUE AS MYSELF. THEY REFERRED ME TO A DOCTOR WHO CAN REMOVE THE ESSURE COILS. SOME OF THE WOMEN IN THE GROUP HAVE HAD TO HAVE HYSTERECTOMIES DUE TO COMPLICATIONS FROM THE ESSURE. I HOPE I DO NOT HAVE TO HAVE THAT DONE. I'M TERRIFIED TO BE CUT ON, ONE OF THE BIGGEST SELLING POINTS FOR THE ESSURE. I AM SCHEDULED FOR AN ALLERGY TEST IN 2 MONTHS, BECAUSE THE ESSURE IS A NICKEL/TITANIUM

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ALLOY. I MAY BE HAVING AN ALLERGIC REACTION TO WHAT IT'S COMPOSED OF. THEY SAY IT'S A RARE SIDE EFFECT, BUT THAT SEEMS TO BE THE MOST COMMON SIDE EFFECT I'VE SEEN. WOMEN SHOULDN'T HAVE TO SUFFER LIKE THIS, OR BE CAUGHT IN A LIFE CHANGING DECISION TO HAVE ALL OR PART OF THEIR FEMALE ORGANS REMOVED BECAUSE WE CHOSE A PRODUCT WE WERE TOLD WAS SAFE AND AFFECTIVE. I HOPE MORE INVESTIGATING IS DONE AND THE LONG TERM EFFECTS STUDIED VERY CLOSELY. THIS IS NOT A GOOD PRODUCT. IT'S NOT A GOOD PRODUCT AT ALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038067	BAYER HEALTHCARE LLC	8/29/2014	9/8/2014

Event Information:

Event Date (B3): 8/28/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): C03090

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

TO THREAD BAYER, ESSURE (PERMANENT BIRTH CONTROL) WIRE THROUGH ESSURE GUIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038057		9/1/2014	9/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): A57108
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/10/2013
Explant Date (E7): 9/1/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE IMPLANTED IN (B)(6) 2013 IN A DOCTORS OFFICE WITH NO ANESTHESIA. HAD LEFT SIDE PAIN AND HORRIBLE BLEEDING AND PAIN. BLEED FROM (B)(6) 2012 (HAD MY BABY) TO (B)(6) 2014. HCG TEST IN (B)(6) 2013 SHOWED RIGHT WAS BLOCKED BUT LEFT HAD PERFORATED MY LEFT FALLOPIAN TUBE (THIS IS THE PAINFUL SIDE). (B)(6) 2013 SURGERY TO FIX THE LEFT TUBE AND PUT A CLAMP ON IT, DID A D&C TO SEE IF THAT WOULD HELP WITH THE BLEEDING BUT DIDN'T. CONTINUED TO BLEED AND HAVE PAIN. SWITCHED DOCTORS AND (B)(6) 2014 I HAD MY ESSURE REMOVED ALONG WITH MY TUBES, MY LEFT ESSURE WAS PERFORATED THRU MY FALLOPIAN TUBE AND WAS GROWING INTO MY ABDOMINAL WALL, HE ALSO DID A UTERINE ABLATION TO HELP WITH BLEEDING BUT THAT DIDN'T HELP EITHER. CONTINUED TO HAVE HEAVY BLEEDING AND PAIN ON THE RIGHT SIDE THIS TIME. COME TO FIND OUT I HAD A PIECE OF ESSURE STUCK IN MY UTERUS. (B)(6) I HAD A (LAVH) HYSTERECTOMY BUT LEFT OVARIES. ON (B)(6) HAD TO GO BACK TO ER FOR AN INFECTION AND ON (B)(6) WENT TO ER FOR HEMORRHAGING AND ON (B)(6) 2014 I HAD TO GO BACK INTO SURGERY FOR MY VAGINAL CUFF OPENING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00351	BAYER HEALTHCARE LLC	9/2/2014	9/2/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/21/2011
Explant Date (E7): 3/18/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5036798) IN UNITED STATES ON (B)(6)-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6)-2011, ESSURE WAS INSERTED. IN 2012, SHE BECAME PREGNANT (PLEASE REFER TO MOTHER´S CASE (B)(6)). IN 2013, SHE HAD TO DELIVER HER SON, BUT HE HAD ALREADY DIED IN UTERO THREE TO FOUR DAYS PRIOR. IN 2013, SHE WENT BACK IN FOR SURGERY TO HAVE FALLOPIAN TUBES REMOVED. UPON AWAKENING SHE WAS INFORMED THE ESSURE ON ONE SIDE HAD MIGRATED AND PERFORATED HER UTERUS WITH A POSSIBILITY OF LATER PUNCTURING HER BOWEL. THEREFORE, SHE NEEDED A HYSTERECTOMY. SHE WENT BACK UNDER TO HAVE THE HYSTERECTOMY, HOWEVER LEAVING OVARIES. THREE DAYS LATER SHE WAS BACK IN THE HOSPITAL WITH A FEVER OF 103. NOTHING CAME OF THE FEVER. THE DATE (B)(6)-2013 WAS REPORTED AS EXPLANT DATE. DEATH AND LIFE-THREATENING WERE SELECTED BY CONSUMER AS EVENT REPORT TYPE AND EVENT OUTCOME, RESPECTIVELY. HOWEVER, IT WAS NOT SPECIFIED WHICH EVENT. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6)-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS

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REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE (B)(6) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER AND REFERS TO HER SON WHO HAD ESSURE MICRO-INSERT EXPOSURE IN UTERO AND HIS MOTHER HAD TO DELIVER HIM, WHO DIED IN UTERO THREE TO FOUR DAYS PRIOR. THE EVENT I HAD TO DELIVER SON DIED IN UTERO THREE TO FOUR DAYS PRIOR INTERPRETED AS FETAL DEATH WAS CONSIDERED SERIOUS AND INCIDENT DUE TO DEATH AND IT IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT CONSUMER'S SON DIED IN UTERO; NO INFORMATION ABOUT THE EXACT CAUSE OF FETAL DEATH WAS PROVIDED; HOWEVER CONSIDERING THAT A DELIVERY WAS REPORTED (IMPLYING A ADVANCED GESTATIONAL AGE AT TIME OF EVENT) A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THIS EVENT WAS, THEREFORE CONSIDERED AS RELATED TO THE SUSPECT INSERT. ACCORDING TO AND PRODUCT TECHNICAL ANALYSIS, NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00352	BAYER HEALTHCARE LLC	9/2/2014	9/2/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/21/2011
Explant Date (E7): 3/18/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5036798) IN UNITED STATES ON 04-AUG-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2011, ESSURE WAS INSERTED. IN 2012, SHE BECAME PREGNANT. IN 2013, SHE HAD TO DELIVER HER SON, BUT HE HAD ALREADY DIED IN UTERO THREE TO FOUR DAYS PRIOR (PLEASE REFER TO CASE NUMBER (B)(4)). IN 2013, SHE WENT BACK IN FOR SURGERY TO HAVE FALLOPIAN TUBES REMOVED. UPON AWAKENING SHE WAS INFORMED THE ESSURE ON ONE SIDE HAD MIGRATED AND PERFORATED HER UTERUS WITH A POSSIBILITY OF LATER PUNCTURING HER BOWEL. THEREFORE, SHE NEEDED A HYSTERECTOMY. SHE WENT BACK UNDER TO HAVE THE HYSTERECTOMY, HOWEVER, LEAVING OVARIES. THREE DAYS LATER SHE WAS BACK IN THE HOSPITAL WITH A FEVER OF 103. NOTHING CAME OF THE FEVER. THE DATE (B)(6) 2013 WAS REPORTED AS EXPLANT DATE. DEATH AND LIFE-THREATENING WERE SELECTED BY CONSUMER AS EVENT REPORT TYPE AND EVENT OUTCOME, RESPECTIVELY. HOWEVER, IT WAS NOT SPECIFIED WHICH EVENT. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 18-AUG-2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. PTC INVESTIGATION RESULT WAS RECEIVED ON 22-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A

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REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE A LACK OF EFFICACY (PREGNANCY) WAS REPORTED. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED; EXPERIENCED A PREGNANCY WITH ESSURE (DEVICE INEFFECTIVE) AND HAD TO DELIVER HER SON WHO DIED IN UTERO 3-4 DAYS PRIOR. SHE ALSO STATED THAT ESSURE MIGRATED AND PERFORATED UTERUS WITH POSSIBILITY OF BOWEL PUNCTURE. SHE WAS SUBMITTED TO FALLOPIAN TUBES REMOVAL AND HYSTERECTOMY; AND AFTER THIS SURGERY WAS HOSPITALIZED DUE TO FEVER. ALL ABOVE REPORTED EVENTS, WITH EXCEPTION OF PREGNANCY, WERE CONSIDERED SERIOUS (LIFE-THREATENING- DELIVER OF DEAD SON, MEDICAL SIGNIFICANCE-PERFORATION AND HOSPITALIZATION-FEVER) AND INCIDENTS (REQUIRED INTERVENTIONS/HOSPITALIZATION). THEY ARE LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE; EXCEPT FOR FEVER AND HAD TO DELIVER HER SON WHO DIED IN UTERO 3-4 DAYS PRIOR WHICH ARE UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS PARTICULAR CASE THE CONSUMER STATED THAT SHE HAD TO DELIVER HER SON WHO DIED IN UTERUS, THIS EVENT, INTERPRETED AS A FETAL DEATH WAS CONSIDERED AS RELATED TO ESSURE, AS A MECHANICAL INTERFERENCE BETWEEN THE SUSPECT INSERT AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED. REGARDING THE EVENT ESSURE MIGRATED AND PERFORATED UTERUS WITH POSSIBILITY OF BOWEL PUNCTURE; THE PERFORATION OF THE UTERUS, FALLOPIAN TUBES AND INTERNAL BODILY STRUCTURES MAY OCCUR DURING ESSURE THERAPY DUE TO INSERT MIGRATION OR DURING INSERTION PROCEDURE; THEREFORE, THIS EVENT WAS CONSIDERED AS RELATED TO ESSURE. FOR THE REPORTED FEVER, AS LIMITED INFORMATION WAS PROVIDED, CAUSALITY CANNOT BE ASSESSED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037976	BAYER	9/2/2014	9/3/2014

Event Information:

Event Date (B3): 4/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5037976 (B)(4). I FORGOT TO MENTION THAT I HAVE ALSO GAINED 50 LBS AND STILL CLIMBING EVEN THOUGH I GO TO THE GYM 4 DAYS A WEEK AND SEE A NUTRITIONIST. I SCHEDULED TO HAVE A TOTAL HYSTERECTOMY ON (B)(6) 2014 AND WILL UPDATE MY FILE AGAIN AFTER I RECOVER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037977	BAYER	9/2/2014	9/3/2014

Event Information:

Event Date (B3): 8/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAINS IN THE VAGINAL AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5037978	BAYER	9/2/2014	9/3/2014

Event Information:

Event Date (B3): 12/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BECAME PREGNANT (B)(6) 2011 AFTER HAVING ESSURE IN (B)(6) 2009 AND DELIVERED A HEALTHY BABY IN (B)(6) 2012. DR'S HAVE NOT YET LOCATED COILS. I HAVE SEVERE STOMACH PAINS HEAVY MENSTRUAL CYCLE AND CLOTTING OF BLOOD DURING THIS TIME. I ALSO HAVE BACK AND RIGHT LEG NUMBNESS AND PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00318	BAYER HEALTHCARE LLC	9/2/2014	9/8/2014

Event Information:

Event Date (B3): 7/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 7/9/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014, WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED FOLLOWING EVENTS. ON (B)(6) 2014, ESSURE WAS INSERTED. IT WAS REPORTED THAT AFTER PLACEMENT, PATIENT STARTED BLEEDING. PHYSICIAN SAW THE INNER COIL AND PULLED IT OUT AND THEN NOTICED THE PATIENT HAD FLUID IMBALANCE OF OVER 1500 CC, HEMATOCRIT PROBLEMS AND THE PATIENT WAS UNSTABLE. SHE WAS ADMITTED OVERNIGHT IN THE HOSPITAL. MOST OF THE FLUID LOSS WAS ABSORBED BY THE PATIENT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. PATIENT'S INITIALS, DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) YEARS OLD FEMALE PATIENT WITH 04 LIVING CHILDREN WITH UNDESIRED FUTURE FERTILITY SECONDARY TO VERY COMPLI

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038137	CONCEPTUS	9/2/2014	9/12/2014

Event Information:

Event Date (B3): 6/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76537

Single Use:
Implant Date (E6): 6/27/2014
Explant Date (E7): 8/26/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2014, I HAD THE ESSURE PERMANENT BIRTH CONTROL INSERTED INTO MY FALLOPIAN TUBES. THE DOCTOR TOLD ME I WOULD BE "GOOD AS NEW THE NEXT DAY." I WAS NOT. I HAD SHARP PAINS IN MY ABDOMEN AND SHOOTING PAINS GOING DOWN MY LEGS. I BLED FOR OVER TWO WEEKS AND HAD SPOTTING FOR 2-3 WEEKS AFTER THAT. THE PAIN WOULD GET WORSE AFTER PROLONGED ACTIVITY AND MY HANDS AND FEET WOULD GET NUMB AND TINGLY. I GO MIGRAINES. AFTER MY INITIAL TWO WEEK CHECK UP, MY DOCTOR THOUGHT I MIGHT JUST HAVE AN INFECTION. SHE GAVE ME AN ANTIBIOTIC. THAT DID NOT MAKE ANYTHING BETTER SO SHE SCHEDULED A CT SCAN FOR (B)(6) 2014. ACCORDING TO THE DOCTOR THE CT SCAN SHOWED THAT THE PLACEMENT OF THE COILS WERE FINE AND THE DOCTOR DETERMINED THAT I WAS ALLERGIC TO THE COILS. I HAD THEM REMOVED (B)(6) 2014. I AM STILL RECOVERING FORM THE SURGERY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00353	BAYER HEALTHCARE LLC	9/2/2014	9/16/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C13145

Single Use: Y
Implant Date (E6): 8/4/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTHCARE PROFESSIONAL IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014, IMPLANT BROKE DURING INSERTION PROCEDURE. EVENT OCCURRED IN OPERATING ROOM. THERE WAS NO CLINICAL CONSEQUENCE. IT WAS NOT REPORTED IF THE PATIENT WAS PREGNANT OR NOT. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2014: THE INITIAL RECEIPT DATE WAS CORRECTED TO (B)(4) 2014. CORRECTION ON (B)(4) 2014 BASED ON INFORMATION FROM INITIAL REPORT ((B)(4) 2014): ESSURE LOT NUMBER WAS C13145. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND IMPLANT BROKE DURING INSERTION PROCEDURE. THERE WERE NO CLINICAL CONSEQUENCES TO HER. THE REPORTED EVENT, REGARDED AS A DEVICE BREAKAGE, IS NON-SERIOUS, UNLISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS CONSIDERED A NEAR-INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, AS THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE INSERTION PROCEDURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 22-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BRE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00354	BAYER HEALTHCARE LLC	9/2/2014	9/16/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): MALFUNCTION	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26941

Single Use: Y
Implant Date (E6): 7/30/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/19/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER C26941. IT WAS REPORTED THAT FAILURE OF IMPLANT PLACEMENT IN LEFT HORN OCCURRED; THE IMPLANT DEPLOYED AND HUNG IN TUBAL AREA. BROKEN IMPLANT REMAINED IN PLACE DESPITE APPROPRIATE MANIPULATION. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED FROM THE GYNECOLOGIST ON (B)(6) 2014. NUMBER OF DEFECTIVE UNIT WAS REPORTED AS 1. EVENT OCCURRED IN OPERATING ROOM DURING INSERTION. BILATERAL INSERTION WAS DONE WITH CONCERNED IMPLANT. DESPITE A GOOD MANIPULATION WITH DELIVERY HANDLE (RELEASE BUTTON AND THUMBWHEEL), IMPLANT DID NOT DELIVER CORRECTLY. A COIL CLUNG TO THE DELIVERY CATHETER AND WHILE TRYING TO REMOVE IT, THE COIL BROKE, LEAVING THE GREEN RELEASE CATHETER AND THE REST OF THE COIL INTO THE FALLOPIAN TUBE. THE GYNECOLOGIST TRIED TO REMOVE IT WITH GRASPING FORCEPS WITHOUT SUCCESS AND SO LEAVING THE REST IN PLACE. IT OCCURRED ON LEFT SIDE FOLLOWING A VERY CORRECT INSERTION AND WITH NO PROBLEM ON RIGHT SIDE. ON X-RAY, IT SEEMED THAT BOTH IMPLANTS WERE ANYWAY CORRECTLY PLACED. THE GYNECOLOGIST WAITED FOR CONFIRMATION BY HYSTEROSALPINGOGRAPHY WHICH WAS PLANNED IN 3 MONTHS. THE GYNECOLOGIST WAS WORRIED ABOUT THE PIECE OF PLASTIC IN THE FALLOPIAN TUBE. NO OTHER NEW MEDICAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED FROM THE GYNECOLOGIST ON (B)(6) 2014. PATIENT'S INITIALS AND DATE OF BIRTH WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. HISTORICAL CONDITION INCLUDED ACARIDAE ALLERGY, ASTHMA UNDER SERETIDE (FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE), HYPERCHOLESTEROLAEMIA TREATED BY

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HOMEOPATHY TREATMENT, DEPRESSION UNDER CYMBALTA (DULOXETIN), ORAL CONTRACEPTION INTOLERANCE (FACIAL ODEMA, HEADACHES), APPENDICECTOMY, CHOLECYSTECTOMY, HYSTEROSCOPY AND CURETTAGE FOR CERVICAL POLYP, MIGRAINES, AND 2 NORMAL DELIVERIES. AT THE BEGINNING, INSERTION WAS PLANNED WITHOUT ANAESTHESIA BUT PASSAGE OF THE CERVIX WAS PAINFUL AND SO, GENERAL ANAESTHESIA WAS MADE. SHE WAS IN GYNAECOLOGICAL POSITION, DISINFECTION WITH BETADINE (POVIDONE-IODINE) WAS DONE, TRIED TO INSERT HYSTEROSCOPE WITHOUT SPECULUM, PASSAGE OF THE CERVIX DISORDER EVEN WITH SPECULUM. THE PATIENT DID NOT BEAR HYSTEROSCOPE INSERTION. GENERAL ANAESTHESIA, COL DILATATION, PASSAGE OF THE HYSTEROSCOPE, CAVITY WAS WELL VISUALIZED AND IMPLANT INSERTION ON RIGHT WITH NO INCIDENT. ON THE LEFT, WHEN IMPLANT WAS DEPLOYED, IT BROKE IN THE MIDDLE. SO, THERE WERE SOME SPIRALS WHICH REMAINED IN THE FALLOPIAN TUBE WITH A PIECE OF INSERTER COVERED BY A GREEN PLASTIC. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A 42 YEAR OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE THERE WAS A FAILURE OF IMPLANT PLACEMENT IN LEFT HORN; IMPLANT DEPLOYED AND HUNG IN TUBAL AREA , BROKEN IMPLANT, REMAINED IN PLACE DESPITE APPROPRIATE MANIPULATION, PASSAGE OF CERVIX WAS PAINFUL AND CERVIX DISORDER. REPORTER CAUSALITY WAS NOT PROVIDED. ALL THE REPORTED EVENTS ARE NON-SERIOUS. DEVICE BREAKAGE DURING INSERTION IS UNLISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS CONSIDERED A OTHER REPORTABLE EVENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE REMAINING EVENTS ARE LISTED AND NON-INCIDENTS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES DURING THE INSERT DEPLOYMENT AND STATED THAT THE IMPLANT HAD BROKEN. A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THE REPORTED EVENTS, HOWEVER CONSIDERING THAT THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, THEIR A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038058	CONCEPTUS	9/3/2014	9/8/2014

Event Information:

Event Date (B3): 11/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTS EXPERIENCING NEGATIVE EFFECTS AFTER ESSURE WAS IMPLANTED. SYMPTOMS INCLUDE TIREDNESS, SEVERE ABDOMINAL CRAMPS, PAINFUL SEXUAL INTERCOURSE, LOWER BACK PAIN, HEADACHES, WEIGHT GAIN AND BLOATING. "I LOOK FOUR MONTHS PREGNANT". PT WANTS DEVICE EXPLANTED BUT CAN NOT FIND A DOCTOR WHO IS WILLING TO EXPLANT THE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038090	BAYER	9/3/2014	9/9/2014

Event Information:

Event Date (B3): 8/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/16/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE - SEVERE CRAMPING, BLEEDING, HEADACHES, NIGHT SWEATS, ABNORMAL CYCLES, OVARIAN CYSTS RUPTURING, EXHAUSTION, DEPRESSION, LACK OF SEX DRIVE AND TEMPER. HAVE EXPLAINED MANY TIMES TO MY DR. SHE SAYS IT'S JUST ENDOMETRIOSIS, BUT WILL NOT DIAGNOSE ON PAPER. I HAVE BEEN IN THE ER TWO TIMES AND THEY CANNOT FIND ANY PROBLEMS. I HAVE ASKED FOR A HYSTERECTOMY TO MAKE SURE THE DEVICE IS REMOVED AND HAVE BEEN DENIED. PRESCRIBED BIRTH CONTROL PILLS TO HELP WITH CYCLES, BLEEDING AND CRAMPS. NOT WORKING!

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00355	BAYER HEALTHCARE LLC	9/4/2014	9/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/9/2010
Explant Date (E7): 7/30/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON (B)(6) 2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5033504, RECEIVED AT FDA ON (B)(4) 2013). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED ANIMA (ANEMIA), HEAVY BLEEDING DURING HER PERIOD EACH MONTH, ENLARGED UTERUS, ADENOMYOSIS, BLOATED, IN PAIN AND HAD BOWEL MOVEMENT WHICH HAD SMALL GRAYISH SILVERISH FRAGMENTS IN THE TOILETS WATER. FDA REPORT TYPE WAS 'INJURY', REPORTED OUTCOME OF EVENTS WAS 'REQUIRED INTERVENTION'. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2010, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. REPORTER STATED SHE WAS ADMITTED INTO HOSPITAL DUE TO ANIMA (ANEMIA). HER BLOOD WAS VERY LOW AND SHE WAS ADMITTED BECAUSE SHE NEEDED A BLOOD TRANSFUSION. WHEN SHE WAS DISCHARGED FROM THE HOSPITAL SHE WAS TOLD TO FOLLOW UP WITH HER DOCTOR. SHE WENT TO GYN DOCTOR (GYNECOLOGIST). DUE TO HER HEAVY BLEEDING DURING HER PERIOD EACH MONTH HE SENT HER FOR A SONO (SONOGRAM) AND SHE WAS TOLD THAT SHE HAS AN ENLARGED UTERUS AND ADENOMYOSIS. SHE NEVER IN LIFE HAD THESE ISSUES. SHE FEELS IT IS THE ESSURE DEVICE. SHE IS BLOATED AND IN PAIN. IN 2013, SHE HAD BOWEL MOVEMENT WHICH HAD SMALL GRAYISH SILVERISH FRAGMENTS IN THE TOILETS WATER. FOLLOW UP INFORMATION RECEIVED FROM CONSUMER ON 20-FEB-2014: PATIENT INFORMATION UPDATED. REPORTER AND EVENTS ADDED. PATIENT IS (B)(6). WEIGHT AND HEIGHT ADDED. HER MEDICAL HISTORY INCLUDED ASTHMA. ESSURE WAS INSERTED 2 MONTHS AFTER LAST DELIVERY. BIRTH CONTROL PILLS AND TOTAL ABSTINENCE WERE THE BACK-UPS CONTRACEPTION METHODS. A FEW MONTHS AFTER INSERTION, PATIENT

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PERFORMED AS HYSTEROSALPINGOGRAM (HSG) THAT SHOWED THAT SHE WAS OK AND THE TUBES WERE BLOCKED. ALL HER SYMPTOMS, INCLUDING HAIR BEEN FALLING OUT, LOW SEX DRIVE, FOUL ODOR AND EARS RINGING, STARTED IN 2010, AFTER ESSURE. THE PAIN STARTED ABOUT 5-6 MONTHS AGO. SHE STILL HAS ALL THE SYMPTOMS. SHE WENT TO THE DOCTOR CONCERNING THESE SYMPTOMS AND HE SAID SHE MIGHT HAVE ADENOMYOSIS AND SHE NEEDS A HYSTERECTOMY. SURGERY IS PLANNED FOR (B)(6) 2014. SHE WAS HOSPITALIZED IN (B)(6) 2013 FOR BLOOD TRANSFUSION FOR THE BLEEDING AND LOW BLOOD COUNT. SHE IS ALSO TAKING IRON PILLS. PATIENT BELIEVES THAT THESE CONDITIONS WERE CAUSED BY THE ESSURE, BECAUSE SHE HAD NO PROBLEMS BEFORE ESSURE PLACEMENT. HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE RECEIVED ON (B)(4) 2014. CASE IS NOW MEDICALLY CONFIRMED. ON (B)(6) 2010 ESSURE WAS INSERTED, 12 WEEKS AFTER LAST DELIVERY (A DISCREPANCY WAS NOTED, SINCE CONSUMER REPORTED INSERTION ON (B)(6) 2010, 2 MONTHS AFTER LAST DELIVERY). INSERTION WAS PERFORMED WITHOUT CERVICAL DILATATION. SOUNDING AND GENERAL ANESTHESIA VIA LARYNGEAL MASK AIRWAY (LMA) WAS PERFORMED. IT WAS AN EASY INSERTION AND THE VISUALIZATION OF TUBAL OSTIUM WAS EASY. THERE WAS NO MORE THAN 1500CC FLUID LOSS DURING HYSTEROSCOPY AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. NO PERFORATION OCCURRED. IT WAS REPORTED THAT PATIENT DID NOT PERFORM AN HSG (A DISCREPANCY WAS NOTED WITH CONSUMER'S INFORMATION). THE PHYSICIAN STATED THAT THE CONDITION WAS NOT CAUSED BY ESSURE DEVICE, PATIENT PRESENTED LEIOMYOMA AND ADENOMYOSIS PRIOR TO ESSURE PLACEMENT. SHE HAD ALSO AN ENDOMETRIAL POLYP SINCE 2007. SHE HAD CURETTAGE IN 2007. ON (B)(6) 2007, THE PATHOLOGY RESULTS OF ENDOMETRIUM CURETTAGE WAS ENDOMETRIAL POLYP AND SECRETORY ENDOMETRIUM WITH STROMAL / GLANDULAR ASYNCHRONY. ON (B)(6) 2012 THE PATHOLOGY RESULTS OF ENDOMETRIUM CURETTAGE WAS CHRONIC ENDOMETRITIS AND FIBROHYALINE NODULE CONSISTENT WITH HISTORY OF INTRAUTERINE PREGNANCY. ON (B)(6) 2013 SHE PERFORMED A FEMALE PELVIC ULTRASOUND THAT SHOWED UTERUS SIZE 11.5 X 5.9 X 7.3 CM. ANTEVERTED. ENLARGED. UTERINE MYOMETRIUM IS DIFFUSELY HETEROGENEOUS IN APPEARANCE. ENDOMETRIAL COMPLEX 1.3 CM IN DIAMETER. NORMA. ECHOGENIC FOCUS: 1.6 X 0.7CM. RIGHT OVARY 3.6 X 2.9 X 1.3CM. NORMAL IN CONTOUR AND CONFIGURATION. ECHOPATTERN-HOMOGENEOUS NORMA. NO FINDINGS. LEFT OVARY 3.6 X 3.0 X 1.9CM. NORMAL IN CONTOUR AND CONFIGURATION. CYSTS:SIZE 1.7 X 1.5 X 1.5CM, SIMPLE; 1.7 X 1.2 X 1.0CM WITH LOW LEVEL ECHO, BUT NO INTERNAL VASCULARITY CONSISTENT WITH HEMORRHAGIC CYST. OTHER STRUCTURES: FLUID IN CUL-DE-SAC NONE ADNEXA NORMAL URINARY BLADDER NORMAL ILIAC VESSELS PATENT. IMPRESSION: UTERINE MYOMETRIUM DIFFUSELY HETEROGENEOUS IN APPEARANCE SUSPICIOUS FOR ADENOMYOSIS. UTERUS IS ALSO ENLARGED; SIMPLE LEFT OVARIAN CYST AND HEMORRHAGIC LEFT OVARIAN CYST; ECHOGENIC FOCUS SEEN IN THE ENDOMETRIUM SUSPICIOUS FOR ENDOMETRIUM POLYP. ESSURE WAS NOT REMOVED NOR THE REMOVAL IS PLANNED (DISCREPANCY WAS NOTED SINCE CONSUMER STATED A HYSTERECTOMY IS SCHEDULE IN (B)(6) 2014). FOLLOW UP INFORMATION RECEIVED ON 05-AUG-2014 FROM CONSUMER: SHE DENIED THAT ANY RELATED DIAGNOSTIC TESTS WERE PERFORMED. ON (B)(6) 2014, SHE WAS SUBMITTED TO A TAH (TOTAL ABDOMINAL HYSTERECTOMY) WITH BILATERAL SALPINGECTOMY. HER UTERUS, FALLOPIAN TUBES WERE REMOVED INTACT ALONG WITH ESSURE COILS AND THE CERVIX WAS REMOVED. SHE DID NOT HAVE ANY PATHOLOGY RESULTS YET. PHYSICIAN SAID TO HER THAT UTERUS WAS VERY LARGE. AFTER SURGERY SHE WAS EXPERIENCING LITTLE PAIN IN ABDOMEN AROUND LOWER STOMACH AREA. SHE ALSO STATED THAT HER MAIN ISSUE (ADENOMYOSIS, HEAVY BLEEDING, ENLARGED UTERUS) WERE GONE. NO FURTHER INFORMATION WAS PROVIDED. THIS CASE WAS UPGRADED TO NEAR-INCIDENT AFTER A COMPANY INTERNAL REVIEW.

Manufacturer Narrative (H10):

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(B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE MEDICAL EVENTS R

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00356	BAYER HEALTHCARE LLC	9/5/2014	9/5/2014

Event Information:

Event Date (B3): 4/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/8/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014, WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN AND GI SYMPTOMS. FOLLOW UP 06.AUG.2014: CASE UPGRADED FROM NON-INCIDENT TO INCIDENT. FOLLOW UP INFORMATION RECEIVED FROM PHYSICIAN. PATIENT'S DATA WERE UPDATED, INCLUDING HER AGE: (B)(6) YEARS OLD. ESSURE INDICATION WAS REPORTED AS STERILIZATION. PHYSICIAN REPORTED THAT PATIENT CAME TO OFFICE ON (B)(6) 2014 COMPLAINING OF GI-LIKE (GASTROINTESTINAL) SYMPTOMS. THERE WAS NO TREATMENT AT THAT TIME. PATIENT CAME BACK TO OFFICE ON (B)(6) 2014 AND SHE DEVELOPED FEVER AND SHE WAS REFERRED FOR ADMISSION TO THE HOSPITAL. SHE WAS GIVEN TRIPLE ANTIBIOTICS IV (INTRAVENOUS), AND WAS DISCHARGED FROM THE HOSPITAL ON (B)(6) 2014. HER DIAGNOSIS WAS ACUTE SALPINGITIS. THE PATIENT WAS QUITE UPSET AND SHE DID NOT EXPECT THE HOSPITALIZATION. PATIENT HAS STILL BEEN USING THE ESSURE. PHYSICIAN WOULD LIKE TO KNOW ABOUT ADDITIONAL INFORMATION TO GIVE TO THE PATIENT. NO FURTHER DETAILS WERE PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 22-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENT IS NOT

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INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION, NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION RECEIVED ON 22-AUG-2014. NEW REPORTERS WERE ADDED. PATIENT´S INITIAL WAS UPDATED. THE PATIENT´S (B)(6). SHE DID NOT SMOKE AND OCCASIONALLY USED ALCOHOL. SHE HAD 2 CHILDREN AND HAD NO KNOWN ALLERGIES. HER MOTHER HAD A (B)(6). SHE RECEIVED THE FOLLOWING CONCOMITANT MEDICATIONS VITAMIN D3, CETIRIZINE FOR ALLERGY SYMPTOMS, VITAMIN B12, DOXYCYCLINE AND ZYRTEC. SHE WAS PRESCRIBED FOR HYDROCODONE-ACETAMINOPHEN, HYOSCYAMINE, ONDANSETRON AND IBUPROFEN PRIOR TO PROCEDURE. ON (B)(6) 2014, ESSURE WAS INSERTED WITH INTRA-MYOMETRIAL BLOCK OF 10CC OF 1% XYLOCAINE. THE FINDINGS WERE NORMAL WITH EXCELLENT VISUALIZATION. AFTER PLACEMENT, 3 TRAILING COILS WERE SEEN ON RIGHT AND LEFT TUBE. PATIENT TOLERATED PROCEDURE WELL AND WAS DISCHARGED IN STABLE CONDITION. PATIENT DESCRIBED A MILD PAIN 15 MINUTES AFTER PROCEDURE. FEW DAYS AFTER, SHE STARTED TO FEEL ABDOMINAL ISSUES LIKE BLOATING AND CONSTIPATION. ON (B)(6) 2014, THE PROBLEMS PERSISTED AND GOT WORSE. THE PATIENT ALSO COMPLAINED ABOUT ANOREXIA, NAUSEA AND SPOTTING. SHE RECEIVED TYLENOL AND MOTRIN. ON (B)(6) 2014, THE DISCOMFORT TURNED INTO PAIN AND FEVER UP TO 103 DEGREES AND ON THE EVENING OF (B)(6) 2014, IT WAS EXCRUCIATING PAINFUL. ON (B)(6) 2014, SHE VISITED HER DOCTOR, A BLOOD WORK AND AN ULTRASOUND WERE DONE AND IT WAS DETERMINED THAT SHE HAD AN INFECTION AND WAS ADMITTED TO HOSPITAL FOR TREATMENT. ACUTE SALPINGITIS WAS DIAGNOSED. ON (B)(6) 2014, HER SYSTOLIC BLOOD PRESSURE WAS LOW (90MMHG). WHITE AND RED BLOOD COUNT CELL, HEMATOCRIT AND HEMOGLOBIN WERE DEPRESSED. NEUTROPHIL AND MONOCYTE COUNT WERE ELEVATED. POLYCHROMASIA AND OVALOCYTES WERE PRESENT (+1). ON (B)(6) 2014, SHE WAS DISCHARGED FROM HOSPITAL. SHE WAS USING DEPO PROVERA AFTER ESSURE PLACEMENT AND BEFORE CONFIRMATION OF OCCLUSION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEARS-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ACUTE SALPINGITIS. SHE WAS HOSPITALIZED AND TREATED WITH INTRAVENOUS ANTIBIOTICS. REPORTER CAUSALITY ASSESSMENT WAS NOT PROVIDED. THIS EVENT WAS CONSIDERED SERIOUS AND AN INCIDENT DUE TO HOSPITALIZATION. IT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES (SALPINGITIS) AND OVARIES. WHILE ESSURE SYSTEM IS STERILE, IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS PARTICULAR CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE EVENT ACUTE SALPINGITIS WAS CONSIDERED AS RELATED TO ESSURE THERAPY. IT WAS ALSO REPORTED THAT PATIENT EXPERIENCED MILD PAIN 15 MINUTES AFTER PROCEDURE (NON-SERIOUS, LISTED AND RELATED - NON-INCIDENT). A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00357	BAYER HEALTHCARE LLC	9/5/2014	9/5/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF. SHE IS A ADULT (>=(B)(6)Y & <(B)(6)Y) FEMALE CONSUMER WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6) AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. INFORMATION REGARDING ESSURE LOT NUMBER WAS NOT REPORTED. CONSUMER REPORTED THAT SHE HAD HER HYSTERECTOMY BECAUSE OF HEAVY BLEEDING. SHE WAS (B)(6) AND WAS GOING FROM AN (B)(6) TO ESSURE BECAUSE SHE DIDN'T WANT KIDS. SHE STATED THAT CURRENTLY HER PERIOD HAS ALWAYS BEEN ON THE HEAVY SIDE AND WHEN SHE WAS IN HER TEENS, SOMETIMES IT WOULD LAST FOR WEEKS BUT THEN SHE WENT ON BIRTH CONTROL AND ULTIMATELY THE (B)(6). AFTER THE ESSURE PROCEDURE AND HAVING HER (B)(6) REMOVED, CONSUMER STARTED BLEEDING AND PRETTY MUCH DIDN'T STOP. HER DOCTOR HAD HER GO ON HORMONES TO STOP THE BLEEDING BUT MOST OF THEM ONLY MADE IT WORK OR MADE HER INSANE. HER DOCTOR ACTUALLY ADVISED AGAINST ABLATION BECAUSE IT COULD SIMPLY COVER UP HER PROBLEM WITHOUT REALLY FIXING IT AND SHE DIDN'T WANT TO HAVE IT DONE ANYWAY. SO AFTER ABOUT 8 MONTHS OF BLEEDING, SHE HAD A TOTAL HYSTERECTOMY PLUS REMOVAL OF HER FALLOPIAN TUBES ON (B)(6) 2013, SURGERY TYPE DVH (DA VINCI HYSTERECTOMY). SHE STILL HAS HAD HER OVARIES AND SHE STILL HAS HAD SOME HORMONE ISSUES. THEY HAVE BEEN TRYING TO CORRECT BUT SHE WAS SO GLAD SHE WENT WITH A HYSTERECTOMY. HOWEVER, IT WAS A PERSONAL CHOICE. SHE FELT LIKE SHE WOULD LOSE MORE QUALITY OF LIFE IF SHE DIDN'T GET IT DONE AND SHE WAS WORRIED SHE WOULDN'T FIND THE CORRECT HORMONE TREATMENT BEFORE SHE GOT SICKER AND SICKER. CONSUMER STATED THAT AN (B)(6) MIGHT HELP, AT LEAST TO GIVE YOU SOME EXTRA TIME BECAUSE SHE FOUND HER REALLY DID HELP LESSEN HER PERIODS WHEN SHE HAD IT IN AND IF SHE

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HAD BEEN TRYING TO PRESERVE HER FERTILITY, SHE MIGHT HAVE GONE WITH THAT BUT SHE JUST DIDN'T WANT TO TRY A TREATMENT TO SEE IF IT WOULD WORK AT THE POINT HER DOCTOR SUGGESTED A HYSTERECTOMY. FOLLOW UP (B)(6) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY IV MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE "RQU" WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT; REFERS TO A FEMALE SUBJECT WHO WAS INVOLVED IN ESSURE ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THE INSERTION PROCEDURE STARTED BLEEDING AND PRETTY MUCH DIDN'T STOP. SHE WAS SUBMITTED TO A TOTAL HYSTERECTOMY WITH REMOVAL OF HER FALLOPIAN TUBES. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE MEDICAL IMPORTANCE, IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. FOLLOWING ESSURE INSERTION GENITAL BLEEDING AND MENORRHAGIA OR PROLONGED MENSES MAY OCCUR; IN THIS PARTICULAR CASE THE CONSUMER HAD A PREVIOUS HISTORY OF HEAVY PERIODS, HOWEVER GIVEN THE POSITIVE TEMPORAL RELATIONSHIP A CAUSAL RELATION BETWEEN THE REPORTED BLEEDING AND THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY THE NON-SERIOUS EVENT HORMONE ISSUES WAS REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION IT WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". MEDICAL PTC EVALUATION CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW-UP INFORMATION IS EXPECTED SINCE THIS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00360	BAYER HEALTHCARE LLC	9/5/2014	9/5/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A73751

Single Use: Y
Implant Date (E6): 3/4/2014
Explant Date (E7): 8/21/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. IT WAS REPORTED THAT ON (B)(6) 2014, HYSTEROSALPINGOGRAM WAS DONE AND REVEALED THAT LEFT DEVICE WAS IN PERITONEAL CAVITY AND THE REST OF THE DEVICE PROXIMAL RADIOGRAPHIC MARKER WAS DISPLACED OR BROKEN FROM. FOLLOW-UP INFORMATION FROM (B)(6) 2014: FOLLOW-UP ATTEMPTS WERE DONE WITHOUT SUCCESS. FOLLOW-UP RECEIVED ON (B)(6) 2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PRODUCT QUALITY ISSUE AND MEDICAL DEVICE NEAR-INCIDENT REPORT). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: A HYSTEROSALPINGOGRAM (HSG) IS AN X-RAY TEST THAT LOOKS AT THE INSIDE OF THE UTERUS AND FALLOPIAN TUBES AND THE AREA AROUND THEM. DURING AN HSG, A DYE (CONTRAST MATERIAL) IS PUT THROUGH A THIN TUBE THAT IS PUT THROUGH THE VAGINA AND INTO THE UTERUS. FOR ESSURE, A MODIFIED HSG IS PERFORMED USING A SLOW-FILL OF CONTRAST. THE ESSURE CONFIRMATION TEST (MODIFIED HSG) IS PERFORMED THREE MONTHS POST-PLACEMENT TO EVALUATE INSERT LOCATION AND FALLOPIAN TUBE OCCLUSION. HSG FILMS SHOULD BE REVIEWED AND INTERPRETED BY A TRAINED MEDICAL PROFESSIONAL, SUCH AS A PHYSICIAN OR RADIOLOGIST. IN MANY HSG IMAGES, ONLY THE RADIOPAQUE MARKERS LOCATED ON THE MICRO-INSERT ARE VISIBLE. IN SOME CASES, THE MICRO-INSERT CAN BE STRETCHED BY MUSCULAR CONTRACTIONS OF THE FALLOPIAN TUBE. WHEN VIEWED ON AN HSG IMAGE, THIS MAY CONTRIBUTE TO THE PERCEPTION THAT THE DEVICE IS BROKEN SINCE THE DISTANCE BETWEEN RADIOPAQUE MARKERS IS LONGER THAN ANTICIPATED; HOWEVER, THE DEVICE IS NOT

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ACTUALLY BROKEN. SINCE THE REMAINING PARTS OF THE DEVICE ARE NOT VISIBLE, HSG IMAGES CAN BE MISINTERPRETED AS BEING "BROKEN" OR "FRAGMENTED." SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED. THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: INCIDENT CATEGORY WAS CHANGED TO INCIDENT. THE PATIENT´S DATE OF BIRTH WAS UPDATED, SHE WAS (B)(6) YEARS OLD. HER WEIGHT WAS (B)(6) KG AND HEIGHT WAS (B)(6) CM (BMI (B)(6)). SHE WAS OBESE. SHE HAD 6 PREGNANCIES WITH 3 BIRTHS AND 3 SPONTANEOUS ABORTIONS. HER MEDICAL HISTORY INCLUDED A HEAVY VAGINAL BLEEDING AND A THYROIDECTOMY FOR BENIGN NODULE. SHE WAS NOT PREGNANT. ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS WERE DENIED. ON (B)(6) 2014 ESSURE WAS INSERTED WITH LOT NUMBER A73751. THE INSERTION WAS NOT PERFORMED IN A POSTPARTUM STATE. CERVICAL DILATION AND CERVICAL BLOCK WERE USED DURING PROCEDURE. THE PATIENT RECEIVED LIDOCAINE. SOUNDING AND GENERAL ANESTHESIA WERE DENIED. THE VISUALIZATION OF OSTIUM WAS CONSIDERED EASY. THE RIGHT INSERTION WAS CONSIDERED WITHOUT PROBLEM, BUT AT THE LEFT SIDE A TUBAL SPASM WAS NOTED, BUT AND WITH GENTLE PRESSURE, IT RESOLVED. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES AND THE FLUID LOSS WAS LESS THAN 1500CC. NO IMAGING TESTS WERE PERFORMED AFTER INSERTION TO CONFIRM PLACEMENT. DEPO WAS USED AS CONTRACEPTION AFTER PLACEMENT. IT WAS REPORTED THAT BECAUSE OF HER HEAVY VAGINAL BLEEDING (MEDICAL HISTORY), A THERMACHOICE ENDOMETRIAL ABLATION WAS PERFORMED AT TIME OF ESSURE INSERTION. ON (B)(6) 2014, PATIENT COMPLAINED ABOUT PAIN IN LEFT LOWER QUADRANT. ON (B)(6) 2014, HYSTEROSALPINGOGRAM WAS DONE AND IN LEFT SIDE, MICRO INSERT WAS NOT IN CORRECT POSITION. RIGHT TUBE WAS OCCLUDED. ACCORDING TO THE REPORTER, UNILATERAL (LEFT) PERFORATION OCCURRED. ANY OTHER INTRA-ABDOMINAL STRUCTURE PERFORATION WAS DENIED. THE PERFORATION DID NOT OCCUR DURING SOUNDING, CERVICAL DILATION OR HYSTEROSCOPY PRIOR ESSURE INSERTION. THE PHYSICIAN DID NOT KNOW IF PERFORATION OCCURRED BEFORE OR AFTER DEPLOYMENT. ON (B)(6) 2014 LAPAROSCOPY WITH VAGINAL HYSTERECTOMY AND SALPINGECTOMY WERE DONE. NO SIGNS OF INFECTION WERE FOUND. DURING SURGERY, THE LOCATION OF DEVICES WAS LEFT CORNEAL REGION WITH OMENTAL ADHESION. PATIENT REQUESTED TO REMOVE ESSURE, SHE ALSO REQUESTED BECAUSE OF HEAVY BLEEDING. ON (B)(6) 2014, PATIENT WENT HOME. THE OUTCOME OF THE EVENT PERFORATION WAS RECOVERING/RESOLVING. ACCORDING TO THE PHYSICIAN, PERFORATION MAYBE OCCURRED DUE TO TUBAL SPASM. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6)-YEARS-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE LEFT DEVICE IN PERITONEAL CAVITY/PROXIMAL RADIOGRAPHIC MARKER IS DISPLACED OR BROKE (DEVICE BREAKAGE) AND UPON RECEIPT OF FOLLOW-UP INFORMATION IT WAS REPORTED THAT AN UNILATERAL PERFORATION/ LEFT DEVICE IN PERITONEAL CAVITY (FALLOPIAN TUBE PERFORATION) OCCURRED. PATIENT WAS SUBMITTED TO A VAGINAL HYSTERECTOMY AND SALPINGECTOMY TO REMOVE ESSURE. THE REPORTED DEVICE BREAKAGE, WAS CONSIDERED NON-SERIOUS AND IS UNLISTED IN THE SAFETY INFORMATION FOR ESSURE; WHILE FALLOPIAN TUBE PERFORATION WAS CONSIDERED SERIOUS

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DUE TO HOSPITALIZATION AND IS LISTED. THIS CASE WAS INITIALLY REGARDED AS OTHER REPORTABLE INCIDENT, HOWEVER UPON RECEIPT OF FOLLOW-UP INFORMATION THE REPORTED PERFORATION WAS CONSIDERED AN INCIDENT, DUE TO THE REQUIRED INTERVENTION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). ALSO, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, THE PHYSICIAN REPORTED THAT PERFORATION MAYBE OCCURRED DUE TO TUBAL SPASM. CONSIDERING THE NATURE OF THE REPORTED EVENTS A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. ALSO, OTHER NON-SERIOUS EVENTS WERE REPORTED: DURING INSERTION LEFT SIDE HAD TUBAL SPASM BUT RESOLVED, COMPLICATION OF DEVICE INSERTION, LEFT LOWER QUADRANT PAIN, AND ENDOMETRIAL ABLATION WAS PERFORMED AT TIME OF ESSURE INSERTION. AN INITIAL PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION WAS PERFORMED; HOWEVER AS LOT NUMBER WAS RECEIVED UPON FOLLOW-UP, AN UPDATED PTC ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-NOV-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THE ESSURE LOT NUMBER WAS RECEIVED AND THEREFORE THE FINAL ASSESSMENT WAS UPDATED.

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00358	BAYER HEALTHCARE LLC	9/5/2014	9/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B60748

Single Use: Y
Implant Date (E6): 7/24/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. ACCORDING TO THE REPORTER, COIL AND CATHETER CAUGHT. CATHETER COILS EXPANDED LIKE A SLINKING AND PART OF THE GREEN PORTION OF THE CATHETER BROKE IN THE PATIENT'S UTERUS. IT WAS EXTRACTED WITH FORCEPS. NO INJURY TO THE PATIENT AND A BILATERAL PLACEMENT ACHIEVED. LOT NUMBER WAS B60748. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT

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PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, BREAKAGE OF THE LARGE TIGHT PITCH COIL, OR BREAKAGE OF A PORTION OF THE DELIVERY CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. THE "GREEN-COLORED" MATERIAL REPORTED IS VERY LIKELY THE GREEN HEAT-SHRINK (PET) TUBING WHICH IS A CATHETER ASSEMBLY COMPONENT LOCATED AT THE DISTAL END OF THE INNER CATHETER. AS OF (B)(6) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE ADDITIONALLY A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED IN THE CONTEXT OF A COMPLICATED INSERTION. THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. 3 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B60748, OF WHICH 2 CASES REFER ALSO TO A SIMILAR TYPE OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH REVEALED NO REASON TO SUSPECT A QUALITY DEFICIT (SEE TECHNICAL STATEMENT). THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP RECEIVED ON 25-AUG-2014: NO RESPONSE TO FOLLOW-UP ATTEMPTS. FOLLOW-UP INFORMATION WAS RECEIVED ON 27-AUG-2014. SHE DENIED ANY RELEVANT MEDICAL HISTORY, PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES. PATIENT'S DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. CONCOMITANT CONDITION INCLUDED OVERWEIGHT (BMI 25.858). SHE WAS NOT ON POSTPARTUM STATE AT THE TIME OF ESSURE INSERTION. ANALGESIA WAS APPLIED DURING INSERTION. CERVICAL DILATATION AND SOUNDING WERE DENIED. THE INSERTION AND THE VISUALIZATION OF THE TUBAL OSTIUM WERE CONSIDERED EASY. THE PROCEDURE TOOK 25 MINUTES (WHICH INCLUDED CONSULTATION ON CONTINUATION OF THE PROCEDURE AFTER THE ADVERSE EVENT OCCURRED) AND FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC. THE PATIENT WAS COUNSELED ON THE EVENTS THAT OCCURRED. SHE WAS GIVEN THE OPTION TO TERMINATE THE PROCEDURE VERSUS PLACEMENT OF ESSURE IN THE RIGHT TUBAL OSTEA. THEY PROCEEDED WITH ESSURE PLACEMENT ON THE RIGHT AND THE PATIENT TOLERATED THE PROCEDURE WELL. THE ESSURE INTRODUCER CAUGHT ON THE ESSURE INSERT. THERE WAS NO RELEASE DESPITE ROTATING THE HANDLE CLOCKWISE OR COUNTERCLOCKWISE. WITH EFFORT, THE DEVICE WAS DISLODGED FROM THE IMPLANT. A SINGLE COIL WAS INITIALLY NOTED AT THE TUBAL OSTEA BUT THEN DISAPPEARED. CONDOMS WERE USED AS BACK-UP CONTRACEPTION. ON (B)(6) 2014 KUB PLAIN FILM WAS PERFORMED. X-RAY

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WAS PERFORMED AND BILATERAL ESSURE INSERTS WERE NOTED. ON THE LEFT (THE SIDE THE EVENT OCCURRED ON), THE INSERT WAS NOTED TO HAVE AN ACUTE ANGLE IN THE PROXIMAL PORTION. NO SIGNS OF INFECTION OR INFLAMMATION. HOSPITALIZATION WAS NOT REQUIRED. HSG (HYSTEROSALPINGOGRAM) WAS NOT PERFORMED YET. ESSURE WAS NOT REMOVED AND REMOVAL WAS NOT PLANNED. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A 33 YEARS-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE COIL AND CATHETER CAUGHT/CATHETER COILS EXPANDED LIKE A SLINKY AND PART OF THE GREEN PORTION OF THE CATHETER BROKE IN THE PATIENTS UTERUS (COMPLICATION OF DEVICE INSERTION) AND ON THE LEFT SIDE INSERT WAS NOTED TO HAVE AN ACUTE ANGLE IN THE PROXIMAL PORTION. ALL THE REPORTED EVENTS, ARE NON-SERIOUS. UPON RECEIPT OF TECHNICAL INVESTIGATION, EVENT COIL AND CATHETER CAUGHT/CATHETER COILS EXPANDED LIKE A SLINKY AND PART OF THE GREEN PORTION OF THE CATHETER BROKE IN THE PATIENTS UTERUS INTERPRETED AS A DEVICE BREAKAGE AND PREVIOUSLY CONSIDERED UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, WAS UPDATED TO LISTED (ANTICIPATED). THIS EVENT WAS CONSIDERED A OTHER REPORTABLE INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES; THE REMAINING EVENT IS LISTED AND NON-INCIDENT. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT A DEVICE BREAKAGE OCCURRED DURING ESSURE PLACEMENT PROCEDURE; THEREFORE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ACCORDING TO PTC FINAL ASSESSMENT, THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE REVIEW OF THE MANUFACTURING AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH REVEALED NO REASON TO SUSPECT A QUALITY DEFICIT .THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00359	BAYER HEALTHCARE LLC	9/5/2014	9/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. REPORTER STATED THAT DURING INSERTION, LEFT INSERT WAS DONE SUCCESSFULLY BUT DURING RIGHT SIDE ATTEMPT, PART OF INSERT BROKE OFF AND REMAINED IN THE PATIENT'S RIGHT FALLOPIAN TUBE. FOLLOW-UP FROM (B)(6) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER GLOBAL REFERENCE NUMBER FOR THE PTC REPORT WAS (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "LEFT IN PATIENT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY

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DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN DEV@COM," BECAUSE THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN DR-3020, DESIGN FMEA FOR ESS305. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED. THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING INSERTION PART OF INSERT BROKE OFF (COMPLICATION OF DEVICE INSERTION). REPORTER CAUSALITY WAS NOT PROVIDED. UPON RECEIPT OF TECHNICAL INVESTIGATION, THE EVENT DURING INSERTION PART OF INSERT BROKE OFF, INTERPRETED AS A DEVICE BREAKAGE AND PREVIOUSLY CONSIDERED UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, WAS UPDATED TO LISTED (ANTICIPATED).THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE CONSIDERING THAT THE REPORTED EVENT OCCURRED DURING ESSURE PLACEMENT PROCEDURE, IT WAS CONSIDERED AS RELATED TO THE SUSPECT INSERT. ACCORDING TO PRODUCT TECHNICAL ANALYSIS; THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00361	BAYER HEALTHCARE LLC	9/5/2014	9/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A78089

Single Use: Y
Implant Date (E6): 4/4/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014, ESSURE WAS INSERTED WITH LOT NUMBER A78089. IT WAS REPORTED A BREAKAGE OF DELIVERY CATHETER AT WITHDRAWAL. A COMPLETE REMOVAL WAS DONE AND A PLACEMENT OF NEW ONE. ANOMALY WAS OBSERVED IN OPERATING ROOM DURING PLACEMENT. NO OTHER ANATOMICAL CAUSE THAT COULD EXPLAIN THE ANOMALY. BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER DEVICE. (B)(6) LOCAL DRUG SAFETY DEPARTMENT ASSESSED THE CAUSAL RELATIONSHIP WITH ESSURE AS NOT APPLICABLE ACCORDING TO THE (B)(6) METHOD OF CAUSALITY. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BREAKAGE OF DELIVERY CATHETER AT WITHDRAWAL AND COMPLICATION OF DEVICE INSERTION. THE EVENTS BREAKAGE OF DELIVERY CATHETER AT WITHDRAWAL AND COMPLICATION OF DEVICE INSERTION ARE CONSIDERED NON-SERIOUS. BOTH EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT BREAKAGE OF DELIVERY CATHETER AT WITHDRAWAL (ASSUMED AS DEVICE BREAKAGE) WAS REGARDED AS NEAR-INCIDENT SINCE THE REPORTER STATED A DEVICE BREAKAGE. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, WAS REPORTED A BREAKAGE OF DELIVERY CATHETER AT WITHDRAWAL. A COMPLETE REMOVAL WAS DONE AND A PLACEMENT OF NEW ONE. ANOMALY WAS OBSERVED IN OPERATING ROOM DURING PLACEMENT. NO OTHER ANATOMICAL CAUSE THAT COULD EXPLAIN THE ANOMALY. BILATERAL PLACEMENT WAS

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PERFORMED WITH ANOTHER DEVICE. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED .

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 22-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038105	BAYER	9/7/2014	9/12/2014

Event Information:

Event Date (B3): 8/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/22/2009
Explant Date (E7): 8/26/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD HEAVY MENSTRUAL CYCLES FOR 6 YEARS, CHRONIC ABDOMINAL PAIN, PAINFUL INTERCOURSE, MIGRAINES, BACK PAIN, DEPRESSION. HYSTERECTOMY BECAUSE COILS MIGRATED TO UTERUS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00362	BAYER HEALTHCARE LLC	9/8/2014	9/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50750351 / C26937

Single Use: Y
Implant Date (E6): 7/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/30/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED DEVICE BROKE DURING PLACEMENT IN LEFT FALLOPIAN TUBE. ON (B)(6) 2014 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 50750351, IMPLANTED. THE DEVICE BROKE DURING PLACEMENT IN LEFT FALLOPIAN TUBE. BILATERAL PLACEMENT WAS PERFORMED. FRANCE BHP LOCAL DRUG SAFETY DEPARTMENT ASSESSED THE CAUSAL RELATIONSHIP WITH ESSURE AS NOT APPLICABLE ACCORDING TO THE FRENCH METHOD OF CAUSALITY.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 22-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT"

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00363	BAYER HEALTHCARE LLC	9/8/2014	9/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06520

Single Use: Y
Implant Date (E6): 8/11/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. ESSURE LOT NUMBER USED, C06520. THE MEDICAL DOCTOR REPORTED THAT UNIT WAS BEING INSERTED INTO WORKING CHANNEL. THE INTRODUCER HAD BEEN REMOVED BUT UNKNOWN TO PROVIDER A PIECE OF IT HAD BROKEN OFF INTO WORKING CHANNEL. UPON INSERTING A NEW INTRODUCER AND INSERTING THE DEVICE, THE TIP OF THE DEVICE BENT MAKING IT NOT USABLE. ESSURE BILATERAL PLACEMENT WAS ACHIEVED. PATIENT HAD NO INJURY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INTRODUCER REMOVED BUT UNKNOWN TO PROVIDER A PIECE OF IT HAD BROKEN OFF INTO WORKING CHANNEL (COMPLICATION OF DEVICE INSERTION) AND TIP OF THE DEVICE BENT. ALL THE EVENTS ARE CONSIDERED NON-SERIOUS. INTRODUCER REMOVED BUT UNKNOWN TO PROVIDER A PIECE OF IT HAD BROKEN OFF INTO WORKING CHANNEL ASSUMED AS A DEVICE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE REMAINING EVENT IS LISTED AND NON-INCIDENT. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE DOCTOR REPORTED THAT UNIT WAS BEING INSERTED INTO WORKING CHANNEL. THE INTRODUCER HAD BEEN REMOVED BUT UNKNOWN TO PROVIDER A PIECE OF IT HAD BROKEN OFF INTO WORKING CHANNEL. UPON INSERTING A NEW INTRODUCER AND INSERTING THE DEVICE, THE TIP OF THE DEVICE BENT MAKING IT NOT USUABLE. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY

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BETWEEN THE REPORTED BREAKAGE AND ESSURE USE WAS CONSIDERED AS RELATED. FOR THE EVENT TIP OF THE DEVICE BENT, GIVEN ITS NATURE (HANDLING ISSUE) IT WAS CONSIDERED UNRELATED TO THE SUSPECT INSERT. PRODUCT TECHNICAL ANALYSIS WILL BE SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	9/8/2014	9/30/2014

Event Information:

Event Date (B3): 8/25/2014 **Report Date (B4): 9/8/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): C06467

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PHYSICIAN INSERTING THE DEVICE WAS A SECOND YEAR RESIDENT. DURING INSERTION, THE DOCTOR WAS UNABLE TO ADVANCE THE COIL TO THE PROPER LENGTH. THE DOCTOR WAS INSTRUCTED BY THE SALES REP ON WHAT TO DO. AFTER REALIZING THAT THE DEVICE WAS NOT GOING TO BE IN THE RIGHT POSITION, THE DOCTOR WAS INSTRUCTED TO REMOVE THE DEVICE BY UNCOILING IT. AFTER SEVERAL ATTEMPTS, THE DEVICE WOULD NOT RELEASE AND HAD TO BE CUT OUT. THE DOCTOR WAS UNABLE TO REMOVE THE TIP OF THE DEVICE WHICH WAS LEFT IN THE PATIENT. NO HARM TO THE PATIENT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00364	BAYER HEALTHCARE LLC	9/9/2014	9/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/26/2012
Explant Date (E7): 4/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2013 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREMELY PAINFUL (LIKE LABOR) PERIODS, EXTREMELY HEAVY CLOTTING PERIODS - BLOOD CLOTS ARE LARGE, BEFORE ESSURE SHE NEVER HAD A PERIOD LONGER THAN 3 DAYS, NOW THEY ARE 7+ DAYS, THEY LEAVE ME ANEMIC, EXTREME EXHAUSTION, SHARP PAIN IN PELVIS - SEEMS TO BE BURNING/INFLAMED PAIN IN PELVIS, MORE PRONE TO INFECTIONS, IRRITATED/SORE THROAT AND SINUS/EAR PASSAGES, MIGRAINES, LOWER BACK PAIN, SWELLING IN BELLY, WEIGHT IN THE EVENING SHOWS 10 POUNDS DIFFERENCE, AND EXTREMELY ALLERGIC TO NICKEL. ADDITIONAL INFORMATION RECEIVED ON (B)(4) 2013. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON (B)(6) 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT ESSURE IMPLANT IS AFFECTING HER ABILITY TO DO HER JOB AND SHE WANTS HER HEALTH AND QUALITY OF LIFE RESTORED. SHE ALSO REPORTED THAT, IF SHE WANTS TO HAVE A CAREER, SHE HAS NO OPTION BUT GET THEM REMOVED AND STATES THAT, IF SHE MUST GO THROUGH SURGERY, SHE WANTS TO MAKE SURE ALL OF THE IMPLANTS MATERIALS ARE REMOVED. CONSUMER STATES THAT SHE WOULD LIKE HER ANATOMY RESTORED AND DOES NOT WANT TO DEAL WITH PREMATURE MENOPAUSE AND DOES WANT TO HAVE THE BEST SURGERY POSSIBLE TO REDUCE RISK OF ECTOPIC PREGNANCY. CONSUMER EXPERIENCED EXTREMELY PAINFUL (LABOR LIKE) AND HEAVY, CLOTTING PERIODS (LARGE CLOTS). BEFORE ESSURE SHE NEVER HAD A PERIOD LONGER THAN 3 DAYS AND COMPARED TO THIS THEY WERE VERY LIGHT. NOW THEY ARE 7+ DAYS AND EXTREMELY PAINFUL, INTERRUPTING HER ABILITY TO WORK. THEY LEAVE HER ANEMIC AND SHE STATES THAT THEY ARE SO AWFUL THAT SHE SUSPECTS THEY MIGHT

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EVEN BE MISCARRIAGES; SHE HAS NEVER HAD BAD MENSTRUAL CYCLE LIKE THIS BEFORE. ADDITIONALLY CONSUMER REPORTED THAT EXTREME EXHAUSTION HAS BEEN ONE OF HER WORST SYMPTOMS, IT STARTED RIGHT AFTER IMPLANTATION AND WILL NOT GO AWAY EVEN WITH CHANGES IN DIET, EXERCISE AND SLEEP TO TRY TO COUNTERACT IT. SHE ALSO EXPERIENCED BURNING IN PELVIS AND STATES THAT, FOR THE FIRST FEW MONTHS, THIS WAS SHARP PAIN BUT NOW IT SEEMS TO BE BURNING/INFLAMED PAIN MORE OFTEN. SHE PRESENTED UNUSUAL RASHES THAT COME AND GO IN PRIVATE AREAS, SOMETIMES ODD PLACES LIKE KNEES AND ANKLES AND IS MORE PRONE TO INFECTIONS OF SINUSES, GLANDS AND SORE THROATS; SHE HAS HAD IRRITATED/SORE THROAT AND SINUS/EAR PASSAGES SINCE THE DAY OF IMPLANTATION. THIS HAS NOT GONE AWAY DESPITE ANTIBIOTICS. CONSUMER ALSO SUFFERS FROM REALLY BAD MIGRAINES, LOW BACK PAIN, SWELLING IN BELLY AND STATES THAT HER WEIGHT, IN THE EVENING, SHOWS10 POUNDS DIFFERENCE. SHE STATES THAT, AT FIRST, THE APPALLING ANSWER FROM THE OB'S OFFICE WAS HYSTERECTOMY. THEN THE OB PUT HER ON BIRTH CONTROL FOR 3 MONTHS AND OFFERED TO REMOVE THE TUBES. HOWEVER, PHYSICIAN HAS NEVER REMOVED ESSURE BEFORE AND CONSUMER DOES NOT HAVE ENOUGH CONFIDENCE IN HER TO REMOVE IT AND STATES THAT SHE IS NOT WILLING TO LOSE PARTS OF HER BODY. SHE REPORTED THAT SHE DIDN'T SIGN UP FOR THAT AND ONE OF THE MAIN REASONS SHE GOT ESSURE WAS SO THAT HER TUBES WOULD NOT HAVE TO BE CUT. NO ONE TOLD HER THAT HYSTERECTOMY WAS A RISK, JUST "MAJOR SURGERY"- WHICH SHE TOOK TO MEAN THE COILS COULD SAFELY BE CUT OUT OF THE TUBES. IF THE LITERATURE OR ANYONE HAD TOLD HER THAT HYSTERECTOMY WAS SUCH A RISK, SHE WOULD NOT HAVE DONE THIS. ADDITIONALLY SHE REPORTED THAT IN (B)(4) 2012, WHEN THE SYMPTOMS WOULD NOT GET BETTER, SHE SAW AN ALLERGIST. SHE IS EXTREMELY ALLERGIC TO NICKEL AND THE TEST CAUSED EXTREMELY ITCHY, PAINFUL BLISTERS OVER HALF OF HER BACK THAT LINGERED FOR ABOUT A MONTH. CONSUMER TRIED TO LIVE WITH THE SYMPTOMS BUT STATED THAT LIVING WITH THESE HORRIFIC CYCLES AND FATIGUE IS DEBILITATING QUALITY OF LIFE TOO MUCH. SHE REALLY LIKE THE IDEA OF ESSURE, BUT IT IS JUST NOT WORKING FOR HER. SHE INFORMED THAT THE IDEA THAT THESE ARE MISCARRIAGES IS VERY DISTRESSING AND SHE DIDN'T SIGN UP FOR THAT. ALSO SHE IS CONCERNED ABOUT THE LONG TERM EFFECTS OF NICKEL ALLERGY AND WONDER WHETHER THE INFLAMMATION WILL CONTRIBUTE TO STROKES, HEART DISEASE OR CANCER? ACCORDING TO HER RECENT STUDIES HAS POINTED TO INFLAMMATION AS A MAJOR CONTRIBUTOR. SHE CANNOT GET A FULL-STRENGTH MRI, OR WHAT IF SHE NEEDS ONE IN A HURRY WHILE PEOPLE ARE TRYING TO FIGURE OUT IF SHE CAN GO IN THE MACHINE OR NOT. ALL THINGS POINT TO IT BEING SAFEST TO HAVING THE COILS REMOVED, ESPECIALLY IN THOSE WHERE ALLERGIC INFLAMMATION IS OCCURRING. REPORTER CAUSALITY WAS NOT REPORTED. CORRECTION ((B)(4) 2103): INCIDENT CATEGORY UPDATED TO NON-INCIDENT AS THERE IS NO CRITERIA TO CONSIDER THE SERIOUS EVENTS AS "SERIOUS INJURY". FOLLOW-UP RECEIVED ON (B)(4) 2013: PTC GLOBAL AND LOCAL NUMBER WERE RECEIVED. FOLLOW-UP RECEIVED ON 19-JAN-2014: DESPITE FOLLOW-UP ATTEMPTS, NO NEW INFORMATION HAS BEEN RECEIVED YET. FOLLOW-UP RECEIVED ON 23-JAN-2014: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT RECEIVED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC) - REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) AND THE LOCAL NUMBER IS (B)(4). IF THE OUTCOME OF THE PTC INVESTIGATION CONFIRMS A QUALITY DEFECT OR A COUNTERFEIT, THIS WILL BE COMMUNICATED IN A FOLLOW-UP REPORT. FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN (B)(4)." FDA EVALUATION - NO TESTING METHODS PERFORMED. RESULTS: NO RESULTS AVAILABLE SINCE NO EVALUATION PERFORMED. CONCLUSIONS: UNABLE TO CONFIRM COMPLAINT; DEVICE NOT RETURNED. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED

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STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW UP INFORMATION RECEIVED ON 13-AUG-2014: CONSUMER WAS REQUESTING LEGAL COMPENSATION OF COSTS INCURRED DUE TO ESSURE BECAUSE THE PRODUCT DID NOT WORK FOR HER. ESSURE WAS IMPLANTED IN (B)(6) 2012. AFTER IMPLANTATION SHE EXPERIENCED PROBLEMS, INCLUDING EXTREME FATIGUE, LONGER, LABOR-LIKE PERIODS, RASHES, HEADACHES, LOWER BACK PAIN AND MORE. AFTER REPORTING LOWER BACK PAIN TO HER PRIMARY PHYSICIAN, HE PUT HER THROUGH PHYSICAL THERAPY TO SEE IF THAT WOULD IMPROVE IT. AFTER HER PRIMARY PHYSICIAN SAW THE ALLERGY TEST RESULTS, HE ADVISED CONSUMER WITH AN ALLERGY LEVEL OF 4 THAT THE ESSURE IMPLANTS SHOULD BE REMOVED AS SOON AS POSSIBLE. IN (B)(6) 2014 ESSURE WAS BILATERALLY REMOVED. MOST ALL OF THE SYMPTOMS RESOLVED AFTER ESSURE WAS REMOVED, INCLUDING THE LOWER BACK PAIN. HER PERIODS ALSO RETURNED BACK TO A NORMAL 2-3 DAYS IN LENGTH WITH NORMAL CRAMPING AND SHE HAS NO NIGHT SWEATS. NO FURTHER INFORMATION WAS PROVIDED. BASED ON THE RECEIVED INFORMATION, THIS CASE WAS UPGRADED TO INCIDENT (SERIOUS INJURY. REQUIRED INTERVENTION) FOLLOW-UP INFORMATION RECEIVED ON 29-AUG-2014: NO RESPONSE TO FOLLOW-UPS ATTEMPTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEARS-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATED THAT SHE WAS MORE PRONE TO INFECTIONS AND HAD AN EXTREME ALLERGY TO NICKEL. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE, THE FIRST IS UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER IS LISTED. IN THIS PARTICULAR CASE THE CONSUMER REPORTED THAT AFTER ESSURE INSERTION SHE WAS MORE PRONE TO INFECTIONS OF SINUSES, GLANDS AND SORE THROATS; CONSIDERING SINUS/THROAT INFECTION PHYSIOPATHOLOGY AND GIVEN ESSURE LOCAL ACTION AT THE FALLOPIAN TUBES A CAUSAL RELATION BETWEEN THIS EVENT AND THE SUSPECT INSERT WAS CONSIDERED AS VERY UNLIKELY AND IT WAS THEREFORE, ASSESSED AS NON-INCIDENT. REGARDING THE EVENT EXTREMELY ALLERGIC TO NICKEL THE CONSUMER EXPERIENCED UNUSUAL RASHES AND ACCORDING TO HER AFTER AN ALLERGY TEST HER PHYSICIAN ADVISED TO REMOVE ESSURE; THE INSERTS WERE REMOVED AND MOST OF HER SYMPTOMS RESOLVED. GIVEN THIS POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE A CAUSAL RELATION BETWEEN THIS EVENT AND ESSURE CANNOT BE EXCLUDED AND DUE TO THE REPORTED INTERVENTION IT WAS CONSIDERED AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS PERFORMED AND CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF ESSURE.

Manufacturer Narrative (H10):

FOLLOW-UP (MEDICAL RECORDS) INFORMATION ON 16-NOV-2015 IT WAS REPORTED THAT ON (B)(6) 2012 ESSURE WAS INSERTED; PATIENT TOLERATED PROCEDURE WELL, STATING SHE HAD ONLY MILD CRAMPS. ON (B)(6) 2012, PATIENT SAID THAT SHE DID NOT LIKE ESSURE AND WOULD LIKE TO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00366	BAYER HEALTHCARE LLC	9/10/2014	9/10/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION IN (B)(6) 2007. IN (B)(6) 2007 SHE WENT FOR THE PROCEDURE AND TOLD TO THE HCP TO CUT, BURN AND TIE HER TUBES. INSTEAD OF THIS, ESSURE WAS INSERTED. EVER SINCE THE PROCEDURE, SHE HAD HEALTH PROBLEMS. IN 2007, SHE HAD KIDNEY STONES THAT REQUIRED SURGERY AND 10 DAYS IN THE HOSPITAL. IN 2008, SHE HAD AN OVARIAN CYST THAT RUPTURED AND REQUIRED ONE NIGHT OF HOSPITALIZATION FOR PAIN AND BLEEDING. IN 2012, SHE HAD AN ECTOPIC PREGNANCY WITH ESSURE. SHE DID NOT GO TO THE HCP AND SPONTANEOUSLY ABORTED. SHE ALSO FOUND OUT THAT SHE HAD A TEAR FROM HER UTERUS TO THE BIRTH CANAL. ESSURE WAS NOT REMOVED. THE OUTCOME OF THE EVENT FIRST ECTOPIC PREGNANCY WITH ESSURE WAS RECOVERED / RESOLVED. CONSUMER ALSO STATED THAT SHE HAD 2 OTHER EPISODES OF ECTOPIC PREGNANCIES ((B)(4)). FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014 FROM CONSUMER. CONSUMER'S WEIGHT AND HEIGHT WERE PROVIDED. SHE DENIED ANY PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES AND RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. IN (B)(6) 2007 (PREVIOUSLY REPORTED AS (B)(6) 2007) SHE HAD ESSURE IMPLANTED 3 MONTHS AFTER LAST DELIVERY. SHE WAS NOT TOLD TO USE ANY TYPE OF BACK-UP CONTRACEPTION. SHE CONFIRMED ALL PREVIOUSLY REPORTED EVENTS AND ADDITIONALLY SHE MENTIONED SHE EXPERIENCED MUCH HEAVIER MENSTRUAL PERIODS. ALL THE PROBLEMS STARTED ABOUT A MONTH AFTER THE ESSURE WAS PLACED. IN 2011 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHE WAS TOLD THEY WERE STILL SEALED AND THEN, SHE WAS TOLD THERE WAS A TEAR IN THE TUBE. IN THE SUMMER OF 2013 SHE HAD AN ECTOPIC PREGNANCY AND AGAIN IN (B)(6) 2014. SHE HAS NOT SEEN THE DOCTOR SINCE 2011. HOME PREGNANCY TESTS

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WERE POSITIVE BUT THEN SHE EXPELLED EVERYTHING AND HAD MISCARRIAGES. SHE DID NOT RECEIVE ANY TREATMENT AND HOSPITALIZATION WAS NOT REQUIRED. SHE WAS STILL HAVING THE TEAR, BLEEDING, PAIN, CYST, KIDNEY STONES AND FEARFUL OF GETTING PREGNANT AND HAVING ANOTHER MISCARRIAGE. ESSURE WAS NOT REMOVED. SHE BELIEVES THE CONDITION WAS CAUSED BY ESSURE BECAUSE SINCE ESSURE WAS PLACED SHE HAD ALL THE PROBLEMS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014: NO RESPONSE TO DATE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER 2014-021871. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE A LACK OF EFFICACY (PREGNANCY) WAS REPORTED. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEARS-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED KIDNEY STONES; OVARIAN CYST RUPTURED; FIRST ECTOPIC PREGNANCY WITH ESSURE; SPONTANEOUSLY ABORTED FROM ECTOPIC PREGNANCY, HAVE A TEAR FROM MY UTERUS TO THE BIRTH CANAL AND THERE WAS A TEAR IN THE TUBE. ALL EVENTS WERE CONSIDERED SERIOUS, THE FIRST TWO DUE TO HOSPITALIZATION WHILE THE REMAINING DUE TO MEDICAL IMPORTANCE; ECTOPIC PREGNANCY IS LISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENTS ARE UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE; WHEN A PREGNANCY OCCURS WITH ESSURE, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE IT. ECTOPIC PREGNANCY IS A GYNECOLOGIC EMERGENCY, GENERALLY REQUIRING EXPEDITIOUS SURGICAL OR MEDICAL TREATMENT. IN THIS PARTICULAR CASE, THE CONSUMER REPORTED 3 EPISODES OF ECTOPIC PREGNANCIES; SHE DID NOT SEEK MEDICAL ATTENTION AND STATED THAT SPONTANEOUSLY ABORTED, NO MEDICAL OR SURGICAL INTERVENTION WAS REPORTED. EVEN WITH THIS UNUSUAL EVOLUTION; A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE CANNOT BE EXCLUDED, AND THEY WERE CONSIDERED INCIDENTS. KIDNEY STONES ARE A COMMON PROBLEM; THE RISKS FOR THEIR DEVELOPMENT INCLUDE URINARY AND DIETARY FACTORS. OVARIAN CYSTS CAN DEVELOP IN FEMALES AT ANY STAGE OF LIFE; OCCASIONALLY, THEY MAY BECOME HEMORRHAGIC. CONSIDERING THESE EVENTS PATHOPHYSIOLOGY AND ESSURE LOCAL ACTION AT FALLOPIAN TUBES THEY WERE REGARDED AS UNRELATED TO ESSURE. FOR THE EVENT HAVE A TEAR FROM MY UTERUS TO THE BIRTH CANAL AND THERE WAS A TEAR IN THE TUBE GIVEN THE LIMITED INFORMATION PROVIDED CAUSALITY CANNOT BE ASSESSED. NON-SERIOUS EVENTS WERE ALSO REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00367	BAYER HEALTHCARE LLC	9/10/2014	9/10/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON (B)(4) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2007 FOR STERILIZATION. THE CONSUMER'S MEDICAL HISTORY INCLUDED 2 PREVIOUS ECTOPIC PREGNANCY, 2 ABORTIONS OF ECTOPIC PREGNANCY, KIDNEY STONES IN 2007 THAT REQUIRED SURGERY, A OVARIAN CYST THAT RUPTURED IN 2008 AND A TEAR FROM HER UTERUS TO THE BIRTH CANAL. IN 2014 (MAYBE IN (B)(6) 2014) THE CONSUMER HAD HER THIRD ECTOPIC PREGNANCY WITH ESSURE. SHE DID NOT GO TO THE HCP AND SPONTANEOUSLY ABORTED. THE OTHER TWO CASES WERE CREATED ((B)(4)). FOLLOW-UP RECEIVED ON (B)(4) 2014: PRODUCT TECHNICAL COMPLAINT GLOBAL ((B)(4)) AND LOCAL ((B)(4)) NUMBERS WERE RECEIVED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE A LACK OF EFFICACY (PREGNANCY) WAS REPORTED. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE

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DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT." IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THIRD ECTOPIC PREGNANCY WITH ESSURE AND ABORTION OF ECTOPIC PREGNANCY. REPORTER CAUSALITY ASSESSMENT WAS NOT PROVIDED. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE; THIRD ECTOPIC PREGNANCY WITH ESSURE IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENT IS UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN A PREGNANCY OCCURS AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. ECTOPIC PREGNANCY IS A GYNECOLOGIC EMERGENCY, GENERALLY REQUIRING EXPEDITIOUS SURGICAL OR MEDICAL TREATMENT. IN THIS PARTICULAR CASE, THE CONSUMER REPORTED 3 EPISODES OF ECTOPIC PREGNANCIES; SHE DID NOT SEEK MEDICAL ATTENTION AND STATED THAT SPONTANEOUSLY ABORTED, NO MEDICAL OR SURGICAL INTERVENTION WAS REPORTED. EVEN WITH THIS UNUSUAL EVOLUTION OF THE REPORTED ECTOPIC PREGNANCIES; A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE CANNOT BE EXCLUDED, AND GIVEN THEIR NATURE THEY WERE CONSIDERED AS INCIDENTS (SERIOUS INJURY). IN ADDITION THE NON-SERIOUS EVENT DEVICE INEFFECTIVE WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND THAT IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 19-SEP-2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00368	BAYER HEALTHCARE LLC	9/10/2014	9/10/2014

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 13-AUG-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2007 FOR STERILIZATION. THE CONSUMER'S MEDICAL HISTORY INCLUDED ONE PREVIOUS ECTOPIC PREGNANCY WITH ESSURE, ONE ABORTION OF ECTOPIC PREGNANCY, KIDNEY STONE, REMOVAL OF KIDNEY STONE, RUPTURE OF OVARIAN CYST AND TEAR FROM HER UTERUS TO THE BIRTH CANAL. IN 2014 (MAYBE IN (B)(6) 2014) THE CONSUMER HAD HER SECOND ECTOPIC PREGNANCY WITH ESSURE. SHE DID NOT GO TO THE HCP AND SPONTANEOUSLY ABORTED. OTHER TWO CASES WERE CREATED ((B)(4)). FOLLOW-UP RECEIVED ON 18-AUG-2014: NO NEW CLINICAL INFORMATION. THE ADVERSE EVENTS REPORTED ON FOLLOW-UP WERE ADDED ON LINKED CASE (B)(4). PRODUCT TECHNICAL COMPLAINT GLOBAL ((B)(4)) AND LOCAL ((B)(4)) NUMBERS WERE ALSO RECEIVED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 29-AUG-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE A LACK OF EFFICACY (PREGNANCY) WAS REPORTED. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS

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INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SECOND ECTOPIC PREGNANCY WITH ESSURE AND SPONTANEOUSLY ABORTED FROM ECTOPIC PREGNANCY. REPORTER CAUSALITY ASSESSMENT WAS NOT PROVIDED. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE; ECTOPIC PREGNANCY IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENT IS UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN A PREGNANCY OCCURS AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. ECTOPIC PREGNANCY IS A GYNECOLOGIC EMERGENCY, GENERALLY REQUIRING EXPEDITIOUS SURGICAL OR MEDICAL TREATMENT. IN THIS PARTICULAR CASE, THE CONSUMER REPORTED 3 EPISODES OF ECTOPIC PREGNANCIES; SHE DID NOT SEEK MEDICAL ATTENTION AND STATED THAT SPONTANEOUSLY ABORTED, NO MEDICAL OR SURGICAL INTERVENTION WAS REPORTED. EVEN WITH THIS UNUSUAL EVOLUTION OF THE REPORTED ECTOPIC PREGNANCIES; A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE CANNOT BE EXCLUDED, AND GIVEN THEIR NATURE THEY WERE CONSIDERED AS INCIDENTS (SERIOUS INJURY). IN ADDITION THE NON-SERIOUS EVENT DEVICE INEFFECTIVE WAS REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED (HEALTH CARE PROFESSIONAL CONTACT INFORMATION).

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION FROM 17-SEP-2014: FOLLOW-ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00369	BAYER HEALTHCARE LLC	9/10/2014	9/10/2014

Event Information:

Event Date (B3): 7/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/9/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 13-AUG-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXPLORATORY LAPAROSCOPY TO RULE OUT TUBE RUPTURE OR PERFORATION, BLEEDING OBSCURED THE HYSTEROSCOPTIC FIELD, AFTER DEPLOYMENT OF THE COILS INTO FALLOPIAN TUBE, THERE WAS A WIRE THAT REMAINED IN UTERINE CAVITY - WIRE PROTRUDED OUT OF THE CERVIX, UPON TRYING TO REMOVE THE WIRE THE PATIENT HAD INCREASED BLEEDING, AND ABDOMEN DISTENDED. ON (B)(6) 2014, AFTER DEPLOYMENT OF THE COILS INTO THE FALLOPIAN TUBE, THERE WAS A WIRE THAT REMAINED IN THE UTERINE CAVITY AND PROTRUDED OUT THE CERVIX. UPON TRYING TO REMOVE THE WIRE, THE PATIENT BEGAN TO HAVE INCREASED BLEEDING AND HER ABDOMEN BEGAN TO DISTEND. BLEEDING THEN OBSCURED THE HYSTEROSCOPIC FIELD. AN EXPLORATORY LAPAROSCOPY WAS PERFORMED TO RULE OUT TUBE RUPTURE OR OBVIOUS PERFORATION. A FILCHE CLIP TUBAL LIGATION WAS PERFORMED IN ORDER TO COMPLETE THE STERILIZATION. THE PATIENT HAD TO BE ADMITTED FOR OBSERVATION. NO CAUSALITY ASSESSMENT WAS GIVEN. PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A

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DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE CASE REFERS ALSO TO A TECHNICAL DEFECT (A WIRE THAT REMAINED IN UTERINE CAVITY). THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN (SEE TECHNICAL STATEMENT). ACCORDING TO THE TECHNICAL ASSESSMENT THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICROINSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE LIMITED AVAILABLE INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT RECEIVED VIA REGULATORY AUTHORITY REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER DEPLOYMENT OF THE COILS INTO FALLOPIAN TUBE, THERE WAS A WIRE THAT REMAINED IN UTERINE CAVITY - WIRE PROTRUDED OUT OF THE CERVIX. IT WAS REPORTED THAT UPON TRYING TO REMOVE THE WIRE THE PATIENT HAD INCREASED BLEEDING AND HER ABDOMEN DISTENDED. THE BLEEDING OBSCURED THE HYSTEROSCOPIC FIELD AND AN EXPLORATORY LAPAROSCOPY WAS PERFORMED TO RULE OUT TUBE RUPTURE OR PERFORATION. BLEEDING OBSCURED THE HYSTEROSCOPIC FIELD AND EXPLORATORY LAPAROSCOPY TO RULE OUT TUBE RUPTURE OR PERFORATION ARE SERIOUS AS LED TO HOSPITALIZATION AND LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. AS RELATED TO ITS INSERTION PROCEDURE, EVENTS WERE CONSIDERED RELATED TO ESSURE. THUS, BLEEDING OBSCURED THE HYSTEROSCOPIC FIELD AND EXPLORATORY LAPAROSCOPY TO RULE OUT TUBE RUPTURE OR PERFORATION WERE REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. AFTER DEPLOYMENT OF THE COILS INTO FALLOPIAN TUBE, THERE WAS A WIRE THAT

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REMAINED IN UTERINE CAVITY - WIRE PROTRUDED OUT OF THE CERVIX, UPON TRYING TO REMOVE THE WIRE THE PATIENT HAD INCREASED BLEEDING AND ABDOMEN DISTENDED ARE NON-SERIOUS EVENTS. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE AWAITED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT"

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00370	BAYER HEALTHCARE LLC	9/10/2014	9/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/11/2006
Explant Date (E7): 2/26/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5032960) IN UNITED STATES ON 13-JAN-2014 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATES THAT THE PROCEDURE WAS EXTREMELY PAINFUL, AND ALSO THAT SINCE INSERTION SHE EXPERIENCED MENSTRUAL CRAMPS, PINCHING FEELING IN HER FALLOPIAN TUBE AREA, CONSTANT ACHING AND TENDERNESS IN EACH SIDE, EXTREME CRAMPING AND PELVIC PAIN, SHOOTING PAINS DOWN HER CERVIX, SHOOTING PAIN DOWN THE BACK OF HER LEGS, LOWER BACK PAIN, JOINT PAIN IN HER LEFT HIP, FATIGUE, HEAVY MENSTRUAL CYCLES AND MASSIVE CLOTTING, ITCHY SKIN, UNEXPLAINED RASH AND BOILS THAT APPEAR ON HER FACE AND LEGS, MIGRAINE, AND, WHEN SHE OVULATES THE PAIN IS SO EXCRUCIATING SHE HAS HAD TO MISS WORK. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2006 THE CONSUMER HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER WAS IMPLANTED WITH ESSURE IN 2006. HER PROCEDURE WAS THE FIRST ONE HER DR HAD PERFORMED IN HIS OFFICE ON A PATIENT NOT UNDER ANESTHESIA. THE PROCEDURE WAS EXTREMELY PAINFUL AND WAS TO TAKE 20 MINUTES, START TO FINISH. HOWEVER, AFTER ABOUT AN HOUR OF NOT BEING ABLE TO INSERT THE ESSURE COILS, PHYSICIAN SAID THAT HE MAY NEED TO STOP AND RESCHEDULE THIS UNDER ANESTHESIA IN THE HOSPITAL. HEALTH CARE PROFESSIONAL FINALLY WAS ABLE TO INSERT THE ESSURE COILS IN THE OFFICE. CONSUMER WAS IN EXTREME PAIN FOR DAYS. ADDITIONALLY CONSUMER REPORTED THAT SINCE HAVING THE ESSURE COILS IMPLANTED, SHE HAD HER FIRST MENSTRUAL CRAMP IN HER LIFE. SHE HAS A DAILY PINCHING FEELING IN HER FALLOPIAN TUBE AREA, CONSTANT ACHING AND TENDERNESS IN EACH SIDE, EXTREME CRAMPING AND PELVIC PAIN 2 PLUS WEEKS A MONTH, SHOOTING PAINS DOWN HER CERVIX AND DOWN

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THE BACK OF HER LEGS, LOWER BACK PAIN, JOINT PAIN IN HER LEFT HIP, FATIGUE, HEAVY MENSTRUAL CYCLES AND MASSIVE CLOTTING, ITCHY SKIN, AND UNEXPLAINED RASH AND BOILS THAT APPEAR ON HER FACE AND LEGS. SHE WAS A HEALTHY WOMAN WITH NO HEALTH ISSUES. SHE DID NOT TAKE OVER-THE-COUNTER PAIN MEDICATION BUT TWICE A YEAR AND NEVER HAD PAINFUL OR ABNORMAL MENSTRUAL CYCLES UNTIL AFTER HAVING ESSURE, SHE HAD HER FIRST MIGRAINE AFTER ESSURE AS WELL. THE PAIN IS SO INTENSE THAT SHE HAS TROUBLE FINISHING A BREATH AND CANNOT MOVE. WHEN SHE OVULATES, THE PAIN IS SO EXCRUCIATING SHE HAS HAD TO MISS WORK. REPORTER CAUSALITY WAS NOT REPORTED. FOLLOW-UP INFORMATION WAS RECEIVED ON 15-AUG-2014. CASE UPGRADED TO INCIDENT DUE TO HYSTERECTOMY. ON (B)(6) 2006 (PREVIOUSLY REPORTED AS (B)(6) 2006) ESSURE WAS IMPLANTED IN THE PHYSICIAN'S OFFICE. THERE WERE COMPLICATIONS DURING THE PROCEDURE. ON AN UNSPECIFIED DATE SHE BEGAN EXPERIENCING UNEXPLAINED PAIN AND SYMPTOMS INCLUDING SEVERE HEAVY BLEEDING AND CLOTTING DURING HER MENSTRUAL CYCLE, HORRIFIC ABDOMINAL AND LOWER BACK PAIN, CONSTANT STABBING IN TUBES, ICE PICK HEADACHES, ITCHING SKIN, RASHES, DEBILITATING JOINT PAIN (HIPS AND HANDS), TWITCHING, ACUTE VAGINAL PAIN, BODY ACHES, PAINFUL INTERCOURSE, IRREGULAR MENSTRUAL CYCLES, SEVERELY ANEMIC. ON (B)(6) 2014 SHE UNDERWENT A HYSTERECTOMY FOR THE PURPOSE OF REMOVING ESSURE AND THE MAJORITY OF THOSE SYMPTOMS WENT. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION FROM 29-AUG-2014: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-SEP-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN DURING OVULATION, PINCHING FEELING IN MY FALLOPIAN TUBE AREA, CONSTANT ACHING AND TENDERNESS IN EACH SIDE/CONSTANT STABBING IN MY TUBES, EXTREME CRAMPING AND PELVIC PAIN AND SEVERELY ANEMIC. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PAIN DURING OVULATION, PINCHING FEELING IN MY FALLOPIAN TUBE AREA, CONSTANT ACHING AND TENDERNESS IN EACH SIDE/CONSTANT STABBING IN MY TUBES, EXTREME CRAMPING AND PELVIC PAIN ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WERE REGARDED AS INCIDENTS DUE TO A REPORTED INTERVENTION (HYSTERECTOMY) TO REMOVE ESSURE. EVENT SEVERELY ANEMIC IS UNLISTED. ABDOMINAL/PELVIC PAIN AND CRAMPING MAY OCCUR WITH ESSURE AND MAY BE A MORE LIKELY OCCURRENCE DURING THE MENSTRUAL PERIOD, DURING AND AFTER SEXUAL INTERCOURSE OR WITH PHYSICAL ACTIVITY. CONSIDERING THE NATURE OF THE EVENTS PAIN DURING OVULATION, PINCHING FEELING IN FALLOPIAN TUBE AREA, CONSTANT ACHING AND TENDERNESS IN EACH SIDE/CONSTANT STABBING IN MY TUBES, EXTREME CRAMPING AND PELVIC PAIN, THEY WERE CONSIDERED RELATED TO ESSURE. SINCE NO INFORMATION WAS PROVIDED REGARDING CONSUMER´S PAST OR CONCURRENT CONDITIONS THAT COULD HAVE CONTRIBUTED FOR THE EVENT SEVERELY ANEMIC, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE CANNOT BE ASSESSED, AND IT WAS THUS CONSIDERED A NON-INCIDENT. IN ADDITION

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NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00371	BAYER HEALTHCARE LLC	9/10/2014	9/10/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/17/2014
Explant Date (E7): 6/23/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 15-AUG-2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. THE CONSUMER REPORTED THAT SHE DEVELOPED RASH THAT ITCHES REALLY BAD, SHE HAD BLEEDING NON-STOP AND WAS PASSING HEAVY BLOOD CLOTS, HER FEET WERE SWOLLEN, SHE HAD SHARP PAIN ON HER RIGHT SIDE THAT FELT LIKE SOMETHING WAS STABBING HER INSIDE NEAR HER UTERUS AND OVARIES. SHE ALSO REPORTED THAT SHE HAD PAIN DURING SEX THAT SHE CAN NOT STAND IT. ON (B)(6) 2014, ESSURE WAS REMOVED. NO FURTHER INFORMATION WAS PROVIDED. (B)(4) THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED

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"UNCONFIRMED QUALITY DEFECT." IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAVE BEEN BLEEDING NON STOP / PASSING HEAVY BLOOD CLOTS. THIS EVENT WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; THEREFORE A CAUSAL RELATIONSHIP BETWEEN THE EVENT HAVE BEEN BLEEDING NON STOP / PASSING HEAVY BLOOD CLOTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS EVENT WAS CONSIDERED AN INCIDENT SINCE ESSURE WAS REMOVED (IMPLYING A SURGERY/REQUIRED INTERVENTION). IN ADDITION THE NON-SERIOUS EVENTS DEVELOPED RASH THAT ITCHES REALLY BAD, FEET HAVE BEEN SWELLING, SHARP PAIN ON RIGHT SIDE THAT FEELS LIKE SOMETHING STABBING ME INSIDE NEAR MY UTERUS AND OVARIES AND PAIN DURING SEX WERE ALSO REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW-UP INFORMATION CAN BE OBTAINED SINCE ANY CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038173	BAYER HEALTHCARE LLC	9/10/2014	9/17/2014

Event Information:

Event Date (B3): 9/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): B53652

Single Use:
Implant Date (E6):
Explant Date (E7): 9/10/2014
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

UPON REMOVAL OF LEFT FALLOPIAN TUBE, BAYER HEALTHCARE LLC, ESSURE DEVICE NOTED TO HAVE PLASTIC-APPEARING SHEATH OVER THE INTRAUTERINE PORTION OF THE IMPLANT. THE DEVICE WAS ORIGINALLY INSERTED ON (B)(6) 2014. THE PATIENT HAD STARTED TO REPORT PAIN SINCE THE IMPLANT'S INTRODUCTION LEADING TO TODAY'S SURGICAL VISIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00365	BAYER HEALTHCARE LLC	9/10/2014	9/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50678466/ A82454

Single Use: Y
Implant Date (E6): 8/11/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/25/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014, LOT NUMBER 50678466 AND A82454. ON THE FIRST SIDE PLACEMENT, WHICH WAS THE RIGHT, THE DEVICE WAS PLACED FINE, BUT WHEN THE CATHETER WAS WITHDRAWN THE DEVICE HAD BROKEN IN 2 AND 5 COILS WERE FLOATING IN THE CAVITY. THE BROKEN PIECE AND THE REST OF THE ESSURE IN SITU WERE REMOVED AND A NEW ONE WAS INSERTED. THE OTHER SIDE WAS DONE WITHOUT ANY PROBLEMS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVICE HAD BROKEN IN 2 AND FIVE COILS WERE FLOATING IN THE CAVITY DURING INSERTION. THE EVENT DEVICE HAD BROKEN IN 2 AND FIVE COILS WERE FLOATING IN THE CAVITY WAS CONSIDERED NON-SERIOUS AND UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PRESENT CASE IT WAS REPORTED THAT WHEN THE ESSURE WAS INSERTED THE CATHETER BROKE IN 2 AND 5 COILS WERE FLOATING IN THE CAVITY. THE PATIENT DOSEN'T HAVE ANY SYMPTOMS AND THE BROKEN PIECE AND THE REST OF THE ESSURE WERE REMOVED AND A NEW ONE WAS INSERTED. BASED ON AVAILABLE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2014. PATIENT INITIALS, AGE AND DATE OF BIRTH WERE PROVIDED (DISCREPANCY BETWEEN AGE 44 AND DOB WAS NOTED). SHE HAD NO RELEVANT HISTORY OR RISK FACTORS. REPORTER CONFIRMED ESSURE DEVICE BROKE ON INSERTION, PATI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00372	BAYER HEALTHCARE LLC	9/11/2014	9/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS BY PHYSICIAN AGAIN FOR CONTROL AFTER ESSURE PLACEMENT 3 MONTHS AGO, IN (B)(6) 2014. HYSTEROSALPINGOGRAPHY SHOWED LEFT INSERT IN PLACE AND RIGHT INSERT IN UTERINE CAVITY. PATIENT WAS ASYMPTOMATIC. NO OTHER INFORMATION AVAILABLE. FOLLOW-UP INFORMATION RECEIVED FROM THE PHYSICIAN ON (B)(6) 2014. HYSTEROSCOPY: INDICATION: (B)(6) FEMALE PATIENT, PARITY 3, UNDER HORMONAL CONTRACEPTION WITH NEXPLANON AND WHO WANTED DEFINITIVE SURGICAL STERILIZATION. INTERVENTION WAS PERFORMED UNDER LOCAL ANAESTHESIA, IN GYNAECOLOGICAL POSITION, DISINFECTION WITH BETADINE, VAGINAL FORNICES INFILTRATION WITH XYLOCAINE (LIDOCAINE), RIGID HYSTEROSCOPE WAS SET-UP WITH PHYSIOLOGICAL SALINE IRRIGATION. OBSERVATIONS: THERE WAS NO LESION ON CERVICAL CANAL, THERE WAS NO ABNORMALITY IN ENDOMETRIAL CAVITY, AND THE 2 OSTIUM WERE WELL PERCEPTIBLE. ESSURE IMPLANT WERE FITTED WITH DELIVERY CATHETER AND WITH 5 EXTENDED OUTER COILS ON RIGHT AND ON LEFT. THE INTERVENTION DURATION WAS 5 MINUTES WITH NO INCIDENT. HYSTEROSCOPY FOR RIGHT IMPLANT REMOVAL: INDICATION: IMPLANT MIGRATION IN UTERINE CAVITY LEADING TO STRONG PAIN EPISODES. IT WAS DECIDED TO REMOVE IMPLANT BY SURGERY. THE PROCEDURE WAS PERFORMED UNDER LOCAL ANAESTHESIA, IN GYNAECOLOGICAL POSITION, DISINFECTION WITH BETADINE. OBSERVATIONS: IMPLANT WAS FOUND IN CERVICAL CANAL AND WAS REMOVED WITH A BIOPSY FORCEPS. UTERINE CAVITY OBSERVATION: IMPLANT WAS FOUND NEAR LEFT ORIFICE WITH 5 EXTENDED OUTER COILS. RIGHT TUBAL OSTIUM WAS NOT WELL VISUALIZED. TRY TO FIT A NEW IMPLANT WITH NO SUCCESS. SURGERY DURATION: 45 MINUTES. FILSHIE CLIPS LIGATURE BY LAPAROSCOPY WAS PROPOSED TO THE PATIENT. NO OTHER NEW MEDICAL

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INFORMATION WAS PROVIDED. CASE CLOSED. CORRECTION ON (B)(6) 2014 FOLLOWING COMPANY INTERNAL REVIEW BASED ON INFORMATION RECEIVED ON (B)(6) 2014: DUE TO REMOVAL OF IMPLANT WITH BIOPSY FORCEPS, THE CASE WAS ASSESSED AS INCIDENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE IMPLANT WAS FOUND IN CERVICAL CANAL. THIS IMPLANT WAS REMOVED BY SURGERY (BIOPSY FORCEPS UNDER LOCAL ANESTHESIA). REPORTER CAUSALITY ASSESSMENT WAS NOT PROVIDED. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE. THIS CASE, INITIALLY CONSIDERED A NON-INCIDENT, WAS UPON COMPANY INTERNAL REVIEW AMENDED TO INCIDENT, DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) AND CAN RESULT IN PAIN. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT ESSURE MIGRATED TO UTERINE CAVITY (RIGHT ESSURE IMPLANT WAS FOUND IN CERVICAL CANAL) LEADING TO STRONG PAIN EPISODES; A HYSTEROSCOPY WAS THEN PERFORMED AND THE DEVICE REMOVED. CONSIDERING THE ABOVE MENTION INFORMATION A CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED EVENT CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00373	BAYER HEALTHCARE LLC	9/11/2014	9/11/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626806

Single Use: Y
Implant Date (E6): 11/11/2008
Explant Date (E7): 12/3/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) STERILIZATION DEVICE LOT NUMBER 626806 INSERTED ON (B)(6) 2008. CONSUMER STATED IT TOOK ALMOST 3 HOURS TO COMPLETE A 10 MINUTES PROCEDURE. THEN SHE HAD TO HAVE A HSG TESTS DONE, BECAUSE THE PHYSICIANS DIDN'T RECORD THE CORRECT MEASUREMENTS ON THE FIRST TEST. SHE IMMEDIATELY BEGAN HAVING PROBLEMS, AND COMPLAINED OFTEN TO HER PHYSICIAN, WHO REPEATEDLY WROTE HER PROBLEMS OFF AS OTHER DIAGNOSES. SHE THOUGHT MAYBE HE WAS RIGHT, UNTIL 2013 WHEN SHE STARTED HAVING HER PERIOD EVERY TWO WEEKS WITH SEVERE BLEEDING AND MAJOR BLOOD CLOTS. SHE ALSO EXPERIENCED CONSTANT HEADACHES, MOOD SWINGS, IRRITABILITY, SEVERE SKIN RASHES, HAIR LOSS, WEIGHT GAIN, FATIGUE, CHEST PAINS, NIGHTMARES, SEVERE PAIN DURING INTERCOURSE, ALMOST ALL OF HER TEETH HAVE BROKEN AND WERE FALLING OUT, DIZZINESS, WEAKNESS, BRAIN FOG, AND MANY OTHER SYMPTOMS. SHE LOST HER ABILITY TO INTERACT WITH HER CHILDREN AND HUSBAND PHYSICALLY AND MENTALLY. SHE SUFFERED FOR ABOUT HALF OF THE YEAR IN 2013. AFTER EXAMS AND BLOOD TESTS, HER PHYSICIAN AGREED THAT SHE WAS POSSIBLE HAVING A REACTION TO THE ESSURE COILS AND WE SCHEDULED A HYSTERECTOMY FOR 2013 (ESSURE REMOVED ON (B)(6) 2013). SHE LOST ALL OF HER REPRODUCTIVE PARTS EXCEPT FOR OVARIES, AND WAS STILL HAVING SOME ISSUES, BUT AT LEAST SHE WAS NOT BLEEDING SEVERELY ANYMORE. CONSUMER ASSESSED HOSPITALIZATION AND INJURY AS EVENT OUTCOME AND EVENT REPORT TYPE, RESPECTIVELY; HOWEVER, IT WAS NOT SPECIFIED FOR EACH EVENT. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION FROM (B)(6) 2014: FOLLOW-UP NOT POSSIBLE DUE TO LACK OF CONTACT INFORMATION FOR REPORTER. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND

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FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: 2014-021992. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. 5 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. (B)(4), OF WHICH 3 CASES REFER ALSO TO SIMILAR TYPES OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH REVEALED NO REASON TO SUSPECT A QUALITY DEFICIT (SEE TECHNICAL STATEMENT). NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERIOD EVERY TWO WEEKS WITH SEVERE BLEEDING AND BLOOD CLOTS. THE EVENT PERIOD EVERY TWO WEEKS WITH SEVERE BLEEDING AND BLOOD CLOTS ASSUMED AS POLYMENORRHOEA, IS SERIOUS; DUE TO HOSPITALIZATION REPORTED AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN SOME OCCASIONS A BLEEDING AFTER ESSURE INSERTION MAY OCCUR; THEREFORE, THIS EVENT WAS REGARDED AS INCIDENT SINCE THE CONSUMER STATED THAT A HYSTERECTOMY AND BILATERAL SALPINGECTOMY WAS PERFORMED AND WAS CONSIDERED AS RELATED TO ESSURE. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00374	BAYER HEALTHCARE LLC	9/11/2014	9/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 789034

Single Use: Y
Implant Date (E6): 11/16/2011
Explant Date (E7): 9/18/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5037042) IN UNITED STATES ON 15-AUG-2014, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2011 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER 789034. ACCORDING TO HER, SHE HAD DEVELOPED A VERY BAD EDEMATOUS, WHICH SHE NEVER HAD, MAJOR STOMACH PAIN AND BACK PAIN. EVERY SINGLE DAY, SHE HAD BACK PAIN WITH INTERCOURSE; HER LIFE WAS TERRIBLE. SHE BEGGED TO DOCTORS TO HELP HER. SHE LOST SO MUCH WEIGHT, SHE COULD NOT EAT OR EVEN SLEEP COMFORTABLE AND SHE HAD FATIGUE. SHE WAS NOT E-FREE, BUT SHE SUFFERED FROM NOT FEELING LIKE A NORMAL WOMAN AND DEPRESSED. ON (B)(6) 2013 ESSURE WAS REMOVED AND A HYSTERECTOMY WAS DONE. AN INJURY (REQUIRED INTERVENTION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP WILL BE REQUESTED. FOLLOW-UP RECEIVED ON 19-AUG-2014: PRODUCT TECHNICAL COMPLAINT GLOBAL ((B)(4)) AND LOCAL ((B)(4)) NUMBERS WERE RECEIVED. FOLLOW-UP INFORMATION FROM 25-AUG-2014: NO RESPONSE TO DATE. PTC INVESTIGATION RESULT WAS RECEIVED ON 29-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE

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ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. 3 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 789034, BUT NONE OF THESE CASES REFER TO SIMILAR TYPES OF ADVERSE EVENTS. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH REVEALED NO REASON TO SUSPECT A QUALITY DEFICIT. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BACK PAIN/BACK PAIN WITH INTERCOURSE. THIS EVENT WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT; IT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS AN INCIDENT SINCE A SURGICAL INTERVENTION (HYSTERECTOMY) WAS PERFORMED TO REMOVE ESSURE. ABDOMINAL, BACK, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE CONSUMER REPORTED BACK PAIN/BACK PAIN WITH INTERCOURSE AFTER ESSURE INSERTION AND WAS SUBMITTED TO A HYSTERECTOMY. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND THE REPORTED EVENT NATURE A CAUSAL RELATION WITH ESSURE THERAPY CANNOT BE EXCLUDED. IN ADDITION THE NON-SERIOUS EVENTS: EDEMATOUS, STOMACH PAIN, COULD NOT EAT AND DEPRESSED WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 20-AUG-2015 AND 21-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00375	BAYER HEALTHCARE LLC	9/11/2014	9/11/2014

Event Information:

Event Date (B3): 5/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/31/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5037043) IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT THEY PLACED 3 COILS INTO HER FALLOPIAN TUBE. SHE HAD SOME DISCOMFORT FOR 2 MONTHS AFTER PROCEDURE WHERE THE COILS WERE PLACED AND FELT FATIGUED, HEAVY PERIODS, CRAMPING AND INTENSE THROBBING PAIN WHERE COILS WERE PLACED THAT WOULD HURT AT RANDOM TIMES, IT DIDN'T MATTER IF SHE WAS SITTING, STANDING, LAYING DOWN OR EXERCISING. SHE HAD HER HSG (HYSTEROSALPINGOGRAM) TEST IN 2013 TO CONFIRM BLOCKAGE AND EVERYTHING WAS CORRECT, ALL COILS IN PLACE. IN 2014 CONSUMER STARTED EXPERIENCING ABNORMAL SYMPTOMS STARTING WITH A MISSED PERIOD, FREQUENT URINATION, BLADDER INFECTIONS, DIZZY SPELLS, NAUSEA, WEIGHT GAIN, SEVERE BLOATING WHERE SHE LOOKED 3 MONTHS PREGNANT, SEVERE CONSTIPATION, SEVERE ABDOMINAL CRAMPING LIKE HER INSIDES WERE BEING TWISTED AND TORN APART AS WELL AS CRAMPING IN PELVIC REGION LIKE HER UTERUS WAS STRETCHING. SHE WENT TO HER GYNECOLOGIST IN 2014 AND SHE DID A VAGINAL EXAM AND URINE TEST AND CAME BACK NEGATIVE. SHE WAS DIAGNOSED WITH HORMONAL IMBALANCE. HER SYMPTOMS BECAME WORSE WITH SEVERE ABDOMINAL CRAMPING TO THE POINT WHERE SHE COULD NOT WALK, THROBBING PAIN IN PELVIC REGION WHERE COILS COULD HAVE BEEN PLACED AND SECOND BELOW, AND SEVERE CONSTIPATION FOR 6 DAYS AND SHE WENT INTO AN URGENT CARE CLINIC IN 2014 AND THEY DIAGNOSED IT AS SEVERE CONSTIPATION AND BLOCKAGE IN HER INTESTINES AS WELL AS BLOOD IN HER STOOL, AND HIGH LEVELS OF PROTEIN. CONSUMER HAD HER SYMPTOMS BECAME EVEN WORSE WITH ABDOMINAL PAIN, FLANK PAIN, UTI (URINARY TRACT INFECTION) AND PREVIOUS SYMPTOMS LISTED PRIOR. SHE

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WENT TO A DOCTOR IN 2014 AND SHE RAN A URINE TEST AS SHE STILL HAD NOT STARTED HER PERIOD AND SHE REQUESTED AN X-RAY AND DIAGNOSED HER WITH A UTI AND THE X-RAY SHOWED SHE HAD BLOCKAGE IN HER INTESTINES AS WELL AS FOUND 3 COILS, 2 IN HER FALLOPIAN, ONE ON EITHER SIDE AND ONE BELOW FALLOPIAN TUBES BUT THOUGHT NOTHING OF IT WHEN WE LOOKED AT IT BECAUSE WE WERE FOCUSED ON THE BLOCKAGE IN HER INTESTINES. HER DOCTOR PRESCRIBED HER WITH SOME ANTIBIOTICS FOR HER UTI. HER SYMPTOMS STILL REMAINED ALL OF THEM LISTED PRIOR THIS TIME HIGH FEVER, LESS THAN 24 HOURS LATER, LEAVING HER OFFICE, EXPERIENCED HIGH FEVER FOR 6 DAYS OF 101-103, SEVERE CRAMPING WHERE SHE COULD NOT MOVE AND SHE BROKE OUT IN A RASH HEAD TO TOE AND HER SYMPTOMS BECAME WORSE AND SHE WOUND UP IN THE EMERGENCY ROOM AND THEY LOOKED AT HER X-RAY AND PERFORMED A CT SCAN AS WELL AS BLOOD WORK. HER DOCTORS CAME IN AND SAID THAT WHAT THEY COULD CONCLUDE FROM HER CT SCAN, X-RAY, BLOOD TESTS AND URINE TESTS THE 3RD COIL HAD BROKEN OFF WHICH SHE WAS AWARE SHE HAD A THIRD COIL AND IT WAS PERFORATING HER UTERUS CAUSING ALL OF HER SYMPTOMS. DOCTORS TOLD HER TO CALL HER GYNECOLOGIST RIGHT AWAY AND TO SCHEDULE SURGERY TO HAVE IT REMOVED IMMEDIATELY. SHE HAD HER BLOOD WORK DONE FOR PRE SURGERY. ON (B)(6) 2014, THE CONSUMER HAD THE FAULTY COIL REMOVED USING LAPAROSCOPIC SURGERY. SHE REQUESTED TO SEE THE IMAGE AND THE COIL WAS BENT, ENTWINED AND DAMAGED. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6)-2014 FROM CONSUMER: PATIENT INFORMATION WAS ADDED. THE CONSUMER HAD NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES NOR RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. SHE IS GRAVIDA 3 AND PARA 0; SHE HAD 3 MISCARRIAGES. ESSURE WERE INSERTED ON (B)(6)-2013. THE PATIENT HAD A MISCARRIAGE IN (B)(6)-2013. SHE USED CONDOMS AS BACK-UP CONTRACEPTION UNTIL TOTAL TUBAL OCCLUSION CONFIRMATION. IN (B)(6)-2013, THE HSG (HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED THE TUBES BLOCKED. IN (B)(6)-2014, CONSUMER WENT TO THE ER WITH PAIN AND HAD AN X-RAY THAT SHOWED 3 COILS AND ONE WAS LOOSE. A CT SCAN WAS ALSO DONE AND SHOWED PERFORATION OF UTERUS, AN OVARIAN CYST AND SCAR TISSUE WITH CHRONIC INFLAMMATION. SHE HAD EXTREME PAIN, SEVERE CONSTIPATION FOR 3 MONTHS, BLOATING (LOOKED LIKE 4 MONTHS PREGNANT), NAUSEA, DIZZINESS, DISCHARGE, UTI (URINARY TRACT INFECTION), BLADDER INFECTION AND HEADACHES. THE PATIENT DID NOT KNOW WHICH SIDE THE THIRD ESSURE CAME FROM (THE OTHER TWO WERE IN PLACE). THE CONSUMER DID NOT KNOW IF THE PERFORATION OCCURRED DURING THE INSERTION PROCEDURE. ON (B)(6)-2014, THE LOOSE COIL WAS REMOVED BUT THE OTHER TWO WERE STILL IN THE PATIENT. THE REMOVAL WAS DONE BY LAPAROSCOPY. CONSUMER REPORTED THAT SHE DID NOT RECOVERED FROM THE REMOVAL PROCEDURE, SHE STILL HAVE OCCASIONAL PAIN WITH EXERCISE OR OVULATING OR DURING HER PERIOD, BLOATING, CONSTIPATION AND THE UTIS. SOME OF THE PAIN WAS RESOLVED. CONSUMER REPORTED THAT SHE BELIEVES THAT ESSURE HAVE CAUSED HER CONDITION. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON (B)(6)-2014. THE PTC GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BROKE", IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE BROKEN". SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "(B)(4)," BECAUSE AN INVESTIGATION OF THE SAME FAILURE MODE HAS ALREADY BEEN

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INITIATED. CONCLUSIONS: THE REPORT DID NOT STATE A PATIENT INJURY OCCURRED. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4). MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE ADDITIONALLY A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED. THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO 27 YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE ESSURE COIL WAS BELOW FALLOPIAN TUBES AND WAS PERFORATING THE UTERUS. SHE ALSO EXPERIENCED BLOCKAGE IN INTESTINES, BLOOD IN STOOLS AND UTI. THE FIRST EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE, LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS CONSIDERED AN INCIDENT AS IT LED TO A SURGICAL REMOVAL (LAPAROSCOPY) OF ESSURE. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE INCLUDING INSERTION OF ESSURE. IN THIS PARTICULAR CASE, UTERINE PERFORATION; IN ADDITION TO THE PRESENCE OF 3 ESSURE COILS WERE DIAGNOSED. ONE OF THE COILS (WHICH WAS LOOSE) WAS REMOVED. BASED ON THE PROVIDED INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED PERFORATION AND ESSURE CANNOT BE EXCLUDED. REGARDING THE SERIOUS, UNLISTED EVENTS: BLOCKAGE IN INTESTINES AND BLOOD IN STOOLS; OBSTRUCTIONS OF BOWELS MAY HAVE SEVERAL CAUSES SUCH AS INFECTIONS, HERNIAS, ADHESIONS, TUMORS, AND KIDNEY OR LUNG DISEASE. GIVEN THE LIMITED INFORMATION PROVIDED, CAUSALITY BETWEEN THESE EVENTS AND ESSURE USE CANNOT BE ASSESSED. FOR THE SERIOUS, UNLISTED EVENT UTI, INTERPRETED AS URINARY TRACT INFECTIONS, ITS PATHOGENESIS IN WOMEN BEGINS WITH COLONIZATION OF THE VAGINAL INTROITUS BY UROPATHOGENS FROM THE FECAL FLORA, GIVEN ITS PATHOPHYSIOLOGY AND CONSIDERING ESSURE LOCAL ACTION AT FALLOPIAN TUBES, IT WAS CONSIDERED AS UNRELATED TO THE SUSPECT INSERT. OTHER NON-SERIOUS EVENTS WERE REPORTED, INCLUDING 3RD COILD HAD BROKEN OFF, INTERPRETED AS A DEVICE BREAKAGE. THIS EVENT INITIALLY CONSIDERED UNLISTED, WAS, UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) UPDATED TO LISTED (ANTICIPATED). THIS PTC ANALYSIS ALSO CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION; THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT OF THE PRODUCT. FOLLOW-UP INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW UP 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00376	BAYER HEALTHCARE LLC	9/11/2014	9/11/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): L2138

Single Use: Y
Implant Date (E6): 11/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5037056) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2005 FOR PERMANENT STERILIZATION. ACCORDING TO HER, SHE EXPERIENCED A LARGE DERMOID CYST ON HER RIGHT OVARY, ECTOPIC PREGNANCY (DEVICE INEFFECTIVE), BAD CRAMPS, MISSED PERIOD, HEAVY BLEEDING, MIGRAINES, LOSS OF FEELING IN PELVIC AREA (TINGLING SENSATIONS), LOSS OF SEX DRIVE, SWELLING IN ABDOMEN, HUGE BLOOD CLOTS DURING PERIOD, DIZZINESS, LIGHTHEADED, BALANCE PROBLEMS, RECURRING YEAST INFECTIONS, FREQUENT URINATION, MOOD SWINGS, DEPRESSION, AND NO ENERGY. SHE STATED THAT IT WAS TAKEN AWAY THE QUALITY OF HER LIFE AND SHE WAS ALONE. AN INJURY (DISABILITY OR PERMANENT DAMAGE) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP WILL BE REQUESTED. FOLLOW-UP RECEIVED ON (B)(4) 2014: INFORMATION RECEIVED FROM A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAS NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES AND DOES NOT HAVE ANY OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS; STATES THAT SHE HAD ESSURE (LOT NUMBER L2138) INSERTED ON (B)(6) 2005. IN ADDITION CONSUMER REPORTED THAT PROCEDURE WAS PERFORMED AFTER PREGNANCY (DELIVERY IN (B)(6) 2005). AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION CONSUMER USED CONDOMS. NO HYSTEROSALPINGOGRAM TEST WAS PERFORMED SINCE SHE HAD LOST HER INSURANCE. CONSUMER CONFIRMED ALL SYMPTOMS PREVIOUSLY REPORTED AND STATES THAT THE MISCARRIAGE OCCURRED IN 2013, BUT SHE IS NOT A 100 PER CENT SURE THAT IT WAS A MISCARRIAGE. SHE STATES THAT SHE PASSED SEVERAL LARGE BLOOD CLOTS AND SOMETHING THAT MIGHT HAVE BEEN AN EARLY FETUS. SHE HAD NOT DONE A PREGNANCY TEST AND WAS ABOUT 5 DAYS

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LATE FOR HER PERIOD WHEN IT HAPPENED. ADDITIONALLY CONSUMER REPORTED THAT THE SYMPTOMS STARTED IN ABOUT 2009-2010 AND INFORMED THAT SHE SAW HER DOCTOR REGARDING THE SYMPTOMS; THE DIAGNOSIS WAS DERMOID CYST OVER OVARY AND SHE HAS TO HAVE IT REMOVED BUT STATES THAT SHE DOES NOT HAVE INSURANCE. CONSUMER WAS NOT HOSPITALIZED. ESSURE DEVICES REMOVAL WAS NOT PERFORMED NEITHER IS PLANNED. HOWEVER, SHE ABSOLUTELY BELIEVES THAT HER CONDITION WAS CAUSED BY THE ESSURE DEVICES OR DID THE ESSURE DEVICES CONTRIBUTE TO THE ISSUE AND STATES THAT SHE NEVER HAD ANY PROBLEM BEFORE. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON (B)(4) 2014. THE PTC GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN (B)(4)," BECAUSE AN INVESTIGATION OF THE SAME FAILURE MODE HAS ALREADY BEEN INITIATED. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, A LACK OF EFFICACY (PREGNANCY) WAS REPORTED. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP RECEIVED ON (B)(4) 2014: THE RECEPTIONIST AT DOCTOR'S OFFICE STATED THAT THE CONSUMER WAS SEEN BACK IN 2005 AND NOT SEEN SINCE THEN. SHE WILL CHECK AND HAVE THE DOCTOR COMPLETE THE FORMS IF THEY COULD GET AN OPERATIVE REPORT FROM THE HOSPITAL WHERE SHE GOT THE PROCEDURE DONE. NO NEW CLINICAL INFORMATION. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ECTOPIC PREGNANCY, SUSPICIOUS OF MISCARRIAGE/PASSED SEVERAL LARGE BLOOD CLOTS AND SOMETHING THAT MIGHT HAVE BEEN AN EARLY FETUS, DERMOID CYST ON MY RIGHT OVARY AND HEAVY BLEEDING. ECTOPIC PREGNANCY, CONSIDERED SERIOUS AS DISABILITY BY CONSUMER, IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ECTOPIC PREGNANCIES HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. EVENT WAS CONSIDERED RELATED TO ESSURE AND REGARDED AS INCIDENT. SUSPICIOUS OF MISCARRIAGE, SPLIT INTO PREGNANCY (NON-SERIOUS, LISTED) AND ABORTION SPONTANEOUS (SERIOUS, UNLISTED). PREGNANCY WAS CONSIDERED RELATED FOR ESSURE, WHILE CAUSALITY FOR ABORTION CANNOT BE ASSESSED DUE TO THE LACK OF INFORMATION. THESE EVENTS ARE REGARDED AS NON-INCIDENT. DUE TO THE LACK OF INFORMATION, IT IS NOT CLEAR IF THE REPORTED ECTOPIC PREGNANCY AND SUSPICION OF MISCARRIAGE ARE THE SAME OR IF THEY REFER TO DIFFERENT EPISODES AND EVEN IF THEY WERE CONFIRMED. THEREFORE, FOR THE TIME BEING, BOTH EVENTS WERE KEPT IN THE CASE. HEAVY BLEEDING (LISTED) AND DERMOID CYST ON MY RIGHT OVARY (UNLISTED) ARE SERIOUS AS MEDICALLY SIGNIFICANT. DURING ESSURE THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; THEREFORE A CAUSAL RELATIONSHIP BETWEEN THE EVENT HEAVY BLEEDING AND ESSURE CANNOT BE EXCLUDED. DERMOID CYSTS (MATURE CYSTIC TERATOMAS) ARE THE MOST COMMON OVARIAN TUMOR. THE MECHANISM BY WHICH THESE CYSTS DEVELOP IS POSSIBLY BY FAILURE OF MEIOSIS. CONSIDERING THE NATURE OF DERMOID CYST ON MY RIGHT OVARY, IT WAS CONSIDERED UNRELATED TO ESSURE THERAPY. ALSO, NON-SERIOUS EVENTS

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WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS AWAITED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 10-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (F

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038143	BAYER	9/11/2014	9/11/2014

Event Information:

Event Date (B3): 3/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING EXTREMELY PAINFUL AND HEAVY PERIODS, MOODINESS, AND MIGRAINES ON THIS DATE....OVER THE COURSE OF THE NEXT 4 YEARS, THE SYMPTOMS AND PROBLEMS JUST CONTINUED TO GET WORSE!! CONTRACTION STYLE PAINS, CHEMICAL SENSITIVITY IN MY HANDS TO CERTAIN ACIDIC FOODS, HAIR LOSS, ANXIETY ATTACKS, INSOMNIA, IRON DEFICIENCY AND A MYRIAD OF OTHER NON LIFE THREATENING SYMPTOMS, ENDOMETRIOSIS, ADENOMYOSIS, POLYPS IN MY UTERUS AND MOST RECENTLY DIAGNOSED WITH STAGE 3B COLON CANCER IN (B)(6) 2014. THE MALIGNANT TUMOR WAS IN THE LOWER ASCENDING PORTION OF MY COLON AND A BENIGN POLYP WAS FOUND IN THE LOWER DESCENDING PORTION OF MY COLON - BOTH DIRECTLY IN LINE WITH MY FALLOPIAN TUBES WHERE THE ESSURE COILS WERE HOUSED. HAVE HAD TO HAVE A DIAGNOSTIC LAPAROSCOPY, HYSTEROSCOPE AND D AND C IN (B)(6) 2014, WHICH RESULTED IN PRE-OP TESTING THAT LED TO THE DISCOVERY OF THE TUMOR IN MY COLON IN (B)(6). ON (B)(6), 2014, I UNDERWENT SURGERY FOR A COLECTOMY, FULL HYSTERECTOMY AND OOPHORECTOMY, AND APPENDECTOMY, ALL ON THE SAME DAY. IN (B)(6) 2014, UNDERWENT ANOTHER SURGERY TO HAVE A CHEMOTHERAPY PORT INSTALLED AND STARTED CHEMOTHERAPY THE SAME MONTH FOR THE NEXT 6 MONTHS....AND YES, I ATTRIBUTE ALL OF THESE ISSUES TO ESSURE, BECAUSE SINCE IT HAS BEEN REMOVED - EVERY SYMPTOM THAT I WAS DEALING WITH IS GONE!!! THIS PRODUCT NEEDS TAKEN OFF THE MARKET!!!! I HAVE NO ALLERGIES WITH THE EXCEPTION OF PENICILLIN AND AMOXICILLIN, WHICH I HAD NOT BEEN ON FOR YEARS, NO ONGOING ILLNESSES, BIRTH DEFECTS OR OTHER MEDICAL CONDITIONS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00377	BAYER HEALTHCARE LLC	9/11/2014	9/12/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/30/2008
Explant Date (E7): 1/7/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY ((B)(4)) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. CONSUMER REPORTED THAT SHE HAD SEVERE PELVIC PAIN; SHE HAD TO UNDERGO A HYSTERECTOMY TO REMOVE THE DEVICES SO THE PELVIC PAIN WOULD SUBSIDE. SHE STATED THAT THE DEVICES ALSO CAUSE HER EXTREMELY HEAVY PERIODS ALONG WITH SEVERE HEADACHES AND CONSTANT OVARIAN CYSTS. NO FURTHER INFORMATION WAS PROVIDED. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON (B)(6) 2014. THE PTC GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN DEV@COM," BECAUSE AN INVESTIGATION OF THE SAME FAILURE MODE HAS ALREADY BEEN INITIATED. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND

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THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE, LISTED IN THE ESSURE REFERENCE SAFETY INFORMATION AND REGARDED AS INCIDENT, DUE TO HYSTERECTOMY PERFORMED (REQUIRED INTERVENTION). ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. THE CONSUMER EXPERIENCED PELVIC PAIN AND UNDERWENT A HYSTERECTOMY TO REMOVE THE DEVICES. GIVEN THE AVAILABLE INFORMATION CAUSAL RELATIONSHIP BETWEEN THE EVENT AND ESSURE USE CANNOT BE EXCLUDED. ADDITIONALLY NON-SERIOUS EVENTS EXTREMELY HEAVY PERIODS, SEVERE HEADACHES AND CONSTANT OVARIAN CYSTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS (PTC) WAS PERFORMED AND CONCLUDED TO UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED (NO FOLLOW-UP WAS POSSIBLE SINCE NO CONTACT INFORMATION WAS PROVIDED).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038145	BAYER	9/11/2014	9/12/2014

Event Information:

Event Date (B3): 4/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE PELVIC PINCHING, STRONG CRAMPS, HEAVY BLEEDING, PASSING EXTREMELY LARGE CLOTS, HEADACHES, LEG CRAMPS, PAIN SHOOTING DOWN LEG, HOT FLASHES, NIGHT SWEATS, BACK PAIN, ACHY JOINTS, EXTREME ANXIETY, DEPRESSION, METAL TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038146	BAYER	9/11/2014	9/12/2014

Event Information:

Event Date (B3): 2/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY FIRST SURGERY IN (B)(6) 2010. I WAS IMMEDIATELY NAUSEOUS AND TIRED. I FELT A PAIN ON MY SIDE THAT SLOWLY GOT WORSE. AFTER A COUPLE OF DAYS I FELT A PAINFUL SNAP THEN PAIN WAS BETTER. AT MY HSG I FOUND OUT THAT ONE OF MY COILS WAS MISSING. THE IMPLANTING DOCTOR CALLED AND SAID SOME OF THE COIL WAS FLOATING IN MY ABDOMEN AND IT WOULD BE FINE. MY SECOND SURGERY WAS (B)(6), 2010. I FELT MORE NAUSEOUS WITH MORE ABDOMINAL PAIN. I BROKE OUT IN HIVES AND NOW AM TAKING ZYRTEC DAILY. I GOT A COPY OF MY HSG RECENTLY AND AM NOW AWARE I HAVE AN ALMOST FULL COIL IMBEDDED IN MY ABDOMEN. I'VE SEEN ALLERGY DOCTORS AND REGULAR PCP DOCTOR. I'M VERY ANGRY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038147	BAYER	9/11/2014	9/12/2014

Event Information:

Event Date (B3): 2/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5038147 #(B)(4) UPDATE OF INFORMATION: (B)(6), 2014. I HAD A SALPINGECTOMY (BILATERAL) WITH ESSURE DEVICE REMOVED. THE RIGHT COIL WAS NOTED INTO THE UTERUS FURTHER THAN WHAT WAS DOCUMENTED AT MY HSG (B)(6) AGO. MY LEFT COIL WAS BROKEN AND POINTED WITH A 90 DEGREE ANGLE INSIDE MY FALLOPIAN TUBE. THE SURGEON STATED VERY CLOSE TO RUPTURING THE TUBE. ALL PIECES OF THE ESSURE COILS WERE REMOVED AND I WAS GIVEN AN XRAY TO CONFIRM THAT NO FRAGMENTS WERE LEFT BEHIND. DURING THIS SURGERY, THE SURGEON NOTED THAT I HAD ENDOMETRIOSIS(ALL THROUGHOUT MY ABDOMINAL CAVITY: STAGE 4), ADENOMYOSIS (ON UTERUS AND OVARY) AND SEVERE ADHESIONS (ALL THROUGHOUT MY ABDOMINAL CAVITY). HIS RECOMMENDATION AFTER SEEING THIS WAS A SECOND SURGERY. HIS RECOMMENDATION WAS A COMPLETE HYSTERECTOMY WITH LEFT OOPHORECTOMY. ALSO A "CLEANING OUT" OF MY ABDOMINAL CAVITY OF ENDOMETRIOSIS AND ADHESIONS. THIS SURGERY WAS PERFORMED ON (B)(6), 2014. LEFT OVARY WAS BURIED DEEP INTO THE BOWEL AND WAS ADHERED TO THE BOWEL BY ADHESIONS. HE FELT I HAD STAGE 4 ENDOMETRIOSIS. NO MENTION WAS EVER MADE TO THE ENDOMETRIOSIS OR ADENOMYOSIS DURING MY C-SECTIONS(1999 AND 2005). SINCE HAVING BOTH SURGERIES IN 2014, IT FEELS LIKE IT HAS BEEN A LONG RECOVERY. A LOT OF THE ABOVE MENTIONED SYMPTOMS HAVE DISAPPEARED WHEN THE ESSURE COILS WERE REMOVED. I AM STILL DEALING WITH SEVERAL ONGOING ISSUES OF JOINT PAIN, OCCASIONAL DIZZINESS, FEELING OF EXTREME COLDNESS, FATIGUE, WEIGHT GAIN, FOOD ALLERGIES AND GLUTEN SENSITIVITIES, DIABETES, AND SLEEP APNEA. THE ESSURE DEVICE IS NOW CURRENTLY OUT OF ME AND WAS GIVEN BACK TO ME. I HAVE IT IN MY POSSESSION IN A STERILE CUP. THE COILS WERE NOT RETURNED TO THE MANUFACTURER.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038191	BAYER	9/11/2014	9/18/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PROCEDURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE BACK IN 2010. I HAVE SEVERE PAIN EVER SINCE. DEBILITATING PAIN IN TRACT. I WAS PRESSURED INTO THE PROCEDURE BY MY OBGYN AT THE TIME FOLLOWING AN UPSETTING MISCARRIAGE. I TOLD MY DOCTOR ABOUT MY SEVERE ALLERGIES TO ANYTHING CONTAINING NICKEL. HE SAID I WOULDN'T HAVE TO WORRY ABOUT IT, THAT I WOULDN'T SUFFER FROM IT. HE DIDN'T DO THE CONFIRMATION TEST AS WELL. HERE IT IS 4 YEARS LATER, I AM STILL DEALING WITH SEVERE PAIN FROM IT. I ALSO WASN'T READY TO STOP HAVING CHILDREN. I WAS (B)(6) WHEN I HAD IT DONE. I AM (B)(6) NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038193	BAYER	9/11/2014	9/18/2014

Event Information:

Event Date (B3): 4/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627757

Single Use:
Implant Date (E6): 4/15/2009
Explant Date (E7): 7/31/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN ME ON (B)(6) 2009. I BEGAN HAVING PELVIC PAIN, NAUSEA, HEADACHES, AND OTHER PROBLEMS WITHIN A FEW MONTHS. I WASN'T AWARE OF SIDE EFFECTS OF THE METAL IN THIS PRODUCT. I ALSO HAD SEVERE BLOATING. I WENT TO MY GYNECOLOGIST (B)(6) 2014 TO DISCUSS THIS MATTER. I WAS DIAGNOSED WITH PELVIS CONGESTION SYNDROME AND DYSMENORRHEA. I WAS THEN SCHEDULED FOR A HYSTERECTOMY ON (B)(6), 2014. IMMEDIATELY AFTER SURGERY AND FOR THE LAST 6 WEEKS ALL OF MY SYMPTOMS HAVE DISAPPEARED. I BELIEVE THE ESSURE PRODUCT CAUSED MY PROBLEMS AND SHOULD NOT BE AN OPTION FOR WOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038194		9/11/2014	9/18/2014

Event Information:

Event Date (B3): 11/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DEVICE IMPLANTED. I THINK IN 2008. I HAVE SEVERE HEADACHES, 50 LB WEIGHT GAIN, AND NARCOLEPSY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00378	BAYER HEALTHCARE LLC	9/12/2014	9/12/2014

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 959220

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A (B)(4) STUDY CASE REPORT RECEIVED FROM A INVESTIGATOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A (B)(4) STUDY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: USE OF TRANSVAGINAL ULTRASOUND TO CONFIRM ESSURE® MICRO-INSERT PLACEMENT IN WOMEN: DEMONSTRATION OF EFFECTIVENESS. PATIENT NUMBER: (B)(6). CENTER NUMBER: (B)(6). INVESTIGATOR REPORTED THAT PATIENT STATED THAT PELVIC PAIN WAS INTERMITTENT FOR 3 MONTHS. BUT SOME TIME LATER THAT PAIN WAS DAILY AND INCREASED DURING MENSES. INVESTIGATOR CONSIDERED THE SEVERITY OF THE EVENT MILD. ON UNSPECIFIED DATE, AN TVU (TRANSVAGINAL ULTRASOUND) WAS DONE AND NO ISSUES WERE FOUND. INVESTIGATOR DISCUSSED TREATMENT OPTIONS WITH THE SUBJECT AND WAS DECIDED TO HAVE THE DEVICES REMOVED. ON (B)(6) 2014, THE PATIENT HAD A LAPAROSCOPIC BILATERAL SALPINGECTOMY REMOVAL OF ESSURE COILS. THE PATIENT RECOVERED WITH TREATMENT. INVESTIGATOR CONSIDERED THE EVENT POSSIBLE RELATED TO ESSURE MICRO-INSERT. FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2014 INVESTIGATOR: PATIENT ID WAS CONFIRMED AS (B)(6). THE DATE OF NOTIFIED ADVERSE EVENT WAS (B)(6) 2014. PRIOR THE PROCEDURE PATIENT USED ORAL CONTRACEPTIVE PILLS. ESSURE INSERTION PROCEDURE WAS DONE IN PHYSICIAN'S OFFICE; INTRAVENOUS SEDATION WAS USED AS ANESTHESIA; SUBJECT DID NOT RECEIVE AN NSAID PRIOR THE PROCEDURE. ADEQUATE VISUALIZATION OF BOTH TUBAL OSTIA WAS ACHIEVED; FOR BOTH SIDES IT WAS USED ESSURE LOT NUMBER 959220. NUMBER OF TRAILING COILS WAS 4 ON RIGHT SIDE AND 3 ON LEFT SIDE. ON (B)(6) 2012, A URINE PREGNANCY TEST WAS PERFORMED AND SHOWED NEGATIVE RESULT. INVESTIGATOR REPORTED THAT AFTER ESSURE REMOVAL PELVIC PAIN ENDED. FOLLOW-UP RECEIVED ON (B)(4) 2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT

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TECHNICAL COMPLAINT (REQUEST FOR CONFIRMATION OF QUALITY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 2 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 959220, BUT NONE OF THOSE CASES REFER TO SIMILAR ADVERSE EVENT TYPES OF EVENTS. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED; STUDY REPORT REFERS TO A FEMALE SUBJECT WHO WAS INVOLVED IN AN INTERVENTIONAL COMPANY-SPONSORED STUDY TO EVALUATE THE USE OF TRANSVAGINAL ULTRASOUND TO CONFIRM ESSURE MICRO-INSERT PLACEMENT IN WOMEN (DEMONSTRATION OF EFFECTIVENESS). STUDY NUMBER (B)(4). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE, IT IS LISTED ACCORDING TO THE INVESTIGATOR´S BROCHURE AND WAS REGARDED AS AN INCIDENT, SINCE INTERVENTION WAS REQUIRED (SUBJECT HAD A LAPAROSCOPIC BILATERAL SALPINGECTOMY AND REMOVAL OF ESSURE COILS). IN THIS PARTICULAR CASE THE SUBJECT DEVELOPED PELVIC PAIN AND RECOVERED AFTER ESSURE REMOVAL. INVESTIGATOR CONSIDERED THIS EVENT POSSIBLY RELATED TO ESSURE MICRO-INSERT; GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE, THE COMPANY AGREES WITH THIS ASSESSMENT. A PRODUCT TECHNICAL ANALYSIS (PTC) WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00379	BAYER HEALTHCARE LLC	9/15/2014	9/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA (B)(6) IN THE UNITED STATES ON 11-NOV-2013 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BROKEN AND FLOATING. FOLLOW UP RECEIVED ON 07-FEB-2014: NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 18-AUG-2014. ON 21-AUG-2014 THE CASE (B)(4) WAS FOUND TO BE A DUPLICATE OF THIS CASE. ALL INFORMATION WAS TRANSFERRED TO THIS CASE. CASE UPGRADED TO INCIDENT DUE TO HYSTERECTOMY. SHE HAD A PERFORATED TUBE AND A HYSTERECTOMY WAS PERFORMED. FIVE PHYSICIANS FAILED TO DIAGNOSE AND TREAT. THE PATIENT UNDERWENT A HYSTERECTOMY BECAUSE SHE COULD NOT BEAR THE PAIN ANY LONGER CAUSED BY ESSURE. SHE HAD TO REMOVE HER UTERUS, FALLOPIAN TUBES, CERVIX AND RIGHT OVARY. NO FURTHER INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-AUG-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE

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DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW UP 03.SEP.2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. ESSURE INDICATION, BIRTH CONTROL, WAS ADDED TO THE CASE. CONSUMER REPORTED THAT IT HAS BEEN 21 DAYS AND FEELING MUCH BETTER AND THAT HER PATHOLOGY REPORT TOLD HER THAT ESSURE CAUSED A LOT OF DAMAGE. NO ADDITIONAL INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERFORATED TUBE, DEVICE BREAKAGE AND PAIN. PERFORATED TUBE AND PAIN WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE WHILE THE REMAINING EVENT IS NON-SERIOUS. DEVICE BREAKAGE IS AN UNLISTED EVENT ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. THIS CASE WAS INITIALLY REGARDED AS OTHER REPORTABLE INCIDENT; HOWEVER, AFTER RECEIPT OF FOLLOW-UP INFORMATION IT WAS AMENDED TO INCIDENT, SINCE THE PATIENT WAS SUBMITTED TO HYSTERECTOMY, BILATERAL SALPINGECTOMY AND RIGHT OOFORECTOMY. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALSO DURING ESSURE THERAPY PELVIC, ABDOMINAL AND UNSPECIFIED PAIN MAY OCCUR. IN THE PRESENT CASE THESE EVENTS WERE REPORTED WITHOUT FURTHER DETAILS, THE INFORMATION RECEIVED STATED THAT THE PATIENT HAD A BROKEN INSERT, PAIN, A PERFORATION WAS DIAGNOSED AND A HYSTERECTOMY WAS PERFORMED. BASED ON AVAILABLE INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS REPORTED AND ESSURE CANNOT BE EXCLUDED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 21-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00380	BAYER HEALTHCARE LLC	9/15/2014	9/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/22/2013
Explant Date (E7): 1/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5036920) IN UNITED STATES ON 18-AUG-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABSOLUTE WORST PAIN DURING THE IMPLANTATION - PAIN JUST KEPT GETTING WORSE, PAIN IN BACK AND PAIN IN STOMACH WAS SO BAD IT WAS HARD TO WORK, WALK AND ENJOY THE SIMPLE THINGS, HAIR STARTED TO THIN AND FALL OUT, STARTED TO GAIN WEIGHT, TWO HORRIBLE SCARS ON STOMACH, AND OTHER HEALTH PROBLEMS. ON (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER EXPERIENCED THE ABSOLUTE WORST PAIN DURING THE IMPLANTATION THAT SHE EVEN CRIED DURING THE PROCEDURE. THE PAIN JUST KEPT GETTING WORSE EACH DAY FROM THE INSERTION OF ESSURE, AND IT DID NOT STOP. SHE HAD ALSO PAIN IN HER BACK AND STOMACH WHICH WAS SO BAD IT WAS HARD TO WORK, WALK AND ENJOY THE SIMPLE THINGS. HER HAIR STARTED TO THIN AND FALL OUT. SHE STARTED TO GAIN WEIGHT. CONSUMER HAD TO HAVE A HYSTERECTOMY AND ESSURE WAS REMOVED ON (B)(6) 2014. NOW SHE HAS TWO HORRIBLE SCARS ON STOMACH. SHE BELIEVES THAT ESSURE HAS LED TO OTHER HEALTHY PROBLEMS THAT SHE IS NOW FACING. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE WAS NOT REPORTED. FOLLOW UP 22.AUG.2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY

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QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY IV. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION FROM 03-SEP-2014: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN IN BACK AND PAIN IN STOMACH WAS SO BAD IT WAS HARD TO WORK, WALK AND ENJOY THE SIMPLE THINGS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE, THEY ARE LISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE, AND WERE REGARDED AS INCIDENTS SINCE INTERVENTION WAS REQUIRED (CONSUMER HAD TO HAVE A HYSTERECTOMY). ABDOMINAL/PELVIC PAIN AND CRAMPING MAY OCCUR WITH ESSURE. PAIN AND CRAMPING MAY BE A MORE LIKELY OCCURRENCE DURING THE MENSTRUAL PERIOD, DURING AND AFTER SEXUAL INTERCOURSE OR WITH OTHER PHYSICAL ACTIVITY. AS WITH CURRENTLY AVAILABLE METHODS OF MECHANICAL PERMANENT CONTRACEPTION (I.E., CLIPS, RINGS), IF THE ESSURE MICRO-INSERT IS TO BE REMOVED, IT IS POSSIBLE THAT SURGICAL REMOVAL OF THE FALLOPIAN TUBES (SALPINGECTOMY) AND UTERUS (HYSTERECTOMY) MAY BE REQUIRED. CONSIDERING THE NATURE OF THE EVENTS PAIN IN BACK AND PAIN IN STOMACH WAS SO BAD IT WAS HARD TO WORK, WALK AND ENJOY THE SIMPLE THINGS, A CAUSAL RELATIONSHIP BETWEEN THESE REPORTED EVENTS AND ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED: ABSOLUTE WORST PAIN DURING THE IMPLANTATION- PAIN JUST KEPT GETTING WORSE, HAIR STARTED TO THIN AND FALL OUT, STARTED TO GAIN WEIGHT, TWO HORRIBLE SCARS ON MY STOMACH AND OTHER HEALTH PROBLEMS. A PRODUCT TECHNICAL ANALYSIS CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND STATED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED. CASE CLOSED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00381	BAYER HEALTHCARE LLC	9/15/2014	9/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 2/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA A (B)(4) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED FLU-LIKE SYMPTOMS, METAL TASTE IN HER MOUTH, SHOOTING PAIN IN HER LEGS, BACK AND NECK, GAINED 45 POUNDS, AND HAD VISION PROBLEMS. IN ADDITION CONSUMER REPORTED THAT SHE DIDN'T WANT TO GET OUT OF BED NEITHER TO GO TO FAMILY EVENTS. CONSUMER WHO IS A MOTHER OF THREE REPORTED THAT, AFTER SHE HAD THE DEVICE IMPLANTED, SHE STARTED HAVING FLU-LIKE SYMPTOMS AND A METAL TASTE IN HER MOUTH. SHE THEN HAD SHOOTING PAINS IN HER LEGS, BACK AND NECK AND STATES THAT SHE DIDN'T WANT TO GET OUT OF BED. CONSUMER GAINED 45 POUNDS AND DIDN'T WANT TO GO TO FAMILY EVENTS, SHE INFORMED THAT PEOPLE WERE WONDERING WHAT WAS THE MATTER WITH HER AND CALLING HER BIPOLAR. CONSUMER ALSO HAD VISION PROBLEMS AND WENT FOR MULTIPLE COLONOSCOPIES, UNTIL SHE FINALLY HAD A HYSTERECTOMY IN (B)(6) 2014 WITH THE DEVICE REMOVAL. ACCORDING TO HER, THE PAIN IN HER BACK WAS GONE AND THE FOG STARTED LIFTING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT RECEIVED VIA (B)(4) REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHOOTING PAINS IN HER BACK. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE, IT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS INCIDENT, SINCE INTERVENTION WAS REQUIRED (CONSUMER HAD A HYSTERECTOMY). IT WAS REPORTED THAT AFTER THE HYSTERECTOMY, HER BACK PAIN WAS GONE. CONSIDERING THE NATURE OF THE EVENT SHOOTING PAINS IN HER BACK AND THE POSITIVE DECHALLENGE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED: FLU-LIKE SYMPTOMS, METAL TASTE IN

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HER MOUTH, SHOOTING PAINS IN HER LEGS, SHOOTING PAINS IN HER NECK, DIDN'T WANT TO GET OUT OF BED, GAINED 45 POUNDS AND VISION PROBLEMS. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FOLLOW-UP INFORMATION CAN BE OBTAINED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 22-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIG

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038249	BAYER	9/15/2014	9/24/2014

Event Information:

Event Date (B3): 9/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT IN 2007. LATER THAT YEAR, I BEGAN TO HAVE HEART PALPITATIONS FOR THE FIRST TIME IN MY LIFE. THEY RESOLVED WITHIN 6 MONTHS, BUT RE-OCCUR ON OCCASION. I HAVE ALSO HAD A STRANGE RASH APPEAR ON MY HANDS AND ARMS. I HAVE SEEN A DERMATOLOGIST REGULARLY SINCE THAT TIME. JUST RECENTLY, IT WAS SUGGESTED TO ME THAT IT ALMOST SEEMS TO BE AN ALLERGIC REACTION TO A METAL. I THEN TRACED THAT BACK TO THE ESSURE IMPLANTATION AND REALIZED THAT THIS RASH BEGAN AFTER THAT PROCEDURE. ALSO, WITHIN THE LAST FEW YEARS I HAVE HAD SEVERE CERVICAL CRAMPS ABOUT ONCE EVERY 6 MONTHS. I HAVE HAD NUMEROUS GYNECOLOGICAL PROCEDURES TO DETERMINE WHY I AM HAVING THESE CRAMPS AND NONE OF THEM HAVE REVEALED ANYTHING. I AM NOW BELIEVING THAT THESE CRAMPS ARE RELATED TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00382	BAYER HEALTHCARE LLC	9/16/2014	9/16/2014

Event Information:

Event Date (B3): 6/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/22/2011
Explant Date (E7): 4/23/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN WHO IS BEING SUED IN THE UNITED STATES ON (B)(4) 2014. THE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION AND EXPERIENCED BLEEDING OFF AND ON SINCE PLACEMENT, BACK PAIN / CHRONIC BACK PAIN, NAUSEA, HEADACHE, STOMACH CRAMPS, NICKEL ALLERGY AND PELVIC PAIN. IN ADDITION PHYSICIAN REPORTED THAT PATIENT HAD HYSTEROSALPINGOGRAM (HSG) SCHEDULED IN THE END OF (B)(6) 2011 BUT NEVER SHOWED. ALSO ACCORDING TO PHYSICIAN, OTHER HEALTH CARE PROFESSIONAL STATED THAT PARTS OF INSERTION DEVICE WERE ATTACHED TO BOTH COILS. ADDITION INFORMATION WAS RECEIVED ON (B)(4) 2014. PHYSICIAN REPORTED THAT PATIENT WAS POST-PARTUM AND HAD ESSURE INSERTED. SHE WAS BLEEDING OFF AND ON SINCE PLACEMENT AND, ON (B)(6) 2013, SHE HAD BILATERAL SALPINGECTOMY AND WAS GIVEN DEPO PROVERA. PHYSICIAN ALSO INFORMED THAT PATIENT EXPERIENCED BACK PAIN, NAUSEA, HEADACHE AND STOMACH CRAMPS AND WAS GIVEN BEYAZ TO TREAT SYMPTOMS. PATIENT HAD HSG SCHEDULED FOR (B)(6) 2011 BUT NEVER SHOWED NEITHER CANCELED IT. IN ADDITION HEALTH CARE PROFESSIONAL STATES THAT PATIENT WAS LAST SEEN IN (B)(6) 2011. ON (B)(6) 2014, PATIENT HAD HYSTERECTOMY FOR ALLEGED PELVIC PAIN SECONDARY TO NICKEL ALLERGY AND INFORMED THAT PATIENT STILL HAS CHRONIC BACK PAIN. FU INFORMATION WAS RECEIVED ON (B)(4) 2014: THE REPORTER PHYSICIAN STATED THAT SHE WAS GETTING SUED BY PATIENT AND WAS GOING TO MEDICAL LEGAL PANEL. THE PHYSICIAN ALSO REPORTED THE PATIENT EVENTS WERE NOT RECOVERED. PTC FINAL ASSESSMENT WAS RECEIVED ON (B)(4) 2014: THESE EVENTS REPORTED WERE RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL

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DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN DEV@COM," BECAUSE AN INVESTIGATION OF THE SAME FAILURE MODE HAS ALREADY BEEN INITIATED. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. ADDITIONALLY, THE AE CASE REFERS TO A TECHNICAL COMPLAINT (PARTS OF INSERTION DEVICE WERE ATTACHED TO BOTH COILS). THE REPORTED TECHNICAL COMPLAINT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED "UNCONFIRMED QUALITY DEFECT." IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING OFF AND ON SINCE PLACEMENT, NICKEL ALLERGY AND PELVIC PAIN. ALL EVENTS ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE; AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE PATIENT HAD HYSTERECTOMY FOR ALLEGED PELVIC PAIN SECONDARY TO NICKEL ALLERGY. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. ALSO, PELVIC PAIN AND BLEEDING (BLEEDING OFF AND ON SINCE PLACEMENT) MAY OCCUR DURING ESSURE THERAPY. IN THIS PARTICULAR CASE, PATIENT HAD BLEEDING AND WAS SUBMITTED TO A HYSTERECTOMY FOR ALLEGED PELVIC PAIN SECONDARY TO NICKEL ALLERGY THAT OCCURRED AFTER ESSURE INSERTION; THEREFORE, A CAUSAL RELATIONSHIP BETWEEN REPORTED EVENTS AND ESSURE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: PARTS OF INSERTION DEVICE WERE ATTACHED TO BOTH COILS, NAUSEA, BACK PAIN / CHRONIC BACK PAIN, STOMACH CRAMPS, AND HAD HSG SCHEDULED END OF (B)(6) BUT NEVER SHOWED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00385	BAYER HEALTHCARE LLC	9/16/2014	9/16/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/25/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. CONSUMER REPORTED THAT SHE EXPERIENCED RASH, HORRIBLE BACK PAIN WITH PAIN UNDER HER RIBS, LIGHTHEADEDNESS, MOOD SWINGS, FIBROIDS WHERE THE TUBE IS AND ENDOMETRIOSIS. SHE STATED THAT SHE WILL HAVE A SURGERY TO REMOVE THE DEVICES. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. CASE UPGRADED TO INCIDENT. CONSUMER'S DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A 39 YEARS OLD FEMALE CONSUMER. CONCOMITANT CONDITION INCLUDED OVERWEIGHT (BMI (B)(6)). SHE DENIED ANY PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES, ANY OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. ON (B)(6) 2012 ESSURE WAS INSERTED AFTER A PREGNANCY (SHE DELIVERED LAST CHILD IN (B)(6) 2012). CONDOMS WERE USED AS BACK-UP CONTRACEPTION. ON UNSPECIFIED DATE. HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED BLOCKED ON BOTH SIDES. ABOUT A YEAR AFTER ESSURE, SYMPTOMS SUDDENLY STARTED. SHE WENT TO THE EMERGENCY ROOM ONE TIME BEFORE FOR BACK PAIN AND WAS GIVEN PAIN MEDICATIONS. ON UNSPECIFIED DATE A SONOGRAM WAS DONE AND SHE WAS DIAGNOSED WITH ENDOMETRIOSIS. SHE ALSO REPORTED THAT SHE HAD A BLOOD CLOT ON THE LEFT TUBE AND SHE THINKS IT WAS ESSURE THAT WAS CAUSING HER TO HAVE ENDOMETRIOSIS. IN (B)(6) 2014 SHE WENT FOR A LAPAROSCOPIC SURGERY. THE DOCTOR WAS GOING TO CUT THE TUBES BUT HE COULD NOT GET THE COILS OUT. BOTH COILS STARTED TO POKE OUT THROUGH THE CERVIX, NOT SURE IF THEY WERE COMING OUT. SO, THE DOCTOR DECIDED FOR HYSTERECTOMY. ON (B)(6) 2014 SHE WAS HOSPITALIZED FOR HYSTERECTOMY AND HAD ESSURE REMOVED AND SHE WAS OK. SHE

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HAD REMOVED FALLOPIAN TUBES, UTERUS, AND BOTH ESSURE COILS, EXCEPT THE OVARIES. SHE HAD NO SIGNS AND SYMPTOMS OF INFECTION. SHE WAS STILL RECOVERING FROM THE PROCEDURE AT THE TIME OF THIS REPORT. HER SYMPTOMS/PAIN RESOLVED AFTER SURGERY. SHE BELIEVES THE CONDITION WAS CAUSED BY THE ESSURE BECAUSE SHE HAS NEVER HAD ANY PROBLEMS BEFORE. ALL OF THE SYMPTOMS STARTED AFTER ESSURE AND SHE WAS FEELING OK AFTER REMOVAL. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2014: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BOTH COILS STARTED TO POKE OUT THROUGH THE CERVIX, NOT SURE IF THEY WERE COMING OUT. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE, IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS INCIDENT SINCE A HYSTERECTOMY WAS PERFORMED AND ESSURE WAS REMOVED. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR IT WAS REPORTED THAT BOTH COILS STARTED TO POKE OUT THROUGH THE CERVIX, NOT SURE IF THEY WERE COMING OUT. THE EXACT DATE AND MECHANISM OF THIS REPORTED DEVICE EXPULSION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE IT WAS CONSIDERED AS RELATED TO ESSURE THERAPY. IN ADDITION OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-SEP-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00388	BAYER HEALTHCARE LLC	9/16/2014	9/16/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A15530

Single Use: Y
Implant Date (E6): 12/7/2012
Explant Date (E7): 7/31/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 21-AUG-2014 WHICH REFERS TO HERSELF. SHE IS A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012 FOR STERILIZATION. CONSUMER REPORTED THAT INITIALLY SHE SAID SHE WAS FINE AND SIX MONTHS AFTER PROCEDURE, (B)(6) 2013, SHE WENT FOR HSG (HYSTEROSALPINGOGRAM) TEST. SHE DID SAY THE DOCTOR HAD A DIFFICULT TIME INSERTING THE COIL ON THE RIGHT SIDE. HSG SHOWED THAT THE COIL ON RIGHT SIDE DID NOT WORK. DOCTOR SAID SHE COULD GET THE RIGHT SIDE DONE AGAIN AND SHE SAID, NO. CONSUMER WAS TOLD THAT SHE COULD GO FOR AN MRI (MAGNETIC RESONANCE IMAGING) BUT SHE SAID, NO. SHE WANTED HER TUBES TIED INSTEAD. SHE THEN DEVELOPED ALL KINDS OF PROBLEMS INCLUDING PAIN ON HER RIGHT SIDE. SHE READ ON THE INTERNET ABOUT THE PROBLEMS POSTED BY OTHER PEOPLE. SHE THEN THOUGHT HER PROBLEMS WERE RELATED TO ESSURE AND SHE WANTED THE METAL OUT. THREE WEEKS AGO, IN (B)(6) 2014, SHE HAD SURGERY AND THEY REMOVED HER FALLOPIAN TUBES. A BIOPSY SHOWED A COIL PRESENT IN THE LEFT TUBE AND NO COIL PRESENT IN THE RIGHT TUBE. SHE WAS WORRIED IT MIGHT BE IN HER BODY STILL BECAUSE THEY DID NOT LOCATE THE RIGHT COIL. WHEN ASKED, SHE HAD NO MEMORY OF THE COIL EXPELLING FROM HER BODY. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 27-AUG-2014 FROM CONSUMER. CONSUMER'S HEIGHT AND WEIGHT WERE PROVIDED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 29-AUG-2014. SHE DENIED ANY PREVIOUS GYNECOLOGICAL PROBLEM OR PROCEDURES, RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. ESSURE WAS NOT INSERTED AFTER A PREGNANCY. CONDOMS WERE USED AS BACK-UP CONTRACEPTION. ON UNSPECIFIED DATE, HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED THAT ONE TUBE WAS BLOCKED AND OTHER TUBE WAS NOT. AFTER DYE

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(HSG) TEST SHE STARTED EXPERIENCING ALL THE PREVIOUSLY REPORTED EVENTS. SHE WENT TO THE DOCTOR CONCERNING THOSE SYMPTOMS, BUT NO PARTICULAR DIAGNOSIS WAS PROVIDED. NO TREATMENT OR HOSPITALIZATION WAS REQUIRED. SHE STATED THAT SHE DOES NOT KNOW IF THE PAIN SHE EXPERIENCED WAS FROM THE SURGERY (TUBES CUT OFF ON (B)(6) 2014 AND ONE ESSURE COIL (LEFT) WAS REMOVED ALONG WITH TUBES, RIGHT COIL WAS NOT IN THE TUBE AND DID NOT KNOW ABOUT WHERE IT WAS) OR FROM BEFORE. ESSURE WAS REMOVED BY LAPAROSCOPY, THEY WENT THROUGH THE BELLY BUTTON AND PUT 3 HOLES. BIOPSY RESULTS OF THE FALLOPIAN TUBES SHOWED THERE WAS HEMORRHAGING. THERE WERE NO SIGNS AND SYMPTOMS OF INFECTION. SHE WAS STILL RECOVERING FROM PROCEDURE. THE INCISION GOT INFECTED AND THERE WAS A POCKET FORMED. SHE BELIEVES THE CONDITION WAS CAUSED BY ESSURE BECAUSE SHE NEVER HAD THOSE SYMPTOMS UNTIL ESSURE IMPLANTED. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE CASE REFERS ALSO TO A USABILITY ISSUE AND AN UNSPECIFIED LACK OF EFFICACY (COIL DID NOT WORK). HOWEVER, LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION. THE REFERRED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. CORRECTION 08-SEP-2014 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT INCISION GOT INFECTED AND THERE WAS A POCKET THAT FORMED WAS SPLIT AND RECODED TO INCISION SITE INFECTION (NON-SERIOUS) AND INCISION SITE ABSCESS (SERIOUS EVENT). FOLLOW-UP INFORMATION WAS RECEIVED ON 08-SEP-2014 VIA ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE. THIS CASE IS NOW MEDICALLY CONFIRMED. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS. MEDICAL HISTORY INCLUDED FIBROIDS SMALL AND RENAL CANCER. ON (B)(6) 2012 ESSURE LOT NUMBER A15530 WAS INSERTED. THE INSERTION WAS CONSIDERED DIFFICULT DUE TO DIFFICULT RELEASE OF DEVICE ON THE RIGHT SIDE. SHE WAS NOT ON POSTPARTUM STATE. ANALGESIA (NORCO, VALIUM) WAS APPLIED DURING INSERTION. CERVICAL DILATATION, SOUNDING AND GENERAL ANESTHESIA WERE NOT APPLIED DURING INSERTION. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. ON (B)(6) 2013 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED. CONDOMS WERE USED AS BACK-UP CONTRACEPTION. MRI PRIOR TO SALPINGECTOMY WAS OFFERED BUT THE PATIENT REFUSED. HOSPITALIZATION WAS NOT REQUIRED. THERE WAS NO CONDITION OTHER THAN DEVICE FAILURE ON THE RIGHT SIDE. ON (B)(6) 2014 LAPAROSCOPIC BILATERAL SALPINGECTOMY WAS PERFORMED. THE PATIENT REQUESTED THE REMOVAL BECAUSE SHE WAS WORRIED SHE WAS HAVING PAIN RELATED TO POSSIBLE PERFORATION ON THE RIGHT SIDE. THERE WERE NO PATHOLOGY RESULTS. DURING SURGERY IT WAS FOUND THAT LEFT WAS PRESENT IN TUBE WITH NO PERFORATION AND THERE WAS NO EVIDENCE OF THE OTHER ESSURE DEVICE IN THE TUBE OR ELSEWHERE. PATIENT HAS NOT BEEN SEEN FOR HER POST-OPERATIVE APPOINTMENT AND THEREFORE OUTCOME WAS NOT PROVIDED. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION AND EXPERIENCED PAIN ON HER

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RIGHT SIDE, BIOPSY SHOWED A COIL PRESENT IN THE LEFT TUBE AND NO COIL PRESENT IN THE RIGHT TUBE AND INCISION GOT INFECTED AND THERE WAS A POCKET THAT FORMED. ALL THE EVENTS WERE CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR INCISION GOT INFECTED AND THERE WAS A POCKET THAT FORMED WHICH IS UNLISTED. ABDOMINAL PAIN AND CRAMPING MAY OCCUR WITH ESSURE. PAIN MAY BE A MORE LIKELY OCCURRENCE DURING THE MENSTRUAL PERIOD, DURING AND AFTER SEXUAL INTERCOURSE OR WITH OTHER PHYSICAL ACTIVITY. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, PATIENT STATED THAT 6 MONTHS AFTER ESSURE INSERTION PROCEDURE, AT HSG (HYSTEROSALPINGOGRAM) TEST, IT WAS FOUND THAT COIL ON RIGHT SIDE DID NOT WORK AND SHE STARTED TO EXPERIENCE PAIN ON HER RIGHT SIDE. HER FALLOPIAN TUBES WERE REMOVED AND BIOPSY SHOWED A COIL PRESENT IN THE LEFT TUBE AND NO COIL PRESENT IN THE RIGHT. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND THE NATURE OF THE REPORTED EVENTS, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE INTERVENTION WAS REQUIRED (FALLOPIAN TUBES SURGICALLY REMOVED). AFTER THE INTERVENTION, THE INCISION GOT INFECTED AND THERE WAS A POCKET FORMED, THEREFORE, THIS EVENT WAS CONSIDERED RELATED TO ESSURE. ALSO, NON-SERIOUS EVENTS WERE REPORTED. AN INITIAL PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION. UPON RECEIPT OF FOLLOW-UP INFORMATION ESSURE LOT NUMBER WAS PROVIDED, AND THUS AN UPDATED PTC ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 22-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00383	BAYER HEALTHCARE LLC	9/16/2014	9/29/2014

Event Information:

Event Date (B3): 8/19/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B66016/B82477

Single Use: Y
Implant Date (E6): 8/19/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014. ADDITIONAL INFORMATION WAS RECEIVED ON (B)(4) 2014 WHICH CONFIRMED THAT THE ESSURE, LOT NUMBER B66016/B82477, WAS IMPLANTED ON (B)(6) 2014 FOR PERMANENT BIRTH CONTROL IN A (B)(6) FEMALE PATIENT AND THEREFORE THE INITIAL RECEIPT DATE OF THIS CASE WAS AMENDED FROM (B)(4) 2014. THE DOCTOR SAID THAT SHE HAD AN ISSUE WITH A DEPLOYMENT OF ESSURE ON THE RIGHT SIDE DURING A PROCEDURE. NO ISSUES WITH THE LEFT SIDE. BUT WITH THE RIGHT SIDE, SHE DID THE USUAL PROCESS AND THE INSERT WOULD NOT DEPLOY FROM CATHETER PROPERLY AND PROVIDER HAD TO RETRIEVE FROM FALLOPIAN TUBE. SO SHE REMOVED THE INSERTER AND THE COIL BUT THERE WAS A PLASTIC PIECE LEFT IN THE TUBE. SHE ATTEMPTED TO REMOVE WITH GRASPERS BUT IT KEPT BREAKING AND WAS UNABLE. THEY REMOVED THE BROKEN PIECES BUT THERE WAS STILL A SMALL PLASTIC PIECE FROM THE INSERT HANGING OUT THE TUBE. THEY TRIED TO REMOVE BUT IT IS STUCK. I REVIEWED THE PROCEDURE WITH HER AND ASKED HER IF SHE IS SURE THE DEVICE DID NOT DEPLOY. SHE EXAMINED THE END OF THE INSERT AND SAID IT LOOKS LIKE A COIL BUT NOT SURE. THE INSERTER WAS STRETCHED OUT AND UNCOILED. A FLAT PLATE X-RAY WAS PERFORMED AND THEY SEE THE FOUR MARKERS ON THE SIDE IN QUESTION (LEFT SIDE). THE LEFT SIDE COMPARED TO THE RIGHT SIDE WAS VERY SIMILAR. THERE WAS A TRAILING PIECE ON THE END OF THE BRIGHTEST MARKER. SHE SAID THAT THE COIL LOOKED AT FIRST LIKE IT WAS OVERLYING ON ITSELF, BUT THEN THEY CHECKED AT A DIFFERENT ANGLE AND IT LOOKED NORMAL. THE X-RAY CONFIRMED THAT THE INSERT WAS IN FACT DEPLOYED AND SHOULD EVAL IT AT 3 MONTHS HSG. THE PATIENT WAS ADVISED TO USE BACKUP CONTRACEPTION. PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER

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(B)(4) AND PTC GLOBAL NUMBER (B)(4) . FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, BREAKAGE OF THE LARGE TIGHT PITCH COIL, OR BREAKAGE OF A PORTION OF THE DELIVERY CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. THE "GREEN-COLORED" MATERIAL REPORTED IS VERY LIKELY THE GREEN HEAT-SHRINK (PET) TUBING WHICH IS A CATHETER ASSEMBLY COMPONENT LOCATED AT THE DISTAL END OF THE INNER CATHETER. AS OF 9/03/2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORDS AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THESE LOTS WERE PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE CASE REFERS ALSO TO A TECHNICAL DEFECT IN THE CONTEXT OF THE REPORTED COMPLICATED INSERTION. HOWEVER, THE REPORTED DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN (SEE TECHNICAL ASSESSMENT). ACCORDING TO THE TECHNICAL ASSESSMENT THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. 2 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B66016 (PRODUCTION DATE 28-AUG-2013, EXPIRATION DATE 31-AUG-2016), BOTH REFERRING TO SIMILAR ADVERSE TYPES OF EVENTS BUT NONE TO SIMILAR TECHNICAL TYPES OF EVENTS, THIS CASE REFERS ALSO TO SIMILAR ADVERSE AND TECHNICAL TYPES OF EVENTS. 2 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B82477 (PRODUCTION DATE 16-OCT-2013, EXPIRATION DATE 31-OCT-2016), BOTH REFERRING TO SIMILAR ADVERSE TYPES OF EVENTS BUT NONE TO SIMILAR TECHNICAL TYPES OF EVENTS, THIS

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CASE REFERS ALSO TO SIMILAR ADVERSE AND TECHNICAL TYPES OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH GAVE NO REASON TO SUSPECT A QUALITY DEFECT (SEE TECHNICAL STATEMENT). THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. FOLLOW-UP INFORMATION FROM 09-SEP-2014: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. FOLLOW-UP RECEIVED ON 09-SEP-2014: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT WHO IS OBESE AND HAS AS PREVIOUS GYNECOLOGICAL INTERVENTIONS A CERVICAL CONIZATION AND A CURETTAGE BOTH PERFORMED IN 1998, A SALPINGECTOMY ON THE LEFT DUE TO ECTOPIC WHICH WAS PERFORMED IN 1995, AND NO PREVIOUS IUS/IUD NOR MYOMECTOMY AND, HAS AS PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES, A CERVICAL DYSPLASIA AND A ECTOPIC PREGNANCY ON THE RIGHT; HAD ESSURE (MODEL ESS305, LOT NUMBER B66016) INSERTED. INSERTION WAS NOT PERFORMED POST-PARTUM AND NO CERVICAL DILATATION, SOUNDING, OR GENERAL ANESTHESIA WAS APPLIED DURING INSERTION. ANALGESIA WITH TORADOL WAS DONE. IN ADDITION PHYSICIAN STATES THAT THE INSERTION ON THE LEFT TUBE WAS VERY EASY, HOWEVER, THE RIGHT TUBE WAS DIFFICULT DUE TO TUBAL SPASM. THE VISUALIZATION OF TUBAL OSTIUM WAS DESCRIBED AS EASY BY HEALTH CARE PROFESSIONAL; THERE WAS NO LOSS MORE THAN 1500CC DURING HYSTEROSCOPY AND THE PROCEDURE TOOK 35 MINUTES. ON (B)(6) 2014 AN IMAGING TEST (FLUOROSCOPY) WAS PERFORMED AND SHOWED THAT MICRO-INSERT WAS NOT IN THE RIGHT TUBE AND ALSO RIGHT SIDE APPEARS TO BE PERFORATED. AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION PATIENT TOOK PROGESTIN ONLY ORAL CONTRACEPTIVE. NO HYSTEROSALPINGOGRAM WAS PERFORMED YET, THERE WAS NO SIGNAL OF INFECTION OR INFLAMMATION AND NO HOSPITALIZATION WAS REQUIRED. IN ADDITION PHYSICIAN HAS CONFIRMED THE EVENTS AND DETAILS AND REPORTED THAT A PERFORATION OCCURRED AND STATES THAT IT WAS ABSOLUTELY RELATED TO ESSURE DEVICE. NO TREATMENT WAS PROVIDED. REGARDING THE EVENTS, REPORTER SUSPECTS THAT ESSURE DEVICES CAUSED OR CONTRIBUTED TO THE ISSUE. THE REMOVAL WAS NOT PERFORMED AND IS NOT PLANNED AT THIS TIME. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND EXPERIENCED MICROINSERT NOT IN TUBE ON R/ FLUOROSCOPY APPEARS THAT RIGHT SIDE WAS PERFORATED, ATTEMPTED TO REMOVE PLASTIC BUT WAS UNABLE TO, IT KEPT BREAKING, INSERT DID NOT DEPLOY FROM CATHETER PROPERLY AND PROVIDER HAD TO RETRIEVE FROM FALLOPIAN, PLASTIC PIECE IN OSTIUM/ON X-RAY THE TRAILING PIECE ON THE END OF THE BRIGHTEST MARKER (COMPLICATION OF DEVICE INSERTION) AND FAILED INSERTION. THE FIRST TWO EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE, WHEREAS THE OTHER EVENTS WERE CONSIDERED NON-SERIOUS. ALL EVENTS ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT PLASTIC PIECE IN OSTIUM/ ON X-RAY THE TRAILING PIECE ON THE END OF THE BRIGHTEST MARKER WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE IT WAS REPORTED THAT INSERT DID NOT DEPLOY FROM CATHETER PROPERLY AND PROVIDER HAD TO RETRIEVE FROM FALLOPIAN TUBE. ONCE RETRIEVED, PROVIDER NOTICED A PLASTIC PIECE IN OSTIUM. AFTER FLAT PLATE X-RAY PERFORMED THE LEFT SIDE COMPARED TO THE RIGHT SIDE WAS VERY SIMILAR. ALTHOUGH THERE WAS A TRAILING PIECE ON THE END OF THE BRIGHTEST MARKER. LATER, IT WAS REPORTED THAT AN IMAGING TEST (FLUOROSCOPY) WAS PERFORMED AND SHOWED THAT MICRO-INSERT WAS NOT IN THE RIGHT TUBE AND ALSO RIGHT SIDE APPEARS TO BE PERFORATED. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE CANNOT BE EXCLUDED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. THE EVENT PLASTIC PIECE IN OSTIUM/ ON X-RAY THE TRAILING PIECE

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ON THE END OF THE BRIGHTEST MARKER, INTERPRETED AS A DEVICE BREAKAGE AND PREVIOUSLY CONSIDERED UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, WAS, UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) UPDATED TO LISTED (ANTICIPATED). FURTHER INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00384	BAYER HEALTHCARE LLC	9/16/2014	9/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97489

Single Use: Y
Implant Date (E6): 8/15/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER NON HEALTH CARE PROFESSIONAL AND FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT BIRTH CONTROL. ESSURE LOT NUMBER USED ON (B)(6) 2014 WAS B97489 WITH EXPIRATION DATE IN NOV.2016. THE HEALTH CARE PROFESSIONAL STATED MALFUNCTIONED, HE WENT TO DEPLOY THE COIL INTO THE OS (FALLOPIAN TUBE ORIFICIUM) AND WAS READY TO BACK OUT AND THE DEVICE CAME APART IN THERE. THE PHYSICIAN'S ASSISTANT WHO CALLED TO THE COMPANY DID NOT KNOW IF DEVICE BROKE IN THE PATIENT AS SHE WAS NOT IN THE ROOM. DEVICE WAS AVAILABLE FOR RETURN. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE

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INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, ADDITIONALLY A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED. THE REPORTED TECHNICAL DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN (SEE TECHNICAL ASSESSMENT). ONE FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B97489, THIS CASE REFERS ALSO TO SIMILAR ADVERSE TYPES OF EVENTS BUT NOT TO SIMILAR TECHNICAL TYPES OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH REVEALED NO REASON TO SUSPECT A QUALITY DEFICIT (SEE TECHNICAL STATEMENT). THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT." IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION FROM 10-SEP-2014: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MALFUNCTIONED, HE WENT TO DEPLOY THE COIL INTO THE OS AND WAS READY TO BACK OUT AND THE DEVICE CAME APART IN THERE. THIS EVENT WAS CONSIDERED NON-SERIOUS AND PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER, UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT THE BREAKAGE OCCURRED DURING INSERTION, HOWEVER THE REPORTER DID NOT KNOW IF THE DEVICE BROKE OFF IN PATIENT. CONSIDERING THE NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND THE REVIEW OF THE MANUFACTURING AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH

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REVEALED NO REASON TO SUSPECT A QUALITY DEFICIT. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT." NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00386	BAYER HEALTHCARE LLC	9/16/2014	9/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C76446

Single Use: Y
Implant Date (E6): 8/19/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT STERILIZATION WITH LOT NUMBER C76446. IT WAS REPORTED THAT HCP INSERTED COIL AND THE TIP OF THE "DEVICE" BROKE OFF AND WENT IN WITH COIL AND DID NOT COME BACK OUT. IT WAS ASKED IF SHE MEANT THE TIP OF THE CATHETER AND SHE WAS NOT SURE. SHE SAID THE TIP OF THE DEVICE WAS TANGLED IN THE COIL AND THE DOCTOR HAD TO REMOVE BOTH, THE TIP OF THE DEVICE AND THE COIL (COMPLICATION OF DEVICE INSERTION). PATIENT HAD BILATERAL PLACEMENT. FOLLOW-UP INFORMATION WAS RECEIVED ON 02-SEP-2014. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. CONCOMITANT CONDITION INCLUDED OVERWEIGHT (BMI (B)(6)). SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS. MEDICAL HISTORY INCLUDED CYSTITIS, AND VULVAR PRURITUS. CERVICAL DILATATION, ANALGESIA AND 10MG VALIUM WERE APPLIED DURING ESSURE INSERTION. GENERAL ANESTHESIA AND SOUNDING WERE DENIED. THE INSERTION WAS DIFFICULT BECAUSE THE DEVICE DID NOT DEPLOY PROPERLY UPON ROLLBACK. THE DEFECTIVE ESSURE WAS REMOVED BY HYSTEROSCOPY AND A NEW DEVICE WAS OPENED AND WAS SUCCESSFULLY IMPLANTED. HYSTERECTOMY OR SALPINGECTOMY WAS NOT NECESSARY. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY AND THE FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC. THE PROCEDURE TOOK 45 MINUTES. NO IMAGING TESTS WERE PERFORMED TO CONFIRM ESSURE PLACEMENT. OCPS (ORAL CONTRACEPTIVE PILLS) WERE USED AS BACK-UP CONTRACEPTION. HSG (HYSTEROSALPINGOGRAM) WAS SCHEDULED TO (B)(6) 2014. THE PHYSICIAN MEDICALLY CONFIRMED THE EVENTS. THERE WERE NO SIGNS OF INFECTION AND INFLAMMATION. HOSPITALIZATION WAS NOT REQUIRED. THE CONDITION WAS CAUSED BY ESSURE BECAUSE IT DID NOT DEPLOY

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PROPERLY. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 04-SEP-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (REPORTED TECHNICAL DEFECT AND REGARDED AS OTHER REPORTABLE INCIDENT). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE CASE REFERS ALSO TO A TECHNICAL DEFECT IN THE CONTEXT OF THE REPORTED COMPLICATED INSERTION. HOWEVER, THE REPORTED DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. THREE (3) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER C76446, OF WHICH 2 CASES REFER TO SIMILAR ADVERSE TYPES OF EVENTS BUT NONE TO SIMILAR TECHNICAL TYPES OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH GAVE NO REASON TO SUSPECT A QUALITY DEFECT (SEE TECHNICAL STATEMENT). THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT." IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) INSERTED AND TIP OF THE "DEVICE" BROKE OFF AND WENT IN WITH COIL AND DID NOT COME BACK OUT/TIP OF THE "DEVICE" WAS TANGLED IN THE COIL AND DOCTOR HAD TO REMOVE BOTH. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER, UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) IT WAS AMENDED TO LISTED (CONSIDERED AN ANTICIPATED EVENT). THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE IT WAS REPORTED THAT THE BREAKAGE OCCURRED DURING INSERTION. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS COMPLICATION OF DEVICE INSERTION AND DEVICE DID NOT DEPLOY PROPERLY UPON ROLLBACK WERE REPORTED. A PTC ANALYSIS WAS PERFORMED AND CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00387	BAYER HEALTHCARE LLC	9/16/2014	9/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B03097

Single Use: Y
Implant Date (E6): 8/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER B03097 FOR PERMANENT CONTRACEPTION. SHE WAS NOT PREGNANT AT TIME OF PROCEDURE. IT WAS REPORTED THAT HCP INSERTED AN ESSURE COIL BUT IT DID NOT DEPLOY CORRECTLY. SHE REMOVED COIL BUT A PIECE OF THE GREEN RELEASE WIRE STAYED IN PATIENT AT THE OSTIUM. SHE ATTEMPTED TO REMOVE IT BUT WAS UNABLE. BILATERAL PLACEMENT WITH OTHER COILS WAS SUCCESSFUL. FOLLOW-UP RECEIVED ON (B)(6) 2014: CASE (B)(6) WAS IDENTIFIED AS A DUPLICATE TO THIS CURRENT CASE, (B)(6) WILL BE DELETED FROM (B)(6) DATABASE AND ALL ITS INFORMATION WAS TRANSFERRED TO THIS CASE. NO NEW INFORMATION WAS PROVIDED FOR THIS CASE. FOLLOW-UP INFORMATION FROM (B)(6) 2014: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL

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THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, BREAKAGE OF THE LARGE TIGHT PITCH COIL, OR BREAKAGE OF A PORTION OF THE DELIVERY CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. THE "GREEN-COLORED" MATERIAL REPORTED IS VERY LIKELY THE GREEN HEAT-SHRINK (PET) TUBING WHICH IS A CATHETER ASSEMBLY COMPONENT LOCATED AT THE DISTAL END OF THE INNER CATHETER. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE CASE REFERS ALSO TO A TECHNICAL DEFECT IN THE CONTEXT OF THE REPORTED COMPLICATED INSERTION. HOWEVER, THE REPORTED DEFECT COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. ACCORDING TO THE TECHNICAL ASSESSMENT THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. NO VALID BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. ONE FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO INVALID BATCH NO. B03097, THIS CASE REFERS ALSO TO SIMILAR ADVERSE AND TECHNICAL TYPES OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH GAVE NO REASON TO SUSPECT A QUALITY DEFECT. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COIL DID NOT DEPLOY CORRECTLY; SHE REMOVED COIL BUT A PIECE OF THE GREEN RELEASE WIRE STAYED IN PATIENT AT THE OSTEUM (COMPLICATION OF DEVICE INSERTION) AND SHE ATTEMPTED TO REMOVE IT BUT WAS UNABLE. ALL THE EVENTS ARE CONSIDERED NON-SERIOUS. SHE REMOVED COIL BUT A PIECE OF THE GREEN RELEASE WIRE STAYED IN PATIENT AT THE OSTEUM (ASSUMED AS DEVICE BREAKAGE) WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE

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BREAKAGE. UPON RECEIPT OF TECHNICAL INVESTIGATION, THE EVENT SHE REMOVED COIL BUT A PIECE OF THE GREEN RELEASE WIRE STAYED IN PATIENT AT THE OSTEUM, INTERPRETED AS A DEVICE BREAKAGE WAS UPDATED TO LISTED (ANTICIPATED) WHILE THE REMAINING EVENTS ARE LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PRESENT CASE, HCP REPORTED THAT DURING ESSURE INSERTION COIL DID NOT DEPLOY CORRECTLY AND A PIECE OF THE GREEN RELEASE WIRE STAYED IN PATIENT AT THE OSTIUM. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED. THE PTC ANALYSIS STATED THAT THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT AND CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00389	BAYER HEALTHCARE LLC	9/17/2014	9/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71771

Single Use: Y
Implant Date (E6): 8/21/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. ESSURE LOT NUMBER USED, B71771. PHYSICIAN REPORTED THAT THE RIGHT ESSURE DEVICE WAS INSERTED AS INSTRUCTED/TYPICAL AND AS DEPLOYED THE COILS WERE NOT VISUALIZED AND ONLY A GREEN SHEATH AND A THIN METAL WIRE WAS NOTED. THE WIRE WAS STILL IN TUBE AND PULLED OUT. THE GREEN SHEATH WAS THEN REMOVED BY POLYP FORCEPS. PHYSICIAN STATED THAT WAS UNSURE IF COIL DEPLOYED OR WHERE IT DEPLOYED. THE RIGHT SIDE DIDN'T DEPLOYED CORRECTLY. PHYSICIAN REQUESTED A CHECK THAT IMPLANT ISN'T PRESENT. NO BILATERAL PLACEMENT ACHIEVED. CORRECTION PERFORMED ON (B)(6) 2014 REGARDING INITIAL REPORT FROM (B)(6) 2014: CASE UPGRADED FROM NON INCIDENT TO OTHER REPORTABLE INCIDENTS. THE INFORMATION REPORTED BY THE PHYSICIAN REGARDING ESSURE INSERTION PROCEDURE THAT THE WIRE PULLED OUT AND GREEN SHEATH REMOVED WITH POLYP FORCEPS WAS ADDED TO THE CASE AS AN EVENT. PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE

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MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, BREAKAGE OF THE LARGE TIGHT PITCH COIL, OR BREAKAGE OF A PORTION OF THE DELIVERY CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. THE "GREEN-COLORED" MATERIAL REPORTED IS VERY LIKELY THE GREEN HEAT-SHRINK (PET) TUBING WHICH IS A CATHETER ASSEMBLY COMPONENT LOCATED AT THE DISTAL END OF THE INNER CATHETER. AS OF (B)(6) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: IN THIS PARTICULAR CASE, A TECHNICAL DEFECT (BREAKAGE) WERE REPORTED TOGETHER WITH USABILITY ISSUES. NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT" (SEE TECHNICAL ASSESSMENT). THREE FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B71771 (PRODUCTION DATE (B)(4) 2013, EXPIRATION DATE 30-SEP-2016). HOWEVER, A BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS WAS NOT APPLICABLE AS NO ADVERSE EVENTS WERE REPORTED. NO CAUSAL RELATIONSHIP BETWEEN THE REPORTED DEFECT AND ADVERSE EVENTS CAN BE ASSESSED AS NO ADVERSE EVENTS WERE REPORTED. THE REFERRED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. FOLLOW-UP INFORMATION WAS RECEIVED ON 12-SEP-2014. IT WAS STATED THAT THE PATIENT WAS NOT INJURED. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED WIRE PULLED OUT AND GREEN SHEATH REMOVED WITH POLYP FORCEPS. CASE WAS UPGRADED FROM NON-INCIDENT TO OTHER REPORTABLE INCIDENT. THIS EVENT WIRE PULLED OUT AND GREEN SHEATH REMOVED WITH POLYP FORCEPS (INTERPRETED AS DEVICE BREAKAGE) WAS CONSIDERED AS NON-SERIOUS AND REGARDED AS OTHER REPORTABLE INCIDENT, AND IS LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENT ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED. OTHER NON-SERIOUS EVENTS WERE ALSO REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN

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UNCONFIRMED QUALITY DEFECT. NO CAUSAL RELATIONSHIP BETWEEN THE REPORTED DEFECT AND ADVERSE EVENTS CAN BE ASSESSED AS NO ADVERSE EVENTS WERE REPORTED. THE REFERRED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. THE EVENT WIRE PULLED OUT AND GREEN SHEATH REMOVED WITH POLYP FORCEPS, PREVIOUSLY CONSIDERED UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, WAS, UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) UPDATED TO LISTED (ANTICIPATED). NO FURTHER INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00390	BAYER HEALTHCARE LLC	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 6/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/18/2014
Explant Date (E7): 8/8/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5037057) IN UNITED STATES ON 15-AUG-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER REPORTED THAT SHE FOLLOWED HER DOCTOR'S OPINION AND ALLOWED HIM TO IMPLANT THE ESSURE, SIMPLY BECAUSE THEY STATED THERE WAS NO DOWN TIME, SHE WOULD BE ABLE TO RETURN TO WORK RIGHT AWAY. OVER A WEEK LATER AND SHE WAS BACK TO THE DOCTOR ALMOST EVERY OTHER DAY AND HE HAS MADE HER TAKE NUMEROUS TESTS AND PLACED HER ON VARIOUS ANTIBIOTICS AND SHE HAS STILL FELT HORRIBLE. HER BODY WAS WEAK; SHE HAD MIGRAINE HEADACHES WHICH SHE HAS NEVER HAD BEFORE. HER KNEE STARTED HURTING ON (B)(6) 2014, HER LOWER BACK AND FRONT OF HER STOMACH WAS IN SO MUCH PAIN THAT IT WAS HARD FOR HER TO SIT, DRIVE AND LAY DOWN FLAT. DISABILITY OR PERMANENT DAMAGE WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. ON (B)(6) 2014 SHE WENT TO HER DOCTOR PLEADING THAT SOMETHING WAS WRONG WITH THE ESSURE BECAUSE SHE WAS HEALTHY BEFORE AND HE STATED THAT HE NEEDED TO DO FURTHER TESTING BECAUSE THE SURGERY WENT WELL, AND ONLY OPTION SHE HAD WAS A HYSTERECTOMY. CONSUMER REPORTED THAT NOTHING WAS WRONG WITH HER FEMALE ORGANS AND BECAUSE FOLLOWING HIS ADVICE SHE HAD TO REMOVE THEM. SHE DID NOT GO IN HIS OFFICE FOR AN ESSURE AND HE RECOMMENDED SHE TIE HER TUBES AND CHOSE THAT PROCEDURE. FOLLOW-UP INFORMATION WAS RECEIVED ON 22-AUG-2014 VIA CONSUMER QUESTIONNAIRE. CASE WAS UPGRADED TO INCIDENT DUE TO LAPAROSCOPIC REMOVAL OF ESSURE AND TUBES. CONSUMER'S DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE CONSUMER. CONCOMITANT CONDITION INCLUDED OBESITY (BMI (B)(6)). SHE DENIED ANY PREVIOUS GYNECOLOGICAL PROBLEMS

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OR PROCEDURES, RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. ON (B)(6) 2014 ESSURE WAS IMPLANTED. SHE WAS ON POSTPARTUM STATE (HER SON WAS BORN IN (B)(6) 2014). THE NEXT DAY AFTER INSERTION SHE STARTED EXPERIENCING MIGRAINES, VISION WAS BLURRY, WEAKNESS, COULDN'T SIT DOWN, GAINED A LOT OF WEIGHT, BACK HURT, KNEE WAS SWOLLEN, STOMACH CRAMPS, BLED BLACK TAR MATERIAL. SHE WAS TREATED WITH PAIN KILLERS. NO HOSPITALIZATION WAS REQUIRED. BETWEEN (B)(6) 2014 SHE HAD A MILLION TESTS, X-RAYS, BLOOD WORK AND NONE OF THEM SHOWED ANYTHING TO HER KNOWLEDGE. HSG (HYSTEROSALPINGOGRAM) TEST WAS NOT PERFORMED. ON (B)(6) 2014 SHE UNDERWENT A LAPAROSCOPIC REMOVAL OF ESSURE AND TUBES. THE PHYSICIAN TOLD HER THAT ESSURE WAS IN THE TUBES AND WERE BOTH PULLED OUT. SHE RECOVERED FROM THE ESSURE REMOVAL PROCEDURE. SHE STATED THAT EVERYTHING STOPPED SINCE SHE HAD ESSURE REMOVED. SHE BELIEVES THE CONDITION WAS CAUSED BY THE ESSURE BECAUSE SHE FELT HORRIBLE WHILE SHE HAD THEM IN AND FELT MUCH BETTER SINCE THEY WERE REMOVED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 28-AUG-2014 VIA ESSURE HEALTH CARE PROVIDER UTERINE/TUBAL PERFORATION QUESTIONNAIRE (FROM PHYSICIAN WHO PERFORMED THE REMOVAL). THIS CASE IS NOW MEDICALLY CONFIRMED. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS. MEDICAL HISTORY INCLUDED ABNORMAL PAP. SHE HAD 04 PREGNANCIES, 03 LIVE BIRTHS AND 01 SPONTANEOUS ABORTION. SHE WAS NOT PREGNANT. NO IMAGING TESTS OR HSG (HYSTEROSALPINGOGRAM) WERE PERFORMED TO CONFIRM ESSURE PLACEMENT. ON UNSPECIFIED DATE SHE EXPERIENCED FATIGUE, JOINT PAIN AND CRAMPS. NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS PERFORATED. NO PERFORATION OCCURRED DURING SOUNDING, CERVICAL DILATION OR HYSTEROSCOPY PRIOR TO ESSURE INSERTION. ON (B)(6) 2014 ESSURE WAS REMOVED. BILATERAL SALPINGECTOMY WAS PERFORMED AND BOTH DEVICES WERE INTACT IN CORNEAL REGION. THERE WERE NO SIGNS AND SYMPTOMS OF INFECTION. THE REMOVAL WAS MEDICALLY NECESSARY AND THE PATIENT REQUESTED. THE PATIENT RECOVERED FROM THE ESSURE REMOVAL PROCEDURE AND THE SYMPTOMS/PAIN RESOLVED AFTER SURGERY. THE CONDITION WAS CAUSED BY ESSURE DEVICES BECAUSE APPARENT NICKEL ALLERGY WAS REPORTED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 08-SEP-2014 VIA PHYSICIAN'S QUESTIONNAIRE (FROM PHYSICIAN WHO PERFORMED THE INSERTION). SHE DENIED ANY PREVIOUS CERVICAL CONIZATION, PREVIOUS IUD/IUS, MYOMECTOMY AND ADNEXAL SURGERY. MEDICAL HISTORY INCLUDED 03 C-SECTIONS AND 01 SUCTION DC. ON (B)(6) 2014 THE PATIENT HAD PERIPHERAL BLOOD SMEAR THAT REVEALED SEVERE LEUKOPENIA SECONDARY TO NEUTROPENIA WITH NO CIRCULATION BLAST IDENTIFIED. ON (B)(6) 2014 ESSURE WAS EASILY IMPLANTED. ANALGESIA (IV SEDATION) WAS APPLIED DURING ESSURE INSERTION. CERVICAL DILATATION AND SOUNDING WERE DENIED. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE TOOK MORE THAN 20 MINUTES. IMAGING TESTS TO CONFIRM ESSURE PLACEMENT WERE NOT PERFORMED. DEPO WAS USED AS BACK-UP CONTRACEPTION. ON (B)(6) 2014 ABDOMINAL ULTRASOUND, PELVIC ULTRASOUND, X-RAY LUMBAR SPINE AND IUP (INTERPRETED AS INTRAUTERINE PESSARY) WERE PERFORMED AND SHOWED NORMAL LIMITS. HOSPITALIZATION WAS NOT REQUIRED. THE REPORTER DID NOT KNOW IF ESSURE WAS REMOVED OR REMOVAL WAS PLANNED BECAUSE PATIENT HAS FOLLOWED UP WITH ANOTHER DOCTOR. NO FURTHER INFORMATION WAS PROVIDED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-SEP-2014: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV

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DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE AND THE MAJORITY OF EVENTS WAS CONSIDERED AS UNRELATED TO THE PRODUCT BY COMPANY. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE AVAILABLE INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT RECEIVED VIA REGULATORY AUTHORITY REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED FRONT OF STOMACH WAS IN SO MUCH PAIN THAT IT WAS HARD FOR HER TO SIT, DRIVE AND LAY DOWN FLAT AND BLED BLACK TAR MATERIAL. EVENT FRONT OF STOMACH WAS IN SO MUCH PAIN THAT IT WAS HARD FOR HER TO SIT, DRIVE AND LAY DOWN FLAT IS SERIOUS DUE TO DISABILITY REPORTED AND IT IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GIVEN THE NATURE OF THIS EVENT, IT WAS ASSESSED AS UNRELATED TO ESSURE AND NON-INCIDENT. BLED BLACK TAR MATERIAL IS SERIOUS DUE TO MEDICAL SIGNIFICANCE, IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, AND WAS REGARDED AS INCIDENT SINCE INTERVENTION WAS REQUIRED (CONSUMER HAD A LAPAROSCOPIC REMOVAL OF THE TUBES). DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THE EVENT BLED BLACK TAR MATERIAL AND ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAIN (PTC) INVESTIGATION WAS PERFORMED AND ACCORDING TO INVESTIGATION RESULTS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED EVENTS AND A POTENTIAL PRODUCT QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED FOR THIS CASE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038229	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 1/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE PLACEMENT TO ESSURE IN (B)(6), I FELT TWINGES WHERE MY FALLOPIAN TUBES ARE. AT THE BEGINNING OF (B)(6), THE TWINGES TURNED INTO PAINS, UTERINE PAIN, LOWER BACK PAIN, CRAMPING, HEADACHES, AND BLOATING. MY AUTO-IMMUNE DISORDER HAS BEEN FLARING UP ALMOST DAILY NOW (BEFORE ESSURE I DIDN'T HAVE MANY FLAIR UPS).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038230	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). METALLIC TASTE IN THE MOUTH, CRAMPS WITHOUT MENSTRUAL PERIOD, FORGETFULNESS,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038231	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 2/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). VERY PAINFUL AND LONG PERIODS. INFLAMMATION IN ABDOMEN. RECURRING OVARIAN CYSTS, LOWER PELVIC AND LOWER BACK PAIN, CONSTANT BLOATING AND PAIN IN STOMACH, AND NAUSEA. ENDED UP HAVING TO HAVE HAD HYSTERECTOMY LEAVING ONLY TUBES (RIGHT NOW) TO GET MY LIFE BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038232	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 5/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INSERTION DAY. HAD PAIN FROM THE FIRST DAY, AS TO BE EXPECTED, BUT THIS PAIN NEVER REALLY WENT AWAY. SIDE EFFECTS BECAME PROGRESSIVELY WORSE UNTIL I HAD IT REMOVED IN (B)(6) OF 2013.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038233	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HEADACHES, NUMBNESS AND TINGLING, STABBING PAIN, HIVES, WEIGHT GAIN/LOSS, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038234	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 3/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5038234 #(B)(4). WANTED TO ADD THAT I'VE ALSO DEVELOPED OVARIAN CYSTS AND WAS DIAGNOSED WITH FIBROMYALGIA IN (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038235	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 2/6/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE BIRTH OF MY 4TH CHILD, I DECIDED IT TO GET A PERMANENT BIRTH CONTROL, AND MY DOCTOR RECOMMENDED ESSURE, IN 2007 ESSURE WAS PLACED, COUPLE MONTHS PAST AND I STARTED TO EXPERIENCE HEAVIER PERIODS THAT LASTED A WEEK AND MORE CRAMPS. SLOWLY A WEIGH GAIN AND LOWER BACK PAINS. A YEAR PASS, AND MORE SYMPTOMS STARTED TO APPEAR HEAD ACHES AND BODY ACHES MORE WEIGH GAIN. AS THE YEARS "WHEN" BY, MORE SYMPTOMS STARTED TO APPEAR BRAIN FOGS, FATIGUE, ACNE, FLAKY SKIN IN MY ELBOWS AND KNEES, MOOD SWINGS, DEPRESSION, JOINT AND MUSCLE PAIN, DIZZY SPELLS, STOMACH ISSUES, TENDER BREAST, PAINFUL INTERCOURSE, TOOTH DECAY, METAL TASTE IN MY MOUTH, DIABETES TYPE 2, HIGH BLOOD PRESSURE, PAIN IN MY ANKLES, SWELLING OF MY ANKLES, PAIN ON THE BOTTOM OF MY HEALS LIKE NEEDLES, TROUBLE FALLING ASLEEP, ALWAYS FEELING DRAINED DURING THE DAY, TIRED ALL THE TIME, AFTER DIFFERENT VISIT TO THE DOCTORS AND COULDN'T FIND THE ROOT OF MY POOR HEALTH AND COMPLAINTS, I STARTED TO DO SOME RESEARCH AND IN THE BEGINNING OF 2014, I CAME ACROSS A GROUP OF LADIES THAT SIMILAR HEALTH ISSUES, THOUSANDS OF LADIES AND THE ONLY THING WE HAD IN COMMON ITS THE ESSURE DEVICE CAME IN CONTACT WITH DOCTORS THAT LISTENED TO ME AND THEY WERE WILLING TO HELP ME FEEL BETTER IN (B)(6) 2014; THE DECISION WAS MADE THAT THE BEST OPTION FOR ME WAS HAVING A HYSTERECTOMY AND SAFELY REMOVE THE DEVICE ESSURE; THIS PROCEDURE WAS DONE IN (B)(6) 2014 DURING THE SURGERY, THE DOCTOR FOUND THAT MY FALLOPIAN TUBES HAD CYSTS IN THEM AND MY UTERUS WAS WEIGHTING 200 GRAMS WHEN A HEALTHY NORMAL UTERUS WEIGHTS 70 GRAMS. RIGHT AFTER I GOT OUT OF SURGERY THE PAIN ON MY ANKLES AND THE SWELLING INSTANTLY DISAPPEARED MY HIGH BLOOD PRESSURE STARTED TO BE IN THE NORMAL SIDE NOW THAT IT HAS BEEN A MONTH I FEEL MUCH BETTER AS MY SYMPTOMS KEEP DISAPPEARING, THE JOINT PAIN ITS GONE, THE CRAMPS ARE

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GONE AND I DON'T FEEL TIRED ALL THE TIME, I AM SLEEPING BETTER AND I CAN CONCENTRATE BETTER. ESSURE WAS A TOXIN IN MY BODY DEFINITELY, I AM SO HAPPY THAT THIS IS OUT OF MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038236	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 2/6/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE BIRTH OF MY 4TH CHILD I DECIDED IT TO GET A PERMANENT BIRTH CONTROL AND MY DOCTOR RECOMMENDED ESSURE. IN 2007 ESSURE WAS PLACED, COUPLE MONTHS PASSED AND I STARTED TO EXPERIENCE HEAVIER PERIODS THAT LASTED A WEEK, AND MORE CRAMPS. SLOWLY A WEIGHT GAIN AND LOWER BACK PAINS. A YEAR PASSED AND MORE SYMPTOMS STARTED TO APPEAR: HEAD ACHES AND BODY ACHES, MORE WEIGHT GAIN. AS THE YEARS WENT BY MORE SYMPTOMS STARTED TO APPEAR: BRAIN FOGS, FATIGUE, ACNE, FLAKY SKIN ON MY ELBOWS AND KNEES, MOOD SWINGS, DEPRESSION, JOINT AND MUSCLE PAIN, DIZZY SPELLS, STOMACH ISSUES, TENDER BREASTS, PAINFUL INTERCOURSE, TOOTH DECAY, METAL TASTE IN MY MOUTH, DIABETES TYPE 2, HIGH BLOOD PRESSURE, PAIN IN MY ANKLES, SWELLING OF MY ANKLES, PAIN ON THE BOTTOM OF MY HEELS LIKE NEEDLES, TROUBLE FALLING ASLEEP, ALWAYS FEELING DRAINED DURING THE DAY TIRED ALL THE TIME. AFTER DIFFERENT VISIT TO THE DOCTORS AND COULDN'T FIND THE ROOT OF MY POOR HEALTH AND COMPLAINTS, I STARTED TO DO SOME RESEARCH AND IN THE BEGINNING OF 2014 I CAME ACROSS A GROUP OF LADIES THAT HAD SIMILAR HEALTH ISSUES, THOUSANDS OF LADIES, AND THE ONLY THING WE HAD IN COMMON IS THE ESSURE DEVICE. CAME IN CONTACT WITH DOCTORS THAT LISTENED TO ME AND THEY WERE WILLING TO HELP ME FEEL BETTER. IN (B)(6) 2014 THE DECISION WAS MADE THAT THE BEST OPTION FOR ME WAS HAVING A HYSTERECTOMY AND TO SAFELY REMOVE THE ESSURE DEVICE. THIS PROCEDURE WAS DONE IN (B)(6) 2014 DURING THE SURGERY, THE DOCTOR FOUND THAT MY FALLOPIAN TUBES HAD CYSTS IN THEM AND MY UTERUS WAS WEIGHTING 200 GRAMS WHEN A HEALTHY NORMAL UTERUS WEIGHTS 70 GRAMS. RIGHT AFTER I GOT OUT OF SURGERY THE PAIN ON MY ANKLES AND THE SWELLING INSTANTLY DISAPPEARED, MY HIGH BLOOD PRESSURE STARTED TO BE IN THE NORMAL SIDE. NOW THAT IT HAS BEEN A MONTH I FEEL MUCH BETTER. AS MY SYMPTOMS KEEP DISAPPEARING THE JOINT

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PAIN IS GONE, THE CRAMPS ARE GONE, AND I DON'T FEEL TIRED ALL THE TIME. I AM SLEEPING BETTER AND I CAN CONCENTRATE BETTER. ESSURE WAS A TOXIN IN MY BODY. DEFINITELY I AM SO HAPPY THAT THIS IS OUT OF MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038237	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 6/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BACK PAIN, PELVIC PAIN, EXTREMELY HEAVY/FREQUENT PERIODS, FATIGUE, PAINFUL SEX, OVARIAN CYSTS, SWELLING/BLOATING, ECZEMA, HAIR LOSS, WEIGHT GAIN/INABILITY TO LOOSE, DIZZINESS, IRRITABILITY, FAINTING SPELLS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038238	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 8/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). MODERATE HAIR LOSS, JOINT PAIN, ABDOMINAL PAIN, RASHES, DRY ITCHY SKIN ALL OVER BODY, ABDOMINAL BLOATING, MIGRAINES,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038239	BAYER	9/19/2014	9/19/2014

Event Information:

Event Date (B3): 6/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5038239 #(B)(4) FOLLOW UP FROM HYSTERECTOMY.... ESSURE COIL WAS FOUND PERFORATED IN MY UTERUS(HALF IN AND HALF OUT). FRAGMENTS IN MY BLADDER AND SURROUNDING MY UTERUS. I WAS DIAGNOSED WITH ENDOMETRIOSIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038307	BAYER MEDICAL	9/19/2014	9/25/2014

Event Information:

Event Date (B3): 5/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE SYSTEM
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/30/2014
Explant Date (E7): 8/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

POSTPARTUM ESSURE PLACEMENT (UNEVENTFUL). DEVELOPED POLYARTHRALGIA. NO NICKEL ALLERGY. RHEUMATOLOGY CONSULT NEGATIVE HAD IMPLANTS REMOVED (B)(6) 2011. PT IMPROVED WITH REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038337	BAYER/CONCEPTUS INC	9/19/2014	9/26/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50512932

Single Use:
Implant Date (E6): 10/30/2011
Explant Date (E7): 9/3/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD SEVERE PELVIC PAIN AND BLEEDING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00391	BAYER HEALTHCARE LLC	9/19/2014	10/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06469

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PERFORMED ON (B)(6) 2014. THE PHYSICIAN ATTEMPTED TO INSERT THE DEVICE FOR PERMANENT BIRTH CONTROL, BUT IT WOULD NOT DISENGAGE EASILY FROM THE CATHETER AND UPON RELEASE, IT DISINTEGRATED/BROKE APART INTO FRAGMENTS. THE PROVIDER REMOVED THE PIECES WITH GRASPERS AND PLACED ANOTHER MICRO-INSERT. THE LOT NUMBER OF THE BROKEN ESSURE DEVICE WAS BC06469 (EXPIRATION DATE: DEC-2016). NO CAUSALITY ASSESSMENT WAS PROVIDED BY THE REPORTER. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE THE DEVICE WOULD NOT DISENGAGE EASILY FROM CATHETER AND UPON RELEASE DISINTEGRATED, BROKE APART INTO FRAGMENTS. THE EVENT UPON RELEASE DISINTEGRATED, BROKE APART INTO FRAGMENTS REGARDED AS A DEVICE BREAKAGE IS NON-SERIOUS, UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE, AND WAS CONSIDERED AN OTHER REPORTABLE INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE REMAINING EVENT IS NON-SERIOUS, LISTED AND NON-INCIDENT. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES DURING THE INSERT DEPLOYMENT AND STATED THAT ESSURE DISINTEGRATED/BROKE. A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR A TECHNICAL EVALUATION; HOWEVER CONSIDERING THAT THE REPORTED EVENTS OCCURRED DURING ESSURE PLACEMENT PROCEDURE; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. FOLLOW-UP INFORMATION IS BEING SOUGHT.

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Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 08-OCT-2014. THE BAYER REFERENCE NUMBER FOR THE (B)(4). LOT NUMBER WAS AMENDED TO C06469 (PRODUCTION DATE 18-DEC-2013; EXPIRATION DATE 31-DEC-2016). FINAL ASSESSMENT: WHEN

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00277	BAYER HEALTHCARE LLC	9/19/2014	10/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/29/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 06/16/2014 WHICH REFERS TO A (B)(6) FEMALE PT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. PHYSICIAN REPORTED THAT THERE WAS STILL A GOLD PIECE VISIBLE ON THE DEVICE IN SITU AND THIS WAS NOT IN KEEPING WITH THE OUTCOME EXPECTED AT THE END OF THE PROCEDURE, WHICH WENT AS PLANNED. PT UNDERWENT ESSURE HYSTEROSCOPIC STERILIZATION ON (B)(6) 2014. CANNULATION WAS UNCOMPLICATED AND CARRIED OUT IN THE USUAL WAY. THE PROCEDURE WAS SUCCESSFULLY COMPLETED ON HER RIGHT SIDE BUT ON THE LEFT THERE APPEARED TO BE A FAILURE OF EJECTION OF THE COIL SYSTEM. THE PROCEDURE WAS NOT DIFFERENT ON EITHER SIDE. A GOLD PIECE OF THE COIL DEVICE WAS STILL VISIBLE IN SITU ON THE LEFT-HAND SIDE. IT WAS PLANNED AN ABDOMINAL X-RAY TO BE PERFORMED IN 3 MONTHS AS PER PROTOCOL. (B)(4).

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 16-OCT-2014 FROM PHYSICIAN: ON (B)(6) 2014, THE PATIENT WENT TO PHYSICIAN`S OFFICE, THREE MONTHS AFTER NOVASURE ENDOMETRIAL ABLATION AND ESSURE STERILIZATION. A TECHNICAL ISSUE WITH THE ESSURE EQUIPMENT OCCURRED BUT AN X-

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038325	CONCEPTUS	9/21/2014	9/26/2014

Event Information:

Event Date (B3): 4/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/5/2013
Explant Date (E7): 7/29/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT ESSURE IN 2013 AND SINCE THEN HAVE HAD HORRIBLE PERIODS AND SHARP STABBING PAIN ON MY LEFT SIDE. I NOW HAVE VERY BAD ACNE THAT I NEVER HAD MY WHOLE LIFE. GAINED WEIGHT AND HAD VERY BAD MOOD SWINGS AND VERY BAD ANXIETY AND VAGINAL SMELL. ONCE REMOVED, I COULD TELL A BIG DIFFERENCE THAT SAME DAY. I NOW AM (B)(6) DEBT FROM HAVING TO TAKE CARE OF THIS ON MY OWN SO I COULD GET IT REMOVED PLUS TRAVEL AND PAIN AND SUFFERING IN MY FAMILY AND MARRIAGE. ESSURE NEEDS TO BE OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00393	BAYER HEALTHCARE LLC	9/22/2014	9/22/2014

Event Information:

Event Date (B3): 8/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/14/2014
Explant Date (E7): 8/20/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 25-AUG-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR STERILIZATION. ON (B)(6) 2014 THE PATIENT WENT TO PHYSICIAN'S OFFICE WITH PAIN/CONTINUED PAIN. AN ULTRASOUND WAS DONE THAT DAY AND THE ESSURE WAS IN THE RIGHT PLACE. THE PAIN CONTINUED SO THE ESSURE WAS REMOVED ON (B)(6) 2014. A BILATERAL TUBAL LIGATION WAS DONE. THE PATIENT HAD RECOVERED. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE LIMITED AVAILABLE INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED,

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SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN/CONTINUED PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IT IS LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. THIS CASE WAS REGARDED AS INCIDENT SINCE INTERVENTION WAS REQUIRED (PATIENT HAD ESSURE SURGICALLY REMOVED AND TUBAL LIGATION WAS PERFORMED). IN THIS PARTICULAR CASE, IT WAS REPORTED THAT THE PATIENT WENT TO PHYSICIAN'S OFFICE WITH PAIN/CONTINUED PAIN. AN ULTRASOUND WAS PERFORMED AND THE RESULT SHOWED ESSURE IN THE RIGHT PLACE. THE PAIN CONTINUED SO THE PATIENT WAS TAKEN TO THE OPERATING ROOM AND THE ESSURE WAS REMOVED. A BILATERAL TUBAL LIGATION WAS DONE. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND SINCE NO PRODUCT WAS RETURNED IT WAS NOT POSSIBLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. SINCE NO VALID LOT NUMBER WAS REPORTED, IT WAS NOT POSSIBLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEREFORE, IT WAS NOT POSSIBLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE LIMITED AVAILABLE INFORMATION. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 25-MAR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038352	BAYER	9/22/2014	9/29/2014

Event Information:

Event Date (B3): 6/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/21/2010
Explant Date (E7): 3/25/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RECEIVED ESSURE IN 2010, AND WAS NOT AWARE OF NICKLE IN PRODUCT BEFORE OR AT THE TIME OF INSERTION. A FEW MONTHS AFTER I RECEIVED ESSURE I STARTED HAVING BAD CRAMPS WITH PERIODS, I WAS BLEEDING FOR WEEKS AT A TIME. I GOT OVARIAN CYSTS FROM THIS AND ALSO HAD TO EVENTUALLY GET A HYSTERECTOMY IN (B)(6) 2013 TO REMOVE ESSURE FROM MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038353	BAYER	9/22/2014	9/29/2014

Event Information:

Event Date (B3): 9/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DX WITH MS IN 1997, I STARTED AVONEX (MS THERAPY DRUG) WITH SUCCESS AND NO RELAPSE FOR THE NEXT 5 YEARS UNTIL MY DAUGHTER WAS BORN. IN (B)(6) 2003, I HAD ESSURE PLACED WITH SUCCESS AT THE TIME. A COUPLE MONTHS LATER I HAD SEVERE PAIN IN WHICH THE DOCTOR TOOK A SONOGRAM, REPORTING I HAD MY LEFT OVARY FULL OF BENIGN CYSTS, NOT TO WORRY, SENT ME ON MY WAY WITH A SCRIPT FOR PAIN PILLS. I LEARNED TO STAY HOME WHEN BLEEDING SEVERELY AND CRAMPING AS IT WOULD PASS FOR THE MOST PART AFTER PERIOD. I MAY MENTION NO TEST FOR NICKEL, NO SERIAL NUMBERS GIVEN AND I WAS NOT TOLD OF THE INFLAMMATORY PROPERTIES, ONLY THAT SCAR TISSUE WOULD BLOCK THE TUBES. AND THIS DID. THE YEAR THAT FOLLOWED BROUGHT MANY SYMPTOMS I ATTRIBUTED TO MS, AND NEEDED THE USE OF A CANE. FIVE YEARS AFTER ESSURE, I STOPPED DRIVING. EIGHT YEARS LATER I NEEDED WHEELCHAIR 24/7 AND 10 LATER I CAN NO LONGER STAND. I HAVE SEVERE BLOATING AND WEIGHT GAIN, WHICH BEING WHEELCHAIR BOUND IS AN ISSUE. I AM CURRENTLY RECEIVING TREATMENT FOR (B)(6) TESTS AND WILL PURSUE FURTHER TREATMENT FOR PAIN. ALL THE OTHER SIDE EFFECTS PEOPLE HAVE COMPLAINED OF, I ALSO HAVE..BUT PALE IN COMPARISON TO WHAT I DEAL WITH PHYSICALLY TRYING TO GET AROUND. I AM DISAPPOINTED AND ANGRY THE ORIGINAL DOCTOR NEVER SHARED THE IMPORTANT INFO REGARDING THE SPECIFIC MATERIALS USED AND POSSIBLE REACTIONS. HAD I BEEN GIVE MORE INFO, I WOULD HAVE POSSIBLY MADE OTHER CHOICES AND DEFINITELY CONSULTED MY NEUROLOGIST, AS HE KNEW NOTHING OF THIS. IN THE THOUGHT THE AVONEX HAD FAILED ME AT THIS POINT, WE SWITCHED TO REBIF FOR SEVERAL YEARS WITH NO SUCCESS. TWO YEARS AGO, WE ARE TRYING TECFIDERA (AN ORAL DRUG) IN THE HOPE THIS WILL HELP. I HAD OVER THE YEARS TRIED IV STEROIDS TO NO AVAIL AND EVEN AN IM SHOT 5X IN A WEEK OF AMPERA, WITH NO SUCCESS. THE NEUROLOGIST CONCURS THAT THE USE OF ANTI INFLAMMATORY IN MY BODY HAD NO EFFECT

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POSSIBLY BECAUSE OF AN INFLAMMATORY DEVICE IN MY BODY. I WAS #12 IN MY AREA TO HAVE THIS DONE AND JUST IN THE PAST YEAR HAVE BEEN MADE AWARE OF THE CORRELATION TO AUTO IMMUNE DISEASE AND ESSURE. I AM FURTHER DISAPPOINTED TO SPEAK TO A DOCTOR IN MY AREA THAT DENIED THE USE OF PET FIBERS IN ESSURE, ALTOGETHER. HE HAS PLACED THE DEVICE IN WOMEN AND DOESN'T EVEN KNOW... A PROBLEM I THINK I WAS VICTIM TO. I URGE THE FDA TO MAKE IT KNOWN. MY STORY IS STILL BEING TOLD AT THIS POINT. (B)(6).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00392	BAYER HEALTHCARE LLC	9/22/2014	10/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN STATED THAT DURING THE PROCEDURE, A SEGMENT OF COILS CAME OFF FROM THE RIGHT DEVICE. THERE WAS OTHERWISE NO DIFFICULTY, NO OBVIOUS PERFORATION. TWO COILS WERE SEEN ON THE RIGHT AND THREE ON THE LEFT. SHE COULDN'T COME FOR A HYSTEROSALPINGOGRAM, THEN A X-RAY WAS PERFORMED FIRST. PHYSICIAN WAS ADVISED BY OTHER PHYSICIAN THAT THE CENTRAL STAINLESS STEEL PART WITH THE NITINOL WAS SEEN IN THE X-RAY, THE PART OF THE COILS CAME OUT AND THE CONNECTION DID NOT WORK PROPERLY. REPORTER STATED THAT WILL TRY AND GET PATIENT IN FOR A HYSTEROSALPINGOGRAM NOW, AS SHE WAS CONCERNED ABOUT THE RIGHT DEVICE. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, A SEGMENT OF THE COILS CAME OFF FROM THE RIGHT DEVICE. THE REPORTED EVENT IS NON-SERIOUS, UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, IT WAS REPORTED THAT DURING THE INSERTION PROCEDURE, A SEGMENT OF COILS CAME OFF FROM THE RIGHT DEVICE. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT, IT WAS CONSIDERED AS RELATED TO ESSURE. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW UP INFORMATION HAVE BEEN REQUESTED.

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Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 24-SEP-2014. NO NEW CLINICAL INFORMATION. FOLLOW-UP INFORMATION RECEIVED ON 14-OCT-2014. THE PATIENT´S INITIALS AND DATE OF BIRTH WERE UPDATED. HER ETHNICITY WAS CAUCASIAN. IT WAS REPORTED THAT A SHORT SEGMENT OF COILS WE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00394	BAYER HEALTHCARE LLC	9/23/2014	9/23/2014

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** AS

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014 (APPROXIMATELY 8 WEEKS BEFORE THIS REPORT). THE PATIENT COMPLAINED OF RIGHT-SIDED ABDOMINAL PAIN INITIALLY. THE PATIENT HAD ENDOMETRIOSIS SO IT WAS DIFFICULT TO EXACTLY CONCLUDE THE CAUSE OF THE PAIN. IN (B)(6) 2014, AN IMAGING INTENSIFIED SCAN SHOWED THAT THE ESSURE HAS MIGRATED AND WAS SITTING UNDER THE DIAPHRAGM. THEY COULD NOT SEE IT LAPAROSCOPICALLY SO THE PHYSICIAN BELIEVED THAT THEY WOULD NOT BE ABLE TO REMOVE THE ESSURE VIA LAPAROTOMY OR LAPAROSCOPY. AT TIME OF THIS REPORT, THE PATIENT WAS NOT EXPERIENCING ANY OTHER ADVERSE EVENTS. THE PHYSICIAN WOULD LIKE TO KNOW IF IT IS OK TO LEAVE THE ESSURE THERE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE(FALLOPIAN TUBE OCCLUSION INSERT)INSERTED AND EXPERIENCED ESSURE HAS MIGRATED AND IS NOW LODGED UNDER THE PATIENTS DIAPHRAGM. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS INCIDENT SINCE INTERVENTION WAS REQUIRED (PATIENT HAD A LAPAROSCOPY PERFORMED IN WHICH THEY COULD NOT SEE THE ESSURE). DURING ESSURE MICRO-INSERT WEARING THERE IS A RISK THAT THE INSERT COULD MOVE OUT OF THE FALLOPIAN TUBES. THIS MOVEMENT COULD BE EXPULSION (MOVEMENT OUT OF THE FALLOPIAN TUBE AND INTO THE UTERINE CAVITY/CERVIX/VAGINA OR OUT OF THE BODY) OR MIGRATION (MOVEMENT TO THE DISTAL FALLOPIAN TUBE OR OUT OF THE FALLOPIAN TUBE AND INTO THE PERITONEAL CAVITY). IN THIS PARTICULAR CASE, IT WAS REPORTED THAT ESSURE HAS MIGRATED AND IS NOW LODGED UNDER THE PATIENT´S DIAPHRAGM. THUS, GIVEN THE NATURE OF THE REPORTED EVENT, IT

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WAS CONSIDERED RELATED TO ESSURE. ALSO, NON-SERIOUS EVENT ABDOMINAL PAIN WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW UP INFORMATION WERE REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00396	BAYER HEALTHCARE LLC	9/23/2014	9/23/2014

Event Information:

Event Date (B3): 8/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATES THAT ESSURE CAUSED EXTREME SIDE EFFECTS. SHE EXPERIENCED CRAMPING, SHARP/STABBING PELVIC PAIN, ABNORMAL MENSES, BACTERIAL VAGINOSIS, CONSTANT SPOTTING, DISCHARGE, HYDROSALPINX (FLUID IN THE FALLOPIAN TUBES), EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), PAINFUL OVULATION (MITTELSCHMERZ), NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS (DYSMENORRHEA), PAINFUL INTERCOURSE (DYSPAREUNIA), BLEEDING BETWEEN PERIODS (METRORRHAGIA), INCONTINENCE, LONG MENSTRUAL CYCLES (POLYMENORRHEA), YEAST INFECTIONS (CANDIDA), URGENT/FREQUENT URINATION, UTI (URINARY TRACT INFECTION), BLADDER INFECTION, ITCHING, BURNING, STINGING AND STABBING OF VAGINAL ENTRANCE (VULVODYNIA, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/TWITCHING/FLUTTERING, BACK, JOINT/HIP, LEG, NECK AND SPINE PAIN, CHRONIC PELVIC PAIN, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, HEADACHES, BRAIN SHOCKS, DIMINISHED BRAIN FUNCTION / BRAIN FOG - CLOUDINESS, FORGETFULNESS, CONFUSION, SHORT TERM MEMORY LOSS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, ANEMIA, IRON DEFICIENCY, LOW FERRITIN, UNEXPLAINED/EASILY BRUISING, ELEVATED BLOOD COUNTS, CYSTS, BOILS, ACNE, SKIN IRRITATION, SKIN ITCHING, HEART PALPITATIONS, COIL MIGRATIONS / COILS BECOMING EMBEDDED IN OTHER TISSUES/ORGANS, SWELLING OF LEGS OR FEET, HAIR LOSS, HAIR CHANGES, HAIR GROWTH IN NEW PLACES, DENTAL ISSUES, INSOMNIA, WEIGHT ISSUES (GAIN), ADHESIONS (SCAR TISSUE IN ABDOMEN), VISION PROBLEMS (BLURRED VISION, FLOATERS, DECREASED VISION), EXCESSIVE SWEATING, DRY SKIN, DRY HAIR AND DRY EYES. IN ADDITION CONSUMER REPORTED THAT

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DEVICE IS PARTIALLY STILL IN UTERUS (PARTS REMOVED). CONSUMER REPORTED THAT ESSURE CAUSED EXTREME SIDE EFFECTS RESULTING IN REMOVAL OF HER FALLOPIAN TUBES AND NOW INVESTIGATING FURTHER SURGERY TO REMOVE UTERUS. SHE ALSO INFORMED THAT THE EVENTS HAPPENED ON (B)(6) 2010 AND STATES THAT ESSURE IS PARTIALLY STILL IN UTERUS (PARTS REMOVED). IN ADDITION, A SERIOUS INJURY WAS REPORTED; HOWEVER IT WAS NOT SPECIFIED FOR WHICH EVENT IT REFERS. CONSENT FOR CONTACT WAS DENIED. COMPANY CAUSALITY COMMENT: THIS NOT MEDICALLY CONFIRMED REPORT, RECEIVED VIA REGULATORY AUTHORITY, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED COIL MIGRATIONS / COILS BECOMING EMBEDDED IN OTHER TISSUES, ORGANS, HYDROSALPINX (FLUID IN THE FALLOPIAN TUBES) AND UTI (URINARY TRACT INFECTION). COIL MIGRATIONS / COILS BECOMING EMBEDDED IN OTHER TISSUES, ORGANS IS SERIOUS AS MEDICALLY SIGNIFICANT AND LISTED EVENT ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN EVENT AND ESSURE CANNOT BE EXCLUDED. IT WAS REPORTED THAT CONSUMER HAD A REMOVAL OF HER FALLOPIAN TUBES. EVEN THOUGH THE EXACT CAUSE FOR THIS PROCEDURE IS UNCLEAR, THIS CASE WAS REGARDED AS INCIDENT. HYDROSALPINX (FLUID IN THE FALLOPIAN TUBES) IS SERIOUS AND LISTED EVENT. DUE TO THE LACK OF INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND ESSURE CANNOT BE FULLY ASSESSED. UTI (URINARY TRACT INFECTION) IS SERIOUS AND UNLISTED EVENT FOR ESSURE. URINARY TRACT INFECTION IS ONE OF THE MOST COMMON INFECTIONS IN ALL AGE GROUPS OF WOMEN. DUE TO ITS WELL KNOWN PATHOPHYSIOLOGY, IT CAN BE CONSIDERED UNRELATED TO ESSURE. SEVERAL NON-SERIOUS EVENTS WERE REPORTED. CONSENT FOR CONTACT WAS DENIED. PTC ASSESSMENT IS AWAITED.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 26-SEP-2014: FINAL ASSESSMENT: THE COMPLAINT NARRATIVE INDICATED THE DEVICE WAS "PARTIALLY STILL IN UTERUS - PARTS REMOVED WITH (B)(6) HOSPITAL". IT IS UNCLEAR FROM THIS DE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00395	BAYER HEALTHCARE LLC	9/23/2014	10/2/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION IN (B)(6) 2014. THE PATIENT HAD A BMI OF (B)(6). SHE REPORTED AN ABNORMAL ABDOMINAL PAIN UP TO 4 WEEKS AFTER THE PROCEDURE. SHE WAS SEEN BY HER PHYSICIAN AND AN ULTRASOUND WAS PERFORMED, BUT THE RESULTS WERE INCONCLUSIVE. A CT SCAN WAS PERFORMED THEN AND THE RESULTS INDICATED THAT ESSURE SEEMS TO BE SPLIT DOWN MIDDLE. HALF OF THE COILS HAVE MIGRATED TOWARD THE SMALL BOWEL AND THE OTHER HALF NEAR HER RIGHT OVARY. NO CAUSALITY ASSESSMENT WAS PROVIDED BY THE REPORTER. FOLLOW-UP RECEIVED ON 10-SEP-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (REPORTED PRODUCT QUALITY ISSUE, BREAKAGE). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY

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ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: IN THIS PARTICULAR CASE, A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED TOGETHER WITH ADVERSE EVENTS. NO BATCH NUMBER WAS REPORTED. NO COMPLAINT SAMPLE WAS PROVIDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT" (SEE TECHNICAL ASSESSMENT). THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABNORMAL ABDOMINAL PAIN UP TO 4 WEEKS AFTER THE PROCEDURE, THEN A CT SCAN WAS PERFORMED AND INDICATED THAT HALF OF THE COILS HAVE MIGRATED TOWARD THE SMALL BOWEL AND THE OTHER HALF NEAR HER RIGHT OVARY (INTERPRETED AS DEVICE DISLOCATION); IT LOOKED LIKE ESSURE WAS SPLIT DOWN MIDDLE. THE REPORTED DEVICE DISLOCATION WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE, WHILE THE REMAINING EVENTS WERE NON-SERIOUS. THE EVENT LOOKS LIKE ESSURE IS SPLIT DOWN MIDDLE INTERPRETED AS DEVICE BREAKAGE, WAS CONSIDERED NON-SERIOUS; REGARDED AS OTHER REPORTABLE INCIDENT AND INITIALLY CONSIDERED AS UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) IT WAS AMENDED TO LISTED, SINCE PTC ANALYSIS CONCLUDED THAT THE BREAKAGE IS AN ANTICIPATED EVENT. THE OTHER EVENTS ARE LISTED. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE CT SCAN RESULTS INDICATED A DEVICE BREAKAGE AND DISLOCATION TO ABDOMINAL CAVITY, BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED. A PTC ANALYSIS WAS PERFORMED AND CONCLUDED THAT THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT

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INDICATIVE OF A QUALITY DEFICIT PER SE. PTC MEDICAL ASSESSMENT CONSIDERED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 26-JAN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN T

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00397	BAYER HEALTHCARE LLC	9/23/2014	10/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06497

Single Use: Y
Implant Date (E6): 8/26/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT ((B)(6)-YEAR-OLD) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT BIRTH CONTROL, WITH LOT NUMBER C06497. THE PHYSICIAN DESCRIBED THAT THE SCOPE WOULD NOT ROLL BACK. THE SALES REPRESENTATIVE ADVISED THE PHYSICIAN TO PULL IT OUT, AND THE DEVICE GOT CAUGHT IN THE OSTIA AND UNRAVELED. THE MAJORITY OF THE DEVICE WAS ABLE TO BE CUT OUT, BUT A FEW COILS REMAINED IN THE PATIENT. THE PHYSICIAN PERFORMED A HYDROTHERMAL ABLATION POST PROCEDURE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEARS-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE SCOPE WOULD NOT ROLL BACK AND THE REP ADVISED THE HCP TO PULL OUT, THE DEVICE GOT CAUGHT IN THE OSTIA AND UNRAVELED (COMPLICATION OF DEVICE INSERTION), THEN MAJORITY OF THE DEVICE WAS ABLE TO BE CUT OUT, BUT A FEW COILS REMAINED IN THE PATIENT. THE REPORTED EVENTS INTERPRETED AS DEVICE DEPLOYMENT ISSUE, SHAPE ALTERATION AND DEVICE MISUSE (PHYSICIAN CUT THE INSERT) WERE CONSIDERED NON-SERIOUS AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR DEVICE GOT CAUGHT IN THE OSTIA AND UNRAVELED WHICH IS UNLISTED. THIS CASE WAS REGARDED AS AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THESE EVENTS DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. IN THIS PARTICULAR CASE, A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THE EVENTS, HOWEVER, CONSIDERING THAT THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED (WITH EXCEPTION OF THE REPORTED MISUSE, WHICH DUE

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TO ITS NATURE WAS CONSIDERED AS UNRELATED TO ESSURE). ADDITIONALLY IT WAS REPORTED THAT PHYSICIAN PERFORMED A HYDROTHERMAL ABLATION POST PROCEDURE. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-MAR-2015. PTC GLOBAL NUMBER (B)(4). BATCH C06497 WAS IDENTIFIED AS INVALID BATCH NUMBER. FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00398	BAYER HEALTHCARE LLC	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 7/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26957

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DELIVERY CATHETER DEFECTIVE, IMPLANT REMAINED CLUNG ON FALLOPIAN TUBE AND IMPLANT BROKE (COMPLICATION OF DEVICE INSERTION). ON AN UNSPECIFIED DATE THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH LOT NUMBER C26957. THE REPORTER STATED THAT DELIVERY CATHETER WAS DEFECTIVE. IMPLANT REMAINED CLUNG TO THE FALLOPIAN TUBE AND BROKE. IMPLANT WAS PLACED ANYWAY AND BILATERAL INSERTION WAS DONE. FOLLOW-UP INFORMATION RECEIVED FROM THE PHARMACIST ON (B)(4) 2014. THIS CASE WAS UPGRADED TO INCIDENT DUE TO SURGERY. PATIENT'S INITIALS AND DATE OF BIRTH WAS PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. MEDICAL HISTORY INCLUDED DELIVERY FROM BELOW (1999 AND 2013), ABORTION WITH NO CURETTAGE, ELECTIVE ABORTION WITH CURETTAGE IN 2004. HOSPITALIZATION REPORT ON (B)(6) 2014 SHOWED THAT AT THE TIME OF THE REPORT, THE PATIENT WAS UNDER (B)(4) (DESOGESTREL) FOR CONTRACEPTION. INTERVENTION WAS UNDER PRE-MEDICATION WITH NON-STEROID ANTI-INFLAMMATORY +PARACETAMOL + HYDROXYZINE. HYSTEROSCOPE WAS INTRODUCED WITHOUT ANY DIFFICULTY. CERVIX ASPECT WAS NORMAL; THERE WAS NO PARTICULARITY ON CERVICO-ISTHMIC OUTLET. NORMAL ASPECT OF THE CAVITY AND NORMAL ASPECT OF ENDOMETRIUM WAS REPORTED. RIGHT AND LEFT TUBAL OSTIUM WAS NORMAL. CATHETER WAS INTRODUCED WITHOUT DIFFICULTY IN RIGHT FALLOPIAN TUBE. IT WAS IMPOSSIBLE TO REMOVE THE SHEATH OF THE CATHETER WHICH WAS CARRYING IMPLANT. IT WAS DECIDED TO REMOVE THE IMPLANT BUT THIS ACTION LEAD TO THE IMPLANT DEPLOYMENT AND IMPLANT BROKE. IMPLANT WAS REMOVED WITH GRASPING FORCEPS AND IMPLANT BROKE UP. DUE TO IMPORTANT PAIN EPISODES, A PART OF THE IMPLANT REMAINED IN PLACE. SO, IT WAS DECIDED

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TO NOT FIT THE CONTRALATERAL IMPLANT AND TO PERFORM LAPAROSCOPY IN ORDER TO REMOVE THE REMAINING PART OF THE IMPLANT AND TO PERFORM FALLOPIAN TUBE STERILIZATION. IMPLANTS WERE SENT FOR (B)(4). PROCEDURE DURATION WAS 15 MINUTES. ACCORDING TO AMBULATORY HOSPITALIZATION REPORT ON (B)(6) 2014, LAPAROSCOPY FOR LEFT FALLOPIAN TUBE STERILIZATION AND RIGHT SALPINGECTOMY WAS PERFORMED AND REMOVAL OF ESSURE PART ON RIGHT. TUBAL STERILIZATION BY LEFT ISTHMIC CUNEIFORM RESECTION WAS DONE. NO FURTHER INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED IMPLANT BROKE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, IT WAS REPORTED THAT IT WAS IMPOSSIBLE TO REMOVE THE SHEATH OF THE CATHETER WHICH WAS CARRYING IMPLANT. IT WAS DECIDED TO REMOVE THE IMPLANT BUT THIS ACTION LEAD TO THE IMPLANT DEPLOYMENT AND IMPLANT BROKE. THEREFORE, GIVEN THE NATURE OF THE EVENT IMPLANT BROKE, IT WAS CONSIDERED RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE INTERVENTION WAS REQUIRED (LAPAROSCOPY WAS PERFORMED IN ORDER TO REMOVE THE REMAINING PART OF THE IMPLANT). ALSO, NON-SERIOUS EVENTS WERE REPORTED: DELIVERY CATHETER DEFECTIVE, IMPLANT REMAINED CLUNG TO THE FALLOPIAN TUBE, PAIN EPISODES, DEVICE REMOVAL FAILED, AND DEVICE INSERTION FAILED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 25-SEP-2014: FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00400	BAYER HEALTHCARE LLC	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 8/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/7/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 28-AUG-2014 WHICH REFERS TO A FEMALE PATIENT (UNSPECIFIED AGE) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD THE FOLLOWING EVENTS. ON (B)(6)-2014, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6)-2014 THE PATIENT EXPERIENCED PATIENT HAD A 2 ½ LITER FLUID DEFICIT DURING ESSURE INSERTION AND THEREFORE THE PATIENT WAS HOSPITALIZED, HCP WAS PULLING THE DEVICE OUT OF THE PATIENT, AND IT HAD BROKEN INTO PIECES, AND HCP HAVING ISSUES WITH DEVICE DURING INSERTION. THE PHYSICIAN PULL ESSURE DEVICE OUT OF THE PATIENT, BECAUSE IT HAD BROKEN INTO PIECES. ALL OF THE PIECES WERE REMOVED FROM THE PATIENT AND A SECOND DEVICE WAS PLACED SUCCESSFULLY. THE PATIENT WAS ADMITTED TO THE HOSPITAL OVERNIGHT, DUE TO A 2 AND HALF LITER FLUID DEFICIT, OBSERVED AND RELEASED THE NEXT DAY. FOLLOW-UP RECEIVED ON 04-SEP-2014: SALES REPRESENTATIVE COULD NOT PROVIDE FURTHER INFORMATION ABOUT THE PATIENT BECAUSE ALL HE/SHE HEARD WAS A CONVERSATION WITH IN A CONVERSATION. THE PHYSICIAN WAS HAVING A CONVERSATION WITH THE SALES REPRESENTATIVE (THIS PHYSICIAN DID NOT HAVE ANY INFORMATION ABOUT THE PATIENT AND HE WAS NOT THE OPERATING DOCTOR) AND MENTIONED THAT HE WAS WORKING IN LABOR AND DELIVERY AND GOT A CALL FROM A PHYSICIAN IN OPERATING ROOM WHO HAS HAVING DIFFICULTIES WITH A ESSURE PATIENT. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE

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COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICROINSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE (B)(6), THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: IN THIS PARTICULAR CASE, A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED TOGETHER WITH USABILITY ISSUES. NO BATCH NUMBER WAS REPORTED. NO COMPLAINT SAMPLE WAS PROVIDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT" (SEE TECHNICAL ASSESSMENT). NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NO CAUSAL RELATIONSHIP BETWEEN THE REPORTED DEFECT AND ADVERSE EVENTS CAN BE ASSESSED AS NO ADVERSE EVENTS WERE REPORTED. THE REFERRED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. FOLLOW-UP RECEIVED ON 12-SEP-2014: NO RESPONSE TO FOLLOW-UP ATTEMPTS. FOLLOW-UP INFORMATION RECEIVED ON 16-SEP-2014: NO NEW INFORMATION. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE INSERTION PROCEDURE HCP WAS PULLING THE DEVICE OUT OF THE PATIENT, AND IT HAD BROKEN INTO PIECES; PATIENT HAD A 2 ½ LITER FLUID DEFICIT DURING ESSURE INSERTION AND HCP HAVING ISSUES WITH DEVICE DURING INSERTION. THE EVENTS HCP WAS PULLING THE DEVICE OUT OF THE PATIENT, AND IT HAD BROKEN INTO PIECES, PATIENT HAD A 2 ½ LITER FLUID DEFICIT DURING ESSURE INSERTION WERE CONSIDERED SERIOUS, THE FIRST DUE TO MEDICAL IMPORTANCE AND THE SECOND DUE TO HOSPITALIZATION REPORTED. THE REMAINING EVENT IS NON-SERIOUS, ALL THE EVENTS ARE LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PATIENT STAYED IN THE HOSPITAL DURING ONE NIGHT. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE DURING INSERTION HCP WAS PULLING THE

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DEVICE OUT OF THE PATIENT, AND IT HAD BROKEN INTO PIECES. SHE HAD TO BE HOSPITALIZED DURING ONE NIGHT DUE TO A 2 ½ LITER FLUID DEFICIT THAT ALSO OCCURRED DURING INSERTION. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS STATED THAT THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO FURTHER INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038263	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 3/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN 2007. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 624474. MY MODEL NUMBER IS ESS205. THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. CHRONIC FATIGUE, BROKEN BONES, VITAMIN D DEFICIENCY, SHINGLES, CURRENTLY A PUNCTURED UTERINE WALL, HEADACHES, BACTERIAL VAGINOSIS, YEAST INFECTIONS, UNCOMFORTABLE SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038264	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 6/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). INCREASED CRAMPING, HEIGHTENED OVERALL PHYSICAL SENSITIVITY TO OVULATING, CRAMPING ON BOTH SIDES OF LOWER ABDOMEN, BREAST SWELLING BEYOND USUAL MENSTRUAL SWELLING, INCREASED BLEEDING DURING MENSES, INCREASED CRAMPING OF LOWER ABDOMEN THROUGH HIGHER LEG AREAS TO KNEE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038265	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 8/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ELEVATED SED RATE, ABNORMAL IGM LEVELS, MUSCLE AND JOINT PAIN, EXTREME FATIGUE, MIGRAINES, I HAVE A HA EVERY DAY. NUMBNESS AND TINGLING IN EXTREMITIES, DECREASE IN IMMUNE SYSTEM (I WAS NEVER SICK, NOW I'M SICK ALL THE TIME), STABBING ABDOMINAL PAIN LOWER QUADRANTS (APART FROM MENSTRUAL CRAMPS) HEAVY PERIODS, BLOOD CLOTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038266	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 3/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). 1 MONTH AFTER HAVING ESSURE I STARTED GETTING SHARP STABBING PAINS ON MY LEFT SIDE THAT WAS CONSTANT, PASSED A FLESHY LOOKING CLOT THE LENGTH OF A PAD, HEAVY PAINFUL PERIODS, CONSTANTLY FATIGUED, JOINT PAINS, DIZZINESS, MORE HEADACHES

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038267	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 8/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN MY MENSTRUAL CYCLE AND HAD SEVERE BLEEDING WITH CLOTS. PRIOR I USUALLY HAD LIGHTER PERIODS. PAINFUL OVULATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038268	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 7/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HIGH ANXIETY BEGAN RIGHT AFTER I HAD THE IMPLANT IN. I JUST PUT IT OFF AS HAVING TWO BOYS. THAT WAS UNTIL I HAD TO GET PUT ON MEDICINE BC OF SEVERE PANIC ATTACKS. ON (B)(6) I GOT MY SECOND PERIOD IN ONE MONTH. THEY WERE ONLY 18 DAYS APART. AFTER THE SECOND PERIOD ENDED I BEGAN SWELLING IN MY ABDOMEN, SEVERE CRAMPING AND FATIGUE. I AM (B)(6) YEARS OLD AND AM IN NEED OF A HYSTERECTOMY. I SHOULDN'T BE THIS TIRED. THE CRAMPING AND FATIGUE HAS TAKEN OVER MY LIFE TO THE POINT I DON'T WANT TO GET OUT OF BED IN THE MORNING. I WANT MY LIFE BACK. I AM A SKINNY GIRL AND LOOK LIKE I AM 4 MONTHS PREGNANT. MY BLOOD LEVELS ARE LOW DUE TO THE ONCOMING PERIODS EVERY 18 DAYS APART. SEX IS EXTREMELY PAINFUL, BUT MY HUSBAND UNDERSTANDS UNLIKE SOME OF THE OTHERS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038269	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 9/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAD THE ESSURE PROCEDURE BACK IN (B)(6) 2012 TO PREVENT PREGNANCY. I STARTED HAVING ISSUES RIGHT AWAY, HEAVY BLEEDING, PERIODS EVERY 3 WEEKS, HORRIBLE CRAMPS, ABDOMINAL PAIN, BACK PAINS, LEG PAIN, DEPRESSION, ANXIETY, PANIC ATTACKS, HAIR LOSS, PAINFUL INTERCOURSE, LOSS OF SEX DRIVE AND ADENOMYOSIS LEADING TO LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY ON (B)(6) 2014 AT ONLY (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038270	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 11/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5038270 #(B)(4). MY ESSURE PLACEMENT TOOK PLACE ON (B)(6), 2010. ON (B)(6), 2010 I HAD RIGHT SALPINGECTOMY DUE TO PERFORATION/MISPLACED OR MIGRATED ESSURE COIL. COIL WAS NOT FOUND AT THE TIME. ANOTHER SIDE EFFECT I NEGLECTED TO MENTION WAS HAIR LOSS. THE LAST 2 YEARS I HAS ESSURE (2012-2014) I REGULARLY LOST A TON OF HAIR, IT WOULD COME OUT IN CLUMPS. ON (B)(6), 2014 I UNDERWENT A LAPAROSCOPIC ASSISTED TOTALING VAGINAL HYSTERECTOMY/LEFT SALPINGECTOMY ORDER TO SAFELY REMOVE THE COILS. THE "MISPLACED" COIL WAS FOUND IN THE MYOMETRIUM OF MY UTERUS NEAR THE CORNUA. IMMEDIATELY FOLLOWING SURGERY, MY RASHES STARTED TO GO AWAY AND I HAVE HAD NO RASHES, HIVES OR ITCHING SINCE THEN. MY HAIR IS NO LONGER FALLING OUT. I HAVE HAD NO PAIN SINCE ESSURE REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038271	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 7/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE COIL WAS PUT INTO MY LEFT TUBE AND IT MIGRATED INTO MY UTERUS CAUSING IT TO PERFORATE MY UTERUS CAUSING INTERNAL BLEEDING. THE COIL STARTED MIGRATING AGAIN INTO MY OVARY AREA AND BOWELS AND BLADDER HAVE HAD TO HAVE TWO MAJOR SURGERIES DUE TO THE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038272	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 6/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #(B)(4). I HAD A PARTIAL HYSTERECTOMY (TUBES AND UTERUS TAKEN) ON (B)(6) 2014 TO REMOVE THE ESSURE COILS AND TO ALLEVIATE THE SYMPTOMS (PRIOR REPORT SENT) I WAS HAVING. IT HAS BEEN 2 AND A HALF WEEKS SINCE MY SURGERY AND I AM ALREADY FEELING SO MUCH BETTER. MY PATHOLOGY REPORT SAYS THEY GOT ALL OF THE COILS OUT INTACT. I AM PLANNING ON HAVING MORE TEST RUN AFTER THE REMOVAL TO MAKE SURE I HAVE NO OTHER TOXINS LEFT IN MY SYSTEM FROM THE ESSURE COIL IMPLANTS. I HAD THE COIL IMPLANTS PLACED IN (B)(6) OF 2009 AND HAD THEM REMOVED IN (B)(6) OF 2014. I WISH I HAD PUT THE SYMPTOMS TOGETHER SOONER AND HAD THEM REMOVED IMMEDIATELY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038273	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 8/18/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN LIVING WITH THIS PAIN FOR 8 YEARS NOW. MY LOWER BACK KILLS ME, CRAMPING ALL THE TIME, CYSTS, EXCESSIVE BLEEDING, PAIN DURING INTERCOURSE. ALSO BLEEDING AFTER SEX. I CANT TAKE MUCH MORE OF THIS PAIN DUE TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038274	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ESSURE COIL DID NOT LOCK INTO PLACE. I HAD LOTS OF PAIN AND DISCOMFORT AND TWO HSP TESTS. I THEN DEVELOPED FIBROIDS AND HAD A DA VINCI HYSTERECTOMY IN (B)(6) 2011. IN (B)(6) OF 2011 I WAS DIAGNOSED WITH AML A RARE FORM OF LEUKEMIA FOR A FEMALE WHO IS ALSO MIDDLE AGED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038275	BAYER	9/24/2014	9/24/2014

Event Information:

Event Date (B3): 11/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 952107, MY MODEL NUMBER ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED APPROXIMATELY (B)(6) 2012. SINCE BEING IMPLANTED I HAVE HAD A NUMBER OFF SIDE EFFECTS, WHICH I FULLY BELIEVE ARE CAUSED BY ESSURE DUE TO THE FACT I HAD NO HEALTH PROBLEMS BEFORE BEING IMPLANTED. FIRST OFF I BLED FOR A YEAR FOLLOWING PLACEMENT, TO THE POINT OF HAVING TO GO TO THE EMERGENCY ROOM. I HAVE HAD HORRIBLE PELVIC, STOMACH, AND BACK PAIN; ABNORMAL MENSTRUAL CYCLES, CONSTANT SPOTTING, CONSTANT DISCHARGE, HOT FLASHES, ITCHING BURNING STINGING OF MY WHOLE BODY AND VAGINAL ENTRANCE; ABDOMINAL TWITCHING FLUTTERING; PAIN IN MY JOINTS LEGS BREAST NECK SPINE HIPS ARMS; CHEST PAIN, HEART PALPITATIONS; NAUSEA CONSTIPATION DIARRHEA HEARTBURN; METALLIC TASTE IN MY MOUTH; NICKEL ALLERGY; HEADACHES, DIZZINESS, TINGLING AND NUMBNESS IN EXTREMITIES; SHARP PAINS IN MY HEAD AND MEMORY LOSS FORGETFULNESS; INSOMNIA; FATIGUE; EXTREME HAIR LOSS; DECREASED VISION; DRY SKIN HAIR AND EYES; EXTREME ANXIETY ATTACKS; TREMORS. I HAVE NOT BEEN SEEN BY ANY DOCTORS REGARDING THESE SYMPTOMS. THE DEVICE IS CURRENTLY STILL INSIDE OF ME. ESSURE HAS BEEN THE ABSOLUTE WORST EXPERIENCE, MISTAKE OF MY LIFE AND I WONDER EVERYDAY WHY ITS STILL ON THE MARKET FOR WOMEN SUCH AS MYSELF TO HAVE TO SUFFER DAILY FROM IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038379	BAYER	9/24/2014	10/1/2014

Event Information:

Event Date (B3): 11/6/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/6/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2006 ESSURE WAS IMPLANTED WITHOUT NICKEL ALLERGY TEST. I WASN'T INFORMED ABOUT SIDE EFFECTS. I JUST PUT MY SYMPTOMS TOGETHER AND REALIZED THIS DEVICE HAS TO BE BAD FOR MY BODY. I HAVE GAINED 40 LBS AND THE CHRONIC FATIGUE, HEADACHES, AND JOINT PAIN IS WORSENING. I WORK FOR A HOSPITAL AND THE PROCEDURE IS DONE WEEKLY ON AT LEAST 3 GIRLS. I JUST WANT TO STOP THIS PROCEDURE. THE WOMEN I'M SURE ARE NOT BEING INFORMED OF POTENTIAL RISK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038381		9/24/2014	10/1/2014

Event Information:

Event Date (B3): 8/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING, PAIN, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00399	BAYER HEALTHCARE LLC	9/24/2014	10/3/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C13145

Single Use: Y
Implant Date (E6): 8/7/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. ESSURE LOT NUMBER C13145. PHARMACIST REPORTED THAT THE IMPLANT BROKE UP AT DELIVERY CATHETER WITHDRAWAL (COMPLICATION OF DEVICE INSERTION). CLINICAL CONSEQUENCES OF THE EVENT WERE THAT A NEW IMPLANT WAS USED AND PROCEDURE WAS PROLONGED. MEDICAL DEVICE WAS NOT KEPT. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE IMPLANT BROKE UP AT DELIVERY CATHETER WITHDRAWAL. THIS EVENT WAS CONSIDERED NON-SERIOUS AND IT IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, IT WAS REPORTED THAT THE IMPLANT BROKE UP AT DELIVERY CATHETER WITHDRAWAL. NO FURTHER DETAILS WERE PROVIDED. BASED ON THE AVAILABLE INFORMATION AND THE NATURE OF THE REPORTED EVENT, IT WAS CONSIDERED RELATED TO ESSURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE. ADDITIONAL INFORMATION FROM REPORTED AND PRODUCT TECHNICAL ANALYSIS HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 24-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BREAK", "BREAKAGE", "BROKE", "BROKEN", "FALLING APART", "FRACTURED", OR "SPLIT"

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038421	BAYER	9/27/2014	10/3/2014

Event Information:

Event Date (B3): 9/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/6/2006
Explant Date (E7): 9/25/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE COILS MIGRATED OUTSIDE MY TUBES AND EMBEDDED INTO MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038423	BAYER	9/27/2014	10/3/2014

Event Information:

Event Date (B3): 10/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL IMPLANT DONE FIVE AND A HALF YEARS AGO. SINCE THEN I'VE HAD SEVERAL PROBLEMS AND FOUND OUT I'M ALLERGIC TO NICKEL. I'VE BEEN SUFFERING WITH BACK AND ABDOMINAL PAIN, HEAVY PAINFUL MENSTRUAL CYCLES THAT INCLUDES CLOTTING, AND FATIGUE. I HAVE VERY LITTLE INTEREST IN SEX BUT WHEN I DO, INTERCOURSE IS PAINFUL AND CAUSES BLEEDING AFTERWARDS. I ALSO HAVE JOINT PAIN AND STIFFNESS THAN MAKES IT DIFFICULT TO GET OUT OF BED. OTHER SYMPTOMS INCLUDE SKIN RASHES, REOCCURRING BLADDER/YEAST INFECTIONS, HOT FLASHES, INSOMNIA, MEMORY FOG, MEMORY LOSS, ANEMIA, AND SEVERE HEADACHES. RECENTLY, I'VE STARTED EXPERIENCING A NUMBNESS AND TINGLING SENSATION IN MY ARMS, LEGS, AND HANDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038395	BAYER	9/28/2014	10/3/2014

Event Information:

Event Date (B3): 3/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/5/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY HEALTH DECLINED FROM ESSURE. CHRONIC FATIGUE, RAISED CRP INFLAMMATION, SWEATS, WEIGHT GAIN, SORE JOINTS, PAIN, WHERE COILS ARE PLACED, SWELLING, BLOATING, ALLERGIES, RASHES, HEADACHES, MIGRATION ETC...

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00403	BAYER HEALTHCARE LLC	9/29/2014	9/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM GREAT BRITAIN WAS DERIVED FROM MEDICAL LITERATURE ON 02-SEP-2014, ARTICLE ENTITLED "A COMPARATIVE STUDY OF ESSURE HYSTEROSCOPIC STERILISATION VERSUS LAPAROSCOPIC STERILISATION". IT REFERS TO AN ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR HYSTEROSCOPIC STERILIZATION AND EXPERIENCED ENDOMETRITIS. TRADE NAME REPORTED WAS ESSURE. CASE DESCRIPTION: THIS CASE REFERS TO ONE FEMALE PATIENT FROM ESSURE GROUP WHO HAD ENDOMETRITIS. AN ADULT FEMALE PATIENT UNDERWENT THE ESSURE PROCEDURE: SHE WAS PLACED IN THE LITHOTOMY POSITION; AND WHERE POSSIBLE, THE VAGINOSCOPIC TECHNIQUE WAS PERFORMED USING A 30 DEGREE HYSTEROSCOPE 5 MM IN DIAMETER WITH CONTINUOUS FLOW BETTOCCHI SHEATHS. NORMAL SALINE UNDER LOW PRESSURE WAS USED TO DILATE THE CERVIX AND FACILITATE VISUALISATION OF THE PROXIMAL PORTION OF EACH FALLOPIAN TUBE LUMEN FOR THE INSERTION OF THE MICROINSERTS. IN FOLLOW-UP PERIOD, SHE REQUIRED A COURSE OF ORAL ANTIBIOTICS FOR A PRESUMED ENDOMETRITIS. NO FURTHER INFORMATION REGARDING THIS PATIENT WAS PROVIDED. AUTHORS COMMENT: AUTHOR REPORTED THAT COMPLICATIONS IN THE ESSURE GROUP CONSISTED OF ONE PATIENT WHO REQUIRED A COURSE OF ORAL ANTIBIOTICS FOR A PRESUMED CASE OF ENDOMETRITIS. ABSTRACT: THE PURPOSE OF THIS STUDY IS TO COMPARE SUCCESS RATE, PATIENT SATISFACTION, DISCOMFORT, PROCEDURE TIME AND INTRAOPERATIVE ADVERSE EVENTS OF HYSTEROSCOPIC (ESSURE) VERSUS LAPAROSCOPIC STERILISATION. THIS STUDY INCLUDES A RETROSPECTIVE CASE CONTROL COMPARATIVE STUDY OF 70 PATIENTS WHO HAD LAPAROSCOPIC OR HYSTEROSCOPIC STERILISATION PERFORMED. SYSTEMATIC CHART REVIEW FOR THE DOCUMENTATION OF PREOPERATIVE COUNSELING, OPERATIVE TIME, INTRAOPERATIVE COMPLICATIONS, DOCUMENTATION OF CORRECT APPLICATION OF ESSURE AND FILSHIE CLIPS AND DURATION OF

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HOSPITAL STAY WAS ALSO DONE. PATIENT FOLLOW-UP WAS ARRANGED AND A QUESTIONNAIRE COMPLETED INCLUDING DETAILS OF POSTOPERATIVE PAIN, SATISFACTION OF PROCEDURE, RECOVERY TIME AND COMPLIANCE WITH CONFIRMATORY HYSTEROSALPINGOGRAM ATTENDANCE AND ASSOCIATED PAIN. THE MAIN OUTCOME MEASURES WERE PREGNANCY RATE FOLLOWING ATTEMPTED TUBAL BLOCKAGE, RETURN TO NORMAL ACTIVITY AND PATIENT SATISFACTION. SECONDARY OUTCOME MEASURES INCLUDE PATIENT DISCOMFORT, PROCEDURE TIME, DEVICE PLACEMENT, COMPLIANCE WITH HYSTEROSALPINGOGRAM, POSTOPERATIVE COMPLICATIONS AND RECOVERY TIME. THERE IS A STATISTICAL DIFFERENCE IN FAVOUR OF ESSURE FOR POSTOPERATIVE PAIN, OPERATIVE TIME, RETURN TO WORK/NORMAL ACTIVITY AND HOSPITAL STAY WITH NO DIFFERENCE IN COMPLICATIONS OR PREGNANCY. AS A CONCLUSION, ESSURE IS A SAFE AND EFFECTIVE ALTERNATIVE TO LAPAROSCOPIC STERILISATION WITH SIGNIFICANTLY LESS PROCEDURE RELATED PAIN. FOLLOW-UP RECEIVED ON (B)(4) 2014. PTC NUMBER ADDED. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE AND REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ENDOMETRITIS. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE, IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT, ITS RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED ENDOMETRITIS, SINCE MEDICAL INTERVENTION WAS REQUIRED (PATIENT RECEIVED A COURSE OF ORAL ANTIBIOTICS). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 29-SEP-2014. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00405	BAYER HEALTHCARE LLC	9/29/2014	9/29/2014

Event Information:

Event Date (B3): 9/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12700

Single Use: Y
Implant Date (E6): 9/2/2014
Explant Date (E7): 9/2/2014
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/16/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2014 AND PRESENTED PROBLEM WITH ESSURE DISCHARGING MECHANISM/IMPLANT DID NOT OPEN AND GO OFF FROM CATHETER. PHYSICIAN HAD TO PULL THE TUBE SO HARD THAT ALREADY DUE TO THAT LAPAROSCOPY WAS APPROPRIATED. INSERTION PROCEDURE HAS FAILED. PHYSICIAN INFORMED ABOUT PROBLEM WITH ESSURE DISCHARGING MECHANISM. IT WAS REPORTED THAT, DURING INSERTION, IMPLANT DID NOT OPEN AND GO OFF FROM CATHETER. ONE END FASTENED IN CATHETER AND WITH THE SAME THE OTHER END FASTENED IN TUBE. THE IMPLANT WAS DIFFICULT TO GET LOOSE AND FINALLY IMPLANT CUT USING A LITTLE FORCE. WITH THE HELP OF OTHER INSTRUMENTS COMPLETELY TO UTERUS DISCHARGED IMPLANT AND ITS COAT WAS MANAGED TO REMOVE. PHYSICIAN HAD TO PULL THE TUBE SO HARD THAT ALREADY DUE TO THAT LAPAROSCOPY WAS APPROPRIATED. THE PATIENT GOT LAPAROSCOPIC STERILISATION DUE TO DEFECTIVE IMPLANT. NO BLEEDING FROM TUBE. AN ABDOMINAL CAVITY WAS CLEAN. INDICATION FOR THE WHOLE STERILISATION WAS THERMOABLATION. THERMOABLATION WAS PERFORMED TOO. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014: ON (B)(6) 2014 ESSURE LOT NUMBER C12700 WAS IMPLANTED. THE IMPLANT WAS STUCK INTO THE TUBE AND COULD NOT BE RELEASED FROM THE CATHETER. OTHER INSTRUMENTS AND SOME FORCE WAS NEEDED TO TAKE THE IMPLANT OUT OF THE PATIENT. BILATERAL PLACEMENT WAS NOT SUCCESSFUL. STERILIZATION WAS PERFORMED IN LAPAROSCOPY. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. PHYSICIAN INFORMED THAT AFTER UNSUCCESSFUL ESSURE INSERTION A LAPAROSCOPY WAS PERFORMED. THEN THERMOABLATION WAS PERFORMED TOO. NO FURTHER INFORMATION WAS PROVIDED. COMPANY

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CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND IMPLANT WAS STUCK INTO THE TUBE/PHYSICIAN HAD TO PULL THE TUBE SO HARD THAT ALREADY DUE TO THAT LAPAROSCOPY WAS APPROPRIATED. THIS EVENT, INTERPRETED AS COMPLICATION OF DEVICE INSERTION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND REGARDED AS INCIDENT (LAPAROSCOPY PERFORMED), AND IS LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. IN THIS CASE, IT WAS REPORTED THAT PATIENT UNDERWENT A LAPAROSCOPIC STERILISATION AFTER UNSUCCESSFUL ESSURE INSERTION, A THERMOABLATION WAS ALSO PERFORMED. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: PROBLEM WITH ESSURE DISCHARGING MECHANISM/IMPLANT DID NOT OPEN AND GO OFF FROM CATHETER; UNSUCCESSFUL INSERTION. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 09-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00406	BAYER HEALTHCARE LLC	9/29/2014	9/29/2014

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO HERSELF. SHE IS A ADULT (B)(6)) FEMALE CONSUMER WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). CONSUMER REPORTED THAT SHE HAS READ THROUGH SOME OF THE POST ABLATION TUBAL STERILIZATION SYNDROME POSTS, BUT SHE WAS STILL FEELING LOST. IN 2010, THE CONSUMER HAD THE ESSURE PROCEDURE DONE. IN 2012, HER BODY STARTED REJECTING IT AND SHE HAD A DOUBLE SALPINGECTOMY (BOTH TUBES REMOVED) AND A UTERINE ABLATION, AND THE DOCTOR SAID TO HER THAT IT WAS A GOOD IDEA SINCE WE WERE DONE HAVING KIDS. EVER SINCE THEN, SHE HAS HAD RIDICULOUS SYMPTOMS. CONSUMER FINALLY SOUGHT HELP IN (B)(6) 2013 AND WAS DIAGNOSED WITH IBS (INTERPRETED AS IRRITABLE BOWEL SYNDROME). SYMPTOMS GOT WORSE SO SHE STARTED TRACKING THEM AND REALIZED THEY WERE IN SYNC WITH HER PERIOD. HER SYMPTOMS POP UP THE DAY OR TWO BEFORE SHE START HER PERIOD. SHE GOT VERY BLOATED (LIKE SHE LOOKED VERY, VERY PREGNANT), SHARP/STABBING PAIN IN HER LOWER LEFT SIDE WHICH RADIATED TO HER LOWER BACK AND SOMETIMES DOWN HER THIGH (RARELY IT WAS ON THE RIGHT SIDE, MOSTLY LEFT). SHE ALSO GOT NAUSEOUS AND DIDN'T EAT ALL DAY, SOMETIMES SHE WILL THROW UP ALL DAY AND HAVE EITHER DIARRHEA OR CONSTIPATION. THE SYMPTOMS GO AWAY AFTER A DAY OR TWO. SHE SAW A NEW GYNECOLOGIST AND THE DOCTOR MENTIONED IT COULD BE POST ABLATION TUBAL STERILIZATION SYNDROME, OR POST ABLATION SYNDROME. SHE WANTED TO START THE CONSUMER ON THE PILL FOR A COUPLE OF MONTHS TO SEE IF THAT WOULD HELP AND IF NOT, THE DOCTOR WOULD CONSIDER A FULL HYSTERECTOMY. THAT IDEA SCARED THE CONSUMER BECAUSE SHE WAS (B)(6) AND TERRIFIED IT WOULD THROW HER INTO EARLY MENOPAUSE, BUT SHE ALSO DIDN'T WANT TO TAKE THE PILL OR BE IN PAIN FOR THE REST OF HER LIFE. CONSUMER STATED THAT SHE WOULD GO IN FOR A SONOGRAM SO THE

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DOCTOR COULD HOPEFULLY SEE WHAT WAS GOING ON WHEN SHE WOULD TYPICALLY HAVE THE SYMPTOMS AT THE BEGINNING OF A CYCLE. CONSUMER MENTIONED THAT SHE WAS EXHAUSTED AND WAS NOT SURE WHAT TO THINK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER ((B)(6)) WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4) AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER BODY STARTED REJECTING IT. THIS EVENT HER BODY STARTED REJECTING IT WAS CONSIDERED AS SERIOUS DUE TO MEDICAL IMPORTANCE AND REGARDED AS INCIDENT SINCE THE CONSUMER UNDERWENT A DOUBLE SALPINGECTOMY (BOTH TUBES REMOVED) AND A UTERINE ABLATION. THIS EVENT IS UNLISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT CONSUMER'S BODY STARTED REJECTING ESSURE. THE EXACT CAUSE WAS NOT SPECIFIED. THE CONSUMER STATED THAT SHE WOULD GO IN FOR A SONOGRAM SO THE DOCTOR COULD HOPEFULLY SEE WHAT WAS GOING ON WHEN SHE WOULD TYPICALLY HAVE THE SYMPTOMS AT THE BEGINNING OF A CYCLE. BASED ON THE INFORMATION RECEIVED AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 29-SEP-2014: PTC (PRODUCT TECHNICAL COMPLAINT) WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEV

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	9/29/2014	10/7/2014

Event Information:

Event Date (B3): 9/3/2014 **Report Date (B4): 9/29/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): A66685

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING HYSTEROSCOPY PROCEDURE, THE ESSURE PERMANENT BIRTH CONTROL DEVICE WOULD NOT DEPLOY. A NEW DEVICE WAS GIVEN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00401	BAYER HEALTHCARE LLC	9/29/2014	10/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12712

Single Use: Y
Implant Date (E6): 8/28/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/16/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 AND THE CATHETER GOT STUCK IN TUBE DURING INSERTION AND WHEN PHYSICIAN GOT IT LOOSE ALSO THE SPIRALS OF IMPLANT OPENED AND IT CAME OUT WITH CATHETER. REPORTING PHYSICIAN WAS NOT SURE IF PART OF IMPLANT REMAINED IN TUBE OR IF ENTIRE IMPLANT CAME OUT WITH CATHETER. SHE WAS GOING TO PERFORM HSG (HYSTEROSALPINGOGRAPHY) TO THE PATIENT AFTER 3 MONTHS. SAMPLE WAS AVAILABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SUSPICION THAT PART OF IMPLANT REMAINED IN TUBE AND CATHETER GOT STUCK IN TUBE DURING INSERTION (COMPLICATION OF DEVICE INSERTION). ALL THE EVENTS ARE CONSIDERED NON-SERIOUS. SUSPICION THAT PART OF IMPLANT REMAINED IN TUBE ASSUMED AS A DEVICE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE REMAINING EVENT IS LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE CATHETER GOT STUCK IN TUBE DURING INSERTION AND WHEN PHYSICIAN GOT IT LOOSE ALSO THE SPIRALS OF IMPLANT OPENED AND IT CAME OUT WITH CATHETER. REPORTING PHYSICIAN WAS NOT SURE IF PART OF IMPLANT REMAINED IN TUBE OR IF ENTIRE IMPLANT CAME OUT WITH CATHETER. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENTS ABOVE AND ESSURE USE WAS CONSIDERED AS RELATED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON (B)(4) 2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). THE PTC INVESTIGATION RESULT WAS PROVIDED. FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00402	BAYER HEALTHCARE LLC	9/29/2014	10/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26939

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C26939, INSERTED. REPORTER STATES THAT AN ANOMALY ON ONE ESSURE INSERT WAS OBSERVED IN THE OPERATING ROOM DURING THE PLACEMENT. ACCORDING TO HEALTH CARE PROFESSIONAL THERE WAS PROBLEM OF CATHETERIZATION OF THE FALLOPIAN TUBES WITH DAMAGE OF THE COILS OF THE ESSURE INSERT. BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER ESSURE SYSTEM. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: AS OF 9/9/2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: IN THIS PARTICULAR CASE, A TECHNICAL DEFECT (DAMAGE) WAS REPORTED TOGETHER WITH A USABILITY ISSUE. NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDE. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT" (SEE TECHNICAL ASSESSMENT). NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. C26939 (PRODUCTION DATE 20-FEB-2014 AND EXPIRATION DATE 28-FEB-2017). NO CAUSAL RELATIONSHIP

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BETWEEN THE REPORTED TECHNICAL DEFECT AND ADVERSE EVENTS CAN BE ASSESSED AS NO ADVERSE EVENTS WERE REPORTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE ESSURE DAMAGED. THE EVENT ESSURE DAMAGED WAS CONSIDERED AS NON-SERIOUS AND IS UNLISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, IT WAS NOT REPORTED THE EXACT ALTERATION OF THE ESSURE. A TECHNICAL INVESTIGATION OF THE AFFECTED ESSURE AND REVIEW OF THE BATCH RECORDS IS NECESSARY TO DETERMINE THE REASON FOR DEVICE DAMAGE. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE DAMAGE (SINCE THE EVENT COULD LEAD TO SERIOUS INJURY). ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED: PROBLEM OF CATHETERIZATION OF THE FALLOPIAN TUBES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT NO CAUSAL RELATIONSHIP BETWEEN THE REPORTED TECHNICAL DEFECT AND ADVERSE EVENTS CAN BE ASSESSED AS NO ADVERSE EVENTS WERE REPORTED. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

ADDITIONAL INFORMATION FROM PTC ASSESSMENT: FINAL ASSESSMENT: THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00404	BAYER HEALTHCARE LLC	9/29/2014	10/7/2014

Event Information:

Event Date (B3): 8/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06471; B97485

Single Use: Y
Implant Date (E6): 8/29/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014, LOT NUMBER C06471, FOR STERILIZATION. ON (B)(6) 2014, THE PROCEDURE OF ESSURE INSERTION WAS DONE IN THE PHYSICIAN'S OFFICE AT FIRST. ON THE RIGHT FALLOPIAN TUBE, THE INSERT WAS PLACED TOO DISTALLY. THE HEALTH CARE PROFESSIONAL TRIED TO PULL IT OUT BUT WAS UNABLE TO, SO THE PHYSICIAN TOOK THE PATIENT TO THE OPERATING ROOM TO REMOVE IT AND REPLACE ANOTHER ONE. THIS ALL HAPPENED ON THE SAME DAY, ON (B)(6) 2014. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER US14042870 AND PTC GLOBAL NUMBER. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO USABILITY ISSUES. ACCORDING TO AE CASE INFORMATION THE INSERT WAS PLACED TOO DISTALLY, REQUIRING REMOVAL. NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT" (SEE TECHNICAL STATEMENT). ONE FURTHER AE CASE

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REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO.C06471 (PRODUCTION DATE DEC-2013 AND EXPIRATION DATE 31-DEC-2016). HOWEVER, A BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS WAS NOT POSSIBLE AS NO ADVERSE EVENTS WERE REPORTED. NO CAUSAL RELATIONSHIP BETWEEN THE REPORTED DEFECT AND ADVERSE EVENTS CAN BE ASSESSED AT THIS POINT IN TIME AS NO ADVERSE EVENTS WERE REPORTED. THE REFERRED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE HEALTH CARE PROFESSIONAL TRIED TO PULL IT OUT BUT WAS UNABLE TO. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, ESSURE WAS NOT INSERTED IN THE CORRECT PLACE (PLACED TOO DISTALLY), HEALTH CARE PROFESSIONAL TRIED TO PULL IT OUT BUT WAS UNABLE TO, SO THE PATIENT WENT TO THE OPERATING ROOM TO REMOVE ESSURE AND REPLACE ANOTHER ONE. IT WAS NOT REPORTED WHAT KIND OF INTERVENTION THE PATIENT HAS UNDERGONE IN THE OPERATING ROOM. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE SUSPECT INSERT IS CONSIDERED RELATED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT SINCE PATIENT WENT TO THE OPERATING ROOM. A PRODUCT TECHNICAL ANALYSIS CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. IT WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 08-MAY-2015 THE REQUIRED NUMBERS OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. FOLLOW-UP RECEIVED ON 20-MAY-2015: ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE WAS RECEIVED. INFORMA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00407	BAYER HEALTHCARE LLC	9/30/2014	9/30/2014

Event Information:

Event Date (B3): 7/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 871972

Single Use: Y
Implant Date (E6): 5/24/2012
Explant Date (E7): 7/31/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 THAT DESCRIBES THE OCCURRENCE OF PREGNANCY (DEVICE INEFFECTIVE) IN A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED ON (B)(6) 2012. THE HSG (HYSTEROSALPINGOGRAPHY) WAS PERFORMED ON (B)(6) 2012 AND SHOWED NO BILATERAL SPILLAGE. THE PATIENT HAD A POSITIVE PREGNANCY TEST ON (B)(6) 2013. NO INFORMATION WAS AVAILABLE ABOUT THE DELIVERY. NO CAUSALITY ASSESSMENT WAS PROVIDED BY THE REPORTER. FOLLOW-UP INFORMATION WAS RECEIVED ON 04-SEP-2014. CASE UPGRADED TO INCIDENT DUE TO SURGERY. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. CONCOMITANT CONDITION INCLUDED OVERWEIGHT (B)(6). SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES, RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. SHE HAS 02 PREGNANCIES AND 02 LIVE BIRTHS. ABORTION, SPONTANEOUS ABORTIONS, ELECTIVE ABORTIONS, THERAPEUTIC ABORTIONS AND ECTOPIC PREGNANCIES WERE DENIED. ON (B)(6) 2012, ESSURE LOT NUMBER 871972 WAS EASILY IMPLANTED. SHE WAS 6 WEEKS POSTPARTUM. CERVICAL DILATATION, GENERAL ANALGESIA AND ANESTHESIA WERE APPLIED DURING INSERTION. SOUNDING WAS DENIED. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. ON (B)(6) 2012, HSG WAS PERFORMED AND SHOWED BILATERAL TUBAL ESSURE DEVICES; NO SPILLAGE. ON (B)(6) 2013, URINE PREGNANCY TEST CONFIRMED PREGNANCY. ON (B)(6) 2013, AN ULTRASOUND WAS PERFORMED AND SHOWED THAT SHE WAS 6 WEEKS 2 DAYS PREGNANT. LMP (LAST MENSTRUAL PERIOD) WAS ON (B)(6) 2013. THERE WERE NO COMPLICATIONS AT THE TIME OF THIS REPORT. EXPECTED DATE OF DELIVERY WAS (B)(6) 2014. ON UNSPECIFIED DATE,

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SHE DELIVERED A LIVE BIRTH. DELIVERY TYPE WAS VAGINAL. GESTATIONAL AGE (B)(6) AND APGAR SCORES 9/9. THERE WERE NO COMPLICATIONS DURING PREGNANCY AND/OR DELIVERY. ON (B)(6) 2014, CT SCAN WAS PERFORMED AND BILATERAL COILS WERE SEEN WITH LEFT DEVICE ALONG ANTERIOR FUNDAL MYOMETRIUM, LODGED IN UTERINE TISSUE. ON (B)(6) 2014, LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY WAS PERFORMED TO REMOVE ESSURE. THE PATIENT RECOVERED FROM THE ESSURE REMOVAL PROCEDURE AND PATIENT'S SYMPTOMS/PAIN RESOLVED AFTER SURGERY. IT WAS UNKNOWN WHETHER THE CONDITION WAS CAUSED BY THE ESSURE DEVICES. PATIENT WAS DOING WELL AT THE TIME OF THIS REPORT. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 12-SEP-2014: THE REPORTER CONFIRMED THE PATIENT'S FULL NAME AND ALSO CONFIRMED THE DELIVERY DATE: (B)(6) 2014. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PREGNANCY, DEVICE INEFFECTIVE AND LEFT DEVICE ALONG ANTERIOR FUNDAL MYOMETRIUM, LODGED IN UTERINE TISSUE. ALL THE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WERE CONSIDERED NON-SERIOUS EXCEPT FOR LEFT DEVICE ALONG ANTERIOR FUNDAL MYOMETRIUM, LODGED IN UTERINE TISSUE WHICH IS SERIOUS DUE TO MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE. PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. THE FAILURE RATE MAY BE INCREASED DUE TO PATIENT NON-COMPLIANCE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION AND THE MICRO-INSERT CAN EMBEDDED IN THE MYOMETRIUM. IN THIS PARTICULAR CASE, ESSURE WAS INSERTED, HYSTEROSALPINGOGRAPHY WAS PERFORMED ON AND SHOWED NO BILATERAL SPILLAGE. AFTER THIS THE PATIENT HAD A POSITIVE PREGNANCY TEST, DURING THE PREGNANCY AND DELIVERY NO COMPLICATION WAS NOTED AND THE OUTCOME WAS HEALTH LIVE BIRTH. AFTER THE DELIVERY A CT SCAN WAS PERFORMED AND BILATERAL COILS WERE SEEN WITH LEFT DEVICE ALONG ANTERIOR FUNDAL MYOMETRIUM, LODGED IN UTERINE TISSUE. DUE TO THIS THE MICRO INSERT WAS REMOVED BY LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY. THUS, THIS CASE WAS REGARDED AS INCIDENT. BASED ON INFORMATION AVAILABLE AND IN THE LACK OF ALTERNATIVE EXPLANATION, THE EVENTS WERE CONSIDERED RELATED TO ESSURE. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 29-SEP-2014: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00409	BAYER HEALTHCARE LLC	9/30/2014	9/30/2014

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 9/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2014, WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON UNSPECIFIED DATE AND UNDERWENT A SURGERY FOR BILATERAL ESSURE REMOVAL ON (B)(6) 2014 DUE TO CHRONIC PELVIC PAIN. PHYSICIAN ANTICIPATED THE ESSURE WERE PROPERLY PLACED. THE SURGERY OUTCOME WAS NOT YET PROVIDED AND THEY DID NOT KNOW IF SHE HAD AN HSG (HYSTEROSALPINGOGRAM) OR ANY OTHER FORM OF TREATMENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED CHRONIC PELVIC PAIN. THIS EVENT WAS CONSIDERED AS SERIOUS DUE TO MEDICAL IMPORTANCE AND REGARDED AS INCIDENT SINCE A SURGERY FOR BILATERAL ESSURE REMOVAL WAS REQUIRED, AND IS LISTED EVENT FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. PELVIC PAIN MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS PARTICULAR CASE, THE TIME FROM START OF THE TREATMENT TO THE ONSET OF THE EVENT AND THE TYPE OF SURGERY WERE UNKNOWN. NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6)2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038361	BAYER	9/30/2014	9/30/2014

Event Information:

Event Date (B3): 10/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNUSUAL HEAVY BLEEDING, WAS PUT ON PILL TO STOP BLEEDING, HAD TO CONTINUOUSLY HAVE IRON LEVELS CHECKED BECAUSE OF LOSS OF BLOOD, SHARP PAINS IN SIDE. SEVERE AND NOW CHRONIC BACK PAIN, AS WELL AS HEAVY MENSTRUAL AND SHARP PAINS IN SIDE. HEADACHES THAT HAVE NOW TURNED INTO CHRONIC MIGRAINES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038362	BAYER	9/30/2014	9/30/2014

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5038362 #(B)(4) I WAS HOSPITALIZED IN OCTOBER 2014 WITH MULTIPLE PULMONARY EMBOLISMS(12) FROM BECOMING PREGNANT WITH ESSURE. I WAS MISCARRYING FOR A MONTH WHICH MADE ME VERY ANEMIC. I ALMOST DIED!!!! I SPENT 2 DAYS IN ICU THEN 4 DAYS IN THE ONCOLOGY UNIT. I HAVE BEEN ON BLOOD THINNERS SINCE. I HAD A BILATERAL SALPINGECTOMY ON (B)(6) 2014 TO REMOVE ESSURE FROM MY BODY. IMMEDIATELY AFTER SURGERY ALL MY PELVIC PAIN WAS GONE. AFTER SURGERY I FOUND OUT THE LEFT SIDE ESSURE WAS ALL THE WAY IN THE TUBE AND THE RIGHT SIDE WAS ALMOST ALL THE WAY INSIDE THE TUBE. I HAD A BIG CYST ON MY RIGHT OVARY THAT HAD TO BE DRAINED. THE PATHOLOGY REPORT STATED THAT MY TUBES ALSO HAD CYST ALL OVER THEM. SINCE SURGERY MY PERIODS ARE BACK TO NORMAL AND I DON'T PASS HUGE BLOOD CLOTS. I DON'T EVEN HAVE MENSTRUAL CRAMPS ANYMORE. MY PERIODS ARE BACK TO LASTING 6-7 DAYS NOT 15-17 DAYS. I CAN HAVE SEX WITHOUT EXCRUCIATING PAIN OR ANY BLEEDING. I HAVEN'T FALLEN OR LOST MY BALANCE. I HAVE HAD TO HAVE MY TEETH REPAIRED BECAUSE MY DENTIST SAYS I HAD DISCOLORATION FROM THE NICKEL POISONING. I HAVEN'T HAD ANY JOINT OR MUSCLE INFLAMMATION SINCE SURGERY. I WAS HOSPITALIZED IN (B)(6) 2015 FOR STROKE LIKE SYMPTOMS WHICH DRS BELIEVE I HAVE EXTENSIVE NERVE DAMAGE FROM HEAVY METAL POISONING (NICKEL). MY EAR, NOSE AND THROAT DR SAYS I'M STILL SUFFERING FROM A SEVERE ALLERGIC REACTION. I STILL HAVE MUSCLE SPASMS ALL OVER MY BODY. I'M STILL ON PAIN MEDS ALMOST DAILY BECAUSE OF NERVE DAMAGE. A FEW DRS HAVE SUGGESTED TO DO A DETOX TO HELP REMOVE ANY TRACE OF NICKEL FROM MY BODY BUT I CAN'T BECAUSE OF BEING ON BLOOD THINNERS. I'M STILL WAITING TO SEE A NEUROLOGIST, ALLERGIST AND TO HAVE A NERVE CONDUCTION TEST. AFTER

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SOME RESEARCH I'VE LEARNED THAT MY IMPLANTING DR DIDN'T DO THE ACTUAL HSG TEST ALTHOUGH I WAS TOLD THAT'S WHAT HE DID. I'VE SINCE LEARNED THAT USING SALINE AND AN ULTRASOUND ISN'T AN ACCURATE TEST TO TELL IF TUBES ARE BLOCKED OR NOT. PLEASE MAKE THIS MADNESS STOP!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038364	BAYER	9/30/2014	9/30/2014

Event Information:

Event Date (B3): 4/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SERIOUS PAIN, APPENDICITIS, ABSCESS, FOOD ALLERGIES, SEVERE BLOATING, HAIR LOSS, INFLAMMATION, DRY EYES, DRY VAGINA, HIP PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038389	BAYER	9/30/2014	9/30/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE CALLED ESSURE IN (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 686079, MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A 3 YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAIN STARTED ON (B)(6) 2011. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE; - EXTREME PAIN WITH INTERCOURSE; - DIZZINESS, - PANIC ATTACKS, - MOOD SWINGS, -HOT FLASHES, -HEAVY PERIODS. I HAVE BEEN SEEN BY MY CURRENT DOCTOR, NOT THE SAME WHO DID THE PROCEDURE. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00408	BAYER HEALTHCARE LLC	9/30/2014	10/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B94872

Single Use: Y
Implant Date (E6): 9/4/2014
Explant Date (E7): 9/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ATTEMPT ON (B)(6) 2014, LOT NUMBER B94872, FOR PERMANENT CONTRACEPTION. ON (B)(6) 2014 THE HEALTH CARE PROFESSIONAL SAW A SMALL BLACK PIECE OF DEBRIS FLOATING AROUND IN THE UTERUS AS THEY COULD SEE VISUALIZATION OF LEFT TUBE. THEY COULD NOT COMPLETELY CANNULATE THE TUBE. THE PATIENT COULD NOT TOLERATE THE PROCEDURE AND ESSURE COIL WAS NOT DEPLOYED. THE PHYSICIAN ABORTED THE PROCEDURE. THEY ARE NOT SURE IF IT WAS PART OF ESSURE OR PART OF THEIR EQUIPMENT. IT WAS SOMETHING LIKE THE SIZE OF THE GOLD BAND ON ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A PHRASE LIKE "...A SMALL BLACK PIECE OF DEBRIS FLOATING..." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED TO BAYER FOR INVESTIGATION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE A PIECE OF THE MICRO-INSERT OR CATHETER ACTUALLY BROKE, OR IF THE DEBRIS WAS FROM ANOTHER SOURCE. AS OF (B)(6) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS

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LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF AND DEPLOYMENT DIFFICULTY EVENTS DURING THE PROCEDURE ARE AN ANTICIPATED EVENTS. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL DEFECT AND USABILITY ISSUES. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDE FOR FURTHER INVESTIGATION. THE REPORTED BATCH B94872 (PRODUCTION DATE 16-NOV-2013 AND EXPIRATION DATE 30-NOV-2016) WAS INVESTIGATED. THE TECHNICAL ASSESSMENT CONCLUDED AN "UNCONFIRMED QUALITY DEFECT". SINCE NO ADVERSE EVENTS WERE REPORTED NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE REFERRED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND HCP SAW A SMALL BLACK PIECE OF DEBRIS FLOATING AROUND IN THE UTERUS/ NOT SURE IF IT PART OF ESSURE OR PART OF THEIR EQUIPMENT, PATIENT COULD NOT TOLERATE THE PROCEDURE AND COULD NOT COMPLETELY CANNULATE THE TUBE AND ABORTED THE PROCEDURE. THESE EVENTS WERE CONSIDERED NON-SERIOUS, AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT HCP SAW A SMALL BLACK PIECE OF DEBRIS FLOATING AROUND IN THE UTERUS/ NOT SURE IF IT PART OF ESSURE OR PART OF THEIR EQUIPMENT, INTERPRETED AS DEVICE BREAKAGE, WAS INITIALLY CONSIDERED UNLISTED, BUT WAS UPDATED TO LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, DURING INSERTION THE HEALTH CARE PROFESSIONAL SAW A SMALL BLACK PIECE OF DEBRIS FLOATING AROUND IN THE UTERUS AND THE PROCEDURE WAS ABORTED SINCE THE PATIENT COULD NOT TOLERATE IT. BASED ON THE AVAILABLE INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE. A PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND STATED THAT THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF AND DEPLOYMENT DIFFICULTY EVENTS DURING THE PROCEDURE ARE ANTICIPATED EVENTS. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED AN "UNCONFIRMED QUALITY DEFECT" AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00410	BAYER HEALTHCARE LLC	9/30/2014	10/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSUIRE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): B91738

Single Use: Y
Implant Date (E6): 9/4/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 04-SEP-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2014 (LOT NUMBER B91738) . ADDITIONAL INFORMATION RECEIVED ON 16 AND 19-SEP-2014. ON (B)(6)-2014, THE PATIENT HAD ESSURE INSERTED WITHOUT DIFFICULTY. BEFORE REMOVING THE HYSTEROSCOPE, THE DOCTOR NOTICED THAT 4 COILS FROM THE RIGHT MICRO INSERT BROKE OFF AND FELL INTO THE UTERUS. HE REMOVED THE WHOLE COIL WITH GRAPERS. SECOND INSERT WAS PLACED ON THE RIGHT SIDE WITH NO DIFFICULTY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND UPON REMOVAL OF INSERTER APPROXIMATELY 4 COILS BROKE OFF AND FELL INTO UTERUS. THIS CASE IS MEDICALLY CONFIRMED. THIS EVENT IS CONSIDERED NON-SERIOUS AND UNLISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. CONSIDERING THAT THE REPORTED EVENT OCCURRED DURING THE INSERTION PROCEDURE, THE CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT SINCE NO SURGICAL PROCEDURE WAS REPORTED. PRODUCT TECHNICAL ANALYSIS WAS REQUESTED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 15-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: AS OF 9/22/2014, SINCE NO PRODU

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038458	BAYER	9/30/2014	10/8/2014

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN HAVING SHARP PAINS IN MY ABDOMEN, AND FOUND A 3X3 MASS IN MY ABDOMEN. SO MY DOCTOR ORDERED CT SCAN THAT SHOWED THAT THE COILS THAT WERE PLACED FROM THE ESSURE PROCEDURE ARE NOT LOCATED WHERE THEY SHOULD BE. I BELIEVE AFTER RESEARCHING MY PAIN IS ALL RELATED TO THIS PROCEDURE. CAN I SUE THE BAYER CORPORATION (THE MAKERS OF THIS PRODUCT)? I HAD THE PROCEDURE IN 2009 HOWEVER, I DISCOVERED FROM MY CT THAT THE COILS THAT ARE SUPPOSED TO BE LOCATED IN MY FALLOPIAN TUBES SCARRED UP AND PERMANENTLY IN PLACE TO PREVENT PREGNANCY, HAVE NOW MIGRATED INSIDE MY BODY. ONE IS LOCATED CURRENTLY INSIDE OF MY UTERUS, AND ONE JUST SWIMMING AROUND IN MY ABDOMEN RANDOMLY. I AM NOT SUE HAPPY HOWEVER, I HURT AND AFTER READING PROBLEMS OTHERS HAVE HAD I KNOW I AM NOT THE ONLY ONE. I FEEL THAT THE LEAST THE COMPANY COULD DO IS REIMBURSE MY INSURANCE COMPANY FOR A PERMANENT METHOD OF BIRTH CONTROL AS ADVERTISED AND DID NOT HELP BUT HURT ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038499		10/2/2014	10/10/2014

Event Information:

Event Date (B3): 9/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/26/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DIAGNOSED WITH ADENOMYOSIS LESS THAN A YEAR LATER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038538	BAYER	10/3/2014	10/14/2014

Event Information:

Event Date (B3): 4/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/30/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2013, I HAD THE BIRTH CONTROL PROCEDURE ESSURE DONE IN MY DOCTOR'S OFFICE AND HAVE HAD SERIOUS COMPLICATIONS EVER SINCE. I HAVE SEVERE INTERNAL INFLAMMATION ON ALMOST A DAILY BASIS, EXTREME FATIGUE, TACHYCARDIA, HYPERTENSION AND FIBROMYALGIA. THAT IS JUST A FEW OF THE MEDICAL PROBLEMS THAT I NOW LIVE WITH DUE TO ESSURE. I HAVE NEVER HAD ANY OF THESE PROBLEMS PRIOR TO HAVE THE PROCEDURE. MY LIFE HAS BEEN DRAMATICALLY AFFECTED. I HAVE 7 CHILDREN THAT DEPEND ON ME TO LOVE, NURTURE, COMFORT AND TAKE CARE OF AND THAT HAS BEEN COMPROMISED DUE TO ESSURE. I NOW HAVE A RHEUMATOLOGIST, CARDIOLOGY AND MANY MORE DOCTORS THAT ARE A PART OF MY LIFE DUE TO ESSURE. I WAS A HEALTHY (B)(6) WOMAN WHO RAN 15 MILES A WEEK AND WEIGHT TRAINED FIVE DAYS A WEEK. NOW I AM BARELY ABLE TO CLIMB OUT OF BED. MY IMMUNE SYSTEM HAS BEEN COMPROMISED SO SIGNIFICANTLY THAT MY RHEUMATOLOGIST WANTS ME TO TAKE IMMUNE SUPPRESSANTS AND ANTI-MALARIA DRUGS. I WANT TO ADVISE OTHER WOMEN OF THE RISKS INVOLVED WITH THIS PROCEDURE. I WISH I NEVER WOULD HAVE GONE THROUGH WITH GETTING ESSURE PUT INTO MY BODY. I WAS COMPLETELY HEALTHY AND FULL OF LIFE UNTIL ESSURE. I FEEL SO ALONE GOING THROUGH THIS PAINFUL TIME IN MY LIFE. I TRY TO DESCRIBE HOW PAINFUL IT IS TO BREATHE TO MY HUSBAND DUE TO THE SEVERITY OF MY INTERNAL INFLAMMATION, BUT WHO COULD TRULY UNDERSTAND UNLESS YOU EXPERIENCE IT YOURSELF? I HAVE COUNTLESS MEDICAL DOCUMENTATION TO SUPPORT EVERYTHING I HAVE SAID.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038529	CONCEPTUS, BAYER	10/5/2014	10/10/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): NOT GIVEN ONE
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/25/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE ESSURE PROCEDURE I BEGAN TO HAVE MAJOR PELVIC PAIN, CRAMPS, HEAVY BLEEDING TO THE POINT OF RESTRICTION TO 1/2 HOUR TO A BATHROOM, STABBING PAIN IN THE FRONT THEN SEVERE LOWER BACK PAIN-CHIROPRACTOR NEEDED TO MOVE, DURING MY PERIODS I CAN BARELY WALK. CONSTANT PAIN WHERE THE COILS ARE. THIS IS IN ADDITION TO THE OTHER SIDE EFFECTS OF METAL TASTE, JOINT PAIN, HEADACHES ETC, THE LIST GOES ON. NOW THAT MY UTERUS IS CONTRACTING AS IF I WERE PREGNANT AND PULLING THE MUSCLES IN MY BACK. THE LONGER YOU LEAVE THIS DEVICE IN THE WORSE IT GETS. I'M FORCED TO HAVE A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038545	BAYER	10/6/2014	10/14/2014

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305; ESS305
Catalog # (E4): ESS305 R-1
Lot #(E4):

Single Use:
Implant Date (E6): 8/30/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER 8 PREGNANCIES AND ONE MISCARRIAGE I DECIDED I WAS DONE HAVING CHILDREN AT THE AGE OF (B)(6). I ASKED MY DOCTOR TO TIE MY TUBES AND SHE SUGGESTED ESSURE. I HAD THE PROCEDURE DONE (B)(6) 2013. I INSTANTLY NOTICED AN INCREASE IN MIGRAINE HEADACHES AND PELVIC PAIN. OVER THE LAST YEAR I HAVE HAD LESS SERIOUS SYMPTOMS THAT I NEVER HAD EXPERIENCED BEFORE ESSURE SUCH AS VERY ITCHY SCALP AND SKIN EVEN WITH LOTION. THERE SEEMS TO BE NO DANDRUFF OR DRY SKIN AND IT IS ONLY WHERE I SWEAT. OCCASIONAL DIZZINESS, RINGING OF EARS AND FORGETFULNESS AND INABILITY TO CONCENTRATE. I HAVE ALSO HAD MORE CONCERNING SYMPTOMS SUCH AS HEART PALPITATIONS, (ONCE I HAD CHEST PAINS), VERY HEAVY PERIODS, BLOOD CLOTS DURING THOSE PERIODS AND EXTREMELY PAINFUL PERIODS. MOST RECENTLY MY LOWER LEGS AND FEET WENT NUMB. I WENT TO THE EMERGENCY ROOM AND THEY DID AN ULTRASOUND FOR BLOOD CLOTS AND FOUND NONE. MY LEGS ARE STILL NUMB/TINGLY AND I DON'T KNOW WHY. I HAVE ON A DAILY BASIS SHARP STABBING PAINS ON MAINLY MY LEFT SIDE OF MY ABDOMEN ALTHOUGH I HAVE THE PAINS ON BOTH SIDES, THE LEFT IS BY FAIR THE WORST. I HAVE GAINED 20 POUNDS, AND HAVE STRONG CRAMPY PAINS RIGHT AROUND THE TIME I OVULATE. OCCASIONALLY MY HANDS WILL SHAKE AND WON'T STOP. ONE OF MY BACK MOLARS HAVE BROKEN IN HALF AND I HAVE NEVER HAD DENTAL PROBLEMS. (ONE CAVITY AND 2 WISDOM TEETH PULLED IN MY 37 YEARS). MY JOINTS HURT SO BAD (NAMELY MY ANKLES, AND NECK). I CAN'T WALK DOWN MY STAIRS IN THE MORNING. MY HAIR HAS ALSO STARTED FALLING OUT AND THINNING VERY QUICKLY. FURTHER, I RECEIVED MY MEDICAL RECORDS REGARDING ESSURE, AND I HAVE WHAT I AM ASSUMING ARE TWO DIFFERENT MODELS ESS305 R-1 AND ESS305. THEY HAVE DIFFERENT LOT NUMBERS AND I HAVE FOUND REPORTS ON THOSE SPECIFIC LOT

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NUMBERS. MINE ARE ESS305 R-1 LOT # 12475788 AND ESS305 LOT # B09711 MY SPECIFIC LOT NUMBERS ARE MENTIONED IN REPORTS MW5033001 AND MW5034725.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038553		10/6/2014	10/14/2014

Event Information:

Event Date (B3): 1/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

NEW AND CONTINUED PAIN IN THE PELVIC AREA AS WELL AS FLANK AND LOWER BACK AREAS. DIDN'T START UNTIL ESSURE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00413	BAYER HEALTHCARE LLC	10/7/2014	10/7/2014

Event Information:

Event Date (B3): 8/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/15/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND THERE WAS A DEVICE MALFUNCTIONED ON RIGHT SIDE, IT BECAME STUCK IN PROXIMAL PORTION OF FALLOPIAN TUBE WITHOUT FULL DEPLOYMENT. PHYSICIAN ATTEMPTED TO REMOVE BUT IT BECAME TOO PAINFUL FOR PATIENT. SHE WILL BE TAKEN TO OPERATING ROOM TO ATTEMPT REMOVAL AND PROPER INSERTION OF A NEW DEVICE. ESSURE BILATERAL PLACEMENT WAS NOT ACHIEVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2014: FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: 1) ROLLBACK TO INITIAL HARD STOP 2) DEPRESS BUTTON 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO "DEPLOYMENT DIFFICULTY." SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICROINSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. AS

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OF (B)(4) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO USABILITY ISSUES. NO COMPLAINT SAMPLE WAS AVAILABLE AT THIS POINT IN TIME FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED AN "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND THERE WAS A DEVICE MALFUNCTION ON RIGHT SIDE, IT BECAME STUCK IN PROXIMAL PORTION OF FALLOPIAN TUBE WITHOUT FULL DEPLOYMENT (INTERPRETED AS DEVICE DEPLOYMENT ISSUE, NON-SERIOUS EVENT). PHYSICIAN ATTEMPTED REMOVAL HOWEVER IT BECAME TOO PAINFUL/BILATERAL PLACEMENT NOT ACHIEVED (CONSIDERED AS DEVICE DIFFICULTY TO REMOVE/FAILED INSERTION AND SERIOUS EVENT DUE TO MEDICAL IMPORTANCE). ALL EVENTS ARE LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, FURTHER DETAILS ABOUT THE ESSURE REMOVAL ARE NEEDED; HOWEVER SINCE THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. ALSO, NON SERIOUS EVENT DR ATTEMPTED REMOVAL HOWEVER IT BECAME TOO PAINFUL (INTERPRETED AS PROCEDURAL PAIN) WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PATIENT WILL BE TAKEN TO OPERATING ROOM TO ATTEMPT ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND STATED THAT THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE TECHNICAL ASSESSMENT CONCLUDED AN "UNCONFIRMED QUALITY DEFECT". FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00414	BAYER HEALTHCARE LLC	10/7/2014	10/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/8/2010
Explant Date (E7): 8/28/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION. PHYSICIAN REPORTED THAT THE PATIENT EXPERIENCED HIGH BLOOD PRESSURE, FATIGUE, DEPRESSION AND CONSTIPATION. IT WAS REPORTED THAT SHE WILL ESSURE DEVICES REMOVED. AT TIME OF THIS REPORT, THE PATIENT WAS NOT RECOVERED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM PHYSICIAN: PATIENT´S WEIGHT AND HEIGHT WERE PROVIDED (BMI=(B)(6)). PREVIOUS GYNECOLOGICAL INTERVENTION, PROBLEMS OR OTHER MEDICAL HISTORY OR CONCOMITANT CONDITION WERE DENIED. ON (B)(6) 2010, ESSURE WAS EASILY INSERTED. VISUALIZATION OF TUBAL OSTIUM WAS ALSO EASY. PATIENT WAS NOT POST-PARTUM AT TIME OF INSERTION. ANALGESIA REPORTED: TIVA AND PARACERVICAL BLOCK. CERVICAL DILATATION, SOUNDING, FLUID LOSS MORE THAN 1500 CC WERE DENIED AND INSERTION DID NOT TAKE MORE THAN 20 MINUTES. ON (B)(6) 2010, HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND SHOWED BOTH TUBES OCCLUDED. REPORTER WAS UNSURE WHAT KIND OF BACK-UP CONTRACEPTION WAS USED BY PATIENT. PERFORATION AND HOSPITALIZATION WERE DENIED. ON (B)(6) 2014, ESSURE WAS REMOVED LAPAROSCOPICALLY BY PATIENT´S REQUEST. NO HYSTERECTOMY OR SALPINGECTOMY WAS NECESSARY. PHYSICIAN REPORTED DEVICES WERE CORRECTLY PLACED AND WAS UNSURE IF SYMPTOMS RESOLVED AFTER REMOVAL. WHEN ASKED ABOUT CAUSALITY, REPORTER ANSWERED NOT APPLICABLE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR

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INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE LIMITED AVAILABLE INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEPRESSION. THIS CASE WAS UPGRADED UPON RECEIPT OF FOLLOW-UP INFORMATION. THE EVENT DEPRESSION WAS CONSIDERED AS SERIOUS DUE TO MEDICAL IMPORTANCE BY THE COMPANY AND REGARDED AS INCIDENT SINCE ESSURE WAS REMOVED LAPAROSCOPICALLY BY PATIENT'S REQUEST. THIS EVENT IS LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. EPIDEMIOLOGICAL STUDIES HAVE SHOWN THAT THE LIFETIME PREVALENCE OF MAJOR DEPRESSIVE DISORDER IS HIGH AND IN WOMEN IT IS ALMOST TWICE THAT IN MEN. WOMEN HAVE THE GREATEST RISK FOR DEVELOPING DEPRESSIVE DISORDERS DURING THEIR CHILD-BEARING YEARS. SEVERAL BIOLOGICAL PROCESSES ARE THOUGHT TO BE INVOLVED IN THE PREDISPOSITION OF WOMEN TO DEPRESSION, INCLUDING GENETICALLY-DETERMINED VULNERABILITY, HORMONAL FLUCTUATIONS RELATED TO VARIOUS ASPECTS OF REPRODUCTIVE FUNCTION, AND AN UNDUE SENSITIVITY TO SUCH HORMONAL FLUCTUATIONS IN BRAIN SYSTEMS THAT MEDIATE DEPRESSIVE STATES. IN THIS PARTICULAR CASE, MEDICAL HISTORY OR CONCOMITANT CONDITION WERE DENIED. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE INSERT CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038565	BAYER	10/7/2014	10/17/2014

Event Information:

Event Date (B3): 9/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MUCH CRAMPING AND PAIN. CONSTANT CRAMPING IN PAIN. EVALUATION OF THIS PRODUCT IS NECESSARY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00411	BAYER HEALTHCARE LLC	10/7/2014	10/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C03094

Single Use: Y
Implant Date (E6): 9/5/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO TRIED TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED LOT NUMBER C03094 FOR PERMANENT CONTRACEPTION ON (B)(6) 2014. THE HEALTH CARE PROFESSIONAL VISUALIZED BOTH TUBES AND PROCEEDED TO ATTEMPT TO INSERT FIRST ESSURE DEVICE. WHEN FEEDING THE DEVICE IN SHE GO TO OS AND DID FIRST WHEEL BACK. DEVICE WOULD NOT DEPLOY AND SHE TRIED AGAIN BUT DEVICE NEVER DEPLOYED. SHE ATTEMPTED TO REMOVE DEVICE. PATIENT HAD A SPASM AND HELD ONTO THE DISTAL END OF DEVICE. HCP ATTEMPTED TO THEN REMOVE IT MANUALLY BUT SOME COILS STILL TRAILING. SOME COILS WERE ALL THE WAY OUTSIDE OF VAGINA AND THE COILS WERE UNDONE LIKE A SLINKY. HCP CUT A FAIR AMOUNT OF COILS OFF BUT SOME STILL INSIDE PATIENT AND WILL HAVE TO BE SURGICALLY REMOVED. PROCEDURE STOPPED. NO COILS PLACED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2014. DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT (B)(4) 2014 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS (B)(4) 2014. PATIENT'S INITIALS AND DATE OF BIRTH WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. ON (B)(6) 2014 ESSURE, LOT NUMBER C03094 INSERTION WAS ATTEMPTED. ESSURE MALFUNCTION WAS REPORTED. THE PROVIDER WAS NOT ABLE TO PRESS BUTTON, UNABLE TO DEPLOY THE MICRO-INSERT FROM INSERTER. BILATERAL PLACEMENT WAS NOT ACHIEVED. A SURGERY WAS SCHEDULED TO REMOVE REMAINING MICRO-INSERT FRAGMENTS. NO FURTHER INFORMATION WAS PROVIDED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2014: FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM

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THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: ROLLBACK TO INITIAL HARD STOP; DEPRESS BUTTON; PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO DEPLOYMENT DIFFICULTY. SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICROINSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. IN THIS CASE, NO SUDDEN / SPONTANEOUS BREAKAGE WAS REPORTED. THE PHYSICIAN CUT THE MICROINSERT IN ORDER TO RESOLVE THE DEPLOYMENT ISSUE. AS OF (B)(4) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF AND DEPLOYMENT DIFFICULTY EVENTS DURING THE PROCEDURE ARE AN ANTICIPATED EVENTS. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. IN THIS PARTICULAR CASE, ALSO A MISUSE WAS REPORTED. ACCORDING TO AE CASE INFORMATION, THE REPORTED DEVICE BREAKAGE OCCURED DUE TO MANIPULATION BY THE HCP, AS THE HCP CUT THE DEVICE. NO COMPLAINT SAMPLE WAS PROVIDE FOR FURTHER INVESTIGATION. THE REPORTED BATCH WAS INVESTIGATED. THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. C03094. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE DEVICE WOULD NOT DEPLOY AND SHE TRIED AGAIN BUT DEVICE NEVER DEPLOYED. PATIENT HAD A SPASM AND HELD ONTO THE DISTAL END OF DEVICE. HCP ATTEMPTED TO THEN REMOVE IT MANUALLY BUT SOME COILS STILL TRAILING/NO COILS PLACED. SOME COILS WERE ALL THE WAY OUTSIDE OF VAGINA AND THE COILS WERE UNDONE LIKE A SLINKY/ REMAINING MICRO-INSERT FRAGMENTS. HCP CUT A FAIR AMOUNT OF COILS OFF. A SURGERY WAS SCHEDULED TO REMOVE ESSURE FRAGMENTS (BUT NOT CONFIRMED AT TIME OF THIS REPORT). THE REPORTED EVENTS, INTERPRETED AS DEVICE DEPLOYMENT ISSUE, FRAGMENTATION, AND COMPLICATION OF REMOVAL/FAILED INSERTION IN ADDITION TO A SPASM OF THE CERVIX AND MISUSE WERE CONSIDERED AS NON-SERIOUS AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR THE REPORTED CERVIX SPASM. UPON RECEIPT THE TECHNICAL ANALYSIS, THE DEVICE FRAGMENTATION WERE CONSIDERED AS LISTED. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED, WITH EXCEPTION OF THE REPORTED MISUSE, THAT DUE TO ITS NATURE WAS CONSIDERED AS UNRELATED TO ESSURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED MALFUNCTION. ACCORDING TO TECHNICAL ANALYSIS, THE TECHNICAL ASSESSMENT

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CONCLUDED AN UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW UP FROM 18-MAR-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER INFORMATION IS EXPECTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00412	BAYER HEALTHCARE LLC	10/7/2014	10/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND ESSURE MAY HAVE BROKEN APART IN A PATIENT. PATIENT WAS UNABLE TO HAVE GENERAL ANESTHESIA. PTC INVESTIGATION RESULT RECEIVED ON 27-SEP-2014. PTC GLOBAL NUMBER WAS (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE BROKEN APART IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE

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NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, BREAKAGE OF THE LARGE TIGHT PITCH COIL, OR BREAKAGE OF A PORTION OF THE DELIVERY CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN DR-3020, DESIGN FMEA FOR ESS305. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE MAY HAVE BROKEN APART IN A PATIENT. THIS EVENT IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS LATER RECEIVED. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PRESENT CASE, PHYSICIAN STATED THAT ESSURE MAY HAVE BROKEN APART IN PATIENT. BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE EVENT AND ESSURE WAS CONSIDERED AS RELATED. THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE (MALFUNCTION). ACCORDING TO TECHNICAL ANALYSIS, THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 26-MAR-2015: FOLLOW-UP ATTEMPTS HAVE BEEN DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE MAY HAVE BROKEN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00415	BAYER HEALTHCARE LLC	10/8/2014	10/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM NETHERLANDS WAS DERIVED FROM MEDICAL LITERATURE ON 01-OCT-2008, ARTICLE ENTITLED "UNINTENDED PREGNANCIES AFTER ESSURE STERILIZATION IN THE NETHERLANDS". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE THAT HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) PLACED AND EXPERIENCED A PREGNANCY WITH CONTRACEPTIVE DEVICE AND DEVICE INEFFECTIVE. IT IS UNKNOWN WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE PATIENT HAD ESSURE INSERTED. THE PATIENT EXPERIENCED A PREGNANCY. MISREAD CONFIRMATION TEST AND TIME TO PREGNANCY 7 MONTHS. OUTCOME WAS NOT REPORTED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN PREGNANCY WITH CONTRACEPTIVE DEVICE AND DEVICE INEFFECTIVE AND ESSURE (ESS205) WAS NOT REPORTED. [(B)(4)]. FOLLOW-UP (10-SEP-2014): THE PATIENT WAS A (B)(6) MULTIPAROUS (PARITY 2) FEMALE ((B)(6)). SHE WAS INCLUDED IN A RETROSPECTIVE MULTICENTER CASE SERIES AND PARTICIPATED IN A TRAINING COURSE FOR HYSTEROSCOPIC STERILIZATION WITH ESSURE. PATIENT WAS ADVISED TO TAKE A NONSTEROIDAL ANTI-INFLAMMATORY DRUG ON THE EVENING BEFORE AND 1 HOUR BEFORE PLACEMENT OF THE ESSURE MICROINSERTS. AFTER ESSURE INSERTION, SHE UNDERWENT ULTRASOUND FOR CONFIRMATION OF CORRECT DEVICE POSITION. IN 2006, THE PATIENT GOT PREGNANT WHILE ON ESSURE AFTER AN INTERVAL BETWEEN ESSURE PLACEMENT AND PREGNANCY OF 7 MONTHS. THE PROCEDURE IN THIS PATIENT WAS COMPLICATED BY A SPONTANEOUS EXPULSION OF THE FIRST DEVICE AND PLACEMENT OF A THIRD DEVICE. ONLY AN ULTRASOUND EXAMINATION WAS DONE TO CONFIRM BILATERAL LOCALIZATION. SHE HAD A MISINTERPRETATION OF THE ULTRASOUND AT 3 MONTHS OF FOLLOW-UP, HAD A COMPLICATED PLACEMENT, WITH PLACEMENT OF A THIRD DEVICE AFTER A SPONTANEOUS EXPULSION OF THE FIRST DEVICE. DURING LAPAROSCOPIC STERILIZATION AFTER TERMINATION OF PREGNANCY,

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ONE DEVICE WAS LOCATED INTRAMURALLY UNDER THE SEROSA BECAUSE OF PARTIAL PERFORATION, WHILE THE OTHER ONE WAS IN A PROPER POSITION IN THE OTHER TUBE. AUTHOR'S COMMENT: THE CAUSE OF ESSURE FAILURE IN THIS PATIENT WAS PERFORATION AND NONADHERENCE TO PROTOCOL. ABSTRACT SUMMARY: OBJECTIVE: TO ANALYZE THE DATA OF CASES OF UNINTENDED PREGNANCIES AFTER ESSURE STERILIZATION. DESIGN: RETROSPECTIVE CASE SERIES ANALYSIS. SETTING: NATIONAL MULTICENTER. PATIENT(S): TEN CASES OF UNINTENDED PREGNANCIES AFTER ESSURE STERILIZATION IN THE NETHERLANDS WERE REPORTED FROM AUGUST 2002 THROUGH MAY 2008. INTERVENTION(S): DATA ON THE HYSTEROSCOPIC ESSURE STERILIZATION PROCEDURES AND POSTPROCEDURE CONFIRMATION TESTS OF THE REPORTED CASES WERE REVIEWED AND ANALYZED BY TWO AUTHORS. THE CAUSES OF THE UNINTENDED PREGNANCIES WERE DETERMINED IN AGREEMENT WITH THE PHYSICIANS WHO PERFORMED THE STERILIZATIONS. MAIN OUTCOME MEASURE(S): MOST PREGNANCIES OCCURRED IN PATIENTS WITH ONLY ONE DEVICE PLACEMENT AND BILATERAL OCCLUSION ON HYSTEROSALPINGOGRAPHY (HSG). OTHER CASES INCLUDED MISINTERPRETATION OF HSG, UNDETECTED ABNORMAL DEVICE POSITION BY ULTRASOUND, ONE UNDETECTED PREPROCEDURE PREGNANCY, AND TWO PATIENT FAILURES TO FOLLOW UP WITH THE PHYSICIAN ADVICE. CONCLUSION(S): THE RISK OF PREGNANCY AFTER HYSTEROSCOPIC STERILIZATION MAY BE REDUCED BY STRICTLY FOLLOWING THE FOLLOW-UP PROTOCOL, PERFORMING A URINARY PREGNANCY TEST ON THE DAY OF THE PROCEDURE, AND INSTRUCTING THE PATIENT TO RETURN FOR THE FOLLOW-UP VISIT. A PROCEDURE WITH ONLY A SINGLE DEVICE PLACEMENT IN A PATIENT WITHOUT A HISTORY OF TUBECTOMY OF THE HETEROLATERAL TUBE SHOULD BE CONSIDERED UNSUCCESSFUL. (B)(4). RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 25-SEP-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, ALSO PERFORATION WAS REPORTED WHICH MAY HAVE INCREASED THE RISK OF PREGNANCY. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REFERRED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. (B)(4). THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 29-SEP-2014 FOR THE FOLLOWING MEDDRA PREFERRED TERM: EMBEDDED DEVICE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT WAS DERIVED FROM LITERATURE, ARTICLE ENTITLED "UNINTENDED PREGNANCIES AFTER ESSURE STERILIZATION IN THE NETHERLANDS" AND REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT WITH CONTRACEPTIVE DEVICE. AFTER TERMINATION OF PREGNANCY, A LAPAROSCOPIC STERILIZATION WAS PERFORMED AND ONE DEVICE WAS LOCATED INTRAMURALLY UNDER THE SEROSA BECAUSE OF PARTIAL PERFORATION. THE EVENT ONE DEVICE WAS

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LOCATED INTRAMURALLY UNDER THE SEROSA BECAUSE OF PARTIAL PERFORATION WAS CONSIDERED AS SERIOUS DUE TO MEDICAL IMPORTANCE WHILE THE PREGNANCY WAS CONSIDERED NON-SERIOUS. BOTH EVENTS ARE LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE INCLUDING ESSURE INSERTION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, PATIENT GOT PREGNANT ABOUT 7 MONTHS AFTER ESSURE INSERTION, THE PREGNANCY WAS TERMINATED AND A UTERINE PERFORATION WAS DIAGNOSED DURING A LAPAROSCOPIC STERILIZATION. THE REPORTER ATTRIBUTED ESSURE FAILURE IN THIS PATIENT TO PERFORATION AND NONADHERENCE TO PROTOCOL; HE BELIEVED THAT THERE WAS A MISINTERPRETATION OF THE CONTROL ULTRASOUND AT 3 MONTHS OF FOLLOW-UP; HOWEVER GIVEN THE REPORTED EVENTS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED INTERVENTION (LAPAROSCOPY). ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: SPONTANEOUS EXPULSION OF THE FIRST DEVICE AND COMPLICATED PLACEMENT. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

(B)(4).

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00416	BAYER HEALTHCARE LLC	10/8/2014	10/8/2014

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED IN 2009 FOR PERMANENT BIRTH CONTROL AND OVER THE COURSE OF THE FOLLOWING 3.5 YEARS EXPERIENCED ABDOMINAL PAIN AND DEVELOPED A VERY ITCHY RASH THAT SPREAD ALL OVER THE BODY. AFTER MUCH TESTING, MULTIPLE BIOPSIES AND CHEMICAL PATCH TESTING FOR ALLERGIES, IT WAS DETERMINED THAT SHE WAS HIGHLY ALLERGIC TO NICKEL. THE ESSURE COILS CONTAIN NICKEL. SHE WAS TREATED WITH CLOBESOL STEROID CREAM ALMOST THE ENTIRE 3 YEARS OF SYMPTOMS TO TRY TO CONTROL THE RASH. SHE HAD NEVER EXPERIENCED ANYTHING RELATED TO THAT PRIOR TO THE INSERTION OF THE ESSURE DEVICE. SHE UNDERWENT A BILATERAL SALPINGECTOMY AND ESSURE COILS WERE REMOVED. HER PAIN WAS GONE IMMEDIATELY AND HER SKIN BEGAN AN IMMEDIATE IMPROVEMENT. SYMPTOMS WENT AWAY FOLLOWING ESSURE SURGICAL REMOVAL. NO FOLLOW-UP FOR ADVERSE EVENTS IS FEASIBLE TO PROCEED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF

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QUALITY. HOWEVER, THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY, AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN AND WAS ALLERGIC TO NICKEL. BOTH EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE CONSUMER DEVELOPED ABDOMINAL PAIN AND AN ITCHY RASH AFTER ESSURE INSERTION; SHE WAS SUBMITTED TO BIOPSIES AND PATCH TESTING AND STATED THAT SHE WAS ALLERGIC TO NICKEL. THEN, SHE UNDERWENT BILATERAL SALPINGECTOMY AND ESSURE COILS WERE REMOVED, BOTH PAIN AND SKIN RASH RECOVERED AFTER THIS PROCEDURE. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, DECHALLENGE AND THE EVENTS NATURE THEY WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT; AND DUE TO THE REQUIRED INTERVENTION, THIS CASE WAS REGARDED AS AN INCIDENT. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED; NO BATCH NUMBER WAS REPORTED NEITHER A COMPLAINT SAMPLE PROVIDED FOR FURTHER TECHNICAL EVALUATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". MEDICAL PTC ASSESSMENT CONSIDERED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW-UP CAN BE PURSUED SINCE THIS IS A HEALTH AUTHORITY CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00417	BAYER HEALTHCARE LLC	10/8/2014	10/8/2014

Event Information:

Event Date (B3): 1/22/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/22/2004
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (B)(4) IN (B)(6) ON 11-SEP-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2004. CONSUMER STATED THAT DEVICE MIGRATED OUT OF FALLOPIAN TUBE (DISCOVERED ON (B)(6) 2005). LOCATION UNKNOWN. PAIN SINCE DATE OF IMPLANT. PHYSICIAN HAD TROUBLE IMPLANTING DEVICE, DEVICE PERFORATED FALLOPIAN TUBE, WAS BACKED OUT AND TRIED AGAIN AFTER NITROGLYCERIN WAS ADMINISTERED. NUMBER OF IMPLANTS UNKNOWN AT THAT TIME. EMERGENCY ROOM VISIT ON (B)(6) 2004 FOR PAIN. SHE WAS TREATED FOR SUSPECTED INFECTION. SO FAR SHE HAS HAD A LEFT SALPINGECTOMY ((B)(6) 2005), DEVICE WAS UNABLE TO BE LOCATED DURING LAPAROSCOPY, A BLADDER LIFT WITH TAPE ((B)(6) 2009), NOVASURE ENDOMETRIAL ABLATION ((B)(6) 2009). CYKLOKAPRON MEDICATION TO HELP WITH EXCESS MENSTRUAL BLEEDING PRIOR TO ABLATION. HYSTEROSCOPY, CYTOSCOPY (B)(6) 2009. SHE WAS DIAGNOSED WITH CELIAC ON (B)(6) 2011. ALLERGIES TO MULTIPLE DRUGS, FOODS, INDOOR AND OUTDOOR ENVIRONMENTAL. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR

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CONFIRMATION OF QUALITY. HOWEVER, THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEVICE MIGRATED OUT OF FALLOPIAN TUBE, COULD NOT BE LOCATED DURING LAPAROSCOPY AND DEVICE PERFORATED FALLOPIAN TUBE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A FALLOPIAN TUBE PERFORATION. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT PHYSICIAN HAD TROUBLE IMPLANTING THE DEVICE AND IT PERFORATED FALLOPIAN TUBE, THIS PERFORATION COULD HAVE CONTRIBUTED FOR THE REPORTED ESSURE MIGRATION. CONSIDERING THE ABOVE MENTION INFORMATION AND THE POSITIVE TEMPORAL RELATIONSHIP THESE EVENTS WERE CONSIDERED AS RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE A LAPAROSCOPY AND LEFT SALPINGECTOMY WERE REQUIRED (DEVICE WAS UNABLE TO BE LOCATED DURING LAPAROSCOPY). ALSO, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO THE PRODUCT TECHNICAL ANALYSIS (PTC) THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED (FURTHER CONTACT WAS DENIED BY CONSUMER).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038558	BAYER	10/8/2014	10/16/2014

Event Information:

Event Date (B3): 10/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PUT IN FIVE YEARS AGO AND HAVE BEEN TO THE ER AND GYNECOLOGIST. I WAS AND STILL HAVING CONSTANT EXTREME PAIN IN MY LOWER LEFT PELVIC AREA, STILL HAVING DAILY MIGRAINES, AND EXTREME FATIGUE. I HAD THREE X-RAYS AND ULTRASOUNDS THAT SHOWED THE LEFT METAL SPRING WAS NOT WHERE IT SHOULD BE; IT WAS MUCH HIGHER AND IT LOOKED LIKE A PIECE OF SPAGHETTI. IT IS TWISTED AND CONTINUES TO MOVE. THE DOCTOR INFORMED ME I WILL NEED A HYSTERECTOMY TO FIX IT. DR. (B)(6) MESSED UP AND PUSHED THE DOING TOO FAR AND I SCREAMED FROM PAIN WHEN IT HAPPENED. HE CALLED THE MAKER OF ESSURE AND TALKED TO THEM AND THEY SAID TO DO THE DYE TEST IN FIVE MONTHS INSTEAD OF THREE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00418	BAYER HEALTHCARE LLC	10/8/2014	10/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 10/29/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 11-SEP-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION FOR PERMANENT BIRTH CONTROL. PHYSICIAN REPORTED ESSURE DEVICE MALFUNCTION. THE BUTTON WOULD NOT PRESS THEREFORE PROVIDER WAS NOT ABLE TO SUCCESSFULLY PLACE MICRO INSERT. TRIED TO REMOVE ENTIRE DEVICE, BUT MICROINSERT WAS STUCK IN PATIENT TUBE. NO FURTHER INFORMATION WAS PROVIDED. (B)(4). FINAL ASSESSMENT: BUTTON DIFFICULTY IS DEFINED AS AN EVENT IN WHICH THE PHYSICIAN IS EITHER (1) UNABLE TO SUCCESSFULLY DEPRESS THE BUTTON AFTER PERFORMING ROLLBACK TO THE INITIAL HARD STOP DUE TO VERY HIGH RESISTANCE, OR (2) ABLE TO SUCCESSFULLY DEPRESS THE BUTTON AFTER ROLLBACK TO THE INITIAL HARD STOP, BUT THE ACTIVITY IS DIFFICULT DUE TO HIGHER THAN EXPECTED LEVEL OF RESISTANCE. SEVERAL FACTORS CAN CONTRIBUTE TO A BUTTON DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE THE PHYSICIAN FAILED TO FULLY COMPLETE INITIAL ROLLBACK TO THE HARD STOP LOCATION, OR A COMPONENT INSIDE THE CATHETER HANDLE HAS SUFFERED DEFORMATION AND IS RESTRICTING MOVEMENT OF THE BUTTON. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE THUMBWHEEL, THE RACK, THE DETENT, AND THE HYPO-TUBE TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF A BUTTON DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN

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INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE AND USABILITY ISSUES. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDE FOR FURTHER INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND THE PHYSICIAN REPORTED ESSURE DEVICE MALFUNCTION. THE EVENT ESSURE DEVICE MALFUNCTION, BUTTON WOULD NOT PRESS THEREFORE PROVIDER WAS NOT ABLE TO SUCCESSFULLY PLACE MICRO INSERT (DEVICE MALFUNCTION) IS A LISTED EVENT FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. IT WAS CONSIDERED AS NON-SERIOUS AND REGARDED AS OTHER REPORTABLE INCIDENT. IN THIS CASE, ESSURE DEVICE MALFUNCTION WAS OBSERVED DURING PROCEDURE AND A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY NON-SERIOUS EVENT WAS REPORTED: TRIED TO REMOVE ENTIRE DEVICE, BUT MICROINSERT WAS STUCK IN PATIENT TUBE (INTERPRETED AS DEVICE DIFFICULT TO USE). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP FROM 03-NOV-2014: PTC RESULT WAS UPDATED UPON RECEIPT OF COMPLAINT SAMPLES. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: BUTTON DIFFICULTY IS DEFINED AS AN EVENT IN WHICH THE PHYSICIAN IS EITHER (1) UNABLE TO SUCCESSFULLY DEPRESS THE BUTTON AFTE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00421	BAYER HEALTHCARE LLC	10/9/2014	10/9/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/19/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION (LOT NUMBER NOT PROVIDED). PHYSICIAN REPORTED THAT NOTED ON PROCEDURE THAT RIGHT ESSURE WAS PLACED CORRECT BUT LEFT TUBE EXCESSIVE COILS AND IT DID NOT DEPLOY PROPERLY. IT KIND OF COILED UP ON ITSELF BUT SHE KEPT IT IN. PATIENT WAS SEEN ON (B)(6) 2014 AND HAD BEEN HAVING PAIN IN LOWER ABDOMEN FOR THE PAST 3 WEEKS AND THAT PATIENT REPORTED METAL PIECE OF ESSURE EXPELLED. PATIENT SAW IT. DOCTOR SAID A FRAGMENT BROKE OFF. NO COMMENT ON HSG (HYSTEROSALPINGOGRAM) BEING DONE. ON (B)(6) 2014 LAPAROSCOPIC HYSTERECTOMY WAS PERFORMED. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION FROM (B)(6) 2014: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "...A FRAGMENT BROKE OFF..." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE

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MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN (B)(4), DESIGN FMEA FOR (B)(4). CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. NO COMPLAINT SAMPLE WAS PROVIDE FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A 25 YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DOCTOR SAID A FRAGMENT BROKE OFF. THIS EVENT INTERPRETED AS DEVICE BREAKAGE WAS CONSIDERED AS SERIOUS DUE TO MEDICAL IMPORTANCE, REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED (LAPAROSCOPIC HYSTERECTOMY), AND WAS INITIALLY CONSIDERED AS UNLISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION; HOWEVER UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) IT WAS AMENDED TO LISTED, SINCE PTC ANALYSIS CONCLUDED THAT THE BREAKAGE IS AN ANTICIPATED EVENT. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE PHYSICIAN REPORTED THAT DURING ESSURE INSERTION THE INSERT ON LEFT SIDE DID NOT DEPLOY PROPERLY; IT KIND OF COILED UP ON ITSELF BUT PATIENT KEPT IT IN, LATER SHE HAD LOWER ABDOMINAL PAIN AND A DEVICE BREAKAGE WAS SEEN BY THE PHYSICIAN. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, OTHER NON-SERIOUS EVENTS WERE REPORTED. THE PTC ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION FROM 31-MAR-2015: FOLLOW-UP ATTEMPTS WERE DONE WITHOUT SUCCESS. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00422	BAYER HEALTHCARE LLC	10/9/2014	10/9/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/28/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA PHYSICIAN (CASE# MW5036655) IN UNITED STATES ON 12-SEP-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. CONSUMER EXPERIENCED VOMITING DURING PROCEDURE BECAUSE THE PAIN WAS SO EXTREME. AFTERWARDS, HER PERIODS WERE EXTREMELY HEAVY AND VERY PAINFUL. SHE ALSO PRESENTED HORRID CRAMPS AND THE BACK PAIN WAS SO SEVERE, THAT SHE COULD NOT GET OUT OF BED, PICK UP AND CARE FOR HER CHILDREN LIKE NORMAL MOMS WOULD DO. DURING HER DYE CONFIRMATION TEST, IT WAS FOUND THAT ONE OF THE COILS PERFORATED A TUBE. SURGERY WAS SCHEDULED TO REMOVE COILS AND OBTAIN THE COILS. DURING SURGERY, ONE COIL WAS CUT FROM TUBE AND TUBE WAS BURNED. THE PERFORATED COIL COULD NOT BE LOCATED. AT THIS TIME, IT WAS BELIEVED COIL HAD EMBEDDED ITSELF IN SCAR TISSUE FROM A PREVIOUS C-SECTION. BACK PAIN, HEAVY AND PAINFUL PERIODS CONTINUED. SHE PRESENTED NUMBNESS IN FEET, WEIGHT GAIN, ACNE, HEADACHES, PAINFUL INTERCOURSE, STABBING PAINS IN ABDOMEN, EXTREME HAIR LOSS, DEPRESSION, BOWEL ISSUES AND ANXIETY. AFTER SUFFERING TO THE POINT, PHYSICIAN AGREED HYSTERECTOMY WOULD BE A GOOD IDEA TO REMOVE COIL AND TO GAIN RELIEF FROM THE SYMPTOMS. HYSTERECTOMY WAS DONE IN 2013. ESSURE COIL COULD NOT BE LOCATED AND WAS SAID TO HAVE TRAVELED OUTSIDE UTERUS. SHE HAD A LONGER HOSPITAL STAY DUE TO BLOOD LOSS AND PAIN CONTROL. THE ONLY RELIEF SHE GAINED FROM THE HYSTERECTOMY WAS HEAVY AND PAINFUL PERIODS. ALL OTHER SYMPTOMS REMAIN. NO FURTHER INFORMATION WAS PROVIDED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 29-SEP-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE

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WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. HOWEVER, THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DYE TEST CONFIRMED ONE COIL PERFORATED A TUBE.THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE CONSUMER VOMITED DURING MICRO-INSERT INSERTION PROCEDURE DUE EXTREME PAIN. AFTERWARDS, HER PERIODS WERE EXTREMELY HEAVY AND VERY PAINFUL. SHE ALSO PRESENTED HORRID CRAMPS AND SEVERE BACK PAIN. THEN, IT WAS FOUND THAT ONE OF THE COILS PERFORATED A TUBE DURING THE DYE CONFIRMATION TEST. SURGERY WAS SCHEDULED TO REMOVE COILS. DURING SURGERY, ONE COIL WAS CUT FROM TUBE AND TUBE WAS BURNED. THE PERFORATED COIL COULD NOT BE LOCATED. AT THIS TIME, IT WAS BELIEVED THE COIL HAD EMBEDDED ITSELF IN SCAR TISSUE FROM A PREVIOUS C-SECTION. THE SYMPTOMS CONTINUED, SO A HYSTERECTOMY WAS PERFORMED TO REMOVE THE REMAINING COIL AND TO GAIN SOME RELIEF. HOWEVER, ESSURE WAS NOT FOUND. THE PERIODS IMPROVED BUT THE OTHER SYMPTOMS REMAINED. ALTHOUGH NO INFORMATION WAS PROVIDED REGARDING THE EXACT DATE AND MECHANISM OF THE PERFORATION, GIVEN ITS NATURE IT WAS CONSIDERED AS CAUSALLY RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTIONS. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015. NO RESPONSE TO FOLLOW-UP ATTEMPTS. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038610	BAYER	10/9/2014	10/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2010, I HAD AN ESSURE PROCEDURE COMPLETED. SINCE THE PROCEDURE WAS COMPLETED, I HAVE EXPERIENCED EXTREMELY HEAVY AND PROLONGED MENSTRUAL BLEEDING. SEVERE ABDOMINAL PAIN AND CRAMPING. I DEVELOPED A RASH ON MY HANDS (PEELING RED SKIN). MY HAIR HAS STARTED FALLING OUT. I HAVE DAYS THAT I CANNOT GET OUT OF BED BECAUSE THE PAIN AND TINGLING IN MY LEGS FOLLOWED BY NUMBNESS THAT MAKES ME FALL. MY JOINS SWELL AND THE MOVEMENT IN MY HANDS AND FEET ARE COMPROMISED AFFECTING MY ABILITY TO GRASP AND HOLD ON TO ITEMS. I AM FATIGUED TO THE POINT THAT I AM UNABLE TO CONTINUE FULL TIME EMPLOYMENT. MY LIFE HAS COMPLETELY CHANGED SINCE I HAD THE PROCEDURE, I WAS TOLD HAD NO SIDE EFFECTS AND NO DOWN TIME. IN 2002, I HAD POST PARTUM DEPRESSION. I WAS CLEARED BEFORE 2010. AFTER THE PROCEDURE, I HAVE HAD SEVERE BOUTS OF DEPRESSION SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038613	BAYER	10/9/2014	10/20/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/21/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE COILS PLACED IN(B)(6) 2012. SINCE THEN, I HAVE HAD PELVIC PAIN, JOINT PAIN, CHRONIC FATIGUE, IRREGULAR BLEEDING AND WORSENED MIGRAINES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038614	BAYER	10/9/2014	10/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE HAS CAUSED RASH, PAIN IN ABDOMEN, IRON DEFICIENCY DUE TO ACCESSIBLE MENSTRUAL CYCLES, ANXIETY, MOOD SWINGS AND PACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038615	BAYER	10/9/2014	10/20/2014

Event Information:

Event Date (B3): 4/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/25/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN (B)(6) OF 2014. SINCE THIS TIME I HAVE EXPERIENCED THE FOLLOWING: WEIGHT GAIN. 30 POUNDS 6 MONTHS. I STARTED EXERCISING DURING THIS TIME AND HAVE NOT LOST, BUT GAINED WEIGHT IN MY MID SECTION. I'VE HAD PERSISTENT PELVIC PAIN. ALMOST LIKE PERIOD CRAMPS, BUT WORSE! AT TIMES THEY ARE AS BAD AS LABOR PAINS. I'VE HAD FLUTTERING IN MY STOMACH. I HAD A PERIOD THE SAME DAY AS MY PROCEDURE, DID NOT HAVE ANOTHER PERIOD UNTIL (B)(6), AND HAVE NOT HAD A PERIOD SINCE. I'VE HAD PAIN IN MY CHEST THAT RADIATES INTO MY BACK. ALL OF THIS DID NOT START UNTIL I HAD THE ESSURE PROCEDURE. MY DOCTOR AND I ARE IN TALKS OF ME HAVING A HYSTERECTOMY AT THE AGE OF (B)(6)!

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00419	BAYER HEALTHCARE LLC	10/9/2014	10/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C80063

Single Use: Y
Implant Date (E6): 9/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN REPORTED THAT A PATIENT WAS HAVING AN ESSURE PLACED ON (B)(6) 2014 (LOT NUMBER NOT PROVIDED) AND IT FAILED TO UNFOIL. THE PHYSICIAN COULD NOT REMOVE IT FROM THE LEFT FALLOPIAN TUBE. THE RIGHT SIDE WAS PLACED FINE. THE PROCEDURE WAS VIDEOTAPED AND WAS ON CD. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014: PATIENT'S INITIALS AND DATE OF BIRTH WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) YEARS OLD FEMALE PATIENT. SHE WAS NOT PREGNANT. ON (B)(6) 2014 THE PHYSICIAN STATED THAT SHE INSERTED ESSURE INTO RIGHT TUBE WHICH WAS THE MORE DIFFICULT TUBE DUE TO LOCATION AND SOME BLOOD CLOTS BUT IT WAS PLACED SUCCESSFULLY. WHEN SHE WAS INSERTING THE ESSURE (LOT NUMBER C80063) INTO LEFT TUBE AND SHE TRIED ROLL BACK IT WOULD NOT ROLL BACK AND IT MADE A NOISE BUT DID NOT CLICK IN TUBE. SHE PULLED THE COIL OUT BUT SOMETHING BEGAN TO UNCOIL, UNRAVEL SO THAT IT WAS UNCOILED FROM THE TUBE TO OUTSIDE THE PATIENT'S BODY. SOME OF THE COIL WAS STILL IN THE PATIENT'S LEFT TUBE. AN X-RAY WAS NOT DONE. UNIT WAS AVAILABLE FOR RETURN. NO FURTHER INFORMATION WAS PROVIDED. FUP INFORMATION WAS RECEIVED ON (B)(6) 2014: THE PHYSICIAN SAID THAT DURING THE PROCEDURE THE INSERTER DID NOT DEPLOY CORRECTLY. SHE PUSHED THE BUTTON AND WAS UNABLE TO DO THE ROLL BACK. SHE REMOVED THE INSERTER, BUT THIS STRETCHED OUT. SHE THEN WENT BACK IN AND IT LOOKED LIKE A FEW CM OF INSERTER COIL WERE LEFT IN THE PATIENT. SHE ALSO THOUGHT SHE SAW A PIECE OF THE GREEN SHEATHING. THE PHYSICIAN WOULD LIKE TO KNOW IF SHE SHOULD CUT THIS AND WHAT TO USE TO CUT IT. AN X-RAY WAS NOT PERFORMED BUT THE PHYSICIAN BELIEVED THE INSERT WAS IN THE PATIENT. THE

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INSERTER WAS CHECKED WITH THE SC AND IT WAS NOT ATTACHED. THE PHYSICIAN DID ATTEMPT TO REMOVE THE FEW CM OF INSERTER COIL BUT IT WOULD NOT DETACH. A TUBAL LIGATION WAS PLANNED. THE PATIENT WANTED AN ABLATION AND DID NOT WANT TO WAIT FOR THE HYSTEROSALPINGOGRAPHY IN 3 MONTHS. SO PHYSICIAN DECIDED FOR A TUBAL LIGATION. PHYSICIAN DOES NOT BELIEVE INSERT HAS PERFORATED. FOLLOW-UP RECEIVED ON (B)(6) 2014: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT, ON (B)(6) 2014, DEVICE ON LEFT TUBE FAILED TO DEPLOY. HEALTH CARE PROFESSIONAL ALSO INFORMED THAT A PART OF DEVICE HAS BEEN LEFT IN THE PATIENT'S TUBE. NO INJURY OCCURRED AND BILATERAL PLACEMENT WAS ACHIEVED. FUP INFORMATION WAS RECEIVED ON (B)(6) AND (B)(6) 2014 FROM PHYSICIAN. IN ADDITION ON (B)(6) 2014 THE PTC FINAL ASSESSMENT WAS RECEIVED. THE PHYSICIAN CONFIRMED THE DEMOGRAPHIC INFORMATION FROM THE PATIENT. THE PHYSICIAN STATED THAT ON (B)(6) 2014 THE ESSURE WAS INSERTED, LOT NUMBER C80063, BUT THE DEPLOYMENT OF DEVICE ON THE LEFT TUBE FAILED. AND A PART OF DEVICE HAS BEEN LEFT IN THE TUBE OF PATIENT. IN ADDITION THE PHYSICIAN CONSIDERED THAT BILATERAL PLACEMENT WAS ACHIEVED. THESE EVENTS REPORTED WERE RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT: (B)(4) AND US(B)(4). FINAL ASSESSMENT: THE PRODUCTION DATE FOR LOT C80063 IS (B)(6) 2014. ROLLBACK DIFFICULTY IS DEFINED AS AN EVENT IN WHICH EITHER THE USER IS (1) UNABLE TO PERFORM INITIAL ROLLBACK OF THE THUMBWHEEL DUE TO VERY HIGH RESISTANCE, OR (2) ABLE TO PERFORM INITIAL ROLLBACK OF THE THUMBWHEEL, BUT THE ACTIVITY IS DIFFICULT DUE TO HIGHER THAN EXPECTED LEVEL OF RESISTANCE. SEVERAL FACTORS CAN CONTRIBUTE TO A ROLLBACK DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE A DEFECTIVE THUMB WHEEL OR DEFECTIVE CATHETER RACK WHICH PREVENTS THE ROLLBACK MECHANISM, INADVERTENT CLOSURE OF A HYSTEROSCOPE VALVE DURING THE PLACEMENT PROCEDURE WHICH BINDS UP THE CATHETER COMPONENTS AND PREVENTS ROLLBACK MOVEMENT, EXCESSIVE SOLDER MATERIAL WHICH COULD PREVENT COMPONENTS FROM SLIDING PAST EACH OTHER, A DAMAGED MICRO-INSERT WHICH COULD BIND THE MICRO-INSERT TO THE OUTER CATHETER AND PREVENT CATHETER MOVEMENT, OR TUBAL SPASMS WHICH BIND CATHETER COMPONENTS AND TEMPORARILY RESTRICT THE MOVEMENT OF CATHETER COMPONENTS. IN THIS CASE, NO SPONTANEOUS BREAKAGE WAS REPORTED. THE PHYSICIAN PULLED THE COIL OUT TO RESOLVE THE ROLLBACK ISSUE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE THUMBWHEEL TEETH, RACK TEETH, DELIVERY WIRE TO DELIVERY WIRE HOLDER SOLDER BOND, HYPO-TUBE TO HANDLE SOLDER BOND, MICRO-INSERT CONDITION, AND CONDITION OF THE OUTER CATHETER TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), PROCESSING ESSURE CASES IN (B)(4), BECAUSE THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN (B)(4), DESIGN (B)(4) FOR (B)(4). MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDE FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH SIGNAL REVIEW FOR SIMILAR AE CASE REPORTS FOR BATCH NO. (B)(4) (PRODUCTION DATE (B)(6) 2014; EXPIRATION DATE 31-JUL-2017) COULD BE CONDUCTED AS NO ADVERSE VENTS WERE REPORTED. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SOME

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OF THE COIL WAS STILL IN THE PATIENT'S LEFT TUBE, PIECE OF THE GREEN SHEATHING IN THE PATIENT. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE PHYSICIAN REPORTED THAT SHE WAS INSERTING THE ESSURE INTO LEFT TUBE AND THE INSERTER DID NOT DEPLOY CORRECTLY (FAILED TO UNFOIL). SHE PUSHED THE BUTTON AND WAS UNABLE TO DO THE ROLL BACK. SHE REMOVED THE INSERTER, BUT THIS STRETCHED OUT. SHE THEN WENT BACK IN AND IT LOOKED LIKE A FEW CENTIMETERS OF INSERTER COIL WERE LEFT IN THE PATIENT. SHE ALSO THOUGHT SHE SAW A PIECE OF THE GREEN SHEATHING. THE RIGHT SIDE INSERTION WAS DIFFICULT BUT DEVICE WAS PLACED CORRECTLY. BASED ON THE INFORMATION RECEIVED, AND GIVEN THE NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE. PHYSICIAN DECIDED FOR A TUBAL LIGATION. PHYSICIAN DOES NOT BELIEVE INSERT HAS PERFORATED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP RECEIVED ON 09-DEC-2014 FROM PHYSICIAN: ON UNSPECIFIED DATE, THE PATIENT HAD A BILATERAL TUBAL LIGATION AND AN ABLATION DONE. AT TIME OF THE REPORT SHE WAS DOING WELL. PHYSICIAN STATED THAT BILATERAL ESSURE DEVICES WERE IN TUBES IN APPROPRIATE P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00420	BAYER HEALTHCARE LLC	10/9/2014	10/22/2014

Event Information:

Event Date (B3): 9/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 977933

Single Use: Y
Implant Date (E6): 9/5/2014
Explant Date (E7): 9/26/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION. ESSURE LOT NUMBER USED, 977933 WITH EXPIRATION DATE IN APR 2015. NURSE REPORTED THAT DURING ATTEMPTED INSERTION INTO RIGHT FALLOPIAN TUBE, THE DEVICE DIDN'T DEPLOY RIGHT AND WAS IN PIECES. THE NURSE STATED THAT THE PHYSICIAN ATTEMPTED TO REMOVE COILS BUT PATIENT WAS IN PAIN, SO ONE OR TWO COILS WERE LEFT IN THE RIGHT FALLOPIAN TUBE AND SOME COILS WERE FLOATING IN THE UTERUS. THE PHYSICIAN RETRIEVED THESE. SAMPLE MAY BE AVAILABLE. THE NURSE ALSO STATED THAT LEFT SIDE WAS NOT ATTEMPTED AND WAS LEFT UNOPENED DUE TO A FILM COVERING THE FALLOPIAN TUBE WAS WOULD NOT ALLOW FOR CANNULATION. NURSE MENTIONED THAT THE TREATMENT WAS REMOVAL AND LAPAROSCOPIC TUBAL LIGATION WAS PLANNED. PATIENT WAS OTHERWISE OKAY. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2014. PTC GLOBAL NUMBER WAS (B)(4). FINAL ASSESSMENT: THE PRODUCTION DATE FOR LOT 977933 IS APRIL 2012. WHEN A TERM LIKE DEVICE BREAKAGE IN PIECES IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE

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FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. SINCE NEITHER PRODUCT WAS RETURNED FOR INSPECTION NOR DO WE HAVE A PHOTOGRAPH OF THE ACTUAL DEVICE, WE CANNOT DETERMINE EXACTLY WHAT THE FAILURE IS. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. ESSURE CASES IN (B)(6), BECAUSE THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN (B)(4), DESIGN (B)(4) FOR (B)(4). CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE (B)(4), THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. NO COMPLAINT SAMPLE WAS PROVIDE FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 977933. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND NURSE REPORTED THAT DURING ATTEMPTED INSERTION INTO RIGHT FALLOPIAN TUBE, THE DEVICE WAS IN PIECES. THE EVENT DURING ESSURE INSERTION, DEVICE WAS IN PIECES (INTERPRETED AS DEVICE BREAKAGE) WAS CONSIDERED NON-SERIOUS AND LISTED UPON RECEIPT OF TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THIS EVENT OCCURRED DURING ATTEMPTED OF ESSURE INSERTION INTO RIGHT FALLOPIAN TUBE. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: DURING ESSURE INSERTION THE DEVICE DID NOT DEPLOY RIGHT; ATTEMPTED TO REMOVE COILS BUT PATIENT WAS IN PAIN; TWO COILS WERE LEFT IN THE RIGHT FALLOPIAN TUBE AND SOME COILS WERE FLOATING IN THE UTERUS WERE RETRIEVED; LEFT SIDE WAS NOT ATTEMPTED AND WAS LEFT UNOPENED DUE TO A FILM COVERING THE FALLOPIAN TUBE WAS WOULD NOT ALLOW FOR CANNULATION (FAILED INSERTION). THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE AND MALFUNCTION. LAPAROSCOPIC TUBAL LIGATION WAS PLANNED (NOT CONFIRMED). ACCORDING TO PRODUCT TECHNICAL COMPLAINT INVESTIGATION

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RESULTS, THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

INCIDENT: SERIOUS INJURY. REQUIRED INTERVENTION AND DEVICE MALFUNCTION FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014 THE COIL DID NOT DETACH PROPERLY FROM RELEASE CATHETER AND BROKE APART. BILATERAL PLACEMENT WAS ACHIEVED (DISCREPANT INFORMATION). PHY

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00423	BAYER HEALTHCARE LLC	10/9/2014	10/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 904753

Single Use: Y
Implant Date (E6): 9/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER 904753 ON (B)(6) 2014. PHYSICIAN SAID WHEN SHE CANNULATED THE TUBE WITH THE INSERT SHE SAW A SPLIT IN THE PLASTIC SHEATH COVERING THE ESSURE AND SO SHE PULLED IT OUT BEFORE DEPLOYING IT. THERE WAS NO INJURY TO THE PATIENT AND BILATERAL PLACEMENT WAS ACHIEVED AFTER ALL. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC (B)(4). FINAL ASSESSMENT: LOT 904753. EXPIRATION DATE: (B)(4) 2014. PRODUCTION DATE:(B)(4) 2011. WHEN A TERM LIKE "...A SPLIT IN THE PLASTIC SHEATH COVERING.." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO

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ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF (B)(4) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. SINCE NEITHER PRODUCT WAS RETURNED FOR INSPECTION NOR DO WE HAVE A PHOTOGRAPH OF THE ACTUAL DEVICE, WE CANNOT DETERMINE EXACTLY WHAT THE FAILURE IS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE (B)(6), THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". SINCE NO ADVERSE EVENTS WERE REPORTED NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. NO CAUSAL RELATIONSHIP BETWEEN THE REPORTED PRODUCT QUALITY ISSUE AND ADVERSE EVENTS CAN BE ASSESSED, AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND WHEN THE PHYSICIAN CANNULATED THE TUBE WITH THE MICRO-INSERT, SHE SAW A SPLIT IN THE PLASTIC SHEATH COVERING. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND INITIALLY CONSIDERED AS UNLISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION; HOWEVER UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) IT WAS AMENDED TO LISTED, SINCE PTC ANALYSIS CONCLUDED THAT THE BREAKAGE IS AN ANTICIPATED EVENT. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE PHYSICIAN STATED THAT WHEN SHE CANNULATED THE TUBE WITH THE MICRO-INSERT, SHE SAW A SPLIT IN THE PLASTIC SHEATH COVERING THE ESSURE, SO SHE PULLED IT OUT BEFORE DEPLOYING IT. THERE WAS NO INJURY AND BILATERAL PLACEMENT WAS ACHIEVED; CONSIDERING THAT IT IS NOT CLEAR IF THE INSERTER WAS ALREADY BROKEN OR IF IT HAD BROKEN DURING THE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE. THE PTC ANALYSIS CONCLUDED TO UNCONFIRMED QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 01-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00424	BAYER HEALTHCARE LLC	10/9/2014	10/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B44011

Single Use: Y
Implant Date (E6): 11/12/2013
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/8/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6)-2013 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED 4 TRAILING COILS REMAINED BROKEN IN CAVITY OF UTERUS. NO INFORMATION WAS GIVEN ON THE PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6)-2013 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED; THE LOT NUMBER B44011 WAS PROVIDED. AFTER RELEASE OF THE IMPLANT IN THE RIGHT TUBE, IT WAS OBSERVED AFTER DELIVERY CATHETER WITHDRAWAL THAT ONLY HALF OF TRAILING COILS HAD BEEN PLACED. THE OTHER HALF (4 TRAILING COILS) REMAINED BROKEN IN THE CAVITY OF UTERUS. THE REPORTER'S CAUSALITY WAS NOT PROVIDED. (B)(4). FINAL ASSESSMENT: THE CASE IS REOPENED TO ADD AE AND UPDATE ASSESSMENT STATEMENT ONLY. NO NEW ADDITIONAL INFORMATION FOR INVESTIGATION. SINCE PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. NO MICRO-INSERT WAS RECEIVED. THE INITIAL ROLLBACK WAS NOT COMPLETED. ABLE TO COMPLETE THE FINAL ROLLBACK WITHOUT ISSUES. WE WERE UNABLE TO IDENTIFY ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. WE ALSO CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO FURTHER AE CASE REPORTS HAVE

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BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B44011. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH DID NOT GIVE ANY REASON TO SUSPECT A QUALITY DEFICIT (SEE TECHNICAL STATEMENT). THE PROVIDED COMPLAINT SAMPLE (DEVICE WITHOUT MICROINSERT) WAS INVESTIGATED AND DURING THE TECHNICAL INVESTIGATION THE FINAL ROLLBACK WAS COMPLETED WITHOUT ISSUES. THE TECHNICAL ASSESSMENT COULD NOT CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY (B)(4) AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE, THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE RE-CODED LEGACY REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED 4 TRAILING COILS REMAINED BROKEN IN CAVITY OF UTERUS (CONSIDERED A DEVICE BREAKAGE AND A COMPLICATION OF DEVICE INSERTION). THIS OTHER REPORTABLE INCIDENT CASE IS MEDICALLY CONFIRMED. BOTH EVENTS ARE CONSIDERED NON-SERIOUS. DEVICE BREAKAGE WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. COMPLICATION OF DEVICE INSERTION IS LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. BASED ON THE PROVIDED INFORMATION, A CAUSAL RELATIONSHIP BETWEEN ESSURE USE AND THE REPORTED EVENTS CANNOT BE EXCLUDED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND TECHNICAL ASSESSMENT COULD NOT CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND CONCLUDED "UNCONFIRMED QUALITY DEFECT". MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED. CASE CLOSED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00425	BAYER HEALTHCARE LLC	10/9/2014	10/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B21576

Single Use: Y
Implant Date (E6): 11/4/2013
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/8/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2013 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED A PIECE OF IMPLANT REMAINED ATTACHED TO THE RELEASE DEVICE AND THEN REMAINED IN CAVITY OF UTERUS, DEVICE INSERTION COMPLICATION. NO INFORMATION WAS GIVEN ON THE PATIENT'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2013 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED; THE LOT NUMBER B21576 WAS PROVIDED. DURING RELEASE OF ESSURE DEVICE ON THE LEFT SIDE, A PART OF DEVICE REMAINED ATTACHED TO THE RELEASE DEVICE AND THEN REMAINED IN CAVITY OF UTERUS. THAT PART WAS WITHDRAWN WITH LITHOTOMY FORCEPS. THE REPORTER'S CAUSALITY WAS NOT PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 12-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THE CASE IS REOPENED TO ADD AE AND UPDATE ASSESSMENT STATEMENT ONLY. NO NEW ADDITIONAL INFORMATION FOR INVESTIGATION. SINCE PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. WE WERE ABLE TO INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. THE OUTER COIL FOUND TO BE BROKEN. ALL IFU STEPS WERE COMPLETED. WE ALSO CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THE CAUSE OF THIS FAILURE IS WELL UNDERSTOOD. IN THE MANUFACTURING ASSEMBLY PROCESS IF THERE IS A SMALL GAP LEFT BETWEEN THE INNER COIL AND INNER CATHETER (THEY SHOULD BE BUTTED TOGETHER

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DURING ASSEMBLY), WHEN THE OUTER COIL OF THE MICRO-INSERT IS WOUND DOWN A SMALL PORTION OF THE COIL CAN BECOME TRAPPED IN THE GAP. IF A DEVICE HAS THIS ISSUE, WHEN THE PHYSICIAN PRESSES THE BUTTON TO RELEASE THE MICROINSERT, THE OUTER COIL MAY SEVER ITSELF AS IT IS BEING DEPLOYED FROM THE CATHETER. IN TYPICAL SITUATIONS, THIS SEVERING OCCURS INSIDE THE CATHETER PRIOR TO THE PIECES BEING DEPLOYED FROM THE CATHETER. THE SEVERING OF THE COILS INSIDE THE CATHETER DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PATIENT. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH DID NOT GIVE ANY REASON TO SUSPECT A QUALITY DEFICIT (SEE TECHNICAL STATEMENT). HOWEVER, THE PROVIDED COMPLAINT SAMPLE (OUTER COIL) WAS FOUND TO BE BROKEN (SEE TECHNICAL STATEMENT). ACCORDING TO THE TECHNICAL ASSESSMENT THE CONFIRMED DEFECT IS AN ISOLATED OCCURENCE WITHIN THE BATCH, CAUSED BY A MANUFACTURING PROCESS PROBLEM. ONE FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B21576, THIS CASE REFERS ALSO TO A SIMILAR TECHNICAL TYPE OF EVENT. THE NUMBER OF CASES INDICATES A POTENTIAL BATCH SIGNAL WHICH REQUIRES FURTHER INVESTIGATION. ACCORDING TO THE TECHNICAL ASSESSMENT RESPECTIVE MEASURES WERE INITIATED TO ADDRESS THE ISSUE. THE TECHNICAL ASSESSMENT CONCLUDED "CONFIRMED QUALITY DEFECT" WITH A FINAL RISK CATEGORY III, WHICH CORRESPONDS TO A QUALITY DEFECT WHICH MAY NOT POSES A SIGNIFICANT HAZARD TO HEALTH. ACCORDING TO THE TECHNICAL ASSESSMENT A PRODUCT DEFECT WAS CONFIRMED. BASED ON THE PROVIDED INFORMATION THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING MEDDRA LLT DEVICE BREAKAGE. IN SUMMARY, BASED ON THE OUTCOME OF THE TECHNICAL INVESTIGATION IT CANNOT BE EXCLUDED THAT THE REPORTED INSERTION COMPLICATIONS WERE CAUSED BY THE CONFIRMED DEFECT AND HENCE A CAUSAL RELATIONSHIP OF THE REPORTED EVENTS WITH A QUALITY DEFICIT IS CONSIDERED POSSIBLE. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE, THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE RE-CODED LEGACY REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A PHARMACIST AND REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED A PIECE OF IMPLANT REMAINED ATTACHED TO THE RELEASE DEVICE (DEVICE DEPLOYMENT ISSUE) AND THEN REMAINED IN CAVITY OF UTERUS (DEVICE BREAKAGE) AND DEVICE INSERTION COMPLICATION, CONSIDERED NON-SERIOUS EVENTS, ALL LISTED BUT DEVICE BREAKAGE, WHICH IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THOUGH, BREAKAGE WAS REPORTED DURING INSERTION AFTER AN INSERTER DEPLOYMENT ISSUE. ESSURE BREAKAGE WAS REGARDED AS A OTHER REPORTABLE INCIDENT. BASED ON THE INFORMATION PROVIDED, CAUSALITY BETWEEN ESSURE AND THE ABOVE MENTIONED EVENTS CANNOT BE EXCLUDED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND ACCORDING TO THE TECHNICAL ASSESSMENT A PRODUCT DEFECT WAS CONFIRMED (COMPLAINT SAMPLE WAS PROVIDED). BASED ON THE OUTCOME OF THE TECHNICAL INVESTIGATION IT CANNOT BE EXCLUDED THAT THE REPORTED INSERTION COMPLICATIONS WERE CAUSED BY THE CONFIRMED DEFECT AND HENCE A CAUSAL RELATIONSHIP OF THE REPORTED EVENTS WITH A QUALITY DEFICIT IS CONSIDERED POSSIBLE. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00426	BAYER HEALTHCARE LLC	10/10/2014	10/14/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A78083

Single Use: Y
Implant Date (E6): 10/18/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. THE PATIENT'S MEDICAL HISTORY INCLUDED 3 SPONTANEOUS PARTUS. THE REPORTER DESCRIBED THAT WERE NO CONTRAINDICATIONS FOR TUBA OBSTRUCTION. THE PHYSICIAN STATED THAT AFTER A PROCEDURE OF 4 MINUTES DURING WHICH THE RIGHT DEVICE WAS PLACED WITHOUT RESISTANCE OR PAIN, THERE WAS ONLY 1 WINDING VISIBLE AT HYSTEROSCOPY. THE LEFT DEVICE WAS ALSO WITHOUT RESISTANCE PLACED, BUT A LITTLE PAINFUL. THE LEFT DEVICE LET 4 WINDINGS VISIBLE IN THE UTERINE CAVITY. THE PATIENT EXPERIENCED FOR ABOUT 1 WEEK LITTLE TENDERNESS OF HER ABDOMEN WITHOUT FEVER OR OTHER COMPLAINTS AFTER INSERTION PROCEDURE. THEREFORE, THE PATIENT WAS SEEN ON THE OUTPATIENT DEPARTMENT FOR AN ULTRASONIC CHECK OF THE ESSURE DEVICES, 3 MONTHS AFTER INSERTION PROCEDURE. THE RIGHT DEVICE WAS CLEARLY VISIBLE AND WELL PLACED, BUT THE LEFT SIDE WAS NOT DETECTED IN A NORMAL POSITION. A HYSTEROSALPHINGOGRAM (HSG) WAS PERFORMED, IT SHOWED NO CONTRAST IN CONTACT WITH THE LEFT DEVICE. ALSO 4 MARKERS OF THE LEFT DEVICE WERE NOT ALIGNED. ACCORDING TO REPORTER IT STRONGLY INDICATED A PERFORATION OF THE LEFT ESSURE DEVICE. THEREFORE A DIAGNOSTIC LAPAROSCOPY WAS PERFORMED. ONLY THE DISTAL PART OF DE LEFT DEVICE WAS DETECTED AND REMOVED FROM THE FUNDUS UTERI NEAR THE TUBAL INSERTION. A LEFT TUBECTOMY WAS PERFORMED. THERE WAS NO REMNANT OF THE DEVICE SEEN BY HYSTEROSCOPY. THE TUBECTOMIE SHOWED NO ESSURE DEVICE. AFTER CONSULTATION OF THE ESSURE EXPERT TEAM A SECOND LAPAROSCOPY WITH GUIDANCE OF X-RAY WAS PLANNED. DURING A HARD SEARCH ESSURE DEVICE WAS FOUND IN THE OMENTUM FULLY ENCAPSULATED. THE ESSURE DEVICE WAS REMOVED BY LAPAROSCOPIC SURGERY. THE

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RECOVERY OF THE PATIENT WAS UNEVENTFUL. FOLLOW-UP INFORMATION WAS RECEIVED ON 11-SEP-2014. PATIENT'S INITIALS AND DATE OF BIRTH WERE PROVIDED. ON (B)(6) 2013 ESSURE, LOT NUMBER A78083 WAS IMPLANTED. AFTER TWO LAPAROSCOPIES EVENTUALLY FOUND ESSURE DEVICE WITH X-RAY GUIDANCE AND REMOVED. AT THE TIME OF THIS REPORT SHE WAS WITHOUT COMPLAINTS. NO COMMENT WAS PROVIDED BY REPORTER ON THE QUESTION CONCERNING PATIENT'S OUTCOME. NO FURTHER INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INDICATED A PERFORATION OF THE LEFT ESSURE/ LEFT ESSURE DEVICE FULLY ENCAPSULATED IN THE OMENTUM AND ONLY DISTAL PART OF ESSURE (LEFT) WAS DETECTED AND REMOVED FROM FUNDUS UTERI (DEVICE BREAKAGE). BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. INDICATED A PERFORATION OF THE LEFT ESSURE/ LEFT ESSURE DEVICE FULLY ENCAPSULATED IN THE OMENTUM IS A LISTED EVENT ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. THIS CASE WAS REGARDED AS INCIDENT SINCE BOTH EVENTS LED TO LAPAROSCOPIC SURGERY AND LEFT TUBECTOMY. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE IT WAS REPORTED THAT INSERTION OF LEFT DEVICE WAS PAINFUL, SUGGESTING THAT THE PERFORATION COULD HAVE OCCURRED DURING INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE CANNOT BE EXCLUDED. ALSO, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, IT WAS REPORTED THAT DURING LAPAROSCOPY ONLY DISTAL PART OF ESSURE (LEFT) WAS DETECTED AND REMOVED FROM FUNDUS UTERI. GIVEN THE NATURE OF THE REPORTED EVENT, IT WAS CONSIDERED RELATED TO ESSURE. ALSO, NON-SERIOUS EVENTS ONLY 1 WINDING VISIBLE AT HYSTEROSCOPY AND PAINFUL INSERTION LEFT DEVICE WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 29-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT INFORMATION ADDED (A78083)

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038661	CONCEPTUS/BAYER	10/11/2014	10/22/2014

Event Information:

Event Date (B3): 7/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): L2843
Lot #(E4): 846837

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DID THE ESSURE PROCEDURE TWO YEARS AGO. I HAVE GAINED 30 POUNDS, HAVE VERY PAINFUL PERIODS, LOTS OF CLOTS AND BLEEDING AND VERY BAD BACK PAINS AT ALL TIMES. ALL THIS AFTER THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038695	BAYER	10/12/2014	10/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE PUT IN AFTER MY LAST SON. I BECAME VERY SICK, ALWAYS THROWING UP, HAD BAD HEADACHES AND ALWAYS TIRED, I WOULD GET DIZZY A LOT, HAD BAD LOWER BACK PAIN AND WHEN I WAS ON MY MENSTRUAL CYCLE I HAD SEVERE PAIN IN MY LOWER BACK AND VAGINA, SHARP SHOOTING PAINS AND MY BELLY BUTTON. I WOULD BLEED SO HEAVY THAT MY BLOOD WAS BLACK WITH BIG BLOOD CLOTS IT EVEN HURT WHEN I WENT TO THE RESTROOM, I HAD TO WEAR THREE PADS. I WAS IN AND OUT OF THE HOSPITAL IN (B)(6) FOR ABDOMINAL PAIN AND THE DOCTORS COULD NEVER FIND OUT WHAT WAS WRONG WITH ME. I EVEN WENT TO SEE A DIFFERENT OB DOCTOR BECAUSE I COULDN'T EVEN HAVE SEX WITH MY HUSBAND ANY MORE DUE TO IT BEING SO PAINFUL DURING INTERCOURSE. WHEN I SAW THIS DOCTOR I TOLD HIM I THINK IT'S THE ESSURE MAKING ME SICK AND I WAS THE FIRST PATIENT DR (B)(6) PUT THE ESSURE DEVICE IN. COME TO FIND OUT THIS DOCTOR KNEW MY OLD DOCTOR. HE SAID, "THEY HAD AN OFFICE TOGETHER AT ONE TIME AND ITS NOT THE ESSURE, MAYBE I'M DEPRESSED". I KNEW HE JUST DIDN'T WANT TO HELP ME BECAUSE THEY WERE OLD FRIENDS. I SAW OTHER DOCTORS AND EVEN WHEN I WENT TO THE HOSPITAL A LOT OF DOCTORS DIDN'T KNOW WHAT ESSURE WAS. I HAD TO TELL THEM AND THEY WOULD GO LOOK IT UP AND COME BACK SAY I HAVE ABDOMINAL PAIN AND SEND ME HOME WITH PAIN MEDS. WELL THIS WENT ON FOR FIVE YEARS. THEN I LOST MY JOB AT (B)(6) DUE TO SO MANY ABSENCES FOR ME BEING SICK BUT I ALWAYS HAD DOCTOR'S NOTES. SO I MOVED TO (B)(6) BECAUSE MY HUSBAND HAD A JOB THERE. I WENT TO THE HOSPITAL A FEW TIMES AND THEN SAW A DOCTOR. I HAD AN ENDOSCOPY DONE AND I HAD NOTHING SERIOUSLY WRONG SO THEN I SAW AN OB. I TOLD HER WHAT I THOUGHT IT WAS. SHE HAD ME TAKE SOME BIRTH CONTROL TO SEE IF THE BLEEDING AND PAIN WOULD SLOW DOWN. IT DIDN'T SO SHE TOLD ME THE ONLY WAY TO REMOVE THE ESSURE DEVICE WAS TO REMOVE MY FALLOPIAN TUBES. I DIDN'T WANT TO BUT I FELT IT

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WAS THE ONLY OPTION I HAD SO I HAD THE SURGERY DONE IN (B)(6). MY DOCTOR TOLD ME I HAD A LOT OF SCAR TISSUE ON MY UTERUS AND THE INSIDE OF MY BELLY BUTTON ALSO MY TUBES. IF SHE WOULD HAVE KNOWN THIS SHE WOULD HAVE DONE A WHOLE HYSTERECTOMY SO I WAS SUPPOSED TO HAVE MY UTERUS REMOVED DUE TO THE ESSURE DEVICE BUT I MOVED BACK TO (B)(6) AND HAD NO HEALTH CARE AND I DON'T TRUST THE DOCTORS OUT HERE. ESSURE DESTROYED MY LIFE FOR YEARS AND I STILL SUFFER TO THIS DAY, JUST NOT AS BAD AS WHEN I HAD ESSURE. I ALSO GOT SEVERE ANXIETY, IN 2010 I WAS DIAGNOSED. I BELIEVE IT HAD TO DO WITH MY ESSURE. ALSO I CALLED THE COMPANY TO ASK THEM TO MAKE A COMPLAINT. THE LADY I SPOKE TO TOLD ME WHERE I WAS CALLING WAS FOR IF I WANTED TO KNOW ABOUT ESSURE. I FELT LIKE I WAS GETTING NO WHERE. WELL, THAT IS SOME OF MY LIFE STORY WITH ESSURE SO ANYTIME I HEAR SOME ONE SAY THEY ARE THINKING ABOUT GETTING IT I TELL THEM PLEASE DON'T AND WHAT HAPPENED TO ME AND THEY SHOULD READ MORE AND LEARN ABOUT IT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00428	BAYER HEALTHCARE LLC	10/14/2014	10/14/2014

Event Information:

Event Date (B3): 9/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B94864

Single Use: Y
Implant Date (E6): 9/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM OTHER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(6) AND HAD ESSURE INSERTED ON (B)(6) 2014, LOT NUMBER B94864. ADDITIONAL INFORMATION WAS RECEIVED FROM NURSE ON (B)(6) 2014. IT WAS REPORTED THAT PHYSICIAN INSERTED ESSURE INTO RIGHT TUBE SUCCESSFULLY; HE THEN ATTEMPTED TO INSERT ESSURE IN LEFT TUBE AND DEVICE WOULD NOT OPEN UP. PHYSICIAN TRIED WITH ANOTHER ESSURE BUT PERFORATED THE TUBE ON LEFT SIDE AND ESSURE WENT INTO ABDOMEN. HE DID LAPAROSCOPIC LIGATION (CAUTERIZED THE TUBES) AND REMOVED COIL FROM ABDOMEN. ESSURE COIL WAS STILL IN PLACE IN RIGHT FALLOPIAN TUBE. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2014. PTC GLOBAL NUMBER (B)(6). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: ROLLBACK TO INITIAL HARD STOP. DEPRESS BUTTON. PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO "DEPLOYMENT DIFFICULTY". SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICROINSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY

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WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. AS OF (B)(6) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT ISSUE AND USABILITY ISSUES. NO COMPLAINT SAMPLE WAS PROVIDED FOR TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. FIVE FURTHER CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B94864 (PRODUCTION DATE 12-NOV-2013; EXPIRATION DATE 30-NOV-2016), BUT NONE OF THEM REFER TO A SIMILAR TYPE OF ADVERSE EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A 36- YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(6) AND HAD ESSURE INSERTED INTO RIGHT TUBE SUCCESSFULLY. THE PHYSICIAN ATTEMPTED TO INSERT ESSURE IN LEFT TUBE AND DEVICE WOULD NOT OPEN UP. THEN, HE TRIED WITH ANOTHER ESSURE BUT PERFORATED TUBE ON LEFT SIDE AND ESSURE WENT IN ABDOMEN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND REGARDED AS INCIDENT (LAPAROSCOPIC LIGATION WAS PERFORMED), AND IS LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE PATIENT EXPERIENCED PERFORATION ON LEFT TUBE AND ESSURE WENT INTO ABDOMEN DURING INSERTION. A LAPAROSCOPIC LIGATION WAS PERFORMED AND REMOVED COIL FROM ABDOMEN. THE PERFORATION IS, THEREFORE, CONSIDERED A COMPLICATION OF THE INSERTION PROCEDURE. A CAUSAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE PERFORATION CAN THUS NOT BE EXCLUDED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 07-APR-2015. THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATI

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	10/14/2014	10/17/2014

Event Information:

Event Date (B3): 10/9/2014 **Report Date (B4): 10/14/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): *
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): A66685

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DISPOSABLE USED FOR TUBAL LIGATION UNRAVELED ABNORMALLY IN THE LEFT FALLOPIAN TUBE. INSTEAD OF LOOKING LIKE A SLINKY, IT LOOKED LIKE A COIL OF WIRE ALL ROLLED AROUND IN A BALL. THE SECOND ESSURE DID NOT SIT PERFECTLY BUT WAS GOOD, AND LEFT IN THE RIGHT FALLOPIAN TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038671		10/14/2014	10/22/2014

Event Information:

Event Date (B3): 11/29/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PAIN OVER LEFT OVARY, EXTREME WEIGHT GAIN, DIZZINESS, CONSTANT METAL TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038690		10/14/2014	10/22/2014

Event Information:

Event Date (B3): 1/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CRAMPS AND CYSTS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00427	BAYER HEALTHCARE LLC	10/14/2014	10/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26937

Single Use: Y
Implant Date (E6): 8/13/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014, LOT NUMBER C26937. NO ANESTHESIA HAD BEEN PERFORMED FOR ESSURE PLACEMENT PROCEDURE. PROCEDURE HAD BEEN STARTED ON RIGHT SIDE AND WAS INTERRUPTED AS IMPLANT DID NOT RELEASE. PHYSICIAN HAD TO CUT IMPLANT WITH SCISSORS AT UTERINE HORN LEVEL AS COMPLETE REMOVAL WAS IMPOSSIBLE. NO HEMORRHAGIC OR PAINFUL COMPLICATION. PHYSICIAN REPORTED THAT THE TWO OSTIA UTERINA AND UTERINE CAVITY HAD NO LESION. THE PLACEMENT OF A SUBCUTANEOUS IMPLANT WAS SUGGESTED TO THE PATIENT IN OUTPATIENT SETTING. NO FURTHER INFORMATION WILL BE PROVIDED. CASE CLOSED PTC INVESTIGATION RESULT WAS RECEIVED ON 09-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: USABILITY ISSUES (UIS) ARE NOT ASSOCIATED WITH TECHNICAL DEFECTS OR ADVERSE EVENTS. UIS ARE TYPICALLY ACTS THAT LEAD TO A DIFFERENT RESULT THAN EXPECTED BY THE USER. EXAMPLES INCLUDE, BUT ARE NOT LIMITED TO, HANDLING ERRORS, DEVIATIONS FROM THE INSTRUCTIONS FOR USE, NON- PRODUCT RELATED ANATOMICAL ISSUES, OR OTHER CUSTOMER SATISFACTION ISSUES. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO USABILITY ISSUES. NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND A HANDLING ERROR. NO COMPLAINT SAMPLE WAS PROVIDED FOR LOT NUMBER C26937 (PRODUCTION DATE 19-FEB-2014 AND EXPIRATION DATE 28-FEB-2017) FOR FURTHER INVESTIGATION. SINCE NO ADVERSE EVENTS WERE REPORTED NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. NO CAUSAL RELATIONSHIP BETWEEN THE CONFIRMED PRODUCT QUALITY

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ISSUE AND ADVERSE EVENTS CAN BE ASSESSED, AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2014 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1.DEVICE DEPLOYMENT ISSUE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 283 CASES. 2.DEVICE DIFFICULT TO USE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 260 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL." COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE IMPLANT DID NOT RELEASE, PROCEDURE WAS INTERRUPTED, NECESSITY TO CUT IMPLANT WITH SCISSORS AT UTERINE HORN LEVEL AND COMPLETE REMOVAL WAS IMPOSSIBLE. THESE EVENTS ARE NON-SERIOUS AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED MALFUNCTION. IN THE PRESENT CASE, INSERTION PROCEDURE WAS INTERRUPTED AS IMPLANT WAS NOT RELEASED. THE REPORTER STATED THAT THERE WAS THE NECESSITY TO CUT IMPLANT WITH SCISSORS AT UTERINE HORN LEVEL AS COMPLETE REMOVAL WAS IMPOSSIBLE. GIVEN THE NATURE OF THE REPORTED EVENTS THEY WERE CONSIDERED AS RELATED TO ESSURE EXCEPT FOR NECESSITY TO CUT IMPLANT WITH SCISSORS AT UTERINE HORN LEVEL (INTERPRETED AS A DEVICE MISUSE) WHICH WAS CONSIDERED UNRELATED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED TO UNCONFIRMED QUALITY DEFECT (NO COMPLAINT SAMPLE WAS PROVIDED) AND A HANDLING ERROR. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00429	BAYER HEALTHCARE LLC	10/14/2014	10/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06522

Single Use: Y
Implant Date (E6): 8/27/2014
Explant Date (E7): 8/27/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C06522, INSERTION ON (B)(4) 2014. PHYSICIAN REPORTED THAT DEVICE DID NOT DEPLOY. THE OUTER COIL ON BOTH WAS STRETCHED OUT AND THE PET FIBERS WERE SOMEWHAT DETACHED / SHREDDED. WHEEL IS COMPLETELY ROLLED BACK ON BOTH BUT IT SEEMS AS IF THE CATHETER IS NOT FULLY RETRACTED. NO INJURY OCCURRED AND NO BILATERAL PLACEMENT WAS ACHIEVED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) 2014. FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: 1) ROLLBACK TO INITIAL HARD STOP. 2) DEPRESS BUTTON. 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO "DEPLOYMENT DIFFICULTY." SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICROINSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND

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POTENTIAL MANUFACTURING DEFICIENCIES. AS OF (B)(6) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM THE DEVICE BREAKAGE. CONCLUSION: THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE AND THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF ARE ANTICIPATED EVENTS. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE BATCH DOCUMENTATION WAS REVIEWED BY THE RQU. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". SINCE NO ADVERSE EVENTS WERE REPORTED, NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ATTEMPT AND THE PET FIBERS WERE SOMEWHAT DETACHED / SHREDDED, INTERPRETED AS DEVICE BREAKAGE. DEVICE BREAKAGE IS A NON-SERIOUS AND LISTED EVENT ACCORDING TO TECHNICAL ANALYSIS. IN THIS PARTICULAR CASE, PHYSICIAN REPORTED THAT DEVICE DID NOT DEPLOY (NO BILATERAL PLACEMENT WAS ACHIEVED). THE OUTER COIL ON BOTH WAS STRETCHED OUT AND THE PET FIBERS WERE SOMEWHAT DETACHED / SHREDDED (COMPLICATION OF DEVICE INSERTION). WHEEL IS COMPLETELY ROLLED BACK ON BOTH BUT IT SEEMS AS IF THE CATHETER IS NOT FULLY RETRACTED. BASED ON THE INFORMATION RECEIVED, AND GIVEN THE NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE. ACCORDING TO PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS, THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION WAS REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 06-APR-2015: LETTER UNDELIVERABLE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORTE REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ATTEMPT AND

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00431	BAYER HEALTHCARE LLC	10/15/2014	10/15/2014

Event Information:

Event Date (B3): 7/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 4/16/2012
Explant Date (E7): 4/30/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR CONTRACEPTION. ON (B)(6) 2012, HSG (HYSTEROSALPINGOGRAM) WAS DONE HOWEVER NO RESULTS WERE PROVIDED. ON (B)(6) 2013, PATIENT HAD A HYSTERECTOMY AND TUBES REMOVED (TO REMOVE ESSURE) RELATED TO CHRONIC BACK AND OTHER BODY PAINS. PHYSICIAN STATED HE DID NOT DO AN X-RAY ON THE PATH. PATIENT CONTINUED TO COMPLAIN OF PAIN AND ON (B)(6) 2014 SHE HAD A LAPAROSCOPY DONE AND IT WAS NOTED THAT PART OF THE INNER COIL WAS IN THE PERITONEAL CAVITY IN THE LOWER REGION NEAR THE COLON. PHYSICIAN DID NOT KNOW IF THE COIL WAS CAUSING THE PAIN AND IF THE INNER COIL WAS BENT DURING THE HYSTERECTOMY. PHYSICIAN PLANS TO ATTEMPT A REMOVAL WITH A GENERAL SURGEON AND WILL X-RAY THE TISSUE THAT WAS REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS

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ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO (B)(6) FEMALE PATIENT WHO HAD AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED AND EXPERIENCED CHRONIC BACK AND OTHER BODY PAINS. SHE UNDERWENT A HYSTERECTOMY TO HAVE ESSURE COILS REMOVED. PAINS PERSISTED AFTER HYSTERECTOMY AND A LAPAROSCOPY WAS PERFORMED SHOWING THAT PART OF THE INNER COIL WAS IN THE PERITONEAL CAVITY IN THE LOWER REGION NEAR THE COLON. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. THE EVENT PART OF THE INNER COIL WAS IN THE PERITONEAL CAVITY IN THE LOWER REGION NEAR THE COLON WAS ASSUMED AS DEVICE BREAKAGE AND ALSO AS A DEVICE DISLOCATION TO PERITONEAL CAVITY. DEVICE BREAKAGE PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. THE REMAINING EVENTS ARE LISTED. DUE TO A POSITIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATIONS, THE CAUSALITIES BETWEEN ALL THE REPORTED EVENTS AND ESSURE USE WERE ASSESSED AS RELATED BY THE COMPANY. THIS CASE WAS REGARDED AS INCIDENT SINCE INTERVENTIONS WERE REQUIRED (HYSTERECTOMY WITH SALPINGECTOMY AND LAPAROSCOPY). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) IS REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 17-MAR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO (B)(6) FEMALE PATIENT WHO HAD AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00432	BAYER HEALTHCARE LLC	10/15/2014	10/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER FROM UNITED STATES ON 17-SEP-2014 WHICH REFERS TO HER AUNT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL. IT WAS REPORTED VIA SOCIAL MEDIA THAT CONSUMER FOUND OUT THAT SHE WAS PREGNANT 1.5 YEAR AFTER PLACEMENT. REPORTER STATED THAT THE SPERM MADE IT THROUGH A SMALL HOLE AND SHE HAD THE BABY MOVED OF HER UTERUS BECAUSE IT WAS STUCK IN THE FALLOPIAN TUBE. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SOLICITED CASE REPORT WAS RECEIVED FROM A CONSUMER AND REFERS TO HER AUNT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT 1.5 YEARS LATER (BABY WAS STUCK IN FALLOPIAN TUBE), INTERPRETED AS ECTOPIC PREGNANCY. ECTOPIC PREGNANCY IS SERIOUS AS MEDICALLY SIGNIFICANT AND LISTED EVENT ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ECTOPIC PREGNANCIES HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. THIS EVENT IS A GYNECOLOGIC EMERGENCY, GENERALLY REQUIRING EXPEDITIOUS SURGICAL OR MEDICAL TREATMENT. A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND ESSURE CANNOT BE EXCLUDED AND GIVEN ITS NATURE, IT WAS REGARDED AS INCIDENT. A DEVICE INEFFECTIVE (NON-SERIOUS EVENT) WAS ALSO CONSIDERED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 31-OCT-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). THE BAYER REFER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00430	BAYER HEALTHCARE LLC	10/15/2014	10/16/2014

Event Information:

Event Date (B3): 9/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO AN ADULT FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007 BY ANOTHER PHYSICIAN (NOT THE REPORTER OF THIS CASE) FOR PERMANENT STERILIZATION. ADDITIONAL INFORMATION WAS RECEIVED ALSO ON (B)(6) 2014. DOCTOR REPORTED THAT WANTED TO TALK TO A SPECIALIST. PATIENT WILL HAVE A SURGERY AND MAY HAVE REMOVAL OF THE FALLOPIAN TUBE AND THE DOCTOR WAS UNSURE ABOUT CLIPPING FOR THIS PATIENT. PATIENT HAD BEEN IN TO SEE THIS DOCTOR FOR TREATMENT OF IRREGULAR BLEEDING. ULTRASOUND WAS DONE ON (B)(6) 2014, BECAUSE OF PATIENT WAS COMPLAINING OF BLEEDING, SHOWED THE MAJORITY OF THE INSERT SEEMED AS THOUGH IT MIGHT BE IN THE UTERUS. IT WAS UNCLEAR IF PART OF THE MICRO-INSERT WAS IN THE FALLOPIAN TUBE OR OSTEA. ON (B)(6) 2014 THE DOCTOR DONE AN ENDOMETRIAL BIOPSY IN THIS PATIENT AND DURING THIS PROCEDURE A BRUSH FROM BIOPSY CAUGHT ON INSERT AND NOW IT IS STRETCHED INTO THE UTERUS AND THERE ARE AT LEAST SIX COILS SEEN IN THE CERVIX. DOCTOR ADDED THAT SOME OF THE COILS SEEN IN CERVIX MIGHT "PUSH BACK" BY THE TIME PATIENT HAS SURGERY AND ALSO ASKED ABOUT CLIPPING AND ASKED WHAT COULD DO TO GET ALL THAT WAS HANGING OUT INTO HER UTERUS. DOCTOR WAS UNSURE ABOUT CLIPPING BECAUSE IT WOULD MAKE A SHARP EDGE AND THERE WAS ALSO A CONCERNING ABOUT PERFORATION. DOCTOR WAS ALSO NOT SURE IF BLEEDING WAS RELATED TO ESSURE OR NOT AND ON HOW TO PROCEED AND TREAT THIS PATIENT. PATIENT HAS BEEN CONTINUING WITH ESSURE AND HAS NOT RECOVERED FROM ALL EVENTS. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. PATIENT IS (B)(6) YEARS OLD. IT WAS REPORTED THAT THEY HAD TAKEN THE PATIENT IN FOR SURGERY ON (B)(6) 2014. NO FURTHER INFORMATION WAS PROVIDED. (B)(4). FINAL ASSESSMENT: CASE WAS CLOSED BEFORE UPGRADE TO INCIDENT

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COULD BE COMPLETED. UPGRADE TO INCIDENT PER CENTRAL. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN DEV@COM," BECAUSE THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN (B)(4), DESIGN FMEA FOR ESS305. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO USABILITY ISSUES AND A REPORTED PRODUCT ISSUE. ACCORDING TO AE CASE INFORMATION DURING ENDOMETRIAL BIOPSY A BRUSH FROM BIOPSY CAUGHT ON INSERT AND NOW IT IS STRETCHED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENT ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEARS OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED IRREGULAR BLEEDING AND ULTRASOUND WAS DONE AND RESULT SHOWED MAJORITY OF THE INSERT SEEMED AS THOUGH IT MIGHT BE IN THE UTERUS (UNCLEAR IF PART OF THE MICRO-INSERT WAS IN THE FALLOPIAN TUBE OR OSTEA) (INTERPRETED AS DEVICE DISLOCATION). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE, ALSO DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE EVENT INTERPRETED AS DEVICE DISLOCATION WAS DIAGNOSED ABOUT 7 YEARS AFTER ESSURE INSERTION. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. PATIENT WAS TAKEN TO SURGERY (REQUIRED INTERVENTION) AND THEREFORE THE EVENT INTERPRETED AS DEVICE DISLOCATION WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: DURING ENDOMETRIAL BIOPSY, BRUSH FROM BIOPSY CAUGHT ON INSERT/COILS WAS PULLED INTO CERVIX, THERE ARE AT LEAST SIX COILS SEEN IN THE CERVIX AND NOW IT IS STRETCHED INTO THE UTERUS (DEVICE SHAPE ALTERATION). A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION). FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 03-MAR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00434	BAYER HEALTHCARE LLC	10/15/2014	10/16/2014

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A20064

Single Use: Y
Implant Date (E6): 10/10/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF ECTOPIC PREGNANCY IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR CONTRACEPTION, LOT NUMBER USED WAS A20064. NURSE REPORTED THAT THE PATIENT WAS DIAGNOSED WITH ECTOPIC PREGNANCY IN (B)(6). SHE ALSO REPORTED THAT THE ESSURE WAS INSERTED BY ANOTHER PHYSICIAN, NOT THE ONE THAT SAW HER IN AUGUST. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON (B)(6) 2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). PTC INVESTIGATION RESULT WAS PROVIDED. FINAL ASSESSMENT: MANUFACTURE DATE: 6/19/2012 EXPIRATION DATE: 6/30/2015 SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. (B)(4). NO BATCH SIGNAL COULD BE IDENTIFIED. NO COMPLAINT SAMPLE WAS PROVIDE FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO

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SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ECTOPIC PREGNANCY (DEVICE INEFFECTIVE). ECTOPIC PREGNANCY IS SERIOUS AS MEDICALLY SIGNIFICANT AND LISTED EVENT ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ECTOPIC PREGNANCIES HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. ECTOPIC PREGNANCY IS A GYNECOLOGIC EMERGENCY, GENERALLY REQUIRING EXPEDITIOUS SURGICAL OR MEDICAL TREATMENT. IN THIS PARTICULAR CASE, NO MEDICAL OR SURGICAL INTERVENTION WAS REPORTED. A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND ESSURE CANNOT BE EXCLUDED AND GIVEN ITS NATURE, IT WAS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014 AND (B)(6) 2014. NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 AND (B)(6) 2014 FROM NURSE: SHE STATED THAT PHYSICIAN HAD REVIEWED THE DOCUMENTATION AND PATIENT DID

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00433	BAYER HEALTHCARE LLC	10/15/2014	10/29/2014

Event Information:

Event Date (B3): 9/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B82477

Single Use: Y
Implant Date (E6): 9/9/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014, LOT NUMBER B82477, FOR STERILIZATION. THE PATIENT'S CONCURRENT CONDITION INCLUDED ENDOMETRIAL HYPERPLASIA. IN (B)(6) 2014 THE PHYSICIAN HAD A DIFFICULT INSERTION OF ESSURE IN BOTH TUBES. IN ONE TUBE THE MICROINSERT WAS VISIBLE OUTSIDE THE TUBE IN A WOUND-DOWN POSITION. IN THE OTHER TUBE, THE MICRO INSERT DEPLOYED BUT PART OF THE CATHETER BROKE OFF INSIDE THE TUBE WITH THE MICRO INSERT. THE PHYSICIAN GOT BACK RESULTS THAT THE PATIENT HAD ENDOMETRIAL HYPERPLASIA. AS A RESULT OF THE PATHOLOGY, HE HAS DECIDED TO DO A COMPLETE HYSTERECTOMY. THE OUTCOME OF THE EVENTS WAS NOT RECOVERED AT TIME OF REPORT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "...BUT PART OF THE CATHETER BROKE OFF INSIDE THE TUBE..." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING

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THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, BREAKAGE OF THE LARGE TIGHT PITCH COIL, OR BREAKAGE OF A PORTION OF THE DELIVERY CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE (BREAKAGE). IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED BATCH WAS INVESTIGATED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B82477. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MICROINSERT DEPLOYED BUT PART OF THE CATHETER BROKE OFF INSIDE ONE TUBE AND THE MICRO INSERT WAS VISIBLE OUTSIDE THE OTHER TUBE IN A WOUND-DOWN POSITION. THE EVENT MICROINSERT DEPLOYED BUT PART OF THE CATHETER BROKE OFF INSIDE ONE TUBE INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS; AND WAS INITIALLY CONSIDERED AS UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) IT WAS AMENDED TO LISTED, SINCE PTC ANALYSIS CONCLUDED THAT THE BREAKAGE IS AN ANTICIPATED EVENT. THE OTHER EVENT, REGARDED AS DEVICE DISLOCATION, IS LISTED AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ALTHOUGH THE EXACT MECHANISM OF THE REPORTED EVENTS WAS NOT PROVIDED, CONSIDERING POSITIVE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, THEY WERE CONSIDERED RELATED TO DEVICE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, DUE TO DEVICE BREAKAGE. ADDITIONALLY THE NON-SERIOUS EVENT DIFFICULT INSERTION OF ESSURE IN BOTH TUBES WAS REPORTED. PTC ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION WAS REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION WAS RECEIVED ON 20-OCT-2014. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. CONCOMITANT CONDITION INCLUDED OVERWEIGHT (B)(6). THE PATIENT DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES, RELEVANT MED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00436	BAYER HEALTHCARE LLC	10/16/2014	10/16/2014

Event Information:

Event Date (B3): 5/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 948836

Single Use: Y
Implant Date (E6): 5/10/2012
Explant Date (E7): 5/5/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A CLINICAL STUDY CASE REPORT RECEIVED FROM AN INVESTIGATOR IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN A INTERVENTIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: USE OF TRANSVAGINAL ULTRASOUND TO CONFIRM ESSURE® MICRO-INSERT PLACEMENT IN WOMEN: DEMONSTRATION OF EFFECTIVENESS. PATIENT NUMBER: (B)(6). ON (B)(6) 2012, THE PATIENT HAD ESSURE INSERTED FOR PERMANENT STERILIZATION, LOT NUMBER USED WAS 948836. INVESTIGATOR REPORTED THAT ON (B)(6) 2012, THE PATIENT START EXPERIENCED PELVIC PAIN OF MODERATE SEVERITY. ON (B)(6) 2014, AN AMBULATORY CERVICAL POLYPECTOMY, REMOVAL OF ESSURE AND A LAPAROSCOPIC BILATERAL SALPINGECTOMY WERE DONE. THE PATIENT RECOVERED WITH TREATMENT. INVESTIGATOR ASSESSED THE EVENT AS POSSIBLE RELATED TO ESSURE. FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2014: PTC (PRODUCT TECHNICAL COMPLAINT) WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: MANUFACTURING DATE: FEB-2012; EXPIRATION DATE: FEB-2015. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN (B)(4). MEDICAL ASSESSMENT: THIS PTC WAS

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INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 948836, OF WHICH 1 CASE REFERS ALSO TO A SIMILAR TYPE OF ADVERSE EVENT. NO UNUSUAL PATTERN COULD BE IDENTIFIED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, CLINICAL STUDY CASE REPORT REFERS TO A (B)(6) FEMALE SUBJECT WHO WAS INVOLVED IN A INTERVENTIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4) AND EXPERIENCED PELVIC PAIN. THIS EVENT WAS CONSIDERED AS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE IN THE INVESTIGATOR'S BROCHURE. PELVIC PAIN MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS PARTICULAR CASE, THE SUBJECT EXPERIENCED THIS EVENT ON THE SAME DAY OF ESSURE INSERTION. THE INVESTIGATOR ASSESSED THE EVENT AS POSSIBLE RELATED TO ESSURE. GIVEN A POSITIVE TEMPORAL RELATIONSHIP, COMPANY AGREES WITH INVESTIGATOR'S ASSESSMENT AND CONSIDERS THE REPORTED EVENT TO BE RELATED TO STUDY DEVICE. THIS CASE WAS REGARDED AS INCIDENT SINCE THE SUBJECT UNDERWENT A LAPAROSCOPIC BILATERAL SALPINGECTOMY. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 28-JAN-2015. ADDITIONALLY, DURING INTERNAL REVIEW IT WAS OBSERVED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE (B)(6) 2014 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS (B)(6) 2014. ESSURE WAS INSERTED ON (B)(6)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00437	BAYER HEALTHCARE LLC	10/16/2014	10/16/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6) 2014, ARTICLE ENTITLED "PROXIMAL OCCLUSION OF HYDROSALPINGES BY ESSURE BEFORE ASSISTED REPRODUCTION TECHNIQUES: A FRENCH SURVEY". IT REFERS TO A ADULT FEMALE PATIENT WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) TO OCCLUDE HYDROSALPINGES BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (PRODUCT USED FOR UNAPPROVED INDICATION) AND EXPERIENCED PYOSALPINX. REPORTED TRADE NAME WAS ESSURE. THIS CASE REPORT CONCERNS 1 OUT OF 41 PATIENTS WITH A SUCCESSFUL ESSURE PLACEMENT. AFTER THE ESSURE PROCEDURE, THIS WOMAN DEVELOPED PYOSALPINX 7 DAYS AFTER THE PROCEDURE. IT RESOLVED FAVOURABLY UNDER COMBINED ANTIBIOTIC THERAPY AND RADIOLOGIC DRAINAGE. AUTHORS COMMENT: THE SURGICAL RISK DURING LAPAROSCOPY, ESPECIALLY FOR WOMEN WITH MAJOR PELVIC ADHESIONS, HAS LED SOME SURGEONS TO USE ESSURE FOR HYSTEROSCOPIC TUBAL OCCLUSION, AN OFF-LABEL USE DIFFERENT FROM ITS PRIMARY PURPOSE OF TUBAL STERILISATION. AUTHORS OBSERVED ONE CASE OF PYOSALPINX. THIS IS RARE BUT IN CASE OF HYDROSALPINX DUE TO PAST HISTORY OF PELVIC INFLAMMATORY DISEASE, THE INFORMATION MUST BE GIVEN TO THE PATIENT AS A RISK OF SIDE EFFECT. DATA WAS COLLECTED FROM ALL CASES IN WHICH DOCTORS ATTEMPTED TO PLACE ESSURE MICROINSERTS TO OCCLUDE ONE OR TWO HYDROSALPINGES BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (INCLUDING IVF, ICSI, AND EMBRYO OR OOCYTE DONATION). ABSTRACT: OBJECTIVES: TO STUDY THE FEASIBILITY AND RESULTS (LIVE-BIRTH AND COMPLICATION RATES) OF PLACEMENT OF ESSURE1 MICROINSERTS BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT OF WOMEN WITH HYDROSALPINX WHEN LAPAROSCOPY SHOULD BE AVOIDED. STUDY DESIGN: NATIONAL SURVEY OF 45 FRENCH HOSPITAL CENTRES PROVIDING ART REPORTING A RETROSPECTIVE ANALYSIS OF 43 WOMEN WITH UNILATERAL OR BILATERAL HYDROSALPINGES AND

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ESSURE1 PLACEMENT. THE RESULTS OF THE FOLLOWING ART CYCLE WERE STUDIED FOR 54 EMBRYO TRANSFERS. RESULTS: THE PLACEMENT SUCCESS RATE REACHED 92.8 PERCENT (65/70 TUBES), AND THE MEAN NUMBER OF VISIBLE INTRAUTERINE COILS WAS 1.61 (RANGE: 0 TO 6). PYOSALPINX OCCURRED IN ONE CASE, AND EXPULSION OF THE DEVICE INTO THE UTERUS IN TWO OTHERS. OF 43 WOMEN, 29 (67.4 PERCENT) HAD A TOTAL OF 54 FRESH OR FROZEN EMBRYOS TRANSFERRED. THE CLINICAL PREGNANCY RATE WAS 40.7 PERCENT (22/54) AND THE LIVE-BIRTH RATE 25.9 PERCENT (14/54). THE IMPLANTATION RATE WAS 29.3 PERCENT (27/92). CONCLUSION: ESSURE1 PLACEMENT IS AN EFFECTIVE METHOD FOR OCCLUSION OF HYDROSALPINGES BEFORE IVF. MONITORING THE LIVE-BIRTH RATE CONFIRMS THAT THIS OPTION IS THE STRONGEST IN CASES WHEN LAPAROSCOPY IS IMPOSSIBLE OR CONTRAINDICATED. OTHER CASES FROM SAME ARTICLE ARE 2014-139928, 2014-140208, 2014-140209, 2014-140250, 2014-140161 AND 2014-140255. FOLLOW-UP RECEIVED ON 06-OCT-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (REQUEST FOR CONFIRMATION OF QUALITY AND OFF LABEL USE). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN THIS PARTICULAR CASE, ALSO AN OFF LABEL USE WAS REPORTED. ACCORDING TO CASE INFORMATION THE PRODUCT WAS USED TO ASSISTED REPRODUCTIVE TECHNOLOGY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE, A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2014 FOR THE FOLLOWING MEDDRA PREFERRED TERM: SALPINGITIS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT WAS DERIVED FROM LITERATURE AND REFERS TO AN ADULT FEMALE PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED TO OCCLUDE HYDROSALPINX (OFF LABEL USE IN UNAPPROVED INDICATION) AND EXPERIENCED PIOSALPINX. PIOSALPINX WAS CONSIDERED SERIOUS, AS MEDICALLY SIGNIFICANT, IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. PYOSALPINX, ALSO REFERRED AS TUBOOVARIAN ABSCESS, IS AN INFLAMMATORY MASS INVOLVING THE FALLOPIAN TUBE, OVARY, AND, OCCASIONALLY, OTHER ADJACENT PELVIC ORGANS. THESE ABSCESSES TYPICALLY RESULT FROM UPPER GENITAL TRACT INFECTION (COMPLICATION OF PELVIC INFLAMMATORY DISEASE). WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS PARTICULAR CASE, 7 DAYS AFTER ESSURE INSERTION PATIENT DEVELOPED PYOSALPINX, WHICH WAS SUCCESSFULLY TREATED. GIVEN PYOSALPINX PHYSIOPATHOLOGY AND THE CLOSE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS

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CASE WAS REGARDED AS INCIDENT SINCE IT REQUIRED MEDICAL INTERVENTION (ANTIBIOTIC THERAPY AND RADIOLOGIC DRAINAGE). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00438	BAYER HEALTHCARE LLC	10/16/2014	10/16/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6) 2014, ARTICLE ENTITLED "PROXIMAL OCCLUSION OF HYDROSALPINGES BY ESSURE BEFORE ASSISTED REPRODUCTION TECHNIQUES: A FRENCH SURVEY". IT REFERS TO A ADULT FEMALE PATIENT WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) TO OCCLUDE HYDROSALPINGES BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (PRODUCT USED FOR UNAPPROVED POPULATION) AND SHE HAD PREMATURE RUPTURE OF THE MEMBRANES, INCOMPLETE PLACENTA PRAEVIA AND INTENDED PREGNANCY WITH ESSURE USE WAS REPORTED. TRADE NAME WAS REPORTED AS ESSURE. FOR ALL WOMEN, AT LEAST ONE IMAGING EXAMINATION WAS PERFORMED (ABDOMINAL RADIOGRAPHY, PELVIC ULTRASOUND, OR HYSTEROSALPINGOGRAPHY). ALL EXAMINATIONS EITHER FOUND THAT THE IMPLANTS WERE CORRECTLY PLACED OR CONFIRMED THE TUBAL OCCLUSION. CLINICAL PREGNANCY WAS DEFINED AS TRANSVAGINAL ULTRASOUND DETECTION OF A GESTATIONAL SAC AFTER EMBRYO TRANSFER, AND THE IMPLANTATION RATE AS THE NUMBER OF GESTATIONAL SACS OBSERVED RELATIVE TO THE NUMBER OF EMBRYOS TRANSFERRED. THIS CASE REFERS TO A WOMAN IN WHOM SINGLE PREMATURE RUPTURE OF THE MEMBRANES WAS OBSERVED, AT 32 WEEKS PLUS 4 DAYS OF GESTATION, IN A PREGNANCY THAT INVOLVED INCOMPLETE PLACENTA PRAEVIA AND HAD NO SIGNS SUGGESTIVE OF CHORIOAMNIONITIS. AUTHORS COMMENT: THE SURGICAL RISK DURING LAPAROSCOPY, ESPECIALLY FOR WOMEN WITH MAJOR PELVIC ADHESIONS, HAS LED SOME SURGEONS TO USE ESSURE FOR HYSTEROSCOPIC TUBAL OCCLUSION, AN OFF-LABEL USE DIFFERENT FROM ITS PRIMARY PURPOSE OF TUBAL STERILISATION. RESULTS IDENTIFIED NO OBVIOUS IMPEDIMENTS TO ART (ASSISTED REPRODUCTIVE TECHNOLOGY) AFTER THESE PROCEDURES. THE CLINICAL PREGNANCY RATE WAS 40.7 PERCENT, THE LIVE-BIRTH RATE 25.9 PERCENT AND THE IMPLANTATION RATE 29.3. FURTHERMORE, THE NUMBER OF COILS LEFT IN THE UTERINE CAVITY DOES NOT SEEM TO AFFECT THE

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LIKELIHOOD OF PREGNANCY. AMONG CLINICAL PREGNANCIES, THERE WERE SEVEN EARLY SPONTANEOUS ABORTIONS (31.8%) AND ONE (4.5%) INTRAUTERINE DEATH DUE TO FETOMATERNAL PLATELET ALLOIMMUNISATION. EVENTUALLY, 18 CHILDREN WERE BORN FROM THESE ATTEMPTS, INCLUDING FOUR SETS OF TWINS FROM DICHORIONIC DIAMNIOTIC PREGNANCIES, FOR 14 LIVE BIRTHS. THE OBSTETRIC COMPLICATIONS IN OUR STUDY WERE PRIMARILY CASES OF FETAL GROWTH RESTRICTION (3/14 LIVE BIRTHS), PROBABLY ATTRIBUTABLE TO THE MULTIPLE PREGNANCY (THREE CASES OF FETAL GROWTH RESTRICTION IN FOUR TWIN PREGNANCIES). THERE WERE NO CASES OF CHORIOAMNIONITIS IN OUR STUDY. ESSURE THUS DOES NOT SEEM TO CAUSE OBSTETRIC COMPLICATIONS. STUDY LOOKED FOR AND FAILED TO FIND ANY EFFECT OF THE NUMBER OF INTRAUTERINE COILS ON EITHER THE CLINICAL PREGNANCY OR SPONTANEOUS ABORTION RATES. SEVERAL REASONS BESIDES LACK OF POWER MAY EXPLAIN THIS RESULT, IN PARTICULAR THE FACT THAT AFTER ESSURE PLACEMENT, OSTIA ARE RECOLONISED BY THE ENDOMETRIUM: SECOND LOOK HYSTEROSCOPY ROUTINELY FINDS COIL ENCAPSULATION. THE MEAN NUMBER OF COILS IN OUR SERIES IS LOWER. FEWER THAN THREE COILS WERE VISIBLE AT THE END OF THE PROCEDURE IN MOST WOMEN. ESSURE DEVICES SHOULD NOT BE USED AS THE FIRST STEP OF THE TREATMENT OF HYDROSALPINX BUT ONLY WHEN LAPAROSCOPIC SALPINGECTOMY IS CONTRAINDICATED BECAUSE OF A MAJOR RISK OF BOWEL INJURY, SUCH AS SEVERE ENDOMETRIOSIS OR PELVIC INFLAMMATORY DISEASE WITH FROZEN PELVIS. ABSTRACT: OBJECTIVES: TO STUDY THE FEASIBILITY AND RESULTS (LIVE-BIRTH AND COMPLICATION RATES) OF PLACEMENT OF ESSURE1 MICROINSERTS BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT OF WOMEN WITH HYDROSALPINX WHEN LAPAROSCOPY SHOULD BE AVOIDED. STUDY DESIGN: NATIONAL SURVEY OF 45 FRENCH HOSPITAL CENTERS PROVIDING ART REPORTING A RETROSPECTIVE ANALYSIS OF 43 WOMEN WITH UNILATERAL OR BILATERAL HYDROSALPINGES AND ESSURE1 PLACEMENT. THE RESULTS OF THE FOLLOWING ART CYCLE WERE STUDIED FOR 54 EMBRYO TRANSFERS. RESULTS: THE PLACEMENT SUCCESS RATE REACHED 92.8 PERCENT (65/70 TUBES), AND THE MEAN NUMBER OF VISIBLE INTRAUTERINE COILS WAS 1.61 (RANGE: 0 TO 6). PYOSALPINX OCCURRED IN ONE CASE, AND EXPULSION OF THE DEVICE INTO THE UTERUS IN TWO OTHERS. OF 43 WOMEN, 29 (67.4 PERCENT) HAD A TOTAL OF 54 FRESH OR FROZEN EMBRYOS TRANSFERRED. THE CLINICAL PREGNANCY RATE WAS 40.7 PERCENT (22/54) AND THE LIVE-BIRTH RATE 25.9 PERCENT (14/54). THE IMPLANTATION RATE WAS 29.3 PERCENT (27/92). CONCLUSION: ESSURE1 PLACEMENT IS AN EFFECTIVE METHOD FOR OCCLUSION OF HYDROSALPINGES BEFORE IVF. MONITORING THE LIVE-BIRTH RATE CONFIRMS THAT THIS OPTION IS THE STRONGEST IN CASES WHEN LAPAROSCOPY IS IMPOSSIBLE OR CONTRAINDICATED. OTHER CASES FROM SAME ARTICLE ARE 2014-139791, 2014-140208, 2014-140209, 2014-140250, 2014-140161 AND 2014-140255. FOLLOW-UP RECEIVED ON 06-OCT-2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: 2014-025393. PTC INVESTIGATION RESULT WAS PROVIDED. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO AN OFF LABEL USE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE PTC CASE REFERS ALSO TO A LACK OF EFFICACY. IN GENERAL CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. HOWEVER, IN THIS PARTICULAR CASE, AN OFF LABEL USE WAS REPORTED. ACCORDING TO CASE REPORT THE PRODUCT WAS USED TO ASSISTED REPRODUCTIVE TECHNOLOGY AND NOT TO PREVENT CONCEPTION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE

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TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2014 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1. PREMATURE RUPTURE OF MEMBRANES. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 2 CASES. 2. PLACENTA PRAEVIA. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 1 CASE. 3. PREGNANCY WITH CONTRACEPTIVE DEVICE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 1863 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT WAS DERIVED FROM LITERATURE AND REFERS A FEMALE PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR OCCLUSION OF HYDROSALPINX BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (ART) (OFF-LABEL USE IN UNAPPROVED INDICATION) AND SUBSEQUENTLY HAD AN INTENDED PREGNANCY WITH ESSURE (UNEXPECTED THERAPEUTIC BENEFIT); WHICH INVOLVED AN INCOMPLETE PLACENTA PREVIA. AT 32 WEEKS OF GESTATION SHE EXPERIENCED PREMATURE RUPTURE OF THE MEMBRANES. THE EVENTS PLACENTA PREVIA AND PREMATURE RUPTURE OF THE MEMBRANES WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE UNLISTED IN ESSURE REFERENCE SAFETY INFORMATION; WHILE THE REMAINING EVENTS ARE NON-SERIOUS AND LISTED, EXCEPT FOR UNEXPECTED THERAPEUTIC BENEFIT WHICH IS UNLISTED. HYDROSALPINGES MAY BE A TUBAL FACTOR OF INFERTILITY AND THEIR PRESENCE DECREASES THE SUCCESS RATE OF ART. REMOVAL OF THE HYDROSALPINGES (BY SALPINGECTOMY) INCREASES THE SUCCESS OF THESE TREATMENTS. IN THIS PARTICULAR CASE, THE PATIENT HAD ESSURE INSERTED AS AN OFF-LABEL TREATMENT OF HER HYDROSALPINX; LATER SHE WAS SUBMITTED TO ART AND BECAME PREGNANT. GIVEN ITS NATURE THE REPORTED OFF-LABEL USE WAS CONSIDERED AS UNRELATED TO ESSURE. PATIENT'S PREGNANCY WAS CONSIDERED AS RELATED TO THE INSERT SINCE IT WAS REGARDED AS AN UNEXPECTED THERAPEUTIC BENEFIT. REGARDING THE REMAINING EVENTS PLACENTA PREVIA REFERS TO THE PRESENCE OF PLACENTAL TISSUE THAT EXTENDS OVER OR LIES PROXIMATE TO THE INTERNAL CERVICAL OS. ITS SEQUELAE INCLUDE POTENTIAL FOR BLEEDING AND PRETERM BIRTH; IT HAS ALSO BEEN ASSOCIATED WITH AN INCREASED RISK OF PREMATURE RUPTURE OF THE MEMBRANES DUE TO ANTEPARTUM BLEEDING. CONSIDERING THE REPORTED EVENTS PHYSIOPATHOLOGY AND THE GESTATIONAL AGE AT MEMBRANES RUPTURE; A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THEY WERE; THEREFORE CONSIDERED AS RELATED TO THE SUSPECT INSERT. THIS CASE WAS REGARDED AS AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00439	BAYER HEALTHCARE LLC	10/16/2014	10/16/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2014, ARTICLE ENTITLED "PROXIMAL OCCLUSION OF HYDROSALPINGES BY ESSURE BEFORE ASSISTED REPRODUCTION TECHNIQUES: A (B)(6) SURVEY". IT REFERS TO AN ADULT FEMALE PATIENT WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) TO OCCLUDE HYDROSALPINGES BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (PRODUCT USED FOR UNAPPROVED POPULATION) AND EXPERIENCED NONSEVERE THREATENED PRETERM DELIVERY AT 32 WEEKS OF GESTATION, WITH NO SUGGESTION OF INFECTION AND INTENDED PREGNANCY WITH ESSURE USE WAS REPORTED. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2014. REPORTED TRADE NAME WAS ESSURE. THIS CASE REPORT CONCERNS 1 PATIENT OUT OF 41 PATIENTS WITH A SUCCESSFUL ESSURE PLACEMENT. AFTER THE ESSURE PROCEDURE, THIS WOMAN HAD A NON SEVERE THREATENED PRETERM DELIVERY AT 32 WEEKS OF GESTATION, WITH NO SUGGESTION OF INFECTION; SHE FINALLY GAVE BIRTH AT TERM. IT WAS OBSERVED NO LATE MISCARRIAGES AND NO EVIDENCE OF CHORIOAMNIONITIS. FOR ALL WOMEN, AT LEAST ONE IMAGING EXAMINATION WAS PERFORMED (ABDOMINAL RADIOGRAPHY, PELVIC ULTRASOUND, OR HYSTEROSALPINGOGRAPHY). ALL EXAMINATIONS EITHER FOUND THAT THE IMPLANTS WERE CORRECTLY PLACED OR CONFIRMED THE TUBAL OCCLUSION. AUTHORS COMMENT: THE SURGICAL RISK DURING LAPAROSCOPY, ESPECIALLY FOR WOMEN WITH MAJOR PELVIC ADHESIONS, HAS LED SOME SURGEONS TO USE ESSURE FOR HYSTEROSCOPIC TUBAL OCCLUSION, AN OFF-LABEL USE DIFFERENT FROM ITS PRIMARY PURPOSE OF TUBAL STERILISATION. AUTHORS OBSERVED ONE CASE OF NONSEVERE THREATENED PRETERM DELIVERY AT 32 WEEKS OF GESTATION, WITH NO SUGGESTION OF INFECTION; SHE FINALLY GAVE BIRTH AT TERM. DATA WAS COLLECTED FROM ALL CASES IN WHICH DOCTORS ATTEMPTED TO PLACE ESSURE MICROINSERTS TO OCCLUDE ONE OR TWO HYDROSALPINGES BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (INCLUDING IVF,

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ICSI, AND EMBRYO OR OOCYTE DONATION). ABSTRACT: OBJECTIVES: TO STUDY THE FEASIBILITY AND RESULTS (LIVE-BIRTH AND COMPLICATION RATES) OF PLACEMENT OF ESSURE MICROINSERTS BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT OF WOMEN WITH HYDROSALPINX WHEN LAPAROSCOPY SHOULD BE AVOIDED. STUDY DESIGN: NATIONAL SURVEY OF 45 (B)(6) HOSPITAL CENTRES PROVIDING ART REPORTING A RETROSPECTIVE ANALYSIS OF 43 WOMEN WITH UNILATERAL OR BILATERAL HYDROSALPINGES AND ESSURE PLACEMENT. THE RESULTS OF THE FOLLOWING ART CYCLE WERE STUDIED FOR 54 EMBRYO TRANSFERS. RESULTS: THE PLACEMENT SUCCESS RATE REACHED 92.8 PERCENT (65/70 TUBES), AND THE MEAN NUMBER OF VISIBLE INTRAUTERINE COILS WAS 1.61 (RANGE: 0 TO 6). PYOSALPINX OCCURRED IN ONE CASE, AND EXPULSION OF THE DEVICE INTO THE UTERUS IN TWO OTHERS. OF 43 WOMEN, 29 (67.4 PERCENT) HAD A TOTAL OF 54 FRESH OR FROZEN EMBRYOS TRANSFERRED. THE CLINICAL PREGNANCY RATE WAS 40.7 PERCENT (22/54) AND THE LIVE-BIRTH RATE 25.9 PERCENT (14/54). THE IMPLANTATION RATE WAS 29.3 PERCENT (27/92). CONCLUSION: ESSURE PLACEMENT IS AN EFFECTIVE METHOD FOR OCCLUSION OF HYDROSALPINGES BEFORE IVF. MONITORING THE LIVE-BIRTH RATE CONFIRMS THAT THIS OPTION IS THE STRONGEST IN CASES WHEN LAPAROSCOPY IS IMPOSSIBLE OR CONTRAINDICATED. OTHER CASES FROM SAME ARTICLE ARE 2014-139791, 2014-139928, 2014-140208, 2014-140209, 2014-140250, 2014-140255. AFTER INTERNAL REVIEW ON (B)(4) 2014: THE EVENT THERAPEUTIC EFFECT UNEXPECTED WAS ADDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2014. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, AN OFF LABEL USE WAS REPORTED, THE PRODUCT WAS USED TO ASSISTED REPRODUCTIVE TECHNOLOGY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN (B)(6). IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2014 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1.THREATENED LABOUR. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 01 CASE. 2.PREGNANCY WITH CONTRACEPTIVE DEVICE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6)CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED TO OCCLUDE HYDROSALPINGES BEFORE ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT (OFF LABEL USE IN UNAPPROVED INDICATION). SHE HAD AN INTENDED PREGNANCY WITH ESSURE USE (UNEXPECTED THERAPEUTIC EFFECT) AND EXPERIENCED NONSEVERE THREATENED PRETERM DELIVERY AT 32 WEEKS OF GESTATION, WITH NO SUGGESTION OF INFECTION. INTENDED PREGNANCY WITH ESSURE USE IS LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION WHILE THE REMAINING EVENT IS UNLISTED. BOTH EVENTS WERE CONSIDERED NON-SERIOUS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE.

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SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, THE PATIENT HAD ESSURE INSERTED AS AN OFF-LABEL TREATMENT OF HER PREVIOUS DIAGNOSED HYDROSALPINX; LATER SHE WAS SUBMITTED TO ASSISTED REPRODUCTIVE TECHNOLOGY AND BECAME PREGNANT. GIVEN ITS NATURE THE REPORTED OFF-LABEL USE WAS CONSIDERED AS UNRELATED TO ESSURE THERAPY. PATIENT'S PREGNANCY WAS CONSIDERED AS RELATED TO ESSURE (REGARDED AS AN UNEXPECTED THERAPEUTIC EFFECT), SINCE THE AUTHORS CONCLUDED THAT ESSURE PLACEMENT IS AN EFFECTIVE METHOD FOR OCCLUSION OF HYDROSALPINGES BEFORE ART. WITH REGARDS TO THE EVENT NONSEVERE THREATENED PRETERM DELIVERY AT 32 WEEKS OF GESTATION, CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, SINCE THIS EVENT COULD HAVE LED TO SERIOUS INJURY, HOWEVER, PATIENT GAVE BIRTH AT TERM AND NO COMPLICATION WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

- ATTACHMENT: [2014-140161_00439_ARTICLE.PDF].

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038655	CONCEPTUS/BAYER	10/16/2014	10/22/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS 305
Catalog # (E4):
Lot #(E4): B30422

Single Use:
Implant Date (E6): 10/8/2013
Explant Date (E7): 10/2/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS PLACED IN (B)(6) 2013. STARTED HAVING SIDE EFFECTS NOT LISTED IN DEVICE LITERATURE AFTER PLACEMENT. STABBING PAINS IN LOWER ABDOMEN/PELVIC AREA WHERE COILS ARE LOCATED. INCREASED FREQUENCY OF URINATION. BLOATING AND WEIGHT GAIN. MID CYCLE (OVULATION) PAIN THAT HAVE NEVER HAD BEFORE. ALL OVER JOINT ACHING PAIN THIS WINTER, NOW IS JUST LOCATED IN HIP AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038709	BAYER	10/16/2014	10/23/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED 2007. SOON AFTER THE PROCEDURE I STARTED FEELING STICK WITH CRAMPS, JOINT PAIN, VAGINAL BLEEDING, LOSS OF ENERGY, PAIN LOWER BACK AND WAS GETTING WORSE. AFTER COUPLE OF YEARS FEELING BAD, MY OBGYN AND I DECIDED TO REMOVE THE ESSURE, AND HAD ABLATION TO STOP THE BLEEDING. AFTER THE SURGERY, STILL WITH PAIN, THE DOCTOR DID A PARTIAL HYSTERECTOMY BECAUSE I HAD ENDOMETRIOSIS, STILL WITH JOINT PAIN. I HAVE BEEN SEEN ALMOST 20 DIFFERENT DOCTORS AND NO ONE CAN EXPLAIN WHY MY HEALTH IS SO BAD TO THE POINT I CAN'T DO ANYTHING. MY BLOOD WORK COMES BACK NORMAL. LAST YEAR THEY REMOVED A LUMP IN MY BREAST. MY LIFE IS A NIGHTMARE AFTER ESSURE, NOW I HAVE ALL KINDS OF ALLERGIES. WHEN BEFORE THE ESSURE I WAS SO HEALTHY NOT EVEN A COLD FOR YEARS, PLAYING TENNIS ALMOST EVERY DAY, NOW MY LIFE IS REDUCED TO TAKING PAIN KILLERS AND GOING TO DOCTORS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00435	BAYER HEALTHCARE LLC	10/16/2014	10/30/2014

Event Information:

Event Date (B3): 9/11/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06468

Single Use: Y
Implant Date (E6): 9/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM ANOTHER (HOSPITAL'S ASSISTANT BUYER) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014, LOT NUMBER C06468. IN (B)(6) 2014 DURING THE INSERTION PROCEDURE, THE SPRING WOULD NOT DETACH AND BROKE BEFORE DEPLOYMENT. THERE WAS NO PATIENT INJURY. THE REPORTER IS REQUESTING ESSURE REPLACEMENT. NO OTHER INFORMATION WAS PROVIDED AND NO ASSESSMENT WAS GIVEN BY THE REPORTER. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "BROKE BEFORE DEPLOYMENT" IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICROINSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE

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MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. SINCE NEITHER PRODUCT WAS RETURNED FOR INSPECTION NOR DO WE HAVE A PHOTOGRAPH OF THE ACTUAL DEVICE, WE CANNOT DETERMINE EXACTLY WHAT THE FAILURE IS. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE. THE AE CASE REFERS ALSO TO USABILITY ISSUES. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE BATCH DOCUMENTATION WAS REVIEWED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". SINCE NO ADVERSE EVENTS WERE REPORTED, NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. LOT NUMBER C06468 (PRODUCTION DATE 18-DEC-2013 AND EXPIRATION DATE 31-DEC-2016). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND, DURING INSERTION PROCEDURE, SPRING WOULD NOT DETACH AND BROKE BEFORE DEPLOYMENT (COMPLICATION OF DEVICE INSERTION/FAILED INSERTION). THE REPORTED EVENTS, INTERPRETED AS A DEVICE DEPLOYMENT ISSUE AND BREAKAGE ARE NON-SERIOUS. DEVICE BREAKAGE DURING INSERTION, PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. ALSO, THE REMAINING EVENT IS LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE REPORTER STATED THAT SPRING WOULD NOT DETACH AND BROKE BEFORE DEPLOYMENT. REPORTER IS REQUESTING ESSURE REPLACEMENT AND SAMPLE IS AVAILABLE FOR RETURN. BASED ON THE INFORMATION RECEIVED, AND GIVEN THE NATURE OF THE REPORTED EVENTS, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

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Manufacturer Narrative (H10):

INFORMATION RECEIVED FROM CONSUMER STATES THAT ONLY HALF OF THE DEVICE WAS DEFECTIVE. SALES REPRESENTATIVE PROVIDED PATIENT'S INITIALS AND DATE OF BIRTH ((B)(6) AT TIME OF EVENT). THE ESSURE PROCEDURE DATE WAS (B)(6)2014. NO FURTHER INFORMATION WAS PROVID

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00440	BAYER HEALTHCARE LLC	10/16/2014	10/30/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/19/2014
Explant Date (E7): 9/19/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2014 FOR STERILIZATION HOWEVER NOT SUCCEEDED. IT WAS REPORTED THAT ESSURE BROKE IN HALF DURING THE INSERTION PROCEDURE; HALF WAS IN THE TUBE AND HALF IN THE UTERUS. PHYSICIAN TRIED TO REMOVE IT WITH GRASPERS, HE BELIEVED THAT THEY REMOVED THEM. PHYSICIAN WAS GOING TO ATTEMPT TO PUT ANOTHER DEVICE. FOLLOW-UP RECEIVED ON 07-OCT-2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). THE PTC INVESTIGATION RESULT WAS PROVIDED. FINAL ASSESSMENT: WHEN A TERM LIKE THE ESSURE BROKE IN HALF IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE

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NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICROINSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICROINSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE (BREAKAGE). IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE INSERTION PROCEDURE ESSURE BROKE IN HALF; DEVICE INSERTION FAILED. THESE EVENTS ARE NON-SERIOUS. ESSURE BROKE IN HALF WAS INITIALLY CONSIDERED AS UNLISTED EVENT ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; HOWEVER UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) IT WAS AMENDED TO LISTED, SINCE PTC ANALYSIS CONCLUDED THAT THE BREAKAGE IS AN ANTICIPATED EVENT; THE OTHER EVENT IS LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE IT WAS REPORTED THAT ESSURE BROKE IN HALF DURING THE INSERTION PROCEDURE. THE PHYSICIAN TRIED TO REMOVE IT WITH GRASPERS, AND HE BELIEVED THAT THEY REMOVED IT AT ALL. CONSIDERING THE AVAILABLE INFORMATION AND GIVEN THE NATURE OF THE REPORTED EVENTS, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE. THE PERFORMED PTC ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 27-OCT-2014 FROM PHYSICIAN. THIS CASE WAS UPGRADED TO INCIDENT DUE TO HYSTEROSCOPY. THE ESSURE DID NOT DEPLOY PROPERLY. THE DOCTOR HAD TO REMOVE IT FROM THE UTERINE CAVITY VIA HYSTEROSCOPE. IT BROKE DURING THE REMOVAL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038766		10/17/2014	10/27/2014

Event Information:

Event Date (B3): 10/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/3/2012
Explant Date (E7): 10/16/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A HIDA SCAN DONE AND IT DETERMINED MY GALLBLADDER WAS NOT FUNCTIONING WELL. AFTER THE SURGERY, I WAS TOLD THAT THEY ALSO REMOVED MY ESSURE DEVICE FROM THE FATTY TISSUE BY MY GALLBLADDER. SO IT WENT A LONG WAY IN MY INSIDES. THAT IS NOT SAFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038768		10/17/2014	10/27/2014

Event Information:

Event Date (B3): 1/15/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/15/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE PRESSURE PLACED IN 2006. IT HAS COME OUT AND I AM NOW EXTREMELY ANEMIC AND I HAVE EXTREME CYCLES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038763		10/19/2014	10/27/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PPMD, ALLERGIC REACTION, WEIGHT GAIN, DEPRESSION, VISION PROBLEMS, UTI PROBLEMS, UTI, EXTREME PELVIC PAIN, VERY PAINFUL AND HEAVY PERIODS, PAINFUL OVULATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00441	BAYER HEALTHCARE LLC	10/20/2014	10/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 9/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A STUDY CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF WHO WAS INVOLVED IN A (B)(4) STUDY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: POST-APPROVAL STUDY PROTOCOL: A STUDY TO EVALUATE THE EFFECTIVENESS OF ESSURE POST-NOVASURE RADIOFREQUENCY ENDOMETRIAL ABLATION PROCEDURE FOLLOWING A SUCCESSFUL ESSURE CONFIRMATION TEST. IT WAS REPORTED THAT ESSURE WAS PLACED IN 2012. SHE BLED HEAVILY AND HAD AN ABLATION NOT KNOWING THAT IT WAS NOT RECOMMENDED. SHE REPORTED THAT SHE HAD POST ABLATION POST TUBAL LIGATION SYNDROME SYMPTOMS EVER SINCE. SHE GOT HER TUBES AND COILS REMOVED 3 WEEKS AGO, FROM THE TIME OF THE REPORT (IMPLYING (B)(6) 2014) DUE TO AUTOIMMUNE AND INFLAMMATORY RESPONSES FROM THE NICKEL AND PET FIBERS. HER UTERUS WAS SCARRED FROM THE ABLATION THAT A HYSTEROSCOPY WAS NOT POSSIBLE. SHE WAS VERY UNCOMFORTABLE, HER UTERUS FELT LIKE IT WAS FULL OF BLOOD AND CAN`T COME OUT. SHE STATED SHE WAS GOING TO HAVE HER POST OP FOLLOW UP AND WILL NEED A HYSTERECTOMY IN THE NEAR FUTURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A (B)(4) STUDY, STUDY NUMBER: (B)(4). THE CONSUMER BLED SO HEAVILY AND SHE HAD AN ABLATION (INTERPRETED AS GENITAL BLEEDING) AND EXPERIENCED POST ABLATION POST TUBAL LIGATION SYNDROME SYMPTOMS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. SHE ALSO REPORTED THAT HER UTERUS FELT LIKE IT WAS FULL OF BLOOD AND CAN'T COME OUT (INTERPRETED AS HAEMATOMETRA), WHICH WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. POST-

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ABLATION TUBAL STERILISATION SYNDROME IS A RARE CONDITION THAT HAS BEEN REPORTED IN WOMEN WITH A HISTORY OF TUBAL STERILISATION WHO UNDERGO ENDOMETRIAL ABLATION; PERFORMING ENDOMETRIAL ABLATION IMMEDIATELY FOLLOWING PLACEMENT OF ESSURE MICRO-INSERTS MAY INCREASE THE RISK OF THIS CONDITION. IN THIS PARTICULAR CASE, THE TIME FROM ESSURE INSERTION TO THE ONSET OF THE EVENTS WERE NOT REPORTED. CONSUMER GOT HER TUBES AND COILS REMOVED (PROBABLY SHE UNDERWENT A SALPINGECTOMY AFTER EXPERIENCING POST ABLATION POST TUBAL LIGATION SYNDROME). BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION (TUBES REMOVED, SALPINGECTOMY) WAS REQUIRED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON (B)(6) 2014. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015. THE PTC GLOBAL REFERENCE NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGAT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00443	BAYER HEALTHCARE LLC	10/20/2014	10/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 9/22/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. PATIENT WAS COMPLAINING OF LEFT QUADRANT PAIN SINCE THE ESSURE WAS INSERTED, AND WAS REQUESTING REMOVAL. THE PHYSICIAN DID A BILATERAL SALPINGECTOMY ON (B)(6) 2014. PATIENT'S LEFT TUBE WAS LEFT INTACT SINCE THE PHYSICIAN FELT THE ESSURE WAS IN THE OUTER LUMEN OF THE TUBE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

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Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN ON 03-FEB-2015. THE PATIENT´S INITIALS AND DATE OF BIRTH WERE UPDATED (SHE WAS (B)(6) AT TIME OF EVENT). ESSURE WAS PLACED IN (B)(6) 2009 BY ANOTHER PHYSICIAN. ON (B)(6) 2014, AN ULTRASOUND WAS DONE AND WAS NO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038789	CONCEPTUS	10/20/2014	10/27/2014

Event Information:

Event Date (B3): 10/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): SS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/20/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN TWO YEARS AGO. EVER SINCE THEN, I'VE HAD HORRIBLE CRAMPING WHEN I MOVE, I CAN'T SLEEP, MENSTRUAL CYCLES HAVE BEEN DEBILITATING, BRAIN FOG, DIZZINESS, AND I DON'T FEEL LIKE MYSELF. ALMOST LIKE I HAVE ALL THESE TOXINS INSIDE OF ME. I AM A VERY HEALTHY FEMALE AND HAVE NEVER IN MY LIFE HAD THIS UNTIL I HAD ESSURE. PLANNED PARENTHOOD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038790	CONCEPTUS	10/20/2014	10/27/2014

Event Information:

Event Date (B3): 1/15/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 1/15/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SERIOUS HAIR LOSS, CHRONIC BACK PAIN, AND JOINT PROBLEMS AFTER THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00442	BAYER HEALTHCARE LLC	10/20/2014	11/6/2014

Event Information:

Event Date (B3): 5/5/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B7165

Single Use:
Implant Date (E6): 5/5/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE VIA REGULATORY AUTHORITY (CASE# (B)(6)) IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER B71765. THE MEDICAL DOCTOR WAS INSERTING ESSURE STERILIZATION COIL VIA HYSTEROSCOPY WHEN COIL DID NOT FULLY RELEASE INTO RIGHT FALLOPIAN TUBE. ONLY PART OF COIL WAS INSERTED. LEFT FALLOPIAN TUBE WENT WITHOUT PROBLEMS. THE EVENTS WERE CONSIDERED MEDICALLY IMPORTANT BY REPORTER THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4)2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: 1) ROLLBACK TO INITIAL HARD STOP. 2) DEPRESS BUTTON. 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICROINSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE

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INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM THE DEVICE BREAKAGE. CONCLUSIONS: THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE AND THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF ARE ANTICIPATED EVENTS. ACCORDING TO THE (B)(6), THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE BATCH DOCUMENTATION WAS REVIEWED BY THE RQU. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS WERE REPORTED, NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY AND REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE COIL DID NOT FULLY RELEASE INTO RIGHT FALLOPIAN TUBE. ONLY PART OF COIL WAS INSERTED. THESE EVENTS INTERPRETED AS A DEVICE BREAKAGE AND DEPLOYMENT ISSUE WERE CONSIDERED SERIOUS BY THE REPORTER DUE TO MEDICAL IMPORTANCE. DEVICE BREAKAGE DURING ESSURE INSERTION WAS INITIALLY CONSIDERED AS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; HOWEVER UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) IT WAS AMENDED TO LISTED, SINCE PTC ANALYSIS CONCLUDED THAT THE BREAKAGE IS AN ANTICIPATED EVENT. THE REMAINING EVENT IS LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE; CONSIDERING THAT THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT THEY WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE MALFUNCTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION CAN BE OBTAINED SINCE THIS IS A HEALTH AUTHORITY CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00448	BAYER HEALTHCARE LLC	10/21/2014	10/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(4) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. SHORTLY AFTER THE ATTEMPT TO HAVE ESSURE INSERTED, APPROXIMATELY 6 MONTHS LATER, CONSUMER BECAME PREGNANT AND IT WAS AN EXTREMELY DIFFICULT PREGNANCY. AFTER DELIVERY, SHE HAD A TUBAL LIGATION DONE IN HOSPITAL. THE PART OF THE FALLOPIAN TUBES THAT ARE SENT OFF TO PATHOLOGY FOUND FLAT METAL WIRES THAT WERE PENETRATING THE FALLOPIAN TUBE. ACCORDING TO CONSUMER, IT WAS CONCLUDED THAT, DURING ESSURE INSERTION PROCEDURE, DESPITE THE INFORMATION FROM THE PHYSICIAN THAT INSERTION HAD FAILED (HE WAS UNABLE TO GET THE DEVICE RELEASED), THE DEVICE RELEASED AND LEFT METAL FRAGMENTS IN THE FALLOPIAN TUBES. SEVERAL OF THESE FRAGMENTS PENETRATED THROUGH THE WALLS OF HER FALLOPIAN TUBE. AFTER DELIVERY, SHE BEGAN HAVING GYNECOLOGY ISSUES. BLEEDING, PAIN, AND PRESSURE AND WENT THRU SEVERAL MEDICATIONS AND BIRTH CONTROL. HER GYNECOLOGIST THOUGHT IT WAS DUE TO THE LEFT FALLOPIAN TUBE HAVING A DISEASE ISSUE. CONSUMER HAD A LEFT OOPHORECTOMY IN THE BEGINNING OF 2009 AND THINGS DIDN'T GET BETTER. SHE TRIED FOR TWO YEARS TO GET AROUND IT. HOWEVER, IT GOT WORSE AND THE BLEEDING BECAME UNCONTROLLABLE. ON 2011, SHE HAD A COMPLETE HYSTERECTOMY AND IT WAS FOUND THAT A SPRING WAS THRU AND THRU HER UTERUS, WHICH WAS CAUSING THE BLEEDING. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "...RELEASED WHICH LEFT METAL FRAGMENT IN THE FALLOPIAN TUBES..." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION

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ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO- INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. NO COMPLAINT SAMPLE WAS PROVIDED FOR TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ACCORDING TO CONSUMER, GYNECOLOGIST SAID ESSURE INSERTION HAD FAILED SINCE HE WAS UNABLE TO GET THE DEVICE RELEASED. SIX MONTHS AFTER ESSURE INSERTION PROCEDURE, SHE BECAME PREGNANT AND IT WAS A DIFFICULT PREGNANCY. AFTER DELIVERY, SHE HAD A TUBAL LIGATION PROCEDURE PERFORMED AND PATHOLOGY REPORT FOUND METAL FRAGMENTS IN THE FALLOPIAN TUBES / SEVERAL FRAGMENTS HAVE PENETRATED WALLS OF HER FALLOPIAN TUBES. CONSUMER CONCLUDED THAT, DESPITE THE INFORMATION FROM THE PHYSICIAN THAT INSERTION HAD FAILED (UNABLE TO GET THE DEVICE RELEASED), THE DEVICE RELEASED AND LEFT METAL FRAGMENTS IN THE FALLOPIAN TUBES. AFTER DELIVERY AND TUBAL LIGATION, SHE STARTED TO HAVE UNCONTROLLABLE BLEEDINGS, PAIN AND PRESSURE IN THE PELVIS. SHE HAD A COMPLETE HYSTERECTOMY AND, DURING THIS PROCEDURE, IT WAS FOUND A SPRING THRU AND THRU HER UTERUS. EVENT METAL FRAGMENT IN THE

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FALLOPIAN TUBES / SEVERAL FRAGMENTS HAVE PENETRATED WALLS OF FALLOPIAN TUBES (INTERPRETED AS A DEVICE BREAKAGE AND EMBEDDED DEVICE) AND EVENT THE SPRING WAS THRU AND THRU THE UTERUS (INTERPRETED AS A DEVICE EXPULSION AND EMBEDDED DEVICE) WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. DEVICE EXPULSION AND DEVICE EMBEDMENT ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE WAS ASSESSED AS LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. BASED ON THE PROVIDED INFORMATION AND THE POSITIVE TEMPORAL RELATIONSHIP, CAUSALITIES BETWEEN ALL THE REPORTED EVENTS AND ESSURE WERE ASSESSED AS RELATED. SINCE INTERVENTION WAS REQUIRED (TOTAL HYSTERECTOMY) THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AND STATED THAT THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 09-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038810	CONCEPTUS	10/21/2014	10/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): EE205
Catalog # (E4):
Lot #(E4): 620754

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2006, I HAD THE ESSURE BIRTH CONTROL SYSTEM INSERTED. I WAS IN PAIN IMMEDIATELY AFTER, WHICH I WAS TOLD WAS NORMAL. I WAITED A FEW MONTHS AND WHEN THE PAIN DIDN'T SUBSIDE, I CALLED THE DOCTOR. THE DOCTOR WHO DID THE PROCEDURE WAS NO LONG AT THAT PRACTICE, AND THEY TOLD ME THERE WAS NOTHING THEY COULD DO. HE WAS UNREACHABLE. TO THIS DAY I AM IN EXTREME PAIN, EVEN WORSE DURING MY MENSTRUAL CYCLE AND NOW HAVE MAJOR DIZZINESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038830	BAYER	10/21/2014	10/29/2014

Event Information:

Event Date (B3): 4/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/17/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I RECEIVED THE ESSURE IN (B)(6) OF 2014 I STARTED TO NOTICE RASHES, HEAD PRESSURE, DIZZINESS, PELVIC PAIN, EYE PROBLEMS, NO ALSO SEVERE BACK PAIN PRIOR TO MY PERIODS, ITCHY SCALP, HAIR LOSS, THROWING UP AND TUBE PAIN. I ALSO SUFFER FROM JOINT PAIN, NOW SWITCHING OF ONE EYE, NUMBNESS OF FINGERS, LIKE NEEDLES. PAIN EVERYDAY, CHEST PAIN I'VE BEEN TO EMERGENCY ROOM THREE TIMES SO FAR.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00444	BAYER HEALTHCARE LLC	10/21/2014	11/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97499

Single Use: Y
Implant Date (E6): 9/26/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON 26-SEP-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER B97499 (EXPIRATION DATE DEC-2016) FOR PERMANENT CONTRACEPTION. ACCORDING TO THE REPORTER, ESSURE DID NOT DEPLOY CORRECTLY ON LEFT SIDE. PHYSICIAN DID THE TYPICAL MOTIONS AND IT LOOKED LIKE COIL DID NOT SEPARATE. RIGHT AT THE OSTIA, IT LOOKED LIKE A JUMBLED COIL. A GRASPER WAS PUT AND PULLED ON COIL AND IT STARTED UNCOILING BUT WOULD NOT COME OUT. THE COIL WAS UNSPRUNG AND THE PHYSICIAN TRIMMED A BIT OF THE EXCESS IN UTERUS AND SOME LEFT IN THE TUBE. ESSURE WAS PLACED IN RIGHT TUBE SUCCESSFULLY. PTC INVESTIGATION RESULT WAS RECEIVED ON 15-OCT-2014. (B)(4). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: ROLLBACK TO INITIAL HARD STOP. DEPRESS BUTTON. PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO "DEPLOYMENT DIFFICULTY". SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICROINSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE

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CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. AS OF 10/13/2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED BY THE RQU. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING INSERTION PROCEDURE ESSURE DID NOT DEPLOY CORRECTLY ON LEFT SIDE. IT WAS REPORTED THAT RIGHT AT THE OSTIA IT LOOKED LIKE A JUMBLED COIL/LOOKED LIKE COIL DID NOT SEPARATE (INTERPRETED AS DEVICE BREAKAGE), THE HEALTH CARE PROFESSIONAL PUT IN A GRASPER AND PULLED ON COIL AND IT STARTED UNCOILING BUT WOULD NOT COME OUT/HE TRIMMED A BIT OF THE EXCESS IN UTERUS AND SOME LEFT IN THE TUBE (INTERPRETED AS DEVICE USE ERROR). AS RESULT A UNILATERAL PLACEMENT WAS ACHIEVED. ALL OF THESE EVENTS ARE NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR DEVICE BREAKAGE, WHICH IS UNLISTED. THESE EVENTS OCCURRED DURING THE INSERTION PROCEDURE THEREFORE THEY WERE ASSESSED AS RELATED TO ESSURE, EXCEPT FOR DEVICE USE ERROR WHICH WAS REGARDED AS UNRELATED TO ESSURE DUE TO ITS NATURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT AND IT WAS ALSO STATED THAT THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW UP INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 04-MAR-2015. THE REQUIRED NUMBERS OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00449	BAYER HEALTHCARE LLC	10/21/2014	11/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B06097

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 12/18/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6)2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT THE PHYSICIAN HAD TO REALLY MOVE FROM SIDE TO SIDE TO FIRE AND SHE DID NOT KNOW IF IT WAS IN SITU. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE PHYSICIAN HAD TO REALLY MOVE FROM SIDE TO SIDE TO FIRE AND DID NOT KNOW IF ESSURE WAS IN SITU. THE REPORTED EVENTS, REGARDED AS DEVICE INSERTION DIFFICULT AND SUSPICION OF DEVICE MISDEPLOYMENT; WERE CONSIDERED NON-SERIOUS AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY NOT BE SUCCESSFUL, IN THIS PARTICULAR CASE THE EXACT CAUSE OF INSERTION DIFFICULTY WAS NOT REPORTED, HOWEVER CONSIDERING THAT THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND GIVEN THE REPORTED MALFUNCTION THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPAR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00445	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/15/2013
Explant Date (E7): 2/12/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5037148) IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR TUBAL OCCLUSION. APPROXIMATELY 6 WEEKS AFTER THE BIRTH OF HER SECOND DAUGHTER, SHE HAD ESSURE COILS PLACED IN FALLOPIAN TUBES DURING AN IN-OFFICE PROCEDURE AT HER PHYSICIAN'S OFFICE. THERE WERE NO COMPLICATIONS OR PROBLEMS DURING THE PROCEDURE. A MONTH LATER (IMPLYING (B)(6)2013), SHE STARTED HAVING ABDOMINAL CRAMPING, INCREASING VAGINAL DISCHARGE AND FEVERS. AFTER REPEATED TRIPS TO HER PHYSICIAN OFFICE, IT WAS FINALLY TIME FOR THE HYSTEROSALPINGOGRAM WHICH WAS INITIALLY DELAYED DUE TO HER SYMPTOMS. THE HSG SHOWED THAT THE LEFT COIL HAD KINKED AND PERFORATED HER LEFT FALLOPIAN TUBE. ON (B)(6) 2014, SHE HAD TO HAVE A PARTIAL HYSTERECTOMY TO REMOVE BOTH COILS. FOLLOW-UP RECEIVED ON (B)(4) 2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED:THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (REPORTED PRODUCT ISSUE - KINK). THE BAYER REFERENCE NUMBER FOR THE (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY AND A REPORTED PRODUCT ISSUE (KINK). THE PTC CASE REFERS ALSO TO A

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USABILITY ISSUE DUE TO THE REPORTED KINK. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION, NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HSG SHOWED LEFT COIL PERFORATED LEFT FALLOPIAN TUBE. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THE PRESENT CASE, IT WAS REPORTED THAT ONE MONTH AFTER INSERTION THE CONSUMER STARTED HAVING ABDOMINAL CRAMPING, INCREASING VAGINAL DISCHARGE AND FEVERS. A HYSTEROSALPINGOGRAM SHOWED THAT THE LEFT COIL HAD KINKED AND PERFORATED HER LEFT FALLOPIAN TUBE. THE CONSUMER HAD TO HAVE A PARTIAL HYSTERECTOMY TO REMOVE BOTH COILS. THEREFORE, CONSIDERING THE AVAILABLE INFORMATION AND GIVEN THE NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE INTERVENTION WAS REQUIRED (PARTIAL HYSTERECTOMY). A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW UP INFORMATION (PERFORATION QUESTIONNAIRE) HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 02-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED WITHOUT RESPONSE TO DATE. NO ADDITIONAL INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00446	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3): 6/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97492

Single Use: Y
Implant Date (E6): 6/12/2014
Explant Date (E7): 6/12/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH CARE PROFESSIONAL VIA REGULATORY AUTHORITY (CASE# MW5037133) IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2014 WITH LOT NUMBER B97492 AND EXPIRATION DATE 30-NOV-2016. ACCORDING TO THE REPORTER, LEFT TUBAL OSTIA WAS IDENTIFIED AND THE ESSURE COIL DEVICE WAS INSERTED IN LEFT TUBAL OSTIA AND DEPLOYED WITHOUT COMPLICATION. THE RIGHT OSTIA WAS IDENTIFIED AND THE ESSURE DEVICE WAS INSERTED AND THE SURGEON ATTEMPTED TO DEPLOY THE COIL. IT WAS REPORTED THAT IT FELT TIGHTER THAN NORMAL AND WHEN HE DEPLOYED HE DID NOT HEAR THE CLICK ASSOCIATED WITH PRESSING THE BUTTON. HE FELT THAT THE SPRING DID NOT DEPLOY AND ATTEMPTED TO REMOVE THE ESSURE DEVICE FROM THE TUBE. AT THIS POINT, HE NOTED THE SPRING UNRATTLEING AND NOT COMING OUT OF THE TUBAL OSTIA. THERE WAS ALSO A STRAIGHT WIRE NOTED TO BE COMING THROUGH THE TUBAL OSTIA. HE REMOVED THE ESSURE INTRODUCER, HOWEVER, THE WIRE WAS COMING THROUGH. A GRASPER WAS UTILIZED IN ATTEMPT TO REMOVE THE REMAINING WIRE AND IT CONTINUED TO BREAK INTO SMALL PIECES. AT THAT POINT THE SURGEON DECIDED TO REMOVE THE RIGHT FALLOPIAN TUBE TRIGGERING THAT THE WIRE WOULD COME OUT WITH THE REMOVAL OF THE TUBE. DEVICE WAS PLACED IN BIOHAZARD BAG AND STILL REMAINS ON SITE. PTC INVESTIGATION RESULT WAS RECEIVED ON 10-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF

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THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. THE AE CASE REFERS ALSO TO AN ADVERSE EVENT. HOWEVER, THIS ADVERSE EVENT WAS CONSIDERED NOT ASSESSABLE AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE BATCH DOCUMENTATION WAS REVIEWED BY THE (B)(6). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO RELATED ADVERSE EVENTS WERE REPORTED, NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. LOT NUMBER B97492, PRODUCTION DATE 27-NOV-2013 AND EXPIRATION DATE 30-NOV-2016. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE THE RIGHT FALLOPIAN TUBE WAS TIGHTER THAN NORMAL; THE SPRING DID NOT DEPLOY AND UNRATTLEING AND WAS NOT COMING OUT OF THE TUBAL OSTIA, A WIRE WAS NOTED TO BE COMING THROUGH THE TUBAL OSTIA AND A GRASPER WAS UTILIZED IN ATTEMPT TO REMOVE REMAINING WIRE AND IT CONTINUED TO BREAK INTO SMALL PIECES (COMPLICATION OF DEVICE INSERTION). THESE EVENTS, INTERPRETED AS A FALLOPIAN TUBE DISORDER, DEVICE DEPLOYMENT ISSUE AND BREAKAGE ARE UNLISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION, EXCEPT FOR THE DEPLOYMENT ISSUE, WHICH IS LISTED. THE REPORTED DEVICE BREAKAGE WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE, WHILE THE REMAINING EVENTS ARE NON-SERIOUS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES IN THE DEPLOYMENT OF THE DEVICE ON RIGHT SIDE DUE TO AN UNSPECIFIED FALLOPIAN TUBE DISORDER (REPORTED AS TIGHTER THAN NORMAL, THIS EVENT COULD NOT BE ASSESSED WITH THE AVAILABLE INFORMATION); HE TRIED TO REMOVE THE DEVICE UNSUCCESSFULLY AND A DEVICE BREAKAGE WAS NOTED. PATIENT UNDERWENT REMOVAL OF RIGHT FALLOPIAN TUBE. CONSIDERING THAT THE REPORTED EVENTS OCCURRED DURING ESSURE INSERTION, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN INCIDENT DUE TO THE REPORTED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-NOV-2014: NO NEW CLINICAL INFORMATION. FOLLOW-UP RECEIVED ON 10-NOV-2014: ESSURE HEALTH CARE PROFESSIONAL QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATED THAT A (B)(6) FEMALE PATIENT WHO HAD NO HISTORY OF CE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00447	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3): 9/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/12/2014
Explant Date (E7): 9/12/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 26-SEP-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR STERILIZATION. PHYSICIAN REPORTED THAT HE PERFORATED THE TUBE. HE OPENED UP THE PATIENT LAPAROSCOPICALLY AND FOUND BOTH COILS SITTING IN THE PELVIC. THE HEALTH CARE PROFESSIONAL DID A REGULAR TUBAL AND REMOVED BOTH COILS. FOLLOW UP INFORMATION FROM 26-SEP-2014: NO NEW CLINICAL INFORMATION PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 07-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON

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THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE HCP PERFORATED THE TUBE, FOUND BOTH COILS SITTING IN THE PELVIC. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED ON THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE THE HEALTH CARE PROFESSIONAL (HCP) PERFORATED THE TUBE DURING INSERTION, SHE PERFORMED A LAPAROSCOPY AND FOUND BOTH COILS IN THE PELVIS. THE HCP DID A REGULAR TUBAL AND REMOVED BOTH COILS. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION (LAPAROSCOPY). A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (NO VALID LOT NUMBER). FOLLOW UP INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00450	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5034285) IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (ESS205) INSERTED IN 2005. CONSUMER REPORTED THAT SHE HAD ESSURE IMPLANTED 9 YEARS AGO, FROM THE TIME OF THE REPORT (IMPLYING 2005). SHE ALSO REPORTED THAT THE EXPIRATION DATE OF ESSURE WAS 01-JAN-2030. ON UNSPECIFIED DATE, SHE STARTED EXPERIENCING TERRIBLE PAIN HER LOWER LEFT BACK, A LITTLE MORE TO THE LEFT SIDE THEN THE SPINE AND THE LEFT FRONT SIDE OF HER LOWER ABDOMEN WITH A THROBBING SENSATION (PAIN TO THE BONE) IN HER LEFT THIGH. SHE DIDN'T SLEEP FOR 7 MONTHS. SHE HAD AN MRI DONE THAT SHOWED NOTHING ABNORMAL IN HER SPINE. SHE HAD AN ULTRASOUND OF ABDOMEN AREA DONE AND THOSE RESULTS ALSO SHOWED NOTHING ABNORMAL. SHE DECIDED TO HAVE AN X-RAY OF HER LOWER ABDOMEN TO SEE ESSURE COILS; THE LEFT COIL LOOKED TO BE MUCH HIGHER THAN THE RIGHT ONE. THE RIGHT COIL LOOKED JUST LIKE A FISH HOOK. THE PHYSICIAN THAT IMPLANTED THEM 9 YEARS AGO SAID THAT THEY DIDN'T LOOK RIGHT. SHE HAD A SURGERY TO REMOVE THEM ON 2013. IT WAS FOUND THAT THE LEFT COIL WAS DEEP INTO HER UTERUS; PHYSICIAN WAS ABLE TO GET IT OUT OF HER UTERUS THEN CAUTERIZED IT. SHE THOUGHT THAT MAY HAVE BEEN THE CAUSE OF HER PAIN. CONSUMER REPORTED THAT THEY REMOVED HER TUBES AND OVARIES. ONE MONTH LATER, SHE STILL EXPERIENCED THE SAME BURNING/INFLAMED PAIN ON HER LEFT BACK BUT THE FRONT PAIN HAS GONE AWAY SINCE REMOVING THE EMBEDDED COIL. SHE OPENED THE CONTAINERS AND REALIZED THAT ONLY THE INNER COILS WERE GIVEN TO HER BY PATHOLOGY. SHE ASKED TO HER PHYSICIAN WHERE THE OUTER COILS WERE AND AFTER ASKING HER PHYSICIAN REVIEWED THE PATHOLOGY REPORT AND IT READ THAT THERE WAS METAL IN THE RIGHT FALLOPIAN TUBE, APPARENTLY IT WAS THE OUTER COIL, BUT NO MENTION OF THE LEFT OUTER COIL. SHE HAD AN X-RAY

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SCHEDULED TO SEE IF IT WAS EMBEDDED SOMEWHERE THAT IS CAUSING HER CONSTANT PAIN. CONSUMER STATED THAT IT HAS BEEN A PHYSICALLY AND EMOTIONALLY EXHAUSTING 7 MONTHS. SHE ALSO REPORTED THAT SHE FOUND OUT THAT THESE COILS HAVE TOXIC MATERIALS IN THE PET FIBERS AND ARE STERILIZED IN A TOXIC SOLUTION. (B)(6) 2013 WAS REPORTED AS AN EVENT DATE BUT NOT ASSIGNED TO ONE OF THE EVENTS. CONSUMER ALSO REPORTED OTHER SERIOUS (MEDICAL IMPORTANT EVENTS) AS SERIOUSNESS CRITERIA BUT ASSIGNED TO ONE OF THE EVENTS AS WELL. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE (BREAKAGE). IN THIS PARTICULAR CASE, ALSO SURGICAL REMOVAL OF COILS WAS REPORTED, BASED ON THE AVAILABLE INFORMATION AT THIS POINT IN TIME IT IS NOT CLEAR IF THE REPORTED BREAKAGE OCCURRED BEFORE OR IN COURSE OF SURGERY. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE LEFT COIL WAS DEEP IN MY UTERUS, RIGHT ONE LOOKED JUST LIKE A FISH HOOK AND SUSPICION THAT PART OF ESSURE WAS EMBEDDED SOMEWHERE. THIS CASE IS NOT MEDICALLY CONFIRMED. THESE EVENTS ARE CONSIDERED SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE ESSURE REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE ESSURE WAS IMPLANTED IN 2005. AFTER A NON-SPECIFIED PERIOD, CONSUMER STARTED EXPERIENCING TERRIBLE PAIN HER LOWER LEFT BACK. DURING THE INVESTIGATION, AFOREMENTIONED SERIOUS EVENTS WERE REPORTED. A SURGERY WAS PERFORMED TO REMOVE ESSURE. GIVEN THE INFORMATION PROVIDED, CAUSALITY BETWEEN REPORTED SERIOUS EVENTS AND ESSURE USE CANNOT BE EXCLUDED. SURGICAL INTERVENTION WAS REPORTED, HENCE THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP ATTEMPTS WERE NOT PERFORMED SINCE NO CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00451	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/26/2013
Explant Date (E7): 6/27/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE (B)(4)) IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. ESSURE WAS REMOVED ON (B)(6) 2013 DUE TO EXCESSIVE BLEEDING, EXTREME PAIN AND BLOATING. CONSUMER WAS DIAGNOSED WITH IMMUNODEFICIENCIES. THE PAIN HAS INCREASED AND SHE IS SCHEDULED FOR A HYSTERECTOMY. A SERIOUS INJURY WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY,

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THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE BLEEDING (CONSIDERED AS GENITAL BLEEDING). THIS CASE IS NOT MEDICALLY CONFIRMED. THE EVENT IS CONSIDERED SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE ESSURE REFERENCE SAFETY INFORMATION. BLEEDING MAY OCCUR WITH ESSURE USE. IN THIS PARTICULAR CASE, NO MUCH INFORMATION WAS PROVIDED ABOUT THIS EVENT. IT WAS ONLY MENTIONED THAT THE ESSURE WAS REMOVED DUE TO EXCESSIVE BLEEDING, EXTREME PAIN AND BLOATING. THE PAIN INCREASED AFTER ESSURE REMOVAL - THE CONSUMER IS SCHEDULED FOR A HYSTERECTOMY. NO INFORMATION WAS PROVIDED REGARDING BLEEDING. CONSUMER WAS ALSO DIAGNOSED WITH IMMUNODEFICIENCIES. GIVEN THE INFORMATION PROVIDED, CAUSALITY BETWEEN BLEEDING AND ESSURE USE CANNOT BE EXCLUDED. ESSURE WAS REMOVED, HENCE THIS CASE IS REGARDED AS AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW UP WAS POSSIBLE SINCE THE CONSUMER DID NOT PROVIDE ANY CONTACT INFORMATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00452	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3): 8/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/9/2013
Explant Date (E7): 1/9/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5037300) IN UNITED STATES ON (B)(6)-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BACK PAIN AND PELVIC PAIN. CONSUMER REPORTED THAT ABOUT 11 MONTHS BEFORE THE TIME OF REPORT ((B)(6)-2013) SHE HAD A BIRTH CONTROL PROCEDURE (ESSURE). DOCTOR INFORMED HER THAT THE PROCEDURE WOULD BE SIMPLE WITH MINIMAL SIDE EFFECTS AND SHE DECIDED TO HAVE THE PROCEDURE DONE. UNFORTUNATELY, FOR 11 MONTH SHE HAS HAD BACK AND PELVIC PAIN WHICH CONTINUES TO PLAQUE HER. HER DOCTORS HAVE MADE VARYING EFFORTS TO HELP HER, YET SHE STILL HAS NO IDEA WHAT THE PROBLEM OR A DIAGNOSIS IS OR WHY SHE IS HAVING PAIN. CONSUMER INFORMED THAT AFTER THE PROCEDURE WAS COMPLETED, ALMOST IMMEDIATELY, SHE EXPERIENCED LOWER BACK PAIN. CONSUMER CONTACTED NURSES VIA PHONE WHO ASSURED HER THAT THE PAIN WOULD SUBSIDE, BUT IT ONLY GOT WORSE. AFTER 2 MONTHS, THE BACK AND PELVIC PAIN BECAME SO EXTREME THAT SHE MISSED WORK DAYS AND TOOK PAIN MEDICATION DAILY. IN 2013, SHE VISITED OBSTETRICIAN/GYNECOLOGIST DOCTOR; HE SUGGESTED REMOVING THE COILS (ESSURE) DEVICE AND SHE AGREED. IN (B)(6)-2014, PHYSICIAN PERFORMED HER LAPAROSCOPIC SURGERY TO REMOVE THE DEVICE. ACCORDING TO CONSUMER THE SURGERY ALSO INCLUDED REMOVING HER FALLOPIAN TUBES. AFTER WEEKS OF RECOVERY AND TIME OFF WORK SHE CONTINUED TO EXPERIENCE PELVIC AND BACK PAIN. DOCTOR TOLD HER THIS WAS NORMAL. AFTER 3 WEEKS OF CONTINUED PAIN, SHE CONTACTED DOCTOR WHO RELEASED HER TO WORK WITHOUT ADDRESSING HER PAIN ISSUES. SHE RECEIVED NO PAIN MANAGEMENT TREATMENT. SHE COMMUNICATED HER SYMPTOMS WITH SEVERAL DOCTORS, INCLUDING HER PRIMARY CARE PHYSICIAN, ON MANY OCCASIONS VIA E-MAIL, PHONE AND DOCTOR VISITS. CONSUMER DID PHYSICAL

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THERAPY, MASSAGE THERAPY, CHIROPRACTIC CARE, EPSON SALT BATHS, HEATING PADS AT WORK/HOME FOR SEVERAL MONTHS, BUT HER PAIN CONTINUED. IN ADDITION SHE REPORTED THAT, AS A PATIENT, SHE IS CONCERNED ABOUT HER HEALTH. SHE TRIES TO BE PROACTIVE IN HER HEALTH AND STATES THAT SHE WAS HEALTHY BEFORE THIS PROCESS BEGAN 11 MONTHS AGO. SHE TRIED TO FOLLOW THE DOCTORS' ORDERS. WHILE SHE RECOGNIZED THERE ARE NO GUARANTEES WITH MEDICAL PROCEDURES, HER CONCERNS ARE LISTED BELOW: SHE DOES NOT BELIEVE HER DOCTORS AND MEDICAL STAFF HAVE COMMUNICATED WITH OTHERS EFFECTIVELY. SHE HAS RECEIVED CONFLICTING ADVICE OR NO ANSWERS TO HER REQUEST. HER BACK AND SURROUNDING AREAS HAVE NOT RECEIVED A FULL EXAMINATION OR TEST BEFORE OR AFTER THE SURGERIES SHE HAS RECEIVED. SHE HAS NOT RECEIVED PAIN MANAGEMENT TREATMENT. SHE DOES NOT HAVE A DIAGNOSES OR REASON FOR THE CHRONIC PAIN. HER MOBILITY AND QUALITY OF LIFE ARE AFFECTED BY THIS CHRONIC PAIN. SHE HAS NO REAL UNDERSTANDING OF WHAT OR WHY THIS PROBLEM PERSISTS. SHE CONTINUE TO TAKE TESTS, DOES EVASIVE PROCEDURES, SPEND MONEY, AND MISS WORK TIME TO ADDRESS THIS ISSUE. THE CONSUMER DID NOT PROVIDE CONTACT INFORMATION, THEREFORE FURTHER INFORMATION CANNOT BE REQUESTED. FOLLOW-UP RECEIVED ON 07-OCT-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (REQUEST FOR CONFIRMATION OF QUALITY). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(6) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BACK PAIN AND PELVIC PAIN. THE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE THE CONSUMER INFORMED THAT SHE WAS SUFFERING FROM BACK AND PELVIC PAIN FOR 11 MONTHS. SHE ALSO STATED AFTER THE INSERTION PROCEDURE WAS COMPLETED, ALMOST IMMEDIATELY, SHE EXPERIENCED LOWER BACK PAIN. AFTER 2 MONTHS, THE PAIN BECAME SO EXTREME THAT SHE MISSED WORK DAYS AND TOOK PAIN MEDICATION DAILY. THE PAIN DID NOT SUBSIDE AND CONTINUED FOR 11 MONTHS. HER OBSTETRICIAN/GYNECOLOGIST DOCTOR SUGGESTED REMOVING THE COILS (ESSURE) DEVICE AND SHE AGREED. THEN, THE PHYSICIAN PERFORMED HER LAPAROSCOPIC SURGERY. ACCORDING TO CONSUMER THE SURGERY ALSO INCLUDED REMOVING HER FALLOPIAN TUBES. AFTER WEEKS OF RECOVERY AND TIME OFF WORK SHE CONTINUED TO EXPERIENCE PELVIC AND BACK PAIN (NEGATIVE DECHALLENGE). ALTHOUGH THE EVENTS HAD NOT IMPROVED AFTER THE MICRO-INSERTS REMOVAL, THE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED, SINCE THE BACK AND PELVIC PAIN HAVE APPEARED AFTER THE DEVICE INSERTION. BESIDES, THE EVENTS LED TO A REQUIRED INTERVENTION, SO THE CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00453	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3): 9/18/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 641436/12401848

Single Use: Y
Implant Date (E6): 9/8/2009
Explant Date (E7): 7/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5037259) IN UNITED STATES ON 24-SEP-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6)-2009 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER (B)(4). ACCORDING TO THE CONSUMER, OVER THE LAST 5 YEARS HER HEALTH HAS DECLINED STEADILY. IT STARTED ON (B)(6)-2009 WITH WEIGHT GAIN, PERIODS EVERY 11 TO 14 DAYS THAT WOULD LAST FOR FIVE TO SEVEN DAYS EACH AND PELVIC PAIN AND PULLING IN LOWER PELVIC REGION. OVER TIME, SHE DEVELOPED A HIP PROBLEM THAT CAUSED GREAT DISCOMFORT AND PAIN. SHE EXPERIENCED ENLARGED LYMPH NODES ON MANY OCCASIONS AND CAUGHT EVERY VIRUS AND BUG THAT WAS AROUND. SHE HAS BEEN SICK CONSTANTLY SINCE BEING IMPLANTED. SHE DEVELOPED ANXIETY AND FELT AS IF HER BODY WAS NEVER ABLE TO RELAX. FATIGUE BECAME A PROBLEM; SHE WOULD TIRE EASILY AND SHE WAS NOT FEELING RIGHT OR WELL. SHE ALSO BEGAN TO SUFFER FROM WHAT SHE CONSIDERED MIGRAINE HEADACHES WITH AURAS, LIGHTNING FLASHES, BLACK SPOTS AND FLOATER; AND LOSE VISION ALONG WITH HAVING TO BE IN DUE TO THE TERRIBLE HEAD PAIN. SHE ALSO EXPERIENCED STRANGE MOMENTS OF HAND AND FEET ITCHING, REDNESS AND SWELLING AND ALSO HAD THE FEELING THAT HER TEETH WERE BEING STRIPPED OF NUTRIENTS. SHE HAD A HORRIBLE METALLIC TASTE IN HER MOUTH WHEN HER TEETH HURT. IN THE YEAR 2013-2014 HER HEALTH GREATLY DECLINED. SHE WAS SICK NONSTOP; SHE WAS BEGINNING TO HAVE TROUBLE WITH MEMORY AND WOULD INCREASINGLY CALL PEOPLE BY THE WRONG NAMES (INCLUDING HER OWN 3 CHILDREN AND HUSBAND). FATIGUE BEGAN TO BECOME UNBEARABLE IN WHICH SHE NO LONGER FELT SHE COULD KEEP UP WITH HER NORMAL LIFE, SCHEDULE AND SHE MISSED MANY EVENTS AND FUNCTIONS. IT TOOK EVERYTHING SHE HAD TO MAKE IT THROUGH A WORK DAY.

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HER BELLY WAS OUT OF CONTROL; SHE HAS ALWAYS BEEN A FIT PERSON AND SHE WAS FRUSTRATED AND STRUGGLING TO FIGURE OUT WHY HER STOMACH WOULD BE PRETTY FLAT ONE MOMENT AND OUT OF NOWHERE SHE WOULD EXPAND TO LOOK LIKE SHE WAS 8 MONTHS PREGNANT. THEN DEVASTATION AND DESPERATION TOOK PLACE WHEN HER BODY BEGAN TO BREAK DOWN AND THERE WAS NOTHING SHE OR ANYONE COULD DO ABOUT IT. SHE BEGAN TO SUFFER FROM HORRIBLE JOINT PAIN THROUGHOUT HER BODY. SHE HAD MUSCLE ACHES AND SPASMS ALONG WITH TREMORS; HAND AND FEET TINGLING ALONG WITH NUMBING AT TIMES. DIZZINESS AND LIGHT HEADED AND SHOOTING PAINS THROUGHOUT HER BODY. HER HAIR BEGAN TO FALL OUT MORE THAN NORMAL (IT WOULD FILL A COMB EVERY MORNING). SHE ALSO HAD WEIRD RASHES ON MY BODY AND HEAVY PERIODS. HER MEMORY PROBLEMS BEGAN TO GET WORSE AND SHE BEGAN TO HAVE SPEECH ISSUES. SHE WAS A TEACHER AND HER STUDENTS AND COWORKERS BEGAN TO WORRY ABOUT BECAUSE SHE WAS DETERIORATING EVERYDAY WITH SPEECH, MEMORY, OVERALL HEALTH AND HER ABILITY TO WALK. SHE COLLAPSED AT WORK AND WAS NOT ABLE TO RETURN TO WORK DUE TO HER WORSENING HEALTH. SHE BEGAN WALKING WITH A GAIT AND WAS UNABLE TO DO NORMAL TASKS AT WORK OR AT HOME WITH HER FAMILY, BECAUSE MENTALLY AND PHYSICAL SHE WAS COMPLETELY BROKEN. SHE VISITED MANY DOCTORS AND SPECIALIST, HAD MANY BLOOD TEST AND SCANS. SHE HAD NONE OF THIS BEFORE GETTING ESSURE INSERTED. SHE WAS A HEALTHY HARD WORKING WIFE, MOM, AND TEACHED MOST OF HER LIFE BUT EVER SINCE IMPLANTING ESSURE SHE HAD A STEADY DECLINE IN HER HEALTH AND WELLBEING. AFTER SPEAKING TO MANY DOCTORS, IT WAS DETERMINED THAT SHE WAS EXPERIENCING INFLAMMATION OF HER NERVOUS SYSTEM (THE REASON WAS UNCLEAR) AND THEN THE DOCTORS BEGAN LOOKING AT THE ONE FOREIGN THING IN HER BODY; ESSURE IMPLANTS. AFTER EXAM WITH GYNECOLOGIST DOCTOR, IT WAS DECIDED TO GO THROUGH WITH A HYSTERECTOMY DUE TO PELVIC PAIN, 2 PERIODS A MONTH, HEAVY PERIODS AND IN HOPES THAT SHE COULD ALSO RID HERSELF OF THE METAL COILS AND TO SEE IMPROVEMENTS WITH ALL AROUND HEALTH. ON (B)(6)-2014 ESSURE WAS REMOVED VIA HYSTERECTOMY. AT TIME OF REPORT, SHE WAS 5 DAYS OUT OF SURGERY AND IMPROVEMENTS BEING SEEN ALREADY. AN INJURY (HOSPITALIZATION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. ALL THE EVENTS WERE CONSIDERED RELATED TO ESSURE BY CONSUMER. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 07-OCT-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). LOT NUMBER 641436 MANUFACTURING DATE: MAY-2009 AND EXPIRATION DATE: MAY-2012. LOT NUMBER 12401848 MANUFACTURING DATE: APR-2009 AND EXPIRATION DATE: APR-2012 FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 641436 NOR 12401848. NO BATCH SIGNAL COULD BE IDENTIFIED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN/ PULLING IN LOWER PELVIC REGION AND INFLAMMATION OF NERVOUS SYSTEM. EVENT PELVIC PAIN/ PULLING IN LOWER PELVIC REGION WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT WAS

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CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS UNLISTED FOR ESSURE. ABDOMINAL/PELVIC PAIN AND CRAMPING MAY OCCUR WITH ESSURE AND MAY BE A MORE LIKELY OCCURRENCE DURING THE MENSTRUAL PERIOD, DURING AND AFTER SEXUAL INTERCOURSE OR WITH PHYSICAL ACTIVITY. THEREFORE, GIVEN THE NATURE OF THE EVENT PELVIC PAIN/ PULLING IN LOWER PELVIC REGION AND LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. EVENT INFLAMMATION OF NERVOUS SYSTEM, DUE TO ITS NATURE AND ESSURE LOCAL ACTION AT FALLOPIAN TUBES WAS CONSIDERED UNRELATED. THIS CASE WAS REGARDED AS INCIDENT SINCE INTERVENTION WAS REQUIRED (CONSUMER HAD A HYSTERECTOMY). IT WAS REPORTED THAT FIVE DAYS AFTER HYSTERECTOMY IMPROVEMENTS WERE BEING SEEN, HOWEVER IT WAS NOT SPECIFIED TO ONE OF THE EVENTS. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED FOR THE BATCH NUMBERS (641436 AND 12401848) AND CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW UP INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION FROM 01-APR-2015: FOLLOW-UP ATTEMPTS WERE DONE WITHOUT SUCCESS. NO FURTHER FOLLOW-UP WILL BE PURSUED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00454	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/16/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5037347) IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. AFTER SHE HAD THE ESSURE PROCEDURE, SHE EXPERIENCED SEVERE BACK PAIN FOLLOWED BY PHYSICIAN'S VISITS, CORTISONE SHOTS, MRI'S (MAGNETIC RESSONANCE IMAGES) AND THERAPY (NOT SPECIFIED). SHE ALSO EXPERIENCED BAD MIGRAINES, CRAMPING, EXCESSIVE BLEEDING, PELVIC PAIN, HAIR LOSS, WEIGHT GAIN, BRAIN FOG, BLOATING, AND IRRITABLE. ESSURE WAS REMOVED ON (B)(6)-2014 VIA HYSTERECTOMY. FOLLOW-UP RECEIVED ON 07-OCT-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (REQUEST FOR CONFIRMATION OF QUALITY). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(6) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL

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ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE BACK PAIN AND EXCESSIVE BLEEDING. BOTH EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE ESSURE REFERENCE SAFETY INFORMATION. BLEEDING AND PAIN MAY OCCUR WITH ESSURE USE. CONSIDERING LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY CANNOT BE EXCLUDED. HYSTERECTOMY WAS REPORTED HENCE THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. ADDITIONAL INFORMATION FROM CONSUMER WERE REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 27-MAR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00455	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3): 9/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C80065

Single Use: Y
Implant Date (E6): 9/24/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REPORTER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C80065, INSERTED ON (B)(6) 2014. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2014. THE HEALTH CARE PROFESSIONAL BELIEVED SHE WAS IN THE CORRECT AREA AND RELEASED THE DEVICE. HOWEVER, IT WENT THROUGH THE UTERINE WALL. THE PATIENT HAD A FLAT PLATE X-RAY AND HCP PERFORMED A LAPAROSCOPIC PROCEDURE. DEVICE WAS REMOVED FROM THE UTERINE WALL. THE PATIENT HAD SUCCESSFUL BILATERAL PLACEMENT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. (B)(4) (PRODUCTION DATE (B)(6) 2014 AND EXPIRATION DATE 31-JUL-2017). NO BATCH SIGNAL COULD BE IDENTIFIED. NO COMPLAINT SAMPLE WAS PROVIDED FOR

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FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WENT THROUGH THE UTERINE WALL. THIS CASE IS NOT MEDICALLY CONFIRMED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). IN THIS CASE IT WAS REPORTED THAT THE UTERINE PERFORATION OCCURRED DURING ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT, IT WAS CONSIDERED RELATED TO ESSURE. A LAPAROSCOPIC PROCEDURE WAS PERFORMED TO REMOVE ESSURE; HENCE THIS CASE IS REGARDED AS AN INCIDENT. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION (PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 26-MAR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00457	BAYER HEALTHCARE LLC	10/22/2014	10/22/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF WHO WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4).STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. CONSUMER REPORTED VIA SOCIAL MEDIA THAT SHE WENT TO HAVE THE ESSURE DONE FOR BIRTH CONTROL AND HAD A REACTION TO THE LIDOCAINE. SHE WAS HOSPITALIZED AND WAS FEELING REALLY LOOPY. SHE REPORTED THAT THE STARTED GETTING DIZZY AND EVERYONE SOUNDED FUNNY. SHE STATED THAT SHE COULDN'T UNDERSTAND WHAT PEOPLE WERE SAYING FOR A BIT AND THAT SHE HAD MOMENTS OF CLARITY AND MOMENTS WHERE SHE COULD NOT FIND THE RIGHT WORDS. SHE REPORTED THAT WAS BEING MONITORED. FOLLOW UP INFORMATION FROM (B)(6) 2014: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN (B)(4), DESIGN FMEA FOR ESS305. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. NO RELATED ADVERSE EVENT WERE REPORTED. A HYPERSENSITIVITY TYPE OF EVENT WAS REPORTED BUT WAS CONSIDERED UNRELATED TO THE PRODUCT AT THIS POINT IN TIME. NO COMPLAINT SAMPLE

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WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE WENT TO HAVE ESSURE DONE AND HAD A REACTION TO LIDOCAINE. THIS CASE IS NOT MEDICALLY CONFIRMED. THIS EVENT WAS INTERPRETED AS DEVICE INSERTION COMPLICATION (LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION) AND HYPERSENSITIVITY TO LIDOCAINE (UNLISTED); IT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION. HYPERSENSITIVITY TO LIDOCAINE IS NOT RELATED DIRECTLY TO ESSURE, HOWEVER AS THIS REACTION OCCURRED AS COMPLICATION OF DEVICE INSERTION, THIS CASE IS REGARDED AS RELATED AND INCIDENT DUE TO HOSPITALIZATION. ACCORDING TO PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS, THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 25-FEB-2015: INFORMATION RECEIVED FROM CONSUMER VIA SOCIAL MEDIA STATED THAT HER WEIGHT HAD BEEN BOUNCING AROUND A BUNCH. SOME OF IT WAS WATER RETENTION; SOME OF IT WAS TOO MUCH FAST FOOD. SHE JUST WANTED TO GET BACK TO HER PRE-SURGE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038777		10/22/2014	10/27/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2010, PT HAD ESSURE IMPLANTED. TWO MONTHS AFTERWARDS, PT BEGAN EXPERIENCING SOB AND ABNORMAL MENSES FOR WHICH SHE WAS PLACED ON BIRTH CONTROL PILLS TO HELP REGULATE. SINCE THEN, PT CONTINUES TO HAVE ABNORMAL BLEEDING FOR THE PAST 3 EARS, WITH CONTINOUS MENSES FOR THE PAST 4 MONTHS, CRAMPS, DIZZINESS, FELS LIKE SHE ABOUT TO FAINT, FATIGUE, HEADACHES, JOIN PAIN AND LOSS OF APPETITE. PT WENT TO EMERGENTLY TO THE ER FOR ABNORMAL MENSES AND WAS PLACED ON ANOTHER BIRTH CONTROL PILL. PT STATES SHE "IS TRYING TO GET THIS RESOLVED". DOCTOR'S ARE TELLING HER THAT HER SYMPTOMS WAS NOTHING TO DO WITH ESSURE. PT. STATES SHE HEARD ON THE NEWS ABOUT THE PROBLEMS WOMEN WERE HAVING WITH ESSURE AND FELT THAT SHE WAS EXPERIENCING SOME OF THE SAME SYMPTOMS. ALSO, PT STATES SHE HAS A DOCTOR'S APPOINTMENT ON (B)(6) 2014 TO ADDRESS HER ONGOING SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038838		10/22/2014	10/29/2014

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PROCEDURE DONE. I'VE BEEN IN CONSTANT STOMACH PAIN SINCE. HURTS TO HAVE INTERCOURSE. HURTS EVEN WORSE DURING MY PERIOD TO WHERE I CAN'T EVEN STAND AND THE BLEEDING IS OFTEN VERY BAD.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00456	BAYER HEALTHCARE LLC	10/22/2014	11/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91743

Single Use: Y
Implant Date (E6): 9/24/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT BIRTH CONTROL; LOT NUMBER USED WAS C91743. IT WAS REPORTED THAT PHYSICIAN INSERTED AN ESSURE INTO THE PATIENTS LEFT TUBE AND THE DEVICES PET FIBERS WERE COMPLETELY HANGING OUT OF THE TUBE. THE ESSURE DEVICE NEEDED TO BE REMOVED. BILATERAL PLACEMENT WAS ACHIEVED. PATIENT HAD NO INJURY. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE BATCH DOCUMENTATION WAS REVIEWED BY THE (B)(4). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS WERE REPORTED, NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY

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DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) FOR PERMANENT BIRTH CONTROL AND PHYSICIAN INSERTED AN ESSURE INTO LEFT TUBE AND THE DEVICES PET FIBERS WERE COMPLETELY HANGING. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS CONSIDERED NON-SERIOUS AND UNLISTED ACCORDING TO TECHNICAL ANALYSIS. UPON THE EVENT OCCURRED DURING THE INSERTION PROCEDURE, THE CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE USE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT SINCE DEVICE BREAKAGE/ MALFUNCTION WAS REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS, THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ADDITIONAL INFORMATION FROM PHYSICIAN WAS REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 02-FEB-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE FROM THE PHYSICIAN. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00458	BAYER HEALTHCARE LLC	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 8/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B72572

Single Use: Y
Implant Date (E6): 8/26/2014
Explant Date (E7): 9/21/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 23-SEP-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B72572, INSERTED ON (B)(6) 2014. PHYSICIAN REPORTED THAT, ON (B)(6) 2014, PATIENT COMPLAINED OF BACK PAIN AND CRAMPING; ON (B)(6) 2014 SHE WENT INTO OFFICE. HEALTH CARE PROFESSIONAL DID PELVIC EXAM AND PROVIDED VICOPROPHEN (AS REPORTED). PAST WEEKEND ((B)(6) 2014) PATIENT WENT TO EMERGENCY ROOM FOR SEVERE INFECTION; SHE HAD TOTAL HYSTERECTOMY AND IS CURRENTLY HOSPITALIZED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: PER THE IFU, STERILE: EACH ESSURE SYSTEM IS STERILIZED USING ETHYLENE OXIDE AND IS SUPPLIED STERILE FOR SINGLE USE ONLY. DO NOT REUSE OR RESTERILIZE. RESTERILIZATION MAY ADVERSELY AFFECT PROPER MECHANICAL FUNCTION AND COULD RESULT IN PATIENT INJURY. CAREFULLY INSPECT THE STERILE PACKAGE FOR DAMAGE OR DEFECTS PRIOR TO USE. DURING THIS LOT NUMBER/BATCH REVIEW, THERE WERE NO DOCUMENTED CONCERNS WITH THE STERILITY OF THE PRODUCT OR THE PROCESS AND ALL SPECIFICATIONS WERE MET. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO REQUEST FOR CONFIRMATION OF

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QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B72572 (PRODUCTION DATE 20-SEP-2013 AND EXPIRATION DATE 30-SEP-2016). NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION WAS REVIEWED BY RQU. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 20-OCT-2014 FROM PHYSICIAN: PATIENT WEIGHT AND HEIGHT WERE ADDED. PATIENT WAS GRAVIDA 4 AND PARA 3; WITH 1 ABORTION (ELECTIVE ABORTION). SHE WAS 11 MONTHS POST-PARTUM AT TIME OF ESSURE INSERTION. ESSURE WAS INSERTED ON (B)(6) 2014. DURING THE INSERTION PROCEDURE, NO CERVICAL DILATATION OR SOUNDING WERE DONE. PHYSICIAN USED PARACERVICAL BLOCK AS ANALGESIA; NO GENERAL ANESTHESIA WAS REQUIRED. THE INSERTION WAS CONSIDERED EASY; WITH EASY VISUALIZATION OF THE TUBAL OSTUIM. NO FLUID LOSS OF MORE THAN 1500CC WAS OBSERVED. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. SYMPTOMS STARTED 3 DAYS POST INSERTION; ON (B)(6) 2014. PATIENT EXPERIENCED PAIN AND WAS TREATED WITH VICOPROFEN AT HS. ON (B)(6) 2014, AN EXAM (NOS) SHOWED LARGE PELVIC MASS. BEDSIDE ULTRASOUND SHOWED MASS OF 8 CM AND A HEMATOMA WAS SUSPECTED. ON (B)(6) 2014, AN ULTRASOUND SHOWED A MASS OF 12.0X10.7X10.8: RIGHT DERMOID VS ENDOMETRITIS INTERPRETED AS HEMATOMA. PATIENT REPORTED FEVER AND KEFLEX WAS STARTED; HER TEMPERATURE WAS 101.3; HB WAS 11.1 AND WBC WAS 12.8. ON (B)(6) 2014, SHE EXPERIENCED SUDDEN ONSET OF SEVERE PAIN AND DIZZINESS. AN EXAM ON ER SHOWED SWOLLEN MASS AND SUSPECTED RUPTURED HEMATOMA. ANTIBIOTICS WERE SHIFTED. ON (B)(6) 2014, PATIENT HAD A TOTAL ABDOMINAL HYSTERECTOMY WITH BILATERAL SALPINGO-OOPHORECTOMY. A RUPTURED DERMOID WITH PERITONITIS WAS OBSERVED. PHYSICIAN SUSPECTED ON RUPTURE DERMOID POSSIBLY INFECTED, POSSIBLY ALLERGIC REACTION TO ESSURE. THE PATHOLOGICAL EXAM SHOWED BILATERAL DERMOIDS WITH EOSINOPHIL IN THE RUPTURED DERMOID SPECIMEN AND OOPHORITIS. PATIENT STAYED IN ICU (INTENSIVE UNIT CARE) FOR 3 DAYS AND THEN WAS DISCHARGED ON (B)(6) 2014. PHYSICIAN REPORTED THAT PATIENT WAS OBESE AND HAD AN ANNUAL EXAM (NOS) ON (B)(6); NO ADNEXAL CYSTS WERE OBSERVED. PHYSICIAN CONSIDERED THE PATIENT'S CONDITION RELATED TO ESSURE DEVICES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 3 DAYS AFTER ESSURE PLACEMENT EXPERIENCED RUPTURED DERMOID CYST POSSIBLY INFECTED WITH PERITONITIS. PHYSICIAN SUSPECTED ON POSSIBLE ALLERGY TO ESSURE. PATIENT WAS HOSPITALIZED, SUBMITTED TO TOTAL HYSTERECTOMY WITH BILATERAL SALPINGO-OOPHORECTOMY AND WAS RECOVERING FROM EVENTS. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND ARE UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION; EXCEPT FOR POSSIBLE ALLERGY TO ESSURE, WHICH IS LISTED. IN THE PRESENT CASE, CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE HOSPITALIZATION AND SURGICAL INTERVENTION WERE REQUIRED AS TREATMENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00459	BAYER HEALTHCARE LLC	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/2/2007
Explant Date (E7): 12/6/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5037354) IN UNITED STATES ON 24-SEP-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2007 ESSURE WAS INSERTED (ACCORDING TO THE CONSUMER´S NARRATIVE, ESSURE WAS INSERTED IN 2002; DISCREPANT INFORMATION). IN 2013 THE CONSUMER STARTED EXPERIENCING CONTINUALLY SWELLING IN HER LEGS AND KNEE WITH GREAT PAIN. THE RHEUMATOLOGIST DID NOT FIND ANYTHING WRONG, SO, SHE WENT TO THE GYNECOLOGIST. ON (B)(6) 2013 ESSURE WAS REMOVED AND A HYSTERECTOMY WAS DONE. ACCORDING TO THE CONSUMER, IT WAS THE BEST THING SHE DID. SHE WAS WITH NO PAIN AND NO SWELLING AFTER ESSURE REMOVAL; SHE FELT THE BEST SHE HAD IN A LONG TIME. AN INJURY (SERIOUS IMPORTANT MEDICAL EVENTS) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW UP INFORMATION FROM 13-OCT-2014: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN DR-3020, DESIGN FMEA FOR ESS305. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS

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IS A ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SWELLING IN HER LEGS AND KNEE WITH GREAT PAIN. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. PAIN IS LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION WHILE SWELLING OF LEGS AND KNEE IS UNLISTED. SWELLING OF EXTREMITIES MAY BE ASSOCIATE VARIETY OF CLINICAL CONDITIONS, SUCH AS RHEUMATOLOGIC DISEASES, HEART FAILURE AND CIRRHOSIS. IN THIS PARTICULAR CASE, THE CONSUMER CONSULTED A RHEUMATOLOGIST AND NO REASON FOR THE REPORTED EVENTS WAS FOUND. LATER SHE WAS SUBMITTED TO A HYSTERECTOMY AND STATED THAT PAIN AND SWELLING RECOVERED. ALTHOUGH ESSURE HAS A LOCAL ACTION AT FALLOPIAN TUBES AND CONSUMER'S SYMPTOMS MAY OCCUR DUE TO SEVERAL CLINICAL CONDITIONS; GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN INCIDENT SINCE ESSURE WAS SURGICALLY REMOVED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION WILL BE SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-NOV-2014: DESPITE FOLLOW-UP ATTEMPTS, NO RESPONSE WAS RECEIVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038712	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 8/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ENDOMETRIOSIS, OVARIAN CYSTS (REMOVED), POLYESTER ALLERGY, MIGRAINES, WEIGHT GAIN, WORSENING EYE SIGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038713	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 9/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PLACED IN (B)(6) 2013, HAD MY FOLLOW UP, I HAVE HAD MASSIVE BLEEDING EVER SINCE! ACNE WHICH I NEVER HAD BEFORE, PAINS DURING SEX, AS IF I CAN FEEL THE SPRINGS, WEIGHT LOSS. LOST 5 LBS. BUT NOT LIKE I HAVE MUCH TO LOSE ANYWAYS. I NOW WEIGH (B)(6). I FEEL TIRED AND WEAK. LOSE OF SEX DRIVE. ATTITUDE CHANGE (NEGATIVE) UNHAPPY. I HAVE NEVER EXPERIENCED ANY OF THIS EVER BEFORE. I WAS A VERY HEALTHY, HAPPY GO LUCKY (B)(6). NOW MY DOCTOR HAS PRESCRIBED ME BIRTH CONTROL PILLS TO TRY TO GET MY BLEEDING UNDER CONTROL, HOWEVER, AFTER A WEEK OF TAKING THE BLEEDING CONTINUED, NOW I'M ADVISED TO TAKE 2 PILLS A DAY TILL THE END OF THE PACK WHEN YOUR PERIOD IS ACTUALLY SUPPOSED TO START, I'M STILL BLEEDING AFTER ANOTHER WEEK OF NOW TAKING TWO PILLS/DAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038714	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 10/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT LOWER BACK PAINS, DULL AND ACHING PAINS ON BOTH SIDES OF LOWER ABDOMINAL AREA, HEAVY CLOTTY BLEEDING FOR MOST OF THE ENTIRE MONTH, WHEN DOES STOP - INTERCOURSE MAKES ME BLEED AGAIN, SWELLING OF BELLY AREA, DEPRESSION, ANXIETY, SHARP PAINS ON MY LEFT SIDE, HOT AND COLD FLASHES, VERY LETHARGIC AT TIMES, MEMORY LOSS, PAINFUL INTERCOURSE, CRYING SPELLS, AND MOODINESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038715	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5038715 #(B)(4) BECAUSE OF THE PET FIBERS IN ESSURE MY RIGHT OVARY IS NOW ATTACHED TO TISSUE ONCE AGAIN CAUSING PELVIC PAIN. THIS WILL RESULT IN ME HAVING A 3RD SURGERY (B)(6), 2015

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038716	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE IMPLANTS WAS PUT IN (B)(6) 2006. STARTING IN (B)(6) 2013 START EXPERIENCING SHARP PELVIC PAIN.....INCREASE FATIGUE...BACK PAIN...LEG NUMBNESS.... INCREASED MENSTRUAL PAIN AND FLOW....VAGINAL DISCHARGE ....CONSTANT HEAD ACHE....NAUSEA....DIZZY SPELLS....CONSTANTLY FEEL UNBALANCED.....CONTINUOUSLY DAILY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038717	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 9/16/2014	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PAIN IS GETTING WORSE. WHEN I SIT DOWN OR MOVE A CERTAIN WAY I FEEL LIKE I AM BEING STABBED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038718	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 9/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SYMPTOMS: ABDOMINAL AND BACK PAIN, NUMBING OF LIMBS, MIGRAINES, HAIR LOSS, SLURRED SPEECH, BLURRED VISION, INNER EAR PAIN, RASHES, HEART PALPITATIONS, UNSTEADY GAIT, NIGHT SWEATS AND UNEXPLAINED FEVERS, ISSUES CONCENTRATING, METALLIC TASTE, TROUBLE SLEEPING, MUSCLE AND JOINT PAIN, LOW BP 80/60, DIZZINESS AND FATIGUE, SWOLLEN GLANDS AND NODES, ISSUES GRABBING, TERRIBLE BLEEDING, LEG CRAMPS, INCONTINENCE, BACTERIAL VAGINOSIS AND CONSTANT UTI'S AND ANXIETY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038719	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 8/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE MY LAST REPORT I HAVE STILL BEEN BLEEDING HEAVILY OFF AND ON. I STILL HAVE HEADACHES AND CRAMPS. I AM FATIGUED ALL OF THE TIME. MY GYNECOLOGIST FINALLY REFERRED ME TO ANOTHER DR. AFTER MY TEST RESULTS OF THE MASS WAS FOUND TO BE BENIGN ACCORDING TO THEM. I HAD GIVEN MY GYNECOLOGIST A LOT OF INFORMATION THAT I GOT FROM THE ESSURE PROBLEMS (B)(6) PAGE. I HONESTLY DON'T EVEN KNOW WHAT I WOULD HAVE DONE IF I HAD NOT FOUND ALL OF THE HELPFUL INFORMATION. SO AS OF NOW... MY HYSTERECTOMY IS SCHEDULED FOR (B)(6) 2014. I DID NOT GET THAT FORM OF BIRTH CONTROL TO HAVE MAJOR SURGERY... I TRUSTED MY DR. AND THIS PRODUCT THAT WAS APPROVED BY THE FDA. AND NOW I HAVE TO AND HAVE BEEN GOING THROUGH A PHYSICAL AND MENTAL EMOTIONAL ROLLER COASTER SINCE THE DAY THAT IT WAS PUT INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038721	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 10/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE GETTING THE ESSURE PLACED I HAVE EXPERIENCE CONSTANT HIP AND ABDOMINAL PAIN AND SHARP STABBING PAINS, HAIR LOSS, ALWAYS EXHAUSTED, METAL TASTE, BRAIN FOG, HEAVY PERIODS, NIGHT SWEETS, AND FINALLY NOW WILL BE GETTING TUBES AND ESSURE REMOVED IN (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038722	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL CYSTS GROWING ON OVARIES. A FEW TIMES A YEAR I VISIT THE ER AND OB-GYN FOR NUMEROUS ULTRASOUNDS AND PAIN MEDS. MY PERIODS NOW ARE EITHER NON-EXISTENT, OR START AND DON'T STOP FOR WEEKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038723	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 7/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NEVER REQUESTED THE DEVICE, REQUESTED BILATERAL TUBAL LIGATION NATURAL TYING OF THE TUBES, AND I WAS GIVEN ESSURE BY DOCTOR (B)(6), OBGYN, WITHOUT MY PERMISSION CONSENT OR KNOWLEDGE ABOUT THE PRODUCT; ON THE DAY OF THE PROCEDURE, I WAS TOLD TO TAKE VALIUM AND COME INTO THE OFFICE (B)(6), THEN I WAS GIVEN TORADOL. IMMEDIATELY AFTER I STARTED EXPERIENCING HEAVY PERIODS BLOOD CLOTS, PAIN DURING INTERCOURSE, EXTREME CRAMPING IRREGULAR PERIODS, FATIGUE, OUTBREAK OF RASHES AND HIVES, IN (B)(6) WHEN I ASKED FOR MY TUBAL TO BE REVERSED THAT'S WHEN I FOUND OUT I HAD ESSURE. LOT# 835439 2 COILS IN THE LEFT 3 IN THE RIGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038724	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 3/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CRAMP AND BLEED NON- STOP. I KEEP A HEADACHE. I HAVE SIDE PAIN. I HAVE JOINT ACHES AND PAINS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038725	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 8/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED EXPERIENCING LOWER BACK PAIN FROM DAY AFTER IMPLANT AND HAVE HAD LBP EVERY SINGLE DAY SINCE. OVER 1 YEAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038726	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 9/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CAME IN FOR CONSULT. I SPOKE WITH MY DR ABOUT OPTIONS AND TOLD HER I'M ALLERGIC TO EVERYTHING. I TOLD HER I GO TO AN ALLERGIST. SHE SAID YOU WON'T NEED TO WORRY ABOUT ANYTHING WITH ESSURE, LETS DO THAT PROCEDURE. SHE SPOKE ABOUT COILS GOING INTO MY TUBES AND WAS AN EASY, PAINLESS PROCEDURE THAT LASTED 5 TO 10 MINUTES. NO LABS WERE DRAWN OR TEST DOWN TO SEE IF I AM ALLERGIC TO COILS. (B)(6) PROCEDURE DAY. AT 1030 AM "I WAS LORAZEPAM" AND A SHOT IN MY HIP THAT WAS NOT TOLD TO ME WHAT IT WAS. I WAS TAKEN BACK INTO THE WAITING ROOM TO SIT WITH MY HUSBAND FOR 20 MINUTES LONGER. I WAS TAKEN TO ANTHER ROOM TO SIT AND WAIT TO BE TAKEN TO THEIR PROCEDURE ROOM. MY LEGS WERE PUT INTO STIRRUPS AND I WAS COVERED UP WITH GREEN SHEETS. I REMEMBER PLACING MY HANDS NEXT TO HIPS ON THE END OF THE TABLE TO HOLD ONTO SOMETHING. THE DR SAID SHE NEEDED TO NUMB MY CERVIX AND SHE DID SIX HORRIFIC TIMES. I BREATHED THROUGH EACH STABBING NEEDLE. THE DR COMMENTED ON HOW WELL I WAS HANDLING THE PROCEDURE. I ASKED HER WHY? SHE SAID MOST GIRL DON'T HANDLE THAT PART WELL. I JUST CLOSED MY EYES. SHE THEN USED HER SCOPE AND I FELT THE WIRE IN MY BODY. I REMEMBERED I COULD WATCH THE SCREEN TO TAKE MY MIND OFF THE HORRIFIC PAIN I WAS GOING THROUGH. FOR THE FIRST TUBE A PIECE OF SKIN WAS IN THE WAY AND THE COIL COULDN'T GO IN. SHE HAD TO REMOVE THE SCOPE TO GET SOME MUCUS OFF IT AND WENT BACK IT. THE COIL WENT RIGHT. I FELT EVERY SINGLE SECOND OF THAT COIL SLIPPING INTO MY BODY AND STILL FEEL IT. THE SECOND COIL MY TUBE WAS WIDE OPEN AND EASY TO INSERT WITH NO PROBLEM. WE EVEN SPOKEN ABOUT THE KIND IF SCOPE THEY WERE USING BECAUSE I'M AN ENDOSCOPY TECH. I WAS JUST TRYING TO KEEP MY MIND OFF THE PAIN. THE NURSE WASN'T SURE OF THE NAME OF THE SCOPE NOR DID THE TECH HELPING. THE DR QUICKLY CHANGED THE SUBJECT. THE DR REMOVED THE WIRES AND THEN SCOPE FROM MY BODY AND WIPED

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ME UP. WHEN I STOOD UP I FELT VERY DIZZY AND FAINT. I WAS WALKED TO ANOTHER ROOM. HOWEVER, NO ONE BOTHERED TO COVER ME UP ON MY LOWER HALF WHILE WALKING OUT THE DOOR IN THE HALLWAY. I WAS TAKEN INTO A ROOM AND WAS TOLD TO WALK TO A CHAIR. I HEARD A DOOR SHUT BEHIND ME. I WAS BY MYSELF ALONE IN A ROOM WITH MIRRORS. I LOOKED DOWN AND BLOOD WAS POURING DOWN MY LEGS AND I FELT FAINT. TO MY RIGHT ABOUT 3 FEET WAS A SINK I STUMBLED TO THAT AND WAS ABLE TO CLEAN MYSELF UP BY MYSELF. I THEN TURNED TO MY LEFT AND WALKED ANOTHER 4 FEET TO A CHAIR TO GET MY CLOTHES ON. BY THE TIME I WAS SITTING I WAS HURTING SO BADLY I THOUGHT I WAS GOING TO PASS OUT. ANOTHER CHAIR WAS SITTING NEXT ME AND I PULLED THAT IN FRONT OF ME IN CASE I PASSED OUT. I COULDN'T FIND A CALL BUTTON, THERE WAS NO CLOCK, NO PHONE IN THE ROOM, I HAVE NO IDEA HOW LONG I STAYED IN THAT ROOM BUT IT WAS FOR A LONG TIME. I LOOKED AT MYSELF IN THE MIRROR AND MY FACE WAS WHITE. WHEN THE NURSE CAME BACK. SHE LOOKED A BIT CONCERNED AND DIDN'T LEAVE MY SIDE. SHE TOOK MY BLOOD PRESSURE BUT WOULDN'T TELL WHAT IT WAS. I TOLD HER MY BACK WAS HURTING REALLY, REALLY BAD AND I WAS CRAMPING IN MY STOMACH. SHE DIDN'T EVEN REPLY. SHE SAID IT WAS TIME TO GO AND I COULD SEE MY HUSBAND. SHE TOLD HIM TO GO GET THE CAR AND PULL UP BY THE DOOR AND SHE WALKED ME OUT. I GOT IN MY CAR AND WHEN SHE WALKED AWAY I TOLD MY HUSBAND TO GET ME HOME. WHEN MY HUSBAND GOT ME HE TOOK ME STRAIGHT TO THE BATHROOM WHERE I PUKED MY GUTS OUT. I WAS IN SO MUCH PAIN AT THIS POINT. MY HUSBAND CALLED THE OFFICE AND THEY TOLD HIM TO GIVE ME MY PAIN MEDS NORCO 235 EVERY 4 HOURS AND MIDOL EVERY 4 HOURS. I TOOK THOSE MEDS FOR 5 DAYS STRAIGHT. IF I DIDN'T TAKE MY MEDS I'D WAKE WITH SEVERE PAIN AND NAUSEA. I HAVE BLED EVERY DAY SINCE THEN AS WELL HAVING SHARP STABBING PAINS IN MY OVARIES AND BLOATING. ON MONDAY I CALLED THE OFFICE (B)(6) WITH SUCH SEVERE CRAMPING I THOUGHT I WAS GOING TO DIE. I WAS CONSTIPATED AND ENDED TO SPEAK TO A NURSE FOR ADVISE. I CALLED AROUND 1040 AM AND NO ONE BOTHERED TO CALL ME BACK. BEING AN ENDOSCOPY TECH I KNOW WHAT TO DO SO I HAD MY HUSBAND HELP ME WITH A FLEET ENEMA THAT HELPED ME CONSIDERABLY, FIVE HOURS LATER NO ONE HAD CALLED ME SO I CALLED THE OFFICE TO LET THEM KNOW THEY DON'T NEED TO BOTHER SPEAKING TO ME AND THAT I AM UPSET. I TOOK MILK OF MAGNESIA FOR THE NEXT COUPLE OF DAYS BUT NOTHING HAS HELPED WITH MY CONSTIPATION. I GO TO MY FAMILY DR AND GET MY ALLERGY SHOTS AND TELL THEM MY SITUATION AND THEY TELL ME GET DULCOLAX. THIS IS (B)(6). AFTER A FEW DAYS I AM FINALLY STARTING TO FEEL A LITTLE BETTER WITH CONSTIPATION THIS IS (B)(6) AT THIS POINT. I AM HAVING MIGRAINES, AND I'VE BEEN BLEEDING SINCE (B)(6) AND I'M TASTING A METALLIC TASTE AS OF (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038727	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 2/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5038727 #(B)(4) HERE IS A LIST OF MY SYMPTOMS: DIZZINESS, EXTREME FATIGUE, EXTREME MIGRAINES ALL THE TIME, BODY ACHES, INFLAMMATION, CARPEL TUNNEL, WEIGHT GAIN, ACHING BONES, ACHING JOINTS, INABILITY TO LOSE WEIGHT DESPITE DIET AND EXERCISE, HIGH BLOOD PRESSURE, PAIN IN LOWER BACK, PAIN IN LEGS, PAIN IN ANKLE, SWOLLEN ANKLE, HEARTBURN, RASH ON ELBOWS KNEES BACK BUTT HOLE BELLY BUTTON, PAIN IN HIPS AND LOWER ABDOMEN, CHRONIC CONSTIPATION DESPITE DIET, BLOATED, BLURRED VISION, ALLERGY SYMPTOMS, CHRONIC COUGH, ASTHMA, ECZEMA, HEAVY CRAMPING ALL THE TIME NOT JUST ON PERIODS, PERIODS LASTING 7-14 DAYS, EXTREMELY HEAVY PERIODS REQUIRING A HEAVY PAD AND THE HEAVIEST TAMPON, EXTREME BREAST AND NIPPLE PAIN, ANXIETY, DEPRESSION, VITAMIN D DEFICIENCY, BLOOD SPOTTING, MUSCLE WEAKNESS I CAN'T A TOOTHBRUSH FOR TWO MINUTES, MONO, EXTREME ANXIETY, DEPRESSION, GINGIVITIS. I JUST HAD A FULL HYSTERECTOMY DONE TO TAKE OUT THE ESSURE COULD LEAVING ONLY THE OVARIES. STARTING THAT DAY MY RASH AND MIGRAINES WENT AWAY. NOW I HAVE NO DEPRESSION OR ANXIETY. ALL SYMPTOMS HAVE GONE. THE BIGGEST CHANGE HAS BEEN THE ABILITY TO LOSE WEIGHT ((B)(6) IN TWO WEEKS SINCE SURGERY), AND MY BLOOD PRESSURE IS BACK TO NORMAL! I NO LONGER HAVE TO TAKE TWO BLOOD PRESSURE MEDICATIONS!!!!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038728	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5038728 #(B)(4) AS OF (B)(6) 2015 I HAD A FULL HYSTERECTOMY WITH THE REMOVAL OF BOTH TUBES, UTERUS AND CERVIX AT THE AGE OF (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038729	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 8/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE MY SURGERY TO IMPLANT ESSURE, I HAVE SUFFERED ONGOING PELVIC AND ABDOMINAL PAIN, BACK PAIN, NON-STOP VAGINAL BLEEDING, DAILY HEADACHES, INCREASE IN MIGRAINES AND EXTREME FATIGUE. IN ADDITION, I HAVE EXTREME ABDOMINAL BLOATING AND WEIGHT GAIN (OF 15 LBS SINCE IMPLANTATION). BEGINNING ON APPROXIMATELY (B)(6) 2014, I STARTED HAVING NUMBNESS AND TINGLING SENSATIONS IN MY HANDS. THIS WAS IMMEDIATELY FOLLOWED BY JOINT PAIN IN MY FINGERS AND MY RIGHT KNEE. MY PHYSICIAN HAS BEEN INFORMED OF THESE EVENTS AND I HAVE BEEN SEEN SEVERAL TIMES OVER THE COURSE OF THE LAST THREE MONTHS (SINCE I HAD ESSURE IMPLANTED). MY PHYSICIAN CLAIMS TO NOT KNOW WHAT IS CAUSING MY SYMPTOMS EVEN THOUGH I'VE EXPRESSED TO HER THAT I BELIEVE (BASED ON MY OWN RESEARCH) THAT ESSURE HAS CAUSED MY SYMPTOMS. MY PHYSICIAN HAS, HOWEVER, AGREED TO REMOVE THE ESSURE COILS BASED ON THE FACT THAT I HAVE CONTINUED PAIN AND BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038730	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 1/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5038730 #(B)(4) I HAD A HYSTERECTOMY REMOVING MY CERVIX, UTERUS, AND BOTH TUBES. PATHOLOGY REPORT CAME BACK THAT MY CERVIX SHOWED CHRONIC INFLAMMATION. IN ADDITION, ONLY ONE COIL WAS FOUND. IN EARLY 2012, AT MY HSG APPOINTMENT IT WAS CONFIRMED THAT I WAS 100% BLOCKED IN BOTH TUBES AND I WAS TOLD THAT THE COILS COULD NOT MIGRATE AT THAT POINT. MY RIGHT TUBE DIDN'T EVEN SHOW SCAR TISSUE AND WAS WIDE OPEN. AN X-RAY WAS DONE AFTER THE HYSTERECTOMY AND WE CANNOT FIND A COIL INSIDE OF ME, SO IT IS ASSUMED THAT IT CAME OUT AT ONE POINT IN MY 3 YEARS OF HAVING ESSURE OR IT MAY HAVE BEEN EMBEDDED IN MY CERVIX SINCE THAT SHOWN CHRONIC INFLAMMATION (WHICH SHOULD HAVE OCCURRED IN THE TUBES) AND THE CERVIX MAY NOT HAVE BEEN THOROUGHLY DISSECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038731	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM THE BEGINNING, I STARTED HAVING ISSUES... I HAD CONSTANT PAIN AND HEAVY BLEEDING (TO THE POINT TO WHERE MY SON FREAKED OUT CAUSE I WAS COOKING DINNER AND STANDING IN A PUDDLE OF BLOOD AND DIDN'T EVEN KNOW IT).. WHEN MY TIME OF THE MONTH COMES AROUND, I START HAVING HORRID SYMPTOMS , FEVER, NAUSEA, BACK PAIN , HIP PAIN, LEG PAIN, HEAD ACHES, VOMITING HAVING TO PUT TOWELS DOWN AT NIGHT IN CASE I BLEED EVERY WHERE ON MY BED, HAVING TO CARRY A BOX OF PADS AND TAMPONS WITH ME AT ALL TIMES, HAVING TO CONSTANTLY CHANGE MY CLOTHES BECAUSE I AM ALWAYS BLEEDING THRU, CAN'T EVEN COUNT HOW MANY TIMES THIS HAS HAPPENED TO ME IN PUBLIC AND NOT TO MENTION THE HORRID MOOD SWINGS.. SEX BECAME PAINFUL WHICH WAS NEVER AN ISSUE BEFORE AND MY PERIOD WOULD COME WHEN EVER IT FELT LIKE IT AND I WOULD BLEED FOR DAYS AND A HEAVY ALMOST PURPLE COLORED BLOOD, I WENT TO A DIFFERENT CLINIC (CAUSE THE DOCTOR WHO INSERTED THIS THING IN ME WAS NO HELP) AND TOLD THEM WHAT MY ISSUES WERE.. THEY DID A PAP AND SAID, OH WELL, IT CAME BACK NEGATIVE, SO YOU ARE OK . AND SENT ME ON MY WAY (NO HELP AT ALL), SO HERE I AM ALMOST 4 YRS AFTER INSERTING THIS THING AND I AM STILL SUFFERING, I HAVE NO ANSWERS AS TO WHAT I CAN DO ABOUT THIS... AND WOULD LIKE TO KNOW WHAT I CAN DO, CAN SOMEONE HELP?... I AM A SINGLE MOTHER NOW EVEN A GRANDMOTHER AND NOT WANTING TO HAVE ANY MORE CHILDREN.. BUT I DO WANT THESE SYMPTOMS TO STOP ALREADY, I DON'T LOOK FORWARD TO MY PERIOD EVERY SINGLE MONTH CAUSE I KNOW IT WILL BE HORRIBLE.. PLEASE HELP

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038732	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 3/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ENSURE PLACED IN (B)(6) 2012 AND STARTING IN (B)(6) 2013 I HAVE HAD MULTIPLE MEDICAL PROBLEMS. SEVERE HEADACHES AND PAIN IN MY NECK. IRREGULAR PERIODS. PERIODS THAT WERE EXTREMELY HEAVY AND SOAKING THROUGH A TAMPON IN LESS THAN TWO HOURS FOR DAYS AT A TIME. ABDOMINAL PAIN THAT IS SOMETIMES DULL AND LONG LASTING AND OTHER TIMES SHARP SHOOTING PAINS THROUGH THE DAY. FATIGUE THAT AT TIMES WOULD CAUSE ME NOT TO BE ABLE TO GET OUT OF BED. I HAVE ALSO HAD TWO RUPTURED CYSTS ON MY OVARY WHICH I HAD NEVER EXPERIENCED BEFORE THE ESSURE PLACEMENT. MUSCLE TENDERNESS AND WEAKNESS. I HAVE HAD TWO CT SCANS, X-RAYS, BLOOD WORK AT LEAST FOUR TIMES, MULTIPLE TYPES OF ULTRASOUNDS, AND A BIOPSY. THE DOCTORS CANNOT FIND ANY ISSUES GOING ON WITH MY BODY THAT WOULD CAUSE THESE SYMPTOMS. I HAVE NO MEDICAL CONDITIONS OR DEFICIENCIES AT ALL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038733	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 5/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE RECENTLY GOTTEN A PARTIAL HYSTERECTOMY ON (B)(6) 2014 DUE TO THE PAIN IN MY BACK AND THE BLEEDING GOT WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038734	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 3/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE PAIN IN MY LOWER ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038735	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER PLACEMENT OF ESSURE I DEVELOPED A VERY SHARP PAIN ON MY LEFT SIDE AND INTO MY BACK AND DOWN MY LEFT LEG. IT CONTINUED TO GET WORSE OVER TIME. I STARTED HAVING MOOD SWINGS, HAIR LOSS, NUMBNESS IN MY ARMS AND LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038736	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 10/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL INTERCOURSE PAIN IN LOWER STOMACH AND BACK PAIN DURING MENSTRUAL CYCLE ALONG WITH HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038737	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 7/25/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE, THE IMPLANT IS CALLED ESSURE, ON (B)(6) 2008. THIS MEDICAL DEVISE IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS L2843 11/11/05. THIS DEVISE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINTS STARTED ON (B)(6) 2009. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: ABDOMINAL PAIN, SEVERE ABDOMINAL BLOATING, PAIN ON INTERCOURSE, PERIODS GOT HEAVIER, BURNING ON MY BODY, ITCHY SKIN, DRY PATCHES ON SKIN. I HAVE BEEN SEEN BY DR. (B)(6), DR. (B)(6), DR. (B)(6), DR. (B)(6), DR. (B)(6). I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS; LOW IRON, SEVERE ITCHY SKIN (REFERRED TO DERMATOLOGY), THYROID. I HAVE HAD THE FOLLOWING SURGERY DUE TO ESSURE: DA VINCI SURGERY, THE REMOVAL OF FALLOPIAN TUBES WITH ESSURE COILS. THE DEVICE WAS REMOVED ON (B)(6) 2014. THE DEVICE WAS NOT RETURNED TO MANUFACTURER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038738	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 10/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CAN'T CHANGE THE DATE BUT I HAD ESSURE PUT IN (B)(6) 2013. I WAS STILL BLEEDING AFTER HAVING IT PUT IN. I BLED FOR 9 MONTHS. IN (B)(6) 2013 I NOTICED I LOST A LOT OF HAIR FROM PRETTY MUCH ALL OVER MY BODY. I HAVE RASHES THAT SHOW UP ON MY BACK AND ON MY LEFT HAND. I WAS DIAGNOSED IN (B)(6) OF THIS YEAR WITH OSTEOPOROSIS OF THE SPINE. I SUFFER HORRIBLE PANIC ATTACKS AND HAVE LOTS OF WEIGHT LOSS. I HAVE HORRIBLE MIGRAINE HEADACHES AND NAUSEA AS WELL. I'M DIZZY ALL THE TIME. I ALSO HAVE ARTHRITIS IN MY HANDS. I SUFFER PAIN ON MY LEFT SIDE ALL THE TIME. FEELING OF PINCHING AND PULLING. I WAS JUST AT THE ER AND HAD A CT SCAN DONE AND THEY TOLD ME I HAVE CYSTS ON MY OVARIES. I HAVE CHRONIC LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038739	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE END OF 2011 PLACEMENT WAS ON (B)(6) 2011. BY (B)(6) 2012 I WAS HAVING VISION PROBLEMS, BALANCE ISSUES, PAIN FROM FEET TO HIPS, SPEECH PROBLEMS, MY SKIN IS ALWAYS RED FROM HEAD TO TOE, PERIOD WENT FROM 4 DAYS TO 10, BECAME SLIGHTLY ANEMIC, ALL BLOOD WORK CAME BACK NORMAL THIS IS THE ONLY THING NEW THAT I HAVE HAD IN MY SYSTEM! I AM HAVING SEIZURES NOW WITH NO EXPLANATION!! I STAY TIRED AND IN PAIN. I AM ONLY (B)(6) I SHOULD BE LIVING, WORKING BUT I CAN'T BECAUSE I FEEL LIKE I'M 80.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038740	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 6/12/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). METAL TASTE, HAIR FALLING OUT, SHARP PAINS ON BOTH SIDES, LEGS GOING NUMB, HEADACHES, PAIN IN LOWER BACK AND PELVIC AREA, EXTREME HEAVY PERIODS, BODY ACHES, DIARRHEA, VOMITING, CRAMPS, INSOMNIA,ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038741	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING PAIN IN MY HIPS TO THE POINT THAT IT HURTS TO SIT OR EVEN STAND. MY PERIOD SUPER HEAVY TO THE POINT MY HUSBAND TOOK ME TO HOSPITAL AND I WAS TOLD THERE THAT I ALMOST HAD TO HAVE A BLOOD TRANSFUSION AND TILL THIS DAY, I HAVE BLOOD CLOTS AND HEAVY BLEEDING. I GET SHARP SHOOTING PAINS IN MY BACK, TINGLING IN MY ARMS AND LEGS AND HANDS AND FEET. THE TOP PART OF MY ARMS HURT SO BAD, THEY LIKE THEY ARE BRUISED AND HURTS TO STRAIGHTEN OR BEND THEM. MY NECK AND SHOULDERS HURT. WHEN I FIRST HAD THE COILS PUT IN, I WAS TOLD TO COME BACK TO MAKE SURE THE COILS WERE IN PLACE BY THEM HAVING A DYE PUT IN ME BUT WHEN THEY DID THE XRAY THEY ONLY SEEN ONE, I ASKED WHERE THE OTHER ONE WENT AND THEY SAID IT PROBABLY FELL OUT BUT NOW I AM NOT SURE, I WENT BACK TO DR AND THEY PUT ANOTHER COIL IN TO REPLACE THE ONE THEY DIDN'T SEE IN XRAY AND I NEVER WENT TO HAVE THEM CHECKED FROM THAT POINT. I HAVE HAD NOTHING BUT ISSUES WITH MY BODY SINCE I HAVE HAD ESSURE DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038742	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 9/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODS EVERY 2 WEEKS, HEAVY BLEEDING THAT LED TO ER VISIT AFTER GOING TO MY OBGYN. HUGE CLOTS, EXTREME FATIGUE, JOINT PAIN, ESPECIALLY IN HIPS, AND EXCRUCIATING PAIN IN MY LOWER BACK. I LOOK 5-6 MONTHS PREGNANT DUE TO BLOATING AND I'M HAVING SOME SORT OF SPASMS IN MY VAGINAL AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038743	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 5/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS: I DON'T KNOW IT. MY MODEL NUMBER IS: I DON'T KNOW THIS EITHER. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6), 2011. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: NUMBNESS IS HANDS AND FEET, WEIGHT GAIN, IRREGULAR MENSTRUAL CYCLES (TAKING BC PILLS TO REGULATE MENSTRUAL CYCLE), PCOS ANDAMP; NOW I'M TAKING SYNTHROID FOR AN UNDER ACTIVE THYROID. I HAVE BEEN SEEN BY 1 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: PCOS AND; HYPOTHYROIDISM. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: NONE THE DEVICE IS STILL INSIDE OF ME AS OF TODAY ((B)(6) 2014).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038744	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE DEVICE I HAVE EXPERIENCED SEVERE AND FREQUENT MIGRAINES, HAIR LOSS, LOST OF BALANCE, DIZZINESS, NAUSEA AND VOMITING, HEAVY PERIODS, SEVERE CRAMPING, HOT FLASHES, HIVES/SKIN RASH, CHRONIC HEMORRHOIDS, BLOATING, GAS, WEIGHT GAIN AND MEMORY ISSUES. ONE OF THE COILS CAME OFF OF MY TUBES AND RESTED ON MY RECTUM. I ENDED UP HAVING TO HAVE MY TUBES REMOVED. I AM STILL EXPERIENCING ISSUES AND WILL MOST LIKELY END UP WITH A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038745	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING INTENSE PAIN IN MY LOWER LEFT SIDE THAT IN DOUBLE OVER CRYING AND HURTING AND I JUST CAN'T TAKE IT I HAD THE ESSURE 9/30/14 AND HAVE NOT STOPPED HAVING PAIN OR BLEEDING SINCE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038746	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 9/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DOCTOR SAID THE BLEEDING WOULD STOP BUT IT NEVER DID; I GOT IT DONE (B)(6) 2012 AND HAD MY PERIOD FOR A CONSECUTIVE 8 MONTHS. I WAS DIAGNOSED WITH HYPERTHYROIDISM 4 MONTHS AFTER THE PROCEDURE WAS DONE. I AM STILL STRUGGLING WITH HYPERTHYROID AND I'VE ALSO HAD A OVARIAN CYST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038747	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED OUT WITH SWELLING/BLOATING. AFTER A FEW MONTHS, THE BLOATING WAS DAILY, I WAS CONFIDENTLY MISERABLE. THEN MY WEIGHT STARTED SLOWLY CLIMBING, SO FAR OVER 50 LBS SINCE ESSURE. NEXT WAS THE HORRIBLE CRAMPING AND IRREGULAR BLEEDING. RADICAL MOOD SWINGS AND EVENTUALLY WITHIN THE LAST TWO YEARS, JOINT PAIN. MOSTLY IN MY RIGHT HIP BUT IN MY BACK AND LEGS TOO. AT NO POINT HAVE ANY OF THESE SYMPTOMS LESSENED OR GONE AWAY, THEY ARE DAILY STRUGGLES. ESPECIALLY WITH THE BLOATING, SWELLING, AND WEIGHT GAIN. I'VE TRIED EVERY THING AND NOTHING HELPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038748	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 6/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAIN. HEAVY AND PROLONGED PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038749	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 1/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I GOT THIS IMPLANT I HAVE DAILY STOMACH PAIN AND BLOATING. I FEEL A STABBING SENSATION IN MY ABDOMEN AND ALSO INTERCOURSE IS EXTREMELY PAINFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038750	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONE MONTH AFTER ESSURE WAS PLACED I BEGAN SEEING AN INCREASE IN THE NUMBER OF MIGRAINES I WAS GETTING. SINCE I WAS 13 YEARS OLD I WOULD GET 1 MIGRAINE PER MONTH. BUT SINCE ESSURE I GET 3-4 PER WEEK. ALSO, I NOW GET SHARP PAIN ON THE RIGHT SIDE OF MY ABDOMEN THAT RADIATES DOWN MY RIGHT LEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038751	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 5/18/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE DEVICE IMPLANTED AND SUBSEQUENTLY BEGAN HAVING EXTREMELY HEAVY/LONG/PAINFUL PERIODS. MY PERIODS GOT LONGER AND LONGER AND EVENTUALLY BECAME NONSTOP. I HAD A UTERINE ABLATION IN (B)(6) 2012 AND WHEN I REALIZED IT HAD DONE NOTHING TO STOP THE BLEEDING, I HAD A TOTAL HYSTERECTOMY PERFORMED IN (B)(6) 2012. I HAD GOTTEN A SECOND AND A THIRD MEDICAL OPINION AND NO ONE WOULD TELL ME WHY I WAS BLEEDING CONSTANTLY AND SUFFERING WITH SO MUCH PAIN. DESPITE SAYING, HE, TOO, WAS BAFFLED, I THINK MY DOCTOR (WHO IMPLANTED THE ESSURE DEVICES, PERFORMED THE ABLATION AND PERFORMED THE HYSTERECTOMY) KNEW WHAT WAS GOING ON AND THAT IS WHY HE INSISTED I HAVE MY HEALTHY FALLOPIAN TUBES REMOVED AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038752	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 9/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY MODEL NUMBER IS ESS305 IF YOU KNOW IT. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2014 THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. EXTREME BLOATING, CHRONIC LOWER BACK PAIN, CERVICAL INFECTIONS, NAUSEA, VOMITING, CONSTIPATION, NO PERIODS, NO SEX DRIVE, PELVIC PAIN, PAIN WITH SEXUAL INTERCOURSE, INSOMNIA, ANXIETY. THIS HAS BEEN SEEN BY 4 DOCTORS. THE DEVICE IS STILL INSIDE OF ME AS OF (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038753	BAYER	10/23/2014	10/23/2014

Event Information:

Event Date (B3): 10/16/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN THE BEGINNING OF ESSURE PLACEMENT, I HAD CONSTANT CRAMPING AND PAIN IN MY LOWER PELVIC REGION, I WAS TOLD IT WAS SCAR TISSUE BUILDING. SIX YEARS LATER THEY DO A PELVIC ULTRASOUND AND TO FIND THAT THE COILS MIGRATED VERY EARLY ON. I NOW WILL HAVE TO UNDERGO ADDITIONAL SURGERY TO HAVE A HYSTERECTOMY BECAUSE OF ESSURE! I NOW AM IN THE EARLY FEELINGS OF MENOPAUSE..... ITS JUST ALOT OF THINGS..

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038852	BAYER	10/23/2014	10/30/2014

Event Information:

Event Date (B3): 12/17/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/17/2007
Explant Date (E7): 5/13/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED IN (B)(6) 2007 BY DR (B)(6). EXPULSION OF R COIL IN 2007 THROUGH VAGINAL OPENING. CONFIRMED HSG TEST THAT BOTH SIDES WERE OCCLUDED. POSITIVE PREGNANCY IN (B)(6) 2009, DELIVERED ON (B)(66) 2009. COMPLICATIONS THROUGHOUT INCLUDES CHRONIC PELVIC PAIN, HEAVY PERIODS, PAINFUL INTERCOURSE, UTERINE POLYPS, OVARIAN CYSTS, PREGNANCY, WEIGHT GAIN, ABDOMINAL SWELLING, INABILITY TO SIT OR STAND FOR SHORT AND LONG PERIODS AT A TIME, EXPULSION OF R COIL, DISPLACEMENT OF LEFT COIL INTO UTERUS, CONSTANT METAL SMELL, CONSTANT YEAR INFECTIONS, EMOTIONAL, PHYSICAL, AND PSYCHOLOGICAL DISTRESS. LEFT COIL WAS SUPPOSEDLY REMOVED ON (B)(6) 2013. CT SCAN ON (B)(6) 2013 CONFIRMED IT WAS STILL IN PLACE. I WAS SEEN BY A SECOND DOCTOR WHO EVENTUALLY HAD TO PERFORM A TOTAL HYSTERECTOMY ON (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00460	BAYER HEALTHCARE LLC	10/23/2014	11/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91739

Single Use: Y
Implant Date (E6): 9/24/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C91739, INSERTION ON (B)(6) 2014. PHYSICIAN REPORTED THAT TIP OF MICRO-INSERT BROKE WHEN TRYING TO REMOVE INSERT WITH GRASPERS; REMOVAL WAS ATTEMPTED SINCE THERE WERE MORE THAN 18 TRAILING COILS IN UTERINE CAVITY. NO INJURY OCCURRED AND NO BILATERAL PLACEMENT WAS ACHIEVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 15-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "...TIP OF MICRO-INSERT BROKE WHEN TRYING TO REMOVE INSERT..." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE

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DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: LOT NUMBER C91739 (PRODUCTION DATE JUL-2014 AND EXPIRATION DATE 31-JUL-2014). THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. THE AE CASE REFERS ALSO TO USABILITY ISSUES. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE BATCH DOCUMENTATION WAS REVIEWED BY THE RQU. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". SINCE NO ADVERSE EVENTS WERE REPORTED, NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE TIP OF MICRO-INSERT BROKE WHEN TRYING TO REMOVE INSERT WITH GRASPERS; THE REMOVAL WAS ATTEMPTED BY THE PHYSICIAN SINCE THERE WERE MORE THAN 18 TRAILING COILS IN UTERINE CAVITY; NO BILATERAL PLACEMENT WAS ACHIEVED. THE PATIENT HAD NO INJURY. THE REPORTED EVENTS, REGARDED AS ESSURE DEVICE MISDEPLOYMENT (MORE THAN 18 TRAILING COILS) FOLLOWED BY BREAKAGE AT REMOVAL ATTEMPT AND FAILED INSERTION, WERE CONSIDERED NON-SERIOUS AND ARE LISTED IN ESSURE REFERENCE SAFETY INFORMATION. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE, MAINLY DURING DIFFICULT REMOVALS OR WHEN REMOVAL IS ATTEMPTED WITH FEWER THAN 18 TRAILING COILS IN UTERINE CAVITY. IN THIS PARTICULAR CASE, CONSIDERING THAT THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT/REMOVAL A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION WAS REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00461	BAYER HEALTHCARE LLC	10/23/2014	11/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/25/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 10/16/2014

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH PROFESSIONAL (MIDWIFE) IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. IT WAS REPORTED THAT PHYSICIAN INSERTED ESSURE TO A RIGHT TUBE NORMALLY. ESSURE WENT NORMALLY TO LEFT TUBE BUT IT DID NOT GET OFF FROM CATHETER. THE OUTCOME WAS THAT PART OF IMPLANT HAD REMAINED IN TUBE; PART OF IT HAD BEEN GOT OFF SOMEHOW. THE PATIENT WILL HAVE A CONTROL VISIT ON (B)(6) 2014. NO FURTHER INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: WHEN A PHRASE LIKE "...PART OF THE IMPLANT STAYED IN THE TUBE..." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES DURING THE PLACEMENT PROCEDURE, IF THE PHYSICIAN BROKE THE IMPLANT DURING DELIVERY SYSTEM REMOVAL, OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUES. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO CAUSAL RELATIONSHIP BETWEEN THE REPORTED PRODUCT QUALITY ISSUE AND ADVERSE EVENTS CAN BE ASSESSED, AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE REPORTED USABILITY ISSUES WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE, ON LEFT FALLOPIAN TUBE, ESSURE DID NOT GET OFF FROM CATHETER AND PART OF ESSURE REMAINED IN TUBE, PART OF IT HAD BEEN GOT OFF SOMEHOW. THESE EVENTS, INTERPRETED AS A DEVICE BREAKAGE AND DEPLOYMENT ISSUE, WERE CONSIDERED NON-SERIOUS. DEVICE BREAKAGE WAS INITIALLY CONSIDERED AS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; HOWEVER UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) IT WAS AMENDED TO LISTED, SINCE PTC ANALYSIS CONCLUDED THAT THE BREAKAGE IS AN ANTICIPATED EVENT. THE REMAINING EVENT IS LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE; CONSIDERING THAT THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT THEY WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE MALFUNCTION. PTC ANALYSIS CONCLUDED TO UNCONFIRMED QUALITY DEFECT (NO COMPLAINT SAMPLE OR BATCH NUMBER WERE PROVIDED). FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 29-DEC-2014: INFORMATION RECEIVED FROM MIDWIFE STATED THAT, DURING A CONTROL VISIT, AN ULTRASOUND EXAMINATION AND STOMACH NATIVE X-RAY WERE TAKEN AND SHOWED THAT BOTH IMPLANTS WERE IN SITU AND THERE WERE NO SIGNS FROM THAT ANY PARTS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00462	BAYER HEALTHCARE LLC	10/23/2014	11/6/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A22174

Single Use: Y
Implant Date (E6): 9/25/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(60 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014; LOT NUMBER USED WAS A22174. IT WAS REPORTED THAT THE PHYSICIAN WAS ABLE TO PLACE ESSURE IN THE LEFT TUBE. WHEN HE WENT TO PLACE THE RIGHT TUBE AND A PIECE OF CATHETER AND THE MICRO INSERT BROKE OFF IN THE PATIENT'S FALLOPIAN TUBE. UPON REVIEW WITH THE SALES CONSULTANT, THE DECISION WAS MADE TO REMOVE BROKEN CATHETER AND HAD A SUCCESSFUL MICRO INSERT ON THE RIGHT SIDE WITH 9 TRAILING COILS. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "...A PIECE OF CATHETER AND THE MICRO INSERT BROKE OFF..." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE

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INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN DR-3020, DESIGN FMEA FOR ESS305. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE BATCH DOCUMENTATION WAS REVIEWED BY THE RQU. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". SINCE NO ADVERSE EVENTS WERE REPORTED, NO BATCH SIGNAL REVIEW FOR SIMILAR ADVERSE EVENTS COULD BE CONDUCTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A PIECE OF CATHETER AND THE MICRO INSERT BROKE OFF IN THE PATIENTS FALLOPIAN TUBE. THIS CASE IS MEDICALLY CONFIRMED. THIS EVENT IS CONSIDERED NON-SERIOUS AND LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. CONSIDERING THAT THE REPORTED EVENT OCCURRED DURING THE INSERTION PROCEDURE, THE CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE CANNOT BE EXCLUDED. THE EVENT WAS CONSIDERED A DEVICE MALFUNCTION; THEREFORE, THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 14-MAY-2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A PIECE OF CATHETER AND THE MICRO INSERT BROKE OFF IN THE PATIENTS FALL

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00463	BAYER HEALTHCARE LLC	10/23/2014	11/6/2014

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 11-JUL-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. IMMEDIATELY UPON INSERTION, CONSUMER FELT NAUSEOUS AND LIGHTHEADED. SHE COMPLAINED OF ABNORMAL PELVIC PAIN ON FOLLOW-UP APPOINTMENT, AND WAS TOLD SHE IS NOT USED TO THE PAINS OF PMS. PAIN CONTINUED TO WORSEN TO INCLUDE THE LOWER BACK AND LEG, AND MUSCLE SPASMS OF THE PELVIS, LEG, AND LOWER BACK. FATIGUE ALSO BEGAN WITH ABNORMAL PERIODS AND EXTREME FLUCTUATIONS OF WATER RETENTION. SHE WENT TO ANOTHER DOCTOR WITH THESE SYMPTOMS AND WAS TOLD IT WAS NOT GYNECOLOGICAL. UPON SPENDING YEARS AND MONEY ON UNSUCCESSFULLY SEARCHING FOR SOURCE OF PAIN, PATIENT IS NOW GOING TO PAY TO HAVE COILS REMOVED. FOLLOW UP 11.AUG.2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE. CASE CLOSED. INTERNAL REVIEW ON 12-SEP-2014: THIS CASE WAS FOUND TO BE A DUPLICATE OF CASE (B)(6). CASE (B)(6)WILL BE DELETED FROM BAYER DATABASE. THE FOLLOWING INFORMATION FROM CASE (B)(6) WAS ADDED: INFORMATION RECEIVED STATES THAT, AFTER ESSURE INSERTION, CONSUMER ALSO EXPERIENCED PAIN IN UPPER BUTTOCKS, PAIN IN HIP, INFLAMMATION AND CONSTIPATION. FOLLOW UP INFORMATION RECEIVED ON 26-SEP-2014 FROM CONSUMER VIA HEALTH AUTHORITY (MW5037442): CASE IS NOW UPGRADED TO OTHER REPORTABLE INCIDENT (PREVIOUSLY NON INCIDENT) AND IN SERIOUSNESS. IN 2008, ESSURE WAS IMPLANTED IN 2008. DURING THE IMPLANTATION, ONE OF THE COILS BROKE, THE DOCTOR WAS ABLE TO RETRIEVE IT, AND INSERT ANOTHER ONE. IMMEDIATELY FOLLOWING THE PROCEDURE, SHE BECAME VERY LIGHTHEADED, ALMOST PASSED OUT, AND HER BLOOD PRESSURE SPIKED. SHORTLY AFTER, SHE STARTED HAVING LEFT SIDE PELVIC PAIN WHICH SHE REPORTED TO HER GYNECOLOGIST, AND WAS TOLD IT WAS NORMAL. PAIN HAS SINCE PROGRESSED

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INTO LEFT SIDE PELVIC PAIN, BACK PAIN, HIP PAIN, AND PAIN GOING DOWN LEFT LEG TO THE KNEE AND SOMETIMES FOOT. SHE EXPERIENCED CONSTANT MUSCLE SPASMS IN THESE AREAS AS WELL, CAUSING A SIGNIFICANT AMOUNT OF PAIN, SINCE HAVING THE IMPLANTS, SHE HAS NORMALLY BLOATED AROUND THE MIDSECTION. THIS BLOATING CAN DISAPPEAR FOR A FEW DAYS, AND RETURN WITHIN A DAY SO IT IS NOT WEIGHT GAIN. HER PERIODS HAVE BEEN IRREGULAR, AND SHE HAS EXPERIENCED FATIGUE DUE TO HYPOTHYROIDISM DIAGNOSED AFTER ESSURE COILS WERE IMPLANTED. SEVERAL IMAGING TESTS WERE PERFORMED, NONE OF WHICH CAN PINPOINT A SOURCE OF THE PAIN. SHE HAD THREE CORTISONE SHOTS TO TRY TO DIAGNOSE AND RELIEVE PAIN, ALL UNSUCCESSFUL. REMOVAL OF ESSURE IS PLANNED FOR 2014. SHE STATED THAT INTERVENTION WAS REQUIRED AND ASSESSED INJURY AS EVENT REPORT TYPE, HOWEVER NO FURTHER INFORMATION WAS PROVIDED ABOUT IT. FOLLOW-UP RECEIVED ON 06-OCT-2014 FROM PHYSICIAN: THIS CASE IS NOW MEDICALLY CONFIRMED. PHYSICIAN REPORTED THAT PATIENT WAS LAST SEEN IN OFFICE ON 26-APR-2010 FOR A ROUTINE GYNECOLOGICAL EXAMINATION. AT THAT TIME SHE REPORTED WATER RETENTION SINCE THE ESSURE PROCEDURE. SHE ALSO HAD COMPLAINED OF ONE EPISODE OF BREAKTHROUGH BLEEDING WITH EXTREME BACK PAIN IN HER MOST RECENT CYCLE, YET SYMPTOMS HAD RESOLVED WHEN PHYSICIAN SAW PATIENT. HEALTH CARE PROFESSIONAL HAS NO FURTHER INFORMATION AS PATIENT HAS NOT BEEN SEEN SINCE THEN. PTC INVESTIGATION RESULT WAS RECEIVED ON 17-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: WHEN A TERM LIKE "..DURING THE IMPLANTATION ONE OF THE COILS BROKE..." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE. UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION, IT IS DIFFICULT TO DETERMINE IF THE REPORTER IS DESCRIBING AN EVENT WHERE THE MICRO-INSERT ACTUALLY BROKE INTO INDIVIDUAL PIECES, IF THE MICRO-INSERT BENT OR STRETCHED INTO AN UNINTENDED SHAPE, AND HENCE WAS CONSIDERED BY THE REPORTER TO BE "BROKEN", OR IF A DIFFERENT PORTION OF THE DELIVERY CATHETER WAS BROKEN OFF INSIDE THE PATIENT. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICRO-INSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR

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RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS CASE WAS UPGRADED UPON RECEIPT OF FOLLOW-UP INFORMATION. THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE IMPLANTATION ONE OF THE COILS BROKE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, WAS CONSIDERED AS SERIOUS DUE TO MEDICAL IMPORTANCE (ASSESSED INJURY AS EVENT REPORT TYPE BY THE PATIENT, HOWEVER NO FURTHER DETAILS ABOUT THE INTERVENTION WAS REPORTED) AND LISTED FOR ESSURE ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE DEVICE BREAKAGE OCCURRED DURING IMPLANTATION. THE DOCTOR WAS ABLE TO RETRIEVE IT AND INSERT ANOTHER ONE. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE (MALFUNCTION) AND SINCE NO DETAILS ABOUT INTERVENTION WAS REPORTED. OTHER NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS, THE TECHNICAL ANALYSIS CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED FROM PHYSICIAN´S OFFICE ON 06-NOV-2014: IT WAS INFORMED THAT THEY WERE NOT ABLE TO FIND A LOT NUMBER FOR ESSURE. THEN, THERE WERE NOT SURE IF THE PROCEDURE WAS DONE BY THEIR OFFICE. NO FURTHER INFORMATION WAS PROVIDED. COMPA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038863		10/24/2014	11/3/2014

Event Information:

Event Date (B3): 8/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/3/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL DEVISE IMPLANTED IN THE SUMMER OF 2012. I HAVE BEEN EXPERIENCING HORRIBLY PAINFUL AND HEAVY PERIODS. MY DOCTOR ORDERED AND ULTRASOUND WHICH SHOWS THE RIGHT SIDE DEVICE HAS SLIPPED DOWN INTO MY UTERUS. I AM AWAITING THE NEXT STEPS MY DOCTOR WANTS TO TAKE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038865		10/24/2014	11/3/2014

Event Information:

Event Date (B3): 4/10/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/10/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) OF 2006. SHORTLY AFTER, I WAS HOSPITALIZED WITH DEBILITATING MIGRAINES AND WAS SENT HOME WITH A PRESCRIPTION. I HAVE HAD CONSTANT NAUSEA, BACK, PELVIC PAINS, SEVERE MENSTRUAL CYCLES, UNABLE TO HAVE INTERCOURSE WITHOUT EXCRUCIATING PAIN, DIZZINESS AND WEIGHT LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038868		10/25/2014	11/3/2014

Event Information:

Event Date (B3): 3/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 3/4/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2010, I HAD A TUBAL AND ALSO HAD THE ESSURE DEVICE PUT IN. THIS WAS PUT IN NOT TO PREVENT PREGNANCIES BUT TO STOP THE HEAVY BLEEDING. IN (B)(6), 2013, I STARTED DEVELOPING SEVERE PAIN IN MY GROIN AND IN MY RIGHT HIP. AFTER NINE LONG MONTHS, SEVERAL MRIS, X-RAYS AND ONE BLADDER DISTENTION IT WAS FINALLY DISCOVERED THAT THE IMPLANTS HAD SLIPPED AND WERE SITTING SIDEWAYS IN MY TUBES. I WAS SCHEDULED FOR SURGERY THE VERY NEXT DAY, AT THAT TIME IT WAS ALSO DISCOVERED I HAD FLUID IN BOTH OF MY TUBES, A CYST AND ENDOMETRIOSIS. THROUGHOUT THE NINE MONTHS THAT IT TOOK FOR ME TO GET DIAGNOSED I WAS UN-RESPONSIVE TO ORAL PAIN MEDS AND FOR THE FIRST TIME I ACTUALLY USED THE #10 TO DESCRIBE MY PAIN. THERE WAS A POINT WERE I WAS UNABLE TO WALK UP A FLIGHT OF STAIRS BECAUSE THE PAIN WAS SO INTENSE AND AT TIMES I HAD ALMOST PASSED OUT FROM PAIN AND NAUSEA. THANK YOU FOR YOUR TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038869		10/25/2014	11/3/2014

Event Information:

Event Date (B3): 2/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2012, MY DOCTOR RECOMMENDED THE ESSURE PERMANENT BIRTH CONTROL IMPLANTS IN LIEU OF THE TUBAL LIGATION I ORIGINALLY ASKED FOR. I CONSENTED TO THE ESSURE IMPLANTS AND HAVE BEEN IN COMPLETE MISERY EVERY SINCE. I HAVE BEEN TO THE HOSPITAL MULTIPLE TIME WITH EXTREME BLEEDING, CRAMPING AND DOUBLED OVER IN PAIN. THEY WERE REMOVED IN (B)(6) ON 2012 BUT THE DAMAGE WAS DONE AND THE PROBLEMS CONTINUED. I AM HAVING A HYSTERECTOMY NEXT MONTH BECAUSE OF THIS PRODUCT. IT IS NOT SAFE AND SHOULD NOT BE AVAILABLE TO ANYONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038898	CONCEPTUS	10/25/2014	11/3/2014

Event Information:

Event Date (B3): 11/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 774387

Single Use:
Implant Date (E6): 1/15/2010
Explant Date (E7): 11/15/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE TUBAL COILS FROM BAYER IN 2010. SOON AFTER I STARTED HAVING SYMPTOMS THAT CHANGED HOW I LIVED MY LIFE. I HAVE VERTIGO, NAUSEA, SHARP PAINS IN MY ABDOMEN TO THE POINT OF DROPPING ME TO MY KNEES, PAIN AND BLEEDING DURING SEXUAL INTERCOURSE, METALLIC TAKE IN MY MOUTH, SEVERE BLOATING, EXTREME FATIGUE...AND PROBABLY SOME OTHER I MAY HAVE LEFT OUT. I WAITED AND EXPLORED POSSIBILITIES WITH MY PHYSICIAN FOR OVER A YEAR BUT BY YEAR 2 I COULDN'T LIVE WITH IT ANYMORE AND WE HAVE EXHAUSTED AL OTHER OPTIONS. MY DOCTOR AGREED TO REMOVE THE ESSURE DEVICE HE HIMSELF PLACED TO ALLEVIATE MY PAIN. THIS OCCURRED IN LATE 2012 AND I COULDN'T BE HAPPIER. ALL OF MY SYMPTOMS ARE GONE. HE SAVED MY LIFE. THESE DEVICES ARE CAUSING HARM TO SO MAY WOMEN AND THEY SHOULDN'T BE ALLOWED TO PROFIT FROM OUR SUFFERING ANY LONGER! PLEASE BAN THESE DEVICES!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038866	BAYER	10/26/2014	11/3/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): B02261

Single Use:
Implant Date (E6): 5/30/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE BIRTH OF MY CHILD IN (B)(6) 2013, I HAD THE ESSURE BIRTH CONTROL IMPLANTS ON (B)(6) 2013. I MADE THIS DECISION BECAUSE I DIDN'T WANT TO HAVE ANYMORE CHILDREN AND DON'T LIKE PILLS. AFTER THE DEVICE THINGS SEEMED OK, I DIDN'T NOTICE ANY SIDE EFFECTS BECAUSE I WAS USING THE DEPO-SHOT FOR THE LAST MONTH. ONCE THE DEPO-SHOT WORE OFF, I DID BEGIN TO HAVE VERY PAINFUL HEAVY MENSTRUAL CYCLES THAT LASTED FOR NEARLY TWO WEEKS. BEFORE 4 DAYS, NO CRAMPS, NO HEAVY BLEEDING AND PAIN MY PELVIC, THIS CONTINUES TO HAPPEN MONTHLY. I WENT TO THE DOCTOR AND HE SAID IT HAD NOTHING TO DO WITH ESSURE IMPLANT. ABOUT A MONTH AGO, I STARTED GETTING PAINFUL HEADACHES PRETTY MUCH NOW THREE TO FOUR TIMES PER WEEK. I NEVER HAD HEADACHES BEFORE. MY WEIGHT GAIN IS DEPRESSING. NO MATTER WHAT I DO THE WEIGHT WON'T COME OFF. I'M VERY DEPRESSED AND ANGRY ALL THE TIME. I NEVER HAD ISSUES LIKE THIS. I ALWAYS WAS HAPPY GO LUCKY PERSON AND FULL OF LIFE. I HAVE RECENTLY WENT DOWNWARD ON MY SEX DRIVE. I FEEL MY LIFE HAS CHANGED FROM A YEAR AGO DRAMATICALLY. THE ONLY THING I HAVE DONE DIFFERENTLY IS HAVE A BABY AND HAVE MY ESSURE IMPLANT. NO ONE KNOWS HOW I OR ANYONE ELSE FEELS INSIDE ONLY ME. I WILL TELL YOU, I REGRET HAVING THIS IMPLANT AND WOULD NOT RECOMMEND IT TO ANYONE. IT HAS PLACED A BURDEN ON MY LIFE AND MY FAMILY. I'M TRULY NOT THE SAME PERSON I USED TO BE. I UNDERSTAND ALL OF THE OTHER COMPLAINTS OUT THERE, SOMEONE NEEDS TO LISTEN AND TAKE INTO CONSIDERATION OF PLACING A RECALL ON THESE IMPLANTS AS THEY HAVE CAUSED ME A LOT OF PAIN AS WELL AS MANY OTHERS. I HAVE THOUGHT ABOUT GOING TO A DOCTOR IN (B)(6) TO HAVE THE COILS REMOVED, NOT BECAUSE I WANT CHILDREN, BUT BECAUSE I WANT MY NORMAL HAPPY LIFE BACK WITHOUT PAIN AND DEPRESSION OF SOME SORT DAILY.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00464	BAYER HEALTHCARE LLC	10/28/2014	10/28/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 664591; 676717

Single Use: Y
Implant Date (E6): 12/10/2009
Explant Date (E7): 7/15/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS INITIALLY RECEIVED FROM A CONSUMER VIA FDA MEDWATCH REPORT: (B)(4) IN UNITED STATES ON (B)(6) 2011 AND LATER CONFIRMED BY A NURSE ON (B)(6) 2011. IT DESCRIBES THE OCCURRENCE OF PREGNANCY WITH CONTRACEPTIVE DEVICE, DEVICE INEFFECTIVE, AND ONE OF THE ESSURE DEVICES IS EMBEDDED IN HER UTERUS IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS UNKNOWN WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2009, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AT TIME OF REPORT THE PATIENT WAS 16 WEEKS AND THREE DAYS PREGNANT. ESTIMATED DUE DATE WAS (B)(6) 2011. ON AN UNSPECIFIED DATE, SHE FOUND OUT SHE WAS PREGNANT AND WAS CARRYING FULL TERM. ONE OF THE ESSURE DEVICES WAS EMBEDDED IN HER UTERUS. HER HSG (HYSTEROSALPINGOGRAPHY) REVEALED THE RIGHT TUBE WASN'T BLOCKED AND HAD A TUBAL LIGATION ON THAT SIDE. ON (B)(6) 2011, PREGNANCY WAS CONFIRMED BY NURSE AT OFFICE PATIENT'S CURRENT DOCTOR. PATIENT WAS ASYMPTOMATIC AND INTENDED TO MAINTAIN PREGNANCY. THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE IS NOT REPORTED. [ADDENDUM: THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO ARGUS ON (B)(6) 2014. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED.] FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM CONSUMER: CONSUMER STATED THAT FOUND OUT SHE WAS PREGNANT AFTER HAVING AN ESSURE. SHE HAD THE ESSURE DONE ON (B)(6) 2009, THEN THE HYSTEROSALPINGOGRAM (HSG) FOLLOWING, IN 2010. THE HSG REPORTED THAT ONE TUBE WAS BLOCKED, THE OTHER WAS OPEN. SHE HAD A TUBAL LIGATION ON THE TUBE THAT WAS FOUND TO BE OPEN BY THE HSG. IN 2011, SHE FOUND OUT THAT WAS PREGNANT WITH AN INTRAUTERINE PREGNANCY. IT WAS THE PHYSICIAN´S BELIEF THAT THIS WAS CAUSED BY FAILURE OF

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THE ESSURE IN THE TUBE THAT WAS REPORTED TO BE CLOSED ON THE HSG TEST RESULTS. LOT NUMBERS PROVIDED: 664591 AND 676717 (EXPLANTED ON (B)(6) 2014). DUE TO REMOVAL OF ESSURE THIS CASE IS NOW CONSIDERED INCIDENT. CONSUMER ASSESSED THE CASE AS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) AND THE EVENT REPORT TYPE AS INJURY, HOWEVER, NO FURTHER INFORMATION WAS PROVIDED ABOUT IT. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). LOT NUMBER 676717: MANUFACTURING DATE: SEP-2009 AND EXPIRATION DATE: SEP-2012. LOT NUMBER 664591 MANUFACTURING DATE: AUG-2009 AND EXPIRATION DATE AUG-2012. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. (B)(4). NO BATCH SIGNAL COULD BE IDENTIFIED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE OF THE ESSURE DEVICES WAS EMBEDDED IN HER UTERUS, ALSO AT HYSTEROSALPINGOGRAM (HSG) THE RIGHT TUBE WASN'T BLOCKED. SHE WAS SUBMITTED TO A TUBAL LIGATION IN THIS SIDE AND LATER HAD A PREGNANCY WITH CONTRACEPTIVE DEVICE (ESSURE); SHE STATED THAT HER PHYSICIAN BELIEF IN A FAILURE OF THE ESSURE IN THE TUBE THAT WAS REPORTED CLOSED ON HSG (LEFT). ALL REPORTED EVENTS ARE LISTED IN ESSURE REFERENCE SAFETY INFORMATION AND WERE CONSIDERED NON-SERIOUS; EXCEPT FOR ONE OF THE ESSURE DEVICES WAS EMBEDDED IN HER UTERUS WHICH WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS PARTICULAR CASE, IT WAS INITIALLY REPORTED AN ESSURE EMBEDMENT IN UTERUS AND RIGHT SIDE TUBAL PATENCY; PATIENT WAS SUBMITTED TO A TUBAL LIGATION IN THIS SIDE, IT WAS UNCLEAR IF THE EMBEDDED DEVICE WAS FROM THE SAME SIDE OF TUBAL PATENCY AND IF EMBEDMENT WAS TREATED; HOWEVER UPON RECEIPT OF NEW INFORMATION AN ESSURE EXPLANT DATE WAS PROVIDED AND PATIENT STATED THAT SHE BECAME PREGNANT AFTER THE RIGHT SIDE TUBAL LIGATION. GIVEN THE ABOVE MENTION INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED EVENTS CANNOT BE EXCLUDED, AND ALTHOUGH IT IS UNCLEAR IF AND HOW ESSURE DEVICES WERE REMOVED, SINCE AN ESSURE EXPLANT DATE WAS PROVIDED THIS CASE WAS CONSIDERED AN INCIDENT UNTIL FURTHER INFORMATION IS OBTAINED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS, THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED (PREGNANCY QUESTIONNAIRE).

Manufacturer Narrative (H10):

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FOLLOW-UP FROM 14-APR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE O

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038795	BAYER	10/28/2014	10/28/2014

Event Information:

Event Date (B3): 10/18/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING THE PROCEDURE DONE, I HAD A GUSH OF GREEN FLUID FROM MY VAGINA. SINCE EVERY MONTH I HAVE HEAVY BLEEDING, SPOTTING IN BETWEEN PERIODS, HEADACHES, PAINFUL JOINTS, INFLAMMATION, BACK PAIN, HAIR LOSS, BRAIN FOG, FATIGUE, AND VAGINAL INFECTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038796	BAYER	10/28/2014	10/28/2014

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5038796 #(B)(4) HYSTERECTOMY REQUIRED (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038797	BAYER	10/28/2014	10/28/2014

Event Information:

Event Date (B3): 9/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM ALLERGIC TO THE NICKEL IN THE COILS FROM THE ESSURE, SO I HAVE AN INFECTION AND THE COILS ARE NOT EVEN WHERE THEY ARE SUPPOSED TO BE.... I HAVE BEEN DIAGNOSED WITH ENDOMETRIOSIS AND I HAVE GOTTEN CYST.. I ENDED UP HAVING TO GET A HYSTERECTOMY AT THE AGE OF (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038798	BAYER	10/28/2014	10/28/2014

Event Information:

Event Date (B3): 1/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, HEAVY IRREGULAR PERIODS 1-3 TIMES A MONTH, DIZZINESS, BLACKING OUT, CHEST PAIN, PALPITATIONS, MUSCLE SPASMS, BACK PAIN, MIGRAINES, SPOTTING BETWEEN PERIODS, MANY EMERGENCY ROOM VISITS, ULTRASOUNDS, BLOOD WORK, BLOOD CLOTS DURING PERIODS, VITAMIN D ISSUES, B12 ISSUES, FATIGUE, INSOMNIA, ABDOMINAL PAIN, DEPRESSION, ANXIETY, PTSD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038799	BAYER	10/28/2014	10/28/2014

Event Information:

Event Date (B3): 8/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD ALL OF THE SYMPTOMS BELOW THAT I CAN ONLY ATTRIBUTE TO THIS DEVICE: HEAVY CONTINUOUS BLEEDING, SPOTTING IN BETWEEN PERIODS AND DURING SEX, PAINFUL SEX, STABBING FEELING ON RIGHT SIDE OF STOMACH, PRONOUNCED STABBING PAIN DURING SEX OR WHEN BENDING, MONTHLY UTI'S, I HAVE PID, BACTERIAL VAGINOSIS, BALL DISCHARGES, FIBER DISCHARGES, LOSS OF LIBIDO, LOSS OF HAIR, SKIN RASHES, INFLAMED LYMPH NODES ALL OVER MY BODY, CONSTANT SKIN ERUPTIONS, ITCHY SKIN, BALDING, FREQUENT URINATIONS, CONSTIPATION, FIBROMYALGIA, FORGETFULNESS, TENDER BREAST, CYSTS ON MY OVARIES, BACK PAIN, HEAVY CRAMPS, YEAST INFECTIONS, SEVERE BLOATING, WEIGHT GAIN, INABILITY TO LOOSE WEIGHT, CONSTANT NAUSEOUSNESS, HEARTBURN, GAS,, FACE PAIN, MOOD SWINGS, PANIC ATTACKS, LOSS OF BALANCE, NUMBNESS ON LEGS, LOTS OF ACNE, SWELLING OF FACE, LEGS, BELLY, IRON AND VITAMIN D DEFICIENCY, MUSCLE SPASMS, AND DRY EYES AND SKIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038800	BAYER	10/28/2014	10/28/2014

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY SIDE AFFECTS STARTED WITH THE ONSET OF TERRIBLE SKIN CONDITION THAT LASTED AND CONTINUED TO GET WORSE FOR ABOUT 1 YR. AT THE SAME TIME I STARTED SUFFERING FROM SEVERE JOINT PAIN HIPS, LEGS, ARMS, SHOULDERS, HAIR LOSS, TERRIBLE MENSTRUAL CRAMPS, EXTREMELY HEAVY BLEEDING, AND TONS OF BLOOD CLOTS FOR 3 OUT OF MY 7 DAY CYCLE. MY PERIODS ARE SO HEAVY THAT I HAVE TO USE EXTRA SUPER TAMPONS AND A NIGHTTIME EXTRA LONG PAD WITH WINGS. NUMBNESS IN BOTH MY HANDS. DIZZINESS, WEIGHT GAIN, BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038801	BAYER	10/28/2014	10/28/2014

Event Information:

Event Date (B3): 9/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS HAVING A NICKEL REACTION CAUSE I DID NOT KNOW I WAS ALLERGIC TO NICKEL. STOMACH PAINS, GALLBLADDER, PANCREAS PROBLEMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038930	CONCEPTUS	10/28/2014	11/6/2014

Event Information:

Event Date (B3): 2/13/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626219

Single Use:
Implant Date (E6): 2/13/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED IN (B)(6) 2008. BEGAN HAVING HEAVY PERIODS, PASSING CLOTS, PROBLEMS WITH ANEMIA, PELVIC PAIN, PAINFUL MENSTRUATION, MIGRAINES, AND FULL BODY ACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038931	BAYER	10/28/2014	11/6/2014

Event Information:

Event Date (B3): 10/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ES305
Catalog # (E4):
Lot #(E4): 794898

Single Use:
Implant Date (E6): 10/17/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6). I HAD THE ESSURE PROCEDURE DONE BACK ON (B)(6) 2011 AND IT FAILED. BOTH MY COILS MIGRATED PRIOR TO MY THREE MONTH HSG TESTING TO CONFIRM IF MY TUBES WERE OCCLUDED OR NOT, THIS WAS (B)(6) 2012. IN (B)(6) 2012, I HAD TO HAVE A TUBAL AND REMOVAL OF THE ESSURE DEVICES SINCE MY BODY REJECTED BOTH. THE DOCTOR TOLD ME HE HAD REMOVED EVERYTHING. AS TIME WENT BY I FOUND OUT IN (B)(6) 2014, THAT HE ACTUALLY DID NOT GET BOTH DEVICES. I STILL HAVE FRAGMENTS AND 1 COIL IN MY PELVIS! SINCE FINDING OUT THAT INFO I HAD TO HAVE TWO MRI'S AND ACCORDING TO THE BOOKLET IT STATES "MRI IS SAFE AS LONG AS THE TESLA IS AT 1.4 OR BELOW!" I FEEL YOU NEED TO KNOW THAT I'M LIVING PROOF THAT MRI IS NOT SAFE IF AN ESSURE COIL OR FRAGMENTS ARE FLOATING IN YOUR PELVIC AREA! I HAVE IMAGING FROM WHEN I FOUND OUT I FIRST HAD METAL STILL INSIDE OF MY PELVIC AREA AND I JUST HAD ANOTHER SET OF IMAGING DONE YESTERDAY, IT CLEARLY SHOWS THE COIL HAS MOVED WHEN YOU COMPARE THE TWO SETS OF IMAGES. THERE NEEDS TO BE ATTENTION BROUGHT ONTO THIS SUBJECT AND THE WORDS NEEDS TO BE CHANGED. THIS IS NOT SAFE AT ALL!

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00465	BAYER HEALTHCARE LLC	10/29/2014	10/29/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013 FOR PERMANENT CONTRACEPTION. IN (B)(6) 2013, THE ESSURE CONFIRMATION TEST WAS DONE AND SHOWED NO SPILLAGE ON EITHER SIDE; LOCATION OF INSERTS NOT GIVEN. ON UNSPECIFIED DATE, THE PATIENT BECAME PREGNANT. IN (B)(6) 2014, IT WAS HER FIRST PRE-NATAL VISIT. SUBSEQUENTLY THE INSERTS WERE LOCATED IN PERITONEAL CAVITY BY BROAD LIGAMENT. PATIENT DECLINED SURGERY. IT WAS REPORTED THAT THE PATIENT WAS NOT HOSPITALIZED FOR PERFORATION BUT SHE WAS FOR THE PREGNANCY (NOS). IT WAS REPORTED THAT THE PHYSICIAN, WHO REPORTED THESE EVENTS, WAS NOT THE PHYSICIAN WHO PERFORMED THE ESSURE PROCEDURE. NO FURTHER INFORMATION WAS REPORTED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED

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STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT AND INSERTS WERE LOCATED IN PERITONEAL CAVITY BY BROAD LIGAMENT. THE EVENT BECAME PREGNANT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION WHILE THE OTHER EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. BOTH EVENTS ARE LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. ALSO, UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, IT WAS NOT REPORTED WHEN THE PATIENT GOT PREGNANT AFTER ESSURE INSERTION. IT WAS ONLY INFORMED THAT IN (B)(6) 2014 SHE HAD HER FIRST PRE-NATAL VISIT AND THEN IT WAS DIAGNOSED THAT THE INSERTS WERE LOCATED IN PERITONEAL CAVITY BY BROAD LIGAMENT. ALTHOUGH TEMPORAL RELATIONSHIP BETWEEN THE ESSURE INSERTION AND THE OCCURRENCE OF THE EVENTS WERE NOT REPORTED, BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. SINCE THE PATIENT WAS HOSPITALIZED FOR THE PREGNANCY, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (NO VALID LOT NUMBER). FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 02-APR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00466	BAYER HEALTHCARE LLC	10/29/2014	10/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 9/30/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. PATIENT COMPLAINED OF ABDOMINAL PAIN AND DEMANDED REMOVAL. ON (B)(6) 2014 THE PHYSICIAN PERFORMED LAPAROTOMY AND REMOVED AND ESSURE DEVICE FROM THE RIGHT SIDE AND A FILSHE CLIP FROM THE LEFT SIDE. NO ESSURE DEVICE WAS ON THE LEFT SIDE. PHYSICIAN STATED THAT THERE WAS NO SIGN OF PERFORATION WITH THE ESSURE DEVICE. IT WAS SUCCESSFULLY REMOVED. PHYSICIAN PERFORMED PARTIAL SALP ON EACH SIDE FOR FUTURE PBC (INTERPRETED AS PERMANENT BIRTH CONTROL). NO OTHER TREATMENT OR ISSUES REPORTED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER US (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR

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FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED ABDOMINAL PAIN AND NO ESSURE DEVICE WAS ON THE LEFT SIDE. ABDOMINAL PAIN AND NO ESSURE DEVICE WAS ON THE LEFT SIDE (INTERPRETED AS DEVICE DISLOCATION) ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE PHYSICIAN STATED THAT THERE WAS NO SIGN OF PERFORATION WITH ESSURE DEVICE. IT WAS NOT REPORTED THE EXACT LOCATION OF LEFT SIDE ESSURE. TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE OCCURRENCE OF THE EVENTS WERE NOT REPORTED. AN ALTERNATE EXPLANATION IS NOT AVAILABLE. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PATIENT UNDERWENT A LAPAROTOMY. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP FROM 08-APR-2015: THE REQUIRED NUMBERS OF FOLLOW UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE O

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00467	BAYER HEALTHCARE LLC	10/29/2014	10/30/2014

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76632

Single Use: Y
Implant Date (E6): 4/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 03-OCT-2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B76632 IMPLANTED FOR CONTRACEPTION ON (B)(6) 2014. IN (B)(6) 2014 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND PER RADIOLOGIST PRESENTED WITH BOTH TUBES OCCLUDED, BUT ONLY 1 MICRO INSERT WAS VISUALIZED. AT THE TIME OF THIS REPORT PATIENT HAS BEEN DIAGNOSED AS POSITIVE PREGNANCY. THE PHYSICIAN WAS NOT SURE IF PREGNANCY WAS ECTOPIC OR INTRAUTERINE AND DID NOT KNOW HOW FAR ALONG PREGNANCY WAS. ESSURE WAS NOT REMOVED. NO FURTHER INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-OCT-2014. (B)(4). FINAL ASSESSMENT: LOT NUMBER B76632 REPORTED IS INVALID. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO VALID BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT.

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IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT AND 1 MICRO INSERT WAS VISUALIZED. PATIENT HAS BEEN DIAGNOSED AS POSITIVE PREGNANCY. THE PHYSICIAN WAS NOT SURE IF PREGNANCY WAS ECTOPIC OR INTRAUTERINE. THE EVENTS OF POSITIVE PREGNANCY, NOT SURE IF PREGNANCY WAS ECTOPIC AND 1 MICRO INSERT WAS VISUALIZED (INTERPRETED AS DEVICE DISLOCATION) ARE SERIOUS DUE TO MEDICAL IMPORTANCE WHILE POSITIVE PREGNANCY, NOT SURE IF PREGNANCY WAS INTRAUTERINE IS NON-SERIOUS. THESE EVENTS ARE LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, IT WAS REPORTED THAT 3 MONTHS AFTER ESSURE INSERTION, A HYSTEROSALPINGOGRAM WAS PERFORMED AND THE RESULT SHOWED BOTH TUBES OCCLUDED. TEMPORAL RELATIONSHIP BETWEEN THE EVENTS AND SUSPECT INSERT IS UNKNOWN. CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED, AND IT WAS THEREFORE CONSIDERED AN INCIDENT. AN INITIAL PTC ANALYSIS WAS DONE BUT THE LOT NUMBER REPORTED AS B76632 WAS INVALID AND THEREFORE A NEW PTC ASSESSMENT WAS REQUIRED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMAL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038906	CONCEPTUS, INC	10/29/2014	11/5/2014

Event Information:

Event Date (B3): 7/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PT HAD AN ESSURE PLACED AT (B)(6) IN (B)(6) 2011. IN (B)(6) 2011, SHE HAD A POSTPROCEDURE HSG CONFIRMING BILATERAL OCCLUSION. SHE HAD SUBSEQUENT SLEEVE GASTRECTOMY AND ABDOMINOPLASTY IN THE FOLLOWING YEARS. IN (B)(6) OF 2014 AT (B)(6) YEAR OLD, SHE FOUND OUT SHE WAS PREGNANT AFTER FEELING FETAL MOVEMENT. SHE WAS FOUND TO BE (B)(6) WEEKS GESTATION - TOO LATE FOR A NONINVASIVE GENETIC SCREENING. SHE MOVED TO (B)(6) AND TRANSFERRED HER CARE TO OUT MILITARY HOSPITAL PRACTICE AT (B)(6) WEEKS GESTATION ON (B)(6) 2014. DIAGNOSIS OR REASON FOR USE: PERMANENT STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038915		10/29/2014	11/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY PROCEDURE DONE IN (B)(6). I HAVE EXPERIENCED PAIN IN BOTH SIDES AND BAD CRAMPING AND BLEEDING FOR OVER THREE MONTHS. RECENTLY, I FOUND OUT THAT MY LEFT COIL IS IN MY UTERUS. (B)(6), I WAS SUPPOSED TO HAVE IT REMOVED, BUT TONIGHT, I FELT THIS FEELING THAT WAS WEIRD. I DECIDED TO CHECK AND THE COIL WAS SURE ENOUGH COMING THROUGH SO I PULLED IT OUT. I AM STILL CURRENTLY IN PAIN AND HAVE NOT SPOKEN TO MY DOCTOR. I WILL DO SO IN THE MORNING. THIS IS DEFINITELY SCARY AND WILL NEVER SUBJECT MY BODY TO ANY PROCEDURE LIKE THIS PAIN. I WISH I WOULD HAVE DONE MY RESEARCH. AND THE F/U PROCEDURE HURTS MORE THAN THE PROCEDURE ITSELF. NEVER AGAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038916		10/29/2014	11/5/2014

Event Information:

Event Date (B3): 2/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED AN ESSURE I BELIEVE IN (B)(6) 2011. I IMMEDIATELY STARTED SWELLING ON MY LEGS, ARMS AND HAD RED ITCHY WELTS MOSTLY IN MY HOT SPOTS, BUT IN GENERAL ALL OVER. I HAVE MASSIVE HEADACHES, JOINT PAIN AND LATELY, SEVERE PAIN IN MY RIGHT SIDE. I CHOSE ANOTHER OPINION THIS DR DID BLOOD TEST AND SAID I WAS HEALTHY AND SHOULD CUT OUT SODIUM. I JUST TURNED (B)(6) AND FEEL PAINFULLY OLD. I SAW THE NEWS AND THIS WAS NEWS TO ME ALL THIS IS FROM ESSURE. AT LEAST I KNOW WHAT'S WRONG AND I'M NOT ALONE, BUT NOW I MIGHT NEED A HYSTERECTOMY TO END THE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038917	BAYER	10/29/2014	11/5/2014

Event Information:

Event Date (B3): 1/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/31/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN THE EARLY PART OF 2011, WHERE TINY SPRINGS ARE INSERTED INTO THE FALLOPIAN TUBES AND SCAR TISSUE IS SUPPOSED TO FORM AROUND THE SPRING, TO PROVIDE A BARRIER PREVENTING PASSING OF EGGS INTO THE UTERUS, AS A FORM OF BIRTH CONTROL. IMMEDIATELY FOLLOWING THE PROCEDURE, IS WHEN THE INFECTIONS STARTED AND CONTINUE ON AN ALMOST CONSTANT BASIS UNTIL THIS VERY DAY. ALMOST 3 YEARS LATER, I'VE BEEN TESTED SEVERAL TIMES FOR VARIOUS SEXUALLY TRANSMITTED DISEASES THAT ALL CAME UP NEGATIVE AND TREATMENT FOR YEAST AND BACTERIAL INFECTIONS HAVE HAD LITTLE TO NO EFFECT. SINCE I'VE HAD THIS PROCEDURE DONE, I HAVE ALSO EXPERIENCED FREQUENT AND DEBILITATING MIGRAINES THAT HAVE LED TO TAKING A LOT OF SICK TIME FROM WORK. MY MENSTRUAL CYCLE HAS BEEN EQUALLY PAINFUL AND DEBILITATING AS THE MIGRAINES, BUT I CAN'T BE SURE WHETHER THAT IS A RESULT OF MY AGE OR THE ESSURE PROCEDURE. I'M EXPERIENCING DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00469	BAYER HEALTHCARE LLC	10/29/2014	11/13/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B02266

Single Use: Y
Implant Date (E6): 10/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER B02266 IMPLANTED ON (B)(6) 2014. IT WAS REPORTED THAT ESSURE COIL BROKE DURING DEPLOYMENT. APPROXIMATELY 4 COILS WERE FLOATING IN UTERINE CAVITY. THE DOCTOR WAS ABLE TO RETRIEVE THEM. BILATERAL PLACEMENT WAS ACHIEVED. THE PATIENT HAD NO INJURY. THE PRODUCT WAS AVAILABLE TO BE SENT BACK. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 14-OCT-2014. NO NEW CLINICAL INFORMATION PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 15-OCT-2014. PATIENT'S DATE OF BIRTH WAS AMENDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE(FALLOPIAN TUBE OCCLUSION INSERT) AND THE COIL BROKE DURING DEPLOYMENT. THE EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE COIL BROKE DURING DEPLOYMENT (MALFUNCTION) AND 4 COILS WERE FLOATING IN UTERINE CAVITY. THE PHYSICIAN WAS ABLE TO REMOVE THEM AND, AFTER THAT, BILATERAL PLACEMENT WAS ACHIEVED. THE PATIENT HAD NO INJURY. CONSIDERING THE NATURE OF THE EVENT, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. SINCE DEVICE BREAKAGE (MALFUNCTION) WAS REPORTED, THE CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. A TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 14-MAY-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00468	BAYER HEALTHCARE LLC	10/29/2014	11/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B02266

Single Use: Y
Implant Date (E6): 10/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 03-OCT-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B02266, IMPLANTED FOR PERMANENT STERILIZATION ON (B)(6)-2014. SHE WAS NOT PREGNANT. IT WAS REPORTED THAT THE PHYSICIAN WENT TO INSERT DEVICE AND HE WENT TO DEPLOY IT, A PORTION OF THE DEVICE BROKE OFF. BROKEN PIECE WAS REMOVED FROM UTERINE CAVITY. THE PHYSICIAN COULD SEE INNER COILS THERE, HE COULD SEE TIP OF COIL AND HE COULD SEE ALL EXCEPT A PORTION OF OUTER COIL. HE CHECKED CATHETER AND THERE WAS NO MICRO-INSERT STILL ATTACHED TO IT. HE SAID THAT ABOUT THREE COILS (THE BROKEN PIECE) WERE EXTRACTED FROM UTERINE CAVITY. PATIENT HAD SUCCESSFUL PLACEMENT ON ONE SIDE. PATIENT WAS COUNSELLED THAT WAS NOT NORMAL AND SHE WAS TOLD TO WAIT TO SEE RESULTS OF HSG TEST. NO TREATMENT WAS REQUIRED. THE PATIENT WAS OK. ESSURE WAS NOT REMOVED. UNIT WAS AVAILABLE FOR RETURN. THE PHYSICIAN HANDED BROKEN PIECE OF COIL IN A BIOHAZARDOUS BAG. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 22-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: LOT B02266. PRODUCTION DATE: FEB-2013. EXPIRATION DATE 29-FEB-2016. WHEN A TERM LIKE "A PORTION OF THE DEVICE BROKE OFF..." IS USED WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE OF THE EVENT FROM THE COMPLAINT DESCRIPTION ALONE OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS

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PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF THE OUTER COILS OF THE MICRO-INSERT PARTIALLY DEPLOY DURING USER ATTEMPTS TO REPOSITIONING THE DEVICE AND THE COIL CATHETER IS NOT FULLY RETRACTED, THE OUTER COILS OF THE MICROINSERT COULD BECOME ENTANGLED WITHIN THE DISTAL PORTION OF THE COIL CATHETER. IF THE OUTER COILS ARE PARTIALLY DEPLOYED, THE INSERT WILL BEGIN TO ANCHOR ITSELF TO THE FALLOPIAN TUBE. IF THE INNER COIL IS STILL AFFIXED TO THE DELIVERY WIRE BECAUSE ALL IFU STEPS HAVE NOT YET BEEN COMPLETED, SUBSEQUENT ATTEMPTS BY THE USER TO REMOVE THE CATHETER ASSEMBLY MAY LEAD TO EITHER A STRETCHING OF THE MICRO-INSERT, STRETCHING OF THE INNER CATHETER LARGE TIGHT PITCH COIL, OR BREAKAGE OF THE LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 10/13/2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE PHYSICIAN WENT TO DEPLOY IT, A PORTION OF THE DEVICE BROKE OFF. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED FOR ESSURE ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION. PHYSICIAN STATED THAT THREE COILS (THE BROKEN PIECE) WERE EXTRACTED FROM UTERINE CAVITY AND PATIENT HAD SUCCESSFUL PLACEMENT ON ONE SIDE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE (MALFUNCTION), AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP FROM (B)(6) 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038940	CONCEPTUS, INC.	10/30/2014	11/6/2014

Event Information:

Event Date (B3): 10/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/29/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE ON (B)(6) 2014. I HAD MY CONFORMATION TEST THIS MORNING FOR THE ESSURE AND MY LEFT FALLOPIAN TUBE WAS PERFORATED AND THE ESSURE DEVICE IS NOT IN THE FALLOPIAN TUBE IT IS IN THE PELVIC AREA. I AM SCHEDULED TO HAVE LAPAROSCOPIC SURGERY TO HAVE THE COIL REMOVED AND MAKE SURE THERE IS NO OTHER DAMAGE IN THE PELVIC AREA AND TO REMOVE THE PERFORATED TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038963	BAYER	10/31/2014	11/7/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTS. HORRIBLE PAIN, CRAMPS. METAL DEVICE IN WOMEN'S TUBES SHOULD NOT BE ALLOWED. WE ARE SUFFERING. SUFFERING HORRIBLY. NO ONE SEEMS TO BE A BIT CONCERNED ABOUT THIS. I JUST CAN'T BELIEVE THE FDA DOESN'T CARE ABOUT HUMAN BEINGS AND THEIR QUALITY OF LIFE. IT'S PRETTY SAD WHEN YOU CAN'T EVEN TRUST YOUR FDA. NEEDLESS TO SAY NO ONE CARES ABOUT WHAT THIS PRODUCT IS DOING. ALL THE SUFFERING. WE LIVE HERE IN THE UNITED STATES. WE'RE SUPPOSED TO HAVE SOME KIND OF HUMANE FDA BUT THIS SEEMS NOT TO EXIST ANYMORE IN THIS COUNTRY. UNBELIEVABLE UNACCEPTABLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039005	CONCEPTUS INC	11/4/2014	11/17/2014

Event Information:

Event Date (B3): 11/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/4/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE PROCEDURE I HAD SWELLING, MUSCLE WEAKNESS, TINGLING IN FACE, ARMS, LEGS, HIP PAIN, MULTIPLE BURSITIS, FOGGINESS, HEADACHES, DIZZY SPELLS, UNEXPLAINED RASH THAT COMES AND GOES, IRREGULAR PERIODS CAUSING BLOOD CLOTS. I HAVE UNDERGONE MULTIPLE TESTING TO RULE OUT CERTAIN DISEASE THAT WOULD CAUSE MY SYMPTOMS ALL HAVE COME BACK NEGATIVE THE LAST TESTING I HAD WAS FOR NICKEL ALLERGY WHICH CAME BACK POSITIVE BECAUSE OF THIS I WILL HAVE TO HAVE A HYSTERECTOMY TO REMOVE THE COILS. THIS HAS EFFECT ME BY NOT BEING ABLE TO WORK FULL TIME. I AM IN CONSTANT PAIN AND ALWAYS TIRED. INSTEAD OF FEELING LIKE (B)(6) I FEEL LIKE 70. I HOPE SOMETHING IS DONE ABOUT ESSURE SOON TO PREVENT OTHER WOMEN FORM HAVING THE SAME COMPLICATIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039006	CONCEPTUS INC	11/4/2014	11/17/2014

Event Information:

Event Date (B3): 3/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/31/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2010 IS WHEN I GOT THE PROCEDURE DONE FOR ESSURE. THE OBGYN SPECIALIST WHO PLACED IT DID INFORM ME THAT THIS WAS A NEW EQUIPMENT AND I WAS HIS FIRST PT TO GET THIS PROCEDURE DONE. SINCE THEN THROUGH OUT THE YEARS. I HAVE BEEN GOING FROM DIFFERENT DOCTORS EXPLAINING MY ISSUES. SINCE THE PROCEDURE WAS DONE IN (B)(6) NO ONE IN (B)(6) KNOWS WHAT ESSURE IS. THEY ARE NOT TRAINED ON THIS PRODUCT AND HAVE BEEN JUST REFERRING ME OR PROMISING TO DO MORE RESEARCH. I HAVE BEEN TO A TOTAL OF 6 DIFFERENT DOCTORS. I FINALLY FOUND ONE WHO IS TRYING TO DO MORE ABOUT IT. FINALLY GOT A ULTRA SOUND. NOT SURE OF WHAT IT IS THAT IS GOING ON, BUT SINCE THIS ITEM WAS INJECTED INTO ME I HAVE BEEN HAVING ABNORMAL MENSTRUAL CYCLES, LOWER ABNORMAL PAIN, BACK PAIN, SMELL TASTE METAL AND HEAR A RINGING NOISE IN MY EARS. I HAVE MIGRAINES. MY TASTE BUDS HAS DECREASED. WHEN I HAVE INTERCOURSE I FEEL THE DISCOMFORT. I WANT THIS OBJECT OUT FROM ME. BUT BECAUSE ITS CONSIDERED A TUBAL LIGATION MY INSURANCE DOESN'T COVER IT. I'M SORRY I DON'T HAVE (B)(6) TO COVER THE COST OF THE PROCEDURES. I AM OK WITH NOT HAVING ANY MORE KIDS. I HAVE FOUR BUT I AM NOT OK WITH HAVING TO DEAL WITH THIS PAIN, I SHOULDN'T HAVE TO STOP ENJOYING MY LIFE WITH MY FAMILY BECAUSE OF THIS PROCEDURE. I WANT HELP AND DON'T KNOW HOW TO. I HAVE CALLED ESSURE AND FILED A REPORT, BUT THAT WAS IT...NO SUGGESTION, NO ANSWERS, NO POINT. IT WAS A WASTE OF TIME. SO IF ANYONE KNOWS ANYTHING I CAN DO TO GET THIS "PROFANITY" OUT OF ME PLEASE HELP. THANK YOU.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039007	CONCEPTUS, INC	11/4/2014	11/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/10/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS IN 2012. EVER SINCE I'VE HAD IT DOWN I'VE HAD NOTHING BUT PROBLEMS. HIP PAIN, NAUSEA, LOWER BACK PAIN, VERY HEAVY PERIODS THAT SOMETIMES LAST 10 DAYS. NOW IM AN ANEMIC. I ALSO MAY HAVE SJOGRENS SYNDROME. THE LIST GOES ON. I HAVE NOT FELT THE SAME EVER SINCE I HAVE RECEIVED THESE IMPLANTS. I'VE BEEN SEEING A RHEUMATOLOGIST SINCE 2013.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00470	BAYER HEALTHCARE LLC	11/4/2014	11/20/2014

Event Information:

Event Date (B3): 8/25/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06467

Single Use: Y
Implant Date (E6): 8/25/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN UNITED STATES ON 06-OCT-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER CD6467, INSERTION ON (B)(6)-2014. DURING INSERTION ATTEMPT, THE DOCTOR WAS UNABLE TO ADVANCE THE COIL TO THE PROPER LENGTH. THE DOCTOR WAS INSTRUCTED BY THE SALES REP ON WHAT TO DO. AFTER REALIZING THAT THE DEVICE WAS NOT GOING TO BE IN THE RIGHT POSITION, THE DOCTOR WAS INSTRUCTED TO REMOVE THE DEVICE BY UNCOILING IT. AFTER SEVERAL ATTEMPTS, THE DEVICE WOULD NOT RELEASE AND HAD TO BE CUT OUT. THE DOCTOR WAS UNABLE TO REMOVE THE TIP OF THE DEVICE WHICH WAS LEFT IN THE PATIENT. THERE WAS NO HARM TO THE PATIENT. IN ADDITION IT WAS REPORTED THAT THE ORIGINAL INTENDED PROCEDURE WAS A HYSTEROSCOPIC VAGINAL TUBAL OCCLUSION. HOWEVER, ACCORDING TO REPORTER, THERE WAS A DEVICE MALFUNCTION SINCE THE DEVICE DID NOT DO WHAT IT WAS SUPPOSED TO DO. THE SERIOUSNESS CRITERIA OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) WAS REPORTED BUT IT WAS NOT SPECIFIED FOR WHICH EVENT. CORRECTION (10-OCT-2014) FOLLOWING COMPANY INTERNAL REVIEW: THE CORRECT LOT NUMBER IS C06467 AND NOT CD6467. PTC INVESTIGATION RESULT WAS RECEIVED ON 23-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: AS OF 10/13/2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER

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REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH C06467 (PRODUCTION DATE 17-DEC-2013 AND EXPIRATION DATE 31-DEC-2016) WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING INSERTION ATTEMPT, THE DOCTOR WAS UNABLE TO REMOVE THE TIP OF THE DEVICE WHICH WAS LEFT IN THE PATIENT (CONSIDERED AS DEVICE REMOVAL FAILED). DURING INSERTION THE DOCTOR WAS UNABLE TO ADVANCE THE COIL TO THE PROPER LENGTH / THE DEVICE WOULD NOT RELEASE (CONSIDERED AS DEVICE DEPLOYMENT ISSUE) AND THE DEVICE HAD TO BE CUT OUT (CONSIDERED AS DEVICE MISUSE). ALL THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. THE SERIOUSNESS CRITERIA OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) WAS REPORTED BUT IT WAS NOT SPECIFIED FOR WHICH EVENT. IN THIS PARTICULAR CASE, THERE WAS NO HARM TO THE PATIENT. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS DEVICE REMOVAL FAILED AND DEVICE DEPLOYMENT ISSUE AND SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE EVENT DEVICE MISUSE, AS THE PHYSICIAN TRIMMED THE TRAILING COILS OF ESSURE MICRO-INSERT WITH SCISSORS, A CAUSAL RELATIONSHIP CAN BE EXCLUDED WITH THE SUSPECT INSERT. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00471	BAYER HEALTHCARE LLC	11/5/2014	11/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. REPORTER STATED THAT A PATIENT'S LEFT COIL WAS REMOVED BUT THE RIGHT COIL COULD NOT BE FOUND BY HEALTHCARE PROFESSIONAL. STATED THAT IT COULD NOT BE DETECTED VIA ULTRASOUND BUT WAS DETECTED VIA CT SCAN. REFUSED INTERVIEW AND FOLLOW UP. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT

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WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD LEFT COIL REMOVED BUT THE RIGHT COIL COULD NOT BE FOUND, IT COULD NOT BE DETECTED VIA ULTRASOUND BUT WAS DETECTED VIA CT SCAN. THE REPORTED EVENT RIGHT COIL COULD NOT BE FOUND, IT COULD NOT BE DETECTED VIA ULTRASOUND BUT WAS DETECTED VIA CT SCAN WAS CONSIDERED AS SUSPICION OF DEVICE MIGRATION. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. SOMETIMES MIGRATION THROUGH THE FALLOPIAN TUBE IS SUSPECTED, BECAUSE THE ESSURE INSERT IS FOUND IN THE ABDOMEN AND NO APPARENT PERFORATION CAN BE IDENTIFIED. IN THIS CASE, IT WAS UNKNOWN THE EXACT LOCATION OF RIGHT COIL. IT WAS NOT REPORTED THE REASON WHY THE LEFT COIL WAS REMOVED. ALSO, THE EXACT DAY OF LEFT COIL REMOVAL AND THE TYPE OF SURGERY WERE UNKNOWN. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. ALTHOUGH THE REASON FOR REMOVAL OF LEFT COIL WAS NOT REPORTED, THIS CASE WAS REGARDED AS INCIDENT. ACCORDING TO PRODUCT TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE REPORTER REFUSED INTERVIEW. NO FURTHER INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00473	BAYER HEALTHCARE LLC	11/5/2014	11/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND COMPLAINED OF PAIN AND IT WAS DETERMINED SHE PROBABLY HAD NICKEL SENSITIVITY. THE ESSURE WAS LAPAROSCOPICALLY REMOVED. THE PHYSICIAN DID NOT HAVE FURTHER INFORMATION. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND

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COMPLAINED OF PAIN. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS REPORTED THE PATIENT PROBABLY HAD NICKEL SENSITIVITY AND ESSURE WAS LAPAROSCOPICALLY REMOVED. GIVEN THE AVAILABLE INFORMATION, THE EVENT IS ASSESSED AS RELATED TO ESSURE USE. SINCE AN INTERVENTION WAS PERFORMED (LAPAROSCOPY), THE CASE IS REGARDED AS INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 12-MAR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSUR

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5038983	CONCEPTUS	11/5/2014	11/10/2014

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/18/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT REPORTS SIDE EFFECTS FROM ESSURE THREE MONTHS AFTER IMPLANT. PT HAS NICKEL ALLERGY AND HER PHYSICIAN FAILED TO DISCLOSE INFORMATION REGARDING NICKEL IN DEVICE. PT HAS SEVERE RIGHT SIDED PAIN IN ABDOMINAL REGION. THIS PAIN KEEPS PT IN BED FOR DAYS. PT FURTHER REPORTS NAUSEA, PAINFUL SEXUAL INTERCOURSE, HEADACHES, JOINT ACHES, BLOATING, INTERMENSTRUAL BLEEDING, HEAVIER MENSES WITH CLOTS AS BIG AS A COIN AND MUSCLE SPASMS THAT LAST FOR DAYS. THE SPASMS ARE FELT ALL OVER PATIENT'S BODY AND IT BEGAN (B)(6) 2013 AND IT KEEPS GETTING WORSE AND WORSE. LASTLY, PT HAD ULTRA SOUND DONE (B)(6) 2014 WHICH SHOWED HER FALLOPIAN TUBES ARE SAGGING DOWNWARDS. PT WANTS DEVICE EXPLANTED AND HAS AN UPCOMING APPOINTMENT ON (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039001		11/5/2014	11/17/2014

Event Information:

Event Date (B3): 1/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 761616/774372

Single Use:
Implant Date (E6): 1/3/2011
Explant Date (E7): 5/9/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE AND STARTING EXPERIENCING HORRIBLE ABDOMINAL PAINS, AFTER A COUPLE MONTHS. I HAD GONE BACK IN TO SEE MY OB/GYN AND THE IMPLANTS HAD ACTUALLY MIGRATED AND I NEEDED TO HAVE SURGERY TO REMOVE THEM AND MY TUBES REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039003		11/5/2014	11/17/2014

Event Information:

Event Date (B3): 7/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE TUBAL LIGATION
Device Type (E2): ESSURE TUBAL LIGATION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/10/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS A HEALTHY MOTHER OF FOUR, WHO DECIDED TO 'TIE MY TUBES'. IN (B)(6) 2014, I DECIDED TO GET THE ESSURE IMPLANT PROCEDURE DONE. IN (B)(6) IT WAS TIME TO DO THREE MONTH CHECK UP, I WASN'T ABLE TO DO THE XRAY FOR I HAD PULLED BY BACK AND HAD TWO DISCS BULGED AND WAS ON BED REST. ON (B)(6) I WENT IN TO MY O.B. FOR A CONCERN OF WHICH MY MENSTRUATION DID NOT COME FOR (B)(6), THERE I FOUND OUT I WAS PREGNANT. I THEN WAS UPSET AND CONCERNED THAT FOLLOWING TUESDAY I STARTED BLEEDING UNCONTROLLABLY AND WAS ADMITTED TO THE E.R. WHERE I FOUND OUT I WAS HAVING A MISCARRIAGE. THEY DID ULTRASOUND AND CONFIRMED THAT MY RIGHT TUBAL WAS SEALED IN, YET MY LEFT SIDE WAS NOT. THEY COULDN'T FIND THE COIL IN MY PLACE, OR MY CERVIX, TUBES OR ANYWHERE. I HAVE BEEN, SINCE THE PROCEDURE, EXPERIENCING SEVERE CRAMPING WITH NO MENSTRUATION, LOWER BACK PAIN, HAIR LOSS, PELVIC PAIN, OVARY PAIN. MIGRAINES, INCREASE OF WEIGHT, BLURRED VISION, DRY MOUTH WITH METALLIC TASTE, MOOD SWINGS THAT ARE UNEXPLAINABLE. I HAVE ALSO BEEN HAVING ACNE FLARE UP, BOTH MY LEGS GO NUMB WITHOUT MOVEMENT OR CAUSE. I HAVE BEEN VERY DISTRAUGHT SINCE THE MISCARRIAGE. I'M CONCERNED ABOUT THE MISSING COIL. I WAS ALSO AT RISK OF ECTOPIC PREGNANCY HENCE I HAD A TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039004	BAYER	11/5/2014	11/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE - SEVERE CRAMPING, HEAVY PERIODS, BACK PAIN, JOINT PAIN, URINATION PROBLEMS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00472	BAYER HEALTHCARE LLC	11/5/2014	11/20/2014

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 09-OCT-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND THE DEVICE BROKE AT ITS EXTREMITY, DIFFICULTY ON PLACEMENT. THE EVENT OCCURRED ON THE WEEK BEFORE THIS REPORT. IT WAS REPORTED THAT THE EVENT WAS MEDICALLY SIGNIFICANT AS HOSPITALIZATION WAS REQUIRED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 04-NOV-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO PRODUCT QUALITY ISSUE AND USABILITY ISSUE. (B)(4). FINAL ASSESSMENT: WHEN THE COMPLAINT NARRATIVE STATES ...THE DEVICE BROKE AT ITS EXTREMITY... WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE AND CAUSE OF THE EVENT UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO

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BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. ACCORDING TO THE DFMEA, THE MOST LIKELY CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND THE DEVICE BROKE AT ITS EXTREMITY. THE EVENT, INTERPRETED AS DEVICE BREAKAGE (MALFUNCTION), IS SERIOUS DUE TO HOSPITALIZATION. INITIALLY IT WAS CONSIDERED UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION; HOWEVER UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) IT WAS AMENDED TO LISTED, SINCE PTC ANALYSIS CONCLUDED THAT THE BREAKAGE IS AN ANTICIPATED EVENT. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, VERY LIMITED INFORMATION WAS PROVIDED. IT WAS ONLY INFORMED THAT DEVICE BROKE AT ITS EXTREMITY AND THERE WAS DIFFICULTY ON PLACEMENT. GIVEN THE NATURE OF THE EVENT, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. HOSPITALIZATION WAS REPORTED, SO THE CASE IS REGARDED AS INCIDENT. THE PERFORMED PTC ANALYSIS CONCLUDED TO UNCONFIRMED QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 08-JAN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00474	BAYER HEALTHCARE LLC	11/6/2014	11/6/2014

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/26/2009
Explant Date (E7): 6/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (B)(4) IN UNITED STATES ON 10-OCT-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2009. IT WAS REPORTED THAT FROM THE MOMENT SHE WOKE UP AFTER SURGERY SHE WAS IN PAIN. HER PELVIC/ABDOMINAL PAIN GREW WORSE AND WORSE. ON (B)(6) 2014, SHE UNDERWENT A HYSTERECTOMY AND HAD BOTH FALLOPIAN TUBES THAT CONTAINED THE ESSURE COILS REMOVED. SHE HAD HORRIBLE PELVIC PAIN, ABDOMINAL CRAMPING, PAIN IN HER UPPER THIGHS, BACK PAIN, AND WEIGHT GAIN. PTC INVESTIGATION RESULT WAS RECEIVED ON 28-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY

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CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PELVIC PAIN AND ABDOMINAL PAIN / CRAMPING. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. PELVIC PAIN/ABDOMINAL CRAMPING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS PARTICULAR CASE, THE CONSUMER EXPERIENCED THESE EVENTS FROM THE MOMENT SHE WOKE UP AFTER ESSURE INSERTION. AN ALTERNATE EXPLANATION IS NOT AVAILABLE. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A HYSTERECTOMY WAS PERFORMED AND THE CONSUMER HAD BOTH FALLOPIAN TUBES REMOVED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: PAIN IN UPPER THIGHS, BACK PAIN AND WEIGHT GAIN. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS (WITH LOT NUMBER) ARE BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-MAR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00475	BAYER HEALTHCARE LLC	11/6/2014	11/6/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/30/2009
Explant Date (E7): 7/23/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. ACCORDING TO THE CONSUMER IN 2010 SHE STARTED HAVING SYMPTOMS THAT INCLUDED DAILY FATIGUE, A SEVERE MENSTRUAL CRAMPING, VOMITING, HIP PAIN, LEG PAIN, JOINT PAIN ON A DAILY BASES. VOMITING WAS A FEW TIMES A MONTH DURING HER CYCLE. PAIN WOULD BE SEVERE TO POINT OF NOT BEING ABLE TO CONTINUE REGULAR DAILY ACTIVITIES. SHE COULD NO LONGER RUN, EXERCISE, OR PRACTICE YOGA. WHEN SHE SNEEZED OR COUGHED, THE INTERNAL PAIN IN HER LOWER ABDOMEN WAS EXCRUCIATING. ON AN UNSPECIFIED DATE, BLOOD TEST WAS DONE AND SHOWED THAT SHE BECOME ANEMIC CAUSING HER TO BE COLD, SHAKY AND EASILY BRUISED. ON (B)(6) 2014, SHE HAD LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY TO REMOVE UTERUS AND FALLOPIAN TUBES TO ENSURE THAT COILS WERE REMOVED AND THERE WOULD BE NO FUTURE PROBLEMS. SHE ALSO HAD CHRONIC INFLAMMATION OF THE UTERUS AND FALLOPIAN TUBES AND LIVER ADHESIONS, AS WELL. TWO DAYS POST OPERATION, HER LEG, HIP AND JOINT PAIN WERE ALREADY GONE AND SHE WAS NO LONGER FATIGUED. EVEN THOUGH, SHE WAS IN PAIN FROM THE SURGERY. SHE STATED THAT SHE ALREADY FELT 10 TIMES BETTER THAN BEFORE HER SURGERY. AN INJURY (SERIOUS IMPORTANT MEDICAL EVENTS) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON 28-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER US (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT

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THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED FATIGUE, LEG PAIN AND JOINT PAIN ON A DAILY BASIS/HIP PAIN. SHE WAS SUBMITTED TO HYSTERECTOMY AND SALPINGECTOMY AND RECOVERED FROM THESE EVENTS. SHE ALSO REPORTED CHRONIC INFLAMMATION OF THE UTERUS AND FALLOPIAN TUBES. ALL ABOVE MENTION EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; EXCEPT FOR LEG PAIN AND CHRONIC INFLAMMATION OF THE FALLOPIAN TUBES WHICH ARE LISTED. ALTHOUGH ESSURE HAS A LOCAL ACTION AT FALLOPIAN TUBES, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE; THE EVENTS FATIGUE, LEG PAIN AND JOINT PAIN ON A DAILY BASIS/HIP PAIN WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. THE SAME CAUSALITY ASSESSMENT IS GIVEN FOR CHRONIC INFLAMMATION OF THE UTERUS AND FALLOPIAN TUBES SINCE A CONTRIBUTORY ROLE OF ESSURE IN ITS OCCURRENCE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION FOR ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. A PRODUCT TECHNICAL ANALYSIS (WITH LOT NUMBER) AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 26-JAN-2015. THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUME

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00476	BAYER HEALTHCARE LLC	11/6/2014	11/6/2014

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2012
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED IN (B)(6) 2012 FOR PERMANENT CONTRACEPTION. IT WAS REPORTED THAT SHE BLED EVERY DAY AFTER PLACEMENT, AND EXPERIENCED CRAMPS. IN THE BEGINNING OF (B)(6) 2012 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED LEFT COIL STILL PATENT. SHE WENT BACK IN (B)(6) 2012 AND LEFT TUBE WAS STILL OPEN AND WAS STILL BLEEDING. SHE WAS TAKING BIRTH CONTROL PILL TO STOP BLEEDING. IN (B)(6) 2013 SHE HAD REGULAR TUBAL LIGATION AND ABLATION TO STOP BLEEDING WHICH WAS SUCCESSFUL BUT STILL HAD A LOT OF PAIN AND LEFT COIL WAS FOUND MISSING. IN (B)(6) 2013 BILATERAL SALPINGECTOMY WITH RIGHT COIL REMOVAL WAS DONE BUT LEFT COIL WAS STILL MISSING. IN (B)(6) 2014 SHE UNDERWENT A HYSTERECTOMY AND LEFT COIL WAS FOUND AND WAS REMOVED WITH UTERUS. THE SYMPTOMS SUBSIDED SINCE HYSTERECTOMY. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 28-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A LACK OF EFFICACY (PATENCY). A LACK

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OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLED EVERY DAY AFTER PLACEMENT, AS TREATMENT SHE WAS SUBMITTED TO ABLATION AND TUBAL LIGATION AND LEFT COIL WAS FOUND MISSING. SHE ALSO REPORTED PAIN, WHICH PERSISTED AFTER THE ABOVE MENTION PROCEDURE, THEN SALPINGECTOMY AND HYSTERECTOMY WERE PERFORMED, LEFT COIL WAS FOUND AND REMOVED AND SHE RECOVERED. THE REPORTED EVENTS, INTERPRETED AS GENITAL BLEEDING, ESSURE DISLOCATION AND UNSPECIFIED PAIN, WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALSO ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. GIVEN THIS INFORMATION AND CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED INTERVENTIONS. OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 07-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00477	BAYER HEALTHCARE LLC	11/6/2014	11/6/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/9/2009
Explant Date (E7): 5/22/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2009. IT WAS AN IN-OFFICE VISIT WITHOUT GENERAL ANESTHESIA. SHE WAS NEVER GIVEN AN IDENTIFICATION CARD WITH INFORMATION ON IT REGARDING THE COILS THAT WERE IMPLANTED SO SHE DID NOT HAVE SERIAL OR LOT NUMBER OR ANYTHING. IN 2009 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED ONE COIL IN PLACE BUT NOT WORKING. THE LOCATION OF THE OTHER COIL COULD NOT FULLY BE DETERMINED. ANOTHER HSG WAS DONE IN 2009 WITH BASICALLY THE SAME RESULTS. SHE HAD TO CHOOSE A DIFFERENT METHOD OF BIRTH CONTROL AFTER SHE'D GONE THROUGH THE INSERTION OF ESSURE. ABDOMINAL PAIN WAS ABUNDANT BUT TESTS REVEALED NO CAUSE. SHE HAD ABDOMINAL ULTRASOUND AND CT SCAN. IN 2010 AN ENDOSCOPY WAS PERFORMED. LATER THAT YEAR SHE DEVELOPED EXTREME FATIGUE, JOINT PAIN, MUSCLE WEAKNESS AND PAIN, SWOLLEN FEET, SWOLLEN ANKLES, DRY EYES, DRY MOUTH, AND A RECURRING EYE RASH. HER LIFE ENDED AS SHE KNEW IT AND MOST DAYS SHE COULDN'T DRAG HERSELF OFF THE COUCH FOR ALL THE PAIN SHE WAS IN AND THE CRUSHING FATIGUE SHE FELT. SHE WAS UNABLE TO CARE FOR HER CHILDREN. UNABLE TO WORK/VOLUNTEER/PARTICIPATE IN ANY OF THE ACTIVITIES SHE WAS USED TO DOING. PRIOR TO THE ESSURE INSERTION SHE WAS VERY HEALTHY, VERY ACTIVE PERSON. IN 2011 SHE SAW A RHEUMATOLOGIST. SHE HAD BEEN BLEEDING RECTALLY FOR A COUPLE MONTHS SO HAD A COLONOSCOPY THAT REVEALED INTERNAL HEMORRHOIDS. IT SEEMED HER ENTIRE BODY WAS INFLAMED. SHE STARTED PLAQUENIL FOR TREATMENT OF THE AUTOIMMUNE DISEASE SJOGREN'S. IN 2012 SHE HAD ANOTHER ENDOSCOPY FOR SEVERE ACID SYMPTOMS. THE ONLY ABNORMALITY IN ANY OF THOSE TESTS AND PROCEDURES WAS A SLIGHTLY ELEVATED ANA AND HER INTERNAL HEMORRHOIDS.

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OTHERWISE, HER BLOOD WORK AND TEST REVEALED THAT SHE WAS THE PICTURE OF HEALTH, BUT SHE WAS NOT. IN 2014 HER BACK-UP BIRTH CONTROL WAS REMOVED SO A THIRD AND FINAL HSG TEST WAS DONE TO DETERMINE THE POSITION OF THE ESSURE AFTER 5 YEARS. ONE COIL WAS STILL IN PLACE, BUT STILL NOT WORKING. THE OTHER COIL WAS EMBEDDED IN HER UTERUS. ON (B)(6) 2014 SHE UNDERWENT A HYSTERECTOMY AS THAT WAS THE ONLY SAFE WAY TO REMOVE THE ESSURE IMPLANTS FROM HER BODY. NINE WEEKS POST OPERATION HER SYMPTOMS WERE 90 PERCENT RESOLVED. SHE WAS WEANING OFF THE SJÖGREN'S MEDS TO SEE HOW SHE DO. ALL OF HER ABDOMINAL PAIN/DISCOMFORT FROM THE ESSURE WAS RESOLVED AND MOST OF HER SJOGREN'S SYMPTOMS WERE RESOLVED. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND 5 YEARS AFTER ESSURE INSERTION A FINAL HSG TEST WAS PERFORMED AND THE RESULT SHOWED ONE COIL WAS STILL IN PLACE, BUT STILL NOT WORKING (DEVICE INEFFECTIVE) AND THE OTHER COIL WAS EMBEDDED IN HER UTERUS (SPLIT IN EMBEDDED DEVICE AND PARTIAL EXPULSION OF DEVICE). SHE ALSO EXPERIENCED ABUNDANT ABDOMINAL PAIN, EXTREME FATIGUE/CRUSHING FATIGUE, JOINT PAIN, MUSCLE PAIN. SHE STARTED PLAQUENIL FOR TREATMENT OF THE AUTOIMMUNE DISEASE SJOGREN'S. THE EVENT OTHER COIL WAS EMBEDDED IN HER UTERUS (CONSIDERED AS EMBEDDED DEVICE) AND ABUNDANT ABDOMINAL PAIN WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. THE REMAINING EVENTS ARE ALSO SERIOUS (SINCE IT WAS REPORTED THAT SHE WAS UNABLE TO WORK/VOLUNTEER/PARTICIPATE IN ANY OF THE ACTIVITIES SHE WAS USED TO DOING) AND ARE UNLISTED EVENTS. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DEVICE EMBEDDED WAS NOT KNOWN. IT WAS REPORTED THAT AFTER ESSURE REMOVAL, SHE RECOVERED FROM ABDOMINAL PAIN/DISCOMFORT (DECHALLENGE POSITIVE). BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP WITH ESSURE THERAPY AND THE REPORTED EVENTS CANNOT BE EXCLUDED. WITH REGARDS THE EVENT AUTOIMMUNE DISEASE SJOGREN'S, GIVEN ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE CONSUMER UNDERWENT HYSTERECTOMY AND ESSURE WERE REMOVED. OTHER NON-SERIOUS EVENTS WERE ADDED. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. FURTHER INFORMATION (PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 28-JAN-2015: NO NEW INFORMATION WAS OBTAINED DESPITE FOLLOW-UP ATTEMPTS. NO FURTHER DETAILS FROM THE REPORTER ARE EXPECTED FOR THIS CASE REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039054	BAYER	11/6/2014	11/18/2014

Event Information:

Event Date (B3): 11/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2003
Explant Date (E7): 11/5/2014
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE COILS INTO MY FALLOPIAN TUBES IN 2003 VIA AN OBGYN IN A HOSPITAL TO PREVENT FUTURE PREGNANCY DUE TO NOT WANTING ANY MORE KIDS. AFTER 3 MONTHS I WAS ASSURED COILS WERE IN PLACE AND THAT I SHOULD HAVE NO COMPLICATIONS, NO NEGATIVE FEEDBACK OR PROBLEMS HAD BEEN REPORTED PER THE DOCTOR AT THAT TIME. I WAS (B)(6)WHEN I GOT THE ESSURE. OVER 9 YEARS I EXPERIENCED CRAMPS, ACNE, HEAVY PROLONGED PERIODS FOR AS LONG AS FOUR MONTHS ONGOING, WEIGHT GAIN, AND RASHES. IN (B)(6) 2014 SYMPTOMS GOT WORSE. I STARTED HAVING HIGH ANXIETY AND PANIC ATTACKS ALONG WITH PROLONGED PERIODS. I WENT TO A NEW OBGYN SINCE THE ONE THAT INSERTED IT WAS NO LONGER AROUND. MY NEW OBGYN SENT ME FOR A PELVIC ULTRASOUND. WHAT THEY FOUND WAS THE RIGHT COIL MIGRATED INTO MY UTERUS AND WAS CAUSING ALL MY ISSUES. I WAS FOUND TO HAVE THE COILS REMOVED WITHOUT A HYSTERECTOMY AT THE AGE OF (B)(6). I WAS EXPEDITED TO SURGERY (B)(6) 2014 WHERE ESSURE COILS, AS WELL AS TUBES, CERVIX AND UTERUS HAD TO BE REMOVED. I HAVE SUFFERED ENOUGH AND ESSURE HAS CAUSED NOT ONLY PHYSICAL TRAUMA BUT MENTAL AS WELL. MY FAMILY, CAREER AND LIFE WAS PUT ON HOLD. ESSURE NEEDS TO OBE TAKEN OFF THE MARKET, IT CAN CAUSE SEVERE MEDICAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00478	BAYER HEALTHCARE LLC	11/6/2014	11/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91743

Single Use: Y
Implant Date (E6): 10/10/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2014; LOT NUMBER USED WAS C91743. IT WAS REPORTED THAT, ON (B)(6)-2014, THE DEVICE BROKE IN HALF. THE PATIENT HAD NO INJURIES AND BILATERAL PLACEMENT WAS ACHIEVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVICE BROKE IN HALF. THIS EVENT, REGARDED AS DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, AS IT WAS REPORTED THAT DEVICE BREAKAGE OCCURRED ON THE SAME DAY OF ESSURE INSERTION; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE. FOLLOW-UP INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039051		11/7/2014	11/18/2014

Event Information:

Event Date (B3): 2/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/3/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A PERMANENT BIRTH CONTROL PROCEDURE CALLED ESSURE DONE ON (B)(6) 2014 BY DOCTOR (B)(6). I HAD A DEPO PROVERA SHOT AS A BIRTH CONTROL METHOD UNTIL I HAVE MY CONFIRMATION TEST. ON (B)(6) 2014 I HAD THE HSG OR CONFIRMATION TEST DONE TO CHECK IF THE PROCEDURE WAS EFFECTIVE. THE TEST DEMONSTRATED BILATERAL FALLOPIAN OCCLUSION, BUT IT ALSO SHOWED THAT THE LEFT ESSURE COIL WAS SOMEWHAT PERIPHERALLY PLACED WITHIN THE LEFT FALLOPIAN TUBE; NEVERTHELESS, IT DEMONSTRATED FALLOPIAN OCCLUSION. ON (B)(6) 2014 I VISITED DR. (B)(6) BECAUSE AFTER THE 3 MONTHS PASSED FO THE ESSURE AND DEPO PROVERA; I HAD HEAVY BLEEDING DURING MY MENSTRUAL CYCLE WHICH LASTED FOR 3 CONSECUTIVE MONTHS. DOCTOR (B)(6) PRESCRIBED PROGESTERONE 100 MG. ON (B)(6) 2014 MY LEFT ESSURE COIL CAME OUT DURING MY MENTRUAL CYCLE, I HAD STOMACH CRAMPS; WHILE I WAS WIPING MYSELF CLEAN AND I WENT TO SEE DR. (B)(6) AND EVEN BROUGHT THE COIL TO HER CLINIC TO SHOW HER. SHE DID AN ULTRASOUND TO MAKE SURE THE COIL DID NOT DAMAGE ANY ORGANS. DR. (B)(6) CHANGED MY PROGESTERONE PILLS TO 220 MG TO CONTROL MY MENTRUAL CYCLE. ON (B)(6) 2014 I VISITED DR. (B)(6) BECAUSE I HAD MISSED MY MENSTRUAL CYCLE IN (B)(6) 2014. SHE DID A PREGNANCY TEST WHICH CAME UP POSITIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039055	BAYER	11/7/2014	11/18/2014

Event Information:

Event Date (B3): 11/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/25/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN THAT IS CONSTANT. MIGRAINES EVERY DAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039048	BAYER	11/8/2014	11/18/2014

Event Information:

Event Date (B3): 11/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626626

Single Use:
Implant Date (E6): 11/10/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN 2009 AND AFTER YEARS OF HORRIBLE PELVIC PAIN, BLEEDING, HEADACHES, VITAMIN D DEFICIENCY, LOWER BACK PAIN, DEPRESSION, IRREGULAR MENSTRUAL CYCLES LASTING MORE THAN THREE MONTHS, SIGNIFICANT UNEXPLAINABLE WEIGHT GAIN, AND AN INCREASE IN BLOOD PRESSURE, I AM NOW HAVING A HYSTERECTOMY AT THE AGE OF 34 TO RESOLVE THOSE ISSUES. AT THE TIME OF SURGERY, IT WILL BE DETERMINED IF THERE ARE ANY OTHER ISSUES, SUCH AS ENDOMETRIOSIS, THAT EXIST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039078		11/10/2014	11/18/2014

Event Information:

Event Date (B3): 9/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/21/2012
Explant Date (E7): 12/20/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2012, I HAD ESSURE PERMANENT BIRTH CONTROL IMPLANTED. THE PROCEDURE WAS DONE AT LOCAL HOSPITAL. UPON WAKING IN THE RECOVERY ROOM, I STARTED COMPLAINING OF SEVERE PAIN ON MY LEFT SIDE. ONCE I WAS SENT HOME, THE PAIN INCREASED AND A PERSISTENT FEVER DEVELOPED. A WEEK LATER, I WENT BACK TO THE DOCTOR AND A VAGINAL ULTRASOUND WAS DONE CHECKING PLACEMENT. EVERYTHING WAS AS IT SHOULD BE. OVER THE COURSE OF THE NEXT YEAR, THE PAIN BECAME WORSE, MY PERIODS BECAME EXTREMELY HEAVY AND PAINFUL, THERE WAS A CONSTANT TUGGING FEELING ON THE LEFT SIDE SENDING PAIN TO MY BACK AND HIP CAUSING SEVERE PAIN WHEN BENDING OR TWISTING. THE FEVER WAS AN ON AND OFF EVENT ALONG WITH HEADACHES AND MY LEFT SIDE FEELING HOT. I REACHED MY LIMIT AND HAD A HYSTERECTOMY ON (B)(6) 2013 REMOVING TUBES, UTERUS AND CERVIX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039081	BAYER	11/10/2014	11/18/2014

Event Information:

Event Date (B3): 3/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/9/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE ALMOST 2 YEARS AGO. IMMEDIATELY FOLLOWING THE INSERTION OF THE COILS I WAS IN EXTREME ABDOMINAL PAIN. THE EXTREME PAIN LASTS FOR WEEKS AT A TIME WITH LESS EXTREME PAIN BETWEEN BOUTS OF EXTREME PAIN. I HAD SEVERAL INSTANCES OF RASH / HIVES IN THE FIRST FEW MONTHS FOLLOWING INSERTION. I HAVE EXCESSIVE BLEEDING DURING MY MENSTRUAL CYCLE, I PASS MULTIPLE BLOOD CLOTS THE SIZE OF A STRAWBERRY EVERY MONTH. I AM FORCED TO TAKE WAY TOO MANY IBUPROFENS JUST TO GET THROUGH MY DAY. I'M CONSTANTLY DEPRESSED DUE TO MY CONSTANT PAIN AND LACK OF ENERGY. I HAVE NO HEALTH INSURANCE CURRENTLY, BUT WHEN I DO I AM GOING STRAIGHT TO THE GYN TO HAVE MY FEMALE PARTS EXAMINED. HOPEFULLY I DON'T HAVE TO GO TO THE EMERGENCY ROOM BEFORE THEN FROM THIS PAIN. IT IS UNBEARABLE AT TIMES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039084	BAYER	11/10/2014	11/18/2014

Event Information:

Event Date (B3): 11/6/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/6/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BRAIN SEIZURES RESULTING IN BLACKOUTS WHICH HAS CAUSED SERIOUS INJURIES. I AM IN CONSTANT, DEBILITATING PAIN AND HAVE NO QUALITY OF LIFE. THANKS ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039085	BAYER	11/10/2014	11/18/2014

Event Information:

Event Date (B3): 10/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C03098

Single Use:
Implant Date (E6): 10/21/2014
Explant Date (E7): 11/10/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2014. HAD HORRIBLE CRAMPING, BLEEDING, LOWER BACK PAIN, HEADACHES, INSOMNIA, INFECTION, SINCE IT WAS PUT IN. MY BODY IS REJECTING THE DEVICE. I'M HAVING SURGERY TODAY TO HAVE IT REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039086	BAYER	11/10/2014	11/18/2014

Event Information:

Event Date (B3): 5/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/30/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I HAD RECEIVED THE ESSURE I STARTED HAVING BILATERAL PELVIC PAIN THAT HAS NEVER EXISTED BEFORE AND REALLY BAD HEADACHES. THESE TWO SOMETIME KEEP ME HOME FROM WORK. THE PAIN IS EXCRUCIATING AND WHEN I WAS HAVING THE PROCEDURE DONE I WAS TOLD THAT THERE ARE NO SIDE EFFECTS AT ALL WHICH NOW HAS RUINED MY LIFE BECAUSE THERE ARE SIDE EFFECTS THAT AT THAT TIME THEY JUST DIDN'T KNOW ABOUT. WE WERE USED LIKE ANIMALS TO DO THIS EXPERIMENT ON US TO SEE IF THERE ARE SIDE EFFECTS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00479	BAYER HEALTHCARE LLC	11/11/2014	11/12/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 629142

Single Use: Y
Implant Date (E6): 6/24/2011
Explant Date (E7): 10/8/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 09-SEP-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 FOR PERMANENT STERILIZATION AND EXPERIENCED BREAST TENDERNESS, HOT FLASHES, MOOD SWINGS, AND SOME BUT RARE HEADACHES. PHYSICIAN STATES THAT PATIENT IS COMPLAINING OF BREAST TENDERNESS, HOT FLASHES, MOOD SWINGS, AND "SOME BUT RARE" HEADACHES. EVENTS ARE ONGOING. HEALTH CARE PROFESSIONAL ALSO REPORTED THAT, PRIOR TO ESSURE, PATIENT WAS ON ORAL CONTRACEPTIVES (NOT SPECIFIED) AND SHE HAD HAD THE SAME SYMPTOMS. DOCTOR STOPPED ORAL CONTRACEPTIVES AND SHE FELT BETTER. IN ADDITION PHYSICIAN INFORMED THAT PATIENT IS CONVINCED THAT HER CURRENT PROBLEMS ARE ESSURE RELATED; HOWEVER DOCTOR THINKS COMPLAINTS ARE HORMONE RELATED AND NOT ESSURE RELATED. PATIENT WANTS ESSURE INSERTS REMOVED. (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS WERE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN (B)(4). THE MEDICAL ASSESSMENT WAS: THAT PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED WAS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF

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A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THAT INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION WAS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE WAS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THAT REPORT. FOLLOW UP INFORMATION RECEIVED ON 14-OCT-2014 FROM PHYSICIAN: THE PATIENT'S DEMOGRAPHICS WERE ADDED (INITIALS, DATE OF BIRTH, WEIGHT AND HEIGHT WERE ADDED). PATIENT HAD HISTORICAL GYNECOLOGICAL INTERVENTIONS: CERVICAL CONIZATION, CURETTAGE AND HAD A CESAREAN SECTION IN 1985. PATIENT HAD NO PREVIOUS IUD; AND NO MYOMECTOMY OR ADNEXAL SURGERY WERE DONE. THE PATIENT WAS NOT POST-PARTUM AT TIME OF INSERTION. ESSURE ESS305 WAS INSERTED IN (B)(6) 2011; LOT NUMBER USED WAS 629142. PER REPORTER, NO UDI NUMBER WAS AVAILABLE. DURING THE PROCEDURE, THE PATIENT HAD CERVICAL DILATATION AND SOUNDING DONE. SHE RECEIVED LIDOCAINE AND NOVOCAIN AS ANALGESIA; NO GENERAL ANESTHESIA WAS APPLIED. THE INSERTION WAS CONSIDERED EASY; WITH EASY VISUALIZATION OF THE TUBAL OSTUIM. NO FLUID LOSS OF MORE THAN 1500CC WAS OBSERVED. ON (B)(6) 2011, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED BILATERAL OCCLUSION; SUCCESSFUL ESSURE. THE PATIENT USED DEPO-PROVERA AS BACK UP CONTRACEPTION UNTIL THE OCCLUSION CONFIRMATION. THE PHYSICIAN CONFIRMED ALL THE EVENTS REPORTED PREVIOUSLY. ON (B)(6) 2014, AN ULTRASOUND WAS DONE AND SHOWED NORMAL SIZE OF THE UTERUS (8.6X4.7X5.5) AND A SMALL MYOMA AND NORMAL ADNEXA. ON (B)(6) 2014, ESSURE DEVICES WERE REMOVED VIA LAPAROSCOPY BY PATIENT REQUEST. NO PATHOLOGY RESULTS WERE PROVIDED. DURING SURGERY, THE CORRECT PLACEMENT OF DEVICES WAS OBSERVED. PHYSICIAN REPORTED THAT SALPINGOSTOMY WAS DONE. PATIENT OUTCOME AFTER SURGERY WAS REPORTED HOWEVER NOT UNDERSTANDABLE IN SOURCE DOCUMENT. THE CASE WAS UPGRADED TO INCIDENT DUE TO INTERVENTION. PTC INVESTIGATION RESULT WAS RECEIVED ON 21-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: CASE UPGRADED TO INCIDENT DUE TO DEVICE REMOVAL AND LOT NUMBER 629142 PROVIDED: PRODUCTION DATE: JANUARY 2009, EXPIRATION DATE: JANUARY 2012. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 629142. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SOME BUT RARE HEADACHES. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURES' REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, PHYSICIAN BELIEVED THAT THE PATIENTS' HEADACHES WERE HORMONE RELATED AND NOT ESSURE RELATED; NEVERTHELESS CONSIDERING THAT HEADACHES HAVE BEEN REPORTED AS POSSIBLE ADVERSE EVENT DURING ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS INITIALLY CONSIDERED A NON-INCIDENT; HOWEVER UPON RECEIPT OF FOLLOW-UP INFORMATION IT WAS UPGRADED TO INCIDENT, SINCE DEVICES WERE REMOVED BY LAPAROSCOPIC

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SURGERY (SALPINGOSTOMY) DUE TO PATIENTS' REQUEST. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039098	BAYER	11/11/2014	11/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/30/2007
Explant Date (E7): 7/10/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PROCEDURE DONE IN 2007, SINCE THEN I HAVE HAD MAJOR PROBLEMS WITH HEADACHES, NAUSEA, ABNORMAL PERIODS, BLOOD CLOTS AND ABDOMINAL PAIN. IN (B)(6) 2014 (7 YEARS AFTER THE DEVICE WAS PLACED) AFTER YEARS OF SUFFERING, MY DOCTOR FOUND THE ONE OF THE ESSURE COILS CAME OUT OF MY FALLOPIAN TUBE AND WAS IN MY UTERUS. THIS REQUIRED SURGERY. UNFORTUNATELY DURING SURGERY MY DOCTOR FOUND THAT PART OF THE COIL WAS STILL IN THE FALLOPIAN TUBE, THEREFORE SHE HAD TO CUT THE COIL AND LEAVE PART OF IT THERE, OTHERWISE RISK PERFORATING MY UTERUS. SINCE THEN I HAVE HAD CONTINUED HEALTH PROBLEMS. MY DOCTOR HAD TO DO A HYSTEROSALPINGOGRAM TO ENSURE MY TUBES WERE ACTUALLY CLOSED. DURING THIS TEST, THEY WERE UNABLE TO LOCATE REMAINING PART OF COIL, AGAIN NOT IN THE FALLOPIAN TUBE WERE THEY CLAIM THEY ARE SUPPOSED TO STAY, BUT MY DOCTOR BELIEVED IT MAY BE EMBEDDED IN MY UTERINE LINING SOMEWHERE. I RECENTLY UNDERWENT AN ABLATION TO TRY AND BELIEVE SOME OF MY SYMPTOMS, BUT IF THIS DOESN'T WORK MY ONLY OPTION WOULD BE A HYSTERECTOMY. I AM ONLY (B)(6) , HAVE A FULL TIME JOB AND FAMILY. NOT ONLY WOULD THIS BE A MAJOR SURGERY WITH RISKS INVOLVED IN MAJOR SURGERIES, BUT FINANCIALLY I WOULD HAVE TO MISS WEEKS OF WORK. THIS PRODUCT SHOULD BE TAKEN OFF THE MARKET, SO NO OTHER WOMEN MAY GO THROUGH WHAT MYSELF AND THOUSANDS OF OTHER WOMEN HAVE HAD PROBLEMS WITH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039101		11/11/2014	11/21/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): A22171
Lot #(E4): ESS305

Single Use:
Implant Date (E6): 8/20/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HORRIBLE PAINS IN MY BACK AND CRAMPING DUE TO THE ESSURE. I THOUGHT OVER TIME IT WOULD GET BETTER, BUT IT HAS NOT. THE WEEK BEFORE, DURING AND AFTER MY PERIOD ARE AWFUL. STABBING PAINS IN SEVERAL AREAS AND I CAN FEEL THOSE FOREIGN OBJECTS IN ME. I HAVE TOLD MY HUSBAND AND FAMILY MEMBERS FROM THE START THIS WAS A MISTAKEN TO HAVE THIS PROCEDURE. SHOULD HAVE HAD MY TUBES TIED LIKE I WANTED BUT FELT BULLIED INTO THIS ESSURE PROCEDURE. I FEEL LIKE A TICKING TIME BOMB AND THAT THE PAIN WILL GET WORSE. NOW I HAVE NO INSURANCE AND I HAVE TO SUFFER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039102	BAYER	11/11/2014	11/21/2014

Event Information:

Event Date (B3): 2/16/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use:
Implant Date (E6): 2/16/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE IMPLANTED 2006, PERIODS BEGAN CRAMPING FOLLOWING MONTH (HAD NEVER CRAMPED BEFORE) EACH MONTH BECAME WORSE AND WORSE PAIN RESULTING IN TIME OFF WORK, BLOOD SUGAR DROPS, BEGAN 2011. INSULIN RESISTANCE AND PANCREAS OVER PRODUCTION OF INSULIN CAUSED MULTIPLE ER TRIPS FOR SUGAR FLUCTUATIONS AND IBS MANY DAYS OF WORK MISSED. METFORMIN AND VICTOZA PRESCRIBED. VITAMIN D LEVEL DANGEROUSLY LOW - LEVEL AT 9, PRESCRIBED VIT D AT 50K UNITS WEEKLY. DEPRESSION AND ANXIETY DIAGNOSED, PRESCRIBED CELEXA AND BUSPIRONE. IN 2013 DEVELOPED EOSOPHILIC ESOPHAGITIS REQUIRING ENDOSCOPY ON (B)(6) 2013, RESULTANT ALLERGY TESTS REVEALED ADULT ONSET ALLERGIES TO MILK PROTEIN, APPLE AND MUSHROOM. IN (B)(6) 2013, CRAMPING PELVIC PAIN NO LONGER LIMITED TO MENSTRUATION, PAIN CONTINUES WITHOUT STOPPING AND INCREASED IN LEVEL OVER THE NEXT 8 MONTHS, PERIODS BEGAT INCREASING IN LENGTH, FLOW AND FREQUENCY. HYDROTHERMAL ABLATION PERFORMED (B)(6) 2014 FOR DYSMENORRHEA AND PAIN, UNSUCCESSFUL - PAIN AND BLEEDING CONTINUED TO INCREASE. TAH SCHEDULED TO REMOVE UTERUS, TUBES, AND OVARIES (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00481	BAYER HEALTHCARE LLC	11/12/2014	11/12/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 17-OCT-2014; IT REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. SHE REPORTED THAT IN THE LAST FEW WEEKS, SHE HAS EXPERIENCED HORRIBLE PREGNANCY SYMPTOMS AND TOOK A PREGNANCY TEST THAT WAS NEGATIVE. SHE ALSO STATED THAT SHE CANNOT EXERCISE OR WALK FOR MORE THAN 10 MINUTES DUE TO THE PAIN ON HER RIGHT SIDE. CONSUMER WANTED TO KNOW IF SHE COULD GET PREGNANT IN HER TUBE. FOLLOW-UP INFORMATION RECEIVED ON 27-OCT-2014 CONSUMER REFUSED TO GIVE ANY INFORMATION. FOLLOW-UP WAS NOT POSSIBLE. PTC INVESTIGATION RESULT WAS RECEIVED ON 05-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN

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SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SUSPECTED A TUBAL PREGNANCY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN A PREGNANCY OCCURS AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. IN THIS PARTICULAR CASE CONSUMER EXPERIENCED PREGNANCY SYMPTOMS AND PAIN ON HER RIGHT SIDE; SHE PERFORMED A PREGNANCY TEST (NOT SPECIFIED) WHICH WAS NEGATIVE. ALTHOUGH ECTOPIC PREGNANCY WAS NOT CONFIRMED AND THE PERFORMED PREGNANCY TEST WAS NEGATIVE, SINCE LIMITED INFORMATION WAS PROVIDED (DATE WHEN TEST WAS PERFORMED, OTHER DIAGNOSTIC EXAMS) A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE TOTALLY EXCLUDED. AS A POSSIBLE SERIOUS INJURY WAS REPORTED, THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. CONSUMER REFUSED TO GIVE ANY INFORMATION, THEREFORE FOLLOW-UP INFORMATION WOULD NOT BE POSSIBLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039117	BAYER	11/12/2014	11/21/2014

Event Information:

Event Date (B3): 11/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B61397

Single Use:
Implant Date (E6): 4/4/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MIGRATED, NO DOCTORS WANT TO TAKE THE COILS OUT. SERIOUS CRAMPS AND BLEEDING FOR OVER 25 DAYS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039134	BAYER	11/12/2014	11/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/19/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVING EXTREME PAIN FOR YEARS. EVER SINCE I HAD THE ESSURE PROCEDURE BACK IN 2001, MENSTRUAL CRAMPS FEELS LIKE I'M GIVING BIRTH. EVEN MILD CRAMPING WHEN I'M NOT ON. INCREASED HEADACHES, FEELING FLUTTERS IN ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00480	BAYER HEALTHCARE LLC	11/12/2014	11/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. A COUPLE OF WEEKS BEFORE THIS REPORT ESSURE WAS INSERTED FOR A PATIENT. ESSURE´S EXTERNAL SPIRALS WERE COMPLETELY BROKEN AT THE PLACE OF 5TH SPIRAL. A PART DROPPED AND IT WAS MANAGED TO REMOVE FROM THE PATIENT´S UTERUS (IT WAS THROWN AWAY). 2 SPIRALS LEFT VISIBLE IN TUBE, WHEN THESE 5 SPIRALS DROPPED. THE INSERTING PHYSICIAN CONCLUDED THAT IF THE IMPLANT WOULD HAVE BEEN IN ONE PART, 7 SPIRALS WERE VISIBLE, SO IT SHOULD NOT BE CONSEQUENCE TO THE EFFECT. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE CANNOT CONFIRM THIS QUALITY COMPLAINT; HOWEVER, BASED ON THE COMPLAINT DESCRIPTION PROVIDED, WE ARE ABLE TO CONCLUDE THAT A QUALITY ISSUE IS PLAUSIBLE. IT IS POSSIBLE DURING THE MANUFACTURING ASSEMBLY PROCESS A SMALL GAP WAS LEFT BETWEEN THE INNER COIL AND INNER CATHETER (THEY SHOULD BE BUTTED TOGETHER DURING ASSEMBLY). WHEN THE OUTER COIL OF THE MICRO-INSERT IS WOUND DOWN A SMALL PORTION OF THE COIL CAN BECOME TRAPPED IN THE GAP. IF A DEVICE HAS THIS ISSUE, WHEN THE PHYSICIAN PRESSES THE BUTTON TO RELEASE THE MICROINSERT, THE OUTER COIL MAY SEVER ITSELF AS IT IS BEING DEPLOYED FROM THE CATHETER. THIS SEVERING OCCURS INSIDE THE CATHETER PRIOR TO THE PIECES BEING DEPLOYED FROM THE CATHETER. THE SEVERING OF THE COILS INSIDE THE CATHETER DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PATIENT. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING

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THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. ACCORDING TO THE TECHNICAL ASSESSMENT A QUALITY DEFECT WAS NOT CONFIRMED BUT CONSIDERED PLAUSIBLE. BASED ON THE PROVIDED INFORMATION THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING MEDDRA LLT: DEVICE BREAKAGE. IN SUMMARY, AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFECT CANNOT BE ASSESSED. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 10-NOV-2014 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 875 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXTERNAL SPIRALS OF ESSURE WERE COMPLETELY BROKEN AT THE PLACE OF 5TH SPIRAL. THE EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. THE 5 BROKEN EXTERNAL SPIRALS DROPPED AND WERE REMOVED FROM THE PATIENT'S UTERUS. 2 SPIRALS LEFT VISIBLE IN TUBE. UPON THE BREAKAGE OCCURRED DURING THE INSERTION PROCEDURE (COMPLICATION OF DEVICE INSERTION) THE EVENT IS ASSESSED AS RELATED TO ESSURE. DEVICE BREAKAGE (MALFUNCTION) WAS REPORTED, SO THE CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED THAT A QUALITY DEFECT WAS NOT CONFIRMED BUT CONSIDERED PLAUSIBLE. ACCORDING TO THE MEDICAL TECHNICAL ASSESSMENT, AS NO ADVERSE EVENTS WERE REPORTED, A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFECT CANNOT BE ASSESSED. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00482	BAYER HEALTHCARE LLC	11/13/2014	11/14/2014

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5037497) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. SHE EXPERIENCED SEVERE BLEEDING, PAINS, MIGRAINES, JOINT PAINS, VOMITING, AND NAUSEA. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: THE CONSUMER´S DATE OF BIRTH WAS UPDATED (SHE WAS (B)(6)). HER WEIGHT WAS 70KG AND HEIGHT WAS 168CM (BMI 24.8). PREVIOUS GYNECOLOGICAL PROBLEMS OR INTERVENTIONS AND CONCURRENT CONDITIONS WERE DENIED. ESSURE WAS INSERTED IN (B)(6) 2012; 2 MONTHS AFTER DELIVERY OF HER SON. LOT NUMBER AND UDI (UNIQUE DEVICE IDENTIFIER) WAS UNKNOWN. AFTER INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION SHE USED OZION (BIRTH CONTROL PILL). ON AN UNSPECIFIED DATE (COUPLE OF MONTHS LATER AFTER INSERTION), HSG WAS DONE AND REVEALED THAT ESSURE COILS WERE IN PLACE. SHE STATED BLEEDING STARTED A COUPLE MONTHS, (2 AND HALF MONTHS) AFTER CONFIRMATION TEST, A COUPLE WEEKS AFTER THAT AND IT COMES AND GOES. PAIN WAS UNBELIEVABLE, PAIN NEAR HER OVARIES, SHE DOUBLE OVER IN PAIN, SOMETIMES FOR A COUPLE OF DAYS, PAIN STARTED 1 YEAR AFTER ESSURE. MIGRAINE STARTED 6-7 MONTHS AFTER INSERTION. JOINT PAINS IN HER KNEES STARTED 6 MONTHS AGO, APPROXIMATELY 1 ½ YEAR AFTER ESSURE. SHE WAS STILL HAVING JOINT PAINS, BUT NOT SO BAD. THE VOMITING COME WITH THE PAIN, IT STARTED WHEN THE SEVERE PAIN STARTED, THE PAIN STARTED AROUND 9 MONTHS AFTER INSERTION, A COUPLE MONTHS AFTER SHE HAD THE ESSURE IN. THE NAUSEA STARTED THE SAME TIME AS EVERYTHING ELSE, AS VOMITING, BUT NOT SO MUCH ANYMORE. SHE RECEIVED PAIN MEDICATIONS, ZOFRAN FOR VOMITING AND TYLENOL WITH CODEINE FOR PAIN. SHE VISITED HER DOCTOR AND WAS ADVISED TO TAKE ESSURE OUT, TO HAVE A HYSTERECTOMY. HOWEVER, SHE DID NOT WANT TO DO,

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SHE WAS TOO YOUNG. SHE STATED THAT HER PHYSICIAN DID THE TEST (THE KIND OF TEST AND THE RESULT WERE NOT PROVIDED). SHE WAS HOSPITALIZED FOR 1 WEEK AT THE END OF (B)(6) AND BEGINNING OF (B)(6) 2012, BUT THE DOCTORS COULD NOT FIND WHAT WAS WRONG. SHE HAD SEVERE ABDOMINAL PAIN AND THE DOCTORS FOUND THAT HER FEMALE ORGANS WERE ALL SWOLLEN AND THEN SHE WAS RELEASED. ON AN UNSPECIFIED DATE SHE HAD A SEVERE SWELLING IN HER BELLY AND LOOKED AS FIVE MONTHS PREGNANT. SHE STATED THAT SHE WAS STILL HAVING MIGRAINES, BLEEDING AND PAINS. HER JOINT PAIN COMES AND GOES. ESSURE WAS NOT REMOVED, BUT SHE WANTED TO HAVE ESSURE REMOVED. SHE BELIEVED THAT HER EVENTS WERE CAUSED BY ESSURE BECAUSE SHE WAS PERFECTLY FINE BEFORE ESSURE INSERTION. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: CASE UPGRADED TO INCIDENT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE BLEEDING. SHE ALSO REPORTED HOSPITALIZATION DUE TO SEVERE ABDOMINAL PAIN AND STATED HER FEMALE ORGANS WERE ALL SWOLLEN. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS; THE FIRST DUE TO MEDICAL IMPORTANCE WHILE THE REMAINING EVENTS DUE TO HOSPITALIZATION. FEMALE ORGANS WERE ALL SWOLLEN IS UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. THE OTHER EVENTS ARE LISTED. GENITAL BLEEDING AND PELVIC, ABDOMINAL AND UNCHARACTERIZED PAIN MAY OCCUR DURING ESSURE USE. IN THIS PARTICULAR CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND THE NATURE OF SEVERE BLEEDING AND ABDOMINAL PAIN A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. REGARDING FEMALE ORGANS WERE ALL SWOLLEN AS LIMITED INFORMATION WAS PROVIDED TO CONCLUDED ON ITS ETIOLOGY; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE ASSESSED. SINCE HOSPITALIZATION WAS REPORTED THIS CASE WAS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 01-APR-2015: HCP ESSURE GENERAL QUESTIONAIRE RECEIVED UNDELIVERED; NO OTHER ADDRESS NOTED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCC

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039130	BAYER	11/13/2014	11/24/2014

Event Information:

Event Date (B3): 10/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/24/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED 3 WEEKS AGO AND I HAVE HAD BAD PELVIC PAIN, SO BAD THAT MOST DAYS I CAN'T GET OFF MY COUCH. I HAVE MIGRAINES THREE TIMES A WEEK SINCE HAVING THE PROCEDURE DONE. I'VE NEVER HAD THEM BEFORE NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039131	BAYER	11/13/2014	11/24/2014

Event Information:

Event Date (B3): 11/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76528, B82471

Single Use:
Implant Date (E6): 4/22/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS IMPLANTED (B)(6) OF 2014 AND IMMEDIATELY STARTED DEVELOPING HORRIBLE SYMPTOMS: WEIGHT GAIN, BLOATING, FATIGUE WORSENING HIGH BLOOD SUGARS, PELVIC PAIN, PAINFUL INTERCOURSE, NAUSEA, VOMITING, MISCARRIED TWICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039133	BAYER	11/13/2014	11/24/2014

Event Information:

Event Date (B3): 5/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/23/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2011 AND HAVE HAD VERY IRREGULAR AND EXTREMELY HEAVY MENSTRUAL CYCLES. I'VE BEEN SUFFERING FROM SEVERE ABDOMINAL PAIN AND HUGE BLOOD CLOTS. MY PERIODS LAST ANYWHERE FROM 11 TO 15 DAYS AND I HAVE TO WEAR SUPER PLUS TAMPON AND AN OVERNIGHT MAXI-PAD. WHEN I'M ON MY PERIOD I USUALLY CHANGE MY TAMPONS AND PADS 6-7 TIMES A DAY. I HAVE BAD HEADACHES ON A DAILY BASIS, I FEEL HOT AND ANGRY THROUGHOUT THE DAY. I'M ALWAYS TIRED AND I'VE BEEN GAINING WEIGHT AND MY HAIR IS THINNING OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039162	BAYER	11/14/2014	11/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/13/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAIR LOSS, EXTREME ABDOMINAL PAIN AT TIMES FEELS LIKE SOMEONE HAS A KNIFE STABBING ME IN MY ABDOMINAL, I HAVE HAD LOWER BACK PAIN THAT MAKES IT DIFFICULT TO STAND FOR LONG PERIODS OF TIME, EXTREME FATIGUE, MUSCLE WEAKNESS. I WAS A NURSING ASSISTANT FOR 17 YEARS, I GAVE IT UP AFTER I STARTED HAVING SYMPTOMS OF WEAKNESS, PAIN, AND I HAVE HAD PERIODIC NUMBNESS IN MY ARMS SINCE THIS PROCEDURE A YEAR AGO. I NO LONGER HAVE THE ENERGY TO DO MY JOB I'VE DONE MY WHOLE LIFE WHICH I FEEL IT'S TAKEN MY LIFE FROM ME. THE WORST PART IS DOCTORS PUSH THIS SO HARD I WANTED MY TUBES TIED BUT WAS BASICALLY GIVEN ONLY THIS OPTION. NOW IT'S AN OPTION I CAN'T HAVE REMOVED UNLESS I GO THROUGH A MAJOR SURGERY, LIKE A HYSTERECTOMY. I'M (B)(6), AND SHOULDN'T HAVE TO DO THIS. I'VE ALSO HAD WEIGHT GAIN AND CAN NOT GET IT OFF. THERE'S NO PROTECTION FOR US WOMEN WHO HAVE SUFFERED FROM THIS ORDEAL AND IT'S SAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039163		11/14/2014	11/24/2014

Event Information:

Event Date (B3): 3/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/21/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE ON (B)(6) 2013, A MONTH LATER I STARTED HAVING SHARP STABBING PAINS ON MY LEFT SIDE, HEAVY PAINFUL MENSTRUAL CYCLES, A CLOT THAT WAS THE LENGTH OF A SUPER MAXI PAD, FATIGUE, INCREASE IN HEADACHES/MIGRAINES, PAIN DURING AND AFTER SEX ALONG WITH BLEEDING, SHARP PAINS ON BOTH SIDES, HAIR LOSS, LIMBS GOING NUMB, DIZZINESS, MOOD SWINGS, ACNE, BLOATING. I DID NOT HAVE PROBLEMS WITH ANY OF THESE UNTIL I GOT ESSURE. IT'S RIDICULOUS THAT AT THE AGE OF (B)(6), I WILL HAVE TO EITHER GET MY TUBES REMOVED OR HAVE A HYSTERECTOMY JUST TO BE NORMAL AGAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039168	BAYER	11/14/2014	11/24/2014

Event Information:

Event Date (B3): 1/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/13/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED (B)(6) 2011. SINCE DAY ONE I HAVE HAD EXTREME PAIN AND AT 6 WEEK CHECK UP, I MENTIONED IT TO MY GYNECOLOGIST AND HE SAID IF IT CONTINUES TO LET HIM KNOW. I LOST MY INSURANCE AFTER THAT AND WAS UNABLE TO FOLLOW UP. WHEN I WAS ABLE TO GO TO THE DOCTOR AGAIN, I FOLLOWED UP WITH MY FAMILY DOCTOR AND HAD MULTIPLE TETS, I EVENTUALLY HAD MY GALL BLADDER MOVED WHICH IS WHAT THEY THOUGHT WAS CAUSING MY PAIN AND A COLONOSCOPY AS WELL WHICH SHOWED NOTHING. THAT WAS IN (B)(6) 2012. NOW, I START TO DO RESEARCH BECAUSE ALL THE STUFF DONE HASN'T FIXED THE PAIN. SINCE THE ESSURE IMPLANT, I HAVE HAD CHRONIC PAIN, HEAVY PERIODS, MISSED PERIODS, VAGINAL CYSTS, OVARIAN CYSTS, UNABLE TO USE TAMPONS, PAINFUL SEX, LACK OF SEXUAL DESIRE, POLYCYSTIC OVARIES, SEVERE CRAMPS EVERY DAY, VERTIGO, BLURRY VISION, SHOOTING PAIN IN MY LEGS AND ARMS, BREAST PAIN, LEAKING, URINARY TRACT INFECTIONS, SWELLING LEGS AND FEET, DIAGNOSED PREDIABETIC, TEETH ISSUES, BACK PAIN, MOOD SWINGS, HOT FLASHES, WEIGHT GAIN, HAIR LOSS, FATIGUE, SLEEP APNEA AND SOME DAYS I CAN'T GET OUT OF BED. I ALMOST FEEL LIKE I'M DYING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039169	BAYER	11/14/2014	11/24/2014

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 901329

Single Use:
Implant Date (E6): 12/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE BIRTH CONTROL ESSURE IN (B)(6) 2011 AND SINCE THE PROCEDURE, I HAVE HAD DEBILITATING MIGRAINES ON A DAILY BASIS, EXTREME BLOATING, WEIGHT GAIN, HEAVY AND IRREGULAR PERIOD, EXTREME ABDOMINAL PAIN AND PAIN IN MY CERVIX/VAGINA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039175	CONCEPTUS, INC.	11/14/2014	11/24/2014

Event Information:

Event Date (B3): 12/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/16/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE IMPLANTS PUT IN, I HAVE BEEN PLAGUED WITH A HEAVY, YET UNPREDICTABLE CYCLE, BLEEDING DURING INTERCOURSE, ABDOMINAL PAIN, JOINT PAIN AND WEIGHT GAIN. NONE OF THIS WAS EVER DESCRIBED AS POSSIBLE SIDE EFFECTS WHEN I CHOSE THIS METHOD OF BIRTH CONTROL, NONE OF THE LITERATURE STATED THIS. THE DEVICE IS NOT HEALTHY AND NEEDS TO BE DISCONTINUED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039177	BAYER	11/14/2014	11/24/2014

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/1/2010
Explant Date (E7): 9/1/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY STORY STARTS IN 2010, AFTER MY THIRD CHILD WAS BORN. I DECIDED TO GET A ESSURE PLACEMENT FOR BIRTH CONTROL. MY BODY IMMEDIATELY REJECTED THE ESSURE COILS. I HAVE NEVER HAD WOMEN ISSUES LIKE THIS UNTIL THE ESSURE PLACEMENT. BEFORE MY PREGNANCY AND PLACEMENT OF COILS , I WAS A HEALTHY WOMAN RUNNING 2 MILES A DAY. ABOUT 3 WEEKS AFTER PLACEMENT I HAD TO GO TO THE EMERGENCY ROOM WITH MASSIVE CRAMPING. I WAS DIAGNOSED WITH A PID INFECTION FROM THE IMPLANTATION OF THE COILS. I HAVE NOT BEEN OUT OF PAIN SINCE, ESPECIALLY THE LEFT SIDE PAIN. I STARTED EXPERIENCING THE FOLLOWING: PERIODS EVERY TWO WEEKS OF SKIPPED PERIODS, EXCESSIVE PAIN IN THE LEFT SIDE (LIKE A KNIFE STICKING INTO YOU), CRAMPS SO BAD I CANNOT STAND UP, EXCESSIVE MENSTRUAL BLEEDING, CLOTS OR TISSUE IN MENSTRUAL BLEEDING, FAINTING, BLACK OUT SPELLS, FATIGUE, INCREASED MIGRAINES, BLURRY VISION, FLOATERS, WEIGHT GAIN, CONSTIPATION, BLOATING, DIARRHEA, NAUSEA, DIZZY SPELLS, FOGGY BRAIN, BACK PAIN, INCREASED UTI'S AND RANDOM RASHES/HIVES. I HAD THE COILS REMOVED AND TUBES REMOVED IN 2013 AND DISCOVERED IN 2014, THEY BROKE APART AND METAL WAS LEFT IN MY UTERUS. I MAY NEED A HYSTERECTOMY NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039180	BAYER	11/14/2014	11/24/2014

Event Information:

Event Date (B3): 6/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I EXPERIENCE SEVERE HEADACHES, PELVIC PAIN, JOINT PAINT, EYE FLOATERS, FATIGUE, AND MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039158	BAYER/CONCEPTUS	11/15/2014	11/24/2014

Event Information:

Event Date (B3): 1/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/30/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2012, ALTHOUGH I ASKED MY DOCTOR FOR A TUBAL LIGATION. I WAS TOLD THAT THIS WAS THE BETTER OPTION BECAUSE OF LESS DOWN TIME. I AGREED, BUT WITHIN A YEAR, I WAS EXPERIENCING ALL KINDS OF ADVERSE REACTIONS. I AM ALWAYS BLOATED TO THE POINT OF LOOKING LIKE I AM 8 MONTHS PREGNANT WHEN I AM NOT. I AM ALWAYS EXPERIENCING SHARP PAINS IN MY TUBAL AREA. I SUFFER FROM EXTREME DEPRESSION AT TIMES AND CAME CLOSE TO DROWNING MYSELF IN THE BATH TUB ONCE. I ASKED THE DOCTOR THAT IMPLANTED THEM, TO PLEASE DO A HYSTERECTOMY BECAUSE I WANTED THE COILS GONE, AND I STILL DID NOT WANT TO HAVE CHILDREN. I WAS TOLD THAT IT WAS "IMPOSSIBLE" THAT MY PROBLEMS WERE LINKED TO THESE FOREIGN OBJECTS IN MY TUBES AND THAT MAY BE I JUST NEEDED TO CHANGE MY DIET AND EXERCISE PROGRAM. I EAT HEALTHY, I SEE A PERSONAL TRAINER, AND YET I AM MISERABLE BECAUSE I DO ALL I CAN TO CHANGE MY BODY IMAGE AND IT'S NOT WORKING! NOW I JUST HAVE TO FIND A DOCTOR THAT IS WILLING TO LISTEN TO ME AND BELIEVE ME ENOUGH TO JUST DO WHATEVER IT TAKES TO REMOVE THEM. I LOST SO MUCH WORK BECAUSE OF THESE COILS THAT WHEN I LEFT MY LAST JOB I HAD TO WRITE THEM A CHECK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039159	CONCEPTUS	11/15/2014	11/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/12/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN (B)(6) 2013. I HAVE HAD COMPLICATIONS EVER SINCE. I HAVE HAD MIGRAINES, BRAIN ZAPS, FATIGUE, METAL TASTE IN MY MOUTH, UNEXPLAINABLE BRUISES, ACNE ON MY BACK, VOMITING, SHARPS PAINS IN MY STOMACH: ACTUALLY FEELS LIKE SOMEONE IS TRYING TO RIP MY INSIDES OUT AT TIMES, AND NUMEROUS OTHER THINGS. I WILL BE SPEAKING WITH MY DOCTOR ABOUT GETTING AN HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039161	BAYER	11/15/2014	11/24/2014

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/12/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE A YEAR AGO AFTER MY LAST CHILD. RIGHT AFTER THE PROCEDURE I HAD SEVERE CRAMPING AND HAD MY PERIOD FOR 3 MONTHS. THE PAIN WAS TERRIBLE. A YEAR AFTER THE PROCEDURE, I HAVE JUST RECENTLY FOUND OUT THAT I AM PREGNANT. IT IS NOT AN ECTOPIC PREGNANCY. THE PREGNANCY HAS BEEN CONFIRMED TO BE IN MY UTERUS BY MY DOCTOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039173	CONCEPTUS, INC.	11/15/2014	11/24/2014

Event Information:

Event Date (B3): 3/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305-R1
Catalog # (E4):
Lot #(E4): 12451361

Single Use:
Implant Date (E6): 3/24/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2011, I WAS IMPLANTED WITH ESSURE IN MY RIGHT TUBE. SINCE THEN, MY HEALTH HAS BEEN ON THE DECLINE. I HAVE HAD EXTREME WEIGHT GAIN, HAIR LOSS, DEPRESSION, ANEMIA, ANXIETY, PAINFUL INTERCOURSE, HORRIBLE BLEEDING, METAL TASTE, THE LIST COULD GO ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039174	CONCEPTUS, INC.	11/15/2014	11/24/2014

Event Information:

Event Date (B3): 11/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/30/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IMPLANTS ON (B)(6) 2012, BECAUSE IT WAS IMPERATIVE FOR HEALTH REASONS THAT I NOT BECOME PREGNANT AGAIN. I CONTINUED BLEEDING AFTER THE PROCEDURE FOR 3 WEEKS. UPON ULTRASOUND INVESTIGATION, IT WAS DETERMINED THAT BOTH COILS HAD MIGRATED; ONE IMPLANTED INTO MY UTERUS AND ANOTHER HAD BROKEN THROUGH MY FALLOPIAN TUBE. I WAS REQUIRED TO UNDERGO ANESTHESIA AND SURGERY TO HAVE THEM REMOVED. AT THIS TIME, MY OB/GYN SAID HE HAD NEVER HEARD OF ANOTHER CASE WHERE THIS HAPPENED AND EVEN CONSULTED WITH THE LOCAL ESSURE REPS, WHO HAD NEVER HEARD OF IT EITHER. BECAUSE HE ASSURED ME THIS WAS AN ABNORMALITY AND THAT THERE WERE NO SIDE EFFECTS, I HAD THE PROCEDURE DONE AGAIN. THE COILS STAYED THIS TIME, HOWEVER, WITHIN A MONTH I BEGAN HAVING THE WORSE PAIN EVER IN MY LOWER BACK AND ABDOMEN, EXCRUCIATING HEADACHES, WANTING TO SLEEP ALL THE TIME, HORRIBLE NIGHT SWEATS (SOAKING SHEETS), EXTREME WEIGHT GAIN, MY ONCE-THICK HAIR IS NOT THIN AND BRITTLE AND I AM HOT ALL THE TIME. AT (B)(6) YEARS OF AGE, THIS SHOULDN'T BE HAPPENING. IN ADDITION, MY HUSBAND SAYS HE NOTICED A CHANGE IN MY MOOD SWINGS AND EMOTIONAL STABILITY AFTER HAVING THE IMPLANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039178	BAYER	11/15/2014	11/24/2014

Event Information:

Event Date (B3): 4/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/20/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE FIRST IMPLANT OF THE ESSURE, MY LEFT TUBE WAS PERFORATED. I HAD AN ADDITIONAL PROCEDURE DONE LATER TO REDO THE ESSURE. I HAVE SINCE BEEN EXPERIENCING PAIN FOR TWO YEARS NOW. I HAVE ALSO HAD FREQUENT MENSTRUAL CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039179	CONCEPTUS, INC.	11/15/2014	11/24/2014

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 638494

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ESSURE AND SINCE IT HAS BEEN PLACED; I HAVE CONSTANT PELVIC PAIN, HEAVIER CYCLES, CONSTANT HEADACHES, I HAVE GAINED 30 POUNDS THAT I CAN'T SEEM TO TAKE OFF AND I AM ALWAYS EXHAUSTED AND MY HAIR IS FALLING OUT!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039160	CONCEPTUS/BAYER	11/16/2014	11/24/2014

Event Information:

Event Date (B3): 11/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/20/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2012 SEVEN WEEKS AFTER THE BIRTH OF MY 4TH CHILD. IMMEDIATELY, I HAD STABBING PAIN IN MY RIGHT PELVIC AREA. MY PERIOD CHANGED AS WELL. I WAS HAVING A PERIOD EVERY 2 WEEKS. TO TREAT THOSE SYMPTOMS, MY DOCTOR PUT ME ON ANOTHER FORM OF BIRTH CONTROL. AT THAT POINT I WAS COVERED BY A DEPOPREVERA SHOT TO COVER THE 3 MONTHS REQUIRED FOR THE ESSURE TO CLOSE MY TUBES AND A BIRTH CONTROL PILL TO CONTROL MY IRREGULAR PERIODS. DURING THIS TIME, I ALSO WAS EXPERIENCING A WHOLE BODY ITCHING THAT FELT LIKE IT WAS ACTUALLY UNDER MY SKIN. I ADVISED MY DOCTOR OF THESE SYMPTOMS. SHE ADVISED THAT PER THE MANUFACTURER'S INFORMATION, THERE WERE NO SIDE EFFECTS FROM ESSURE THAT COULD BE CAUSING ADVISED DEVISED MY OF MY ISSUES. OVER THE COURSE OF THE LAST 2.5 YEARS MY SYMPTOMS HAVE GROWN. I NOW FACE EXTREME FATIGUE, ACHY JOINTS, TIGHT, SORE , MUSCLES, STABBING PELVIC AND GENITALIA PAIN, VITAMIN D DEFICIENCY, LOW PLATELET COUNT, AND HAVE TESTED POSITIVE FOR AN AUTO IMMUNE DISEASE. I ALSO HAVE PROBLEMS WITH FOCUS, CONCENTRATION, MOOD SWINGS, DEPRESSION, AND ANXIETY. I ALSO SWEAT PROFUSELY. I HAVE NOW BEEN REFERRED TO A RHEUMATOLOGIST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039167	BAYER	11/16/2014	11/24/2014

Event Information:

Event Date (B3): 9/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/8/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXPERIENCING SEVERE NECK, SHOULDER, AND JOINT PAIN AFTER GETTING ESSURE IN (B)(6) 2014. ALSO EXPERIENCING DEPRESSION. APPOINTMENT MADE WITH DOCTOR TO HAVE IT REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039208		11/17/2014	11/24/2014

Event Information:

Event Date (B3): 1/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/29/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE DONE (B)(6) 2014, HSG TEST SHOWED COILS EXPELLED/MIGRATED FROM TUBES NOT QUIRE SURE WHERE THEY ARE NOW. HAVE CRAMPING, LOWER BACK PAIN, HEADACHE, PRESSURE IN PELVIC AREA WHICH MAKES IT UNCOMFORTABLE TO SIT SOMETIMES, PASS TISSUE AT TIMES, IRREGULAR PERIODS, CONSTIPATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039209	CONCEPTUS	11/17/2014	11/24/2014

Event Information:

Event Date (B3): 12/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/26/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2013, I HAD THE ESSURE (REF- (B)(4), LOT #B61393) BIRTH CONTROL DEVICE IMPLANTED. I WAS TOLD I WOULD HAVE VERY LITTLE PAIN ONLY LASTING UP TO 48 HOURS. THE PAIN WAS CONTINUALLY WORSENED. THE PAIN IS SO BAD I NEED PRESCRIPTION PAIN PILLS JUST TO EASE IT, BUT UNFORTUNATELY I HAVE 5 CHILDREN AND AM UNABLE TO FUNCTION ON PAIN MEDICINE. I HAVE TO DEAL WITH CONSTANT PAIN THAT WORSENS DURING MY MENSTRUAL CYCLE. MY OB/GYN TOLD ME THIS IS IRREVERSIBLE. PLEASE HELP. I CANNOT HANDLE THIS PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00484	BAYER HEALTHCARE LLC	11/18/2014	11/18/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 9/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(4) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED 2011 FOR PERMANENT CONTRACEPTION. THE CONSUMER STATED THAT IN 2011, SHE STARTED EXPERIENCING HEAVY CRAMPING AND BLEEDING. HER BLOOD WAS RED THIN AND CAME OUT FAST. SHE ALSO HAD PAIN DURING MENSTRUAL CYCLE. PREGNANCY WAS DENIED. IN (B)(6) 2014 ESSURE WAS REMOVED DUE TO THE EVENTS LAPAROSCOPICALLY (SALPINGOSTOMY) AND TUBES WERE REPAIRED. SHE RECEIVED MILD PAIN MEDICATION AND REST MORE WHILE ON PERIOD. AFTER ESSURE REMOVAL, CRAMPING WAS LESS AND BLEEDING DIMINISHED. SHE WAS WITH MORE ENERGY AND HER BODY FELT BETTER. THE OUTCOME OF THE EVENTS WAS RECOVERING / RESOLVING. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBERS FOR THE PTC REPORT ARE: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED

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FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A 37 YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING AFTER ESSURE INSERTED/HER BLOOD WAS THIN AND CAME OUT FAST. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS PARTICULAR CASE, CONSUMER EXPERIENCED THIS EVENT AFTER ESSURE INSERTION. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE CONSUMER HAD ESSURE REMOVED LAPAROSCOPICALLY (SALPINGOSTOMY) DUE TO THE EVENTS. THE TUBES WERE REPAIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: SHE EXPERIENCED HEAVY CRAMPING AFTER ESSURE INSERTED, PAIN DURING MENSTRUAL CYCLE. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 16-APR-2015. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING AFTER ESSURE INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00486	BAYER HEALTHCARE LLC	11/18/2014	11/19/2014

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50678466

Single Use: Y
Implant Date (E6): 3/12/2014
Explant Date (E7): 8/14/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE ADVERSE EVENTS AS DESCRIBED BELOW. ADDITIONAL INFORMATION WAS ALSO RECEIVED ON 08.JUL.2014. ESSURE INSERTION DATE WAS REPORTED AS (B)(6) 2014 (DISCREPANT INFORMATION TO BE CLARIFIED) AND HSG (HYSTEROSALPINGOGRAM) DATES WERE REPORTED AS (B)(6) 2014 (DISCREPANT INFORMATION TO BE CLARIFIED). LOT NUMBER PROVIDED TU00. PHYSICIAN REPORTED THAT IT LOOKED LIKE THE COIL IN THE RIGHT TUBE MIGRATED DISTALLY. ONE MARKER WAS NEAR TUBAL OSTIA AND OTHER THREE MARKERS NEAR DISTAL END OF TUBE. THERE WAS NO SPILL. ESSURE INSERT NOT IN CORRECT LOCATION. REPORT- REMAINING COIL WAS SEPARATED MORE LATERALLY IN THE PELVIS. THESE FINDINGS MAY INDICATE MIGRATION. THE LEFT SIDE WAS OKAY. DOCTOR ADVISED PATIENT TO CONTINUE BACK-UP BIRTH CONTROL AND ALSO SAID THAT IT WAS HARD TO TELL IF COIL WAS MORE THAN 30MM INTO TUBE. THE SIZE OF COIL WAS GIVEN TO THE DOCTOR (WOUND DOWN AND AFTER DEPLOYMENT) AND SHE BELIEVED THAT THIS COIL WAS MORE THAN 30MM INTO TUBE. SHE SAID COIL WAS ABOUT 6 OR 7CM FROM CORNUA, IN OTHER WORDS, PROXIMAL COIL WAS MORE THAN 30MM FROM CORNUA. DOCTOR CONFIRMED THERE WAS NO PERFORATION. DOCTOR WANTED SOMEONE TO LOOK AT FILMS OR GIVE HER INFORMATION ON WHAT TO TELL THE PATIENT. DOCTOR WILL REPEAT HSG; HOWEVER, DOCTOR MIGHT HAVE TO PERFORM LAPAROSCOPIC PROCEDURE WHICH WAS INVASIVE. SHE WAS LOOKING FOR INFORMATION. SHE ASKED ABOUT SAFETY WHEN USING ELECTRICITY NEAR COIL. SHE ASKED HOW TO SEE COIL DURING LAPAROSCOPIC PROCEDURE. FOLLOW-UP INFORMATION WAS RECEIVED ON 18-JUL-2014. ON (B)(6) 2014 REPEATED HSG WAS PERFORMED AND SHOWED THAT THE ESSURE COIL WAS COMPLETELY OUTSIDE OF THE RIGHT

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TUBE, AND WAS LOCATED IN THE LLQ INTERPRETED AS LEFT LOWER QUADRANT (PREVIOUSLY REPORTED AS REMAINING COIL WAS SEPARATED MORE LATERALLY IN THE PELVIS). NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP 31JUL.2014: NO RESPONSE FROM THE REPORTER PHYSICIAN AFTER FOLLOW UP ATTEMPTS FOR ADDITIONAL INFORMATION. CASE CLOSED. FOLLOW UP FROM 07-AUG-2014: ESSURE INDICATION WAS UPDATED FROM CONTRACEPTION TO PERMANENT STERILIZATION. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 13-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO VALID BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON 20-OCT-2014 VIA ESSURE HEALTH CARE PROVIDER TUBAL PERFORATION QUESTIONNAIRE. CASE UPGRADED TO INCIDENT DUE TO LAPAROTOMY WITH SALPINGECTOMY. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED (B)(6). SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES. MEDICAL HISTORY OR CONCURRENT CONDITIONS INCLUDED HYPERTENSION AND IBS (INTERPRETED AS IRRITABLE-BOWEL SYNDROME). SHE HAD 04 PREGNANCIES, 03 LIVE BIRTHS AND 01 SPONTANEOUS ABORTION. SHE DENIED ELECTIVE ABORTIONS, THERAPEUTIC ABORTIONS AND ECTOPIC PREGNANCIES. ON (B)(6) 2014 ESSURE LOT NUMBER 50678466 WAS IMPLANTED. SHE WAS NOT ON POSTPARTUM AT THE TIME OF INSERTION AND SHE WAS NOT PREGNANT. CERVICAL DILATATION AND ANALGESIA (VALIUM 10MG, TORADOL 30MG, PARACERVICAL BLOCK, CARBOCAINE 2%) WERE APPLIED DURING INSERTION. SOUNDING AND GENERAL ANESTHESIA WERE DENIED. THE INSERTION AND THE VISUALIZATION OF THE TUBAL OSTIUM WERE EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. ORAL CONTRACEPTIVES WERE USED AS BACK-UP CONTRACEPTION. ON (B)(6) 2014, HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED POSSIBLE DISRUPTION OR MIGRATION OF PORTION OF RIGHT ESSURE COIL. ON (B)(6) 2014, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED MIGRATED RIGHT ESSURE COIL OUT OF RIGHT FALLOPIAN TUBE INTO LLQ (LEFT LOWER QUADRANT) PELVIC SOFT TISSUE. SHE DID NOT HAVE ANY SYMPTOMS AND THERE WERE NO ORGAN OR INTRA-ABDOMINAL STRUCTURE PERFORATION. ON (B)(6) 2014, SHE UNDERWENT A LAPAROTOMY WITH SALPINGECTOMY FOR REMOVAL OF ESSURE DEVICE. ON UNSPECIFIED DATE, FLAT PLATE X-RAY WAS PERFORMED POSTOP AND SHOWED NEGATIVE. THE PATIENT NOT RECOVERED FROM THE ESSURE REMOVAL PROCEDURE. NO FURTHER INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 22-OCT-2014. (B)(4). FINAL ASSESSMENT: CASE UPGRADED TO INCIDENT AND LOT NUMBER RECEIVED: LOT 50678466. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT

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THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 50678466. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. INTERNAL REVIEW PERFORMED ON 23-OCT-2014: UPON INTERNAL REVIEW, IT WAS NOTED THAT THE (B)(4) IS A DUPLICATED REPORT FORM THIS CASE. (B)(4) WILL BE DELETED FROM (B)(4) DATA BASE AND THIS CASE WAS UPDATED ACCORDINGLY. INFORMATION IMPORTED FROM DUPLICATED CASE STATES THAT PATIENT WAS SEEN IN THE EMERGENCY ROOM FOR PELVIC PAIN. THE HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND SHOWED THE TUBES WERE OCCLUDED BUT THE COIL MIGRATED. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COIL WAS COMPLETELY OUTSIDE OF THE RIGHT TUBE, AND WAS LOCATED IN THE LLQ PELVIC SOFT TISSUE (PREVIOUSLY REPORTED AS COIL WAS COMPLETELY OUTSIDE OF THE RIGHT TUBE, AND WAS LOCATED IN THE LLQ). THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. CONSIDERING POSITIVE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, EVENT WAS CONSIDERED RELATED TO DEVICE. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PATIENT UNDERWENT LAPAROTOMY WITH SALPINGECTOMY) (CASE UPGRADED, THIS CASE WAS PREVIOUSLY CONSIDERED AS NON-INCIDENT). ADDITIONALLY, THE NON-SERIOUS EVENT PELVIC PAIN WAS REPORTED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

UTERINE PERFORATION QUESTIONNAIRE RECEIVED ON (B)(6) 2015 FROM PHYSICIAN. HER LAST MENSTRUAL PERIOD WAS ON (B)(6) 2013 (ON CONTINUOUS BIRTH CONTROL). THE INSERTION WAS NOT DONE AFTER A C-SECTION AND PATIENT WAS NOT BREASTFEEDING AT TIME OF PROCEDURE. NO U

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039223	BAYER	11/18/2014	11/26/2014

Event Information:

Event Date (B3): 11/14/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/28/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IMPLANTED (B)(6) OF 2007 COMPLETED ALL INSTRUCTIONS FOR THE PROCEDURE TO INCLUDE THE CONFIRMATION OF THE (HSG) HYSTEROSALPINGOGRAM. IN (B)(6) OF 2010 DURING A TRIP TO (B)(6), I DEVELOPED A SEVERE SKIN RASH, ACCOMPANIED BY BURNING, ITCHING AND HIVES. THE SKIN ALLERGY STARTED IN THE CHEST, MOVED TO FOREARMS AND LEGS. FIRST THE SKIN, ITCHES, THEN IT BURNS THEN BUMPS DEVELOP FOLLOWED BY DAYS OF FEELING LIKE A 3RD DEGREE IN THE SKIN. IN 2011, I NOTICED THE ALLERGY WOULD TRIGGER IN THE SPRING AND SUMMER. DUE TO ALLERGIES PROGRESSION I SOUGHT A DERMATOLOGIST AND ALLERGIST WHO BEGAN TESTING COLLECTIVELY TO DETERMINE THE PROBLEM. I HAD A SKIN BIOPSY DONE WHICH WAS NOT CONCLUSIVE. I THEN SOUGHT OUT ALLERGIST WHO DID LABS AND CAME BACK NEGATIVE THEN I RETURNED TO THE DERMATOLOGIST WHO PERFORMED A SKIN PATCH TEST WHICH TESTED POSITIVE TO NICKEL ALLERGY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00483	BAYER HEALTHCARE LLC	11/18/2014	12/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06523

Single Use: Y
Implant Date (E6): 6/3/2014
Explant Date (E7): 11/18/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(4)-YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION. ON (B)(6) 2014, DURING 3 MONTH MODIFIED HSG TEST, RIGHT INSERT WAS SHOWN IN UTERUS AND NOT IN FALLOPIAN TUBE. CONSUMER WAS OTHERWISE OK. ESSURE WAS NOT REMOVED. UPON FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM PHYSICIAN THIS CASE WAS UPGRADED TO OTHER REPORTABLE INCIDENT: PHYSICIAN WAS ADDED AS REPORTER AND THIS CASE WAS CONSIDERED MEDICALLY CONFIRMED. IT WAS REPORTED THAT ESSURE PROCEDURE WAS DONE ON (B)(6) 2014; THE LOT NUMBER USED WAS C06523. THE ESSURE COIL BROKE OFF AT THE TIP AND THE REMAINDER WAS EXPULSED (NOT SPECIFIED WHEN). THE PATIENT WAS RESCHEDULED FOR RIGHT COIL INSERTION. PATIENT HAD NO INJURIES. BILATERAL PLACEMENT WAS ACHIEVED. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN

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TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. C06523 (PRODUCTION DATE 30-DEC-2013 AND EXPIRATION DATE 31-DEC-2016). NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND COIL BROKE OFF AT THE TIP AND REMAINDER WAS EXPULSED. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE ESSURE BROKE OFF AT THE TIP AND THE REMAINDER WAS EXPULSED. GIVEN THE NATURE OF THE REPORTED EVENT, ITS CAUSAL RELATIONSHIP WITH ESSURE USE IS ASSESSED AS RELATED. PREVIOUSLY, IT WAS INFORMED THAT AT HSG (HYSTEROSALPINGOGRAM) THE RIGHT INSERT WAS IN UTERUS AND NOT IN FALLOPIAN TUBE AND THE CASE WAS ASSESSED AS NON-INCIDENT. LATER, BASED ON DEVICE BREAKAGE INFORMATION (MALFUNCTION) RECEIVED, THE CASE WAS UPGRADED TO OTHER REPORTABLE INCIDENT. A PTC ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

ESSURE HEALTH CARE PROFESSIONAL GENERAL QUESTIONNAIRE WAS RECEIVED ON 23-FEB-2015. IT STATES THAT A (B)(6) FEMALE PATIENT WHO HAD NO PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURE, HAD ESSURE (LOT NUMBER C06523, EXPIRATION DATE 31-DEC-2016) I

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00485	BAYER HEALTHCARE LLC	11/18/2014	12/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B72572

Single Use: Y
Implant Date (E6): 10/20/2014
Explant Date (E7): 10/20/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2014 FOR CONTRACEPTION; LOT NUMBER USED WAS B72572. IT WAS REPORTED THAT DURING THE INSERTION PROCEDURE, ESSURE DEVICE DEPLOYED TOO EARLY AND PHYSICIAN HAD TO FISH IT OUT IN PIECES. REPORTER STATED THAT PATIENT HAD NO INJURIES. ESSURE WAS NOT CONTINUED. FOLLOW UP FROM (B)(6) 2014: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: WHEN THE COMPLAINT NARRATIVE STATES IT OUT IN PIECES WHEN DESCRIBING A DEVICE EVENT, IT IS DIFFICULT TO DETERMINE THE TRUE NATURE AND CAUSE OF THE EVENT UNLESS ADDITIONAL DETAIL IS PROVIDED IN THE EVENT DESCRIPTION OR PRODUCT IS RETURNED FOR INVESTIGATION. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE

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INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF AND OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE ARE AN ANTICIPATED EVENTS. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED; THEREFORE, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE ESSURE DEVICE DEPLOYED TOO EARLY AND PHYSICIAN HAD TO FISH IT OUT IN PIECES. ESSURE WAS NOT CONTINUED. THE REPORTED EVENTS, REGARDED AS DEVICE DEPLOYMENT ISSUE, BREAKAGE AND FAILED INSERTION ARE NON-SERIOUS. DEVICE BREAKAGE WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER, UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. THE REMAINING EVENTS ARE ALSO LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, CONSIDERING THAT THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED; AND GIVEN THE REPORTED DEVICE MALFUNCTION THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00487	BAYER HEALTHCARE LLC	11/19/2014	12/1/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/5/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA SOCIAL MEDIA IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. IT WAS REPORTED THAT THE PATIENT EXPERIENCED PAIN IMMEDIATELY FOLLOWING THE INSERTION PROCEDURE. ON UNSPECIFIED DATE, A CT SCAN WAS DONE AND REVEALED THAT THE DEVICE WAS IN 2 PIECES; PROXIMAL PART WAS IN ISTHMAL PORTION; AND THE DISTAL WAS BETWEEN UTERUS AND BOWEI. IT WAS PLANNED TO DO A LAPAROSCOPY REMOVAL OF DEVICE AND A TUBAL LIGATION. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON (B)(6) 2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR

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INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. ACCORDING TO THE TECHNICAL ASSESSMENT A QUALITY DEFECT WAS NOT CONFIRMED BUT CONSIDERED PLAUSIBLE. BASED ON THE PROVIDED INFORMATION THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING MEDDRA LLT: DEVICE BREAKAGE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. HOWEVER, BASED ON THE NATURE OF THE REPORTED MEDICAL EVENTS A CAUSAL RELATIONSHIP WITH A POTENTIAL TECHNICAL DEFICIT CANNOT BE TOTALLY EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A CT SCAN SHOWED THE DEVICE WAS IN 2 PIECES; WITH THE DISTAL PART BETWEEN UTERUS AND BOWEL. THE FIRST EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO PRODUCT TECHNICAL INVESTIGATION (PTC) RESULTS; WHILE THE REMAINING EVENT, INTERPRETED AS DEVICE MIGRATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALSO, DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF THE REPORTED EVENTS IS NOT KNOWN; GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE MALFUNCTION (BREAKAGE). PTC ANALYSIS CONCLUDED, BASED ON THE NATURE OF THE REPORTED MEDICAL EVENTS A CAUSAL RELATIONSHIP WITH A POTENTIAL TECHNICAL DEFICIT CANNOT BE TOTALLY EXCLUDED. NO FOLLOW-UP WAS PURSUED SINCE THIS IS A (B)(4) CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00488	BAYER HEALTHCARE LLC	11/20/2014	11/20/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS0049 (INVALID)/C06470

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT ONE MICRO-INSERT FROM LOT C06470 WAS INSERTED INTO THE RIGHT TUBE. WHILE ATTEMPTING TO PLACE ESSURE IN LEFT SIDE, THEY HAD TO TRY TWICE, THE SECOND FROM ANOTHER KIT (LOT CS0049), THE PHYSICIAN HAD CREATED A FALSE PASSAGE AND PROCEDURE WAS CONVERTED TO BILATERAL TUBAL LIGATION. PATIENT HAS BICORNUATE UTERUS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: INVALID LOT #CS0049 AND VALID LOT # C06470 (PRODUCTION DATE 19-DEC-2013 AND EXPIRATION DATE 31-DEC-2016). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THREE FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. C06470, OF WHICH

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ONE CASE REFERS ALSO TO A SIMILAR TYPE OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED VALID BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND HCP MAY HAVE CREATED A FALSE PASSAGE. THE EVENT, INTERPRETED A UTERINE PERFORATION POST PROCEDURE, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE DEVICE WAS INSERTED WELL INTO RIGHT TUBE. WHEN THE PHYSICIAN ATTEMPTED TO INSERT THE MICRO-INSERT INTO THE LEFT TUBE, HE DID NOT SUCCEED AND HAD TO OPEN ANOTHER KIT OF DEVICES. EVEN THEN, HE DID NOT ACHIEVE THE PLACEMENT INTO THAT SIDE, SINCE A FALSE PASSAGE WAS CREATED AND HAD TO CONVERT THE PROCEDURE TO BILATERAL TUBAL LIGATION. ALTHOUGH THE PATIENT HAD BICORNUATE UTERUS, WHICH COULD HAVE CONTRIBUTED TO THE PERFORATION, THE EVENT OCCURRED DURING THE ESSURE INSERTION PROCEDURE, SO CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE AND SINCE AN INTERVENTION (TUBAL LIGATION) WAS PERFORMED, THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION (PERFORATION QUESTIONNAIRE) HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 10-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIEN

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039265	CONCEPTUS/BAYER	11/20/2014	11/28/2014

Event Information:

Event Date (B3): 7/25/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/25/2006
Explant Date (E7): 11/4/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

YES I WOULD LIKE TO FILE AN ADVERSE EVENT REPORT ON A MEDICAL DEVICE CALLED ESSURE MANUFACTURED BY (B)(4). I HAD THESE INSERTED SOMETIME IN (B)(6) 2006 WHICH I HAD NO PROBLEMS. AFTER ABOUT 6 YEARS, I STARTED HAVING HEALTH ISSUES STARTING WITH VERTIGO WHICH WHEN I WENT TO THE DOCTORS AND WAS TOLD IT HAD TO DO WITH SINUS ISSUES AFTER THAT THING PROGRESS, I STARTED GETTING ITCHING AND SWELLING AND RASHES ON DIFFERENT PARTS OF MY BODY. THE SCARIEST WAS TO MY THROAT, A NUMBER OF TIMES, ALONG WITH HAVING ALLERGIES TO FOOD THAT USED TO BE ABLE TO EAT, TO THE NUMBNESS IN MY HANDS THAT WOULD COME AND GO FOR SHORT PERIODS OF TIME BEFORE I COULD DO ANYTHING TO MY CROWNS IN MY MOUTH JUST FALLING OUT, MY HAIR, THINNING OUT/ FALLING OUT, WEIGHT GAIN. I HAVE BEEN ON SO MANY STEROIDS THAT I ENDED UP HAVING ACUTE PANCREATITIS, HEADACHES. THESE ARE JUST SOME OF THE ISSUES. I HAVE BEEN TO SO MANY DOCTORS FOR THEM TO TELL ME DIFFERENT DIAGNOSES, BUT STILL WAS HAVING THE ISSUES UNTIL ONE DAY AS MY HAND WAS SO SWELLED THAT I THOUGHT THAT IT WOULD POP AND I JUST PRAYED FOR THIS TO JUST GO AWAY. THEN FOR NO REASON ESSURE POPPED IN MY HEAD. I STARTED (B)(6) TO SEE IF THERE WAS ISSUES WITH THESE AND THAT HOW I FOUND OUT THE (B)(6) PAGE. I HAVE SINCE HAD THEM REMOVED ALONG WITH MY FALLOPIAN TUBES AND WHAT A DIFFERENCE IT MADE MY HANDS WHICH I DIDN'T REALIZE WERE SWOLLEN FOR SOMETIME NOW. THE SWELLING HAS GONE DOWN, JUST WAITING TO SEE HOW OTHER ISSUES THAT HAVE AFFECTED MY BODY GO AWAY. I HAVE PICTURES, HOSPITAL BILLS ETC IF NEEDED, BUT THE REASON THAT I AM WRITING THIS IS THAT THESE MEDICAL DEVICES REALLY NEED TO BE TAKEN OFF THE MARKET. IF YOU HAVE ASKED ME WHEN I FIRST GOT THEM, I'VE NOT BUT GOOD THINGS TO SAY BUT MY LIFE FOR THE LAST TWO YEARS HAS

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BEEN COMPLETELY AWFUL NOT KNOWING THE ROOT TO THE ISSUE WOULD DRIVE YOU CRAZY. I AM HOPING AND PRAYING THAT THINGS RETURN TO NORMAL FOR ME BUT I WOULD NOT WISH THIS FOR ANY OTHER WOMEN TO GO THROUGH THIS. PLEASE TAKE THEM OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039267	BAYER	11/20/2014	11/28/2014

Event Information:

Event Date (B3): 1/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE IN (B)(6) OF 2012. PLACED AND RECOMMENDED BY MY OB/GYN WHOM I ADORE, HOWEVER, SINCE THE PROCEDURE MY HEALTH HAS SIGNIFICANTLY DECLINED. I NOTICED THAT MY HAIR WAS FALLING OUT AND ALSO NOTICED NO MATTER WHAT I DID, I CONTINUE TO GAIN WEIGHT. I WENT TO MY GP AND WAS TESTED FOR A THYROID PROBLEM. EVERYTHING CAME BACK PERFECT. I ALSO NOTICED THAT MY ENERGY LEVEL DECREASED TO ALMOST LETHARGIC. MY PERIOD IS UNCOMFORTABLY HEAVY TO THE TUNE OF USING 4 ENTIRE BOXES OF TAMPONS DURING MY CYCLE AND THE CRAMPS A WEEK PRIOR TO AND THROUGH MY ENTIRE CYCLE AS WELL AS THE WEEK AFTER ARE ALMOST UNBEARABLE. I HAVE NOTICED SIGNIFICANT PAIN IN MY PELVIC REGION AS WELL AS HORRENDOUS PAIN IN MY JOINS IN MY KNEES AND HIPS. I HAVE BLOATING IN MY ABDOMEN AND PAIN IN MY LOW BACK ALL THE TIME. THE ONLY THING THAT HAS CHANGED IN THIS TIME FRAME IS I HAD THE ESSURE PROCEDURE DONE. I HAVE LOST MY JOB DUE TO MY LACK OF CONCENTRATION AND COMPLETE EXHAUSTION. I COULD NO LONGER FUNCTION TO THE JOB REQUIREMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039268	CONCEPTUS	11/20/2014	11/28/2014

Event Information:

Event Date (B3): 10/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/14/2010
Explant Date (E7): 10/2/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS HAVING CHRONIC PAIN, FATIGUE, WEIGHT GAIN, RESPIRATORY ISSUES. AFTER 4 YEARS OF SUFFERING UNEXPLAINED PAIN, I HAD TO REMOVE MY FALLOPIAN TUBES TO REMOVE THE IMPLANTS. IT WAS INSERTED (B)(6) AND REMOVED (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039201	BAYER HEALTHCARE	11/21/2014	11/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): TUBAL OCCLUSION INSERT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE DEVICE WAS PLACED, REPORTER IS MENSTRUAL CYCLE WAS INCREASED DRAMATICALLY FROM 4 DAYS TO 14 DAYS. REPORTER EXPERIENCES PELVIC PRESSURE AND FATIGUE. DOCTOR SAYS SHE WILL HAVE TO PAY OUT-OF-POCKET IN ORDER TO HAVE. THE DEVICES REMOVED AND A SEARCH ON THE INTERNET SHOWED THAT COULD BE FROM (B)(6). AND REPORTER DOES NOT WANT A HYSTERECTOMY IN ORDER TO HAVE THEM REMOVED. INSERTS PLACED 3-4 YEARS AFTER HER DAUGHTER WAS BORN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039289	BAYER	11/21/2014	12/1/2014

Event Information:

Event Date (B3): 2/9/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/9/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE (B)(6) 2014. SINCE THEN I HAVE HAD SEVERE PAIN IN MY WHOLE BODY. WORST PAIN IS IN MY ABDOMEN AND BACK. SEVERE BLOATING ALWAYS. I AM ALWAYS ASKED WHEN I AM DUE. NOT COOL. I HAVE BEEN DIAGNOSED WITH SEVERE DEPRESSION SINCE ESSURE. I HAVE A ONE AND FOUR YEAR OLD TO TAKE CARE OF. I CANNOT HARDLY DO THAT BECAUSE MY BODY HURTS SO BAD. I HAVE GAINED 30 LBS SINCE ESSURE. I HAVE NEVER HAD A WEIGHT PROBLEM BEFORE. I FEELING LIKE I AM SLOWLY DYING. THANKS TO ESSURE. IT NEEDS TO BE TAKEN OFF THE MARKET. I AM ONE OF THE (B)(6) WOMEN ON ESSURE PROBLEMS ON (B)(6). WE ARE REAL AND ALL HAVE CHILDREN THAT WE CAN BARELY TAKE CARE OF BECAUSE OF ESSURE. MOST OF US CANNOT AFFORD TO PAY FOR A HYSTERECTOMY TO REMOVE THEM FROM OUR BODIES. I AM (B)(6) BUT FEEL 95. I CRY EVERYDAY ABOUT MY PAIN KNOWING I CAN'T JUST TAKE IT OUT AND BE THE MOM AND WIFE I ONCE WAS BEFORE ESSURE. THANKS FOR READING MY REVIEW ON ESSURE. I SURELY HOPE SOMETHING HAPPENS SOON ABOUT THIS TERRIBLE PRODUCT!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039291	BAYER	11/21/2014	12/1/2014

Event Information:

Event Date (B3): 11/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/14/2010
Explant Date (E7): 11/20/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE PLACED OVER 4.5 YEARS AGO. I HAVE DONE THE X-RAY TO ASSURE THE TUBES WERE OCCLUDED AT 3 MONTHS POST PROCEDURE. I ALSO HAVE ULTRASOUND 2 YEARS AGO SHOWING THE ESSURE COILS WERE IN PLACE. THEN 6 MONTHS AGO I BEGAN CRAMPING AND BLEEDING PRETTY BAD, THEN 6 WEEKS AGO EVERY TIME I HAD SEXUAL INTERCOURSE I WOULD BLEED HEAVY BRIGHT RED BLEEDING. ULTRASOUND FOUND MY LEFT ESSURE EXPELLED INTO MY UTERINE CAVITY. THE ESSURE HAD TO BE REMOVED IN THE OFFICE UNDER SEDATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039293	BAYER	11/22/2014	12/1/2014

Event Information:

Event Date (B3): 3/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED ESSURE COILS IN 2010. I IMMEDIATELY HAD PAIN THAT NEVER SUBSIDED. THE PAIN IS CRAMPING, PINCHING, ACHING, AND PIERCING IN STOMACH AND BACK FROM MILD TO INTENSE AT VARIOUS TIMES OF THE MONTH. IN 2012 I DEVELOPED UNEXPLAINED JOINT PAIN IN BOTH HIPS, SHOULDERS AND ONE ANKLE. HEAVY BLEEDING DURING MENSTRUAL PERIOD FOR AN INCREASED TIME FRAME. IN 2014 INFECTION AND IRRITATION MIMICKING VAGINAL YEAST WITH NO SIGN OF THE PRESENCE OF ABNORMAL YEAST LEVELS THE WILL NOT SUBSIDED WITH ANY TREATMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039295	BAYER	11/22/2014	12/1/2014

Event Information:

Event Date (B3): 12/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2013
Explant Date (E7): 11/5/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED (B)(6) 2013 SINCE THEN CHRONIC PELVIC PAIN, HEAVY BLEEDING, NON STOP BLEEDING FOR 4 MONTHS, PAINFUL INTERCOURSE, HAIR LOSS, RASHES, WEIGHT GAIN, DEPRESSION, HOT FLASHES, NIGHT SWEATS, INSOMNIA, CONFIRMED DIAGNOSIS OF ENDOMETRIOSIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039297	CONCCEPTUS INC./BERYER	11/23/2014	12/1/2014

Event Information:

Event Date (B3): 11/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): FIN: 15420510001
Catalog # (E4): MRN: 1542051
Lot #(E4): 20224430

Single Use:
Implant Date (E6): 2/25/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL IMPLANTED ON (B)(6) 2010 BY A (B)(6). THE PRODUCT REFERENCE NUMBER IS (B)(4) AND LOT NUMBER IS 20224430. THE LEFT COIL FAILED AND HAS SINCE CAUSED CONSTANT PAIN IN MY LEFT LOWER ABDOMEN. I HAD TO HAVE A TUBAL LIGATION, IN ADDITION TO THE ESSURE TO ENSURE NO MORE PREGNANCY. THE SAME DR. PERFORMED THIS OPERATION AND LEFT BOTH ESSURE COILS IN MY FALLOPIAN TUBES.. BEFORE THIS IMPLANT MY PERIODS WERE PAINLESS WITH LIGHT BLEEDING, AFTER THE ESSURE MY BMP PERIODS ARE ACCOMPANIED BY DEPILATING PAIN WITH HEAVY BLEEDING. I ALSO AM LOSING HAIR AND NOW HAVE A RECEDING HAIRLINE THAT ALL STARTED AFTER THE IMPLANT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00489	BAYER HEALTHCARE LLC	11/24/2014	11/24/2014

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A25168

Single Use: Y
Implant Date (E6): 3/6/2013
Explant Date (E7): 10/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013 LOT NUMBER A25168 FOR BILATERAL TUBAL STERILIZATION. PHYSICIAN REPORTED THAT THE PATIENT HAD ESSURE CONFIRMATION TEST ON (B)(6) 2013, WHICH SHOWED BILATERAL TUBAL OCCLUSION. PATIENT RECENTLY REPORTED PREGNANCY ((B)(6) 2014). NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 29-SEP-2014: THE OFFICE NURSE CONFIRMED THAT THE ESSURE INSERTION DATE WAS (B)(6) 2013. FOLLOW-UP RECEIVED ON 17-OCT-2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). THE PTC INVESTIGATION RESULT WAS PROVIDED. FINAL ASSESSMENT: MANUFACTURING DATE: 7/2012. EXPIRATION DATE: 7/2015. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. HOWEVER, CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. A25168. NO BATCH SIGNAL COULD BE IDENTIFIED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON 27-OCT-2014 VIA HEALTH CARE PROVIDER PREGNANCY QUESTIONNAIRE. THIS CASE WAS UPGRADED TO INCIDENT. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. CONCOMITANT CONDITION INCLUDED OBESITY (B)(6). SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS (CERVICAL CONIZATION, CURETTAGE, PREVIOUS IUS/IUD, MYOMECTOMY, ADNEXAL SURGERY), GYNECOLOGICAL PROBLEMS OR PROCEDURES AND ANY RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. SHE HAD 03 PREGNANCIES, 02 LIVE BIRTHS AND 01 SPONTANEOUS ABORTION. ON (B)(6) 2013, ESSURE LOT NUMBER A25168 WAS EASILY IMPLANTED. SHE WAS NOT ON POSTPARTUM STATE. PARACERVICAL BLOCK WAS PERFORMED AND CERVIX WAS PREPPED. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. LEFT TUBE CANNULIZED AND IMPLANT DISCHARGED AT CORRECT DEPTH. A TIGHT METAL COIL DISCHARGED WITH THE TYPICAL OUTER COIL. THE DOCTOR WAS NOT SURE IF THAT REPRESENTS A MALFUNCTION OF THE DEVICE. THERE WAS NO DIFFICULTY WITH THE WHEEL OR BUTTON ON THE INSERTER; ALL SEEMED TO FUNCTION WITH NO RESISTANCE NOR DIFFICULTY. THE OUTER COIL WAS SEEN AT THE OS. THE RIGHT IMPLANT WAS PLACED EASILY AND APPEARED NORMAL. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. ALL INSTRUMENTS THEN REMOVED. ON (B)(6) 2013, HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND THE IMPLANTS ARE NOTED TO BE POSITIONED PROPERLY WITHIN THE PROXIMAL SEGMENT OF EACH FALLOPIAN TUBE AND THERE WAS NO CONTRAST ESCAPING ALONG SIDE EITHER. THE CONTRAST REACHED THE CORNEAL REGIONS AND ABRUPTLY STOPPED ON BOTH SIDES. THE ENDOMETRIAL CAVITY AND ARCHITECTURE WERE ALSO NOTED TO BE NORMAL. THE PATIENT WAS INFORMED TO DISCONTINUE HER BACKUP BIRTH CONTROL. ON A WEEK PRIOR TO (B)(6) 2014 SHE CALLED PHYSICIAN'S OFFICE TO REPORT A POSITIVE HOME PREGNANCY TEST. PREGNANCY WAS CONFIRMED BY URINE AND BLOOD TEST. SINCE THEN, QUANTITATIVE HCG TITERS SHOWED AS FOLLOW: (B)(6) 2014 THE RESULT WAS 26.0, ON (B)(6) 2014 WAS 62.0, ON (B)(6) 2014 WAS 66.0 AND ON (B)(6) 2014 WAS 17.0. SHE HAD NO PAIN OR BLEEDING. ON (B)(6) 2014 A TVS (TRANSVAGINAL PELVIC ULTRASOUND) WAS PERFORMED AND SHOWED A 41.8 X 20.8 X 39.2 MM MASS IN THE RIGHT CORNEAL REGION. THE ECHOGENICITY WAS SUGGESTIVE OF BLOOD. NO GESTATIONAL SAC, YOLK SAC OR FETUS WERE SEEN. IN THE ENDOMETRIAL CANAL WAS A TINY FLUID COLLECTION 2.9 MM IN DIAMETER. THE INTERIOR WAS ANECHOIC, BUT NO YOLK SAC OR FETAL POLE WAS SEEN. TRANSABDOMINAL PELVIC ULTRASOUND WAS DONE AND SHOWED NORMAL APPEARING BILATERAL OVARIES, BUT A POSSIBLE COMPLEX MASS IN THE CORNEAL REGION ON THE RIGHT. AT THE TIME OF THIS REPORT SHE HAD NO COMPLICATIONS. HER ECTOPIC PREGNANCY WAS TREATED WITH METHOTREXATE. ON (B)(6) 2014, SHE PRESENTED FOR SURGICAL STERILIZATION. THE PATIENT WAS TAKEN TO THE OPERATIVE ROOM AND PLACED UNDER GENERAL ANESTHESIA. THE RIGHT FALLOPIAN TUBE WAS QUITE NORMAL IN APPEARANCE THROUGHOUT IT WAS FULL COURSE. THERE WAS NO RESIDUAL EVIDENCE OF HAVING HAD A CORNEAL OR ECTOPIC PREGNANCY ALONG THE FULL LENGTH OF THE TUBE. THEREFORE, THE TUBE WAS GRASPED AT ITS ISTHMIC PORTION AND A SINGLE SILASTIC BAND PLACED. THE LEFT TUBE WAS LIKEWISE NORMAL IN APPEARANCE, AND SINGLE SILASTIC BAND PLACED AT ITS ISTHMIC PORTION AS WELL. THERE WAS NO PATHOLOGY OR FOREIGN BODIES SEEN IN THE PELVIS. ESTIMATED BLOOD LOSS WAS LESS THAN 2ML WITH NO COMPLICATIONS. NORMAL UTERUS, TUBES, OVARIES AND PELVIS WAS REPORTED. THE PATIENT WAS TRANSFERRED TO THE RECOVERY ROOM IN STABLE CONDITION. NO FURTHER INFORMATION WAS PROVIDED. UPDATED PTC INVESTIGATION RESULT WAS RECEIVED ON 30-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED

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PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. A25168. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION) INSERTED AND RIGHT CORNUAL ECTOPIC PREGNANCY; PSEUDOSAC IN THE ENDOMETRIUM WAS DIAGNOSED. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN ESSURE REFERENCE SAFETY INFORMATION. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. IN THIS PARTICULAR CASE, IT WAS INFORMED THAT DURING THE DEVICE INSERTION A TIGHT METAL COIL DISCHARGED WITH THE TYPICAL OUTER COIL. THE DOCTOR WAS NOT SURE IF THAT REPRESENTS A MALFUNCTION OF THE DEVICE. NEVERTHELESS, THE BILATERAL PLACEMENT WAS ACHIEVED AND THREE MONTHS LATER, CONFIRMATION TEST SHOWED BILATERAL TUBAL BLOCKAGE. A PREGNANCY WAS FOUND OUT A FEW MONTHS AFTER THE INSERTION AND A DECLINING HCG TITER LED TO ENDOVAGINAL ULTRASOUND. THE SCAN SHOWED A MASS IN THE RIGHT CORNEAL REGION AND NO FETUS WAS SEEN. HER ECTOPIC PREGNANCY WAS TREATED WITH METHOTREXATE AND SHE ALSO UNDERWENT A SURGICAL STERILIZATION. GIVEN THE EXPLANATION ABOVE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. PREVIOUSLY, ONLY THE PREGNANCY DIAGNOSIS HAD BEEN INFORMED, SO THE CASE WAS CONSIDERED AS NON-INCIDENT. AFTER RECEIVING FOLLOW UP INFORMATION, SERIOUS INJURY AND REQUIRED INTERVENTION WERE REPORTED AND THE CASE WAS UPGRADED TO INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00490	BAYER HEALTHCARE LLC	11/24/2014	11/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT HCP ATTEMPTED TO PLACE ESSURE BUT COULD NOT VISUALIZE THE RIGHT TUBE DUE TO FIBROID. THE PHYSICIAN STOPPED THE ATTEMPT AND PERFORMED MYOSURE TO REMOVE FIBROID WHICH WAS SUCCESSFUL. THE PATIENT'S LEFT TUBE WAS ATTEMPTED AND ESSURE WAS PLACED SUCCESSFULLY. THE RIGHT TUBE COULD NOT BE CANULATED AGAIN AND THE PROCEDURE WAS STOPPED. THEN, THE PHYSICIAN ATTEMPTED NOVASURE BUT COULD NOT COMPLETE BECAUSE LEFT SIDE ESSURE INSERT PERFORATED THE TUBE. A TUBAL LIGATION WAS DONE DUE TO ESSURE BEING PLACED ONLY IN ONE SIDE. FOLLOW-UP RECEIVED ON 12-NOV-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY AND TO A USABILITY ISSUE. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS

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REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERFORATION OF LEFT TUBE DURING PROCEDURE. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT PHYSICIAN STOPPED THE ATTEMPT AND PERFORMED MYOSURE TO REMOVE FIBROID WHICH IS AN OFF LABEL USE. THE PERFORATION OF LEFT TUBE OCCURRED DURING ESSURE PROCEDURE AND A TUBAL LIGATION WAS PERFORMED. THE MYOSURE PROCEDURE COULD HAVE CONTRIBUTED FOR THE OCCURRENCE OF PERFORATION. NEVERTHELESS, GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE INTERVENTION WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENT WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 24-MAR-2015 FOLLOW-UP ATTEMPTS TO CONTACT PHYSICIAN WERE DONE, WITHOUT SUCCESS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039321	BAYER	11/24/2014	12/4/2014

Event Information:

Event Date (B3): 10/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/11/2004
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS FORCED INTO HAVING ESSURE IMPLANTED AS OPPOSED TO HAVING A TUBAL BY DR (B)(6) FROM (B)(6) IN (B)(6) IN 2004, 10 WEEKS AFTER HAVING MY SECOND CHILD. I WAS NOT TOLD THE F/U TEST WOULD BOTH BE COVERED UNDER MY INSURANCE WHICH LEFT ME UNABLE TO AFFORD THE DYE TEST REQUIRED TO SEE IF PLACEMENT WAS CORRECT AND PREGNANCY COULD BE PREVENTED. IT HAS BEEN TEN YEARS AND I HAVE NOT BEEN PERMANENT BUT I IMMEDIATELY FELT THAT SOMETHING WAS NOT RIGHT WITH THE PRODUCT OR MY BODY. I HAVE SEVERE PAIN IN MY PELVIC REGION WHICH HAS COST ME MANY TRIPS TO DOCTOR AND THE ER LEAVING DOCTORS BAFFLED AND OFFERING ME NO SOLUTIONS TO MY PROBLEM. I AM SEVERELY ALLERGIC TO NICKEL SO MUCH SO THAT I NO LONGER WEAR EARRINGS BECAUSE IT INFECTS MY EARS IF IT IS NOT STERLING SILVER. I WAKE UP EVERYDAY OF MY LIFE EXHAUSTED AND FEELING LIKE A 90 Y/O WOMAN. MY JOINTS HURT, I HAVE TERRIBLE LOWER BACK PAIN AND STOMACH PAIN WHICH LEAVES ME UNABLE TO MOVE DUE TO BLOATING. I HAVE SHARP, STABBING PAINS IN MY PELVIC REGION AND LOWER BACK. SOMETIMES I FEEL AS IF MY UTERUS IS GONG TO FALL THROUGH MY VAGINA. MY MOOD SWINGS HAVE BECOME SO SEVERE THAT I FEEL LIKE I HAVE PERMANENT POSTPARTUM DEPRESSION. NONE OF THESE SYNDROME CAME ABOUT UNTIL ESSURE WAS IMPLANTED IN MY BODY. I NOW AM UNABLE TO AFFORD HEALTH COVERAGE, MEDICAL BILLS ARE BEING GARNISHED FROM MY CHEST FROM VISITS REGARDING THE ABOVE MENTIONED ISSUES. I LIVE WITH THESE SYMPTOMS EVERY DAY OF MY LIFE. MY PERIODS ARE FREQUENT AND HEAVY WITH HUGE BLOOD CLOTS. I AM UNABLE TO FUNCTION THAT TIME OF THE MONTH. I HAVE SEVERE ABDOMINAL ISSUES THAT CANNOT BE SOLVED. I WAS NEVER ASKED ABOUT ANY METAL ALLERGIES AND NEVER WARNED ABOUT HAVING MRIS I HAVE HAD 3 SINCE ESSURE PLACEMENT. PLEASE SOMEONE HELP ME.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039323	BAUER	11/24/2014	12/4/2014

Event Information:

Event Date (B3): 5/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B61390

Single Use:
Implant Date (E6): 3/17/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE BIRTH CONTROL. I HAVE EXTREME PAIN IN THE PLACES WHERE THE DEVICES HAVE BEEN IMPLANTED. ALONG WITH DIZZINESS, BACK PAIN, CHRONIC HEAD ACHES, STOMACH SICKNESS. IT HAS BEEN AN ONGOING ISSUE FOR 6 MONTHS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039324	BAYER	11/24/2014	12/4/2014

Event Information:

Event Date (B3): 1/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/30/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANT OF ESSURE BIRTH CONTROL DEVICE ((B)(6) 2009) HAS CAUSED MULTIPLE HEALTH PROBLEMS INCLUDING SEVERE ANEMIA, CONSTANT BACK AND LEG PAIN, HAIR LOSS, HEART ARRHYTHMIA, NERVE DAMAGE IN BOTH LEGS, ITCHY "CRAWLING" SENSATIONS MAINLY IN ARMS, FACE, BACK AND LEGS, SEVERE SWELLING OF LEGS, ABDOMEN AND ARMS, EXCESS WEIGHT GAIN (60 LBS). I HAVE BEEN SEEING A NEUROENDOCRINOLOGIST SINCE (B)(6) 2009 TO ASSIST WITH MONITORING/ASSISTANCE IN CONTROLING ISSUES. I WAS MADE AWARE OF OTHER WOMEN WITH THE SAME ISSUES IN (B)(6) OF 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039325	BAYER	11/24/2014	12/4/2014

Event Information:

Event Date (B3): 7/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/9/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) OF 2012 NOT KNOWING THE SIDE EFFECTS OF IT, I HAD BEEN ASSURED BY MY DOCTOR THAT IS WAS SAFE AND WOULD PROTECT FROM PREGNANCY. I INSTANTLY NOTICED ISSUES WITH 6 MONTHS OF BLEEDING, WEIGHT GAIN THAT WAS EXCESSIVE AND COULD NOT GET RID OF, BLOATING IN THE STOMACH, PAINS IN MY LOWER RIGHT SIDE, A RED BUMPY RASH THAT I CANNOT GET RID OF THAT I HAVE HAD FOR OVER 3 MONTHS NOW. DEPRESSION WITH SUICIDAL THOUGHTS, ANXIETY THAT IS SO BAD THAT I HAD TO QUIT MY JOB. I BALL UP IN THE FETAL POSITION IN PAIN, IT IS HORRIBLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039326	BAYER	11/24/2014	12/4/2014

Event Information:

Event Date (B3): 4/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/18/2014
Explant Date (E7): 11/24/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS GIVEN THE ESSURE PERMANENT BIRTH CONTROL PROCEDURE IN (B)(6) 2014. SINCE THEN I HAVE BEEN IN SEVERE PAIN AND CONSTANTLY FATIGUED. I HAVE TWO SMALL CHILDREN WHO I CAN BARELY PICK UP AND WHO NEED ME AT MY BEST. THIS PRODUCT HAS CAUSED SHARP SHOOTING PAIN IN MY BACK AND ABDOMEN. MY PERIODS WHICH WERE NEVER PAINFUL ARE NOW UNBEARABLE. I AM (B)(6) AND NOW I HAVE TO GET A HYSTERECTOMY TO REMOVE THIS DEVICE. THIS PRODUCT SHOULD NOT BE ALLOWED TO BE GIVEN TO OTHER WOMEN. IT CAUSES SEVERE SYMPTOMS THAT CAN ONLY BE FIXED BY SURGERY. AT THE VERY LEAST YOU SHOULD BE REQUIRED TO ENSURE PT KNOWS OF THE PROBLEMS THOUSANDS ARE EXPERIENCING. I CAN BARELY GET OUT OF BED AND EACH NIGHT GOING TO SLEEP IS DIFFICULT AND SCARY. THERE ARE NIGHTS WHERE THE PAIN IS SO BAD I CAN BARELY BREATHE. PLEASE RECALL THIS PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039327		11/24/2014	12/4/2014

Event Information:

Event Date (B3): 8/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/8/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED ON (B)(6) 2014. TWO MONTHS AFTER THIS PROCEDURE I BEGAN TO LOSE MY HAIR AND HAVE DEBILITATING MIGRAINE HEADACHES. MY VISION IS BLURRY AT TIMES AND I HAVE NO ENERGY. THIS IS EFFECTING MY LIFE IN A NEGATIVE WAY. THE HEADACHES ARE SO BAD I HAVE TO STAY IN BED AND SLEEP UNTIL THEY ARE GONE. THE HAIR LOSS HAS CAUSED EMOTIONAL STRESS; THERE ARE TIMES I DON'T WANT TO BE SEEN. I HAVE CALLED MY DOCTOR BUT HAVE GOTTEN NO WHERE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039336	BAYER	11/24/2014	12/5/2014

Event Information:

Event Date (B3): 9/26/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 509814

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IT WAS (B)(6) 2006. AFTER I HAD GIVEN BIRTH TO MY LAST CHILD, MY OBGYN TOLD ME THAT IF I EVER GOT PREGNANT AGAIN IT WOULD KILL ME, HE SAID I HAD TO HAVE ESSURE IMPLANTED AND THAT I DIDN'T HAVE ANY OTHER BIRTH CONTROL CHOICES. WITHIN DAYS AFTER THE SURGERY, I STARTED HAVING REALLY BAD PAINS IN MY PELVIC AREA. OVER THE COURSE OF A YEAR, I STARTED HAVING PROBLEMS EATING CERTAIN FOODS, I STARTED HAVING BAD MIGRAINES CONSTANTLY, MY MENSTRUAL CYCLE WENT FROM FOUR DAYS TO 14 DAYS WITH SPOTTING IN BETWEEN. INTERCOURSE IS PAINFUL, I STARTED HAVING DEPRESSION AND BAD MOOD SWINGS, I HAVE DRUG ALLERGIES NOW, I HAVE DEVELOPED CYSTS ON MY OVARIES, MY IMMUNE SYSTEM IS RIDICULOUSLY WEAK AND I GET SICK A LOT NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039337	BAYER	11/24/2014	12/5/2014

Event Information:

Event Date (B3): 10/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/23/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN, CRAMPING, LEG PAIN, JOINT PAIN, LOWER BACK PAIN, FEELING OF BURNING, AND FEELING OF SWELLING AFTER USING THE BATHROOM. ALL AFTER HAVING ESSURE, AND MY RIGHT TUBE NEVER CLOSED. IT'S BEEN OVER A YEAR.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00491	BAYER HEALTHCARE LLC	11/25/2014	11/25/2014

Event Information:

Event Date (B3): 8/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 10-OCT-2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED SOMETIME IN 2006 FOR CONTRACEPTION. IT WAS REPORTED THAT IN 2013 HER PERIODS STARTED LASTING FOR MONTHS; SHE STATED THAT SHE HAD TO WEAR 5 PADS AT A TIME. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 28-OCT-2014 AND ADDITIONAL INFORMATION RECEIVED ON 05-NOV-2014: CONSUMER IS (B)(6) YEAR-OLD. THE CONSUMER´S WEIGHT WAS (B)(6). HER CONCURRENT CONDITION INCLUDED OBESITY. HER ETHNICITY WAS UPDATED. DRUG ALLERGIES, NON-DRUG ALLERGIES, ALCOHOL USE AND SMOKING HISTORY WERE DENIED. CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED IN (B)(6) 2006 AND, IN THE SAME MONTH ((B)(6) 2006), SHE EXPERIENCED THE EVENT. SHE WAS HOSPITALIZED FOR THREE WEEKS. CONSUMER DOES NOT HAVE THE LOT NUMBER. THE OUTCOME OF THE EVENT WAS REPORTED AS OTHER (NOT SPECIFIED). ACCORDING TO HER, ESSURE NEED TO BE REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: CASE UPGRADED TO INCIDENT. THIS IS FOR ESSURE PRODUCT ESS205 SINCE THE PATIENT HAD PLACEMENT IN 2006. THE SAP NUMBER FOR 305 HAD TO BE USED IN THE DEVACOM SYSTEM SINCE THE 205 PRODUCT WAS NOT SET UP IN SAP. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO

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CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION, NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO (B)(6) YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE EXPERIENCED PERIODS HAVE BEEN LASTING FOR MONTHS AND USE 5 PADS AT A TIME. THE EVENT PERIODS HAVE BEEN LASTING FOR MONTHS AND USE 5 PADS AT A TIME IS SERIOUS DUE TO HOSPITALIZATION AND LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, THE CONSUMER EXPERIENCED THIS EVENT IN THE SAME MONTH OF ESSURE INSERTION AND SHE WAS HOSPITALIZED FOR THREE WEEKS. ESSURE WERE NOT REMOVED. AN ALTERNATE EXPLANATION IS NOT AVAILABLE. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED FROM NON-INCIDENT TO INCIDENT SINCE CONSUMER WAS HOSPITALIZED DUE TO THE REPORTED EVENT. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00493	BAYER HEALTHCARE LLC	11/25/2014	11/25/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 29-OCT-2014 WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. CONSUMER STATED THAT IN 2007 SHE LOST HER SECOND CHILD AT 8 MONTHS OLD. HER DAUGHTER DIED DUE TO ACID REFLUX AND HAD A DRY DROWNING. AT THE TIME SHE WAS PREGNANT (B)(6). SHE HAD ESSURE INSERTED FOR BIRTH CONTROL. SEVERAL YEARS LATER SHE STARTED EXPERIENCING PAIN ON HER LEFT SIDE. SHE WENT THROUGH EMERGENCY ROOM DOCTORS AND SHE WAS TOLD THAT IT WAS ALL IN HER HEAD, ANXIETY, AND A FEW EVEN TOLD HER IT WAS GRIEF PAIN. FINALLY SHE FOUND A DOCTOR WHO BELIEVED THAT SHE WAS INDEED IN A LOT OF PAIN AND IT WAS BEING CAUSED FROM THE COILS, WHICH LED TO THE DECISION TO HAVE THE HYSTERECTOMY. PATIENT WAS RECOVERING FROM THE SURGERY. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 17-NOV-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR

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A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT; REFERS TO A FEMALE SUBJECT WHO WAS INVOLVED IN ESSURE ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN ON HER LEFT SIDE. THIS EVENT WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT THE SUBJECT HAD PAIN ON HER LEFT SIDE AFTER ESSURE INSERTION AND WAS SUBMITTED TO A HYSTERECTOMY. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF ALTERNATIVE EXPLANATION; A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS REGARDED AS AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW UP WILL BE PURSUED SINCE NO CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00494	BAYER HEALTHCARE LLC	11/25/2014	11/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM PHYSICIAN VIA SALES REPRESENTATIVE IN THE UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION SIX OR SEVEN YEARS BEFORE THIS REPORT. PREGNANCY WAS DENIED. PATIENT HAD THE ESSURE PROCEDURE AND SHE DID HAVE A NICKEL ALLERGY. BACK THEN, ACCORDING TO SALES REPRESENTATIVE, NICKEL ALLERGY WAS CONTRAINDICATED. SHE EXPERIENCED SIDE EFFECTS, INCLUDING PELVIC PAIN AND JOINT PAIN. SHE WAS SUBMITTED TO A SALPINGOTOMY TO REMOVE ESSURE MICRO-INSERTS. EVEN AFTER SURGERY, A SMALL PIECE OF ESSURE INSERT WAS LEFT INSIDE PATIENT. THE REPORTING PHYSICIAN WAS THE ONE WHO IDENTIFIED THAT SHE HAD A PIECE OF ESSURE INSERT STILL INSIDE. PATIENT'S ATTORNEY CONTACTED THIS DOCTOR AND ASKED HIM TO BE AN EXPERT WITNESS FOR ESSURE INFORMATION IN THIS LEGAL CASE, ON THE PATIENT SIDE. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A PATIENT HAVING AN ALLERGIC REACTION TO THE ESSURE DEVICE WAS ANTICIPATED DURING THE PRODUCT DESIGN PROCESS. A WARNING STATEMENT IS

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INCLUDED IN THE INSTRUCTIONS FOR USE (IFU) WHICH WARNS PHYSICIANS THAT PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE, ESPECIALLY THOSE WITH A HISTORY OF METAL ALLERGIES. THE DEVICE BREAKAGE AND ALLERGIC REACTIONS ARE CONSIDERED ANTICIPATED EVENTS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT." NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN AND JOINT PAIN. SHE WAS SUBMITTED TO SALPINGOTOMY TO REMOVE THE MICRO-INSERTS, AND A SMALL PIECE OF ESSURE INSERT WAS LEFT INSIDE PATIENT AFTER THIS SURGERY. THE REPORTED PELVIC AND JOINT PAIN WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE; PELVIC PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION WHILE JOINT PAIN IS UNLISTED. THE REMAINING EVENT, REGARDED AS DEVICE BREAKAGE, IS NON-SERIOUS AND PREVIOUSLY REGARDED AS UNLISTED; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT DEVICE BREAKAGE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE A CAUSAL RELATIONSHIP BETWEEN PELVIC PAIN AND THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING JOINT PAIN LIMITED INFORMATION WAS PROVIDED (ABOUT ITS LOCATION OR PATIENT'S CONCOMITANT CONDITIONS); THUS CAUSALITY WITH ESSURE CANNOT BE ASSESSED BY NOW. FOR DEVICE BREAKAGE, ALTHOUGH IT MAY HAVE OCCURRED AS A CONSEQUENCE OF THE REPORTED SURGERY A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION FOR ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

NO FURTHER INFORMATION WILL BE PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN AND JOINT P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00495	BAYER HEALTHCARE LLC	11/25/2014	11/25/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN, WHO IS THE PATIENT, VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(4) 2014. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. PATIENT REPORTED MANY INFECTIONS, ULTRASOUNDS DUE TO CONSTANT PAIN IN RIGHT SIDE, CHANGE OF BOWEL MOVEMENTS, DIZZINESS, AND NAUSEA CONSTANTLY. ULTRASOUNDS WERE DONE. SHE PRESENTED INFECTION AFTER SURGERY, PAIN IMMEDIATELY FOLLOWED UP. PATIENT ASSESSED THE CASE AS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS); HOWEVER DID NOT SPECIFY IT. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. IN

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SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT PAIN IN RIGHT SIDE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO A POSSIBLE SURGICAL INTERVENTION RELATED TO ESSURE AND LISTED ACCORDING TO ESSURE´S REFERENCE SAFETY INFORMATION. PAIN, CRAMPING AND VAGINAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, ALTHOUGH THE DATE OF INSERTION WAS PROVIDED, THE ONSET DATE OF EVENTS WAS NOT REPORTED. CONSIDERING THAT THIS CASE HAS LIMITED INFORMATION AND CONSIDERING THAT THE REPORTER IS A PHYSICIAN, WORST CASE SCENARIO WAS ASSUMED. IT WAS INTERPRETED THAT THIS UNSPECIFIED SURGERY WAS PERFORMED TO REMOVE ESSURE AND THEREFORE RELATED TO ESSURE. DUE TO THIS INTERPRETED ESSURE-RELATED SURGERY, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW-UP WILL BE PURSUED SINCE NO CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00496	BAYER HEALTHCARE LLC	11/25/2014	11/25/2014

Event Information:

Event Date (B3): 9/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/15/2008
Explant Date (E7): 6/25/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5037638) IN UNITED STATES ON 31-OCT-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. WITHIN ONE MONTH, SHE STARTED EXPERIENCING EXTREMELY HEAVY MENSTRUAL BLEEDING, ABDOMINAL PAIN, SERIOUS CRYING SPELLS, DEPRESSION, MOOD SWINGS. AT THE TIME, SHE DID NOT ATTRIBUTE THE ISSUES TO ESSURE, BUT TO POSSIBLE PERIMENOPAUSAL SYMPTOMS. THE CRYING, DEPRESSION, MOOD SWINGS WERE VERY SEVERE AND REQUIRED PSYCHIATRIC ATTENTION. SHE WAS PLACED ON OVER TEN DIFFERENT MEDICATIONS, NON HELPED, SOME MADE SYMPTOMS WORSE. FOR SEVERAL YEARS, SHE EXPERIENCED THE SYMPTOMS AND WENT TO VARIOUS MENTAL HEALTH PROFESSIONALS, GYNECOLOGICAL DOCTORS. NOTHING WAS EVER MENTIONED CONCERNING ESSURE. THE SYMPTOMS WERE SO BAD, SHE BECAME SUICIDAL. ON (B)(6) 2013, SHE HAD ESSURE REMOVED. AFTER REMOVAL, HER MOOD SWINGS WERE GONE, EPISODES OF RAGE, PHYSICAL SYMPTOMS, ABDOMINAL AND LEG PAIN. CONSUMER ASSESSED THE CASE AS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS); HOWEVER DID NOT SPECIFY IT. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO U.S FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME SUICIDAL. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. WOMEN HAVE HIGH RISK FOR DEVELOPING DEPRESSIVE DISORDERS. SEVERAL BIOLOGICAL PROCESSES ARE THOUGHT TO BE INVOLVED IN THE PREDISPOSITION OF WOMEN TO DEPRESSION, INCLUDING AN UNDUE SENSITIVITY TO HORMONAL FLUCTUATIONS IN BRAIN SYSTEMS THAT MEDIATE DEPRESSIVE STATES (PARTICULARLY IN PREMENSTRUAL SYNDROME, PREGNANCY AND MENOPAUSE). DEPRESSION OR SOME DEPRESSED MOOD IS PREDICTED WITH ESSURE USE, HOWEVER; NEITHER MAJOR DEPRESSION, NOR SUICIDAL IDEATION IS EXPECTED. IN THIS CASE, THE CONSUMER WAS IN PERIMENOPAUSE AND PRESENTED HEAVY MENSTRUAL BLEEDING, ABDOMINAL PAIN, SERIOUS CRYING SPELLS, DEPRESSION AND MOOD SWINGS, WHICH STARTED ONE MONTH AFTER DEVICE INSERTION. THE SYMPTOMS WERE SO BAD, SHE BECAME SUICIDAL. BESIDES, AFTER ESSURE REMOVAL, THE MOOD SWINGS, RAGE, ABDOMINAL PAIN AND LEG PAIN WERE GONE (POSITIVE DECHALLENGE). ALTHOUGH PRE-CLIMACTERIC SYNDROME COULD BE AN ALTERNATIVE EXPLANATION FOR THE EVENT, THE PATIENT HAD IMPROVED AFTER DEVICE REMOVAL, SO CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THE CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00492	BAYER HEALTHCARE LLC	11/25/2014	12/4/2014

Event Information:

Event Date (B3): 10/20/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53559

Single Use: Y
Implant Date (E6): 10/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER B53559 INSERTED ON (B)(6) 2014. REPORTER STATED THAT ESSURE WOULD NOT OPEN AND THEN CAME APART. IT BROKE INTO THREE PIECES AND ALL PIECES WERE REMOVED. BILATERAL PLACEMENT WAS ACHIEVED. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS

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CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD B53559 (PRODUCTION DATE 24-JUL-2013 AND EXPIRATION DATE 31-JUL-2016) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND THE DEVICE WOULD NOT OPEN AND BROKE INTO 3 PIECES. THE EVENTS ARE NON-SERIOUS. THE FIRST EVENT, INTERPRETED AS DEVICE DEPLOYMENT ISSUE, IS LISTED WHILE THE REMAINING EVENT, SEEN AS DEVICE BREAKAGE, IS LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION OR REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE AND DEPLOYMENT ISSUES. IN THIS PARTICULAR CASE, THE ESSURE WOULD NOT OPEN AND BROKE INTO 3 PIECES DURING THE INSERTION PROCEDURE (COMPLICATION OF DEVICE INSERTION). ALL PIECES WERE REMOVED AND BILATERAL PLACEMENT WAS ACHIEVED. SINCE THE EVENTS OCCURRED DURING THE INSERTION PROCEDURE AND CONSIDERING THE NATURE OF DEVICE BREAKAGE AND DEVICE DEPLOYMENT ISSUES (MALFUNCTION), COMPANY CONSIDERS A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT AS RELATED AND REGARDS THIS CASE AS OTHER REPORTABLE INCIDENT. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

ESSURE QUESTIONNAIRE RECEIVED FROM THE PHYSICIAN WITH FOLLOW UP INFORMATION. PATIENT'S AGE WAS (B)(6). ESSURE WAS INSERTED 4 MONTHS POSTPARTUM. CERVICAL DILATATION WAS PERFORMED AND PATIENT RECEIVED LOCAL PARACERVICAL BLOCK AS ANALGESIA. NO GENERAL ANESTH

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039330	CONCEPTUS	11/25/2014	12/5/2014

Event Information:

Event Date (B3): 5/22/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/15/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE IMPLANTS AND I'M HAVING HORRIBLE SIDE EFFECTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039333		11/25/2014	12/5/2014

Event Information:

Event Date (B3): 10/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/29/2012
Explant Date (E7): 2/21/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED THREE YEARS AGO AND HAVE SINCE HAD TO HAVE IT REMOVED. EVEN AFTER HAVING IT REMOVED I'M STILL HAVING SEVERE HEALTH ISSUES. I EXPERIENCE SEVERE MIGRAINES, CHRONIC ABDOMINAL PAIN, BACK PAIN, DISPLACEMENT OF LEFT OVER FEMALE ORGANS AND AT TIMES VERY SEVERE NAUSEA. I HAVE LOST MY JOB DUE TO MY MED ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039334	BAYER	11/25/2014	12/5/2014

Event Information:

Event Date (B3): 9/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN IN PAIN BUT NEVER FOUND OUT WHAT WAS GOING ON. I WAS ADMITTED ON (B)(6) WITH CHILLS, FEVER, AND EXTREME ABDOMINAL PAIN. I WAS HOSPITALIZED FOR 2 WEEKS AND 3 DAYS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039341	BAYER	11/25/2014	12/5/2014

Event Information:

Event Date (B3): 2/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/13/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IS THE DEVIL IT HAS RUINED MY LIFE. I'VE HAD TO HAVE SURGERY TO CORRECT THE ISSUES THAT CAME ALONG WITH THIS (B)(6). I WAS NORMAL BEFORE THIS. I HAVE WEIGHT GAIN BLOATING ALMOST CONSTANT PAIN IN MY LOWER STOMACH AND PELVIC AREA. I BLEED LIKE A SCOLDED DOG CONSTANTLY. TAKE THIS OFF THE MARKET IT'S NOT SAFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039342	CONCEPTUS/BAYER	11/25/2014	12/5/2014

Event Information:

Event Date (B3): 10/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE BEING IMPLANTED WITH ESSURE, I HAVE SUFFERED FROM MIGRAINE HEADACHES, SIGNIFICANT WEIGHT GAIN, CHRONIC PAIN IN LEFT SIDE OF ABDOMEN, TROUBLE SLEEPING, JOINT PAIN, NIGHT SWEATS, IRREGULAR MENSTRUAL CYCLES, AND DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039343	BAYER	11/25/2014	12/5/2014

Event Information:

Event Date (B3): 2/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4): 2/2010
Lot #(E4): 752412

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GETTING ESSURE, I BEGAN TO EXPERIENCE SEVERE LEFT SIDED PAIN, AND CHRONIC INFLAMMATION IN MY PELVIC REGION. PAIN HAS NOW GONE TO MY JOINTS AND HIPS. I HAVE SIGNIFICANT SWELLING ON MY LEFT SIDE, THAT APPEARS LIKE A TUMOR. I HAVE EXPERIENCED PAIN WITH INTERCOURSE, MEMORY ISSUES, AND PINS AND NEEDLES IN BOTH FEET. THE DOCTOR HAS REPORTED THAT MY LIVER ENZYMES ARE ALSO ELEVATED, AND HAS NOT FOUND AN EXPLANATION FOR IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039344	BAYER CORPORATION	11/25/2014	12/5/2014

Event Information:

Event Date (B3): 11/4/2009 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20183879

Single Use:
Implant Date (E6): 11/4/2009
Explant Date (E7): 11/3/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOR THE PAST YEAR I HAVE HAD PROBLEMS WITH ALLERGIES, ASTHMA, SKIN RASHES, BLISTERS, HEART PALPITATIONS, GASTROINTESTINAL PROBLEMS, MUSCLE AND JOINT PROBLEMS, SEVERAL INFLAMMATION, MIGRAINES (WHICH I NEVER SUFFERED BEFORE), SEIZURES, PASSING OUT, AND MANY OTHER PROBLEMS WHICH ALL CIRCLED AROUND PELVIC PAIN. I WENT TO THE EMERGENCY ROOM FOUR TIMES AND WAS SENT HOME WITH PAIN PILLS EVERY TIME AND NO ONE COULD FIGURE OUT THE PROBLEM. MY GENERAL PRACTITIONER NEVER FIGURED THE PROBLEM OUT. I RETURNED TO MY GYN THREE TIMES TO PUSH THE POSSIBILITY OF CANCER. FINALLY, I STARTED RESEARCHING AND FOUND THAT I HAD AN ALLERGIC REACTION TO NICKEL AND HAD METAL POISONING. I WAS NEAR DEATH. FOR WEEKS I COULD NOT TAKE CARE OF MY FAMILY AND LOST SEVERAL WEEKS OF WORK DUE TO THE INABILITY TO EVEN STAND OR THINK. I COULD NOT EAT. I LOST 20 POUNDS IN LESS THAN TWO WEEKS. I DID FURTHER RESEARCH AND FOUND THAT ESSURE WAS THE ROOT CAUSE OF MY PROBLEMS. I ENDED WITH A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00497	BAYER HEALTHCARE LLC	11/26/2014	12/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B85137

Single Use: Y
Implant Date (E6): 7/15/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA A COMPANY SALES REPRESENTATIVE IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014, IMPLANT LOT NUMBER B85137 AND EXPIRATION DATE OCT-2016 BROKE AT THE TIME OF INSERTION IN TUBAL OSTIUM. DEFECTIVE PART WAS REMOVED. DISPOSITIVE WAS NOT KEPT. THERE WAS NO ANATOMIC CAUSE. BILATERAL INSERTION WAS DONE WITH A NEW DISPOSITIVE. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND IT BROKE AT THE TIME OF INSERTION IN TUBAL OSTIUM. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE DEVICE BROKE AT TIME OF INSERTION. DEFECTIVE PART WAS REMOVED. A NEW DISPOSITIVE WAS INSERTED. NO INTERVENTION WAS REQUIRED. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 12-FEB-2015: NO FURTHER INFORMATION WAS OBTAINED DESPITE OF FOLLOW-UP ATTEMPTS. CASE CONSIDERED TO BE CLOSED. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039375		11/26/2014	12/5/2014

Event Information:

Event Date (B3): 3/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6) AND I AM (B)(6). I HAVE 3 HEALTHY BEAUTIFUL KIDS AND MY HUSBAND AND I DECIDED THAT WE WERE DONE HAVING KIDS. SO, MY DOCTOR THOUGHT ESSURE WAS THE WAY TO GO. NOPE. EVER SINCE I GOT THESE COILS ON (B)(6), 2013 MY LIFE HAS BEEN HELL. I HAVE CONSTANT PAIN, NAUSEA, VOMITING, TIRED ALL THE TIME AND HORRIBLE MOOD SWINGS. THE PAIN IS SO HORRIBLE THAT I WOULD NOT WISH IT ON MY WORST ENEMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039376		11/26/2014	12/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL PROCEDURE DONE SEVERAL YEARS AGO, AND I HAVE HAD COMPLICATIONS SINCE THEN INCLUDING; ENDOMETRIOSIS, FIBROIDS, PELVIC PAIN, LOWER BACK PAIN, NAUSEA, HAIR LOSS AND IRREGULAR BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039360		11/27/2014	12/5/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE GETTING ESSURE IN (B)(6) 2012, I HAVE SUFFERED DEBILITATING MENSTRUAL CRAMPING AND BLEEDING. EXTREME FATIGUE AND I HAVE HAD JOINT PAIN THAT HAS LEFT ME UNABLE TO MAINTAIN THE ACTIVE LIFE I ONCE LIVED. I AM SO SAD ABOUT ALL THAT HAS TAKEN PLACE IN MY LIFE SINCE ESSURE. I WISH I WOULD HAVE KNOW THEN WHAT I KNOW NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039363		11/29/2014	12/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE INSERTED IN (B)(6) 2007. SINCE THEN I HAVE HAD PERSISTENT PAIN & BLOATING DURING OVULATION; BURNING SENSATION IN VAGINA DURING PERIODS, CONSTANT UTI'S, PAINFUL INTERCOURSE, WEIGHT GAIN, SWOLLEN FEET, SEVERE PAIN IN FEET & KNEES, MOOD SWINGS, DEPRESSION, MEMORY LOSS, BLURRED VISION & SEVERE HOT FLASHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039373	CONCEPTUS	11/29/2014	12/5/2014

Event Information:

Event Date (B3): 3/13/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN (B)(6) 2007. THE RIGHT COIL IMMEDIATELY MIGRATED BEFORE GETTING HOME FROM THE PROCEDURE. I HAD SEVERE CRAMPING AND IT WAS PAINFUL TO LIE ON MY RIGHT SIDE. I WENT FOR HSG AFTER THREE MONTH TIME PERIOD TO FIND OUT THAT ONE TUBE WAS BLOCKED YET THE OTHER WAS COMPLETELY OPEN AND THE COIL WAS MISPLACED. MY DR. SAID I WOULD HAVE TO REDO THE RIGHT SIDE ESSURE AND THAT THE ONE THAT MIGRATED COULD STAY WHERE IT WAS BECAUSE IT WOULD CAUSE NO TROUBLE BEING THAT IT WAS LIKE A "NEEDLE IN A HAYSTACK". I BEGAN HAVING PAIN WHEN DOING ABDOMINAL EXERCISES AS IF SOMETHING WERE CUTTING INTO MY UTERUS. I ASKED MY DR. ON AT LEAST THREE OCCASIONS THROUGH THE YEARS AND HE SAID EACH TIME THAT THE ESSURE COULD NOT CAUSE THE PAIN. I NOW HAVE BEEN DIAGNOSED WITH SLEEP APNEA BECAUSE OF SEVERE DAYTIME SLEEPINESS THAT BEGAN IN 2010. I HAVE HAD BLOOD TESTS FOR RHEUMATOID ARTHRITIS WHICH CAME BACK NEGATIVE IN (B)(6) 2014. I HAVE SEVERE ACHING AND JOINT PAIN THAT STARTED IN MY FEET AND NOW IS THROUGHOUT MY ENTIRE BODY. MY EYES HAVE WORSENED AT A SPEED QUICKLY AND HAD BEEN CONSISTENT YEARS PRIOR ESSURE. I HAVE DRY EYES AND SKIN. MY BACK HAS A RASH AND MY WAIST OFTEN ITCHES UNCONTROLLABLY. I AM NAUSEOUS BEFORE BED FREQUENT FOR NO REASON. I HAVE BEEN HOSPITALIZED FOR SEVERE ABDOMINAL PAIN TWICE. I HAVE DIARRHEA THAT HAS AN OFFENSIVE ODOR (CHEMICAL ODOR). INTERCOURSE IS PAINFUL DUE TO THE COIL THAT IS CUTTING THE UTERUS. I CAN NO LONGER EXERCISE DUE TO PAIN WHERE THE COIL IS IN MY UTERUS. MY MOODS ARE VERY INCONSISTENT. I AM SAD FREQUENTLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039374		11/29/2014	12/5/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE WAS INSERTED 6 YEARS AGO. I HAVE HAD NOTHING BUT PROBLEMS SINCE THEY WERE INSERTED THAT I NEVER HAD PREVIOUSLY. I HAVE SEVERE MENSTRUAL BLEEDING, CRAMPING, CYSTS, ABDOMINAL PAIN, ETC. I HAD TO HAVE ALL MY FEMALE PARTS REMOVED. I CONTACTED ESSURE AND THEY INDICATED IT IS PART OF THE RISKS. MY DOCTOR CONTACTED THEM AS WELL. I DO NOT RECOMMEND THIS PRODUCT TO ANYONE AS IT CAUSES MORE MEDICAL PROBLEMS THAN PREVENTING PREGNANCY AND COSTS (B)(6) IN MEDICAL BILLS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039371	CONCEPHES, INC.	11/30/2014	12/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): IMPLANT ESSURE
Device Type (E2): IMPLANT ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IN 2005. I HAVE HAD CONSTANT PAIN IN MY RIGHT HIP AREA FOR THE LAST YEAR AND HALF. I'VE BEEN TO SEVERAL SPECIALISTS WITH NO REASON AS TO WHY. I FINALLY WENT TO A DIFFERENT OBGYN WHO DID A VAGINAL ULTRASOUND AND SAID MY COILS MIGRATED TO THE END OF MY TUBES. THE ONLY OPTION IS HYSTERECTOMY. I'M BARELY (B)(6). I ALSO HAVE TO TAKE BIRTH CONTROL ALONG WITH THE IMPLANTS BECAUSE IN THE LAST YEAR I'VE STARTED CYCLING EVERY 2 WEEKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039372	BAYER	11/30/2014	12/5/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/6/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A FEW MONTHS AFTER THE ESSURE, MY BODY STARTED REJECTING IT. I NOW SUFFER FROM NIGHT SWEATS, MAJOR HEADACHES, JOINT PAIN, INFLAMMATION, PREMENOPAUSAL, LOW VITAMIN D, AND THE LIST GOES ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039385	BAYER	12/1/2014	12/8/2014

Event Information:

Event Date (B3): 10/7/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE ONGOING MIGRAINES FOR OVER A YEAR, RA LIKE SYMPTOMS, HIP AND BACK PAIN, ALLERGIC TO NICKLE CONTINUE TO HAVE TO GO TO WEEKLY DR. APPOINTS, WAS DIAGNOSED WITH CHRONIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039393	BAYER	12/1/2014	12/8/2014

Event Information:

Event Date (B3): 8/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 922603

Single Use:
Implant Date (E6): 7/11/2012
Explant Date (E7): 11/4/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE HEALTH PROBLEMS DEVELOPED AFTER PLACEMENT OF THIS MEDICAL DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039394	CEPTUS, INC.	12/1/2014	12/8/2014

Event Information:

Event Date (B3): 6/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/19/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE 6 MONTHS AGO, I HAVE HAD SERIOUS PAIN IN MY ABDOMEN LOWER QUADRANT. PAIN IS ACHY AND AT TIME SEVERE STABBING MAKES ME NAUSEATED, DIZZY AND SWEATY. I HAVE BEEN ON A DIET AND EXERCISE WHEN I GET BLOATED MY STOMACH CAN GO FROM A 39 TO A 44, SO I MEASURE OFTEN, MY STOMACH IS TENDER AND PAINFUL WHEN IT HAPPENS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00498	BAYER HEALTHCARE LLC	12/2/2014	12/2/2014

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN GETS SO BAD, SHE HAS TO CRAWL DOWN THE HALLWAY. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE CURRENTLY USES THE METHOD (ESSURE) AND SOMETIMES THE PAIN GETS SO BAD THAT IN ORDER FOR HER TO GET TO HER KIDS. SHE HAS TO CRAWL DOWN THE HALLWAY. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN PAIN GETS SO BAD, SHE HAS TO CRAWL DOWN THE HALLWAY AND ESSURE IS NOT REPORTED. FOLLOW UP INFORMATION RECEIVED ON 03-NOV-2014: CASE IS NOW UPGRADED TO INCIDENT. CONSUMER WAS EXPERIENCING EXCRUCIATING PAIN, EXTREME BLOATING AND SKIN RASHES. IN (B)(6) 2014, CONSUMER CHOSE TO HAVE A HYSTERECTOMY WITH REMOVAL OF HER UTERUS, CERVIX AND TUBES. SHE STATED THE METAL UNCOILED AND MIGRATED OUT OF THE FALLOPIAN TUBE. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT RECEIVED VIA SOCIAL MEDIA, REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE MIGRATED OUT OF FALLOPIAN TUBE. THE EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE CONSUMER EXPERIENCED EXCRUCIATING PAIN, EXTREME BLOATING AND

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SKIN RASHES. ALSO, SHE STATED THE METAL (DEVICE) UNCOILED AND MIGRATED OUT OF FALLOPIAN TUBE. A HYSTERECTOMY WAS THEN PERFORMED TO REMOVE UTERUS, CERVIX AND TUBES. GIVEN THE NATURE OF THE EVENT, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. INITIALLY ONLY THE PAIN (NON-SERIOUS EVENT) HAD BEEN INFORMED AND THE CASE WAS REGARDED AS NON-INCIDENT. THE INFORMATION REGARDING THE DISLOCATION AND THE REQUIRED INTERVENTION WAS LATER PROVIDED AND THE CASE WAS UPGRADED TO INCIDENT. TECHNICAL ANALYSIS HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 30-NOV-2014. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00499	BAYER HEALTHCARE LLC	12/2/2014	12/2/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 6/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) OLD FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. SHE IS MOTHER OF TWO. SHE SAID ESSURE WAS THE WORST DECISION OF HER LIFE AND SHE KNOWS 100%, WITHOUT A DOUBT, HER PAIN AND HER PROBLEMS WAS CAUSED BY ESSURE. THE PAIN WAS UNBEARABLE. IN (B)(6) 2014 SHE UNDERWENT A HYSTERECTOMY TO REMOVE THE ESSURE COILS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON (B)(4) 2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL

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QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO (B)(6) YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PAIN WHICH WAS UNBEARABLE. THE EVENT PAIN WAS UNBEARABLE IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PAIN MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, PAIN OCCURRED AN UNKNOWN TIME AFTER ESSURE INSERTION. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE CONSUMER UNDERWENT A HYSTERECTOMY IN ORDER TO REMOVE ESSURE COILS. ADDITIONALLY, NON-SERIOUS EVENT PROBLEMS WITH ESSURE WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039404	BAYER	12/2/2014	12/9/2014

Event Information:

Event Date (B3): 11/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): A50514

Single Use:
Implant Date (E6): 12/17/2012
Explant Date (E7): 11/25/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE IN 2012 AFTER THE BIRTH OF MY FOURTH CHILD. I ONLY HAD ONE TUBE AND ONE OVARY DUE TO AN ECTOPIC IN 2003. I WANTED A TUBAL, BUT THE DOCTOR COAXED ME INTO GETTING THE ESSURE BECAUSE IT WAS LESS INVASIVE AND VIRTUALLY PAINLESS. I HAVE HAD MULTIPLE COMPLICATIONS SINCE THEN. I HAVE GONE BACK TO HIM AND HE SAID BASICALLY, I WAS FINE AND IT WAS NOTHING. I FELT VERY INSULTED. I KNEW SOMETHING WAS WRONG WITH ME AND NO ONE WOULD LISTEN, I HAVE SUFFERED FROM 2 MISCARRIAGES, MULTIPLE CYSTS ON MY OVARY, SEVERE DYSMENORRHEA, ABDOMINAL LOW BACK PAIN, AND PAINFUL INTERCOURSE. I FINALLY WENT TO ANOTHER DOCTOR WHO DID A VAGINAL EXAM AND VAGINAL ULTRASOUND AND SAID MY OVARY WAS LARGE AND SWOLLEN, HAD A CYST AND HE COULD NOT SEE THE IMPLANT ON THAT DIE. HE DID SEE THE ONE ON MY LEFT, HOWEVER, WHERE THE DOCTOR WHO PLACED IT SAID "IT WENT SOMEWHERE." WHEN I ASKED WHERE HE PUT IT, CONSIDERING I HAD NOTHING THERE..WEIRD. ANYWAY, (B)(6) 2014, I HAD TO HAVE A COMPLETE HYSTERECTOMY DUE TO MY SEVERE COMPLICATIONS AND PAIN. I WAS TIRED OF REPEATED ER VISITS AND PAIN SHOTS. WHEN HE REMOVED EVERYTHING HE SAID MY ESSURE IMPLANTS HAVE GONE THROUGH MY TUBES AND PERFORATED MY UTERUS. I HAVE SUFFERED ALL THIS PAIN AND THAT WAS THE CAUSE. FIRST OF ALL, I SHOULD HAVE NEVER HAD IT PLACED DUE TO THE FACT THAT I ONLY HAVE ONE TUBE AND OVARY, SECOND, DUE TO THE FACT I HAD A PREVIOUS ECTOPIC AND THIRD BECAUSE I WANTED A TUBAL AND THE PT IS ALWAYS RIGHT. I HAVE SUFFERED FOR SO LONG! I AM (B)(6) AND NOW HAVE A HIP TO HIP INCISION WITH 32 STAPLES ALL BECAUSE THE ESSURE FAILED ME. MY DOCTOR FAILED ME.. PLEASE HELP. THREE MONTHS ESSURE CONFIRMATION TEST SHOWED COMPLETE BLOCKAGE. VAGINAL EXAM AND ULTRASOUND DONE IN 2014 LARGE CYST ON RIGHT OVARY AND LARGE AND SWOLLEN OVARY. ESSURE IMPLANT WAS SEEN ON LEFT SIDE WHERE TUBE WAS SUPPOSED TO BE. "TUBE AND

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OVARY WERE REMOVED IN 2003." IMPLANT WAS NOT SEEN ON RIGHT SIDE. AFTER HYSTERECTOMY, IMPLANTS WERE FOUND TO HAVE GONE THROUGH THE TUBES AND PERFORATED THE UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039410	BAYER	12/2/2014	12/9/2014

Event Information:

Event Date (B3): 11/23/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 6/20/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD CHRONIC PELVIC AND LOWER BACK PAIN SINCE HAVING THIS DEVICE INSERTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00500	BAYER HEALTHCARE LLC	12/3/2014	12/3/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 04-NOV-2014, ARTICLE ENTITLED "HYSTEROSCOPIC AND LAPAROSCOPIC ESSURE MICROINSERT REMOVAL 320 DAYS POST-ESSURE PLACEMENT". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION AND EXPERIENCED RIGHT LOWER PELVIC ORGASM PAIN, THE LEFT INNER COILS WERE GRASPED AND EXTRACTED BY STEP-WISE, AND THE WHOLE LEFT OUTER COILS WERE REMOVED HYSTEROSCOPICALLY AND THE RIGHT OUTER COILS DID NOT FOLLOW THE INNER COILS AFTER EXTRACTION, DURING HYSTEROSCOPY, THEN REMOVED LAPAROSCOPICALLY. TRADE NAME OF THE BAYER PRODUCT WAS REPORTED AS ESSURE. STUDY OBJECTIVE: HYSTEROSCOPIC FALLOPIAN OCCLUSION BY ESSURE MICROINSERT IS BECOMING MORE WIDELY USED, AND SUBSEQUENTLY PATIENTS ARE INCREASINGLY PRESENTING FOR REMOVAL. WE EXPLORED THE FEASIBILITY OF HYSTEROSCOPIC ESSURE MICROINSERT REMOVAL 12 WKS POST-ESSURE INSERTION. PATIENTS: THE PATIENT DESIRED ESSURE MICROINSERT REMOVAL DUE TO RIGHT LOWER PELVIC ORGASM PAIN. THE PROCEDURE WAS PERFORMED BY HYSTEROSCOPY AND LAPAROSCOPY 320 DAYS POST-ESSURE PLACEMENT. MEASUREMENTS AND MAIN RESULTS: WE ARE REPORTING AN ESSURE MICROINSERT REMOVAL BY HYSTEROSCOPY AND LAPAROSCOPY 320 DAYS AFTER PLACEMENT. WE WERE ONLY ABLE TO HYSTEROSCOPICALLY VISUALIZE THE INNER COILS IN THE LEFT OSTIUM. THE INNER COILS WERE GRASPED AND EXTRACTED BY STEP-WISE EXTRACTION. SUBSEQUENTLY, THE DISTAL PORTION OF THE LEFT OUTER COILS WAS VISIBLE AT THE OSTIUM, AND THE WHOLE OUTER COILS WERE REMOVED HYSTEROSCOPICALLY. THE RIGHT OSTIUM WAS EXPLORED WITH BLUNT DISSECTION. THE OUTER COILS COULD NOT BE IDENTIFIED, BUT THE INNER COILS WERE LOCATED AND REMOVED. UNFORTUNATELY, THE RIGHT OUTER COILS DID NOT FOLLOW THE INNER COILS AFTER EXTRACTION. THESE WERE THEN

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REMOVED LAPAROSCOPICALLY. CONCLUSION: WE RECOMMEND A TRIAL OF HYSTEROSCOPIC APPROACH OF ESSURE MICROINSERT BY STEP-WISE EXTRACTION PRIOR TO LAPAROSCOPIC ATTEMPT IF THE PATIENT DESIRES ESSURE REMOVAL. FOLLOW UP (B)(6) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE IN THE CONTEXT OF A COMPLICATED DEVICE REMOVAL. THE AE CASE REFERS TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 02-DEC-2014 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1. PELVIC PAIN: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASES. 2. ORGASM ABNORMAL: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASE. 3. DEVICE BREAKAGE: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, MEDICAL LITERATURE CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RIGHT LOWER PELVIC ORGASM PAIN AND THE RIGHT OUTER COILS DID NOT FOLLOW THE INNER COILS AFTER EXTRACTION, DURING HYSTEROSCOPY, THEN REMOVED LAPAROSCOPICALLY. THE EVENT RIGHT LOWER PELVIC ORGASM PAIN WAS SPLIT IN RIGHT LOWER PELVIC PAIN (LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION) AND ORGASM PAIN (UNLISTED FOR ESSURE). THE EVENT THE RIGHT OUTER COILS DID NOT FOLLOW THE INNER COILS AFTER EXTRACTION, DURING HYSTEROSCOPY, THEN REMOVED LAPAROSCOPICALLY, INTERPRETED AS DEVICE BREAKAGE, IS ALSO LISTED. ALL THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESS BREAKAGE. IN THIS PARTICULAR CASE, PATIENT EXPERIENCED RIGHT LOWER PELVIC ORGASM PAIN AND THE LEFT MICRO-INSERT WAS REMOVED BY HYSTEROSCOPY. DURING REMOVAL OF RIGHT MICRO-INSERT, THE DEVICE BREAKAGE OCCURRED DURING HYSTEROSCOPY. THEN, THE PATIENT UNDERWENT A LAPAROSCOPY. ESSURE MICROINSERT WAS REMOVED 320 DAYS AFTER PLACEMENT. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE MICROINSERT WAS REMOVED BY HYSTEROSCOPY AND LAPAROSCOPY. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED: THE LEFT INNER COILS WERE GRASPED AND EXTRACTED BY STEP-WISE, AND THE WHOLE LEFT OUTER COILS WERE REMOVED HYSTEROSCOPICALLY (DEVICE MISUSE). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00501	BAYER HEALTHCARE LLC	12/3/2014	12/12/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): MALFUNCTION	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A MARKET RESEARCH ACTIVITY, (B)(4). REPORTER STATED THAT FAILURE ON INSERTION FOLLOWING THE IMPOSSIBILITY TO INSERT THE DELIVERY SYSTEM WHICH BROKE-UP. THE FAILURE ON INSERTION OCCURRED A FEW DAYS BEFORE THIS INITIAL REPORT. THE PHYSICIAN WANTED TO REMAIN ANONYMOUS. NO FURTHER INFORMATION WILL BE AVAILABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WHICH OCCURRED A FAILURE ON INSERTION FOLLOWING THE IMPOSSIBILITY TO INSERT THE DELIVERY SYSTEM WHICH BROKE-UP. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESS BREAKAGE. IN THIS PARTICULAR CASE, THE DEVICE BREAKAGE OCCURRED DURING INSERTION AND ESSURE WAS NOT INSERTED (FAILED INSERTION). BASED ON THIS INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. FURTHER INFORMATION WILL NOT BE REQUESTED SINCE THE REPORTER WANTED TO REMAIN ANONYMOUS.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTEL

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00502	BAYER HEALTHCARE LLC	12/3/2014	12/15/2014

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B60755

Single Use: Y
Implant Date (E6): 2/28/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/14/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER B60755 (EXPIRATION DATE AUG-2016) FOR PERMANENT CONTRACEPTION. PREGNANCY WAS DENIED. ON AN UNSPECIFIED DATE, HSG (HYSTEROSALPINGOGRAM) WAS DONE. ESSURE PROXIMAL MARKER WAS IN THE CORNUA AND THE REST OF THE DEVICE WAS IN THE ABDOMEN; BROKEN ON RIGHT SIDE. ESSURE WAS CONTINUED. THE OUTCOME OF THE EVENT WAS NOT RECOVERED/RESOLVED. HOWEVER, PATIENT WAS OKAY. FOLLOW-UP INFORMATION RECEIVED ON 11-NOV-2014: PHYSICIAN REQUESTED INFORMATION ABOUT DEVICE BREAKING AFTER INSERTED IN PATIENT. SHE STATED THE DEVICE WAS CLEARLY BROKEN (NOT STRETCHED) ON THE HSG. FOLLOW-UP INFORMATION WAS RECEIVED ON 12-NOV-2014. IT WAS REPORTED THAT THE DOCTOR WILL BE DOING A LAPAROSCOPY TO SEE THE LOCATION OF THE DEVICES AND ALSO THE PATIENT WOULD LIKE THE DEVICES REMOVED. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: (B)(4) 2014: SPOKE TO THE SALES REP AND THE DOCTOR WILL BE DOING A LAPAROSCOPY TO SEE THE LOCATION OF THE DEVICES AND ALSO THE PATIENT WOULD LIKE THE DEVICES REMOVED. SALES REP WILL SEND FOLLOW-UP INFORMATION. A HYSTEROSALPINGOGRAM (HSG) IS AN X-RAY TEST THAT LOOKS AT THE INSIDE OF THE UTERUS AND FALLOPIAN TUBES AND THE AREA AROUND THEM. DURING AN HSG, A DYE (CONTRAST MATERIAL) IS PUT THROUGH A THIN TUBE THAT IS PUT THROUGH THE VAGINA AND INTO THE UTERUS. FOR ESSURE, A MODIFIED HSG IS PERFORMED USING A SLOW-FILL OF CONTRAST. THE ESSURE CONFIRMATION TEST (MODIFIED HSG) IS PERFORMED THREE MONTHS POST-PLACEMENT TO EVALUATE INSERT

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LOCATION AND FALLOPIAN TUBE OCCLUSION. HSG FILMS SHOULD BE REVIEWED AND INTERPRETED BY A TRAINED MEDICAL PROFESSIONAL, SUCH AS A PHYSICIAN OR RADIOLOGIST. IN MANY HSG IMAGES, ONLY THE RADIOPAQUE MARKERS LOCATED ON THE MICROINSERT ARE VISIBLE. IN SOME CASES, THE MICRO-INSERT CAN BE STRETCHED BY MUSCULAR CONTRACTIONS OF THE FALLOPIAN TUBE. WHEN VIEWED ON AN HSG IMAGE, THIS MAY CONTRIBUTE TO THE PERCEPTION THAT THE DEVICE IS BROKEN SINCE THE DISTANCE BETWEEN RADIOPAQUE MARKERS IS LONGER THAN ANTICIPATED; HOWEVER, THE DEVICE IS NOT ACTUALLY BROKEN. SINCE THE REMAINING PARTS OF THE DEVICE ARE NOT VISIBLE, HSG IMAGES CAN BE MISINTERPRETED AS BEING "BROKEN" OR "FRAGMENTED." SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE A REPORTED PRODUCT QUALITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. ONE FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. B60755 (PRODUCTION DATE 16-AUG-2013 AND EXPIRATION DATE 31-AUG-2016), BUT THIS CASE DOES NOT REFER TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM CONSUMER´S HUSBAND, WHICH IS A LAWYER: ON (B)(6) 2014, CONSUMER HAD ESSURE BIRTH CONTROL DEVICE, LOT NUMBER B60755, INSERTED. THE PROCEDURE WAS VERY PAINFUL. ON (B)(6) 2014, CONSUMER RETURNED TO PHYSICIAN´S OFFICE AND SHE WAS ADVISED THAT THERE WAS A PROBLEM WITH THE ESSURE COIL AND TO CONTINUE TAKING HER REGULAR ORAL BIRTH CONTROL WHILE SHE STUDIED THE X-RAYS. ON (B)(6) 2014, CONSUMER RETURNED TO PHYSICIAN´S OFFICE AND WAS SUBSEQUENTLY ADVISED THAT THE TIP OF THE ESSURE DEVICE IMPLANTED IN RIGHT FALLOPIAN TUBE BROKE OFF AND THAT PART OF THE DEVICE HAD MIGRATED INTO PELVIS (PREVIOUSLY REPORTED AS PROXIMAL MARKER IS IN THE CORNUA AND THE REST OF THE DEVICE IS IN THE ABDOMEN). SHE WAS ALSO ADVISED THAT SHE WOULD DEFINITELY NOT BE ABLE TO BECOME STERILE WITH THE POSITION OF THE ESSURE DEVICE AND BECAUSE OF ITS SEPARATION. THIS CAUSED CONSUMER A GREAT DEAL OF CONCERN AND WORRY, AND SHE HAS BEEN ADVISED THAT SHE MUST UNDERGO LAPAROSCOPIC SURGERY TO HAVE THE SEPARATED DEVICE REMOVED AND HER RIGHT FALLOPIAN TUBE STERILIZED. SINCE LEARNING OF THE FOREGOING, CONSUMER HAS BEEN UNABLE TO SLEEP AND SHE WAS CONSTANTLY WORRIED THAT PART OF THE ESSURE DEVICE (FLOATING FREE IN HER PELVIS) WOULD PUNCTURE AN INTERNAL ORGAN OR CAUSE SOME OTHER PROBLEM. IT WAS STATED THAT HER SURGERY WILL BE SCHEDULED FOR (B)(6) 2014. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE WAS BROKEN ON RIGHT SIDE, THE TIP OF THE ESSURE DEVICE IMPLANTED IN RIGHT FALLOPIAN TUBE BROKE OFF AND PART OF THE DEVICE HAD MIGRATED INTO PELVIS (PREVIOUSLY REPORTED PROXIMAL MARKER WAS IN THE CORNUA AND THE REST OF THE DEVICE WAS IN THE ABDOMEN). THE REPORTED EVENTS WERE INTERPRETED AS ESSURE DISLOCATION INTO ABDOMINAL CAVITY AND BREAKAGE. DEVICE BREAKAGE IS A NON-SERIOUS AND UNLISTED EVENT ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE DEVICE DISLOCATION IS LISTED AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF THE REPORTED EVENTS ARE NOT KNOW; GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN OTHER

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REPORTABLE INCIDENT DUE TO DEVICE MALFUNCTION (DEVICE BREAKAGE). IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THE PERFORMED PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION (EVENT'S OUTCOME) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED VIA MEDICAL RECORDS ON 16-OCT-2015: HER MEDICAL HISTORY INCLUDED: USE OF ESTROGEN CREAM OCCASIONALLY FOR VAGINAL IRRITATION, MILD PROLAPSE OF BLADDER AND RECTUM, SHE COULD NOT RETAIN TAMPONS SINCE HER LAST DELIVERY WHICH WAS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00503	BAYER HEALTHCARE LLC	12/3/2014	12/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 04-NOV-2014, ARTICLE ENTITLED "ESSURE PERFORATION; AN INTRA ABDOMINAL SEARCH". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION AND HAD PERFORATION OF AN ESSURE DEVICE INTRA ABDOMINALLY AND ONLY THE DISTAL PART OF DE LEFT DEVICE WAS DETECTED AND REMOVED. TRADE NAME WAS REPORTED AS ESSURE. AUTHORS COMMENTS: A PERFORATION OF AN ESSURE DEVICE INTRA ABDOMINALLY CAN LEAD TO A LONG AND HARD SEARCH. ABSTRACT: OBJECTIVES: AUTHORS GOAL IS TO DESCRIBE THE DIFFICULTIES DURING THE SEARCH OF AN INTRA ABDOMINALLY PERFORATED ESSURE DEVICE AFTER HYSTEROSCOPIC STERILIZATION. METHODS: THIS IS A CASE REPORT OF A PATIENT WHO HAD A HYSTEROSCOPIC STERILIZATION WITH ESSURE DEVICES. ONLY AFTER 3 MONTHS THE LEFT DEVICE WAS NOT DETECTED IN A NORMAL POSITION BY ULTRASONIC EXAMINATION. THE PATIENT WAS ASYMPTOMATIC. RESULTS: AT FIRST A HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND IT SHOWED NO CONTRAST IN CONTACT WITH THE LEFT DEVICE. ALSO 4 MARKERS OF DE LEFT DEVICE WERE NOT ALIGNED. THIS STRONGLY INDICATED A PERFORATION OF THE LEFT ESSURE DEVICE. THEREFORE A DIAGNOSTIC LAPAROSCOPY WAS PERFORMED. ONLY THE DISTAL PART OF THE LEFT DEVICE WAS DETECTED AND REMOVED. A LEFT TUBECTOMY WAS PERFORMED. THERE WAS NO REMNANT OF THE DEVICE SEEN BY HYSTEROSCOPY. AFTER CONSULTATION OF THE ESSURE EXPERT TEAM A SECOND LAPAROSCOPY WITH GUIDANCE OF X-RAY WAS PLANNED. DURING A HARD SEARCH WE FOUND THE ESSURE DEVICE IN THE OMENTUM FULLY ENCAPSULATED. THE ESSURE DEVICE WAS REMOVED BY LAPAROSCOPIC SURGERY. THE RECOVERY OF THE PATIENT WAS UNEVENTFUL. CONCLUSIONS: A PERFORATION OF AN ESSURE DEVICE INTRA ABDOMINALLY CAN LEAD TO A LONG AND HARD SEARCH. AUTHORS WOULD STRONGLY ADVISE TO PERFORM A

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LAPAROSCOPIC PROCEDURE IN COMBINATION TO X-RAY. FOLLOW UP RECEIVED ON 18-NOV-2014. PTC GLOBAL NUMBER WAS RECEIVED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-DEC-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE, A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2014 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1. FALLOPIAN TUBE PERFORATION: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 173 CASES. 2. DEVICE BREAKAGE: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 886 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT WAS DERIVED FROM LITERATURE AND REFERS TO A FEMALE PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A PERFORATION OF AN ESSURE DEVICE INTRA ABDOMINALLY; A DIAGNOSTIC LAPAROSCOPY WAS PERFORMED AND ONLY THE DISTAL PART OF DE LEFT DEVICE WAS DETECTED AND REMOVED. PATIENT WAS SUBMITTED TO A SECOND LAPAROSCOPY WITH GUIDANCE OF X-RAY, ESSURE DEVICE WAS FOUND IN THE OMENTUM AND WAS REMOVED. SHE RECOVERED FROM THE EVENTS. THE REPORTED EVENTS, INTERPRETED AS FALLOPIAN TUBE PERFORATION AND DEVICE BREAKAGE WERE CONSIDERED SERIOUS, AS MEDICALLY SIGNIFICANT. DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE THE REMAINING EVENT IS LISTED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF THESE EVENTS ARE NOT KNOWN, GIVEN THEIR NATURE THEY WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT AND DUE TO THE REQUIRED INTERVENTIONS, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00504	BAYER HEALTHCARE LLC	12/4/2014	12/4/2014

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 12/9/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SOLICITED CASE REPORT FROM A CONSUMER IN THE UNITED STATES WAS DETECTED ON (B)(4) 2014 VIA (B)(6). THE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009, PROCEDURE WAS VERY PAINFUL, SINCE INSERTION SHE EXPERIENCED PAIN IN PELVIC AREA, IT HURTS WHEN SHE IS SITTING OR WALKING, MILD ENDOMETRIOSIS WAS DETECTED, SHE HAD PAINFUL CRAMPING THAT MADE HER LOSE HER BREATH SOMETIMES, IT WAS PAINFUL DURING INTERCOURSE, PERIODS WERE PAINFUL, LEGS FEEL TIRED ALL THE TIME, SHE HAD BAD HEADACHES, AND FEELS DEPRESSED. FOLLOW-UP INFORMATION WAS RECEIVED ON 15-OCT-2014. SHE HAD ESSURE (PERMANENT BIRTH CONTROL) IMPLANTED WHICH HER BODY WAS REJECTING AND WAS EXPERIENCING PELVIC PAIN SINCE SHE GOT THEM IN 2008. SHE WOKE UP WITH SHOOTING PAIN IN PELVIC AREA AND THE HIP. SHE STATED THAT THE ONLY SAFE WAY TO REMOVE ESSURE COILS WAS TAKING UTERUS AND THE TUBES TOGETHER. SHE WAS SCARED OF THE LIFE AFTER HYSTERECTOMY. SHE WAS ALSO SCARED OF GAINING WEIGHT, GOING INTO EARLY MENOPAUSE, NOT HAVING SEX LIFE, BUT SHE CANNOT LIVE WITH THE PAIN SHE WAS FEELING AT THE TIME OF THIS REPORT, IT HURTS WHEN SHE WAS SITTING, SHE FELT LIKE SOMEONE WAS STABBING HER DOWN, THE SEX WAS NOT ALL THAT ENJOYABLE BECAUSE OF THE PAIN. SHE WAS FEELING SCARED, SCARED, SCARED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED 22-OCT-2014: CONSUMER STATED THAT SHE IS GOING TO HAVE X-RAY PERFORMED BEFORE SURGERY TO MAKE SURE WHERE THE COILS ARE LOCATED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP 05.NOV.2014: FOLLOW UP INFORMATION PROVIDED BY CONSUMER. CASE UPGRADED FROM NON INCIDENT TO INCIDENT. CONSUMER REPORTED THAT IN 2008 SHE HAD ESSURE IMPLANTED BECAUSE HER OLD OBSTETRIC TALKED HER INTO IT. SINCE THEN HER SYMPTOMS STARTED SLOWLY 6 MONTHS TO A YEAR AFTER THE

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PROCEDURE WAS DONE AND HER HEALTH STARTED GOING DOWN. PRIOR TO THE PROCEDURE SHE WENT TO DOCTOR FOR HER ROUTINE ANNUAL PHYSICALS ONLY BUT AFTER 2008 SHE HAD SEEN UROLOGIST, GASTROENTEROLOGIST AND WAS TOLD SHE SHOULD SEE RHEUMATOLOGIST. OBSTETRIC VISITS, TESTS, ETC. IT STARTED WITH PELVIC PAINS (DULL, SHARP, STABBING, CRAMPING. ETC.). HER NEW DOCTOR TOLD HER IT WOULD BE PROBABLY ENDOMETRIOSIS AND SHE DID LAPAROSCOPY (NO RESULTS MENTIONED). SHE WAS TOLD IT WAS MILD CASE AFTER THE SURGERY AND SHE WASN'T SURE IF THAT WAS CAUSING HER PAIN. AFTER THAT SURGERY SHE GOT HERNIA ABOVE HER BELLY BUTTON AND HAD TO HAVE SURGERY BUT THE HERNIA CAME BACK ONE YEAR LATER AND SHE HAD TO HAVE ANOTHER SURGERY A COUPLE YEARS AFTER THAT. SHE DECIDED TO GO BACK TO THE DOCTOR AND TO FIND OUT WHAT WAS GOING ON WITH HER. HER OBSTETRIC SUGGESTED LAPAROSCOPY TO CHECK ENDOMETRIOSIS BUT THIS TIME SHE SAID NO. SHE SENT HER TO UROLOGIST. UROLOGIST SAID THAT HER PELVIC MUSCLES WERE INFLAMED AND THAT SHE NEEDED A PHYSICAL THERAPY. DURING THE 5 MONTHS OF THE PAINFUL THERAPY SHE ALSO DID TRIGGER POINT INJECTIONS TO HER PELVIC MUSCLES TWO DIFFERENT TIMES. SHE WAS ALSO SENT TO GASTROENTEROLOGIST AND SHE WAS TOLD SHE HAD IBS (IRRITABLE BOWEL SYNDROME). HER BODY FELT TIRED ALL THE TIME AND SHE HAD NO ENERGY. SHE GAINED 40 POUNDS SINCE THE ESSURE AND WAS DIAGNOSED WITH DEPRESSION. CONSUMER NEVER CONNECTED DOTS THAT HER ISSUES COULD BE RELATED TO ESSURE UNTIL SHE SAW ON TV HOW MANY WOMEN DEVELOPED THE SAME ISSUES AFTER THE COILS WERE IMPLANTED IN THEIR BODIES. SHE STARTED HER RESEARCH AND SHE WAS SHOCKED. SHE WAS ANGRY THAT HER OLD OBSTETRICS NEVER TOLD HER ABOUT ANY SIDE EFFECTS AND SHE WAS NEVER TESTED FOR NICKEL ALLERGY. SO, SHE WAS NOT SURE IF SHE HAD ALLERGIC REACTION TO THE METALS IN COILS. SHE WAS HAPPY THAT SHE FOUND THE DOCTOR THAT WAS AWARE OF THE ESSURE COMPLICATIONS AND SIDE EFFECTS AND HOW IT COULD BE THE CAUSE OF HER HEALTH ISSUES. HE AGREED THAT ESSURE HAD TO COME OUT AND TOLD HER THAT THE SAFEST WAY TO REMOVE COILS WAS BY REMOVING TUBES AND THE UTERUS AS A WHOLE. THIS WAY THE RISK OF THE FRAGMENTS BEING LEFT BEHIND IS MINIMIZED. HER SURGERY WAS SCHEDULED FOR (B)(6) 2014 (TLH, TOTAL LAPAROSCOPIC HYSTERECTOMY, KEEPING 1 OR BOTH OVARIES) AND SHE WAS GETTING REALLY NERVOUS. SHE WAS SCARED OF COMPLICATIONS, LONG TERM SIDE EFFECTS AND THAT SHE WAS GOING TO REGRET HAVING HYSTERECTOMY. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION RECEIVED ON 25-NOV-2014. THE CONSUMER STATED THAT HER SURGERY WAS SCHEDULE FOR (B)(6) AND HER UTERUS, CERVIX AND TUBES WOULD BE REMOVED. COMPANY CAUSALITY COMMENT: THIS SOLICITED CASE REPORT, RECEIVED VIA SOCIAL MEDIA, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN IN PELVIC AREA, HURTS WHEN SHE WAS SITTING OR WALKING, PELVIC PAINS, DULL, SHARP, STABBING, CRAMPING AND HERNIA CAME BACK ONE YEAR AND SHE HAD TO HAVE ANOTHER SURGERY. THE EVENTS THAT WERE INTERPRETED AS PELVIC PAINS AND UMBILICAL HERNIA REPAIR ARE SERIOUS DUE THEIR MEDICAL IMPORTANCE. THE PELVIC PAIN IS LISTED, WHILE THE UMBILICAL HERNIA IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL,

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PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE CONSUMER STARTED TO EXPERIENCE PELVIC PAINS SINCE INSERTION WHICH WAS INITIALLY DIAGNOSED AS ENDOMETRIOSIS BY HER PHYSICIAN, AS SUSPICION OF INFLAMMATION IN PELVIC MUSCLES BY UROLOGIST AND AS IRRITABLE BOWEL SYNDROME BY THE GASTROENTEROLOGIST. ENDOMETRIOSIS COULD BE THE CAUSE OF THIS INTENSE PELVIC PAIN. HOWEVER, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED AND CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. DURING ESSURE USE, SHE ALSO EXPERIENCED TWO EPISODES OF UMBILICAL HERNIA THAT WERE CORRECTED WITH SURGERY. GIVEN THE NATURE OF UMBILICAL HERNIAS, THIS EVENT IS CONSIDERED UNRELATED TO ESSURE. CONSIDERING A LAPAROSCOPY WAS PERFORMED, THE CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 10-DEC-2014 FROM CONSUMER: SHE STATED VIA SOCIAL MEDIA THAT SHE HOPE SHE GET HER ENERGY BACK. SHE GAINED (B)(6) SINCE ESSURE WAS IMPLANTED 6 YEARS AGO AND HOPEFULLY BY REMOVING THIS TOXIC OUT OF HER BODY SHE WILL GET HER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00505	BAYER HEALTHCARE LLC	12/4/2014	12/4/2014

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 11/22/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 06-NOV-2014 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011 FOR PERMANENT STERILIZATION. PHYSICIAN REPORTED THAT DURING ESSURE INSERTION THERE WAS NO DIFFICULTY, NO ISSUES, 4 TRAILING COILS ON LEFT AND NONE ON RIGHT. AROUND 2011, PATIENT UNDERWENT TWO HYSTEROSALPINGOGRAMS (HSGS): 3 MONTHS HSG RIGHT OCCLUDED GOOD LOCATION AND LEFT 50% COIL TRAILING BY HALF OF DEVICE IN ENDOMETRIAL CAVITY AND PATENT, 3 MONTHS ANOTHER HSG- SAID LEFT SIDE WAS OCCLUDED BUT UNSATISFACTORY LOCATION GREATER THAN 50% OF INNER COIL TRAILING, RIGHT SIDE TUBAL PERFORATION MYOMETRIAL OR PERITONEAL LOCATION HAD PATENCY. TWO DIFFERENT RADIOLOGISTS PERFORMED THE HSGS. DURING (B)(6) 2012 PATIENT HAD ANOTHER CONFIRMATION TEST DONE, WHERE THERE WAS SUCCESSFUL OCCLUSION ON RIGHT SIDE AND ON LEFT SIDE THERE WAS NO OCCLUSION. IN (B)(6) 2012 IT WAS PERFORMED A LAPAROSCOPY-ELECTROCAUTERY AND TIED THE TUBES ABOUT 3CM DOWN DID NOT APPRECIATE ANY COILS. THE HEALTH PROFESSIONAL DID AN "ELECTRO CAUTERING" TO BLOCK FALLOPIAN TUBE. JUST RECENTLY, IN (B)(6) 2014, PATIENT EXPERIENCED SEVERE ABDOMINAL PAIN, HAVING PAIN, LEFT SIDE PAIN STARTED TWO CYCLES AGO, ACUTE PELVIC PAIN, AND SHE WENT TO EMERGENCY ROOM AND DID NOT SEE ANY CYST RUPTURE. PATIENT HAD AN XRAY AND ULTRASOUND PERFORMED AND THE HEAD OF RADIOLOGY REPORTED THAT THE TESTS SHOWED 1.4CM OF COIL IN THE ENDOMETRIAL CAVITY, AND THE RADIOLOGIST HAS CONCERN THAT IT IS PERFORATING THE MYOMETRIUM. RIGHT SIDE IS IN CORRECT LOCATION. NOW PATIENT WANTED THE COILS OUT. IT`S BEEN THREE YEARS, PHYSICIAN IS UNSURE OF HOW TO REMOVE IT AND DISCUSSED THIS FURTHER AND SHE SUGGESTED EVALUATING VIA HYSTEROSCOPY TO EVALUATE THE CURRENT LOCATION OF THE INSERT AND DETERMINE ITS

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LOCATION DUE TO THE DIFFERENCE IN REPORTS. SHE ASKED IF SHE COULD CUT THE INSERT. DOCTOR ALSO ASKED ABOUT REMOVAL ON THE OTHER SIDE. PHYSICIAN REFUSED ANY AVAILABLE DOCUMENTATION AND WANTED TO SPEAK WITH SOMEONE LIVE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 20-NOV-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. PTC GLOBAL NUMBER IS (B)(4). FOLLOW UP INFORMATION RECEIVED ON 06-NOV-2014: NO NEW INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AROUND 2011, SHE UNDERWENT TWO HYSTEROSALPINGOGRAM (HSGS): 3 MONTHS HSG RIGHT OCCLUDED GOOD LOCATION AND LEFT 50% COIL TRAILING BY HALF OF DEVICE IN ENDOMETRIAL CAVITY AND PATENT (INTERPRETED AS DEVICE DISLOCATION) AND 3 MONTHS ANOTHER HSG- SAID LEFT SIDE WAS OCCLUDED BUT UNSATISFACTORY LOCATION GREATER THAN 50% OF INNER COIL TRAILING, RIGHT SIDE TUBAL PERFORATION MYOMETRIAL OR PERITONEAL LOCATION HAD PATENCY. IN (B)(6) 2014, SHE UNDERWENT AN X-RAY AND ULTRASOUND WHICH SHOWED 1.4CM OF COIL IN THE ENDOMETRIAL CAVITY, RADIOLOGIST HAS CONCERN THAT IS PERFORATING THE MYOMETRIUM (INTERPRETED AS SUSPICION OF UTERINE PERFORATION). THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT DURING ESSURE PLACEMENT THERE WAS NO DIFFICULTY, HOWEVER 4 TRAILING COILS ON LEFT AND NONE ON RIGHT (CONSIDERED AS DEVICE MISDEPLOYMENT (LOCATION)). AT 3 MONTHS, AN HSG SHOWED LEFT 50% COIL TRAILING BY HALF OF DEVICE IN ENDOMETRIAL CAVITY AND PATENT AND ANOTHER HSG SHOWED LEFT SIDE WAS OCCLUDED BUT UNSATISFACTORY LOCATION GREATER THAN 50% OF INNER COIL TRAILING, RIGHT SIDE TUBAL PERFORATION MYOMETRIAL OR PERITONEAL LOCATION HAD PATENCY. A LAPAROSCOPY-ELECTROCAUTERY AND TIED THE TUBES WERE PERFORMED. 2 YEARS LATER, A SUSPICION OF UTERINE PERFORATION OCCURRED. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE PATIENT UNDERWENT A LAPAROSCOPY-ELECTROCAUTERY. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW UP INFORMATION (TUBAL PERFORATION QUESTIONNAIRE) RECEIVED ON 16-MAR-2015 FROM PHYSICIAN: PATIENT'S WEIGHT AND HEIGHT WERE ADDED. THE PATIENT WAS GRAVIDA 5 AND PARA 4 WITH 1 VOLUNTARY PREGNANCY TERMINATION. HER LAST DELIVERY WAS IN 2009 AND IT WAS N

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039425	BAYER	12/4/2014	12/11/2014

Event Information:

Event Date (B3): 3/23/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/13/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE DEVICES PUT IN (B)(6) 2009. HAVE HAD HEADACHES, BLOATING, SWELLING, SEVERE ABDOMINAL PAIN, AND SHARP STABBING PAINS. I AM HAVING TEST DONE NOW FOR POSSIBLE TOXICITY DO TO THE NICKEL IN THESE DEVICES AND WILL KNOW SHORTLY IF THEY HAVE POISONED ME. ALSO MAY END UP HAVING TO HAVE HYSTERECTOMY OR SOME KIND OF SURGERY TO GET THESE TOXIC COILS OUT OF MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039426	BAYER	12/4/2014	12/11/2014

Event Information:

Event Date (B3): 7/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/11/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE SINCE 2011. WHEN IT WAS PLACED I HAD SEVERE PAIN THAT HAS BEEN THERE EVER SINCE ON MY RIGHT LOWER QUADRANT. I HAVE PERIODS THAT DON'T END, THEY MAY LIGHTEN TO SPOTTING BUT NEVER END). MIGRAINES, SKIN ISSUES, DENTAL PROBLEMS, I HAVE BEEN CHECKED DUE TO SYMPTOMS OF TIA AND SEIZURES, HAVE BEEN PLACED ON HEART MONITORS. NONE OF THE PROBLEMS WERE BEFORE THIS PROCEDURE. I AM NOW, AT AGE 38 GOING TO HAVE A HYSTERECTOMY TO REMOVE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039436	CONCEPTUS, INC.	12/4/2014	12/11/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): OTHER	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE AS A PERMANENT BIRTH CONTROL IN 2011. I HAVE HAD SEVERAL ISSUES SINCE THIS DEVICE WAS PLACED IN ME. SOME OF MY PROBLEMS ARE ABNORMAL BLEEDING BEING ON MY MENSTRUAL CYCLE FOR 30+ DAYS AND VERY HEAVY, CRAMPING, ALONG WITH CRAMPING I HAVE PAINS THAT ALL OF A SUDDEN TRAVEL TO MY LEGS, FREQUENT INFECTIONS AMONG SOME OTHERS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00506	BAYER HEALTHCARE LLC	12/4/2014	12/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT ONE DEVICE DID NOT DETACH AND WAS WHEELED BACK A SECOND TIME; AND WOULD NOT DETACH AND UNRAVELED. THE SECOND DEVICE THE MICRO INSERT DID NOT DETACH AND WAS PULLED BACK TWICE AND THE GREEN TUBING WAS STILL IN THE PATIENT AND UNRAVELED. CONSUMER HAD BILATERAL ESSURE PLACEMENT. FOLLOW UP (B)(4) 2014: PTC INVESTIGATION RESULTS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DETACHMENT DIFFICULTY AND DEVICE BREAKAGE EVENTS DURING THE PROCEDURE ARE ANTICIPATED EVENTS. FINAL RISK CLASSIFICATION: RISK CATEGORY IV. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL

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QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE ONE DEVICE DID NOT DETACH AND WAS WHEELED BACK A SECOND TIME; IT WOULD NOT DETACH AND UNRAVELED. FOR THE SECOND DEVICE THE MICRO INSERT DID NOT DETACH AND IT WAS PULLED BACK TWICE AND THE GREEN TUBING WAS STILL IN THE PATIENT AND UNRAVELED. THESE EVENTS, INTERPRETED AS DEVICE DEPLOYMENT ISSUE, HANDLING ERROR AND BREAKAGE WERE CONSIDERED NON-SERIOUS AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. EVENT DEVICE BREAKAGE WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, AS THE REPORTED DEVICE DEPLOYMENT ISSUE AND BREAKAGE OCCURRED DURING ESSURE INSERTION, THEIR CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED HANDLING ERRORS (DEVICE UNRAVELED), GIVEN THEIR NATURE, THEY WERE CONSIDERED AS UNRELATED TO ESSURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE MALFUNCTION (BREAKAGE). THE PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND STATED THAT THE POSSIBILITY OF A DETACHMENT DIFFICULTY AND DEVICE BREAKAGE EVENTS DURING THE PROCEDURE ARE ANTICIPATED EVENTS. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 12-MAR-2015 NO RESPONSE WAS OBTAINED AFTER FOLLOW-UP ATTEMPTS. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCL

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00507	BAYER HEALTHCARE LLC	12/4/2014	12/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20214171

Single Use: Y
Implant Date (E6): 12/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4)2014 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009 FOR BIRTH CONTROL. IN (B)(6) 2014, PATIENT EXPERIENCED MILD DISCOMFORT. ULTRASOUND WAS DONE AND WAS NEGATIVE (NOT SPECIFIED). IN (B)(6) 2014, SHE WAS STILL WITH DISCOMFORT, SO ANOTHER ULTRASOUND WAS DONE ON (B)(6) 2014 AND SHOWED A FOREIGN BODY IN LOWER UTERINE SEGMENT. ON AN UNSPECIFIED DATE, DOCTOR REMOVED THE OUTER COIL FROM THE CERVICAL CANAL WITHIN THE LAST 2 WEEKS. INNER COIL COULD NOT ANYWHERE TO BE FOUND (WHAT SIDE THAT THIS OCCURRED WAS UNCLEAR). HSG WAS DONE ON (B)(6) 2014 AND SHOWED NO DEVICE ON ONE SIDE, AND DEVICE AND OCCLUSION ON THE OTHER SIDE. NO VISIBLE SIGN OF PERFORATION. THE OUTCOME OF THE EVENT PATIENT WITH MILD DISCOMFORT/STILL WITH DISCOMFORT WAS NOT RECOVERED / NOT RESOLVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR LARGE TIGHT PITCH COIL. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED

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WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE IN THE CONTEXT OF A COMPLICATED DEVICE REMOVAL. THE AE CASE REFERS TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT INNER COIL COULD NOT ANYWHERE TO BE FOUND. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THE DEVICE BREAKAGE OCCURRED DURING REMOVAL. IT WAS REPORTED THAT DOCTOR REMOVED THE OUTER COIL FROM THE CERVICAL CANAL WITHIN THE LAST 2 WEEKS. INNER COIL COULD NOT ANYWHERE TO BE FOUND (WHAT SIDE THAT THIS OCCURRED WAS UNCLEAR). BASED ON THIS INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. FURTHER INFORMATION IS BEING SOUGHT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014. THE PATIENT´S WEIGHT WAS (B)(6) AND 172.5 CM (BMI (B)(6)). HER CONCURRENT CONDITION INCLUDED OVERWEIGHT. CERVICAL CONIZATION, CURETTAGE, PREVIOUS IUD/IUS, MYOMECTOMY, ADNEXAL SURGERY, GYNECOLOGICAL PROBLEMS O

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	12/4/2014	1/14/2015

Event Information:

Event Date (B3): 7/31/2014 **Report Date (B4): 12/4/2014** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL
Model # (E4): ESS305
Catalog # (E4): *
Lot #(E4): A78084

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT CAME IN FOR AN OUTPATIENT PROCEDURE FOR PERMANENT STERILIZATION. DURING PLACEMENT OF ESSURE DEVICE ON THE RIGHT OSTIA, DEVICE FAILED TO DEPLOY AND DID NOT RELEASE ON THE SECOND RECOILING. WHEN REMOVING THE DEVICE, MOST OF THE COIL WAS OUT. UNABLE TO REMOVE HALF OF THE DEVICE. DECISION WAS MADE TO PROCEED WITH THE PROCEDURE LAPAROSCOPICALLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039461	BAYER	12/5/2014	12/12/2014

Event Information:

Event Date (B3): 11/28/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/10/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HSG TEST FOR ESSURE PROCEDURE SHOWED JUST MY LEFT TUBE BLOCKED AFTER OVER 4 MONTHS AFTER THE PROCEDURE. RIGHT ONE UNBLOCKED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039459	BAYER	12/6/2014	12/12/2014

Event Information:

Event Date (B3): 9/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/17/2014
Explant Date (E7): 11/26/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD NONSTOP BLEEDING SINCE IMPLANT OF ESSURE, CONSTANT PAIN, HEADACHES, WEIGHT GAIN, COULDN'T BE INTIMATE WITH MY HUSBAND AS IT HURT TOO BAD, WAS ALWAYS TIRED, CRANKY AND IRRITABLE, HAD RASHES, ALMOST CONSTANTLY JOINT PAIN, SEVERE ABDOMINAL PAIN ALL OF WHICH IS GONE NOW WHAT I HAD A COMPLETE HYSTERECTOMY, ESSURE RUINED MY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039460	CONCEPTIS, INC.	12/6/2014	12/12/2014

Event Information:

Event Date (B3): 6/1/2002 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 6/1/2002
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN 2002. SINCE THAT TIME PAIN, FATIGUE, AND LOSS OF HAIR HAVE BEEN A MAJOR ISSUE. I HAVE BEEN TO THE DOCTOR AND THEY HAVE RAN ALL BLOOD WORK AND SONOGRAMS TO FIGURE OUT WHAT IS CAUSING IT. EVERYTHING COMES BACK NORMAL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00509	BAYER HEALTHCARE LLC	12/8/2014	12/8/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 11-NOV-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT PATIENT HAD DIFFICULT ESSURE PLACEMENT. THE REPORTER STATED THAT THERE WERE NO TRAILING COILS. THEN, SHE CHECK THE INSERTERS AND THE COILS WERE NOT PRESENT. AN X-RAY WAS DONE ON THE DAY OF THE PLACEMENT AND COILS WERE PRESENT BUT NOT VISIBLE IN THE TUBES. FIVE DAYS LATER, A LAPAROSCOPY WAS DONE TO DO BILATERAL SALPINGECTOMY AND COILS WERE NOT IN TUBES UPON REMOVAL OR VISUALIZABLE. FOLLOW UP INFORMATION IS NOT EXPECTED SINCE REPORTER FORBIDS FURTHER CONTACT OR INTERVIEW. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS

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PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBES OCCLUSION INSERT) INSERTED. THE INSERTION WAS DIFFICULT AND IN THE SAME DAY OF PLACEMENT, THE X-RAY SHOWED THAT COILS WERE PRESENT BUT NOT VISIBLE IN THE TUBES. THE EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, DURING THE DIFFICULT INSERTION PROCEDURE, THE PHYSICIAN DID NOT FIND THE COILS. SHE CHECKED THE INSERTERS BUT THE DEVICES WERE NOT THERE. X-RAY WAS PERFORMED AND SHOWED THE COILS WERE PRESENT BUT NOT VISIBLE IN TUBES. THEN, FIVE DAYS LATER, A LAPAROSCOPY WAS DONE TO PERFORM BILATERAL SALPINGECTOMY AND UPON REMOVAL, THE MICRO-INSERTS WERE NOT IN TUBES AND WERE NOT VISUALIZED. GIVEN THE NATURE OF THE EVENT, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE AND SINCE BILATERAL SALPINGECTOMY (SERIOUS INJURY) WAS PERFORMED, THE CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW UP INFORMATION IS NOT EXPECTED SINCE REPORTER FORBIDS FURTHER CONTACT OR INTERVIEW.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00508	BAYER HEALTHCARE LLC	12/8/2014	12/16/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38213

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/30/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C38213 (EXPIRATION DATE 31-MAR-2017) INSERTION ATTEMPTED. AFTER INSERTION OF DELIVERY SYSTEM IN RIGHT FALLOPIAN TUBE, DURING RELEASE OF DEVICE, THE DELIVERY SYSTEM WAS CAUGHT IN DEVICE AND LED TO INCOMPLETE RELEASE. THE DELIVERY SYSTEM BROKE AND HALF OF THE DEVICE WAS IN FALLOPIAN TUBE. DEVICE AND DELIVERY SYSTEM WAS REMOVED. ANOTHER ATTEMPT TO INSERT DEVICE FAILED DUE TO STRESS OF PATIENT DURING INTERVENTION. INSERTION WAS STOPPED AND POSTPONED. NO FURTHER INFORMATION WOULD BE AVAILABLE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: AS OF (B)(4) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE AND DIFFICULTY DETACHMENT EVENT ARE ANTICIPATED EVENTS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE

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WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE DELIVERY SYSTEM WAS CAUGHT IN DEVICE AND LED TO INCOMPLETE RELEASE. DELIVERY SYSTEM BROKE AND HALF OF THE DEVICE WAS IN FALLOPIAN TUBE (COMPLICATION OF DEVICE INSERTION). ANOTHER ATTEMPT TO INSERT DEVICE FAILED DUE TO STRESS OF PATIENT DURING INTERVENTION. INSERTION WAS STOPPED. THE REPORTED EVENTS, INTERPRETED AS DEVICE DEPLOYMENT ISSUE, BREAKAGE AND FAILED INSERTION DUE TO PATIENT UNSPECIFIED STRESS, WERE CONSIDERED NON-SERIOUS. STRESS IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE THE REMAINING EVENTS ARE LISTED. DEVICE BREAKAGE WAS PREVIOUSLY REGARDED AS UNLISTED; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. IN THIS PARTICULAR CASE, CONSIDERING THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED; AND GIVEN THE REPORTED DEVICE MALFUNCTION (BREAKAGE) THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 06-JAN-2015: THIS CASE REFERS TO (B)(6) FEMALE PATIENT. PATIENT HISTORY INCLUDES INFECTIONS WITH IUD AND SHE WAS MULTIPAROUS AND DID NOT TOLERATE ORAL CONTRACEPTION. DURING THE INSERTION PROCEDURE, THE HYSTEROSCOPY FOUND

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039561		12/8/2014	12/16/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/17/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE STERILIZATION IN (B)(6) 2009. IN (B)(6) 2011, I HAD TO HAVE SURGERY TO REMOVE MY RIGHT DEVICE AND FALLOPIAN TUBE. THE DEVICE WAS LODGED IN MY WOMB AND THEREFORE HAD TO HAVE A REPAIR TO MY WOMB. I FELT BETTER FOR SOME TIME, BUT SINCE 2011 MY HEALTH HAS PROGRESSIVELY GONE DOWN HILL, HEAVY AND PROLONGED PERIODS INCLUDING LARGE CLOTS, SEVERE PAIN IN MY LOWER STOMACH AND BACK, AND WEIGHT GAIN. I HAVE JUST HAD FURTHER TESTS CARRIED OUT IN HOSPITAL WHICH HAS CONFIRMED MY LEFT DEVICE HAS MOVED TO THE RIGHT SIDE OF MY BODY. I AM CURRENTLY AWAITING MY SECOND SURGERY DUE TO ESSURE STERILIZATION. I AM IN DAILY PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00512	BAYER HEALTHCARE LLC	12/9/2014	12/9/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5037833) IN UNITED STATES ON 12-NOV-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. ACCORDING TO THE CONSUMER, SHE HAD ESSURE COILS PLACED IN 2013. EVER SINCE THEN, SHE HAD EXCRUCIATING PELVIC PAIN, ABDOMINAL AND PELVIC PAIN (TO THE POINT OF CRYING AFTER INTERCOURSE), MIGRAINES EVERYDAY AND EXCESSIVE ITCHING. SHE WAS HOSPITALIZED FOUR TIMES BECAUSE OF PAIN IN HER PELVIS. IT FELT LIKE A SHARP STAB OR PINCHED NERVE. SHE WAS BLOATED ALL THE TIME AND FELT NAUSEATED EVERYDAY. ESSURE COMPLETELY RUINED HER AND HER CHILDREN'S LIVES BECAUSE EVER SINCE SHE GOT IT, HER HEALTH AND DAILY ACTIVITIES HAVE GONE DOWNHILL. SHE WAS NEVER WARNED BY ANY DOCTORS THAT THE IMPLANTS WERE NICKEL; SHE WAS ALLERGIC TO NICKEL. SHE HAD THREE MISCARRIAGES SINCE SHE HAD THE ESSURE COILS PLACED (OTHER 2 CASES WERE CREATED). CORRECTION PERFORMED ON (B)(6) 2014: AFTER INTERNAL REVIEW, THE LISTEDNESS OF THE EVENT MISCARRIAGE WAS AMENDED TO UNLISTED. THE EVENT PRURITUS WAS CHANGED TO LISTED AND ITS COMPANY CAUSALITY WAS AMENDED TO RELATED TO ESSURE. ALSO, SINCE THE CONSUMER STATED THAT SHE WAS NAUSEATED EVERYDAY, THE NAUSEA DID NOT OCCUR POST INSERTION PROCEDURAL, THEREFORE, IT WAS CONSIDERED UNLISTED TOO. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 04-DEC-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE

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TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, EXPERIENCED PAIN IN MY PELVIS, IT FEELS LIKE A SHARP STAB OR PINCHED NERVE IN MY PELVIS, BECAME PREGNANT AND MISCARRIED. PELVIC PAIN IS SERIOUS DUE HOSPITALIZATION AND LISTED. PREGNANCY IS NON-SERIOUS AND ALSO LISTED, WHILE MISCARRIAGE IS SERIOUS DUE MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE. PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. THEREFORE, A DEVICE INEFFICACY CANNOT BE TOTALLY EXCLUDED AND CAUSAL RELATIONSHIP WITH ESSURE USE IS ASSESSED AS RELATED. ALTHOUGH GESTATIONAL AGE HAS NOT BEEN PROVIDED, SPONTANEOUS ABORTIONS OCCUR MOSTLY DURING THE (B)(6) WEEKS OF PREGNANCY AND THE VAST MAJORITY OF THESE CASES ARE DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS, SO THE EVENT IS CONSIDERED AS UNRELATED TO ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS REPORT, SINCE THE INSERTION, THE PATIENT EXPERIENCED EXCRUCIATING PELVIC PAIN AND WAS HOSPITALIZED FOUR TIMES DUE TO THIS PAIN. GIVEN THE NATURE OF THE EVENT AND THE FACT THAT IT LED TO HOSPITALIZATION, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE AND THE CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00510	BAYER HEALTHCARE LLC	12/9/2014	12/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38211

Single Use: Y
Implant Date (E6): 11/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/25/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN FRANCE ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C38211. THE PROBLEM HAPPENED IN THE GYNECOLOGICAL OPERATING ROOM. AT THE PLACEMENT OF ESSURE SYSTEM, IT WAS NOT POSSIBLE TO RELEASE IT IN THE FALLOPIAN TUBE. INDEED, THE COIL WAS ATTACHED TO THE SHEATH THAT SURROUNDED IT. THE SHEATH AND THE INSERT HAD TO BE REMOVED BY REMOVING THE DELIVERY CATHETER. ONE PART OF THE COIL WAS REMOVED AND A PORTION OF THE INSERT REMAINED IN INTRATUBULAR AREA. LIGATING OF THE UTERINE TUBES WAS PERFORMED VIA CELIOSCOPY DUE TO FAILURE OF THE METHOD WITH ESSURE SYSTEM. SERIOUSNESS WAS NOT REPORTED BY THE REPORTER. FOLLOW UP INFORMATION RECEIVED ON 26-NOV-2014: THE PATIENT HAD NO PARTICULAR PAST MEDICAL HISTORY. THE PATIENT HAD A TWIN PREGNANCY WHICH DELIVERY WAS A C-SECTION IN 2010; SHE ALSO HAD AN ELECTIVE ABORTION IN 2012. ON (B)(6) 2014, THE PATIENT HAD HER UTERINE TUBES TIED VIA CELIOSCOPY DUE TO FAILURE OF THE METHOD WITH ESSURE. WHEN THE FIRST ESSURE WAS PLACED IN THE LEFT FALLOPIAN TUBE, IT WAS IMPOSSIBLE TO RELEASE THE INSERT WHICH LED TO PARTIAL REMOVAL OF ESSURE SYSTEM. NO FURTHER INFORMATION WILL BE AVAILABLE. CASE CLOSED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-NOV-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO

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DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 20-NOV-2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF AND DETACHMENT DIFFICULTY EVENTS DURING THE PROCEDURE ARE ANTICIPATED EVENTS. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE IN THE CONTEXT OF A DIFFICULT DEVICE INSERTION. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFECT CANNOT BE ASSESSED. SAMPLE IS EXPECTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE ESSURE SYSTEM WAS UNABLE TO BE RELEASED IN THE FALLOPIAN TUBE/THE COIL WAS ATTACHED TO THE SHEATH THAT SURROUNDED IT. THE DELIVERY CATHETER WAS REMOVED AND ONE PART OF THE COIL WAS REMOVED AND A PORTION OF THE INSERT REMAINED IN INTRATUBULAR AREA. THESE EVENTS, INTERPRETED AS A DEVICE DEPLOYMENT ISSUE, BREAKAGE AND REMOVAL FAILURE WERE CONSIDERED NON-SERIOUS. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THE EVENTS ARE LISTED. PRODUCT TECHNICAL ANALYSIS (PTC) CORROBORATES THIS BY STATING THAT THERE IS A POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF AND DETACHMENT DIFFICULTY EVENTS DURING THE PROCEDURE AND THEREFORE THEY ARE ANTICIPATED EVENTS. DURING ESSURE REMOVAL, ESSURE MICRO-INSERT MAY BREAK. IN THIS CASE, THE PHYSICIAN HAD DIFFICULTIES IN THE DEPLOYMENT OF THE DEVICE; HE TRIED TO REMOVE IT UNSUCCESSFULLY AND A BREAKAGE OCCURRED. IT WAS ALSO REPORTED THAT THE PATIENT WAS SUBMITTED TO A TUBAL LIGATION DUE TO FAILURE OF THE METHOD WITH ESSURE SYSTEM. CONSIDERING THAT THE REPORTED EVENTS OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE. SO FAR, NEITHER BATCH NUMBER NOR SAMPLE WAS PROVIDED, THUS THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. A REVIEW OF THE MANUFACTURING BATCH RECORD WAS CONDUCTED AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME, A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFECT CANNOT BE ASSESSED. FURTHER INFORMATION IS EXPECTED AFTER THE RECEIPT OF ESSURE SAMPLE.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 09-APR-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C38211; PRODUCTION DATE: 20-MAR-2014; EXPIRATION DATE: 3

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00511	BAYER HEALTHCARE LLC	12/9/2014	12/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2014. IT WAS REPORTED THAT PATIENT WAS IN THE OR (OPERATING ROOM) AND PHYSICIAN HAD OPENED 3 ESSURE DEVICES UNTIL THE TIME OF THIS REPORT; 1 DEVICE DID NOT RELEASE THE COIL, 2 DEVICES HAVE BROKEN, AND THERE WERE SCREWS INSIDE THE TUBES. THE PTC INVESTIGATION RESULT (PTC NUMBER (B)(4)) RECEIVED ON 20-NOV-2014 HAD DISCREPANT INFORMATION AND A NEW PTC (B)(4) WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 25-NOV-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS:(B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 20-NOV-2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT,

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OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF AND DETACHMENT DIFFICULTY EVENTS DURING THE PROCEDURE ARE ANTICIPATED EVENTS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 01-DEC-2014: IT WAS REPORTED THAT FIRST DEVICE DID NOT DETACH FROM INSERTION CANNULA FOR 15 MINUTES. SECOND AND THIRD DEVICES APPEARED TO DEPLOY AN ADDITIONAL PART; IT LOOKED STRANGE AFTER DEPLOYMENT. THERE WERE ONLY 2 OR 3 COILS VISIBLE, BUT ADDITIONALLY PIECE (PERHAPS THE INNER COIL) WAS VISIBLE, SO IT WAS REMOVED WITH A GRASPING FORCEPS DURING HYSTEROSCOPY. PATIENT WAS FINE AFTER DISCHARGED HOME POST-OPERATIVELY. THERE WERE NO RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. NO RELATED DIAGNOSTIC TESTS WERE PERFORMED (ULTRASOUND, FLAT PLATE X-RAY, MRI, CAT-SCAN, RELEVANT BLOOD TESTS OR ALLERGY TESTS). NO PATHOLOGY RESULTS. NO HYSTERECTOMY AND SALPINGECTOMY WERE NECESSARY. NO PERFORATION OCCURRED. HOSPITALIZATION DID NOT OCCUR AND TREATMENT WAS NOT PROVIDED. ANY PREVIOUS GYNECOLOGICAL INTERVENTION, PROBLEMS AND PROCEDURES WERE DENIED. DIAGNOSTIC HYSTEROSCOPY WAS NORMAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE 1 DEVICE DID NOT RELEASE THE COIL, 2 DEVICES HAVE BROKEN AND THERE ARE SCREWS INSIDE THE TUBES/AN ADDITIONAL PIECE (PERHAPS THE INNER COIL) WAS VISIBLE. THESE EVENTS, INTERPRETED AS ESSURE DEPLOYMENT ISSUE AND BREAKAGE WERE CONSIDERED NON-SERIOUS. DEPLOYMENT ISSUE IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DEVICE BREAKAGE, PREVIOUSLY CONSIDERED UNLISTED, WAS, UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) UPDATED TO LISTED (ANTICIPATED). SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, AS THE REPORTED EVENTS OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE. OTHER NON-SERIOUS EVENT WAS REPORTED: 2ND AND 3RD DEVICE APPEARED TO DEPLOY AN ADDITIONAL PART/THERE WERE ONLY 2 TO 3 COILS VISIBLE/IT LOOKED STRANGE AFTER DEPLOYMENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039600		12/9/2014	12/17/2014

Event Information:

Event Date (B3): 3/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/11/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2013, DUE TO WHEN MY DAUGHTER WAS BORN IN 2010. I LOST A LOT OFF BLOOD, THEY COULD NOT TIE MY TUBES AT THAT TIME. SINCE SHE WAS BORN, I WOULD BLEED SO BAD I WOULD HEMORRHAGE. SO THE DOCTOR DECIDED TO DO A DNC, AND ABLATION. SINCE THAT TIME I HAVE GAINED OVER 50 LBS, I HAVE A SEVER STOMACH PAIN, I NOW HAVE COMPLEX MIGRAINES, HEART PALPITATIONS, CHEST PAIN, PASSING OUT EPISODES, I AM LOOSING MY HAIR IN CLIPS AND NOT TO MENTION THE MOOD SWINGS. MY DOCTOR TOLD ME THERE WAS NO COMPLICATIONS TO THESE SPRINGS. I WENT BACK TO HIM 3-4 TIMES. HE TOLD ME I WAS RETAINING FLUID UP THERE AND MY HORMONES WERE NOT RIGHT AND TRIED TO START MY MONTHLY COMING BACK. NOW, I AM ON A HUNT TO HAVE THESE REMOVED AND TRY TO GET ME BACK TO MY OLD SELF. IF THAT IS AT ALL POSSIBLE. IF IT WAS NOT FOR OTHER PEOPLE HAVING THESE SAME ISSUES, I WOULD HAVE THOUGHT I WAS LOOSING MY MIND WITH ALL THE TESTING THAT HAS BEEN DONE TO ME MEDICALLY AND NOTHING BE WRONG. NO ONE IS GOING TO PAY THE BILLS FOR ALL OF THIS BUT ME. THESE THINGS SHOULD NOT BE ALLOWED TO GO IN ANY MORE WOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039601		12/9/2014	12/17/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/6/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN MY FALLOPIAN TUBES (B)(6) 2010. SINCE THEN, I HAVE HAD HORRIBLE CRAMPS, WEIGHT GAIN, MIGRAINES, BACK PAIN, DEPRESSIONS, HIVES, CONFUSION AND MUCH MORE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00513	BAYER HEALTHCARE LLC	12/10/2014	12/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627312

Single Use: Y
Implant Date (E6): 10/21/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5032996) IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO HERSELF A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING AND PAIN IN PELVIC AREA, PAIN HAS NOW TAKEN OVER MY ENTIRE BODY, HEAVY BLEEDING, HORRIBLE RASH, ONE OF THE COILS HAD MIGRATED AND WAS NOT WHERE IT SHOULD BE, INCREASE IN MIGRAINE HEADACHES, INCREASE IN MUSCLE PAIN, INCREASE IN WEAKNESS, SEVERE DEPRESSION AND ANXIETY, BAD SWELLING THROUGHOUT MY BODY, AND BURNING PAIN IN MY LOWER BACK AND LEGS. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. SHE WAS NEVER TESTED FOR A NICKEL ALLERGY PRIOR TO HAVING THE ESSURE PUT IN. ON (B)(6) 2008 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER 627312. ON THE 3 MONTHS POST PROCEDURE, THE DOCTOR SHOWED HER THE ULTRASOUND AND COULD CLEARLY SEE THAT ONE OF THE COILS HAD MIGRATED AND WAS NOT WHERE IT SHOULD BE. SINCE THE PROCEDURE, THE CONSUMER HAS HAD SEVERAL HEALTH ISSUES. IMMEDIATELY FOLLOWING THE PROCEDURE, SHE HAD HORRIBLE CRAMPING AND PAIN WHICH STARTED IN HER PELVIC AREA AND HAS TAKEN OVER HER ENTIRE BODY AT THE TIME OF REPORT. THERE HAVE BEEN WEEKS THAT SHE WAS UNABLE TO GET OUT OF BED TO TAKE CARE OF HER FAMILY BECAUSE THE PELVIC PAIN WAS SO BAD. SHE HAD VERY HEAVY BLEEDING WHICH HER DOCTOR TREATED WITH ANOTHER PROCEDURE (HYSTEROSCOPIC THERMAL ABLATION). SHE HAS DEVELOPED A HORRIBLE RASH THAT WOULD NOT GO AWAY AND WAS GETTING WORSE DAY BY DAY, ALTHOUGH SHE HAD BEEN GIVEN SEVERAL MEDICATIONS BY THE DERMATOLOGIST NONE OF THEM WORKED. SHE HAS HAD AN INCREASE IN MIGRAINE HEADACHES AND MUSCLE PAIN AND WEAKNESS. SHE HAS ALSO DEVELOPED SEVERE DEPRESSION

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AND ANXIETY SINCE HAVING THE ESSURE PROCEDURE. SHE HAS ALSO HAD VERY BAD SWELLING THROUGHOUT HER BODY AND OFTEN GOT A BURNING PAIN IN HER LOWER BACK AND LEGS. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS RELATED. INTERNAL CORRECTION ON (B)(4) 2014 AFTER INTERNAL REVIEW, THIS CASE WAS CONSIDERED AS NON-INCIDENT (NONE INTERVENTION WAS DESCRIBED). A DOWNGRADE WAS PERFORMED. FOLLOW UP INFORMATION RECEIVED ON 14-NOV-2014: IT WAS REPORTED VIA SOCIAL MEDIA THE CONSUMER HAD HYSTERECTOMY DONE BECAUSE OF ESSURE. CASE INCIDENT CATEGORY AMENDED TO INCIDENT. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER (B)(4). FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH ONE CASE REFERS ALSO TO SIMILAR TYPES OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, CORRECTION ON (B)(4) 2014: FOLLOWING COMPANY INTERNAL REVIEW, THE LAST SENTENCE OF PREVIOUS NARRATIVE WAS AMENDED TO: IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING AND AN ULTRASOUND SCAN SHOWED ONE OF THE ESSURE COILS HAD MIGRATED AND WAS NOT WHERE IT SHOULD BE. SHE UNDERWENT A HYSTERECTOMY. THE REPORTED EVENTS, INTERPRETED AS GENITAL BLEEDING AND DEVICE DISLOCATION WERE CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; ALSO DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE REPORTED EVENTS AND ESSURE USE CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. ACCORDING TO PRODUCT TECHNICAL COMPLAINT ANALYSIS, A REVIEW OF THE MANUFACTURING BATCH RECORD CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. HOWEVER, SINCE NO PRODUCT RETURNED IT WAS NOT POSSIBLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. ALSO, 4 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH ONE CASE REFERS ALSO TO SIMILAR TYPES OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THEREFORE, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW UP INFORMATION (QUESTIONNAIRE TO RULE OUT PERFORATION) IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 29-AUG-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00514	BAYER HEALTHCARE LLC	12/10/2014	12/11/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/13/2014
Explant Date (E7): 8/14/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER VIA REGULATORY AUTHORITY (CASE# MW5037898) IN UNITED STATES ON 12-NOV-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2014. IT WAS REPORTED THAT UPON CHECKUP ON (B)(6)-2014, IT WAS DEEMED UNSUCCESSFUL BECAUSE ESSURE WAS BROKEN AND WAS NOT IN THE PROPER POSITION. ON (B)(6)-2014 ESSURE DEVICE AND TUBES WERE REMOVED. THE CONSUMER WAS STILL RECOVERING AND STILL IN PAIN. THE OUTCOME OF THE EVENT STILL IN PAIN WAS NOT RECOVERED / NOT RESOLVED, WHILE THE OUTCOME OF THE EVENTS NOT IN THE PROPER POSITION AND IT WAS BROKEN WAS RECOVERING / RESOLVING. AN INJURY (HOSPITALIZATION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP WILL BE REQUESTED PTC INVESTIGATION RESULT WAS RECEIVED ON 20-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS

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POSSIBLE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING CHECK UP IT WAS FOUND OUT THAT ESSURE WAS BROKEN AND WAS NOT IN PROPER POSITION. THE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND HOSPITALIZATION. THE FIRST EVENT, SEEN AS DEVICE BREAKAGE, IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT, INTERPRETED AS DEVICE DISLOCATION, IS LISTED. DURING DIFFICULT INSERTIONS OR REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE CHECK UP, PERFORMED A FEW MONTHS AFTER THE DEVICE PLACEMENT, SHOWED THAT ESSURE WAS BROKEN AND WAS NOT IN PROPER POSITION. THE TUBES AND DEVICES WERE REMOVED ONE MONTH LATER AND THE CONSUMER WAS HOSPITALIZED. IN THIS CASE, LIMITED INFORMATION WAS RECEIVED. THE CIRCUMSTANCES THAT LED TO HOSPITALIZATION AND SURGICAL INTERVENTION ARE NOT CLEAR, HOWEVER; GIVEN THE EVENT'S NATURE, CAUSALITY IS ASSESSED AS RELATED AND SINCE REQUIRED INTERVENTION WAS REPORTED, THE CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-MAR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00515	BAYER HEALTHCARE LLC	12/10/2014	12/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOCIAL MEDIA CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 AND REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT ESSURE WAS EMBEDDED OUTSIDE OF HER UTERUS. SHE HAD A HYSTERECTOMY AT (B)(6) YEARS OLD. SHE ALSO REPORTED PAIN AND SUFFERING. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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INSERTED AND ESSURE WAS EMBEDDED OUTSIDE OF HER UTERUS. SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF THE FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION, MIGRATION TO ABDOMINAL CAVITY OR OCCUR AS A RESULT OF AN UTERINE OR FALLOPIAN TUBE PERFORATION DURING INSERTION. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF DEVICE EMBEDMENT WERE NOT REPORTED; GIVEN THIS EVENT'S NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, DUE TO THE REPORTED INTERVENTION (HYSTERECTOMY). ADDITIONALLY THE NON-SERIOUS EVENT PAIN WAS REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION CAN BE OBTAINED SINCE THIS A SOCIAL MEDIA CASE. CASE CLOSED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00516	BAYER HEALTHCARE LLC	12/10/2014	12/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 7/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOCIAL MEDIA CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 AND REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT ESSURE WAS EMBEDDED OUTSIDE OF HER UTERUS. SHE HAD A HYSTERECTOMY AT (B)(6) YEARS OLD. SHE ALSO REPORTED PAIN AND SUFFERING. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

INSERTED AND ESSURE WAS EMBEDDED OUTSIDE OF HER UTERUS. SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF THE FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION, MIGRATION TO ABDOMINAL CAVITY OR OCCUR AS A RESULT OF AN UTERINE OR FALLOPIAN TUBE PERFORATION DURING INSERTION. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF DEVICE EMBEDMENT WERE NOT REPORTED; GIVEN THIS EVENT'S NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, DUE TO THE REPORTED INTERVENTION (HYSTERECTOMY). ADDITIONALLY THE NON-SERIOUS EVENT PAIN WAS REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION CAN BE OBTAINED SINCE THIS A SOCIAL MEDIA CASE. CASE CLOSED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 24-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE (FDA-2014-N-0736-1722), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEM

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00517	BAYER HEALTHCARE LLC	12/10/2014	12/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT, ON AN UNSPECIFIED DATE, SHE HAD A HYSTERECTOMY BECAUSE OF ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A HYSTERECTOMY DONE. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL

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IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF REMOVAL OF ESSURE MICRO-INSERTS IS NECESSARY; SURGERY (SALPINGECTOMY OR HYSTERECTOMY) IS USUALLY REQUIRED. IN THIS PARTICULAR CASE, AS CONSUMER REPORTED SHE HAD A HYSTERECTOMY BECAUSE OF ESSURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. NO FURTHER INFORMATION CAN BE OBTAINED SINCE THIS A SOCIAL MEDIA CASE. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00518	BAYER HEALTHCARE LLC	12/10/2014	12/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS POSTED ONLINE BY A (B)(6) YEAR-OLD FEMALE CONSUMER ON (B)(6) 2014 AT AN UNITED STATES SOCIAL MEDIA PLATFORM DESCRIBING AN ADVERSE EVENT ATTRIBUTED TO USE OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). THE CONSUMER STATED THAT ESSURE COST HER TIME AWAY FROM HER FAMILY, CONSTANT PAIN AND NOW SHE LOST HER UTERUS, CERVIX AND TUBES. FOLLOW-UP INFORMATION FROM 19-NOV-2014: NO FOLLOW-UP WAS POSSIBLE (UNABLE TO CONTACT THE CONSUMER). RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 28-NOV-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. PTC GLOBAL NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT, RECEIVED VIA SOCIAL MEDIA, REFERS TO A (B)(6) YEAR-

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OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT PAIN. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, VERY LIMITED INFORMATION WAS PROVIDED. THE CONSUMER EXPERIENCED CONSTANT PAIN AND LOST HER UTERUS, CERVIX AND TUBES. GIVEN THE NATURE OF THE EVENT, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. APPARENTLY, A HYSTERECTOMY WAS PERFORMED, THEREFORE THE CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FOLLOW-UP WAS POSSIBLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039645	BAYER	12/10/2014	12/19/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE FATIGUE, WEIGHT GAIN, BODY PAIN ESPECIALLY IN PELVIS AND HIPS, HEADACHES, SEVERE BLEEDING DURING MENSTRUATION, DEPRESSION FROM NOT BEING ABLE TO FUNCTION AS A MOM. HAVE HAD SEVERE SYMPTOMS SINCE IMPLANT AND STILL DO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039646	CONCEPTUS	12/10/2014	12/19/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53033

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE IS MAKING ME SICK ALL THE TIME. I GOT CRAMPS LIKE SOMEONE IS STABBING ME WITH A KNIFE. I'M HURTING. I WANT TO REMOVE THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00519	BAYER HEALTHCARE LLC	12/11/2014	12/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN THE UNITED STATES ON 14-NOV-2014 AND REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED YEARS BACK (DATE UNSPECIFIED). ON AN UNSPECIFIED DATE(S), THE PATIENT COMPLAINED OF PAIN. REPORTER REMOVED THE ESSURE COILS LAPAROSCOPICALLY (DATE UNSPECIFIED). FURTHER CONTACT WAS DENIED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-NOV-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED

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AND EXPERIENCED PAIN. ESSURE COILS WERE REMOVED LAPAROSCOPICALLY. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE A CAUSAL RELATIONSHIP BETWEEN PAIN AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND STATED THAT THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW-UP WILL BE PURSUED SINCE PHYSICIAN DENIED CONTACT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00520	BAYER HEALTHCARE LLC	12/11/2014	12/11/2014

Event Information:

Event Date (B3): 1/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 796910/ R112564598

Single Use: Y
Implant Date (E6): 2/9/2011
Explant Date (E7): 4/16/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6)-YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(6)-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ACCORDING TO THE CONSUMER, SHE HAD 2 COILS PLACED IN (B)(6)-2011 TO PREVENT PREGNANCIES WITH LOT NUMBER 796910. AFTER THREE MONTHS CONFIRMATION TEST, EVERYTHING WAS GOOD. IN (B)(6)-2011 (REPORTED AS (B)(6)-2011), SHE GOT PREGNANT. SHE KNEW, BECAUSE SHE GOT SICK. HER BABY WAS BORN ON (B)(6)-2012. HER SON WAS BORN 5 WEEKS EARLY AND SPENT 8 DAYS IN NICU WITH APNEA AND EAT AND BREATHING PROBLEMS (CASE (B)(4)). SHE HAD A HISTORY OF PREVIOUS PREGNANCIES WITH HYPEREMESIS. IN (B)(6)-2013, IT WAS FOUND THAT THE TUBE WAS NOT CLOSED AND THE THIRD COIL WAS PLACED. SHE ALSO STATED THAT HAD ALL KINDS OF PROBLEMS AND ISSUES SINCE SHE HAD THE ESSURE PLACED. SHE HAD PAIN AND BLOATING, HAIR LOSS, BACK PAIN, JOINT PAIN, PELVIC PAIN, ABDOMINAL PAIN, MIGRAINES ON DAILY BASIS, A LOT OF ISSUES WITH BRAIN FOG AND FORGETFULNESS, HOT FLASHES AND MOOD SWINGS. SHE ALSO HAD EXTREME HEAVY BLEEDING AFTER THE FIRST TWO COILS PLACED AND THEN AFTER THE THIRD COIL, IT GOT EVEN WORSE. SHE HAD A PERIOD THAT LATEST 3 WEEKS (GOT A TWO TO THREE DAY BREAK AND IT WOULD STARTED ALL OVER AGAIN). SHE HAD AN ENDOMETRIAL ABLATION TO GET RID OF THAT JUNE 2014. AFTER THAT, THE BLEEDING LIGHTENED UP SOME BUT THE PATTERN AND PAIN DIDN'T CHANGE, SO THEY ENDED UP DOING A PARTIAL HYSTERECTOMY IN AUGUST OF THIS YEAR. I HAD EVERYTHING REMOVED BUT THE OVARIES REMAINED. TWO OF THE THREE COILS WERE FOUND. A FEW DAYS LATER OF SURGERY, SHE HAD A HEMATOMA AND WAS HOSPITALIZED FOR 24 HOURS. SHE ALSO HAD A VERY LARGE OVARIAN CYST THAT CAUSED MORE PAIN. A SURGERY WAS DONE IN (B)(6)-2014 TO REMOVE ONE OF THE CYST AND 500CC OF FLUID FROM ABDOMEN (HCP ASSUMED THAT WAS FROM THE CYST BURSTING). THEY CYST WAS ON THE RIGHT SIDE AND IT WAS ALSO

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CAUSING BLADDER ISSUE. SHE WAS STILL HAVING PROBLEMS WITH CYSTS THAT COME IN AND A LARGE ONE BURST BUT HER DOCTOR DID NOT WANT TO PUT HER UNDER THE KNIFE AGAIN. PROBABLY, SHE WILL HAVE TO REMOVE HER OVARIES. THE OUTCOME OF THE EVENTS I HAD A VERY LARGE OVARIAN CYST CAUSING MORE PAIN, PAIN, BLOATING, HAIR LOSS, BACK PAIN, JOINT PAIN, ABDOMINAL PAIN, PELVIC PAIN, MIGRAINES ON A DAILY BASIS, A LOT OF ISSUES WITH BRAIN FOG, AND FORGETFULNESS WAS NOT RECOVERED / NOT RESOLVED. THE OUTCOME OF THE EVENT I GOT PREGNANT LAST (B)(6) 2011 WAS RECOVERED / RESOLVED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6)-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). BATCH NUMBER 796910 PRODUCTION DATE NOV-2010; EXPIRATION DATE NOV-2013). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. (B)(4) FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, OF WHICH (B)(4) CASES REFERS ALSO TO A SIMILAR LACK OF EFFICACY TYPE OF EVENT. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME HEAVY BLEEDING AFTER THE FIRST TWO COILS PLACED, AND THEN AFTER THE THIRD COIL, IT GOT EVEN WORSE, ONLY TWO OF THREE COILS WERE FOUND (LOCATION), PAIN AND GOT PREGNANT LAST (B)(6) 2011, WHICH ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO EXPERIENCED CYST BURSTING ON RIGHT SIDE, HAD A VERY LARGE OVARIAN CYST CAUSING MORE PAIN ON THE RIGHT SIDE, HEMATOMA THAT SHE WAS HOSPITALIZED FOR 24 HOURS AND HER SON BORN 5 WEEKS EARLY (PREMATURE DELIVERY), WHICH ARE UNLISTED. THE EVENT HEMATOMA THAT SHE WAS HOSPITALIZED FOR 24 HOURS WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND THE REST OF THE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. ALSO, PAIN MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, THREE MONTHS AFTER ESSURE INSERTION IT WAS CONFIRMED THAT THE TUBES WERE OCCLUDED. ABOUT 4 MONTHS AFTER ESSURE INSERTION SHE GOT PREGNANT. A CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED EVENTS CANNOT BE EXCLUDED. FOR CYST BURSTING ON RIGHT SIDE, HAD A VERY LARGE OVARIAN CYST CAUSING MORE PAIN ON THE RIGHT SIDE AND HEMATOMA, CAUSALITY CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE CONSUMER UNDERWENT A PARTIAL HYSTERECTOMY AND WAS HOSPITALIZED. OTHER NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 12-DEC-2014 FROM CONSUMER: SHE STATED THAT SHE HAVE BEEN HURT SO DEEPLY; NOT JUST PHYSICALLY BUT EMOTIONALLY AND MENTALLY. SHE ALSO STATED THAT SHE FELT LIKE A HORRIBLE MOTHER, WIFE, AND PERSON IN GENERAL BECAUSE SHE WAS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00521	BAYER HEALTHCARE LLC	12/11/2014	12/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 796910

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF (B)(6) IN UNITED STATES ON 14-NOV-2014 WHICH REFERS TO A CHILD ((B)(6)) MALE PATIENT. THE MOTHER HAD ESSURE INSERTED IN (B)(6) 2011 WITH LOT NUMBER 796910 TO PREVENT PREGNANCY. IN (B)(6) 2011 SHE GOT PREGNANT ((B)(4)). ON (B)(6) 2012, THE BABY WAS BORN 5 WEEKS EARLY. THE BABY SPENT 8 DAYS IN NICU WITH APNEA, EATING PROBLEMS AND BREATHING PROBLEMS. PTC INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: CASE UPGRADE TO INCIDENT. LOT NUMBER 796910. MANUFACTURING DATE: 11/2010. EXPIRATION DATE: 11/2013. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. HOWEVER, THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. (B)(4)FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, OF WHICH (B)(4) CASES REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A MALE CHILD WHO HAD ESSURE MICRO-INSERT EXPOSURE IN UTERO AND SPENT 8 DAYS IN NICU WITH APNEA. THE EVENT OF SPENT 8 DAYS IN NICU WITH APNEA IS SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MOST OF PREMATURE BIRTHS OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES (EG, PREECLAMPSIA, PLACENTA PREVIA, ABRUPTIO PLACENTA, FETAL GROWTH RESTRICTION). THESE EVENTS MAY POSE SIGNIFICANT RISKS OF MORBIDITY AND MORTALITY FOR BOTH THE FETUS AND THE MOTHER. ALTHOUGH, IN THIS CASE, NO INFORMATION WAS PROVIDED ABOUT THE REASON FOR PREMATURE DELIVERY, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THIS EVENT WAS THUS, CONSIDERED AS RELATED TO THE SUSPECT INSERT AND AN INCIDENT (SERIOUS INJURY). ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: EAT PROBLEMS AND BREATHING PROBLEMS. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON (B)(6) 2015 FROM PHYSICIAN: ACCORDING TO THE PHYSICIAN, THERE WERE NO COMPLICATIONS DURING PREGNANCY OR DELIVERY. THE CHILD WAS BORN ON (B)(6) 2012 AT 35 WEEKS THROUGH C-SECTION DUE TO PROLONGED CONTRACTIONS (4-10 MINUTES). HIS WEIGH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00522	BAYER HEALTHCARE LLC	12/11/2014	12/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS SOCIAL MEDIA CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE REPORTED THAT ESSURE TOOK HER TUBES. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2014. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN (B)(4). IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2014 FOR THE

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FOLLOWING (B)(4) PREFERRED TERM: SALPINGECTOMY. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 7 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE TOOK HER TUBES. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, SINCE REPORTER REGARDED THE EVENTS AS A CONSEQUENCE OF ESSURE USE AND NO FOLLOW-UP WILL BE POSSIBLE (SOCIAL MEDIA CASE); COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY REPORT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00523	BAYER HEALTHCARE LLC	12/11/2014	12/11/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED VIA SOCIAL MEDIA THAT ESSURE TOOK HER TUBES (BILATERAL SALPINGECTOMY), THEN HER UTERUS (HYSTERECTOMY). PTC INVESTIGATION RESULT RECEIVED ON 03-DEC-2014. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN

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THE DATABASE WAS PERFORMED ON (B)(6) 2014 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: SALPINGECTOMY: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. HYSTERECTOMY: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL." COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE TOOK HER TUBES (BILATERAL SALPINGECTOMY), THEN HER UTERUS (HYSTERECTOMY). THE REPORTED EVENTS WERE CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, SINCE REPORTER REGARDED THE EVENTS AS A CONSEQUENCE OF ESSURE USE AND NO FOLLOW-UP WILL BE POSSIBLE (SOCIAL MEDIA CASE); COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE INTERVENTIONS THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00524	BAYER HEALTHCARE LLC	12/11/2014	12/11/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN (B)(6) ON 14-NOV-2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER WAS (B)(6) YEARS OLD AT TIME OF THIS REPORT. SHE REPORTED VIA SOCIAL MEDIA THAT ESSURE TOOK HER UTERUS, TUBES AND CERVIX. THIS WAS HER 3RD SURGERY THIS YEAR (IMPLYING 2014). RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-DEC-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4)DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. PTC GLOBAL NUMBER IS (B)(4). THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO

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BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2014 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1. SALPINGECTOMY. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 07 CASES. 2. HYSTERECTOMY. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 11 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE TOOK HER UTERUS, TUBES AND CERVIX. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, SINCE REPORTER REGARDED THE EVENTS AS A CONSEQUENCE OF ESSURE USE AND NO FOLLOW-UP WILL BE POSSIBLE (SOCIAL MEDIA CASE); COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039473	BAYER	12/11/2014	12/11/2014

Event Information:

Event Date (B3): 2/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS901326 MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2014. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: MIGRAINES, JAW PAIN, JOINT PAIN (KNEE), FACIAL HAIR, DECLINE IN MEMORY, NOT REGULAR PERIOD CYCLES. (SOMETIMES I WILL ONLY BLEED A DAY OTHER TIMES 8 DAYS. MY CYCLES HAVE BEEN AS LONG AS 60 DAYS.) I HAVE/HAVE NOT BEEN SEEN BY 2 DOCTORS. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039474	BAYER	12/11/2014	12/11/2014

Event Information:

Event Date (B3): 5/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I MISSED MY PERIOD THAT MONTH AND FOR A FEW MONTHS AFTER I STARTED GETTING SHARP PAINS THAT GO FROM MY PELVIC AROUND TO MY BACK. MY PERIODS STARTED MUCH MORE PAINFUL AND HEAVIER THEN EVER. THROUGH THE YEARS SINCE THEN I HAVE BEEN SUFFERING WITH ABDOMINAL PAIN, PELVIC PAIN, BURNING SENSATIONS THROUGHOUT MY BODY, TEETH FALLING APART. ANXIETY IS HORRIBLE. MY BODY PARTS GET NUMB AND TINGLING FOR HOUR AT A TIME . MOST OF THE TIME. THE LIST GOES ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039475	BAYER	12/11/2014	12/11/2014

Event Information:

Event Date (B3): 11/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN 2009. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN 2013. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. WEIGHT GAIN, SEVERE JOINT AND MUSCLE PAIN, CRAMPING IN MY LEFT SIDE, RADIATING DOWN MY ENTIRE LEFT LEG, CHANGE IN VOICE (DEEPER), HAIR LOSS. I HAVE BEEN SEEN BY 3 DOCTORS. WITH AN APPOINTMENT WITH A 4TH. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: N/A. THE DEVICE IS STILL INSIDE OF ME. THE DEVICE WAS/WAS NOT RETURNED TO THE MANUFACTURER: N/A. THE DEVICE IS IN MY POSSESSION (IF APPLICABLE).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039476	BAYER	12/11/2014	12/11/2014

Event Information:

Event Date (B3): 2/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 740656. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE,(B)(6) 2010. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. - CONSTANT DULL ACHE ON LOWER LEFT SIDE OF PELVIS (NEAR OVARY). ((B)(6) 2010 THROUGH PRESENT). - SHARP STABBING PAINS COME AND GO ON BOTH SIDES OF LOWER PELVIC AREA. ((B)(6) 2010 AND -; PRESENT). - MIGRAINE HEADACHES AND -; ((B)(6) 2010 AND - ; PRESENT). - HAIR THINNING ((B)(6) 2010 AND -; PRESENT). - DEPRESSION ((B)(6) 2011 AND -; PRESENT). - PANIC/ANXIETY ((B)(6) 2011 ANDNDASH; PRESENT). - FREQUENT MEMORY LOSS AND "BRAIN FOG AND" AND - (B)(6) 2011 AND -PRESENT). - EXTREME FATIGUE AND - ((B)(6) 2010 AND - PRESENT). - DIZZINESS/LIGHTHEADEDNESS DAILY BASIS AND - ((B)(6) 2010 AND - PRESENT). - DIFFICULTY STAYING FOCUSED/CONCENTRATION AND - ((B)(6) 2010 AND - PRESENT). - OVERALL INCREASED SKIN SENSITIVITY - ((B)(6) 2014 - PRESENT). - HEART PALPITATIONS (ALL HEART AND NEURO ISSUES RULED OUT) AND - ((B)(6) 2013 AND - PRESENT). - METALLIC TASTE IN MOUTH AND - ((B)(6) 2010 AND - PRESENT). - HEAVY PERIODS AND - ((B)(6) 2013 AND - PRESENT). - EXTREME BLOATING AND - (B)(6) 2010 AND - PRESENT). - OVARIAN CYSTS AND - ((B)(6) 2014). I HAVE BEEN SEEN BY 5 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS - OVARIAN CYSTS. - OVARIAN TORSION. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039477	BAYER	12/11/2014	12/11/2014

Event Information:

Event Date (B3): 10/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN DURING SEX. BLEEDING AFTER SEX. HEADACHES. BOWEL ISSUES. "INCHING". JOINT PAINS. HEAVY PERIOD. CANCER CELLS REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039478	BAYER	12/11/2014	12/11/2014

Event Information:

Event Date (B3): 10/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PINCHING AND STABBING PAINS NUMBNESS IN MY LEGS AND CONSTANT INFECTIONS DUE BEING ALLERGIC TO THE MATERIALS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039479	BAYER	12/11/2014	12/11/2014

Event Information:

Event Date (B3): 10/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LAPAROSCOPY DONE FOR CHRONIC PELVIC PAIN IN (B)(6) 2015, FINDINGS OF ADHESIONS AND ENDOMETRIOSIS, TOTAL HYSTERECTOMY WILL BE DONE (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039480	BAYER	12/11/2014	12/12/2014

Event Information:

Event Date (B3): 11/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE METAL TASTE, "NANDAACUTE; USEAS", BACKACHES NOT ABLE TO STAND FOR 10 MINUTES, NO SEX LIFE, DEPRESSION, MOODS AND ANXIETY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039481	BAYER	12/11/2014	12/12/2014

Event Information:

Event Date (B3): 6/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5039481 (B)(4). I'M SCHEDULED FOR MY HYSTERECTOMY (B)(6) TO GET RID OF MY SIDE EFFECTS CAUSED BY ESSURE. I'M (B)(6) AND I CAN'T TAKE THIS ANYMORE! MY SURGERY DATE CAN'T GET HERE SOON ENOUGH! I'M READY TO GET RID OF THIS EVIL DEVICE AND GET MY LIFE BACK AND MY KIDS TO HAVE THEIR MOM BACK!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039482	BAYER	12/11/2014	12/12/2014

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC BLEEDING , PELVIC PAIN AND BLOATING. JOINT PAIN AND INFLAMMATION. HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039483	BAYER	12/11/2014	12/12/2014

Event Information:

Event Date (B3): 10/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE ON (B)(6) 2013. A MONTH AFTER I STARTED GETTING SHARP PAINS ON MY LEFT SIDE, PASSED A SUPER LENGTH PAD SIZED CLOT, EXTREME FATIGUE, LOSS OF SEX DRIVE, PAINFUL SEX, HORRIBLY PAINFUL PERIODS, INCREASE ON PERIOD FLOW, CRAMPS CONSTANTLY , RANDOM SHARP PAINS ON MY RIGHT SIDE, FEELING LIKE MY INSIDES ARE GOING TO FALL OUT OF MY VAGINA, JOINT (EVERY JOINT) PAINS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00525	BAYER HEALTHCARE LLC	12/12/2014	12/12/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 7/16/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5037794) IN UNITED STATES ON 12-NOV-2014 WHICH REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. THE CONSUMER STATED THAT SHE BEGAN EXPERIENCING PROBLEMS NOT LONG AFTER ESSURE INSERTION. HORMONAL AND OTHERWISE, SHE HAD EXTREME FLUCTUATIONS IN BEHAVIOR; ANGER AND ANXIETY BEING THE MOST NOTABLE. THEN SHE BEGAN HAVING HORRIBLE CYST-LIKE ACNE ON FACE AND THE SAME PAINFUL PIMPLES IN VAGINAL AREA (NOT PLACES WHERE THERE WOULD BE ANY HAIR FOLLICLES). SHE DEVELOPED A DRY, ITCHY INVISIBLE SPOT ON ONE SIDE OF VAGINA (ALL STD-SEXUALLY TRANSMITTED DISEASES TESTS, BACTERIA AND YEAST TESTS WERE NEGATIVE). SHE HAD PHANTOM PERIODS WHICH INCLUDED CRAMPING AND A CLEAR, STRANGE, SMELLY DISCHARGE (ALSO STUMPED THE DOCTORS). SHE HAD ELEVATED COPPER LEVEL AND REDUCED SEX DRIVE. IDIOPATHIC PERIPHERAL NEUROPATHY WAS DEVELOPED IN 2012. PERIODS BECAME HEAVIER AND CLOTTY. DURING AND BEFORE PERIODS SHE WOULD HAVE DIZZY SPELLS. HYSTERECTOMY TO REMOVE DEVICE ENTIRELY AND NOT RISK HAVING ANY PIECE LEFT AS PER THE CONCEPTUS INFO PAMPHLET. ESSURE EXPLANT DATE WAS (B)(6) 2014. AN INJURY (REQUIRED INTERVENTION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT RECEIVED ON 08-DEC-2014. PTC GLOBAL NUMBER (B)(6). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO

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CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER PERIODS BECAME HEAVIER AND CLOTTY. SHE UNDERWENT A HYSTERECTOMY FOR DEVICES REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; THEREFORE A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND STATED THAT THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-MAR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00526	BAYER HEALTHCARE LLC	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 2/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 796910

Single Use: Y
Implant Date (E6): 2/9/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) YEAR-OLD FEMALE PATIENT IN UNITED STATES ON (B)() 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PATIENT'S MEDICAL HISTORY INCLUDED PREGNANCIES WITH HYPEREMESIS. ACCORDING TO THE CONSUMER, SHE HAD 2 COILS PLACED IN (B)(6) 2011 TO PREVENT PREGNANCIES WITH LOT NUMBER 796910. AFTER THREE MONTHS CONFIRMATION TEST, EVERYTHING WAS GOOD, IT LOOKED LIKED IT WAS CLOSED UP AND NONE OF DYE WENT THROUGH. IN (B)(6) 2011 (REPORTED AS (B)(6) 2011), SHE GOT PREGNANT (FIRST PREGNANCY, CASE (B)(4)). IN (B)(6) 2012 SHE GOT PREGNANT AGAIN (DEVICE INEFFECTIVE); SHE STARTED GETTING SICK AGAIN AND HAD TO HAVE PICC (PERIPHERALLY INSERTED CENTRAL CATHETERISATION) LINE ALL OVER AGAIN FOR THE FOURTH TIME. ON (B)(6) 2013, HER DAUGHTER WAS BORN 5 WEEKS EARLY. SHE WAS TINY, BUT PERFECT. IN (B)(6) 2013, IT WAS FOUND THAT THE TUBE WAS NOT CLOSED AND A THIRD COIL WAS PLACED. THE OUTCOME OF THE EVENT PREGNANT WITH ESSURE WAS RECOVERED / RESOLVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, BECAME PREGNANT, AND HER DAUGHTER BORN 5 WEEKS EARLY (INTERPRETED AS PREMATURE DELIVERY). PREMATURE DELIVERY WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE PREGNANCY IS NON-SERIOUS AND LISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, THE FIRST TEST PERFORMED SHOWED TUBAL OCCLUSION;

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AFTER THE DELIVERY ANOTHER TEST WAS PERFORMED AND THE TUBE WAS NOT CLOSED. ALTHOUGH, IN THIS CASE PREGNANCY MAY HAVE OCCURRED DUE TO TUBAL PATENCY, AN ESSURE'S CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT, MOST OF PREMATURE BIRTHS OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES (EG, PREECLAMPSIA, PLACENTA PREVIA, ABRUPTIO PLACENTA, FETAL GROWTH RESTRICTION). THESE EVENTS MAY POSE SIGNIFICANT RISKS OF MORBIDITY AND MORTALITY FOR BOTH THE FETUS AND THE MOTHER. ALTHOUGH, IN THIS CASE, NO INFORMATION WAS PROVIDED ABOUT THE REASON FOR PREMATURE DELIVERY, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THIS CASE WAS THUS, CONSIDERED AN INCIDENT (SERIOUS INJURY). FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

THE PATIENT´S WEIGHT WAS 63 KG AND HEIGHT WAS 155 CM (BMI 26.2). HER MEDICAL HISTORY INCLUDED 4 PREGNANCIES WITH 3 PARITIES AND 1 SPONTANEOUS ABORTION AND 3 PREVIOUS C-SECTIONS (B)(4)). PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES WERE DEN

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039484	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 11/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, PELVIC PAIN, HAIR LOSS, HEAVY PERIODS WHICH TURNED INTO ALMOST NO PERIODS, I HAVE TO PUSH OUT MY BLOOD NOW, AND IT IS ALL QUARTER TO HALF DOLLAR SIZED CLOTS. JOINT PAIN, PAIN DURING INTERCOURSE, SHARP STABBING PAINS ON BOTH SIDES IN THE FALLOPIAN TUBES. OBGYN SAYS MY UTERUS IS INFLAMED AS WELL AS ALL OF MY OTHER FEMALE ORGANS. FREQUENT URINATION. TROUBLE HAVING A NORMAL BOWEL MOVEMENT. ITCHY RASHES THAT EVENTUALLY TURN TO HIVES. HOT FLASHES/NIGHT SWEATS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039485	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SIX MONTHS AFTER HAVING THE ESSURE PLACEMENT I BEGAN HAVING VERY HEAVY PERIODS THAT BECAME IRREGULAR OVER TIME AND AT TIMES CONTINUOUS SPOTTING THROUGHOUT THE MONTH. IRON AND VITAMIN DEFICIENCIES. MOOD SWINGS, HEADACHES, CONTINUOUS PAIN IN MY LOWER BACK AND ABDOMEN THAT RESEMBLE MENSTRUAL CRAMPING CONTINUOUSLY MOST OF THE TIME. UTERUS SPASMS THAT WOULD RESEMBLE BIRTHING CONTRACTIONS. JOINT PAIN THAT RESEMBLES ARTHRITIS. I AM (B)(6). HIGH BLOOD PRESSURE ISSUES AND EXCESSIVE WEIGHT GAIN. ISSUES WITH CONCENTRATION, BRAIN FOG, EXTREMELY TIRED ALL THE TIME EVEN AFTER A FULL NIGHTS SLEEP. HOT FLASHES, VAGINAL DRYNESS AND NUMEROUS YEAST INFECTIONS. PAIN DURING INTERCOURSE. WILL BE HAVING ESSURE REMOVED VIA HYSTERECTOMY TO RESOLVE ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039486	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 10/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD SURGERY ON (B)(6) 2005...OVER PAST 4-5 YEARS I HAVE BEEN DEALING WITH MULTIPLE MEDICAL ISSUE..HEAVY BLEEDING..HORRIBLE CRAMPING. NUMBING AND TINGLING THROUGH OUT MY ENTIRE BODY. PELVIC PAIN. UNCOMFORTABLE AND PAINFUL INTERCOURSE. NOT GETTING MY PERIOD FOR MONTHS AT A TIME. PAIN IS SPREADING THROUGH MY BODY MORE AND MORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039487	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 11/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO HAVE A FULL HYSTERECTOMY BECAUSE THE COILS BENT INTO MY UTERUS AND CAUSED ME A LOT OF PAIN SHARP, STABBING PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039488	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 3/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PLACED. DR HAD DIFFICULTY DURING PLACEMENT. HAVE HAD CONSTANT PAIN, HEADACHES, WEIGHT GAIN, DEPRESSION, FATIGUE, WORSENING HYPOTHYROIDISM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039490	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD A MAJOR SURGERY DUE TO HAVING A LOT OF PAIN WHICH I HAD MY GALLBLADDER REMOVED SINCE WAS FULL OF SLUSH AND INFLAMED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039491	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 12/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2009. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 664588 MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2009. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. SEVERE BLEEDING, SEVERE DEBILITATING ABDOMINAL PAIN AND CRAMPS, LARGE CLOTS, HEADACHES, DEPRESSION, EXTREME DRY SKIN, SLEEPLESSNESS, LOSS OF SEX DRIVE, FATIGUE, MEMORY LOSS, BLOATING, WEIGHT GAIN. I HAVE BEEN SEEN BY 1 DOCTOR. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039492	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 9/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WENT IN FOR PLACEMENT CHECK AND BOTH COILS WERE OUT OF PLACE. ONE COIL WAS NOT SEEN ON SCAN. ON (B)(6) BOTH COILS AND TUBES WERE REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039493	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN TO HAVE SHARP PAINS IN MY ABDOMINAL AREA AND WENT TO THE LOCAL ER AND THE DOCTORS BUT THE ONLY ANSWER THEY HAD WAS THAT I NEEDED TO HAVE A BOWEL MOVEMENT AND THAT SHOULD MAKE IT BETTER. SO I DID TAKE LAXATIVES TO FORCE MORE BOWEL MOVEMENTS BUT THIS DIDN'T HELP WITH THE PAIN AND JUST MADE ME MORE UNCOMFORTABLE HAVING TO USE THE BATHROOM SO MUCH. I WAS THAN TOLD TO GO SEE MY GYNECOLOGIST BECAUSE THE ONLY THING THEY COULD THINK OF WAS SOMETHING FOR MY GYNECOLOGIST TO LOOK INTO. SO I WENT TO SEE HIM (B)(6) AND TOLD HIM ABOUT THE PAIN AND ALSO THAT I NOTICED THAT MY STOMACH WAS LOOKING LIKE I WAS PREGNANT WHEN I WASN'T. HE TOLD ME "I WAS JUST FAT AND NEEDED TO START DOING SIT-UPS." SO I LEFT AND WENT BACK AGAIN A WEEK LATER OR SO AND HE DID ANOTHER EXAM AND SAID THAT I HAD CYSTS ON MY OVARIES AND ALSO HAD ENDOMETRIOSIS SO I HAD SURGERY FOR THOSE THINGS ON (B)(6) 2013. AFTER THE SURGERY I WAS STILL HAVING PAIN AND WAS STILL GAINING WEIGHT FOR UNKNOWN REASON AT THE SAME TIME. I WENT BACK TO THE DOCTOR AND HE TOLD ME THAT IT WAS STILL THE ENDOMETRIOSIS AND HE WANTED TO PUT ME ON MORE MEDICINE BUT IT WAS GOING TO TRIGGER ME TO FEEL LIKE I WAS GOING THROUGH MENOPAUSE SO I SAID NO AND ASKED HIM TO REMOVE THE ESSURE COILS THAT HE INSERTED INTO ME AND HE TOLD ME THAT I NEEDED TO BRING HIM PROOF THAT THAT COULD CAUSE SIDE EFFECTS, SO I DID, AND HE TOLD ME THAT THE FDA REPORT ON IT STATING THAT WOMEN DID HAVE THESE ISSUES AFTER THE INSERTION OF THE DEVICE AND HE TOLD ME THAT THERE WASN'T ENOUGH WOMEN THAT HAD THAT HAPPEN FOR IT TO BE LISTED AND TOLD ME TO GET A SECOND OPINION THAN. SO I WENT TO A SECOND DOCTOR AND FOUND OUT THAT SOMEONE IN MY AREA HAD THE SAME ISSUES AND HAD THE COILS REMOVED BY A DOCTOR CLOSE TO MY HOME SO I QUICKLY SWITCHED TO HIM (B)(6) AND HE PERFORMED THE SURGERY REMOVING THE FALLOPIAN TUBES

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AND COILS WITH THEM ON (B)(6) 2013. I WAS STILL HAVING SOME PROBLEMS SO I WENT IN AND FOUND OUT THAT THERE WAS STILL A SMALL PIECE OF ONE OF THE COILS LEFT INSIDE MY UTERUS THAT CAUSES ME PAIN STILL BUT I'M MANAGING AND DEALING WITH IT BECAUSE THE ONLY OTHER CHOICE LEFT IS TO HAVE MY UTERUS REMOVED AND I CAN'T HANDLE ANOTHER SURGERY. I HAVE HOWEVER GONE FROM (B)(6) AT THE TIME OF SURGERY ON (B)(6) 2013 TO (B)(6) NOW AND DIDN'T CHANGE A THING IN MY DIET OR DAY TO DAY LIFE. I ALSO HAD SIDE EFFECTS THAT STARTED ABOUT A MONTH AFTER INSERTION, THOSE INCLUDE THESE USES, ABDOMINAL PAIN, GAS, BLOATING, WEIGHT GAIN, EXHAUSTION, FURTHER DEPRESSION AND ANXIETY, HIGH BLOOD PRESSURE, FACIAL HAIR GROWTH, ACNE, AND MORE THAT I'M SURE I'M FORGETTING THERE ARE JUST SO MANY, ALL OF WHICH HAVE GOTTEN BETTER OR COMPLETELY GONE AWAY SINCE MOST OF THE DEVICE IS OUT OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039494	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 8/3/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH SEVERE BLOATING LOOKED LIKE I WAS PREGNANT, BODY ACHES HEAVY MENSTRUAL PERIOD. SEVERE CRAMPING, FATIGUE, PAIN SHOOTING DOWN THE LEGS BACK PAIN, LARGE CLOTTING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039495	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 5/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2011. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 810880, MY MODEL NUMBER IS ESS305. SHORTLY AFTER HAVING THE ESSURE PROCEDURE DONE I STARTED HAVING EXTREMELY HEAVY PERIODS WITH VERY STRONG CRAMPING IN MY LOWER BACK. I DIDN'T THINK MUCH ABOUT IT, BUT IT STEADILY GOT WORSE. I COULD HAVE 7 DAYS WORTH OF A PERIOD IN 2-3 DAYS! THE CRAMPS ARE SO SEVERE THAT I SPEND AT LEAST 2 DAYS UNABLE TO DO MUCH MORE THAN LIE IN BED CURLED IN A BALL. I WAS ALSO PLAGUED WITH EXCESSIVE FATIGUE WHICH HAS ALSO SLOWLY WORSENED. I STAY BLOATED, AND HAVE GAINED 20 POUNDS THAT DIET AND EXERCISE CAN'T REMOVE. AFTER TWO YEARS I DEVELOPED CHEST PAINS. I HAVE HAD SEVERAL EKG'S, CHEST X-RAYS, A STRESS TEST, AND AN ECHOCARDIOGRAM, BUT NO PROBLEMS OR DEFECTS CAN BE FOUND. I WAS TREATED FOR DEPRESSION. I NOW ALSO SUFFER FROM JOINT PAIN IN MY KNEES AND HIPS. I AM (B)(6) AND FEEL LIKE MY BODY HAS FELL APART SINCE I HAD ESSURE DONE. I AM CURRENTLY TRYING TO HAVE THE COILS REMOVED, BUT MY DOCTOR DOESN'T WANT TO DO AN "UNNECESSARY" SURGERY. I'M SURE IF IT WAS HER BODY, SHE MIGHT FIND THE SURGERY TO BE A LITTLE MORE NECESSARY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039496	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 8/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UPPER LEFT THIGH PAIN, CRAMPING, BACK PAIN, HAIR LOSS AND WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039497	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHORTLY AFTER I HAD ESSURE PLACED, I BEGAN TO HAVE PROBLEMS. I STARTED GETTING HEAVY PERIODS THAT LASTED LONGER AND WITH MUCH HEAVIER BLEEDING. THIS WAS ACCOMPANIED BY SHARP PAINS IN MY LOWER RIGHT SIDE AT MOST TIMES...NOT JUST DURING MY PERIOD. MY RIGHT COIL HAD SLIPPED OUT OF MY TUBE AND INTO MY UTERUS. I HAD GASTRITIS PRIOR TO ESSURE WITH A FLARE UP OF PAIN IN THE MIDDLE OF MY STOMACH ONCE EVERY YEAR TO TWO YEARS. ESSURES INFLAMMATORY RESPONSE HAS FLARED UP MY GASTRITIS TO THE POINT WHERE I AM NOW GETTING FLARE UPS EVERY WEEK AND A HALF TO TWO WEEKS. I HAVE BEEN TO THE EMERGENCY ROOM MANY TIMES FOR THIS. I HAVE DEALT WITH THIS STOMACH ISSUE MY ENTIRE LIFE AND HAD IT MANAGED WITH PRILOSEC UNTIL I HAD ESSURE PLACED. NOW I AM TAKING PROTONICS FOR MY STOMACH, BUT IT IS STILL NOT UNDER CONTROL. THE HARDEST PART IS THE CRAMPING PAIN IN THE LOWER RIGHT SIDE OF MY STOMACH. THE PAIN IS EXCRUCIATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039498	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 4/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, HEMORRHAGING AND TWO MISCARRIAGES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039499	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 10/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD 3 MISCARRIAGES FROM THIS DEVICE AND I'M SURE THAT WON'T BE THE LAST ...BLOATING TO THE POINT OF LOOKING 6 MONTHS PREGNANT. HORRIBLE CRAMPS. VERY BAD PERIOD WITH HEAVY CLOTTING. HEADACHES DAILY. HAIR FALLING OUT. EXTREMELY TIRED ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039500	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 6/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL INTERCOURSE, HEADACHES, IRREGULAR CYCLE, HAIR LOSS, WEIGHT GAIN, ANXIETY, STABBING PAINS, MOODY, TIRED, NO ENERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039501	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMERLY BY CONCEPTUS INC. MY LOT NUMBER IS 735709. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED APPROXIMATELY 2-3 WEEKS LATER THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. THYROID DISEASE, PMDD (PREMENSTRUAL DYSPHORIC DISORDER) PROBABLE ENDOMETRIOSIS, WEIGHT ISSUES (GAIN), I HAVE A KNOWN METAL ALLERGY (NICKEL), ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE (VULVODYNIA) MULTIPLE OVARIAN CYSTS, CHRONIC PELVIC PAIN, FATIGUE/LOSS OF ENERGY/CHRONIC, DIMINISHED BRAIN FUNCTION (BRAINFOG/CONFUSION/CLOUDY/ FORGETFULNESS/SHORT TERM MEMORY LOSS) URGENT/FREQUENT URINATION, SKIN ACNE, PAINFUL OVULATION (MITTELSCHMERZ), EXCESSIVE SWEATING, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), SKIN IRRITATION/ITCHING, UNEXPLAINED/EASILY BRUISING, MOOD DISORDERS, INSOMNIA, NIGHT SWEATS, LOSS OF LIBIDO, CHEST PAINS, NECK/SPINE PAIN, PAINFUL INTERCOURSE (DYSPAREUNIA), GASTROINTESTINAL ISSUES (CONSTIPATION, AND GAS), HAIR LOSS, DRY SKIN/HAIR, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS (DYSMENORRHEA), HIP PAIN, SEVERE BLOATING, JOINT PAIN, NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SHARP/STABBING PELVIC PAIN, DIZZINESS, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/FLUTTERING, BACK PAIN, ALL OVER BODY ACHES/PAIN, THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039502	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 10/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN OR AROUND (B)(6) 2014 HEAVY VAGINAL BLEEDING BEGAN THAT WOULD NOT STOP. IN (B)(6) I WENT TO MD WHO RAN SEVERAL TESTS AND STARTED HORMONE THERAPY TO TRY AND STOP THE BLEEDING. IN (B)(6) I WENT BACK FOR FOLLOW UP OF FAILED HORMONE THERAPY AND TOTAL HYSTERECTOMY WAS SCHEDULED FOR AND PERFORMED ON (B)(6) , 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039503	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 10/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) GALLBLADDER ISSUES, CONSTANT PELVIC PAIN, PAINFUL INTERCOURSE, LOSS OF LIBIDO, IF I TURN CERTAIN WAYS I FEEL LIKE I'M BEING STABBED, DAILY MIGRAINES, AND HORRIBLE CONSTANT LOWER BACK PAIN AND I HAVE TO HAVE A HYSTERECTOMY AND BILATERAL SALPINGOOPHERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039504	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 3/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE HISTORY OF NICKEL ALLERGY. DEPRESSION, PAINFUL PERIODS, PELVIC PAIN, NUMBNESS IN ARMS, LEGS, AND SIDES. FIBROMYALGIA DIAGNOSED IN (B)(6) 2012. SYMPTOMS OF CROHNS DISEASE, METALIC TASTES IN MOUTH, I NOW HAVE CYSTS ON OVARIES, THINNING HAIR, MIGRAINES, SINUS PRESSURE, ALLERGIES, BLADDER LEAKAGE, DEEP MUSCLE PAIN, ISSUES WITH EYES, PAINFUL INTERCOURSE, STOMACH CRAMPING, AND MEMORY ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039505	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 8/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PLACEMENT (B)(6) 2011. (B)(6) 2014 HAD HORRIBLE PAIN IN RIGHT LOWER PELVIS. IT HAD GOTTEN SO BAD THAT EVERY TIME I TOOK A DEEP BREATH I HAD SHARP PAIN IN THE RIGHT SIDE OF MY NECK. I WAS TAKEN TO THE E.R. FOR THEM TO DO AN ULTRASOUND. MY ABDOMEN WAS SO FULL OF FLUID IT HAD WORKED INTO MY CHEST. ULTRASOUND ALSO FOUND BLOOD CLOT(DARK MASS) IN LOWER RIGHT SIDE. SAID THEY THOUGHT IT WAS CYST TO RUPTURE. NEEDED TO FOLLOW UP WITH MY DR IN ONE MONTH TO SEE IF EVERYTHING WAS BETTER. (THE DR THAT PLACED MY ESSURE). WENT IN AND THEY SAID MY BODY HAD ABSORBED FLUID BUT I WAS STILL TELLING HER I WAS STILL HURTING SO BAD ON THE RIGHT SIDE. SHE DID A FLAT PELVIC XRAY AND I WAITED TO HEAR. A WEEK LATER I GOT A CALL FROM THE NURSE THAT SAID EVERYTHING LOOKED FINE. ALL THIS TIME I AM HAVING SUCH BAD LOWER BACK PAIN WHICH IS NOW EFFECTING MY LEFT SIDE. I DECIDED TO GO FOR A SECOND OPINION. THE DR WANTED TO DO AN HSG TEST. WHERE HE FOUND NOT ONE COIL BUT TWO IN MY RIGHT SIDE. THE RIGHT TUBE IS PERFORATED AND THE DYE SPILLED OUT INTO MY AB. NOT SURE WHERE THE COILS ARE IN MY AB UNTIL WE DO EXPLORATORY SURGERY. I HAVE HAD BAD HEADACHES, BAD BRUISING THAT WONT GO AWAY AND MY ABDOMEN HAS SWOLLEN OUT SO MUCH. DR HAS MENTIONED DOING A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039506	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 7/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE CALLED ESSURE IN (B)(6) OF 2006. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED AROUND (B)(6) 2010. MY SIDE EFFECTS HAVE BEEN SEVERE ABDOMINAL PAINS AND HIP PAIN. I HAVE SEEN SEVERAL DOCTORS CONCERNING MY SYMPTOMS. AS OF TODAY THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039507	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 2/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING THIS DEVICE FOR 2 YEARS. THE COILS MIGRATED TO MY UTERUS AND I END UP HAVING A HYSTERECTOMY AT (B)(6). THE LOT NUMBER IS A36514. THE COILS WERE IMPLANTED IMPROPERLY AT ON 2 TRAILING COILS IN ONE AND JUST TIP ON LEFT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039508	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 10/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM THE TIME OF PLACEMENT I HAVE BEEN HAVING CRAMPING, SHARP STABBING PAINS, BLEEDING, CLOTS, LOWER BACK PAIN, AND NOW DIARRHEA, NAUSEA, INSOMNIA, LEG PAIN, HIP PAIN, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039509	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 2/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, BOWEL ISSUES, VOMITING, STABBING PAINS, LOWER BACK PAIN, LEG PAIN, PELVIC PAIN, INFECTIONS, BLADDER INFECTION, PTSD, IRREGULAR MENSTRUAL, MOOD SWINGS, ANXIETY, ALLERGIC REACTION, ENDOMETRIOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039510	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 12/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY 3RD BABY AND DIDN'T WANT ANYMORE. GOT IT DONE AND FOUND OUT 4 MONTHS LATER I WAS PREGNANT. NOW I HAVE A ALMOST 6 WEEK OLD BABY. NOW I HAVE TO GET A PARTIAL HYSTO TO GET RID OF THEM. I ALSO FEEL SICK ALL THE TIME AND HAVE PAIN ON THE LEFT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039511	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 12/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HOT FLASHES, UNPLANNED PREGNANCY, EXTREMELY PAINFUL SEX, INCREASED VAGINAL DISCHARGE, HIGH BLOOD PRESSURE, KIDNEY INFECTIONS, PRETERM DELIVERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039512	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED ABOUT TWO YEARS AGO WITH PAIN IN OVARIAN AREA, PELVIS GOES NUMB AT TIMES SHOOTING PAIN. PAIN DURING INTERCOURSE. MOOD SWINGS. BRAIN FOGGING. HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039513	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 9/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HIVES, HEAVY BLEEDING, INFLAMMATION, RASH, BLISTERS, EXTREME PAIN, NICKEL ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039514	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 11/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I GOT THE ESSURE I BLED FOR 2 YEARS STRAIGHT, I HAVE HAD MIGRAINES, MISSED PERIODS, DEPRESSION, ANXIETY, CONSTANT PAIN IN MY ABDOMEN AND BACK, LACK OF LIBIDO, BREAST TENDERNESS, WEIGHT GAIN, BLOATING, NUMBNESS IN MY ARMS AND LEGS, BAD CIRCULATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039515	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 7/20/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE IMPLANTED MID 2006 AS MY SON WAS 5 AND WE WERE NOT INTENDING TO HAVE ANY FURTHER CHILDREN. DYSMENORRHEA, DYSMORPHIA AND MENSTRUAL CRAMPS FOLLOWING (I HAD NEVER HAD CRAMPS BEFORE) THIS HAS WORSENED FROM PERIOD TO PERIOD, RESULTING NOW IN A CHRONIC PELVIC PAIN EVEN OUTSIDE OF MENSTRUAL ONSET. I HAVE NO PHYSICAL INDICATORS TO EXPLAIN THIS PAIN, WILL BE UNDERGOING A TAH AND "OVOOSTOMY" LATER THIS MONTH TO TRY TO COMBAT THE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039516	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 6/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 6 MONTHS AFTER HAVING PROCEDURE DONE, I STARTED HAVING PERIODS THAT LASTED OVER 2 WEEKS, UNBEARABLE MIGRAINES, BURNING ON THE BOTTOM OF MY RIGHT FOOT, CRAMPS, AND DIZZY SPELLS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039517	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 12/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY HEAVY PERIODS, CRAMPING AND SEVERAL PAIN, BACK PAIN, HEAD ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039518	BAYER	12/12/2014	12/12/2014

Event Information:

Event Date (B3): 2/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT INTO THE DR OFFICE TO HAVE THE ESSURE PLACED IN TO NOT HAVE ANY MORE CHILDREN. MUCH TO MY SURPRISE I HAD A 4TH CHILD ON (B)(6) 2012 AS YOU SEE THIS DID NOT DO WHAT IT SHOULD HAVE. THE RIGHT COIL MIGRATED TO MY UTERUS AND THANK GOD DID NOT EFFECT MY BABY. AFTER HAVING MY 4TH CHILD, 6 WEEKS LATER MY NEW DR HAD TO GO IN AND REMOVE THE ONE COIL FROM MY UTERUS, AND REPAIR THAT AND DO A TUBAL SO THIS DOESN'T HAPPEN TO ME AGAIN. THIS DEVICE HAS CAUSE ME MANY ISSUES. I BREAK OUT IN HIVES AND IN PAIN ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039519	BAYER	12/12/2014	12/15/2014

Event Information:

Event Date (B3): 11/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BECAME PREGNANT 2 AND A HALF YEARS AFTER GETTING THE ESSURE IN (B)(6) 2009. I GAVE BIRTH AT 7 MONTHS. THE PREGNANCY WAS HORRIBLE. PREECLAMPSIA, HIGH BLOOD PRESSURE, KIDNEY INFECTIONS, SPOTTING AND CONSTANT PELVIC PAIN. PRIOR TO GETTING THE ESSURE, MY PERIODS WERE VERY LIGHT SPOTTING FOR ROUGHLY 3 DAYS AND NOW IT IS HEAVY FOR 7-8 DAYS. I STILL HAVE CONSTANT PELVIC PAIN, PAINFUL SEX, HEAD ACHES, CONSTANT CRAMPING, HIGH BLOOD PRESSURE, MOOD SWINGS, LOW/NO SEX DRIVE (HUSBAND HAS HARD TIME ACCEPTING THIS), SKIN RASHES, AND A SLEW OF OTHER ISSUES. THIS WAS BY FAR THE WORSE THING I COULD HAVE EVER DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039520	BAYER	12/12/2014	12/15/2014

Event Information:

Event Date (B3): 1/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS ESS305 MY MODEL NUMBER IS A57108. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2013. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. SHARP/STABBING PELVIC PAIN, CONSTANT SPOTTING, LOSS OF LIBIDO, MENORRHAGIA, MITTELSCHMERZ, BLEEDING/SPOTTING AFTER SEX, DYSMENORRHEA, DYSPAREUNIA, METRORRHAGIA, NAUSEA, METALLIC TASTE IN MOUTH, HEADACHES OR MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN FOG AND CLOUDINESS, FORGETFULNESS, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS) NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), CHEMICAL AND FOOD SENSITIVITIES, METAL ALLERGIES (NICKEL), ACNE, SKIN IRRITATION/ITCHING, HAIR LOSS , WEIGHT GAIN, AND ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING THE DEVICE IS STILL INSIDE OF ME AND WILL BE REMOVED (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039521	BAYER	12/12/2014	12/15/2014

Event Information:

Event Date (B3): 10/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS NIGHTMARE OF A DEVICE IS COMPLETELY TAKING AWAY THE QUALITY OF LIFE THAT I DESERVE. I'M IN PAIN CONSTANTLY WITH EVERY STEP I TAKE. PRESSURE IN THE PELVIC AREA RADIATING PAIN SO BAD. I'M LOOKING FORA SURGICAL PROCEDURE TO REMOVE THIS DEVICE AFFECTING MY FAMILY, MY WORK, MY LOVE FOR JUST WORKING OUT AT THE GYM AND ANY OTHER DAY TODAY ENJOYMENT. EVERY STEP I TAKE I FEEL THIS PAIN JUST WANT THE DEVICE OUT I WANT MY LIFE BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039522	BAYER	12/12/2014	12/15/2014

Event Information:

Event Date (B3): 10/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME CRAMPING SENSATION IN THE LOWER ABDOMINAL/PELVIC AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039703		12/12/2014	12/23/2014

Event Information:

Event Date (B3): 3/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B66021

Single Use:
Implant Date (E6): 3/5/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE BIRTH CONTROL DEVICE IMPLANTED. PAIN AND SIDE EFFECTS OCCURRED AFTER IMPLANT OF DEVICE. PROBLEMS AND PAIN CONTINUE. GOING TO TAKE THE NEXT STEPS TO REMOVE THE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039701		12/14/2014	12/23/2014

Event Information:

Event Date (B3): 4/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT ON (B)(6) 2014. FIRST COUPLE OF MONTHS WERE OK. THEN ABOUT 3-4 MONTHS IN I BEGAN TO NOTICE SEVERE FATIGUE, WEIGHT GAIN, CONSTANT BODY ACHES. THEN MOST RECENTLY I'VE DEVELOPED A SEVERE PAIN IN MY LOWER ABDOMEN THAT GOES ALL AROUND MY SIDE AND INTO LOWER BACK. I HAVE ALSO NOW DEVELOPED OVARIAN CYST, WHICH I'VE NEVER HAD BEFORE IN MY LIFE. I'VE NOW ALSO BEEN DIAGNOSED WITH HYPOTHYROIDISM. I FEEL WORSE THAN I EVER HAVE IN MY ENTIRE LIFE. I EVEN WALK WITH A LIMP FROM THE PAIN IN LOWER ABDOMEN/BACK. MY GYN IS CURRENTLY RECOMMENDING A HYSTERECTOMY! I WAS HEALTHY PRIOR TO ESSURE WITH NO MEDICAL PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039704	BAYER	12/14/2014	12/23/2014

Event Information:

Event Date (B3): 4/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/9/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN 2010 AND WAS NEVER CHECKED FOR A NICKEL ALLERGY. I WAS NOT FULLY INFORMED THAT MY BODY MAY HAVE ADD'L REACTIONS YEARS LATER. I WAS PROVIDED A PAMPHLET AND THE DEVICE WAS INSERTED IN (B)(6) 2010. I WAS CHECKED THREE MONTHS LATER TO ENSURE THE TUBES WERE BLOCKED, WHICH THEY WERE. SINCE THEN, I HAVE HAD SEVERE WEIGHT GAIN, MIGRAINES, SWELLING OF THE HANDS AND FEET, DIZZY AND FAINTING SPELLS, BLEEDING DURING AND AFTER INTERCOURSE ALONG WITH PAINFUL INTERCOURSE, NOT TO MENTION IRREGULAR PAP SMEARS WITH CERVICAL DYSPLASIA SHOWING SIGNS OF HPV; HOWEVER I HAD THE SAME SEXUAL PARTNER. I NOW HAVE BEEN DIAGNOSED WITH HYPOTHYROIDISM, POTS, ANXIETY AND OBESITY. I HAVE MULTIPLE VITAMIN DEFICIENCIES THAT CANNOT BE CURED WITH ANY MEDICATIONS PROVIDED OR DIET/EXERCISE. I BELIEVE THIS DEVICE SHOULD BE TAKEN OFF THE MARKET ASAP AND ALL OF THE PTS WHO DESIRE TO HAVE THE DEVICE REMOVED SHOULD BE ALLOWED TO DO THAT AT BAYER'S EXPENSE. IT WAS NOT UNTIL THIS LAST WEEK THAT I WAS ABLE TO FIND ADD'L RESEARCH AND LINK TO TWO ITEMS TOGETHER. IN ADDITION, MY HUSBAND HAS MENTIONED IN THE LAST WEEK THAT HE FELT SOMETHING "POKING HIM DURING INTERCOURSE. THAT IS EXTREMELY SCARY. I AM GOING TO GET TESTED FOR A NICKEL ALLERGY AS MY RING FINGERS HAVE SWOLLEN AND CANNOT WEAR MY WEDDING RINGS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00527	BAYER HEALTHCARE LLC	12/15/2014	12/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS SOCIAL MEDIA RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 16-NOV-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER STATED THAT SHE HAD TO HAVE HER FALLOPIAN TUBES REMOVED TO REMOVE THE DEVICE DUE TO AN ALLERGY TO MATERIALS ESSURE WAS MADE OF. SHE SAID THAT SHE WAS ALSO KILLED BY THEM; SHE WAS DIAGNOSED WITH LEUKEMIA 9 MONTHS AFTER IMPLANTATION. SHE HAD ESSURE INSERTED FOR 6 1/2 YEARS. SHE FELT MUCH BETTER AFTER REMOVAL. THE OUTCOME OF THE EVENT ALLERGY TO MATERIALS ESSURE IS MADE OF WAS RECOVERED / RESOLVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6)-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL

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QUALITY DEFICIT. (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALLERGY TO MATERIALS ESSURE IS MADE OF AND WAS DIAGNOSED WITH LEUKEMIA 9 MONTHS AFTER IMPLANTATION. THE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE. THE FIRST EVENT IS LISTED WHILE THE REMAINING EVENT IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. THE CONSUMER HAD TO HAVE HER FALLOPIAN TUBES REMOVED DUE TO AN ALLERGY TO MATERIALS ESSURE WAS MADE OF AND FELT MUCH BETTER AFTER REMOVAL (POSITIVE DECHALLENGE); THEREFORE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. LEUKEMIA IS A HETEROGENOUS GROUP OF DISEASES CHARACTERIZED BY CLONAL CELLS THAT EXHIBIT MATURATION DEFECTS THAT CORRESPOND TO STAGES IN HEMATOPOIETIC DIFFERENTIATION. IN THIS CASE, THE PATIENT WAS DIAGNOSED WITH THE EVENT NINE MONTHS AFTER ESSURE IMPLANTATION. CONSIDERING THE PATHOPHYSIOLOGY OF LEUKAEMIAS AND ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES, THE EVENT IS ASSESSED AS UNRELATED TO ESSURE USE. SINCE AN INTERVENTION WAS MENTIONED, THE CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FOLLOW-UP INFORMATION CAN BE OBTAINED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00528	BAYER HEALTHCARE LLC	12/15/2014	12/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF, A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR 7 YEARS. CONSUMER IS A MOTHER OF 5 KIDS. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED SEVERE MIGRAINES, BLOATING, AND BAD PELVIC PAIN. CONSUMER HAD AN HYSTERECTOMY AND SINCE SURGERY ALL HER SYMPTOMS ARE GONE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6) 2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE MIGRAINES, BLOATING AND

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BAD PELVIC PAIN. SEVERE MIGRAINES IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE BLOATING AND BAD PELVIC PAIN ARE LISTED. THESE EVENTS WERE CONSIDERED SERIOUS BY THE COMPANY DUE TO MEDICAL IMPORTANCE. PELVIC PAIN MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, TEMPORAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT WAS UNKNOWN. CONSUMER STATED THAT SHE UNDERWENT A HYSTERECTOMY AND THEN ALL SYMPTOMS WERE GONE. BASED ON THIS INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE CONSUMER HAD AN HYSTERECTOMY. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FOLLOW-UP INFORMATION CAN BE OBTAINED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00529	BAYER HEALTHCARE LLC	12/15/2014	12/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM SOCIAL MEDIA BY FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT SHE WAS HAVING A PARTIAL HYSTERECTOMY AT (B)(6) YEARS OLD BECAUSE THE COILS MIGRATED INTO HER UTERUS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 28-NOV-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. HOWEVER, THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). FOLLOW-UP INFORMATION RECEIVED ON 25-NOV-2014. NEW REPORTERS WERE ADDED. THE CONSUMER STATED THAT SHE WAS HEADED TO THE HOSPITAL FOR HER LAVH (LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY). COMPANY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATED SHE WAS HAVING A PARTIAL HYSTERECTOMY BECAUSE ESSURE COILS MIGRATED INTO HER UTERUS. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED. SINCE PARTIAL HYSTERECTOMY WAS REPORTED THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION. NO BATCH NUMBER WAS REPORTED THEREFORE REVIEW OF THE MANUFACTURING BATCH RECORD WAS NOT POSSIBLE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW-UP WILL BE PURSUED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00530	BAYER HEALTHCARE LLC	12/15/2014	12/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED ON (B)(4) 2014, VIA (B)(4) FROM UNITED STATES, WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ON AN UNSPECIFIED DATE THE CONSUMER STATED THAT THE ESSURE PROCEDURE CAUSED HER HEALTH ISSUES AND THE REMOVAL OF HER UTERUS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. PTC GLOBAL NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, RECEIVED VIA (B)(4), REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEALTH ISSUES. THE EVENT IS SERIOUS DUE

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MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, VERY LIMITED INFORMATION WAS PROVIDED. THE CONSUMER STATED THAT THE ESSURE PROCEDURE CAUSED HER HEALTH ISSUES (NOT SPECIFIED) AND HER UTERUS WAS REMOVED. GIVEN THE AVAILABLE INFORMATION, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE AND SINCE AN INTERVENTION WAS REPORTED, THE CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD SINCE NO LOT NUMBER WAS PROVIDED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS NOT EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00531	BAYER HEALTHCARE LLC	12/15/2014	12/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7): 10/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR PERMANENT BIRTH CONTROL. CONSUMER DID NOT WANT TO HAVE ANOTHER BABY SINCE SHE WAS WITH MORE THAN (B)(6) YEARS OLD. AT TIME OF THE REPORT CONSUMER STATED THAT SHE WAS ALMOST (B)(6) YEARS OLD. SHE REPORTED VIA SOCIAL MEDIA THAT HER PHYSICIAN TRUSTED ESSURE BECAUSE IT HAD NO HORMONES AND NO DOWNTIME. ON (B)(6) 2013, PHYSICIAN TOOK HER UTERUS, OVARIES AND CERVIX; EVERYTHING SHE WANTED IN CASE HER DAUGHTER HAD TROUBLE CARRYING A BABY. ALL WAS GONE ALONG WITH HER SPINE BEING THAT OF (B)(6) YEARS OLD (NOS). SHE STATED THAT HER LIFE WAS ROBED FROM HER AND HER CHILDREN; AND THAT SHE COULDN'T WORK BECAUSE SHE WAS IN PAIN EVERY SECOND OF EVERY MINUTE OF EVERY DAY. ALL SHE WANTED WAS A PERMANENT BIRTH CONTROL AND NOT A LIFE SENTENCE OF SUFFERING. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED.

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WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN EVERY SECOND OF EVERY MINUTE OF EVERY DAY. SHE WAS SUBMITTED TO A HYSTERECTOMY. THE REPORTED PAIN WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND STATED THAT THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 25-MAR-2015: CONTACT INFORMATION FOR THE CONSUMER WAS NOT AVAILABLE AND NO FURTHER FOLLOW-UP COULD BE PURSUED AT THIS TIME. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00532	BAYER HEALTHCARE LLC	12/15/2014	12/15/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS POSTED ONLINE BY A (B)(6) FEMALE CONSUMER ON (B)(6) 2014 ON A UNITED STATES (B)(4) AND REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED SHE WAS DEPRESSED AND SHE HAD AN HYSTERECTOMY DONE. ACCORDING TO HER EVEN THOUGH SHE STILL HAVE PROBLEMS LIFE CAN GET BETTER WITHOUT ESSURE. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2014. PTC GLOBAL NUMBER WAS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO U.S. FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, (B)(4) CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME DEPRESSED. THE REPORTED EVENT WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO ESSURE'S REFERENCE

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SAFETY INFORMATION. DURING ESSURE THERAPY A WOMAN MAY EXPERIENCE MILD DEPRESSION OR OTHER EMOTIONAL DISTURBANCES. THEREFORE, IN THIS PARTICULAR CASE, ALTHOUGH LIMITED INFORMATION WAS PROVIDED; A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE CONSUMER UNDERWENT HYSTERECTOMY. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 25-MAR-2015: THERE IS NO CONTACT INFORMATION AVAILABLE FOR THE CONSUMER. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039523	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 2/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT IN AND I ASK MY DOCTOR TO TIE MY TUBES AND HE TOLD ME THAT HE COULDN'T DO THAT AND VERY WELL CONVINCE ME TO DO ESSURE. AT THE TIME WHEN I DID MY RESEARCH ON IT I DIDN'T FIND ANYTHING BAD ABOUT IT SO I WENT AHEAD AND DID IT. SINCE I'VE HAD IT IN I'VE HAD SEVERE BLEEDING , HEADACHES, STABBING PAINS, BACK PAIN, BLISTERS AND RASHES ON MY HAND,.PELVIC PAIN, SEX PAIN, AND RANDOM DIZZINESS SPELLS AND BLACKOUTS, AND PAINFUL CYST ON MY OVARY. AND EXTREME FATIGUE WHICH MAKES IT HARD TO TAKE CARE OF THREE KIDS. THIS DEVICE HAS ABSOLUTELY MADE ME MISERABLE AND IN MY EYES I FEEL LIKE IT IS NOT SAFE AND I'VE ASKED TO HAVE IT TAKEN OUT BUT HAVE BEEN REJECTED 3 TIMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039524	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 7/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD PAIN RIGHT AFTER IMPLANTATION, UNTIL I HAD IT REMOVED. SHARP SHOOTING PAIN GOING INTO MY THIGHS BACK, STOMACH AND PELVIC AREA. INTENSE HOT FLASHES, FELT LIKE THEY WERE TRYING TO PUSH OUT OF MY BODY, STABBING PAIN, ITCHING, HIVES, BIG SWOLLEN LIPS, THROWING UP FROM BEING IN SO MUCH PAIN, NOT BEING ABLE TO SLEEP, AND NONSTOP BLEEDING!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039525	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVING BEEN EXPERIENCING HEADACHE , PAIN AND DIZZY SINCE THE DEVICES WAS PUT IN. GOT WORSE OVER THE YEARS .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039526	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 9/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOOD SENSITIVITY, PAINFUL PERIODS, HOT FLASHES, GASTROINTESTINAL ISSUES, LOSS OF LIBIDO, EXTREME PELVIC PAIN, HIP PAIN, JOINT PAIN, ALL SINCE ESSURE WAS IMPLANTED IN 2009.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039527	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OVER ALL DECLINE IN HEALTH SINCE 2008. CHRONIC PELVIC PAIN. YOUR DATE THING WON'T LET ME CHANGE YEAR. SCHEDULED FOR HYSTERECTOMY IN A FEW MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039528	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 6/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). POSITIVE NICKEL METAL ALLERGY WAS DETECTED. HAIR LOSS, CHRONIC PELVIC PAIN, CHRONIC HEADACHES, EXCESSIVE SWEATING, BLOOD CLOTTING DURING MENSTRUAL PERIODS, EXTREME MOOD SWINGS, PELVIC CRAMPING, METALLIC TASTE IN MOUTH, EXTREME FATIGUE, WEAKNESS, EXTREME JOINT PAIN, MUSCLE PAIN IN THE LOWER BACK, LOW LIBIDO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039529	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 5/27/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED ON (B)(6), 2008. THE PROCEDURE WAS DONE IN A HOSPITAL AND I HAD GENERAL ANESTHESIA. I CHECKED INTO THE HOSPITAL AT 1PM AND WAS RELEASED AT 5PM. A WEEK LATER I WENT BACK TO COMPLAIN ABOUT PELVIC PAIN, CRAMPING, BLOATING, VAGINAL ITCHINESS, MIGRAINE HEADACHES. ESS305, LOT# 626438.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039530	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 8/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED DEALING WITH NUMBNESS AND NERVE DAMAGE...STARTED TO GET NUMEROUS ABSCESS ON OUTER PELVIC AREA AND RECENTLY HAVE HAD ANOTHER THIS PAST MONTH..BOILS. ITCHING. IRRITATED FEELING. PAIN PAIN AND MORE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039531	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A POSITIVE PREGNANCY TEST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039532	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 5/26/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN DURING SEXUAL INTERCOURSE EVER SINCE, IRREGULAR MENSTRUAL CYCLES, HEAVY CLOTTING, MAJOR CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039533	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 12/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD HEAVY PAINFUL PERIODS, SEVERE WEIGHT GAIN, SEVERE CRAMPS, AND I WAS ALWAYS SICK. I HAD A UTERINE ABLATION DONE A YEAR LATER THEN IN 2012, I HAD TO HAVE A HYSTERECTOMY DONE TO REMOVE THE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039534	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 3/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NUMBNESS OF THE FINGERS, BLOATING, NUMBNESS OF THE FRONT PART OF MY LEG, HEAVY, HEAVY MENSTRUAL BLEEDING WITH CLOTS AND FEELING FAINT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039535	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE PROCEDURE DONE IN (B)(6) 2008 AFTER THE BIRTH OF MY DAUGHTER. I DIDN'T HAVE ANY PROBLEMS UNTIL I STARTED GETTING MY PERIODS AGAIN A YEAR LATER, AFTER I WAS FINISHED WITH NURSING. MY SYMPTOMS STARTED OUT MILD WITH BAD MENSTRUAL CRAMPING AND A YEAST INFECTION EVERY MONTH. AS TIME WENT ON, I WAS SEEN NUMEROUS TIMES FOR NUMEROUS INFECTIONS, INCLUDING YEAST INFECTIONS, VAGINITIS, AND CERVICITIS. OVER TIME MY PERIODS WERE GETTING HEAVIER AND SO MUCH MORE PAINFUL. MY PERIODS LASTED 10-14 DAYS AND I HAD PAIN EVEN WHEN I WASN'T ON MY PERIOD. MY DR TOOK ULTRASOUNDS AND OTHER TESTS INCLUDING BLOODWORK TO RULE OUT OTHER THINGS. HE PUT ME ON THE PILL FOR AWHILE BUT THAT DIDN'T HELP. THE PAIN WAS GETTING UNBEARABLE. HE PRESCRIBED MANY PAIN KILLERS AND NARCOTICS AND THEN FINALLY SUGGESTED A HYSTERECTOMY. HE TOLD ME THAT SINCE I HAD THE ESSURE COILS IN MY TUBES THAT THE BLOOD FROM MY PERIODS HAD NO WHERE TO GO BUT TO OVERFLOW INTO MY UTERUS, THUS CAUSING EXTREME PAIN. IN (B)(6) OF 2013 I HAD A HYSTERECTOMY. I LIVED IN PAIN FROM 2009-2013, ABOUT 4 YEARS. VERY MUCH UNCALLED FOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039536	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME SWELLING IN MY STOMACH, I HAVE TWO TO THREE PERIODS A MONTH. I STAY NAUSEOUS. I FATIGUE AND SOMETIMES INSOMNIA. MY WEIGHT GOES UP AND DOWN. I KEEP HEADACHES AND VAGINAL PAIN AND LOWER ABDOMINAL PAIN. AT TIMES I SWEAT PROFUSELY AND JUST NO STRENGTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039537	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE I'VE EXPERIENCED HEAVY BLEEDING, CRAMPING, SHARP STABBING PAIN, CHEST PAIN, FATIGUE, LOSS OF ENERGY, HEADACHE, NAUSEA, DIZZINESS, BLOATING, HAIR LOSS, HAIR GROWTH IN NEW PLACES, ABNORMAL PERIODS, UTI/BLADDER INFECTION, TEETH ISSUES, HEART BURN, SPOTTING, CLOTS WITH MY PERIODS, MOOD SWINGS, RASHES, HOT FLASHES, ITCHY BREAST AND NIPPLES, LOWER BACK PAIN, PELVIC PAIN, OVARIAN CYST, NUMBNESS IN LEGS, HANDS AND FEET, LOSS INTEREST IN SEX, PAINFUL SEX, VERY GASSY MOVEMENT IN MY STOMACH, EXTREME WEIGHT GAIN IN MY STOMACH AND FACE. ESSURE IS AFFECTING MY DIABETES AND HAS RUINED MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039538	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 10/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, SPLOTCHY RED RASH ON CHEST, AND HEADACHE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039539	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOOD CLOTS, SEVERE UTERUS PAIN, BACK PAIN, INFLAMMATION, LEG PAIN, DIZZINESS, WEIGHT PROBLEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039540	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE REAL BAD HEAD ACHES, REAL BAD STOMACH ACHES AT THE BOTTOM OF MY STOMACH AND I BEEN HAVING MOOD SWINGS THAT I HAVEN'T.....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039541	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 8/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INITIAL IMPLANTATION WAS BOTCHED FIRST WAS DEPLOYED, NOT SEEN, THEN ANOTHER WAS DEPLOYED SAME SIDE, ON ONE MONTH DYE- XRAY, SHOWED THE FIRST HAD PERFORATED MY TUBE, AND WAS FREE FLOATING IN MY ABDOMEN, SOMEWHERE NEAR MY RECTUM/COLON. I WAS SCHEDULED TO HAVE AN UMBILICAL HERNIA FIXED AFTER MY LAST CHILD IN 2011...AND TALKED THAT SURGEON INTO HELPING MY OB-GYN TO REMOVE THE FIRST DEPLOYED IMPLANT. I HAD TO PUT MY FOOT DOWN AND DEMAND MY SURGEON REMOVE THE ONE THAT PERFORATED MY TUBE. INITIALLY I WAS SKEPTICAL OF THE WHOLE PROCEDURE...I HAD NEVER HEARD OF THESE, HE TOLD ME HE HAD DONE 'A LOT' OF THESE, AND I REQUESTED QUANTITATIVE AND LONGITUDINAL REPORTS (WHICH HE NEVER GAVE ME) -HIS ADVICE WAS THAT I "WAS TOO HEAVY TO HAVE ANYMORE CHILDREN", AND HE PRESSURED ME INTO THESE IMPLANTS AS MY BEST OPTION, MINIMALLY INVASIVE, SHORT RECOVERY FOR AN OUTPATIENT PROCEDURE. I FEEL THIS OB-GYN WAS PROBABLY PAID OR REWARDED HANDSOMELY, FOR 'RECOMMENDING' THESE, ALL THE WHILE, NOT DOING HIS DUE DILIGENCE IN FINDING OUT IF THEY WERE SAFE FOR THE LONG RUN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039542	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 8/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NOTICED CONSIDERABLE LOWER BACK PAIN. DEPRESSION/ANXIETY. LACK OF SEX DRIVE. MOOD SWINGS. FATIGUE/LETHARGY. VERY PAINFUL OVULATION (YES, I CAN FEEL IT). VERY PAINFUL/CHANGED PMS SYMPTOMS. ANIMAL ALLERGIES/ITCHING. WEIGHT GAIN/UNABLE TO LOSE WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039544	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVERY SINCE I HAD THE ESSURE PUT IN I HAVE I PROBLEMS WITH MY STOMACH. MY PERIODS HAS BEEN ALL OFF. BUT THE STOMACH PAINS ARE HORRIBLE, I HAVE WENT TO NUMEROUS DOCTORS OVER THE STOMACH PAINS. I FINALLY HAD IT TAKEN OUT. WHEN I WOULD START MY PERIODS THE STOMACH PAINS WAS TERRIBLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039545	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 10/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT 3-5 MONTHS AFTER MY PROCEDURE I BEGAN HAVING CRIPPLING MIGRAINES, VERTIGO, MUSCLE WEAKNESS AND ABDOMINAL PAIN. I CONTINUE TO BATTLE COMPLEX MIGRAINES, INCLUDING LOSS OF VISUAL FIELD, LOSS OF BALANCE AND SPEECH PROBLEMS. I CONTINUE TO HAVE BOUTS OF MUSCLE WEAKNESS IN MY EXTREMITIES. I HAVE HAD TO HAVE MANY MEDICAL TESTS AND PROCEDURES TO TRY AND FIGURE OUT WHAT IS CAUSING ALL OF MY HEADACHES, SEVERE DIZZINESS AND OTHER ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039546	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE IN 2011 AND I SOON REGRETTED IT. THEY SAID NO PAIN BUT I WAS LAID OUT FOR A WEEK. I HAVE WEIGHT GAIN, HORRIBLE STABBING PAIN BY MY OVARIES, FEVERS WHEN I GET MY MENSTRUAL, SEVERE MENSTRUAL BLEEDING, FATIGUE, HEADACHES, AND MUSCLE SPASMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039547	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 5/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE ESSURE I NOW HAVE A PERIOD TWICE A MONTH, HAIR LOSS, EXTREME BLOATING, WEIGHT GAIN, HORRIBLE MEMORY, WAS DIAGNOSED WITH CONNECTIVE TISSUE DISEASE, ARTHRITIS IN MY LOWER SPINE, DEVELOPED A SENSITIVITY TO DAIRY, AND LOW SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039550	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE FOR THREE YEARS. DURING THIS TIME I EXPERIENCED CHRONIC DEPRESSION, JOINT /BONE PAIN, BACK PAIN, NAUSEA, HEADACHES, UNEXPLAINED RASHES, ITCHINESS, INTERNAL INFLAMMATION, FOGGINESS, AND VAGINAL DISCOMFORT. I HAD ESSURE REMOVED THREE MONTHS AGO AND SINCE THE REMOVAL I NO LONGER EXPERIENCE THE SYMPTOMS PREVIOUSLY LISTED. DURING THESE PAST THREE MONTHS THERE HAS BEEN NO CHANGES IN MY DIET OR LIFESTYLE. THE ONLY SIGNIFICANT CHANGE HAS BEEN THE REMOVAL OF ESSURE. I AM CONVINCED WITHOUT A DOUBT THAT ESSURE WAS THE SOURCE OF ALL THE SYMPTOMS I EXPERIENCED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039552	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 3/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BREAST AND ANKLE SWELLING, HEADACHES, STABBING PAINS IN MY VAGINA, CONTINUOUSLY BLEEDING , NIGHT SWEATS , AND SEVERE LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039557	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEEN IMPLANT SINCE 2013. HAVE CONSTANT MIGRAINES, LOWER BACK PAIN, ABDOMINAL PAIN, HAIR LOSS, HOT FLASHES WERE MAKES MY SKIN FEEL LIKE IT'S PINS AND NEEDLES, HEAVY PERIODS, SHAKES, EVEN NAUSEA AT TIMES WITH DIZZY SPELLS...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039559	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 6/4/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONE TUBE WAS CLOSED . THE OTHER WASN'T SO I HAVE 2 COILS IN MY RIGHT TUBE. THE PAIN WAS HORRIBLE.. I HAD CRYOABLATION DONE AFTER BLEEDING WOULDN'T STOP. THAT MADE IT WORSE. NOW I HAVE CLUSTER HEADACHES AND I'M STILL BLEEDING AND THE FOUL ODOR IS MORE THAN I CAN BEAR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039562	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5039562 #(B)(4) SURGERY WAS (B)(6), 2015 TO REMOVE ESSURE. I HAD A PERFORATION IN MY RIGHT TUBE. BOTH COILS WERE GRADE 3 PLACEMENT AND THE LEFT SIDE WAS PLACED IN AN AWKWARD WAY WHICH WAS PROBABLY CAUSING ALL MY PAIN ON THAT SIDE. I ALSO HAD A LARGE CYST ON MY RIGHT OVARY THAT WAS REMOVED AND SENT TO PATHOLOGY SINCE IT WAS GRAY IN COLOR. LUCKILY IT WAS NOT CANCER. I ALSO HAD ENDOMETRIOSIS REMOVED. ALTHOUGH I WAS RECOVERING FROM SURGERY, THE CONSTANT PAIN I HAD EVERY DAY WITH ESSURE WAS GONE. MY HEADACHES HAVEN'T RETURNED AND I'M ABLE TO TALK FLUENTLY WITHOUT FUMBLING OVER MY WORDS. MY HEAVY BLEEDING HAS STOPPED AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039565	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BAD STOMACH PAIN AND MY KNEE HURT AND MY HIP GO OUT EVERY OTHER WEEK AND I AM SOME MUCH PAIN AND I HAVE TO USE A HEAT PAD EVERY MONTH WHEN MY PERIOD COMES ON. AND DONT LIKE FEELING LIKE THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039571	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DON'T RECALL THE START DATE, BUT I GET PAIN LIKE MY ORGANS ARE MOVING AROUND MY ABDOMEN. IT IS HARD TO BREATHE WHEN THESE PAINS HAPPEN. IT IS SIMILAR TO WHEN AN 8 MONTH OLD FETUS IS MOVING AROUND EXCEPT ACTUALLY PAINFUL. I HAVE BEGUN TO HAVE REGULAR MIGRAINES, UNCONTROLLABLE WEIGHT GAIN AND REALLY HEAVY MENSTRUAL CYCLES. I HAVE BEEN HOSPITALIZED TWICE FOR THE PAIN, BUT DIDN'T THINK IT WAS CAUSED BY THE ESSURE; THOUGH I DID REPORT THAT I HAD THE COILS TO THE ATTENDING PHYSICIANS. THE PAINS COME ON MORE OFTEN, IN ADDITION TO HEAD ACHES. I HAVE NO WAY TO SEE A DOCTOR TO KNOW IF IT'S EVEN POSSIBLE TO GET THE COILS REMOVED, SO IF I DIE, I HAVE TO MAKE SURE IT'S ON RECORD SOMEWHERE THAT I REPORTED THAT THIS PRODUCT IS DANGEROUS AND LIFE THREATENING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039573	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M ALWAYS IN PAIN ON MY RIGHT OVARIES EVEN DURING SEX I BLEED AFTER SEX AS WELL. MY PERIOD WOULD LAST A WHOLE MONTH AT TIME AND SOMETIMES THREE WEEKS. MY LOWER BACK HURTS. THERE'S TIME WHERE I'M JUST LAYING DOWN IN BED CAUSE I'M IN PAIN BADLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039576	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MANY MIGRAINES STEAMING FROM NECK AND SHOULDER PAIN. JOINT PAIN AND BLOTCHY RED RASHES AT TIMES. RIGHT SIDE ABDOMINAL PAIN RADIATING BACK TO FRONT NEAR PUBIC BONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039577	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP3 #FDAMW5039577 #(B)(4). MY ANXIETY IS OUT OF CONTROL CAUSING PANIC ATTACKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039580	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASHES ON MY FACE. ON MY FACE. PAIN IN MY ABDOMEN. EXTRA PERIODS? WEIGHT GAIN. LIKE I DON'T EVEN KNOW WHAT TO DO ABOUT IT. THESE ARE ABSOLUTELY UNPRECEDENTED HEALTH-RELATED ISSUES. IS IT DEATH RELATED? SHOULD I CHECK THAT? MY HUSBAND SAYS I SHOULD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039585	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 2/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER BACK PAIN. ALL OVER BACK PAIN. ANXIETY. PELVIC BONE HURT ALL THE TIME. MOOD SWINGS. SHORTER PERIOD (LIGHT 1ST DAY, LIKE A RUNNING FAUCET THE 2ND DAY, THEN TAPERS OFF THE 3-5TH DAY LIGHT) BLOATED. NO RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039587	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 11/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FEELING BLOATED ALL THE TIME. CRAMPS IN MY STOMACH FEELS LIKE SOMEONE IS PULLING MY OVARIES. IRREGULAR PERIODS 2 WEEKS AT A TIME SOMETIMES RECENTLY GOT DIAGNOSED WITH MS. ON GOING MIGRAINES. NEVER HAD ANY PROBLEMS UNTIL I HAD ESSURE INSERTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039588	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 10/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ONGOING DEBILITATING MIGRAINE HEADACHES, PELVIC PAIN, CONSTANT NAUSEA. I HAVE TO TAKE NAUSEA PILLS ON A DAILY BASIS. I AM LOSING MY HAIR. ALL I WANT TO DO IS SLEEP. I HAVE MISSED SO MUCH WORK DUE TO MY ILLNESS CAUSED FROM ESSURE. I ALSO WAS DIAGNOSED WITH DIVERTICULOSIS. I HAVE A NICKEL ALLERGY. I HAD NO IDEA WHEN I WAS IMPLANTED WITH ESSURE THAT IT CONTAINED NICKEL. THAT WOULD HAVE BEEN A HUGE RED FLAG FOR ME!! VERY DISAPPOINTED... I WILL BE HAVING A HYSTERECTOMY (B)(6), 2015!! THANKS ESSURE!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039589	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 4/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODS THAT WERE VERY HEAVY AND PAINFUL THAT LASTED FOR 2 WEEKS, WOULD STOP FOR 2 WEEKS AND THEN WOULD RETURN. CHRONIC PELVIC PAIN, BLEED DURING AND AFTER SEX, PAINFUL SEX, OVARIAN CYSTS THAT REQUIRED SURGERY, ABDOMINAL BLOATING, FATIGUE AND WORSENED MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039590	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 4/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODS THAT WERE VERY HEAVY AND PAINFUL THAT LASTED FOR 2 WEEKS, WOULD STOP FOR 2 WEEKS AND THEN WOULD RETURN. CHRONIC PELVIC PAIN, BLEED DURING AND AFTER SEX, PAINFUL SEX, OVARIAN CYSTS THAT REQUIRED SURGERY, ABDOMINAL BLOATING, FATIGUE AND WORSENED MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039591	BAYER	12/15/2014	12/15/2014

Event Information:

Event Date (B3): 1/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS WITH LARGE CLOTS TO THE POINT OF NEEDING TOWELS TO SIT IN MY CAR OR IN MY BED ALWAYS BLEEDING THRU MY CLOTHES. DEPRESSION AND ANXIETY. STABBING PAINS IN STOMACH AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039592	BAYER	12/15/2014	12/16/2014

Event Information:

Event Date (B3): 11/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE LAST COMMENT, I HAVE HAD TWO SURGERIES TO REMOVE ALL OF THE PIECES/PARTS OF ESSURE AND NOW LIVE WITH CHRONIC DEVASTATING PAIN ALL OVER MOST OF MY BODY BUT SPECIFICALLY LOW BACK AND PELVIS. I AM NOW IN THE PROCESS OF BEING SEEN BY THE RHEUMATOLOGIST FOR SUSPECTED AUTOIMMUNE DISORDER (ANKYLOSING SPONDYLITIS). THESE DISORDERS GET TURNED ON BY INFLAMMATION, STRESS, AND TRAUMA--ALL OF WHICH CAME FROM ESSURE. I HAVE BEEN THROUGH EVERY MAJOR DEPARTMENT IN THE HOSPITAL FOR ALL OF MY MANY ISSUES AND AM NOW BASICALLY BEING TOLD I WILL JUST HAVE TO SUCK IT UP. I HAVE BEEN SCOPED IN EVERY REGION POSSIBLE, TESTS RUN, EXAMS RUN, YOU NAME IT. I AM A VETERAN OF THE IRAQ WAR. I DID NOT SERVE MY COUNTRY TO COME HOME AND BE TREATED LIKE THIS. WHAT GIVES?

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039593	BAYER	12/15/2014	12/16/2014

Event Information:

Event Date (B3): 5/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE RIGHT ABDOMINAL PAIN, FAINTING SPELLS, PAIN DURING INTERCOURSE, 50+LBS WEIGHT GAIN, FATIGUE, PASSING EGG SIZE VAGINAL BLOOD CLOTS FELT LIKE LABOR, BLEEDING FOR MONTHS ON END. CONSTANT HEAD ACHE, ACHE THAT WOULD NOT GO AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039594	BAYER	12/15/2014	12/16/2014

Event Information:

Event Date (B3): 11/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WOULD HAVE HEAVY CLOTTING AND BLEEDING DURING MY MONTHLIES. MY RED BLOOD CELL COUNT IS NOW LOW AND I HAVE MOST IF NOT ALL SIDE EFFECTS FROM IT!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039595	BAYER	12/15/2014	12/16/2014

Event Information:

Event Date (B3): 6/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) OF 2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. I DO NOT HAVE MY LOT NUMBER, I WILL HAVE TO GET IT FROM MY PROVIDER WHO IMPLANTED IT AS WELL AS MY MODEL NUMBER. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2014. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: EXTREME PAIN IN THE RIGHT SIDE OF MY STOMACH. FELT LIKE SOMEONE WAS TAKING A NEEDLE NOSE PLIERS AND PUTTING IT IN MY STOMACH, ON THE RIGHT SIDE, AND TWISTING IT. I WENT INTO MY OBGYN WHO DID THE IMPLANT. SHE DID AN EXAM AND "FOUND BLOOD AND PUS", HER EXACT QUOTE. SHE STATED I HAD AN INFECTION. SHE GAVE ME A SHOT OF ANTIBIOTICS ON THE DAY OF MY EXAM, AS WELL AS 2 MORE ANTIBIOTICS TO TAKE FOR THE NEXT 2 WEEKS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: I HAD THE T.R.U.E TEST DONE ON (B)(6) BY A DERMATOLOGIST. RESULTS ARE HIGHLY ALLERGIC TO GOLD AS WELL AS NICKEL. DUE TO THE EXTREME PAIN I WENT TO THE EMERGENCY ROOM ON (B)(6) 2014. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: I HAD LAPAROSCOPIC VAGINAL HYSTERECTOMY ON (B)(6) 2014 TO REMOVE THE ESSURE DEVICES IN EACH FALLOPIAN TUBE. MY UTERUS, FALLOPIAN TUBES, CERVIX AND OVARIES WERE REMOVED. I WENT INTO THE EMERGENCY ROOM 3 (THREE) TIMES AFTER THE HYSTERECTOMY AS I WAS STILL EXPERIENCING THE EXTREME PAIN MENTIONED ABOVE. THE DATES I WENT INTO THE EMERGENCY ROOM ARE AS FOLLOWS: (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039596	BAYER	12/15/2014	12/16/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE EXCESSIVE DRAINAGE IN MY THROAT FOR ONE. TWO, I WAS VERY IRREGULAR WITH MY MENSTRUAL CYCLES ALL MY LIFE; 2 - 3 TIMES A YEAR AND THEY WERE VERY LIGHT TO MEDIUM. THIS INSTALLATION MADE ME REALLY REGULAR WITH MENSTRUAL CYCLES LASTING MORE THAN 2 WEEKS AT A TIME AND WERE HEAVY. LEFT WORK FOR WORK ONE DAY, BECAUSE I WAS BLEEDING SO MUCH. I DIDN'T KNOW WHAT WAS WRONG WITH ME. I HAD JUST HAD THE ESSURE A COUPLE MONTHS BEFORE THAT, BUT THE DOCTOR ASSURED ME IT WOULDN'T CAUSE ANY HEAVY BLEEDING LIKE THAT, IF ANY THING IT CAUSES LIGHTER. THAT WAS NOT MY CASE. I SUFFERED WITH LONG HEAVY PERIODS FOR 5 YEARS WITH THIS IMPLANT. MY FACE GOT REALLY OILY AND I HAVE HAD PAIN IN THE LEFT GROIN AREA (WHERE HE TOOK LONGER TO PLACE DEVICE THAN THE RIGHT) SINCE DAY ONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039597	BAYER	12/15/2014	12/16/2014

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A NICKEL ALLERGY WAS FORMED. I HAVE SEVERE ABDOMINAL PAIN AND JOINT PAIN. MEMORY LOSS. ANEMIA THAT I NEVER HAD BEFORE. MY CYCLE IS OFF AND MY PERIODS ARE EXTREMELY ABNORMAL. I HAVE MIGRAINES 4-6 TIMES A WEEK I'M BLOATED AND HAVE GAINED 10 LBS SINCE THE ESSURE WAS PLACED. ALL OF THESE SYMPTOMS ARE BRAND NEW SINCE (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039598	BAYER	12/15/2014	12/16/2014

Event Information:

Event Date (B3): 10/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP SHOOTING PAINS IN LOWER ABDOMEN ON LEFT AND RIGHT SIDE, DIZZINESS, NAUSEA, MIGRAINES, JOINT PAIN, BODY ACHES, LACK OF ENERGY, LOSS OF EMOTIONAL CONTROL, HOT COLD SPELLS SWEATING SHALLOW BREATH INCREASED ANXIETY BOWEL ISSUES EYE SIGHT FLUCTUATING SOAR EYES UNQUENCHABLE THIRST AT TIMES

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039682	BAYER	12/15/2014	12/23/2014

Event Information:

Event Date (B3): 3/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE AFTER MY THIRD CHILD. I STARTED HAVING HORRIBLE PAIN IN MY ABDOMEN, WAS NAUSEOUS, DIZZY AND OFF BALANCE. I TOLD MY DOCTOR AND AFTER AN ALLERGY TEST AND FURTHER DISCUSSION DETERMINE IT WAS THE ESSURE COILS THAT WERE CAUSING THE ISSUE AS I AM ALLERGIC TO NICKEL. EVEN THOUGH THE ESSURE REP SAID THAT THERE IS HARDLY ANY NICKEL IN THE PRODUCT AND THAT IT IS IMPOSSIBLE FOR WHAT TO BE THE ISSUE! THE DOCTOR ENDED UP HAVING TO DO SURGERY TO REMOVE THE COILS AND WHEN SHE TOOK THEM OUT THEY WERE BURNING INTO MY TUBES AND WOULD HAVE BEEN A HORRIBLE SITUATION IF WE HADN'T REMOVED THEM. SHORTLY AFTER THAT REMOVAL OF MY TUBES I STARTED HAVING MAJOR BLEEDING PROBLEMS AND FELT ANEMIC. I HAD TO HAVE A HYSTERECTOMY TO TAKE CARE OF THAT PROBLEM. I AM SO UPSET THAT THIS PROCEDURE HAS CAUSED ME TO NEED A HYSTERECTOMY. THIS HAS CAUSED MAJOR DEPRESSION AND ANXIETY IN MY LIFE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00533	BAYER HEALTHCARE LLC	12/15/2014	12/30/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C95075

Single Use: Y
Implant Date (E6): 11/17/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER C95075 FOR STERILIZATION. IT WAS REPORTED THAT THE HCP WAS INSERTING AN ESSURE ON THE RIGHT SIDE AND THE DEVICE BROKE IN THE FALLOPIAN TUBE DURING PLACEMENT. PHYSICIAN WENT TO DEPLOY AND THE WHEEL DID NOT ROLL BACK AND THE ESSURE BROKE. HE WENT BACK IN WITH THE GRASPER AND THE GREEN SHEATH WAS STILL ON THE DEVICE AND HE WAS NOT ABLE TO PULL THE DEVICE BACK OUT. THE PHYSICIAN FAILED TO BE ABLE TO SEE THE AMOUNT OF COILS SHOWING, BUT WAS NOT ABLE TO SEE THE GOLD BAND. THE COIL PART OF THE DEVICE WAS STILL IN THE FALLOPIAN TUBE AND THE HCP PLANS TO SEND THE PATIENT FOR AN X-RAY. IT DID NOT DEPLOY CORRECTLY AND THE HCP WAS UNSURE WHERE THE COIL WAS. IT LOOKED A LITTLE DEEP, THE COIL STRETCHED. THIS WAS ALL ON THE RIGHT SIDE; ON THE LEFT SIDE THE FALLOPIAN TUBE WAS DISEASED AND NO COIL WAS ATTEMPTED. PTC INVESTIGATION RESULT RECEIVED ON 02-DEC-2014. PTC GLOBAL NUMBER WAS (B)(4) . FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-

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INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF AND DEPLOYMENT DIFFICULTY DURING THE PROCEDURE ARE ANTICIPATED EVENTS. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ON THE RIGHT SIDE THE DEVICE BROKE IN THE FALLOPIAN TUBE DURING PLACEMENT/GREEN SHEATH WAS STILL ON THE DEVICE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND IT WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THE DEVICE BREAKAGE OCCURRED DURING ESSURE PLACEMENT. A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. NON-SERIOUS EVENTS WERE ADDED: HE WAS NOT ABLE TO PULL THE DEVICE BACK OUT, IT DID NOT DEPLOY CORRECTLY/NOT ABLE TO SEE THE GOLD BAND, THE HCP IS UNSURE WHERE THE COIL WAST/IT LOOKED A LITTLE DEEP, THE COIL STRETCHED AND ON THE LEFT SIDE, NO COIL WAS ATTEMPTED. THE PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND STATED THAT THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF AND DEPLOYMENT DIFFICULTY DURING THE PROCEDURE ARE ANTICIPATED EVENTS. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMAL

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00534	BAYER HEALTHCARE LLC	12/16/2014	12/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B93881

Single Use: Y
Implant Date (E6): 11/18/2014
Explant Date (E7): 11/18/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 (LOT NUMBER B93881). DOCTOR EXPERIENCED TUBAL RESISTANCE IN FIRST TUBE. FIRST DEVICE WAS STRETCHED UPON CANNULATION. A SECOND DEVICE WAS USED. DEVICE WAS SUCCESSFULLY CANNULATED BUT WAS DIFFICULT TO ROLL BACK UPON SECOND WHEEL BACK. DEVICE DID NOT EASILY RELEASE FROM CATHETER AND SIGNIFICANTLY STRETCHED THE INNER COIL. WHILE ATTEMPTING REMOVAL OF THE ESSURE DEVICE WITH HYSTEROSCOPIC GRASPERS, THE COIL WAS BROKEN A COUPLE OF TIMES. ONE PIECE OF THE OUTER COIL WAS UNACCOUNTED FOR AT THE PROCEDURE END. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 08-DEC-2014: BATCH NUMBER B93881 (PRODUCTION DATE 09-NOV-2013; EXPIRATION DATE 30-NOV-2016). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS 05-DEC-2014, SINCE NO PRODUCT WAS RETURNED

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TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE AND ROLLBACK DIFFICULTY EVENT ARE ANTICIPATED EVENTS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. ONE FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, WHICH REFERS ALSO TO A SIMILAR TYPE OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4) . COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHILE ATTEMPTING REMOVAL OF THE ESSURE WITH HYSTEROSCOPIC GRASPERS, COIL WAS BROKEN A COUPLE OF TIMES (ONE PIECE OF THE OUTER COIL OF DEVICE UNACCOUNTED FOR AT END OF PROCEDURE). THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THE DEVICE BREAKAGE OCCURRED DURING ESSURE PLACEMENT, BUT WHILE ATTEMPTING REMOVAL IF THE ESSURE DEVICE WITH HYSTEROSCOPIC GRASPERS. A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. OTHER NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 12-JAN-2015: ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE RECEIVED FROM THE PHYSICIAN. PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES INCLUDE FIBROID. ON (B)(6)-2014 THE PHYSICIAN DONE CERVICAL DILATATION, SOUNDING AND GENERAL ANESTHESIA DUR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00535	BAYER HEALTHCARE LLC	12/17/2014	12/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A NURSE AT A GYNECOLOGIST/OBSTETRICIAN'S OFFICE IN THE UNITED STATES ON 27-JAN-2014. THE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS PREGNANT WITH THE ESSURE COILS (DEVICE INEFFECTIVE). NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION. ON AN UNSPECIFIED DATE, THE PATIENT CAME IN THE OFFICE AND WAS PREGNANT AND HAD ESSURE COILS. NO FURTHER DETAILS WERE REPORTED. OUTCOME WAS REPORTED AS UNKNOWN, REPORTER WAS UNSURE IF ESSURE WAS CONTINUED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP. FOLLOW-UP RECEIVED ON 17-FEB-2014: NO NEW INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 21-NOV-2014 VIA ESSURE HEALTH CARE PROVIDER PREGNANCY QUESTIONNAIRE. PATIENT'S PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES AND ANY OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS WERE DENIED. SHE HAD 04 PREVIOUS PREGNANCIES WITH 02 LIVE BIRTHS AND 02 ABORTIONS. ELECTIVE ABORTIONS, THERAPEUTIC ABORTIONS AND ECTOPIC PREGNANCIES WERE DENIED. ESSURE WAS PLACED AT ANOTHER INSTITUTION. PER PATIENT, SHE NEVER HAD POST-ESSURE HSG (HYSTEROSALPINGOGRAM). THE FIRST DAY OF THE PATIENT'S LAST MENSTRUAL PERIOD WAS (B)(6) 2013. ON (B)(6) 2013 AN ULTRASOUND WAS PERFORMED AND SHOWED 7-0 WEEKS IUP (INTERPRETED AS INTRA-UTERINE PREGNANCY), LIVE, SINGLETON. EXPECTED DATE OF DELIVERY (B)(6) 2014. THERE WERE NO COMPLICATIONS AND SHE DECIDED TO CONTINUE THE PREGNANCY. AT THAT TIME, ESSURE WAS NOT REMOVED AND REMOVAL WAS NOT PLANNED. COMPLICATIONS DURING PREGNANCY INCLUDED PRETERM CONTRACTION. ON UNSPECIFIED DATE PATIENT DELIVERED A LIVE

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BIRTH. DELIVERY TYPE WAS VAGINAL (NSDV - SPONTANEOUS VAGINAL DELIVERY). ON AN UNSPECIFIED DATE, PATIENT UNDERWENT A TOTAL BILATERAL SALPINGECTOMY FOR ESSURE REMOVAL. HSG WAS PERFORMED POST ESSURE REMOVAL. CASE UPGRADED TO INCIDENT DUE TO TOTAL BILATERAL SALPINGECTOMY. (B)(4). FINAL ASSESSMENT: PREGNANCY IS THE CONDITION OF CARRYING DEVELOPING OFFSPRING WITHIN THE BODY. THE TIME PERIOD DURING WHICH THIS CONDITION EXISTS; GESTATION. PROBABLE CAUSES FOR PREGNANCY INCLUDE: UNSUCCESSFUL BILATERAL TUBAL OCCLUSION (COMPLETE TISSUE INGROWTH), EXPULSION (RELATED TO MICRO-INSERT PLACEMENT ACCURACY), NO 3-MONTH CONFIRMATION TEST (HSG) OR MIS-READ OF HSG, LACK OF PATIENT COMPLIANCE TO IFU (I.E. USE OF ALTERNATE CONTRACEPTION UNTIL CONFIRMATION OF BILATERAL OCCLUSION). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN THIS PARTICULAR CASE, ALSO TO A TREATMENT NON-COMPLIANCE WAS REPORTED AS THE PATIENT DID NOT PERFORM THE ESSURE CONFIRMATION TEST TO DETERMINE IF TUBAL OCCLUSION IS PRESENT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, NEVER HAD POST ESSURE HSG (HYSTEROSALPINGOGRAM) AND BECAME PREGNANT WITH ESSURE COILS (DEVICE INEFFECTIVE). DURING PREGNANCY SHE HAD PRETERM CONTRACTIONS. SHE DELIVERED A LIVE BIRTH. LATER, A TOTAL BILATERAL SALPINGECTOMY FOR ESSURE REMOVAL WAS PERFORMED. ALL REPORTED EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT FOR PRETERM CONTRACTIONS WHICH IS UNLISTED. THE REPORTED SALPINGECTOMY WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE, WHILE THE REMAINING EVENTS WERE CONSIDERED NON-SERIOUS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG) TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR, THE PATIENT DID NOT PERFORM HSG. ALTHOUGH PREGNANCY IN THE PRESENT CASE MAY BE CONSIDERED RATHER A CONSEQUENCE OF NON-COMPLIANT USE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING TOTAL BILATERAL SALPINGECTOMY, ALTHOUGH LIMITED INFORMATION WAS PROVIDED, SINCE PHYSICIAN STATED THIS PROCEDURE WAS PERFORMED FOR ESSURE REMOVAL, IT WAS CONSIDERED AS RELATED TO THE SUSPECT INSERT; AND DUE TO THIS INTERVENTION THIS CASE WAS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW UP FROM 18-MAR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER INFORMATION IS EXPECTED FOR THIS CASE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00536	BAYER HEALTHCARE LLC	12/17/2014	12/17/2014

Event Information:

Event Date (B3): 10/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/23/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 04-NOV-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION. SHE WAS NOT PREGNANT. THE PHYSICIAN INFORMED THAT 3 PATIENTS HAD HSG (HYSTEROSALPINGOGRAM) DONE ON (B)(6) 2014 AND HAD PATENCY OR POSSIBLE PERFORATION BUT HE DID NOT SPECIFY WHICH PATIENT HAD WHAT. ESSURE WAS CONTINUED. FOLLOW UP 21.NOV.2014: CASE UPGRADED FROM NON INCIDENT TO INCIDENT. ESSURE QUESTIONNAIRE RECEIVED WITH FOLLOW UP INFORMATION FROM THE PHYSICIAN. PATIENT RECEIVED GENERAL ANESTHESIA DURING ESSURE INSERTION WHICH DIDN'T TAKE MORE THAN 20 MINUTES. THE ESSURE INSERTION AND THE VISUALIZATION OF THE TUBAL OSTIUM WERE EASY. NO FLUID LOSS DURING HYSTEROSCOPY MORE THAN 1500CC. PATIENT USED CONDOMS AS BACK UP CONTRACEPTION UNTIL ESSURE OCCLUSION CONFIRMATION. NO CERVICAL CONIZATION. NO CURETTAGE. NO PREVIOUS IUS/IUD. NO MYOMECTOMY. NO ADNEXAL SURGERY. NO GYNECOLOGICAL PROBLEMS OR PROCEDURES. NO RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. PHYSICIAN CONFIRMED THE EVENT PREVIOUSLY REPORTED BUT WAS NOT SURE OF PERFORATION. NO TREATMENT WAS PROVIDED FOR THE EVENT. DURING HSG ONE SIDE THE COIL SHOWED THAT IT WAS NOT FOLLOWING THE TRAJECTORY OF THE TUBE. UNSURE IF THERE WAS PERFORATION. NO PATHOLOGY RESULTS. NO HOSPITALIZATION. NO OUTCOME WAS PROVIDED. ESSURE WAS NOT REMOVED. NO MEDICALLY NECESSARY OR PATIENT REQUESTED THE ESSURE REMOVAL. LAPAROSCOPIC TUBAL LIGATION WAS PERFORMED. NO SALPINGECTOMY WAS NECESSARY. DURING THE LAPAROSCOPY NOTHING WAS VISUALIZED AND NO EXTRUSION OF COIL WAS NOTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) INSERTED AND AT HYSTEROSALPINGOGRAM (HSG) THERE WAS PATENCY OR POSSIBLE PERFORATION. THE REPORTED EVENTS, REGARDED AS FALLOPIAN TUBE PATENCY AND SUSPICION OF UTERINE PERFORATION ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE, WHILE THE REMAINING EVENT IS NON-SERIOUS. UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN CASES OF UNILATERAL OR BILATERAL INSERT PERFORATION FALLOPIAN TUBES MAY APPEAR PATENT AT CONTROL HYSTEROSALPINGOGRAM. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF THE REPORTED EVENTS IS NOT KNOWN, GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. PATIENT UNDERWENT A LAPAROSCOPIC TUBAL LIGATION, THUS THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4)2014. THE BAYER REFERENCE NUMBER FOR THE (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00537	BAYER HEALTHCARE LLC	12/17/2014	12/17/2014

Event Information:

Event Date (B3): 11/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06467

Single Use: Y
Implant Date (E6): 11/14/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 19-NOV-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION (LOT NUMBER C06467). PHYSICIAN REPORTED THAT ONE TUBE OF THE DEVICE PERFORATED (THE SIDE WAS NOT REPORTED). THE HEALTH CARE PROFESSIONAL DEPLOYED THE MICRO INSERT IN ONE TUBE AND WENT TO CUT THE LATERAL TUBE AND COULD NOT PLACE THE DEVICE DUE TO ADHESIONS. IT WAS UNILATERAL PLACEMENT AND THE PATIENT CONSENTED TO A LAP TUBAL. UPON CONVERTING, THE HCP DISCOVERED ONE MICRO INSERT HAD PERFORATED THE TUBE AND ALSO NOTICED THE SIDE THAT COULD NOT DEPLOY THE DEVICE HAD ADHESIONS. NO INJURIES TO THE PATIENT. THE PATIENT HAD THE LAPAROSCOPIC TUBAL ON (B)(6) 2014. THE SALES REPRESENTATIVE DID CONFIRM THE HCP REMOVED THE INSERT. (B)(4). FINAL ASSESSMENT: A PERFORATION IS A HOLE OR OPENING MADE THROUGH THE ENTIRE THICKNESS OF A MEMBRANE OR OTHER TISSUE OR MATERIAL. PROBABLE CAUSES FOR PERFORATION: PHYSICIAN ENCOUNTERS POOR VISIBILITY DURING THE PROCEDURE, PHYSICIAN TECHNIQUE AND EXPERIENCE, ADVANCING DELIVERY CATHETER WHEN PATIENT IS EXPERIENCING EXTRAORDINARY PAIN OR DISCOMFORT, ATTEMPTING TO ADVANCE DELIVERY CATHETER TO BLACK POSITIONING MARKER AFTER ENCOUNTERING UNDUE RESISTANCE, FURTHER ADVANCING DELIVERY CATHETER ONCE THE BLACK POSITIONING MARKER HAS REACHED THE TUBAL OSTIUM, ATTEMPTED REMOVAL OF AN IMPLANTED MICRO-INSERT WITH FEWER THAN 18 TRAILING COILS INTO THE UTERUS, INACCURATE PLACEMENT OF THE MICRO-INSERT IN THE FALLOPIAN TUBE BY THE PHYSICIAN. ACCORDING TO THE PRODUCT IFU, THE MICRO-INSERT MUST BE PLACED FAR ENOUGH INTO THE FALLOPIAN TUBE TO PREVENT EXPULSION (LESS THAN 18 TRAILING COILS).PERFORATIONS ARE A KNOWN RISK OF THE ESSURE

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PROCEDURE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE MICRO INSERT HAD PERFORATED THE TUBE DURING ESSURE INSERTION. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE FALLOPIAN TUBE PERFORATION OCCURRED DURING ESSURE PLACEMENT. IT WAS REPORTED THAT THE PHYSICIAN COULD NOT PLACE THE DEVICE DUE TO ADHESIONS (NON-SERIOUS EVENT ADDED). BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PATIENT UNDERWENT A LAPAROSCOPIC TUBAL. ESSURE WERE REMOVED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-APR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00538	BAYER HEALTHCARE LLC	12/17/2014	12/17/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS POSTED ONLINE BY A CONSUMER ON (B)(6) 2014 ON A UNITED STATES SOCIAL MEDIA PLATFORM WHICH REFERS TO ANOTHER FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE REPORTER STATED THAT THE CONSUMER WAS IN EMERGENCY SURGERY DUE TO 2 DEEP CUTS IN UTERUS AND HEAVY BLEEDING. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-DEC-2014. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED 2 DEEP CUTS IN UTERUS AND HEAVY BLEEDING. THESE EVENTS ARE SERIOUS DUE TO

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MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. ALSO, DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, THE EXACT DATE AND THE MECHANISM OF PERFORATION ARE NOT KNOWN. IT WAS ALSO UNKNOWN THE TIME BETWEEN ESSURE INSERTION AND THE ONSET OF HEAVY BLEEDING. HOWEVER, BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE IT WAS REPORTED THAT THE CONSUMER WAS IN EMERGENCY SURGERY. THE PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND STATED THAT THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW-UP INFORMATION CAN BE OBTAINED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 16-DEC-2015. CONSUMER STATED THAT ESSURE WAS KILLING HER IMMUNE SYSTEM AND THE FLU FELT 10 TIMES WORSE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039717		12/17/2014	12/29/2014

Event Information:

Event Date (B3): 3/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/21/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY ESSURE IMPLANTS MAKE ME HURT CONSTANTLY. THEY ALSO ONLY ALLOW ME TO BLEED 2 DAYS OUT OF A MONTH. I FEEL NAUSEATED AND CANNOT EAT. I HAVE NOT GONE TO A DOCTOR ABOUT IT YET, BUT I WOULD ADVISE AGAINST ANYONE GETTING THIS FORM OF BIRTH CONTROL. I FEEL PREGNANT ALTHOUGH I'M NOT. I WISH I'D NEVER GOTTEN THIS FORM OF PERMANENT BIRTH CONTROL. IT ALSO KEEPS ME ANGRY. MY HEADACHES ARE ALSO WORSE NOW THAN THEY HAVE EVER BEEN. THANK YOU, (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039727		12/17/2014	12/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE 7 YEARS AGO. ESSURE REF: (B)(4) LOT: 626347. SINCE HAVING THE COILS PLACED, I HAVE EXPERIENCED THE FOLLOWING HEALTH PROBLEMS WHICH HAVE CONTINUED TO INCREASE IN SEVERITY WITH EACH PASSING MONTH: CRAMPING - NOW AT A LEVEL WHERE THE PAIN IS SO UNBEARABLE THAT I BECOME DIZZY OR LIGHT HEADED. MY HEART WILL OFTEN RACE AS I DOUBLE OVER IN PAIN. HEAVY BLEEDING -SOME MONTHS, I EXPERIENCED SUCH HEAVY BLEEDING THAT 3-4 SUPER ABSORBENT TAMPONS WILL BE SATURATED IN AN HOUR. THIS CAN LAST FOR 2-3 DAYS. NOW THE CYCLES ARE ANYWHERE FROM 13-29 DAYS APART. SOME MONTHS I HAVE 2 PERIODS WITH ONLY A 5-7 DAY BREAK IN BETWEEN. MOST MONTHS, THEY LAST FOR 10-12 DAYS. I WILL OFTEN SPOT IN BETWEEN PERIODS TOO. PMS - I'VE STARTED TO HAVE ANXIETY FOR SEVERAL DAYS LEADING UP TO MY PERIOD BECAUSE THE PAIN FROM THE CRAMPS OFTEN KEEP ME FROM BEING ABLE TO ENJOY LIFE. I CAN BARELY STAND TO GET OUT OF BED AND TRYING TO BE AT WORK OR TO FUNCTION AS A PARENT AT HOME BECAUSE I'M IN SO MUCH PAIN. I HAVE CONSIDERED THE OPTION OF HAVING THE COILS REMOVED, BUT THE COST IS MORE THAN OUR FAMILY CAN TAKE ON RIGHT NOW AND CURRENTLY THEIR IS NO ONE NEAR OUR HOME TOWN OF (B)(6) WHO WILL DO THE PROCEDURE. I DON'T FEEL THAT A HYSTERECTOMY IS MY BEST OPTION EITHER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00539	BAYER HEALTHCARE LLC	12/18/2014	12/19/2014

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12705

Single Use: Y
Implant Date (E6): 7/7/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR STERILIZATION. THE ESSURE LOT NUMBER USED WAS C12705. SINCE THE CONSUMER HAD ESSURE INSERTED SHE HAD A FEW PROBLEMS. SHE SUFFERED WITH A UTI (URINE TRACT INFECTION) WHICH LASTED FOR SEVERAL DAYS AFTER THE PROCEDURE, INTERMITTENT VULVODYNIA, MITTELSCHMERZ EVERY MONTH, MENORRHAGIA WITH EXCESSIVE CLOTTING, DYSMENORRHEA AND POLYMENORRHEA EVERY MONTH AND SHE HAD A CONSTANT PAIN IN HER LOWER LEFT ABDOMEN. SHE WAS NOT SURE IF IT WAS COINCIDENCE BUT HER LEFT FOOT AND LOWER LEG SUFFERED WITH NUMBNESS AND TINGLING WHICH WAS NOT PRESENT BEFORE THE PROCEDURE. SHE ALSO HAD A FLUTTERING SENSATION IN HER LOWER RIGHT ABDOMEN FOR APPROXIMATELY ONE WEEK AFTER THE PROCEDURE AND PAIN AND SPOTTING DURING AND AFTER INTERCOURSE. THE CONSUMER STATED THAT THESE SYMPTOMS CANNOT BE ATTRIBUTED TO HORMONAL CHANGES AS SHE HAD NOT USED THE CONTRACEPTIVE PILL OR OTHER HORMONE-BASED CONTRACEPTIVE DEVICES FOR OVER 14 YEARS. HER PHYSICIAN ADVISED THAT HE WOULD NOT LOOK FURTHER INTO THIS UNTIL AFTER THE ROUTINE 3 MONTH HSG (HYSTEROSALPINGOGRAM). HOWEVER, DUE TO HER CONCERNS ABOUT AN HSG AGGRAVATING HER PAIN AND BLEEDING SHE CANCELLED THE X-RAY APPOINTMENT. CONSUMER WAS WILLING TO HAVE A NORMAL X-RAY TO CHECK IF THE INSERTS ARE IN PLACE AND HAVE NOT MIGRATED, BUT WHEN SHE RANG TO CANCEL HER APPOINTMENT SHE WAS TOLD THAT SHE WOULD BE DISCHARGED FROM CLINIC AND THE REASON WOULD BE RECORDED AS "NO FURTHER TREATMENT REQUIRED". CONSUMER STATED THAT SHE FILED HER REPORT WITH THE HEALTH AUTHORITY AS SHE WAS CERTAIN THAT THESE PROBLEMS WERE A DIRECT RESULT OF THE ESSURE PROCEDURE. SHE WOULD LIKE TO MAKE IT CLEAR

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THAT SHE DID NOT REGRET BEING STERILIZED AT ALL, JUST THE METHOD USED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014: THIS CASE IS NOW A POTENTIAL LEGAL CASE. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM CONSUMER AND ON (B)(6) 2014 FROM HEATH AUTHORITY: CONSUMER PROVIDED DATE OF BIRTH, AT TIME OF THE REPORT SHE WAS (B)(6) YEARS OLD. HEALTH AUTHORITY REPORT RECEIVED FROM (B)(4) AND THE REFERENCE NUMBER WAS (B)(4). CONSUMER STATED THAT MINOR INJURY OCCURRED. SHE REPORTED SHE HAD SEVERE UTI FOR SEVERAL DAYS AFTER THE PROCEDURE AND HEAVY, DRAGGING PAINS IN LOWER ABDOMEN. SINCE HAVING THE PROCEDURE SHE HAVE EXPERIENCED PAIN AND BLEEDING DURING OVULATION, HER PERIODS HAVE GONE FROM 3 OR 4 DAYS TO 7 OR 8 DAYS AND WERE INCREDIBLY PAINFUL, HEAVY AND SHE WAS LOSING CLOTS SOME OF WHICH HAVE BEEN THE SIZE OF MY PALM. HER LIBIDO HAS DECREASED DRAMATICALLY AND WHEN SHE HAD SEX SHE EXPERIENCED SPOTTING AND PAIN FOR THE NEXT COUPLE OF DAYS - THIS SOMETIMES STARTS DURING SEX AND SHE HAD TO STOP. SHE ALSO STATED SHE HAS BEEN TIRED A LOT OF THE TIME EVEN AFTER A GOOD NIGHT'S SLEEP, HAD EXPERIENCED MORE MIGRAINES THAN SHE USED TO HAVE AND FEEL GENERALLY RUN DOWN WITH ACHES AND PAINS IN HIPS AND LEGS. ACCORDING TO HER, SHE DID NOT KNOW IF THE DEVICES WERE IN PLACE OR HAVE MIGRATED. THE HEALTH AUTHORITY VIEW THIS AS AN INCIDENT REPORT; THEREFORE, THE CASE WAS UPGRADED. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2014. PTC GLOBAL NUMBER (B)(6). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO TREATMENT NONCOMPLIANCE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. (B)(4) . NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION FROM (B)(6) 2014: NO RESPONSE FROM CONSUMER REGARDING WRITTEN/SIGNED CONSENT, UNABLE TO FOLLOW-UP WITH HEALTHCARE PROFESSIONAL WITHOUT THIS WRITTEN/SIGNED CONSENT. CASE CLOSED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: CONSUMER NO LONGER WILLING TO PROVIDE CONSENT TO CONTACT RELEVANT HCPS, NO FURTHER INFORMATION IS NOW EXPECTED CASE HAS BEEN CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 12-DEC-2014 FOR THE FOLLOWING (B)(4) PREFERRED TERMS: (B)(4) PT: DYSMENORRHOEA: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 45 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UTI AND PERIODS INCREDIBLY PAINFUL/ DYSMENORRHEA. UTI, INTERPRETED AS URINARY TRACT INFECTION AND PERIODS INCREDIBLY PAINFUL/ DYSMENORRHEA ARE SERIOUS DUE TO MEDICAL IMPORTANCE. ACCORDING TO ESSURE´S REFERENCE SAFETY INFORMATION UTI IS UNLISTED AND DYSMENORRHEA IS LISTED. UTI ARE COMMON IN FEMALES. MOST OFTEN, THEY ARE CAUSED BY ENTERIC COLIFORM BACTERIA (EG, ESCHERICHIA COLI) THAT INHABIT THE PERIURETHRAL VAGINAL INTROITUS AND ASCEND INTO THE BLADDER VIA THE URETHRA. CONSIDERING EVENT'S INFECTIOUS NATURE AND

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LOCALIZED ACTION OF ESSURE IN FALLOPIAN TUBES, THIS EVENT IS CONSIDERED UNRELATED TO SUSPECTED DEVICE. MENSES PATTERN CHANGES AND DYSMENORRHEA MAY OCCUR WITH ESSURE THERAPY. CONSIDERING POSITIVE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, EVENT WAS CONSIDERED RELATED TO ESSURE. ALTHOUGH NEITHER HOSPITALIZATION NOR SURGICAL INTERVENTION RELATED TO ESSURE WAS REPORTED, THIS CASE IS REGARDED AS INCIDENT, IN LINE WITH HEALTH AUTHORITY´S ASSESSMENT. OTHER NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00540	BAYER HEALTHCARE LLC	12/18/2014	12/19/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER FROM UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF, A (B)(6) FEMALE CONSUMER WHO HAD FALLOPIAN TUBE OCCLUSION INSERT (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007 FOR STERILIZATION. THE CONSUMER'S MEDICAL HISTORY INCLUDED GRAVIDA 3 AND PARITY 3. AFTER 7 MONTHS OF ESSURE INSERTION CONSUMER'S PERIODS STARTED GETTING IRREGULAR AND MUCH MORE PAINFUL CRAMPS WITH CLOTS AND VERY BAD PELVIC PAIN. IN 2010, THE CONSUMER GOT PREGNANT AND HAD A MISCARRIED. AFTER 3 YEARS, SHE GOT PREGNANT AGAIN (ANOTHER CASE WAS CREATED FOR THIS PREGNANCY: (B)(4)). IN 2014, AFTER CONSUMER'S CHILD BIRTH SHE WENT TO A PHYSICIAN AND UNDERWENT TO A DIAGNOSTIC LAPAROSCOPY. THE PHYSICIAN WAS ABLE TO REMOVE ONE ESSURE COIL ON THE RIGHT SIDE (RIGHT TUBE). HE CUT INTO HER LEFT TUBE TO GET THE ESSURE OUT BUT IT WASN'T THERE. IT WAS EMBEDDED IN THE WALL OF HER UTERUS. AFTER THAT (ON AN UNSPECIFIED DATE) CONSUMER HAD AN HYSTERECTOMY DONE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE.

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IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP (B)(4) 2014: NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, GOT PREGNANT, MISCARRIED AND THE DEVICE WAS FOUND EMBEDDED IN THE WALL OF HER UTERUS DURING LAPAROSCOPY. THE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE, EXCEPT PREGNANCY WHICH IS NON-SERIOUS. THE THIRD EVENT, INTERPRETED AS DEVICE EMBEDMENT, AND PREGNANCY ARE LISTED, WHILE MISCARRIAGE IS UNLISTED. DEVICE EMBEDMENT CAN BE INTERPRETED AS PARTIAL PERFORATION, I.E. THE MICRO-INSERT OR PARTS OF IT HAVE PENETRATED THE FALLOPIAN TUBE OR THE MYOMETRIUM. IN THIS CASE, DURING DIFFICULT DEVICE REMOVAL IN THE LEFT SIDE, THE MICRO-INSERT WAS FOUND OUT EMBEDDED IN UTERINE WALL. GIVEN THE NATURE OF THE EVENT, IT IS ASSESSED AS RELATED TO ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE. PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. IT IS NOT POSSIBLE TO KNOW WHEN THE DEVICE MIGRATION AND EMBEDMENT ACTUALLY OCCURRED, IF IT WAS BEFORE OR AFTER THE CONCEPTION, THEREFORE, A DEVICE INEFFICACY CANNOT BE TOTALLY EXCLUDED AND CAUSAL RELATIONSHIP WITH ESSURE USE IS ASSESSED AS RELATED. ALTHOUGH GESTATIONAL AGE HAS NOT BEEN PROVIDED, SPONTANEOUS ABORTIONS OCCUR MOSTLY DURING THE FIRST 12 WEEKS OF PREGNANCY AND THE VAST MAJORITY OF THESE CASES ARE DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS, SO THE EVENT IS CONSIDERED AS UNRELATED TO ESSURE. SINCE A DIAGNOSTIC LAPAROSCOPY AND LATER, A HYSTERECTOMY HAVE BEEN PERFORMED, THE CASE IS ASSESSED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039746	BAYER	12/18/2014	12/29/2014

Event Information:

Event Date (B3): 6/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/20/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2012 AND HAVE HAD PELVIC PAIN SINCE. I HAVE HAD MANY OTHER SIDE EFFECTS INCLUDING MEMORY ISSUES, FATIGUE, PELVIC BLEEDING, PELVIC STABBING PAIN, UTI'S, BACTERIAL VAGINOSIS, WARTS, MIGRAINES, NECK AND SHOULDER PAIN, FALLOPIAN TUBE SPASMS, CONSTANT CLEAR VAGINAL DISCHARGE, MUSCLE SPASMS, BURNING LEG PAIN, SCIATIC NERVE PAIN, TAILBONE PAIN, NUMBNESS IN FINGERS, MY WHOLE BODY FEELS SWOLLEN ALL THE TIME, PAIN DURING SEX, GAINED 50 LBS, AND I LOOK PREGNANT. DUE TO ABDOMINAL SWELLING, CONSTANT PERIOD LIKE CRAMPS AND ITCHY ARMS, I HAVE BEEN DIAGNOSED WITH FIBROMYALGIA, OCCIPITAL NEURALGIA, MUSCLE SPASMS AND DIABETES. I RECEIVE TREATMENT AT (B)(6) TO COUNTERACT THE CONSTANT OCCIPITAL MIGRAINES. I ALSO GET TRIGGER POINT INJECTIONS. I GET REGULAR MASSAGES TO TRY TO BREAK UP THE SPASMS IN MY BACK AND HIPS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00541	BAYER HEALTHCARE LLC	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT AN ESSURE REMOVAL WAS PERFORMED AND THE PATIENT WAS HOSPITALIZED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN THIS PARTICULAR CASE, NO FURTHER ADVERSE EVENTS DESPITE THE REFERRED REMOVAL WERE REPORTED AND NO REASONS FOR THE DEVICE REMOVAL WERE GIVEN AT THIS POINT IN TIME IT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT:

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THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PHYSICIAN PERFORMED AN ESSURE REMOVAL. THIS EVENT, INTERPRETED AS ESSURE SURGICAL REMOVAL, WAS CONSIDERED SERIOUS, DUE TO HOSPITALIZATION AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT PROCEDURE FOR ESSURE REMOVAL WAS NOT SPECIFIED, SINCE DEVICE REMOVAL WAS REQUIRED, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED AND DUE TO THE PROBABLE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION CAN BE OBTAINED SINCE PHYSICIAN DENIED CONTACT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00542	BAYER HEALTHCARE LLC	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 FOR PERMANENT CONTRACEPTION. IT WAS REPORTED THAT HSG WAS DONE (DATE NOT SPECIFIED), BUT IT WAS NOT ON FILE. THE ESSURE WAS EMBEDDED INTO ENDOMETRIUM AND HCP (HEALTH CARE PROFESSIONAL) ACTUALLY REMOVED 1/2 CM PORTION OF COIL IN 2010 (EXACT DATES NOT PROVIDED). PATIENT BECAME PREGNANT AND PREGNANCY WAS TERMINATED A FEW YEARS AGO. PATIENT HAS BEEN COMPLAINING OF CHRONIC PAIN EVER SINCE. THE PHYSICIAN CALLED TO GAIN INSIGHT ON BEST WAY TO REMOVE COILS. PATIENT'S LAST APPOINTMENT WAS ON (B)(6) 2014 AND X-RAY WAS ORDERED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: A PERFORATION IS A HOLE OR OPENING MADE THROUGH THE ENTIRE THICKNESS OF A MEMBRANE OR OTHER TISSUE OR MATERIAL. PROBABLE CAUSES FOR PERFORATION: 1) PHYSICIAN ENCOUNTERS POOR VISIBILITY DURING THE PROCEDURE, 2) PHYSICIAN TECHNIQUE AND EXPERIENCE, 3) ADVANCING DELIVERY CATHETER WHEN PATIENT IS EXPERIENCING EXTRAORDINARY PAIN OR DISCOMFORT, 4) ATTEMPTING TO ADVANCE DELIVERY CATHETER TO BLACK POSITIONING MARKER AFTER ENCOUNTERING UNDUE RESISTANCE, 5) FURTHER ADVANCING DELIVERY CATHETER ONCE THE BLACK POSITIONING MARKER HAS REACHED THE TUBAL OSTIUM, 6) ATTEMPTED REMOVAL OF AN IMPLANTED MICRO-INSERT WITH FEWER THAN 18 TRAILING COILS INTO THE UTERUS, 7) INACCURATE PLACEMENT OF THE MICRO-INSERT IN THE FALLOPIAN TUBE BY THE PHYSICIAN. ACCORDING TO THE PRODUCT IFU, THE MICRO-INSERT MUST BE PLACED FAR ENOUGH INTO THE FALLOPIAN TUBE TO PREVENT EXPULSION (LESS THAN 18 TRAILING

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COILS).PERFORATIONS ARE A KNOWN RISK OF THE ESSURE PROCEDURE. PREGNANCY IS THE CONDITION OF CARRYING DEVELOPING OFFSPRING WITHIN THE BODY. THE TIME PERIOD DURING WHICH THIS CONDITION EXISTS; GESTATION. PROBABLE CAUSES FOR PREGNANCY INCLUDE: 1) UNSUCCESSFUL BILATERAL TUBAL OCCLUSION (COMPLETE TISSUE INGROWTH), 2) EXPULSION (RELATED TO MICRO-INSERT PLACEMENT ACCURACY), 3) NO 3-MONTH CONFIRMATION TEST (HSG) OR MIS-READ OF HSG, 4) LACK OF PATIENT COMPLIANCE TO IFU (I.E. USE OF ALTERNATE CONTRACEPTION UNTIL CONFIRMATION OF BILATERAL OCCLUSION). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PERFORATION IS AN ANTICIPATED EVENT. THE POSSIBLE DEVICE BREAKAGE COULD HAVE BEEN CAUSED BY PHYSICIAN HANDLING ERROR. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. HOWEVER, CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE AE CASE REFERS ALSO TO A REPORTED DEVICE BREAKAGE AND USABILITY ISSUES. IN THIS PARTICULAR CASE IT WAS REPORTED, THAT ESSURE WAS EMBEDDED AND THE HCP REMOVED 1/2 CM PORTION OF COIL. AT THIS POINT IN TIME NO FURTHER INFORMATION WAS PROVIDED IF THE REMOVED 1/2CM OF ESSURE COIL WAS BROKEN OR WERE CUT OFF BY THE HCP. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THEREFORE THE REPORTED BREAKAGE COULD NOT BE EVALUATED IN MORE DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND A HANDLING ERROR. ACCORDING TO THE TECHNICAL ASSESSMENT THE POSSIBLE DEVICE BREAKAGE COULD HAVE BEEN CAUSED BY PHYSICIAN HANDLING ERROR. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE ESSURE WAS EMBEDDED INTO ENDOMETRIUM. AN ATTEMPT TO REMOVE IT WAS MADE BUT HCP REMOVED ONLY 1/2 CM PORTION OF COIL (INTERPRETED AS DEVICE BREAKAGE). THIS PATIENT HAD A PREGNANCY AND TERMINATED THE PREGNANCY. THIS ESSURE EMBEDMENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND PREGNANCY AND DEVICE BRAKEAGE ARE NON-SERIOUS. THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE EMBEDMENT CAN BE INTERPRETED AS PARTIAL PERFORATION, I.E. THE MICRO-INSERT OR PARTS OF IT HAVE PENETRATED THE FALLOPIAN TUBE OR MYOMETRIUM. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE. IN THIS CASE, IT IS NOT CLEAR IF THE PERFORATION OCCURRED DURING INSERTION OR AFTERWARDS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, IT IS NOT POSSIBLE TO DETERMINE IF THE PREGNANCY OCCURRED AS A CONSEQUENCE OF A MALPOSITIONED INSERT OR INEFFECTIVE DEVICE. CONSIDERING THE POSITIVE TEMPORAL, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. AS THAT THE PATIENT UNDERWENT A PROCEDURE TO REMOVE ESSURE, THE CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND STATED THAT THE POSSIBLE DEVICE BREAKAGE COULD HAVE BEEN CAUSED BY PHYSICIAN

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HANDLING ERROR. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION). FURTHER INFORMATION (PERFORATION AND PREGNANCY QUESTIONNAIRES) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP FROM (B)(6) 2014: WAS IDENTIFIED AS DUPLICATE OF THIS CASE. (B)(4) WILL BE DELETED FROM BAYER DATABASE. THE FOLLOWING INFORMATION FROM CASE (B)(4) WAS ADDED: DOCTOR REPORTED THAT HAD PATIENT WITH PERFORATION THROUGH MYOMETRIUM (PREVIOUSLY REPORT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039647	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING ACHY MUSCLES THEN INCREASED INTO SEVERE LOWER BACK/PELVIC PAIN. HAD XRAYS DONE AND THEY SHOWED A BROKEN COIL EMBEDDING INTO MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039648	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT MY ESSURE 2012. IT'S THE DAY I REGRET. IT HURT AS SOON AS THEY PUT IT IN. I BLEED A LOT FOR LIKE THREE MONTHS. I ALWAYS I MEAN ALWAYS HAVE BAD BAD CRAMPS LIKE WHERE I CRY MYSELF . I HAVE DIFFERENT MOOD SWINGS AND I WASN'T EVER LIKE THAT. ALWAYS HAPPY BEFORE ESSURE. I HAVE ISSUES WITH MY SEX LIFE IT INTERFERE BECAUSE IT HURTS SO MUCH. I FEEL BAD FOR MY HUSBAND. NO INTEREST ANYMORE BECAUSE KNOWING IT HURTS. MY PERIOD IS OFF THE CHARTS DON'T KNOW WHEN OR IF I'LL GET ONE. IT'S WEIRD I ALWAYS FEEL LIKE A PREGNANT TO SYMPTOMS. VOMITING, SORE BREAST, NO PERIOD, HEADACHES,ETC... I HAVE ALSO EXTREME BACK PAIN... I HAVE BEEN IN THE ER DID TO THESE PROBLEMS. I HAVE MAJOR DEPRESSION AND ANXIETY I HAVE MEDICATION FOR. I HATE MY LIFE BECAUSE OF ESSURE. I FEEL LIKE AM WAY TO YOUNG FOR HYSTERECTOMY. PLEASE HELP ME WHAT DO I DO. I HAVE THREE BEAUTIFUL GIRLS. ALSO GAIN WEIGHT CAUSE ME TO HAVE HIGH BLOOD SUGAR WERE I HAVE PRE DIABETES HAVE TO ALSO TAKE MEDICATION FOR. BEFORE I WAS A HEALTHY WOMAN I WANT THAT BACK!!!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039649	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AWFUL EXPERIENCE LOTS OF SIDE EFFECTS SUCH AS VOMITING, ITCHING JOINT ACHE, DEPRESSION, FATIGUE METAL TASTE IN MOUTH, BLURRED VISION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039650	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASHES, HAIR LOSS, MOOD CHANGES, TASTE METAL IN MY MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039651	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED NOTICING VERY HEAVY BLEEDING (I HAVE TO LINE MY UNDERWEAR WITH 2 TO 3 OF THE OVERNIGHT PADS EACH TIME I HAVE MY MENSTRUATION AND WITH EACH CHANGING OF THOSE PADS I HAVE TO REPLACE THEM WITH 2 TO 3 PADS EACH TIME INCREASING MY FINANCIAL EXPENSES ON FEMININE PRODUCTS), PAINFUL MENSTRUAL CYCLES, EXTENDED MENSTRUAL CYCLES. AS I CONTINUED FOR THE LAST FEW YEARS I HAVE NOTICED ODD ALLERGY REACTIONS TO DIFFERENT THINGS THAT NORMALLY WOULDN'T GIVE ME AN ODD REACTION. HAIR LOSS, SKIN CHANGES, HORMONE CHANGES, AND NOW RECENTLY SEVER BACK PAIN THAT NEVER ENDS. ODD ABDOMINAL PAINS AND TWITCHING THAT FEEL LIKE THERE IS A KICKING BABY INSIDE, BUT THERE ISN'T ONE. I SEEM TO GET SICK MUCH MORE EASILY THAN I HAD IN THE PAST. ODD METALLIC TASTES FROM TIME TO TIME. EASY BRUISING WITH NO REAL CAUSE. I WAS ALSO TOLD THIS PROCEDURE COULD BE REVERSED, AND NOW I HAVE FOUND OUT THAT IT CANNOT BE. WEIGHT GAIN FOR NO REAL APPARENT REASON. MY DIET OR EXERCISE PLANS HAVE CHANGED. DRS TELL ME MY ONLY HOPE TO BE RELIEVED OF A LOT OF MY CONDITIONS THAT I HAVE ACQUIRED DUE TO THIS DEVICE IS TO HAVE A HYSTERECTOMY. I WANTED TO ALSO HAVE ANOTHER BABY, AND NOW I AM ALSO TOLD THAT THAT MAY NOT BE A POSSIBILITY DUE TO THIS DEVICE. THAT I THINK HURTS THE MOST. WHY WASN'T I WARNED THESE THINGS COULD HAPPEN? MY LIFE IS NEVER GOING TO BE THE SAME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039653	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 3/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LONG PAINFUL PERIODS, SEVER CRAMPING, LARGE BLOOD CLOTS, HAIR LOSS, THE FEELING OF BEING STABBED IN MY LOWER BACK AND AT TIMES A STABBING TWIST FEELING INSIDE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039654	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PERIODS ARE EXCESSIVELY HEAVY WITH TENNIS BALL BLOOD CLOTS. I BLEED THROUGH PADS IN AN HOUR. I'VE GAINED A LOT OF WEIGHT. MY HAIR FALLS OUT. I'M ALWAYS CRAMPING AND IN PAIN. MY LEFT EYE HAS TWITCHED EVER SINCE I GOT ESSURE. I HAVE CONSTANT FLUTTERS IN MY CERVIX. SEX IS PAINFUL. MY PERIODS LAST 8-12 DAYS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039655	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALL KINDS OF PAIN - KNEES AND BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039656	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ABOVE DATE IS A GUESS. I HAD ESSURE IMPLANTED BEFORE THEN, AND UPON IMPLANTATION, I HAD A PERSISTENT ACHE IN MY PELVIC AREA. WHEN I COUGHED I COULD FEEL THE COILS. NOW, IN 2014, WHEN I SIT AROUND THE HOUSE I FEEL THEM, WHEN I GO TO BED, WHEN I GO FOR A WALK WHEN I DO ANYTHING I FEEL THEM. SOMETIMES MY PELVIS IS SO INFLAMED THAT IT HURTS TO HAVE A BOWEL MOVEMENT. I AM ALMOST ALWAYS BLOATED, AND DURING THE WEEK OF MY MENSTRUAL CYCLE IT IS THE WORST. NONE OF MY CLOTHES WILL FIT, I AM UNCOMFORTABLE. ON TOP OF THE BLOATING, I AM IN EXCRUCIATING PAIN THE ENTIRE TIME OF MY CYCLE. I HAVE TO DOUBLE UP ON PROTECTION ESPECIALLY WHEN I GO TO BED AT NIGHT, SO THAT I DON'T DESTROY MY CLOTHES/SHEETS. MY HORMONAL BALANCE IS OUT OF WHACK NOW. I'M GROWING HAIR ON MY CHIN, AND I HAVE AWFUL MOOD SWINGS DURING MENSES. I AM CONSTANTLY TIRED. I NEVER HAVE ENERGY. I FALL ASLEEP AT INAPPROPRIATE TIMES IN INAPPROPRIATE PLACES. I AM CONSTANTLY SORE. MY JOINTS ACHE, I'VE BURNING FEELINGS LIKE "HOT SPOTS" THROUGHOUT MY BODY AT TIMES, I HAVE A DIMINISHED SEX DRIVE, AND VAGINAL DRYNESS, MY EYES BLUR TO THE POINT THAT I CAN'T FOCUS SEVERAL TIMES A DAY. THESE ARE ALL THEY SYMPTOMS THAT I CAN THINK OF AT THE MOMENT. I'M SURE THERE ARE MORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039657	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE PAIN IS HORRIBLE, IT'S LIKE BARB WIRE IN MY STOMACH THAT IS SO BAD, I WOULD NOT WISH IT ON MY WORST ENEMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039658	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, BACK PAIN, LOSS OF LIBIDO, OVARIAN CYSTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039659	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING PAIN AND JOINT PROBLEMS MIGRAINES, HEAVY BLEEDING, CRAMPING, FATIGUE, WEIGHT GAIN, BLOATING, MOODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039660	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE JOINT PAIN, HEAVY PERIODS LASTING 2 WEEKS, BLEEDING DURING INTERCOURSE, SEVERE MOOD SWINGS, HEAVY SWEATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039661	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 8/31/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, MOOD SWINGS, HEAVY PERIODS, CONSTANT PAIN, LOWER ABDOMEN PAIN, LOWER BACK PAIN, FATIGUE, ITCHING, HAIR LOSS, VAGINAL INFECTIONS, LOW LIBIDO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039662	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 2/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, PAIN IN JOINTS, BAD BLEEDING ANYTIME OF THE MONTH, EXCESSIVE BLEEDING, HAIR LOSS, MAJOR MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039663	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 11/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT BLOATING, SEVERE WEIGHT GAIN, HEAVY PERIODS, STABBING CRAMPS THAT WOULDN'T LET UP, DEPRESSION, MIGRAINES, LOSS OF ENERGY, LOSS OF SEX DRIVE, NUMBNESS TO LEG AND ARMS, RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039664	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE INSERTION: EXTREMELY HEAVY MENSTRUAL CYCLES, PMDD, FIBROIDS, PAINFUL INTERCOURSE, RASHES, ITCHING, ABDOMINAL PAIN, NO INTEREST IN SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039665	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE INSERTION: EXTREMELY HEAVY MENSTRUAL CYCLES, PMDD, FIBROIDS, PAINFUL INTERCOURSE, RASHES, ITCHING, ABDOMINAL PAIN, NO INTEREST IN SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039666	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN HAVING MULTIPLE SYMPTOMS. IT STARTED WITH NAUSEA, MIGRAINE (THAT LAST DAYS AT TIME), FAINTING SPELLS, LIGHTHEADED, BLOATED, HAIR LOSS, RASHES, EXTREMELY FATIGUED, NO LIBIDO, TOOTH PAIN, NUMBNESS, HORRIBLE MOOD SWINGS, DEPRESSION, WEIGHT GAIN, HEART PALPITATIONS, CHEST PAIN, BACK, NECK AND ABDOMINAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039667	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 2/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I HAVE HAD ESSURE INSERTED I EXPERIENCE HEAVY BREATHING, BACK PROBLEMS, OVARIAN CYSTS, LEG SPASMS, AND VERY HEAVY PERIODS WITH CLOTS ALONG WITH SEVERE OVARIAN PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039668	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 3/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT DISCOMFORT IN OVARIES. CONSTANT VAGINAL BLEEDING. EXTENDED ABDOMEN. HAIR LOSS. BOWEL BLOCKAGE, CONSTIPATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039669	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ESSURE WAS PLACED (B)(6) 2011. STARTING (B)(6) 2012 I DEVELOPED A RASH OVER MY BODY IN ODD SPOTS INCLUDING ARMS, FACE AND CHEST. STILL TO THIS DAY, (B)(6) 2014, MANY DERMATOLOGISTS (INCLUDING MANY BIOPSIES) AND MEDICATIONS STILL HAVE NOT GONE AWAY AND STILL NO ANSWER TO WHAT IT MAY BE OR WHAT COULD BE CAUSING IT. THAT ITSELF HAS BEEN THE HARDEST TO DEAL WITH. IT HAS MADE ME SO SELF CONSCIOUS THAT I DON'T LIKE TO BE AROUND PEOPLE BECAUSE I'M EMBARRASSED AND EVEN MY OWN HUSBAND HAS SUFFERED BECAUSE I DON'T LIKE NOT HAVING CLOTHES ON TO COVER IT AND MY FACE I CAN'T COVER ALWAYS. I WOULDN'T GO ANYWHERE WITH HIM IN FEAR THAT HE WAS EMBARRASSED OF ME. I HAVE HAD OTHER SIDE EFFECTS AS WELL. ANXIETY, FORGETFULNESS, LOW SEX DRIVE, MOOD SWINGS THAT MAKE ME FEEL UNCOMFORTABLE (MY POOR HUSBAND GOT THE BRUNT OF THAT AS WELL. WE EVEN WENT TO COUNSELING TOGETHER). FEELING FAINT AND DIZZY WHEN MOVING TOO FAST OR EVEN SITTING STILL, JOINT PAIN EVERYWHERE BUT ESPECIALLY IN MY LOWER BACK AND HIPS, PAIN SO SEVERE IN MY LOWER ABDOMEN (MORE ON THE RIGHT SIDE) THAT RADIATED AROUND TO MY BACK THAT SENT ME TO THE ER 4 TIMES IN THE LAST YR - (B)(6) 2013 AND (B)(6) 2014. THAT SEVERE PAIN WILL COME AND GO WHEN IT FEELS LIKE IT BUT I HAVE ABDOMINAL DISCOMFORT DAILY ALONG WITH BLOATING. WITH MY ER VISITS I HAD MULTIPLE ULTRASOUNDS, TWO TOO MANY CT SCANS, XRAYS, BLOOD WORK, URINE TESTS ETC AND NOT ONE ANSWER FOR ANY OF THEM. IN ALL MY SCANS AND XRAYS THE COILS ARE SEEN. I HAVE SEEN 2 HEMATOLOGISTS WITH BLOOD WORK SHOWING NOTHING DUE TO CHRONIC FATIGUE, NIGHT SWEATS, HOT FLASHES, PAIN IN ABDOMEN. I'VE SEEN A RHEUMATOLOGIST WHO HAS TESTED FOR MANY INFLAMMATORY DISEASES AND CAME UP WITH NOTHING DUE TO MY CHRONIC JOINT PAIN, RANDOM FEVERS AND RASHES. I'VE HAD GI ISSUES AS WELL WITH BLOATING, BELLY PAIN AND EVEN MY RASH (THINKING CELIAC) SO I SAW A GI DOCTOR.

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AFTER A TRIAL OF DIFFERENT MEDS TO HELP AND DIDN'T I HAD AN UPPER ENDO AND COLONOSCOPY DONE (B)(6) 2013 AND CAME OUT WITH NOTHING AS WELL. IN THE MIDDLE OF ALL OF THIS I HAD A HYSTERECTOMY (B)(6) 2013 WITH ONLY REMOVING MY UTERUS AND CERVIX BUT LEFT MY OVARIES (DUE TO ONLY BEING (B)(6) SHE DIDN'T WANT ME TO BE PUT INTO MENOPAUSE THAT YOUNG) AND WHY I'M STILL NOT SURE BOTH COILS WERE LEFT TOO. I'VE EVEN SEEN MY GYNECOLOGIST IN REGARDS TO THE PAIN AFTER MY HYSTERECTOMY AND NOTHING. I HAVE EVEN MENTIONED THE COULD THE COILS BE THE REASON AND THEY ALL SAID NO. I'VE NEVER HAD TO DEAL WITH SO MANY MEDICAL ISSUES IN MY PREVIOUS (B)(6) LIKE I HAVE IN THE PAST 2YRS AFTER I HAD MY ESSURE PROCEDURE. ALL OF THIS HAS EFFECTED MYSELF AND ESPECIALLY MY FAMILY. ITS ALSO BEEN A BATTLE WITH MEDICAL BILLS DUE TO THE PAIN AND OTHER SIDE EFFECTS THAT HAVE MADE LIFE A DAILY STRUGGLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039670	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 4/1/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS, LARGE BLOOD CLOTTING, 7 TO 10 DAY CYCLES, FLU TYPE BODY ACHES, STOMACH PAINS, DIARRHEA, PMS, WEIGHT GAIN OF 100LB PLUS .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039671	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 1/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, HEAVING BLEEDING, HOT FLASHES, STABBING PAIN, HEADACHES, FAINTNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039672	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 7/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC MIGRAINES, CHRONIC FATIGUE, EXTREME MUSCLE WEAKNESS, ALLOVER PAIN ESP BACK AND SHOULDERS. ABDOMINAL PAIN AND BLOATING. PERIODS LASTING FOR 21-30 DAYS. BECAME PERMANENTLY DISABLED IN MARCH 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039673	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 3/27/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE PROCEDURE, I'VE HAD PAINFUL PERIODS LASTING WEEKS AT A TIME, CHRONIC FATIGUE SYNDROME, ARTHRITIS TYPE SYMPTOMS, HAIR LOSS, EYELASH LOSS, NICKEL ALLERGY, BLOATING, SWELLING, MIGRAINES, FOOD ALLERGIES (NEW SINCE ESSURE), ACNE, SLEEP PROBLEMS, DENTAL PROBLEMS, EMOTIONAL DISTRESS, LOSS OF LIBIDO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039674	BAYER	12/19/2014	12/19/2014

Event Information:

Event Date (B3): 12/18/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, CRAMPING, CHRONIC FATIGUE, GALLBLADDER PROBLEMS, BACK AND NECK PROBLEMS. LOOKING LIKE I AM 6 MONTHS PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039675	BAYER	12/19/2014	12/22/2014

Event Information:

Event Date (B3): 12/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL CRAMPS, NAUSEA DAILY, LOW VITAMIN D LEVELS, HEAVY BLEEDING WITH MENSTRUAL CYCLE, SEVERE HEADACHES, TAIL BONE PAIN. I WAS IMPLANTED IN 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039801	BAYER	12/19/2014	12/30/2014

Event Information:

Event Date (B3): 6/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305626404

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER RECEIVING THE ESSURE (B)(6) 2008 AT THE (B)(6), WITHIN 2 MONTHS I STARTED HAVING JOINT PAIN, HEAVY PERIODS, SEVERE HEADACHES WHICH LEAD ME TO BE DIAGNOSED WITH RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS, MIGRAINES, PMDD, HIGH BLOOD PRESSURE, I STARTED GETTING ABSCESSED TEETH AND THEY STARTED BREAKING. I ENDED UP LOSING ALL MY TEETH. MY STOMACH STARTED SWELLING. I WEIGHED (B)(6) THE DAY I GOT THE ESSURE AND WITHIN 3 MONTHS GAINED (B)(6) I NOW WEIGHT (B)(6), WHICH I CANNOT LOSE EVEN WITH THE HELP OF DOCTORS AND PRESCRIPTION MEDICATIONS FOR WEIGHT LOSS. I AM NOW CONSIDERED OBESE. I LOOK 9 MONTHS PREGNANT FROM SWELLING AND WATER RETENTION ALL IN MY STOMACH; NO OTHER PART OF MY BODY LOOKS LIKE THIS. I HAVE ALSO BEEN DIAGNOSED WITH DEPRESSION FROM ALL OF THESE PROBLEMS. I BREAK OUT IN SEVERE HIVES ALL OVER MY BODY FOR NO APPARENT REASON. I WAS A HEALTHY, HAPPY (B)(6) BEFORE ESSURE WITH NO HEALTH PROBLEMS. NOW, EVEN WITH THE HELP OF MEDICATIONS, HEADACHES AND CRAMPS ARE STILL DEBILITATING TO THE POINT I DO NOT LEAVE MY HOUSE UNLESS IT IS ABSOLUTELY NECESSARY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039803		12/19/2014	12/30/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS AND I'VE HAD SERIOUS CRAMPS, HEADACHES AND MY DOCTOR SAID THEY MIGRATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039812	BAYER	12/20/2014	12/30/2014

Event Information:

Event Date (B3): 12/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2008. APPROXIMATELY 4 YEARS LATER I STARTED DEVELOPING A RASH. I HAD SKIN TESTING AND DERMATOLOGY PATHOLOGY TESTING TO CONCLUDE I HAVE DEVELOPED A GOLD ALLERGY. I LATER LEARNED THAT ESSURE CONTAINS GOLD IN THE DEVICE. I RECENTLY HAD A HYSTERECTOMY TO HAVE ESSURE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00543	BAYER HEALTHCARE LLC	12/22/2014	12/22/2014

Event Information:

Event Date (B3): 10/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/9/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 04-NOV-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION. SHE WAS NOT PREGNANT. THE PHYSICIAN INFORMED THAT 3 PATIENTS HAD HSG (HYSTEROSALPINGOGRAM) DONE ON (B)(6) 2014 AND HAD PATENCY OR POSSIBLE PERFORATION, BUT HE DID NOT SPECIFY WHICH PATIENT HAD WHAT. ESSURE WAS CONTINUED. FOLLOW-UP INFORMATION FROM GENERAL ESSURE QUESTIONNAIRE RECEIVED ON 24-NOV-2014 FROM PHYSICIAN: THE INCIDENT CATEGORY WAS CHANGED TO INCIDENT. THE PATIENT´S (B)(4). IN 2009, CURETTAGE WAS PERFORMED. CERVICAL CONIZATION, PREVIOUS IUS/IUD, MYOMECTOMY AND ADNEXAL SURGERY WERE DENIED. ANY PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES AND RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS WERE ALSO DENIED. ON (B)(6) 2014 ESSURE WAS INSERTED UNDER GENERAL ANESTHESIA. THE INSERTION AND THE VISUALIZATION OF THE TUBAL OSTIUM WERE CONSIDERED EASY. THE FLUID LOSS WAS LESS THAN 1500CC AND THE TIME OF PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. AFTER INSERTION AND BEFORE OCCLUSION CONFIRMATION, THE PATIENT USED CONDOMS. ON (B)(6) 2014, HYSTEROSALPINGOGRAM WAS DONE. DURING HSG, ONE SIDE THE COIL SHOWED THAT IT WAS NOT FOLLOWING THE TRAJECTORY OF THE TUBE, UNSURE IF THERE WAS PERFORATION. THE PHYSICIAN STATED A FAILED CLOSURE (THE PREVIOUS REPORTED EVENT PATENCY OR POSSIBLE PERFORATION WAS AMENDED TO SUSPICION OF PERFORATION: ONE SIDE THE COIL SHOWED THAT IT WAS NOT FOLLOWING THE TRAJECTORY OF THE TUBE AND PATENCY/FAILED CLOSURE). HOSPITALIZATION DID NOT OCCUR. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THERE WAS A SUSPICION OF PERFORATION:

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ONE SIDE THE COIL SHOWED THAT IT WAS NOT FOLLOWING THE TRAJECTORY OF THE TUBE AND PATIENT UNDERWENT A LAPAROSCOPIC TUBAL LIGATION. THESE EVENTS WERE INTERPRETED AS UTERINE PERFORATION CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND FALLOPIAN TUBE PATENCY WAS CONSIDERED NON-SERIOUS. BOTH EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN CASES OF UNILATERAL OR BILATERAL INSERT PERFORATION, FALLOPIAN TUBES MAY APPEAR PATENT AT CONTROL HYSTEROSALPINGOGRAM. IN THIS CASE, IT IS NOT CLEAR IF THERE WAS A UTERINE PERFORATION OR IF DEVICE WAS INEFFECTIVE. HOWEVER, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND GIVEN THE NATURE OF THESE EVENTS, UTERINE PERFORATION AND DEVICE INEFFECTIVITY WERE CONSIDERED RELATED TO ESSURE. AS THE PATIENT UNDERWENT A LAPAROSCOPIC TUBAL LIGATION, THEREFORE, THE CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 22-DEC-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00544	BAYER HEALTHCARE LLC	12/22/2014	12/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A PERSON SHE KNEW, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. ON AN UNSPECIFIED DATE THE CONSUMER HAD TO HAVE HER INSERTS REMOVED DUE TO PAIN AND "INSERT BALLS WERE MOVED". PTC INVESTIGATION RESULT RECEIVED ON 08-DEC-2014. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE AE CASE REFERS ALSO TO AN UNSPECIFIED PRODUCT ISSUE, HOWEVER, NO DETAILED INFORMATION WERE AVAILABLE AT THIS POINT IN TIME REGARDING THE NATURE OF THE ISSUE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED,

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SPONTANEOUS CASE REPORT REFERS TO A FEMALE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT AN UNKNOWN TIME AFTER ESSURE INSERTION AND SHE HAD HER INSERTS REMOVED. BASED ON THIS INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE SURGICAL INTERVENTION (NOT SPECIFIED) REQUIRED TO REMOVE THE INSERTS. ADDITIONALLY, NON-SERIOUS EVENT WAS ADDED: INSERT BALLS WERE MOVED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW-UP INFORMATION WILL BE POSSIBLE SINCE NO CONTACT INFORMATION IS AVAILABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00546	BAYER HEALTHCARE LLC	12/22/2014	12/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON 25-NOV-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. ESSURE WAS INSERTED FOR BIRTH CONTROL. CONSUMER REPORTED THAT SHE EXPERIENCED A HUGE AMOUNT OF PAIN. THE OPERATIVE PROCEDURE TOOK 4 HOURS AND THEY STRUGGLED TO GET THE UTERUS OUT. CONSUMER ALSO STATED THAT ESSURE COILS HAVE BEEN EVICTED. NO ADDITIONAL INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 18-DEC-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A

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CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 19-DEC-2014: NO FURTHER INFORMATION CAN BE OBTAINED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE A CAUSAL RELATIONSHIP BETWEEN PAIN AND THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL PROCEDURE FOR UTERUS REMOVAL WAS REPORTED, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION COULD BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00547	BAYER HEALTHCARE LLC	12/22/2014	12/22/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF, A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. IN 2012 THE CONSUMER HAD FALLOPIAN TUBE OCCLUSION INSERT (ESSURE) INSERTED. ON AN UNSPECIFIED DATE THE COIL PERFORATED CONSUMER'S FALLOPIAN TUBE AND HER UTERUS. SHE WAS DIAGNOSED WITH THE MIGRATING COIL IN THE FIRST WEEK OF (B)(6) 2014 AND IN THE FIRST WEEK OF (B)(6) 2014 SHE HAD TO HAVE A HYSTERECTOMY (UTERUS, TUBE AND CERVIX). SHE HAS BEEN ON AN "EMOTIONAL ROLLER COASTER" THROUGH THIS ALL. THE SURGERY WENT WELL BUT SHE STARTED TO BLEED. HER VAGINAL CUFF WAS RESTITCHED AND SHE WAS DOING A LOT BETTER. FOLLOW UP (B)(6) 2014: NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2014. PTC GLOBAL NUMBER (B)(6). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. POST PROCEDURAL BLEEDING MAY OCCUR FOLLOWING OR DURING ANY SURGICAL PROCEDURE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL

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MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SOLICITED CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COIL PERFORATED HER FALLOPIAN TUBE AND HER UTERUS. A HYSTERECTOMY WAS PERFORMED AND THE PATIENT STARTED TO BLEED AFTER SURGERY. THE FIRST EVENT, SEEN AS UTERINE AND FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE REMAINING EVENT, INTERPRETED AS POST PROCEDURAL BLEEDING, IS ALSO SERIOUS BUT UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. POST PROCEDURAL BLEEDING MAY OCCUR FOLLOWING OR DURING ANY SURGICAL PROCEDURE. IN THIS CASE, THE PATIENT WAS DIAGNOSED WITH DEVICE MIGRATION AND ONE MONTH LATER SHE UNDERWENT A HYSTERECTOMY. THE SURGERY OCCURRED WELL, BUT SHE STARTED TO BLEED JUST AFTER THE PROCEDURE. SHE WAS RESTITCHED IN VAGINAL CUFF AND RECOVERED. GIVEN THE NATURE OF PERFORATION, THE EVENT IS ASSESSED AS RELATED TO ESSURE USE. AS THE BLEEDING STARTED AFTER HYSTERECTOMY, IT CAN BE CONSIDERED AS A COMPLICATION OF THE PROCEDURE. CONSIDERING THAT THIS SURGERY WAS PERFORMED DUE TO PERFORATION CAUSED PER ESSURE MICRO-INSERT, CAUSALITY BETWEEN THE POST PROCEDURAL BLEEDING AND ESSURE USE IS ASSESSED AS RELATED. THIS CASE WAS REGARDED AS INCIDENT (ANTICIPATED) SINCE A INTERVENTION WAS REQUIRED (SURGERY TO REMOVE ESSURE COIL AND ALSO HYSTERECTOMY). COMPLAIN SAMPLE HAD NOT RETURNED TO PRODUCT TECHNICAL ANALYSIS AND NO BATCH NUMBER WAS REPORTED (WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE). ACCORDING TO ANALYSIS RESULT, THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00548	BAYER HEALTHCARE LLC	12/22/2014	12/22/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 11/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 25-NOV-2014 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: (B)(4). THE CONSUMER HAD THE FALLOPIAN TUBE OCCLUSION INSERT INSERTED. SHE EXPERIENCED SEVERE PAIN ALL THE TIME, HAIR LOSS, RASH ON ENTIRE BACK, HER PERIOD THAT LASTED 10-13 DAYS A MONTH AND TWICE A MONTH, AND ANEMIC. FALLOPIAN TUBE OCCLUSION INSERT WAS REMOVED ON (B)(6) 2014. SHE WAS 2 WEEKS AND 2 DAYS POST-OP AT THE TIME OF REPORT AND SHE HAD RECOVERED FROM THE EVENTS. PTC INVESTIGATION RESULT RECEIVED ON 09-DEC-2014. PTC GLOBAL NUMBER(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY

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COMMENT: THIS NON MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN ALL THE TIME. ESSURE WAS REMOVED. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THE PRESENT CASE, THE CONSUMER REPORTED THAT SHE WAS FREE FROM THE SYMPTOMS AFTER ESSURE REMOVAL. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT AND POSITIVE DECHALLENGE, A CAUSAL RELATIONSHIP BETWEEN SEVERE PAIN ALL THE TIME AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. ADDITIONALLY, NON SERIOUS EVENTS HAIR LOSS, RASH ON ENTIRE BACK, HER PERIOD THAT LASTED 10-13 DAYS A MONTH AND TWICE A MONTH, AND ANEMIC WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND STATED THAT THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP WAS NOT POSSIBLE SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00549	BAYER HEALTHCARE LLC	12/22/2014	12/23/2014

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 25-NOV-2014 WHICH REFERS TO ANOTHER FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A (B)(6), STUDY NUMBER: (B)(4). CONSUMER REPORTED VIA SOCIAL MEDIA THAT AN ESISTER (ESSURE SISTER) WAS SUFFERING; ESSURE WAS EMBEDDED IN HER BOWEL. SHE ASKED HOW THIS WAS NOT A PROBLEM FROM ESSURE. SHE POSTED IN A SOCIAL NETWORKING A LAPAROSCOPY PICTURE SHOWING THE EMBEDDED DEVICE (AN INTERVENTION WAS IMPLIED). FOLLOW UP 16.DEC.2014: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SOLICITED CASE REPORT, RECEIVED VIA SOCIAL MEDIA, REFERS TO A FEMALE CONSUMER WHO HAD

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ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) EMBEDDED IN BOWEL. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION IS SERIOUS DUE MEDICAL SIGNIFICANCE (IMPLIED REQUIRED INTERVENTION). DISLOCATION IS A LISTED EVENT ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD RESULT IN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION/DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THERE WAS AN EMBEDMENT OF ESSURE IN BOWEL. GIVEN THE NATURE OF THIS EVENT, THE DISLOCATION WAS CONSIDERED RELATED TO ESSURE. SINCE THERE IS AN IMPLIED INTERVENTION (IMAGE FROM LAPAROSCOPY) THE CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: NO FURTHER INFORMATION CAN BE OBTAINED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SOLICITED CASE REPORT, RECEIVED VIA SOCIAL MEDIA, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00545	BAYER HEALTHCARE LLC	12/22/2014	1/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76527

Single Use: Y
Implant Date (E6): 7/14/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 (LOT NUMBER B76527). ADDITIONAL INFORMATION ALSO RECEIVED ON (B)(6) 2014 FROM THE PHYSICIAN. PHYSICIAN REPORTED THAT HAD AN URGENT REQUEST AS THE PATIENT WAS ON THE TABLE WITH HER ESSURE HSG (HYSTEROSALPINGOGRAM) ON (B)(6) 2014 AND THE IMAGE SHOWED THE ESSURE WAS NOT IN THE FALLOPIAN TUBE BUT THE COILS WERE VISIBLE IN THE OSTIUM AND DOCTOR WONDERED IF THE ESSURE WAS BROKEN. DOCTOR REPORTED THAT PROCEDURE WAS A NORMAL PLACEMENT ON (B)(6) 2014. AT 3 MONTHS SHE CONDUCTED HSG, HAD OCCLUSION OF LEFT WITH GOOD PLACEMENT, THE REPORT INDICATED THAT THE RIGHT TUBE WAS OPEN AND THE UNIT WAS MORE CAUDAL THAN EXPECTED HOWEVER THERE WAS ONE MARKER IN ONE IN THE AREA OF OSTIA. BASED ON IMAGES, ON (B)(6) 2014, THE DOCTOR WENT INTO WITH A HYSTEROSCOPE TO LOCATE AND INSERT ESSURE ON THE RIGHT SIDE AS THE HCP EXPECTED THE UNIT TO BE IN THE UTERUS. HOWEVER, SHE FOUND 2 COILS IN RIGHT OSTIA, BUT NO UNIT. DOCTOR THOUGHT IT WAS A PERFORATION BUT SHE HAD NOT SEEN THIS TYPE OF IMAGE BEFORE. THE PATIENT HAD A RETROVERTED UTERUS PLUS COLPOSCOPY PERFORMED A MONTH AGO ((B)(6) 2014, RESULTS NOT PROVIDED). BASED ON THE IMAGES, SHE THOUGHT THE ESSURE UNIT WAS IN THE ABDOMEN OR FALLEN INTO THE PELVIS BUT THE DOCTOR WOULD REALLY LIKE A SECOND OPINION ON THE HSGS AND WAS WILLING TO SEND THEM. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014. IT WAS REPORTED THAT ON (B)(6) 2014, A CONFIRMATION TEST WAS DONE AND SHOWED THAT DEVICE WAS OUTSIDE OF THE RIGHT TUBE. HOWEVER, ON (B)(6) 2014, THERE WERE VISIBLE COILS (2 OR 3) IN THE RIGHT OSTIUM. IT WAS ALSO REPORTED A POSSIBLE BAND DETACHMENT (THE PREVIOUS REPORTED EVENT WONDERED IF THE ESSURE WAS BROKEN WAS UPDATED

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TO WONDERED IF THE ESSURE WAS BROKEN/POSSIBLE BAND DETACHMENT). NO INJURY TO THE PATIENT WAS DESCRIBED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). BATCH NUMBER B76527 (PRODUCTION DATE (B)(6) 2013; EXPIRATION DATE (B)(6) 2016). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF (B)(6) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A 35 YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DOCTOR WONDERED IF THE ESSURE WAS BROKEN/ POSSIBLE BAND DETACHMENT. DOCTOR FOUND 2 COILS IN RIGHT OSTIA, BUT NO UNIT AND SHE THOUGHT ESSURE WAS PERFORATED AND ALSO SHE THOUGHT THE ESSURE UNIT WAS IN THE ABDOMEN OR FALLEN INTO THE PELVIS. THE EVENT FOUND 2 COILS IN RIGHT OSTIA, BUT NO UNIT (THOUGHT ESSURE WAS PERFORATED AND ALSO SHE THOUGHT THE ESSURE UNIT WAS IN THE ABDOMEN OR FALLEN INTO THE PELVIS), INTERPRETED AS SUSPICION OF UTERINE PERFORATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE OTHER EVENT INTERPRETED AS SUSPICION OF DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED. INITIALLY, THIS BREAKAGE WAS CONSIDERED AS UNLISTED. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS SPECIFIED AS POSSIBLE BAND DETACHMENT AND THEREFORE WAS ASSESSED AS LISTED. UTERINE OR FALLOPIAN TUBE PERFORATION AND DEVICE BREAKAGE MAY OCCUR WITH ESSURE USE. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT BASED ON THE HYSTEROSALPINGOGRAM, PATIENT HAD OCCLUSION OF LEFT TUBE, BUT THE RIGHT TUBE WAS OPEN AND THE UNIT WAS MORE CAUDAL THAN EXPECTED. THE DOCTOR WAS SUSPECTING OF DEVICE BREAKAGE AND BAND DETACHMENT. A NEW UNSPECIFIED EXAM WAS PERFORMED 4 DAYS LATER AND THERE WERE VISIBLE COILS (2

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OR 3) IN THE RIGHT OSTIUM. SHE WAS SUSPECTING OF PERFORATION AND THAT ESSURE COULD BE LOCATED IN THE ABDOMEN OR FALLEN INTO THE PELVIS. ALTHOUGH THE PERFORATION AND DEVICE BREAKAGE WERE NOT CONFIRMED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 07-APR-2015 THE PATIENT´S WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS AND PROCEDURES WERE DENIED. HER MEDICAL HISTORY INCLUDED 3 PREGNANCIES WITH 3 PARITIES. ACTUAL PREGNANCY WA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00550	BAYER HEALTHCARE LLC	12/23/2014	12/23/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26960

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/16/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 30-SEP-2014 (WITH ADDITIONAL INFORMATION RECEIVED FROM MEDICAL RECORDS ON (B)(6)-2014) AND REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED, LOT NUMBER C6960. THE PATIENT'S MEDICAL HISTORY INCLUDED 2 VAGINAL DELIVERIES AND 1 CESAREAN DELIVERY. ANTIGONE (DESOGESTREL) WAS USED AS CONTRACEPTION AT TIME OF INSERTION PROCEDURE. PATIENT HAD THE ESSURE IMPLANTED WITH NO ANESTHESIA. AS PREMEDICATION, NSAID (NON-STEROIDAL ANTI-INFLAMMATORY DRUG) AND DOLIPRANE WERE USED. THE INTRODUCTION OF RIGID DIAGNOSIS HYSTEROSCOPE WAS WITH NO DIFFICULTY AND MADE ACCORDING TO THE BETOCCHI TECHNIQUE. THE CAVITY WAS SLIGHTLY ENLARGED AND WIDENED BOTTOM; HOWEVER, WAS EASY TO WELL INDIVIDUALIZE LEFT OSTIUM. IT WAS NOTICED A PROBLEM WHILE MAKING THE TRACKWHEEL ROLL. THE TRACKWHEEL SEEMED TO TURN BLANK, WITH NO BLOCKING. AFTER A CERTAIN TIME IT WAS DECIDED TO TRY TO RELEASE THE IMPLANT BY PRESSING THE APPROPRIATE BUTTON. HOWEVER, THE IMPLANT DID NOT GET RELEASED AND THE STENT SEEMED TO BE WOUND ON THE ROD OF THE DEVICE ESSURE. IT WAS THEN TRIED TO REMOVE STEP BY STEP THE DEVICE BUT THE STENT BROKE UP AND STAYED FOR THE 3/4 INTRACAVITARY AND FOR 1/4 INTRA TUBAL. THE PROCEDURE WAS STOPPED. ACCORDING TO THE REPORTING PHYSICIAN, THE EVENT WAS A SERIOUS INCIDENT AND A NEW SURGERY (UNSPECIFIED) HAD TO BE DONE TO REMOVE ESSURE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND, DURING THE INSERTION PROCEDURE, THE IMPLANT (ESSURE) DID NOT GET RELEASED AND THE STENT BROKE UP. THE EVENT IMPLANT (ESSURE) DID NOT GET RELEASED AND THE STENT BROKE UP WAS SEEN AS A DEVICE BREAKAGE AND WAS

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CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE BY THE REPORTING PHYSICIAN. IT IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PRESENT CASE, REPORTING PHYSICIAN STATED THAT THE DEVICE DID NOT GET RELEASED FROM THE DELIVERY CATHETER AND THEN BROKE UP. CONSIDERING THE NATURE OF REPORTED EVENT AND ALSO IT HAS OCCURRED IN CONNECTION WITH INSERTION PROCEDURE, COMPANY ASSESSES DEVICE BREAKAGE AS RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT AS, ACCORDING TO REPORTING PHYSICIAN, A NEW SURGERY TO REMOVED ESSURE HAD TO BE DONE. NO FURTHER INFORMATION FROM REPORTER IS WILL BE AVAILABLE. PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 02-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND ALSO TO A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00552	BAYER HEALTHCARE LLC	12/23/2014	12/23/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 11/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 FOR STERILIZATION. THE NURSE REPORTED THAT PATIENT WITH ESSURE HAD HYSTERECTOMY ON (B)(6) 2014 DUE TO PELVIC PAIN. DURING THE HYSTERECTOMY, IT WAS NOTED THAT THE ESSURE COIL WAS EVIDENT AT THE SURFACE OF THE RIGHT CORNUA. THE COILS CAME OUT WITH THE UTERUS (HYSTERECTOMY WITH REMOVAL OF BOTH ESSURE COILS.). HER ESSURE WAS INSERTED BY ANOTHER DOCTOR. SHE WENT TO THE CLINIC AS A NEW PATIENT ON (B)(6) 2014 COMPLAINING OF PELVIC PAIN. FOLLOW UP 04.DEC.2014: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL

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QUALITY DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. THIS PAIN LED TO HYSTERECTOMY AND DURING THE SURGICAL PROCEDURE, IT WAS NOTED THAT ESSURE COIL WAS EVIDENT AT THE SURFACE OF THE RIGHT CORNUA (INTERPRETED AS DEVICE DISLOCATION). BOTH EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE PATIENT WENT TO PHYSICIAN'S OFFICE COMPLAINING ABOUT PELVIC PAIN. FIVE MONTHS LATER, HYSTERECTOMY WAS PERFORMED DUE THE PAIN AND THE MICRO-INSERT WAS FOUND AT THE SURFACE OF THE RIGHT CORNUA. THE DEVICES WERE REMOVED WITH UTERUS. BASED ON PROVIDED INFORMATION AND NATURE OF THE EVENTS, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE AND SINCE REQUIRED INTERVENTION WAS REPORTED, THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY REPORT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED FROM NURSE ON 05-JAN-2015: THE PATIENT´S MEDICAL HISTORY INCLUDED ALLERGY TO BACTRIN, TO SULFA AND TO WHITE RICE. THE PATIENT DID NOT SMOKE AND DID NOT DRINK ALCOHOL. IT WAS REPORTED THAT ESSURE WAS PLACED IN 2011 FOR PERMAN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00551	BAYER HEALTHCARE LLC	12/23/2014	12/24/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE (VIA SOCIAL MEDIA WEBSITE) IN UNITED STATES ON (B)(4) 2014. CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED ON (B)(4)2014. CONSUMER REPORTED THAT ESSURE HAS RUINED HER LIFE AND STATES THAT SHE WILL TELL HER HORROR HISTORY. IN ADDITION CONSUMER REPORTED THAT SHE EXPERIENCED CRAMPING AND SHE WILL HAVE HYSTERECTOMY PREOPERATIVE ON (B)(4) 2014. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4)2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL

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QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(4)2014 AND (B)(4) 2014 FROM CONSUMER VIA SOCIAL MEDIA: SHE STATED THAT SHE HAD INSOMNIA AGAIN, PERFORATED UTERUS, COLLAPSED LUNG, 5 INFECTIONS, CELLULITIS, 150 ML PUS POCKET AND A HYSTERECTOMY. ALL EVENTS WERE CONSIDERED ESSURE PROBLEMS. SHE ALSO REPORTED THAT HER PAIN MANAGEMENT DOCTOR BELIEVES THAT ESSURE SHOULD BE PULLED OUT OF MARKET. THIS CASE WAS UPGRADED TO INCIDENT DUE TO SURGICAL INTERVENTION. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2014. PTC GLOBAL NUMBER (B)(4) FINAL ASSESSMENT: CASE UPGRADED TO INCIDENT. FINAL RC UPDATED TO USER LETTER 8. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A PERFORATED UTERUS, COLLAPSED LUNG AND CELLULITIS. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION PERFORATED UTERUS IS LISTED WHILE THE OTHER EVENTS ARE UNLISTED. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE. WITH ESSURE, UTERINE PERFORATIONS MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, IT IS NOT CLEAR WHEN THE PERFORATION OCCURRED. HOWEVER, CONSIDERING THE NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. GIVEN THE PATHOPHYSIOLOGY OF THE EVENTS COLLAPSED LUNGS AND CELLULITIS AND TAKING INTO CONSIDERATION THE DEVICE'S LOCAL ACTION IN FALLOPIAN TUBES, THESE EVENTS WERE CONSIDERED UNRELATED TO ESSURE. THIS CASE HAS LIMITED INFORMATION. IT WAS INTERPRETED THAT THE HYSTERECTOMY IS AN ESSURE-RELATED SURGERY. THEREFORE, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. A PERFORATION QUESTIONNAIRE FOLLOW UP IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 27-MAR-2015: UNSUCCESSFUL FOLLOW-UP ATTEMPT TO OBTAIN PRIMARY REPORTER'S CONTACT INFORMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039834	BAYER	12/23/2014	1/2/2015

Event Information:

Event Date (B3): 6/15/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): L2606
Lot #(E4): 509799

Single Use:
Implant Date (E6): 6/15/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IN PLACE IN (B)(6) 2006, EVER SINCE MY FIRST PERIOD. THEY HAVE BEEN HORRIBLE. SEVERE CRAMPS, BLOATING, NAUSEA, HEADACHE, ACNE, BLEEDING CLOTHS, HORRIBLE PMS, MOOD SWINGS, DIAGNOSED WITH DIVERTICULITIS AT AGE (B)(6). I HAD MY GALLBLADDER REMOVED (B)(6) 2007. DIAGNOSED 2014 WITH CHRONIC FATIGUE SYNDROME, CONSTANT FEELING OF TIRED AND BODY ACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039753	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 4/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING FROM (B)(6) 2014- TO TOTAL HYSTERECTOMY ON (B)(6) 2014. LEGS GOING NUMB, RASH ON RIGHT HIPS, WEIGHT GAIN, BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039754	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 12/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN, HEAVIER/PAINFUL PERIODS, PAINFUL OVULATION, ACNE, MUSCLE SPASMS, BLOATING, SPOTTING BETWEEN PERIODS, BLEEDING DURING/AFTER SEX, INCREASED VAGINAL INFECTIONS, URINARY INFECTIONS, CONSTIPATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039755	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 8/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWO YEARS AND THREE MONTHS AGO, I HAD A SURGICAL STERILIZATION PROCEDURE DONE. SOME OF THE SYMPTOMS I'VE EXPERIENCED THAT HAVE ONLY DEVELOPED SINCE THE SURGERY HAVE BEEN: ABDOMINAL PAIN THAT LASTS FOR ABOUT 15 DAYS OR MORE PER MONTH THAT HAS ME STUCK WITH HEAVY DUTY PAIN MANAGEMENT, I LIVE WITH HEAVY AND AWFUL MENSTRUATION THAT ALSO LASTS FOR 15+ DAYS, DECREASED LIBIDO, ABDOMEN CENTERED WEIGHT GAIN IN EXCESS OF 60LBS THAT DOESN'T RESPOND TO DIET AND EXERCISE, ACNE, BRAIN FOG, AND MANY MORE. I HAVE SPENT THE LAST TWO YEARS BEING BOUNCED FROM DOCTOR TO DOCTOR BEFORE I FINALLY FOUND ONE IN (B)(6) WHO'D EVEN BOTHER TO LISTEN TO THE POSSIBILITY. TOGETHER, SHE AND I HAVE HAD A BARRAGE OF TESTS DONE.... BLOOD WORK, ULTRASOUNDS, MRI, HEAVY METAL TESTING, ALLERGY TESTING, ETC. AND SO FAR ESSURE HAS PROVEN TO BE THE CULPRIT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039756	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN; PAIN WHEN TWISTING TORSO, SITTING DOWN, OR USING THE RESTROOM; WEIGHT GAIN OF APPROXIMATELY 40 POUNDS; CHRONIC HEADACHES AND MIGRAINES FOR WHICH I NOW HAVE TO TAKE MEDICATION TO CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039757	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 7/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING MIGRAINE, HEADACHES, JOINT PAIN, BACK PAIN, FATIGUE. HAVE HAD MRI OF HEAD AND BACK. LAB WORK ALL GOOD. NO EXPLANATION OF SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039758	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 5/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE PROCEDURE I HAVE HAD A CONSTANT PAIN IN MY LOWER LEFT SIDE AROUND THE AREA OF MY FALLOPIAN TUBE. I HAVE ALSO DEALT WITH HOT FLASHES, MIGRAINES, AND CONSTANT FATIGUE. I HAVE ALSO SINCE BEEN PLACED ON ZOLOFT FOR ANXIETY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039759	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STOMACH SWELLING, SEVERE BREAKOUT ON FACE, SEVERE LOWER BACK PAIN, PAIN WHEN INTAMITE, LOWER SHARP PAINS WHEN MOVING CERTAIN WAYS, AND WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039761	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 5/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN , FATIGUE , ACNE/BOILS, DENTAL PROBLEMS, CONSTANT HEADACHES, FOOT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039762	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 11/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE ITCHING. SEVERE DRYNESS ALL OVER MY BODY. I CAN'T SIT STILL. IT HAS AFFECTED MY DAILY LIFE. MY DOCTOR TESTED ME FOR A NICKEL ALLERGY AND IT CAME BACK AS POSITIVE. I AM NOW SCHEDULED FOR SURGERY TO REMOVE MY FALLOPIAN TUBES. MY DOCTOR TOLD ME THAT IN THE BEGINNING YEARS OF IMPLANTATION, THE FDA REQUIRED A NICKEL ALLERGY TEST, BUT DID AWAY WITH IT BEING A REQUIREMENT SEVERAL YEARS AGO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039763	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 7/10/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THE ESSURE PUT IN I HAVE HAD BAD HURTING CRAMPPING, HEAVIER BLEEDING WHERE I WELL BLEED THROUGH MY CLTHOES . I HAVE PAINS WHERE MY OVAIARYS ARE AND THEY SWELL UP. I HAVE BEEN HAVING MORE AND MORE PAIN THROUGH ALL OF MY FEMALE ORAGANS THROUGH MY INTIRE ABDOMAN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039764	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 9/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTING HAVING IRREGULAR HEAVY BLEEDING. A WEEK LATER I PASSED 2 PIECES OF LIGHT PINK TISSUE. THE BLEEDING CAME BACK..AND DIDN'T STOP FOR TWENTY DAYS. HAS BEEN IRREGULAR SINCE. RIGHT PELVIC PAIN. PAINFUL SEX, BLEEDING AFTER SEX. MEMORY PROBLEMS. ULTRASOUND COULDN'T SEE MY COIL ON THE RIGHT. I HAD AN MRI OF MY C-SPINE AUG 21ST (UNRELATED INJURY) AND CAN'T HELP BUT WONDER IF IT DISLODGED MY RIGHT COIL. I AN SCHEDULED FOR FURTHER TESTING TOO FIND THE COIL. IF IN MY UTERINE CAVITY I WILL HAVE TO HAVE A HYSTERECTOMY! NOT IN MY PLANS!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039765	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 9/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN THE ESSURE WAS PLACED IT HURT VERY BAD. ABOUT A WEEK AFTER I HAD IT INSERTEDY RIGHT OVARIE HURT LIKE SOMEONE PUNCHED ME. ABOUT ANOTHER WEEK ONE OF MY COILS FEEL OUT WHILE I WAS AT WORK AND I CALLED MY DOCTOR AND TOLD HER AND THE NURSE THE NURSE INFORMED ME THAT IT WASN'T A COIL AND WE NEEDED TO DO THE DYE TEST. WHEN MY DYE TEST WAS DONE THE GUY TOLD ME I ONLY HAD ONE COIL IN. ABOUT A MONTH AFTER I STARTED GETTING LIGHT HEADED AND DIZZY WHEN I WOULD DO CERTAIN THINGS. I ALSO HAVE GOTTEN SLIGHTLY MOODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039766	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 6/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD HEAVY BLEEDING NON STOP FOR 6 MONTHS WITH EXCRUCIATING PAIN WHICH EVENTUALLY LED TO AN ABLATION, DNC, AND REMOVAL OF LEFT TUBE AND OVARY DUE TO SERIOUS INFECTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039767	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 1/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PUT IN 2010, 3 MONTHS LATER I WAS BLEEDING HEAVILY WITH HUGE CLOTS. TO THE POINT OF FEELING WEAK, LIGHTHEADED. BLEEDING THROUGH SUPER TAMPONS IN 20 MIN. I DEVELOPED STABBING PAINS ON MY RIGHT SIDE, HIP PAIN, JOINT PAIN, HAND WEAKNESS, WEIGHT GAIN, BLOATING, MOOD SWINGS, LOW SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039768	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 9/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE PROCEDURE DONE 4 YEARS AGO. STARTED EXPERIENCING LOWER LEFT ABDOMINAL PAIN WITHIN A YEAR, HEAVIER PERIODS, AND BLEEDING IN BETWEEN CYCLES. HAVE BEEN BLEEDING HEAVILY FOR 2 WEEKS NOW WITH NO END IN SITE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039770	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 11/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOW VITAMIN-D LEVELS, SEVERE JOINT PAIN, EXTREMELY HEAVY MENSTRUAL CYCLES, FATIGUE, DEPRESSION, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039771	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 4/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD PELVIC PAIN SINCE THE DAY ESSURE WAS IMPLANTED IN MY TUBES. I HAVE CONSTANT CHRONIC PELVIC PAIN, WHICH A CT SCAN SHOWS NORMAL, MY ONLY OPTION PER MY DR IS HYSTERECTOMY. I ALSO SUFFER HAIR LOSS, BACK AND PELVIC PAIN, ARTHRITIC HANDS FEET AND HIPS, BLEEDING AND PAIN DURING AND AFTER INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039772	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 10/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5039772 #(B)(4). I NOW HAVE A VITAMIN B12 DEFICIENCY AND SWOLLEN STOMACH ALSO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039773	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 1/16/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BECAME EXTREMELY TIRED AND WAS STARTING TO GAIN WEIGHT. WENT TO ORIGINAL DR. AND HE TESTED ME FOR HYPOTHYROIDISM. CAME BACK POSITIVE, DR. PUT ME ON SYNTHROID. WAS HAVING CRAMPING BETWEEN PERIODS AND MY ACTUAL PERIODS WERE MORE PAINFUL AND WERE HEAVIER THAN BEFORE. DR. SAID MEDICATION FOR HYPOTHYROIDISM SHOULD HELP. CONTINUED TO HAVE PAIN, HEADACHES, CRAMPING. WENT BACK TO DR. AND WAS DISMISSED. I WAS TOLD TO STOP READING THINGS ONLINE. WENT ON WITH ALL PREVIOUS SYMPTOMS AND STARTED HAVING JOINT AND BACK PAIN. WAS STILL GAINING WEIGHT DESPITE MEDICATION. IN 2013 WENT TO FAMILY DR. AND HE TESTED MY THYROID AGAIN, NO HYPOTHYROIDISM. HE QUESTIONED WHY I WAS ON THE MEDICATION TO BEGIN WITH. HE SENT ME BACK TO ORIGINAL DR. FOR FURTHER TESTING. HAD AN INTERNAL ULTRASOUND DONE. DR. WANTED ME TO HAVE AN ABLATION, NO MENTION OF HYPOTHYROIDISM EXCEPT TO SAY I WAS TOO OVERWEIGHT. I ASKED AGAIN ABOUT ESSURE AND WAS TOLD MY ISSUES COULDN'T BE BECAUSE OF ESSURE SINCE HE HASN'T HAD ANYONE HAVE PROBLEMS WITH IT. I REFUSED ABLATION AND AM STILL SUFFERING WITH HEAVY PAINFUL PERIODS, WEIGHT GAIN, JOINT AND BACK PAIN, LEG AND FEET SWELLING AND HORRIBLE HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039775	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED IN (B)(6) 2013 AND SINCE THEN I EXPERIENCE DIZZY SPELLS, FATIGUE, SEVERE STABBING PAINS IN LOWER ABDOMEN, UNEXPLAINED BRUISES, WEIGHT GAIN, AND NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039783	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 3/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE FIBROIDS AND CONSISTENT PAIN ON MY LEFT SIDE AS WELL AS BACK PAIN, MIGRAINES, WEIGHT GAIN, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039784	BAYER	12/24/2014	12/24/2014

Event Information:

Event Date (B3): 8/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5039784 #(B)(4) HAD A HYSTERECTOMY (B)(6), 2014 TO REMOVE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039760	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 11/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING SHARP PAINS ON MY LEFT SIDE IN MY PELVIC AREA. I HAD AN ULTRASOUND DONE AND THE RESULTS WERE THE COIL WAS FINE. (B)(6) 2014, I STARTED HAVING LOWER BACK PAIN ANDAMP; BAD CRAMPS IN MY PELVIC AREA. I MISCARRIED TWINS AT HOME WENT TO THE ER HAD CT SCAN DONE THEY SAID I HAD A CYST ON MY KIDNEY. THE PAIN BECAME UNBEARABLE THAT SATURDAY I WENT BACK TO THE ER SCREAMING FROM PAIN SWEATING BENT OVER. THEY DID AN ULTRASOUND ANDAMP; XRAYS STILL NOTHING. SUNDAY AT 5:30AM I WAS BACK IN THE ER SCREAMING FROM PAIN UNABLE TO TALK ANOTHER ULTRASOUND ANDAMP; XRAYS AND FINALLY A GYNECOLOGIST THAT SAID THE COIL DID NOT LOOK RIGHT BUT BECAUSE OF THE INFLAMMATION HE COULDN'T SEE MY LEFT SIDE CLEARLY. A WEEK LATER I'M IN HIS OFFICE HE DOES A PELVIC ULTRASOUND AND SAYS THE COIL IS OUT OF PLACE IT WAS NO LONGER IN MY LEFT TUBE. TWO WEEKS LATER I HAD TO HAVE A PARTIAL HYSTORECTOMY. MY SURGERY TOOK LONGER THAN USUAL BECAUSE OF ALL THE SCAR TISSUE. MY UTERUS WAS FUSED TOGETHER AND THE DR SAID WHEN HE OPENED MY UTERUS THE COIL WAS IN THE MIDDLE EMBEDDED IN THE TOP LAYER OF MUSCLE OF NY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039769	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER GETTING ESSURE I BLED FOR TEN MONTHS NON STOP. I GAINED 45 POUNDS, I GOT UTI'S, I GOT CHRONIC MIGRAINES, SHARP ABDOMINAL PAINS, PAIN DURING INTERCOURSE, FATIGUE, AND MANY OTHER PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039774	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 4/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALL MY JOINTS WERE STIFF. I COULD NOT MOVE WITH OUT PAIN. I FELT LIKE I HAD VERTIGO. I STARTED TO VISIT WITH A CHIROPRACTOR BUT THE PAIN NEVER WENT AWAY. I WAS TOLD I WAS DEPRESSED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039776	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LACK OF ENERGY, FATIGUE, MOOD SWINGS, HOT FLASHES, WEIGHT GAIN, INABILITY TO LOSE WEIGHT, DEPRESSION, BLOATING, IRRITABILITY, PAIN AND PINCHING, THROBBING IN MOSTLY LEFT SIDE, BOILS, HORMONE ISSUE, PAIN WHEN ON MY PERIOD, HEAVY BLEEDING, LOTS OF CLOTS, EXTREME CRAMPS, PAIN IN LEFT FALLOPIAN TUBE AREA DURING BOWEL MOVEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039777	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HEADACHES/MIGRANES, WEIGHT GAIN, LACK OF ENERGY, IRREGULAR BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039778	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 8/6/2009	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOUND OUT I WAS PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039779	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 7/10/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THE ESSURE PUT IN I HAVE HAD BAD HURTING CRAMPPING, HEAVIER BLEEDING WHERE I WELL BLEED THROUGH MY CLTHOES . I HAVE PAINS WHERE MY OVAIARYS ARE AND THEY SWELL UP. I HAVE BEEN HAVING MORE AND MORE PAIN THROUGH ALL OF MY FEMALE ORAGANS THROUGH MY INTIRE ABDOMAN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039780	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 11/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5039780 #(B)(4) HOSPITALIZED IN (B)(6) 2015, FOR EXTREME PAIN IN MY LOWER ABDOMEN. AFTER BLOOD WORK, PELVIC EXAMS, AND ULTRASOUNDS, THE PAIN WAS COMING FROM A VERY LARGE OVARIAN CYST ON MY RIGHT OVARY. I WAS THEN TOLD TO GO ON BEDREST, UNTIL IT BURST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039781	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 12/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN AND TINGLING STARTING RIGHT AFTER ESSURE WAS PLACED. CRAMPS THAT COME AND GO.. EXTREMELY SENSITIVE STOMACH/BELLY. LOW BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039782	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 12/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UTI, RECURRING YEAST INFECTIONS, RECURRING BV, WILL NOT RESPOND TO PRESCRIPTION. FOUL ODOR, EXTREME DISCHARGE THAT WON'T STOP. WHITE DISCHARGE, CLEAR DISCHARGE. BUMPS/CYSTS ON GENITAL AREAS, BURNING ON THE INSIDE, PAINFUL INTERCOURSE, SHARP PAIN IN OVARIES, EYE DISCHARGE, CONSTANT RUNNY NOSE, BLURRED VISION, HEADACHES. ANXIETY, MENTAL ANGUISH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039785	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 12/27/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY HEAVY BLEEDING HEADACHE. JOINT PAIN LOWER BACK PAIN. ABDOMINAL PAIN BLOATING. WEIGHT GAIN DISCHARGE. FACE BREAKS OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039786	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 5/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SO MANY SIDE EFFECTS IT'S CRAZY AND I GUESS I NEVER PUT 2+2 TOGETHER UNTIL NOW... MOOD SWINGS, DEPRESSION, HAIR LOSS, CRAZY PERIODS (LATE UP TO 2 WEEKS AND HEAVY) FATIGUE, JOINT PAIN, MIGRAINES, BACK PAIN AND ABDOMINAL CRAMPING (NOT CYCLE RELATED).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039787	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 11/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHERE SHOULD I START VERY HEAVY BLEEDING, PAINFUL PERIODS,PAIN DURING INTERCOURSE,CHRONIC HEADACHES, HAIR LOSS, FATIGUE, DEPRESSION, EMOTIONAL, MOOD SWINGS,WEIGHT LOSS PROBLEMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039788	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED TO FEEL A DULL STABBY PAIN IN MY LEFT HIP. THIS WAS ON AND OFF FOR SEVERAL MONTHS BUT CONTINUED TO WORSEN. BY (B)(6) 2013, I COULD BARELY WALK. I NOW HAVE CONSTANT EXTREME PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039789	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 7/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASHES, MIGRAINES, ITCHES, EXCESSIVE PERIODS, BLOATING, CRAMPS, NERVE PAIN, JOINT PAIN, MALAISE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039790	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, HEAVY BLEEDING, BLOOD CLOTS, BACK AND PELVIC PAIN AND CRAMPING, CONTRACTIONS DURING MENSTRAL, NAUSEA, WEEKNESS, ENLARGED UTEROUS DURING MENSTRAL EVER SINCE INSTALLATION. TRIED BIRTH CONTROL PILLS, EXCERSIZE, DIET CHANGE, 2 DIFFERENT ABLATIONS, TAKE LYSTEDA MONTHLY TO CALM THE BLEEDING, NARCOTIC PRESCRIBED FOR MIGRAINES. HYSTERECTOMY SCHEDULED IN JANUARY 2015 TO REMOVE THE ESSURE. MY DR SEES NO OTHER OPTION TO STOP THE SIDE EFFECTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039791	BAYER	12/24/2014	12/29/2014

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GO MONTHS WITH NO PERIODS. MY SKIN/ SCALP IS EXCESSIVELY DRY (ITS EXTREMELY EMBARRASSING). I HAVE A HARD TIME EATING FOOD BECAUSE OF THE TERRIBLE METAL TASTE I ALWAYS HAVE IN MY MOUTH. I CANT WEAR JEWELRY WITH GETTING ITCHY AND BREAKING OUT. I HAVE NO SEX DRIVE, SERIOUSLY NONE. I HAVE PINCHING CRAMPING PAIN BETWEEN MY PERIODS. I CAN FEEL THE DEVICES PULLING ON MY INSIDES IF I MOVE A CERTAIN WAY. WHEN I AM ACTUALLY ON MY PERIOD MY CRAMPS ARE SO UNBEARABLE I HATE GETTING OUT OF BED, AND I GET SICK TO MY STOMACH. I HAVE HEADACHES THAT GET SO BAD I GET BLURRED VISON AND THROW UP. I HAVE BEEN DIETING AND EXERCISING FOR A YEAR AND CANT LOSE WEIGHT. I LOOK LIKE I AM 7 MONTHS PREGNANT ALL THE TIME. I HAVE RIDICULOUS MOOD SWINGS. MY HAIR FALLS OUT AT AN ALARMING RATE (SERIOUSLY I AM AFRAID I AM GOING TO END UP BALD). I HAVE BACK PAIN ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039856	BAYER	12/24/2014	1/5/2015

Event Information:

Event Date (B3): 12/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/1/2012
Explant Date (E7): 12/19/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT HAD ESSURE PLACED FOR STERILIZATION, SUBSEQUENTLY EXPERIENCED INCREASED DYSMENORRHEA, WEIGHT GAIN, HOT FLASHES, FATIGUE, AND SLEEP DISTURBANCES. SHE REQUESTED REMOVAL OF THE IMPLANTS AND UNDERWENT TOTAL VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY. PATIENT THINKS HER SYMPTOMS ARE DUE TO NICKEL ALLERGY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00553	BAYER HEALTHCARE LLC	12/29/2014	12/29/2014

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A78079

Single Use: Y
Implant Date (E6): 4/25/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON 01-DEC-2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR CONTRACEPTION (LOT NUMBER A78079; EXPIRATION DATE DEC-2016). PHYSICIAN REPORTED THAT ON (B)(6) 2013, IT WAS DETERMINED VIA HSG (HYSTEROSALPINGOGRAM) THAT THE ESSURE WAS EXPELLED. ON (B)(6) 2013 AN ABDOMINAL CT (COMPUTED TOMOGRAPHY) SCAN WAS DONE THAT ALSO DETERMINED THE ESSURE HAD MIGRATED INTO THE OMENTUM. OPERATIVE LAP WAS DONE ON (B)(6) 2013, OMENTUMECTOMY AND TUBAL. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-DEC-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). BATCH NUMBER A78079 (PRODUCTION DATE DEC-2012; EXPIRATION DATE 31-DEC-2015). FINAL ASSESSMENT: AN EXPULSION IS THE MOVEMENT OF THE DEVICE OUT OF THE FALLOPIAN TUBE AND INTO THE UTERINE CAVITY/CERVIX/VAGINA OR OUT OF THE BODY) OR MIGRATION (MOVEMENT TO THE DISTAL FALLOPIAN TUBE OR OUT OF THE FALLOPIAN TUBE AND INTO THE PERITONEAL CAVITY). PROBABLE CAUSES FOR AN EXPULSION: 1) TUBAL SPASM, 2) INACCURATE PLACEMENT OF THE MICRO-INSERT IN THE FALLOPIAN TUBE BY THE PHYSICIAN. ACCORDING TO THE PRODUCT IFU (INSTRUCTION FOR USE), THE MICRO-INSERT MUST BE PLACED FAR ENOUGH INTO THE FALLOPIAN TUBE TO PREVENT EXPULSION (LESS THAN 18 TRAILING COILS). EXPULSIONS ARE A KNOWN RISK OF THE ESSURE PROCEDURE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL

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PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. EXPULSION IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 5 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH ONE CASE REFERS TO SIMILAR TYPES OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN ABDOMINAL CT (COMPUTED TOMOGRAPHY) SCAN WAS PERFORMED AND THE RESULT SHOWED ESSURE HAD MIGRATED INTO THE OMENTUM. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH NOT REPORTED AS SUCH, THE MOST LIKELY MECHANISM FOR THE LEFT COIL TO BE FOUND IN THE OMENTUM, WOULD BE THROUGH A UTERINE/FALLOPIAN TUBE PERFORATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THIS EVENT WAS DIAGNOSED ABOUT 7 MONTHS AFTER ESSURE INSERTION. IT WAS NOT REPORTED WHICH SIDE OF ESSURE MIGRATED INTO THE OMENTUM. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. SINCE THE PATIENT UNDERWENT AN OPERATIVE LAP, OMENTUMECTOMY AND TUBAL, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED: IT WAS DETERMINED VIA HSG THAT ESSURE EXPELLED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 15-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD E

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00554	BAYER HEALTHCARE LLC	12/29/2014	12/29/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A14895

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 20-NOV-2014, ARTICLE ENTITLED "PREVENTING TUBAL SPASM DURING ESSURE PROCEDURE". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERFORATION. BAYER PRODUCT ESSURE WAS REPORTED. CASE REPORT: THIS FEMALE PATIENT OF AN UNSPECIFIED AGE HAD PERFORATION BEFORE STARTING TO USE EMOTIONAL FREEDOM THERAPY. AUTHOR'S COMMENT: THIS FEMALE PATIENT OF AN UNSPECIFIED AGE HAD PERFORATION BEFORE STARTING TO USE EMOTIONAL FREEDOM THERAPY. ABSTRACT: OBJECTIVES: ESSURE IS A METHOD OF VAGINAL STERILIZATION. 5% OF PATIENTS EXPERIENCE TUBAL SPASM THAT CAN LEAD TO PROCEDURE FAILURE AND PERFORATION. USE OF NSAIDS ORALLY 1HR PRIOR TO PROCEDURE IS RECOMMENDED AS PREVENTION. OUR AIM WAS TO COMPARE 150 MG OF KETOPROPHENUM VS. 5 MG TROSPIUM CHORIDE, AS TROSPIUM CHLORIDE INTRAVENOUSLY IS SUGGESTED TO RESOLVE PROLONGED TUBAL SPASM. METHODS: WE INCLUDED 82 PATIENTS IN DOUBLE-BLINDED STUDY. ALL RECEIVED 2 MG OF DIAZEPAM AND RANDOMLY 150MG KETOPROPHENUM OR 5 MG TROSPIUM CHLORIDE ORALLY 1 HR PRIOR TO PROCEDURE. WE DEFINED TUBAL SPASM AS INABILITY TO PASS IMPLANTS THROUGH TUBAL OSTIUM AFTER MORE THAN 30 SECONDS OF GENTLE PRESSURE. PATIENTS WERE ASKED TO EVALUATE PAIN DURING PROCEDURE USING VISUAL ANALOGUE SCALE (VAS). SUCCESS WAS EVALUATED 3 MONTHS AFTER USING ULTRASOUND OR HYSTEROSALPINGOGRAPHY IN COMPLICATED CASES. DURING THE STUDY A SURPRISING FINDING OCCURRED, AS ONE PATIENT AFTER 8 MINUTES OF PERSISTENT SPASM PERFORMED EMOTIONAL FREEDOM THERAPY (EFT), AFTER WHICH SPASM RESOLVED IN 20 SECONDS. EFT IS A FORM OF PSYCHOLOGICAL ACCUPRESSURE. WHILE GENTLY TAPPING WITH FINGERPOINTS ON CERTAIN POINTS OF THE BODY, PERSON IDENTIFIES THE PROBLEM AND VERBALLY TRANSFORMS NEGATIVE FEELINGS INTO

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POSITIVE. SINCE DISCOVERING THIS TECHNIQUE, WE HAVE ASKED PATIENTS WITH TUBAL SPASM TO USE IT. RESULTS: FROM 82 PATIENTS, 39 RECEIVED TROSPIUM CHLORIDE AND 40 KETOPROPHENUM, 3 REFUSED ANY MEDICATION. IN TROSPIUM CHLORIDE GROUP, 29/39 PATIENTS HAD UNEVENTFUL SUCCESSFUL PROCEDURE, AVG. VAS WAS 3,4. 7/39 HAD TUBAL SPASM, AVG. DURATION OF SPASM WAS 235 SECONDS, AVG VAS 4,3. IN 3 PROCEDURES WITH TUBAL SPASM WE ASKED PATIENTS TO PERFORM EFT. TWO (5%) WERE UNSUCCESSFUL, ONE DUE TO TUBAL SPASM BEFORE LEARNING ABOUT EFT, ONE DESPITE USING EFT WHICH ON LAPAROSCOPY AFTERWARDS TURNED OUT TO BE DUE TO CHRONIC SALPINGITIS. IN KETOPROPHENUM GROUP (40 PATIENTS), 2 WERE EXCLUDED DUE TO PATHOLOGICAL FINDINGS DURING HYSTEROSCOPY. 28/38 REMAINING PATIENTS HAD A SUCCESSFUL UNEVENTFUL PROCEDURE WITH AVG. VAS 2,7. 9/38 HAD TUBAL SPASM, AVG. DURATION OF SPASM WAS 115 SECONDS, AVG. VAS 4,5. THREE PROCEDURES WERE UNSUCCESSFUL, 2 DUE TO SPASM AND ONE DUE TO PERFORATION, ALL BEFORE STARTING TO USE EFT. THREE PATIENTS WITH NO PREMEDICATION HAD UNEVENTFUL SUCCESSFUL PROCEDURES, AVG. VAS WAS 3. CONCLUSIONS: AUTHORS NOTICED A HIGH INCIDENCE OF TUBAL SPASM, PROBABLY DUE TO OUR LIBERAL DEFINITION (INABILITY TO PASS IMPLANTS THROUGH OSTIUM AFTER MORE THAN 30 SECONDS OF GENTLE PRESSURE). KETOPROPHENUM AND TROSPIUM CHLORIDE ORALLY PRIOR TO PROCEDURE HAVE COMPARABLE EFFECT IN PREVENTING TUBAL SPASM, ALTHOUGH AVG. DURATION OF SPASM WAS SIGNIFICANTLY LONGER IN TROSPIUM GROUP. KETOPROPHENUM IS PROBABLY BETTER IN ALLEVIATING PAIN DURING THE PROCEDURE. EFT MIGHT BE A VALUABLE TECHNIQUE IN RESOLVING TUBAL SPASM, BUT PERSEVERING APPLYING GENTLE PRESSURE COULD GIVE THE SAME RESULTS. METHOD NEEDS FURTHER RESEARCH. OTHER CASES CREATED FROM SAME ARTICLE ARE 2014-173031, 2014-173118 AND 2014-173137. FOLLOW-UP (02-DEC-2014): THIS CASE IS NOW CONSIDERED INCIDENT. THIS CASE REFERS TO PATIENT NUMBER 4 AS REPORTED IN ADDITIONAL DATA PROVIDED BY CORRESPONDING AUTHOR. IN THIS FEMALE PATIENT OF UNSPECIFIED AGE EXPERIENCED PERFORATION OF THE RIGHT FALLOPIAN TUBE. LPCS (INTERPRETED AS LAPAROSCOPIC STERILIZATION) WAS PERFORMED. LEFT FALLOPIAN TUBE INCLUDING THE IMPLANT WAS REMOVED. D (UNCLEAR ABBREVIATION) STERILIZATION. IT WAS NOT POSSIBLE TO LOCATE THE IMPLANT IN THE ABDOMEN, AND DIASCOPY (INTRAOPERATIVE X-RAY CONTROL) WAS CARRIED OUT. LPSC WAS REPEATED DUE TO THE MILD PAIN WHICH OCCURRED A FEW MONTHS LATER AND THE IMPLANT WAS LOCATED IN THE OMENTUM AND WAS REMOVED. AUTHOR'S COMMENT: THIS CASE REPORT WAS INCLUDED WITHIN DATA ON UNSUCCESSFUL PROCEDURES. IN THE ABOVE LISTED PROCEDURE(S), COMPLICATIONS WERE NOT INDUCED BY THE IMPLANT ITSELF; HOWEVER, THE AUTHORS ARE SEARCHING FOR THE BEST POSSIBLE IMPLANT INSERTION PROTOCOL, WHICH WOULD REDUCE THE POSSIBILITY OF COMPLICATIONS. (B)(4). FINAL ASSESSMENT: A PERFORATION IS A HOLE OR OPENING MADE THROUGH THE ENTIRE THICKNESS OF A MEMBRANE OR OTHER TISSUE OR MATERIAL. PROBABLE CAUSES FOR PERFORATION: 1) PHYSICIAN ENCOUNTERS POOR VISIBILITY DURING THE PROCEDURE, 2) PHYSICIAN TECHNIQUE AND EXPERIENCE, 3) ADVANCING DELIVERY CATHETER WHEN PATIENT IS EXPERIENCING EXTRAORDINARY PAIN OR DISCOMFORT, 4) ATTEMPTING TO ADVANCE DELIVERY CATHETER TO BLACK POSITIONING MARKER AFTER ENCOUNTERING UNDUE RESISTANCE, 5) FURTHER ADVANCING DELIVERY CATHETER ONCE THE BLACK POSITIONING MARKER HAS REACHED THE TUBAL OSTIUM, 6) ATTEMPTED REMOVAL OF AN IMPLANTED MICRO-INSERT WITH FEWER THAN 18 TRAILING COILS INTO THE UTERUS, 7) INACCURATE PLACEMENT OF THE MICRO-INSERT IN THE FALLOPIAN TUBE BY THE PHYSICIAN. ACCORDING TO THE PRODUCT IFU, THE MICRO-INSERT MUST BE PLACED FAR ENOUGH INTO THE FALLOPIAN TUBE TO PREVENT EXPULSION (LESS THAN 18 TRAILING COILS). PERFORATIONS ARE A KNOWN RISK OF THE ESSURE PROCEDURE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A

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REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 22-DEC-2014 FOR THE FOLLOWING MEDDRA PREFERRED TERM: UTERINE PERFORATION: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 120 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, CASE REPORT DERIVED FROM ARTICLE ENTITLED "PREVENTING TUBAL SPASM DURING ESSURE PROCEDURE". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERFORATION OF RIGHT FALLOPIAN TUBE, IMPLANT WAS LOCATED IN THE OMENTUM AND WAS REMOVED. FALLOPIAN TUBE PERFORATION IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. IN THIS PRESENT CASE, THE AUTHORS STATED THAT, PERFORATION OF RIGHT FALLOPIAN TUBE HAD OCCURRED AND ESSURE COIL WAS REMOVED FROM OMENTUM BY SURGERY. IT WAS NOT MENTIONED IF PERFORATION HAD OCCURRED DURING INSERTION PROCEDURE; HOWEVER, GIVEN THE NATURE OF THIS REPORTED EVENT, THE CAUSALITY WAS ASSESSED AS RELATED BY THE COMPANY. THIS CASE WAS REGARDED AS INCIDENT AS AN INTERVENTION WAS REQUIRED TO REMOVE ESSURE FROM PATIENT'S ABDOMEN. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW-UP 16 FEB 2015: LOT NUMBER WAS RECEIVED: A14895. PTC INVESTIGATION RESULT RECEIVED ON 25-FEB-2015. (B)(4). FINAL ASSESSMENT: PRODUCTION DATE: 5/2012 EXPIRATION DATE: 5/2015. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00555	BAYER HEALTHCARE LLC	12/29/2014	12/30/2014

Event Information:

Event Date (B3): 10/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/25/2014
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# 2014/010/020/401/(B)(4)) IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THAT THE ON THE (B)(6) 2014 THE CONSUMER HAD AN ALLERGIC REACTION TO THIS DEVICE AND IS EXPERIENCING PAIN ON RIGHT SIDE (NO INTERVENTION REPORTED). NO ONE WAS INJURED. ESSURE DEVICE REMAINS IN SITU. NO FURTHER INFORMATION. CORRECTION <(B)(4) 2014>: AFTER INTERNAL REVIEW, THIS CASE WAS UPGRADED TO INCIDENT DUE TO HEALTH AUTHORITY ASSESSMENT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: AN ALLERGY IS A HYPERSENSITIVITY TO A SUBSTANCE THAT CAUSES THE BODY TO REACT TO ANY CONTACT WITH THAT SUBSTANCE. COMMON INDICATIONS OF ALLERGY MAY INCLUDE SNEEZING, ITCHING, SKIN RASHES AND HIVES. PROBABLE CAUSE FOR AN ALLERGIC RESPONSE IN PATIENT - AN ALLERGIC RESPONSE TO THE ESSURE MICRO-INSERT IS MOST OFTEN DUE TO THE PATIENT'S SENSITIVITY TO NICKEL. ACCORDING TO THE PRODUCT IFU, THE ESSURE SYSTEM SHOULD NOT BE USED ON ANY PATIENT WITH A KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS

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TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW UP (B)(4) 2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER. CONSUMER INFORMED HER AGE AS (B)(6) AND ESSURE 305 INSERTION DATE AS (B)(6) 2014. CONSUMER REPORTED THAT SHE EXPERIENCED SEVERE PAIN DURING THE PROCEDURE AND THEREAFTER CONTINUOUS CRAMPS THAT WERE WORSE IN THE MIDDLES OF HER CYCLE. SHE BEGAN BREAKING OUT IN HIVES AND LUMPS A FEW WEEKS AFTER THE ESSURE WAS IMPLANTED AND SHE BELIEVED THIS TO BE A REACTION FROM THE NICKEL IN THE DEVICE. SHE ADVISED HER DOCTOR SHE WAS ALLERGIC TO NICKEL. CONSUMER HAS HAD TO UNDERGO SURGERY TO REMOVE BOTH HER FALLOPIAN TUBES AND ESSURE ON (B)(6) 2014 AND HAS HAD A TOTAL OF SIX WEEKS SICKNESS. SHE NOTED THAT SHE WAS ADMITTED TO HOSPITAL BECAUSE OF THE REACTION. SHE ALREADY FEELS BETTER IN JUST TWO WEEKS AND CONFIRMED THAT ESSURE WAS CAUSING PAIN AND ALLERGIC REACTIONS. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2014 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: MEDDRA PT- ALLERGY TO METALS: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4)CASES. MEDDRA PT- ABDOMINAL PAIN: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PT. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2014. NO NEW CLINICAL INFORMATION PROVIDED. A SIGNED CONSENT TO CONTACT HCP FROM CONSUMER WAS NOT RECEIVED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NOT MEDICALLY CONFIRMED REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD AN ALLERGIC REACTION TO THIS DEVICE (REACTION FROM THE NICKEL) AND HAD BEEN EXPERIENCING PAIN ON THE RIGHT SIDE (INTERPRETED AS ABDOMINAL PAIN). THE CONSUMER STATED THAT A SURGICAL INTERVENTION (BILATERAL SALPINGECTOMY) AND HOSPITALIZATION WERE REQUIRED DUE TO THE EVENTS, THEREFORE, THEY WERE CONSIDERED SERIOUS. BOTH EVENTS ARE LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE EVENT OCCURRED AFTER DEVICE INSERTION AND A POSITIVE DECHALLENGE WAS REPORTED. THE CONSUMER'S HISTORICAL CONDITION OF NICKEL ALLERGY REINFORCES A CAUSAL RELATIONSHIP BETWEEN THE ALLERGIC REACTION AND ESSURE INSERT. THERE IS A POSITIVE TEMPORAL RELATIONSHIP BETWEEN ABDOMINAL PAIN AND ESSURE INSERT AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION. THEREFORE, COMPANY CONSIDERS BOTH EVENTS AS RELATED TO ESSURE. DUE TO THE INTERVENTION REPORTED, THIS CASE IS REGARDED AS INCIDENT. BASED ON PRODUCT TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT QUALITY DEFICIT OF THE PRODUCT. ADDITIONALLY, NON-SERIOUS EVENTS SEVERE PAIN DURING THE PROCEDURE AND CONTINUOUS CRAMPS THAT WERE WORSE IN THE MIDDLES OF HER CYCLE WERE REPORTED. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW UP INFORMATION RECEIVED ON 12-FEB-2015 THE CONSUMER REPLIED THAT SHE HAS RE-SENT THE CONSENT FORM TO CONTACT HER HCP FOR FOLLOW UP INFORMATION. PTC ASSESSMENT WAS UPDATED ON 17-FEB-2015 WITHOUT MAJOR CHANGES. PTC INVESTIGATION RESULT FROM DUPLICATE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039899	CONCEPTUS	12/29/2014	1/6/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CHRONIC PELVIC PAIN AND IRREGULAR PERIODS STARTED AFTER ESSURE PLACEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039901		12/29/2014	1/6/2015

Event Information:

Event Date (B3): 2/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN EARLY 2005 IN ORDER TO PREVENT PREGNANCY BECAUSE I TAKE LIFE-SUSTAINING MEDICATION THAT COULD HARM A FETUS. A FEW MONTHS AFTER THE PROCEDURE, MY CYCLE BECAME VERY UNPREDICTABLE. I WAS BLEEDING FOR WEEKS AT A TIME, OVER A MONTH IN SOME CASES. THE ABDOMINAL PAIN WAS UNBEARABLE. NOW I HAVE TO TAKE A BIRTH CONTROL DRUG IN ORDER TO STOP MY CYCLE COMPLETELY, BECAUSE OF WHAT I BELIEVE ARE THE SEVERE SIDE EFFECTS OF THIS PROCEDURE. I COULD HAVE JUST TAKEN BIRTH CONTROL AND NOT HAD THE PROCEDURE AND NOT HAD THIS ISSUE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00557	BAYER HEALTHCARE LLC	12/30/2014	12/30/2014

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. PHYSICIAN REPORTED THAT ESSURE WAS PLACED BY ANOTHER DOCTOR AND ON (B)(6) 2014, THE PATIENT REFERRED TO HER BECAUSE OF HEAVY BLEEDING REQUIRING BLOOD TRANSFUSION AND IRON. SHE ALSO REPORTED THAT SHE DID A HYSTEROSCOPY EXAM AND FOUND HER COILS WERE SITTING OUT, 10 COILS WERE OUTSIDE THE OSTIA. IT WAS STRETCHED OUT TO ABOUT ONE AND HALF CENTIMETERS. ONE COIL WAS PULLED OUT A LITTLE BIT AND MUST HAVE BEEN RUBBING AGAINST THE UTERUS. THE COIL GOT PULLED OUT WITH THE HYSTEROSCOPE. PHYSICIAN WAS ASKING IF THERE A DEVICE OR A HYSTEROSCOPIC WIRE CUTTER TO REMOVE OR CUT THE EXTRA COIL OR A FULL HYSTERECTOMY SHOULD BE DONE. ON UNSPECIFIED DATE, THE HSG (HYSTEROSALPINGOGRAM) WAS MADE AND SHOWED BILATERAL TUBE OCCLUSION. PHYSICIAN STATED THAT THE PATIENT MUST HAVE BEEN SEEN IN THE ER THE WEEKEND BEFORE THE PHYSICIAN'S VISIT, BUT SHE WAS NOT ADMITTED. THE EVENT WAS ONGOING AT TIME OF THE REPORT. NO FURTHER INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. BLEEDING IS AN

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ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE AND A REQUEST FOR CONFIRMATION OF QUALITY. NO BATCH NUMBER WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE REPORTED PRODUCT ISSUE COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING REQUIRING BLOOD TRANSFUSION. ALSO, DURING HYSTEROSCOPY, IT WAS OBSERVED THAT 10 COILS WERE OUTSIDE THE OSTIA. THE EVENTS, SEEN AS GENITAL BLEEDING AND DEVICE DISLOCATION, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. BESIDES THAT, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE PATIENT STARTED TO EXPERIENCE SEVERE BLEEDING AND HAD TO HAVE BLOOD TRANSFUSION AND IRON TREATMENT. SHE WAS REFERRED TO THE REPORTER PHYSICIAN AND A HYSTEROSCOPY WAS PERFORMED. THE ESSURE COILS WERE FOUND SITTING OUT OF OSTIA. IT WAS STRETCHED OUT TO ABOUT ONE AND HALF CENTIMETERS AND GOT PULLED OUT WITH THE HYSTEROSCOPE. CONSIDERING THE NATURE OF THE EVENTS, CAUSALITY IS ASSESSED AS RELATED WITH ESSURE USE AND SINCE THE GENITAL BLEEDING LED TO A BLOOD TRANSFUSION (MEDICAL INTERVENTION), THE CASE IS REGARDED AS INCIDENT. ACCORDING TO PRODUCT TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 20-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00558	BAYER HEALTHCARE LLC	12/30/2014	12/30/2014

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A50514

Single Use: Y
Implant Date (E6): 12/17/2012
Explant Date (E7): 11/25/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 REFERRING TO HERSELF, A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ABOUT (B)(6) 2012, LOT NUMBER A50514, FOR STERILIZATION. THE CONSUMER'S MEDICAL HISTORY INCLUDED ECTOPIC PREGNANCY AND LOST OF LEFT TUBE AND OVARY. SHE HAS 3 SMALL CHILDREN. THE CONSUMER REPORTED SHE HAD MULTIPLE COMPLICATIONS THAT IMMEDIATELY STARTED AFTER SHE HAD THE ESSURE. THE COILS WENT THROUGH HER TUBE, AND PERFORATED HER UTERUS. SHE WAS HAVING SEVERE DYSMENNORHEA, IRREGULAR PAINFUL PERIODS, MULTIPLE CYSTS ON RIGHT OVARY. SHE HAD SEVERE PAIN WITH HER LAST PERIOD. SHE WAS PREGNANT TWICE (PLEASE, SEE CASE (B)(6)FOR THE SECOND PREGNANCY), AND HAD 2 MISCARRIAGES. IT WAS VERY PAINFUL, HER ABDOMEN WAS VERY PAINFUL, A LOT OF LOW BACK PAIN. WHEN SHE HAD THE ESSURE, THE PHYSICIAN INSERTED TWO COILS, ALTHOUGH CONSUMER HAS ONLY THE RIGHT TUBE. HE STUCK IT SOMEWHERE ON THE LEFT. APPARENTLY, IT LEFT A LITTLE OF THE TUBE WHERE HE STUCK IT. THE CONSUMER WENT TO ANOTHER PHYSICIAN AND HAD A VAGINAL EXAM, AND AN ULTRASOUND DONE. HER RIGHT OVARY WAS SWOLLEN AND ENLARGED, AND HAD A LARGE CYST. THIS PHYSICIAN COULD NOT SEE THE RIGHT COIL, BUT HE COULD SEE THE COIL ON THE LEFT, LIKE IT WAS IN A FLAP OF THE TUBE. SHE HAD A COMPLETE HYSTERECTOMY DONE ON (B)(6)2014 WITH 34 STAPLES. THE COILS CAME OUT WITH THE SURGERY. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 16-DEC-2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: 2014-033699 FINAL ASSESSMENT: PREGNANCY IS THE CONDITION OF CARRYING DEVELOPING OFFSPRING WITHIN THE BODY. THE TIME PERIOD DURING WHICH THIS CONDITION EXISTS; GESTATION. PROBABLE CAUSES FOR PREGNANCY INCLUDE: 1) UNSUCCESSFUL BILATERAL TUBAL OCCLUSION (COMPLETE TISSUE INGROWTH), 2) EXPULSION

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(RELATED TO MICRO-INSERT PLACEMENT ACCURACY), 3) NO 3-MONTH CONFIRMATION TEST (HSG) OR MIS-READ OF HSG, 4) LACK OF PATIENT COMPLIANCE TO IFU (I.E. USE OF ALTERNATE CONTRACEPTION UNTIL CONFIRMATION OF BILATERAL OCCLUSION). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PREGNANCY AND PERFORATIONS ARE ANTICIPATED EVENTS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN ADDITION, ONE OF THE ASSOCIATED AE CASES REFERS TO A MEDICATION ERROR. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND THE COILS WENT THROUGH THE TUBE AND PERFORATED HER UTERUS. PHYSICIAN COULD NOT SEE THE RIGHT COIL. SHE GOT PREGNANT TWICE AND EXPERIENCED 2 MISCARRIAGES. THE EVENTS WENT THROUGH THE TUBE AND PERFORATED HER UTERUS AND COULD NOT SEE THE RIGHT COIL ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MISCARRIAGE IS SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED. PREGNANT IS NON-SERIOUS AND LISTED. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBE, THIS MOVEMENT COULD BE A DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALSO, SPONTANEOUS ABORTIONS OCCUR MOSTLY DURING THE FIRST 12 WEEKS OF PREGNANCY AND THE VAST MAJORITY OF THESE CASES ARE DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS. IN THIS CASE, RELEVANT HISTORY INCLUDED ECTOPIC PREGNANCY AND THE CONSUMER LOST HER LEFT TUBE AND OVARY. PHYSICIAN INSERTED TWO COILS, ALTHOUGH CONSUMER HAD ONLY THE RIGHT TUBE (DEVICE USE ERROR). THE EXACT DATE AND THE MECHANISM OF PERFORATION ARE NOT KNOWN. SINCE THE GESTATIONAL AGE HAS NOT BEEN PROVIDED, CAUSALITY BETWEEN MISCARRIAGE AND SUSPECT INSERT CANNOT BE ASSESSED. WITH REGARDS TO THE OTHER EVENTS, A CAUSAL RELATIONSHIP CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE THE CONSUMER UNDERWENT A COMPLETE HYSTERECTOMY AND THE COILS CAME OUT WITH THE SURGERY. OTHER NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN ON 17-MAR-2015 NO NEW CLINICAL INFORMATION PROVIDED. THIS HCP, WHO RECEIVED QUESTIONNAIRE, WAS NOT PHYSICIAN WHO PLACED THE ESSURE. ESSURE PREGNANCY QUESTIONNAIRE RECEIVED ON 06-APR-2015 FROM PHYSICIAN THAT IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00560	BAYER HEALTHCARE LLC	12/30/2014	12/31/2014

Event Information:

Event Date (B3): 11/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/18/2013
Explant Date (E7): 1/28/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 04-DEC-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013 FOR STERILIZATION. PATIENT HAD ESSURE PLACED AND IMMEDIATELY HAD POST-OP PAIN ON BOTH SIDES AND THE PAIN CONTINUED FOR THE ENTIRE TIME ESSURE WAS IN PLACE. AN HSG WAS DONE ON (B)(6) 2014 AND SHOWED PERFECT PLACEMENT WITH BILATERAL OCCLUSION. THE PAIN CONTINUED SO ON (B)(6) 2014 THE ESSURE WAS REMOVED BILATERALLY. SINCE THE ESSURE WAS REMOVED THE PATIENT WAS PAIN FREE AND WAS PLACED ON BIRTH CONTROL PILLS. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-DEC-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PAIN IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT

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CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMMEDIATELY HAD POSTOP PAIN ON BOTH SIDES AND IT CONTINUED FOR THE ENTIRE TIME ESSURE WAS IN PLACE. ESSURE WAS REMOVED BILATERALLY AND SINCE THEN SHE WAS PAIN FREE. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE, GIVEN THE NATURE OF THE EVENT AND POSITIVE DECHALLENGE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 13.JAN.2015: ESSURE QUESTIONNAIRE WITH FOLLOW UP INFORMATION RECEIVED FROM THE PHYSICIAN. PATIENT'S (B)(6). NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. NO RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. DURING ESSURE INSERTION PROCEDURE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00563	BAYER HEALTHCARE LLC	12/30/2014	12/31/2014

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B66014

Single Use: Y
Implant Date (E6): 3/11/2014
Explant Date (E7): 7/3/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 04-DEC-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE 305 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 PERMANENT CONTRACEPTION. PATIENT ALSO HAD ESSURE 505 INSERTED AND DURING PLACEMENT PROCEDURE THE CATHETER BROKE OFF IN FALLOPIAN TUBE (DEVICE MALFUNCTION) (B)(4). HER ETHNICITY WAS CAUCASIAN. HER (B)(4). AN HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED ON (B)(6) 2014 AND SHOWED THAT THE RIGHT DEVICE COILED BACK ON ITSELF. ON (B)(6) 2014, PATIENT UNDERWENT A BILATERAL SALPINGECTOMY; A RIGHT TUBAL PERFORATION WITH ESSURE 305 WAS DIAGNOSED (CONSIDERED AS SEVERE AND AS ANOTHER MEDICALLY IMPORTANT SERIOUS EVENT). ESSURE WAS REMOVED AND PATIENT RECOVERED FROM THE RIGHT TUBAL PERFORATION. FOLLOW-UP RECEIVED ON 18-DEC-2014: ESSURE LOT NUMBER (B66014) WAS RECEIVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT HAD ESSURE 305 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RIGHT TUBAL PERFORATION. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE RIGHT TUBAL PERFORATION WAS DIAGNOSED ABOUT 136 DAYS AFTER ESSURE 305 INSERTION. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT AS AN INTERVENTION WAS REQUIRED (BILATERAL SALPINGECTOMY). FURTHER INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT NUMBER B66014 PRODUCTION D

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00561	BAYER HEALTHCARE LLC	12/30/2014	1/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS PROVIDED) AND WAS SCHEDULED FOR THE OR (OPERATING ROOM) TO REMOVE A COIL THAT HAS BROKEN WITH ONE PIECE IN THE PATIENT'S TUBE AND THE REMAINDER IN HER ABDOMINAL CAVITY. THE PATIENT HAD A FOLLOW UP APPOINTMENT ON (B)(6) 2014. FOLLOW UP (B)(6) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FINAL RISK CLASSIFICATION: RISK CATEGORY V. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING

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DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. AT THIS POINT IN TIME NO FURTHER INFORMATION WAS AVAILABLE REGARDING CIRCUMSTANCES AND MECHANISMS OF THE REPORTED BREAKAGE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THEREFORE NO FURTHER TECHNICAL EVALUATION OF THE REPORTED BREAKAGE WAS POSSIBLE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE COIL HAS BROKEN WITH ONE PIECE IN THE PATIENT'S TUBE AND THE REMAINDER IN HER ABDOMINAL CAVITY. THE FIRST EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. THE REMAINING EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE PHYSICIAN STATED THAT A PATIENT OF HERS WAS SCHEDULED TO REMOVE A COIL THAT HAS BROKEN WITH ONE PIECE IN THE PATIENT'S TUBE AND THE REMAINDER IN HER ABDOMINAL CAVITY. ALTHOUGH THE CIRCUMSTANCES AND MECHANISMS OF THE EVENTS HAVE NOT BEEN INFORMED, DUE TO THEIR NATURE, BOTH ARE ASSESSED AS RELATED TO ESSURE USE. SINCE DEVICE BREAKAGE (MALFUNCTION) WAS REPORTED, THE CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 23-APR-2015. THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00562	BAYER HEALTHCARE LLC	12/30/2014	1/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B21574

Single Use: Y
Implant Date (E6): 12/5/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN (B)(6) 2014. THE LOT NUMBER USED WAS B21574. PHYSICIAN ATTEMPTED TO INSERT ESSURE, AND A PIECE OF THE GREEN CATHETER BROKE OFF INSIDE THE PATIENT`S RIGHT TUBE ALONG WITH THE INSERT. THE LEFT SIDE WAS PERFECT; BUT THE RIGHT SIDE DID INSERTION REMOVED INSERTER, THE COIL STRETCHED AND DEVICE CAME OUT, SHE BELIEVED THAT SHE GOT MOST OF IT OUT AND THOUGHT THE INSERT WAS STILL IN THE TUBE. THE CATHETER WAS INSIDE THE UTERUS, AND THE PHYSICIAN TOOK A LOT OF THE DEVICE OUT JUST A SMALL PIECE WAS LEFT. THE PATIENT THEN HAD A TUBAL SPASM. NO OTHER ISSUES WERE REPORTED. PHYSICIAN SAID SHE WILL DO X-RAY TO CONFIRM. NO FURTHER INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO

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LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. ACCORDING TO CASE INFORMATION A PIECE OF THE GREEN CATHETER BROKE OFF INSIDE THE PATIENT'S RIGHT TUBE ALONG WITH THE INSERT DURING ESSURE INSERTION ATTEMPT. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 3 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH ALL CASES REFER TO A SIMILAR ADVERSE TYPE OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE PIECE OF GREEN CATHETER BROKE OFF INSIDE THE PATIENT'S RIGHT TUBE ALONG WITH THE INSERT. SHE TOOK A LOT OUT JUST A SMALL PIECE LEFT. THE EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND ANTICIPATED ACCORDING PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THIS CASE, ACCORDING TO PHYSICIAN, LEFT SIDE WAS PERFECT BUT IN THE RIGHT SIDE, SHE DID THE INSERTION, REMOVED INSERTER AND THE PATIENT HAD A TUBAL SPASM. THE ESSURE COIL STRETCHED AND DEVICE CAME OUT. SHE STATED THAT SHE GOT MOST OF IT OUT AND THINKS THE INSERT OR A SMALL PIECE OF IT IS STILL IN THE TUBE. GIVEN THE NATURE OF THE REPORTED EVENT, AND CONSIDERING THAT IT OCCURRED IN CONNECTION WITH INSERTION PROCEDURE, COMPANY ASSESSES IT AS RELATED TO ESSURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS IT COULD HAVE LED SERIOUS DETERIORATION OF HEALTH IF IT HAD OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITHOUT THE COMPLAINT SAMPLE. A REVIEW OF THE MANUFACTURING BATCH RECORD CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THERE IS NO REASON TO SUSPECT ABOUT CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 12-MAY-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PAT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2014-00559	BAYER HEALTHCARE LLC	12/31/2014	12/31/2014

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 22-JAN-2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY WITH ESSURE (DEVICE INEFFECTIVE) IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013, THE PATIENT HAD ESSURE IMPLANTED FOR PERMANENT BIRTH CONTROL. ON (B)(6) 2013, CONFIRMED HSG (HYSTEROSALPINGOGRAPHY). AT TIME OF REPORT, THE PATIENT WAS PREGNANT (DRUG INEFFECTIVE). NO ASSESSMENT FOR DRUG-EVENT RELATIONSHIP WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 12-FEB-2014: FOLLOW UP ATTEMPTS DONE WITH NO RESPONSE. CASE CLOSED. FOLLOW-UP INFORMATION RECEIVED ON 03-DEC-2014 AND CORRECTION ON 10-NOV-2014. NEW REPORTERS WERE ADDED. ESSURE WAS INSERTED IN (B)(6) 2013 FOR CONTRACEPTION. IT WAS REPORTED THAT ON AN UNSPECIFIED DATE, A TUBAL LIGATION WAS DONE AS ANOTHER FORM OF CONTRACEPTION. ON AN UNSPECIFIED DATE, PATIENT HAD ESSURE REMOVED BY BILATERAL SALPINGECTOMY. IT WAS DONE LAPAROSCOPICALLY. IT WENT WELL, WITHOUT COMPLICATIONS. IT WAS A SEPARATE PROCEDURE, NOT PART OF A TUBAL LIGATION. INCIDENT CATEGORY WAS CHANGED TO INCIDENT. FOLLOW UP 15.DEC.2014: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: CASE UPGRADED TO INCIDENT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD.

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WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND GOT PREGNANT. THIS EVENT IS NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, AN UNKNOWN TIME AFTER ESSURE INSERTION, PREGNANCY WAS CONFIRMED. A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. INITIALLY THIS CASE WAS REGARDED AS NON-INCIDENT, UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS INFORMED THAT A LAPAROSCOPIC SALPINGECTOMY WAS PERFORMED TO REMOVE THE ESSURE COILS, SO THE CASE WAS UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION (PREGNANCY OUTCOME) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 14-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMAL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040055	BAYER	1/1/2015	1/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 12281414

Single Use:
Implant Date (E6): 10/27/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MULTIPLE SIDE EFFECTS FROM MY ESSURE DEVICE: ABDOMINAL PAIN, BLOATING, HEAVY BLEEDING, IRREGULAR PERIODS, OVARIAN CYSTA FIBROIDS, MOOD SWINGS, ACNE, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040056	BAYER	1/1/2015	1/9/2015

Event Information:

Event Date (B3): 8/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/31/2006
Explant Date (E7): 8/31/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EMERGENCY SURGERY, TUBAL REMOVAL, PREGNANCY THREE TIMES WITH LIVE BIRTH. CHRONIC PAIN, HEADACHES, MEDICAL COMPLICATIONS DURING PREGNANCY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040042	BAYER	1/2/2015	1/9/2015

Event Information:

Event Date (B3): 8/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/11/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE PROCEDURE IN 2011, I HAVE SINCE EXPERIENCED SEVERE PAIN, CONTINUOUS BLEEDING DAILY REQUIRING CONSTANT USE OF FEMININE PRODUCTS AND EMOTIONAL DISTRESS. AFTER HAVING AN ULTRASOUND, IT WAS DETERMINED THE ESSURE SPRING HAS MOVED AND LODGED ITSELF INTO MY UTERUS. THE PRODUCT HAS BEEN TRAVELING THROUGH MY UTERINE MUSCLE FOR TWO YEARS NOW. THE DOCTOR WOULD LIKE TO PERFORM A HYSTERECTOMY, BUT, DUE TO ECONOMY AND MY CURRENT LAPSE OF INSURANCE. I AM UNABLE TO HAVE THE PROCEDURE. I AM (B)(6). TO DATE. I HAVE ALWAYS BEEN HEALTHY WITH NO HEALTH CONDITIONS. I DO NOT SMOKE, DRINK OR USE DRUGS AT ALL. THIS PRODUCT HAS CAUSED ME INDESCRIBABLE PAIN, MY INTIMATE LIFE WITH MY SPOUSE IS NONEXISTENT. I HAVE TO LIMIT PLAY WITH MY CHILDREN AND TAKE FREQUENT BREAKS AT WORK DUE TO PAIN AND BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040062		1/2/2015	1/9/2015

Event Information:

Event Date (B3): 8/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/8/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS INSERTED INTO MY FALLOPIAN TUBES (B)(6) OF 2012 AND HAVE HAD MANY SIDE EFFECTS THAT HAVE GONE UNEXPLAINED. I HAVE SEVERE PAIN IN MY LOWER ABDOMEN THAT MAY BEGIN AS A PIERCING STABBING PAIN AND THEN TURN INTO A STABBING PAIN SEVERAL TIMES A MONTH. I HAVE A LOT OF FATIGUE AND BRAIN FOG. I ALSO HAVE A DISTENDED ABDOMEN IN WHICH I LOOK AS IF I AM 6 MONTHS PREGNANT. DURING MY PERIOD, I HAVE AT LEAST A WEEK'S WORTH OF VERY HEAVY BLEEDING WITH QUARTER SIZE OR LARGER CLOTS. ALL OF MY SYMPTOMS GOT PROGRESSIVELY WORSE INSTEAD OF BETTER AS TIME GOES BY. I ALSO SUFFER FROM MIGRAINES THAT MY USUAL MIGRAINE MEDICINE CANNOT HELP WITH ANY LONGER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040063		1/3/2015	1/9/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/7/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE 2006 AND 7 YEARS LATER, I HAVE BEEN EXPERIENCING EXCRUCIATING PAIN DURING MY CYCLE. MY PAIN STARTED A FEW YEARS AGO AND MY CURRENT DOCTOR COULDN'T EXPLAIN WHY. I'VE HAD 2 ULTRASOUNDS DONE, IN WHICH THEY SHOW MY UTERUS IS NOW THE SIZE OF A 3 MONTH PREGNANT WOMAN. AFTER DOING MY OWN RESEARCH, I STRONGLY FEEL THAT ESSURE IS THE REASON FOR MY PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00001	BAYER HEALTHCARE LLC	1/5/2015	1/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B59463

Single Use: Y
Implant Date (E6): 4/11/2014
Explant Date (E7): 11/11/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR STERILIZATION (LOT NUMBER B59463). DOCTOR STATED THAT PATIENT'S ESSURE CONFIRMATION TEST SHOWED TUBAL PATENCY ON ONE SIDE AFTER BILATERAL PLACEMENT OF MICRO-INSERTS. FURTHER EXAMINATION DETERMINED THAT ONE MICRO INSERT WAS PERFORATED THROUGH THE UTERINE WALL. PATIENT REQUESTED BOTH TUBES RESECTED TO REMOVE DEVICES DUE TO PAIN. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: A PERFORATION IS A HOLE OR OPENING MADE THROUGH THE ENTIRE THICKNESS OF A MEMBRANE OR OTHER TISSUE OR MATERIAL. PROBABLE CAUSES FOR PERFORATION: PHYSICIAN ENCOUNTERS POOR VISIBILITY DURING THE PROCEDURE, PHYSICIAN TECHNIQUE AND EXPERIENCE, ADVANCING DELIVERY CATHETER WHEN PATIENT IS EXPERIENCING EXTRAORDINARY PAIN OR DISCOMFORT, ATTEMPTING TO ADVANCE DELIVERY CATHETER TO BLACK POSITIONING MARKER AFTER ENCOUNTERING UNDUE RESISTANCE, FURTHER ADVANCING DELIVERY CATHETER ONCE THE BLACK POSITIONING MARKER HAS REACHED THE TUBAL OSTIUM, ATTEMPTED REMOVAL OF AN IMPLANTED MICRO-INSERT WITH FEWER THAN 18 TRAILING COILS INTO THE UTERUS, INACCURATE PLACEMENT OF THE MICRO-INSERT IN THE FALLOPIAN TUBE BY THE PHYSICIAN. ACCORDING TO THE PRODUCT IFU, THE MICRO-INSERT MUST BE PLACED FAR ENOUGH INTO THE FALLOPIAN TUBE TO PREVENT EXPULSION (LESS THAN 18 TRAILING COILS). PERFORATIONS ARE A KNOWN RISK OF THE ESSURE PROCEDURE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL

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DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PATENCY AND PERFORATION ARE ANTICIPATED EVENTS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 5 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH B59463 (PRODUCTION DATE 02-AUG-2013 AND EXPIRATION DATE 31-AUG-2016), BUT NONE OF THEM REFER TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE CONFIRMATION TEST SHOWED TUBAL PATENCY ON ONE SIDE AFTER BILATERAL PLACEMENT. FURTHER EVALUATION DETERMINED THAT ONE MICRO INSERT WAS PERFORATED THROUGH THE UTERINE WALL. ONE MICRO INSERT WAS PERFORATED THROUGH THE UTERINE WALL IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, HYSTEROSALPINGOGRAM TEST SHOWED TUBAL PATENCY ON ONE SIDE AFTER BILATERAL PLACEMENT AND FURTHER EVALUATION (NOT SPECIFIED) REVEALED UTERINE PERFORATION (TESTS DATES WERE NOT SPECIFIED). PATIENT WAS EXPERIENCING PAIN AND REQUESTED ESSURE COILS TO BE REMOVED. BOTH TUBES WERE RESECTED THEN. THIS CASE WAS REGARDED AS INCIDENT (ANTICIPATED) SINCE PERFORATION WAS CONSIDERED RELATED TO ESSURE AND SURGICAL INTERVENTION WAS REPORTED. IN THIS CASE, A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. AFTER REVIEW, 5 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED, UNTIL (B)(6) 2014, IN RELATION TO THE REPORTED BATCH, BUT NONE OF THEM REFER TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP (PERFORATION QUESTIONNAIRE) INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-APR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED A

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039903	BAYER	1/5/2015	1/5/2015

Event Information:

Event Date (B3): 8/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS HAVING A SHORT OF BREATH, TURN OUT I HAVE ASTHMA. I WAS HAVING DIARRHEA, VOMITING, BLOATING, HEADACHES AND SOME OTHER SMALL THINGS. I NOW HAVE GERD (ACID REFLUX DISEASE). I KEPT HAVING TINGLY NUMB FEELINGS IN MY LEGS, ARMS, FEET. DOCTOR SAYS IT WAS THE MEDICINES. I HAD UNEXPLAINED HEADACHE AND MIGRAINE. MY PERIODS IS NOW EVERY 1 1/2- 2 WEEKS APART. I CONSTANTLY HAVE YEAST AND BLADDER INFECTION. I WENT INTO ER FOR A VERY BAD UTI. I WAS BURST INTO RASH ONCE A YEAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039904	BAYER	1/5/2015	1/5/2015

Event Information:

Event Date (B3): 8/31/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5039904 #(B)(4). SUBMISSION OF FURTHER COMPLICATIONS FROM ESSURE I EXPERIENCED. ONSET 2008. SEVERE DEPRESSION, PTSD, SUICIDAL ISSUES, CONFUSION, BRAIN FOG, BRAIN 'ZAPS', TWITCHING, SEVERE HEADACHES, CYSTS ON BUTTOCKS AND UPPER THIGH. TOOTH LOSS AND SEVERE DECAY, WEIGHT GAIN, BLOOD THICKENING, DIZZINESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039905	BAYER	1/5/2015	1/5/2015

Event Information:

Event Date (B3): 1/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5039905 #(B)(4). MODEL: ESS305, LOT: 787224, CONFIRMED BY IMPLANTING DOCTORS OFFICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039906	BAYER	1/5/2015	1/5/2015

Event Information:

Event Date (B3): 4/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I QUICKLY GAINED WEIGHT (40 LBS SINCE I GOT THE DEVICE), SERIOUS BLEEDING, HEADACHES, BODY ACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039907	BAYER	1/5/2015	1/5/2015

Event Information:

Event Date (B3): 3/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SINCE HAVING THE ESSURE DEVICE IMPLANTED I HAVE BEEN IN AND OUT OF THE HOSPITAL. I HAVE BEEN IN SEVERE PAIN, HAVE HEAVY BLEEDING, MY INTESTINES ARE INFLAMED, SEVERE HEAD ACHES AND BODY JOINT AND MUSCLE PAIN. I HAVE HAD NAUSEA AND VOMITING WITH FREQUENT UNEXPLAINED FEVERS AND MY WHITE BLOOD CELL COUNT IS ALL OVER THE PLACE. SINCE HAVING THESE EVEN MY BLOOD SUGAR IS ALL OVER THE PLACE AND I AM NOT DIABETIC. I HONESTLY FEEL LIKE I'M DYING A SLOW AND VERY PAINFUL DEATH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039908	BAYER	1/5/2015	1/5/2015

Event Information:

Event Date (B3): 12/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING VERY SHARP PAIN IN MY ABDOMINAL AREA. THEN I STARTED BLEEDING VERY HEAVY FOR OVER 3 MONTHS. ON TOP OF THAT, I HAVE BEEN HAVING MIGRAINES AND FAINTING SPELLS. INTERCOURSE IS VERY DIFFICULT. I HAVE ALSO GAINED OVER 50LBS AND HAVE NOT BEEN ABLE TO GET IT OFF NOT EVEN WITH DIETING NOR EXERCISE. MY MOOD SWINGS ARE HORRIBLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039909	BAYER	1/5/2015	1/5/2015

Event Information:

Event Date (B3): 2/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC DIARRHEA. NOT DAILY, BUT NEARLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039910	BAYER	1/5/2015	1/5/2015

Event Information:

Event Date (B3): 11/15/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MAJOR PAIN AND WAS BLEEDING THE ENTIRE TIME AFTER THE SURGERY, ALL THE WAY UP UNTIL I HAD THE ESSURE REMOVED. I WAS UNABLE TO KEEP FOOD DOWN, HOLD MY NEWBORN CHILD, DO DAILY ACTIVITIES UNTIL IT WAS REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039911	BAYER	1/5/2015	1/5/2015

Event Information:

Event Date (B3): 3/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDA MW5039911 #(B)(4). HAIR LOSS, HIP PAIN AND/OR JOINT, FEEL LIKE I CANT CONTROL MY MOODS, HEART PALPS, HIVES THE LIST GOES ON.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00002	BAYER HEALTHCARE LLC	1/5/2015	1/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B09703

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 09-DEC-2014, ARTICLE ENTITLED "MANAGEMENT OF PERFORATED ESSURE WITH MIGRATION INTO SMALL AND LARGE BOWEL MESENTERY: A CASE REPORT". IT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION AND EXPERIENCED LEFT FALLOPIAN TUBE PERFORATION WITH ESSURE MIGRATION INTO SMALL AND LARGE BOWEL MESENTERY AND ESSURE FRAGMENTS IN THE ABDOMINAL CAVITY. CASE REPORT: A (B)(6)-YEAR-OLD WOMAN, GRAVIDA 2 PARA 2, PRESENTED TO HER PRIMARY GYNECOLOGIST'S OFFICE FOR ESSURE HYSTEROSCOPIC TUBAL OCCLUSION. HER PROCEDURE HISTORY INCLUDED 2 VAGINAL DELIVERIES, 2 LOOP ELECTROSURGICAL EXCISION PROCEDURES AND AN APPENDECTOMY. SHE WAS OTHERWISE HEALTHY WITHOUT SIGNIFICANT PAST MEDICAL HISTORY. AFTER OBTAINING INFORMED CONSENT, THE PATIENT UNDERWENT IN-OFFICE ESSURE PLACEMENT USING A 30 DEGREE HYSTEROSCOPE. THE PROCEDURE WAS PERFORMED WITHOUT DIFFICULTY AND THERE WERE 2 TRAILING COILS NOTED BILATERALLY. THE PATIENT RECEIVED AN INJECTION OF DEPO-PROVERA AND WAS THEN DISCHARGED HOME IN STABLE CONDITION. ON POST-OPERATIVE DAY 8, THE PATIENT WAS SEEN AGAIN IN HER GYNECOLOGIST'S OFFICE SECONDARY TO WORSENING ABDOMINAL PAIN FOR 24-48 HOURS. SHE HAD GENERALLY BEEN FEELING WELL AFTER THE PROCEDURE, BUT BEGAN TO EXPERIENCE ABDOMINAL PAIN 2 DAYS AGO, WHICH HAS WORSENED IN THE LAST 24 HOURS. SHE DESCRIBED HER PAIN AS DIFFUSE, SHARP PAIN AND SEVERE CRAMPING IN THE UPPER AND LOWER ABDOMEN. THE PAIN WAS EXACERBATED BY MOVEMENT AND IMPROVED WITH REST. SHE ALSO NOTED LOOSE STOOLS SINCE THE ONSET OF PAIN. SYMPTOMS WERE NOT ASSOCIATED WITH FEVERS, CHILLS, NAUSEA OR EMESIS. VITAL SIGNS SHOWED A TEMPERATURE OF 36.9C, BLOOD PRESSURE 111/74 AND PULSE 78 BPM. ABDOMINAL EXAM DEMONSTRATED DIFFUSE UPPER AND LOWER

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ABDOMINAL TENDERNESS WITH MILD GUARDING. THERE WAS SIGNIFICANT UTERINE AND BILATERAL ADNEXAL TENDERNESS WITHOUT ANY ABNORMAL VAGINAL DISCHARGE. PELVIC ULTRASOUND CONFIRMED THE PRESENCE OF AN ESSURE DEVICE IN THE RIGHT FALLOPIAN TUBE, HOWEVER, DID NOT SHOW AN ESSURE DEVICE IN THE LEFT FALLOPIAN TUBE. THE UTERUS AND BOTH OVARIES APPEARED NORMAL ON ULTRASOUND, WITHOUT SIGNS OF HYDROSALPINX OR FREE FLUID IN THE PELVIS. GIVEN CONCERN FOR PERFORATION AND PELVIC INFLAMMATORY DISEASE, THE PATIENT WAS SENT TO THE EMERGENCY DEPARTMENT FOR EVALUATION AND INPATIENT ADMISSION. UPON EVALUATION IN THE EMERGENCY DEPARTMENT, THE PATIENT'S VITAL SIGNS REMAINED STABLE. WHITE BLOOD CELL COUNT WAS 9.8 THOUSAND/MCL (NORMAL 4.2-11.0 THOUSAND/MCL) AND HEMOGLOBIN 14.3 G/DL (NORMAL 12.0 -15.5 G/DL). A CT (COMPUTERISED TOMOGRAM) SCAN WITH CONTRAST WAS PERFORMED AND CONFIRMED PROPER LOCATION OF THE RIGHT ESSURE COIL AT THE CORNUAL TUBAL JUNCTION. IN THE LEFT FALLOPIAN TUBE, THERE WAS A SMALL METAL DENSITY IN THE EXPECTED LOCATION OF THE LEFT CORNUAL TUBAL JUNCTION. HOWEVER, REMAINDER OF ESSURE COIL WAS VISUALIZED IN THE SMALL BOWEL MESENTERY. THE COIL APPEARED TO BE IN ABUTTING LOOPS OF THE SMALL BOWEL, HOWEVER WAS OUTSIDE OF THE BOWEL LUMEN BASED ON IMAGES. A SMALL AMOUNT OF FREE FLUID WAS NOTED IN THE PELVIS. THERE WAS NO EVIDENCE OF FREE INTRAPERITONEAL AIR TO SUGGEST BOWEL PERFORATION. GIVEN THE ABOVE FINDINGS, PATIENT WAS GIVEN INTRAVENOUS CEFOXITIN AND METRONIZADOLE, AND SUBSEQUENTLY TRANSFERRED TO OPERATING ROOM FOR SURGICAL MANAGEMENT. DIAGNOSTIC LAPAROSCOPY WAS PERFORMED WITH A 5MM UMBILICAL PORT AND TWO 5MM ACCESSORY PORTS IN RIGHT AND LEFT LOWER QUADRANTS. SURVEY OF THE PELVIS REVEALED A SMALL SEGMENT OF ESSURE PROTRUDING FROM AN EPIPLOIC APPENDAGE OF THE RECTUM. THE LEFT FALLOPIAN TUBE WAS NOTED TO BE PERFORATED BUT NOT ACTIVELY BLEEDING. THE ESSURE WAS REMOVED FROM THE EPIPLOICA OF THE RECTUM WITHOUT ANY BLEEDING NOTED. EXAMINATION OF THE RETRIEVED MATERIAL CONFIRMED A STRETCHED, HOMOGENOUS, METALLIC COIL MEASURING 1.2CM IN LENGTH. DUE TO SIGNIFICANT DISTORTION OF THE ESSURE MATERIAL, WE WERE UNABLE TO IDENTIFY THE SPECIFIC PARTS OF THE ESSURE COIL. GIVEN PERFORATION OF THE LEFT FALLOPIAN TUBE AND THE PATIENT'S DESIRE FOR PERMANENT STERILIZATION, BILATERAL SALPINGECTOMY WAS PERFORMED. AFTER REMOVAL OF THE RIGHT FALLOPIAN TUBE, AN ESSURE COIL WAS NOTED TO BE PROTRUDING FROM THE RIGHT CORNUA AND WAS REMOVED BLUNTLY WHILE MAINTAINING EXCELLENT HEMOSTASIS. AFTER REMOVAL, THIS ESSURE COIL WAS EXAMINED AND APPEARED AS A SLIGHTLY STRETCHED, SPRING-LIKE METALLIC MATERIAL, MEASURING 4.2CM IN LENGTH AND APPEARED INTACT. ATTENTION WAS THEN TURNED TO THE ABDOMEN WHERE ADHESIONS WERE NOTED BETWEEN THE OMENTUM AND ANTERIOR ABDOMINAL WALL. ADHESIONS WERE LYSED USING THE LIGASURE. AT THIS POINT THERE WERE NO FURTHER ESSURE COILS VISIBLE IN THE ABDOMEN. HOWEVER, GIVEN OUR INABILITY TO IDENTIFY DISTINCT PORTIONS OF THE RETRIEVED LEFT SIDED ESSURE COIL, A DECISION WAS MADE TO EVALUATE FOR RETAINED ESSURE FRAGMENTS WITH INTRAOPERATIVE IMAGING. A PLAIN FILM RADIOGRAPH OF THE ABDOMINAL AND PELVIS WAS PERFORMED, DEMONSTRATING A RADIOPAQUE COIL IN THE LEFT UPPER QUADRANT. WHEN EVALUATING THE LEFT UPPER QUADRANT LAPAROSCOPICALLY, HOWEVER, WE INITIALLY FAILED TO IDENTIFY ANY ESSURE MATERIAL. AFTER SEVERAL PLAIN FILM X-RAYS WERE TAKEN, IT WAS APPARENT THAT THE ESSURE FRAGMENT WAS FREELY MOVING WITH THE SMALL BOWEL AND LIKELY EMBEDDED IN THE SMALL BOWEL MESENTERY. AT THIS POINT, THE DECISION WAS MADE TO PROCEED WITH FLUOROSCOPY TO ASSIST IN LOCALIZATION, AND THE OR TABLE AND C-ARM WERE PREPARED FOR FLUOROSCOPIC IMAGING. WITH THE ASSISTANCE OF FLUOROSCOPY, WE WERE ABLE TO IDENTIFY THE PORTION OF THE SMALL BOWEL CONTAINING THE ESSURE FRAGMENT. THE ESSURE FRAGMENT WAS THEN SUCCESSFULLY LOCATED LAPAROSCOPICALLY AND GENTLY PULLED FROM THE SMALL BOWEL MESENTERY USING A BLUNT GRASPER. THE BOWEL APPEARED INTACT WITHOUT ENTRY INTO BOWEL LUMEN. THE ESSURE COIL WAS STRETCHED SIGNIFICANTLY DURING REMOVAL AND APPEARED AS A GRAY, METALLIC MATERIAL MEASURING 8.4CM IN LENGTH AFTER REMOVAL. ONE FINAL FLUOROSCOPIC IMAGE WAS OBTAINED AT THE CONCLUSION OF THE CASE IN ORDER TO CONFIRM THAT THERE WERE NO REMAINING ESSURE FRAGMENTS IN THE ABDOMINAL CAVITY. THE PATIENT HAD AN

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UNCOMPLICATED POSTOPERATIVE COURSE AND WAS DISCHARGED HOME ON THE FIRST POSTOPERATIVE DAY. AUTHORS COMMENT: THE CASE DESCRIBED ABOVE, A RARE COMPLICATION OF ESSURE PLACEMENT OCCURRED IN WHICH THE MICROINSERT APPEARS TO HAVE PERFORATED THROUGH THE FALLOPIAN TUBE AND FRAGMENTED. A PORTION OF THE ESSURE COIL WAS FOUND TO HAVE MIGRATED INTO BOTH THE SMALL AND LARGE BOWEL MESENTERY. DIAGNOSTIC LAPAROSCOPY WAS SUFFICIENT TO DETECT A PORTION OF THE MICROINSERT ON THE LARGE BOWEL; HOWEVER WE WERE NOT ABLE TO IDENTIFY ALL PARTS OF THE ESSURE COIL WITH LAPAROSCOPY ALONE. ULTIMATELY, INTRAOPERATIVE IMAGING WAS REQUIRED TO COMPLETELY RETRIEVE ALL PARTS OF THE ESSURE COIL. FOLLOW-UP 10 DEC 2014: LOT NUMBER AND EXPIRY DATE WAS RECEIVED. RT ESSURE: LOT#B09703, REF#ESS305, 03/2016; LT ESSURE: LOT# B09703, REF#ESS305, 03/2016. PTC INVESTIGATION RESULT WAS RECEIVED ON 18-DEC-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT NUMBER B09703. MANUFACTURING DATE: 3/2013. EXPIRATION DATE: 3/2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PERFORATION IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LEFT FALLOPIAN TUBE WAS NOTED TO BE PERFORATED. ALSO, THE REMAINDER OF ESSURE COIL WAS VISUALIZED IN THE SMALL BOWEL MESENTERY AND PROTRUDING FROM AN EPIPLOIC APPENDAGE OF THE RECTUM (INTERPRETED AS GASTROINTESTINAL INJURY AND DEVICE EMBEDDED) WITH ESSURE FRAGMENTS IN THE ABDOMINAL CAVITY (INTERPRETED AS DEVICE BREAKAGE). ALL EVENTS ARE SERIOUS DUE TO HOSPITALIZATION. ALL EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR DEVICE BREAKAGE THAT IS CONSIDERED ANTICIPATED ONLY ACCORDING TO PRODUCT TECHNICAL COMPLAINT ANALYSIS. FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. DUE TO THE ANATOMICAL RELATIONSHIP BETWEEN BOWEL AND UTERUS, THE BOWEL IS THE MOST COMMONLY AFFECTED ORGAN. ACCORDING TO THE AUTHOR, A RARE COMPLICATION OF ESSURE PLACEMENT OCCURRED. THE MICROINSERT APPEARS TO HAVE PERFORATED THROUGH THE FALLOPIAN TUBE AND FRAGMENTED. A PORTION OF THE ESSURE COIL WAS FOUND TO HAVE MIGRATED INTO BOTH THE SMALL AND LARGE BOWEL MESENTERY. THERE WAS NO EVIDENCE OF FREE INTRAPERITONEAL AIR TO SUGGEST BOWEL PERFORATION. CONSIDERING THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PATIENT WAS HOSPITALIZED AND A BILATERAL SALPINGECTOMY WAS PERFORMED. A REVIEW OF MANUFACTURING BATCH RECORD CONFIRMED THAT THIS LOT MET ALL RELEASE REQUIREMENTS. HOWEVER, SINCE NO PRODUCT WAS RETURNED IT WAS NOT POSSIBLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION. SINCE NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED UNTIL 18-DEC-2014 IN RELATION TO THE REPORTED BATCH, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00003	BAYER HEALTHCARE LLC	1/5/2015	1/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2014 , ARTICLE ENTITLED "LAPAROSCOPIC MANAGEMENT OF HYSTEROSCOPIC ESSURE STERILIZATION COMPLICATIONS: REPORT OF 3 CASES." IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR ELECTIVE STERILIZATION AND A DISPLACED LEFT TUBAL MICROINSERT WAS VISUALIZED IN HYSTEROSALPINGOGRAM. LATER, DURING LAPAROSCOPIC REMOVAL, THE DEVICE WAS ADHERENT TO THE PERITONEUM WITH A SMALL AMOUNT OF ADHESIONS. AUTHORS REPORT 3 CASES OF ESSURE HYSTEROSCOPIC STERILIZATION COMPLICATIONS THAT WERE REFERRED TO THEIR MINIMALLY INVASIVE GYNECOLOGIC SURGICAL SERVICE AND SUCCESSFULLY MANAGED LAPAROSCOPICALLY. (REFER TO COMPANY CASE NUMBERS: 2014-181925, 2014-181926 AND 2014-181927). CASE 1: A (B)(4) NULLIPAROUS WOMAN WHO UNDERWENT AN UNCOMPLICATED HYSTEROSCOPIC STERILIZATION PROCEDURE WITH ESSURE, HAD A 3-MONTH FOLLOW-UP HYSTEROSALPINGOGRAM (HSG) NOTABLE FOR A DISPLACED LEFT TUBAL MICROINSERT WITH AN APPROPRIATELY PLACED RIGHT TUBAL MICROINSERT. THE PATIENT WAS ASYMPTOMATIC AT THE TIME OF THIS FINDING. THE PATIENT'S MEDICAL AND SURGICAL HISTORY WAS SIGNIFICANT FOR IDIOPATHIC GASTROPARESIS FOR WHICH SHE HAD A GASTRIC PACER. AFTER THE PATIENT WAS COUNSELED AS TO HER TREATMENT OPTIONS, SHE ELECTED TO UNDERGO LAPAROSCOPIC REMOVAL OF THE MISPLACED MICRO-INSERT WITH BILATERAL TUBAL LIGATION. THE PATIENT'S REOPERATION TOOK PLACE APPROXIMATELY 4 MONTHS AFTER THE INITIAL HYSTEROSCOPIC STERILIZATION PROCEDURE. INTRAOPERATIVELY, THE MISPLACED MICROINSERT WAS DISCOVERED IN THE RIGHT POSTERIOR CUL-DE-SAC, ADHERENT TO THE PERITONEUM WITH A SMALL AMOUNT OF ADHESIONS TO OVERLYING BOWEL EPIPLOICA . THE ADHESIONS WERE EASILY LYSED WITH A COMBINATION OF BLUNT AND SHARP DISSECTION USING THE LAPAROSCOPIC SCISSORS. MONOPOLAR ENERGY WAS NOT APPLIED

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BECAUSE OF THE GASTRIC PACER. APPROXIMATELY 3 CM OF THE ISTHMIC PORTION OF THE FALLOPIAN TUBE WAS COAGULATED WITH THE BIPOLAR FORCEPS DURING THE BILATERAL TUBAL LIGATION, ESPECIALLY NEAR THE CORNEAL REGION WHERE THE MICROINSERT WAS INITIALLY PLACED. THE PATIENT TOLERATED THE PROCEDURE WELL AND HAD AN UNCOMPLICATED POSTOPERATIVE COURSE. AUTHORS COMMENT: WE REPORT SUCCESSFUL LAPAROSCOPIC REMOVAL OF MICROINSERT FROM COMPLICATED HYSTEROSCOPIC ESSURE STERILIZATION BEYOND THE 12-WEEK POSTOPERATIVE PERIOD. IN THIS CASE, THE MICROINSERT WAS LOCATED IN THE RIGHT POSTERIOR CUL-DE-SAC WITH ADHESIONS ATTACHED TO THE SURROUNDING BOWEL EPIPLOICA AND PERITONEUM. THESE ADHESIONS WERE EASILY LYSED LAPAROSCOPICALLY WITH ONLY A SMALL AMOUNT OF FIBROSIS NOTED AROUND THE DISPLACED MICROINSERT. FOLLOW-UP 10-DEC-2014: THE GLOBAL PTC NUMBER WAS PROVIDED. FOLLOW UP 15.DEC.2014: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. ACCORDING TO CASE INFORMATION, DURING LAPAROSCOPIC REMOVAL, THE DEVICE WAS ADHERENT TO THE PERITONEUM. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP 29-DEC-2014: TO DATE THERE HAS BEEN NO RESPONSE FROM THE AUTHOR TO THE COMPANY'S REQUEST FOR THE BATCH NUMBER. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DERIVED FROM MEDICAL LITERATURE ARTICLE ENTITLED "LAPAROSCOPIC MANAGEMENT OF HYSTEROSCOPIC ESSURE STERILIZATION COMPLICATIONS: REPORT OF 3 CASES" REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING HYSTEROSALPINGOGRAM PERFORMED THREE MONTHS AFTER PLACEMENT, IT WAS FOUND OUT THAT THE LEFT TUBAL MICRO-INSERT WAS DISPLACED. THE EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE PATIENT HAD A 3-MONTH FOLLOW-UP HYSTEROSALPINGOGRAM (HSG) NOTABLE FOR A DISPLACED LEFT TUBAL MICROINSERT WITH AN APPROPRIATELY PLACED RIGHT TUBAL MICROINSERT. THEN THE PATIENT ELECTED TO UNDERGO LAPAROSCOPIC REMOVAL OF THE MISPLACED MICRO-INSERT WITH BILATERAL TUBAL LIGATION. INTRAOPERATIVELY, THE MICRO-INSERT WAS DISCOVERED IN THE RIGHT POSTERIOR CUL-DE-SAC, ADHERENT TO THE PERITONEUM WITH A SMALL AMOUNT OF ADHESIONS TO OVERLYING BOWEL EPIPLOICA. THE PROCEDURE OCCURRED WELL WITHOUT COMPLICATIONS. GIVEN THE NATURE OF DISLOCATION, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE AND SINCE INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039912	BAYER	1/5/2015	1/6/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CONSISTENT WEIGHT GAIN AND INABILITY TO LOSE WEIGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039913	BAYER	1/5/2015	1/6/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN ON LEFT SIDE NEAR OVARY. UNABLE TO WEAR TAMPONS DUE TO PAIN. ALSO, UNBEARABLE PAIN DURING SEX. CHRONIC FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040094	BAYER	1/5/2015	1/12/2015

Event Information:

Event Date (B3): 1/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): C76446

Single Use:
Implant Date (E6): 8/20/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6) 2014. DURING THE PROCEDURE ONE OF THE COILS BENT WHEN THE DOCTOR INSERTED IT INTO MY RIGHT FALLOPIAN TUBE. HE REDID THAT COIL AND ALL WAS GOOD. I BLED FOR A MONTH STRAIGHT AND HAD BAD CRAMPS AND PAINS ON MY RIGHT SIDE. I HAD THE CONFIRMATION TEST DONE (B)(6) 2014 VIA AN ULTRASOUND THAT SHOWED BOTH COILS IN PLACE, HOWEVER THE RIGHT COIL WAS ONLY 3/4 THE WAY IN THE TUBE THE OTHER 1/4 WAS PROTRUDING INTO MY UTERUS. I WAS TOLD THE PROCEDURE WORKED AND IT WAS OK TO STOP USING ALL FORMS OF BIRTH CONTROL. (B)(6) 2015 I AM 6 DAYS LATE WITH A CONFIRMED POSITIVE PREGNANCY TEST. NOW I HAVE NO OPTION BUT TO HAVE AN ABORTION BECAUSE I CAN'T AFFORD ANOTHER BABY WHICH IS THE REASON I HAD THE PROCEDURE DONE TO BEGIN WITH. I DON'T THINK THE RISKS OF PREGNANCY, ESPECIALLY ECTOPIC PREGNANCY, IS FULLY DISCLOSED NOR ACCURATE FROM BAYER. FURTHERMORE, BAYER SHOULD NOT HAVE IMMUNITY FROM LAWSUITS WHEN THERE ARE WOMEN BEING HARMED PHYSICALLY/EMOTIONALLY/MENTALLY EVERYDAY AND THEY JUST TURN THEIR HEADS. I AM EMOTIONALLY DISTRAUGHT AND WORDS CAN'T DESCRIBE HOW I FEEL. I RECOMMEND THIS PRODUCT BE TAKEN OFF THE MARKET. IF I COULD GO BACK I WOULD HAVE JUST GOTTEN A TUBAL DONE AND SAVE MYSELF THE PAIN AND HEARTACHE. EVEN IF I COULD AFFORD TO KEEP THIS BABY THE RISKS ARE TOO MAJOR. WITH THE COIL PROTRUDING INTO MY UTERUS IT WOULD PUT THE FETUS AT RISK AND POSSIBLY END UP WITH A STILL BORN. SOMEONE NEEDS TO BE RESPONSIBLE FOR THIS FAULTY DEVICE THAT IS TREATED LIKE A WALK IN THE PARK, EASY, PAINLESS ETC AND I ASSURE YOU WHAT THE WEBSITE SAID, IT'S NOT WHAT I FELT DURING OR AFTER THE PROCEDURE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040097	CONCEPTUS	1/5/2015	1/12/2015

Event Information:

Event Date (B3): 1/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): NO IDEA
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE DEVICE IMPLANTED IN (B)(6) OF 2012. SINCE THEN I HAVE SUFFERED DEBILITATING PAIN IN MY LOWER RIGHT ABDOMINAL AREA. THE PAIN IS GETTING WORSE AS EACH MONTH PASSES AND I AM ACTIVELY SEEKING TO HAVE THE IMPLANTS REMOVED. WHEN I SPOKE WITH MY OBGYN, WHO PERFORMED THE PROCEDURE, SHE ASSURED ME IT WASN'T FROM THE DEVICE AND THAT, "MOST WOMEN EXPERIENCE SOME PAIN OR DISCOMFORT DURING THEIR PERIODS." HOWEVER, I NEVER HAD PAIN DURING MY PERIOD BEFORE ESSURE AND IT IS FAR BEYOND DISCOMFORT. I CAN NOT WALK OR DO MUCH OF ANYTHING OTHER THAN GO INTO THE FETAL POSITION AND CRY. ADDITIONALLY, I HAVE EXPERIENCED ONGOING VAGINAL PH IMBALANCE SINCE THE PROCEDURE. I NEVER EXPERIENCED SUCH AN ISSUE BEFORE THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00004	BAYER HEALTHCARE LLC	1/6/2015	1/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6) 2014 , ARTICLE ENTITLED "LAPAROSCOPIC MANAGEMENT OF HYSTEROSCOPIC ESSURE STERILIZATION COMPLICATIONS: REPORT OF 3 CASES". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR ELECTIVE STERILIZATION AND EXPERIENCED BILATERAL PELVIC PAIN, BILATERAL LOWER ABDOMINAL PAIN, IRREGULAR VAGINAL BLEEDING, AND REQUESTED LAPAROSCOPIC REMOVAL OF BOTH MICRO-INSERTS. AUTHORS REPORT 3 CASES OF ESSURE HYSTEROSCOPIC STERILIZATION COMPLICATIONS THAT WERE REFERRED TO THEIR MINIMALLY INVASIVE GYNECOLOGIC SURGICAL SERVICE AND SUCCESSFULLY MANAGED LAPAROSCOPICALLY. (B)(4). CASE 2: A (B)(6) GRAVIDA 2, PARA 2 WOMAN HAD AN HYSTEROSALPINGOGRAM (HSG) REVEALING CORRECTLY PLACED BILATERAL MICROINSERTS 3 MONTHS AFTER AN UNCOMPLICATED HYSTEROSCOPIC STERILIZATION PROCEDURE WITH ESSURE. SHE COMPLAINED OF BILATERAL LOWER ABDOMINAL AND PELVIC PAIN ALONG WITH IRREGULAR VAGINAL BLEEDING. ON EXAMINATION, THE PATIENT HAD BILATERAL ADNEXAL TENDERNESS. ULTRASOUND FINDINGS WERE WITHIN NORMAL LIMITS. AFTER EXTENSIVE COUNSELING REGARDING ALL TREATMENT OPTIONS, THE PATIENT REQUESTED LAPAROSCOPIC REMOVAL OF BOTH MICRO-INSERTS WITHOUT ANY FURTHER SURGICAL STERILIZATION TECHNIQUES. SHE DECLINED A TUBAL LIGATION OR SALPINGECTOMY AT THE TIME OF SURGERY EVEN THOUGH SHE WAS COUNSELED REGARDING HER INCREASED RISKS OF ECTOPIC PREGNANCY AND OUR INABILITY TO GUARANTEE CONTINUED STERILIZATION WITHOUT FURTHER CONTRACEPTIVE MEASURES. THE LAPAROSCOPIC SURGERY TOOK PLACE APPROXIMATELY 8 MONTHS AFTER THE HYSTEROSCOPIC STERILIZATION. INTRAOPERATIVELY, BOTH FALLOPIAN TUBES APPEARED WITHIN NORMAL LIMITS WITH NO EVIDENCE OF TUBAL PERFORATION OR EROSION. THERE WAS NO EVIDENCE OF ANY PELVIC PATHOLOGY, SUCH AS ENDOMETRIOSIS, WHICH COULD

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EXPLAIN HER SYMPTOMATOLOGY. EACH MICROINSERT WAS LAPAROSCOPICALLY PALPATED WITH THE GRASPING FORCEPS AND NOTED TO BE APPROPRIATELY PLACED AT THE UTEROTUBAL JUNCTION AND ISTHMIC PORTIONS OF THE FALLOPIAN TUBES. DILUTE VASOPRESSIN WAS INJECTED ON THE ANTIMESENTERIC BORDER OF THE TUBAL ISTHMUS AND A LINEAR SALPINGOSTOMY WAS MADE AT THIS SITE WITH THE MONOPOLAR ENDOSHEARS. THE EXPOSED MICROINSERTS WERE RETRIEVED FROM THE FIBROSED ENDOSALPINGES OF THE FALLOPIAN TUBES WITH MINIMAL FORCE. THERE WERE NO INTRAOPERATIVE COMPLICATIONS AND THE PATIENT RECOVERED WELL POSTOPERATIVELY. A 3 MONTH FOLLOWUP HSG REVEALED BILATERAL TUBAL OCCLUSION AND THE PATIENT'S PELVIC PAIN AND ABNORMAL VAGINAL BLEEDING RESOLVED. AUTHORS COMMENT: IT IS ALSO INTERESTING TO NOTE THAT THE PATIENT IN CASE 2 HAD PERSISTENT BILATERAL TUBAL OCCLUSION AT HER HSG AFTER LAPAROSCOPIC REMOVAL OF BOTH MICROINSERTS. THESE FINDING SUGGEST FIBROSIS OF THE ENDOSALPINGES RESULTING IN TUBAL OCCLUSION MAY PERSIST EVEN AFTER REMOVAL OF THESE DEVICES. EVEN WITH THIS FINDING, WE RECOMMEND THE USE OF AN ALTERNATIVE MODE OF CONTRACEPTION AFTER MICROINSERT REMOVAL GIVEN THE LACK OF DATA. FURTHERMORE, ALTHOUGH THE DEVICES CAN BE REMOVED LAPAROSCOPICALLY, THE PERSISTENT FIBROSIS INDICATED BY THE BILATERAL TUBAL OCCLUSION SUPPORTS THE IDEA THAT HYSTEROSCOPIC ESSURE STERILIZATION PROCEDURES ARE IRREVERSIBLE AND SHOULD BE CONSIDERED PERMANENT. FOLLOW-UP 10-DEC-2014: THE GLOBAL PTC NUMBER HAS BEEN ASSIGNED. FOLLOW UP 16.DEC.2014: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP 29-DEC-2014: TO DATE THERE HAS BEEN NO RESPONSE FROM THE AUTHOR TO THE COMPANY'S REQUEST FOR THE BATCH NUMBER. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DERIVED FROM MEDICAL LITERATURE ARTICLE ENTITLED "LAPAROSCOPIC MANAGEMENT OF HYSTEROSCOPIC ESSURE STERILIZATION COMPLICATIONS: REPORT OF 3 CASES" REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BILATERAL PELVIC PAIN. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE PATIENT HAD THE CONFIRMATION TEST PERFORMED THREE MONTHS AFTER PLACEMENT AND THE INSERTS WERE CORRECTLY POSITIONED. SHE STARTED TO EXPERIENCE BILATERAL LOWER ABDOMINAL AND PELVIC PAIN ALONG WITH IRREGULAR VAGINAL BLEEDING. THEN, SHE REQUESTED FOR LAPAROSCOPIC REMOVAL OF BOTH MICRO-INSERTS. THE PROCEDURE OCCURRED WITHOUT COMPLICATIONS AND THE PATIENT RECOVERED WELL. THREE MONTHS LATER, A FOLLOW UP HSG WAS AGAIN PERFORMED AND REVEALED BILATERAL TUBAL OCCLUSION AND THE PATIENT'S PELVIC PAIN AND ABNORMAL VAGINAL BLEEDING RESOLVED. GIVEN THE NATURE OF THE EVENT, IT IS ASSESSED AS RELATED TO ESSURE USE. SINCE A LAPAROSCOPY TO REMOVE THE MICRO-INSERTS WAS PERFORMED (REQUIRED INTERVENTION), THE CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY,

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THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00005	BAYER HEALTHCARE LLC	1/6/2015	1/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2014 , ARTICLE ENTITLED "LAPAROSCOPIC MANAGEMENT OF HYSTEROSCOPIC ESSURE STERILIZATION COMPLICATIONS: REPORT OF 3 CASES." IT REFERS TO A (B)(6) FEMALE PATIENT WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) FOR ELECTIVE STERILIZATION AND EXPERIENCED PERSISTENT RIGHT LOWER QUADRANT PAIN, DEVICE PLACEMENT PROCEDURE WAS COMPLICATED BY PLACEMENT OF 2 MICROINSERTS IN THE RIGHT FALLOPIAN TUBE, DUE TO DIFFICULTY DEPLOYING THE RIGHT MICROINSERT FROM THE CATHETER, AND LAPAROSCOPIC REMOVAL OF THE RIGHT MICROINSERTS. AUTHORS REPORT 3 CASES OF ESSURE HYSTEROSCOPIC STERILIZATION COMPLICATIONS THAT WERE REFERRED TO THEIR MINIMALLY INVASIVE GYNECOLOGIC SURGICAL SERVICE AND SUCCESSFULLY MANAGED LAPAROSCOPICALLY. (REFER TO COMPANY CASE NUMBERS: (B)(4)). CASE 3: A (B)(6) WOMAN REPORTED PERSISTENT RIGHT LOWER QUADRANT PAIN 3 MONTHS AFTER A HYSTEROSCOPIC STERILIZATION PROCEDURE THAT WAS COMPLICATED BY PLACEMENT OF 2 MICROINSERTS IN THE RIGHT FALLOPIAN TUBE. HER GYNECOLOGIC HISTORY INCLUDED AN ECTOPIC PREGNANCY FOR WHICH SHE UNDERWENT A LAPAROSCOPIC SALPINGOSTOMY. THE PATIENT COULD NOT RECALL WHETHER THE ECTOPIC INVOLVED THE RIGHT OR LEFT TUBE. SHE ALSO HAD A HISTORY OF CERVICAL DYSPLASIA MANAGED BY 2 LOOP ELECTROSURGICAL EXCISION PROCEDURES. HER OBSTETRIC HISTORY ALSO INCLUDED 4 PRIOR SPONTANEOUS ABORTIONS, A FULL-TERM VAGINAL DELIVERY, AND A PRETERM VAGINAL DELIVERY SECONDARY TO PRETERM LABOR AND PRETERM PREMATURE RUPTURE OF THE MEMBRANES. HER MEDICAL AND SURGICAL HISTORY WAS OTHERWISE INSIGNIFICANT. DURING THE HYSTEROSCOPIC STERILIZATION PROCEDURE, THE SURGEON HAD DIFFICULTY DEPLOYING THE RIGHT MICROINSERT FROM THE CATHETER. THE ESSURE CATHETER WAS THREADED THROUGH THE RIGHT TUBAL OSTIA WITHOUT DIFFICULTY TO THE

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APPROPRIATE LEVEL WHERE THE BLACK POSITIONING MARKER REACHES THE FALLOPIAN TUBE OSTIUM. WHEN ROTATING THE THUMBWHEEL BACK, THE INSTRUMENT DID NOT WITHDRAW THE PROTECTIVE SHEATH IN THE USUAL FASHION TO EXPOSE THE ORANGE RELEASE CATHETER. THE BUTTON TO DEPLOY THE DEVICE WAS PRESSED, AND THE SHEATH STILL DID NOT RETRACT. THE SURGEON CONCLUDED THERE WAS AN INSTRUMENT FAILURE AND REPLACED THE ORIGINAL CATHETER WITH ANOTHER DEVICE. A SECOND DEVICE WAS USED TO SUCCESSFULLY DEPLOY THE MICROINSERT INTO THE RIGHT TUBAL OSTIA. FINALLY, A THIRD DEVICE WAS USED TO PLACE A MICROINSERT INTO THE LEFT OSTIA. AT THE END OF THE CASE, 4 COILS FROM THE RIGHT OSTIA AND 8 COILS FROM THE LEFT OSTIA WERE VISUALIZED. POSTOPERATIVELY, THE PATIENT WAS ADMITTED OVERNIGHT FOR PAIN CONTROL. SHE HAD ABDOMINAL AND PELVIC PAIN NOT RELIEVED WITH INTRAVENOUS MORPHINE OR KETORALAC. A COMPUTED TOMOGRAPHY SCAN OF THE ABDOMEN AND PELVIS REVEALED 2 MICROINSERTS LOCATED WITHIN THE RIGHT TUBE AND ONE IN THE LEFT. FREE FLUID WAS NOTED IN THE DEPENDENT PORTIONS OF THE PELVIS AND NO OTHER ABNORMALITIES WERE SEEN. A DIAGNOSTIC LAPAROSCOPY WAS PERFORMED ON POSTOPERATIVE DAY 1 TO RULE OUT A TUBAL PERFORATION. INSPECTION OF THE ABDOMEN AND PELVIS REVEALED NO EVIDENCE OF TUBAL PERFORATION, A NORMAL APPENDIX, AND NO OTHER PATHOLOGY TO EXPLAIN THE PATIENT´S SYMPTOMS. THE PATIENT WAS TRANSITIONED TO ORAL PAIN DRUGS AND DISCHARGED HOME. THREE DAYS AFTER HER INITIAL SURGERY, THE PATIENT CAME TO THE EMERGENCY DEPARTMENT WITH PERSISTENT PAIN. ABDOMINAL RADIOGRAPH SERIES REVEALED NO EVIDENCE OF FREE AIR. THE PATIENT WAS DISCHARGED HOME WITH PAIN DRUGS AND PRECAUTIONS. AT THE 3-MONTH FOLLOW-UP HSG, THE PATIENT CONTINUED TO HAVE PERSISTENT PAIN, BOTH AT REST AND DURING INTERCOURSE. BECAUSE THE SCOUT FILMS FOR THE HSG SHOWED 2 COILS THAT APPEARED ABNORMALLY POSITIONED ON THE RIGHT AND 1 CORRECTLY POSITIONED COIL ON THE LEFT, THE HSG WAS NOT PERFORMED. GIVEN THE PATIENT´S PERSISTENT SYMPTOMS, THE PATIENT RETURNED TO THE OPERATING DEPARTMENT APPROXIMATELY 4 MONTHS AFTER THE INITIAL HYSTEROSCOPIC STERILIZATION FOR LAPAROSCOPIC REMOVAL OF THE RIGHT MICROINSERTS AND RIGHT SALPINGECTOMY. LAPAROSCOPIC FINDINGS REVEALED NORMAL-APPEARING TUBES BILATERALLY WITHOUT EVIDENCE OF ANY TUBAL ABNORMALITIES, PERFORATION, OR EROSION. THE 2 MICROINSERTS WITHIN THE RIGHT FALLOPIAN TUBE WERE PALPATED LAPAROSCOPICALLY AND NOTED TO BE LYING END TO END IN SUCCESSION WITHOUT OVERLAP. A PORTION OF THE RIGHT FALLOPIAN TUBE BETWEEN THE ENDS OF THE 2 MICROINSERTS WAS INCISED TO EXPOSE THE TIPS OF EACH MICROINSERT. THE DISTAL AND PROXIMAL MICROINSERTS WERE VISUALIZED AND PULLED OUT OF THE TUBE WITHOUT DIFFICULTY; THE ESSURE MICROINSERT WAS IN PIECES AFTER LAPAROSCOPIC REMOVAL. ALTHOUGH THE INSERTS WERE NOTED TO BE FIBROSED WITHIN THE ENDOSALPINX, THE LEVEL OF FIBROSIS DID NOT REQUIRE SIGNIFICANT FORCE TO RETRIEVE THE INSERTS FROM THE FALLOPIAN TUBE. A RIGHT SALPINGECTOMY WAS THEN PERFORMED, REMOVING THE ENTIRE LENGTH OF THE RIGHT FALLOPIAN TUBE. CHROMOTUBATION WAS PERFORMED AND THERE WAS NO EXTRAVASATION OF DYE FROM THE LEFT FALLOPIAN TUBE OR RIGHT CORNUA (UTEROTUBAL JUNCTION). THE PATIENT TOLERATED THE PROCEDURE WELL AND WAS DISCHARGED HOME IN STABLE CONDITION THAT SAME DAY. AUTHORS COMMENT: AS IN THIS CASE REPORT, THE MICROINSERT MAY BE INSERTED TOO DEEP INTO THE TUBAL OSTIUM WITHOUT VISIBLE COILS, MISLEADING THE GYNECOLOGIST TO THINK THE MICROINSERT DID NOT DEPLOY. WE BELIEVE A LAPAROSCOPIC APPROACH TO REMOVE ESSURE MICROINSERTS FOLLOWED BY A TUBAL LIGATION OR BILATERAL SALPINGECTOMY IS A SAFE AND FEASIBLE MINIMALLY INVASIVE OPTION THAT CAN HELP AVOID MORE EXTENSIVE SURGERY AND PROVIDE PERMANENT STERILIZATION FOR THE PATIENT. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2014 (PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR

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DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE ADVERSE EVENT CASE REFERS TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP 29-DEC-2014: TO DATE THERE HAS BEEN NO RESPONSE FROM THE AUTHOR TO THE COMPANY'S REQUEST FOR THE BATCH NUMBER. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DERIVED FROM MEDICAL LITERATURE ARTICLE ENTITLED "LAPAROSCOPIC MANAGEMENT OF HYSTEROSCOPIC ESSURE STERILIZATION COMPLICATIONS: REPORT OF 3 CASES" REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PERSISTENT RIGHT LOWER QUADRANT PAIN. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN ESSURE´S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE PHYSICIAN PLACED 2 INSERTS IN RIGHT FALLOPIAN TUBE AFTER HAVING DIFFICULTY TO DEPLOY THE INSERT. THE PLACEMENT OF TWO INSERTS MAY HAVE CONTRIBUTED TO CAUSE THE ABDOMINAL PAIN, THEREFORE THIS EVENT WAS CONSIDERED RELATED TO ESSURE. SINCE THE PATIENT UNDERWENT A LAPAROSCOPIC SURGERY TO REMOVE THE ESSURE INSERTS THIS CASE IS REGARDED AS INCIDENT. IN ADDITION NON-SERIOUS WERE REPORTED. THE PRODUCT TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00007	BAYER HEALTHCARE LLC	1/6/2015	1/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN THE UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HIS PARTNER, A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PAIN. THE INSERTS WERE REMOVED LAPAROSCOPICALLY AND HE BELIEVES SHE HAS FILED A LEGAL CASE. HE ALSO REPORTED THAT HE HAD HEARD VIA THE MEDIA THAT THERE HAVE BEEN PATIENTS COMPLAINING OF A LOT OF PAIN WITH THE ESSURE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS

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TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PAIN. PHYSICIAN STATED THAT HE BELIEVED PATIENT HAS FILED A LEGAL CASE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND WAS CONSIDERED LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PAIN MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, THE TIME FROM ESSURE INSERTION TO THE ONSET OF THE EVENT WAS UNKNOWN. AN ALTERNATIVE EXPLANATION IS NOT AVAILABLE. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS REQUIRED (THE INSERTS WERE REMOVED LAPAROSCOPICALLY. SINCE NEITHER LOT NUMBER NOR PRODUCT COMPLAINT SAMPLE WAS PROVIDED IT IS NOT POSSIBLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. ALSO, ACCORDING TO PRODUCT TECHNICAL ANALYSIS, THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THEREFORE, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00008	BAYER HEALTHCARE LLC	1/6/2015	1/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2013 VIA INTERNET WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THAT ESSURE WAS LOST INSIDE HER BODY AND SHE REPORTED "WOMAN SICK AND DYING". THIS CASE WAS NOT MEDICALLY CONFIRMED AT THE TIME OF THE REPORT. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT DRUGS AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE INSERTED. IT WAS NOT REPORTED WHETHER ESSURE WAS USED PREVIOUSLY. THE CONSUMER REPORTED THAT ESSURE WAS LOST IN HER BODY AND "WOMAN SICK AND DYING". THE CONSUMER'S OUTCOME WAS UNKNOWN AT THE TIME OF THE REPORT. REPORTER CAUSALITY: NO CAUSALITY COMMENT WAS GIVEN. FOLLOW-UP RECEIVED ON 25-OCT-2013: CASE CATEGORY WAS CHANGED FROM INCIDENT TO NON-INCIDENT. NO PTC WILL BE CREATED. FOLLOW-UP RECEIVED ON 25-OCT-2013: REPORTER DID NOT PROVIDE ANY RESPONSE. CASE CONSIDERED TO BE CLOSED. FOLLOW-UP RECEIVED ON 29-OCT-2014: INFORMATION RECEIVED FROM CONSUMER STATES THAT ESSURE MADE HER FEEL LIKE SHE WAS DYING FOR 6 YEARS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP 10.DEC.2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. CASE UPGRADED TO INCIDENT. ESSURE FOR BIRTH CONTROL WAS ADDED. CONSUMER REPORTED THAT HAD ESSURE COIL REMOVED AND STILL SICK AND HAD HYSTO STILL FIGHTING. NO ADDITIONAL INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED VIA INTERNET AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE WAS LOST INSIDE HER BODY. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED. ADDITIONALLY NON-SERIOUS EVENT WAS REPORTED. THIS CASE WAS UPGRADED FROM NON-INCIDENT TO INCIDENT SINCE ESSURE DEVICE WERE REMOVED. THE PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION. NO VALID LOT NUMBER WAS PROVIDED, THUS NO REVIEW OF THE MANUFACTURING BATCH WAS POSSIBLE. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00009	BAYER HEALTHCARE LLC	1/6/2015	1/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SOLICITED CASE REPORT FROM A CONSUMER IN THE UNITED STATES WAS DETECTED ON (B)(6) 2014 VIA ESSURE GENERIC ACTIVE ONLINE LISTENING. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PROVIDED A PHOTO SHOWING TWO ESSURE COILS WITH DEVICE SHAPE ALTERATION AND DEVICE BREAKAGE OF LEFT COIL. CONSUMER STATED IT NEARLY KILLED HER. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL. CONSUMER PROVIDED A PHOTO SHOWING TWO EXPLANTED ESSURE COILS WITH DEVICE SHAPE ALTERATION AND DEVICE BREAKAGE OF LEFT COIL. CONSUMER ASKED WHETHER THIS LOOKED LIKE SOMETHING THAT SHOULD LAST A LIFETIME, AND STATED NO, IT LASTED SEVEN YEARS AND NEARLY KILLED HER. NO FURTHER DETAILS WERE REPORTED AND CAN BE OBTAINED. FOLLOW-UP 20-FEB-2014 AND 25-FEB-2014: CONSUMER REPORTED HER CASE IN THE SOCIAL MEDIA IN THE INTERNET. ON (B)(6) 2014, CONSUMER REPORTED THAT SHE IS GROWING A PAIR (NOT OTHERWISE SPECIFIED) AND IS TELLING HER ENTIRE STORY IN THAT WEEK. CONSUMER STATED ESSURE CAUSES CANCER AND THE FDA KNEW IT. ON (B)(6) 2014, CONSUMER AGAIN REPORTED THAT ESSURE ALMOST KILLED HER. NO FURTHER DETAILS WERE REPORTED. FOLLOW UP INFORMATION RECEIVED ON 19-MAR-2014: NEW REPORTER WAS ADDED. THE CONSUMER STATED ESSURE WAS CRUMBLING INSIDE HER. FOLLOW UP INFORMATION RECEIVED ON 10-DEC-2014: A PICTURE OF TWO ESSURE COILS BROKEN AND KINKED WAS PROVIDED. THE CONSUMER STATED THAT ESSURE ALMOST KILLED HER. CASE UPGRADED TO INCIDENT. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 19-DEC-2014. THE PTC GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO

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PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. POSSIBLE ESSURE DEVICE REMOVAL WAS IDENTIFIED AS AN ANTICIPATED EVENT DURING THE DESIGN PROCESS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 31-DEC-2014: CONSUMER CONTACT INFORMATION UNAVAILABLE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE WAS REMOVED. AFTER THE PROCEDURE, THE DEVICES WERE FOUND BROKEN AND WITH DEVICE SHAPE ALTERATION IN A PICTURE PROVIDED. THE FIRST EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND THE OTHERS ARE NON-SERIOUS. ALL EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT THE BREAKAGE WHICH IS UNLISTED. IN THIS CASE, VERY LIMITED INFORMATION WAS INFORMED. A PICTURE OF THE DEVICES WAS PROVIDED WITH TWO COILS. THE PHOTO PRESENTED TWO MICRO-INSERTS WITH DEVICE SHAPE ALTERATION AND DEVICE BREAKAGE. AN INTERVENTION WAS IMPLIED, SINCE THE PICTURES SHOWED SURGICAL MATERIAL AND A SURGERY IS NECESSARY TO REMOVE THE MICRO-INSERTS. THE CIRCUMSTANCES AND MECHANISM OF BREAKAGE AND THE REASON OF THE REMOVAL ARE NOT KNOWN. HOWEVER, GIVEN THE NATURE OF THE EVENTS, CAUSALITY IS ASSESSED AS RELATED TO ESSURE. INITIALLY, THE CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, THE MATERIAL OF THE NEW PICTURE WAS INTERPRETED AS A PRODUCT OF A SURGICAL PROCEDURE, THEREFORE AN INTERVENTION REQUIRED WAS IMPLIED AND THE CASE WAS UPGRADED TO INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW UP WAS POSSIBLE SINCE CONSUMER CONTACT INFORMATION WAS UNAVAILABLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039914	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE CRAMPING AND PAIN IN THE VAGINAL ARE DURING MENSTRUATION. IN ALL MY YEARS, I'M (B)(6) I DIDN'T THINK I'D START GETTING CRAMPS AND PMS. WEIGHT GAIN, MEMORY LOSS, RASH, ITCHY SKIN, THINNING HAIR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039915	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). AFTER HAVING ESSURE IMPLANTED I STARTED HAVING SEVERE HEADACHES, HAIR LOSS AND BACK PAIN. OVER THE PAST TWO YEARS I HAVE HAD PROBLEMS WITH MY MENTAL CYCLE AND MOOD CHANGES AS WELL. AS TIME HAS WENT ON I HAVE DEVELOPED JOINT PAIN IN MY HIPS AND KNEES AS WELL. SOME DAYS MY LOWER BACK PAIN IS SO SEVERE THAT I CAN HARDLY WALK TO TAKE CARE OF MY FOUR KIDS. IT SEEMS THAT THINGS ARE PROGRESSIVELY GETTING WORSE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039916	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 6/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAVE GAINED WEIGHT, BACK PAIN, EXTREME FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039917	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAD SUDDEN ONSET OF PELVIC PAIN, SHARP SEVERE PAINS IN MY LOWER ABDOMEN, CRAMPING, BLOATING, WEIGHT GAIN (ABNORMAL), PAIN WITH INTERCOURSE AND GI SYMPTOMS INCLUDING NAUSEA, DIARRHEA AND CONSTIPATION. THESE ISSUES HAVE BEEN ON GOING DAILY FOR OVER 6 MONTHS NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039918	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 6/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4) THIS WAS PLACED ON (B)(6) 2014. I BEGAN HAVING 2 DARK RUST COLOR PERIODS A MONTH. BACK IN (B)(6), I STARTED HAVING MIGRAINES SO BAD, I AM HAVING VIOLENT THOUGHTS. I HAVE NEVER HAD A MIGRAINE IN MY (B)(6) YEARS OF LIFE TILL THEN AND NOW I HAVE ANYWHERE FROM 2-4 A WEEK LASTING A COUPLE DAYS EACH ONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039919	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 9/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONLY SINCE I'VE HAD THE ESSURE I GET MAJOR MIGRAINES, PAINFUL INTERCOURSE, CONSTANT LOWER ABDOMINAL PAIN, HEAVY HEAVY PERIODS. AN IF YOU PUSH ON MY LOWER ABDOMEN I GET A SHARP PAIN THAT MAKES ME NAUSEOUS. I'VE BEEN TO THE DOCTORS AN ILL I GET TOLD IS I'M FINE. I'M NOT FINE I'M IN CONSTANT PAIN AN WANT HELP. SOMETHING HAS TO BE DONE TO STOP THIS PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039920	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THE ESSURE DEVICE PLACED, I HAVE EXPERIENCED: HIVES, WEIGHT GAIN, MIGRAINES, MENTAL FOG, SHORT TERM MEMORY LOSS, PELVIC PAIN, PAIN WITH INTERCOURSE, IRREGULAR BLEEDING, INSOMNIA, MOOD SWINGS, FATIGUE, ANEMIA, AND BOWEL ISSUES, TO NAME A FEW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039921	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 8/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5039921 #(B)(4) I HAD HYSTERECTOMY ON (B)(6), 2014 BECAUSE OF ESSURE. I AM ALLERGIC TO NICKEL. MY LIFE HAVE GOTTEN SO MUCH BETTER SINCE I HAD ESSURE REMOVED. I DO NOT HAVE TO TAKE ANYMORE OF DAILY MEDICINES LIKE I HAVE USED TO. I DON'T HAVE TO WORRY ABOUT SPENDING HUNDREDS ON MEDICINES EVERY MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039922	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 7/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) FOR THE PAST 5 YEARS I HAVE HAD ONGOING PAIN ON MY LOWER RIGHT SIDE, RIGHT WHERE THE IMPLANT WOULD BE LOCATED. MY PERIODS HAVE CHANGED TO BEING EXTREMELY BLOODY AND FULL OF CLOTS, I HAVE HAD UNEXPLAINED WEIGHT GAIN, LOSS OF CONCENTRATION, HEADACHES...IT IS PAINFUL TO HAVE INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039923	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 5/31/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY HEAVY, LONG, AND PAINFUL PERIODS WHICH RESULTED IN HYSTERECTOMY IN 2009. CRAMPING, STABBING PAINS, PAINFUL OVULATION, VAGINAL DISCHARGE WITH ODOR, HOT FLASHES, NIGHT SWEATS, INCONTINENCE, URGENT AND FREQUENT URINATION, BREAST TENDERNESS, ABDOMINAL FLUTTERS, BODY ACHES, ESPECIALLY JOINTS, NAUSEA, EXTREME BLOATING, BOWEL ISSUES (CONSTIPATION AND DIARRHEA), DIZZINESS, NUMBNESS IN EXTREMITIES, SHORT TERM MEMORY ISSUES, FORGETFULNESS, ANXIETY(WORSENED), DEPRESSION, DIZZINESS, FOOD SENSITIVITIES, EXTREME ITCHING, HEART PALPITATIONS, HAIR LOSS, RECEDING GUMS, INSOMNIA, EXTREME WEIGHT GAIN, MUSCLE SPASMS, "FLOATERS" IN VISION, EXCESSIVE SWEATING, ONGOING CRAMPING AFTER HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039924	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 12/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A FEW WEEKS AFTER HAVING THE ESSURE PROCEDURE, I STARTED HAVING STRONG LOWER ABDOMINAL CRAMPING, HEAVY MENSTRUAL BLEEDING, PAINFUL INTERCOURSE, LOWER BACK PAIN, AND OCCASIONAL STABBING PAINS THROUGH MY LOWER ABDOMEN FROM HIP BONE TO HIP BONE AND ALWAYS BELOW THE BELLY BUTTON. A FEW TIMES I FELT A "POPPING" SENSATION BELOW MY BELLY BUTTON WHICH WOULD COME WITH EXCRUCIATING PAIN. I WAS CHECKED FOR STDS, I HAD NUMEROUS XRAYS, MRIS, ULTRASOUNDS, AND CT SCANS BUT NOTHING WAS EVER FOUND. IN (B)(6) 2011 MY DOCTOR DIAGNOSED ME WITH ADENOMYOSIS AND SAID I NEEDED A HYSTERECTOMY. THE PATHOLOGY REPORT SHOWED NO ADENOMYOSIS AND MY DOCTOR ADVISED ME THAT I HAD AN ADVERSE REACTIVE TO THE COILS. SHE EXPLAINED THAT MY FALLOPIAN TUBES AND UTERUS WERE VERY RED, SWOLLEN, AND "ANGRY LOOKING."

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039925	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). EXCESSIVE BLEEDING, SWELLING, PAIN, HEADACHES, MEMORY LOSS, BRAIN FOG, NUMBNESS, MUSCLE FATIGUE, GI ISSUES, LOSS OF LIBIDO, LACK OF ENERGY, ANXIETY, DEPRESSION, MUSCLE SPASMS, NERVES TWITCHING IN FACE, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039926	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEBILITATING JOINT PAIN, SEVERE HAIR LOSS, RAYNAUD'S SYNDROME, FATIGUE, HEAVY MENSTRUAL CYCLE, WEIGHT GAIN, CHEST PAINS, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039927	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 8/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE CRAMPING, EXCESSIVE BLEEDING AND PASSING BLOOD CLOTS, SPOTTING SEVERAL TIMES A MONTH, DIZZINESS, SHORTNESS OF BREATH, JOINT PAIN, MUSCLE PAIN, BONE PAIN, ARTHRITIS IN UPPER SPINE AND CHEST, DEPRESSION, BLOATING IN LOWER ABDOMEN, BREAST SWELLING, BOWEL ISSUES, CHRONIC FATIGUE, TROUBLE BREATHING, STABBING PAIN IN MY LOWER LEFT SIDE OF ABDOMEN AND BACK

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039972	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 4/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER. I HAVE POSSESSION OF MY ESSURE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039973	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 9/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). STARTED 6 MOS AFTER PROCEDURE. ABDOMINAL PAIN RADIATING FRONT TO BACK. WAS OCCASIONAL BUT NOW IT'S A CONSTANT AND WORSENING. PELVIC PAIN TO THE POINT WALKING IS ALMOST IMPOSSIBLE. REOCCURRING SWELLING ON RIGHT SIDE. JOINT/ MUSCLE PAIN. TINGLING NUMBNESS DOWN RIGHT LEG. MANY MIGRAINES STEAMING FROM NECK AND SHOULDER PAIN. MOOD SWINGS AND MEMORY LOSS. VAGINAL DISCHARGE NO ODOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039974	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 1/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ESSURE POKE HOLES IN MY TUBES ESSURE WAS LEAKING FLUID DOWN TO MY GALLBLADDER SO THEY HAD TO REMOVE BOTH TUBES AND GALLBLADDER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039975	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 11/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY, STOMACH ALWAYS HURTS. BAD CRAMPS, LEFT LEG TINGLING, CHEST PAINS, HEART PALPITATIONS, HARD TO BREATH AT TIMES, LOSING HAIR, GAINING WEIGHT, LOW BLOOD PRESSURE, VITAMIN D DEFICIENCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039976	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). FROM THE MOMENT OF INSERTION, I WAS IN UNBEARABLE PAIN WHICH RADIATED INTO MY LEGS, FOLLOWED BY A WEIGHT LOSS OF 40 POUNDS, HEADACHES, BODY ACHES, LOSS OF APPETITE, IRREGULAR PAINFUL PERIODS, SKIN DETERIORATION (DRYNESS, INEXPLICABLE RASHES AND BUMPS, ACNE) AND OTHER SYMPTOMS THROUGHOUT THE BODY THAT WERE EXTREMELY PAINFUL. THE PAIN WORSENED OVER A PERIOD OF 14 MONTHS UNTIL I ULTIMATELY HAD TO HAVE A HYSTERECTOMY ON (B)(6) 2014 WHERE IMMEDIATELY WHEN I CAME TO, ALL THE PAIN WAS GONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039977	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 9/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HAD ESSURE IMPLANTED (B)(6) 2014. HAVEN'T STOPPED CRAMOING AND THEY HAVE BECOME DEBILITATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039979	BAYER	1/6/2015	1/6/2015

Event Information:

Event Date (B3): 5/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5039979 #(B)(4) NEED TO ADD MORE I'M BRUISES. I'M TIRED ALL THE TIME. AND I'M GETTING SICK MORE. AND I'M ALSO GETTING NIGHT SWEATS NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039978	BAYER	1/6/2015	1/7/2015

Event Information:

Event Date (B3): 11/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). MY BABY (B)(6) WAS BORN BY C-SECTION AND THE COILS WERE STICKING OUT OF MY UTERUS. COULD HAVE RUPTURED THE AMNIOTIC SACKS. HAD TO HAVE THEM CUT OUT. MY BABY WAS TONG TIED AT BIRTH AND COULD NOT EAT. AFTER 24 HOURS THEY SURGICALLY CUT HIM SO HE COULD NURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039980	BAYER	1/6/2015	1/7/2015

Event Information:

Event Date (B3): 11/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I HAVE HAD MINOR ISSUES LIKE PELVIC PAIN SEVER BLOATING BUT I AM NOW 4 WEEKS PREGNANT AND I HAVE HAD ESSURE SINCE (B)(6) 2010.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00006	BAYER HEALTHCARE LLC	1/6/2015	1/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PATIENT HAD THE HSG (HYSTEROSALPINGOGRAM) DONE AND THE RIGHT AND LEFT SIDE WERE OCCLUDED AND DISASSEMBLED. LEFT SIDE IS WELL INTO FALLOPIAN TUBE MOST LIKELY BEYOND ISMIC SECTION INTO AMPULLARY PORTION OF THE TUBE. THE DEVICE APPEARS TO BE PARTIALLY DISSEMBLED WITH SPRINGLIKE COMPONENT NOTED MEDIAL TO MAIN BODY OF THE DEVICE. ON THE RIGHT SIDE, THE PROXIMAL END OF THE DEVICE IS FRACTURED OR DISASSOCIATED TO THE BODY. FOLLOW UP INFORMATION RECEIVED ON 16-DEC-2014: PTC (PRODUCT TECHNICAL COMPLAINT) PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NOT ENOUGH INFORMATION TO DETERMINE OR CONFIRM IF THERE WAS ANY DEVICE BREAKAGE IN THIS CASE. NO FURTHER INFORMATION COULD BE OBTAINED FROM THE RADIOLOGIST. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT HYSTEROSALPINGOGRAM (HSG) THE LEFT DEVICE APPEARED TO BE PARTIALLY DISASSEMBLED WITH SPRINGLIKE COMPONENT NOTED MEDIAL TO MAIN BODY OF THE DEVICE AND RIGHT SIDE PROXIMAL END OF THE DEVICE IS FRACTURED OR DISSOCIATED TO THE BODY. THE REPORTED EVENT, INTERPRETED AS SUSPICION OF DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING HSG EVALUATION, ESSURE PROXIMAL MARKERS MAY MOVE OR SEEM STRETCHED BECAUSE OF THE FLEXIBILITY OF THE OUTER COIL; THIS CAN LEAD TO HSG RESULTS MISINTERPRETATION. IN THIS PARTICULAR CASE, THERE WAS NOT ENOUGH INFORMATION TO DETERMINE OR CONFIRM A DEVICE BREAKAGE. NEVERTHELESS, UNTIL FURTHER DATA IS OBTAINED AND GIVEN THE REPORTED EVENT'S NATURE COMPANY CONSIDERS A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED AND REGARDS THIS CASE AS OTHER REPORTABLE INCIDENT DUE TO SUSPICION OF DEVICE MALFUNCTION (DEVICE BREAKAGE). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-APR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT H

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039981	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 9/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DATE OF IMPLANTATION I EXPERIENCED SEVERE PAIN THAT NEVER WENT AWAY. HEAVY BLEEDING FOR TWO YEARS. ALLERGIC REACTION TO COILS. HAIR LOSS. WEIGHT GAIN. PELVIC PAIN. PAINFUL PERIODS. PAINFUL SEX. LOSS OF SEX DRIVE. CONSTANT METAL TASTE IN MY MOUTH. I HAVE A BICORNATE UTERUS WITH SEPTUM AND NEVER SHOULD HAVE BEEN IMPLANTED TO BEGIN WITH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039982	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 9/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESS BLEEDING (NEEDED OBLATION), MIGRAINES, BACK PAIN, UNEXPLAINED WEIGHT GAIN, CYSTIC ACNE, NAUSEA/FATIGUE, BLOATING, WEIRD TINGLING IN SEVERAL AREAS, ABDOMEN PAIN/SEVERE CRAMPING WITH PERIODS, DEPRESSION, IRRITABILITY, INSOMNIA (AT FIRST) ALWAYS TOO TIRED TO GET OUTTA BED NOW, VERY HAZY/MEMORY LOSS, CONSTANT UTI'S/BLADDER ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039983	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 3/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD LOWER BACK PAIN ABDOMINAL PAIN HAIR LOSS INSOMNIA GAINING WEIGHT NIGHT SWEATS TINGLING IN MY LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039984	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 9/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM ALLERGIC TO NICKLE I TOLD MY DR THIS AND HE DIDN'T LISTEN. I DIDN'T WANT THE ESSURE. I HAVE CHRONIC PELVIC PAIN, LOSS OF HAIR, JOINT PAIN,HEADACHES, MOOD SWINGS, DEPRESSION, EXTREME FATIGUE, MUSCLE SPASMS, NAUSEA, BACK PAIN, BLOATING, NO ENERGY, NO SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039985	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I FELT AS IF I WAS HAVING CONTRACTIONS, I WOULD GET VERY SHARP PAINS IN MY LEFT AND RIGHT SIDE IN MY ABDOMEN. I BROKE OUT INTO A RASH ON MY ABDOMEN. WENT INTO THE HOSPITAL SEVERAL TIMES AND TO THE ER WITH EXTREME PAIN NAUSEA DIARRHEA HEADACHE, VERTIGO, I PASSED OUT SEVERAL TIMES. HAIR FALLING OUT, I HAVE FREQUENT MIGRAINES. VIBRATING IN PELVIC AREA, ACNE ON FACE BACK AND CHEST, WEIGHT GAIN, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039986	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 1/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CONSTANT CRAMPING, HEADACHES, WEIGHT GAIN, BLOATING, SPOTTING, PAIN WITH INTERCOURSE, OVARIAN CYSTS, ENDOMETRIOSIS, ACNE, NIGHT SWEATS, RESTLESS LEGS, EXTREME FATIGUE, TEMPER, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039987	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 7/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ABOUT 2-3 MONTHS AFTER MY PROCEDURE, I STARTED HAVING REALLY PAINFUL CRAMPS, BODY ACHES, MUSCLE PAIN, SHARP PAIN IN MY LEGS AND SHOULDERS AND NECK, AND HIPS. MY SKIN STARTED GETTING WELTS ALL OVER AT THE SMALLEST TOUCH, INCLUDING MY FACE. I HAVE A SERIOUS NICKEL ALLERGY AND DIDN'T FIND OUT UNTIL YEARS LATER THAT THE PRESSURE HAD NICKEL IN IT. A YEAR AFTER HAVING THE PROCEDURE I WAS DIAGNOSED WITH FIBROMYALGIA AFTER COUNTLESS TESTS AND BLOOD WORK AND EXAMS. THIS WAS DONE IN (B)(6) OF 2008. I RECENTLY HAD A TOTAL ABDOMINAL HYSTERECTOMY DUE TO FIBROIDS, AN OVERLY ENLARGED UTERUS, EXCESS BLEEDING DURING AND BETWEEN PERIODS, PAINFUL INTERCOURSE. MY CURRENT GYNECOLOGIST SAYS I WAS NEVER A CANDIDATE FOR PRESSURE DUE TO MY PREVIOUS PROBLEMS DURING MY LAST PREGNANCY. AND THAT THE DOCTOR WHO DID IT SHOULD NOT HAVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039988	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 5/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MAJOR WEIGHT LOSS OR 40 POUNDS OR MORE IN JUST THREE MONTHS AFTER I GOT ESSURE. DEVELOPED AN ALLERGIC REACTION TO NICKEL. RASHES AND BUMPS ALL OVER MY STOMACH, LEGS AND ARMS. VERY ITCHY SKIN. (B)(6) 2014, MY BELLY STARTED TO SWELL AND I QUICKLY PUT ON 50 PLUS POUNDS OVER THE NEXT 4 MONTHS WITH CONTINUED RASHES FROM THE NICKEL. (B)(6) 2014, I DEVELOPED OVARIAN AND FIBROID CYSTS ON MY UTERUS. THIS CAUSED SEVERE PAIN, MORE BLOATING AND VERY LONG, HEAVY PERIODS THAT CAME EVERY 18 DAYS VS, 28 DAYS. (B)(6) 2010, I HAD TO HAVE A FULL HYSTERECTOMY LOSING MY CERVIX, UTERUS, AND TUBES BECAUSE OF THE CONTINUED CYSTS AND PAIN THE DEVICE WAS CAUSING IN MY TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039989	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN PELVIC AREA, THAT TURNED OUT TO BE RIGHT COIL COMING THROUGH MY RIGHT FALLOPIAN TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039990	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 2/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CONSTANT HEAVY BLEEDING, MIGRAINES, ITCHY SKIN WITH RASH FROM WAIST DOWN, BLURRED VISION, DIZZINESS AND NAUSEATED, EXTREME LOWER BACK AND PELVIC PAIN AND MOMENTS OF IMMOBILITY IN HIPS AND LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039991	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). APPROXIMATELY A MONTH AFTER THE TEST CONFIRMING MY TUBES WERE SEALED I BEGAN GAINING WEIGHT (30 LBS), HAVING SEVERE ACNE AND HAIR LOSS. AT THE END OF (B)(6) I GOT MY PERIOD, IT LASTED FOR 4 WEEKS AND WAS VERY HEAVY. AROUND (B)(6) DEBILITATING HEADACHES THAT LAST FOR 4-7 DAYS BEGAN. MY PERIOD AGAIN WAS PROLONGED (6 WEEKS THIS TIME) AND AGAIN VERY HEAVY. I WAS GOING THROUGH A TAMPON/PAD EVERY 2 HOURS. I'VE DEVELOPED FORGETFULNESS, BACK PAIN AND SPASMS IN MY STOMACH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039992	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE ITCHING, MIGRAINES CONSISTENT CRAMPING, BLOATING, BLEEDING AFTER SEX, SEVERE MENSTRUAL CYCLES, SEVERE BLEEDING, BACK ACHES, MOOD SWINGS, PAINFUL INTERCOURSE, LOSS OF ENERGY, DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039993	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 11/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ESSURE COIL EXPELLED FROM BODY, HAD PELVIC AND ABDOMINAL PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039994	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 7/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHE FOR THE PAST 6 YEARS HEAVY PERIOD STOMACH AND SIDE PAINS DURNING AND AFTER SEX WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039995	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 9/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP STABBING PAIN IN MY CLITORAL AREA...IT BECAME SO SWOLLEN THAT I COULDN'T EVEN TOUCH THE AREA. IT HURT TO WIPE, SIT DOWN OR WHEN MY UNDIES OR PANTS WOULD RUB ON THAT AREA. I WENT TO THE ER AND THEY PUT ME ON ANTIBIOTICS. NOW I AM HAVING SHARP PAINS IN MY LOWER LEFT ABDOMEN AREA. IT HURTS EVEN WORSE WHEN I MOVE AROUND.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039996	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 9/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING IN UTERINE AREA DAILY, MENSTRUAL CYCLE AND SEVERITY CHANGES, HEADACHES DURING MENSTRUATING, EXTREME MOOD SWINGS AND OTHER PMS SYMPTOMS THAT ARE NEW SINCE MY ESSURE INSERTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039997	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING ISSUES AFTER HAVING ESSURE REMOVED REQUIRED A HYSTERECTOMY. POWER MORCELLATION WAS USED AND I WAS DIAGNOSED WITH HODGKIN'S LYMPHOMA AFTER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039998	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TOTAL HYSTERECTOMY SCHEDULED FOR (B)(6) 2015 DUE TO ONGOING ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5039999	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 8/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). "PANDEACUTE;LVIC" PAIN, INFLAMATION, BACK PAIN, HAIR LOSS, BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040000	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I DON'T KNOW HOW TO CHANGE THE DATE BACK FURTHER. BUT I GET VERY SHARP STABBING PAINS HEAVY FLOWS WHEN I HAVE A PERIOD SOMETIMES ITS MONTHLY SOMETIMES ITS 3 OR 4 MONTHS. I JUST CAN'T GET OVER THE PAIN. I'M MAKING AN APPOINTMENT WITH A DOCTOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040001	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I DON'T KNOW HOW TO CHANGE THE DATE BACK FURTHER. BUT I GET VERY SHARP STABBING PAINS HEAVY FLOWS WHEN I HAVE A PERIOD SOMETIMES ITS MONTHLY SOMETIMES ITS 3 OR 4 MONTHS. I JUST CAN'T GET OVER THE PAIN. I'M MAKING AN APPOINTMENT WITH A DOCTOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040002	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 11/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I GOT THE ESSURE (B)(6). SINCE I'VE HAD IT I'VE EXPERIENCED EXTREME PAIN ON BOTH SIDES FRONT AND BACK. IT IS ESPECIALLY PAINFUL DURING MY PERIOD AND WHEN I'M OVULATING. IT IS SO PAINFUL IT HURTS TO MOVE. I'VE BEEN TO THE EMERGENCY ROOM AND THEY JUST SEND ME HOME WITH PAIN MEDICATION AND MUSCLE RELAXERS WHICH BARELY HELP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040003	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 6/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HEADACHES, PELVIC PAIN, HAIR LOSS, BLOATING, TOOTH DECAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040004	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5040004 #(B)(4). AS OF (B)(6) 2015 I AM ESSURE FREE BUT NOT WITHOUT COMPLICATIONS. THE COILS WERE EMBEDDED IN MY UTERUS AND TWO SOFTBALL SIZE FIBROIDS WERE ALSO REMOVED. PLEASE TAKE THIS DEVICE OFF OF THE SHELVES SO THAT NO ONE ELSE WILL EVER HAVE TO DEAL WITH THE THINGS THAT MYSELF ALONG WITH OTHERS WILL HAVE TO ENDURE. THANK YOU.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040005	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SINCE I HAVE HAD ESSURE I HAVE HAD SEVERE CRAMPS, STOMACH PAINS, HEADACHES, DEPRESSION, MOOD SWING, MISSED PERIODS, PASSING CLOTS, WEIGHT GAIN, LOW SEX DRIVE, EXTREME ABDOMINAL PAINS, CANT EAT, TIRED ALL THE TIME, NO ENERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040006	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 12/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SINCE I GOT ESSURE I HAVE HAD SEVERE PAIN , IRREGULAR PERIODS, SEVERAL A MONTH, WEIGHT GAIN AND THE PAIN IS SO BAD WILL TAKE YOU TO YOUR KNEES. I WISH I WOULD NOT HAVE LET MY DOCTOR TALK ME INTO GETTING THIS DONE BUT HE TALK SO HIGHLY AND HOW WONDERFUL IT WAS. ITS A JOKE .....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040007	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 9/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN FROM DEVICE, IRREGULAR PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040008	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 9/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CRAMPING SHARP/STABBING, PELVIC PAIN, ABNORMAL MENSES, CONSTANT SPOTTING, DISCHARGE ODOR/NO ODOR, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS, PAINFUL INTERCOURSE, BLEEDING BETWEEN PERIODS, INCONTINENCE, LONG MENSTRUAL CYCLES, INCONTINENCE, URGENT/FREQUENT URINATION, ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE. BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP PAIN. CHRONIC PELVIC PAIN ALL OVER BODY ACHES/PAIN, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEADACHES OR MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN SHOCKS, NERVE PAIN, BRAIN FOG CLOUDINESS, FORGETFULNESS. ANXIETY/PANIC ATTACKS, MOOD SWINGS, STROKE SYMPTOMS, DEPRESSION, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS). NUMBNESS IN THIGH, NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET). SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN. NERVE PAIN, TREMORS/SHAKINESS, DIZZINESS, UNEXPLAINED/EASILY BRUISING. RHEUMATOID ARTHRITIS, FIBROMYALGIA,CHRONIC FATIGUE SYNDROME, RAYNAUD'S SYNDROME. CYSTS, BOILS, ACNE. HEART PALPITATIONS, SWELLING OF LEGS OR FEET. DENTAL ISSUES TEETH CRACKING/BREAKING FILLINGS FALLING OUT, TEETH SENSITIVITY, GUM SENSITIVITY WEIGHT GAIN OF 50+LBS INABILITY TO LOSE. MUSCLE SPASMS, VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040009	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PROCEDURE DONE IN JUNE OF 2012. I LIVE IN (B)(6), AND A WELL REFERRED OB PERFORMED THE PROCEDURE. I STARTED FEELING HORRIBLE, FOR A LACK OF BETTER WORDS, ABOUT A YEAR LATER. MY SYMPTOMS INCLUDE, WEIGHT LOSS (20 LBS), VAGINAL BLEEDING, ANAL BLEEDING, JOINT AND MUSCLE PAINS, LOWER PELVIC PAIN, LOWER BACK PAIN, HEADACHES, DEPRESSION, POOR COLORING, LOSS OF HAIR, AND PROBABLY THE WORST PART OF ALL IS THAT I AM TIRED ALL THE TIME. I HAVE ALWAYS BEEN A "SPASTIC" PERSON, WITH LOTS OF ENERGY, AND THESE COILS INSIDE MY BODY HAVE ME BED RIDDEN! I DON'T HAVE INSURANCE ANYMORE, AND I CAN'T AFFORD THE (B)(6) OFFICE VISIT JUST TO SEE THE DOCTOR. I HAVE BEEN TO THE ER TWICE FOR THE PAINS IN MY LOWER PELVIC AREA, AND FOR THE BLEEDING AS WELL. NOTHING! BLOOD WORK COMES BACK NORMAL, AND THEY SEND ME HOME. I HAVE FELT ALONE FOR SO LONG UNTIL READING THE THOUSANDS OF OTHER WOMEN'S COMPLAINTS ABOUT ESSURE AS WELL. THIS PRODUCT IS A NIGHTMARE FOR US WOMEN! NOW I UNDERSTAND THAT I'M SUPPOSED TO PAY OUT OF POCKET FOR THE REMOVAL OF THIS DEVICE? UNACCEPTABLE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040010	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 3/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). START HAVING SEVERE LOWER BACK PAIN AND FATIGUE HAS START TO SET IN A DISCOMFORT IN MY STOMACH LIKE A POKING OR A STABBING LIKE PAIN. MY VAGINA STARTED TO ITCH AND IT WAS NOT A YEAST INFECTION OR A STD WENT TO DR FOR THAT. MY VISION IS STARTING TO GO BLURRED AT TIMES AND I HAVE 20/20 VISION. AND PAIN IN MY HAND NERVES STARTING TO AFFECT ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040011	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 8/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). STOMACH PAIN, HAIR LOSS, HEAVY PERIODS, SEVERE MIGRAINES, LIBIDO LOSS, SEVERE BACK PAIN, WEIGHT GAIN, DIZZINESS, BLACKOUT SPELLS...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040012	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 12/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPS, HEADACHE, NAUSEA, JOINT PAIN, PELVIC PAIN, PELVIC PRESSURE, LIGHTHEADED, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040013	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 5/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE BLEEDING AFTER THE PROCEDURE, PCOS LIKE SYMPTOMS, AUTO IMMUNE LIKE SYMPTOMS, HANDS AND FEET NUMB ANDAMP; TINGLY AND TURN BLUE, EXTREME OVERWHELMING EXHAUSTION, PAINFUL SEX, COIL EMBEDDED IN UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040014	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 12/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ESSURE PROCEDURE WAS (B)(6) 2009; I RECALL SORE BELLY APPROXIMATE 2-3 WEEKS AFTERWARDS AND ONGOING. PERIODS STARTED BEING VERY HEAVY WITH CLOTTING AND PROGRESSED AS YEARS HAVE PASSED. I WILL HAVE 2 CYCLES PER MONTH ALONG WITH SEVERE FATIGUE, CONSISTENT HEADACHES (AT LEAST 5 DAYS A WEEK), ALSO DIAGNOSED MIGRAINES AND VERTIGO (HAD NOT EXPERIENCED THESE SYMTOMS PRIOR TO ESSURE). OVER THE LAST 2 YEARS, THINGS HAVE BECOME SO BAD THAT I HAVE BECOME SEVERELY EMOTIONAL DUE TO NOT BEING ABLE TO BE ACTIVE DUE TO FATIGUE, ACHY BONES/JOINTS, BRAIN FOG, DIZZINESS (ASSOCIATED WITH HEADACHES) AND BLOATED BELLY (APPEARING TO BE 6+ MONTHS PREGNANT).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040015	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 9/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHANGE IN PERIODS, LONG PERIODS LASTING UP TO 2 AND A HALF WEEKS, CRAMPING ON AND OFF THROUGH THE MONTH, HAIR LOSS, JOINT PAIN IN LEFT HIP, TROUBLE HEALING FROM ILLNESS AND WOUNDS, THIS ALL RESULTED IN A HYSTERECTOMY TO GET ESSURE OUT. HYSTERECTOMY WAS DONE (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040016	BAYER	1/7/2015	1/7/2015

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY HEAVY MENSTRUAL CYCLES THAT DIDN'T OCCUR UNTIL AFTER PLACEMENT. TEARING TYPE PAINS IN RIGHT AND LEFT QUADRANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040017	BAYER	1/7/2015	1/8/2015

Event Information:

Event Date (B3): 2/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOUND OUT I WAS PREGNANT 1 YEAR AND 6 MONTHS AFTER COILS WERE PLACED. HAD A NORMAL PREGNANCY. DELIVERED (B)(6) 2010. HAD MY TUBES CUT, TIED, AND BURNED (B)(6) 2010. NOTHING WAS REMOVED AT TIME OF TUBAL. HAVE EXPERIENCED DEBILITATING JOINT PAIN WHICH STARTED IN MY KNEES AND HAS MOVED TO MY HIPS AND ELBOWS. AT TIMES I CAN BARLEY WALK DUE TO THE FACT THAT IT FEELS AS THOUGH MY HIPS ARE GOING TO PULL OUT OF SOCKET. ELBOWS PREVENT ME FROM LIFTING ANYTHING AT TIMES. I EXPERIENCE HAIR LOSS, HEADACHES ON A DAILY, TOOTH DECAY, BLOATING, HEARTBURN NIGHTLY, FATIGUE, LOW SEX DRIVE, STABBING ABDOMINAL PAIN WHEN I COUGH OR DEFECATE, LOWER BACK PAIN, AND EDEMA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040018	BAYER	1/7/2015	1/8/2015

Event Information:

Event Date (B3): 12/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERFECTLY HEALTH BEFORE ESSURE. HOT/COLD FLASHES ON LEGS. BELCHIN, INFLAMMATION , ABDOMINAL PAIN, MUSCLE PAIN, PELVIC PAIN, MIGRANES. AXIS REFLUX, SHORTNESS OF BREATH AND CHEST PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040167		1/7/2015	1/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/2/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ALMOST A YEAR AGO. FOR THE FIRST MONTH AND A HALF, I BLED. WENT AND DID MY CONFIRMATION TEST, WHICH DURING THE PROCEDURE I PASSED OUT. THE TEST CAME BACK CONFIRMED (MY TUBES WAS BLOCKED). I'VE NOTICE SINCE MY ESSURE WAS DONE. I'VE HAD MANY SIDE EFFECTS. WEIGHT GAIN THAT I CAN'T LOSE, HEART PALPITATIONS, ANXIETY, BREAK OUTS OF PIMPLES, FACIAL HAIR GROWTH, HEADACHE, AND THE WORSE-CRAMPING. MY CRAMPING ALMOST FEELS LIKE MY INSIDES ARE FALLING OUT. NO OTC MEDS WILL HELP WITH THE PAIN. I JUST WANT TO SIT MY CRY. I FEEL AS THOUGH MY COILS ARE RIPPING THROUGH MY ENTIRE BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040176	BAYER	1/7/2015	1/14/2015

Event Information:

Event Date (B3): 4/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/29/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2014. SINCE THAT TIME I HAD ISSUES WITH MY MONTHLY CYCLE. IN AUGUST, I HAD A SERIOUS BOUT OF FATIGUE AND UNEXPLAINED WEIGHT LOSS WHICH LED TO EXTENSIVE BLOODWORK THAT REVEALED NOTHING. IN JANUARY, AFTER OTHER MEDICAL COMPLICATIONS I HAVE BEEN DIAGNOSED WITH HYPOTHYROIDISM AND NOW AM ON SYNTHETIC HORMONES FOR THE REST OF MY LIFE. ONE OF THE MOST COMMON CAUSES OF HYPOTHYROIDISM IS AN AUTO-IMMUNE DISORDER. ESSURE SET THE IMMUNE SYSTEM ON OVERDRIVE SO MY IMMUNE SYSTEM HAS ATTACKED MY OWN THYROID.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040083	BAYER	1/7/2015	1/21/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2011, PT HAD ESSURE IMPLANTED. PT STATES AT FIRST SHE WAS FEELING FINE, THEN A FEW MONTHS LATER, DEVELOPED SEVERE PELVIC PAIN. PT. STATES AT TIMES THE PAIN WOULD BE SO BAD SHE WOULD BE "DOUBLED OVER" AND THAT THE PAIN NOW IS "20 TIMES WORSE". ON (B)(6) 2014, PT HAD AN X-RAY, ULTRASOUND AND BLOOD WORK DONE. PT STATES THAT THE DOCTOR TOLD HER THAT THE ESSURE IMPLANT "EXPLODED IN HER TUBES" AND THAT THERE WERE "METAL FRAGMENTS" EVERYWHERE INSIDE HER TUBES. PT'S DOCTOR RECOMMENDS SHE GET A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00010	BAYER HEALTHCARE LLC	1/7/2015	1/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C03097

Single Use: Y
Implant Date (E6): 12/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER C03097. IT WAS REPORTED THAT DEVICE FELL APART WHEN INSERTING. NO INJURY TO THE PATIENT. BILATERAL PLACEMENT ACHIEVED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE FELL APART WHEN INSERTING. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE AND COMPLICATION OF DEVICE INSERTION, IS NON-SERIOUS. DEVICE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE COMPLICATION OF DEVICE INSERTION IS LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW UP INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW UP 13.JAN.2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00011	BAYER HEALTHCARE LLC	1/7/2015	1/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51340

Single Use: Y
Implant Date (E6): 11/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (LOT NUMBER C51340). PHYSICIAN REPORTED THAT IMPLANT BROKE IN CONTACT WITH THE TUBE. THE ANOMALY WAS OBSERVED IN THE OPERATING ROOM DURING THE PLACEMENT. THERE WAS NO ANATOMICAL CAUSE TO EXPLAIN THE ANOMALY. THE ANOMALY CONCERNED THE IMPLANT ITSELF. THE IMPLANT WAS AFTERWARDS UNUSABLE. BILATERAL PLACEMENT WAS PERFORMED WITH THE OTHER DEVICE. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMPLANT BROKE IN CONTACT WITH THE TUBE (DURING PLACEMENT). BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER DEVICE. THIS EVENT, INTERPRETED AS A DEVICE BREAKAGE AND COMPLICATION OF DEVICE INSERTION, IS NON-SERIOUS. DEVICE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE COMPLICATION OF DEVICE INSERTION IS LISTED. DURING DIFFICULT INSERTION AND REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE BREAKAGE OCCURRED DURING THE INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE REPORTED EVENT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW UP INFORMATION ARE EXPECTED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RE-FOLLOW UP 14.JAN.2015: PTC INVESTIGATION RESULTS WERE PROVIDED. BATCH NUMBER (B)(4) (PRODUCTION DATE 01-MAY-2014; EXPIRATION DATE 31-MAY-2017). (B)(4) FINAL ASSESSMENT: FAILURE MODE / MECHANISM. THE ESSURE INSERT IS MADE UP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00013	BAYER HEALTHCARE LLC	1/8/2015	1/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/27/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE IS A CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY IN THE UNITED STATES, ON BEHALF OF A PLAINTIFF/CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(4) 2004 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. ON OR ABOUT (B)(6) 2012 PLAINTIFF WENT TO THE IMPLANTING PHYSICIAN TO HAVE ESSURE IMPLANTED IN HER FALLOPIAN TUBES. AFTER BEING IMPLANTED WITH ESSURE, PLAINTIFF BEGAN TO SUFFER FROM INJURIES INCLUDING FATIGUE, INSOMNIA, PELVIC PAIN, NAUSEA, DIMINISHED BRAIN FUNCTIONS, NUMBNESS IN LIMBS, HEADACHES, AND VISION ISSUES. ON OR ABOUT (B)(6) 2013, PLAINTIFF DELIVERED A CHILD. THE CHILD NOW SUFFERS FROM BIRTH DEFECTS INCLUDING ARTERIAL DEFECTS. PLAINTIFF HAD THE ESSURE DEVICE MIGRATED FROM HER FALLOPIAN TUBES TO HER UTERUS/RECTUM RESULTING IN A PREGNANCY (THE CHILD WAS BORN WITH DEFECTS INCLUDING ARTERIAL DEFECTS) AND REQUIRING A HOSPITALIZATION AND PARTIAL HYSTERECTOMY. CURRENTLY, PLAINTIFF IS LEFT WITH ONE COIL, BROKEN INTO TWO PIECES, IN HER UTERUS. ON OR ABOUT (B)(6) 2013, PLAINTIFF HAD TO HAVE A SALPINGECTOMY, THE SURGICAL REMOVAL OF HER FALLOPIAN TUBES DUE TO ESSURE. ONLY ONE ESSURE COIL WAS LOCATED. THE REMAINING COIL REMAINS IN HER UTERUS, BROKEN IN TWO PIECES. PLAINTIFF IS IN NEED OF A COMPLETE HYSTERECTOMY. PLAINTIFF HAD TO UNDERGO NUMEROUS SURGICAL PROCEDURES, DIAGNOSTIC PROCEDURES, AND MAY HAVE TO UNDERGO SURGERIES, DIAGNOSTIC TESTING, TREATMENT AND REHABILITATION IN THE INDEFINITE FUTURE. PLAINTIFF SUSTAINED SIGNIFICANT PAIN AND SUFFERING, BOTH PHYSICAL AND MENTAL, AND WILL CONTINUE TO DO SO INTO THE INDEFINITE FUTURE. PLAINTIFF NOW ALSO SUFFERS FROM AUTO IMMUNE AND ADHESION DISORDERS. NO ADDITIONAL INFORMATION WAS PROVIDED. THERE IS A LINKED CASE FOR THE CHILD WITH REFERENCE NUMBERS (B)(4). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN

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INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PREGNANCY IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2014: UPDATED PTC RESULT. FINAL ASSESSMENT: FOLLOW-UP CASE OPENED SINCE TO PROVIDE UPDATED ASSESSMENT SINCE MULTIPLE ADVERSE EVENTS WERE LISTED IN THIS CASE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PREGNANCY, DEVICE DISLOCATION, DEVICE BREAKAGE, DEVICE MIGRATION WERE IDENTIFIED AS ANTICIPATED EVENTS DURING THE DESIGN PROCESS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. ADDITIONALLY A PRODUCT QUALITY ISSUE WAS REPORTED (COIL REMAINS IN HER UTERUS, BROKEN IN TWO PIECES). THE REPORTED BREAKAGE COULD NOT BE INVESTIGATED IN MORE DETAIL DUE TO LACK OF COMPLAINT SAMPLE RETURN. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A LAWYER/ATTORNEY AND REFERS TO A PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE DEVICE MIGRATED FROM FALLOPIAN TUBES TO HER UTERUS/RECTUM, SHE WAS SUBMITTED TO A SALPINGECTOMY, ONE COIL WAS LOCATED AND THE REMAINING COIL REMAINED IN HER UTERUS AND BROKEN IN TWO PIECES. ADDITIONALLY A PREGNANCY AND AUTO IMMUNE DISORDERS WERE REPORTED. PREGNANCY WAS CONSIDERED NON-SERIOUS, WHILE THE REMAINING EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND HOSPITALIZATION (ESSURE MIGRATION). ALL EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION AND ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC) RESULTS, EXCEPT FOR AUTO IMMUNE DISORDERS WHICH IS UNLISTED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND THE MECHANISM OF THE REPORTED DEVICE MIGRATION AND BREAKAGE ARE NOT KNOWN; GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING PREGNANCY, THE PLAINTIFF STATED IT RESULTED FROM ESSURE MIGRATION TO UTERUS/RECTUM; NEVERTHELESS SINCE IT IS UNCLEAR FROM THE AVAILABLE INFORMATION IF THIS DEVICE MIGRATION WAS DIAGNOSED BEFORE OR AFTER PREGNANCY ONSET ESSURE CONTRACEPTIVE FAILURE CANNOT BE TOTALLY EXCLUDED. FOR THE EVENT AUTO IMMUNE

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DISORDERS, A CONTRIBUTORY ROLE OF ESSURE IS UNLIKELY GIVEN ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED HOSPITALIZATION AND INTERVENTION (SALPINGECTOMY). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ADDITIONAL INFORMATION WILL BE OBTAINED THROUGH THE NORMAL LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00014	BAYER HEALTHCARE LLC	1/8/2015	1/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2012
Explant Date (E7): 4/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY IN THE UNITED STATES, ON BEHALF OF A FEMALE PLAINTIFF/CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED IN (B)(6) 2012. AFTER BEING IMPLANTED WITH ESSURE, SHE BEGAN TO SUFFER FROM SEVERE PELVIC PAIN, NIGHT SWEATS, NUMBNESS, TINGLING AND WEIGHT GAIN. SHE ALSO SUSTAINED SIGNIFICANT PAIN, PHYSICAL AND MENTAL PAIN. IT WAS REPORTED THAT THE ESSURE DEVICE MIGRATED FROM FALLOPIAN TUBES TO HER UTERUS/RECTUM, REQUIRING FIVE HOSPITALIZATIONS AND A HYSTERECTOMY ON (B)(6) 2014. SHE WAS ALSO EXPERIENCING AUTO IMMUNE DISORDERS AND ADHESION DISORDERS. IT WAS REPORTED THAT THE DEFECTIVE CONDITION OF ESSURE WAS THE FACTUAL CAUSE OF PLAINTIFF'S HYSTERECTOMY AND PREGNANCY. NO FURTHER INFORMATION WAS PROVIDED. CORRECTION ((B)(6) 2014) FOLLOWING COMPANY INTERNAL REVIEW: THE EVENT AUTO IMMUNE DISORDERS WAS UPGRADED. FOLLOW UP (B)(6) .2014: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: PREGNANCY IS THE CONDITION OF CARRYING DEVELOPING OFFSPRING WITHIN THE BODY. THE TIME PERIOD DURING WHICH THIS CONDITION EXISTS, GESTATION.
PROBABLE CAUSES FOR PREGNANCY INCLUDE: 1) UNSUCCESSFUL BILATERAL TUBAL OCCLUSION (COMPLETE TISSUE INGROWTH), EXPULSION (RELATED TO MICRO-INSERT PLACEMENT ACCURACY), NO 3-MONTH CONFIRMATION TEST (HSG) OR MIS-READ OF HSG, LACK OF PATIENT COMPLIANCE TO IFU (I.E. USE OF ALTERNATE CONTRACEPTION UNTIL CONFIRMATION OF BILATERAL OCCLUSION). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID

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LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT REFERS TO A FEMALE PLANTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE ESSURE DEVICES MIGRATED FROM FALLOPIAN TUBES TO HER UTERUS / RECTUM AND PREGNANCY OCCURRED. SHE EXPERIENCED AUTO IMMUNE DISORDERS. THE FIRST EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE HOSPITALIZATION WHILE PREGNANCY IS NON-SERIOUS. BOTH ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AUTO IMMUNE DISORDERS IS SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, IT WAS STATED THAT THE DEFECTIVE CONDITION OF ESSURE WAS THE FACTUAL CAUSE OF PLANTIFF'S HYSTERECTOMY AND PREGNANCY. IT IS NOT KNOWN IF THE CONCEPTION OCCURRED BEFORE OR AFTER THE DISLOCATION, SO THE DEVICE INEFFICACY CANNOT BE EXCLUDED. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION OR DISLOCATION. IN THIS CASE, IT WAS FOUND OUT THAT THE DEVICE MIGRATED TO HER UTERUS / RECTUM, WHICH RESULTED IN HOSPITALIZATION AND HYSTERECTOMY. THE SURGERY WAS PERFORMED TWO YEARS AFTER INSERTION. GIVEN THE NATURE OF THE DISLOCATION, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE AND SINCE HYSTERECTOMY WAS REQUIRED, THE CASE IS REGARDED AS INCIDENT. FOR THE EVENT AUTO IMMUNE DISORDERS, A CONTRIBUTORY ROLE OF ESSURE IS UNLIKELY GIVEN ITS LOCAL ACTION AT FALLOPIAN TUBES, THUS CAUSALITY CAN BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 13-JUL-2015. COMPANY CAUSALITY COMMENT: THIS CASE REPORT REFERS TO A FEMALE PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE ESSURE DEVICES MIGRATED FROM FALLOPIAN TUBES TO HER UTERUS / RECTUM AND PREGN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00015	BAYER HEALTHCARE LLC	1/8/2015	1/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/19/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY IN THE UNITED STATES, ON BEHALF OF A PLAINTIFF/ CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 10-DEC-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED THE RIGHT COIL ON (B)(6)-2010 AND THE LEFT COIL WAS INSERTED ON (B)(6)-2010 BECAUSE THE DOCTOR DID NOT HAVE THE PROPER HYSTEROSCOPE TO PLACE THE DEVICE DURING THE FIRST VISIT. AFTER BEING IMPLANTED WITH ESSURE, PLAINTIFF BEGAN TO SUFFER FROM BLADDER INFECTIONS, SEVERE PELVIC PAIN, AND SEVERE BLEEDING WHICH RENDERED HER INCAPABLE OF FUNCTIONING. ON (B)(6)-2014 SHE UNDERWENT A HYSTERECTOMY BECAUSE OF THE BLADDER INFECTIONS, SEVERE PELVIC PAIN AND SEVERE BLEEDING. SHE SUSTAINED SIGNIFICANT PAIN AND SUFFERING, BOTH PHYSICAL AND MENTAL, AND ALSO UNSPECIFIED INJURIES, SERIOUS INJURIES, SEVERE INJURIES, OR PERMANENT INJURIES. SPECIFICALLY, THE ESSURE DEVICE MIGRATED FROM CONSUMER'S FALLOPIAN TUBES TO HER UTERUS/RECTUM, REQUIRING HOSPITALIZATIONS AND AN EVENTUAL HYSTERECTOMY. THE DEFECTIVE CONDITION OF ESSURE WAS THE FACTUAL CAUSE OF CONSUMER'S HYSTERECTOMY AND PREGNANCY. THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE WAS CONSIDERED RELATED BY REPORTER. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4)-2014: FINAL ASSESSMENT: A PERFORATION IS A HOLE OR OPENING MADE THROUGH THE ENTIRE THICKNESS OF A MEMBRANE OR OTHER TISSUE OR MATERIAL. PROBABLE CAUSES FOR PERFORATION : 1) PHYSICIAN ENCOUNTERS POOR VISIBILITY DURING THE PROCEDURE, 2) PHYSICIAN TECHNIQUE AND EXPERIENCE, 3) ADVANCING DELIVERY CATHETER WHEN PATIENT IS EXPERIENCING EXTRAORDINARY PAIN OR DISCOMFORT, 4) ATTEMPTING TO ADVANCE DELIVERY CATHETER TO BLACK POSITIONING MARKER AFTER ENCOUNTERING UNDUE RESISTANCE, 5) FURTHER ADVANCING DELIVERY CATHETER ONCE THE BLACK POSITIONING MARKER HAS REACHED THE TUBAL

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OSTIUM, 6) ATTEMPTED REMOVAL OF AN IMPLANTED MICRO-INSERT WITH FEWER THAN 18 TRAILING COILS INTO THE UTERUS, 7) INACCURATE PLACEMENT OF THE MICRO-INSERT IN THE FALLOPIAN TUBE BY THE PHYSICIAN. ACCORDING TO THE PRODUCT INSTRUCTIONS FOR USE, THE MICRO-INSERT MUST BE PLACED FAR ENOUGH INTO THE FALLOPIAN TUBE TO PREVENT EXPULSION (LESS THAN 18 TRAILING COILS). PERFORATIONS ARE A KNOWN RISK OF THE ESSURE PROCEDURE. PREGNANCY IS THE CONDITION OF CARRYING DEVELOPING OFFSPRING WITHIN THE BODY. THE TIME PERIOD DURING WHICH THIS CONDITION EXISTS; GESTATION. PROBABLE CAUSES FOR PREGNANCY INCLUDE: 1) UNSUCCESSFUL BILATERAL TUBAL OCCLUSION (COMPLETE TISSUE INGROWTH), 2) EXPULSION (RELATED TO MICRO-INSERT PLACEMENT ACCURACY), 3) NO 3-MONTH CONFIRMATION TEST (HSG) OR MIS-READ OF HSG, 4) LACK OF PATIENT COMPLIANCE TO IFU (I.E. USE OF ALTERNATE CONTRACEPTION UNTIL CONFIRMATION OF BILATERAL OCCLUSION). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED LEGAL CASE REPORT RECEIVED REFERS TO A PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED BLADDER INFECTIONS, SEVERE PELVIC PAIN, SEVERE BLEEDING, PREGNANCY AND ESSURE DEVICE MIGRATED FROM CONSUMER'S FALLOPIAN TUBES TO HER UTERUS/RECTUM. BLADDER INFECTIONS IS SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SEVERE PELVIC PAIN AND SEVERE BLEEDING ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED. ESSURE DEVICE MIGRATED FROM CONSUMER'S FALLOPIAN TUBES TO HER UTERUS/RECTUM IS SERIOUS DUE TO HOSPITALIZATION AND LISTED. PREGNANCY IS NON-SERIOUS AND LISTED. SEXUAL INTERCOURSE MAY LEAD TO CYSTITIS, BUT IT IS NOT NECESSARY TO BE SEXUALLY ACTIVE TO DEVELOP IT. ALL WOMEN ARE SUSCEPTIBLE TO CYSTITIS BECAUSE OF THEIR ANATOMY - SPECIFICALLY, THE CLOSE PROXIMITY OF THE URETHRA TO THE ANUS AND THE SHORT DISTANCE FROM THE URETHRAL OPENING TO THE BLADDER. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, IT WAS REPORTED THAT THE EVENTS OCCURRED AFTER ESSURE INSERTION (TEMPORAL RELATIONSHIP WAS NOT REPORTED). BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS, EXCEPT FOR BLADDER INFECTIONS, CANNOT BE EXCLUDED. GIVEN ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES AND BASED ON THE PATHOPHYSIOLOGY OF BLADDER INFECTION, A CAUSAL RELATIONSHIP WITH ESSURE CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT AS THE PLAINTIFF UNDERWENT A HYSTERECTOMY. NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ADDITIONAL INFORMATION WILL BE OBTAINED THROUGH THE NORMAL LITIGATION PROCESS.

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Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 13-JUL-2015 COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED LEGAL CASE REPORT RECEIVED REFERS TO A PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED BLADDER INFECTIONS, SEVERE PELVIC PAI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00017	BAYER HEALTHCARE LLC	1/8/2015	1/8/2015

Event Information:

Event Date (B3): 8/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53029

Single Use: Y
Implant Date (E6): 8/11/2014
Explant Date (E7): 12/11/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 11-DEC-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6)-2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER B53029 FOR CONTRACEPTION. PREGNANCY WAS DENIED. ON (B)(6)-2014, PHYSICIAN WAS AWARE THAT ESSURE PLACEMENT WAS NOT CORRECT, WITH POSSIBLE PERFORATION. ON (B)(6)-2014 ESSURE WAS REMOVED VIA LAPAROSCOPY. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 19-DEC-2014. THE PTC GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: ESSURE REMOVAL SHOULD BE PERFORMED AS FOLLOWS PER PRODUCT IFU: A CORNUAL RESECTION OF THE PROXIMAL FALLOPIAN TUBE WILL BE REQUIRED IF THE MICRO-INSERT IS PROPERLY LOCATED ACROSS THE UTEROTUBAL JUNCTION (UTJ). AN ESSURE MICRO-INSERT THAT HAS BEEN IMPROPERLY PLACED OR HAS MIGRATED BEYOND THE UTJ SHOULD BE REMOVED WITH TRADITIONAL LINEAR SALPINGOTOMY OR SALPINGECTOMY ACCOMPLISHED VIA LAPAROSCOPY OR LAPAROTOMY. PROBABLE CAUSES FOR ESSURE MICRO-INSERT REMOVAL - 1) PHYSICIAN INADVERTENTLY DEPLOYED MICRO-INSERT IN THE UTERINE CAVITY AND NOT INTO THE TUBE, 2) PHYSICIAN DETERMINES THE MICRO-INSERT IS INACCURATELY PLACED IN THE FALLOPIAN TUBE, 3) UNUSUAL UTERINE ANATOMY AND/OR INADEQUATE VISUALIZATION LEADS TO A MISPLACED MICRO-INSERT. IMPORTANT: IF THE MICRO-INSERT WAS INADVERTENTLY DEPLOYED IN THE UTERINE CAVITY AND NOT INTO THE TUBE, THE MICRO-INSERT SHOULD BE REMOVED FROM THE UTERUS AND ANOTHER ATTEMPT MADE AT MICROINSERT PLACEMENT IN THE TUBE. WARNING: MICRO-INSERT REMOVAL SHOULD NOT BE ATTEMPTED HYSTEROSCOPICALLY ONCE THE MICRO-INSERT HAS BEEN PLACED. THE ONLY EXCEPTION IS DURING THE ACTUAL PLACEMENT PROCEDURE WHEN REMOVAL MAY BE ATTEMPTED IF 18 OR MORE COILS OF THE ESSURE MICROINSERT ARE TRAILING INTO THE

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UTERINE CAVITY. BECAUSE OF MICRO-INSERT ANCHORING, HOWEVER, REMOVAL MAY NOT BE POSSIBLE EVEN IMMEDIATELY AFTER PLACEMENT. ATTEMPTED REMOVAL OF A MICRO-INSERT HAVING LESS THAN 18 COILS TRAILING INTO THE UTERINE CAVITY MAY RESULT IN FALLOPIAN TUBE PERFORATION OR OTHER PATIENT INJURY. MICRO-INSERT REMOVAL SHOULD ONLY BE ATTEMPTED IF A PATIENT IS EXPERIENCING AN ADVERSE EVENT(S) WITH THE MICRO-INSERT OR IF SHE DEMANDS MICRO-INSERT REMOVAL. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. REMOVING THE ESSURE DEVICE VIA MEDICAL INTERVENTION IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE PLACEMENT WAS NOT CORRECT, WITH POSSIBLE PERFORATION. THIS EVENT, INTERPRETED AS UTERINE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE IT WAS REPORTED THAT 4 MONTHS AFTER ESSURE INSERTION THE PHYSICIAN WAS AWARE THAT ESSURE PLACEMENT WAS NOT CORRECT, WITH POSSIBLE PERFORATION. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF PRODUCT. FOLLOW UP INFORMATION (PERFORATION QUESTIONNAIRE) ARE EXPECTED.

Manufacturer Narrative (H10):

ESSURE PERFORATION QUESTIONNAIRE RECEIVED ON 02-FEB-2015 FROM PHYSICIAN: THE PATIENT´S HEIGHT WAS (B)(6) AND WEIGHT WAS (B)(6). HER CONCURRENT CONDITION INCLUDED OVERWEIGHT. THE PATIENT´S MEDICAL HISTORY INCLUDED GRAVIDA 5, PARITY 4, ONE SPONTANEOUS ABORT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040066	BAYER	1/8/2015	1/8/2015

Event Information:

Event Date (B3): 12/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OVARIAN CRAMPING, SEVERE PAIN, ABDOMINAL SWELLING, MIGRAINE, JOINT PAIN, LOWER BACK PAIN, LOW FERRITIN, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040067	BAYER	1/8/2015	1/8/2015

Event Information:

Event Date (B3): 7/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST OF ALL I WAS GETTING HEADACHES WHEN IT WAS COMING UP TO PERIOD THEN BLURRED VISION THEN I REGULAR PERIODS AND BACK ACHE ARM AND BACK ACHE THROBBING IN GROIN AREA MOODINESS FEELING SICK SORE BREASTSTROKE WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040069	BAYER	1/8/2015	1/8/2015

Event Information:

Event Date (B3): 12/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE CRAMPING AFTER PERIODS FOR ABOUT 6 MONTHS. NOW I AM PREGNANT! I HAD MY ESSURE PLACED IN 2008! I AM SHOCKED AND SCARED!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040075	BAYER	1/8/2015	1/8/2015

Event Information:

Event Date (B3): 3/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD ENSURE FOR 4 YEARS AND I'VE BEEN SICK FOR THE ENTIRE 4 YEARS. MIGRAINES DIZZY VERTIGO HEART PALPITATIONS FATIGUE INSOMNIA SHAKING ELEVATED BLOOD COUNT IRON B12 AND D DEFICIENCY VISION PAINFUL INTERCOURSE TINGLING AND NUMB IN FACE HANDS FEET DEPRESSION NIGHT SWEATS HOT FLASHES CRAMPING CHRONIC FATIGUE UTI BLADDER AND KIDNEY INFECTIONS... THE LIST GOES ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040068	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 12/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5040068 #(B)(4) I SAW A REPRODUCTIVE SPECIALIST ON (B)(6) 2014 AND WAS ALSO DIAGNOSED MY POLYCYSTIC OVARIAN SYNDROME. THIS DID NOT EXIST PRIOR TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040070	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 6/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, SWELLING, WEIGHT GAIN, MUSCLE TWITCHING, HAIR LOSS, DEPRESSION, MUSCLE ACHES, JOINT PAIN, PELVIC PAIN, PAIN WITH INTERCOURSE, BACK PAIN, SEVERAL BACTERIAL VAGINOSIS INFECTIONS AND YEAST INFECTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040071	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 5/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIFTY PLUS POUND WEIGHT GAIN, DAILY MIGRAINE HEADACHES, CONSTANT NAUSEA, WEAKNESS, FATIGUE, EXTREME BLEEDING WITH GOLF BALL SIZED CLOTS, DISCHARGE, IRRITABILITY, DEPRESSION, PAIN DURING INTERCOURSE, FREQUENT UTI.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040072	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 11/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ON BOTH SIDES OF MY STOMACH BACK PAIN SOMETIMES I CAN'T GET UP OUT OF BED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040073	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 3/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). DURING A MRI TO RULE OUT APPENDICITIS IT WAS DISCOVERED THAT THE LEFT COIL HAD MIGRATED INTO THE FATTY TISSUE NEAR MY SIGMOID COLON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040074	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN (B)(6) 2012, I HAD THE ESSURE PLACED SOON AFTER I EXPERIENCED SOME PELVIC PAIN DURING MY MENSTRAL PERIODS. BUT; IN (B)(6) 2013, AFTER A SERVER GALL BLADDER ATTACK WHICH LEAD TO AN EMERGENCY OPERATION, THE LAB REPORTS AND CT SHOWED THAT I WAS 5WKS PREGNANT...WHICH MEANT THAT THE DEVICE FAILED. IN (B)(6) OF 2014, I HAD A TUBAL LIGATION DONE. THE REASON FOR THE ESSURE WAS TO AVOID SURGERY AND IT FAILED!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040076	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 7/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ARTHRITIS IN MY RIGHT KNEE NOW. PAIN IN MY LOWER STOMACH, HIVES, HEADACHE, DIZZY AT TIMES, THROWING UP A LOT, BACK PAIN, HAIR FELLING, MY CYCLES ARE HEAVY AND SOMETIMES TWICE A MONTH. THE PAIN HAS STOPPED ME FROM NOT GETTING OUT OF BED AND DOCTORS VISIT AND WE VISIT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040077	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 11/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HORRIBLE ABDOMINAL PAIN. PELVIC PAIN. BLOATING. DIAHRREAH. COIL MIGRATED TO MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040078	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING VERY LONG PERIODS WITH PAIN. HEADACHES THAT WOULDN'T GO AWAY, SEVERE MOOD SWINGS AND CRAMPS IN MY STOMACH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040079	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 11/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED BLEEDING HEAVY. BLED FOR OVER A YEAR. BECAME ANEMIC. ESSURE PRODUCT NOT IN RIGHT LOCATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040080	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 4/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE FOR 9 MONTHS. FIRST OF ALL. I MUST EXPLAIN MY HEALTH PREVIOUS TO ESSURE. I AM A HEALTH COACH, AND A RUNNER/YOGA INSTRUCTOR. SO HEALTH PROBLEMS AND OR MEDICATIONS WERE SLIM TO NONE. AND IF SOME BUG DID COME UP, I HAD AN IMMUNE SYSTEM OF AN ELEPHANT BECAUSE OF THE FOODS AND SUPPLEMENTS I NOURISH MY BODY WITH. THAT BEING STATED. I BEGAN HAVING UNEXPLAINABLE SYMPTOMS A TWO MONTHS AFTER BEING IMPLANTED. MY SYMPTOMS WERE: WEIGHT GAIN AND SEVERE BLOATING IN BELLY, BUTT, AND THIGHS (THAT NO MATTER HOW MUCH EXERCISE COULD NOT BE BUDGED), BONE AND JOINT PAIN IN WRISTS, KNEES, AND ANKLES- LOWER RIGHT BACK PAIN (THE BACK PAIN BECAME SO SEVERE THAT I COULD NOT STAND UP STRAIGHT), HAIR LOSS, METAL TASTE IN MOUTH, THYROID AND ADRENAL PROBLEMS, RASH ON BELLY AND HANDS. I CALLED MY DOCTOR 2 MONTHS IN, HE SAID IT IS NOT FROM THE ESSURE, AND THE PRODUCT DOES NOT CONTAIN NICKEL, WHICH I AM ALLERGIC TO, AND WAS NOT TESTED FOR WHEN PUT IN! THE PRODUCT DOES HAVE NICKEL. WHY ARE THE DOCTORS SO UNEDUCATED ABOUT THE SIDE EFFECTS AND CONTENTS OF THE ESSURE? I ENDED UP GETTING SO BLOATED I APPEARED 8 MONTHS PREGNANT. MY FAMILY, FRIENDS, AND CLIENTS KEPT ASKING ME IF I WAS!! I HAD LITTLE MOBILIZATION AT 8 MONTHS, MY BACK AND WRISTS WERE SO BAD I COULD NOT STAND OR USE MY RIGHT WRIST. I ENDED UP AT MY IMPLANTING DOCTOR WHOM WAS SHOCKED AT MY APPEARANCE. RAN EVERY TEST AND FINALLY CAME TO CONCLUSION, YES IT WAS ESSURE. HE STILL STATED THAT THERE WAS NO NICKEL. I SWITCHED DOCTORS, AND HAD TO HAVE A LAPAROSCOPIC HYSTERECTOMY. SINCE THEN SYMPTOMS HAVE DISSIPATED. HAD TO ORDER SUPPLEMENT TO HEAL ENDOCRINE SYSTEM AND STIMULATE REGULAR FUNCTION OF THYROID AGAIN. I ENDURED A HEAVY METAL DETOX WHICH HELPED IMMENSELY. I HAVE BALD SPOTS STILL WHERE HAIR WAS LOST. AND MY RIGHT WRIST JOINT AND BONE WILL NEVER HAVE FULL RECOVERY. I GAVE UP

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MY UTERUS, TUBES, AND CERVIX. AND MOST OF ALL I GAVE UP MY HEALTH FOR AWHILE PHYSICALLY, MENTALLY, EMOTIONALLY, BUT NOT SPIRITUALLY! I KNEW I AM AND WAS AN EDUCATED, HEALTHY, CONSCIENTIOUS WOMAN WHOM WOULD OVERCOME THIS! BUT DAD THERE ARE WOMEN, THOUSANDS OF WOMEN, WHO ARE ENDURING THE SIDE EFFECTS OF THE ESSURE. I KINDLY ASK YOU WHY IN THE WORLD IS THIS PRODUCT ALLOWED TO BE ON THE MARKET? THE NUMBERS AND STORIES CLEARLY AND ADEQUATELY TELL THE TRUTH OF THIS MATTER. I WOULD RATE THIS PRODUCT VERY DANGEROUS TO SAY THE LEAST. I ALSO WOULD SAY THAT THE TRIAL RUN WAS BASED ON VERY INADEQUATE INFORMATION. I AGAIN KINDLY AND FIRMLY ASK YOU TO TAKE A LOOK AT WHAT IS SURROUNDING THIS PRODUCT. DOING SO WILL SAVE MANY WOMEN FROM MUCH PAIN AND SUFFERING!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040081	BAYER	1/8/2015	1/9/2015

Event Information:

Event Date (B3): 2/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5040081 #(B)(4). AFTER SEEING 5 DIFFERENT DOCTORS I HAD TO HAVE A HYSTERECTOMY ON (B)(6), 2015 IN ORDER TO GET THE ESSURE OUT OF MY BODY. THE METALLIC TASTE IN MY MOUTH IS GONE AND SO IS THE CONSTANT STABBING PAINS IN MY PELVIS. ESSURE IS THE DEVIL!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040193	CONCEPTUS, INC.	1/8/2015	1/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) OF 2013. SINCE THEN I HAVE HAD SEVERE PAIN IN MY PELVIS, BLOATING AND HEADACHES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00012	BAYER HEALTHCARE LLC	1/8/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C55828

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (LOT NUMBER C55828). PHYSICIAN REPORTED THAT IMPLANT BROKE IN CONTACT WITH THE UTERINE WALL. THE ANOMALY WAS OBSERVED IN THE OPERATING ROOM DURING THE PLACEMENT. THERE WAS NO ANATOMICAL CAUSE TO EXPLAIN THE ANOMALY WHICH CONCERNED THE IMPLANT ITSELF. BILATERAL PLACEMENT WAS PERFORMED WITH THE OTHER DEVICE. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PHYSICIAN REPORTED THAT IMPLANT BROKE IN CONTACT WITH THE UTERINE WALL (DURING THE PLACEMENT). THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE DEVICE BREAKAGE OCCURRED DURING ESSURE PLACEMENT. IT WAS OBSERVED IN THE OPERATING ROOM. BILATERAL PLACEMENT WAS PERFORMED WITH THE OTHER DEVICE. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP FROM 13-APR-2015: NO FURTHER INFORMATION OBTAINED DESPITE FOLLOW-UP ATTEMPT. CASE CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE W

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00016	BAYER HEALTHCARE LLC	1/8/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51342

Single Use: Y
Implant Date (E6): 12/5/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/19/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2014, LOT NUMBER C51342. ON (B)(6) 2012 DURING THE ESSURE INSERTION, AT THE TIME OF STENT RELEASING, THE DELIVERY HANDLE (THE RELEASE BUTTON) MADE AN AMAZING NOISE AND THEN PHYSICIAN SAW THE STENT COMING BACK FROM THE HORN TO THE UTERUS. AFTER, DELIVERY HANDLE WAS CONTROLLED AND A PART WAS MISSING. BILATERAL INSERTION WAS MADE BUT DEVICE WAS IN A VERY BAD POSITION AND THE TIP OF THE DEVICE (INSERTER) REMAINED ON STENT (MIRO-INSERT). PHYSICIAN THINKS THAT ITS EFFECTIVENESS COULD BE AFFECTED AND COULD HAVE A RISK OF PERFORATION AS CONSEQUENCE OF THIS BAD POSITION OF ESSURE. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE THERE WAS A VERY BAD ESSURE PLACEMENT AND THE TIP OF THE DEVICE REMAINED ON STENT / A PART OF DELIVERY HANDLE IS MISSING. THE EVENTS, SEEN AS DEVICE DEPLOYMENT ISSUE AND DEVICE BREAKAGE (INSERTER BROKE), ARE NON-SERIOUS. DEPLOYMENT ISSUE IS LISTED, WHILE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, DURING THE ESSURE INSERTION, ONE OF THE DEVICES WAS NOT PROPERLY DEPLOYED. THE DELIVERY HANDLE MADE A NOISE AND THEN THE PHYSICIAN SAW THE MICRO-INSERT (STENT) COMING BACK FROM THE HORN OF THE UTERUS. AFTER, DELIVERY HANDLE WAS CONTROLLED AND REMOVED. IT WAS FOUND OUT THAT A PART OF DELIVERY HANDLE (INSERTER) WAS MISSING. BILATERAL INSERTION WAS ACHIEVED BUT ONE ESSURE COIL WAS IN A VERY BAD POSITION AND THE TIP OF THE INSERTER DEVICE REMAINED ON MICRO-INSERT (STENT). UPON THE EVENTS OCCURRED DURING ESSURE INSERTION

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AND CONSIDERING DEVICE BREAKAGE (MALFUNCTION) WAS REPORTED, CAUSALITY IS ASSESSED AS RELATED TO ESSURE AND THE CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. FURTHER INFORMATION AND TECHNICAL ANALYSIS HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 14.JAN.2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4) FINAL ASSESSMENT: FAILURE MODE / MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00018	BAYER HEALTHCARE LLC	1/8/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C95076

Single Use: Y
Implant Date (E6): 12/11/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2014, LOT NUMBER C95076, FOR PERMANENT STERILIZATION. AT TIME OF ESSURE INSERTION, THE HEALTH CARE PROFESSIONAL PLACED THE PATIENT'S RIGHT SIDE SUCCESSFULLY. WHEN SHE WENT TO PLACE THE LEFT SIDE, THE DEVICE DEPLOYED IN THE TUBE BUT WOULD NOT DETACH FROM THE CATHETER WIRE. THE PHYSICIAN COULD NOT GET IT TO SEPARATE. SHE HAD THE SCOPE AND CATHETER IN PATIENT CAVITY AND WENT THRU SERIES OF TECHNIQUES TO HELP IT DETACH, MAKE SURE WHEEL ON HANDLE WAS ROTATED ALL THE WAY BACK, DEPRESSED THE BUTTON AND ROTATED THE HANDLE BACK AND FORTH, AND IT WOULD STILL WOULD NOT RELEASE. WHEN TRYING TO RELEASE, THE COIL ACTUALLY BROKE IN A NON DESIRABLE POSITION. THE PHYSICIAN GOT AN X-RAY, TWO FLAT PLATES. SHE HAS THE IMAGES BUT DOES NOT HAVE THE VERBAL ASSESSMENT. FOLLOW-UP RECEIVED ON (B)(6) 2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER

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ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE ADVERSE EVENT CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION AND, DURING INSERTION PROCEDURE, WHEN TRYING TO RELEASE, THE COIL ACTUALLY BROKE IN A NON DESIRABLE POSITION. THE EVENT WHEN TRYING TO RELEASE, THE COIL ACTUALLY BROKE IN A NON DESIRABLE POSITION, SEEN AS A DEVICE BREAKAGE IS NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE REPORTED PHYSICIAN STATED THAT, DUE TO A DEVICE DEPLOYMENT ISSUE, THE ESSURE LEFT COIL BROKE DURING INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT, AND CONSIDERING THAT IT OCCURRED IN CONNECTION WITH INSERTION PROCEDURE, COMPANY ASSESSES IT AS RELATED TO ESSURE. THIS CASE WAS REGARDED AS OTHER-REPORTABLE INCIDENT AS IT COULD HAVE LED TO SERIOUS DETERIORATION OF HEALTH IF IT HAD OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 13-MAY-2015. UPON INTERNAL REVIEW PERFORMED ON 27-MAY-2015, THIS CASE WAS UPDATED WITH INFORMATION FROM DUPLICATED REPORT. THE PROCEDURE WAS PERFORMED IN OFFICE BY A PHYSICIAN WHO WAS EXPERIENCED WITH ESSURE. THE PATIENT RECEIVED

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040228		1/9/2015	1/20/2015

Event Information:

Event Date (B3): 1/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/28/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD GOTTEN THE ESSURE PROCEDURE IN 2010, NOW 2015 I HAVE TO HAVE A FULL HYSTERECTOMY DUE TO ALL THE PAIN FROM THE COILS. I' VE BEEN HOSPITALIZED TWICE AND THE ONLY CONCLUSION IS THE COILS. I HAVE REALLY BAD PAINS, AWFUL HEADACHES. I HAD CT SCANS AND EVERYTHING LOOKS FINE, ULTRASOUND EVERYTHING IS FINE. I GO TO THE DOCTORS TODAY, AND HER SUGGESTION IS TO REMOVE THE COILS BECAUSE THAT'S WHAT IS CAUSING MY CONSTANT PAIN, DISCOMFORT, THE PAIN IS LIKE BEING IN LABOR, COMES AND GOES. I GOT HOSPITALIZED LAST YEAR AND HAD AN OBGYN DR COME IN AFTER HAVING GI TEST, THAT DR ALSO TOLD ME SHE WANTED TO REMOVE MY TUBES TO TAKE OUT THE COILS, DUE TO THE FACT THAT ONE OF THEM WAS OUT OF PLACE AND IT WAS GOING TO CONTINUE TO CAUSE ME PAIN. I DIDN'T HAVE HEALTH INSURANCE AT THE TIME, SO I JUST DEALT WITH IT. I AM (B)(6) Y/O. I GOT IT DONE AT (B)(6) AFTER MY THIRD CHILD. I DON'T BELIEVE THIS SHOULD BE AN OPTION FOR ANY WOMEN UNDER THE AGE OF 30, IF EVEN AN OPTION, NOW I SIT HERE AND HAVE TO GET A FULL HYSTERECTOMY AT (B)(6) Y/O. BECAUSE OF A DECISION I MADE AT (B)(6), THAT HAS CAUSED ME NOTHING BUT PROBLEMS, AFTER HAVING THE PROCEDURE, THE DR PUT ME TO SLEEP, I GOT AN INFECTION FROM IT, WAS SO SICK FOR 2 MONTHS, PUT STITCHES IN AND NEVER TOLD ME, WORST DECISION I HAVE EVER MADE IN MY LIFE. NOT ONLY CAN I NEVER HAVE KIDS AGAIN, MAKING THAT DECISION AT (B)(6), STILL NOT REALLY AN ADULT, BUT ALL THE COMPLICATIONS AFTER, I NOW WOULD HAVE NEVER GOTTEN IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040231	BAYER	1/9/2015	1/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/19/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT WAS IMPLANTED WITH ESSURE ON (B)(6), 2012. SINCE THEN HAVE VERY SHARP PAINS IN MY SIDES, PAINFUL MENSTRUAL CYCLE WITH HEAVY BLEEDING, TASTE OF METAL. HORRIBLE HEADACHES, LOSS OF LIBIDO, MOOD SWINGS, HEART PALPITATIONS, NUMBNESS IN TOES, PAINFUL INTERCOURSE AND A VERY FRUSTRATED FAMILY. MODEL NUMBER NEVER GIVEN TO ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040217	BAYER	1/10/2015	1/20/2015

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE I HAVE EITHER NOT HAD A PERIOD OR HAD AWFUL PAIN WITH MY PERIODS ALONG WITH HEAVY BLEEDING AND BLOOD CLOTS. I HAVE PAIN IN MY RIGHT LOWER BACK/HIP REGION THAT WON'T GO AWAY. WHEN I DO HAVE A PERIOD I FEEL LIKE MY VAGINA IS GOING TO FALL OUT. I BELIEVE I AM ALLERGIC TO NICKEL AND I DO NOT UNDERSTAND WHY THE NICKEL ALLERGY TEST ISN'T REQUIRED. MEDWATCHER #(B)(4).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040099	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HAIR LOSS, DEPRESSION, HIP PAIN, HEAVIER PERIODS, PASSING LARGE CLOTS DURING MENSES, OCCASIONAL STABBING PAIN IN RIGHT GROIN AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040100	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 6/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY HAIR IS FALLING OUT, MY LIVER ENZYMES HAVE INCREASED ALOT, I HAVE NO ENERGY TO DO ANYTHING, I BREAK OUT IN HIVES FOR NO APPARENT REASON, I HAVE A HUGE AMOUNT OF PELVIC PAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040101	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 2/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SWELLING IN MY RIGHT POINTER FINGER AND MIDDLE FINGER KNUCKLES. IT LOOKED AS IF I HAD BRUISED THEM WITHOUT THE DISCOLORATION. HAD THE ESSURE DEVICE PUT IN (B)(6) AND NOTICED THE SWELLING IN (B)(6). BECAME MORE INFLAMED AND WAS DIAGNOSED WITH RA IN (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040102	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TAIL BONE PAIN, SEVERE ABDOMINAL CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040103	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5040103 #(B)(4) I AM NOW SCHEDULE FOR A HYSTERECTOMY ON (B)(6),2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040104	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 7/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BLEEDING PROFUSELY AFTER SEX. STARTED HAVING MIGRAINES. AND DAILY HEADACHES NAUSEA PAIN IN MY RIGHT HIP AND SIDE LOW BACK PAIN AND CHRONIC FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040105	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 1/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN HAVING LOWER ABDOMINAL PAIN AND HORRIBLE PAIN WHERE MY OVARIES ARE LOCATED. I WENT TO DOCTORS AND HAD AN MRI, BLOOD WORK, AND OTHER TESTS DONE. I SAW A NEUROLOGIST, A GENERAL PRACTITIONER, AND MY OB/GYN. I CONTINUED TO HAVE THE PAIN AND BEGAN HAVING LOWER BACK PAIN. I ALSO HAVE HEADACHES, FATIGUE, AND HEAVY MENSTRUAL CYCLES. NONE OF THIS HAPPENED BEFORE MY DEVICE WAS IMPLANTED. FURTHERMORE, I BEGAN HAVING ANXIETY ATTACKS AND DIZZINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040106	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CHRONIC CRAMPING, BACK PAIN, HIP PAIN, HYPOTHYROID, NICKEL ALLERGY, CYSTS ON OVARIES, WEIGHT GAIN, ANXIETY, DEPRESSION, PANIC ATTACKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040107	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 4/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ENSURE IMPLANTS I DEVELOPED HIVES AND RASHES AND MANY OTHER SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040108	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAVE HAD MUSCLE SPASMS, TINGLENESS IN MY LEGS, TOES AND FINGERS, ABDOMEN PAIN IN MY LEFT SIDE, TWITCHING IN MY NECK AND EYES, FATIGUE AND LOSS OF APPETITE, LOSS OF SEXUAL DESIRE, INCREASE OF WEIGHT ESPECIALLY TO MY BELLY, ITCHINESS TO PUBIC HAIR AREA, RESTLESSNESS AND FREQUENT URINATION , NOT TO MENTION, CONSTANTLY WANTING WATER. BESIDES THINKING I MIGHT BE PREMENOPAUSAL I ALSO THOUGHT I WAS PREDIABETIC BUT I AM 100% CONVINCED ESSURE CAUSED THIS BECAUSE I DIDN'T HAVE THESE COMPLICATIONS BEFORE .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040109	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 3/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. MIGRAINES, HEAVY PERIODS, BIG BLOOD CLOTS, WEIGHT GAIN, DEPRESSION, ANXIETY, LOW SEX DRIVE, JOINT PAIN, BACK PAIN, SHARP/STABBING PELVIC PAIN, HOT FLASHES, CERVICAL DYSPLASIA, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION, NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS, PAINFUL INTERCOURSE, BLEEDING BETWEEN PERIODS, LONG MENSTRUAL CYCLES, YEAST INFECTIONS, URGENT/FREQUENT URINATION, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, PAIN...BACK, JOINT, CHEST, LEG,NECK, SPINE, HIP. CHRONIC PELVIC PAIN, FACE PAIN, ALL OVER BODY ACHES/PAIN, METALLIC TASTE IN MOUTH, NUMBNESS, BRAIN SHOCKS, NERVE PAIN. I HAVE/HAVE NOT BEEN SEEN BY (NUMBER IF ANY) OF DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS (LIST IF ANY). I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE (LIST IF ANY). THE DEVICE IS STILL INSIDE OF ME/ OR HAS BEEN REMOVED (LIST DATE IF ANY). THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040110	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 10/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BREAK OUT IN HUGE HIVES ALL OVER MY BODY AND CANT BREATHE. I HAVE GAINED 30LBS THAT NO MATTER WHAT I CANT LOSE. SEX HURTS AS IF SOMEONE IS CUTTING MY OVARY'S OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040111	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MOOD SWINGS, DEPRESSION, ANXIETY, BRAIN FOG, RASHES, KNEE PAIN, HIP ANDAMP; BACK PAIN, JOINT PAIN, ABDOMINAL PAIN, INFLAMMATION, WEIGHT GAIN, EMOTIONAL HIGHS ANDAMP; LOWS, LOW SEX DRIVE, LACK ENERGY, LACK OF DRIVE, DEPLETED ATTENTION SPAN, VERY EASILY ANNOYED, CHANGES IN EYE SIGHT ANDAMP; HEARING,HOT FLASHES, NIGHT SWEATS, SYMPTOMS OF PREMATURE ONSET OF MENOPAUSE , CHANGES IN MENSES, BOWL CHANGES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040112	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 6/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED IN (B)(6) OF 2013 AND HAS ONLY GOTTEN WORSE OVER TIME....STILL HAVING PROBLEMS TODAY ((B)(4), 2014). I HAVE MY PERIODS EVERY 2 WEEKS...THEY ARE VERY HEAVY AND LAST FOR 10-14 DAYS...PASSING CLOTS....SEVERE ABDOMINAL AND PELVIC PAIN, SEVERE LOWER BACK PAIN, BLOATING, EXTREME FATIGUE, SEIZURES, BLACK OUTS, UNEXPLAINED WEIGHT GAIN, MASSIVE SWELLING OF LEGS AND FEET, DIFFICULTY IN LOSING WEIGHT, MEMORY LOSS, CONFUSION, BRAIN FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040113	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BLEEDING VERY HEAVY WITH QUARTER SIZE BLOOD CLOTS. I WAS HAVING UNBEARABLE PAIN IN MY ABDOMEN. SHARP, STABBING, CRAMP PAINS. EVERY SINCE THAT DAY THE PAIN STILL REMAINS. I WENT FROM BEING PERFECTLY HEALTHY TO HAVING CONSTANT PAIN, BLEEDING AND UTI'S. I AM NOW TAKING SEVERAL MEDICATIONS, THOSE OF WHICH I HAVE NEVER HAD TO USE BEFORE. HIGH PB MEDS, PAIN MEDS, MUSCLE RELAXERS, ANTI-INFLAMMATORY, 2 ANTIBIOTICS. I ALSO HAVE PAIN WITH INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040114	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY, VERTIGO, HEAVY MENSTRUATED FLOW, HEAVY PAIN DURING MENSTRUAL, BODY PAIN, BACK PAIN, HEADACHES, DIARRHEA, HEARTBURN, PAINFUL INTERCOURSE, LOW SEX DRIVE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040115	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 8/1/2011	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE MIGRAINES NUMBNESS IN EXTREMITIES. MUSCLE SPASMS AN GI ISSUES. I HAVE NOW BEEN DIAGNOSED WITH FIBROSIS AS WELL AS ENDOMETRIOSIS WHICH I NEVER HAD BEFORE THE IMPLANT I AM LOOKING AT A FULL HYSTERECTOMY AT THE AGE OF (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040116	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE SHARP STABBING PAINS WHEN I BEND OVER. KEEP RASH FROM NICKEL ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040117	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 3/3/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE LEFT SIDE FACE PAIN WITH MIGRAINE HEADACHE, LEFT SIDE GROIN PAIN, REALLY HEAVY PERIODS, BAD CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040118	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING EXTREME PAIN. MUSCLE WEAKNESS RASH MIGRAINES MEMORY LOSS. CONSTANT ABDOMINAL CRAMS PAINFUL SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040119	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 10/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAVE HAD THE PROCEDURE I HAVE BEEN BLEEDING HEAVILY, CRAMPING CONSTANTLY, HEADACHES, FATIGUE, SHARP STABBING PAINS IN MY SIDE, BLOATING, MOOD SWINGS, AND MOST RECENTLY PASSING PIECES OF TISSUE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040120	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 3/3/2014	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AS SOON AS THE IMPLANTS WERE PUT IN I WAS IN DISCOMFORT. WENT THREW THE RECOMMENDED DYE TEST, ALWAYS FELT DISCOMFORT AND PAIN IN PELVIC AREA. STARTED GETTING ALLOT OF HEADACHES, STOMACH PROBLEMS, RASH, PAIN DURING SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040121	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 1/13/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HODGKINS LYMPHOMA .RASHES, HIVES, ANXIETY , NEUROPATHY, DEPRESSION AND CHEMOTHERAPY AND RADIATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040122	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 2/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PELVIC PAIN,EXTREMLY HEAVY AND IRREGULAR MENSTRUAL CYCLE, MOOD DISORDER, ANXIETY, HIGH BLOOD PRESSURE, SWELLING, WEIGHT GAIN 30 POUNDS, DIAGNOSED WITH ULCERATIVE COLITIS AND PELVIC INFLAMMATORY DISEASE, BACK AND JOINT PAIN, AND CYSTS ON LEFT OVARY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040123	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HEAVY PERIOD WITH BLOOD CLOTS PAINFUL SEX ALWAYS GET UTI. ALL WAS HAVE A DISCHARGE. PELVIC PAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040124	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 11/26/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABOUT ONE MONTH AFTER I GOT ESSURE, MY HAIR STARTED FALLING OUT. MY HAIR IS ABOUT HALF AS THIN AS IT WAS BEFORE I HAD ESSURE IMPLANTED. ABOUT 5 MONTHS AFTER I RECEIVED ESSURE, I BEGAN BREAKING OUT IN A RASH, SIMILAR TO HIVES, ON MY UPPER ARMS. THE RASH IS VERY VERY ITCHY, RAISED, RED, AND WILL BLISTER AND THEN SCAB. IN THE LAST 6 MONTHS, THE "RASH" HAS STARTED TO SPREAD ONTO MY CHEST AND FACE. IT WILL COME AND GO BUT IT IS PROGRESSIVELY GETTING WORSE. MY FAMILY DOCTOR HAS TRIED TO TREAT IT WITH STEROIDS AND AN ANTIHISTAMINE TO TREAT THE ITCHING. I HAVE HAD A SKIN BIOPSY DONE AND THE PATHOLOGY REPORT SHOWS NOTHING. I HAVE BEEN TO THE EMERGENCY ROOM ON A COUPLE DIFFERENT OCCASIONS DUE TO ABDOMINAL RIGHT LOWER QUADRANT PAIN. THEY HAVE SUSPECTED ECTOPIC PREGNANCY, HOWEVER ULTRASOUND HAS SHOWN NOTHING. I ALSO FEEL AS IF A BABY IF KICKING IN MY BELLY, AND AGAIN ALL PREGNANCY TESTS ARE NEGATIVE AND ULTRASOUNDS SHOW NOTHING. I SUFFER FROM BLOATING AND SWELLING IN MY STOMACH ALMOST CONSTANTLY. I LOST 65 LBS IN ABOUT A YEAR, HOWEVER DUE TO THE SWELLING AND BLOATING, I STILL LOOK ABOUT 5 MONTHS PREGNANT ALMOST DAILY. MY WORST SIDE EFFECTS IS THE DAILY PAIN AND MOOD SWINGS THAT I KNOW LIVE WITH. I SUFFER FROM EXTREME LOWER BACK PAIN, HIP PAIN, SHOULDER PAIN, NECK PAIN, KNEE PAIN, ON A DAILY BASIS. I HAVE HAD 3 EPIDURAL NERVE BLOCKS, THERAPY, FACET INJECTIONS, ABLATION OF NERVES, A TENS UNIT THAT I USE DAILY, AND ON PAIN MANAGEMENT. MY MEDICINE CABINET JUST KEEPS GROWING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040125	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 5/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M ALWAYS TIRED AND SLEEPY.
MY MOOD CHANGES EVERY MOMENT.
I GET A LOT OF MIGRAINE.
MY TEETH ARE GETTING ROTTEN.
THE BIG ONE FOR ME IS THE MEMORY LOST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040126	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABNORMALLY PAINFUL CRAMPS, PAINS IN MY BACK AND ABDOMEN, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040127	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 6/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ABDOMINAL PAIN, BLOATING, BACK SPASMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040128	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I WAS IN CHRONIC PAIN AND CONSTANTLY BLEEDING I ALSO HAD BACK PAIN (NEVER HAD BEFORE EESURE) AND MIGRAINES AT LEAST TWICE A WEEK SINCE EESURE WAS PUT IN AND BLOATING TO WERE I LOOKED 6 MONTHS PREGNANT . AS OF NOW I HAD TO HAVE A HYSTERECTOMY TO REMOVE EESURE AND I HAVE QUIT BLEEDING AND THE PAIN IS FROM THEM REMOVING MY UTERUS AND TUBES

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040129	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE HAS BEEN RULED BY MY DR. THAT ONE OF THE COILS ARE OUT OF PLACE. SINCE THE ESSURE I HAVE HEAVY BLEEDING, ABDOMINAL/PELVIC PAIN, HAIR THINNING, CONSTANT JOINT PAIN, MY BODY IS NOT THE SAME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040130	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 4/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2011. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. CRAMPING (DAILY), PELVIC PAIN, ABNORMAL PERIODS (PROLONGED AND LARGE CLOTTING), OVARIAN CYSTS, ADENOMYOSIS, UTERINE INFLAMMATION, ABNORMAL PAPS, METRORRHAGIA (BLEEDING IN BETWEEN PERIODS, ABDOMINAL SPASMS, MUSCLE SPASMS, TWITCHING, JOINT PAIN, VITAMIN D DEFICIENCY, UNEXPLAINED/EASILY BRUISING, INFLAMMATORY ARTHRITIS, HAIR LOSS, DRY EYES. I HAVE BEEN SEEN BY 8 DOCTORS TO FIGURE OUT WHAT IS CAUSING MY SYMPTOMS, INCLUDING MY IMPLANTING OBGYN, GENERAL PRACTITIONER, OPHTHALMOLOGIST, OPTOMETRIST, RHEUMATOLOGIST, CURRENT OBGYN, AND 2 ORTHOPEDIC SURGEONS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS ADENOMYOSIS, VITAMIN D DEFICIENCY, UTERINE INFLAMMATION, OVARIAN CYSTS, CHRONIC DRY EYES, METRORRHAGIA, MENORRHAGIA, AND INFLAMMATORY ARTHRITIS. I WILL BE HAVING THE FOLLOWING SURGERIES DUE TO ESSURE, LAPAROSCOPIC VAGINAL HYSTERECTOMY, BILATERAL SALPINGECTOMY, AANDAMP; P REPAIR. THE DEVICE IS STILL INSIDE OF ME AND WILL BE REMOVED ON (B)(6) 2015. I HAVE REQUESTED THAT MY COILS BE RETURNED TO ME AFTER SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040131	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 6/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SINCE I GOT ESSURE MY PERIOD DIDN'T STOP FOR 7 MONTHS UNTIL I WENT TO EMERGENCY AND THEY FIND OUT THAT ONE OF THE COILS WAS IN MY UTERO SO THEY SEND ME TO A DOCTOR TO DO THE SURGERY TO REMOVE IT AND CUT MY TUBES TO GET THE OTHER ONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040132	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 6/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I GOT ESSURE MY PERIOD DIDN'T STOP FOR 7 MONTHS UNTIL I WENT TO EMERGENCY AND THEY FIND OUT THAT ONE OF THE COILS WAS IN MY UTERO SO THEY SEND ME TO A DOCTOR TO DO THE SURGERY TO REMOVE IT AND CUT MY TUBES TO GET THE OTHER ONE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040133	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 6/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING. PAIN ON BOTH SIDES. DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040134	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 4/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGY TO NICKEL SEVERE CRAMPING HEAVY BLEEDING CLOTS TINGLING ARMS HANDS LEGS FEET HIP PAIN SEVERE DIARRHEA HEADACHES HIVES RASHES WEIGHT GAIN METALLIC TASTE IN MOUTH LOSS OF APPETITE TROUBLE BREATHING

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040135	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 5/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM (B)(6) YEARS OLD AN MY LIFE IS STILL NOT BACK TO WHERE IT SHOULD BE DUE TO THE ESSURE COILS BEING PLACED IN ME. I HAD A PARTIAL HYSTERECTOMY REMOVING THE COILS BUT CONTINUE TO SUFFER DAILY DUE TO THE SIDE AFFECTS ESSURE CREATED INSIDE ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040136	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IRREGULAR PERIOD, HEAVY BLEEDING AND PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040137	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 8/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. I WAS NOT GIVEN A LOT NUMBER OR MODEL NUMBER. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. SHARP, POKING AND CONTINUOUS PAIN. LOWER BACK CRAMPING FROM MILD TO SEVERE. OFF AND ON BACK PAIN, MID BACK MOSTLY LEFT SIDE. MULTIPLE EPISODES OF BLOOD IN URINE (4-5). BLADDER PAIN. 2-3 EPISODES OF YEAST INFECTIONS. PAINFUL SEX, SHARP PAIN AS IF THERE IS A PENCIL INSIDE ME. LOW TO NONEXISTENT LIBIDO. MULTIPLE MIGRAINES INCLUDING NAUSEA AND VERTIGO. EXTREMELY PAINFUL MENSES AND VERY HEAVY FLOW. THEN MY MENSES STOPPED ALTOGETHER. HOT FLASHES AND NIGHT SWEATS. EXTREME MOODINESS. CONSTIPATION WHICH MAKES LOWER ABDOMINAL (LEFT SIDE) VERY PAINFUL. INSOMNIA. MEMORY PROBLEMS. AT TIMES, LOWER LEFT ABDOMINAL PAIN SEVERE ENOUGH IT IS DIFFICULT TO WALK ESPECIALLY UP/DOWN STAIRS. I ALSO HAVE AN ALLERGY TO SOME POLYMERS THAT INCLUDE PINE ROSIN (WHICH IT TURNS OUT IS IN THIS PRODUCT.) I HAVE NOT BEEN SEEN BY ANY OTHER DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS INTERSTITIAL CYSTITIS, HOWEVER, INTERVENTIONS HAVE HAD LITTLE EFFECT ON THE SHARP PAIN, ESP. ON LEFT SIDE OF ABDOMEN. THERE HAVE BEEN TWO TIMES THAT I HAVE ATTEMPTED TO GO TO ER FOR PAIN RELATED TO MENSES AND MIGRAINE BUT DID NOT STAY AT ER DUE TO ER BEING EXTREMELY BUSY. I UTILIZED HEATING PADS, ICE PACKS, IBUPROFEN, AND BED REST UNTIL PAIN ALLEVIATED. I HAVE LOST TIME AT WORK DUE TO PAIN. I HAVE HAD NO SURGERIES DUE TO ESSURE AT THIS TIME. THE DEVICE IS STILL INSIDE OF ME.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040138	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5040138 #(B)(4) ALSO LEG SWELLING, CONSTANTLY TIRED, I KEEP GETTING RANDOM SHARP PAINS IN MY ABDOMEN AND SHARP PAINS STRAIGHT UP MY VAGINA, CONSTANT CRAMPING WITH MY PERIOD AND MOST OF THE MONTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040139	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 6/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). PHYSICIAN UNABLE TO PLACE BOTH COILS AT TIME OF INSERTION. WHAT WAS MEANT TO BE A 10 MINUTE PROCEDURE TURNED INTO A 45 MINUTE NIGHTMARE THAT RESULTED IN ME HAVING TO RETURN THE FOLLOWING MONTH FOR PLACEMENT OF SECOND COIL. SIDE EFFECTS SINCE INSERTION - CHRONIC PELVIC PAIN, CHRONIC JOINT PAIN (HIPS AND KNEES,) MENSTRUAL PAINS DAILY - IN AND OUT OF CYCLE, ABNORMALLY HEAVY BLEEDING WITH CLOTS, ANXIETY, WEIGHT GAIN, DEPRESSION, HAIR LOSS AND OTHERS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040140	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 7/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE PAIN, BECAME B12 DIFFECNT,EXCESSIVE TIREDNESS, HAIR LOSS,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040141	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 11/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAVE HAD SEVERE LOWER BACK PAIN. ABDOMINAL PAIN. INFECTIONS IN MY UTERUS. CONTINOUS OUTBREAK IN HIVES. DYSFUNCTIONAL UTERINE BLEEDING. PELVIC PAIN. CERVICAL CYSTS. OVARIAN CYSTS JUST TO NAME A FEW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040142	BAYER	1/11/2015	1/12/2015

Event Information:

Event Date (B3): 12/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). EVER SINCE I HAD IT DONE MY RIGHT SIDE OVARIES IS ALWAYS IN PAIN. I CAN'T ENJOY MY SEX LIFE CAUSE OF BEING IN PAIN ON MY RIGHT SIDE OVARIES. I GET SHARP SHOOTING PAINS. MY BACK HURTS I'M ALWAYS IN DIFFERENT MOODS SWING MY PERIOD HURTS A LOT MORE NOW AND IT'S IN CLOTS. I GET HEADACHES TIME TO TIME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00019	BAYER HEALTHCARE LLC	1/12/2015	1/12/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/21/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 15-DEC-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2014 FOR PERMANENT STERILIZATION. THE PATIENT EXPERIENCED TUBAL PERFORATION. DOCTOR PERFORMED LAPAROSCOPIC TUBAL LIGATION ON (B)(6) 2014. IT IS UNKNOWN IF BOTH SIDES OF FALLOPIAN TUBE WERE OPERATED ON. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 19-DEC-2014. THE PTC GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: A PERFORATION IS A HOLE OR OPENING MADE THROUGH THE ENTIRE THICKNESS OF A MEMBRANE OR OTHER TISSUE OR MATERIAL. PROBABLE CAUSES FOR PERFORATION: PHYSICIAN ENCOUNTERS POOR VISIBILITY DURING THE PROCEDURE, PHYSICIAN TECHNIQUE AND EXPERIENCE, ADVANCING DELIVERY CATHETER WHEN PATIENT IS EXPERIENCING EXTRAORDINARY PAIN OR DISCOMFORT, ATTEMPTING TO ADVANCE DELIVERY CATHETER TO BLACK POSITIONING MARKER AFTER ENCOUNTERING UNDUE RESISTANCE, FURTHER ADVANCING DELIVERY CATHETER ONCE THE BLACK POSITIONING MARKER HAS REACHED THE TUBAL OSTIUM, ATTEMPTED REMOVAL OF AN IMPLANTED MICRO-INSERT WITH FEWER THAN 18 TRAILING COILS INTO THE UTERUS, INACCURATE PLACEMENT OF THE MICRO-INSERT IN THE FALLOPIAN TUBE BY THE PHYSICIAN. ACCORDING TO THE PRODUCT IFU, THE MICRO-INSERT MUST BE PLACED FAR ENOUGH INTO THE FALLOPIAN TUBE TO PREVENT EXPULSION (LESS THAN 18 TRAILING COILS). PERFORATIONS ARE A KNOWN RISK OF THE ESSURE PROCEDURE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A

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REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PERFORATION IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED TUBAL PERFORATION. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE EXACT DATE AND THE MECHANISM OF PERFORATION ARE NOT KNOWN. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS REQUIRED (LAPAROSCOPIC TUBAL LIGATION). SINCE NEITHER LOT NUMBER NOR PRODUCT COMPLAINT SAMPLE WAS PROVIDED IT IS NOT POSSIBLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. ALSO, ACCORDING TO PRODUCT TECHNICAL ANALYSIS, THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THEREFORE, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP FROM 15-APR-2015: THE REQUIRED NUMBER OF FOLLOW UP REQUESTS WAS PERFORMED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00021	BAYER HEALTHCARE LLC	1/12/2015	1/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** IT

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 16-DEC-2014, ARTICLE ENTITLED "RISK OF ESSURE MICROINSERT ABDOMINAL MIGRATION: CASE REPORT AND REVIEW OF LITERATURE". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR STERILIZATION. CASE REPORT: PATIENT INCLUDES GRAVIDA 3, PARA 2 AS HISTORICAL CONDITION. SHE HAD DYSLIPIDEMIA AND HER BODY MASS INDEX WAS 25. FOUR YEARS EARLIER SHE HAD SUFFERED A STROKE WHILE USING ORAL CONTRACEPTIVES. THIS EVENT CAUSED PERSISTENT MILD NEUROLOGICAL DEFICITS. CYCLES WERE REGULAR AND GYNECOLOGICAL EXAMINATION WAS NORMAL. DURING THE ESSURE INSERTION, THE HYSTEROSCOPIC STERILIZATION WAS HAMPERED BY THE PRESENCE OF ENDOMETRIAL CAVITY ADHESIONS OBSCURING LEFT TUBAL OSTIUM. BY USING MICROSCISSORS THE ADHESIONS WERE PROGRESSIVELY LYSED. SINCE THE PROCEDURE HAD BECOME VERY PAINFUL, THE PATIENT REQUIRED GENERAL ANESTHESIA. ONCE ADHESION LYSIS WAS COMPLETED, THE TUBAL OSTIUM WAS WELL VISIBLE. BOTH DEVICES WERE THEN EASILY INTRODUCED INTO THE FALLOPIAN TUBES. AT THE END OF THE PROCEDURE, FIVE COILS WERE VISIBLE ON THE RIGHT SIDE AND FIVE COILS ON THE LEFT SIDE, AS RECOMMENDED. THE PROCEDURE WAS COMPLETED IN 25 MINUTES. THE SAME DAY THE PATIENT WAS DISCHARGED AND SHE WAS DOING WELL. DURING THE FOLLOWING WEEKS, THE PATIENT DID NOT COMPLAIN OF ANY SYMPTOMS. THE 3-MONTH HYSTEROSALPINGOGRAM (HSG) FOLLOW-UP SHOWED THAT THE RIGHT TUBE WAS OCCLUDED AND THE DEVICE WAS CORRECTLY PLACED. CONVERSELY, THE LEFT TUBE WAS PATENT AND THE DEVICE WAS ABNORMALLY LOCATED IN THE LEFT SIDE OF THE PELVIS, AWAY FROM THE TUBAL DISTAL EXTREMITY. ALTHOUGH THE PATIENT WAS ASYMPTOMATIC, SHE WAS COUNSELED TO UNDERGO LAPAROSCOPY IN ORDER TO REMOVE THE DEVICE AND COMPLETE TUBAL STERILIZATION. LAPAROSCOPY SHOWED THAT THE LEFT DEVICE WAS DISPLACED IN THE LEFT LOWER

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QUADRANT, EMBEDDED INTO THE OMENTUM, WITHOUT SIGNS OF INFLAMMATION OR ADHESIONS. THE UTERUS AND THE FALLOPIAN TUBES APPEARED NORMAL, AND NO SIGNS OF PERFORATION WERE DETECTED. THE DEVICE WAS EASILY REMOVED BY BLUNT AND SHARP DISSECTION. BILATERAL TUBAL STERILIZATION WAS SUBSEQUENTLY PERFORMED BY BIPOLAR COAGULATION. THE PATIENT'S POSTOPERATIVE COURSE WAS UNEVENTFUL. AUTHOR'S COMMENT: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE WAS NOT REPORTED BY THE AUTHORS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, CASE REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND IN THE 3-MONTH HYSTEROSALPINGOGRAM (HSG) FOLLOW-UP SHOWED THAT THE RIGHT TUBE WAS OCCLUDED AND THE DEVICE WAS CORRECTLY PLACED. CONVERSELY, THE LEFT TUBE WAS PATENT AND THE DEVICE WAS ABNORMALLY LOCATED IN THE LEFT SIDE OF THE PELVIS, AWAY FROM THE TUBAL DISTAL EXTREMITY. A LAPAROSCOPY WAS PERFORMED AND THE RESULT SHOWED THAT THE LEFT DEVICE WAS DISPLACED IN THE LEFT LOWER QUADRANT, EMBEDDED INTO THE OMENTUM. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH NOT REPORTED AS SUCH, THE MOST LIKELY MECHANISM FOR THE LEFT COIL TO BE FOUND IN THE ABDOMEN, WOULD BE THROUGH A UTERINE/FALLOPIAN TUBE PERFORATION. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THIS EVENT WAS DIAGNOSED BY LAPAROSCOPY ABOUT 3 MONTHS AFTER ESSURE INSERTION. IT WAS REPORTED THAT THERE WERE NO SIGNS OF PERFORATION. THE DEVICE WAS EASILY REMOVED BY BLUNT AND SHARP DISSECTION. GIVEN A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A BILATERAL TUBAL STERILIZATION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: PAINFUL PROCEDURE DURING ESSURE INSERTION AND THE HYSTEROSCOPIC STERILIZATION WAS HAMPERED BY THE PRESENCE OF ENDOMETRIAL CAVITY ADHESIONS (DEVICE DIFFICULT INSERTION). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 16-JAN-2015 (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00022	BAYER HEALTHCARE LLC	1/12/2015	1/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** IT

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE "THE ESSURE HYSTEROSCOPIC STERILISATION PROCEDURE" ON 16-DEC-2014. THIS ARTICLE WAS DERIVED FROM A LITERATURE REVIEW TITLED "RISK OF ESSURE MICROINSERT ABDOMINAL MIGRATION: CASE REPORT AND REVIEW OF LITERATURE". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION. CASE REPORT: THIS FEMALE PATIENT OF AN UNSPECIFIED AGE WHO HAD TUBAL OSTIA WERE VERY LATERAL, ONE OF THE DEVICES WAS EVENTUALLY FOUND TO HAVE MIGRATED DISTALLY AND THE OTHER TO HAVE PERFORATED THE TUBE NEAR THE CORNUA. ALTHOUGH THE CORRECT NUMBER OF COILS WAS SEEN IN THE CAVITY AT THE END OF THE INITIAL PROCEDURE, THE WOMAN DID EXPERIENCE PAIN AT THE TIME OF INSERTION, WHICH SETTLED SPONTANEOUSLY. SHE WAS WELL ENOUGH TO GO HOME, BUT SUBSEQUENTLY PRESENTED SIX DAYS LATER WITH PAIN ON THE LEFT SIDE. AN ULTRASOUND SCAN REVEALED BRIGHT ECHOES OF THE DEVICES WITHIN THE MYOMETRIUM AND NO OTHER PATHOLOGY WAS NOTED. SHE WAS TREATED WITH ANTIBIOTICS FOR A POSSIBLE INFECTION AND ALLOWED HOME THE SAME DAY. THE ABDOMINAL X-RAY AT THREE MONTHS SUGGESTED THAT THE LEFT DEVICE WAS INAPPROPRIATELY SITED; THIS WAS CONFIRMED BY OUTPATIENT HYSTEROSCOPY, WHICH REVEALED AN ABSENT DEVICE ON THE LEFT SIDE. THE PATIENT WAS THEREFORE OFFERED A DIAGNOSTIC LAPAROSCOPY AND TUBAL STERILISATION. AT LAPAROSCOPY THE CORNUAL PERFORATION WAS APPARENT ON THE RIGHT SIDE AND THE LEFT DEVICE WAS LOCATED FREE ON THE OMENTUM. BOTH DEVICES WERE REMOVED WITHOUT DIFFICULTY. AUTHORS COMMENT: EVEN IF THE MICROINSERT WAS COMPLETELY EMBEDDED INTO THE OMENTUM, NO SIGNS OF INFLAMMATION OR ADHESIONS WERE OBSERVED. DEVICE DISPLACEMENT MIGHT BE EXPLAINED BY THE PRESENCE OF LATERALLY SITED OSTIA, BY TUBAL RESISTANCE, OR BY ENDOMETRIAL CAVITY

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ADHESIONS. ABSTRACT: ESSURE HYSTEROSCOPIC STERILISATION IS A MINIMALLY INVASIVE, OUTPATIENT APPROACH TO FEMALE STERILISATION, WHICH AVOIDS THE POSSIBLE COMPLICATIONS OF LAPAROSCOPIC STERILISATION. WE PRESENT OUR EXPERIENCE OF THE FIRST 100 CASES OF THE PROCEDURE PERFORMED IN OUR UNIT BETWEEN NOVEMBER 2002 AND NOVEMBER 2005. THE MODIFIED ESSURE DEVICES WERE INTRODUCED IN APRIL 2004 (37 PROCEDURES WERE PERFORMED WITH THE OLD DEVICES AND 63 PROCEDURES WITH THE MODIFIED DEVICES). THE SUCCESSFUL PLACEMENT RATE OVERALL WAS 87%. INSERTION FAILURE, MORE COMMON WITH THE OLDER DEVICES AND IN THE EARLIER PART OF THE SERIES, WAS DUE TO PRE-EXISTING TUBAL DAMAGE IN THE MAJORITY OF CASES. OUR PATIENT SATISFACTION SURVEY REVEALED THAT THE PROCEDURE WAS ASSOCIATED WITH LOW PAIN SCORES AND HIGH SATISFACTION LEVELS. OTHER CASES FROM SAME ARTICLE ARE (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, CASE REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT LAPAROSCOPY THE CORNUAL PERFORATION WAS APPARENT ON THE RIGHT SIDE (INTERPRETED AS UTERINE PERFORATION) AND THE LEFT DEVICE WAS LOCATED FREE ON THE OMENTUM (INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY). BOTH EVENT ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE EXACT DATE AND THE MECHANISM OF DISLOCATION AND PERFORATION ARE NOT KNOWN. NO SIGNS OF INFLAMMATION OR ADHESIONS WERE OBSERVED. THESE EVENTS WERE DIAGNOSED ABOUT 3 MONTHS AFTER ESSURE INSERTION DURING LAPAROSCOPY. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS REQUIRED (BOTH DEVICES WERE REMOVED BY LAPAROSCOPY). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 16.JAN.2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOUL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040143	BAYER	1/12/2015	1/12/2015

Event Information:

Event Date (B3): 9/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BLOATING (PREGNANT LOOKING), PAIN AND CRAMPING, SPOTTING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040263	BAYER	1/12/2015	1/22/2015

Event Information:

Event Date (B3): 4/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/6/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE PERMANENT BIRTH CONTROL. I HAD IT PLACE IN (B)(6) 2014. SINCE THEN, MY QUALITY OF LIFE HAS LESSENED DRASTICALLY. I HAVE HAD TO GO TO THE ER FOR PAIN A COUPLE OF TIMES, BECAUSE THE PAIN WAS SO BAD (MOSTLY WHEN I AM OVULATING) THAT I COULDN'T EVEN CARE FOR MY CHILDREN. I HAVE DEVELOPED CYSTIC ACNE, WHEN I NEVER HAD ACNE PROBLEMS BEFORE. MY MENSTRUAL CYCLES ARE EXTREMELY HEAVY AND FULL OF CLOTS. I HAVE NEVER EXPERIENCED THIS BEFORE ESSURE. WHEN I AM OVULATING I HAVE SEVERE PAIN IN MY PELVIS THAT FEELS LIKE A KNIFE STABBING ME. I HAVE GAINED WEIGHT, NO MATTER HOW MUCH I EXERCISE OR DIET. I AM BLOATED SEVERELY AT TIMES, SO MUCH SO I LOOK LIKE I AM QUITE PREGNANT. KEEP IN MIND, I AM ONLY (B)(6). THIS IS NO LIFE FOR ANYONE. I WANT DESPERATELY TO HAVE THIS REMOVED BY NO DOCTORS WILL LISTEN AND THE ONLY WAY TO HAVE IT REMOVED WITHOUT HAVING A FULL HYSTERECTOMY IS TO PAY THOUSANDS OF DOLLARS OUT OF POCKET. I GOT THIS DEVICE AS A PERMANENT BIRTH CONTROL BECAUSE I WAS TOLD IT WAS THE LEAST INVASIVE. IT HAS RUINED MY LIFE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00020	BAYER HEALTHCARE LLC	1/12/2015	2/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B66021

Single Use: Y
Implant Date (E6): 12/15/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2014, LOT NUMBER B66021, FOR PERMANENT CONTRACEPTION. ON (B)(6) 2014, THE ESSURE COIL PLACED FINE ON LEFT SIDE BUT THE PROXIMAL PART OF OUTER COIL, THE SILVER BAND, FELL OFF AND WENT INTO UTERUS AND SILVER BAND REMOVED. BILATERAL PLACEMENT ACHIEVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 03-JAN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE CANNOT CONFIRM THIS QUALITY COMPLAINT; HOWEVER, BASED ON THE COMPLAINT DESCRIPTION PROVIDED, WE ARE ABLE TO CONCLUDE THAT A QUALITY ISSUE IS PLAUSIBLE. IT IS POSSIBLE DURING THE MANUFACTURING ASSEMBLY PROCESS A SMALL GAP WAS LEFT BETWEEN THE INNER COIL AND INNER CATHETER (THEY SHOULD BE BUTTED TOGETHER DURING ASSEMBLY). WHEN THE OUTER COIL OF THE MICRO-INSERT IS WOUND DOWN A SMALL PORTION OF THE COIL CAN BECOME TRAPPED IN THE GAP. IF A DEVICE HAS THIS ISSUE, WHEN THE PHYSICIAN PRESSES THE BUTTON TO RELEASE THE MICROINSERT, THE OUTER COIL MAY SEVER ITSELF AS IT IS BEING DEPLOYED FROM THE CATHETER. THIS SEVERING OCCURS INSIDE THE CATHETER PRIOR TO THE PIECES BEING DEPLOYED FROM THE

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CATHETER. THE SEVERING OF THE COILS INSIDE THE CATHETER DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PATIENT. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO REPORTED PRODUCT TECHNICAL ISSUE (BREAKAGE). THE AE CASE REFERS ALSO TO A USABILITY ISSUE (COMPLICATED INSERTION). HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS WERE REPORTED. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH B66021 (PRODUCTION DATE 30-AUG-2013 AND EXPIRATION DATE 31-AUG-2016) WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT, BUT PLAUSIBLE. ACCORDING TO THE TECHNICAL ASSESSMENT A QUALITY DEFECT WAS NOT CONFIRMED BUT CONSIDERED PLAUSIBLE. BASED ON THE PROVIDED INFORMATION THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING (B)(4): DEVICE BREAKAGE. HOWEVER, AN ASSESSMENT REGARDING A CAUSAL RELATIONSHIP BETWEEN A POTENTIAL QUALITY DEFECT AND AN ADVERSE EVENT IS NOT POSSIBLE AS NO ADVERSE EVENT WAS REPORTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND DURING ESSURE INSERTION THE PROXIMAL PART OF OUTER COIL, THE SILVER BAND, FELL OFF AND WENT INTO UTERUS. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS IT WAS REGARDED AS LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THIS EVENT OCCURRED DURING ESSURE INSERTION. THE SILVER BAND WAS REMOVED. BILATERAL PLACEMENT WAS ACHIEVED. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT, BUT PLAUSIBLE. ACCORDING TO THE TECHNICAL ASSESSMENT A QUALITY DEFECT WAS NOT CONFIRMED, BUT CONSIDERED PLAUSIBLE. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED ON 12-JUN-2015. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00023	BAYER HEALTHCARE LLC	1/13/2015	1/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE "THE ESSURE HYSTEROSCOPIC STERILISATION PROCEDURE" ON 16-DEC-2014. THIS ARTICLE WAS EXTRACTED FROM A LITERATURE REVIEW TITLED "RISK OF ESSURE MICROINSERT ABDOMINAL MIGRATION: CASE REPORT AND REVIEW OF LITERATURE". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION. BAYER DEVICE ESSURE WAS REPORTED. CASE REPORT: IN THIS FEMALE PATIENT OF UNSPECIFIED AGE, NORMALLY SITED DEVICE MIGRATED IN A WOMAN WHO DID NOT EXPERIENCE PAIN AT THE TIME OF THE PROCEDURE. A HYSTEROSALPINGOGRAM AT THREE MONTHS REVEALED IN FACT ABSENT FILLING OF EITHER TUBE, WITH A CORRECTLY SITED DEVICE ON THE RIGHT, BUT A MORE DISTAL PLACEMENT ON THE LEFT SIDE. AN OUTPATIENT HYSTEROSCOPY AND TRANSVAGINAL SCAN CONFIRMED THE ABSENCE OF A CORRECTLY SITED DEVICE ON THE LEFT SIDE AND AT A SUBSEQUENT LAPAROSCOPY, THE MIGRATED DEVICE WAS AGAIN LOCATED ON THE OMENTUM AND EASILY REMOVED. AUTHORS COMMENT: EVEN IF THE MICROINSERT WAS COMPLETELY EMBEDDED INTO THE OMENTUM, NO SIGNS OF INFLAMMATION OR ADHESIONS WERE OBSERVED. DEVICE DISPLACEMENT MIGHT BE EXPLAINED BY THE PRESENCE OF LATERALLY SITED OSTIA, BY TUBAL RESISTANCE, OR BY ENDOMETRIAL CAVITY ADHESIONS. ABSTRACT: ESSURE HYSTEROSCOPIC STERILISATION IS A MINIMALLY INVASIVE, OUTPATIENT APPROACH TO FEMALE STERILISATION, WHICH AVOIDS THE POSSIBLE COMPLICATIONS OF LAPAROSCOPIC STERILISATION. WE PRESENT OUR EXPERIENCE OF THE FIRST 100 CASES OF THE PROCEDURE PERFORMED IN OUR UNIT BETWEEN NOVEMBER 2002 AND NOVEMBER 2005. THE MODIFIED ESSURE DEVICES WERE INTRODUCED IN APRIL 2004 (37 PROCEDURES WERE PERFORMED WITH THE OLD DEVICES AND 63 PROCEDURES WITH THE MODIFIED DEVICES). THE SUCCESSFUL PLACEMENT RATE OVERALL WAS 87%. INSERTION FAILURE,

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MORE COMMON WITH THE OLDER DEVICES AND IN THE EARLIER PART OF THE SERIES, WAS DUE TO PRE-EXISTING TUBAL DAMAGE IN THE MAJORITY OF CASES. OUR PATIENT SATISFACTION SURVEY REVEALED THAT THE PROCEDURE WAS ASSOCIATED WITH LOW PAIN SCORES AND HIGH SATISFACTION LEVELS. OTHER CASES FROM SAME ARTICLE ARE (B)(4). COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE, ARTICLE ENTITLED "THE ESSURE HYSTEROSCOPIC STERILISATION PROCEDURE" WHICH WAS EXTRACTED FROM A LITERATURE REVIEW TITLED "RISK OF ESSURE MICROINSERT ABDOMINAL MIGRATION: CASE REPORT AND REVIEW OF LITERATURE". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING CONFIRMATION TEST LEFT DEVICE WAS IMPROPERLY SITED IN OMENTUM. THE EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE ESSURE REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE HYSTEROSALPINGOGRAM PERFORMED AT THREE MONTHS REVEALED A CORRECTLY SITED DEVICE ON THE RIGHT, BUT A MORE DISTAL PLACEMENT ON THE LEFT SIDE. A HYSTEROSCOPY AND TRANSVAGINAL SCAN CONFIRMED THE ABSENCE OF DEVICE ON THE LEFT AND AT A SUBSEQUENT LAPAROSCOPY, THE MIGRATED DEVICE WAS LOCATED ON THE OMENTUM AND WAS EASILY REMOVED. GIVEN THE NATURE OF THE EVENT, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. REQUIRED INTERVENTION (LAPAROSCOPY) WAS REPORTED, THEREFORE, THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 16-JAN-2015. THE PTC GLOBAL (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00024	BAYER HEALTHCARE LLC	1/13/2015	1/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** IT

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 16-DEC-2014, ARTICLE ENTITLED "INCORRECT POSITION OF ESSURE MICROINSERTS 3 MONTHS AFTER SUCCESSFUL BILATERAL PLACEMENT". IT REFERS TO A (B)(6) FEMALE PATIENT WHO UNDERWENT HYSTEROSCOPIC STERILIZATION USING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). THIS PATIENT'S CASE REPORT WAS ALSO MENTIONED IN THE ARTICLE ENTITLED "RISK OF ESSURE MICROINSERT ABDOMINAL MIGRATION: CASE REPORT AND REVIEW OF LITERATURE". BAYER DEVICE ESSURE WAS REPORTED. CASE REPORT: PATIENT WAS A (B)(6) MULTIPAROUS WOMAN. NO ABNORMALITIES WERE SEEN DURING HYSTEROSCOPY. DURING INSERTION OF THE MICROINSERT IN THE LEFT FALLOPIAN TUBE, A RESISTANCE OCCURRED AND WAS EVENTUALLY OVERWON. THIS WAS THOUGHT TO BE A TUBAL SPASM. WHEN BILATERAL PLACEMENT WAS COMPLETED, THREE COILS WERE VISIBLE ON THE RIGHT SIDE AND SIX COILS ON THE LEFT SIDE. PROCEDURE TIME WAS 10 MIN. AT TVU (TRANSVAGINAL ULTRASOUND) FOLLOW-UP AFTER 3 MONTHS, BOTH INSERTS WERE NOT CLEARLY VISIBLE. ON PELVIC X-RAY AN ABNORMAL CONFIGURATION OF THE LEFT MICROINSERT WAS SEEN. IN EVALUATING MICROINSERT POSITION WITH X-RAY OR HSG (HYSTEROSALPINGOGRAM), IT IS VERY IMPORTANT TO NOTE THE MARKERS FOR THE PROXIMAL AND DISTAL ENDS OF THE INNER AND OUTER COIL. THE INNER COIL CAN BE RECOGNIZED VERY EASILY AS A THIN LINE STRUCTURE WITH TWO LANDMARKS: THE DISTAL END, MOST LATERAL (FIRST MARKER), AND THE PROXIMAL END (THIRD MARKER). THE DISTAL END OF THE OUTER COIL (SECOND MARKER) IS NEXT TO THE FIRST MARKER, AND THE PLATINUM BAND AT THE PROXIMAL END OF THE OUTER COIL IS VISIBLE AS THE FOURTH MARKER. IN A NORMAL CONFIGURATION, THE FOURTH MARKER IS IN LINE WITH THE OTHER THREE MARKERS. IN THIS CASE, THE FOURTH MARKER WAS NOT IN LINE WITH THE OTHER THREE MARKERS AND TOO CLOSE TO THE SECOND MARKER. THE HSG SHOWED PATENCY OF THE

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LEFT TUBE. RETROSPECTIVELY, THE PATIENT HAD EXPERIENCED ABDOMINAL PAIN FOR SEVERAL WEEKS AFTER PLACEMENT OF THE ESSURE SYSTEM. PERFORATION OF THE LEFT DEVICE INTO THE ABDOMINAL CAVITY WAS SUSPECTED, AND A LAPAROSCOPY WAS PERFORMED. THE ESSURE MICROINSERT WAS DETECTED IN THE OMENTUM. NO SIGNS OF INFLAMMATION OR ADHESIONS WERE SEEN. DURING LAPAROSCOPY, THE INSERT WAS REMOVED, AND TUBAL LIGATION OF THE LEFT TUBE WAS PERFORMED USING A FILSHIE CLIP. AUTHORS COMMENT: THE LEFT INSERT PERFORATED INTO THE ABDOMINAL CAVITY, A RESISTANCE THOUGHT TO BE A TUBAL SPASM WAS OVERWON. IN RETROSPECT, THIS WAS PROBABLY THE MOMENT OF PERFORATION. THE INSERT MIGRATED TO THE ABDOMINAL CAVITY IN THE WEEKS AFTER THE PROCEDURE, CAUSING THE PATIENT ABDOMINAL PAIN. TUBAL SPASMS CAN OCCUR DURING A HYSTEROSCOPIC PROCEDURE. ABSTRACT: OBJECTIVE: TO DESCRIBE INCORRECT POSITIONS OF ESSURE MICROINSERTS DETECTED AT 3 MONTHS FOLLOW-UP. DESIGN: CASE REPORT. SETTING: OUTPATIENT DEPARTMENT OF OBSTETRICS AND GYNECOLOGY IN A DUTCH TEACHING HOSPITAL. PATIENT(S): INITIAL SERIES OF 100 PATIENTS WHO UNDERWENT HYSTEROSCOPIC STERILIZATION USING ESSURE BETWEEN DECEMBER 2003 AND JUNE 2004. INTERVENTION(S): HYSTEROSCOPIC PLACEMENT OF THE ESSURE SYSTEM, FOLLOW-UP AT 3 MONTHS WITH TRANSVAGINAL ULTRASOUND (TVU), AND HYSTEROSALPINGOGRAPHY. MAIN OUTCOME MEASURE(S): BILATERAL PLACEMENT RATE, TUBAL OBSTRUCTION, AND DETECTION OF INCORRECT ESSURE MICROINSERT LOCALIZATION AT FOLLOW-UP AFTER APPARENT SUCCESSFUL BILATERAL PLACEMENT. RESULT(S): BILATERAL PLACEMENT OF ESSURE MICROINSERTS IN ONE SESSION WAS SUCCESSFUL IN 93 WOMEN (93%). IN 90 OF THESE WOMEN (96.8%), TUBAL OBSTRUCTION WAS PROVEN AT FOLLOW-UP 3 MONTHS LATER. THREE INCORRECT POSITIONS OF AN ESSURE INSERT WERE SEEN: TWO EXPULSIONS AND ONE PERFORATION INTO THE ABDOMINAL CAVITY. CONCLUSION(S): INCORRECT POSITION OF ESSURE MICROINSERTS WAS SEEN ONLY WHEN THE INITIAL PLACEMENT PROCEDURE WAS DIFFICULT. WHEN A PLACEMENT PROCEDURE WAS DIFFICULT OR OTHER SUBOPTIMAL CONDITIONS ARE PRESENT DURING THE PROCEDURE, WE ADVISE PERFORMING A TVU OR PELVIC X-RAY IN THESE WOMEN 4 WEEKS AFTER THE PROCEDURE OR AFTER THE FIRST VAGINAL BLEEDING, INSTEAD OF WAITING FOR FOLLOW-UP AFTER 3 MONTHS. OTHER CASES FROM SAME ARTICLE ARE (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT WAS DERIVED FROM LITERATURE AND REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE A TUBAL RESISTANCE/ TUBAL SPASM OCCURRED. LATER DURING FOLLOW-UP A PERFORATION OF THE LEFT DEVICE INTO THE ABDOMINAL CAVITY WAS SUSPECTED; PATIENT WAS SUBMITTED TO A LAPAROSCOPIC SURGERY AND ESSURE MICRO-INSERT WAS DETECTED IN OMENTUM. THE REPORTED EVENTS, REGARDED AS FALLOPIAN TUBE SPASM AND UTERINE PERFORATION ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION; UTERINE PERFORATION WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE, WHILE THE REMAINING EVENT IS NON-SERIOUS. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A COMPLETE PERFORATION HAS OCCURRED, ESSURE CAN BE FOUND IN THE ABDOMINAL CAVITY AS IT PERFORATES THE WHOLE UTERINE WALL (MYOMETRIUM). IN THIS PARTICULAR CASE THE PATIENT PRESENTED ABDOMINAL PAIN AND A PERFORATION OF ESSURE WAS DIAGNOSED; THE INSERT WAS SURGICALLY REMOVED. THE REPORTER CONSIDERED THAT THE PERFORATION PROBABLY OCCURRED DURING ESSURE INSERTION. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED EVENTS CANNOT BE EXCLUDED AND DUE TO THE REQUIRED INTERVENTION, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON 16-JAN-2015. (B)(4) FINAL ASSESSMENT THIS IS AN ESSURE 205 CASE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00026	BAYER HEALTHCARE LLC	1/13/2015	1/13/2015

Event Information:

Event Date (B3): 11/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/29/2013
Explant Date (E7): 11/20/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 16-DEC-2014. IT DESCRIBES A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR PERMANENT STERILIZATION. IT WAS REPORTED THAT HSG CONFIRMATION TEST WAS NOT DONE. PREGNANCY AND MISCARRIAGE OCCURRED DURING (B)(6) 2014. ON (B)(6) 2014, PATIENT UNDERWENT A LAP TUBAL AND PHYSICIAN FOUND THAT ONE OF THE INSERTS WAS SITTING ON THE ROUND LIGAMENT IN THE CAVITY. BOTH TUBES WERE TAKEN AND PATIENT WAS FINE. THE OUTCOME OF THE EVENTS ONE OF THE INSERTS SITTING ON THE ROUND LIGAMENT IN CAVITY AND PREGNANCY WITH SUBSEQUENT MISCARRIAGE WAS RECOVERED / RESOLVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, GOT PREGNANCY WITH SUBSEQUENT MISCARRIAGE AND DURING LAB TUBAL, IT WAS FOUND OUT THAT ONE OF THE INSERTS WAS SITTING ON THE ROUND LIGAMENT IN CAVITY. THE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE, EXCEPT PREGNANCY WHICH IS NON-SERIOUS. THE THIRD EVENT, INTERPRETED AS DEVICE DISLOCATION, AND PREGNANCY ARE LISTED, WHILE MISCARRIAGE IS UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE A DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALSO, UNINTENDED PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, THE CONFIRMATION TEST WAS NOT DONE AND PREGNANCY AND MISCARRIAGE OCCURRED

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ONE YEAR AFTER THE PLACEMENT PROCEDURE. THE PREGNANCY COULD BE A CONSEQUENCE OF NON-COMPLIANT USE OR A RESULT OF THE DEVICE DISLOCATION. HOWEVER, IT IS NOT POSSIBLE TO KNOW WHEN THIS DISLOCATION REALLY OCCURRED, THEREFORE, A DEVICE INEFFICACY CANNOT BE TOTALLY EXCLUDED AND CAUSAL RELATIONSHIP REGARDING PREGNANCY AND DISLOCATION WITH ESSURE USE IS ASSESSED AS RELATED. ALTHOUGH GESTATIONAL AGE HAS NOT BEEN PROVIDED, SPONTANEOUS ABORTIONS OCCUR MOSTLY DURING THE FIRST 12 WEEKS OF PREGNANCY AND THE VAST MAJORITY OF THESE CASES ARE DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS, SO THE EVENT IS CONSIDERED AS UNRELATED TO ESSURE. SINCE DURING LAP TUBAL, A SALPINGECTOMY WAS PERFORMED, THE CASE IS ASSESSED AS INCIDENT. THE PATIENT RECOVERED. FURTHER INFORMATION AND TECHNICAL ANALYSIS HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 19-JAN-2015. THE (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040179	BAYER	1/13/2015	1/13/2015

Event Information:

Event Date (B3): 10/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME ANXIETY, FATIGUE, SCIATIC LEG PAIN, SEVERE OUTRAGEOUS PAINFUL CRAMPS, HEADACHES, POSSIBLE CANCER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040180	BAYER	1/13/2015	1/13/2015

Event Information:

Event Date (B3): 7/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOSS OF HAIR, NUMBNESS IN ARMS AND HANDS, SEVERE BACK PAIN AND SEVERE ABDOMINAL PAIN WITH ONSET OF OVULATION AND MENSTRUATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040181	BAYER	1/13/2015	1/13/2015

Event Information:

Event Date (B3): 7/13/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN, NAUSEA, BLOAT, METALLIC TASTE IN MOUTH, HEADACHES, DIZZINESS, WEIGHT GAIN....ALL LABS NORMAL, CONSULT TO REMOVE COILS/HYSTERECTOMY COMING UP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040182	BAYER	1/13/2015	1/13/2015

Event Information:

Event Date (B3): 4/28/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN BACK, HIPS AND LEGS. FATIGUE. TERRIBLE INFLAMMATION. MIGRAINES. PELVIC PAIN. VERTIGO. STROKE. SEIZURES. WEAKNESS IN LEFT HAND SIDE OF BODY. NUMBNESS. BURNING IN HANDS AND FEET. NIGHT SWEATS. HEAVY PERIODS. (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040183	BAYER	1/13/2015	1/13/2015

Event Information:

Event Date (B3): 12/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MENSTRUAL PERIODS ARE VERY PAINFUL, BACK PAIN, FATIGUE, BLOATED, WEIGHT GAIN, TINGLE IN FEET, HEADACHES, RASH ON LEG, PERIODS COME WHENEVER THEY FEEL LIKE IT AND I ALWAYS FEEL PREGNANT, I LEAK URINE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040184	BAYER	1/13/2015	1/13/2015

Event Information:

Event Date (B3): 8/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD ESSURE PUT INTO MY BODY, I HAVE HAD THE FOLLOWING PROBLEMS. SOME PROBLEMS ARE GETTING WORSE. SEVERE PELVIC PAIN, WEIGHT GAIN, HEAVY/SEVERELY PAINFUL PERIODS WHICH REQUIRED SEVERAL D AND C'S, URINARY INCONTINENCE, DIABETES, GALL BLADDER REMOVAL, FIBROMYALGIA, UNEXPLAINED PAIN ALL OVER MY BODY, FIBROIDS, INCREASED ALLERGIES, WEAKNESS, TIREDNESS, DEBILITATING MIGRAINES/HEADACHES, PROBLEMS CONCENTRATING, EYE PROBLEMS, UNEXPLAINED INFECTIONS, CONTINUES YEAST INFECTIONS AND UTI'S. AT (B)(6), I AM IN MENOPAUSE AND SCHEDULED FOR A HYSTERECTOMY IN (B)(6) BECAUSE DESPITE THE FACT THAT I NO LONGER HAVE PERIODS, I HAVE PAIN. THESE ARE JUST A FEW OF THE PROBLEMS I HAVE EXPERIENCED SINCE HAVING ESSURE IMPLANTED. I DO HAVE OTHER PROBLEMS AS WELL BUT SINCE I DON'T HAVE MY MEDICAL RECORDS RIGHT IN FRONT OF ME, I AM UNABLE TO THINK OF THE OTHER DIAGNOSES I'VE BEEN GIVEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040185	BAYER	1/13/2015	1/13/2015

Event Information:

Event Date (B3): 7/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, BLOAT, METALLIC TASTE IN MOUTH, HEAVY PERIODS WITH BLOOD CLOTS, HEADACHES, JOINT PAIN, PAINFUL SEX. ALL LAB WORK HAS BEEN NORMAL, AND HAVE A CONSULT FOR COILS TO BE REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040186	BAYER	1/13/2015	1/13/2015

Event Information:

Event Date (B3): 10/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I HAD ESSURE PUT IN MY BLOOD PRESSURE DROPPED AND I HAD CHILLS AND WEAKNESS. IT WAS SUPPOSED TO BE LESS THAN 30 MINUTES AND I WAS AT THE DR OFFICE FOR ALMOST 3 HRS WAITING FOR MY BLOOD PRESSURE TO COME BACK UP. THE DR ALMOST HAD TO SEND ME TO THE HOSPITAL. AFTER HAVING THE ESSURE I HAD NUMEROUS COMPLAINTS INCLUDING PAINFUL INTERCOURSE, NO PERIOD FOR ALMOST A YEAR, PAIN IN MY ABDOMEN LEFT AND RIGHT. I ENDED UP HAVING TO TAKE BIRTH CONTROL PILLS TO TRY TO FIX THE SIDE EFFECTS. THAT DIDN'T WORK. AFTER NUMEROUS OPTIONS I HAD TO HAVE A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040269	BAYER	1/13/2015	1/22/2015

Event Information:

Event Date (B3): 1/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 10/10/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, CRAMPS, SEVERE BLEEDING, CLOTS WITH CYCLES, HEADACHES, BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040270	BAYER	1/13/2015	1/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/12/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MAJOR HEALTH ISSUES AFTER ESSURE: ITCHING, BLOATING, HORRIBLE CRAMPS, WEIGHT GAIN, EXTREMELY HEAVY BLEEDING WITH LARGE CLOTS, AUTOIMMUNE DISEASE (FIBROMYALGIA), SEVERE HEADACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040273	BAYER	1/13/2015	1/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN GETTING NAUSEOUS, UNBEARABLE PELVIC PAIN, NEEDLE LIKE PAIN, HEADACHES, LOWER BACK PAIN, NEEDLE LIKE PAIN SHOOTING DOWN MY LEGS, ABDOMINAL PAIN, PAIN RUNNING TOWARDS MY LOWER BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040274	CONCEPTUS, INC	1/13/2015	1/22/2015

Event Information:

Event Date (B3): 8/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE IN 2009, HANDS AND FEET SWELL, BACK PAIN. IN 2010 BECAME PREGNANT WITH A 100% CONFIRMED TUBES BLOCKED. IN 2012, HORRIBLE LOWER BACK PAIN, INFLAMMATION, FATIGUE, HIVES, ANXIETY, STOMACH PAIN, DEPRESSION. BEFORE ESSURE I WAS VERY HEALTHY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040275	BAYER	1/13/2015	1/22/2015

Event Information:

Event Date (B3): 5/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 8/8/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN 09. WITHIN MONTHS I STARTED HAVING ABDOMINAL PAIN, HEADACHES, WEIGHT GAIN, AND DEPRESSION. AS THE YEARS PROGRESSED MY SYMPTOMS WORSENED AND BECAME MORE COMPLEX. FOUR AND A HALF YEARS LATER I HAD DEBILITATING WIDE SPREAD PAIN, CHRONIC FATIGUE, AND SEVERE ABDOMINAL PAIN AS WELL AS BACK PAIN, BREAST PAIN, DIZZINESS, STABBING PELVIC PAIN, ANXIETY, PANIC ATTACKS, FREQUENT URINATION, BRAIN FOG, LOSS OF ENERGY, DENTAL ISSUES, EXCESSIVE VAGINAL DISCHARGE, LOTS OF YEAST INFECTIONS, ALLERGY AND SINUS PROBLEMS, PAINFUL INTERCOURSE, KIDNEY STONES, AND BLADDER INFECTIONS. MY DOCTORS DIAGNOSED ME WITH FIBROMYALGIA AND CHRONIC FATIGUE SYNDROME. ANXIETY AND DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040282		1/13/2015	1/22/2015

Event Information:

Event Date (B3): 8/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2007
Explant Date (E7): 8/25/2011
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2007 IN AN OUTPATIENT HOSPITAL PROCEDURE. LESS THAN 6 MONTHS FOLLOWING ITS PLACEMENT, I BEGAN TO NOTICE INCREASED ABDOMINAL CRAMPING OUTSIDE OF MENSES, AND INTENSIFIED DURING MENSES. I EXPERIENCED THIS CONSISTENTLY WITH MODERATE TO SOMETIMES SEVERE PAIN. MENSES WERE AT TIMES HEAVIER THAN PRIOR TO THE PLACEMENT. DURING PHYSICAL ACTIVITIES LIKE EXERCISE THE PAIN INTENSIFIED MAKING IT DIFFICULT TO FINISH. SEXUAL INTERCOURSE WAS PAINFUL WITH A TIGHT SQUEEZING AND STABBING SENSATION STARTING ON BOTH SIDES OF MY PELVIC REGION AND LASTING FOR MORE THAN AN HOUR AFTER. I DID NOT HAVE THESE ISSUES UNTIL I HAD ESSURE IMPLANTED. I WAS TOLD BY A DOCTOR I WAS EXPERIENCING ALLERGIC REACTION TO THE COILS SO I FOUND A DOCTOR WHO WOULD REMOVE THE COILS AND HAD THE PROCEDURE COMPLETED IN (B)(6) 2011. I WAS MISERABLE FOR THE 4 YEARS THEY WERE IMPLANTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040289	BAYER	1/13/2015	1/22/2015

Event Information:

Event Date (B3): 10/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/18/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2012. BEFORE ESSURE I WAS HAVING CLOTTING ISSUES AND HEAVY PERIODS. MY DR TOLD ME HE FELT ESSURE WAS THE ANSWER FOR ME. THE FIRST YEAR WAS GOOD. THEN ABOUT 9 MONTHS AGO, THE VERY HEAVY LONG PERIODS STARTED, ALONG WITH WORSE CLOTTING THAN I HAD BEFORE. IN (B)(6), FOR THE FIRST TIME SINCE I HAD MY SON 13 YEARS AGO I WAS LATE FOR MY PERIOD. I GOT ONLINE AND DISCOVERED THAT A LOT OF WOMEN WERE HAVING THE SAME PROBLEM AS I. THANKS HEAVENS I WAS NOT PREGNANT, BUT THEN THE CRAMPING STARTED AND I STARTED DOUBLING OVER IN PAIN. EVERYDAY, I DON'T KNOW HOW BAD THE PAIN WILL BE. SOME DAYS LITTLE, BUT LOTS OF DAYS I AM DOUBLING OVER IN PAIN. MY DR DID AN INTERNAL AND EXTERNAL ULTRASOUND AND THE ESSURE STILL IN PLACE BUT SHE FEELS I WILL NEED A HYSTERECTOMY. I AM IN GOOD HEALTH AND ONLY 42. I AM WORSE OFF NOW THAN I WAS BEFORE IT WAS IMPLANTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00025	BAYER HEALTHCARE LLC	1/13/2015	2/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/11/2014
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. THE PROCEDURE WAS PERFORMED IN OFFICE BY A PHYSICIAN WHO WAS EXPERIENCED WITH ESSURE. THE PATIENT RECEIVED CONSCIOUS SEDATION AND WAS COMFORTABLE. THE FIRST DEVICE WAS INSERTED WITHOUT PROBLEMS. THE SECOND DEVICE WAS PLACED INTO TUBE AND THE PHYSICIAN STATED THAT THE GOLD BAND WAS CLEARLY VISIBLE OUTSIDE OSTIUM (OF NOTE, PRIOR TO DEPLOYMENT THE PHYSICIAN'S ASSISTANT ROTATED THE DEVICE IN ORDER TO MAKE SURE THAT IT WAS THE GOLD BAND THAT WAS VISIBLE). THE DEPLOYMENT PROCESS WAS PERFORMED AND THE PHYSICIAN BELIEVED THAT SHE COULD SEE THE DEPLOYED OUTER COILS AT THE OSTIUM. AFTER ROLLING BACK THE THUMBWHEEL SECOND TIME, THE DELIVERY CATHETER APPEARED TO REMAIN ATTACHED. THE SALES REPRESENTATIVE THAT WAS PRESENT ADVISED THE PHYSICIAN TO WAIT A FEW MINUTES. SHE DID NOT WAIT LONG AND ROTATED THE DEVICE IN AN ATTEMPT TO DETACH IT. SHE WAS AGAIN ADVISED TO WAIT IN CASE THERE WAS A DEGREE OF TUBAL SPASM. THE PHYSICIAN CONTINUED TO ATTEMPT DETACHMENT AND, AT THAT POINT, THE OUTER COIL BROKE (MORE THAN 50 %, ACCORDING TO HER). THE DELIVERY CATHETER THEN DETACHED. THERE WAS STILL COIL LEFT IN THE TUBE, WHICH THE PHYSICIAN REMOVED WITH FORCEPS, AND ALSO AN UNWOUND COIL (UNCLEAR IF IT WAS FROM DELIVERY CATHETER), WHICH SHE ATTEMPTED TO REMOVE. WIRE WAS LEFT INSIDE OF THE TUBE. PHOTOS OF THE COILS AND DELIVERY CATHETER WERE TAKEN, AND IT APPEARED THAT THE OUTER COIL WAS DETACHED AND CAUGHT ON THE APPLICATOR (IT WAS THE DISTAL PORTION OF THE COIL AND IT CONTAINED APPROXIMATELY 22 COILS). A SEPARATE PHOTO OF THE PROXIMAL PORTION OF THE OUTER COIL WAS ALSO AVAILABLE AND IT SHOWED APPROXIMATELY 7

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COILS ATTACHED OR NEXT TO UNIDENTIFIED MATERIAL (PROBABLY PET FIBERS) AND A STRETCHED OUT WIRE. THE DELIVERY CATHETER WAS ENTIRELY INTACT, SO IT APPEARED THAT THE WIRE WAS PART OF THE INNER COIL. A FLAT PLATE WAS PERFORMED BY THE PHYSICIAN AND IT SHOWED WHAT APPEARED TO BE THE BALL TIP OF THE INNER COIL AND A DENSITY CONSISTENT WITH THE INNER COIL, WITH NO OTHER MARKERS. NO CAUSALITY ASSESSMENT WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE FIRST DEVICE WAS INSERTED WITHOUT PROBLEMS. DURING INSERTION OF SECOND DEVICE, AFTER ROLLING BACK THE THUMBWHEEL SECOND TIME, THE DELIVERY CATHETER APPEARED TO REMAIN ATTACHED (DEVICE DEPLOYMENT ISSUE). THEN, THE PHYSICIAN CONTINUED TO ATTEMPT DETACHMENT AND, AT THAT POINT, THE OUTER COIL BROKE (CONSIDERED AS DEVICE BREAKAGE). THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THE DEVICE BROKE DURING ESSURE PLACEMENT PROCEDURE. NO SURGICAL INTERVENTION WAS REPORTED. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 14-JAN-2015. PTC GLOBAL NUMBER (B)(4). LOT NUMBER WAS REPORTED AS C95076 (PRODUCTION DATE 15-AUG-2014; EXPIRATION DATE 31-AUG-2017). FINAL ASSESSMENT, FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00027	BAYER HEALTHCARE LLC	1/13/2015	2/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B82482

Single Use: Y
Implant Date (E6): 12/16/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2014, LOT NUMBER B82482, INSERTED FOR PERMANENT CONTRACEPTION. PHYSICIAN HAD INSERTED TWO ESSURE DEVICES IN PATIENT, BI-LATERALLY. UPON REMOVING THE DELIVERY CATHETER FROM THE DEPLOYED SECOND ESSURE, WITH NO DEPLOYMENT PROBLEMS, THE PROXIMAL END OF THE ESSURE OUTER COIL, WITH APPROXIMATELY FIVE COILS AND MARKER, BROKE OFF AND FELL INTO THE UTERUS. THE PIECE WAS RETRIEVED FROM THE UTERUS BY THE PHYSICIAN AT THAT TIME AND IS BEING SAVED. PHYSICIAN STATED THERE WERE NO PROBLEMS WITH THE INSERTION OR DEPLOYMENT OF EITHER OF THE ESSURE DEVICES IN THIS PATIENT AND KNOWS OF NO CAUSE THAT WOULD HAVE CONTRIBUTED TO THIS SITUATION'S OCCURRENCE. FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2014: NO NEW INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2014. (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE

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MICRO-INSERT. AS OF (B)(6) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO REPORTED PRODUCT TECHNICAL ISSUE (BREAKAGE). HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS WERE REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND THE PROXIMAL END OF THE ESSURE OUTER COIL BROKE OFF AND FELL INTO THE UTERUS. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS LISTED ACCORDING TO TECHNICAL ANALYSIS AND CONSIDERED A NON-SERIOUS EVENT. IN THIS CASE, THE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE. CONSIDERING THIS INFORMATION, THE BREAKAGE WAS ASSESSED AS RELATED TO ESSURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND CONSIDERED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 20-APR-2015: FINAL FOLLOW-UP ATTEMPT HAS BEEN SENT WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00028	BAYER HEALTHCARE LLC	1/14/2015	1/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ON AN UNSPECIFIED DATE THE CONSUMER WAS SUBMITTED TO A TOTAL HYSTERECTOMY BECAUSE OF ESSURE. SHE STATED SHE HAD REAL SYMPTOMS (NOT SPECIFIED). RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6) 2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. (B)(4). FOLLOW UP INFORMATION RECEIVED ON 17-DEC-2014 FROM CONSUMER: SHE REPORTED VIA SOCIAL MEDIA THAT HAD HIVES, SWOLLEN LIPS AND NICKEL ALLERGY DUE TO ESSURE. CASE UPGRADED TO INCIDENT DUE TO INTERVENTION REQUIRED PREVIOUSLY REPORTED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL

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MEDIA CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL ALLERGY (PREVIOUSLY REPORTED AS ONLY TOTAL HYSTERECTOMY WITHOUT FURTHER SPECIFICATION). THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A (B)(4). ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE CONSUMER STATED THAT SHE HAD EXPERIENCED HIVES AND SWOLLEN LIPS AS SYMPTOMS OF A NICKEL ALLERGY, REQUIRING A TOTAL HYSTERECTOMY. GIVEN THE NATURE OF THE REPORTED EVENT AND THE POSITIVE TEMPORAL RELATIONSHIP, THE CAUSALITY BETWEEN THE EVENT NICKEL ALLERGY AND ESSURE WAS ASSESSED AS RELATED BY THE COMPANY. THE COMPLAINT SAMPLE DID NOT RETURN FOR PRODUCT TECHNICAL COMPLAINT ANALYSIS. ALSO, NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT ABOUT A QUALITY DEFECT OF THE PRODUCT. THIS CASE WAS REGARDED AS INCIDENT (ANTICIPATED) AS A TOTAL HYSTERECTOMY WAS REQUIRED. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00029	BAYER HEALTHCARE LLC	1/14/2015	1/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/30/2014
Explant Date (E7): 12/16/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION. IT WAS REPORTED THAT PATIENT COMPLAINED OF PAIN. ON (B)(6) 2014, BILATERAL SALPINGECTOMY WAS DONE AND ESSURE WAS REMOVED. THE EVENT STOPPED AT THE SAME DAY. THE OUTCOME OF THE EVENT PAIN WAS RECOVERED / RESOLVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: ESSURE REMOVAL SHOULD BE PERFORMED AS FOLLOWS PER PRODUCT IFU: A CORNEAL RESECTION OF THE PROXIMAL FALLOPIAN TUBE WILL BE REQUIRED IF THE MICRO-INSERT IS PROPERLY LOCATED ACROSS THE UTERO-TUBAL JUNCTION (UTJ). AN ESSURE MICRO-INSERT THAT HAS BEEN IMPROPERLY PLACED OR HAS MIGRATED BEYOND THE UTJ SHOULD BE REMOVED WITH TRADITIONAL LINEAR SALPINGOTOMY OR SALPINGECTOMY ACCOMPLISHED VIA LAPAROSCOPY OR LAPAROTOMY. PROBABLE CAUSES FOR ESSURE MICRO-INSERT REMOVAL - PHYSICIAN INADVERTENTLY DEPLOYED MICRO-INSERT IN THE UTERINE CAVITY AND NOT INTO THE TUBE, PHYSICIAN DETERMINES THE MICRO-INSERT IS INACCURATELY PLACED IN THE FALLOPIAN TUBE, UNUSUAL UTERINE ANATOMY AND/OR INADEQUATE VISUALIZATION LEADS TO A MISPLACED MICRO-INSERT. IMPORTANT: IF THE MICRO-INSERT WAS INADVERTENTLY DEPLOYED IN THE UTERINE CAVITY AND NOT INTO THE TUBE, THE MICRO-INSERT SHOULD BE REMOVED FROM THE UTERUS AND ANOTHER ATTEMPT MADE AT MICROINSERT PLACEMENT IN THE TUBE. WARNING: MICRO-INSERT REMOVAL SHOULD NOT BE ATTEMPTED HYSTEROSCOPICALLY ONCE THE MICRO-INSERT HAS BEEN PLACED. THE ONLY EXCEPTION IS DURING THE ACTUAL PLACEMENT PROCEDURE WHEN REMOVAL MAY BE ATTEMPTED IF 18 OR MORE COILS OF THE ESSURE

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MICROINSERT ARE TRAILING INTO THE UTERINE CAVITY. BECAUSE OF MICRO-INSERT ANCHORING, HOWEVER, REMOVAL MAY NOT BE POSSIBLE EVEN IMMEDIATELY AFTER PLACEMENT. ATTEMPTED REMOVAL OF A MICRO-INSERT HAVING LESS THAN 18 COILS TRAILING INTO THE UTERINE CAVITY MAY RESULT IN FALLOPIAN TUBE PERFORATION OR OTHER PATIENT INJURY. MICRO-INSERT REMOVAL SHOULD ONLY BE ATTEMPTED IF A PATIENT IS EXPERIENCING AN ADVERSE EVENT(S) WITH THE MICRO-INSERT OR IF SHE DEMANDS MICRO-INSERT REMOVAL. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. REMOVING THE ESSURE DEVICE VIA MEDICAL INTERVENTION IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THE PRESENT CASE, IT WAS REPORTED THAT ESSURE COILS WERE REMOVED AND THE EVENT STOPPED AT THE SAME DAY. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT AND POSITIVE DECHALLENGE, A CAUSAL RELATIONSHIP BETWEEN PAIN AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN ON 17-MAR-2015. THE PATIENT´S WEIGHT WAS (B)(6) AND HEIGHT WAS 168CM (BMI 27.9). HER CONCURRENT CONDITION INCLUDED OVERWEIGHT. HER MEDICAL HISTORY INCLUDED 2 PREVIOUS CESAREAN DELIVERIES. PREVIOUS GYNECOLOGICA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040271	CONCEPTUS, INC	1/14/2015	1/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/15/2013
Explant Date (E7): 8/6/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE BIRTH CONTROL COILS IN 2013 (SUPPOSED TO BE ONE METAL COIL IN EACH FALLOPIAN TUBE). TURNS OUT MY DR IMPLANTED 1 IN THE RIGHT TUBE AND 2 IN THE LEFT TUBE (TOTAL OF 3) AND DID NOT INFORM ME OF SUCH. THE THIRD COIL PUNCTURED FROM MY TUBE AND CAUSED SEVERE BLEEDING AND I HAD TO HAVE EMERGENCY SURGERY TO HAVE MY REPRODUCTIVE ORGANS REMOVED. I WAS IN DEBILITATING PAIN FROM THE DATE OF IMPLANTATION AND IT TOOK DOCTORS 10 MONTHS TO FIND THE SOURCE OF THE PAIN. THERE WAS NO OPTION FOR ME BUT SURGERY AT THAT POINT. I SUFFERED IN PAIN UNTIL I STARTED BLEEDING HEAVILY AND BECOMING WEAK AND DIZZY AND MY NEW DR DECIDED TO REPEAT THE X-RAY AND FIND THE PROBLEM IN (B)(6) 2014 AND DID EMERGENCY SURGERY THAT DAY TO KEEP ME FROM BLEEDING TO DEATH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040298	BAYER	1/14/2015	1/22/2015

Event Information:

Event Date (B3): 4/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893037

Single Use:
Implant Date (E6): 7/13/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BABY WAS CONCEIVED AFTER HAVING THE ESSURE DEVICE IMPLANTED IN THE MOTHER. THIS REQUIRED CONSTANT MONITORING OF THE PREGNANCY AND THE RISK OF BIRTH DEFECT, INJURY, MISCARRIAGE, AND A MYRIAD OF OTHER POSSIBLE SITUATIONS SINCE PREGNANCY WAS NOT SUPPOSED TO BE POSSIBLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040299	BAYER	1/14/2015	1/22/2015

Event Information:

Event Date (B3): 6/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/6/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN 2012 AND HAVE BEEN EXTREMELY SICK SINCE. SEVERE PELVIC PAIN ON A DAILY BASIS; DEBILITATING PAIN DURING PERIOD AND OVULATION. AUTOIMMUNE ISSUES HAVE BEGAN AND I REMAIN SICK FOR 30 DAYS PLUS WHEN I CONTRACT A COLD. MY BODY IS ATTACKING THE COILS DUE TO A NICKEL ALLERGY. I WAS TOLD THEY WERE TITANIUM COILS WHEN I HAD THEM PLACED AND IT TURNS OUT THEY HAVE NICKEL IN THEM. I SUFFER FROM SEVERE ANXIETY ON A DAILY BASIS WHICH REQUIRES A LOT OF MEDICATION TO FIX. I HAVE SIGNIFICANT BLOATING DAILY AND LOOK ABOUT 4 MONTHS PREGNANT. I HAVE TO REMAIN IN MY BED FOR THE ENTIRE WEEK OF MY PERIOD AND DURING THE 3 TO 5 DAYS OF MY OVULATION. I HAVE INCREASED INCONTINENCE THAT CAUSES SIGNIFICANT PROBLEMS AND HAVE NO INFECTIONS IN MY URINARY OR VAGINAL AREA THAT WOULD OTHERWISE CAUSE THE PROBLEM. I AM NOW FACING EITHER A REMOVAL OF MY FALLOPIAN TUBES OR A FULL HYSTERECTOMY DEPENDING ON WHAT THE DOCTOR SEES ONCE IN THERE. I AM ONLY (B)(6) AND SHOULD NOT HAVE TO HAVE MY FULL FALLOPIAN TUBES OR ENTIRE REPRODUCTIVE SYSTEM REMOVED; BUT, DUE TO ESSURE MAKING ME EXTREMELY SICK, I NOT HAVE TO. I HAVE TWO CHILDREN WHO ARE AFFECTED BY THIS BECAUSE THEIR MOTHER HAS TO MANAGE DAILY PAIN AND ANXIETY, AND IS BED RIDDEN 2 WEEKS OUT OF EACH MONTH FROM CYCLE CHANGES INTERACTING WITH THIS DEVICE. MY MEDICAL COSTS FOR ER VISITS, MEDICATIONS, LABS, XRAYS, AND OB VISITS ARE HUGE, PUTTING A SIGNIFICANT FINANCIAL STRAIN ON MY FAMILY. ESPECIALLY BECAUSE MY HUSBAND IS THE ONLY ONE WHO CAN WORK DUE TO ME BEING IN DEBILITATING PAIN FOR HALF OF EVERY MONTH. SINCE HAVING ESSURE PLACED MY HEALTH AND QUALITY OF LIFE HAS BEEN EXTREMELY POOR. IT IS SAD THAT MY WHOLE FAMILY AND I HAVE TO SUFFER DAY IN AND DAY OUT BECAUSE I WANTED TO PREVENT FUTURE PREGNANCIES. TWO CHILDREN IS ENOUGH FOR ME, AND IT IS DEVASTATING THAT MYSELF, MY HUSBAND, MY 5 YEAR OLD

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SON, AND MY 3 YEAR OLD DAUGHTER HAVE TO BE PUNISHED ON A DAILY BASIS BECAUSE OF THE DECISION BY MY DOCTOR THAT THIS WOULD BE THE BEST DEVICE FOR ME AS OPPOSED TO A REGULAR TUBAL LIGATION. MY LIFE WILL NEVER BE THE SAME AGAIN AND MY FAMILY WILL FOREVER BE AFFECTED BY THIS AWFUL PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040300	CONCEPTUS	1/14/2015	1/22/2015

Event Information:

Event Date (B3): 6/13/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 624474

Single Use:
Implant Date (E6): 6/13/2007
Explant Date (E7): 9/24/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN 2007. AFTER HAVING SOME PAIN, MY DOCTOR SENT ME FOR A SCAN IN 2014. THE RESULTS WERE THAT ONE COIL HAD MIGRATED TO MY UTERINE WALL. I MADE AN APPOINTMENT WITH MY OBGYN AND A HYSTERECTOMY WAS SCHEDULED. BETWEEN TIME, I HAD DEVELOPED SHINGLES, EXTREME CHRONIC FATIGUE, BROKEN BONES, VITAMIN D DEFICIENCY, CONSTANT PROBLEMS WITH YEAST INFECTIONS AND BACTERIAL VAGINOSIS (WHICH TOOK A COMPOUNDED MEDICATION TO GET RELIEF FROM), HIGHER (THAN MY NORMAL) BLOOD PRESSURE, AND FREQUENT URINATION. DATE LISTED IS APPROXIMATE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040301		1/14/2015	1/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/14/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE. EVER SINCE, I HAVE HAD PAIN NEAR MY RIGHT OVARY, ABNORMAL SWELLING FROM OVULATION UNTIL CYCLE DAY ONE. MY TEETH HAVE ROTTED (I HAVE SIX TOP TEETH LEFT). I HAVE HEART ISSUE, AND THIS YEAR HAVE HAD SEVERAL EPISODES OF TACHYCARDIA GREATER THAN 250 BMP. MY PERIODS ARE IRREGULAR SINCE MY IMPLANTATION. MY SEX DRIVE HAS DECREASED. MY PANIC ATTACKS AND DEPRESSION HAVE INCREASED. I WAS NOT GIVEN A NICKEL ALLERGY TEST PRIOR TO MY SURGERY. MY PMS IS NOW OFF THE CHARTS. I HAVE GAINED 40 LBS SINCE MY IMPLANTATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040302	BAYER	1/14/2015	1/22/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN, IN 2011. PLACEMENT WAS CONFIRMED AND WAS TOLD I WAS SET. ABOUT 10 MONTHS LATER I WAS TOLD I WAS 7 WEEKS PREGNANT. I HAD A MISCARRIAGE AND I STILL HAVE PAIN AND ISSUES WITH MY PERIOD TO THIS DATE. THIS PRODUCT IS A FAIL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040343	BAYER	1/14/2015	1/27/2015

Event Information:

Event Date (B3): 3/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): A64631

Single Use:
Implant Date (E6): 3/6/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PAIN, PAIN ALL OVER, JOINT PAINT, GROIN PAIN, WEIGHT GAIN, HAIR LOSS, DECREASED ENERGY, LOSS OF LIBIDO. IRREGULAR PERIODS, AND PAINFUL PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040314	BAYER	1/15/2015	1/23/2015

Event Information:

Event Date (B3): 9/7/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): BAYER ESSYRE PERMANENT STERILIZATION
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/7/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FOUR YEARS WITH BAYERS ESSURE NOTHING BUT PROBLEMS. I'M ALLERGIC TO NICKEL WELL AT MY IMPLANTATION APPOINTMENT IT NEVER SAID NICKEL ALLERGIES. I HAVE JOINT PAIN ONLY (B)(6). BEEN TO SEVERAL DOCTORS; GI AND OB TEST CAME BACK NORMAL. THEY TOLD ME IT MUST BE ESSURE PET FIBERS. SO ONLY WAY OF REMOVAL IS A HYSTERECTOMY AT A YOUNG AGE. AND MORE WOMEN HAVE GOTTEN PREGNANT,. AND ONE EVEN DIED FROM THIS DEVICE. IT CAUSES MOOD SWINGS, HORRIBLE PERIODS, AUTOIMMUNE DISEASE, AND BIG TIME DOCTOR BILLS. ESSURE MUST BE DEALT WITH. CONCEPTUS NEVER DID EXTENSIVE RESEARCH AND OVER 12,900 WOMEN SUFFER. AND MANY MORE LIKE THEM I WAS TOLD, IT COULDN'T BE ESSURE WELL AFTER MANY TEST AND DOCTORS FINALLY THEY AGREED IT WAS ESSURE. WHAT'S THE PROBLEM FDA? I CALL ESSURE FALSE ADVERTISEMENT. IT IS NOT AS EFFECTIVE AS STATED. AND IT CAN BE REVERSED UNLIKE IT STATES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040317	BAYER	1/15/2015	1/23/2015

Event Information:

Event Date (B3): 1/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/17/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(4) 2011, SINCE THEN I HAVE HAD SERIOUS BLOATING, MENSTRUAL PERIODS THAT WOULD LAST 19 DAYS BE OFF MY CYCLE FOR 3 DAYS, JUST TO START ALL OVER AGAIN. I HAVE HAD MUSCLE SPASMS IN MY BACK, ACNE/RASHES OVER MY FACE, , NECK, BACK OF EARS, BACK AND CHEST, WHICH I DID NOT HAVE PRIOR. I HAD AN ABLATION IN 2013 TO HELP STOP THE HEAVY LONG MENSTRUAL CYCLES. SINCE THEN, MY SYMPTOMS HAVE GOTTEN WORSE EXCEPT FOR MY MENSTRUAL CYCLE HAS EASED UP EXCEPT FOR THE FACT THAT I NOW PASS LARGE BLOOD CLOTS. I HAVE EXTREME FATIGUE, ANXIETY AND DEPRESSION AND AT TIMES I LOOK 5 MONTHS PREGNANT, WHICH I NEVER HAD A GUT PRIOR. THIS IS JUST TO SAY SOME OF THE SYMPTOMS THAT I HAVE DEVELOPED SINCE GETTING ESSURE. MY OBGYN HAS NOW SCHEDULED ME AN APPOINTMENT WITH A PARTNERING SURGEON IN 1 WEEK TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040318		1/15/2015	1/23/2015

Event Information:

Event Date (B3): 11/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/5/2014
Explant Date (E7): 11/19/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED (B)(6) /2014, EVERYTHING WENT GREAT, BUT COULD ONLY GET THE LEFT TUBE DONE. THEN ON (B)(6) 2014 I WOKE UP WITH THE WORST PAIN I'VE EVER HAD ON MY LEFT SIDE. MY DOCTOR GOT ME IN THE OFFICE ON (B)(6) 2014, DID AN ULTRASOUND EVERYTHING LOOKED FINE, BUT WHEN SHE WOULD PUSH ON THAT SIDE THE PAIN WOULD BRING TEARS TO MY EYES, ON (B)(6) 2014, WE DID SURGERY TO REMOVE ESSURE AND MY TUBES. I HAD DEVELOPED A RASH ON MY CHEST THE DAY AFTER MY SURGERY. THE RASH WAS ALMOST GONE THREE DAYS LATER, YOU COULDN'T TELL I HAD A RASH.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00030	BAYER HEALTHCARE LLC	1/15/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91764

Single Use: Y
Implant Date (E6): 12/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER C91764. IT WAS REPORTED THAT PROXIMAL PART OF THE INSERT FELL OFF. IT WAS RETRIEVED AND PLACED ANOTHER. NO INJURY TO THE PATIENT. BILATERAL PLACEMENT ACHIEVED. THE OUTCOME OF THE EVENT WAS RECOVERED / RESOLVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF (B)(6) 2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE,

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WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO REPORTED PRODUCT TECHNICAL ISSUE (BREAKAGE). THE AE CASE ALSO REFERS TO A USABILITY ISSUE (COMPLICATED INSERTION). HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS WERE REPORTED. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH C91764 (PRODUCTION DATE 01-AUG-2014 AND EXPIRATION DATE 31-AUG-2017) WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THIS EVENT IS ANTICIPATED PER DESIGN FMEA. IN SUMMARY, AN ASSESSMENT REGARDING A CAUSAL RELATIONSHIP BETWEEN A POTENTIAL QUALITY DEFECT AND AN ADVERSE EVENT IS NOT POSSIBLE AS NO ADVERSE EVENT WAS REPORTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE PROXIMAL PART OF THE INSERT FELL OFF/RETRIEVED AND PLACED ANOTHER DEVICE. THE EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS IT WAS REGARDED AS LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THIS CASE, ACCORDING TO PHYSICIAN, PROXIMAL PART OF THE INSERT FELL OFF DURING THE INSERTION. IT WAS RETRIEVED AND ANOTHER DEVICE WAS PLACED. SINCE BREAKAGE WAS REPORTED AND OCCURRED DURING INSERTION PROCEDURE (COMPLICATION OF DEVICE INSERTION), CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED AND THE CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THIS EVENT IS ANTICIPATED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00031	BAYER HEALTHCARE LLC	1/15/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/15/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION. PREGNANCY WAS DENIED. IT WAS REPORTED A PARTIAL EXPULSION OF PART OF ESSURE COIL FROM LEFT FALLOPIAN TUBE AND PART OF ESSURE COIL PASSED IN A CLOT ON (B)(6) 2014. ON (B)(6) 2014, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED BILATERAL OCCLUSION OF TUBES. HOWEVER, LEFT SIDE WAS SHORTER. ESSURE WAS NOT REMOVED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER WAS (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT

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NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS ANTICIPATED PER DESIGN FMEA. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT PART OF ESSURE COIL PASSED IN A CLOT. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND PREVIOUSLY CONSIDERED UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, WAS, UPON RECEIPT OF PRODUCT TECHNICAL INVESTIGATION (PTC) UPDATED TO LISTED (ANTICIPATED). DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, IT WAS NOT CLEAR WHETHER THE ESSURE COIL BROKE DURING INSERTION. BASED ON THE INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: PARTIAL EXPULSION OF PART OF ESSURE COIL FROM LEFT FALLOPIAN TUBE AND LEFT SIDE WAS SHORTER. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 13-MAY-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATI

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00032	BAYER HEALTHCARE LLC	1/15/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A95863

Single Use: Y
Implant Date (E6): 12/19/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)2014 WITH LOT NUMBER A95863 (EXPIRATION DATE JAN-2016) FOR STERILIZATION. THE CONTRACEPTION PART THAT DELIVERS THE COIL CAME OUT WITH THE COIL. IT SEEMED LIKE A PORTION OF THAT CATHETER WAS LEFT INSIDE; THE COIL WAS EXPELLED AND PLACED CORRECTLY IN THE TUBE. THE PHYSICIAN WAS CONCERNED THAT THERE WAS A PORTION OF THE CATHETER ATTACHED TO THE LEFT DEPLOYED COIL. SHE SAID THE INSERTION SEEMED TO BE NORMAL UNTIL THE SECOND ROLLBACK, THAT SHE DID NOT FEEL LIKE IT WAS A HARD STOP LIKE USUAL. DUE TO THE TIMING OF THE PROCEDURE, SHE WENT TO THE OTHER SIDE AND PLACED THE SECOND ESSURE UNIT BEFORE RETURNING TO THE SIDE WITH THE CATHETER REMNANT. SHE ATTEMPTED TO USE GRASPER'S HYSTEROSCOPICALLY BUT THE PIECE WOULD NOT BUDGE. SHE THOUGHT THE PIECE WAS 2-2.5 CM. THE OUTCOME OF THE EVENT SEEMS LIKE A PORTION OF CATHETER IS LEFT INSIDE WAS NOT RECOVERED / NOT RESOLVED. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2014. IT WAS REPORTED THAT ESSURE CATHETER DID NOT ROLL BACK, WHEEL ROLLED BUT SHEATH AND DEPLOYING COIL BROKE IN THE PATIENT. PROVIDER TRIED TO REMOVE AS MUCH AS SHE COULD. PART OF DEVICE CATHETER STILL IN PATIENT. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4)FINAL ASSESSMENT: LOT A95863. EXPIRATION DATE: JAN 31, 2016. PRODUCTION DATE: (B)(6)2013. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT

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ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. THE AE CASE ALSO REFERS TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THIS EVENT IS ANTICIPATED PER DESIGN FMEA. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. FIVE (5) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER A95863 BUT NONE OF THESE CASES REFER TO A SIMILAR MEDICAL EVENT. NO BATCH SIGNAL CAN BE IDENTIFIED AT THIS TIME. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT SEEMED LIKE A PORTION OF CATHETER WAS LEFT INSIDE/ SHEATH AND DEPLOYING COIL BROKE IN THE PATIENT. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS IT WAS REGARDED AS LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE PLACEMENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: ATTEMPTED TO USE GRASPER'S HYSTEROSCOPICALLY BUT THE PIECE WOULD NOT BUDGE (DEVICE MISUSE); COIL WAS EXPELLED AND PLACED CORRECTLY IN THE TUBE AND ESSURE CATHETER DID NOT ROLL BACK. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THIS EVENT IS ANTICIPATED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 13-MAY-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00033	BAYER HEALTHCARE LLC	1/16/2015	1/16/2015

Event Information:

Event Date (B3): 12/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS000E5

Single Use: Y
Implant Date (E6): 12/16/2014
Explant Date (E7): 12/19/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER CS000E5 INSERTED ON (B)(4) 2014. IT WAS REPORTED A TUBAL PERFORATION AND ON (B)(4) 2014 PATIENT WAS TAKEN TO SURGERY FOR REMOVAL AND TUBAL LIGATION. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. THE PTC GLOBAL REFERENCE NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 2 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, BUT NONE OF THOSE CASES REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS

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CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED TUBAL PERFORATION. SHE WAS TAKEN TO SURGERY FOR ESSURE REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE AND FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING ESSURE INSERTION. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF TUBAL PERFORATION WAS NOT REPORTED; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE SURGICAL FOR ESSURE REMOVAL WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 17-MAR-2015 PATIENT´S (B)(6). PREVIOUS GYNECOLOGICAL INTERVENTIONS WERE DENIED. PREGNANCY WAS ALSO DENIED. ON (B)(6) 2014 ESSURE WAS INSERTED WITH LOT NUMBER CS000E5 (EXPIRATION DATE JAN-2017). CERVICAL DILATION WAS DONE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040345		1/16/2015	1/27/2015

Event Information:

Event Date (B3): 1/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/8/2008
Explant Date (E7): 1/22/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2008, I HAD A PROCEDURE, ONE CALLED ESSURE. THIS PROCEDURE WAS DONE BY A DOCTOR IN A HOSPITAL, HER NAME WAS (B)(6) AT (B)(6). AFTER HAVING THE PROCEDURE DONE I STARTED HAVING PROBLEMS LIKE HEADACHES, BACKACHES, PROBLEMS WITH INTIMACY, SWELLING AND ABDOMINAL PAIN. I WENT TO MY REGULAR DOCTOR AND THEY TOOK BLOOD TESTS, ULTRASOUNDS, OTHER TESTS TO SEE WHAT WAS GOING ON AND WHEN I MENTIONED ABOUT MY INTIMACY THEY TOLD ME THAT I NEED TO SEE MY GYNECOLOGIST. THIS HAD BEEN WITHIN A YEAR OF HAVING THE ESSURE PUT IN. WHEN I NOTICED THAT THE HEADACHES WERE NOT GOING AWAY AND THE NAUSEA, THE BACK ACHES, STOMACH PAINS, BLOATING HAD NOT CEASED. I WENT TO MY GYNECOLOGIST AND SHE TOLD ME I HAD A YEAST INFECTION AND PRESCRIBED ME YEAST INFECTION MEDICINE. I ASKED HER IF THERE COULD BE A PROBLEM WITH THE ESSURE AND SHE SAID NO BUT LET'S LOOK AND MAKE SURE THAT NOTHING WAS WRONG BUT THAT TEST NEVER CAME AND THAT WAS IN 2010 WHEN I WAS SUPPOSED TO HAVE A TEST DONE AFTER A YEAR OF TRYING TO GET IN THE OFFICE AND SEE MY ORIGINAL GYNECOLOGIST FOR THE APPOINTMENT. TO BE DONE WAS A DYE TEST THAT I NEVER RECEIVED TO MAKE SURE THEY WERE IN ACCURATELY. AFTER HAVING A PREGNANCY SCARE AND NOT KNOWING WHAT WAS GOING ON AND COULDN'T GET IN HER OFFICE TO HAVE HER CHECK ME OUT. BECAUSE I WAS GETTING THE RUNAROUND AND MY SYMPTOMS WERE INCREASING TO WHERE I COULD BARELY WALK, I COULDN'T HOLD MY HEAD UP LONGER THAN AN HOUR, I WAS LITERALLY IN PAIN 24/7. I WAS TAKING IBUPROFEN PAIN RELIEVERS AND SOMETIMES A MUSCLE RELAXER IF MY DOCTOR WOULD GIVE ME ONE. THERE WERE MANY OTHER TIMES THAT I WENT INTO MY DOCTOR BECAUSE MY BACK WAS HURTING SO MUCH AND MY HEAD WAS HURTING SO MUCH THAT THEY REALLY COULDN'T FIND ANYTHING WRONG WITH ME AND THEY NEVER CHECKED THE ESSURE IMPLANT. IN 2011 I WENT TO A NEW DOCTOR, THE GYNECOLOGIST WHICH WAS THE

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END OF 2011 AND I LITERALLY HAD TWO TO THREE VISITS AND SHE NOTICED THAT THERE WAS SOME INFLAMMATION OR SOMETHING WRONG AND SHE NEEDED TO ACTUALLY GO IN SURGICALLY TO SEE WHAT THE PROBLEM WAS AND THAT WAS THE END OF (B)(6) 2011. THIS (B)(6) 2012, ON THE 22ND I WAS SCHEDULED FOR SURGERY. WHILE IN SURGERY DR (B)(6)HAD FOUND THAT MY FALLOPIAN TUBES WERE INFLAMED AND THAT THE COILS WERE THE CAUSE OF HER NEEDING TO EXTRACT MY UTERUS AND CERVIX. ON TOP OF THAT I HAD NICKEL SIZED CYST ON MY OVARIES AND HAS SCARRED A LITTLE BIT SO SHE NOTICED THAT THERE WAS NO SAVING MY UTERUS FROM THE INFLAMMATION OF HAVING DONE THE SAME TIME WHICH WAS CAUSING ME TO BLEED INTERNALLY FOR FOUR YEARS. AFTER A WEEK WENT BY, AFTER THE SURGERY, I NOTICED MY HEADACHES, MY BACKACHES, MY STOMACH PAIN ALL AROUND WAS GONE. NOT ONLY DID I NOT RECEIVE CORRECT CARE BUT I ALSO LOST A PART OF ME THAT I'LL NEVER GET BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040350	ESSURE	1/16/2015	1/27/2015

Event Information:

Event Date (B3): 6/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 827945

Single Use:
Implant Date (E6): 6/24/2011
Explant Date (E7): 11/17/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IN (B)(6) AND HAVE HAD A DRASTIC HIT TO MY OVER ALL HEALTH. THE PAIN STARTED 8 WEEKS AFTER THE PROCEDURE AND FATIGUE, BRAIN FOG, MIGRAINES, CONSTANT BLADDER PAIN AND INFECTIONS, ALL OVER BODY ACHES, INSOMNIA, MOOD SWINGS, HORRIFIC MENSTRUAL CYCLES, PAINFUL INTERCOURSE, WEIGHT GAIN FOLLOWED SOON AFTER. THE HIP PAIN WAS SO BAD THAT I COULDN'T STAND UP WITHOUT HELP. I HAVE 4 CHILDREN AND THEY HAVE LOST THEIR MOM FOR 3 YEARS. I WASN'T ABLE TO DO THE THINGS THAT I USED TO DO. I COULD NOT GO TO THE PARK LET ALONE THE GROCERY STORE. THE DRS WERE STUMPED. I WAS DIAGNOSED WITH FIBROMYALGIA AND PUT ON PAIN MEDICATION THAT MADE ME SICKER. I FINALLY FOUND THAT I WASN'T THE ONLY ONE WITH THESE PROBLEMS AND WENT TO MY GYNECOLOGIST AND TALKED TO HIM. I HAVE A COMPLETE HYSTERECTOMY ON (B)(6) 2014 AND NOTICED MY HIP PAIN WAS GONE INSTANTLY. I AM STARTING TO FINALLY GET MY LIFE BACK AFTER GETTING ESSURE OUT OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040351	CONCEPTUS	1/16/2015	1/27/2015

Event Information:

Event Date (B3): 7/28/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 403326

Single Use:
Implant Date (E6): 7/28/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2008, I WAS IMPLANTED WITH ESSURE. I AM SCHEDULED FOR A HYSTERECTOMY IN (B)(6) 2015 TO REMOVE THE ESSURE IMPLANTS DUE TO EXCESSIVE BLEEDING, CLOTTING, BACK ACHES, AND FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040375	BAYER	1/17/2015	1/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6), I WAS IMPLANTED WITH THE ESSURE BIRTH CONTROL DEVICE. SINCE IMPLANTATION, I HAVE SEVERE SKIN ALLERGY ISSUES, SEVERE PELVIC PAIN, HEAVY IRREGULAR MENSES, HOT FLASHES, HEADACHES, FIBROMYALGIA, RESULTING IN DEPRESSION BEING EXACERBATED. I ATTRIBUTE ALL OF THESE TO BE CAUSED BY THE ESSURE DEVICE, AND I'M CURRENTLY UNDER MEDICAL SUPERVISION, AND LIKELY TO HAVE A HYSTERECTOMY IN MY FUTURE TO REMOVE THESE DEVICES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040361	BAYER	1/18/2015	1/27/2015

Event Information:

Event Date (B3): 12/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/15/2011
Explant Date (E7): 5/8/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY LIFE HAS BEEN RUINED BECAUSE MY OBGYN DIDN'T GIVE ME ANY OTHER CHOICE BUT ESSURE WHEN I ASKED TO HAVE MY TUBES TIED. ONE COIL MOVED AND CREATED SCAR TISSUE. THE SCAR TISSUE CREATED A BARRIER SO MY PERIODS COULD NOT FLOW OUT LIKE NORMAL. INSTEAD I HAD 8 OR SO MONTHS OF MY PERIOD BUILT UP INSIDE ME. I WOKE UP SCREAMING IN PAIN ONE MORNING. AFTER EMERGENCY ROOM DOCTOR PERFORMED PELVIC EXAM AND TESTS HE WAS ABLE TO RELEASE THE PRESSURE. I THEN HAD A HYSTERECTOMY BY THE SAME OBGYN. HE USED THE DA VINCI ROBOTIC LASER MACHINE TO PERFORM THE HYSTERECTOMY WHICH HAS CREATED SEVERE ISSUES. LESS THAN A MONTH FROM MY OBGYN DOING THE HYSTERECTOMY I RECEIVED A LETTER STATING I NEEDED TO FIND A NEW OBGYN. THERE WAS NO REASON AS TO WHY GIVEN THOUGH I HAD ALREADY MADE THE CHOICE TO FIND A NEW ONE. BUT I GOT MY MEDICAL RECORDS AND THE WAY DR. (B)(6) TRANSCRIBED THEM MADE IT CLEAR SOMETHING WASN'T RIGHT. ONCE I FINALLY GOT THE PATHOLOGY REPORT I FOUND THE ANSWERS. BOTH TUBES HAD METAL FOREIGN DEBRIS COILS THAT MEASURED AT DIFFERENT LINKS AND WERE BOTH IN DIFFERENT AREAS. ONE HAD MOVED INTO MY UTERUS AND PUNCTURED INTO MY OVARY. DR. (B)(6) PULLED THE PART OUT OF MY OVARY WHEN REMOVING MY UTERUS, TUBES, CERVIX. NOTHING WAS EVER MENTIONED TO ME OR MY FAMILY ABOUT THIS. NEITHER DOES THE OPERATIVE REPORTS, I CAN'T SEEM TO FIND A OBGYN TO HELP ME DUE TO LOSING MY INSURANCE AND NO DOCTORS SEEM TO KNOW ANYTHING ABOUT THIS PROCEDURE TO EVEN HELP ME. I ENDED UP IN THE EMERGENCY ROOM AND NEEDED HELP GETTING WHATEVER ISSUES THAT HAVE BEEN CREATED FIXED. MY ENTIRE LIFE HAS BEN RUINED, MY SON, CAREER, HOME, ARE EITHER SUFFERING FROM MY EXTREME PAIN AND ISSUES.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00035	BAYER HEALTHCARE LLC	1/19/2015	1/20/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2012
Explant Date (E7): 9/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. PATIENT HAD ESSURE SUCCESSFULLY INSERTED ON (B)(6) 2012 AND SINCE THEN SHE HAD BEEN EXPERIENCING PAIN. SHE WAS WORKED UP FOR SEVERAL THINGS AND RULED OUT EVERYTHING. BILATERAL SALPINGECTOMY AND REMOVAL OF ESSURE DEVICES WERE PERFORMED ON (B)(6) 2014 AND PAIN WENT AWAY. FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD

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ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BEEN EXPERIENCING PAIN SINCE ESSURE PLACED. SHE WAS SUBMITTED TO BILATERAL SALPINGECTOMY AND REMOVAL OF ESSURE DEVICES AND RECOVERED FROM THE EVENT. PAIN WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 13-MAY-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATI

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040354	CONCEPTUS INCORPORATED	1/19/2015	1/27/2015

Event Information:

Event Date (B3): 5/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 8/5/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE TUBAL COILS ESSURE PUT IN (B)(6) 2013. SINCE THEN, SEXUAL INTERCOURSE IS EXTREMELY PAINFUL AND I GET INFECTIONS FROM IT WHICH IS NOT NORMAL. SEX SHOULD NOT BE PAINFUL AND ONLY STARTED AFTER I'VE HAD THE ESSURE. I KNOW HAVE DAILY PELVIC PAIN AND BLOATING. AND NOW I AM AFRAID TO HAVE SEX. SO PSYCHOLOGICALLY IT'S TAKEN A TOLL AS WELL. NOW THE FUTURE LOOKS GRIM AND THE DRS. DON'T TELL YOU THAT TO GET THESE NASTY COILS OUT YOU WILL MORE THAN LIKELY HAVE TO HAVE A HYSTERECTOMY. THIS PRODUCT IS DANGER TO ALL WOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040355	CONCEPTUS	1/19/2015	1/27/2015

Event Information:

Event Date (B3): 1/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/8/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE BEING IMPLANTED IN (B)(6) 2013, WITH ESSURE, MY BODY GONE THROUGH TERRIBLE CHANGES. BEFORE GETTING IMPLANTED WITH ESSURE I WAS A (B)(6), VERY HEALTHY BEING NEVER HOSPITALIZED, NO MAJOR SURGERIES, GYNECOLOGICAL ISSUES AND OR HEALTH ISSUES. SINCE BEING IMPLANTED WITH ESSURE I HAVE DEVELOPED RED SKIN RASHES, CONSTANT ITCHY SKIN, SIGNIFICANT HAIR LOSS, FREQUENT URINARY TRACT INFECTIONS, FREQUENT BACTERIAL VAGINOSIS INFECTIONS, OVARIAN CYST, PELVIC FLOOR PAIN, DEPRESSION, MIGRAINES, HIGH BLOOD PRESSURES, BLOOD CLOTS/HEAVY BLEEDING DURING PERIOD CYCLES AND MORE. ALL OF WHICH HAVE CAUSED ME TO MISS SIGNIFICANT AMOUNTS OF WORK AND RACK UP MEDICAL BILLS DUE TO CONSTANT TRIPS TO THE HOSPITAL EMERGENCY ROOM. I DON'T FEEL LIKE A (B)(6)DUE TO ALWAYS HAVING HEALTH ISSUES, ESSURE HAS TAKEN MY PRIDE AND HEALTH AWAY. WHAT A TERRIBLE MISTAKE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00034	BAYER HEALTHCARE LLC	1/19/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06470

Single Use: Y
Implant Date (E6): 12/22/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C06470, INSERTED ON (B)(6) 2014. ON (B)(6) 2014, WHILE THE HEALTH CARE PROFESSIONAL WAS INSERTING THE CATHETER, HE KEPT TWISTING THE CATHETER. HOWEVER, THE ESSURE DID NOT DEPLOY CORRECTLY AND BROKE OFF IN THE PATIENT. IT IS UNKNOWN HOW MUCH OF DEVICE WAS REMOVED OR REMAINS IN PATIENT. THE SECOND ASIDE WAS PLACED PERFECT. FOLLOW UP 05.JAN.2014: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD

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AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DEPLOYMENT DIFFICULTY ARE ANTICIPATED EVENTS. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO REPORTED PRODUCT TECHNICAL ISSUE (BREAKAGE). THE AE CASE ALSO REFERS TO A USABILITY ISSUE (COMPLICATED INSERTION). HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS WERE REPORTED. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THIS EVENT IS ANTICIPATED PER DESIGN FMEA. IN SUMMARY, AN ASSESSMENT REGARDING A CAUSAL RELATIONSHIP BETWEEN A POTENTIAL QUALITY DEFECT AND AN ADVERSE EVENT IS NOT POSSIBLE AS NO ADVERSE EVENT WAS REPORTED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE INSERTION PROCEDURE THE DEVICE BROKE OFF IN THE PATIENT. THIS EVENT IS NON-SERIOUS AND UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS IT WAS REGARDED AS LISTED FOR ESSURE. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, DURING INSERTION THE DEVICE DID NOT DEPLOY CORRECTLY (NON-SERIOUS EVENT) AND IT BROKE OFF IN THE PATIENT. IT IS UNKNOWN HOW MUCH OF DEVICE WAS REMOVED OR REMAINS IN PATIENT (NON-SERIOUS EVENT). BASED ON THE INFORMATION RECEIVED, AND GIVEN THE NATURE OF THE REPORTED EVENTS A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME AND CONCLUDED UNCONFIRMED QUALITY DEFECT. FOLLOW UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4)DEC 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C06470, INSERTED ON (B)(6) 2014. ON (B)(6)

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040401	BAYER	1/20/2015	1/27/2015

Event Information:

Event Date (B3): 1/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/24/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE INSERTED IN (B)(6) 2012, AND HAD A FEW MONTHS OF NO SYMPTOMS OTHER THAN BLEEDING. IMMEDIATELY FOLLOWING THE DYE CONFIRMATION TEST, AND PERSISTENT THROUGHOUT THE LAST YEAR I HAVE HAD VERY PAINFUL AND PERSISTENT SYMPTOMS (IRREGULAR BLEEDING, PAIN IN MY SIDES THAT WILL NOT GO AWAY, LOWER BACK PAIN THAT WILL NOT GO AWAY, ABDOMINAL PAIN, JOINT PAIN. I FEEL LIKE MY OVARIES HURT. IF THAT MAKES SENSE, CONSTANT BLOATING). I AM THE MOST HEALTHY PERSON I KNOWN. AFTER A YEAR OF THESE SYMPTOMS AND NO RELIEF, I HAVE COME TO THE CONCLUSION THAT IT'S THE IMPLANTS. I WOULD LIKE TO HAVE THEM REMOVED AS SOON AS POSSIBLE, BUT DO NOT WANT REVERSAL. I HAD THEM INSERTED TO AVOID PREGNANCY. ALSO, IN ANOTHER STRIKE AGAINST EQUALITY FOR WOMEN, INSURANCE CONSIDERS THIS AN "ELECTIVE" PROCEDURE, AND I'LL HAVE TO PAY (B)(6) TO HAVE THE ESSURE IMPLANTS REMOVED. AT THIS POINT, I'M WILLING TO GO HOMELESS TO BE RID OF THEM AND THE PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00036	BAYER HEALTHCARE LLC	1/20/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C13145

Single Use: Y
Implant Date (E6): 6/16/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6)-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2014 WITH LOT NUMBER C13145. IT WAS REPORTED THAT THE PHYSICIAN WANTED TO REMOVE THE DEVICE DUE TO RELEASE DISORDER. THE COIL WHICH HAVE BEEN UNWINDED AT THE DISTAL EXTREMITY, BROKE IN TWO. ONE PIECE OF THE COIL WHICH COULD NOT BE REMOVED NEITHER BY HYSTEROSCOPY OR COELIOSCOPY, REMAINED IN UTERINE HORN. CLINICAL CONSEQUENCES NOTED: COELIOSCOPY PERFORMED. DEVICE NOT INSERTED. NO FURTHER INFORMATION WAS AVAILABLE AT THE TIME OF THIS REPORT. PTC INVESTIGATION RESULT RECEIVED ON 14-JAN-2015: BATCH NUMBER C13145 (PRODUCTION DATE 21-JAN-2014; EXPIRATION DATE 31-JAN-2017). (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY ARE ANTICIPATED EVENTS. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO REPORTED PRODUCT TECHNICAL ISSUE (BREAKAGE). THE AE CASE ALSO REFERS TO A USABILITY ISSUE (COMPLICATED INSERTION). HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS WERE REPORTED. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY ARE ANTICIPATED EVENTS. IN SUMMARY, AN ASSESSMENT REGARDING A CAUSAL RELATIONSHIP BETWEEN A POTENTIAL QUALITY DEFECT AND AN ADVERSE EVENT IS NOT POSSIBLE AS NO ADVERSE EVENT WAS REPORTED. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN (B)(4). IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6)-2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE COIL BROKE IN TWO. THIS EVENT IS NON-SERIOUS AND PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THE DEVICE BROKE DURING ESSURE INSERTION. A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED: RELEASE DISORDER (INTERPRETED AS DEVICE DEPLOYMENT ISSUE). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. IN SUMMARY, AN ASSESSMENT REGARDING A CAUSAL RELATIONSHIP BETWEEN A POTENTIAL QUALITY DEFECT AND AN ADVERSE EVENT IS NOT POSSIBLE AS NO ADVERSE EVENT WAS REPORTED. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION FROM 11-SEP-2015: AFTER CONFIRMING WITH REPORTER, THIS CASE WAS IDENTIFIED AS A DUPLICATE TO CASE (B)(4) AND WILL BE DELETED FROM BAYER DATABASE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00037	BAYER HEALTHCARE LLC	1/20/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18711

Single Use: Y
Implant Date (E6): 12/22/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR STERILIZATION (LOT NUMBER C18711). SHE WAS NOT PREGNANT. PHYSICIAN REPORTED THAT, ON (B)(6) 2014, THE ACTUAL DELIVERY CATHETER FOR THE ESSURE DID NOT DISENGAGE FROM THE MICRO-INSERT, LEAVING SOME OF THE GREEN SHEATHING OVER THE MICRO-INSERT. SHE TOOK PICTURES OF THE VIEW FROM THE MONITOR AND THEY CAPTURED ALL THE PIECES. REPORTER ALSO STATED THE DELIVERY CATHETER EXTENDED AND BROKE, AND THEY HAVE TO USE A LAPAROSCOPIC GRASPER TO RETRIEVE. THEY WERE ABLE TO RETRIEVE ALL THE PIECES FROM THE DELIVERY CATHETER EXCEPT FOR THE GREEN SHEATHING, THAT WAS THE ONLY THING LEFT. PATIENT HAD BILATERAL PLACEMENT AND ESSURE WAS CONTINUED. PTC INVESTIGATION RESULT RECEIVED ON 09-JAN-2015: PTC GLOBAL NUMBER WAS (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT

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WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY ARE ANTICIPATED EVENTS. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO REPORTED PRODUCT TECHNICAL ISSUE (BREAKAGE). THE AE CASE ALSO REFERS TO A USABILITY ISSUE (COMPLICATED INSERTION). HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS WERE REPORTED. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THIS EVENT IS ANTICIPATED PER DESIGN FMEA. IN SUMMARY, AN ASSESSMENT REGARDING A CAUSAL RELATIONSHIP BETWEEN A POTENTIAL QUALITY DEFECT AND AN ADVERSE EVENT IS NOT POSSIBLE AS NO ADVERSE EVENT WAS REPORTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE DELIVERY CATHETER FOR THE ESSURE DID NOT DISENGAGE FROM THE MICROINSERT. THE DELIVERY CATHETER EXTENDED AND BROKE/LEAVING SOME OF THE GREEN SHEATHING OVER THE MICROINSERT. PHYSICIAN WAS ABLE TO RETRIEVE ALL PIECES FROM DELIVERY CATHETER EXCEPT FOR THE GREEN SHEATHING; ESSURE BILATERAL PLACEMENT WAS ACHIEVED. THE REPORTED EVENTS, INTERPRETED AS DEVICE DEPLOYMENT ISSUE, FOLLOWED BY HANDLING ISSUE (CATHETER EXTENDED), DEVICE BREAKAGE AND FAILED CATHETER REMOVAL WERE CONSIDERED NON-SERIOUS AND ARE LISTED (ANTICIPATED) ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC) RESULTS (DEVICE BREAKAGE) AND ESSURE'S REFERENCE SAFETY INFORMATION (REMAINING EVENTS). SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, AS THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT, THEY WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT; WITH EXCEPTION OF THE REPORTED HANDLING ISSUE. THIS CASE WAS CONSIDERED OTHER REPORTABLE INCIDENT DUE TO DEVICE MALFUNCTION (BREAKAGE). PTC ANALYSIS CONCLUDED TO UNCONFIRMED QUALITY DEFECT AND CONSIDERED AN ASSESSMENT REGARDING A CAUSAL RELATIONSHIP BETWEEN A POTENTIAL QUALITY DEFECT AND AN ADVERSE EVENT IS NOT POSSIBLE AS NO ADVERSE EVENT WAS REPORTED. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 26-FEB-2015: HEALTH CARE PROFESSIONAL GENERAL QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT WHO HAS NO PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES AND DOES NOT HA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040331	CONCEPTUS	1/21/2015	1/27/2015

Event Information:

Event Date (B3): 4/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305A73746
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/12/2013
Explant Date (E7): 7/30/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT REPORTS SHE HAD AN ESSURE PLACED ON (B)(6) 2013. IMMEDIATELY AFTER IMPLANT SHE EXPERIENCED SEVERE PAIN. THE PAIN WAS RIGHT SIDED. "IT FELT LIKE SOMETHING WAS DIGGING INTO ME." THIS CAUSED PT A LOT OF DISCOMFORT AND AFFECTED HER ABILITY TO EXERCISE AND TO WORK. PT ALSO EXPERIENCED ABDOMINAL CRAMPING AND BLOATING. ON THE (B)(6) 2013, SHE WAS ADVISED BY PHYSICIAN THE ONLY WAY TO EXPLANT IS THROUGH SURGERY. DEVICE WAS EXPLANTED SURGICALLY ON (B)(6) 2013 LEAVING HER WITH TWO SCARS. PT WANTS ESSURE TAKEN OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040479	BAYER	1/21/2015	1/30/2015

Event Information:

Event Date (B3): 1/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): BAYER ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/21/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT ESSURE IMPLANTED ON (B)(6) 2012 AND IT HAS BEEN A NIGHTMARE. NEVER HAD AN ISSUE WITH MENSES IN MY LIFE AND NOW; I BLEED; NEVER ON A NORMAL CYCLE AND IT'S SO BAD IT'S AS IF I HAD JUST GIVEN BIRTH. NEVER HAD A WEIGHT PROBLEM; I HAVE GAINED OVER 50 LBS. FEEL A PINCHING SENSATION REGULARLY ON MY RIGHT SIDE IN THE PELVIC REGION. EXCESSIVE FLUID RETENTION WHICH NEVER WAS THERE PRIOR. I AM HAVING AN ULTRASOUND TODAY TO SEE WHAT'S GOING ON. I WANT THE ESSURE REMOVED AS SOON AS POSSIBLE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00038	BAYER HEALTHCARE LLC	1/22/2015	1/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B11728

Single Use: Y
Implant Date (E6): 6/20/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR PERMANENT CONTRACEPTION (LOT NUMBER B11728; EXPIRATION DATE MAR-2016). ADDITIONAL INFORMATION WAS PROVIDED ON (B)(4) 2014. PATIENT HAD A HSG (HYSTEROSALPINGOGRAM) DONE ON (B)(6) 2013 WHICH SHOWED BOTH COILS IN PLACE. ON (B)(6) 2014 THE PATIENT HAD A POSITIVE HCG TEST. ON (B)(6) 2014 IT WAS DETERMINED SHE HAD MISCARRIED AND ON (B)(6) 2014 AND ON THIS SAME DAY SUCTION DILATATION AND CURETTAGE AND TUBAL. ON (B)(6) 2014 PATIENT UNDERWENT A LATVH (LOWER ABDOMINAL VAGINAL HYSTERECTOMY). PATIENT WAS ALSO CLAIMING THAT HER ESSURE CAUSED HER TO DEVELOP RHEUMATOID ARTHRITIS. CORRECTION ((B)(4) 2014) FOLLOWING COMPANY INTERNAL REVIEW: LISTEDNESS OF THE EVENT MISCARRIAGE WAS UPDATED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2014. (B)(4). FINAL ASSESSMENT: PREGNANCY IS THE CONDITION OF CARRYING DEVELOPING OFFSPRING WITHIN THE BODY. THE TIME PERIOD DURING WHICH THIS CONDITION EXISTS; GESTATION. PROBABLE CAUSES FOR PREGNANCY INCLUDE: UNSUCCESSFUL BILATERAL TUBAL OCCLUSION (COMPLETE TISSUE INGROWTH), EXPULSION (RELATED TO MICRO-INSERT PLACEMENT ACCURACY), NO 3-MONTH CONFIRMATION TEST (HSG) OR MIS-READ OF HSG, LACK OF PATIENT COMPLIANCE TO IFU (I.E. USE OF ALTERNATE CONTRACEPTION UNTIL CONFIRMATION OF BILATERAL OCCLUSION). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE

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CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PREGNANCY IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH ONE CASE REFERS ALSO TO SIMILAR LACK OF EFFICACY TYPE OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. INTERNAL REVIEW ON (B)(4) 2014: (B)(4). THE FOLLOWING INFORMATION FROM (B)(4) WAS ADDED: ESSURE WAS INSERTED AND BOTH COILS WERE IN PLACE AND LOOKED GOOD. THREE MONTHS LATER, THE PATIENT BECAME PREGNANT AND HAD A MISCARRIAGE. AN EXAM REVEALED THE R (INTERPRETED AS RIGHT) ESSURE COIL WAS IN PLACE, AND THE LEFT COIL COULD NOT BE FOUND. FURTHER EXAM REVEALED THE LEFT COIL WAS BURIED IN THE UTERUS. AN ADDITIONAL PROCEDURE WAS DONE AND PATIENT HAD TO HAVE A HYSTERECTOMY. CASE WAS UPGRADED TO INCIDENT DUE TO INTERVENTION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A POSITIVE HCG TEST. PATIENT EXPERIENCED MISCARRIAGE AND CLAIMING THAT HER ESSURE CAUSED HER TO DEVELOP RHEUMATOID ARTHRITIS. ADDITIONALLY, IT WAS REPORTED LEFT COIL WAS BURIED IN THE UTERUS, PATIENT UNDERWENT A LOWER ABDOMINAL VAGINAL HYSTERECTOMY. MISCARRIAGE AND RHEUMATOID ARTHRITIS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED EVENTS IN ESSURE'S REFERENCE SAFETY INFORMATION. LEFT COIL WAS BURIED IN THE UTERUS IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED. IN THIS CASE, PREGNANCY WAS DIAGNOSED ABOUT 9 MONTHS AFTER INSERTION, THUS CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THIS EVENT CANNOT BE EXCLUDED. MISCARRIAGES USE TO OCCUR MAINLY DURING THE FIRST TRIMESTER OF PREGNANCY. THIS IS CONSIDERED TO BE DUE TO A HIGH NUMBER OF ABNORMAL EMBRYOS PRESENTING WITH EITHER CHROMOSOMAL AND/OR GROSS MORPHOLOGICAL ABNORMALITIES. CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THE REPORTED EVENT WAS CONSIDERED AS UNRELATED TO ESSURE. REGARDING RHEUMATOID ARTHRITIS, GIVEN ITS PATHOPHYSIOLOGY AND CONSIDERING ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES, THIS EVENT WAS ALSO CONSIDERED AS UNRELATED TO THE INSERT. FOR THE EVENT LEFT COIL WAS BURIED IN THE UTERUS, REGARDED AS DEVICE EMBEDMENT, ALTHOUGH THE EXACT DATE AND MECHANISM OF ITS OCCURRENCE WERE UNKNOWN, DUE TO ITS NATURE IT WAS CONSIDERED AS RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE PATIENT WAS SUBMITTED TO HYSTERECTOMY. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT ABOUT A CAUSAL RELATIONSHIP TO A POTENTIAL PRODUCT QUALITY DEFICIT BASED ON THIS REPORT. ADDITIONAL INFORMATION WAS REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 04-MAY-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00039	BAYER HEALTHCARE LLC	1/22/2015	1/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON 18-DEC-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DAY ON THE PAST SPRING. IT WAS REPORTED THAT PATIENT HAD COMPLAINED OF LOWER ABDOMINAL PAIN. PREGNANCY TEST WAS NEGATIVE. FOLLOW-UP INFORMATION RECEIVED ON 26-DEC-2014: NURSE STATED PATIENT HAD COMPLAINED OF LOWER ABDOMINAL PAIN AND HAD THE RIGHT ONE (ESSURE) OUT DUE TO PAIN. CASE WAS UPGRADED IN SERIOUSNESS AND REGARDED AS INCIDENT. FOLLOW-UP INFORMATION RECEIVED ON 05-JAN-2015 FOLLOW-UP ATTEMPTS WERE DONE WITHOUT SUCCESS. FOLLOW-UP FROM 20-JAN-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LOWER ABDOMINAL PAIN. ESSURE ON THE RIGHT SIDE WAS REMOVED. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE ESSURE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION WAS OBTAINED DESPITE FOLLOW-UP ATTEMPTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040468	BAYER	1/23/2015	1/30/2015

Event Information:

Event Date (B3): 1/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/15/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN MY TUBES IN (B)(6) 2014. AFTERWARDS, EXPERIENCED SEVERE BLEEDING, CRAMPS, TINGLING AND NUMBNESS IN HANDS AND LEGS. MY PERIODS BECAME VERY HEAVY WITH BLOOD CLOTS. I HAD ABDOMINAL PAIN AND LOWER BACK PAIN. IN JANUARY, I HAD THE HCG TEST DONE. IT TURNS OUT THAT ONE OF THE COILS HAS EXPELLED ITSELF FROM MY TUBE. I WILL HAVE TO HAVE SURGERY TO REMOVE IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040472	BAYER	1/23/2015	1/30/2015

Event Information:

Event Date (B3): 4/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/30/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE PLACED IN 2010. SINCE THEN I HAVE EXPERIENCED MANY SIDE EFFECTS. I USED TO HAVE NO CRAMPING IN MY BODY, NOW I HAVE PAIN THAT SHOOTS DOWN MY RIGHT LEG AND UP MY BACK. I NO LONGER BLEED WITH MY CYCLE IN A HEALTHY MANNER. I SIT ON THE TOILET AND HUGE CLOTS OF BLOOD FALL FROM MY BODY. I AM NO LONGER ABLE TO WEAR ANY SORT OF METAL JEWELRY WHETHER PURE GOLD OR NOT MY SKIN TURNS GREEN. A MONTH AGO, I WAS UNABLE TO STAND FOR APPROX. 18 HOURS DUE TO PAIN IN MY UTERUS AFTER INTERCOURSE. I WENT TO THE DOCTOR. THEY ARE UNABLE, AFTER AN ULTRASOUND, TO LOCATE THE RIGHT COIL, BUT THE LEFT ONE HAS MIGRATED AND IMPLANTED ITSELF INTO MY UTERUS. I BLED FOR 3 WEEKS AFTER HAVING THE PROCEDURE DONE. THE DOCTOR WHO DID IT TOLD ME THAT IT WAS FINE. IN (B)(6) THEY ARE RECOMMENDING A HYSTERECTOMY TO REMOVE MY UTERUS BEFORE MORE DAMAGE IS DONE TO MY BODY. I WILL BE MEETING WITH AN OB SURGEON ON THE (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040379	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 8/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). PELVIC PAIN, ABDOMINAL PAIN, DIARRHEA., NAUSEA, HAIR LOSS, WEIGHT GAIN, BLOOD COUNTS HIGH, MIGRATING COIL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040380	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 4/26/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT PREGNANT 5 MONTHS AFTER MY HSG TEST. I DEVELOPED ASTHMA A YEAR AFTER HAVING ESSURE IMPLANTED. MY MOODS WERE OF THE CHARTS. AFTER TWO YEARS, I STARTED LOSING LARGE AMOUNTS OF HAIR WHICH FREAKED ME OUT. I AFTER FOUR YEARS HAVE STARTED GETTING HEART PALPS OFF AND ON AS WELL HAD MAKE HIP PAIN BACK AND SHARP PAINS IN MY LEFT SIDE. I HAVE RECENTLY BEEN GETTING HIVES ON MY ARMS. NOT TO MENTION I FEEL LIKE I AM GOING CRAZY AND HAVE NO CONTROL OVER MY MOODS EMOTIONS OR MIND. SO MUCH I AM STARTING TO THINK ABOUT SEEING A DR UNTIL I FOUND OUT I WANT ALONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040381	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 3/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). MY UTERUS BEGAN CONTRACTING REGULARLY, THE PAIN BECAME UNBEARABLE, I FINALLY SAW A DOCTOR WHO PERFORMED SEVERAL DIAGNOSTIC TESTS, HYSTEROSCOPE, ULTRASOUND AND MRI. THE DIAGNOSIS WAS THE COILS MIGRATED AND EMBEDDED IN MY UTERUS AND HAD TO BE SURGICALLY REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040382	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 5/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAVEN'T HAD A PERIOD SINCE THE ESSURE WAS PUT IN, I HAVE SEVERE BLOATING, WEIGHT GAIN OF 27 LBS SO FAR AND CLIMBING, PAINFUL INTERCOURSE, NO SEXUAL DRIVE, AND EXTREMELY HARD TO REACH ORGASM, AND JOINT PAIN HAS BECOME ALLOT WORST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040383	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). PROLONGED BLEEDING, SEVERE CONSTANT PELVIC PAIN, OVARIAN CYST, BLOATING, GENERAL ILL FEELING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040384	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 12/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ONGOING TO HOSPITAL FOR MAJOR INFECTIONS, HEADACHES, LOWER PAIN. HAIR LOSS JUST PLAIN OUT SICK ALL THE TIME WITH NO ENERGY. IN LOTS OF PAIN ALL THE TIME, THAT WON'T GO AWAY!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040385	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 9/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SURGERY TO REMOVE EMBEDDED COILS FROM MY UTERUS, THE COILS MIGRATED FROM THE FALLOPIAN TUBES AND EMBEDDED INTO MY UTERUS CAUSING SEVERE PAIN, I WAS IN SURGERY FOR 5 1/2 HOURS WHILE THE DOCTOR TRIED TO REPAIR THE DAMAGE TO MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040386	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 5/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SINCE HAD A HYSTERECTOMY ! I NO LONGER HAVE ANY SHARP PAINS, ABDOMINAL SWELLING OR INFECTED LOOKING DISCHARGE. IT'S SAD THAT AT (B)(6) I HAD TO GO THROUGH THIS!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040387	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SKIN ALWAYS BROKEN OUT, WEIGHT GAIN, PAINFUL UTERUS AREA, BAD BLEEDING DURING MONTHLY PERIODS, HORRIBLE CRAMPS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040388	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 10/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, MEMORY LOSS, POOR CALCIUM IN MY TEETH, WEIGHT GAIN, EMOTIONAL DISTRESS, ANXIETY/DEPRESSION, HEADACHES, NAUSEA, LEG CRAMPS, ABDOMINAL CRAMPS, BLOATING, GAS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040389	BAYER	1/26/2015	1/27/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY CYCLES, INFLAMMATION, UTI, BACK AND HIP PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040497	ESSURE	1/26/2015	2/2/2015

Event Information:

Event Date (B3): 1/26/2015 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** UK

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE DEVICE FITTED IN 2013 DUE TO ALREADY LOSING A TUBE DUE TO AN ECTOPIC IN 2009 AND MY AGE. I WAS TOLD WE COULD NOT CONCEIVE. WE THEN WENT ON TO HAVE A SON IN 2012. WE DECIDED TO GET STERILIZED DUE TO THE HIGHER RISKS. I WAS TOLD BY MY "CONSULTED" THIS WAS PERFECT FOR ME. I HAVE RECENTLY FOUND OUT I'M PREGNANT AND I HAVE READ THIS SHOULD NOT HAVE BEEN PERFORMED IN ONLY ONE TUBE OR BLOCKED TUBE. I HAD BEEN VERY CONCERNED. I RANG THE HOSPITAL STATING CONCERNS AND HAVE BEEN DISMISSED WITH NO ANSWERS AND TOLD TO COME BACK IN A WEEK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040500	CONCEPTUS	1/26/2015	2/2/2015

Event Information:

Event Date (B3): 1/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE 2005
Device Type (E2): ESSURE 2005
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/24/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WAS IMPLANTED WITH ESSURE IN 2005, CHRONIC PAIN IN LEFT LOWER QUADRANT UNTIL 2009, EXPLORATORY LAPAROSCOPY REVEALED ADHESIONS ON LEFT BOWEL. THIS MOST INDICATED TO BE CAUSED BY PROBLEMS WITH INSERTION OF DEVICE ON LEFT FALLOPIAN TUBE. (INSERTING PHYSICIAN COULD NOT GET THE COIL IN SMOOTHLY AND HAD TO SEDATE ME). SINCE THEN, HAVE CONTINUED TO HAVE PAIN ON THIS SIDE, SEVERE BLOATING, CYSTS ON LEFT OVARY, NO DOCTOR WILLING TO DO ESSURE REMOVAL IN MY AREA. RECENTLY FOUND A DOCTOR WHO WILL REMOVE COILS VIA HYSTERECTOMY. HAVE EXPERIENCED A MULTITUDE OF OTHER SIDE EFFECTS AND EVEN DEVELOPED AUTOIMMUNE DISORDER AFTER PLACEMENT OF ESSURE. ALLERGIST CONFIRMED NICKEL ALLERGY. NO NICKEL TEST WAS DONE PRIOR TO INSERTION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00040	BAYER HEALTHCARE LLC	1/26/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B30423

Single Use: Y
Implant Date (E6): 12/26/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 29-DEC-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6)-2014. THE PHYSICIAN STATED SHE HAD A DEVICE FAILURE, SHE STATED "THE DEVICE SOUNDED LIKE IT RELEASED, SHE ROLLED BACK, BUT IT DID NOT RELEASE TOTALLY, AND SHE BELIEVES THERE IS A PIECE OF THE DEVICE LEFT IN THE TUBE." SHE STATED SHE SAW SOME METAL IN THE TUBE. SHE ATTEMPTED TO INSERT A SECOND DEVICE, AND BELIEVES THE TUBE MAY HAVE SPASMED AND THE INSERT COULD NOT BE PLACED. THE SECOND TUBE INSERT WAS PLACED WITHOUT ANY DIFFICULTY. FOLLOW-UP INFORMATION RECEIVED ON (B)(4)-2014: ON (B)(6)-2014 THE MEDICAL DOCTOR STATED THAT SHE DID NOT SEE ANY TRAILING COILS ON ONE SIDE, AND CONFIRMED THAT ON THE OTHER SIDE PLACEMENT WAS OK. SHE DID SEE SOME METAL IN THE TUBE AND SUGGESTED FLAT PLATE OF ABDOMEN TO DETERMINE IF COIL IS IN TUBE. SHE DID NOT SEE ANY COILS IN THE UTERUS. THE CORRECT INITIAL RECEIPT DATE IS (B)(6)-2014 AND NOT (B)(6)-2014 AS PREVIOUSLY REPORTED. PTC INVESTIGATION RESULT RECEIVED ON 13-JAN-2015. (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT

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IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY ARE ANTICIPATED EVENTS. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE. THE AE CASE REFERS ALSO TO USABILITY ISSUES. IN THIS PARTICULAR CASE, DEVICE BREAKAGE WAS REPORTED IN THE CONTEXT OF A DIFFICULT INSERTION. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY ARE ANTICIPATED EVENTS. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE PHYSICIAN ROLLED BACK, BUT ESSURE DID NOT RELEASE TOTALLY/SHE DID NOT SEE ANY TRAILING COILS ON ONE SIDE, PHYSICIAN BELIEVED THERE WAS A PIECE OF THE DEVICE LEFT IN THE TUBE AS SHE SAW SOME METAL IN THE TUBE. SHE ATTEMPTED TO INSERT ANOTHER DEVICE BUT TUBE MAY HAVE SPASMED AND THE INSERT COULD NOT BE PLACED. THESE EVENTS, INTERPRETED AS A DEVICE DEPLOYMENT ISSUE AND BREAKAGE; FOLLOWED BY A FAILED INSERTION DUE TO TUBAL SPASM WERE CONSIDERED NON-SERIOUS AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT FOR DEVICE BREAKAGE, WHICH WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, CONSIDERING THAT THE REPORTED EVENTS OCCURRED IN RELATION WITH ESSURE INSERTION PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED OTHER REPORTABLE INCIDENT DUE TO DEVICE MALFUNCTION (BREAKAGE). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP FROM 18-MAY-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. GENERAL QUESTIONNAIRE RECEIVED ON 22-MAY-2015 FROM PHYSICIAN: THE PATIENT DID NOT HAVE ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PRO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00041	BAYER HEALTHCARE LLC	1/27/2015	1/27/2015

Event Information:

Event Date (B3): 9/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/30/2012
Explant Date (E7): 9/21/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY IN THE UNITED STATES, ON BEHALF OF A PLAINTIFF IN UNITED STATES ON 10-SEP-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012 FOR STERILIZATION AND EXPERIENCED PERMANENT AND CONTINUING INJURIES. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION FROM 13-OCT-2014: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN DR-3020, DESIGN FMEA FOR ESS305. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN THIS PARTICULAR CASE, A MEDICAL EVENT WAS REPORTED, BUT NOT FURTHER SPECIFIED. NO FURTHER INFORMATION WAS AVAILABLE AT THIS POINT IN TIME. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A

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CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 30-DEC-2014: MEDICAL RECORDS RECEIVED. CONSUMER'S DEMOGRAPHIC INFORMATION WAS PROVIDED. HISTORICAL CONDITION INCLUDED: NICOTINE USE, GRAVIDA 3 AND PARA 3, PRETERM LABOR ((B)(6) 2012), INFECTIONS OF GENITOURINARY TRACT ANTEPARTUM ((B)(6) 2012), PRETERM LABOR WITH PRETERM DELIVERY ((B)(6) 2011), YEAST INFECTION, GERD (GASTROESOPHAGEAL REFLUX DISEASE) AND ANXIETY. ON (B)(6) 2012, PELVIC ULTRASOUND COMPLETE INCLUDING TRANSVAGINAL WAS PERFORMED FOR IRREGULAR BLEEDING, PATIENT 5 WEEKS POST PARTUM. ON (B)(6) 2012, ESSURE WAS INSERTED FOR PERMANENT BIRTH CONTROL. ON (B)(6) 2012, NOTES INCLUDED THAT PATIENT WAS PRESENTING RIGHT LOWER QUADRANT ABDOMINAL PAIN. SHE WAS DISCHARGED HOME WITH LORTAB FOR PAIN. ON (B)(6) 2012, PATIENT WAS PRESENTING ABDOMINAL PAIN, MORE LOCALIZED OVER ABDOMEN. PAIN RELIEVED WITH TORADOL. CT WAS PERFORMED AND SHOWED MILD PROMINENCE OF THE RIGHT RENAL COLLECTING SYSTEM WITH RIGHT EXTRA-RENAL PELVIS. HEPATIC CYST. A FEW SCATTERED RIGHT LOWER QUADRANT MESENTERIC LYMPH NODES WHICH MAY REFLECT MESENTERIC ADENITIS. OCCLUSION DEVICE OVER THE RIGHT FALLOPIAN TUBE/ADNEXA. DISCHARGE DIAGNOSES: ABDOMINAL PAIN, GENERALIZED. GASTROENTERITIS. ON (B)(6) 2012, PATIENT WAS PRESENTING LOWER ABDOMINAL PAIN, CRAMPING IN NATURE, MODERATE IN SEVERITY, NO RADIATION. NAUSEA, VOMITING (EVERY FEW DAYS) AND DIARRHEA (1XDAY FOR THE LAST 5 DAYS). EPISODE GRADUAL ONSET 2-3 WEEKS. COMPLAINED OF ABDOMINAL PAIN X 4 DAYS AGO SINCE PROCEDURE WAS DONE, PATIENT HAD RECENT CT THAT INDICATED KIDNEY STONES AND A COIL MISSING FROM THE FALLOPIAN TUBE FROM PROCEDURE DONE IN (B)(6). CLINICAL IMPRESSION: ACUTE ABDOMINAL PAIN; UTI (LOWER URINARY TRACT INFECTION). ON (B)(6) 2012, PATIENT WAS PRESENTING PERSISTENT RIGHT LOWER QUADRANT PAIN. LAST MENSTRUAL PERIOD WAS ON (B)(6) 2012. SHE WAS PRESENTING BLEEDING, POST DMPA (INTERPRETED DEPOT MEDROXYPROGESTERONE ACETATE). OPERATIVE NOTE: DIAGNOSTIC LAPAROSCOPY. ESSURE COIL IN RIGHT TUBE AND EXTRUDING BACK THROUGH THE FUNDUS. IMPLANTED INTO PERI-COLIC FAT OF THE BOWEL. REMOVED LAPAROSCOPICALLY WITHOUT DIFFICULTY. PELVIS WAS OTHERWISE NORMAL, INCLUDING APPENDIX. COIL WAS GRASPED NEAR THE INSERTION INTO THE BOWEL PERI-COLIC FAT AND TEASED OUT. IT WAS THEN REMOVED FROM THE FUNDUS OF THE UTERUS. INSPECTION REVEALED ANOTHER SECTION OF COIL STILL IN THE PERI-COLIC FATE, WHICH WAS TEASED OUT GENTLY. THE COIL WAS REMOVED IN ENTIRETY. ON (B)(6) 2012, A CT SCAN WAS PERFORMED AND SHOWED A MILD RIGHT HYDROURETER-NEPHROSIS OF QUESTIONABLE ETIOLOGY. ON (B)(6) 2012, PROGRESS NOTES INCLUDED THAT SHE WAS STILL PRESENTING SEVERE PAINS. SHE WAS SEEN IN ER AND TOLD SHE HAD KIDNEY STONE, BUT NEVER PASSED ONE. SHE WAS ALSO HAVING PAIN ON THE LEFT SIDE. ON (B)(6) 2012, OPERATIVE NOTE INCLUDE CYSTO RT RGP (INTERPRETED CYSTOSCOPY RIGHT WITH RETROGRADE PYELOGRAM) STENT PLACEMENT FOR RIGHT HYDRONEPHROSIS. ON (B)(6) 2012, PATIENT WAS STILL PRESENTING ABDOMINAL PAIN. SHE WAS COMPLAINING OF VAGINAL BLEEDING. ON (B)(6) 2012: THE STENT WAS REMOVED FROM RIGHT URETER. BLOODY EFFLUX LEFT URETER. BLADDER DRAINED. CURRENT IMPRESSION: HYDRONEPHROSIS; ABDOMINAL PAIN; MICROSCOPIC HEMATURIA. ON (B)(6) 2012, YEAST INFECTION INVOLVING VAGINAL AND SURROUNDING AREA. FROM (B)(6) 2012, HISTORY AND PHYSICAL NOTES INCLUDED: PELVIC PAIN AFTER HER ESSURE REMOVAL PROCEDURE, AND AFTER WORKUP, UNDERWENT LSC WHERE THE ESSURE COIL IN THE RIGHT TUBE WAS FOUND TO BE PROTRUDING THROUGH THE FUNDUS, AND SUPERFICIALLY ADHERED TO THE BOWEL. THE DISTAL END WAS IN THE TUBE. OPERATIVE NOTE: TOTAL LAPAROSCOPIC HYSTERECTOMY (TLH). SURGICAL PATHOLOGY FROM (B)(6) 2012 INCLUDED CHRONIC CERVICITIS. PROLIFERATIVE ENDOMETRIUM. LINES OF PERITONEAL REFLECTION. ON (B)(6) 2012, PATIENT WAS PRESENTING CHEST PAIN. DISCHARGE DIAGNOSES: CHEST WALL PAIN, COSTOCHONDRITIS. ON (B)(6) 2012, A CHEST X-RAY WAS PERFORMED AND SHOWED MINIMAL PERIBRONCHIAL CUFFING. MILD REACTIVE AIRWAYS DISEASE OR VIRAL PNEUMONITIS COULD NOT BE EXCLUDED. ON (B)(6) 2013, SHE WAS PRESENTING ABDOMINAL PAIN, GENERALIZED, NAUSEA, CONSTIPATION AND PAINFUL URINATION. ON (B)(6) 2013, SHE WAS STILL PRESENTING ABDOMINAL PAIN. CT WAS DONE AND SHOWED MULTIPLE AMORPHOUS TINY METALLIC FOREIGN BODIES SITUATED ALONG THE SUPERIOR MARGINS OF THE VAGINAL CUFF. ON (B)(6) 2013,

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PATIENT PRESENTED WITH PELVIC PAIN. SHE PASSED SOME METAL PIECES THROUGH HER VAGINA 4 DAYS BEFORE. SHE HAD ESSURE BIRTH CONTROL IMPLANT THAT WAS REMOVED, BUT THERE WERE PIECES LEFT BEHIND THAT NOW PASS THROUGH HER VAGINA. CT SHOWED METALLIC FBS (INTERPRETED FOREIGN BODIES), BUT NO OTHER ACUTE PROCESSES. ON (B)(6) 2013, PATIENT RETURNED TO ED (EMERGENCY DEPARTMENT) DEMANDING REMOVAL OF THE COILS AS SHE COMPLAINED OF PERSISTENT SHARP STABBING PAIN. CT SHOWED APPARENT METALLIC COILS IN THE CUFF. COLONOSCOPY SHOWED IBS (INTERPRETED IRRITABLE BOWEL SYNDROME). OPERATIVE NOTE: EXCISION OF VAGINAL CUFF. UPON OPENING THE CUFF, THERE WERE 3 TIE KNOT FASTENERS THAT HAD BEEN USED TO CLOSE THE VAGINAL CUFF DURING TLH. THESE WERE EXCISED. ON (B)(6) 2013, PATIENT WAS PRESENTING PELVIC PAIN, DYSPAREUNIA AND DYSURIA. ON (B)(6) 2013, TWO VIEWS OF ABDOMEN AND PELVIS SHOWED THREE SMALL RADIOPAQUE FOREIGN BODIES IN THE LEFT HEMIPELVIS WHICH MAY BE REMNANT OF ESSURE IMPLANT. ON (B)(6) 2013, A CT OF ABDOMEN AND PELVIS WAS PERFORMED AND SHOWED 1 CM SIMPLE CYST IN THE RIGHT LOBE OF THE LIVER AND 3 SMALL RADIOPAQUE FOREIGN BODIES IN THE LEFT ADNEXA. ON (B)(6) 2013, HISTORY AND PHYSICAL NOTES INCLUDED: SHE COULD NOT HAVE INTERCOURSE SECONDARY TO PAIN IN HER VAGINA. SHE COMPLAINED OF ABDOMINAL PAIN WITH URINATION AND DEFECATION. SHE REPORTED RECTAL PRESSURE. PELVIC PAIN WAS WORSE AS THE DAY GOES ON. SHE REPORTED A PRESSURE SENSATION WHEN HER BLADDER IS FULL AND THAT TENDS TO GET BETTER WHEN SHE EMPTIES HER BLADDER, AS WELL AS PELVIC PRESSURE WHEN HER COLON IS FULL AND IT TENDS TO GET BETTER WITH DEFECATION. SHE WAS ADMITTED FOR DIAGNOSTIC LAPAROSCOPY AND REMOVAL OF FALLOPIAN TUBES BILATERALLY AND HOPEFULLY REMOVAL OF THE REMAINING ESSURE COILS. OPERATIVE NOTE: NORMAL APPEARING FALLOPIAN TUBES AND OVARIES BILATERALLY. UNDER FLUOROSCOPIC GUIDANCE IT BECAME APPARENT THAT THE METALLIC OBJECTS SEEN ON THE X-RAY WERE IN THE VAGINAL CUFF AND NOT IN THE FALLOPIAN TUBES, AND AT THAT POINT IN TIME IT WAS DECIDED NOT TO REMOVE THE FALLOPIAN TUBES OR OVARIES, SINCE THEY DID NOT APPEAR TO BE PART OF THE PROBLEM. THAT PORTION OF THE VAGINAL CUFF WAS REMOVED. ADDITIONALLY, A LEFT RETROGRADE PYELOGRAPHY WAS PERFORMED SHOWING NORMAL DELICATE URETER THROUGHOUT. ON (B)(6) 2013, PATIENT WAS PRESENTING BACK PAIN, RECURRENT PROBLEM. SEVERE, STABBING AND SHOOTING PAIN RADIATES TO THE LEFT THIGH LEFT KNEE AND LEFT FOOT. ASSOCIATED SYMPTOMS INCLUDE LEG PAIN PARASTHESIAS AND TINGLING. CLINICAL IMPRESSION: LUMBAR RADICULOPATHY. ON (B)(6) 2013, MRI OF LUMBAR SPINE WAS PERFORMED AND SHOWED MULTILEVEL BILATERAL MILD FACET JOINT HYPERTROPHY. ON (B)(6) 2013, SHE WAS PRESENTING CHEST PAIN, BEGAN THE DAY BEFORE, OCCURS INTERMITTENTLY AND GRADUALLY WORSENING, ASSOCIATED WITH BREATHING AND COUGHING. DESCRIBED AS PLEURITIC, SHARP AND TIGHTNESS. ON (B)(6) 2014, HISTORY AND PHYSICAL NOTES INCLUDED: PATIENT HAD A RETURN OF PAIN MORE ON THE RIGHT THAN ON THE LEFT, SINCE (B)(6). SHE WAS PLACED ON ACTIVE BIRTH CONTROL PILLS TO TREAT ANY ENDOMETRIOSIS THAT MAY BE REMAINING WITH NO IMPROVEMENT. PAIN TRAVELS TO HER BACK AND DOWN RIGHT LEG. CYSTOSCOPY FOR INTERSTITIAL CYSTITIS NORMAL, COLONOSCOPY FOUND INFLAMMATION, IRRITATION AND SWELLING WHICH HAS IMPROVED WITH PROBIOTICS. SHE REPORTED SOME SQUEEZING WHEN SHE EMPTIES HER BLADDER. OPERATIVE NOTE: LAPAROSCOPIC DIAGNOSTIC/OPERATIVE SALPINGO-OOPHORECTOMY AND ABLATION OF ENDOMETRIOSIS, LAPAROSCOPIC APPENDECTOMY. FINDINGS: NORMAL APPEARING FALLOPIAN TUBES AND OVARIES, ENDOMETRIOSIS IN THE CUL-DE-SAC AND ON THE BLADDER AND IN THE RIGHT OVARIAN FOSSA, NORMAL APPEARING APPENDIX. FOLLOW UP FROM 13-JAN-2015: UPDATED PTC RESULT. FINAL ASSESSMENT: CASE UPGRADED TO INCIDENT. ASSESSMENT REVISED: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE

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EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A LAWYER/ATTORNEY AND REFERS TO A (B)(6) FEMALE PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RIGHT LOWER ABDOMINAL PAIN, SHE WAS SUBMITTED TO A DIAGNOSTIC LAPAROSCOPY AND ESSURE COIL IN RIGHT TUBE WAS EXTRUDING BACK THROUGH THE FUNDUS OF THE UTERUS INTO THE PERICOLIC FAT, THIS COIL WAS REMOVED. LATER, PATIENT HAD PERSISTENT PELVIC PAIN AND HYSTERECTOMY AND ANOTHER LAPAROSCOPY WERE PERFORMED. THE REPORTED EVENTS; INTERPRETED AS UTERINE PERFORATION AND PELVIC PAIN, WERE CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND ARE LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). ESSURE IS CONTRAINDICATED FOR PATIENTS WHO DELIVERED LESS THAN 6 WEEKS BEFORE DEVICE PLACEMENT, AND ITS SAFETY AND EFFECTIVENESS IS NOT ESTABLISHED IN PATIENTS WHO DELIVERED 8-12 WEEKS BEFORE THE PROCEDURE. IN THIS PARTICULAR CASE, PATIENT WAS APPROXIMATELY 7 WEEKS POSTPARTUM AT THE TIME OF ESSURE INSERTION. THIS CONDITION MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED UTERINE PERFORATION. NEVERTHELESS, CONSIDERING THIS EVENT'S NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING PELVIC PAIN, SINCE IT PERSISTED AFTER ESSURE COIL REMOVAL AND PATIENT HAD ENDOMETRIOSIS AND IRRITABLE BOWEL SYNDROME AS POSSIBLE ALTERNATIVE EXPLANATIONS, THIS EVENT WAS CONSIDERED UNRELATED TO ESSURE. THIS CASE WAS CONSIDERED AN INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 22-APR-2015: MEDICAL RECORDS RECEIVED: CONSUMER'S MEDICAL HISTORY INCLUDED FAMILY HISTORY OF ARTHRITIS AND IODINE ALLERGY. SHE DOES NOT USE ALCOHOL OR NICOTINE (PREVIOUSLY REPORTED AS NICOTINE USER). ON (B)(6) 2013, DURING CONSULTATI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00042	BAYER HEALTHCARE LLC	1/27/2015	1/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 10/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (B)(6) ON (B)(6) 2014 WHICH REFERS TO HERSELF, A FEMALE OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 FOR STERILIZATION. CONSUMER REPORTED SHE WAS TOLD THE ESSURE WAS MADE FROM (B)(4). IN (B)(6) 2013, THE CONSUMER HAD TO UNDERGO A SUB TOTAL HYSTERECTOMY THE ONLY WAY TO REMOVE THESE IMPLANTS BECAUSE SHE HAD A NICKEL ALLERGY, SHE FOUND OUT THESE IMPLANTS CONTAIN (B)(4). CONSUMER SUFFERED FROM CHEST PAINS, PALPITATIONS, ANEMIA THROUGH BLOOD LOSS AS HER PERIODS WERE VERY VERY HEAVY ALL THROUGH THIS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER 28300-14 AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN (B)(4). IT INCLUDES RECENT CASES RECEIVED BY (B)(4) AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: ALLERGY TO METALS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 100 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS SUBMITTED TO A SUBTOTAL HYSTERECTOMY BECAUSE SHE HAD NICKEL ALLERGY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. ESSURE INSERT CONSISTS OF A (B)(4), ALLERGIC REACTIONS MAY HAPPEN, AND ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND DUE TO THE LACK OF AN ALTERNATIVE EXPLANATION THE REPORTED EVENT WAS CONSIDERED AS RELATED TO ESSURE THERAPY, AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. THIS IS A HEALTH AUTHORITY CASE; NO FURTHER INFORMATION WILL BE ACTIVELY SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 03-FEB-2015. CONSUMER WILL NOT SIGN CONSENT FORM AS INSTRUCTED BY LEGAL REPRESENTATIVE; CASE MARKED AS POTENTIAL LEGAL CASE. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00043	BAYER HEALTHCARE LLC	1/27/2015	1/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 836525

Single Use: Y
Implant Date (E6): 11/13/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 30-SEP-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN HAS A PATIENT WHO HAS BEEN COMPLAINING OF PAIN. SHE WANTS ESSURE REMOVED AND SALPINGECTOMY. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP FROM 30-OCT-2014: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN DR-3020, DESIGN FMEA FOR ESS305. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT

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BASED ON THIS REPORT. GENERAL QUESTIONNAIRE PROVIDED BY PHYSICIAN ON 31-DEC-2014: THIS CASE WAS UPGRADED TO INCIDENT DUE TO INTERVENTION. THE PATIENT'S HISTORY INCLUDES A CERVICAL CONIZATION IN 2006 AND CURETTAGE IN 2012. SHE HAD 3 NORMAL SPONTANEOUS VAGINAL DELIVERIES. IN 2009, SHE EXPERIENCED A UTERINE PERFORATION WITH IUD (NOS). THE PATIENT HAD HYPOTHYROIDISM. ON (B)(6)-2012, ESSURE WAS INSERTED. THE LOT NUMBER USED WAS 836525. THE PATIENT WAS NOT POST-PARTUM AT TIME OF THE PROCEDURE. THE INSERTION WAS CONSIDERED EASY WITH EASY VISUALIZATION OF BOTH TUBAL OSTIUM. GENERAL ANESTHESIA WAS APPLIED DURING INSERTION. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. THE PATIENT USED CONTRACEPTIVE PATCHES AS BACK-UP CONTRACEPTION BEFORE TOTAL OCCLUSION CONFIRMATION. IN (B)(6) 2013, THE HSG WAS DONE WITH NORMAL RESULTS. ON UNSPECIFIED DATE, A LAPAROSCOPY WAS MADE AND SHOWED ESSURE DEVICE IN THE RIGHT CORNUA, PROTRUDING THROUGH THE SEROSA. THE PHYSICIAN STATED THAT A HYSTERECTOMY WAS NOT NECESSARY, BUT THE PATIENT HAD A BILATERAL SALPINGECTOMY DONE. HOWEVER, IT IS ALSO STATED THAT ESSURE DEVICES WERE NOT REMOVED AND WAS NOT PLANNED (CONTRADICTORY INFORMATION). PATIENT'S SYMPTOMS RESOLVED AFTER SURGERY. PHYSICIAN STATED THAT THE PATIENT'S CONDITION WAS NOT CAUSED OR CONTRIBUTED BY ESSURE DEVICES. FOLLOW UP (B)(6).2014: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: CASE UPGRADED TO INCIDENT WITH LOT INFO RECEIVED, ASSESSMENT UPDATED: LOT NUMBER 836525. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS REPORT CASE RECEIVED FROM A PHYSICIAN REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) IMPLANTED AND EXPERIENCED PELVIC PAIN AND ESSURE DEVICE IN THE RIGHT CORNUA, PROTRUDING THROUGH THE SEROSA, INTERPRETED AS UTERINE PERFORATION. THE EVENTS PELVIC PAIN AND UTERINE PERFORATION ARE SERIOUS DUE TO REQUIRED INTERVENTION. BOTH EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALTHOUGH THE EXACT DATE WAS NOT REPORTED, SHE RECOVERED AFTER ESSURE REMOVAL. CONSIDERING THIS INFORMATION AND THE NATURE OF THIS EVENT, PELVIC PAIN WAS CONSIDERED RELATED TO ESSURE USE. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF THE REPORTED EVENT IS NOT KNOWN, GIVEN ITS NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN CONTRAST, THE PHYSICIAN STATED THAT THE PATIENT'S CONDITION WAS NOT CAUSED OR CONTRIBUTED BY ESSURE. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. A PERFORATION QUESTIONNAIRE FOLLOW UP IS ALSO BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 15-MAY-2015 NO NEW CLINICAL INFORMATION PROVIDED. FOLLOW-UP FROM 30-JUN-2015: THE MAXIMUM NUMBER OF ATTEMPTS HAVE ALREADY BEEN ACHIEVED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS REPORT CASE RECEIVED FROM A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00044	BAYER HEALTHCARE LLC	1/27/2015	1/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039766) IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT SHE PRESENTED HEAVY BLEEDING NONSTOP FOR 6 MONTHS WITH EXCRUCIATING PAIN WHICH EVENTUALLY LED TO AN ABLATION; DNC (TERM NOT SPECIFIED); AND REMOVAL OF LEFT TUBE AND OVARY DUE TO SERIOUS INFECTION. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING NON-STOP FOR 6 MONTHS AND SERIOUS INFECTION. THESE EVENTS, INTERPRETED AS GENITAL HAEMORRHAGE AND PELVIC INFLAMMATORY DISEASE RESPECTIVELY, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS REPORT, THE CONSUMER HAD THIS BLEEDING WITH EXCRUCIATING PAIN WHICH EVENTUALLY LED TO AN ABLATION. GIVEN THE NATURE OF THE EVENT, CAUSALITY IS ASSESSED AS RELATED TO ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS CASE, THE CONSUMER HAD A REMOVAL OF LEFT TUBE AND A OVARY DUE SERIOUS INFECTION. ALTHOUGH THE ONSET DATE OF INFECTION WAS NOT SPECIFIED, THE ESSURE DEVICES ARE

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PLACED AND ACTS LOCALLY IN FALLOPIAN TUBES AND ARE VERY CLOSE TO THE OVARIES, SO THE EVENT IS ASSESSED AS RELATED TO ESSURE USE. SINCE BOTH EVENTS LED TO A REQUIRED INTERVENTION (ABLATION AND LEFT TUBE AND OVARY REMOVAL) THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 01-FEB-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RET

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00045	BAYER HEALTHCARE LLC	1/27/2015	1/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039760) IN UNITED STATES ON 15-JAN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE STARTED HAVING SHARP PAINS ON HER LEFT SIDE PELVIC AREA. ON AN UNSPECIFIED DATE, SHE HAD AN ULTRASOUND DONE AND THE RESULTS WERE THE COIL WAS FINE. IN 2014, SHE STARTED HAVING LOWER BACK PAIN AND; BAD CRAMPS IN MY PELVIC AREA. SHE STATED THAT SHE MISCARRIED TWINS AT HOME AND WENT TO THE ER, WHERE SHE HAD CT-SCAN DONE AND THEY SAID SHE HAD A CYST ON HER KIDNEY. THE PAIN BECAME UNBEARABLE THAT SHE WENT BACK TO THE ER SCREAMING FROM PAIN, SWEATING AND BENT OVER. THEY DID AN ULTRASOUND AND X-RAYS BUT STILL FOUND NOTHING. IN THE NEXT DAY, SHE WAS BACK IN THE ER SCREAMING FROM PAIN UNABLE TO TALK. ANOTHER ULTRASOUND AND X-RAYS AND FINALLY A GYNECOLOGIST SAID THE COIL DID NOT LOOK RIGHT BUT BECAUSE OF THE INFLAMMATION. HE COULDN'T SEE THE LEFT SIDE CLEARLY. A WEEK LATER SHE WAS ON PHYSICIAN'S OFFICE AND HAD A PELVIC ULTRASOUND DONE; THE PHYSICIAN SAID THE COIL WAS OUT OF PLACE, IT WAS NO LONGER IN THE LEFT TUBE. TWO WEEKS LATER SHE HAD TO HAVE A PARTIAL HYSTERECTOMY. HER SURGERY TOOK LONGER THAN USUAL BECAUSE OF ALL THE SCAR TISSUE; HER UTERUS WAS FUSED TOGETHER AND THE PHYSICIAN SAID WHEN HE OPENED HER UTERUS THE COIL WAS IN THE MIDDLE EMBEDDED IN THE TOP LAYER OF MUSCLE OF THE UTERUS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT ULTRASOUND ESSURE COIL WAS OUT OF PLACE. SHE WAS SUBMITTED TO A PARTIAL HYSTERECTOMY AND DURING THIS SURGERY ESSURE COIL WAS FOUND IN THE MIDDLE OF UTERUS EMBEDDED IN THE TOP LAYER OF MUSCLE OF THE UTERUS. ADDITIONALLY

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CONSUMER STATED SHE MISCARRIED TWINS AT HOME. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE; MISCARRIAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE THE REMAINING EVENT, REGARDED AS DEVICE EMBEDMENT (PARTIAL UTERINE PERFORATION) IS LISTED. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE INCLUDING ESSURE PLACEMENT. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED DEVICE EMBEDMENT/PARTIAL UTERINE PERFORATION IS UNKNOWN, GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED MISCARRIAGE, IT IS UNCLEAR FROM THE AVAILABLE INFORMATION IF THIS EVENT OCCURRED BEFORE OR AFTER ESSURE INSERTION. CONSIDERING THE LIMITED INFORMATION PROVIDED, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE ASSESSED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-FEB-2015. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00046	BAYER HEALTHCARE LLC	1/27/2015	1/27/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HOLD AF 01-29 THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# MW5039753) IN UNITED STATES ON 15-JAN-2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE EXPERIENCED HEAVY BLEEDING FROM 2014 (UNREADABLE DATE) TO TOTAL HYSTERECTOMY ON 2014 (UNREADABLE DATE). IN ADDITION CONSUMER INFORMED THAT HER LEGS WERE GOING NUMB AND SHE EXPERIENCED RASH ON RIGHT HIPS, WEIGHT GAIN AND BLOATING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; THEREFORE A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE EVENT HEAVY BLEEDING CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED: LEGS GOING NUMB, RASH ON RIGHT HIP, WEIGHT GAIN AND BLOATING. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 01-FEB-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00047	BAYER HEALTHCARE LLC	1/27/2015	1/27/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY (B)(4) IN UNITED STATES ON (B)(6) 2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER STATED APPROXIMATELY 4 YEARS LATER (2012) SHE STARTED DEVELOPING A RASH. SHE HAD SKIN TESTING AND DERMATOLOGY PATHOLOGY TESTING TO CONCLUDE SHE HAD DEVELOPED A GOLD ALLERGY. IN ADDITION, ACCORDING TO HER, SHE LATER LEARNED THAT ESSURE CONTAINS GOLD IN THE DEVICE AND, RECENTLY, SHE HAD A HYSTERECTOMY TO HAVE DEVICE REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO DEVELOPED RASH AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH INSERTS REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, CONSUMER UNDERWENT SKIN TEST WHICH CONCLUDED ON GOLD ALLERGY; ALTHOUGH ESSURE IS COMPOSED OF NICKEL-TITANIUM, SINCE IN METAL-ALLERGY PATCH TESTS FALSE POSITIVE OR NEGATIVE REACTIONS CAN OCCUR, AN ASSOCIATION BETWEEN THE REPORTED RASH WITH AN ALLERGY TO ESSURE COMPONENTS CANNOT BE EXCLUDED AND DUE TO THE INTERVENTION REPORTED, THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-FEB-2015. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR IN

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040407	BAYER	1/27/2015	1/27/2015

Event Information:

Event Date (B3): 12/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD INTENSE DEBILITATING CRAMPING THE DAY OF IMPLANTATION OF WHICH I GOT USED TO USING OTC PAIN MEDS. I COULD STILL FUNCTION UNLESS IT WAS COMING UP ON A PERIOD. THE CRAMPING AND SEVERE BLOOD FLOW (1 SUPER PLUS TAMPON PER HR W/ A MAXI PAD) AND BECAME QUICKLY ANEMIC. THE LOWER BACK PAIN WAS INTENSE AND MADE MY ROUTINE EXERCISE OF RUNNING UNBEARABLE. WHICH, SET UP THE DEPRESSION AND ANXIETY THAT WOULD LAST FOR THE YEARS TO COME. I HAD NO IDEA PAIN WOULD HAVE SUCH AN IMPACT EMOTIONALLY. SOME MONTHS, I WOULD HAVE MIGRAINES-I DID NOT HAVE THAT PROBLEM IN MY LIFE. I'VE HAD MONTHS WHERE THE BLOATING AND PAIN WAS SO BAD I WOULD VOMIT REPEATEDLY. WE DID NOT HAVE INSURANCE DURING THOSE YEARS, BUT WERE SELF-EMPLOYED

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040408	BAYER	1/27/2015	1/27/2015

Event Information:

Event Date (B3): 1/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I STARTED HAVING CHRONIC FATIGUE , SERIOUS BLOATING, WEIGHT GAIN, PAINFUL PERIODS, CONSTIPATION, BODY ACHES, LOWER BACK PAIN, CRAMPS, IN 2013 I WAS DIAGNOSED WITH FIBROMYALGIA. I HAVE MY THYROID CHECKED FREQUENTLY AND WITH MY MEDICATION, IS NORMAL. I HAVE ALSO BEEN DEALING WITH BRAIN FOG. THIS AND THE FATIGUE HAS CAUSED ME PROBLEMS W/WORK. I HAVE CUT MY HOURS AND I STILL HAVE ISSUES JUST GETTING THROUGH THE DAY, NOT TO MENTION I HAVE A TEENAGER AT HOME. SOME DAYS I AM SO EXHAUSTED, I HAVE TO STAY IN BED MOST OF THE DAY. I HAD THIS DONE IN 2008. I REMARRIED IN 2009 AND MY HUSBAND HAS SAID HE HAS WATCHED MY HEALTH GO DOWNHILL EVERSINCE. MY DOCTOR SAYS THE SAME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040409	BAYER	1/27/2015	1/27/2015

Event Information:

Event Date (B3): 12/14/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE HAD ESSURE SINCE (B)(6) 2004 SINCE THEN I HAVE EXPERIENCED-ABDOMINAL PAIN, PAINFUL INTERCOURSE, EXTREME JOINT PAIN IN ELBOWS, SHOULDERS, HIPS AND BACK AND DENTAL ISSUES. HAVE HAD SHOTS IN HIPS, BACK AND ELBOWS NOTHING HELPS. HAD HIP SURGERY IN 2009.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040410	BAYER	1/27/2015	1/27/2015

Event Information:

Event Date (B3): 10/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIES, PAIN, ANXIETY, PANIC ATTACKS, PALPITATIONS, RASHES, AUTO-IMMUNE, UVEITIS, SEVERE JOINT AND BACK PAIN., DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00048	BAYER HEALTHCARE LLC	1/27/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM FEMALE CONSUMER OF UNSPECIFIED AGE VIA A REGULATORY AUTHORITY (CASE# MW5039682) IN UNITED STATES ON 15-JAN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE HAD THE ESSURE PROCEDURE AFTER HER THIRD CHILD. SHE STARTED EXPERIENCING HORRIBLE PAIN IN HER ABDOMEN, WAS NAUSEOUS, DIZZY AND OFF BALANCE. SHE TOLD HER DOCTOR AND AFTER AN ALLERGY TEST AND FURTHER DISCUSSION DETERMINE IT WAS THE ESSURE COILS THAT WERE CAUSING THE ISSUE AS SHE WAS ALLERGIC TO NICKEL. EVEN THOUGH THE ESSURE REPRESENTATIVE SAID THAT THERE WAS HARDLY ANY NICKEL IN THE PRODUCT AND THAT IT WAS IMPOSSIBLE FOR WHAT TO BE THE ISSUE, HER PHYSICIAN ENDED UP HAVING TO DO SURGERY TO REMOVE THE COILS AND WHEN SHE TOOK THEM OUT THEY WERE BURNING INTO CONSUMER´S TUBES. SHORTLY AFTER THAT REMOVAL OF HER TUBES, SHE STARTED EXPERIENCING MAJOR BLEEDING PROBLEMS AND SHE FELT ANEMIC. SHE HAD TO HAVE A HYSTERECTOMY TO TAKE CARE OF THAT PROBLEM AND WAS UPSET THAT THIS HAS CAUSED MAJOR DEPRESSION AND ANXIETY IN HER LIFE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE INSERT) IMPLANTED AND EXPERIENCED ALLERGY TO NICKEL AND MAJOR DEPRESSION AMONG OTHER NON-SERIOUS EVENTS. MAJOR DEPRESSION AND ALLERGY TO NICKEL ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ALLERGY TO NICKEL IS ALSO SERIOUS DUE TO REQUIRED INTERVENTION. ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE, ALLERGY TO NICKEL IS LISTED AND MAJOR DEPRESSION IS UNLISTED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL.

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IN THIS PARTICULAR CASE, SHE EXPERIENCED NAUSEA, DIZZINESS AND BALANCE DISORDER THAT SHE ATTRIBUTED TO HER ALLERGY TO NICKEL. CONSIDERING THAT ESSURE IS A NICKEL-TITANIUM ALLOY, THE ALLERGY WAS CONSIDERED RELATED TO ESSURE. THE CAUSE OF DEPRESSION IS MULTIFACTORIAL. ENVIRONMENTAL FACTORS, INCLUDING COEXISTING ILLNESSES OR SUBSTANCE ABUSE, MAY AFFECT NEUROTRANSMITTERS AND HAVE AN INDEPENDENT INFLUENCE ON DEPRESSION. IN THIS PARTICULAR CASE, NO RISK FACTORS WERE REPORTED. HOWEVER, CONSIDERING THE NATURE OF DEPRESSION AND THE FACT THAT ESSURE HAS A LOCALIZED ACTION IN THE FALLOPIAN TUBES, THE MAJOR DEPRESSION IS CONSIDERED UNRELATED TO SUSPECTED DEVICE. SINCE THE PATIENT UNDERWENT A SURGERY TO REMOVE THE COILS, THE CASE WAS REGARDED AS INCIDENT. PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FOLLOW-UP WILL BE PURSUED SINCE NO CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 01-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040517		1/27/2015	2/3/2015

Event Information:

Event Date (B3): 1/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/17/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PERSISTENT, SEVERE, UNEXPLAINABLE PAIN IN LOWER ABDOMINAL (RIGHT SIDE AND CENTER SPECIFICALLY), RADIATING INTO LOWER BACK. PAIN FIRST NOTICED IN 2009, APPROXIMATELY ONE YEAR AFTER PLACEMENT OF ESSURE. OTHER ASSOCIATED PROBLEMS: PAINFUL INTERCOURSE, IRREGULAR MENSTRUATION BEFORE IMPLANT PLACEMENT, "CLOCK-WORK" REGULAR, SIGNIFICANT WEIGHT GAIN, EXTREME FATIGUE, HEADACHES, AND NAUSEA. THESE SYMPTOMS HAVE BEEN PERSISTENT, WITH NO RELIEF FOR SIX YEARS. REGULAR TRIPS TAKEN TO GYN AND GASTRO PHYSICIANS, NEITHER OF WHO CAN FIND A DIAGNOSABLE ISSUE. TO PHYSICIANS, THE SYMPTOMS ARE "UNEXPLAINABLE". SYMPTOMS HAVE AFFECTED "SHE'S" EVERYDAY LIVING. DATES OF USE: SINCE 2009, STILL USING. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00049	BAYER HEALTHCARE LLC	1/28/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER REGULATORY AUTHORITY (CASE# MW5039790) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO THE CONSUMER HERSELF, OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE EXPERIENCED MIGRAINES; HEAVY BLEEDING; BLOOD CLOTS; BACK AND PELVIC PAIN AND CRAMPING; CONTRACTIONS DURING MENSTRUAL; NAUSEA; WEAKNESS; ENLARGED UTERUS DURING MENSTRUAL EVER SINCE ESSURE INSTALLATION. SHE TRIED BIRTH CONTROL PILLS; EXERCISE; DIET CHANGE; 2 DIFFERENT ABLATIONS; TOOK LYSTEDA MONTHLY TO CALM THE BLEEDING AND NARCOTIC PRESCRIBED FOR MIGRAINES. A HYSTERECTOMY IS SCHEDULED IN (B)(6) 2015 TO REMOVE THE ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, THE CONSUMER EXPERIENCED MIGRAINES; HEAVY BLEEDING; BLOOD CLOTS; BACK AND PELVIC PAIN AND CRAMPING; CONTRACTIONS DURING MENSTRUAL; NAUSEA; WEAKNESS; ENLARGED UTERUS DURING MENSTRUAL EVER SINCE ESSURE INSTALLATION. SHE TRIED BIRTH CONTROL PILLS; EXERCISE; DIET CHANGE; 2 DIFFERENT ABLATIONS; TOOK LYSTEDA MONTHLY TO CALM THE BLEEDING AND NARCOTIC PRESCRIBED FOR MIGRAINES. GIVEN THE NATURE OF THE EVENT, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE AND SINCE AN INTERVENTION WAS REQUIRED (2 ABLATIONS) THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS HAS BEEN REQUESTED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 30-JAN-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00050	BAYER HEALTHCARE LLC	1/28/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM REGULATORY AUTHORITY (B)(4) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. IN 2012, SHE DEVELOPED A RASH OVER HER BODY IN ODD SPOTS INCLUDING ARMS, FACE AND CHEST. SHE HAS SEEN MANY DERMATOLOGISTS, HAD MANY BIOPSIES PERFORMED AND TOOK SEVERAL MEDICATIONS, BUT SHE HAS NOT RECOVERED YET AND NO CAUSE WAS FOUND FOR HER EVENT. SHE ALSO HAD OTHER SIDE EFFECTS SUCH AS ANXIETY, FORGETFULNESS, LOW SEX DRIVE, MOOD SWINGS THAT MAKE HER FEEL UNCOMFORTABLE, FEELING FAINT AND DIZZY WHEN MOVING TOO FAST OR EVEN SITTING STILL, JOINT PAIN EVERYWHERE BUT ESPECIALLY IN LOWER BACK AND HIPS AND A PAIN SO SEVERE IN LOWER ABDOMEN (MORE ON THE RIGHT SIDE) THAT RADIATED AROUND TO BACK AND SENT HER TO THE ER (EMERGENCY ROOM) 4 TIMES BETWEEN 2013 AND 2014. THAT SEVERE PAIN COMES AND GOES WHEN IT FEELS LIKE IT, BUT SHE ALSO HAS ABDOMINAL DISCOMFORT DAILY ALONG WITH BLOATING. DURING HER ER VISITS SHE HAD MULTIPLE ULTRASOUNDS, CT SCANS, X-RAYS, BLOOD WORK AND URINE TESTS, BUT NO EXAM PROVIDED ANY ANSWER CONCERNING HER EVENTS; IN ALL OF HER SCANS AND X-RAYS, THE COILS WERE SEEN. SHE WAS SEEN BY 2 HEMATOLOGISTS DUE TO CHRONIC FATIGUE, BUT BLOOD WORK REVEALED NOTHING. SHE ALSO EXPERIENCED NIGHT SWEATS, HOT FLASHES AND PAIN IN ABDOMEN. SHE WAS SEEN BY A RHEUMATOLOGIST WHO HAS TESTED HER FOR MANY INFLAMMATORY DISEASES, BUT FOUND NOTHING REGARDING HER CHRONIC JOINT PAIN, RANDOM FEVERS AND RASHES. SHE HAD GI ISSUES AS WELL WITH BLOATING, BELLY PAIN AND EVEN RASH (SHE THOUGH THAT SHE COULD BE CELIAC), SO SHE VISITED A GI DOCTOR. AFTER A TRIAL OF DIFFERENT MEDICATIONS THAT HAD NO EFFECT, SHE HAD AN UPPER ENDOSCOPY AND COLONOSCOPY PERFORMED IN 2013, BUT NOTHING WAS FOUND. IN ADDITION

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TO ALL THAT, SHE HAD A HYSTERECTOMY PERFORMED IN 2013 DURING WHICH ONLY HER UTERUS AND CERVIX WERE REMOVED, LEAVING HER OVARIES; SHE WAS NOT SURE WHETHER BOTH COILS WERE REMOVED OR NOT. SHE HAS SEEN HER GYNECOLOGIST IN REGARDS TO PAIN AFTER THE HYSTERECTOMY AND NOTHING; SHE MENTIONED TO HIM THAT THE COILS COULD BE THE REASON BEHIND HER PROBLEMS, BUT SHE WAS TOLD THAT IT COULD NOT BE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN SO SEVERE IN LOWER ABDOMEN (MORE ON THE RIGHT SIDE) THAT RADIATED AROUND TO BACK. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT AN UNKNOWN TIME AFTER ESSURE INSERTION. SEVERAL TESTS WERE PERFORMED AND THE RESULTS DID NOT SHOW NOTHING AND THE COILS WERE SEEN. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A HYSTERECTOMY WAS REQUIRED. ADDITIONALLY, SEVERAL NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 02-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00051	BAYER HEALTHCARE LLC	1/28/2015	1/28/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY FDA (B)(4) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. CONSUMER REPORTED THAT THE ONSET OF HER COMPLAINT STARTED IN 2014. THIS IS A LIST OF HER SIDE EFFECTS AND SYMPTOMS THAT SHE HAS EXPERIENCED DUE TO ESSURE: EXTREME PAIN IN THE RIGHT SIDE OF HER STOMACH. FELT LIKE SOMEONE WAS TAKING A NEEDLE NOSE PLIERS AND PUTTING IT IN HER STOMACH, ON THE RIGHT SIDE, AND TWISTING IT. SHE WENT INTO HER GYNECOLOGIST WHO DID THE IMPLANT AND DID AN EXAM AND FOUND BLOOD AND PUS, HER EXACT QUOTE. SHE STATED SHE HAD AN INFECTION. SHE GAVE HER A SHOT OF ANTIBIOTICS ON THE DAY OF HER EXAM, AS WELL AS 2 MORE ANTIBIOTICS TO TAKE FOR THE NEXT 2 WEEKS. ADDITIONALLY CONSUMER HAS BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: SHE HAD THE T.R.U.E (THIN-LAYER RAPID USE EPICUTANEOUS PATCH) TEST DONE BY A DERMATOLOGIST AND THE RESULTS WERE HIGHLY ALLERGIC TO GOLD AS WELL AS NICKEL. DUE TO THE EXTREME PAIN SHE WENT TO THE EMERGENCY ROOM IN 2014. SHE HAS HAD THE FOLLOWING SURGERIES DUE TO ESSURE: SHE HAD LAPAROSCOPIC VAGINAL HYSTERECTOMY IN 2014 TO REMOVE THE ESSURE DEVICES IN EACH FALLOPIAN TUBE, HER UTERUS, FALLOPIAN TUBES, CERVIX AND OVARIES WERE REMOVED. SHE WENT INTO THE EMERGENCY ROOM 3 (THREE) TIMES AFTER THE HYSTERECTOMY AS SHE WAS STILL EXPERIENCING THE EXTREME PAIN MENTIONED ABOVE. THE DATES SHE WENT INTO THE EMERGENCY ROOM WERE IN 2014. CONSUMER INFORMED THAT SHE WILL HAVE TO GET THE LOT NUMBER FROM HER PROVIDER WHO IMPLANTED IT AS WELL AS HER MODEL NUMBER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, EXPERIENCED INFECTION

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AND FOUNDED SHE WAS HIGHLY ALLERGIC TO NICKEL. SHE WAS SUBMITTED TO A HYSTO-SALPINGO-OOPHORECTOMY AND THE DEVICES WERE REMOVED. SHE CONSIDERED HER EVENTS AS RELATED TO THE SUSPECT INSERT. THE REPORTED EVENTS, REGARDED AS PELVIC INFECTION AND NICKEL ALLERGY, WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A (B)(4). ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. REGARDING PELVIC INFECTION, ESSURE MICRO-INSERTS ARE SUPPLIED STERILE AND PLACED UNDER HYSTEROSCOPIC GUIDANCE IN THE PROXIMAL FALLOPIAN TUBE. HOWEVER, AS WITH ALL TRANS-CERVICAL PROCEDURES, ESSURE PLACEMENT CAN CAUSE INFECTION DUE TO A BACTERIAL CONTAMINATION DURING INSERTION. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED (NO INFORMATION WAS GIVEN ABOUT INFECTION ONSET DATE OR NICKEL ALLERGY SYMPTOMS); NEVERTHELESS SINCE CONSUMER RELATED THESE EVENTS TO ESSURE AND AS AN INTERVENTION WAS REQUIRED AS TREATMENT, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-FEB-2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINC

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00052	BAYER HEALTHCARE LLC	1/28/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE ((B)(4)) IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT ONE TUBE WAS CLOSED AND THE OTHER WASN'T. SO SHE HAD 2 COILS IN HER RIGHT TUBE. THE PAIN WAS HORRIBLE AND SHE HAD CRYOABLATION DONE AFTER BLEEDING WOULDN'T STOP THAT MADE IT WORSE. NOW, SHE HAS CLUSTER HEADACHES AND IS STILL BLEEDING AND THE FOUL ODOR IS MORE THAN SHE CAN BEAR. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER REPORTED THAT ONE TUBE WAS CLOSED AND THE OTHER WASN'T. SO SHE HAD 2 COILS IN HER RIGHT TUBE. THE PAIN WAS HORRIBLE AND SHE HAD CRYOABLATION DONE AFTER BLEEDING WOULDN'T STOP THAT MADE IT WORSE. AT THAT MOMENT, SHE HAS CLUSTER HEADACHES AND IS STILL BLEEDING AND THE FOUL ODOR IS MORE THAN SHE CAN BEAR. GIVEN THE AVAILABLE INFORMATION AND EVENT'S NATURE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE AND SINCE INTERVENTION WAS REQUIRED (CRYOABLATION) THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW-UP INFORMATION RECEIVED ON 09-FEB-2015 - (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00053	BAYER HEALTHCARE LLC	1/28/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039550) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT THE CONSUMER HAD ESSURE INSERTED FOR 3 YEARS. DURING THIS TIME SHE EXPERIENCED CHRONIC DEPRESSION, JOINT /BONE PAIN, BACK PAIN, NAUSEA, HEADACHES, UNEXPLAINED RASHES, ITCHINESS, INTERNAL INFLAMMATION, FOGGINESS AND VAGINAL DISCOMFORT. ON AN UNSPECIFIED DATE, SHE HAD ESSURE REMOVED AND SINCE THEN SHE HAD NO LONGER EXPERIENCED THE SYMPTOMS PREVIOUSLY LISTED. DURING THESE PAST THREE MONTHS (AFTER REMOVAL) THERE WERE NO CHANGES IN HER DIET OR LIFESTYLE. THE ONLY SIGNIFICANT CHANGE HAS BEEN THE REMOVAL OF ESSURE; SHE WAS CONVINCED WITHOUT A DOUBT THAT ESSURE WAS THE SOURCE OF ALL THE SYMPTOMS SHE EXPERIENCED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BACK PAIN, WHICH RECOVERED AFTER ESSURE REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, BACK, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND AS THE EVENT RECOVERED WITH DEVICE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

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Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-FEB-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00054	BAYER HEALTHCARE LLC	1/28/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(4)2015 WHICH REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT THE INITIAL ESSURE IMPLANTATION WAS BOTCHED; THE FIRST DEVICE WAS DEPLOYED BUT NOT SEEN; THEN ANOTHER WAS DEPLOYED ON THE SAME SIDE. THE ONE MONTH DYE X-RAY SHOWED THE FIRST ESSURE HAD PERFORATED HER TUBE; AND WAS FREE FLOATING IN ABDOMEN; SOMEWHERE NEAR HER RECTUM/COLON. SHE WAS SCHEDULED TO HAVE AN UMBILICAL HERNIA FIXED AFTER HER LAST CHILD IN 2011 AND TALKED THAT SURGEON INTO HELPING HER GYNECOLOGIST TO REMOVE THE FIRST DEPLOYED IMPLANT. SHE HAD TO PUT HER FOOT DOWN AND DEMANDED HER SURGEON TO REMOVE THE INSERT THAT PERFORATED HER TUBE. CONSUMER ALSO STATED SHE WAS INITIALLY SKEPTICAL ABOUT THE WHOLE ESSURE PROCEDURE, SHE HAD NEVER HEARD OF THESE; HER GYNECOLOGIST TOLD HER THAT HE HAD DONE "A LOT" OF THESE; AND SHE REQUESTED QUANTITATIVE AND LONGITUDINAL REPORTS (WHICH HE NEVER GAVE HER). THE PHYSICIAN'S ADVICE WAS THAT SHE "WAS TOO HEAVY TO HAVE ANY MORE CHILDREN" AND HE PRESSURED HER INTO THE IMPLANTS AS HER BEST OPTION; MINIMALLY INVASIVE; SHORT RECOVERY FOR AN OUTPATIENT PROCEDURE. SHE FELT THIS PHYSICIAN WAS PROBABLY PAID OR REWARDED HANDSOMELY; FOR "RECOMMENDING" THESE; ALL THE WHILE; NOT DOING HIS DUE DILIGENCE IN FINDING OUT IF THEY WERE SAFE FOR THE LONG RUN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A X-RAY SHOWED FIRST ESSURE HAD PERFORATED HER TUBE AND WAS FREE FLOATING IN HER ABDOMEN; SOMEWHERE NEAR TO HER RECTUM/COLON. THIS DEVICE WAS SURGICALLY REMOVED. THE REPORTED EVENT, REGARDED AS FALLOPIAN TUBE

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PERFORATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURES (E.G. HYSTEROSCOPY, CURETTAGE) INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, CONSUMER STATED ONE ESSURE DEVICE WAS DEPLOYED BUT WAS NOT SEEN BY THE PHYSICIAN; THIS MAY SUGGEST THAT THE REPORTED FALLOPIAN TUBE PERFORATION MAY HAVE OCCURRED DURING ESSURE INSERTION. GIVEN THE ABOVE MENTION INFORMATION AND CONSIDERING THE REPORTED EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION FOR ESSURE REMOVAL ADDITIONALLY THE NON-SERIOUS EVENT THE FIRST DEVICE WAS DEPLOYED BUT NOT SEEN; THEN ANOTHER WAS DEPLOYED SAME IDE (REGARDED AS A DEVICE USE ERROR) WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-FEB-2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINC

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00055	BAYER HEALTHCARE LLC	1/28/2015	1/28/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5039535) IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. IT WAS REPORTED THAT SHE GOT THE PROCEDURE DONE 2008 AFTER THE BIRTH OF HER DAUGHTER. SHE DID NOT HAVE ANY PROBLEMS UNTIL SHE STARTED GETTING HER PERIODS AGAIN A YEAR LATER, AFTER SHE WAS FINISHED WITH NURSING. HER SYMPTOMS STARTED OUT MILD WITH BAD MENSTRUAL CRAMPING AND A YEAST INFECTION EVERY MONTH. SHE WAS SEEN NUMEROUS TIMES FOR NUMEROUS INFECTIONS, INCLUDING YEAST INFECTIONS, VAGINITIS AND CERVICITIS. OVER TIME HER PERIODS WERE GETTING HEAVIER AND SO MUCH MORE PAINFUL, HER PERIODS LASTED 10-14 DAYS AND SHE HAD PAIN EVEN WHEN SHE WAS NOT ON PERIOD. ULTRASOUNDS AND OTHER TESTS INCLUDING BLOOD WORK TO RULE OUT OTHER THINGS WERE DONE. SHE WAS PUT ON THE PILL FOR A WHILE BUT THAT DID NOT HELP. THE PAIN GOT UNBEARABLE AND SHE WAS PRESCRIBED WITH MANY PAIN KILLERS AND NARCOTICS AND THEN, FINALLY, SHE WAS SUGGESTED FOR HYSTERECTOMY. PHYSICIAN TOLD HER THAT SINCE SHE HAD THE ESSURE COILS IN HER TUBES, THAT THE BLOOD FROM HER PERIODS HAD NO WHERE TO GO BUT TO OVERFLOW INTO HER UTERUS, CAUSING EXTREME PAIN. IN 2013 SHE HAD A HYSTERECTOMY. SHE LIVED IN PAIN FROM 2009-2013; ABOUT 4 YEARS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THE PRESENT CASE, THE CONSUMER REPORTED THAT AFTER SHE HAD A HYSTERECTOMY THE EVENT RESOLVED.

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THEREFORE A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE REPORTED EVENT PAIN CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-FEB-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00057	BAYER HEALTHCARE LLC	1/28/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD PAIN RIGHT AFTER ESSURE IMPLANTATION UNTIL SHE HAD IT REMOVED. SHE STATED THAT IT WAS A SHARP SHOOTING PAIN GOING INTO HER THIGHS BACK, STOMACH AND PELVIC AREA. SHE HAD INTENSE HOT FLASHES. SHE FELT LIKE THEY WERE TRYING TO PUSH OUT OF HER BODY AND EXPERIENCED STABBING PAIN, ITCHING, HIVES, BIG SWOLLEN LIPS, THROWING UP FROM BEING IN SO MUCH PAIN AND NONSTOP BLEEDING. ASO, SHE WAS NOT BEING ABLE TO SLEEP. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN RIGHT AFTER ESSURE IMPLANTATION UNTIL HAD IT REMOVED AND NONSTOP BLEEDING. THESE EVENTS INTERPRETED AS PELVIC PAIN AND GENITAL HAEMORRHAGE RESPECTIVELY, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. ALSO, ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER REPORTED THAT SHE HAD PAIN RIGHT AFTER ESSURE IMPLANTATION UNTIL SHE HAD IT REMOVED. SHE STATED THAT IT WAS A SHARP SHOOTING PAIN GOING INTO HER THIGHS BACK, STOMACH AND PELVIC AREA. ALSO, CONSUMER INFORMED SHE EXPERIENCED INTENSE HOT FLASHES AND HIVES. SHE FELT LIKE THEY WERE TRYING TO PUSH OUT OF HER BODY AND SHE WAS NOT BEING ABLE TO SLEEP. GIVEN THEIR NATURE, THE SERIOUS EVENTS

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ARE ASSESSED AS RELATED TO ESSURE USE. SINCE AN INTERVENTION WAS IMPLIED (THE CONSUMER MENTIONED THAT ESSURE WAS REMOVED) THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 11-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4).

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00058	BAYER HEALTHCARE LLC	1/28/2015	1/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5039518) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. IN 2012 THE CONSUMER HAD A 4TH CHILD BECAUSE ESSURE DID NOT DO WHAT IT SHOULD HAVE (DEVICE WAS INEFFECTIVE). ON AN UNSPECIFIED DATE THE RIGHT COIL MIGRATED TO HER UTERUS, BUT DID NOT AFFECT HER BABY. SIX WEEKS AFTER THE BABY'S BIRTH SHE WENT TO HER PHYSICIAN TO REMOVE THIS ONE ESSURE FROM HER UTERUS AND REPAIR IT. SHE UNDERWENT A TUBAL. SHE ALSO BROKE OUT IN HIVES AND HAD PAIN ALL THE TIME ON AN UNSPECIFIED DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND RIGHT COIL MIGRATED TO HER UTERUS AND HAD A 4TH CHILD. THE FIRST EVENT, INTERPRETED AS DEVICE EXPULSION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND THE OTHER EVENT (PREGNANCY) IS NON-SERIOUS. ALL EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALSO, UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, THE CONSUMER STATED THAT SHE HAD A 4TH CHILD BECAUSE ESSURE DID NOT DO WHAT IT SHOULD HAVE. THE RIGHT

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COIL MIGRATED TO HER UTERUS BUT DID NOT AFFECT HER BABY. SIX WEEKS AFTER THE BABY BIRTH, SHE WENT TO HER PHYSICIAN TO REMOVE THIS MICRO-INSERT FROM HER UTERUS AND REPAIR IT. SHE UNDERWENT A TUBAL. ADDITIONALLY, SHE BROKE OUT IN HIVES AND HAD PAIN ALL THE TIME. THE CIRCUMSTANCES AND MECHANISM OF THIS EXPULSION WERE NOT INFORMED AND IT IS NOT POSSIBLE TO KNOW IF THE EVENT INITIATED BEFORE OR AFTER THE CONCEPTION, THEREFORE DEVICE INEFFICACY CANNOT BE EXCLUDED. BESIDES, GIVEN ITS NATURE, THE EXPULSION IS ASSESSED AS RELATED TO ESSURE USE. SINCE AN INTERVENTION REQUIRED WAS IMPLIED (ESSURE WAS REMOVED, THE UTERUS REPAIRED AND A TUBAL LIGATION WAS PERFORMED) THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 02-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). (B)(4). FINAL A

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040556	BAYER	1/28/2015	2/4/2015

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 5/10/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT ESSURE (B)(6) 2010. DID THE HCG TEST AND ALL WAS BLOCKED AND WHERE IT WAS SUPPOSED TO BE. AFTER ABOUT 6 MO., I HAVE HAD HIGH BLOOD PRESSURE, IRREGULAR PERIODS, PAINFUL INTERCOURSE, HIP AND JOINT PAIN, INSOMNIA, WEIGHT GAIN, MUSCLE SPASM, DRY EYES/SKIN/HAIR, CRAMPING, SHARP STABBING PELVIC PAIN, HOT FLASHES, PCOS EXCESSIVE BLEEDING IN PERIODS , LONG MENSTRUAL CYCLES, SPOTTING AFTER INTERCOURSE, ITCHING OF VAGINAL ENTRANCE AND LIPS, BREAST TENDERNESS, ABDOMINAL FLUTTERING, BACK HIP/JOINT PELVIC PAIN, ALL OVER BODY ACHES, FATIGUE, METAL TASTE IN MOUTH, HEARTBURN, HEADACHES AND MIGRAINES, DIZZINESS, FAINTING, TINGLING, AND NUMBNESS IN ARMS/HANDS/LEGS/FEET, FORGETFULNESS, RINGING IN EARS, SKIN FEELS LIKE ITS BURNING OR TINGLING, TREMORS/SHAKINESS AND EASILY UNEXPLAINED BRUISING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040557	BAYER	1/28/2015	2/4/2015

Event Information:

Event Date (B3): 1/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/9/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ESSURE COILS AND THEY HAVE CAUSED ME MANY DOCTOR VISITS/HOSP VISITS. I NOW HAVE TO HAVE A HYSTERECTOMY DUE TO ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00056	BAYER HEALTHCARE LLC	1/29/2015	1/29/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# MW5039001) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT CONSUMER STARTED EXPERIENCING HORRIBLE ABDOMINAL PAINS. AFTER A COUPLE MONTHS, SHE SAW HER PHYSICIAN AND WAS SEEN THAT THE IMPLANTS HAD ACTUALLY MIGRATED AND SHE NEEDED TO HAVE SURGERY TO REMOVE THEM AND HER TUBES REMOVED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY, REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER A COUPLE MONTHS IT WAS SEEN THAT THE IMPLANTS

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HAD MIGRATED. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE PATIENT SAW HER PHYSICIAN A COUPLE OF MONTHS AFTER INSERTION AND IT WAS SEEN THAT THE IMPLANTS HAD ACTUALLY MIGRATED AND SHE NEEDED TO HAVE SURGERY TO REMOVE THE DEVICES AND HER TUBES. ALTHOUGH THE EXACT MECHANISM AND CIRCUMSTANCES OF THIS DISLOCATION ARE NOT CLEAR, GIVEN THE NATURE OF THE EVENT, IT WAS ASSESSED AS RELATED TO ESSURE USE. SINCE AN INTERVENTION WAS REPORTED, THE CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040414	BAYER	1/29/2015	1/29/2015

Event Information:

Event Date (B3): 6/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ONGOING, WORSENING FATIGUE, BRAIN FOG...IRREGULAR CYCLES, BLEEDING, ABDOMINAL PAIN, IBS SYMPTOMS AND AUTO-IMMUNE DIAGNOSES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040415	BAYER	1/29/2015	1/29/2015

Event Information:

Event Date (B3): 12/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) SHARP ABDOMINAL PAIN, DEPRESSION, PAINFUL SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040416	BAYER	1/29/2015	1/29/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, PAIN MAJORITY IN RIGHT SIDE OVARY AREA DOWN MY BACK. NUMBNESS OF TOES, ACHING BONES/JOINTS, IRREGULAR PERIODS. MEMORY LOSS, WEIGHT GAIN, MOOD SWINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040417	BAYER	1/29/2015	1/29/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE ABDOMINAL PAIN, SWELLING AND TENDERNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040418	BAYER	1/29/2015	1/29/2015

Event Information:

Event Date (B3): 11/20/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEPRESSION, LONG PERIODS, BLOOD CLOTS, ABDOMINAL PAINS, BACTERIA "VAGINOUS", HURTS DURING SEX, HEADACHES, LOSS OF APPETITE ETC..

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040419	BAYER	1/29/2015	1/29/2015

Event Information:

Event Date (B3): 9/4/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NO MEDICAL ISSUES. ESSURE PLACEMENT (B)(6) 2008, EXTREME PAIN ON RIGHT SIDE AND BACK MORE SO DURING MY REAL CYCLE, CONTINUING TO PRESENT. (B)(6) 2014. CONSTANT JOINT PAIN, SPORADIC JOINTS, EFFECTED ONE IS ALWAYS ACHING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040604	BAYER HEALTH CARE	1/30/2015	2/9/2015

Event Information:

Event Date (B3): 3/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONE DAY I WOKE UP IN THE MOST TERRIBLE PAIN EVER. I WENT TO THE DOCTOR THE NEXT DAY AND WAS TOLD IT WAS BECAUSE OF THE ESSURE BIRTH CONTROL I HAD GOTTEN. SO MY DOCTOR REMOVED IT AND AFTER THAT I CONTINUED TO SUFFER FROM TERRIBLE PAIN STILL TODAY. I HAVE TO TAKE PAIN MEDICINE JUST TO GET THROUGH MY DAYS. IT'S BECOMING HECTIC ON MY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040605	BAYER	1/30/2015	2/9/2015

Event Information:

Event Date (B3): 1/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/14/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS INSERTED ON (B)(6), 2015. SINCE THAT DAY I HAVE NOT STOPPED BLEEDING OR CRAMPING. I HAVE SEVERE LEG AND BACK PAIN AND TERRIBLE HEADACHES. I CONTACTED MY DR ONE WEEK AFTER MY PROCEDURE TO REPORT MY CONTINUE BLEEDING AND PAIN AND THEY SAID THIS WAS NORMAL AND CONTINUE WITH IBUPROFEN. I CONTACTED MY DR AGAIN TWO WEEKS AFTER MY PROCEDURE TO REPORT MY SYMPTOMS AGAIN AND WAS TOLD THIS SOUNDS ACCEPTABLE AND CONTINUE TO MONITOR "UNLESS BECOMES WORSE." LAST NIGHT THERE WAS A NEWS STORY ABOUT ESSURE WITH INTERVIEWS OF WOMEN SUFFERING FROM DEBILITATING SYMPTOMS AND I NOW UNDERSTAND WHERE MY LEG AND BACK PAIN IS COMING FROM. THESE SIDE EFFECTS WERE NOT DISCLOSED IN MY CONSULTATION AND I'VE READ THE ESSURE WEBSITE AND IT'S NOT DISCLOSED HOW TERRIBLE THESE IMPLANTS CAN BE FOR SOME WOMEN. IT ONLY STATES "RARE INCIDENTS" WHEN THERE ARE THOUSANDS OF WOMEN SUFFERING AND OVER 12,000 HAVE SIGNED A PETITION AGAINST THIS PRODUCT. I WANT THESE COILS REMOVED AND I'M NOT SURE MY INSURANCE IS GOING TO PAY FOR THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040606	BAYER	1/30/2015	2/9/2015

Event Information:

Event Date (B3): 1/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/6/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS (B)(6) 2015. HAD THE PROCEDURE IN MY OBGYN OFFICE. I'VE HAD NOTHING BUT PAIN SINCE THE DAY THEY WERE PUT IN, SEVERE CRAMPING AND PAIN, HEADACHES, FATIGUE, LEG PAIN AND LOWER BACK PAIN, BLEEDING STILL. I AM ON 4 DIFFERENT PAIN PILLS TO CONTROL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040601	BAYER	1/31/2015	2/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/28/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL PROCEDURE DONE IN (B)(6) 2011 AFTER MY LAST SON. THREE WEEKS AFTER MY DR PLACED THE COILS, THE COIL ON THE LEFT SIDE FELL OUT. I TOOK IT TO MY DR AND SHOWED THEM, WHICH WAS GOOD BECAUSE THEY SAID I WAS LYING, IT COULDN'T HAPPEN, UNTIL I SHOWED THEM THE COIL. I ASKED THEM TO TAKE THE RIGHT SIDE OUT SINCE IT WOULD DO NO GOOD TO HAVE ONE SIDE IN AND NOT THE OTHER PLUS I WAS WORRIED IF ONE MOVED THE OTHER MAY BE MOVING, STUCK SOMEWHERE OR ON IT'S WAY OUT. MY DR REFUSED SAYING THEY WERE SURE IT WAS FINE AND THEY WOULDN'T NEED TO DO ANYTHING FURTHER WITH ME, MEANING AFTER TEST TO SEE IF IT WAS CLOSED OFF ON THE RIGHT. I HAVE BEEN HAVING MAJOR HEALTH PROBLEMS SINCE INCLUDING; SEVERE HEADACHES, SEVERE ABDOMEN AND BACK PAIN, SHOOTING PAIN DOWN MY RIGHT LEG, WEIGHT LOSS, TIRED CONSTANTLY, ALWAYS SICK, NOT SLEEPING, HEART PALPITATIONS, CHEST PAINS, RACING HEART, BOWEL PAIN, SEVERE CONSTIPATION, DIARRHEA, FEVER, NIGHT SWEATS, HOT FLASHES. I HAVE BEEN TO DR AFTER DR TRYING TO FIND SOMEONE TO LISTEN TO ME ABOUT ALL MY SYMPTOMS, MOSTLY THE ABDOMEN PAIN AS IT FEELS LIKE I'M BEING ROOTED APART MORE THEN NOT ANYMORE. EVERY DR DID NOT DO TESTS OR ANYTHING TO SEE WHAT THE PROBLEM WAS. MOST JUST SAID IT COULDN'T BE THE ESSURE. I'VE ASKED SEVERAL FOR A HYSTERECTOMY TO JUST TAKE THE ESSURE OUT, BUT HAVEN'T FOUND A DR THAT WILL DO IT. I RECENTLY FOUND A OB DR THAT IS AMAZING AND WANTS TO RUN A BUNCH OF BLOOD TESTS AND SCANS TO SEE IF SHE CAN FIGURE OUT THE PROBLEM. SHE DID CONFIRM THAT I HAVE AN INFECTION IN MY UTERUS AT THIS TIME SO I STARTED ANTIBIOTICS (B)(6). ENDOSCOPY AND COLONOSCOPY (B)(6) 2012- SHOWED GASTRITIS IN MY STOMACH AND NOTHING MUCH WRONG WITH MY COLON. CT SCAN (B)(6) 2013-

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SHOWED THE COIL, BUT IT SEEMED TO BE IN THE WRONG PLACE OF MY TUBE. ALSO WAS SHOWN A CYST ON MY RIGHT SIDE THAT I'VE NEVER HAD BEFORE. CT SCAN (B)(6) 2014- AGAIN SHOWED THE COIL, BUT APPEARED TO BE IN THE WRONG PLACE OF MY TUBE. ALSO SHOWN A CYST ON MY RIGHT SIDE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040609		2/1/2015	2/9/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE AFTER MY 2ND DAUGHTER WHO WAS CONCEIVED WHILE ON THE MIRENA IUD. I HAD A TROUBLED PREGNANCY AND HAD HER 6 WEEKS EARLY AND WAS TOLD I PROBABLY WOULDN'T SURVIVE ANOTHER PREGNANCY. SO TO CURE THE PROBLEM, I WENT WITH THE ESSURE. THIS WAS ALMOST 3 YEARS AGO. SHORTLY AFTER THE ESSURE PROBLEM OCCURRED SUCH AS BACTERIAL INFECTIONS, YEAST INFECTIONS, SEVERE CRAMPS DAILY, HEAVY AND PAINFUL MENSTRUAL CYCLES. I WAS IN AND OUT OF THE DOCTOR AT LEAST 3-4X A MONTH. OVER TIME IT PROGRESSED TO NUMBNESS IN MY VAGINAL AREA, HOT FLASHES, LACK OF SEX DRIVE AND THE ABILITY TO GET "WET" PRETTY MUCH A COMPLETE HORMONAL SHIFT. I AM 23 YEARS OLD. NOT GOOD. I'VE BEEN THROUGH LOTS OF TESTS AND POSSIBILITIES OF WHAT ALL THE PROBLEMS COULD BE BEFORE BLAMING THE ESSURE. ALL FINGERS ARE POINTING AT THE IMPLANT NOW AFTER 3 YEARS OF THE GUESSING GAME AND SEARCHING FOR THE PROBLEM. IT HAS RUINED MY LIFE FOR SURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00059	BAYER HEALTHCARE LLC	2/2/2015	2/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS STATED THAT ESSURE COILS WERE REMOVED LAPAROSCOPICALLY. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COILS WERE REMOVED LAPAROSCOPICALLY. THIS EVENT, INTERPRETED AS ESSURE SURGICAL REMOVAL, WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND

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LISTED IN ESSURE REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, SINCE DEVICE REMOVAL WAS REQUIRED, A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 28-MAY-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSUR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00061	BAYER HEALTHCARE LLC	2/2/2015	2/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT FROM A CONSUMER IN UNITED STATES WAS IDENTIFIED IN THE INTERNET ON (B)(6) 2013 ON A PAGE OF A NEWSPAPER IN THE UNITED STATES. THE REPORT REFERS TO THE REPORTING (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY PERIODS, JOINT PAIN, SHARP PELVIC PAIN, THE COILS HAD MOVED INTO HER UTERUS AND BECAME EMBEDDED THERE, COILS REMOVED VAGINALLY BUT XRAYS SHOW SEVERAL FOREIGN BODIES IN UTERUS, SHE BELIEVES THESE (FOREIGN BODIES) MAY BE ESSURE FRAGMENTS, AND SHE WAS DEBILITATED BY PAIN. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. IN 2009, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IN 2011, CONSUMER FOUNDED A (B)(6) GROUP ON ESSURE PROBLEMS AFTER SHE HAD EXPERIENCED HEAVY PERIODS, JOINT PAIN, SHARP PELVIC PAIN, AND OTHER SYMPTOMS (UNSPECIFIED) BEFORE LEARNING THE COILS HAD MOVED INTO HER UTERUS AND BECAME EMBEDDED THERE. THE COILS WERE REMOVED VAGINALLY BUT X-RAYS SHOW SEVERAL FOREIGN BODIES IN UTERUS, SHE BELIEVES THESE (FOREIGN BODIES) MAY BE ESSURE FRAGMENTS. CONSUMER PLANS TO SCHEDULE A HYSTERECTOMY, SHE DID NOT KNOW WHETHER THIS WOULD MAKE IT ANY BETTER, BUT SHE HAS BEEN DEBILITATED BY PAIN. CONSUMER CONSIDERED THE EVENTS RELATED TO ESSURE. FOLLOW UP (B)(6) 2014 AND (B)(6) 2014: NO NEW INFORMATION. UNABLE TO PROCEED WITH FOLLOW-UP AS CONTACT INFORMATION NOT AVAILABLE FOR CONSUMER. ON (B)(6) 2014 THE CASE WAS CLOSED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: THE REPORTING CONSUMER STATED THAT THE CONSUMER REFERRED IN THIS CASE HAD SUFFERED A LIFE-THREATENING EVENT. FOLLOW-UP RECEIVED ON (B)(6) 2014: ACCORDING TO THE CONSUMER ESSURE COIL PUNCTURED A UTERUS, ADHERED TO OUTSIDE (THE PREVIOUS REPORTED EVENT THE COILS HAD MOVED

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INTO HER UTERUS AND BECAME EMBEDDED THERE WAS AMENDED TO ESSURE COIL PUNCTURED A UTERUS, ADHERED TO OUTSIDE). THE CONSUMER WAS NOT HOSPITALIZED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014 FROM CONSUMER (POSTED ON A WEBSITE PLATFORM): ESSURE WAS INSERTED FOR BIRTH CONTROL. CONSUMER STATED THAT SHE WAS TAKING IBUPROFEN BECAUSE WAS PRESENTING JOINT DETERIORATION AND THAT THE INFLAMMATION WAS PAINFUL. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON (B)(6) 2014: INFORMATION RECEIVED FROM CONSUMER (POSTED ON A WEBSITE PLATFORM), STATES THAT ESSURE HAS LEFT HER WITH CHRONIC PAIN. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6) 2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE MEDICAL ASSESSMENT: IN THIS PARTICULAR CASE, A TECHNICAL DEFECT (BREAKAGE) WAS REPORTED TOGETHER WITH USABILITY ISSUES (COMPLICATED REMOVAL). NO BATCH NUMBER WAS REPORTED. NO COMPLAINT SAMPLE WAS PROVIDE. THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANSCERVICAL INTRAUTERINE PROCEDURE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015 FROM LAY PRESS: IT WAS STATED PATIENT´S DEVICE BROKE INTO PIECES INSIDE HER UTERUS AND ULTIMATELY SHE UNDERWENT A HYSTERECTOMY. NO FURTHER INFORMATION PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE COILS HAD MOVED INTO HER UTERUS AND BECAME EMBEDDED THERE/ESSURE COIL PUNCTURED A UTERUS, ADHERED TO OUTSIDE, INTERPRETED AS AN EMBEDDED DEVICE (PARTIAL PERFORATION). AFTER COILS WERE REMOVED VAGINALLY, THE ULTRASOUND SHOWED FOREIGN BODIES AND SHE BELIEVED THESE (FOREIGN BODIES) COULD BE ESSURE FRAGMENTS. THE PARTIAL PERFORATION WAS CONSIDERED SERIOUS BY THE REPORTER DUE TO LIFE-THREATENING CONDITION. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION AND THEREFORE THE CASE WAS REGARDED AS INCIDENT. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THE PARTIAL PERFORATION IS LISTED AND THE BREAKAGE IS UNLISTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS, THE BREAKAGE IS AN ANTICIPATED FAILURE MODE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EMBEDMENT WAS DIAGNOSED AFTER AN UNKNOWN TIME OF ESSURE USE. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, IT IS NOT CLEAR WHEN THE DEVICE BREAKAGE OCCURRED, BUT SINCE THERE IS NO ALTERNATIVE EXPLANATION, THIS EVENT WAS CONSIDERED RELATED TO ESSURE. OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED SINCE THIS IS A LAY-PRESS/SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 12-AUG-2015: CONSUMER REPORTED VIA REGULATORY (REFERENCE# FDA-2014-N-0736-0017/ FDA-2014-N-0736-0015) THAT SHE WAS IMPLANTED WITH ESSURE IN 2009. SHE STATES THAT SHE FOUND OUT HER COILS WERE EMBEDDED IN HER UTERUS IN 2011. AFTER IMPR

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00060	BAYER HEALTHCARE LLC	2/2/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12712

Single Use: Y
Implant Date (E6): 12/31/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/2/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(4) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO GET ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER C12712. PHYSICIAN REPORTED THAT ESSURE SPIRAL DID NOT OPEN NORMALLY DURING INSERTION BUT IT GOT STUCK IN TUBE. PROCEDURE PROLONGED CONSIDERABLY BUT SPIRAL WAS HOWEVER GOT OFF BY GRABBING DURING HYSTEROSCOPY. NEW SPIRAL FROM DIFFERENT BATCH WORKED NORMALLY AND INSERTION WAS SUCCESSFUL FOR BOTH TUBES. THE PATIENT DID NOT GET SERIOUS COMPLICATIONS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THIS PROCEDURE ESSURE SPIRAL DID NOT OPEN NORMALLY BUT IT GOT STUCK IN TUBE. THE PROCEDURE PROLONGED CONSIDERABLY BUT THE INSERT WAS REMOVED BY GRABBING WITH HYSTEROSCOPY AND REPLACED. PATIENT HAD NO SERIOUS COMPLICATIONS. THE REPORTED EVENTS, REGARDED AS DEVICE DEPLOYMENT ISSUE FOLLOWED BY A COMPLICATION OF INSERTION AND AS A INSERTION DIFFICULT WERE CONSIDERED NON-SERIOUS AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL; IN THIS PARTICULAR CASE A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THE REPORTED EVENTS; HOWEVER CONSIDERING THAT THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENT DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON 26-FEB-2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). ESSURE PRODUCTION DATE IS 16-JAN-2014 AND THE EXPIRATION DATE IS 31-JAN-2017 THE FINAL ASSESSMENT WAS: DETACHMENT DIFFICULTY IS DEFINED

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040613	BAYER	2/2/2015	2/9/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER IMPLANT OF THE ESSURE DEVICE I STARTED EXPERIENCING SKIN DISORDERS. AFTER SIX MONTH FROM IMPLANT I STARTED FEELING VERTIGO LIKE SYMPTOMS SUCH AS EXTREME DIZZINESS, NAUSEA, AND LETHARGIC FEELING. AROUND 12 MONTHS AFTER IMPLANT I BEGAN HAVING VERY HEAVY BLEEDING DURING PERIOD, DEBILITATING ABDOMINAL AND LOWER BACK PAIN, MOOD SWINGS, AND DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00062	BAYER HEALTHCARE LLC	2/3/2015	2/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS PROVIDED). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(4) 2014. CONSUMER REPORTED PROBLEMS WITH ESSURE, INCLUDING PAIN (FELT LIKE TINY MEN WITH ICE PICKS WERE TRYING TO BURROW THEIR WAY OUT OF HER STOMACH), ALMOST BALD, CLOTS ALMOST THE SIZE OF BASEBALLS, RASH ON HER HIPS BURNS AND ITCHES AND IS NOW LEAVING SCARS FROM SCRATCHING IN THE MIDDLE OF THE NIGHT. SHE STATED THAT NICKEL IN ESSURE IS RELEASED INTO METABOLIC SYSTEM AND SHE WAS SLOWLY BEING POISONED. CONSUMER REPORTED THAT TWO DAYS BEFORE THE (B)(6), ON (B)(6) 2014, SHE WILL HAVE A HYSTERECTOMY. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP (B)(4) 2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. CONSUMER REPORTED THAT SHE HAD ANOTHER SLEEPLESS NIGHT UP WITH STABBING ESSURE PAIN. FOLLOW-UP INFORMATION WAS RECEIVED FROM THE CONSUMER ON (B)(6) 2014 VIA SOCIAL MEDIA: CONSUMER REPORTED THAT HER LIFE WAS HAPPENING AND SHE WAS SIDELINED ON THE COUCH DUE TO ESSURE PROBLEMS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2014: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL

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ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2015: CONSUMER POSTED ONLINE PICTURES OF HER INCISIONS FROM HER HYSTO BC (INTERPRETED AS HYSTERECTOMY). CASE UPGRADED TO INCIDENT. FOLLOW UP (B)(4) 2015: PTC INVESTIGATION RESULTS UPDATED AND PROVIDED. (B)(4). FINAL ASSESSMENT: CASE UPGRADED TO INCIDENT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON (B)(4) 2015. NO FURTHER INFORMATION IS EXPECTED FOR THIS REPORT. CASE CLOSED. FOLLOW-UP INFORMATION RECEIVED BY CONSUMER ON (B)(6) 2015. ACCORDING TO THE CONSUMER, SHE LOST 12 LBS SINCE HER TOTAL HYSTERECTOMY BC ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED CLOTS ALMOST THE SIZE OF BASEBALLS (INTERPRETED AS GENITAL BLEEDING) AND TOO MUCH ABDOMINAL PAIN/STABBING ESSURE PAIN. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE ESSURE MICRO-INSERT PLACEMENT PROCEDURE. ALSO, DURING ESSURE THERAPY ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; NEVERTHELESS CONSIDERING THE EVENT'S NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE, INITIALLY CONSIDERED NON-INCIDENT, WAS AMENDED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION, SINCE CONSUMER STATED SHE UNDERWENT A HYSTERECTOMY. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 04-MAY-2015 IT WAS REPORTED A WOUND AFTER SURGERY TO REMOVE ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040630	BAYER	2/3/2015	2/10/2015

Event Information:

Event Date (B3): 2/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): 1244
Catalog # (E4):
Lot #(E4): UNK

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DEVICE IMPLANTED SEVERAL YEARS AGO. SINCE THEN, I HAVE HAD NUMEROUS HEALTH ISSUES AND PAIN. PELVIC, BACK PAIN, MIGRAINES, EXTREMELY HEAVY PERIODS, DIAGNOSED FIBROMYALGIA, FATIGUE AND ANEMIA. ULTRA SOUND OF UTERINE WALL SHOWING ISSUES WITH MY PERIODS. NO EXPLANATION ABOUT THE STABBING PAINS I GET IN MY SIDE/PELVIC AREA AND BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040632	BAYER	2/3/2015	2/10/2015

Event Information:

Event Date (B3): 2/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): REF 625647

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2007 I HAD A DEVICE CALLED ESSURE IMPLANTED IN MY FALLOPIAN TUBES. IT IS NOW (B)(6) 2015 AND I'VE HAD PLENTY OF SIDE EFFECTS. I NOW HAVE SPINAL STENOSIS IN MY LOWER SPINE. I HAVE BEEN DIAGNOSED WITH PTSD, ANXIETY AND DEPRESSION SINCE I'VE HAD THIS IMPLANT. ALSO, MY PERIODS HAVE BEEN A LOT DIFFERENT WITH CRAMPS THAT DOUBLE ME OVER. BEFORE ESSURE I WAS COMPLETELY HEALTHY WITH NO PROBLEMS AT ALL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040634	BAYER	2/3/2015	2/10/2015

Event Information:

Event Date (B3): 1/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/11/2010
Explant Date (E7): 2/2/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE IMPLANTED 2010, WHICH I USED AS A PERMANENT BIRTHCONTROL. I HAD CONTINUOUS BLEEDING AND CRAMPS FOR 3/6MO AFTER PROCEDURE ONLY WITH A DAY OR 2 WITHOUT AT A TIME. AN ABLATION WAS PERFORMED TO TRY TO MINIMIZE BLEEDING IN 2010 AND THEN BEGAN DEVELOPING CYSTS ON MY OVARIES. ON 2015, PARTIAL HYSTERECTOMY DUE TO ENLARGED CYST AND OVARY ON MY RIGHT SIDE. I ALSO DEVELOPED MIGRAINES IN 2010. THESE SMALL COILS DID NOT MIGRATE BUT STILL CAUSED DISCOMFORT, PAIN, AND MY HEALTH.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00065	BAYER HEALTHCARE LLC	2/4/2015	2/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 09-JAN-2015 , ARTICLE ENTITLED "CONFIRMATION OF ESSURE PLACEMENT USING TRANSVAGINAL ULTRASOUND". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO INSERTED ESSURE 205 (FALLOPIAN TUBE OCCLUSION INSERT) FOR STERILIZATION. BAYER DEVICE ESSURE WAS REPORTED. CASE REPORT: THIS FEMALE PATIENT OF AN UNSPECIFIED AGE HAD A COMPLICATED PLACEMENT, WITH A LEVONORGESTREL IUD IN SITU. AFTER PLACEMENT OF THE FIRST DEVICE, THE IUD WAS REMOVED; HOWEVER, THE OTHER OSTIUM COULD NOT BE OBSERVED. DURING THE SECOND ATTEMPT WITH THE PATIENT UNDER GENERAL ANESTHESIA IN THE OPERATING ROOM, THIS OSTIUM WAS OPENED WITH A GRASPING FORCEPS, AND A SECOND DEVICE WAS PLACED EASILY. THE TVU (TRANSVAGINAL ULTRASOUND) AT 4 WEEKS AFTER THE SECOND PROCEDURE SHOWED BOTH DEVICES IN A NORMAL TUBOCORNUAL POSITION. THE HSG (HYSTEROSALPINGOGRAM) AFTER 3 MONTHS SHOWED BILATERAL TUBAL OCCLUSION. SHE BECAME PREGNANT AND DURING LAPAROSCOPIC EXAMINATION AFTER TERMINATION OF PREGNANCY, 1 DEVICE WAS INTRAMURAL UNDER THE SEROSA DUE TO PARTIAL PERFORATION, AND THE OTHER WAS IN A PROPER POSITION IN THE CONTRALATERAL TUBE. DURING LAPAROSCOPY, TUBAL PATENCY COULD BE EVOKED USING METHYLENE BLUE PERTUBATION WITH HIGH PRESSURE AUTHORS COMMENT: THE 24-MONTH CUMULATIVE PREGNANCY RATE WAS 3.86 PER 1000 (4 OF 1037 PATIENTS) WHICH IS LOWER THAN THE CUMULATIVE PREGNANCY RATE WITH LAPAROSCOPIC STERILIZATION METHODS. NONE OF THE 4 PREGNANCIES WAS RELATED TO FAILURE OF THE STERILIZATION METHOD WHEN THE DEVICE WAS PROPERLY PLACED; IN 1, THE DEVICE WAS ABSENT OR INCORRECTLY POSITIONED AND IN 3, THERE WAS NONCOMPLIANCE WITH THE PROTOCOL. ABSTRACT: STUDY OBJECTIVE: TO EVALUATE THE PROTOCOL FOR CONFIRMATION OF SATISFACTORY ESSURE PLACEMENT USING TRANSVAGINAL ULTRASOUND. DESIGN:

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PROSPECTIVE MULTICENTER COHORT STUDY (CANADIAN TASK FORCE CLASSIFICATION II-2). SETTING: OUTPATIENT DEPARTMENTS OF 4 TEACHING HOSPITALS IN THE (B)(6). PATIENTS: ELEVEN HUNDRED FORTY-FIVE WOMEN WHO UNDERWENT HYSTEROSCOPIC STERILIZATION USING THE ESSURE DEVICE BETWEEN MARCH 2005 AND DECEMBER 2007. INTERVENTION: TRANSVAGINAL ULTRASOUND EXAMINATION 12 WEEKS AFTER UNCOMPLICATED SUCCESSFUL BILATERAL PLACEMENT OR AS INDICATED ACCORDING TO THE TRANSVAGINAL ULTRASOUND PROTOCOL AFTER 4 WEEKS, AND HSG AT 12 WEEKS TO CONFIRM CORRECT PLACEMENT OF THE DEVICE AFTER 3 MONTHS. MEASUREMENTS AND MAIN RESULTS: THE RATE OF SUCCESSFUL PLACEMENT WAS 88.4% INITIALLY. IN 164 WOMEN (15%), SUCCESSFUL PLACEMENT WAS CONFIRMED AT HSG ACCORDING THE PROTOCOL. IN 9 PATIENTS (0.84%), INCORRECT POSITION OF THE DEVICE WAS OBSERVED AT HSG. THE CUMULATIVE PREGNANCY RATE AFTER 18 MONTHS WAS 3.85 PER THOUSAND WOMEN. CONCLUSION: TRANSVAGINAL ULTRASOUND SHOULD BE THE FIRST DIAGNOSTIC TEST USED TO CONFIRM THE ADEQUACY OF HYSTEROSCOPIC ESSURE STERILIZATION BECAUSE IT IS MINIMALLY INVASIVE, AVERTS IONIZING RADIATION, AND DOES NOT DECREASE THE EFFECTIVENESS OF THE ESSURE PROCEDURE. (B)(4). FOLLOW UP RECEIVED ON 13-JAN-2015. PTC GLOBAL NUMBER RECEIVED. PTC INVESTIGATION RESULT RECEIVED ON 18-JAN-2015. PTC GLOBAL (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, ALSO AN OFF LABEL USE WAS REPORTED. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 14-JAN-2015: THE PHYSICIAN REPORTED THAT THE BATCH NUMBERS WERE NOT INCLUDED IN THEIR DATABASE SO HE WAS AFRAID THEY WERE HARD TO FIND, BUT HE WAS GOING TO MAKE AN EFFORT. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE AND REFERS TO A FEMALE PATIENT WHO HAD A COMPLICATED ESSURE 205 (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT ATTEMPT, WITH A LEVONORGESTREL IUD IN SITU (OFF-LABEL USE). ONE DEVICE WAS PLACED, BUT AFTER IUD REMOVAL THE OTHER OSTIUM COULD NOT BE OBSERVED. ANOTHER ATTEMPT WAS DONE SUCCESSFULLY AND HER 3-MONTH CONFIRMATION HSG (HYSTEROSALPINGOGRAM) SHOWED TUBAL OCCLUSION. LATER SHE BECAME PREGNANT AND DURING LAPAROSCOPIC EXAMINATION AFTER TERMINATION OF PREGNANCY; 1 DEVICE WAS LOCATED INTRAMURAL UNDER THE SEROSA DUE TO PARTIAL PERFORATION. ALL REPORTED EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED NON-SERIOUS, EXCEPT FOR THE REPORTED PARTIAL UTERINE PERFORATION WHICH IS SERIOUS DUE TO MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG) TO DETERMINE IF TUBAL OCCLUSION IS PRESENT. IN THIS CASE, HSG SHOWED TUBAL OCCLUSION. THE REPORTER STATED DURING LAPAROSCOPY, THERE WAS A PARTIAL PERFORATION OF ONE DEVICE AND TUBAL PATENCY COULD BE EVOKED WITH HIGH PRESSURE. ALTHOUGH IN THIS CASE, HSG RESULTS MAY HAVE BEEN COMPROMISED (TECHNICAL LIMITATION DURING DYE INSTILLATION?), SINCE IT IS UNCLEAR THE EXACT MECHANISM AND DATE OF PERFORATION (WHETHER IT OCCURRED PRIOR OR

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AFTER PREGNANCY) AN ESSURE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED AND ALL EVENTS WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT, EXCEPT FOR THE REPORTED OFF-LABEL USE. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SERIOUS INJURY (REQUIRED INTERVENTION). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 11-MAR-2015: DESPITE FOLLOW UP ATTEMPTS, NO FURTHER INFORMATION OBTAINED. CASE CLOSED. DEVICE SIMILAR CASE LISTING: THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00066	BAYER HEALTHCARE LLC	2/4/2015	2/4/2015

Event Information:

Event Date (B3): 1/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 10/10/2007
Explant Date (E7): 1/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007 FOR PERMANENT STERILIZATION. PREGNANCY WAS DENIED. IT WAS REPORTED THAT PATIENT HAD PROBLEMS WITH ESSURE, STARTING BACK IN 2007 AND PHYSICIAN REMOVED THE INSERTS ON AN UNSPECIFIED DATE. ON (B)(6) 2014 THE PATIENT WAS SEEN AND WAS COMPLAINING OF PAIN. PHYSICIAN SUSPECTED THAT A PIECE OF THE COIL MAY STILL BE INSIDE THE PATIENT. FOLLOW-UP RECEIVED ON (B)(6) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE

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INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON (B)(4) 2015: THE PATIENT HAD ESSURE REMOVED IN 2007. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2015: IT WAS REPORTED THAT BROKEN ESSURE COIL FRAGMENT WOULD BE REMOVED ON (B)(4) 2015. THE DOCTOR THOUGHT THAT THERE WAS SOMETHING WRONG WITH THE COIL FRAGMENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND PHYSICIAN REMOVED THE INSERTS. LATER, SHE EXPERIENCED PAIN AND HE SUSPECTED THAT A PIECE OF THE COIL MAY STILL BE INSIDE OF HER. THE REPORTED EVENTS WERE INTERPRETED AS ESSURE SURGICAL REMOVAL, UNSPECIFIED PAIN AND SUSPICION OF DEVICE BREAKAGE. ESSURE REMOVAL WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE, WHILE THE REMAINING EVENTS ARE NON-SERIOUS. DEVICE BREAKAGE IS LISTED ACCORDING TO TECHNICAL ANALYSIS AND THE OTHER EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT PROCEDURE FOR ESSURE REMOVAL WAS NOT SPECIFIED, AN INTERVENTION WAS IMPLIED. THEREFORE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. CONSIDERING THE NATURE OF REMAINING EVENTS, THEY WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. THIS CASE WAS REGARDED AS AN INCIDENT DUE TO THE PROBABLE SURGICAL INTERVENTION FOR ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-MAY-2015 ESSURE WAS INSERTED ON (B)(6) 2007. IT WAS REPORTED THAT ON LEFT TUBE ONLY 2-3 RINGS WERE VISIBLE AFTER SECOND ATTEMPT AT PLACEMENT OF COIL. LAPAROSCOPY WAS DONE ON (B)(6) 2007 DUE TO SEVERE LEFT LOWER QUADRAN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00067	BAYER HEALTHCARE LLC	2/4/2015	2/4/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SINCE SHE ALREADY HAD THREE CHILDREN; IN (B)(6) 2014, SHE PLANNED ON GETTING A TUBAL LIGATION, BUT HER DOCTOR OFFERED HER ESSURE INSTEAD. FROM THE DAY OF THE IMPLANT, SHE BLED CONSTANTLY, WHICH DRAINED HER OF ENERGY AND LEFT HER MOODY AND TIRED. HER DOCTOR SAID ESSURE WAS NOT THE CAUSE. CONSUMER FOUND THE E-SISTERS (ESSURE SISTERS) PAGE IN THE INTERNET IN (B)(6) 2014, AND STARTED REALIZING THAT HER CONDITION WAS NOT NORMAL. SHE HAD A HYSTERECTOMY IN (B)(6) 2014 AND HAS RECOVERED HER HEALTH. SHE STATED THAT THE FDA NEEDED TO TAKE THIS OFF THE MARKET BECAUSE IT WAS CAUSING TOO MANY WOMEN PROBLEMS. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. THE PTC GLOBAL REFERENCE NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER

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NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO BLED CONSTANTLY SINCE THE DAY OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANT. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, THIS EVENT STARTED ON THE DAY OF ESSURE IMPLANT AND THEREFORE IS CONSIDERED RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. ACCORDING TO MEDICAL TECHNICAL ASSESSMENT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION IDENTIFIED ON 03-OCT-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00063	BAYER HEALTHCARE LLC	2/4/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 09-JAN-2015 , ARTICLE ENTITLED "CONFIRMATION OF ESSURE PLACEMENT USING TRANSVAGINAL ULTRASOUND". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. BAYER DEVICE ESSURE WAS REPORTED. CASE REPORT: THIS FEMALE PATIENT OF AN UNSPECIFIED AGE HAD A COMPLICATED PLACEMENT AND A THIRD DEVICE WAS PLACED AFTER SPONTANEOUS EXPULSION OF FIRST DEVICE. VIOLATION OF THE CONTROL PROTOCOL OCCURRED IN THAT ONLY TVU (TRANSVAGINAL ULTRASOUND) WAS PERFORMED INSTEAD OF HSG (HYSTEROSALPINGOGRAM) AT 3 MONTHS. AT THIS TVU, THE POSITION OF THE DEVICES WAS MISINTERPRETED. SHE BECAME PREGNANT AND DURING LAPAROSCOPIC STERILIZATION AFTER TERMINATION OF PREGNANCY, ONE DEVICE WAS LOCATED INTRAMURAL UNDER THE SEROSA DUE TO PARTIAL PERFORATION AND 1 WAS IN THE PROPER POSITION IN THE CONTRALATERAL TUBE. AUTHORS COMMENT: THE 24-MONTH CUMULATIVE PREGNANCY RATE WAS 3.86 PER 1000 (4 OF 1037 PATIENTS), WHICH IS LOWER THAN THE CUMULATIVE PREGNANCY RATE WITH LAPAROSCOPIC STERILIZATION METHODS. NONE OF THE 4 PREGNANCIES WAS RELATED TO FAILURE OF THE STERILIZATION METHOD WHEN THE DEVICE WAS PROPERLY PLACED; IN 1, THE DEVICE WAS ABSENT OR INCORRECTLY POSITIONED AND IN 3, THERE WAS NONCOMPLIANCE WITH THE PROTOCOL. ABSTRACT: STUDY OBJECTIVE: TO EVALUATE THE PROTOCOL FOR CONFIRMATION OF SATISFACTORY ESSURE PLACEMENT USING TRANSVAGINAL ULTRASOUND. DESIGN: PROSPECTIVE MULTICENTER COHORT STUDY (CANADIAN TASK FORCE CLASSIFICATION II-2). SETTING: OUTPATIENT DEPARTMENTS OF 4 TEACHING HOSPITALS IN THE NETHERLANDS. PATIENTS: ELEVEN HUNDRED FORTY-FIVE WOMEN WHO UNDERWENT HYSTEROSCOPIC STERILIZATION USING THE ESSURE DEVICE BETWEEN MARCH 2005 AND DECEMBER 2007. INTERVENTION: TRANSVAGINAL

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ULTRASOUND EXAMINATION 12 WEEKS AFTER UNCOMPLICATED SUCCESSFUL BILATERAL PLACEMENT OR AS INDICATED ACCORDING TO THE TRANSVAGINAL ULTRASOUND PROTOCOL AFTER 4 WEEKS, AND HYSTEROSALPINGOGRAPHY (HSG) AT 12 WEEKS TO CONFIRM CORRECT PLACEMENT OF THE DEVICE AFTER 3 MONTHS. MEASUREMENTS AND MAIN RESULTS: THE RATE OF SUCCESSFUL PLACEMENT WAS 88.4% INITIALLY. IN 164 WOMEN (15%), SUCCESSFUL PLACEMENT WAS CONFIRMED AT HSG ACCORDING THE PROTOCOL. IN 9 PATIENTS (0.84%), INCORRECT POSITION OF THE DEVICE WAS OBSERVED AT HSG. THE CUMULATIVE PREGNANCY RATE AFTER 18 MONTHS WAS 3.85 PER THOUSAND WOMEN. CONCLUSION: TRANSVAGINAL ULTRASOUND SHOULD BE THE FIRST DIAGNOSTIC TEST USED TO CONFIRM THE ADEQUACY OF HYSTEROSCOPIC ESSURE STERILIZATION BECAUSE IT IS MINIMALLY INVASIVE, AVERTS IONIZING RADIATION, AND DOES NOT DECREASE THE EFFECTIVENESS OF THE ESSURE PROCEDURE. OTHER CASES CREATED FROM SAME ARTICLE ARE 2015-003979, 2015-004054, 2015-004063, 2015-004152 AND 2015-004157. FOLLOW-UP FROM 14-JAN-2015: THE PHYSICIAN REPORTED THAT THE BATCH NUMBERS WERE NOT INCLUDED IN THEIR DATABASE SO HE WAS AFRAID THEY WERE HARD TO FIND, BUT HE WAS GOING TO MAKE AN EFFORT. NO FURTHER INFORMATION WAS PROVIDED. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 21-JAN-2015. THE PTC GLOBAL REFERENCE NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY AND A USABILITY ISSUE. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, ALSO COMPLICATED PLACEMENT AND EXPULSION OF FIRST DEVICE WAS REPORTED. FURTHERMORE IT WAS REPORTED THAT ONLY TVU (TRANSVAGINAL ULTRASOUND) WAS PERFORMED INSTEAD OF HSG (HYSTEROSALPINGOGRAM) TO CONFIRM TUBAL OCCLUSION AND THAT AT THIS TVU, THE POSITION OF THE DEVICES WAS MISINTERPRETED. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE AND REFERS TO A FEMALE PATIENT WHO HAD A COMPLICATED ESSURE 205 (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT. SHE EXPERIENCED A SPONTANEOUS EXPULSION OF THE FIRST DEVICE AND A THIRD DEVICE WAS PLACED. LATER, SHE BECAME PREGNANT AND DURING LAPAROSCOPIC STERILIZATION AFTER TERMINATION OF PREGNANCY; 1 DEVICE WAS LOCATED INTRAMURAL UNDER THE SEROSA DUE TO PARTIAL PERFORATION. ALL REPORTED EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED NON-SERIOUS, EXCEPT FOR THE REPORTED PARTIAL UTERINE PERFORATION WHICH IS SERIOUS DUE TO MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, ESSURE WAS REPLACED AFTER A DEVICE EXPULSION AND A TRANSVAGINAL ULTRASOUND (TVU) WAS PERFORMED TO CONFIRM PLACEMENT; THE REPORTER BELIEVED THE POSITION OF THE DEVICES WAS MISINTERPRETED IN THIS EXAM, SINCE PATIENT BECAME PREGNANT AND A PARTIAL PERFORATION WAS DIAGNOSED DURING A LAPAROSCOPY. ALTHOUGH PREGNANCY IN THIS CASE

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MAY HAVE BEEN RATHER A CONSEQUENCE OF TVU MISINTERPRETATION, ESSURE CONTRACEPTIVE FAILURE CANNOT BE TOTALLY EXCLUDED AND ALL REPORTED EVENTS WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SERIOUS INJURY (REQUIRED INTERVENTION). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 11-MAR-2015: DESPITE FOLLOW UP ATTEMPTS, NO FURTHER INFORMATION OBTAINED. CASE CLOSED. DEVICE SIMILAR CASE LISTING: THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER P

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00064	BAYER HEALTHCARE LLC	2/4/2015	2/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B61395

Single Use: Y
Implant Date (E6): 12/19/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A SURGICAL BUYER IN UNITED STATES ON 08-JAN-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION FOR PERMANENT BIRTH CONTROL ON (B)(6) 2014, LOT NUMBER USED B61395 (EXPIRATION DATE AUG-2016). IT WAS REPORTED THAT THE ESSURE WIRE BROKE DURING PLACEMENT PROCEDURE. NO FURTHER INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-JAN-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE. (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 14-JAN-2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE,

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WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE. THE ADVERSE EVENT (AE) CASE REFERS ALSO TO A USABILITY ISSUE. NO FURTHER ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. SINCE NO FURTHER ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS, A QUALITY DEFECT WAS NOT CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING PLACEMENT PROCEDURE, ESSURE WIRE BROKE. THIS EVENT IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. CONSIDERING THAT THE ESSURE WIRE BROKE DURING PLACEMENT, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN 24-MAR-2015 IT WAS REPORTED THAT THE CONSUMER'S BMI WAS (B)(6). GYNECOLOGICAL INTERVENTIONS, PROBLEMS AND PROCEDURES WERE DENIED. HER CONCURRENT CONDITION INCLUDED HTN (INTERPRETED AS HYPERTENSION) AND OBESITY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00068	BAYER HEALTHCARE LLC	2/4/2015	2/5/2015

Event Information:

Event Date (B3): 1/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B27983

Single Use: Y
Implant Date (E6): 10/10/2014
Explant Date (E7): 2/3/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER IN UNITED STATES ON 09-JAN-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2014 WITH LOT NUMBER B27983. ON (B)(6)-2015, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND REVEALED THAT LEFT INNER COIL DETACHED FROM THE OUTER COIL AND WAS IN THE PERITONEUM. CONSUMER WILL DO A SALPINGECTOMY IN THE FUTURE. ESSURE WAS NOT REMOVED. FOLLOW-UP RECEIVED ON 09-JAN-2015 WITH NO NEW CLINICAL INFORMATION. FOLLOW-UP RECEIVED ON 15-JAN-2015 FROM PHYSICIAN, WHO WAS IDENTIFIED AS THE ORIGINAL REPORTER OF THIS CASE. NO PROCEDURE HAS BEEN CONDUCTED OR COMPLETED BY THE PHYSICIAN UNTIL THE REPORTING DATE. PTC INVESTIGATION RESULT RECEIVED ON 22-JAN-2015.(B)(4). FINAL ASSESSMENT: LOT B27983. PRODUCTION DATE: APRIL 2013. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATE WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 1/20/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE (BREAKAGE). THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 4 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, NONE OF THOSE CASES REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE LEFT INNER COIL DETACHED FROM THE OUTER COIL AND WAS IN THE PERITONEUM. THIS EVENT WAS INTERPRETED AS DEVICE DISLOCATION AND DEVICE BREAKAGE. DEVICE DISLOCATION IS A SERIOUS EVENT AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE DEVICE BREAKAGE IS NON-SERIOUS AND ALSO LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALSO, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, HYSTEROSALPINGOGRAM WAS DONE AND REVEALED THAT LEFT INNER COIL DETACHED FROM THE OUTER COIL (DEVICE BREAKAGE) AND WAS IN THE PERITONEUM (DEVICE DISLOCATION). THEREFORE, GIVEN THE AVAILABLE INFORMATION AND NATURE OF THE REPORTED EVENTS, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE MALFUNCTION (BREAKAGE). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 19-MAY-2015. NEW REPORTER WAS ADDED. ON (B)(6) 2015, SALPINGECTOMY WAS PERFORMED AND PATIENT TOLERATED THE PROCEDURE WELL. HER ABDOMINAL PAIN IS MUCH BETTER. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS SPON

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040647	BAYER	2/4/2015	2/11/2015

Event Information:

Event Date (B3): 2/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/26/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE DONE (B)(6). TEST DONE ON (B)(6) CONFIRMED THAT THE RIGHT COIL IS PROTRUDING OUT OF FALLOPIAN TUBE AND STUCK IN UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040582	BAYER	2/6/2015	2/6/2015

Event Information:

Event Date (B3): 9/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AS OF (B)(6) 2015: NEARLY 4 WEEKS PREMATURE, I DELIVERED MY DAUGHTER BY C-SECTION ON (B)(6) 2015. AT THIS POINT, SHE APPEARS TO BE HEALTHY AND DEVELOPING WELL. ON (B)(6) 2015, I HAD AN HSG TEST DONE AT (B)(6) HOSPITAL IN (B)(6), AND PER THE RESULTS, I LEARNED THAT NOT ONE BUT BOTH ESSURE DEVICES HAVE MIGRATED OUTSIDE OF THE FALLOPIAN TUBES. ONE DEVICE APPEARS TO BE LOCATED AT THE BACK OF MY UTERUS AND THE OTHER APPEARS TO BE LOCATED OUTSIDE OF THE UTERUS ON THE RIGHT SIDE OF MY LOWER PELVIS. THE TEST ALSO INDICATED THAT THE LEFT FALLOPIAN TUBE APPEARS TO BE OCCLUDED WHILE THE RIGHT FALLOPIAN TUBE IS FULLY OPEN, WITH THE TEST DYE FLOWING FREELY THROUGH THE TUBE. IN ADDITION TO THE HSG, X-RAYS PERFORMED ON(B)(6) 2015 CONFIRMED THE RESULTS OF THE HSG TEST. I HAVE CONTINUED TO EXPERIENCE HEAVY MENSTRUAL CYCLES WITH LARGE CLOTS, SEVERE MENSTRUAL CRAMPING, SHARP PAIN IN MY LOWER ABDOMEN AND PELVIS. I HAVE ALSO NOW STARTED TO EXPERIENCE ALMOST CONSTANT PAIN AND PRESSURE IN MY LOWER BACK AND TAILBONE AREA. IN ORDER TO RELIEVE MY SYMPTOMS AND PREVENT ANY FUTURE PREGNANCIES, I AM UNDERGOING A BILATERAL SALPINGECTOMY IN CONJUNCTION WITH ESSURE DEVICE REMOVAL ON (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040583	BAYER	2/6/2015	2/6/2015

Event Information:

Event Date (B3): 11/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). MY LEGS BEGAN TO BREAK OUT IN A RASH. MY MENSTRUAL CYCLES WERE HEAVIER, AND PELVIC PAIN SEVERE AND PERSISTENT FOR THREE WEEKS OUT OF THE MONTH. SO SEVERELY IN FACT THAT IT WENT DOWN MY LEGS TO MY KNEES ON BOTH SIDES. MY INSIDES FELT SWOLLEN, MY MOOD SWINGS WERE HORRIFIC AND SUDDEN, AND I STARTED LOOSING MY HAIR AND MY APPETITE. I LOST 4 PANT SIZES FROM THEN UNTIL PRESENT. I EVEN STARTED GOING TO A PAIN MANAGEMENT CLINIC AFTER A MILLION DIFFERENT TEST. I AM A WEEK AWAY FROM HAVING A HYSTERECTOMY, AS THE PAIN IS SO UNBEARABLE I HAVE BEEN FORCED TO TAKE FMLA FROM WORK....

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040584	BAYER	2/6/2015	2/6/2015

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). WEIGHT GAIN, CRAMPS, BONE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040585	BAYER	2/6/2015	2/6/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL SWELLING, PAIN. LARGE MUSCLE SPASM THAT FEELS LIKE A BABY. RECTAL PAINS AND ISSUES HAVING BOWEL MOVEMENTS. BREAST TENDERNESS, ABDOMINAL BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040599	BAYER	2/6/2015	2/6/2015

Event Information:

Event Date (B3): 7/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BLOATING, STOMACH ISSUES, PAIN, TIRED - SERIOUS WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040611	BAYER	2/6/2015	2/6/2015

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, ABDOMINAL PAIN, HEAVY BLEEDING WITH CLOTS, PAINFUL OVULATION, HEADACHES, HOT FLASHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040624	BAYER	2/6/2015	2/6/2015

Event Information:

Event Date (B3): 5/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PELVIC PAIN, BODY ACNE, MUSCLE ACHES, HEADACHES, SWELLING, UNCONTROLLABLE BLEEDING. HAD TO HAVE COMPLETE HYSTERECTOMY DUE TO AFFECTS OF ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040693	BAYER	2/8/2015	2/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD THE ESSURE FOR MANY YEARS NOW AND HAVE HAD PROBLEMS WITH HEADACHES, BODY ACHES, JOINT PAIN, DIZZINESS, HEAVY BLEEDING AND CLOTTING, BLOATING, WEIGHT GAIN, MOOD SWINGS AND PAIN IN THE PELVIC AREA...ALSO PAINFUL INTERCOURSE!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040686	BAYER HEALTHCARE	2/10/2015	2/18/2015

Event Information:

Event Date (B3): 11/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNABLE
Catalog # (E4): REF# ESS305
Lot #(E4): C06461

Single Use:
Implant Date (E6): 11/24/2014
Explant Date (E7): 11/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3): 1/20/2015

Event Description (B5):

M.D HOLDING ESSURE DEVICE DURING A HYSTEROSCOPY, ESSURE COILS DEPLOYED BEFORE THE BUTTON TO DEPLOY THE DEVICE WAS ACTIVATED. COILS ADHERED TO URINE TISSUE NEAR LEFT FALLOPIAN TUBE, REMOVED PER M.D. CASE CONVERTED TO LAPAROSCOPIC BILATERAL TUBAL LIGATION. NO DAMAGE NOTED TO LEFT FALLOPIAN TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040761		2/10/2015	2/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): BIRTH CONTROL IMPLANT ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/6/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE BIRTH CONTROL IMPLANT AND IT HAS GIVEN ME SO MANY PROBLEMS IN THE PAST 4 YEARS. I GOT IT PUT IN (B)(6) 2007, IT HURTS SO BAD TO HAVE INTERCOURSE MY MONTHLY CYCLE IS REALLY MESSED UP. I HAVE HAD PAINS IN MY OVARIES AND STOMACH ALMOST EVERY DAY, BAD HEADACHES, NAUSEA, FATIGUE. IRREGULAR HEARTBEATS, LOWER BACK PAIN, AND SO MUCH MORE. I JUST WISHED IT WAS OUT SO I CAN HOPEFULLY START FEELING BETTER! PLEASE HELP ME... I CAN'T TAKE THE PAIN ANYMORE. ON (B)(6) 2014, THEY SAID I NEEDED TO BE CHECKED BY OB DR BUT, I DON'T HAVE THE INSURANCE OR MONEY TO SEE ONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040762		2/10/2015	2/19/2015

Event Information:

Event Date (B3): 2/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PERFORMED IN (B)(6) 2013. AS TIME PASSES, I HAVE DEVELOPED SERIOUS SIDE EFFECTS THAT HAVE CAUSED ME SEVERE ABDOMINAL PAIN ON WEEKLY BASIS. IT HAS BECOME SO SEVERE THAT I AM LOSING TIME ON MY JOB. NOW I'M DEVELOPING BACK PAIN AS WELL. I STARTED TO NOTICE A RASH AND HAIR LOSS SHORTLY AFTER THE SURGERY. I AM VERY DISSATISFIED WITH ESSURE AND WOULD LIKE TO KNOW IF IT CAN BE REVERSED. THE ONLY OPTION I AM BEING GIVEN RIGHT NOW IS TO HAVE A HYSTERECTOMY. I HAVE BEEN TO URGENT CARE TWICE WITHIN THE PAST FOUR MONTHS FOR LOWER ABDOMINAL PAIN AS RECENT AS (B)(6) 2015. THE PAIN WAS SO SEVERE I COULD NOT SIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00069	BAYER HEALTHCARE LLC	2/11/2015	2/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 932164

Single Use: Y
Implant Date (E6): 7/19/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN THE UNITED STATES ON (B)(4) 2014. IT DESCRIBES THE OCCURRENCE OF POSITIVE BLOOD PREGNANCY TEST, LEVELS WERE ELEVATED (DEVICE INEFFECTIVE) IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2012, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 932164, INSERTED. THE PATIENT HAD AN HSG (HYSTEROSALPINGOGRAM) TEST ON (B)(6) 2012 THAT SHOWED BILATERAL TUBAL OCCLUSION. IN THE WEEK BEFORE TIME OF REPORTING (IN (B)(6) 2014), THE PATIENT HAD A BLOOD PREGNANCY TEST THAT WAS POSITIVE AND THE LEVELS WERE ELEVATED. AN ULTRASOUND DID NOT SHOW A PREGNANCY, AND PATIENT WILL BE HAVING MORE BLOOD WORK AND AN ULTRASOUND IN THE WEEK AFTER TIME OF REPORTING. ESSURE WAS CONTINUED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP. FOLLOW UP INFORMATION RECEIVED ON 20-FEB-2014. THREE FOLLOW UP ATTEMPTS WITH NO RESPONSE. FOLLOW-UP INFORMATION WAS RECEIVED ON 25-FEB-2014 FROM PHYSICIAN: THE PATIENT'S MEDICAL HISTORY INCLUDED A LEEP (LOOP ELECTROCAUTERY EXCISION PROCEDURE) IN 2009. THE PATIENT HAD 3 PREGNANCIES WITH 3 DELIVERIES IN HISTORY. THERE WERE NO ABORTIONS (SPONTANEOUS, ELECTIVE OR THERAPEUTIC) AND NO ECTOPIC PREGNANCIES. THE PATIENT'S DEMOGRAPHIC INFORMATION WERE UPDATED. BMI: (B)(6). AT 12 WEEKS POST PARTUM THE PATIENT HAD ESSURE INSERTED ON (B)(6) 2012, WITH LOT NUMBER 932164. THE PHYSICIAN DESCRIBED THAT THE PROCEDURE WAS PERFORMED UNDER SEDATION AND ANESTHESIA. THE PROCEDURE WAS DESCRIBED AS EASY, WITHOUT FLUID LOSS. A CERVICAL DILATATION WAS MADE, SOUNDING WAS 6 MM. THE VISUALIZATION OF TUBAL OSTIUM WAS EASY. ON (B)(6) 2012 HYSTEROSALPINGOGRAPHY WAS PERFORMED AND SHE

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USED DEPO-PROVERA AS BACK-UP CONTRACEPTION. ON (B)(6) 2013 HER LAST MENSTRUAL PERIOD OCCURRED. ON (B)(6) 2014 THE FIRST BLOOD TEST WAS PERFORMED AND IT CONFIRMED THE PREGNANCY ((B)(6)). ON (B)(6) 2014 BLOOD TEST WAS PERFORMED ((B)(6)). IN 2014, AN ULTRASOUND WAS PERFORMED AND IT SHOWED A SINGLE UTERINE PREGNANCY. THE DATE OF THE FIRST DAY OF THE PATIENT'S LAST MENSTRUAL PERIOD WAS (B)(6) 2013. AT THE TIME OF THE REPORT NO COMPLICATIONS WERE KNOWN. EXPECTED DELIVERY DATE WAS (B)(6) 2014. THE PATIENT CONTINUED WITH PREGNANCY. ESSURE WAS NOT REMOVED, NO REMOVAL WAS PLANNED. PTC INVESTIGATION RESULT WAS RECEIVED ON 25-APR-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE EVENTS REPORTED ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE. LACK OF EFFECTIVENESS IN ITSELF IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT AS IT MAY OCCUR WITH THE USE OF ANY PRODUCT. ADDITIONALLY, PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THREE (3) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER 932164 BUT NONE OF THESE CASES REFERS TO ANY SIMILAR TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP INFORMATION FROM PREGNANCY QUESTIONNAIRE, MEDICAL RECORDS AND PATHOLOGY RESULTS WERE RECEIVED FROM PHYSICIAN ON 12-JAN-2015: UPGRADED TO INCIDENT. ON (B)(6) 2014, THE PATIENT HAD A VAGINAL DELIVERY THAT WAS INDUCED AT 38.6 WEEKS DUE TO LOW AFI (AMNIOTIC FLUID INDEX). SHE HAD 1 LIVE BIRTH. THE WEIGHT OF INFANT WAS 3664 GRAMS AND THE APGAR SCORES WERE 8 AND 9 AT 1 MIN AND 5 MIN, RESPECTIVELY. MOTHER AND INFANT HAD NO COMPLICATIONS DURING DELIVERY. ON (B)(6) 2014, A MINI EXPLORATORY LAPAROTOMY WITH PARTIAL BILATERAL SALPINGECTOMIES AND REMOVAL OF ESSURE WAS DONE, BECAUSE PATIENT DESIRED PERMANENT STERILIZATION, POST PARTUM. DURING THE PROCEDURE, LEFT ESSURE COIL WAS FELT AND SEEN TO BE PROTRUDING FROM LEFT CORNUAL REGION. THE TUBE WAS THEN FOLLOWED OUT TO TIS FIMBRIATED END AND A COMPLETE FIMBRIECTOMY AND PARTIAL SALPINGECTOMY WERE PERFORMED. THE TUBE WAS DOUBLED TIED AND TUBE WAS ALLOWED TO RETURN TO ABDOMINAL CAVITY. THE RIGHT TUBE WAS IDENTIFIED AND FOLLOWED OUT TO ITS FIMBRIATED END AND A PARTIAL SALPINGECTOMY AND FIMBRIECTOMY WAS PERFORMED AGAIN WITHOUT INCIDENT. THE RIGHT COIL WAS NOT SEEN AND WAS NOT REMOVED, BUT IT WAS PALPATED WITHIN REMAINING TUBE. THE SURGICAL PATHOLOGY RESULT SHOWED THAT BENIGN LEFT AND RIGHT FALLOPIAN TUBE BUT ONLY THE LEFT PORTION INCLUDED A MEDICAL DEVICE CONSISTENT WITH ESSURE. PATIENT RECOVERED FROM ESSURE REMOVAL PROCEDURE. ACCORDING THE PHYSICIAN, THE UNPLANNED PREGNANCY WAS CAUSED BY ESSURE. PTC INVESTIGATION RESULT UPDATE RECEIVED ON 16-JAN-2015. THE PTC GLOBAL REFERENCE NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER 932164, MANUFACTURING DATE: DEC-2011, EXPIRATION DATE: DEC-2014. CASE UPGRADED TO INCIDENT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. THREE FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO

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THE REPORTED BATCH, NONE OF THEM REFERRING TO A SIMILAR LACK OF EFFICACY TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD A POSITIVE BLOOD PREGNANCY TEST ABOUT 1 YEAR AND 7 MONTHS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. WHEN SHE WAS 38.6 WEEKS PREGNANT, LABOR WAS INDUCED DUE TO LOW AMNIOTIC FLUID VOLUME AND SHE GAVE BIRTH TO A HEALTHY CHILD. DURING POST-PARTUM LAPAROTOMY, THE LEFT ESSURE COIL WAS FELT AND SEEN TO BE PROTRUDING FROM LEFT CORNUAL REGION, INTERPRETED AS DEVICE EMBEDDED (PARTIAL PERFORATION). PERFORATION AND LOW AMNIOTIC FLUID INDEX ARE SERIOUS DUE TO MEDICAL IMPORTANCE WHILE THE EVENT PREGNANCY IS NON-SERIOUS. PERFORATION AND PREGNANCY ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION BUT LOW AMNIOTIC FLUID INDEX IS UNLISTED. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE. IN THIS CASE, EVEN THOUGH THE PERFORATION WAS DIAGNOSED AT THE TIME OF REMOVAL, SINCE IT OCCURRED AFTER ESSURE PLACEMENT, THIS EVENT WAS CONSIDERED RELATED TO ESSURE. THIS PERFORATION COULD EXPLAIN THE PREGNANCY, HOWEVER, IT IS NOT POSSIBLE TO DETERMINE, IN THIS CASE, IF PREGNANCY OCCURRED AS A CONSEQUENCE OF PERFORATION OR INEFFECTIVE DEVICE. THEREFORE PREGNANCY WAS ALSO CONSIDERED RELATED TO ESSURE. OLIGOHYDRAMNIOS REFERS TO AMNIOTIC FLUID VOLUME THAT IS LESS THAN EXPECTED FOR GESTATIONAL AGE. IF DIAGNOSED IN THE THIRD TRIMESTER, IS OFTEN ASSOCIATED WITH PRETERM PREMATURE RUPTURE OF MEMBRANES OR WITH UTEROPLACENTAL INSUFFICIENCY DUE TO CONDITIONS SUCH AS PREECLAMPSIA OR OTHER MATERNAL VASCULAR DISEASES. IN THIS CASE,THE REPORTED EVENT WAS CONSIDERED AS RELATED TO ESSURE DUE TO THE LACK OF ALTERNATIVE EXPLANATION AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF THE ESSURE DEVICE IN THE AMNIOTIC SAC CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO THE LABOR INDUCTION (MEDICAL REQUIRED INTERVENTION). ACCORDING TO PRODUCT TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00070	BAYER HEALTHCARE LLC	2/11/2015	2/11/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71767

Single Use: Y
Implant Date (E6): 7/22/2014
Explant Date (E7): 11/20/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER B71767 FOR CONTRACEPTION. IT WAS REPORTED THAT PATIENT HAD BLEEDING AND HIP PAIN AFTER INSERTION. HSG (HYSTEROSALPINGOGRAM) WAS DONE AT 3 MONTHS; LEFT TUBE WAS OCCLUDED AND RIGHT TUBE HAD SPILLAGE AND ESSURE WAS SEEN OUTSIDE OF THE TUBE (REPORTED AS ESSURE PERFORATION). ON (B)(6) 2014, HYSTERECTOMY WAS PERFORMED, THE SPECIMEN HAD ESSURE IN LEFT TUBE, BUT NOT IN RIGHT SIDE. ON AN UNSPECIFIED DATE, AN UPRIGHT X-RAY WAS DONE AND COULD NOT SEE ESSURE ANYWHERE IN THE BODY. PATIENT WAS NOT HOSPITALIZED. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. (B)(4). BATCH NUMBER B71767 (PRODUCTION DATE 13-SEP-2013; EXPIRATION DATE 30-SEP-2016). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 4 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, NONE OF THE CASES REFER ALSO TO A SIMILAR ADVERSE TYPES OF EVENTS. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS

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REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO EXPERIENCED BLEEDING (GENITAL BLEEDING) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. LATER, AT 3-MONTH CONFIRMATORY TEST (HYSTEROSALPINGOGRAM) ESSURE WAS SEEN OUTSIDE OF THE TUBE; THIS WAS REGARDED AS AN ESSURE PERFORATION BY THE REPORTER. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. ALSO, AFTER ESSURE PLACEMENT ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE EVENTS IS UNKNOWN A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE PATIENT WAS SUBMITTED TO A HYSTERECTOMY. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 10-AUG-2015 IT WAS REPORTED THAT TORADOL, CARBICAINE AND XANAX WERE USED AS ANALGESIA. SHE HAD A HISTORY OF 2 C-SECTIONS. THE PERFORATION DID NOT OCCUR DURING SOUNDING, CERVICAL DILATION OR HYSTEROSCOPY PRIOR TO INSERTION

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00071	BAYER HEALTHCARE LLC	2/11/2015	2/12/2015

Event Information:

Event Date (B3): 9/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C76455

Single Use: Y
Implant Date (E6): 9/16/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE WITH LOT NUMBER C76455. IT WAS REPORTED THAT DURING CONFIRMATION TEST, A SPILLAGE OF RIGHT TUBE WAS SEEN AND CLEARLY SHOWED A PERFORATION. PATIENT WAS TAKEN TO OPERATING ROOM; HYSTEROSCOPY SHOWED THAT INSERT WAS IN OCS. HOWEVER, DURING LAPAROSCOPY, INSERT WAS NOT IN TUBE, BUT POSSIBLY IN BROAD LIGAMENT. TUBAL LIGATION WAS DONE ON RIGHT TUBE ON (B)(6) 2015. PATIENT DID NOT COMPLAIN ABOUT SYMPTOMS. FOLLOW UP 20.JAN.2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). BATCH NUMBER (B)(4) (PRODUCTION DATE 15-JUL-2014; EXPIRATION DATE 15-JUL-2017). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 5 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, NONE OF THOSE CASES REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED

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BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER CONFIRMATORY TEST SHOWED A PERFORATION. SHE WAS SUBMITTED TO A LAPAROSCOPY AND DURING THE PROCEDURE INSERT WAS NOT IN TUBE, BUT POSSIBLY IN BROAD LIGAMENT. PATIENT WAS ASYMPTOMATIC. THE REPORTED EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A COMPLETE PERFORATION OCCURS, ESSURE CAN BE FOUND IN THE ABDOMINAL CAVITY AS IT PERFORATES THE WHOLE FALLOPIAN TUBE WALL. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM AND DATE OF PERFORATION ARE UNKNOWN, GIVEN THE ABOVE MENTION INFORMATION A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT DUE TO THE REQUIRED INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 24-MAR-2015 FROM PHYSICIAN: THE PATIENT WAS (B)(6) AT TIME OF THE REPORT. SHE HAD A D&C (DILATION AND CURETTAGE) IN 2003 AND A C-SECTION IN 2014. NO OTHER PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES. THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00072	BAYER HEALTHCARE LLC	2/11/2015	2/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESSURE
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM THE MEDICAL LITERATURE ON (B)(4) 2015, ARTICLE ENTITLED "PELVIC PAIN ASSOCIATED WITH AN ESSURE DEVICE AND NICKEL ALLERGY. IN RELATION TO 3 CASES". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) FOR PERMANENT CONTRACEPTION. CASE REPORT: A FEMALE PATIENT WITH NICKEL ALLERGY NOT DETECTED BEFORE ESSURE USE EXPERIENCED PELVIC PAIN AFTER INSERTION. THE PAIN RESOLVED AFTER REMOVAL OF THE DEVICE. ABSTRACT: ESSURE IS THE FIRST INTRATUBAL DEVICE FOR PERMANENT CONTRACEPTION INSERTED UNDER HYSTEROSCOPIC GUIDANCE. A RARE COMPLICATION OF THIS DEVICE IS PELVIC PAIN, WHICH CAN BE RELATED TO ALLERGY TO ONE OR MORE OF ITS COMPONENTS, MAINLY NICKEL. NICKEL IS THE MOST COMMON CONTACT ALLERGEN IN THE INDUSTRIALIZED WORLD, AND CONSEQUENTLY THE NUMBER OF PUBLISHED REPORTS MAY NOT REFLECT THE TRUE EXTENT OF THIS COMPLICATION IN WOMEN WITH AN ESSURE DEVICE. THREE CASES OF PELVIC PAIN IN PATIENTS WITH NICKEL ALLERGY ARE REPORTED THAT WAS NOT DETECTED BEFORE ESSURE INSERTION. THE PAIN RESOLVED AFTER REMOVAL OF THE DEVICE IN 2 WOMEN. AN EXPECTANT ATTITUDE WAS ADOPTED IN THE THIRD WOMAN. CURRENTLY, FEW CASES HAVE BEEN REPORTED ON THIS TOPIC. IT IS GENERALLY ACCEPTED THAT THE DEVICE SHOULD BE REMOVED IN WOMEN WITH PELVIC PAIN LASTING FOR MORE THAN 6 WEEKS. IN ADDITION, THESE WOMEN SHOULD ALSO UNDERGO TESTING FOR NICKEL ALLERGY. (B)(4). FOLLOW-UP (29-JAN-2015): FURTHER CASE DETAILS WERE DERIVED FROM THE ENGLISH FULL TEXT TRANSLATION. THIS 40-YEAR-OLD MULTIPAROUS PATIENT (CASE 1), WITH NO RELEVANT PERSONAL OR FAMILY HISTORY, WAS SEEN BY THE GYNAECOLOGIST FOR A PERMANENT BIRTH CONTROL VISIT. UP UNTIL THAT TIME, SHE HAD BEEN TAKING ORAL HORMONAL CONTRACEPTIVES. THE GYNAECOLOGICAL EXAMINATION WAS NORMAL AND INSERTION OF THE ESSURE® INTRATUBAL

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DEVICE WAS RECOMMENDED. INSERTION WAS PERFORMED HYSTEROSCOPICALLY ON AN OUTPATIENT BASIS WITH NO COMPLICATIONS, EXCEPT FOR INTENSE PAIN DURING CANALISATION OF THE FALLOPIAN TUBES. AFTER FOUR MONTHS, THE PATIENT UNDERWENT A PLAIN X-RAY OF THE ABDOMEN TO CONFIRM THE CORRECT POSITIONING OF THE DEVICES. ONE MONTH AFTER THIS CHECK-UP, THE PATIENT REPORTED HYPOGASTRIC DISORDERS THAT LIMITED HER DAILY LIFE ACTIVITIES AND THAT SHE ASSOCIATED WITH THE ESSURE® DEVICE. SHE WAS SEEN BY SEVERAL GYNAECOLOGISTS, BUT NO DISORDERS WERE DETECTED DURING THE EXAMINATIONS. AFTER REPEATING HER PERSONAL MEDICAL HISTORY IN DETAIL, THE PATIENT REPORTED THAT SHE IS ALLERGIC TO METALS, THEREFORE IT WAS DECIDED TO REMOVE THE ESSURE® DEVICE. A LAPAROSCOPY WAS PERFORMED, VISUALISING OEDEMA IN BOTH FALLOPIAN TUBES WITH NO OTHER FINDINGS. BILATERAL SALPINGECTOMY WAS PERFORMED WITH EXTRACTION OF THE RIGHT ESSURE® DEVICE TOGETHER WITH THE TUBE; HYSTEROSCOPIC REMOVAL OF THE CONTRALATERAL INTRATUBAL DEVICE, WHICH WAS MAINLY INSIDE THE LEFT UTERINE HORN, WAS NECESSARY. THE PATIENT WAS DISCHARGED 24 HOURS LATER AND THE PELVIC PAIN HAD DISAPPEARED IN SUBSEQUENT CHECK[?]UPS. AUTHORS' COMMENT: DUE TO THE COMPOSITION OF THE DEVICE, ALLERGY TO METALS IS A RELATIVE CONTRAINDICATION. ALLERGY TO METALS, MORE SPECIFICALLY TO NICKEL, IS A TYPE IV OR DELAYED HYPERSENSITIVITY REACTION... IT IS GENERALLY ACCEPTED THAT IF ABDOMINAL PAIN LASTS MORE THAN 6 WEEKS AFTER INSERTION, REMOVAL OF THE ESSURE® DEVICE SHOULD BE CONTEMPLATED. IN THESE CASES, IT IS COMPULSORY TO TEST THE PATIENT FOR ALLERGY TO METALS. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE. IT REFERS TO A FEMALE PATIENT WITH A HISTORY OF METAL ALLERGY, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN AFTER DEVICE PLACEMENT. THE REPORTED EVENT PELVIC PAIN WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THE PRESENT CASE, THE PATIENT HAD A HISTORY OF METAL ALLERGY AND PRESENTED WITH PELVIC PAIN APPROXIMATELY 5 MONTHS AFTER DEVICE INSERTION. HER PHYSICIAN DECIDED TO REMOVE ESSURE AND THE PELVIC PAIN DISAPPEARED AFTER REMOVAL. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND SINCE THE REPORTED PAIN RECOVERED AFTER DEVICE REMOVAL, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND PELVIC PAIN CANNOT BE EXCLUDED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THE PRESENT CASE, NO SUCH SYMPTOMS WERE REPORTED. ALSO, NON-SERIOUS EVENT INTENSE PAIN DURING CANALISATION OF THE FALLOPIAN TUBES WAS REPORTED. DUE TO THE INTERVENTION REPORTED, THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 26-FEB-2015, WITH (B)(4): FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00073	BAYER HEALTHCARE LLC	2/11/2015	2/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(4) WAS DERIVED FROM THE MEDICAL LITERATURE ON 13-JAN-2015, ARTICLE ENTITLED "PELVIC PAIN ASSOCIATED WITH AN ESSURE DEVICE AND NICKEL ALLERGY. IN RELATION TO 3 CASES." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION. CASE REPORT: A FEMALE PATIENT WITH NICKEL ALLERGY NOT DETECTED BEFORE ESSURE USE EXPERIENCED PELVIC PAIN AFTER INSERTION. THE PAIN RESOLVED AFTER REMOVAL OF THE DEVICE. ABSTRACT: ESSURE IS THE FIRST INTRATUBAL DEVICE FOR PERMANENT CONTRACEPTION INSERTED UNDER HYSTEROSCOPIC GUIDANCE. A RARE COMPLICATION OF THIS DEVICE IS PELVIC PAIN, WHICH CAN BE RELATED TO ALLERGY TO ONE OR MORE OF ITS COMPONENTS, MAINLY NICKEL. NICKEL IS THE MOST COMMON CONTACT ALLERGEN IN THE INDUSTRIALIZED WORLD, AND CONSEQUENTLY THE NUMBER OF PUBLISHED REPORTS MAY NOT REFLECT THE TRUE EXTENT OF THIS COMPLICATION IN WOMEN WITH AN ESSURE DEVICE. THREE CASES OF PELVIC PAIN IN PATIENTS WITH NICKEL ALLERGY ARE REPORTED THAT WAS NOT DETECTED BEFORE ESSURE INSERTION. THE PAIN RESOLVED AFTER REMOVAL OF THE DEVICE IN 2 WOMEN. AN EXPECTANT ATTITUDE WAS ADOPTED IN THE THIRD WOMAN. CURRENTLY, FEW CASES HAVE BEEN REPORTED ON THIS TOPIC. IT IS GENERALLY ACCEPTED THAT THE DEVICE SHOULD BE REMOVED IN WOMEN WITH PELVIC PAIN LASTING FOR MORE THAN 6 WEEKS. IN ADDITION, THESE WOMEN SHOULD ALSO UNDERGO TESTING FOR NICKEL ALLERGY. OTHER CASES DERIVED FROM THE SAME ARTICLE ARE (B)(4). PTC INVESTIGATION RESULT RECEIVED ON 27-JAN-2015 AND ADDITIONAL INFORMATION RECEIVED ON 29-JAN-2015 (ENGLISH FULL TEXT TRANSLATION): PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY

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MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER CASE DETAILS WERE DERIVED FROM THE ENGLISH FULL TEXT TRANSLATION. THIS (B)(6) MULTIPAROUS PATIENT (CASE 2) WAS SEEN BY THE GYNAECOLOGIST FOR DEFINITIVE BIRTH CONTROL. UP UNTIL THAT POINT SHE HAD USED BARRIER METHODS. HER PAST MEDICAL HISTORY WAS UNEVENTFUL, WITH NO KNOWN ALLERGIES. THE GYNAECOLOGICAL EXAMINATION WAS NORMAL. BOTH INTRAUTERINE DEVICES WERE INSERTED WITHOUT DIFFICULTIES. THE CORRECT POSITIONING OF BOTH DEVICES WAS CHECKED THREE MONTHS LATER VIA ABDOMINAL X-RAY. THE PATIENT REPORTED PELVIC PAIN RADIATING TOWARDS THE RIGHT ILIAC FOSSA SINCE INSERTION OF THE ESSURE® DEVICE; THE GYNAECOLOGICAL EXAMINATION WAS NORMAL. A METAL ALLERGY STUDY WAS REQUESTED AND ONE MONTH LATER, THE PATIENT RETURNED WITH AN ALLERGOLOGY REPORT CONFIRMING AN ALLERGY TO NICKEL. SHE WAS STILL IN PAIN AND A BILATERAL SALPINGECTOMY WAS PERFORMED LAPAROSCOPICALLY, EXTRACTING BOTH DEVICES VIA THIS ROUTE. THE PATIENT WAS DISCHARGED IN THE FOLLOWING 24 HOURS AND IS CURRENTLY ASYMPTOMATIC. HER FALLOPIAN TUBES WERE SENT TO THE PATHOLOGICAL ANATOMY DEPARTMENT, AND TUBAL WALL CONGESTION WITH MINIMAL LYMPHOCYTE INFILTRATES WAS CONFIRMED IN BOTH TUBES. AUTHORS' COMMENT: DUE TO THE COMPOSITION OF THE DEVICE, ALLERGY TO METALS IS A RELATIVE CONTRAINDICATION. ALLERGY TO METALS, MORE SPECIFICALLY TO NICKEL, IS A TYPE IV OR DELAYED HYPERSENSITIVITY REACTION. THE SYMPTOMS RELATED TO NICKEL HYPERSENSITIVITY WERE: SWELLING, NAUSEA, RASH, ITCHING, URTICARIA, ASTHMA AND PELVIC PAIN. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: ALLERGY TO METALS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 106 CASES. PELVIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 290 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE. IT REFERS TO A FEMALE PATIENT WITH NICKEL ALLERGY NOT DETECTED BEFORE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION, WHO EXPERIENCED PELVIC PAIN AFTER DEVICE PLACEMENT. THE DEVICES WERE REMOVED AND SHE RECOVERED FROM PAIN. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. ADDITIONALLY, ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND SINCE THE REPORTED PAIN RECOVERED AFTER DEVICE REMOVAL, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A BILATERAL SALPINGECTOMY (BOTH DEVICES WERE REMOVED) WAS PERFORMED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS

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PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00074	BAYER HEALTHCARE LLC	2/11/2015	2/12/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER, OF UNSPECIFIED AGE, IN (B)(6) ON (B)(6) 2015. IT DESCRIBES THE OCCURRENCE OF AN ECTOPIC PREGNANCY IN HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED VIA SOCIAL MEDIA THAT SHE WAS ONE OF THOSE (B)(6) WOMEN AND THEY WERE NOT A FEW PEOPLE AS WAS NOTICED; HER STRUGGLE BEGAN IN (B)(6) 2014 AFTER AN ECTOPIC PREGNANCY. PTC INVESTIGATION RESULT RECEIVED ON 01-FEB-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT

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(CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ECTOPIC PREGNANCY WITH CONTRACEPTIVE DEVICE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 28 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD AN ECTOPIC PREGNANCY (DEVICE INEFFECTIVE). ECTOPIC PREGNANCY IS A SERIOUS EVENT DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS NOT REPORTED WHETHER A CONFIRMATION TEST WAS PERFORMED OR THE TIME INTERVAL BETWEEN ESSURE INSERTION AND THE ECTOPIC PREGNANCY. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS REPORT WAS REGARDED AS AN INCIDENT DUE TO SERIOUS INJURY (ECTOPIC PREGNANCY). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW UP WAS NOT POSSIBLE SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION WAS RECEIVED ON 28-MAY-2015: NCA NUMBER ADDED TO THE CASE ((B)(4)). THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE P

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040763	BAYER	2/11/2015	2/19/2015

Event Information:

Event Date (B3): 1/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): C76456

Single Use:
Implant Date (E6): 1/20/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE 3 WEEKS AGO AND MY LIFE HAS BEEN A LIVING NIGHTMARE EVER SINCE. THE PROCEDURE ITSELF WAS EXCRUCIATINGLY PAINFUL. I HAVE HAD SEVERE CRAMPING IN MY STOMACH AND LOWER BACK. I AM BLOATED AND TIRED, NOT TO MENTION THAT I HAVE BEEN BLEEDING SINCE THE PROCEDURE WAS DONE. THE PAIN THAT THIS DEVICE HAS CAUSED ME HAS ALMOST BEEN UNBEARABLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040771	BAYER	2/11/2015	2/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RECEIVED THE ESSURE BIRTH CONTROL/STERILIZATION PROCESS. I HAD REQUESTED TO HAVE A TUBAL LIGATION AND THE OB HIGHLY RECOMMENDED THAT I GO WITH ESSURE IN ITS PLACE. WITHIN SIX MONTHS, I STARTED HAVING EXTREME PSORIASIS ON HANDS - I HAD NEVER HAD THIS BEFORE. WITHIN ONE YEAR, BLOATING OF THE ABDOMEN AND PAIN IN THE BACK BEGAN TO OCCUR. THIS IS EXTREME BLOATING AND NOTHING HAS HELPED TO GET RID OF THIS . INVESTIGATING THE PROCESS TO HAVE THE COILS REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040776	BAYER	2/11/2015	2/20/2015

Event Information:

Event Date (B3): 12/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/8/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEADACHE, HAIR LOSS, WEIGHT GAIN, BLOATING, HOT FLASHES, ACNE, BLACKHEADS, ABDOMINAL PAIN, HEAVY PERIODS LASTING FOR UP TO 14 DAYS, LARGE CLUMPS OF BLOOD/TISSUE THE SIZE OF A BASEBALL COMING OUT OF VAGINA WHEN I'M ON MY PERIOD AND THESE SYMPTOMS GET WORSE EACH YEAR IT SEEMS LIKE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00075	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 915879

Single Use: Y
Implant Date (E6): 3/15/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(4) 2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY AND DEVICE INEFFECTIVE IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED 2 YEARS PRIOR TO THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 13-JAN-2015. NO FURTHER INFORMATION OBTAINED DESPITE FOLLOW-UP ATTEMPTS. CASE CLOSED. FOLLOW-UP RECEIVED ON 14-JAN-2015: THE PATIENT WAS(B)(6) AT THE TIME OF HER EVENT. HER WEIGHT WAS REPORTED AS (B)(6) AND HER HEIGHT AS (B)(6). HER DRUG HISTORY WAS POSITIVE FOR THE USE OF MICRO-PROGESTOGEN IMPLANT SINCE (B)(6) 2009 (SHE EXPERIENCED AMENORRHEA ON THIS DRUG). SHE HAD ESSURE MODEL ESS305 (LOT NUMBER 915879) INSERTED ON (B)(6) 2012; NO UTERINE ABNORMALITIES WERE OBSERVED PRIOR PROCEDURE. THE HSG (HYSTEROSALPINGOGRAM) PERFORMED ON (B)(6) 2012 CONFIRMED TUBAL OCCLUSION AND, BECAUSE OF THAT SHE DISCONTINUED HER MICRO-PROGESTOGEN IMPLANT ON (B)(6) 2012. HER PREGNANCY WAS MEDICALLY CONFIRMED AND THE IMPLANTS WERE FOUND TO BE IN PLACE AT THE TIME OF THE DIAGNOSIS; SHE DESIRED TO INTERRUPT THE PREGNANCY. IT WAS REPORTED THAT THE IMPLANTS WERE REMOVED (REMOVAL METHOD: LAPAROSCOPY AND HYSTEROSCOPY). THE OUTER COIL OF THE LEFT DEVICE WAS BROKEN BY GYNECOLOGIST AND REMOVED TO ALLOW THE PROCEDURE OF INTERRUPTION OF PREGNANCY (ASPIRATION). THE REST OF THE DEVICE (INNER COIL) WAS REMOVED LATER BY HYSTEROSCOPY ON (B)(6) 2014. IT WAS MENTIONED THAT THE RIGHT IMPLANT WAS NOT SEEN DURING LAPAROSCOPY, BUT IT WAS FOUND DURING A POST-SURGERY PLAIN ABDOMEN (DISCREPANT WITH PREVIOUS INFORMATION ABOUT DEVICE REMOVAL). NO PATHOLOGICAL RESULTS, SIGNS OF INFECTION OR INFLAMMATION WERE OBSERVED. ACCORDING TO THE PHYSICIAN, THE REMOVAL OF THE IMPLANTS WAS NOT MEDICALLY NECESSARY AND WAS NOT PERFORMED DUE TO

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PATIENT'S DEMAND. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO BECAME PREGNANT 2 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE DECIDED TO TERMINATE THE PREGNANCY; DURING THIS PROCEDURE THE OUTER COIL OF THE LEFT DEVICE WAS BROKEN BY GYNECOLOGIST AND REMOVED, THE REST OF LEFT DEVICE WAS REMOVED LATER BY HYSTEROSCOPY. A LAPAROSCOPY WAS ALSO PERFORMED AND RIGHT IMPLANT WAS NOT FOUND, BUT IT WAS SEEN DURING POST-SURGERY PLAIN ABDOMEN X-RAY. THE REPORTED PREGNANCY WAS CONSIDERED NON-SERIOUS AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. THIS EVENT WAS CONSIDERED AS RELATED TO THE SUSPECT INSERT SINCE PATIENT HAD ESSURE CONFIRMATORY TEST, WHICH SHOWED TUBAL OCCLUSION. THEREFORE, AN ESSURE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, INTERPRETED AS A DEVICE MISUSE FOLLOWED BY DEVICE BREAKAGE ON LEFT SIDE AND DEVICE DISLOCATION ON RIGHT SIDE, THEY WERE CONSIDERED AS SERIOUS (EXCEPT FOR DEVICE MISUSE) DUE TO MEDICAL IMPORTANCE AND ARE LISTED. ONCE ESSURE IS PLACED, MICRO-INSERT REMOVAL SHOULD NOT BE ATTEMPTED HYSTEROSCOPICALLY UNLESS 18 OR MORE COILS OF THE MICRO-INSERT ARE TRAILING. ALSO, THE REMOVAL SHOULD BE ATTEMPTED IMMEDIATELY FOLLOWING THE PLACEMENT. IF IT IS ATTEMPTED, THE MICRO-INSERT MAY BREAK. FOR THIS PARTICULAR CASE, CONSIDERING THE ABOVE MENTION INFORMATION, THE REPORTED DEVICE BREAKAGE COULD BE CONSIDERED RATHER A CONSEQUENCE OF DEVICE MISUSE; NEVERTHELESS GIVEN THIS EVENT'S NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. FOR THE REPORTED DEVICE DISLOCATION AS IT WAS CONFIRMED BY LAPAROSCOPY AND X-RAY IT WAS REGARDED AS RELATED TO ESSURE. THIS CASE WAS CONSIDERED AS INCIDENT, AS ALTHOUGH PHYSICIAN STATED REMOVAL OF THE IMPLANTS WAS NOT MEDICALLY NECESSARY, INTERVENTIONS WERE REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 06-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: BATCH NUMBER 915879 MFG DATE:

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00076	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2014 WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, (B)(4). ESSURE WAS INSERTED FOR BIRTH CONTROL. CONSUMER STATED SHE WAS SCHEDULED FOR A TOTAL HYSTERECTOMY ON (B)(6) 2015 BECAUSE ESSURE MIGRATED AND PERFORATED HER UTERUS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP 05.JAN.2014: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP POSTED ONLINE BY THE CONSUMER AND RECEIVED BY THE COMPANY ON (B)(4) 2015: THE CONSUMER HAD A TOTAL HYSTERECTOMY DONE ON (B)(6) 2015 AND REPORTED THAT THE PHYSICIAN ALSO HAD TO PERFORM A BILATERAL SALPINGO-OOPHORECTOMY BECAUSE HER

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OVARIES WERE DAMAGED FROM THE ESSURE COILS THAT HAD PERFORATED HER FALLOPIAN TUBES AND MIGRATED (THE PREVIOUSLY REPORTED EVENT ESSURE HAVING MIGRATED AND HAS PERFORATED MY UTERUS WAS AMENDED TO THIS NEWLY REPORTED TERMS). DURING RECOVERY SHE HAD PROBLEMS WITH GAS, BUT AT THE REPORTING TIME ALL HER GAS PAIN WAS GONE. ACCORDING TO HER, SHE COULD NOT KEEP HER EYES OPEN FOR NOW AND WAS READY TO START HEALING. FOLLOW-UP RECEIVED ON 22-JAN-2015: PTC RESULT WAS REVIEWED AFTER CASE UPGRADED TO INCIDENT; HOWEVER FINAL ASSESSMENT AND MEDICAL ASSESSMENT REMAINED UNCHANGED. COMPANY CAUSALITY COMMENT: THIS SOLICITED NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COILS HAD PERFORATED HER FALLOPIAN TUBES (PREVIOUSLY REPORTED AS ESSURE MIGRATED AND HAS PERFORATED HER UTERUS) (CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE). HER OVARIES WERE DAMAGED FROM THE ESSURE COILS (CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED). UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE THE EXACT TIMING OF THE PERFORATION WAS NOT REPORTED. THE OCCURRENCE OF OVARIES DAMAGED MAY BE CONSIDERED A CONSEQUENCE OF FALLOPIAN TUBE PERFORATION. A CAUSAL RELATIONSHIP BETWEEN BOTH EVENTS WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT DUE TO THE SURGICAL INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENT WERE ADDED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW UP WAS POSSIBLE DUE TO NO CONSUMER CONTACT INFORMATION (SOCIAL MEDIA CASE).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00080	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 910509

Single Use: Y
Implant Date (E6): 6/19/2012
Explant Date (E7): 12/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER/PLAINTIFF IN (B)(6) ON (B)(4) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR STERILISATION WITH LOT NUMBER 910509. FOLLOW-UP INFORMATION WAS RECEIVED ON 15-JAN-215, WHEN THE CASE COMPLETED ALL CRITERIA TO BECOME A CASE FOR CENTRAL. THIS IS A POTENTIAL LEGAL CASE. IT WAS REPORTED THAT THE CONSUMER DEVELOPED POST PROCEDURE PAIN AND BLEEDING. BY (B)(6) 2012 THE PAIN WAS SEVERE AND SHE WAS VOMITING. SHE WAS ALSO STILL BLEEDING HEAVILY. THE PAIN WAS SO SEVERE THAT SHE SUFFERED SEVERAL EPILEPTIC SEIZURES. SHE WAS SO CONCERNED THAT SHE CONTACTED THE GYNECOLOGY DEPARTMENT AND WAS ADVISE TO GO STRAIGHT TO EMERGENCY. THE EMERGENCY CARE ASSESSMENT DOCUMENTATION FOR THAT ATTENDANCE STATED PAINFUL PROCEDURE FOLLOWING DAY 5 FITS DUE TO PAIN. SINCE THEN PV BLEEDING. INITIAL PAIN WAS AT RIF (RIGHT ILIAC FOSSA) BUT NOW THROUGHOUT LOWER ABDOMEN. THE CONSUMER'S SYMPTOMS FAILED TO IMPROVE AND SHE THEREFORE VISITED HER PHYSICIAN ON (B)(6) 2012. THE CLINICAL NOTES STATED SHE HAD ESSURE STERILIZATION AND HAD FOUND PROCEDURE VERY PAINFUL. LOTS OF POST-OPERATIVE BLEEDING AND RIF DISCOMFORT. PASSING CLOTS ++ AND FEELING UNWELL. PAIN WAS NOT WELL CONTROLLED ON DISCHARGE. SHE HAD STRUGGLED TO CONTINUE NORMAL ACTIVITY. SHE WAS SAW BY PHYSICIAN 4 D AGO (IN (B)(6) 2012) AND EXAMS WERE NORMAL. SHE CONTACTED THE GYNECOLOGY DEPARTMENT AND WAS ADVISED TO START ON AUGMENTIN AND NORETHISTERONE FOR BLEEDING THE BLEEDING AND PAIN CONTINUED. SHE THEREFORE CONTACTED HER PHYSICIAN AGAIN ON (B)(6) 2012 AND THE DECISION WAS MADE TO REFER HER TO EMERGENCY FOR ASSESSMENT BY THE GYNECOLOGY TEAM WHERE SHE WAS TREATED WITH DICLOFENAC AND ANTIBIOTICS. DESPITE THIS TREATMENT HER PAIN CONTINUED. BY (B)(4) 2012 (REPORTED AS 2011) THE CLAIMANT HAD CONTACTED HER

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DOCTOR SURGERY AGAIN. THE CLINICAL NOTES FOR THIS ATTENDANCE STATED PERSISTENT PAIN AND BLEEDING WITH NO IMPROVEMENT WITH MEDICATION. THE LETTER WRITTEN TO HOSPITAL STATED THAT WHEN PHYSICIAN INITIALLY REVIEWED HER ONE WEEK AFTER THE PROCEDURE SHE WAS PASSING A LOT OF CLOTS AND WAS TENDER IN THE RIGHT ILIAC FOSSA. SHE WAS PRESCRIBED WITH SOME TRAMADOL AND ON AUGMENTIN AND NORETHISTERONE. UNFORTUNATELY HER PAIN BECAME WORSE AND SHE WAS REFERRED TO GYNECOLOGIST FOR REVIEW. EXAMINATION SWABS AT THIS POINT WERE NORMAL AND SHE WAS GIVEN AN INCREASED DOSE OF NORETHISTERONE, AS THE PAIN AND BLEEDING WERE NOT GETTING BETTER. THE CONSUMER WAS THEREFORE ADMITTED TO THE WARD WHERE HER PAIN AND BLEEDING WERE NOTED. SHE UNDERWENT A CT SCAN THE FOLLOWING DAY AND WAS DISCHARGED HOME. SHE REMAINED IN TERRIBLE PAIN AND DISCOMFORT. ON (B)(6) 2012, SHE CONTACTED HER GYNECOLOGIST. THE RECORDS FROM THAT DATE STATED PAIN IN RIF, MUCH MORE SEVERE AGAIN, NOT CONTROLLED WITH ORAL ANALGESIA AND BLEEDING HAD STARTED AGAIN - HEAVIER THAN NORMAL PERIODS. SHE WAS URGENTLY REFERRED BACK TO HOSPITAL WHERE SHE UNDERWENT DIAGNOSTIC LAPAROSCOPY, DIAGNOSTIC HYSTEROSCOPY/LAPAROSCOPIC ADHESIOLYSIS. IN A LETTER FROM THE HOSPITAL TO THE CONSUMER'S PHYSICIAN DATED (B)(4) 2012, THE FOLLOWING WAS STATED: DURING THE LAPAROSCOPY THE LEFT TUBE WAS SCARRED AND ADHERED TO THE LEFT SIDE WALL AND THIS WAS DISSECTED SO THEREFORE THE PAIN WAS MOST PROBABLY DUE TO THIS, THE LEFT SIDED PAIN MAY BE DUE TO THAT. CONSUMER WAS OBVIOUSLY VERY ANGRY REGARDING THE PAIN SHE WAS EXPERIENCING POST OPERATIVELY AND SHE WISHED THAT THIS HAD BEEN EXPLAINED TO HER AT THE TIME. ON (B)(6) 2012, SHE WAS ADMITTED TO HOSPITAL BY AMBULANCE. THE AMBULANCE RECORDS FOR THAT DATE STATED THAT SHE WAS LYING ON THE FLOOR, DISTRESSED. THE HOSPITAL RECORDS FOR THAT DATE STATED SHE PRESENTED WITH SUDDEN ONSET SEVERE PAIN, SUPRAPUBIC RADIATING TO RIF, LIKE BEING STABBED WITH A KNIFE AND HAVING IT DRAGGED ACROSS HER LOWER ABDOMEN. LASTED THIS SEVERELY FOR APPROXIMATELY 15 MINUTES, THE CONSUMER THOUGHT SHE MAY HAVE BLACKED OUT WITH THE PAIN - PARTNER SAID HE FOUND HER SLUMPED ON THE SOFA, AWOKE WITHIN SECONDS. PAIN EASED A LITTLE BY CURLING LEGS UP AND HOLDING RIF. FOLLOWING THAT ATTENDANCE THE CONSUMER UNDERWENT HYSTERECTOMY TOGETHER WITH HYSTEROSCOPIC REMOVAL OF THE ESSURE. BY (B)(6) 2013, HOWEVER, THE PAIN HAD RETURNED. IT WAS DESCRIBED IN HER PHYSICIAN NOTES ON (B)(6) 2013 AS BEING EXACTLY THE SAME PAIN AS POST STERILIZATION. IT WAS NOTED AT THAT TIME THAT SHE HAD TAKEN TRAMADOL WITHOUT EFFECT. THE CONSUMER HAD SINCE BEEN GIVEN A NUMBER OF GNRH ANALOGUE INJECTIONS. THESE HOWEVER HAD NOT RESULTED IN AN END TO HER PAIN. SHE IS LEFT WITH THE POSSIBILITY THAT SHE WILL HAVE TO UNDERGO FURTHER SURGERY AGAIN. FOLLOW-UP INFORMATION RECEIVED ON 21-JAN-2015: MHRA (ADVERSE INCIDENT CENTER) PROVIDED THEIR REFERENCE NUMBER ((B)(4)). PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 27-JAN-2015. THE PTC GLOBAL REFERENCE NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER 910509 IS VALID. MANUFACTURING DATE: OCT-2011 AND EXPIRATION DATE: OCT-2014. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES

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RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: ABDOMINAL PAIN LOWER. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 95 CASES. GENITAL HAEMORRHAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 160 CASES. SUPRAPUBIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 1 CASE. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS RECEIVED FROM AN LAWYER ON BEHALF OF A (B)(6) FEMALE CONSUMER/PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED POST PROCEDURE BLEEDING WITH CLOTS AND POST PROCEDURE PAIN (INITIALLY ON RIGHT ILIAC FOSSA-RIF, AND LATER THROUGHOUT LOWER ABDOMEN/RIF DISCOMFORT), DUE TO PAIN SHE EXPERIENCED SEVERAL EPILEPTIC SEIZURES. SHE WAS HOSPITALIZED. THE PAIN AND BLEEDING PERSISTED AND SHE UNDERWENT A DIAGNOSTIC LAPAROSCOPY. AFTER THIS PROCEDURE, SHE HAD AN EPISODE OF SUDDEN ONSET SEVERE PAIN, SUPRAPUBIC RADIATING TO RIF (SHE BLACKED OUT WITH THIS PAIN) AND WAS HOSPITALIZED AND SUBMITTED TO HYSTERECTOMY WITH ESSURE REMOVAL. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND HOSPITALIZATION. EPILEPTIC SEIZURES AND BLACKED OUT ARE UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE OTHER EVENTS ARE LISTED. DURING ESSURE MICRO-INSERT THERAPY PAIN AND GENITAL BLEEDING OR SPOTTING MAY OCCUR. IN THIS PARTICULAR CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED BLEEDING AND PAIN A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, VASOVAGAL REACTIONS (SYNCOPE) ARE COMMONLY TRIGGERED BY PAIN. IN CASES OF LONG-LASTING CEREBRAL HYPO PERFUSION SEIZURE-LIKE MOVEMENTS ARE OBSERVED IMITATING AN EPILEPTIC SEIZURE. RECOVERY IS SPONTANEOUS, COMPLETE AND LASTS NO LONGER THAN 30 SECONDS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED ABOUT CONSUMER'S SEIZURES/BLACK OUT; HOWEVER, SINCE THESE EVENTS WERE RELATED BY CONSUMER TO HER PAIN; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT DUE TO HOSPITALIZATION AND REQUIRED INTERVENTION FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00081	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2015 WHO WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, (B)(4). ON AN UNSPECIFIED DATE, ESSURE WAS INSERTED FOR BIRTH CONTROL. CONSUMER REPORTED THAT ON (B)(6) 2015, A TOTAL HYSTERECTOMY WAS DONE, BECAUSE SHE WAS BEING POISONED WITH HEAVY METALS FROM ESSURE DEVICE. SHE WAS STILL IN A FAIR AMOUNT OF PAIN AND WAS WONDERING IF THAT WAS NORMAL. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. THE (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. METAL POISONING IS NOT AN IDENTIFIED FAILURE MODE OF ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION

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INSERT) INSERTED AND WAS SUBMITTED TO A TOTAL HYSTERECTOMY BECAUSE SHE WAS BEING POISONED WITH HEAVY METALS FROM THE ESSURE DEVICE. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. PATIENTS WHO ARE ALLERGIC TO NICKEL TITANIUM MAY SUFFER AN ALLERGIC REACTION TO THE MICRO-INSERT. IN THIS PARTICULAR CASE, ALTHOUGH LIMITED INFORMATION WAS PROVIDED (CONSUMER'S SYMPTOMS WERE NOT SPECIFIED); SINCE THE CONSUMER RELATED THE EVENT TO THE SUSPECT INSERT AND CONSIDERING A HYSTERECTOMY WAS REQUIRED; CAUSALITY CANNOT BE EXCLUDED AND THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY THE NON-SERIOUS STILL IN FAIR AMOUNT OF PAIN WAS REPORTED. NO FOLLOW-UP WILL BE PURSUED SINCE THIS IS A SOCIAL MEDIA CASE. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00082	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A FEMALE CONSUMER, OF UNSPECIFIED AGE, IN UNITED STATES ON 14-JAN-2015 WHICH REFERS TO HERSELF WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). CONSUMER REPORTED VIA (B)(4) THAT SHE HAD ESSURE INSERTED IN 2011 AND HAD A TOTAL HYSTERECTOMY. SHE RELATED THE SURGERY TO ESSURE PROBLEMS. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 27-JAN-2015 AND FOLLOW-UP INFORMATION RECEIVED ON 28-JAN-2015. THE PTC GLOBAL REFERENCE NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. SINCE NO CONTACT DETAILS ARE AVAILABLE FOR THE CONSUMER, NO FURTHER INFORMATION IS EXPECTED FOR THIS CASE REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS

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TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A TOTAL HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR HYSTERECTOMY WAS NOT SPECIFIED, SINCE CONSUMER RELATED THIS SURGERY TO ESSURE PROBLEMS, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00083	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (MW5039078) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012 FOR PERMANENT BIRTH CONTROL. IT WAS REPORTED THAT PROCEDURE WAS DONE AT LOCAL HOSPITAL. UPON WAKING IN THE RECOVERY ROOM, SHE STARTED COMPLAINING OF SEVERE PAIN ON MY LEFT SIDE. ONCE SHE WAS SENT HOME, THE PAIN INCREASED AND A PERSISTENT FEVER DEVELOPED. A WEEK LATER, SHE WENT BACK TO THE DOCTOR AND A VAGINAL ULTRASOUND WAS DONE CHECKING PLACEMENT. EVERYTHING WAS AS IT SHOULD BE. OVER THE COURSE OF THE NEXT YEAR, THE PAIN BECAME WORSE AND HER PERIODS BECAME EXTREMELY HEAVY AND PAINFUL. THERE WAS A CONSTANT TUGGING FEELING ON THE LEFT SIDE SENDING PAIN TO HER BACK AND HIP CAUSING SEVERE PAIN WHEN BENDING OR TWISTING. THE FEVER WAS AN ON AND OFF EVENT ALONG WITH HEADACHES AND ON HER LEFT SIDE SHE WAS FEELING HOT. SHE REACHED AT HER LIMIT AND HAD A HYSTERECTOMY DONE IN 2013 REMOVING TUBES, UTERUS AND CERVIX. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 30-JAN-2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE

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REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN ON LEFT SIDE / THE PAIN BECAME WORSE. THIS EVENT, INTERPRETED AS PELVIC FEMALE PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT AFTER ESSURE INSERTION, STARTING UPON WAKING IN THE RECOVERY ROOM. A WEEK AFTER INSERTION, A VAGINAL ULTRASOUND WAS PERFORMED AND EVERYTHING WAS AS IT SHOULD BE. OVER THE COURSE OF THE NEXT YEAR, THE PAIN BECAME WORSE. THEN, CONSUMER UNDERWENT A HYSTERECTOMY, REMOVING TUBES, UTERUS AND CERVIX. GIVEN A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00084	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2003
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039054) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF, WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2003 TO PREVENT FUTURE PREGNANCY. AFTER 3 MONTHS OF PROCEDURE, SHE WAS ASSURED COILS WERE IN PLACE AND THAT SHE SHOULD HAVE NO COMPLICATIONS; NO NEGATIVE FEEDBACK OR PROBLEMS HAD BEEN REPORTED PER THE DOCTOR AT THAT TIME. OVER 9 YEARS, SHE EXPERIENCED CRAMPS, ACNE, HEAVY PROLONGED PERIODS FOR AS LONG AS FOUR MONTHS ONGOING, WEIGHT GAIN AND RASHES. IN 2014 SYMPTOMS GOT WORSE; SHE STARTED HAVING HIGH ANXIETY AND PANIC ATTACKS ALONG WITH PROLONGED PERIODS. SHE WENT TO A NEW PHYSICIAN SINCE THE ONE THAT INSERTED IT WAS NO LONGER AROUND AND HE SENT HER FOR A PELVIC ULTRASOUND, WHICH FOUND THAT THE RIGHT COIL MIGRATED INTO HER UTERUS AND WAS CAUSING ALL HER ISSUES. IN 2014 ESSURE COILS AS WELL AS TUBES, CERVIX AND UTERUS HAD TO BE REMOVED. SHE STATED SHE SUFFERED ENOUGH AND ESSURE HAD CAUSED NOT ONLY PHYSICAL TRAUMA BUT MENTAL AS WELL. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE

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REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A PELVIC ULTRASOUND SHOWED RIGHT COIL MIGRATED INTO HER UTERUS. HER UTERUS, FALLOPIAN TUBES AND CERVIX ALONG WITH ESSURE COILS WERE REMOVED. THE REPORTED EVENT, INTERPRETED AS PARTIAL DEVICE EXPULSION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALTHOUGH, IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF THE EVENT IS UNKNOWN, GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 23-MAR-2015: THE CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED ON (B)(6) 2003 AND IT WERE REMOVED ON (B)(6) 2014. AN INJURY WAS MENTIONED AS SERIOUSNESS CRITERIA AND REQUIRED INTERVENTION AS EVENT OUTCOME BUT THEY WERE N

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00086	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/30/2007
Explant Date (E7): 7/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. CONSUMER REPORTED THAT SINCE SHE HAD ESSURE PROCEDURE DONE SHE HAS HAD MAJOR PROBLEMS WITH HEADACHES, NAUSEA, ABNORMAL PERIODS, BLOOD CLOTS AND ABDOMINAL PAIN. IN 2014 (7 YEARS AFTER THE DEVICE WAS PLACED) AFTER YEARS OF SUFFERING, HER DOCTOR FOUND THE ONE OF THE ESSURE COILS CAME OUT OF HER FALLOPIAN TUBE AND WAS IN HER UTERUS AND THIS REQUIRED SURGERY. DURING SURGERY HER DOCTOR FOUND THAT PART OF THE COIL WAS STILL IN THE FALLOPIAN TUBE, THEREFORE SHE HAD TO CUT THE COIL AND LEAVE PART OF IT THERE, OTHERWISE RISK PERFORATING HER UTERUS. SINCE THEN SHE HAS HAD CONTINUED HEALTH PROBLEMS. HER DOCTOR HAD TO DO A HYSTEROSALPINGOGRAM TO ENSURE HER TUBES WERE ACTUALLY CLOSED. DURING THIS TEST, THEY WERE UNABLE TO LOCATE REMAINING PART OF COIL, AGAIN NOT IN THE FALLOPIAN TUBE WERE THEY CLAIM THEY WERE SUPPOSED TO STAY BUT HER DOCTOR BELIEVED IT MIGHT BE EMBEDDED IN HER UTERINE LINING SOMEWHERE. RECENTLY, CONSUMER UNDERWENT AN ABLATION TO TRY AND BELIEVE SOME OF HER SYMPTOMS BUT IF THIS DID NOT WORK HER ONLY OPTION WOULD BE A HYSTERECTOMY. CONSUMER ASSOCIATED ALL OF THESE EVENTS TO ESSURE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE DEVICE BREAKAGE AND THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO

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LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND HANDLING ERROR. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER DOCTOR FOUND THE ONE OF THE ESSURE COILS CAME OUT OF HER FALLOPIAN TUBE AND WAS IN HER UTERUS (CONSIDERED AS DEVICE EXPULSION) AND THIS REQUIRED SURGERY. DURING SURGERY, HER DOCTOR FOUND THAT PART OF THE COIL WAS STILL IN THE FALLOPIAN TUBE (INTERPRETED AS DEVICE BREAKAGE), THEREFORE SHE HAD TO CUT THE COIL AND LEAVE PART OF IT THERE (DEVICE MISUSE). A HYSTEROSALPINGOGRAM WAS PERFORMED AND IT WAS UNABLE TO LOCATE REMAINING PART OF COIL AND HER DOCTOR BELIEVED IT MIGHT BE EMBEDDED IN HER UTERINE LINING SOMEWHERE (INTERPRETED AS DEVICE EMBEDDED). THE EVENTS DEVICE EXPULSION AND DEVICE EMBEDDED WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS CASE, THE EVENT DEVICE EXPULSION WAS SEEN BY THE DOCTOR 7 YEARS AFTER ESSURE INSERTION, HOWEVER THE EXACT DATE AND THE MECHANISM OF EXPULSION ARE NOT KNOWN. CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGERY WAS REQUIRED. ADDITIONALLY, OTHER NON-SERIOUS EVENTS WERE ADDED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 14-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CON

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00087	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039102) IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (ESS205) INSERTED IN 2006. SHE STATED HER PERIODS BEGAN CRAMPING FOLLOWING MONTH (HAD NEVER CRAMPED BEFORE) EACH MONTH BECAME WORSE AND WORSE PAIN RESULTING IN TIME OFF WORK; BLOOD SUGAR DROPS; BEGAN 2011. INSULIN RESISTANCE AND PANCREAS OVER PRODUCTION OF INSULIN CAUSED MULTIPLE ER (EMERGENCY ROOM) TRIPS FOR SUGAR FLUCTUATIONS AND IBS (IRRITABLE BOWEL SYNDROME) MANY DAYS OF WORK MISSED. METFORMIN AND VICTOZA WERE PRESCRIBED. VITAMIN D LEVEL DANGEROUSLY LOW - LEVEL AT 9; SHE WAS PRESCRIBED VIT D AT 50K UNITS WEEKLY. DEPRESSION AND ANXIETY DIAGNOSED; PRESCRIBED CELEXA AND BUSPIRONE. IN 2013 DEVELOPED EOSOPHILIC ESOPHAGITIS REQUIRING ENDOSCOPY IN 2013; RESULTANT ALLERGY TESTS REVEALED ADULT ONSET ALLERGIES TO MILK PROTEIN; APPLE AND MUSHROOM. IN 2013, CRAMPING PELVIC PAIN NO LONGER LIMITED TO MENSTRUATION; PAIN CONTINUED WITHOUT STOPPING AND INCREASED IN LEVEL OVER THE NEXT 8 MONTHS; PERIODS BEGAN INCREASING IN LENGTH, FLOW AND FREQUENCY. HYDROTHERMAL ABLATION PERFORMED IN 2014 FOR DYSMENORRHEA AND PAIN; UNSUCCESSFUL - PAIN AND BLEEDING CONTINUED TO INCREASE. TAH (TOTAL ABDOMINAL HYSTERECTOMY) WAS SCHEDULED TO REMOVE UTERUS, TUBES AND OVARIES IN 2014. FOLLOW-UP RECEIVED ON 01-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO

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PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER PERIODS BEGAN CRAMPING. LATER, SHE DEVELOPED CRAMPING PELVIC PAIN NO LONGER LIMITED TO MENSTRUATION AND HER PERIODS BEGAN INCREASING IN LENGTH, FLOW AND FREQUENCY. SHE WAS SUBMITTED TO AN ENDOMETRIAL ABLATION. THE REPORTED EVENTS WERE CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN AND ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, SINCE THE REPORTED EVENTS STARTED AFTER ESSURE INSERTION AND AN ALTERNATIVE EXPLANATION WAS NOT PROVIDED, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED AND DUE TO THE REQUIRED INTERVENTION (ENDOMETRIAL ABLATION) THIS CASE WAS REGARDED AS INCIDENT. IN ADDITION NON-SERIOUS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW UP 03-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEM

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00088	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2010
Explant Date (E7): 4/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE STATED HER STORY STARTED IN 2010, AFTER HER THIRD CHILD WAS BORN. SHE DECIDED TO GET AN ESSURE PLACEMENT FOR BIRTH CONTROL. HER BODY IMMEDIATELY REJECTED IT. SHE NEVER HAD WOMEN ISSUES LIKE THIS UNTIL THE ESSURE PLACEMENT. BEFORE PREGNANCY AND PLACEMENT OF COILS, SHE WAS A HEALTHY WOMAN RUNNING 2 MILES A DAY. ABOUT 3 WEEKS AFTER PLACEMENT, SHE WENT TO THE EMERGENCY ROOM WITH MASSIVE CRAMPING AND WAS DIAGNOSED WITH A PID (PELVIC INFLAMMATORY DISEASE) INFECTION FROM THE IMPLANTATION OF THE COILS. SHE HAS NOT BEEN OUT OF PAIN SINCE; ESPECIALLY THE LEFT SIDE PAIN. SHE STARTED EXPERIENCING THE FOLLOWING: PERIODS EVERY TWO WEEKS OF SKIPPED PERIODS, EXCESSIVE PAIN IN THE LEFT SIDE (LIKE A KNIFE STICKING INTO YOU), CRAMPS SO BAD SHE COULD NOT STAND UP, EXCESSIVE MENSTRUAL BLEEDING, CLOTS OR TISSUE IN MENSTRUAL BLEEDING, FAINTING, BLACK OUT SPELLS, FATIGUE, INCREASED MIGRAINES, BLURRY VISION, FLOATERS, WEIGHT GAIN, CONSTIPATION, BLOATING, DIARRHEA, NAUSEA, DIZZY SPELLS, FOGGY BRAIN, BACK PAIN, INCREASED UTI (URINARY TRACT INFECTION) AND RANDOM RASHES/HIVES. SHE HAD THE COILS REMOVED AND TUBES REMOVED IN 2013 AND DISCOVERED IN 2014, THEY BROKE APART AND METAL WAS LEFT IN HER UTERUS. SHE STATED MAY NEED A HYSTERECTOMY NOW. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. NO DEVICE BREAKAGE COULD BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR

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INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. IN THIS PARTICULAR CASE A BREAKAGE WAS REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE REMOVAL. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PID (PELVIC INFLAMMATORY DISEASE) INFECTION. AFTER ESSURE REMOVAL, IT WAS DISCOVERED THAT ESSURE BROKE APART AND METAL WAS LEFT IN HER UTERUS (INTERPRETED AS DEVICE BREAKAGE). PID (PELVIC INFLAMMATORY DISEASE) INFECTION IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BROKE APART AND METAL WAS LEFT IN HER UTERUS IS NON-SERIOUS AND LISTED. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS CASE, CONSUMER WAS DIAGNOSED WITH PID ABOUT 3 WEEKS AFTER ESSURE INSERTION. THEREFORE, GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. WITH REGARDS TO THE DEVICE BREAKAGE, SINCE IT OCCURRED DURING ESSURE REMOVAL, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE COILS AND TUBES WERE REMOVED. ADDITIONALLY, OTHER SERIOUS EVENT BLACK OUT SPELLS (UNRELATED TO ESSURE) WAS ADDED AND SEVERAL NON-SERIOUS EVENTS WERE ADDED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 02-APR-2015: ESSURE WAS INSERTED ON (B)(6) 2010 AND IT WAS REMOVED ON (B)(6) 2013. FOLLOW UP INFORMATION ON 26-MAY-2015 FROM CONSUMER: CONSUMER'S DEMOGRAPHIC INFORMATION WAS PROVIDED, SHE WAS A (B)(6) OBESE FEMALE. HER ME

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00089	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5039533) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER EXPERIENCED HEAVY PAINFUL PERIODS, SEVERE WEIGHT GAIN, SEVERE CRAMPS AND SHE WAS ALWAYS SICK. SHE HAD AN UTERINE ABLATION DONE A YEAR LATER IN 2012. SHE HAD TO HAVE A HYSTERECTOMY DONE TO REMOVE THE COILS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-FEB-2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY

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CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY PAINFUL PERIODS. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALSO, DURING ESSURE THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE, SCARCE INFORMATION WAS PROVIDED. THE TIME INTERVAL BETWEEN ESSURE INSERTION AND THE EVENT WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL (HYSTERECTOMY). A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00090	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039174) IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012 BECAUSE IT WAS IMPERATIVE FOR HEALTH REASONS THAT SHE NOT BECOME PREGNANT AGAIN. SHE STATED THAT SHE CONTINUED BLEEDING AFTER THE PROCEDURE FOR 3 WEEKS. UPON ULTRASOUND INVESTIGATION IT WAS DETERMINED THAT BOTH ESSURE COILS HAD MIGRATED; ONE IMPLANTED INTO HER UTERUS AND ANOTHER HAD BROKEN THROUGH HER FALLOPIAN TUBE. IT WAS REQUIRED TO UNDERGO ANESTHESIA AND SURGERY TO HAVE THEM REMOVED. AT THAT TIME; HER GYNECOLOGIST SAID HE HAD NEVER HEARD OF ANOTHER CASE WHERE THIS HAPPENED AND EVEN CONSULTED WITH THE LOCAL ESSURE REPRESENTATIVES; WHO HAD NEVER HEARD OF IT EITHER. BECAUSE HE ASSURED HER THIS WAS AN ABNORMALITY AND THAT THERE WERE NO SIDE EFFECTS; SHE HAD THE PROCEDURE DONE AGAIN. THE COILS STAYED THIS TIME; HOWEVER; WITHIN A MONTH SHE BEGAN HAVING THE WORSE PAIN EVER IN HER LOWER BACK AND ABDOMEN; EXCRUCIATING HEADACHES; WANTING TO SLEEP ALL THE TIME; HORRIBLE NIGHT SWEATS (SOAKING SHEETS); EXTREME WEIGHT GAIN; HER ONCE-THICK HAIR WAS NOT THIN AND BRITTLE AND SHE WAS HOT ALL THE TIME. SHE STATED THAT AT HER AGE THIS SHOULD NOT BE HAPPENING. IN ADDITION; HER HUSBAND SAID HE NOTICED A CHANGE IN HER MOOD SWINGS AND EMOTIONAL STABILITY AFTER HAVING THE IMPLANTS. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. NO DEVICE BREAKAGE COULD BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM

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AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN ULTRASOUND SCAN SHOWED BOTH COILS HAD MIGRATED, ONE IMPLANTED IN HER UTERUS AND ANOTHER HAD BROKEN THROUGH HER FALLOPIAN TUBE. SHE UNDERWENT A SURGERY WITH DEVICES REMOVAL. THE REPORTED EVENTS, INTERPRETED AS DEVICE EMBEDMENT (PARTIAL UTERINE PERFORATION) INTO UTERUS IN ONE SIDE AND DEVICE BREAKAGE WITH FALLOPIAN TUBE PERFORATION IN THE OTHER SIDE WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; EXCEPT FOR DEVICE BREAKAGE WHICH IS UNLISTED. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE AND MAY HAPPEN WITH ESSURE THERAPY, MOST OFTEN DURING INSERTION. ALSO, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED EVENTS IS UNKNOWN, CONSIDERING THE ABOVE MENTION INFORMATION AND THE EVENTS'S CHARACTERISTICS, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00091	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# (B)(4)) IN UNITED STATES ON 15-JAN-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT SHE BECAME PREGNANT 2 AND A HALF YEARS AFTER GETTING THE ESSURE IN 2009. SHE GAVE BIRTH AT 7 MONTHS AND THE PREGNANCY WAS HORRIBLE. SHE HAD PRE-ECLAMPSIA, HIGH BLOOD PRESSURE, KIDNEY INFECTIONS, SPOTTING AND CONSTANT PELVIC PAIN. PRIOR TO GETTING THE ESSURE, HER PERIODS WERE VERY LIGHT SPOTTING FOR ROUGHLY 3 DAYS AND NOW IT IS HEAVY FOR 7-8 DAYS. CONSUMER WAS STILL HAVING CONSTANT PELVIC PAIN, PAINFUL SEX, HEADACHES, CONSTANT CRAMPING, HIGH BLOOD PRESSURE, MOOD SWINGS, LOW/NO SEX DRIVE, SKIN RASHES, AND A SLEW OF OTHER ISSUES. CONSUMER STATED THAT THIS WAS BY FAR THE WORSE THING SHE COULD HAVE EVER DONE. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT

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CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT 2.5 YEARS AFTER ESSURE (FALLOPIAN TUBE INSERTS) INSERTION. DURING PREGNANCY SHE HAD PRE-ECLAMPSIA, SPOTTING (HEMORRHAGE DURING PREGNANCY) AND KIDNEY INFECTIONS. SHE GAVE BIRTH AT 7 MONTHS (PREMATURE DELIVERY) AND EXPERIENCED OTHER NON-SERIOUS EVENTS. THE PREGNANCY WAS CONSIDERED NON-SERIOUS AND OTHER EVENTS ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, PREGNANCY IS LISTED, WHILE THE REMAINING EVENTS ARE UNLISTED. UNINTENDED PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE, AS WITH ANY CONTRACEPTIVE. IF INSERTS ARE CORRECTLY PLACED, TUBAL OCCLUSION SHOULD OCCUR AFTER 3 MONTHS. IN THIS CASE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND THE LACK OF INFORMATION REGARDING THE INSERTS LOCALIZATION AND TUBAL OCCLUSION, THE PREGNANCY WAS CONSIDERED RELATED TO ESSURE (DEVICE INEFFECTIVE). GIVEN THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS NOT EXPECTED THAT THE INSERTS COULD HAVE A CONTRIBUTORY ROLE IN THE ONSET OF PRE-ECLAMPSIA AND KIDNEY INFECTIONS. THEREFORE, THOSE EVENTS WERE CONSIDERED UNRELATED TO ESSURE. ON THE OTHER HAND, SINCE THERE IS A PART OF ESSURE THAT LIES IN THE UTERUS, A MECHANICAL INTERFERENCE IN THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THEREFORE, THE EVENTS OF PREMATURE DELIVERY AND HEMORRHAGE IN PREGNANCY ARE CONSIDERED RELATED TO ESSURE DESPITE THE EXISTENCE OF PRE-ECLAMPSIA AND KIDNEY INFECTIONS, WHICH ALTERNATIVE EXPLANATIONS. THE CASE WAS REGARDED AS INCIDENT DUE TO PREMATURE DELIVERY. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00092	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/25/2006
Explant Date (E7): 11/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE, VIA REGULATORY AUTHORITY (CASE# MW5039265) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO HERSELF, WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. CONSUMER REPORTED THAT SHE HAD NO PROBLEMS, HOWEVER ABOUT 6 YEARS AFTER PLACEMENT SHE STARTED HAVING HEALTH ISSUES STARTING WITH VERTIGO, SHE WENT TO THE DOCTORS AND WAS TOLD IT HAD TO DO WITH SINUS ISSUES. LATER, SHE STARTED GETTING ITCHING AND SWELLING AND RASHES ON DIFFERENT PARTS OF HER BODY, SHE STATED THAT THE SCARIEST WAS HER THROAT. SHE HAD THESE SYMPTOMS A NUMBER OF TIMES, ALONG WITH HAVING ALLERGIES TO FOOD THAT USED TO BE ABLE TO EAT TO NUMBNESS IN HER HANDS THAT WOULD COME AND GO FOR SHORT PERIODS OF TIME BEFORE SHE COULD DO ANYTHING TO. HER CROWNS IN MOUTH JUST FALLING OUT; HER HAIR THINNING OUT/ FALLING OUT; WEIGHT GAIN. SHE TOOK SO MANY STEROIDS THAT SHE ENDED UP HAVING ACUTE PANCREATITIS AND HEADACHES. THESE WERE JUST SOME OF THE ISSUES. SHE HAVE BEEN TO SO MANY DOCTORS AND THEY TELL HER DIFFERENT DIAGNOSES; BUT SHE WAS STILL HAVING THE ISSUES UNTIL ONE DAY HER HAND WAS SO SWELLED THAT SHE THOUGHT THAT IT WOULD POP AND SHE JUST PRAYED FOR THIS TO JUST GO AWAY. THEN FOR NO REASON ESSURE POPPED IN HER HEAD. SHE REPORTED THAT SINCE SHE HAD THEY REMOVED ALONG WITH HER FALLOPIAN TUBES THE SWELLING OF HER HANDS HAS GONE DOWN; AND SHE WAS JUST WAITING TO SEE HOW OTHER ISSUES THAT HAVE AFFECTED HER BODY GO AWAY. SHE HAS PICTURES; HOSPITAL BILLS IF NEEDED; BUT SHE STATED THAT THE MEDICAL DEVICES REALLY NEED TO BE TAKEN OFF THE MARKET. SHE ALSO STATED THAT HER LIFE FOR THE LAST TWO YEARS HAS BEEN COMPLETELY AWFUL AND NOT KNOWING THE ROOT OF THE ISSUE WOULD DRIVE HER CRAZY. CORRECTION 02-FEB-2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT

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"CROWNS IN MY MOUTH JUST FALLING OUT" WAS RECODED TO MEDDRA LLT "DEVICE DISLOCATION". PTC INVESTIGATION RESULT RECEIVED ON 02-FEB-2015. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RASHES ON DIFFERENT PARTS OF BODY AND DEVELOPED ACUTE PANCREATITIS. SHE WAS SUBMITTED TO A SALPINGECTOMY WITH REMOVAL OF ESSURE DEVICES. ADDITIONALLY, SHE REPORTED CROWNS IN HER MOUTH JUST FALLING OUT. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. RASH IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE REMAINING EVENTS ARE UNLISTED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED, CONSUMER STATED SHE HAD FOOD ALLERGIES WHICH COULD ALSO LED TO RASHES; HOWEVER GIVEN THE POSITIVE TEMPORAL RELATIONSHIP CAUSALITY BETWEEN THE REPORTED RASHES AND ESSURE CANNOT BE EXCLUDED. REGARDING ACUTE PANCREATITIS, CONSIDERING ITS POSSIBLE ETIOLOGIES (GALLSTONES, ALCOHOL ABUSE, HYPERTRIGLYCERIDEMIA, HYPERKALEMIA AND DRUGS) AND GIVEN ESSURE LOCAL ACTION AT FALLOPIAN TUBES, CAUSALITY WITH THE INSERT IS CONSIDERED VERY UNLIKELY, THIS SAME ASSESSMENT IS GIVEN TO THE EVENT CROWNS IN HER MOUTH JUST FALLING OUT. DUE TO THE REPORTED INTERVENTION THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 28-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00093	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# MW5039511) IN UNITED STATES ON 15-JAN-2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE EXPERIENCED HOT FLASHES, UNPLANNED PREGNANCY, EXTREMELY PAINFUL SEX, INCREASED VAGINAL DISCHARGE, HIGH BLOOD PRESSURE, KIDNEY INFECTIONS AND PRETERM DELIVERY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-FEB-2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY

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CONFIRMED, SPONTANEOUS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, BECAME PREGNANT AND HAD A PRETERM DELIVERY. ADDITIONALLY, SHE REPORTED KIDNEY INFECTIONS. PREGNANCY WAS CONSIDERED NON-SERIOUS AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE REMAINING EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS PARTICULAR CASE, ALTHOUGH LIMITED INFORMATION WAS PROVIDED AN ESSURE'S CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING PREMATURE DELIVERY, MOST OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES. ALTHOUGH, IN THIS CASE, NO INFORMATION WAS PROVIDED ABOUT THE REASON FOR PREMATURE DELIVERY, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THIS EVENT WAS THUS, CONSIDERED AS RELATED TO THE SUSPECT INSERT. THE REPORTED KIDNEY INFECTIONS WERE CONSIDERED AS UNRELATED TO ESSURE DUE TO ITS LOCAL ACTION AT FALLOPIAN TUBES. THIS CASE WAS REGARDED AS INCIDENT DUE TO SERIOUS INJURY (PRETERM DELIVERY). A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00094	BAYER HEALTHCARE LLC	2/12/2015	2/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A36514

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (LOT NUMBER PROVIDED AS A36514). CONSUMER REPORTED THAT AFTER HAVING THIS DEVICE FOR 2 YEARS, THE COILS MIGRATED TO HER UTERUS AND SHE END UP HAVING A HYSTERECTOMY. THE COILS WERE IMPLANTED IMPROPERLY AT ON 2 TRAILING COILS IN ONE AND JUST TIP ON LEFT SIDE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-FEB-2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE ADVERSE EVENT CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR ADVERSE EVENT CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT

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CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER HAVING ESSURE FOR 2 YEARS, THE COILS MIGRATED TO HER UTERUS. THIS EVENT, INTERPRETED AS DEVICE MIGRATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, IT WAS REPORTED THAT THE COILS WERE IMPLANTED IMPROPERLY AT ON 2 TRAILING COILS IN ONE AND JUST TIP ON LEFT SIDE (DEVICE PLACEMENT AT INCORRECT LOCATION) WHICH COULD EXPLAIN THE OCCURRENCE OF DEVICE MIGRATION. HOWEVER, GIVEN THE NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A HYSTERECTOMY WAS REQUIRED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00079	BAYER HEALTHCARE LLC	2/12/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM SALES REPRESENTATIVE ON BEHALF OF HEALTH CARE PROFESSIONAL IN UNITED STATES ON 14-JAN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT HCP (HEALTH CARE PROFESSIONAL) WAS IN ESSURE PROCEDURE, TRYING TO REMOVE THE ESSURE COIL BECAUSE IT WAS EMBEDDED IN THE UTERINE CAVITY; THERE WERE COUPLE OF SMALL FRAGMENTS LEFT IN THE UTERINE CAVITY. THE HCP WANTED TO KNOW IF THE PATIENT CAN DO AN ENDOMETRIAL ABLATION. (B)(4). . FINAL ASSESSMENT: THIS IS A CONFIRMED DEVICE BREAKAGE CASE AS THE PHYSICIAN WAS TRYING TO REMOVE THE ESSURE COILS AND THE BREAKAGE OF THE COILS TOOK PLACE DURING THE DEVICE REMOVAL. SOME FRAGMENTS WERE LEFT BEHIND IN THE PATIENT'S UTERINE CAVITY. THE DEVICE WAS NOT AVAILABLE FOR RETURN. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND HANDLING ERROR. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED

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STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE HCP (HEALTH CARE PROFESSIONAL) WAS TRYING TO REMOVE THE ESSURE COIL BECAUSE IT WAS EMBEDDED IN THE UTERINE CAVITY (INTERPRETED AS EMBEDDED DEVICE). THERE WERE COUPLE OF SMALL FRAGMENTS LEFT IN THE UTERINE CAVITY (INTERPRETED AS DEVICE BREAKAGE). THE EVENT EMBEDDED DEVICE IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE DEVICE BREAKAGE IS NON-SERIOUS AND ALSO LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. ALSO, DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, IT WAS NOT CLEAR WHETHER DEVICE BREAKAGE OCCURRED DURING ESSURE PLACEMENT PROCEDURE OR REMOVAL. THE EXACT DATE AND THE MECHANISM OF EMBEDMENT ARE NOT KNOWN. NEVERTHELESS, A CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND HANDLING ERROR. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00095	BAYER HEALTHCARE LLC	2/12/2015	2/13/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5039502) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT IN OR AROUND 2014 HEAVY VAGINAL BLEEDING BEGAN THAT WOULD NOT STOP. SHE WENT TO MEDICAL DOCTOR WHO RAN SEVERAL TESTS AND STARTED HORMONE THERAPY TO TRY AND STOP THE BLEEDING. SHE WENT BACK FOR FOLLOW UP OF FAILED HORMONE THERAPY AND TOTAL HYSTERECTOMY WAS SCHEDULED FOR AND PERFORMED IN 2014. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-FEB-2015. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY VAGINAL BLEEDING. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE, SCARCE INFORMATION WAS PROVIDED. HOWEVER, CONSIDERING THE AVAILABLE INFORMATION AND NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED INTERVENTION (HYSTERECTOMY). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00096	BAYER HEALTHCARE LLC	2/12/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/14/2010
Explant Date (E7): 10/2/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE WAS HAVING CHRONIC PAIN, FATIGUE, WEIGHT GAIN AND RESPIRATORY ISSUES. AFTER 4 YEARS OF SUFFERING UNEXPLAINED PAIN, SHE HAD TO REMOVE HER FALLOPIAN TUBES TO REMOVE THE IMPLANTS. ESSURE INSERTION AND REMOVAL DATES WERE UNREADABLE. FOLLOW-UP RECEIVED ON 02-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THE PRESENT CASE, SCARCE INFORMATION WAS PROVIDED. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE CHRONIC PAIN CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED: FATIGUE, WEIGHT GAIN AND RESPIRATORY ISSUES. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION TO REMOVE HER FALLOPIAN TUBES AND IMPLANTS. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 18-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00097	BAYER HEALTHCARE LLC	2/12/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(4) 2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED SHE HAD ESSURE PLACED OVER FOUR AND A HALF YEARS AGO. SHE HAD DONE THE X-RAY TO ASSURE THE TUBES WERE OCCLUDED AT 3 MONTHS POST PROCEDURE AND ALSO HAD AN ULTRASOUND 2 YEARS AGO SHOWING THE ESSURE COILS WERE IN PLACE. THEN, 6 MONTHS AGO, SHE BEGAN CRAMPING AND BLEEDING PRETTY BAD. IN ADDITION CONSUMER REPORTED THAT, 6 WEEKS AGO, EVERY TIME SHE HAD SEXUAL INTERCOURSE SHE WOULD BLEED HEAVY (BRIGHT RED BLEEDING). AN ULTRASOUND WAS PERFORMED AND FOUND HER LEFT ESSURE EXPELLED INTO HER UTERINE CAVITY. THE ESSURE HAD TO BE REMOVED IN THE OFFICE UNDER SEDATION. FOLLOW-UP RECEIVED ON (B)(4) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE

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REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 4.5 YEARS LATER AN ULTRASOUND SHOWED LEFT ESSURE COIL EXPELLED INTO UTERINE CAVITY, THIS IMPLANT WAS REMOVED UNDER SEDATION. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) AND CAN RESULT ON PAIN AND BLEEDING. CONSIDERING THE ABOVE MENTION INFORMATION CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, DUE TO THE REQUIRED MEDICAL INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00098	BAYER HEALTHCARE LLC	2/12/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# MW5039341) IN UNITED STATES ON (B)(6) 2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT ESSURE IS THE DEVIL AND STATES THAT IT HAS RUINED HER LIFE. SHE HAS HAD TO HAVE SURGERY TO CORRECT THE ISSUES THAT CAME ALONG WITH ESSURE. CONSUMER INFORMED THAT SHE WAS NORMAL BEFORE THIS. SHE HAS WEIGHT GAIN, BLOATING, ALMOST CONSTANT PAIN IN HER LOWER STOMACH AND PELVIC AREA AND STATES THAT SHE BLED LIKE A SCOLDED DOG CONSTANTLY. FOLLOW UP 02-FEB-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN

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SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALMOST CONSTANT PAIN IN HER LOWER STOMACH AND PELVIC AREA AND BLED LIKE A SCOLDED DOG CONSTANTLY (INTERPRETED AS GENITAL BLEEDING). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. ALSO, ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE TIME FROM ESSURE INSERTION TO THE ONSET OF THE EVENTS IS UNKNOWN. SHE STATED THAT SHE HAS HAD TO HAVE SURGERY TO CORRECT THE ISSUES THAT CAME ALONG WITH ESSURE. CONSIDERING THIS INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 07-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00077	BAYER HEALTHCARE LLC	2/12/2015	2/20/2015

Event Information:

Event Date (B3): 1/14/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51341

Single Use: Y
Implant Date (E6): 1/14/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 14-JAN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO GET ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C51341. IT WAS REPORTED THAT BY RELEASING THE ESSURE, THE PROTECTION SLEEVE BROKE AND REMAINED IN THE FALLOPIAN TUBE. EVENT WAS OBSERVED IN THE OPERATING ROOM. CONSEQUENCES OF THE EVENT WERE REPORTED AS REMOVAL OF THE SLEEVE WITH BLEEDING OF THE FALLOPIAN TUBE AND POST-OPERATORY SURVEILLANCE. BILATERAL PLACEMENT WAS NOT PERFORMED; THE PROCEDURE WAS STOPPED. THE DEVICE WAS NOT KEPT. NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. FOLLOW-UP RECEIVED ON 02-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE. (B)(4). FINAL ASSESSMENT: LOT NUMBER: C51341; EXPIRATION DATE: 31-MAY-2017; PRODUCTION DATE: 02-MAY-2014. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO

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BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE (BREAKAGE). THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. ONE FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, BUT THIS CASE DOES NOT REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO GET ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT BY RELEASING THE ESSURE, THE PROTECTION SLEEVE BROKE AND REMAINED IN THE FALLOPIAN TUBE. CONSEQUENCES OF THE EVENT WERE REPORTED AS REMOVAL OF THE SLEEVE WITH BLEEDING OF THE FALLOPIAN TUBE (INTERPRETED AS PROCEDURAL BLEEDING). THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND WAS REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. THE EVENT PROCEDURAL BLEEDING IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALSO, GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT/REMOVAL PROCEDURE. IN THIS CASE, THESE EVENTS OCCURRED DURING ESSURE INSERTION. BILATERAL PLACEMENT WAS NOT PERFORMED AND THE PROCEDURE WAS STOPPED (DEVICE INSERTION FAILED). THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 12-FEB-2015: THE PATIENT'S MEDICAL HISTORY INCLUDED 3 CHILDREN, 2 NORMAL PREGNANCIES, QUICK DELIVERIES, VENOUS INSUFFICIENCY, APPENDECTOMY AND CURETTAGE. SHE HAD A CONTRA-INDICATION FOR EOSTRO-PROGESTATIVES AND DID NOT TO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00078	BAYER HEALTHCARE LLC	2/12/2015	2/20/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) -2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE IN 2014 FOR CONTRACEPTION. IT WAS REPORTED THAT IN (B)(6)-2014, ONE WEEK BEFORE ESSURE CONFIRMATION TEST, PATIENT HAD CRAMPING AND CLOT AND SAW A PORTION OF THE INSERT. IT WAS EXPELLED IN THE BLEEDING; IT WAS IF ESSURE HAD FRACTURED. ON AN UNSPECIFIED DATE, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND THE REMAINDER OF THE INSERT STAYED IN THE PATIENT. BOTH TUBES WERE OCCLUDED AND INSERTS WERE IN CORRECT POSITION. HCP (HEALTH CARE PROFESSIONAL) RETAINED THE PIECE THAT WAS EXPELLED IN THE BLEEDING. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 23-JAN-2015: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE DEVICE BREAKAGE COULD NOT BE CONFIRMED. THE HSG FILMS ARE WAITING TO BE REVIEWED BY THE PHYSICIAN CONSULTANT FOR FURTHER EVALUATION. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH

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SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CLOT/BLEEDING AND IT WAS IF IT HAD FRACTURED / REMAINDER OF THE INSERT STAYED IN THE PATIENT. EVENT CLOT/BLEEDING, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE EVENT IT WAS IF IT HAD FRACTURED/ REMAINDER OF THE INSERT STAYED IN THE PATIENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED. DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. ALSO, DURING DIFFICULT INSERTIONS/ REMOVALS SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THE BREAKAGE WAS NOT REPORTED. ALONG WITH THE GENITAL BLEEDING THE PATIENT HAD CRAMPING AND PART OF INSERT WAS EXPELLED IN THE BLEEDING (NON SERIOUS EVENTS). A HYSTEROSALPINGOGRAM WAS DONE AND SHOWED THE REMAINDER OF THE INSERT STAYED IN THE PATIENT. THEREFORE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE REPORTED EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE (MALFUNCTION). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW UP INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 18-MAY-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040789	BAYER	2/12/2015	2/23/2015

Event Information:

Event Date (B3): 1/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/16/2011
Explant Date (E7): 1/30/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE DEVICE IN (B)(6) 2011. BEGAN HAVING MULTIPLE SIDE EFFECTS AFTER IMPLANTATION. SEVERE HEADACHES, CHANGES IN MENSTRUAL CYCLE, RAPID WEIGHT GAIN, SHARP PAINS IN FALLOPIAN TUBES, NUMBNESS IN LIMBS, RASHES, AND DIZZINESS. AFTER SEVERAL TRIPS TO THE DR. WITH MULTIPLE TESTS, NO REASONS WERE GIVEN FOR THESE PROBLEMS. DID EXTENSIVE RESEARCH, REALIZED IT WAS THE COILS CAUSING THE PROBLEMS. HAD THEM REMOVED IN (B)(6) 2015. ALL SYMPTOMS HAVE STOPPED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040796	ESSURE	2/12/2015	2/23/2015

Event Information:

Event Date (B3): 1/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED IN (B)(6) 2012 BEGAN HAVING HAIR LOSS, WEIGHT GAIN, UNCONTROLLABLE VAGINAL BLEEDING FOR 6+ MONTHS AND AS IN THAT REQUIRED RX PAIN KILLERS. HEADACHES, MEMORY LOSS, AS WELL AS RASHES. HAD A HYSTERECTOMY TO REMOVE THE DEVICES. AFTER 18 MONTHS OF HELL, ALL SYMPTOMS GONE. I WAS (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040797	BAYER	2/12/2015	2/23/2015

Event Information:

Event Date (B3): 2/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/9/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE (B)(6) 2011 (DATE OF IMPLANT), I HAVE HAD MULTIPLE ADVERSE SIDE EFFECTS AND HEALTH PROBLEMS... INCLUDING HIP PAIN / PROBLEMS, LOWER BACK PAIN (2 BULGING DISCS), MIGRAINES, CRAMPING, SHARP PAINS IN RIGHT LOWER PELVIC AREA, FEEL OF INFLAMMATION, LOSS OF LIBIDO, PAINFUL PERIODS, PAINFUL INTERCOURSE, LONG MENSTRUAL CYCLES, UNABLE TO ORGASM, BREAST PAIN/ TENDERNESS (CYSTS/TUMORS), ABDOMINAL SPASMS, JOINT PAIN, CHRONIC PELVIC PAIN, ALL OVER ACHES AND PAINS, BLOATING, BRAIN FOG, MEMORY LOSS, ANXIETY, PANIC ATTACKS, DEPRESSION, DIMINISHED BRAIN FUNCTION, BRAIN CLOUDINESS, FORGETFULNESS, CONFUSION, SHORT TERM MEMORY LOSS, VITAMIN D DEFICIENCY, FOLIC ACID DEFICIENCY, INSOMNIA, VISION PROBLEMS (BLURRED VISION), DECREASED EYE SIGHT, NIGHT SWEATS, DRY SKIN, BLOOD IN URINE, LEG PAIN, TREMORS/ TWITCHING, DIZZINESS, UNEXPLAINED EASY BRUISING, CYSTS ON OVARIES, MOOD SWINGS, HEART PALPITATIONS, CYST ON RIGHT HIP, HIGHER THAN NORMAL BLOOD PRESSURE, NECK PAIN. I AM NOW IN THE PROCESS OF FINDING A DOCTOR TO REMOVE THE ESSURE IMPLANT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00085	BAYER HEALTHCARE LLC	2/12/2015	3/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5039647) IN UNITED STATES ON (B)(6)-2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT STARTED HAVING ACHY MUSCLES WHICH INCREASED INTO SEVERE LOWER BACK / PELVIC PAIN. SHE HAD X-RAYS DONE AND THEY SHOWED A BROKEN COIL EMBEDDING INTO HER UTERUS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 01-FEB-2015: FINAL ASSESSMENT: THIS WAS REPORTED BY AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. DEVICE BREAKAGE AND THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE

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REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN X-RAY SHOWED A BROKEN ESSURE COIL EMBEDDING INTO HER UTERUS. THE REPORTED DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED NON-SERIOUS, WHILE THE ESSURE EMBEDMENT INTO UTERUS WAS REGARDED AS SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND THE MECHANISM OF THE REPORTED EVENTS ARE NOT KNOWN; GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, DUE TO DEVICE BREAKAGE THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW-UP WILL BE PURSUED SINCE NO CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00099	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): 11/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. REPORTER INFORMED THE DATE (B)(6) 2013 AS EVENT DATE, HOWEVER SHE DID NOT SPECIFY IT. THE ESSURE COILS BENT INTO CONSUMER'S UTERUS AND SHE EXPERIENCED A LOT OF SHARP PAIN, STABBING PAIN. SHE HAD TO HAVE A FULL HYSTERECTOMY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-

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MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED A LOT OF SHARP PAIN, STABBING PAIN AND ESSURE COILS BENT INTO CONSUMER'S UTERUS (INTERPRETED AS DEVICE DISLOCATION). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS CASE, THE TIME FROM ESSURE INSERTION TO THE ONSET OF THE EVENTS IS UNKNOWN. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A FULL HYSTERECTOMY WAS PERFORMED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00100	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20183879 (INVALID)

Single Use: Y
Implant Date (E6): 11/4/2009
Explant Date (E7): 11/3/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5039344) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT SHE HAD PROBLEMS WITH ALLERGIES, ASTHMA, SKIN RASHES, BLISTERS, HEART PALPITATIONS, GASTROINTESTINAL PROBLEMS, MUSCLE AND JOINT PROBLEMS, SEVERAL INFLAMMATION, MIGRAINES (WHICH SHE NEVER SUFFERED BEFORE), SEIZURES, PASSING OUT, AND MANY OTHER PROBLEMS WHICH ALL CIRCLED AROUND PELVIC PAIN. SHE WENT TO THE EMERGENCY ROOM FOUR TIMES AND WAS SENT HOME WITH PAIN PILLS EVERY TIME AND NO ONE COULD FIGURE OUT THE PROBLEM. HER GENERAL PRACTITIONER NEVER FIGURED THE PROBLEM OUT. SHE RETURNED TO HER PHYSICIAN THREE TIMES TO PUSH THE POSSIBILITY OF CANCER. FINALLY; SHE STARTED RESEARCHING AND FOUND THAT SHE HAD AN ALLERGIC REACTION TO NICKEL AND HAD METAL POISONING. SHE WAS NEAR DEATH. FOR WEEKS SHE COULD NOT TAKE CARE OF HER FAMILY AND LOST SEVERAL WEEKS OF WORK DUE TO THE INABILITY TO EVEN STAND OR THINK. SHE COULD NOT EAT AND LOST 20 POUNDS IN LESS THAN TWO WEEKS. SHE DID FURTHER RESEARCH AND FOUND THAT ESSURE WAS THE ROOT CAUSE OF HER PROBLEMS. SHE ENDED WITH A HYSTERECTOMY. FOLLOW-UP RECEIVED ON (B)(6) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS 2015-002836. FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE

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ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE INSERT) IMPLANTED AND HAD PELVIC PAIN, ALLERGIC REACTION TO NICKEL, METAL POISONING, SEIZURES AND SHE PASSED OUT. ALL THESE EVENTS ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. PELVIC PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION WHILE OTHER SERIOUS EVENTS ARE UNLISTED. PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSIDERING THE IMPLIED POSITIVE TEMPORAL RELATIONSHIP, THE PELVIC PAIN WAS CONSIDERED RELATED TO ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. CONSIDERING THAT ESSURE IS A NICKEL-TITANIUM ALLOY, AND AN IMPLIED POSITIVE TEMPORAL RELATIONSHIP, THE ALLERGY IS RELATED TO ESSURE. ALTHOUGH, IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM THIS DEVICE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE A METAL POISONING (UNRELATED). VASOVAGAL SYNCOPE IS COMMONLY TRIGGERED BY PAIN, EMOTIONAL OR ORTHOSTATIC STRESS. CLINICAL PRESENTATION INCLUDES BRIEF LOSS OF CONSCIOUSNESS AND IN THE CASE OF LONG-LASTING CEREBRAL HYPO PERFUSION SEIZURE-LIKE MOVEMENTS ARE OBSERVED IMITATING AN EPILEPTIC SEIZURE. IN THIS CASE, THE CONSUMER REPORTED LOSS OF CONSCIOUSNESS (PASSING OUT) AND SEIZURES THAT OCCURRED DUE TO HER PELVIC PAIN. THESE EVENTS, INTERPRETED AS SYMPTOMS OF VASOVAGAL SYNCOPE, ARE CONSIDERED RELATED AS THEY COULD BE TRIGGERED BY THE PELVIC PAIN RELATED TO ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE IS REGARDED AS INCIDENT DUE TO HYSTERECTOMY. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 16-APR-2015: INFORMATION RECEIVED STATES THAT CONSUMER HAD ESSURE (LOT NUMBER 20183879) INSERTED ON (B)(6) 2009. ALSO ACCORDING TO REPORTER, SHE HAS SUFFERED FROM THE SYMPTOMS FOR THE PAST YEAR (2014) AND, ON (B)(6) 2014, SHE HAD ESS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00101	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED SHE HAD NOTHING BUT PROBLEMS SINCE THE DEVICE WAS INSERTED THAT SHE NEVER HAD PREVIOUSLY. ON AN UNSPECIFIED DATE SHE EXPERIENCED SEVERE MENSTRUAL BLEEDING, CRAMPING, CYSTS, AND ABDOMINAL PAIN. SHE HAD TO HAVE ALL HER FEMALE PARTS REMOVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4)2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON

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THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THE PRESENT CASE, SCARCE INFORMATION WAS PROVIDED. THE CONSUMER REPORTED THAT SINCE THE DEVICE WAS INSERTED SHE HAD PROBLEMS SHE NEVER HAD PREVIOUSLY, INCLUDING THE ABDOMINAL PAIN. THEREFORE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE ABDOMINAL PAIN CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED: SEVERE MENSTRUAL BLEEDING, CRAMPING, AND CYSTS. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION (SHE HAD TO HAVE HER FEMALE PARTS REMOVED). A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

.FOLLOW UP INFORMATION RECEIVED ON 28-APR-2015: ESSURE DEVICE WAS INSERTED 6 YEARS AGO (2009). NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION (GENERAL QUESTIONNAIRE) RECEIVED ON 07-JUL-2015 FROM CONSUMER: THE CONSUMER WAS (B)(6) AT TIME OF THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00102	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (B)(4) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT SHE HAD NONSTOP BLEEDING SINCE IMPLANT OF ESSURE, CONSTANT PAIN, HEADACHES, WEIGHT GAIN, COULDN'T BE INTIMATE WITH HER HUSBAND AS IT HURT TOO BAD, SHE WAS ALWAYS TIRED, CRANKY AND IRRITABLE, HAD RASHES, ALMOST CONSTANTLY JOINT PAIN AND SEVERE ABDOMINAL PAIN ALL OF WHICH WAS GONE NOW WHAT SHE HAD A COMPLETE HYSTERECTOMY. FOLLOW-UP RECEIVED ON 02-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED

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STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT PAIN/SEVERE ABDOMINAL PAIN AND NON STOP BLEEDING SINCE IMPLANT OF ESSURE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND THEY ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALSO, DURING ESSURE THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE, CONSUMER REPORTED SHE HAD NONSTOP BLEEDING SINCE IMPLANT OF ESSURE AND CONSTANT PAIN/SEVERE ABDOMINAL PAIN, AND HER SYMPTOMS WERE GONE AFTER SHE HAD A COMPLETE HYSTERECTOMY. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENTS AND POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION (HYSTERECTOMY). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 21-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00103	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039492) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER WENT IN FOR PLACEMENT CHECK AND BOTH COILS WERE OUT OF PLACE. ONE COIL WAS NOT SEEN ON SCAN. BOTH COILS AND TUBES WERE REMOVED. REPORTER INFORMED THE DATE (B)(4) 2014, HOWEVER DID NOT SPECIFY IT. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON

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THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, WENT IN FOR PLACEMENT CHECK AND BOTH COILS WERE OUT OF PLACE/ ONE COIL WAS NOT SEEN ON SCAN. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, THE EXACT LOCATION OF THE DEVICE WAS NOT REPORTED. HOWEVER, DESPITE THE SCARCE INFORMATION, GIVEN THE NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION (BOTH COILS AND TUBES WERE REMOVED). A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00104	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 FOR STERILIZATION. IN 2011, CONSUMER HAD TO HAVE SURGERY TO REMOVE HER RIGHT ESSURE DEVICE AND FALLOPIAN TUBE. THE DEVICE WAS LODGED IN HER WOMB AND THEREFORE SHE HAD TO HAVE A REPAIR TO HER WOMB. SHE FELT BETTER FOR SOME TIME BUT, SINCE 2011, HER HEALTH HAD PROGRESSIVELY GONE DOWNHILL. CONSUMER REPORTED HEAVY AND PROLONGED PERIODS INCLUDING LARGE CLOTS, SEVERE PAIN IN LOWER STOMACH AND BACK AND WEIGHT GAIN. SHE WAS SUBMITTED TO FURTHER TESTS CARRIED OUT IN HOSPITAL WHICH HAD CONFIRMED HER LEFT DEVICE HAD MOVED TO THE RIGHT SIDE OF HER BODY. SHE IS CURRENTLY AWAITING HER SECOND SURGERY DUE TO ESSURE AND IS IN DAILY PAIN. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS

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REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND APPROXIMATELY TO 2 YEARS LATER WAS SUBMITTED TO A SURGERY TO REMOVE RIGHT ESSURE DEVICE, BECAUSE IT WAS LODGED IN HER WOMB. LATER, SHE WAS SUBMITTED TO FURTHER TESTS, WHICH SHOWED LEFT DEVICE HAD MOVED TO THE RIGHT SIDE OF HER BODY. THE REPORTED EVENTS, REGARDED AS RIGHT DEVICE EMBEDMENT (PARTIAL UTERINE PERFORATION) AND LEFT DEVICE MIGRATION, WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A COMPLETE PERFORATION OCCURS, ESSURE CAN BE FOUND IN THE ABDOMINAL CAVITY AS IT PERFORATES THE WHOLE UTERINE WALL. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED EVENTS IS UNKNOWN; GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE SURGICAL ESSURE REMOVAL WAS REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00105	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STARTED WITH SHARP PAINS IN ABDOMINAL AREA AND WENT TO THE LOCAL ER AND SHE WAS TOLD THAT SHE NEEDED TO HAVE A BOWEL MOVEMENT AND THAT SHOULD MAKE IT BETTER. SO SHE DID TAKE LAXATIVES TO FORCE MORE BOWEL MOVEMENTS BUT THIS DIDN'T HELP WITH THE PAIN AND JUST MADE HER MORE UNCOMFORTABLE HAVING TO USE THE BATHROOM SO MUCH. SO SHE WENT TO SEE HER GYNECOLOGIST AND TOLD HIM ABOUT THE PAIN AND ALSO THAT SHE NOTICED THAT HER STOMACH WAS LOOKING LIKE SHE WAS PREGNANT WHEN SHE WASN'T. HE TOLD HER SHE WAS FAT AND NEEDED TO START DOING SIT-UPS. AN UNSPECIFIED EXAM WAS PERFORMED A WEEK LATER AND CONSUMER WAS TOLD SHE HAD CYSTS ON OVARIES AND ALSO ENDOMETRIOSIS SO A SURGERY WAS PERFORMED FOR THOSE THINGS IN 2013. AFTER THE SURGERY SHE WAS STILL HAVING PAIN AND WAS STILL GAINING WEIGHT FOR UNKNOWN REASON AT THE SAME TIME. SHE WAS TOLD IT WAS STILL THE ENDOMETRIOSIS. CONSUMER ASKED TO HAVE ESSURE REMOVED. SHE FOUND OUT THAT SOMEONE IN HER AREA EXPERIENCED THE SAME ISSUES AND HAD THE COILS REMOVED. CONSUMER WAS SUBMITTED TO A SURGERY REMOVING THE FALLOPIAN TUBES AND COILS WITH THEM IN 2013. SHE WAS STILL PRESENTING SOME PROBLEMS SO SHE FOUND OUT THAT THERE WAS STILL A SMALL PIECE OF ONE OF THE COILS LEFT INSIDE HER UTERUS THAT CAUSED HER PAIN STILL. SHE ALSO EXPERIENCED SIDE EFFECTS THAT STARTED ABOUT A MONTH AFTER INSERTION, INCLUDING: ABDOMINAL PAIN, GAS, BLOATING, WEIGHT GAIN, EXHAUSTION, FURTHER DEPRESSION AND ANXIETY, HIGH BLOOD PRESSURE, FACIAL HAIR GROWTH AND ACNE. ALL OF WHICH HAVE GOTTEN BETTER OR COMPLETELY GONE AWAY SINCE MOST OF THE DEVICE IS OUT OF HER. REPORTER INFORMED THE DATA (B)(6)

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2010 AS EVENT DATE, HOWEVER, SHE DID NOT SPECIFY IT. FOLLOW-UP RECEIVED ON (B)(4) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND DUE TO USABILITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. THE DEVICE "BREAKAGE" OF "SMALL PIECE OF ONE OF THE COILS LEFT INSIDE MY UTERUS" COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE (BREAKAGE) REPORTED IN THE CONTEXT OF A DIFFICULT DEVICE REMOVAL. THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP PAINS IN ABDOMINAL AREA. AFTER REMOVAL OF THE FALLOPIAN TUBES AND COILS, SHE WAS STILL PRESENTING SOME PROBLEMS AND SHE FOUND OUT THAT THERE WAS STILL A SMALL PIECE OF ONE OF THE COILS LEFT INSIDE HER UTERUS (INTERPRETED AS DEVICE BREAKAGE). SHARP PAINS IN ABDOMINAL AREA WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE IS NON-SERIOUS AND LISTED. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALSO, DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE TIME FROM ESSURE INSERTION TO THE ONSET DATE OF SHARP PAINS IN ABDOMINAL AREA IS UNKNOWN. CONSUMER UNDERWENT A SURGICAL REMOVAL OF THE FALLOPIAN TUBES AND COILS. AFTER THAT THE DEVICE BREAKAGE WAS NOTICED. THE DEVICE BREAKAGE IS PROBABLY A COMPLICATION OF DEVICE REMOVAL. BASED ON THE INFORMATION RECEIVED AND CONSIDERING AN IMPLIED TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL REMOVAL. ADDITIONALLY SERIOUS EVENTS (CYSTS ON OVARIES AND ENDOMETRIOSIS, BOTH UNRELATED TO ESSURE) AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00106	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE BEGAN TO HAVE SHARP PAINS IN HER ABDOMINAL AREA AND WENT TO THE LOCAL EMERGENCY ROOM AND THE DOCTORS SAID THAT SHE NEEDED TO HAVE A BOWEL MOVEMENT AND THAT SHOULD MAKE IT BETTER. SO, SHE DID TAKE LAXATIVES TO FORCE MORE BOWEL MOVEMENTS BUT THIS DIDN'T HELP WITH THE PAIN AND JUST MADE HER MORE UNCOMFORTABLE HAVING TO USE THE BATHROOM SO MUCH. SHE WAS THAN TOLD TO GO SEE HER GYNECOLOGIST BECAUSE THE ONLY THING THEY COULD THINK OF WAS SOMETHING FOR HER GYNECOLOGIST TO LOOK INTO. SO SHE WENT TO SEE HIM AND TOLD HIM ABOUT THE PAIN AND ALSO THAT SHE NOTICED THAT HER STOMACH WAS LOOKING LIKE SHE WAS PREGNANT WHEN SHE WASN'T. THE DOCTOR TOLD TO CONSUMER SHE WAS JUST FAT AND NEEDED TO START DOING SIT-UPS. SO, SHE LEFT AND WENT BACK AGAIN A WEEK LATER OR SO AND HE DID ANOTHER EXAM AND SAID THAT SHE HAD CYSTS ON HER OVARIES AND ALSO HAD ENDOMETRIOSIS. SHE HAD SURGERY FOR THOSE THINGS IN 2013. AFTER THE SURGERY SHE WAS STILL HAVING PAIN AND WAS STILL GAINING WEIGHT FOR UNKNOWN REASON AT THE SAME TIME. SHE WENT BACK TO THE DOCTOR AND HE TOLD HER THAT IT WAS STILL THE ENDOMETRIOSIS AND HE WANTED TO PUT HER ON MORE MEDICINE BUT IT WAS GOING TO TRIGGER TO FEEL LIKE SHE WAS GOING THROUGH MENOPAUSE SO SHE NO AND ASKED DOCTOR TO REMOVE THE ESSURE COILS THAT HE INSERTED INTO HER BUT THIS DOCTOR TOLD HER TO GET A SECOND OPINION THAN. CONSUMER WENT TO A SECOND DOCTOR AND FOUND OUT THAT SOMEONE IN HER AREA HAD THE SAME ISSUES AND HAD THE COILS REMOVED BY A DOCTOR CLOSE TO HER HOME SO SHE QUICKLY SWITCHED TO THIS DOCTOR AND HE PERFORMED THE SURGERY

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REMOVING THE FALLOPIAN TUBES AND COILS WITH THEM IN 2013. THIS CASE BELONGS TO SOMEONE WHO HAD THE SAME ISSUES AND HAD THE COILS REMOVED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP PAINS IN ABDOMINAL AREA. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE TIME FROM ESSURE INSERTION TO THE ONSET DATE OF SHARP PAINS IN ABDOMINAL AREA IS UNKNOWN. CONSUMER UNDERWENT A SURGICAL REMOVAL OF THE FALLOPIAN TUBES AND COILS. BASED ON THE INFORMATION RECEIVED AND CONSIDERING AN IMPLIED TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL REMOVAL. ADDITIONALLY SERIOUS EVENTS (CYSTS ON OVARIES AND ENDOMETRIOSIS, SERIOUS SINCE A SURGERY WAS PERFORMED AND BOTH ARE UNRELATED TO ESSURE) AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00107	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A50514

Single Use: Y
Implant Date (E6): 12/17/2012
Explant Date (E7): 11/25/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER REPORTED THAT SHE HAD THE ESSURE PROCEDURE DONE IN 2012 AFTER THE BIRTH OF HER FOURTH CHILD. SHE ONLY HAD ONE TUBE AND ONE OVARY DUE TO AN ECTOPIC IN 2003. THREE MONTHS ESSURE CONFIRMATION TEST SHOWED COMPLETE BLOCKAGE. CONSUMER STATED THAT SHE HAS HAD MULTIPLE COMPLICATIONS SINCE THEN. SHE HAS GONE BACK TO PHYSICIAN AND HE SAID BASICALLY SHE WAS FINE AND IT WAS NOTHING. SHE FELT VERY INSULTED AND STATED THAT SHE KNEW SOMETHING WAS WRONG WITH HER AND NO ONE WOULD LISTEN. SHE HAS SUFFERED FROM 2 MISCARRIAGES, MULTIPLE CYSTS ON OVARY, SEVERE DYSMENORRHEA, ABDOMINAL PAIN, LOW BACK PAIN AND PAINFUL INTERCOURSE. CONSUMER FINALLY WENT TO ANOTHER DOCTOR WHO DID A VAGINAL EXAM AND VAGINAL ULTRASOUND. IT SHOWED LARGE CYST ON RIGHT OVARY AND LARGE AND SWOLLEN OVARY. PHYSICIAN ALSO COULD NOT SEE THE IMPLANT ON THAT DIE BUT DID SEE THE ONE ON LEFT WHERE TUBES WERE SUPPOSED TO BE (CONSUMER HAD LEFT SALPINGO-OOPHORECTOMY IN 2003). IMPLANT WAS NOT SEEN ON RIGHT SIDE. THE DOCTOR WHO PLACED IT SAID "IT WENT SOMEWHERE" WHEN CONSUMER ASKED WHERE HE PUT IT, CONSIDERING SHE HAD NOTHING THERE. CONSUMER WAS TIRED OF REPEATED EMERGENCY ROOM VISITS AND PAIN SHOTS AND, ON UNSPECIFIED DATE IN 2014, SHE HAD TO HAVE A COMPLETE HYSTERECTOMY DUE TO HER SEVERE COMPLICATIONS AND PAIN. WHEN PHYSICIAN REMOVED EVERYTHING HE SAID HER ESSURE IMPLANTS HAVE GONE THROUGH HER TUBES AND PERFORATED HER UTERUS. SHE HAS SUFFERED ALL THIS PAIN AND THAT WAS THE CAUSE. ACCORDING TO REPORTER, FIRST OF ALL, SHE SHOULD HAVE NEVER HAD IT PLACED DUE TO THE FACT THAT SHE ONLY HAVE ONE TUBE AND OVARY; SECOND

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DUE TO THE FACT SHE HAD A PREVIOUS ECTOPIC AND THIRD BECAUSE SHE WANTED A TUBAL AND THE PATIENT IS ALWAYS RIGHT. SHE HAS SUFFERED FOR SO LONG AND NOW HAS A HIP TO HIP INCISION WITH 32 STAPLES ALL BECAUSE THE ESSURE FAILED AND DOCTOR FAILED HER. SECOND MISCARRIAGE WAS REPORTED IN CASE (B)(4). THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT PHYSICIAN COULD NOT SEE THE IMPLANT ON THAT DIE, ESSURE IMPLANTS HAVE GONE THROUGH TUBES AND PERFORATED UTERUS (CONSIDERED AS UTERINE PERFORATION). SHE ALSO HAD A MISCARRIAGE. THE EVENT UTERINE PERFORATION WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE EXACT DATE AND THE MECHANISM OF PERFORATION ARE NOT KNOWN. IT WAS REPORTED THAT THE UTERINE PERFORATION WAS DIAGNOSED AFTER UNDERGOING A COMPLETE HYSTERECTOMY. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING MISCARRIAGE (SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED) (SPONTANEOUS ABORTION), IT IS THE MOST COMMON COMPLICATION OF EARLY HUMAN PREGNANCY, OCCURRING MAINLY DURING THE FIRST TRIMESTER OF PREGNANCY. THIS IS CONSIDERED TO BE DUE TO A HIGH NUMBER OF ABNORMAL EMBRYOS PRESENTING WITH EITHER CHROMOSOMAL AND/OR GROSS MORPHOLOGICAL ABNORMALITIES. IN THIS CASE, GESTATIONAL AGE HAS NOT BEEN PROVIDED. GIVEN THE ABOVE MENTION INFORMATION AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THE REPORTED EVENT WAS CONSIDERED AS UNRELATED TO THE INSERT. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 28-AUG-2015 PTC RESULT RECEIVED WITHOUT ANY CHANGES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00108	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA (B)(4) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. CONSUMER STATED SHE HAD ESSURE INSERTED IN 2013 BECAUSE WHEN HER DAUGHTER WAS BORN IN 2010 SHE LOST A LOT OF BLOOD AND THEY COULD NOT TIE HER TUBES AT THAT TIME. SINCE HER DAUGHTER WAS BORN, SHE WOULD BLEED SO BAD SHE WOULD HEMORRHAGE. SO THE DOCTOR DECIDED TO DO A DILATATION AND CURETTAGE, AND ABLATION. SINCE THAT TIME SHE HAS GAINED OVER 50 LBS, SHE HAS A SEVERE STOMACH PAIN; SHE NOW HAS COMPLEX MIGRAINES, HEART PALPITATIONS, CHEST PAIN, PASSING OUT EPISODES. SHE WAS LOSING HER HAIR IN CLIPS AND NOT TO MENTION THE MOOD SWINGS. HER DOCTOR TOLD HER THERE WAS NO COMPLICATIONS TO THESE SPRINGS. CONSUMER WENT BACK TO HER DOCTOR 3-4 TIMES AND HE TOLD HER SHE WAS RETAINING FLUID UP THERE AND HER HORMONES WERE NOT RIGHT. NOW SHE IS ON A HUNT TO HAVE ESSURE REMOVED AND TRYING TO GET HER BACK TO HER OLD SELF. SHE HAD UNSPECIFIED TESTS PERFORMED AND NOTHING WAS WRONG. FOLLOW UP 02-FEB-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. FINAL RISK CLASSIFICATION: RISK CATEGORY V.

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MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLEED SO BAD SHE WOULD HEMORRHAGE. SHE WAS SUBMITTED TO DILATION AND CURETTAGE AND ABLATION AS TREATMENT. ADDITIONALLY, SHE HAD PASSING OUT EPISODES. THE REPORTED EVENTS, INTERPRETED AS GENITAL BLEEDING AND LOSS OF CONSCIOUSNESS EPISODES, WERE CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT. GENITAL BLEEDING IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE REMAINING EVENT IS UNLISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; IN THIS PARTICULAR CASE DISCREPANT INFORMATION WAS RECEIVED. IT IS UNCLEAR IF THE REPORTED INTERVENTIONS WERE PERFORMED BEFORE OR AFTER ESSURE INSERTION; CONSUMER REPORTED HER BLEEDING STARTED AFTER HER DAUGHTER WAS BORN (BEFORE ESSURE INSERTION) AND LATER STATED SHE WANTED ESSURE REMOVED. ALTHOUGH DISCREPANT INFORMATION WAS RECEIVED; SINCE NO FOLLOW-UP CAN BE PURSUED IN THIS CASE (NO CONTACT INFORMATION AVAILABLE); CONSIDERING THE REPORTED EVENT'S NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE EVENT PASSING OUT EPISODES, GIVEN ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES CAUSALITY IS CONSIDERED VERY UNLIKELY. DUE TO THE REPORTED INTERVENTIONS, THIS CASE WAS CONSIDERED AN INCIDENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW-UP WILL BE PURSUED SINCE NO CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 24-AUG-2015: FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUB

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00109	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO THE CONSUMER HERSELF, OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD ESSURE PLACED FOR THREE YEARS AND HAVE SINCE HAD TO HAVE IT REMOVED. SHE STATED THAT EVEN AFTER HAVING IT REMOVED SHE STILL EXPERIENCED SEVERE HEALTH ISSUES. SHE EXPERIENCED SEVERE MIGRAINES; CHRONIC ABDOMINAL PAIN; BACK PAIN; DISPLACEMENT OF LEFT OVER FEMALE ORGANS AND AT TIMES SHE HAD VERY SEVERE NAUSEA. SHE ALSO REPORTED THAT SHE HAVE LOST HER JOB DUE TO HER MED ISSUES. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY

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DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE ESSURE REMOVED. THIS EVENT, CONSIDERED AS MEDICAL DEVICE REMOVAL, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. SINCE THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED AND NO FOLLOW-UP WILL BE POSSIBLE; COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00110	BAYER HEALTHCARE LLC	2/13/2015	2/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (NUMBER (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAS BEEN IN PAIN BUT NEVER FOUND OUT WHAT WAS GOING ON. SHE WAS ADMITTED WITH CHILLS, FEVER AND EXTREME ABDOMINAL PAIN. SHE WAS HOSPITALIZED FOR 2 WEEKS AND 3 DAYS. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA

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REGULATORY AUTHORITY) REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN AND FEVER. THESE EVENTS ARE SERIOUS DUE TO HOSPITALIZATION. ABDOMINAL PAIN IS LISTED, WHILE FEVER IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE THE PATIENT HAD CHILLS, FEVER AND ABDOMINAL PAIN AND WAS HOSPITALIZED FOR 2 WEEKS AND 3 DAYS. ABDOMINAL PAIN ASSOCIATED WITH FEVER COULD BE A SIGN OF INFECTION OR ACUTE ABDOMEN, WHICH COULD BE AN ALTERNATIVE EXPLANATION; HOWEVER, LIMITED INFORMATION WAS PROVIDED AND THEREFORE CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. CONSIDERING THE CONSUMER WAS HOSPITALIZED THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW UP 07-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA RE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040718	BAYER	2/13/2015	2/13/2015

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (B)(6) 2013 FIRST COIL PLACED. COULDN'T GET THE SECOND ONE IN PLACE AT THAT TIME. (B)(6) 2013 SECOND COIL PLACED. DEBATED ON HAVING THE SECOND ONE PLACED BECAUSE THE FIRST ONE CONSTANTLY HURT. BUT AGAINST MY BETTER JUDGEMENT DID IT ANYWAY. MY STOMACH HAD A RASH ON IT. MY LEFT LEG AND FOOT KEPT GOING NUMB. I FELL SEVERAL TIMES BECAUSE OF MY LEG. I WOULD BLEED 2-3 WEEKS AT A TIME. STOP FOR TWO DAYS START AGAIN. SEX WAS OUT OF THE QUESTION. IT HURT WAY TO BAD. STARTED HAVING VERTIGO. MY LYMPH NODES WERE SORE AND SWOLLEN IN MY LEGS. I FELT TERRIBLE, HEADACHES, FATIGUE. FELT LIKE I HAD MONO. MY IMMUNE SYSTEM TODAY IS STILL A 2.7. WENT TO MY FAMILY DR. BECAUSE MY OB DR SAID THE ESSURE HAD NOTHING TO DO WITH MY PROBLEMS. MY FAMILY DR. TESTED ME FOR LYMPH NODE CANCER. IT CAME BACK NEGATIVE. MY FAMILY DR. SAID HE FELT LIKE MY BODY WAS REJECTING THE COILS. I ASKED IF I COULD GO TO A DIFFERENT OB DR. HE TOLD ME NO ONE WOULD WANT TO BE RESPONSIBLE FOR THE ISSUES I WAS HAVING. I WOULD HAVE TO GO BACK TO MY OB DR. I WANTED MY TUBES TIED. I HAVE EPILEPSY. STARTED HAVING THEM AFTER HAVING MY SECOND BABY. RECENTLY REMARRIED AND WANTED PERMANENT BIRTH CONTROL. MY OB DR SAID THIS WAS THE BETTER OPTION FOR ME. LESS DOWN TIME. HAD A HYSTERECTOMY (B)(6) 2013, 3 MONTHS AFTER FIRST COIL PLACED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040727	BAYER	2/13/2015	2/13/2015

Event Information:

Event Date (B3): 10/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, CRAMPING, EXCESSIVE VAGINAL BLEEDING ALL COMING TOGETHER WHEN ONE DAY A COIL FELL OUT WHEN I WIPED AFTER URINATING. NOW EXPERIENCING CONSTANT PAIN STILL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040736	BAYER	2/13/2015	2/13/2015

Event Information:

Event Date (B3): 10/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON ((B)(6)2010). THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 683283 LEFT, 683283 RIGHT. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2010. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: - PAIN IN MY RIGHT SHOULDER BLADE/UPPER BACK WITH BURNING/TINGLING AND NUMBNESS IN RIGHT HAND - SEVERE VAGINAL BLEEDING CAUSING LOW IRON AND LOW FERRITIN. - NIGHT SWEATS. - SENSITIVITY TO METALS (SKIN RASHES WHEN WEARING JEWELRY). - SLEEP APNEA. - BLOATING/BODY ACHES/FEELING DRAINED. - HEADACHES. - PELVIC PAIN (CRAMPING PERIODICALLY, PAIN WITH INTERCOURSE). - ENDOMETRIOSIS. - ACNE/EXCESSIVE SWEATING. I HAVE BEEN SEEN BY TWELVE OR MORE DOCTORS, SPECIALISTS, AND PHYSICAL THERAPISTS DUE TO SIDE EFFECTS I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS CHRONIC PAIN IN SHOULDER BLADE AND UPPER BACK; EXCESSIVE BLEEDING, AND ACUTE HEADACHE. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE - ESSURE REMOVAL DUE TO BLEEDING AND PAIN (B)(6) 2014. THE DEVICE HAS BEEN REMOVED (B)(6) 2014. THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER. THE DEVICE WAS REQUESTED IN WRITING TO BE ATTAINED AT (B)(6).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00111	BAYER HEALTHCARE LLC	2/13/2015	2/18/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (B)(4) IN UNITED STATES ON 15-JAN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER EXPERIENCED CHRONIC MIGRAINES, CHRONIC FATIGUE, EXTREME MUSCLE WEAKNESS, ALL OVER PAIN ESP (SIC) BACK AND SHOULDERS, ABDOMINAL PAIN, BLOATING AND PERIODS LASTING FOR 21-30 DAYS. SHE BECAME PERMANENTLY DISABLED IN (B)(6) 2013. SHE INFORMED THE DATE (B)(6) 2010 AS EVENT ONSET DATE; HOWEVER, SHE DID NOT SPECIFY WHICH EVENT. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-FEB-2015. (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE AND WERE REPORTED WITH AN OCCURRENCE OVER 4.5 YEARS. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION, NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO

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SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND BECAME PERMANENTLY DISABLED. THIS EVENT IS SERIOUS DUE TO DISABILITY AND UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THIS PARTICULAR CASE HAS LIMITED INFORMATION. THE TIME LAPSE BETWEEN ESSURE PLACEMENT AND ONSET OF THIS EVENT IS NOT KNOWN. ALSO, THE CONDITIONS THAT LED TO THE PERMANENT DISABILITY WERE NOT MENTIONED. CONSIDERING THIS LIMITED INFORMATION AND CONSIDERING THAT FOLLOW UP MAY NOT BE SUCCESSFUL, A CONSERVATIVE APPROACH WAS USED. IT WAS INTERPRETED THAT THIS PERMANENT DISABILITY WAS RELATED TO ESSURE AND THEREFORE THIS CASE WAS REGARDED AS INCIDENT. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00112	BAYER HEALTHCARE LLC	2/13/2015	2/18/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5039475) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN 2009. CONSUMER STATED THAT SHE DID NOT HAVE THE EXPIRATION DATE. CONSUMER REPORTED THAT THE ONSET OF HER COMPLAINT STARTED IN 2013. THIS IS A LIST OF HER SIDE EFFECTS AND SYMPTOMS THAT SHE HAS EXPERIENCED DUE TO ESSURE: WEIGHT GAIN, SEVERE JOINT AND MUSCLE PAIN, CRAMPING IN HER LEFT SIDE RADIATING DOWN HER ENTIRE LEFT LEG, CHANGE IN VOICE (DEEPER), HAIR LOSS. SHE HAS HAD SURGERIES DUE TO ESSURE (UNSPECIFIED). SHE STATED THAT THE ONE DEVICE IS STILL INSIDE OF HER AND ANOTHER ONE WAS NOT RETURNED TO THE MANUFACTURER. IT IS IN HER POSSESSION. FOLLOW-UP INFORMATION RECEIVED ON 10-FEB-2015 - (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. THE STATEMENTS MADE BY THE PATIENT ARE NOT CLEAR IF DEVICE REMOVAL WAS DONE OR NOT AS THE PATIENT STATED "THE DEVICE IS IN MY POSSESSION (IF APPLICABLE)." SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT

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THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING IN HER LEFT SIDE RADIATING DOWN HER ENTIRE LEFT LEG. THIS EVENT, SEEN AS ABDOMINAL PAIN, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, LIMITED INFORMATION REGARDING THE EVENT WAS PROVIDED. HOWEVER, GIVEN ITS NATURE, THE ABDOMINAL PAIN IS ASSESSED AS RELATED TO ESSURE USE. ALTHOUGH THE REMOVAL WAS NOT CONFIRMED, SURGERIES WERE MENTIONED AND IT WAS STATED THAT THE CONSUMER HAD ONE DEVICE IN HER POSSESSION; IT WAS NOT RETURNED TO MANUFACTURER. THE POSSIBILITY OF DEVICE HAD BEEN REMOVED CANNOT BE EXCLUDED, THEREFORE THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE REPORTED. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00113	BAYER HEALTHCARE LLC	2/13/2015	2/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5039373) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. CONSUMER STATED THAT THE RIGHT COIL IMMEDIATELY MIGRATED BEFORE GETTING HOME FROM THE PROCEDURE. SHE HAD CRAMPING AND IT WAS PAINFUL TO LIE ON HER RIGHT SIDE. SHE WENT FOR HSG (HYSTEROSALPINGOGRAM) AFTER THREE MONTH TIME PERIOD TO FIND OUT THAT ONE TUBE WAS BLOCKED YET THE OTHER WAS COMPLETELY OPEN AND THE COIL WAS MISPLACED. HER DOCTOR SAID SHE WOULD HAVE TO DO AGAIN THE RIGHT SIDE ESSURE AND THAT THE ONE THAT MIGRATED COULD STAY WHERE IT WAS BECAUSE IT WOULD CAUSE NO TROUBLE BEING THAT IT WAS LIKE A NEEDLE IN A HAYSTACK. CONSUMER REPORTED THAT SHE BEGAN HAVING PAIN WHEN DOING ABDOMINAL EXERCISES AS IF SOMETHING WERE CUTTING INTO HER UTERUS. SHE ASKED HER DOCTOR ON AT LEAST THREE OCCASIONS THROUGH THE YEARS AND HE SAID EACH TIME THAT THE ESSURE COULD NOT CAUSE THE PAIN. SHE HAS BEEN DIAGNOSED WITH SLEEP APNEA BECAUSE OF SEVERE DAYTIME SLEEPINESS THAT BEGAN IN 2010. SHE HAS HAD BLOOD TESTS FOR RHEUMATOID ARTHRITIS WHICH CAME BACK NEGATIVE IN 2014. SHE HAD SEVERE ACHING AND JOINT PAIN THAT STARTED IN HER FEET AND WAS THROUGHOUT HER ENTIRE BODY. HER EYES HAVE WORSENED AT A SPEED QUICKLY AND HAD BEEN CONSISTENT YEARS PRIOR ESSURE. SHE HAD DRY EYES AND SKIN. SHE ALSO MENTIONED THAT HER BACK HAD A RASH AND HER WAIST OFTEN ITCHES UNCONTROLLABLY. SHE WAS NAUSEOUS BEFORE BED FREQUENTLY FOR NO REASON. SHE HAS BEEN HOSPITALIZED FOR SEVERE ABDOMINAL PAIN TWICE. SHE HAD DIARRHEA THAT HAD AN OFFENSIVE ODOR (CHEMICAL ODOR). INTERCOURSE WAS PAINFUL DUE TO THE COIL THAT WAS CUTTING THE UTERUS. SHE COULD NO LONGER EXERCISE DUE TO PAIN WHERE

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THE COIL WAS IN HER UTERUS. HER MOODS WERE VERY INCONSISTENT. SHE WAS SAD FREQUENTLY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE ABDOMINAL PAIN AND HSG FIND OUT THE OTHER TUBE (RIGHT SIDE) WAS COMPLETELY OPEN, THE RIGHT COIL IMMEDIATELY MIGRATED/THE COIL WAS MISPLACED/COIL WAS CUTTING THE UTERUS (INTERPRETED AS DEVICE EMBEDDED). SEVERE ABDOMINAL PAIN IS SERIOUS DUE TO HOSPITALIZATION AND THE EVENT DEVICE EMBEDDED, IS SERIOUS DUE TO MEDICAL IMPORTANCE. BOTH EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS CASE, TEMPORAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT IS UNKNOWN. HOWEVER, GIVEN ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE HOSPITALIZATION WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 16-FEB-2015 - PTC INVESTIGATION RESULT: (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT W

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00114	BAYER HEALTHCARE LLC	2/13/2015	2/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE MW5039544) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PATIENT REPORTED THAT SINCE SHE HAD ESSURE INSERTED SHE HAS STOMACH PAINS AND HER PERIODS HAS BEEN ALL OFF. SHE STATED THAT WHEN SHE WOULD START HER PERIODS, THE STOMACH PAINS WERE HORRIBLE. SHE HAD THE ESSURE REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STOMACH PAINS WERE HORRIBLE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. IN THIS CASE, IT WAS REPORTED THAT THIS EVENT OCCURRED SINCE ESSURE INSERTION. AN ALTERNATE EXPLANATION IS NOT AVAILABLE. BASED ON THIS INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE WERE REMOVED. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED: HER PERIODS HAS BEEN ALL OFF. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 13-FEB-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00115	BAYER HEALTHCARE LLC	2/13/2015	2/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039571) IN UNITED STATES ON 15-JAN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER DIDN´T RECALL THE START DATE, BUT SHE PRESENTED PAIN LIKE HER ORGANS WERE MOVING AROUND HER ABDOMEN. IT WAS HARD TO BREATHE WHEN THESE PAINS HAPPENED AND IT WAS SIMILAR TO WHEN AN 8 MONTH OLD FETUS IS MOVING AROUND EXCEPT ACTUALLY PAINFUL. SHE ALSO EXPERIENCED REGULAR MIGRAINES, UNCONTROLLABLE WEIGHT GAIN AND REALLY HEAVY MENSTRUAL CYCLES. SHE WAS HOSPITALIZED TWICE FOR THE PAIN, BUT STATED SHE DIDN'T THINK IT WAS CAUSED BY THE ESSURE, THOUGH SHE DID REPORT THAT HAD THE COILS TO THE ATTENDING PHYSICIANS. THE PAINS COME ON MORE OFTEN, IN ADDITION TO HEADACHES. CONSUMER INFORMED THE DATE (B)(6)-2011 AS EVENT ONSET DATE; HOWEVER SHE DID NOT SPECIFY IT. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-FEB-2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO

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BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN LIKE MY ORGANS ARE MOVING AROUND MY ABDOMEN. THIS EVENT IS SERIOUS DUE HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE CONSUMER PRESENTED PAIN LIKE HER ORGANS WERE MOVING AROUND HER ABDOMEN. IT WAS HARD TO BREATHE WHEN THESE PAINS HAPPENED AND IT WAS SIMILAR TO WHEN AN 8 MONTH OLD FETUS IS MOVING AROUND. SHE WAS HOSPITALIZED TWICE FOR THE PAIN. ALTHOUGH REPORTER DID NOT THINK THE ESSURE CAUSED THE EVENT AND HER HOSPITALIZATION, A CONTRIBUTORY ROLE OF ESSURE TO THE PAIN CANNOT BE TOTALLY EXCLUDED, THEREFORE CAUSALITY IS ASSESSED AS RELATED TO ESSURE AND THE CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT OF PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040868	CONCEPTUS, INC.	2/13/2015	2/25/2015

Event Information:

Event Date (B3): 1/7/2001 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 898935

Single Use:
Implant Date (E6): 1/7/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

POKING PINCHING PAINS SINCE I RECEIVED ESSURE. WEIGHT GAIN, PELVIC AND LOWER BACK PAIN THAT'S CONSTANT, HEADACHE, FOGGY BRAIN, HEAVY BLEEDING, TIREDNESS, THE FILLING OF BEING SWOLLEN ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040846	CONCEPTUS INC	2/14/2015	2/25/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ENSURE WAS HIGHLY RECOMMENDED AND I WAS TOLD IT WAS BETTER THAN THE TUBAL LIGATION AND EVERY SINCE I HAVE HAD IT IN; I HAVE HAD DEBILITATING PAIN AND BLEEDING EVERY DAY. SINCE I HAD IT PUT IN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040841	CONCEPTUS	2/15/2015	2/25/2015

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/8/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE DEVICE FOR STERILIZATION. I HAVE BEEN IN PAIN SINCE I GOT THEM 2 YEARS AGO. I BLEED EVERYDAY. I HAVE ENDOMETRIOSIS NOW BECAUSE OF THE ESSURE DEVICE. I HAVE NEVER HAD ANY HEALTHCARE PROBLEMS PREVIOUSLY. HAIR LOSS, SCIATICA PAIN, BODY RASH, NUMBNESS IN LEGS AND TOES, IRREGULAR PAINFUL BLEEDING, WEIGHT GAIN, BLOATING, MIGRAINES, AND THE LIST GOES ON. I COULDN'T TAKE THE PAINS ANYMORE AND TIRED OF TAKING IBUPROFEN 800 MG 5 TIMES A DAY TO RELIEVE MY SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00116	BAYER HEALTHCARE LLC	2/16/2015	2/18/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BILATERAL HYDROSALPINX. THE PATIENT'S MEDICAL HISTORY INCLUDED 3 SUBUMBILICAL MIDLINE LAPAROTOMIES FOR RECTAL PROLAPSE; AND 2 UNSUCCESSFUL MEDICALLY ASSISTED PROCREATION. THE PATIENT'S MEDICAL REPORT ON (B)(6) 2014: A HYSTEROGRAPHY HAD SHOWED BILATERAL HYDROSALPINX AND THE DECISION OF TUBAL STERILIZATION WITH ESSURE PROCEDURE WAS DONE BEFORE NEW MEDICALLY ASSISTED PROCREATION ATTEMPT. BILATERAL PLACEMENT OF ESSURE HAD BEEN PERFORMED. THE UTERINE CAVITY HAD BEEN NORMAL; AND BOTH OSTIA HAD BEEN WELL SEEN. CATHETERIZATION OF BOTH OSTIA HAD BEEN PERFORMED WITHOUT ANY PROBLEM ENABLING ESSURE IMPLANTS PLACEMENT IN PROXIMAL PART OF BOTH FALLOPIAN TUBES. THREE TRAILING COILS HAD BEEN VISIBLE ON LEFT SIDE; ONE TRAILING COIL HAD BEEN VISIBLE ON RIGHT SIDE. AN ULTRASOUND WAS PERFORMED 9 MONTHS AFTER PLACEMENT, DURING STIMULATION, SHOWED LEFT ESSURE IMPLANT IN CONTACT WITH ENDOMETRIUM. THERE WAS NO CAUSAL RELATIONSHIP RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. A REPEAT DIAGNOSTIC HYSTEROSCOPY SHOWED BAD PLACEMENT OF LEFT ESSURE IMPLANT WITH 12 TRAILING COILS IN UTERINE CAVITY; WHICH WAS AN INDICATION FOR LEFT ESSURE IMPLANT WITHDRAWAL AND THEN RE-PLACEMENT. AN INTERVENTION WAS PERFORMED ON (B)(6) 2014. DURING THE INTERVENTION PROCEDURE, THE RIGHT ESSURE IMPLANT WAS NOT VISIBLE IN UTERINE CAVITY. THE LEFT ESSURE IMPLANT WAS VISIBLE WITH 10 INTRACAVITARY TRAILING COILS AND WAS WITHDRAWN WITH BETTOCCHI PLIERS. A NEW ESSURE IMPLANT WAS PLACED IN LEFT SIDE WITH 4 INTRACAVITARY TRAILING COILS VISIBLE. NO BLEEDING WAS OBSERVED IN THE END OF THE INTERVENTION. THE PATIENT'S MEDICAL REPORT ON (B)(6) 2014: THE INTERVENTION WENT WELL,

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POSTOPERATIVE COURSE WAS SIMPLE. FOLLOW-UP RECEIVED ON (B)(4) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A USABILITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: PHYSICIAN HAD PLACEMENT DIFFICULTIES AND CORRECTED PLACEMENT BY USING ANOTHER ESSURE DEVICE. ESSURE DEVICES WERE USED FOR BILATERAL HYDROSALPINX, WHICH IS NOT INDICATED ON THE INSTRUCTIONS FOR USE; THEREFORE OFF-LABEL. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. IN THIS PARTICULAR CASE, OFF LABEL USE WAS REPORTED. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND A HANDLING ERROR. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 287 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BILATERAL HYDROSALPINX (CONSIDERED AS OFF LABEL USE) AND AN ULTRASOUND SHOWED LEFT ESSURE IMPLANT BAD PLACEMENT IN CONTACT WITH ENDOMETRIUM WITH 10 INTRACAVITARY TRAILING COILS (INTERPRETED AS DEVICE DISLOCATION). THE RIGHT ESSURE IMPLANT WAS NOT VISIBLE IN UTERINE CAVITY (INTERPRETED AS DEVICE DISLOCATION). THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE BAD PLACEMENT OF LEFT ESSURE IMPLANT WAS DIAGNOSED 9 MONTHS AFTER ESSURE INSERTION. AN INTERVENTION WAS REQUIRED FOR REMOVAL (WITH BETTOCCHI PLIERS, WHICH IS AN OFF LABEL USE) AND DURING THIS PROCEDURE, THE RIGHT ESSURE IMPLANT WAS NOT VISIBLE. BASED ON AVAILABLE INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 21-MAY-2015: NO NEW INFORMATION PROVIDED. CASE CLOSED. NCA NUMBER (B)(4). THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES R

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00117	BAYER HEALTHCARE LLC	2/16/2015	3/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51341

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/5/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 19-JAN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE LOT NUMBER USED WAS C51341. DURING INSERTION PROCEDURE, THE ESSURE DID NOT DETACH FROM THE DELIVERY SYSTEM; ESSURE REMOVAL WAS IMPOSSIBLE. A PART OF THE COIL WAS VERY CLOSE TO THE CERVIX. IT WAS REPORTED THAT THE PHYSICIAN'S TRAINING TO PLACEMENT OF ESSURE WAS VERY ANCIENT. THE CONDITIONS OF PLACEMENT WERE USUAL. BILATERAL PLACEMENT WAS PERFORMED. IT WAS REPORTED THAT THE CONSEQUENCES FOR THE PATIENT COULD BE THE RISK OF WOUND AND MIGRATION OF THE COIL IN THE UTERINE CAVITY. THE CONTROL TEST WILL BE DONE IN 3 MONTHS. NO FURTHER INFORMATION WAS AVAILABLE AT THE TIME OF THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING ESSURE INSERTION PROCEDURE, THE ESSURE DID NOT DETACH FROM THE DELIVERY SYSTEM AND ESSURE REMOVAL WAS IMPOSSIBLE. A PART OF THE COIL WAS VERY CLOSE TO THE CERVIX (INTERPRETED AS DEVICE BREAKAGE), WHICH IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THE DEVICE BREAKAGE OCCURRED DURING ESSURE PLACEMENT, THEREFORE A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FOLLOW-UP INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 13-FEB-2015 - PTC INVESTIGATION RESULT: BATCH NUMBER: C51341 (PRODUCTION DATE 02-MAY-2014; EXPIRATION DATE 31-MAY-2017). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00118	BAYER HEALTHCARE LLC	2/16/2015	3/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C55828

Single Use: Y
Implant Date (E6): 1/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/25/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 19-JAN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015 WITH LOT NUMBER C55828. IT WAS REPORTED THAT AT THE TIME OF THE ADJUSTMENT AND POSITIONING OF THE GOLD BAND, COILS RUPTURED. THIS EVENT OCCURRED IN OPERATING ROOM DURING INSERTION UNDER GENERAL ANESTHESIA. REPORTER STATED TUBAL CATHETERISM WAS DIFFICULT. HE SUSPECTED A SPASM DURING INSERTION AS A CAUSE RELATED TO THE PATIENT, WHICH COULD EXPLAIN THE EVENT. IT WAS DECIDED TO REMOVE IMPLANT WITH HYSTEROSCOPIC PLIERS FOR LIGATURE. BILATERAL INSERTION WAS DONE WITH ANOTHER DEVICE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE, TUBAL CATHETERISM WAS DIFFICULT AND AT THE TIME OF THE ADJUSTMENT AND POSITIONING OF THE GOLD BAND, COILS RUPTURED. REPORTER SUSPECTED A SPASM DURING INSERTION AS AN EXPLANATION FOR THE EVENT. ALL REPORTED EVENTS WERE CONSIDERED NON-SERIOUS AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; EXCEPT FOR THE REPORTED COILS RUPTURE (REGARDED AS DEVICE BREAKAGE) WHICH IS UNLISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES IN THE DEPLOYMENT OF THE DEVICE AND A BREAKAGE OCCURRED. CONSIDERING THAT THESE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

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Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 22-MAY-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). THE PTC ASSESSMENT WAS UPDATED DUE TO SAMPLE ARRIVAL. FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00119	BAYER HEALTHCARE LLC	2/17/2015	2/18/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B09708

Single Use: Y
Implant Date (E6): 8/4/2014
Explant Date (E7): 1/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014 FOR STERILIZATION; THE LOT NUMBER USED WAS B09708. IT WAS REPORTED THAT UPON HSG (HYSTEROSALPINGOGRAM) EXAMINATION, THE COILS WERE LOCATED IN HER PELVIS. ALTHOUGH THE EVENT WAS ONGOING, THE PATIENT WAS DOING FINE; THERE ARE NO PROBLEMS WITH HER. AT TIME OF THE REPORT, AS PHYSICIAN KNOWLEDGE, ESSURE WERE CONTINUED. FOLLOW-UP RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). THE PTC INVESTIGATION RESULT WAS PROVIDED. FINAL ASSESSMENT: MANUFACTURING DATE: 3/2013. EXPIRATION DATE: 3/2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. FOUR FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, BUT NONE OF THEM REFER TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT

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SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN ON (B)(6) 2015. CASE WAS UPGRADE TO INCIDENT. PATIENT'S INITIALS WERE UPDATED. THE PATIENT'S WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 3 PREGNANCIES, 3 PARITIES AND ONE C-SECTION. PREVIOUS GYNECOLOGICAL INTERVENTION WAS DENIED. ON (B)(6) 2014, ESSURE WAS INSERTED IN A POST-PARTUM STATE (7 WEEKS AND 2 DAYS), BUT NOT AFTER A C-SECTION AS LAST DELIVERY. SHE WAS BREASTFEEDING AT TIME OF PROCEDURE. PRIOR INSERTION, NOTHING ABNORMAL WAS SEEN IN UTERUS. A CERVICAL DILATION WAS DONE. THE INSERTION AND VISUALIZATION OF TUBAL OS WERE EASY. THE FLUID LOSS WAS LESS THAN 1500CC AND THE TIME OF PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. THE PATIENT DID NOT HAVE ANY COMPLAIN IMMEDIATELY AFTER INSERTION. ON (B)(6) 2014, HYSTEROSCOPY AND ESSURE CONFIRMATION TEST (HSG) DONE WERE DONE AND SHOWED BILATERAL ESSURE DEVICE IN PELVIS; TUBAL OCCLUSION WAS NOT CONFIRMED. ANY ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS PERFORATED. PATIENT PRESENTED WITHOUT SYMPTOMS. SECOND CONFIRMATION TEST WAS NOT DONE. ON (B)(6) 2015, LAPAROSCOPY/TUBAL LIGATION WERE DONE AND ONLY ONE ESSURE WAS FOUND (ESSURE WAS INTACT). PHYSICIAN WAS UNABLE TO LOCATE SECOND DEVICE. UTERUS, TUBES AND OVARIES WERE WNL (INTERPRETED AS WITHIN NORMAL LIMITS). BILATERAL SALPINGECTOMY WAS PERFORMED, FOR STERILITY PURPOSE. ACCORDING TO PHYSICIAN, IT WAS NOT MEDICALLY NECESSARY TO REMOVE ESSURE; DEVICE WAS REMOVED BECAUSE OF PATIENT REQUEST. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. FOLLOW-UP RECEIVED ON (B)(4) 2015: PATIENT'S DATE OF BIRTH AND INITIALS WERE UPDATED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT UPON HSG (HYSTEROSALPINGOGRAM) EXAMINATION, THE COILS WERE LOCATED IN HER PELVIS. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH NOT REPORTED AS SUCH, THE MOST LIKELY MECHANISM FOR THE COILS TO BE FOUND IN THE PELVIS, WOULD BE THROUGH A UTERINE/FALLOPIAN TUBE PERFORATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND THE MECHANISM OF DISLOCATION ARE NOT KNOWN. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. INITIALLY, NO INTERVENTION NEITHER HOSPITALIZATION WAS INFORMED, HOWEVER; AFTER RECEIPT OF FOLLOW UP INFORMATION, IN WHICH IT WAS REPORTED THE PATIENT UNDERWENT BILATERAL SALPINGECTOMY, THE CASE WAS UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00121	BAYER HEALTHCARE LLC	2/17/2015	2/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE IS A SOLICITED CASE REPORT RECEIVED VIA SOCIAL MEDIA (WEBSITE) FROM A MEMBER OF AN ESSURE PROBLEMS SUPPORT GROUP IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION (NO DETAILS REPORTED). THE REPORTER INFORMED A CASE WHICH OCCURRED WITH ONE OF THE WOMEN FROM THE GROUP WHO WAS PREGNANT WITH ESSURE IMPLANTED. SHE FOUND OUT SHE WAS EXPECTING TWINS AND POSTED ON THE GROUP THAT SHE LOST HER BABIES. HER PLACENTA OBTAINED A TEAR (METAL COILS COULD AND DID MIGRATE OUT OF FALLOPIAN TUBES INTO UTERUS), SHE LEAKED FLUID FROM HER PLACENTA AT 15 WEEKS AND ENDED UP HAVING TO BURY 2 BEAUTIFUL LITTLE GIRLS. NO ADDITIONAL INFORMATION WAS PROVIDED. THERE ARE TWO LINKED CHILD CASES: (B)(4).THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN

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THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT WITH ESSURE. HER PLACENTA OBTAINED A TEAR (INTERPRETED AS PLACENTAL DISORDER). METAL COILS COULD AND DID MIGRATE OUT OF FALLOPIAN TUBES INTO UTERUS (INTERPRETED AS DEVICE MIGRATION). SHE LEAKED FLUID FROM HER PLACENTA AT 15 WEEKS AND ENDED UP HAVING TO BURY 2 BEAUTIFUL LITTLE GIRLS (INTERPRETED AS AMNIORRHEXIS AND ABORTION LATE). THE EVENTS PLACENTAL DISORDER, AMNIORRHEXIS AND ABORTION LATE ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE MIGRATION IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED. PREGNANCY IS NON-SERIOUS AND LISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE EXACT DATE AND THE MECHANISM OF MIGRATION AND PREGNANCY ARE NOT KNOWN. A CAUSAL RELATIONSHIP BETWEEN PREGNANCY, DEVICE MIGRATION AND SUSPECT INSERT CANNOT BE EXCLUDED. THE CONSUMER PRESENTED PLACENTAL DISORDER (NOT SPECIFIED) AND AMNIORRHEXIS DURING GESTATION, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THE DEATH OF TWINS. HOWEVER, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED. THUS, THIS CASE WAS REGARDED AS INCIDENT. NO FOLLOW-UP INFORMATION CAN BE OBTAINED SINCE THIS IS A SOCIAL MEDIA CASE. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00122	BAYER HEALTHCARE LLC	2/17/2015	2/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE IS A SOLICITED CASE REPORT RECEIVED VIA SOCIAL MEDIA (WEBSITE) FROM A MEMBER OF AN ESSURE PROBLEMS SUPPORT GROUP IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE'S CONSUMER DAUGHTER WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERO. THE REPORTER INFORMED A CASE WHICH OCCURRED WITH ONE OF THE WOMEN FROM THE GROUP WHO WAS PREGNANT WITH ESSURE IMPLANTED ((B)(6)). SHE FOUND OUT SHE WAS EXPECTING TWINS AND POSTED ON THE GROUP THAT SHE LOST HER BABIES (IN 2014). HER PLACENTA OBTAINED A TEAR (METAL COILS COULD AND DID MIGRATE OUT OF FALLOPIAN TUBES INTO UTERUS), SHE LEAKED FLUID FROM HER PLACENTA AT 15 WEEKS AND ENDED UP HAVING TO BURY 2 BEAUTIFUL LITTLE GIRLS (THIS CASE REFERS TO ONE OF THE 2 GIRLS, PLEASE REFER TO THE OTHER GIRL CASE (B)(6)). IT WAS ALSO REPORTED THAT SHE LOST HER BABIES BECAUSE OF MIGRATING COILS. FOLLOW-UP INFORMATION RECEIVED ON 27-JAN-2015: NO FURTHER INFORMATION IS EXPECTED FOR THIS CASE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER AND REFERS TO HER DAUGHTER, WHO WAS EXPOSED TO ESSURE MICRO-INSERT IN UTERO AND DIED DUE PREGNANCY COMPLICATIONS IN HER MOTHER. THE REPORTED FETAL DEATH WAS CONSIDERED SERIOUS AND IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT CONSUMER'S TWIN DAUGHTERS DIED AFTER HER MOTHER EXPERIENCED A PLACENTAL TEAR AND FLUID LEAKAGE AT 15 WEEKS OF GESTATION; ALTHOUGH NO INFORMATION ABOUT THE EXACT CAUSE OF BABIES DEATH WAS PROVIDED AND DISCREPANT INFORMATION WAS RECEIVED (GESTATIONAL AGE IS NOT CLINICALLY COMPATIBLE WITH EVENT'S CHARACTERISTICS); A MECHANICAL INTERFERENCE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THE REPORTED DEATH WAS, THUS CONSIDERED AS RELATED TO THE SUSPECT INSERT AND THIS CASE WAS REGARDED AS AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WILL BE SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 18-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00120	BAYER HEALTHCARE LLC	2/17/2015	3/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51343 / C51339

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER IN (B)(6) ON 20-JAN-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD TWO ATTEMPTS TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBERS C51343 AND C51339. IT WAS REPORTED THAT INSERT (FROM LOT NUMBER C51343) DID NOT CORRECTLY RELEASE. IT REMAINED ATTACHED TO THE SUPPORT DESPITE THE CORRECT INSERTION. INSERT WAS REMOVED RELEASING AN INSERTED FRAGMENT DETACHED FROM THE REST OF THE SYSTEM. THIS EVENT WAS OBSERVED IN THE OPERATING ROOM DURING ESSURE PLACEMENT. AFTER THIS PLACEMENT ATTEMPT, REMAINING OF SATELLITE LOOP FROM ESSURE C51343, DESTERILIZATION OF ESSURE C51339 WAS PERFORMED AND CATHETERIZATION OF THE FALLOPIAN TUBE WITH ESSURE C51339 WHERE REMAINED A FRAGMENT OF THE OTHER SYSTEM WAS IMPOSSIBLE. THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. NO CONSEQUENCES FOR THE PATIENT. BILATERAL PLACEMENT WAS NOT PERFORMED AND THE PROCEDURE WAS STOPPED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD TWO ATTEMPTS TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE, INSERT DID NOT CORRECTLY RELEASE AND REMAINED ATTACHED TO SUPPORT; THEN THIS INSERT WAS REMOVED RELEASING AN INSERTED FRAGMENT DETACHED FROM THE REST OF THE SYSTEM. ANOTHER ESSURE SYSTEM WAS OPENED, BUT CATHETERIZATION OF THE FALLOPIAN TUBE WHERE REMAINED A FRAGMENT OF THE OTHER SYSTEM WAS IMPOSSIBLE. BILATERAL PLACEMENT WAS NOT PERFORMED AND THE PROCEDURE WAS STOPPED. ALL REPORTED EVENTS WERE CONSIDERED NON-SERIOUS AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; EXCEPT FOR INSERT WAS REMOVED RELEASING AN INSERTED FRAGMENT DETACHED FROM THE REST OF THE SYSTEM, REGARDED AS DEVICE BREAKAGE, WHICH IS UNLISTED. SINGLE

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CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES IN THE DEPLOYMENT OF THE DEVICE AND A BREAKAGE OCCURRED. CONSIDERING THE ABOVE MENTION INFORMATION AND AS THE REPORTED BREAKAGE AND DIFFICULT/FAILED INSERTION OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE EVENT CATHETERIZATION OF THE FALLOPIAN TUBE WHERE REMAINED A FRAGMENT OF THE OTHER SYSTEM WAS IMPOSSIBLE, IT WAS CONSIDERED AS UNRELATED TO ESSURE, SINCE IT WAS REGARDED AS A DEVICE MISUSE (ESSURE INSERTION ATTEMPT IN A FALLOPIAN TUBE WITH AN ESSURE FRAGMENT). THIS CASE WAS CONSIDERED OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP O

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Report Type: MANUFACTURER **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00123	BAYER HEALTHCARE LLC	2/18/2015	2/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE IS A SOLICITED CASE REPORT RECEIVED VIA SOCIAL MEDIA (WEBSITE) FROM A MEMBER OF AN ESSURE PROBLEMS SUPPORT GROUP IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE'S CONSUMER DAUGHTER WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERO. THE REPORTER INFORMED A CASE WHICH OCCURRED WITH ONE OF THE WOMEN FROM THE GROUP WHO WAS PREGNANT WITH ESSURE IMPLANTED (CASE NUMBER (B)(4)). SHE FOUND OUT SHE WAS EXPECTING TWINS AND POSTED ON THE GROUP THAT SHE LOST HER BABIES (IN 2014). HER PLACENTA OBTAINED A TEAR (METAL COILS COULD AND DID MIGRATE OUT OF FALLOPIAN TUBES INTO UTERUS), SHE LEAKED FLUID FROM HER PLACENTA AT (B)(6) WEEKS AND ENDED UP HAVING TO BURY 2 BEAUTIFUL LITTLE GIRLS (THIS CASE REFERS TO ONE OF THE 2 GIRLS, FOR THE OTHER GIRL PLEASE REFER TO (B)(4)). IT WAS ALSO REPORTED THAT SHE LOST HER BABIES BECAUSE OF MIGRATING COILS. FOLLOW-UP RECEIVED ON 27-JAN-2015. NO FURTHER INFORMATION IS EXPECTED FOR THIS CASE REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER AND REFERS TO HER DAUGHTER, WHO WAS EXPOSED TO ESSURE MICRO-INSERT IN UTERO AND DIED DUE PREGNANCY COMPLICATIONS IN HER MOTHER. THE REPORTED FETAL DEATH WAS CONSIDERED SERIOUS AND IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT CONSUMER'S TWIN DAUGHTERS DIED AFTER HER MOTHER EXPERIENCED A PLACENTAL TEAR AND FLUID LEAKAGE AT (B)(6) WEEKS OF GESTATION; ALTHOUGH NO INFORMATION ABOUT THE EXACT CAUSE OF BABIES DEATH WAS PROVIDED AND DISCREPANT INFORMATION WAS RECEIVED (GESTATIONAL AGE IS NOT CLINICALLY COMPATIBLE WITH EVENT'S CHARACTERISTICS); A MECHANICAL INTERFERENCE

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BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THE REPORTED DEATH WAS, THUS CONSIDERED AS RELATED TO THE SUSPECT INSERT AND THIS CASE WAS REGARDED AS AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WILL BE SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 18-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00124	BAYER HEALTHCARE LLC	2/18/2015	2/18/2015

Event Information:

Event Date (B3): 7/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A78084

Single Use: Y
Implant Date (E6): 7/31/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH PROFESSIONAL IN UNITED STATES VIA REGULATORY AUTHORITY (REPORT NUMBER (B)(4)) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER A78084 ON (B)(6) 2014. IT WAS REPORTED THAT PATIENT CAME IN FOR AN OUTPATIENT PROCEDURE FOR PERMANENT STERILIZATION. DURING PLACEMENT OF ESSURE DEVICE ON THE RIGHT OSTIA, DEVICE FAILED TO DEPLOY AND DID NOT RELEASE ON THE SECOND RECOILING. WHEN REMOVING THE DEVICE, MOST OF THE COIL WAS OUT. UNABLE TO REMOVE HALF OF THE DEVICE. DECISION WAS MADE TO PROCEED WITH THE PROCEDURE LAPAROSCOPICALLY. REPORTER CONSIDERED IT AS SERIOUS (IMPORTANT MEDICAL EVENTS). DEVICE WAS NOT AVAILABLE FOR EVALUATION. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: LOT A78084. PRODUCTION DATE: (B)(4) 2012. DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: 1) ROLLBACK TO INITIAL HARD STOP. 2) DEPRESS BUTTON. 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO "DEPLOYMENT DIFFICULTY". SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING

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PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE REMOVAL. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE, DEVICE FAILED TO DEPLOY AND DID NOT RELEASE ON THE SECOND RECOILING. WHEN PHYSICIAN TRIED TO REMOVE THE ESSURE, HE WAS UNABLE TO REMOVE HALF OF THE DEVICE AND DECIDED TO PERFORM A LAPAROSCOPY. ALL REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE EVENT UNABLE TO REMOVE HALF OF THE DEVICE, REGARDED AS DEVICE BREAKAGE, WAS CONSIDERED SERIOUS, WHILE THE REMAINING EVENT IS NON-SERIOUS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT REMOVALS. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES IN THE DEPLOYMENT OF THE DEVICE AND A BREAKAGE OCCURRED WHEN HE TRIED TO REMOVE IT. CONSIDERING THE ABOVE MENTION INFORMATION AND AS THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT DUE TO THE REPORTED INTERVENTION (LAPAROSCOPY). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. IT WAS ALSO INFORMED THAT THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015. THE PATIENT´S DATE OF BIRTH WAS UPDATED. HER HEIGHT WAS (B)(6) CM AND WEIGHT WAS (B)(6) KG (BMI (B)(6)). HER CONCURRENT CONDITION INCLUDED OBESITY. PREVIOUS GYNECOLOGICAL INTERVENTION, PROBLEMS AND PROCEDURES

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040839	BAYER	2/18/2015	2/25/2015

Event Information:

Event Date (B3): 2/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): C03090

Single Use:
Implant Date (E6): 7/7/2014
Explant Date (E7): 2/10/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD TO HAVE TOTAL HYSTERECTOMY TO HAVE ESSURE REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00126	BAYER HEALTHCARE LLC	2/19/2015	2/20/2015

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 731606

Single Use: Y
Implant Date (E6): 12/16/2010
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. ACCORDING TO THE CONSUMER, HER SIDE EFFECTS STARTED 48 HOURS LATER THAN SHE WENT INTO THE TREATMENT. FIRSTLY, 5 ROUNDED SPOTS AROSE IN HER RIGHT LUMBAR AREA AND ALSO THREE SPOTS APPEARED IN THE LEFT ZONE. SHE DID NOT HAVE ANY CONCERN AT THE BEGINNING; SHE BELIEVED THERE WERE SIGNALS COMING FROM THE PRESSURE OF HER CLOTHES, BUT SHE SOON STARTED TO BE FULL OF PIMPLES AND STARTED TO SUFFER A TERRIBLE ITCHING THAT WAS NOT STOPPING. SHE WENT TO THE HOSPITAL EMERGENCY SERVICES AND SHE WAS TOLD IT WAS AN ALLERGIC REACTION. WHEN THEY ASKED HER ABOUT WHAT SHE HAD BEEN DOING LATELY, ESSURE SEEMED TO BE THE ONLY REASON, AS SHE HAD PREVIOUSLY USED THE MEDICINES SHE WAS PRESCRIBED TO USE BEFORE THE PROCEDURE WITHOUT A PROBLEM AND THERE WAS NOT ANY ALTERNATIVE EXPLANATION. THE PHYSICIAN WHO EXAMINED HER SUGGESTED HER TO GET IN TOUCH WITH THE GYNECOLOGISTS OF THE HOSPITAL WHERE THE DEVICE WAS INSERTED IN ORDER TO INVESTIGATE WHAT THE DEVICE WAS MADE OF. THIS WAS WHAT SHE DID AND SHE WAS SURPRISED WHEN SHE HEARD, AS AN INITIAL RESPONSE, THAT ESSURE WAS HYPOALLERGENIC AND THAT WAS HAPPENING TO ME WAS A FOOD ALLERGY. DAYS WERE PASSING BY AND SHE KEPT WITH PIMPLES AND ITCHING WHEN SHE RECEIVED A CALL FROM THE HYSTEROSCOPY DEPARTMENT OF THE HOSPITAL WHERE THE DEVICE WAS PLACED TELLING HER THAT IF HER SYMPTOMS WERE PERSISTING SHE SHOULD GO TO AN ALLERGIST, AS ESSURE WAS CONTAINING NICKEL AND THIS WOULD PROBABLY BE THE CAUSE FOR HER ITCHING. THE TESTS RESULTS SHOWED THAT SHE WAS HIGHLY ALLERGIC TO NICKEL ALTHOUGH THEY WERE NEGATIVE WITH REGARD TO ALLERGY TO TITANIUM. ESSURE WAS ALSO MADE OF STEEL AND

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PET FIBERS, ALTHOUGH SHE WAS NOT TESTED ABOUT ALLERGY TO THESE MATERIALS AT THAT TIME. THE ALLERGIST RECOMMENDED THAT THE DEVICE SHOULD BE REMOVED FROM HER BODY, DUE TO HER SEVERE ALLERGY TO NICKEL, AND IT WAS NOT KNOWN HOW HER ALLERGY MAY BECOME. ADDITIONALLY HE PRESCRIBED HER A TREATMENT WITH EBASTEL FORTE THAT DID NOT REDUCE HER SYMPTOMS. SHE REQUESTED FOR REMOVAL OF THE DEVICE BUT SHE WAS INFORMED THAT THIS REMOVAL WAS COMPLICATED AND THEY RECOMMENDED HER TO WAIT BECAUSE AFTER THREE MONTHS, ONCE A FIBROSIS HAD BEEN GENERATED HER PIMPLES AND ITCHING WOULD DISAPPEAR. IT WAS LIKE THIS, IT WAS TRUE THAT TO, A BIG EXTENT, THE PIMPLES AND THE ITCHING CEASED AND STOPPED BEING A PROBLEM. HOWEVER, SHE STARTED TO NOTE THE REST OF SYMPTOMS THAT THE DEVICE WAS CAUSING IN HER. SHE HAD CHANGES IN MENSTRUATION; SHE NOTICED FROM THE BEGINNING THAT HER MENSTRUATION BECAME NOT REGULAR. SHE THOUGHT IT WAS RATHER NORMAL THAT THIS WAS OCCURRING DURING THE FIRST SEVERAL MONTHS AFTER A PROCEDURE LIKE THIS ONE, BUT AS OF TODAY WAS NOT NORMAL AT ALL. SOME MONTHS THE START WAS QUITE DELAYED, OTHER MONTHS IT WAS STARTING TOO EARLY AND OTHERS SHE HAVE BLEEDING BETWEEN TWO MENSTRUATIONS. SHE ALSO EXPERIENCED BLEEDING AFTER HAVING SEXUAL RELATIONSHIPS OR AFTER DEFECATIONS, MENSTRUATIONS THAT HAD BECOME REALLY PAINFUL, ABDOMINAL PAIN AND DAILY PAIN IN HER UTERUS (THIS WAS A CONSTANT PAIN AS IF THE UTERUS WAS GOING TO EXPLODE), SEVERE VAGINAL AND VULVAR ITCHING THAT WERE NOT RELIEVED BY ANY TREATMENT AND THAT WERE NOT DUE TO ANY INFECTION OR CANDIDA AS THE RESULTS OF THE CYTOLOGICAL TESTS WERE NORMAL, HAIR LOSS (THAT WAS FALLING IN LOCKS). SHE ALSO HAD WEIGHT GAIN AND ABDOMINAL SWELLING; WEIGHT GAIN WITHOUT ANY CHANGE IN HER LIFE OR HER HABITS. HER ABDOMEN WAS SWELLING TO THE POINT THAT SHE OFTEN LOOKED A SIX-MONTH PREGNANT WOMAN. SHE HAD DEPRESSION AND MALAISE: THE DAMAGE SUFFERED BECAUSE SHE FELT MISUNDERSTOOD DUE TO THE PAIN AND THE DAMAGE THAT ESSURE WAS CAUSING DEEPLY IN HER BODY BUT THAT NO ONE ELSE WAS UNDERSTANDING; COUPLE RELATIONSHIP WAS ALMOST BROKEN UP DUE TO ESSURE HAS BEEN VERY HARD AND DIFFICULT TO OVERCOME. SHE STATED THAT SHE WILL HAVE A SALPINGECTOMY. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS ASSESSED AS RELATED. CORRECTION ((B)(4) 2015) FOLLOWING COMPANY INTERNAL REVIEW: NCA NUMBER WAS ADDED TO THE RESPECTIVE STRUCTURED FIELD. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ALLERGY TO METALS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 105 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY

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SIGNAL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED VIA HEALTH AUTHORITY AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALLERGY TO NICKEL AND DAILY PAIN IN HER UTERUS. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. ADDITIONALLY, ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THE REPORTED EVENT'S NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. OTHER NON-SERIOUS EVENTS WERE ALSO REPORTED. CONSUMER STATED SHE WILL HAVE A SALPINGECTOMY, ALTHOUGH THIS PROCEDURE WAS NOT CONFIRMED AT THE TIME OF THIS REPORT, THIS CASE WAS CONSIDERED AN INCIDENT IN AGREEMENT WITH HEALTH AUTHORITY ASSESSMENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

UPON INTERNAL REVIEW REGARDING INFORMATION RECEIVED ON 01-FEB-2015, THE DEVICE SIMILAR CASE LISTING WAS UPDATED (ON 03-MAR-2015). NO NEW CLINICAL INFORMATION HAS BEEN RECEIVED. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00127	BAYER HEALTHCARE LLC	2/19/2015	2/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B11715

Single Use: Y
Implant Date (E6): 10/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4); INCIDENT - (B)(4)) IN (B)(4) ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. CONSUMER STATED THAT SHE PRESENTED LEG PAIN SINCE PROCEDURE IN (B)(6) 2013. CONSTANT HEADACHES, EYE AND VISION PROBLEMS, BLOOD CLOTS, STOMACH BLOATING, BOWEL PROBLEMS, UNEXPLAINED WEIGHT GAIN, PAIN IN THE ABDOMEN/PELVIC AREA AND COMPLETE LOSS OF LIBIDO. SHE WAS HEALTHY BEFORE THIS PROCEDURE BUT NOW EVERY DAY IS A STRUGGLE. IT WAS STATED THAT IT HAPPENED ON (B)(6) 2013, HOWEVER NOT SPECIFIED. CONSENT TO CONTACT DENIED. NO FURTHER INFORMATION PROVIDED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 01-FEB-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT

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SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: GENITAL HAEMORRHAGE: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 160 CASES. ABDOMINAL PAIN: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 253 CASES. PELVIC PAIN: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 290 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLOOD CLOTS (INTERPRETED AS GENITAL BLEEDING), PAIN IN THE ABDOMEN AND PAIN IN PELVIC AREA. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING, ABDOMINAL/PELVIC PAIN MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, TEMPORAL RELATIONSHIP BETWEEN THE ESSURE INSERTION AND THE OCCURRENCE OF THESE EVENTS IS NOT CLEAR. HOWEVER, BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT IN AGREEMENT WITH REGULATORY AUTHORITY. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION WILL BE REQUESTED BECAUSE CONSENT TO CONTACT WAS DENIED BY THE REPORTER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00129	BAYER HEALTHCARE LLC	2/19/2015	2/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2015 WHO WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4), STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING, AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR BIRTH CONTROL. THE CONSUMER STATED THAT SHE WAS STILL HEALING FROM THE MASSES OF ISSUES FROM IT. ON AN UNSPECIFIED DATE, ESSURE WAS REMOVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-FEB-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, CASE REPORT RECEIVED FROM A FEMALE CONSUMER INVOLVED IN AN

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ACTIVE ONLINE LISTENING HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATED THAT ESSURE WAS REMOVED AND STILL WAS HEALING FROM THE MASSES OF ISSUES FROM IT. THIS EVENT, CONSIDERED AS DEVICE MEDICAL REMOVAL, WAS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THIS CASE WAS REPORTED WITH LIMITED INFORMATION. SINCE THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED AND NO FOLLOW-UP WILL BE POSSIBLE; COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 02-SEP-2015 (THE PREVIOUSLY EVENT ESSURE WAS REMOVED AND STILL WAS HEALING FROM THE MASSES OF ISSUES FROM IT WAS DELETED). THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00128	BAYER HEALTHCARE LLC	2/19/2015	3/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61989

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/10/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 23-JAN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2015. THE PHYSICIAN REPORTED THAT ON (B)(6) 2015, DURING THE INSERTION OF ESSURE, THE PASSAGE THROUGH THE OPERATING CANAL WAS EASY; HOWEVER BILATERAL INSERTION WAS NOT DONE. A SUBSEQUENT LAPAROSCOPY WAS PROPOSED. DURING INSERTION, A SMALL BLACK FRAGMENT (INFERIOR TO 1MM) WAS EXTERIORIZED AT DISTAL EXTREMITY OF AN IMPLANT. THERE WAS NO CAUSE RELATED TO THE PATIENT. THE POSTOPERATIVE PERIOD WAS SIMPLE. THE TWO COMPLETE (DELIVERY HANDLE AND IMPLANT) DEVICES WERE STORED IN PHARMACY. THE LOT NUMBER OF THIS PRODUCT IS C61989. THE SURGERY REPORT FROM (B)(6) 2015 MENTIONED THAT BEFORE DOING THE PROCEDURE, THE PATIENT MADE A PREGNANCY TEST WHICH WAS NEGATIVE. AT THAT MOMENT, SHE WAS UNDER MICROPROGESTATIVE CONTRACEPTION. SHE WAS GRAVIDA 1, PARA 2 AND SHE HAS AN ANTEVERTED UTERUS. ON THAT DAY, THE PATIENT WAS SUBMITTED TO A SURGICAL INTERVENTION TO PLACE THE PERMANENT CONTRACEPTIVE ESSURE THROUGH HYSTEROSCOPY UNDER SEDATION. DURING THE HYSTEROSCOPIC EXPLORATION, THE VISUALIZATION OF OSTIA WAS CORRECT. DURING TUBAL OCCLUSION, THE INSERTION ON THE RIGHT SIDE WAS IMPOSSIBLE. DESPITE GOOD OSTIUM VISUALIZATION, OF CLASSIC ASPECT, THE TUBAL CATHETERIZATION WAS IMPOSSIBLE. DISTAL EXTREMITY OF ESSURE IMPLANT HAD AN IMMEDIATE DEFORMATION AND THE IMPLANT SPREAD OUT WITHOUT ANY MANIPULATION OF THE THUMBWHEEL. ON THE LEFT SIDE, THE INSERTION WAS IMPOSSIBLE. THERE WAS AN INEXPLICABLE FAILURE IDENTICAL TO THE ONE SEEN ON THE RIGHT SIDE. THE PROCEDURE TOOK 20 MINUTES. INCIDENTS INCLUDED THE BILATERAL INSERTION FAILURE WITH TWO DIFFERENT ESSURE INSERTS. THERE IS A DOUBT ABOUT DEVICE DEFECT AND THEREFORE TWO

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INSERTS WERE KEPT. AT PRE-OPERATIVE APPOINTMENT, THE PATIENT HAS SHOWN THE INTEREST OF HAVING A TUBAL STERILIZATION THROUGH HYSTEROSCOPY IN CASE OF ESSURE INSERTION FAILURE. THIS WOULD BE DONE SOON. NO FURTHER INFORMATION WAS PROVIDED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 04-FEB-2015: FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE AND A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE INSERTS) IMPLANTED, HOWEVER A SMALL BLACK FRAGMENT (INFERIOR TO 1MM) WAS EXTERIORIZED AT DISTAL EXTREMITY OF AN IMPLANT ON BOTH SIDES DURING INSERTION AND THERE WAS A BILATERAL INSERTION FAILURE. THE EVENT SMALL BLACK FRAGMENT (INFERIOR TO 1MM) WAS EXTERIORIZED AT DISTAL EXTREMITY OF AN IMPLANT WAS INTERPRETED AS A SUSPICION OF DEVICE BREAKAGE AND IS CONSIDERED A NON-SERIOUS EVENT AND UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. HOWEVER, UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS, THE BREAKAGE WAS AMENDED TO LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. HOWEVER, IN THIS CASE, THE PHYSICIAN STATED THE PASSAGE THROUGH THE CANAL WAS EASY. FURTHERMORE, THE PHYSICIAN STATED THAT ESSURE IMPLANTS SPREAD OUT WITHOUT ANY MANIPULATION OF THE THUMBWHEEL. BASED ON THE INFORMATION RECEIVED, AND GIVEN THE NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE. ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION IT COULD HAVE LED TO IT UNDER LESS FORTUNATE CIRCUMSTANCES. A REVIEW OF THE MANUFACTURING BATCH RECORD WAS CONDUCTED AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME, A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFECT CANNOT BE ASSESSED. THE

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PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. AN UPDATED PTC ANALYSIS IS EXPECTED AFTER RECEIPT OF COMPLAINT SAMPLE.

Manufacturer Narrative (H10):

ADDITIONAL INFORMATION RECEIVED FROM PRODUCT TECHNICAL COMPLAINT INVESTIGATION ON 26-FEB-2015: FINAL ASSESSMENT: NO BREAKAGE OF THE RETURNED DEVICES WAS DETECTED. BOTH DEVICES WERE INTACT, BUT STRETCHED. ROLLBACK DIFFICULTY IS DEFINED AS AN EVENT IN WHICH

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Report Type: MANUFACTURER **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00125	BAYER HEALTHCARE LLC	2/20/2015	2/20/2015

Event Information:

Event Date (B3): 1/22/2015 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D01976

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO DIED DURING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PROCEDURE. ADDITIONAL INFORMATION RECEIVED FROM MEDICAL DOCTOR ON (B)(6) 2015. A FEMALE PATIENT WITH NO KNOWN MEDICAL CONDITIONS PRESENTED FOR ELECTIVE PLACEMENT OF ESSURE FOR PERMANENT CONTRACEPTION. PRIOR TO THE PROCEDURE, SHE WAS ADMINISTERED TORADOL (30 MINUTES PRIOR) AND PERCOCET (60 MINUTES PRIOR). VITAL SIGNS WERE REPORTED AS NORMAL. THE PATIENT WAS PREPPED FOR THE PROCEDURE AND LIDOCAINE 1% WAS ADMINISTERED IN A PARACERVICAL BLOCK. THE LEFT FALLOPIAN TUBE WAS CANNULATED AND THE ESSURE DEVICE DEPLOYED WITHOUT INCIDENT. A SECOND BAG OF DISTENTION FLUID WAS STARTED. THE OPENING TO THE RIGHT FALLOPIAN TUBE WAS NOT WELL VISUALIZED. THE OPERATOR GENTLY PUSHED AGAINST THE SIDE OF THE UTERUS (DESCRIBED BY THE SURGEON AS PROBING) ADJACENT TO THE OPENING OF THE RIGHT FALLOPIAN TUBE WITH THE TIP OF THE ESSURE CATHETER AND ADVANCED THE CATHETER UP TO THE BLACK LINE. THE PATIENT SUDDENLY CODED. PRIOR TO CODING THE PATIENT WAS NOTED TO BE SHAKING A LOT AND EXPERIENCED GENERALIZED SEIZURE ACTIVITY. AUTOPSY (VERBAL REPORT) NOTED A 5MM PERFORATION IN THE RIGHT CORNUAL REGION ADJACENT TO THE TUBAL OSTIA WITH NO VASCULAR DAMAGE. THE PATHOLOGIST REPORTED THAT THE CAUSE OF DEATH DOES NOT APPEAR TO BE HEMORRHAGIC SHOCK AND IS NOT RELATED TO THE PROCEDURE. FOLLOW-UP RECEIVED ON (B)(6) 2015 FROM PHYSICIAN'S OFFICE MANAGER: ESSURE LOT NUMBER WAS REPORTED AS D01976 (EXPIRATION DATE: 31-AUG-2017). THE FINAL AUTOPSY REPORT IS NOT AVAILABLE YET. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD

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INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. DEATH IS NOT A KNOWN FAILURE MODE RELATED TO ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THIS PROCEDURE SHE CONVULSED AND DIED (SUDDENLY CODED DURING INSERTION) DESPITE CARDIOPULMONARY RESUSCITATION ATTEMPTS. PRELIMINARY AUTOPSY RESULTS SHOWED A PERFORATION IN THE CORNUAL REGION OF THE UTERUS NEAR THE RIGHT TUBE AND 500 CC OF BLOOD IN ABDOMEN. THE REPORTED UTERINE PERFORATION WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURES (E.G. HYSTEROSCOPY, CURETTAGE) INCLUDING INSERTION OF A FALLOPIAN TUBE OCCLUSION INSERT (ESSURE). THEREFORE, THE REPORTED UTERINE PERFORATION WAS REGARDED AS RELATED TO THE SUSPECT INSERT. THIS CASE WAS CONSIDERED AN INCIDENT, AS ALTHOUGH THE EXACT CAUSE OF PATIENT'S DEATH WAS NOT CLARIFIED (AUTOPSY FINAL REPORT IS PENDING), AN ASSOCIATION WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, SINCE DEATH OCCURRED DURING ESSURE PLACEMENT PROCEDURE. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION (FINAL AUTOPSY RESULTS) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 19-MAR-2015. IT WAS REPORTED THE AUTOPSY WAS DONE ON (B)(6); THE CAUSE OF PATIENT'S DEATH IS STILL UNDER INVESTIGATION. THE COMPLETE REPORT (HISTOLOGY SLIDES AND TOXICOLOGY RESULTS) ARE EXPECTED. REPORTER STATED THAT THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00132	BAYER HEALTHCARE LLC	2/20/2015	2/20/2015

Event Information:

Event Date (B3): 12/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS000N0

Single Use: Y
Implant Date (E6): 12/10/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR VIA SALES REPRESENTATIVE IN UNITED STATES ON 23-JAN-2015 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER CS000N0 ON (B)(6) 2014. PHYSICIAN WAS ATTEMPTING TO PLACE AN ESSURE AND THE ESSURE PERFORATED INTO THE ABDOMINAL CAVITY (SIDE UNKNOWN TO REPORTER AT THIS TIME) AND NO COILS WERE PLACED. THE ESSURE PERFORATED WHILE IT WAS STILL IN THE DEVICE AND WAS NOT RELEASED FROM THE DEVICE. SHE GOT A TUBAL LIGATION (DATE UNKNOWN TO REPORTER AT THIS TIME). THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 10-FEB-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A

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CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). THE ESSURE PERFORATED INTO THE ABDOMINAL CAVITY BEFORE IT WAS RELEASED FROM THE DEVICE AND NO COILS WERE PLACED. SHE UNDERWENT A TUBAL LIGATION. THE PERFORATION OF ABDOMINAL CAVITY, INTERPRETED AS UTERINE PERFORATION, IS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING THE INSERTION OF ESSURE INTO THE FALLOPIAN TUBES. MOST OFTEN, IT OCCURS DURING INSERTION. CONSIDERING THE NATURE OF THIS EVENT AND THAT IN THIS PARTICULAR CASE, THE PERFORATION OCCURRED DURING INSERTION, THE PERFORATION IS CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 24-MAR-2014 BY PHYSICIAN (PERFORATION QUESTIONNAIRE): PATIENT'S INITIALS, WEIGHT AND HEIGHT WERE UPDATED. HER MEDICAL HISTORY INCLUDES GRAVIDA 2, PARA 2. PATIENT WAS NOT POST-PARTUM WHEN ESSURE WAS INSERTED. THE SOUNDING AND CERVICAL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040783	BAYER	2/20/2015	2/20/2015

Event Information:

Event Date (B3): 2/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED ON (B)(6) 2014. I HAD SOME PAIN AFTER PLACEMENT BUT I ALSO HAD BLEEDING WHICH DID NOT STOP FROM THE TIME OF PLACEMENT UNTIL I HAD A HYSTERECTOMY ON (B)(6) 2014. THE PAIN WAS ANYWHERE FROM SHARP PELVIC PAIN TO A CONSTANT ACHE. THE PAIN WOULD SHOOT DOWN MY LEFT LEG, MY HIPS HURT, MY KNEES WOULD ACHE. MY HAIR WAS FALLING OUT, MY SCALP, AND SKIN WOULD ITCH. TERRIBLE BRAIN FOG, BLOATING THAT WOULD MAKE ME LOOK PREGNANT. UNDER MY IMPLANTING DOCTORS CARE WE TRIED BIRTH CONTROL PILLS, HAD BLOOD WORK DONE TO RULE OUT ABNORMALITIES/INFECTION WHICH MY RESULTS CAME BACK NORMAL. AFTER BEING IN PAIN WITH NO APPARENT CAUSE AND BLEEDING THAT WOULD ONLY STOP SPORADICALLY FOR A MAX OF A WEEK AT A TIME DURING THE MONTH MY DR AND I DECIDED A HYSTERECTOMY WOULD BE THE BEST ROUTE. I AM 2 WEEKS POST OP AND THE PAIN IS GONE, MY JOINTS NO LONGER ACHE AND I'VE NOTICED THAT MY WRISTS ARE NORMAL. I DIDN'T NOTICE THAT THEY WERE SWOLLEN BEFORE UNTIL AFTER SURGERY. I DID NOT HAVE ANY OF THESE SYMPTOMS PRIOR TO ESSURE. MY MENSTRUAL CYCLE WAS REGULAR PRIOR TO ESSURE ALSO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040786	BAYER	2/20/2015	2/20/2015

Event Information:

Event Date (B3): 12/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NOW DIABETIC. HAVE "TACACARDIA". HAD SHINGLES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040801	BAYER	2/20/2015	2/20/2015

Event Information:

Event Date (B3): 9/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INSOMNIA, PELVIC PAIN, DAILY MIGRAINES, BLOATING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00130	BAYER HEALTHCARE LLC	2/20/2015	2/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 23-JAN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. IT WAS REPORTED THAT ON AN UNSPECIFIED DATE, THE PATIENT EXPERIENCED HEADACHES. ESSURE WAS REMOVED ON (B)(6) 2015. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-FEB-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEADACHES. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO

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ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; HOWEVER CONSIDERING THAT HEADACHES HAS BEEN REPORTED AS POSSIBLE ADVERSE EVENT DURING ESSURE THERAPY A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN INCIDENT SINCE ESSURE DEVICE WAS REMOVED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 21-MAY-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00131	BAYER HEALTHCARE LLC	2/20/2015	3/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91766

Single Use: Y
Implant Date (E6): 1/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR VIA SALES REPRESENTATIVE IN UNITED STATES ON 23-JAN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C91766 INSERTED ON (B)(6) 2015 FOR STERILIZATION. REPORTER STATED IT WAS A UNILATERAL PLACEMENT ONLY (DID NOT KNOW WHICH SIDE). PROVIDER ATTEMPTED TO PUT THE FIRST MICRO INSERT, AFTER THE SECOND ATTEMPT, IT WAS NOT DEPLOYING AS IT SHOULD. THE PROVIDER TRIED TO WIGGLE THE HANDLE, AND WAS ABLE TO DEPLOY THE COIL. SHE WENT TO ATTEMPT ON THE OTHER SIDE, IT WAS THE SAME ISSUE, IT DIDN'T DEPLOY. SHE TRIED TO WIGGLE, AND IT DIDN'T WORK. WHEN SHE WENT TO WITHDRAW THE ENTIRE DELIVERY SYSTEM, THE DISTAL PORTION OF THE COIL WAS STILL IN THE PATIENT. THE MICRO INSERT OR DELIVERY WIRE UNRAVELLED, NOT SURE WHICH ONE. SHE HAD TO USE SCISSORS TO CUT WHAT WAS UNRAVELLED. THEN SHE USED HYSTEROSCOPIC GRASPERS TO REMOVE WHAT WAS LEFT ON THE PATIENT. SHE WAS ABLE TO REMOVE IT, AND TRIED TO INSERT ANOTHER. THE SAME THING HAPPENED, IT DIDN'T DEPLOY. IT DIDN'T UNRAVEL THOUGH. SO SHE TERMINATED THE PROCEDURE. ESSURE WAS ONGOING. (B)(4). FINAL ASSESSMENT FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT

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IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY ARE ANTICIPATED EVENTS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE AFTER THE SECOND ATTEMPT, IT WAS NOT DEPLOYING AS IT SHOULD; WHEN PHYSICIAN TRIED TO WITHDRAW THE ENTIRE DELIVERY SYSTEM DISTAL PORTION OF THE COIL WAS STILL IN THE PATIENT (INTERPRETED AS SUSPICION OF DEVICE BREAKAGE), MICRO INSERT OR DELIVERY WIRE UNRAVELLED, SO SHE HAD TO USE SCISSORS TO CUT WHAT WAS UNRAVELLED AND FINALLY ACHIEVED UNILATERAL PLACEMENT/ SHE TERMINATED THE PROCEDURE. THESE EVENTS ARE NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR THE SUSPICION OF DEVICE BREAKAGE WHICH IS UNLISTED. HOWEVER, UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS, THE BREAKAGE WAS AMENDED TO LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, BASED ON THE AVAILABLE INFORMATION, A DEVICE BREAKAGE IS SUSPECTED. HOWEVER, CONSIDERING THAT THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED (EXCEPT FOR THE EVENT HAD TO USE SCISSORS TO CUT WHAT WAS UNRAVELLED WHICH WAS CONSIDERED UNRELATED TO ESSURE DUE TO ITS NATURE). THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE SUSPICION OF DEVICE BREAKAGE THAT COULD HAVE LED TO DEATH OR SERIOUS HEALTH DETERIORATION UNDER LESS FORTUNATE CIRCUMSTANCES. A REVIEW OF THE MANUFACTURING BATCH RECORD WAS CONDUCTED AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME, A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFECT CANNOT BE ASSESSED. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 24-JUN-2015: FOLLOW UP INFORMATION RECEIVED FROM THE PHYSICIAN. PATIENT'S WEIGHT WAS ADDED, (B)(6) LBS. NO PREVIOUS GYNECOLOGICAL INTERVENTIONS AS CERVICAL CONIZATION, CURETTAGE, MYOMECTOMY OR ADNEXAL SURGERY WERE PERFORMED. NO PREVIOUS IUS/IUD

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040930		2/21/2015	2/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/31/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAVE HAD THE ESSURE IMPLANTS, I HAVE EXPERIENCED HORRIBLE HEADACHES AND HEAVIER BLEEDING THAN NORMAL DURING MY MENSTRUATION. I WOULD LOVE TO HAVE THESE REMOVED, BUT CANNOT AFFORD THE REMOVAL SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040931		2/21/2015	2/27/2015

Event Information:

Event Date (B3): 2/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/5/2008
Explant Date (E7): 2/8/2010
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A DEVICE CALLED ESSURE PUT IN ME TO PREVENT PREGNANCY AND THE DEVICE CAUSED ME TO HAVE A REACTION AND I ENDED UP HAVING TO GET IT REMOVED ALONG WITH MY UTERUS, FALLOPIAN TUBES AND OVARIES. THE ESSURE COILS CAUSED THIS AND I BECAME SEPTIC AND I ALMOST DIED AND HAD MANY SURGERY BECAUSE OF THIS. I AM NOW IN SURGICAL MENOPAUSE AND HAVE A BIG SCAR FROM ALL THE SURGERIES. I HAVE SUFFERED SO MUCH FROM THIS DEVICE. THIS DEVICE RUINED MY LIFE AND SHORTENED MY LIFESPAN. I AM LUCKY TO BE ALIVE. THIS DEVICE SHOULD NOT BE PUT INTO HUMANS. I LOST MY REPRODUCTIVE SYSTEM OVER THIS. I HAVE TO BE ON MEDICATIONS EVERYDAY BECAUSE OF THIS. I HAVE ALL MY RECORDS IF YOU NEED ME TO FAX THEM OR MAIL COPIES AND TONS OF PHOTOS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00133	BAYER HEALTHCARE LLC	2/23/2015	2/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. THE CONSUMER STATED THAT SHE HAD THE ESSURE PROCEDURE IN 2013 AND SHE HAD SINCE BECOME PREGNANT. SHE HAD SINCE LOOKED UP THAT SHE SHOULD NOT HAVE HAD ONE FITTED IN JUST ONE TUBE OR IN BLOCKED TUBES. THE HOSPITAL WAS REFUSING TO TAKE HER CALLS; SHE THOUGHT IT WAS BECAUSE SHE WAS TAKING LEGAL ACTION AGAINST THE DOCTOR. SHE HAD NO PROBLEM AT ALL WITH ESSURE, JUST WITH THE DOCTOR. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON (B)(6) 2015: SHE IS CURRENTLY MAKING A COMPLAINT TO THE HOSPITAL AND CONSULTANT WHO FITTED THE ESSURE AS SHE DID NOT THINK THAT SHE WAS A SUITABLE CANDIDATE AS SHE HAS A BLOCKED TUBE. SHE STATED THAT IN 2009 SHE HAD A IVF (IN VITRO FERTILIZATION) DUE TO BLOCKED TUBES AND ALSO EXPERIENCED A ECTOPIC PREGNANCY. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON (B)(6) 2015: CONSUMER HAD ESSURE INSERTED IN 2013 AND HAD ONLY ONE TUBE AS SHE HAD LOST ONE IN 2009. SHE HAD FOUND OUT THAT THE 100 PERCENT JOB DID NOT WORK AND SHE IS PREGNANT AGAIN AT A HIGHER RISK TO THE AGE AND DISABILITIES IN HER FAMILY. SHE WAS DEVASTATED TO LEARN THAT DOCTORS PERFORM THIS WITHOUT GIVING HER FULL KNOWLEDGE OF THE SIDE EFFECTS; IT'S NEVER FAILED, IS WHAT SHE WAS TOLD. SHE DID NOT KNOW IF SHE WILL BE HARMED OR IF THE BABY WILL BE HARM, OR THE LONG TERM EFFECTS. SHE WAS NOT INFORMED OF THE DIFFICULTY OF GETTING THE DEVICE OUT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015: MHRA REFERENCE WAS RECEIVED AS (B)(4). FOLLOW-UP FROM (B)(6) 2015: NO RESPONSE TO FURTHER FOLLOW UP ATTEMPTS FOR ADDITIONAL INFORMATION/ CLARIFICATION FROM CONSUMER. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT REFERS TO A FEMALE

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PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, CONSUMER STATED SHE WAS NOT A SUITABLE CANDIDATE FOR ESSURE SINCE SHE HAD ONLY ONE TUBE DUE TO A PREVIOUS ECTOPIC PREGNANCY. ALTHOUGH NO INFORMATION WAS PROVIDED ABOUT ESSURE INSERTION PROCEDURE OR CONFIRMATION TEST, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NO COMPLICATIONS RELATED TO THE PREGNANCY WERE REPORTED, NEVERTHELESS THIS EVENT WAS REGARDED AS SERIOUS AND THIS CASE WAS CONSIDERED AN INCIDENT, IN LINE WITH HEALTH AUTHORITY REQUIREMENTS. FURTHER INFORMATION COULD NOT BE OBTAINED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 09-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: PER THE PATIENT REPORT, SHE HA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00134	BAYER HEALTHCARE LLC	2/23/2015	2/24/2015

Event Information:

Event Date (B3): 2/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 796910

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER IN UNITED STATES ON (B)(6)2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER 796910 INSERTED ON (B)(6) 2011 TO PREVENT PREGNANCIES, AND BECAME PREGNANT DURING ITS USE IN (B)(6)2012 (FOR MORE INFORMATION, REFER TO (B)(4)). THIS REPORT REFERS TO HER NEONATE (<1M), A FEMALE CHILD, WHO WAS BORN ON (B)(6)2013. ADDITIONAL INFORMATION RECEIVED FROM PHYSICIAN. DURING DELIVERY, THERE WAS FETAL DECELERATION (HEART RATE DECREASED) AND INCREASED FREQUENCY UTERINE CONTRACTIONS, WHICH WERE LONG AND PAINFUL. THE CONSUMER REQUESTED A C-SECTION AND AFTER DISCUSSING THE RISKS VERSUS BENEFITS, THE DOCTOR PERFORMED THE PROCEDURE ON (B)(6) 2013. THE CHILD WAS BORN 5 WEEKS EARLY AND WAS TINY, BUT OTHERWISE PERFECT. NO CAUSALITY ASSESSMENT WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: MANUFACTURING DATE: 11/2010 EXPIRATION DATE: 11/2013. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. HOWEVER, THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 9 FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, OF WHICH 2 CASES (LINKED CASES) REFER ALSO TO SIMILAR ADVERSE TYPES OF EVENTS. NO

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UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE NEONATE WHO HAD ESSURE MICRO-INSERT EXPOSURE IN UTERO AND EXPERIENCED FETAL DECELERATION (HEART RATE DECREASED) IN UTERO. SHE WAS BORN 5 WEEKS EARLY VIA C-SECTION. ALL REPORTED EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE; EXCEPT FOR ESSURE MICRO-INSERT EXPOSURE IN UTERO WHICH IS NON-SERIOUS AND LISTED. MOST OF PREMATURE BIRTHS OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES (E.G. PREECLAMPSIA, PLACENTA PREVIA, ABRUPTIO PLACENTA, FETAL GROWTH RESTRICTION). THESE EVENTS MAY POSE SIGNIFICANT RISKS OF MORBIDITY AND MORTALITY FOR BOTH THE FETUS AND THE MOTHER. IN THIS CASE, GIVEN THE GESTATIONAL AGE AT BABY'S BIRTH, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THE REPORTED EVENTS WERE THUS, CONSIDERED AS RELATED TO THE SUSPECT INSERT AND THIS CASE REGARDED AS AN INCIDENT (SERIOUS INJURY). A PRODUCT TECHNICAL COMPLAINT ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041114	BAYER HEALTH	2/23/2015	3/6/2015

Event Information:

Event Date (B3): 12/3/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE COILS IN (B)(6) 2007. I STARTED HAVING SEVERE BACK PAIN, HAIR LOSS, WEIGHT GRAIN, PAIN DURING SEX, DEPRESSION, AND EVENTUALLY DUE TO COMPLICATIONS I NEEDED A HYSTERECTOMY. IF I WAS INFORMED BY MY DOCTOR OR ANYONE OF THESE COMPLICATIONS I NEVER WOULD HAVE GOTTEN THIS PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041126	BAYER	2/23/2015	3/6/2015

Event Information:

Event Date (B3): 1/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/6/2015
Explant Date (E7): 2/20/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE PROCEDURE DONE (B)(6) 2015 AND MY DOCTOR MADE IT SOUND SAFE AND THE BEST WAY FOR ME TO GO AND WOULD HAVE NO DOWN TIME. I HAD SEVERE PAIN AND CRAMPING IN MY PELVIS FROM THE START. THEN OTHER SYMPTOMS STARTED SHORTLY AFTER, INCLUDING LEG PAIN, HIP PAIN, HEADACHES, MAJOR FATIGUE, OFF AND ON BLEEDING, WEIGHT LOSS AND APPETITE. FELT LIKE I WAS GIVING BIRTH EVERYDAY. SOME DAYS WERE SO BAD I COULDN'T GET OUT OF BED. I MISSED 15 DAYS OF WORK, MADE 2 ER TRIPS AND 1 CT SCAN. MY DOCTOR AND I FINALLY MADE THE DECISION TO REMOVE THE COILS WHICH WOULD RESULT IN BOTH TUBES BEING REMOVED TO PREVENT MORE COMPLICATIONS AND ANY MORE SEVERE PAIN. ON (B)(6) 2015 I HAD MY SURGERY TO HAVE BOTH MY TUBES REMOVED. NOW I'M MISSING 2 WEEKS OF WORK TO RECOVER FROM MY SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041693	BAYER	2/23/2015	4/1/2015

Event Information:

Event Date (B3): 3/19/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06513

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE FAILED TO FIRE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00135	BAYER HEALTHCARE LLC	2/24/2015	2/24/2015

Event Information:

Event Date (B3): 1/26/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C95077

Single Use: Y
Implant Date (E6): 1/26/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO GET ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C95077. IT WAS REPORTED THAT HCP WAS REMOVING LEFT MICRO INSERT DUE TO 14 TRAILING COILS. PATIENT WAS GOING TO DO A D+C (INTERPRETED AS DILATION AND CURETTAGE) IN O.R (OPERATIVE ROOM) AND LAP TUBAL ON THAT SIDE. PATIENT HAD NO INJURY; BILATERAL PLACEMENT WAS NOT ACHIEVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND PHYSICIAN REMOVED THE DEVICE SINCE THERE WAS 14 TRAILING COILS ON LEFT SIDE. ADDITIONALLY, REPORTED STATED HE WOULD DO A DILATION AND CURETTAGE AND A TUBAL LIGATION ON THE SAME SIDE. THE REPORTED EVENT, REGARDED AS DEVICE DEPLOYMENT ISSUE, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS, ESSURE MICRO-INSERT PLACEMENT MAY BE UNSUCCESSFUL. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED, NEVERTHELESS CONSIDERING THE REPORTED EVENT OCCURRED IN ASSOCIATION WITH ESSURE INSERTION PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. FOLLOW-UP INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON 26-FEB-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00136	BAYER HEALTHCARE LLC	2/24/2015	2/24/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A REPORTER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN AN ESSURE GENERIC ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4)/AOL AND FOUND OUT THAT ESSURE DIDN'T TAKE ON ONE SIDE. CONSUMER ALSO REPORTED THAT, PREVIOUSLY, SHE HAD MIRENA (LEVONORGESTREL) INSERTED FOR 5 MONTHS; SHE STATES THAT SHE BLEW UP AND HER HAIR FELL OUT AT AN ALARMING RATE. ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2014. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: THE CONSUMER REPORTED SHE GOT ESSURE WHEN SHE HAD MIRENA REMOVED AND ONE OF COLIS TRAVELLED AND ONE TUBE DID NOT CLOSE. SHE WOULD HAVE ONE TUBE TIED. FOLLOW-UP RECEIVED ON (B)(6) 2014: ON AN UNSPECIFIED DATE THE CONSUMER UNDERWENT A TUBAL LIGATION (SHE REPORTED SHE TIED ONE TUBE BECAUSE ESSURE DIDN'T TAKE ON ONE SIDE). FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: IT WAS REPORTED THAT MIRENA WAS USED FOR CONTRACEPTION. IT WAS REPORTED THAT THE CONSUMER EXPERIENCED WEIGHT GAIN, LOST HAIR AND NEVER WANTS SEX. SHE CONSIDERED THE EVENTS RELATED TO MIRENA. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT:

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THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP RECEIVED ON (B)(6) 2014: CONSUMER REPORTED THAT SHE HAD A BABY LAST YEAR AND STATED THAT IT DID NOT MAKE HER FAT BUT MIRENA DID. THEN SHE GOT ESSURE AND FOUND OUT MANY PEOPLE GOT FAT FROM THAT TOO. ACCORDING TO CONSUMER SHE NEEDS TO LOSE 50 POUNDS AT LEAST AND STATED THAT SHE IS (B)(6) YEARS OLD SO HER METABOLISM SURE IS NOT WHAT IT WAS. IN ADDITION CONSUMER REPORTED THAT SHE HAD NO WILL POWER AND DISCIPLINE AND BELIEVED SHE IS ADDICTED TO FOOD, SHE INFORMED THAT SHE COULD NEVER STAY EATING HEALTHILY AND SHE DRINKS. SHE ALSO REPORTED THAT SHE HAD 3 KIDS INCLUDING A BABY AND 3 STEP KIDS SO BY THE TIME SHE WORKS, GOES HOME, COOKS AND CLEANS UP SOME SHE IS TOO EXHAUSTED TO EXERCISE. CONSUMER INFORMED THAT SHE IS PRETTY TOUGH BUT SHE HATES HER BODY. FOLLOW-UP (B)(6) 2015: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. CONSUMER REPORTED THAT AFTER SHE HAD A BABY SHE GOT A MIRENA INSERTED AND AFTER THAT SHE HAD ESSURE INSERTED. SHE STATED THAT SHE DIDN'T RECOMMEND BECAUSE SHE HAS GAINED SO MUCH WEIGHT AND HER JOINT HURT AND HER FALLOPIAN TUBES FEEL AS IF THEY WILL EXPLODE PRIOR TO AND DURING HER PERIOD. FOLLOW-UP INFORMATION POSTED ONLINE BY THE CONSUMER ON (B)(6) 2014, (B)(6) 2014 AND (B)(6) 2015 AND COLLECTED BY THE COMPANY ON (B)(6) 2015. HER LAST DELIVERY TOOK PLACE IN (B)(6) 2013 AND SHE HAD GAINED ONLY 12 POUNDS DURING PREGNANCY. AFTER THAT, IN (B)(6) 2013, SHE GOT MIRENA INSERTED. OVER THE NEXT 5 MONTHS, SHE GAINED 30 POUNDS (REPORTED PREVIOUSLY AS ON MIRENA FOR 5 MONTHS I BLEW UP) AND LOST HALF OF HER HAIR. ACCORDING TO HER, THE SAME HAPPENED IN THE PAST WHILE SHE WAS ON DEPO. SHE HAD IT REMOVED AND IN (B)(6) 2013 SHE HAD ESSURE INSERTED. SHE RECEIVED XANAX BEFORE THE PROCEDURE AND ALL WENT FINE; SHE WAS OUT OF THE OFFICE WITHIN AN HOUR AND HAD ONLY MINIMAL BLEEDING. IN (B)(6) 2014 SHE HAD THE CONFIRMATION TEST PERFORMED TO MAKE SURE THAT BOTH TUBES WERE OCCLUDED. ONE OF THE COILS HAD TRAVELLED AND THE RESPECTIVE TUBE WAS NOT BLOCKED, SO SHE HAD A TUBAL LIGATION PERFORMED ON THAT SIDE AS AN OUTPATIENT SURGERY UNDER GENERAL ANESTHESIA. ACCORDING TO HER, SHE THEN NOTICED THAT HER LEGS AND KNEES STARTED HURTING. SINCE (B)(6) 2014 HER HIPS, BACK AND FALLOPIAN TUBES HURT BEFORE HER MENSTRUATION; SHE CAN TOLERATE THE PAIN, BUT IT FEELS LIKE SHE IS GOING TO EXPLODE AND IT HURTS WHEN SHE SLEEPS ON HER SIDE. SHE THINKS THAT THIS IS RELATED TO ESSURE. SHE CONTINUES GAINING WEIGHT. FOLLOW-UP INFORMATION ON (B)(6) 2015 FROM CONSUMER: SHE STATED THAT HER TUBES WERE MUTILATED BY A BOTCHED ESSURE. CASE UPGRADED TO INCIDENT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AFTER THE REMOVAL OF MIRENA (LEVONORGESTREL) AND HAD ONLY MINIMAL BLEEDING AFTER ESSURE INSERTION (INTERPRETED AS POST PROCEDURAL BLEEDING). LATER ONE OF THE COILS TRAVELLED (INTERPRETED ESSURE MIGRATION). SHE ALSO STATED HER TUBES WERE MUTILATED. ALL EVENTS WERE CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR MUTILATED FALLOPIAN TUBES, WHICH IS UNLISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING CAN OCCUR; THUS CAUSALITY BETWEEN THE REPORTED POST PROCEDURAL BLEEDING AND THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, THE CONSUMER REPORTED THAT ONE OF ESSURE COILS TRAVELLED, AND SINCE TUBAL OCCLUSION FAILED TO OCCUR ON ONE SIDE, SHE UNDERWENT TUBAL LIGATION. SINCE IT IS NOT CLEAR FROM THE AVAILABLE INFORMATION IF THE REPORTED MUTILATED FALLOPIAN TUBES REFERS TO THIS SURGERY AND AS NO FOLLOW-UP WILL BE POSSIBLE IN THIS CASE (SOCIAL MEDIA CASE), COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE REPORTED TERM "MUTILATION" THIS CASE; INITIALLY REGARDED AS NON-INCIDENT WAS UPGRADED TO INCIDENT DUE TO SERIOUS INJURY. ADDITIONALLY, NON-SERIOUS EVENT WERE REPORTED. ACCORDING TO THE UPDATED PRODUCT TECHNICAL INVESTIGATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00137	BAYER HEALTHCARE LLC	2/26/2015	2/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON 20-JAN-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT ESSURE LEAD TO A DEATH OF A CONSUMER DURING SURGERY FOR REMOVAL. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 22-JAN-2015: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE ARE NO KNOWN DEATH CASES WHICH WERE CONFIRMED TO BE CAUSED BY ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE AND IS CONSIDERED NOT ASSESSABLE BY THE COMPANY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). ON 28-JAN-2015, UPON INTERNAL REVIEW, COMPANY REASSESSED DEATH DURING SURGERY REMOVAL AS RELATED TO ESSURE. FOLLOW-UP INFORMATION RECEIVED ON 28-JAN-2015 AND ADDITIONAL INFORMATION RECEIVED FROM PRODUCT TECHNICAL COMPLAINT (PTC)

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ANALYSIS ON 30-JAN-2015: CONSUMER HAD 2 CHILDREN. IT WAS REPORTED THAT THE CONSUMER DIED DUE TO AN EMBOLISM DURING A SURGERY TO REMOVE HER REPRODUCTIVE ORGANS. SHE HAD TO UNDERGO THIS PROCEDURE DUE TO PROBLEMS WITH ESSURE. ACCORDING TO PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS RECEIVED, THE SYMPTOMS/DEATH REPORTED COULD NOT BE CONFIRMED. EMBOLISM AND DEATH ARE NOT RELATED FAILURE MODES TO ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT RECEIVED VIA SOCIAL MEDIA REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DIED OF AN EMBOLISM DURING A SURGERY TO REMOVE HER REPRODUCTIVE ORGANS. CONSUMER HAD TO UNDERGO THIS PROCEDURE (INTERPRETED AS HYSTERECTOMY) DUE TO PROBLEMS WITH ESSURE. THE REPORTED EVENT DIED OF AN EMBOLISM DURING A SURGERY TO REMOVE HER REPRODUCTIVE ORGANS WAS CONSIDERED SERIOUS DUE TO ITS FATAL OUTCOME AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT INTERPRETED AS HYSTERECTOMY WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED. EMBOLIC EVENTS ARE KNOWN AS POSSIBLE COMPLICATION OF SURGICAL PROCEDURES. THIS CASE WAS REPORTED WITH LIMITED INFORMATION, NEITHER TYPE OF EMBOLISM NOR ADDITIONAL RISK FACTORS WERE PROVIDED. ALTHOUGH THE EXACT REASON FOR REPRODUCTIVE ORGANS REMOVAL WAS NOT SPECIFIED BUT IT WAS MENTIONED THAT THE PROCEDURE OCCURRED DUE TO PROBLEMS WITH ESSURE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THUS, THIS CASE WAS REGARDED AS INCIDENT DUE TO THE SURGICAL INTERVENTION AND FATAL OUTCOME. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). ACCORDING TO FINAL ASSESSMENT, EMBOLISM AND DEATH ARE NOT RELATED FAILURE MODES TO ESSURE. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00138	BAYER HEALTHCARE LLC	2/26/2015	2/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A STUDY CASE REPORT POSTED ONLINE BY A CONSUMER IN UNITED STATES AND RECEIVED BY BAYER ON 15-JAN-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. THE CONSUMER STATED THAT ESSURE CAUSED HER PAIN AND PROBLEMS (UNSPECIFIED). THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 01-FEB-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN THIS PARTICULAR CASE, PAIN AND NOT FURTHER SPECIFIED PROBLEMS WERE REPORTED. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 29 AND ON 30-JAN-2015. THE CASE WAS UPGRADED TO SERIOUS AND TO INCIDENT. THE CONSUMER STATED THAT ESSURE MADE HER MAD, CRY, BLOATED, ITCHY, RED AND HOT. SHE EVEN GOT PREGNANT

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AGAIN (ESSURE FAILURE). SHE ALSO REPORTED A COIL MIGRATION, MOOD SWINGS, PRICELESS, HYSTERECTOMY AND TUBAL LIGATION. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS UPDATED ON 18-FEB-2015: THE FINAL ASSESSMENT WAS: THIS CASE UPGRADED TO INCIDENT DUE TO HYSTERECTOMY FOR THIS SOCIAL MEDIA CASE WHICH IS NOT CONFIRMED. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND COIL MIGRATION AND PREGNANCY HAVE OCCURRED. THE FIRST EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCY IS NON-SERIOUS AND ALSO LISTED. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION OR A DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). THUS, GIVEN ITS NATURE, THE DISLOCATION IS ASSESSED AS RELATED TO ESSURE USE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED AND IT IS NOT POSSIBLE TO KNOW WHEN THIS DISLOCATION REALLY OCCURRED, IF IT WAS BEFORE OR AFTER THE CONCEPTION, THEREFORE, A DEVICE INEFFICACY CANNOT BE TOTALLY EXCLUDED. INITIALLY ONLY NON-SERIOUS EVENTS WITHOUT INTERVENTIONS WERE MENTIONED, THE CASE WAS THEN REGARDED AS NON-SERIOUS AND NON-INCIDENT. AFTER RECEIPT OF FOLLOW UP INFORMATION, SERIOUS EVENT AND TUBAL LIGATION AND HYSTERECTOMY WERE REPORTED, HENCE THIS CASE WAS UPGRADED TO SERIOUS AND INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00141	BAYER HEALTHCARE LLC	2/26/2015	4/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38216

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/9/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 30-JAN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). ESSURE WAS INSERTED EASILY AND DISCHARGED, BUT IMPLANT DID NOT GET OFF NORMALLY. WHEN THE IMPLANT GOT OFF FROM CATHETER IT MADE A KINK, IMPLANT WAS REMOVED. NO FURTHER INFORMATION PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). ESSURE WAS INSERTED EASILY AND DISCHARGED, BUT IMPLANT DID NOT GET OFF NORMALLY. WHEN THE IMPLANT GOT OFF FROM CATHETER IT MADE A KINK, IMPLANT WAS REMOVED. THESE EVENTS ARE CONSIDERED NON-SERIOUS AND LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE IS A FLEXIBLE IMPLANT DEVICE THAT ALLOWS THE INSERT TO BEND AND FLEX BACK WHEN ENCOUNTERING ANATOMICAL ISSUES SUCH AS STENOTIC FALLOPIAN TUBES, A UTERINE WALL, FIBROIDS, ENDOMETRIAL FLUFF, OR A TUBAL SPASM. HANDLING ERRORS, DEVIATIONS FROM THE INSTRUCTIONS FOR USE, NON-PRODUCT RELATED ANATOMICAL ISSUES, OR OTHER CUSTOMER SATISFACTION ISSUES ARE FACTORS THAT CAN CAUSE THE SHAPE ALTERATION OF ESSURE. CONSIDERING THE NATURE OF EVENT, IT IS CONSIDERED RELATED TO ESSURE. IN LINE WITH LOCAL REQUIREMENTS, THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT SINCE THIS DEVICE ISSUE COULD HAVE LED A SERIOUS OR NON-SERIOUS INJURY. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 10-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE PRODUCT WAS RETURNED TO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00140	BAYER HEALTHCARE LLC	2/26/2015	4/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** AS

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51348

Single Use: Y
Implant Date (E6): 1/29/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/6/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HOSPITAL'S SUPPLY MANAGER ON BEHALF OF PHYSICIAN IN (B)(6) ON 30-JAN-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN COMMENT THAT DESPITE CAREFUL ADHERENCE TO PRODUCT INFORMATION/SPECIFICATION, THE COIL DID NOT RELEASE FROM INTRODUCER AND IT NEED TO BE PULLED OUT. REPORTED STATED THAT IT DID NOT CAUSE ANY HARM TO THE PATIENT BUT THE POSSIBILITY EXISTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND THE COIL DID NOT RELEASE FROM INTRODUCER AND PHYSICIAN NEEDED TO PULLED IT OUT. THE REPORTED EVENTS, REGARDED AS DEVICE DEPLOYMENT ISSUE FOLLOWED BY A FAILED INSERTION WERE CONSIDERED NON-SERIOUS AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS, ESSURE PLACEMENT MAY BE UNSUCCESSFUL; IN THIS PARTICULAR CASE A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THE REPORTED EVENTS; HOWEVER CONSIDERING THAT THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS THE REPORTER STATED THE EVENTS DID NOT CAUSE ANY HARM TO THE PATIENT BUT THE POSSIBILITY EXISTED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

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RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-MAR-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM.

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00142	BAYER HEALTHCARE LLC	2/26/2015	4/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61984

Single Use: Y
Implant Date (E6): 1/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 29-JAN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER C61984). ON (B)(6) 2015, WHILE ESSURE INSERTS WERE PLACING IN THE FALLOPIAN TUBES, SMALL PLASTIC DEPOSITS AT 4CM FROM THE EXTREMITY DETACHED FROM THE SYSTEM IN THE UTERUS. EVENT OBSERVED DURING THE PLACEMENT (IN OPERATING ROOM). THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS PERFORMED WITH THE INSERT C61984. ESSURE SYSTEM WAS NOT KEPT. IT WAS PLACED. THE POST-OPERATIVE COURSE: SMALL PLASTIC DEPOSITS IN THE UTERUS. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING PLACEMENT SMALL PLASTIC DEPOSITS AT 4 CM FROM THE EXTREMITY DETACHED FROM THE SYSTEM IN THE UTERUS. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE AND COMPLICATION OF DEVICE INSERTION, IS NON-SERIOUS. DEVICE BREAKAGE IS AN UNLISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THIS CASE, WHILE ESSURE WAS BEING PLACED IN THE FALLOPIAN TUBES, SMALL PLASTIC DEPOSITS AT 4CM FROM THE EXTREMITY DETACHED FROM THE SYSTEM IN THE UTERUS. BILATERAL PLACEMENT WAS ACHIEVED. SINCE BREAKAGE WAS REPORTED AND OCCURRED DURING INSERTION PROCEDURE, CAUSALITY WITH ESSURE IS ASSESSED AS RELATED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW UP INFORMATION HAVE BEEN REQUESTED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 27-FEB-2015. (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00139	BAYER HEALTHCARE LLC	2/27/2015	2/27/2015

Event Information:

Event Date (B3): 1/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** AS

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50748021, C68799

Single Use: Y
Implant Date (E6): 1/28/2015
Explant Date (E7): 1/28/2015
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/6/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2015 FOR PERMANENT FEMALE CONTRACEPTION. REPORTER STATED THAT FIRST ESSURE FAILED TO DEPLOY (LOT NUMBER 50748021, EXPIRATION DATE (B)(6) 2016) AND THEN PERFORATION OF UTERUS OCCURRED FOR SECOND DEVICE (LOT NUMBER C68799, EXPIRATION DATE (B)(6) 2017). BOTH INSERTS ARE AWAITING PICK UP FROM HOSPITAL BY BIOHAZARD COURIER. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). HOWEVER, THE FIRST ESSURE FAILED TO DEPLOY AND THEN PERFORATION OF UTERUS OCCURRED FOR SECOND DEVICE. THE EVENT PERFORATION OF UTERUS DURING INSERTION IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (INCLUDING ESSURE PROCEDURE). WITH ESSURE, IT OCCURS MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE PERFORATION OCCURRED DURING THE INSERTION AND THEREFORE IT WAS CONSIDERED RELATED TO ESSURE. IN LINE WITH LOCAL REQUIREMENTS, THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT SINCE THIS CASE IS REGARDED AS AN OTHER REPORTABLE INCIDENT SINCE THE UTERINE PERFORATION COULD LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION UNDER LESS FORTUNATE CIRCUMSTANCES. THE NON-SERIOUS EVENT ESSURE FAILED TO DEPLOY WAS ALSO REPORTED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-MAR-2015: NO FURTHER INFORMATION IS EXPECTED. PTC INVESTIGATION RESULT WAS RECEIVED ON 23-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00143	BAYER HEALTHCARE LLC	2/27/2015	2/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. CONSUMER HAD ESSURE INSERTED FOR BIRTH CONTROL. CONSUMER REPORTED THAT HYSTERECTOMY HELPED, BUT STILL SUFFERING EFFECTS OF ESSURE AFTER 9 MOS (INTERPRETED AS MONTHS). SHE REFERRED ESSURE AS A POISON AND ASSOCIATED THE EVENTS WITH ESSURE. NO ADDITIONAL INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 06-FEB-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. "POISON" AS REPORTED BY THE PATIENT, IS NOT A KNOWN FAILURE MODE RELATED TO ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT

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BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN AN ACTIVE ONLINE LISTENING. THE PATIENT HAD ESSURE INSERTED AND HAD A HYSTERECTOMY. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED ABOUT INDICATION AND NATURE OF THE REPORTED SURGERY. IT WAS ONLY INFORMED THAT HYSTERECTOMY HELPED BUT SHE WAS STILL SUFFERING EFFECTS OF ESSURE AFTER 9 MONTHS. BASED ON AVAILABLE INFORMATION, CAUSALITY WITH ESSURE IS ASSESSED AS RELATED AND SINCE A ESSURE REMOVAL VIA HYSTERECTOMY WAS IMPLIED, THE CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00145	BAYER HEALTHCARE LLC	2/27/2015	2/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2013
Explant Date (E7): 12/16/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. CONSUMER REPORTED THAT ESSURE WAS PLACED IN (B)(6) 2013 AND ON (B)(6) 2014 SHE HAD LAPAROSCOPIC HYSTERECTOMY. SHE STATED THAT THEY (MICRO-INSERTS) TORE THROUGH HER FALLOPIAN TUBES, ONE WAS EMBEDDED IN HER UTERUS, PROTRUDING THROUGH IT ACTUALLY. THE OTHER WAS FLOATING AROUND IN HER ABDOMEN. CONSUMER ASSOCIATED ALL THE EVENTS TO ESSURE AND STATED THAT SHE WAS 5 WEEKS POST-OPERATIVE AND FELT BETTER. FOLLOW-UP RECEIVED ON (B)(6) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL

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MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A SOLICITED CASE REPORT WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THEY (ESSURE COILS) TORE THROUGH HER FALLOPIAN TUBES. THE EVENT, SEEN AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. IN THIS CASE, THE MICRO-INSERTS TORE THROUGH HER FALLOPIAN TUBES. ONE DEVICE WAS EMBEDDED IN HER UTERUS (PROTRUDING THROUGH IT) AND THE OTHER ONE WAS FLOATING AROUND IN HER ABDOMEN. AT THE TIME OF THE REPORT, SHE WAS 5 WEEKS POST-OPERATIVE AND WAS FEELING BETTER (RECOVERING). BASED ON AVAILABLE INFORMATION AND EVENT'S NATURE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE AND SINCE A LAPAROSCOPIC HYSTERECTOMY WAS PERFORMED (REQUIRED INTERVENTION), THE CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040940	BAYER	2/27/2015	2/27/2015

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DAYS AFTER IMPLANTATION I BEGAN GETTING HEADACHES THAT LAST FOR DAYS AT A TIME, I BEGAN FEELING EXTREME FATIGUE AND A GENERAL FEELING OF NOT BEING WELL. AS TIME WENT ON I BEGAN HAVING STABBING PAINS STARTING IN MY PELVIC ARES SHOOTING THROUGH MY LOWER BACK AND HIPS. I ALSO HAVE BEEN HAVING PAINS THAT FEEL LIKE ELECTRIC SHOCKS IN MY FINGER TIPS, LEGS AND FEET. SINCE GETTING ESSURE MY BODY STAYS BROKE OUT IN ACNE AND I HAVE MOOD SWINGS. I HAVE HAD INSTANCES WHERE I HAVE TROUBLE REMEMBERING THINGS, MIXING UP MY WORDS AND FEELING LIKE MY BRAIN IS NOT FUNCTIONING PROPERLY. I WILL NOW BE HAVING A BILATERAL SALPINGECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00144	BAYER HEALTHCARE LLC	2/27/2015	2/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT POSTED ONLINE BY A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(4) 2015 WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. CONSUMER STATED SHE WAS SUBMITTED TO A HYSTERECTOMY TO HAVE ESSURE REMOVED. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2015. NO NEW CLINICAL INFORMATION PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER WHO WAS SUBMITTED TO A HYSTERECTOMY TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO

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MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR HYSTERECTOMY WAS NOT SPECIFIED, SINCE CONSUMER RELATED THIS SURGERY TO ESSURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED AND DUE TO THE REPORTED SURGICAL INTERVENTION, THIS CASE WAS REGARDED AS INCIDENT. NO FOLLOW-UP WILL BE PURSUED (SOCIAL MEDIA CASE). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00146	BAYER HEALTHCARE LLC	2/27/2015	3/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE ON BEHALF OF A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2015 FROM HOSPITAL'S SURGERY COORDINATOR. ON (B)(6) 2015 THE NURSE REPORTED THAT THE PATIENT WAS SCHEDULED FOR REMOVAL OF ESSURE. LATER, HOSPITAL'S SURGERY COORDINATOR CONFIRMED THAT THE SURGERY WAS PERFORMED ON (B)(6) 2015. REASON FOR ESSURE REMOVAL WAS THAT THE PATIENT COMPLAINED OF MONTHLY HIVES EVER SINCE ESSURE WAS INSERTED AND SHE HAD NICKEL ALLERGY. SHE ALSO STATED THAT ESSURE WAS NOT INSERTED BY REPORTING PHYSICIAN AND SHE DID NOT KNOW ESSURE LOT NUMBER. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON (B)(4) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL ALLERGY. THE DEVICE WAS SURGICALLY REMOVED. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CAUSALITY CANNOT BE EXCLUDED. DUE TO THE INTERVENTION REPORTED, THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00147	BAYER HEALTHCARE LLC	2/27/2015	3/2/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): NOT REPORTED

Single Use: Y
Implant Date (E6): 12/1/2012
Explant Date (E7): 11/2/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER, OF UNSPECIFIED AGE, IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED TO A BROADCAST NEWS MEDIA THAT AS SOON AS ESSURE WAS PLACED, IT CHANGED HER LIFE; AND THAT THERE WAS NOT A SINGLE DAY THAT SHE WAS NOT IN PAIN OR HAVING SOME KIND OF ILLNESS. IN THE NEWS, SHE WAS REFERRED AS A FORMER ESSURE USER AND WAS PART OF A GROUP THAT INDICATED THEY'D HAD HYSTERECTOMIES AS PART OF GETTING THE COILS REMOVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED

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VIA NEWS MEDIA AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. SHE WAS SUBMITTED TO A HYSTERECTOMY FOR DEVICES REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; NEVERTHELESS GIVEN THE REPORTED EVENT'S NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 11-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA REFERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00148	BAYER HEALTHCARE LLC	2/27/2015	3/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. THE CONSUMER'S MEDICAL HISTORY INCLUDED 2 SONS. TWO WEEKS AFTER GETTING ESSURE, THE CONSUMER EXPERIENCED EXCRUCIATING PAIN IN LOWER BACK, LEG AND PELVIS. SHE HAD NAUSEA AND WAS IN CONSTANT PAIN. SHE ALSO FELT LIKE SHE HAD MILD CASE OF THE FLU EVERY DAY. SHE UNDERWENT TO A HYSTERECTOMY AND TWO WEEKS AFTER SHE WAS BACK TO HER OLD SELF. SHE HAD HER ENERGY LEVEL BACK, DIDN'T FEEL SICK AND DIDN'T HAVE THE PAIN. SHE FELT BACK TO NORMAL. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON (B)(6) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING PAIN IN LOWER BACK, LEG AND PELVIS. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, TWO WEEKS AFTER PLACEMENT, THE CONSUMER PRESENTED THIS EXCRUCIATING PAIN. EVENTUALLY, SHE HAD A HYSTERECTOMY PERFORMED. A COUPLE OF WEEKS AFTER THE PROCEDURE, SHE HAD HER ENERGY LEVEL BACK, DIDN'T FEEL SICK AND DIDN'T HAVE THE PAIN ANYMORE (POSITIVE DECHALLENGE). CONSIDERING THE EVENT'S NATURE AND POSITIVE DECHALLENGE, THE REPORTED ADVERSE EVENT IS ASSESSED AS RELATED TO ESSURE USE AND SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY) THE CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040939	BAYER	2/27/2015	3/2/2015

Event Information:

Event Date (B3): 9/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INSOMNIA, PELVIC PAIN, DAILY MIGRAINES, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041256		2/27/2015	3/9/2015

Event Information:

Event Date (B3): 1/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED AN ESSURE PROCEDURE ON (B)(6) 2015 AND SIX DAYS LATER MY HEALTH BEGAN TO DECLINE. I HAVE THE WORSE HEADACHES AND BACK PAIN. I AM VERY UNCOMFORTABLE. I HAVE A GREAT DEAL OF PRESSURE IN MY PELVIC AREA. I HAVE BEEN TO ER SEVEN TIMES IN A MONTH. MY BP IS VERY HIGH. THESE PROBLEMS DEVELOPED AFTER ESSURE. I AM A NURSING MOM TO A NOW FOUR MONTH OLD TWO MONTHS ADJUSTED BABY AND THESE PROBLEMS ARE AFFECTED MY DAILY LIVING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041241	BAYER HEALTH	2/28/2015	3/9/2015

Event Information:

Event Date (B3): 2/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6). DR (B)(6) (ESSURE) 2005 TO 2007 DELIVERED 2 KIDS - ASKED FOR TUBES TIED AND IUD AND DENIED BOTH AND ESSURE WAS PUT IN. (B)(6) WRECK (B)(6) (1997-1998) 8:00 PM - 8:00 AM. INVOLUNTARY MUSCLE MOVEMENTS IN JAW, HANDS, FEET. (B)(6) - (B)(6) 2009 WAS DIAGNOSED WITH THE FLU. (B)(6) ON (B)(6) 2009 ER (I RECEIVED AN IV BECAUSE I WAS DEHYDRATED AND I WAS COMPLAINING OF MY SIDE HURTING SO BAD AND HE FELT ON MY STOMACH AND SAID I HAD A HERNIA THE SIZE OF A GOLF BALL, I ALSO WAS COMPLAINING OF MEDICAL REACTION TO RELENZA. IT CAUSED INVOLUNTARY MOVEMENTS. I ASKED FOR BRAIN SCAN, BUT NEVER RECEIVED ONE. I WAS SENT HOME WITH A LORATAB. DR COLEMAN (PAIN) 2009 - 2015 SHARP SHOOTING PAINS IN MY HEART, THEIR DIAGNOSIS WAS ANGINA OF THE HEART. WHICH IS ARTHRITIS OF THE HEART. (B)(6) 2008-2015 - COUNTLESS NUMBER OF PRESCRIPTIONS FILLED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041236		3/1/2015	3/9/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE DONE 2 1/2 YEARS AGO. IT WAS THE WORST THING I EVER DID. ALWAYS IN PAIN IN MY STOMACH, I LOOK LIKE I'M 9 MONTHS PREGNANT AND I AM NOT. THANKS TO "ESSURE" I AM DEPRESSED A LOT, HEADACHES A LOT, SWELLING IN MY HANDS, FEET AND FACE. MY BACK HURTS A LOT. CAN'T EVEN HOLD MY TODDLER BECAUSE IT HURTS A LOT. NEVER HAD THIS PROBLEM BEFORE I GOT THIS "ESSURE" DONE. BIG MISTAKE GETTING IT DONE. PLEASE HELP ME. I AM TRYING TO GET IT REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041238	BAYER	3/1/2015	3/9/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE BED SIDE EFFECTS AFTER HAVING THE ESSURE PROCEDURE DONE. RASHES, MIGRAINES, FAINTING, VARICOSE VEIN ON UTERUS CAUSING MAJOR PAIN. ALSO EXPERIENCED VOMITING, UTI AND CHEST PAINS. HOSPITALIZED FOR MANY TEST TO BE RAN, CAT SCAN ETC. HOSPITAL RULED OUT TO HAVE DEVICES REMOVED FOR HEALTH CONCERN REASONS. SURGERY FOR REMOVAL IS NOT COVERED UNDER MY HEALTH INSURANCE UHC. I MUST PAY THE FULL COST BY CASH TO SAVE MY LIFE BEFORE DEATH. PLEASE HELP ME! I HAVE BEEN TO SEVERAL DOCTORS AROUND THE DFW METROPLEX. UPON REQUEST WILL UPLOAD ALL DOCUMENTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041262	BAYER	3/1/2015	3/9/2015

Event Information:

Event Date (B3): 9/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/3/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE SIDE EFFECTS CAUSE ME RANDOM PAIN, CHRONIC FATIGUE, PASS OUT SPELLS, NAUSEA, BOWEL ISSUES, IRREGULAR CYCLES, ITCHING IN VARIOUS AREAS, HEADACHES, BLOATING, SLEEP ISSUES, MEMORY ISSUES AND LACK OF FOCUS. THIS ALL HAS PROGRESSED SINCE I HAD ESSURE PUT IN 2008. AS TIME GOES ON MORE THINGS START HAPPENING AND OTHERS PROGRESS AND GET WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041264	BAYER	3/1/2015	3/9/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 846830

Single Use:
Implant Date (E6): 11/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACED IN 2011. SINCE THEN I HAVE BEEN STRUGGLING WITH SEVERE FATIGUE, BLOATING IN MY ABDOMEN, CRAMPING AND BLEEDING DURING INTERCOURSE, PAINFUL CRAMPING DURING MY MENSTRUAL CYCLE (I HAVE NEVER HAD DISCOMFORT DURING A PERIOD IN MY LIFE BEFORE ESSURE), AND PAIN AND CRAMPING ON MY RIGHT SIDE EVERY DAY. THIS PRODUCT HAS AFFECTED MY QUALITY OF LIFE. I SHOULD HAVE DONE MORE RESEARCH ON THIS PRODUCT BEFORE I HAD IT IMPLANTED INTO MY BODY. IT LOOKED LIKE SUCH A QUICK AND SIMPLE PROCEDURE. I KNEW I DID NOT WANT TO HAVE ANY MORE CHILDREN AND THIS SEEMED LIKE THE RESPONSIBLE AND EASIEST WAY TO ACCOMPLISH THAT. I HAVE REGRETTED THIS DECISION FOR 3 YEARS. MY DOCTOR LAUGHS AT ME AND SAYS THAT EVERYTHING I READ ON THE INTERNET ISN'T TRUE. THIS ISN'T JUST SOMETHING I READ ON THE INTERNET, WHAT I AM FEELING IS REAL AND IS MY DAILY REALITY. IT JUST HAPPENS TO BE THAT MANY OTHER WOMEN ARE FEELING THE SAME THING AND ARE POSTING IT ONLINE SO OTHERS WILL BE EDUCATED BEFORE THEY MAKE THIS DECISION THEMSELVES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00149	BAYER HEALTHCARE LLC	3/2/2015	3/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/2/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN THE UNITED STATES AND DETECTED ON (B)(6) 2014 VIA AN ESSURE GENERIC AOL/ACTIVE ONLINE LISTENING ACTIVITY. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MANY SIGNS THAT COULD BE LINKED TO NICKEL SUCH AS FREQUENT NAUSEA, HEADACHES, HEART PALPITATIONS, ASTHMA. FOLLOW UP (B)(6) 2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. SHE REPORTED THAT A PELVIC PAIN ALMOST BEEN UNBEARABLE 2DAY. SHE WOULD LIKE HER DOCTOR GET ESSURE OUT OF HER. SHE WANTED A HYSTO (UNSPECIFIED BY CONSUMER). FOLLOW-UP RECEIVED ON (B)(6) 2014. NO NEW CLINICAL INFORMATION RECEIVED. FOLLOW UP (B)(6) 2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED FOR STERILIZATION AND HER DOCTOR WANTED TO GIVE HER BIRTH CONTROL PILLS FOR PAIN (PREVIOUSLY SPECIFIED AS PELVIC PAIN HAS ALMOST BEEN UNBEARABLE 2DAY) CAUSED BY ESSURE AND PROZAC BECAUSE OF DEPRESSION COULD BE CAUSING HER PAIN. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6)2014: THE CONSUMER REPORTED THAT SHE INSERTED ESSURE 5 YEARS AGO. SHE STATED THAT SHE WAS IN PAIN DAILY AND HER PHYSICIANS TOLD HER THAT IT IS IN HER HEAD. FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA ON (B)(4) 2014: CASE UPGRADED TO SERIOUS DUE TO MEDICALLY SIGNIFICANT EVENT RECEIVED. CONSUMER REPORTED THAT SHE WAS EXPERIENCING SO MUCH PAIN IN THE RIGHT. SHE ALSO STATED THAT ESSURE WAS PUSHED TOO FAR IN. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6)2014. ACCORDING TO THE CONSUMER, SHE WAS GOING TO HAVE HYSTERECTOMY TO HELP CHRONIC PELVIC PAIN CAUSED BY ESSURE. SHE WAS SAD, BECAUSE SHE DID NOT

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HAVE INS (INTERPRETED AS INSURANCE). THE PREVIOUS REPORTED EVENT PELVIC PAIN HAS ALMOST BEEN UNBEARABLE 2 DAY WAS UPDATED TO CHRONIC PELVIC PAIN HAS ALMOST BEEN UNBEARABLE 2 DAY. FOLLOW UP INFORMATION FROM (B)(6) 2014: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. PTC GLOBAL NUMBER: 2014-023426. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN DR-3020, DESIGN FMEA FOR ESS305. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE AVAILABLE INFORMATION. FOLLOW UP (B)(6)2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. CONSUMER REPORTED THAT SHE WOULD GO TO SEE HER DOCTOR FOR HER PRE-OP, HER SURGERY WOULD BE ON (B)(6) 2014 HAVE ESSURE REMOVED. SHE HAS HAD NOTHING BUT PROBLEMS SINCE GETTING THEM PUT IN. SHE TALKED TO OTHER WOMEN ON THE SOCIAL MEDIA THAT HAD ESSURE AND FROM WHAT SHE COULD SEE WHAT SHE WAS DOING WAS THE BEST AND HER DOCTOR THOUGHT SO TOO. ESSURE PROBLEMS ON THE WEBPAGE HAS HELPED HER AND HER DOCTOR TO DECIDE A VAGINAL HYSTERECTOMY WAS THE WAY TO GO AND LESS RECOVERY TIME. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP (B)(6) 2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. CONSUMER REPORTED THAT SHE HAD BRAIN FOG WHICH WAS WORSE. SHE WAS ALSO FEELING DIZZY AND HAD PELVIC PAIN (PREVIOUSLY REPORTED). CONSUMER ASSOCIATED THESE EVENTS TO ESSURE. FOLLOW-UP RECEIVED ON (B)(6)2015: INFORMATION RECEIVED FROM CONSUMER VIA SOCIAL MEDIA STATED THAT SHE EXPERIENCED HEADACHES, NAUSEA, PELVIC PAIN (EVENTS PREVIOUSLY REPORTED) AND BACK PAIN. IN ADDITION, CONSUMER INFORMED THAT 3 DAYS POST-OPERATIVE FROM HYSTERECTOMY DUE TO ESSURE PROBLEMS AND SHE WAS ALREADY FEELING BETTER AND STATED THAT HER STOMACH WAS LESS SWOLLEN THAN WITH ESSURE. FOLLOW-UP RECEIVED ON (B)(6) 2015: INFORMATION RECEIVED FROM CONSUMER VIA SOCIAL MEDIA STATES THAT SHE IS ONE OF NINE HAVING HYSTERECTOMY DUE TO ESSURE PROBLEMS. FOLLOW UP RECEIVED ON (B)(6) 2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. FOLLOW-UP RECEIVED ON (B)(6)2015: CONSUMER REPORTED THAT SHE HAD THE ESSURE FOR 6 YEARS AND AFTER THE HYSTERECTOMY TO REMOVE ESSURE, SHE WAS FEELING MUCH BETTER. SHE HAD NO MORE PELVIC PAIN, HEADACHES AND HEARTBURN. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON (B)(6) 2015. NO NEW CLINICAL INFORMATION PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATED THAT ESSURE WAS PUSHED TOO FAR IN (INTERPRETED AS DEVICE DISLOCATION) AND EXPERIENCED CHRONIC PELVIC PAIN HAS ALMOST BEEN UNBEARABLE 2 DAY. THIS CASE WAS UPGRADED. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR, THE EXACT LOCATION OF ESSURE WAS UNKNOWN. BASED ON THE

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INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A HYSTERECTOMY WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: HEART PALPITATIONS, FREQUENT NAUSEA, HEADACHES, ASTHMA, COULD BE LINKED TO NICKEL, DEPRESSION, PAIN/PAIN DAILY, SO MUCH PAIN IN THE RIGHT, BRAIN FOG, FEELING DIZZY, BACK PAIN AND STOMACH SWOLLEN. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE AVAILABLE INFORMATION. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 27-AUG-2015 AND 15-SEP-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMB

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00150	BAYER HEALTHCARE LLC	3/2/2015	3/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER (B)(6) WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, (B)(4). (B)(4). NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT ESSURE CAUSED HER HYSTERECTOMY DUE TO ALL THE SICKNESS (UNSPECIFIED). EVENTS OUTCOMES WERE NOT REPORTED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN HYSTERECTOMY AND SICKNESS AND ESSURE IS RELATED. FOLLOW-UP INFORMATION RECEIVED ON 02-APR-2014: A PICTURE OF UNSPECIFIED ORGAN WITH ESSURE WAS RECEIVED FROM SOCIAL MEDIA WITHOUT FURTHER INFORMATION. NO DIAGNOSTIC WAS PROVIDED. THE REPORTER ONLY STATED THAT ESSURE DID THAT (PICTURE) TO PATIENT'S ORGANS. FOLLOW-UP INFORMATION RECEIVED ON 22-APR-2014: FOLLOW-UP ATTEMPT WILL NOT BE COMPLETED (DUE TO LACK OF PRIMARY REPORTER CONTACT INFORMATION). FOLLOW UP INFORMATION RECEIVED ON 27-AUG-2014: CONSUMER REPORTED VIA SOCIAL MEDIA THAT SHE HAD HER 4TH SURGERY DUE TO EFFECTS OF ESSURE. SHE STATED THAT EVEN AFTER REMOVAL ESSURE CAUSED MORE HARM THAN GOOD. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT

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OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE LIMITED AVAILABLE INFORMATION. FOLLOW UP INFORMATION RECEIVED ON 14-NOV-2014: CONSUMER REPORTED VIA SOCIAL MEDIA ESSURE CAUSED HER HYSTERECTOMY AT (B)(6) BECAUSE ITS ESSURE PROBLEMS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 01-DEC-2014 FROM CONSUMER: NO NEW RELEVANT INFORMATION FOR THIS CASE WAS PROVIDED. FOLLOW-UP RECEIVED ON 31-JAN-2015: INFORMATION RECEIVED FROM CONSUMER VIA SOCIAL MEDIA STATES THAT HYSTERECTOMY HELPED BUT SHE WAS STILL SUFFERING EFFECTS OF ESSURE AFTER 9 MONTHS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SOLICITED CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SICKNESS (UNSPECIFIED). SICKNESS WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NEITHER EVENT START DATE NOR CONSUMER PAST MEDICAL HISTORY AND CONCURRENT CONDITIONS/MEDICATIONS WERE REPORTED. ALTHOUGH THIS CASE WAS REPORTED WITH LIMITED INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THE EVENT SICKNESS AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A HYSTERECTOMY WAS PERFORMED. ACCORDING TO PTC RESULTS, NOR BATCH NUMBER WAS REPORTED, NEITHER A COMPLAINT SAMPLE WAS PROVIDED, THUS THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE LIMITED AVAILABLE INFORMATION. NEW PTC RESULTS IS EXPECTED.

Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 28-APR-2015. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SOLICITED CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SICKNESS (UNSPECIFIED). SI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00151	BAYER HEALTHCARE LLC	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 12/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91762

Single Use: Y
Implant Date (E6): 12/18/2014
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN FROM A HEALTH CARE INSTITUTION IN (B)(6) ON (B)(4) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 (LOT NUMBER C91762). ESSURE DEVICE DID NOT PROPERLY DEPLOY THE COIL INTO THE PATIENT'S FALLOPIAN TUBE. SURGEON STATED THAT THE COILS SNAPPED OFF WHILE THE DEVICE WAS ENGAGING AND SOME OF THE DEVICE MATERIAL WAS LEFT IN WITH THE COIL IN THE PATIENT'S FALLOPIAN TUBE. PATIENT REQUIRED AN ADDITIONAL SURGERY THE FOLLOWING MONTH ((B)(6) 2015) TO LAPAROSCOPICALLY REMOVE THE COILS AND RESULTING IN REMOVING BOTH FALLOPIAN TUBES. THE DEVICE WAS AVAILABLE AND THE COILS REMOVED FROM THE PATIENT WERE NOT SAVED. INTERNAL CORRECTION ON (B)(4) 2015. DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE (B)(4) 2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS (B)(4) 2015. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ESSURE DEVICE DID NOT PROPERLY DEPLOY THE COIL INTO THE PATIENT'S FALLOPIAN TUBE (INTERPRETED AS DEVICE DEPLOYMENT ISSUE) AND THE COILS SNAPPED OFF WHILE DEVICE WAS ENGAGING AND SOME OF THE DEVICE MATERIAL WAS LEFT IN WITH THE COIL IN THE PATIENT'S FALLOPIAN TUBE (INTERPRETED AS DEVICE BREAKAGE). THE EVENT DEVICE BREAKAGE WAS CONSIDERED AS SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE PATIENT

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UNDERWENT A SURGICAL INTERVENTION (LAPAROSCOPIC REMOVAL OF THE COILS AND BOTH FALLOPIAN TUBES). FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 02-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT:

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00152	BAYER HEALTHCARE LLC	3/2/2015	3/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2003
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A STUDY CASE REPORT POSTED ONLINE ON 30-JAN-2015 BY A FEMALE CONSUMER IN UNITED STATES AND RECEIVED BY BAYER ON (B)(4) 2015. SHE WAS INVOLVED IN AN ACTIVE ONLINE LISTENING PROJECT, STUDY NUMBER: (B)(4), AND HAD ESSURE MODEL 205 INSERTED IN 2003. STUDY DESCRIPTION: ESSURE 205 AOL. ACCORDING TO HER, ESSURE CAUSED A LOT OF HEALTH PROBLEMS. SHE HAD HER TUBES REMOVED AND PROBABLY WILL NEED ANOTHER SURGERY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON (B)(4) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: THIS IS A CASE REFERENCING TO THE ESSURE 205 DEVICE AS THE REPORTER STATED THEY HAD ESSURE 12 YEARS AGO. THIS IS NOT A CONFIRMED SOCIAL MEDIA REPORT. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-

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MEDICALLY CONFIRMED, SOLICITED CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HER TUBES REMOVED. THE REPORTED EVENT, INTERPRETED AS BILATERAL SALPINGECTOMY, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, CONSUMER STATED SHE HAD HEALTH PROBLEMS (UNSPECIFIED) DUE TO ESSURE AND HER FALLOPIAN TUBES WERE REMOVED. ALTHOUGH LIMITED INFORMATION WAS PROVIDED, IT CANNOT BE EXCLUDED THAT THE REPORTED SURGERY OCCURRED AS A CONSEQUENCE OF ESSURE. THEREFORE, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 24-APR-2015: CONSUMER STATED VIA SOCIAL MEDIA THAT SHE WAS GOING TO SEE ABOUT SURGERY WITH HER PHYSICIAN TO HAVE A MIGRATED ESSURE COIL REMOVED. SHE WAS NERVOUS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040941	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 9/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5040941 #(B)(4). I ALSO HAVE SEVERE AND DEBILITATING MIGRAINES WEEKLY, WEIGHT GAIN,AND SEVERE BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040942	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 11/24/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, CRAMPING, OVARIAN CYSTS, DISCHARGE WITH ODOR, HOT FLASHES, NIGHT SWEATS, LOSS OF SEX DRIVE, PAINFUL PERIODS, LONG PERIODS, SEXUAL DISFUNCTION, MISSED PERIODS, UTI'S, BURNING AND TEARING VAGINAL TISSUE, BREAST PAIN AND TENDERNESS, ABDOMINAL SPASMS, PAIN ALL OVER BODY, FIBROMYALGIA, NAUSEA, GAS, BLOATING, CONSTIPATION, METALLIC TASTE IN MOUTH, BOWEL ISSUES, HEADACHES DAILY, MIGRAINES, TINGLING SENSATIONS ALL OVER BODY, NERVE PAIN, BRAIN FOG, MOOD SWINGS, DEPRESSION, RINGING IN EARS, ALLERGIES, SENSITIVITIES TO FOOD, METAL ALLERGIES, ACNE, SWELLING OF FEET AND LEGS, HAIR LOSS, DENTAL ISSUES, INSOMNIA, GALL BLADDER REMOVED, WEIGHT ISSUES, MUSCLE SPASMS, VISION ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040943	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 10/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH STABBING PAIN IN PELVIC AREA. CONSTANT FEELING OF BEING BLOATED AND FULL, NAUSEA, HIP AND PELVIC PAIN. LATER HAD MULTIPLE CASES OF PID AND BACTERIAL VAGINITIS. THE STABBING PAIN AND BLOATED FEELING HAS NEVER GONE AWAY AND NOW I HAVE NO PERIOD AND EXCRUCIATING LOWER BACK A PELVIC PAIN WITH IT RADIATING DOWN MY LEFT LEG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040944	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 8/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BLEEDING FOR MONTH,S WEIGHT GAIN, PELVIC PAIN ENDOMETRIAL, THREE PREGNANCIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040945	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 10/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PIERCING "UTERIAL" PAIN, LOWER BACK PAIN, AND HEADACHE. INFLAMED LIPS, RIGHT FINGER, HUGE PAINFUL LEFT INNER THIGH, THAT HURT TO WALK, BEND, SIT, HAD TO BE CUT OPEN AND DRAINED AT MY DOCTOR'S OFFICE. HUGE AMOUNT OF PUS AND BLOOD CAME OUT. ON ANTIBIOTICS, IT STILL HAS PUS IN IT NOW . MY FEET ARE NOW ALWAYS DRY AND PEELING, I HAVE BEEN USING ALL KINDS OF FOOT CREAMS STILL HAVEN'T WORKED. MY BELLY IS BLOATED ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040946	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 8/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING FOR MONTHS. WEIGHT GAIN. PELVIC PAIN. ENDOMETRIAL. THREE PREGNANCIES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040947	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 7/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BLEEDING EVERY TIME I WOULD PUSH TO HAVE A BOWEL MOVEMENT OR BLOW MY NOSE. THEN I STARTED BLEEDING HEAVY EVERY TIME I HAD SEX. I HAD CONSTANT PAIN ON MY RIGHT SIDE AND LOWER BACK. I ALSO KEPT A LOW GRADE FEVER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040948	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 6/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I KEEP GETTING REALLY BAD PAIN TO WHERE I CAN'T MOVE. I HAVE ENDOMETRIOSIS THAT I NEVER HAD BEFORE I HAD THE ESSURE PUT IN. I KEEP GETTING CYST ON MY OVARIES. I CAN'T SEEM TO LOSE WEIGHT AND I HAVE TRIED EVERYTHING. I DON'T HAVE REGULAR BOWEL MOVEMENT THEY COME ONCE TO TWICE A MONTH. I HAVE MAJOR MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040949	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 2/1/2007	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTING BEING VERY LETHARGIC WITH EXTREME FATIGUE, JOINT PAIN, HEADACHES, MEMORY LOSS, HAIR LOSS, HEAVY MENSTRUAL CYCLES, CRAMPING AND BLOATING EVEN AFTER CYCLES, COLD ALL THE TIME, AND REAL BAD TEETH ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040950	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 6/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5040950 #(B)(4) FORGOT TO MENTION STRANGE RASH THAT DEVELOPED OUT OF THE BLUE WITHIN MONTHS AFTER HAVING ESSURE IMPLANTED. NEVER HAD A PROBLEM LIKE THIS IN MY LIFE. DERMATOLOGIST HAS BEEN TREATING IT FOR ABOUT A YEAR AND STILL UNABLE TO DETERMINE WHAT CAUSED IT. RASH ON WRISTS, HANDS, ELBOWS, INNER ELBOWS, PATCH ON RIGHT BUTTOCK AND PERIODIC OUTBREAK ALL OVER FACE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040951	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 12/3/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5040951 #(B)(4) HAD ESSURE REMOVED (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040952	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 7/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO HAVE MY GALLBLADDER REMOVED DUE TO CALL STONE NO ONE IN MY FAMILY EVER HAD THIS BEFORE JUST ME ONLY AFTER ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040953	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 11/4/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A PROCEDURE THAT WAS SAID WOULD TAKE 15 MINUTES ACTUALLY TOOK OVER 45 MINUTES, THE DR COULD NOT PLACE THE DEVICE INSIDE OF ME AND SAID HE DIDN'T WANT TO SEND ME HOME AND THEN HAVE TO DO IT ALL OVER AGAIN, SO HE ATTEMPTED MORE TRIES UNTIL FINALLY IT WAS INSIDE OF ME BUT THE PAIN WAS SO INTENSE, I CRIED THROUGH OUT THE WHOLE PROCEDURE. I WAS SHAKING SO BAD AND COULD NOT STAND UP COMPLETELY AFTER IT WAS COMPLETED. MY BLEEDING WAS SO PROFUSELY THAT I FILLED A PAD IN LESS THAN 10 MINUTES. WHEN I LEFT, I WALKED OUT HUNCHED OVER UNABLE TO COMPLETELY STAND UP. MY CRAMPS AND FLOW OF BLOOD WERE SO BAD THAT IT LASTED 3 YEARS AND I BECAME ANEMIC. ACNE BEGAN FOR ME SO BAD, I NEVER HAD A NO ACNE PROBLEM! MY DR PUT ME ON BIRTH CONTROL PILLS TO REGULATE MY PERIOD AND PRESCRIBED PILLS AND A FACIAL GEL TO HELP WITH MY ACNE PROBLEM. IT HELPED SOME FOR ME... THEN THE HEAVY CLOGS OF BLOOD IN MY PERIODS WERE GETTING BIGGER AND BIGGER THAT THEY WERE BECOMING MORE PAINFUL AS TIME WENT BY. I SPOKE TO MY DR WHICH NONE NOT EVEN MY OBGYN'S BELIEVED THAT IT WAS CAUSED BY ESSURE. BUT THEN AGAIN THEY DON'T KNOW MUCH ABOUT IT... I JUST HAD THE MIRENA INSERTED IN ME TO HELP WITH THE HEAVY FLOW OF MY BLOOD AND BLOOD CHUNKS.... MY ONLY OPTIONS ARE FULL OR PARTIAL HYSTERECTOMY. . . WHY DO I HAVE TO GO THROUGH THAT IF ESSURE SHOULD BE THE ONE'S TO REMOVE MY TUBES! WEIGHT GAIN IS ANOTHER PROBLEM I HAVE, I WALK FOR MANY MILES DAILY AND EXERCISE AND NOTHING SEEMS TO HELP ME. MY STOMACH ALSO LOOKS AND FEELS BLOATED... I HAVE BLOOD SPOTS ON ONE OF MY LEGS. I HAVE MY PERIOD 2 TO 3 TIMES A MONTH... I'M GIVING MIRENA A CHANCE BUT THEY RECOMMEND 6 TO 9 MONTH WAIT... I'M WILLING TO GIVE IT THAT, SO I DON'T HAVE TO DO THE HYSTERECTOMY. FATIGUE IS A PROBLEM BECAUSE I'M A VERY ACTIVE PERSON AND I HATE FEELING THAT WAY DAILY.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040954	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, PAINFUL PERIODS, HEAVY PERIODS, DEPRESSION, PAINFUL INTERCOURSE, BODY PAIN, INSOMNIA, FATIGUE, BLOATING, NAUSEA, AND IRRITABILITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040955	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 6/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE BLOATING, WEIGHT GAIN, FATIGUE, EXTREME HAIR LOSS , ABNORMAL PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040958	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 12/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE CRAMPING, NO PERIODS. WHEN I GET A PERIOD, IT'S HEAVY LONG PERIODS. WEIGHT GAIN, CHRONIC RIGHT LEG PAIN. SHARP STABBING PAIN ON RIGHT SIDE, ABDOMINAL. HAIR LOSS, SEVERE FATIGUE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040959	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 3/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2015, I HAD A HYSTERECTOMY WITH REMOVAL OF TUBES, UTERUS, AND CERVIX TO REMOVE THE ESSURE COILS FROM MY BODY. THE PATHOLOGY CAME BACK NEGATIVE FOR ADENOMYOSIS. IN (B)(6) 2015, MY HIP PAIN BECAME WORSE. I SAW A RHEUMATOLOGIST WHO DID BLOOD WORK AND TOOK X-RAYS. IN (B)(6), I WAS DIAGNOSED WITH RHEUMATOID ARTHRITIS, AN AUTO IMMUNE DISORDER RELATED TO CHRONIC INFLAMMATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040960	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS. WEIGHT GAIN. HEADACHES. ABDOMINAL PAIN. HEAVY LONGER PERIODS. BAD CRAMPS. ALLERGIES. HIVES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040961	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 1/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD COMPLETE LOSS OF LIBIDO, HEADACHES, RASHES, SEVERE BACK PAIN, NUMBNESS IN ARM, LEFT SHOULDER PAIN, HAIR LOSS, ACNE, AND MANY MORE SYMPTOMS SINCE I HAD THIS DEVICE IMPLANTED! MY LIFE HAS BEEN A NIGHT MARE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040962	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE HAD BADLY EFFECTED MY LIFE. ONE OF THE COULD BROKE INSIDE MY FALLOPIAN TUBE A RESULT WAS HAVING MY TUBE SURGICALLY REMOVED. ALSO DEVELOPED A HUGE CYST ON MY OVARY AND HAD TO HAVE BOTH REMOVED. PAIN IN ABDOMEN. HAIR LOSS. DEPRESSION. HORMONAL CHANGES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040963	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 1/25/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE PLACEMENT OF PRESSURE I HAVE HAD MIGRAINES, MEMORY LOSS, BRAIN FOG, BACK PAIN, SHARP PAINS ON ONE OR BOTH SIDES, LOSS OF PERIOD, COLD FINGERS AND TOES, INSOMNIA, JOINT PAIN , WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040964	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 8/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN, THYROID MEDICATION HAD TO BE INCREASED, WEIGHT GAIN, NAUSEA, HEADACHES, BLEEDING, RIGHT SIDE IMPLANT NOT VISIBLE AT 3 MO HSG, TIRED ALL THE TIME. I HAD AN ABLATION AND RECTOCELE REPAIR DONE A MONTH AFTER IMPLANT. PRE OP FOR THAT SURGERY SHOWED ANEMIA WHICH ENDED UP BEING IRON DEFICIENCY ANEMIA. FIVE DAYS OF IRON INFUSIONS, 50,000 VITAMIN D A WEEK, AND A RETURN TO WORK DATE THAT WAS SUPPOSED TO BE IN 3 DAYS TURNED INTO 5 WEEKS. I BLED FOR ABOUT 4 WEEKS POST OP. POST OP LABS SHOWED IRON INCREASING BUT THYROID MEDICINE HAS TO BE INCREASED. STILL NO PERMANENT STERILIZATION AND NO UTERINE LINING. PLANNING HYSTERECTOMY IN (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040965	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 9/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DURING MENSTRUAL CYCLE I NOW HAVE EXTREME HEAVY BLEEDING. HEADACHES CONSTANTLY, FATIGUE, MALAISE, WEIGHT GAIN, LOSS OF SEX DRIVE, CONSTANT ABDOMINAL PAIN, PAIN DURING INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040966	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 8/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5040966 #(B)(4). MORE SIDE AFFECTS: CRAMPING, SHARP STABBING PELVIC PAIN, DISCHARGE (ODOR/NO ODOR), HOT FLASHES, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), PAINFUL OVULATION, NIGHT SWEATS, BLEEDING SPOTTING AFTER SEX, PAINFUL PERIODS (DYSMENORRHAGIA), BLEEDING BETWEEN PERIODS, LONG MENSTRUAL CYCLES, BREAST PAIN/TENDERNESS, BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP, CHRONIC PELVIC PAIN, ALL OVER BODY ACHES, GASTROINTESTINAL, NAUSEA, VOMITING, GAS, DIARRHEA, SEVERE BLOATING, HEARTBURN, BOWEL ISSUES, MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, NERVE PAIN, BRAIN FOG- CLOUDINESS, FORGETFULNESS, NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SKIN IRRITATION, SEVERE HAIR LOSS, HAIR GROWTH IN NEW PLACES, DENTAL ISSUES, WEIGHT ISSUES, SWELLING OF LEGS AND FEET, MUSCLE SPASMS, VISION PROBLEMS, EXCESSIVE BLOATING, DRY SKIN AREAS, INABILITY TO LOOSE WEIGHT, I AM SURE I CAN ADD MORE IF I PUT IN SOME MORE THOUGHT IN TO IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040967	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 4/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACES IN (B)(6) 2014, IN THE HOSPITAL UNDER ANESTHESIA. WHEN I AWOKE, I WAS IN TERRIBLE PAIN IN MY ABDOMEN. THEY GAVE ME A PRESCRIPTION FOR A PAIN KILLER AND SENT ME HOME. THE PAIN IN MY LOWER ABDOMEN HAS NEVER GONE AWAY. A MONTH AFTER THE ESSURE PROCEDURE, I WAS TAKEN BY AMBULANCE TO THE ER FOR SEVER ABDOMINAL PAIN AND DIARRHEA. THE ER DOCTORS RAN SEVERAL TESTS, INCLUDING BLOOD, FECAL, X-RAY AND CT SCANS. THEY REFERRED ME TO A GASTROENTEROLOGIST. I SAW A GASTRO DOCTOR WHO DID A COLONOSCOPY, ENDOSCOPY AND SEVERAL ROUNDS OF XRAYS (WITH DYE). THEY DETERMINED I HAD CONTRACTED A CDIFF INFECTION, BUT WE'RE UNABLE TO LOCATE HOW I CONTRACTED THE INFECTION. I HAD NOT PREVIOUSLY BEEN ON AN ANTIBIOTIC AND TO GET SUCH AN INFECTION AN ANTIBIOTIC MUST KILL OFF A CERTAIN BACTERIA TO ALLOW FOR THE BAD BACTERIA TO FLURISH. MY PERIODS HAVE GOTTEN LONGER BY 3-4 DAYS OR MORE, I HAVE DEBILITATING CRAMPS, I BLEED VERY HEAVILY WITH BIG CLOTS AND I USUALLY GET 2-3 PERIODS A MONTH NOW. MY CYCLE USE TO BE NORMAL, ON TIME EVERY MONTH AND ONLY LAST 3 DAYS. I CAN'T HAVE SEX WITH MY HUSBAND BECAUSE THE PAIN IN MY ABDOMEN IS EXCRUCIATING WHEN WE TRY TO HAVE SEX. I AM BLOATED ALL THE TIME, PAINFULLY SOMETIMES. I LOOK LIKE I'M 5-9 MONTHS PREGNANT, DEPENDING ON THE DAY. I GET HEADACHES NOW, WHEREAS I RARELY EVER GOT HEADACHES BEFORE. I AM HAVING DENTAL ISSUES, I HAD NEVER HAD, SO MUCH AS A CAVITY IN MY LIFE BEFORE ESSURE. WHEN I WENT FOR MY HSG MY GYNO DOCTOR, WHO ALSO PLACED THE ESSURE, SAID THAT THE DEVICES WERE PLACED CORRECTLY AND I WAS 100% BLOCKED IN MY OVARIES. ACCORDING TO THE ESSURE MANUAL, THE DEVICES INSIDE ME ARE NOT CORRECTLY PLACED. I WAS A HEALTHY WOMAN BEFORE ESSURE, MY OVER ALL HEALTH HAS DECLINED DRASTICALLY SINCE (B)(6) 2014.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040968	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 12/5/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ALMOST A WEEK AFTER I WAS IN A LOT OF PAIN CALLED DOCCOIL OFFICE TALKED TO A DIFFERENT DOCTOR WITHIN THE OFFICE SAID I SHOULDN'T HAVE BEEN IN PAIN THEY CALLED SOMETHING IN FOR ME WAS MOODY SLEPT A LOT DEPRESSED WENT FOR THE THREE MONTH CHECK UP MY LEFT COIL NEEDED TO BE TAKEN OUT AFTER IT WAS TAKEN OUT I AM STILL IN A LOT OF PAIN I HAVE A BIG KNOT NEAR MY OVARY PERIODS ARE MORE PAINFUL I FEEL LIKE I AM GOING THROUGH MENOPAUSE I HAVE HAD A REALLY BAD KIDNEY INFECTION ON THE LEFT SIDE JOINT PAIN BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040969	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 1/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN, SEVERE MIGRAINES, HEAVY BLEEDING, MOOD SWINGS, DEPRESSION, ANXIETY, MAJOR WEIGHT GAIN, I'VE ALSO HAD A SEIZURE LAST YEAR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040971	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 3/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (B)(6) 2010, I EXPERIENCED BACK SPASM WHERE I COULD NOT SIT OR LAY DOWN FOR ONE WHOLE MONTH. MY PCP SAID THEY COULD FIND NOTHING WRONG WITH ME, SO I STARTED SEE A CHIROPRACTOR FOR 2 MONTHS. ON (B)(6) 2010, I EXPERIENCE MUSCLE AND JOINT PAIN IN MY HANDS AND SHOULDERS, SAW MY PCP AND SHE FOUND NOTHING WRONG WITH ME AGAIN. WITHIN THE PAST COUPLE YEARS THE JOINT PAIN, MUSCLE PAIN HAS GOTTEN SO BAD I AM SOMETIMES UNABLE TO LEAVE MY BED. I ALSO EXPERIENCE SHORTNESS OF BREATH. SAW MY PCP THEY TOOK BLOOD WORK AND I NOW HAVE AN AUTOIMMUNE DISEASE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040972	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO HAVE A HYSTERECTOMY IN (B)(6) 2011 AS A RESULT. ONLY A YEAR AFTER PLACEMENT BECAUSE IT WAS SO PAINFUL AND THAT WAS THE ONLY SAFE WAY TO REMOVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040973	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PLACED. EVER SINCE PLACEMENT WOULD HAVE VERY HEAVY PERIOD, EXTREME BLEEDING, SEVERE PAIN WHEN MOVING. ALMOST FELT LIKE SOMETHING WAS STABBING ME. I GAINED A TON OF WEIGHT AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040975	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 4/30/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD MY UTERUS FULL OF SCAR TISSUE AND IS THE PAST 9 MONTHS HAVE HAD TO HAVE IT CLEANED OUT 3 TIMES AND NOW I HAVE TO HAVE A HYSTERECTOMY. I AM VERY BLOATED, IN PAIN ALL THE TIME IN MY LOWER RIGHT AND LEFT SIDES AND MY LOWER BACK. I HAVE VERY LOW ENERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040976	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 11/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HEAVY NON STOP BLEEDING, HEART BURN, SEX DRIVE STOPPED. MOOD SWINGS, DEPRESSION

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040977	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 7/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE (B)(6), 2014. I GOT THE HSG (B)(6), 2014 AND WAS CONFIRM CLOSED. I MISSED MY (B)(6) PERIOD AND IN (B)(6) STILL NO PERIOD I JUST FIGURED IT WAS FROM THREE HSG. THEN I STARTED TO GET MORNING SICKNESS SO I TOOK A PREGNANCY TEST AND IT CAME BACK POSITIVE. I WAS CONFIRMED PREGNANT BY MY DOCTOR LATE (B)(6). I HAVE ALSO STARTED EXPERIENCING HEAD ACHES AND CRAMPING SINCE HAVING THE ESSURE PUT IN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040978	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 4/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ESSURE FAILED AND I AM CURRENTLY PREGNANT. I WAS BEING TREATED AS HIGH RISK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040979	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 9/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NOTICE A DISCOMFORT IN LEFT PELVIC SIDE AND ABNORMAL PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040980	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 11/26/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5040980 #(B)(4) WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040981	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 1/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD THE ESSURE IMPLANTS FOR 5 YEARS. MY PERIODS HAVE CHANGED SO DRAMATICALLY SINCE, THEY ARE UNBEARABLE MONTHLY. MY MOODS, THE BLEEDING, MY ZOMBIE LIKE TIREDNESS AND THE CRAMPING IS UNLIKE ANYTHING I HAD EVER HAD IN THE 20 PLUS YEARS OF HAVING NORMAL PERIODS BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040982	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 5/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MANY NEW ILLNESSES, CHRONIC PAIN, MUSCLE SPASMS, MIGRAINES, AND MUCH MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040983	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HIP PAIN AND SWOLLEN LEFT HIP, LEG CRAMPS AND ANKLE AND FEET SWELLING, EXTREME CRAMPS AND PELVIC PAIN, SHARP AND STABBING PELVIC PAIN, LOWER BACK PAIN, HEADACHES, DEPRESSION, STRESS AND ANXIETY, MOOD SWINGS, EXTREME HOT FLASHES, I FEEL LIKE I';M GOING THROUGH MENOPAUSE - BEEN TESTED FOR IT BUT DR SAID MY TESTS CAME OUT FINE, DRY VAGINAL, PAINFUL DURING SEX, VAGINAL ODOR, BELLY BUTTON LEAKAGE, PAINFUL PERIODS, NIPPLES ARE VERY SORE AND SENSITIVE, HEARTBURN, FORGETFULNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040984	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY, PROLONGED PERIODS. CONSTANT PELVIC CRAMPING, HIGH BLOOD PRESSURE, MIGRAINES, DIZZINESS, HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040985	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 10/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHE,S MOOD SWINGS, FANTOM PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040986	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE SURGERY EACH MONTH MY PERIODS GET HEAVIER WITH MORE CLOTS. SUPER SIZE TAMPONS ARE NOT BIG ENOUGH. THE PAIN WHILE ON MY CYCLE IS ALMOST UNBEARABLE. (B)(6) RELIEVES IT BUT I'M TAKING IT EVERY 4 HRS FOR 3-4 DAYS. SHARP STABBING PAINS, BURNING/ITCHING. JOINT PAIN, FLU LIKE SYMPTOMS, EXTREME FATIGUE....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040987	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE SURGERY EACH MONTH MY PERIODS GET HEAVIER WITH MORE CLOTS. SUPER SIZE TAMPONS ARE NOT BIG ENOUGH. THE PAIN WHILE ON MY CYCLE IS ALMOST UNBEARABLE. PAMPERIN RELIEVES IT BUT I'M TAKING IT EVERY 4 HRS FOR 3-4 DAYS. SHARP STABBING PAINS, BURNING/ITCHING. JOINT PAIN, FLU LIKE SYMPTOMS, EXTREME FATIGUE....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040988	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 1/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I ENDED UP IN THE ER THE DAYS AFTER THE PROCEDURE FOR ESSURE. THAT WAS THE MOST PAINFUL SURGERY AND RECOVERY I EVER HAD. I'VE HAD ABDOMINAL PAIN, REALLY HEAVY BLEEDING, MIGRAINES, SKIN RASHES, JOINT PAIN, SEVERE ASTHMA ATTACKS, EXTREME FATIGUE, HAIR LOSS, AND MUCH MORE "EVER" THE PROCEDURE. I LOST ABOUT 30% OF MY HAIR AFTER THE PROCEDURE AND IT TOOK ABOUT A YEAR TO GROW BACK IN, BUT IT ISN'T THE SAME. IT'S THINNER AND FINER. MY MIGRAINES CAN BE DEBILITATING ABOUT 4-6 DAYS A MONTH ON AVERAGE, BUT THERE IS ALREADY AT LEAST AN UNCOMFORTABLE HEADACHE PLAGUING ME. MY BACK ACHES ALL THE TIME AS WELL. I HAVE ENDLESS INSOMNIA. I GAINED 20+ POUNDS AND CAN'T TAKE IT OFF "BOO BATTERY" WHAT I DO EITHER. I'M EXHAUSTED BY THESE THINGS, BUT REALLY MAD TO FIND OUT IT MAY ALL BE FROM THE SUPPOSEDLY SAFE ESSURE PROCEDURE I HAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040989	BAYER	3/2/2015	3/2/2015

Event Information:

Event Date (B3): 1/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, BLOATING, PERIODS LASTING 4 WEEKS AT A TIME, PAINFUL INTERCOURSE, BOWEL ISSUES, PAINFUL OVULATION., MOOD SWINGS, DEPRESSION, JOINT PAIN, BACK PAIN, FREQUENT URINATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040990	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 9/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING MIGRAINES 3 TIMES A WEEK BACK IN (B)(6) AND IT HAS ALL GONE DOWN HILL SINCE THEN. HAIR LOSS, WEIGHT GAIN, SWELLING OF MY HANDS AND FEET, LEFT OVARY PAIN ALMOST DAILY, DISCHARGE, NIGHT SWEATS, DIZZINESS, MOOD SWINGS, RINGING IN EARS, ACNE, HIGH BLOOD PRESSURE, ANXIETY, LONG MENSTRUAL CYCLE, LOSS OF LIBIDO, BACK PAIN, NECK PAIN, NAUSEA, VOMITING, BLOOD CLOTS AND DARK BLOOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040991	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE I HAVE EITHER NOT HAD A PERIOD OR HAD AWFUL PAIN WITH MY PERIODS ALONG WITH HEAVY BLEEDING AND BLOOD CLOTS. I HAVE PAIN IN MY RIGHT LOWER BACK/HIP REGION THAT WON'T GO AWAY. WHEN I DO HAVE A PERIOD I FEEL LIKE MY VAGINA IS GOING TO FALL OUT. I BELIEVE I AM ALLERGIC TO NICKEL AND I DO NOT UNDERSTAND WHY THE NICKEL ALLERGY TEST ISN'T REQUIRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040993	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 8/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM THE DAY IT WAS PUT IN I HURT ON MY LEFT SIDE EVERY DAY, BACK PAIN, HEAD ACHES. IT IS MISERABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040996	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 1/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE ON (B)(6) 2014. IN (B)(6) I BEGAN TO GET SUCH BAD MIGRAINES THEY MADE ME ANGRY AND MEAN. NEVER HAD A MIGRAINE IN MY (B)(6) YEARS OF LIFE TILL THEN AND NOW THEY ARE 23 A WEEK. SEX WHAT HAS ALWAYS BEEN AN ENJOYABLE PART OF MY MARRIAGE. WITH 5 KIDS AND HECTIC LIVES WE HAVE MANAGED TO KEEP OUR LOVE AFFAIR GOING. BUT NOW IT IS SO MISERABLE AND PAINFUL AND WE WENT FROM EVERY NIGHT FOR THE LAST 8 YEARS TO MAYBE 2 TIMES A MONTH. I AM SCHEDULED FOR A HYSTERECTOMY (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040997	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THESE ARE ON GOING PROBLEMS OF MY LIFE NOW..... PAIN IN LOWER STOMACH AND BACK. STABBING PAINS ON BOTH SIDES. BREATH TAKING CRAMPS ALL THE TIME. PERIODS ARE LIKE CHILD BIRTH ALWAYS PASSING BLOOD CLOTS THE SIZE OF HALF DOLLARS AND BIGGER. CHANGING TAMPONS EVERY 10 TO 15 MINUTES. LOSING HAIR. DIZZY SPELLS. THIS WILL NOT LET ME CHANGE THE NEXT QUESTION ANSWER . I HAVE BEEN TO HOSPITAL FOR THESE PROBLEMS MULTIPLE TIMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040998	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 9/29/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD HEADACHES LASTING 6 DAYS, BLOATING, WEIGHT GAIN, IRRITABILITY, DEPRESSION, PAIN IN LEG,S SORE MUSCLES, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5040999	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 8/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM THE DAY IT WAS PUT IN I HURT ON MY LEFT SIDE EVERY DAY, BACK PAIN, HEADACHES. IT IS MISERABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041000	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM DAY ONE I HAD PELVIC PAIN AND CRAMPING. APPROXIMATELY 6 MONTHS AFTER A LOT OF OTHER SYMPTOMS STARTED. I HAVE HAD TESTS RAN AND THEY ALL CAME BACK NORMAL. SYMPTOMS I AM DEALING WITH ARE: CONSTANT FATIGUE; HEADACHES; PAIN IN MY PELVIC AREA, BACK AND JOINTS; SIGNIFICANT HAIR LOSS; WEIGHT GAIN; BREAKOUTS; VITAMIN D DEFICIENCY; ANXIETY; MOOD SWINGS; NO PERIOD. I NOW HAVE BEEN DIAGNOSED WITH ARTHRITIS TOO IN MY LOWER BACK RIGHT HIP AND NECK (I AM (B)(6)). I AM HAVING A HYSTERECTOMY (WHICH I WAS TRYING TO AVOID) TO REMOVE THE ONE COIL THAT STAYED IN MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041002	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, CHRONIC PAIN IN SIDE, HAIR LOSS, CYSTIC ACNE, WEIGHT GAIN, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041004	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THESE ARE ON GOING PROBLEMS OF MY LIFE NOW..... PAIN IN LOWER STOMACH AND BACK. STABBING PAINS ON BOTH SIDES. BREATH TAKING CRAMPS ALL THE TIME. PERIODS ARE LIKE CHILD BIRTH ALWAYS PASSING BLOOD CLOTS THE SIZE OF HALF DOLLARS AND BIGGER. CHANGING TAMPONS EVERY 10 TO 15 MINUTES. LOSING HAIR. DIZZY SPELLS. THIS WILL NOT LET ME CHANGE THE NEXT QUESTION ANSWER . I HAVE BEEN TO HOSPITAL FOR THESE PROBLEMS MULTIPLE TIMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041005	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 9/29/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD HEADACHES LASTING 6 DAYS, BLOATING, WEIGHT GAIN, IRRITABILITY, DEPRESSION, PAIN IN LEGS, SORE MUSCLES, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041006	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 8/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). GET ESSURE AND WHILE PLACING HAVING TOO MUCH PAIN AFTER 1 MONTH GET INTO HOSPITAL WITH INFLAMMATION AND CHRONIC PAIN SINCE THEN EVERY DAY USING IBUPROFEN TO GET THROUGH THE DAY. NEXT WEEK THEY TAKE ESSURE OUT BY TOTAL HYSTERECTOMY. I'M HAVING SO MUCH TROUBLE CAUSE OF THE NICKEL INSIDE OF THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041007	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 5/27/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER GETTING ESSURE IMPLANTED I HAVE SUFFERED LOTS OF PELVIC PAIN, HEAVY BLEEDING, CLOTS, BLOATING ,DIZZINESS, HEADACHES, RASHES, NO SEX DRIVE. HAVE HAD MANY BIOPSIES OF UTERINE WALL AND A AND C DONE. HOPING TO HAVE A HYSTERECTOMY AND GET MY NORMAL LIFE BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041008	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 12/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5041008 #(B)(4) HAD TAH-BSO ON (B)(6) 2015. SO MANY SYMPTOMS I HAVE HAD SINCE GETTING ESSURE HAVE DISAPPEARED. RASH THAT I HAVE HAD FOR ABOUT THE LAST 4 YEARS IS GONE. STARTED CLEARING UP WITHIN HOURS OF SURGERY. I TESTED NEGATIVE TO A NICKEL ALLERGY SO IT WAS ONE OF THE OTHER TOXINS IN THE COILS THAT WAS CAUSING THE RASH. I AM 15 DAYS POST OP AND DOWN 16 POUNDS WITH NO DIET OR EXERCISE. IT SEEMS THE SYSTEMIC INFLAMMATION CAUSED BY ESSURE IS LEAVING MY BODY. MY ANKLES NO LONGER HURT AND LOCK UP SINCE REMOVAL. THAT HAPPENED IMMEDIATELY AFTER SURGERY ALSO. MY RIGHT COIL WAS TOO FAR IN THE UTERUS AND THAT WAS THE RIGHT SIDE PAIN I HAD BEEN COMPLAINING ABOUT FOR YEARS. I ALSO HAD CYSTS ON MY RIGHT OVARY AND ADENOMYOSIS. I NOW HAVE TO GO ON BHRT BECAUSE I AM (B)(6) AND IN SURGICAL MENOPAUSE. NO WOMAN SIGNED UP FOR ALL OF THIS!! THIS GARBAGE NEEDS TO GO. I AM NO LONGER AT THE MERCY OF ANY MEDICAL BOOK, CLINICAL TRIALS, OR SCIENTIFIC DATA. THE PROOF IS IN THE RESPONSE OF MY BODY SINCE THE POISON HAS BEEN REMOVED. ESSURE NEEDS TO BE TAKEN OFF THE MARKET!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041009	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 6/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). REALLY BAD PELVIC PAIN ON BOTH SIDES MORE ON MY RIGHT SIDE. I HAVE HEAVY BLEEDING DURING CYCLE WITH HUGE BLOOD CLOTS AND HORRIBLE CRAMPS. I GET REALLY BAD HEADACHES AND I GET DIZZY. SINCE GETTING THE ESSURE I'VE BEEN VERY EMOTIONAL BECAUSE THE PAIN KEEPS ME FROM INTERACTING WITH MY KIDS. I GET A TINGLING / NUMBNESS ON MY THIGHS AND IN MY FEET. PAIN DURING INTERCOURSE . I CAN'T EVEN EXERCISE OR STRETCH BECAUSE IT FEELS LIKE SOMEONE IS DOWN THERE PULLING MY STUFF APART.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041010	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 11/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWO WEEKS POST OP I STARTED HAVING REALLY BAD STOMACH CRAMPS THAT WRAPPED AROUND TO MY LOWER BACK, I IMMEDIATELY WENT TO MY DR THAT PLACED MY DEVICE AND AFTER AN ULTRASOUND HE ONLY TOLD ME THAT EVERYTHING LOOKED NORMAL AND IT SHOULD STOP IN A COUPLE OF DAYS OR A WEEK OR TWO AT THE MOST. I WAS SENT HOME WITH NO WAY TO CONTROL THE PAIN, OTC MEDICATIONS DIDN'T HELP AT ALL, AND TRY TO RETURN BACK TO WORK AND GO ON ABOUT MY NORMAL ACTIVITIES WITH THE HOPE THE STOMACH AND BACK PAINS WOULD EVENTUALLY STOP, AFTER TWO WEEKS OF NON STOP PAIN AND THE PAIN SLOWLY INCREASING EACH DAY I HAD ENOUGH AND RUSHED TO THE ER IN TERRIBLE PAIN. I HAD TO LEAVE WORK EARLY ON SEVERAL OCCASIONS WHICH ULTIMATELY LEAD TO ME BEING FIRED FOR DAYS MISSED AND ONLY BEING ABLE TO WORK HALF DAYS. AT THE ER THEY HAD NO IDEA WHAT THE PROCEDURE WAS OR HOW IT WAS DONE AND JUST LOOKED AT ME LIKE THEY HAD NO CLUE WHAT I WAS TALKING ABOUT, EVEN THOUGH THE DEVICE WAS PLACED IN THEIR HOSPITAL BY AN OBGYN THEY ARE PARTNERS WITH. I WAS SENT HOME WITH A WRONG DIAGNOSES AFTER WAITING FOR SEVERAL HOURS. THEY SAID I WAS ONLY CONSTIPATED AND GAVE ME INSTRUCTIONS ON WHAT TO DO ABOUT I., THAT WAS A MONTH AGO AND THE PAIN IS STILL PERSISTENT EVERYDAY, SOME DAYS FORCING ME TO STAY IN THE BED EVEN THOUGH I HAVE I TWO YOUNG BOYS WHO NEED ME TO BE ABLE TO MOVE AND STAND UP CONSTANTLY EVERYDAY. I FINALLY MADE AN APPOINTMENT WITH THE DR ONLY TO FIND OUT THAT MY INSURANCE WOULD NOT COVER POST FOLLOW UP VISITS EVEN IF THE DEVICE IS CAUSING PROBLEMS SO I HAD TO PAY OUT OF POCKET FOR MY VISIT ONLY TO NOT EVEN BE EXAMINED BY THE DR. HE TOLD ME THAT HE SEES NO REASON FOR ME TO HAVE THESE PAINS FOR THIS LONG SINCE HIS ULTRASOUND 2 MONTHS AGO SHOWED THAT THE DEVICES "LOOKED" LIKE THEY WERE IN THE RIGHT PLACE AND IT WAS "HIGHLY UNLIKELY" THAT THEY COULD HAVE MOVED SINCE THEN.

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SINCE I HAVE HAD THESE DEVICES PLACED I HAVE HAD NOTHING BUT PAIN EVERYDAY, I WAS DIAGNOSED WITH MIGRAINES 2 YEARS AGO AND PUT ON MEDICATION TO CONTROL THEM BUT SINCE THIS DEVICE ALONG WITH THE BACK PAINS I AM BACK TO HAVING TERRIBLE MIGRAINES AT LEAST ONCE A WEEK WITH HEADACHES DAILY. MY MEDICATION IS NO LONGER WORKING AND MY WHOLE LIFE HAS BEEN TURNED UPSIDE DOWN SINCE PLACING THESE DEVICES AND NOW THAT I HAVE LOST MY JOB I ALSO LOST MY INSURANCE WHICH HAS PUT ME IN A BAD SITUATION WHERE I CAN'T EVEN GO TO FIND OUT WHAT'S WRONG OR TO DO MY CONFIRMATION TEST BECAUSE I CAN'T AFFORD TO PAY TO HAVE EITHER DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041011	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS IMPLANTED IN (B)(6) OF 2010. PRIOR TO ESSURE, I WAS A VERY HEALTHY ADULT. I TOOK NO PRESCRIPTION MEDS. OTHER THAN BEING SLIGHTLY OVERWEIGHT, I HAD NO "ABNORMAL" HEALTH ISSUES. SYMPTOMS/SIDE EFFECTS/ADVERSE EVENTS SINCE THEN: FATIGUE, THE INABILITY TO LOSE WEIGHT, DECREASED FOCUS (BRAIN FOG), MEMORY LOSS, HEADACHES, CRAMPING, HEAVIER BLEEDING AND CLOTTING DURING MENSTRUAL CYCLES, BLEEDING AFTER INTERCOURSE, ABNORMAL BLEEDING (3+ MONTHS), ABNORMAL ENDOCRINE BLOOD PANEL, BLOATED ABDOMEN, PAIN IN BREASTS, MOOD SWINGS, DECREASED LIBIDO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041012	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IRREGULAR, HEAVY PERIODS. SEVERE ABDOMINAL PAIN. CONSTANT HIP PAIN. LOWER BACK PAIN. DIAGNOSED WITH DEPRESSION AND FIBROMYALGIA. DAILY MIGRAINES AND ICE PICK HEADACHES. LACK OF SEX DRIVE. NO ENERGY. WEIGHT GAIN. DIZZY SPELLS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041013	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 1/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, DEVELOPMENT OF UTERINE FIBROIDS, HEMORRHAGIC CYSTS, MIGRAINES, WEIGHT GAIN, ABDOMINAL BLOATING, HYSTERECTOMY SCHEDULED FOR (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041015	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 3/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, CHRONIC FATIGUE, INFLAMMATION, CHRONIC HEADACHES, DIZZY SPELLS, NAUSEA, HEAVY BLEEDING, CHRONIC BACTERIAL VAGINITIS, HEAVY BLEEDING AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041016	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 6/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, PAINFUL CRAMPS IN ABDOMEN AREA, BLEEDING BETWEEN MENSTRUAL CYCLE, PAINFUL SEX, HAIR LOSS, MEMORY/CONCENTRATION ISSUES, CYSTIC ACNE STARTED, HEADACHES, DIZZY SPELLS, SHARP PAINS IN ABDOMEN, DULL ACHING IN HIPS AND PELVIC AREA, AND MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041017	BAYER	3/2/2015	3/3/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, CHRONIC PAIN IN SIDE, HAIR LOSS, CYSTIC ACNE, WEIGHT GAIN, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041014	BAYER	3/2/2015	3/4/2015

Event Information:

Event Date (B3): 2/20/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THE ESSURE SURGERY I'VE HAD BACK/HIP PROBLEMS, ER RETINA DAMAGE THAT REQUIRED SURGERY, DEVELOPED ALLERGY TO NICKEL, BECOME ANEMIC, LOW IRON, BECAUSE OF HEAVY PERIODS THAT LAST 3 WEEKS, HAD AN ABLATION DONE THAT HASN'T HELPED, DYSMENORRHEA, SPOTTING BETWEEN PERIODS, HEADACHES, HAIR LOSS, HAIR GROWTH ON FACE, ACNE, RINGING IN EARS AND BOWEL ISSUES CAUSING SEVERE BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041018	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODS LASTING FOR 10-14 DAYS, 2 PERIODS A MONTH. HEAVY BLEEDING, CLOTTING, SEVERE PELVIC PAIN, PAINFUL INTERCOURSE, METALLIC TASTE, FATIGUE, BACK PAIN, NIGHT SWEATS, BLOATING, WEIGHT GAIN, THE DEVICE PINCHED MY INSIDES WHEN SITTING, STABBING PAIN, CHRONIC PAIN ON A DAILY BASIS, MIGRAINES, INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041019	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 10/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THROUGHOUT THE DAY AND; PERIODICALLY DURING SEX I HAVE SEVERE CRAMPING PAINS THAT EMBOLIZE ME TREMENDOUSLY. I FEEL AS IF SOMETHING IS JABBING INTO MY SKIN AROUND MY LOWER STOMACH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041021	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 8/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAS A TERRIBLE SPELL THOUGHT I WAS DYING, FELT LIKE I WAS. HAD TO BE TOOK TO HOSPITAL BY AMBULANCE. FOUND OUT I WAS SEVERELY ANEMIC. HAD TO HAVE IRON TRANSFUSIONS FOR A FEW MONTHS TO BUILD MY IRON BACK UP. HAD NO IDEA BECAUSE I WAS HAVING TWO PERIODS A MONTH AND BLEEDING PROFUSELY WHILE ON IT, THAT IT WOULD CAUSE THIS. THIS IS WHERE I BEGAN TO PUT TWO AND TWO TOGETHER ON THE OTHER SYMPTOMS I HAVE HAD. SEVERE BACK PAIN FOR TWO YEARS WHEN I FIRST GOT IT PUT IN, IN 2008. THEN I JUST GOT USE TO IT. SEVERE BLEEDING WITH PERIODS, SEVERE CRAMPS AND PAIN WITH PERIODS, HAIR LOSS, RASHES, NIGHT SWEATS, INSOMNIA. NUMB AND WARM SPOTS IN SIDES OR HIPS. LOSS OF SEX DRIVE, PAIN WITH SEX. DEPRESSION, ANXIETY, MOOD SWINGS. THE LIST COULD GO ON AND ON. AND NOW I HAVE TO HAVE A HYSTERECTOMY IN A WEEK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041022	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 10/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN HAVING CONSTANT PAIN, BLEEDING, BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041023	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 1/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE EXPERIENCED SEVERE BLOATING, MIGRAINES, HEAVY PERIODS, CLOTS, SEVERE ABDOMINAL PAIN AND CRAMPS, WEIGHT GAIN, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041024	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 12/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, MIGRAINES, PAINFUL CRAMPS, LOSS OF BALANCE, NUMBNESS, HAIR LOSS, CANT SIT COMFORTABLY, CANT LAY COMFORTABLY, STABBING PAIN AT TIMES, LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041025	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 1/13/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN: FEELING FLU LIKE SYMPTOMS; WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041026	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 4/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN WITH SEVERE ABDOMINAL CRAMPS. LOW BACK AND HIP PAIN. MIGRAINE HEADACHES. HAIR LOSS. DEPRESSION. ANXIETY. SEVERE MOOD SWINGS. EXCESSIVE WEIGHT GAIN. JOINT PAIN. EXCESSIVE AND EXTREME BLEEDING AND PASSING OF BLOOD CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041027	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 9/25/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT CAUSED ME TO BE IN CONSTANT SEVERE PAIN EVERYDAY. CYST ON MY OVARIES. ENDOMETRIOSIS. I HAD TUMORS ON MY UTERUS. MY BLADDER AND BOWEL WAS STUCK TOGETHER. HAD ENDOMETRIOSIS IN MY COLON AND DIDN'T HAVE THIS UNTIL AFTER ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041028	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 2/19/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THIS PROCEDURE I HAVE HAD EXTREMELY HEAVY PERIODS, IRREGULAR PERIODS, PAINFUL CRAMPS, HEADACHES, DIARRHEA, FATIGUE, HIGH BLOOD PRESSURE, IRREGULAR HEARTBEAT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041029	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 7/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIC REACTION-LIP SWELLING, BAD RASH, AND ANXIETY. I WENT INTO THE EMERGENCY ROOM TO BE TREATED AS I NEVER HAD AN ALLERGIC REACTION BEFORE IN MY LIFE. NO ALLERGY TESTING OR LAB WORK WAS DONE ON ME PRIOR TO THIS DEVICE BEING IMPLANTED IN ME. I HAD NO PRIOR HISTORY WITH ANXIETY BEFORE THIS DEVICE WAS IMPLANTED IN ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041030	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 9/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). EXTREME CRAMPING (SO BAD I CANT GET OUT OF BED AT TIMES, POINT IT MAKES ME BREAK OUT IN A COLD SWEAT AND SICK TO MY STOMACH AT TIMES), HEAVY BLEED(LASTING UP TO 3 WEEKS), HEADACHES DAILY, WEIGHT GAIN (SINCE I GOT THE DEVICE I HAVE GAIN 30LBS), BLOATING IN THE STOMACH AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041031	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 1/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE MIGRAINES, ENDOMETRIOSIS, BLOATING, HIP PAIN, BOILS, BACK PAIN, OVARIAN CYST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041033	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 5/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041033 #(B)(4). I'VE BEEN TWO THE HOSPITAL TWICE THIS YEAR FOR STOMACH AND PELVIC PAIN WHEN TO MY PRIMARY CARE DOCTOR AFTER TALKING WITH H ABT EVERYTHING HE CALLED ANOTHER DOCTOR HE LOOKED STRAIGHT AT ME AND SAID HE BELIEVED THE ESSURE NEEDED TO COME OUT THAT NO ONE SHOULD DEAL WITH THIS PAIN FOR 2 YEARS BUT I'D HAVE TO FOLLOW UP WITH MY OBGYN ABOUT GETTING IT REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041034	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 12/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST OF ALL I ASK FOR A TUBAL BUT MY DR REFUSED SO I TRIED GOING TO ANOTHER DR THAT WAS WILLING TO DO IT BEFORE MY INS RAN OUT BUT OTHER DR WOULDN'T SEND MY MEDICAL RECORDS OVER SO I HAD TO GO BACK TO HIM AND HE STILL WOULDN'T DO THE TUBAL AND BASICALLY FORCED THIS ESSURE CRAP ON ME. I STARTED HAVING PROBLEMS AS SOON AS I GOT ESSURE. I STARTED HAVING HIGH BLOOD PRESSURE, RAPID HEART RATE, DEPRESSION, MIGRAINES, PAINFUL INTERCOURSE, LACK OF SEXUAL INTEREST, SEVERE LEFT SIDE AND BACK PAIN, BAD MENSTRUAL CRAMPS, BLEEDING AND LARGE CLOTS. THEN I HAD A MIS CARRIAGE 3 YEARS AFTER HAVING ESSURE AND THAT'S WHAT MADE ME LOOK INTO ESSURE PROBLEMS ANND SURE ENOUGH OTHERS WERE GOING THROUGH THE EXACT SAME THING, AND MOST GOING THROUGH MORE THAN ME. SO AFTER GOING TO THE DR FOR MANY YEARS AND BEING PUT MEDICINE FOR THIS REASON AND THAT, I DID A NICKEL TEST AND SURE ENOUGH I WAS EXTREMELY ALLERGIC. THAT'S WHEN I LOOKED INTO REMOVAL AND SHORTLY AFTER HAD THE COILS REMOVED ON (B)(6), 2014. I HATE THAT I WAS FORCE TO GET SUCH A HORRIBLE PRODUCT PUT IN MY BODY, IT TOOK SI MANY YEARS AWAY FROM MY 3 LIVING CHILDREN AS WELL AS ADDED HEARTACHE TO OUR FAMILY. I AM NOW SINGLE BECAUSE OF IT AND HAVE BEEN FOR 2 AND A HALF YEARS, IT'S REALLY HARD. I WILL NEVER AGAIN PUT ANYTHING IN MY BODY THAT DOESN'T BELONG THERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041035	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH THE ESSURE DEVICE IN (B)(6) OF 2010. THE PROCEDURE ITSELF WAS PRETTY PAINFUL BUT NOT HORRIBLE. I HAD ALOT OF BAD CRAMPING AND BLOATING FOR 2 WEEKS AFTER, BUT THE BLOATING HAS NEVER WENT AWAY, ONLY GOTTEN WORSE. MY STOMACH IS HARD AND LOOKS LIKE I'M 7 MONTHS PREGNANT. ASIDE FROM THE BLOATING THE FIRST YEAR WAS OK, THEN MY MENSTRUAL CYCLE COMPLETELY CHANGED. I WENT FROM HAVE A 3-4 DAY REGULAR CYCLE TO A 7-10 DAY VERY HEAVY CYCLE SOMETIMES TWICE IN ONE MONTH WITH HORRIBLE CRAMPS, HUGE BLOOD CLOTS, AND AGAIN MAJOR BLOATING. I ALSO NOTICED THAT I WAS HAVING ALOT OF HEADACHES. ALMOST EVERY DAY FOR A YEAR, NOW 4 YEARS LATER AND STILL ALMOST CONSTANT HEADACHES. AT THE TWO YEAR MARK I WOKE UP ONE MORNING WITH SEVERE PAINS ON MY LEFT SIDE. TOOK SOME OVER THE COUNTER IBPROFFEN AND WHEN THAT DIDN'T WORK I WENT TO UGENT CARE. THEY DID AN ULTRASOUND AND XRAY, SAID THEY COULDN'T SEE ANYTHING BUT MORE THAN LIKELY A KIDNEY STONE. THAT PAIN HAS NEVER WENT AWAY IN OVER TWO YEARS. EVERY E.R TRIP IS THE SAME, OH A KIDNEY STONE EVEN THOUGH WE CAN'T FIND THEM. NOT ONE OF THE DOCTOR'S I'VE EVER ENCOUNTERED AT THE E.R OR URGENT CARE HAS HEARD OF ESSURE. EITHER HAS MY PCP UNTIL I EXPLAINED IT TO HER AND SHE DID SOME RESEARCH. THAT IS VERY CONCERNING TO ME. OTHER SYMPTOMS INCLUDE HAIR LOSS, UNEXPLAINED RASHES, MEMORY LOSS, BRAIN FOG, CHRONIC FATIGUE, DIAGNOSED IBS, ACHY JOINTS, BACK PAIN, INTERSTITIAL CYSTITIS, NAILS HAVE BECOME VERY BRITTLE AND PRACTICALLY SEE THRU, I CATCH VIRUS'S VERY EASILY NOW WHICH I NEVER WAS SICK MUCH BEFORE ESSURE. ALSO ANEMIC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041038	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 7/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I GOT WHAT I THOUGHT WAS THE STOMACH FLU. I HAVE HAD ABDOMINAL PAIN ON AND OFF SENSE THEN. I HAVE CHRONIC DIARRHEA. MY THYROID BECOMES HYPERACTIVE WITHOUT CAUSE, I HAVE VERY INSUFFICIENT LEVELS OF VITAMIN D, TACHYCARDIA, SPIKES IN BLOOD PRESSURE AND GLUCOSE, CONSTANT NAUSEA, LOSS OF APPETITE, HAIR LOSS, WEIGHT LOSS, VIBRATING SENSATION IN LOWER ABDOMEN, SEVERE PAIN ON RIGHT SIDE, SEVERE CRAMPING DAYS BEFORE AND DURING CYCLE, LONG MENSTRUAL CYCLE WITH HEAVY BLEEDING CLOTTING AND CRAMPING, ANXIETY, DEPRESSION, MOOD SWINGS, LOSS OF LIBIDO, DRY SKIN, ACNE, MUSCLE ACHES, JOINT ACHES, MUSCLE CRAMPS, NASAL CONGESTION, FATIGUE. LAB WORK GOES FROM ABNORMAL TO NORMAL THE NEXT DAY. WAS SENT TO ER FOR SEVERE TACHYCARDIA, RESTING HEART RATE WAS 176, ABNORMAL LABS THAT DOCTORS CAN'T EXPLAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041039	BAYER	3/3/2015	3/3/2015

Event Information:

Event Date (B3): 10/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER SURGERY I HAD CONTINUOUS PAIN AND DISCOMFORT. MY PERIODS HAVE BECOME IRREGULAR AND OFTEN LAST FOR MORE THEN 7 DAYS AND ARE EXTREMELY HEAVY. I HAVE PAIN DAILY THAT DOMINANTLY STAYS ON MY RIGHT LOWER QUADRANT. I HAVE MUSCLE SPASMS THAT FEEL LIKE KICKING AND CAN BE PAINFUL. I HAVE MORE INFECTIONS AFTER THE DEVICES WHERE IMPLANTED. SYMPTOMS AFTER PROCEDURE INCLUDING TO DATE: CRAMPING. SHARP/STABBING PELVIC PAIN. ABNORMAL MENSES. OVARIAN CYSTS. BACTERIAL VAGINITIS. CONSTANT SPOTTING. DISCHARGE (ODOR/NO ODOR). EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA). PAINFUL OVULATION. NIGHT SWEATS. LOSS OF LIBIDO. BLEEDING/SPOTTING AFTER SEX. PAINFUL PERIODS (DYSMENORRHEA). PAINFUL INTERCOURSE. BLEEDING BETWEEN PERIODS. LONG MENSTRUAL CYCLES. YEAST INFECTIONS. BACTERIAL VAGINITIS. URGENT/FREQUENT URINATION. UTI (URINARY TRACT INFECTION), BLADDER INFECTION. I WAS ALSO DIAGNOSED WITH SARCOIDOSIS AFTER THE IMPLANTATION OF THE DEVICES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041040	BAYER	3/3/2015	3/4/2015

Event Information:

Event Date (B3): 1/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAD ESSURE PLACED IN EITHER (B)(6) OF 2012. BEFORE I HAD ESSURE PLACED I WAS NOT IN ANY TYPE OF PAIN AND I DID NOT HAVE ANY ISSUES OR PROBLEMS UNTIL AFTER I HAD THE DEVICE INSERTED. AND NOW MY LIFE IS RUINED. I SUFFER FROM EXTREME PELVIC PAIN EVERY SINGLE DAY. I HAVE BAD MIGRAINES PAINS IN MY LEGS. IRREGULAR MENSTRUAL CYCLES. AND MY LOWER STOMACH/ABDOMEN STAYS CRAMPING. MAJORITY OF THE TIME I CAN'T EVEN PLAY OR WORK OR ENJOY LIFE'S ACTIVITIES BECAUSE I AM SUFFERING FROM SEVERE PELVIC PAIN. THE PAIN IN MY PELVIC AREA IS SO CRUCIAL IT FEELS LIKE SOMETHING IS TWISTING AND TURNING AND POKING ME. THEN IT FEELS LIKE SOMETHING IS GOING TO FALL OUT OF MY VAGINAL AREA AS WELL. NO PAIN MEDS WILL TAKE THIS PAIN AWAY. I ALSO GET A BAD TASTE IN MY MOUTH LIKE I'M EATING QUARTERS OR SOMETHING. MY STOMACH IS SO BLOATED ITS EMBARRASSING. BUT THE PAIN IS THE WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041041	BAYER	3/3/2015	3/4/2015

Event Information:

Event Date (B3): 8/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ESSURE COIL HAS MIGRATED AND PERFORATED MY UTERUS. I WILL BE HAVING A HYSTERECTOMY ON (B)(6) 2015 TO REMOVE ESSURE, MY DAMAGED UTERUS, FALLOPIAN TUBES, ETC. THE MIGRATION WAS CONFIRMED THROUGH AN ULTRASOUND. I HAVE BEEN HAVING DEBILITATING PELVIC PAIN AS A RESULT. I HAVE ALSO GAINED A LOT OF WEIGHT, HAVE TERRIBLE MOOD SWINGS, BRAIN FOG, HIGH BLOOD PRESSURE, BLOATED STOMACH, AND MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041042	BAYER	3/3/2015	3/4/2015

Event Information:

Event Date (B3): 11/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LONG HEAVY PERIODS, LOWER BACK PAIN, PAINFUL INTERCOURSE, INFECTIONS, HEMMROIDS, FIBROIDS, BUMPS ON THE VAGINA, INFECTED (B)(6) C-SECTION SCAR, SKIN IRRITATIONS, DIAGNOSED WITH LICHEN PLANUS, POSITIVE ANA RESULTS, DIAGNOSED WITH FIBROMYALGIA AND ARTHRITIS, MIGRAINES, EYE SITE IS GETTING WORSE, FATIGUE, BRAIN FOG, HAIR FALLING OUT, METAL TASTE, HYPOTHYROID, EXCESSIVE WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041043	BAYER	3/3/2015	3/4/2015

Event Information:

Event Date (B3): 11/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, BACK AND HIP PAIN, LIVER DAMAGE, FIBROIDS, ENLARGED UTERUS, PRE-DIABETIC, BLOOD PRESSURE, FATIGUE, NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041414	BAYER	3/3/2015	3/17/2015

Event Information:

Event Date (B3): 2/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SYMPTOMS SINCE ESSURE PLACEMENT CONSISTED OF: HIGH BLOOD PRESSURE, BLOATING, FATIGUE, EYE TWITCHES, MUSCLE CRAMPS, MUSCLE SPASMS, BACK PAIN, SHARP PAINS IN LOWER STOMACH, PULLING SENSATION IN LOWER STOMACH, LONG PERIODS, HEAVY PERIODS, MISSING PERIODS, WEIGHT GAIN/UNABLE TO LOSE WEIGHT, DEPRESSION (BECAUSE OF WEIGHT GAIN AND CONSTANTLY BEING ASKED HOW FAR ALONG I WAS OR IF I WAS HAVING A BOY OR A GIRL), PAINFUL INTERCOURSE, COULDN'T DO NORMAL THINGS WITH MY CHILDREN BECAUSE OF THESE SYMPTOMS, STRESS WITHIN MY RELATIONSHIP BECAUSE OF THESE ISSUES, AND MORE. FINALLY, A HYSTERECTOMY THAT HAS RESOLVED MANY ISSUES WITHIN DAYS. IMPLANTED (B)(6) 2012/ HYSTERECTOMY (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00153	BAYER HEALTHCARE LLC	3/3/2015	4/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38210

Single Use: Y
Implant Date (E6): 11/6/2014
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 1/15/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 20-NOV-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C38210 ON (B)(6) 2014. NUMBER OF DEFECTIVE UNIT: ONE. OPERATORY REPORT FROM THE GYNECOLOGIST FROM (B)(6) 2014: PERINEAL AND VAGINAL DISINFECTION. INTRODUCTION OF THE HYSTEROSCOPE UNDER A STREAM OF PHYSIOLOGICAL SALINE HEATED BY VAGINOSCOPY, WITHOUT SPECULUM. CAVITY OF NORMAL ASPECT, NO VISIBLE LESION. MUCOUS OF NORMAL ASPECT. EASY CATHETERIZATION OF THE LEFT OSTIUM, BUT DIFFICULTY TURNING THE DEPLOYMENT WHEEL NOT ALLOWING TO ACTIVATE THE RELEASE BUTTON OF THE IMPLANT. NO OTHER POSSIBILITY OF RELEASE. STOP OF THE PROCEDURE. ATTEMPT OF TOTAL WITHDRAWAL IMPOSSIBLE INSPITE OF GRIPPING CLAMP. IMPLANT CUT AT THE ENTRY OF THE CERVIX. REMAINING PART TO THE UTERINE LEVEL. NO ATTEMPT TO THE RIGHT. OPERATORY FOLLOWINGS: NORMAL, NO BLEEDING, NO PAIN. DISCHARGE: ON THE SAME DAY, WITH CONVOCATION FOR LAPAROSCOPIC EXPLORATION WITH REMOVAL OF THE IMPLANTS AND TUBAL STERILIZATION. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: LOT NUMBER C38210 (PRODUCTION DATE 19-MAR-2014 AND EXPIRATION DATE 31-MAR-2017). DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: ROLLBACK TO INITIAL HARD STOP. DEPRESS BUTTON. PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM

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THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. AS OF 11/26/2014, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT AND THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE ARE ANTICIPATED EVENTS. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. ACCORDING TO THE DFMEA, THE MOST LIKELY CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT ISSUE. THE AE CASE REFERS ALSO TO USABILITY ISSUES. NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED; THEREFORE A BATCH INVESTIGATION WITH REGARD TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO ADVERSE EVENTS WERE REPORTED. FOLLOW-UP RECEIVED ON 02-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: (B)(4). FINAL ASSESSMENT: LOT NUMBER: C38210; EXPIRATION DATE: 31-MAR-2017; PRODUCTION DATE: 19-MAR-2014. SINCE PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. WE TYPICALLY INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. AS RECEIVED, MICRO-INERT FOUND TO BE BROKEN AND DETACHED. THE FINAL ROLLBACK WAS NOT COMPLETED. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. WE ALSO CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT AND BROKEN IMPLANT DURING THE PROCEDURE ARE ANTICIPATED EVENTS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. THE RETURNED COMPLAINT SAMPLE WAS INVESTIGATED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED A BATCH INVESTIGATION WITH REGARD TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN (B)(4). IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 12-FEB-2015 FOR THE FOLLOWING

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(B)(4) PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND ACCORDING TO PRODUCT TECHNICAL ANALYSIS, MICRO-INERT FOUND TO BE BROKEN AND DETACHED. THIS EVENT, CONSIDERED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED FOR ESSURE BASED ON THE PRODUCT TECHNICAL ANALYSIS (PTC) RECEIVED WHICH STATED THAT THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT AND BROKEN IMPLANT DURING THE PROCEDURE ARE ANTICIPATED EVENTS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE BREAKAGE OCCURRED DURING ESSURE PLACEMENT PROCEDURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041044	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 5/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE I LOST MY HAIR. BAD HEADACHES PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041045	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 4/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY EXPERIENCE WAS HORRIFIC. I WAS FIRST DIAGNOSED WITH IBS. THEN I HAD PROBLEMS DIGESTING THE FOOD I ATE AND HAD ONGOING URINATION AND BOWEL PROBLEMS. I ENDED UP HAVING A COLONOSCOPY, AND ENDOSCOPY WHICH CAME OUT CLEAN SO NOBODY COULD TELL WHAT WAS CAUSING ALL OF MY DEBILITATING PAIN. THEN I WAS IN THE EMERGENCY ROOM THREE TIMES WITHIN THREE WEEKS. I HAD MULTIPLE BLOOD, URINE, AND CT SCANS. I FINALLY ENDED UP HAVING A PARTIAL HYSTERECTOMY. I THOUGHT I WAS IN THE CLEAR BUT I AM STILL BATTLING MEMORY LOSS, MUSCLE TWITCHING IN HANDS, NUMBNESS IN MY LEGS AND HANDS, INABILITY TO FOCUS. WEAK, TIRED, AND SEVERELY DEPRESSED. HAVE A SEVERE CASE OF ENDOMETRIOSIS WHICH HAS CAUSED ME TWO MORE SURGERIES WITH THE LAST ONE COMING UP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041047	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 8/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CONTINUED WITH SERIOUS HEAVY BLEEDING AND REQUIRED AN ESSURE REMOVAL OF TUBES AND COILS AND THEN A COUPLE MONTH LATER BECAUSE OF THE DAMAGE DONE TO MY UTERUS I WAS IN SURGERY AGAIN FOR A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041048	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 8/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONTINUED WITH SERIOUS HEAVY BLEEDING AND REQUIRED AN ESSURE REMOVAL OF TUBES AND COILS AND THEN A COUPLE MONTH LATER BECAUSE OF THE DAMAGE DONE TO MY UTERUS I WAS IN SURGERY AGAIN FOR A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041049	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 3/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041049 #(B)(4) I AM SCHEDULED TO HAVE A HYSTERECTOMY ON (B)(6) 2015 AS A RESULT OF THESE COMPLICATIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041050	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 6/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/27/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH LOWER BACK PAIN, NOW I HAVE CONSTANT BACK PAIN, VITAMIN D DEFICIENCY,CYSTS ON MY OVARIES, HEAVY MENSTRUATION,OR SKIPPED MENSTRUATION, UNABLE TO REACH CLIMAX DURING SEX, LOW SEX DRIVE,JOINT PAIN, MIGRAINES,DIZZINESS,FATIGUE, TIRED EASILY,NO ENERGY,DEPRESSION, ANXIETY,MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041051	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 12/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE LEG,FOOT,AND HIP PAIN. MENSTRUAL CYCLES ARE 17 TO 20 DAYS APART AND BLEED VERY HEAVILY. I HAVE A CONSTANT RASH ON BACK AND CHEST GET BOILS UNDER BREASTS, AROUND WAIST AND LOWER. PAIN AND NUMBNESS IN ARMS AND HANDS. GET HEADACHES DAILY AND FEEL HOT SPOTS THROUGH BODY. CONSTANT FATIGUE AND CAN'T GET ENOUGH SLEEP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041052	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY FIRST SYMPTOMS WERE SHOOTING PAIN ARMS HANDS THIGHS LEGS. WEAKNESS. INCREASED PERIOD AND PELVIC PAIN. BACK AND HIP PAIN. RASH. INCREASED ALLERGIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041053	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AUTOIMMUNE DISEASES, CHRONIC MIGRAINES SYNDROME, CHRONIC VAGINAL BLEEDING, CHRONIC FATIGUE SYNDROME, WEIGHT LOSS, JOB LOSS, HAIR LOSS, BRUISING, NIGHT SWEATS, PRE MENOPAUSAL, BRAIN FOG, BODY NUMBNESS, WHOLE BODY PAIN, FIBROMYALGIA, MIGRATED COILS, CONFIRMED LUPUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041054	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 5/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE. FATIGUED. INSOMNIA. BLOATING. VITAMIN D DEFICIENCY. LEG PAIN. LEG NUMBNESS. HEAD FOG. SLURRED SPEECH. FORGETFULNESS. ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041055	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 12/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE LEG, FOOT, AND HIP PAIN. MENSTRUAL CYCLES ARE 17 TO 20 DAYS APART AND BLEED VERY HEAVILY. I HAVE A CONSTANT RASH ON BACK AND CHEST, GET BOILS UNDER BREASTS, AROUND WAIST AND LOWER. PAIN AND NUMBNESS IN ARMS AND HANDS. GET HEADACHES DAILY AND FEEL HOT SPOTS THROUGH BODY. CONSTANT FATIGUE AND CAN'T GET ENOUGH SLEEP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041056	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 1/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, HEAD ACHES, ALLERGIES, RASHES, PELVIC PAIN (CONSTANT), SHOOTING PAIN, HORMONE IMBALANCE, EXCESSIVE BLEEDING, CHEST PAIN, BLOATING, WATER RETENTION (ONSET WAS (B)(6) 2013, COULD NOT CHANGE DATE ON FORM).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041057	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 1/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, HEAD ACHES, ALLERGIES, RASHES, PELVIC PAIN (CONSTANT), SHOOTING PAIN, HORMONE IMBALANCE, EXCESSIVE BLEEDING, CHEST PAIN, BLOATING, WATER RETENTION (ONSET WAS (B)(6) 2013, COULD NOT CHANGE DATE ON FORM).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041058	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 8/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAIN IN BOTH SIDES OF LOWER ABDOMINAL AREA TO THE POINT OF NOT BEING ABLE TO MOVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041059	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 6/24/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE IMPLANTING THE ESSURE INTO MY BODY, I HAVE EXPERIENCED SEVERE HIVES AND OTHER ALLERGIC REELECTIONS FROM THE MATERIALS. I HAVE SEVERE ONGOING PERIODS, EXTREME PAIN COMING FROM MY FALLOPIAN AREAS- PARTICULARLY DURING SEXUAL ACTS, MENSTRUATION, AND ANY FORM OF EXERCISE. WORKING OUT HAS BECOME DEBILITATING. I HAVE DEVELOPED SEVERE REFLUX, BARRETT'S ESOPHAGUS, AND SEVERE DENTAL DECAY SINCE IMPLANTING THIS DEVICE. THIS IS WHILE MAINTAINING A VERY ACTIVE AND HEALTHY LIFESTYLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041060	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 8/23/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAD THE ESSURE IN (B)(6) 2009. FROM THE MOMENT I HAD THE PROCEDURE DONE I HAD SEVERE RIGHT SIDE PAIN WHICH RESULTED IN ONE OF MY FALLOPIAN TUBES BEING REMOVED IN (B)(6) OF 2011 (THE RIGHT COIL HAD MIGRATED AND WAS LODGED IN MY WOMB). MY SYMPTOMS WERE BETTER FOR A WHILE, THEN IN 2012, I STARTED HAVING LONGER PERIODS, LOSING BLOOD CLOTS AND MORE PAIN. THIS THEN PROGRESSED TO OTHER HEALTH ISSUES SUCH AS LOWER BACK AND PELVIC PAIN STOMACH PAIN AND CRAMPS, CONSTIPATION AND PERIODS THAT LASTED FOR MONTHS. I WAS IN SERIOUS AGONY TO THE POINT WHERE IT TOOK CONTROL OF MY EVERY DAY LIFE. ON (B)(6) 2015, I HAD A TOTAL HYSTERECTOMY LEAVING JUST ONE OVARY. SINCE MY HYSTERECTOMY (ASIDE FROM POST OP PAIN) EVERY SINGLE ONE OF MY SYMPTOMS HAS COMPLETELY DISAPPEARED AND I FEEL LIKE A DIFFERENT PERSON. AFTER MY SURGERY IN 2011 THE LEFT COIL ALSO MIGRATED AND GOODNESS KNOWS WHAT ELSE IT HAS DONE TO MY BODY. I AM AWAITING PATHOLOGY REPORTS AND PICTURES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041061	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 5/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) ELEVATED HEART RATE, CONTINOUS CONTRACTING OF MY UTERUS, MIGRAINE HEADACHE, CRAMPING AND IN ALOT OF PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041062	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 9/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HIGH BLOOD PRESSURE, BLADDER/UTI, CYSTS ON OVARIES, AND CERVIX, FIBROMYALGIA, CHRONIC PAIN IN FEMALE AREA, PAIN DURING SEX, BLEEDING AT LEAST 20 DAYS A MONTH, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041063	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 5/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN AND CRAMPING. EXCESSIVELY HEAVY BLEEDING. SEVERE BACK PAIN. INABILITY TO WALK UPRIGHT. DIFFICULTY BREATHING. SEVERE NAUSEA. EXCESSIVE SWEATING. EXTREMELY PAINFUL BOWEL MOVEMENTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041066	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 4/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THE ESSURE PROCEDURE IN (B)(6) 2012, MY PERIODS HAVE CHANGED DRAMATICALLY. (I DID NOT USE ANY HORMONAL BIRTH CONTROL BEFORE THIS, SO I KNOW WHAT MY PERIODS WERE LIKE.) I HAVE SEVERE CRAMPING, BLOATING, AND LOSS OF ENERGY THAT RENDERS ME UNABLE TO PERFORM MY DUTIES 1-3 DAYS OF MY CYCLE. I HAVE EXTREMELY HEAVY BLEEDING AND CLOTS BIGGER THAN A HALF DOLLAR. AFTER MY PERIOD, I HAVE BROWN SPOTTING FOR UP TO A WEEK. BEFORE MY PERIOD, I LOSE A CLEAR FLUID FOR 2-3 DAYS. I ALSO HAVE RANDOM CRAMPING THROUGHOUT THE MONTH, PAIN BY EITHER HIP BONE, AND POKING, STABBING PAIN ON THE LEFT SIDE. I AM NOW HAVING VERY TENDER (SORE) BREASTS, AS WELL. I HAVE SEEN A DOCTOR FOR THESE SYMPTOMS, BUT WAS TOLD MY TESTS WERE "NORMAL." AT THIS TIME, I HAVE NOT SEEN THE ULTRASOUND IMAGES FOR MYSELF.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041067	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 9/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THOUGHT WHAT I WAS FEELING PHYSICALLY WAS FROM THE SURGERY. AS DAYS WENT BY I WOULD FEEL EXHAUSTED, WEAK. I WAS TOLD I COULD GO BACK TO NORMAL ROUTINE AFTER SURGERY. I WAS JUST NOT FEELING MY NORMAL SELF. DAYS WENT TO WEEKS, MONTHS WENT YEARS OF ME NOT FEELING WELL! BLEEDING HEAVY, CRAMPING, BLOATING AS I LOOKED, FELT PREGNANT. BODY ACHES,PAIN CONSTANTLY ON LEFT SIDE OF NECK. PAINS IN LOWER BACK. RIGHT HIP, LEG PAINS, TENDERNESS, SHOOTING ACHES AND UNBEARABLE!!PAIN!!! BONES IN MY BODY STIFF, SORE EVERYDAY. CHANGES IN MY SKIN COLOR, TONE. UNDER EYE BAGS DUE TO NOT SLEEPING OR FEELING WELL. NASTY TASTE IN MY MOUTH WHEN WAKING UP IN MORNING. NOTICE FROM DENTIST MY ENAMEL IS THINNING. LACK OF INTIMACY WITH THE ONE I LOVE DUE TO FEELING UNCOMFORTABLE IN MY VAGINA AS SOMETHING IS IN THERE THAT SHOULD NOT BE! PHYSICALLY AND MENTALLY DRAINED FROM WORRY, DR APPOINTMENTS MRI XRAY, ER TRIPS!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041084	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 9/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRATION, NON-STOP PAIN IN ABDOMINAL AREA ,BACK , CONSTANT MIGRAINES DAILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041088	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 4/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041088 #(B)(4) MY LOT NUMBERS ARE: REF - (B)(4) LOT- 12475788. REF- (B)(4) LOT- 886675.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041089	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 3/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YEAST INFECTIONS, BACTERIAL VAGINOSIS, CHRONIC PELVIC PAIN. PAINFUL INTERCOURSE, PAINFUL OVULATION, PAINFUL MENSTRUATION, STABBING UTERINE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041090	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 3/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YEAST INFECTIONS, BACTERIAL VAGINOSIS, CHRONIC PELVIC PAIN. PAINFUL INTERCOURSE, PAINFUL OVULATION, PAINFUL MENSTRUATION, STABBING UTERINE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041091	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 3/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YEAST INFECTIONS, BACTERIAL VAGINOSIS, CHRONIC PELVIC PAIN. PAINFUL INTERCOURSE, PAINFUL OVULATION, PAINFUL MENSTRUATION, STABBING UTERINE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041092	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 12/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER MY PROCEDURE, I BLED FOR ABOUT 3 WEEKS. EVERYTHING SEEMED FINE AFTERWARDS. HAD MY CONFIRMATION TEST WHICH I PASSED OUT DURING. WHEN I WOKE UP, MY DOCTOR TOLD ME I WAS 100% BLOCKED. THEN I STARTED GETTING HEADACHES EVERY SINGLE DAY. I WAS DIAGNOSED WITH PYELONEPHRITIS, I HAVE THE WORST CRAMPS EVER, PAIN IN MY LOWER RIGHT ABDOMEN AND PELVIC AREA, WEIGHT GAIN, BLOATING AND DISTENDED ABDOMEN, BRAIN FOG, NUMBNESS AND TINGLING IN ARMS AND LEGS, FATIGUE, NAUSEA, ACHY BODY (EVERYTHING HURTS NOT JUST ONE PART OF MY BODY), NO ENERGY, MOOD SWINGS, DIARRHEA ALL THE TIME, AND NOW I AM DIAGNOSED WITH "SACROLILITIS".

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041106	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD 6 MISCARRIAGES. I HAVE CHRONIC MIGRAINES. I HAVE CONSTANT LOWER ABDOMINAL PAIN AND BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041110	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 1/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN! LONGER DEBILITATING PERIODS, NAUSEA, WEIGHT GAIN, BLOATING, HEADACHES, MIGRAINES, CLOTTING, I COULD GO ON FOR DAYS. I WENT TO THE OB/GYN ON (B)(6), 2015, I AM (B)(6) WITH A PROLAPSED UTERUS, HAVING A HYSTERECTOMY IN (B)(6). I'M SURE WE WILL FIND OTHER ISSUES WHEN HE TAKES THEM OUT. I HAVE HAD MY DEVICES ALMOST 6 YEARS. ALL THE SYMPTOMS BEGAN IMMEDIATELY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041116	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 1/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WITHIN 12 HOURS OF HAVING DEVICE IMPLANTED I BEGAN TO GET SHARP STABBING PAINS ON MY RIGHT PELVIC SIDE THAT SHOT UP BY BACK AND DOWN MY LEG I ALSO NOTICED SHORTNESS OF BREATH, EXTREME BACK PAIN THAT ALMOST HAS A STINGY THROBBING PAIN. ITCHY SKIN THAT COMES AND GOES. VERY FATIGUE AS THOUGH I'VE RAN A MARATHON AND THIS FEELING DOES NOT SUBSIDE. THE PAIN HAS NOT GONE AWAY SINCE DAY OF IMPLANTATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041119	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 2/27/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDA MW5041119 #(B)(4) I HAD AN ABDOMINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY ON (B)(6) 2015, WHEREIN THE DOCTOR REMOVED MY UTERUS, CERVIX, AND BOTH FALLOPIAN TUBES, (INCLUDING THE ESSURE INSERTS) DUE TO MANY ADVERSE SIDE EFFECTS, AS WELL AS CHRONIC PAIN ON MY RIGHT SIDE, AND A SECOND HSG TEST (SEVEN YEARS AFTER ESSURE WAS ORIGINALLY PLACED IN MY TUBES) SHOWED THE RIGHT COIL PERFORATED MY RIGHT FALLOPIAN TUBE AND SPILLAGE WAS NOTED COMING OUT DURING THE TESTS, WHICH CONFIRMED THE INSERT HAD MALFUNCTIONED AND I WAS IMMEDIATELY SCHEDULED FOR THE HYSTERECTOMY SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041124	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 6/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE PLACED I HAVE EXPERIENCED: CHRONIC HIVES (DAILY), MIGRAINES, VISION CHANGES, TEETH BREAKING, SEVERE BLOATING, HAIR LOSS AND BALDING, LOSS OF LIBIDO, PAINFUL INTERCOURSE, LONGER HEAVY MENSTRUAL CYCLES, CRAMPING, BACK PAIN, FATIGUE, DEPRESSION, METAL TASTE IN MOUTH, LOSS OF APPETITE, INSOMNIA, COLD SWEATS, LIGHT HEADED AND DIZZINESS HEART BURN, INDIGESTION, NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041128	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 6/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE PLACED I HAVE EXPERIENCED: CHRONIC HIVES (DAILY), MIGRAINES, VISION CHANGES, TEETH BREAKING, SEVERE BLOATING, HAIR LOSS AND BALDING, LOSS OF LIBIDO, PAINFUL INTERCOURSE, LONGER HEAVY MENSTRUAL CYCLES, CRAMPING, BACK PAIN, FATIGUE, DEPRESSION, METAL TASTE IN MOUTH, LOSS OF APPETITE, INSOMNIA, COLD SWEATS, LIGHT HEADED AND DIZZINESS HEART BURN, INDIGESTION, NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041143	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 7/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, RASHES, CRAMPING, MOOD SWINGS, DEPRESSION, SHARP STABBING PAINS IN MY SIDES. HOT FLASHES, DISCHARGE, PAINFUL INTERCOURSE, INFLAMMATION, PELVIC PAIN, BOWEL ISSUES, HEADACHES, CYSTS, WEIGHT GAIN, THYROID PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041148	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 10/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041148 #(B)(4). FORGOT TO MENTION THE BRAIN FOG, BODY ACHES, AND PAIN WHEN HAVING SEX. I FEEL LIKE I DON'T EVEN KNOW WHO I AM ANYMORE. I HAVE NO ENERGY TO DO ANYTHING. THIS ISN'T ME. THIS IS DESTROYING MY LIFE...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041157	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT ALL STARTED WITH SOME SHARP PAIN IN MY ABDOMEN UNDER MY RIB CASE . THEN SHARP SHOCKING PAIN IN MY BREAST AND CHEST. THEN THE PAIN SHUTS UP TO MY BACK, PINCH NECK. RESTLESS NIGHT, CAN'T SLEEP, MY DR PRESCRIBED LOTS OF EXAMS AND EVERY THING CAME OUT NORMAL. WE CAME UP WITH THE CONCLUSION IT IS THE ESSURE. I AM HAVING A NICKEL ALLERGY TO THIS ESSURE THAT HAS BEEN (B)(6) IN MY LIFE. I HAVE PAIN ALL OVER MY BODY. I WISH THEY NEVER INVENTED THIS PRODUCT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041158	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 5/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TO THIS DAY, I HAVE LONGER AND EXTREMELY HEAVY PERIODS. I FILL UP A SUPER PLUS TAMPON IN 2 HRS ALONG WITH BLOOD CLOTS THE SIZE OF QUARTERS, BAD CRAMPING AND I HAVE SEVER LOWER BACK PAIN, NAUSEA, ANXIETY, MOOD SWINGS. PAINFUL BREASTS. I NEVER HAD ANY PROBLEMS UNTIL I GOT THIS ESSURE. I WANT IT OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041159	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE REMOVED IN 2010 AFTER YRS OF PAIN. I HAD NO PAIN FOR ABOUT 1YR THEN THE PAIN CAM BACK AFTER 1 YR THE PAIN GOT SO BAD AND I COULD NOT USE THE BATHROOM. I WENT TO THE ER AND WAS HOSPITALIZED IN (B)(6) 2012. AFTER A COLONOSCOPY AND 11 DAYS IN THE ER THE DRS FOUND THE PROBLEM. THEY HAD TO REMOVE A PART OF THE DEVICE THAT WAS LEFT IN ME. I HAD TO GET A PARTIAL HYSTERECTOMY BC THE PART WENT THROUGH THE TUBE AND SNAGGED MY UTERUS AND A FATTY TISSUE OF MY COLON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041160	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS ALLERGIC TO THE NICKEL IN THE COILS. MY DOCTOR DISCOVERED INFLAMMATION WHEN HE TOOK THEM OUT. I HAD TO HAVE MY FALLOPIAN TUBES REMOVED. BEFORE I HAD THEM REMOVED, I HAD BLOATING, SEVERE PAIN ON BOTH SIDES, AND WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041161	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 11/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME LOWER BACK AND GROIN PAIN, HEAVY FREQUENT PERIODS, MIGRATED INTO UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041162	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 1/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOUND OUT I WAS PREGNANT WITH MY DAUGHTER IN (B)(6). AFTER HAVING HER FOUND OUT THE COILS HAD BECOME EMBEDDED IN MY BOWELS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041163	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 10/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SENSE I GOT THE IMPLANTS I HAD LOTS OF PROBLEMS. VERY BAD PAINS BELOW, VERY HEAVY PERIODS, PAINFUL SEX, ON THE SIDE VERY SHARP PAINS. JUST DON'T FEEL RIGHT SINCE I'VE GOTTEN THEM. I WOULD LIKE FOR THEM TO BE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041164	BAYER	3/4/2015	3/4/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PUT IN AFTER MY 4TH CHILD WAS BORN. IT WORKED FOR 5 YEARS AND FOUND OUT I WAS PREGNANT (B)(6) 2013 WITH BABY # 5. I SHOULD NOT HAVE BECOME PREGNANT. I HAVE TERRIBLE PAIN IN MY FALLOPIAN TUBE AS WELL. MY DOCTOR HAS IGNORED MY PAIN AS WELL AS THE FACT I HAVE GOTTEN PREGNANT AND WONT CHECK IF THE COILS ARE STILL IN PLACE. INSTEAD SHE WANTS TO GIVE ME A TUBAL LIGATION. I SHOULD NOT HAVE TO HAVE A TUBAL LIGATION IF I HAD ESSURE. NOW I AM IN CONSTANT WORRY THAT BABY #6 MIGHT HAPPEN. THIS IS FRUSTRATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041095	BAYER	3/4/2015	3/5/2015

Event Information:

Event Date (B3): 11/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE THIS DEVICE ENTER MY BODY, IT HAS GIVING ME NOTHING MORE THAN TROUBLE. STARTING WITH IRREGULAR PERIODS THAT COME AND GO AS THEY PLEASE, MAY HAVE 2 PERIODS WITHIN A MONTH WITH OUT ANY WARNING SIGNS (BEFORE WAS VERY REGULAR ON THE DOT), TO BRAIN FOGGINESS, VERTIGO (NEED TO HOLD SELF TO NOT FALL DOWN), I FEEL VERY DIZZY MOST OF THE TIME, VERY TEMPERAMENTAL OUT BURST FOR LITTLE THINGS. SHARP ABDOMINAL PAIN ON MY LEFT SIDE (MOSTLY), LOWER BACK PAIN, HEADACHES (VERY RARELY I SUFFER ONE UNTIL NOW). EXTREMELY FORGETFUL, VERY TIRED (FATIGUED) DURING THE ENTIRE DAY, LACK OF MOTIVATION, AND STRENGTH. UNABLE TO LOOSE WEIGHT (UNTIL NOW DUE TO EXTREME DIET), MY LEGS TINGLE LIKE SOMETHING IS CRAWLING ON THEM. TENDERNESS DURING SEX (CAN FILL A POKING PAINFUL SENSATION IN MY UTERUS, AND MAY BLEED AFTER INTERCOURSE (NEVER HAD THIS EXPERIENCE, ONLY DURING A TIME I USE THE MERINA DEVICE WHICH I HAD TO REMOVE DUE TO THE PAIN, IT ALSO CAUSE ALONG WITH THE BLEEDING). CONSTIPATION, STOMACH BLOATING (LOOK LIKE I'M 7TH PREGNANT). A LOT OF DISCHARGE FROM VAGINA, SOME TIMES IT HAS A SMELL TO IT (LIKE ROTTEN FISH), MAY BE EXTRA THICK AND CREAMY (NEVER HAD THIS PROBLEM BEFORE) IT ITCHES BUT NOT STD RELATED (HAVE RECENTLY BEEN TESTED AND CAME NEGATIVE TO ALL OF THEM). I AM A VERY HEALTHY PERSON. NEVER HAD A COMPLAINT BEFORE WITH ANY HOSPITAL, OR DR. I'M SO HEALTHY THAT EVEN WITH INSURANCE I NEVER REALLY HAD TO GO TO THE DR.'S OFFICE FOR NOTHING MORE THAN A COMMON COLD, HERE AND THERE, OR FOR BIRTH REASONS. I NEVER HAD A COMPLAINT OF ANYTHING MORE THAN JUST THE USUAL NORMAL LIFE. EVEN MY HEMOGLOBIN, PRESSURE, ALL BLOOD WORK'S, THYROID, EVERYTHING ALWAYS FINE, SO I DIDN'T REALLY GO TO THE DR. VERY OFTEN. NOW THAT

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MY INSURANCE RAN OUT AND I NO LONGER CAN AFFORD AN INSURANCE PLAN, AND CAN REALLY WORK DUE TO MY VERTIGO, FATIGUE, AND OTHER SYMPTOMS, NOW I NEED A DR. AND ALL THANKS TO ESSURE FOR THE CHANGE OF LIFE FOR THE WORST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041166	BAYER	3/4/2015	3/5/2015

Event Information:

Event Date (B3): 5/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HURT IN MY HIPS, I CRAMP, I CAN NOT LIFT MY RIGHT LEG OR SET CROSS LEGGING ANYMORE, IS SO HARD TO WORK ANYMORE BECAUSE ALL THE PAIN IM IN, THERE IS SO MUCH MORE THAT I GO THROGH EVERYDAY AND MY HAIR IS FALLING OUT NOW AND MY TEETH. WISH I WOULD HAVE NEVER GOT THEM BEEN IN (PROFANITY) SINCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041167	BAYER	3/4/2015	3/5/2015

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SERIOUS BACK, NECK AND ABDOMINAL PAIN, MUSCLE PAIN, HEAVY MENSTRUATION WITH BLOOD CLOTS, EXTREME FATIGUE, RESTLESS LEGS, MIGRAINES LASTING FOR 4-5 DAYS ONES A WEEK, NUMBNESS IN EXTREMITIES, OVARIAN CYSTS, COLD HANDS AND FEET, NIGHT SWEATS, FLUSHED SKIN AND PALENESS, SENSITIVE TEETH, ITCHY AND BUMPY SKIN, AS WELL AS VOMITING AND NAUSEA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041168	BAYER	3/4/2015	3/5/2015

Event Information:

Event Date (B3): 1/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY HEAVY BLEEDING, FEELING A POKING FEELING, STAYING NAUSEOUS A LOT, PAINS IN LOWER STOMACH, VERY WEAK AND TIRED DURING MENSTRUAL TIMES, BACK PAINS ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041169	BAYER	3/4/2015	3/5/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING MY SECOND HIGH RISK PREGNANCY AND HAVING 2 PRE-MATURE NICU BABIES, I DECIDED TO GET ESSURE. MY DR. WAS SO POSITIVE ABOUT THIS DEVICE AND WAS COMPLETELY CONFIDENT THAT THIS WAS THE BEST WAY TO GO. AFTER HAVING THE COILS PLACED, I IMMEDIATELY FELT A LOT OF PAIN. PAIN WHICH CONTINUED AND WORSENED OVER A YEAR AND HALF. MY DR. BRUSHED ME OFF AND REPEATEDLY SAID I WAS FINE. AFTER 2 YEARS OF SUFFERING, I FOUND ANOTHER PHYSICIAN IN ANOTHER PRACTICE. SHE DID A SCOPE AND TO HER SURPRISE SHE COULD NOT FIND THE DEVICE. IT INFACT WAS PLACED IN WRONG. THE COIL UNRAVELED AND WAS PIERCING MY OVARY. SHE THEN REMOVED MY FALLOPIAN TUBE AND PART OF MY VAGINAL WALL. WHICH IS NOW COMPLETELY PROLAPSED. I HAVE TO GO IN FOR NERVE BLOCKS INSIDE MY VAGINA EVERY 4 MONTHS BECAUSE I CANNOT BARE THE PAIN. I LOOKED FOR A LAWYER TO PICK UP MY CASE BUT HAVE BEEN UNSUCCESSFUL. I JUST WANT THIS DEVICE OFF THE MARKET SO OTHER WOMEN DO NOT SUFFER THE SAME WAY I DID.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00154	BAYER HEALTHCARE LLC	3/4/2015	4/6/2015

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06464

Single Use: Y
Implant Date (E6): 7/1/2014
Explant Date (E7): 3/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 02-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. CONSUMER PRESENTED A LOT OF PAIN DURING RIGHT SIDED IMPLANTATION. HEALTHCARE PROFESSIONAL (HCP) USED ONE ESSURE AND THERE WAS A LOT OF PAIN. HE THEN INSERTED A SECOND ONE ON THE SAME SIDE. CONSUMER EXPERIENCED SOME PAIN AFTER THAT LIKE A DULL ACHE SINCE JULY WHICH GETS WORSE WHEN SHE GETS JARRED DURING EXERCISE. HYSTEROSALPINGOGRAM (HSG) WAS DONE AND THERE WAS A LOT OF PAIN ON THE RIGHT SIDE AGAIN. HCP HAD LEFT A PIECE OF ONE INSERT IN THE UTERINE WALL AND WHEN HE PLACED THE SECOND DEVICE, IT PERFORATED THE FALLOPIAN TUBE. ADDITIONALLY, THERE WERE VISIBLE FIBROIDS ON RIGHT SIDE OF THE CONSUMER'S UTERUS. ACCORDING TO HER, HCP SUGGESTED REMOVAL OF INSERTS AND FALLOPIAN TUBES. CONSUMER STATED EVENTS AND ESSURE WERE ONGOING. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 14-FEB-2015: (B)(4). THE FINAL ASSESSMENT WAS: THE REPORTER STATED THAT HCP HAD LEFT A PIECE OF ONE INSERT IN THE UTERINE WALL. THAT COULD NOT BE CONFIRMED AS DEVICE BREAKAGE BUT INTERPRETED AS THE DEVICE PERFORATED THE UTERINE WALL. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL

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ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER, WHO HAD TWO ESSURES (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON THE SAME FALLOPIAN TUBE AND WHEN HCP PLACED SECOND DEVICE IT PERFORATED THE FALLOPIAN TUBE. ADDITIONALLY SHE STATED PHYSICIAN HAD LEFT A PIECE OF ONE INSERT IN THE UTERINE WALL. PHYSICIAN SUGGESTED DEVICES REMOVAL; HOWEVER THIS PROCEDURE WAS NOT CONFIRMED AT THE TIME OF THIS REPORT. THE REPORTED EVENTS, INTERPRETED AS FALLOPIAN TUBE PERFORATION DURING INSERTION AND SUSPICION OF DEVICE BREAKAGE WITH EMBEDMENT OF ESSURE FRAGMENT IN UTERINE WALL WERE CONSIDERED SERIOUS, AS MEDICALLY SIGNIFICANT AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; EXCEPT FOR DEVICE BREAKAGE WHICH IS UNLISTED. UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. ALSO, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, TWO DEVICES WERE INSERTED IN THE SAME FALLOPIAN TUBE; THIS DEVICE MISUSE MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED EVENTS; NEVERTHELESS, GIVEN THEIR NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY OTHER NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

UTERINE PERFORATION QUESTIONNAIRE RECEIVED ON 21-SEP-2015 FROM PHYSICIAN WHO INSERTED ESSURE: PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES WERE DENIED SHE HAD 01 PREGNANCY AND 01 LIVE BIRTH. MEDICAL HISTORY INCLUDED A C-SECTI

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00155	BAYER HEALTHCARE LLC	3/4/2015	4/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18710

Single Use: Y
Implant Date (E6): 1/16/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4)2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C18710 ON (B)(6) 2015. DURING ESSURE INSERTION PROCEDURE, THE HEALTHCARE PROFESSIONAL (HCP) PLACED THE ESSURE AND IT LOOKED LIKE A SLINKY, IT WAS PLACED TO DISTAL, THE TUBE BEGAN TO HAVE A SPASM, AND THE GREEN CATHETER DETACHED FROM THE CATHETER AND SEPARATED FROM DEVICE; HCP REMOVED IT AND STOPPED PROCEDURE (REPORTER STATED THAT EVERYTHING WAS REMOVED). BILATERAL PLACEMENT WAS NOT ACHIEVED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON (B)(4) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE REPORTED EXPIRATION DATE IS 31-JAN-2017 AND THE PRODUCTION DATE IS 29-JAN-2014. THE FINAL ASSESSMENT WAS: A TUBAL SPASM IS A TRANSIENT ANATOMICAL EVENT WHERE THE FALLOPIAN TUBE IS CONSTRICTED BY MUSCULAR CONTRACTION AND DOES NOT ALLOW CANNULATION BY A MEDICAL DEVICE. A TUBAL SPASM CAN BE TRIGGERED BY THE PHYSICIAN DURING THE PROCEDURE IF THE PHYSICIAN DOES NOT ADVANCE THE CATHETER WITH GENTLE, CONSTANT FORWARD MOVEMENT DURING CANNULATION. ACCORDING TO THE PRODUCT IFU, THERE IS A PRECAUTION: UNUSUAL UTERINE ANATOMY MAY MAKE IT DIFFICULT TO PLACE THE ESSURE MICRO-INSERTS. THE COMPLAINT NARRATIVE ALSO MENTIONS THE GREEN CATHETER DETACHED; BUT WAS REMOVED WHICH IS INTERPRETED AS A BREAKAGE EVENT. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE

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CATHETER. IT IS LIKELY THE TUBAL SPASM EVENT CONTRIBUTED TO THE BREAKAGE OF THE CATHETER. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, THEY CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. TUBAL SPASMS AND THE POSSIBILITY OF THE CATHETER BREAKING DURING PLACEMENT ARE ANTICIPATED EVENTS. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. ONE FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, WHICH REFERS ALSO TO A SIMILAR TYPE OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE, ESSURE LOOKED LIKE A SLINKY, IT WAS PLACED TO DISTAL, THEN THE FALLOPIAN TUBE BEGAN TO HAVE A SPASM, AND THE GREEN CATHETER DETACHED FROM THE CATHETER AND SEPARATED FROM DEVICE; HCP REMOVED IT. BILATERAL PLACEMENT WAS NOT ACHIEVED. ALL REPORTED EVENTS WERE CONSIDERED NON-SERIOUS AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT FOR GREEN CATHETER DETACHED FROM THE CATHETER AND SEPARATED FROM DEVICE, WHICH WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, THE PHYSICIAN HAD DIFFICULTIES IN THE DEPLOYMENT OF THE DEVICE AND A BREAKAGE OF INSERTION CATHETER OCCURRED. AS THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

ESSURE GENERAL QUESTIONNAIRE WAS RECEIVED ON 20-APR-2015 FROM PHYSICIAN: THE PATIENT WAS NOT POST-PARTUM AT TIME OF INSERTION. THE INSERTION WAS CONSIDERED EASY WITH EASY VISUALIZATION OF BOTH TUBAL OSTIUM. DURING THE PROCEDURE, CERVICAL DILATATION AND SO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00156	BAYER HEALTHCARE LLC	3/5/2015	3/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON 26-SEP-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND THE ONLY ADVERSE EVENT WAS A FAILED SECOND HSG AND THE PHYSICIAN WOULD REMOVE THE FALLOPIAN TUBES THE FOLLOWING WEEK. PTC INVESTIGATION RESULT WAS RECEIVED ON 31-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. HOWEVER, A LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 03-FEB-2015: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT GENERAL ANESTHESIA WAS APPLIED DURING ESSURE INSERTION. THE INSERTION WAS DESCRIBED AS DIFFICULT AND HEALTH CARE PROFESSIONAL INFORMED THAT

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ESSURE DID NOT DEPLOY CORRECTLY (INTRODUCER FELL APART). VISUALIZATION OF TUBAL OSTIUM WAS EASY. HYSTEROSALPINGOGRAM WAS PERFORMED AND SHOWED DEVICE EXTRA UTERINE (TUBE WAS NOT OCCLUDED). PATIENT WAS TAKEN FOR OPERATION ROOM FOR LAPAROSCOPIC SALPINGECTOMY AND REMOVAL OF DEVICE EMBEDDED IN MESOSALPINX. PATIENT'S OUTCOME WAS GOOD. PATIENT USED CONDOMS AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. IN ADDITION, REPORTER INFORMED THAT PERFORATION WAS RELATED TO ESSURE DEVICE MALFUNCTION. FOLLOW UP 12-FEB-2015: PTC INVESTIGATION RESULTS WERE UPDATED AND PROVIDED. (B)(4). FINAL ASSESSMENT: DEVICE BREAKAGE COULD NOT BE CONFIRMED WITH THE STATEMENT THE DEVICE FELL APART....."D" COMPLETED ON THE QUESTIONNAIRE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE (BREAKAGE - INTRODUCER FELL APART, MALFUNCTION), USABILITY ISSUES AND LACK OF EFFICACY (PATENCY). IN THIS PARTICULAR CASE, THE REPORTER INFORMED THAT ESSURE DID NOT DEPLOY CORRECTLY (INTRODUCER FELL APART), HSG SHOWED DEVICE EXTRA UTERINE (TUBE WAS NOT OCCLUDED- PATENCY). DEVICE WAS FOUND EMBEDDED IN MESOSALPINX AND REPORTER INFORMED THAT PERFORATION WAS RELATED TO ESSURE DEVICE MALFUNCTION. HOWEVER, THE REPORTED PRODUCT QUALITY ISSUE COULD NOT BE EVALUATED IN MORE DETAIL DUE TO LACK OF SAMPLE RETURN. NO BATCH NUMBER PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS ALSO NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. A HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND THE RESULT SHOWED DEVICE EXTRAUTERINE (EMBEDDED IN MESOSALPINX) / FALLOPIAN TUBE PERFORATION. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE EXACT DATE AND THE MECHANISM OF PERFORATION ARE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A LAPAROSCOPIC SALPINGECTOMY AND REMOVAL OF ESSURE WERE PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00159	BAYER HEALTHCARE LLC	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 9/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 10/6/2006
Explant Date (E7): 9/25/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5038421) IN UNITED STATES ON 03-FEB-2015. SHE HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2006. ON (B)(6) 2014 IT WAS OBSERVED THAT ESSURE COILS HAD MIGRATED OUTSIDE HER TUBES AND WERE EMBEDDED INTO HER UTERUS, WHICH WAS CONSIDERED AS AN IMPORTANT MEDICAL EVENT BY THE CONSUMER. THE DEVICES WERE REMOVED ON (B)(6) 2014. FOLLOW UP 16-FEB-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. (B)(4). MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND APPROXIMATELY 8 YEARS LATER, IT WAS

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OBSERVED ESSURE COILS HAD MIGRATED OUTSIDE HER TUBES AND WERE EMBEDDED INTO HER UTERUS. THE DEVICES WERE REMOVED. THE REPORTED EVENT, REGARDED AS DEVICE EMBEDMENT (PARTIAL UTERINE PERFORATION), WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED EVENT IS UNKNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE ESSURE REMOVAL (IMPLYING A SURGICAL INTERVENTION) WAS REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 20-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00160	BAYER HEALTHCARE LLC	3/5/2015	3/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 15-DEC-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER STATED THAT SHE WOKE UP EVERY DAY IN SEVERE PAIN. PTC INVESTIGATION RESULT WAS RECEIVED ON 04-JAN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: PAIN IS PHYSICAL SUFFERING OR DISTRESS, AS DUE TO INJURY, ILLNESS, ETC. PROBABLE CAUSES FOR PAIN INCLUDE: TISSUE IRRITATION OR DAMAGE, INACCURATE PLACEMENT OF THE MICRO-INSERT. ACCORDING TO THE PRODUCT IFU, PAIN IS A KNOWN RISK OF THE ESSURE PROCEDURE, DURING OR POST-PLACEMENT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PAIN IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT

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BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 04-FEB-2015: CONSUMER REPORTED VIA SOCIAL MEDIA THAT SHE HAD A HYSTERECTOMY TO REMOVE HER ESSURE. THE COILS WERE CAUSING HER MUCH BS (NO OTHER SPECIFIED). SHE REPORTED THAT AFTER HAVING HER CERVIX, UTERUS AND TUBES REMOVED SHE STILL FELT SEVERE PAIN. SHE WENT TO THE URGENT CARE AND HAD AN X-RAY DONE WHICH SHOWED THAT OTHER COIL WAS ATTACHED IN HER INTESTINES OR BLADDER. SHE STATED THAT WILL HAVE ANOTHER SURGERY IN THE NEAR FUTURE. CASE WAS UPGRADED TO INCIDENT. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS UPDATED ON 20-FEB-2015: THE FINAL ASSESSMENT WAS: THIS CASE UPGRADED TO INCIDENT BECAUSE OF HYSTERECTOMY. THIS SOCIAL MEDIA REPORT WAS NOT CONFIRMED. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN. ALSO, A X-RAY SHOWED ESSURE COIL WAS ATTACHED IN HER INTESTINES OR BLADDER. THE EVENTS, SEEN AS PELVIC PAIN AND DEVICE DISLOCATION, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE PATIENT WOKE UP EVERY DAY IN SEVERE PAIN AND AFTER HAVING HER CERVIX, UTERUS AND TUBES REMOVED SHE STILL FELT PAIN. SHE WENT TO THE URGENT CARE AND HAD AN X-RAY DONE WHICH SHOWED THAT A COIL WAS ATTACHED IN HER INTESTINES OR BLADDER. GIVEN THE EVENT'S NATURE AND AVAILABLE INFORMATION, CAUSALITY BETWEEN THE EVENTS AND ESSURE USE IS ASSESSED AS RELATED AND SINCE REQUIRED INTERVENTION WAS REPORTED, THE CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FOLLOW-UP INFORMATION CAN BE OBTAINED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 21-DEC-2015: FOLLOW UP ATTEMPTS WERE MADE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00162	BAYER HEALTHCARE LLC	3/5/2015	3/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5037927) IN UNITED STATES ON 06-FEB-2015 WHICH REFERS TO THE CONSUMER HERSELF, OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD HER UTERUS REMOVED DUE TO BEING ALLERGIC TO THE ESSURE DEVICE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 16-FEB-2015: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS ALLERGIC TO ESSURE. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE

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REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS ONLY MENTIONED THAT THE CONSUMER HAD HER UTERUS REMOVED DUE TO BEING ALLERGIC TO ESSURE DEVICE. THUS, CAUSALITY IS ASSESSED AS RELATED TO ESSURE AND SINCE HER UTERUS WAS REMOVED (REQUIRED INTERVENTION) THE CASE IS REGARDED AS INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00163	BAYER HEALTHCARE LLC	3/5/2015	3/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/22/2009
Explant Date (E7): 8/26/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE (B)(4)) IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. THE CONSUMER EXPERIENCED HEAVY MENSTRUAL CYCLES FOR 6 YEARS, CHRONIC ABDOMINAL PAIN, PAINFUL INTERCOURSE, MIGRAINES, BACK PAIN, DEPRESSION, AND ON (B)(6) 2014 SHE UNDERWENT A HYSTERECTOMY BECAUSE THE ESSURE COILS MIGRATED TO HER UTERUS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT

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REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COILS MIGRATED TO HER UTERUS. THIS EVENT, INTERPRETED AS PARTIAL EXPULSION OF DEVICE, WAS CONSIDERED SERIOUS AND LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM THE REPORTED EVENT WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A HYSTERECTOMY WAS PERFORMED BECAUSE THE ESSURE COILS MIGRATED TO HER UTERUS. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 09-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUME

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041170	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 11/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RECURRING BACTERIAL VAGINITIS AFTER PROCEDURE WAS DONE. VERY HEAVY AND PAINFUL MENSTRUAL CYCLES. CONTINUOUS ABDOMINAL PAIN, BODY ACHES,FATIGUE, INSOMNIA, DENTAL ISSUES, HEADACHES, METALLIC TASTE IN MOUTH, PAINFUL INTERCOURSE, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041171	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, PANIC ATTACKS, SENSITIVE SKIN, PAINFUL INTERCOURSE, IBS, WEIGHT GAIN, FATIGUE, ABDOMINAL PAIN, SEVERE CRAMPING, IRREGULAR MENSTRUATION, HEAVY BLEEDING, DIZZINESS, NUMBNESS AND TINGLING IN HANDS AND ARMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041172	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 9/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE VERY HEAVY BLEEDING WHEN ON MY PERIOD THAT LASTS ABOUT TWO WEEKS AT A TIME. I HAVE A STABBING PAIN ON MY LOWER RIGHT SIDE OF MY ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041173	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I HAD ESSURE IMPLANTED, MY PERIODS HAVE BECOME EXTREMELY HEAVY, SOMETIMES SOAKING THRU A SUPER PLUS TAMPON IN LESS THAN AN HOUR, AND THEY HAVE ALSO BECOME MORE FREQUENT, COMING ABOUT EVERY THREE WEEKS NOW. I HAVE HORRIBLE STABBING PAINS IN MY PELVIC REGION FREQUENTLY, SOMETIMES PAINFUL ENOUGH TO CAUSE ME TO NOT EVEN BE ABLE TO STAND UP. SERIOUSLY, THE PAIN IS WORSE THAN BEING IN LABOR. I HAVE COMPLETELY LOST MY SEX DRIVE BECAUSE SEX IS PAINFUL NOW. I DID NOT HAVE ANY OF THESE PROBLEMS BEFORE RECEIVING ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041174	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 10/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY PAINFUL SIDE PAINS .

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041175	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, MAJOR WEIGHT GAIN MAINLY IN STOMACH. STABBING PAIN ON BOTH SIDES, HEAVY BLEEDING, ANXIETY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041176	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 3/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING SHARP PAINS IN LEFT SIDE FROM NAVEL DOWN TO VAGINA, BAD HEADACHES, PAINS DURING SEXUAL INTERCOURSE, LOSS OF SEX DRIVE DUE TO PAINS AND HURTING. IMPLANTS IN LEFT TUBE BROKE IN TWO OR THREE PIECES. I WAS EMOTIONALLY SCARED OF WHAT WAS WRONG WITH ME. DR DID EXAM AFTER IMPLANTS WAS PUT IN AND SHE STATED THEY WERE IN PLACE WHERE NEEDED, THAT I WAS FINE. RECOVERY WAS 8 WEEKS SHE SAID OF BLEEDING WHICH LASTED ABOUT SIX WEEKS STRAIGHT, HEAVY! I WENT FROM HAVING SEX SEVERAL TIMES A DAY TOO NONE AT ALL DUE TO THE IMPLANTS AND ME BLEEDING AFTER SEX PAINS. I HAVE A PLATE, ROD, SCREWS, AND A CAGE IN MY BACK DUE TO MY SPINE DETERIORATION. SO I FIGURED THIS WAS THE BEST THING DR RECOMMENDED TO GET. I HAVE JUST HAD PAPILLARY CARCINOMA THYROID CANCER IN BOTH THYROID GLANDS AND FOUND OUT I HAD A BLACK SPOT WHICH CAME BACK NON CANCEROUS. NOW I TAKE THYROID MEDICATION THE REST OF MY LIFE! MY BODY NOW IS NOT PRODUCING MUCH. I'M ON "ASK KINDA" MEDS, POTASSIUM MEDS, FOLIC K, PAIN MEDS, NEURONTIN, LASIX,AND ALBUTEROL FOR ASTHMA. INHALERS FOR ASTHMA. I HAD SURGERY AND HAD THEM REMOVED. DR RECOMMENDED ME TO REMOVE THEM DUE TO LEFT SIDE WAS BROKEN IN SEVERAL PIECES! SINCE REMOVAL PAINS IN LEFT SIDE ARE GONE, HEADACHES ARE LESS AND SEX DRIVE STILL NO IMPROVEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041177	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HYSTERECTOMY ON (B)(6) 2015. SINCE THEN, DEALING WITH EARLY MENOPAUSE, PELVIC PAIN, BUT ALL OTHER SYMPTOMS HAVE VANISHED. NO MORE JOINT PAIN, CONSTANT MIGRAINES, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041178	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 12/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN AND MAJOR BLOATING, MOSTLY IN MY STOMACH. MOST DAYS I LOOK AND FEEL 8 MONTHS PREGNANT. LOTS OF HEADACHES, MOOD SWINGS, DEPRESSION. VERY FOGGY MINDED AND FORGETFUL. SHARP PAIN ON MY SIDES IF I MOVE A CERTAIN WAY OR TOO FAST. HEAVY MENSTRUAL BLEEDING AND CLOTS. DULL HIP PAIN AND MANY MORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041179	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 12/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041179 #(B)(4). DUE TO THE MIGRATION OF ESSURE COIL, I HAD TO HAVE A TOTAL HYSTERECTOMY ON (B)(6), 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041180	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 7/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PLACED IN (B)(6) 2012. SEVERE HEADACHES, WEIGHT GAIN, FATIGUE, GREYISH SKIN, MOOD SWINGS RESULTING IN A HYSTERECTOMY AT THE YOUNG AGE OF (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041181	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 1/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, CONSTANT HEADACHES, NO MENSTRUAL FOR A YEAR AND THEN HEAVY MENSTRUAL, CRAMPING, EXTREME FATIGUE, HAD TWO LARGE CYSTS ON MY FALLOPIAN TUBES (WHICH HAD TO BE SURGICALLY REMOVED TAKING ONE OVARY AND BOTH TUBES).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041182	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2011. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 774400. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINTS STARTED WITHIN 6 MONTHS OF IMPLANTATION. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: CRAMPING, SHARP/STABBING PELVIC PAIN, VAGINAL DISCHARGE, HOT FLASHES, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), NIGHT SWEATS, LOSS OF LIBIDO, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS (DYSMENORRHEA), PAINFUL INTERCOURSE (DYSPAREUNIA), INCONTINENCE, LONG MENSTRUAL CYCLES (POLYMENORRHEA), SEXUAL DYSFUNCTION (UNABLE TO ORGASM OR FEEL PLEASURE), YEAST INFECTIONS (CANDIDA), URGENT/FREQUENT URINATION, UTI (URINARY TRACT INFECTION), BLADDER INFECTION, ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE , ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, BACK PAIN, JOINT PAIN, LEG PAIN, HIP PAIN, CHRONIC PELVIC PAIN, ALL OVER BODY ACHES/PAIN, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, HEADACHES OR MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS NERVE PAIN, BRAIN FOG AND; CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN (PARESTHESIA), NERVE PAIN, HIGH BLOOD PRESSURE, ALLERGIES/SENSITIVITIES, METAL ALLERGIES (NICKEL), HEIGHTENED ALLERGIES/ ALLERGIC REACTIONS, ALLERGIC REACTIONS, HIVES, RASHES, CYSTS, BOILS, ACNE, SKIN IRRITATION/ITCHING, SWELLING OF LEGS OR FEET, HAIR LOSS OR CHANGES, HAIR GROWTH IN NEW PLACES, DENTAL ISSUES, GALLBLADDER ISSUES

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(GALLSTONES/REMOVAL), WEIGHT ISSUES (LOSS/ GAIN), SWELLING OF LEGS/FEET, MUSCLE SPASMS, VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION), EXCESSIVE SWEATING, DRY SKIN/HAIR/EYES, SEVERE BLOATING. I HAVE BEEN SEEN BY 2 DIFFERENT DOCTORS. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: REMOVAL OF FALLOPIAN TUBES, PART OF UTERUS, AND THE COILS. THE DEVICE HAS BEEN REMOVED ON (B)(6) 2014. THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER THE DEVICE IS NOT IN MY POSSESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041183	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 10/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD BEEN SUFFERING FROM SEVERE ABDOMINAL PAINS, BACK PAINS, JOINT ACHES AND HEAVY, HEAVY BLEEDING. MY MENSTRUAL STARTED ON (B)(6) 2014 AND I WAS GOING THRU A SUPER PLUS TAMPON AND SUPER PAD IN LESS THEN AN HOUR AN A HALF. I WENT TO DR. (B)(6) ON (B)(6) AND HE PRESCRIBED MEGESTROL TO STOP THE BLEEDING. THIS HAD BEEN HAPPENING OVER THE LAST 2 YEARS BUT THIS TIME WAS THE WORSE. I COULD NOT GET OUT OF BED, THE CRAMPING AND BLEEDING WAS SO BAD. I HAD A PARTIAL HYSTERECTOMY ON (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041184	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 11/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE CRAMPING, HEADACHES, WEIGHT GAINED, MOOD SWING AND FIND MYSELF VERY IRRITABLE. IT HAS BEEN EFFECTING MY LIFE FOR OVER TWO YEARS AND JUST DON'T FEEL LIKE MYSELF ANYMORE!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041185	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I NOTICED WITHIN A FEW MONTHS OF IMPLANTATION THAT I WAS SUDDENLY LOSING A LOT OF HAIR. A YEAR HAS PASSED SINCE I FIRST NOTICED IT AND THE LOSS IS INTENSIFYING. MY HAIR IS NOW EXTREMELY THIN AND I MUST WEAR IT UP ALL OF THE TIME (THE SHEDDING IS VERY NOTICABLE - THE BACK OF MY SHIRT GETS COVERED WITH HAIR OTHERWISE). I ALSO HAVE DISCOMFORT AND SOMETIMES SHARP PAIN, MOSTLY ON THE RIGHT SIDE OF MY PELVIC AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041186	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN (B)(6) OF 2013, I HAD THE ESSURE PROCEDURE DONE. MY DOCTOR GUARANTEED THIS PRODUCT 100%. SHE SAID THERE WERE NO KNOWN SIDE EFFECTS. AND THAT I WAS A GOOD CANDIDATE FOR IT DUE TO MY BUSY LIFE STYLE. ONCE I HAD THIS DEVICE IMPLANTED, I BLEED FOR 3 MONTHS AFTER IT WAS PLACED. MY DOCTOR HAD TOLD ME AT THE TIME (B)(6) WOULD COVER THE DYE TEST AT 3 MONTHS TO MAKE SURE THE COILS WERE PLACED RIGHT. 3 MONTHS CAME AROUND AND (B)(6) WOULD NOT COVER THE DYE TEST. AT THAT POINT, I HAD ALREADY KNOWN SOMETHING WAS WRONG. I HAD ALREADY RECEIVED TERRIBLE MIGRAINES AND MY PERIODS WENT FROM 7 DAYS TO 14 DAYS LONG NOT TO MENTION THE CHUNKS OF HAIR I WAS LOOSING AND THE CONSTANT ABDOMINAL PAIN. WITHIN 6MONTHS OF HAVING ESSURE, I CONSTANTLY FELT BLOATED AND I STARTED BLEEDING IN BETWEEN PERIODS. I'M AT THE POINT NOW WHERE I CONSTANTLY BLEED. I HAVE RECENTLY PURCHASED HEALTH INSURANCE AND AM WAITING FOR IT TO BECOME ACTIVE TO RETURN TO THE DOCTOR. I JUST WANT MY BODY BACK AND TO BE ABLE TO FEEL NORMAL AGAIN. OTHER THAN THE MILD CASE OF ASTHMA, I HAVE BEEN A COMPLETELY HEALTHY PERSON. I HAVE NEVER SUFFERED FROM HEADACHES OR ANY OF THE ABOVE SYMPTOMS LISTED; I ALSO ALWAYS STAYED AT A GOOD WEIGHT AND SINCE THIS PROCEDURE, I NOW STRUGGLE WITH MY WEIGHT REGARDLESS OF HOW MUCH I EXERCISE, I ALWAYS STAY WITHIN (B)(6) OF MY CURRENT WEIGHT WHICH IS 15 TO 20LBS MORE THAN MY WEIGHT BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041187	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 4/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BOTH COILS WERE SUCCESSFULLY IMPLEMENTED IN 2012 AND HSG TEST SHOWED TUBES WERE 100% BLOCKED. ENDED UP PREGNANT TWICE, (B)(6) 2014 AND AGAIN IN (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041190	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN , PREGNANT ANDA ABORTION, HAEMORRHAGIA EVERY DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041191	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 6/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INTENSE ABDOMINAL PAIN AND HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041192	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 9/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DIDN'T KNOW IT HAD NICKEL. I'M ALLERGIC TO DIFFERENT METALS. A LOT OF DAYS I STAY IN BED IN PAIN ON LEFT SIDE LOWER BELLY, PAIN DURING SEX, VERY TIRED ALL THE TIME, SKIN IRRITATIONS, BELLY ITCHY. HAD TO REMOVE PIERCING FROM BELLY. FEET TINGLING AND FALL ASLEEP, CYCLE COMING OUT LIKE POWDER, DIZZY AND BLACKOUTS, BACTERIAL INFECTION. EVERY TIME SEEN AT (B)(4) CLINIC AND CERVICITIS EVERY TIME. DEPRESSION, ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041194	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 4/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY AND PAINFUL PERIODS, CHRONIC FATIGUE, JOINT PAIN (HIPS,ANKLES,SHOULDERS,PELVIC REGION); BREAST PAIN, BLOATING, OVARIAN CYSTS, OTHER CYSTS, PARTIAL HYSTERECTOMY TO CORRECT PROBLEMS LEAVING OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041196	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 2/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ISSUES STARTED 4 DAYS AFTER THE PROCEDURE WHEN I WAS OUT TO DINNER WITH MY HUSBAND FOR OUR 10 YEAR WEDDING ANNIVERSARY. IT BEGAN WITH DEEP CHILLS FOLLOWED BY SWEATING. MY HEARING BECAME MUFFLED AND MY VISION STARTED GOING BLACK. I FELT AS THOUGH I WAS GOING TO PASS OUT. THE NEXT 7 DAYS WERE THE WORST. I WENT THROUGH VARIOUS SPELLS (I DON'T KNOW WHAT ELSE TO CALL THEM). I WOULD BE FREEZING, THEN SWEATY HOT, THEN SHAKING, DISORIENTED, I WOULD SEE SPLOTCHES OF COLOR IN MY VISION (LIKE A PSYCHEDELIC LIGHT SHOW).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041197	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STOMACH CRAMPING, BACK ACHING, BLOOD IN STOOL, GAINED ABOUT 15 POUNDS, AND STOMACH BLOATING ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041198	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 12/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD IMMEDIATE PAIN, BLOATING, HEAD ACHES, DEPRESSION. THEN WHEN I GET MY PERIOD I HAVE BEEN BLEEDING NON STOP SINCE IT STARTED IN AN ABNORMALLY LARGE AMOUNT. I'VE ALSO BROKEN OUT WITH A RASH OVER MY LYMPH NODES ON MY NECK. I HAVE MUSCLE STIFFNESS AND JOINT PAIN. I'VE ALSO BEEN EXPERIENCING LARGE HORMONAL SWINGS WHERE BEFORE THEY WERE STABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041199	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING BACK PAIN, ABDOMINAL PAIN/CRAMPING, ABNORMAL PERIODS, CONSTANT SICK FEELING. WEAK IMMUNE SYSTEM, LOW ENERGY, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041200	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 6/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING INTERMITTENT PAIN IN MY RIGHT SIDE. SLOWLY PROGRESSED GETTING WORSE OVER THE NEXT 6 MONTHS. I BEGAN HAVING OTHER ISSUES AS WELL JUST AS MIGRAINES, EXCESSIVE BLEEDING, BACTERIAL VAGINOSIS, MULTIPLE UTI'S, JOINT PAIN. IN (B)(6) 2015 MY PAIN BECAME MORE INTENSE AND WOULDN'T GO AWAY. I HAD 2 ULTRASOUNDS AND A CT SCAN THAT CONFIRMED MY COIL ON MY RIGHT SIDE HAD MIGRATED INTO MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041201	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 6/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED TO HAVE RIGHT SIDED PAIN FOR ABOUT 2 WEEKS OUT OF EVERY MONTH. THE PAIN GRADUALLY GOT WORSE. WITH IN THE PAST FEW MONTHS THE PAIN STARTED TO TRAIL DOWN TO MY LOWER PELVIC/ PUBIC AREA. THE PAIN STARTED TO RADIATE DOWN MY INNER RIGHT LEG. I ALSO GOT RANDOM, INTERMITTENT PAINS INSIDE MY VAGINA. THIS PAIN WAS A SHARP, STABBING, SHOOTING PAIN. I WENT TO MY GYNECOLOGIST AND REPORTED THIS PAIN. I HAD A TRANSVAGINAL ULTRASOUND THAT SHOWED BOTH MY ESSURE COILS MIGRATED OUT OF MY FALLOPIAN TUBES AND ARE NOT STUCK AT THE TOP OF MY CERVIX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041202	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 12/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THOUGHT I WAS HAVING A HEART ATTACK SO WENT TO ER. THEY SAID ALL "REST" WERE GOOD FOR MY HEART BUT DIAGNOSED ME WITH PLEURISY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041204	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 5/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIZZINESS AND NAUSEA STARTED TO THE POINT I TOOK A PREGNANCY TEST. IT WAS NEGATIVE. THEN THE PROBLEMS WITH FOOD STARTED. SUDDENLY LACTOSE INTOLERANT, CANNOT EAT ANY FAT WITHOUT DISCOMFORT, ALMOST IMMEDIATE ELIMINATION WHEN ANY FAT OR DAIRY CONSUMED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041205	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 1/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PROCEDURE DONE (B)(6) 2015; BY (B)(6) 2015, I HAD CRIPPLING STABBING PAIN IN MY LOWER ABDOMINAL AREA I WENT TO THE ER TWICE I HAVE HAS CT SCANS, X RAYS, BLOOD WORK, A COLONOSCOPY DUE TO SUDDEN SWELLING OF MY INTESTINES. I HAVE NEVER HAD HEALTH ISSUES UNTIL NOW. EACH DAY IT GETS WORSE . TODAY IS (B)(6) 2015 AND MY HEALTH ISSUES NOW INCLUDE SHARP STABBING PAIN IN MY ABDOMEN HAVE TO TAKE PAIN PILLS . VOMITING, SEVERE STOMACH BLOATING AND HEAVINESS, VAGINAL DISCHARGE, BURNING HOT FEELING IN MY PELVIC AREA, SPOTTING ON AND OFF, PAINFUL SWOLLEN LEAKING BREASTS, WHITE BUMPS AROUND NIPPLES, CONSTANTLY COLD, LETHARGIC, STOMACH IS TENDER TO THE TOUCH, LOWER BACK PAIN, PAINFUL INTERCOURSE, STABBING PAIN INSIDE VAGINA, BRAIN FOG, FORGETFULNESS, HAIR LOSS/DRY HAIR, HEADACHES, FLUTTERING IN PELVIC AREA, PRESSURE ON MY VAGINA , MUSCLE JOINT PAIN , STINGING STABBING IN VAGINAL ENTRANCE , ANXIETY, PANIC ATTACKS, METALLIC TASTE IN MY MOUTH, INSOMNIA, PAIN WHILE WASHING VAGINAL AREA . I CAN NOT PICK UP MY 4 MONTH OLD OR MY 22 MONTH OLD CHILDREN DUE TO THE INTENSE PAIN. I AM ALLERGIC TO NICKEL AND ALL METALS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041206	BAYER	3/5/2015	3/5/2015

Event Information:

Event Date (B3): 7/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIDN'T HAVE MY CALL TO CONFIRM THE COILS WERE BLOCKED, AFTER THE THREE MONTHS START HAVING PREGNANCY SYMPTOMS- LATER FEEL LIKE PRODUCING BREST MILK. THE MOST HORRIBLE ONE IS FEELING BELLY BLOATING, LOOKING LIKE I AM PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00164	BAYER HEALTHCARE LLC	3/5/2015	3/6/2015

Event Information:

Event Date (B3): 2/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C76452

Single Use: Y
Implant Date (E6): 2/3/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD THE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT PROCEDURE DONE IN (B)(6) 2015. THE LOT NUMBER USED WAS C76452. PHYSICIAN REPORTED THAT THE HYSTEROSCOPE PERFORATED THE UTERUS OF PATIENT DURING THE PROCEDURE TO PLACE ESSURE. THE ESSURE STERILE PACKAGING HAD NOT YET BEEN OPENED WHEN THE PERFORATION OCCURRED. UNILATERAL PLACEMENT WAS ACHIEVED AS THE SITE OF THE PERFORATION OBSCURED THE PHYSICIAN'S ABILITY TO DETERMINE WHERE THE PATIENT RIGHT OSTEUM WAS. THE PATIENT WAS HOSPITALIZED, PER SURGERY CENTER PROTOCOL, FOR 23 HOURS FOR OBSERVATION DUE TO SALINE USED TO DISTEND THE UTERUS FOR THE PURPOSE OF PLACING THE ESSU INTERNAL CORRECTION ON (B)(6) 2015 AND PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE (B)(6) 2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: THIS IS A HANDLING ERROR BY THE PHYSICIAN, CAUSING THE PERFORATION BY THE SCOPE, NOT THE ESSURE DEVICE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO

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COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND HANDLING ERROR. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD THE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT PROCEDURE DONE, BUT THE HYSTEROSCOPE PERFORATED THE UTERUS DURING THIS PROCEDURE. THIS EVENT IS SERIOUS DUE TO HOSPITALIZATION AND LISTED FOR ESSURE ACCORDING TO THE REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE UTERINE PERFORATION OCCURRED DURING ESSURE INSERTION PROCEDURE. THE PERFORATION IS, THEREFORE, CONSIDERED A COMPLICATION OF THE INSERTION PROCEDURE. A CAUSAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE PERFORATION CAN THEREFORE NOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PATIENT WAS HOSPITALIZED. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED: UNILATERAL PLACEMENT WAS ACHIEVED (DEVICE INSERTION FAILED). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 11-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. PERFORATION QUESTIONNAIRE RECEIVED ON 01-JUL-2015 FROM PHYSICIAN: PATIENT WAS APPROXIMATELY (B)(6). PRE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00165	BAYER HEALTHCARE LLC	3/5/2015	3/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(4) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION. PREGNANCY WAS DENIED. PATIENT COMPLAINED OF PELVIC PAIN AND HAD A TOTAL HYSTERECTOMY PERFORMED ON (B)(6) 2015. THE PATIENT ACTUALLY HAD TWO COILS IN THE LEFT TUBE. ESSURE WAS REMOVED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND COMPLAINED OF PELVIC PAIN. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE

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AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE PATIENT HAD PELVIC PAIN AND A TOTAL HYSTERECTOMY WAS PERFORMED. THEREFORE, THE CASE IS ASSESSED AS RELATED TO ESSURE AND SINCE AN INTERVENTION WAS REQUIRED, THE CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 09-JUN-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041207	BAYER	3/5/2015	3/6/2015

Event Information:

Event Date (B3): 6/3/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING FOR MONTHS EXTRICATE PAIN HEADACHES AND MEMORY ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041208	BAYER	3/5/2015	3/6/2015

Event Information:

Event Date (B3): 4/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY (B)(4), FORMALLY BY (B)(4), MY LOT NUMBER IS 915887. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF SOME OF MY COMPLAINTS STARTED IMMEDIATELY AFTER THE PROCEDURE AND FURTHER EVALUATION WAS DONE THROUGHOUT 2012 THROUGH NOW, 2015. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. BLEEDING IMMEDIATELY AFTER THE PROCEDURE, NOTICED TINGLING IN BACK AND HANDS, SEVERE PAIN IN LOWER BACK, SENSATION OF WATER RUN DOWN LEGS AND ONTO FEET, PAIN IN UPPER AND LOWER EXTREMITIES, PELVIC PAIN AND A RANDOM STABBING FEELING IN PELVIC AREA, PAIN/DISCOMFORT DURING INTERCOURSE, VAGINAL DISCOMFORT/ITCHING/BURNING AND IRRITATION AND HAD TO HAVE A BIOPSY OF THE VULVA, VAGINAL DRYNESS, TREMORS/INVOLUNTARY MOVEMENT, SPEECH AND VISION PROBLEMS. I'VE HAD SYMPTOMS THAT MIMIC AN AUTOIMMUNE DISEASE. BLOOD SHOWS POSITIVE/ELEVATED ASO TITER AND INFLAMMATION. I HAVE BEEN SEEN BY 8-10 DOCTORS. I WAS EVALUATED FOR MS, WHICH WAS RULED OUT. I WAS HOSPITALIZED BECAUSE OF THE SYMPTOMS FOR POSSIBLE STROKE, BUT RULED OUT. I WAS TOLD I MAY HAVE YOUNG ONSET PARKINSON'S DISEASE WHICH WAS RULED OUT AS WELL. I HAVE BEEN SCHEDULED FOR A HYSTERECTOMY DUE TO ESSURE. THE DEVICE IS STILL INSIDE OF ME, BUT WILL BE REMOVED (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041210	BAYER	3/5/2015	3/6/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY PAINFUL, SHARP, STABBING PAINS IN MY ABDOMEN. PAINFUL ABDOMINAL BLOATING WITH DISTENSION. CHRONIC GAS. HAIR THINNING AND LOSS. HEADACHES. PAINFUL OVULATION. PAINFUL MENSTRUAL CRAMPS. HEAVY PERIODS (NEVER HAD BEFORE) WITH CLOTTING. BACK PAIN. FATIGUE. DEPRESSION AND MOOD SWINGS. LOSS OF ENERGY. BACK PAIN. WEIGHT GAIN DESPITE DIET AND EXERCISE. INABILITY TO LOSE WEIGHT. PREMENOPAUSE AT (B)(6). LOW LIBIDO AND PAIN DURING SEX. OVERACTIVE BLADDER. LEG CRAMPS. NUMBNESS IN TOES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041211	BAYER	3/5/2015	3/6/2015

Event Information:

Event Date (B3): 1/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE PAIN AND CRAMPING FROM DAY ONE, HEADACHES, FATIGUE, PAIN IS IN MY HIPS, LEGS AND LOWER BACK, I HAVE GOTTEN A RASH AND I AM ON 4 DIFFERENT PAIN PILLS TO GET THROUGH THE DAYS AND NIGHTS. I'VE HAD BLEEDING SINCE THE ESSURE IMPLANTS SOME HEAVY DAYS SOME NOT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041212	BAYER	3/5/2015	3/6/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME CHRONIC DIARRHEA BLOATING CRAMPING NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00157	BAYER HEALTHCARE LLC	3/5/2015	4/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12707

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/17/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON 03-FEB-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C12707, INSERTION. ADDITIONAL INFORMATION WAS RECEIVED ON 04-FEB-2015. SHE INFORMED ABOUT A SUSPICION OF DEFECTIVE ESSURE. THE APPLICATOR DID NOT WIND OFF OR DISCHARGE. ACCORDING TO HER; THE PHYSICIAN HAD PUSH A BUTTON BUT IMPLANT DID NOT DISCHARGE. ANYWAY THE IMPLANT GOT STUCK IN PATIENT'S TUBE AND THE PHYSICIAN HAD "TO WORK" TO GET IMPLANT OFF. THE IMPLANT WAS MANAGED TO BE REMOVED AND A NEW IMPLANT WAS INSERTED. CONCLUSION WAS ACHIEVED BUT IT TOOK MORE TIME AND IT CAUSED EXTRA PAIN FOR THE PATIENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND THERE WAS A SUSPICION OF DEFECTIVE ESSURE, SINCE THE IMPLANT DID NOT GET OFF OR DISCHARGE. THE IMPLANT STUCK IN PATIENT'S TUBE. PHYSICIAN HAD TO WORK TO GET IMPLANT OFF. THE IMPLANT WAS REMOVED AND REPLACED BY A NEW ONE. PATIENT EXPERIENCED EXTRA PAIN. THE REPORTED EVENTS, REGARDED AS DEVICE DEPLOYMENT ISSUE AND PROCEDURAL COMPLICATION FOLLOWED BY A DIFFICULT ESSURE REMOVAL AND PAIN WERE CONSIDERED NON-SERIOUS AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL; IN THIS PARTICULAR CASE A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THE REPORTED EVENTS; HOWEVER CONSIDERING THAT THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE

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WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, IT MIGHT HAVE LED IF IT OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: ROLLBACK DIFFICULTY IS DEFINED

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00158	BAYER HEALTHCARE LLC	3/5/2015	4/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06461

Single Use: Y
Implant Date (E6): 10/30/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 03-FEB-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION WAS RECEIVED ON 05-FEB-2015 VIA SALES REPRESENTATIVE. PHYSICIAN REPORTED ESSURE CONFIRMATION TEST CONCERNS WITH PLACEMENT; THE IMAGE HAD A GOLD BAND ATTACHMENT AND THERE WAS A PORTION OF THE INNER CATHETER EVIDENT ON THE IMAGE. ADDITIONALLY, PHYSICIAN STATED SHE HAD PLACED INSERT DISTALLY ON PURPOSE BECAUSE OF A PLANNED ABLATION. FOLLOW-UP RECEIVED ON 12-FEB-2015: THE SALES REPRESENTATIVE STATED THAT PATIENT HAD ESSURE INSERTED ON (B)(6) 2014, LOT NUMBER C06461. SHE ALSO REPORTED THAT IT WAS BILATERAL PLACEMENT BUT SHE WAS NOT SURE IF IT IS TOO FAR DISTAL. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON 24-FEB-2015: (B)(4). THE FINAL ASSESSMENT WAS: PRODUCTION DATE: 13-DEC-2013 AND EXPIRATION DATE: 31-DEC-2016. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED FOR

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INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. IN THIS CASE, THEY CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND HANDLING ERROR. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE CONFIRMATION TEST IMAGE HAD A GOLD BAND ATTACHMENT AND THERE WAS A PORTION OF THE INNER CATHETER EVIDENT ON THE IMAGE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, WAS CONSIDERED NON-SERIOUS AND IS LISTED (ANTICIPATED) ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC) RESULTS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF THE REPORTED EVENT IS NOT KNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY THE NON-SERIOUS EVENT HCP HAD PLACED INSERT DISTALLY ON PURPOSE WAS REPORTED. PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00161	BAYER HEALTHCARE LLC	3/5/2015	4/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C35389

Single Use: Y
Implant Date (E6): 2/6/2015
Explant Date (E7): 2/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(4) ON (B)(4) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C35389, INSERTED ON (B)(6) 2015. DURING ESSURE PLACEMENT, IN THE OPERATING ROOM, THE DEVICE DID NOT RELEASE AT THE RIGHT TIME. ON DEVICE WITHDRAWAL THE METAL WIRE UNRAVELED AND THE PLASTIC SHEATH BROKE INTO THE UTERINE CAVITY AND THERE WAS A NEED TO REMOVAL WITH PLIERS. THE PROCEDURE WAS STOPPED AND BILATERAL PLACEMENT WAS NOT PERFORMED. REPORTER STATED CONSEQUENCES FOR THE PATIENT WERE THE IMPLANTS NOT PLACED AND SPASMS OF THE UTERUS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE, THE DEVICE DID NOT RELEASE AT THE RIGHT TIME. ON DEVICE WITHDRAWAL THE METAL WIRE UNRAVELED AND THE PLASTIC SHEATH BROKE INTO THE UTERINE CAVITY. PROCEDURE WAS STOPPED AND BILATERAL PLACEMENT WAS NOT PERFORMED. ADDITIONALLY, SPASMS OF THE UTERUS WERE REPORTED. ALL REPORTED EVENTS WERE CONSIDERED NON-SERIOUS AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT FOR THE PLASTIC SHEATH BROKE INTO THE UTERINE CAVITY, INTERPRETED AS DEVICE BREAKAGE, AND SPASMS OF THE UTERUS WHICH ARE UNLISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED TO FURTHER EVALUATE THE REPORTED EVENTS; NEVERTHELESS SINCE THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE

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EXCLUDED. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED FROM THE PHARMACIST ON (B)(6) 2015: PATIENT HAD A SMALL SUBSEROSAL FIBROMA IN THE UTERUS AS CONCOMITANT CONDITION. SHE WAS ON CONTRACEPTION UNDER CERAZETTE DURING ESSURE PROCEDURE WHICH WAS DONE UNDER GENERAL ANESTHESIA WITH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00166	BAYER HEALTHCARE LLC	3/6/2015	3/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 5/7/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION. PATIENT WAS PRESENTING A VARIETY OF PROBLEMS AFTER PROCEDURE. PAIN AND MORE PROBLEMS. PATIENT WAS SENT TO A RHEUMATOLOGIST AND THIS DOCTOR SAID PATIENT DEVELOPED A HYPERSENSITIVITY TO ESSURE. ON (B)(6) 2014, A HYSTERECTOMY WAS PERFORMED. ESSURE WAS REMOVED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(6). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN.

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THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENT WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION (HYSTERECTOMY) FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 10-JUN-2015: FOLLOW UP ATTEMPTS WERE DONE, WITHOUT RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00168	BAYER HEALTHCARE LLC	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 1/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A57108

Single Use: Y
Implant Date (E6): 1/10/2013
Explant Date (E7): 9/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038057) IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). SHE PRESENTED BLEEDING FROM 2012, WHEN SHE HAD THE BABY, UNTIL 2014. ESSURE (LOT NUMBER A57108) WAS INSERTED DURING THIS PERIOD. IT WAS INSERTED ON (B)(6) 2013, IN DOCTOR'S OFFICE WITH NO ANESTHESIA AND SHE PRESENTED LEFT SIDE PAIN, HORRIBLE BLEEDING AND PAIN. THE HYSTEROSALPINGOGRAM (HSG) TEST WAS PERFORMED IN 2013 AND SHOWED RIGHT WAS BLOCKED BUT LEFT HAD PERFORATED LEFT FALLOPIAN TUBE (THIS WAS THE PAINFUL SIDE). IN 2013, SHE HAD A SURGERY TO FIX THE LEFT TUBE AND PUT A CLAMP ON IT. A D&C (DILATION AND CURETTAGE) WAS PERFORMED TO SEE IF THAT WOULD HELP WITH THE BLEEDING BUT IT DIDN'T. SHE CONTINUED TO BLEED AND HAVE PAIN. ON (B)(6) 2014, SHE HAD ESSURE REMOVED ALONG WITH TUBES BECAUSE THE LEFT ESSURE HAD PERFORATED THE FALLOPIAN TUBE AND WAS GROWING INTO ABDOMINAL WALL. THE PHYSICIAN ALSO DID A UTERINE ABLATION TO HELP WITH BLEEDING BUT THAT DIDN'T HELP EITHER. SHE CONTINUED TO PRESENT HEAVY BLEEDING AND PAIN ON THE RIGHT SIDE. IT WAS FOUND OUT THAT A PIECE OF ESSURE WAS STUCK IN HER UTERUS. A HYSTERECTOMY WAS PERFORMED BUT OVARIES WERE LEFT. SHE HAD TO GO BACK TO EMERGENCY ROOM (ER) FOR AN INFECTION. LATER,SHE WENT TO ER FOR HEMORRHAGING AND IN A THIRD MOMENT, SHE HAD TO GO BACK INTO SURGERY FOR VAGINAL CUFF OPENING. FOLLOW-UP RECEIVED ON (B)(6) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUE. (B)(4). FINAL ASSESSMENT: LOT NUMBER: A57108; EXPIRATION DATE: SEP-2015; PRODUCTION DATE SEP-2012. SINCE NO PRODUCT WAS RETURNED TO US FOR

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INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SEVEN FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, OF WHICH ONE CASE REFERS ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO UNUSUAL PATTERN COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE HAD BLEEDINGS PRIOR TO ESSURE INSERTION, WHICH CONTINUED AFTERWARDS. SHE PRESENTED HORRIBLE BLEEDING AFTER ESSURE INSERTION. HYSTEROSALPINGOGRAM SHOWED A PERFORATION IN LEFT FALLOPIAN TUBE SO SHE UNDERWENT A TUBAL LIGATION. A DILATION AND CURETTAGE WAS UNSUCCESSFULLY PERFORMED TO STOP THE BLEEDING. FALLOPIAN TUBES WERE THEN REMOVED AND AN ABLATION WAS UNSUCCESSFULLY PERFORMED FOR THE BLEEDING. NEXT, A PIECE OF ESSURE WAS FOUND STUCK IN UTERUS. SHE HAD A HYSTERECTOMY. AFTER THAT, SHE HAD HEMORRHAGING AND SHE HAD TO UNDERGO A SURGERY FOR VAGINAL CUFF OPENING. ALL EVENTS ARE CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND PRODUCT TECHNICAL ANALYSIS (PTC), EXCEPT FOR VAGINAL DEHISCENCE. BLEEDINGS MAY OCCUR DURING AND FOLLOWING ESSURE REMOVAL/INSERTION. IN THIS CASE, SHE HAD PROCEDURAL BLEEDINGS AFTER ESSURE INSERTION AND AFTER HYSTERECTOMY. ALTHOUGH, SHE STARTED HAVING BLEEDINGS (GENITAL) BEFORE ESSURE INSERTION, THE CONTRIBUTION OF ESSURE CANNOT BE EXCLUDED. IN THIS CASE, THE EXACT DATE AND MECHANISM OF UTERINE/FALLOPIAN TUBE PERFORATIONS AND DEVICE BREAKAGE ARE NOT KNOWN. GIVEN THE NATURE OF THESE EVENTS, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. LASTLY, CONSIDERING THAT VAGINAL DEHISCENCE MAY OCCUR AS A COMPLICATION OF HYSTERECTOMY AND THAT IN THIS CASE, THE VAGINAL DEHISCENCE OCCURRED AFTER AN INFECTION POST-HYSTERECTOMY THE DEHISCENCE IS ALSO CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTIONS. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 10-JUN-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REFERS TO A FEMALE CONS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00169	BAYER HEALTHCARE LLC	3/6/2015	3/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/5/2013
Explant Date (E7): 6/11/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2013. THE CONSUMER GOT PREGNANT WITH ESSURE IMPLANT PLACED AND HER DAUGHTER WAS BORN AT (B)(6) GESTATIONAL AGE DUE TO THE DEVICE. ESSURE WAS REMOVED ON B)(6) 2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON (B)(6) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(6). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER WHO HAD ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, GOT PREGNANT AND HER DAUGHTER WAS BORN AT (B)(6) GESTATIONAL AGE. THE FIRST EVENT, SEEN AS PREMATURE LABOUR, IS SERIOUS DUE MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE PREGNANCY IS NON-SERIOUS AND LISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. ALSO, PREMATURITY IS DEFINED AS A BIRTH THAT OCCURS BEFORE 37 COMPLETED WEEKS OF GESTATION. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. THEREFORE, THE DEVICE INEFFICACY CANNOT BE EXCLUDED AND THE PREGNANCY AND ITS COMPLICATION, PREMATURITY, ARE ASSESSED AS RELATED TO ESSURE. CONSIDERING THE PREMATURITY IS A SERIOUS INJURY AND THE ESSURE WAS REMOVED (REQUIRED INTERVENTION WAS IMPLIED), THE CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 11-JUN-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER WHO HAD ESSUR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00170	BAYER HEALTHCARE LLC	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT POSTED ONLINE BY A (B)(6) FEMALE CONSUMER IN UNITED STATES AND FOUND BY THE COMPANY ON (B)(6) 2015. SHE WAS INVOLVED IN (B)(6), AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007 WITH LOCAL ANESTHESIA WHEN SHE WAS (B)(6). ACCORDING TO HER, SHE WAS VERY HAPPY WITH HER DEVICE. STUDY DESCRIPTION: (B)(6). THE CONSUMER'S MEDICAL HISTORY INCLUDED PCOS (POLYCYSTIC OVARIAN SYNDROME - DIAGNOSED AFTER SHE TRIED TO GET PREGNANT FOR YEARS); SHE ALSO REPORTED THAT SHE HAD 3 EARLY LOSSES AND ENDED UP ADOPTING A CHILD. HER MOTHER HAD A HYSTERECTOMY PERFORMED DUE TO A CERVICAL CANCER, WHICH METASTASIZED TO THE UTERUS. SINCE 2013 SHE HAS BEEN EXPERIENCING HOT FLASHES, REGULAR CYCLES AND OVULATION, WHICH NOW WAS PAINFUL. SHE IS CONCERNED BECAUSE SHE IS NOT SURE WHETHER SHE HAS THIS PAIN DUE TO ESSURE OR JUST FROM HER OVARIES. SHE HAD AN ABDOMINAL HYSTERECTOMY PLANNED FOR (B)(6) 2015 DUE TO A 23-DAY CYCLE WITH CLOTS AND HEAVY FLOW (SHE REPORTED THAT SHE DID NOT HAVE FULL FLOW THE WHOLE TIME). SHE WAS FEELING MISERABLE AND THIS WAS GOING TO BE HER FIRST REAL SURGERY. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 - PTC INVESTIGATION RESULT: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER

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SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED A 23 DAY MENSTRUAL CYCLE WITH CLOTS AND HEAVY FLOW. THE REPORTED EVENT WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, THE PATIENT HAD AN ABDOMINAL HYSTERECTOMY PLANNED DUE TO A 23-DAY CYCLE WITH CLOTS AND HEAVY FLOW. CONSIDERING THE EVENT'S NATURE AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE A HYSTERECTOMY (REQUIRED INTERVENTION) WAS REPORTED, THE CASE IS REGARDED AS INCIDENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. UPDATED TECHNICAL ANALYSIS IS EXPECTED. NO FOLLOW-UP WILL BE PURSUED SINCE NO CONTACT INFORMATION WAS PROVIDED (SOCIAL MEDIA CASE).

Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 04-MAY-2015 COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED A 23 DAY MENSTRUAL CYCLE WITH CLOTS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041213	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041213 (B)(4). I NOW HAVE WENT THRU ALLERGY TESTING AND ALLERGIC TO NICKEL. I ALSO HAVE A EXTREMELY LOW VITAMIN D LEVEL. I HAVE TESTED VERY LOW FOR PNEUMOCOCCAL TITERS WHICH MEANS AN AUTO IMMUNITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041214	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 3/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) OF 2011. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) OF 2013. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE, WEIGHT GAIN, HAIR LOSS, OVARIAN CYSTS, SEVERE LOWER ABDOMINAL PAIN BEFORE PERIODS, SEVERE CONSTIPATION, HIP PAIN, ABDOMINAL BLOATING, MIGRAINES, BACK ACHES. I HAVE/HAVE BEEN SEEN BY 4 DIFFERENT DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS, OVARIAN CYSTS, THICKENING OF THE UTERUS WALLS, CONSTIPATION, I HAVE ALSO FOUND THAT I HAVE AN ALLERGY TO NICKEL WHICH IS IN ESSURE. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041215	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 2/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHORTLY AFTER BEING IMPLANTED WITH THE DEVICE, I BEGAN TO EXPERIENCE MIGRAINES, HIVES, LIGHT HEADEDNESS, DIZZINESS, MEMORY LOSS, LOWER RIGHT ABDOMINAL PAIN, HEAVIER MORE PAINFUL PERIODS (TO THE POINT OF SPENDING A WEEK IN BED EACH MONTH), EXTREME FATIGUE, SWOLLEN PAINFUL LYMPH NODES, PAIN DURING INTERCOURSE, SEVERE ABDOMINAL SWELLING, LOW BACK PAIN. IT WAS SO BAD THAT I HAD A HYSTERECTOMY AT THE AGE OF (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041216	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 3/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WELL FROM DAY OF IT BEING PUT IN EXTREMELY PAINFUL. HEAVY BLEEDING. A PROCESS THAT WAS TO TAKE 10 MIN TOOK 45 ON ONE SIDE ALONE. BLED FOR 6 MONTHS UNTIL DOCTOR SAID THAT SHE WOULD DO "ABLISION". WHICH HELPED BUT WAS IN A LOT OF PAIN THAT WAS CONSTANT. NUMBEROUS ULTRASOUNDS DERMATOLOGIST CONTACT DERMATITIS. IT HAS HORRIBLE. NOW 3 YEARS LATER I AM HAVING HYSTERECTOMY ON THE 18 OF THIS MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041217	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 9/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041217 #(B)(4) ESSURE CAUSED SEVERE BLOATING, PAIN, FEVER, FATIGUE AND HEAVY PERIODS THAT VARIED IN LENGTH FROM 3 DAYS TO OVER A MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041218	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 9/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS IMPLANTED (B)(6) 2013. AN ABLATION WAS DONE IN CONJUNCTION WITH THE IMPLANTATION. THE PROCEDURE WAS DONE IN THE HOSPITAL AND I WAS UNCONSCIOUS. WHEN I WOKE UP, I COMPLAINED OF SEVERE PAIN ON MY LEFT SIDE. I WAS TOLD BY THE RECOVERY NURSE THAT IT WAS FROM TUGGING THAT TOOK PLACE DURING THE PROCEDURE. I WAS SENT HOME IN SEVERE PAIN. BY THE NEXT DAY, I WAS RUNNING A FEVER AND WAS BACK IN THE DR OFFICE THE FOLLOWING MONDAY. AN ULTRASOUND WAS DONE TO CHECK PLACEMENT. I WAS TOLD THE PAIN WOULD GO AWAY. THREE DAYS LATER, I HAD THE WORST PERIOD I HAD EVER EXPERIENCED. HEAVY BLEEDING, CLOTTING AND EXTRAORDINARY CRAMPS. THE PAIN NEVER LEFT AND EVENTUALLY GOT WORSE. THE PAIN OFTEN SPREAD TO MY LEFT LEG, AND WHEN I WOULD BEND OVER OR TURN MY WAIST, I EXPERIENCED A SHARP TUGGING SENSATION. OVER THE NEXT WEEKS, I BEGAN RUNNING A LOW GRADE FEVER ON AND OFF. I WAS CONSTANTLY TIRED AND ALWAYS IN PAIN. THE FOLLOWING MONTHS, THE PAIN LEVEL INCREASED AND MY PERIODS BECAME A HELLISH NIGHTMARE. MY LEFT SIDE BECAME TENDER TO THE TOUCH AND I STOPPED BEING INTIMATE WITH MY HUSBAND BECAUSE IT WAS PAINFUL AND CAUSED THE PAIN IN MY LEFT SIDE TO BECOME EVEN MORE INTENSE. AT MY NEXT YEARLY APPOINTMENT, I TOLD MY DR THAT I COULD NOT TAKE THE PAIN ANY LONGER AND ASKED FOR A PARTIAL HYSTERECTOMY. I HATE THAT (B)(6) YEARS OLD I WOULD LOSE WHAT MAKES ME A WOMAN. THE SURGERY TOOK PLACE ON (B)(6) 2014. THE SURGERY ITSELF WENT FINE AND I WAS RELEASED AFTER A DAY IN THE HOSPITAL. UNFORTUNATELY, 3 DAYS AFTER I CAME HOME, DEVELOPED AN ILLIUS AND ENDED UP IN THE HOSPITAL FOR TWELVE DAYS. ESSURE CAUSED ME TO SUFFER PAIN, STRESS, AND SELF HATRED. IT NEEDS TO BE REMOVED FROM THE MARKET.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041219	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 7/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT AFTER ESSURE WAS IMPLANTED, I HAD HEAVY BLEEDING, SHARP STABBING AND POKING IN PELVIC AREA, ITCHY, INTENSE HOT FLASHES, AND SHOOTING PAIN INTO THIGHS. I DID AS LITTLE AS I COULD EVERYDAY SO I WOULDN'T HURT. I COULDN'T EVEN LIFT MY CHILDREN WITH OUT BEING IN PAIN... MIND YOU I HAD A (B)(6) AND (B)(6) AT THE TIME. MY DOCTOR SAID SHE THOUGHT IT COULD BE FROM ONE NOT BEING IN PLACE. SHE DID A BILATERAL SALPINGECTOMY AND REALIZED ONE HAD PERFORATED MY TUBE. SHE REMOVED THEM AND TOLD ME THAT SHE HAD PULLED ON ONE TO REMOVE IT. AFTER SURGERY MY PAIN GOT EXTREMELY WORSE. MY DOCTOR DIDN'T BELIEVE IT WAS ANYTHING EVEN WITH BREAKING OUT WITH HIVES ALL OVER MY ABDOMEN AND MY LIPS SWELLED SO BIG I COULDN'T TALK. I HAD TO GET A STEROID SHOT FROM MY PCP AND WENT TO A DERMATOLOGIST FOR MY HIVES. WENT TO AN ER THAT DID A CT SCAN THAT SHOWED I HAD A FRAGMENT EMBEDDED IN MY UTERUS AND HAD TO GET A TOTAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041220	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 6/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY HEALTH SPIRALED DOWN HILL WHEN I GOT THE ESSURE DEVICE. I HAD MAJOR HAIR LOSS, JOINT PAIN, NUMBNESS AND TINGLING IN MY LEGS AND ARMS, HEART RACING AND SKIPPING BEATS, MAJOR CRAMPING, STOMACH PAIN AND BLEEDING WITH HUGE CLOTS, BOWEL ISSUES, MAJOR DAYTIME FATIGUE TO THE POINT I COULDN'T TAKE CARE OF MYSELF LET ALONE MY KIDS, I FELT LIKE I HAD THE FLU 24/7, I FELT DEPRESSED, I GOT PREGNANT EVEN THOUGH MY TUBES WERE BLOCKED, I THEN HAD A LOST MIGRATING COIL. I HAD A HYSTERECTOMY TO GET RID OF THE COILS IN (B)(6) 2014. ESSURE WAS MY WORST NIGHTMARE AND I AM CONTINUING TO HAD LINGERING EFFECTS FROM ESSURE, MY BODY HASN'T BEEN THE SAME SINCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041221	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 11/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON THIS DATE, I HAD ESSURE PLACED AND FROM THE POINT OF INSERTION, I WAS IN ALOT OF PAIN. IT WAS ASHARP AND STABBING PAIN THAT HASN'T GONE AWAY. IT'S BEEN CHRONIC SINCE ONCE MY PERIOD RETURNED AFTER THE PLACEMENT, IT WAS VERY HEAVY. I WAS PUT ON TRI-PRIVEFEM TO REGULATE IT AND IT BECAME WORSE. JUST IN THE LAST MONTH I'VE HAD MY CYCLE FOR ALL BUT 7 DAYS. I'M CONSTANTLY TIRED, PAINFUL SEX, HIP AND BACK PROBLEMS STARTED AFTER PLACEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041222	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 11/27/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN AND FATIGUE, SHARP PAINS IN MY ABDOMEN, ABNORMAL MENSES, TWICE MONTHLY MENSES, MUSCLE SPASMS AND PAIN, MIGRAINES, SWOLLEN ABDOMEN, BRITTLE BONES AND TEETH, ANXIETY, DEPRESSION, JOINT PAIN AND SWELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041223	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 11/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE CRAMPING AND PAIN IN ABDOMINAL AREA. THEN I STARTED HAVING SCIATICA. I HAVE HAD IT FOR ALMOST 3 MONTHS NOW WITH PAIN IN LEG HIP BACK AND LEFT FRONT ABDOMIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041224	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 6/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #APP157422 CONSTANT DISCHARGE, CRAMPING, PAINFUL INTERCOURSE AFTER PLACEMENT IN 2005. SEVERE PAIN IN SIDE TO POINT COULDN'T WALK,PERFORATED TUBE, HIGH INFLAMMATION, ANEMIA, CANCEROUS TUMOR IN OVARY, FOUND AFTER HYSTERECTOMY IN 2013

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041225	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 6/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT DISCHARGE, CRAMPING, PAINFUL INTERCOURSE AFTER PLACEMENT IN 2005. SEVERE PAIN IN SIDE TO POINT COULDN'T WALK,PERFORATED TUBE, HIGH INFLAMMATION, ANEMIA, CANCEROUS TUMOR IN OVARY, FOUND AFTER HYSTERECTOMY IN 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041226	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL PELVIC PAIN, BLOATING, BLEEDING, PAIN DURING SEX, RHEUMATOID ARTHRITIS, HEADACHES, MOOD SWINGS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041227	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 10/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONE OF THE COILS SHOT INTO MY OVARY, WHICH WAS NOT FOUND UNTIL MY FOLLOW UP APPT. TUBAL LIGATION HAD TO SCHEDULED, COIL WAS REMOVED FROM MY OVARY, BUT ONE COIL WAS LEFT. I HAVE SUFFERED FROM ACCUTEUTIS. ONE THAT RESULTED IN A HOSPITAL STAY BECAUSE IT BECAME A SEVERE KIDNEY INFECTION. SEVERE LOWER BACK PAIN, HEADACHES, WEIGHT GAIN, LEG/KNEE PAIN, RLS SYMPTOMS, HAIR LOSS, HAIR DRYNESS, DRY SKIN, FATIGUE, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041228	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 11/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE, I HAVE DEALT WITH A CONSTANT INDESCRIBABLE PAIN. I FEEL AS IF SOMETHING IS RIPPING MY INSIDES APART. I HAVE HAD ISSUES WITH OVARIAN CYST, FATIGUE, NAUSEA, HEADACHES, WEIGHT GAIN,BACK PAIN AND TERRIBLE PELVIC PRESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041229	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 1/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE HAS CAUSED ME OVER 6 MONTHS OF BLEEDING, IRRITABILITY, MOOD SWINGS, HORRIBLE PERIODS (BLOOD CLOTS, HEAVY BLEEDING, SEVERE CRAMPS, HORRIBLE PRESSURE), PELVIC PAIN, STABBING PAIN IN PELVIC AREA, WEIRD LOSS OF MEMORY, INCONTINENCE, SORE JOINTS, MUSCLE PROBLEMS, HEADACHES, STOMACH ISSUES, BOWEL ISSUES, BLOATING, GAINING OVER 80 LBS, LOSS OF BALANCE, DIZZINESS, BLURRED VISION, TINGLING FEELING IN ARM AND LEG, AND MANY MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041230	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 10/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWELLING OF THE FEET, KNEES, SPINE AND ELBOWS. PAIN AT ALL JOINTS AREAS EXTREME WEIGHT GAIN BLOATING DIFFICULT WITH WALKING, STANDING AND SITTING DOWN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041231	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, HEART PALPITATIONS, FORGETFULNESS, INSOMNIA, PAINFUL SEX, PELVIC PAIN, SEVERE CONSTIPATION, STOMACH/CHEST PAIN, WORSENING BACK PAIN. ALSO HAS BEEN GOING ON SINCE (B)(6) 2014. DIDN'T HAVE THIS SELECTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041235	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 1/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041235 #(B)(4). I HAD SURGERY (B)(6) FOR REMOVAL. I WAS STILL ON MY "PERIOD" FOR 4 WEEKS AFTER. I STILL HAVE IT TWICE A MONTH. I HAVE NOT HAD A MIGRAINE OR STROKE LIKE SYMPTOMS SINCE THE SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041240	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 2/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WOULD HAVE THROBBING ACHING PAIN ON MY RIGHT AND LEFT SIDE CONSTANT WOULD GET WORSE WITH BENDING OR SITTING. BLURRED VISION AND MIGRAINES. METAL TASTE IN MY MOUTH AT ALL TIMES. WEIGHT GAIN. MY TEETH WERE BRITTLE. DIZZINESS. HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041247	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 7/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER EXCESSIVE BLEEDING FOR SEVERAL MONTHS, I AM NOW STRUGGLING WITH ALMOST DAILY MIGRAINES, PAINFUL OVULATION, AND PERSISTENT CYSTIC ACNE. I FEEL SICK TO MY STOMACH. I'M LETHARGIC AND OFTEN FEEL ACHY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041257	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 9/24/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) GOT ESSURE IMPLANTED AND HAVE HAD CRAMPS, NAUSEA, AND BLEEDING EVER SINCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041259	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 2/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GAINED 100 LBS WITHIN 3 MONTHS OF HAVING IT PUT IN. I COULD NOT DO ANYTHING FOR A LONG TIME. I HAD SEVERE ABDOMINAL PAIN CONSTANTLY. I COULD NOT HAVE SEX FOR LIKE 2 YEARS. I HAD TO GO TO THE DOCTORS AND HOSPITAL CONSTANTLY. I HAD TO HAVE A COMPLETE HYSTERECTOMY JUST TO GET THE ESSURE OUT. AND NOW I ALSO SUFFER REAL BAD BACK PAIN AND IT'S BEEN SO HARD TO LOOSE ANY WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041260	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 2/8/2015 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GAINED 100 LBS WITHIN 3 MONTHS OF HAVING IT PUT IN. I COULD NOT DO ANYTHING FOR A LONG TIME. I HAD SEVERE ABDOMINAL PAIN CONSTANTLY. I COULD NOT HAVE SEX FOR LIKE 2 YEARS. I HAD TO GO TO THE DOCTORS AND HOSPITAL CONSTANTLY. I HAD TO HAVE A COMPLETE HYSTERECTOMY JUST TO GET THE ESSURE OUT. AND NOW I ALSO SUFFER REAL BAD BACK PAIN AND IT'S BEEN SO HARD TO LOOSE ANY WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041266	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 11/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING BETWEEN PERIODS, UTERINE FIBROIDS, OVARIAN CYST, CONSTANT BLOATING, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041269	BAYER	3/6/2015	3/6/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HAVE NOT FELT LIKE MYSELF EXHAUSTED ALL THE TIME HAVING THE WORSE MIGRAINES PERIODS ARE LASTING LONGER ALSO BLEEDING VERY HEAVY LOW VITAMIN D JOINT PAIN LOTS OF PAIN IN MY MOUTH JAW AND TEETH VERY IRRITABLE WEIGHT GAIN HAVEN'T BEEN ABLE TO FEEL HEALTHY FOR A VERY LONG TIME TINGLING SENSATION THROUGHOUT MY BODY VISION SEEMS TO FADE IN AND OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041401	BAYER HEALTH	3/6/2015	3/17/2015

Event Information:

Event Date (B3): 1/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): CONTRACEPTION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS HAVING MY PERIOD 5 DAYS AFTER MY LAST PERIOD OVER AND OVER AGAIN WITH NO END IN SIGHT. I WAS TOLD SOMETHING COULD BE DONE TO STOP THE TOO CLOSE CYCLES. I WANTED A HYSTERECTOMY, BUT THE DOCTOR SAID NO. SHE TOLD ME SHE COULD TIE MY TUBES AND GIVE ME AN ABLATION, BUT INSTEAD OF TYING MY TUBES THE BROCHURE WAS CALLED ESSURE. SHE SAID THAT IS THE WAY THEY DO IT NOW, NOT ACTUALLY TIE THE TUBES SHUT. ESSURE WAS THE WORST THING THAT HAPPENED TO ME. MY SYMPTOMS HAVE INCREASED IN THESE LAST 2 YEARS AND INCLUDE: CHRONIC FATIGUE, CONSTANT CONGESTION THAT NEVER GOES AWAY AND TURNS INTO SINUS INFECTIONS AND EAR INFECTIONS, SEVERE BLOATING, DRY SKIN/HARI/EYES, BLURRED VISION/FLOATERS, HAIR LOSS, SWELLING OF MY LEGS AND OTHER PLACES, CRAMPING, SHARP/STABBING PELVIC PAIN, SHOOTING PAIN DOWN INTO MY THIGHS, DISCHARGE, HOT FLASHES, NIGHT SWEATS/DAY SWEATS, LOSS OF LIBIDO, PAINFUL INTERCOURSE, YEAST INFECTIONS, URGENT/FREQUENT URINATION, ITCHING/BURNING/STINGING STABBING OF VAGINAL ENTRANCE AND INSIDE, BREAST TENDERNESS AND PAIN ALL THE TIME, ABDOMINAL SPASMS/TWITCHING/FLUTTERING, PAIN: BACK, JOINT, CHEST, LEGS, BREAST, BACK OF NECK, HIPS AND LOWER BACK. PELVIC PAIN, FACIAL PAIN, ALL OVER BODY ACHES/PAIN, NAUSEA, GAS, CONSTIPATION, DIARRHEA, HEARTBURN, HEADACHES AND MIGRAINES, DIZZINESS, NUMBNESS, NERVE PAIN, BRAIN FOG, RINGING IN THE EARS, NUMBNESS FEELING IN MY THIGHS, SENSATION OF PRICKING OF SKIN BY A SHARP NEEDLE ALL OVER MY BODY. ESSURE NEEDS TO BE OFF THE MARKET SO NO ONE ELSE HAS TO SUFFER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041403	BAYER HEALTH	3/6/2015	3/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): CONTRACEPTION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE MY IMPLANTS I'VE HAD CHRONIC BACK PAIN WORSENING WHEN MENSTRUATING. HEAVY BLEEDING , MIGRAINES, JOINT PAIN, CONFUSION, FATIGUE ALL OF WHICH I BELIEVE IS THE CAUSE OF MY SEVERE DEPRESSION, FATIGUE AND PAIN. IS THERE SOME WAY THAT I CAN HAVE IT REMOVED , I NO LONGER HAVE FAITH IN HEALTHCARE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00167	BAYER HEALTHCARE LLC	3/6/2015	4/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN UNITED STATES ON 06-FEB-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION WAS RECEIVED FROM THE MEDICAL DOCTOR ALSO ON 06-FEB-2015. THE HEALTH CARE PROFESSIONAL WHO WAS IN THE OPERATING ROOM AND REPORTED THAT THE COIL'S ON ONE SIDE DID NOT LOOK NORMAL AND THE COILS WERE NOT EXPANDING AND THE TIP WAS CURVED. THE MEDICAL DOCTOR ALSO REPORTED THAT SHE PLACED THE INSERT AND IT SEEMED LIKE THE OUTER COILS DID NOT FULLY EXPAND. THE INSERTER DID NOT DETACH. AFTER THAT, IT WAS DETACHED BUT SHE THOUGHT IT LEFT A PIECE OF THE INNER CATHETER ATTACHED TO THE COIL. NO OTHER ISSUES. THE SAME THING HAPPENED ON THE OTHER SIDE. SHE THOUGHT SHE WAS DOING SOMETHING WRONG. PHYSICIAN NOT THINK THAT TUBAL SPASM OCCURRED AT ALL. SHE DID NOT SEE THE GOLD MARK EVEN AFTER ADJUSTING IT. SHE DID THE ROLL BACK AND SAID WAS NOT SURE IF SHE DID IT TO A HARD STOP BEFORE SHE PUSHED THE BUTTON. FOLLOW-UP FROM 17-FEB-2015: NO FURTHER INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS UPDATED ON 24-FEB-2015: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-

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INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 02-MAR-2015: WITH REGARDS TO THE EVENT INSERTER LEFT A PIECE OF THE INNER CATHETER ATTACHED TO THE COIL, THE PHYSICIAN STATED IT WAS JUST FINE. THEY THOUGHT THERE WAS AN ISSUE BUT THE PHYSICIAN SAW THE INTERPRETATION OF PLACEMENT AND THERE WAS NO ISSUE. THE PHYSICIAN STATED THE ISSUE MIGHT HAVE BEEN WITH HIM. DOCTOR DECLINED ANY FURTHER EXPLANATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND COIL'S ON ONE SIDE DID NOT LOOK NORMAL AND WERE NOT EXPANDING AND THE TIP WAS CURVED. THE INSERTER DID NOT DETACH. THEN, WHEN IT EVENTUALLY RELEASED IT, THE INSERTER LEFT A PIECE OF THE INNER CATHETER ATTACHED TO THE COIL. THE EVENTS, INTERPRETED AS DEVICE SHAPE ALTERATION, DEVICE DEPLOYMENT ISSUE AND DEVICE BREAKAGE, ARE NON-SERIOUS. DEVICE SHAPE ALTERATION IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION WHILE DEVICE BREAKAGE IS LISTED ACCORDING TO TECHNICAL ANALYSIS. CONSIDERING THE EVENTS OCCURRED DURING INSERTION PROCEDURE, CAUSALITY BETWEEN THE EVENTS AND ESSURE USE IS ASSESSED AS RELATED AND SINCE A DEVICE BREAKAGE (MALFUNCTION) WAS REPORTED, THE CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041413	BAYER	3/8/2015	3/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/9/2009
Explant Date (E7): 9/16/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEIZURES, FIBROIDS, WEIGHT GAIN, FATIGUE, FOOD ALLERGIES, CONSTANT PERIODS, GRAPEFRUIT SIZE BLOOD CLOT, ECT! ALL CAUSED BY THE ESSURE IMPLANTS BIRTH CONTROL. I HAD ALMOST EVERY SIDE EFFECT THAT WAS LISTED FOR THESE DEVICES. I HAD MASS FIBROIDS THROUGHOUT MY UTERUS. THE BIGGEST ONES GROWING AROUND THE ESSURE DEVICES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041270	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (ESSURE IMPLANTED IN (B)(6) 2013, SYMPTOMS BEGAN IN (B)(6) 2014.) HERE IS MY STORY: I STARTED TO HAVE LOWER BACK PAIN ON MY RIGHT SIDE THEN TURNED TO SEVERE BACK PAIN. I HAD NEVER HAD BACK PAIN AT THIS LEVEL BEFORE, I HAVE ALWAYS BEEN ACTIVE WITH NO HEALTH ISSUES. FOLLOWING THE BACK PAIN, JOINT PAIN STARTED IN MY ELBOWS AND BY (B)(6) 2014 MY ELBOWS WERE SORE TO THE TOUCH. SPOTTING/BROWN IN COLOR STARTED IN MID (B)(6) WHICH WAS ON AND OFF UNTIL (B)(6). A SMELL ALSO CAME WITH THIS SPOTTING, IT WAS A SWEET SMELL, NOTHING I HAD EVER HAD BEFORE EITHER! A FULL PERIOD STARTED IN (B)(6) WITH TERRIBLE SIDE EFFECTS (SHARP BACK PAINS, CRAMPING, HEAVY BLEEDING, MIGRAINES, WEIGHT GAIN.) PAIN SO BAD IN MY RIGHT SIDE I WENT TO MY OB. AN ULTRASOUND SPOTTED A FUNCTIONAL CYST, NO HISTORY OF CYSTS BEFORE ESSURE IMPLANTED. I WAS NOW TAKING AN ANTI-DEPRESSANT TO HELP WITH THE LACK OF MOTIVATION I WAS FEELING B/C THE PAIN IN MY BACK WAS DAILY. I WENT BACK TO MY OB IN (B)(6), MY PERIOD HAD LASTED OVER A MONTH WITH HEAVY BLEEDING. OB CONTRIBUTED EXCESSIVE BLEEDING TO THE CYST AND IT SHOULD STOP. I HAD FIVE DAYS OF NO BLEEDING FROM (B)(6) UNTIL (B)(6). THIS WAS HEAVY BLEEDING WITH FLESH COMING OUT OF MY BODY. THE BLEEDING FROM ESSURE IS NOT JUST A TYPICAL PERIOD, IT IS ACCOMPANIED BY A METALLIC, SWEET SMELL AND IN THE BLOOD ARE SMALL CHUNKS OF FLESH, WHICH RANGE FROM LONG AND SKINNY TO A SMALL PIECE/CHUNK OF SKIN. THE BACK PAIN WAS DAILY AND WOULD SPREAD INTO MY SHOULDERS AND NECK, CAUSING SEVERE HEADACHES. THERE WERE DAYS I COULD BARELY FUNCTION B/C OF THE PAIN THAT WAS GOING INTO MY NECK. ALSO, THE JOINT PAIN WAS IN MY ELBOWS,, BUT WOULD POP UP IN OTHER JOINT AREAS WITH NO RHYME OR REASON. FOR EXAMPLE, MY FOREARMS AND FINGERS WOULD GO NUMB, MY WRISTS WOULD BE VERY SORE FOR DAYS AND THEN IT WOULD CEASE FOR A FEW DAYS AND COME BACK. FEELING WORSE AND

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WORSE, I CHOSE TO HAVE THE ESSURE COILS REMOVED BY (B)(6), A PERSONAL CHOICE, (B)(6). I WANTED TO LEAVE ALL OF MY FEMALE ORGANS. WITHIN 24 HOURS THE BACK PAIN WAS TOLERABLE. AT 72 HOURS IT WAS COMPLETELY GONE. MY ELBOWS ARE NO LONGER SORE TO THE TOUCH AND HAVE CONTINUED TO GET BETTER. I DO NOT EVEN NOTICE THE PAIN. I HAD SURGERY ON (B)(6) AND IT IS (B)(6) AND I AM PAIN FREE IN MY BACK. I COULD NOT GET OUT OF BED WITHOUT BEING IN MAJOR PAIN STARTING IN MY LOW BACK. I HAVE STOPPED TAKING MY PAIN MEDS GIVEN TO ME BY (B)(6). I STILL HAVE PAIN FROM MY INCISION, HOWEVER I WANTED TO BE SURE THE PAIN IN MY BACK WAS GONE AND IT IS. I AM CERTAIN ESSURE COILS CAUSE SERIOUS SIDE EFFECTS IN WOMEN, SUCH AS THE ONES I NOTED. I HAD THESE IMPLANTED IN (B)(6) 2013 AND I BARELY MADE IT A YEAR BEFORE THEIR SIDE EFFECTS CAUSED MAJOR PROBLEMS IN MY DAILY LIFE. WHEN YOU ARE AN ACTIVE YOGI WITH PURPOSE AND GO TO LIFE OF DAILY PAIN AND RELY ON MEDS, AND ONLY ONE THING HAS CHANGED IN OUR LIFE....YOU TRUSTED A DEVICE CALLED ESSURE. MY LIFE IS A JOURNEY AND I AM ON MY WAY BACK. I AM USING THIS TO HELP OTHERS WHO MIGHT NOT BE ABLE TO AFFORD THE PROCEDURE I GOT, DOVE INTO THE RESEARCH AND REFUSED TO LET THIS DEVICE RUN MY LIFE!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041271	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE THESE SHARP PAINS ALL OVER. ARMS , FEET, HANDS, MY WHOLE BACK HURSTS ALL THE TIME. NO ENERGY AND I KEEP SMELLING LIKE A FUNGUS OR MOLD, WHEN MY PERIOD COMES I FEEL LIKE I'M CATCHING A BUG ... I'M JUST PUTTING THIS DOWN CAUSE I DON'T REMEMBER IF I PUT IT ON MY OTHER THING. I TYPED OUT OF ALL THE SYMPTOMS BEEN GOING ON FOR OVER TWO YRS OR MORE. MY MEMORY SUCKS. ALSO "DIE" TO THIS I CAN'T REMEMBER DATES OR SOMETIMES YESTERDAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041272	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

B)(4). EXTREMELY BAD CRAMPING ALL THE TIME. BAD HEADACHES WERE I CAN'T EVEN OPEN MY EYES. SHARP PAINS DOWN STAIRS.... TIRED AND FATIGUED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041273	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE DEVICE PUT IN THE BEGINNING OF 2010. I STARTED EXPERIENCING A SHARP STABBING PAIN IN MY LOWER ABDOMEN AND THE LOWER LEFT SIDE OF MY BACK. I'VE ALSO BEEN EXPERIENCING HEADACHES ALMOST EVERY DAY AND MORE FREQUENT MIGRAINES, FATIGUE, HEAVIER AND MORE PAINFUL PERIODS, VITAMIN DEFICIENCIES, DEPRESSION, LOSS OF SLEEP BECAUSE OF ALL THIS HELL, PAIN DURING AND AFTER SEX HALF THE TIME AND DARK CIRCLES UNDER MY EYES THAT JUST WON'T GO AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041274	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 9/15/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONSET OF PSORIASIS SOON AFTER IMPLANTS, ALSO PSORIATIC ARTHRITIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041275	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 9/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE PAIN CRAMPS AND SWELLING LEGS AND HIPS AND RASHES EVERYWHERE. PAIN DURING SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041276	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ONGOING SHARP PELVIC PAIN. I HAVE ACHY JOINTS AND MUSCLES AND UNEXPLAINED WEIGHT GAIN THAT I CANNOT USE. I HAVE HEAVY PERIODS AND STOMACH BLOAT. I ALSO HAVE DRY HAIR, HAIR LOSS AND RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041277	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 12/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VAGINAL BLEEDING, ABDOMINAL CRAMPING, SEVERE PAIN, NAUSEA, FEVER, BODY ACHES AND DECREASE IN BREAST MILK SUPPLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041278	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 9/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE COILS ON (B)(6) 2013 AT (B)(6). MY FOLLOW-UP HSG (B)(6) 2013 SHOWED ONE TUBE SUCCESSFULLY BLOCKED, ONE TUBE PATENT, THE COIL HAVING MIGRATED AND EMBEDDED IN MY UTERINE TISSUE. THE EMBEDDED COIL CAUSED CHRONIC PELVIC PAIN LEADING TO TOTAL HYSTERECTOMY (B)(6) 2015. I HAVE ALSO EXPERIENCED RECURRING SHINGLES WHICH I BELIEVE IS AN EFFECT OF THE CHRONIC INFLAMMATION CAUSED BY ESSURE COMPROMISING MY IMMUNE SYSTEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041279	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 10/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING, NUMBNESS OF HANDS, RASH ON FACE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041280	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 1/2/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VARIOUS SIDE EFFECTS THAT I WAS NOT INFORMED ABOUT INCLUDING WEIGHT GAIN, FATIGUE, HAIR LOSS, EXTREME DRY SKIN, PAINFUL BUMPS ON BODY, JOINT PAIN, BACK PAIN WHEN LAYING, ABDOMINAL PAIN AND SWELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041281	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 7/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD PAIN IN THE LEFT FALLOPIAN TUBE AREA SINCE INSERTION IN 2011 THAT INCREASED DRAMATICALLY; PRIOR TO REMOVAL THE PAIN WAS SO BAD PRIOR TO MY PERIOD THAT I COULDN'T WALK FOR 2 DAYS. A YEAR AFTER PLACEMENT MY PERIODS BECAME EXTREMELY HEAVY, LASTED 3 WEEKS OUT OF THE MONTH AND I PASSED LARGE MULTIPLE CLOTS. AN ULTRASOUND ON (B)(6) 2015 DID SHOW I HAD DEVELOPED UTERINE FIBROIDS. SINCE PLACEMENT OF ESSURE MY LIBIDO HAS COMPLETELY DISAPPEARED. I ALSO HAD ISSUES WITH CONTINUAL VAGINAL DISCHARGE OF UNKNOWN CAUSE. I HAD ISSUES WITH URINARY URGENCY AND BLADDER LEAKAGE. THE HARDEST PART HAS BEEN THE SHORT TERM MEMORY ISSUES; I CAN'T REMEMBER ANYTHING UNLESS I WRITE IT DOWN. THIS HAS CAUSED ME SERIOUS PROBLEMS AT WORK. ON (B)(6) 2015 I HAD A TRANSVAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY. SINCE THEN THE MAJORITY OF MY SYMPTOMS HAVE GREATLY IMPROVED IF NOT RESOLVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041282	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). RECURRING YEAST INFECTIONS, FOUL ODOR FROM VAGINA, SYMPTOMS OF PREGNANCY BUT NEVER PREGNANT, RASH WHEN I'M ABOUT TO START MY PERIOD. UNUSUAL BLEEDING, THEY PUT ME ON BIRTH CONTROL THEN IT STILL DOESN'T HELP. PAIN IN ABDOMEN AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041283	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/12/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE PAIN BLEEDING HORRIBLE RASH MIGRATION MIGRAINES HAD TO HAVE A HYSTO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041284	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 6/18/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDA MW5041284 #(B)(4) HYSTERECTOMY (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041285	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5041285 #(B)(4) REF#(B)(4) LOT#626287.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041286	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 10/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SPOTTING, WEIGHT GAIN, FATIGUE/NAUSEA, BLOATING/PRESSURE, TIRED, WEIRD TASTE IN MOUTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041287	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE (STABBING) PELVIC AND BACK PAIN, LESIONS ON CERVIX, DIAGNOSED WITH PELVIC INFLAMMATORY DISEASE, DIAGNOSED WITH INTERSTITIAL CYSTITIS, HEAVY ABNORMAL BLEEDING, WEIGHT GAIN OF 45 LBS,CONSTANT BLOATING, PAINFUL SEXUAL INTERCOURSE,DEPRESSION,ANXIETY,SWELLING IN HANDS AND FEET,STIFF PAINFUL JOINTS, DAILY HEADACHES WITH DIZZINESS,GALLSTONES(REQUIRING SURGERY TO REMOVE GALLBLADDER)RASH ON FACE STOMACH AND BACK, CONSTANTLY FEELING LIKE I HAVE A BLADDER INFECTION

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041288	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 8/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN TO EXPERIENCE HEAVY, IRREGULAR MONTHLY BLEEDING AS WELL AS CHRONIC PELVIC PAIN, FREQUENT BLADDER INFECTIONS, BACTERIAL VAGINOSIS, AND PAIN WITH INTERCOURSE. IN (B)(6) 2015 I FOUND OUT THE DEVICE HAD PERFORATED MY LEFT FALLOPIAN TUBE AND I HAD TO HAVE SURGERY TO REMOVE MY FALLOPIAN TUBES ALONG WITH THE ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041289	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE MORE HEALTH ISSUES THEN THE TIME SUBMITTED. I ALSO HAVE NOW BEEN SCHEDULED FOR MY HYSTERECTOMY SURGERY IN (B)(6) 2015 DUE TO EXCESSIVE PELVIC PAIN AND HEAVY BLEEDING. I HAVE NOW DEVELOPED VERY SENSITIVE TEETH AND HAVE NOW STARTED GOING TO THE CHIROPRACTOR IN HOPES IT WILL RELIEVE MY NECK AND BACK PAIN AS WELL AS THE HORRIBLE MIGRAINES I KEEP HAVING TO GO TO THE ER FOR TEMPORARY RELIEF. I HAVE A HUGE PATCH ON MY BACK WITH RAISED BUMPS AND MY SKIN IS PEELING OFF IT BURNS AND ITCHES LIKE CRAZY. THIS HAS JUST STARTED IN THE LAST FEW WEEKS AND I HAVE NOT CHANGED ANYTHING I USE. I CANNOT WEAR A BRA FOR THE LAST MONTH OR, SO BC I ALSO NOW A HAVE A LARGE LUMP UNDER MY ARM PIT AND ALONG MY LEFT BREAST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041290	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED TO BLEED SO HEAVY I WOULD ALMOST PASS OUT, BLOOD CLOTS SO BIG I WOULD GO THROUGH 5 PADS IN AN HOUR, DIZZINESS, STOMACH PAINS THAT WOULD HAVE ME IN FETAL POSITION, NOT WANTING TO MOVE. HAIR FALLING OUT IN CHUNKS. CHRONIC FATIGUE, DEPRESSION OF NOT WANTING TO DO ANYTHING. GAINED WEIGHT, RASH ON FACE. PAINFUL SEX, NOT WANTING SEX ANYMORE, NOT BEING ABLE TO USE TAMPONS, LOOSE STOOL, VAGINAL DRYNESS, BOILS , TOOTH PAIN .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041291	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). IMPLANTED IN 2007. I HAD SERIOUS HIVES ALL OVER MY BODY THAT NEVER WENT AWAY UNTIL HYSTERECTOMY; ADENOMYOSIS, ENDOMETRIOSIS, PELVIC PAIN, JOINT PAIN, ABDOMINAL SWELLING, CRAMPING IN UPPER STOMACH, SWELLING, LOSS OF BLADDER CONTROL, LACK OF ENERGY, BODY FELT LIKE IT WAS SHUTTING DOWN, EXCESSIVE NIGHT SWEATS, ALWAYS FELT LIKE I HAD A FEVER, WEIGHT GAIN, CONSISTENTLY AT THE DOCTORS, HAIR LOSS, BREAK THROUGH BLEEDING WHEN PARTICIPATING IN GYM EXERCISES, INFLAMMATION. SINCE MY SURGERY ON (B)(6) 2014, I STILL HAVE SLIGHT PELVIC PAIN, ABDOMINAL SWELLING, AND BLADDER ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041292	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 12/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HEAVY CYCLES, BLOOD CLOTS, STOMACH SWELLS. CHRONIC BACK PAIN. HAND AND LEG NUMBNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041293	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 11/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BLED FOR 4 MONTHS AFTER IT WAS PUT IN. IT WAS HORRIBLE BECAUSE I JUST HAD A NEW BABY. SEVERE LOWER BACK PAIN THAT EITHER SHOOTS PAIN DOWN MY LEFT LEG OR HAS WENT UP MY BACK AND CAUSED MY BACK TO GO NUMB. IT IS A SEVERE BURNING SENSATION TO THE POINT I CAN STAND AND HAVE TO SIT DOWN. I'VE HAD CLUMPS OF HAIR COMING OUT AND GAINED 13 LBS WITHOUT CAUSE. I'VE BEEN TO THE DOCTOR AND AFTER EXAMINING ME SHE COULD NOT FIND AN EXPLANATION FOR THE THINGS I'M EXPERIENCING AND THE SYMPTOMS STARTED A MONTH AFTER ESSURE. I HAVE NEVER HAD ANY OF THESE SYMPTOMS BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041294	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 8/5/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON ((B)(6) 2008). ON MY (B)(6) BIRTHDAY ON MY LEFT SIDE, ALSO ON ((B)(6) 2008) FOR MY RIGHT SIDE. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS (626531) MY MODEL NUMBER IS (ESS305). THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON ((B)(6) 2009). THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: I HAVE BEEN SEEN BY A COUPLE OF DRS FROM TRIPS TO THE ER AND 2 OBGYN. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: RECENTLY WAS DIAGNOSED WITH OVARIAN CYSTS AND MOST LIKELY ENDOMETRIOSIS. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: LAPAROSCOPIC HYSTERECTOMY TO HAVE ESSURE REMOVED, WITH NO SUCCESS BECAUSE I STILL HAVE THEM IMPLANTED IN ME. THE DEVICE IS STILL INSIDE OF ME, AND IT IS CAUSING ME A MUCH MORE WORSE PAIN THAN BEFORE THE HYSTERECTOMY WAS DONE, MY LEFT SIDE IS ALWAYS HURTING, I WAKE UP WITH BAD HEADACHES, NOT TO MENTION THE PAIN THAT SHOOTS DOWN MY LEG AND MY HIP. THE STABBING FEELING IS THE WORST AND BECAUSE OF IT I CAN'T COUGH, SNEEZE OR EVEN LAUGH BECAUSE IT FEELS LIKE A SHARP OBJECT IS TRYING TO RIP THROUGH MY SKIN. I HAVE HAIR LOSS BY THE BUNCH, AND I AM ALWAYS TIRED, AMONGST MUCH MORE OTHER ISSUES THE ESSURE HAS CAUSED, LIKE THE CONSTANT PREGNANT LOOK THANKS TO THE BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041295	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 12/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS IMPLANTED ON (B)(6), 2012. SIDE EFFECTS SUCH AS PELVIC PAIN, PAIN DURING INTERCOURSE, PAIN DURING OVULATION, HEAVIER AND LONGER MENSTRUAL CYCLES AND YEAST INFECTIONS SOON AFTER STARTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041296	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED WITH STOMACH PAIN, THEN LEG PAIN AND NUMBNESS, THEN SEVERE CONSTIPATION AND NOW ALL OVER SEVERE CHRONIC BODY PAIN. I HAVE NO OTHER MEDICAL CONDITIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041297	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 6/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWELLING OF FEET AN LEGS, BLOATING, PAIN DURING INTERCOURSE , A MENSTRUAL CYCLE 3 WEEKS OUT OF A MONTH SOME TIMES MORE, MOOD SWINGS, LOSS OF SEXUAL DESIRE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041298	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2013 THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: SEVERE CRAMPING, PELVIC PAIN, LARGE BLOOD CLOTS DURING MENSES, PAINFUL PERIOD, LONG MENSTRUAL CYCLES, BREAST TENDERNESS, JOINT, BREAST AND NECK PAIN, ALL OVER BODY ACHES, NAUSEA, GAS, CONSTIPATION, DIARRHEA, SEVERE FATIGUE, SEVERE BLOATING, HEARTBURN, HEADACHES, MIGRAINES, DIZZINESS, BRAIN FOG, NUMBNESS OF EXTREMITIES, HIVES ON MY LEGS, SWELLING OF HANDS, LEGS AND FEET, HAIR LOSS, THIN BRITTLE NAILS, UNEXPLAINED FEVERS, WEIGHT GAIN, LOSS OF LIBIDO. I HAVE/HAVE NOT BEEN SEEN BY 5 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: ALLERGIES, IRON DEFICIENCY, VITAMIN D DEFICIENCY, OVERWEIGHT, GASTRITIS, AND IRREGULAR, HEAVY AND PAINFUL PERIODS. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041299	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 10/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I GOT IT I HAVE HAD HIGH BLOOD PRESSURE; REACTING LYMPH NODES; DEPRESSION; SECURE SEVERE PAIN IN MY ABDOMEN, LOWER BACK AND SIDES. I GET MIGRAINE HEADACHES EVERYDAY. I SPOT FOR MONTHS, LOSE BLOOD CLOTS, EVERYTHING I HAVE A PERIOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041300	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 11/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT THE TIME OF PLACEMENT I WAS IN SO MUCH PAIN. MY BODY WENT IN TO SHOCK. I BLED FOR TWO AND HALF WEEKS WITH HEAVY FLOW. AFTER A COUPLE DAYS OFF MY PERIOD I STARTED TO NOTICE I WAS HAVING PELVIC PAIN AND CRAMPING. SOON AFTER THAT I HAD SEX AND IT WAS SO PAINFUL AND I BLED AFTER. SEX LIFE HAS WENT DOWN SOME. I'VE BEGINNING TO NOTICE THAT MY FACE IS STARTING TO BRAKE OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041301	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 6/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) CHRONIC PELVIC PAIN, ABNORMAL BLEEDING, HEADACHES, CHRONIC BLEEDING, JOINT PAIN, HAIR LOSS, LOSS OF LIBIDO, PAIN DURING INTERCOURSE, INCREASED BP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041302	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 3/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) CHRONIC PAIN FOR HOURS AT A TIME, TO WERE I CAN'T MOVE, MY WHOLE BODY BROKE OUT AND SCARS ARE EVERYWHERE. UNABLE TO HAVE SEX OR WORK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041304	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 11/24/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN 2008. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 627452. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON 2009. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: ALWAYS IN LOWER BACK PAIN, STOMACH IS ALWAYS BLOATED (LOOKS LIKE I'M PREGNANT), STOMACH CRAMPS A LOT, I HAD A MISCARRIAGE IN 2013, ALWAYS FATIGUED, I HAVE BEEN SEEN BY 2 DOCTORS. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041305	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 5/2/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP3 #FDAMW5041305 #(B)(4). HAD AN ABALATION FOR HEAVY PERIODS STILL HAVE A MENSTRUAL...MUSCLE ACHES ...SEVERAL UTI'S ....FIBROIDS ...FATIGUE ...BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041306	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 5/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041306 #(B)(4) I HAVE BEEN SEEN BY A DOCTOR THE FIRST PART OF (B)(6) AND I'M SCHEDULED (B)(6) TO HAVE A HYSTERECTOMY TO REMOVE ESSURE. SHE THINKS MY RIGHT SIDE ISN'T WHERE IT SHOULD BE. SINCE ESSURE IT HURTS TO HAVE SEX, I'M TIRED ALL THE TIME, MY HAIR IS SLOWLY FALLING OUT, MY BODY ACHES ALL THE TIME, I HAVE NO ENERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041307	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CONSISTENT ALLERGIC REACTIONS TO THE NICKLE IN THE ESSURE COILS, I BREAK OUT IN A BAD BURNING ITCHY RASH ALL OVER MY BODY. ESSURE CAUSES ME SEVERE PELVIC PAIN, LIKE THE COILS ARE STABBING ME FROM THE INSIDE OUT. I HAVE EXTREME BLOATING AND FEEL GUSHES OF BLOAT RUSH TO MY STOMACH WHEN I STAND UP FROM A SITTING POSITION. I AM SCHEDULED FOR A HYSTERECTOMY THIS MONTH, I'M ONLY (B)(6) YEARS OLD AND OTHER THAN THE SIDE EFFECTS OF ESSURE I AM IN PERFECT HEALTH. ESSURE IS NOT SAFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041309	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ABDOMINAL PAIL ALL THE TIME, IT NEVER GOES AWAY. NOTHING TAKES THE PAIN AWAY EITHER. I HAVE INFECTIONS ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041310	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 6/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOUND OUT THE PROCEDURE HAD FAILED, THEN PREGNANT WITH 4TH CHILD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041313	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 4/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY HAIR IS BREAKING, I HAVE SEVERE PAIN ON MY LEFT SIDE, I HAVE ACNE ON MY NECK AND CYSTS ON MY JAW LINE, I'M ALWAYS TIRED, MY LOWER AND UPPER BACK HURT, SOMETIMES I'LL ALSO HAVE A STABBING PAIN THAT WILL AFFECT MY LEFT SIDE. I FEEL SICK AND STOMACH HURTS OFTEN, I'M IN AND OUT OF THE DOCTOR. THEY KEEP TELLING ME THAT MY BLOOD WORK IS FINE, EVERYTHING IS FINE. REALLY I'M NOT FINE AND I'M TIRED OF FEELING THIS WAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041315	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 2/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED TO HAVE CHRONIC PELVIC PAIN AND ABDOMINAL PAIN, LIKE SOMEONE WAS STABBING ME, PAINFUL INTERCOURSE AND LOSS OF LIBIDO, PROBLEMS SLEEPING, DEPRESSION AND MIGRAINES AND SEVERE BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041316	BAYER	3/9/2015	3/9/2015

Event Information:

Event Date (B3): 3/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I'VE HAD PELVIC PAIN, CLOTTING, HEAVY PERIODS, STOMACH ISSUES, WEIGHT GAIN, FATIGUE, BRAIN FOG, MUSCLE ACHES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00171	BAYER HEALTHCARE LLC	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/14/2012
Explant Date (E7): 9/5/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2013. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED ONE OR TWO YEARS AGO (DEVICE FAILURE). NO INFORMATION WAS GIVEN ON PATIENT'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, ONE - TWO YEARS BEFORE TIME OF REPORTING, THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED BY REPORTING PHYSICIAN. INDICATION FOR USE, LOT NUMBER, DURATION OF USE WERE UNKNOWN TO REPORTER. PHYSICIAN REPORTED THAT A PATIENT WAS NOW PREGNANT AFTER AN ESSURE WAS INSERTED ONE OR TWO YEARS EARLIER. HCP (HEALTHCARE PROFESSIONAL) WANTED TO KNOW WHAT TO DO WITH THIS PREGNANCY, WHICH WAS ONGOING AT THE TIME OF REPORTING. NO ASSESSMENT OF DEVICE-EVENT RELATIONSHIP WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 12-NOV-2013 FROM PHYSICIAN: PATIENT'S INITIALS AND DATE OF BIRTH WERE PROVIDED. ESSURE WAS INSERTED ON (B)(6) 2012 TO PREVENT PREGNANCY AND A HSG WAS PERFORMED ON (B)(6) 2012 (HSG READING: FILMS INDICATE BL ESSURE PROCEED, NO CONTRAST IS IDENTIFIED BEYOND THE CORNEAL REGION OF THE UTERUS, NO DEFINITE FREE OPACIFICATION OF THE FALLOPIAN TUBES. IMPRESSION SP PROCEED NO DEFINITE FREE SPILL OF CONTRAST BILATERALLY). IN (B)(6) 2013, PREGNANCY WAS DIAGNOSED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP 21-APR-2014: FOLLOW UP INFORMATION RECEIVED FROM THE SOCIAL MEDIA (NEWSPAPER). CONSUMER BECAME PREGNANT DESPITE ESSURE AND WORRIED THAT THE COILS MIGHT HAVE MIGRATED AND COULD PUNCTURE HER UTERUS. SHE RECENTLY WAS ABLE TO CONFIRM THEY HAVE BEEN IN THE RIGHT PLACE BUT SHE HAS STILL PLANNED TO HAVE A HYSTERECTOMY AFTER THE BABY IS BORN IN ORDER TO REMOVE THE COILS. CONSUMER SAID THAT SHE ORIGINALLY

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WANTED A TUBAL LIGATION BUT HER DOCTOR STEERED HER TOWARD ESSURE. SHE HAD THE PROCEDURE IN (B)(6) 2012, AND THE THREE-MONTH FOLLOW UP TEST CONFIRMED HER TUBES WERE FULLY BLOCKED. HER FOURTH CHILD IS DUE IN (B)(6) 2014. SHE WAS PREGNANT WITH THESE COILS IN HER BODY AND THERE'S NO STUDY TO TELL HER IT'S GOING TO BE FINE. HER PHYSICIAN SAID THAT HE HAS BEEN IMPLANTING ESSURE IN PATIENTS FOR SEVEN YEARS AND SHE WAS THE FIRST TO BECOME PREGNANT. PHYSICIAN MENTIONED THAT TO HIS THE BIGGEST ISSUE WAS WHETHER THE FOLLOW UP TEST WAS RELIABLE ENOUGH TO CONFIRM THE TUBES WERE BLOCKED. FOLLOW-UP INFORMATION WAS RECEIVED ON 02-MAY-2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN MADE, WITH NO RESPONSE TO DATE. FOLLOW-UP RECEIVED ON 22-MAY-2014 AND 23-MAY-2014 FROM LAY PRESS (NEWSPAPER). THE EXPECTED DELIVERY DATE FOR THE CONSUMER IS JUL-2014. FOLLOW-UP INFORMATION RECEIVED ON 06-OCT-2014. NEW REPORTER WAS ADDED AND PATIENT'S INITIALS AND DATE OF PROCEDURE WERE CONFIRMED. THE PATIENT'S DATE OF BIRTH OF WAS UPDATED. PATIENT WANTED TO KNOW THE NUMBER OF CASE, TO MAKE SURE THAT ALL INFORMATION WAS SENT TO APPROPRIATE PEOPLE. AT THE HSG, HER TUBES WERE BLOCKED. ACCORDING TO THE REPORTER, THE BABY WAS DELIVERED (DATE WAS UNKNOWN). FOLLOW UP INFORMATION RECEIVED ON 18-NOV-2014: CONSUMER STATED THAT SHE HAD EXCRUCIATING PAIN. SHE REPORTED SHE WAS PREGNANT AGAIN WITH OVER 40 YEARS. NO FURTHER INFORMATION WAS REPORTED. FOLLOW UP 28-NOV-2014: PTC INVESTIGATION RESULTS PROVIDED. (B)(4). FINAL ASSESSMENT: PREGNANCY IS THE CONDITION OF CARRYING DEVELOPING OFFSPRING WITHIN THE BODY. THE TIME PERIOD DURING WHICH THIS CONDITION EXISTS; GESTATION. PROBABLE CAUSES FOR PREGNANCY INCLUDE: UNSUCCESSFUL BILATERAL TUBAL OCCLUSION (COMPLETE TISSUE INGROWTH), EXPULSION (RELATED TO MICRO-INSERT PLACEMENT ACCURACY), NO 3 MONTH CONFIRMATION TEST (HSG) OR MIS-READ OF HSG, LACK OF PATIENT COMPLIANCE TO IFU (I.E. USE OF ALTERNATE CONTRACEPTION UNTIL CONFIRMATION OF BILATERAL OCCLUSION). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION (PREGNANCY QUESTIONNAIRE) RECEIVED ON 10-FEB-2015 FROM PHYSICIAN: PATIENT'S WEIGHT WAS PROVIDED (BODY MASS INDEX (B)(6)). PATIENT'S PAST MEDICAL HISTORY INCLUDED: 5 PREVIOUS PREGNANCIES WITH 4 NORMAL SPONTANEOUS VAGINAL DELIVERIES ((B)(4)); DEPRESSION (WELLBUTRIN), MODERATE PAINFUL MENSTRUAL CYCLES AND ADULT ATTENTION DEFICIT DISORDER. HER PAST SURGICAL HISTORY WAS: MID URETHRAL SLING, AND A CHOLECYSTECTOMY. HER FAMILY HISTORY WAS SIGNIFICANT FOR THYROID CANCER. SHE DENIED USE OF TOBACCO, ALCOHOL, OR RECREATIONAL DRUGS. SHE DENIED ANY ABNORMAL PAP SMEARS AND DID NOT REPORT ANY KNOWN DRUG ALLERGIES. ESSURE WAS EASILY INSERTED FOR UNDESIRED FERTILITY. CERVICAL DILATATION AND GENERAL ANESTHESIA WERE APPLIED DURING INSERTION. PHYSICIAN DENIED FLUID LOSS MORE THAN 1500 CC DURING INSERTION AND ALSO DENIED THAT THE PROCEDURE TOOK MORE THAN 20 MINUTES. DESPITE A CONFIRMATORY HSG DOCUMENTED TUBAL OCCLUSION, THE PATIENT CONCEIVED SPONTANEOUSLY. THE DATE (B)(6) 2013 WAS ASSESSED AS EVENT ONSET DATE. ON (B)(6) 2014, NORMAL VAGINAL DELIVERY WAS REPORTED. THERE WAS NO COMPLICATION (NORMAL FETAL OUTCOME). LATER, PATIENT REQUESTED ESSURE DEVICES WERE EXCISED FROM

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HER BODY, THUS ON (B)(6) 2014, SHE WAS ADMITTED FOR DA VINCI ASSISTED TOTAL LAPAROSCOPIC HYSTERECTOMY AND BILATERAL SALPINGECTOMY. AT ADMISSION, HER CHIEF COMPLAINT WAS RETAINED FOREIGN BODY AND RIGHT LOWER QUADRANT PAIN. DURING THE SURGICAL PROCEDURE, EXAMINATION REVEALED THAT THE UTERUS WAS NORMAL IN SIZE AND CONFIGURATION. BOTH OVIDUCTS AND BOTH OVARIES WERE EASILY SEEN. ON THE PATIENT'S LEFT SIDE THERE WAS EVIDENCE OF AN ESSURE IMPLANT JUST UNDERNEATH THE SEROSA OF THE LEFT CORNUA AND GOING INTO THE LEFT OVIDUCT. ON THE PATIENT'S RIGHT SIDE, THE IMPLANT WAS JUST BELOW THE SEROSA OF THE RIGHT CORNUA AND APPEARED TO COIL BACK ON ITSELF UNDERNEATH THE SEROSA. RATHER THAN GO ALL THE WAY DOWN THE OVIDUCT. THERE WAS NO EVIDENCE THAT THE IMPLANT EVER PUNCTURED THE SEROSA LAYER OF TISSUE. BOTH OVIDUCTS WERE NORMAL IN SIZE AND DID NOT APPEAR TO HAVE ANY SCARRING ON THE OUTSIDE. BOTH OVARIES APPEARED NORMAL. DIAGNOSIS AT PATHOLOGY REPORT INCLUDED LEIOMYOMATA IN THE MYOMETRIUM, MILD CHRONIC CERVICITIS AND FOREIGN BODY (COILED GRAY METAL WIRES AT BILATERAL CORNUA) IN FALLOPIAN TUBES. PATIENT WAS RECOVERED. EVENTS WERE ASSESSED AS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) BY THE PHYSICIAN. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS UPDATED ON 20-FEB-2015: THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO BECAME PREGNANT ONE YEAR AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. AFTER A NORMAL VAGINAL DELIVERY, SHE REQUESTED ESSURE REMOVAL AND PHYSICIAN PERFORMED A TOTAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY; DURING THIS PROCEDURE IT WAS FOUND ON PATIENT'S LEFT SIDE ESSURE IMPLANT WAS JUST UNDERNEATH THE SEROSA OF THE LEFT CORNUA AND ON HER RIGHT SIDE, THE IMPLANT WAS JUST BELOW THE SEROSA OF THE RIGHT CORNUA AND APPEARED TO COIL BACK ON ITSELF UNDERNEATH THE SEROSA. THE DEVICES WERE REMOVED AND SHE RECOVERED FROM SURGERY. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS BY THE REPORTER DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN ESSURE'S REFERENCE SAFETY. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS PARTICULAR CASE, ESSURE CONFIRMATION TEST SHOWED BILATERAL TUBAL OCCLUSION. THEREFORE, AN ESSURE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, INTERPRETED AS DEVICE EMBEDMENT IN UTERINE/FALLOPIAN TUBE WALL AND SHAPE ALTERATION, ALTHOUGH THEIR EXACT DATE AND MECHANISM ARE NOT KNOW; GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE, INITIALLY CONSIDERED A NON-INCIDENT WAS REGARDED AS AN INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION REPORTING THE SURGICAL INTERVENTION FOR ESSURE REMOVAL . THE PRODUCT TECHNICAL

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COMPLAINT ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 21-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CASE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00173	BAYER HEALTHCARE LLC	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B40022; B34593

Single Use: Y
Implant Date (E6): 11/8/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ESSURE DEVICE LEFT SIDE WAS PLACED THROUGH THE CORNUA AND DEVICE WAS LEFT IN PLACE DUE TO DIFFICULTY REMOVAL. NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2014, THE PATIENT HAD A LAPAROSCOPIC TUBAL LIGATION PERFORMED SUBSEQUENT TO ESSURE DEVICE IN THE LEFT SIDE WAS PLACED THROUGH THE CORNUA AND DEVICE WAS LEFT IN PLACE DUE TO DIFFICULTY REMOVAL. THE OUTCOME OF THE EVENTS ESSURE DEVICE LEFT SIDE WAS PLACED THROUGH THE CORNUA AND DEVICE WAS LEFT IN PLACE DUE TO DIFFICULTY REMOVAL WAS UNKNOWN. NO ASSESSMENT WAS GIVEN. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE A USABILITY ISSUE (DEVICE DIFFICULT TO USE) WAS REPORTED. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER

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REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. DUE TO LACK OF SAMPLE RETURN AND ANY VALID BATCH INFORMATION THE RQU WAS UNABLE TO CONFIRM ANY QUALITY DEFECT AND THEREFORE CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. FOLLOW-UP RECEIVED ON 09-JUN-2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE. FOLLOW-UP INFORMATION RECEIVED ON 13-FEB-2015 FROM PHYSICIAN: PATIENT WAS (B)(6). SHE HAD ONE PREVIOUS PREGNANCY WITH EMERGENCY CD (CESAREAN DELIVERY) FOR FETAL INDICATIONS. SHE HAD NO HISTORY OF ABNORMAL PAP TESTS, CERVICAL PROCEDURES, D&C (DILATION AND CURETTAGE), UTERINE SURGERIES OR OTHER ABDOMINAL OR PELVIC SURGERIES. SHE WAS OBESE (BMI OF 35.3 AT THE TIME OF ESSURE INSERTION), HAD HIGH ANXIETY, HYPERTENSION (HTN) WELL CONTROLLED, ABNORMAL UTERINE BLEEDING AND WANTED AN ENDOMETRIAL ABLATION (PURPOSE OF STERILIZATION WAS TO PROCEED WITH ABLATION). ON (B)(6) 2013, ESSURE WAS INSERTED WITH LOT NUMBER B40022 RIGHT TUBE (EXPIRATION DATE 01-JUN-2016), AND B34593 LEFT TUBE (EXPIRATION 01-MAY-2016). PATIENT WAS NOT POSTPARTUM. DURING THE PROCEDURE, WHICH WAS PERFORMED UNDER GENERAL ANESTHESIA WITH TORADOL ON CALL TO OR (OPERATIVE ROOM) FOR TUBAL SPASM PROPHYLAXIS, CERVICAL DILATION WAS USED. THE UTERUS WAS NOT SOUNDED. HYSTEROSCOPY WAS PERFORMED AND THE BILATERAL COILS WERE PLACED EASILY WITH 4 COILS TRAILING ON RIGHT AND 6 ON LEFT. FORCE WAS NOT USED TO INSERT THE DEVICES BILATERALLY. TUBAL OSTIA WERE EASILY SEEN AS PATIENT WAS ON DEPO PROVERA FOR 1 MONTH PRIOR TO SCHEDULING. SHE WAS POSITIVE FOR ENDOMETRIAL POLYPS SO ENDOMETRIAL BIOPSY WAS DONE AFTER THE ESSURE COILS WERE PLACED. THE FLUID DEFICIT FOR PROCEDURE WAS 0CC. PROCEDURE WAS NORMAL TIME LIMIT AT APPROXIMATELY OUT OF OR IN LESS THAN 30 MIN. EBL (ESTIMATED BLOOD LOSS) WAS 3 CC. PATIENT CONTINUED ON DEPO PROVERA UNTIL THE HYSTEROSALPINGOGRAM (HSG) TO CONFIRM CLOSURE WAS PERFORMED. HSG WAS ATTEMPTED ON (B)(6) 2014 UNDER USUAL CIRCUMSTANCES AND WAS NOT SUCCESSFUL DUE TO PATIENT'S INTOLERANCE. LATER, HSG WAS COMPLETED BY THE INTERVENTIONAL RADIOLOGY DEPARTMENT UNDER CONSCIOUS SEDATION ON (B)(6) 2014 AND BOTH COILS WERE FOUND MALPOSITIONED. RIGHT COIL APPEARED TO BE IN THE PELVIC CAVITY AND LEFT COIL WAS PARTIALLY IN THE LEFT TUBE. THERE WAS BILATERAL CONTRAST SPILLAGE TO PERITONEUM AND BOTH TUBES FILLED WITH CONTRAST. PATIENT WAS TREATED WITH DOXYCYCLINE FOR 10 DAYS. PATIENT DID NOT HAVE ANY SYMPTOMS THAT WERE CONCERNING FOR PAIN OR INFECTION POSTOPERATIVELY AND WAS SEEN 1 WEEK AFTER THE PROCEDURE. SHE WAS TAKEN TO THE OR FOR LAPAROSCOPY BTL (BILATERAL TUBAL LIGATION). DURING THE SURGERY, PHYSICIAN WAS UNABLE TO FIND THE RIGHT COIL ON ABDOMINAL AND PELVIC EXPLORATION. THE LEFT COIL WAS SEEN TO BE PROTRUDING FROM THE CORNUA AND WAS LYING ALONG THE CEPHALAD PART OF THE TUBE, COVERED IN SEROSAL TISSUE. AFTER DISCUSSION WITH THE ESSURE REPRESENTATIVE AND EVALUATION, DECISION TO LEAVE COIL RATHER THAN OPEN THE CORNUA TO REMOVE THE COIL WITH POSSIBLE INCREASE BLEEDING AND DAMAGE WITH POSSIBLE HYSTERECTOMY. PROCEED WITH LAPAROSCOPIC BTL BY FILSHIE CLIPS. PATIENT HAD A CERVICAL LACERATION AT THE TIME OF THIS SURGERY AND ENDOMETRIAL ABLATION WAS ABORTED. PATIENT IS CURRENTLY NOT SEXUALLY ACTIVE AND HAD THE ABLATION COMPLETED RECENTLY. CASE UPGRADED TO INCIDENT. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS UPDATED ON 24-FEB-2015: THE FINAL ASSESSMENT WAS: FOR LOT #B34593, THE PRODUCTION DATE IS MAY-2013 AND EXPIRATION DATE IS MAY-2016. FOR LOT #B40022, THE PRODUCTION DATE IS JUN-2013 AND EXPIRATION DATE IS JUN-2016. THE COMPLAINT NARRATIVE INDICATES A PERFORATION EVENT WITH THE PERFORATED IMPLANT LEFT IN PLACE. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK OR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, THEY CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT

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MET ALL RELEASE REQUIREMENTS. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCHES WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCHES B34593 AND B40022. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT HYSTEROSALPINGOGRAM (HSG) RIGHT COIL APPEARED TO BE IN THE PELVIC CAVITY AND LEFT COIL WAS PARTIALLY IN THE LEFT TUBE. SHE WAS SUBMITTED TO A LAPAROSCOPIC SURGERY AND DURING THE PROCEDURE, PHYSICIAN WAS UNABLE TO FIND THE RIGHT COIL ON ABDOMINAL AND PELVIC EXPLORATION. THE LEFT COIL WAS SEEN TO BE PROTRUDING FROM THE CORNUA AND WAS LYING ALONG THE CEPHALAD PART OF THE TUBE, COVERED IN SEROSAL TISSUE. THIS COIL WAS LEFT IN PLACE AND PHYSICIAN PERFORMED A TUBAL LIGATION. THE REPORTED EVENTS, INTERPRETED AS DEVICE DISLOCATION AND FALLOPIAN TUBE PERFORATION, WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A COMPLETE PERFORATION OCCURS, ESSURE CAN BE FOUND IN THE ABDOMINAL CAVITY AS IT PERFORATES THE WHOLE FALLOPIAN TUBE WALL. IN THIS PARTICULAR CASE, PHYSICIAN REPORTED AN EASY ESSURE INSERTION. ALTHOUGH THE EXACT MECHANISM OF THE REPORTED EVENTS IS UNKNOWN, GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT DUE TO THE REPORTED INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS FOR THE REPORTED BATCHES B34593 AND B40022 CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041312	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE ON (B)(6) 2012. IT WAS IMPLANTED AT MY DR'S OFFICE BUT SHORTLY AFTER LEAVING FROM THE PROCEDURE I HAD THE WORST CRAMPING. I WAS IN BED FOR 2 DAYS AFTER THE PROCEDURE DUE TO THE PAIN I WAS FEELING. THE FOLLOWING MONTH I HAD MY 1ST PERIOD AFTER HAVING ESSURE PLACED AND I THOUGHT I MIGHT BLEED TO DEATH AND HAVE NEVER EXPERIENCED SUCH A HEAVY PERIOD. I'VE HAD CHRONIC BACK PAIN, PELVIC AND ABDOMINAL PAIN, HEAVY PERIODS WITH HUGE BLOOD CLOTS, PAIN DURING SEX, BRAIN FOG, ANXIETY, MOOD SWINGS. I HAVE SEEN MY DR AND HE HAS TOLD ME I HAVE ADENOMYOSIS AND WILL REQUIRE A HYSTERECTOMY. I STILL HAVE ESSURE AT THIS TIME BUT I RETURN TO MY DR ON (B)(6) 2015 TO SET UP SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041317	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 8/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DAILY 24/7 HEADACHES, FATIGUE, PAINFUL SEX DURING AND AFTER, CHRONIC SINUS INFECTIONS, MEMORY LOSS, MOOD CHANGES, WORSENING DEPRESSION, ANXIETY, INSOMNIA, HEART PALPITATIONS, HEAVY PERIODS, BLOATING, UTERUS PAIN, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041318	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE IMPLANTATION I HAVE HAD WEIGHT GAIN AND HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041319	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 10/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FACIAL PAIN AND TEETH IRRITATION STARTED. SINUS INFECTION STARTED SHORTLY AFTER AND IS STILL RELEVANT. TOOTH LOSS SHORTLY AFTER THAT. BACK AND ABDOMINAL PAIN, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041320	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 1/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMPLANTED WITH ESSURE (B)(6) 2015. BY (B)(6) 2015 HAD SEVERE STABBING ABDOMINAL PAIN, SEVERE BLOATING. BY (B)(6) 2015 I WAS IN THE ER FOR SEVERE PAIN. COULDN'T BEND OVER, SIT OR STAND. COULDN'T PICK UP MY CHILDREN. HAD A CT SCAN, X RAYS, ULTRA SOUNDS. BY (B)(6) 2015 I WAS BACK IN THE ER IN TEARS FROM THE PAIN, THEN HAD JOINT PAIN , STABBING PAIN INSIDE MY VAGINA, JOINT PAIN, BLURRED VISION, BRAIN FOG, METALLIC TASTE IN MY MOUTH, VAGINAL DISCHARGE, ANXIETY/PANIC ATTACKS , WAS HAVING A MENSTRUAL CYCLE EVERY WEEK . COULDN'T FUNCTION . ON (B)(6) 2015 ALSO HAD A COLONOSCOPY AND DUE TO ESSURE I HAVE NOW BEEN DIAGNOSED WITH CHRON'S. I AM ALSO ALLERGIC TO METALS, IE NICKEL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041321	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 4/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT FOR MY HSG AND THE PERSON DID IT WRONG. A FEW HOURS LATER I WAS VERY WEAK. A PART OF MY STOMACH TISSUE CAME. OUT I FAINTED AND WAS VERY WEAK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041322	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 11/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT EXTREME ABDOMINAL AND LOW BACK PAIN, HAD BLOOD CLOTS COMING OUT OF MY RECTUM, WENT TO THE ER AND CATSCAN DONE AND MY ESSURE COILS ARE TEARING UP MY INSIDES, TUBE AND UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041323	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 2/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) HAD ESSURE PUT IN MY TUBES. HAD THEM CUT TUBES OUT. HAVE HAD BLEEDING EVER SINCE. MANY, MANY OTHER ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041324	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, HORRIBLE PERIODS, HUGE CLOTS, HEAD ACHES, BODY ACHES, DEPRESSION, MOOD SWINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041325	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 7/11/2012	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE CALLED ESSURE ON (B)(6) 2012 BY DR. (B)(6) AT (B)(6). THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS, INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THE EXPIRATION DATE. THE ONSET OF MY COMPLAINTS STARTED ON (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: EXCESSIVE BLADDER AND KIDNEY INFECTIONS/ISSUES, EITHER NO MENSTRUATION OR UNPREDICTABLE, SEVERE UTERINE PRESSURE AND PAIN MAKING IT SOMETIMES UNBEARABLE AND UNABLE TO DO DAILY ACTIVITIES, SEVERE HEADACHES, DRYNESS AND FATIGUE, PAINFUL INTERCOURSE, VERTIGO AND DIZZINESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041326	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 2/15/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041326 #(B)(4). THE LOT NUMBER FOR MY ESSURE IS LOT#B26273. I AM SCHEDULED TO HAVE A FULL HYSTERECTOMY ON (B)(6), 2015 TAKING UTERUS, CERVIX AND FALLOPIAN TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041327	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 3/5/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M HOME RECOVERING FROM A FULL HYSTERECTOMY AND BOTH TUBE REMOVAL FOR THE NEXT 4-6 WEEKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041328	BAYER	3/9/2015	3/10/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOR A FEW YEARS AFTER I GOT ESSURE EVERYTHING WAS FINE BUT THEN I STARTED BEING TIRED ALL THE TIME. HAD RASHES FOR NO REASON, PAIN IN MY SIDES, BAD CLOTTING WITH MY PERIODS, MOOD SWINGS, AND NOW PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041429	BAYER	3/9/2015	3/17/2015

Event Information:

Event Date (B3): 4/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/4/2009
Explant Date (E7): 4/26/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN 2009. A YEAR AFTER I HAD IT DONE I STARTED HAVING PAIN AND HEAVIER PERIODS. I STILL HAD TO BE ON BIRTH CONTROL TO GET PERIODS. THEY WERE STILL HEAVY. IT KEPT ON GOING UNTIL 2012 WHEN MY FORMER OBGYN NOTICED A COIL OF THE ESSURE HAD WENT THROUGH MY RIGHT TUBE. I HAD A HYSTERECTOMY AND PARTIAL REMOVAL OF MY RIGHT FALLOPIAN TUBE AND REMOVAL OF THE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00172	BAYER HEALTHCARE LLC	3/9/2015	4/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C13141

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 2/17/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6)-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER C13141. PHYSICIAN REPORTED THAT ESSURE IMPLANT DID NOT GET OFF FROM CATHETER NORMALLY, IT STUCK IN CATHETER AND ALSO IN PATIENT, WHILE REMOVING THE IMPLANT, STRUCTURE OF THE CATHETER HAD BROKEN AND SOME GREEN MATERIAL HAD APPEARED. THE IMPLANT WAS ANYWAY MANAGED TO REMOVE FROM PATIENT AND A NEW IMPLANT WAS SUCCESSFULLY INSERTED SO BILATERAL INSERTION OF IMPLANTS WAS ACHIEVED. SAMPLE IS AVAILABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING ESSURE INSERTION PROCEDURE, IMPLANT DID NOT GET OFF FROM CATHETER (DEVICE DEPLOYMENT ISSUE), IT STUCK IN PATIENT (EMBEDDED DEVICE) AND WHILE REMOVING THE IMPLANT, STRUCTURE OF CATHETER HAD BROKEN AND SOME GREEN MATERIAL HAD APPEARED (DEVICE BREAKAGE). THE EVENT EMBEDDED DEVICE IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. ALSO, DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE BREAKAGE AND EMBEDMENT OCCURRED DURING ESSURE PLACEMENT PROCEDURE, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS

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ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULTS RECEIVED ON 09-MAR-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSIC

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041329	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 3/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING FOR 3 MONTHS AFTER ESSURE DOC RECOMMEND AND PERFORMED ABLATION. BACK PAIN OVARIAN CYSTS AND ENDOMETRIOSIS. END RESULT RIGHT TUBE AND OVARY REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041330	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 3/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041331	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 1/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED WITH CRAMPING DAILY, AND IMMEDIATELY I WENT FROM SHORT REGULAR PERIODS EVERY 28 DAYS TO PERIODS THAT ARE ABOUT 2 WEEKS LONG WITH 2 WEEK OFF AND RIGHT BACK ON. I ALSO HAVE ISSUES WITH SWELLING PREDOMINANTLY IN MY FEET AND LEGS. I AM TIRED NOW ALL THE TIME, CONSTANTLY FEELING EXHAUSTED. I HAVE BEGUN TO HAVE ISSUES WITH JEWELRY IRRITATION WHEN I'VE NEVER HAD ISSUE BEFORE. I HAVE ALSO NOTICED MY HEART SKIPPING BEATS MORE OFTEN (I HAD A MINOR HEART MURMUR BEFORE). I GET FREQUENT HEADACHES AND MIGRAINES. I HAD A NORMAL SEX DRIVE AND ACTIVE SEX LIFE UNTIL I HAD THIS DEVICE PUT IN. NOW SEX IS PAINFUL, AND I OFTEN BLEED DURING OR AFTER IT, AND I HAVE NO INTEREST IN IT. I HAVE ALSO NOTICED I'M LOSING MORE HAIR THAN I USED TO LOSE. I AM ALSO MUCH MORE LIKELY TO HAVE ISSUES WITH DISCHARGE OR INFECTIONS (UTI, YEAST, ETC) THAN BEFORE THIS PROCEDURE. I HAVE TENDER BREASTS MOST OF THE MONTH, OCCASIONALLY NOW HAVE NIGHT SWEATS AND/OR HOT FLASHES. I ALSO NOW HAVE ISSUES WITH HIP AND PELVIC PAIN. I HAVE ALSO NOTICED MY BACK PAIN IS MUCH MORE SIGNIFICANT THAN BEFORE THE PROCEDURE. LASTLY I HAVE ALWAYS HAD ISSUES WITH MY TEETH, BUT IN THE LAST YEAR THE NUMBER OF ISSUES INCLUDING CAVITIES AND BREAKING TEETH HAS EXTREMELY INCREASED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041332	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 3/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HYSTERECTOMY / DUE TO SEVERE SIDE EFFECTS. (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041333	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CHRONIC HEADACHES. BLOATING , OVARIAN CYSTS , ITCHY SKIN , SEBORROTIC ECZEMA , PSORIASIS , NUMBNESS, CONSTIPATION , HAVING TO SELF CATHERISE , ROSASEA , BLEPHERITIS , BLURRED EYES , SPASMS , VITAMIN D DEFICIENCY , NERVE SPINAL DAMAGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041334	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 6/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDA MW5041334, #(B)(4). I NOW HAVE JOINT PAIN IN MY SHOULDER, FINGERS, HEEL OF MY FOOT, AND KNEES. I HAD MY TUBES AND COILS REMOVED ON (B)(6) 2015; I HAD SCARRING AND CYSTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041335	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 9/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING FOR AN OVER 2 WEEK PERIOD MONTHLY, INCREASE IN MIGRAINE HEADACHES, BODY ACHES, RASHES, SKIN BREAK OUTS, ABDOMINAL CRAMPING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041336	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCRUCIATING ABDOMINAL PAIN ACCOMPANIED WITH PIERCING SENSATION. LOWER BACK PAIN SHOOTING DOWN MY THIGHS. PRESSURE IN MY PELVIS. ACNE, INSOMNIA, DEPRESSION, AND ANXIETY. JUST HAD HEADACHES WITH BLURRED VISION, CLOUDY MEMORY, AND A CONSTANT METALLIC TASTE IN MY MOUTH. FEELING LETHARGIC. I WAS IN THE ER LAST NIGHT WHERE I WAS GIVEN ATIVAN. FOR YEARS I'VE PUT OFF AND ON DIFFERENT BC PILLS TO TRY TO MANAGE THE HEAVY BLEEDING AND CLOTS. AT MY WORST, I HAD TO CHANGE MY TAMPON EVERY TWENTY MINUTES AND THE PILLS DON'T WORK ANYMORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041337	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 11/1/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD THIS IMPLANT FOR OVER 10 YEARS. I HAVE EXPERIENCED OVER THE YEARS, THE FOLLOWING SYMPTOMS: CRAMPING, SHARP STABBING PELVIC PAIN, ABNORMAL MENSES, PERIOD STOPS, CONSTANT SPOTTING, DISCHARGE, HOT FLASHES, PMDD, NIGHT SWEATS, PAINFUL PERIOD, PAINFUL INTERCOURSE, UTI, ITCHING, BURNING, STINGING, STABBING AT THE VAGINAL ENTRANCE, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS, TWITCHING, FLUTTERING. BACK PAIN, JOINT, CHEST , LEG, BREAST, NECK, SPINE AND HIP PAIN. CHRONIC PELVIC PAIN, ALL OVER BODY ACHES AND PAINS. NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, HEADACHES OR MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN SHOCKS, NERVE PAIN, BRAIN FOG CLOUDINESS, FORGETFULNESS, ANXIETY, MOOD SWINGS. DEPRESSION, RINGING IN THE EARS, DIMINISHED BRAIN FUNCTION. SENSATION OF BURNING, STINGING, OR PRICKLING OF SKIN, NUMBNESS IN THE THIGH, HIGH BLOOD PRESSURE, VITAMIN D DEFICIENCY, HEART PALPITATIONS, THYROID DISEASE, WEIGHT ISSUES, ADRENAL PROBLEMS, MUSCLE SPASMS, VISION ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041338	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 3/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE STOMACH PAIN, RAPID WEIGHT LOSS. SINCE HAVING ESSURE PLACED I HAVE HAD NUMEROUS GI ISSUES, AS WELL AS HORRIBLE PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041339	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD BEEN DIAGNOSED WITH FIBROMYAGLA AND ENDOMETRIOSIS PRIOR TO GETTING ESSURE. HOWEVER, MY PAIN WASN'T THAT EXTREME AND I HADN'T NEEDED MEDICATION FOR OVER 10 YEARS. ABOUT 2 MONTHS AFTER GETTING ESSURE I STARTED HAVING ALL SORTS OF PROBLEMS INCLUDING CONSTANT BURNING WHEN URINATING AND LOWER BACK PAIN - CLASSIC SIGNS OF A UTI. ALL URINE CULTURES CAME BACK NORMAL BUT PAIN PERSISTED. MY PERIODS BECAME EVEN MORE IRREGULAR AND IT TOOK 3 ROUNDS OF PROVEA TO START ME, WHEN IN THE PAST ONE ROUND WOULD HAVE WORKED. I AM CONSTANTLY FATIGUED TO THE POINT THAT I ALMOST FALL ASLEEP BEHIND THE WHEEL NO MATTER HOW MUCH SLEEP I GET. THE PAIN HAS BECOME UNBEARABLE. I HURT AND ACHE ALL OVER. MY DEPRESSION HAS WORSENED AND I HAVE THOUGHT OF SUICIDE MORE OFTEN THAN BEFORE. SEX IS VERY PAINFUL. CONSTANT HEADACHES AND SORE MUSCLES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041340	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 6/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKEL ALLERGY. SEVERE BLOATING. SEVERE WEIGHT GAIN. SHARP ABDOMINAL PAIN. IRREGULAR BLEEDING. HEAVY MENSTRUAL CYCLE. LACK OF SEX DRIVE. DEPRESSION, ANXIETY DISORDER. VISION LOSS, LEAKING/OOZING SORES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041341	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY VITAMIN D !; KIDNEY FUNCTIONS ARE LOW! I'VE HAD LABS DONE 2 TIMES IN 3 MONTHS !; THEY ARE STILL LOW! NEVER HAD THIS PROBLEM BEFORE! SEVERE BLOATING, ABDOMINAL PAIN AND MOOD SWINGS! NOW ON VITAMIN D, PROZAC !; KLONOPINS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041342	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 1/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY FIRST TROUBLE WAS PAIN ON LEFT LOWER ABDOMEN. DR SAID WOULD GO AWAY. DIDN'T. I WENT INTO VOMITING FOR 12HRS STRAIGHT. WHEN I BROKE OUT IN RASH/HIVES AND MY EARS SWELLED SO BIG, THE POPPED OUT OF MY HAIR AND I COULDN'T HEAR. TO THE ER WE WENT. THREE KIDS IN TOW. TOLD I HAD AN ALLERGIC REACTION BUT NO CLUE WHY. TOOK MY TWO SHOTS OF STEROIDS AND ANTI PUKE MED. NEVER THOUGHT OF ESSURE. NOW I HAVE CHRONIC PAIN. BEEN DIAGNOSED WITH RHEUMATOID ARTHRITIS AND FIBROMYALGIA. CHRONIC FATIGUE. PUKE DAYS IN A ROW. RANDOM FEVERS. RASHES HIVES. I'M DIZZY A LOT HEADACHES! FACIAL TWITCHES, THAT'S NOW ARE FULL ON HEAD TWITCH OR MY ARM WILL SHOOT OUT. I ALSO HAVE BLOOD FOR STOOL FOR DAYS AFTER PUKING SPELLS. ANXIETY, DEPRESSION. I HAD ZERO HEALTH ISSUES BEFORE ESSURE. I HAVE FALLEN APART IN THE LAST THREE YEARS. PAST YEAR BEING THE WORST. I HAVE NEVER BEEN ABLE TO WEAR CHEAP EAR RINGS AND THEY ARE MADE OF NICKEL. I'M GETTING ESSURE REMOVED IN (B)(6)!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041343	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESSIVE AND PAINFUL CRAMPING, HEAVY BLEEDING FOR MORE THAN 7 DAYS, OFTEN HAD BLEEDING FOR 2 TO 3 WEEKS OF THE MONTH, URINARY TRACTS INFECTIONS, FIBROIDS, TIREDNESS, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041344	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 3/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE INSERTION ON THE RIGHT SIDE WAS EXCRUCIATINGLY PAINFUL. THE DOCTOR MENTIONED SEVERAL TIMES THAT "OF COURSE I WAS LATERAL". THEY ATTEMPTED MULTIPLE TIMES ON THE LEFT SIDE AND WERE NOT ABLE TO GET THE IMPLANT IN. ON THE 3RD ATTEMPT, I BEGGED THE DOCTOR TO STOP AS I COULD NO LONGER TAKE THE PAIN OF THE INSERTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041345	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 6/5/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIS PLACED COIL (OUT OF PLACE AND NOT EVER FOUND). DEPRESSION. BLOATED STOMACH. WEIGHT GAIN. HAIR LOSS. LOSS OF APPETITE. SEVERE HEADACHES. FATIGUE. SEVERE ABDOMINAL PAIN. LOTS OF VISITS TO THE E.R. LOTS OF XRAYS, ULTRASOUNDS ETC. THIS PRODUCT HAS KEPT ME DOWN FOR 2 YEARS NOW. I AM FINALLY REMOVING TUBES AND COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041346	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS WITH EXTREME CRAMPS AND BLOOD CLOTS, CHRONIC PELVIC, BACK AND LEG PAIN, MIGRAINES, BLURRED VISION, BLOOD CLOTS, HEART ATTACK, TIA, ANEMIA (DUE TO PERIODS) OSTEOPENA RESULTING IN MULTIPLE FRACTURES AND HOSPITALIZATION, HYPOTHYROIDISM, DEPRESSION, ANXIETY, FATIGUE, DEGENERATIVE ARTHRITIS, BREAST HEALTH ISSUES, MUSCLE ACHES AND JOINT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041347	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 3/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: N
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I WILL TRY TO MAKE THIS AS SHORT AS POSSIBLE.. I HAD ESSURE PLACED IN 2010 AFTER HAVING 5 CHILDREN. I WAS (B)(6) YEARS OLD AND DECIDED I WAS DONE. SO MY DOCTOR RECOMMENDED ESSURE AS IT WAS A EASY PROCEDURE WITH ALMOST NO PAIN AND I WOULDN'T HAVE TO BE PUT TO SLEEP (BOTH LIES). WHEN I MADE IT HOME, THE PAIN WAS SO BAD I FELT LIKE I DID WHEN I WAS IN LABOR. WHEN I CALLED THE DOCTOR THEY TOLD ME TO USE A HEATING PAD, WHICH WAS A JOKE IN ITS SELF. THE PAIN LASTED FOR THREE DAYS.. IT WAS UNBEARABLE. I WAS HAPPY WHEN IT WAS FINALLY OVER. THEN CAME THE NAUSEA (THAT I STILL HAVE ALMOST DAILY 5 YEARS LATER) AND THE HEAD ACHES. BODY PAIN, UPPER AND LOWER BACK PAIN. AT (B)(6) YEARS OLD I COULD HARDLY STAND OR PLAY WITH MY CHILDREN BECAUSE THE PAIN IN MY BACK WAS AND STILL IS TOO MUCH FOR ME. AND FORGET ABOUT DOCTORS HELPING WITH PAIN MANAGEMENT WHEN YOU'RE UNDER 40 BECAUSE IF THEY CAN'T SEE IT THEN YOU MUST BE LYING OR JUST TRYING TO GET PAIN MEDS. SAD BUT TRUE. OTHER THINGS I HAVE INCLUDE HEAVY PERIODS WITH HUGE BLOOD CLOTS THAT LAST SOMETIMES TWO WEEKS, PAIN DURING SEX, BRAIN FOG, EXTREAM ANXIETY, MOOD SWINGS, DEPRESSION, HAIR LOSS AND TOOTH LOSS. NOW THE OTHER KICKER. 8 MONTHS AFTER I HAD THE PROCEDURE I WENT TO THE DOCTOR BECAUSE THE NAUSEA BECAME TOO MUCH AND HE ASKED IF I COULD BE PREGNANT AND I SAID NO. I HAD ESSURE DONE IN (B)(6). HE ASKED ME TO DO A TEST ANYWAY TO BE SAFE. WHEN HE CAME BACK IN THE ROOM A LITTLE LATER AND SAID YOUR PREGNANCY TEST WAS POSITIVE. I LOOKED AT HIM AND WAITED FOR HIM TO SAY JUST KIDDING. INSTEAD HE SAID I NEED TO SEND YOU FOR ULTRASOUND RIGHT AWAY. BECAUSE OF THE ESSURE THE BABY IS PROBABLY IN YOUR TUBE. I WAS SCARED BECAUSE I HAD HAD AN ECTOPIC RUPTURE BEFORE AND ONLY HAVE ONE TUBE. AS IT TURNS OUT THE BABY WAS IN THE UTERUS. SHE IS NOW ALMOST (B)(6). BUT THE PREGNANCY WAS SCARY BECAUSE NO ONE KNEW WHAT COULD

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HAPPEN WITH THE ESSURE IN PLACE. I DELIVERED 6 WEEKS EARLY AND WHILE IN LABOR MY PLACENTA RUPTURED AND SHE GOT BLOOD IN HER LUNGS AND HAD TO STAY IN THE NICU FOR TWO WEEKS. WAS ESSURE TO BLAME?? WHO KNOWS. WHEN I WENT BACK AFTER I HAD TO HER TO HAVE THE DYE TEST TO MAKE SURE THE COIL WAS STILL IN PLACE THEY SAID IT WAS AND NO ONE KNEW HOW IT HAPPENED. IT MUST HAVE BEEN A FLUKE RIGHT?? WRONG. ON (B)(6) 2015 THREE YEARS LATER. I HAD A SON BY C-SECTION. I HAD PLACENTA PREVIA AND HE TOO WAS BORN EARLY. I HONESTLY DON'T KNOW IF ESSURE HAD ANYTHING TO DO WITH MY PREGNANCY ISSUES WITH EITHER CHILD BUT I DO KNOW NEITHER OF THEM SHOULD HAVE HAPPENED. I LOVE THEM BOTH VERY MUCH. BUT I CHOSE TO STOP AT 5 CHILDREN. NOW AFTER SEVEN MY TUBE HAS BEEN TIED THE RIGHT WAY AND I CAN FINALLY SAY I'M DONE. PLEASE LADIES IF YOU ARE OFFERED ESSURE REFUSE!! IT HAS RUINED MANY LIVES. THANKS FOR READING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041348	BAYER	3/10/2015	3/10/2015

Event Information:

Event Date (B3): 4/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED GETTING A RASH AROUND MY BELLY, AROUND MY VAGINAL AREA AND INSIDE MY VAGINA. THIS STARTED IN (B)(6) 2015. SINCE I GOT THE ESSURE, SHARP PAIN MY BELLY ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00175	BAYER HEALTHCARE LLC	3/11/2015	3/11/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE (B)(4)) IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED SHE HAS NOT FELT HERSELF SINCE ESSURE WAS INSERTED. SHE EXPERIENCED HEADACHES, BACK ACHE, MOODINESS AND ABDOMINAL DISCOMFORT. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAS NOT FELT HERSELF SINCE ESSURE WAS

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INSERTED. THIS EVENT, INTERPRETED AS FEELING ABNORMAL, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT TIME BETWEEN ESSURE INSERTION AND THE OCCURRENCE OF THIS EVENT IS UNKNOWN. IT WAS NOT SPECIFIED WHAT REALLY SHE WAS EXPERIENCING. HOWEVER, BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT BY THE REGULATORY AUTHORITY. ADDITIONALLY, NON-SERIOUS EVENTS WERE ADDED: HEADACHES, BACK ACHE, MOODINESS AND ABDOMINAL DISCOMFORT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED FROM CONSUMER ON 01-APR-2015: THE CONSUMER WAS (B)(6) AT TIME OF THE REPORT. THE CONSUMER STATED SHE HAS REACTIONS TO JELLERIES IF THEY ARE NOT REAL. ESSURE WAS INSERTED IN (B)(6) 2013. IT WAS ALSO REPORTED THAT FROM (B)(6)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00176	BAYER HEALTHCARE LLC	3/11/2015	3/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 689935

Single Use: Y
Implant Date (E6): 2/1/2010
Explant Date (E7): 2/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012 FOR CONTRACEPTION. IT WAS REPORTED THAT PATIENT REQUESTED REMOVAL OF ESSURE DEVICE 3 YEARS POST PLACEMENT DUE TO BACK PAIN. THE HYSTERECTOMY WAS DONE ON (B)(6) 2015 TO REMOVE THE INSERTS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) IMPLANTED AND EXPERIENCED BACK PAIN. THREE YEARS AFTER ESSURE PLACEMENT, THE

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INSERTS WERE REMOVED THROUGH HYSTERECTOMY. THE BACK PAIN IS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION AND IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. BACK PAIN AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE PAIN OCCURRED DURING ESSURE USE. CONSIDERING THIS POSITIVE TEMPORAL RELATIONSHIP AND THE NATURE OF THIS EVENT, THIS PAIN IS CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL COMPLAINT ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 02-JUN-2015: ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT WHO HAS AS PREVIOUS GYNECOLOGICAL INTERVENTION A CERVICAL CONIZATION PERFORMED APPRO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00177	BAYER HEALTHCARE LLC	3/11/2015	3/11/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/24/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN A HOSPITAL ON (B)(6) 2012 FOR CONTRACEPTION. AFTER ESSURE INSERTION THE CONSUMER EXPERIENCED HAIR LOSS, IRREGULAR MENSTRUATIONS, AND UNBEARABLE HEADACHES. IRREGULAR MENSTRUATIONS WAS ONGOING THE TIME OF THIS REPORT. IN (B)(6)2014 SHE HAD AN ECTOPIC PREGNANCY FROM WHICH SHE WAS NOT RECOVERED YET. HER MENSTRUATION HAD NOT COME BACK AND SHE WAS UNDER TREATMENT. UNTIL SOME DAYS BEFORE THE REPORT DATE THERE WAS SPRING THAT WAS LOST IN HER BODY (IT WAS NOT BEING FOUND). THEN IT WAS FOUND IN CONSUMER'S ABDOMEN. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD AN ECTOPIC PREGNANCY. IT WAS ALSO REPORTED THAT A SPRING WAS FOUND IN ABDOMEN (INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY). BOTH EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. ALSO, ALTHOUGH NOT REPORTED AS SUCH, THE MOST LIKELY MECHANISM FOR THE LEFT COIL TO BE FOUND IN THE ABDOMEN, WOULD BE THROUGH A UTERINE/FALLOPIAN TUBE PERFORATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE

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MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SERIOUS INJURY (ECTOPIC PREGNANCY). ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 24-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00178	BAYER HEALTHCARE LLC	3/11/2015	3/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT PHYSICIAN SAW A PATIENT WHO HAD ESSURE AND TUBAL LIGATION PROCEDURE BY ANOTHER PHYSICIAN. ONLY ONE COIL WAS PLACED IN LEFT TUBE. PATIENT HAD PELVIC PAIN ALMOST IMMEDIATELY AND HAD A TUBAL LIGATION ONE MONTH LATER. THE SURGEON CAUTERIZED THE LEFT TUBE EVEN THOUGH THE ESSURE COIL WAS PLACED. PATIENT NOW COMPLAINS OF BLEEDING AND PELVIC PAIN. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON (B)(6) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: THE PHYSICIAN PERFORMED CAUTERY, EVEN WITH THE ESSURE IN PLACE, WHICH IS NOT ADVISED AND THIS WOULD BE CONSIDERED A HANDLING ERROR BY THE PHYSICIAN. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND HANDLING ERROR. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE

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EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD PELVIC PAIN ALMOST IMMEDIATELY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ONE MONTH LATER, SHE WAS SUBMITTED TO A TUBAL LIGATION. AFTER THIS SURGERY SHE COMPLAINED OF BLEEDING. THE REPORTED EVENTS, INTERPRETED AS POST PROCEDURAL PAIN AND GENITAL BLEEDING, WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC, UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND PAIN, THIS EVENT WAS CONSIDERED AS RELATED TO THE SUSPECT INSERT. REGARDING THE REPORTED BLEEDING, IF A LAPAROSCOPIC STERILIZATION (TUBAL LIGATION) IS PERFORMED IN PATIENTS WITH ESSURE, IT IS RECOMMENDED TO CLIP OR COAGULATE BOTH FALLOPIAN TUBES DISTAL OR PROXIMAL TO THE INSERT. CLIPPING OR COAGULATION ADJACENT TO OR OVER THE INSERT MAY CAUSE PATIENT INJURY, SINCE THE ESSURE INSERT MAY CONDUCT ENERGY IF CONTACTED BY AN ACTIVE ELECTROSURGICAL DEVICE. IN THIS CASE, THE SURGEON CAUTERIZED THE LEFT TUBE WITH ESSURE COIL IN PLACE; THIS HANDLING ERROR MAY HAVE BEEN A CONTRIBUTORY ROLE IN PATIENT'S BLEEDING. NEVERTHELESS, SINCE IT SEEMS THE DEVICE REMAINED IN PLACE, CAUSALITY CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION. A PRODUCT TECHNICAL ANALYSIS (PTC) WAS PERFORMED; TECHNICAL ASSESSMENT CONCLUDED TO UNCONFIRMED QUALITY DEFECT AND HANDLING ERROR. MEDICAL PTC ASSESSMENT STATED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 12-JUN-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD PELVIC PAIN ALMOST IMMEDIATELY AFTER ESSURE (F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00179	BAYER HEALTHCARE LLC	3/11/2015	3/12/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A45112

Single Use: Y
Implant Date (E6): 11/21/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR CONTRACEPTION. ON (B)(6) 2014, THE PATIENT WAS SEEN WITH COMPLAINT OF PAIN. AN X-RAY WAS DONE AND SHOWED THE LEFT INSERT MISPLACED, NOT IN TUBE. IT WAS EITHER IN UTERINE CAVITY, ENDOMETRIUM OR JUST OUTSIDE UTERINE CAVITY. ON (B)(6) 2014, A TUBAL WAS DONE LAPAROSCOPICALLY AND DID NOT FIND THE COIL AT THAT TIME. A LAPAROSCOPIC PROCEDURE WAS SCHEDULED FOR (B)(6) 2015 TO DO A SALPINGECTOMY. AT TIME OF THE REPORT, ESSURE DEVICE WAS CONTINUED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON (B)(6) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN X-RAY SHOWED THE LEFT INSERT WAS MISPLACED, IT WAS NOT IN TUBE. SHE WAS SUBMITTED TO A LAPAROSCOPY; BUT PHYSICIAN COULD NOT LOCATE THE COIL, ANOTHER LAPAROSCOPY WAS SCHEDULED. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF THE REPORTED DISLOCATION IS NOT KNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE REPORTED SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 28-APR-2015: ESSURE HEALTH CARE PROFESSIONAL GENERAL QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT WHO HAS NO PREVIOUS GYNECOLOGICAL INTERVENTIONS, MEDICAL HISTORY OR CONCURRENT C

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00174	BAYER HEALTHCARE LLC	3/11/2015	4/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C40061

Single Use: Y
Implant Date (E6): 2/10/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 6/15/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN'S ASSISTANT IN (B)(6) ON 11-FEB-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. ESSURE WAS INSERTED IN ONE THE FALLOPIAN TUBE WITHOUT PROBLEMS. DURING INSERTION IN THE OTHER FALLOPIAN TUBE THE ESSURE DID NOT RELEASE. FORCEPS HAD TO BE USED TO REMOVE THE ESSURE. THIS WAS VERY PAINFUL FOR THE PATIENT. FOLLOW UP INFORMATION RECEIVED ON 13-FEB-2015 FROM GYNECOLOGIST: AS ADDITIONAL INFORMATION SHE WAS ABLE TO TELL THAT A PART OF THE MICRO INSERT WAS STILL IN THE PATIENT, THAT A PART WAS IN THE INTRODUCER AND THAT A PART WAS IN THE GARBAGE CAN. THE MICRO INSERT WAS TRAPPED IN THE TUBA AND THE INTRODUCER DUE TO WHICH IT STRETCHED. FIRST IT WAS TRIED TO CUT THE MICRO INSERT WITH SCISSORS BUT THAT DID NOT WORKED AFTER WHICH THE TANG WAS USED. THE PATIENT WILL GET A LAPAROSCOPY JUST TO BE SURE. CASE UPGRADED TO OTHER REPORTABLE INCIDENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE, ESSURE DID NOT RELEASE IN ONE FALLOPIAN TUBE. THE MICRO INSERT WAS TRAPPED IN THE TUBA AND THE INTRODUCER DUE TO WHICH IT STRETCHED. PHYSICIAN TRIED UNSUCCESSFULLY TO CUT THE MICRO INSERT WITH SCISSORS; THEN A FORCEPS WAS USED TO REMOVE IT. THIS WAS VERY PAINFUL FOR THE PATIENT. AT THE END OF THE PROCEDURE; PART OF THE MICRO INSERT WAS STILL IN THE PATIENT. ALL REPORTED EVENTS WERE CONSIDERED NON-SERIOUS AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT FOR PART OF THE MICRO INSERT WAS STILL IN THE PATIENT, INTERPRETED AS DEVICE BREAKAGE, WHICH IS UNLISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT

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INSERTIONS. IN THIS PARTICULAR CASE, A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED TO FURTHER EVALUATE THE EVENTS; NEVERTHELESS SINCE THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE EVENT IT WAS TRIED TO CUT THE MICRO INSERT WITH SCISSORS, IT WAS CONSIDERED AS UNRELATED TO ESSURE, SINCE IT WAS REGARDED AS A DEVICE MISUSE. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 12-JUN-2015: NO FURTHER FOLLOW-UP INFORMATION IS EXPECTED. NCA REFERENCE NUMBER FOR THIS CASE: (B)(4). PTC (PRODUCT TECHNICAL COMPLAINT) ANALYSIS WAS RECEIVED ON 17-JUN-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: RETURN SAMPLE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00180	BAYER HEALTHCARE LLC	3/12/2015	3/12/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627757

Single Use: Y
Implant Date (E6): 4/15/2009
Explant Date (E7): 7/31/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038193) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 WITH LOT NUMBER 627757. THE CONSUMER STATED THAT SHE BEGAN HAVING PELVIC PAIN, NAUSEA, HEADACHES AND OTHER PROBLEMS WITHIN A FEW MONTHS. SHE ALSO HAD SEVERE BLOATING. SHE WENT TO HER GYNECOLOGIST IN 2014 TO DISCUSS THIS MATTER AND WAS DIAGNOSED WITH PELVIS CONGESTION SYNDROME AND DYSMENORRHEA. ON (B)(6) 2014, A HYSTERECTOMY WAS DONE. IMMEDIATELY AFTER SURGERY, ALL OF HER SYMPTOMS HAVE DISAPPEARED. SHE BELIEVED THAT ESSURE CAUSED HER PROBLEMS. THE OUTCOME OF THE EVENTS WAS RECOVERED / RESOLVED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON (B)(4) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: PRODUCTION DATE: 8/2008 AND EXPIRATION DATE: 8/2010. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE

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BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. THE EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE CONSUMER PRESENTED PELVIC PAIN WITHIN A FEW MONTHS AFTER ESSURE INSERTION. 4 YEARS LATER, SHE WENT TO HER GYNECOLOGIST AND WAS DIAGNOSED WITH PELVIS CONGESTION SYNDROME. A HYSTERECTOMY WAS PERFORMED AND IMMEDIATELY AFTER SURGERY, ALL OF HER SYMPTOMS DISAPPEARED (POSITIVE DECHALLENGE). THE PELVIC CONGESTION SYNDROME COULD BE AN ALTERNATIVE EXPLANATION FOR PELVIC PAIN. HOWEVER, CONSIDERING THE EVENT'S NATURE AND POSITIVE DECHALLENGE, A CONTRIBUTORY ROLE OF ESSURE TO THE REPORTED EVENT CANNOT BE TOTALLY EXCLUDED. SINCE HYSTERECTOMY (REQUIRED INTERVENTION) WAS PERFORMED THE CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE REPORTED. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00181	BAYER HEALTHCARE LLC	3/12/2015	3/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/21/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011 FOR STERILIZATION. THE CONSUMER STATED THAT IN (B)(6) 2014, SHE DEVELOPED A RASH IN HER VAGINA AND TUMMY. SHE DID NOT KNOW THE REASON AND AFTER SEARCHED SIDE EFFECTS OF ESSURE, SHE THOUGHT THAT IT COULD BE DUE TO NICKEL ALLERGY. IN (B)(6) 2014, SHE HAD A NICKEL ALLERGY TEST POSITIVE. ON (B)(6) 2015, A SURGERY WAS DONE TO REMOVE ESSURE. PHYSICIAN SAID THAT ESSURE INSERTS WERE NOT IN HER FALLOPIAN TUBES. ONE WAS IN HER UTERUS AND THE OTHER, PHYSICIAN COULD NOT FIND. ONLY INSERT THAT WAS FOUND IN HER UTERUS WAS REMOVED. ON (B)(6) 2015, SHE WENT TO EMERGENCY ROOM FOR ABDOMINAL PAIN AND BLOATING. X-RAY OF PELVIS WAS DONE AND WAS SAID THAT THE ESSURE THAT WAS NOT FOUND EARLIER WAS THERE IN UTERUS, BUT IT WAS NOT REMOVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO

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COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS POSITIVE TO NICKEL ALLERGY. DURING SURGERY TO REMOVE THE MICRO-INSERTS, ESSURE WERE NOT IN HER FALLOPIAN TUBES. ONE DEVICE WAS IN UTERUS (DEVICE EXPULSION), AND WAS REMOVED AND THE OTHER ONE WAS NOT FOUND. TWO DAYS LATER, THE CONSUMER WENT TO EMERGENCY ROOM COMPLAINING OF ABDOMINAL PAIN AND BLOATING AND A X-RAY SHOWED ESSURE THAT WAS NOT FOUND EARLIER WAS THERE IN UTERUS (DEVICE EXPULSION). THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. CONSIDERING THE EVENT'S NATURE AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION OR A DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF THE EXPULSION IS NOT KNOWN. HOWEVER CONSIDERING THE NATURE OF THE EVENT AND AVAILABLE INFORMATION, CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED, THE CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE AVAILABLE INFORMATION. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 15-APR-2015 FROM CONSUMER. ON (B)(6) 2015 A SURGERY (NAME OF SURGERY NOT PROVIDED) WAS PERFORMED TO REMOVE THE DEVICE (ESSURE) THAT WAS ON THE RIGHT SIDE BY A DOCTOR WHO WAS NOT CERTIFIED BY ESSURE. THE DOCTOR COULDN'

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00182	BAYER HEALTHCARE LLC	3/12/2015	3/12/2015

Event Information:

Event Date (B3): 1/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B60744

Single Use: Y
Implant Date (E6): 4/21/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER B60744 FOR CONTRACEPTION. ON (B)(6) 2015, PATIENT EXPERIENCED EXCRUCIATING PAIN. HCP THOUGHT IT MIGHT BE APPENDICITIS AND SENT PATIENT TO EMERGENCY ROOM. SOME IMAGES WERE TAKEN AND IT LOOKED LIKE THE TUBE WAS KINKED WHERE ESSURE WAS IN TUBE (RIGHT OR LEFT NOT SPECIFIED). PHYSICIAN SURGICALLY REMOVED THE COIL AND SECTION OF TUBE WHERE ESSURE WAS AND PAIN SUBSIDED. THE OUTCOME OF THE EVENT EXCRUCIATING PAIN WAS RECOVERED / RESOLVED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED ON (B)(4) 2015: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THE PRESENT CASE, IMAGES WERE TAKEN AND IT LOOKED LIKE THE TUBE WAS KINKED WHERE ESSURE WAS IN TUBE. AFTER SURGICAL REMOVAL OF THE COIL AND SECTION OF TUBE WHERE ESSURE WAS, THE PAIN RESOLVED. THEREFORE, CONSIDERING THE AVAILABLE INFORMATION, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE REPORTED EVENT EXCRUCIATING PAIN CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL REMOVAL OF ESSURE AND SECTION OF THE TUBE. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00183	BAYER HEALTHCARE LLC	3/12/2015	3/12/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76537

Single Use: Y
Implant Date (E6): 6/27/2014
Explant Date (E7): 8/26/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038137) IN UNITED STATES ON 13-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER B76537. THE CONSUMER STATED THAT SHE HAD SHARP PAINS IN ABDOMEN AND SHOOTING PAINS GOING DOWN HER LEGS. SHE BLED FOR OVER TWO WEEKS AND HAD SPOTTING FOR 2-3 WEEKS AFTER THAT. THE PAIN GOT WORSE AFTER PROLONGED ACTIVITY AND HER HANDS AND FEET WOULD GET NUMB AND TINGLY. SHE ALSO HAD MIGRAINES. AFTER HER INITIAL TWO WEEK CHECKUP, HER DOCTOR THOUGHT SHE COULD HAVE AN INFECTION AND GAVE HER AN ANTIBIOTIC THAT DID NOT MAKE ANYTHING BETTER, SO A CT SCAN WAS SCHEDULED FOR 2014. ACCORDING TO THE DOCTOR THE CT SCAN SHOWED THAT THE PLACEMENT OF THE COILS WAS FINE. THE DOCTOR DETERMINED THAT SHE WAS ALLERGIC TO THE COILS. ON (B)(6) 2014, ESSURE WAS REMOVED. AT THE TIME OF REPORT, SHE WAS STILL RECOVERING FROM THE SURGERY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 24-FEB-2015: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT

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PER SE. (B)(4) FURTHER ADVERSE EVENT CASE REPORTS HAVE BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, BUT NONE OF THE CASES REFERS ALSO TO SIMILAR ADVERSE TYPES OF EVENTS. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. THE PHYSICIAN DETERMINED THAT SHE WAS ALLERGIC TO THE COILS. SHE ALSO BLED FOR OVER TWO WEEKS (INTERPRETED AS GENITAL BLEEDING). THESE EVENTS ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE PATIENT HAD PAIN IN ABDOMEN AND LEG. A CT SCAN CONFIRMED THAT THE COILS WERE CORRECTLY PLACED, SO THE PHYSICIAN SUSPECTED THAT THE PATIENT COULD BE ALLERGIC TO COILS. THE COILS WERE THEN, SURGICALLY REMOVED. CONSIDERING THAT ESSURE IS A NICKEL-TITANIUM ALLOY, AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, THE ALLERGY IS CONSIDERED RELATED TO ESSURE. DURING ESSURE THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE REPORTED EVENT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED SURGERY. OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00185	BAYER HEALTHCARE LLC	3/12/2015	3/12/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53652

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7): 9/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE VIA REGULATORY AUTHORITY (CASE# MW5038173) IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. ESSURE LOT NUMBER IS B53652. THE PATIENT HAD STARTED TO REPORT PAIN SINCE THE IMPLANT'S INTRODUCTION IN 2014, LEADING TO A REMOVAL SURGERY ON (B)(6) 2014. UPON REMOVAL OF LEFT FALLOPIAN TUBE, THE ESSURE DEVICE WAS NOTED TO HAVE PLASTIC-APPEARING SHEATH OVER THE INTRAUTERINE PORTION OF THE IMPLANT. FOLLOW UP 24-FEB-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: LOT NUMBER PROVIDED B53652 IS INVALID. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO

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VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE. NEITHER VALID BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. ACCORDING TO THE RQU THE REFERRED LOT NUMBER IS INVALID. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO VALID BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO EXPERIENCED PAIN SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INTRODUCTION AND UPON REMOVAL, IT WAS NOTED THAT ESSURE DEVICE HAD A PLASTIC-APPEARING SHEATH OVER THE INTRAUTERINE PORTION OF THE IMPLANT, INTERPRETED AS DEVICE BREAKAGE. THE PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND THE DEVICE BREAKAGE IS NON-SERIOUS. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THE PAIN IS LISTED AND DEVICE BREAKAGE IS UNLISTED. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE PATIENT HAD PAIN SINCE ESSURE PLACEMENT. CONSIDERING THAT THE PRESENCE OF A FOREIGN BODY IN THE FALLOPIAN TUBES MAY CAUSE PAIN, THIS PAIN IS CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE AVAILABLE INFORMATION. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 16-JUN-2015: REPORTER DID NOT PROVIDE FURTHER INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO EXPERIENCED PAIN SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INTRODUCTION AN

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041504	BAYER/CONCEPTUS	3/12/2015	3/19/2015

Event Information:

Event Date (B3): 2/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/3/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2012, I WAS IMPLANTED WITH ESSURE. I WASN'T INFORMED THE DEVICE CONTAINED NICKEL, NOR GIVEN ANY TYPE OF SENSITIVITY TEST FOR IT. THE FIRST ADVERSE EFFECT I NOTICED WAS THAT I WOULD SET OFF ANTI-THEFT DEVICES UPON ENTERING/EXITING STORES, WHICH WAS EMBARRASSING. I WAS TOLD BY MY IMPLANTING DOCTOR THAT MY PERIODS WOULD BECOME LIGHTER AS A RESULT. THEY DID NOT. I'VE HAD TO LEAVE WORK SEVERAL TIMES TO CHANGE CLOTHES BECAUSE THEY WERE SO HEAVY, SOMETHING I HADN'T HAD TO DO IN ABOUT 20 YEARS. I ALSO EXPERIENCE BLEEDING FROM MY URETHRA. MY SKIN IS EXTREMELY DRY, WHERE AS IT USED TO BE MORE OILY, RESULTING IN SOME SORT OF DERMATITIS OR ADULT ACNE, ALTHOUGH NOTHING MY DERMATOLOGIST PRESCRIBED ME SEEMED TO HELP. I HAVE DIGESTIVE ISSUES THAT SEEMED TO START AFTER I HAD ESSURE IMPLANTED, ALTHOUGH MY GASTROLOGIST CANNOT FIND THE EXACT CAUSE OF MY PROBLEMS. I EXPERIENCE PELVIC PAIN ON A DAILY BASIS AND HAVE HAD A FEW UTIS TOO. MY IRON, HEMOGLOBIN AND FERRITIN LEVELS HAVE BEEN SO LOW THAT I'VE HAD TO RECEIVE IV IRON INFUSIONS. I WAS THE YOUNGEST PERSON AT THE CANCER CENTER WHERE I RECEIVED THE IV IRON INFUSIONS AND WAS EVEN PRESCRIBED MORE THAN SOME PATIENTS RECEIVING CHEMOTHERAPY.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	3/12/2015	3/20/2015

Event Information:

Event Date (B3): 9/24/2014 **Report Date (B4): 3/12/2015** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): C91739

Single Use:
Implant Date (E6): 9/24/2014
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE WAS BEING USED ON THE RIGHT FALLOPIAN TUBE BY THE PHYSICIAN. THE DEVICE WOULD NOT MOVE FORWARD AND WAS BENDING UPON ATTEMPTS TO ADVANCE. A SMALL PIECE OF THE ALUMINUM FROM THE DEVICE BROKE OFF.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	3/12/2015	3/20/2015

Event Information:

Event Date (B3): 9/15/2014 **Report Date (B4): 3/12/2015** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): B27984

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE DID NOT RELEASE COIL INTO PATIENT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00184	BAYER HEALTHCARE LLC	3/12/2015	4/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5040083) IN UNITED STATES ON 13-FEB-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER STATES THAT, AT FIRST, SHE WAS FEELING FINE, THEN A FEW MONTHS AFTER ESSURE PLACEMENT, SHE DEVELOPED SEVERE PELVIC PAIN AND INFORMED THAT, AT TIMES, THE PAIN WOULD BE SO BAD SHE WOULD BE DOUBLED OVER AND THAT THE PAIN NOW IS 20 TIMES WORSE. IN 2014, CONSUMER HAD AN X-RAY, ULTRASOUND AND BLOOD WORK DONE. REPORTER STATED THAT THE DOCTOR TOLD HER THAT THE ESSURE IMPLANT EXPLODED IN HER TUBES AND THAT THERE WERE METAL FRAGMENTS EVERYWHERE INSIDE HER TUBES. CONSUMER'S DOCTOR RECOMMENDED SHE GET A HYSTERECTOMY. PTC INVESTIGATION RESULT RECEIVED ON 02-MAR-2015. (B)(4). FINAL ASSESSMENT: THIS IS NOT A CONFIRMED DEVICE BREAKAGE CASE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT

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INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT IMPLANT EXPLODED IN HER TUBES/ THERE WERE METAL FRAGMENTS EVERYWHERE INSIDE HER TUBES. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, IT WAS UNKNOWN WHEN ESSURE HAS BROKEN. HOWEVER, BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENT WAS ADDED: SEVERE PELVIC PAIN. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00186	BAYER HEALTHCARE LLC	3/13/2015	3/13/2015

Event Information:

Event Date (B3): 9/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97498

Single Use: Y
Implant Date (E6): 9/8/2014
Explant Date (E7): 9/9/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER B97498. IT WAS REPORTED THAT IT WAS UNABLE TO OBTAIN FULL PROCEDURE BECAUSE DEVICE BROKE AND PATIENT WAS TAKEN TO OR INSTEAD OF REPEAT. NO INJURY TO THE PATIENT. FOLLOW-UP RECEIVED ON 25-FEB-2015: INFORMATION RECEIVED STATES THAT THE ESSURE COIL BROKE IN HALF AFTER HEALTH CARE PROFESSIONAL DEPLOYED THE DEVICE AND TRIED TO WITHDRAW THE CATHETER. HALF CAME OUT WITH THE CATHETER AND HALF WAS STILL IN THE FALLOPIAN TUBE. PHYSICIAN THEN TOOK PATIENT TO OPERATION ROOM AND REMOVED THE HALF OF THE COIL WHICH WAS STILL IN THE FALLOPIAN TUBE. TUBAL LIGATION WAS PERFORMED. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. (B)(4). FINAL ASSESSMENT: EMAIL FROM SALES REP CONFIRMING THAT ONE ESSURE COIL BROKE IN HALF DURING PLACEMENT AND THE BROKEN COIL WAS REMOVED FROM THE PATIENT AND A TUBAL LIGATION WAS PERFORMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO

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COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND THE PHYSICIAN WAS UNABLE TO OBTAIN FULL PROCEDURE BECAUSE THE DEVICE BROKE IN A HALF AND INSTEAD OF REPEATING IT, THE PATIENT WAS TAKEN TO THE OPERATION ROOM, FOR ESSURE REMOVAL. THE DEVICE BREAKAGE IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, ESSURE COIL BROKE IN A HALF AFTER HEALTH CARE PROFESSIONAL DEPLOYED THE DEVICE AND TRIED TO WITHDRAW THE CATHETER. HALF CAME OUT WITH THE CATHETER AND HALF WAS STILL IN FALLOPIAN TUBE. PHYSICIAN THEN TOOK PATIENT TO OPERATION ROOM AND REMOVED THE PIECE OF THE COIL WHICH WAS STILL IN THE FALLOPIAN TUBE. CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE INSERTION AND GIVEN ITS NATURE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. SINCE ESSURE WAS REMOVED (INTERVENTION REQUIRED IMPLIED) THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

GENERAL ESSURE QUESTIONNAIRE RECEIVED ON 11-MAY-2015 FROM PHYSICIAN: THE PATIENT HAD NO PREVIOUS GYNECOLOGICAL INTERVENTIONS. THE ESSURE LOT NUMBER USED WAS B97498 WITH EXPIRATION DATE 31-DEC-2016. THE PATIENT WAS NOT POST-PARTUM STATE AT TIME OF THE INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00187	BAYER HEALTHCARE LLC	3/13/2015	3/13/2015

Event Information:

Event Date (B3): 2/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91747 / C22917

Single Use: Y
Implant Date (E6): 2/11/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE LOT NUMBERS USED WERE C91747 AND C22917. DURING THE PLACEMENT PROCEDURE, 2 DEVICES HAD BENT TIPS. THE PHYSICIAN USED A NEW ESSURE KIT AND BOTH SIDES WERE SUCCESSFULLY OCCLUDED. THE PATIENT WAS HOSPITALIZED FOR OBSERVATION DUE TO 1000ML PROCEDURAL FLUID DEFICIT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS HOSPITALIZED FOR OBSERVATION DUE TO 1000 ML OF FLUID DEFICIT DURING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PROCEDURE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE PLACEMENT PROCEDURE, THERE IS A RISK OF FLUID ABSORPTION DUE TO THE SOLUTION USED FOR DISTENTION OF THE UTERUS DURING HYSTEROSCOPY. THIS RISK IS INHERENT TO ANY HYSTEROSCOPIC PROCEDURE AND IS NOT UNIQUE TO ESSURE. TO REDUCE RISK OF HYPERVOLEMIA, HYSTEROSCOPY MUST BE TERMINATED IF DISTENSION FLUID DEFICIT EXCEEDS 1500CC OR HYSTEROSCOPIC TIME EXCEEDS 20 MINUTES. IN THIS PARTICULAR CASE, ALTHOUGH FLUID DEFICIT WAS 1000ML THE PATIENT WAS HOSPITALIZED FOR OBSERVATION. FURTHER INFORMATION ABOUT THE PROCEDURE AND PATIENT'S OUTCOME WILL BE REQUESTED; HOWEVER BASED ON THE AVAILABLE INFORMATION AND AS THE REPORTED EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE CAUSALITY CANNOT BE EXCLUDED AND DUE TO THE REPORTED HOSPITALIZATION THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 13-MAR-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). LOT NUMBER C91747 (PRODUCTION DATE 30-JUL-2014; EXPIRATION DATE 31-JUL-2017). LOT NUMBER C22917 (PRODUCTION DATE 12-FEB-2014; EXPIRAT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041523	BAYER	3/13/2015	3/20/2015

Event Information:

Event Date (B3): 11/13/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/13/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE IMPLANTS IN (B)(6) OF 2008. SINCE THEN, I HAVE EXPERIENCED MULTIPLE SYMPTOMS THAT I BELIEVE ARE TIED TO THE DEVICE. I HAVE GAINED AN INCREDIBLE AMOUNT OF WEIGHT. I CURRENTLY WEIGH (B)(6) LBS AND HAVE NEVER WEIGHED MORE THAN (B)(6) LBS, INCLUDING BEING FULL TERM PREGNANT. I HAVE HAD MOOD SWINGS, DEPRESSION WHICH LED TO HOSPITALIZATION, EXHAUSTION, HEADACHES AND CHRONIC BACK AND JOINT PAIN. THE BACK PAIN IS TO THE POINT THAT I HAVE SEEN A PAIN MANAGEMENT SPECIALIST AND HAD MULTIPLE PROCEDURES DONE, TO LITTLE AVAIL. IT IS TO THE POINT NOW THAT I CANNOT STAND FOR MORE THAN 5 MINUTES WITHOUT EXPERIENCING EXCRUCIATING BACK PAIN. I WOULD LIKE TO REPORT THIS AS I KNOW I AM NOT THE ONLY WOMAN WHO HAS EXPERIENCED SYMPTOMS LIKE THIS SINCE HAVING THE IMPLANTS DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041538	BAYER	3/15/2015	3/20/2015

Event Information:

Event Date (B3): 11/7/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/7/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PAIN IN BACK AND HIPS, NAUSEA, IRREGULAR BLEEDING. CRAMPS EVERY TWO WEEKS. THE PAIN HAS BEEN SO BAD I HAVE BEEN TO THE ER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00188	BAYER HEALTHCARE LLC	3/16/2015	3/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES SOCIAL MEDIA PLATFORM ON (B)(4) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4) AND EXPERIENCED BELLS PALSY. STUDY DESCRIPTION: (B)(6). NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED BELLS PALSY. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN BELLS PALSY AND ESSURE WAS NOT REPORTED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: CONSUMER REPORTED VIA SOCIAL MEDIA THAT ESSURE CAUSED HER A HYSTERECTOMY. NO FURTHER INFORMATION WAS PROVIDED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6)2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO

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COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. (B)(4). FOLLOW UP (B)(6) 2014: DESPITE FOLLOW UP ATTEMPTS, NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. FOLLOW UP ((B)(6) 2015: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. CONSUMER REPORTED THAT ESSURE CAUSED HER 3 SURGERIES AND 4 HOSPITAL STAYS. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED BELL'S PALSY AND ESSURE CAUSED HER A HYSTERECTOMY, 3 SURGERIES AND 4 HOSPITAL STAYS. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. BELL'S PALSY AND SURGERY ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE HYSTERECTOMY IS LISTED. BELL'S PALSY IS THE MOST COMMON CAUSE OF UNILATERAL FACIAL PARALYSIS AND APPEARS TO BE A POLYNEURITIS WITH POSSIBLE VIRAL, INFLAMMATORY, AND ISCHEMIC ETIOLOGIES. CONSIDERING THE NATURE OF BELL'S PALSY AND LOCAL ACTION OF ESSURE INSERT, CAUSALITY IS CONSIDERED UNLIKELY. REGARDING THE REMAINING EVENTS, ALTHOUGH LIMITED INFORMATION WAS PROVIDED AND NO REASON FOR HOSPITALIZATION WAS PROVIDED; IT CANNOT BE EXCLUDED THAT THE REPORTED SURGERIES AND HOSPITALIZATIONS OCCURRED AS A CONSEQUENCE OF ESSURE. THEREFORE THIS CASE, INITIALLY CONSIDERED A NON-INCIDENT, WAS REGARDED AS INCIDENT DUE TO THE REFERRED HOSPITALIZATION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00189	BAYER HEALTHCARE LLC	3/16/2015	4/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06520

Single Use: Y
Implant Date (E6): 1/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REIMBURSEMENT COUNSELOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE LOT NUMBER USED WAS C06520 (EXPIRATION DATE DEC-2016). CONSUMER REQUESTED AN ESSURE REPLACEMENT FOR 1 ESSURE COIL. IT WAS STATED THAT THE ESSURE COIL BROKE AND THE PHYSICIAN HAD TO USE A DIFFERENT ESSURE COIL TO COMPLETE THE INSERTION. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS.

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WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP 06-MAR-2015: FOLLOW UP INFORMATION RECEIVED FROM THE QUALITY DEPARTMENT IN THE MEDICAL CENTER. REPORTER STATED THAT THEY DID NOT KNOW IF THEY COULD GIVE OUT THE DOCTOR'S CONTACT INFORMATION BUT IT WOULD BE CONFIRMED. IN ADDITION, IT WAS REPORTED THAT WHEN THE DOCTOR WENT TO USE THE ESSURE COILS CAME LOOSE AND UNRAVELED AND THE INSERTER DEVICE SEEMED STRIPPED. THERE WERE SEVERAL COILS LEFT OUTSIDE OF THE FALLOPIAN TUBE. THE DOCTOR LEFT COILS REMAINING INSIDE THE PATIENT. ESSURE LOT NUMBER WAS C06520 AND THE SERIAL NUMBER WAS (B)(4) WITH EXPIRATION DATE ON 30-DEC-2016. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ESSURE COIL BROKE AND THE PHYSICIAN HAD TO USE A DIFFERENT ESSURE COIL TO COMPLETE THE INSERTION. THIS EVENT IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DEVICE HAS BROKEN DURING INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 24-JUN-2015: ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT WHO HAS NO PREVIOUS GYNECOLOGICAL INTERVENTION, PROBLEMS OR PROCEDURES, HAS AS MEDIC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00191	BAYER HEALTHCARE LLC	3/17/2015	3/17/2015

Event Information:

Event Date (B3): 1/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** AS

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/15/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014 FOR PERMANENT FEMALE CONTRACEPTION. ON (B)(6) 2015, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND FOUND THAT BOTH MICRO-INSERTS WERE ON THE RIGHT HAND SIDE. ONE WAS IN THE CORRECT POSITION. THE OTHER WAS THOUGHT TO HAVE MIGRATED FROM THE LEFT OSTIUM INTO THE ABDOMINAL CAVITY; INCORRECT PLACEMENT/PERFORATION WAS REPORTED. ACCORDING TO PHYSICIAN, PATIENT WAS INJURED AND WAS HOSPITALIZED. ESSURE PERFORATION QUESTIONNAIRE RECEIVED FROM THE PHYSICIAN ON 13-MAR-2015: PATIENT'S DATA WERE UPDATED, INCLUDING HER AGE, (B)(6). SHE HAD AS PREVIOUS HISTORY 2 PREGNANCIES (WITH 2 LIVE BIRTHS) AND NO PREVIOUS GYNECOLOGICAL INTERVENTIONS OR C-SECTIONS. ON (B)(6) 2015 ESSURE WAS EASILY INSERTED UNDER GENERAL ANESTHESIA, POST-CURETTAGE. PATIENT WAS NOT BREASTFEEDING AND NO ABNORMAL UTERINE FINDINGS WERE NOTED PRIOR TO INSERTION. CERVICAL DILATATION AND SOUNDING WERE PERFORMED. THE VISUALIZATION OF TUBAL OS WAS EASY. THE FLUID LOSS WAS NOT MORE THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. PATIENT HAD NO COMPLAINTS IMMEDIATELY AFTER INSERTION. ON (B)(6) 2015 UNILATERAL LEFT ESSURE PERFORATION WAS DIAGNOSED BY ULTRASOUND, X-RAY AND HSG (HYSTEROSALPINGOGRAM). THE PERFORATION WAS COMPLETE AND THE LEFT ESSURE WAS FOUND IN THE RIGHT SIDE PELVIS. NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS PERFORATED AND THE PERFORATION DID NOT OCCUR BEFORE DEPLOYMENT. THE RIGHT ESSURE WAS FOUND DISTAL POSITION AT FALLOPIAN TUBE. PATIENT DID NOT HAVE SYMPTOMS AND THE DIAGNOSES WERE MADE IN A ROUTINE CHECK-UP. THE PHYSICIAN ALSO REPORTED HSG ON (B)(6) 2015 CONFIRMED TUBAL OCCLUSION. ESSURE WILL BE REMOVED BY LAPAROSCOPY IN THE NEAR

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FUTURE AND THE PATIENT IS RECOVERING. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER CONTROL HSG (HYSTEROSALPINGOGRAM) SHOWED A LEFT SIDE PERFORATION: MICROINSERT HAD MIGRATED FROM THE LEFT OSTIUM INTO THE ABDOMINAL CAVITY AND THE RIGHT ESSURE WAS FOUND DISTAL IN TUBE (REGARDED AS DEVICE DISLOCATION). THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND HOSPITALIZATION AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). ADDITIONALLY, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALTHOUGH, IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF THE REPORTED EVENTS IS UNKNOWN, GIVEN THEIR NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, AS ALTHOUGH NOT SPECIFIED HOSPITALIZATION AND INJURY WERE MENTIONED BY REPORTING PHYSICIAN. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 18-MAR-2015 THE PATIENT HAS NOT BEEN HOSPITALIZED SINCE THE INSERTION. NO DATE HAS BEEN SCHEDULED FOR THE ESSURE REMOVAL PROCEDURE. IT WAS REPORTED THAT THE PATIENT IS RETURNING FOR A FOLLOW UP VISIT IN 2 WEEKS. NO FU

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041584	CONCEPTUS INC.	3/17/2015	3/25/2015

Event Information:

Event Date (B3): 3/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 686082

Single Use:
Implant Date (E6): 5/28/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE IMPLANT IN MY FALLOPIAN TUBES. IT HAS BEEN NEARLY 5 YEARS AND ALL THE SUDDEN I HAVE HAD MASSIVE PELVIC PAIN, NAUSEA, FATIGUE, FEVER ETC. I AM IN THE EMERGENCY ROOM AGAIN RIGHT NOW DUE TO THIS DEVICE EFFECTING MY BODY. I WAS NEVER TOLD IT WAS AN EXPERIMENTAL DEVICE WHEN IT WAS IMPLANTED. I HAVE LOST DAYS AT WORK AND LOST TIME WITH MY CHILD DUE TO ME BEING ILL. I AM NOT A HAPPY NOR HEALTHY CONSUMER THANKS TO THIS PRODUCT!

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00190	BAYER HEALTHCARE LLC	3/17/2015	4/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91770

Single Use: Y
Implant Date (E6): 2/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A NON-PREGNANT (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C91770 AND EXPIRATION DATE AUG-2017, INSERTION ON (B)(6) 2015 FOR PERMANENT STERILIZATION. PHYSICIAN REPORTED THAT ESSURE MICRO-INSERT BROKE DURING INSERTION. HEALTH CARE PROFESSIONAL WAS ABLE TO RETRIEVE IT AND STATED THAT HAD BROKEN INSERT, IN A CONTAINER, FOR RETURN. IN ADDITION, IT WAS REPORTED THAT THEY WERE ABLE TO INSERT ONLY ONE ESSURE COIL. THE OTHER BROKE. PATIENT STILL HAS ESSURE INSERTED UNILATERALLY. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT (B)(4) 2015: LEFT MESSAGE WITH DOCTOR OFFICE TO OBTAIN FURTHER INFORMATION. (B)(4) 2015: CALLED DOCTOR OFFICE AND NURSE NOT AVAILABLE TO ANSWER QUESTIONS, LEFT MESSAGE TO CALL BACK ONCE AGAIN. (B)(4) 2015: NO RESPONSES RECEIVED BACK TO CONFIRM DEVICE BREAKAGE. IT IS NOT CLEAR FROM THE REPORTER AS TO WHAT BROKE DURING THE INSERTION. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C91770 (PRODUCTION DATE 05-AUG-2014 AND EXPIRATION DATE 31-AUG-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A

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USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ESSURE MICRO-INSERT BROKE DURING INSERTION. THIS EVENT IS NON-SERIOUS AND LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DEVICE HAS BROKEN DURING INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENT WAS ADDED: BILATERAL PLACEMENT NOT ACHIEVED. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00193	BAYER HEALTHCARE LLC	3/18/2015	3/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 17-FEB-2015 WHICH REFERS TO AN ADULT (30'S) FEMALE PATIENT WHO WAS INVOLVED IN AN ESSURE® GENERIC MARKET RESEARCH PROGRAM, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION RECEIVED ON 17-FEB-2015. PHYSICIAN REPORTED THAT A PATIENT, WHO HAD ESSURE INSERTED FOR STERILIZATION, HAD A PERFORATION DURING INSERTION. ON UNSPECIFIED DATE, ESSURE WAS REMOVED VIA A LAPAROSCOPY PROCEDURE DUE TO PAIN. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD A PERFORATION DURING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICE WAS REMOVED VIA A

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LAPAROSCOPY PROCEDURE DUE TO PAIN. THE REPORTED EVENTS, INTERPRETED AS UTERINE PERFORATION AND PELVIC PAIN, WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE); IF A PERFORATION OCCURS PATIENT MAY EXPERIENCE PAIN OR DISCOMFORT. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED IN THIS CASE. DUE TO THE REQUIRED INTERVENTION, THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 18-JUN-2015: CASE CONSIDERED CLOSED. FOLLOW UP INFORMATION RECEIVED ON 06-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00195	BAYER HEALTHCARE LLC	3/18/2015	3/18/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 20-FEB-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. ACCORDING TO THE REPORTER, INSERTION WAS COMPLETELY NORMAL BUT AFTER DAY OR TWO THE PATIENT TOOK A CONTACT BECAUSE SHE HAD PAIN. SHE WAS GIVEN A SICK LEAVE. ON AN UNSPECIFIED DATE, THE PATIENT WENT TO HOSPITAL DUE TO PAIN AND WAS DECIDED TO REMOVE TUBES BY LAPAROSCOPY. DURING OPERATION, IT WAS NOTICED THAT IMPLANTS WERE CORRECTLY IN SITU. THE REPORTER'S OPINION WAS THAT REMOVAL OF TUBES WAS UNNECESSARY AND THAT THE PATIENT'S SYMPTOM WAS CAUSED BY SOMETHING ELSE THAN ESSURE IMPLANTS. INTERNAL COMMUNICATION ON 24-FEB-2015: FOLLOW-UP WITH REPORTER IS NOT POSSIBLE. (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN (B)(6). IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 27-FEB-2015 FOR THE FOLLOWING (B)(6) PREFERRED TERM: PELVIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 299 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO EXPERIENCED PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A LAPAROSCOPIC BILATERAL SALPINGECTOMY. THE REPORTED PAIN, REGARDED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, ALTHOUGH THE REPORTER REGARDED THE EVENT AS UNRELATED TO THE SUSPECT INSERT, GIVEN ITS CLOSE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION, COMPANY CONSIDERS CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). FOLLOW-UP INFORMATION IS NOT POSSIBLE. CASE CLOSED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00196	BAYER HEALTHCARE LLC	3/18/2015	3/18/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 5/30/2014
Explant Date (E7): 8/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA REGULATORY AUTHORITY (CASE# MW5038307) IN UNITED STATES ON 18-FEB-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. IT WAS REPORTED THAT ESSURE WAS PLACED IN A POSTPARTUM STATE (UNEVENTFUL) AND IN (B)(6) 2014, PATIENT DEVELOPED POLYARTHRALGIA. SHE HAD NO NICKEL ALLERGY AND RHEUMATOLOGY CONSULT WAS NEGATIVE. ON (B)(6) 2014 (REPORTED AS 2011 BY PHYSICIAN IN THE NARRATIVE), ESSURE WAS REMOVED AND PATIENT IMPROVED. AN INJURY (SERIOUS IMPORTANT MEDICAL EVENTS) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO THE EVENT. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 26-FEB-2015, WITH PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. "POLYARTHRALGIA", AS REPORTED BY THE ANONYMOUS PHYSICIAN IS NOT A KNOWN FAILURE MODE RELATED TO ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION, NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY

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DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED POLYARTHRALGIA, WHICH IMPROVED AFTER ESSURE REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ALTHOUGH ESSURE HAS A LOCAL ACTION AT FALLOPIAN TUBES AND ARTHRALGIA IS NOT AN EXPECTED ADVERSE EVENT FOR THIS DEVICE; SINCE PATIENT RECOVERED FROM POLYARTHRALGIA AFTER ESSURE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED; AND THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FOLLOW-UP WILL BE PURSUED SINCE NO CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00197	BAYER HEALTHCARE LLC	3/18/2015	3/18/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 4/5/2013
Explant Date (E7): 7/29/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 18-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. ACCORDING TO THE CONSUMER, SINCE INSERTION, SHE HAD HORRIBLE PERIODS AND SHARP STABBING PAIN ON HER LEFT SIDE. SHE ALSO HAD VERY BAD ACNE THAT SHE NEVER HAD HER WHOLE LIFE; SHE GAINED WEIGHT, HAD VERY BAD MOOD SWINGS AND VERY BAD ANXIETY AND HAD VAGINAL SMELL. ON (B)(6) 2014, ESSURE WAS REMOVED AND SHE COULD FEEL A BIG DIFFERENCE ON THE SAME DAY. AN INJURY (OTHER SERIOUS IMPORTANT MEDICAL EVENTS) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP RECEIVED ON 26-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4)AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE

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GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP STABBING PAIN ON LEFT SIDE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE CONSUMER EXPERIENCED THIS EVENT AN UNKNOWN TIME AFTER ESSURE INSERTION. AN ALTERNATE EXPLANATION IS NOT AVAILABLE. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE WAS REMOVED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00198	BAYER HEALTHCARE LLC	3/18/2015	3/18/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50512932

Single Use: Y
Implant Date (E6): 10/30/2011
Explant Date (E7): 9/3/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038337) IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 WITH LOT NUMBER 50512932. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: ZOLOFT (SERTRALINE) 25MG, ONCE A DAY. ON (B)(6) 2014 THE CONSUMER STARTED EXPERIENCING SEVERE PELVIC PAIN AND BLEEDING. ON (B)(6) 2014 ESSURE WAS REMOVED. AN INJURY (HOSPITALIZATION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP WILL BE REQUESTED. FOLLOW UP INFORMATION RECEIVED ON 26-FEB-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT

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A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY), REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PELVIC PAIN AND BLEEDING (GENITAL BLEEDING). THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR. IN THIS CASE, THE CONSUMER STARTED TO EXPERIENCE THE EVENTS THREE YEARS AFTER THE INSERTION AND EIGHT MONTHS LATER, ESSURE WAS REMOVED. GIVEN POSITIVE TEMPORAL RELATIONSHIP AND THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. IT WAS INFORMED THAT ESSURE WAS REMOVED (INTERVENTION REQUIRED WAS IMPLIED) SO THE CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 17-JUN-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT (RECEIVED VIA REG

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00194	BAYER HEALTHCARE LLC	3/18/2015	4/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627742

Single Use: Y
Implant Date (E6): 11/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RASH WAS AN ALLERGIC REACTION TO SOMETHING, PERIODS WERE MESSED-UP, IT WAS EITHER TOO EARLY OR TOO LATE, CHRONIC PAIN IN HER PELVIS, PAIN IN HER JOINTS, STOMACH PAIN. WHEN SHE COUGHS OR SNEEZES, SHE HAS A GRABBING PAIN ON THE RIGHT SIDE WHERE HER FALLOPIAN TUBE WOULD BE, INSOMNIA, WEIGHT GAIN, AND FEELING NOT LIKE HERSELF, JUST A BAD FEELING. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015 FROM CONSUMER: SHE STATED THAT WAS HAVING A TOTAL ABDOMINAL HYSTERECTOMY (DATE NOT PROVIDED) DUE TO BOTH COILS BREAKING AND MIGRATING. SHE WAS STILL PRESENTING A RASH THAT WAS WORSE IN HOT WEATHER. THE PATCH TESTING DID NOT SHOW WHAT SHE WAS ALLERGIC TO BUT IT MAY BE THE PET POLYESTER FIBERS ON THE COILS WHICH IS SIMILAR TO ANTIFREEZE OR NICKEL. THESE FIBERS LEACH INTO THE BODY. NO FURTHER INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. (B)(4). FINAL ASSESSMENT: LOT NUMBER: 627742; EXPIRATION DATE: JUL-2010; PRODUCTION DATE: JUL-2008. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW

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FAILURE MODE HAS BEEN IDENTIFIED. DEVICE BREAKAGE COULD NOT BE CONFIRMED IN THIS PATIENT REPORT CASE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THREE FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH ONE CASE REFERS ALSO TO SIMILAR ADVERSE TYPES OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BOTH COILS BROKE AND MIGRATED. BOTH COILS BROKE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE BOTH COILS MIGRATED IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT ANALYSIS, THIS BREAKAGE IS LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE EXACT DATE AND MECHANISM OF MIGRATION WERE NOT KNOWN. IT WAS ALSO UNKNOWN WHEN BOTH COILS BROKEN. IT WAS REPORTED THAT A TOTAL ABDOMINAL HYSTERECTOMY WILL BE PERFORMED. GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PTC ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCL

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00192	BAYER HEALTHCARE LLC	3/18/2015	4/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SW

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12701

Single Use: Y
Implant Date (E6): 1/29/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C12701, INSERTION ON (B)(6)2015. PHYSICIAN REPORTED THAT, DURING THE PLACEMENT PROCEDURE, WHEN PULLING BACK THE INTRODUCER IT GOT STUCK AND WAS BROKEN. EVERYTHING HAD TO BE TAKEN OUT. THE PATIENT HAD NO INJURIES AND BILATERAL PLACEMENT WAS ACHIEVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 10-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: AS OF FEBRUARY 19, NO PRODUCT HAS RETURNED TO US FOR INVESTIGATION SO WE ARE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT AT THIS TIME. IF THE COMPLAINED DEVICE IS RETURNED IN THE FUTURE, A CHILD COMPLAINT WILL BE OPENED TO DOCUMENT THE RECEIPT AND INVESTIGATION OF THE RETURNED DEVICE. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT C12701 (PRODUCTION DATE 08-JAN-2014 AND EXPIRATION DATE 31-JAN-2017) WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT OR A CATHETER BREAKAGE DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH

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WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 12-MAR-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 955 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE, WHEN PULLING BACK THE INTRODUCER IT GOT STUCK AND WAS BROKEN. THE DEVICE WAS REMOVED. PATIENT HAD NO INJURY. THE REPORTED EVENTS, INTERPRETED AS COMPLICATION OF DEVICE INSERTION AND DEVICE BREAKAGE WERE CONSIDERED NON-SERIOUS. DEVICE BREAKAGE WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. THE OTHER EVENT IS LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED TO FURTHER EVALUATE THE EVENTS; NEVERTHELESS SINCE THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00200	BAYER HEALTHCARE LLC	3/19/2015	3/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA SOCIAL MEDIA IN (B)(6) ON (B)(6) 2015. SHE WAS INVOLVED (B)(6). CONSUMER REPORTED SHE RECENTLY HAD THE ESSURE PROCEDURE AND THEY HAD TO PUSH THE LEFT COIL IN FURTHER. AFTER AN INFECTION AND TAKING 3 LOTS OF ANTIBIOTICS SHE IS STILL IN PAIN; SHE IS ON TRAMADOL AND PARACETAMOL WHICH ONLY DULLS THE PAIN. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN (B)(4). IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA

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STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: PELVIC INFECTION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 5 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED AN INFECTION; SHE WAS TAKING 3 LOTS OF ANTIBIOTICS. THE REPORTED EVENT, INTERPRETED AS PELVIC INFECTION, WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ESSURE MICRO-INSERTS ARE SUPPLIED STERILE AND PLACED UNDER HYSTEROSCOPIC GUIDANCE IN THE PROXIMAL FALLOPIAN TUBE. HOWEVER, AS WITH ALL TRANS-CERVICAL PROCEDURES, THIS MICRO-INSERT PLACEMENT CAN CAUSE PELVIC INFECTION DUE TO BACTERIAL CONTAMINATION DURING INSERTION. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; HOWEVER, AS CONSUMER STATED ESSURE INSERTION WAS RECENT, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED PELVIC INFECTION AND ESSURE PROCEDURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN INCIDENT SINCE A MEDICAL INTERVENTION (ANTIBIOTIC THERAPY) WAS REQUIRED AS EVENT'S TREATMENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION WILL BE REQUESTED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00201	BAYER HEALTHCARE LLC	3/19/2015	3/19/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/21/2010
Explant Date (E7): 3/25/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038352) IN UNITED STATES ON 18-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. THE CONSUMER STATED THAT SHE WAS NOT AWARE OF NICKEL IN PRODUCT BEFORE OR AT THE TIME OF INSERTION. A FEW MONTHS AFTER PLACEMENT, SHE STARTED HAVING BAD CRAMPS WITH PERIODS AND SHE WAS BLEEDING FOR WEEKS AT A TIME. SHE ALSO HAD OVARIAN CYSTS FROM THIS AND ON (B)(6) 2013 SHE HAD A HYSTERECTOMY TO REMOVE ESSURE. AN INJURY (REQUIRED INTERVENTION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP WILL BE REQUESTED. FOLLOW-UP RECEIVED ON 26-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: THIS IS NOT A CONFIRMED REPORT FROM A PATIENT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. CYSTS ARE NOT A KNOWN FAILURE MODE RELATED TO ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT

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THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING FOR WEEKS AT A TIME. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE REPORTED EVENT CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION TO REMOVE ESSURE (HYSTERECTOMY). A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00204	BAYER HEALTHCARE LLC	3/19/2015	3/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT WHEN SHE HAD HER ESSURE COILS IN, SHE FELT LIKE SHE HAD THE FLU CONSTANTLY. SHE WAS (B)(6), AND HER YOUNGEST SON WAS JUST (B)(6). CONSUMER INFORMED THAT SHE WAS GOING THROUGH ALL THESE HEALTH PROBLEMS AND HAD TO HAVE A TOTAL HYSTERECTOMY TO REMOVE THE COILS. HOWEVER, ACCORDING TO REPORTER, THE RECOVERY PROCESS DID NOT END WITH THE REMOVAL AND STATED THAT SHE WAS MAD. NO FOLLOW-UP IS POSSIBLE. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2015. NO NEW CLINICAL INFORMATION PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE A TOTAL HYSTERECTOMY TO REMOVE THE COILS. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED REGARDING THE REASON FOR THE PROCEDURE. HOWEVER, AS THE PROCEDURE WAS PERFORMED DUE TO ESSURE PROBLEMS, COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: FELT LIKE SHE HAD THE FLU CONSTANTLY AND HEALTH PROBLEMS. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT (LACK OF COMPLAINT SAMPLE AND ANY VALID BATCH INFORMATION). NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00202	BAYER HEALTHCARE LLC	3/19/2015	4/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/19/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH PROFESSIONAL IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR CONTRACEPTION. IT WAS REPORTED THAT ESSURE BROKE OFF; WHEN PHYSICIAN DID THE REMOVAL OF THE INSERTER IT WAS STUCK AND THE COIL STRETCHED OUT; THERE WAS A PIECE TO THE SIDE AND THREE COILS WAS IN CORNUA. PHYSICIAN DID INITIAL ROLL BACK, THEN HIT BUTTON, BUT MAY HAVE PULLED BACK SLIGHTLY BEFORE ANOTHER ROLL BACK. PHYSICIAN WAS ABLE TO IDENTIFY THE GOLD BAND AT THE END OF THE STRETCHED INNER CATHETER. FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE / MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND

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ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER AND/OR MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. FINAL RISK CLASSIFICATION RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE AND A USABILITY ISSUE, ALSO A DEVICE USE ERROR WAS REPORTED. IN THIS PARTICULAR CASE, DEVICE BREAKAGE IN THE CONTEXT OF A COMPLICATED INSERTION WAS REPORTED. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WAS CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PLACEMENT PROCEDURE, THE INSERTER WAS STUCK, THEN THE INNER CATHETER OF THE INSERTER STRETCHED OUT / COIL STRETCHED OUT. THE PHYSICIAN MAY HAVE PULLED BACK SLIGHTLY BEFORE ANOTHER ROLL BACK AND THE INSERT BROKE OFF AND THREE COILS REMAINED IN CORNUA. THESE EVENTS, SEEN AS COMPLICATION OF DEVICE INSERTION, DEVICE USE ERROR AND DEVICE DEPLOYMENT ISSUE RESPECTIVELY, ARE NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE IS NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THIS CASE, THE PHYSICIAN HAD PROBLEMS RELEASING THE MICRO-INSERT, THE INSERTER CATHETER AND THE ESSURE COILS WERE STRETCHED OUT AND THEN BROKE WITH THREE COILS REMAINING IN CORNUA. SINCE BREAKAGE WAS REPORTED AND IT OCCURRED ASSOCIATED TO INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER FOLLOW UP CAN BE PURSUED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00199	BAYER HEALTHCARE LLC	3/19/2015	4/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): C68120

Single Use: Y
Implant Date (E6): 2/9/2015
Explant Date (E7): 2/9/2015
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/25/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE LOT NUMBER USED WAS C68120. DURING ESSURE PLACEMENT PROCEDURE, IN THE OPERATING ROOM, THE PHYSICIAN HAD A PLACEMENT WITH NO DIFFICULTY OF THE ESSURE MATERIAL IN LEFT ORIFICE. ON REMOVAL OF THE DELIVERY CATHETER, PERSISTENCE OF THE METALLIC DISTAL TIP OF THE EXTREMITY OF THE DELIVERY CATHETER OCCURRED. THE REMOVAL WAS EASY WITH PLIERS. THE PATIENT HAD PLACEMENT OF ANOTHER IMPLANT. NO CLINICAL CONSEQUENCE WAS OBSERVED, EXCEPT THE USE OF ANOTHER IMPLANT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE

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INVOLVED IN THIS COMPLAINT. IF PRODUCT IS RECEIVED BACK AT A FUTURE DATE, A CHILD COMPLAINT WILL BE OPENED TO DOCUMENT THE DEVICE INVESTIGATION. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT C68120 (PRODUCTION DATE 19-JUN-2014 AND EXPIRATION DATE 30-JUN-2017) WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015. PATIENT´S DATE OF BIRTH WAS UPDATED (SHE WAS (B)(6) YEARS OLD). IT WAS REPORTED THAT ON (B)(6) 2014 SHE HAD AN ABORTION BY SUCTION ON GENERAL ANESTHESIA FOLLOWING PREGNANCY ON IUD. ON (B)(6) 2015, ESSURE WAS PLACED BY HYSTEROSCOPY. PREHENSION OF THE CERVIX BY A MUSEUX PLYER WAS DONE. HYSTEROSCOPE WAS INTRODUCED AND OSTIAS WERE VISUALIZED. PLACEMENT OF ONE ESSURE. ON THE LEFT, NUMBER OF COILS VISIBLE IN THE UTERINE CAVITY WAS 1 AND THEN ON THE RIGHT, NUMBER OF COILS VISIBLE IN THE UTERINE CAVITY WAS 1 TOO. PROCEDURE WAS DONE WITH NO SPECIFIC DIFFICULTY. TEMPORARY TECHNICAL PROBLEM OCCURRED WITH MATERIAL WHICH WAS REMOVED WITHOUT DIFFICULTY (RUPTURE OF THE EXTREMITY). THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IT INCLUDES RECENT CASES RECEIVED BY BAYER PHARMA AND OLDER CASES RECEIVED FROM THE PREVIOUS OWNER OF THE ESSURE PRODUCT (CONCEPTUS). THESE LEGACY REPORTS HAVE BEEN RE-CODED ACCORDING TO BAYER PHARMA STANDARDS. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 960 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. THIS INCLUDES CONSIDERATION OF THE LEGACY CASES IN SAFETY ANALYSES. THE CUMULATIVE REVIEW OF THE REPORTS HAS NOT YIELDED ANY NEW SAFETY SIGNAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ON REMOVAL OF THE DELIVERY CATHETER, PERSISTENCE OF THE METALLIC DISTAL TIP (RUPTURE OF EXTREMITY) WAS NOTED. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THE BREAKAGE DURING INSERTION IS UNLISTED. HOWEVER, ACCORDING TO PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS, THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED WITH ESSURE. IN THE PRESENT CASE, THE BREAKAGE OCCURRED DURING INSERTION PROCEDURE; THEREFORE, CAUSALITY WITH ESSURE IS ASSESSED AS RELATED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PTC ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON 02-APR-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFOR

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00203	BAYER HEALTHCARE LLC	3/19/2015	4/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71763

Single Use: Y
Implant Date (E6): 11/4/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 19-FEB-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B71763, INSERTED ON (B)(6) 2014. PHYSICIAN REPORTED THAT HYSTEROSALPINGOGRAM PERFORMED ON (B)(6) 2015 SHOWED THE TUBES ARE CLOSED ON BOTH SIDES. HOWEVER, THE DEVICE ON LEFT SIDE LOOKS BROKEN DOWN IN TWO PIECES; IT CONSISTS OF TWO SEPARATE COMPONENTS, ONE IS MORE PROXIMAL THAN THE OTHER, THE OTHER IS DISTAL TO THE END OF THE TUBE. ACCORDING TO REPORTER, THE RIGHT SIDE IS COMPLETELY OCCLUDED AND IS IN THE RIGHT IN POSITION. HEALTH CARE PROFESSIONAL ALSO INFORMED THAT, WHEN DID THE ULTRASOUND, WITH THE CONTRAST MATERIAL, THE RIGHT, THAT WAS NORMAL, WAS OCCLUDED (IT IS IN THE PROXIMAL POSITION OF THE JUNCTION OF THE CORNUA). ON THE LEFT, THERE WAS NO FILLING BUT IT SEEMS OCCLUDED. THE SMALLER FRAGMENT WAS A LITTLE MORE PERIPHERAL AND LOOKS LIKE DISRUPTION OF THE COIL. ESSURE DEVICES WERE NOT REMOVED AND PHYSICIAN WONDERS WHETHER PATIENT IS PROTECTED OR ANY FURTHER STUDY SHOULD BE DONE. HEALTH CARE PROFESSIONAL ALLOWED FURTHER CONTACT. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: 2.28.2015: THE MLS SPOKE TO THE PHYSICIAN ON 2.24.2015 AND THERE IS NO CONFIRMED ESSURE DEVICE BREAKAGE AND HOW THE FILMS WERE BEING INTERPRETED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT B71763 (PRODUCTION DATE 11-SEP-2013 AND EXPIRATION DATE 30-SEP-

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2016) WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 5 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, BUT NONE OF THE CASES REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE HYSTEROSALPINGOGRAM (HSG) PERFORMED 3 MONTHS AFTER INSERTION SHOWED ONE OF THE DEVICES LOOKS BROKEN DOWN IN TWO PIECES WHICH IS THE LEFT SIDE. THIS EVENT IS NON-SERIOUS AND LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). ADDITIONALLY, THE HSG SHOWED THE SMALLER FRAGMENT IS A LITTLE MORE PERIPHERAL, IT LOOKS LIKE DISRUPTION OF THE COIL / THE OTHER IS DISTAL TO THE END OF THE TUBE. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). THEREFORE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENTS, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 17-JUN-2015. FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041556	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 1/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWO PERIODS A MONTH SINCE THE BEGINNING OF THE YEAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041558	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 2/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041558 #(B)(4). WILL BE HAVING A HYSTERECTOMY ON (B)(6) 2015 TO REMOVE MY UTERUS, FALLOPIAN TUBES, AND MY CERVIX BECAUSE OF ESSURE. I'M ONLY (B)(6), I SHOULDN'T HAVE TO HAVE THIS SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041559	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 7/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS IMPLANTED ON (B)(6) 2014. I CALLED THE CLINIC THAT EVERY DAY TO REPORT THE SEVERE BLOATING - I WAS THE SIZE OF A 9 MONTH PREGNANT FEMALE. THEY SAID THIS SHOULD BE NORMAL. A WEEK LATER, I STILL HAD THE SEVERE BLOATING AND EXTREME FATIGUE SO I WENT IN. I WAS TOLD IT COULDN'T BE THE ESSURE, THAT IT MUST BE A GI ISSUE AND THAT MY ONLY ALTERNATIVE WAS A HYSTERECTOMY. OVER THE NEXT 7 MONTHS, I GAINED 25 POUNDS AND HAD FATIGUE, BLOATING, PAIN, HOT FLASHES; I WAS SENT TO 3 DIFFERENT GI DOCTORS, HAD 3 ULTRASOUNDS AND A CAT, FOUND ENLARGED SPLEEN AND RIGHT OVARY AND NODULES ON MY LUNGS, SENT TO A PULMONOLOGIST AND A HEMATOLOGIST, RECEIVED AN IRON TRANSFUSION, HAD AN ENDOSCOPY AND COLONOSCOPY, HAD A 2ND ENDOSCOPY TO CUT OUT AND CAUTERIZE 2 POLYPS FOUND IN MY STOMACH, SAW AN ENDOCRINOLOGIST WHERE IT WAS CONFIRMED I WAS NOT PERIMENOPAUSAL, DID NOT HAVE AN AUTOIMMUNE DISEASE, DID NOT HAVE CELIACS DISEASE, THYROID WAS FINE, DID NOT HAVE CORITSOL ISSUES. SAW IN INTERNIST TO HELP ME BRING ALL OF THESE TESTS AND RESULTS TOGETHER AND UNDERSTAND WHY THEY WERE NOT FINDING ANYTHING WHEN SOMETHING WAS CLEARLY WRONG WITH MY HEALTH. SHE SAID IT LOOKED FINE AND RECOMMENDED I CHANGE SOME OF MY MEDICATIONS. I DID THIS WITH NO RESULTS. I FINALLY HAD A CONSULTATION WITH A GYNECOLOGIST YESTERDAY, (B)(6) 2015 THAT BELIEVES ME AND IS GOING TO REMOVE THE ESSURE, ALONG WITH MY TUBES, ON (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041560	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 10/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONSET OF MIGRAINE HEADACHES, CRAMPING AND SEVERE PAIN AND BLEEDING DURING MENSTRUATING. FEELING OF VIBRATIONS IN PUBIC REGION. METALLIC TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041561	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) SEVERE BLOATING!!! I LOOK 9 MONTHS PREGNANT ALL THE TIME! SWOLLEN LEGS, MY BODY BASICALLY THOUGHT IT WAS PREGNANT AGAIN - AND I AM NOT! EHELL REMOVED AND TUBES REMOVED (AFTER ONLY IN FOR 3 MONTHS!) AND AT 1 WEEK POST SURGERY NO AB PAIN, NO UTERUS PAIN, NO STOMACH ACHES, NO HEADACHES OR BRAIN FOG, I HAVE LOST WEIGHT, NO SWELLING, NO CRAMPING EXCEPT AT SURGICAL SITE. ENERGY IS COMING BACK AND PRAYING THIS BELLY GOES AWAY AND MY HAIR STARTS GROWING AGAIN. THIS PRODUCT NEEDS REMOVED FROM THE MARKET IMMEDIATELY!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041562	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 5/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT ABDOMINAL CRAMPING, EXCESSIVE BLEEDING WITH MENSTRUAL CYCLE, PROBLEMS SLEEPING, HAIR LOSS, ACHY PAIN IN LEGS AND HIPS. SHARP STABBING PAIN WITH INTERCOURSE, UNABLE TO ORGASM, LOSS OF LIBIDO, UTERINE FIBROID S, BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041563	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 11/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STAY ON A DEPRESSING MODE, MY MOODS ARE DIFFERENT. I'VE BEEN GETTING THESE AWFUL HEADACHES, BLURRED VISION, AND MY PERIODS AINT REGULATED, I'LL EVEN SKIP A MONTH NOW. I STAY BLOATED, AND ON TOP OF THAT I EAT VERY HEALTHY AND SEEMS INSTEAD I'VE GAINED A LOT OF WEIGHT SINCE HAVING THIS PROCEDURE DONE IN (B)(6) OF 2013! I'VE HAD SO MANY ISSUES WHICH INCLUDES HOSPITAL VISIT BECAUSE MY BLOOD PRESSURE STAYING UP AND HAVING THESE BENT OVER PELVIC PAINS AND OVARY PAINS. MY LEFT SIDE RIGHT NOW YOU CAN'T TOUCH IT! I'M CURRENTLY IN THE PROCESS OF GETTING THIS AWFUL FOREIGN OBJECT REMOVED LIKE ANY OTHER STUPID FOREIGN BIRTH CONTROL OBJECT! I'M SICK OF THESE SUPPOSE TO BE SAFE OF PREGNANCY PREVENTION PRODUCTS BECAUSE I'VE DONE HAD SEVERAL FRIENDS BECOME PREGNANT! AND IT SEEMS TO ME THIS PRODUCT AIN'T SAFE BECAUSE I WILL HAVE MIX SINGLES MY BODY IS PREGNANT AND I HAVE TO GO TO THE HOSPITAL BECAUSE I'M BLEEDING WEIRD OR IN EXTREME PAIN! THIS PRODUCT NEEDS TO BE TOOK OFF OF THE SHELF NOW! I'M TIRED OF GOING TO THE HOSPITAL WITH THESE PAINS AND HAVING MENSTRUAL CYCLE ISSUES AND PAIN MEDICINE JUST AIN'T CUTTING IT. THERE'S DAYS I CAN'T MOVE BECAUSE I'M HURTING! IT'S LIKE SOMEONE TAKING A KNIFE CUTTING ME OR STABBING ME! AND NOW MY RIGHT OVARY IS IN THE CENTER OF MY UTERUS PRONOUNCE BY THE DOCTOR ON THE VAGINAL ULTRASOUND! I ADVISE YOU GET THIS UNSAFE PRODUCT OFF THE SHELF PUTTING MYSELF AND OTHERS AT RISK !

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041564	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 9/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED IN (B)(6) 2014. THINGS WERE GOING WELL OR SO I THOUGHT. IN THE MIDDLE OF (B)(6) 2014, I STARTED GETTING SEVERE CRAMPS WITH MY PERIOD. UP UNTIL THIS POINT, I VERY RARELY HAD CRAMPS IN THE 23 YRS I'VE BEEN MENSTRUATING. FROM THAT POINT ON, IT'S BEEN DOWN HILL FOR ME. I NOW HAVE SEVERE CRAMPS ALMOST DAILY, I HAVE ISSUES WITH MY BOWELS, I HAVE ALWAYS BEEN "REGULAR". NOW I GO FROM HAVING THE DIARRHEA TO BEING CONSTIPATED BACK TO THE DIARRHEA AND SO ON. I FEEL BLOATED ALMOST DAILY. THE BLOAT IS SO BAD THAT I LOOK PREGNANT AT TIMES. THERE ALWAYS SEEMS TO PRESSURE IN MY PELVIC REGION. I AM NAUSEOUS ON A PRETTY REGULAR BASIS AND OFTEN HAVE PROBLEMS EATING BECAUSE OF IT. I HAVE BEEN HAVING A TINGLING SENSATIONS IN MY HANDS AND FEET. MY FEET AND HANDS HAVE ALSO BEEN GETTING SO COLD TO THE POINT THAT I NEED A HEATING PAD. MY ANXIETY HAS WORSENED TENFOLD AND I NOW HAVE SEVERE MOOD SWINGS. DEPRESSION. INSOMNIA, ISSUES WITH MY BLOOD SUGAR, SEVERE LOWER BACK PAIN, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041565	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 10/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABNORMAL CYCLES, BLEEDING MORE DAYS THAN NOT. PAIN DURING AND AFTER SEXUALLY INTERCOURSE. PELVIC PAIN, PINCHING, ALMOST LIKE BARB WIRE ON THE INSIDE. CHRONIC FATIGUE. EXCRUCIATING CRAMPS EVEN WITH AND WITHOUT THE CYCLE. SORENESS OF THE BREAST. NUMBNESS IN THE LEGS. HAIR LOSS. WEIGHT GAIN. DEPRESSION. FOGGED MEMORY. NICKEL ALLERGY!!!!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041566	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 3/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, BLOATING, PELVIC PAIN, JOINT PAIN, BACK PAIN, CRAMPING, BRAIN FOG, CHRONIC FATIGUE, HOT FLASHES, SHARP PAIN IN LOWER ABDOMINAL AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041567	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 3/12/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). XRAY SHOWED COIL WAS NOT IN PLACE PROPERLY AND I HAVE MIGRAINES, SEVERE HEAVY PERIODS WITH LARGE CLOTS, ANEMIA, CHRONIC FATIGUE, AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041568	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 3/12/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING CHRONIC UTIS OVER THE COURSE OF TWO MONTHS WHEN PREVIOUSLY, I HAD THEM INFREQUENTLY

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041569	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 8/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN! OVARY PAIN OVULATION PAIN. CONSTANT ILLNESSES. INFECTIONS. MIGRAINES. TIRED. NAUSEOUS. "AKNEY". PAIN!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041570	BAYER	3/20/2015	3/20/2015

Event Information:

Event Date (B3): 7/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS ADMITTED TO HOSPITAL DUE TO A UNEXPLAINED ATTACK THEY LABELED AS DIVERTICULITIS. NEVER HAD ANYTHING LIKE THAT BEFORE OR SINCE. AFTER THAT THE ABNORMAL PAP TEST STARTED. PRECANCEROUS CELLS, PCOS. I'VE HAD ABDOMINAL SWELLING AND PAIN FOR YEARS. UNEXPLAINED RASHES, ITCHING ON SKIN EVEN WHEN RASH ISN'T PRESENT. CONSTANT SPOTTING. HOT FLASHES. NIGHT SWEATS. PAINFUL PERIODS. PAINFUL INTERCOURSE. BLEEDING BETWEEN PERIODS. LONG MENSTRUAL CYCLES. BREAST PAIN. ABDOMINAL SPASMS/FLUTTERING. VAGINAL DISCHARGE/NO ORDER. BOWEL ISSUES, NAUSEA, GAS, CONSTIPATION, DIARRHEA, DIZZINESS, HEADACHES, MOOD SWINGS, DEPRESSION, BRAIN FOG, LEFT HIP PAIN, PRICKING OF SKIN, SOMETIMES NUMBNESS, HIGH BLOOD PRESSURE, FATIGUE, ACNE, CYSTS, HEART PALPITATIONS, COIL MIGRATION, SWELLING OF LEGS/FEET, HAIR LOSS, HAIR GROWTH IN NEW PLACES, INSOMNIA, WEIGHT ISSUES, UNEXPLAINED FEVERS, MUSCLE SPASMS, EXCESSIVE SWEATING, DRY EYES/SKIN, SEVERE BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041670		3/21/2015	4/1/2015

Event Information:

Event Date (B3): 3/9/2015 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7): 3/9/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I EXPERIENCED CHRONIC PELVIC PAIN AND HEAVY PERIODS AFTER THE ESSURE PLACEMENT IN 2008. THESE SYMPTOMS BEGAN IN 2011/2012. I UNDERWENT A HYSTERECTOMY (B)(6) 2015 AND THEY FOUND MY RIGHT FALLOPIAN TUBE WAS PERFORATE BY THE ESSURE COIL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00206	BAYER HEALTHCARE LLC	3/23/2015	3/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06466

Single Use: Y
Implant Date (E6): 9/8/2014
Explant Date (E7): 2/16/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 16-FEB-2015 WHICH REFERS TO A NON-PREGNANT (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED APPROXIMATELY 5 MONTHS AGO ((B)(6) 2014) FOR STERILIZATION. PHYSICIAN REPORTED THAT A PATIENT WITH ESSURE DEVELOPED PELVIC PAIN (DATE PAIN BEGAN, SIDE AND SEVERITY OF PAIN UNKNOWN TO REPORTER AT THIS TIME) AND STATES THAT SHE IS HAVING BILATERAL REMOVAL OF THE ESSURE IMPLANTS TODAY ((B)(6) 2015). NO FURTHER INFORMATION IS AVAILABLE AT THIS TIME AND A FOLLOW-UP WAS REQUESTED. FOLLOW-UP INFORMATION RECEIVED 24-FEB-2015. IT WAS REPORTED THAT ESSURE WAS PLACED ON (B)(6) 2014 AND REMOVED ON (B)(6) 2015 (CASE UPGRADED TO INCIDENT). PTC INVESTIGATION RESULT WAS RECEIVED ON 02-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL

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ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 02-MAR-2015. ESSURE LOT NUMBER WAS C06466 WITH EXPIRATION DATE 31-DEC-2016. PTC INVESTIGATION RESULT WAS RECEIVED ON 12-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT C06466 (PRODUCTION DATE 16-DEC-2013 AND EXPIRATION DATE 31-DEC-2016) WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 3 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, BUT NONE OF THE CASES REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED PELVIC PAIN. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE CAUSALITY BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS UPGRADED TO INCIDENT SINCE ESSURE REMOVAL (SURGICAL INTERVENTION IMPLIED) WAS REPORTED DURING FOLLOW-UP WITH REPORTER. ACCORDING TO PRODUCT TECHNICAL COMPLAINT ANALYSIS, A REVIEW OF THE MANUFACTURING BATCH RECORD CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. HOWEVER, SINCE NO PRODUCT RETURNED IT WAS NOT POSSIBLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. ALSO, (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, BUT NONE OF THE CASES REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THEREFORE, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 25-AUG-2015: ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT WHO HAS NO PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES NOR MEDICAL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00208	BAYER HEALTHCARE LLC	3/23/2015	3/23/2015

Event Information:

Event Date (B3): 8/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A36514, 77440 (INVALID)

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER A36514 INSERTED IN 2011. IT WAS STATED THAT BILATERAL PLACEMENT WAS ACHIEVED. ON (B)(6)-2013, PATIENT WAS COMPLAINING OF HEADACHES AND BLOATING AND WANTED THE ESSURE REMOVED. PHYSICIAN DID NOT THINK HER SYMPTOMS WERE DUE TO THE ESSURE DEVICES HOWEVER WILL BE REMOVING THE DEVICES LAPAROSCOPICALLY IN THE NEAR FUTURE. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP (B)(6)-2014: NO RESPONSE FROM THE REPORTER PHYSICIAN AFTER FOLLOW UP ATTEMPTS. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. FOLLOW-UP RECEIVED ON (B)(6)-2014: ESSURE HEALTH CARE PROVIDER QUESTIONNAIRE WAS RECEIVED. PATIENT INFORMATION WAS UPDATED. INFORMATION RECEIVED STATES THAT A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAS NO HISTORY OF PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES AND HAS ANXIETY DISORDER AS RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITION; HAD ESSURE (LOT NUMBER 77440; EXPIRATION DATE: 30-SEP-2013) INSERTED. PATIENT WAS NOT POST-PARTUM AT THE TIME OF INSERTION. NO SOUNDING OR GENERAL ANESTHESIA WAS APPLIED DURING PROCEDURE; HOWEVER A HYDRODILATATION WITH SCOPE AS WELL AS LOCAL ANESTHESIA WITH MHC (AS REPORTED) WAS PERFORMED. IN ADDITION REPORTER INFORMED THAT IT WASN'T SHE WHO DID THE INSERTION PROCEDURE BUT, ACCORDING TO NOTES, APPEARS THAT PROCEDURE HAD BEEN EASY AS WELL AS THE TUBAL OSTIUM VISUALIZATION. THERE WAS NO FLUID LOSS MORE THAN 1500 CC DURING HYSTEROSCOPY AND, AS LONG AS, THE INSERTION WAS NORMAL REPORTER ASSUMES THAT INSERTION TOOK 20 MINUTES OR LESS. ON (B)(6)-2012, HYSTEROSALPINGOGRAM WAS PERFORMED AND SHOWED NORMAL PLACEMENT AND TUBES CLOSED. PATIENT USED UNSPECIFIED BACK-UP

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CONTRACEPTION METHOD AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. ACCORDING TO REPORTER IT IS DOUBTFUL THAT PATIENT'S HEADACHE AND BLOATING ARE RELATED TO ESSURE DEVICES. A LAPAROSCOPY SURGERY TO REMOVE DEVICES IS PLANNED TO BE PERFORMED ON (B)(6)-2014. FOLLOW UP INFORMATION RECEIVED ON (B)(6)-2015: NO NEW INFORMATION. FOLLOW-UP INFORMATION RECEIVED ON (B)(6)-2015. IT WAS REPORTED THAT PATIENT HAD INSERTS SURGICALLY REMOVED AND HAD NOT BEEN BACK TO THE OFFICE WITH ANY COMPLAINTS. CASE UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6)-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THE LOT NUMBER PROVIDED 77440 WAS ASSESSED AS INVALID BY RESPONSIBLE QUALITY UNIT (RQU). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH NUMBER A36514. NO BATCH SIGNAL COULD BE IDENTIFIED. THE AE CASE REFERS ALSO TO THE LOT NUMBER 77440, WHICH IS INVALID ACCORDING TO THE RQU. THE BATCH DOCUMENTATION OF THE REPORTED VALID BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEADACHES AND BLOATING. THE DEVICES WERE SURGICALLY REMOVED. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE PHYSICIAN WAS NOT SURE IF PATIENT'S SYMPTOMS WERE RELATED TO ESSURE; NEVERTHELESS SINCE HEADACHES AND ABDOMINAL BLOATING MAY OCCUR DURING ESSURE THERAPY A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS AMENDED TO INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION FOR DEVICES REMOVAL REPORTED UPON FOLLOW-UP WITH REPORTER. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 15-APR-2015: PHYSICIAN DENIED FURTHER CONTACT. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00209	BAYER HEALTHCARE LLC	3/23/2015	3/24/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B60751

Single Use: Y
Implant Date (E6): 6/3/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B60751, INSERTED ON (B)(6) 2014 AND BILATERAL PLACEMENT WAS ACHIEVED. THE LEFT INSERT WAS NOT VISIBLE DURING CONFIRMATION TEST PERFORMED ON (B)(4) 2014. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2014: FINAL ASSESSMENT: ALTHOUGH THE DEVICE WAS NOT VISIBLE ON THE HSG FILMS, THERE IS NO DEVICE BREAKAGE FOR THIS CASE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. HOWEVER, THE REPORTED ADVERSE EVENTS IS A KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. 4 FURTHER ADVERSE EVENT CASE REPORTS HAVE BEEN RECEIVED TO DATE WITH THIS BATCH, NONE OF THEM REFERRING ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

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(B)(4). FOLLOW-UP INFORMATION RECEIVED ON 26-FEB-2015. IT WAS REPORTED THAT HYSTEROSCOPY WAS DONE WHERE THE LEFT ESSURE DEVICE WAS NOTED EMBEDDED IN UTERINE WALL 0.5CM FROM THE TUBAL ORIFICE (THE PREVIOUS REPORTED EVENT LEFT INSERT WAS NOT VISIBLE DURING CONFIRMATION TEST WAS UPDATED). THE HSG (HYSTEROSALPINGOGRAM) HAD REPORTED LEFT ESSURE ADJACENT TO PATENT LEFT FALLOPIAN TUBE. ATTEMPTS TO REMOVE THE ESSURE EMBEDDED RESULTED IN UNRAVELING OF ESSURE DEVICE, BUT IT COULD NOT BE PULLED OUT UTERUS AND WAS LEFT COILED WITHIN UTERINE CAVITY. A SECOND ESSURE WAS PLACED EASILY INTO THE LEFT TUBAL ORIFICE. PATIENT RETURNED FOR POSTOPERATIVE CHECK 2 WEEKS LATER AND WAS ASYMPTOMATIC. CASE WAS UPGRADED TO INCIDENT. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 5 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, BUT NONE OF THE CASES REFER ALSO TO SIMILAR ADVERSE TYPES OF EVENTS. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT HYSTEROSALPINGOGRAM THE LEFT INSERT WAS NOT VISIBLE. LATER, THE PHYSICIAN PERFORMED A HYSTEROSCOPY AND DURING THIS PROCEDURE LEFT ESSURE DEVICE WAS NOTED EMBEDDED IN UTERINE WALL; HE TRIED TO REMOVE IT UNSUCCESSFULLY AND THE DEVICE WAS LEFT IN PLACE. PATIENT WAS ASYMPTOMATIC. THE REPORTED EVENT, INTERPRETED AS DEVICE EMBEDMENT IN UTERINE CAVITY, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE'S THE REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR DUE TO A UTERINE PERFORATION/EMBEDMENT DURING INSERTION. IN THIS CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF DEVICE EMBEDMENT ARE NOT KNOWN; GIVEN ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT; HOWEVER UPON RECEIPT OF FOLLOW-UP INFORMATION IT WAS AMENDED TO INCIDENT DUE TO THE REPORTED INTERVENTION TO ATTEMPT TO REMOVE ESSURE. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 02-JUN-2015 FROM PHYSICIAN: ON (B)(6) 2015, THE HSG TEST WAS DONE AND SHOWED BOTH TUBES OCCLUDED AND A PERSISTENT SHORT SEGMENT OF THE PREVIOUSLY NOTED EXTRA TUBAL MICRO-INSERT. THE UTERINE CAVITY WAS NOTED TO BE NORMAL W

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00210	BAYER HEALTHCARE LLC	3/23/2015	3/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A57110

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GENERAL PRACTITIONER IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. GENERAL PRACTITIONER MENTIONED THAT HE SAW A PATIENT A LONG TIME AGO WITH AN ECTOPIC PREGNANCY ON ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ECTOPIC PREGNANCY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE

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REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN A PREGNANCY OCCURS AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; NEVERTHELESS CONSIDERING THE REPORTED EVENT NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 24-MAR-2015 FROM GENERAL PRACTITIONER VIA ACCOUNT MANAGER: THE PATIENT WAS (B)(6) OLD AT TIME OF THE EVENT. IT WAS REPORTED THAT THE INSERTION PROCEDURE WAS PROBABLY IN (B)(6) 2013. THE GENERAL PRACTITIONER RECEIVED A LETTER FROM THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00211	BAYER HEALTHCARE LLC	3/23/2015	3/24/2015

Event Information:

Event Date (B3): 12/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS000E5

Single Use: Y
Implant Date (E6): 11/18/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6)-YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(6)-2015 HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON RIGHT TUBE ON (B)(6)-2014 AND ON LEFT TUBE ON (B)(6)-2014 WITH LOT NUMBER CS000E5 FOR LOT OF PERIODS. SHE STATED THAT SHE WAS HAVING A LOT OF PERIODS AND ESSURE AND NOVASURE WERE DONE AT THE SAME TIME ON (B)(6)-2014. PHYSICIAN WAS ABLE TO DO THE RIGHT SIDE, BUT COULD NOT DO THE LEFT SIDE BECAUSE IT WAS KINKED. ON (B)(6)-2014, PHYSICIAN DID THE LEFT SIDE AT HIS OFFICE. IT WENT BAD, BECAUSE HER LEFT FALLOPIAN TUBE WAS PERFORATED. ON THE NEXT DAY ((B)(6)-2014), SHE WENT BACK TO THE DOCTOR'S OFFICE FOR SEVERE PAIN. SHE WAS ADMITTED ON (B)(6)-2014 AND STAYED IN THE HOSPITAL FOR 3 DAYS. A LAPAROSCOPIC REMOVAL OF THE ESSURE FROM THE LEFT SIDE AND A TUBAL LIGATION ON BOTH SIDES WERE DONE ON (B)(6)-2014. SHE HAD BLUE (INTERPRETED AS HEMATOMA) WHERE HE WENT IN TO REMOVE ESSURE; HE WENT TO HER BELLY BUTTON AND LOWER ABDOMEN. SHE WAS HAVING BLADDER ISSUE AND STILL HAS ESSURE ON THE RIGHT SIDE. FOLLOW UP (B)(6)-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE AND USABILITY ISSUE. IN THIS

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PARTICULAR CASE, ALSO OFF LABEL USE WAS REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 3 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, OF WHICH 1 CASE REFERS ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO UNUSUAL PATTERN COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CASUAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT PERFORATED LEFT FALLOPIAN TUBE DURING THE PROCEDURE (COMPLICATION OF DEVICE INSERTION). THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE ESSURE REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. IN THIS REPORT, THE PATIENT WAS HAVING LOTS OF PERIODS, SO ESSURE AND NOVASURE WERE DONE AT THE SAME TIME (OFF LABEL USE). PHYSICIAN WAS ABLE TO INSERT THE MICRO-INSERT IN THE RIGHT SIDE, BUT COULD NOT ACHIEVE THE LEFT SIDE PLACEMENT BECAUSE IT WAS KINKED. ONE MONTH LATER, THE LEFT SIDE INSERTION WAS DONE BUT HER LEFT FALLOPIAN TUBE WAS PERFORATED. THE CONSUMER RETURNED WITH SEVERE PELVIC PAIN, WAS HOSPITALIZED FOR 3 DAYS AND A LAPAROSCOPIC REMOVAL OF THE ESSURE FROM THE LEFT SIDE AND A TUBAL LIGATION ON BOTH SIDES WERE PERFORMED. CONSIDERING THIS EVENT OCCURRED ASSOCIATED TO INSERTION PROCEDURE AND GIVEN ITS NATURE, THE PERFORATION IS ASSESSED AS RELATED TO ESSURE USE. SINCE A LAPAROSCOPY WAS PERFORMED TO REMOVE LEFT ESSURE AND A HOSPITALIZATION OCCURRED, THE CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION (PERFORATION QUESTIONNAIRE) HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

ESSURE PERFORATION QUESTIONNAIRE RECEIVED FROM THE PHYSICIAN ON 31-MAR-2015. PATIENT'S DEMOGRAPHIC DATA WAS UPDATED. ON (B)(6) 2010 THE PATIENT HAD DILATATION AND CURETTAGE WAS PERFORMED FOR THE MISCARRIAGE. PATIENT HAD 5 PREGNANCIES WITH 2 LIVE BIRTHS AN

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00207	BAYER HEALTHCARE LLC	3/23/2015	4/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38210

Single Use: Y
Implant Date (E6): 2/16/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 4/20/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C38210. IT WAS REPORTED THAT AT THE SAME DAY OF INSERTION, PART OF DELIVERY CATHETER REMAINED CONNECTED TO INTERNAL PART OF IMPLANT. IT WAS IMPOSSIBLE TO REMOVE IMPLANT ON LEFT SIDE, DESPITE EASY PLACEMENT IN ONE ATTEMPT AND WITHOUT RISKY MANIPULATIONS FOR THE DEVICE. THERE WAS NO IMMEDIATE CONSEQUENCE AND EVENT OCCURRED IN OPERATING ROOM. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THIS PROCEDURE PART OF DELIVERY CATHETER REMAINED CONNECTED TO INTERNAL PART OF IMPLANT. ALSO, IMPLANT WAS IMPOSSIBLE TO REMOVE ON LEFT SIDE. THESE EVENTS, SEEN AS DEVICE BREAKAGE AND DEVICE REMOVAL FAILURE, ARE NON-SERIOUS. THE BREAKAGE IS UNLISTED IN REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE OTHER EVENT IS LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THIS CASE, THE PHYSICIAN STATED THAT PART OF CATHETER REMAINED CONNECTED TO INTERNAL PART OF IMPLANT AND AFTER THIS, DESPITE EASY PLACEMENT IN ONE ATTEMPT AND WITHOUT RISKY MANIPULATIONS FOR THE DEVICE, IT WAS IMPOSSIBLE TO REMOVE THE IMPLANT ON THE LEFT SIDE. CONSIDERING THE EVENTS OCCURRED IN ASSOCIATION WITH INSERTION PROCEDURE AND GIVEN THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE AND SINCE DEVICE BREAKAGE WAS REPORTED THE CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. TECHNICAL ANALYSIS IS EXPECTED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 04-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE PRODUCT WAS RETURNED TO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00205	BAYER HEALTHCARE LLC	3/23/2015	4/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91763

Single Use: Y
Implant Date (E6): 1/28/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 03-FEB-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER C91763. ON (B)(6) 2015 AT TIME OF INSERTION, ONE DEVICE BENT TIP AND THE OTHER DEVICE BROKE AND HAD TO BE RETRIEVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT TIME OF INSERTION, ONE DEVICE BENT TIP (DEVICE USE ERROR) AND THE OTHER DEVICE BROKE AND HAD TO BE RETRIEVED. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, SINCE THE DEVICE BREAKAGE OCCURRED AT TIME OF ESSURE INSERTION, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON 09-APR-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00212	BAYER HEALTHCARE LLC	3/24/2015	3/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(4) ON 27-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED APPROXIMATELY IN (B)(6) 2012. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED BLEEDING FOR OVER A YEAR, GAINED WEIGHT, BLOATED, PAINFUL INTERCOURSE EVERY TIME, HEADACHE, MOOD SWINGS, LOWER BACK PAIN, CRAMPING, TIRED, DEPRESSION, NIGHT SWEAT, ODOUR AND ITCHINESS. HYSTERECTOMY WAS PERFORMED IN 2013. FOLLOW-UP INFORMATION RECEIVED ON 02-MAR-2015: THE PATIENT´S DATE OF BIRTH WAS UPDATED. SHE HAD 4 CHILDREN. ACCORDING TO HER, SHE HAS FIBROMYALGIA (WAY BEFORE ESSURE). ESSURE WAS IMPLANTED IN (B)(6) 2012 AND IT WAS THE WORST PROCEDURE EVER; IT TOOK HER 10 MINUTES AND IT HURT. SHE ALSO REPORTED THAT SHE WAS NOT HERSELF FOR OVER A YEAR. SHE BLEED, SHE HAD HEADACHES, LOWER BACK PAIN, CRAMPING, ODOR FROM VAGINAL (THE PREVIOUS REPORTED EVENT ODOR WAS UPDATED), PAINFUL INTERCOURSE, WEIGHT GAIN ((B)(6)), DEPRESSION, MOOD SWINGS, LOT OF PAIN AND SUFFERING. IN (B)(6) 2013, SHE HAD A HYSTERECTOMY AND HER ISSUES WENT AWAY. CORRECTION ON 02-MAR-2015: THE CONSUMER'S (NOT PATIENT) DATE OF BIRTH WAS UPDATED. SHE STATED THAT SHE WEIGHTED (B)(6) AND AFTER HYSTERECTOMY, HER WEIGHT IS (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING FOR OVER A YEAR. SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, LIMITED INFORMATION

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WAS PROVIDED REGARDING THE BLEEDING. LATER, THE CONSUMER STATED THAT AFTER HYSTERECTOMY ALL HER ISSUES WENT AWAY (POSITIVE DECHALLENGE). CONSIDERING THE REPORTED EVENT'S NATURE AND POSITIVE DECHALLENGE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 05-AUG-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00214	BAYER HEALTHCARE LLC	3/24/2015	3/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/25/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038529) IN UNITED STATES ON 26-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. AFTER THE ESSURE PROCEDURE, CONSUMER STARTED TO HAVE MAJOR PELVIC PAIN, CRAMPS, HEAVY BLEEDING TO THE POINT OF RESTRICTION TO 1/2 HOUR TO A BATHROOM, STABBING PAIN IN THE FRONT THEN SEVERE LOWER BACK PAIN-CHIROPRACTOR NEEDED TO MOVE, DURING PERIODS SHE CAN BARELY WALK, CONSTANT PAIN WHERE THE COILS ARE. THIS IS IN ADDITION TO THE OTHER SIDE EFFECTS OF METAL TASTE, JOINT PAIN, HEADACHES AND THE LIST GOES ON. HER UTERUS WAS CONTRACTING AS IF SHE WAS PREGNANT AND PULLING THE MUSCLES IN HER BACK. SHE STATED SHE WAS FORCED TO HAVE A HYSTERECTOMY. CONSUMER STATED THAT AN INTERVENTION WAS REQUIRED. PTC INVESTIGATION RESULT WAS RECEIVED ON 09-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE

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FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MAJOR PELVIC PAIN, CONSTANT PAIN WHERE THE COILS ARE AND HEAVY BLEEDING. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. ALSO, GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE OCCURRENCE OF THESE EVENTS IS UNKNOWN. BASED ON THE INFORMATION PROVIDED AND GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A HYSTERECTOMY WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00215	BAYER HEALTHCARE LLC	3/24/2015	3/25/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/14/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT CONTRACEPTION ON (B)(6) 2010. PREGNANCY WAS DENIED. IN 2010 PATIENT EXPERIENCED UNUSUAL UTERINE BLEEDING AND UNDERWENT A DNC (INTERPRETED AS DILATATION AND CURETTAGE). IN 2013 SONOGRAM WAS PERFORMED AND SHOWED SMALL FIBROIDS. SIX MONTHS PRIOR TO THIS REPORT THE PATIENT STARTED EXPERIENCING UNUSUAL UTERINE BLEEDING WHICH WAS STILL ONGOING. ESSURE WAS NOT CONTINUED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 AND EXPERIENCED 2 EPISODES OF UNUSUAL UTERINE BLEEDING. FOR THE FIRST ONE, WHICH OCCURRED IN THE SAME YEAR OF ESSURE INSERTION, SHE WAS SUBMITTED TO A DILATION AND CURETTAGE. THE SECOND EPISODE STARTED IN 2014 AND WAS STILL ONGOING. ADDITIONALLY SHE WAS DIAGNOSED WITH UTERINE FIBROIDS IN 2013. THE REPORTED UTERINE BLEEDINGS WERE CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, FURTHER INFORMATION WAS REQUESTED TO CLARIFY IF PATIENT ALREADY HAD FIBROIDS AT THE TIME OF ESSURE INSERTION; NEVERTHELESS BASED ON THE INFORMATION AVAILABLE AND GIVEN THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN THE FIRST BLEEDING EPISODE AND ESSURE INSERTION CAUSALITY CANNOT BE EXCLUDED. THE SECOND BLEEDING EPISODE WAS CONSIDERED UNRELATED TO ESSURE GIVEN THE PROVEN ALTERNATIVE EXPLANATION (FIBROIDS). DUE TO THE REQUIRED DILATION AND CURETTAGE (INTERVENTION) THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATI

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00213	BAYER HEALTHCARE LLC	3/24/2015	4/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68119

Single Use: Y
Implant Date (E6): 2/20/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/25/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON 27-FEB-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. IT WAS STATED THAT, IN OPERATING ROOM, DURING ESSURE PLACEMENT THE COIL WAS BROKEN AND IT WAS IMPOSSIBLE TO PLACE ESSURE IMPLANT. THE DEVICE WAS KEPT (1 IMPLANT ONLY WAS KEPT). THERE WAS NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER DEVICE. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 19-MAR-2015. (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTION FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 10-MAR-2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE

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MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE (BREAKAGE) AND A USABILITY ISSUE (COMPLICATED INSERTION, DIFFICULT USE). HOWEVER, NO ADVERSE EVENTS (AE) WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WAS CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 23-MAR-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: (B)(6) PT - DEVICE BREAKAGE: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 964 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, THE COIL WAS BROKEN AND IT WAS IMPOSSIBLE TO PLACE ONE ESSURE IMPLANT. ANOTHER ESSURE DEVICE WAS SUCCESSFULLY PLACED IN PATIENT. THE REPORTED EVENTS WERE CONSIDERED NON-SERIOUS. DEVICE BREAKAGE WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS, WHILE THE OTHER EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, SINCE IT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS STATED THAT THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WAS CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 07-APR-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C68119; PRODUCTION DATE: 18-JUN-2014; EXPIRATION DATE: 3

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00216	BAYER HEALTHCARE LLC	3/24/2015	4/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18706

Single Use: Y
Implant Date (E6): 2/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 27-FEB-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C18706, INSERTION ON (B)(6) 2015 AND THE DISTAL TIP OF MICRO INSERT BROKE OFF AND HAD TO BE REMOVED WITH GRASPER. THE PATIENT HAD NO INJURY AND BILATERAL PLACEMENT WAS ACHIEVED. PRODUCT WAS NOT AVAILABLE TO BE SENT BACK. PTC INVESTIGATION RESULT WAS RECEIVED ON 13-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT C18706 (PRODUCTION

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DATE JAN-2014 AND EXPIRATION DATE 31-JAN-2017) WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE (BREAKAGE) AND A USABILITY ISSUE (COMPLICATED INSERTION). HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WERE CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A(B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE DISTAL TIP OF MICRO INSERT BROKE OFF. THIS DEVICE WAS REMOVED AND PATIENT HAD NO INJURY. THE REPORTED EVENT WAS CONSIDERED NON-SERIOUS AND IS LISTED ACCORDING TO TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, SINCE THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THERE WAS NO DEATH OR SERIOUS HEALTH DETERIORATION FOR THE PATIENT THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00218	BAYER HEALTHCARE LLC	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 1/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/14/2015
Explant Date (E7): 2/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR STERILIZATION. ON (B)(6) 2015, PATIENT DEVELOPED ACUTE PELVIC PAIN AND WENT BACK TO THE OFFICE FOR AN ULTRASOUND AND ALSO TO BE CHECKED. THE ESSURE APPEARED TO BE IN GOOD PLACEMENT BILATERALLY. SHE WENT TO SEE AN ALLERGIST FOR ALLERGY TESTING. SHE WAS CONFIRMED TO BE ALLERGIC TO NICKEL. SHE SAW THE HEALTHCARE PROFESSIONAL (HCP) AGAIN ON (B)(6) 2015 AND THEN HAD A HYSTERECTOMY ON (B)(6) 2015 IN WHICH BILATERAL TUBES WERE REMOVED. SHE HAD NO FURTHER COMPLAINTS OF THE SAME PELVIC PAIN. ESSURE WAS REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND ON THE FOLLOWING DAY, SHE DEVELOPED ACUTE PELVIC PAIN AND LATER ON RECEIVED THE CONFIRMATION THAT SHE WAS ALLERGIC TO NICKEL. AFTER REMOVING ESSURE SHE RECOVERED FROM THE SAME PAIN. BOTH EVENTS ARE SERIOUS DUE TO REQUIRED INTERVENTION AND ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THEY ARE LISTED. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. CONSIDERING THAT IN THIS PARTICULAR CASE, THE TEMPORAL RELATIONSHIP IS POSITIVE, CONSIDERING THE NATURE OF THE REPORTED EVENT AND ALSO THAT THE PATIENT RECOVERED FROM THE PAIN AFTER PERFORMING A HYSTERECTOMY AND REMOVED BOTH FALLOPIAN TUBES AND ESSURE, THE PELVIC PAIN IS CONSIDERED RELATED TO ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. CONSIDERING THE EVENT'S NATURE AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. NEITHER HOSPITALIZATION NOR SURGICAL INTERVENTION WERE REPORTED, HENCE THIS CASE IS REGARDED AS NON-INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUN-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00219	BAYER HEALTHCARE LLC	3/25/2015	3/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 10/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER REPORTED THAT SHE STARTED BLEEDING AFTER ESSURE INSERTED AND BLED FOR OVER 100 DAYS NONSTOP. ACCORDING TO REPORTER, HER DYE TEST SAID HER TUBES WERE 100% BLOCKED. HOWEVER, SHE BECAME PREGNANT WITHIN ABOUT 6 TO 7 MONTHS AFTER ESSURE INSERTED. CONSUMER HAD A MISCARRIAGE WHEN SHE WAS ABOUT A MONTH ALONG AND STATES THAT SHE PASSED A BIG CLOT AND THE PREGNANCY CAME OUT WITH IT (SHE FLUSHED IT DOWN THE TOILET). IN ADDITION CONSUMER REPORTED THAT SHE HAD PAIN AND ALMOST GOT DIVORCED SINCE SHE COULD NOT HAVE RELATIONS WITH HER HUSBAND. IT HURT SO MUCH WITH RELATIONS AND SHE WOULD START TO BLEED AGAIN AFTERWARDS. SHE HAD ESSURE REMOVED SURGICALLY AND BOTH TUBES REMOVED IN (B)(6) 2013. HCP SAID ONE COIL HAD PERFORATED HER TUBE AND THE OTHER COIL WAS FOUND NEXT TO HER CERVIX NOT IN THE TUBE. CONSUMER ALSO INFORMED THAT SHE IS AFRAID THAT SOME FRAGMENTS OF THE COIL MIGHT HAVE BROKEN OFF AND STILL BE IN HER UTERUS SINCE SHE STILL HAS A LITTLE PAIN. SHE IS ABOUT 80 TO 90 % BETTER. SHE NEVER HAD CRAMPS WITH HER PERIODS BEFORE ESSURE AND STATES THAT, EVEN WITH IT REMOVED, HER PERIOD IS HORRIBLE. SHE CANNOT EVEN GET OUT OF BED. ADDITIONALLY, CONSUMER REPORTED THAT SHE HAS A (B)(6) FRIEND THAT HAD TO HAVE A TOTAL ABDOMINAL HYSTERECTOMY DUE TO ESSURE ((B)(4)). PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO

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VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE AE CASE REFERS ALSO TO A PRODUCT QUALITY ISSUE (BREAKAGE) AS THE PATIENT STATED SHE WERE AFRAID THAT SOME FRAGMENTS OF THE COIL MIGHT HAVE BROKEN OFF. HOWEVER, BASED ON THE AVAILABLE INFORMATION NO ACTUAL BREAKAGE WAS OBSERVED BUT ONLY FEARED. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT AND HAD A MISCARRIAGE / PASSED A BIG CLOT AND THE PREGNANCY CAME OUT WITH IT (INTERPRETED AS SPONTANEOUS ABORTION). SHE STARTED BLEEDING AFTER ESSURE INSERTED AND BLED FOR OVER 100 DAYS NONSTOP (INTERPRETED AS GENITAL BLEEDING). IT WAS ALSO REPORTED THAT ONE COIL HAD PERFORATED HER TUBE AND SHE WAS AFRAID THAT SOME FRAGMENTS OF THE COIL MIGHT HAVE BROKEN OFF AND STILL BE IN HER UTERUS (SUSPICION OF DEVICE BREAKAGE). THE EVENT SPONTANEOUS ABORTION AND SUSPICION OF DEVICE BREAKAGE ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. ALL THESE EVENTS, EXCEPT FOR PREGNANCY AND SUSPICION OF DEVICE BREAKAGE, ARE SERIOUS DUE TO MEDICAL IMPORTANCE. PREGNANCY AND SUSPICION OF DEVICE BREAKAGE ARE NON-SERIOUS. MISCARRIAGE (SPONTANEOUS ABORTION), IT IS THE MOST COMMON COMPLICATION OF EARLY HUMAN PREGNANCY, OCCURRING MAINLY DURING THE FIRST TRIMESTER OF PREGNANCY. THIS IS CONSIDERED TO BE DUE TO A HIGH NUMBER OF ABNORMAL EMBRYOS PRESENTING WITH EITHER CHROMOSOMAL AND/OR GROSS MORPHOLOGICAL ABNORMALITIES. IN THIS CASE, MISCARRIAGE OCCURRED ABOUT ONE MONTH AFTER CONCEPTION. GIVEN THE ABOVE MENTION INFORMATION AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THE REPORTED EVENT WAS CONSIDERED AS UNRELATED TO THE INSERT. WITH REGARDS TO THE OTHER EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT WAS CONSIDERED AS RELATED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE AND BOTH TUBES WERE REMOVED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION WAS RECEIVED ON 11-AUG-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE (#FDA-2014-N-0736-0253), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00220	BAYER HEALTHCARE LLC	3/25/2015	3/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER'S FRIEND IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. REPORTER, WHO ALSO HAD ESSURE INSERTED, REPORTED THAT SHE HAS A (B)(6) YEAR OLD FRIEND THAT HAD TO HAVE A TOTAL ABDOMINAL HYSTERECTOMY DUE TO ESSURE. ((B)(4)). PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2015: CONSUMER´S FRIEND INFORMED THAT SHE DOES NOT HAVE HER FRIEND´S CONTACT

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INFORMATION. NO NEW INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A TAH (TOTAL HYSTERECTOMY) DUE TO ESSURE. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. A REPORTERS'S FRIEND HAD TO HAVE A TAH (TOTAL HYSTERECTOMY) DUE TO ESSURE. ALTHOUGH THE PATIENT'S MEDICAL HISTORY AND THE CIRCUMSTANCES OF THE HYSTERECTOMY HAD NOT BEEN INFORMED, CAUSALITY BETWEEN THE REPORTED EVENT AND SUSPECTED INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION COULD NOT BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00224	BAYER HEALTHCARE LLC	3/25/2015	3/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PREGNANCY WAS DENIED. REPORTER STATED PATIENT COMPLAINED OF PAIN AND THOUGHT ESSURE WAS PERFORATING TUBES. HYSTERECTOMY AND REMOVAL OF ESSURE COILS WERE REPORTED AS TREATMENT. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED; EXPERIENCED PAIN AND THOUGHT ESSURE

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WAS PERFORATING HER TUBES. THE DEVICES WERE REMOVED AND A HYSTERECTOMY WAS PERFORMED. THE REPORTED EVENTS, INTERPRETED AS PELVIC PAIN AND FALLOPIAN TUBE PERFORATION, WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A PERFORATION OCCURS PATIENT MAY EXPERIENCE PAIN OR DISCOMFORT. IN THIS PARTICULAR CASE, GIVEN THE ABOVE MENTION INFORMATION A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED AND DUE TO THE REPORTED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 01-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED; EXPERIE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00225	BAYER HEALTHCARE LLC	3/25/2015	3/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 05-MAR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DOCTOR´S WIFE REPORTED THAT PATIENT BROKE OUT IN A HEAD TO TOE RASH AFTER 6 MONTHS AFTER ESSURE PLACEMENT. BLOOD TEST WAS PERFORMED AND RESULTS SAID PATIENT HAD HIGHER LEVEL OF NICKEL SO IT WAS THOUGHT TO BE A NICKEL REACTION. HYSTERECTOMY AND REMOVAL OF ESSURE COILS WERE REPORTED. SYMPTOMS SUBSIDED AFTER ESSURE COILS REMOVED. PREGNANCY WAS DENIED. PTC INVESTIGATION RESULT WAS RECEIVED ON 18-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON

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THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER INTENSE RASH, BLOOD TEST RESULTS SAID PATIENT HAD HIGHER LEVEL OF NICKEL (NICKEL REACTION). THIS EVENT, SEEN AS ALLERGY TO METALS, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE PATIENT BROKE OUT IN A HEAD TO TOE RASH 6 MONTHS AFTER ESSURE PLACEMENT. BLOOD TEST WAS PERFORMED AND RESULTS SAID PATIENT HAD HIGHER LEVEL OF NICKEL SO IT WAS THOUGHT TO BE A NICKEL REACTION. THE SYMPTOMS SUBSIDED AFTER ESSURE COILS HAD BEEN REMOVED VIA HYSTERECTOMY. THEREFORE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE AND SINCE HYSTERECTOMY WAS PERFORMED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 01-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00226	BAYER HEALTHCARE LLC	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 10/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 910512

Single Use: Y
Implant Date (E6): 1/3/2012
Explant Date (E7): 10/16/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038766) IN UNITED STATES ON (B)(6) 2015, WHICH REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. CONSUMER STATED THAT A HIDA SCAN (CHOLESCINTIGRAPHY SCAN) WAS PERFORMED AND IT DETERMINED HER GALLBLADDER WAS NOT FUNCTIONING WELL. AFTER THE SURGERY, SHE WAS TOLD THAT HER ESSURE WAS ALSO REMOVED FROM THE FATTY TISSUE BY HER GALLBLADDER AND STATED IT WENT A LONG WAY IN HER INSIDES. ESSURE REMOVAL DATE WAS REPORTED AS (B)(6) 2014. CONSUMER ASSESSED THE EVENT AS SERIOUS. FOLLOW-UP RECEIVED ON (B)(4) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER

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TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO UNDERWENT A SURGERY, APPROXIMATELY 2 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION, AS HER GALLBLADDER WAS NOT FUNCTIONING WELL. DURING THIS PROCEDURE, ESSURE WAS ALSO REMOVED FROM THE FATTY TISSUE BY HER GALLBLADDER. THE REPORTED EVENTS, REGARDED AS UNSPECIFIED GALLBLADDER DISORDER AND ESSURE DISLOCATION INTO ABDOMINAL CAVITY, WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. DEVICE DISLOCATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE OTHER EVENT IS UNLISTED. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR ABDOMINAL CAVITY). ALTHOUGH, IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF THE REPORTED DISLOCATION IS UNKNOWN, GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. REGARDING THE REPORTED GALLBLADDER DISORDER, LIMITED INFORMATION WAS PROVIDED; NEVERTHELESS SINCE MOST OF CHOLECYSTECTOMIES ARE PERFORMED DUE TO SYMPTOMS OR COMPLICATIONS RELATED TO GALLSTONES A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT IS CONSIDERED UNLIKELY. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 20-APR-2015: ESSURE CONSUMER GENERAL QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM A (B)(6) FEMALE CONSUMER WHO HAS NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES STATES THAT SHE HAD ESSURE PLACED ON (B)(6) 2012 (6 WEEKS PO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041611	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 2/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLOATING, CONSTANT UTI'S, HEADACHES, BRAIN SHOCKS, MEMORY LOSS, LOSS OF SEX DRIVE, PAINFUL INTERCOURSE, ALL OVER BODY ACHES AND PAINS, HEAVY MENSTRUAL BLEEDING WITH CLOTS, CRAMPING, SKIN RASHES, DRY SKIN, HAIR LOSS, MOOD SWINGS, ADENOMYOSIS, HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041612	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 9/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, CRAMPING, IRREGULAR CYCLES, BLOTTING, BLOOD SUGAR PROBLEMS, INSOMNIA, FATIGUED, UTI'S.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041613	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 3/13/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 1ST OFF I WASN'T TOLD IT WAS NONREVERSIBLE I HAVE HEAVY BLEEDING FOR WEEKS ..LOWER BACK AND ABDOMEN PAIN..HORRIBLE HEADACHES. DEPRESSION CAUSE I HEAR SO MUCH ABOUT THIS PRODUCT, WANTING IT OUT BUT KNOWING I CAN'T GET THAT...WEIGHT LOSS AND CLOTS WITH MENSTRUAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041614	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 9/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ALMOST CONSTANT BLEEDING FOR FIRST YEAR. PROBLEMS WITH BOWELS, PASS OUT SPELLS, NAUSEA, SHARP PAINS IN VARIOUS AREAS, MOSTLY MY LEFT SIDE BE THE CREASE OF MY LEG AND LOWER ABDOMEN, TINGLING IN LEGS AND FINGER TIPS, BLOATING, HOT AND COLD FLASHES PULMONARY EMBOLISM, LIGHT HEADED AND DIZZY SPELLS, AND CHRONIC FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041615	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 1/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). IMMENSE PAIN FROM THE MOMENT THE DEVICE WAS IMPLANTED. PAIN HAS LESSENED WITH TIME BUT HAS NEVER GONE AWAY. SYMPTOMS WERE DISMISSED BY DOCTOR AND ATTRIBUTED TO INTERSTITIAL CYSTITIS. HOWEVER THE MAIN INDICATING SYMPTOMS FOR IC DID NOT START UNTIL THE EXACT MOMENT THE DEVICE WAS IMPLANTED. DOCTORS CONTINUE TO TELL ME THAT THE PAIN I FEEL IS NOT FROM THE DEVICE/IMPLANT SITE. HOWEVER ALL IC TREATMENTS AND MEDICATIONS DO NOT REMOVE THE PAIN THAT I HAVE BEEN TOLD IS MY BLADDER, AND NOT MY FALLOPIAN TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041616	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABNORMAL PERIODS AND PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041617	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 4/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME BACK PAIN. COLD/FLU LIKE SYMPTOMS. FEVER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041618	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 12/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS TAKING BACTRIM FOR A UTI. THE SIDE EFFECTS WERE RIPPING MY INSIDES APART. MY BACK ACHED LIKE I WAS DROPPED FROM A TALL BUILDING. I WANTED TO GO TO THE ER. I STAYED IN BED DRINKING WATER TO FLUSH OUT THE INFECTION AND THE BACTRIM. I FELT BETT...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041619	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 12/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE INTERNAL PAIN IN THE PELVIC REGION. TERRIBLE BACK PAIN. MY HEALTH HAS BEEN DETERIORATING EVER SINCE. MY STOMACH IS DISTENDED, I'M EXTREMELY TIRED. MY UTERUS IS ENLARGED 3 OVARIAN CYSTS PERIOD EVERY 2 WEEKS PAINFUL PERIODS AND SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041620	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 10/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY SIDE EFFECTS ARE INCLUDING BUT NOT LIMITED TO: GYNECOLOGICAL, ETC. CRAMPING - RANDOM, NOT CONNECTED TO MY PERIODS OR BOWEL MOVEMENTS, RANDOM SPOTTING, INCREASED DISCHARGE (ODOROUS), HOT FLASHES, LOSS OF LIBIDO. GASTROINTESTINAL: METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES - FREQUENT AND LARGE. NEUROLOGICAL, MENTAL HEALTH: BRAIN FOG AND CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, DEPRESSION - INCREASED CELEXA DOSAGE, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS); MOOD DISORDERS. BLOOD ISSUES HIGH BLOOD PRESSURE 130/80-150/90; UNEXPLAINED/EASILY BRUISING. OTHERS INCREASED HAIR LOSS, INCREASE GREY AND WON'T HOLD COLOR; DENTAL ISSUES - INCREASED CALCIFICATION AND DETERIORATING ENAMEL EXCESSIVE FATIGUE 10-12 HRS AT NIGHT AND TWO 2 HR NAPS DAILY. NAPS ARE SUDDEN, VERY LITTLE WARNING. WEIGHT ISSUES - INABILITY TO LOSE EVEN WITH WEIGHT LOSS HELP FROM DOCTOR. VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION) EXCESSIVE SWEATING; DRY SKIN ON HANDS TO POINT OF CRACKING AND BLEEDING; NEED (NOT CRAVING) FOR HIGH SODIUM DIET. IF I DONT, I GET SEVERE MIGRAINES; WEARING OF ANY JEWELRY THAT IS NOT PURE GOLD OR STAINLESS STEEL CAUSES MIGRAINES FOR ENTIRE TIME OF WEARING AND FOR 24-48 HOURS AFTER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041621	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 10/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP3 #FDAMW5041621 #(B)(4). ON (B)(6) 2015 I DEVELOPED A NEW PROBLEM. INSTEAD OF NORMAL BLEEDING AND CLOTTING WHEN SCRATCHED, SCRAPED OR CUT, IT IS VERY THIN BLOOD AND I BLEED LONGER THAN NORMAL. I HAVE TO APPLY PRESSURE TO EVEN THE SMALLEST PIN PRICK SIZED WOUND TO GET THE BLEEDING TO STOP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041622	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 4/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLOATING IN MY ABDOMEN, HEAD ACHES, HAIR LOSS, JOINT PAIN, BACK PAIN, FATIGUE, FEELING FAINTNESS, PELVIC PAIN, COILS MOVED OUT OF THE TUBE, SWOLLEN FEET, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041623	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 1/6/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I JUST WANT IT CHECKED AND OUT OF ME NOW. THIS WAS NOT OUR FAULT. THE DOCTORS DIDN'T CARE ENOUGH TO TELL US WHAT REALLY WAS GOING ON. MONEY JUST MAKES PEOPLE DO DUMB THINGS AND WE HAVE TO PAY FOR IT, NO I WILL NOT. ITS NOT FAIR....

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041624	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 3/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT DIAGNOSED WITH GIST CANCER AND HAD TO GET ON CHEMO BUT I HAD TO GET MY TUBES TIED FIRST. SO THE SAME MONTH, I STARTED BOTH TREATMENTS,EVER SINCE THEN I HAVE HAD COMPLETE BRAIN FOG, CONFUSION, BLOATING, EXTREMELY HEAVY AND PAINFUL MENSTRUAL CYCLES, I HAVE GAINED WEIGHT AND HAD A HARD TIME LOSING WEIGHT AND BEFORE HAND, I HAD NOT GAINED ANY WEIGHT DURING MY PREGNANCY OR ANYTHING. I DON'T HAVE MUCH OF A APPETITE AND I AM VERY FATIGUED MOST DAYS. I HAVE SEVERE DIARRHEA AND ACID REFLUX AS WELL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041625	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 5/24/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, BLOATING, OVARIAN CYST, HEAVY BLEEDING, MIGRAINES, INSOMNIA, WEIGHT GAIN, MOOD SWINGS, ABDOMINAL PAIN, HIGH BLOOD PRESSURE, DECREASE IN LIBIDO, PAIN DURING INTERCOURSE, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041626	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 2/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE LOWER ABDOMINAL PAIN, LOWER BACK PAIN, AND LEG PAIN. STOMACH BLOATING, WEIGHT GAIN. CONTINUED SEVERE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041627	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 1/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD AN ULTRASOUND (B)(6) 2015 (NOT SURE OF EXACT DATE) AND ONE OF THE ESSURE COILS WAS NOT IN THE TUBE. PATHOLOGY REPORTED THAT IT MAY BE IN THE UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041628	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 3/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE IMPLANTS PLACED IN 2009. AFTER THE PROCEDURE, I HAD EXTREME CRAMPING, PELVIC PAIN AND BLOATING FOR MOST OF A YEAR. I HAD PAIN WITH INTERCOURSE, LOW LABIDO, SKIN RASHES, PAIN IN MY SCALP OR MAY BE MY BRAIN THAT FELT LIKE ELECTRIC SHOCKS. I HAVE CHRONIC FATIGUE AND CHRONIC HEADACHES, LEG AND JOINT PAIN. INCREASED DEPRESSION AND ANXIETY, MOOD SWINGS. METALLIC TASTE IN MY MOUTH. SEVERE CRAMPING AND BLOATING AFTER INTERCOURSE. LEFT SIDE ABDOMINAL PAIN. TUBAL SPASMS. DENTAL ISSUES, CHEST PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041629	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 4/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE PAIN, BLOATING, HEAVY BLEEDING AND HUGE CLOTS. SO MUCH PAIN FOR A YEAR THAT I COULDN'T GET OUT OF BED. A COIL EVEN MIGRATED VAGINALLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041630	BAYER	3/25/2015	3/25/2015

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE CAUSED ME TO HAVE CYST EXTREME PAIN AND BLEEDING I HAD TO GET A HYSTERECTOMY ON (B)(6) 2015 IN OR TO REMOVE THESE FROM MY BODY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00222	BAYER HEALTHCARE LLC	3/25/2015	4/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D01975

Single Use: Y
Implant Date (E6): 2/27/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 04-MAR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER D01975, INSERTED ON (B)(6) 2015 FOR STERILIZATION. PHYSICIAN REPORTED THAT HE WAS PLACING ESSURE AND THE RIGHT SIDE PLACED FINE. HOWEVER, THE LEFT SIDE HAD TROUBLE INSERTING INTO THE FALLOPIAN TUBE AND THE COIL CAME UNRAVELED AND BROKE WITH THE DISTAL TIP FIRMLY ATTACHED TO THE FALLOPIAN TUBE AND IT CANNOT BE REMOVED. ESSURE DEVICE IS ONLY ON THE RIGHT SIDE, THERE IS NO DEVICE ON THE LEFT SIDE. FOLLOW UP 04-MAR-2014: NO NEW INFORMATION WAS PROVIDED. FOLLOW UP 04-MAR-2015: FOLLOW UP INFORMATION RECEIVED FROM THE MEDICAL DOCTOR WHO EXPLAINED THE EVENT DEVICE BREAKAGE, PREVIOUSLY REPORTED. THE MEDICAL DOCTOR REPORTED THAT WHEN HE WENT TO PLACE THE INSERT HE HAD DIFFICULTY AND HE WAS GOING TO GIVE UP ON THE INSERTION. HE HAD NOT YET DID ANY ROLL BACKS OR PRESSED THE BUTTON. HE WENT TO PULL BACK ON THE INSERTER TO STOP THE PLACEMENT AND IT WAS STUCK. HE THEN DECIDED TO YANK THE DEVICE (INSERTER) AND IT CAME APART. HE SAID THE INNER COIL AND THE CORE WERE OUT AS WELL AS THE PET FIBERS AND OUTER COIL. THE ONLY THING LEFT WAS A PIECE OF THE INNER WIRE AND DISTAL TIP. THIS WIRE WAS STRETCHED AND WAS TRAILING INTO THE UTERINE CAVITY AND INTO INTERNAL OS (ORIFICIUM) OF CERVIX. THE DOCTOR REPORTS PATIENT FELT FINE NO COMPLAINTS. HE SAID THAT HE TRIED TO REMOVE THIS WIRE BUT WAS UNABLE TO. THE PATIENT DID NOT WANT A SALPINGECTOMY. HE REPORTED THAT THE CONTRALATERAL SIDE HAD NO ISSUES AND INSERT PLACED FINE. PTC INVESTIGATION RESULT WAS RECEIVED ON 13-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS

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EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT D01975 (PRODUCTION DATE 27-AUG-2014 AND EXPIRATION DATE 31-AUG-2017) WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE (BREAKAGE) AND A USABILITY ISSUE (COMPLICATED INSERTION, DIFFICULT USE). HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WERE CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. CODING CORRECTION PERFORMED ON 19-MAR-2015: THE EVENT COIL CAME UNRAVELED AND BROKE WITH THE DISTAL TIP FIRMLY ATTACHED TO FALLOPIAN TUBE PREVIOUSLY CODED TO DEVICE BREAKAGE, AFTER INTERNAL REVIEW, WAS SPLIT AND ALSO CODED TO DEVICE SHAPE ALTERATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT COIL CAME UNRAVELED AND BROKE WITH THE DISTAL TIP FIRMLY ATTACHED TO FALLOPIAN TUBE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE AND DEVICE SHAPE ALTERATION, IS NON-SERIOUS. DEVICE BREAKAGE IS LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED: ESSURE PLACED ONLY ON THE RIGHT SIDE / LEFT SIDE HAD TROUBLE INSERTING INTO FALLOPIAN TUBE / IT CANNOT BE REMOVED (DEVICE INSERTION DIFFICULT) AND WIRE WAS STRETCHED. PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW UP 22-JUN-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE P

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00223	BAYER HEALTHCARE LLC	3/25/2015	4/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C95075

Single Use: Y
Implant Date (E6): 2/27/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. PHYSICIAN DESCRIBED DELIVERY WIRE DID NOT DETACH UPON SECOND ROLLBACK. WHEN SHE TRIED TO RETRIEVE WIRE IT BROKE WITH PART OF WIRE STILL ATTACHED TO MICRO-INSERT INNER COIL. HEALTH CARE PROFESSIONAL DESCRIBES ONE MILLIMETER OR LESS BROKE OFF. NO INJURY TO THE PATIENT OCCURRED AND BILATERAL PLACEMENT WAS ACHIEVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: AS OF (B)(4) 2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT C95075 (PRODUCTION DATE 14-AUG-2014 AND EXPIRATION DATE 31-AUG-2017) WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE (BREAKAGE) AND A USABILITY ISSUE (COMPLICATED INSERTION). HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WERE CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT WHEN THE PHYSICIAN TRIED TO RETRIEVE WIRE IT BROKE WITH PART OF THE WIRE STILL ATTACHED TO THE MICROINSERT INNER COIL. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE. CONSIDERING THIS INFORMATION, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 26-MAY-3015. THE PATIENT'S DATE OF BIRTH WAS UPDATED (SHE WAS (B)(6) AT TIME OF EVENT). HER WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). HER CONCURRENT CONDITION INCLUDED OBESITY. PREVIOUS GYNECOLOGICAL PROBLEMS AND INTERVENT

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00217	BAYER HEALTHCARE LLC	3/25/2015	4/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/2/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 02-MAR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR CONTRACEPTION. MEDICAL DOCTOR (MD) PLACED ESSURE ON LEFT SIDE WITH NO ISSUES. ON RIGHT SIDE, THE INSERT STRETCHED AND MAY HAVE BROKE BUT SHE WAS UNSURE. THE DOCTOR HAD A PIECE OF COIL OUTSIDE OF THE PATIENT AND THE PIECE WHICH WAS STILL INSIDE WAS THE OUTER COIL THAT WAS STRETCHED AND BROKEN OFF (SHE SAID THE BLUNT TIP OF THE TRAILING COILS). SHE SAW WHAT SHE THINKS IS THE INNER COIL STICKING OUT OF THE OSTIA. AN X-RAY WAS PERFORMED AND PHYSICIAN ONLY SAW 3 MARKERS, BELIEVED THAT THE LAST MARKER BROKEN OFF DURING INSERTION. SHE WILL WAIT FOR HSG. PTC INVESTIGATION RESULT WAS RECEIVED ON 13-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE (BREAKAGE) AND USABILITY ISSUES (USE ERROR. COMPLICATED INSERTION). HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. FURTHERMORE, NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH

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SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). ON LEFT SIDE THE MICRO-INSERT WAS PLACED WITH NO ISSUES. ON RIGHT SIDE, THE INSERT STRETCHED AND MAY HAVE BROKEN AND A PIECE WAS STILL INSIDE THE PATIENT. APPARENTLY THE INNER COIL WAS STICKING OUT OF THE OSTIA. AFTER THE PROCEDURE, X-RAY WAS PERFORMED AND SHE ONLY SAW 3 MARKERS ON XRAY AND BELIEVED THAT THE LAST MARKER BROKEN OFF DURING INSERTION. THIS EVENT, SEEN AS DEVICE BREAKAGE AND DEVICE USE ERROR, IS NON-SERIOUS. DEVICE USE ERROR IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE DEVICE BREAKAGE IS LISTED (ANTICIPATED) ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. CONSIDERING THE EVENTS OCCURRED IN ASSOCIATION WITH INSERTION PROCEDURE AND GIVEN THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. SINCE BREAKAGE, MALFUNCTION, WAS REPORTED THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. THE PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00221	BAYER HEALTHCARE LLC	3/25/2015	4/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61990

Single Use: Y
Implant Date (E6): 2/10/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 06-MAR-2015 WHICH REFERS TO A (B)(6) OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C61990, INSERTED ON (B)(6) 2015. PHYSICIAN REPORTED THAT THE IMPLANT DISINTEGRATED ON INTRODUCTION IN THE HORN. IN ADDITION HEALTH CARE PROFESSIONAL INFORMED THAT THE EVENT OCCURRED ON THE OPERATION ROOM AND BILATERAL PLACEMENT WAS DONE, WITH ANOTHER DEVICE. THERE IS NO CAUSE RELATED TO THE PATIENT TO EXPLAIN THE EVENT. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING PLACEMENT PROCEDURE, THE IMPLANT DISINTEGRATED ON INTRODUCTION IN THE HORN. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THIS CASE, THE IMPLANT DISINTEGRATED DURING INTRODUCTION IN THE UTERINE HORN. BILATERAL PLACEMENT WAS ACHIEVED WITH ANOTHER SET OF DEVICES. CONSIDERING THE EVENT OCCURRED DURING INSERTION PROCEDURE AND GIVEN ITS NATURE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. SINCE DEVICE BREAKAGE, MALFUNCTION, WAS INFORMED, THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. FURTHER INFORMATION AND TECHNICAL ANALYSIS HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00227	BAYER HEALTHCARE LLC	3/26/2015	3/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 855622

Single Use: Y
Implant Date (E6): 3/14/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM SPAIN WAS DERIVED FROM MEDICAL LITERATURE ON 05-MAR-2015, ARTICLE ENTITLED "DEFINITIVE CONTRACEPTION WITH ESSURE DEVICE: SINGLE INSTITUTIONAL EXPERIENCE ON 517 PROCEDURES". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT AND IRREVERSIBLE METHOD OF BIRTH CONTROL. CASE REPORT: FEMALE PATIENT HAD ESSURE INSERTED AND PRESENTED DEVICE MIGRATION. THE PATIENT HAD MIGRATION OF BOTH DEVICES TO THE ABDOMINAL CAVITY, WHICH WERE IDENTIFIED AND REMOVED PROPERLY DURING LAPAROSCOPIC TUBAL OCCLUSION. AUTHOR'S COMMENT: THE ESSURE METHOD OF PERMANENT BIRTH CONTROL IS EASY TO INSERT, WITH VERY HIGH APPLICATION RATES AND A VERY LOW PERCENTAGE OF COMPLICATIONS DURING INSERTION. IT ALSO HAS AN ADDED ADVANTAGE IN THAT IT CAN BE PERFORMED AS AN OUTPATIENT SERVICE, WITH NO ANAESTHESIA OR SURGICAL INCISIONS. IN CONCLUSION, THE POSSIBILITY OF ROUTINE HYSTEROSALPINGOGRAPHY SHOULD BE RECONSIDERED, AS RECOMMENDED BY THE FDA, AND PLAIN X-RAYS SHOULD NOT BE CONSIDERED SUFFICIENT, AS THE EUROPEAN HEALTH AUTHORITIES HAVE SUGGESTED. WHEN CONFIRMING TUBAL OCCLUSION, HYSTEROSALPINGOGRAPHY IS NOT PERFECT; THEREFORE, PATIENTS WITH NO PREVIOUS SALPINGECTOMY AND WITH A UNILATERAL INSERTION OF ESSURE SHOULD NOT BE CONSIDERED A SUCCESS, EVEN IF THE HYSTEROSALPINGOGRAM SHOWS BILATERAL OCCLUSION. PUBLICATION ABSTRACT: OBJECTIVES: TO ANALYSE THE OUTCOMES OF PATIENTS UNDERGOING ESSURE STERILIZATION (FROM 2008 TO 2013) IN A SINGLE INSTITUTION, INTERNS OF COMPLICATIONS AND TECHNIQUE FAILURE. PATIENTS AND METHODS: RETROSPECTIVE DESCRIPTIVE STUDY OF 517 PATIENTS (BETWEEN 30 AND 42 YEARS OLD) UNDERWENT DEFINITIVE CONTRACEPTION WITH ESSURE DEVICE IN OUTPATIENT HYSTEROSCOPY OFFICE WITHOUT ANESTHESIA AND CONTROLLED AT 3 MONTHS WITH ABDOMINAL RADIOGRAPHY, ULTRASONOGRAPHY AND

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HYSTEROSALPINGOGRAPHY IN SELECTED CASES. RESULTS: THE SUCCESS RATES OF THE INSERTION OF ESSURE WAS 96.8%, SIMILAR TO DATA REPORTED IN THE LITERATURE WITH 3.7% OF VAGAL REACTIONS, AS MOST PREVALENT COMPLICATION. 7 (1.35%) UNINTENDED PREGNANCIES WERE OBSERVED. CONCLUSIONS: ESSURE IS A PERMANENT BIRTH CONTROL DEVICE, WITH HIGH RATE OF SUCCESSFUL INSERTION AND A LOW RATE OF COMPLICATIONS. UNINTENDED PREGNANCIES IN OUR STUDY ARE HIGH AND WE MUST CHANGE THE PROTOCOLS OF PLACEMENT AND MONITORING, CONSIDERING HYSTEROSALPINGOGRAPHY AS A ROUTINE CONTROL TEST. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6)2015, REFERRING TO PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE (B)(4) PREFERRED TERMS: DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 297 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED MIGRATION OF BOTH DEVICES TO ABDOMINAL CAVITY. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR A DISLOCATION (DISTAL FALLOPIAN TUBE OR ABDOMINAL CAVITY). IN THIS CASE, THE PATIENT HAD MIGRATION OF BOTH DEVICES TO THE ABDOMINAL CAVITY, WHICH WERE IDENTIFIED AND REMOVED PROPERLY DURING LAPAROSCOPIC TUBAL OCCLUSION. THE EXACT MECHANISM AND CIRCUMSTANCES OF THIS DISLOCATION ARE NOT KNOWN, HOWEVER; CONSIDERING ITS NATURE, CAUSALITY BETWEEN REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION (LAPAROSCOPY) WAS PERFORMED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 14-JUL-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: 855622; PRODUCTION DATE: APR-2011; EXPIRATION DATE: APR-

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00228	BAYER HEALTHCARE LLC	3/26/2015	3/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(4) 2015, WHICH REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER HAD ESSURE INSERTED AFTER HER LAST SON. SHE STATED SHE BECAME VERY SICK; ALWAYS THROWING UP, WITH BAD HEADACHES AND WAS ALWAYS TIRED. SHE WOULD GET DIZZY A LOT, HAD LOWER BACK PAIN AND WHEN SHE WAS ON MENSTRUAL CYCLE, HAD SEVERE PAIN IN LOWER BACK AND VAGINA, SHARP SHOOTING PAINS AND BELLY BUTTON, SHE WOULD BLEED SO HEAVY THAT HER BLOOD WAS BLACK WITH BIG BLOOD CLOTS IT EVEN HURT WHEN SHE WENT TO THE RESTROOM, SHE HAD TO WEAR THREE PADS. SHE REPORTED SHE WAS IN AND OUT OF THE HOSPITAL FOR ABDOMINAL PAIN AND THE DOCTORS COULD NEVER FIND OUT WHAT WAS WRONG WITH HER. SHE WENT TO A DIFFERENT PHYSICIAN BECAUSE SHE COULD NOT HAVE SEX WITH HER HUSBAND ANYMORE DUE TO PAIN DURING INTERCOURSE. SHE TOLD TO HER PHYSICIAN THAT WAS ESSURE THAT WAS MAKING HER SICK AND SHE WAS THE FIRST PATIENT THAT THE OTHER PHYSICIAN INSERTED. HER NEW PHYSICIAN SAID TO HER THAT THE ESSURE WAS NOT CAUSING HER CONDITION AND THAT MAYBE SHE WAS DEPRESSED. THE ER PHYSICIANS SAID TO HER THAT SHE JUST HAD AN ABDOMINAL PAIN AND SEND HER HOME WITH PAIN MEDS. SHE STATED THAT THIS WENT ON FOR FIVE YEARS. SHE LOST HER JOB DUE TO MANY ABSENCES FOR HER BEING SICK. ON AN UNSPECIFIED DATE SHE HAD AN ENDOSCOPY DONE AND SHOWED NOTHING SERIOUSLY WRONG AND THEN SHE WENT TO SEE A GYNECOLOGIST. THE PHYSICIAN MADE HER TOOK SOME BIRTH CONTROL PILLS TO SEE IF THE BLEEDING AND PAIN WOULD SLOW DOWN. ON AN UNSPECIFIED DATE, THE CONSUMER HAD A SURGERY DONE FOR REMOVAL OF DEVICES. HER PHYSICIAN SAID SHE HAD A LOT OF SCAR TISSUE IN HER UTERUS AND THE INSIDE OF HER BELLY BUTTON AND ALSO IN HER TUBES. IN 2010, SHE WAS DIAGNOSED WITH SEVERE

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ANXIETY, AND SHE BELIEVED THAT IT HAD TO DO WITH ESSURE. CONSUMER STATED THAT SHE STILL SUFFER TO THIS DAY (DAY OF THE REPORT), BUT NOT AS BAD AS WHEN SHE HAD ESSURE. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WENT TO THE HOSPITAL SEVERAL TIMES DUE TO ABDOMINAL PAIN. ESSURE DEVICES WERE SURGICALLY REMOVED. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND AS CONSUMER STATED, AFTER SURGERY SHE WAS NOT SUFFERING AS BAD AS WHEN SHE HAD ESSURE (SUGGESTING AN IMPROVEMENT OF HER SYMPTOMS) CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 01-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00229	BAYER HEALTHCARE LLC	3/26/2015	3/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON 2007. CONSUMER REPORTED THAT, SOON AFTER THE PROCEDURE, SHE STARTED FEELING STICK WITH CRAMPS, JOINT PAIN, VAGINAL BLEEDING, LOSS OF ENERGY, PAIN LOWER BACK AND WAS GETTING WORSE. AFTER COUPLE OF YEARS FEELING BAD, HER OBSTETRICIAN/GYNECOLOGIST AND SHE DECIDED TO REMOVE THE ESSURE, AND HAD ABLATION TO STOP THE BLEEDING. AFTER THE SURGERY, STILL WITH PAIN; THE DOCTOR DID A PARTIAL HYSTERECTOMY BECAUSE SHE HAD ENDOMETRIOSIS, STILL WITH JOINT PAIN. IN ADDITION, CONSUMER REPORTED THAT HER DAILY ACTIVITIES WERE IMPAIRED. SHE HAS BEEN SEEN SEVERAL DOCTORS, BUT NOTHING WAS DIAGNOSED. HER BLOOD WORK CAME BACK NORMAL. LAST YEAR A LUMP WAS REMOVED FROM CONSUMER'S BREAST. SHE STATED THAT SHE WAS HEALTHY BEFORE ESSURE AND NOW SHE HAS ALL KINDS OF ALLERGIES AND HER LIFE WAS REDUCED TO TAKING PAIN KILLERS AND GOING TO DOCTORS. FOLLOW UP 18-MAR-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS

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REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SOON AFTER THE PROCEDURE, STARTED FEELING STICK WITH CRAMPS AND HAD PAIN LOWER BACK AND WAS GETTING WORSE. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, SOON AFTER PLACEMENT PROCEDURE THE CONSUMER FELT STICK WITH CRAMPS AND PRESENTED PAIN LOWER BACK AND WAS GETTING WORSE. ESSURE WAS REMOVED BUT AFTER THE SURGERY, SHE WAS STILL IN PAIN. THE DOCTOR DID A PARTIAL HYSTERECTOMY BECAUSE SHE HAD ENDOMETRIOSIS. ALTHOUGH THE PAIN DID NOT IMPROVE AFTER ESSURE REMOVAL AND THE ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THE REPORTED EVENTS, A CONTRIBUTORY ROLE OF ESSURE TO CRAMPS AND BACK PAIN CANNOT BE TOTALLY EXCLUDED. SINCE A SURGERY WAS PERFORMED TO REMOVE ESSURE, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 01-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00230	BAYER HEALTHCARE LLC	3/26/2015	3/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 836495

Single Use: Y
Implant Date (E6): 9/14/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(4) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2015, ARTICLE ENTITLED "DEFINITIVE CONTRACEPTION WITH ESSURE DEVICE: SINGLE INSTITUTIONAL EXPERIENCE ON 517." IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR DEFINITE CONTRACEPTION AND EXPERIENCED VASOVAGAL REACTION DURING INSERTION. CASE REPORT: IN TOTAL, 19 PATIENTS (3.7%) HAD A VAGAL EPISODE DURING INSERTION OF THE DEVICES, ONLY ONE OF WHICH (0.2%) REQUIRED THE USE OF A HALF VIAL OF INTRAVENOUS ATROPINE (0.5 MG). AUTHOR'S COMMENT: THE ESSURE METHOD OF PERMANENT BIRTH CONTROL IS EASY TO INSERT, WITH VERY HIGH APPLICATION RATES AND A VERY LOW PERCENTAGE OF COMPLICATIONS DURING INSERTION. IT ALSO HAS AN ADDED ADVANTAGE IN THAT IT CAN BE PERFORMED AS AN OUTPATIENT SERVICE, WITH NO ANAESTHESIA OR SURGICAL INCISIONS. PUBLICATION ABSTRACT: OBJECTIVES: TO ANALYSE THE OUTCOMES OF PATIENTS UNDERGOING ESSURE STERILIZATION (FROM 2008 TO 2013) IN A SINGLE INSTITUTION, INTERNS OF COMPLICATIONS AND TECHNIQUE FAILURE. PATIENTS AND METHODS: RETROSPECTIVE DESCRIPTIVE STUDY OF 517 PATIENTS UNDERWENT DEFINITIVE CONTRACEPTION WITH ESSURE DEVICE IN OUTPATIENT HYSTEROSCOPY OFFICE WITHOUT ANESTHESIA AND CONTROLLED AT 3 MONTHS WITH ABDOMINAL RADIOGRAPHY, ULTRASONOGRAPHY AND HYSTEROSALPINGOGRAPHY IN SELECTED CASES. RESULTS: THE SUCCESS RATES OF THE INSERTION OF ESSURE WAS 96.8%, SIMILAR TO DATA REPORTED IN THE LITERATURE WITH 3.7% OF VAGAL REACTIONS, AS MOST PREVALENT COMPLICATION. SEVEN (1.35%) UNINTENDED PREGNANCIES WERE OBSERVED. CONCLUSIONS: ESSURE IS A PERMANENT BIRTH CONTROL DEVICE, WITH HIGH RATE OF SUCCESSFUL INSERTION AND A LOW RATE OF COMPLICATIONS. UNINTENDED PREGNANCIES IN OUR STUDY ARE HIGH AND WE MUST CHANGE THE PROTOCOLS OF PLACEMENT AND MONITORING, CONSIDERING

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HYSTEROSALPINGOGRAPHY AS A ROUTINE CONTROL TEST. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015, REFERRING TO PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE ADVERSE EVENT CASE REFERS ALSO TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PRESYNCOPE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 19 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, CASE REPORT DERIVED FROM MEDICAL LITERATURE ENTITLED "DEFINITIVE CONTRACEPTION WITH ESSURE DEVICE: SINGLE INSTITUTIONAL EXPERIENCE ON 517" REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED VASOVAGAL REACTION DURING INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. INSERTION AND REMOVAL OF ESSURE MAY PRECIPITATE FAINTING AS A VASOVAGAL REACTION. IN THIS PARTICULAR CASE, THE PATIENT EXPERIENCED THIS EVENT DURING ESSURE INSERTION PROCEDURE. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PATIENT REQUIRED THE USE OF A HALF VIAL OF INTRAVENOUS ATROPINE. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-JUN-2015 FROM PHYSICIAN: ESSURE LOT NUMBER 836495 WAS INSERTED ON (B)(6) 2011. FOLLOW-UP RECEIVED ON 30-JUN-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00231	BAYER HEALTHCARE LLC	3/27/2015	3/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 654833

Single Use: Y
Implant Date (E6): 2/17/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM SPAIN WAS DERIVED FROM MEDICAL LITERATURE ON 05-MAR-2015, ARTICLE ENTITLED "DEFINITIVE CONTRACEPTION WITH ESSURE DEVICE: SINGLE INSTITUTIONAL EXPERIENCE". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR DEFINITIVE CONTRACEPTION AND EXPERIENCED NICKEL ALLERGY. CASE REPORT: A FEMALE PATIENT HAD ESSURE INSERTED, SHE WAS ALLERGIC TO NICKEL, WHICH WAS NOT KNOWN BEFORE INSERTION, AND WHICH CAUSED GENERALIZED ECZEMATOUS SKIN LESIONS THAT WERE LATER EVALUATED BY THE DERMATOLOGISTS AND DID NOT IMPROVE WITH TOPICAL TREATMENT INDICATED; THE PATIENT UNDERWENT A HYSTERECTOMY WITH SALPINGECTOMY, WITH NO COMPLICATIONS. BECAUSE THE PATIENT FAILED TO ATTEND THE POST-SURGERY FOLLOW-UPS, IT WAS NOT POSSIBLE TO REPORT ON WHETHER SHE IMPROVED WITH REGARD TO HER ECZEMATOUS LESIONS AFTER THE DEVICES WERE REMOVED. AUTHOR'S COMMENT: THE ESSURE METHOD OF PERMANENT BIRTH CONTROL IS EASY TO INSERT, WITH VERY HIGH APPLICATION RATES AND A VERY LOW PERCENTAGE OF COMPLICATIONS DURING INSERTION. IT ALSO HAS AN ADDED ADVANTAGE IN THAT IT CAN BE PERFORMED AS AN OUTPATIENT SERVICE, WITH NO ANAESTHESIA OR SURGICAL INCISIONS. PUBLICATION ABSTRACT: OBJECTIVES: TO ANALYSE THE OUTCOMES OF PATIENTS UNDERGOING ESSURE STERILIZATION (FROM 2008 TO 2013) IN A SINGLE INSTITUTION, INTERNS OF COMPLICATIONS AND TECHNIQUE FAILURE. PATIENTS AND METHODS: RETROSPECTIVE DESCRIPTIVE STUDY OF 517 PATIENTS UNDERWENT DEFINITIVE CONTRACEPTION WITH ESSURE DEVICE IN OUTPATIENT HYSTEROSCOPY OFFICE WITHOUT ANESTHESIA AND CONTROLLED AT 3 MONTHS WITH ABDOMINAL RADIOGRAPHY, ULTRASONOGRAPHY AND HYSTEROSALPINGOGRAPHY IN SELECTED CASES. RESULTS: THE SUCCESS RATES OF THE INSERTION OF ESSURE WAS 96.8%, SIMILAR TO DATA REPORTED IN THE LITERATURE WITH 3.7% OF VAGAL REACTIONS, AS MOST PREVALENT

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COMPLICATION. 7 (1.35%) UNINTENDED PREGNANCIES WERE OBSERVED. CONCLUSIONS: ESSURE IS A PERMANENT BIRTH CONTROL DEVICE, WITH HIGH RATE OF SUCCESSFUL INSERTION AND A LOW RATE OF COMPLICATIONS. UNINTENDED PREGNANCIES IN OUR STUDY ARE HIGH AND WE MUST CHANGE THE PROTOCOLS OF PLACEMENT AND MONITORING, CONSIDERING HYSTEROSALPINGOGRAPHY AS A ROUTINE CONTROL TEST. FOLLOW-UP INFORMATION WAS RECEIVED ON 11-MAR-2015. NO ADDITIONAL INFORMATION FOR THE CASE WAS RECEIVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 24-MAR-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ALLERGY TO METALS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 110 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, CASE REPORT DERIVED FROM MEDICAL LITERATURE ENTITLED "DEFINITIVE CONTRACEPTION WITH ESSURE DEVICE: SINGLE INSTITUTIONAL EXPERIENCE" REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL ALLERGY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE EVENT OCCURRED AFTER DEVICE INSERTION; THEREFORE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PATIENT UNDERWENT A HYSTERECTOMY WITH SALPINGECTOMY. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-JUN-2015 FROM PHYSICIAN: ESSURE LOT NUMBER 654833 WAS INSERTED ON 17-FEB-2010. PTC INVESTIGATION RESULT RECEIVED ON 25-JUN-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: BATCH NUMBER 654833, PRODUCTION DATE: JUL-2009

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00232	BAYER HEALTHCARE LLC	3/27/2015	3/27/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68122

Single Use: Y
Implant Date (E6): 2/20/2015
Explant Date (E7): 2/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 IN ASSOCIATION WITH NOVASURE (TUBAL STERILIZATION + MENOMETRORRHAGIA). ACCORDING TO REPORTER, THERE WAS NO PROBLEM AT THE MOMENT OF OPENING OF THE DEVICE IN THE UTERUS. ON (B)(6) 2015, THE PATIENT EXPERIENCED MORE PAIN THAN USUAL, BUT RETURNED HOME. ON (B)(6) 2015, AN EXPLORATIVE LAPAROSCOPY WAS PERFORMED (SUSPICION OF MIGRATION OF ESSURE +/- PERFORATION). ON (B)(6) 2015, A SURGICAL REVISION (SUTURE OF SMALL INTESTINE WITH HYSTERECTOMY) AND RESECTION + OSTOMY WERE DONE. AS CLINICAL CONSEQUENCES HEALTH CARE PROFESSIONAL REPORTED (ANAPATHOLOGICAL RESULTS): THERMAL NECROSIS OF THE SMALL INTESTINE AND EXTENSION OF THE NECROSIS TO THE WHOLE THICKNESS OF THE STOMA. ESSURE DEVICES WERE REMOVED AND KEPT. FOLLOW UP (B)(6) 2015: FOLLOW UP INFORMATION RECEIVED FROM THE HEALTH AUTHORITIES IN (B)(6)(REFERENCE NUMBER 201503049). NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER 2015-008123 FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH

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WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN ASSOCIATION WITH NOVASURE PROCEDURE. TWO DAYS LATER, SHE WAS SUBMITTED TO AN EXPLORATIVE LAPAROSCOPY DUE TO PAIN; PHYSICIAN SUSPECTED OF MIGRATION OF ESSURE +/- PERFORATION. LATER, SHE UNDERWENT A HYSTERECTOMY; RESECTION/SUTURE OF SMALL INTESTINE AND OSTOMY. PATHOLOGY REPORT REVEALED A THERMAL NECROSIS OF THE SMALL INTESTINE. THE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. THERMAL NECROSIS IS UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE OTHER EVENT IS LISTED. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE) AND ENDOMETRIAL ABLATION PROCEDURES (E.G. NOVASURE). IN THIS REPORT, NO INFORMATION WAS PROVIDED ABOUT UTERINE FINDINGS DURING SURGERY/PATHOLOGY REPORT; HOWEVER, GIVEN THIS EVENT NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING BOWEL THERMAL NECROSIS, ESSURE IS INSERTED BY HYSTEROSCOPY, NO ELECTRICAL ENERGY IS APPLIED. NOVASURE IS A BIPOLAR ELECTRODE ARRAY USED TO CREATE A THERMAL LESION ON THE INTERIOR SURFACE OF THE UTERINE CAVITY; THERMAL INJURY TO THE BOWEL MAY OCCUR WHEN MULTIPLE THERAPY CYCLES ARE PERFORMED DURING THE SAME ATTEMPT. BESIDES, IF INTRAUTERINE ELECTRICAL ENERGY THERAPIES ARE USED IN PATIENTS WITH ESSURE, IT IS RECOMMENDED TO AVOID CONTACT WITH THE INSERT (SINCE IT MAY CONDUCT ENERGY AND CAUSE LOCALIZED PATIENT INJURY). IN THIS CASE, BOWEL NECROSIS EXTENDED TO THE WHOLE THICKNESS OF THE STOMA; GIVEN THIS INFORMATION AND CONSIDERING NOVASURE AS ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN BOWEL THERMAL INJURY AND ESSURE IS CONSIDERED UNLIKELY. THIS CASE WAS REGARDED AS INCIDENT DUE TO SUSPICION OF ESSURE PERFORATION HAD LED TO AN INTERVENTION. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 28-MAY-2015. NEW REPORTER WAS ADDED. THE PATIENT'S CONCOMITANT CONDITION INCLUDED MULTIPLE SCLEROSIS. FOLLOW UP INFORMATION RECEIVED ON 09-JUN-2015: NO FURTHER INFORMATION WAS RECEIVED. CASE CONSIDERED CLOSED. THE LIST OF

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041774	BAYER	3/27/2015	4/3/2015

Event Information:

Event Date (B3): 9/24/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/24/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS ARE CAUSING EXTREME PAIN. SOME HOW THEY ARE IN BEDDED IN MY UTERUS. I AM SCHEDULED FOR SURGERY BECAUSE THEY ARE CAUSING ME SO MUCH PAIN THAT IT MAKES IT IMPOSSIBLE TO FUNCTION DAILY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041776	BAYER	3/27/2015	4/3/2015

Event Information:

Event Date (B3): 8/1/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE STINTS-COILS
Device Type (E2): BIRTH CONTROLL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2004
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS MY SECOND REQUEST. TAKE ESSURE OFF THE MARKET, I HAD THESE IN SINCE (B)(6) 2004 AND THE CHRONIC PAIN AND MY HEALTH IS DETERIORATING BECAUSE OF THESE. I AM ALREADY A WIDOW. I HAVE 4 KIDS TO TAKE CARE OF. PLEASE FIND ME A DOCTOR IN (B)(6) THAT WILL TAKE THESE OUT. I HAVE HAD NO SUCCESS BECAUSE IT IS UNDER LITIGATION. HELP ME PLEASE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041777	BAYER	3/27/2015	4/3/2015

Event Information:

Event Date (B3): 6/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A15526 - 919015

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM HAVING AN ALLERGIC REACTION TO THE ESSURE SPRINGS. I HAVE RASHES ON MY FACE, NECK AND ARMS. A SKIN TEST AT THE ALLERGY DOCTOR FOUND THAT I AM ALLERGIC TO NICKEL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00233	BAYER HEALTHCARE LLC	3/27/2015	5/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91768

Single Use: Y
Implant Date (E6): 3/5/2015
Explant Date (E7): 3/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 05-MAR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015. WHEN PHYSICIAN WAS WITHDRAWING CATHETER FROM LEFT TUBE A PIECE OF IT BROKE OFF. HEALTH CARE PROFESSIONAL WAS ABLE TO REMOVE IT AND INFORMED THAT RIGHT INSERT COULD NOT BE PLACED DUE TO POSSIBLE TUBAL SPASM OF OCCLUSION. PLACEMENT WAS DISCONTINUED. IN ADDITION IT WAS REPORTED THAT PATIENT IS OK BUT STILL HAVING PAIN ON LEFT SIDE. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. ADDITIONALLY, A USABILITY ISSUE WAS REPORTED. THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT

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SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THE POSSIBILITY OF CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. BASED ON THE LIMITED INFORMATION AVAILABLE, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 05-MAR-2015. LOT NUMBER WAS C91768. IT WAS REPORTED A TUBAL SPASMS ON BOTH SIDES. ON LEFT SIDE, A PIECE OF MICRO INSERT CAME OFF AND WAS REMOVED WITH GRASPERS. NO INJURY TO THE PATIENT. FOLLOW-UP INFORMATION WAS RECEIVED ON 25-MAR-2015. THE CASE (B)(4) WAS FOUND TO BE A DUPLICATE OF THIS CASE AND WAS DELETED. ALL INFORMATION WAS TRANSFERRED TO THIS RETAINED CASE. PATIENT'S DATE OF BIRTH WAS AMENDED, SHE WAS (B)(6). NO NEW CLINICAL INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A(B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND WHEN HCP (HEALTH CARE PROFESSIONAL) WAS WITHDRAWING CATHETER FROM LEFT TUBE AND A PIECE OF IT BROKE OFF. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. AN UPDATED PRODUCT TECHNICAL ANALYSIS (LOT NUMBER RECEIVED UPON FOLLOW-UP) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP ON 27-MAR-2015: UPON RECEIVING OF THE LOT NUMBER C91768 THE PTC INVESTIGATION RESULTS WERE UPDATED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041781	BAYER	3/28/2015	4/3/2015

Event Information:

Event Date (B3): 12/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/17/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY ESSURE IMPLANT WAS FORCEFULLY INSERTED INTO MY RIGHT FALLOPIAN TUBE. ABOUT TWO WEEKS LATER, I NOTICED MY CONSTANT DRY MOUTH AND SOME EMBARRASSING INCONTINENCE. IT HAS BEEN THREE MONTHS SINCE I GOT ESSURE AND I HAVE RECURRING YEAST INFECTIONS, SORENESS AND ITCHING IN MY VAGINAL AREA, SPORADIC BLEEDING, WORSENING INCONTINENCE, NO SEX DRIVE, AND QUESTIONABLE VAGINAL DISCHARGE. NONE OF THESE SYMPTOMS BECAME A PART OF MY LIFE UNTIL ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041782	BAYER HEALTH	3/28/2015	4/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/31/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACEMENT 2009. SEVERE CRAMPING, HEAVY BLEEDING INCLUDING BLOOD CLOTS, BREAST TENDERNESS, THINNING OF HAIR, WEIGHT GAIN, BLOATING, CONSTANT HEADACHES. THESE SIDE EFFECTS STARTED IN 2009 AFTER PLACEMENT AND SEEMS TO BE WORSENING OVER TIME. IN 2014 ER VISIT FOR BREAST SWELLING AND VERY TENDER FOR 36 DAYS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041798	CONCEPTUS/ BAYER	3/29/2015	4/3/2015

Event Information:

Event Date (B3): 2/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/20/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL PAIN, PAINFUL PERIODS, CONSTANT BLOATING, MIGRAINES, BRUISING, BROKEN TEETH, BACK PAIN AND VOMITING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041799	BAYER	3/29/2015	4/3/2015

Event Information:

Event Date (B3): 8/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/5/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2011. THEN THREE MONTHS LATER, I HAD THE HSG TEST WHICH CONFIRMED THAT THE COILS WERE PERMANENT AND IN THE RIGHT LOCATION TO BLOCK MY FALLOPIAN TUBES FROM CONCEPTION. THEN IN 2012 I BECAME PREGNANT WITH MY FIFTH CHILD. NOW I AM PREGNANT WITH MY SIXTH CHILD. I HAVE BAD ABDOMINAL PAIN AND LOWER BACK PAIN SINCE HAVING THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041749	BAYER	4/1/2015	4/1/2015

Event Information:

Event Date (B3): 9/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN AFTER INSERTION. PROLONGED BLEEDING - NEARLY FOUR MONTHS. PELVIC PAIN, HIVES, WEIGHT GAIN, FATIGUE, HEADACHES AND IRREGULAR AND PAINFUL PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041750	BAYER	4/1/2015	4/1/2015

Event Information:

Event Date (B3): 12/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BACK PAIN. BLOATING IN ABDOMEN. MISSED PERIODS. HIGH IRRITABILITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041751	BAYER	4/1/2015	4/1/2015

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT LOWER ABDOMEN CRAMPING. SHARP STABBING PAINS. BLEEDING DURING INTERCOURSE. PAINFUL INTERCOURSE. HEADACHES. BRAIN FOG. WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041869	BAYER	4/1/2015	4/8/2015

Event Information:

Event Date (B3): 3/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/1/2010
Explant Date (E7): 3/23/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A PROCEDURE CALLED ESSURE ABOUT 4 YEAR AGO. DIDN'T HAVE PROBLEMS AT FIRST, UNTIL I STARTED HAVING INTERCOURSE OFTEN, FIRST CAME PAIN WITH SEX, PELVIC PAIN ALMOST EVERY DAY, MIGRAINE, METAL TASTE: IN MY MOUTH, STOP MY PANCREAS FROM PRODUCING INSULIN, BECAME DIABETIC, HAD KIDNEY PROBLEM HOSPITALIZE FOR BOTH. I'M NOT OBESE, THE ENDOCRINE DR COULDN'T EXPLAIN HOW I BECAME DIABETIC, IT DOESN'T RUN MY FAMILY. NAUSEA, FATIGUE ALL THE TIME. I ALWAYS FELT LIKE I WAS PREGNANT BUT I WASN'T. I BECAME DEPRESSED THAN NORMAL, ANXIETY REALLY BAD. I WENT TO GYN AND HE TOLD ME THE COILS MIGRATED AND HAD TO BE TAKEN OUT. THEY TOOK OUT MY TUBES AND COILS, AFTER THAT, I WENT BACK TO NORMAL AND I LOST PAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041901	BAYER	4/1/2015	4/8/2015

Event Information:

Event Date (B3): 2/13/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE PLACED 6 MONTHS POSTPARTUM AT OUTSIDE FACILITY. INITIAL HSG AT 3 MONTHS SHOWED UNILATERAL TUBAL OCCLUSION. SECOND HSG AT 6 MONTHS SHOWED BILATERAL TUBAL OCCLUSION. TWELVE MONTHS LATER (FIRST ENCOUNTER WITH THIS FACILITY) HAD LEFT CORNUAL ECTOPIC PREGNANCY REQUIRING EMERGENCY SURGERY AND SALPINGECTOMY. POST-OPERATIVE HSG SHOWED RIGHT TUBAL PATENCY; DEVICE APPEARS 'EXTRALUMINAL' (BUT NOT VISUALIZED AT THE TIME OF SURGERY). THIS APPEARS TO BE A BILATERAL THERAPEUTIC FAILURE. DATES OF USE: (B)(6) 2014 - (B)(6) 2015. DIAGNOSIS OR REASON FOR USE: UNDESIRED FERTILITY, STERILIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041764	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 1/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BRAIN SHOCKS. LOWER ABDOMEN PAIN, LEG PAIN, ARM PAIN. HAND AND FINGERS PAIN. BREAST PAIN. HEADACHES. NAUSEA. DIZZINESS. EXTREME FATIGUE. DEPRESSED. MOOD SWINGS. SUICIDAL THOUGHTS. BLURRY EYES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041765	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PLACED IN (B)(6) OF 2010 THE FIRST 4 MONTHS I HAD TO VISIT MY DOCTOR SEVERAL TIMES DUE TO EITHER HEAVY BLEEDING, OR MISSED CYCLES. IT SEEMED TO LEVEL OUT BUT AFTER A FAIRLY NORMAL YEAR I STARTED TO HAVE LOWER ABDOMINAL PAIN, AND PAIN DURING INTERCOURSE. THEN IT PROGRESSIVELY GOT WORSE I STARTED HAVING PAIN WITH BOWEL MOVEMENTS, LOWER BACK PAIN, EXCESSIVE WEIGHT GAIN IN SHORT PERIODS OF TIME, EXHAUSTED ALL THE TIME, AND MISSING MENSTRUAL CYCLES OFTEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041766	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 8/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN HAVING 2 HEAVY CLOTTY PERIODS PER MONTH. SEVERE PAIN IN PELVIC/HIPS..HEADACHES..CONSTANT BLOATING AND DISCOMFORT IN STOMACH..HAIR LOSS..MOOD SWINGS...SUGAR DROPPING...MEMORY LOSS...IRITIS..NO INTEREST IN SEX...CRAMPING AFTER SEX..NOT ABLE TO MAKE IT TO PEE SOMETIMES JUST STARTS DRIBBLING OUT..JOINT PAIN..BACK AND NECK PAIN..METAL TASTE ON TONGUE..

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041767	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 2/4/2014	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN. SEVERE LOWER BACK PAIN, LEG PAIN, AND HIP PAIN. WEIGHT GAIN. MOOD SWINGS. IRRITABLE BOWEL BEFORE REMOVAL OF THE COILS. I HAD TO HAVE A TOTAL HYSTERECTOMY IN ORDER TO STOP THE PAIN AND TRY TO REVERSE DAMAGES. HYSTERECTOMY WAS PERFORMED ON (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041768	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 4/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED ON (B)(6) 2014 AND I WAS IN PAIN AFTER THE IMPLANT BUT AFTER TWO WEEKS I WENT INTO SEVERE PAIN IN MY STOMACH AND PELVIC AREA THAT I COULDN'T GET OUT OF BED. I TOOK PAIN MEDICATION AND NOTHING AFTER THAT I STARTED TO HAVE HEADACHES EVERY SINGLE DAY TO THE POINT THAT IT WAS CONSISTENT NO MEDS WERE WORKING NOTHING AFTER THAT OTHER THINGS STARTED TO BEGIN. MY NIGHTMARE WAS BEGINNING MY EYES WOULD CROSS ON THEIR OWN AND MAKE ME DIZZY, TINGLING IN MY FINGER TIPS, SEVERE PAIN WHEN I STAND FOR LONGER THAN 10 MINUTES I WOULD GET PAIN IN MY HIPS AND TAILBONE AREA SO BAD I HAD TO QUIT MY JOB. THEN ALSO STARTED GETTING WHAT FELT LIKE ELECTRIC SHOCKS IM MY LEFT SIDE OF HEAD, I GET NAUSEOUS, I HAVE SUCH PAIN DURING MY MENSTRUAL THAT I BALL UP, MY TUBES EVEN HURT, I GAINED WEIGHT, MY HAIR FALLS, I GET BUMPS OVER MY SKIN AND AM ITCHY, I GET ITCHY SCALP SO BAD. WHEN I FIRST GOT ESSURE I CAN TELL MY BODY WAS OFF AND EVEN THE SMELL. I AM NOT SUPPOSED TO GET PREGNANT BECAUSE I ALMOST DIED IN 2013 WITH MY SON'S BIRTH NOW I BUY TESTS EVERY MONTH BECAUSE IF I DO GET PREGNANT I HAVE TO TERMINATE AND I'M SUCH A STRONG VOICE FOR NOT TERMINATING BABIES SO IN THAT EVENT I WOULDN'T I WOULD CHOOSE THE BABY OVER ME. BUT I HAVE SIDE EFFECTS EVERYDAY NO ENERGY LEFT I HAVE UNEXPLAINED BRUISING ON MY BODY ESP FEET EVERYTHING ITS A TOTAL MESS. CHEST PAIN, HOSPITAL VISITS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041769	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 3/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE EXPERIENCED, EXTREME BELLY BLOATING, CRAMPING, IRREGULAR PERIODS, BLOOD CLOTS, HEAVY BLEEDING, DEPRESSION, LOSS OF HAIR, WEIGHT GAIN, NOT ABLE TO LOSE WEIGHT, EXTREME PELVIC PAIN, NUMEROUS CYST, SHARP PELVIC PAIN, CONSTANT SPOTTING, JOINT PAIN, DIZZINESS, BRAIN FOG, RINGING IN EARS, ALL OVER BODY ACHES, INSOMNIA, DRY SKIN/ HAIR, AND ADENOMYOSIS AND MANY MORE SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041770	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 11/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME ABDOMINAL PAIN STARTED TO BE CHRONIC IN (B)(6) 2014. THE PAIN ESCALATED TO THE POINT OF MISSING WORK AND LOSING TIME WITH MY FAMILY. I HAD TO TAKE PAIN MEDICATIONS EVERYDAY UP UNTIL THE DAY OF SURGERY. SURGERY TO REMOVE ESSURE WAS SUCCESSFUL ON (B)(6) 2015. MY PAIN IS OF COURSE GONE! THIS PRODUCT MUST BE REMOVED FROM THE MARKET! THE ONE SUCCESS STORY IS NOT WORTH THE ONE WOMAN THAT SUFFERS! THIS IS A HORRIBLE PRODUCT AND RUINED MY LIFE!!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041772	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 10/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHILE THE PROCESS WAS GOING ON IT WAS EXTREMELY PAINFUL. MY STOMACH HURT SO BAD TO THE POINT I CRYING AND SCREAMING AND THE DR PRESCRIBED ME TYLENOL 3 WITH CODEINE FOR 10 DAYS. MY STOMACH NEVER STOPS CRAMPING AS OF TODAY I'M STILL HAVING 24/ 7 STOMACH PAIN AND ITS VERY HARD AND PAINFUL TO MAKE BOWEL MOVEMENTS. MY PERIOD IS WAY HEAVIER AND PAINFUL THAN BEFORE I GOT THE PROCEDURE DONE. MY SEX DRIVE HAS PLUMMETED BECAUSE WHEN I DO HAVE SEX IT HURTS SO VERY BAD. AND ALL OF THIS SO I WOULDN'T HAVE ANOTHER BABY AND GUESS WHAT... I HAD A BABY BOY (B)(6) 2014 THAT I HAD TO GIVE UP FOR ADOPTION WHICH BY THE WAY IS THE HARDEST DECISION I'VE EVER HAD OR WILL EVER MAKE. I DEAL WITH DEPRESSION AND HEARTACHE ON A DAILY BASIS DUE TO ALL 9 THE ABOVE MENTIONED. THANK YOU IN ADVANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041778	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 6/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN IN PELVIS. IRREGULAR PERIODS WITH LARGE CLOTS. WEIGHT GAIN AND CONTINUAL BELLY BLOAT. THINNING HAIR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041783	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 1/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING OR PINCHING PAIN IN BACK. NOTICED BLOATED FEELING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041784	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 11/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN,HAIR LOSS, HEADACHES, VISION PROBLEMS, LOW BACK PAIN DURING PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041785	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 4/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST OF ALL THE PROCEDURE WAS VERY PAINFUL. I STARTED HAVING PAIN AND NUMBNESS IN MY LEFT LEG, WEIGHT GAIN, BLOATING, CHRONIC PELVIC PAIN, TENDERNESS ON LEFT SIDE, PAIN DURING INTERCOURSE, IRREGULAR/EXTREMELY HEAVY PERIODS, PERIODS LASTING 3 WEEKS AT A TIME, AND BACK PAIN/SPASMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041807	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 7/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). COIL BROKE DURING INSERTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041808	BAYER	4/2/2015	4/2/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INCREASINGLY WORSENING ISSUES WITH SKIN RASHES, DEBILITATING MIGRAINES, EXCESSIVE FATIGUE, MEMORY ISSUES, BOWEL ISSUES, JOINT PAIN/INFLAMMATION, PELVIC AND LOWER BACK PAIN, ATYPICAL CHEST PAIN REQUIRING MULTIPLE ER VISITS...ALL ATTRIBUTED TO EITHER FIBROMYALGIA OR DEPRESSION AND ALL NOT RESPONSIVE TO TREATMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041959	BAYER	4/2/2015	4/9/2015

Event Information:

Event Date (B3): 4/2/2015 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 620734

Single Use:
Implant Date (E6):
Explant Date (E7): 11/21/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN 2008. FROM THE TIME I WOKE UP (B)(6) 2014 I HAVE BEEN IN PAIN. I GAINED OVER 100 POUNDS. BLOOD CLOTS THE SIZE OF GOLF BALLS. MY HAIR HAS FALLEN OUT. EYE LASHES DISAPPEARED. NO SEX DRIVE. WHEN I DID HAVE SEX IT WAS SO PAINFUL. I WOULD BLEED FOR DAYS AFTER SEX. I HAD TO HAVE 2 ABLATIONS DONE BECAUSE THE DOCTORS COULD NOT FIGURE OUT WHY I WAS IN SO MUCH PAIN. I GOT PREGNANT TWICE, ALL ENDING IN DEATH OF FETUS. I HAD SEVERAL PANIC ATTACKS BECAUSE OF THE PAIN. HEART ISSUES. CYST ON MY OVARIES THE SIZE OF QUARTERS OR BIGGER. ESSURE MIGRATED THROUGH MY TUBES AND END UP WRAPPED AROUND OTHER ORGANS. NOW THAT THE DEVICES ARE OUT I FEEL 100% BETTER. ALL MY SIDE EFFECTS GONE. THIS PRODUCT TOOK THE QUALITY OF MY LIFE. I WAS NOT ABLE TO DO THE NORMAL THINGS THAT MOTHERS SHOULD BE ABLE TO DO WITH THEIR CHILDREN OR THEIR HUSBANDS. THE SWELLING ALL OVER MY BODY AND THE PAIN THAT I WAS IN EVERY DAY WAS CAUSED BY ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041960	BAYER/CONCEPTUS	4/2/2015	4/9/2015

Event Information:

Event Date (B3): 8/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 855628

Single Use:
Implant Date (E6): 8/9/2011
Explant Date (E7): 6/3/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED (B)(6) 2011 AND ABOUT ONE YEAR AFTER THEM BEING IMPLANTED I STARTED HAVING SEVERE SIDE EFFECTS. I SUFFERED FROM EXTREME PAIN WHILE I WAS OVULATING EACH MONTH. I HAD TROUBLE WITH EVERYDAY TASK. THE OVULATING PAIN WOULD LAST FOR ABOUT A WEEK SOMETIMES LONGER. THEN I WOULD BE UNCOMFORTABLE AND EXTREMELY BLOATED ONLY TO THEN HAVE EXTREME PAIN AGAIN THE WEEK BEFORE MY PERIOD. THE EXTREME PAIN I WAS HAVING WOULD BE ABOUT 3 WEEKS OUT OF THE MONTH. I WAS ALWAYS BLOATED AND UNCOMFORTABLE. THE PAIN THAT I DEALT WITH ON A REGULAR BASIS LEFT ME FEELING DEPRESSED AND IRRITABLE ALL THE TIME. I ALSO GAINED 30 POUNDS SINCE HAVING THE ESSURE IMPLANTED. AFTER HAVING DEALT WITH THE PAIN FOR SO LONG I WENT BACK TO MY IMPLANTING DOCTOR HE DID NOT THINK MY SIDE EFFECTS WERE CAUSED BY ESSURE. HE DID ORDER A MRI TO SEE WHAT WAS GOING ON. THE TEST SHOWED THE ESSURE WERE STILL CORRECTLY IN PLACE BUT HE FELT IF I THOUGH IT WAS THE ESSURE CAUSING ALL MY PAIN THEN THEY SHOULD BE REMOVED. ALTHOUGH HE IMPLANTED THEM HE DOES NOT PERFORM REMOVALS. HE DID REFER ME TO A DOCTOR THAT DOES REMOVE THE ESSURE DEVICES. I HAD MY TUBES REMOVED WITH THE ESSURE DEVICES IN THEM ON (B)(6) 2014. THE SURGERY WENT WELL BUT THE FIRST MENSTRUAL CYCLE AFTER HAVING THEM REMOVED I HAD HEAVY BLEEDING. I BELIEVED THAT I HAD TO GIVE MY BODY TIME TO HEAL AFTER THE SURGERY. TO DATE I STILL HAVE EXTREMELY HEAVY CYCLES. I PASS BLOOD CLOTS THROUGHOUT MY CYCLE. I ALSO HAVE DEVELOPED OVARIAN CYSTS SINCE MY ESSURE REMOVAL. I AM ABOUT TO HAVE AN ENDOMETRIAL ABLATION TO SEE IF I GET ANY RELIEF OF MY HEAVY MENSTRUAL CYCLES. I AM ALSO DEALING WITH ANEMIA. I HAVE HAD SO MANY FEMALE ISSUES SINCE HAVING THE ESSURE IMPLANTED AND EVEN AFTER HAVING THEM REMOVED I AM STILL SUFFERING THE SIDE EFFECTS THAT THEY HAVE CAUSED MY BODY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041994	BAYER	4/3/2015	4/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DUE TO THE ESSURE COILS, I WAS IN SO MUCH BACK PAIN AND PELVIC PAIN, MIGRAINES AND MASSIVE BLOOD CLOTS, I ENDED UP HAVING TO HAVE A HYSTERECTOMY TO END THE NIGHTMARE. PLEASE TAKE A LOOK AT THIS PRODUCT AND SAVE OTHER WOMEN FROM THIS HORROR. (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041996		4/3/2015	4/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I BLEED FOR OVER A YEAR, BECAME ANEMIC AND HAD TO HAVE A HYSTERECTOMY AS ONE COIL WAS MISSING. NOTHING WAS WRONG WITH ME BEFORE ESSURE AND NOTHING WRONG AFTER EVERYTHING WAS TAKEN OUT. ESSURE PLACEMENT WAS THE ONLY TIME I HAD SEVERE MEDICAL PROBLEMS (PAIN EXCESSIVE BLEEDING).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041997	BAYER	4/3/2015	4/10/2015

Event Information:

Event Date (B3): 8/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/21/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN 2012 AND I HAVE HAD CHRONIC PID NOW ALSO HAIR LOSS BLOATING BACK PAIN SHARP PAINS IN PELVIC AREA, WEIGHT GAIN, SEVERE DEPRESSION, PLUS MANY MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041987	BAYER	4/4/2015	4/10/2015

Event Information:

Event Date (B3): 3/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/17/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED BACK IN 2010. AND SHORTLY AFTER THAT, I WAS DIAGNOSED WITH HYPOTHYROIDISM. I ALSO HAVE BEEN EXPERIENCING CHRONIC BACK PAIN, HIP PAIN, SEVERE BLOATING, AND WEIGHT GAIN. I WAKE UP WITH A HEADACHE EVERY MORNING SINCE I HAD THE ESSURE PLACED. I HAVE RECENTLY BEEN DIAGNOSED WITH AN ENLARGED UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041809	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 12/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC ITCHINESS, ABNORMAL MENSTRUAL CYCLE EVERY 2 WEEKS, HEAVY BLEEDING WHILE ON MY MENSES, BRUISES ON MY BODY CAUSE BY SCRATCHING DUE TO THE CHRONIC ITCHINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041810	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 6/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD STEADILY GAINED WEIGHT, SHARP PELVIC PAIN, PAIN DURING INTERCOURSE, SPOTTING FOR 3 DAYS AFTER INTERCOURSE, LOW BACK PAIN, CYSTS ON MY OVARIES, TOWARD THE END I HAD MISSED MY PERIOD FOR 2 MONTHS, HEADACHES, I GET SO BLOATED THAT I LOOK 8 MONTHS PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041811	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 8/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2004. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED AROUND A YEAR LATER. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. WEIGHT GAIN, SEVERE BLOATING, LONGER PERIODS, VERY HEAVY PERIODS WITH LARGE BLOOD CLOTS, DULL PELVIC PAIN DAILY, PAINFUL PERIODS, HAIR LOSS, HEADACHES AND DIZZINESS. I HAVE HAD THE FOLLOWING SURGERIES SCHEDULED DUE TO ESSURE: HYSTERECTOMY THE DEVICE IS STILL INSIDE OF ME AS OF NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041812	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 1/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN RIGHT SIDE, CAME AND WENT AT FIRST BUT NOW IS CONSTANT. I HAD AN X-RAY FOR A LOW BACK INJURY AND IT SHOWED THAT ON THE SIDE THAT HURTS THE ESSURE COIL IS LOWER THAN THE SIDE THAT DOESN'T BOTHER ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041813	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 5/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN DURING SEX, MESSED UP AND HEAVY PERIODS, MIGRAINES, VITAMIN DEFICIENCIES, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041814	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 1/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESSIVE HAIR LOSS; PAINFUL AND ITCHY SKIN IRRITATIONS COVERING 80% OF BODY; HOT FLASHES; MILD FEVERS; SHORT TERM MEMORY LOSS; AND FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041815	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041815 #(B)(4). I HAVE SINCE HAD A LAVH/BS BECAUSE OF THE ABNORMAL BLEEDING AND PAIN I WAS DEALING WITH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041816	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 1/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOOD CLOTS, EXTREMELY HEAVY BLEEDING, MIGRAINES, SEVERE CRAMPING IN THE ABDOMINAL AREA, ANEMIA DUE TO LOSS OF BLOOD, AND WEIGHT GAIN/BLOATING LOOKING LIKE IM 4 MONTH PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041817	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 3/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, WEIGHT GAIN, ACNE, MOOD SWINGS, DEPRESSION, DIFFICULTY COMPLETING TASKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041818	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 3/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER EXPERIENCING A LOT OF PAIN IN MY RIGHT SIDE, I MADE AN APPOINTMENT WITH MY PRIMARY CARE PHYSICIAN WHO CONFIRMED I AM SIX WEEKS PREGNANT. THE COIL IN MY RIGHT FALLOPIAN TUBE SHIFTED WHICH RESULTED IN PREGNANCY. I AM NOW SUBJECTED TO BEING IN A VERY HIGH RISK PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041819	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 3/27/2015 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). REPORTED ON (B)(6) SITE ESSURE PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041820	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 1/29/2015 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SUICIDE, DEATH. PAIN AND PROBLEMS FROM ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041821	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 11/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).SINCE GETTING ESSURE I HAVE FREQUENT HEADACHES AND DEBILITATING CRAMPS AT THE TIME OF THE MONTH LIKE IM IN LABOR AND IN MY BACK. EVERY NOW AND THAN IF I TWIST WRONG I'LL HAVE A SHARP PAIN IN LOWER LEFT ABDOMEN. VERY FATIGUED AROUND THE TIME OF THE MONTH AND DAYS AFTER. SOMETIMES SEX IS PAINFUL. IT FEELS LIKE SOMEONE IS STABBING MY INSIDES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041822	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 3/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN, HIVES, RASHES, SKIN IRRITATION, SHARP SHOOTING PAIN, NUMBING OF LIMBS, METALLIC TASTE, EXCESSIVE WEIGHT GAIN, CONSTIPATION, IRRITABILITY, HEAVY BLEEDING, ABNORMAL PERIODS, CRAMPING, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041823	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 8/6/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). WELL, MY PERIODS ARE ABNORMAL. I WON'T GET IT FOR 2 MONTHS THEN IT'LL COME AND I'LL BLEED FOR LIKE 3 DAYS AND HUGE BLOOD CLOTS, TERRIBLE CRAMPING. HURTS DURING INTERCOURSE ALL THE TIME. HORMONES ARE WACKED. URINATE MORE THEN NORMAL. BEEN TO ER LOTS DUE TO HEAVY BLEEDING AND CRAMPING THOUGHT HAD A MISCARRIAGE A FEW TIMES. GET BLADDER INFECTIONS MORE FREQUENTLY, NEVER REALLY HAD THEM TILL THEN. BODY IS WORSE THEN BEFORE I GOT THIS AND ALSO GAINED SOME SERIOUS WEIGHT FROM IT OVER THE YEARS!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041824	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 7/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER CHECKING THAT THE COILS WERE PLACED, I HAVE HAD CONSTANT DULL TO VERY SHARP PAINS WHERE MY COILS ARE AT. MY PERIODS HAVE NOT BEEN NORMAL. I SKIP MONTHS AND THAN THEY ARE HEAVY OTHER MONTHS. AND SEX ISN'T ALWAYS PLEASURABLE LIKE IT USED TO BE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041825	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM THE DAY THEY WENT IN MY COILS CAUSED ME FATIGUE AND BRAIN FOG. IF ANYONE AROUND ME GOT SICK, I WAS USELESS IN BED WITH A MONTH LONG FLU. SIDE EFFECTS THEN STARTED SLOWLY ADDING ON, ON (B)(6) 2014 I WOKE UP FEELING LIKE DEATH AND THEN MY SIDE EFFECTS WENT FROM ABOUT 5 TO 65 BY (B)(6) 2014 WHEN I HAD A COMPLETE HYSTERECTOMY SENDING ME INTO MEDICAL MENOPAUSE AT THE AGE OF (B)(6). THESE ARE ALL MY SIDE EFFECTS: CRAMPING, SHARP AND STABBING PELVIC PAIN, ABNORMAL MENSES, CONSTANT SPOTTING, DISCHARGE DAILY, HOT FLASHES, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), NIGHT SWEATS, LOSS OF LIBIDO, PAINFUL PERIODS, EARLY MENOPAUSE, INCONTINENCE, LONG MENSTRUAL CYCLES, URGENT AND FREQUENT URINATION, ITCHING/BURNING/STABBING OF VAGINAL ENTRANCE, SEVERE BREAST PAIN AND TENDERNESS, ABDOMINAL SPASMS/TWITCHING/FLUTTERING, PAIN IN BACK/JOINT/CHEST/LEG/NECK/HIP, CHRONIC PELVIC PAIN, NAUSEA, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, HEADACHE OR MIGRAINE DAILY, TINGLING SENSATIONS AND NUMBNESS, BRAIN FOG, ANXIETY/PANIC ATTACKS, SEVERE MOOD SWINGS (OFTEN ENDING IN A BREAKDOWN WITH TEARS AND SORRIES TO WHOMEVER I HAD YELLED AT), DEPRESSION (SEVERAL TIMES THOUGHT MY KIDS WOULD BE BETTER OFF WITHOUT A SICK MOM LAYING ON THE COUCH ALL DAY), RINGING IN EARS, NEAR FAINTING EPISODES, DIMINISHED BRAIN FUNCTION (NO SHORT-TERM MEMORY), TINGLING IN EXTREMITIES, SENSATION OF STINGING OR PRICKLING OF SKIN, SHAKINESS, DIZZINESS, HIGH BLOOD PRESSURE, UNEXPLAINED/EASILY BRUISING, HYPOGLYCEMIA, CHRONIC FATIGUE SYNDROME, CHEMICAL AND FOOD SENSITIVITIES, METAL ALLERGIES, HEIGHTENED ALLERGIC REACTIONS, FOOD ALLERGIES, GLUTEN SENSITIVE, ALLERGIC TO DYES, RASHES, HIVES, ACNE, HEART PALPITATIONS, SWELLING OF LEGS/FEET/HANDS/FINGERS/WRISTS/FACE/STOMACH, HAIR GROWTH FASTER AND DARKER, DENTAL ISSUES (DAMAGED GUMS

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AND LOSE OFF TEETH WITHOUT EXPLANATION), INSOMNIA (SLEPT ABOUT 2 HOURS PER NIGHT DESPITE FATIGUE), WEIGHT ISSUES (GAINING NO MATTER WHAT DIETARY CHANGES WERE MADE OR EXERCISE DONE), SWOLLEN GLANDS, SWELLING OF LIPS, UNEXPLAINED FEVERS (ALMOST DAILY), MUSCLE SPASMS, VISION WAS GETTING WORSE, EXCESSIVE SWEATING, DRY SKIN/HAIR, HAIR LOSS, SEVERE BLOATING, AND ADENOMYOSIS. I HAVE NEVER HAD ALLERGIES IN MY LIFE. I KNOW HAVE ALLERGIES THAT MAY NEVER GO AWAY, SOME CAUSED ME TO LOSE MY 10 YR CAREER AS I CAN NO LONGER WEAR THE PRODUCT I WAS SELLING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041826	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN IN A LOT OF PAIN. BOTH SIDES WHERE THE COILS ARE PLACED. SEX IS PAINFUL AND UNCOMFORTABLE WITH MY HUSBAND WHO IS SUFFERING AS WELL. THE PAIN IS SOMETIMES SHARP AND CONSTANT , OTHER TIMES ITS JUST UNBEARABLE. I HAVE GAINED A TREMENDOUS AMOUNT OF WEIGHT. I'M DEPRESSED AND STRESSED OUT FROM ALL OF THE CONSTANT HEADACHE S AND EAR RINGING. I KEEP AN INFECTION OF SOME SORT WETHER IT BE EAR, BACTERIA, UTI, OR SOMETHING. MY BODY ACHES FROM MY JOINTS TO JUST IN GENERAL. I'M ALWAYS TIRED NEVER HAVING MUCH ENERGY TO DO ANYTHING. MY CHILDREN ARE SUFFERING. I WAS PERFECTLY FINE AND COMPLETELY HEALTHY BEFORE THIS LIFE ALTERING PROCEDURE. IMMEASURABLE, MOOD SWINGS, EXTREMELY HEAVY PERIODS, CRAMP. I'M ALWAYS MOODY FROM ALL OF THE CHANGES MY BODY HAS BEEN GOING THROUGH. THE WORST THING IS THAT WHEN YOU DON'T HAVE INSURANCE YOU JUST HAVE TO SUFFER THROUGH THIS. THESE DEVICES AREN'T MEANT TO GO INTO THE HUMAN BODY AND IF I HAD OF KNOWN I WOULD SUFFER TO THIS DEGREE I WOULD HAVE JUST PREFERRED TO GIVE LIFE. THIS IS BY FAR THE WORST DECISION I HAVE EVER MADE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041827	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 6/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT IN WITH THE IDEA THAT THE IMPLANTATION WOULD BE SLIGHTLY UNCOMFORTABLE, ACCORDING TO MY DR CONSULTATION. WELL, MY IDEA WAS SHATTERED WITH PURE PAIN AS THE IMPLANTING BEGAN. MY DR TALKED TO ME THROUGH EACH STEP, BUT IT DIDN'T HELP. I BEGAN TO CRY AND GROAN THROUGH AGONY. SHE ASKED IF I WAS FEELING A LOT OF PAIN. I REPLIED, "YES." BEFORE BEGINNING THE 2ND IMPLANTATION, SHE GAVE ME SOME ADDITIONAL LOCAL ANESTHETIC. SHE AND HER COLLEAGUES LEFT THE ROOM. ONE OF THE DR'S COLLEAGUES PLACED HER HAND ON MY SHOULDER WHILE I LAID ON THE TABLE, AS TO GIVE ME COMFORT THROUGH THE PAIN. A FEW MINUTES WENT BY AND THEY RETURNED. THE 2ND IMPLANT WAS JUST AS HORRIBLE AS THE FIRST. AFTER THE IMPLANTATION WAS FINISHED THE DR CAME IN AND ASKED HOW I FELT. I TOLD HER THAT I COULD FEEL THE COILS INSIDE OF ME. SHE EXPLAINED THAT WHAT I FEELING IS SORENESS AND IT SHOULD GO AWAY. WEEKS LATER, I COULD STILL FEEL THE COILS INSIDE OF ME. WITHIN ONE MONTH I BEGAN TO EXPERIENCE SEVERE HOT FLASHES. I WOULD WAKE UP IN THE MIDDLE OF THE NIGHT FULL OF SWEAT. ALONG WITH THE HOT FLASHES, MY PERIOD BECAME EXTREMELY HEAVY, CLOTTY, AND PAINFUL. PRIOR TO ESSURE, MY PERIODS WERE LIGHT AND PAINLESS. ONE MONTH AFTER ESSURE, MY WEIGHT ALSO BEGAN TO CLIMB. I HAD GAINED 23 POUNDS IN 11 WEEKS. I WAS EXERCISING REGULARLY, ALONG WITH A BALANCED DIET. DR DID NOTATE THAT MY WEIGHT SAW A SIGNIFICANT INCREASE. AS MONTHS WENT BY MORE SIDE EFFECTS BEGAN TO SURFACE. PELVIC PAIN (THIS IS DAILY), PAIN DURING INTERCOURSE, YEAST INFECTIONS, BACTERIAL INFECTIONS, FATIGUE, MOOD SWINGS, HAIR LOSS AND INFLAMED BELLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041828	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 12/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED GETTING SEVERE HEADACHES, FEELING FOGGY HEADED, SEVERE ABDOMINAL PELVIC PAIN, ESPECIALLY BY TUBE AREA SIDES, JOINT PAIN, DIZZINESS, PAIN IN HIP, LEFT LEG. NOW THREE YEARS LATER, I HAVE BEEN SICK CONSTANTLY, HAD ER VISIT, AFTER WE VISIT, CYSTS NOW IN OVARIES, CHRONIC PAIN, SEVERE AND PAINFUL PERIODS WITH HEAVY BLEEDS, CHRONIC FATIGUE, HEADACHES THAT HAVE NOT GONE AWAY, SKIN RASHES THAT COME AND GO WITH TEST DINE TO RULE OUT MAJOR ISSUES THAT ARE NEGATIVE BUT SYMPTOMS AUTO IMMUNE STUFF NEVER HAD TILL ESSURE, VISION ISSUES, LOSS IF HAIR, BLOAT THAT WON'T GO AWAY, DEPRESSION, PALPITATIONS YET HEART IS HEALTHY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041829	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 11/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT FIRST IT CAME ON AS THE WORST MIGRAINE OF MY LIFE. I HAD NEVER EXPERIENCED MIGRAINES BEFORE. THEY STILL CONTINUE TILL THIS DAY. I ALSO STARTED TO GAIN WEIGHT WHICH I STILL CAN NOT GET OFF. THERE'S NO DOCTOR THAT CAN FIGURE OUT WHY. I ALSO HAVE EXTREME FATIGUE THAT INHIBITS MY DAILY FUNCTIONS. AND DEPRESSION, I DON'T KNOW IF IT'S FROM THE MIGRAINES, WEIGHT GAIN AND FATIGUE BUT IT'S THERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041830	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 3/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT'S AMAZING HOW GETTING THE ESSURE REMOVED FROM YOUR BODY CAN MAKE YOU FEEL. I NO LONGER HAVE HOT FLASHES, NIGHT SWEATS, HIVES, ITCHY SKIN, MY HAIR IS NO LONGER COMING OUT IN GABS. I'M NO LONGER ON ANTI DEPRESSANTS. AND THE CHRONIC BACK PAIN I HAD IS GONE. ESSURE DOES NOT WORK. I'M PROVE. PREGNANT YEAR AFTER IMPLANT AND BEING CONFIRMED BLOCKED. THEN YEARS LATER A MIGRATED COIL. HOW CAN YOU ALLOW THIS TO REMAIN ON THE MARKET. SINCERELY, (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041831	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 8/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPS, WORSEN BACK PAIN, HAIR LOSS, POOR CIRCULATION, HORMONAL IMBALANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041832	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC MIGRAINES, CHRONIC FATIGUE, WEIGHT GAIN, BLOATING, INFLAMMATION, HEAT INTOLERANCE, HEAVY BLEEDING, BACK PAIN, CRAMPS, SHARP PAINS, BRAIN FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041833	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 8/15/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATED STOMACH, RINGING IN EARS, BRAIN FOG, NO DESIRE TO HAVE SEX AND SKIN REACTIONS ON MY FACE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041834	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 1/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED IN (B)(6), DESPITE THE FACT THAT I HAD WANTED A TUBAL LIGATION. SINCE THE DAY OF (B)(6) 2015 I HAVE HAD BLOATING. SERIOUS PAINS IN MY STOMACH AND BACK. I HAVE GAINED 23 POUNDS SINCE DESPITE THE FACT THAT I EAT HEALTHY AND WORK OUT 4 TIMES A WEEK. SOME DAYS I CAN NOT GET UP. I RECENTLY HAD A MISCARRIAGE ON (B)(6) 2015. I OFTEN PASS OUT, I AM ALWAYS FATIGUED. I HAVE DAILY PAIN. NO AMOUNT OF MEDICATION I TAKE MAKES THE PAIN SUBSIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041835	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWELLING OF THE ABDOMEN. EXTREMELY HEAVY PROLONGED MENSTRUAL. MIGRAINES (EVERYDAY). WEIGHT GAIN (60 PDS). BECAUSE OF THE WEIGHT GAIN, I HAVE BLOOD PRESSURE AND PRE-DIABETIC. HAIR THINNING. INSOMNIA. DEPRESSION. MEMORY FOG. MUSCLE WEAKNESS. JOINT PAIN. SWOLLEN CERVIX (DURING PAP SMEARS) AND BLEEDING AT THE TOUCH OF THE SWAB. PAIN DURING INTERCOURSE. UNBEARABLE PAIN DURING MENSTRUATION. PAIN ON MY LEFT SIDE OF MY ABDOMEN. ABDOMINAL CRAMPING. INCREASED DISCHARGE. MOOD SWINGS. BODY TEMPERATURE IS HIGHER AND HAVE NIGHT SWEATS. SKIN PATCHES AND ACNE. LETHARGIC. LOSS OF ENERGY. EYE SIGHT ISSUES. "HANDS ARE SWOLLEN AND NUDE ALMOST EVERYDAY."

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041836	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 11/12/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DENTAL CRACKING. JOINT ISSUES. FIBROMYALGIA. ACNE. MIGRAINES. SKIN ISSUES. SEVERE WEIGHT GAIN. CONSTANT BONE PAIN. IRREGULAR CYCLES. ABNORMALLY HEAVY CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041837	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 2/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BACK PAIN, MIGRAINES, MOOD SWINGS, STOMACH BLOATING, STOMACH CRAMPS, TIREDNESS, LEGS CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041838	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 8/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEFT SIDE MIGRAINE HEADACHES, BACK ACHES, PELVIC PAIN, EXTRA SCAR TISSUE, COIL MOVENT AND NEED OF A HYSTO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041839	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIC REACTIONS/RASH, ITCHY FEELING INSIDE, HEAVY WORSE PERIODS, WEIGHT GAIN, MAJOR BLOATING, SIDE PAIN, HEADACHES, TOOTH DECAY AND LOSS. ANXIETY, HAIR LOSS, HAIR THINNING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041840	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 10/23/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE SYMPTOMS HAVE BEEN ONGOING SINCE 2009 WHEN I GOT ESSURE. HORRIBLE BLOATING ALL THE TIME, PAIN HEAVY MENSTRUATION AND OVULATION THAT FEEL LIKE LABOR PAINS, LOWER BACK PAIN, WEIGHT GAIN, THINNING HAIR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041841	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 6/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041841 #(B)(4) AFTER DISCUSSION WITH MY PCP, SHE AGREED TO HELP ME INVESTIGATE TO SEE IF ESSURE IS CAUSING MY SYMPTOMS. SHE REFERRED ME TO AN ALLERGIST WHO DID A T.R.U.E PATCH TEST, WHICH REVEALED THAT I AM ALLERGIC TO BOTH NICKEL AND AMP; GOLD. MY ALLERGIST, DR. (B)(6), TOLD ME, "YOU NEED TO GET THOSE COILS OUT OF YOU." MY PCP THEN REFERRED ME TO AN OB/GYN, DR. (B)(6), WHO IS FULLY AWARE OF THE PROBLEMS WITH ESSURE, AND HAS, IN FACT, SO FAR REMOVED THE ESSURE COILS FROM FOUR PATIENTS. I WILL BE HER FIFTH ESSURE REMOVAL. MY HYSTERECTOMY IS SCHEDULED FOR (B)(6), 2015. PLEASE TAKE THIS MEDICAL DEVICE OFF THE MARKET. IT IS ADVERSELY AFFECTING THOUSANDS OF WOMEN. IT SHOULD NEVER HAVE BEEN PUT ON THE MARKET AS THERE WERE NEVER ANY LONG-TERM STUDIES DONE. THE FDA FAILED IN ITS OVERSIGHT IN THE CASE OF ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041842	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 5/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTING IN (B)(6) OF 2013 I STARTED HAVING BAD PERIODS THAT WERE LONGER AND BLED A LITTLE MORE. THEN I STARTED TO HAVE BOWEL PROBLEMS WITH BLEEDING HAD TO HAVE SURGERY TO FIX A FISSURE. ALSO HAVE RECURRING HEMORRHOIDS. THEN IN (B)(6) OF 2014 I STARTED HAVING URINE PROBLEMS BAD TO WHERE I STARTED WETTING MYSELF AND HAVING EVEN MORE UTIS AND CONSTANT PAIN IN MY KIDNEY AREA ALSO LOWER BACK PAIN. I HAVE HAD SUCH BAD MOOD SWINGS SINCE PLACEMENT OF THE DEVICES TO WHERE I HAVE TO BE ON MEDICATION. I HAVE BEEN ANEMIC ALSO. STARTING IN (B)(6) OF 2015 MY PERIODS STARTED GETTING SO BAD I WAS HOSPITALIZED AND HAVE BEEN TAKING PAIN MED FOR CONSTANT ABDOMINAL PAIN. I HAVE TO HAVE SURGERY TO HAVE THEM REMOVED ALONG WITH MY UTERUS AND FALLOPIAN TUBES BECAUSE OF EVERYTHING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041843	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 5/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, HEAVY MENSTRUAL CYCLE, NAUSEA, VOMITING, LEG CRAMPS, HOT FLASHES, HAIR GROWTH ON MY FACE, MOOD SWINGS, DEPRESSION, MOST OF ALL SEVERE ABDOMINAL PAIN, UNEXPLAINED RASHES AND ECZEMA ON MY HANDS. ALSO BOUTS OF COLITIS THAT I'VE BEEN HOSPITALIZED FOR. CONSTIPATION AND DIARRHEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041844	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 11/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RED, BUMPY RASH THROUGHOUT STOMACH, BACK, CHEST AND UPPER THIGHS. NO ALLERGIES KNOWN, NO CHANGE IN DETERGENTS, SOAPS, LOTIONS ETC. FREQUENT MIGRAINES. IRREGULAR MENSTRUAL CYCLES. INCLUDING LARGE CLOTS, PAIN WITH USE OF TAMPONS, PAINFUL INTERCOURSE, LACK OF SEXUAL DESIRE, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041845	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 9/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN UNDER RIGHT RIB. PAIN IN RIGHT SIDE PELVIC AREA. SHORTNESS OF BREATH. HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041846	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 12/31/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN RADIATING TO BOTTOM RIB FRONT AND BACK. LEFT ESSURE COIL IS MISSING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041847	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 3/24/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SKIN RASH, JOINT AND MUSCLE ACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041848	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 3/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN 2006-2007 BLEEDING, CRAMPING AND ANEMIA. IN 2007 PARTIAL HYSTERECTOMY. IN 2007-2015 CRAMPING, STOMACH SWELLING, HEAD ACHES, VAGINAL PAIN, FATIGUE, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041849	BAYER	4/6/2015	4/6/2015

Event Information:

Event Date (B3): 8/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM EXPERIENCING TERRIBLE BACK PAIN AND FATIGUE. SINCE ESSURE I GAINED 20LBS, HAVE TERRIBLE HEADACHES AND MAJOR CRAMPING. SINCE I GOT ESSURE I HAVEN'T HAD A CYCLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042061	BAYER	4/6/2015	4/14/2015

Event Information:

Event Date (B3): 10/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use:
Implant Date (E6): 10/31/2012
Explant Date (E7): 12/31/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED ON (B)(6) 2012 BY MY OB/GYN. ABOUT 6 MONTHS AFTER THE IMPLANT I BEGAN TO FEEL THINGS THAT WERE NOT RIGHT WITH MY BODY. I WENT TO SEE MY PRIMARY DOCTOR AND WE RAN SOME TESTS (BLOOD, XRAYS) AND NOTHING WAS FOUND. I WENT TO THE ALLERGIST WHO FOUND THAT I HAD MANY ALLERGIC REACTIONS I HAD NOT HAD PREVIOUSLY. I TESTED POSITIVE FOR NICKEL, AN ALLERGY I HAD ALWAYS HAD. I WENT BACK TO MY PRIMARY AND AFTER GOING THROUGH MY CHART, I BEGAN RESEARCHING ESSURE SIDE EFFECTS. THIS WAS THE ONLY OUT OF THE ORDINARY PROCEDURE IN MY MEDICAL HISTORY. BEFORE MY BILATERAL SALPINGECTOMY, MY SYMPTOMS WERE: CRAMPING, STABBING PELVIC PAIN, HOT FLASHES, NIGHT SWEATS, BLEEDING AND SPOTTING AFTER SEX, PAINFUL INTERCOURSE, FREQUENT YEAST INFECTIONS, SWELLING OF THE VAGINA, ITCHING, BURNING AND STINGING OF MY VAGINAL ENTRANCE, ABDOMINAL SPASMS AND TWITCHING, BACK, JOINT, LEG AND HIP PAIN, NAUSEA, GAS AND CONSTIPATION, SEVERE BLOATING AND SWELLING OF THE ABDOMINAL AREA, HEARTBURN, HEADACHES AND MIGRAINES, CONSTANT DIZZINESS, BRAIN FOG, CLOUDINESS AND FORGETFULNESS, ANXIETY ATTACKS, MOOD SWINGS, DEPRESSION, CONSTANT RINGING IN EARS, HEIGHTENED ALLERGIES AND ALLERGIC REACTIONS, HIVES AND RASHES, CYSTS AND BOILS IN VAGINAL AND RECTAL AREA, SWELLING OF THE LEGS AND FEET, HAIR LOSS AND WELTS IN SCALP, TEETH SENSITIVITY, BLURRED VISION AND FLOATERS, DRY SKIN AND EYES. AFTER MY BILATERAL SALPINGECTOMY, MY SYMPTOMS ARE: VAGINAL DISCHARGE, CRAMPING, STABBING PELVIC PAIN, URGENT AND FREQUENT URINATION, BLEEDING AND SPOTTING AFTER SEX, PAINFUL INTERCOURSE, FREQUENT YEAST INFECTIONS, SWELLING OF THE VAGINA, ITCHING, BURNING AND STINGING OF MY VAGINAL ENTRANCE, BACK, JOINT, LEG AND HIP PAIN, NAUSEA, GAS AND CONSTIPATION, SEVERE BLOATING AND SWELLING OF THE ABDOMINAL AREA, HEARTBURN, HEADACHES AND MIGRAINES, CONSTANT DIZZINESS, TINGLING

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AND NUMBNESS IN ARMS, DEPRESSION, CONSTANT RINGING IN EARS, HEIGHTENED ALLERGIES AND ALLERGIC REACTIONS, HIVES AND RASHES, CYSTS AND BOILS IN VAGINAL AND RECTAL AREA, SWELLING OF THE LEGS AND FEET, HAIR LOSS AND WELTS IN SCALP, TEETH SENSITIVITY, BLURRED VISION AND FLOATERS, DRY SKIN AND EYES, SEVERE BLOATING AND SWELLING OF THE ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00234	BAYER HEALTHCARE LLC	4/7/2015	4/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/17/2007
Explant Date (E7): 5/13/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT FROM A CONSUMER IN UNITED STATES WAS IDENTIFIED ON AN INTERNET PLATFORM ON (B)(4) 2013. THE FEMALE CONSUMER OF UNSPECIFIED AGE REPORTED SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PREGNANCY (DEVICE FAILED). ADDITIONAL INFORMATION RECEIVED ON (B)(4) 2013. NO INFORMATION WAS GIVEN ON CONSUMER'S PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. CONSUMER HAD THREE CHILDREN. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT BIRTH CONTROL. ON AN UNSPECIFIED DATE, THE CONSUMER HAD HER FOURTH CHILD WITH ESSURE. SHE ALSO STATED THAT SHE EXPERIENCED EXCRUCIATING PAIN AND, DUE TO THIS PAIN, SHE COULD NEITHER SIT NOR STAND. NO FURTHER DETAILS WERE REPORTED. CONSUMER CONSIDERED THAT BOTH EVENTS WERE RELATED TO ESSURE. ADDITION DUE TO INTERNAL REVIEW OF INFORMATION RECEIVED ON (B)(4) 2013: IT WAS STATED THAT CONSUMER'S FOURTH CHILD WAS FOUR AT THE TIME OF REPORTING. FOLLOW-UP INFORMATION RECEIVED FROM THE CONSUMER VIA HEALTH AUTHORITY (#(B)(4)) ON B)(4) 2015: CONSUMER REPORTED ESSURE WAS PLACED ON (B)(6) 2007 AND SHE EXPERIENCED EXPULSION OF R (INTERPRETED AS RIGHT) COIL IN 2007 THROUGH VAGINAL OPENING. HSG (HYSTEROSALPINGOGRAM) TEST CONFIRMED THAT BOTH SIDES WERE OCCLUDED (DATE NOT REPORTED). IN 2009 SHE HAD A POSITIVE PREGNANCY AND DELIVERY. COMPLICATIONS THROUGHOUT INCLUDED CHRONIC PELVIC PAIN, HEAVY PERIODS, PAINFUL INTERCOURSE, UTERINE POLYPS, OVARIAN CYSTS, WEIGHT GAIN, ABDOMINAL SWELLING, INABILITY TO SIT OR STAND FOR SHORT AND LONG PERIODS AT A TIME. DISPLACEMENT OF LEFT COIL INTO UTERUS, CONSTANT METAL SMELL, CONSTANT YEAR INFECTIONS, EMOTIONAL, PHYSICAL, AND PSYCHOLOGICAL DISTRESS. THE LEFT COIL WAS SUPPOSEDLY REMOVED IN 2013. CT (COMPUTED TOMOGRAPHY) SCAN IN 2013 CONFIRMED IT WAS STILL IN

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PLACE AND THE CONSUMER WAS SEEN BY A SECOND DOCTOR WHO EVENTUALLY HAD TO PERFORM A TOTAL HYSTERECTOMY ON (B)(6) 2014. CASE UPGRADED TO INCIDENT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED; EXPERIENCED EXPULSION OF R (RIGHT) COIL THROUGH VAGINAL OPENING AND 2 YEARS LATER HAD A PREGNANCY WITH ESSURE. APPROXIMATELY, 5 YEARS AFTER DELIVERY SHE WAS SUBMITTED TO A TOTAL HYSTERECTOMY DUE TO DISPLACEMENT OF LEFT COIL INTO UTERUS. ALL EVENTS ARE LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. DISPLACEMENT OF LEFT COIL INTO UTERUS, REGARDED AS DEVICE DISLOCATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE, WHILE THE REMAINING EVENTS ARE NON-SERIOUS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, RIGHT ESSURE COIL WAS EXPELLED IN THE SAME YEAR OF ESSURE INSERTION; THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED PREGNANCY; HOWEVER, SINCE CONSUMER STATED HSG TEST REVEALED BILATERAL TUBAL OCCLUSION AN ESSURE'S CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALTHOUGH, IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF THE DISPLACEMENT OF LEFT COIL INTO UTERUS IS UNKNOWN, GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED AND DUE TO THE REQUIRED INTERVENTION (HYSTERECTOMY) THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW UP 01-JUL-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00235	BAYER HEALTHCARE LLC	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 4/4/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5038865) IN UNITED STATES ON 09-MAR-2015 WHICH REFERS TO THE CONSUMER HERSELF OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2006. SHE REPORTED THAT SHORTLY AFTER THE ESSURE PROCEDURE SHE WAS HOSPITALIZED WITH DEBILITATING MIGRAINES AND WAS SENT HOME WITH A PRESCRIPTION. SHE ALSO EXPERIENCED CONSTANT NAUSEA, BACK AND PELVIC PAINS, SEVER MENSTRUAL CYCLES, WAS UNABLE TO HAVE INTERCOURSE WITHOUT EXCRUCIATING PAIN, DIZZINESS AND WEIGHT LOSS. FOLLOW-UP FROM 23-MAR-2015: UNABLE TO REACH CONSUMER BY PHONE. HENCEFORTH, NO FURTHER FOLLOW UP CAN BE PURSUED BY PHONE. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 31-MAR-2015. (B)(4). FINAL ASSESSMENT THIS CASE IS FOR ESSURE 205 WITH PLACEMENT DONE IN 2006. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT

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CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED CASE REPORT RECEIVED VIA REGULATORY AUTHORITY REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHORTLY AFTER PROCEDURE, WAS HOSPITALIZED WITH DEBILITATING MIGRAINES. THIS EVENT IS SERIOUS DUE HOSPITALIZATION AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MIGRAINE IS AN EPISODIC DISORDER, CHARACTERIZED BY A SEVERE HEADACHE GENERALLY ASSOCIATED WITH NAUSEA, AND/OR LIGHT AND SOUND SENSITIVITY. GIVEN THE CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE TOTALLY EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 02-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED CASE REPORT RECEIVED VIA REGULATORY AUTHORITY REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00236	BAYER HEALTHCARE LLC	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/10/2012
Explant Date (E7): 11/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 09-MAR-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2012 FOR CONTRACEPTION, AS SHE SAID THAT SHE WAS DONE HAVING CHILDREN. CONSUMER REPORTED TO A NEWS MEDIA THAT THE ESSURE IMPLANTATION WAS PAINFUL (THE PAIN WAS EXCRUCIATING), LEAVING HER FAINT AND DIZZY. OTHER SYMPTOMS CAME ALMOST IMMEDIATELY: SWOLLEN LYMPH NODES; A BURNING SENSATION IN HER VEINS, PELVIS AND ABDOMEN; NUMBNESS IN HER FACE AND ARM; MUSCLE TWITCHES; FATIGUE; A JOLTING SENSATION THAT FELT LIKE ELECTRICAL SHOCKS; AND A METALLIC TASTE IN HER MOUTH. SHE ADDED THAT SHE LOST 10 POUNDS IN THE TWO WEEKS AFTER IMPLANTATION. SHE STATED THAT SHE HAD AN IMMEDIATE REACTION. THE CONSUMER FOLLOWED UP WITH HER DOCTOR, WHO SAID HER ESSURE IMPLANTS WERE FINE. WHATEVER WAS GOING ON WITH HER, HE SAID, WASN'T DUE TO THE IMPLANTS. SHE WAS REFERRED TO THREE DIFFERENT DOCTORS AND VISITED THE EMERGENCY ROOM NUMEROUS TIMES. THREE PAIN-FILLED MONTHS AFTER GETTING HER ESSURE PROCEDURE, SHE SAID SHE CONNECTED WITH A SURGEON WHO AGREED THAT WHATEVER WAS GOING ON LIKELY STEMMED FROM THE IMPLANTS IN HER FALLOPIAN TUBES. IN (B)(6) 2012, SHE HAD BOTH HER FALLOPIAN TUBES REMOVED IN A DOUBLE SALPINGECTOMY. DESPITE HAVING HAD HER FALLOPIAN TUBES REMOVED, HER SYMPTOMS HAVE PERSISTED. SO, FINALLY, IN (B)(6) 2014 SHE WENT IN FOR A FULL HYSTERECTOMY. AFTER THE SURGERY, A PATHOLOGY REPORT REVEALED SHE WAS SUFFERING FROM ENDOSALPINGIOSIS, WITH FALLOPIAN TUBE TISSUE GROWING ON THE OUTSIDE OF HER UTERUS. AFTER THAT, THE CONSUMER WAS FEELING HEALTHIER, FOR THE MOST PART, BUT STILL STRUGGLES. EARLIER IN 2015 SHE WENT TO THE EMERGENCY ROOM TWICE IN A SINGLE WEEK WITH INTENSE PAIN AND NUMBNESS, SYMPTOMS OF THE FIBROMYALGIA SHE BELIEVED STEMS FROM HER ESSURE IMPLANTS.

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FOLLOW-UP RECEIVED ON 12-MAR-2015: INFORMATION RECEIVED STATES THAT CONSUMER BELIEVES HER FIBROMYALGIA WAS CAUSED BY ESSURE IMPLANTS. SHE CONTINUES TO SUFFER YEARS AFTER HER INITIAL PROCEDURE AND WORRIES HER ENERGY WILL NEVER RETURN. ADDITIONALLY, IT WAS REPORTED THAT CONSUMER WAS FORCED TO GO TO THE EMERGENCY ROOM BECAUSE OF HER FIBROMYALGIA. SHE SPENT MONTHS IN PAIN AND, EVENTUALLY, HAD SURGERY TO REMOVE THE IMPLANTS, BUT HER HEALTH CONTINUES TO SUFFER. ALSO ACCORDING TO CONSUMER, SHE BEGAN TO DEVELOP PROBLEMS IMMEDIATELY AFTER THE PROCEDURE, AND THEY CONTINUE TO AFFECT HER LIFE. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 18-MAR-2015. (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BURNING SENSATION IN PELVIS; SHE STATED SHE HAD THREE PAIN-FILLED MONTHS UNTIL ESSURE DEVICES WERE REMOVED BY BILATERAL SALPINGECTOMY. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, GIVEN THE CLOSE TEMPORAL RELATIONSHIP BETWEEN THE REPORTED PAIN AND ESSURE PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION FOR DEVICES REMOVAL. IN ADDITION NON-SERIOUS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW UP WILL BE PURSUED SINCE THIS IS A LAYPRESS CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00237	BAYER HEALTHCARE LLC	4/7/2015	4/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 09-MAR-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER, WHO IS MOTHER OF THREE, STATES THAT ABOUT SIX MONTHS AFTER ESSURE PLACEMENT, FELT HER HEALTH DECLINE RAPIDLY. SHE BEGAN LOSING CLUMPS OF HER HAIR, GAINED 75 POUNDS, GOT MIGRAINES FOR THE FIRST TIME IN HER LIFE AND SUFFERED CONSTANT FATIGUE, ANXIETY AND DEPRESSION. CONSUMER ALSO INFORMED THAT, WHEN SHE FINALLY FIGURED OUT IT WAS ESSURE CAUSING HER HEALTH PROBLEMS, THE IDEA GAINED LITTLE TRACTION IN THE MEDICAL COMMUNITY. ACCORDING TO HER A STRING OF DOCTORS TOLD HER THAT WHATEVER WAS GOING ON WITH HER HAD NOTHING TO DO WITH THE BIRTH CONTROL IMPLANTS. CONSUMER HAS BEEN FEELING HEALTHIER SINCE A HYSTERECTOMY PERFORMED IN 2012. FOLLOW-UP RECEIVED ON 18-MAR-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO

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BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SIX MONTHS LATER FELT HER HEALTH DECLINE RAPIDLY. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. 6 MONTHS AFTER PLACEMENT SHE FELT HER HEALTH DECLINE RAPIDLY. SHE GOT MIGRAINES FOR THE FIRST TIME IN HER LIFE AND SUFFERED CONSTANT FATIGUE, ANXIETY AND DEPRESSION. AFTER HYSTERECTOMY PERFORMED SHE WAS FEELING HEALTHIER. SINCE HYSTERECTOMY WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00238	BAYER HEALTHCARE LLC	4/7/2015	4/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 3/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038868) IN UNITED STATES ON 09-MAR-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT IN 2010 SHE HAD A TUBAL AND ALSO HAD THE ESSURE DEVICE PUT IN. ACCORDING TO REPORTER, ESSURE WAS PUT IN NOT TO PREVENT PREGNANCIES BUT TO STOP THE HEAVY BLEEDING. IN 2013, SHE STARTED DEVELOPING SEVERE PAIN IN HER GROIN AND IN HER RIGHT HIP AND, AFTER NINE LONG MONTHS, SEVERAL MAGNETIC RESONANCE IMAGES, X-RAYS AND ONE BLADDER DISTENTION, IT WAS FINALLY DISCOVERED THAT THE IMPLANTS HAD SLIPPED AND WERE SITTING SIDEWAYS IN HER TUBES. SHE WAS SCHEDULED FOR SURGERY THE VERY NEXT DAY ((B)(6) 2014), AT THAT TIME IT WAS ALSO DISCOVERED SHE HAD FLUID IN BOTH OF HER TUBES, A CYST AND ENDOMETRIOSIS. THROUGHOUT THE NINE MONTHS THAT IT TOOK FOR HER TO GET DIAGNOSED SHE WAS UN-RESPONSIVE TO ORAL PAIN MEDS AND FOR THE FIRST TIME SHE ACTUALLY USED THE NUMBER 10 TO DESCRIBE HER PAIN. THERE WAS A POINT THAT SHE WAS UNABLE TO WALK UP A FLIGHT OF STAIRS BECAUSE THE PAIN WAS SO INTENSE AND AT TIMES SHE HAD ALMOST PASSED OUT FROM PAIN AND NAUSEA. PTC INVESTIGATION RESULT WAS RECEIVED ON 18-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A

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REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LATER IT WAS DISCOVERED THE IMPLANTS HAD SLIPPED AND WERE SITTING SIDEWAYS IN HER TUBES. THE IMPLANTS WERE SURGICALLY REMOVED. THE REPORTED EVENT, INTERPRETED AS DEVICE DISLOCATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALTHOUGH, IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF THE EVENT IS UNKNOWN, GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 14-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00239	BAYER HEALTHCARE LLC	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038869) IN UNITED STATES ON (B)(6)2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT HER DOCTOR RECOMMENDED THE ESSURE PERMANENT BIRTH CONTROL IMPLANTS IN LIEU OF THE TUBAL LIGATION THAT SHE ORIGINALLY ASKED FOR. EVER SINCE, SHE HAS BEEN TO THE HOSPITAL MULTIPLE TIMES WITH EXTREME BLEEDING, CRAMPING AND DOUBLED OVER IN PAIN. SHE HAD THE ESSURE REMOVED IN 2012 BUT STATES THAT THE DAMAGE WAS DONE AND THE PROBLEMS CONTINUED. SHE IS HAVING A HYSTERECTOMY NEXT MONTH BECAUSE OF ESSURE. FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: 2015-008874 FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A

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POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME BLEEDING AND CRAMPING SHE DOUBLE OVER IN PAIN. THE DEVICES WERE REMOVED IN THE SAME YEAR OF INSERTION. THESE EVENTS, INTERPRETED AS GENITAL BLEEDING AND LOWER ABDOMINAL PAIN, WERE CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR; IN THIS CASE CONSIDERING THE CLOSE TEMPORAL RELATION BETWEEN THE REPORTED EVENTS AND ESSURE PROCEDURE AND IN THE LACK OF ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REPORTED (IMPLYING SURGICAL INTERVENTION) THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 02-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE C

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041850	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 2/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED TO PAIN WHILE HAVING INTECOURSE THEN BLEEDING AND BLOODING HEAD ACHE AND BODY SORENESS PLUS FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041859	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 9/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWO WEEK MENSTRUAL CYCLES, BOILS, ABDOMINAL PAINS, HIP AND JOINT PAIN, MAJOR BLOATING, BRAIN FOG, BLURRED VISION, BLEEDING DURING SEX, LACK OF SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041860	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 3/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN HAVING CONSTANT PAIN IN MY LOWER BACK THAT WON'T GO AWAY. THE PAIN SHOOTS AROUND THROUGH MY SIDES. I'M HAVING MUSCLE SPASM ON THE LEFT SIDE OF MY BACK. INFLAMMATION IN MY BACK. I WENT TO ER VISIT AND NOW STILL SEEING DOCTORS FOR THE NEXT STEP. I EXPERIENCE HEAVY BLEEDING DURING MY CYCLES, PAIN IN MY PELVIC AREA SOMETIMES FEELS LIKE YOUR RIPPING OUR INSIDE OUT WHEN YOU STAND UP. TERRIBLE HEADACHES. TO SCARED TO SEE WHAT THE OUTCOME IS GOING TO BE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041861	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 3/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I HAD ESSURE DONE IT TOOK A WHILE TO "PUT IT TOGETHER" WHAT THE PROBLEM WAS, OVER TIME IT BECAME INCREASINGLY WORSE, I HAD PAIN IN MY ABDOMEN, SHARP LOWER LEFT STOMACH PAIN, BACK PAIN, MY BLOOD PRESSURE WENT VERY HIGH AND I HAD TO TAKE MEDICATION FOR THIS, THEN THE EXTREME BLEEDING AND CLOTTING STARTED. IT JUST GOT WORSE AND WORSE UNTIL I WAS PRETTY SURE IT WAS THE ESSURE AND WENT TO THE DOCTOR. AFTER I DID , I WAS DIAGNOSED WITH ENDOMETRIOSIS AND AN ENLARGED UTERUS DUE TO THE ESSURE. I HAD TO THEN HAVE A PARTIAL HYSTERECTOMY. WHEN THEY OPENED ME UP THEY FOUND THAT THE LEFT ONE HAD PERFORATED MY LEFT TUBE, AND WAS BENT COMPLETELY BACK ON ITSELF. ALSO ALL OF MY VEINS AND WORKINGS GOING FROM MY UTERUS TO MY OVARY ON THE LEFT SIDE WAS INFLAMED TO BEING LIKE VARICOSE VEINS. I FEEL THIS WAS LIFE THREATENING DUE TO THE PERFORATION. IF THE ESSURE HAD COMPLETELY GONE THROUGH MY TUBE IT COULD HAVE BEEN THEN MIGRATING AND PERFORATING OR RUPTURING OTHER ORGANS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041863	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 1/7/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE EXPERIENCED WEIGHT GAIN, HAIR LOSS, EXTREME FATIGUE, CHRONIC PAIN IN MY MUSCLES AND JOINTS....HIPS, BACK, SHOULDERS, WRISTS, SWELLING, STIFFNESS, HIGH BLOOD PRESSURE, NOW HAVE TYPE 2 DIABETES, BLURRY VISION FOR YEARS AND NOT LOSING VISION IN MY RIGHT EYE MORE THAN LEFT, PAIN IN ABDOMEN, A LOT MORE PAINFUL CRAMPING AND SOMETIMES EXCESSIVE BLEEDING OR LONGER PERIODS, UNEXPLAINED HEART ATTACK TYPE SYMPTOMS BUT NO REASON CAN BE FOUND, DRY DRY SKIN, BLOATED BELLY LOOKING PREGNANT MOST OF THE TIME, VERY MOODY, ANXIETY, DEPRESSION DUE TO ALL THE PROBLEMS THAT KEEP POPPING UP, HEADACHES, AND FROM ALL THE ABOVE, I DO NOT FUNCTION AS I DID BEFORE ESSURE. I HAVE MISSED SOME OF THE BEST YEARS OF MY LIFE, NOT BEING ABLE TO BE WITH MY FAMILY NOR LIVING LIKE I WOULD HAVE, HAD I NEVER GOTTEN ESSURE! I WAS HEALTHY, HAPPY, FULL OF ENERGY, WOMAN, BEFORE ESSURE. I HARDLY EVER GOT SICK AND THE ONLY THING I EVER HAD DONE, WAS I HAD MY GALLBLADDER REMOVED IN 1992. NOW, I FEEL LIKE AN OLD WOMAN! I AM TRYING TO FIND A DOCTOR TO REMOVE THESE TOXIC COILS FROM MY BODY, SO THEY DO NOT CONTINUE TO KILL ME. HOPEFULLY, THEY HAVE NOT MIGRATED LIKE THEY HAVE ON SO MANY OTHER WOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041864	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 3/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE UPPER ABDOMEN PAIN AND SWELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041865	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 8/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN AND DISCOMFORT. MIGRAINES AND HEADACHES DAILY. EXTREME WEIGHT GAIN. EXTREME FATIGUE. NAUSEA. ANGER AND DEPRESSION. ENERGY LOSS. BACK PAIN DAILY. MUSCLE SPASMS. VISION LOSS. HAIR LOSS. MISSED MENSTRUAL CYCLES. MONTH LONG MENSTRUAL CYCLES. INSOMNIA YET, EXTREMELY TIRED. ABDOMINAL PAIN. UTI'S. YEAST INFECTIONS. PAINFUL INTERCOURSE. UNBALANCED. MEMORY LOSS. NICKEL ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041866	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 10/13/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN RUNNING DOWN RIGHT LEG, TEETH PAIN SO SEVERE THAT I COULDN'T CHEW FOOD, FIBROMYALGIA, DIFFICULTY STANDING AND WALKING, SVT EPISODES, ANAL FISTULA, ANAL FISSURE, EXCESS WEIGHT GAIN, FATIGUE, HASHIMOTOS, SEVERE HYPOTHYROIDISM, BLOATING/ABDOMINAL PAIN, IBS, ACID REFLUX, CHILLS, HOT FLASHES, EAR PAIN, SORE THROAT, SINUS INFECTIONS/SURGERY, FEVER, PRE DIABETES, MENTAL FOG, DEHYDRATION, NEUROPATHY , INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041867	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 11/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). AFTER ESSURE WAS IMPLANTED IN 2010.... I NOTICED I WAS CRAMPING A LOT, IN ADDITION TO LOWER BACK CRAMPS, LOW ENERGY AND MOOD SWINGS. I WENT TO MY DOCTOR SEVERAL TIMES AND HE SAID I WAS JUST EXPERIENCING REALLY BAD PMS. IN 2013, MY DOCTOR ORDERED AN ULTRA SOUND JUST TO MAKE SURE MY COILS WERE IN PLACE AND HE DETERMINED MY COILS WERE FINE. NOW IN (B)(6) OF 2014...I STARTED TO EXPERIENCE A SHARP PAIN IN MY LOWER RIGHT SIDE. I WENT TO MY REGULAR DOCTOR TO MAKE SURE I WASN'T HAVING ISSUES WITH MY KIDNEYS, APPENDIX OR ANYTHING ELSE. WHEN SHE PRESSED DOWN ON MY LOWER FRONT RIGHT SIDE, WE REALIZED THE PAIN WAS NEAR MY OVARIES. AT THIS POINT SHE ORDERED ME AN ULTRA SOUND, VAGINAL AND REGULAR. THE ONLY SHE SAW WAS A BLEEDING CYST ON MY LEFT OVARY...BUT MY PAIN IS ON THE RIGHT SIDE. SO SHE INSTRUCTED ME TO SEE MY OBGYN. HE SAID MY COILS APPEAR TO BE WHERE THEY SHOULD BE. AND INSTRUCTED ME TO RETURN TO SEE HIM ON TWO MONTHS TO SEE IF I CONTINUE TO FEEL THE PAIN. NEEDLESS TO SAY, THE PAIN IS CONSTANT AND HASN'T GONE AWAY. I AM CONCERNED AND AM ONLY WAITING FOR MY INSURANCE AT WORK TO KICK IN, IN ORDER TO HAVE THE COILS REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041868	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 3/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE DEVELOPED CYST MAJOR PAIN ALL IN MIDSECTION AND LOWER BACK HAIR LOSS FATIGUE MAJOR WEIGHT GAIN AND SEVER TENDERNESS ON MIDSECTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041877	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 4/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TESTING BLOOD WORK, ULTRASOUNDS, MEDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041879	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 12/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I FELT A SHARP SHIFT IN MY RIGHT SIDE AND BECAME DIZZY AND NAUSEOUS, FELT LIKE I COULD BE PREGNANT, WAS NAUSEOUS EVERY MORNING FOR 3 WEEKS, ALL TESTS CAME BACK NEGATIVE. I SKIPPED A PERIOD THEN BEGAN SPOTTING EVERY 2 WEEKS FOR 3 DAYS DOCTOR SAID MUST BE HORMONES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041921	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 3/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE FIBROMYALGIA, SO IT HAS ALWAYS BEEN EASY FOR ME TO WRITE EACH SYMPTOM OFF TO THAT, BUT THE MORE I HAVE RESEARCHED, I HAVE FOUND EVERY INDICATION LEANING TO ESSURE ISSUES. I NOW HAVE A HYSTERECTOMY SCHEDULED FOR (B)(6) 2015 TO REMOVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041922	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 9/19/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHE, BACK PAIN, ABDOMINAL PAIN, VISION PROBLEMS, HIP PAIN, HAIR LOSS, INSOMNIA, STOMACH PROBLEMS, BODY ACHING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041923	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 12/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, BLOATING OF STOMACH, CHRONIC PAIN (ENTIRE BODY), MUSCLE SPASMS IN BACK, SIDES AND LEGS ESPECIALLY WHEN SITTING OR DRIVING FOR LONG PERIOD OF TIME, DIZZINESS, BRAIN FOG, HEAVIER PERIODS, MIGRAINES, PROBLEMS COMPREHENDING WHAT PEOPLE SAY OR I READ, TROUBLE CONCENTRATING (USED TO MULTITASK, NOT ANYMORE). TROUBLE STANDING WHILE DOING DISHES DUE TO BACK PAIN. LOSS OF INTEREST IN ACTIVITIES AND HOBBIES DUE TO PAIN. RINGING IN EARS, DARK URINE, LOST INTEREST IN SEXUAL INTERCOURSE, PAINFUL WHEN I WAS HAVING SEXUAL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041924	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 3/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, BLEEDING, ANEMIA, NAUSEA, DIZZINESS AND FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041925	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 2/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN IN ABDOMEN AND BACK, FATIGUE, DENTAL ISSUES, DIFFICULTY WITH INTIMACY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041926	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 12/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE MONTHLY PERIODS. EXTREMELY HEAVY WITH PASSING OF MANY CLOTS. DEBILITATING CRAMPS AND SHARP PAINS. THIS HAS STARTED SINCE IMPLANTATION OF ESSURE DEVICE. I WAS NEVER ON A REGULAR CYCLE BUT NOW IT'S EVERY MONTH, SOME MONTHS I HAVE TWO PERIODS. I HAVE ALSO GAINED WEIGHT. MY HAIR IS FALLING OUT. MY STOMACH IS ALWAYS TENDER TO THE TOUCH. I HAVE BACK PAIN. I HAVE HORRIBLE LEG PAIN IN BOTH LEGS. I ALWAYS FEEL SHARP PAINS ON BOTH SIDES OF MY LOWER ABDOMEN. MY STOMACH BLOATS TO THE POINT OF LOOKING PREGNANT ON A DAILY BASIS. I HAVE ALWAYS BEEN A VERY ACTIVE BUSY WOMEN. I HAVE SPENT MORE TIME WITH HEATING PAD AND LYING DOWN SINCE THIS PROCEDURE. MY SEXUAL DESIRES HAVE LESSENED TO THE POINT OF MAKING MYSELF BE INTERESTED. MY HUSBAND AND I HAVE ALWAYS HAD HEALTHY SEX LIFE. I BLEED AFTER SEX AS WELL. INTERCOURSE IS PAINFUL TOO. I AM (B)(6) YEARS OLD WITH THREE CHILDREN. I CHOSE THIS METHOD OF BIRTH CONTROL BECAUSE IT SEEMED LIKE SIMPLE EASY WAY. HORMONES MAKE ME NAUSEATED, SO BIRTH CONTROL PILLS WERE NOT AN OPTION. I FEEL THAT THIS HAS RUINED MY LIFE. I AM SCHEDULED FOR A HYSTERECTOMY ON (B)(6). DUE TO THICK ENDOMETRIUM LINING AFTER 8 DAY EXTREMELY BAD PERIOD. I DO NOT WANT TO HAVE REOCCURRING D AND CS TO CONSTANTLY CHECK FOR CANCER. MY OB/GYM SUGGESTED THIS TO GET MY QUALITY OF LIFE BACK. I WONDER HOW BEING THROWN INTO MENOPAUSE IS THE ANSWER BUT AT LEAST PAIN WILL BE GONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041927	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 5/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODS BECAME VERY HEAVY, WITH LARGE CLOTS, AND SEVERE CRAMPING. HAIR LOSS, LOWER ABDOMINAL PAIN, WIDESPREAD JOINT PAIN, SIGNIFICANT DECREASE IN SEX DRIVE, AND WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041928	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, HEAVY, IRREGULAR PERIODS, CONSTANT PAIN AND CRAMPING. I ENDED UP GETTING A HYSTERECTOMY DUE TO THE SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041929	BAYER	4/7/2015	4/7/2015

Event Information:

Event Date (B3): 2/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HOT FLASHES, SEVERE PAIN IN RIGHT LOWER ABDOMEN, PAIN IN LOWER BACK, MIGRAINES, NAUSEA, WEIGHT LOSS, FATIGUE, DEPRESSION, ABDOMINAL SWELLING, WORSE PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041930	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 6/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SOON AFTER HAD CONSTANT BLOATING, FATIGUE, PAIN AND SORENESS IN PELVIC AREA. EVERY MONTH I THOUGHT I WAS PREGNANT FROM BEING SO NAUSEATED AND MENSTRUAL WASN'T ON TIME. WHEN IT DOES COME, I HAVE HEAVY BLEEDING UNLIKE EVER BEFORE AND VERY PAINFUL CRAMPS. MIGRAINES STARTED. NOW THEY GET SO BAD AND LAST FOR MONTHS AT A TIME. TEETH ARE BREAKING AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041931	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 7/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING CONSTANT HEADACHES AND ABDOMNAL PAIN, BLOATING AND VERY HEAVY PAINFUL MENSTRAL CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041932	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 11/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DON'T HAVE MY CYCLE FOR SIX TO SEVEN MONTHS. THEN WHEN I FINALLY DO I'M IN SO MUCH PAIN I CAN'T MOVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041933	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 3/16/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD SINCE I HAD THE PROCEDURE DONE. ALL I SUFFERED IS FROM BLOATING, WEIGHT GAIN, MY PERIODS ARE ALL OVER THE PLACE, PELVIC PAIN. I ALSO SUFFER FROM DULL BAD PAIN. I AM ALWAYS TIRED. I FEEL LIKE I HAVE NO STRENGTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041934	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 11/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALWAYS ITCHING, PELVIC PAIN, IRREGULAR PERIODS, HEADACHES, TINGLING OF LEGS, FATIGUE, ANXIETY, HAIR LOSS, SWEATS, LOWER BACK, PAIN WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041935	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 10/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED GETTING REALLY BAD MONTHLY MENSTRUAL PERIODS. SEVERE CRAMPING, PASSING LARGE BLOOD CLOTS, ABNORMAL BLEEDING AND SEVERE HEADACHES AT THIS TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041936	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ISSUES STARTED APPROXIMATELY 6 MONTHS AFTER SURGERY BUT I DON'T REMEMBER DATE OF PROCEDURE, I WILL GET THAT INFO. I STARTED WITH BLOATING AND PAIN IN MY ABDOMEN, APPROXIMATELY A YEAR AFTER PROCEDURE, I STARTED HAVING ITCHING AND "DISCHARGE IN MY VAGINAL AREA. OTHER ISSUES I HAVE CURRENTLY" HAVE HAD, HAIR THINNED, MEMORY ISSUES, ALLERGIES, BLOATING, CELLULITIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041937	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 8/2/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE PLACEMENT HAVE HAD THE FOLLOWING AFFECTS : BACK PAIN SHARP PAIN IN ABDOMEN AND VAGINA, LOW LIBIDO, DRYNESS, BOILS ON BODY, ACNE ON FACE THAT IS NOW DIAGNOSED AS LUPUS OF SKIN, CYST OVARIES, TENDERNESS OF BREAST, ELEVATED BLOOD LEVELS, HEADACHES, JOINT AND MUSCLE PAIN, BLACK OUT SPELLS, RINGING IN EARS, TINGLING OF HANDS AND FEET AS WELL AS SWELLING OF LEGS, FEET AND JOINTS . MUSCLE SPASMS OF ABDOMEN AND ARMS. PAIN IN RIGHT SIDE BODY FROM ABDOMEN DOWNWARD. KIDNEY CYST. VISION BLURRED RIGHT EYE. STILL HAVE DEVICE IN CURRENTLY . GOING TO NEW DR . REGARDING THIS IN (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041939	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 1/7/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, VAGINAL DISCHARGE, MAJOR DEPRESSION WITH SUICIDAL THOUGHTS, WEIGHT GAIN, ABDOMINAL DISTENTION, BODY ACHES, ELEVATED BLOOD PRESSURE, HEADACHES, GALLBLADDER ISSUES REQUIRING LAPAROSCOPIC REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041940	BAYER	4/7/2015	4/8/2015

Event Information:

Event Date (B3): 4/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PROBLEMS WITH ESSURE BEGAN IMMEDIATELY AFTER IMPLANTATION (B)(6) 2010. I BLED FOR 6 MONTHS AND WAS TOLD ITS NORMAL COURSE AFTER COIL INSERTION. SINCE THEN I'VE ALWAYS HAD TO WEAR A SUPER THICK TAMPON AND OVERNIGHT PAD WHEN 'IM ON MY MONTHLY CYCLE AND DON'T DARE GO ANYWHERE INCLUDING WORK. HAVING ESSURE HAS AFFECTED ME, MY CHILDREN, MY FAMILY AND MY INCOME. I SUFFERED FROM SEVERE PMDD ESPECIALLY A FEW DAYS BEFORE MY CYCLE. HAVING NEVER HAD CHRONIC HEADACHES MIGRAINES PRIOR TO ESSURE, I NOW HAVE WEEKLY HEADACHES THAT PREVENT ME FROM WORKING A FULL WEEK. HAVING TO TAKE SO MUCH TIME OFF HAS AFFECTED MY ANNUAL PAY BY AS MUCH AS (B)(6) BECAUSE OF THESE HEADACHES. MY EYESIGHT HAS RAPIDLY DETERIORATED IN 5YRS AND HAVE BEEN EXTREMELY SENSITIVE TO LIGHT AT TIMES WHERE I CANNOT OPEN MY EYES AND NEED ASSISTANCE WALKING. AN EYE DR SUGGESTED THAT AN AUTOIMMUNE DISEASE SUCH AS LUPUS COULD BE THE CULPRIT OF MY EYES REACTING TO INTERNAL INFLAMMATION. (ESSURES MAIN DESIGN IS TO CAUSE INFLAMMATION) MY HAIR ALSO HAS NOT GROWN PAST SHOULDER LENGTH DESPITE FREQUENT HAIRCUTS, TREATMENTS ETC. BEING A (B)(6) FEMALE, MY HAIR HAD NEVER BEEN THIS BRILLO TYPE TEXTURE PRIOR TO ESSURE. I CANNOT GET IT TO GROW AND IT REMAINS VERY OVER PROCESSED LOOKING. I HAVE NOT DYED OR COLOR TREATED MY HAIR IN ALMOST 4YRS. MY TEETH HAVE ALSO GROWN MORE YELLOW IN COLOR DESPITE ME BRUSHING AS MANY AS 3 TIMES A DAY. THEY FEEL SENSITIVE, WEAK, LOOSE, TINGLY ALMOST EVERYDAY. I CAN ALMOST PINPOINT EXACTLY WHERE THE RIGHT SIDE COIL IS BECAUSE I HAVE CONSTANT PRESSURE THERE. MANY TIMES I'M STOPPED IN WHATEVER I AM DOING WITH SHARP PELVIC PAINS THAT MAKE ME WANT TO PASS OUT. THESE PAINS ARE NEVER GRADUAL AND COME SUDDENLY. ITS NOT UNCOMMON TO HUNCH OVER AND HOLD ON TIGHTLY TO SOMETHING WHEN THESE PAINS COME. I'VE HAD TO WEAR UP TO 3

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PANTYLINERS PER DAY DUE TO DAILY UNCOMFORTABLE DISCHARGE. SEX WITH MY HUSBAND IS VERY PAINFUL, BUT WE MANAGE AND HAVE BECOME CREATIVE. MY NECK AND BACK ARE USUALLY SORE AND UNCOMFORTABLE. MY NIGHTS ARE SPENT TOSSING AND TURNING AND TRYING TO IGNORE THE PAIN IN MY BODY. ESSURE IS A MONSTER!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042041	BAYERS	4/7/2015	4/14/2015

Event Information:

Event Date (B3): 4/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/11/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVING PROBLEM WITH ESSURE BIRTH CONTROL DEVICE. SINCE IMPLANT (B)(6) 2012 HAVE GAINED 30 POUNDS. MOST WEIGHT GAIN IN THE FIRST YEAR, HAVE GONE FROM SIZE 2 TO SIZE 16. I AM HAVING BACK PROBLEM THAT IRRADIATE IN LEFT SIDE HIPS AND LEG, DIZZINESS, MEMORY PROBLEM, SHARP PAIN IN THE UTERUS AREA ON LEFT SIDE NOT CONSTANT, BUT HAPPEN A FEW TIMES A MONTH, MAJOR BLEEDING DURING PERIOD. I NOW HAVE TO WEAR DOUBLE PROTECTION FOR MINIMUM 8 DAYS STRAIGHT EVERY MONTH, LOSS OF LIBIDO, BLOATING EVERY EVENING, MY SIZE 16 IS TOO LARGE IN THE MORNING, AT THE END OF THE DAY WHERE I HAVE TO UNTIE MY PANTS THEY ARE TOO SMALL. I TOOK 7-8 MONTHS PREGNANT. EVEN IF I HAVE STARTED TRAINING SINCE THE PAST 2 YEARS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042048	BAYER	4/7/2015	4/14/2015

Event Information:

Event Date (B3): 12/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE PELVIC PAIN, HEAVY MENSTRUAL CYCLE, EXTREME WEIGHT GAIN. IRREGULAR MENSTRUAL CYCLE, BLOATING. MY BODY HAS NOT BEEN THE SAME SINCE GETTING THESE COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042068	BAYER HEALTH	4/7/2015	4/14/2015

Event Information:

Event Date (B3): 1/22/2015 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PERFORATION OF UTERUS DURING ELECTIVE HYSTEROSCOPIC TUBAL OCCLUSION PROCEDURE WITH ESSURE DEVICE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00240	BAYER HEALTHCARE LLC	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 774387

Single Use: Y
Implant Date (E6): 1/15/2010
Explant Date (E7): 11/15/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038898) IN UNITED STATES ON 09-MAR-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 774387, INSERTED ON (B)(6) 2010. SOON AFTER INSERTION, SHE STARTED HAVING SYMPTOMS THAT CHANGED HOW SHE LIVED HER LIFE. SHE HAD VERTIGO, NAUSEA, SHARP PAINS IN HER ABDOMEN TO THE POINT OF DROPPING HER TO HER KNEES, PAIN AND BLEEDING DURING SEXUAL INTERCOURSE, METALLIC TAKE (AS REPORTED) IN HER MOUTH, SEVERE BLOATING AND EXTREME FATIGUE. IN ADDITION CONSUMER REPORTED THAT SHE WAITED AND EXPLORED POSSIBILITIES WITH HER PHYSICIAN FOR OVER A YEAR BUT BY YEAR 2 SHE COULDN'T LIVE WITH IT ANYMORE AND THEY HAVE EXHAUSTED ALL OTHER OPTIONS. HER DOCTOR AGREED TO REMOVE THE ESSURE DEVICE HE HIMSELF IN ORDER TO ALLEVIATE CONSUMER'S PAIN. REMOVAL OCCURRED IN (B)(6) 2012 AND ALL OF HER SYMPTOMS ARE GONE. PTC INVESTIGATION RESULT RECEIVED ON 23-MAR-2015 (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED MEDICAL EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. (B)(4) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER

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774387 BUT NONE OF THESE CASES REFER TO A SIMILAR MEDICAL EVENT. NO BATCH SIGNAL CAN BE IDENTIFIED AT THIS TIME. REVIEW OF ASSOCIATED BATCH DOCUMENTATION DID NOT REVEAL ANY DEFICIENCIES OR GIVE ANY REASON TO SUSPECT A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SOON AFTER DEVICE PLACEMENT EXPERIENCED SHARP PAINS IN ABDOMEN TO THE POINT OF DROPPING ME TO MY KNEES. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, SOON AFTER INSERTION THE CONSUMER STARTED TO EXPERIENCE SHARP PAINS IN ABDOMEN TO THE POINT OF DROPPING TO HER KNEES . THEN, TWO YEARS LATER, ESSURE WAS REMOVED AND THE SYMPTOM HAS GONE (POSITIVE DECHALLENGE). CONSIDERING CLOSE TEMPORAL RELATIONSHIP AND POSITIVE DECHALLENGE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE INTERVENTION WAS IMPLIED (ESSURE REMOVAL) THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 17-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041941	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 8/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD PROBLEMS AS SOON AS THE DEVICE WAS IMPLANTED. I HAD SEVERE CRAMPING/STABBING PELVIC PAIN, CONSTANT BLEEDING, MEMORY LOSS, AND EXTREME FATIGUE. RESULTED IN MIGRATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041942	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 9/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN, ABNORMAL BLEEDING, WEIGHT GAIN, DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041943	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 8/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HEAVY VAGINAL BLEEDING AT THE BEGINNING OF (B)(6) OF 2014 AND IT WOULD NOT STOP. WAS IN THE HOSPITAL TWICE FOR BLOOD TRANSFUSIONS. ENDED UP HAVING A HYSTERECTOMY AT THE END OF (B)(6) OF 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041944	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 2/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS IS A LIST OF SYMPTOMS I HAVE SINCE ESSURE WAS PLACED. I AM GETTING COPIES OF REPORTS FROM MY HOSPITAL STAY, AND LABS I HAVE HAD SINCE ESSURE WAS PLACED LATER THIS WEEK. ANEMIA/ IRON DEFICIENCY; SHARP/STABBING PELVIC PAIN; OVARIAN CYSTS; PCOS (POLYCYSTIC OVARIAN SYNDROME); WEIGHT GAIN; MUSCLE SPASMS; HAIR GROWTH IN NEW PLACES; SKIN IRRITATION/ITCHING; GAS, CONSTIPATION, DIARRHEA; SEVERE BLOATING; BREAST PAIN/TENDERNESS; PAINFUL PERIODS; PAINFUL OVULATION; ANXIETY/PANIC ATTACKS; MOOD SWINGS; HEADACHES OR MIGRAINES; HEARTBURN; BOWEL ISSUES; CRAMPING; DISCHARGE; INSOMNIA; ALLERGIC REACTIONS HIVES, RASHES; CYSTS, BOILS, ACNE; PAINFUL INTERCOURSE; HEART PALPITATIONS; NAUSEA, VOMITING; BLEEDING/SPOTTING AFTER SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041945	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 6/18/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SOMETIME AFTER I RECEIVED THE ENSURE IMPLANT, MY MENSTRUAL CYCLE BECAME MUCH HEAVIER. THEN I STARTED BLEEDING IN BETWEEN PERIODS. THEN I STARTED HAVE PAIN IN UTERUS. FOUND OUT IN (B)(6) 2014 THAT THE ENSURE COIL HAD MIGRATED THROUGH MY FALLOPIAN TUBE AND PERFORATED MY UTERUS. I HAVE A HYSTERECTOMY SCHEDULED ON (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041949	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 3/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 2008 ((B)(6)) ESSURE PLACED. WT. GAIN. PAINFUL PERIODS. 2009 WT. GAIN PAINFUL PERIODS. RASH ON HANDS. SMALL FLUID FILLED BUMPS VERY ITCHY FOLLOWED BY PEELING SKIN LEAVING A BURNING RAW RED AREA. 2010-2011 ((B)(6)) WT GAIN. RASH CONTINUES PAINFUL PERIODS CONTINUE. INCREASED GAS AND BLOATING. 2012 GAS AND BLOATING SWELLING OF RIGHT ARM AND LEFT LEG. 2013 ((B)(6)) GAS AND BLOATING INCREASED SWELLING OF RIGHT ARM AND LEFT LEG SWELLING OF LEFT EYE. DIAGNOSED WITH GLUTEN INTOLERANCE. 2014 ((B)(6)) MIGRAINE HEADACHES. SWELLING OF ARMS AND LEGS SWELLING OF LEFT EYE AND FACE CONTINUE. MULTIPLE CHEMICAL SENSITIVITY. UNABLE TO USE MOST SOAPS LOTIONS AND SHAMPOO WITHOUT GETTING SICK. BRAIN FOG. ASTHMA LIKE EPISODES. ALLERGIC TO ALMOST EVERYTHING IT SEEMS. CAN'T BE AROUND PEOPLE THAT USE NORMAL PRODUCTS BECAUSE THIS CAUSES ME TO DEVELOP A RASH / MAKES IT HARD TO BREATHE IF I GET TO CLOSE. PAINFUL PERIODS CONTINUE. PAINFUL INTERCOURSE. (B)(6) 2015- PAINFUL PERIODS CONTINUE. PAIN MOSTLY IN THE LOWER BACK AND GROIN AREA HEAVY BLEEDING LASTING ABOUT 1 TO 2 WEEKS. SWELLING EPISODES WORSE THE WEEK BEFORE AND WEEKS OF MY PERIOD. DIAGNOSED WITH URTICARIA AND ANGIOEDEMA. PRIMARY CARE PHYSICIAN BELIEVES TO BE MOST LIKELY DUE TO ALLERGIC REACTION TO ESSURE IMPLANTS. WAITING FOR GYNECOLOGIST APPOINTMENT IN HOPES OF GETTING A HYSTERECTOMY SOON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041951	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 3/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING WITH MENSTRUAL CYCLE, FATIGUE, SEVERE HAIR LOSS, INSOMNIA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041952	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE LOWER ABDOMINAL PAIN, MY PERIODS ARE EXCRUCIATING AND REALLY HEAVY AND I HAVE SOFT BALL SIZES BLOOD CLOTS THAT COME OUT WHILE ON MY PERIOD I HAVE MUSCLE AND JOINT PAIN , I HAVE SEVERE PAIN DURING AND AFTER INTERCOURSE, I HAVE HORRIBLE MIGRAINES I HAVE STABBING PAINS IN MY LOWER ABDOMEN I HAVE WEIGHT GAIN AND I CAN'T LOSE IT. I HAVE HORRIBLE PAIN EVERYDAY THAT MAKES IT HARD FOR ME TO FUNCTION ESPECIALLY TAKING CARE OF 2 SMALL CHILDREN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041966	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 2/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE FIRST SYMPTOM THAT I FEEL WAS YEAST INFECTION BUT THE TEST CAME OUT NEGATIVE. THIS HAPPENED A FEW TIMES. THE DOCTOR SAID IT WAS VAGINITIS AND SUGGESTED TO CHANGE SOAP AND AVOID THE USE OF SOFTENERS SOMETHING THAT I ALREADY DO SINCE I WAS A TEENAGER. I USED DIFFERENT OINTMENTS AND DIDN'T STOPPED. I SUGGEST TO THE DOCTOR THAT IF IT COULD BE A POSSIBLE SIDE EFFECT OF THE NICKEL ON THE COILS AND SHE SAID THAT IT COULDN'T BE POSSIBLE SINCE THE COILS SHE PLACED ON ME WHERE NOT METAL. I ALSO COMPLAINT ABOUT LOWER BACK PAIN WHICH SHE DIAGNOSED AS ARTHRITIS AND PRESCRIBED NAPROXEN AND A MUSCLE RELAXER WHICH I STOPPED BECAUSE I STILL HAD LOWER BACK PAIN AND MUSCLE RELAXER MADE ME FEEL NUMBED AND SLEEPY. SINCE THE DOCTOR DIDN'T BELIEVE AND HAD NO INTEREST ON CAME UP WITH THE REAL PROBLEM, I STOPPED GOING WITH HER AND THEN I MOVED CITIES. I DIDN'T HAD A PRIMARY DOCTOR IN THIS CITY. NEITHER MEDICAL INSURANCE. THE BACK PAIN WAS VERY PERSISTENT AND EVERY TIME GETTING WORSE. I STARTED TO HAVE THERAPY AND MASSAGES FOR ABOUT TWO YEARS UNTIL MY THERAPIST SAID TO ME THAT HE COULDN'T UNDERSTAND WHY I WAS GETTING WORSE EVERY TIME INSTEAD OF GETTING BETTER. DURING THIS TIME, MY PHYSICAL COMPLAINTS WEREN'T ONLY LOWER BACK PAIN IT WAS ALSO UPPER BACK PAIN, JOINT PAIN, STOMACH BLOATING LIKE A PREGNANT WOMEN, GAINED WEIGHT, HEADACHES, MUSCLE STIFFNESS, PELVIC PAIN AND PAINFUL CRAMPS LIKE NEVER BEFORE AND EVERY TIME MORE PAINFUL. LEFT LEG PAIN AND PAIN IN BOTH HEELS, ANXIETY, ACNE IN FACE BUT MOST IN MY BODY, BREAST TENDERNESS AND PAINFUL LITTLE GLANDS WHEN I TOUCHED THEM AND PAINFUL AREAS IN MY BODY LIKE INNER LEGS, UNDER ARM , CLOSE TO THE RIBS AND UPPER HIPS THAT LATER WAS DIAGNOSED AS FIBROMYALGIA. IN (B)(6) 2015 I HAD MEDICAL INSURANCE COVERAGE WHICH FINALLY I HAD A DOCTOR APPOINTMENT. I HAD A COMPLETE BLOOD AND URINE LAB TEST WHICH EVERY THING

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CAME UP NORMAL. THE DOCTOR DECIDE TO HAVE A STOMACH ULTRASOUND TO CHECK ALL MY ORGANS AND SEE WHAT WAS CAUSING THE BLOATING. EVERY THING WAS NORMAL EXCEPT MY GALLBLADDER SHOWED STONES AND I WAS REFEREED TO THE SURGEON IMMEDIATELY SINCE SHE THOUGH THAT WAS THE CAUSE OF THE UPPER BACK PAIN. THE SURGEON REFEREED ME TO HAVE A ENDOSCOPY, BIOPSY AND A ANOTHER TEST TO CHECK THE FUNCTION OF THE GALLBLADDER WHICH SHOWED STILL GOOD FUNCTIONING. NO SURGERY TO HAVE GALLBLADDER REMOVED WAS NEEDED. SHE ALSO ORDER A TRANSVAGINAL ULTRASOUND WHICH DOCTOR SAID WAS NORMAL AND SHE REFEREED ME TO A OB/GYN. WHEN I ASKED FOR MEDICATION TO EASE THE PAIN SHE SUGGESTED TO SEE A PSYCHOLOGIST AND DIAGNOSED ME WITH "DEPRESSION" . AFTER I HAD ALL THIS TEST DONE, I WENT TO MY PRIMARY DOCTOR TO HAVE SOME KIND OF PAIN MEDICATION AND HE DIAGNOSED ME WITH FIBROMYALGIA AND PRESCRIBED CYMBALTA 30 MG WHICH HAS HELPED ME WITH ALL THIS MUSCLE PAIN BUT STILL IF SOME TOUCHES ME OR HUGS ME TIGHT; IT STILL PAINFUL BUT STILL HAVE UPPER AND LOWER BACK PAIN. AFTER WAITED ALMOST 3 MONTHS FOR THE OB/GYN APPOINTMENT. THIS DOCTOR PERFORMED A PAP TEST WHICH WAS VERY PAINFUL AND HAD BLOODY DISCHARGE FOR 4 DAYS AND SHE SUGGESTED TO PUT ME FOR 5 MONTHS ON BIRTH CONTROL PILLS AFTER I INFORMED HER AND SHE WITNESSED THE PELVIC PAIN WHICH IS MORE AGGRESSIVE ON THE LEFT SIDE, CRAMPS THAT SEEMS CONTRACTIONS AND BLOATED THAT SEEMS A 5 MONTH PREGGO BELLY. WHY BC PILLS IF I HAVE ESSURE A PERMANENT BIRTH CONTROL ??? TO REGULATE MY PERIODS SHE SAID. HAVE YOU TOUGH ON THE POSSIBILITY OF AN ALLERGIC REACTION OR SIDE EFFECT OF ESSURE? SHE SAID THERE IS NO SCIENTIFIC EVIDENCE OF SUCH THING SHE SAID AND SHE WALK OFF THE OFFICE; THEN THE NURSE SHOWED UP TO SEE THAT THE OFFICE MANAGER WANTED TO TALK TO ME. SHE SAID THAT I WOULD HAVE TO BE SEEN BY ANOTHER PROVIDER. LUCKILY THIS NEW PROVIDER WAS OPEN TO THE POSSIBILITY TO HAVE A POSSIBLE SIDE EFFECT OF THIS DEVICE AND SHE ORDER A HSG SONOGRAM TO SEE WHERE AND HOW THE COILS ARE PLACED AFTER 4 YEARS AND SHE ALSO ORDERED A NICKEL ALLERGY TEST WHICH I WASN'T TEST PRIOR TO HAVE ESSURE PLACED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041967	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 2/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I IMMEDIATELY WENT INTO THE WORST DEPRESSIVE EPISODE IN MY LIFE, AND IT HAPPENED OVERNIGHT. ONE DAY I WAS STABLE, AND THE NEXT, IN A FULL BLOWN DEPRESSED STATE. I WAS SUICIDAL, NOT BATHING (NEVER LIKE ME) NOT CLEANING MY HOUSE (NEVER LIKE ME) I FELT SICK EVERYDAY, HEADACHES, EXTREME FATIGUE, WOULD SLEEP ALL OF THE TIME, OR NOT ALL. WAS ANGRY, AND HAD VERBAL OUTBURSTS TO MY FAMILY. MOSTLY SHOWED NO EMOTION AT ALL, COMPLETE FLAT AFFECT OR CRIED. I COULDN'T EXPLAIN WHAT WAS BOTHERING ME, AND BASICALLY WANTED TO DIE. I ATTEMPTED SUICIDE SEVERAL TIMES, AND TOLD NO ONE. MY FAMILY WAS FEARFUL THAT I WOULD KILL MYSELF. I SUFFERED PAINS IN MY SIDES, AND OTHER PAINS, BUT MOSTLY THE EMOTIONAL WAS THE WORST FOR ME, AND IT TOOK A TOLL ON ME, BUT IT REALLY TOOK AN EMOTIONAL TOLL ON MY MOM AND ESPECIALLY MY KIDS, WHO WERE IN FEAR OF LOSING ME EVERY SINGLE DAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041968	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN HURTING ON MY LEFT SIDE, I STARTED LOSING MY HAIR. OVER THE LAST 5 YEARS I HAVE GAINED WEIGHT THAT I CAN NOT LOSE. I'VE BEEN DIAGNOSED WITH HIGH BLOOD PRESSURE AND CHOLESTEROL. JUST RECENTLY I'VE BEEN DIAGNOSED WITH ANXIETY AND HAVING PANIC ATTACKS. I HAVE LOW ENERGY, I'M IN CONSTANT PAIN, I'VE BEEN HAVING NUMBNESS ON MY LEFT SIDE ESPECIALLY IN MY LEG AND FOOT. I'VE ALSO HAD SEVERAL TEETH JUST BREAK OFF.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041969	BAYER	4/8/2015	4/8/2015

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: N
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, INFLAMMATION, SCIATICA PAIN, NUMBNESS IN MY LEGS AND FEET, HEAVY AND IRREGULAR BLEEDING, DIZZINESS, MIGRAINES, HAIR LOSS, EXTREME DEBILITATING FATIGUE DUE TO THE PAINS. PAINFUL PERIODS, PAINFUL INTERCOURSE, VOMITING, STABBING PELVIC PAIN AND VAGINAL PAIN, RASHES ALL OVER THE BODY, BEEN LIKE THIS FOR 2 YEARS, WILL BE NEEDING A HYSTERECTOMY TO REMOVE DEVICE SEEN ONCOLOGIST. ALSO ABNORMAL CANCER LABS TESTED POSITIVE UNSPECIFIED CANCER AND ABNORMAL HORMONE LAB RESULTS. UNEXPLAINED WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041970	BAYER	4/8/2015	4/9/2015

Event Information:

Event Date (B3): 12/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5041970 #(B)(4). HAIR LOSS, LOSS OF INTEREST IN SEX, SPOTTING AND 10+ DAY LONG PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041971	BAYER	4/8/2015	4/9/2015

Event Information:

Event Date (B3): 6/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NAUSEA, RESTLESS LEG (LEG PAIN), LETHARGIC, LACK OF ENERGY, COULD NOT KEEP UP WITH DAY TO DAY FUNCTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041972	BAYER	4/8/2015	4/9/2015

Event Information:

Event Date (B3): 9/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). COULD FEEL COILS FOR MONTHS AFTER INSERTION; CONSTANT RINGING IN EARS; SEVERE INFLAMMATION IN STOMACH; WEAKNESS THROUGHOUT BODY; CYSTIC ACNE AT ALMOST (B)(6) YEARS OLD; RANDOM SHOOTING PAINS THROUGH LOWER STOMACH AND VAGINA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042128	BAYER HEALTH	4/8/2015	4/21/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2031
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PT FOUND A SUPPORT GROUP ON (B)(6) FOR WOMEN WHO SUFFER FROM ESSURE SIDE EFFECTS. IN 2013 PT HAD ESSURE IMPLANTED. AFTER ONE YEAR SHE STARTED TO HAVE SYMPTOMS FROM ESSURE SIDE EFFECTS INCLUDING HEADACHE, FATIGUE, NERVE PAIN, NUMBNESS ABDOMINAL PAIN, PELVIC PAIN, CRAMPING, DENTAL ISSUE, EYE ISSUE, HOT FLASHES, NIGHT SWEAT, METAL TASTE IN HER MOUTH, MOODY, NAUSEA, DIZZINESS. SHE WAS HEALTHY BEFORE ESSURE IMPLANTED. PT CONTINUES TO HAVE SYMPTOMS ESPECIALLY HEADACHE ALL DAY EVERY DAY, FATIGUE, CRAMPING AND DENTAL PAIN. SHE WANTS ESSURE OUT AND MADE AN APPOINTMENT TO CHECK WITH HER DR ON (B)(6) 2015. DEVICE IS STILL INSIDE THE PT. PT HOPES "ESSURE WILL BE RECALLED FROM THE MARKET AND ALL THE WOMEN GOING THROUGH THE SURGERY TO TAKE OUT ESSURE SHOULD GET THEIR MONEY BACK."

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042243	BAYER	4/8/2015	4/28/2015

Event Information:

Event Date (B3): 7/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS306
Catalog # (E4): ESS306
Lot #(E4): A96184

Single Use:
Implant Date (E6): 6/20/2014
Explant Date (E7): 8/12/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO WEEKS AFTER HAVING ESSURE COILS IMPLANTED, I EXPERIENCED SEVERE NAUSEA, LOWER ABDOMINAL PAIN, BLOATING AND BLEEDING. THESE SYMPTOMS CONTINUED UNTIL I HAD THE COILS REMOVED ON (B)(6) 2014. ONCE THE COILS WERE REMOVED, ALL OF THESE SYMPTOMS DISAPPEARED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00242	BAYER HEALTHCARE LLC	4/9/2015	4/9/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(6)2014 VIA A COMPANY INTERNET SITE. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED AUTO-IMMUNE DISORDER. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED SHE HAS AN AUTO-IMMUNE DISORDER AT TIME OF REPORTING THAT SHE NEVER HAD BEFORE. THE CONSUMER CONSIDERED THE AUTO-IMMUNE DISORDER WAS RELATED TO ESSURE FOLLOW-UP INFORMATION POSTED ONLINE BY CONSUMER ON (B)(6) 2015: CONSUMER HAD ESSURE AND HAD AN ALLERGIC REACTION TO THE NICKEL IN THE DEVICE. EIGHT WEEKS AFTER IMPLANTATION, THE DEVICES WERE REMOVED SURGICALLY. A YEAR AFTER THIS SHE HAD A HYSTERECTOMY BECAUSE METAL FRAGMENTS WERE LEFT BEHIND. SHE HAS HAD DEBILITATING PAIN AND FATIGUE THROUGHOUT THIS EXPERIENCE, AND ON (B)(6) 2015 SHE WAS DIAGNOSED WITH FIBRO (INTERPRETED AS FIBROMYALGIA). SHE WAS JUST FEELING HOPELESS. CASE UPGRADED TO INCIDENT. FOLLOW UP INFORMATION FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS

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INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. ADDITIONALLY REPORTED WERE USABILITY ISSUES (DUE TO ASSOCIATE PRODUCT QUALITY ISSUE). THE REPORTED MEDICAL EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED, 8 WEEKS AFTER ITS IMPLANTATION, DUE TO AN ALLERGIC REACTION TO THE NICKEL IN THE DEVICE. ONE YEAR LATER, SHE UNDERWENT A HYSTERECTOMY DUE TO METAL FRAGMENTS, WHICH WERE LEFT BEHIND. ADDITIONALLY SHE REPORTED AUTOIMMUNE DISORDER. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE; EXCEPT FOR METAL FRAGMENTS WERE LEFT BEHIND, INTERPRETED AS A DEVICE BREAKAGE, WHICH WAS LISTED ACCORDING TO TECHNICAL ANALYSIS. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, ALLERGIC REACTIONS TO ESSURE MAY HAPPEN, AND ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. ADDITIONALLY, IF ESSURE REMOVAL IS ATTEMPTED, THERE IS A POSSIBILITY THAT THE REMOVAL WILL NOT BE SUCCESSFUL OR THAT THE MICRO INSERT MAY BREAK, LEAVING A FRAGMENT IN VIVO. IN THIS PARTICULAR CASE, CONSIDERING THE ABOVE MENTION INFORMATION AND GIVEN THE POSITIVE TEMPORAL RELATIONSHIP CAUSALITY BETWEEN THE REPORTED DEVICE BREAKAGE/NICKEL ALLERGY AND THE SUSPECT INSERT ESSURE CANNOT BE EXCLUDED. REGARDING AUTO IMMUNE DISORDER, A CONTRIBUTORY ROLE OF ESSURE IS CONSIDERED UNLIKELY GIVEN ITS LOCAL ACTION AT FALLOPIAN TUBES. THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS AMENDED TO INCIDENT DUE TO THE INTERVENTIONS LATER REPORTED BY CONSUMER (HYSTERECTOMY AND ESSURE REMOVAL). THE PRODUCT TECHNICAL COMPLAINT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO FURTHER INFORMATION WILL BE ACTIVELY REQUESTED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00243	BAYER HEALTHCARE LLC	4/9/2015	4/9/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER IN UNITED STATES ON (B)(6)-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS POSTED ON BAYER (B)(6) PAGE. CONSUMER STATED THAT SHE WAS NOT EVEN 30 AND HAVE TO HAVE A HYSTERECTOMY. SHE ALSO STATED THAT ESSURE IS HURTING WOMEN EVERY DAY. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION HAS BEEN REQUESTED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014 ACCORDING TO THE CONSUMER, SHE WILL CONTACT HER LAWYER BEFORE GIVE MORE INFORMATION (POTENTIAL LEGAL CASE NOW). FOLLOW-UP RECEIVED ON (B)(6) 2014: INFORMATION RECEIVED FORM CONSUMER STATES THAT SHE GOT SWELLING FROM ESSURE. IN ADDITION CONSUMER REPORTED THAT SHE HAD TO HAVE HYSTERECTOMY IN (B)(6)AT AGE OF (B)(6) SHE IS IN PAIN AND HAS ISSUES THANKS TO ESSURE. FOLLOW UP (B)(6) 2015: CASE UPGRADED TO INCIDENT. CONSUMER REPORTED VIA SOCIAL MEDIA THAT WITH ESSURE SHE EXPERIENCED PAIN, SUFFERING, AND HAD HYSTERECTOMY BEFORE THE AGE OF (B)(6). SHE ALSO INFORMED THAT SHE TALKED TO HER LAWYER AND WILL NOT GIVE HER CONTACT DETAILS. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY.

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THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY CONFIRMED, POTENTIAL LEGAL, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. THE EVENT HAVE TO HAVE A HYSTERECTOMY WAS DELETED SINCE THE REASON FOR THIS PROCEDURE WAS REPORTED. PAIN WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER EXPERIENCED PAIN AND SHE UNDERWENT A HYSTERECTOMY. TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE OCCURRENCE OF THIS EVENT IS UNKNOWN. CONSIDERING THE INFORMATION PROVIDED THE CAUSAL RELATIONSHIP BETWEEN ESSURE THERAPY AND THE REPORTED EVENT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED FROM NON-INCIDENT TO INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

FOLLOW UP FROM 10-APR-2015: NO NEW INFORMATION PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 24-APR-2015: THIS REPORT REFERS TO A (B)(6) FEMALE CONSUMER. SHE HAD A HYSTO TO STOP THE PAIN AND RARE CYSTS. THE CONSUMER CONSIDER THAT THE EVENT WAS POSSIBLY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00247	BAYER HEALTHCARE LLC	4/9/2015	4/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/4/2014
Explant Date (E7): 3/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR CONTRACEPTION. THE DEVICE WAS PLACED CORRECTLY AND 3 COILS TRAILING WERE INTO CAVITY AT PLACEMENT. PATIENT THEN WENT TO PHYSICIAN'S OFFICE COMPLAINING OF PAIN AND IT SHOWED THAT ESSURE COIL HAD MIGRATED INTO ABDOMEN. PATIENT UNDERWENT A LAPAROSCOPY SURGERY TO REMOVE ESSURE AND BOTH TUBES ON (B)(6) 2015. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED MEDICAL EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION,

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THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT" THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ESSURE COIL MIGRATED INTO ABDOMEN. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH NOT REPORTED AS SUCH, THE MOST LIKELY MECHANISM FOR THE ESSURE TO BE FOUND IN THE ABDOMEN, WOULD BE THROUGH A UTERINE/FALLOPIAN TUBE PERFORATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF MIGRATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A LAPAROSCOPY SURGERY TO REMOVE ESSURE AND BOTH TUBES WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 25-AUG-2015 - TUBAL PERFORATION QUESTIONNAIRE PROVIDED: THE PATIENT'S HISTORY INCLUDED GRAVIDA 1, PARA 1. CONCURRENT CONDITIONS INCLUDED OVERWEIGHT (B)(6). SHE WAS NOT POST-PARTUM AT THE TIME OF ESSURE INSERTION. THE ESSU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00248	BAYER HEALTHCARE LLC	4/9/2015	4/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C95071 (INVALID)

Single Use: Y
Implant Date (E6): 11/26/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 13-MAR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 LOT NUMBER C95071 (EXPIRATION DATE AUG-2017) FOR CONTRACEPTION. WHEN PATIENT WENT TO THE HSG (HYSTEROSALPINGOGRAM) TEST ON (B)(6) 2015, BOTH TUBES OCCLUDED BUT SHOWED AN ABNORMALITY WITH THE MARKERS. A CT SCAN WAS DONE AND IT READ: LEFT SIDED ESSURE DEVICE APPEARS TO BE BROKEN. A SMALL FRAGMENT OF DEVICE IS LOCATED WITHIN LATERAL ASPECT OF MYOMETRIUM, MOST LIKELY AT ORIFICE OF FALLOPIAN TUBE. OTHER FRAGMENT APPEARS TO BE EXTRA LUMINAL WITHIN THE ANATOMIC PELVIS JUST SUPERIOR TO THE UTERUS. THIS IS BEST SEEN ON THE CORONAL RECONSTRUCTION. NO ABSCESS OR OBSTRUCTION IDENTIFIED. ESSURE DEVICES WERE NOT REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 23-MAR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: LOT NUMBER PROVIDED C95071 IS INVALID. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. A VALID BATCH NUMBER WAS NOT REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER

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REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP INFORMATION RECEIVED ON 01-APR-2015 (CASE UPGRADED TO INCIDENT): ON AN UNSPECIFIED DATE, THE PHYSICIAN SURGICALLY REMOVED THE ESSURE FRAGMENTS FROM THE PATIENT; A TUBAL LIGATION WAS ALSO PERFORMED AT THE SAME TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT CT SCAN LEFT SIDE ESSURE DEVICE APPEARS TO BE BROKEN (INTERPRETED AS DEVICE BREAKAGE). A SMALL FRAGMENT OF DEVICE IS LOCATED WITHIN LATERAL ASPECT OF MYOMETRIUM MOST LIKELY AT ORIFICE (INTERPRETED AS EMBEDDED DEVICE) AND OTHER FRAGMENT APPEARS TO BE EXTRA LUMINAL WITHIN THE ANATOMIC PELVIS SUPERIOR TO THE UTERUS (INTERPRETED AS DEVICE DISLOCATION). DEVICE BREAKAGE IS SERIOUS DUE TO REQUIRED INTERVENTION TO REMOVE THE FRAGMENTS AND LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). EMBEDDED DEVICE AND DEVICE DISLOCATION ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF THESE EVENTS WERE NOT KNOWN. NO SURGICAL INTERVENTION WAS REPORTED. GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS WITH ESSURE THERAPY CANNOT BE EXCLUDED. THE ESSURE FRAGMENTS WERE SURGICALLY REMOVED AND A TUBAL LIGATION WAS PERFORMED AT THE SAME TIME. AFTER FOLLOW UP INFORMATION, THE CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PERFORMED PTC ANALYSIS CONCLUDED, BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00249	BAYER HEALTHCARE LLC	4/9/2015	4/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/17/2010
Explant Date (E7): 3/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON 13-MAR-2015 WHICH REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 FOR STERILIZATION. ON AN UNSPECIFIED DATE THE PATIENT DEVELOPED PELVIC PAIN AND A RASH TO METALS SUCH AS JEWELRY (WHICH SHE NEVER HAD BEFORE). SHE ALSO DEVELOPED METAL TASTE IN HER MOUTH, AND VAGINAL DISCHARGE WITH METAL ODOR. ONCE THESE SYMPTOMS BEGAN IT ADVANCED QUICKLY AND THE PATIENT HAD THE BILATERAL ESSURES REMOVED VIA A LAPAROSCOPIC SALPINGECTOMY ON (B)(6) 2015. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 24-MAR-2015, (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT.

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BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED PELVIC PAIN. SHE WAS SUBMITTED TO BILATERAL SALPINGECTOMY FOR DEVICES REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, ALTHOUGH LIMITED INFORMATION WAS PROVIDED, GIVEN THE REPORTED EVENT'S NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 05-MAY-2015: ESSURE HEALTH CARE PROVIDER QUESTIONNAIRE WAS RECEIVED. PHYSICIAN DOES NOT HAVE FURTHER INFORMATION REGARDING INSERTION SINCE ESSURE WAS NOT PLACED BY HER. HEALTH CARE PROFESSIONAL INFORMED THAT PATIENT HAD REQUESTED ESS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041974	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNEXPLAINABLE ABDOMINAL PAIN FREQUENTLY, INCREASED CRAMPING DURING MENSTRUATION, HEAVY BLEEDING DURING PERIOD, PAINFUL INTERCOURSE, LOSS ALL DESIRE FOR INTERCOURSE WITH HUSBAND, VAGINAL DRYNESS, HAIR THINNING, HAIR LOSS, PALE SKIN, RASHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041976	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 9/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH THE MEDICAL DEVICE ESSURE FOR STERILIZATION PURPOSES. SINCE IMPLANTATION, I HAVE NOT HAD A MENSES. I INSTEAD HAVE SUFFERED DEBILITATING CRAMPING IN THE OVARY REGIONS, AND IN MY STOMACH. I HAVE LOWER BACK PAIN SO EXTREME THAT IT DROPS ME TO MY KNEES ON A REGULAR BASIS. I CAN NO LONGER WALK LONG DISTANCES, WITHOUT BEING IN SEVERE PAIN. SEXUAL INTERCOURSE IN ALMOST NON EXISTENT WITH MY HUSBAND AS THERE IS ALWAYS PAIN INVOLVED DURING AND AFTERWARDS. IF I BEND THE WRONG WAY, OR STRETCH OUT TO LAY DOWN, SOMETIMES THERE IS A KINK LIKE FEELING INSIDE, OR A FEELING LIKE I AM BEING POKED. THE PAIN IS QUITE SEVERE. I HAVE BEEN TESTED FOR LUPUS, LYME, SARCADOSIS, A PLETHORA OF AUTO IMMUNE DISORDERS, INFLAMMATION ISSUES, EARLY MENOPAUSE, MY HAIR IS GREYING OVER MY ENTIRE HEAD, IT IS BRITTLE AND FALLING OUT. I HAVE SUCH TERRIBLE MUSCLE FATIGUE AND AM EXTREMELY VITAMIN D DEFICIENT ALL THE TIME SINCE GETTING THIS DEVICE. I STAY NAUSEATED ALL THE TIME AS WELL, ESPECIALLY AFTER TRYING TO EAT. I HAVE ALSO HAD A OVER ABUNDANCE OF MIGRAINES SINCE IMPLANTATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041977	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 10/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BAD CRAMPING ALL THE TIME. PAINFUL PERIODS HEAVY BLEEDING. HEAD ACHES, DEPRESSION, HAIR LOSS. BLEEDING GUMS WHEN I BRUSH MY TEETH. LEG PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041978	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC POPPING PAIN IN LOWER ABDOMEN, SEVERE MENSTRUAL CYCLES, CRAMPING, LOW IRON, BACK PAIN, LABOR LIKE CONTRACTIONS, KIDNEY PAIN, SYMPTOMS OF LUPUS CAUSED BY ESSURE COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041979	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 11/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE HEADACHES, CRAMPS THAT FEEL LIKE CONTRACTIONS, ABDOMINAL PAIN, NAUSEA, FATIGUE, MOOD SWINGS, SKIN RASHES, LOSS OF BALANCE, DIZZINESS, BLOATING, RANDOM SHARP PAINS IN MY ABDOMEN DURING EXERCISE, SPONTANEOUS HEAVY MENSTRUAL CYCLES, PAIN IN MY ABDOMEN AFTER SEX, LOSS OF LIBIDO ALL SINCE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5041999	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PELVIC PAIN (BOTH SIDES, BUT MAINLY THE LEFT), NAUSEA, WEIGHT LOSS, LACK OF ENERGY, HEADACHES, DEPRESSION, LOSS OF LIBIDO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042002	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 4/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, IRREGULAR PERIODS, BLOATING, WEIGHT GAIN, HAVEN'T HAD SEX IN TWO YEARS, THINK I AM ALLERGIC TO THE NICKEL IN IT, HAVE TO HAVE A HYSTERECTOMY TO GET IT OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042003	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 4/3/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD ESSURE PUT IN, IN (B)(6) OF 2014, I HAVE HAD ONGOING HEADACHES AND MIGRAINES, UNEXPLAINABLE RASHES AND BREAKOUTS, MORE JOINT PAIN, FATIGUE, FLUTTERS IN MY STOMACH AS IF SOMETHING IS MOVING BUT WITH A NEGATIVE PREGNANCY TEST. FEELINGS AS IF SOMETHING IS STUCK IN MY THROAT WHEN NOTHING IS THERE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042004	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 4/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THINGS HAVE STARTED A WHILE BACK. I GOT ESSURE IN 2013. BUT I STARTED HAVING HORRIBLE PAINS IN VAGINA HAVE EVEN PASSED OUT FROM THEM. STOMACH PAINS. RECENTLY HAVE HAD RASHES AND NOW AM ALLERGIC TO MY BELTS AND JEWELRY. I HAVE BLOOD TESTS DONE EVERYTHING SEEMS FINE SO THEY DONT KNOW. BACK PAINS. HEADACHES SEVERE NAUSEA. RECENTLY WAS LATE ON PERIOD. HAVING SYMPTOMS LIKE IM PREGNANT DR ORDERED PREGNANCY TEST. THEN NOT EVEN TWO WEEKS LATER WHICH IS NOW STARTED HAVING WEIRD PAINS STARTED SPOTTING AND NOW LOTS OF BLOOD. NOT JUST LIKE A NORMAL PERIOD. BUT THESE PAINS NAUSEA ARE ABSOLUTELY HORRIBLE. NOT TO MENTION THE RASHES THAT COME FROM JEWELRY AND BELTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042005	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 10/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE PLACED INSIDE ME I HAVE HAD AWFUL CRAMPING IN LOWER ABDOMEN, MY PERIODS HAVE GOTTEN REALLY HEAVY, AND I BECAME PREGNANT AND HAD MY SON EXACTLY 2 YEARS FROM THE DAY I HAD MY ESSURE PLACED. HE WAS BORN 2 MONTHS PREMATURE AND THE WHOLE TIME I WAS PREGNANT I HAD MANY COMPLICATIONS. I HAD A BLOOD CLOT THE SIZE OF A SOFTBALL ON THE LEFT SIDE OF MY UTERUS THAT BLED THE WHOLE TIME I CARRIED MY SON AND CAUSED ME TO GO IN TO LABOR ON (B)(6) 2013 MAKING MY SON BE BORN AT (B)(6) WEEKS. RECENTLY I HAVE NOTICED THAT MY HAIR FALLS OUT CONSTANTLY AND I HAVE BAD HEADACHES AT LEAST TWICE A WEEK!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042006	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT PREGNANT DESPITE HAVING BEEN SHOWN FULLY OCCLUDED ON VIA HSG THREE MONTHS AFTER IMPLANT (IMPLANT (B)(6), HSG (B)(6)).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042007	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 9/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BECAME PREGNANT ON ESSURE. DEVICE WAS NOT WORKING AND HAD CAUSED LOWER ABDOMINAL PAIN (2 ER TRIPS), SO I HAD A FULL HYSTERECTOMY AND BILATERAL TUBE REMOVAL. SURGERY REVEALED R ESSURE COIL WAS NOT IN MY TUBE, BUT EMBEDDED IN MY UTERUS. HSG THREE MONTHS AFTER IMPLANT SHOWED TUBES BLOCKED AND ESSURE PLACED CORRECTLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042008	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DATE IS AN APPROXIMATION FATIGUE, LOSS OF ENERGY, CRAMPING EVEN AFTER MENSTRUATION, PINCHING SENSATION IN AREA OF OVARIES WHEN BENDING OR STRETCHING, ACHY BODY, ESPECIALLY LOWER LEGS, IRREGULAR CYCLES (EVERY OTHER MONTH), NUMBNESS AND OR TINGLING OF EXTREMITIES AFTER SITTING OR SLEEPING, MOODY/IRRITABLE, DEPRESSION, ITCHY SKIN, RED SPOTS ON LEGS, NAUSEA, SORE BREASTS AND PREGNANCY LIKE SYMPTOMS BEFORE MENSTRUATION, LEG CRAMPS, UPPER BACK PAIN AND INCREASE IN LOWER BACK PAIN, ABDOMINAL MUSCLE TWITCH (PHANTOM FLUTTER KICKS), ABDOMINAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042009	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 2/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NUMEROUS SIDE EFFECTS...TOO ANY TO LIST. SURGERY FOR REMOVAL SCHEDULED NEXT WEEK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042010	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 4/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE RASH AND HIVES FROM THE TIME I GOT THIS DEVICE. SUFFERING FROM MIGRAINE HEADACHES, THYROID ISSUES, WEIGHT GAIN, JOINT PAIN, ABDOMINAL PAIN/PIERCING PAIN, AND EXTREME HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042011	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 4/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I FIRST GOT IT, MY PERIOD WAS PAINFUL. THEN I WAS SWOLLEN AS COMING UP WITH PREGNANCY SYMPTOMS AND AS SOON I GOT MY PERIOD, SICKNESS WOULD GO AWAY. I HAVE FELT DEPRESSED FOR THE LAST 8 YEARS. I FEEL LIKE I AM ENTERING MENOPAUSE EARLY. ALWAYS HOT AND I AM CRANKY OFTEN. CURRENTLY, I HAVE A PROBLEM WITH MY RIGHT LEG AND 4 BULGING DISC AND MY NERVES ARE BAD. I HAD TO HAVE MY BREAST EXAM BECAUSE I HAVE LUMPS IN THEM. I HAVE NOT HAD THESE PROBLEMS BEFORE. MY TEETH ARE WEAK. I HAD TO GET THEM FIXED AND OR PULLED OUT. I CAN TELL MY BODY IS DIFFERENT AND I DON'T LIKE THE WAY I FEEL. I HAVEN'T THEN AND DON'T LIKE IT NOW. I HAVE ASKED MY DOCTOR NUMEROUS TIMES TO TAKE IT OUT BUT NO RESPONSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042012	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 4/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOSS OF SMELL FOLLOWED BY SEVERE ARTHRITIC TYPE PAIN IN UPPER BODY THAT TRAVELED TO DIFFERENT JOINTS THEN TOTALLY DISAPPEARED UNTIL NEXT ATTACK. FATIGUE, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042013	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 2/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL SEX, LEG PAINS, ABDOMINAL PAIN, CERVIX PAIN, BACK PAIN, HEADACHES ALL THE TIME, HEART PROBLEMS AND MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042014	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 5/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNEXPLAINABLE ABDOMINAL PAIN FREQUENTLY. INCREASED CRAMPING DURING MENSTRUATION. HEAVY BLEEDING DURING PERIOD. PAINFUL INTERCOURSE. LOSS ALL DESIRE FOR INTERCOURSE WITH HUSBAND. HAIR LOSS IN CLUMPS. DEPRESSION WITH " CUTTING URGES" WHICH I HAVE NEVER HAD BEFORE AND NOW HAVE TO BE ON A LOW DOSE OF PAXIL TO FIX IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042015	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 8/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, LOWER BACK PAIN, PREGNANCIES AFTER ESSURE IMPLANTATION WAS 2 KIDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042016	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 4/4/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I GOT THIS ESSURE IMPLANTED, I WAS NEVER TESTED FOR A NICKEL ALLERGY AND SINCE HAVING IT DONE, I'VE EXPERIENCED WEIGHT GAIN, HEADACHES, BLOATING, ANXIETY/PANIC ATTACKS, LOSS OF SEXDRIVE, HAIR LOSS, CRAMPING ALL THE TIME, PAIN ON MY LEFT SIDE ALL THE WAY DOWN MY LEG, MIGRAINES, PAIN DURING SEX, BOWEL PROBLEMS, SURGERY TO REMOVE MY GALLBLADDER, AND THE LIST JUST KEEPS GETTING LONGER AS I STILL HAVE IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042017	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN THAT WOULD DOUBLE ME OVER ABOUT TWICE A MONTH UNTIL (B)(6) 2015; CONSTANT BACK PAIN , HAIR LOSS, PAIN THAT HAD ME ON THE FLOOR UNABLE TO FIND RELIEF, WEIGHT GAIN, BLOATING. SURGERY IN (B)(6) 2015 TO REMOVE ENDOMETRIOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042018	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 5/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING VERY BAD PERIODS, BLEEDING SO MUCH I HAD TO WEAR DEPENDS DURING MY PERIODS; STARTED BLEEDING AS LONG AS 6 MONTHS AT A TIME. SEVERE PAIN IN MY STOMACH AND ABDOMEN. NAUSEA, VOMITING, NOT ABLE TO EAT OR DRINK WITHOUT GETTING SICK. I AM ALLERGIC TO NICKEL AND HAVE A SPOT ON MY ARM THAT HAS BEEN SPREADING SINCE I GOT ESSURE. PAIN SO SEVERE THAT I WOULD PASS OUT OR FALL ONTO THE FLOOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042019	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 1/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A FEW MONTHS AFTER GETTING ESSURE, I STARTED SUFFERING FROM ANXIETY, DEPRESSION, METALLIC TASTE IN MY MOUTH, DIZZINESS, PELVIC PAIN, HEAVY MENSTRUAL BLEEDING, IRREGULAR PERIODS, FATIGUE, (B)(6), LOW VITAMIN D, BOILS AND PELVIC PRESSURE. I ALSO HAD A PULMONARY EMBOLISM. I STILL HAVE ALL OF THE SYMPTOMS EXCEPT THE EMBOLISM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042020	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BLED AND COULD NOT STOP. DOCTOR ADVISED ME TO TAKE 3 BIRTH CONTROL PILLS TO GIVE THE ESTROGEN. THIS DID NOT WORK. BLED UNTIL (B)(6). NO RELIEF SAW DOCTOR 2X AND MULTIPLE PHONE CALLS TO THE DOCTOR OFFICE STOPPED BLEEDING FOR 7 DAYS BEFORE STARTING BACK AGAIN WITH HUGE CLOTS AND HAVING HAVE A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042021	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 4/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, CRAMPING ALL THE TIME EVEN WHEN I'M NOT ON MY PERIOD, SEVERE PAIN IN LOWER BACK GETS WORSE WHEN ON PERIOD. CAN'T LIFT HEAVY OBJECTS BECAUSE OF PAIN. HEADACHES AND NECK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042022	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 5/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACE IN 2010 AFTER MY DAUGHTER WAS BORN. I STARTED NOTICING PROBLEMS AS SOON AS 2 MONTHS AFTER I HAD ESSURE. I WAS HAVING INTENSE BLEEDING FOR MY PERIODS, ALSO"MY HAIR STARTED TO FALL OUT, AND MY JOINTS STARTED TO HURT TO THE POINT WHERE WHEN I GET OUT OF BED IN THE MORNING -- IT'S ALMOST IMPOSSIBLE TO WALK, I HAD TO BE STOPPING SO MANY TIMES. I FELT LIKE I WAS A 90YR OLD. I SUFFER ON A DAILY BASIS FROM CONSTANT, SEVERE BACK PAIN, ABDOMEN PAIN, "BLEEDING EVERY DAY" AND DEVELOPING A "SPIDERWEB" OF SCAR TISSUE. "I FELT MY INSIDES WERE ON FIRE." STARTED GETTING EXTREMELY BLOATED, IN ADDITION TO SEVERAL FRUSTRATED MEMORY LOST AND LOST MY NOT OF SEX, REGULAR ACTIVITIES WITH MY KIDS AND GAIN ABOUT 50LB THAT ARE SO HARD TO TAKE AWAY AND LOSS FELT IN TO DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042023	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 3/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP LOWER ABDOMINAL PAINS ON LEFT AND RIGHT WHEN STRETCHING, CONTRACTIONS (NOT PREGNANT), LOST LIBIDO, HEAVY IRREGULAR PERIODS WITH LOTS OF CLOTTING, EXTREME MENSTRUAL CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042024	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 2/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NON STOP VAGINAL BLEEDING. DR CLAIMED THE DEPRO SHOT CAUSED THE BLEEDING AND WAS A SIDE EFFECT OF SHOT. CONTINUED TO BLEED FOR THE NEXT 1.5 YEARS. PAINFUL INTERCOURSE, HORRIBLE MOOD SWINGS, SERVER ABDOMINAL PAIN, SPONTANEOUS VAGINAL SPOTTING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042025	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS COMPLETELY HEALTHY BEFORE ESSURE; NO MEDICAL PROBLEMS. I HAVE EXPERIENCED THE FOLLOWING SINCE ESSURE WAS PLACED 4 YEARS AGO: BLEEDING SPOTTING AFTER SEX; CRAMPING; CHRONIC PELVIC PAIN; SHARP STABBING PAINS IN ABDOMEN/BACK AREA; OVARIAN CYSTS; DISCHARGE (ODORLESS); MENORRHAGIA; PAINFUL OVULATION; BLOATING; FREQUENT URINATION; UTI; BREAST PAIN/TENDERNESS; IBS SYMPTOMS; BOWEL ISSUES; HEADACHES; VISION PROBLEMS (BLURRY); DIZZINESS; RINGING IN THE EARS; BRAIN FOG; MEMORY ISSUES; CHRONIC FATIGUE; SLEEP APNEA SYMPTOMS; ACNE WITH CYSTS AND BOILS; HAIR CHANGES; INSOMNIA; WEIGHT ISSUES (CAN'T LOSE EVEN WITH EATING AND EXERCISING); DRY SKIN. IN ORDER TO RID THESE ISSUES, IT WILL REQUIRE A HYSTERECTOMY TO REMOVE THIS POISON!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042026	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 3/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NUMBNESS, TINGLING AND PAIN RIGHT SIDE STARTED SHOULDER DOWN MY ARM TO MY FINGERS. THEN PROCEEDED OVER WEEKS TO THE BACK OF MY NECK WITH A HOT SENSATION TO BEHIND MY EAR AND SIDE OF MY FACE AND HEAD. HAVE BEEN EXTREMELY DIZZY, CONFUSED AND FATIGUE. ER DOCTOR SAID I HAD UNEXPLAINED PERIPHERAL NEUROPATHY AFTER AN EKG, CT SCAN, CHEST XRAY AND BLOOD WORK. I HAVE BEEN REFERRED TO A NEUROLOGIST FOR MORE TESTS THEY STATED I SHOULD HAVE AN EMG. I AM STILL EXPERIENCING ALL SYMPTOMS IT'S BEEN ABOUT 3 WEEKS .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042027	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 3/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT SIDE PELVIC PAIN, RIGHT HAND NUMBNESS, DIZZINESS, RIGHT SIDE BACK PAIN, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042028	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 3/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT SIDE PELVIC PAIN, RIGHT HAND NUMBNESS, DIZZINESS, RIGHT SIDE BACK PAIN, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042029	BAYER	4/9/2015	4/9/2015

Event Information:

Event Date (B3): 6/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE BEEN HAVE CONTRACTION. MASSIVE CRAMPING. IN PAIN ALL THE TIME SINCE HAVING PROCEDURE DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042031	BAYER	4/9/2015	4/10/2015

Event Information:

Event Date (B3): 3/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). POSITIVE PREGNANCY TEST AT HOME. ULTRASOUND CONFIRMED PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042030	BAYER	4/9/2015	4/13/2015

Event Information:

Event Date (B3): 3/30/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A LOT OF PAIN IN MY ABDOMEN AND WENT TO THE LOCAL ER THEY THEN SAID I HAVE A CYST ON MY OVARIES THAT ERUPTED. I NEVER HAD THAT HAPPEN BEFORE THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042083	CONCEPTUS INC. USA BAYER	4/9/2015	4/16/2015

Event Information:

Event Date (B3): 10/9/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4): 12277837

Single Use:
Implant Date (E6): 8/24/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS I HAD PLACED IN 2005 AND HAD NON STOP BLEEDING/PAIN PROBLEMS, THAT BROUGHT ME TO A HYSTERECTOMY IN 2008, LEAVING MY OVARIES AND FALLOPIAN TUBES. BUT NOW I'M WONDERING AS MY SURGICAL PATHOLOGY REPORT STATES THAT THERE WAS A 1.5 CM TWISTED METAL WIRE PRESENT WITHIN THE LEFT CORNU, REVEALING A SIMILAR METAL REMNANT WITHIN THE RIGHT CORNU. MY POINT BEING, IF I STILL HAVE MY FALLOPIAN TUBES AND THE ESSURE COILS MEASURE 1.5" WHERE IS THE REST OF THE COILS WITH THE PET FIBERS THEN?

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042084	BAYER	4/9/2015	4/16/2015

Event Information:

Event Date (B3): 4/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2012, SINCE HAVING ESSURE PLACED MY OVERALL HEALTH AND QUALITY OF LIFE HAS DECLINED. SINCE IMPLANTATION I HAVE HAD THE FOLLOWING SYMPTOMS: LOWER BACK PAIN, HIP PAIN, SHOOTING PAIN IN THE LOWER BACK, HIP AND GROIN, CRAMPING, HEAVY MENSTRUAL PERIODS, SPOTTING, SEVERE FATIGUE, MENTAL CLOUDINESS, TEETH SENSITIVITY, HEADACHES, DECREASE OF APPETITE, HAIR LOSS, JOINT PAIN, BLURRED VISION, IRRITABILITY, METALLIC TASTE IN MY MOUTH, SKIN LESIONS, HOT FLASHES AND SENSITIVITY TO NOISE. I WAS A HEALTHY WOMAN BEFORE THIS DEVICE WAS IMPLANTED IN ME. I HAVE NEVER HAD ANY OF THE SYMPTOMS LISTED ABOVE BEFORE (B)(6) 2012.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00246	BAYER HEALTHCARE LLC	4/9/2015	5/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06521

Single Use: Y
Implant Date (E6): 3/10/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C06521 (EXPIRATION DATE DEC-2016), INSERTION ON (B)(6)-2015. REPORTER STATES THAT, ON (B)(6)-2015, AN ESSURE DEVICE BROKE OFF AFTER DEPLOYMENT. AN ATTEMPT TO REMOVE THE DEVICE WAS UNSUCCESSFUL. IN ADDITION IT WAS INFORMED THAT AN X-RAY WAS DONE AND A PIECE OF THE COIL REMAINED IN THE PATIENT. DEVICE IS AVAILABLE FOR RETURN. PTC INVESTIGATION RESULT RECEIVED ON 24-MAR-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT. FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD

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AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. ADDITIONALLY REPORTED WERE USABILITY ISSUES (DUE TO ASSOCIATE PRODUCT QUALITY ISSUE). NO MEDICAL EVENTS WERE REPORTED AT THIS TIME THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. REVIEW OF ASSOCIATED BATCH DOCUMENTATION DID NOT REVEAL ANY DEFICIENCIES OR GIVE ANY REASON TO SUSPECT A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. AS NO MEDICAL EVENTS WERE REPORTED, AN ASSESSMENT OF A RELATIONSHIP IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND IT WAS REPORTED THAT ESSURE DEVICE BROKE OFF AFTER DEPLOYMENT. THIS EVENT IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DEVICE BREAKAGE OCCURRED DURING ESSURE PLACEMENT PROCEDURE. IT WAS REPORTED THAT AN ATTEMPT TO REMOVE THE DEVICE WAS UNSUCCESSFUL (DEVICE REMOVAL FAILED). BASED ON THIS INFORMATION, A CAUSAL RELATIONSHIP BETWEEN DEVICE BREAKAGE AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 24-JUN-2015 NO NEW CLINICAL INFORMATION WAS RECEIVED. FOLLOW-UP FROM 07-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00241	BAYER HEALTHCARE LLC	4/9/2015	5/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97485

Single Use: Y
Implant Date (E6): 1/16/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; THE LOT NUMBER USED WAS B97485. PHYSICIAN REPORTED THAT THE TIP OF THE INSERT BROKE WHILE ATTEMPTING TO CANNULATE THE PATIENT. A SECOND ATTEMPT WAS MADE AND IT WAS SUCCESSFUL; BILATERAL PLACEMENT OF ESSURE DEVICE WAS ACHIEVED AND THE PATIENT HAD NO INJURIES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE TIP OF THE INSERT BROKE WHILE ATTEMPTING TO CANNULATE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, SINCE THE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW UP INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 09-APR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SI

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00244	BAYER HEALTHCARE LLC	4/9/2015	5/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C28941

Single Use: Y
Implant Date (E6): 7/30/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH PROFESSIONAL VIA REGULATORY AUTHORITY ((B)(6)) IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014; THE LOT NUMBER USED WAS C28941. DURING THE PLACEMENT PROCEDURE, IN THE OPERATING ROOM, THE ESSURE PLACEMENT IN LEFT FALLOPIAN TUBE FAILED. THE INSERT WAS RELEASED AND ATTACHED AT TUBAL LEVEL BUT DEVICE BROKE DESPITE APPROPRIATE MANIPULATION, DEVICE WAS LEFT IN PLACE DUE TO RISK OF FALLOPIAN TUBES DAMAGES. THE PATIENT WAS TO BE SEEN IN 3 MONTHS. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT THE REPORTED LOT NUMBER C28941 WAS CONSIDERED INVALID BY RQU (RESPONSIBLE QUALITY UNIT). FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE

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INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. ADDITIONALLY, A USABILITY ISSUE WAS REPORTED. NO MEDICAL EVENTS WERE REPORTED AT THIS TIME. A VALID BATCH NUMBER WAS NOT REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. AS NO MEDICAL EVENTS WERE REPORTED, AN ASSESSMENT OF RELATABILITY IS NOT APPLICABLE. DEVICE SIMILAR CASE LISTING: THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE, A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE (B)(4) PTS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE ESSURE PLACEMENT IN LEFT FALLOPIAN TUBE FAILED. THE INSERT WAS RELEASED AND ATTACHED AT TUBAL LEVEL BUT DEVICE BROKE DESPITE APPROPRIATE MANIPULATION. THE REPORTED EVENTS WERE CONSIDERED NON-SERIOUS. DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE OTHER EVENT IS LISTED. HOWEVER, ACCORDING TO PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS, THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION; NEVERTHELESS SINCE THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW-UP WILL BE PURSUED SINCE THIS IS A HEALTH AUTHORITY CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00245	BAYER HEALTHCARE LLC	4/9/2015	5/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26957

Single Use: Y
Implant Date (E6): 3/12/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 4/2/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN (B)(6) ON (B)(6)-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2015. INFORMATION RECEIVED FROM A SURGEON, WHO WAS TRAINED TO ESSURE PROCEDURE, STATES THAT AN EQUIPMENT PROBLEM HAPPENED DURING THE PLACEMENT IN THE OPERATING ROOM. ACCORDING TO REPORTER DELIVERY CATHETER DETACHED FROM THE HANDLE (DEVICE BREAKAGE). COMPLETE ESSURE SYSTEM (INSERT + HANDLE) WAS KEPT. IN ADDITION, HEALTH CARE PROFESSIONAL INFORMED THAT THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER ESSURE SYSTEM. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6)-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). LOT NUMBER C26957 (PRODUCTION DATE 24-FEB-2014; EXPIRATION DATE 28-FEB-2017). FINAL ASSESSMENT FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A

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GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF (B)(6)-2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. ADDITIONALLY, A USABILITY ISSUE (DUE TO ASSOCIATE PRODUCT QUALITY ISSUE) WAS REPORTED. NO MEDICAL EVENTS WERE REPORTED AT THIS TIME THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. REVIEW OF ASSOCIATED BATCH DOCUMENTATION DID NOT REVEAL ANY DEFICIENCIES OR GIVE ANY REASON TO SUSPECT A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT AND NOTED THAT THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. AS NO MEDICAL EVENTS WERE REPORTED, AN ASSESSMENT OF A RELATIONSHIP IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT DELIVERY CATHETER DETACHED FROM THE HANDLE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE DEVICE BREAKAGE OCCURRED DURING THE ESSURE PLACEMENT IN THE OPERATING ROOM. CONSIDERING THIS POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, AS NO MEDICAL EVENTS WERE REPORTED, AN ASSESSMENT OF A RELATIONSHIP IS NOT APPLICABLE. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-JUL-2015: NO FURTHER INFORMATION OBTAINED DESPITE FOLLOW-UP ATTEMPTS. CASE CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042033	BAYER	4/10/2015	4/13/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, SEVERE CRAMPING, HAIR LOSS, ADENOMYOSIS, HEADACHES, RASHES, CHIPPED TEETH, BACK PAIN, JOINT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042034	BAYER	4/10/2015	4/13/2015

Event Information:

Event Date (B3): 1/10/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE INSERTION OF ESSURE, I HAVE HAD HORRIBLE PAINS IN MY LOWER ABDOMEN, LEGS AND BACK. I HAVE VAGINAL BACTERIAL INFECTIONS CONSTANTLY. I HAVE NUMBNESS AND TINGLING IN MY FACE, HANDS AND FEET. I HAVE TEETH CRUMBLING. MY VISION BLURS. I HAVE BLOATING IN MY STOMACH. THE CRAMPS DURING MY PERIOD ARE EXCRUCIATING (I DIDN'T HAVE ANY CRAMPING DURING MENSTRUATION PRIOR TO ESSURE). I HAVE DARK CIRCLES AROUND MY EYES AT ALL TIMES. I DEVELOP CONSTANT HIVES ON MY KNEES AND ARMS AND SOMETIMES THROUGHOUT MY ENTIRE BODY. I CANT SLEEP FOR ANYTHING! I HAVE WEAKNESS AND NAUSEA. I DON'T HAVE ANY ENERGY AT ALL! I WAS DIAGNOSED WITH A TIA STROKE IN (B)(6) 2013.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042035	BAYER	4/10/2015	4/13/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD GOTTEN ESSURE PLACED (B)(6) 2007 AFTER I HAD MY SON. MY DOCTOR RUSHED THROUGH THE PAPER WORK NEVER ONCE SAID ANYTHING ABOUT IT BEING PERMANENT BECAUSE I VOICED MY OPINION OF WANTING THE OPTION TO HAVE MORE CHILDREN IN THE FUTURE AND I ALSO NEVER RECEIVED THE CARD WITH THE COIL INFORMATION ON IT. SINCE THE COIL IMPLANT I'VE DEVELOPED PELVIC PAIN, OVARIAN PAIN, HAIR LOSS, ANXIETY AND DEPRESSION, RANDOM RASHES AND WELTS, NAUSEA, TINGLING IN MY RIGHT HAND AND ARM, BACK PAIN, LOSS OF SEXUAL AROUSAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042036	BAYER	4/10/2015	4/13/2015

Event Information:

Event Date (B3): 9/9/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING MIGRAINES THAT ARE SO DEBILITATING THAT I'M BED BOUND. I CAN'T HELP MY CHILDREN WITH ANYTHING. IT'S LIKE I HAVE TO SLEEP THEM AWAY. SOMETIMES THE MIGRAINES GET SO BAD THAT I CANNOT KEEP MY FOOD DOWN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042037	BAYER	4/10/2015	4/13/2015

Event Information:

Event Date (B3): 2/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE EXPERIENCED HAIR LOSS. I HAD SHOULDER LENGTH HAIR AND STARTED TO NOTICE I WAS SHEDDING HAIR LIKE A DOG. MY HAIR NOW BARELY TOUCHES MY NECK. I'M AFRAID THAT I'M GOING TO BE BALD SOON. I CANNOT COMB MY HAIR WITHOUT LOSING LOTS OF MY STRANDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042038	BAYER	4/10/2015	4/13/2015

Event Information:

Event Date (B3): 10/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ISSUES BEGAN ABOUT 1 YEAR AFTER HAVING ESSURE PROCEDURE. HORRIBLE VERY LONG PERIODS, CRAMPING, PELVIC PAIN, BACK ACHE, PAIN DURING SEX, BLEEDING DURING SEX, HORRIBLE CLOTTING WITH PERIODS, HEART FLUTTERS, ABDOMINAL BLOATING, FLOATERS IN VISION. MY OB GYN WILL NOT LOOK INTO MY ISSUES AS SHE SAYS THIS IS ALL NOTHING TO WORRY ABOUT. GETTING A SECOND OPINION SOON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042039	BAYER	4/10/2015	4/13/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. I DO NOT HAVE A LOT NUMBER AS NO ONE EVER PROVIDED ME WITH AN ENSURE CARD. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN (B)(6) 2011. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. EXTREME HAIR LOSS, BACK PAIN, PELVIC PAIN, LOSS OF LIBIDO, NIGHT SWEATS, HEADACHES, DIZZINESS, SENSITIVITY TO CHEMICALS I'VE ALWAYS USED, SENSITIVITY TO FOOD I'VE EATEN FOR YEARS, I'M COLD ALL THE TIME EVEN IT IT'S 80 DEGREES IN MY HOUSE I AM IN LAYERS AND SHIVERING, MOOD SWINGS, MEMORY LOSS, JOINT PAIN THAT WAS SO BAD WHEN I WAS PREGNANT THE SECOND TIME WHILE BEING ON ESSURE THAT MY FINGERS WOULD BE STIFF AND HAD TO POP TO GET THEM TO MOVE - THE PAIN WAS EXTREME, I BRUISE EASILY NOW AND SOMETIMES HAVE NO IDEA WHERE THE BRUISE CAME FROM AS I DIDN'T HIT ANYTHING - TOTALLY UNEXPLAINABLE, EXCESS FATIGUE, I HAVE GOTTEN PREGNANT TWICE AFTER HAVING A CONFIRMED HSG AS POSITIVE OF BLOCKAGE, DRY SKIN, MY MUSCLES TWITCH, MY MENSTRUAL CYCLE IS LONGER AND MUCH HEAVIER AND MY CRAMPS LAST AFTER MY MENSTRUAL CYCLE IS FINISHED. I HAVE NOT BEEN SEEN BY ANY DOCTORS AS OF YET BUT NOW THAT I AM AWARE THAT THIS IS THE PROBLEM I WILL BE SEEING MY DR. NEXT WEEK TO FIND OUT HOW TO GET THIS POISON OUT OF MY BODY. THE DEVICE IS STILL INSIDE OF ME AS OF TODAY, (B)(6) 2015 BUT HOPEFULLY THAT WILL BE TAKEN CARE OF SOON AND THEY WILL BE REMOVED!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042114	BAYER	4/10/2015	4/17/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE (B)(6) 2013, AFTER A FEW MONTHS AND OVER THE LAST 2 YEARS I HAVE EXPERIENCED THE FOLLOWING SYMPTOMS: LONGER HEAVIER PERIODS EVERY 29 DAYS, LASTING 12-15 DAYS, BROWN SPOTTING IN BETWEEN PERIODS, WORSENING DEPRESSION WHILE ON PROZAC, FREQUENT HEADACHES, MORE MIGRAINES, EYE FLOATERS BLURRED VISION, SEVERE JOINT PAIN 4-5 TIMES A MONTH, LASTING 3-4 DAYS AT A TIME, LOW BACK PAIN WITH SPASMS, BLOATED FEELING ALL THE TIME AND BACK SPASMS. FEELING LIKE I HAVE THE FLU EVERY OTHER WEEK. TUMMY TROUBLES - SOFT STOLLS, CRAMPS, SHOOTING PAINS IN LOW COLON AREA, UNEXPLAINED NAUSEA, PAINFUL SEX, CANNOT USE TAMPONS, SEVERAL LOW GRADE FEVERS, 99-100, BRAIN FOG, FORGETFULNESS AND 30 LB WEIGHT GAIN. I AM ALWAYS TIRED TO POINT OF EXHAUSTION. I HAVE INSOMNIA WITHOUT MELATONIN USE. I HAVE EXCESSIVE HAIR GROWTH ON CHEST AND FACE, NOISE SENSITIVITY, ALWAYS THIRSTY, EXCESSIVE GAS. ALL OF THESE ARE MAKING MY DAILY LIFE VERY DIFFICULT TO LIVE IN. I AM CRABBY ALL OF THE TIME WITH MY FAMILY. PLEASE, PLEASE DON'T LET OTHER WOMEN GO THROUGH THIS!

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00250	BAYER HEALTHCARE LLC	4/10/2015	5/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON 14-MAR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION WAS RECEIVED ON 16-MAR-2015. PHYSICIAN (WHO WAS NOT THE INSERTING PHYSICIAN) REPORTED THAT THE PATIENT SENT A FILM SHOT OF HER HYSTEROSALPINGOGRAM (HSG). HE FORWARDED THE FILM AND IT APPEARS THAT THERE ARE 5 IMPLANTS IN THE TUBE AND ONE COULD HAVE BEEN THE DELIVERY CATHETER. FOLLOW-UP INFORMATION RECEIVED ON 23-MAR-2015 AND PTC INVESTIGATION RESULT RECEIVED ON 24-MAR-2015 PHYSICIAN STATED THAT HE DID NOT HAVE INFORMATION REGARDING ANY SPECIFICS OF THE PATIENT. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AS WELL AS A USABILITY ISSUE. NO MEDICAL EVENTS WERE REPORTED AT THIS TIME. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. AS NO MEDICAL EVENTS WERE REPORTED, AN ASSESSMENT OF

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A RELATIONSHIP IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT HYSTEROSALPINGOGRAM (HSG) IT APPEARED 5 IMPLANTS WERE IN THE TUBE; REPORTER SUSPECTED ONE COULD HAVE BEEN THE DELIVERY CATHETER. THESE EVENTS, REGARDED AS DEVICE MISUSE AND SUSPICION OF DEVICE BREAKAGE, WERE CONSIDERED NON-SERIOUS. DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE OTHER EVENT IS LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE AND MECHANISM OF THE REPORTED DEVICE BREAKAGE IS NOT KNOWN; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THE REMAINING EVENT WAS CONSIDERED AS UNRELATED TO ESSURE DUE TO ITS NATURE (MISUSE). THIS CASE WAS REGARDED AS AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THE SUSPECTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042110	BAYER	4/11/2015	4/17/2015

Event Information:

Event Date (B3): 9/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 975385

Single Use:
Implant Date (E6): 9/4/2012
Explant Date (E7): 1/8/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE DEVICE ON (B)(6) 2012. IT WAS DONE AT AN OUTPATIENT HOSPITAL FACILITY, WHICH I DID NOT REALIZE THIS WOULD BE A SURGERY IN A HOSPITAL UNTIL ABOUT A WEEK PREVIOUS. AFTER THE PROCEDURE I HAD CRAMPING AND BLEEDING, HOWEVER THE PAIN IN MY LOWER, LEFT ABDOMEN CONTINUED TO HURT. WHILE AT MY THREE MONTH CHECK OF THE ESSURE PLACEMENT I EXPLAINED THE PAIN I WAS STILL HAVING TO MY OB/GYN WHO DID THE PROCEDURE, SHE SAID THAT IT SOUNDED LIKE A MUSCLE THAT WAS CAUSING MY PAIN. THIS PAIN IN MY LEFT ABDOMEN CONTINUED TO HURT, AND I STARTED TO HAVE OTHER PROBLEMS AS WELL, LIKE CONSTANT HEADACHES, BOWEL PROBLEMS, CHRONIC PELVIC PAIN, TOTAL LACK OF A SEX DRIVE, TINGLING IN MY LEGS AND ARMS, PAIN DURING INTERCOURSE, FEELING WORN OUT AND TIRED ALL OF THE TIME, AND MY ABDOMEN WAS SWOLLEN AND WAS TENDER, IT ALSO WOULD HURT TO EXERCISE AS WELL AS EVEN TO SIT DOWN TOO FAST. I WENT TO THE EMERGENCY ROOM A FEW TIMES FOR HORRIBLE PELVIC PAIN, AS WELL AS TO MY FAMILY DOCTOR TO FIND OUT WHAT WAS GOING ON. EACH TIME AFTER MANY TESTS AND ULTRASOUNDS, THEY COULD NOT EXPLAIN WHY I WAS FEELING THIS WAY. I EVENTUALLY WENT TO A NEW DOCTOR AS I HAD MOVED TO A NEW TOWN, THE DOCTOR DID AN ULTRA SOUND AND THEY SAID I HAD AN ENLARGED UTERUS, FIBROIDS, THIS WAS A SHOCK BECAUSE NOT EVEN TWO YEARS EARLIER I HAD NO PROBLEMS WITH MY UTERUS AT ALL. I TRIED GOING BACK TO MY OB/GYN WHO DID THE ESSURE PROCEDURE, AS SUGGESTED BY MY DOCTOR, HOWEVER SHE DID NOT ACCEPT MY INSURANCE UNLESS IT WAS PREGNANCY RELATED. FINALLY I WAS REFERRED TO AN OB/GYN WHO ACCEPTS MY INSURANCE AND ENDED UP HAVING TO HAVE A LAVH HYSTERECTOMY TAKING EVERYTHING EXCEPT MY OVARIES ON (B)(6) 2015. SINCE MY HYSTERECTOMY I NO LONGER HAVE THE CHRONIC PELVIC PAIN THAT WAS IN MY LOWER LEFT ABDOMEN, AND THE PAIN DURING INTERCOURSE IS NO LONGER THERE. SLOWLY MY OTHER

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PROBLEMS I WAS EXPERIENCING ARE GOING AWAY. I WAS NEVER INFORMED OF THESE POTENTIAL PROBLEMS WHILE CONSIDERING THE ESSURE PROCEDURE AND IF I WOULD HAVE BEEN, I DON'T THINK I WOULD HAVE CHOSEN TO GET THIS PROCEDURE DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042093	BAYER	4/12/2015	4/17/2015

Event Information:

Event Date (B3): 4/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESSURE COILS
Catalog # (E4):
Lot #(E4): 975389

Single Use:
Implant Date (E6): 12/9/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE 2 YEARS AGO AND SINCE THEN I HAVE SEVERE PAIN IN THE LOWER ABDOMEN, HEAVY PERIOD, DIZZINESS, CYSTS IN THE LEFT OVARY, JOINT PAIN, DRY SKIN, AND NAUSEA.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00252	BAYER HEALTHCARE LLC	4/13/2015	4/13/2015

Event Information:

Event Date (B3): 11/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 5/15/2014
Explant Date (E7): 12/18/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 10-DEC-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT STERILIZATION. THE PATIENT WAS NOT PREGNANT. THE RADIOLOGIST KEPT PUTTING OFF THE HSG (HYSTEROSALPINGOGRAM) FOR THE PATIENT BECAUSE SHE WAS SPOTTING. SHE WAS ON DEPO PROVERA. THE PATIENT WAS EXPERIENCING CRAMPING AND DISCOMFORT ON THE RIGHT SIDE WHICH IS WHY THE DOCTOR WANTED TO REMOVE THE ESSURE. THE REPORTER DID NOT KNOW WHEN THE SPOTTING, CRAMPING, AND DISCOMFORT STARTED OR IF SHE WAS STILL SPOTTING. THE HSG WAS DONE (B)(6) 2014 AND SHOWED THE LEFT SIDE OCCLUDED AND ON THE RIGHT SIDE THE ESSURE HAD PERFORATED. THE REPORT NOTED THAT IT APPEARED TO PROJECT INTO THE CORNUA, BUT THE CETHALD (AS REPORTED) DID NOT GO INTO THE TUBE. IT CURLED BACK AROUND INTO THE MYOMETRIUM. THE RIGHT FALLOPIAN TUBE FILLED LATERALLY WITH FREE SPILL. ESSURE WAS ONGOING. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-DEC-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS:(B)(4). FINAL ASSESSMENT: A PERFORATION IS A HOLE OR OPENING MADE THROUGH THE ENTIRE THICKNESS OF A MEMBRANE OR OTHER TISSUE OR MATERIAL. PROBABLE CAUSES FOR PERFORATION: PHYSICIAN ENCOUNTERS POOR VISIBILITY DURING THE PROCEDURE, PHYSICIAN TECHNIQUE AND EXPERIENCE, ADVANCING DELIVERY CATHETER WHEN PATIENT IS EXPERIENCING EXTRAORDINARY PAIN OR DISCOMFORT, ATTEMPTING TO ADVANCE DELIVERY CATHETER TO BLACK POSITIONING MARKER AFTER ENCOUNTERING UNDUE RESISTANCE, FURTHER ADVANCING DELIVERY CATHETER ONCE THE BLACK POSITIONING MARKER HAS REACHED THE TUBAL OSTIUM, ATTEMPTED REMOVAL OF AN IMPLANTED MICRO-INSERT WITH FEWER THAN 18 TRAILING COILS INTO THE UTERUS, INACCURATE

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PLACEMENT OF THE MICRO-INSERT IN THE FALLOPIAN TUBE BY THE PHYSICIAN. ACCORDING TO THE PRODUCT IFU, THE MICRO-INSERT MUST BE PLACED FAR ENOUGH INTO THE FALLOPIAN TUBE TO PREVENT EXPULSION (LESS THAN 18 TRAILING COILS).PERFORATIONS ARE A KNOWN RISK OF THE ESSURE PROCEDURE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. PERFORATION IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ESSURE PERFORATION QUESTIONNAIRE WAS RECEIVED FROM THE PHYSICIAN ON 16-MAR-2015: PATIENT'S WEIGHT AND HEIGHT WERE ADDED ((B)(6)). SHE HAD 2 PREVIOUS PREGNANCIES (GRAVIDA 2, PARITY 2. LAST VAGINAL DELIVERY ON (B)(6) 2014) AND LEEP AND COLPOSCOPY AS PREVIOUS GYNECOLOGICAL INTERVENTIONS. ESSURE WAS INSERTED AT POSTPARTUM STATE UNDER PARACERVICAL BLOCK WITH ROPIVACAINE AND LIDOCAINE WITH EPINEPHRIN. TORADOL, HYDROCODONE WITH ACETAMINOPHEN AND VALIUM WERE ALSO USED AS ANALGESIA. NO CERVICAL DILATATION OR SOUNDING WERE APPLIED AND THE INSERTION WAS EASY, EXCEPT FOR TUBAL OSTIUM VISUALIZATION (DIFFICULTY IN MAINTAINING DISTENSION). FLUID LOSS WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. DEPO PROVERA WAS USED AS BACKUP CONTRACEPTION. ON (B)(6) 2014 THE PATIENT UNDERWENT HSG (HYSTEROSALPINGOGRAM) WHICH SHOWED THE PARTIAL PERFORATION ON THE RIGHT SIDE. NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS PERFORATED AND ACCORDING TO PHYSICIAN, THE PERFORATION DID NOT OCCURRED DURING SOUNDING, CERVICAL DILATATION OR HYSTEROSCOPY PRIOR TO ESSURE. IT WAS UNKNOWN IF THE PERFORATION OCCURRED BEFORE OR AFTER DEPLOYMENT. ON (B)(6) 2014 THE RIGHT ESSURE COIL WAS REMOVED BY LAPAROSCOPY (BIPOLAR TUBAL); THE LEFT COIL REMAINED. NO COILS WERE SEEN ON HYSTEROSCOPY PRIOR TO REMOVAL; ONE COIL WAS STICKING OUT OF RIGHT CORNUA. PHYSICIAN REPORTED THAT THE REMOVAL WAS MEDICALLY NECESSARY AND NO DIAGNOSTIC TESTS OR PATHOLOGY RESULTS WERE PERFORMED POST ESSURE REMOVAL. NO HYSTERECTOMY OR SALPINGECTOMY WAS NECESSARY. THE PATIENT RECOVERED AFTER ESSURE REMOVAL AND THE PHYSICIAN RELATED THE EVENTS TO ESSURE. CASE UPGRADED TO INCIDENT. PTC INVESTIGATION RESULT RECEIVED ON 25-MAR-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A

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POTENTIAL QUALITY DEFECT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A(B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HYSTEROSALPINGOGRAM (HSG) SHOWED ON THE RIGHT SIDE ESSURE HAD PERFORATED; SHE WAS SUBMITTED TO A HYSTEROSCOPY/LAPAROSCOPY AND THE COIL WAS SEEN STICKING OUT OF RIGHT CORNUA. SHE RECOVERED AFTER SURGERY. THE REPORTED EVENT, REGARDED AS UTERINE PERFORATION, WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND LISTED ACCORDING TO THE ESSURE REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED PERFORATION WAS UNKNOWN; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFECT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00253	BAYER HEALTHCARE LLC	4/13/2015	4/13/2015

Event Information:

Event Date (B3): 1/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 761616; 774372

Single Use: Y
Implant Date (E6): 1/3/2011
Explant Date (E7): 5/9/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039001) IN UNITED STATES ON 16-MAR-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 761616/774372, INSERTED ON (B)(6) 2011. CONSUMER STARTED EXPERIENCING HORRIBLE ABDOMINAL PAINS A COUPLE OF MONTHS AFTER ESSURE PLACEMENT. SHE HAD GONE BACK TO SEE HER OBSTETRICIAN/GYNECOLOGIST AND THE IMPLANTS HAD ACTUALLY MIGRATED. SHE NEEDED TO HAVE SURGERY ON (B)(6) 2011 TO REMOVE THEM AND HER TUBES. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 25-MAR-2015, (B)(4): FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORDS AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THESE LOTS WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED MEDICAL EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. (B)(4) ADDITIONAL ADVERSE EVENT CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER 761616 BUT THIS CASE DOES NOT REFER TO SIMILAR MEDICAL EVENT. NO ADDITIONAL ADVERSE EVENT CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER 774372. NO BATCH SIGNALS CAN BE IDENTIFIED AT THIS TIME. REVIEW OF ASSOCIATED BATCH DOCUMENTATION DID NOT REVEAL ANY

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DEFICIENCIES OR GIVE ANY REASON TO SUSPECT A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANT CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE IMPLANTS MIGRATED. THEY WERE SURGICALLY REMOVED. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED DEVICE MIGRATION IS NOT KNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 28-JUL-2015 PHYSICIAN SAID THAT HE DID NOT TREAT PATIENT WITH ESSURE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00254	BAYER HEALTHCARE LLC	4/13/2015	4/13/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 794898

Single Use: Y
Implant Date (E6): 10/17/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5038931) IN UNITED STATES ON 16-MAR-2015 WHICH REFERS TO THE CONSUMER HERSELF OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011; THE LOT NUMBER USED WAS 794898. CONSUMER STATED THAT HER PROCEDURE FAILED BECAUSE BOTH HER COILS MIGRATED PRIOR TO HER THREE MONTH HSG (HYSTEROSALPINGOGRAM) TESTING TO CONFIRM IF HER TUBES WERE OCCLUDED OR NOT; SHE STATED THAT THIS WAS IN 2012. SHE REPORTED THAT ALSO IN 2012 SHE HAD TO HAVE A TUBAL AND REMOVAL OF THE ESSURE DEVICES SINCE HER BODY REJECTED BOTH. THE PHYSICIAN TOLD HER HE HAD REMOVED EVERYTHING; HOWEVER AS TIME WENT BY SHE FOUND OUT IN 2014, THAT HE ACTUALLY DID NOT GET BOTH DEVICES. SHE STILL HAD FRAGMENTS AND 1 COIL WAS IN HER PELVIS SINCE FINDING OUT THAT INFO SHE HAD TO HAVE TWO MRI'S AND ACCORDING TO THE BOOKLET IT STATES "MRI IS SAFE AS LONG AS THE TESLA IS AT 1.4 OR BELOW!" SHE STATED THAT MRI IS NOT SAFE IF AN ESSURE COIL OR FRAGMENTS WERE FLOATING IN PELVIC AREA; SHE HAD IMAGING FROM WHEN SHE FOUND OUT THE FIRST METAL STILL INSIDE OF PELVIC AREA AND JUST HAD ANOTHER SET OF IMAGING DONE ONE DAY BEFORE THE REPORT, AND IT CLEARLY SHOWED THE COIL HAS MOVED WHEN YOU COMPARE THE TWO SETS OF IMAGES. AN INJURY WAS MENTIONED AS SERIOUSNESS CRITERIA BUT NOT SPECIFIED OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATIONAL RESULTS RECEIVED ON 31-MAR-2015: (B)(4). FINAL ASSESSMENT: PRODUCTION DATE: OCT-2010. EXPIRATION DATE: OCT-2013. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT

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FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE (BREAKAGE). THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED MEDICAL EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, BUT NONE OF THE CASES REFER ALSO TO A SIMILAR ADVERSE TYPES OF EVENTS. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT BOTH HER COILS MIGRATED PRIOR TO MY THREE MONTH HSG (HYSTEROSALPINGOGRAM) TESTING (INTERPRETED AS DEVICE DISLOCATION). AFTER REMOVAL OF THE ESSURE DEVICES, SHE STILL HAD FRAGMENTS AND 1 COIL WAS IN HER PELVIS (INTERPRETED AS DEVICE BREAKAGE) AND AFTERWARDS, THE COIL HAS MOVED (INTERPRETED AS DEVICE DISLOCATION). THE EVENTS DEVICE DISLOCATION ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION AND DEVICE BREAKAGE WERE NOT KNOWN, HOWEVER GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042226		4/13/2015	4/24/2015

Event Information:

Event Date (B3): 4/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/23/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6) 2013. SINCE THEN I SUFFER FROM JOINT PAINS, REALLY BAD HEADACHES, VERY HEAVY PERIODS, AND BAD CRAMPS. OVER THE WEEKEND (B)(6) 2015, I WAS IN SO MUCH PAIN I WAS RUSHED TO THE EMERGENCY ROOM. AFTER DOING A LOT OF BLOOD WORK AND OTHER TEST, THEY FOUND OUT THAT I WAS PREGNANT AND IT MAY BE IN THE TUBES. HOW COULD THIS BE IF I GOT A PROCEDURE DONE SO I COULDN'T HAVE BABIES ANYMORE. NOW I HAVE TO GO THROUGH MORE PAIN BECAUSE OF THIS FAULTY PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00251	BAYER HEALTHCARE LLC	4/13/2015	5/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. PHYSICIAN REPORTED THAT THE DELIVERY WIRE AND CATHETER WERE BENT WHEN PACKAGE WAS OPENED. THE MECHANISM WORKED BUT THE CATHETER LOOKED FRACTURED. NO INJURY OCCURRED TO THE PATIENT. BILATERAL PLACEMENT WAS ACHIEVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE MECHANISM WORKED BUT CATHETER LOOKED FRACTURED. THE REPORTED EVENT, REGARDED AS SUSPICION OF DEVICE BREAKAGE, WAS CONSIDERED NON-SERIOUS AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, PHYSICIAN STATED DEVICES TIPS WERE BENT WHEN THE PRODUCT WAS OPENED; A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION; NEVERTHELESS SINCE THE REPORTED EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THERE WAS NO DEATH OR SERIOUS HEALTH DETERIORATION TO THE PATIENT THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: AS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042160	BAYER	4/15/2015	4/22/2015

Event Information:

Event Date (B3): 2/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/27/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE IMPLANTED I HAVE HAD HEADACHES, ABDOMINAL PAIN, SKIN RASHES, LETHARGY AND MY THROAT FEELS LIKE ITS CLOSING. I HAVE A NICKEL ALLERGY AND WAS MISLED ON THE AFFECTS IT WOULD HAVE ON ME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00255	BAYER HEALTHCARE LLC	4/16/2015	4/16/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** PO

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/26/2014
Explant Date (E7): 11/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 11-NOV-2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT (NURSE) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED ON 13-NOV-2014. ON (B)(6) 2014 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED, EASY AND RAPID ON THE LEFT TUBE WITH 3 RINGS, MORE DIFFICULT DUE TO OEDEMA ON THE LEFT (DISCREPANT INFORMATION) BUT WITH DEEP ENTRY WITH 1 RING. NO PAIN. ON (B)(6) 2014, SHE DID A PELVIS X-RAY WITH SEPARATION OF ESSURE RINGS AND THEREFORE SHE DID HYSTEROSALPINGOGRAM WHICH REVEALED SOME CONTRAST LEAK ON THE RIGHT. CONSEQUENTLY, ON (B)(6) 2014, A NEW ESSURE WAS INSERTED IN THE RIGHT TUBE, WITH 3 RINGS. ON (B)(6) 2014, THE PATIENT EXPERIENCED DERMATITIS IN THE INFRAMAMMARY RIDGE, AXILLAE, INGUINAL REGION AND ABDOMEN, BY ORDER OF APPEARANCE (AN INFRAMAMMARY SPOT SHOWED FOR THE FIRST TIME ALONG THE BRA LINING). NICKEL ALLERGY TEST WAS ALREADY DONE AND WAS POSITIVE (THIS IN ORDER TO EXCLUDE OTHER CAUSES BEFORE SURGICAL INTERVENTION). THE PATIENT WAS TREATED WITH LEPICORTINOLO (PREDNISOLONE) 30MG WITH NO IMPROVEMENT; IT ONLY IMPROVED WITH THE CORTICOID INCREASE TO 40MG. SHE WAS ALSO TREATED WITH FLUCONAZOLE, WITH INITIAL IMPROVEMENT BUT AS THE CORTICOID DOSE HAS DECREASED, SHE GOT WORSE AGAIN. SHE VISITED 2 DERMATOLOGISTS WHO SHARED THE OPINION THAT THIS WAS AN ALLERGIC REACTION INITIALLY BELIEVED TO BE FOOD RELATED BUT LATER AND AFTER THE [MEDICAL] HISTORY, CONSIDERED RELATED TO ESSURE. CURRENTLY SHE MAINTAINS LESIONS, WHICH GET WORSE WITH HEAT AND SWEAT AND WAS TAKING CORTICOIDS AND FLUCONAZOLE. THE OUTCOME OF THE EVENT DERMATITIS IN THE INFRAMAMMARY RIDGE, AXILLAE, INGUINAL REGION AND ABDOMEN, BY ORDER OF APPEARANCE WAS NOT RECOVERED / NOT RESOLVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION

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RECEIVED ON 27-NOV-2014: FINAL ASSESSMENT: AN ALLERGY IS A HYPERSENSITIVITY TO A SUBSTANCE THAT CAUSES THE BODY TO REACT TO ANY CONTACT WITH THAT SUBSTANCE. COMMON INDICATIONS OF ALLERGY MAY INCLUDE SNEEZING, ITCHING, SKIN RASHES AND HIVES. PROBABLE CAUSE FOR AN ALLERGIC RESPONSE IN PATIENT. AN ALLERGIC RESPONSE TO THE ESSURE MICRO-INSERT IS MOST OFTEN DUE TO THE PATIENT'S SENSITIVITY TO NICKEL. ACCORDING TO THE PRODUCT IFU, THE ESSURE SYSTEM SHOULD NOT BE USED ON ANY PATIENT WITH A KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE ADVERSE EVENT CASE REFERS ALSO TO A USABILITY ISSUE AND A LACK OF EFFICACY (PATENCY). HOWEVER, LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER COMPLAINT SAMPLE NOR BATCH NUMBER WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. (B)(4). FOLLOW-UP FROM 07-JAN-2015: NO REPLIED OBTAINED. FOLLOW-UP RECEIVED FROM RESIDENT PHYSICIAN ON 19-MAR-2015: INFORMATION RECEIVED FROM A GYNECOLOGIST RESIDENT STATES THAT PATIENT EXPERIENCED HYPERSENSITIVITY TO ESSURE'S NICKEL. AFTER CONFIRMATION OF ALLERGY IN THE EPICUTANEOUS TESTS AND EXCLUSION OF OTHER DIAGNOSES, BOTH ESSURE DEVICES WERE REMOVED. THE DEVICE PLACED 9 MONTHS AGO WAS REMOVED BY HYSTEROSCOPY AND THE OTHER, PLACED 6 MONTHS AGO, WAS REMOVED BY LAPAROSCOPY. IN ADDITION, HEALTH CARE PROFESSIONAL INFORMED THAT RASH AND PRURITUS SYMPTOMS HAVE DISAPPEARED ONE MONTH AFTER THE INTERVENTION. CASE CONSIDERED AN INCIDENT. PTC INVESTIGATION RESULT WAS RECEIVED ON 10-APR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO REQUEST FOR CONFIRMATION OF QUALITY, A LACK OF EFFICACY (CONTRAST LEAK ON THE RIGHT) AND USABILITY ISSUES. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS ALSO NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, ALSO A DEVICE MISUSE WAS REPORTED. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. CORRECTION BASED ON INFORMATION RECEIVED ON 10-APR-2015: AFTER A COMPANY INTERNAL REVIEW DEVICE SIMILAR CASE LISTING WAS ATTACHED TO THE CASE. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 15-APR-2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: ALLERGY TO METALS. THE ANALYSIS IN THE GLOBAL SAFETY

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DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HYPERSENSITIVITY TO ESSURE'S NICKEL (TEST FOR NICKEL ALLERGY WAS POSITIVE). THE DEVICES WERE SURGICALLY REMOVED AND SHE RECOVERED FROM THE EVENT. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, AFTER ESSURE INSERTION, PATIENT EXPERIENCED A PRURIGINOUS DERMATITIS WHICH RECOVERED WITH DEVICES REMOVAL. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE REQUIRED INTERVENTION FOR DEVICES REMOVAL REPORTED UPON FOLLOW-UP, THIS CASE, INTIALLY REGARDED AS NON-INCIDENT WAS AMENDED TO INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED TO UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00256	BAYER HEALTHCARE LLC	4/16/2015	4/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 18-MAR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN REPORTED THAT THE PATIENT WAS BEING TAKEN TO THE OPERATING ROOM DUE TO A PERFORATION OF ESSURE DEVICE, THE PATIENT'S RIGHT DEVICE WAS IN HER PELVIS. PHYSICIAN ASKED IF SHE SHOULD REMOVE THE ESSURE OF LEFT SIDE BECAUSE THE PATIENT WAS COMPLAINING OF PAIN ON THAT SIDE. PHYSICIAN REPORTED THAT THE LEFT TUBE WAS BLOCKED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 25-MAR-2015, REFERRING TO (B)(4): FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP

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BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A PERFORATION OF AN ESSURE DEVICE. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A COMPLETE PERFORATION OCCURS, ESSURE CAN BE FOUND IN THE PELVIC CAVITY AS IT PERFORATES THE WHOLE FALLOPIAN TUBE WALL. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE PERFORATION IS UNKNOWN, GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. SINCE PHYSICIAN STATED PATIENT WAS BEING TAKEN TO THE OPERATING ROOM DUE TO THE EVENT, THIS CASE WAS REGARDED AS INCIDENT (REQUIRED INTERVENTION). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 10-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PAT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042200	BAYER	4/16/2015	4/24/2015

Event Information:

Event Date (B3): 4/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/4/2012
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2012, (B)(6) ESSURE, (B)(6) 2013, (B)(6) UTERINE ABLATION FOR SEVERE BLEEDING, SEVERAL HOSPITAL VISITS AND ULTRASOUNDS LATER, (B)(6) 2015, (B)(6) HYSTERECTOMY, 2 DAYS AGO ANOTHER ER VISIT WITH X-RAYS SHOWING THE INTENSE FLANK PAIN WAS SITE OF COIL ON LEFT, RIGHT COIL NOT FOUND IN X-RAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042202	BAYER	4/16/2015	4/24/2015

Event Information:

Event Date (B3): 4/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN (B)(6) 2013, I HAD MY CONFIRMATION TEST DONE AND BY (B)(6) 2014 I HAD 3 MENSTRUAL CYCLES. I WENT TO GYN AND HE DIDN'T FIND ANYTHING. A WEEK LATER, I WENT TO ER TO HEAR THE MOST DEVASTATING NEWS THAT I WAS PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042203		4/16/2015	4/24/2015

Event Information:

Event Date (B3): 4/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/22/2013
Explant Date (E7): 2/24/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PUT IN (B)(6) 2013, SINCE THEN I HAVE HAD PROBLEMS WITH ANXIETY, DEPRESSION, MIGRAINES 3 OR MORE TIMES A WEEK, PAIN IN MY SIDE, AND ITCHING OF THE SKIN. ON (B)(6) 2014 HAD TO HAVE A TUBULIZATION BECAUSE ONE TUBE WAS STILL OPEN. (B)(6) 2015, HAD MY TUBES/ESSURE REMOVED. PRE OP APPOINTMENT, I FOUND OUT SOME INFO THAT GOT ME WONDERING WHY THE ESSURE WAS EVEN PUT ON THE MARKET. ONE THE PAPER ON MY HBG TEST STATES THAT THE RIGHT MICRO INSERT WAS NORMAL. THE LEFT MICRO INSERT IS MEDIAL TO THE FEET OF THE TUBE AND OUTSIDE OF ENDOMETRIAL CAVITY WITH THE DISTAL PORTION PARTIALLY OVERLYING THE LEFT UTERINE CORNU. MY XRAY SHOWED THAT ONE OF THEM WAS NOT EVEN IN MY TUBE. IT WAS IN MY UTERINE WALL AND THE OTHER WAS POLING THROUGH. SINCE MY SURGERY. I FEEL 100% BETTER. I HAVE NOT HAD A MIGRAINE SINCE MY SURGERY. I HAVE COPIES OF ALL MY RECORDS AND PICTURES FROM ALL THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042204	BAYER	4/16/2015	4/24/2015

Event Information:

Event Date (B3): 4/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD TO HAVE TWO MAJOR SURGERIES TO REMOVE FROM MY TUBES. THE LEFT SIDE PERFORATED MY TUBE AND STUCK TO MY BOWEL. CAUSED ME PAIN, LOST WAGES FROM BEING OFF WORK.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00257	BAYER HEALTHCARE LLC	4/16/2015	5/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C55829

Single Use: Y
Implant Date (E6): 1/20/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/10/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN FRANCE ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; LOT NUMBER C55829. THE PATIENT MEDICAL HISTORY INCLUDES GRAVIDA IV, PARA II, C-SECTION, THERAPEUTIC ABORTION DUE TO TOXOPLASMOSIS SEROCONVERSION WITH SEVERE INTRAUTERINE GROWTH RESTRICTION AND MULTIFETAL PREGNANCY REDUCTION. CONCURRENT CONDITION INCLUDES INSULIN-REQUIRING DIABETES. PHYSICIAN STATED THAT THE EVENT OCCURRED DURING THE PLACEMENT IN THE OPERATING ROOM. ON THE RIGHT SIDE THE ATTEMPT OF INTRATUBAL ESSURE DEVICE PLACEMENT OCCURRED WITH MANIPULATIONS WELL RESPECTED BUT THE INSERT WAS COMPLETELY WITHDRAWN AND UNCOILED, LEAVING IN PLACE THE GREEN RELEASE CATHETER. THIS LATER WAS REMOVED IN TWO CATCHES WITH HELP OF CROCODILE CLIP. ON THE LEFT SIDE, THE INSERT RELEASE WAS DIFFICULT WHEREAS PROCEDURE WAS CORRECTLY PERFORMED. HOWEVER, INSERT WAS SUCCESSFULLY RELEASED THANKS TO BACK AND FORTH MOVEMENTS WITH LATERAL INCLINATION. THE PLACEMENT INTERVENTION LASTED FOR 30 MIN. THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER ESSURE SYSTEM DEVICE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DURING THE PLACEMENT ON THE RIGHT SIDE, THE INSERT WAS COMPLETELY WITHDRAWN AND UNCOILED, LEAVING IN PLACE THE GREEN RELEASE CATHETER. THIS LATER WAS REMOVED IN TWO CATCHES WITH HELP OF CROCODILE CLIP. ON THE LEFT SIDE, THE INSERT RELEASE WAS DIFFICULT WHEREAS PROCEDURE WAS CORRECTLY PERFORMED. THE BILATERAL PLACEMENT WAS ACHIEVED WITH ANOTHER SET OF DEVICES. THESE EVENTS, SEEN AS DEVICE BREAKAGE AND DEVICE INSERTION DIFFICULTY, ARE NON-

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SERIOUS. THE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE OTHER EVENT IS LISTED. DEVICE BREAKAGE MAY OCCUR MOST OFTEN DURING DIFFICULT INSERTIONS. CONSIDERING THE REPORTED EVENTS ARE ASSOCIATED TO THE INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT. TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 06-OCT-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C55829; PRODUCTION DATE: 12-MAY-2014; EXPIRATION DATE: 3

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042293	BAYER	4/17/2015	4/28/2015

Event Information:

Event Date (B3): 4/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/12/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANT (B)(6) 2014 EVER SINCE HAVE HAD ISSUES INCLUDING BLEEDING, SPOTTING FOR DAYS, SEVERE CRAMPING, WEIGHT GAIN, HEADACHES, BODY ACHES DAILY, BACK PAIN, HIP AND LEG PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042294	BAYER	4/17/2015	4/28/2015

Event Information:

Event Date (B3): 4/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 12/22/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

COIL MIGRATION FROM RIGHT FALLOPIAN TUBE AFTER HAVING ESSURE FOR 4 YEARS AND 3 MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042295	BAYER	4/17/2015	4/28/2015

Event Information:

Event Date (B3): 2/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305-R1
Catalog # (E4): 125451361
Lot #(E4): 755529

Single Use:
Implant Date (E6): 4/11/2011
Explant Date (E7): 2/16/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED EARLY 2011 AND AFTER 3 MONTHS STARTED HAVING SEVERE ABDOMINAL AND PELVIC PAIN, DIGESTIVE ISSUES, ENERGY LOSS, AND CONSTANT AND SEVERE MENSTRUAL BLEEDING. GI WAS SUSPECTED CAUSE AND I AM SEEN BY TWO DIFFERENT GI SPECIALISTS AND A GENERAL SURGEON WHO GAVE ME 4 LOWER ENDOSCOPIES, TWO UPPER ENDOSCOPIES, AND A CAPSULE ENDOSCOPY. I ALSO HAD TO SEE PAIN MANAGEMENT AS I WAS ON SOME PRETTY POWERFUL PAIN KILLERS JUST TO FUNCTION. WAS DIAGNOSED WITH PEPTIC ULCERS AND POSSIBLE JEJUNOILEITIS. BEFORE ESSURE, I WAS COMPLETELY HEALTHY. FINALLY AN ER DOC HELPED ME AND GOT A REFERRAL FOR ME TO AN OB/GYN SPECIALIST IN (B)(6) 2015. I HAD A LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY WITH A BILATERAL SALPINGECTOMY TO REMOVE BOTH ESSURE COILS AND WHAT THEY HAD AFFECTED. MY PATHOLOGY REPORT REVEALED NUMEROUS CYSTS COVERING MY FALLOPIAN TUBES AND ONE CYST ON AN OVARY. SINCE MY HYSTERECTOMY, I HAVE NOT HAD ANY PAIN AT ALL OR DIGESTIVE ISSUES. MY HAIR IS NO LONGER FAILING OUT AND MY ENERGY LEVEL IS RECOVERING. MY QUALITY OF LIFE HAS BEEN RETURNED TO ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042296	BAYER	4/17/2015	4/28/2015

Event Information:

Event Date (B3): 3/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/8/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE (B)(6) 2013 AND 6 MONTHS LATER, I STARTED HAVING BAD SIDE EFFECTS. I TOLD THE DOCTOR WHO IMPLANTED IT AND SHE SAID THAT I WASN'T DUE TO ESSURE AND THAT IF I'M HAVING PAINFUL CRAMPS, BLOOD CLOTS REAL BAD EVERY PERIOD AND HEAVY BLEEDING THAT SHE COULD PUT ME ON ANOTHER BIRTH CONTROL WITH THE ESSURE. I HAVE BEEN HAVING SHARP PAINS IN MY VAGINA AND RIGHT SIDE EVERY SINCE I HAVE BEEN HAVING ESSURE. I HAVE BURNING, ITCHING, TINGLING AND NUMBNESS ALSO GOING ON. MY SEX PARTNER CAN FEEL THE COILS WHEN WE ARE HAVING SEX MY HAIR HAS FALLING OUT, I HAVE FOUL DISCHARGES FROM TIME TO TIME, I'M DEPRESSED A LOT. HAVE HAD MOOD SWINGS AND THE LIST GOES ON AND ON. I WANT ESSURE OUT OF ME BUT DON'T HAVE THE MONEY NOR INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042312	BAYER	4/18/2015	4/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED AND SINCE HAVE BEEN EXPERIENCING MIGRAINES, DEBILITATING FATIGUE, MEMORY LOSS, DEPRESSION, ANXIETY, PANIC ATTACKS, SEVERE BLOATING, PAINFUL AND HEAVY PERIODS, EXTREME PAIN IN MY LOWER LEFT ABDOMEN AND BACK AND HAVE NOW BEEN DIAGNOSED WITH ENDOMETRIOSIS. BECAUSE OF MY SEVERE PAIN, I WILL BE GOING FOR TESTING TO SEE IF THEY HAVE MIGRATED OR GONE THROUGH THE WALL OF MY FALLOPIAN TUBE. REGARDLESS OF THE RESULTS I WILL NOW REQUIRE A HYSTERECTOMY AT AGE (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042313	CONCEPTUS	4/18/2015	4/28/2015

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/1/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE PROCEDURE, I HAVE EXPERIENCED CHRONIC FATIGUE, EXCRUCIATING MENSTRUAL PAIN AND EXTREME BREAST TENDERNESS, IRREGULAR PERIODS, EXTREME WEIGHT GAIN AND BLOATING, UNEXPLAINED JOINT AND BACK PAIN, CHRONIC SWEATING, CONSTANT BOUGHT OF BACTERIAL VAGINOSIS, HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042314	BAYER	4/18/2015	4/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): 297551
Lot #(E4): B04948

Single Use:
Implant Date (E6): 10/14/2013
Explant Date (E7): 4/18/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PUT IN 2013 AND HAVE HAD CHRONIC PAIN IN MY ABDOMEN FATIGUE AND SWOLLEN ABDOMEN. ULTRASOUND SHOWS MY DEVICE MIGRATED INTO MY UTERUS. I AM HAVING TO HAVE A FULL HYSTERECTOMY TO HAVE THEM REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042315	BAYER	4/18/2015	4/28/2015

Event Information:

Event Date (B3): 6/11/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/11/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PERMANENT BIRTH CONTROL IMPLANTED IN ME IN 2008. I HAVE EXTREME JOINT PAIN, HIP PAIN, HEAVY AND PAINFUL MENSTRUAL CYCLES. MY HAIR IS FALLING OUT. I DIDN'T KNOW WHAT WAS CAUSING ALL MY PAIN AND FINALLY DID SOME RESEARCH AND THE EXACT SYMPTOMS I HAVE OTHER WOMEN HAVE WITH ESSURE. I WANT THIS OUT OF MY BODY AND AM DOING EVERYTHING POSSIBLE TO GET THIS OUT OF MY BODY. I AM (B)(6) OTHERWISE HEALTHY WOMEN AND MY MOM WHO IS (B)(6) CAN GET AROUND EASIER THAN I CAN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042300	BAYER	4/19/2015	4/28/2015

Event Information:

Event Date (B3): 2/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/11/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM WRITING THIS TO REPORT THE ADVERSE EFFECTS OF ESSURE. I HAD THE ESSURE PROCEDURE DONE (B)(6) 2014. PRIOR TO THE PROCEDURE, I WAS A HEALTHY WOMAN WHO HAD ALWAYS HAD REGULAR PERIODS WITH MINIMAL TO NONEXISTENT CRAMPS. MY PERIODS LASTED A MAXIMUM OF 7 DAYS, WITH THE FIRST 2 DAYS BEING SLIGHTLY HEAVIER FLOW. THE DOCTOR WHO PERFORMED THE PROCEDURE NEVER ASKED ME IF I HAD ANY METAL ALLERGIES. I HAVE EXPERIENCED SEVERE ABDOMINAL PAIN, DISCOMFORT AND BLOATING EVERY SINGLE DAY FROM THE 1ST DAY THE PROCEDURE WAS DONE. MY PERIODS ARE NO LONGER REGULAR. MY PERIODS ARE SO HEAVY THAT I AM FORCED TO WEAR DEPENDS, AS USING THE HEAVIEST MAXI PAD OR TAMPON ONLY MANAGES THE INTENSE BLOOD FLOW FOR A MAXIMUM TIME OF 30 MINS. I FREQUENTLY PASS BLOOD CLOTS UP TO AND INCLUDING THE SIZE OF BASEBALLS. THE CLOTS VARY FROM DENSE TO STRINGY TISSUE. I HAVE EXPERIENCED ANAL BLEEDING DURING THE TIME I AM ON MY PERIOD. THE CRAMPS I EXPERIENCE DURING MY PERIOD ARE DEBILITATING AND HAVE ADVERSELY AFFECTED MY ABILITY TO FUNCTION IN MY WORKPLACE. I AM NO LONGER ABLE TO PARTICIPATE IN MY NORMAL DAILY ACTIVITIES SUCH AS RUNNING OR MODERATE EXERCISE; THIS IS BECAUSE WHEN I WALK, BEND OR OTHERWISE ENGAGE MY CORE MUSCLES I EXPERIENCE SEVERE AND/OR ACUTE PAIN DIRECTLY IN THE OVARY/LOWER ABDOMINAL PART OF MY BODY. MY HAIR IS FALLING OUT AND MY HAIRLINE HAS RECEDED SINCE THE PROCEDURE. MY SKIN FREQUENTLY BREAKS OUT IN RASHES IF I COME INTO CONTACT WITH METAL. MY FAVORITE METAL/SILVER JEWELRY CAN NO LONGER BE WORN DUE TO THIS NEW METAL SENSITIVITY. DEODORANTS CONTAINING ALUMINUM IMMEDIATELY CAUSE INTENSE ITCHING, SWELLING AND RASH WHEN APPLIED TO MY SKIN. I AM UNABLE TO LOSE ANY WEIGHT, EVEN WHEN FOLLOWING A STRICT MEAL PLAN AND INTENSE EXERCISE SCHEDULE. MY ABDOMEN BECOMES GROSSLY BLOATED BY THE END OF EACH DAY, APPROX 8 HRS FROM THE TIME I WAKE UP.

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MY ABDOMEN IS COVERED IN BRIGHT RED AND PURPLE STRETCH MARKS DUE TO THIS INTENSE BLOATING, OF WHICH I DID NOT CONTAIN ANY STRETCH MARKS PRIOR TO THE PROCEDURE. I HAVE NEVER HAD CHILDREN EITHER. I FREQUENTLY FEEL NAUSEOUS AND EXPERIENCE DIFFICULTY DIGESTING CERTAIN FOODS. PRIOR TO THE PROCEDURE, I EXPERIENCED NONE OF THE SIDE EFFECTS LISTED ABOVE. THIS DEVICE HAS ADVERSELY AFFECTED MY LIFE AND MY DAILY ACTIVITIES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00258	BAYER HEALTHCARE LLC	4/20/2015	4/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C03098

Single Use: Y
Implant Date (E6): 10/21/2014
Explant Date (E7): 11/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5039085) IN UNITED STATES ON 15-JAN-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. SHE STATED THAT PRESENTED HORRIBLE CRAMPING, BLEEDING, LOWER BACK PAIN, HEADACHES, INSOMNIA, INFECTION SINCE IT WAS INSERTED. HER BODY WAS REJECTING THE DEVICE. SHE WAS SCHEDULED TO REMOVE ESSURE AT THE DAY OF THIS REPORT. NO FURTHER INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 31-JAN-2015. (B)(4). FINAL ASSESSMENT THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT

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BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 23-MAR-2015. THE CONSUMER'S INITIAL WAS UPDATED. ESSURE WAS INSERTED ON (B)(6) 2014 WITH LOT NUMBER C03098. ON (B)(6) 2014, ESSURE WAS REMOVED. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING SINCE THE DEVICE PLACEMENT. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE EVENT IS ASSESSED AS RELATED TO ESSURE USE. THIS CASE WAS PREVIOUSLY SEEN AS NON-INCIDENT. LATER, IT WAS INFORMED THAT ESSURE WAS REMOVED (REQUIRED INTERVENTION IMPLIED) AND THEREFORE THIS CASE WAS UPGRADED TO INCIDENT. OTHER NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION AND UPDATED TECHNICAL ANALYSIS ARE EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION UPDATED ON 24-JUN-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT BATCH NUMBER C03098; PRODUCTION DATE 10-DEC-2013; EXPIRATION DATE 31-DEC-2016 SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00260	BAYER HEALTHCARE LLC	4/20/2015	4/20/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53560

Single Use: Y
Implant Date (E6): 2/9/2015
Explant Date (E7): 3/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 23-MAR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; THE LOT NUMBER USED WAS B53560. PHYSICIAN REPORTED THAT ESSURE WAS PLACED BILATERALLY WITHOUT INCIDENCE. THE PATIENT RETURNED TO THE OFFICE COMPLAINING OF POPPING FEELING IN ABDOMEN, CRAMPING, MILD FEVER OF 99 DEGREES, ITCHY ALL OVER AND LOWER BACK PAIN. ON 05-MAR-2015, PER PATIENT DEMAND, A HYSTERECTOMY WAS PERFORMED FOR REMOVAL. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 01-APR-2015. (B)(4). LOT NUMBER B53560 (PRODUCTION DATE 25-JUL-2013; EXPIRATION DATE 31-JUL-2016). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. ONE FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, BUT THIS CASE DOES NOT REFER TO A SIMILAR ADVERSE TYPE OF EVENT. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL

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INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING AND LOWER BACK PAIN. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND THEY ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE, CONSIDERING THE NATURE OF THE REPORTED EVENTS, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION FOR ESSURE REMOVAL (HYSTERECTOMY). ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 04-MAY-2015 ESSURE WAS PLACED ON (B)(6) 2015. IT WAS REPORTED THAT PATIENT REQUESTED ESSURE REMOVAL DUE TO COMPLICATIONS. PATIENT HAD A X-RAY WHEN SHE FELT AND CRACKED TAILBONE AND DOCTOR TOLD HER THAT COILS WERE OUT OF P

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042267	BAYER	4/20/2015	4/28/2015

Event Information:

Event Date (B3): 12/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/26/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN (B)(6) 2014. I HAVE HAD VAGINAL BLEEDING, SEVERE BLOATING, EXCRUCIATING PELVIC PAIN, LOTS OF HAIR LOSS, AND MIGRAINE HEADACHES SINCE HAVING THIS PLACED. I HAVE TIMES WHERE MY LEGS GO NUMB, WHERE I BLEED ENOUGH TO FILL A PAD EACH HOUR, AND HAVE BEEN UNABLE TO WORK. I HAD THE HSG TEST TO CHECK PLACEMENT AS WELL IF MY TUBES WERE THEN BLOCKED. ONE OF MY COILS HAS MIGRATED AND I AM HAVING A TOTAL HYSTERECTOMY TO REVERSE THIS PROCEDURE (B)(6) 2015. I HAD NOT HAD A SINGLE SYMPTOM UNTIL THE DAY THE ESSURE WAS PLACED. BAYER DOES NOT TELL YOU THE CORRECT SIDE EFFECTS. THIS SHOULD BE REMOVED FROM THE MARKET AS SOON AS POSSIBLE BEFORE MORE WOMEN ARE HURT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00259	BAYER HEALTHCARE LLC	4/20/2015	5/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38216

Single Use: Y
Implant Date (E6): 1/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 3/9/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON (B)(4) 2015 WHICH REFERS FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015 WITH LOT NUMBER C38216. IT WAS REPORTED THAT DURING ESSURE INSERTION ATTEMPT, THE IMPLANT DID NOT DISCHARGE NORMALLY AND GOT STUCK IN TUBAL ORIFICE AND PHYSICIAN HAD TO PULL AWAY. NEW ESSURE HAD NOT BEEN INSERTED BECAUSE ACCORDING TO PHYSICIAN, PATIENT'S BOTH SIDES WERE EITHER IN DIFFICULT POSITION OR SCARRING. LAPAROSCOPIC STERILIZATION HAS BEEN PLANNED FOR THE PATIENT. ADDITIONALLY, IT WAS REPORTED PATIENT HAD MIRENA (LEVONORGESTREL) INSERTED IN THE PAST (20 MCG/24HR, CONTINUOUSLY, INTRA-UTERINE) AND BECOME PREGNANT DURING MIRENA AND A MISCARRIAGE HAD OCCURRED. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2015. THE PATIENT'S MEDICAL HISTORY INCLUDED 3 PARITIES (GRAVIDA 4). PREGNANCY HAD STARTED DURING MIRENA AND MISCARRIAGE OCCURRED. THEN SHE GOT DIFFICULT UTERINE INFECTION AND PROLONGED BLEEDING FOR WHICH SHE HAD TO USE TWO ANTIBIOTIC CURES. IT WAS PLANNED TO PERFORM NOVASURE PROCEDURE DUE TO HEAVY MENSTRUAL BLEEDING AND COMBINED WITH ESSURE. HER LAST MENSTRUATION WAS ON (B)(6) 2015. CONDOM USED AS CONTRACEPTION. ON (B)(6) 2015 ESSURE INSERTION FOR BOTH SIDES WAS TRIED. IMPLANT DID NOT DISCHARGE; IT WAS MOVED AND ALSO PUSHED FROM THE TOP OF STOMACH, BUT IT DID NOT HELP. THEN MUCOSA WAS SWOLLEN AND TUBAL ORIFICES WERE NOT VISIBLE ANYMORE. IT HAS CHECKED THAT IMPLANT WAS TOTALLY REMOVED. THERE WAS IMPRESSION THAT BOTH SIDES WERE EITHER SO DIFFICULTY SCARRING OR TUBES WERE IN DIFFICULT POSITION THAT NEW ESSURE WAS NOT WORTH TO TRY INSERTION AGAIN. PIPELLE SAMPLE (BIOPSY) HAD TAKEN FROM UTERINE CAVITY, IF THE RESULT IS NORMAL, LAPAROSCOPIC CLIP STERILIZATION WILL BE PERFORMED IN CONNECTION WITH NOVASURE.

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FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2015: FURTHER INFORMATION IS NOT AVAILABLE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. WE TYPICALLY INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. AS RECEIVED, DISTAL END OF MICRO-INSERT WAS BROKEN. MICRO-INSERT STILL INTACT TO DELIVERY CATHETER. ALL IFU STEPS WERE COMPLETED. WE ALSO CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C38216 (PRODUCTION DATE 24-MAR-2014 AND EXPIRATION DATE 31-MAR-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIALLY INITIATED DUE TO A USABILITY ISSUE AND REFERS TO ESSURE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. THE PROVIDED COMPLAINT SAMPLE WAS INVESTIGATED WITH THE DISTAL END OF MICRO-INSERT FOUND BROKEN. THE TECHNICAL ASSESSMENT CONCLUDED CONFIRMED QUALITY DEFECT. BASED ON THE PROVIDED INFORMATION THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING MEDDRA LLT: DEVICE BREAKAGE. BASED ON THE RESULTS OF THE TECHNICAL INVESTIGATION, THE INCIDENT CATEGORY OTHER REPORTABLE INCIDENT IS RECOMMENDED. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME IN ASSOCIATION WITH ESSURE. SINCE NO ESSURE RELATED ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, NO CAUSAL RELATIONSHIP BETWEEN THE CONFIRMED PRODUCT QUALITY ISSUE AND ADVERSE EVENTS CAN BE ASSESSED, AS NO ESSURE RELATED ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 966 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT WHO HAD MIRENA (LEVONORGESTREL) INSERTED IN THE PAST; BECAME PREGNANT DURING MIRENA AND HAD A MISCARRIAGE FOLLOWED BY UTERINE INFECTION AND PROLONGED BLEEDING. RECENTLY, SHE HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION, BUT THE IMPLANT DID NOT DISCHARGE NORMALLY AND GOT STUCK IN TUBAL ORIFICE. PHYSICIAN REMOVED IT AND A NEW ESSURE HAD NOT BEEN INSERTED. LATER, A SAMPLE OF THE DEVICE WAS INVESTIGATED AND DISTAL END OF MICRO-INSERT WAS BROKEN (DEVICE BREAKAGE). ALL EVENTS ARE NON-SERIOUS; EXCEPT FOR MISCARRIAGE, INFECTION AND BLEEDING WHICH WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. THE EVENTS ASSOCIATED WITH MIRENA AND ESSURE ARE LISTED IN THEIR REFERENCE SAFETY INFORMATION. DEVICE BREAKAGE IS LISTED ACCORDING TO TECHNICAL ANALYSIS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE. IUS IN-SITU DURING PREGNANCY MAY INCREASE THE RISK OF ABORTION. IN THIS CASE, CAUSALITY BETWEEN MIRENA AND THE PREGNANCY AND SUBSEQUENT MISCARRIAGE CANNOT BE EXCLUDED DUE TO A COMPATIBLE TEMPORAL ASSOCIATION. FOR UTERINE INFECTION AND PROLONGED BLEEDING, IT CANNOT BE EXCLUDED THAT THESE EVENTS OCCURRED AS A CONSEQUENCE OF MISCARRIAGE. REGARDING THE REMAINING EVENTS, IN CASES OF DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL. IN THIS CASE, PHYSICIAN STATED PATIENT BOTH SIDES WERE IN DIFFICULT POSITION OR WITH SCARRING. THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN ESSURE INSERTION FAILURE. NEVERTHELESS, AS THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT CAUSALITY CANNOT BE EXCLUDED. BASED ON THE RESULTS OF THE TECHNICAL INVESTIGATION, THIS CASE (PREVIOUSLY SEEN AS NON-INCIDENT) WAS UPGRADED TO OTHER REPORTABLE

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INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED CONFIRMED QUALITY DEFECT. HOWEVER, NO CAUSAL RELATIONSHIP BETWEEN THE CONFIRMED PRODUCT QUALITY ISSUE AND ADVERSE EVENTS CAN BE ASSESSED, AS NO ESSURE RELATED ADVERSE EVENTS WERE REPORTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00261	BAYER HEALTHCARE LLC	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B21581

Single Use: Y
Implant Date (E6): 5/23/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 30-JAN-2015 WHICH REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN MAY-2014 OR AUG-2014. THE HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED IN (B)(6) 2014 AND REVEALED THAT ONE TUBE HAD PERFECT PLACEMENT, BUT THE SECOND DEVICE HAD VERY DISTAL PLACEMENT AT THE FIMBRIA END OF THE TUBE. THE PHYSICIAN WAS PLANNING ON REMOVING THE DEVICE AND TUBE ON A FUTURE DATE. NO CAUSALITY ASSESSMENT WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(4) 2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON 13-MAR-2015: PATIENT'S INITIALS

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WERE UPDATED. ESSURE WAS PLACED BY ANOTHER PHYSICIAN; HOWEVER HE STATED THAT HE MIGHT HAVE THE LOT NUMBER FROM A NOTE FROM THE PROVIDER. THE PHYSICIAN WILL PROVIDE THE REQUESTED INFORMATION. FOLLOW-UP INFORMATION RECEIVED ON 24-MAR-2015 AND PTC INVESTIGATIONAL RESULT RECEIVED ON 31-MAR-2015: DEMOGRAPHIC DATA WERE ADDED. SHE WAS (B)(6) AT TIME OF THE EVENTS. PATIENT HAD ESSURE PLACED BILATERALLY ON 23-MAY-2014 FOR STERILIZATION. LOT NUMBER (B21581) AND EXPIRATION DATE (23-APR-2016) WERE PROVIDED. ON (B)(6) 2014 SHE UNDERWENT AN HSG WHICH SHOWED PROPER PLACEMENT IN THE LEFT TUB, RIGHT TUBE HAD DISTAL PLACEMENT; PROXIMAL END OF COIL 230MM FROM UTERINE CORNU (MALPLACEMENT ACCORDING TO REPORTER). ON 06-JAN-2015 THE PATIENT WAS SEEN BY THE REPORTING PHYSICIAN TO SCHEDULE A LAPAROSCOPIC COIL AND RIGHT TUBE REMOVAL. ON 12-MAR-2015 LAPAROSCOPY AND RIGHT SALPINGECTOMY BUT THE COIL WAS NOT VISUALIZED. INTRAOPERATIVE X-RAY SHOWED PRESENCE OF BOTH COILS, BUT THE PHYSICIAN COULD NOT IDENTIFY OR REMOVE THE RIGHT COIL. (B)(4). FINAL ASSESSMENT: PRODUCTION DATE: 4/2013, EXPIRATION DATE 30-APR-2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. FIVE FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH ONE CASE REFERS ALSO TO A SIMILAR ADVERSE TYPES OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 09-APR-2015: NO NEW INFORMATION FROM PTC TEAM. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE HYSTEROSALPINGOGRAM (HSG) REVEALED THAT ONE DEVICE HAD VERY DISTAL PLACEMENT AT THE FIMBRIA END OF THE TUBE, A LAPAROSCOPY AND SALPINGECTOMY WERE DONE BUT THE COIL WAS NOT VISUALIZED. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED LAPAROSCOPY AND RIGHT SALPINGECTOMY. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00262	BAYER HEALTHCARE LLC	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 2/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91768

Single Use: Y
Implant Date (E6): 2/24/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER UNKNOWN, INSERTED ON (B)(6) 2015 FOR CONTRACEPTION. PHYSICIAN BELIEVES THAT, ON INSERTION, SHE PERFORATED THE PERITONEAL CAVITY. ESSURE WAS NOT SEEN ON HYSTEROSCOPY. HEALTH CARE PROFESSIONAL DID NOT REMOVE THE ESSURE AND PATIENT WILL UNDERGO A SCAN TO SEE WHERE THE ESSURE IS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 23-MAR-2015, REFERRING TO PTC GLOBAL NUMBER (B)(6) : FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION (PERFORATION QUESTIONNAIRE) RECEIVED ON 24-MAR-2015 FROM

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PHYSICIAN: THE PATIENT WAS (B)(6) AT TIME OF THE REPORT. SHE WAS OBESE AND HAD AS PREVIOUS HISTORY: MYOMECTOMY DONE VIA LAPAROSCOPY IN 2010 AND 3 PREVIOUS PREGNANCIES WITH VAGINAL DELIVERIES. SHE DID NOT HAVE ANY OTHER GYNECOLOGICAL INTERVENTIONS. ON (B)(6) 2015, THE ESSURE PROCEDURE WAS DONE UNDER INTRAVENOUS SEDATION; THE LOT NUMBER USED WAS C91768 WITH EXPIRATION DATE OF AUG-2017. THE PATIENT WAS NOT POSTPARTUM AT TIME OF PROCEDURE. THE VISUALIZATION OF BOTH TUBAL OSTIUM WAS CONSIDERED EASY. DURING THE PROCEDURE, CERVICAL DILATATION AND SOUNDING WERE DONE. THE INSERTION WAS CONSIDERED DIFFICULT, THE INTRODUCER WAS INSERTED INTO PERFORATION THAT LOOKED LIKE OSTIA AND THEN RELEASED BUT NO COILS WERE SEEN AND WITH THAT THE PHYSICIAN THOUGHT IT WAS AN OBVIOUS PROBLEM. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES AND THERE WERE NO MORE THAN 1500CC OF FLUID LOSS. NO IMAGING TESTS WERE PERFORMED TO CONFIRM ESSURE PLACEMENT. THE ESSURE INCORRECT POSITION WAS DETERMINED ON THE SAME DAY OF THE INSERTION PROCEDURE; A COMPLETE UNILATERAL RIGHT PERFORATION WAS CONFIRMED VIA HYSTEROSCOPY. NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS PERFORATED. THE PHYSICIAN WAS NOT SURE IF THE PERFORATION OCCURRED DURING SOUNDING, CERVICAL DILATION OR HYSTEROSCOPY; HE STATED THAT IT WAS PROBABLY BEFORE THE DEPLOYMENT. THE PATIENT WAS ASYMPTOMATIC. SHE WAS TAKEN IMMEDIATELY FOR LAPAROSCOPIC TUBAL; DURING THIS PROCEDURE, THE DEVICE WAS LOCATED IN CUL DE SAC, AND A SMALL PERFORATION IN THE RIGHT CORNUA WAS NOTED. ESSURE WAS REMOVED. HYSTERECTOMY AND SALPINGECTOMY WERE NOT NECESSARY. THE PATIENT RECOVERED FROM THE ESSURE REMOVAL PROCEDURE. CASE CONSIDERED INCIDENT. FOLLOW-UP RECEIVED ON 31-MAR-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4) . FINAL ASSESSMENT: LOT NUMBER: C91768; EXPIRATION DATE: 31-AUG-2017; PRODUCTION DATE: 04-AUG-2014. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 3 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, BUT NONE OF THE CASES REFER ALSO TO A SIMILAR ADVERSE TYPES OF EVENTS. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD A SMALL PERFORATION IN RIGHT UTERINE CORNUA DURING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ON THE SAME DAY, SHE WAS SUBMITTED TO A LAPAROSCOPY AND ESSURE WAS REMOVED FROM CUL DE SAC. PATIENT RECOVERED. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A COMPLETE PERFORATION OCCURS, ESSURE CAN BE FOUND IN THE PELVIC CAVITY AS IT PERFORATES THE WHOLE UTERINE WALL. IN THIS PARTICULAR CASE, AS THE REPORTED PERFORATION OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE SURGICAL INTERVENTION REPORTED UPON FOLLOW-UP; THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL

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PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042143	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 7/6/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME ABDOMINAL PAIN AND PAIN IN MY BACK, MAJOR HEADACHES, BLOATING, HARDENING OF THE ABDOMEN, POSSIBLE CYSTS ACCORDING TO DOC, UNEXPLAINED RASHES, HIGH ACID TARNISHES METALS, PAINFUL INTERCOURSE, HEAVY BLEEDING DURING PERIODS, EXTREME CRAMPING, MEMORY PROBLEMS, ACNE, WEIGHT GAIN, LOW SEX DRIVE BECAUSE OF PAIN, AND TROUBLE CONCENTRATING....I THINK THERE IS MORE JUST CAN'T NAME THEM OFF THE TOP OF MY HEAD...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042144	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 8/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATELY AFTER DEVICE IMPLANTED, I BEGAN HAVING STABBING PAINS, HEAVY PERIODS THAT LAST DAYS LONGER, SWEATING SPELLS, NIGHT SWEATS, HAIR LOSS, BLOATING AND WEIGHT GAIN...VERY DEBILITATING STOMACH PAINS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042145	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 8/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED ON (B)(6) 2014. WITHIN A FEW MONTHS, I WAS EXPERIENCES MENOPAUSE LIKE SYMPTOMS. I WAS HAVING HOT FLASHES, MAJOR FATIGUE, HEADACHES, MY MENSTRUAL CYCLE WAS EVERY TWO WEEKS AND WAS LASTING A WEEK AT TIME. ONE WOULD BE REAL HEAVY, NEXT WOULD BE VERY LIGHT. THESE SYMPTOMS WENT ON FOR A FEW MONTHS THEN GRADUALLY WENT AWAY. THEN STARTED THE MAJOR CRAMPING ALL THE TIME AND WORSE WHEN ON MY CYCLE. I AM NOT ABLE TO ENJOY SEX ANYMORE IF IT ISN'T HURTING DURING I GET MAJOR CRAMPS AFTER LIKE I AM IN EARLY STAGES OF LABOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042146	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 8/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED ON (B)(6) 2014 WITHIN A FEW MONTHS I WAS EXPERIENCES MENOPAUSE LIKE SYMPTOMS. I WAS HAVING HOT FLASHES, MAJOR FATIGUE, HEADACHES, MY MENSTRUAL CYCLE WAS EVERY TWO WEEKS AND WAS LASTING A WEEK AT TIME. ONE WOULD BE REAL HEAVY NEXT WOULD BE VERY LIGHT. THESE SYMPTOMS WENT ON FOR A FEW MONTHS THEN GRADUALLY WENT AWAY. THEN STARTED THE MAJOR CRAMPING ALL THE TIME AND WORSE WHEN ON MY CYCLE. I AM NOT ABLE TO ENJOY SEX ANYMORE IF IT ISN'T HURTING DURING I GET MAJOR CRAMPS AFTER LIKE I AM IN EARLY STAGES OF LABOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042147	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODS BECAME EXTREMELY HEAVY WITH LARGE CLOTS. ABDOMINAL CRAMPS, BACK PAIN, JOINT PAIN, ABDOMINAL BLOATING, RAPID WEIGHT GAIN 25 LBS, BRAIN FOG, INABILITY TO CONCENTRATE, EXHAUSTED ALL THE TIME, YEAST INFECTIONS FROM FREQUENT SPOTTING. DR PERFORMED A D AND C IN (B)(6) 2014 AND AN ABLATION NOVASURE (B)(6) 2014. NONE OF WHICH HELPED ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042148	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS, BLOT CLOTTING, HEADACHES, CRAMPING 24/7, UPPER LEG CRAMPS, HEART PALPITATIONS, ANXIETY, MOOD SWINGS, ALWAYS TIRED, OVARIES IN PAIN ALL THE TIME, CANNOT HAVE SEX IT HURTS SO BAD, FEEL LIKE I'M BEING STABBED BY KNIFE IN LOWER STOMACH, STOMACHS BLOATING EVERY TIME I EAT, GAINED 100 LBS SUDDENLY, DIZZY, HEAD FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042149	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 6/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAIN IN VAGINA AT RANDOM TIMES. TOTALLY IRREGULAR PERIODS. EXTREMELY HEAVING BLEEDING WITH EXCESSIVE CLOTS AND WEIRD FIBER LOOKING THINGS. FINGERNAILS WITH SEVERE RIDGES AND WHITE AT THE BASE HAS INCREASED. CONTINUAL NAUSEA. BRAIN FOG, DIFFICULTY CONCENTRATING, TOOTH DECAY, DIFFICULTY SLEEPING. NEW DR (B)(6) ESSURE COULD BE AN ISSUE. LOST INSURANCE SO UNABLE TO REMOVE AT THIS TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042150	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 1/7/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN EVERY JOINT. WEAKNESS. ABDOMINAL PAIN. BACK PAIN . SCIATICA. BLOATING. IBS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042151	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 3/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5042151 #(B)(4). I ALSO HAVE HAD OVARIAN CYSTS, CLOTS, FATIGUE, SEVERE PAIN, HEADACHES, CONSTANT STABBING FEELING, BOWEL ISSUES, BLOATING, SWELLING OF THE HANDS AND FEET, THE CHILLS EVEN WHEN IT'S HOT,AND SO MUCH MORE!!ESSURE HAS RUINED MY BODY AND I PRAY TO GET IT OUT SO I CAN END THE PAIN AND GET MY LIFE BACK!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042152	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 9/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OTHER SYMPTOMS ARE: HAIR LOSS, CRAMPS, ALL OVER BODY ACHES, CHRONIC PELVIC PAIN, BACK AND JOINT PAIN, BRAIN FOG, ANXIETY, PANIC ATTACKS, DEPRESSION, LOSS OF LIBIDO, BLEEDING AFTER SEX, PAINFUL PERIODS, PAINFUL INTERCOURSE, INCONTINENCE, YEAST INFECTIONS, URGENT AND FREQUENT URINATION, ABDOMINAL SPASMS/TWITCHING/FLUTTERING, FATIGUE, HEIGHTENED ALLERGIES AND SENSITIVITIES, HIVES, RASHES, SKIN IRRITATION, ITCHING, HEART PALPITATIONS, BLADDER FUSSED TO UTERUS, INSOMNIA, WEIGHT GAIN, NAIL WEAKNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042153	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 9/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN AND BLOATING STARTED AS SOON AS ESSURE WAS IMPLANTED. THE SYMPTOMS NEVER WENT AWAY. SINCE THEN I HAVE EXPERIENCE FATIGUE, MUSCULAR AND JOINT PAIN, HAIR THINNING, NAIL WEAKENING, HEAVY PERIODS (NOT LONGER), VERY PAINFUL OVULATIONS, SKIN RASH AND HIVES. I WILL HIGHLIGHT THAT PAINFUL OVULATIONS, PAIN ALL MONTH AROUND AND SEVERE BLOATING ARE THE THREE WORST SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042154	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 3/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THESE ARE ALL OF MY SIDE EFFECTS SINCE GETTING ESSURE (B)(6) 2014. I HAD NONE OF THESE BEFORE ESSURE: INSTANT WEIGHT GAIN LOSE WEIGHT BUT STOMACH NEVER CHANGES, CONSTANT HEADACHE, HEART PALPITATIONS FLUTTERS, RAPID TOOTH DECAY, PELVIC PAIN, JOINT PAIN, SWELLING HANDS FEET LEGS, MUSCLE SPASM FEEL LIKE VIBRATION IN BONES, HAIR LOSS, BACK PAIN / MUSCLES, ANXIETY, PAIN IN REPLACED HIP AREA, INSOMNIA, NIGHT SWEATS, FATIGUE EXTREME, ACNE CYSTS, RASHES, VAGINAL ITCHING WITH NO INFECTION OR BACTERIA, NUMBNESS ARMS, NAUSEA VOMITING, SHAKING, MEMORY FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042155	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 8/24/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN 2005 I HAD THE ESSURE COILS PLACED AND HAD TROUBLE WITH NON STOP BLEEDING/PAIN THAT BROUGHT ME TO A HYSTERECTOMY IN 2008. LEAVING MY OVARIES AND F TUBES. IN THE SURGICAL PATHOLOGY REPORT THAT I HAVE FROM IT, SOUNDS LIKE THE ESSURE COILS MAY HAVE BEEN CUT AT THAT TIME AS WHAT THE REPORT READS, LEAVING ME WONDER WHERE ON EARTH THE REST OF THE COILS MAYBE. PLEASE BAND THIS DEVICE IT'S NOT SAFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042156	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 4/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD ISSUES SINCE IMPLANTATION IN 2007. HAIR LOSS, IRREGULAR PERIODS, FATIGUE, DEPRESSION, DIZZY SPELLS, ANXIETY, INSOMNIA, VERY PAINFUL PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042172	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 11/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PREGNANCY, COMPLETE PREVIA WITH HEMMORAGE AND PREMATURE BIRTH OF SON. BACK PAIN, CRAMPING, BLOATING, FLUTTERS, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042178	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 4/28/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERELY ANEMIC. STOMACH ULCERS. STAYED IN ICU FOR 4 DAYS IN THE HOSPITAL TO CONTROL THE BLEED AND RECEIVE BLOOD PRODUCTS. COLITIS. INFLAMED PANCREAS. INFLAMED APPENDIX THAT RESULTED IN SURGERY TO REMOVE PRIOR TO RUPTURE. BACK PAIN. HIP PAIN. BLOATED. CONSTIPATION. INSOMNIA. NO SEX DRIVE. INABILITY TO ORGASM. RASHES. SEVERE SWELLING IN MY LEGS. WEIGHT GAIN. CURRENTLY PREGNANT. NUMEROUS CT SCANS. NUMEROUS X RAYS. NUMEROUS DOCTORS VISITS. NUMEROUS LAB DRAWS. FATIGUE. DEPRESSION. MUST SEE A PAIN MANAGEMENT DOCTOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042183	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, SEVERE ABDOMINAL PAIN, MOSTLY ON MY RIGHT SIDE, NICKEL ALLERGY, METALLIC TASTE IN MOUTH, MIGRAINES, CHRONIC BACTERIA VAGINOSIS, SKIN IRRITATION, PAIN AND BLEEDING DURING AND AFTER INTERCOURSE, LACK OF A SEX DRIVE, SEVERE FATIGUE, INSOMNIA, IRREGULAR PERIODS, BLOATING, CIRCULATION ISSUES, HEART ISSUES, PHANTOM FLUTTERING, CHRONIC YEAST INFECTIONS, CONSTANT PAIN ALL OVER, ABNORMALLY HIGH BP. THESE ARE THE ONES THAT COME TO MIND IMMEDIATELY. THERE ARE MANY MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042186	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 4/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANEMIA. OUT D DEFICIENCY. PAIN. HEAVY MENSES. MIGRAINES. JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042187	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 1/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MULTIPLE SIDE AFFECTS BACK PAIN,HAIR LOSS,WEIGHT GAIN,JOINT PAIN,NAUSEA,TO NAME A FEW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042188	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER STOMACH PAIN, NO BOWELS, HEART BURN, HEART BEAT FAST, BRAIN FOG, AND CAN'T REMEMBER AGAIN. HEADACHE, NO ENERGY AT ALL, SHARP STABBING PAINS, SHARP PAIN IN LOWER BUTT BONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042189	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 4/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING SEXUAL INTERCOURSE MY MATE SAID IT FELT LIKE SOMETHING WAS SCRATCHING THE TIP OF HIS PENIS AND I WAKE UP WITH HEADACHES AND HAVE THEM ALL THROUGH THE DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042191	BAYER	4/21/2015	4/21/2015

Event Information:

Event Date (B3): 3/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN DIAGNOSED WITH PID.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042173	BAYER	4/21/2015	4/22/2015

Event Information:

Event Date (B3): 12/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SOON AFTER IMPLANTATION OF THE DEVICE, I WAS DIAGNOSED WITH A SEVERE URINARY TRACT INFECTION THAT LASTED SEVERAL WEEKS AND REQUIRED TWO HOSPITAL VISITS. I ALSO DEVELOPED A SHARP "PINCHING" TYPE OF PAIN ON THE L AND R SIDE OF MY LOWER ABDOMEN. WITHIN A COUPLE OF MONTHS, I STARTED PRESENTING WITH LOWER BACK PAIN THAT WAS EVENTUALLY ACCOMPANIED BY HIP PAIN, SHOOTING PAIN, PELVIC PAIN, TAILBONE PAIN, SACRUM PAIN, NUMBING, TINGLES. AFTER APPROXIMATELY 18 MONTHS OF PAIN, I STARTED SEEING A DR. WHO TOOK X-RAYS AND ORDERED AN MRI. X-RAY SHOWED THE SPINE WAS COMPLETELY STRAIGHT, LACKING ALL CURVATURE. MRI SHOWED L4, L5 AND S1 DISCS WERE BULGING, DEGENERATIVE, SCIATICA WAS PRESENT AND MUSCLES ON EITHER SIDE OF MY SPINE STAY IN CONSTANT SPASM. OVER TIME, SYMPTOMS PROGRESSED AND ULTIMATELY RESULTED IN OVER 100 SYMPTOMS THAT HAVE ESSENTIALLY RUINED MY LIFE. HERE IS A LIST OF THOSE SYMPTOMS: SEVERE LOWER BACK PAIN; PERMANENT NERVE DAMAGE; CONSTANT MUSCLE SPASMS IN BACK, SHOULDERS AND ABDOMEN; SHOOTING NERVE PAIN/NUMBNESS IN BACK, LEGS AND SHOULDERS; SHOOTING NERVE PAIN IN NECK/SHOULDERS; MUSCLE FATIGUE, BURNING, STIFFNESS; HIP PAIN AND DISCOMFORT; EXTREME PAIN/STIFFNESS IN MORNINGS AND AFTER ACTIVITY; OVERALL BODY ACHES AND FEELING "FLU LIKE" WHICH INCREASES IN EVENINGS AND IS EXTREMELY SEVERE AFTER ACTIVITY; FREQUENT LOW-GRADE FEVERS; FREQUENT SEVERE HEADACHES; BLURRED VISION; SEVERE BLOATING; SWELLING IN HANDS, FEET, ANKLES; TINGLING IN HANDS AND FEET; NUMBNESS IN FINGERS; EXTREME COLD IN HANDS AND FEET; NOISE SENSITIVITY; TOTAL LACK OF ENERGY, NO MOTIVATION; SEVERE FATIGUE; INSOMNIA; NIGHT TERRORS; NAUSEA; FREQUENT DIARRHEA; TROUBLE TAKING A DEEP BREATH (FEELS AS IF I CAN'T GET ENOUGH OXYGEN); EXTREME HEART PALPITATIONS/"FLUTTERS" WHICH CAN BE FELT IN PULSE; GENERAL FEELINGS OF "DOOM"; SUDDEN ANXIETY/DEPRESSION; COLD SENSITIVITY; DENTAL

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PROBLEMS (DECAY, CAVITIES, GUM DISEASE, CRACKING/BREAKING/CHIPPING/HOLLOWING TEETH, TOOTH LOSS, YELLOWING OF TEETH); PAIN AND LIMITED RANGE OF MOTION IN L AND R SHOULDERS; SUDDEN SHOOTING PAIN IN L AND R CLAVICLE; PAIN IN L AND R ELBOWS; SEVERE HIP PAIN (AS OF (B)(6) 2015, R HIP WAS ROTATED SO FAR OUT OF PLACE IT WAS NEARLY DISLOCATED AND L HIP WAS POSITIONED ABOUT 1/2" HIGHER THAN NORMAL); HOT FLASHES; SUDDEN ONSET OF ALLERGIES; "FLOATERS" IN VISION; FREQUENT "LUMP" IN THROAT/SWOLLEN GLANDS; TROUBLE CONCENTRATING/REMEMBERING, OVERALL "FOGGY" FEELING; LOSS OF INTEREST; LACK OF APPETITE; WEIGHT GAIN; EXTREME "RASH" COVERING 80% OF BACK (HAS BEEN PRESENT FOR NEARLY 2 YEARS); SMALL "FRAGMENT" OF SOME KIND SEEN IN ONE LUNG VIA CT SCAN; LOW SELF ESTEEM; LIMITED RANGE OF MOTION IN ENTIRE BODY; EXTREME PAIN/STIFFNESS AFTER HOLDING ONE POSITION FOR MORE THAN 15 MINUTES; FREQUENT URINARY TRACT INFECTIONS; SEVERE PELVIC FLOOR PAIN; IRREGULAR PERIODS; HEAVY PERIODS; FREQUENT VAGINAL INFECTIONS (YEAST, BACTERIAL VAGINOSIS); DULL PAIN ON L AND R SIDE OF VERY LOW ABDOMEN; SHARP, SHOOTING PAIN ON L AND R SIDE OF VERY LOW ABDOMEN WHEN BENDING, STANDING TOO ; QUICKLY, LEANING TO EITHER SIDE; FREQUENT "TWITCHES" IN LOWER ABDOMEN; PAIN DURING INTERCOURSE; LOSS OF LIBIDO; BLOTCHY SKIN TONE; HAIR LOSS; EXTREMELY ITCHY BREASTS; LUMPS IN L AND R BREASTS; WHEEZING; VERICOSE VEINS; FREQUENT/EASY BRUISING; RANDOM HIGH BLOOD PRESSURE. I HAVE BEEN TESTED FOR RHEUMATOID ARTHRITIS (TWICE), ARTHRITIS, LUPUS, CANCER, MONO, ETC. THYROID IS PERFECT, HEART SHOWS WELL ON EKG, BLOOD WORK IS NORMAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042184	BAYER	4/21/2015	4/22/2015

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I WAS (B)(6), I ALREADY HAD 2 CHILDREN AND DIDN'T WANT ANYMORE AS I JUST BECAME A SINGLE MOTHER. I GOT THE ESSURE AND IT WAS DONE AS A IN AND OUT PATIENT OPERATION. MEANING NOT IN THE DOCTOR OFFICE BUT IN THE SURGERY CENTER OF THE HOSPITAL UNDER GENERAL ANESTHESIA. I COULDN'T WALK SIT OR EVEN LAY DOWN THAT NIGHT OR THE NEXT WEEK. WHEN I SAT, IT FELT LIKE A SHARP ROD IN MY LEFT SIDE GOING UP IT HURT REAL BAD. I WENT FOR MY POST CHECK AND IT WAS FINE GOOD RESULTS. THEN I STARTED NOTICING SEX WAS UNCOMFORTABLE, I CRIED A RELATIONSHIP FAILED BECAUSE OF THE PAIN AND MOOD SWINGS. I WOULD GO TO THE ER AND SEVERAL DR APPOINTMENTS COMPLAINING ABOUT PAIN ON MY LEFT SIDE. I WAS GIVEN 500 MG OF NAPROXEN TAKEN TWICE A DAY. I WAS FINALLY SEEN AND SENT TO AN ULTRA SOUND AND MY LEFT COIL WAS "SLIGHTLY" OUT OF PLACE. NO MY LEFT COIL WAS OUT OF MY FALLOPIAN TUBE AND EMBEDDED INTO MY UTERUS. WE FOUND THAT OUT AFTER GETTING A LAPAROSCOPIC DONE. SO ONCE AGAIN, I WAS PUT UNDER GENERAL ANESTHESIA AND HAD TO TAKE OFF WORK. I WAS (B)(6) YEARS OLD WHEN I RECEIVED MY PARTIAL HYSTERECTOMY MISSING 8 WEEKS OF WORK AND ONLY GETTING PAID TO 2 OF THEM. SINCE THIS OPERATION, I HAVE BEEN IN THE ER MORE THAN 6 TIMES FOR THE PAIN. I HAVE BEEN TOLD THAT NOW I HAVE CYST AND POLYPS THAT RUPTURE EVERY 3-6 MONTHS. I AM CONTINUALLY MISSING WORK OR GOING IN AN UNABLE TO DO MY JOB TO THE FULLEST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042185	BAYER	4/21/2015	4/22/2015

Event Information:

Event Date (B3): 4/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAVE HAD THIS DEVICE IMPLANTED HAVE HAD NOTHING BUT PAIN AND ODD PROBLEMS. THE DAY OF MY IMPLANTS MY DR. FORGOT TO PUT THE TUBE ON THAT RELEASES THE COIL IN TO MY RIGHT TUBE. WHICH CAUSED IT TO INFLAMMATION HE THE PROCEEDED TO THE LEFT SIDE. THIS TOOK WELL, 30 MIN LATER BACK TO THE RIGHT SIDE. THIS WAS VERY PAINFUL BUT DONE AFTER I LAY ON THE TABLE FOR A WHILE WITH MY HUSBAND BY MY SIDE. TALKING WITH ABOUT WHAT JUST HAPPENED. MY BLOOD PRESSURE WAS TAKEN WAS A LITTLE HIGH. A FEW DAYS LATER I RETURNED TO THE OFFICE WITH EXTREME PAIN ON MY RIGHT SIDE. WAS TOLD THIS IS NORMAL HOWEVER THIS WAS CONSTANT. FINALLY THE DR DECIDED I NEED TO HAVE THIS TUBE REMOVED. SO I WAS SCHEDULED FOR SURGERY THE FOLLOWING DAY. THIS WENT WELL. HOWEVER THEIR HAS BEEN NO CHANGE! I AM STILL IN PAIN. I ALSO HAVE A FEW OTHER EFFECT'S I BELIEVE THAT IS DUE TO THIS ESSURE. HOT SWEATS,PAINFUL LONG PERIODS,INTERCOURSE IS EXTREMELY PAINFUL, BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042190	BAYER	4/21/2015	4/22/2015

Event Information:

Event Date (B3): 2/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS HAVING A CONVERSATION ALL OF A SUDDEN MY MIND WAS SHUTTING DOWN AND I THOUGHT I WAS GOING BLIND. THEN CAME THE HEAVY BLEEDING AND HUGE CLOTS. I ALWAYS FEEL DAZED AND CONFUSED. THROWING UP 3-4 TIMES A WEEK. VISION HAS GOTTEN WORSE. ABDOMINAL PAIN. BACK PAIN. DIZZINESS/LIGHT HEADED. SWELLING IN MY FEET AND BLOATED STOMACH. SORES ON MY ARMS AND LEGS. DEPRESSION AND ANXIETY. DEPTH PERCEPTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042192	BAYER	4/21/2015	4/22/2015

Event Information:

Event Date (B3): 7/13/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN BATTLING SYMPTOMS FOR YEARS AND CAN NOT GET ANYONE TO LISTEN OR HELP ME. CHRONIC FATIGUE, FIBROMYALGIA, JOINT PAIN, THINNING HAIR WITH BALD SPOTS, MAJOR WEIGHT GAIN, DEPRESSION, ACNE, LOWER STOMACH PAIN, IBS, HIGH BLOOD PRESSURE, FLUID RETENTION AND HOT FLASHES. I DID HAVE A PARTIAL HYSTERECTOMY IN 2010 BECAUSE OF HEAVY BLEEDING BUT THESE OTHER SYMPTOMS CONTINUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042241		4/21/2015	4/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY ESSURE DONE IN 2011 AND 2013. I STARTED GETTING THESE SYMPTOMS, CRAMPING, SHARP/STABBING PELVIC PAIN, ABNORMAL MENSES, CONSTANT SPOTTING, DISCHARGE WITH ODOR AND WITHOUT, HOT FLASHES, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION, NIGHT SWEATS, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS, BLEEDING BETWEEN PERIODS, LONG MENSTRUAL CYCLES, SEXUAL DYSFUNCTIONS UNABLE TO ORGASM OR FEEL PLEASURE, YEAST INFECTION, FREQUENT URINATION, URINARY TRACT INFECTION, BREAST PAIN, BACK, JOINT, LEGS, BREAST, NECK, SPINE AND HIP PAIN, CHRONIC PELVIC PAIN, ALL OVER BODY ACHES/PAIN, NAUSEA, VOMITING EVERY MORNING, GAS, CONSTIPATION, METALLIC TASTE IN MOUTH, HEARTBURN, LOTS OF HEADACHES AND MIGRAINES, DIZZINESS, ANXIETY, PANIC ATTACKS, MOOD SWINGS, DEPRESSION, SADNESS, MOOD DISORDERS, SWELLING OF LEGS OR FEET, HAIR LOSS, HAIR GROWING IN NEW PLACES, DENTAL ISSUES, INSOMNIA, WEIGHT ISSUES, GAIN, SLEEP APNEA, BLURRED VISION, EXCESSIVE SWEATING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00263	BAYER HEALTHCARE LLC	4/21/2015	5/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C03100

Single Use: Y
Implant Date (E6): 3/24/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION; THE LOT NUMBER USED WAS C03100. PHYSICIAN STATED THAT, DURING THE INSERTION PROCEDURE, THE ANCHOR TO OUTER COIL WAS NOT VISIBLE AND PART OF GREEN CATHETER CAME OFF IN PATIENT UTERUS (RIGHT OR LEFT TUBE WAS NOT SPECIFIED). THERE WERE 5 COILS TRAILING ONTO UTERUS AND THE PART OF GREEN CATHETER THAT BROKE OFF WAS NOT REMOVED. AT TIME OF THE REPORT, THE DEVICE WAS CONTINUED. FOLLOW-UP FROM 01-APR-2015: NO CALL BACK FROM PHYSICIAN. ADDITIONALLY, PTC INVESTIGATION RESULT WAS RECEIVED ON 02-APR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C03100 (PRODUCTION DATE 11-DEC-2013 AND EXPIRATION DATE 31-DEC-2016) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE

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WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE INSERTION PROCEDURE THE ANCHOR TO OUTER COIL WAS NOT VISIBLE AND PART OF GREEN CATHETER THAT BROKE OFF WAS NOT REMOVED (RIGHT OR LEFT TUBE NOT SPECIFIED). THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. CONSIDERING THAT, IN THIS PARTICULAR CASE, THE BREAKAGE OCCURRED DURING THE ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

GENERAL QUESTIONNAIRE AND MEDICAL RECORDS RECEIVED ON 28-APR-2015 FROM PHYSICIAN: ACCORDING TO THE GENERAL QUESTIONNAIRE, THE PATIENT DID NOT HAVE ANY PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. SHE WAS G4P3013 (UNDERSTOOD AS GRAVIDA 4, PARA 3 WITH 3 L

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00264	BAYER HEALTHCARE LLC	4/21/2015	5/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06515 / CS0008W

Single Use: Y
Implant Date (E6): 3/20/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER C06515). ON INSERTION PROCEDURE, ESSURE MICRO INSERT APPEARED TO HAVE A PORTION OF THE SHEATH STILL SURROUNDING THE INSERT WHICH DID NOT FULLY DEPLOY. UNIT WAS REMOVED AND ANOTHER INSERT WAS SUCCESSFULLY PLACED. PRODUCT TECHNICAL COMPLAINT ANALYSIS WAS RECEIVED ON 07-APR-2015. (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 01-APR-2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT

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MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE AND DEPLOYMENT DIFFICULTY IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING INSERTION PROCEDURE, ESSURE MICRO INSERT APPEARED TO HAVE A PORTION OF THE SHEATH STILL SURROUNDING THE INSERT WHICH DID NOT FULLY DEPLOY. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. SINCE THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PERFORMED PTC CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP (GENERAL QUESTIONNAIRE) INFORMATION RECEIVED ON 29-JUN-2015: THE PATIENT MEDICAL HISTORY INCLUDES ABNORMAL UTERINE BLEEDING AND ENDOMETRIAL BIOPSY ON (B)(6) 2015. THE ESSURE LOT INSERTED ON RIGHT SIDE WAS CS0008W AND ON LEFT WAS C06515. DURING T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00265	BAYER HEALTHCARE LLC	4/22/2015	4/22/2015

Event Information:

Event Date (B3): 8/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 10/22/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6)-2012 WITH ADDITIONAL INFORMATION RECEIVED ON (B)(6)-2012, (B)(6)-2012, (B)(6)-2012, (B)(6)-2012. INITIALLY GIVEN DOCTOR COULD NOT CONFIRM CASE. ON (B)(6)-2012, NEW DOCTOR WAS CALLED FOR TO REPORT DETAILS (NO INFORMATION PROVIDED), ON (B)(6)-2012, PATIENT COULD NOT BE CONFIRMED, CASE IS NOT MEDICALLY CONFIRMED. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED ONE DEVICE IS STILL IN THE PERITONEAL CAVITY, MIGRAINES, NAUSEA, MAJOR VERTIGO, SEVERE ABDOMINAL PAIN, AND PAIN IN HER LOWER ABDOMINAL AREA THAT MIGRATES INTO HER LOWER BACK. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6)-2009 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. IT WAS NOT REPORTED WHETHER ESSURE WAS USED PREVIOUSLY. CONSUMER REPORTED THAT SHE HAD A PARTIAL HYSTERECTOMY ON (B)(6)-2012, BUT DID NOT SAY WHY, AND THAT NO COILS WERE REMOVED AT THIS TIME. SHE CLAIMED THAT ONE DEVICE WAS STILL IN THE PERITONEAL CAVITY CAUSING HER PAIN. SHE HAS GONE TO THE DOCTOR SEVERAL TIMES FOR MIGRAINES, NAUSEA, MAJOR VERTIGO AND SEVERE ABDOMINAL PAIN TO THE POINT SHE CANNOT GET UP. SHE HAD THE ESSURE PROCEDURE (B)(6)-2009; HER HSG WAS DONE ON (B)(6)-2010. SHE HAD A PELVIC ULTRASOUND (B)(6)-2011 AND A PARTIAL HYSTERECTOMY (B)(6)-2011 (DISCREPANT INFORMATION REPORTED). AFTER HER PARTIAL HYSTERECTOMY SHE STILL EXPERIENCED PAIN IN HER LOWER RIGHT ABDOMINAL AREA THAT MIGRATES INTO HER LOWER BACK. THE RELATIONSHIP BETWEEN ONE DEVICE IS STILL IN THE PERITONEAL CAVITY, MIGRAINES, NAUSEA, MAJOR VERTIGO, SEVERE ABDOMINAL PAIN, AND PAIN IN HER LOWER ABDOMINAL AREA THAT MIGRATES

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INTO HER LOWER BACK AND ESSURE WAS NOT REPORTED. THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO ARGUS ON (B)(6)-2013. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED. ON (B)(6)-2013 IT WAS DETECTED THAT FOLLOW-UP WAS RECEIVED FOR THIS CASE, ALL INFORMATION WAS TRANSFERRED TO THIS CASE, DUPLICATE BAYER CASE NUMBER (B)(4) IS DELETED. A SPONTANEOUS CASE REPORT FROM A CONSUMER IN UNITED STATES WAS IDENTIFIED IN THE INTERNET ON (B)(6)-2013 (BAYER NUMBER (B)(4)). ADDITIONAL INFORMATION WAS RECEIVED FROM CONSUMER ON (B)(6)-2013 VIA PHONE AND E-MAIL. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER (BORN IN (B)(6)) WHO RECEIVED ESSURE (TWO FALLOPIAN TUBE OCCLUSION INSERTS), AND EXPERIENCED ONE DEVICE MIGRATED OUTSIDE OF FALLOPIAN TUBE - CT SCANS AND ULTRASOUNDS HAVE NOT BEEN ABLE TO LOCATE THE COIL, HSG CAME BACK NEGATIVE, DYE WENT STRAIGHT THROUGH RIGHT SIDE, 11 DAYS AFTER HSG TEST PREGNANCY TEST POSITIVE, LABOR AT 34 WEEKS, EXTREME SEVERE NAUSEA DURING PREGNANCY - BAD MORNING SICKNESS - COULD HARDLY GET OUT OF BED TO CARE FOR SON AND COULD NOT HOLD FOOD, LOST 10 POUNDS DURING PREGNANCY, DURING PREGNANCY WOKE UP SO DIZZY - HAD TO HOLD ON TO THE WALLS TO WALK - REMEMBER WAKING UP 5 HOURS LATER, CONSTANT SEVERE MIGRAINES - NOW MIGRAINE THREE TIMES A WEEK, MAJOR VERTIGO DURING PREGNANCY, SEVERE ABDOMINAL PAIN - PAIN IN LOWER ABDOMINAL AREA THAT MIGRATES INTO LOWER BACK FEELS LIKE WORST CRAMP EVER - PAIN IN RIGHT SIDE AT TIMES SHARP OR STRONG AND DULL, BLOATING, BACK PAIN, PAIN GOING DOWN THE LEG, LEG REMAINS NUMB, FATIGUED, SKIN ISSUES - UNEXPLAINED RASHES AND BUMPS - SKIN SENSITIVE, LEFT OVARY WITH CYSTS ADHERED TO VAGINAL CUFF, DYSPAREUNIA, AND SINCE INSERTION, PERIODS HEAVIER, VERY PAINFUL AND IRREGULAR. CONSUMER'S MEDICAL HISTORY INCLUDED OCCASIONAL MIGRAINE PRIOR TO INSERTION AND PARA II. CONSUMER HAD A SON BORN IN (B)(6), NINE YEARS AFTER HER OLDEST DAUGHTER ((B)(6)), AND CONSUMER AND HUSBAND FELT THEIR FAMILY WAS COMPLETE. CONSUMER WAS NURSING HER SON. IN (B)(6)-2009, ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT BIRTH CONTROL. SINCE INSERTION, CONSUMER'S PERIODS WERE HEAVIER, VERY PAINFUL AND IRREGULAR. AT THREE MONTHS POST INSERTION, ON (B)(6)-2010, JUST PRIOR TO THE HSG (HYSTEROSALPINGOGRAM) TEST, CONSUMER HAD A BLOOD SERUM PREGNANCY TEST THAT WAS NEGATIVE. AT TIME OF INSERTION WAS TAKING 'POPS' (PROGESTERONE ONLY PILL), A LOW ESTROGEN PILL AS SHE WAS NURSING HER SON. HSG CAME BACK (B)(6), DYE WENT STRAIGHT THROUGH RIGHT SIDE, LEFT SIDE WAS BLOCKED. ONE COIL HAD MIGRATED OUTSIDE OF FALLOPIAN TUBE. ON (B)(6)-2010, WHEN BEING DUE FOR CYCLE FOR 16 HOURS, CONSUMER TOOK A TEST WHICH WAS (B)(6) FOR PREGNANCY. CONSUMER STATED ELEVEN DAYS AFTER THE HSG TEST; SHE HAD A SERUM PREGNANCY TEST THAT WAS (B)(6). DURING HER PREGNANCY, STARTING IN (B)(6)-2010 OR (B)(6)-2010, CONSUMER EXPERIENCED SEVERE ABDOMINAL PAIN, MAJOR VERTIGO, CONSTANT SEVERE MIGRAINES, AND EXTREME NAUSEA, LOST 10 POUNDS DURING PREGNANCY, BACK PAIN AND PAIN GOING DOWN THE LEG. THE PAIN IN HER LEG WAS BETTER, BUT IT REMAINS NUMB AND SHE HAS SKIN ISSUES, UNEXPLAINED RASHES AND BUMPS. SHE STATED HER DOCTOR DID NOT TEST FOR NICKEL ALLERGY. SHE HAD SUCH BAD MORNING SICKNESS SHE COULD HARDLY GET OUT OF BED TO CARE FOR HER SON AND COULD NOT HOLD FOOD. SHE HAD TO FORCE HERSELF TO EAT SOUP ONE SPOON AT A TIME. ONE DAY ((B)(6)-2010), SHE WOKE UP SO DIZZY SHE HAD TO HOLD ON TO THE WALLS TO WALK TO GET HER SON A BOTTLE AND THE PHONE AND CALLED FOR HELP TILL THEY ARRIVED NEVER DID FIGURE OUT WHAT WAS WRONG, SHE JUST REMEMBERS WAKING UP FIVE HOURS LATER. IN (B)(6)-2010, CONSUMER HAD TO HAVE TO GET A SHOT TO STOP HER LABOR AT (B)(6) WEEKS OF GESTATION, THAT WAS THE ONLY THE ONLY COMPLICATION. CONSUMER DELIVERED A HEALTHY BABY GIRL ON (B)(6)-2010 AT (B)(6) WEEKS CONSIDERED TERM. AFTER GIVING BIRTH, CONSUMER WANTED THE ESSURE REMOVED BECAUSE SHE BELIEVED HER PAIN CAME FROM THE MIGRATED COIL. THE CONSUMER HAD A TOTAL/PARTIAL HYSTERECTOMY AND CERVIX REMOVED ON (B)(6)-2011. THE PATHOLOGY REPORT STATED NO ESSURE COIL WAS FOUND OR REMOVED. AFTER THAT SURGERY CONSUMER WAS STILL HAVING EXTREME PAIN IN ABDOMINAL AREA ALONG WITH CHRONIC MIGRAINES, BACK PAIN, DIZZINESS AND SKIN SENSITIVITY. PAST MEDICAL HISTORY INCLUDED AN OCCASIONAL MIGRAINE PRIOR TO INSERTION, BUT NOW HAS THEM THREE TIMES A WEEK. SHE HAS BEEN PRESCRIBED

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NUMEROUS MEDICATIONS, THAT DID NOT WORK, BUT THE ONE NOW IS HELPING A LITTLE BIT (CONSUMER COULD NOT RECALL THE MEDICATION AT THIS TIME). CONSUMER CONTINUED TO SEE A NEUROLOGIST FOR HER MIGRAINES, SHE HAD BEEN TO PHYSICAL THERAPY FOR MONTHS TO HELP WITH HER BACK PAIN, ALL THAT HAS NOT HELPED HER, AND SHE SEES HER FNP (NURSE PRACTITIONER) MONTHLY. CONSUMER IS FATIGUED. CONSUMER CONTINUED TO HAVE PAIN IN HER RIGHT SIDE THAT AT TIMES IS SHARP AND AT TIMES IS STRONG AND DULL. CONSUMER RECEIVED IBUPROFEN 800 FOR THE PAIN. CONSUMER HAS HAD MULTIPLE CT SCANS AND ULTRASOUNDS THAT HAVE NOT BEEN ABLE TO LOCATE THE COIL. GALLBLADDER, LIVER, KIDNEYS WERE HEALTHY. LEFT OVARY WAS FOUND WITH CYSTS ADHERED TO VAGINAL CUFF. DOCTOR SUGGESTED SURGERY FOR THE PAIN, SHE SAID PAIN ON THE RIGHT WAS COMING FROM THE LEFT SIDE, DOCTOR DENIED A RELATIONSHIP WITH ESSURE. CONSUMER WAS SCHEDULED FOR ANOTHER CT SCAN ON (B)(6)-2013. CONSUMER BELIEVED HER PAIN CAME FROM THE MIGRATED COIL. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6)-2013: THE PATIENT DEMOGRAPHIC INFORMATION WAS RECEIVED IN (B)(6)-2009 ESSURE WAS INSERTED, FOR CONTRACEPTION. SHE USED AN ADDITIONAL BIRTH CONTROL, PROGESTIN PILLS (POPS), AND SHE STILL NURSING HER SOON. THE CONSUMER GOT PREGNANCY WITH ESSURE SHORTLY AFTER IT WAS INSERTED IN 2009. PREGNANCY TEST CONFIRMED WAS PERFORMED ON (B)(6)-2010. THE CONSUMER ALSO REPORTED THAT SHE ALSO HAD HAD PAIN IN UPPER RIGHT QUADRANT. IN 2011 UNDERWENT HYSTERECTOMY BECAUSE OF THE PAIN, BUT ESSURE WAS NOT REMOVED. THE UTERUS WEIGHT WAS (B)(6) GRAMS AND THE CERVIX HAD CHRONIC INFLAMMATION. ON (B)(6)-2011 X-RAY WAS PERFORMED, IT SHOWED THAT PERFORATED COIL ON THE RIGHT SIDE, BUT THE DOCTOR DID NOT FIND IT. ON (B)(6)-2013 A COMPUTERIZED SCAN SHOWED THE RIGHT COIL WAS 3.5 MM METALLIC FOCUS AND ANTERIOR TO THE PROXIMAL ASCENDING COLON IN THE RIGHT LOWER ABDOMEN. IT WAS COMPATIBLE WITH FRAGMENTS OF ESSURE COILS. ON (B)(6)-2013 A COMPUTERIZED SCAN OF ABDOMEN SHOWED TINY METALLIC FOCUS IN ANTERIOR RIGHT SIDE OF THE ABDOMEN DIRECTLY ANTERIOR TO THE PROXIMAL ASCENDING COLON IS SLIGHTLY MORE LATERAL IN LOCATION ON THE CURRENT EXAM. THE CONSUMER WOULD LIKE TO HAVE THE ESSURE REMOVED. A SURGERY WAS SCHEDULED TO (B)(6)-2013 WITH A CT SCAN . FOLLOW-UP RECEIVED ON (B)(6)-2013: IT WAS REPORTED THAT THE PATIENT HAD A SURGERY AND THE LEFT TUBE WAS ALSO PERFORATED AND THE RIGHT COIL WAS NOT ABLE TO BE LOCATED. FOLLOW-UP RECEIVED ON (B)(6)-2013, WAS DETECTED ON (B)(6)-2013 AS DUPLICATE BAYER CASE NUMBER (B)(4) (WILL BE DELETED): CONSUMER CALLED IN TO PROVIDE FURTHER INFORMATION. THE ESSURE COIL PERFORATED THE RIGHT FALLOPIAN TUBE AND MIGRATED TO THE ASCENDING COLON. THE HCP (HEALTHCARE PROFESSIONAL) WAS UNABLE TO RETRIEVE THAT COIL ON (B)(6)-2013. HOWEVER, SHE DID RETRIEVE REPORTER BELIEVES PART OF THE ESSURE COIL ON THE LEFT. IT WAS NOT MEASURING TO THE LENGTH OR THE WIDTH OF THE ESSURE COIL. IT WAS NOTED THAT THE COIL ON THE LEFT HAD PERFORATED THE LEFT FALLOPIAN TUBE. IT MEASURED 2CM STRETCHED OUT ACCORDING TO THE PATHOLOGY. REPORTER DOES NOT KNOW WHERE THE REST OF IT THE COIL WAS. THE WHOLE STRAIGHT PIECE WAS NOT THERE. CONSUMER HAS BEEN IN A LOT OF PAIN. SHE WAS GOING TO SEE ANOTHER HCP ON TUESDAY ((B)(6)-2013) WHO WAS ANOTHER OBGYN (OBSTETRICIAN/GYNECOLOGIST). SHE WAS NOT GIVING OUT NAMES NOW. SHE WAS GOING TO SEE A GI (GASTROENTEROLOGY) SPECIALIST AND WAS WAITING ON A REFERRAL. THE HCP WHO WAS REMOVING THE ESSURE, DENIED HER THE USE OF FLUOROSCOPY WHICH WAS THEN RECOMMENDATION BY THE ESSURE INSERT PACKET THAT WAS AT THE PREOPERATION VISIT. CONSUMER WANTS TO MAKE A COMPLAINT AGAINST THE HCP. SHE STATED SHE WAS FALLING VICTIM AS THE PATIENT. PTC INVESTIGATION RESULT RECEIVED ON (B)(6)-2014 THE PTC (PRODUCT TECHNICAL COMPLAINT) GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN (B)(4), PROCESSING ESSURE CASES IN DEV@COM. MEDICAL ASSESSMENT THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE FOR A QUALITY DEFICIT PER SE. CONTRACEPTIVE FAILURE MAY OCCUR UNDER ANY CONTRACEPTIVE. THE CASE REFERS ALSO TO A DEVICE BREAKAGE AND A USABILITY ISSUE. THE MEDICAL EVENTS WERE REPORTED WITH

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AN OCCURRENCE OVER A PERIOD OF 3.3 YEARS AND ARE OF BROAD NATURE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. FOLLOW-UP (B)(6)-2015: FOLLOW UP INFORMATION RECEIVED FROM THE PHYSICIAN. PATIENT'S DATA WERE UPDATED. PATIENT HAS HISTORY OF CERVICAL DYSPLASIA. ESSURE INSERTION DATE WAS UPDATED TO (B)(6)-2009. LOT NUMBER WAS NOT AVAILABLE. ESSURE WAS INSERTED IN SURGICAL CENTER UNDER GENERAL ANESTHESIA. THERE WERE PHOTOS FROM AFTER INSERTION THAT SHOWED ESSURE IN GOOD PLACEMENT. HSG (HYSTEROSALPINGOGRAM) PERFORMED ON (B)(6)-2010 SHOWED LEFT SIDE OCCLUDED BUT RIGHT SIDE NOT OCCLUDED. NO OTHER INFORMATION THAT SHE WENT FOR ANOTHER HSG. ON (B)(6)-2010, THE PATIENT WAS SEEN WITH COMPLAINT OF PELVIC PAIN AND FOR CONSULT FOR HYSTERECTOMY. IN (B)(6)-2011 AN ULTRASOUND WAS DONE FOR PAIN TO RULE OUT OVARIAN CYSTS. NO MASS SEEN AND EVERYTHING APPEARED TO BE NORMAL BUT IT DID NOTE A 16ML ENDOMETRIAL LINING. A HYSTERECTOMY AND REMOVAL OF ESSURE COILS PERFORMED ON (B)(6)-2011. THE SALES REPRESENTATIVE THOUGHT THE HCP TOLD HER THAT WHEN SHE WENT IN TO DO SURGERY SHE DID NOT FIND THE RIGHT COIL. POST OPERATIVE VISIT ON (B)(6)-2011 NO VAGINAL BLEEDING NOTED AND EVERYTHING DOING WELL. ANOTHER POST OP VISIT ON (B)(6)-2011 PATIENT WAS FEELING WELL BUT HAD SOME LEFT CRAMPING AND BACK PAIN. ON (B)(6)-2011 SHE CAME IN WITH COMPLAINT OF RIGHT PELVIC PAIN AND ABDOMINAL PAIN CLOSER TO UMBILICUS, NAUSEA BUT NO VOMITING. PATIENT WAS SAW NURSE, NOT DOCTOR AT THIS VISIT. SHE WAS SENT FOR ULTRASOUND TO RULE OUT GALLSTONES. ULTRASOUND ON (B)(6)-2011 FOR PELVIC PAIN AND ABDOMINAL STUDY SAID GALLBLADDER NORMAL, RIGHT OVARY AND ADNEXA NORMAL, LEFT OVARY SIMPLE HAS 2.6CM CYST. ON (B)(6)-2011 VISIT, THE PATIENT HAD 2 SEPARATE PAINS, ONE IN RIGHT LOW LEFT QUADRANT THAT HAD BEEN WORSENING FOR THE PAST 3 DAYS AND THE OTHER PAIN WAS MID ABDOMEN. PATIENT WAS CONCERNED THAT ESSURE IMPLANT CAUSING THE PAIN. PATIENT REASSURED OF ESSURE INABILITY FOR IDEOLOGY OF PAIN EVEN IF IT HAD PERFORATED AND WAS LOCATED IN ABDOMEN. ON (B)(6)-2011, THE PATIENT SIGNED RECORD RELEASE AND WENT TO SEE DIFFERENT DOCTOR. A SMALL PORTION OF MICRO-INSERT FOUND IN BOWEL BY DIFFERENT PHYSICIAN. A BOARD OF ACTION PENDING AGAINST A DOCTOR. FOLLOW UP (B)(6)-2015: PTC INVESTIGATION RESULTS WERE UPDATED AND PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY CONTRACEPTIVE FAILURE MAY OCCUR UNDER ANY CONTRACEPTIVE. THE CASE REFERS ALSO TO A DEVICE BREAKAGE AND A USABILITY ISSUE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE, WERE REPORTED WITH AN OCCURRENCE OVER A PERIOD OF 3.3 YEARS AND ARE OF BROAD NATURE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6)-2015. ON (B)(6)-2010 LEEP (INTERPRETED AS LOOP ELECTROSURGICAL EXCISION PROCEDURE) WAS PERFORMED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED

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ON (B)(6)-2015: NO NEW CLINICAL INFORMATION. COMPANY CAUSALITY COMMENT: THIS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED COIL PERFORATED ON RIGHT SIDE, CT SHOWED RIGHT COIL WAS 3.5MM METALLIC FOCUS ANTERIOR TO PROXIMAL ASCENDING COLON, COMPATIBLE WITH FRAGMENTS - LEFT TUBE WAS ALSO PERFORATED; SHE ALSO HAD LABOR AT (B)(6) WEEKS; DURING PREGNANCY WOKE UP SO DIZZY - HAD TO HOLD ON TO THE WALLS TO WALK - REMEMBER WAKING UP 5 HOURS LATER; LEFT OVARY WITH CYSTS ADHERED TO VAGINAL CUFF; AND HCP DID RETRIEVE PART OF THE COIL ON THE LEFT - THE WHOLE STRAIGHT PIECE WAS NOT THERE (INTERPRETED AS DEVICE BREAKAGE DURING REMOVAL ATTEMPT FROM ABDOMEN). THESE EVENTS ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. COIL PERFORATED ON RIGHT SIDE, CT SHOWED RIGHT COIL WAS 3.5MM METALLIC FOCUS ANTERIOR TO PROXIMAL ASCENDING COLON CONT, COMPATIBLE WITH FRAGMENTS - LEFT TUBE WAS ALSO PERFORATED IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE OTHER EVENTS ARE UNLISTED. BASED ON THE PROVIDED INFORMATION, A CAUSAL RELATIONSHIP BETWEEN ESSURE USE AND THE SERIOUS EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO PREMATURE LABOR AND SINCE A SURGICAL INTERVENTION WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PTC INVESTIGATION RESULT WAS RECEIVED: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD REVIEW COULD BE DONE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00266	BAYER HEALTHCARE LLC	4/22/2015	4/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2004
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF. SHE IS A (B)(6) FEMALE CONSUMER WHO HAD ESSURE ((B)(4)) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2005. CONSUMER REPORTED THAT SHE HAD A PROBLEM WITH ESSURE BIRTH CONTROL. SHE HAS TO HAVE A HYSTERECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015 AND FOLLOW-UP WAS RECEIVED ON (B)(4) 2014. THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE AND IS CONSIDERED NOT ASSESSABLE BY THE COMPANY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP (B)(4) 2015: CASE UPGRADED TO INCIDENT. FOLLOW UP INFORMATION RECEIVED FROM THE

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CONSUMER. CONSUMER REPORTED THAT SHE WAS MOTHER OF FOUR AND AFTER HAVING TWINS SHE DID NOT WANT ANYMORE CHILDREN. SHE WAS TOLD OF ESSURE, NO DOWN TIME OR SIDE EFFECTS. ESSURE WAS PLACED IN (B)(6) 2005 AND HAD A HYSTERECTOMY ON (B)(6) 2015. SHE WAS (B)(6) AND NOW DEALING WITH MENOPAUSE AND THE FEW THAT PASSED. SHE PASSED OF COMPILATIONS OF HAVING ESSURE REMOVED. THIS CASE WAS MARKED AS A POTENTIAL LEGAL CASE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS AND POTENTIAL LEGAL CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE ((B)(4)) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD PROBLEM WITH ESSURE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THIS CASE WAS REPORTED WITH LIMITED INFORMATION. IT WAS NOT SPECIFIED WHAT TYPE OF PROBLEM THE CONSUMER EXPERIENCED. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A HYSTERECTOMY WAS PERFORMED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 06-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00267	BAYER HEALTHCARE LLC	4/22/2015	4/22/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN (CONSULTANT) IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD TWO ATTEMPTS OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. PHYSICIAN REPORTED THAT A COLLEAGUE PERFORMED ESSURE INSERTION IN RIGHT FALLOPIAN TUBE BUT ON THAT DAY ((B)(6) 2015); LEFT TUBE WAS NOT VISUALIZED PROPERLY. THEREFORE, THE PATIENT WAS BROUGHT BACK AGAIN AFTER HER PERIOD. THE SECOND TIME AS WELL THE INSERTION WAS NOT FEASIBLE; THEREFORE, SHE WAS BOOKED FOR LAP STERILIZATION. AT LAPAROSCOPIC STERILIZATION, A PERFORATION WAS NOTED AT RIGHT CORNUA, THROUGH THE POSTERIOR WALL. THE MICRO-INSERT HAS UNRAVELLED AND WAS ATTACHED TO THE OMENTUM AND SEEMED TO BE STUCK TO BOWEL. PATIENT WAS COMPLETELY ASYMPTOMATIC AND THIS WAS AN INCIDENTAL FINDING AT LAPAROSCOPY. FOLLOW-UP RECEIVED ON (B)(4) 2015: (B)(4). PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A USABILITY ISSUE AND A REPORTED PRODUCT ISSUE (MICROINSERT HAS UNRAVELLED). THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS

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INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD 2 UNSUCCESSFUL ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ATTEMPTS. LATER, DURING A LAPAROSCOPIC STERILIZATION A UTERINE PERFORATION WAS NOTED AT RIGHT CORNUA, THROUGH THE POSTERIOR WALL. ESSURE WAS FOUND UNRAVELLED AND SEEMED TO BE STUCK TO BOWEL. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A COMPLETE PERFORATION OCCURS, ESSURE CAN BE FOUND IN THE ABDOMINAL CAVITY AS IT PERFORATES THE WHOLE UTERINE WALL. ADDITIONALLY, INTERNAL ORGANS PERFORATION MAY OCCUR WITH ESSURE, DUE TO DEVICE MIGRATION OR DURING INSERTION PROCEDURE. THE BOWEL IS THE MOST COMMONLY AFFECTED ORGAN DUE TO ITS ANATOMICAL RELATIONSHIP WITH UTERUS. IN THIS PARTICULAR CASE, ESSURE INSERTION WAS DIFFICULT; THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE EVENTS. BASED ON THE AVAILABLE INFORMATION AND CONSIDERING THE REPORTED EVENTS NATURE CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN INCIDENT; AS ALTHOUGH PHYSICIAN CONSIDERED THE EVENTS AS AN INCIDENTAL FINDING DURING LAPAROSCOPY, A SURGICAL INTERVENTION WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 01-MAY-2015 FROM PHYSICIAN: THIS PATIENT HAD STRAIGHT FORWARD INSERTION ON ONE SIDE AND THEY COULD NOT INSERT THE SECOND DEVICE. THEY SUSPECTED THAT SHE MAY HAVE A TUBAL OCCLUSION. THIS PATIENT THEN CAME FOR LAPAROSCOPIC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00268	BAYER HEALTHCARE LLC	4/22/2015	4/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY IN THE UNITED STATES, ON BEHALF OF CONSUMER'S FAMILY IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER HAD A KNOWN NICKEL ALLERGY. SHE HAD ESSURE INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN. AT ONE POINT THERE WAS AN ATTEMPT TO REMOVE THE INSERTS AND EVENTUALLY SHE HAD A HYSTERECTOMY. FOLLOW UP (B)(4) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF NOT

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REPORTED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE CONSUMER HAD A KNOWN NICKEL ALLERGY AND AFTER ESSURE INSERTED, PRESENTED CHRONIC PELVIC PAIN. GIVEN AVAILABLE INFORMATION AND ITS NATURE, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE USE AND SINCE HYSTERECTOMY WAS REPORTED THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00269	BAYER HEALTHCARE LLC	4/22/2015	4/22/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B60753

Single Use: Y
Implant Date (E6): 12/6/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR BIRTH CONTROL. THE CONSUMER STATED SHE HAD NOTHING BUT PROBLEMS SINCE ESSURE WAS INSERTED. MOSTLY IT WAS PAIN SINCE THE MOMENT SHE GOT IT PUT IN - SHE WAS IN HOSPITAL BECAUSE OF IT. THE FIRST TIME SHE WAS IN HOSPITAL WAS (B)(6) 2014. THE NEXT TWO TIMES WERE(B)(6) 2014, SHE WAS ADMITTED FOR PAIN. THE PAIN WAS BOTH THE RIGHT AND LEFT SIDE LOWER MID ABDOMEN. SHE ALSO MENTIONED BLEEDING, WHICH AT FIRST DID NOT STOP AND NOW SHE COULD NOT GET IT TO START. SHE WAS ON HORMONAL MEDICATION TO HAVE A PERIOD EVERY MONTH (MEDROXYPROGESTERONE) SINCE (B)(6) 2015 AND WAS STILL ON PAIN MEDICATION. ESSURE WAS CONTINUED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT - SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT - THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GLOBAL PHARMACOVIGILANCE DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE

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WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS HOSPITALIZED DUE TO PAIN IN BOTH THE RIGHT AND LEFT SIDE OF HER LOWER MID ABDOMEN. SHE DEVELOPED THIS PAIN SINCE THE MOMENT SHE GOT ESSURE PUT IN. ADDITIONALLY SHE REPORTED BLEEDING (REGARDED AS GENITAL BLEEDING), WHICH AT FIRST DID NOT STOP. ALL EVENTS WERE CONSIDERED SERIOUS, DUE TO HOSPITALIZATION (PAIN) AND MEDICAL IMPORTANCE (BLEEDING) AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR; IN THIS CASE CONSIDERING THE CLOSE TEMPORAL RELATION BETWEEN THE REPORTED EVENTS AND ESSURE PROCEDURE AND IN THE LACK OF ALTERNATIVE EXPLANATION CAUSALITY CANNOT BE EXCLUDED. DUE TO THE HOSPITALIZATION REPORTED, THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 02-JUN-2015 FROM PATIENT: PATIENT'S DEMOGRAPHIC INFORMATION WAS PROVIDED. SHE DENIED RELEVANT HISTORICAL AND CONCOMITANT CONDITIONS. IT WAS STATED SHE HAD A PREGNANCY ON (B)(6) 2011 AND 23 MONTHS AFTER THAT ((B)(6) 2013),

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00272	BAYER HEALTHCARE LLC	4/22/2015	4/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893028

Single Use: Y
Implant Date (E6): 8/24/2012
Explant Date (E7): 3/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. THE PATIENT HAD ESSURE PLACED THE WEEK BEFORE THE DATE OF REPORT AND HAD TO HAVE ESSURE SURGICALLY REMOVED OVER THE WEEKEND ((B)(6) 2015). FOLLOW-UP RECEIVED ON (B)(6) 2015: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6)-YEAR-OLD FEMALE PATIENT WHO IS NOT PREGNANT; HAD ESSURE (LOT NUMBER 893028) INSERTED FOR CONTRACEPTION ON (B)(6) 2012. PHYSICIAN INFORMED THAT PATIENT WAS IN PAIN AND, ON (B)(6) 2015, SHE HAD A COMPUTERIZED TOMOGRAPHY SCAN DONE. ON BOTH DATES IT WAS FOUND THAT 5 COILS WERE IN THE LEFT TUBE AND 4 COILS WERE IN THE RIGHT TUBE. IN ADDITION, IT WAS REPORTED THAT THE RIGHT ESSURE DEVICE WAS PROPERLY PLACED IN THE FALLOPIAN TUBE. HOWEVER, THE LEFT ESSURE DEVICE WAS SEEN ANTERIORLY IN THE LEFT LOWER QUADRANT (A LONG DISTANCE FROM THE LEFT FALLOPIAN TUBE), AND WAS ADJACENT TO THE MEDIAL ASPECT OF THE SIGMOID COLON. HEALTH CARE PROFESSIONAL SURGICALLY REMOVED THE ESSURE ON (B)(6) 2015. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: LOT NUMBER 893028 PRODUCTION DATE: 8/2011 EXP DATE: 8/2014. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS.

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WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 3 FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH , NONE OF THEM REFERRING ALSO TO A SIMILAR TYPE OF ADVERSE EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LEFT ESSURE DEVICE WAS SEEN ANTERIORLY IN THE LEFT LOWER QUADRANT (A LONG DISTANCE FROM THE LEFT FALLOPIAN TUBE). THE PREVIOUSLY REPORTED EVENT SURGICALLY REMOVED, INTERPRETED AS MEDICAL DEVICE REMOVAL, WAS DELETED. THE REPORTED EVENT, INTERPRETED AS DEVICE DISLOCATION, IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THE EVENT IS CONSIDERED LISTED. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE SURGICAL INTERVENTION. A REVIEW OF THE MANUFACTURING BATCH RECORD WAS CONDUCTED AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. ALSO, FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH , NONE OF THEM REFERRING ALSO TO A SIMILAR TYPE OF ADVERSE EVENT. THEREFORE, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 29-JUN-2015 THE PATIENT'S DATE OF BIRTH WAS UPDATED. PREVIOUS GYNECOLOGICAL INTERVENTIONS WERE DENIED. CHRONIC RIGHT LOWER QUADRANT PAIN WAS REPORTED AS PREVIOUS GYNECOLOGICAL PROBLEM. CERVICAL DILATION SOUNDING AND GENER

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042261	BAYER HEALTHCARE	4/22/2015	4/28/2015

Event Information:

Event Date (B3): 8/1/2006 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): IUD
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER REPORTS HAVING ESSURE IMPLANTED IN (B)(6) 2006. THE DEVICE WAS ONLY SUCCESSFULLY IMPLANTED ON ONE SIDE. TWO MONTHS LATER, CALLER HAD REVISION PROCEDURE WHEN THE ONE IMPLANTED WAS REMOVED AND A NEW ONE WAS INSERTED ALONG WITH THE SIDE THAT DID NOT HAVE DEVICE INITIALLY INSERTED. CALLER STATED THAT FOR THE LAST 2 YEARS SHE'S BEEN EXPERIENCING EXCRUCIATING PAIN CAUSED BY THE ESSURE. SHE IS NOT SEEKING A SECOND OPINION BY AN OBGYN SPECIALIST IN HOPES TO REMOVE THE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042326	BAYER	4/22/2015	4/29/2015

Event Information:

Event Date (B3): 12/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/18/2014
Explant Date (E7): 4/21/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE COILS PUT IN MY TUBES ON (B)(6) 2014. I HAD SEVERE BACK PAIN AFTERWARDS FOR ABOUT 2 WEEKS, BUT THOUGHT I HAD JUST PULLED A MUSCLE ON THAT SIDE. I WENT IN FOR THE HSG (B)(6) 2015 AND FOUND OUT THAT ONE OF THE COILS HAD MIGRATED OUT OF MY FALLOPIAN TUBE AND FELL BACK BEHIND MY UTERUS. I HAD SURGERY ON (B)(6) 2015 TO FIND AND REMOVE IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042327	BAYER	4/22/2015	4/29/2015

Event Information:

Event Date (B3): 4/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/9/2009
Explant Date (E7): 3/30/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE INSERTED IN 2009, AND IT WAS VERY PAINFUL. OVER THE NEXT FEW YEARS I HAD LOW BACK PAIN, HEAVY PERIODS, LONG PERIODS AND NO SEX DRIVE. I DID NOT RELATE THESE TO ESSURE. MY OB/GYN THOUGHT THEY WERE DUE TO BEING PRE-MENOPAUSAL. I HAD ESSURE REMOVED (B)(6) 2015, AND THREE DAYS POST OP MY CHRONIC BACK PAIN WAS GONE! (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042328	BAYER	4/22/2015	4/29/2015

Event Information:

Event Date (B3): 4/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/24/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

RECEIVED THE ESSURE BIRTH CONTROL IN (B)(6) 2014. A MONTH LATER, I NOTICED SHOOTING PAINS THAT STARTED IN THE AREA OF MY LEFT OVARY AND SHOT TO MY LEFT KNEE. I THOUGHT IT WAS TEMPORARY, AND IT CONTINUED. AT MY FIRST FOLLOW UP, I INFORMED MY DOCTOR WHO IMPLANTED THE DEVICE OF MY ISSUES AND HE ASSURED IT WASN'T RELATED TO ESSURE. DIDN'T DO ANY TEST, JUST SENT ME HOME. I HAD NEVER IN MY LIFE EXPERIENCED THAT PAIN, I EVEN GAINED 30 POUNDS. I FINALLY BUILT UP MY ANGER AND CALLED FOR ANOTHER APPOINTMENT BUT WAS INFORMED MY PREVIOUS OB/GYN NO LONGER PRACTICED THERE. SO I WAS REFERED TO ANOTHER OB/GYN AT THE SAME OFFICE. SHE LISTENED AND SENT ME TO RUN TESTS. INCLUDING THE ONE TO MAKE SURE THE COILS WERE IN PLACE AND BLOCKING. I STILL EXPERIENCE THAT PAIN, DAILY IF NOT 24 HOURS OF THE DAY. MY CYCLE IS HORRIBLE, BLOOD GUSHES DOWN MY LEGS NO MATTER WHAT PAD OR TAMPON I USE. I HAVE THREE CHILDREN THAT NEED ME AND MY LIFE IS NOT THE SAME. I CAN'T FUNCTION 100 PERCENT BECAUSE OF THIS!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042335	BAYER	4/22/2015	4/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 958707

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE IS MAKING ME HAVE VERY SHARP LOWER PELVIC PAIN, HEAVY IRREGULAR PERIODS, AND BACTERIAL VAGINOSIS REGULARLY. VERY BLOATED STOMACH ON DAYS, HEADACHES, AND NAUSEA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042336	BAYER	4/22/2015	4/29/2015

Event Information:

Event Date (B3): 4/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 12/5/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2014, I HAD THE ESSURE PROCEDURE DONE. AND A WEEK LATER, AN ENDOMETRIAL ABLATION. I HAVE SUFFERED FROM HAIR LOSS, EXTREME FATIGUE, FREQUENT EPISODES OF PELVIC CRAMPING AND 3 EPISODES OF SPOTTING. IN (B)(6) 2015 THE SPOTTING STARTED OUT OF THE BLUE WITH EXTREME PELVIC CRAMPS WARRANTING AN EMERGENCY ROOM VISIT. TODAY (B)(6), 2015, I HAD THE ESSURE CONFIRMATION TEST DONE AT THE HOSPITAL AND I WAS FOUND TO HAVE 1 COIL MISSING. THE ESSURE COILS FAILED. I AM AWAITING A FURTHER PLAN OF ACTION FROM MY OBGYN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042337	BAYERS	4/22/2015	4/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): B09711

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE PROCEDURE DONE 2014 AND IT HAS BEEN BAD SINCE IMPLANTED. I WOULD NOT STOP BLEEDING. THEN THE DOCTOR PERFORMED ABLATION AND MY PERIODS WENT BACK TO SOME WHAT NORMAL. THEN IN (B)(6) 2014 MY PERIODS STOPPED COMPLETELY AND MY SEX LIFE WENT AWAY. I HAVE PAIN ALL THE TIME. DOCTOR PRESCRIBED PAIN MEDICATION. I HAVE HEADACHES AS WELL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042338	BAYER	4/22/2015	4/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/11/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SIDE EFFECTS FROM ESSURE INCLUDING (BUT NOT LIMITED TO): PIERCING HEADACHES, EDEMA, NEUROPATHY OF ARMS, PREGNANCY LIKE SYMPTOMS DURING PERIOD, LACK OF ENERGY, WEIGHT GAIN, "E BELLY."

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00270	BAYER HEALTHCARE LLC	4/22/2015	5/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18708

Single Use: Y
Implant Date (E6): 3/27/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER C18708. THE OUTER PLASTIC CATHETER RELEASED WITH MICRO INSERT. THE PHYSICIAN HAD TO USE A SECOND DEVICE. P.E.T. REMAINED IN TUBE. BILATERAL PLACEMENT WAS ACHIEVED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 PTC GLOBAL NUMBER (B)(4) FINAL ASSESSMENT FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY

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DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE IN THE CONTEXT OF A DIFFICULT DEVICE INSERTION. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WAS CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 PREGNANCY WAS DENIED. ESSURE WAS INSERTED FOR CONTRACEPTION. WHEN PHYSICIAN WAS DOING INSERTION, THE OUTER PLASTIC RELEASED WITH MICRO- INSERT .THE HCP WENT IN WITH GRASPER AND REMOVED THE COIL AND THE OUTER PLASTIC. HOWEVER, THE PET FIBERS REMAINED IN PATIENT'S LEFT TUBE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) IMPLANTED. HOWEVER, DURING INSERTION, THE OUTER PLASTIC CATHETER RELEASED WITH MICRO INSERT. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE DEVICE BREAKAGE OCCURRED DURING INSERTION. THE PHYSICIAN HAD TO REMOVE IT BUT POLYETHYLENE TEREPHTHALATE (PET) FIBERS REMAINED IN THE TUBE. A SECOND ESSURE INSERT WAS USED AND BILATERAL PLACEMENT WAS ACHIEVED. CONSIDERING THE NATURE OF DEVICE BREAKAGE, THE POSITIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATIONS, THE EVENT OF DEVICE BREAKAGE IS CONSIDERED RELATED TO ESSURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WAS CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 22-JUN-2015: FOLLOW UP ATTEMPT WITHOUT ANSWER (LETTER RETURNED UNDELIVERABLE). NO NEW INFORMATION WAS PROVIDED. FOLLOW UP 28-JUL-2015: HCP FOLLOW UP LETTER RETURNED TO SENDER AND NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY CO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00271	BAYER HEALTHCARE LLC	4/22/2015	5/26/2015

Event Information:

Event Date (B3): 9/24/2014 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91739

Single Use: Y
Implant Date (E6): 9/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL VIA REGULATORY AUTHORITY ((B)(4)) IN UNITED STATES ON 27-MAR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014, LOT NUMBER C91739 (EXPIRATION DATE 01-JUL-2017). ON (B)(6) 2014, THE ESSURE DEVICE WAS BEING USED ON THE RIGHT FALLOPIAN TUBE BY THE PHYSICIAN. THE DEVICE WOULD NOT MOVE FORWARD AND WAS BENDING UPON ATTEMPTS TO ADVANCE. A SMALL PIECE OF THE ALUMINUM FROM THE DEVICE BROKE OFF. DEVICE MALFUNCTION WAS REPORTED - THE DEVICE DID NOT DO WHAT IT WAS SUPPOSED TO DO. THE REPORTER MENTIONED OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) AS EVENT OUTCOME, HOWEVER DID NOT SPECIFY IT. FOLLOW-UP RECEIVED ON 06-APR-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A USABILITY ISSUE. (B)(4). FINAL ASSESSMENT: LOT NUMBER: C91739; EXPIRATION DATE: 31-JUL-2017; PRODUCTION DATE: JUL-2014. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A

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GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE IN THE CONTEXT OF A DIFFICULT DEVICE INSERTION. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. AT THIS POINT IN TIME NO ADVERSE EVENTS HAVE BEEN REPORTED THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS QUALITY DEFECT WAS NOT CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE INSERTION PROCEDURE A PIECE OF THE ALUMINUM FROM THE DEVICE BROKE OFF (DEVICE MALFUNCTION). THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, WAS CONSIDERED SERIOUS BY THE REPORTER DUE TO MEDICAL IMPORTANCE AND IT WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, DURING INSERTION THE DEVICE WOULD NOT MOVE FORWARD AND WAS BENDING UPON ATTEMPTS TO ADVANCE (NON-SERIOUS EVENT); AND A SMALL PIECE OF THE ALUMINUM FROM THE DEVICE BROKE OFF. THEREFORE, CONSIDERING THAT THE REPORTED EVENTS OCCURRED DURING THE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS QUALITY DEFECT WAS NOT CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 15-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIEN

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042349	BAYER	4/23/2015	4/30/2015

Event Information:

Event Date (B3): 12/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/12/2011
Explant Date (E7): 4/15/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS PLACED IN (B)(6). PAIN AND ISSUES BEGAN WITHIN 6 MONTHS RELATING TO ESSURE. HIGH BLOOD PRESSURE, SEVERE TUBAL PAIN, HEAVY BLEEDING/PASSING CLOTS, MIGRAINES, WEIGHT GAIN, HAIR LOSS, LOSS OF LIBIDO, MOOD SWINGS, AND MANY MANY OTHER ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042350	BAYER	4/23/2015	4/30/2015

Event Information:

Event Date (B3): 2/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 2/23/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2014, I HAD THE ESSURE STERILIZATION DEVICES PLACED IN MY BODY. FROM THAT MOMENT ON, I HAVE EXPERIENCED 2 ABNORMAL PAPS (NEVER HAD ANY UNTIL IMPLANTS), I SUFFER FROM EXTREMELY EXCESSIVE BLEEDING, ABDOMINAL PAIN, VAGINAL PAIN, FATIGUE, WEIGHT GAIN, MIGRAINES AND METALLIC TASTE IN MY MOUTH. TOOTH DECAY AND SENSITIVITY AND LOW BLOOD PRESSURE. ALSO MY LEFT TUBE ISN'T BLOCKED AT ALL WHICH MEANS THE DEVICE HAS FAILED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042351	BAYER	4/23/2015	4/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/27/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE INSERTED (B)(6) 2012. BECAME PREGNANT WITH TWINS BORN (B)(6) 2014. SINCE PROCEDURE HAVE HAD MIGRAINES, NUMBING OF HANDS AND FEET/LEGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042357	BAYER	4/23/2015	4/30/2015

Event Information:

Event Date (B3): 4/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): BAYER
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/12/2011
Explant Date (E7): 4/15/2015
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS HAD PERFORATED ONE TUBE AND MIGRATED OUT OF THE OTHER EMBEDDING 2CM INTO UTERUS. DATES OF USE: (B)(6) 2011- (B)(6) 2015. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042227	BAYER	4/24/2015	4/24/2015

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MULTIPLE EPISODES THROUGHOUT THE MONTH OF VARYING DEGREES OF ABDOMINAL/PELVIC PAIN. PAINFUL INTERCOURSE, CYSTS ON OVARIES, MULTIPLE INFECTIONS, BLOOD IN URINE, FATIGUE, DRY SKIN, SIGNIFICANT LOSS OF HAIR. OVERALL SENSE OF SOMETHING WRONG, MOSTLY ON THE LEFT SIDE OF THE BODY. LOSS OF HEARING IN THE LEFT EAR ALONG WITH TINNITUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042228	BAYER	4/24/2015	4/24/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER (B)(4). NUMBNESS PAIN TINGLING LOSS OF VISION, SORE THROAT, BLADDER INFECTION, EXTREMELY FATIGUE, CONFUSION, LOW BLOOD PRESSURE; HAD AN MRI OF MY BRAIN AND NECK WITH AND WITHOUT CONTRAST. FINDINGS THYROID MASS LEFT SIDE AND OSTEOARTHRITIS REFERRAL TO RHEUMATOLOGIST, NEUROLOGIST AND ENDOCRINOLOGIST

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042229	BAYER	4/24/2015	4/24/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER (B)(4). VERY TIRED, WEIGHT GAIN, VERY IRRITABLE, MUSCLE WEAKNESS, MUSCLE PAIN, HEADACHES, MIGRAINES, ANEMIC, STOMACH ULCER, LOW VITAMIN D, LOW VITAMIN B, SEVERE DEPRESSION,. I HAVE BEEN TO NUMEROUS DIFFERENT DOCTORS WITH THESE PROBLEMS AND HAD NUMEROUS TEST DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042238	BAYER	4/24/2015	4/24/2015

Event Information:

Event Date (B3): 10/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5042238 #(B)(4) MY HYSTERECTOMY WAS ON (B)(6), 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042239	BAYER	4/24/2015	4/24/2015

Event Information:

Event Date (B3): 10/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A DEVICE CALLED ESSURE. I SUFFERED WITH DEBILITATING PAIN IN MY ABDOMEN, PELVIS, BACK, MIGRAINE HEADACHES, SEVERE BLEEDING DURING WHAT WERE SUPPOSED TO BE NORMAL CYCLE TIMES, I HEMORRHAGED NUMEROUS TIMES, I HAVE A NICKEL ALLERGY, I LOST COLORING IN MY FACE, I BECAME A PRISONER IN MY OWN BODY BECAUSE I COULDN'T FUNCTION, TAKE CARE OF MY KIDS, TAKE CARE OF MY HOUSE. I STILL HAVE MEMORY LOSS THAT I DIDN'T HAVE BEFORE HAVING ESSURE PLACED IN MY BODY. I ULTIMATELY HAD TO HAVE A HYSTERECTOMY BECAUSE OF THIS PRODUCT AND LOST 7 MONTHS WITH MY KIDS THAT I WILL NEVER GET BACK! I HAD NUMEROUS CT SCANS, PANELS OF BLOODWORK, XRAYS, ULTRASOUNDS, DOCTORS APPT'S, HOSPITAL ER VISITS (TO WHICH RESULTED IN ME BEING FLAGGED SO NOW WHEN I GO IN THEY WON'T TREAT ME). I DON'T REMEMBER IF I PREVIOUSLY FILED AN ADVERSE REACTION REPORT OR NOT DUE TO MEMORY LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042352	BAYER	4/24/2015	4/30/2015

Event Information:

Event Date (B3): 7/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/22/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2007 AND SHORTLY AFTER, I HAD HEAVY PERIODS AND PAINFUL CRAMPS. I HAVE HAD ABDOMINAL PAIN HOSPITALIZED AND 2 SURGERIES IN (B)(6) 2012. IN (B)(6), I HAD MY RIGHT TUBE REMOVED BECAUSE IT WAS BENT AND BLOOD VESSEL WRAPPED AROUND IT CAUSING PAIN. I'M STILL IN CONSTANT ABDOMINAL PAIN ALMOST DAILY. I HAVE BEEN DIAGNOSED WITH ANEMIA. WHEN I ASKED MY DOCTOR IN 2007 IF IT WAS SAFE TO PLACE THIS BECAUSE OF THE NICKEL SINCE I HAVE REACTIONS TO NICKEL, HE SAID IT WAS FINE AND ESSURE HAD VERY MINIMAL AMOUNT OF NICKEL. I SUFFER DAILY WITH HEAVY BLEEDING FILLING PADS AND TAMPONS WITH STILL LEAKING ON MY CLOTHES AND CRAMPS SO SEVERE THAT I CAN'T FUNCTION. I HAVE BEEN DIAGNOSED WITH MIGRAINES IN 2009.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042393	BAYER	4/24/2015	5/1/2015

Event Information:

Event Date (B3): 4/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/23/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN (B)(6) 2013. SINCE THAT TIME I HAVE HAD ONGOING MEDICAL ISSUES. PAIN IN MY ABDOMEN, CYSTS ON ALL DIFFERENT BODY PARTS THAT I NEVER HAD BEFORE, I HAVE HAD FIBROIDS REMOVED FROM MY UTERUS AND CHECKED TO SEE IF THEY ARE CANCEROUS. I HAVE WEIGHT GAIN THAT I CAN'T GET RID OF, I HAVE RANDOM, HEAVY BLEEDING WITH HUGE CLOTS AND BLEEDING EVERYWHERE. I AM CONSTANTLY LIVING MY LIFE AROUND THE EFFECTS OF THIS ESSURE PRODUCT. ALL OF THIS WAS NEVER A PROBLEM BEFORE ESSURE. I WAS HEALTHY AND VERY ACTIVE. ALL OF THAT HAS CHANGED. I HAD TO ADJUST MY LIFE BECAUSE OF ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042374	BAYER	4/25/2015	4/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/8/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY WIFE HAS ESSURE; SHE HAD IT SINCE (B)(6) 2013. SHE HAS BEEN HAVING A LOT OF MEDICAL ISSUES SINCE. EVERY TIME I HAVE HAD INTERCOURSE WITH HER WHICH IS NOT OFTEN DUE TO HER PAINS, I HAVE CUTS ON MY PENIS, SWELLING, REDNESS, AND PAIN THAT LASTS FOR A WEEK. THIS ONLY HAPPENS EVERY TIME WE HAVE INTERCOURSE TOGETHER SAME RESPONSE EVERY TIME!! THIS IS NOT NORMAL; SOMETHING IS WRONG WITH THIS PRODUCT IS AFFECTING ME AS WELL. THIS ESSURE NEEDS TO BE REMOVED FROM THE MARKET!!! THIS ISN'T NORMAL!!! THIS ALL STARTED 6 MONTHS AGO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042365	BAYER	4/25/2015	5/1/2015

Event Information:

Event Date (B3): 4/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/25/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL INSERTED IN 2009. SINCE THEN I HAVE EXPERIENCED PAINFUL AND HEAVY PERIODS, EXTREME SWELLING OF BY ABDOMEN, DAILY MIGRAINES, NUMBNESS IN MY FINGERS, SWELLING IN MY LEGS, MENTAL FOG AND MEMORY ISSUES, JOINT PAIN, FATIGUE AND SEVERE PAIN IN MY LEFT LOWER ABDOMEN AND BACK. I HAVE NOW BEEN DIAGNOSED WITH SEVERE ENDOMETRIOSIS WHICH HAS DEVIATED MY UTERUS WAY OVER TO THE LEFT AND TRAPPED MY LEFT OVARY UNDER IT. MY LEFT COIL IS IN MY UTERUS AND MY RIGHT COIL IS OUT OF PLACE AS WELL. I WILL NOW HAVE TO HAVE A COMPLETE HYSTERECTOMY AT THE AGE OF (B)(6)! MY GYNECOLOGIST SAYS I'LL BE LUCKY TO GET TO KEEP MY RIGHT OVARY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042367	BAYER	4/25/2015	5/1/2015

Event Information:

Event Date (B3): 1/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WITH ESSURE MY PERIODS HAVE STOPPED AND I HAVE GAINED A LOT OF WEIGHT AND CRAMPING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042368	BAYER	4/25/2015	5/1/2015

Event Information:

Event Date (B3): 5/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71766

Single Use:
Implant Date (E6): 2/14/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DURING HSG TESTING, ESSURE WAS FOUND TO BE TOO FAR INTO THE FALLOPIAN TUBES AND THE PROXIMAL END MARKER ON THE LEFT COIL APPEARS BROKEN OR SEPARATED FROM INNER COIL. ASSOCIATED PAIN WAS RESULTED IN THE LOCALIZED AREA. SINCE INSERTION, MENSTRUAL CYCLE HAS CONSISTED OF HEAVY BLEEDING WITH HEMORRHAGING, SOFT BALL-SIZED BLOOD CLOTS AND PERIODS LASTING UP TO FOURTEEN DAYS. OVULATION ALSO CAUSES EXTREME LOWER BACK AND ABDOMINAL PAIN. INSERTION WAS PERFORMED ON (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042369	BAYER	4/25/2015	5/1/2015

Event Information:

Event Date (B3): 4/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/8/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042370	BAYER	4/25/2015	5/1/2015

Event Information:

Event Date (B3): 4/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY DOCTOR PLACED ESSURE (B)(6) 2012. I WENT THREE MONTHS LATER AND HAD TEST TO CONCLUDE BLOCKAGE. I IMMEDIATELY HAD UNEXPLAINED WEIGHT GAIN, RASHES, HAIR LOSS, PAIN, BLOATING. A YEAR LATER HAD SEVERE NON STOP PAIN, DEBILITATING CHRONIC FATIGUE AND PAIN ON A DAILY BASIS. (B)(6) OF 2013 I WAS ELECTROCUTED AND THE ESSURE COILS KEPT THE CURRENT INSIDE OF ME INSTEAD OF IT LEAVING. I WAS IN THE HOSPITAL FOR SEVERAL DAYS RECOVERING FROM BURNS. I HAD CONTINUED PAIN. I WAS DIAGNOSED AT (B)(6) WITH FIBROMYALGIA AND CHRONIC FATIGUE SYNDROME. TWENTY TWO EMERGENCY ROOM VISITS LATER A DOCTOR LISTENED TO ME. I HAD A BILATERAL SALPINGECTOMY TO REMOVE TUBES AND COILS. LEFT COIL INTACT IN FALLOPIAN TUBE, RIGHT SIDE HAD PERFORATION. ALSO MY TUBES WERE NECROTIC AND BLACK FROM THE ALLERGIC REACTION TO THE NICKEL. I RECOVERED FROM THAT EMERGENCY SURGERY TO HAVE A SECOND TWO MONTHS LATER. HYSTERECTOMY BY EMERGENCY SURGERY TO REMOVE AN OVER SIZED UTERUS. PATHOLOGY REPORT STATED ADENOMYOSIS AND NECROSIS OF UTERUS. I JUST HAD AN APPENDECTOMY RULED SUSPICIOUS BC MY APPENDIX WAS HUGELY ENLARGED BUT NO INFECTION? MY DOCTOR SEEMS TO BELIEVE IT WAS CAUSED BY STRAY PET FIBERS FROM THE ESSURE DEVICES. ALL SURGERIES WERE EMERGENCY... NO TIME TO PREPARE AND I ALMOST LOST LIFE ON THE OPERATING TABLE DURING MY SECOND SURGERY. I WAS ADMITTED FOR 16 DAYS DUE TO COMPLICATIONS AND SIDE EFFECTS OF ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042384	BAYER	4/25/2015	5/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MANY SIDE EFFECTS INCLUDING: BLOATING, CRAMPING, HEADACHES, PAINFUL PERIODS, INCONTINENCE, GAS, WEIGHT GAIN, VISION CHANGES, EXTREMELY HEAVY MENSTRUATION, EXCESSIVE BLOOD CLOTS DURING MENSTRUATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042386	BAYER	4/25/2015	5/1/2015

Event Information:

Event Date (B3): 4/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/22/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAD THIS PROCEDURE DONE I'VE HAD SEVERE, CRAMPING, BLOATING, MUSCLE SPASMS, SEVERE MIGRAINES DUE TO PAIN AND HIGH BLOOD PRESSURE EVERYDAY, EXCRUCIATING JOINT PAIN THAT I BARELY CAN TAKE, WEAKNESS, LIGHTHEADED, FAINT SPELLS THAT MY HUSBAND HAD TO LIE ME DOWN, SEVERE FATIGUE, HIP PAIN, WEIGHT GAIN, HAIR LOSS, BLURRED VISION, FEELS LIKE I'M BEING STABBED IN MY BODY. AND I BLEED SO HEAVY WHERE IT'S TO THE POINT WHERE I WAS SOAKING A PAD HALF AND HOUR. I NEVER HAD THESE PROBLEMS UNTIL I HAD THE ESSURE PLACED IN; HIGH BP NONE OF IT. YOU ALL NEED TO TAKE THIS THING OFF THE MARKET. PEOPLE ARE HAVING SO MANY COMPLICATIONS DUE TO THIS PROCEDURE AND I HAVE BEEN MISERABLE ALMOST 3 WEEKS TO A MONTH AFTER IT HAS BEEN PLACED IN. I GO INTO IT WITH MY PRIMARY PHYSICIAN BECAUSE I WAS EXPLAINING MY HURT, PAIN, AND CONCERN WITH THIS AND SHE HAS IGNORED ME. SO I'M PRAYING THAT Y'ALL TAKE MY STATEMENT INTO CONSIDERATION BECAUSE IT'S SERIOUS AND I'M ONE PERSON THAT DOESN'T PLAY ABOUT MY HEALTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042388	BAYER	4/25/2015	5/1/2015

Event Information:

Event Date (B3): 4/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE PUT IN MY TUBES IN 2003 AND HAVE HAD SEVERAL ISSUES SINCE. I HAVE SHARP PAINS COME AND GO. THE WORST IS WHEN I HAVE MY PERIOD. NOTHING SEEMS TO EASE IT. I'VE NEVER HAD ANY PROBLEMS WITH CYSTS AND I HAD TO HAVE 12 GOLF BALL SIZED CYSTS REMOVED FROM MY OVARIES. WHEN I ASKED MY DOCTOR TO REMOVE THE ESSURE HE REFUSED TO BECAUSE I WAS TOO YOUNG. THEY WERE NOT GOING IN THE DIRECTION THEY ARE SUPPOSED TO INSTEAD THEY WERE PUSHING AGAINST MY TUBES. MY PERIODS ARE ONLY A DAY LONG AND MY DOCTOR PERFORATED MY OVARIES TO MAKE MY PERIODS LONGER. I HAVE PUT ON SO MUCH WEIGHT WITH THEM AND IT'S EXTREMELY HARD TO LOSE THE WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042389	BAYER	4/25/2015	5/1/2015

Event Information:

Event Date (B3): 4/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 5/16/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED 3 YEARS AGO. SINCE THEN I HAVE SUFFERED EXTREME PELVIC PAIN, CHRONIC FATIGUE, PAIN RADIATING DOWN MY BACK AND LEGS, STABBING PAINS IN LOWER BACK. MY QUALITY OF LIFE HAS BEEN EFFECTED. I CAN BARELY STAND UP STRAIGHT WITHOUT EXCRUCIATING PAIN, I CAN HARDLY EXERCISE DUE TO THE PAIN IN MY LEGS. WHEN MY PERIOD COMES I'M PRETTY MUCH BEDRIDDEN. THE ESSURE IMPLANT IS RUINING SO MANY WOMENS LIVES AND THEIR HEALTH. THIS NEEDS TO BE ILLEGAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042395	BAYER	4/26/2015	5/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 12/5/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL DEVICE IMPLANTED IN 2007. I STARTED HAVING ADVERSE REACTIONS SOON AFTER, INCLUDING LOW BACK PAIN, BOWEL ISSUES INCLUDING DIARRHEA, LOSS OF BLADDER FUNCTION, SEVERE ABDOMINAL PAINS THAT LASTED OVER MONTHS. FINALLY, IN (B)(6) 2014, I WAS ADMITTED TO THE HOSPITAL AFTER 3 EMERGENCY ROOM VISITS IN 10 DAYS WHERE MY OBGYN DID A LAPAROSCOPIC BILATERAL SALPINGECTOMY BECAUSE THE ESSURE COIL ON THE RIGHT SIDE HAD PERFORATED MY FALLOPIAN TUBE AND WAS STUCK TO MY COLON.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00273	BAYER HEALTHCARE LLC	4/27/2015	4/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/1/2012
Explant Date (E7): 8/19/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 23-JAN-2015 WHICH REFERS TO AN ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN REPORTED THAT HE HAS A PATIENT WHO IS HAVING HER ESSURE REMOVED DUE TO BLEEDING. THE APPOINTMENT IS NOT SCHEDULED YET BUT IT IS SUPPOSED TO BE NEXT WEEK. HEALTH CARE PROFESSIONAL DOES NOT KNOW THE AMOUNT OF BLEEDING OR WHEN IT STARTED OR ANY OTHER INFORMATION. IN ADDITION PHYSICIAN INFORMED THAT ESSURE WAS PLACED AT ANOTHER OFFICE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 05-FEB-2015: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ESSURE GENERAL QUESTIONNAIRE RECEIVED FROM PHYSICIAN ON 30-MAR-2015: CASE UPGRADED TO INCIDENT. PATIENT'S

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DEMOGRAPHIC DATA UPDATED. NO PREVIOUS GYNECOLOGICAL INTERVENTIONS (CERVICAL CONIZATION, CURETTAGE, PREVIOUS IUS/IUD, MYOMECTOMY AND ADNEXAL SURGERY). NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. IN (B)(6) 2012 ESSURE WAS INSERTED BY ANOTHER PHYSICIAN AND THE INSERTION DETAILS WERE UNKNOWN. IN 2012, AN HSG WAS PERFORMED BUT RESULTS WERE NOT PROVIDED. IN (B)(6) 2013 A PELVIC ULTRASOUND WAS PERFORMED AND SHOWED TUBAL OCCLUSION DEVICE ON THE RIGHT PREVIOUSLY ON THE LEFT NOW ABSENT ON HSG (HYSTEROSALPINGOGRAM). ON (B)(6) 2013 THE PHYSICIAN REMOVED THE ESSURE FROM L/S LEFT SIDE (PERFORATION) BY GYNECOLOGICAL LAPAROSCOPY (OUTPATIENT) AND THE PATHOLOGY RESULTS INFLAMMATION WAS NEGATIVE. THE PATIENT REQUESTED TO REMOVE ESSURE DUE TO PAIN. NEITHER HYSTERECTOMY NOR SALPINGECTOMY WAS NECESSARY. PATIENT HAD A GOOD OUTCOME AND RECOVERED FROM THE EVENTS AFTER ESSURE REMOVAL. PHYSICIAN CONSIDERED THE FALLOPIAN TUBE PERFORATION AS RELATED TO ESSURE. FOLLOW-UP RECEIVED ON 02-APR-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERFORATED LEFT TUBE AND BLEEDING. THE FALLOPIAN TUBE PERFORATION IS SERIOUS DUE TO REQUIRED INTERVENTION AND BLEEDING, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, BOTH EVENTS ARE LISTED. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. IN THIS PARTICULAR CASE, AFTER AN UNSPECIFIED PERIOD, AN HSG AND RESULTS SHOWED BILATERAL TUBAL OCCLUSION. AFTER 1 YEAR AND 2 MONTHS A PELVIC ULTRASOUND WAS PERFORMED AND SHOWED TUBAL OCCLUSION DEVICE ON THE RIGHT. IN A SECOND HSG, RIGHT TUBAL OCCLUSION ON RIGHT SIDE AND TUBAL OCCLUSION ON LEFT SIDE WAS ABSENT. CONSIDERING THE NATURE OF THIS EVENT AND POSITIVE TEMPORAL RELATIONSHIP, THE PERFORATION IS RELATED TO ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. THE REPORTER DID NOT KNOW THE AMOUNT OF BLEEDING OR WHEN IT STARTED OR ANY OTHER INFORMATION. GIVEN THE AVAILABLE INFORMATION AND EVENT'S NATURE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED SURGICAL INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED (PERFORATION QUESTIONNAIRE).

Manufacturer Narrative (H10):

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FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EX

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00274	BAYER HEALTHCARE LLC	4/27/2015	4/27/2015

Event Information:

Event Date (B3): 1/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/4/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT, UNANTICIPATED (SERIOUS INJURY: HOSPITALIZATION AND REQUIRED INTERVENTION). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY IN THE UNITED STATES, ON BEHALF OF AN ADULT (>=18Y & <65Y) FEMALE CONSUMER IN UNITED STATES ON 30-MAR-2015, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. THIS IS A POTENTIAL LEGAL CASE. THE ESSURE DEVICE WAS ATTEMPTED TO BE PLACED IN THE CONSUMER'S FALLOPIAN TUBE. AS THE DEVICE WAS BEING PLACED, IT BROKE CAUSING HER DAMAGES. SHE SUFFERED SEVERE AND SERIOUS INJURIES AND DAMAGES. THE CONSUMER SUFFERED A HYSTERECTOMY, A GALLBLADDER REMOVAL AND OTHER SERIOUS AND SEVERE MEDICAL ISSUES. SHE HAD SUFFERED A GREAT PAIN AND MENTAL ANGUISH. ALSO, HER GENERAL HEALTH, STRENGTH AND VITALITY HAD BEEN IMPAIRED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS AND POTENTIAL LEGAL CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT DEVICE BROKE CAUSING HER DAMAGES / A PORTION OF THE ESSURE COIL TO BECOME DETACHED INTO THE TUBE. THIS EVENT IS SERIOUS DUE TO HOSPITALIZATION AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE CONSUMER WAS HOSPITALIZED AND SHE UNDERWENT A HYSTERECTOMY. ADDITIONALLY, OTHER SERIOUS EVENT GALLBLADDER REMOVAL AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-APR-2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00275	BAYER HEALTHCARE LLC	4/27/2015	4/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/13/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR STERILIZATION. THE HCP (HEALTH CARE PROFESSIONAL) REPORTED A DIFFICULT INSERTION DUE TO THE ANGLE OF THE TUBES. ON AN UNSPECIFIED DATE WHEN THE PATIENT WENT TO DO THE HSG (HYSTEROSALPINGOGRAM), THERE HAD BEEN A PERFORATION ON BOTH SIDES AND BOTH SIDES WERE IN THE MYOMETRIUM. THE PATIENT ENDED UP GETTING A SALPINGECTOMY (DATE NOT PROVIDED). SHE HAD NO PAIN IN THE MYOMETRIUM SO THE DEVICES WERE LEFT WHERE THEY WERE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT

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CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED A PERFORATION ON BOTH SIDES (BOTH SIDES WERE IN THE MYOMETRIUM). THIS EVENT, INTERPRETED AS UTERINE PERFORATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SALPINGECTOMY WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 16-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATI

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042318	BAYER	4/27/2015	4/27/2015

Event Information:

Event Date (B3): 4/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HEREDITARY SPHEROCYTOSIS THAT MADE ME HAVE A SPLENECTOMY AT THE AGE OF 6. ALWAYS WITH BLOOD ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042319	BAYER	4/27/2015	4/27/2015

Event Information:

Event Date (B3): 2/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEEN NOTICING THROUGHOUT THE MONTHS ABOUT MY SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00413	BAYER HEALTHCARE LLC	4/27/2015	6/22/2015

Event Information:

Event Date (B3): 4/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/16/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE PATIENT EXPERIENCED NICKEL ALLERGY. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2015 FROM THE PHYSICIAN (UPGRADED TO INCIDENT). PATIENT'S DATE OF BIRTH WAS PROVIDED. THIS REPORT REFERS TO A (B)(6) YEARS OLD FEMALE PATIENT. ON (B)(6) 2015 ESSURE WAS INSERTED. ON (B)(6)

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2015 SHE EXPERIENCED NICKEL ALLERGY AND WAS ADMITTED TO EMERGENCY ROOM. RE-OPERATED ON (B)(6) 2015. SHE WAS FEELING WELL. SHE WAS WAITING FOR ALLERGY TEST. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP FROM (B)(6) 2015: PTC RESULT WAS UPDATED. NO MAJOR CHANGES IN PREVIOUS ASSESSMENT. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL ALLERGY ALMOST A MONTH LATER, SHE WAS RE-OPERATED AND WAS FEELING WELL. NICKEL ALLERGY IS NOW CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS EVENT IS LISTED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE PATIENT EXPERIENCED THE ALLERGY APPROXIMATELY A MONTH AFTER INSERTION AND WAS RE-OPERATED. CONSIDERING THAT ESSURE IS A NICKEL-TITANIUM ALLOY AND CONSIDERING ALSO THE POSITIVE TEMPORAL RELATIONSHIP, THE NICKEL ALLERGY IS CONSIDERED RELATED TO ESSURE. THE CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PERFORMED PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO ADDITIONAL INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(4) FEMALE PATIENT W

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00447	BAYER HEALTHCARE LLC	4/28/2015	7/2/2015

Event Information:

Event Date (B3): 10/14/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/14/2008
Explant Date (E7): 10/24/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2008 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2008 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). PATIENT DENIED ANY MEDICAL HISTORY AND HAD NO CHILDREN. MEDICATION AT TIME OF INSERTION INCLUDED COMBINED PILL. HER LAST MENSTRUAL PERIOD BEFORE INSERTION OCCURRED ON (B)(6) 2008. SHE WAS NOT PREGNANT (BETA HCG WAS NEGATIVE). ON (B)(6) 2008 THE PATIENT HAD ESSURE 305 (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT STERILIZATION. BENZODIAZEPINE WAS USED AS PREMEDICATION AND IV SEDATION AS ADDITIONAL ANESTHESIA. UTERINE CAVITY WAS WITHIN NORMAL CONDITIONS. HER UTERUS WAS RETROVERTED. VISUALIZATION OF OSTIUM WAS GOOD BILATERALLY. THE PROCEDURE WAS STARTED ON LEFT SIDE. IT WAS EASY TO INTRODUCE THE CATHETER INTO THE TUBES. THE PHYSICIAN USED 2 INSERTS. THE PROCEDURE TOOK 5 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. AT THE END OF PROCEDURE SHE HAD 4 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 3 COILS ON RIGHT SIDE. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. THE PATIENT WAS VERY SATISFIED WITH THE PROCEDURE AND NO ADDITIONAL PROCEDURE WAS PERFORMED AT THE SAME TIME. PATIENT PRESENTED PAIN DURING INSERTION AND AFTER THE PROCEDURE. INVESTIGATOR HAD IMPRESSION OF PERFORATION ON LEFT SIDE DURING PLACEMENT. HYSTEROSALPINGOGRAPHY WAS ASKED FOR CONTROL.

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ON (B)(6) 2008 IMPLANTS WERE WITHDRAWN DUE TO PERFORATION ON THE LEFT SIDE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 2(B)(4) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: UTERINE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 145 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE SUBJECT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY (STUDY NUMBER: (B)(6)). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERFORATION ON THE LEFT REQUIRING IMPLANT REMOVAL. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, INVESTIGATOR HAD IMPRESSION OF PERFORATION ON LEFT SIDE DURING ESSURE PLACEMENT. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT/INSERTION PROCEDURE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED FOR DEVICES REMOVAL, THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 02-APR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00276	BAYER HEALTHCARE LLC	4/29/2015	4/29/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015. IT DESCRIBES THE OCCURRENCE OF ECTOPIC PREGNANCY IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN REPORTED THAT PATIENT HAD ESSURE PLACED BY A DIFFERENT PHYSICIAN ONE YEAR AGO, IN 2014, AND WAS SEEN APPROXIMATELY 2 MONTHS AGO, (B)(6) 2015, FOR AN ECTOPIC PREGNANCY, AND HAD SURGERY. THE PATIENT HAD AN HSG (HYSTEROSALPINGOGRAM) RECENTLY (DATE NOT REPORTED), AND THE REPORT STATED THAT THE DEVICE WAS EXTRA LUMINAL, PARALLEL ALONG THE TUBE. THE PATIENT HAD ECTOPIC PREGNANCY AND TUBE WAS REMOVED ON THAT SIDE. SOME COIL LEFT IN MYOMETRIUM (SHOWED 1 MARKER ON HSG). OTHER SIDE INSERT WAS OUTSIDE OF THE FALLOPIAN TUBE. PATIENT WAS ASYMPTOMATIC AND DID NOT HAVE COMPLAINTS OR ADVERSE EVENTS. THE DOCTOR WOULD LIKE TO KNOW IF SHE SHOULD REMOVE THE PERFORATED INSERT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR

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COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ECTOPIC PREGNANCY AND AFTER TUBE REMOVAL SOME COIL WAS LEFT IN MYOMETRIUM. ON THE OTHER SIDE, THE DEVICE WAS EXTRA LUMINAL, PARALLEL ALONG THE TUBE. EVENTS ECTOPIC PREGNANCY AND DEVICE EXTRA LUMINAL, PARALLEL ALONG THE TUBE, INTERPRETED AS UTERINE PERFORATION, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND THE COIL LEFT IN MYOMETRIUM AFTER TUBE REMOVAL, INTERPRETED AS DEVICE BREAKAGE, IS CONSIDERED NON-SERIOUS. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THIS PARTICULAR CASE, IT IS NOT CLEAR IF THE PERFORATION OCCURRED DURING INSERTION OR AFTERWARDS. HOWEVER, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, IT WAS CONSIDERED RELATED TO ESSURE PROCEDURE. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. IN THE PRESENT CASE, THE ECTOPIC PREGNANCY OCCURRED APPROXIMATELY ONE YEAR AFTER ESSURE INSERTION. ALTHOUGH A PERFORATION WAS MENTIONED ON THE OPPOSITE SIDE, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED (DEVICE INEFFECTIVE). SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THE PRESENT CASE, IT IS NOT CLEAR WHEN THE BREAKAGE OCCURRED, NEVERTHELESS CONSIDERING THE NATURE OF THIS EVENT AND LACK OF ALTERNATIVE EXPLANATION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION (PERFORATION QUESTIONNAIRE) IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED FROM THE PHYSICIAN VIA HEALTH AUTHORITY (FDA MAUDE #MW5041901) ON 22-JUN-2015: PHYSICIAN REPORTED THAT ESSURE DEVICE WAS PLACED 6 MONTHS POSTPARTUM AT OUTSIDE FACILITY. INITIAL HSG AT 3 MONTHS SHOWED UNILATERAL TUBAL OCCLUSI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00277	BAYER HEALTHCARE LLC	4/29/2015	4/29/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2010
Explant Date (E7): 3/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (LOT NUMBER NOT PROVIDED). CONSUMER REPORTED THAT SHE HAD ESSURE PLACED 4 YEARS AGO, IN 2011. SHE WANTED TO REPORT WHAT HAPPENED TO HER WHILE SHE HAD ESSURE. AT FIRST SHE DID NOT HAVE ANY ISSUES, BUT THEN SINCE INSERTION SHE WAS NAUSEATED, FATIGUED, HAD A METALLIC TASTE AND HAD MIGRAINES. LAST YEAR, IN 2014, SHE EXPERIENCED SEVERAL BLADDER INFECTIONS, AND WHEN SHE HAD INTERCOURSE IT WAS PAINFUL, AND IT "TOOK A TOLL ON HER BODY". IN (B)(6) 2014, SHE WAS HOSPITALIZED WITH A KIDNEY INFECTION. SHORTLY AFTER THAT, SHE WAS HOSPITALIZED BECAUSE HER SUGAR GOT SO HIGH AND PANCREAS STOPPED WORKING, AND WAS DIAGNOSED WITH DIABETES AND PLACED ON INSULIN. CONSUMER STATED SHE HAS READ THAT ESSURE COULD DAMAGE THE PANCREAS. IN (B)(6) 2015, IT WAS DISCOVERED THE ESSURE HAD MOVED AND WAS OUT OF PLACE. SHE HAD SURGERY ON (B)(6) 2015 TO REMOVE THE ESSURE, AND SHE WAS NOT NAUSEOUS ANYMORE, AND FELT HER BODY WAS BETTER. SHE STATED THAT SHE WAS HEALING SLOWLY, DUE TO HER DIABETES. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE

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HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE ESSURE HAD MOVED AND WAS OUT OF PLACE, SHE HAD SEVERAL BLADDER INFECTIONS, KIDNEY INFECTION, WAS DIAGNOSED WITH DIABETES, AND HER PANCREAS STOPPED WORKING. EVENTS THE ESSURE HAD MOVED AND WAS OUT OF PLACE AND SEVERAL BLADDER INFECTIONS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE WHILE THE REMAINING EVENTS WERE CONSIDERED SERIOUS DUE TO HOSPITALIZATION. EVENT THE ESSURE HAD MOVED AND WAS OUT OF PLACE, INTERPRETED AS DEVICE DISLOCATION, IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENTS ARE UNLISTED. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, THE EXACT POSITION OF THE DEVICE WAS NOT INFORMED, HOWEVER GIVEN THE NATURE OF THE EVENT ESSURE HAD MOVED AND WAS OUT OF PLACE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THE OTHER SERIOUS EVENTS WERE CONSIDERED UNRELATED TO ESSURE DUE TO THEIR NATURE. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REPORTED INTERVENTION (SURGERY TO REMOVE ESSURE). ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 22-JUN-2015: INFORMATION RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5041869) STATES THAT SHE HAD ESSURE PROCEDURE ON (B)(6) 2010 (ABOUT 4 YEARS AGO) FOR BIRTH CONTROL. SHE DIDN'T HAVE PROBLEMS AT FIRST, UNTIL SHE STARTE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00278	BAYER HEALTHCARE LLC	4/29/2015	4/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS WERE REPORTED). CONSUMER STATED THAT SHE JUST HAD HER ESSURE REMOVED AND THE HCP (HEALTH CARE PROFESSIONAL) SAID THAT THERE WAS STILL SOME STAINLESS STEEL IN HER. CONSUMER ASKED WHAT METALS ARE IN ESSURE. THE PHONES CONNECTION ABRUPTLY DISCONNECTED BEFORE GETTING CONTACT INFORMATION. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE REMOVAL. THE AE CASE REFERS TO USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL

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EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED AND THERE WAS STILL SOME STAINLESS STEEL IN HER (REGARDED AS DEVICE BREAKAGE). ALL EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. THEY ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION (ESSURE REMOVAL) AND PRODUCT TECHNICAL (PTC) ANALYSIS RESULTS (DEVICE BREAKAGE). SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; CONSUMER STATED ESSURE WAS REMOVED AND A PIECE OF IT REMAINED IN SITU. GIVEN THE NATURE OF THE REPORTED EVENTS AND IN THE LACK OF ALTERNATIVE EXPLANATION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION FOR ESSURE REMOVAL. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW-UP WILL BE PURSUED SINCE NO CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042359	BAYER	4/29/2015	4/29/2015

Event Information:

Event Date (B3): 3/15/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AUTO IMMUNE TISSUE TESTING CAME BACK POSITIVE FOR OVARIES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042360	BAYER	4/29/2015	4/29/2015

Event Information:

Event Date (B3): 3/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5042360 #(B)(4). I HAD A XRAY DONE ON (B)(6) 2015 SHOWING MY RIGHT SIDE COIL IS SHAPED LIKE A C I WENT INTO A HOSPITAL AFTER HAVING SEVERE RIGHT PELVIC PAIN WHEN THE COMPLETED A ULTRASOUND STATING THEY COULD NOT LOCATE MY RIGHT SIDE COIL. I NOW NOT ONLY HAVE ALL OF THESE SIDE EFFECTS BUT NOW A HAVE COIL THAT IS FLOATING AROUND INSIDE ME SOMEWHERE THEY DOCTORS CAN NOT FIND!!!! BAN THIS ASAP!!!!!!!!!!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042361	BAYER	4/29/2015	4/29/2015

Event Information:

Event Date (B3): 10/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (B)(6) I HAD ESSURE PUT IN. IT PERFORATED MY UTERUS. FIFTY THREE DAYS OF HEMORRHAGING. EXTREME LOWER BACK ACHE. CRAMPING AND NAUSEA AND NOW HYSTERECTOMY FOR (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042362	BAYER	4/29/2015	4/29/2015

Event Information:

Event Date (B3): 7/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY HEAVY BLEEDING AND CLOTTING FOR 2 DAYS BEFORE I WAS SEEN IN THE ER. HAVE BEEN SUFFERING WITH MIGRAINES (ALMOST DAILY), PAIN IN MY HIP AND KNEE JOINTS, EXTREME NAUSEA SOMETIMES LASTING FOR DAYS, AND MOOD SWINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042363	BAYER	4/29/2015	4/29/2015

Event Information:

Event Date (B3): 10/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). (B)(6) I HAD ESSURE PUT IN. IT PERFORATED MY UTERUS. 53 DAYS OF HEMMORHAGING, EXTREME LOWER BACK ACHE, CRAMPING AND NAUSEA AND NOW HYSTERECTOMY FOR (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00279	BAYER HEALTHCARE LLC	4/30/2015	4/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/12/2009
Explant Date (E7): 3/31/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009 FOR CONTRACEPTION (LOT NUMBER NOT PROVIDED). CONSUMER REPORTED THAT IN THE NEXT 2-3 YEARS AFTER ESSURE INSERTION SHE HAD CRIPPLING ARTHRITIC PAIN ALL OVER, IT TRAVELED ALL AROUND HER BODY. SHE CONTACTED A METAL TESTING COMPANY AND WAS TOLD THAT SOME OF THE SYMPTOMS OF TITANIUM ALLERGIES WERE ARTHRITIC PAINS. SHE HAD TO HAVE HER ESSURE REMOVED ON (B)(6) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE AND IS CONSIDERED UNRELATED BY THE COMPANY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015 FROM CONSUMER: SHE STATED THAT ESSURE WAS INSERTED ON (B)(6) 2009 FOR STERILIZATION AND REMOVED ON (B)(6) 2015. DURING CONSULTATION AT TIME OF THE INSERTION PROCEDURE, THE PATIENT HAD NEGATIVE PAP HPV AND WAS ON BIRTH CONTROL PILLS. SHE WAS NOT PREGNANT; SHE WAS GRAVIDA 3 AND PARA 2, HER LAST NSVD (INTERPRETED AS NORMAL SPONTANEOUS VAGINAL DELIVERY) WAS IN (B)(6) 2008. THE CONSUMER DENIED ALLERGY TO SHELLFISH, IODINE, NICKEL OR IVP (INTERPRETED AS INTRAVENOUS PYELOGRAM) DYE; SHE HAD NO CONTRAINDICATIONS TO THE PROCEDURE. TORADOL, VALIUM AND MOTRIN WERE USED AS PREMEDICATION; PARACERVICAL BLOCK WAS APPLIED DURING THE PROCEDURE. APPROXIMATELY 2 YEARS AFTER INSERTION SHE LOST HER SENSE OF SMELL ALMOST COMPLETELY. HER PHYSICIAN COULD NOT FIND A KNOWN CAUSE FOR THIS AFTER RUNNING A CT SCAN, MRI AND VISITED HER NEUROLOGIST AND ENT SPECIALIST. SOON AFTER THE LOSS OF HER SENSE OF SMELL SHE STARTED HAVING JOINT PAINS IN BOTH ARMS AND NECK. THIS ARTHRITIC LIKE PAINS BECAME SO SEVERE AND TRAVELED FROM JOINT TO JOINT THAT SHE HAD EXTREME TROUBLE CARING HER CHILDREN AND PERFORMING DUTIES AT WORK. SHE ALSO HAD GENERAL FATIGUE AND HARD TIME SLEEPING; SHE FELT LIKE WAS BEING SLOWLY POISONED. CONSUMER MENTIONED THAT HER PHYSICIAN REMOVED ALMOST THE ENTIRE ESSURE DEVICE MINUS A SMALL AMOUNT OF STAINLESS STEEL THAT HE COULD NOT FIND. IN HER MEDICAL RECORDS IT WAS MENTIONED THAT THE PORTION OF THE TUBE CONTAINING THE DEVICE WAS DISSECTED AT THE JUNCTION OF THE MESOSALPINX AND THE TUBE PROCEEDING MEDIALLY. THE CENTER CORE OF THE ESSURE WAS REMOVED AND THEN THE OUTER SPRING. THE MEDIAL PORTION OF THE FALLOPIAN TUBE WAS LIGATED AND BURIED IN THE MESOSALPINX. THE HYSTERECTOMY WAS CLOSED WITH EIGHT SUTURES. HER BLOOD LOSS WAS NEGLIGIBLE, THE PATIENT AWOKE AND WENT TO THE RECOVERY ROOM IN GOOD CONDITION. THE OPERATION TIME WAS ONE HOUR AND 5 MINUTES. WITHIN 24 HOURS AFTER THE REMOVAL HER CHRONIC ARTHRITIC LIKE PAIN WAS MUCH IMPROVED AND REMAINED MUCH IMPROVED AT TIME OF THE REPORT. SHE REPORTED THAT SHE ONLY HAS RESIDUAL EFFECTS LIKE STIFFNESS; HER SENSE OF SMELL HAS NOT RETURNED SO FAR. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IN THE NEXT 2-3 YEARS AFTER ESSURE INSERTION SHE HAD CRIPPLING ARTHRITIC PAIN ALL OVER / JOINT PAINS IN BOTH ARMS AND NECK (INTERPRETED AS POLYARTHRITIS). SHE HAD TO HAVE HER ESSURE REMOVED. PHYSICIAN REMOVED ALMOST THE ENTIRE ESSURE DEVICE MINUS A SMALL AMOUNT OF STAINLESS STEEL THAT HE COULD NOT FIND (INTERPRETED AS DEVICE BREAKAGE). THE REPORTED EVENT, INTERPRETED AS POLYARTHRITIS, IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND LISTED. ARTHRITIS IS INFLAMMATION OF ONE OR MORE OF YOUR JOINTS. URIC ACID CRYSTALS, INFECTIONS OR UNDERLYING DISEASE, SUCH AS PSORIASIS OR LUPUS, CAN CAUSE SOME TYPES OF ARTHRITIS. ALTHOUGH IT IS NOT EXPECTED THAT ESSURE COULD CONTRIBUTE TO POLYARTHRITIS DEVELOPMENT, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, COMPANY CONSIDERS CAUSALITY WITH THE SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED IN THIS CASE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE REMOVAL, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. FURTHER INFORMATION (PTC UPDATED) IS EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 08-OCT-2015 THIS CASE IS POTENTIAL LEGAL CASE NOW. NEW REPORTERS WERE ADDED. HER ETHNICITY WAS REPORTED AS CAUCASIAN. HER MEDICAL HISTORY INCLUDED 3 PREGNANCIES, 2 PARITIES, ONE ABORTION AND HYPOTHYROIDISM (SHE TOOK LEVOT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00280	BAYER HEALTHCARE LLC	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 4/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71768

Single Use: Y
Implant Date (E6): 4/2/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION (LOT NUMBER B71768). PHYSICIAN REPORTED THAT DURING ROLLBACK OF DEVICE ON LEFT SIDE IT WOULD NOT DEPLOY. HCP TRIED TO REMOVE DEVICE AND IT FELL APART INTO PIECES IN THE PATIENT. HCP WAS NOT ABLE TO RETRIEVE ALL OF THE PIECES FROM PATIENT. ESSURE PLACED IN RIGHT TUBE AND THE PATIENT HAS BEEN CONTINUING WITH THIS ONE. HCP TALKED TO PATIENT ABOUT POSSIBLE LAPAROSCOPIC SURGERY. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE

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INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT B71768 (PRODUCTION DATE (B)(4)2013 AND EXPIRATION DATE (B)(4) 2016) WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DEPLOYMENT DIFFICULTY IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION AND REMOVAL. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(4)-OLD FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING ROLLBACK OF DEVICE ON LEFT SIDE IT WOULD NOT DEPLOY. THE PHYSICIAN TRIED TO REMOVE DEVICE AND IT FELL APART INTO PIECES IN THE PATIENT. THE PHYSICIAN WAS NOT ABLE TO RETRIEVE ALL OF THE PIECES FROM PATIENT. EVENT DEVICE BREAKAGE WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, SINCE THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THE PHYSICIAN MENTIONED A POSSIBLE LAPAROSCOPIC SURGERY. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 29-JUL-2015 THE REQUIRED NUMBERS OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATI

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042379	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 6/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THIS DEVICE, MY HEALTH WENT DOWN HILL. I'M (B)(6) YEARS OLD. I HAVE 3 MINOR CHILDREN. TWO MONTHS AFTER GETTING THIS, I NOTICED PROBLEMS SUCH AS PAINFUL SEX, HORRIBLE PERIODS, TO NOW NO PERIOD AT ALL, HAIR LOSS, TEETH HURTING AND BREAKING OFF, MY JAWS LOCK UP ABOUT 3 TIMES A DAY, GOT KNOTS FORMING DOWN MY BACK, AWFUL PAIN ON LEFT SIDE, CONSTANT PAIN, MY NECK HURTS WHEN I HOLD MY HEAD DOWN, WEIGHT GAIN IS UNREAL BUT MY STOMACH IS SHAPE AS A PREGNANCY STOMACH, I FEEL LIKE SOMETHING'S CRAWLING AND BITING ME FROM HEAD TO TOE; I HAVE A REALLY BAD RASH THAT I'M BROKE OUT WITH; I HAVE NO CLUE OF WHAT IT IS; MY LEGS STAY NUMB; I HAVE A HORRIBLE TASTE IN MY MOUTH AND THE ROOF OF MY MOUTH HAS WHITE STUFF ON IT; TERRIBLE HEARTBURN THAT I CAN'T STOP; MY FACE, HANDS, AND FEET STAY SWOLLEN ALL DAY; I'VE HAD DIARRHEA FOR 4 MONTHS; NOW UNCONTROLLABLE AWFUL MIGRAINES; I HAVE NO ENERGY WHATSOEVER; HURTS TO MOVE MOST DAYS; BY LUNCH TIME, I'M CRYING IN PAIN AND IT'S JUST NOT FAIR; I HAVE 3 BEAUTIFUL KIDS WHO DEPEND ON ME AND NEED ME; I HAVE TO SUCK IT UP AND DO WHAT I HAVE TO DO BUT I DON'T FEEL IT'S FAIR; I'M SUFFERING WITH ALL THESES PAINS AND CAN'T GET HELP. PLEASE UNDERSTAND, I KNOW MY BODY AND SOMETHING IS DEFINITELY WRONG. PLEASE HELP!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042382	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 10/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I ALMOST IMMEDIATELY WENT FROM 2-3 DAY REGULAR LIGHT CYCLES TO DRASTICALLY DIFFERENT PERIODS. THEY WERE 7-8 DAYS VERY HEAVY AND WOULD START WITH A BLACK TAR BLOOD THAT SMELLED HORRIFIC. I ALSO NOTICED IT WAS PAINFUL TO WEAR TAMPONS AND SEX STARTED HURTING. THESE PROBLEMS PERSISTED AND I ALSO HAD UNEXPLAINED ALL OVER RASHES, BREAK OUT WITH SORES ON MY FEMALE PARTS BUTT AND SCALP, HAD A METALLIC TASTE IN MY MOUTH, INCREASED IBS, DRASTIC ACCELERATION OF SPINAL STENOSIS WITH HERNIATED DISC, SCIATIC PAIN AND BACK PAIN NOT RELIEVED WITH 3 SURGERIES, HEADACHES, ANXIETY AND MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042385	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 10/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5042385 #(B)(4). THE ABDONIMAL PAIN IS GETTING WORSE ON A DAILY BASIS. MY BLOOD WORK AND TEST ALWAYS COME BACK NORMAL. I AM SCHEDULE FOR ANOTHER UPPER GI AND COLONOSCOPY ON (B)(6), 2015. I AM HAVING A HARD TIME WORKING BECAUSE OF THE PAIN AND I HAVE FILE BANKRUPTCY WITH THE STATE OF (B)(6) DUE TO ALL MY MEDICAL BILLS. THIS IS EFFECTING MY HOME AND WORK LIKE!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042391	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE. ACNE BRUISES. CRAMPS. HEAVY PERIODS. WEIGHT GAIN. DEPRESSION. MOOD SWINGS. PAIN. BLOATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042396	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 10/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5042396 #(B)(4). I JUST HAD MY HYSTERECTOMY ON (B)(6) AND JUST RECEIVED THE PATHOLOGY REPORT. I DON'T UNDERSTAND ANYTHING ON THIS REPORT BUT WHEN I GO FOR MY FOLLOW UP I WILL FIND OUT WHAT ALL THIS MEANS. ANYWHO, MY HYSTERECTOMY PATHOLOGY REVEALED PRESENCE OF ENDOMETRIOSIS OF THE UTERUS CALLED ADENOMYOSIS. I HAD A ANNUAL PAP BEFORE I HAD ESSURE PLACED AND NEVER HAD ANY MENTION OF ENDOMETRIOSIS, I DIDN'T EVEN KNOW WHAT IT WAS UNTIL I GOT THIS REPORT AND LOOKED IT UP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042399	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 3/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, BLOATING, ALLERGIES, MOOD SWINGS, ANXIETY, ABDOMINAL PAIN, HORRIBLE CRAMPING, LONG HEAVY PERIODS, BLOOD CLOTS, DECAYING OF TEETH, FATIGUE, DIZZINESS, DEPRESSION, HIGH CHOLESTEROL, CONSTANT RASH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042400	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 11/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, GOT PREGNANT, HEADACHES, CELVIX PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042401	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD SIDE PAIN. WEIGHT GAIN. FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042402	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, SHORTNESS OF BREATH, LEG CRAMPS, BLOOD PUSTULES ON LEGS, DIAGNOSED IN (B)(6) WITH SEVERE ANEMIA. WITH CONTINUED TREATMENT, BLOOD COUNTS WILL NOT STAY UP EVEN THOUGH NO BLEEDING IS OCCURING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042403	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 5/26/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN, NAUSEA, ODD PERIODS, HOT FLASHES, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042404	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 4/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THE ESSURE, I FEEL LIKE I HAVE TO PUSH SOMETHING OUT OF MY BODY. I HAVE FATIGUE AND DROWSINESS CONSTANTLY, I CAN TASTE METAL AT TIMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042407	BAYER	4/30/2015	4/30/2015

Event Information:

Event Date (B3): 9/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE VERY HEAVY PERIODS. I HAVE SHARP PAINS IN MY SIDES, RIGHT SIDE MORE OFTEN.. I HAVE UNCOMFORTABLE SEX, IT HURTS SOMETIMES DURING SOMETIMES AFTER.. I LOST A LOT OF HAIR ON MY HEAD. I GET RED SPOTS THAT LOOK LIKE "WEPS" ON MY BODY. I HAVE VERY BAD HEADACHES ALMOST DAILY. I HAVE NEVER HAD PANIC ATTACKS AND I DO NOW. I HAVE LOWER BACK PAIN. NOT SURE BUT MY 10 MONTH OLD BREASTFEEDING FEEDS AND HAS HAD A LOT OF DIAPER RASHES AND HE SAID IT COULD BE CAUSED BY THE MILK, SO I WONDER IF THE MILK HAS NICKEL IN IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042405	BAYER	4/30/2015	5/1/2015

Event Information:

Event Date (B3): 3/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THIS DEVICE WAS IMPLANTED I GAINED 60 LBS. EVEN THOUGH I WASN'T THIN BEFORE, MY BELLY NEVER LOOKED LIKE THIS. I HAVE SOME BLADDER CONTROL ISSUES. MY HAIR USE TO BE SUPER THICK AND NOW IT'S THINNED A LOT. DURING OVULATION MY LOWER SIDE HURTS EVERY MONTH. MORE BLOOD CLOTS DURING PERIODS. ALTHOUGH I USE TO HAVE SOME DANDRUFF PROBLEMS I NOW HAVE MODERATE TO SEVERE PSORIATIC ARTHRITIS. FIBROMYALGIA. I CAN'T DO ANYTHING WITHOUT MY BODY BEING INFLAMED OR IN PAIN FOR DAYS AND I NEVER HAD THAT ISSUE BEFORE. I HAD A FIBROADENOMA REMOVED FROM MY BREAST BUT I DON'T KNOW IF THAT'S RELATED. THIS ALL STARTED IN 2008 AND HAS GOTTEN GRADUALLY WORSE. THE WEIGHT GAIN HAPPENED IN THE FIRST YEAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042406	BAYER	4/30/2015	5/1/2015

Event Information:

Event Date (B3): 4/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT FIRST I THOUGHT THIS WAS A MIRACLE DEVICE WHEN I HAD THE PROCEDURE DONE IN 2009. NOW I BELIEVE IT IS SLOWLY KILLING ME. MY SYMPTOMS THAT I HAVE ONLY HAD SINCE I HAD THE PROCEDURE. EXTREME PAIN IN ABDOMEN. LOCALLY OVER LEFT FALLOPIAN TUBE. PAIN IN BACK AND THIGHS. PAIN IN JOINTS. PERIODS WITH EXTREME PAIN. HEAVY PERIODS WITH CLOTTING LASTING UP TO TWO WEEKS AND SPOTTING REGULARLY. MY HANDS AND FEET GO NUMB CONSTANTLY. TIRED DRAINED NO ENERGY EVER. BLOATED LOOK IN MY STOMACH. MIGRAINES. ANEMIC. VISION ISSUES. MAJOR TEETH ISSUES. PAIN!!!!!!! I ALSO HAVE A LUMP OVER MY LEFT FALLOPIAN TUBE THAT SWELLS ABOUT EVERY 3 MONTHS WHICH CAUSE DEBILITATING PAIN. I HAVE HAD 3 UTI WHICH I HAD NEVER HAD BEFORE. DIZZINESS, LACK OF APPETITE. TROUBLE SLEEPING DUE TO WHEN I SLEEP I GET UNGODLY HOT AND WAKE UP CONSTANTLY SHORT OF BREATH AND SWEATING LIKE I'M RUNNING A FEVER. MY BOYFRIEND SAYS THAT I FEEL LIKE I'M BURNING UP AT NIGHT. I AM A MOTHER OF THREE AND THE PAIN AND LACK OF ENERGY HAS NOT JUST EFFECTED ME BUT EVERYONE. I HOPE THIS INFORMATION WILL STOP SOMEONE FROM GETTING THIS PROCEDURE. AS I HAVE YET TO FIND A DOCTOR WHO TAKES ME SERIOUS OR WHO RELATE THESE ISSUES TO THE ESSURE. I NEED THEM REMOVED BEFORE THEY CAUSE ANY MORE DAMAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042408	BAYER	4/30/2015	5/1/2015

Event Information:

Event Date (B3): 3/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESSIVE BLEEDING AND CLOTTING AND PASSING OF TISSUE . HAIR LOSS, WEIGHT GAIN, HEAD ACHES, BACK PAIN, STABBING PAIN IN RIGHT SIDE, EXTREME FATIGUE, CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042409	BAYER	4/30/2015	5/1/2015

Event Information:

Event Date (B3): 12/6/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD HOT SWEATS, SWELLING, BLOOD CLOTS, DIZZINESS, CHEST PAINS, ANXIETIES, LONG PERIODS, BLOOD IN MY STOOL, FLU LIKE SYMPTOMS, A HARD TIME GETTING OUT OF BED AS WELL VERY SHARP STABBING PAINS IN MY BOTTOM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042410	BAYER	4/30/2015	5/1/2015

Event Information:

Event Date (B3): 12/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, HEADACHES, JOINT PAIN, PAINFUL INTERCOURSE, RASHES ABDOMINAL PAIN CRAMPS BLOATING HAIR LOSS. METALLIC TASTE...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042411	BAYER	4/30/2015	5/1/2015

Event Information:

Event Date (B3): 12/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE PAIN ON MY LEFT SIDE, MIGRAINES, SEVERE BLOATING, HAIR LOSS, PAIN IN MY LEGS AND HURTS WHEN I HAVE SEX. I AM NOW HAVING TO GET A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042412	BAYER	4/30/2015	5/1/2015

Event Information:

Event Date (B3): 4/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, HORRIBLE PERIODS AND CRAMPING, LOSE OF 3 BABIES AND THINK I AM IN EARLY MENOPAUSE AT AGE (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042413	BAYER	4/30/2015	5/1/2015

Event Information:

Event Date (B3): 5/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD ESSURE PLACED, OVER EXPERIENCED WEIGHT GAIN, HAIRLOSS, SWOLLEN LEGS AND FEET, PAINFUL PERIODS, FLUTTERING IN MY STOMACH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042414	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 4/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE WAS IMPLANTED IN 2010, MY THYROID HAS GONE OUT OF CONTROL, HYPOTHYROID. I HAVE CONSTANT LOWER ABDOMEN PAIN. HAD TO HAVE A D AND C 2 WEEKS AGO BECAUSE OF DUB AND AN ENDOMETRIAL POLYP. I AM IN THERAPY FOR MODERATE DEPRESSION AND ANXIETY AS WELL AS INSOMNIA. CONSTANT PAIN IN LOWER ABDOMEN AND WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042415	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 1/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLOATING, HEAVIER PERIODS, ABDOMINAL PAIN DX AS PELVIC INFLAMMATORY DISEASE, WEIGHT GAIN AND ECZEMA

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042416	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (B)(6) 2012, (B)(6) Y/O ESSURE, (B)(6) 2013, (B)(6) Y/O UTERINE ABLATION FOR SEVERE BLEEDING, SEVERAL HOSPITAL VISIT AND ULTRASOUNDS LATER, (B)(6) 2015, (B)(6) Y/O HYSTERECTOMY, 2 DAYS AGO, ANOTHER ER VISIT WITH X-RAYS SHOWING THE INTENSE FLANK PAIN WAS SITE OF COIL ON LEFT, RIGHT COIL NOT FOUND IN XRAY. STILL IN PAIN! STILL HAVE METAL LEFT IN ME!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042417	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 2/5/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD "PULLING" PAIN IN LEFT SIDE ABOUT 2 MONTHS AFTER I GOT THE PROCEDURE. ALMOST A YEAR AND A HALF NOW, THE PAIN IS GETTING WORSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042418	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 8/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING MY SECOND HIGH RISK DELIVERY, MY OBGYN OFFERED THE ESSURE TO ME. SHE HIGHLY RECOMMEND IT AND SAID IT WAS BASICALLY RISK FREE AND NON-EVASIVE PROCEDURE. I HAD IT DONE SINCE IT WAS HIGHLY RECOMMEND TO ME. IMMEDIATELY FOLLOWING THE PROCEDURE, I WAS IN A LOT OF PAIN AND HEAVY BLEEDING. MY OBGYN SAID IT WAS NORMAL AND EVERYTHING WAS OKAY. AT 6 WEEK, I HAD THE SONOGRAM WHERE THEY CHECK TO MAKE SURE THEY WERE PLACED CORRECTLY. EVERYTHING CHECKED OUT FINE BUT I WAS STILL BLEEDING AND IN A LOT OF PAIN. MY OBGYN THOUGHT I WAS BEING OVERLY DRAMATIC AND BASICALLY BRUSHED ME OFF. I DECIDED TO MAKE AN APPOINTMENT WITH ANOTHER OBGYN WITHIN THE SAME PRACTICE AND SHE TOO BRUSHED ME OFF BUT DID DO SOME BLOOD WORK, AN INTERNAL EXAM AND A SONOGRAM. THE ONLY THING THEY FOUND WAS A SMALL CYST. AFTER A YEAR OF BEING IN CONSTANT PAIN AND HEAVY PERIODS, I WENT TO ANOTHER OBGYN PRACTICE ALL TOGETHER. SHE TOOK A SCOPE INSIDE OF ME AND FROM THAT END, SHE COULDN'T FIND THE ESSURE ON MY LEFT SIDE. SHE ASSUMED IT WAS MISPLACED OR IT HAD MIGRATED TO SOME WHERE ELSE INSIDE OF ME. THEREFORE, I HAD TO HAVE SURGERY AND HAD THE ESSURE TAKEN OUT ALONG WITH MY FALLOPIAN TUBE AND MY OVARY. HOWEVER, THE PAIN DID NOT END THERE I AM IN CONSTANT PAIN TILL THIS DAY. I HAVE A COMPLETELY PROLAPSED VAGINAL WALL AND AM IN CONSTANT PAIN. I HAVE TO HAVE NERVE BLOCKERS (INJECTIONS) PERIODICALLY BECAUSE THE MUSCLES INSIDE OF MY UTERUS ARE KNOTTED UP! THIS IS WHAT THE ESSURE HAS DONE TO ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042420	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE IRREGULAR BLEEDING, CONSTANT LOWER BACK PAIN, DISCHARGE, SWELLING, BLOATING , HEADACHES, PAIN DURING SEX, BLEEDING AFTER SEX, ABDOMINAL CRAMPING, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042421	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 3/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, DIZZINESS, MIGRAINES, NUMBNESS IN TOE AND FINGER....LOSS OF SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042422	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 4/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE NOW LOST MY EYELASHES, MY CONFIDENCE. I FEEL WEAK AND I CAN'T CONTROL IT. GOING IN FOR FIRST SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042423	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 10/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5042423 #(B)(4). MY PROCEDURE WAS COMPLETED (B)(6), 2007 AFTER MY DAUGHTER WAS BORN. I STARTED HAVING THE CHRONIC INFLAMMATION ISSUES IN LATE 2007.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042424	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 5/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PRIOR TO ESSURE PLACEMENT, I HAD NORMAL PERIODS. THEY WERE NOT PAINFUL. LASTED 5-7 DAYS. THE DAY ESSURE WAS PLACED, I NEVER STOPPED BLEEDING. I HAD TO GO THROUGH SEVERAL ROUNDS OF PROGESTERONE WHICH DID NOT WORK. I WAS PUT BACK ON BIRTH CONTROL PILLS TO STOP THE BLEEDING. I STAYED ON THE PILL FOR ABOUT A YEAR AND A HALF. EVEN ON THE PILL, MY PERIODS WERE LONGER THAN NORMAL FOR ME. LASTED AROUND 9 DAYS. IN (B)(6) 2014, MY DOCTOR TOLD ME TO STOP THE PILL AND SEE IF MY PERIODS WOULD BE NORMAL. EVERY MONTH SINCE THEY GOT LONGER AND LONGER. I NOW BLEED AROUND 21 DAYS AND THEY ARE PAINFUL. IT FEELS LIKE MY INSIDES ARE ON FIRE. I HAVE BAD CRAMPING. BLOOD CLOTS THAT ARE AROUND 6 INCHES LONG. I AM NOW BORDERLINE ANEMIC BECAUSE OF HOW MUCH I BLEED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042425	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 1/17/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD PAIN IN PELVIC AREA, PERIOD GOT HEAVY AND LASTED UP TO 14 DAYS; SPOTTING AFTER SEX; THIS WAS JUST IN TERMS BEGIN. STARTED TO HAVE OTHER ISSUES SUCH AS NUMB FEELING IN MY RIGHT CALF AND TOE, FATIGUE, MUSCLE ACHES, DOCTOR DID ABLATION FOR BLEEDING. HAD BLOOD TEST; CAME BACK NEGATIVE. HAD BLADDER LEAKING, YEAST INFECTION, BACTERIAL INFECTIONS ENDED UP WITH GETTING BLADDER SLING; WAS SUPPOSED TO BE SAME DAY SURGERY, BUT I SWELLED SO BAD; WAS ADMITTED TO THE HOSPITAL, THEN GOT KIDNEY STONE NEEDED SURGERY, THEN HAD CHRONIC DIARRHEA, ADMITTED TO HOSPITAL FOR 3 DAYS. UNEXPLAINED RASH. SO TIRED AND GETTING WORSE, FEEL VERY ITCHY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042426	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 6/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNEXPLAINED WEIGHT GAIN, HEAVY PERIODS WITH CLOTS, SPOTTING BETWEEN CYCLES, DEPRESSION, EXHAUSTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042427	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 9/26/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SUDDENLY FELT A HORRIBLE STABBING FEELING AND CHRONIC PAIN CONSISTENT THEREAFTER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042428	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 12/18/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN AND NUMBNESS IN MY LOWER ABDOMEN AND PELVIC REGIONS, BLURRED VISION, NIGHT SWEATS, PANIC/ANXIETY ATTACKS, 7 TO 10 DAY MENSTRUAL CYCLE WITH EXCESSIVE BLEEDING AND CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042429	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD MY PROCEDURE AND COILS PLACED IN 2007. I HAVE STRUGGLED WITH MY HEALTH SINCE. RECURRENT UPPER RESPIRATORY INFECTION, IRON/FERRITIN ISSUE - LOW - UNABLE TO CORRECT WITH ORAL IRON. REQUIRE IV IRON AS NEEDED. IRREGULAR PERIODS WITH HEAVY BLEEDING, CLOTS, AND PAIN. METALLIC TASTE IN MY MOUTH FOR THE PAST YEAR. JOINT PAIN, CHRONIC FATIGUE. I'M EITHER SICK WITH INFECTION OR STRUGGLING WITH JOINT PAIN. SHORT OF BREATH. TEETH HAVE BEEN BREAKING, REQUIRING EXTRACTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042430	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 2/28/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NO CYCLE FOR MONTH OF FEB, NAUSEA, WEIGHT GAIN, FATIGUE, PELVIC PAIN AND PRESSURE, LIGHT HEADED, MIND NOT AS SHARP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042431	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 5/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I HAD IT IN "J" GOT HUGE AND I HAD ALL TYPES OF INFECTIONS IN MY VAGINAL AREA AND I KEPT GETTING BAD MIGRAINES AND WAS ALWAYS NAUSEOUS AND I HAD YEAST INFECTIONS IN MY MOUTH AND BAD BACK PAIN AND BAD PAIN IN MY OVARY AREA. MY PERIODS CAME BACK TO BACK. I WAS ALWAYS GOING TO THE DR FOR STUFF. I LIVED IN PAIN AND WITH FREQUENT PROBLEMS SUCH AS SPRAYING BLOOD OUT MY VAGINA DURING INTERCOURSE ALL THE WAY UP TILL I GOT IT OUT. WHEN I GOT IT OUT, I FELT 100 TIMES BETTER . I HAD NO ENERGY AND WAS ALWAYS ANEMIC. ALL I WANTED TO DO IS SLEEP ALL THE TIME . WAS LIKE THAT FOR 4 YEAR . I ALSO HAD ONSET MENTAL ISSUES THAT ARE GONE NOW AND I USED TO BLACK OUT AND NOT BE ABLE TO BREATH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042432	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 6/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). NOT ONLY WAS I PREGNANT, BUT I ALSO WAS HAVING MIGRAINES EVERYDAY, JOINT PAIN, MAJOR HAIR LOSS, AND LOSS IN SEX DRIVE. AFTER HAVING MY SON WHOM I WENT INTO LABOR WITH THE FIRST TIME ON (B)(6)... I HAD HIM 5 WEEKS EARLY. HE WAS IN THE NICK FOR 8 DAYS AND GOT TO COME HOME. HE WAS HAVING APNEA EPISODES, JAUNDICE ISSUES, AND NOT BEING ABLE TO EAT AND BREATHE AT THE SAME TIME. MY DOCTOR THEN TOLD ME THAT MY BODY MUST HAVE NEEDED MORE TIME TO HEAL. A FEW MONTHS LATER, WE FOUND OUT THAT I WAS PREGNANT YET AGAIN. YOU SEE, THE REASON FOR GETTING GOOD ESSURE WAS THAT I GET VERY SEVERE HYPEREMESIS GRAVIDARUM THROUGH OUT MY ENTIRE PREGNANCIES. SO AS SOON AS I BEGAN TO GET SICK, I KNEW WHAT WAS GOING ON. I HAD MY DAUGHTER 5 WEEKS EARLY AS WELL, BUT WITH HER THANK GOD THERE WERE NO HEALTH ISSUES. SHE WAS JUST REALLY SMALL. THANKS TO PREGNANCIES I HAVE HAD THOUSANDS OF IVS AND 10 PICC LINES PLACED OVER THE LAST 7 YEARS. MY DOCTOR DID A MORE INVASIVE TEST TO CONFIRM THE COIL PLACEMENT. TURNED OUT THAT MY RIGHT TUBE WAS NOT FULLY BLOCKED. I TOLD HIM ABOUT ALL OF THE CONTINUED PELVIC PAIN THAT I WAS HAVING AS WELL HAS HAIR LOSS, MOOD SWINGS, JOINT PAIN, BLOATING, MIGRAINES, MEMORY ISSUES, UNEXPLAINED RASHES, VERY HEAVY MENSTRUAL PERIODS... HE JUST SAID THAT IT WAS NOT RELATED TO ESSURE AND THAT IT WOULD PASS. I WANTED TO HAVE MY UTERUS REMOVED, BUT HE TALKED MY HUSBAND AND MYSELF I TO GETTING A 3RD COIL AGAIN. WE GOT IT PLACED AND THEN WITHIN A MATTER OF A COUPLE OF WEEKS THE PERIODS GOT EVEN HEAVIER AND MUCH MORE PAINFUL. WE TALKED ABOUT DOING AN ABLATION BECAUSE OF THE PAIN, BLEEDING, AND THEY FOUND FIBROIDS. THE PERIODS WERE SUPER HEAVY AND LASTING 3 WEEKS AND THE I WOULD GET A COUPLE OF DAYS BREAK AND THEN IT WOULD START ALL OVER AGAIN. THE ABLATION HELPED WITH THE AMOUNT OF BLEEDING BUT I WAS STILL IN THE

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SAME 3 WEEK PATTERN. THE PAIN CONTINUED TO WORSEN AND SO DID THE BLOATING. I HAD AN ULTRASOUND DONE AND FOUND OUT THAT I HAD A VERY LARGE CYST THAT HAD FORMED ON MY OVARY. THEY WAITED A LITTLE BIT TO SEE IF IT WOULD TAKE CARE OF ITS SELF. IT JUST GOT BIGGER. THEY DECIDED TO DO SURGERY TO REMOVE THE CYST AND THE DOC SAID THAT HE COULD REMOVE THE OVARIES. WELL... HE DECIDED NOT TO BECAUSE THEY LOOKED HEALTHY. WELL THINGS GOT BETTER FOR A FEW WEEKS. THEN WE TOOK THE UTERUS OUT BECAUSE THE BLEEDING WAS NOT GETTING ANY BETTER. I CONTINUED TO HAVE PROBLEMS WITH CYSTS BURSTING ON A DAILY BASIS CAUSING A LARGE AMOUNT OF BLOATING. I HAD TO FIND A NOT OK WHO WOULD LISTEN TO ME. SHE WAS WONDERFUL. SHE TRIED SOME MEDS TO SHUT OFF THE OVARIES TO SEE IF IT WOULD MAKE A DIFFERENCE, AND BECAUSE IT DID, SHE SAID THAT IT WOULD BE BEST TO JUST TAKE THE OVARIES OUT. WE GOT THEM OUT AND I AM NOW 4 WEEKS POST OP AND THINGS ARE GOING GREAT. PAIN WISE! NOW TO ALL OF THE DOCS SAYING THAT THE HAIR LOSS AND ALL OF THE OTHER SIDE EFFECTS THAT ALL OF US WOMEN HAVE EXPERIENCED... A MATTER OF A COUPLE OF WEEKS AFTER HAVING ESSURE REMOVED... MY HAIR WAS STARTING TO GROW BACK, MY JOINTS NO LONGER HURT, MIGRAINES SLOWED DOWN, FEELING OF KICKING IN MY UTERUS (LIKE A PHANTOM BABY KICK) WENT AWAY...ALL OF MY MAJOR PROBLEMS WENT AWAY... WITH THE EXCEPTION OF THE OVARIAN CYSTS AND BLOATING DUE TO FLUID BUILD UP. WHICH REMINDS ME. WHEN MY FIRST OK TOOK OUT MY UTERUS, TUBES, AND COILS AS WELL AS REMOVING THE LARGE CYST. HE ALSO SAID THAT HE HAD TO REMOVE AN EXCESSIVE AMOUNT OF FLUID FROM THE ABDOMEN AS WELL. MY MARRIAGE WAS ALMOST RUINED, MY HEALTH WENT WAY DOWN, AND BECAUSE OF MY 3RD AND 4TH PREGNANCIES (E-BABIES) I WAS VOMITING SO MUCH THAT I NOW HAVE THE TEETH OF A "BELEMIC". I DON'T SMILE WITH MY TEETH ANYMORE, BECAUSE I'M SO EMBARRASSED OF HOW I LOOK. I USED TO BE A PRETTY CONFIDENT PERSON, BUT NOT SO MUCH ANY MORE. ESSURE NEEDS TO COME OFF THE MARKET SO NO OTHER WOMEN HAVE TO SUFFER AS I HAVE OR WORSE!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042433	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 2/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). EXTREME PAIN, IRREGULAR BLEEDING, MOOD SWINGS, LOSS OF ENERGY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042434	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 9/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ABDOMEN HURTS ALL THE TIME NEVER STOPS HURTING, MY LOWER BACK NOW HURTS, I HAVE EMOTIONAL PROBLEMS, AND I HAVE CONSTANT BLADDER INFECTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042435	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED EXPERIENCING BLOATING, CYSTS IN MY OVARIES, LOWER BACK PAIN, PAINS IN MY LEGS, FATIGUE, MIGRAINES, SENSITIVITY TO MY STOMACH, NUMBNESS IN MY ARMS, ANXIETY AND THE TASTE OF METAL IN MY MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042436	BAYER	5/1/2015	5/1/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED NOTICING HAIR LOSS, WEIGHT GAIN, PAINFUL PERIODS, PERIODS LASTING FOR 23 DAYS. AS OF (B)(6) 2015 I'M NOW GETTING OVARIAN CYSTS THAT CAUSE PAIN EVEN WHEN NOT ON MY PERIOD. EXTREME FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042536	CONCEPTUS INC	5/3/2015	5/8/2015

Event Information:

Event Date (B3): 4/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS205624837

Single Use:
Implant Date (E6): 11/22/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE MY IMPLANTATION OF ESSURE IN 11/2007, MY PERIODS ARE HEAVIER, CLOUTIER AND A LOT MORE PAINFUL. I HAVE HAD CONTINUAL LOWER BACK PAIN AND PELVIC PAIN THAT IS ALMOST UNBEARABLE DURING OVULATION AND MY PERIOD. THESE SHARP STABBING AND SHOOTING PAINS. I HAVE BEEN PRESCRIBED TRAMADOL AND 800MG IBUPROFEN FOR THE PAINS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00281	BAYER HEALTHCARE LLC	5/4/2015	5/4/2015

Event Information:

Event Date (B3): 2/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT STERILIZATION. ON (B)(6) 2015, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED SATISFACTORY LOCATION AND OCCLUSION ON RIGHT SIDE. LEFT SIDE WAS PERFORATED. PATIENT HAD SURGERY ON (B)(6) 2015; TUBAL LIGATION WAS PERFORMED ON LEFT SIDE. MICRO-INSERT WAS SEEN AND REMOVED. PATIENT HAD UNILATERAL TUBAL. ESSURE CONTINUED IN ONE SIDE ONLY. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A

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FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HSG SHOWED LEFT COIL HAD PERFORATED. THIS EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THE PRESENT CASE, HYSTEROSALPINGOGRAM WAS DONE APPROXIMATELY 4 MONTHS AFTER ESSURE INSERTION AND SHOWED LEFT COIL HAD PERFORATED. LEFT TUBAL LIGATION AND REMOVAL OF THE LEFT COIL WERE PERFORMED. THEREFORE, CONSIDERING THE AVAILABLE INFORMATION AND NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION (SURGERY FOR TUBAL LIGATION AND ESSURE REMOVAL). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

HEALTH CARE PROVIDER UTERINE/TUBAL PERFORATION QUESTIONNAIRE WAS RECEIVED ON 29-JUN-2015: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT WHO HAD AS MEDICAL HISTORY OBESITY; HAD ESSURE INSERTED ON (B)(6) 2014. ACCORDING TO HEALTH C

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042572	BAYER	5/4/2015	5/11/2015

Event Information:

Event Date (B3): 11/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 11/14/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE DEVICE I HAVE HAD A LOT OF SKIN ISSUES. IT IS LIKE I HAVE RASH ON MY FACE THAT CONSTANTLY ITCHES. ALSO HAVE LOTS OF BLOATING AND WEIGHT GAIN IN THE ABDOMEN REGION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00282	BAYER HEALTHCARE LLC	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 10/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/16/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 22-OCT-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN RECENTLY RECEIVED HYSTEROSALPINGOGRAM (HSG) REPORT STATING ESSURE COIL WAS VISUALIZED IN THE PERITONEAL CAVITY AND WANTED GUIDANCE AND RECOMMENDATION ON PROTOCOL. PTC INVESTIGATION RESULT WAS RECEIVED ON 23-NOV-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON 07-APR-2015 FROM PHYSICIAN (CASE UPGRADED TO INCIDENT). PATIENT'S INITIALS, DATE OF BIRTH AND WEIGHT WERE PROVIDED. THIS REPORT REFERS TO A

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(B)(6) FEMALE PATIENT. SHE DENIED ANY RELEVANT HISTORY INCLUDING PREEXISTING MEDICAL CONDITIONS. ON (B)(6) 2014 ESSURE WAS INSERTED WITH NO DIFFICULTY. DURING PROCEDURE, THERE WERE USUAL FINDINGS AND NO INTRAOPERATIVE COMPLICATIONS. ON (B)(6) 2014 RADIOLOGIST STATED THAT ESSURE COIL WAS IN ABDOMEN. ON (B)(6) 2014, A LAPAROSCOPY WAS DONE TO PERFORM BILATERAL TUBAL OCCLUSION (PARTIAL SALPINGECTOMIES) AND TO TRY TO RETRIEVE THE ESSURE COIL THAT WAS FREE IN THE ABDOMEN/PELVIS. PHYSICIAN DID NOT FIND THE ESSURE COIL. IT WAS EXPLAINED TO THE PATIENT THAT IF NO SYMPTOMS, THERE WAS NO NEED TO ATTEMPT TO REMOVE IT. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 14-APR-2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COIL WAS VISUALIZED IN PERITONEAL CAVITY ON HSG (HYSTEROSALPINGOGRAM). THIS EVENT, INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY, WAS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, BASED ON THE AVAILABLE INFORMATION AND DUE TO LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED. A PARTIAL SALPINGECTOMY WAS PERFORMED IN BOTH TUBES VIA LAPAROSCOPY AND THE PHYSICIAN TRIED TO RETRIEVE THE ESSURE COIL THAT WAS IN ABDOMEN, BUT COULD NOT FIND IT. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00283	BAYER HEALTHCARE LLC	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 2/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06518

Single Use: Y
Implant Date (E6): 10/21/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT STERILIZATION (LOT NUMBER C06518). ADDITIONAL INFORMATION WAS PROVIDED BY PHYSICIAN ALSO ON (B)(6) 2015. THE PHYSICIAN MENTIONED THAT HE HAD A PROBLEM WITH EXPULSION OF ESSURE INTO THE ABDOMINAL CAVITY. IT WAS REPORTED THAT ON (B)(6) 2015 HYSTEROSALPINGOGRAM CONFIRMATION TEST WAS PERFORMED AND SHOWED SATISFACTORY LOCATION AND SATISFACTORY OCCLUSION WERE NOT ACHIEVED. RADIOLOGY REPORT SHOWED RIGHT MICRO-INSERT HAD SLIGHT PERFORATION WITH PARTIAL EXPULSION VERSUS COMPLETE EXPULSION IN THE DISTAL END OF THE RIGHT FALLOPIAN TUBE. DOCTOR PERFORMED A LAPAROSCOPIC RIGHT SALPINGECTOMY ON (B)(6) 2015. DOCTOR DID NOT SEE MICRO-INSERT AND THE MICRO-INSERT WAS NOT IN FALLOPIAN TUBE EITHER (TUBE WAS SENT TO PATHOLOGY FOR EXAMINATION). DOCTOR WILL BE CALLING THE COMPANY ON HOW TO LOCATE MICRO-INSERT IF, IN FACT, THE MICRO-INSERT HAS EXPELLED INTO PELVIC CAVITY. THE PATIENT CONTINUED WITH THE LEFT ESSURE. THE LEFT HAD COMPLETE OCCLUSION. FOLLOW-UP RECEIVED ON (B)(6) 2015 FROM PHYSICIAN: MEDICAL DOCTOR WANTS TO KNOW IF SHE SHOULD REMOVE THE PERFORATED INSERT. THE INSERT WAS NOT SEEN WHEN SHE WENT IN TO DO THE SALPINGECTOMY. SHE REPORTED THAT THE PATIENT HAS NO SYMPTOMS BUT IS ANXIOUS AND CONCERNED. HEALTH CARE PROFESSIONAL ASKED WHAT WOULD BE THE RISK AND WHETHER THIS WILL BE A PROBLEM IN THE FUTURE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A USABILITY ISSUE. (B)(4). FINAL ASSESSMENT: LOT NUMBER: C06518; PRODUCTION DATE: 26-DEC-2013; EXPIRATION DATE: 31-

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DEC-2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE RIGHT MICRO-INSERT HAD SLIGHT PERFORATION WITH PARTIAL EXPULSION VERSUS COMPLETE EXPULSION IN THE DISTAL END OF THE RIGHT FALLOPIAN TUBE. A LAPAROSCOPIC RIGHT SALPINGECTOMY WAS PERFORMED. THIS EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THE PRESENT CASE, THE PERFORATION WAS DIAGNOSED ON THE HYSTEROSALPINGOGRAM CONFIRMATION TEST, 4 MONTHS AFTER INSERTION. CONSIDERING THE AVAILABLE INFORMATION AND NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ALSO, IT WAS REPORTED THAT DURING SALPINGECTOMY THE DOCTOR DID NOT SEE THE MICRO INSERT AND IT WAS NOT IN FALLOPIAN TUBE EITHER (NON-SERIOUS EVENT). THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION (LAPAROSCOPIC RIGHT SALPINGECTOMY). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 03-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW CLINICAL INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00284	BAYER HEALTHCARE LLC	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 4/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/7/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR CONTRACEPTION (LOT NUMBER NOT PROVIDED). PHYSICIAN REPORTED THAT ON (B)(6) 2015 INSERTED THE LEFT ESSURE INSERT AND PERFORATION OCCURRED. ON THE SAME DAY, (B)(6) 2015, LAPAROSCOPICALLY REMOVED LEFT INSERT AT THAT TIME. ESSURE USE CONTINUED. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY

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COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHEN PHYSICIAN INSERTED LEFT ESSURE INSERT, PERFORATION OCCURRED. LEFT INSERT WAS LAPAROSCOPICALLY REMOVED. THIS EVENT, INTERPRETED AS UTERINE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE PERFORATION OCCURRED WHEN PHYSICIAN INSERTED THE LEFT DEVICE. THEREFORE, SINCE PERFORATION OCCURRED DURING THE INSERTION PROCEDURE A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION (LAPAROSCOPY AND REMOVAL OF LEFT INSERT). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 18-MAY-2015: ESSURE HEALTH CARE PROVIDER PERFORATION QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A NON-PREGNANT (B)(6) FEMALE PATIENT WHO IS GRAVIDA 0, HAS NO PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROB

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00285	BAYER HEALTHCARE LLC	5/5/2015	5/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 919013 / 869754

Single Use:
Implant Date (E6): 7/2/2013
Explant Date (E7): 11/21/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 13-JUN-2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY WITH ESSURE, NO HSG TEST DONE AND ONLY ABLE TO FIND THE RIGHT COIL AND AT PLACEMENT AND HAD DIFFICULTY PLACING THE LEFT COIL IN A (B)(6) FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014 (DISCREPANT INFORMATION) THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION. IT WAS REPORTED THAT NO CONFIRMATION TEST (HSG) WAS DONE. ON (B)(6) 2014 AN ULTRASOUND WAS DONE AND A (B)(6) PREGNANCY WAS CONFIRMED (DEVICE INEFFECTIVE). ACCORDING TO THE REPORTER, ONLY RIGHT COIL WAS ABLE TO FIND AND AT PLACEMENT THEY HAD DIFFICULTY PLACING THE LEFT COIL. SHE IS CONTINUING THE PREGNANCY. FOLLOW UP INFORMATION RECEIVED ON 23-JUN-2014 FROM NURSE: SHE STATED THAT ESSURE WAS INSERTED ON (B)(6) 2013. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 25-JUN-2014. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES, ANY RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. SHE HAD 04 PREGNANCIES, 02 LIVE BIRTHS AND 02 ABORTIONS. ESSURE WAS INSERTED UNDER ORAL ANALGESIA. SHE WAS 12 WEEKS POSTPARTUM AT THE TIME OF INSERTION. THE INSERTION WAS DIFFICULT DUE TO INITIAL RESISTANCE TO COIL PLACEMENT, BUT THEN PLACED EASILY ON LEFT (FIRST COIL BENT, USED 2ND COIL WHICH WERE PLACED EASILY). THE SAME PROBLEM OCCURRED ON RIGHT. THE PROCEDURE TOOK 30 MIN. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC. CONDOMS WERE USED AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. NO HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED. ON UNSPECIFIED DATE PREGNANCY WAS CONFIRMED BY BLOOD TEST. ON (B)(6) 2014 ULTRASOUND WAS

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PERFORMED AND SHOWED GESTATIONAL AGE (B)(6). EXPECTED DATE OF DELIVERY WAS REPORTED AS (B)(6) 2015. AT THE TIME OF THIS REPORT THERE WERE NO COMPLICATIONS. SHE CONTINUED WITH PREGNANCY. ESSURE WAS NOT REMOVED AND REMOVAL WAS NOT PLANNED. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-AUG-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC).(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED REVIEWS OF THE MANUFACTURING BATCH RECORDS AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE A LACK OF EFFICACY (PREGNANCY) WAS REPORTED. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO 919013, OF WHICH (B)(4) CASE REFERS ALSO TO SIMILAR LACK OF EFFICACY TYPE OF EVENTS AND (B)(4) CASE REFERS ALSO TO SIMILAR USABILITY ISSUE TYPE OF EVENTS. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO 869754, WHICH DOES REFER ALSO TO SIMILAR USABILITY ISSUE TYPE OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING AND RELEASE DOCUMENTATION OF THE CONCERNED BATCHES REVEALED NO REASON TO SUSPECT A QUALITY DEFICIT (SEE TECHNICAL STATEMENT). THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. FOLLOW-UP RECEIVED ON 09-APR-2015: HEALTH CARE PROVIDER PREGNANCY QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A FEMALE PATIENT WHO HAS AS MEDICAL HISTORY GRAVIDA 5, PARA 2, 3 ABORTIONS (1 SPONTANEOUS AND 2 THERAPEUTIC), NO ECTOPIC PREGNANCY AND HAS AS PREVIOUS GYNECOLOGICAL INTERVENTIONS A CURETTAGE FOR MISCARRIAGE AND AS GYNECOLOGICAL PROBLEMS OR PROCEDURES A FIBROID; HAD ESSURE INSERTED ON (B)(6) 2013 FOR CONTRACEPTION. ACCORDING TO HEALTH CARE PROFESSIONAL, CERVICAL DILATATION (HYDRADILATATION) AND ANALGESIA WERE APPLIED DURING INSERTION. NO SOUNDING OR GENERAL ANESTHESIA WAS DONE. PHYSICIAN CONSIDERED THE VISUALIZATION OF TUBAL OSTIUM EASY BUT STATED THAT INSERTION WAS DIFFICULT. HEALTH CARE PROFESSIONAL INFORMED THAT FIRST ATTEMPT AT RIGHT COIL PLACEMENT HAD SOME RESISTANCE AND COIL BENT. NEW COIL PASSED EASILY. THERE WAS NO FLUID LOSS MORE THAN 1500CC DURING HYSTEROSCOPY AND PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION PATIENT USED CONDOMS. NO IMAGING TEST TO CONFIRM ESSURE PLACEMENT OR HYSTEROSALPINGOGRAM TEST WAS PERFORMED. PATIENT HAD PREGNANCY CONFIRMED ON (B)(6) 2014 BY URINE AND BLOOD TEST. ON (B)(6) 2014, ULTRASOUND SHOWED (B)(6) PREGNANCY. FATAL GENETIC DEFECT OF FETUS OCCURRED (JOUBERT SYNDROME) AND, ON (B)(6) 2014, PATIENT HAD A TERMINATION OF PREGNANCY AT 18 WEEKS. NO HYSTERECTOMY OR SALPINGECTOMY WAS NECESSARY. (CHILD CASE (B)(4)). ON (B)(6) 2014 PATIENT HAD ESSURE DEVICES REMOVED BY LAPAROSCOPY. ACCORDING TO PHYSICIAN, DEVICES ON BOTH SIDES WERE STUCK TO POSTERIOR UTERUS IN SEROSA. TUBES WERE LIGATED AND PATIENT HAS RECOVERED FROM ESSURE REMOVAL PROCEDURE AND FROM OTHER SYMPTOMS. IN ADDITION, HEALTH CARE PROFESSIONAL CONSIDERED THAT ESSURE DEVICES CAUSED OR CONTRIBUTED TO PATIENT'S CONDITION DUE TO NOT PROPER LOCATION. CORRECTION PERFORMED REGARDING INFORMATION RECEIVED ON 09-APR-2015: THE EVENT SPONTANEOUS ABORTION WAS DELETED AFTER INTERNAL REVIEW. PTC INVESTIGATION RESULT RECEIVED ON 15-APR-2015. (B)(4). FINAL

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ASSESSMENT" LOT #919013: PRODUCTION DATE: 10/2011, EXPIRATION DATE: 10/2014. LOT #869754: PRODUCTION DATE: 6/2011, EXPIRATION DATE: 6/2014. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY AND A USABILITY ISSUE. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN ADDITION, THE AE CASE REFERS TO A TREATMENT NONCOMPLIANCE. THE BATCH DOCUMENTATION OF THE REPORTED BATCHES WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO 919013, OF WHICH (B)(4) CASE REFERS ALSO TO SIMILAR LACK OF EFFICACY TYPE OF EVENTS. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH NUMBER 869754. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN A DIFFICULT PLACEMENT AND ONE YEAR LATER GOT PREGNANT. AFTER A COUPLE OF MONTHS, SHE HAD TERMINATION OF PREGNANCY. THREE MONTHS LATER, ESSURE DEVICES WERE REMOVED PER LAPAROSCOPY AND IT WAS OBSERVED THAT THE DEVICES ON BOTH SIDES WERE STUCK IN POSTERIOR SEROSA. PREGNANCY IS NON-SERIOUS AND THE OTHER EVENT, INTERPRETED AS DEVICE EMBEDMENT, IS SERIOUS DUE MEDICAL IMPORTANCE. THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE SOME OF PREGNANCIES WITH ESSURE USE OCCURS DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, THE CONFIRMATION TEST (HSG) WAS NOT PERFORMED. ALTHOUGH THE PREGNANCY SHOULD BE A CONSEQUENCE OF NON-COMPLIANT USE OR A RESULT OF DEVICE EMBEDMENT, A DEVICE FAILURE CANNOT BE TOTALLY EXCLUDED. DURING ESSURE USE THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE DISLOCATION OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS REPORT, THE EXACT DATE AND MECHANISM OF EMBEDMENT WERE NOT KNOWN. NEVERTHELESS, GIVEN ITS NATURE, THE EVENT IS ASSESSED AS RELATED TO ESSURE. SINCE REQUIRED INTERVENTION TO REMOVE THE DEVICES WAS LATER INFORMED THIS CASE WAS UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042456	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 11/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVER PELVIC PAIN, HEAVY BLEEDING ON MY PERIOD AND OFF, MIGRAINES, EXTREME FATIGUE, INFLAMMATION IN THE PELVIC AREA, PAIN WITH PASSING STOOL AND CONSTANT VAGINAL INFECTIONS, LOSING MY HAIR, WEIGHT GAIN AND LOSS. I HAVE TALKED TO MY OBGYN ABOUT THIS AND SEEMS TO NOT CARE ABOUT THE PAIN. I HAVE HAD AN ULTRA SOUND FOR THE PAIN TO SEE IF IT HAD MIGRATED AT THE TIME IT HADN'T BUT I RECENTLY TOOK AN X-RAY AND FOUND THAT MY LEFT SIDE ESSURE HAS MIGRATED TO MY LOWER LEFT PELVIC AREA AND IS BOUNCING AROUND. I HAVE AN APPOINTMENT TO SEE MY DOCTOR AND GET IT REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042457	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 10/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN BOTH TUBES WERE THE COILS ARE AND THROBBING. AS I WAS STANDING IN THE SHOWER, THE PAIN HIT OUT OF NOWHERE. IT WAS SO BAD THAT I DOUBLED OVER, HOLDING MY LOWER ABDOMINAL AREA AND WAS IN TEARS. I BECAME WEAK FROM THE PAIN. THE PAIN LASTED FOR AT LEAST 30 MINUTES. THE PAIN AND THROBBING CONTINUE TO HIT SPORADICALLY EVERYDAY AND LASTS ANYWHERE FROM A FEW MOMENTS TO SEVERAL HOURS. I'VE HAD TO GO TO THE ER SEVERAL TIMES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042458	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 9/1/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE MY REPORT I HAVE BEEN SEEING MY GYNECOLOGIST. I HAVE HAD AN ULTRA SOUND WHICH SHOWED CYSTS AND THICK UTERUS. I HAD A BIOPSY, NO CANCER. I HAVE HAD A HSG WHICH SHOWED ONE COIL IS NOT IN MY LEFT FALLOPIAN TUBE. THE TUBE HAS CYSTS AND DIVERTICULITIS. NOTHING HAS HELPED MY ANXIETY, BRAIN FOG, CHRONIC PAIN, INSOMNIA, ITCHY SKIN, HEAVY BLEEDING, MEMORY LOSS AND OTHERS LISTED ABOVE AS WELL AS ONES I HAVE SO MANY IT'S HARD TO LIST. I'M SCHEDULED FOR A DAVINCI HYSTERECTOMY BSO IN (B)(6). THESE SYMPTOMS ARE REAL. THERE ARE THOUSANDS OF WOMEN SUFFERING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042459	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 1/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY, PAINFUL BLOOD CLOTS DURING MENSTRUAL CYCLE, BLOATING, HAIR LOSS, MIGRAINE HEADACHES, NAUSEA, THINNING HAIR, SKIN IRRITATION, ITCHY SKIN, SKIN BURNS, SEVERE STOMACH PAIN, SEVERE ABDOMINAL PAIN CONSTANTLY. NO DESIRE TO HAVE SEX, PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042460	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 6/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY TEETH STARTED BREAKING, WITH CAVITIES EVERYWHERE. TWO CROWNS HAD TO BE PLACED. ROOT CANAL DONE. NEXT, I COULD NOT MOVE MY NECK SIDEWAYS EITHER WAY FOR A YEAR. WAS GOING TO P.T. NEXT, I HAVE NEVER HAD ACNE IN MY LIFE. BUT SINCE ESSURE, I CAN'T GET RID OF IT. FURTHERMORE, THE PAIN FROM SEVERE BLOATING AND CRAMPING EVERY NIGHT WAS UNBEARABLE. I GAINED 25 LBS AND 4 INCHES IN MY BELLY ALONE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042461	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, SHARP SHOOTING PAIN, BLOATING, METAL TASTE IN MOUTH, JOINT ACHES AND PAIN, SENSITIVITY TO TOUCH FIBROMYALGIA SYMPTOMS, TIRED ALL THE TIME, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042462	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 12/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN RIGHT SIDE ... DR TOLD ME TO WAIT AND WAIT... SEE IF IT WOULD GO AWAY OTHERWISE WE WOULD MOVE FORWARD WITH HYSTERECTOMY. I GOT CRAMPING RELIEF FROM CHIROPRACTIC CARE A SHORT TERM FIX BUT WILL HAVE HYSTERECTOMY WHEN I DON'T HAVE TO LIFT MY BABIES EVERY DAY. BLOATING EVERY DAY ISSUE .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042463	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 11/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVER PELVIC PAIN, HEAVY BLEEDING ON MY PERIOD AND OFF, MIGRAINES, EXTREME FATIGUE, INFLAMMATION IN THE PELVIC AREA, PAIN WITH PASSING STOOL AND CONSTANT VAGINAL INFECTIONS, LOSING MY HAIR, WEIGHT GAIN AND LOSE. I HAVE TALKED TO MY OBGYN ABOUT THIS AND SEEMS TO NOT CARE ABOUT THE PAIN. I HAVE HAD AN ULTRA SOUND FOR THE PAIN TO SEE IF IT HAD MIGRATED AT THE TIME IT HADN'T BUT I RECENTLY TOOK AN X-RAY AND FOUND THAT MY LEFT SIDE ESSURE HAS MIGRATED TO MY LOWER LEFT PELVIC AREA AND IS BOUNCING AROUND. I HAVE AN APPOINTMENT TO SEE MY DOCTOR AND GET IT REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042464	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PUT IN SOON AFTER HEAVY BLEEDING .. PAIN IN BACK AND LEFT SIDE FROM BACK DOWN LEG, SICK TO STOMACH ALL THE TIME, THINNING HAIR... ANXIETY, EXTREME FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042465	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 4/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE PAIN IN MY LEFT SIDE ABOUT ONCE A MONTH FOR THE LAST 7 MONTHS, NO PAIN MEDS HELP IT GO AWAY, IT LASTS A WHOLE DAY AND THEN IT GOES AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042466	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, PELVIC/LOWER BACK PAIN, SWELLING OF LEGS AND ANKLES, CONFUSION, FOGGINESS, FORGETFULNESS, DIZZY, LOSS OF LIBIDO, MIGRAINES, ENDOMETRIOSIS, OVARIAN CYSTS, BLOATING (LOOK LIKE I AM 7 MONTHS PREGNANT), MOOD SWINGS, JOINT PAIN, EXTREME FATIGUE, BRUISING EASIER THAN USUAL, HAIR IS FALLING OUT, LOSS OF ENERGY, LOSS OF APPETITE, WEIGHT GAIN, CAN NOT LOSE WEIGHT NO MATTER WHAT I DO. MULTIPLE ER AND DOCTOR VISITS OVER THE PAST 2 YEARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042468	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 12/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONE OF THE INSERTS MIGRATED OUT OF MY FALLOPIAN TUBE AND ENDED UP BEHIND MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042469	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 10/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5042469 #(B)(4). I HAD A HYSTERECTOMY TO REMOVE ESSURE (B)(6) 2015. THE LEFT COIL HAD MIGRATED INTO THE UTERUS. CHRONIC INFLAMMATION WAS SEEN THROUGH OUT THE ORGANS. ALL OF THE ALLERGY SYMPTOMS HAVE DISAPPEARED. NASAL DRAINAGE, CONSTANT THROAT CLEARING, ASTHMA LIKE SYMPTOMS, SENSITIVITY TO COMMON ALLERGENS, WIDESPREAD ITCHING, AND RASHES ARE CLEARING UP. MOST OF THE OTHER SYMPTOMS ARE GONE AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042470	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 7/16/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, MIGRAINES, BLOATING, NICKEL ALLERGY, EXCESSIVE BLEEDING, HORRIBLE MOOD SWINGS, LETHARGY, NO MOTIVATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042471	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 5/21/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BLEEDING SO BAD. I WAS GOING THROUGH A SUPER PLUS TAMPON IN 10-15 MINUTES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042472	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 1/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWO AND A HALF YEARS LATER STILL HAVING ISSUES WITH BLADDER AND PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042473	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS UPDATE IS TO ADD THAT I REQUESTED AND RECEIVED MY HYSTEROSALPINGOGRAM, HSG, RECORDS LAST WEEK. IT WAS IMMEDIATELY APPARENT THAT THE RIGHT ESSURE COIL HAD EITHER STRETCHED AT THE PROXIMAL TIP AND THE COIL HAD SPLIT. OR THE PROXIMAL TIP HAD BROKEN OFF. NO ONE TOLD ME THAT BOTH COILS WERE GRADE 3, ONLY THAT BOTH OF MY FALLOPIAN TUBES WERE OCCLUDED. IN ADDITION, I AM CHANGING MY CYSTIC ACNE SIDE EFFECT SUBMITTED PREVIOUSLY TO BARTHOLIN CYSTS. THESE CYSTS ARE ALWAYS PAINFUL, CONTRARY TO WHAT (B)(6) STATES. SINCE MY HYSTERECTOMY, SOME OF MY SIDE EFFECTS HAVE DISAPPEARED. MY LOW VITAMIN B AND LOW FERRITIN IMPROVED CONSIDERABLY. UNFORTUNATELY, THE PLMS, PERIODIC LIMB MOVEMENT SYNDROME, HAS NOT. WITHOUT MEDICATION, I AM UNABLE TO ALWAYS FORMULATE A SENTENCE BY 10 A.M. MY MEMORY AND MY THINKING SKILLS HAVE SUFFERED. I HAVE TWO MASTER'S DEGREES AND WAS FLUENT IN CHINESE. FOR ME TO BE UNABLE TO START A 10 WORD SENTENCE AND BE UNABLE TO FINISH IT OR TO REMEMBER THE DATE OF MY CHILDREN'S BIRTHDAYS' IS, OF COURSE, EXTREMELY UPSETTING, BUT ALSO AN INDICATION OF HOW MUCH I HAVE DETERIORATED. I AM FACING A FUTURE OF UNEMPLOYMENT DUE TO MY CHRONIC PAIN AND MY DIMINISHED MENTAL AND PHYSICAL CAPACITIES. I CANNOT IMAGINE A JOB THAT PERMITS ME TO SIT DOWN, WORK ONLY A FEW HOURS IN THE MORNING FOR 4 MORNINGS A WEEK, SO THAT I CAN HAVE A NO-MEDICINE DAY, PER DOCTOR'S ORDERS, GRANTS ME THE FLEXIBILITY TO VISIT THE DOCTORS I NEED TO, ALSO DURING THE MORNING BECAUSE I AM EXHAUSTED IN THE AFTERNOON, AND PAYS ENOUGH TO COVER TAXES AND CHILD CARE. WORDS DON'T REALLY CONVEY HOW ESSURE HAS DESTROYED MY HEALTH AND THEREFORE MY CAREER, FINANCES, SOCIAL LIFE AND PLACED A GREAT DEAL OF STRESS ON MY MARRIAGE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042474	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 7/31/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE (B)(6) 2007, HEADACHES/MIGRAINES, RIGHT PELVIC PAIN, PAINFUL INTERCOURSE, FREQUENT YEAST INFECTIONS, HAIR LOSS, SENSITIVITY TO COSTUME JEWELRY, OUT OF RANGE LIVER BLOOD TESTS, HGSIL, HEART BURN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042477	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 4/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PLACED IN (B)(6) 2010, NOTHING BUT PROBLEMS FROM THERE ON OUT HEADACHES, BLOAT, HEAVY AND VERY PAINFUL PERIODS, CLOTS, BRAIN FOG, MOOD SWINGS, ANXIETY, AND THEN MY RIGHT COIL EXPELLED FROM MY BODY; BACK TO THE DOCTOR; "ULTRASOULTRASOUNDS," CERVICAL BIOPSY, UTERINE BIOPSY AND IN THE NEXT COUPLE OF WEEKS, A HYSTERECTOMY. THIS IS WHAT I ASK FOR, ALL I WANTED WAS TO BE STERILIZED, SO I COULDN'T HAVE ANOTHER CHILD BEING A I HAD LOST TWO BOYS AND GAVE BIRTH TO ANOTHER SON WHO IS WITH US TODAY, GET THIS NIGHTMARE OFF THE MARKET, IT'S INJURED TO MANY WOMEN.....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042486	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 3/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THREE WEEKS AFTER I HAD THE PROCEDURE DONE. I STARTED GETTING VERY SEVERE PAINS IN MY PELVIC AREA. IT HURTS TO HAVE INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042493	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 4/22/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE A YEAR AGO. SINCE THEN I HAVE BEEN IN CONSTANT PAIN. IT HURTS SO BAD IT IMPACTS MY LIFE. I HAVE SEVERE PAIN FROM MY LOWER RIGHT ABDOMEN. FROM MY LOWER ABDOMEN DOWN BELOW MY KNEE IT GOES NUMB. I HAVE PAIN IN MY LOWER BACK BECAUSE OF IT. MY LOWER ABDOMEN IS ALWAYS SWOLLEN. I BLEED MORE THAN I EVER HAVE. WITH HUGE BLOOD CLOTS. BEFORE THE ESSURE I WAS A EXTREMELY ACTIVE WOMAN. NOW I CANT DO HALF THE STUFF I USE TO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042494	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE GETTING ESSURE I HAVE BEEN EXPERIENCING OVERWHELMING LETHARGY, BRAIN FOG, MEMORY LOSS, HEADACHES, DEBILITATING MENSTRUAL PAIN, CHRONIC ABDOMINAL PAIN (RIGHT LOWER QUADRANT), HAIR LOSS, AND PAINFUL BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042495	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 4/17/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE HAD ONGOING ABDOMINAL PAIN FOR THREE YEARS, BED RIDDEN FOR 3-4 DAYS A MONTH WITH TERRIBLE PAIN AND PRESCRIBED PAIN MEDS, SWELLING, HOT FLASHES, BRAIN FOG, MEMORY LOSS, JOINT PAIN, TIREDNESS, LETHARGY, AND HEART PALPITATIONS NOW HAVE BEEN SCHEDULED FOR COMPLETE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042497	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN AND CRAMPING, EXCESSIVE WEIGHT GAIN, SEVERE BLOATING, SEVERE CONSTIPATION, OVARIAN CYSTS, SEVERE BLEEDING DURING MENSTRUATION, CHANGES IN PERIODS, VISION CHANGES, ABNORMAL DISCHARGE, PAIN IN MY LEFT SIDE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042498	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 4/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS REQUIRED TO HAVE A HYSTERECTOMY TO REMOVE THE ESSURE BECAUSE OF THE NICKEL ALLERGY AND SERIOUS SIDE EFFECTS IT WAS CAUSING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042499	BAYER	5/5/2015	5/5/2015

Event Information:

Event Date (B3): 2/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED TO GAIN WEIGHT IMMEDIATELY, STOMACH PAINS, PERIODS HEAVIER THAN THEY WERE WITH GOLF BALL SIZE CLOTS. I HAVE CONTINUED WITH THE BLOATED STOMACH WITH OVERALL WEIGHT GAIN SINCE INSERTION. NORMAL WEIGHT (B)(6). NOW AT (B)(6) AND RISING, DESPITE EXERCISE AND HEALTHY EATING. I HAVE HAD BACTERIAL VAGINITIS, AND THICKENING IF THE UTERINE WALL SINCE INSERTION .

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042467	BAYER	5/5/2015	5/6/2015

Event Information:

Event Date (B3): 11/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UPDATE - (B)(6) 2015 A HYSTEROSCOPY WAS PERFORMED. DURING THE PROCEDURE IT WAS CLEAR THAT MY RIGHT COIL HAS MIGRATED INTO MY UTERUS. THE COIL IS STRETCHED OUT AND FREE FLOATING IN THE UTERINE CAVITY. THIS NOW EXPLAINS THE ABNORMALLY LONG AND FREQUENT PERIODS, HEAVY BLEEDING, HUGE BLOOD CLOTS AND DEBILITATING PAIN. A HYSTERECTOMY IS NOW SCHEDULED FOR (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042479	BAYER	5/5/2015	5/6/2015

Event Information:

Event Date (B3): 2/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER MY SECOND CHILD WAS BORN AT (B)(6), I HAD SERIOUS BLEEDING ISSUES THAT CONTINUED FOR 9 MONTHS. MY OBGYN DID AN ABLATION, WHICH I SHOULD NEVER HAVE HAD BECAUSE I HAD RA, WHICH HAD BEEN IN REMISSION SINCE 1997. MY DOCTOR WAS SUPPOSED TO DO A TUBAL WHEN MY SON WAS BORN, BUT SHE HAD TROUBLE FINDING MY OVARIES DUE TO A BUILD UP OF SCAR TISSUE FROM THE BIRTH OF MY DAUGHTER 5 YEARS EARLIER. THAT WAS THE REASON I HAD THE ABLATION FIRST, WHICH DID NOT STOP THE BLEEDING. THE NEXT STEP WOULD HAVE BEEN A HYSTERECTOMY, BUT INSTEAD OF THAT, MY DOCTOR PUSHED ME TO HAVE ESSURE PLACED. I WAS GIVEN A TWO PAGE PAMPHLET TO READ, WHICH WAS ALL POSITIVE. I WAS NOT ASKED ANY QUESTIONS, SUCH AS IF I WAS ALLERGIC TO NICKLE, WHICH I AM EXTREMELY ALLERGIC TO! I WAS NOT TOLD THAT THE INSERTS WERE MADE OF PET FIBERS OR NICKLE! ESSURE WAS PLACED IN 2008, 9 MONTHS AFTER THE BIRTH OF MY SON. AFTERWARDS, I DEVELOPED SEVERE STOMACH PAIN, IBS, GERD, MIGRAINES, FATIGUE, HOT FLASHES, LETHARGY, AND A GENERAL FEELING OF NOT BEING WELL, AND I TASTED METAL IN MY MOUTH. I STILL HAVE ALL OF THESE SYMPTOMS TODAY. BY 2010, MY SPINE BEGAN TO DEGENERATE RAPIDLY, AND MY DOCTORS HAD NO EXPLANATION. I DEVELOPED EVEN MORE SYMPTOMS SUCH AS SEVERE ANXIETY, MOODS SWINGS, HAIR LOSS, ANGRY OUTBURSTS, DEPRESSION, INSOMNIA, NEUROPATHY IN MY ARMS AND LEGS, MUSCLE WEAKNESS, THE INABILITY TO WALK, STAND, OR SIT FOR EVEN A SHORT LENGTH OF TIME, AND ABDOMINAL AND CHEST WALL PAIN. I WAS HOSPITALIZED IN EARLY 2010 WITH SEVERE CHEST PAINS, AND HAD SURGERY TO REMOVE MY GALLBLADDER. AFTERWARDS, I STILL HAD SEVERE STOMACH PAIN. I HAD MY SECOND SURGERY IN 2011 WHEN I HAD A FUSION IN MY NECK TO TRY TO RELIEVE THE NEUROPATHY IN MY ARMS. AT THAT TIME, I HAD DEVELOPED 10 BULGING OR PROTRUDING DISKS IN MY SPINE, AND NO ONE KNEW WHY. MY SPINE HAS DEGENERATED SO SEVERELY, THAT I AM NOW ON

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DISABILITY. I TAUGHT SCHOOL FOR 25 YEARS, AND WAS ONLY TWO YEARS AWAY FROM RETIREMENT. OF THE 10 BAD DISKS IN MY BACK, THERE IS ONE IN MY THORACIC SPINE THAT CAN NOT BE SURGICALLY REPAIRED. I AM LOSING THE ABILITY TO WALK, AND AM IN CONSTANT PAIN. THIS PAST SUMMER, JUNE OF 2014, I HAD A BREAST REDUCTION TO TRY TO RELIEVE SOME OF THE PRESSURE OFF MY THORACIC SPINE. I DEVELOPED NECROTIC TISSUE AND INFECTIONS THREE TIMES, AND HAD A TOTAL OF 4 SURGERIES TO TRY REMOVE NECROTIC TISSUE, LEAVING ME DISFIGURED. TODAY, MY RA IS NO LONGER IN REMISSION, AND I WILL NEED ANOTHER SURGERY IN MY NECK TO FUSE MORE DISKS THAT ARE CAUSING MORE NEUROPATHY. MY FAMILY HAS TO TRY TO SURVIVE ON MY DISABILITY INCOME, AND THAT OF MY HUSBAND, WHO IS IN LAW ENFORCEMENT. EACH DAY, MY CONDITION WORSENS. I AM FEARFUL THAT I HAVE, OR WILL DEVELOP TUMORS ON MY SPINE, LIKE SO MANY OF MY E-SISTERS, BECAUSE MY SPINAL CORD IS ALREADY IRRITATED. I AM TOO WEAK TO DO MORE THAN HELP MAKE DINNER, AND THAT IS A GOOD DAY. I HAVE FLARE UPS SO OFTEN, THAT I HAVE ONLY A FEW GOOD DAYS A WEEK NOW. I STILL HAVE SEVERE STOMACH PAIN, MY RA, AND MY SPINE HURTS CONSTANTLY. THE ONLY THING THAT HELPS ME IS A HEATING PAD, BUT NOTHING TAKES AWAY THE PAIN, AND IT IS DEBILITATING. I ALWAYS FEEL SICK, AND I SMILE AND ACT LIKE NOTHING IS WRONG, EVEN THOUGH I KNOW THAT I AM BEING POISONED A LITTLE MORE EACH DAY. ONCE MY INSERTS ARE TAKEN OUT, I WILL NOT GET WELL BECAUSE MOST OF MY PROBLEMS ARE NOW PERMANENT. FOR MYSELF AND MY FAMILY, THAT IS HEARTBREAKING!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042496	BAYER	5/5/2015	5/6/2015

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT ALL BEGAN WITH CRAMPING AND WEIGHT GAIN, I CRAMP NONE STOP, SOME MONTHS I BARLEY HAVE A PERIOD OTHER MONTHS THEY ARE SO BAD WITH HEAVY BLEEDING, CLOTTING, CRAMPING, SEVERE MOOD SWINGS. I FEEL SICK A LOT I AM ALWAYS TIRED AND HAVE A LOT OF HEADACHES. MAJOR BLOATING AND A LOT OF INFLAMMATION. LEG PAIN, SHARP ABDOMINAL PAINS, I HAVE HAD A LOT OF DISCHARGE AND DISCOMFORT IN MY VAGINA, YOU CAN'T PUSH ON MY LOWER ABDOMEN WITH OUT PAIN. FEELING SICK ALL THE TIME. I HAVE ALSO HAD TO HAVE A TOOTH PULLED AND I HAVE HAD A LOT OF THROAT INFECTIONS ABCESSES ON THE BACK OF MY THROAT NEVER HAD ANYTHING LIKE IT IN MY LIFE UNTIL ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042500	BAYER	5/5/2015	5/6/2015

Event Information:

Event Date (B3): 9/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE INFLAMMATORY ARTHRITIS,REYNAUDS, OSTEOARTHRITIS,FIBROMYALGIA, CONSTANT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042501	BAYER	5/5/2015	5/6/2015

Event Information:

Event Date (B3): 9/1/2006	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE INFLAMMATORY ARTHRITIS,REYNAUDS, OSTEOARTHRITIS,FIBROMYALGIA, CONSTANT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042599		5/5/2015	5/13/2015

Event Information:

Event Date (B3): 4/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/30/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WELL, I WAS INTERESTED IN A TUBAL LIGATION AFTER HAVING MY LAST CHILD, AND MY DOCTOR RECOMMEND THAT I GO WITH ESSURE. SHE STATED THAT I HAD LOTS OF SCARS FROM PRIOR SURGERIES AND I PROBABLY HAD LOTS OF SCAR TISSUE AND SHE FELT THAT ESSURE WAS BETTER FOR ME AS IT WAS NONSURGICAL. SHE FELT THAT IF SHE HAD TO OPEN ME UP FOR TUBAL LIGATION SHE'D FALL INTO COMPLICATION. SO I TRUSTED MY DOCTOR AND WENT ALONG WITH IT AS SHE STATED IT WAS FAST, EASY, PERMANENT AND 99.9% EFFECTIVE WITH BIRTH CONTROL. SHE ONLY PROVIDED ME WITH AN ESSURE BROCHURE. I DID READ THE BROCHURE AND EVERYTHING I READ SEEMED PROMISING. I'VE NOTICED THAT MY BODY HAS CHANGED AND I KEEP HAVING ACHES AND PAINS, 6 MONTHS LATER, I EXPERIENCED A VERY ABNORMAL AND PAINFUL MENSTRUAL. I WAS BLEEDING OUT OF CONTROL THAT MY PAD COULD NOT HANDLE ABSORPTION FOR MORE THAN 5 MINS, LITERALLY. I WAS FRIGHTENED AND TOOK MYSELF TO THE EMERGENCY ROOM. THEY ENDED UP SENDING ME HOME AND TOLD ME IF IT DOESN'T LET UP IN COUPLE OF DAYS, THEN I AM TO GO BACK. I DIDN'T KNOW HOW TO TAKE THAT IN AS I WANTED ANSWERS OF REASON WHY THIS WAS HAPPENING. THEY THEMSELVES DIDN'T EVEN KNOW. I FELT ALONE, BUT A FEW DAYS LATER, THE BLEEDING GOT LIGHTER. I COULDN'T MAKE AN APPT WITH MY OB/GYN AS I NO LONGER HAD INSURANCE. I GET SEVERE HEADACHES, BACK ACHES, RASHES, MY TEETH HAVE BEEN CHIPPING BADLY, LOTS OF ACNE (WHEN MY FACE IS PRETTY MUCH CLEAR), BLEEDING AND PAIN DURING INTERCOURSE, AND ABDOMINAL PAIN OFF AND ON, MORE ON THAN OFF. I MISS MENSTRUAL AND SOMETIMES HAVE IT TWICE IN A MONTH. I FEEL MY BODY IS ALL OVER THE PLACE WITH PAIN AND AWKWARDNESS, LIKE MY HORMONES DON'T KNOW HOW TO ACT. I RECENTLY GOT HEALTH INSURANCE AGAIN AND I JUST HAD AN APPT WITH OB/GYN. I LET

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HER KNOW OF MY SYMPTOMS. SHE ORDERED A PELVIC ULTRASOUND, AND I'M WAITING ANXIOUSLY WITH THE RESULTS. I'M SO WORRIED AND HOPE MY COILS HAVE NOT MIGRATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042600	BAYER	5/5/2015	5/13/2015

Event Information:

Event Date (B3): 3/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): D01975

Single Use:
Implant Date (E6): 3/27/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EXPERIENCING MULTIPLE SYMPTOMS: NUMBNESS IN HANDS/ARM/FEET, WEIGHT GAIN AND RECURRENCE OF PMDD SYMPTOMS. NUMBNESS/TINGLING: I STARTED FEELING TINGLING/NUMBNESS IN MY RIGHT HAND AROUND (B)(6) 2015 AND IN MY LEFT HAND ON (B)(6) 2015. ON MY RIGHT SIDE, THE TINGLING/NUMBNESS WAS BROUGHT ON WHEN I WOULD LAY DOWN WITH MY HAND UNDER A PILLOW OR WHEN I WOULD LAY ON MY SIDE. I DIDN'T THINK MUCH OF IT BECAUSE IT IS THE SAME FEELING THAT YOU GET WHEN YOUR HAND 'FALLS ASLEEP.' OVER THE NEXT SEVERAL DAYS, THE TINGLING OCCURRED THROUGHOUT THE DAY AND I COULD NOT IDENTIFY A PATTERN THAT MIGHT BE CAUSING THE ISSUE. AS THE DAYS WENT BY THE TINGLING/NUMBNESS MOVED UP THROUGH MY FOREARM AND NOW STOPS AT MY ELBOW. THERE ARE TIMES WHEN MY WHOLE ARM, FROM THE ELBOW DOWN THROUGH MY FINGERS, WILL BE NUMB AND OTHER TIMES WHEN JUST MY HAND IS NUMB. THERE HAVE ALSO BEEN INSTANCES WHERE I HAVE LOST CIRCULATION IN A FEW OF THE FINGERS ON MY RIGHT HAND. WHEN THIS HAPPENS MY FINGERS TURN WHITE AND THERE IS A DISTINCT DIFFERENCE IN THE TEMPERATURE TO THE EFFECTED VS NON-EFFECTED FINGERS. FOR MY LEFT HAND THE NUMBNESS STARTED ABOUT A MONTH LATER. AT THIS POINT, THE TINGLING IS ISOLATED TO MY FINGERS AND HAS NOT MOVED INTO THE PALM OF MY HAND, FOREARM OR ELBOW. THE NUMBNESS IN MY TOES PRIMARILY OCCURS WHEN I AM SITTING DOWN. IF BOTH LEGS ARE ON THE GROUND THEN THE TINGLING/NUMBNESS SENSATION IS ABOUT THE SAME. IF I SIT WITH MY LEGS CROSSED, THERE IS A SIGNIFICANT DIFFERENCE BETWEEN THE NUMBNESS OF EACH FOOT. WEIGHT GAIN: I HAVE GAINED 10 LBS SINCE THE DATE OF MY PROCEDURE, WHICH WAS (B)(6) 205. PMDD SYMPTOMS: I WAS DIAGNOSED WITH PMDD SEVERAL YEARS AGO BY MY OB/GYN. I HAVE BEEN ABLE TO CONTROL THE SYMPTOMS THROUGH BIO-IDENTICAL HORMONE THERAPY, EXERCISE AND SSRI'S. HOWEVER, AT THE ONSET OF MY FIRST CYCLE, AFTER ESSURE INSERTION, IT

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

WAS EVIDENT THAT THE PMDD SYMPTOMS WERE BACK. THE MOOD SWINGS WERE ATROCIOUS, IRRITABILITY INTOLERABLE, ANXIETY AND EXTREME FATIGUE. THE MOOD SWINGS AND IRRITABILITY STARTED ON (B)(6) AND RAN THROUGH THE WEEK. THE FOLLOWING WEEK, WHEN MY CYCLE STARTED, I COULD BARELY GET OUT OF BED. I WANTED TO SLEEP ALL DAY AND WHEN I WASN'T SLEEPING, I WAS EXHAUSTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042601	BAYER	5/5/2015	5/13/2015

Event Information:

Event Date (B3): 3/8/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/30/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IMPLANTED IN (B)(6) 2013. I FOUND OUT (B)(6) 2015 THAT MY LEFT COIL IS MISSING, CAN'T FIND IT VIA ULTRASOUND (3X) AND NOW I'M PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042518	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 1/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FEELS LIKE RIGHT COIL IS DIGGING INTO MY SIDE. PAIN ALL DAY AND NIGHT. NO SIGNS OF CYSTS OF RIGHT OVARY TO CAUSE PAIN. ITCHING ON AND OFF WHERE COILS WERE PLACED. NICKEL ALLERGY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042519	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 11/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONE OF THE COILS CAME OUT WHEN I WENT TO THE BATHROOM AND WIPED. SINCE THEN I'VE BEEN HAVING CRAMPS, SHARP NEEDLE PAIN, IRREGULAR BOWEL MOVEMENTS, FATIGUE, INSOMNIA, HEAVY BLEEDING, CLEAR MUCUS IN URINE, LACK OF MENTAL CLARITY, ETC. I DIDN'T GO TO THE DOCTOR BECAUSE I HAD NO INSURANCE. I PLAN ON GOING THIS YEAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042520	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 4/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEIGHTENED ALLERGIC REACTION CAUSING ANAPHYLACTIC SHOCK FROM SULFATE WHICH I'D NEVER BEEN ALLERGIC BEFORE ESSURE CAUSING HOSPITALIZATION....SEVERE AND OCCASIONAL UNKNOWN RASHES NEVER HAD BEFORE ESSURE....METAL TASTE IN MY MOUTH...EXTREME HEAVY BLEEDING WITH LARGE CLOTS...NEVER HAD BEFORE ESSURE ...PAINFULLY CRAMPING EXCESSIVE BLOATING...SEVERE CONSTIPATION ..BLOOD IN STOOL....LOST LIBIDO..PAIN DURING SEX BLEEDING AFTERWARDS ...ALL SINCE I HAD THE ESSURE 3 YEARS AGO ONGOING AND WORSENING !!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042521	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY BAD PAIN, FLUID IN ABDOMINAL AREA OF THE IMPLANTS, HAIR LOSS, SLOWLY GAINING WEIGHT, INFLAMED ABDOMEN, PERIODS HEAVY AND LARGE BLOOD CLOTS, SHARP PAINS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042522	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NO PREVIOUS PROBLEMS. AFTER ESSURE I BLED EVERYDAY FOR 6 MONTHS. WHEN I CALLED THE DOCTOR HE SAID THAT WASN'T A SIDE EFFECT OF ESSURE. I EXPERIENCED ALL OVER BODY PAIN. HEADACHES. PAINFUL PERIODS. AFTER THE 6 MONTHS OF BLEEDING I THEN WENT DOWN TO 3 PERIODS A MONTH THEN DOWN TO 2 A MONTH THEN NOW DOWN TO ONE A MONTH AFTER 2 1/2 YEARS. I STILL HAVE BREAKTHROUGH BLEEDING ABOUT 3-4 TIMES A MONTH THAT LASTS ABOUT A DAY OR 2.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042523	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 6/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING EXTREME BLOATING OF MY HANDS , STOMACH SINCE LAST YEAR. HIGH BLOOD PRESSURE. MIGRAINES. IRREGULAR PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042524	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 4/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5042524 #(B)(4). I FORGOT TO MENTION THAT AFTER GETTING ESSURE I HAVE HORRIBLE AND PAINFUL BOWL MOVEMENTS, I OFTEN GET HORRIBLE HEADACHES AND I'M ALWAYS SUPER FATIGUED. THE BLOATING THAT COMES ALONG WITH MY PERIOD IS LIKE NOTHING I'VE EVER EXPERIENCED BEFORE, I LOOK LIKE I'M 6-7 MONTHS PREGNANT FROM HOW SEVER THE BLOATING IS. I HAVE NEVER IN MY LIFE HAD A PROBLEM WITH PERIOD CRAMPING/PAIN OR BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042525	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 4/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD STOMACH PROBLEMS SINCE IMPLANTED WITH ESSURE AND HEAVY BLEEDING AND BLEEDING BETWEEN PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042526	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 10/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ESSURE SINCE 2008. AT FIRST, I HAD NO SIDE EFFECTS UNTIL 7 MONTHS AGO. IT STARTED WITH SEVERE BACK PAIN, THEN WHEN I HAD MY CYCLE, I WAS BLEEDING SO BAD THAT MY PERIOD ONLY LASTED FOR 24 HOURS WHICH IS ABNORMAL. SINCE THEN, I HAVE HAD NOTHING BUT VERY HEAVY BLEEDING AND SEVERE BACK PAIN. I HAVE TO USE A (B)(4), AN OVERNIGHT PAD BECAUSE I SOAK THROUGH THE TAMPONS WITHIN AN HOUR TO AN HOUR AND HALF. ALSO I AM EXPERIENCING PAIN WHERE MY FALLOPIAN TUBES ARE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042528	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 11/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, JOINT PAIN, MUSCLE PAIN, MEMORY ISSUES, DIZZINESS, WEIGHT GAIN, EYE PAIN, VISION CHANGES, A DIAGNOSIS OF ARTHRITIS, ANXIETY AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042529	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING CHRONIC PELVIC PAIN, ABNORMAL MENSES, MIGRAINES, FREQUENT UTI AND PYELONEPHRITIS, DEBILITATING PAIN, BODY TREMORS, NIGHT SWEATS, MOOD SWINGS, WEIGHT FLUCTUATIONS, FREQUENT ILLNESS, LOW IRON, LOW POTASSIUM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042530	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 4/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ITCHY ALL THE TIME, RASHES ON BODY, PAIN IN MY LOWER SIDES DAILY, DEPRESSION, ANXIETY, KEEP GETTING BACTERIAL INFECTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042531	BAYER	5/6/2015	5/6/2015

Event Information:

Event Date (B3): 10/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INFECTION, COLD SWEAT, LOOSING MY HAIR, GAIN WEIGHT A LOT, HEAVY PERIODS WITH CLOTS, CAN'T STRETCH, CAN'T BEND, CAN'T USE TIDE PANTS LIKE BEFORE, TOO MUCH PAIN, FEEL TICKLING INSIDE THAT BEFORE DIDN'T, MY HANDS GET CRAMPING AND SLEEP, SEX DRIVE IS OVER, DON'T FEEL ANY PLEASURE, NO MORE LIKE BEFORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042593	BAYER	5/6/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE IMPLANTED I STARTED HAVE VERY HEAVY, IRREGULAR PERIODS. MY DOCTOR PERFORMED AN ABLATION WHICH I LATER LEARNED SHOULD NOT BE PERFORMED WITH ESSURE. I HAVE EXPERIENCED EXCESSIVE HAIR LOSS, CONSTANT NAUSEA WHICH LED ME TO HAVE AN ENDOSCOPY PERFORMED. THE RESULTS SHOWED I HAD SEVERE STOMACH INFLAMMATION. THIS STARTED RIGHT AFTER I HAD THE ESSURE IMPLANTS PUT IN. I HAVE EXPERIENCED EXCESSIVE WEIGHT GAIN AND ABDOMINAL CRAMPING. I HAVE ALSO EXPERIENCED BLEEDING AFTER INTERCOURSE. I BROUGHT THESE CONCERNS TO MY DOCTOR WHO DID NOT THINK THEY WERE ESSURE RELATED. I HAVE NEVER EXPERIENCED A SINGLE ONE OF THEM UNTIL I HAD THEM IMPLANTED. I AM NOW HAVING MY TUBES AND COILS REMOVED ON (B)(6) IN WHICH I WILL BE MISSING 3 DAYS OF WORK WITHOUT PAY. THIS DEVICE SHOULD BE TAKEN OFF THE MARKET. IT IS NOT SAFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042597	ESSURE	5/6/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE COIL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 919013

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE COILS IN YEAR 2013 AFTER MY DAUGHTER WAS BORN AND I NOW HAVE PAIN IN MY PELVIC AREA. ALSO, WHEN I WALK, I FEEL STABBING IN MY PELVIC AREA AND I HAVE PREGNANCY SYMPTOMS SUCH AS MORNING SICKNESS AND TENDER BREAST AND ALSO NO PERIOD. THIS CRAP NEEDS TO BE OFF MARKET AND OFF MARKET NOW. I ALSO PEE ON MYSELF. THIS IS CRAP. I FEEL TIRED AND NO ENERGY. I HAVE KIDS AND I MOSTLY STAY IN BED WHERE I AM SO TIRED DUE TO THIS PIECE OF CRAPPY, ALL LET THEM PUT ONLINE TO DAMAGE US AND KILL US.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00286	BAYER HEALTHCARE LLC	5/7/2015	5/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS EXPERIENCING METALLIC TASTE IN MOUTH POST ESSURE PLACEMENT. CORRECTION ON (B)(4) 2015 AFTER A COMPANY INTERNAL REVIEW: CASE WAS CONSIDERED MEDICALLY CONFIRMED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT NOT INDICATIVE OF A QUALITY DEFICIT PER SE AND WAS CONSIDERED UNRELATED BY COMPANY AT THIS POINT IN TIME. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015 FROM PHYSICIAN: PHYSICIAN STATED SHE DID REMOVE THE ESSURE COILS AND THE PATIENT'S METALLIC TASTE WENT AWAY. THE PATIENT WAS DOING

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A LOT BETTER. THE METALLIC TASTE OCCURRED DURING THE 3 MONTH WAITING PERIOD FOR THE HSG (HYSTEROSALPINGOGRAM) TEST AND THE PATIENT DIDN'T WANT TO WAIT ANYMORE. SHE HAD ALSO COMPLAINED ABOUT SOME JOINT PAINS AND FATIGUE. THE PATIENT HAD THE ESSURE REMOVED AND ALL HER SYMPTOMS RESOLVED. CASE WAS UPGRADED TO INCIDENT. FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO EXPERIENCED METALLIC TASTE IN HER MOUTH POST ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT. THE DEVICES WERE REMOVED AND SHE RECOVERED FROM THIS EVENT. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. A LARGE NUMBER OF MEDICAL DISORDERS CAN BE ASSOCIATED WITH GUSTATORY DYSFUNCTION, INCLUDING INFECTIONS, DRUG USE AND CHEMICAL EXPOSURE. THE ESSURE MICRO-INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED (NO INFORMATION WAS GIVEN ABOUT PATIENT'S CONCOMITANT CONDITIONS/OR DRUGS). NEVERTHELESS, CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED EVENT AND AS PATIENT RECOVERED WITH DEVICES REMOVAL; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE ESSURE REMOVAL WAS REQUIRED. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 03-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) F

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042645	CONCEPTUS / BAYER	5/7/2015	5/14/2015

Event Information:

Event Date (B3): 4/28/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** AS

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS204
Catalog # (E4):
Lot #(E4): 12267443

Single Use:
Implant Date (E6): 4/28/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD AUTO IMMUNE ISSUES AND LEFT HIP PAIN SINCE NOT LONG AFTER THE IMPLANTATION OF ESSURE BIRTH CONTROL DEVICES. CURRENTLY TREATING WITH NATURAL SUPPLEMENTS DUE TO SENSITIVE NATURE OF THE BODY NOW AFTER ESSURE, MANY MEDICATIONS DO NOT WORK OR CAUSE MASSIVE COMPLICATIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042647		5/7/2015	5/14/2015

Event Information:

Event Date (B3): 5/20/2005 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE EXPERIENCED QUITE A BIT OF PELVIC PAIN, WHICH I NEVER HAD UNTIL I HAD ESSURE CONTRACEPTION. THE PAIN HAS NOT BEEN CONSTANT, BUT WHEN IT FLARES UP, IT IS INTENSE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00287	BAYER HEALTHCARE LLC	5/7/2015	6/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51344

Single Use: Y
Implant Date (E6): 4/10/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 10-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER C51344). PHYSICIAN STATED THAT HE HAD AN ODD INCIDENT WITH A DEVICE. AT THE POINT OF RELEASE OF THE COIL IN THE RIGHT TUBE THE PROXIMAL (UTERINE) PORTION OF THE COIL SHEARED OFF AND FELL INTO THE UTERINE CAVITY. THERE WERE NO DIFFICULTIES WITH THE INSERTION AND THE DISTAL PART OF THE COIL COULD STILL BE SEEN WITHIN THE CORNUA. FOLLOW-UP RECEIVED ON 14-APR-2015: ACKNOWLEDGEMENT NUMBER WAS RECEIVED FROM (B)(6). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT THE POINT OF RELEASE OF THE COIL IN THE RIGHT TUBE THE PROXIMAL (UTERINE) PORTION OF THE COIL SHEARED OFF AND FELL INTO THE UTERINE CAVITY. THE EVENT OF COIL SHEARED OFF, INTERPRETED AS DEVICE BREAKAGE, IS CONSIDERED NON-SERIOUS AND UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, THE PHYSICIAN STATED THERE WERE NO DIFFICULTIES DURING INSERTION AND THAT PART OF THE COIL COULD STILL BE SEEN IN THE CORNUA. CONSIDERING THAT THE REPORTED EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH THERE WAS NO DEATH OR SERIOUS HEALTH DETERIORATION TO THE PATIENT THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL COMPLAINT AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 25-JUN-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00288	BAYER HEALTHCARE LLC	5/7/2015	6/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61987

Single Use: Y
Implant Date (E6): 4/10/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 10/25/2015

Event Description (B5):

OTHER REPORTABLE INCIDENT (MALFUNCTION -BREAKAGE). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 10-APR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER PROVIDED, C61987 WITH EXPIRATION DATE ON 31-MAY-2017). THE PHARMACIST REPORTED THE OCCURRENCE OF BREAKAGE OF THE INTRODUCER'S EXTREMITY AT THE TIME OF INSERTION OF THE HYSTEROSCOPE. HCP MENTIONED THAT THE PHYSICIAN WHO MADE THE ATTEMPT TO PLACE THE ESSURE HAD BEEN TRAINED TO ESSURE PROCEDURE. THERE WAS 1 UNIT CONCERNED AND FULL ESSURE SYSTEM DEVICE (INSERT AND HANDLE) WAS KEPT. THE BROKEN EXTREMITY WAS RETRIEVED WITH A LOT OF DIFFICULTIES. THE FAILURE OF PLACEMENT OCCURRED DUE TO OTHER REASONS. THE MUCOUS MEMBRANES WERE TOO THICK. THE INSERT WAS NOT PUT IN CONTACT WITH THE PATIENT. THE EVENT OCCURRED IN THE OPERATORY ROOM, BEFORE PLACEMENT. NO CAUSE LINKED TO THE PATIENT COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS NOT DONE, THE PROCEDURE WAS STOPPED. THE MATERIAL PROBLEM HAD NO CONSEQUENCES BECAUSE THE PATIENT'S MUCUS WAS TOO THICK AND IT WOULD HAVE BEEN IMPOSSIBLE TO PLACE THE DEVICE. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED BUT THERE WAS A BREAKAGE OF THE INTRODUCER'S EXTREMITY AT THE TIME OF INSERTION OF THE HYSTEROSCOPE AND THE PROCEDURE WAS STOPPED. THE PHYSICIAN STATED THAT PATIENT'S MUCUS WAS TOO THICK AND IT WOULD BE IMPOSSIBLE TO PLACE INSERTS ANYWAY. THERE WERE NO CONSEQUENCES TO THE PATIENT. THE BREAKAGE OF ESSURE INTRODUCER IS CONSIDERED NON-SERIOUS AND UNLISTED ACCORDING TO ESSURE' REFERENCE SAFETY INFORMATION.

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SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, THE INTRODUCER'S BROKE AT THE TIME OF INSERTION IF THE HYSTEROSCOPE. CONSIDERING THAT THE REPORTED EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT AS IT COULD HAVE LED TO DEATH OR SERIOUS DETERIORATION IN HEALTH UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL COMPLAINT AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

UPDATE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 (DEVICE RETURNED): FINAL ASSESSMENT: SINCE PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAI

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00289	BAYER HEALTHCARE LLC	5/7/2015	6/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C22917

Single Use: Y
Implant Date (E6): 3/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN UNITED STATES ON 10-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C22917, INSERTION IN (B)(6) 2015. THE HCP (HEALTH CARE PROFESSIONAL) STATED THE DEVICE WOULD NOT ADVANCE AND BROKE OFF; NO PIECES WERE LEFT IN THE PATIENT. FOLLOW-UP RECEIVED ON 23-APR-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A USABILITY ISSUE. (B)(4). FINAL ASSESSMENT: LOT NUMBER: C22917; PRODUCTION DATE: 12-FEB-2014; EXPIRATION DATE: 28-FEB-2017. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE,

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WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE THE DEVICE BROKE OFF. NO PIECES WERE LEFT IN THE PATIENT. THE REPORTED EVENT WAS CONSIDERED NON-SERIOUS AND IS LISTED ACCORDING TO TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, IT SEEMED DEVICE INSERTION WAS DIFFICULT (PHYSICIAN STATED THE DEVICE WOULD NOT ADVANCE; HOWEVER THE REASON WAS NOT SPECIFIED). ALTHOUGH LIMITED INFORMATION WAS PROVIDED IN THIS CASE, AS DEVICE BREAKAGE OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN OTHER REPORTABLE INCIDENT AS ALTHOUGH DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-MAY-2015: REPORTER INFORMED SHE DOES NOT HAVE INSERTING HCP CONTACT INFORMATION. FOLLOW-UP IS NOT POSSIBLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042668	BAYER HEALTHCARE PHARMACEUTICALS	5/8/2015	5/15/2015

Event Information:

Event Date (B3): 10/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/16/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE. IT HAS BEEN ALMOST 3 YEARS OF PAIN SOMETIMES WHILE INTIMATE. BACK PAIN, SWELLING IN THE STOMACH (ON SIDES BY HIPS) FOR NO REASON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042681	BAYER	5/8/2015	5/15/2015

Event Information:

Event Date (B3): 5/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97498

Single Use:
Implant Date (E6): 3/20/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS SEEKING A PERMANENT CONTRACEPTION AND MY DOCTOR SUGGESTED ESSURE, AT NO GIVEN POINT, WAS I WARNED OF ANY SIDE EFFECTS AND POSSIBLE PROBLEMS THAT I WOULD ENDURE IF I CHOSE ESSURE. I TRUSTED MY DOCTOR AND WENT THROUGH WITH THE IMPLANTATION OF THE COILS. TWO WEEKS AFTER THE SURGERY, I BEGAN TO FEEL EXTREMELY BLOATED, BUT THIS WAS NOT YOUR AVERAGE BLOATING, IT HURT. THIS WENT ON FOR TWO WEEKS WITH NOTHING BUT UNCOMFORTABLENESS. I CALLED THE DOCTORS AND THEY SAID THAT IT WAS MY HORMONES ADJUSTING TO THINGS AND THAT I SHOULD NOT WORRY. THE BLOATING NEVER WENT AWAY AND TWO MONTHS LATER I'M STILL BATTLING WITH THIS PAINFUL BLOATING THAT MAKES ME LOOK LIKE I'M 5 MONTHS PREGNANT. NONE OF MY CLOTHES FIT AND I'M IN CONSTANT DISCOMFORT BECAUSE OF IT. TODAY, I WENT TO THE DOCTORS AND WAS TOLD THAT THERE IS NO RELATION TO THE COILS AND MY SYMPTOMS, I KNOW IT IS NOT TRUE BECAUSE I'VE FOUND (B)(4) WOMEN THAT SHARE THE SAME AND EVEN WORSE SYMPTOMS AS MYSELF. PLEASE REMOVE THIS DEVICE FROM THE MARKET AND END THIS FOR ALL OF US WOMEN WHO BECAME VICTIMS OF THIS NIGHTMARE THAT OUR DOCTORS COULD HAVE PREVENTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042680	BAYER	5/9/2015	5/15/2015

Event Information:

Event Date (B3): 1/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/14/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE BEEN IN PAIN FROM THE MOMENT ESSURE WAS IMPLANTED IN MY FALLOPIAN TUBE. BEEN HOSPITALIZED 2 TIMES AND CURRENTLY SEEKING TO HAVE THIS COIL REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00290	BAYER HEALTHCARE LLC	5/11/2015	5/11/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12712

Single Use: *
Implant Date (E6): 3/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 4/20/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON 13-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN (B)(6) 2015 (C12712, SAMPLE WAS AVAILABLE). ON 15-APR-2015 ADDITIONAL INFORMATION WAS PROVIDED. NURSE REPORTED THAT A PHYSICIAN WAS INSERTING ESSURE IN A PATIENT BUT ESSURE IMPLANT DISCHARGED EVEN IF IT WAS NOT YET BEEN DISCHARGED. THE PATIENT HAD AN INTRAUTERINE SYSTEM INSERTED. CERVIX WAS TIGHT, THREADS WERE NOT VISIBLE. THREADS WERE IN THE UTERINE CAVITY, IUS OTHERWISE NORMALLY IN SITU. BOTH TUBE ORIFICES WERE VISUALIZED, UTERUS STARTED TO CONTRACT BEFORE ESSURE WAS INSERTED TO THE UTERUS. WHILE AWAITING ENDING OF THE CONTRACTION IT WAS DECIDED TO REMOVE IUS. AFTER THAT, ESSURE INSERTION TO THE LEFT SIDE STARTED AGAIN, INSTRUMENT WENT WELL TO TUBE ORIFICE. HOWEVER, THE GOLD MARK WAS NOT ABLE TO GET VISIBLE EVEN WHEN INSTRUMENT WAS MOVED BACK AND FORTH. AT THIS POINT IT WAS FOUND OUT THAT IMPLANT HAS DISCHARGED EVEN IT HAS NOT BEEN DISCARDED YET. END OF SPIRAL SEEMED TO BE STUCK IN BACK WALL OF UTERUS AND IT WAS NOT MANAGED TO REMOVE IT BY PULLING OFF WITH FORCEPS. OTHER END OF SPIRAL WAS ANYWAY MANAGED TO GET OUT FROM CERVICAL CANAL AND IT WAS CAUGHT WITH KOCHER. FINALLY HAD TO CUT SPIRAL WITH SCISSORS, SO THAT PART OF IT STILL REMAINED IN MYOMETRIUM. FOR THE MOST PART SPIRAL WAS GOT OUT FROM UTERUS. AT THIS POINT ESSURE ATTEMPT WAS GIVEN UP (UNSUCCESSFUL) AND LAPAROSCOPY WAS PERFORMED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 27-APR-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE

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FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTION FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE PRODUCT WAS RETURNED TO US FOR THIS COMPLAINT, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE RETURNED PRODUCT. WE TYPICALLY INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. NO MICRO-INSERT WAS RETURNED. THE FINAL ROLLBACK WAS NOT COMPLETED. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. WE ALSO CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THE POSSIBILITY OF MICRO-INSERT HAS A PREMATURE DEPLOYMENT IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. THE RETURNED COMPLAINT SAMPLE WAS INVESTIGATED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO SIMILAR ADVERSE EVENT CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING PLACEMENT THE END OF SPIRAL STUCK IN BACK OF UTERUS AND IT STILL REMAINED IN MYOMETRIUM. THIS EVENT, SEEN AS DEVICE EMBEDMENT, IS SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT USE THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS PARTICULAR CASE, THE DEPLOYMENT OCCURRED BEFORE PROPER TIME AND THE MICRO-INSERT GOT STUCK IN MYOMETRIUM. THE DEVICE WAS HANDLED TO GET OUT FROM CERVICAL CANAL AND IT WAS CAUGHT WITH KOCHER. EVENTUALLY, THE PHYSICIAN HAD TO CUT SPIRAL WITH SCISSORS, SO THAT PART OF IT STILL REMAINED IN MYOMETRIUM. CONSIDERING THIS EVENT IS ASSOCIATED TO THE INSERTION PROCEDURE AND GIVEN ITS NATURE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. SINCE LAPAROSCOPY WAS REPORTED, THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 24-JUL-2015: FURTHER INFORMATION HAS NOT BEEN RECEIVED DESPITE OF ATTEMPTS. CASE CONSIDERED CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00291	BAYER HEALTHCARE LLC	5/11/2015	5/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NON-HEALTH PROFESSIONAL (SECRETARY) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS WERE PROVIDED). THE SECRETARY STATED THAT HCP REMOVED COILS AND FALLOPIAN TUBE. NO ADDITIONAL INFORMATION WAS PROVIDED. CORRECTION PERFORMED REGARDING INFORMATION RECEIVED ON (B)(4) 2015: THE EVENT HCP REMOVED COILS AND FALLOPIAN TUBE PREVIOUSLY CODED TO MEDDRA PT: MEDICAL DEVICE REMOVAL, AFTER INTERNAL REVIEW WAS RECODED TO MEDDRA PT: SALPINGECTOMY. FOLLOW-UP RECEIVED ON (B)(4) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL

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ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HCP REMOVED COILS AND FALLOPIAN TUBE. THIS EVENT, SEEN AS SALPINGECTOMY, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY) MAY BE REQUIRED. IN THIS CASE, VERY LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING ITS NATURE, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 04-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00293	BAYER HEALTHCARE LLC	5/11/2015	5/11/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA SALES REPRESENTATIVE IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN STATED SHE HAD A PATIENT A COUPLE OF YEARS AGO WHO HAD NICKEL ALLERGY AND THE ESSURE DEVICES WERE REMOVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL ALLERGY. THE

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DEVICES WERE REMOVED. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, ALTHOUGH LIMITED INFORMATION WAS PROVIDED, CONSIDERING THE REPORTED EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REPORTED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 06-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00295	BAYER HEALTHCARE LLC	5/11/2015	5/11/2015

Event Information:

Event Date (B3): 4/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71767; CS000N0

Single Use: *
Implant Date (E6): 4/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 13-APR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO UNDERWENT AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER B71767). PHYSICIAN REPORTED THAT ESSURE DEPLOYED BEFORE FINAL ROLLBACK IN THE TUBE AND WHEN ATTEMPTED TO REMOVE, PART OF ESSURE/PET FIBERS BROKE APART. SALPINGECTOMY WAS PERFORMED WITH ESSURE COIL IN TUBE. NO BILATERAL PLACEMENT WAS ACHIEVED. FOLLOW-UP RECEIVED ON 06-MAY-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE (BREAKAGE). (B)(4). FINAL ASSESSMENT: LOT NUMBER: B71767; PRODUCTION DATE: 13-SEP-2013; EXPIRATION DATE: 30-SEP-2016. LOT NUMBER: CS000N0; PRODUCTION DATE: 01-OCT-2014; EXPIRATION DATE: 28-AUG-2017. (B)(4). AS OF 4/27/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THESE LOTS WERE PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE (BREAKAGE) IN THE CONTEXT OF A COMPLICATED INSERTION. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCHES WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS QUALITY DEFECT WAS NOT CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHEN ATTEMPTED TO REMOVE, PART OF ESSURE/PET FIBERS BROKE APART. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SALPINGECTOMY WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: ESSURE DEPLOYED BEFORE FINAL ROLL BACK IN TUBE AND BILATERAL PLACEMENT NOT ACHIEVED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS QUALITY DEFECT WAS NOT CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 07-AUG-2015 THE REQUIRED NUMBERS OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00296	BAYER HEALTHCARE LLC	5/11/2015	5/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF A SUSPICION OF PREGNANCY IN A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011 FOR STERILIZATION. CONSUMER STATED THAT SHE HAD A HSG (HYSTEROSALPINGOGRAM) TEST PERFORMED IN (B)(6) 2011 AND THE HCP (HEALTH CARE PROFESSIONAL) SAID THE LEFT SIDE HAD A CURVE TO IT BUT IT WOULD BE FINE. NOW SHE HAS BEEN A REGULAR PARTNER AND THINKS SHE MAY BE PREGNANT. SHE SUPPOSES TO START HER PERIOD NEXT WEEK SO SHE WILL FINE OUT THEN. SHE HAS HAD SOME MORNING SICKNESS AND HER BREASTS WERE TENDER. CONSUMER ALSO REPORTED THAT WHEN SHE FIRST HAD IT PLACED SHE HAD SOME CRAMPING AND A PERIOD EVERY 2 WEEKS FOR 6 MONTHS TO 1 YEAR. THE HCP GAVE HER SOME PILLS (NAME OF PILL CONFIRMED UNKNOWN TO REPORTER) TO TAKE 10 DAYS ON AND 10 DAYS OFF FOR 2 CYCLES AND THEN THE PERIODS BECAME REGULAR AND NORMAL. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: PREGNANCY IS THE CONDITION OF CARRYING DEVELOPING OFFSPRING WITHIN THE BODY. THE TIME PERIOD DURING WHICH THIS CONDITION EXISTS; GESTATION. PROBABLE CAUSES FOR PREGNANCY INCLUDE: UNSUCCESSFUL BILATERAL TUBAL OCCLUSION (COMPLETE TISSUE INGROWTH), EXPULSION (RELATED TO MICRO-INSERT PLACEMENT ACCURACY), NO 3-MONTH CONFIRMATION TEST (HSG) OR MIS-READ OF HSG, LACK OF PATIENT COMPLIANCE TO IFU (I.E. USE OF ALTERNATE CONTRACEPTION UNTIL CONFIRMATION OF BILATERAL OCCLUSION). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT

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ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN THIS PARTICULAR CASE, CONTRACEPTIVE FAILURE WAS SUSPECTED ADDITIONALLY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON (B)(6) 2015 THE CONSUMER STATED THAT SHE WAS SUPPOSED TO SEE A DOCTOR REGARDING THE PAIN IN (B)(6), BUT SHE DEVELOPED PNEUMONIA. ON (B)(6) 2015 ULTRASOUND WAS DONE AND THE LEFT DEVICE HAD CUT OFF THE BLOOD SUPPLY TO HER OVARY AND SHE IS SCHEDULED FOR A PARTIAL HYSTERECTOMY ON (B)(6) 2015. SHE ALSO STATED THAT DURING THE INSERTION SHE WAS TOLD THERE WAS SCAR TISSUE IN THE LEFT OVARY AND IT WAS BLOCKING THE TUBE, BUT AFTER A WHILE PHYSICIAN WAS ABLE TO INSERT THE DEVICE. AFTER INSERTION SHE HAD PAIN AND DISCOMFORT AND WAS PRESCRIBED WITH PILLS THAT SHE WAS SUPPOSED TO TAKE 16 DAYS ON AND 10 DAYS OFF. SHE SAID THAT THE PILLS DID NOT HELP AND IT AFFECTED HER ULCER, SO SHE COULD NOT CONTINUE ON THEM. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 FROM A NURSE: NEW REPORTER WAS ADDED. ACCORDING TO THE NURSE, CONSUMER REPORTED PAIN, HEAVY MENSTRUAL BLEEDING, PAINFUL PERIODS, AND LEFT LOWER QUADRANT PAIN. SHE HAD A HYSTERECTOMY ON (B)(6) 2015, DUE TO HER PAIN AND HEAVY PERIODS. LEFT OVARY AND LEFT FALLOPIAN TUBE WERE REMOVED ALONG WITH HYSTERECTOMY. PATIENT IS NOT PREGNANT SINCE ESSURE (THE PREVIOUS REPORTED EVENT THINKS SHE MAY BE PREGNANT WAS DELETED). CASE WAS UPGRADED TO INCIDENT. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY MENSTRUAL BLEEDING AND LEFT LOWER QUADRANT PAIN. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH LEFT SALPINGO-OOPHORECTOMY. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR; IN THIS CASE CONSIDERING THE EVENTS NATURE AND IN THE LACK OF ALTERNATIVE EXPLANATION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED.

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ADDITIONALLY, THE SERIOUS EVENTS PNEUMONIA AND LEFT DEVICE HAD CUT OFF BLOOD SUPPLY TO HER OVARY WERE REPORTED; THEY ARE UNLISTED FOR ESSURE AND DUE TO THEIR NATURE WERE CONSIDERED AS UNRELATED TO THE SUSPECT INSERT. ALSO, AT INITIAL REPORT CONSUMER SUSPECTED ON A PREGNANCY, HOWEVER THIS EVENT WAS LATER DENIED. THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS UPGRADED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION (HYSTERECTOMY CONFIRMED, REQUIRED INTERVENTION). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00297	BAYER HEALTHCARE LLC	5/11/2015	5/11/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/2/2009
Explant Date (E7): 2/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT (>=18Y & <65Y) FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2014 REFERRING TO HERSELF. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009 FOR STERILIZATION. SHE WAS NOT PREGNANT. IN AN UNSPECIFIED DATE THE CONSUMER WENT TO THE EMERGENCY ROOM (ER) FOR A STOMACH VIRUS. SHE HAD A CT SCAN (COMPUTERIZED TOMOGRAM) AND HER ESSURE SHIFTED. SHE HAD BEEN BLEEDING FOR OVER 3 WEEKS. ESSURE WAS ONGOING. FOLLOW UP (B)(4) 2014: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(4) 2015 VIA ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE. PATIENT'S INITIALS, DATE OF BIRTH, HEIGHT

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AND WEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. CONCOMITANT CONDITION INCLUDED OVERWEIGHT. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES AND ANY OTHER RELEVANT MEDICAL HISTORY. ON (B)(6) 2009 ESSURE WAS EASILY INSERTED. SHE WAS NOT POSTPARTUM AT THE TIME OF INSERTION. LIDOCAINE 1%, TORDAL AND 10MG VALIUM WERE APPLIED DURING INSERTION. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. PAIN MEDICATION POST PROCEDURE 24 HOURS WAS GIVEN. SEASONIQUE WAS USED AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. ON (B)(6) 2010 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED IMPLANTS IN PLACE AND TUBES OCCLUDED. THERE WAS NO PERFORATION. ANY PATHOLOGY RESULTS WERE DENIED AND THE PATIENT WAS NOT HOSPITALIZED. THE PHYSICIAN COULD NOT BE SURE THAT THE CONDITION WAS CAUSED BY ESSURE. ON (B)(6) 2015 ESSURE WAS REMOVED BY HYSTERECTOMY/SALPINGECTOMY (LAVH/BSO). IT WAS REPORTED THAT THE REMOVAL WAS MEDICALLY NECESSARY. ULTRASOUND WAS PERFORMED POST ESSURE REMOVAL. PATHOLOGY RESULTS SHOWED SECRETORY ENDOMETRIUM. THE SYMPTOMS/PAIN RESOLVED AFTER SURGERY. THE OUTCOME WAS REPORTED AS GOOD. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER ESSURE SHIFTED AND SHE WAS BLEEDING FOR OVER 3 WEEKS. THESE EVENTS, INTERPRETED AS DEVICE DISLOCATION AND GENITAL BLEEDING, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND THEY ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. ALSO, DURING ESSURE MICRO-INSERT USE THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, CONSUMER HAD A CT SCAN WHICH SHOWED HER ESSURE SHIFTED. NO INFORMATION WAS PROVIDED REGARDING THE EXACT POSITION OF THE INSERT. SHE ALSO REPORTED THAT SHE HAS BEEN BLEEDING FOR OVER 3 WEEKS. CONSIDERING THE AVAILABLE INFORMATION AND NATURE OF THE REPORTED EVENTS A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENT WAS REPORTED. THIS CASE WAS INITIALLY SEEN AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS UPGRADED TO INCIDENT, SINCE IT WAS INFORMED THAT A REQUIRED INTERVENTION (HYSTERECTOMY) WAS PERFORMED TO REMOVE ESSURE. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042702	BAYER	5/11/2015	5/18/2015

Event Information:

Event Date (B3): 4/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/11/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2013. I HAVE HAD CONSTANT PROBLEMS SINCE. IT FORCED ME INTO MENOPAUSE, I HAVE CONSTANT LOWER ABDOMEN PAIN, BACK PAIN, SEVERE BLOATING, HEADACHES, AND MY ORGANS ARE CONSTANTLY HURTING. I HAVE BEEN IN AND OUT OF THE EM. I HAVE HAD CAT SCANS, FULL BODY X-RAYS AND NOBODY CAN TELL ME ANYTHING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042707	BAYER	5/11/2015	5/18/2015

Event Information:

Event Date (B3): 7/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 7/13/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED IN (B)(6) 2012. WITHIN A MONTH HAD NAUSEA AND SEVERAL HEADACHES, FATIGUE. CONTINUED HAD SLEEP PROBLEMS, GI PROBLEMS, WEIGHT GAIN, AND BLOATED BELLY. HAD HYSTO (B)(6) "2016". COIL HAD PROTRUDED THRU.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00292	BAYER HEALTHCARE LLC	5/11/2015	6/9/2015

Event Information:

Event Date (B3): 4/13/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71767

Single Use: Y
Implant Date (E6): 4/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 13-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION. THE LOT NUMBER USED WAS B71767. THE ESSURE COIL WAS INSERTED IN LEFT TUBE; HOWEVER UPON INSERTION IN RIGHT TUBE THE DEVICE WOULD NOT HAVE FINAL ROLL BACK AND THE BUTTON COULD NOT BE PRESSED. AT THIS POINT THE PHYSICIAN TRIED TO REMOVE WHOLE DEVICE AND IT WAS ALREADY DEPLOYED. UPON REMOVAL THE DEVICE WAS IN PIECES. THEY HAD TO REMOVE PIECES OF IT AND PERFORM A SALPINGECTOMY; ALL PIECES WERE REMOVED. ONE PIECE OF COIL WAS SENT TO LAB ALONG WITH THE RIGHT FALLOPIAN TUBE. THE ESSURE ON LEFT SIDE WAS CONTINUED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 27-APR-2015. (B)(4). FINAL ASSESSMENT : FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE REMOVAL. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE PHYSICIAN TRIED TO REMOVE THE DEVICE AND UPON REMOVAL IT WAS IN PIECES (INTERPRETED AS DEVICE BREAKAGE), HAD TO REMOVE PIECES AND DID SALPINGECTOMY. DEVICE BREAKAGE WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND, AS IT OCCURRED DURING AN ATTEMPT TO REMOVE THE INSERT, WAS CONSIDERED LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, UPON INSERTION IN RIGHT TUBE THE ESSURE WOULD NOT HAVE FINAL ROLL BACK AND BUTTON COULD NOT BE PRESSED. THE PHYSICIAN TRIED TO REMOVE THE DEVICE AND UPON REMOVAL THE DEVICE WAS IN PIECES. A SALPINGECTOMY WAS PERFORMED AND ALL PIECES OF ESSURE WERE REMOVED FROM THE RIGHT SIDE. CONSIDERING THAT THE BREAKAGE OCCURRED DURING THE PROCEDURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS ASSESSED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION (SALPINGECTOMY). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 04-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00294	BAYER HEALTHCARE LLC	5/11/2015	6/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C76452

Single Use: *
Implant Date (E6): 4/7/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 13-APR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C76452 INSERTED ON (B)(6) 2015. ON (B)(6) 2015, TIP OF ESSURE WITH 4 COILS DETACHED AFTER DEPLOYMENT. BILATERAL PLACEMENT WAS ACHIEVED. THERE WAS NO INJURY TO THE PATIENT. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-APR-2015. (B)(4). FINAL ASSESSMENT: LOT C76452; EXPIRATION DATE: 31-JUL-2017 MANUFACTURING DATE: 14-JUL-2014. THE REPORTER NOTED A SAMPLE WAS AVAILABLE FOR RETURN, BUT WE HAVE NOT YET RECEIVED THE RETURNED SAMPLE. SINCE NO PRODUCT HAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE CANNOT CONFIRM THIS QUALITY COMPLAINT; HOWEVER, BASED ON THE COMPLAINT DESCRIPTION PROVIDED, WE ARE ABLE TO CONCLUDE THAT A QUALITY ISSUE IS PLAUSIBLE. IT IS POSSIBLE DURING THE MANUFACTURING ASSEMBLY PROCESS A SMALL GAP WAS LEFT BETWEEN THE INNER COIL AND INNER CATHETER (THEY SHOULD BE BUTTED TOGETHER DURING ASSEMBLY). WHEN THE OUTER COIL OF THE MICRO-INSERT IS WOUND DOWN A SMALL PORTION OF THE COIL CAN BECOME TRAPPED IN THE GAP. IF A DEVICE HAS THIS ISSUE, WHEN THE PHYSICIAN PRESSES THE BUTTON TO RELEASE THE MICRO-INSERT, THE OUTER COIL MAY SEVER ITSELF AS IT IS BEING DEPLOYED FROM THE CATHETER. THIS SEVERING OCCURS INSIDE THE

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CATHETER PRIOR TO THE PIECES BEING DEPLOYED FROM THE CATHETER. THE SEVERING OF THE COILS INSIDE THE CATHETER DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PATIENT. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT - BUT PLAUSIBLE. ACCORDING TO THE TECHNICAL ASSESSMENT A QUALITY DEFECT WAS NOT CONFIRMED BUT CONSIDERED PLAUSIBLE. BASED ON THE PROVIDED INFORMATION THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING MEDDRA LLT: DEVICE BREAKAGE. ALTHOUGH THE TECHNICAL INVESTIGATION CONCLUDED A POTENTIAL CAUSAL RELATIONSHIP BETWEEN THE TECHNICAL ISSUE REPORTED AND A QUALITY DEFECT, THE ASSIGNED FINAL RISK CATEGORY IV REFLECTS A DEFECT WHICH DOES NOT POSE A HAZARD TO PATIENT'S HEALTH. IN SUMMARY, A CAUSAL RELATIONSHIP BETWEEN THE POTENTIAL PRODUCT QUALITY ISSUE AND ADVERSE EVENTS CANNOT BE ASSESSED, AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE TIP OF ESSURE WITH 4 COILS DETACHED AFTER DEPLOYMENT. BILATERAL PLACEMENT WAS ACHIEVED. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. PHYSICIAN REPORTED THAT AFTER DEPLOYMENT THE TIP OF ESSURE WITH 4 COILS DETACHED. THEREFORE, SINCE THE BREAKAGE OCCURRED DURING THE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ACCORDING TO THE PRODUCT TECHNICAL ANALYSIS, A QUALITY DEFECT WAS NOT CONFIRMED BUT CONSIDERED PLAUSIBLE, AND ALTHOUGH THE TECHNICAL INVESTIGATION CONCLUDED A POTENTIAL CAUSAL RELATIONSHIP BETWEEN THE TECHNICAL ISSUE REPORTED AND A QUALITY DEFECT, THE ASSIGNED FINAL RISK CATEGORY REFLECTS A DEFECT WHICH DOES NOT POSE A HAZARD TO PATIENT'S HEALTH. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 28-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00299	BAYER HEALTHCARE LLC	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 2/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91747

Single Use:
Implant Date (E6): 2/27/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C91747 FOR STERILIZATION. IT WAS REPORTED THAT PHYSICIAN WAS ABLE TO GET THE RIGHT SIDE AND THE DEVICE WAS IN WITH 0 TRAILING COILS. THERE WAS A POSSIBLE PIERCE ON THE LEFT WHERE DOCTOR COULD NOT GET IT IN. THE PROCEDURE WAS TERMINATED. THE DOCTOR WAS ATTEMPTING TO DO THE NOVASURE AFTER THE ESSURE (OFF LABEL USE) BUT THERE WAS SPECULATION THAT THERE WAS TOO MUCH FLUID DEFICIT. THE PROCEDURE TOOK 18 MINUTES. PHYSICIAN USED A PRESSURE BAG FOR THE FLUIDS; SHE ALWAYS USE THAT. THE PATIENT WAS DESATTING. THE DOCTOR SAID SHE WAS DOING OKAY. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: LOT NUMBER C91747 PRODUCTION DATE: 7/30/14 EXPIRATION DATE: 7/31/17. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED

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QUALITY DEFECT AND HANDLING ERROR. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON (B)(4) 2015: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT ESSURE REPRESENTATIVE WAS PRESENT THROUGHOUT THE PROCEDURE. ACCORDING TO HEALTH CARE PROFESSIONAL, REPRESENTATIVE KEPT SUGGESTING INCREASING PRESSURE IN PRESSURE BAG WITHOUT ACCOUNTABILITY FOR FLUID DEFICIT. THEY ENDED UP WITH 2.5 L NS DEFICIT. IN ADDITION, PHYSICIAN INFORMED THAT PROCEDURE WAS LONGER THAN NORMAL AND REPRESENTATIVE SUGGESTED NOT LEAVING ANY TRAILING COILS (RIGHT SIDE) BECAUSE THEY WERE DOING NOVASURE AFTERWARDS. ON LEFT SIDE, TUBAL OSTIUM COULDN'T BE READILY VISUALIZED SO ESSURE WAS ABANDONED. AT THAT TIME, FLUID DEFICIT WAS DISCOVERED BY PHYSICIAN. PATIENT HAD DESATURATED TO 80 AND CAME BACK TO NORMAL. PATIENT WAS HOSPITALIZED. DIAGNOSTIC LAPAROSCOPY WAS DONE AND NO UTERINE OR FALLOPIAN TUBE PERFORATION WAS SEEN. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2015: NEW REPORTERS WERE ADDED. PATIENT'S INITIAL AND DATE OF BIRTH WERE UPDATED. HER WEIGHT WAS (B)(6). SHE WAS NULLIPAROUS AND WAS NOT PREGNANT (HCG WAS NEGATIVE). ON (B)(6) 2010, MIRENA WAS INSERTED. SHE COMPLAINED OF FIBROIDS, MENORRHAGIA, VAGINAL SPOTTING AND IRREGULAR BLEEDING WITH MIRENA. SHE WAS GIVEN 1 MONTH OF GENERESS BIRTH CONTROL PILL FOR VAGINAL BLEEDING BUT IT WAS NOT SURE IF SHE TOOK THE MEDICATION. ON (B)(6) 2015, PATIENT HAD AN ATTEMPT TO GET MIRENA REMOVED BUT FAILED. THREADS WERE NOT VISUALIZED AT THE CERVICAL OS. PATIENT DECIDED TO HAVE PERMANENT STERILIZATION AND HENCEFORTH DECIDED TO HAVE ESSURE. ON (B)(6) 2015, MIRENA WAS REMOVED UNDER HYSTEROSCOPIC GUIDANCE. ESSURE WAS PLACED UNDER GENERAL ANESTHESIA AT THE SAME DAY. SHE WAS NOT IN A POSTPARTUM STATE AT TIME OF PROCEDURE. THE RIGHT FALLOPIAN TUBAL OSTIUM WAS IDENTIFIED AND ESSURE WAS PLACED WITHOUT DIFFICULTY. THE INSERTION OF ESSURE WAS DIFFICULT ON LEFT SIDE; LEFT FALLOPIAN TUBE WAS IDENTIFIED AND ESSURE DEPLOYMENT ATTEMPTED. IT WAS SOON DISCOVERED THAT WHAT HAPPENED TO BE A TUBAL OSTIUM WAS ACTUALLY A SHORT FALSE TRACT AND IN FACT THE OSTIUM WAS OBSCURED FROM VIEW UNDERNEATH THE THICKENED ENDOMETRIUM PRESENT IN THE VICINITY. ATTEMPT WAS MADE TO REMOVE THE ENDOMETRIAL TISSUE WITHOUT SUCCESS. DECISION WAS MADE TO ABANDON THE PROCEDURE AND PROCEED WITH DILATION AND CURETTAGE. CERVIX WAS DILATED TO 11 MM. NOVASURE DEVICE OPENED AND BARELY PASSED THROUGH VAGINA WHEN FLUID DEFICIT WAS NOTED (FLUID LOSS WAS 2.5L; NS DEFICIT). PROCEDURE WAS ABANDONED AND NOVASURE DEVICE RETRACTED. DURING THIS TIME, PATIENT EXPERIENCED AN EPISODE OF HYPOTHERMIA AND HYPOTENSION FROM ANESTHETIC (NAME OF ANESTHETIC WAS NOT PROVIDED) GIVEN. PATIENT WAS EXAMINED AND ABDOMINAL DISTENTION WAS NOTED. THE TIME OF PROCEDURE WAS LONGER THAN NORMAL. IT WAS DECIDED TO PERFORM A DIAGNOSTIC LAPAROSCOPY TO LOOK FOR POTENTIAL CAUSE OF FLUID DEFICIT. NO PERFORATION WAS IDENTIFIED. HOWEVER MODERATE FLUID IN THE CUL DE SAC WAS IDENTIFIED AND EVACUATED. AT THIS TIME, A BILATERAL TUBAL FULGURATION WAS DONE BECAUSE PATIENT DESIRED FOR PERMANENT STERILIZATION AND BECAUSE INSERTION OF ESSURE ON LEFT SIDE FAILED. PATIENT WAS ADMITTED FOR FURTHER OBSERVATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO HAD MIRENA (LEVONORGESTREL) INSERTED AND EXPERIENCED IRREGULAR BLEEDING. LATER, DURING IUD REMOVAL ATTEMPT, THE THREADS OF MIRENA WERE NOT VISUALIZED AT THE CERVICAL OS. IN THE SAME DAY, SHE HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING PLACEMENT THERE WAS TOO MUCH FLUID DEFICIT / 2.5 L NS DEFICIT AND THEN PATIENT WAS DESATTING (PATIENT HAD DESATURATED TO 80) AND PRESENTED HYPOTHERMIA. ALL EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND HOSPITALIZATION. THE EVENTS WITH MIRENA, SEEN AS GENITAL BLEEDING AND DEVICE DISLOCATION ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND MIRENA. THE EVENTS OCCURRED DURING ESSURE INSERTION ARE UNLISTED FOR BOTH REFERENCE SAFETY DATA, EXCEPT FLUID DEFICIT WHICH IS LISTED ONLY FOR ESSURE.

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REGARDING THE EVENTS THAT OCCURRED WITH MIRENA THERAPY, CAUSALITY WITH THE IUD IS ASSESSED AS RELATED. SYSTEMIC LEAKAGE OF FLUIDS MAY OCCUR DURING DIFFICULT AND PROLONGED ESSURE INSERTIONS. HYPOXEMIA IS A DECREASE IN THE PARTIAL PRESSURE OF OXYGEN IN THE BLOOD, WHILE HYPOTHERMIA IS DEFINED AS A CORE BODY TEMPERATURE BELOW 35ºC. IN THIS CASE, PHYSICIAN INSERTED ESSURE ON THE RIGHT SIDE BUT WITH 0 TRAILING COILS VISIBLE IN CORNUA. ON LEFT SIDE TUBAL OSTIUM COULDN'T BE READILY VISUALIZED SO ESSURE WAS ABANDONED. THEN, THE DOCTOR ATTEMPTED TO DO THE NOVASURE AFTER THE ESSURE (OFF LABEL USE) BUT THERE WAS TOO MUCH FLUID DEFICIT (2,5 L NS). THE PROCEDURE WAS LONGER THAN NORMAL AND PATIENT WAS DESATTING AND HAD HYPOTHERMIA AND HYPOTENSION. HENCE, NOVASURE WAS NOT DONE. AFTERWARDS, THE PHYSICIAN INFORMED THE PATIENT WAS HOSPITALIZED FOR FURTHER OBSERVATION. CONSIDERING THE SUSPECTED EVENTS OCCURRED DURING ESSURE INSERTION OR SHORTLY THEREAFTER, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. LATER, IT WAS INFORMED THE PATIENT WAS HOSPITALIZED; THEREFORE THIS CASE WAS UPGRADED TO INCIDENT. UPDATED PTC ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP FROM 12-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. CORRECTION PERFORMED REGARDING INFORMATION RECEIVED ON 12-JUN-2015: UPON INTERNAL REVIEW, NO UPDATED PTC RESULTS WILL BE PROVIDED (NO CHANGES IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00300	BAYER HEALTHCARE LLC	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/25/2012
Explant Date (E7): 1/22/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. IT WAS REPORTED THAT WITHIN WEEKS OF THE PROCEDURE SHE WAS FEELING EXTREME PAIN IN LOWER BACK AND ABDOMEN, MIGRAINES, BLOATING, NAUSEA AND STOMACH PAIN. THE CONSUMER WAS IGNORED BY THE PHYSICIAN THAT IMPLANTED THESE DEVICES AND HAD TO SEEK ANOTHER DOCTOR. THE NEW PHYSICIAN PERFORMED A HYSTERECTOMY ON (B)(6) 2013. THE ESSURE COILS WERE REMOVED DURING THIS SURGERY AND ALL SYMPTOMS DISAPPEARED AFTERWARDS. FOLLOW UP FROM (B)(4) 2015: NO NEW INFORMATION PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED EXTREME PAIN IN LOWER BACK AND ABDOMEN. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH DEVICES REMOVAL AND RECOVERED FROM THE EVENTS. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC, BACK AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, A CLOSE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE EVENTS WAS REPORTED. GIVEN THIS INFORMATION AND CONSIDERING CONSUMER'S SYMPTOMS DISAPPEARED WITH DEVICES REMOVAL; CAUSALITY BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE REQUIRED INTERVENTION, THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FURTHER INFORMATION WILL BE REQUESTED SINCE THIS IS A HEALTH AUTHORITY CASE.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 29-JUL-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE W

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042609	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 1/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MENSTRUAL CYCLE WOULD LAST FOR OVER A MONTH. CONSTANT HEADACHE, STABBING ABDOMINAL PAIN, FATIGUE, JOINT PAIN, HOT FLASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042610	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5042610 #(B)(4) I ALSO PLAN TO GET THEM REMOVED BUT HAVE TO WAIT UNTIL I CAN AFFORD IT AND TAKE THE TIME OFF. MY LOT # IS 678819.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042611	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DATE IS WHEN I GOT PROCEDURE. I CAN'T REALLY PIN POINT WHEN I STARTED HAVING SIDE EFFECTS, AS I WASN'T REALLY LOOKING FOR ANYTHING. SYMPTOMS ARE OCCASIONAL SEVERE ABDOMINAL PAIN, MIGRAINES AT LEAST 3 X A MONTH VERY RARELY BEFORE, NIGHT SWEATS, OCCASIONAL BLURRY VISION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042612	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ON THE RIGHT SIDE. WORSE DURING CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042613	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 4/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEFORE ESSURE I WAS HEALTHY. NO MEDICINE. NO PROBLEMS. SINCE I SUFFER FROM MIGRAINES, PAINFUL PERIODS AND SEX, HEAVIER PERIODS, MUSCLE SPASMS, WEIGHT GAIN, HIGH BLOOD PRESSURE, ANXIETY, DEPRESSION, NAUSEA, VOMITING, DIARRHEA, SWELLING OF MY STOMACH, PAIN THROUGHOUT MY BODY, HAIR GROWING IN PLACES I NEVER HAD BEFORE, AND A METALLIC TASTE AT TIMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042614	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 4/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD THIS PELVIC PAIN AND SWELLING ALONG SKIN PROBLEMS, ITCHING THAT I CANNOT SCRATCH CAUSE ITS INTERNAL, ENLARGED ABDOMEN, HEADACHE, IRREGULAR MENSES, RECENTLY FEET SWELLING, TINGLING IN FINGERS AND TOES, HAIR LOSS, METAL TASTE IN MOUTH, BURNING SENSATION IN ABDOMEN, YEAST INFECTION, BACTERIAL VAGINITIS. IM ALLERGIC TO NICKEL. I HAD AN ULTRASOUND WAITING FOR RESULTS AND I NEED A BIOPSY FOR IRREGULAR CELLS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042615	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 3/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVEN'T STOP BLEEDING AND BAD CRAMPS TO THE POINT I DON'T WANT ANYBODY TO TOUCH ME. IF I SIT STILL NO PAIN BUT SOON AS I START ANY ACTIVITY I GET PAIN IN THE LOWER ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042616	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 8/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, SWELLING, MIGRAINES, SEVERE FATIGUE, WEIGHT GAIN AND LOSS, HAIR FALLING OUT, NAUSEA, CRAMPING, ALLERGIES, FREQUENT COLDS, TROUBLE BREATHING, ANXIETY, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042617	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP 1 #FDA MW5042617 #(B)(4). AS OF (B)(6), I HAVE NOW BEEN GIVEN DIAGNOSES OF FIBROMYALGIA AND AN ALLERGY TO SILVER. ALSO, INTERCOURSE HAS BEGUN TO BE PAINFUL. AND I NOW HAVE CONSTANT PAINS THAT FEEL LIKE CONTRACTIONS THAT YOU HAVE DURING THE BEGINNING OF LABOR. MENSTRUAL PAIN HAS BECOME SO BAD IT'S HARD TO EVEN GET OUT OF BED THE FIRST DAY, AND HAS BECOME HEAVY ENOUGH THAT I CAN GO THROUGH A SUPER ABSORBANT TAMPON EVERY 1-2 HOURS. FOLLOWED BY CLOTS RANGING FROM SMALL (LESS THAN DIME SIZED) TO LARGE (APPROX. QUARTER - HALF DOLLAR SIZED)

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042618	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE DAY MY ESSURE COILS WERE INSERTED I'VE HAD SEVERE PAIN ON THE RIGHT SIDE OF MY BODY. SO SEVERE AT TIMES I CANNOT STAND OR WALK. MY PERIODS ARE EXCRUCIATINGLY PAINFUL AND I BLEED EXCESSIVELY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042619	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 1/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STOMACH BLOATING TO WHERE I LOOKED MONTHS ALONG IN PREGNANCY, HAIR LOSS, MISSED PERIODS FOR MONTHS, HEAVY HEMORRHAGING MENSTRUAL CYCLES, BRAIN FOG, LOWER BACK KIDNEY PAIN, UNABLE TO FEEL RESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042620	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC BLOATING DUE TO PET FIBER, INFLAMMATION, EXTREMELY HEAVY PERIOD, LOSS OF LIBIDO, HAIR LOSS, FATIGUE, SEIZURES, MIGRAINES, ABDOMINAL PAIN, INCREASING ALLERGY TO NICKEL, GASTROINTESTINAL ISSUES, BRITTLE NAILS, DENTAL PROBLEMS, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042621	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 5/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE FIRST PROCEDURE WAS BOTCHED BY MY DR AND RESULTED IN A PERFORATION TO MY UTERUS. ONE MONTH LATER HE WAS ABLE TO INSERT THE DEVICES IN BOTH TUBES. THE PROCEDURE WAS INCREDIBLY PAINFUL! THE COIL HE TRIED TO PLACE IN THE LEFT TUBE FELL APART ON INSERTION AND HAD TO BE REMOVED AND REPLACED. THE RIGHT SIDE WAS PLACED WITH MUCH FORCE. I WAS HOLDING MY HUSBAND'S HAND AS WELL AS THE ULTRASOUND TECH'S AND TRYING TO DO LAMAZE BECAUSE IT WAS EXCRUCIATING! I STARTED HAVING SEVERE CRAMPING AND BLEEDING THE SAME DAY. THIS WENT ON FOR ALMOST FOUR MONTHS. CONSTANT PAIN, VOMITING BLEEDING. AN ULTRASOUND CONFIRMED THE RIGHT COIL WAS MIGRATING AND CAUSING DAMAGE TO MY FALLOPIAN TUBE. I HAD SURGERY TO REMOVE BOTH TUBES AND COILS AND HAD TO GIVE PERMISSION FOR A FULL HYSTERECTOMY IF THE DAMAGE WAS BEYOND THE TUBES. I ENDED UP WITH AN INFECTION IN ONE OF THE INCISION SITES DUE TO HAVING TO HAVE IT REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042622	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED FEELING SORE ALL OVER ALL OF MY JOINTS WERE STIFF AND I CAME OUT WITH A TERRIBLE RASH ON MY HANDS. SEVERE NIGHT SWEATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042623	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 11/8/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAIN IN PELVIC AREA, FATIGUE, NOT NORMAL PAIN DURING MENSTRUATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042624	BAYER	5/12/2015	5/12/2015

Event Information:

Event Date (B3): 8/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD PAIN IN LEFT HIP RADIATING DOWN TO FOOT, BAD CHEST PAINS, VERY EXHAUSTED, PAIN IN LEFT ARM, BAD PELVIC PAIN FEELS LIKE ELECTRICAL SHOCKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042704	BAYER	5/12/2015	5/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2008, I HAD A DEVICE INSERTED TO HELP PREVENT PREGNANCY. THE DEVICE WAS CALLED ESSURE. FOR THE PAST YEAR, I HAVE BEEN EXPERIENCING PROBLEMS AND WITHIN THE PAST 6 MONTHS MY PROBLEMS HAVE GOTTEN WORSE. AT FIRST, I EXPERIENCED WEIGHT GAIN AND MAJOR BLOATING. NOT, I HAVE EXCESSIVE BLEEDING, ABNORMAL PERIODS, PAIN IN MY LOWER ABDOMEN THAT SHOOTS INTO MY BACK AND DOWN MY LEGS. I CAN NO LONGER LAY FLAT AS I EXPERIENCE A BURNING SENSATION THROUGHOUT MY LOWER ABDOMEN, MOOD SWINGS, DRY BRITTLE HAIR, ETC., AND MY OB SAYS THEY ONLY WAY TO FIX THE PROBLEM IS TO HAVE A HYSTERECTOMY WHICH MY INSURANCE MAY NOT EVEN COVER (BY THE WAY IS A (B)(6) PROCEDURE). I HAVE BEEN UNABLE TO WORK BECAUSE OF THE PAIN. THE PRODUCT NEEDS TO BE TAKEN OFF THE MARKET. I AM NOT SURE OF THE EXACT DATE I HAD THE PROCEDURE DONE, HOWEVER I AM GUESSING IN 2009-2010.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042731	BAYER/CONCEPTUS	5/12/2015	5/19/2015

Event Information:

Event Date (B3): 5/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 676715

Single Use:
Implant Date (E6): 5/31/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ESSURE COILS IMPLANTED AND SINCE HAVING THEM INSERTED I HAVE BEEN HAVING MORE BODY ACHES, NECK ACHES, PAIN IN MY ABDOMEN OFF AND ON AS WELL AS NO MORE PERIODS, DRY, PAINFUL SEX, AND BRAIN FOG. WITHIN WEEKS OF THE IMPLANT I HAD PAIN, BLOATING, AND PAIN IN MY LEFT SIDE FOR OVER 8-9 MONTHS. THE PAIN DID SUBSIDE BUT I STILL HAVE THE ABOVE MENTIONED SYMPTOMS. I HAVE NECK/SHOULDER/UPPER BACK PAIN DAILY. MY NECK IS SO STIFF I CAN HARDLY MOVE IT SOME DAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042736	BAYER HEALTHCARE	5/12/2015	5/19/2015

Event Information:

Event Date (B3): 5/12/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): C40242

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE BAYER ESSURE PERMANENT BIRTH CONTROL DEVICE WAS DEPLOYED INTO PT'S RIGHT FALLOPIAN TUBE. THE COILS WERE RELEASED AS THE DEVICE WAS EXITING THE FALLOPIAN TUBE. THE COILS DID NOT IMPLANT INTO THE FALLOPIAN TUBE AND WERE THEN REMOVED. ANOTHER DEVICE WITH A DIFFERENT LOT NUMBER WAS USED WITHOUT ANY FURTHER ISSUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00298	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A56796 / 948836

Single Use:
Implant Date (E6): 12/21/2012
Explant Date (E7): 3/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR STERILIZATION. THE HSG (HYSTEROSALPINGOGRAM) WAS DONE IN (B)(6) 2013 AND SHOWED SUCCESSFUL OCCLUSION AND LOCATION. PATIENT WENT TO PHYSICIAN'S OFFICE ON (B)(6) 2015 AND SHE DID NOT COMPLAIN OF ANY ISSUES. TWELVE DAYS LATER PATIENT CAME BACK, COMPLAINED OF BLEEDING, CHEST PAIN, PAIN, DEPRESSION, FATIGUE, BACK PAIN AND LOSS OF LIBIDO. THE PHYSICIAN THINKS THAT IT IS IBS (IRRITABLE BOWEL SYNDROME) OR GI (GASTROINTESTINAL) RELATED. THEY'RE SCHEDULING HER HYSTERECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON(B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(6)-2015 FROM PHYSICIAN: HE REPORTED THAT ESSURE LOT NUMBER USED ON RIGHT SIDE WAS A56796 AND ON LEFT WAS 948836. PHYSICIAN ALSO REPORTED THAT THE PATIENT HAD A "GI EVAL" (UNDERSTOOD AS GASTROINTESTINAL EVALUATION) WITHOUT SPECIFIC FINDINGS. HE SUSPECTED ON GLUTEN SENSITIVITY. HER MEDICAL HISTORY INCLUDED ANXIETY AND MULTIPLE VAGUE SYMPTOMS (NO OTHER SPECIFIED). ON (B)(6) 2005 (DISCREPANT DATE REPORTED), THE PATIENT HAD A HYSTERECTOMY WITH BILATERAL SALPINGECTOMY DONE. THE PATHOLOGICAL FINDINGS WERE BENIGN WITH UNREMARKABLE TUBES; NO EVIDENCE OF INFLAMMATION AT TIME OF SURGERY OR PATHOLOGY. FOLLOW-UP RECEIVED ON (B)(4) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: 948836; PRODUCTION DATE: (B)(4) 2012; EXPIRATION DATE: FEB-2015. LOT NUMBER: A56796; PRODUCTION DATE: (B)(6)2012; EXPIRATION DATE: SEP-2015. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH 948836 OR (B)(4). NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCHES WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING AND PAIN. SHE WAS SUBMITTED TO BILATERAL SALPINGECTOMY AND HYSTERECTOMY. THESE EVENTS, INTERPRETED AS GENITAL BLEEDING AND PELVIC PAIN, ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, PHYSICIAN BELIEVED PATIENT'S SYMPTOMS WERE GASTROINTESTINAL (GI) RELATED; HOWEVER UPON FOLLOW-UP HE STATED HER GI EVALUATION HAD NO SPECIFIC FINDINGS. GIVEN THIS INFORMATION AND CONSIDERING THE REPORTED EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS UPGRADED TO INCIDENT DUE TO THE REPORTED HYSTERECTOMY WITH BILATERAL SALPINGECTOMY. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 26-MAY-2015 FROM PHYSICIAN: PATIENT REQUESTED HYSTERECTOMY DUE TO CONCERNS SHE HAD THAT HER MULTIPLE SYMPTOMS WERE DUE TO ESSURE PROCEDURE: NAUSEA, CRAMPING, NIGHT SWEATS, BLOATING, PAINFUL INTERCOURSE, NON-FOCAL ABDOMINA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00301	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/1/2013
Explant Date (E7): 11/5/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (B)(4) IN UNITED STATES ON 15-JAN-2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. CONSUMER REPORTED THAT SHE HAD ESSURE IMPLANTED IN 2013, AND SINCE THEN CHRONIC PELVIC PAIN, HEAVY BLEEDING, NONSTOP BLEEDING FOR 4 MONTHS, PAINFUL INTERCOURSE, HAIR LOSS, RASHES, WEIGHT GAIN, DEPRESSION, HOT FLASHES, NIGHT SWEATS, INSOMNIA AND CONFIRMED DIAGNOSIS OF ENDOMETRIOSIS. FOLLOW-UP INFORMATION RECEIVED ON 05-FEB-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON

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THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 16-APR-2015: THE CONSUMER MENTIONED THE DATES (B)(6) 2013 AND (B)(6) 2014 AS IMPLANT DATE AND EXPLANTED DATE, RESPECTIVELY (NO OTHER SPECIFIED). THE CONSUMER MENTIONED THE SERIOUSNESS CRITERIA HOSPITALIZATION BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. CORRECTION PERFORMED REGARDING INFORMATION RECEIVED ON 16-APR-2015: THE SERIOUSNESS CRITERIA REQUIRED INTERVENTION WAS TICKED FOR THE EVENT HEAVY BLEEDING / NON STOP BLEEDING FOR 4 MONTHS. ALSO, IN THE SAME EVENT, THE FIELD NON-DRUG TREATMENT REQUIRED WAS AMENDED TO YES, SURGERY. FOLLOW UP INFORMATION RECEIVED ON 21-APR-2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING / NON STOP BLEEDING FOR 4 MONTHS. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND HOSPITALIZATION AND IS LISTED IN TE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, GIVEN ITS NATURE, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE USE. OTHER NON-SERIOUS EVENTS WERE REPORTED. LATER, IT WAS INFORMED THAT ESSURE WAS REMOVED (REQUIRED INTERVENTION IMPLIED), HENCE THIS CASE WAS UPGRADED TO INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00302	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/18/2014
Explant Date (E7): 11/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039326) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL IN 2014. CONSUMER HAS TWO SMALL CHILDREN. SINCE THE INSERTION SHE WAS EXPERIENCING SEVERE PAIN, CONSTANTLY FATIGUED, SHARP SHOOTING PAIN IN HER BACK AND ABDOMEN, HER PERIODS WHICH WERE NEVER PAINFUL ARE NOW UNBEARABLE. SHE STATED A HYSTERECTOMY IS NEEDED TO REMOVE THIS DEVICE. SHE COULD BARELY GET OUT OF BED AND EACH NIGHT GOING TO SLEEP IS DIFFICULT AND SCARY. THERE WERE NIGHTS WHERE THE PAIN WAS SO BAD SHE COULD BARELY BREATHE. CONSUMER INFORMED THE DATE (B)(6) 2014 AS EVENT ONSET DATE, HOWEVER SHE DID NOT SPECIFY IT. FOLLOW UP (B)(4) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN

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THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2015. PATIENT'S INITIAL WAS UPDATED. ESSURE WAS INSERTED ON (B)(6) 2014 AND WAS REMOVED ON (B)(6) 2014. AN INJURY (HOSPITALIZATION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP WILL BE REQUESTED. CASE UPGRADED TO INCIDENT. FOLLOW UP FROM (B)(4) 2015: PTC RESULT WAS UPDATED. NO MAJOR CHANGE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP SHOOTING PAIN IN MY ABDOMEN. THIS EVENT IS SERIOUS DUE HOSPITALIZATION AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE USE. IN THIS CASE, THE CONSUMER WAS EXPERIENCING SEVERE PAIN, SHARP SHOOTING PAIN IN HER BACK AND ABDOMEN SINCE THE DEVICE INSERTION. THEREFORE, GIVEN ITS NATURE AND CLOSE TEMPORAL RELATIONSHIP, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE USE. SINCE ESSURE REMOVAL WAS MENTIONED (REQUIRED INTERVENTION IMPLIED) THIS CASE WAS REGARDED AS INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 12-JUN-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00303	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY". IT REFERS TO A 35-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN SEPTEMBER-2012 AND JULY-2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT . THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE IS DERIVED FROM TABLE 1 TITLED: 'PATIENT BASELINE CHARACTERISTICS'. PATIENT 1: A 35 YEAR OLD WHITE FEMALE; PARITY 3 AND BMI = 24.7 (BODY MASS INDEX). HER CO-MORBIDITIES WERE ASTHMA AND CHRONIC LOW BACK PAIN . THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL WAS NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 5 YEARS. [THERE IS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS: THIS STUDY DIFFERS FROM PREVIOUS STUDIES ON THIS TOPIC, AS IT SURVEYED PATIENTS

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FEELINGS DURING THE POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. CASES FROM THIS ARTICLE: (B)(6). FOLLOW-UP (B)(4) 2015: PTC NUMBER RECEIVED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A 35-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY IN MOST OF THEM. THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL; THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00304	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. SERIOUS INJURY. ANTICIPATED. REQUIRED INTERVENTION. THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 15-APR-2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY." IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN SEPTEMBER 2012 AND JULY 2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT . THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE IS DERIVED FROM TABLE 1 TITLED: PATIENT BASELINE CHARACTERISTICS. PATIENT 2: A (B)(6) WHITE FEMALE. PARITY 3; BMI (B)(6). HER CO-MORBIDITIES WERE MIGRAINE AND CHRONIC LOW BACK PAIN. THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL ARE NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 9 YEARS. [THERE IS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS THIS STUDY

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DIFFERS FROM PREVIOUS STUDIES ON THIS TOPIC, AS IT SURVEYED PATIENTS FEELINGS DURING THE POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. THE MAJORITY OF PATIENTS IN THIS SERIES WHO UNDERWENT SURGERY FOR SYMPTOMS RELATED TO ESSURE EXPERIENCED IMPROVEMENT. HOWEVER, A SMALL PERCENTAGE CONTINUED TO HAVE SYMPTOMS. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. (B)(4). FOLLOW-UP 21-APR-2015: PTC NUMBER RECEIVED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-APR-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA; WHICH IMPROVED AFTER THE SURGERY IN MOST OF THEM. THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED SURGERY FOR ESSURE REMOVAL THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

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Manufacturer Narrative (H10):

FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00305	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 15-APR-2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY." IT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN SEPTEMBER 2012 AND JULY 2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT . THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE WAS DERIVED FROM TABLE 1 TITLED: PATIENT BASELINE CHARACTERISTICS. PATIENT 3 A (B)(6) YEAR OLD FEMALE. PARITY 2; BMI (B)(6). HER CO-MORBIDITIES WERE CONSTIPATION AND CHRONIC LOW BACK PAIN. THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL WERE NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 7 YEARS. [THERE WAS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS: THIS STUDY DIFFERS FROM PREVIOUS STUDIES ON THIS TOPIC, AS

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IT SURVEYED PATIENTS FEELINGS DURING THE POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. CASES FROM THIS ARTICLE: 2015-137630, 2015-139162, 2015-139163, 2015-139164, 2015-139165, 2015-139166, 2015-139167, 2015-139168, 2015-139169, 2015-139170, 2015-139171. FOLLOW-UP (B)(6) 2015: PTC NUMBER RECEIVED. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY. THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00306	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6) 2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN (B)(6) 2012 AND (B)(6) 2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT . THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE IS DERIVED FROM TABLE 1 TITLED: PATIENT BASELINE CHARACTERISTICS. PATIENT 4 A (B)(6) OLD WHITE FEMALE. PARITY 7; BMI 19.7. HER CO-MORBIDITY WAS CHRONIC LOW BACK PAIN. THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL ARE NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 2 YEARS. [THERE IS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS THIS STUDY DIFFERS FROM PREVIOUS STUDIES ON THIS TOPIC, AS IT SURVEYED PATIENTS FEELINGS DURING THE POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR

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SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. THE MAJORITY OF PATIENTS IN THIS SERIES WHO UNDERWENT SURGERY FOR SYMPTOMS RELATED TO ESSURE EXPERIENCED IMPROVEMENT. HOWEVER, A SMALL PERCENTAGE CONTINUED TO HAVE SYMPTOMS. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. CASES FROM THIS ARTICLE: 2015-137630, 2015-139162, 2015-139163, 2015-139164, 2015-139165, 2015-139166, 2015-139167, 2015-139168, 2015-139169, 2015-139170, 2015-139171. FOLLOW-UP (B)(6)2015: PTC NUMBER RECEIVED FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY. THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00307	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 15-APR-2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY". IT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN SEPTEMBER 2012 AND JULY 2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT . THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE IS DERIVED FROM TABLE 1 TITLED: PATIENT BASELINE CHARACTERISTICS. PATIENT 5 A (B)(6) YEAR OLD WHITE FEMALE. PARITY 2; BMI (B)(6). HER CO-MORBIDITY WAS CHRONIC HEADACHE. THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL ARE NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 5 YEARS. [THERE IS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS: THIS STUDY DIFFERS FROM PREVIOUS STUDIES ON THIS TOPIC, AS IT SURVEYED PATIENTS

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FEELINGS DURING THE POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA. PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. THE MAJORITY OF PATIENTS IN THIS SERIES WHO UNDERWENT SURGERY FOR SYMPTOMS RELATED TO ESSURE EXPERIENCED IMPROVEMENT. HOWEVER, A SMALL PERCENTAGE CONTINUED TO HAVE SYMPTOMS. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. CASES FROM THIS ARTICLE: 2015-137630, 2015-139162, 2015-139163, 2015-139164, 2015-139165, 2015-139166, 2015-139167, 2015-139168, 2015-139169, 2015-139170, 2015-139171. FOLLOW-UP 21-APR-2015: PTC NUMBER RECEIVED. FOLLOW-UP RECEIVED ON 23-APR-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS 2015-013909. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY (IN MOST OF THEM). THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP ON 06-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00308	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

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PATIENTS FEELINGS DURING THE POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. (B)(4). FOLLOW-UP 21-APR-2015: PTC NUMBER RECEIVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 23-APR-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY (IN MOST OF THEM). THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP ON 06-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00309	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 15-APR-2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY". IT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN SEPTEMBER 2012 AND JULY 2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT. THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE WAS DERIVED FROM TABLE 1 TITLED: PATIENT BASELINE CHARACTERISTICS. PATIENT 7: A (B)(6) YEAR OLD WHITE FEMALE. PARITY 2; BMI (B)(6). HER CO-MORBIDITIES WERE CONSTIPATION, CHRONIC LOW BACK PAIN AND ASTHMA. THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL ARE NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 2 YEARS. [THERE WAS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS THIS STUDY DIFFERS FROM PREVIOUS STUDIES ON THIS

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TOPIC, AS IT SURVEYED PATIENTS FEELINGS DURING THE POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. CASES FROM THIS ARTICLE: 2015-137630, 2015-139162, 2015-139163, 2015-139164, 2015-139165, 2015-139166, 2015-139167, 2015-139168, 2015-139169, 2015-139170, 2015-139171. FOLLOW-UP 21-APR-2015: PTC NUMBER RECEIVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 22-APR-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS:(B)(4). FINAL ASSESSMENT : SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY (IN MOST OF THEM). THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP ON 06-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00310	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 15-APR-2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY". IT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN SEPTEMBER 2012 AND JULY 2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT . THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE WAS DERIVED FROM TABLE 1 TITLED: PATIENT BASELINE CHARACTERISTICS. PATIENT 8 A (B)(6) YEAR OLD WHITE FEMALE. PARITY 2; BMI (B)(6). SHE REPORTED NO COMORBIDITIES. THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL WERE NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 1 YEAR. [THERE WAS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS: THIS STUDY DIFFERS FROM PREVIOUS STUDIES ON THIS TOPIC, AS IT SURVEYED PATIENTS

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FEELINGS DURING THE POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. CASES FROM THIS ARTICLE: (B)(6). FOLLOW-UP (B)(6) 2015: PTC NUMBER RECEIVED. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER, HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY (IN MOST OF THEM). THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP ON 06-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00311	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 15-APR-2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY." IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN SEPTEMBER 2012 AND JULY 2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT . THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE WAS DERIVED FROM TABLE 1 TITLED: PATIENT BASELINE CHARACTERISTICS. PATIENT 9: A (B)(6) WHITE FEMALE. PARITY 4; (B)(6). SHE REPORTED NO COMORBIDITIES. THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL WERE NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 0.5 YEARS. [THERE WAS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS: THIS STUDY DIFFERS FROM PREVIOUS STUDIES ON THIS TOPIC, AS IT SURVEYED PATIENTS FEELINGS DURING THE

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POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA. PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. CASES FROM THIS ARTICLE: 2015-137630, 2015-139162, 2015-139163, 2015-139164, 2015-139165, 2015-139166, 2015-139167, 2015-139168, 2015-139169, 2015-139170, 2015-139171. FOLLOW-UP 21-APR-2015: PTC # RECEIVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 22-APR-2015. (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT, DERIVED FROM MEDICAL LITERATURE, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY IN MOST PATIENTS. THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP ON 06-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT, DERIVED FROM MEDICAL LITERATURE, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00312	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY." IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN (B)(6) 2012 AND (B)(6) 2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT . THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE IS DERIVED FROM TABLE 1 TITLED: PATIENT BASELINE CHARACTERISTICS. PATIENT 10- A (B)(6) FEMALE. (B)(6). HER COMORBIDITIES ARE JOINT PAIN AND CHRONIC HEADACHE. THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL ARE NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 1 YEAR. [THERE IS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS: THIS STUDY DIFFERS FROM PREVIOUS STUDIES ON THIS TOPIC, AS IT SURVEYED PATIENTS FEELINGS DURING THE POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR

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SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA. PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. THE MAJORITY OF PATIENTS IN THIS SERIES WHO UNDERWENT SURGERY FOR SYMPTOMS RELATED TO ESSURE EXPERIENCED IMPROVEMENT. HOWEVER, A SMALL PERCENTAGE CONTINUED TO HAVE SYMPTOMS. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. CASES FROM THIS ARTICLE: 2015-137630, 2015-139162, 2015-139163, 2015-139164, 2015-139165, 2015-139166, 2015-139167, 2015-139168, 2015-139169, 2015-139170, 2015-139171. FOLLOW-UP: (B)(4) 2015: PTC NUMBER RECEIVED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT, DERIVED FROM MEDICAL LITERATURE, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER, HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY IN MOST OF THEM. THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP ON 06-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT, DERIVED FROM MEDICAL LITERATURE, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00313	BAYER HEALTHCARE LLC	5/13/2015	5/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 15-APR-2015, ARTICLE ENTITLED "ESSURE SURGICAL REMOVAL AND SUBSEQUENT SYMPTOM RESOLUTION: CASE SERIES AND FOLLOW-UP SURVEY". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION AND SUBSEQUENTLY HAD ESSURE REMOVED (ESSURE SURGICAL REMOVAL). AUTHORS REPORT A RETROSPECTIVE CASE SERIES OF 11 WOMEN WHO REQUESTED, AND THEN UNDERWENT SURGICAL REMOVAL OF ESSURE BY HYSTEROSCOPY, SALPINGECTOMY AND/OR HYSTERECTOMY, BETWEEN SEPTEMBER 2012 AND JULY 2014. THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO SURVEY WOMEN REGARDING SYMPTOM RESOLUTION FOLLOWING REMOVAL OF ESSURE DEVICES. INFORMATION WAS OBTAINED FROM AN EIGHT-QUESTION SURVEY THAT WAS COMPLETED BY EACH PATIENT . THE MEDIAN TIMEFRAME BETWEEN REMOVAL OF THE ESSURE IMPLANT AND COMPLETION OF THE SURVEY WAS 5 (RANGE 1-23) MONTHS. (WOMEN WHO UNDERWENT ESSURE REMOVAL DUE TO DESIRE FOR FUTURE PREGNANCY OR STERILIZATION REGRET WERE EXCLUDED). THE AUTHORS SUMMARIZED THE REASONS FOR REQUESTING DEVICE REMOVAL AS: PAIN (N=10; 90.91%), BLEEDING (N=6; 54.54%) AND/OR DYSPAREUNIA (N=5; 45.45%). THE SPECIFIC REASON(S) OR SYMPTOM(S) FOR WHICH EACH PATIENT REQUESTED DEVICE REMOVAL ARE NOT UNIQUELY REPORTED. PATIENT INFORMATION FOR THIS CASE IS DERIVED FROM TABLE 1 TITLED: PATIENT BASELINE CHARACTERISTICS. PATIENT 11: A (B)(6) WHITE FEMALE; PARITY 2 AND (B)(6). SHE REPORTED NO COMORBIDITIES. THE SPECIFIC SYMPTOM OR SYMPTOMS FOR WHICH THIS PATIENT SOUGHT DEVICE REMOVAL WERE NOT REPORTED. THE DURATION OF SYMPTOMS (NOS) UNTIL SURGERY DATE WAS 0.5 YEARS. [THERE IS NO OTHER INFORMATION SPECIFIC TO THIS PATIENT]. AUTHORS COMMENTS: THIS STUDY DIFFERS FROM PREVIOUS STUDIES ON THIS TOPIC, AS IT SURVEYED PATIENTS FEELINGS DURING THE

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POSTOPERATIVE PERIOD FOLLOWING SURGERY FOR SYMPTOMS THAT THEY BELIEVED TO BE ESSURE-RELATED. IN THIS CASE SERIES, MOST PATIENTS (N=8; 72.72%) EXPERIENCED IMPROVEMENT OF SYMPTOMS FOLLOWING SURGICAL REMOVAL OF ESSURE VIA SALPINGECTOMY AND/OR HYSTERECTOMY. HOWEVER, THREE PATIENTS REPORTED ONGOING SYMPTOMS AFTER SURGERY AND TWO REPORTED WORSENING SYMPTOMS OF PAIN AND DYSPAREUNIA. PAIN WAS THE MOST COMMONLY REPORTED SYMPTOM IN OUR PATIENT COHORT. IT IS IMPORTANT TO NOTE THAT THE CAUSAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND SYMPTOMS OF PAIN CANNOT BE VALIDATED BY A RETROSPECTIVE STUDY DESIGN. MOREOVER, 5 OF THE PATIENTS IN THIS STUDY HAD PREEXISTING CHRONIC PELVIC PAIN, WHICH CONFOUNDS PAIN REPORTED AFTER ESSURE PLACEMENT. IT HAS BEEN REPORTED THAT PATIENTS WITH PREVIOUS CHRONIC PELVIC PAIN ARE MORE LIKELY TO REPORT BOTH ACUTE AND CHRONIC PAIN AFTER HYSTEROSCOPIC STERILIZATION. IN OUR CASE SERIES, THERE WERE THREE (27.27%) CASES ASSOCIATED WITH ALLERGIC REACTION. ONE OF THESE CASES IS NOT ENTIRELY THOUGHT TO BE ASSOCIATED WITH THE DEVICE, SINCE THIS PATIENT WAS DIAGNOSED WITH HODGKINS LYMPHOMA CONCURRENT TO SYMPTOM DEVELOPMENT. BLEEDING WAS ANOTHER COMMONLY REPORTED ISSUE DURING THIS SURVEY. IT IS AN IMPORTANT PART OF THE INFORMED CONSENT TO DISCUSS WITH PATIENTS THE RISK OF ONGOING SYMPTOMS PRIOR TO PERFORMING ESSURE IMPLANT REMOVAL. CASES FROM THIS ARTICLE: 2015-137630, 2015-139162, 2015-139163, 2015-139164, 2015-139165, 2015-139166, 2015-139167, 2015-139168, 2015-139169, 2015-139170, 2015-139171. FOLLOW-UP 21-APR-2015: PTC # RECEIVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 23-APR-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BY SURGERY. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE AUTHOR DID NOT SPECIFY THE REASON FOR ESSURE REMOVAL IN THIS PATIENT; HOWEVER, HE STATED MOST OF THE PATIENTS IN HIS REPORT HAD ESSURE REMOVED DUE TO PAIN, BLEEDING OR DYSPAREUNIA, WHICH IMPROVED AFTER THE SURGERY (IN MOST OF THEM). THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED, AND DUE TO THE REQUIRED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP ON 06-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042625	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 3/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED AT THE BEGIN OF (B)(6) AND THE FIRST ISSUE I HAD WAS PIERCING PAIN IN THE PELVIC AREA. WHEN I SAT DOWN IT FELT LIKE THE COILS WHERE POKING ME. I WENT TO THE DOCTOR AND THEY TOLD ME IT WAS NORMAL. THE PAIN DID NOT STOP FOR 2-3 YEARS. I DON'T CURRENTLY FEEL THE COILS POKING ME. THE SECOND ISSUE IS I CONSTANTLY SPOT AND BLEED THROUGHOUT THE MONTH. THAT STARTED IN 2011 AND CONTINUES TO DATE ((B)(6) 2015). NEXT, I HAVE SEVERE PAIN ON BOTH SIDES WHERE MY OVARIES ARE AND THE PAIN IS CONSTANT. GETS MUCH WORK AS MY PERIOD GETS CLOSER. I HAVE HAD SEVERE SWELLING/BLOATING IN MY STOMACH-LOOKS LIKE I AM PREGNANT. THIS HAS BEEN CONTINUOUS SINCE THE PLACEMENT. AGAIN, I WENT TO THE DOCTOR AND THEY TOLD ME THAT EVERYTHING WAS OK. FOR THE PAST 4 YEARS I HAVE EXPERIENCED EXTREME FATIGUE - I AM ALWAYS TIRED, CAN'T DO THINGS THAT I COULD BEFORE AND I AM NOT THE SAME PERSON I WAS BEFORE PLACEMENT. MY SEX DRIVE COMPLETELY WENT AWAY ONCE I HAD THE ESSURE PLACED - DOCTORS HAVE CHECKED MY BLOOD WORK AND TELL ME EVERYTHING IS NORMAL. FOR THE PAST 12 MONTHS I HAVE BEEN LOOSING MY HAIR IN LARGE AMOUNTS. PRETTY SOON, I WILL PROBABLY BE BALD, UNLESS I GET THESE COILS REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042626	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING BAD PAIN IN MY LEGS, FEET, AND ARMS TO THE POINT WHERE I COULD HARDLY WALK BY THE END OF THE DAY AND THEY WERE THROBBING AT NIGHT PREVENTING ME FROM SLEEPING. I HAD A BLOOD TEST AND IT SHOWED BY BODY WAS PRODUCING AMA CELLS WHICH USUALLY INDICATE AN AUTOIMMUNE DISORDER, BUT I WAS TESTED FOR LUPUS, RA, AND A COUPLE OTHER AUTO IMMUNE THAT MIGHT AFFECT THE MUSCLES AND EVERYTHING CAME BACK NEGATIVE. MY PCP AND THE SPECIALIST STILL HAVE NOT FOUND ANYTHING THAT COULD BE CAUSING IT. AT THAT TIME, MY NAIL BEDS WERE ALL DENTED AND MY HAIR WAS COMING OUT IN CLUMPS. THINGS GOT A LITTLE BETTER FOR A SHORT TIME BUT NOW I HAVE ALL THOSE SYMPTOMS, PLUS MY PERIODS ARE EXTREMELY HEAVY WITH LARGE BLOOD CLOTS, MY STOMACH IS BIGGER THAN IT HAS EVER BEEN IN MY WHOLE LIFE, AND I AM ALWAYS TIRED. I GOT THE ESSURE IN (B)(6) 2014 AND MY HEALTH SEEMS TO BE GETTING WORSE BY THE MONTH. IT IS VERY HARD TO TAKE CARE OF A (B)(6) YEAR OLD WITH ALL THIS PAIN AND FATIGUE. I'M MAKING AN APPOINTMENT TO SEE ABOUT GETTING MY TUBES OUT AND PRAYING THESE PROBLEMS WILL ALL GO AWAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042627	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 5/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LESS THAN A YEAR AFTER I BEGAN GETTING MASSIVE HEADACHES, THEN PUBIC LUMPS THAT WOULD BURST AND PUSS/BLOOD WOULD SATURATE MY CLOTHING, SEVERE CRAMPING ON THE RIGHT SIDE OF MY PELVIC AREA, 7MM OVARIAN CYST THAT WAS SURGICALLY REMOVED, KIDNEY STONE, HAIR LOSS, HAIR GROWTH IN ODD PLACES, FIBROIDS, INSOMNIA, DEPRESSION, NO SEX DRIVE, PAINFUL SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042628	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNEXPLAINED WEIGHT GAIN, CLOTTY PERIODS, EXHAUSTION, MIGRAINES, JOINT PAIN, SWELLING, DIZZINESS, NO SEX DRIVE, SHARP STABBING LIKE PAINS DURING PERIOD, MAJOR BELLY BLOAT, ABNORMAL PAP (GLANDULAR CELLS).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042630	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 4/6/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE ONSET OF BLEEDING AND PAINFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042631	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE. NOW OVER THE YEARS WITH IT IN BLEEDING OUT IN ONE DAY. HIP PAIN OVER THE LAST 3 MONTHS MAJOR CLOTS (SOFTBALL SIZE) MAJOR CRAMPS. AND NICKEL ALLERGIES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042632	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 9/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SERIOUS MOOD SWINGS, PELVIC PAIN, TINGLING IN FEET, NIGHT SWEATS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042633	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 6/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED UNDER GENERAL ANESTHESIA IN (B)(6) 2004, NOT LONG AFTER I BEGAN EXPERIENCING A MYRIAD OF SEEMINGLY UNRELATED SYMPTOMS. IMMEDIATELY MY PERIODS BECAME SUBSTANTIALLY HEAVIER AND INTERCOURSE BECAME UNBEARABLY PAINFUL. I STARTED GAINING WEIGHT AND STARTED HAVING ACNE BREAKOUTS ON MY FACE, CHEST, AND BACK. I WAS ALWAYS BLOATED AND HAD CHRONIC PAIN IN MY GENERALIZED REPRODUCTIVE ORGAN AREA. I WAS CONSTANTLY PUFFY AND INFLAMED AND HAD SUCH SEVERE GUM SWELLING THAT 3 OF MY TEETH CAME OUT. BY 2010 MY SYMPTOMS BECAME MARKEDLY WORSE, WHAT WAS PERSISTENT TROUBLING CHRONIC INFLAMMATION BASED SYMPTOMS STARTED MANIFESTING MORE ACUTELY ALSO. I ASSUMED I WAS SUFFERING EITHER EARLY MENOPAUSE OF THYROID ISSUES AS I HAD NO ENERGY, NO SEX DRIVE, HORRIBLE MEMORY IMPAIRMENT AND NASTY BRAIN FOG; MY HORMONAL TESTING KEPT COMING UP NORMAL THOUGH. IN 2011 MY PANCREAS BEGAN INFLAMING WITH PERSISTENT PANCREATITIS. I HAD HAIR AND BLOOD TESTS TO DETERMINE THE CAUSE AND I TESTED POSITIVE FOR METAL TOXICITY, THIS WAS TREATED WITH MONTHS OF NON-INSURANCE COVERED INTRAVENOUS NUTRIENT THERAPY. IN 2012 I WAS DIAGNOSED WITH INTERSTITIAL CYSTITIS, WHICH IS A CHRONIC BLADDER INFLAMMATION DISORDER. IN 2013 I HAD AN ATTACK OF BLACK TAR VOMIT AND WAS HOSPITALIZED, TESTING REVEALED INFLAMMATION OF MY INTESTINES. AFTER THIS HOSPITALIZATION I WAS ONCE AGAIN TESTED FOR HORMONE PROBLEMS AND HEAVY METALS, ONCE AGAIN MY HORMONES WERE FINE BUT I WAS RIDDLED WITH TOXINS...IT WAS THEN THAT I CONSIDERED ESSURE MIGHT BE RELATED TO MY DECLINING HEALTH. AFTER 2 MORE YEARS OF CHRONIC PAIN AND CONTINUED INFLAMMATION I WAS DIAGNOSED WITH ENDOMETRIOSIS AND ADENOMYOSIS, AND WAS SCHEDULED FOR HYSTERECTOMY. I HAD HYSTERECTOMY ON (B)(6) 2105 AND MY PATHOLOGY REPORT NOTED SEVERAL LEIOMYOMATA, A DILATED CYST AT

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MY RIGHT CORNU CONNECTED TO THE ESSURE COIL, MULTIPLE PARATUBAL CYSTS,ERYTHEMATOUS AND HEMORRHAGIC UTERINE TISSUE, A HEMORRHAGE CERVIX, FIVE FIBROIDS, AND 1 BROKEN COIL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042654	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDA MW5042654 #(B)(4). WENT TO THE ER MONDAY, (B)(6) 2015. I HAD MIGRAINES, DIZZINESS, LOSS OF VISION, NAUSEA, EXTREME PELVIC PAIN AND CRAMPING. THE ER DOCTOR ORDERED A PELVIC ULTRASOUND WHICH SHOWED A MASS ON MY CERVIX IN WHICH SHE WANTED ME TO REPORT TO MY GYN ASAP. I HAD AN APPOINTMENT ON (B)(6) 2015 WITH MY GYN WHO STATED THAT MY PELVIC PAIN IS NORMAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042655	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 7/8/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAD PAIN , PELVIC PAIN, LOWER BACK PAIN, IRREGULAR PERIODS, HEAVY PERIODS, MOOD SWINGS, LEG NUMBNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042656	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN DURING INSERTION. PAIN CONTINUED NON STOP FOR ALMOST A MONTH. FROM THT POINT ON I HAVE SEVERE CRAMPS THAT FEEL LIKE LABOR PAINS ESPECIALLY ON MY RIGHT SIDE THE WEEK BEFORE MY PERIOD AND THE WEEK OF. SEXUAL INTERCOURSE IS ALSO VERY PAINFUL DURING THAT TIME. MY RIGHT HIP AND LEG HURT SO MUCH THAT I CAN BARELY WALK OR FUNCTION NORMALLY. I SUFFER FROM BELLY SWELLING AS WELL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042657	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME SWEATING NO MATTER THE SURROUNDING TEMP, EXTREME CRYING. I CRIED OVER EVERYTHING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042658	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 7/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME SWEATING NO MATTER THE SURROUNDING TEMP, EXTREME CRYING. I CRIED OVER EVERYTHING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042659	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 7/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN SWELLING ALL OVER BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042660	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 8/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIAGNOSED WITH ANGIOEDEMA WITH ANAPHYLAXIS, SWELL WHOLE BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042661	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 10/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANOTHER ANAPHYLAXIS EVENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042662	BAYER	5/13/2015	5/13/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN LOOSING HAIR, BEGAN BEING HOT AND FREEZING AT SAME TIME, COULD NOT LOOSE WEIGHT, ONLY GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042629	BAYER	5/13/2015	5/14/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOLLOWING THE MIDTERM MISCARRIAGE I HAD IN 2008, IN A STATE OF EMOTIONAL DISTRESS I TOLD MY DOCTOR THAT I WANTED MY TUBES TIED, AS I BELIEVED I COULD NEVER LIVE THROUGH ANOTHER MISCARRIAGE. AT THE TIME OF MY MISCARRIAGE (2008), I RECEIVED STATE INSURANCE ((B)(6)), THAT WOULD ONLY PROVIDE 30 DAYS OF COVERAGE POST THE LOSS OF PREGNANCY. AS THE LAW REQUIRES A WAIVER FOR PERMANENT BIRTH CONTROL BE OBTAINED BY A DOCTOR 90 DAYS PRIOR TO THE PROCEDURE, MY STATE SUPPLEMENTAL INSURANCE WOULD HAVE LONG RUN OUT PRIOR TO THE SURGERY DATE. IT WAS AT THAT TIME MY DOCTOR TOLD ME ABOUT ESSURE. HE OFFERED TO BACK DATE MY WAIVER FOR THE PROCEDURE TO THREE MONTHS PRIOR, THE DATE OF MY FIRST OBGYN APPOINTMENT. HE EXPLAINED THIS WOULD ENSURE COVERAGE WHEN IT CAME TO MY INSURANCE. ALL I HAD TO DO WAS CHOOSE ESSURE OVER TRADITIONAL METHODS. IMMEDIATELY FOLLOWING MY SURGERY, I HAD IMMENSE PAIN, CONSTIPATION, NAUSEA, AND VAGINAL BLEEDING. AT FIRST I ACCREDITED THIS TO POST SURGICAL RECOVERY. THE PAIN NOT ONLY CONTINUED, BUT GOT WORSE AS TIME WENT ON. I BEGAN VOMITING EVERY MORNING DUE TO THE NAUSEA. ABDOMINAL PAIN HAS BEEN SO SEVERE ITS LEFT ME CRIPPLED FOR DAYS. I'VE BECOME SUBJECT TO FREQUENT BLADDER INFECTIONS AND HORRID VAGINAL RASHES, AS WELL AS RASHES OVER ALL MY BODY. I AM CONSTANTLY BLOATED, SUFFER FROM CHRONIC DIARRHEA WHEN I AM NOT CONSTIPATED. I HAVE PAIN IN ALL OF MY JOINTS AND FREQUENT NUMBNESS OF EXTREMITIES. I LOOSE GRIP EASILY WITH MY HANDS AND TEND TO BE UNSTEADY WITH WEIGHT ON MY LEGS. I HAVE EXCESSIVE HAIR LOSS AND LOSS OF MUSCLE TONE, REGARDLESS OF REGULAR EXERCISE AND ACTIVITY. THIS IS NOT TO MENTION THE EMOTIONAL DISTRESS THIS HAS PUT ON MY LIFE. AFTER A SCARY HOSPITAL STAY, I KNEW

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THEY HAD TO BE REMOVED BEFORE THEY KILLED ME. I FOUND A DOCTOR WILLING TO PREFORM A TUBAL LIGATION IN 2010. SINCE SURGERY, SYMPTOMS HAVE LIGHTENED, BUT ARE STILL VERY PRESENT AND VERY REAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042663	BAYER	5/13/2015	5/14/2015

Event Information:

Event Date (B3): 3/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LAB VALUES OF MY HORMONE LEVELS DRAWN- DUE TO SUSPECTED HAIR LOSS TESTS RESULTS.

RESULT (B)(6) RESULT (B)(6)

DHEAS AND MDASH: 33 13 33
ESTRADOL AND MDASH: 42 42 AND LT: 25
PROGESTERONE 0.3 0.9
PROLACTIN 5.5

FREE T4 AND MDASH: 0.88 0.088
PROGESTERONE- 0.3 0.3
TESTESTERONE- 16 16
TSHANDMDASH: 1.22 1
VIT D 25 HYDROXY AND MDASH: 34 34
TSH W/ REFLEX T4- 1.27 1.27
G6DP QUANT AND NDASH: 14.9 14.6

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042749	BAYER	5/13/2015	5/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/6/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM IN DAILY PAIN DUE TO ESSURE. SEVERE BACK AND PELVIC PAIN, NEUROPATHY, HEADACHES AND WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00316	BAYER HEALTHCARE LLC	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 3/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61989

Single Use: Y
Implant Date (E6): 3/5/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA REGULATORY AUTHORITY (CASE# (B)(6)) IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO UNDERWENT AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER PROVIDED, C61989). THE PHYSICIAN REPORTED THAT DURING RELEASE, THE SECOND IMPLANT UNROLLED ITSELF AND ONE PART OF THE INSERT WAS ANCHORED IN THE TUBE, THE OTHER EXTREMITY WAS IN THE VAGINA. THE NUMBER OF UNITS CONCERNED WAS 1. DEVICE WAS NOT KEPT. THE EVENTS OCCURRED IN THE OPERATING ROOM DURING PLACEMENT. THERE WAS NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS NOT DONE. THE PROCEDURE WAS STOPPED. THE SURGERY WAS CONVERTED DUE TO THE SURGEON HAD TO PERFORM A BILATERAL SALPINGECTOMY BY LAPAROSCOPY. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: PREMATURE DEPLOYMENT/DETACHMENT IS DEFINED AS THE EXPANSION OF THE OUTER COILS OF THE MICROINSERT AND SUBSEQUENT DETACHMENT OF THE MICRO-INSERT ASSEMBLY FROM THE DELIVERY WIRE PRIOR TO THE PHYSICIAN COMPLETING ALL DEPLOYMENT STEPS OUTLINED IN THE INSTRUCTIONS FOR USE (IFU). SEVERAL FACTORS CAN CONTRIBUTE TO A PREMATURE DEPLOYMENT/DETACHMENT EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS, WHICH PREMATURELY PULL THE MICRO-INSERT FROM THE DELIVERY CATHETER, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS, WHICH LOOSENS THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. ACCORDING TO THE COMPLAINT NARRATIVE "ONE PART OF THE INSERT WAS ANCHORED IN THE TUBE, THE OTHER EXTREMITY WAS IN THE VAGINA." THIS INDICATES

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THERE MAY HAVE BEEN A DETACHMENT DIFFICULTY EVENT WHERE PART OF THE MICRO-INSERT WAS PLACED WITHIN THE FALLOPIAN TUBE AND THE REMAINDER OF THE MICRO-INSERT WAS STRETCHED AND FINALLY RELEASED FROM THE CATHETER AT OR IN THE VAGINAL CANAL. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE LANDING AREA OF THE DELIVERY WIRE, THE LENGTH OF RELEASE RIBBON, AND THE INNER DIAMETER OF THE DISTAL END OF THE DELIVERY CATHETER. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C61989 (PRODUCTION DATE 30-MAY-2014 AND EXPIRATION DATE 31-MAY-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A PREMATURE DEPLOYMENT/DETACHMENT EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE PHYSICAL PROPERTY ISSUE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 72 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THIS PROCEDURE ONE IMPLANT UNROLLED ITSELF; ONE PART OF IT WAS ANCHORED IN THE TUBE, THE OTHER EXTREMITY WAS IN THE VAGINA. THE PROCEDURE WAS STOPPED AND PATIENT WAS SUBMITTED TO A BILATERAL SALPINGECTOMY. THESE EVENTS; REGARDED AS A DEVICE SHAPE ALTERATION DUE TO A DEPLOYMENT ISSUE, ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE REPORTED DEVICE SHAPE ALTERATION WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. IN THIS PARTICULAR CASE, A PRODUCT TECHNICAL ANALYSIS (PTC) WAS PERFORMED AND CONCLUDED THE EVENT'S DESCRIPTION INDICATED THERE MAY HAVE BEEN A DETACHMENT DIFFICULTY EVENT WHERE PART OF THE MICRO-INSERT WAS PLACED WITHIN THE FALLOPIAN TUBE AND THE REMAINDER OF THE MICRO-INSERT WAS STRETCHED AND FINALLY RELEASED FROM THE CATHETER AT OR IN THE VAGINAL CANAL. ACCORDING TO PTC THE POSSIBILITY OF A PREMATURE DEPLOYMENT/DETACHMENT EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT AND SEVERAL FACTORS CAN CONTRIBUTE TO IT, INCLUDING TUBAL SPASMS, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THE ANALYSIS WAS UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION. ALTHOUGH PTC ANALYSIS CONCLUDED TO UNCONFIRMED QUALITY DEFECT; CONSIDERING THE REPORTED EVENTS OCCURRED IN ASSOCIATION WITH ESSURE INSERTION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED AND DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL, THIS CASE WAS CONSIDERED AN INCIDENT. NO FURTHER INFORMATION IS EXPECTED; SINCE THIS CASE WAS RECEIVED VIA REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00317	BAYER HEALTHCARE LLC	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 4/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 15-APR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 FOR STERILIZATION. ON (B)(6) 2015, PHYSICIAN DID A HYSTERECTOMY ON THE PATIENT FOR COMPLAINT OF CHRONIC PELVIC PAIN AND THE PATIENT WAS BLAMING IT ON THE ESSURE. THE FIRST TIME THE PATIENT CAME TO THE DOCTOR WAS (B)(6) 2014 WITH COMPLAINTS OF PELVIC PAIN. THE HCP CUT DISTAL TO THE INSERTS; THE INSERTS AND THE UTERUS CAME OUT TOGETHER. THE PATIENT REQUESTED THE ESSURE COILS TO BE SENT HOME WITH HER BUT INSERTS WERE SENT TO PATHOLOGY. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 23-APR-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL

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QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE USE. IN THIS CASE, THE PATIENT HAD PELVIC PAIN 5 YEARS AFTER PLACEMENT. ESSURE WAS THEN REMOVED VIA HYSTERECTOMY. SINCE REQUIRED INTERVENTION WAS MENTIONED TO REMOVE ESSURE, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE WAS RECEIVED ON 10-JUL-2015: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT THE PATIENT HAD ESSURE INSERTED IN 2009. SHE PRESENTED CHRONIC PAIN SINCE ESSURE PLACEMENT AND REQUESTED DEVICE REMOVAL. COMPUTE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00318	BAYER HEALTHCARE LLC	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/6/2014
Explant Date (E7): 3/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 16-APR-2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT STERILIZATION. PATIENT WANTED COILS REMOVED; SHE BELIEVED COILS WERE CAUSING HER SUSPECTED MULTIPLE SCLEROSES. PATIENT ALSO SUFFERS FROM IRRITABLE BOWEL SYNDROME AND ANXIETY. NEUROLOGIST TOLD PATIENT THAT SHE MAY HAVE MULTIPLE SCLEROSIS BUT, SO FAR, THIS DIAGNOSIS HAS NOT BEEN CONFIRMED. HCP REMOVED ESSURE COILS DURING (B)(6) 2015 VIA MINI LAPAROTOMY AND, PER DOCTOR, ESSURE COIL REMOVAL WAS SUCCESSFUL TO THE BEST OF HER KNOWLEDGE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE AND ARE CONSIDERED UNRELATED BY THE COMPANY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE

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TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MULTIPLE SCLEROSIS AND LATER A MINI-LAPAROTOMY WAS PERFORMED TO REMOVE THE DEVICES. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE. THE MINI-LAPAROTOMY IS LISTED WHILE THE OTHER EVENT IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE MOST COMMON AUTOIMMUNE INFLAMMATORY DEMYELINATING DISEASE OF THE CENTRAL NERVOUS SYSTEM IS MULTIPLE SCLEROSIS (MS). IN THIS PARTICULAR CASE, NEUROLOGIST TOLD PATIENT THAT SHE MAY HAVE MS BUT, SO FAR, THIS DIAGNOSIS HAS NOT BEEN CONFIRMED. HENCEFORTH, CONSIDERING THE ESSURE'S LOCAL ACTION, CAUSALITY WITH ESSURE IS VERY UNLIKELY. IF ESSURE REMOVAL IS NECESSARY, SURGERY MAY BE REQUIRED. IN THIS CASE, HCP PERFORMED A MINI LAPAROTOMY TO REMOVE THE DEVICES. THEREFORE, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE USE AND THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 11-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW-UP INFORMATION RECEIVED ON 13-AUG-2015: THE PATIENT REQUESTED THAT THE ESSURE BE REMOVED. IT W

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00319	BAYER HEALTHCARE LLC	5/14/2015	5/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/7/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON 17-APR-2015 WHICH REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 FOR STERILIZATION (LOT NUMBER 9630 WITH EXPIRATION DATE IN SEP-2011). ON (B)() 2011, A HYSTEROSALPINGOGRAM (HSG) WAS DONE AND SHOWED BILATERAL OCCLUSION. ON AN UNSPECIFIED DATE, THE PATIENT CAME IN TO SEE THE NURSE PRACTITIONER FOR EXTREME PAIN WITH MENSES AND WAS SCHEDULED TO SEE HER MEDICAL DOCTOR BUT ENDED UP GOING TO THE EMERGENCY ROOM INSTEAD. SHE HAD AN ULTRASOUND AND CT SCAN AND THE RIGHT COIL WAS FOUND IN THE ENDOMETRIAL CAVITY. SHE HAD AN INFECTION, WHICH WAS TREATED (MEDICATION REPORTED AS UNKNOWN) AND A HYSTEROSCOPY WAS DONE TO REMOVE THE COIL IN THE ENDOMETRIAL CAVITY ON (B)(6) 2015. ACCORDING TO THE PHYSICIAN, THE LEFT ESSURE LOOKED GOOD ON ULTRASOUND AND CT SCAN. THE DOCTOR PLANNED TO DO AN HSG WHEN THE PATIENT WAS RECOVERED TO MAKE SURE BOTH SIDES WERE OCCLUDED. FOLLOW-UP ON 20-APR-2015: NO NEW CLINICAL INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 23-APR-2015. (B)(4). FINAL ASSESSMENT THE REPORTED LOT NUMBER 9630 PROVIDED WAS ASSESSED AS INVALID BY RQU (RESPONSIBLE QUALITY UNIT). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST

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FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO VALID BATCH NUMBER WAS REPORTED. THE AE CASE REFERS TO THE LOT NUMBER 9630, WHICH IS INVALID ACCORDING TO THE RQU. WITHOUT VALID BATCH INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN ULTRASOUND/CT SCAN SHOWED THE RIGHT COIL WAS IN THE ENDOMETRIAL CAVITY; THIS COIL WAS REMOVED BY HYSTEROSCOPY. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) AND CAN RESULT IN PAIN AND BLEEDING. IN THIS CASE, THE PATIENT PRESENTED PAIN WITH MENSES AND A DEVICE EXPULSION WAS DIAGNOSED. ALTHOUGH THE EXACT MECHANISM OF THIS EVENT IS UNKNOWN; GIVEN ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, THE NON-SERIOUS EVENT INFECTION (UNSPECIFIED) WAS REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, DUE TO THE REQUIRED MEDICAL INTERVENTION FOR ESSURE REMOVAL. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 30-JUL-2015: FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO AN ADULT FEMALE PATIENT WHO HA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042664	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING PAIN, LOSS OF ENERGY, SEX DRIVE, FATIGUE. WEIGHT GAIN HUGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042684	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I UNDERWENT A BILATERAL SALPINGECTOMY/TUBAL LIGATION SURGERY TO REMOVE THE COILS. I WAS IMPLANTED IN 2008 AND SINCE 2009, I HAVE MULTIPLE SIDE EFFECTS INCLUDING, BUT NOT LIMITED TO, ALL OVER BODY PAIN, NUMBNESS, TINGLING, LOSS OF SENSATION IN MY LEFT SIDE EXTREMITIES, PELVIS, HIPS, AND LOWER BACK. NEUROLOGICAL ISSUES INCLUDING MEMORY LOSS, FORGETFULNESS, SLURRED SPEECH, AND UNABLE TO CONCENTRATE. INSOMNIA, HAIR LOSS, FRAIL/BRITTLE NAILS. I AM ALLERGIC TO NICKEL AND I WAS NOT PROPERLY INFORMED THAT THE DEVICE CONTAINED NICKEL. I BREAK OUT IN UNEXPLAINED HIVES, RASHES, AND BOILS. CONSTANT BURNING AND SHARP PAIN IN MY PELVIS REGION. IRREGULAR PERIODS INCLUDING MISSING MY PERIOD FOR WEEKS AT A TIME, HAVING MULTIPLE PERIODS IN ONE MONTH, AND EXTREME HEAVY BLEEDING WITH BLOOD CLOTS. I HAVE HAD MAJOR ISSUES WITH MY TEETH INCLUDING MULTIPLE TEETH BEING REMOVED (5), CONSTANT CRACKING AND CHIPPING BECAUSE THE ENAMEL IS SO WEEK, MULTIPLE FILLINGS AND ROOT CANALS. NO ENERGY TO COMPLETE MY DAILY LIVING TASK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042687	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 1/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ACHES, HARDLY ABLE TO WALK, PAIN IN ABDOMINAL, LEG AND FEET PAIN, GURGLING IN STOMACH, SEX PAIN, NUMBNESS ALL OVER, FATIGUE, SICK ALL OF THE TIME, WEIGHT GAIN, BLOATING, I HAVE 2 CHILDREN NOW 6 AND 3 I CAN'T EVEN ENJOY. MY LIFE WAS ENDED WHEN ESSURE WAS IMPLANTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042689	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 4/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, HEAVY BLOOD, HEADACHES, DIZZIED, ALLERGIES, HAIR AND NAIL LOSS, NUMBED LEFT LEG AND ARM,. VITAMIN D DEFICIENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042690	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 1/2/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE PLACEMENT I AM IN CONSTANT UNBEARABLE PAIN. I AM SEVERELY DEPRESSED. SUICIDAL THOUGHTS. NO LIBIDO. LOSS OF TEETH. CHRONIC MIGRAINES AT LEAST 4 DAYS OUT OF EVERY WEEK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042691	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING PROBLEMS LOSING WEIGHT, PAIN DURING AND AFTER INTIMACY, SWELLING OF PELVIC AREA, CYSTS ON OVARIES, HEAVY PERIODS WITH BLOOD CLOTS, UNEXPLAINED FEVERS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042692	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 5/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN BLEEDING VERY HEAVILY AND CRAMPING VERY BAD. MY PERIOD WAS NOT DUE UNTIL THE END OF THE MONTH. THIS BECAME A NORMAL THING IN THE ALMOST 2 YEARS I'VE HAD THE DEVICE. MY BACK HURT ALL THE TIME. I HAD STABBING PAINS IN MY RIGHT SIDE FOLLOWED BY BLOATING THAT MADE ME LOOK 9 MONTHS PREGNANT. I HAD NO ENERGY. I SPENT MOST OF MY TIME IN BED. DEPRESSION AND MOOD SWINGS FOLLOWED. I HAD PANIC ATTACKS. MY LEGS WOULD TINGLE ALL THE TIME. ESPECIALLY THE RIGHT. I HAD SEVERE HEADACHES. I WOULD SEE BLACK FLOATIES IN MY EYES. MY MEMORY WAS COMPLETELY GONE. I HAD TO WRITE EVERYTHING DOWN IN ORDER TO REMEMBER IT. I HAD A CASE OF SERIOUS BRAIN FOG. MY HAIR BECAME BRITTLE NO MATTER WHAT I USED. EVERY TIME I SHOWERED,COMBED OR RAN MY FINGERS THROUGH MY HAIR IT WOULD COME OUT IN CLUMPS. I GOT SKIN RASHES. MY SKIN WAS DULL AND LIFELESS. MY BREASTFED BABY HAD RASHES AND BRITTLE HAIR. AS SOON AS I. NOTICED SHE HAD MY SYMPTOMS I STOPPED NURSING HER. HER SYMPTOMS WENT AWAY. I HAD RINGING IN MY EARS AS WELL. RESULTING IN A HYSTERECTOMY AT THE AGE OF (B)(6). ONCE ESSURE WAS REMOVED EVERY SYMPTOMS WENT AWAY INSTANTLY. ALL PAIN, RASHES, HAIR LOSS, STOMACH BLOATING, BLACK SPOTS ON MY EYES, HEADACHES,EVERYTHING... WENT AWAY. THIS DEVICE IS DEADLY AND I DON'T UNDERSTAND HOW IT MADE IT TO MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042693	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 2/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE HYSTERECTOMY DATE SHOULD READ (B)(6) 2015. MY APOLOGIES FOR THE MISTAKE. I ALSO WANT TO ADD THAT I ALSO HAD BOILS THAT OCCURRED ONLY AFTER HAVING ESSURE PLACED HAVE NOT REOCCURRED SINCE MY HYSTERECTOMY. I ALSO HAD VERY BAD BACKPAIN. I AT FIRST ASSOCIATED THIS WITH AN OLD BACK INJURY. HOWEVER, THE PAIN WAS DIFFERENT THAN ANYTHING I HAD PRIOR TO HAVING ESSURE PLACED. IT WAS MORE OF A RIPPING OR TEARING SENSATION IN MY BACK MUSCLES ACROSS MY LOWER BACK. (MY BACK INJURY WAS ISOLATED TO MY RIGHT LOWER BACK.) I CAN NOT EXPRESS ENOUGH HOW DEBILITATING THE PELVIC PAIN WAS. THIS WAS NOT PERIOD CRAMPS. THIS WAS DAILY PAIN THAT FELT LIKE MY INSIDES WERE TWISTING. I REMEMBER THINKING AT THE TIME THAT IT FELT LIKE SOMEONE HAD GRABBED MY FALLOPIAN TUBES AND WAS PULLING AND TWISTING THEM. IT ALSO FELT LIKE THE PRESSURE OF AN ELEPHANT STANDING ON MY PELVIS. I ALSO EXPERIENCED A CONSTANT PAIN IN MY LEFT PELVIC REGION AND LEFT HIP. THIS WAS DAILY. INTERMITTENTLY, BUT STILL EVERY WEEK, I WOULD EXPERIENCE A SHARP STABBING PAIN NEAR MY PUBIC BONE. THE PAIN WAS SO GREAT THAT I CONSIDERED GOING TO THE EMERGENCY ROOM. ALL OF THIS PAIN WAS NOT HELPED BY ANY OVER THE COUNTER PAIN KILLERS. I ALSO WANT TO POINT OUT THAT PRIOR TO MY SURGERY, I COULD BARELY STAY AWAKE IN THE EVENING. AFTER MY SURGERY, I AM AWAKE PAST 8:30 PM EVEN THOUGH MY SCHEDULE HAS CHANGED AND I HAVE TO WAKE UP AN HOUR EARLIER THAN BEFORE. MY ESSURE COILS WERE IN PLACE AND HAD NOT MIGRATED. I BELIEVE THAT THE INFLAMMATION CAUSED BY THE ESSURE IS WHAT CAUSED ALL OF MY PROBLEMS. I FEEL THAT IF DOCTORS WOULD HAVE BEEN BETTER EDUCATED ABOUT THE COMPLICATIONS FROM ESSURE AND LISTENED TO ME WHEN I WENT IN DESCRIBING MY PAIN, I WOULD HAVE LESS OF AN UPHILL BATTLE TO GET BETTER. (IT GOT SIGNIFICANTLY WORSE THE LAST YEAR THAT I HAD THE ESSURE IN, EVEN THOUGH I WAS SHOWING SIGNS FOR TWO YEARS

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BEFORE THAT.) IF ESSURE DOESN'T GET RECALLED, I THINK THAT DOCTORS NEED TO BE BETTER EDUCATED SO NOT ONE MORE WOMEN HAS TO BE MADE TO FEEL LIKE THEY ARE CRAZY WHEN THEY GO IN COMPLAINING OF PAIN. NO ONE SHOULD HAVE TO ENDURE THE PAIN THAT I DID. AND NO ONE SHOULD BE TOLD THAT PAIN IS NORMAL, THAT THEY ARE GETTING OLD (AT (B)(4)), THAT HEAVY BLEEDING IS NORMAL. WOMEN DESERVE BETTER FROM THE MEDICAL COMMUNITY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042694	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 8/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SO MANY ISSUES FROM THIS; I HAD TO HAVE MY GALLBLADDER REMOVED IN AN EMERGENCY SURGERY. I HAVE HAD BLEEDING IN BETWEEN PERIODS AND DURING SEX. I HAVE A SWOLLEN BELLY THAT LOOKS LIKE I AM PREGNANT THAT I CAN'T GET RID OF. I HAVE HAD DECLINING DENTAL HEALTH SINCE IMPLANTATION OF ESSURE. I HAVE RANDOM PAIN DURING AND AFTER SEX WHICH I DID NOT HAVE BEFORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042695	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5042695 #(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (INSERT DATE). (B)(4). THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED APPROXIMATELY ONE MONTH AFTER IMPLANTATION ((B)(6) 2013) I WILL BE SEEING A DOCTOR IN 2 WEEKS FOR TESTING TO SEE IF THE IMPLANTS HAVE MOVED/PERFORATED, AND FOR POSSIBLY REMOVAL (HYSTERECTOMY) THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042696	BAYER	5/14/2015	5/14/2015

Event Information:

Event Date (B3): 5/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE DEPRESSION, HEARTH PALPITATIONS, FATIGUE, FOGGY, DISCOMFORT IN MY GROIN AFTER SEX, ITCHY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00314	BAYER HEALTHCARE LLC	5/14/2015	6/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** PO

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12711

Single Use:
Implant Date (E6): 4/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN (B)(6) ON 15-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (LOT NUMBER C12711). THE HEALTH CARE PROFESSIONAL REPORTED THAT AFTER ESSURE INTRODUCTION IN THE TUBE WITHOUT ANY DIFFICULTY, THE DISTAL EXTREMITY BROKE, REMAINING INSIDE THE TUBE. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 24-APR-2015: CLINICAL DATA REFERRING TO DEFECT OF ESSURE MICRO-TUBE IMPLANT PLACED ON (B)(6) 2015. PATIENT´S DEMOGRAPHIC INFORMATION WAS PROVIDED. EASY INSERTION OF HYSTEROSCOPE, ALLOWING THE OBSERVATION OF A NORMAL CERVICAL CANAL, UTERINE CAVITY WITH NO MALFORMATIONS, WITH VISIBLE TUBAL ORIFICES. EASY INSERTION OF ESSURE IN THE RIGHT TUBAL ORIFICE, PLACED ACCORDING TO TECHNIQUE AS PER GUIDELINES. ESSURE (REF. (B)(4) LOT C12711) WAS INSERTED WITH NO DIFFICULTIES AND ACCORDING TO ADEQUATE TECHNIQUE IN THE LEFT TUBAL ORIFICE, BUT THE RINGS HAVEN'T EXPANDED. DEVICE WAS REMOVED FROM THE FALLOPIAN TUBE AND IT WAS VERIFIED THAT A SMALL PART OF THE DISTAL EXTREMITY WAS RETAINED INSIDE THE TUBE, THEREFORE LEADING TO THE ASSUMPTION THAT IT WAS BROKEN DURING THE PROCEDURE. A NEW ESSURE WAS THEREFORE INSERTED IN THAT TUBE, WITH AN EASY INSERTION AND THAT OCCURRED WITH NO INCIDENTS, HAVING BEEN PLACED ACCORDING TO THE GUIDELINES. DURING THE PROCEDURE, PATIENT DID AN ANESTHETIC - FENTANYL, PROPOFOL, DYNASTAT (PARECOXIB), PARACETAMOL. ANESTHESIA OCCURRED WITH NO COMPLICATIONS, AS WELL AS RECOVERY AFTER THE SURGICAL PROCEDURE; PATIENT WAS DISCHARGED FROM HOSPITAL, FEELING WELL, WITH NO COMPLAINTS, BEING REFERRED TO THE EXTERNAL CONSULTATION FOR FOLLOW-UP. PATIENT WAS ASYMPTOMATIC. FOLLOW UP INFORMATION RECEIVED ON 30-APR-2015: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

- THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 16-APR-2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP FROM 30-APR-2015: NO NEW INFORMATION. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 30-APR-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER ESSURE INTRODUCTION IN THE TUBE, THE DISTAL EXTREMITY BROKE, REMAINING INSIDE THE TUBE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED; REPORTER MENTIONED THAT THE BREAKAGE OCCURRED AFTER ESSURE INTRODUCTION IN THE FALLOPIAN TUBE. SINCE THE BREAKAGE OCCURRED IN CONNECTION WITH ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00315	BAYER HEALTHCARE LLC	5/14/2015	6/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68790

Single Use: Y
Implant Date (E6): 3/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 17-APR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE LOT NUMBER USED WAS C68790. DURING THE INSERTION PROCEDURE IN THE OPERATING ROOM, THE DEVICE WAS ADVANCED WITHOUT DIFFICULTY, BUT DURING RELEASE THE ESSURE SYSTEM BROKE AND PLACEMENT WAS IMPROPER; THE DEVICE WAS REMOVED AND NOT KEPT. THERE WAS NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT OF ESSURE WAS DONE WITH ANOTHER DEVICE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE ESSURE SYSTEM BROKE DURING RELEASE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, DURING INSERTION PROCEDURE THE DEVICE WAS ADVANCED WITHOUT DIFFICULTY BUT DURING RELEASE THE ESSURE BROKE. THEREFORE, SINCE THE BREAKAGE OCCURRED DURING THE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042698	BAYER	5/15/2015	5/15/2015

Event Information:

Event Date (B3): 1/31/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SUCH SEVERE ABDOMINAL AND PELVIC PAIN I COULD HARDLY WALK.....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042706	BAYER	5/15/2015	5/15/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NEW DOCTOR DID ULTRASOUND DUE TO PAIN AND BLEEDING DURING INTERCOURSE AND PASSING LARGE GOLF BALL SIZED CLOTS WITH PERIOD AT MY ANNUAL VISIT. COIL FOUND TO BE MIGRATED OUT OF TUBE AND EMBEDDED IN MY UTERUS. RECOMMENDATION TO REMOVE ESSURE VIA PARTIAL HYSTERECTOMY. PRE-OP SCHEDULED FOR THIS THURSDAY (B)(6) 2015, AND HYSTERECTOMY SURGERY SCHEDULED FOR WEDNESDAY (B)(6) 2015. I DON'T UNDERSTAND WHAT I HAVE DONE WRONG TO DESERVE THIS. MY HUSBAND AND I TRIED TO BE PROACTIVE TO PREVENT PREGNANCY, NOW I HAVE DOCTORS TELLING ME THAT SINCE MY COIL MIGRATED AND EMBEDDED ITSELF MY PAIN AND CLOTTING WAS MY RIGHT TUBE NOT BEING FULLY BLOCKED, THAT IT'S MOST LIKELY I HAVE BEEN MISCARRYING. SINCE FUNDING THIS OUT WE HAVE HAD TO USE BACKUP BIRTH CONTROL AND LOW AND BEHOLD THE CLOTTING HAS STOPPED, HOWEVER, I STILL NEED A HYSTERECTOMY TO SAFELY REMOVE THE EMBEDDED DEVICE. MY FAMILY DOESN'T DESERVE THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042720	BAYER	5/15/2015	5/15/2015

Event Information:

Event Date (B3): 8/18/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCRUCIATING PAIN, SWELLING IN STOMACH, PAINFUL INTERCOURSE, HEAVY BLEEDING, IRREGULAR MENSTRUAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042721	BAYER	5/15/2015	5/15/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE I HAVE EXPERIENCED THE FOLLOWING: LOSS OF SEX DRIVE/LIBIDO! LOSS OF HAIR (HAVE BOTH BALD SPOT AND RECEDING HAIR LINE) HOT FLASHES, SWEATS, MOOD SWINGS, CRYING FOR NO REASON. SEVERE WEIGHT GAIN WITHOUT BEING ABLE TO LOOSE WEIGHT. SWELLING OF LEGS, HANDS, FEET. JOIN PAIN IN MY HIPS AND LOWER BACK DISABLING AT TIMES. I AM UNABLE TO WALK FOR EXTENDED PERIOD OF TIME, STAND FOR EXTENDED TIME. DIFFICULTY SLEEPING, EXTREME FATIGUE . MIGRAINES. I HAVE HAD BLOOD WORK DONE ALMOST EVERY 6 MONTHS TESTING ALL MY HORMONE LEVELS TESTING FOR THINGS FROM THYROID, DIABETES TO EARLY MENOPAUSE AND LUPS. ALL MY TEST COME BACK NORMAL AND OK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042722	BAYER	5/15/2015	5/15/2015

Event Information:

Event Date (B3): 2/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT SIDE PAIN, HEAVY BLEEDING, CYSTS, HEMORRHAGIC CYSTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042723	BAYER	5/15/2015	5/15/2015

Event Information:

Event Date (B3): 6/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VISION PROBLEMS, VERTIGO, SPEECH PROBLEMS, TOOTH DECAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042724	BAYER	5/15/2015	5/15/2015

Event Information:

Event Date (B3): 12/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED (B)(6) 2014 AND HAVE HAD CONSTANT VAGINAL BLEEDING EVERYDAY SINCE. I HAVE SUFFERED SEVERE ABDOMINAL PAIN, HIGH FEVER, AND ANEMIA. I AM NOW SCHEDULED FOR A COMPLETE HYSTERECTOMY NEXT MONTH TO REMOVE THE DEVICE AND ALL MY REPRODUCTIVE ORGANS; EXCEPT OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042725	BAYER	5/15/2015	5/15/2015

Event Information:

Event Date (B3): 1/7/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE MENSES PAIN ALONE WITH MASSIVE BLEEDING AND PROLONGED PERIODS. SEVERE BACK PAIN AND HEADACHES. EXTREME EMOTIONAL SWINGS. BLOATING CONSTANTLY THAT DOES NOT SUBSIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042795		5/15/2015	5/26/2015

Event Information:

Event Date (B3): 1/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A36519

Single Use:
Implant Date (E6): 12/6/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE LOWER BELLY PAIN, HAIR LOSS, DEPRESSION, SHARP PAIN IN BELLY, CAN'T SLEEP AND HEAVY PAINFUL LONG PERIOD EVERY 10 DAYS. ALSO I HAVE TEETH PROBLEMS, DIZZINESS, TIRED, FEEL SICK ALL THE TIME AND WEIGHT GAIN OF 25 LBS IN 2+ YEARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00320	BAYER HEALTHCARE LLC	5/18/2015	5/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A33570

Single Use:
Implant Date (E6): 11/21/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 05-JUN-2014. IT DESCRIBES THE OCCURRENCE OF 2ND PREGNANCY WITH ESSURE IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR PERMANENT CONTRACEPTION. PATIENT DID NOT GO FOR HSG CONFIRMATION TEST AND BECAME PREGNANT. SHE DELIVERED THE BABY ON (B)(6) (PLEASE REFER TO CASE NUMBER (B)(4)). SHE WENT FOR HSG CONFIRMATION TEST ON (B)(6) 2014 AND BOTH TUBES WERE OCCLUDED. SHE BECAME PREGNANT AGAIN. ULTRASOUND PERFORMED ON (B)(6) 2014 CONFIRMED PREGNANCY. SHE WAS SEEN ON (B)(6) 2014 BY HEALTHCARE PROFESSIONAL AND PREGNANCY TEST DONE IN OFFICE WAS POSITIVE. SHE WAS (B)(6) PREGNANT. ESSURE WAS NOT REMOVED. FOLLOW-UP INFORMATION WAS RECEIVED ON 09-JUN-2014. THE PATIENT HAD ESSURE LOT NUMBER A33570 WITH EXPIRATION 01-JUL-2015 INSERTED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 13-JUN-2014. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES. SHE HAD 04 PREGNANCIES AND 04 LIVE BIRTHS. ON (B)(6) 2012 ESSURE WAS EASILY IMPLANTED. SHE WAS ON POSTPARTUM STATE (SHE DELIVERED ON (B)(6) 2012). CERVICAL DILATATION AND ANALGESIA WERE APPLIED DURING INSERTION. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. HYSTEROSCOPY DURING PROCEDURE WAS PERFORMED TO CONFIRM ESSURE PLACEMENT. SHE NEVER HAD HSG TO CONFIRM OCCLUSION AND GOT PREGNANT AND DELIVERED ON (B)(6) 2013. SHE THEN HAD HSG CONFIRMATION TEST ON (B)(6) 2014 WHICH SHOWED TUBES WERE BOTH OCCLUDED. ON (B)(6) 2014 SHE EXPERIENCED HER LAST MENSTRUAL PERIOD. ON (B)(6) 2014 BLOOD TEST CONFIRMED PREGNANCY. ON (B)(6) 2014

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ULTRASOUND WAS PERFORMED AND SHOWED GESTATIONAL AGE OF (B)(6). (B)(6) 2014 WAS THE EXPECTED DATE OF DELIVERY. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-JUN-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. IN THIS PARTICULAR CASE A LACK OF EFFICACY WAS REPORTED. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. A33570, OF WHICH (B)(4) CASES ALSO REFER TO SIMILAR LACK OF EFFICACY TYPE OF EVENTS. ONE OF THEM REFERS TO THE 2ND PREGNANCY OF THE SAME PATIENT. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REVIEW OF THE MANUFACTURING- AND RELEASE DOCUMENTATION OF THE CONCERNED BATCH DID NOT GIVE ANY REASON TO SUSPECT A QUALITY DEFICIT (SEE TECHNICAL STATEMENT). NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 20-APR-2015 FROM PHYSICIAN: HE REPORTED THAT THE FETAL OUTCOME WAS NORMAL (DELIVERY DATE NOT REPORTED). ON AN UNSPECIFIED DATE, A PARTIAL SALPINGECTOMY AND REMOVAL OF A PERFORATED ESSURE FROM RIGHT CORNUAL AREA BY LAPAROSCOPY WERE DONE. NO PATHOLOGY RESULT WAS AVAILABLE. PHYSICIAN STATED THAT THE PATIENT'S CONDITION WAS CAUSED BY ESSURE DEVICE, DUE TO PERFORATION. THE PATIENT HAD BEEN STERILIZED BY LAPAROSCOPY. PTC INVESTIGATION RESULT RECEIVED ON 23-APR-2015 (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN ADDITION, THE AE CASE REFERS TO TREATMENT NONCOMPLIANCE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH (B)(4) CASES REFER ALSO TO A SIMILAR LACK OF EFFICACY TYPE OF EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT. AFTER DELIVERY, SHE WAS SUBMITTED TO A LAPAROSCOPY AND ESSURE WAS FOUND PERFORATED FROM RIGHT CORNUAL AREA; THIS DEVICE WAS REMOVED ALONG WITH A PARTIAL SALPINGECTOMY. ALL EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. PREGNANCY WAS CONSIDERED NON-SERIOUS, WHILE PERFORATION WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR

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DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HYSTEROSALPINGOGRAM/HSG). IN THIS PARTICULAR CASE, PATIENT HAD 2 PREGNANCIES WITH ESSURE; FOR THE FIRST PREGNANCY SHE DID NOT HAVE HER HSG; HOWEVER BEFORE THE SECOND PREGNANCY (THIS CASE) A HSG WAS PERFORMED AND SHOWED BILATERAL OCCLUSION. CONSIDERING THIS INFORMATION, AN ESSURE'S CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING THE REPORTED UTERINE PERFORATION, ALTHOUGH ITS EXACT MECHANISM IS NOT KNOWN; DUE TO ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS UPGRADED TO INCIDENT DUE TO THE INTERVENTION REPORTED UPON FOLLOW-UP. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00321	BAYER HEALTHCARE LLC	5/18/2015	5/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON (B)(6)-2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. CONSUMER REPORTED THAT SHE BROKE HER TOE BECAUSE SHE GOT DIZZY (AGAIN) AND ASSOCIATED THESE EVENTS TO ESSURE. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON (B)(6)-2015: INFORMATION RECEIVED FROM CONSUMER VIA SOCIAL MEDIA STATES THAT THE LAST SIX MONTHS OF HER LIFE HAS BEEN HELL BETWEEN ESSURE AND LUPUS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6)-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: THIS IS NOT A CONFIRMED REPORT VIA SOCIAL MEDIA. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. A BROKEN TOE AND DIZZINESS ARE NOT KNOWN FAILURE MODES RELATED TO ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN THIS PARTICULAR CASE, CONSUMER STATED THAT SHE BROKE HER TOE BECAUSE SHE GOT DIZZY DUE TO ESSURE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE AND WERE CONSIDERED UNRELATED BY COMPANY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV

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DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON (B)(6)-2015: CONSUMER REPORTED (VIA SOCIAL MEDIA) SHE WAS AT 12 DAYS POST-OPERATIVE FROM ESSURE REMOVAL AND SHE HAS ALL SORTS OF PAIN IN HER BELLY. FOLLOW UP INFORMATION RECEIVED ON (B)(6)-2015: PTC ASSESSMENT UPDATED RECEIVED WITHOUT MAJOR CHANGES. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SOME TIME LATER, HAD ESSURE REMOVED. THIS EVENT IS SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF ESSURE REMOVAL IS NECESSARY, SURGERY MAY BE REQUIRED. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. THE CONSUMER STATED SHE WAS AT 12 DAYS POS-OP FROM ESSURE REMOVAL. GIVEN ITS NATURE, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE USE. THIS CASE WAS PREVIOUSLY REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION (VIA SOCIAL MEDIA) IT WAS UPGRADED TO INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00322	BAYER HEALTHCARE LLC	5/18/2015	5/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** TU

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): FALLOPIAN TUBE OCCLUSION INSERT
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON (B)(6) 2015, ARTICLE ENTITLED "ESSURE MICROINSERT HYSTEROSCOPIC TUBAL STERILIZATION: EIGHT-YEARS FOLLOW-UP RESULTS". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION AND A PREGNANCY WAS DETECTED 9 MONTHS AFTER CESSATION OF THE ALTERNATIVE CONTRACEPTIVE PERIOD. AUTHORS REPORT RESULTS OF A PROSPECTIVE, INTERVENTIONAL STUDY OF 34 PATIENTS WHO UNDERWENT BILATERAL MICROINSERT PLACEMENT FOR TUBAL STERILIZATION, BETWEEN JANUARY 2004 AND DECEMBER 2005. IN THE 8 YEARS OF FOLLOW-UP, ONE PREGNANCY WAS DETECTED. "ONE INTRAUTERINE PREGNANCY WAS DETECTED IN ONE OF THE PATIENTS NINE MONTHS AFTER CESSATION OF THE ALTERNATIVE CONTRACEPTIVE PERIOD. THIS PATIENT WAS EXCLUDED FROM THE FOLLOW-UP". [THERE IS NO FURTHER INFORMATION ON THIS PATIENT OR THE PREGNANCY OUTCOME. THIS INFORMATION WAS NOTED IN THE ARTICLE ABSTRACT. THE FULL ARTICLE HAS BEEN ORDERED]. STUDY ABSTRACT OBJECTIVES: TO EVALUATE THE EFFECTIVENESS AND RELIABILITY OF MICROINSERT HYSTEROSCOPIC STERILIZATION METHOD AT SHORT- AND LONG-TERM. MATERIALS AND METHODS: IN THE PERIOD BETWEEN JANUARY 2004 AND DECEMBER 2005, 34 PATIENTS WHO SUBMITTED TO THE PRESENT GYNECOLOGY OUTPATIENT CLINIC SEEKING FOR PERMANENT CONTRACEPTION AND ACCEPTED TUBAL STERILIZATION WITH MICROINSERT METHOD WERE INCLUDED IN THIS PROSPECTIVE, INTERVENTIONAL STUDY. RESULTS: BILATERAL MICROINSERT PLACEMENT WAS SUCCESSFUL IN 28 (87.5%) OF 32 PATIENTS THAT UNDERWENT THE PROCEDURE. IN ALL OF THE 30 PATIENTS (100%) IN WHOM THE PLACEMENT PROCEDURE WAS ATTEMPTED, BILATERAL TUBAL OCCLUSION WAS DOCUMENTED BY HYSTEROSALPINGOGRAM (HSG) INCLUDING THE TWO PATIENTS IN WHOM UNILATERAL PLACEMENT WAS CARRIED OUT. FIRST THREE PROCEDURES WERE

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PERFORMED UNDER GENERAL ANESTHESIA. LOCAL OR GENERAL ANESTHESIA WAS NOT ADMINISTERED IN ANY OTHER CASES (97.5%). THE MEAN VISUAL ANALOGUE SCALE SCORE FOR PAIN FELT DURING THE PROCEDURE WAS 3.1. THE MEAN PROCEDURE TIME WAS 11.5 ± 4.88 (5-22) MINUTES, THE AVERAGE TIME FROM BEGINNING THE PROCEDURE TO DISCHARGE OF THE PATIENTS WAS 41.7 ± 18.5 (15-94) MINUTES. ONE INTRAUTERINE PREGNANCY WAS DETECTED IN ONE OF THE PATIENTS NINE MONTHS AFTER CESSATION OF THE ALTERNATIVE CONTRACEPTIVE PERIOD. THIS PATIENT WAS EXCLUDED FROM THE FOLLOW-UP. AT SHORT-TERM ALL PATIENTS RATED THEIR MICROINSERT-WEARING TOLERANCE AS GOOD OR EXCELLENT. AT EIGHTH YEAR, THREE PATIENTS WERE LOST TO FOLLOW-UP. MEAN FOLLOW-UP TIME WAS 83.4 ± 15.0 (36-103) MONTHS. DURING 2,420 WOMAN-MONTHS OF FOLLOW-UP, NO OTHER PREGNANCIES WERE DETECTED. ALMOST ALL OF THE PATIENTS WERE HAPPY WITH THE PROCEDURE AND RECOMMENDED IT TO A FRIEND. CONCLUSION: ESSURE MICROINSERT IS A SAFE, EFFECTIVE, MINIMALLY INVASIVE STERILIZATION METHOD WHICH CAN BE PERFORMED IN OUTPATIENT SETTINGS WITHOUT ANY ANESTHESIA REQUIREMENT. IT APPEARS TO BE A GOOD ALTERNATIVE TO LAPAROSCOPIC TUBAL STERILIZATION. THE PROCEDURE TIME AND THE TIME TO DISCHARGE ARE BRIEF. PATIENT TOLERANCE DURING THE PROCEDURE AND AT LONG-TERM IS VERY GOOD. FOLLOW-UP:(B)(4) 2015: THE FULL ARTICLE WAS RECEIVED AND PROVIDED THE FOLLOWING PATIENT INFORMATION: THE HSG (HYSTEROSALPINGOGRAM) FILM HAD DEMONSTRATED NO PASSAGE BILATERALLY. THE PATIENT BECAME PREGNANT AT MONTH NINE OF ABANDONING THE ALTERNATIVE CONTRACEPTION METHOD. A SIX-WEEK PREGNANCY WITH POSITIVE FETAL CARDIAC ACTIVITY WAS DETECTED BY TRANSVAGINAL SONOGRAPHY. THE PREGNANCY WAS TERMINATED DUE TO THE REQUEST OF THE PATIENT AND SHE UNDERWENT HYSTEROSCOPY AGAIN SIX WEEKS AFTER HER CURETTAGE. THE TAIL LENGTH OF THE RIGHT AND LEFT MICROINSERTS WERE TWO AND SIX COILS, RESPECTIVELY, AND BOTH TWO TAILS WERE MONITORED ALIGNED AT THE TUBAL OSTIUM. DESPITE THIS, TO ELIMINATE MYOMETRIAL PLACEMENT, BILATERAL CANNULATION OF THE TUBES WAS RE-ATTEMPTED, UNFORTUNATELY THIS ATTEMPT HAD FAILED. ONE DAY AFTER OFFICE HYSTEROSCOPY A SECOND HSG WAS PERFORMED. IT WAS VERY INTERESTING THAT NO BILATERAL PASSAGE WAS MONITORED IN THE NEW HSG. ALTHOUGH PASSAGE COULD NOT BE MONITORED BY HSG, IT WAS THOUGHT THAT THE TUBAL OCCLUSION AT THE LEFT ASYMMETRIC MICROINSERT HAD NOT BEEN COMPLETED OR THAT THE MICROINSERT WAS PLACED INTRA-MYOMETRIALLY LOCATED AT THE COMUAL REGION, AND THEREFORE LAPAROSCOPIC TUBAL STERILIZATION WAS APPLIED UPON REQUEST BY THE PATIENT. NO PERFORATING MICROINSERT, EXTENDING TOWARDS THE ABDOMINAL CAVITY FROM THE MYOMETRIUM WAS MONITORED DURING LAPAROSCOPY. THIS PATIENT WAS WITHDRAWN FROM THE FOLLOW-UP. AUTHOR'S COMMENT ONE NEW GESTATION HAD OCCURRED IN ONE PATIENT DESPITE THE DOCUMENTATION OF TUBAL BLOCK TWICE VIA HSG PERFORMED ONE YEAR APART IN THE SAME PATIENT. COMPARED TO THE FIRST HSG, THE MICROINSERT AT RIGHT TUBE SEEMED TO LOCATE MORE DISTALLY AT THE SECOND YEAR HSG. INTERESTINGLY, THE LAPAROSCOPY PROCEDURE OF THIS PARTICIPANT REVEALED NO MYOMETRIAL PERFORATION BY ESSURE AND UNINTENDED GESTATION MAY BE DUE TO THE INADEQUATE FIBROSIS OF TUBA UTERINA. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH

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NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON (B)(4) 2015: PTC ASSESSMENT (ONLY RISK CLASSIFICATION UPDATED) RECEIVED WITHOUT MAJOR CHANGES. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6)-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1. DEVICE DISLOCATION: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 34 CASES. 2. PREGNANCY WITH CONTRACEPTIVE DEVICE: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 224 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE AND REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A PREGNANCY 9 MONTHS AFTER CESSATION OF THE ALTERNATIVE CONTRACEPTIVE PERIOD. SHE UNDERWENT AN ELECTIVE ABORTION. PREGNANCY IS A NON-SERIOUS AND LISTED EVENT IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HYSTEROSALPINGOGRAM/HSG). IN THE PRESENT CASE, PATIENT HAD A HSG SHOWING BILATERAL TUBAL OCCLUSION PRIOR TO PREGNANCY ONSET, THIS EXAM WAS REPEATED AFTER THE ELECTIVE ABORTION CONFIRMING OCCLUSION. ACCORDING TO THE AUTHOR, PREGNANCY IN THIS CASE MIGHT BE DUE TO INADEQUATE FIBROSIS OF THE TUBA. GIVEN THE ABOVE MENTION INFORMATION, COMPANY CONSIDERS AN ESSURE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. AFTER THE ELECTIVE ABORTION, PHYSICIAN SUSPECTED THE MICRO INSERT AT RIGHT TUBE WAS LOCATED MORE DISTALLY AT THE SECOND HSG, HE THOUGH THE MICRO-INSERT COULD HAVE BEEN PLACED MYOMETRIALLY. HE PERFORMED A LAPAROSCOPIC TUBAL STERILIZATION; DURING THE SURGERY NO PERFORATION WAS FOUND. ALTHOUGH THE SURGERY IN THIS CASE WAS PERFORMED DUE TO PATIENT'S REQUEST AND NO PERFORATION WAS FOUND; SINCE AN INTERVENTION RELATED TO ESSURE WAS PERFORMED THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042733	BAYER	5/18/2015	5/18/2015

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE HAVING ESSURE I HAVE EXPERIENCED HORRIBLY PAINFUL PERIODS WITH LARGE CLOTS AND EXTREMELY HEAVY BLEEDING. I AM BLOATED AND LOOK PREGNANT. I HAVE SEVERE ABDOMINAL PAIN AND LOWER BACK PAIN. I HAVE SHARP PAINS IN MY OVER AREAS THAT TAKE ME TO THE GROUND CRYING IN PAIN. I HAVE FREQUENT UTI'S AS WELL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042735	BAYER	5/18/2015	5/18/2015

Event Information:

Event Date (B3): 4/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THESE INSERTS PLACED (B)(6) 2014. AT THE 3 MONTH HSG CHECK ONE WAS IN THE TUBE WHERE IT WAS SUPPOSED TO BE, THE OTHER WAS COMPLETELY OUT OF THE TUBE AND HOOKED ON THE UTERINE WALL. THEY WERE UNABLE TO TELL IF IT WAS INSIDE OR OUTSIDE THE UTERUS. ON (B)(6) I HAD A BILATERAL SALPINGECTOMY TO REMOVE THE TUBED ALL TOGETHER. I HAVE HAD SOME SIGNIFICANT POST OP COMPLICATIONS AND WILL HAVE TO BE OFF WORK TO RECOVER. AND TODAY ON THE POST OP XRAY-THE INSERT IS STILL THERE, PROBABLY EMBEDDED IN THE UTERUS WHERE IT WILL *HOPEFULLY POSE NO THREAT. I AM ANGRY AND UPSET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042756	BAYER	5/18/2015	5/19/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MESSED UP MENSTRUAL CYCLE...SORE JOINTS...HEADACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042802	BAYER	5/18/2015	5/26/2015

Event Information:

Event Date (B3): 9/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/16/2010
Explant Date (E7): 12/18/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2010. MY PERIODS PROGRESSIVELY BECAME MORE PAINFUL WITH HEAVIER BLEEDING CAUSING LARGE BLOOD CLOTS TO PASS. EVERY MONTH PRIOR TO MY MENSTRUAL CYCLE I WOULD ENDUE A 2 DAY MIGRAINE HEADACHE THAT PREVENTED ME FROM DAILY ACTIVITY. THE CRAMPING FROM MY PERIODS BECAME UNBEARABLE. AFTER TRYING SEVERAL PRESCRIPTION MIGRAINE MEDICATIONS FROM MY PRIMARY DOCTOR MY OBGYN RECOMMENDED A HYSTERECTOMY IN 2014. THE PROCEDURE WAS SCHEDULED TO BE LAPAROSCOPIC, BUT DUE TO MY LEFT COIL PUNCTURING MY FALLOPIAN TUBE THEY HAD TO GO IN ABDOMINALLY TO REMOVE THE SEVERE ENDOMETRIOSIS. I WAS NEVER DIAGNOSED OR HAD DIFFICULTY WITH ENDOMETRIOSIS UNTIL AFTER ESSURE. I HAD EVERYTHING REMOVED IN (B)(6) OF 2014 EXCEPT MY RIGHT OVARY (THE LEFT WAS REMOVED DUE TO THE DAMAGE AND I AM NOW BEING TREATED FOR AN ENDOMETRIAL CYST ON MY RIGHT OVARY WHICH IS CAUSED SEVERE PAIN AND CRAMPING DAILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042804		5/18/2015	5/26/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE AS A PERMANENT BIRTH CONTROL (B)(6). SINCE THEN I HAVE CONSISTENT, SOMETIMES DEBILITATING PAIN. I HAVE ABNORMAL BLEEDING DURING MY MENSTRUAL CYCLE. I WOULD LOVE TO HAVE THEM REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042805	BAYER HEALTH	5/18/2015	5/26/2015

Event Information:

Event Date (B3): 7/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL, PERMANENT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/13/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE MEDICAL DEVICE IN (B)(6) 2013 AND SINCE THEN HAVE HAD INCREASING PROBLEMS WITH MY MONTHLY CYCLE - SEVERE CRAMPING, AND CLOTTING. I HAVE INCREASED FATIGUE ALL THE TIME, NIGHT SWEATS, HOT FLASHES. I HAVE GAINED 40 LBS IN ONE YEAR. I HAVE HAD A KIDNEY INFECTION AND OTHER FEMALE INFECTIONS. I HAVE SEVERE MOOD SWINGS AND DEPRESSION. I OFTEN AM HAVING PAIN IN MY OVARIES AREA.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE, LLC	5/18/2015	6/10/2015

Event Information:

Event Date (B3): 2/27/2015 **Report Date (B4): 5/18/2015** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305-R1
Lot #(E4): CS000E5; C91745; C06520

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE WAS ATTEMPTED TO BE PLACED IN THE PATIENT'S RIGHT FALLOPIAN TUBE. HOWEVER, UPON THE ENTRANCE OF THE ESSURE DEVICE INTO THE THREADING CATHETER, THE ESSURE WOUND BEND AT A 90 DEGREE ANGLE. THIS WAS ATTEMPTED TO BE STRAIGHTENED, COULD NOT BE DONE. THE SECOND ESSURE WAS ABLE TO BE PLACED INTO THE UTERUS, BROUGHT TO THE FALLOPIAN TUBE AND THEN TUBAL SPASM WAS PRESENT WHICH THEN BENT THE TIP OF THE ESSURE. THE THIRD ESSURE WAS BENT AGAIN WITH INSERTION THROUGH THE GUIDANCE CATHETER. AT THIS POINT, THE DECISION WAS MADE TO PROCEED WITH LAPAROSCOPIC TUBAL. NO HARM TO PATIENT; NO EXCESSIVE BLOOD LOSS. THE PROCEDURE COMPLETED WAS LAPAROSCOPIC TUBAL LIGATION.
==========
MANUFACTURER RESPONSE FOR PERMANENT BIRTH CONTROL, ESSURE PERMANENT BIRTH CONTROL (PER SITE REPORTER).
==========
RETURNED TO REP.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00323	BAYER HEALTHCARE LLC	5/18/2015	6/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 20-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND ONE OF ESSURE DEVICES WAS DYSFUNCTIONAL, IT DID NOT FIRE RIGHT. THE DOCTOR WOULD HAVE TO TAKE THE PATIENT TO THE OR (OPERATING ROOM) TO TAKE IT OUT. PTC INVESTIGATION RESULT WAS RECEIVED ON 07-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: 1) ROLLBACK TO INITIAL HARD STOP. 2) DEPRESS BUTTON. 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO DEPLOYMENT DIFFICULTY. SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. AS OF 4/29/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE

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INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS AND NO BATCH NUMBER HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND ONE ESSURE DEVICE WAS DYSFUNCTIONAL, IT DIDN'T FIRE RIGHT. THIS EVENT, SEEN AS DEVICE DEPLOYMENT ISSUE, IS SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEPLOYMENT ISSUES MAY OCCUR DURING DIFFICULT INSERTIONS. IN THIS CASE, ONE OF ESSURE DEVICES WAS DYSFUNCTIONAL, IT DID NOT FIRE RIGHT. THE PHYSICIAN WOULD HAVE TO TAKE THE PATIENT TO OPERATING ROOM TO REMOVE IT. CONSIDERING THE EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS IMPLIED TO REMOVE THE MICRO-INSERT, THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION COULD NOT BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00324	BAYER HEALTHCARE LLC	5/19/2015	5/19/2015

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 836496

Single Use:
Implant Date (E6): 7/1/2009
Explant Date (E7): 7/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5032855) IN UNITED STATES ON (B)(6) 2014. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NO SEX DRIVE, PAINFUL SEX, PROLONGED PERIODS, UNNATURAL BLEEDING AND DEPRESSION FIGATIVE. NO INFORMATION WAS GIVEN ON THE CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2011 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE EXPERIENCED REALLY BAD SIDE EFFECTS FROM ESSURE, SUCH AS NO SEX DRIVE, PAINFUL SEX, PROLONGED PERIODS, UNNATURAL BLEEDING AND DEPRESSION "FIGATIVE". SHE HAD IT REMOVED ON (B)(6) 2013 AND REPORTED THAT SHE HAS LOST HER LIFE DURING THOSE YEARS THAT SHE HAD ESSURE IN PLACE AND IS STILL NOT FULLY BACK TO HER NORMAL SELF. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014. PATIENT DEMOGRAPHIC DATA WERE ADDED. SHE WAS (B)(6) AT TIME OF EVENTS. THE PATIENT STATED THAT, BEFORE ESSURE, SHE USED MIRENA FOR A WHILE, BUT SHE REMOVED IT DUE TO MASSIVE SIDE EFFECTS (ALREADY REPORTED). SHE ALSO EXPERIENCED REACTIONS TO DEPO. ACCORDING TO HER SHE HAS ADVERSE REACTIONS TO A LOT OF THINGS. OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITION WAS DENIED. IN (B)(6) 2009 (DATE UPDATED) THE PATIENT HAD ESSURE MICRO-INSERT INSERTED, LOT NUMBER WAS 836496. THE INSERTION OCCURRED ABOUT 1 YEAR AFTER DELIVERY. IN (B)(6) 2009 THE PATIENT UNDERWENT A HSG (HYSTEROSALPINGOGRAPHY) AND IT SHOWED THAT THE COILS WERE PLACED PROPERLY. THE REPORTER CONFIRMED ALL PREVIOUSLY REPORTED EVENTS AND ASKED TO CORRECT THE EVENT DEPRESSION FIGATIVE TO DEPRESSION FATIGUE. THE EVENTS STARTED AFTER (B)(6) 2009. PATIENT WAS ALSO DIAGNOSED WITH ENDOMETRIOSIS AND WAS TOLD IT WAS INOPERABLE AND THAT THERE WAS NOTHING THE PHYSICIANS COULD DO AFTER SHE DECLINED

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THE TREATMENT WITH DEPO-LUPRON SHOTS. SO, SHE WENT TO A DIFFERENT PHYSICIAN WHO PERFORMED A LAPAROTOMY AND REMOVED THE ESSURE IN (B)(6) 2013. THE MICRO-INSERTS WERE IN THE CORRECT LOCATION OCCLUDING THE TUBES. HYSTERECTOMY OR SALPINGECTOMY WAS NOT NECESSARY. THE REPORTING CONSUMER STATED THAT THE ESSURE REMOVAL WAS MEDICALLY NECESSARY AND THAT SHE HAD UNDERGONE NUMEROUS X-RAYS, ULTRASOUNDS, AND LAB STUDIES BUT NO ALLERGY TESTS WERE PERFORMED. AFTER ESSURE REMOVAL THE PATIENT UNDERWENT X-RAYS TO MAKE SURE THE FRAGMENTS WERE ALL REMOVED AND NOTHING WAS LEFT OVER. THERE WERE NO PATHOLOGY RESULTS, BUT THE DOCTOR TOLD THE PATIENT SHE HAD NO ENDOMETRIOSIS. HOSPITALIZATION WAS DENIED AND SHE RECOVERING FROM THE EVENTS AFTER THE DEVICE REMOVAL; SHE WAS STILL EXPERIENCING PAINFUL INTERCOURSE AND NO SEX DRIVE. THE PATIENT BELIEVED THAT THE EVENTS WERE CAUSED BY ESSURE ONCE DIDN'T HAVE ANY OF THESE ISSUES PRIOR IT INSERTION. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2014 - PTC INVESTIGATION RESULT PROVIDED: (B)(4). MEDICAL ASSESSMENT: THE EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR TECHNICAL INVESTIGATION. NO FURTHER ADVERSE EVENT WAS REPORTED AT THE TIME OF THIS ASSESSMENT. NO ADDITIONAL AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 836496. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REVIEW OF THE LOT HISTORY RECORDS FOUND THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AT THE TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN (B)(4). FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2014: NO NEW CLINICAL INFORMATION PROVIDED. FOLLOW-UP RECEIVED ON (B)(4) 2015: INFORMATION RECEIVED STATES THAT CONSUMER HAS BLACK SPOTS ALL OVER HER TEETH. SHE IS ALLERGIC TO NICKEL AND INFORMED THAT SHE WAS NOT MARKED FOR NICKEL ALLERGIES AT THE TIME OF INSERTION. CONSUMER ALSO REPORTED THAT SHE CAN FEEL IT BURNING AND SIZZLING, SHE EXPERIENCED EXCRUCIATING PAIN AND STOMACH BLOATS. CONSUMER HAD FULL HYSTERECTOMY AND PRESENTED INSTANT RELIEF. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING PAIN AND UNNATURAL BLEEDING (INTERPRETED AS GENITAL BLEEDING). BOTH EVENTS WERE CONSIDERED SERIOUS AND ARE CONSIDERED LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON AVAILABLE INFORMATION AND CONSIDERING A POSITIVE DECHALLENGE, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND EVENTS IS POSSIBLE AND ASSESSED RELATED. THIS CASE WAS REGARDED AS INCIDENT DUE TO FULL HYSTERECTOMY PERFORMED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. ADDITIONALLY, NON-SERIOUS EVENTS WERE ADDED. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00325	BAYER HEALTHCARE LLC	5/19/2015	5/19/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA LAY PRESS IN UNITED STATES ON (B)(6)-2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD ABDOMINAL PAIN WHICH BECAME CHRONIC. HER PAIN LEVEL WAS AN 8 OUT OF 10. SHE WENT BACK TO THE DOCTOR AND WAS TOLD THAT IT COULD NOT BE RELATED TO ESSURE BECAUSE THERE WERE NO SIDE EFFECTS TO ESSURE. SHE SAID THAT IT TOOK TWO YEARS OF LOOKING TO FIND A DOCTOR WHO WOULD REMOVE ESSURE THROUGH A FULL HYSTERECTOMY. CONSUMER STATED THAT SHE IMMEDIATELY WOKE UP AND FELT BETTER. THE NURSES WERE SHOCKED AT HOW WELL SHE WAS FEELING AFTER A FULL HYSTERECTOMY. SHE SAID THAT DID NOT KNOW THE KIND OF PAIN SHE HAS BEEN LIVING IN FOR THE PAST TWO YEARS AND THE PAIN FROM THE SURGERY WAS NOTHING COMPARED TO EVERYDAY PAIN THAT SHE HAS BEEN DEALING WITH. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6)-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT

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PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN WHICH BECAME CHRONIC (PAIN LEVEL WAS 8 OUT OF 10). THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE USE. IN THIS CASE, THE PATIENT HAD INTENSE ABDOMINAL PAIN (PAIN LEVEL WAS AN 8 OUT OF 10) WHICH BECAME CHRONIC. A HYSTERECTOMY WAS PERFORMED AND SHE IMMEDIATELY FELT BETTER (POSITIVE DECHALLENGE). CONSIDERING THE EVENTS' S NATURE AND POSITIVE DECHALLENGE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. SINCE HYSTERECTOMY WAS REPORTED, THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION COULD NOT BE OBTAINED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 21-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00326	BAYER HEALTHCARE LLC	5/19/2015	5/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR VIA SOCIAL MEDIA IN UNITED STATES ON 21-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS PROVIDED). THE PHYSICIAN REPORTED THAT OUT OF THE DOZENS OF PATIENTS HE HAS IMPLANTED ESSURE, HE HAS ONLY REMOVED ONE. NO ADDITIONAL INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 06-MAY-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD IT REMOVED. THIS EVENT WAS

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CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. THE PHYSICIAN REPORTED THAT OUT OF DOZENS OF PATIENTS HE HAS IMPLANTED ESSURE, HE HAS ONLY REMOVED ONE. THE EXACT REASON FOR THE REMOVAL WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REPORTED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 11-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIEN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00327	BAYER HEALTHCARE LLC	5/19/2015	5/19/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C76446

Single Use: *
Implant Date (E6): 12/30/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT STERILIZATION (LOT NUMBER C76446). PHYSICIAN REPORTED THAT PER HYSTEROSALPINGOGRAM DONE ON (B)(6) 2015, NO COILS WERE FOUND. THE RIGHT SIDE WAS BLOCKED BUT THERE WERE NO COILS. HCP (HEALTH CARE PROFESSIONAL) SAID THAT THE LEFT SIDE HAD NO COILS AS WELL. PATIENT WAS IN HOSPITAL ON (B)(6) 2015 FOR LAP (LAPAROSCOPY) WITH OPTION TO DO TUBAL. NO ADDITIONAL INFORMATION WAS PROVIDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. PTC INVESTIGATION RESULT WITH CORRECT CASE NUMBER WAS RECEIVED ON (B)(4) 2015. LOT NUMBER: C76446; PRODUCTION DATE: 7/2/2014 AND EXPIRATION DATE: 7/31/2017. PTC UPDATED WITH CASE NUMBER WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT PER HSG TEST, NO COILS FOUND (RIGHT AND LEFT). THIS EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, A HYSTEROSALPINGOGRAM WAS PERFORMED ABOUT 4 MONTHS AFTER ESSURE INSERTION AND THE RESULT SHOWED NO COILS WERE FOUND. THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO HOSPITALIZATION AND REQUIRED INTERVENTION (LAPAROSCOPY WITH OPTION TO DO TUBAL). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 04-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00329	BAYER HEALTHCARE LLC	5/19/2015	5/19/2015

Event Information:

Event Date (B3): 4/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06520

Single Use:
Implant Date (E6): 3/11/2015
Explant Date (E7): 4/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 21-APR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C06520 FOR PERMANENT STERILIZATION. DURING PROCEDURE, HCP (HEALTH CARE PROFESSIONAL) COULD ONLY GET LEFT TUBE DONE AND HAD VISUALIZATION PROBLEMS. ON (B)(6) 2015 PATIENT CALLED PHYSICIAN AND COMPLAINED OF RASH. PATIENT HAD TAKEN BENADRYL BUT IT DID NOT HELP. PHYSICIAN PRESCRIBED MEDROL DOSE PACK, THAT DID NOT HELP EITHER. THEN ON (B)(6) 2015 SURGERY WAS PERFORMED AND ONE ESSURE COIL WAS REMOVED. THEN, HER TUBES WERE TIED. PTC INVESTIGATION RESULT WAS RECEIVED ON 06-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C06520 (PRODUCTION DATE 27-DEC-2013 AND EXPIRATION DATE 31-DEC-2016) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED.

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NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RASH. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE EVENT OCCURRED AFTER DEVICE INSERTION; THEREFORE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENT WAS ADDED: COULD ONLY GET ONE TUBE DONE/VISUALIZATION PROBLEMS. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION (GENERAL QUESTIONNAIRE) RECEIVED ON 02-JUN-2015: THE PHYSICIAN MEDICALLY CONFIRMED THE PREVIOUS EVENTS AND DETAILS REPORTED. THE PATIENT DID NOT HAVE ANY PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. THE PATIENT HAD AN UNMENTIONED N

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042757	BAYER	5/19/2015	5/19/2015

Event Information:

Event Date (B3): 5/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER INSERTED, I BLEED FOR A MONTH AND HALF, HAD LOWER BACK PAIN AND SEVERE PAIN ON MY LEFT SIDE . THEN GAIN ABOUT 40 LBS AND STILL HAD PAIN EVERYDAY IN LOWER ABDOMEN, DON'T HAVE REGULAR PERIODS, I HAVEN'T BLEED FOR MORE THAN ONE DAY A MONTH SINCE THEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042758	BAYER	5/19/2015	5/19/2015

Event Information:

Event Date (B3): 4/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DAY OF IMPLANTATION I HAD SEVERE PAIN TO POINT OF HOSPITALIZATION. STILL HAVE EXTREME PAIN EVERY DAY. NO PERIODS. AND IF I DO, IT'S LIKE ONE DAY. HAIR FALLING OUT. WEIGHT GAIN THAT CAN'T BE LOST. NAUSEA, VOMITING. SPASMS IN RIGHT SIDE WHERE OVARY IS. MOOD SWINGS THAT DO NOT ASSOCIATE WITH MY BIPOLAR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042759	BAYER	5/19/2015	5/20/2015

Event Information:

Event Date (B3): 2/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN THE PELVIC AREA, PAIN DURING AND AFTER INTERCOURSE, SEVERE MENSTRUAL PAIN, AND CERVICAL DYSPLASIA. TENDERNESS IN THE BREAST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE, LLC	5/19/2015	5/26/2015

Event Information:

Event Date (B3): 2/26/2015 **Report Date (B4): 5/19/2015** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): *
Catalog # (E4): ESS305
Lot #(E4): D01976

Single Use:
Implant Date (E6): 2/26/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS WERE INSERTED INTO FALLOPIAN TUBES; WHILE PLACING COIL, THE COIL DISLODGED FROM THE IMPLANT DEVICE, MAKING IT NON-IMPLANTABLE. WE REPLACED THE NON-IMPLANTABLE ESSURE WITH A NEW ONE, WHICH WAS THEN IMPLANTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042800	BAYERS	5/19/2015	5/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A MIRENA THEN SWITCHED TO ESSURE ABOUT 2 1/2 YEARS AGO. I HAVE CALLED SO MANY TIMES TO COMPLAIN THAT I'M BLEEDING SO MUCH IN AN HOUR DURING CYCLE, ABDOMEN AND PELVIS PAIN WHERE I'M IN FETAL POSITION. ALL THEY COULD TELL ME IS LET IT SETTLE IN AND IT WILL GO AWAY. IT HAS NEVER STOPPED HURTING... AND I CALLED AGAIN NOT TO LONG AGO THEY ASKED ME TO SEE ANOTHER DOCTOR BECAUSE THAT DOCTOR DOESN'T BELIEVE IT'S CAUSE IS ESSURE. NOT HAPPY. ALL I WANT IS FOR THEM TO REVERSE IT AND LET ME BE BACK TO NORMAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042812	CONCEPTUS/BAYER	5/19/2015	5/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 2005

Single Use:
Implant Date (E6): 5/19/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS REGARDING 2005 ESSURE IMPLANTS. DEVELOPED AUTOIMMUNE DISORDER SHORTLY AFTER INSERTION, CHRONIC LEFT LOWER QUADRANT PAIN, WHICH AFTER EXPLORATORY SURGERY 3 YEARS LATER SHOWED ADHESIONS OF LEFT SIDE, CHRONIC BLOATING, FATIGUE, HEAVY PERIODS, CLOTTING, CRAMPING, CHRONIC FATIGUE, CHRONIC TINNITUS,DEPRESSION, ANXIETY, METAL TASTE IN MOUTH, EXCESSIVE HAIR LOSS, RECURRENT OVARIAN CYSTS, CHRONIC AND SYSTEMIC INFLAMMATION OF EVERY SYSTEM, NICKEL SENSITIVITY, ALL PROGRESSIVELY BECOMING INCREASINGLY WORSE OVER THE YEARS UNTIL (B)(6) 2015, UNDERWENT ABDOMINAL HYSTERECTOMY TO REMOVE ESSURE. PATHOLOGY REPORT SHOWED OVARIAN CYSTS, VASCULAR CONGESTION OF TUBES AND PARA TUBULAR CYSTS IN BOTH TUBES, FIBROIDS AND ADEMYOSIS. SINCE REMOVAL, SKIN HAS IMPROVED, HAIR IS GROWING BACK, NO BLOATING, NO PAIN, NO TINNITUS, NO METAL TASTE, AND ALL BLOOD WORK HAS RETURNED TO NORMAL. MY ENERGY HAS RETURNED, DEPRESSION GONE, ANXIETY GONE. I UNDERWENT 2 MAJOR SURGERIES DUE TO CHRONIC PAIN AND DEBILITATION AFTER ESSURE IMPLANTATION AND ALTHOUGH THE COILS WERE PLACED CORRECTLY MY BODY SEEMED TO REJECT THEM DUE TO INFLAMMATION SYSTEMICALLY. THESE ARE JUST SOME OF THE SIDE EFFECTS I SUFFERED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042813	BAYER	5/19/2015	5/28/2015

Event Information:

Event Date (B3): 3/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

EXTREME PAIN IN PELVIS AREA, BACK AND PAIN DOWN MY LEGS. UTERUS AND OVARIES FEEL SWOLLEN ALL THE TIME. LEFT OVARY FEELS LIKE IT'S TWISTING. MENSES ARE EXCRUCIATING, HEAVY BLEEDING, LOTS OF CLOTS, SEVERE CRAMPING IN STOMACH, BACK AND DOWN LEGS. CONSTANTLY BLOATED. BREAST ALWAYS HURTS. HORMONES ARE OUT OF WACK. CAN'T SLEEP. EXTREME CHRONIC MIGRAINES EVEN FOR WEEKS AT A TIME. VARICOSE VEINS HAVE INCREASED. TOOTH DECAY SINCE THEN. MOOD SWINGS CHRONICALLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042814	BAYER	5/19/2015	5/28/2015

Event Information:

Event Date (B3): 3/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/10/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE HAD THE FOLLOWING SIDE EFFECTS WHICH STARTED AS SOON AS I WAS IMPLANTED WITH ESSURE: BLOATING, CRAMPS, ABDOMINAL PAIN. BOTH ACHING AND STABBING, FATIGUE, NON-STOP SPOTTING, IRREGULAR PERIODS, NAUSEA, HEADACHES, HAIRLOSS. I HAVE HAD ESSURE SINCE (B)(6), 2014 AND HAVE SUFFERED THESE SIDE EFFECTS DAILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042816	BAYER	5/19/2015	5/28/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/23/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT THE ESSURE TUBAL STERILIZATION PROCEDURE IN (B)(6) 2014. FOUND OUT (B)(6) 2015 THAT I AM PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00328	BAYER HEALTHCARE LLC	5/19/2015	6/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26965

Single Use: *
Implant Date (E6): 4/17/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 21-APR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION (LOT NUMBER C26965). THE PHYSICIAN REPORTED THAT PART OF ONE OF COILS BROKE OFF DURING PLACEMENT BUT THE HCP (HEALTH CARE PROFESSIONAL) WAS ABLE TO RETRIEVE THE PIECE OF COIL AND WAS ABLE TO COMPLETE THE BILATERAL PLACEMENT. PATIENT WAS OKAY. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 29-APR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C26965 (PRODUCTION DATE 27-FEB-2014 AND EXPIRATION DATE 28-FEB-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY

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DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT PART OF ONE OF COILS BROKE OFF DURING PLACEMENT. THIS EVENT IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. SINCE THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: ON (B)(6) 2015, THE HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND SHOWED BILATERAL OCCLUSION. THE PHYSICIAN WAS JUST NOT CONFIDENT ON THE ONE SIDE WHERE THE COILS WERE BROKEN. COMPANY CAUSALITY COMMENT: TH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00330	BAYER HEALTHCARE LLC	5/20/2015	5/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED 4-5 YEARS AGO. CONSUMER ASKED WHAT DOES THE ESSURE LOOKS LIKE AND WONDERS IF IT IS A 6 LITTLE PLASTIC PIECES. ACCORDING TO HER, SHE DOESN'T THINK SHE HAS IT ANYMORE. THE DEVICES CAME OUT IN HER PERIOD AND SHE WENT TO THE HEALTH CARE PROFESSIONAL A SHORT WHILE AFTER IT CAME OUT. SHE THINKS IT HAS BEEN AWHILE, 2-3 YEARS. IN ADDITION, CONSUMER REPORTED SHE HAD AN X-RAY OF HER PELVIS FOR SOMETHING ELSE, FOLLOWING HER CHIROPRACTOR REQUEST TWO WEEKS PREVIOUS TO THIS REPORT. THE EXAM SHOWED ONE (DEVICE) IS FLOATING AROUND IN HER PELVIC AREA. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH

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CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP INFORMATION (ESSURE QUESTIONNAIRE) RECEIVED ON (B)(6) 2015 FROM CONSUMER: CONSUMER DEMOGRAPHICS WERE ADDED. THE CONSUMER WAS (B)(6) AT TIME OF THIS REPORT. SHE WAS GRAVIDA 2 AND PARA 1, ON AN UNSPECIFIED DATE SHE HAD A SPONTANEOUS ABORTION. ESSURE WAS INSERTED IN 2009/2010; AND IT WAS NOT INSERTED AFTER A PREGNANCY. THE CONSUMER USED CONDOMS AS BACK UP CONTRACEPTION. ON (B)(6) 2015, A PELVIC X-RAY WAS DONE (NO RESULTS PROVIDED). SHE STATED THAT EXPERIENCED SOME CRAMPING, BLOATING AND A UTERINE FIBROID TUMOR. WHEN ASKED IF A PARTIAL PERFORATION/EMBEDMENT OCCURRED THE CONSUMER REPLY WAS YES. SHE STATED THAT "SOME MOST THRU A HEAVY MENSTRUAL CYCLE" (NO OTHER SPECIFIED - UNDERSTOOD AS ONE ESSURE DEVICE) AND THE OTHER WAS STILL LODGE IN HER UTERUS. SHE WAS NOT SURE IF THE UTERINE FIBROID TUMOR WAS AFFECTED. THE PERFORATION DID NOT OCCUR DURING THE INSERTION PROCEDURE. SHE ALSO MENTIONED THAT PREGNANCY DID NOT OCCUR. THE ESSURE DEVICES WERE NOT COMPLETELY REMOVED; AND THERE WAS NO PLAN TO REMOVE IT. ON (B)(6) 2015, A LAPAROSCOPY WAS DONE ALONG WITH A HYSTERECTOMY, WHICH SHE STATED THAT IT WAS NECESSARY. NO PATHOLOGY RESULT WAS AVAILABLE. WHEN ASKED IF SHE RECOVERED FROM THE ESSURE REMOVAL PROCEDURE HER REPLY WAS "UNKNOWN". FOLLOW UP FROM (B)(6)2015: PTC RESULT UPDATED WITH NO MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IN A X-RAY OF HER PELVIS, ONE (DEVICE) WAS FLOATING AROUND IN HER PELVIC AREA (SEEN AS DEVICE DISLOCATION). IT WAS ALSO REPORTED THAT THE OTHER WAS STILL LODGE IN HER UTERUS (SEEN AS DEVICE EMBEDDED). BOTH EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS CASE, THE EXACT DATE AND CIRCUMSTANCES OF THESE EVENTS ARE NOT KNOWN, HOWEVER; GIVEN THEIR NATURE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. OTHER NON-SERIOUS EVENTS WERE MENTIONED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED..

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 20-MAY-2015: CONSUMER REPORTED THAT X-RAY SHOWED THERE IS A LARGE MASS IN HER UTERUS (DISCREPANT INFORMATION RECEIVED) OR OVARY AND IT LOOKS LIKE THE ESSURE IS IN THE MIDDLE OF IT. FOLLOW-UP RECEIVED ON 20-MAY-2015: NO NEW INFORMATIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00332	BAYER HEALTHCARE LLC	5/20/2015	5/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON 24-APR-2015 WHICH REFERS TO A (B)(6) OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR STERILIZATION. PHYSICIAN STATED THAT SHE WAS NOT THE PROVIDER WHO PLACED THE DEVICE ORIGINALLY. THE PRELIMINARY INVESTIGATION DETERMINED THAT PATIENT WAS EXPERIENCING DISCOMFORT AND ONE DEVICE WAS NOT IN PROPER POSITION AND IT APPEARED TO BE IN THE UTERINE WALL. PHYSICIAN WAS ABLE TO SUCCESSFULLY REMOVE THE ENTIRE MICRO INSERT FROM PATIENT'S UTERINE CAVITY BY HYSTEROSCOPY ON (B)(6) 2015. PTC INVESTIGATION RESULT WAS RECEIVED ON 06-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A

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POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A(B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN INVESTIGATION REVEALED ONE DEVICE WAS NOT IN PROPER POSITION; IT APPEARED TO BE IN THE UTERINE WALL. THIS DEVICE WAS SUCCESSFULLY REMOVED BY HYSTEROSCOPY. THE REPORTED EVENT, REGARDED AS DEVICE EMBEDMENT INTO UTERUS (PARTIAL UTERINE PERFORATION), WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED DEVICE EMBEDMENT IS UNKNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE AN INTERVENTION WAS REQUIRED FOR ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 12-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMAL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042760	BAYER	5/20/2015	5/20/2015

Event Information:

Event Date (B3): 11/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING PELVIC PAIN, EXTREME BLOATING, MESSED UP PERIODS, IBS SYMPTOMS, WORSENING ALLERGIES, BRAIN FOG, HAIR LOSS, FEELING COLD ALL THE TIME, SHARP/STABBING PELVIC PAIN, HOT FLASHES, NIGHT SWEATS, INCONTINENCE, HEART PALPITATIONS, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042761	BAYER	5/20/2015	5/20/2015

Event Information:

Event Date (B3): 8/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UPON INSERTION I BLED NON STOP FOR THREE MONTHS, ABOUT TWO MONTHS AFTER INSERTION THE PELVIC PAIN STARTED. OVER A PERIOD OF TWO YEARS I SUFFERED CONSTANT PELVIC PAIN, HEADACHES, HAIR LOSS, LOWER BACK PAIN, MEMORY FOG, CHRONIC FATIGUE, MOOD SWINGS, ANXIETY, DEPRESSION, HOT FLASHES AND IRREGULAR PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042762	BAYER	5/20/2015	5/20/2015

Event Information:

Event Date (B3): 1/7/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BECAME PREGNANT AFTER 2 YEARS OF HAVING ESSURE IN PLACE. SEVERE PAIN IN LEGS AND SIDE. SEVERE BLEEDING IN BETWEEN MENSTRUAL CYCLE AND CLOTTING DURING. ITCHY SKIN IN STOMACH AREA. METAL TASTE IN MOUTH. BAD TEETH DECAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042763	BAYER	5/20/2015	5/20/2015

Event Information:

Event Date (B3): 2/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME WEIGHT GAIN IN EXCESS OF 80LBS WITHIN THE FIRST YEAR. SEVERE DEPRESSION/ SUICIDAL. EXTREMELY PAINFUL JOINTS. FATIGUE. EXTREMELY PAINFUL OVULATION AND MENSTRUATION. MIGRAINES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042828		5/20/2015	5/28/2015

Event Information:

Event Date (B3): 1/31/2011	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WITHIN ONE YEAR OF THE ESSURE PROCEDURE I GAINED 40 LBS. NOW, 5 YEARS LATER, I EXPERIENCE LOWER ABDOMINAL PAIN AND BLOATING DAILY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042833	BAYER	5/20/2015	5/28/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/15/2013
Explant Date (E7): 11/21/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DEVICE IMPLANTED ALMOST 2 YEARS AGO. FIVE MONTHS AGO I WAS HOSPITALIZED BECAUSE ONE OF THE COILS SLIPPED INTO MY UTERUS AND HAD TO BE SURGICALLY REMOVED. I NOW HAVE UNBEARABLE PAIN FOR OVER A MONTH AND PREPARING TO HAVE MY TUBE REMOVED TO HAVE COIL REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042835		5/20/2015	5/28/2015

Event Information:

Event Date (B3): 5/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN 2007 AFTER MY SECOND CHILD WAS BORN. THIS PRODUCT HAS STOPPED FERTILITY, BUT HAS CAUSED MY UTERUS TO SWELL CAUSING PAIN, DISCOMFORT, AND HEAVY BLEEDING. I FOUND OUT MY UTERUS WAS SWOLLEN BY MY GYNECOLOGIST WHO THOUGHT THAT IT COULD BE MY BLADDER CAUSING THESE SYMPTOMS. I WENT TO A UROLOGIST, HAD SEVERAL TESTS DONE ONLY TO FIND OUT THAT MY UTERUS IS SWOLLEN FROM THE ESSURE PROCEDURE. I FOUND OUT A FEW YEARS AGO THAT IF YOU HAVE A NICKEL ALLERGY THAT THIS PRODUCT IS NOT SAFE TO INSERT INTO THE TUBES AND WILL CAUSE SIDE EFFECTS. I HAVE UNFORTUNATELY HAVE A NICKEL ALLERGY. I WAS NOT TOLD THAT A NICKEL ALLERGY WOULD CAUSE THESE SIDE EFFECTS WITH THE ESSURE PROCEDURE. THIS PRODUCT NEEDS TO BE RECALLED FOR ANY WOMEN THAT HAVE A NICKEL ALLERGY. IT IS THE FDA'S RESPONSIBILITY TO MAKE SURE THAT PEOPLE ARE AWARE OF THE DAMAGING SIDE EFFECTS OF ANY PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00331	BAYER HEALTHCARE LLC	5/20/2015	6/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012 (NO DETAILS PROVIDED). CONSUMER STATED THAT SHE HAD AN ESSURE PLACED AND THE HYSTEROSALPINGOGRAM TEST SHOWED BILATERAL OCCLUSION (DATE NOT REPORTED). SHE STARTED HAVING A SHARP INTERMITTENT DAILY PAIN IN (B)(6) 2014 AND WENT TO HER HCP (HEALTH CARE PROFESSIONAL) AT THAT SAME MONTH. THEY DID A VAGINAL ULTRASOUND AND SAID THE ESSURE ROD ON THE RIGHT WAS BROKEN AND ON THE LEFT ROD WAS FINE. SHE GOT PREGNANT IN (B)(6) 2014 AND HAD AN ELECTIVE ABORTION IN (B)(6) 2014. THE PAIN HAS BEEN CONTINUING AND AT TIME OF THE INITIAL REPORT WAS ABOUT A 7 IN A SCALE OF A 1 TO 10. HER HCP DID NOT DO ESSURE REMOVALS WITHOUT REMOVING THE WHOLE TUBE AND SHE DID NOT WANT THAT. SHE WANTED TO KNOW A HCP THAT COULD REMOVE IT. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 07-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED

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DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE GOT PREGNANT AND HAD AN ELECTIVE ABORTION. IT WAS ALSO REPORTED THAT ESSURE ROD ON THE RIGHT WAS BROKEN. THE EVENT PREGNANCY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, ESSURE ROD ON THE RIGHT WAS BROKEN IS LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC) RESULTS. BOTH EVENTS ARE NON-SERIOUS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, HYSTEROSALPINGOGRAM WAS PERFORMED AN UNKNOWN TIME AFTER ESSURE INSERTION AND THE RESULT SHOWED BILATERAL OCCLUSION. A CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED PREGNANCY CANNOT BE EXCLUDED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, CONSUMER STARTED EXPERIENCING SHARP INTERMITTENT DAILY PAIN ABOUT 1 YEAR AND 10 MONTHS AFTER INSERTION. A VAGINAL ULTRASOUND WAS PERFORMED AND THE RESULT SHOWED ESSURE ROD ON THE RIGHT WAS BROKEN. A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 07-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOP

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00334	BAYER HEALTHCARE LLC	5/20/2015	6/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C40062

Single Use:
Implant Date (E6): 4/23/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 23-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION (LOT NUMBER C40062). PHYSICIAN REPORTED THAT A RESIDENT DEPLOYED THE COIL DISTALLY IN RIGHT TUBE. THERE WAS AN ISSUE WITH DETACHMENT OF UNIT DELIVERY SYSTEM. THE DELIVER SYSTEM BROKE APART AND THEY WENT IN WITH A GRASPER AND REMOVED REMAINDER OF SYSTEM THAT BROKE OFF. THE COIL WAS LEFT IN RIGHT TUBE AND TUBAL LIGATION WAS PERFORMED. BILATERAL PLACEMENT WAS NOT ACHIEVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 07-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C40062 (PRODUCTION DATE 01-APR-2014 AND EXPIRATION DATE 30-APR-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL

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INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND THE DELIVER SYSTEM BROKE APART. THIS EVENT IS NON-SERIOUS AND LISTED IN ACCORDING TO TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MOSTLY DURING DIFFICULT INSERTIONS OR REMOVALS. IN THIS PARTICULAR CASE, THE PHYSICIAN DEPLOYED THE ESSURE COIL DISTALLY IN RIGHT TUBE. THERE WAS AN ISSUE WITH DETACHMENT OF UNIT DELIVERY SYSTEM. THEN, THE DELIVER SYSTEM BROKE APART AND THE PIECE REMAINDER WAS REMOVED WITH A GRASPER. THE COIL WAS LEFT IN RIGHT TUBE AND TUBAL LIGATION WAS PERFORMED. BILATERAL PLACEMENT WAS NOT ACHIEVED. CONSIDERING THE REPORTED EVENTS OCCURRED ASSOCIATED TO INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED. ALTHOUGH TUBAL LIGATION WAS PERFORMED, IT WAS APPARENTLY DONE DUE TO FAILED INSERTION AS CONTRACEPTIVE METHOD. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. THE TECHNICAL INVESTIGATION CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00333	BAYER HEALTHCARE LLC	5/20/2015	6/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C95070

Single Use: Y
Implant Date (E6): 4/17/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN VIA SALES REPRESENTATIVE IN UNITED STATES ON 24-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR STERILIZATION (LOT NUMBER C95070 WITH EXPIRATION DATE IN AUG-2017). GYNECOLOGIST REPORTED THAT WAS DOING AN ESSURE PLACEMENT AND CANNULATED ONE SIDE (UNSPECIFIED) AND ON THE WHEELBACK SOMETHING STUCK AND WHEN THEY PULLED THE CATHETER OUT SOMETHING SNAPPED OFF. THE SALES REPRESENTATIVE MENTIONED THAT HE COULD SEE THE COILS COMING OUT AND IT DID NOT LOOK LIKE IT ALL DEPLOYED. THE HCP THOUGHT IT WAS IN THE PATIENT BUT DID NOT HAVE ACCESS TO X-RAY SINCE THIS WAS AN IN OFFICE PLACEMENT. THE DEVICE WAS AVAILABLE FOR RETURN. PTC INVESTIGATION RESULT WAS RECEIVED ON 07-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 4/29/2015,

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SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C95070 (PRODUCTION DATE 11-AUG-2014 AND EXPIRATION DATE 31-AUG-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND SOMETHING SNAPPED OFF DURING PLACEMENT. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MOSTLY DURING DIFFICULT INSERTIONS OR REMOVALS. IN THIS PARTICULAR CASE, THE PHYSICIAN CANNULATED ONE SIDE AND ON THE WHEELBACK HE FELT THAT SOMETHING GOT STUCK AND THEN, WHEN THEY PULLED THE CATHETER OUT SOMETHING SNAPPED OFF. APPARENTLY THE COILS WERE COMING OUT AND IT DID NOT LOOK LIKE IT ALL DEPLOYED. CONSIDERING THE EVENT OCCURRED ASSOCIATED TO INSERTION PROCEDURE, CAUSALITY IS ASSESSED AS RELATED TO ESSURE. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015. THE PATIENT'S DATE OF BIRTH AND INITIALS WERE UPDATED (SHE WAS (B)(6) OLD WHEN EVENT HAPPENED). HER WEIGHT WAS (B)(6) KG AND HEIGHT WAS (B)(6) CM (BMI (B)(4)). PREVIOUS GYNECOLOGICAL INTERVENTION, PROBLEMS AN

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00335	BAYER HEALTHCARE LLC	5/20/2015	6/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SF

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 3130

Single Use: N
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA LICENSE PARTNER FROM A PHYSICIAN IN (B)(6) ON 22-APR-2015 WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C51067. IT WAS STATED THAT THE NORMAL PROCEDURE WAS FOLLOWED TO INSERT ESSURE, TUBES WERE OCCLUDED. PHYSICIAN ADMINISTERED BUSCOPAN 20MG, WAITED AND TRIED AGAIN, BUT NO SUCCESS BILATERAL. WHEN TRIED A THIRD TIME, IT COULD NOT GET THE ESSURE THROUGH THE INSERTER AND THE PROCEDURE WAS ABORTED. THEY OPTED FOR LAPAROSCOPIC STERILIZATION. ALSO STATED THAT UPON WASHING THE BETTOCCHI, PARTS OF THE INSERTION GUIDE CAME OUT IN PIECES. NO FURTHER INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED 12-MAY-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. (B)(4). FINAL ASSESSMENT: LOT NUMBER: C51067, PRODUCTION DATE: 21-APR-2014, EXPIRATION DATE: 30-APR-2017. FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE

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MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 5/06/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE REMOVAL. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) BUT THERE WAS NO BILATERAL SUCCESS. AFTER THE ATTEMPT, PARTS OF THE INSERTION GUIDE CAME OUT IN PIECES. THE ESSURE PROCEDURE WAS ABORTED AND A LAPAROSCOPIC STERILIZATION WAS OPTED. THE EVENT PARTS OF THE INSERTION GUIDE CAME OUT IN PIECES, INTERPRETED AS DEVICE BREAKAGE IS CONSIDERED NON-SERIOUS. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THE BREAKAGE IS UNLISTED. HOWEVER, ACCORDING TO PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS, THE MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE PHYSICIAN MADE THE FIRST ATTEMPT TO PLACE THE ESSURE INSERTS, BUT TUBES WERE OCCLUDED. THE PHYSICIAN MADE TWO ADDITIONAL ATTEMPTS TO INSERT BUT AT THE THIRD TIME, THEY COULD NOT GET THE ESSURE THROUGH THE INSERTER AND ABORTED THE PROCEDURE. UPON WASHING THE BETTOCCHI, PARTS OF THE INSERTION GUIDE CAME OUT IN PIECES. CONSIDERING THAT THE BREAKAGE OCCURRED DURING A DIFFICULT ESSURE INSERTION PROCEDURE, THE BREAKAGE IS CONSIDERED RELATED TO ESSURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 14-JUL-2015: NO FURTHER INFORMATION IS EXPECTED REGARDING THIS CASE. CASE CLOSED. COMPANY CUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TU

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042779	BAYER	5/21/2015	5/21/2015

Event Information:

Event Date (B3): 5/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS BLEEDING HEAVILY FOR 14 MONTHS WAS TOLD THAT WAS NORMAL. BEGAN GAINING WEIGHT. DEPRESSION, AMONGST THE MANY OTHER SIDE EFFECTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042780	BAYER	5/21/2015	5/21/2015

Event Information:

Event Date (B3): 5/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN WHEN SNEEZING OR GET UP QUICKLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042781	BAYER	5/21/2015	5/21/2015

Event Information:

Event Date (B3): 8/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD MIGRAINES AND HEADACHES, ABDOMINAL PAIN, BACK PAIN, SWELLING OF ABDOMINAL AREA, HURTFUL INTERCOURSE, PERIOD CYCLE ALL OFF.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042878	BAYER	5/22/2015	6/4/2015

Event Information:

Event Date (B3): 8/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/10/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE COILS AND I WAS NEVER TOLD ABOUT THE NICKEL COMPONENT AND NOW IT'S CAUSED A LOT OF PAIN AND MEDICAL PROBLEMS FOR ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042877	BAYER	5/23/2015	6/4/2015

Event Information:

Event Date (B3): 5/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/17/2009
Explant Date (E7): 7/23/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD TO GET HYSTERECTOMY DESPITE HAVING ESSURE COILS REMOVED (B)(6) 2013, BECAUSE OF DEVELOPMENT OF ADENOMYOSIS AND INCREASED COMPLICATIONS OF ENDOMETRIOSIS. ALSO HAD CYSTS ON RIGHT OVARY AND IN RIGHT FALLOPIAN TUBE. AFTER HYSTERECTOMY HAD TO BE READMITTED DUE TO AN INFECTION OF UNKNOWN ORIGIN REQUIRING A 3 DAY HOSPITAL STAY WITH IV ANTIBIOTICS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00337	BAYER HEALTHCARE LLC	5/26/2015	5/26/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/17/2015
Explant Date (E7): 3/12/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 27-APR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR CONTRACEPTION. SHE WAS NOT PREGNANT. PHYSICIAN REPORTED THAT ESSURE WAS PLACED BY ANOTHER PRACTICE AND THE PATIENT WAS EXPERIENCING PAIN THAT SHE WAS ASSOCIATING WITH ESSURE. ON (B)(6) 2015, ESSURE WAS REMOVED AND A BILATERAL SALPINGECTOMY PERFORMED. PHYSICIAN STATED THE INSERTS LOOKED WELL PLACED AT THE TIME OF REMOVAL. AT FOLLOW-UP VISIT, PATIENT'S PAIN WAS RESOLVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 08-MAY-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

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COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED PAIN, WHICH SHE ASSOCIATED WITH ESSURE. SHE WAS SUBMITTED TO A BILATERAL SALPINGECTOMY WITH DEVICES REMOVAL AND RECOVERED. THIS EVENT, REGARDED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED EVENT AND AS IT RECOVERED WITH DEVICES REMOVAL; CAUSALITY CANNOT BE EXCLUDED. DUE TO THE REQUIRED INTERVENTION, THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042913	BAYER	5/26/2015	6/4/2015

Event Information:

Event Date (B3): 5/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626598

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS IN 2007 AT AGE (B)(6). A YEAR LATER, I BEGAN EXPERIENCING ABDOMINAL PAIN THAT FELT LIKE MY FALLOPIAN TUBES WERE BURSTING, (SIMILAR TO APPENDICITIS ERUPTION) AND VERY PAINFUL AND LONG PERIODS. AS OF TODAY THE EXCRUCIATING PAIN RECURS MONTHLY AND CONTINUES TO BE 7-15 DAYS PAINFUL AND HEAVY. I HAVE SEEN A HEMATOLOGIST AND HAVE AN ABNORMALLY LOW WHITE BLOOD COUNT THAT IS MONITORED QUARTERLY. I'VE HAD A BONE MARROW BIOPSY, HAD TO DISCONTINUE MY JOB, BECAUSE I LACK THE ENERGY AND ENDURANCE TO PERFORM EFFECTIVELY. I HAVE DEVELOPED PAINFUL MOVEMENT IN MY SHOULDER AND HIP JOINTS. I HAVE ALWAYS BEEN VERY HEALTHY AND FIT. I FEEL LIKE A SCIENCE PROJECT GONE WRONG, CAN'T FIX, UNLESS I RISK SURGERY TO HAVE THEM REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00336	BAYER HEALTHCARE LLC	5/26/2015	6/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN (B)(6) WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. RADIOLOGY NOTED PLACEMENT OF MICRO INSERTS BUT SUSPECTED FROM MARKERS THAT ONE MICRO INSERT MIGHT HAVE SPLIT ITS INNER COIL FROM ITS OUTER COIL. BOTH TUBES SHOWED SOME DEGREE OF PATENCY (HIGHER SPILLAGE ON LEFT SIDE THAN RIGHT SIDE). PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A

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REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE. THE AE CASE REFERS ALSO TO A LACK OF EFFICACY DUE TO PATENCY. A LACK OF EFFICACY MAY OCCUR WITH THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE MICROINSERT MIGHT HAVE SPLIT ITS INNER COIL FROM ITS OUTER COIL. THIS EVENT, INTERPRETED AS SUSPICION OF DEVICE BREAKAGE, IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. RADIOLOGY NOTED THAT BOTH TUBES SHOWED SOME DEGREE OF PATENCY AND SUSPECTED FROM MARKERS THAT ONE MICRO INSERT MIGHT HAVE SPLIT ITS INNER COIL FROM ITS OUTER COIL. CONSIDERING THE AVAILABLE INFORMATION AND NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00338	BAYER HEALTHCARE LLC	5/27/2015	5/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM NEWS MEDIA IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THAT CONSUMER GOT PREGNANT, THE 4TH CHILD IS NOW DUE IN (B)(6), AND SHE DID NOT RETURN FOR THE FOLLOW UP TEST IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. IN (B)(6) 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AT UNK. CONSUMER USED OTHER CONTRACEPTION FOR THREE MONTHS BUT DID NOT RETURN FOR THE FOLLOW-UP TEST, IN PART BECAUSE STATE HER ASSURANCE DID NOT COVER IT. SHE SAID HER FOURTH CHILD IS NOW DUE IN (B)(6). SHE STATED THAT AFTER HAVING THIS PROCEDURE AND KNOWING HOW LOW THEY STATE THE PERCENTAGE IS, SHE HAS NEVER THOUGHT IN A MILLION YEARS SHE WOULD GET PREGNANT. AT THE MOMENT OF REPORT SHE PLANS TO HAVE A HYSTERECTOMY AFTER HER BABY IS BORN. THE OUTCOME OF THE EVENTS WAS NOT REPORTED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS NOT REPORTED. FOLLOW-UP INFORMATION RECEIVED ON 29-APR-2015: THE CONSUMER´S MEDICAL HISTORY INCLUDED 3 CHILDREN. ESSURE WAS INSERTED IN 2012. SHE HAD THE DEVICE FOR 15 MONTHS WHEN SHE FELT CRAMPING AND DECIDED TO TAKE A PREGNANCY TEST WHICH CAME BACK POSITIVE. SHE DID NOT UNDERGO THE FOLLOW-UP VISIT BECAUSE HER INSURANCE WOULD NOT PAY FOR THE VISIT. HER DOCTOR ADVISED AGAINST IT, WORRYING THE DYE COULD CAUSE THE TUBE TO OPEN BACK UP. ON AN UNSPECIFIED DATE, THE DOCTORS DISCOVERED THAT THE COIL HAD MOVED INTO HER UTERUS. THROUGHOUT HER PREGNANCY, SHE WAS CONSIDERED HIGH RISK DUE TO CONCERNS THE COIL COULD BREAK HER WATER PREMATURELY. ON AN UNSPECIFIED DATE, HER BABY WAS BORN HEALTHY. ON AN UNSPECIFIED DATE, ESSURE WAS REMOVED.

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SHE STATED THAT FELT BETTER AFTER REMOVAL. CASE UPGRADED TO INCIDENT. PTC INVESTIGATION RESULT RECEIVED ON 06-MAY-2015. (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN THIS PARTICULAR CASE, ALSO A TREATMENT NONCOMPLIANCE (DID NOT RETURN FOR THE FOLLOW UP TEST - TUBAL OCCLUSION WAS NOT CONFIRMED) WAS REPORTED. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, GOT PREGNANT (DEVICE INEFFECTIVE) AND DOCTORS DISCOVERED THAT THE COIL HAD MOVED INTO HER UTERUS. THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. EVENT COIL HAD MOVED INTO HER UTERUS, INTERPRETED AS PARTIAL EXPULSION OF DEVICE, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE WHILE THE REMAINING EVENT IS NON-SERIOUS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, THE CONSUMER DID NOT UNDERGO CONFIRMATION TEST. FIFTEEN MONTHS AFTER ESSURE INSERTION THE PREGNANCY WAS DIAGNOSED. IT WAS REPORTED THAT DOCTORS DISCOVERED THAT THE COIL HAD MOVED INTO HER UTERUS. IT IS NOT KNOWN WHETHER ESSURE WAS IN-SITU DURING CONCEPTION OR NOT, THUS, THE POSSIBILITY OF CONTRACEPTIVE FAILURE CANNOT BE TOTALLY EXCLUDED. THE BABY WAS BORN HEALTHY. SINCE ESSURE REMOVAL WAS REPORTED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. THE TECHNICAL INVESTIGATION CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00339	BAYER HEALTHCARE LLC	5/27/2015	5/27/2015

Event Information:

Event Date (B3): 9/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/21/2012
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2012 FOR STERILIZATION AND PATIENT DID NOT GO FOR THE CONFIRMATION TEST. ON (B)(6) 2014 SHE CAME TO THE DOCTOR WITH A 25-WEEK PREGNANCY AND SHE WAS GOING TO HAVE THE BABY. SHE HAD A DIFFERENT DOCTOR WHO INSERTED THE ESSURE, AND ANOTHER ONE SHE WENT TO WITH HER PREGNANCY. ESSURE WAS NOT REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 07-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN THIS PARTICULAR CASE, ALSO A MEDICATION ERROR (TREATMENT NONCOMPLIANCE) WAS REPORTED. NO BATCH NUMBER WAS REPORTED. NO COMPLAINT SAMPLE WAS PROVIDE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT (SEE TECHNICAL ASSESSMENT). IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 17-MAR-2015: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT WHO HAS AS MEDICAL

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HISTORY GRAVIDA 6, PARA 3, 2 SPONTANEOUS ABORTION, AND NO ECTOPIC PREGNANCY NOR ELECTIVE OR THERAPEUTIC ABORTION (DISCREPANT INFORMATION), HAS AS PREVIOUS GYNECOLOGICAL INTERVENTION A CERVICAL CONIZATION (LOOP ELECTROSURGICAL EXCISION PROCEDURE) AND DOES NOT HAVE PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES NOR OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS; HAD ESSURE INSERTED ON (B)(6) 2012. PATIENT WAS NOT POST-PARTUM AT THE TIME OF INSERTION. HER UTERUS WAS DESCRIBED AS ANTEVERTED AND HER CERVIX HAD A WART-LIKE APPEARANCE. THERE WAS A QUESTIONABLE (B)(6). IN ADDITION, PHYSICIAN INFORMED THAT CERVICAL DILATATION AS WELL AS GENERAL ANESTHESIA WAS APPLIED DURING PROCEDURE. NO SOUNDING WAS DONE. HEALTH CARE PROFESSIONAL DESCRIBED THE INSERTION AS EASY AND STATED THAT RIGHT TUBAL OSTIUM WAS "DILATED". THE VISUALIZATION OF TUBAL OSTIUM WAS ALSO EASY AND BOTH TUBES WERE VISUALIZED. THERE WAS NO FLUID LOSS MORE THAN 1500CC DURING HYSTEROSCOPY AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. ACCORDING TO PHYSICIAN, THERE WAS A LITTLE BIT OF BLEEDING AFTER PROCEDURE, WHICH WAS HEMOSTATIC AFTER A RING WAS PLACED ON THE CERVIX AND REMOVED. NO IMAGING TEST WAS PERFORMED TO CONFIRM ESSURE PLACEMENT AND NO HYSTEROSALPINGOGRAM WAS DONE TO CONFIRM TOTAL OCCLUSION. ON (B)(6) 2014 PREGNANCY WAS CONFIRMED BY URINE TEST AND SONOGRAM. THE EXPECTED DATE OF DELIVERY WAS (B)(6) 2014 BUT, ON (B)(6) 2014, DUE TO GESTATIONAL HYPERTENSION, PATIENT DELIVERED A LIVE BIRTH (DELIVERY TYPE: VAGINAL; GESTATIONAL AGE 37 WEEKS; APGAR SCORES 8/9). NO OTHER COMPLICATION OCCURRED DURING PREGNANCY OR DELIVERY. NO ABNORMALITIES WERE OBSERVED IN THE FETUS. ADDITIONALLY PHYSICIAN REPORTED THAT ESSURE WAS NOT REMOVED BUT REMOVAL IS PLANNED IF PATIENT FOLLOW-UP WITH HIM. FOLLOW UP INFORMATION RECEIVED ON 13-APR-2015: IT WAS REPORTED THAT THE PATIENT IS SCHEDULED FOR (B)(6) 2015 TO REMOVE BOTH OVARIES. REPORTER DID NOT KNOW IF THE ESSURE DEVICES WILL BE REMOVED DURING THE PROCEDURE. FOLLOW-UP INFORMATION RECEIVED ON 30-APR-2015: IT WAS REPORTED THAT PATIENT HAD HER SURGERY DONE AND SHE WAS GOING TO GET HER X-RAY DONE THIS WEEK TO CHECK IF ALL IS OK WITH ESSURE. THE PHYSICIAN STATED THAT THIS PATIENT HAD HER ESSURE PLACED BY ANOTHER DOCTOR AND SHE CAME TO HIS WHEN SHE GOT PREGNANT. SHE HAD A NORMAL PREGNANCY AND DELIVERY WITH NO COMPLICATIONS. WHEN A LAPAROSCOPIC TUBAL WAS DONE ABOUT A WEEK OR TWO AGO, ESSURE COIL ON THE LEFT SIDE WAS FOUND AND PHYSICIAN REMOVED THE LEFT TUBE AND THE LEFT COIL. WHEN RIGHT TUBE WAS DISSECTED, DOCTOR DID NOT SEE THE COIL; THE RIGHT TUBE WAS REMOVED AND SENT TO PATHOLOGY. COMPLETE SALPINGECTOMY WAS DONE. ON PATHOLOGY REPORT, NO COIL WAS SEEN IN THE TUBE. THE COIL WAS NOT SEEN ANYWHERE LOOSE IN THE PELVIS. PHYSICIAN DID NOT KNOW WHETHER IT WAS NEVER PLACED OR IF IT EXPELLED OR IF IT WAS LOOSE IN THE ABDOMEN OR EMBEDDED IN THE OMENTUM OR ELSEWHERE. PATIENT WAS GOING TO HAVE HER X-RAY DONE THIS WEEK TO CHECK FOR THE MISSING COIL. CASE UPGRADED TO INCIDENT. THE UPDATED PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 06-MAY-2015. PTC ASSESSMENT WAS UPDATED WITHOUT MAJOR CHANGES. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. FOLLOW UP INFORMATION RECEIVED ON 11-MAY-2015 FROM NURSE: SHE STATED THAT SHE ALREADY TALKED WITH THE PATIENT AND SHE PLANNED TO POSSIBLY HAVE X-RAY DONE IN THE NEXT DAYS. FOLLOW UP INFORMATION RECEIVED ON 14-MAY-2015 FROM NURSE: SHE STATED ON (B)(6) 2015 X-RAY WAS PERFORMED AND SHOWED MISSING ESSURE COIL WAS FOUND IN THE PELVIS (PREVIOUSLY REPORTED AS NO COIL WAS SEEN IN THE TUBE/MISSING COILS). FOLLOW-UP RECEIVED ON 14-MAY-2015: INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT; HAD ESSURE INSERTED BY ANOTHER PRACTICE ABOUT 2 OR 3 YEARS AGO. ACCORDING TO REPORTER, PATIENT NEVER WENT FOR HYSTEROSALPINGOGRAM AFTER ESSURE PLACED AND BECAME PREGNANT. HEALTH CARE PROFESSIONAL DELIVERED THE BABY ON (B)(6) 2014. IN ADDITION, HE PERFORMED A BILATERAL SALPINGECTOMY ON (B)(6) 2015

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AND WAS ABLE TO SEE COIL IN LEFT TUBE AND COULD REMOVE IT FROM TUBE. THE RIGHT TUBE WENT TO PATHOLOGY AND THERE WAS NO COIL IN TUBE. KUB (INTERPRETED AS KIDNEY, URETER, BLADDER) DONE AND COIL WAS SEEN IN PELVIS, POSSIBLY IN OMENTUM. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LITTLE BIT OF BLEEDING AND SHE GOT PREGNANT AFTER ESSURE INSERTION. PATIENT GAVE BIRTH TO A HEALTHY BABY WITHOUT COMPLICATION DURING PREGNANCY OR DELIVERY. PATIENT UNDERWENT A COMPLETE SALPINGECTOMY. A X-RAY SHOWED THAT THE PREVIOUSLY REPORTED MISSING COIL, WHICH WAS NOT SEEN IN THE TUBE, WAS FOUND IN THE PELVIS, POSSIBLY IN OMENTUM. LITTLE BIT OF BLEEDING, INTERPRETED AS PROCEDURAL BLEEDING, AND MISSING ESSURE COIL WAS FOUND IN THE PELVIS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCY IS NON-SERIOUS AND LISTED. IN THIS PARTICULAR CASE, THE PATIENT GOT PREGNANT ABOUT 1 YEAR AND 5 MONTHS AFTER ESSURE INSERTION AND SHE DID NOT RETURN FOR THE ESSURE CONFIRMATION TEST AFTER THE INSERTION. ALTHOUGH PREGNANCY IN THE PRESENT CASE MAY BE CONSIDERED RATHER A CONSEQUENCE OF NON-COMPLIANT USE, THE CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE PREGNANCY CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED SURGICAL INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED: GESTATIONAL HYPERTENSION.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 16-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CASE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00340	BAYER HEALTHCARE LLC	5/27/2015	5/27/2015

Event Information:

Event Date (B3): 9/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C76446

Single Use:
Implant Date (E6): 9/4/2014
Explant Date (E7): 9/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT STERILIZATION. PREGNANCY WAS DENIED. PHYSICIAN STATED THAT SHE WAS IN THE OPERATION ROOM AND ABLE TO PLACE ONE SIDE CORRECTLY BUT WHEN DID THE WHEEL BACK COULD NOT FIND THE GOLD BAND. AS SHE MOVED THE DELIVERY DEVICE AS PULLING OUT AT THE INITIAL SITE, IT LOCKED ON AND WOULD NOT COME OUT. PHYSICIAN DID NOT KNOW IF THE PATIENT WAS HAVING A TUBAL SPASM AND ENDED UP STRETCHING THE ENTIRE DEVICE AS PULLING OUT OF TUBE AND FINALLY SHE GOT OUT AS MUCH AS SHE COULD SEE AND CONVERTED OVER TO A TUBAL. NO FURTHER INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT (PTC) RESULTS RECEIVED ON 07-OCT-2014 AND UPDATED ON 17-OCT-2014: (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: ROLLBACK TO INITIAL HARD STOP. DEPRESS BUTTON. PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICROINSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO

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TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL ARE WITHIN MANUFACTURING SPECIFICATIONS. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. CONCLUSIONS: THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. ACCORDING TO THE DFMEA, THE MAIN CONSEQUENCE IS A PHYSICIAN INCONVENIENCE BECAUSE THE PROCEDURE COULD NEED TO BE ABORTED OR RESCHEDULED. NO BREAKAGE EVENT WAS REPORTED. AS REPORTED THE DEVICE WAS STRETCHED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKETING SURVEILLANCE MONITORING. BASED ON THE RECEIVED PTC RESULTS (NO BREAKAGE EVENT) THIS CASE WAS DOWNGRADED TO NON-SERIOUS, NON-INCIDENT. FOLLOW UP FROM 06-APR-2015: THE REQUIRED NUMBERS OF FOLLOW UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. FOLLOW-UP INFORMATION WAS RECEIVED ON 29-APR-2015 FROM PHYSICIAN. PATIENT'S INITIALS, DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT WITH NO PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES, NO RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. SHE WAS NOT ON POSTPARTUM STATE AT THE TIME OF ESSURE INSERTION. ON (B)(6) 2014 ESSURE (LOT NUMBER C76446) WAS INSERTED UNDER GENERAL ANESTHESIA FOR STERILIZATION. PATIENT'S UTERUS WAS ANTEVERTED AND THERE WAS NO ADNEXAL MASSES. THE UTERUS WAS SOUNDED TO 6CM AND CERVIX WAS DILATED UP TO 5.5 HAGAR DILATOR. BOTH TUBAL OSTIA WERE VISUALIZED AND WERE NORMAL, FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC. THE ESSURE DEVICE WAS EASILY IMPLANTED IN THE LEFT OSTIUM WITH 3 COILS VISUALIZED IN THE CAVITY. THE PROCEDURE TOOK MORE THAN 20 MINUTES BECAUSE THE DEVICE MALFUNCTIONED ON INSERTION INTO THE RIGHT OSTIUM. THE DEVICE WAS INTRODUCED INTO THE RIGHT OSTIUM AND ADVANCED WITHOUT DIFFICULTY INTO THE TUBE; THE COIL WAS DEPLOYED BUT ACCORDING TO THE PHYSICIAN, THE SLEEVE PROTECTING THE COIL DID NOT ALLOW FOR VISUALIZATION OF THE MARKERS FOR PLACEMENT OF THE DEVICE. SHE ATTEMPTED TO WITHDRAWN THE DEVICE FROM THE UTERUS BUT IT WAS ADHERENT TO THE TUBE. PARTIAL COILS AND WIRE WERE REMOVED IN SEVERAL PIECES FROM RIGHT OSTIUM WITH THE OPERATIVE GRASPERS. A SMALL PORTION OF THE COIL REMAINED ADHERENT INSIDE THE TUBE. A SMALL AMOUNT OF BLEEDING WAS NOTED ON ANTERIOR LIP OF CERVIX. GIVEN THE DESIRE FOR STERILIZATION, THE CASE WAS CONVERTED TO LAPAROSCOPIC SALPINGECTOMY. DURING THIS SURGERY THE UTERUS, TUBES AND OVARIES WERE NORMAL. BILATERAL SALPINGECTOMY WAS PERFORMED AND ESSURE COIL WAS REMOVED FROM LEFT TUBE. THE PORTION OF COIL WAS NOT SEEN IN RIGHT TUBE. PATIENT WAS TAKEN TO THE RECOVERY ROOM IN A STABLE CONDITION, HAVING SUFFERED NO APPARENT UNTOWARD EVENT. PATHOLOGY RESULTS WERE NORMAL WITH DEVICE PLACED UNILATERALLY. PHYSICIAN STATED ESSURE REMOVAL WAS MEDICALLY NECESSARY. THIS CASE WAS UPGRADED TO INCIDENT. UPDATED PTC INVESTIGATION RESULT (WITH LOT NUMBER C76446) RECEIVED ON 06-MAY-2015: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS

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WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE REMOVAL. THE AE CASE REFERS TO AUSABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 6 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH 4 CASES REFER ALSO TO SIMILAR TYPES OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 05-MAY-2015: NO NEW INFORMATION PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) EASILY INSERTED IN LEFT FALLOPIAN TUBE; IN RIGHT FALLOPIAN TUBE HOWEVER; THE INSERTION WAS DIFFICULT AND WHEN THE PHYSICIAN TRIED TO WITHDRAWAL THE DEVICE PARTIAL COILS AND WIRE WERE REMOVED IN SEVERAL PIECES FROM THE RIGHT OSTIUM. PATIENT WAS SUBMITTED TO A LAPAROSCOPIC BILATERAL SALPINGECTOMY. DURING THIS SURGERY, ESSURE WAS REMOVED FROM LEFT SIDE; NO PORTION OF COIL WAS SEEN IN RIGHT TUBE. THE REPORTED EVENT, REGARDED AS DEVICE BREAKAGE DURING AN ATTEMPT OF ESSURE REMOVAL, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ONCE ESSURE IS PLACED, HYSTEROSCOPIC INSERT REMOVAL SHOULD NOT BE PERFORMED UNLESS 18 OR MORE TRAILING COILS ARE SEEN INSIDE THE UTERINE CAVITY. ATTEMPTED REMOVAL WITH LESS THAN 18 TRAILING COILS MAY RESULT IN FRACTURED INSERT, FALLOPIAN TUBE PERFORATION OR OTHER INJURY. IN THIS PARTICULAR CASE, CONSIDERING THE REPORTED DEVICE BREAKAGE OCCURRED IN ASSOCIATION WITH A DIFFICULT ESSURE INSERTION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, IT WAS REPORTED A SMALL AMOUNT OF BLEEDING IN ANTERIOR LIP OF CERVIX; THIS EVENT IS LISTED FOR ESSURE AND AS IT OCCURRED DURING ESSURE PROCEDURE IT WAS CONSIDERED AS RELATED TO THE SUSPECT DEVICE. THIS CASE WAS PREVIOUSLY REGARDED AS NON-INCIDENT; HOWEVER UPON RECEIPT OF FOLLOW-UP INFORMATION IT WAS UPGRADED TO INCIDENT, DUE TO THE REQUIRED INTERVENTION FOR DEVICE REMOVAL. A PRODUCT TECHNICAL COMPLAINT ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00341	BAYER HEALTHCARE LLC	5/27/2015	5/27/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/4/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 FOR DEFINITIVE CONTRACEPTION. PATIENT'S MEDICAL HISTORY INCLUDED TIBIA FRACTURE, NODULAR HYPERPLASIA AND APPENDICECTOMY. HER CONCOMITANT CONDITIONS INCLUDED ASTHMA AND ALLERGY TO POLLEN. SHE DENIED NICKEL ALLERGY. ACCORDING TO THE GYNECOLOGIST; THE PATIENT HAD ANAPHYLACTIC SHOCK EPISODES. HE DID NOT KNOW THEIR CAUSE BUT ANAMNESIS UNDERLINED THAT THESE ANAPHYLACTIC SHOCK EPISODES STARTED THE YEAR THAT SHE HAD BEEN FITTED WITH ESSURE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ANAPHYLACTIC SHOCK EPISODES. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ANAPHYLAXIS MOST OFTEN RESULTS FROM AN IMMUNOGLOBULIN E MEDIATED ALLERGIC REACTION TO FOODS, INSECT STINGS, AND MEDICATIONS. PATIENT'S COMORBIDITIES, SUCH AS ASTHMA, MAY IMPACT ANAPHYLAXIS SEVERITY (INCREASED RISK OF DEATH). SHOCK FROM ANAPHYLAXIS IS MOST COMMONLY ENCOUNTERED IN PATIENTS WITH SEVERE ALLERGIC REACTIONS. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY; ALLERGIC REACTIONS TO THIS DEVICE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY. IN THIS PARTICULAR CASE, THE PHYSICIAN WAS UNSURE ABOUT EVENT'S ETIOLOGY AND THE PATIENT DENIED NICKEL ALLERGY. NEVERTHELESS, SINCE A POSITIVE TEMPORAL RELATIONSHIP BETWEEN EVENT'S ONSET AND ESSURE INSERTION WAS MENTIONED BY THE PHYSICIAN AND GIVEN PATIENT'S ASTHMA AS A CONTRIBUTORY CONDITION FOR THE SEVERITY OF HER REACTION (SHOCK); CAUSALITY WITH ESSURE CANNOT BE EXCLUDED BASED ON THE LIMITED INFORMATION

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PROVIDED. DUE TO THE NATURE OF THE REPORTED EVENT, THIS CASE WAS REGARDED AS AN OTHER REPORTABLE INCIDENT, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, IT MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION (FOOD ALLERGY HISTORY AND CONCOMITANT DRUGS) ARE BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 29-MAY-2015: THE PATIENT'S MEDICAL HISTORY ALSO INCLUDES: TIBIA FRACTURE AND AN UNEXPLAINED ANAPHYLACTIC SHOCK (ALLERGOLOGICAL TEST NOT SEEN). THE ESSURE PLACEMENT PROCEDURE WAS ON (B)(6) 2010. THE TUBAL STERILIZATION WIT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00342	BAYER HEALTHCARE LLC	5/27/2015	5/27/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. THE CONSUMER STATED THAT SHE INSTANTLY WOKE UP IN PAIN AND HAD BEEN BLEEDING SINCE PROCEDURE. SHE GOT ESSURE REMOVED AND WELL TUBES CUT OUT. SHE RECEIVED INDERMETROS AND HAD 4 SURGERIES AND THEY WERE STILL FINDING PIECES EMBEDDED IN HER. SHE COULD NOT QUIT BLEEDING. SHE STATED THAT ESSURE RUINED HER LIFE AND SHE (AND HER LIFE) WERE GETTING WEAK. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015 FROM CONSUMER: CONSUMER STATED THAT SHE WOKE UP IN EXTREME PAIN. SHE HEMORRHAGED FOR A YEAR. SHE FINALLY FOUND A PHYSICIAN THAT BELIEVED HER AND HE FOUND OUT THE SPRINGS WERE PUT IN WRONG. ON HER RIGHT SIDE THE SPRING WAS STICKING OUT; SHE COULD FEEL IT CUTTING IN HER STOMACH. WHEN THEY WENT TO TAKE IT OUT, THEY COULDN'T AND HAD TO GIVE HER A TUBAL LIGATION, SHE DID NOT KNOW THE DATE. SHE NO LONGER HAS THE ESSURE COILS. SHE REPORTED THAT WHEN THEY DID THE CAUTERIZATION AND TUBAL LIGATION SHE WAS FULL OF ENDOMETRIOSIS. SHE DID NOT HAVE A FAMILY HISTORY OF THAT AND BUT SHE HAD C-SECTIONS, SHE NEVER HAD ENDOMETRIOSIS BEFORE. IN THE LAST 2 YEARS, SHE HAS BEEN OPENED UP 3 TIMES AND THEY KEEP FINDING METAL PIECES INSIDE HER; SHE HAD SO MANY SURGERIES SHE DID NOT REMEMBER THE DATES. SHE STATED THAT SHE WAS PUT ON MEDICATIONS AND CAN'T THINK CLEARLY (CONSUMER DID NOT PROVIDE ANY FURTHER INFORMATION). SHE REPORTED THAT SHE WAS STILL BLEEDING AND NOT GETTING BETTER. SHE WAS IN EXTREME PAIN ALL THE TIME AND BLEEDING VERY BADLY, SHE WAS LOSING WEIGHT AND GETTING WEAK. SHE WAS NOT ABLE TO WORK FOR 3-4 YEARS. SHE STATED THAT ESSURE RUINED HER LIFE AND MARRIAGE. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE

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RECEIVED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE PTC CASE REFERS ALSO TO A DEVICE BREAKAGE AS IT WAS REPORTED THAT PIECES OF THE DEVICE WERE IMBEDDED. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND INSTANTLY WOKE UP IN PAIN / EXTREME PAIN (SEEN AS PELVIC PAIN) AND HAD BEEN BLEEDING SINCE PROCEDURE (COULD NOT QUIT BLEEDING) / HEMORRHAGED (SEEN AS GENITAL BLEEDING). ON HER RIGHT SPRING WAS STICKING OUT, COULD FEEL IT CUTTING IN MY STOMACH (SEEN AS FALLOPIAN TUBE PERFORATION). SHE HAS BEEN OPENED UP 3 TIMES AND THEY KEEP FINDING THESE METAL PIECES IN SIDE HER (SEEN AS DEVICE BREAKAGE). THE CONSUMER GOT ESSURE REMOVED AND TUBES CUT OUT. SHE HAD MANY SURGERIES AND THEY WERE STILL FINDING PIECES EMBEDDED IN HER. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR THE EVENT DEVICE BREAKAGE WHICH IS LISTED ACCORDING TO TECHNICAL ANALYSIS. IN THIS CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. DUE TO REQUIRED INTERVENTION, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY, ANOTHER SERIOUS EVENT (CAN'T THINK CLEARLY) AND OTHER NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION (GENERAL QUESTIONNAIRE) RECEIVED ON 01-JUL-2015: THE PHYSICIAN REPORTED THAT HE DID NOT PLACE THE ESSURE DEVICES. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP FROM 02-JUL-2015: FOLLOW-UP WILL NO LONGER BE PURSUED. COMPANY CAUSALITY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00343	BAYER HEALTHCARE LLC	5/27/2015	5/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 898927

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A NON-PREGNANT (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 898927, INSERTED FOR PERMANENT CONTRACEPTION. ON (B)(6) 2015, DURING INTERCOURSE; PATIENT'S HUSBAND FELT DISCOMFORT AND WAS ABLE TO FEEL DEVICE AT HER CERVIX. IN ADDITION, IT WAS INFORMED THAT PATIENT HAS HAD CRAMPING THAT'S BEEN GOING ON BUT OTHERWISE ASYMPTOMATIC. THE INNER COIL WAS PROTRUDING FROM PATIENT'S CERVIX; WHEN HEALTH CARE PROFESSIONAL TUGGED ON IT, SHE HAD DISCOMFORT ON LEFT. LEFT COIL WAS BENT DURING PLACEMENT. PATIENT HAD TO BE PUT TO SLEEP UNDER CONSCIOUS SEDATION AND OTHER HCP (HEALTH CARE PROFESSIONAL) REMOVED AND REPLACED IT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: LOT NUMBER 898927 PRODUCTION DATE: 8/2011, EXPIRATION DATE: 8/2014. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE

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REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE INNER COIL WAS PROTRUDING FROM HER CERVIX (CONSIDERED AS PARTIAL EXPULSION OF DEVICE). WHEN HEALTH CARE PROFESSIONAL TUGGED ON IT, SHE HAD DISCOMFORT ON LEFT AND LEFT COIL WAS BENT DURING PLACEMENT. SHE EXPERIENCED CRAMPING. SHE HAD TO BE PUT TO SLEEP UNDER CONSCIOUS SEDATION AND ESSURE WAS REMOVED AND REPLACED. THE EVENT PARTIAL EXPULSION OF DEVICE WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 14-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042864	BAYER	5/27/2015	6/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/6/2012
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COIL INSERTED AND HAD A TERRIBLE ALLERGIC REACTION. ALL THE MUSCLES IN MY BODY STIFFENED AND I COULD HARDLY WALK, ESPECIALLY AFTER SITTING STILL FOR A WILE (EXAMPLE: AFTER DRIVING OR WORKING AT MY DESK). I COMPLAINED TO MY DOCTORS AND THEY ALL INSISTED THIS WAS NOT THE CAUSE OF MY TROUBLE. I WAS DIAGNOSED WITH FIBROMYALGIA BECAUSE THEY COULD NOT FIGURE OUT THE CAUSE OF PAIN. I SWITCHED DOCTORS (CLINICS). THE NEW DOCTOR SENT ME TO A GYNECOLOGIST AND SHE DID A HYSTERECTOMY. THE PAIN IS GONE. A TEST WAS NEVER DONE TO SEE IF I HAD AN ALLERGIC REACTION TO NICKEL OR WHAT THE DEVICE WAS MADE FROM. IT WAS THE WORST 2 YEARS EVER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00345	BAYER HEALTHCARE LLC	5/28/2015	5/28/2015

Event Information:

Event Date (B3): 4/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 REFERRING TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 FOR STERILIZATION. ABOUT 3 MONTHS AFTER THE ESSURE PLACEMENT AN HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND THE PATIENT CLAIMED THE FALLOPIAN TUBES WERE PATENT BILATERALLY. SHE HAD A SECOND HSG AND CLAIMED THIS SECOND HSG SHOWED BILATERAL OCCLUSION BUT THERE WAS NO MENTION TO HER ABOUT THE PLACEMENT OF THE ESSURE. THE PATIENT THEN GOT PREGNANT ON UNSPECIFIED DATE AND HAD AN ELECTIVE ABORTION AND BILATERAL LAPAROSCOPIC TUBAL SURGERY FOR CONTRACEPTION ON THE SAME DATE. AT THIS SURGERY PHYSICIAN NOTED ON ONE SIDE THERE WAS AN ESSURE IN GOOD PLACEMENT. ON THE OTHER SIDE THERE WERE 3 ESSURE WHICH HAD ALL PERFORATED THE UTERUS. ALL 4 ESSURE WERE REMOVED (DATE CONFIRMED UNKNOWN TO REPORTER). THE PATIENT HAS NOW RECOVERED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN THIS PARTICULAR CASE, ALSO A USE ERROR WAS

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REPORTED. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT. ELECTIVE ABORTION AND BILATERAL LAPAROSCOPIC TUBAL SURGERY FOR CONTRACEPTION WERE THEN PERFORMED AND DURING THE PROCEDURE, ON ONE SIDE, THERE WERE 3 ESSURES WHICH HAD ALL PERFORATED THE UTERUS. ALL ESSURE DEVICES WERE REMOVED AND PATIENT RECOVERED. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE EXACT DATE AND MECHANISM OF THIS PERFORATION IS NOT KNOWN. HOWEVER, GIVEN THE EVENT'S NATURE, CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THE PRESENT CASE, THE ESSURE CONFIRMATION TEST (HSG) WAS PERFORMED THREE MONTHS AFTER PLACEMENT AND SHOWED BILATERAL TUBAL PATENCY. A SECOND HSG WAS PERFORMED AND SHOWED BILATERAL OCCLUSION. ALTHOUGH IN THE PRESENT CASE THE PERFORATION COULD HAVE A CONTRIBUTORY ROLE TO DEVICE INEFFICACY, IT IS NOT KNOWN THE EXACT DATE OF THE REPORTED EVENT (IF IT WAS BEFORE OR AFTER THE CONCEPTION), THEREFORE CAUSALITY BETWEEN PREGNANCY AND ESSURE USE CANNOT BE TOTALLY EXCLUDED. CONSIDERING THE ESSURE DEVICES WERE REMOVED (REQUIRED INTERVENTION) THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW UP 14-JUL-2015: THE DOCTOR REPORTED THAT PATIENT HAD A FOLLOW-UP X-RAY AND SHOWED IMPROPER PLACEMENT OF THE COILS. BUT INSTEAD OF LAPAROSCOPIC SURGERY TO ADDRESS THE ISSUE AS SHOULD HAPPEN, THE PATIENT WHO ULTIMATELY BECAME PREGNANT, UNDERWENT THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00346	BAYER HEALTHCARE LLC	5/28/2015	5/28/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/1/2015
Explant Date (E7): 4/30/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN THE WEEK OF (B)(6) 2015. THE PATIENT DEVELOPED HIVES AND PAIN AND WAS DIAGNOSED WITH A NICKEL ALLERGY. ESSURE DEVICES WERE COMPLETELY REMOVED ON (B)(6) 2015. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND

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EXPERIENCED NICKEL ALLERGY. THE DEVICES WERE REMOVED. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE EXACT EVENT'S ONSET DATE WAS NOT PROVIDED; HOWEVER ESSURE WAS REMOVED APPROXIMATELY ONE MONTH AFTER ITS INSERTION. THEREFORE, CAUSALITY BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE ESSURE REMOVAL WAS REPORTED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 14-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUB

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00347	BAYER HEALTHCARE LLC	5/28/2015	5/28/2015

Event Information:

Event Date (B3): 3/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D01977

Single Use:
Implant Date (E6): 12/5/2014
Explant Date (E7): 5/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014, LOT NUMBER D01977. HYSTEROSALPINGOGRAM TEST WAS PERFORMED ON (B)(6) 2015 AND REVEALED THAT ONE INSERT WAS IN THE MYOMETRIUM. ON (B)(6) 2015, THE PATIENT HAD A HYSTEROSCOPY. THE DEVICE WAS REMOVED AND ANOTHER INSERT WAS PLACED SUCCESSFULLY. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 4 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH 1 CASES REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. COMPANY

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CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, A HYSTEROSALPINGOGRAM WAS DONE AFTER 3 MONTHS AND REVEALED THAT ONE INSERT WAS IN THE MYOMETRIUM. THIS EVENT, REGARDED AS PARTIAL UTERINE PERFORATION (PARTIAL EXPULSION OF DEVICE) IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE THE EXACT DATE OF THE PERFORATION WAS NOT REPORTED. A HYSTEROSALPINGOGRAM SHOWED ONE INSERT WAS IN THE MYOMETRIUM 3 MONTHS AFTER INSERTION. THE PATIENT UNDERWENT A HYSTEROSCOPY AND THE DEVICE WAS REMOVED. ANOTHER INSERT WAS PLACED SUCCESSFULLY. CONSIDERING THE AVAILABLE INFORMATION AND NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED AND DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL (HYSTEROSCOPY) THIS CASE WAS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 16-JUN-2015 FROM PHYSICIAN: PATIENT'S DEMOGRAPHIC INFORMATION WAS PROVIDED. THIS CASE REFERS TO A (B)(6) NON-PREGNANT FEMALE PATIENT. SHE HAD 4 PREVIOUS PREGNANCIES AND DELIVERIES (GRAVIDA 4, PARA 4); PREVIOUS GYNECOLOGIC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00349	BAYER HEALTHCARE LLC	5/28/2015	5/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91761

Single Use: Y
Implant Date (E6): 2/26/2015
Explant Date (E7): 4/30/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. PHYSICIAN IS GOING TO PERFORM SURGERY TO REMOVE AN ESSURE DEVICE WHICH FELT INTO THE ENDOMETRIUM. HCP DID NOT INSERT THE DEVICES AND WILL BE PERFORMING A TUBAL. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION

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INSERT) INSERTED AND THE DEVICE FELT INTO HER ENDOMETRIUM; HER PHYSICIAN IS GOING TO PERFORM A SURGERY TO REMOVE IT. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN THE EVENT'S NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE AN INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 24-JUN-2015 NEW REPORTERS WERE ADDED. THE PATIENT´S INITIAL AND DATE OF BIRTH WERE UPDATED (SHE WAS (B)(6) AT TIME OF EVENT). HER WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). ESSURE WAS INSERTED ON (B)(6) 2015 WITH LOT NUMBER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00350	BAYER HEALTHCARE LLC	5/28/2015	5/28/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF, WHO WAS INVOLVED IN AN ESSURE® GENERIC ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6). CONSUMER HAD HER COILS REMOVED LAST YEAR. ACCORDING TO HER, SHE FEELS MUCH BETTER AFTER HAVING ESSURE REMOVED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S

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REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT PROCEDURE FOR ESSURE REMOVAL WAS NOT SPECIFIED AND NO TEMPORAL RELATION BETWEEN INSERTION AND REMOVAL PROCEDURES WAS PROVIDED; SINCE PATIENT STATED SHE WAS FEELING BETTER AFTER DEVICE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE PROBABLE SURGICAL INTERVENTION FOR DEVICES REMOVAL; THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION CAN BE OBTAINED SINCE THIS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00351	BAYER HEALTHCARE LLC	5/28/2015	5/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. CONSUMER ALREADY HAD TWO BOYS WHEN SHE UNDERWENT ESSURE INSERTION PROCEDURE IN THE SUMMER OF 2013. SHE DID NOT UNDERGO THE FOLLOW-UP VISIT BECAUSE HER INSURANCE WOULD NOT PAY FOR IT. A YEAR AFTER HAVING THE DEVICE PLANTED (2014); SHE SUSPECTED THAT SHE COULD BE PREGNANT. A PREGNANCY TEST WAS PERFORMED AND THE RESULT WAS POSITIVE. SHE WORRIED SHE MIGHT HAVE AN ECTOPIC PREGNANCY, BUT HER BABY WAS BORN HEALTHY. ADDITIONALLY, SHE STATED DOCTORS WERE NEVER ABLE TO LOCATE ONE OF HER COILS (THE DEVICE HAS MOVED OUT OF PLACE). ON AN UNSPECIFIED DATE, ESSURE WAS REMOVED; CONSUMER STATED SHE FELT MUCH BETTER AFTER HAVING THE COILS REMOVED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS

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REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE DELIVERED A HEALTHY CHILD. ACCORDING TO HER, DOCTORS WERE NEVER ABLE TO LOCATE ONE OF ESSURE COILS (THE DEVICE HAS MOVED OUT OF PLACE). SHE HAD ESSURE REMOVED. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE. ADDITIONALLY, IF DEVICE MOVEMENT (MIGRATION OR EXPULSION) OCCURS DURING ESSURE THERAPY, ITS CONTRACEPTIVE EFFICACY MAY BE COMPROMISED, RESULTING IN PREGNANCIES. IN THIS PARTICULAR CASE, CONSUMER NEVER RETURNED FOR HER CONFIRMATION TEST; AND ONE OF ESSURE COILS WAS LATER FOUND DISLOCATED. ALTHOUGH PREGNANCY IN THE PRESENT CASE MAY BE CONSIDERED RATHER A CONSEQUENCE OF NON-COMPLIANT USE; SINCE IT OCCURRED APPROXIMATELY ONE YEAR AFTER ESSURE INSERTION; AND AS IT IS UNKNOWN IF THE REPORTED DEVICE DISLOCATION OCCURRED BEFORE OR AFTER PREGNANCY ONSET, AN ESSURE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE REMOVAL (INTERVENTION IMPLIED) WAS REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW-UP INFORMATION IS EXPECTED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CASE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042894		5/28/2015	6/4/2015

Event Information:

Event Date (B3): 9/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/13/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE TUBAL IMPLANT. APPARENTLY SEVERED BLOOD SUPPLY TO OVARIES, INDUCING PERIMENOPAUSE AT AGE OF (B)(6). EVIDENTLY THIS HAS HAPPENED TO MANY WOMEN BUT IT HAS NOT BEEN MADE A MANDATORY DISCLOSURE TO POTENTIAL PTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042897	BAYER	5/28/2015	6/4/2015

Event Information:

Event Date (B3): 1/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/22/2013
Explant Date (E7): 2/6/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL DEVICE PUT IN (B)(6) 2013. AFTER 15 DAYS OF HORRIBLE PAIN AND PAIN THAT GOT WORSE AND WORSE A DIFFERENT OBGYN REMOVED THE ESSUE TO FIND 2 ESSURE COILS IN MY RIGHT FALLOPIAN TUBE. WHILE ONE IN MY LEFT. I STILL HAD PAIN SO THEY WENT IN AGAIN TO LOOK FOR OTHER CAUSES THE PAIN. AS OF TODAY I STILL HAVE PAIN IN MY RIGHT SIDE OF MY ABDOMEN DURING INTERCOURSE AND DURING MENSTRUATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00344	BAYER HEALTHCARE LLC	5/28/2015	6/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64470

Single Use: Y
Implant Date (E6): 4/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 6/15/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 THE PATIENT STARTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WITH LOT NUMBER C64470. ON (B)(6) 2015, ESSURE DISTENDED ON RELEASE. NO INCIDENCE ON THE PATIENT. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ESSURE DISTENDED ON RELEASE. THIS EVENT, INTERPRETED AS SUSPICION OF DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, THE DEVICE BREAKAGE WAS CONSIDERED AS SUSPICION AND FURTHER DETAILS ARE REQUIRED. A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE SUSPICION OF DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULTS WERE PROVIDED ON 08-JUN-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: ACCORDING TO THE COMPLAINT NARRATIVE, THE INSERT WAS DAMAGED (MOST LIKELY THE DISTAL TIP OF THE INSERT) DURING RELEASE FROM THE CATHETER. AS OF 11-MAY-201

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00348	BAYER HEALTHCARE LLC	5/28/2015	6/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51060

Single Use: *
Implant Date (E6): 4/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C51060, ON (B)(6) 2015. HEALTH CARE PROFESSIONAL REPORTED THAT SHE WAS INSERTING ESSURE INTO THE RIGHT SIDE AND ALL WAS GOING WELL UNTIL SHE PRESSED THE BUTTON. SOMETHING WENT WRONG, THE DEVICE WAS NOT COMING OUT PROPERLY AND ON THE SECOND WHEEL BACK THE SPRING DID NOT RELEASE FROM THE OUTER COIL (THE INSERTER DID NOT COME OUT AT ALL). IT WAS NOT CLEAR WHETHER PHYSICIAN MEANT THE DELIVERY CATHETER OR MICRO-INSERT. PHYSICIAN TRIED TO REMOVE THE MICRO-INSERT AND THE INNER COIL FRACTURED INTO TWO PIECES. THE HCP REMOVED HALF OF THE INNER COIL BUT IT STRETCHED OUT. SHE REINSERTED THE CAMERA AND USED THE GRASPERS TO ATTEMPT TO REMOVE THE OTHER HALF AND IT WOULD NOT REMOVE AND WAS LEFT BEHIND. SHE THEN ABORTED THE PROCEDURE. THE LEFT SIDE WAS NOT ATTEMPTED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER

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COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE REMOVAL. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING PLACEMENT INTO RIGHT SIDE THE DEPLOYMENT FAILED AND THE PHYSICIAN TRIED TO REMOVE THE MICRO-INSERT AND THE INNER COIL FRACTURED INTO TWO PIECES. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. HOWEVER, ACCORDING TO PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS, MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MOSTLY DURING DIFFICULT INSERTIONS OR REMOVALS. IN THIS CASE, THE PHYSICIAN WAS INSERTING ESSURE INTO RIGHT SIDE BUT THE SPRING DID NOT RELEASE FROM THE OUTER COIL. THE DEVICE DID NOT COME OUT. SHE TRIED TO REMOVE THE MICROINSERT AND THE INNER COIL FRACTURED INTO TWO PIECES. THE HCP REMOVED HALF OF THE INNER COIL BUT IT STRETCHED OUT. SHE USED THE GRASPERS TO ATTEMPT TO REMOVE THE OTHER HALF BUT IT FAILED AND WAS LEFT BEHIND. SHE THEN ABORTED THE PROCEDURE. CONSIDERING THE EVENT OCCURRED ASSOCIATED TO INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 29-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT, WHO HAD AN ATTEMPT TO INSERT ESSU

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042855	BAYER	5/29/2015	5/29/2015

Event Information:

Event Date (B3): 1/24/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HORRIBLE PELVIC PAIN AND CRAMPING, BLEEDING AT LEAST 20 DAYS A MONTH, HEADACHE EVERYDAY, EXTREMELY TIRED ALL THE TIME, HORRIBLE MOOD SWINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042856	BAYER	5/29/2015	5/29/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ACTUAL (B)(6) 2012. SEVERE CRAMPING, IRREGULAR BLEEDING, NIGHT SWEATS, HOT FLASHES, SWELLING OF PELVIC AREA AND LEGS, CLOTTING, HAIR THINNING, INCREASED ANXIETY. ALLERGIC TO NICKEL AND NOT TOLD THERE IS NICKEL IN THESE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042969	BAYER	5/31/2015	6/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/4/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING SEIZURES (B)(6) AFTER I HAD THE ESSURE PUT IN AND NEVER HAD THEM BEFORE. I ALWAYS HAVE BODY ACHES, BLOATING, WEIGHT GAIN. MY PERIOD IS VERY IRREGULAR WITH HEMORRHAGING WHEN I DO GET IT. I AM SEEKING TO HAVE IT REMOVED. IT SHOULD BE TAKEN OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00352	BAYER HEALTHCARE LLC	6/1/2015	6/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE IS A SOLICITED CASE REPORT ((B)(6)) RECEIVED FROM A NOT SPECIFIED REPORTER FROM UNITED STATES ON 28-APR-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ESSURE USER STILL GETS PREGNANT AND DEVICE INEFFECTIVE. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL. REPORTER STATED THAT ESSURE USER STILL GETS PREGNANT. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION ON 06-MAY-2014: NO FOLLOW-UP CAN BE OBTAINED DUE TO LACK OF PRIMARY REPORTER CONTACT INFORMATION. CASE CLOSED. FOLLOW-UP INFORMATION WAS RECEIVED ON 09-JUL-2014. SHE STATED THAT ESSURE RUINED HER HEALTH. NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 26-FEB-2015. THE CONSUMER REPORTED AN UNSPECIFIED NERVOUS SYSTEM DISORDER. FOLLOW-UP INFORMATION POSTED ONLINE BY THE CONSUMER ON AN UNSPECIFIED DATE AND COLLECTED BY THE COMPANY ON 04-MAY-2015: SHE REPORTED THAT, AT TIME OF THE REPORT, IT HAS BEEN 4 YEARS SINCE ESSURE WAS INSERTED AND 1.5 YEARS SINCE ITS REMOVAL. SHE STATED THAT SHE WAS STILL STRUGGLING DAILY. SHE POSTED A PICTURE OF HER BELLY, AT TIME OF THIS REPORT, APPEARING TO BE PREGNANT. CASE UPGRADED TO INCIDENT. FOLLOW UP INFORMATION RECEIVED ON 15-MAY-2015: PTC (PRODUCT TECHNICAL COMPLAINT) PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER

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FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. INTERNAL CORRECTION PERFORMED ON 20-MAY-2015: DURING INTERNAL CODING REVIEW THE EVENT "ESSURE USER STILL GETS PREGNANT" WAS RECODED TO MEDDRA PT: MATERNAL EXPOSURE BEFORE PREGNANCY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOCIAL MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED 2.5 YEARS AFTER ITS INSERTION. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. ALTHOUGH THE REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED; IT CANNOT BE EXCLUDED THAT IT OCCURRED AS A CONSEQUENCE OF ESSURE THERAPY. THEREFORE, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, CONSUMER POSTED A PHOTO OF HERSELF SHOWING A POSSIBLE PREGNANCY AT THE TIME OF THIS REPORT. SINCE THIS EVENT OCCURRED AFTER ESSURE REMOVAL; IT WAS CONSIDERED AS UNRELATED TO THE SUSPECT DEVICE. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION CAN BE OBTAINED AS THIS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE PHARMACEUTICALS INC.	6/1/2015	6/25/2015

Event Information:

Event Date (B3): 4/29/2015 **Report Date (B4): 6/1/2015** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL
Model # (E4): 0817D01974Q
Catalog # (E4): *
Lot #(E4): DO1974

Single Use:
Implant Date (E6): 4/29/2015
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

AT THE TIME OF THE PROCEDURE THERE WAS DIFFICULTY RELEASING THE MICRO-INSERT FROM THE DELIVERY DEVICE. THE DELIVERY SYSTEM REMOVED REQUIRED PULLING AND TWISTING OF THE DELIVERY DEVICE. WHEN THE DELIVERY DEVICE WAS REMOVED IT HAD STRETCHED. IT APPEARED THAT THE MICRO-INSERT HAD BECOME UNRAVELED BUT HAD NOT DEPLOYED. A SECOND DEVICE WAS USED AND A MICRO-INSERT WAS DEPLOYED. THE DEVICE WAS EXAMINED BY THE ESSURE REPRESENTATIVE AND CONFIRMED THAT THE FIRST MICRO-INSERT HAD BEEN DEPLOYED. THE PATIENT LIKELY HAS TWO MICRO-INSERTS IN HER RIGHT FALLOPIAN TUBE. THERE WAS NO HARM TO THE PATIENT. THE PATIENT WILL HAVE AN HSG (HYSTEROSALPINGOGRAM). ROUTINE AFTER THIS PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00353	BAYER HEALTHCARE LLC	6/2/2015	6/2/2015

Event Information:

Event Date (B3): 5/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64472

Single Use: Y
Implant Date (E6): 5/5/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 6/22/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(4) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER C64472. PHYSICIAN STATES THAT PATIENT HAD SPASM DURING PLACEMENT AND INFORMED THAT SPRING BROKE ON RELEASE. IN ADDITION, DOCTOR REPORTED THAT RIGHT IMPLANT SEEMED TO BE PLACED UPSIDE-DOWN WITH TERMINAL RELEASE OF DISTAL EXTREMITY. BILATERAL INSERTION WAS DONE WITH THE CONCERNED IMPLANTS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON (B)(4) 2015: INFORMATION RECEIVED FROM SURGEON STATES THAT INSERTION WAS PERFORMED ON (B)(6) 2015. PROCEDURE WAS DONE UNDER GENERAL ANESTHESIA. PATIENT'S UTERINE CAVITY WAS NORMAL WITH SMALL NON-SUSPECT ENDOMETRIUM POLYP AT ANTERIOR WALL. BOTH OSTIUM WERE WELL VISIBLE. LEFT TUBAL OSTIUM CATHETERIZATION WITH ESSURE IMPLANT PLACEMENT OCCURRED ACCORDING TO PROCEDURE BUT WITH HARD FRICTION. ON RIGHT, THERE WAS THE SAME FRICTION WHICH EVOKED A SMALL SPASM, UNUSUAL FEELING OF INCORRECT RELEASE. THE PROXIMAL EXTREMITY REMAINED FIXED TO THE DELIVERY SYSTEM REQUIRING TRACTIVE EFFORT TO RELEASE IMPLANT WITH SPRING BREAKAGE. AN EXTREMITY APPEARED LIKE A DISTAL PART OF THE IMPLANT AS IF IT HAD BEEN ASSEMBLED UPSIDE-DOWN BUT THEY HAD NOT BEEN ABLE TO SEE ANY REVERSAL OF THE IMPLANT ON ITSELF AND WITHOUT INTRA-CAVITY DEPRESSION WHICH EVOKED A PERFORATION. AT THE END OF THE PROCEDURE, THERE WERE 5 EXPANDED OUTER COILS ON LEFT AND A BIG PART OF CENTRAL ACTIVE PART OF THE IMPLANT IN THE MIDDLE OF RIGHT OSTIUM. NO OTHER MEDICAL INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE SPRING BROKE ON RELEASE (INTERPRETED

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AS DEVICE BREAKAGE). IT WAS ALSO REPORTED A SUSPICION OF PERFORATION. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE SUSPICION OF PERFORATION IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALSO, UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THE PRESENT CASE, A TUBAL SPASM DURING PLACEMENT OCCURRED AND DOCTOR REPORTED THAT RIGHT IMPLANT SEEMED TO BE PLACED UPSIDE-DOWN WITH TERMINAL RELEASE OF DISTAL EXTREMITY AND THE SPRING BROKE ON RELEASE. IT WAS REPORTED THAT AN EXTREMITY APPEARED LIKE A DISTAL PART OF THE IMPLANT AS IF IT HAD BEEN ASSEMBLED UPSIDE-DOWN BUT THEY HAD NOT BEEN ABLE TO SEE ANY REVERSAL OF THE IMPLANT ON ITSELF AND WITHOUT INTRA-CAVITY DEPRESSION WHICH EVOKED A PERFORATION. SINCE THE BREAKAGE AND THE SUSPICION OF PERFORATION OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 12-AUG-2015: PTC INVESTIGATION RESULTS WERE UPDATED AND PROVIDED. ONE DEVICE WAS RECEIVED ON 22-JUN-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00354	BAYER HEALTHCARE LLC	6/2/2015	6/2/2015

Event Information:

Event Date (B3): 11/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38210

Single Use: *
Implant Date (E6): 11/6/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN (B)(6) ON (B)(4) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2014 WITH LOT NUMBER C38210. IT WAS REPORTED THAT TUBAL STERILIZATION WITH ESSURE WAS ATTEMPTED ON PATIENT'S REQUEST AND DUE TO DIFFERENT CONTRACEPTION METHODS FAILURE. DURING THE PROCEDURE, IN THE OPERATING ROOM, THERE WAS A PROCEDURE FAILURE. DEFECT AND NO RELEASE OF LEFT IMPLANT. AS CLINICAL CONSEQUENCES PATIENT WAS SUBMITTED TO A LAPAROSCOPIC EXAMINATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND A DEFECT OCCURRED; NO RELEASE OF LEFT IMPLANT. SHE WAS SUBMITTED TO A LAPAROSCOPIC EXAMINATION ON THE SAME DAY. THIS EVENT, REGARDED AS A DEVICE DEPLOYMENT ISSUE, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, PHYSICIAN STATED A DEFECT OCCURRED DURING THE INSERTION PROCEDURE AND LEFT ESSURE DID NOT RELEASE; ACCORDING TO HIM, THE PERFORMED LAPAROSCOPY WAS A CONSEQUENCE OF THE EVENTS. ALTHOUGH LIMITED INFORMATION WAS PROVIDED; SINCE THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE INSERTION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE INTERVENTION REPORTED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 08-JUN-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). BATCH NUMBER C38210 PRODUCTION DATE 19-MAR-2014 EXPIRATION DATE 31-MAR-2017. FINAL ASSESSMENT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00357	BAYER HEALTHCARE LLC	6/2/2015	6/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT PATIENT DID NOT HAVE A TEST FOR NICKEL ALLERGY AND HAS BEEN HAVING MANY COMPLICATIONS; LOSING HER HAIR AND SKIN LESIONS. PATIENT THOUGHT THAT IT WAS DUE TO NICKEL ALLERGY. SHE HAD A SALPINGECTOMY DONE ON AN UNSPECIFIED DATE. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(4) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A

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FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SKIN LESIONS AND LOSING HER HAIR. SHE THOUGHT THAT IT WAS DUE TO NICKEL ALLERGY. A SALPINGECTOMY WAS PERFORMED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS CASE, PATIENT DID NOT HAVE A TEST FOR NICKEL ALLERGY AND AN UNKNOWN TIME AFTER ESSURE INSERTION, SHE EXPERIENCED NICKEL ALLERGY. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE REQUIRED INTERVENTION, THIS CASE WAS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00358	BAYER HEALTHCARE LLC	6/2/2015	6/2/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/3/2008
Explant Date (E7): 6/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6)-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4) AND EXPERIENCED HORRIBLE ISSUES AND PARTIAL HYSTERECTOMY. STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. IN (B)(6)-2008 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED HORRIBLE ISSUES. IN (B)(6)-2011 THE CONSUMER HAD A PARTIAL HYSTERECTOMY DONE. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE IS NOT REPORTED. FOLLOW UP INFORMATION RECEIVED ON (B)(6)-2014. THIS INFORMATION WAS TRANSFERRED FROM CASE (B)(4), AFTER INTERNAL REVIEW ON (B)(4)-2014. ADDITIONAL INFORMATION WAS RECEIVED ON (B)(4)-2014. CONSUMER STATED THAT THE BABY WAS BEEN THREATENED BY AN ESSURE COIL THAT WAS FREE IN THE UTERUS. SHE ALSO STATED AGAIN THAT A HYSTERECTOMY WAS PERFORMED BUT NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6)-2014 IT WAS REPORTED THAT SHE HAD ESSURE IN 2008 AND HAD HORRID SIDE EFFECTS. IN 2011 SHE HAD A HYSTERECTOMY. FOLLOW UP INFORMATION FROM (B)(6)-2014: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO

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CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED FAILURE MODE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN (B)(4), DESIGN FMEA FOR (B)(4). MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF DRUG EFFECT. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, ALSO EXPULSION WAS REPORTED WHICH MAY HAVE INCREASED THE RISK OF PREGNANCY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP (B)(6) 2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. CONSUMER REPORTED THAT SHE HAD ESSURE IMPLANTED IN (B)(6).2008, HAD DEBILITATING BLEEDING, AND PARTIAL HYSTERECTOMY IN (B)(6).2011. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6)-2015: NO NEW CLINICAL INFORMATION PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6)-2015: CONSUMER STATED VIA SOCIAL MEDIA THAT SHE HAD A HYSTERECTOMY BECAUSE OF ESSURE. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEBILITATING BLEEDING. ADDITIONALLY, SHE BECAME PREGNANT WITH THE DEVICE AND ESSURE COIL WAS FOUND FREE IN HER UTERUS. SHE WAS SUBMITTED TO A PARTIAL HYSTERECTOMY 2.5 YEARS AFTER ESSURE PLACEMENT. ALL REPORTED EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCY AND COIL THAT FREE IN THE UTERUS (ASSUMED AS DEVICE EXPULSION) ARE NON-SERIOUS, WHILE THE REMAINING EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). ADDITIONALLY, IF DEVICE EXPULSION OCCURS DURING ESSURE THERAPY, ITS CONTRACEPTIVE EFFICACY MAY BE COMPROMISED. IN THIS PARTICULAR CASE, IT IS UNKNOWN IF THE REPORTED DEVICE EXPULSION PRECEDED PREGNANCY OR VICE-VERSA; NEVERTHELESS GIVEN THESE EVENTS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, LIMITED INFORMATION WAS PROVIDED. IT IS UNCLEAR IF THE HYSTERECTOMY WAS RELATED TO CONSUMER'S BLEEDING OR TO ESSURE EXPULSION, AND NO ALTERNATIVE EXPLANATIONS WERE REPORTED. ALTHOUGH THE REASON FOR THE HYSTERECTOMY WAS UNKNOWN; SINCE CONSUMER RELATED THIS SURGERY TO ESSURE, COMPANY CONSIDERS A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS AMENDED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION (CONSUMER STATED HER HYSTERECTOMY WAS BECAUSE OF ESSURE). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 27-AUG-2015, ON 08-SEP-2015 AND ON 16-SEP-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00360	BAYER HEALTHCARE LLC	6/2/2015	6/2/2015

Event Information:

Event Date (B3): 3/1/2000 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2000
Explant Date (E7): 1/1/2001
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (B)(6) IN (B)(6) ON 07-MAY-2015. THE FEMALE CONSUMER OF UNSPECIFIED AGE HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2000. CONSUMER STATED THAT SHE WAS ON A TRIAL IN 2000. SHE WAS GIVEN 2 IBUPROFEN 5 MINUTES BEFORE PROCEDURE. SHE WAS IN AGONY FROM THE START. SHE EXPERIENCED CONSTANT PAIN AND CONSTANT BLEEDING, HEADACHES, NAUSEA AND DIZZINESS. A HYSTERECTOMY WAS PERFORMED WITHIN A COUPLE OF MONTHS OF HAVING ESSURE FITTED (18 MONTHS). NO FURTHER INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-MAY-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: THIS IS AN ESSURE ESS205 CASE SINCE THE PATIENT HAD PLACEMENT IN 2000. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A

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TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 02-JUN-2015: NO RESPONSE TO FOLLOW UP REQUESTS FOR FURTHER INFORMATION. CASE CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERMS: GENITAL HAEMORRHAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. ABDOMINAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT PAIN AND CONSTANT BLEEDING (SEE AS GENITAL BLEEDING). A HYSTERECTOMY WAS PERFORMED. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PAIN AND GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, SHE EXPERIENCED THESE EVENTS AN UNKNOWN TIME AFTER ESSURE INSERTION. AN ALTERNATE EXPLANATION IS NOT AVAILABLE. BASED ON THE INFORMATION PROVIDED AND CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE PERFORMED SURGICAL INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 29-OCT-2015 FROM CONSUMER: CONSUMER STATED THAT SHE STRUGGLE TO EAT, THERE IS NOTHING SHE WANTS TO EAT . SHE IS UNDERWEIGHT. SHE CAN EAT CHOCOLATE AND DRINK COFFEE WITH PLENTY OF SUGAR SO THAT'S HOW SHE HAS SURVIVED THE LAST 15 YEARS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00361	BAYER HEALTHCARE LLC	6/2/2015	6/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 07-MAY-2015, ARTICLE ENTITLED "HYSTEROSCOPIC ESSURE INSERTS FOR PERMANENT CONTRACEPTION-EXTENDED FOLLOW-UP RESULTS OF A PHASE III, MULTICENTER, INTERNATIONAL STUDY". IT REFERS TO A ADULT FEMALE PATIENT WHO HAD ESSURE (ESS205 MODEL) INSERTED FOR PERMANENT CONTRACEPTION. TRADE NAME WAS REPORTED AS ESSURE INSERT (ESS205 MODEL). CASE REPORT: THIS CASE CONCERNS A FEMALE PATIENT WHO WAS INVOLVED IN A PHASE III, MULTICENTER, INTERNATIONAL STUDY OF ESSURE SYSTEM TO DESCRIBE SAFETY, EFFECTIVENESS, TOLERABILITY, AND SATISFACTION RESULTS FROM 5 YEARS OF FOLLOW-UP. IN THIS PATIENT ESSURE FALLOPIAN TUBE OCCLUSION INSERT PLACEMENT WAS DONE. THIS WOMAN REPORTED LOWER ABDOMINAL PAIN AND VERY HEAVY PERIODS AT THE 18-MONTH FOLLOW-UP VISIT AND DESCRIBED HER PAIN AS SHARP, ACHING, AND CONTINUOUS AT HER 24-MONTH FOLLOW-UP VISIT. SHE ALSO REPORTED IRREGULAR MENSTRUAL BLEEDING ALONG WITH PELVIC PAIN. SHE ULTIMATELY UNDERWENT HYSTERECTOMY AT 34 MONTHS. AUTHORS COMMENTS: THE FINDINGS FROM THE 5-YEAR FOLLOW-UP OF THE PHASE III TRIAL CONFIRM INITIAL RESULTS THAT THE ESSURE INSERT IS AN EFFECTIVE AND WELL-TOLERATED NONHORMONAL, NONINCISIONAL, OPTION FOR PERMANENT CONTRACEPTION. THE FINDINGS IN THE REPORT HEREIN ARE CONSISTENT WITH EFFECTIVENESS RESULTS WITH ESSURE INSERTS IN PREVENTING PREGNANCY IN THE PUBLISHED LITERATURE. BOTH THE HYSTEROSCOPIC STERILIZATION PROCEDURE AND ESSURE INSERT WEARING WERE GENERALLY SAFE AND WELL TOLERATED. AFTER 5 YEARS OF FOLLOW-UP, MORE THAN 90% OF PARTICIPANTS RATED THE OVERALL COMFORT WITH WEARING AS EXCELLENT, AND MORE THAN 96% OF PARTICIPANTS WERE VERY SATISFIED WITH THE ESSURE INSERTS AT THE END OF THE STUDY. ADVERSE EVENTS DURING THE FIRST YEAR OF WEARING WERE RATED AS EITHER MILD OR MODERATE IN SEVERITY, AND OCCURRED MORE

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COMMONLY DURING THE 3-MONTH PERIOD FOLLOWING PLACEMENT. THROUGHOUT 5 YEARS OF FOLLOW-UP, RELATIVELY FEW ADVERSE EVENTS WERE REPORTED THAT WERE DEEMED POSSIBLY RELATED TO THE ESSURE INSERTS. PELVIC PAIN ASSOCIATED WITH ESSURE INSERT PLACEMENT HAS BEEN A RECENT TOPIC OF INTEREST. THROUGHOUT 5 YEARS OF FOLLOW-UP IN THE PHASE III TRIAL DESCRIBED HEREIN, PELVIC PAIN (DYSMENORRHEA, DYSPAREUNIA, OVULATORY, OR OTHER) WAS REPORTED IN NO MORE THAN 7% OF STUDY PARTICIPANTS AT ANY VISIT. NO SUBJECTS REPORTED PERSISTENT PELVIC PAIN OF ANY KIND AT THE 3, 4, AND 5-YEAR FOLLOW-UP VISITS. FURTHERMORE, AT THE COMPLETION OF FOLLOW-UP, OVERALL COMFORT WITH WEARING WAS RATED AS EXCELLENT BY MORE THAN 90% OF WOMEN, AND OVERALL SATISFACTION WAS RATED AS VERY SATISFIED BY MORE THAN 96% OF WOMEN. HISTORY OF ABNORMAL AND INTERMENSTRUAL BLEEDING WAS ELICITED FROM PATIENTS POST ESSURE INSERT PLACEMENT. THE INCIDENCE WAS HIGHEST IMMEDIATELY POST HYSTEROSCOPIC STERILIZATION AS WOULD BE EXPECTED AFTER ANY INTRAUTERINE INSTRUMENTATION. A HISTORICAL COMPLAINT OF ABNORMAL BLEEDING WAS ELICITED FROM 5-12% OF WOMEN AFTER STOPPING USE OF ALTERNATIVE CONTRACEPTION. CHANGES IN THE AMOUNT OF BLEEDING AS WELL AS BLEEDING INTERVALS ARE QUITE VARIABLE OVER A WOMANS LIFETIME AND CAN BE AFFECTED BY MANY FACTORS INCLUDING AGE, WEIGHT AND CONTRACEPTIVE USE. FIFTEEN HYSTERECTOMIES WERE REPORTED IN THIS COHORT OVER 5 YEARS OF FOLLOW-UP, WHICH TRANSLATES TO 3.8% (15/397) OF EVALUABLE PARTICIPANTS. THE ESTIMATED ANNUAL HYSTERECTOMY RATE IN THE GENERAL POPULATION OF WOMEN 40-50 YEARS OF AGE IS APPROXIMATELY 9.6 PER 1,000. THEREFORE AUTHORS WOULD EXPECT APPROXIMATELY 4 WOMEN EACH YEAR FOR A TOTAL OF 20 HYSTERECTOMIES OVER A 5 YEAR STUDY. ONE MIGHT EXPECT AN EVEN HIGHER INCIDENCE OF HYSTERECTOMIES IN THIS STUDY POPULATION AS MANY WERE USING HORMONAL CONTRACEPTIVES, WHICH MAY MASK BLEEDING AND PAIN SYMPTOMS PRIOR TO CHANGING TO A NON-HORMONAL CONTRACEPTIVE. FURTHERMORE, THERE IS SOME LIMITED DATA SHOWING THAT WOMEN AFTER TUBAL STERILIZATION HAVE A HIGHER RATE OF HYSTERECTOMY. EVEN SO, THE HYSTERECTOMY RATE SEEMS TO BE IN ACCORDANCE WITH EXPECTATIONS. IN ONLY 2 INSTANCES DID THE RESPECTIVE INVESTIGATOR DEEM THE HYSTERECTOMY TO BE POSSIBLY RELATED TO THE ESSURE INSERTS (ONE WOMAN AS DESCRIBED ABOVE WHO REPORTED HEAVY AND IRREGULAR MENSTRUAL BLEEDING ALONG WITH PELVIC PAIN). NONE OF THE OTHER HYSTERECTOMIES WERE DEEMED BY THE INVESTIGATORS AS BEING DEFINITELY OR PROBABLY RELATED TO THE ESSURE INSERTS. ABSTRACT STUDY OBJECTIVE: TO DESCRIBE SAFETY, TOLERABILITY, AND EFFECTIVENESS RESULTS THROUGH 5 YEARS OF FOLLOW-UP OF A PHASE III TRIAL WITH ESSURE INSERTS. DESIGN: MULTICENTER, NONRANDOMIZED, SINGLE-ARM, INTERNATIONAL STUDY. DESIGN CLASSIFICATION: (B)(4) TASK FORCE CLASSIFICATION II-3. SETTING: 13 CLINICAL STUDY CENTERS IN THE UNITED STATES, EUROPE, AND AUSTRALIA. PATIENTS: 518 PREVIOUSLY FERTILE WOMEN SEEKING PERMANENT CONTRACEPTION. INTERVENTION: THE OBJECTIVE OF THE HYSTEROSCOPIC STERILIZATION PROCEDURE WAS BILATERAL ESSURE INSERT PLACEMENT (ESS205 MODEL) AND TUBAL OCCLUSION. WOMEN WITH SATISFACTORY DEVICE LOCATION AND TUBE OCCLUSION (BASED ON MODIFIED HYSTEROSALPINGOGRAM) WERE INSTRUCTED TO DISCONTINUE ALTERNATIVE CONTRACEPTION AND TO RELY ON THE ESSURE INSERTS FOR PERMANENT CONTRACEPTION. MEASUREMENTS AND MAIN RESULTS: THE PRIMARY END POINT FOR THE PHASE III STUDY WAS THE RATE OF PREGNANCIES OCCURRING DURING THE FIRST YEAR OF RELYING (IE, CONFIRMED HSG OCCLUSION) ON THE ESSURE INSERTS FOR PERMANENT CONTRACEPTION (IE, 12 MONTHS FOLLOWING HSG). FOR THE FULL 5 YEARS OF FOLLOW-UP (5 YEARS IN TOTAL OF RELYING ON THE ESSURE INSERTS FOR CONTRACEPTION), THE END POINTS OF INTEREST WERE SAFETY, PREVENTION OF PREGNANCY, AND SATISFACTION. NO PREGNANCIES WERE REPORTED AMONG WOMEN RELYING ON THE ESSURE INSERTS WHO COMPLETED THE FULL 5 YEARS OF FOLLOW-UP. AS OF DECEMBER 5, 2007, 449 WOMEN WITH SUCCESSFUL BILATERAL PLACEMENT RELYING ON THE ESSURE INSERTS CONTRIBUTED A TOTAL 24,942 WOMAN-MONTHS OF FOLLOW-UP FOR ASSESSING THE EFFECTIVENESS. OVERALL, THE ESSURE INSERTS WERE GENERALLY WELL TOLERATED, WITH PARTICIPANT COMFORT RATED AS GOOD TO EXCELLENT BY 99% (382/385) OF WOMEN AFTER 5 YEARS OF WEARING. SIMILARLY, OVERALL SATISFACTION WAS RATED AS SOMEWHAT TO VERY SATISFIED BY 98% (376/384) OF WOMEN AFTER 5 YEARS OF WEARING.

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THE MAJORITY OF ADVERSE EVENTS REPORTED DURING THE 5 YEARS OF FOLLOW-UP WERE RATED AS EITHER MILD OR MODERATE IN SEVERITY. THREE SEVERE EVENTS WERE REPORTED IN 2 SUBJECTS DURING FOLLOW-UP AS BEING POSSIBLY RELATED TO THE PROCEDURE OR INSERTS (ABDOMINAL PAIN WITH VERY HEAVY PERIODS, AND IRREGULAR MENSTRUAL BLEEDING). CONCLUSIONS: THE FINDINGS FROM EXTENDED FOLLOW-UP OF THE PHASE III TRIAL WITH ESSURE INSERTS FURTHER SUPPORT THE EFFECTIVENESS, TOLERABILITY, AND SATISFACTION OF THIS NONHORMONAL, NONINCISIONAL, OPTION FOR PERMANENT CONTRACEPTION. OTHER CASES FROM SAME ARTICLE: (B)(4). FOLLOW UP RECEIVED ON (B)(6)2015. PTC GLOBAL NUMBER WAS RECEIVED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED STUDY CASE REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (ESS205 MODEL, FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LOWER ABDOMINAL PAIN AND VERY HEAVY PERIODS. SHE ULTIMATELY UNDERWENT A HYSTERECTOMY AT 34 MONTHS FOLLOW UP VISIT. BOTH EVENTS WERE CONSIDERED SERIOUS BY THE REPORTER DUE TO MEDICAL IMPORTANCE AND THE ABDOMINAL PAIN WAS ALSO CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION. ACCORDING TO ESSURE'S INVESTIGATOR'S BROCHURE, BOTH EVENTS ARE LISTED. ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES AND LOWER ABDOMINAL PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE PATIENT COMPLAINED OF LOWER ABDOMINAL PAIN AND HEAVY BLEEDING AT 18-MONTH FOLLOW UP VISIT AND STATED THE PELVIC PAIN CONTINUED AT 24-MONTH FOLLOW UP VISIT. CONSIDERING THAT THE PRESENCE OF A FOREIGN BODY IN THE FALLOPIAN TUBES MAY CAUSE THIS PAIN, THIS PAIN WAS CONSIDERED RELATED TO ESSURE. ALSO, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE HEAVY PERIODS WERE CONSIDERED RELATED TO ESSURE. THE HYSTERECTOMY PERFORMED WAS DEEMED TO BE POSSIBLY RELATED TO ESSURE INSERTS OR PROCEDURE BY THE AUTHOR. THIS CASE IS REGARDED AS INCIDENT DUE TO THE HYSTERECTOMY PERFORMED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00362	BAYER HEALTHCARE LLC	6/2/2015	6/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON (B)(4) 2015, ARTICLE ENTITLED "HYSTEROSCOPIC ESSURE INSERTS FOR PERMANENT CONTRACEPTION-EXTENDED FOLLOW-UP RESULTS OF A PHASE III, MULTICENTER, INTERNATIONAL STUDY". IT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (ESS205 MODEL) INSERTED FOR PERMANENT CONTRACEPTION. TRADE NAME WAS REPORTED AS ESSURE INSERT (ESS205 MODEL). CASE REPORT: THIS CASE CONCERNS A FEMALE PATIENT WHO WAS INVOLVED IN A PHASE III, MULTICENTER, INTERNATIONAL STUDY OF ESSURE SYSTEM TO DESCRIBE SAFETY, EFFECTIVENESS, TOLERABILITY, AND SATISFACTION RESULTS FROM 5 YEARS OF FOLLOW-UP. IN THIS PATIENT ESSURE FALLOPIAN TUBE OCCLUSION INSERT PLACEMENT WAS DONE. THIS WOMAN REPORTED CONTINUOUS BLEEDING. SHE ULTIMATELY UNDERWENT HYSTERECTOMY. AUTHORS COMMENTS: THE FINDINGS FROM THE 5-YEAR FOLLOW-UP OF THE PHASE III TRIAL CONFIRM INITIAL RESULTS THAT THE ESSURE INSERT IS AN EFFECTIVE AND WELL-TOLERATED NONHORMONAL, NONINCISIONAL, OPTION FOR PERMANENT CONTRACEPTION. BOTH THE HYSTEROSCOPIC STERILIZATION PROCEDURE AND ESSURE INSERT WEARING WERE GENERALLY SAFE AND WELL TOLERATED. AFTER 5 YEARS OF FOLLOW-UP, MORE THAN 90% OF PARTICIPANTS RATED THE OVERALL COMFORT WITH WEARING AS EXCELLENT, AND MORE THAN 96% OF PARTICIPANTS WERE VERY SATISFIED WITH THE ESSURE INSERTS AT THE END OF THE STUDY. ADVERSE EVENTS DURING THE FIRST YEAR OF WEARING WERE RATED AS EITHER MILD OR MODERATE IN SEVERITY, AND OCCURRED MORE COMMONLY DURING THE 3-MONTH PERIOD FOLLOWING PLACEMENT. THROUGHOUT 5 YEARS OF FOLLOW-UP, RELATIVELY FEW ADVERSE EVENTS WERE REPORTED THAT WERE DEEMED POSSIBLY RELATED TO THE ESSURE INSERTS. PELVIC PAIN ASSOCIATED WITH ESSURE INSERT PLACEMENT HAS BEEN A RECENT TOPIC OF INTEREST. THROUGHOUT 5 YEARS OF FOLLOW-UP IN THE PHASE III TRIAL DESCRIBED HEREIN, PELVIC PAIN

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(DYSMENORRHEA, DYSPAREUNIA, OVULATORY, OR OTHER) WAS REPORTED IN NO MORE THAN 7% OF STUDY PARTICIPANTS AT ANY VISIT. NO SUBJECTS REPORTED PERSISTENT PELVIC PAIN OF ANY KIND AT THE 3, 4, AND 5-YEAR FOLLOW-UP VISITS. FURTHERMORE, AT THE COMPLETION OF FOLLOW-UP, OVERALL COMFORT WITH WEARING WAS RATED AS EXCELLENT BY MORE THAN 90% OF WOMEN, AND OVERALL SATISFACTION WAS RATED AS VERY SATISFIED BY MORE THAN 96% OF WOMEN. HISTORY OF ABNORMAL AND INTERMENSTRUAL BLEEDING WAS ELICITED FROM PATIENTS POST ESSURE INSERT PLACEMENT. THE INCIDENCE WAS HIGHEST IMMEDIATELY POST HYSTEROSCOPIC STERILIZATION AS WOULD BE EXPECTED AFTER ANY INTRAUTERINE INSTRUMENTATION. A HISTORICAL COMPLAINT OF ABNORMAL BLEEDING WAS ELICITED FROM 5-12% OF WOMEN AFTER STOPPING USE OF ALTERNATIVE CONTRACEPTION. CHANGES IN THE AMOUNT OF BLEEDING AS WELL AS BLEEDING INTERVALS ARE QUITE VARIABLE OVER A WOMANS LIFETIME AND CAN BE AFFECTED BY MANY FACTORS INCLUDING AGE, WEIGHT AND CONTRACEPTIVE USE. FIFTEEN HYSTERECTOMIES WERE REPORTED IN THIS COHORT OVER 5 YEARS OF FOLLOW-UP, WHICH TRANSLATES TO 3.8% (15/397) OF EVALUABLE PARTICIPANTS. THE ESTIMATED ANNUAL HYSTERECTOMY RATE IN THE GENERAL POPULATION OF WOMEN 40-50 YEARS OF AGE IS APPROXIMATELY 9.6 PER 1,000. THEREFORE AUTHORS WOULD EXPECT APPROXIMATELY 4 WOMEN EACH YEAR FOR A TOTAL OF 20 HYSTERECTOMIES OVER A 5 YEAR STUDY. ONE MIGHT EXPECT AN EVEN HIGHER INCIDENCE OF HYSTERECTOMIES IN THIS STUDY POPULATION AS MANY WERE USING HORMONAL CONTRACEPTIVES, WHICH MAY MASK BLEEDING AND PAIN SYMPTOMS PRIOR TO CHANGING TO A NON-HORMONAL CONTRACEPTIVE. FURTHERMORE, THERE IS SOME LIMITED DATA SHOWING THAT WOMEN AFTER TUBAL STERILIZATION HAVE A HIGHER RATE OF HYSTERECTOMY. EVEN SO, THE HYSTERECTOMY RATE SEEMS TO BE IN ACCORDANCE WITH EXPECTATIONS. IN ONLY 2 INSTANCES DID THE RESPECTIVE INVESTIGATOR DEEM THE HYSTERECTOMY TO BE POSSIBLY RELATED TO THE ESSURE INSERTS (ONE WOMAN AS DESCRIBED ABOVE WHO REPORTED HEAVY AND IRREGULAR MENSTRUAL BLEEDING ALONG WITH PELVIC PAIN). NONE OF THE OTHER HYSTERECTOMIES WERE DEEMED BY THE INVESTIGATORS AS BEING DEFINITELY OR PROBABLY RELATED TO THE ESSURE INSERTS. ABSTRACT: STUDY OBJECTIVE: TO DESCRIBE SAFETY, TOLERABILITY, AND EFFECTIVENESS RESULTS THROUGH 5 YEARS OF FOLLOW-UP OF A PHASE III TRIAL WITH ESSURE INSERTS. (B)(4). INTERVENTION: THE OBJECTIVE OF THE HYSTEROSCOPIC STERILIZATION PROCEDURE WAS BILATERAL ESSURE INSERT PLACEMENT (ESS205 MODEL) AND TUBAL OCCLUSION. WOMEN WITH SATISFACTORY DEVICE LOCATION AND TUBE OCCLUSION (BASED ON MODIFIED HYSTEROSALPINGOGRAM) WERE INSTRUCTED TO DISCONTINUE ALTERNATIVE CONTRACEPTION AND TO RELY ON THE ESSURE INSERTS FOR PERMANENT CONTRACEPTION. MEASUREMENTS AND MAIN RESULTS: THE PRIMARY END POINT FOR THE PHASE III STUDY WAS THE RATE OF PREGNANCIES OCCURRING DURING THE FIRST YEAR OF RELYING (IE, CONFIRMED HSG OCCLUSION) ON THE ESSURE INSERTS FOR PERMANENT CONTRACEPTION (IE, 12 MONTHS FOLLOWING HSG). FOR THE FULL 5 YEARS OF FOLLOW-UP (5 YEARS IN TOTAL OF RELYING ON THE ESSURE INSERTS FOR CONTRACEPTION), THE END POINTS OF INTEREST WERE SAFETY, PREVENTION OF PREGNANCY, AND SATISFACTION. NO PREGNANCIES WERE REPORTED AMONG WOMEN RELYING ON THE ESSURE INSERTS WHO COMPLETED THE FULL 5 YEARS OF FOLLOW-UP. AS OF DECEMBER 5, 2007, 449 WOMEN WITH SUCCESSFUL BILATERAL PLACEMENT RELYING ON THE ESSURE INSERTS CONTRIBUTED A TOTAL 24,942 WOMAN-MONTHS OF FOLLOW-UP FOR ASSESSING THE EFFECTIVENESS. OVERALL, THE ESSURE INSERTS WERE GENERALLY WELL TOLERATED, WITH PARTICIPANT COMFORT RATED AS GOOD TO EXCELLENT BY 99% (382/385) OF WOMEN AFTER 5 YEARS OF WEARING. SIMILARLY, OVERALL SATISFACTION WAS RATED AS SOMEWHAT TO VERY SATISFIED BY 98% (376/384) OF WOMEN AFTER 5 YEARS OF WEARING. THE MAJORITY OF ADVERSE EVENTS REPORTED DURING THE 5 YEARS OF FOLLOW-UP WERE RATED AS EITHER MILD OR MODERATE IN SEVERITY. THREE SEVERE EVENTS WERE REPORTED IN 2 SUBJECTS DURING FOLLOW-UP AS BEING POSSIBLY RELATED TO THE PROCEDURE OR INSERTS (ABDOMINAL PAIN WITH VERY HEAVY PERIODS, AND IRREGULAR MENSTRUAL BLEEDING). CONCLUSIONS: THE FINDINGS FROM EXTENDED FOLLOW-UP OF THE PHASE III TRIAL WITH ESSURE INSERTS FURTHER SUPPORT THE EFFECTIVENESS, TOLERABILITY, AND SATISFACTION OF THIS NONHORMONAL, NONINCISIONAL, OPTION FOR PERMANENT CONTRACEPTION. OTHER CASES FROM SAME ARTICLE: 2015-214616, 2015-215062, TO 2015-215068. FOLLOW UP

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RECEIVED ON (B)(4) 2015. PTC GLOBAL NUMBER WAS RECEIVED. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED STUDY CASE REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (ESS205 MODEL, FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION AND EXPERIENCED CONTINUOUS BLEEDING. SHE ULTIMATELY UNDERWENT A HYSTERECTOMY. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS BLEEDING IS LISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, CONSIDERING AN IMPLIED POSITIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CONTINUOUS BLEEDING WAS CONSIDERED RELATED TO ESSURE AND THE HYSTERECTOMY PERFORMED WAS DEEMED TO BE POSSIBLY RELATED TO ESSURE BY THE AUTHOR. THIS CASE IS REGARDED AS INCIDENT DUE TO THE HYSTERECTOMY PERFORMED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00363	BAYER HEALTHCARE LLC	6/2/2015	6/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 07-MAY-2015; ARTICLE ENTITLED "HYSTEROSCOPIC ESSURE INSERTS FOR PERMANENT CONTRACEPTION-EXTENDED FOLLOW-UP RESULTS OF A PHASE III, MULTICENTER, INTERNATIONAL STUDY". THE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED (ESS205 MODEL) FOR PERMANENT CONTRACEPTION. TRADE NAME WAS REPORTED AS ESSURE INSERT (ESS205 MODEL). CASE REPORT: THIS CASE CONCERNS A FEMALE PATIENT WHO WAS INVOLVED IN A PHASE III, MULTICENTER, INTERNATIONAL STUDY OF ESSURE SYSTEM TO DESCRIBE SAFETY, EFFECTIVENESS, TOLERABILITY, AND SATISFACTION RESULTS FROM 5 YEARS OF FOLLOW-UP. IN THIS PATIENT ESSURE FALLOPIAN TUBE OCCLUSION INSERT PLACEMENT WAS DONE. SHE EXPERIENCED SEVERE IRREGULAR MENSTRUAL BLEEDING, WHICH RESOLVED FOLLOWING DILATION AND CURETTAGE. THIS SEVERE ADVERSE EVENT WAS REPORTED DURING FOLLOW-UP AS BEING "POSSIBLY" RELATED TO THE ESSURE INSERTS OR PROCEDURE. AUTHORS COMMENTS: THE FINDINGS FROM THE 5-YEAR FOLLOW-UP OF THE PHASE III TRIAL CONFIRM INITIAL RESULTS THAT THE ESSURE INSERT IS AN EFFECTIVE AND WELL-TOLERATED NONHORMONAL, NONINCISIONAL, OPTION FOR PERMANENT CONTRACEPTION. BOTH THE HYSTEROSCOPIC STERILIZATION PROCEDURE AND ESSURE INSERT WEARING WERE GENERALLY SAFE AND WELL TOLERATED. AFTER 5 YEARS OF FOLLOW-UP, MORE THAN 90% OF PARTICIPANTS RATED THE OVERALL COMFORT WITH WEARING AS EXCELLENT, AND MORE THAN 96% OF PARTICIPANTS WERE VERY SATISFIED WITH THE ESSURE INSERTS AT THE END OF THE STUDY. ADVERSE EVENTS DURING THE FIRST YEAR OF WEARING WERE RATED AS EITHER MILD OR MODERATE IN SEVERITY, AND OCCURRED MORE COMMONLY DURING THE 3-MONTH PERIOD FOLLOWING PLACEMENT. THROUGHOUT 5 YEARS OF FOLLOW-UP, RELATIVELY FEW ADVERSE EVENTS WERE REPORTED THAT WERE DEEMED POSSIBLY RELATED TO THE ESSURE

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INSERTS. PELVIC PAIN ASSOCIATED WITH ESSURE INSERT PLACEMENT HAS BEEN A RECENT TOPIC OF INTEREST. THROUGHOUT 5 YEARS OF FOLLOW-UP IN THE PHASE III TRIAL DESCRIBED HEREIN, PELVIC PAIN (DYSMENORRHEA, DYSPAREUNIA, OVULATORY, OR OTHER) WAS REPORTED IN NO MORE THAN 7% OF STUDY PARTICIPANTS AT ANY VISIT. NO SUBJECTS REPORTED PERSISTENT PELVIC PAIN OF ANY KIND AT THE 3, 4, AND 5-YEAR FOLLOW-UP VISITS. FURTHERMORE, AT THE COMPLETION OF FOLLOW-UP, OVERALL COMFORT WITH WEARING WAS RATED AS EXCELLENT BY MORE THAN 90% OF WOMEN, AND OVERALL SATISFACTION WAS RATED AS VERY SATISFIED BY MORE THAN 96% OF WOMEN. HISTORY OF ABNORMAL AND INTERMENSTRUAL BLEEDING WAS ELICITED FROM PATIENTS POST ESSURE INSERT PLACEMENT. THE INCIDENCE WAS HIGHEST IMMEDIATELY POST HYSTEROSCOPIC STERILIZATION AS WOULD BE EXPECTED AFTER ANY INTRAUTERINE INSTRUMENTATION. A HISTORICAL COMPLAINT OF ABNORMAL BLEEDING WAS ELICITED FROM 5-12% OF WOMEN AFTER STOPPING USE OF ALTERNATIVE CONTRACEPTION. CHANGES IN THE AMOUNT OF BLEEDING AS WELL AS BLEEDING INTERVALS ARE QUITE VARIABLE OVER A WOMANS LIFETIME AND CAN BE AFFECTED BY MANY FACTORS INCLUDING AGE, WEIGHT AND CONTRACEPTIVE USE. IT IS ESTIMATED THAT 30% OF ALL WOMEN REPORT HAVING HAD MENORRHAGIA AT SOME POINT IN THEIR LIVES AND APPROXIMATELY 9% TO 30% OF REPRODUCTIVE AGE WOMEN HAVE MENSTRUAL IRREGULARITIES REQUIRING MEDICAL EVALUATION. LASTLY IT IS IMPORTANT TO NOTE THAT 43% OF PARTICIPANTS WERE USING ORAL CONTRACEPTIVES PRIOR TO THE ESSURE PROCEDURE AS THEIR BIRTH CONTROL MODALITY, UNDERLYING ABNORMAL AND HEAVY BLEEDING AS WELL AS PELVIC PAIN MAY HAVE BEEN MASKED WITH THE USE OF HORMONAL CONTRACEPTION. ABSTRACT STUDY OBJECTIVE: TO DESCRIBE SAFETY, TOLERABILITY, AND EFFECTIVENESS RESULTS THROUGH 5 YEARS OF FOLLOW-UP OF A PHASE III TRIAL WITH ESSURE INSERTS. DESIGN: MULTICENTER, NONRANDOMIZED, SINGLE-ARM, INTERNATIONAL STUDY. DESIGN CLASSIFICATION: (B)(4) TASK FORCE CLASSIFICATION II-3. SETTING: 13 CLINICAL STUDY CENTERS IN THE UNITED STATES, EUROPE, AND AUSTRALIA. PATIENTS: 518 PREVIOUSLY FERTILE WOMEN SEEKING PERMANENT CONTRACEPTION. INTERVENTION: THE OBJECTIVE OF THE HYSTEROSCOPIC STERILIZATION PROCEDURE WAS BILATERAL ESSURE INSERT PLACEMENT (ESS205 MODEL) AND TUBAL OCCLUSION. WOMEN WITH SATISFACTORY DEVICE LOCATION AND TUBE OCCLUSION (BASED ON MODIFIED HYSTEROSALPINGOGRAM) WERE INSTRUCTED TO DISCONTINUE ALTERNATIVE CONTRACEPTION AND TO RELY ON THE ESSURE INSERTS FOR PERMANENT CONTRACEPTION. MEASUREMENTS AND MAIN RESULTS: THE PRIMARY END POINT FOR THE PHASE III STUDY WAS THE RATE OF PREGNANCIES OCCURRING DURING THE FIRST YEAR OF RELYING (IE, CONFIRMED HSG OCCLUSION) ON THE ESSURE INSERTS FOR PERMANENT CONTRACEPTION (IE, 12 MONTHS FOLLOWING HSG). FOR THE FULL 5 YEARS OF FOLLOW-UP (5 YEARS IN TOTAL OF RELYING ON THE ESSURE INSERTS FOR CONTRACEPTION), THE END POINTS OF INTEREST WERE SAFETY, PREVENTION OF PREGNANCY, AND SATISFACTION. NO PREGNANCIES WERE REPORTED AMONG WOMEN RELYING ON THE ESSURE INSERTS WHO COMPLETED THE FULL 5 YEARS OF FOLLOW-UP. AS OF DECEMBER 5, 2007, 449 WOMEN WITH SUCCESSFUL BILATERAL PLACEMENT RELYING ON THE ESSURE INSERTS CONTRIBUTED A TOTAL 24,942 WOMAN-MONTHS OF FOLLOW-UP FOR ASSESSING THE EFFECTIVENESS. OVERALL, THE ESSURE INSERTS WERE GENERALLY WELL TOLERATED, WITH PARTICIPANT COMFORT RATED AS GOOD TO EXCELLENT BY 99% (382/385) OF WOMEN AFTER 5 YEARS OF WEARING. SIMILARLY, OVERALL SATISFACTION WAS RATED AS SOMEWHAT TO VERY SATISFIED BY 98% (376/384) OF WOMEN AFTER 5 YEARS OF WEARING. THE MAJORITY OF ADVERSE EVENTS REPORTED DURING THE 5 YEARS OF FOLLOW-UP WERE RATED AS EITHER MILD OR MODERATE IN SEVERITY. THREE SEVERE EVENTS WERE REPORTED IN 2 SUBJECTS DURING FOLLOW-UP AS BEING POSSIBLY RELATED TO THE PROCEDURE OR INSERTS (ABDOMINAL PAIN WITH VERY HEAVY PERIODS, AND IRREGULAR MENSTRUAL BLEEDING). CONCLUSIONS: THE FINDINGS FROM EXTENDED FOLLOW-UP OF THE PHASE III TRIAL WITH ESSURE INSERTS FURTHER SUPPORT THE EFFECTIVENESS, TOLERABILITY, AND SATISFACTION OF THIS NONHORMONAL, NONINCISIONAL, OPTION FOR PERMANENT CONTRACEPTION. OTHER CASES FROM SAME ARTICLE: (B)(4). FOLLOW UP RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER WAS RECEIVED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE

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INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE AND REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED IRREGULAR MENSTRUAL BLEEDING. THE PATIENT UNDERWENT A DILATION AND CURETTAGE AND THE EVENT RESOLVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. THE TIME INTERVAL BETWEEN ESSURE INSERTION AND THE ONSET OF IRREGULAR MENSTRUAL BLEEDING WAS NOT REPORTED. THIS EVENT WAS REPORTED DURING FOLLOW-UP AS BEING POSSIBLY RELATED TO THE ESSURE INSERTS OR PROCEDURE. CONSIDERING THE NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION (DILATION AND CURETTAGE). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043009	BAYER	6/2/2015	6/11/2015

Event Information:

Event Date (B3): 4/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/26/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER RECEIVING ESSURE I HAVE EXPERIENCED EXTREMELY BRUTAL PERIODS THAT ARE SO HEAVY I CAN'T LEAVE THE HOUSE. I HAVE GAINED WEIGHT, HAVE CONSTANT PAIN, EXPERIENCED HAIR LOSS, HEADACHES/MIGRAINES, EXTREME TIREDNESS. I'M PRETTY SURE EVERYTHING HAS GONE DOWNHILL SINCE I HAD THE ESSURE DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043014	ESSURE	6/2/2015	6/11/2015

Event Information:

Event Date (B3): 12/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN 2010. SHORTLY AFTER, I BEGAN TO NOTICE SEVERE PELVIC PAIN, EXCESSIVE BLEEDING, AND ABNORMAL MENSTRUAL CYCLES. I HAVE GONE TO THE HOSP BECAUSE OF THE PAIN BEING UNBEARABLE. I FEEL LIKE I AM GIVING BIRTH AT TIMES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043017	BAYER	6/2/2015	6/11/2015

Event Information:

Event Date (B3): 5/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/21/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

WITHIN 6 WEEKS ON IMPLANTATION MY BODY STARTED HAVING ADVERSE REACTIONS. MY SYMPTOMS INCLUDED A RASH THAT WENT UP MY NECK AND ACROSS MY FACE, DIZZINESS, INCREASED NUMBER AND SEVERITY OF HEADACHES, BACK AND BODY ACHES, BLOATING AND WEIGHT GAIN, EXTREME FATIGUE, NAUSEA, MOODINESS, ABDOMINAL PAIN AFTER MEALS, HEAVY IRREGULAR PERIODS, HIGH BLOOD PRESSURE AND ACCELERATED RESTING HEART RATE. I HAVE SINCE DEVELOPED 2 AUTOIMMUNE DISEASES DUE TO MY BODY ATTACKING THE IMPLANTATION AND IN TURN ATTACKING ITSELF. I AM CURRENTLY UNDERGOING MED ATTENTION TO DIAGNOSE A POTENTIAL HEART CONDITION THAT HAS DEVELOPED POST IMPLANTATION. I WAS VERY HEALTHY, NO ILLNESS OR IRREGULAR BLOOD WORK PRIOR TO ESSURE IMPLANTATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00355	BAYER HEALTHCARE LLC	6/2/2015	6/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38211

Single Use: Y
Implant Date (E6): 11/12/2014
Explant Date (E7): 11/12/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2014. ACCORDING TO REPORTER THE EVENT OCCURRED IN OPERATING ROOM. AT THE TIME OF THE ESSURE PLACEMENT, IT WAS IMPOSSIBLE TO RELEASE IT IN FALLOPIAN TUBE. INDEED, SPRING WAS HUNG TO THE SURROUNDED SHEATH AND THE TEAM HAD TO REMOVE THE SHEATH AND THE IMPLANT BY REMOVING DELIVERY SYSTEM. A PART OF THE SPRING COULD BE REMOVED; HOWEVER A PORTION OF THE IMPLANT REMAINED INTRA-TUBAL. A TUBAL LIGATION BY LAPAROSCOPY, DUE TO ESSURE FAILURE PROCEDURE, WAS PERFORMED. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND AT TIME OF ESSURE PLACEMENT, IT WAS IMPOSSIBLE TO RELEASE IT IN FALLOPIAN TUBE AND SPRING WAS HUNG TO THE SURROUNDED SHEATH. A PART OF THE SPRING WAS REMOVED, HOWEVER A PORTION OF THE IMPLANT REMAINED INTRA-TUBAL (INTERPRETED AS DEVICE BREAKAGE). THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW UP 08-JUN-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). BATCH NUMBER C38211 PRODUCTION DATE 20-MAR-2014 EXPIRATION DATE 31-MAR-2017. FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OU

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00356	BAYER HEALTHCARE LLC	6/2/2015	6/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64475

Single Use: Y
Implant Date (E6): 5/5/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 5/27/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 05-MAY-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015, WITH LOT NUMBER C64475. PHYSICIAN HAD BEEN TRAINED TO THE ESSURE PROCEDURE. DURING ATTEMPT OF PLACEMENT ON THE RIGHT SIDE THE OSTIUM WAS WELL SEEN AND THE PROTOCOL WAS RESPECTED. ACCORDING TO PHYSICIAN, THE IMPLANT REMAINED HUNG TO THE DELIVERY CATHETER AND UNROLLED IN THE CAVITY. IMPLANT WAS SECONDARILY REMOVED WITH PLIERS FOR FOREIGN BODIES WITHDRAWAL. THE EVENTS OCCURRED IN THE OPERATORY ROOM, DURING PLACEMENT. THERE WAS NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS NOT DONE AND THE PATIENT WAS TO BE CONVOKED AGAIN AFTER 3 MONTHS. HYSTEROSCOPIC CONTROL ON THE LEFT WAS OK (3 COILS). NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE RIGHT IMPLANT REMAINED HUNG ON THE DELIVERY CATHETER (INTERPRETED AS DEVICE DEPLOYMENT ISSUE) AND UNROLLED IN THE CAVITY (DEVICE SHAPE ALTERATION). THESE EVENTS ARE NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE IMPLANT WAS SECONDARILY REMOVED WITH PLIERS AND BILATERAL PLACEMENT WAS NOT DONE. THE LEFT SIDE WAS INSERTED SUCCESSFULLY, WITH 3 TRAILING COILS ON HYSTEROSCOPIC CONTROL. SINCE THE REPORTED EVENTS OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR

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SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 09-SEP-2015 NO FURTHER INFORMATION WAS RECEIVED AFTER FOLLOW-UP ATTEMPTS. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00359	BAYER HEALTHCARE LLC	6/2/2015	6/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68120

Single Use: Y
Implant Date (E6): 4/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 8/12/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C68120 INSERTED. IT WAS STATED THAT THE PAIRS OF ESSURE BROKE IN THE HYSTEROSCOPE. EVENT OCCURED IN GYNAECOLOGICAL UNIT. CONSEQUENCES OF THE EVENT: THE DEVICE WAS CHANGED AND EXTENSION OF THE SURGERY. IMPLANTS WERE KEPT. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE PAIRS OF ESSURE BROKE IN THE HYSTEROSCOPE. THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED IN ASSOCIATION WITH ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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UPDATED PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 01-SEP-2015 UPON RECEIPT DEVICE SAMPLE (ONE DEVICE WAS RECEIVED ON 12-AUG-2015). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FAIL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00364	BAYER HEALTHCARE LLC	6/3/2015	6/3/2015

Event Information:

Event Date (B3): 4/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26966

Single Use: *
Implant Date (E6): 4/24/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C26966, INSERTED ON (B)(6) 2015. THERE WERE SOME TECHNICAL PROBLEMS WITH THE EQUIPMENT AND THE SCOPES WERE NOT WORKING PROPERLY. IN ADDITION, IT WAS REPORTED THAT AFTER THE PROCEDURE THE PATIENT EXPERIENCED WHEEZING AND PULMONARY EDEMA. PATIENT SPENT THE NIGHT IN THE HOSPITAL, AND WAS DISCHARGED (HOSPITALIZATION FROM (B)(6) 2015). NO OTHER SIDE EFFECTS WERE REPORTED BY MEDICAL DOCTOR. ESSURE DEVICES WERE NOT REMOVED AND PATIENT HAS RECOVERED FROM EVENTS. FOLLOW UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: BATCH NUMBER C26966 PRODUCTION DATE 28-FEB-2014; EXPIRATION DATE 28-FEB-2017. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A

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TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) -YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THE PROCEDURE, THE PATIENT EXPERIENCED PULMONARY EDEMA. SHE SPENT THE NIGHT IN THE HOSPITAL AND WAS DISCHARGED. ESSURE INSERTS WERE NOT REMOVED. THIS EVENT IS SERIOUS DUE TO HOSPITALIZATION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS EVENT IS UNLISTED. HYPERVOLEMIA MAY RESULT FROM COMPROMISED REGULATORY MECHANISMS FOR SODIUM AND WATER AS SEEN IN CONGESTIVE HEART FAILURE (CHF), KIDNEY FAILURE, AND LIVER FAILURE BUT IT ALSO CAN BE CAUSED BY INTRAOPERATIVE AND POSTOPERATIVE FLUID ADMINISTRATION. THERE IS A RISK OF FLUID ABSORPTION DUE TO THE SOLUTION USED FOR DISTENTION OF THE UTERUS DURING HYSTEROSCOPY. THIS RISK IS INHERENT TO ANY HYSTEROSCOPIC PROCEDURE AND IS NOT UNIQUE TO ESSURE. EXCESS FLUID ABSORPTION CAN CAUSE PULMONARY EDEMA. IN THIS PARTICULAR CASE, THE PULMONARY EDEMA OCCURRED AFTER THE ESSURE PROCURE (SAME DAY). ACCORDING TO THE PHYSICIAN, TECHNICAL PROBLEMS WITH THE EQUIPMENT WERE EXPERIENCED AND SCOPES WERE NOT WORKING PROPERLY DURING THE PROCEDURE. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, THE NATURE OF THIS EVENT, AND CONSIDERING THAT NO ALTERNATIVE EXPLANATION IS AVAILABLE, PULMONARY EDEMA IS CONSIDERED RELATED TO ESSURE INSERTION PROCEDURE. THIS CASE IS REGARDED AS INCIDENT DUE TO THE HOSPITALIZATION. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 28-JUL-2015 FROM PHYSICIAN: THE PHYSICIAN REPORTED THE FLUID OVERLOAD THAT PROMPTED THE ADMISSION OF THE PATIENT TO THE HOSPITAL FOR 24 HOURS WAS DUE TO THE MALFUNCTIONING EQUIPMENT, ALL THE WHILE THE PATIENT GOT FLUID TH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00365	BAYER HEALTHCARE LLC	6/3/2015	6/3/2015

Event Information:

Event Date (B3): 4/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015. IT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013 FOR CONTRACEPTION. ON (B)(6) 2015, PATIENT WENT TO THE EMERGENCY ROOM DUE TO BLEEDING AND HAD A MISCARRIAGE. ON (B)(6) 2015, SHE WENT TO DOCTOR'S OFFICE. THE NOTES FROM THE HOSPITAL INCLUDED ULTRASOUND RESULTS WHICH SHOWED SOMETHING WAS DANGLING IN THE CAVITY EXTENDING TOWARDS THE LEFT CORNUA. THE PATIENT IS SCHEDULED FOR A HYSTEROSCOPY ON (B)(6) 2015. ESSURE NOT REMOVED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT (SEE TECHNICAL ASSESSMENT). THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO

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REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT. SHE WENT TO EMERGENCY ROOM WITH BLEEDING AND A MISCARRIAGE WAS DIAGNOSED. THE ULTRASOUND THEN PERFORMED SHOWED SOMETHING WAS DANGLING IN THE CAVITY EXTENDING TOWARDS THE LEFT CORNUA. THESE EVENTS, SEEN AS PREGNANCY, SPONTANEOUS ABORTION AND DEVICE DISLOCATION RESPECTIVELY ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE THE DISLOCATION IS NOT CLEAR. THIS REPORTED "SOMETHING DANGLING" COULD BE JUST THE REGULAR ESSURE'S TRALING COILS. HOWEVER, IN A WORST CASE SCENARIO APPROACH, THE EVENT WAS CONSIDERED A DISLOCATION AND GIVEN ITS NATURE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS CASE, IT IS NOT POSSIBLE TO KNOW FOR SURE IF THE DISLOCATION REALLY OCCURRED, SO THE POSSIBILITY OF DEVICE FAILURE CANNOT BE TOTALLY EXCLUDED. ALTHOUGH THE VAST MAJORITY OF MISCARRIAGES ARE CAUSED PER MORPHOLOGIC MALFORMATION OR CHROMOSOME'S ABNORMALITIES, IN THE PRESENT CASE THE PHYSICIAN INFORMED THAT SOMETHING WAS DANGLING IN THE UTERINE CAVITY EXTENDING TOWARDS THE LEFT CORNUA. APPARENTLY THE DEVICE WAS DISLOCATED TOWARDS THE UTERINE CAVITY AND COULD HAVE MADE A MECHANICAL INTERFERENCE IN DEVELOPING PREGNANCY. SO, THE SPONTANEOUS ABORTION IS ASSESSED AS RELATED TO ESSURE USE AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 05-JUN-2015 FROM PHYSICIAN: THE PATIENT PRESENTED TO EMERGENCY ROOM ON (B)(6) 2015 WITH PAIN AND HEAVY BLEEDING AND MISCARRIED IN THE COMMODE AT WORK. PHYSICIAN STATED SHE ONLY MET THE PATIENT AS A NEW PATIENT AFTER HER V

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00366	BAYER HEALTHCARE LLC	6/3/2015	6/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/1/2012
Explant Date (E7): 12/19/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR STERILIZATION. SHE HAD ESSURE PLACED AND SUBSEQUENTLY EXPERIENCED INCREASED DYSMENORRHEA, WEIGHT GAIN, HOT FLASHES, FATIGUE, AND SLEEP DISTURBANCES. SHE REQUESTED REMOVAL OF THE IMPLANTS AND, ON (B)(6) 2014, UNDERWENT TOTAL VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY. PATIENT THINKS HER SYMPTOMS ARE DUE TO NICKEL ALLERGY. IN ADDITION, THE SERIOUSNESS CRITERIA OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) WAS REPORTED. HOWEVER IT WAS NOT SPECIFIED FOR WHICH EVENT. FOLLOW UP INFORMATION FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL

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INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INCREASED DYSMENORRHEA. SHE REQUESTED REMOVAL OF THE IMPLANTS AND UNDERWENT A TOTAL VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY TWO AND A HALF YEARS AFTER INSERTION. THE EVENT INCREASED DYSMENORRHEA WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THE PRESENT CASE, THE PATIENT HAD ESSURE INSERTED AND SUBSEQUENTLY EXPERIENCED INCREASED DYSMENORRHEA. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED INTERVENTION FOR REMOVAL OF ESSURE. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 19-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIEN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00367	BAYER HEALTHCARE LLC	6/3/2015	6/3/2015

Event Information:

Event Date (B3): 5/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/4/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2015. PHYSICIAN STATES THAT THE PROCEDURE WAS UNEVENTFUL AND WITHOUT ANY ISSUES. HOWEVER, WITHIN THIRTY MINUTES OF THE PROCEDURE, THE PATIENT DEVELOPED A FEVER OF 104 DEGREES. NO OTHER SYMPTOMS WERE INDICATED. IN ADDITION, IT WAS REPORTED THAT, ON (B)(6) 2015, PATIENT WAS IN THE HOSPITAL. SHE IS SUPPOSED TO BE HAVING A SALPINGECTOMY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL

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INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED A FEVER OF 104 DEGREES. THIS EVENT IS SERIOUS DUE TO HOSPITALIZATION AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, PATIENT EXPERIENCED THIS EVENT WITHIN THIRTY MINUTES POST ESSURE PROCEDURE. NO ALTERNATIVE EXPLANATION IS AVAILABLE. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO HOSPITALIZATION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW 13-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00368	BAYER HEALTHCARE LLC	6/3/2015	6/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/7/2010
Explant Date (E7): 10/7/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 FOR PERMANENT STERILIZATION. ON (B)(6) 2010, HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND RESULTS WERE SATISFACTORY. PATIENT WENT TO SEE PHYSICIAN DURING (B)(6) 2014. PATIENT COMPLAINED OF ALL OF THE THINGS ON INTERNET. SHE HAD PELVIC PAIN, HEAVY BLEEDING, DIZZINESS AND FATIGUE. ON (B)(6) 2014, PHYSICIAN SURGICALLY REMOVED COILS. IMMEDIATELY, POST PROCEDURE, PATIENT PRAISED PHYSICIAN ON HOW HE CHANGED HER LIFE. SHE WAS HAPPY THE DAY AFTER SURGERY. THEN, ON (B)(6) 2014, PATIENT SAID ALL OF HER SYMPTOMS HAD RETURNED. SYMPTOMS RETURNED ON AN UNKNOWN DATE. PHYSICIAN CURRENTLY EVALUATING PATIENT FOR OTHER CAUSES OF HER SYMPTOMS. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE

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EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, IT WAS REPORTED THAT PATIENT UNDERWENT HYSTEROSALPINGOGRAM ABOUT 2 MONTHS AFTER ESSURE INSERTION AND THE RESULTS WERE SATISFACTORY. PATIENT HAD MICRO-INSERTS SURGICALLY REMOVED. AN ALTERNATE EXPLANATION IS NOT AVAILABLE. BASED ON THE INFORMATION PROVIDED AND GIVEN ITS NATURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. ADDITIONALLY, ANOTHER SERIOUS EVENT (HEAVY BLEEDING) AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 24-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00369	BAYER HEALTHCARE LLC	6/3/2015	6/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED ISSUES SHE EXPERIENCED WITH ESSURE. OVER ONE MONTH SHE GAINED 20 LBS AND LOOKED 6 MONTHS PREGNANT. SHE FELT AS THOUGH SOMETHING WAS STABBING THROUGH HER. SHE HAD THEM IN HER FOR 3 YEARS AT THIS POINT AND HAD NO PROBLEMS UP TO THEN. SHE WAS ONLY (B)(6). SHE HAD THE SAME GYNECOLOGIST FOR ALMOST 9 YEARS AND THROUGH 2 PREGNANCIES. HE ACTED AS IF SHE WAS CRAZY AND JUST SAID HER SWELLING AND CHRONIC PAIN WAS STRANGE. HE FINALLY AGREED TO REMOVE ESSURE. ONE MONTH LATER SHE WAS NORMAL AGAIN. NO MORE PREGNANT BELLY. NO LONGER DEBILITATING PAIN, THE ONLY REMAINING ISSUE SHE HAD WAS SEVERE PAIN WHILE ON HER PERIOD BECAUSE OF THE ADENOMYOSIS THOSE COILS CAUSED. HER GYNECOLOGIST WAS WILLING TO REMOVE THE ENDOMETRIOSIS CAUSED BY THE COILS. CONSUMER MENTIONED THAT SHE ALSO HAD TO HAVE AT LEAST 8 INVASIVE HORRIBLE AND PAINFUL TESTS RUN ON HER TO RULE OUT ANY SUSPECTED CAUSES OF HER PAIN AND SWELLING BEFORE SHE COULD GET HER IMPLANTING DOCTOR TO REMOVE ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON 22-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE

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HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FELT AS THOUGH SOMETHING WAS STABBING THROUGH HER, CHRONIC PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, CONSUMER ALSO HAD ADENOMYOSIS AND ENDOMETRIOSIS WHICH COULD HAVE CONTRIBUTED FOR THE OCCURRENCE OF PAIN, HOWEVER SINCE THE PAIN STARTED APPROXIMATELY 3 YEARS AFTER ESSURE INSERTION AND ONE MONTH AFTER ESSURE REMOVAL SHE NO LONGER HAD PAIN, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE TOTALLY EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE WAS REMOVED (INTERVENTION IMPLIED). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042931	BAYER	6/3/2015	6/3/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHOOTING STABBING PAINS IN MY LEFT SIDE. NEVER ATTRIBUTED IT TO ESSURE. STILL HAPPENING AT LEAST ONCE A MONTH IF NOT MORE. I CAN'T MOVE WHEN THE PAIN HITS. IT'S ALMOST UNBEARABLE. I ALSO GET CONSTANT MIGRAINES, I'M ALWAYS TIRED AND NEVER FEEL WELL RESTED, NO ENERGY, CAN'T LOSE WEIGHT EVENTHOUGH I WORK OUT 5-6 DAYS A WEEK. ALWAYS BLOATED. HAVE SEEN A DOCTOR. SAID I HAVE A COIL POKING OUT IF MY LEFT TUBE. SAYS I NEED A HYSTERECTOMY. I'M (B)(6) AND JUST NOT MENTALLY READY FOR THAT SURGERY. ESSURE IS ONE OF MY BIGGEST REGRETS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5042995	BAYER	6/3/2015	6/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AFTER MY SON WAS BORN. SHORTLY AFTER I HAD THE HCG TEST I STARTED HAVING NUMBNESS AND TINGLING DOWN ONE SIDE OF MY BODY. MY FAMILY DOCTOR REFERRED ME TO A NEUROLOGIST. MY NEUROLOGIST THINKS IT COULD BE CAUSED BY ESSURE. I AM SEEING MY OB/GYN TO SEE ABOUT A HYSTERECTOMY ON MONDAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043026	BAYER	6/4/2015	6/11/2015

Event Information:

Event Date (B3): 1/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE HAD SIGNIFICANT WEIGHT GAIN. HEADACHES. LOSS OF SEX DRIVE. MOODINESS. DIDN'T ASSOCIATE WITH ESSURE UNTIL A POSITIVE PREGNANCY TEST ON (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00370	BAYER HEALTHCARE LLC	6/5/2015	6/5/2015

Event Information:

Event Date (B3): 12/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53554

Single Use:
Implant Date (E6): 12/22/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. DURING PLACEMENT PROCEDURE, PHYSICIAN ATTEMPTED TO DEPLOY THE ESSURE IN ONE TUBE, AND IT DID NOT DEPLOY CORRECTLY. THEN THE PHYSICIAN PULLED ON THE COIL AND IT UNRAVELED, HE CUT THE WIRE AT THE PATIENT'S VAGINA. THE REST OF THE COIL REMAINED IN THE PATIENT'S TUBE AND UTERUS. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT (B)(6) 2015 PTC GLOBAL NUMBER (B)(4) FINAL ASSESSMENT CASE DOWNGRADED TO NON-INCIDENT PER CENTRAL ACTION ITEM ON (B)(6) 2014. DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: 1) ROLLBACK TO INITIAL HARD STOP. 2) DEPRESS BUTTON. 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO DEPLOYMENT DIFFICULTY. SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL

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MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT THIS PTC WAS IMITATED DUE TO USABILITY ISSUES. HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS WERE REPORTED. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(6)2015. CASE UPGRADED TO INCIDENT. PATIENT'S DEMOGRAPHIC INFORMATION WAS PROVIDED. POSSIBLY LEEP YEARS AGO. NO OTHER MEDICAL HISTORY. ESSURE LOT NUMBER B53554 WAS EASILY INSERTED WITH MINIMAL CERVICAL DILATATION AND TORADOL WAS USED AS ANALGESIA. FLUID LOSS MORE THAN 1500 CC WAS DENIED AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. NO BACK UP CONTRACEPTIVE WAS USED. PERFORATION WAS DENIED. AT THE LAST STEPS, WHERE THE MICROINSERT SHOULD SPRING OPEN AND DETACH, A PROBLEM WITH REMOVING DELIVERING CATHETER WAS ENCOUNTERED. THE WIVE HAD TO BE CUT 4 CM FROM THE CERVIX OS. IT WAS INTENTIONALLY LEFT INSIDE BECAUSE IT WOULD NOT DISCHARGE FROM THE COIL. LAPAROSCOPIC BILATERAL SALPINGECTOMY (ESSURE, WIVE AND TUBES WERE REMOVED) WAS PERFORMED TO TREAT THE EVENTS. PATHOLOGY RESULTS WERE NOT AVAILABLE. HOSPITALIZATION WAS REPORTED. REPORTER RELATED THE EVENTS TO ESSURE. OUTCOME WAS POSITIVE. FOLLOW-UP RECEIVED ON (B)(6) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(6) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: B53554; PRODUCTION DATE: (B)(6) 2013; EXPIRATION DATE: (B)(6)2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO USABILITY ISSUES. HOWEVER, AT THIS POINT IN TIME NO ADVERSE EVENTS WERE REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HCP ATTEMPTED TO DEPLOY THE ESSURE IN ONE TUBE, AND IT DID NOT DEPLOY CORRECTLY, HCP PULLED ON THE COIL AND IT UNRAVELED, THE REST OF THE COIL REMAIN IN THE PATIENTS TUBE AND UTERUS AND HCP CUT THE WIRE AT THE PATIENT'S VAGINA. THE EVENT THE REST OF THE COIL REMAIN IN THE PATIENTS TUBE AND UTERUS (SEEN AS DEVICE REMOVAL FAILED) WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND IS LISTED IN THE REFERENCE

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SAFETY INFORMATION FOR ESSURE. THE OTHER EVENTS ARE NON-SERIOUS. IN THIS CASE, INSERTION OCCURRED EASILY, BUT A PROBLEM WITH REMOVING DELIVERING CATHETER WAS ENCOUNTERED. IT WAS REPORTED THAT PERFORATION DID NOT OCCUR. CONSIDERING POSITIVE TEMPORAL RELATIONSHIP, THE EVENT WAS CONSIDERED RELATED TO DEVICE. SINCE PATIENT UNDERWENT LAPAROSCOPIC BILATERAL SALPINGECTOMY, THIS CASE WAS UPGRADED TO INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00371	BAYER HEALTHCARE LLC	6/5/2015	6/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/4/2009
Explant Date (E7): 11/3/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 FOR STERILIZATION. IT WAS UNKNOWN WHETHER ESSURE WAS USED PREVIOUSLY. ON AN UNSPECIFIED DATE THE PATIENT STARTED EXPERIENCING ABDOMINAL PAIN, RASH, SKIN LESION, APPETITE CHANGE, WEIGHT GAIN, NAUSEA, VOMITING, DIARRHEA, HEADACHE, DIZZINESS, DIMINISHED BRAIN FUNCTION, AND BRAIN FOG. ON (B)(4)-2014 ESSURE WAS REMOVED. THE OUTCOME OF THE EVENTS WAS REPORTED AS ONGOING. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(6) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS

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AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN AND RASH AMONG OTHER NON-SERIOUS EVENTS. ESSURE WAS REMOVED AND EVENTS ARE ONGOING. BOTH EVENTS ARE SERIOUS DUE TO REQUIRED INTERVENTION AND ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, BOTH EVENTS ARE LISTED. THIS CASE HAS LIMITED INFORMATION. THE ONSET DATES OF THE ABDOMINAL PAIN AND RASH WERE NOT REPORTED. HOWEVER, CONSIDERING THE IMPLIED TEMPORAL RELATIONSHIP AND THAT ABDOMINAL PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE ABDOMINAL PAIN CANNOT BE EXCLUDED. SINCE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY. IN THIS PARTICULAR CASE, SHE EXPERIENCED RASH. CONSIDERING THAT ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, AND THAT NICKEL MAY CAUSE ALLERGIC REACTIONS, SINCE THERE IS AN IMPLIED POSITIVE TEMPORAL RELATIONSHIP, THE RASH WAS CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 17-AUG-2015: HCP QUESTIONNAIRE WERE RECEIVED FROM THE NURSE. PATIENT'S DATA WERE UPDATED, INCLUDING HER AGE, (B)(6). THE NURSE REPORTED ESSURE INSERTION DATE, POSTPARTUM STATE, LOT NUMBER AND INSERTION DETAILS AS UNKNOWN. THE NURSE INFORMED THAT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00372	BAYER HEALTHCARE LLC	6/5/2015	6/5/2015

Event Information:

Event Date (B3): 1/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18716

Single Use:
Implant Date (E6): 1/23/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 11-MAY-2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER C18716). PHYSICIAN REPORTED THAT LEFT ESSURE DID NOT PASS THROUGH THE TUBE TO ITS NORMAL LENGTH. LONG PART REMAINED OUTSIDE OF THE TUBE. ON (B)(6) 2015 THE LEFT ESSURE WAS REMOVED AND PATIENT OPTED FOR TUBAL LIGATION IN THE OPERATING ROOM. NO INJURY. RIGHT TUBE DEVICE WAS PLACED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 22-MAY-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C18716; PRODUCTION DATE: 04-FEB-2014; EXPIRATION DATE: 28-FEB-2017. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE BATCH DOCUMENTATION OF THE REPORTED

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BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6)-YEAR-OLD FEMALE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LEFT ESSURE DID NOT PASS THROUGH THE TUBE TO ITS NORMAL LENGTH. LONG PART REMAINED OUTSIDE OF THE TUBE. APPROXIMATELY TWO WEEKS LATER, ESSURE WAS REMOVED AND PATIENT OPTED FOR TUBAL LIGATION IN THE OPERATING ROOM. NO INJURY. RIGHT TUBE DEVICE WAS LEFT IN PLACE. ESSURE DID NOT PASS THROUGH THE TUBE TO ITS NORMAL LENGTH, INTERPRETED AS DEVICE DEPLOYMENT ISSUE, IS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS EVENT IS LISTED. DURING DIFFICULT INSERTIONS, ESSURE PLACEMENT MAY BE UNSUCCESSFUL. CONSIDERING THAT IT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 08-JUN-2015: FOLLOW UP INFORMATION WAS RECEIVED FROM THE PHYSICIAN (HCP QUESTIONNAIRE). PATIENT WAS NOT POST-PARTUM AT TIME OF ESSURE INSERTION. SOUNDING WAS PERFORMED DURING PROCEDURE. THE INSERTION AND VISUALIZATION OF TUBAL OSTIUM WAS EASY. N

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00373	BAYER HEALTHCARE LLC	6/8/2015	6/8/2015

Event Information:

Event Date (B3): 5/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64465

Single Use: Y
Implant Date (E6): 5/11/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C64465, INSERTED ON (B)(6) 2015. THE PHYSICIAN WHO PLACED THE ESSURE DID NOT RECEIVE THE TRAINING FROM BAYER HEALTH CARE PROFESSIONAL (BHCP) TRAINING DEPARTMENT, BUT BY PHYSICIAN COLLEAGUES. HEALTH CARE PROFESSIONAL REPORTED THAT, ON (B)(6) 2015 DURING ESSURE PLACEMENT, TWO IMPLANTS IN, WHERE A PART OF THE INSERTER REMAINED (AS REPORTED) AND INFORMED THAT IT WAS IMPOSSIBLE TO RELEASE THE INSERTS. THE EVENT TOOK PLACE IN THE OPERATORY ROOM. THERE WAS NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS DONE, WITH ANOTHER DEVICE. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT TWO IMPLANTS IN WHERE A PART OF THE INSERTER REMAINED (INTERPRETED AS DEVICE BREAKAGE). IT WAS IMPOSSIBLE TO RELEASE THE INSERTS. THE EVENT DEVICE BREAKAGE WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE (BY THE REPORTER) AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-AUG-2015: NO FURTHER INFORMATION WAS OBTAINED. CASE CONSIDERED CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICUL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043067	BAYER	6/8/2015	6/17/2015

Event Information:

Event Date (B3): 2/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/13/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT PAIN, HEADACHES, PAIN WITH ANY KIND OF MOVEMENT, PERIODIC BLEEDING, BLOATING, LEG PAIN, BACK PAIN, RASH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043069	BAYER	6/8/2015	6/17/2015

Event Information:

Event Date (B3): 5/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/11/2010
Explant Date (E7): 6/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

WITHIN 12 HOURS OF RECEIVING ESSURE PERMANENT BIRTH CONTROL, I BROKE OUT IN HIVES AND A RASH THAT CONTINUED TO WORSEN OVER 2 WEEKS. I TRIED CREAMS AND OTHER MEDICATIONS TO RELIEVE AND ELIMINATE THE RASH AND NOTHING WORKED. FINALLY, THE DOCTOR WHO DID THE PROCEDURE SAID WE COULD TRY TO REMOVE THE COILS BUT IF HE'S NOT ABLE TO REMOVE THEM, I WOULD HAVE TO HAVE A HYSTERECTOMY. THANKFULLY HE WAS ABLE TO REMOVE THE COILS AND WITHIN 12 HOURS OF HAVING THEM OUT, THE RASH WENT AWAY. I WAS NOT WARNED ABOUT ANY POSSIBLE ALLERGIC REACTION AND BELIEVE THERE SHOULD BE WARNINGS ABOUT THIS SIDE AFFECT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043071		6/8/2015	6/17/2015

Event Information:

Event Date (B3): 1/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DECIDED TO HAVE THE ESSURE IMPLANTED IN ME IN 2010, I WAS TOLD BY DOCTOR IT WAS BETTER THAN TRYING TUBES OR CUTTING BECAUSE IT KEPT TISSUES INTACT THEREFORE LEAVING "COMMUNICATION LINES" OPEN THE OVARY AND UTERUS THUS FAR CAUSING LESS HORMONAL IMBALANCES. TO BE USED AS CONTRACEPTIVE AND WAS AND IN AND OUT PROCEDURE WITH LITTLE OR NO DOWNTIME. SINCE THE IMPLANTS I HAVE HAD LOTS OF ALLERGY ISSUES, RASHES, SEVERE PELVIC PAIN, LOWER BACK PAIN, NUMBNESS IN LEGS, BUTTOCKS. I WAS TOLD I HAVE FIBROMYALGIA. I FREQUENTLY HAVE "KNIFE-STABBING (TURNING) SENSATIONS IN MY OVARY AREA, FRONT HIP BONES POCKET LEVEL, THEY STOP MED DEAD IN MY TRACKS. I HAVE URINARY INCONTINENCE. THE WORST OF ALL IS THE CONSTANT PAIN, SOME DAYS I CAN WALK WELL OTHER DAYS I CAN'T. IT IS A BUILDING UP IN A SENSE. I CAN'T SLEEP WELL DUE TO THE PELVIC PAIN. I HAVE CHANGED MY BED, FOR A NEW ONE AND NO SUCCESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043072	BAYER	6/8/2015	6/17/2015

Event Information:

Event Date (B3): 5/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2007
Explant Date (E7): 5/22/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED ESSURE PERMANENT BIRTH CONTROL IN 2007. UNTIL THEN I HAD NEVER HAD PROBLEMS WITH MY MONTHLY PERIODS. AFTER GETTING ESSURE I WAS NEVER THE SAME, I HAD A PERIOD EVERY TWO WEEKS AND THEY WERE SO HEAVY I WOULD GET LIGHTHEADED AT TIMES. I ALSO HAD ATLEAST ONCE A YEAR EXTREME PAIN IN MY LOWER ABDOMEN THAT I WENT TO THE EMERGENCY ROOM FOR. THERE WAS NEVER A REASON. NOW I RECENTLY HAD TO UNDERGO A COMPLETE HYSTERECTOMY BECAUSE OF THE HORRIBLE TIME I HAVE HAD WITH ESSURE. THEY REMOVED MY FALLOPIAN TUBES AND UTERUS AND ONLY FOUND A TINY PORTION OF THE DEVICE STILL IN ME. THE REST WHO KNOWS WHERE IT WENT. SO IN SOMETIME BETWEEN 2007-2015 THEY BROKE AND WERE EXPELLED FROM MY BODY WITHOUT ME KNOWING. WHO KNOWS THAT DAMAGE THEY DID IN THE MEAN TIME. I NOW HAVE HOSPITAL BILLS AND DEBITS FROM THIS HORRIBLE DEVICE. NO WOMEN SHOULD HAVE TO GO THROUGH THIS JUST TO NOT GET PREGNANT. PLEASE REMOVE FROM THE MARKET SO NO ONE ELSE GOES THROUGH THIS. THANKS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00374	BAYER HEALTHCARE LLC	6/9/2015	6/9/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/1/2010
Explant Date (E7): 5/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED APPROXIMATELY IN 2010 BY ANOTHER PHYSICIAN. PHYSICIAN REPORTED THAT THE PATIENT HAS EXPERIENCED BAD PELVIC PAIN SINCE ESSURE INSERTION. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 PTC GLOBAL NUMBER (B)(4) FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2015 FROM TREATING PHYSICIAN - (UPGRADED TO INCIDENT). PATIENT´S INITIAL AND DATE OF BIRTH WERE UPDATED. HER WEIGHT WAS (B)(6) HER CONCURRENT CONDITION INCLUDED OBESITY. PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS

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AND PROCEDURES WERE DENIED. IT WAS REPORTED THAT PATIENT HAD A TUBAL LIGATION AS MEDICAL HISTORY (DISCREPANT INFORMATION). THIS PHYSICIAN DID NOT HAVE INFORMATION ABOUT INSERTION, SINCE THIS PHYSICIAN DID NOT PLACE THE ESSURE DEVICES. THE PATIENT WAS SEEN AT INITIAL VISIT WITH PELVIC PAIN POSSIBLE ASSOCIATED WITH ESSURE INSERTION. IT WAS REPORTED THAT SHE WAS NOT IN A POST-PARTUM STATE AT TIME OF PROCEDURE. ON (B)(6) 2015, X-RAY OF ABDOMEN WAS DONE AND BILATERAL ESSURE COILS APPEARED TO BE IN PLACE. ULTRASOUND WAS ALSO PERFORMED AND LEFT ESSURE COIL WAS CLEARLY IDENTIFIED IN SITU ON 3D IMAGING. THE RIGHT ESSURE WAS NOT IDENTIFIED. ON (B)(6) 2015, ESSURE WAS REMOVED DUE TO PATIENT REQUEST. LSC (LAPAROSCOPIC) BILATERAL SALPINGECTOMY WAS DONE. DURING SURGERY, IT WAS DIAGNOSED THAT ESSURE COIL PERFORATED ONE TUBE. ON (B)(6) 2015, AFTER PROCEDURE VISIT, PATIENT DEVELOPED VAGINAL PAIN WITH ITCHY AND IRRITATED BURNING. A CULTURE WAS DONE AND SHOWED POSITIVE GARDNERELLA. PREOPERATIVE PAIN HAS RESOLVED SINCE SURGERY. FOLLOW-UP RECEIVED ON (B)(6) 2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: PHYSICIAN'S OFFICE WAS CONTACTED AND REPORTED THAT THE PATIENT WAS PREVIOUSLY SEEN AT TWO DIFFERENT PLACES; BUT THEY DID NOT KNOW WHERE ESSURE WAS INSERTED. THEY DID NOT HAVE RECORDS OF WHO OR WHERE IT WAS INSERTED. THE PATIENT WENT TO THEM BECAUSE OF POSSIBLE ISSUES WITH ESSURE POST INSERTION. SHE WAS A NEW PATIENT FOR AND THEM AND THEY BELIEVE THAT ESSURE WAS INSERTED IN 2011. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO EXPERIENCED PELVIC PAIN SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. A LAPAROSCOPIC BILATERAL SALPINGECTOMY WAS PERFORMED AND ESSURE INSERTS WERE REMOVED. DURING SURGERY, IT WAS DIAGNOSED THAT ESSURE COIL HAD PERFORATED ONE TUBE, INTERPRETED AS FALLOPIAN TUBE PERFORATION. EVENTS PELVIC PAIN AND FALLOPIAN TUBE PERFORATION WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, BOTH EVENTS ARE LISTED. UTERINE/FALLOPIAN TUBE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE PERFORATION WAS DIAGNOSED APPROXIMATELY 5 YEARS AFTER ESSURE INSERTION DURING THE BILATERAL SALPINGECTOMY PERFORMED TO REMOVE ESSURE INSERTS. ALTHOUGH THE EXACT ONSET DATE IS NOT KNOWN, DUE TO THE NATURE OF THIS EVENT AND POSITIVE TEMPORAL RELATIONSHIP, THIS EVENT IS CONSIDERED RELATED TO ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE PATIENT EXPERIENCED PELVIC PAIN SINCE ESSURE INSERTION. MOREOVER, A FALLOPIAN TUBE PERFORATION CAUSED BY ESSURE COIL COULD CONTRIBUTE TO THE PELVIC PAIN. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENT, A CAUSAL RELATIONSHIP BETWEEN THE PELVIC PAIN AND ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00377	BAYER HEALTHCARE LLC	6/9/2015	6/9/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA NATIONAL TV BROADCASTING IN (B)(6) ON (B)(6) 2015; WHICH REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER HAD 3 CHILDREN. SHE REPORTED THAT ESSURE PLACEMENT WENT PROSPEROUS AND THE NEXT DAY SHE WAS BACK TO WORK. AFTER A SHORT TIME SHE EXPERIENCED A TERRIBLE ITCH IN THE SKIN; ECZEMA ALL OVER THE BODY, SCRATCHING UNTIL IT BLEEDS. THE ITCH DID NOT DISAPPEAR. SHE ALSO EXPERIENCED HAY FEVER AND WAS ALWAYS NAUSEATED. A PHOTO WAS SHOWN ON TV AND PATIENT DESCRIBED THE FOLLOWING: STUFFED EYES, VERY WEEPY EYES, AND ACCORDING TO HER OPINION A DEFORMED FACE: STUFFED, THICK, CIRCLES, OEDEMA AND ITCHING. THE CONSUMER HAD SEVERAL EXAMINATIONS (NOS). SHE WAS TREATED WITH TABLETS AGAINST HAYFEVER (NOS) AND A SPECIAL OINTMENT (NOS); NOTHING WORKED. SHE ASKED HER DERMATOLOGIST IF THE COMPLAINTS COULD BE RELATED TO THE IMPLANTS AND ACCORDING TO THE DERMATOLOGIST THIS WAS NOT THE CASE. SHE ALSO STATED THAT THE COMPLAINTS STARTED AFTER PLACEMENT OF ESSURE AND DISAPPEARED AFTER REMOVAL OF ESSURE (NO OTHER SPECIFIED). FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015: THE CONSUMER, WHO WAS (B)(6) WHEN ESSURE WAS INSERTED, HAD COMPLAINTS FOR 5 YEARS UNTIL SHE HAD THE METAL FEATHERS REMOVED EARLY THIS YEAR. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ECZEMA. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 3 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(4) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ECZEMA ALL OVER THE BODY; WHICH RECOVERED WITH ESSURE REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED (NO INFORMATION WAS GIVEN ABOUT CONSUMER'S ALLERGIES OR CONCOMITANT CONDITIONS). THE CONSUMER STATED HER DERMATOLOGIST BELIEVED HER COMPLAINTS WERE NOT RELATED TO ESSURE. HOWEVER, AS SHE STATED THE EVENT STARTED AFTER ESSURE INSERTION AND IMPROVED WITH DEVICES REMOVAL; COMPANY CONSIDERS CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED WITH THE AVAILABLE INFORMATION. THIS CASE WAS REGARDED AS INCIDENT, SINCE ESSURE REMOVAL (INTERVENTION IMPLIED) WAS REPORTED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO ACTIVE FOLLOW-UP WILL BE PURSUED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00379	BAYER HEALTHCARE LLC	6/9/2015	6/9/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51341

Single Use: Y
Implant Date (E6): 4/10/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/6/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(4) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015 WITH LOT NUMBER C51341 (EXPIRATION DATE MAY-2017). IT WAS REPORTED A GOOD PLACEMENT OF DELIVERY CATHETER INTO LEFT OSTIUM WITH EASY INSERTION. DIFFICULTIES OF RELEASE OF LEFT ESSURE DESPITE GOOD POSITIONING AND THUMBWHEEL ACTIVATION, AND FINALLY WHEN THE DEVICE WAS RELEASED, IT REMAINED ATTACHED AND SHOULD BE REMOVED WITH PLIERS. ACCORDING TO THE PHYSICIAN, THE CONSEQUENCES FOR THE PATIENT WERE LONGER SURGICAL TIME, RISK OF LESION OF THE OSTIUM AND FALLOPIAN TUBE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING THE PROCEDURE, THERE WERE DIFFICULTIES IN DEVICE RELEASING; AND IT REMAINED ATTACHED TO THE FALLOPIAN TUBE. PHYSICIAN HAD TO REMOVE THE DEVICE WITH PLIERS. THE REPORTED EVENTS, REGARDED AS A DEVICE DEPLOYMENT ISSUE FOLLOWED BY AN INSERTION COMPLICATION, ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL. IN THIS PARTICULAR CASE A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THE REPORTED EVENTS; HOWEVER CONSIDERING THAT THEY OCCURRED IN ASSOCIATION WITH ESSURE INSERTION, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT; SINCE ACCORDING TO THE REPORTER, THE PATIENT HAD A RISK OF OSTIUM AND FALLOPIAN TUBE LESION DUE TO THE EVENTS. FOLLOW-UP INFORMATION IS BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 21-SEP-2015: NO FURTHER INFORMATION WAS PROVIDED DESPITE FOLLOW UP ATTEMPTS. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00380	BAYER HEALTHCARE LLC	6/9/2015	6/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO AN ADULT (~18Y & ~65Y) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013 FOR PERMANENT CONTRACEPTION. THE CONSUMER EXPERIENCED AN ALLERGIC REACTION TO ESSURE. SHE DEVELOPED HIVES, ITCHING, METAL TASTE IN MOUTH, LOTS OF DISCOMFORT, PAIN, EXCESSIVE WEIGHT GAIN (B)(6), AND THE HEALTHCARE PROFESSIONAL FOUND ENDOMETRIOSIS SINCE ESSURE INSERTED. SHE GAINED THE WEIGHT EVEN WITH CHANGE IN DIET AND EXERCISE. ONSET DATE OF EVENT (NOT SPECIFIED WHICH EVENT) WAS IN (B)(6) 2013. ON (B)(6) 2015, A TUBAL LIGATION WAS DONE TO REMOVE THE COILS BUT HCP DISCOVERED THE LEFT TUBE DID NOT CONTAIN A COIL. ULTRASOUND WAS DONE ON (B)(6) 2015 AND SHOWED THE COIL FROM LEFT TUBE WAS IN UTERUS. SHE HAS STILL HAD SOME HIVES AND THE PAIN ON LEFT SIDE OF ABDOMEN HAS INCREASED. SHE FELT PAIN EVEN IF SHE RUN HER FINGER OVER THE SKIN ON ABDOMEN ON LEFT SIDE. IT DOUBLES HER OVER. CONSUMER WOULD LIKE TO KNOW IF ESSURE THAT WAS IN UTERUS COULD BE REMOVED BY HYSTEROSCOPY OR SHOULD HYSTERECTOMY BE DONE. ADVERSE EVENTS WERE TREATED WITH OTC ALLERGY MEDICINE, HYDROCODONE AS NEEDED. HIVES WERE BETTER AND METAL TASTE IN MOUTH WAS GONE BUT PAIN PERSISTED. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT

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TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PAIN ON ABDOMEN ON LEFT SIDE. A TUBAL LIGATION WAS DONE BUT ONE TUBE WAS NOT FOUND. THE ULTRASOUND PERFORMED A FEW WEEKS LATER, SHOWED THAT COIL FROM LEFT TUBE WAS IN UTERUS. PAIN PERSISTED AFTER TUBAL LIGATION. THIS EVENT IS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS EVENT IS LISTED. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE ONSET DATE OF THIS PAIN IS NOT CLEAR. HOWEVER, THERE IS AN IMPLIED POSITIVE TEMPORAL RELATIONSHIP. CONSIDERING THIS INFORMATION AND ALSO THAT THE PRESENCE OF A FOREIGN BODY IN THE FALLOPIAN TUBES MAY CAUSE PAIN, THIS PAIN IS CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 24-AUG-2015 FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00381	BAYER HEALTHCARE LLC	6/9/2015	6/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 BY ANOTHER HEALTHCARE PROFESSIONAL FOR STERILIZATION. PHYSICIAN REPORTED THAT PT CAME TO THE OFFICE EARLY (B)(6) 2015 WITH COMPLAINT OF PELVIC PAIN. SHE WAS BIOPSIED AND DIAGNOSED WITH ENDOMETRIOSIS AND FIBROIDS. THE ESSURE COIL PARTIALLY PERFORATED INTO THE MYOMETRIUM ON THE LEFT SIDE. THE RIGHT SIDE WAS OK AND WAS OCCLUDED. THE HEALTHCARE PROFESSIONAL WONDERED IF THE FIBROID GROWTH ON THE LEFT SIDE PUSHED THE COIL TO PARTIALLY PERFORATE THE MYOMETRIUM. ON (B)(6) 2015, THE HCP DID A LAPAROSCOPY AND REMOVED THE LEFT FALLOPIAN TUBE. THE RIGHT SIDE WAS LEFT IN PLACE. THE PATIENT WAS FINE. THE HCP STATED THE PATIENT WAS NOT GOING TO MENTION LITIGATION. THE PHYSICIAN TOLD THE PATIENT IT WAS REMOVED DUE TO ANATOMY. FOLLOW-UP RECEIVED ON (B)(4) 2015: NO NEW INFORMATION. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM AN QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE

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GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(4) 2015. NO NEW CLINICAL INFORMATION PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 BY ANOTHER HEALTHCARE PROFESSIONAL FOR STERILIZATION AND ESSURE COIL PARTIALLY PERFORATED INTO THE MYOMETRIUM ON THE LEFT SIDE. A LAPAROSCOPY WAS PERFORMED AND THE LEFT FALLOPIAN TUBE WAS REMOVED. THE RIGHT INSERT WAS LEFT IN PLACE. THIS EVENT, INTERPRETED AS UTERINE PERFORATION IS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION THIS EVENT IS LISTED. UTERINE/FALLOPIAN TUBE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE PERFORATION WAS DIAGNOSED A FEW YEARS AFTER INSERTION. HOWEVER, THE EXACT DATE AND THE MECHANISM OF THIS PERFORATION ARE NOT KNOWN. ALTHOUGH THE PHYSICIAN WONDERED IF THE FIBROID GROWTH ON THE LEFT SIDE COULD HAVE PUSHED THE COIL TO PARTIALLY PERFORATE THE MYOMETRIUM, THE CAUSAL RELATIONSHIP BETWEEN THE PERFORATION AND THE ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 17-JUN-2015: PATIENT´S MEDICAL HISTORY INCLUDED GRAVIDA 3, PARA 1, SPONTANEOUS ABORTION 1 AND ELECTIVE ABORTION 1 AND SHE WAS NOT PREGNANT AT MOMENT OF THE REPORT. ESSURE WAS INSERTED AT ANOTHER FACILITY. LEFT SALPINGECTO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00383	BAYER HEALTHCARE LLC	6/9/2015	6/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/31/2006
Explant Date (E7): 8/31/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2006. CONSUMER REPORTED THAT SHE HAD EMERGENCY SURGERY, TUBAL REMOVAL, PREGNANCY THREE TIMES WITH LIVE BIRTH (THIS CASE REFERS TO THE THIRD PREGNANCY), CHRONIC PAIN, HEADACHES AND MEDICAL COMPLICATIONS DURING PREGNANCY. ESSURE WAS REMOVED ON (B)(6) 2014. FOR THE OTHER TWO PREGNANCY EPISODES, PLEASE SEE CASE 2015-247699 AND 2015-247700. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER

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NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015. NO RESPONSE AFTER FOLLOW-UP ATTEMPTS. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A PREGNANCY WITH LIVE BIRTH. SHE ALSO EXPERIENCED CHRONIC PAIN (INTERPRETED AS CHRONIC PELVIC PAIN), AND REPORTED AN EMERGENCY SURGERY AND TUBAL REMOVAL. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THE PRESENT CASE, THE CONSUMER HAD A PREVIOUS HISTORY OF 2 PREGNANCIES WITH ESSURE. NO INFORMATION WAS PROVIDED ON WHETHER A CONFIRMATION TEST WAS PERFORMED OR THE TIME INTERVAL BETWEEN ESSURE INSERTION AND THE PREGNANCY. HOWEVER, GIVEN THE NATURE OF THE EVENT PREGNANCY, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. THE TIME INTERVAL BETWEEN ESSURE INSERTION AND THE ONSET OF PAIN WAS NOT REPORTED. HOWEVER, CONSIDERING THE NATURE OF THE EVENT CHRONIC PAIN, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION (EMERGENCY SURGERY AND TUBAL REMOVAL). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION COULD NOT BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043078	BAYER	6/9/2015	6/17/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE DEVICE MOVED FROM A FALLOPIAN TUBE INTO MY UTERUS. I DONT' KNOW HOW IT HAPPENED, IT'S BEEN IN 13 YEARS AND I RECENTLY TRIED TO HAVE ANOTHER PROCEDURE DONE (NOVASURE) BUT COULD NOT BECAUSE OF THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043079	BAYER	6/9/2015	6/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE PLACED (B)(6) 2014. I HAVE EXPERIENCED SEVERE BLOATING, BACK PAIN, PELVIC PAIN, FATIGUE, HEADACHES AND MY PERIODS HAVE BECOME SO PAINFUL AND HEAVY. MY BODY FEELS AS IF IT IS OUT OF CONTROL. THE PAIN IS BECOMING UNBEARABLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043090	BAYER	6/9/2015	6/17/2015

Event Information:

Event Date (B3): 9/9/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/9/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ONGOING PAIN AND TENDERNESS SINCE HAVING MY ESSURE BIRTH CONTROL IMPLANT, IMPLANTED IN 2013. REPORTED TO MY DOCTOR IN 2013 WHEN THE PROCEDURE WAS FORMED, AND WAS TOLD IT WAS MY BODY ADJUSTING TO THE IMPLANT DEVICE. HAD SEVERAL FOLLOW-UPS AFTERWARD WHICH RESULTED IN NO CHANGE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00375	BAYER HEALTHCARE LLC	6/9/2015	7/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68791

Single Use: Y
Implant Date (E6): 4/8/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015. THE SURGEON WAS TRAINED TO ESSURE PROCEDURE. REPORTER INFORMED THAT THE INSERT BROKE AT THE PLACEMENT PERFORMED BY CELIOSCOPY. THE EVENT WAS OBSERVED IN THE OPERATING ROOM. HEALTH CARE PROFESSIONAL REPORTED THAT THE PIECE OF ESSURE SYSTEM THAT BROKE WAS DIFFICULT TO REMOVE. ACCORDING TO REPORTER, THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS NOT PERFORMED BECAUSE THE PROCEDURE WAS STOPPED. ESSURE SYSTEM WAS NOT KEPT. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD NA ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND THE INSERT BROKE AT THE PLACEMENT PERFORMED BY CELIOSCOPY. THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS OR REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE INSERT BROKE AT PLACEMENT AND THE PIECE OF ESSURE SYSTEM THAT BROKE WAS DIFFICULT TO REMOVE. THEN, BILATERAL PLACEMENT WAS NOT ACHIEVED BECAUSE THE PROCEDURE WAS STOPPED. CONSIDERING THE EVENT OCCURRED AT PLACEMENT, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. IN ADDITION, THE AE CASE REFERS TO A USA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00382	BAYER HEALTHCARE LLC	6/9/2015	7/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SW

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12701

Single Use: Y
Implant Date (E6): 4/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO UNDERWENT AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER C12701). ADDITIONAL INFORMATION WAS RECEIVED FROM THE HCP (HEALTH CARE PROFESSIONAL) ON (B)(6) 2015. THE HCP REPORTED THAT ON (B)(6) 2015, WHEN PULLING BACK THE INTRODUCER IT GOT STUCK AND WAS BROKEN. EVERYTHING HAD TO BE TAKEN OUT. WHEN THE WHEEL WAS DRAWN BACK AS FAR AS WAS POSSIBLE, NO CLICK WAS HEARD WHICH NORMALLY DID. PRESSED THE RELEASE BUTTON AND WAITED A FEW SECONDS, THEN STARTED REVERSING THE WHEEL AGAIN. THE COIL DID NOT RELEASE FROM THE INSTRUMENT AND THUS CAME OUT INTO THE CAVITY AGAIN. THE INNER PART HOWEVER WAS LEFT IN THE TUBE. PULLED WITH FORCEPS IN THE CAVITY PART OF THE COIL TO GET IT OUT FROM THE TUBE BUT IT CAME OUT IN SMALLER PIECES, COULD NOT GET THE INNER PART LOOSE SO IT WAS LEFT IN THE TUBE. THE LEFTOVERS OF THE COIL HAVE BEEN THROWN AWAY (THE DEVICE WILL NOT BE SENT BACK). NO INJURY TO THE PATIENT. NO BILATERAL PLACEMENT WAS ACHIEVED. THE HCP STATED THAT UNDERSTOOD THAT IT WAS THE INSTRUMENTARIUM ITSELF THAT DID NOT WORK OPTIMALLY AND THUS DID NOT RELEASE THE COIL CORRECTLY. IN ADDITION THEY HAVE RECENTLY TAUGHT ADDITIONAL COLLEAGUES AT THE CLINIC AND SEVERAL OF THEM HAVE REACTED TO THAT IT WAS QUITE DIFFICULT TO SEE IF ONE WAS ENOUGH FAR INSIDE WITH THE IMPLANT. PROPOSAL FOR IMPROVEMENT WAS THUS THAT THE MARK FOR CORRECT POSITION WAS MADE MORE CLEAR. FOLLOW UP FROM 29-MAY-2015: PTC (PRODUCT TECHNICAL COMPLAINT). (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF

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UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE WHEN PULLING BACK THE INTRODUCER IT GOT STUCK AND WAS BROKEN. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, THE COIL DID NOT RELEASE FROM THE INSTRUMENT AND CAME OUT INTO THE CAVITY, HOWEVER THE INNER PART WAS LEFT IN THE TUBE. HEALTH CARE PROFESSIONAL PULLED THE PART OF THE COIL TO GET IT OUT FROM THE TUBE BUT IT CAME OUT IN PIECES AND COULD NOT GET THE INNER PART LOOSE, SO INNER PART WAS LEFT IN THE TUBE. BILATERAL PLACEMENT WAS NOT ACHIEVED. SINCE THE REPORTED EVENTS OCCURRED DURING THE INSERTION PROCEDURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-JUN-2015: NO FURTHER INFORMATION RECEIVED. CASE CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 18-JUN-201

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00376	BAYER HEALTHCARE LLC	6/9/2015	7/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER (VIA (B)(6)) IN (B)(6) ON 14-MAY-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER HAD 2 CHILDREN. DURING PLACEMENT IT WENT WRONG (IT WAS PAINFUL). CONSUMER WAS EXPERIENCING PELVIS, PAIN IN LEGS AND GROINS, ABDOMINAL PAIN, NAUSEA AND VOMITING CONSTANTLY. SHE WAS NOT ABLE TO STAND, WALK OF LIFT. SHE COULDN'T DO ANYTHING, NOT EVEN PLAY WITH HER CHILDREN. AFTER A FEW YEARS SHE ASKED FOR A SECOND OPINION. RESULT: PERFORATION OF LEFT TUBE, FEATHER WAS LOCATED IN THE ABDOMEN. ESSURE WAS REMOVED IMMEDIATELY. ONE AND A HALF YEAR AGO THE UTERUS WAS REMOVED. CONSUMER RELATED THE EVENTS PAIN DURING INSERTION, PERFORATION OF LEFT TUBE/ FEATHER LOCATED IN ABDOMEN TO ESSURE. FOLLOW-UP INFORMATION RECEIVED ON 18-MAY-2015. IN 2010 PATIENT WAS STERILIZED AND STILL SHE HAS COMPLAINTS. IT IS NOT POSSIBLE TO PERFORM FOLLOW UP FOR THIS CASE. FOLLOW-UP RECEIVED ON 22-MAY-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE

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EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 26-MAY-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: FALLOPIAN TUBE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER A FEW YEARS SHE WAS DIAGNOSED WITH PERFORATION OF LEFT TUBE (INSERT LOCATED IN ABDOMEN) AMONG OTHER NON-SERIOUS EVENTS. THIS EVENT IS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS EVENT IS LISTED. UTERINE/FALLOPIAN TUBE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE PERFORATION WAS DIAGNOSED A FEW YEARS AFTER INSERTION. HOWEVER, THE EXACT DATE AND THE MECHANISM OF PERFORATION ARE NOT KNOWN. BASED ON THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. IT IS NOT POSSIBLE TO PERFORM FOLLOW UP OF THIS CASE.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 17-JUN-2015: NO FOLLOW UP INFORMATION RECEIVED, NOR CAN BE OBTAINED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00378	BAYER HEALTHCARE LLC	6/9/2015	7/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68122 / C3821.2

Single Use: Y
Implant Date (E6): 5/6/2015
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C68122 ON (B)(6) 2015. IT WAS REPORTED, DURING ESSURE PROCEDURE, THE LEFT BLIND HAD IMPASSABLE OSTIUM. WHILE DISASSEMBLING THE EQUIPMENT FOR LEFT ESSURE PLACEMENT, AFTER REMOVING THE DELIVERY CATHETER, ONLY ONE HALF WAS RETRIEVED, THE OTHER PART REMAINED INTO THE BETTOCCHI CHANNEL. ADDITIONALLY, RIGHT TUBAL OSTIUM OEDEMA APPEARED DURING THE PROCEDURE. BILATERAL PLACEMENT WAS NOT PERFORMED AND THE PROCEDURE WAS STOPPED. ACCORDING TO THE REPORTER, THERE WERE NO CONSEQUENCES FOR THE PATIENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT. SHE HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THIS PROCEDURE, ONLY ONE HALF OF LEFT ESSURE DEVICE WAS RETRIEVED, THE OTHER PART REMAINED INTO THE BETTOCCHI CHANNEL. THIS EVENT, REGARDED AS DEVICE BREAKAGE, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, ESSURE INSERTION WAS DIFFICULT DUE TO FALLOPIAN TUBE OEDEMA (RIGHT SIDE) AND OBSTRUCTION (LEFT SIDE); THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED BREAKAGE. AS THIS EVENT OCCURRED IN ASSOCIATION WITH A COMPLICATED ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT; AS ALTHOUGH PATIENT SUFFERED NO CONSEQUENCES, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 06-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00384	BAYER HEALTHCARE LLC	6/10/2015	6/11/2015

Event Information:

Event Date (B3): 11/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B85134

Single Use: Y
Implant Date (E6): 11/5/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON 14-MAY-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION. SINCE THE SAME MOMENT OF THE INSERTION, SHE WAS SUFFERING FROM BLOOD LOSS OUT OF HER MENSTRUAL PERIOD, STRONG ABDOMINAL PAIN AND LUMBAR PAIN THAT WAS GOING TO HER LEGS AND WAS INCLUDING CRAMPS. ACCORDING TO HER, SHE WAS NEVER INFORMED OF SIDE EFFECTS. SHE HAD NEVER BEEN TOLD THAT IF THE DEVICE WAS WRONGLY PLACED, HER TUBES AND UTERUS WOULD HAVE TO BE REMOVED. FOLLOW-UP INFORMATION RECEIVED FROM A PHYSICIAN ON 03-JUN-2015: THE PHYSICIAN MENTIONED THAT THEY HAVE STUDIED THE CASE AND THEY HAVE CONCLUDED THAT THERE IS NOT RELATIONSHIP BETWEEN THE EVENTS AND ESSURE. FOLLOW-UP INFORMATION WILL BE PROVIDED. CORRECTION <09-JUN-2015>: AFTER INTERNAL REVIEW OF INFORMATION FROM 14-MAY-2015, LOT NUMBER (B85134) AND ONSET DATES WERE PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLOOD LOSS OUT OF HER MENSTRUAL PERIOD (REGARDED AS GENITAL BLEEDING). THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THE PHYSICIAN CONSIDERED THE EVENTS AS NOT RELATED TO ESSURE. HOWEVER, CONSIDERING THE EVENT'S NATURE AND LACK OF ALTERNATIVE EXPLANATION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THE COMPANY CONSIDERS THAT THIS CASE DOES NOT QUALIFY FOR AN INCIDENT, SINCE NEITHER HOSPITALIZATION NOR SURGICAL/MEDICAL INTERVENTION

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WAS CONFIRMED AT THE TIME OF THIS REPORT. NEVERTHELESS, IN LINE WITH HEALTH AUTHORITY'S ASSESSMENT THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL COMPLAINT IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 07-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043080	ESSURE	6/10/2015	6/17/2015

Event Information:

Event Date (B3): 9/24/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2010 AND HAVE HAD ISSUES EVER SINCE. I HAVE SEVERE BLOATING, LOOK EIGHT MONTHS PREGNANT, HAVE SEVERE MIGRAINES, HAVE A METALLIC TASTE IN MY MOUTH, PELVIC PAIN I CAN'T EVEN COUGH WITHOUT FEELING LIKE MY TUBES ARE BEING RIPPED OUT AND SINCE THE PROCEDURE I COUGH A LOT. DOCTORS CAN'T FIGURE OUT WHY SEVERE BACK PAIN BUT EVERY TIME I SEE A DOCTOR ABOUT ANY OF THESE PROBLEMS THEY DON'T KNOW ANYTHING BECAUSE THEY HAVE NEVER HEARD OF THE ESSURE, I DO HAVE METAL ALLERGIES BUT WAS NEVER CHECKED BEFORE INSERTION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00385	BAYER HEALTHCARE LLC	6/11/2015	6/11/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2013
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA NEWSPAPER IN (B)(6) ON 18-MAY-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER STATED SHE INDICATED THAT SHE HAD A NICKEL ALLERGY AT THE TIME OF ESSURE PLACEMENT, BUT THIS WAS NO IMPEDIMENT. AFTER 3 MONTHS SHE GOT COMPLAINTS THAT BECAME WORSE. ON INTERNET SHE FOUND INFORMATION THAT ESSURE SHOULD NOT BE PLACED IN CASE OF NICKEL ALLERGY OR AUTOIMMUNE DISEASE. SHE MENTIONED THAT SHE HAS HAD THAT TOO. ACCORDING TO HER; HER OWN TREATING PHYSICIAN DID NOT RESPOND/ HEAR SOMETHING THAT OTHER WOMEN TELL AS WELL. ALSO, HE DID NOT WANT TO REMOVE THE COILS. TYPICAL: OTHER GYNAECOLOGISTS ARE WILLING TO DO IT. SHE STATED ESSURE COILS WERE REMOVED A COUPLE OF MONTHS AGO. SHE DID NOT FEEL SEA SICK THE WHOLE TIME ANYMORE. PTC INVESTIGATION RESULT RECEIVED ON 28-MAY-2015: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL

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INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 28-MAY-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ALLERGY TO METALS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 115 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED NEWSPAPER CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL ALLERGY. THE DEVICES WERE REMOVED. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. THE CONSUMER, WHO WAS ALLERGIC TO NICKEL, STARTED EXPERIENCING COMPLAINTS 3 MONTHS AFTER ESSURE PLACEMENT AND HAD THE DEVICE REMOVED 3 YEARS LATER. SHE RELATED HER COMPLAINTS TO HER ALLERGY AND STATED SHE WAS FEELING BETTER WITH DEVICE REMOVAL. GIVEN THIS INFORMATION AND CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND HER COMPLAINTS; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICES REMOVAL (IMPLIED INTERVENTION) WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION CAN BE OBTAINED AS THIS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 02-JUL-2015 FROM (B)(6) HEALTH AUTHORITY (CASE#(B)(4)): THE PATIENT WAS (B)(6) AT TIME OF ESSURE INSERTION AND EVENTS. PATIENT HAD ESSURE STERILIZATION IN (B)(6) 2013. SHE HAS A NICKEL ALLERGY, BUT ACCORDING TO GYNECOLOGI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00386	BAYER HEALTHCARE LLC	6/11/2015	6/11/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/28/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5040228) IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. CONSUMER REPORTED THAT SHE HAD GOTTEN THE ESSURE PROCEDURE IN 2010, AFTER HER THIRD CHILD, AND IN 2015 SHE WOULD HAVE TO HAVE A FULL HYSTERECTOMY DUE TO ALL THE PAIN FROM THE COILS. SHE HAS BEEN HOSPITALIZED TWICE AND THE ONLY CONCLUSION WAS THE COILS. SHE HAD REALLY BAD PAINS, AWFUL HEADACHES. SHE HAD CT SCANS AND EVERYTHING LOOKED FINE, ULTRASOUND EVERYTHING WAS FINE. SHE SAW A DOCTOR ON (B)(6) 2015, AND HER SUGGESTION WAS TO REMOVE THE COILS BECAUSE THAT WHAT WAS CAUSING HER CONSTANT PAIN, DISCOMFORT, THE PAIN WAS LIKE BEING IN LABOR, ON AND OFF. CONSUMER WAS HOSPITALIZED LAST YEAR AND HAD AN GYNECOLOGIST CAME IN AFTER HAVING GI TEST (UNSPECIFIED) AND THAT DOCTOR ALSO TOLD HER SHE WANTED TO REMOVE HER TUBES TO TAKE OUT THE COILS, DUE TO THE FACT THAT ONE OF THEM WAS OUT OF PLACE AND IT WAS GOING TO CONTINUE TO CAUSE HER PAIN. CONSUMER ALSO MENTIONED THAT AFTER THE ESSURE PROCEDURE THE DOCTOR PUT HER TO SLEEP, SHE GOT AN INFECTION FROM IT, WAS SO SICK FOR 2 MONTHS, PUT STITCHES IN AND NEVER TOLD HER. SHE STATED THAT BECAUSE OF ALL THE COMPLICATIONS AFTER ESSURE PROCEDURE, SHE WOULD HAVE NEVER GOTTEN IT. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY

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MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INFECTION (INTERPRETED AS PELVIC INFECTION) AFTER ESSURE PROCEDURE. IT WAS ALSO REPORTED THAT DUE TO THE FACT THAT ONE OF THEM WAS OUT OF PLACE (INTERPRETED AS DEVICE DISLOCATION) AND IT WAS GOING TO CONTINUE TO CAUSE HER PAIN AND SHE WAS HOSPITALIZED TWICE. SHE WOULD HAVE TO HAVE A FULL HYSTERECTOMY DUE TO ALL THE PAIN FROM THE COILS. THE EVENT DEVICE DISLOCATION IS SERIOUS DUE TO HOSPITALIZATION AND THE EVENT PELVIC INFECTION IS SERIOUS DUE TO MEDICAL IMPORTANCE. BOTH ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. WITH REGARDS TO THE EVENT DEVICE DISLOCATION, THE EXACT DATE AND MECHANISM FOR THIS OCCURRENCE WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. WITH REGARDS TO THE EVENT PELVIC INFECTION, SINCE IT OCCURRED AFTER ESSURE PROCEDURE (PROBABLY IT OCCURRED WITHIN 4 WEEKS AFTER INSERTION), A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO HOSPITALIZATION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION (CONFIRM WHETHER FULL HYSTERECTOMY WAS PERFORMED) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 27-AUG-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00387	BAYER HEALTHCARE LLC	6/11/2015	6/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/1/2009
Explant Date (E7): 8/8/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5040275) IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT WITHIN MONTHS AFTER ESSURE INSERTION SHE STARTED HAVING ABDOMINAL PAIN, HEADACHES, WEIGHT GAIN, AND DEPRESSION. AS THE YEARS PROGRESSED HER SYMPTOMS WORSENED AND BECAME MORE COMPLEX. FOUR AND A HALF YEARS LATER SHE HAD DEBILITATING WIDE SPREAD PAIN, CHRONIC FATIGUE, AND SEVERE ABDOMINAL PAIN AS WELL AS BACK PAIN, BREAST PAIN, DIZZINESS, STABBING PELVIC PAIN, ANXIETY, PANIC ATTACKS, FREQUENT URINATION, BRAIN FOG, LOSS OF ENERGY, DENTAL ISSUES, EXCESSIVE VAGINAL DISCHARGE, LOTS OF YEAST INFECTIONS, ALLERGY AND SINUS PROBLEMS, PAINFUL INTERCOURSE, KIDNEY STONES, AND BLADDER INFECTIONS. HER DOCTORS DIAGNOSED HER WITH FIBROMYALGIA AND CHRONIC FATIGUE SYNDROME, ANXIETY AND DEPRESSION. ON (B)(6) 2014 ESSURE WAS REMOVED. NO ADDITIONAL INFORMATION WAS PROVIDED. THE SERIOUSNESS CRITERIA HOSPITALIZATION WAS MENTIONED IN THE SOURCE DOCUMENT IN THE SECTIONS EVENT REPORT TYPE AND EVENT OUTCOME BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP RECEIVED ON (B)(4) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER

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FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A FEW MONTHS LATER SHE EXPERIENCED SEVERE ABDOMINAL PAIN AMONG OTHER NON-SERIOUS EVENTS. ESSURE INSERTS WERE REMOVED APPROXIMATELY AFTER 5 YEARS. THIS EVENT IS SERIOUS DUE TO HOSPITALIZATION AND IMPLIED REQUIRED INTERVENTION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS ABDOMINAL PAIN IS LISTED. ABDOMINAL PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, A FEW MONTHS AFTER ESSURE INSERTION, SHE STARTED HAVING ABDOMINAL PAIN THAT WORSENED, AS YEARS PROGRESSED, TO A SEVERE ABDOMINAL PAIN FOUR AND A HALF YEARS LATER. SINCE ESSURE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED) THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 27-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00388	BAYER HEALTHCARE LLC	6/12/2015	6/12/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 624474

Single Use:
Implant Date (E6): 6/13/2007
Explant Date (E7): 9/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# (B)(4)) IN UNITED STATES ON 18-MAY-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007 (LOT NUMBER 624474). CONSUMER REPORTED THAT AFTER HAVING SOME PAIN, HER DOCTOR SENT HER FOR A SCAN IN 2014 AND THE RESULTS WERE THAT ONE COIL HAD MIGRATED TO HER UTERINE WALL. SHE MADE AN APPOINTMENT WITH HER GYNECOLOGIST AND A HYSTERECTOMY WAS SCHEDULED. BETWEEN TIME, SHE HAD DEVELOPED SHINGLES, EXTREME CHRONIC FATIGUE, BROKEN BONES, VITAMIN D DEFICIENCY, CONSTANT PROBLEMS WITH YEAST INFECTIONS AND BACTERIAL VAGINOSIS WHICH TOOK A COMPOUNDED MEDICATION TO GET RELIEF FROM, HIGHER (THAN HER NORMAL) BLOOD PRESSURE, AND FREQUENT URINATION. ON (B)(6) 2014, ESSURE WAS REMOVED. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 22-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT NUMBER 624474, PRODUCTION DATE: 5/2007, EXPIRATION DATE: 4/2009. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED

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ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ONE COIL HAD MIGRATED TO HER UTERINE WALL. A HYSTERECTOMY WAS SCHEDULED AND ESSURE WAS REMOVED. THIS EVENT, INTERPRETED AS EMBEDDED DEVICE, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF EMBEDMENT WERE NOT KNOWN, HOWEVER, GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION AND REMOVAL OF ESSURE. ADDITIONALLY, ANOTHER SERIOUS EVENT (BROKEN BONES, UNRELATED TO ESSURE) AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00389	BAYER HEALTHCARE LLC	6/12/2015	6/12/2015

Event Information:

Event Date (B3): 1/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2007
Explant Date (E7): 8/25/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE ((B)(4)) IN UNITED STATES ON 18-MAY-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007. CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN AN OUTPATIENT HOSPITAL PROCEDURE AND LESS THAN 6 MONTHS FOLLOWING ITS PLACEMENT, SHE BEGAN TO NOTICE INCREASED ABDOMINAL CRAMPING OUTSIDE OF MENSES, AND INTENSIFIED DURING MENSES. SHE EXPERIENCED THIS CONSISTENTLY WITH MODERATE TO SOMETIMES SEVERE PAIN. MENSES WERE AT TIMES HEAVIER THAN PRIOR TO THE PLACEMENT. DURING PHYSICAL ACTIVITIES LIKE EXERCISE THE PAIN INTENSIFIED MAKING IT DIFFICULT TO FINISH. CONSUMER ALSO REPORTED SEXUAL INTERCOURSE WAS PAINFUL, WITH A TIGHT SQUEEZING AND STABBING SENSATION STARTING ON BOTH SIDES OF HER PELVIC REGION AND LASTING FOR MORE THAN AN HOUR AFTER. SHE DID NOT HAVE THESE ISSUES UNTIL SHE HAD ESSURE IMPLANTED. SHE WAS TOLD BY A DOCTOR SHE WAS EXPERIENCING ALLERGIC REACTION TO THE COILS SO SHE FOUND A DOCTOR WHO WOULD REMOVE THE COILS, AND HAD THE PROCEDURE ON (B)(6) 2011. SHE MENTIONED THAT SHE WAS MISERABLE FOR THE 4 YEARS THEY WERE IMPLANTED. DUE TO UNAVAILABLE REPORTER CONTACT INFORMATION, NO FOLLOW UP IS POSSIBLE. PTC INVESTIGATION RESULT WAS RECEIVED ON 22-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE

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MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INCREASED ABDOMINAL CRAMPING OUTSIDE OF MENSES/ MODERATE TO SOMETIMES SEVERE PAIN, AND INTENSIFIED DURING PHYSICAL ACTIVITIES LIKE EXERCISE (INTERPRETED AS ABDOMINAL PAIN), AND AN ALLERGIC REACTION TO THE COILS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND THEY ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, THE CONSUMER STARTED EXPERIENCING THE ABDOMINAL PAIN LESS THAN 6 MONTHS FOLLOWING INSERTION. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE, ESPECIALLY THOSE WITH A HISTORY OF METAL ALLERGIES. IN THE PRESENT CASE, NO INFORMATION ON MEDICAL HISTORY WAS PROVIDED. IT IS NOT KNOWN WHETHER THE CONSUMER HAD A HISTORY OF METAL ALLERGY. NO TYPICAL ALLERGY SYMPTOMS WERE REPORTED. HOWEVER, GIVEN THE NATURE OF THE EVENT ALLERGIC REACTION TO THE COILS, CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE CONSUMER UNDERWENT REMOVAL OF THE COILS (INTERVENTION IMPLIED). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP IS NOT POSSIBLE DUE TO UNAVAILABLE REPORTER CONTACT INFORMATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00390	BAYER HEALTHCARE LLC	6/12/2015	6/12/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/5/2014
Explant Date (E7): 11/19/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# (B)(4)) IN UNITED STATES ON 18-MAY-2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER REPORTED THAT EVERYTHING WENT GREAT WHEN ESSURE WAS INSERTED, BUT COULD ONLY GET THE LEFT TUBE DONE. THEN WOKE UP WITH THE WORST PAIN SHE HAS EVER HAD ON HER LEFT SIDE. HER DOCTOR GOT HER IN THE OFFICE AND DID AN ULTRASOUND AND EVERYTHING LOOKED FINE, BUT WHEN SHE WOULD PUSH ON THAT SIDE THE PAIN WOULD BRING TEARS TO HER EYES. ON (B)(6) 2014, THEY DID A SURGERY TO REMOVE ESSURE AND HER TUBES. SHE HAD DEVELOPED A RASH ON HER CHEST THE DAY AFTER HER SURGERY. THE RASH WAS ALMOST GONE THREE DAYS LATER. A HOSPITALIZATION WAS MENTIONED BUT WAS NOT SPECIFIED AND/OR ASSIGNED TO AN EVENT. PTC INVESTIGATION RESULT WAS RECEIVED ON 26-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL

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CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A FEW DAYS LATER SHE EXPERIENCED THE WORST PAIN SHE EVER HAD IN HER LEFT SIDE. ESSURE INSERTS WERE REMOVED THE SAME MONTH. THIS EVENT, INTERPRETED AS ABDOMINAL PAIN, IS SERIOUS DUE TO HOSPITALIZATION AND IMPLIED REQUIRED INTERVENTION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS EVENT IS LISTED. ABDOMINAL PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE PATIENT STATED EVERYTHING WAS FINE AFTER INSERTION. HOWEVER, A FEW DAYS AFTER, SHE STARTED HAVING THE WORST PAIN EVER. HER DOCTOR DID AN ULTRASOUND AND EVERYTHING LOOKED FINE. CONSIDERING THE STRONG POSITIVE TEMPORAL RELATIONSHIP AND THAT THE PRESENCE OF A FOREIGN BODY IN THE FALLOPIAN TUBES MAY CAUSE THIS PAIN, THIS PAIN WAS CONSIDERED RELATED TO ESSURE. SINCE ESSURE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED) THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REG

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00391	BAYER HEALTHCARE LLC	6/12/2015	6/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/17/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5040317) IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. CONSUMER REPORTED THAT SINCE ESSURE WAS INSERTED SHE HAS HAD SERIOUS BLOATING, MENSTRUAL PERIODS THAT WOULD LAST 19 DAYS BE OFF HER CYCLE FOR 3 DAYS, JUST TO START ALL OVER AGAIN. SHE HAS HAD MUSCLE SPASMS IN HER BACK, ACNE/RASHES OVER FACE, NECK, BACK OF EARS, BACK AND CHEST, WHICH SHE DID NOT HAVE PRIOR. SHE HAD AN ABLATION IN 2013 TO HELP STOP THE HEAVY LONG MENSTRUAL CYCLES. SINCE THEN, HER SYMPTOMS HAVE GOTTEN WORSE EXCEPT FOR HER MENSTRUAL CYCLE HAS EASED UP EXCEPT FOR THE FACT THAT SHE NOW PASS LARGE BLOOD CLOTS. SHE HAD EXTREME FATIGUE, ANXIETY AND DEPRESSION AND AT TIMES SHE LOOK 5 MONTHS PREGNANT, WHICH NEVER HAD PRIOR. SHE RELATED ALL THE MENTIONED EVENTS TO ESSURE AND HER GYNECOLOGIST SCHEDULED HER AN APPOINTMENT WITH A PARTNERING SURGEON IN 1 WEEK TO HAVE A HYSTERECTOMY. NO ADDITIONAL INFORMATION WAS PROVIDED. THE SERIOUSNESS CRITERIA REQUIRED INTERVENTION WAS MENTIONED IN THE SOURCE DOCUMENT IN THE SECTION EVENT OUTCOME BUT IT WAS NOT SPECIFIED/ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE

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MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MENSTRUAL PERIODS THAT WOULD LAST 19 DAYS AND HEAVY AND LARGE BLOOD CLOTS. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, IT WAS REPORTED THAT SINCE INSERTION OF ESSURE, SHE EXPERIENCED THIS EVENT. SHE UNDERWENT AN ABLATION IN ORDER TO HELP STOP THE HEAVY LONG MENSTRUAL CYCLE. AFTER THAT, HER MENSTRUAL CYCLE HAS EASED UP EXCEPT FOR THE FACT THAT SHE PASSED LARGE BLOOD CLOTS. AN HYSTERECTOMY IS PLANNED. CONSIDERING POSITIVE TEMPORAL RELATIONSHIP AND GIVEN THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO ABLATION PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00392	BAYER HEALTHCARE LLC	6/12/2015	6/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/15/2013
Explant Date (E7): 8/6/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT SHE WAS IMPLANTED WITH THE ESSURE IN 2013 (SUPPOSED TO BE ONE METAL COIL IN EACH FALLOPIAN TUBE) AND TURNED OUT HER DOCTOR IMPLANTED IN THE RIGHT TUBE AND 2 IN THE LEFT TUBE (TOTAL OF 3) AND DID NOT INFORM HER OF SUCH. THE THIRD COIL PUNCTURED FROM HER TUBE AND CAUSED SEVERE BLEEDING AND SHE HAD TO HAVE EMERGENCY SURGERY TO HAVE HER REPRODUCTIVE ORGANS REMOVED. SHE WAS IN DEBILITATING PAIN FROM THE DATE OF IMPLANTATION AND IT TOOK DOCTORS 10 MONTHS TO FIND THE SOURCE OF THE PAIN. THERE WAS NO OPTION FOR HER BUT SURGERY AT THAT POINT. SHE SUFFERED IN PAIN UNTIL SHE STARTED BLEEDING HEAVILY AND BECOMING WEAK AND DIZZY AND HER NEW DOCTOR DECIDED TO REPEAT THE X-RAY AND FIND THE PROBLEM IN 2014 AND DID EMERGENCY SURGERY THAT DAY TO KEEP HER FROM BLEEDING TO DEATH. ON (B)(6) 2014 ESSURE WAS REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR

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CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD 3 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTS IMPLANTED. ONE INSERT WAS PLACED IN THE RIGHT TUBE AND 2 IN THE LEFT TUBE (TOTAL OF 3). THE THIRD COIL PUNCTURED FROM HER TUBE AND CAUSED SEVERE BLEEDING. SHE HAD HER REPRODUCTIVE ORGANS REMOVED ALONG WITH ESSURE INSERTS APPROXIMATELY 10 MONTHS AFTER INSERTION. THE EVENTS, SEEN AS GENITAL BLEEDING AND FALLOPIAN TUBE PERFORATION, ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THESE EVENTS ARE LISTED. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, THE SEVERE BLEEDING STARTED AFTER INSERTION. CONSIDERING THAT THE PHYSICIAN PLACED 2 INSERTS ON ONE SIDE AND THAT THIS MIGHT HAVE CAUSED THE FALLOPIAN TUBE PERFORATION WHICH MAY HAVE CONTRIBUTED TO THE SEVERE BLEEDING, THE EVENTS OF PERFORATION AND BLEEDING ARE CONSIDERED RELATED TO ESSURE. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REG

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00394	BAYER HEALTHCARE LLC	6/12/2015	6/12/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/9/2009
Explant Date (E7): 12/31/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PROFUSE BLEEDING EVERY MONTH DUE TO ESSURE, DIZZINESS, EXTREME LOWER BACK PAIN, KNEE AND HIP PAIN, PELVIC AREA PAIN, HEADACHE, AND TO FATIGUED TO CARRY OUT DAILY ACTIVITIES. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. IN (B)(6) 2009 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT SINCE THE BEGINNING SHE PRESENTS PROFUSE BLEEDING EVERY MONTH DUE TO ESSURE, DIZZINESS, EXTREME LOWER BACK PAIN, KNEE AND HIP PAIN, PELVIC AREA PAIN, HEADACHE, AND TO FATIGUED TO CARRY OUT DAILY ACTIVITIES. THE OUTCOME OF THE EVENTS PROFUSE BLEEDING EVERY MONTH DUE TO ESSURE, DIZZINESS, EXTREME LOWER BACK PAIN, KNEE AND HIP PAIN, PELVIC AREA PAIN, HEADACHE, AND TO FATIGUED TO CARRY OUT DAILY ACTIVITIES WAS NOT RECOVERED / NOT RESOLVED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: THE LOCAL HEALTH AUTHORITY WAS ADDED AS REPORTER UNDER THE REFERENCE NUMBER (B)(4). ON (B)(6) 2009 ESSURE WAS IMPLANTED. IT WAS REPORTED THAT AFTER THE IMPLANTATION OF THE ESSURE DEVICE SHE BLED FOR 47 DAYS STRAIGHT. IRON LEVELS FELL AND SHE WAS GIVEN A SPECIAL DIET AND IRON PILLS. AFTER THE BLEEDING STOPPED SHE NOTICED A NAGGING PAIN ON THE RIGHT SIDE AND THEN IN HER LOWER BACK. SHE WOULD TELL HER GYNECOLOGIST AND HE SNUBBED HER OFF. SHE FELT LIKE SHE WAS BULLIED INTO THAT BECAUSE HE WAS SUPPOSED TO TIE AND CUT HER TUBES AFTER SHE GAVE BIRTH. SHE WOULD HAVE THIRD CHILD NATURAL WITHOUT AN EPIDURAL BUT SHE GOT IT SO THAT HER TUBES COULD BE TIED. AT THE END OF 2009 HER CYCLE

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BEGAN, BLEEDING PROFUSELY, AND PAINFULLY. I LASTED ABOUT A FULL WEEK AND APPROXIMATELY 12 DAYS LATER IT CAME BACK. SHE THOUGHT SHE WAS CRAZY. FROM 2009 TO 2014 SHE HAD 2 PERIODS A MONTH. SHE EXPERIENCED EXTREME FATIGUE, LOWER ABDOMINAL PAIN, LOWER BACK PAIN, HEADACHES, NAUSEA, PAIN IN THE SAME SPOT ON THE RIGHT SIDE OF HER LOWER STOMACH, SWELLING THAT HAS PLAGUED HER SINCE 2009. IN 2012 SHE CHANGED THE DOCTORS AND A SONOGRAM WAS PERFORMED WHICH SHOWED THAT THE ESSURE WERE STILL IN PLACE BUT SEEMED LOW. IN 2014 SHE WAS FED UP AND WENT BACK TO HER NEW DOCTOR. SHE DISCOVERED SHE HAD POLYPS ALL AROUND THE OPENINGS OF HER FALLOPIAN TUBES. SO, SHE HAD AN EMERGENCY D AND C PERFORMED TO REMOVE ALL OF THEM AND A HYSTEROSCOPY AND THE REASON HE SUGGESTED THAT WAS BECAUSE SHE HAD BEEN BLEEDING CLOTS THE SIZE OF A LARGE PRUNE. SO, POST D AND C SHE STILL HAD 2 PERIODS A MONTH IN BETWEEN BLEEDING. SUPER PLUS TAMPONS ALONG WITH OVERNIGHT PADS EVERY 2 TO 30 MINUTES MUST BE CHANGED. THE FATIGUE WAS BACK WITH A VENGEANCE. SHE HAD A CYST ON HER LEFT OVARY, AND AT THE TIME OF THIS REPORT SHE WAS HAVING THE PAINS SHOOTING UP AND DOWN HER LEGS ON BOTH SIDES WITH THAT STABBING PAIN FROM HER RIGHT NOW ON THE LEFT IN THE FRONT AND THE BACK OF HER STOMACH AND LOWER BACK, HEADACHES, REPEATED NAUSEA, ETC. SHE WENT BACK FOR ANOTHER SONOGRAM TO SEE WHY AFTER 5 YEARS SHE WAS STILL HURTING AND PAIN. SHE FELT STABBING PAIN IN BETWEEN PERIODS AND EVERY MONTH IT SWAPS SIDES. BECAUSE SHE HAD 2 PERIODS A MONTH SHE EXPERIENCED THAT PAIN ON EITHER SIDE TWICE A MONTH EVERY MONTH. SHE BLED INTO THE SEAT OF CARS 20 MINUTES AFTER SHE LEFT FOR WORK, FELT FAINT AND ALL STARTED AFTER ESSURE. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2014. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. HOWEVER, THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE EVENTS WERE REPORTED OVER A LONG PERIOD OF 5 YEARS AND ARE OF BROAD NATURE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON (B)(6) 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. FOLLOW-UP RECEIVED ON (B)(6) 2015: INFORMATION RECEIVED STATES THAT CONSUMER HAD ESSURE EXPLANTED ON (B)(6) 2014. THE SERIOUSNESS CRITERIA REQUIRED INTERVENTION WAS MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS FOLLOW-UP RECEIVED ON (B)(6) 2015 FROM CONSUMER: SHE STATED THAT RETAINED AN ATTORNEY. THIS IS NOW CLASSIFIED AS LEGAL CASE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER INSERTION BLED FOR 47 DAYS STRAIGHT, LATER AT ULTRASOUND ESSURE WERE STILL IN PLACE BUT SEEMED LOW AND SHE DEVELOPED POLYPS ALL AROUND THE OPENING OF HER FALLOPIAN TUBES. THIS CASE IS POTENTIAL LEGAL CASE. THESE EVENTS WERE CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE EXCEPT THE EVENT POLYPS WHICH ARE UNLISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; THEREFORE, A CAUSAL RELATIONSHIP BETWEEN BLED FOR 47 DAYS STRAIGHT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. ALSO DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION

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(INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALTHOUGH LIMITED INFORMATION WAS PROVIDED ABOUT THE EVENT ESSURE WERE STILL IN PLACE BUT SEEMED LOW, GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. REGARDING POLYPS ALL AROUND THE OPENING OF HER FALLOPIAN TUBES, ENDOMETRIAL POLYPS ARE ONE OF THE MOST COMMON ETIOLOGIES OF ABNORMAL GENITAL BLEEDING IN BOTH PREMENOPAUSAL AND POSTMENOPAUSAL WOMEN. ENDOMETRIAL HYPERPLASIA, OVEREXPRESSION OF AROMATASE, AND GENE MUTATIONS HAVE BEEN PROPOSED TO PLAY A ROLE IN THEIR DEVELOPMENT. IN THIS PARTICULAR CASE, CONSUMER REPORTED CHANGES IN MENSTRUAL BLEEDING AFTER ESSURE INSERTION, LATER SHE WAS DIAGNOSED WITH POLYPS AND TREATED WITH HYSTEROSCOPY AND DILATION/CURETTAGE. CONSIDERING POLYP'S PHYSIOPATHOLOGY AND ESSURE LOCAL ACTION A CAUSAL RELATIONSHIP WITH THIS INSERT WAS CONSIDERED VERY UNLIKELY. THIS CASE WAS UPGRADED TO INCIDENT SINCE ESSURE EXPLANT DATE WAS REPORTED (INTERVENTION IMPLIED). ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. ADDITIONAL INFORMATION WILL BE OBTAINED THROUGH THE NORMAL LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043124	BAYER	6/12/2015	6/22/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN ME ABOUT 4 YEARS AGO. SINCE THEN I'VE GAINED WEIGHT, GET MIGRAINES AND BREAK OUT WITH RASHES AROUND HIP AND STOMACH AREA. NOT TO MENTION DEPRESSION AND NOT HAVING ANY ENERGY, AND BEING VERY FORGETFUL AT TIMES. I'VE NOTICED THESE SYMPTOMS WEEKS AFTER HAVING THE ESSURE IMPLANTED. MY PERIODS ARE HEAVY NOT TO MENTION MY CRAMPS ARE HORRIBLE. I FEEL AS I AM GOING INTO LABOR.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00393	BAYER HEALTHCARE LLC	6/12/2015	7/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38209

Single Use: *
Implant Date (E6): 5/12/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 18-MAY-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION (LOT NUMBER C38209). NO PREGNANCY WAS REPORTED. PHYSICIAN STATED THAT, DURING THE ESSURE INSERTION PROCEDURE, THE LEFT INSERT CONTAINED AN EXTRA PIECE OF METAL AND THE DEVICE DID NOT DEPLOY PROPERLY. HE HAD TO WORK HARD TO REMOVE THE PIECE OF METAL. THERE WERE 3 TRAILING COILS OUTSIDE THE LEFT OS. PRODUCT TECHNICAL COMPLAINT ANALYSIS WAS RECEIVED ON 11-JUN-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF

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THE MANUFACTURING BATCH RECORD C38209 (PRODUCTION DATE 19-MAR-2014 AND EXPIRATION DATE 31-MAR-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND DEPLOYMENT DIFFICULTY IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, PHYSICIAN NOTED THE LEFT INSERT CONTAINED AN EXTRA PIECE OF METAL. THIS EVENT, REGARDED AS DEVICE BREAKAGE, IS LISTED (ANTICIPATED) ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, CONSIDERING THE EVENT OCCURRED DURING ESSURE INSERTION PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 27-AUG-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION I

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00395	BAYER HEALTHCARE LLC	6/12/2015	7/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SW

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38215

Single Use:
Implant Date (E6): 2/4/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 5/11/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN (B)(6) ON 16-MAR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE DEVICE DID NOT RELEASE THE CORRECT WAY AT TIME OF INSERTION. THE PATIENT IS OK. FOLLOW-UP INFORMATION RECEIVED ON 13-MAY-2015 FROM PHYSICIAN. ADDITIONAL INFORMATION RECEIVED ON 15-MAY-2015: PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION. THIS CASE REFERS TO A (B)(6) FEMALE PATIENT. ON (B)(6) 2015, ESSURE LOT NUMBER C38215 WAS INSERTED. ACCORDING TO THE PHYSICIAN, AS INSERTING AFTER PRESSING THE RELEASE BUTTON THE IMPLANT DID NOT COME LOOSE. WHEN THE CATHETER WAS WITHDRAWN THE INNER COIL WAS EXTENDED. ESSURE WAS NOT REMOVED. PATIENT HAD NO INJURY AND SHE WAS RECOVERED FROM THE EVENT. PHYSICIAN STATED THE EVENT COULD NOT HAVE LED TO SERIOUS INJURY UNDER LESS FORTUNATE CIRCUMSTANCES. REPORTED ALSO PROVIDED (B)(6) 2015 AS EVENT DATE (DISCREPANCY). INITIAL PRODUCT TECHNICAL COMPLAINT INVESTIGATION (UPDATED ANALYSIS WITH THE PROVIDED LOT NUMBER WAS REQUESTED): THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: THE COMPLAINANT DESCRIBES AN EVENT WHERE THERE WAS DIFFICULTY GETTING THE INSERT TO RELEASE FROM THE CATHETER. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND

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POTENTIAL MANUFACTURING DEFICIENCIES. AS OF MAY 12, 2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS TO A USABILITY ISSUE. NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 18-MAY-2015. ADDITIONAL INFORMATION (UPDATED PTC RESULTS) RECEIVED ON 21-MAY-2015: THE (B)(6) HEALTH AUTHORITY INFORMED THAT THE MEDICAL PRODUCTS AGENCY HAS ANALYSED THE INFORMATION GIVEN TO THEM AND HAVE DECIDED TO CLOSE THE FILE ON THIS CASE. NO CLINICAL NEW INFORMATION WAS RECEIVED FROM THE HEALTH AUTHORITY. PTC RESULTS WERE UPDATED BASED ON THE REPORTED LOT NUMBER C38215 AND ON THE SAMPLE RECEIVED AT MANUFACTURER. (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: ROLLBACK TO INITIAL HARD STOP; DEPRESS BUTTON; PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. WE TYPICALLY INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. THE DEVICE WAS RECEIVED WITHOUT MICRO-INSERT. ALL IFU STEPS WERE COMPLETED. THE CATHETER LARGE TIGHT PITCH COIL FOUND TO BE STRETCHED AND BROKEN. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. WE ALSO CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. THE RETURNED COMPLAINT SAMPLE WAS INVESTIGATED. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. CASE CONSIDERED OTHER REPORTABLE INCIDENT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 27-MAY-2015 FOR THE

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FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 1006 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A 38 YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE DEVICE DID NOT RELEASE THE CORRECT WAY; WHEN PHYSICIAN REMOVED THE CATHETER THE INNER COIL WAS EXTENDED; ESSURE INSERT WAS LEFT IN PLACE AND PATIENT HAD NO INJURY. ALL THE EVENTS WERE CONSIDERED NON-SERIOUS AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, A PRODUCT TECHNICAL ANALYSIS (PTC) WAS PERFORMED WITH ANALYSIS OF THE COMPLAINT SAMPLE (WHICH INCLUDED THE DEVICE WITHOUT THE MICRO-INSERT). AT COMPLAINT SAMPLE INSPECTION THE CATHETER LARGE TIGHT PITCH COIL WAS FOUND TO BE STRETCHED AND BROKEN. THE PTC ANALYSIS CONCLUDED THAT THE REPORTED DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT AND CONSIDERED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT. HOWEVER, UPON RECEIPT OF COMPLAINT SAMPLE ANALYSIS (WHICH REVEALED A DEVICE BREAKAGE), IT WAS AMENDED TO OTHER REPORTABLE INCIDENT; AS ALTHOUGH PATIENT HAD NO SERIOUS INJURY THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043126	BAYER	6/13/2015	6/22/2015

Event Information:

Event Date (B3): 12/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/10/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE SHOULD BE TAKEN OFF THE MARKET. I'VE HAD NOTHING BUT PROBLEMS SINCE I HAD MINE PUT IN AROUND 2011/2012, DOCTORS SHOULD NOT RECOMMEND THIS PRODUCT. I GET HORRIBLE OVARIAN CYSTS WHERE ONE OF THE COILS IS LOCATED AT, I'VE HAD UTERINE BLEEDING FROM THIS PRODUCT, PLEASE BE AWARE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043136		6/13/2015	6/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/15/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE DONE BACK IN 2011. FROM THE START I KNEW SOMETHING WAS WRONG. I HAVE BEEN AT THE HOSP SEVERAL TIMES AND TO MY FAMILY PHYSICIAN FOR PAIN SWELLING AND HEAVY BLEEDING. I HAVE BEEN SO MANY TIMES THAT I CAN'T GET HELP ANY MORE. I LIVE IN PAIN EVERY DAY. EVERYONE SAYS THE SAME THING. THAT IT NEEDS TO COME OUT, BUT NO ONE IS WILLING TO DO IT. I HAVE TRIED GOING BACK TO (B)(6) BUT DR. (B)(6) SAYS HE DID NOTHING WRONG. I HAVE TALKED TO SEVERAL LAWYERS BUT NONE WILL HELP SAYING IT'S A CONFLICT OF INTEREST BECAUSE THEIR WIVES USE (B)(6). I JUST REALLY WANT HELP, I HAVE LOST SEVERAL JOBS BECAUSE OF TAKING TIME OFF FROM WORK DUE TO PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043156	BAYER-CONCEPTUS	6/13/2015	6/22/2015

Event Information:

Event Date (B3): 6/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): 748469
Lot #(E4): ESS305

Single Use:
Implant Date (E6): 11/12/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2010 IN MY DOCTOR'S OFFICE. A FEW DAYS AFTER THE PROCEDURE, I WOUND UP WITH A TERRIBLE VAGINAL INFECTION. MY PERIODS ARE HEAVIER THAN THEY WERE PRIOR TO THE PROCEDURE, LAST 8-10 DAYS ON AVERAGE. I HAVE CONSTANT PAIN IN MY LEFT OVARY AND HAVE GONE TO THE EMERGENCY ROOM ON SEVERAL OCCASIONS DUE TO THE INTENSITY OF THE PAIN. I WAS TOLD THAT THE DEVICE IS PLACED CORRECTLY. THE DOCTOR WHO DID THE PROCEDURE WAS TOLD ME THE ONLY WAY TO RECTIFY THE ISSUES IS WITH A HYSTERECTOMY, AND THE LEFT OVARY WOULD ALSO NEED TO BE REMOVED. I HAVE HAD NO PRIOR HISTORY OF MIGRAINE HEADACHES UNTIL I HAD THIS PROCEDURE. SINCE THE PROCEDURE, I HAVE HAD MIGRAINE HEADACHES AT LEAST 4-5 PER WEEK. THE DOCTOR STATES THE TWO ARE UNRELATED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043157	BAYER	6/13/2015	6/22/2015

Event Information:

Event Date (B3): 4/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/13/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE 2 YEARS AGO SINCE THEN I HAVE BEEN EXPERIENCING SEVERAL SYMPTOMS, SUCH AS PELVIC PAIN, PAINFUL CRAMPING, FATIGUE, NAUSEA AND LOTS OF DISCOMFORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00397	BAYER HEALTHCARE LLC	6/15/2015	6/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN UNITED STATES ON 21-MAY-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR PERMANENT STERILIZATION. IT WAS REPORTED THAT DEVICE PERFORATED THROUGH PATIENT´S FALLOPIAN TUBE ON AN UNKNOWN DATE. HCP (HEALTH CARE PROFESSIONAL) SURGICALLY REMOVED ESSURE ON (B)(6) 2015; IT SOUNDED LIKE JUST ONE SIDE WAS REMOVED. ESSURE CONTINUED IN ONE SIDE ONLY. PTC INVESTIGATION RESULT WAS RECEIVED ON 27-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

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COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE PERFORATED THROUGH PATIENT'S FALLOPIAN TUBE. ESSURE WAS SURGICALLY REMOVED. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/ FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE), INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THE PRESENT CASE, THE TIME INTERVAL BETWEEN ESSURE INSERTION AND THE DIAGNOSIS OF PERFORATION WAS NOT REPORTED. HOWEVER, CONSIDERING THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REPORTED SURGICAL INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00398	BAYER HEALTHCARE LLC	6/15/2015	6/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4)2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ON AN UNSPECIFIED DATE, ESSURE WAS REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON AN UNSPECIFIED DATE, ESSURE WAS REMOVED. THIS EVENT, CONSIDERED AS DEVICE

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MEDICAL REMOVAL, WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, NEITHER THE EXACT REASON FOR ESSURE REMOVAL NOR THE TYPE OF SURGERY WERE PROVIDED. NEVERTHELESS, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE TOTALLY EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 02-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00399	BAYER HEALTHCARE LLC	6/15/2015	6/15/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/25/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ANTICIPATED INCIDENT (SERIOUS INJURY-REQUIRED INTERVENTION). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO HERSELF. SHE IS A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. CONSUMER REPORTED THAT ONE ESSURE COIL HAD PERFORATED THE UTERINE WALL AND CAUSED DAMAGE TO THE UTERINE WALL, GREAT PAIN AND EXTREME CONTINUOUS BLEEDING. UPON REMOVAL OF THIS COIL ON (B)(6) 2009 IT SHOWED THE OTHER ESSURE COIL DISAPPEARED AND IT WAS APPARENTLY SPONTANEOUSLY REPELLED AFTER PREVIOUS CHECKS WHICH ESTABLISHED THAT IT WAS SITTING CORRECT. CONSUMER WAS THEREFORE UNPROTECTED AGAINST PREGNANCY WITHOUT THIS KNOWLEDGE. MOREOVER, SHE COULD NOT BECOME PREGNANT BECAUSE INTERCOURSE WAS IMPOSSIBLE BECAUSE OF THE PAIN. IN THE COURSE OF TIME, AFTER INSERTION, SHE HAD MORE AND MORE ALLERGIC SYMPTOMS, INFLAMMATION, AND FATIGUE. PAIN, BLEEDING, ALLERGIC SYMPTOMS, INFLAMMATION, AND FATIGUE CONTINUE UP TO THE DATE OF REPORT. THE ESSURE COIL WAS NOT ENTIRELY REMOVED, MATERIAL APPEARED TO HAVE REMAINED BEHIND. CONSUMER DID NOT REPORT THE TIME BETWEEN INSERTION AND THE REPORTED COMPLAINTS. FOLLOW UP (B)(4) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ESSURE HAD PERFORATED THE UTERINE WALL AND CAUSED EXTREME CONTINUOUS BLEEDINGS. THE OTHER ESSURE COIL DISAPPEARED. THESE EVENTS WERE RESPECTIVELY INTERPRETED AS UTERINE PERFORATION, GENITAL BLEEDING, ESSURE DISLOCATION. ALL THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND UTERINE PERFORATION IS ALSO SERIOUS DUE TO REQUIRED INTERVENTION. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THESE EVENTS ARE LISTED. IN THIS CASE, THE CONSUMER UNDERWENT EXAMS ESTABLISHING THAT THE INSERTS WERE CORRECTLY PLACED. HOWEVER, THE CONSUMER WAS EXPERIENCING EXTREME CONTINUOUS BLEEDING AND UPON REMOVAL IT WAS OBSERVED THAT ONE OF THE COILS HAD PERFORATED THE UTERINE WALL AND THE OTHER COIL DISAPPEARED. THE EXACT ONSET DATES OF THESE EVENTS ARE NOT CLEAR, BUT THEY OCCURRED AFTER ESSURE INSERTION. CONSIDERING THIS POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THESE EVENTS, THEY WERE CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION TO REMOVE ESSURE INSERTS. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 26-JUN-2015: CONSUMER DID NOT RESPOND TO INFORMED CONSENT REQUEST. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A S

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043131	BAYER	6/15/2015	6/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL PUT IN ABOUT 6 YEARS AGO AND HAVE HAD TREMENDOUS PAIN IN MY ABDOMEN AREA. WENT TO THE DOCTOR AND THEY CAN'T FIND OUT WHAT'S WRONG. IT HURTS SO BAD THAT I CRY AND BEND OVER IN PAIN. I'VE HAD 3 CHILDREN AND ONE NATURAL AND STILL HAVE NEVER FELT THIS MUCH PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043135		6/15/2015	6/22/2015

Event Information:

Event Date (B3): 4/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/30/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED AFTER MY THIRD CHILD. ON (B)(6), I HAD THE PROCEDURE PLACED. AN HOUR AFTER LEAVING, I CALLED MY DOCTOR COMPLAINING AND CRYING OF PAIN THAT I THOUGHT WAS TOO INTENSE TO BE NORMAL. I WAS LAUGHED OFF AND TOLD TO USE A HEATING PAD. SO FEELING DISMISSED, I TOUGHED IT OUT. HAVING A (B)(6), (B)(6) OLD AND A (B)(6) IS A CHALLENGE FOR ANY PERSON, BUT HAVING TO SMILE THROUGH THE PAIN OF BODY ACHES, PELVIC PAIN AND SPASMS AND CONSTANT BLEEDING HAS TAKEN THE JOY OUT OF MY LIFE. I WENT TO THE ER COMPLAINING OF PAIN AND THEY HAD NEVER HEARD OF THE PROCEDURE AT ALL. THEN I F/U WITH MY DOCTOR WHO TOLD ME I WAS CRAZY AND NO WAY I WAS ABLE TO FEEL THE COILS. EVEN AFTER I SHOWED HIM MY RAISED PELVIS AND HAD HIM FEEL THE COILS, HE CHOSE THE FIRST BITE ON MY LEG THAT HE SAW AND SAID YOU PROBABLY HAVE TICK FEVER. I WAS SO INSULTED. I DON'T WANT TO RETURN IF HE WON'T LISTEN TO MY CONCERNS. I HAVE BEEN SHUT DOWN AND NO ONE WILL HELP ME GET JUSTICE FOR THE HORRIBLE PRODUCT THAT WAS PLACED INSIDE OF ME. I WAS TOLD NO PAIN, NO SIDE EFFECTS, NO RISK. THAT WAS THE WORST MISTAKE OF MY LIFE IN ACCEPTING THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043139	BAYER	6/15/2015	6/22/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ABOUT 5 YEARS AGO AND EVER SINCE I HAVE BEEN IN CONSTANT PAIN, HAD WEIGHT GAIN, HAIR FALLING OUT, ACNE, IRREGULAR MENSTRUAL CYCLES, DIZZINESS, LIGHTHEADED, NUMBNESS IN HANDS, HIGH BLOOD PRESSURE, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043143		6/15/2015	6/22/2015

Event Information:

Event Date (B3): 5/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): B94870

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

BEEN HAVING MORE PAIN IN BACK, ABDOMEN, LEGS, HIPS, HEADACHES, LIGHT HEADED, ACHY BODY, WORSE DEPRESSION, HEAVY FLOW ON PERIOD, LOT OF CLOTS WHEN ON PERIOD AND HAVING PERIOD LONGER, ABOUT TWICE A MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043148		6/15/2015	6/22/2015

Event Information:

Event Date (B3): 2/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/20/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE IMPLANTED INSIDE ME I HAVE HAD A CYST BURST ON MY LEFT OVARY, MAJOR PAIN IN MY LOWER ABDOMEN, HAIR LOSS, WORSE PERIOD CRAMPS, LONGER AND HEAVIER PERIODS WITH LOSING MORE BLOOD, BLOOD CLOTS QUARTER SIZE OR LARGER. I'VE BEEN TO THE EMERGENCY AND OB DOCTOR MANY TIMES FOR THE PAIN. NOW HAVING TO GO THROUGH GETTING PART OF MY CERVIX CUT OUT TO CHECK FOR CANCER AND DEALING WITH THAT PAIN SO I CAN BE SET UP FOR A HYSTERECTOMY AT THE AGE OF (B)(6) TO GET THE ESSURE OUT OF ME. ALSO HAD TO HAVE BLOOD WORK DONE. NEVER EVEN GOT A CARD WITH THE MODEL NUMBER OR ANYTHING ON IT SHOWING I HAVE THE ESSURE INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00396	BAYER HEALTHCARE LLC	6/15/2015	7/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61994

Single Use: *
Implant Date (E6): 5/21/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE LOT NUMBER USED WAS C61994. ADDITIONAL INFORMATION WAS RECEIVED ON 25-MAY-2015. THE PHYSICIAN REPORTED THAT AFTER INSERTION THE COIL HAS BEEN ATTACHED TO THE FALLOPIAN TUBE AND A GREEN PLASTIC PIECE HAS BEEN ATTACHED TOO. THE PHYSICIAN EXPLAINED THAT THE PIECE OF THE CATHETER WAS STILL INSERTED. THEY WILL TRY TO REMOVE IT. SHE ALSO REPORTED THAT THE PATIENT HAD A VASOVAGAL REACTION. THE PATIENT RECOVERED. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER INSERTION, THE COIL WAS ATTACHED TO THE FALLOPIAN TUBE AND A GREEN PLASTIC PIECE WAS ATTACHED TOO (REGARDED AS DEVICE BREAKAGE). THE PHYSICIAN EXPLAINED THAT THE PIECE OF THE CATHETER WAS STILL INSERTED. THEY WILL TRY TO REMOVE IT. DEVICE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MOSTLY DURING DIFFICULT REMOVALS. IN THIS CASE, THE PHYSICIAN STATED THAT AFTER INSERTION, A GREEN PIECE (CATHETER) WAS ALSO ATTACHED IN THE FALLOPIAN TUBE. THE PIECE OF CATHETER WAS STILL INSERTED BUT AN ATTEMPT TO REMOVE IT WILL BE MADE. CONSIDERING THE EVENT OCCURRED ASSOCIATED TO INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL COMPLAINT ANALYSIS AND FURTHER INFORMATION ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP FROM 30-NOV-2015: NO FOLLOW-UP INFORMATION WAS OBTAINED FROM THE REPORTER DESPITE ATTEMPTS. THE REGULATORY AUTHORITY NUMBER FOR THIS CASE IS (B)(4). COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00400	BAYER HEALTHCARE LLC	6/16/2015	6/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 20-MAY-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ON AN UNSPECIFIED DATE, ESSURE WAS REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 27-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). NERVUS FEMORALIS.. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THEN HAD ESSURE REMOVED. IF ESSURE REMOVAL IS NECESSARY, SURGERY MAY BE REQUIRED. IN THIS CASE,

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LIMITED INFORMATION WAS PROVIDED. HOWEVER, GIVEN EVENT'S NATURE, CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED. SINCE DEVICE REMOVAL WAS REPORTED (INTERVENTION IMPLIED) THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 02-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00401	BAYER HEALTHCARE LLC	6/16/2015	6/16/2015

Event Information:

Event Date (B3): 4/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A73746

Single Use: Y
Implant Date (E6): 4/12/2013
Explant Date (E7): 7/30/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER STATED THAT IMMEDIATELY AFTER INSERTION SHE EXPERIENCED SEVERE PAIN, THE PAIN WAS RIGHT SIDED AND SHE FELT LIKE SOMETHING WAS DIGGING INTO HER. THIS CAUSED DISCOMFORT AND AFFECTED HER ABILITY TO EXERCISE AND TO WORK. SHE ALSO EXPERIENCED ABDOMINAL CRAMPING AND BLOATING. ON (B)(6) 2013, ESSURE WAS EXPLANTED SURGICALLY LEAVING HER WITH 2 SCARS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMMEDIATELY AFTER IMPLANT SHE EXPERIENCED SEVERE PAIN, THE PAIN WAS RIGHT SIDED. ESSURE WAS SURGICALLY EXPLANTED 3 MONTHS AFTER INSERTION. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, CONSUMER REPORTED THE PAIN STARTED IMMEDIATELY AFTER INSERTION. THEREFORE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE SURGICAL INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

INTERNAL COMMUNICATION RECEIVED ON 04-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00403	BAYER HEALTHCARE LLC	6/16/2015	6/16/2015

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 827945

Single Use: Y
Implant Date (E6): 6/24/2011
Explant Date (E7): 11/17/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO THE CONSUMER HERSELF OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011; THE LOT NUMBER USED WAS 827945. CONSUMER STATED THAT SHE HAD A DRASTIC HIT IN HER OVERALL HEALTH. THE PAIN STARTED 8 WEEKS AFTER THE PROCEDURE AND FATIGUE, BRAIN FOG, MIGRAINES, CONSTANT BLADDER PAIN AND INFECTIONS, ALL OVER BODY ACHES, INSOMNIA, MOOD SWINGS, HORRIFIC MENSTRUAL CYCLES, PAINFUL INTERCOURSE, AND WEIGHT GAIN FOLLOWED SOON AFTER. THE HIP PAIN WAS SO BAD THAT SHE COULD NOT STAND UP WITHOUT HELP. SHE HAD 4 CHILDREN AND THEY HAVE LOST THEIR MOM FOR 3 YEARS. SHE WAS NOT ABLE TO DO THE THINGS THAT SHE USED TO DO. SHE WAS DIAGNOSED WITH FIBROMYALGIA AND PUT ON PAIN MEDICATION THAT MADE HER SICKER. SHE FINALLY FOUND THAT SHE WASN'T THE ONLY ONE WITH THESE PROBLEMS AND WENT TO HER GYNECOLOGIST AND TALKED TO HIM. ON (B)(6) 2014 SHE HAD A COMPLETE HYSTERECTOMY AND ESSURE REMOVAL AND NOTICED HER HIP PAIN WAS GONE INSTANTLY. SHE STATED THAT SHE WAS STARTING TO GET HER LIFE BACK AFTER GETTING ESSURE OUT OF HER. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 03-JUN-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). PRODUCTION DATE: FEB-2011 AND EXPIRATION DATE: FEB-2014. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, THEY CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS.

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THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE WAS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PAIN STARTED 8 WEEKS AFTER THE PROCEDURE (INTERPRETED AS PELVIC PAIN), SHE ALSO REPORTED HIP PAIN THAT WAS SO BAD SHE COULDN'T STAND UP WITHOUT HELP. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE REMAINING EVENT IS UNLISTED. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE THE CONSUMER INFORMED THAT THE PAIN STARTED 8 WEEKS AFTER THE PROCEDURE. THEREFORE GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. SHE UNDERWENT A HYSTERECTOMY AND ESSURE REMOVAL 3 YEARS AFTER INSERTION AND NOTICED THE HIP PAIN WAS GONE INSTANTLY; THEREFORE THIS EVENT WAS ALSO ASSESSED AS RELATED TO ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED HYSTERECTOMY. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE WAS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00404	BAYER HEALTHCARE LLC	6/16/2015	6/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/8/2008
Explant Date (E7): 1/22/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5040345) IN UNITED STATES ON 22-MAY-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. AFTER HAVING THE PROCEDURE DONE SHE STARTED HAVING PROBLEMS LIKE HEADACHES, BACKACHES, PROBLEMS WITH INTIMACY, SWELLING AND ABDOMINAL PAIN. SHE WENT TO HER REGULAR DOCTOR AND THEY TOOK BLOOD TESTS, ULTRASOUNDS, OTHER TESTS TO SEE WHAT WAS GOING ON AND WHEN SHE MENTIONED ABOUT HER INTIMACY, THEY TOLD HER THAT SHE NEEDED TO SEE HER GYNECOLOGIST. THIS HAD BEEN WITHIN A YEAR OF HAVING THE ESSURE PUT IN. WHEN SHE NOTICED THAT THE HEADACHES WERE NOT GOING AWAY AND THE NAUSEA, THE BACK ACHES, STOMACH PAINS, BLOATING HAD NOT CEASED SHE WENT TO HER GYNECOLOGIST AND SHE TOLD HER THAT SHE HAD A YEAST INFECTION AND PRESCRIBED HER YEAST INFECTION MEDICINE. SHE ASKED HER PHYSICIAN IF THERE COULD BE A PROBLEM WITH THE ESSURE AND SHE SAID NO. SHE NEVER RECEIVED A TEST DYE TO MAKE SURE THAT ESSURE WERE IN ACCURATELY. AFTER HAVING A PREGNANCY SCARE AND NOT KNOWING WHAT WAS GOING ON AND COULD NOT GET IN THE DOCTOR´S OFFICE TO HAVE HER CHECKED OUT. SHE WAS GETTING THE RUNAROUND AND HER SYMPTOMS WERE INCREASING TO WHERE SHE COULD BARELY WALK; SHE COULD NOT HOLD HER HEAD UP LONGER THAN AN HOUR, SHE WAS LITERALLY IN PAIN AND WAS TAKING IBUPROFEN PAIN RELIEVERS AND SOMETIMES A MUSCLE RELAXER. THERE WERE MANY OTHER TIMES THAT SHE WENT INTO DOCTOR BECAUSE HER BACK WAS HURTING SO MUCH AND HER HEAD WAS HURTING SO MUCH THAT THEY REALLY COULDN'T FIND ANYTHING WRONG WITH HER AND THEY NEVER CHECKED THE ESSURE IMPLANT. IN 2011, SHE WENT TO A NEW DOCTOR AND SHE NOTICED THAT THERE WAS SOME INFLAMMATION OR SOMETHING WRONG AND SHE NEEDED TO ACTUALLY GO IN SURGICALLY TO SEE WHAT THE PROBLEM

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WAS. SHE WAS SCHEDULED FOR A SURGERY ON (B)(6) 2012 OR 2013 (DISCREPANT INFORMATION). WHILE IN SURGERY, THE PHYSICIAN HAD FOUND THAT HER FALLOPIAN TUBES WERE INFLAMED AND THAT THE COILS WERE THE CAUSE OF NEEDING TO EXTRACT UTERUS AND CERVIX. ON TOP OF THAT, SHE HAD NICKEL SIZED CYST ON OVARIES AND HAS SCARRED A LITTLE BIT SO SHE NOTICED THAT THERE WAS NO SAVING FOR HER UTERUS FROM THE INFLAMMATION OF HAVING DONE THE SAME TIME WHICH WAS CAUSING HER TO BLEED INTERNALLY FOR FOUR YEARS. A WEEK AFTER THE SURGERY, CONSUMER NOTICED THAT HER HEADACHES, BACKACHES STOMACH PAIN ALL AROUND WERE GONE. PTC INVESTIGATION RESULT WAS RECEIVED ON 03-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD A PREGNANCY SCARE, BLEEDING FOR FOUR YEARS AND SOME YEARS AFTER INSERTION, HER FALLOPIAN TUBES WERE INFLAMED AND THE ESSURE COILS WERE THE REASON TO REMOVE HER UTERUS AND CERVIX. THE EVENT FALLOPIAN TUBES WERE INFLAMED, INTERPRETED AS SALPINGITIS, IS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION. THE BLEEDING, INTERPRETED AS UTERINE BLEEDING, AND PREGNANCY SCARE ARE SERIOUS DUE TO MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THESE EVENTS ARE LISTED. BLEEDINGS MAY OCCUR WITH ESSURE. IN THIS PARTICULAR CASE, CONSIDERING THAT SHE EXPERIENCED BLEEDING WHILE ON ESSURE, THIS EVENT IS CONSIDERED RELATED TO ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO AN INCORRECT LOCATION OF ESSURE. IN THIS PARTICULAR CASE, THERE IS LIMITED INFORMATION. A PREGNANCY SCARE WAS MENTIONED BUT THERE IS NO OTHER INFORMATION WHETHER IT WAS CONFIRMED OR NOT AND NO INFORMATION REGARDING PREGNANCY DEVELOPMENT AND OUTCOME DESPITE MENTIONING OTHER EVENTS THAT OCCURRED AFTER THIS PREGNANCY SCARE. HOWEVER, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION THE PREGNANCY SCARE IS CONSIDERED RELATED TO ESSURE. IN THIS PARTICULAR CASE, THE SALPINGITIS WAS DIAGNOSED AFTER APPROXIMATELY 3 YEARS. CONSIDERING THE NATURE OF THIS EVENT AND THE POSITIVE TEMPORAL RELATIONSHIP, THIS EVENT IS CONSIDERED RELATED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 03-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00406	BAYER HEALTHCARE LLC	6/16/2015	6/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/24/2005
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5040500) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2005. THE CONSUMER STATED THAT ESSURE WAS INSERTED IN 2005 AND HAD CHRONIC PAIN IN LEFT LOWER QUADRANT UNTIL 2009 WHEN AN EXPLORATORY WAS DONE AND REVEALED ADHESIONS ON LEFT BOWEL. SHE SAID THAT THIS MOST INDICATED TO BE CAUSED BY PROBLEMS WITH INSERTION OF DEVICE ON LEFT FALLOPIAN TUBE (INSERTING PHYSICIAN COULD NOT GET THE COIL IN SMOOTHLY AND HAD TO SEDATE HER). SINCE THEN, SHE HAD CONTINUED PAIN ON LEFT SIDE, SEVERE BLOATING AND CYSTS ON LEFT OVARY. RECENTLY, SHE FOUND A DOCTOR WHO WILL REMOVE COILS VIA HYSTERECTOMY. SHE ALSO HAD MULTITUDE OF OTHER SIDE EFFECTS AND DEVELOPED AUTOIMMUNE DISORDER AFTER PLACEMENT. THE ALLERGIST CONFIRMED NICKEL ALLERGY (NO NICKEL TEST WAS DONE PRIOR TO INSERTION). PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE

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(B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE WAS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PAIN IN LEFT LOWER QUADRANT UNTIL 2009 WHEN AN EXPLORATORY WAS DONE AND REVEALED ADHESIONS ON LEFT BOWEL. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SOME CAUSES OF ABDOMINAL ADHESIONS ARE ABDOMINAL SURGERY, PERITONITIS AND ENDOMETRIOSIS. ALTHOUGH THE EXACT CAUSE FOR OCCURRENCE OF THIS EVENT IS UNKNOWN, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE INTERVENTION PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE WAS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 29-JUL-2015 VIA REGULATORY AUTHORITY (CASE #MW5042812): CONSUMER STATED THAT THIS REPORT WAS REGARDING 2005 ESSURE IMPLANTS. SHE REPORTED THAT ESSURE WAS INSERTED ON (B)(6) 2015 (DISCREPANT INFORMATION PROVIDED) AND THE L

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043183	CONCEPTUS	6/16/2015	6/23/2015

Event Information:

Event Date (B3): 8/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/7/2013
Explant Date (E7): 3/3/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON 5(B)(6) 2013 I DELIVERED MY 5TH CHILD AT (B)(6), THIS WAS AN UNPLANNED PREGNANCY. ON (B)(6) 2013 I HAD THE ESSURE DEVICE IMPLANTED. ON (B)(6) 2013 WHILE ATTEMPTING TO HAVE HSG I WAS TURNED AWAY DUE TO POSITIVE PREGNANCY TEST. ON (B)(6) 2013 I EXPERIENCED SEVERE CHRONIC FATIGUE AND DEPRESSION SYMPTOMS. ON (B)(6) 2014 I MISCARRIED AND CONTINUED SUFFERING CHRONIC FATIGUE AND DEPRESSION. I WAS UNAWARE AT THE TIME WHAT WAS HAPPENING TO ME AND NEEDED INTERVENTION TO GET HELP. ON (B)(6) 2014 I WAS PRESCRIBED MEDICATIONS AND SPENT THE NEXT 8 WEEKS GETTING BACK TO MY NORMAL ACTIVITY ROUTINES AND ABLE TO FUNCTION AGAIN. ON (B)(6) 2014 I HAD MY FIRST HSG AND DETERMINED ONLY ONE IMPLANT WAS PRESENT, I WAS TOLD THE OTHER ONE PROBABLY FELL OUT. BECAUSE I WAS UNABLE TO FIND ANY NEGATIVE REVIEWS ONLINE PRIOR TO THE PROCEDURE I STARTED DOING RESEARCH AGAIN TO SEE IF THERE WERE ANY NEW CONCERNS. I STARTED READING ABOUT OTHER WOMEN WITH THE SAME ISSUES AND PROBLEMS I HAD AND WAS STILL EXPERIENCING. I READ AND STUDIED THE IDENTIFICATION CARD OF SIDE EFFECTS AND IMPLANT INFO THAT WAS GIVEN TO ME AFTER THE IMPLANT PROCEDURE (B)(6) 2013 AND IT STILL LISTED CONCEPTUS AS THE MANUFACTURER AND DID NOT LIST ANY ALLERGY OR COMMON SIDE EFFECT INFO I WAS EXPERIENCING. I WAS CONCERNED ONE OF THE IMPLANTS WAS LOST INSIDE ME AND WAS TOLD THAT THEY COULD NOT SEE IT. I WANTED TO HAVE AN X RAY TO MAKE SURE THE OTHER IMPLANT WAS NOT SOME OTHER PLACE INSIDE ME BUT LEARNED THAT THE MATERIAL OR NICKEL USED FOR THE MANUFACTURING COULD NOT BE VIEWED BY X-RAYS, THAT SEEMS QUITE IRRESPONSIBLE OF THE MANUFACTURER. I FELT LUCKY FOR NOT EXPERIENCING THE PHYSICAL PAIN THAT WAS NOT PRESENT. TWO THOUSAND FOURTEEN WAS THE WORST YEAR OF MY LIFE AND I HAD NEVER EXPERIENCED THE DEPTH OF EMOTIONAL PAIN I SUFFERED DUE TO THE SYMPTOMS I WAS EXPERIENCING. ON (B)(6) 2013 I ELECTIVELY HAD MY

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FALLOPIAN TUBES REMOVED AND OVER THE NEXT COUPLE OF MONTHS MY CHRONIC FATIGUE SYMPTOMS WENT AWAY. ANOTHER SIDE EFFECT I EXPERIENCED WAS A DERMATITIS TYPE RASH AND LESIONS ON MY SCALP THAT HAVE ALSO GONE AWAY AFTER REMOVAL SURGERY. I AM STILL TREATING MY DEPRESSION IN AN EFFORT TO AVOID POTENTIAL RELAPSE SYMPTOMS. I AM STILL PICKING UP THE PIECES FROM THE DAMAGES THAT WERE CAUSED EMOTIONALLY, AND FINANCIALLY. AT THIS TIME I AM STILL UNAWARE IF THERE MAY BE A LOST IMPLANT SOMEWHERE IN MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043186		6/16/2015	6/23/2015

Event Information:

Event Date (B3): 12/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/19/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE DEVICE PLACED AND ONE TUBE SPASMED DURING PROCEDURE, CAUSING THE COIL TO MIGRATE AND NOW I NEED IT REMOVED. I AM CONSTANTLY TIRED, FEEL ACHES AND PAINS IN MY JOINTS AND THE SIDE WHERE THE COIL MIGRATED. I AM LOOKING FORWARD TO REMOVAL BUT SCARED OF NEEDING A HYSTERECTOMY. I AM ONLY (B)(6) SO IF I DO NEED TO HAVE A HYSTERECTOMY FROM IT WILL SUCK. IT WILL THROW OFF MY HORMONES FOREVER AND COULD PUT ME INTO AN EARLY MENOPAUSE. THIS DEVICE WAS SAID TO HAVE NO SIDE EFFECTS AND WAS SUPPOSED TO BE SAFE AND EASY. I FEEL LIKE I WAS LIED TO AND THE DEVICE CAN CAUSE MORE HARM THAN GOOD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043188	CONCEPTUS	6/16/2015	6/23/2015

Event Information:

Event Date (B3): 6/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESSURE
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 9/10/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

REPEATED EMERGENCY ADMISSIONS FOR ABDOMINAL PAIN OF NO KNOWN CAUSE. BLACK MENSTRUAL DISCHARGE ON A REGULAR BASIS. ABDOMEN HAS SWELLED UP LIKE AN APPLE. NO PHYSICIAN WILL TREAT OR REMOVE THESE IMPLANTS. I'VE BEEN TESTED FOR EVERYTHING FROM CROHN'S TO COLON CANCER AND DIVERTICULITIS FOR MY ABDOMINAL PAIN. I HAVE HAD REPEATED ULTRASOUNDS. I HAVE A KNOWN NICKEL ALLERGY. NO ONE EVER DISCLOSED THIS DEVICE IS MADE OF NICKEL. NO ONE HAS TAKEN THIS SERIOUSLY. CHRONIC FATIGUE, HAIR FALLING OUT, LOW ENERGY, ACHING JOINTS, BAD COMPLEXION, CHRONIC INFECTED BOILS ON BUTTOCKS AND LEGS. PIECES OF COILS COME OUT VIA URINE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043189	BAYER	6/16/2015	6/23/2015

Event Information:

Event Date (B3): 6/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/4/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE MY IMPLANTATION I HAVE HAD SHARP, STABBING PAINS IN MY LOWER ABDOMEN. I CONTACTED THE DR WHO SAID IT SHOULDN'T BE FROM THE PROCEDURE YET I STILL HAVE THIS PAIN. NEXT WEEK I GO FOR MY POST OP VISIT. I HAD THE PROCEDURE DONE ON (B)(6) 2015, I HAD NO PAIN UNTIL FIRST THING THE NEXT MORNING. THE PAIN THEN PROCEEDED TO GET PROGRESSIVELY WORSE. TO A POINT OF NOT EVEN THE PAIN KILLERS HELP TO REMOVE THE PAIN. I ALSO HAVE, SINCE THE PROCEDURE, BEEN HAVING HIGH RUNNING BLOOD PRESSURE. MY BLOOD PRESSURE HAS ALWAYS BEEN GOOD EVEN THE WHOLE TIME I WAS PREGNANT IT RAN NORMAL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00402	BAYER HEALTHCARE LLC	6/16/2015	7/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18713

Single Use: *
Implant Date (E6): 5/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 22-MAY-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C18713 FOR PERMANENT STERILIZATION. IT WAS REPORTED THAT MARKER 1 BROKE OFF OF THE INSERT DURING THE PROCEDURE. THIS HAPPENED ON THE PATIENT'S LEFT SIDE. PHYSICIAN LEFT MICRO-INSERT IN PLACE AND HE COULD SEE TWO TRAILING COILS IN PATIENT'S UTERUS. EVERYTHING ELSE LOOKED FINE; THE MICRO-INSERT STILL HAD THREE MARKERS. THERE WAS NO STRUGGLE WITH THE ESSURE SYSTEM AND NO TRAUMA. PHYSICIAN DID FIND PIECE THAT BROKE OFF AND WAS ABLE TO REMOVE IT. BILATERAL PLACEMENT WAS ACHIEVED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 03-JUN-2015: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 27-MAY-2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. THE

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POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE WAS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND MARKER 1 BROKE OFF OF THE INSERT DURING THE PROCEDURE ON THE PATIENT'S LEFT SIDE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ACCORDING TO PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS, THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, NO DIFFICULTY DURING ESSURE INSERTION WAS REPORTED. THERE WAS NO STRUGGLE WITH THE ESSURE SYSTEM AND NO TRAUMA, EVERYTHING ELSE LOOKED FINE. HOWEVER, SINCE THE BREAKAGE OCCURRED DURING THE INSERTION PROCEDURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 20-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIEN

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00405	BAYER HEALTHCARE LLC	6/16/2015	7/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26965

Single Use: *
Implant Date (E6): 5/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 22-MAY-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C26965, INSERTED ON (B)(6) 2015. HEALTH CARE PROFESSIONAL REPORTED THAT DEVICE DID NOT CANULATE. PHYSICIAN RETRIEVED THE MICRO-INSERT FROM UTERINE CAVITY WITH A GRASPER AND THAT'S WHEN IT BROKE APART. BREAKAGE DID NOT OCCUR PRIOR TO USING THE GRASPER. PTC INVESTIGATION RESULT WAS RECEIVED ON 03-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: AS OF 5/27/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C26965 (PRODUCTION DATE 27-FEB-2014 AND EXPIRATION DATE 28-FEB-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT

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APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING PLACEMENT THE DEVICE DID NOT CANULATE AND HCP RETRIEVED THE MICROINSERT FROM UTERINE CAVITY WITH A GRASPER AND THAT'S WHEN IT BROKE APART. THESE EVENTS, SEEN AS DEVICE DEPLOYMENT ISSUE AND DEVICE BREAKAGE RESPECTIVELY, ARE NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS OR REMOVALS, SINGLE CASES OF DEVICE BREAKAGE AND PROBLEMS OF DEPLOYMENT HAVE BEEN REPORTED. IN THIS CASE THE EVENTS OCCURRED ASSOCIATED TO PLACEMENT PROCEDURE, SO CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

DEVICE BREAKAGE QUESTIONNAIRE RECEIVED ON 25-AUG-2015 FROM PHYSICIAN. THE PATIENT'S INITIAL WAS UPDATED. HER WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). ESSURE WAS INSERTED ON (B)(6) 2015. IT WAS REPORTED THAT DEVICE BREAKAGE OCCURRED DURING PLACEMENT; IMPLA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043184	BAYER	6/17/2015	6/23/2015

Event Information:

Event Date (B3): 7/3/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 641429

Single Use:
Implant Date (E6): 7/3/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

MY DR RECOMMENDED ESSURE FOR BIRTH CONTROL. HE SAID IT WAS SAFE WITH NO COMPLICATIONS. ON (B)(6) 2009 I HAD THE PROCEDURE. ON 7(B)(6) 2009 I STARTED TO BLEED AND CONTINUED TO BLEED FOR OVER TWO MONTHS. CALLED DR AND HE SAID EVERYTHING IS FINE. SINCE HAVING THE ESSURE PROCEDURE I HAVE DEVELOPED NUMEROUS AND NEW HEALTH PROBLEMS INCLUDING HEAVY BLEEDING, SEVERE PELVIC PAIN, CHRONIC FATIGUE, SKIN DISORDERS, SEVERE BLOATING, HYPERTENSION AND A HEART MURMUR. DATES OF USE: 6 YEARS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00407	BAYER HEALTHCARE LLC	6/18/2015	6/18/2015

Event Information:

Event Date (B3): 4/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/5/2014
Explant Date (E7): 4/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN FRANCE ON (B)(6) 2015 REFERRING TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PLACEMENT WAS NORMAL AND OCCURRED ON (B)(6) 2014. CONTROL HYSTEROSALPINGOGRAPHY WAS REPORTED WITH NO RESULT. PATIENT GOT PREGNANT. NO FURTHER INFORMATION WAS PROVIDED. PREGNANCY QUESTIONNAIRE AND MEDICAL RECORDS WERE RECEIVED ON (B)(6) 2015 FROM PHYSICIAN. THIS CASE WAS UPGRADED TO INCIDENT. PATIENT'S INITIALS AND DATE OF BIRTH WAS PROVIDED. THIS REPORT REFERS TO A (B)(6) YEARS OLD FEMALE PATIENT. ON (B)(6) 2014 ESSURE WAS IMPLANTED. THE INSERTION WAS PERFORMED DURING FOLLICULAR PHASE. HYSTEROSCOPE HAD BEEN INSERTED EASILY. THE CAVITY HAD A NORMAL ASPECT. ENDOCERVICAL OUTLET WAS NORMAL. BOTH INSERTS WERE PLACED WITH 4 TRAILING COILS ON THE LEFT AND 6 TRAILING COILS ON THE RIGHT. NO INCIDENT DURING THE PLACEMENT. UTERINE FINDINGS PRIOR TO INSERTION SHOWED NO ABNORMAL FINDINGS. MINESSE (ETHINYLESTRADIOL, GESTODENE) WAS USED AS ALTERNATIVE CONTRACEPTION AFTER ESSURE PLACEMENT UNTIL (B)(6) 2014. IN (B)(6) 2014, ESSURE CONFIRMATION TEST WAS DONE BY HYSTEROSALPINGOGRAM (HSG) AND BY TRANSVAGINAL ULTRASOUND. THE CONFIRMATION TEST CONFIRMED BILATERAL TUBAL OCCLUSION. THE PATIENT WAS ADVISED BY THE DOCTOR TO RELY ON ESSURE BASED ON THE RESULT OF THE TEST. ON (B)(6) 2015, RIGHT CORNUAL PREGNANCY WAS CONFIRMED BY THE DOCTOR. LEFT INSERT WAS NOT SEEN ON ULTRASOUND AND RIGHT INSERT WAS WELL PLACED. OCCLUSION SEEN VIA HYSTEROSALPINGOGRAM WITH LEFT INSERT SLIGHTLY FARAWAY IN THE FALLOPIAN TUBE. SURGERY WAS PERFORMED UNDER GENERAL ANESTHESIA: BILATERAL SALPINGECTOMY, REMOVAL OF ESSURE ON MESENTERY AREA, LEFT CORNEAL RESECTION AND ASPIRATION CURETTAGE. ESSURE WAS NOT IN SITU AFTER DIAGNOSIS OF PREGNANCY.

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ESSURE WAS REMOVED VIA LAPAROSCOPY. IT WAS MEDICALLY NECESSARY TO REMOVE ESSURE. ESSURE WAS NOT REMOVED BECAUSE OF PATIENT REQUEST. NO PATHOLOGY RESULTS, SIGNS OF INFECTION, INFLAMMATION AND ETC. NO FURTHER INFORMATION WILL BE AVAILABLE. FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT. IT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A RIGHT CORNUAL PREGNANCY CONFIRMED (PREVIOUSLY REPORTED AS PREGNANCY AND INTERPRETED AS UTERINE PREGNANCY). A BILATERAL SALPINGECTOMY, REMOVAL OF ESSURE FROM MESENTERY AREA AND LEFT CORNEAL RESECTION WITH ASPIRATION CURETTAGE WERE PERFORMED. THE RIGHT CORNUAL PREGNANCY, INTERPRETED AS ECTOPIC PREGNANCY WITH CONTRACEPTIVE DEVICE, AND THE ESSURE FOUND IN MESENTERY AREA DURING SURGERY FOR REMOVAL, INTERPRETED AS DEVICE MIGRATION (IMPLIED PERFORATION), WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THESE EVENTS ARE LISTED. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THIS PARTICULAR CASE, THE PRESENCE OF ESSURE IN THE MESENTERIC AREA WAS NOTICED DURING SURGERY FOR ITS REMOVAL. IT IS NOT CLEAR IF THE MIGRATION (PERFORATION) OCCURRED DURING INSERTION OR AFTERWARDS. HOWEVER, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND GIVEN THE NATURE OF THIS EVENT, IT WAS CONSIDERED RELATED TO ESSURE PROCEDURE. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. IN THIS PARTICULAR CASE, THE ECTOPIC PREGNANCY WAS DIAGNOSED APPROXIMATELY 8 MONTHS AFTER ESSURE INSERTION. BASED ON AVAILABLE INFORMATION, THE PREGNANCY COULD BE RELATED TO AN INEFFECTIVE DEVICE OR INCORRECT LOCALIZATION OF INSERTS. THEREFORE, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. UPDATED PTC ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 23-JUL-2015 NCA NUMBER RECEIVED AS (B)(4). FOLLOW UP 28-JUL-2015: PTC INVESTIGATION RESULTS WERE UPDATED WITHOUT MAJOR CHANGES AND WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00408	BAYER HEALTHCARE LLC	6/18/2015	6/18/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/11/2010
Explant Date (E7): 2/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN UNITED STATES ON (B)(6)-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 FOR PERMANENT BIRTH CONTROL. THE CONSUMER REPORTED THAT SHE HAD CONTINUOUS BLEEDING AND CRAMPS FOR 3/6 MONTHS AFTER ESSURE PROCEDURE, ONLY WITH A DAY OR 2 WITHOUT AT A TIME. SHE HAD AN ABLATION PERFORMED TO TRY TO MINIMIZE THE BLEEDING IN 2010 AND THEN BEGAN DEVELOPING CYSTS ON HER OVARIES. SHE ALSO DEVELOPED MIGRAINES IN 2010. IN 2015, A PARTIAL HYSTERECTOMY WAS DONE DUE TO ENLARGED CYST AND OVARY ON HER RIGHT SIDE. SHE STATED THE COILS DID NOT MIGRATE BUT STILL CAUSED DISCOMFORT AND PAIN. ADDITIONALLY, AN ESSURE EXPLANT DATE ((B)(4) 2015) WAS PROVIDED. THE CONSUMER MENTIONED THE SERIOUSNESS CRITERIA HOSPITALIZATION BUT IT WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO

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BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO EXPERIENCED CONTINUOUS BLEEDING FOR 3/6 MONTHS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PROCEDURE. SHE WAS SUBMITTED TO AN ENDOMETRIAL ABLATION AS EVENT'S TREATMENT. ADDITIONALLY, SHE DEVELOPED AN ENLARGED CYST AND OVARY ON HER RIGHT SIDE AND WAS SUBMITTED TO A PARTIAL HYSTERECTOMY. THE REPORTED BLEEDING, REGARDED AS GENITAL BLEEDING, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. THE REMAINING EVENT IS UNLISTED AND WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, GIVEN THE CLOSE TEMPORAL RELATIONSHIP BETWEEN THE REPORTED BLEEDING AND ESSURE INSERTION, CAUSALITY CANNOT BE EXCLUDED. REGARDING OVARIAN CYST AND ENLARGEMENT; OVARIAN CYSTS CAN DEVELOP IN FEMALES AT ANY STAGE OF LIFE, AND ARE USUALLY HORMONE RELATED. ESSURE IS A METALLIC DEVICE WITH A LOCAL ACTION AT FALLOPIAN TUBES; NO DRUG IS RELEASE FROM THE INSERT. GIVEN THE ABOVE MENTION INFORMATION, CAUSALITY BETWEEN THIS EVENT AND ESSURE IS CONSIDERED VERY UNLIKELY. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REPORTED ENDOMETRIAL ABLATION (REQUIRED INTERVENTION) FOR BLEEDING'S TREATMENT. ADDITIONALLY, CONSUMER PROVIDED AN ESSURE EXPLANT DATE; HOWEVER NO INFORMATION WAS GIVEN ABOUT ESSURE REMOVAL. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FOLLOW-UP CAN BE PURSUED SINCE NO CONTACT INFORMATION IS AVAILABLE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00409	BAYER HEALTHCARE LLC	6/18/2015	6/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/9/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. THE CONSUMER STATED THAT SHE HAD ESSURE COILS AND THEY CAUSE HER MANY DOCTOR AND HOSPITAL VISITS AND NOW SHE HAVE TO HAVE A HYSTERECTOMY DUE TO ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND NOW SHE HAS TO HAVE A HYSTERECTOMY DUE TO ESSURE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE SURGERY WAS NOT CONFIRMED AT THE TIME OF THIS REPORT AND THE EXACT ADVERSE EVENT WHICH LED TO IT WAS NOT SPECIFIED; CONSUMER RELATED THE PROCEDURE TO ESSURE. THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. CONSIDERING CONSUMER STATED A SURGERY (INTERVENTION) WILL BE REQUIRED AND SINCE NO FOLLOW-UP WILL BE POSSIBLE (DUE TO ABSENCE OF CONTACT INFORMATION); THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00410	BAYER HEALTHCARE LLC	6/18/2015	6/18/2015

Event Information:

Event Date (B3): 3/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/27/2015
Explant Date (E7): 5/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION ON (B)(6) 2015. PATIENT WAS NOT PREGNANT. THE PHYSICIAN REPORTED THAT THE PATIENT JUST CONTINUED TO COMPLAIN OF CRAMPING SINCE ESSURE WAS PLACED. ON (B)(6) 2015, A HYSTERECTOMY WAS DONE AND THEY REMOVED THE PATIENT'S UTERUS AND BOTH TUBES WITH COILS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

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COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE PATIENT JUST CONTINUED TO COMPLAIN OF CRAMPING SINCE ESSURE WAS PLACED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, PATIENT EXPERIENCED THIS EVENT SINCE ESSURE INSERTION. PATIENT UNDERWENT A HYSTERECTOMY AND BOTH TUBES WITH COILS WERE REMOVED. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND GIVEN THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS REQUIRED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 08-SEP-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00412	BAYER HEALTHCARE LLC	6/18/2015	6/19/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2013
Explant Date (E7): 8/8/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 19-MAY-2014 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ONE TUBE FROM THE FIRST PROCEDURE DID NOT TAKE AND WAS REDONE, ONE FALLOPIAN TUBE HAVING TWO COILS INSERTED, LOT OF PAIN IN HER PELVIS, STOMACH INFLAMMATION, LOTS OF RASHES, HEADACHES, BLOATING, BACK PAIN, AND POSSIBLE NICKEL ALLERGY. FOLLOW UP INFORMATION RECEIVED ON 23 AND ON 29-MAY-2014: HEIGHT AND WEIGHT ADDED. PATIENT HAS NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. NO RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. REPORTER INFORMATION UPDATED. ONE ESSURE WAS INSERTED IN (B)(6) 2013 AND ONE WAS PLACED IN THE END OF (B)(6) 2013. ESSURE WAS NOT INSERTED AFTER A PREGNANCY. PATIENT USED BIRTH CONTROL PILLS BEFORE TOTAL OCCLUSION CONFIRMATION TEST. THE HYSTEROSALPINGOGRAM WAS PERFORMED IN (B)(6) 2013 AND SHOWED ONE SIDE WAS STILL OPEN. HER SYMPTOMS STARTED LAST YEAR, AFTER THE SECOND ESSURE WAS PLACED. SHE ALSO EXPERIENCED HAIR FALLING OUT, STOMACH SWELLING, GAINING WEIGHT, SHE USED TO WEIGH LESS THAN 140LBS BUT NOW WEIGHS (B)(6) LBS. SHE IS HAVING PELVIC PAIN ALL THE TIME ON HER RIGHT SIDE AND IT IS LIKE HER SIDE IS BURNING DURING EXERCISE. STATED THAT SHE CANNOT SIT FOR A LONG TIME AND THAT IT IS INTERFERING WITH HER WORK. HER BLOOD TEST WAS NORMAL AS WELL AS PELVIC ULTRASOUND. HER DOCTOR SAID THAT MAYBE THIS IS AN ALLERGY TO ESSURE. SHE TOOK PAIN KILLERS TO TREAT SOME OF THOSE EVENTS. ESSURE WAS NOT REMOVED. PATIENT BELIEVES THAT ESSURE CAUSED HER THESE CONDITIONS BECAUSE THE PROBLEMS ARE GETTING WORSE AFTER THE SECOND ESSURE WAS PLACED. CORRECTION PERFORMED ON 01-JUN-2014 REGARDING FOLLOW UP INFORMATION RECEIVED ON 29-MAY-2014: FIRST ESSURE INSERTION WAS PERFORMED IN (B)(6) 2013 (PREVIOUSLY REPORTED AS

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(B)(6) 2013). NO NEW INFORMATION WAS PROVIDED. FOLLOW UP 05-JUN-2014: NO RESPONSE FROM THE CONSUMER AFTER FOLLOW UP ATTEMPTS. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. FOLLOW-UP RECEIVED ON 08-JUL-2014. NEW REPORTER WAS ADDED AND THE CASE IS MEDICALLY CONFIRMED NOW. THERE WAS NO EVIDENCE OF INFECTION AND NO PATHOLOGY REPORTED. SHE HAD NOT UNDERGONE CERVICAL CONIZATION, D&C, MYOMECTOMY, ADNEXAL SURGERY OR OTHER INTERVENTIONS. ACCORDING TO THE PHYSICIAN, A MINIMAL DILATATION WAS REQUIRED, THE UTERUS WAS NOT SOUNDED AND PROPOFOL ANESTHETIC WAS USED DURING INSERTION PROCEDURE. THE INSERTION ON LEFT SIDE WAS VERY EASY, BUT THERE WAS SOME RESISTANCE ON THE RIGHT WHICH WAS OVERCOME WITH GENTLE PRESSURE. THE VISUALIZATION OF THE TUBAL ON BOTH SIDES WAS EASY. FLUID LOSS WAS MINIMAL (LESS THAN 500ML) AND THE PROCEDURE TOOK LESS THAN 10 MINUTES (POSSIBLY CLOSER TO 8 MINUTES).THE FINAL RESULT WAS SATISFACTORY AND SYMMETRIC. AFTER INSERTION AND BEFORE CONFIRMATION OF TUBAL OCCLUSION, SPRINTEC ORAL CONTRACEPTIVE WAS USED. ON (B)(6) 2013, HYSTEROSALPINGOGRAM WAS PERFORMED AND SHOWED OCCLUSION IN THE LEFT FALLOPIAN TUBE, BUT PATENCY ON THE RIGHT. THE MICRO-INSERT WAS SEEN TO BE SOMEWHAT DISTAL WITH THE PROXIMAL EXTENT NOT EXTENDING INTO THE UTERINE CAVITY. ON (B)(6) 2013, IN VIEW OF THE FAILURE OF THE RIGHT SIDE, A NEW ESSURE INSERTION WAS DONE (RIGHT SIDE) WITH LOT NUMBER CS0002F. THREE VISIBLE COILS WERE SEEN AND THE INSERTION OCCURRED WITHOUT SIGNIFICANT RESISTANCE OR DIFFICULT. ON (B)(6) 2014 HYSTEROSALPINGOGRAM WAS DONE AGAIN AND SHOWED COMPLETE OCCLUSION OF BOTH SIDES; 2 MICRO-INSERTS WERE IDENTIFIED ON THE RIGHT SIDE AS EXPECTED. NO PERFORATION WAS EVIDENT IN EITHER OF THE HYSTEROSCOPIES. PATIENT CONTINUED TO COMPLAIN PF PELVIC PAIN, TOTAL BODY ITCHING, RIGHT FLANK PAIN, LOWER ABDOMINAL PRESSURE, BLOATING, HEADACHES, HAIR LOSS, WEIGHT GAIN AND LOWER BACK PAIN. SHE WAS NOT HOSPITALIZED. ACCORDING TO THE PHYSICIAN, IT WAS UNCLEAR WHETHER OR NOT THE PATIENT HAD A NICKEL ALLERGY, BUT THE ALLEGATION WAS A CONTRIBUTING FACTOR TO THE ISSUES OR SYMPTOMS THAT SHE EXPERIENCED. SHE HAS BEEN IN GOOD HEALTH. THE PATIENT WAS CONVINCED THAT ALL EVENTS, WHICH WERE APPARENTLY NEW SINCE INSERTION, WERE RELATED TO ESSURE. THE PATIENT WOULD LIKE TO HAVE ESSURE DEVICES REMOVED. FOLLOW-UP RECEIVED ON 27-MAY-2015: AFTER A COMPANY INTERNAL REVIEW, CASE WAS NOT CONSIDERED MEDICALLY CONFIRMED. CONSUMER, WHO IS NOT PREGNANT, REPORTED THAT SHE HAD BILATERAL ESSURE AND FALLOPIAN TUBES REMOVED BY LAPAROSCOPIC SURGERY ON (B)(6) 2014. ALL OF THE SYMPTOMS SHE HAD HAVE SINCE DISAPPEARED. SHE WOULD LIKE LEGAL COMPENSATION FOR EXPENSES INCURRED IN PLACEMENT AND REMOVAL OF ESSURE. ESSURE REMOVAL METHOD: LAPAROSCOPY. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 04-JUN-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT CONTROL HYSTEROSALPINGOGRAM (HSG) THE MICRO-INSERT AT RIGHT SIDE WAS SEEN TO BE SOMEWHAT DISTAL WITH THE PROXIMAL EXTENT NOT

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EXTENDING INTO THE UTERINE CAVITY (REGARDED AS DEVICE DISLOCATION). PHYSICIAN DECIDED TO PERFORM A NEW PROCEDURE AND PLACED 2 INSERTS IN RIGHT FALLOPIAN TUBE. THE CONSUMER STARTED EXPERIENCING A LOT OF PAIN IN HER PELVIS (ON HER RIGHT SIDE), WHICH RECOVERED WITH DEVICES REMOVAL BY LAPAROSCOPY. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY . IN THIS CASE, CONSUMER'S SYMPTOMS STARTED AFTER THE SECOND ESSURE PROCEDURE; WHEN PHYSICIAN PLACED TWO INSERTS IN THE SAME FALLOPIAN TUBE. THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED PAIN AND SINCE THIS EVENT RECOVERED WITH DEVICES REMOVAL; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT; HOWEVER UPON RECEIPT OF FOLLOW-UP INFORMATION IT WAS UPGRADED TO INCIDENT DUE TO ESSURE REMOVAL BY SURGERY. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043208		6/18/2015	6/26/2015

Event Information:

Event Date (B3): 6/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2011. SINCE THEN I HAVE EXPERIENCED SEVERE CRAMPING, LONG PERIODS, HEADACHES, AND NOW I HAVE FIBROIDS. THIS DEVICE HAS TURNED MY WORLD UPSIDE DOWN. THE INSURANCE WILL NOT PAY TO HAVE IT REMOVED SO I HAVE TO PAY OUT OF POCKET FEES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043210	BAYER	6/18/2015	6/26/2015

Event Information:

Event Date (B3): 12/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/18/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM NOW A CHRONIC MIGRAINE SUFFERER, I HAVE CHRONIC PELVIC PAIN, I AM VITAMIN D DEFICIENCY, HAIR LOSS, TEETH ARE DECAYING RAPIDLY. THE LIST GOES ON. I DEVELOPED SLEEP APNEA NARCOLEPSY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043215	BAYER	6/18/2015	6/26/2015

Event Information:

Event Date (B3): 2/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): B82471

Single Use:
Implant Date (E6): 2/4/2015
Explant Date (E7): 6/17/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HYSTEROSCOPIC ESSURE PLACEMENT WAS PERFORMED ON (B)(6) 2015. THE ESSURE APPLICATOR WAS NOT FUNCTIONING PROPERLY (SHEATH DID NOT RETRACT AND DEVICE WAS NOT DEPLOYED). THE APPLICATOR WAS COMPARED TO A NEW AND USED APPLICATOR AND THE ESSURE INSERT APPEARED TO BE PRESENT IN THE APPLICATOR; THEREFORE, A NEW APPLICATOR WAS USED TO PLACE THE INSERT INTO THE LEFT TUBAL OSTIA (SUCCESSFUL PLACEMENT IN RIGHT TUBAL OSTIA WAS ALREADY PERFORMED). THE DEFECTIVE APPLICATOR WAS RETURNED TO THE MANUFACTURER. THE HSG CONFIRMATORY TEST WAS PERFORMED IN (B)(6) 2015 WHICH SHOWED TWO ESSURE INSERTS ON THE LEFT AND ONE ON THE RIGHT. A DIAGNOSTIC LAPAROSCOPY WAS PERFORMED ON (B)(6) 2015 WHICH SHOWED ONE OF THE INSERTS ON THE LEFT PERFORATED THROUGH THE UTERINE CORNUA. IT WAS REMOVED SUCCESSFULLY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00411	BAYER HEALTHCARE LLC	6/18/2015	7/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS0003V/C80064

Single Use:
Implant Date (E6): 5/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2015. IT WAS REPORTED THAT THE COIL AND DISTAL TIP OF ESSURE LOT NUMBER CS0003V CAME APART AND THE DOCTOR USED GRASPER TO REMOVE MICRO INSERT. BOTH PIECES WERE SUCCESSFULLY REMOVED. ADDITIONALLY, BENT TIP WHILE TRYING TO CANNULATE OCCURRED WITH ESSURE LOT NUMBER C80064. BILATERAL PLACEMENT WAS ACHIEVED AND THE PATIENT HAD NO INJURY. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: LOT CS0003V: EXPIRATION DATE 31-DEC-2015, PRODUCTION DATE: OCT-2013. LOT C80064: EXPIRATION DATE 31-JUL-2017, PRODUCTION DATE JUL-2014. FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THESE LOTS WERE PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE AND BENT TIP IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCHES WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE ESSURE COIL AND DISTAL TIP CAME APART. PHYSICIAN WAS ABLE TO REMOVE BOTH PIECES. PATIENT HAD NO INJURY. THIS EVENT, REGARDED AS DEVICE BREAKAGE, WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE REPORTED EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, THE NON-SERIOUS EVENT BENT TIP WHILE TRYING TO CANNULATE WAS REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH PATIENT HAD NO INJURY THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 23-JUN-2015: ESSURE DEVICE BREAKAGE QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) YEAR-OLD FEMALE PATIENT HAD ESSURE (LOT NUMBERS CS0003V AND C80064) INSERTED ON (B)(6) 2015. PHYSICIAN INFORMED

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043221		6/19/2015	6/26/2015

Event Information:

Event Date (B3): 5/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 685783

Single Use:
Implant Date (E6): 5/20/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS DONE AT (B)(6) HEALTH CENTER IN (B)(6) BY DOCTOR (B)(6), ON (B)(6) 2010. GENERAL SYMPTOMS INCLUDE FREQUENT JOINT ACHES, SKIN RASH, FATIGUE, DECREASED LIBIDO, AND REGRET. I NOW HAVE ABNORMAL UTERINE BLEEDING AND CYSTS. I EXPERIENCE CONSTANT PELVIC PAIN, PELVIC PRESSURE, AND PAIN DURING SEXUAL INTERCOURSE. I BLOAT WAY WORSE THAN BEFORE I HAD THE PROCEDURE. MY HAIR IS COMING OUT EVERY TIME I WASH IT. I GET HIVES AND WORSE ALLERGIES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043222		6/20/2015	6/26/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN THE LAST COUPLE OF YEARS, I STARTED HAVING HORRIBLE RANDOM PELVIC/ABDOMEN PAIN. THE PAIN WAS LIKE A KNIFE STABBING ME REPEATEDLY. THE PAIN WOULD START OUT OF THE BLUE AND STOP ME FROM DOING WHATEVER I WAS DOING AT THE TIME. THE PAIN WOULD STOP ME FROM BEING ABLE TO FUNCTION UNTIL IT SUBSIDED. I ALSO HAVE EXPERIENCED EXTREME FATIGUE AND WEIGHT GAIN. THE PAIN WAS SO BAD THAT I WENT TO MY OBGYN WHO PLACED THE ESSURE PRODUCT IN 2006. LAB WORK AND AN ULTRASOUND WERE DONE TO TRY TO DIAGNOSE THAT COULD BE CAUSING THE PAIN. THE VAGINAL ULTRASOUND DID NOT SHOW ANYTHING ABNORMAL. MY DOCTOR DID NOT THINK THE ESSURE PRODUCT COULD BE CAUSING THIS PAIN OR MY OTHER SYMPTOMS, BUT I DID NOT HAVE THESE SYMPTOMS BEFORE HAVING THE ESSURE PRODUCT PLACED. IF I HAD BEEN INFORMED OF THESE SIDE EFFECTS BEFORE PLACEMENT OF THE ESSURE PRODUCT, I WOULD HAVE CHOSEN ANOTHER FORM OF STERILIZATION/BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00414	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): 4/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/17/2015
Explant Date (E7): 5/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6)-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN REPORTED THAT A PATIENT HAD ESSURE REMOVED THREE WEEKS BEFORE THE TIME OF THIS REPORT (IN (B)(6)-2015), DUE TO PERSISTING ABDOMINAL PAIN. ESSURE WAS REMOVED LAPAROSCOPICALLY WITHOUT ANY PROBLEMS. THE DEVICE WAS PLACED BY ANOTHER GYNECOLOGIST. FOLLOW UP FROM 09-JUN-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN

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TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN. ESSURE WAS REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. THE TIME INTERVAL BETWEEN ESSURE INSERTION AND THE ONSET OF PAIN WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED LAPAROSCOPY FOR ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 09-AUG-2015: FOLLOW UP INFORMATION RECEIVED FROM THE REPORTER PHYSICIAN. (B)(4). PATIENT'S AGE WAS PROVIDED, SHE WAS A (B)(6) FEMALE PATIENT. ESSURE WAS INSERTED ON (B)(6) 2015, PROCEDURE WAS FLUENT, TOOK 7 MINUTES AND WAS NOT PAINFUL. IN PRINCI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00416	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): 5/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C12710

Single Use: Y
Implant Date (E6): 2/17/2015
Explant Date (E7): 5/19/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6)-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. PHYSICIAN STATED THE PATIENT HAD A PERFORATION ON ESSURE TWO WEEKS BEFORE THE TIME OF THIS REPORT. HE WAS ABLE TO REMOVE THE ESSURE AND ACCORDING TO HIM, THE PATIENT WAS DOING FINE AGAIN. FOLLOW UP AFTER RECONCILIATION FROM 28-MAY-2015: THERE WERE ENOUGH WINDINGS IN THE CAVUM, HOWEVER PATIENT EXPERIENCED PAIN ON THE LEFT SIDE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD A PERFORATION ON ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). PHYSICIAN REMOVED THE DEVICE AND THE PATIENT WAS DOING FINE. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEITHER EVENT'S MECHANISM NOR ESSURE REMOVAL METHOD WAS SPECIFIED. NEVERTHELESS, GIVEN THE EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION IS USUALLY REQUIRED FOR ESSURE REMOVAL; THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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UPDATED PRODUCT TECHNICAL COMPLAINT RESULTS RECEIVED ON 11-SEP-2015: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00418	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): 4/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C22911

Single Use: Y
Implant Date (E6): 4/13/2015
Explant Date (E7): 4/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN A (B)(4). ON (B)(6) 2015 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR CONTRACEPTION. DURING THE PROCEDURE, A COIL PERFORATED THROUGH HER RIGHT FALLOPIAN TUBE. SHE WAS SENT TO THE HOSPITAL IMMEDIATELY FOR AN ABDOMINAL CT, WHICH CONFIRMED THE PERFORATION. ON THE SAME DAY, PATIENT HAD A LAPAROSCOPY AND THE COIL WAS COMPLETELY REMOVED. FOLLOW UP FROM (B)(4) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A (B)(6)

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FEMALE PATIENT WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING PLACEMENT PROCEDURE, A COIL PERFORATED THROUGH HER RIGHT FALLOPIAN TUBE. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. IN THIS CASE, THE ESSURE COIL PERFORATED HER RIGHT FALLOPIAN TUBE DURING INSERTION. THE PATIENT WAS SENT TO HOSPITAL IMMEDIATELY FOR AN ABDOMINAL CT, WHICH CONFIRMED THE PERFORATION. THEN, A LAPAROSCOPY WAS PERFORMED AND ESSURE WAS COMPLETELY REMOVED. CONSIDERING THE EVENT OCCURRED ASSOCIATED TO PLACEMENT PROCEDURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED TO REMOVE THE DEVICE, THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 14-JUL-2015: ESSURE HEALTH CARE PROVIDER UTERINE/TUBAL PERFORATION QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A NON-PREGNANT (B)(6) FEMALE PATIENT WHO HAS AS PREVIOUS GYNECOLOGICAL INTERVENTIONS 2 C-S

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00419	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5040604) IN UNITED STATES ON 27-MAY-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, FOR BIRTH CONTROL. THE CONSUMER STATED THAT ONE DAY SHE WOKE UP IN THE MOST TERRIBLE PAIN EVER. SHE WENT TO HER PHYSICIAN THE NEXT DAY AND WAS TOLD IT WAS BECAUSE OF THE ESSURE BIRTH CONTROL SHE HAD GOTTEN. SO HER PHYSICIAN REMOVED IT AND AFTER THAT SHE CONTINUED TO SUFFER TERRIBLE PAIN AND WAS STILL HAVING THE PAIN AT TIME OF THE REPORT. SHE HAD TO TAKE PAIN MEDICINE JUST TO GET THROUGH HER DAYS. FOLLOW-UP RECEIVED ON 04-JUN-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL

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INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE DAY SHE WOKE UP IN THE MOST TERRIBLE PAIN EVER. ESSURE WAS REMOVED AND THE PAIN CONTINUED. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. THE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND ONSET OF THE PAIN WAS NOT INFORMED NEITHER WAS CONSUMER´S MEDICAL HISTORY OR CONCURRENT CONDITIONS. THE PAIN PERSISTED AFTER ESSURE REMOVAL WHAT MAKES A CAUSAL RELATIONSHIP WITH ESSURE UNLIKELY. HOWEVER, SINCE NO ALTERNATIVE EXPLANATION FOR THE PAIN WAS PROVIDED, IN A CONSERVATIVE APPROACH, THIS EVENT WAS ASSESSED AS RELATED TO ESSURE UNTIL FURTHER INFORMATION IS OBTAINED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE WAS REMOVED (INTERVENTION IMPLIED). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 11-AUG-2015 FROM CONSUMER: THE CONSUMER'S DATE OF BIRTH WAS UPDATED (SHE WAS (B)(6) AT TIME OF EVENT). HER WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). PREVIOUS GYNECOLOGICAL PROCEDURE, PROBLEMS AND CONCURRENT CONDITIONS WERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00420	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ESSURE PATIENT MICRO INSERT REMOVAL INQUIRY WAS REPORTED. FOLLOW UP FROM (B)(4) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT. PTC GLOBAL NUMBER:(B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM (B)(6)2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE PATIENT MICRO INSERT REMOVAL INQUIRY WAS REPORTED. THIS

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EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. IT IS UNCLEAR IF ESSURE WAS ACTUALLY REMOVED OR IF PHYSICIAN WAS JUST REQUESTING INFORMATION ABOUT IT. NEVERTHELESS, GIVEN THE EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED AND DUE TO THE IMPLIED INTERVENTION, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. DESPITE FOLLOW-UP ATTEMPTS, NO FURTHER INFORMATION WAS OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00421	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/27/2011
Explant Date (E7): 8/9/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER/ ATTORNEY IN THE UNITED STATES, ON BEHALF OF A PLAINTIFF/CONSUMER IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 FOR BIRTH CONTROL. THIS IS A POTENTIAL LEGAL CASE. AT SOME TIME AFTER (B)(6)2012, CONSUMER WAS DAMAGE BY THE DEVICE. THE ESSURE PRODUCT FAILED AND SHE BECAME PREGNANT. ON OR ABOUT (B)(6) 2012, CONSUMER WAS FEELING SICK AND THROWING UP. ON (B)(6) 2012, SHE WENT TO THE DOCTOR AND DISCOVERED SHE WAS PREGNANT. ON (B)(6) 2013, AN ULTRASOUND REVEALED THAT SHE WAS PREGNANT WITH TWINS. ON (B)(6) 2013, THE TWINS WERE BORN PREMATURELY BY CAESAREAN SECTION. AT THE TIME OF C-SECTION, ESSURE COILS WERE REMOVED BECAUSE OF THE PAIN SHE HAD ENDURED AS A RESULT OF THE FAILED COILS. HOWEVER, ONE OF THE COILS COULD NOT BE FOUND. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT

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PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS RECEIVED FROM A LAWYER ON BEHALF OF A FEMALE PLAINTIFF WHO BECAME PREGNANT WITH TWINS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE TWINS WERE BORN PREMATURELY BY CESAREAN SECTION. AT THE TIME OF THIS SURGERY, PHYSICIAN DECIDED TO REMOVE ESSURE DUE TO PLAINTIFF'S PAIN, BUT ONE OF THE COILS COULD NOT BE FOUND. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION; EXCEPT FOR CESAREAN SECTION AND PREMATURE BIRTH, WHICH ARE UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS CASE NO INFORMATION WAS PROVIDED ABOUT HSG. AT THE TIME OF ESSURE REMOVAL PHYSICIAN WAS UNABLE TO FIND ONE OF THE ESSURE COILS; THIS DEVICE DISLOCATION COULD BE AN ALTERNATIVE EXPLANATION FOR ESSURE FAILURE (PREGNANCY). HOWEVER, SINCE IT IS UNCLEAR IF DISLOCATION OCCURRED BEFORE OR AFTER PREGNANCY ONSET; AND AS PREGNANCY OCCURRED APPROXIMATELY 1 YEAR AFTER ESSURE INSERTION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING PREMATURE BIRTH, MOST OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES. ALTHOUGH LIMITED INFORMATION WAS PROVIDED; GIVEN THE ADVANCED GESTATIONAL AGE AT THE TIME OF THIS EVENT, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO ESSURE REMOVAL BECAUSE OF PAIN AND PREMATURE BIRTH. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00422	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/30/2012
Explant Date (E7): 5/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 28-MAY-2015 WHICH REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. IT WAS REPORTED THAT PATIENT COMPLAINED OF PAIN. AS A RESULT, ESSURE WAS REMOVED ON (B)(6) 2015. THE PHYSICIAN WAS NOT SURE OF THE SOURCE OF THE PAIN, OR IF IT COULD BE ATTRIBUTED TO ESSURE. FOLLOW UP FROM 04-JUN-2015: PTC (PRODUCT TECHNICAL COMPLAINT). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO DEVELOPED PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICES WERE REMOVED. THE

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REPORTED EVENT, REGARDED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. THE PHYSICIAN WAS UNSURE IF PATIENT'S PAIN WAS RELATED TO ESSURE. NEVERTHELESS, GIVEN THE EVENT'S NATURE AND SINCE DEVICES REMOVAL WAS REQUIRED; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THEREFORE, THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 09-SEP-2015: FOLLOW UP ATTEMPTS WERE DONE, WITHOUT RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO DEVELOPED PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00423	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT THAT WAS POSTED ONLINE ON A SOCIAL MEDIA PLATFORM (B)(6) IN UNITED STATES ON (B)(6) 2014 BY A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED FULL HYSTERECTOMY. NO INFORMATION WAS GIVEN ON THE CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. IN 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IN 2014 THE DEVICES WERE REMOVED. SHE REPORTED THAT SHE UNDERWENT A FULL HYSTERECTOMY, BUT NO FURTHER DETAILS WERE PROVIDED. THE REPORTER CONSIDERED THAT HER EVENT WAS RELATED TO ESSURE. FOLLOW-UP RECEIVED ON 14-MAR-2014: NO NEW CLINICAL INFORMATION. FOLLOW-UP RECEIVED ON 01-JUN-2015: INFORMATION RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY (B)(4) STATES THAT SHE HAD ESSURE IMPLANTED IN 2012 AND BEGAN HAVING HAIR LOSS, WEIGHT GAIN, UNCONTROLLABLE VAGINAL BLEEDING FOR 6+ MONTHS THAT REQUIRED PRESCRIPTION OF PAIN KILLERS. IN ADDITION, CONSUMER REPORTED HEADACHES, MEMORY LOSS AS WELL AS RASHES. SHE HAD A HYSTERECTOMY TO REMOVE THE DEVICES AND INFORMED THAT, AFTER 18 MONTHS OF HELL, ALL SYMPTOMS GONE. ADDITIONALLY, THE SERIOUSNESS CRITERION "REQUIRED INTERVENTION" WAS REPORTED. HOWEVER IT WAS NOT SPECIFIED FOR WHICH EVENT. FOLLOW UP 18-JUN-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UNCONTROLLABLE VAGINAL BLEEDING FOR 6+ MONTHS. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE EVENT FULL HYSTERECTOMY PREVIOUSLY REPORTED WAS DELETED SINCE ITS INDICATION WAS REPORTED LATER IN A FOLLOW UP INFORMATION. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, THE CONSUMER EXPERIENCED THE VAGINAL BLEEDING AND OTHER NON-SERIOUS EVENTS AFTER THE DEVICE PLACEMENT. THEN, A COUPLE OF YEARS LATER, SHE HAD A HYSTERECTOMY TO REMOVE THE DEVICES AND INFORMED THAT, AFTER 18 MONTHS OF HELL, ALL SYMPTOMS GONE (POSITIVE DECHALLENGE). CONSIDERING AVAILABLE INFORMATION AND POSITIVE DECHALLENGE THE EVENT IS ASSESSED AS RELATED TO ESSURE USE AND SINCE REQUIRED INTERVENTION WAS PERFORMED TO REMOVE THE DEVICES THIS CASE WAS UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 10-SEP-2015: FOLLOW UP ATTEMPTS WERE DONE, WITHOUT RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00424	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A72332

Single Use: Y
Implant Date (E6): 4/19/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2013, LOT NUMBER A72332. IN (B)(6) 2015 THE PHYSICIAN SAW THE PATIENT WITH PAIN AND DISCOMFORT. REPORTEDLY AFTER TESTS, ESSURE WAS FOUND IN THE ENDOMETRIAL CANAL. PTC INVESTIGATION RESULT RECEIVED ON 02-FEB-2015. (B)(4). FINAL ASSESSMENT: PRODUCTION DATE: 11/2012, EXPIRATION DATE: 11/2015. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY . THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 2 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, NONE OF THEM REFERRING TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP 27-MAY-2015: FOLLOW UP INFORMATION RECEIVED FROM THE PHYSICIAN. NO PREVIOUS CERVICAL CONIZATION, CURETTAGE, IUS/IUD,

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MYOMECTOMY OR ADNEXAL SURGERY. NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. NO RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. PATIENT WAS NOT POST-PARTUM STATE AT TIME OF ESSURE INSERTION ON (B)(6) 2013. DURING THE PROCEDURE THE SOUNDING WAS DONE AND PATIENT RECEIVED LOCAL ANESTHESIA. THE INSERTION AND VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. NO FLUID LOSS MORE THAN 1500CC AND PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. IN (B)(6) 2014 HYSTEROSALPINGOGRAM WAS PERFORMED AND SHOWED SUCCESSFUL OCCLUSION IN BILATERAL FALLOPIAN TUBES WITH ESSURE DEVICES. NO PERFORATION OCCURRED. ON AN UNSPECIFIED DATE A PELVIC CT SCAN WAS PERFORMED AND SHOWED ESSURE IN ENDOMETRIAL CANAL. ON (B)(6) 2015 OTHER HSG WAS PERFORMED AND NO ESSURE WAS VISUALIZED IN THE LEFT FALLOPIAN TUBE AND IT WAS IN ENDOMETRIAL CAVITY. ESSURE WAS NOT REMOVED. FOLLOW UP INFORMATION RECEIVED ON 01-JUN-2015 FROM MEDICAL ASSISTANT: ACCORDING TO REPORTER, PATIENT HAD HER ESSURE ON (B)(6) 2015 (DISCREPANT INFORMATION). ON THE SAME DAY ((B)(6) 2015), SHE HAD ENDOMETRIUM CURETTAGE AND ENDOCERVIX FOREIGN BODY REMOVED. SHE DID NOT HAVE A TUBAL LIGATION DONE. PATIENT CAME IN FOR A POSTOPERATIVE VISIT ON (B)(6) 2015 AND SHE DID RECOVER ALREADY. SHE WAS SCHEDULED FOR A GYNECOLOGY CONSULT ON (B)(6) 2015. CASE CONSIDERED INCIDENT. FOLLOW UP 10-JUN-2015: PTC INVESTIGATION RESULTS WERE UPDATED AND PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. FINAL RISK CLASSIFICATION RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY . THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, NONE OF THEM REFERRING TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 11-JUN-2015 FROM NURSE: REPORTER CONFIRMED ESSURE INSERTION DATE ((B)(6) 2013). SHE STATED THAT PHYSICIAN DID CURETTAGE FOR A DIFFERENT CONDITION, IT WAS FOR HER MENORRHAGIA AS SHE HAD BLEEDING PROBLEMS. A BTL (BILATERAL TUBAL LIGATION) WAS PERFORMED ON (B)(6) 2015 IN OPERATING ROOM UNDER ANESTHESIA FOR PERMANENT STERILIZATION, IT WAS NOT AN ESSURE PROCEDURE. IT WAS THE ESSURE IN THE ENDOMETRIAL CAVITY FLOATING AND DOCTOR REMOVED IT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. SHE WAS SUBMITTED TO A HYSTEROSALPINGOGRAM (HSG), WHICH REVEALED LEFT ESSURE IN THE ENDOMETRIAL CANAL (DEVICE EXPULSION). THEN, ESSURE WAS REMOVED AND DILATATION AND CURETTAGE WAS PERFORMED TO TREAT MENORRHAGIA AND BLEEDING PROBLEMS (GENITAL HAEMORRHAGE). THE REPORTED EVENTS WERE CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY ABDOMINAL PAIN AND GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN ADDITION, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES AND THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY). IN THIS PARTICULAR CASE, PATIENT HAD A FIRST HSG; WHICH REVEALED SUCCESSFUL OCCLUSION OF FALLOPIAN TUBES. THEN, DUE TO PAIN, SHE WAS SUBMITTED TO ANOTHER HSG, APPROXIMATELY 2 YEARS AFTER ESSURE PLACEMENT, AND ESSURE WAS FOUND IN THE ENDOMETRIAL CANAL. ENDOMETRIUM CURETTAGE WAS

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PERFORMED AND THE MICRO-INSERT WAS REMOVED. ALTHOUGH THE EXACT MECHANISM OF THESE EVENTS IS UNKNOWN; GIVEN THEIR NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ALTHOUGH THE REPORTER STATED THAT THE DILATATION AND CURETTAGE WERE NOT RELATED TO ESSURE, A CONTRIBUTORY ROLE FROM ESSURE USE TO THE BLEEDING EVENTS CANNOT BE EXCLUDED AND SINCE THE INTERVENTION WAS MADE TO TREAT THESE EVENTS, THIS CASE IS REGARDED AS INCIDENT. UPDATED TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 30 SEP 2015.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00425	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/16/2011
Explant Date (E7): 1/30/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED... VIA REGULATORY AUTHORITY (CASE# MW5040789) IN UNITED STATES ON 01-JUN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. CONSUMER REPORTED THAT SHE BEGAN HAVING MULTIPLE SIDE EFFECTS AFTER IMPLANTATION: SEVERE HEADACHES, CHANGES IN MENSTRUAL CYCLES, RAPID WEIGHT GAIN, SHARP PAIN IN FALLOPIAN TUBES, NUMBNESS IN LIMBS, RASHES AND DIZZINESS. AFTER SEVERAL TRIPS TO HER PHYSICIAN WITH MULTIPLE TESTS AND NO REASON WAS GIVEN FOR HER PROBLEMS, SHE REALIZED IT WAS THE COILS CAUSING THEM. ON (B)(6) 2015, SHE HAD THE COILS REMOVED AND ALL HER SYMPTOMS HAVE STOPPED. PTC INVESTIGATION RESULT WAS RECEIVED ON 18-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR

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A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP PAIN IN FALLOPIAN TUBES. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, SHE EXPERIENCED THIS EVENT AFTER ESSURE INSERTION. SHE HAD THE COILS REMOVED. BASED ON THE NATURE OF THE EVENT AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 10-SEP-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00426	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C03090

Single Use: Y
Implant Date (E6): 7/7/2014
Explant Date (E7): 2/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5040839) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 WITH LOT NUMBER C03090. IT WAS REPORTED THAT CONSUMER HAD TO HAVE TOTAL HYSTERECTOMY TO HAVE ESSURE REMOVED. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C03090; PRODUCTION DATE: 04-DEC-2013; EXPIRATION DATE: 31-DEC-2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN

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SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE TOTAL HYSTERECTOMY TO HAVE ESSURE REMOVED. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, SINCE REPORTER REGARDED THE EVENT AS A CONSEQUENCE OF ESSURE USE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 13-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00427	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): 4/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A27186

Single Use: Y
Implant Date (E6): 2/3/2012
Explant Date (E7): 4/8/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER A27186 (EXPIRATION DATE 31-JUL-2015) INSERTED ON (B)(6) 2012. THERE WAS A MALFUNCTION WITH ONE OF INSERTION INSTRUMENTS. IT OCCURRED ON THE SECOND SIDE DURING ESSURE PROCEDURE ON (B)(6) 2012. THE DEVICE ITSELF CAUGHT AT THE RELEASE PART. SO THE PROCEDURE WAS INTERRUPTED. DOCTOR TOOK OUT THE MICRO-INSERT COIL WITH GRASPERS. IT WAS THE PATIENT'S CHOICE TO ABORT THE PROCEDURE AS SHE DIDN'T WANT TO FINISH THE PROCEDURE AFTER THE FIRST SIDE WAS COMPLETED. SHE THEN HAD ISSUES 3 YEARS LATER WITH THE ONE SIDE THAT WAS SUCCESSFUL. SHE COMPLAINED OF PAIN AND ON (B)(6) 2015 SHE WENT TO THE EMERGENCY ROOM. SURGERY WAS DONE (B)(6) 2015 ON THE ONE SIDE TO REMOVE THE ESSURE BECAUSE IT WAS CAUSING PAIN. THERE HAVE BEEN NO NEW COMPLAINTS FROM THE PATIENT SO THEY WERE ASSUMING THE OUTCOME WAS GOOD. FOLLOW UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN

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POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FOLLOW-UP FROM (B)(6) 2015: NO NEW INFORMATION PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. DURING ESSURE INSERTION PROCEDURE, THE DEVICE ITSELF CAUGHT AT THE RELEASE PART. THE PROCEDURE WAS INTERRUPTED. PATIENT UNDERWENT A SURGERY ON THE SIDE TO REMOVE THE ESSURE. THIS EVENT, SEEN AS ABDOMINAL PAIN, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. GIVEN THE NATURE OF THE EVENT AND A COMPATIBLE TEMPORAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00428	BAYER HEALTHCARE LLC	6/22/2015	6/22/2015

Event Information:

Event Date (B3): 2/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/5/2008
Explant Date (E7): 2/8/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 01-JUN-2015. ON (B)(6) 2008, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED TO PREVENT PREGNANCY. ACCORDING TO HER ON (B)(6) 2010, THE DEVICE CAUSED A REACTION AND SHE ENDED UP HAVING THE ESSURE REMOVED ALONG WITH HER UTERUS, FALLOPIAN TUBES AND OVARIES ON (B)(6) 2010. ADDITIONALLY SHE BECAME SEPTIC, ALMOST DIED AND UNDERWENT MANY SURGERIES BECAUSE OF THIS. AT TIME OF THIS REPORT THE CONSUMER WAS IN SURGICAL MENOPAUSE; RECEIVING DAILY MEDICATIONS AND HAD A BIG SCAR FROM ALL THE SURGERIES. THE CONSUMER STATED THAT THE DEVICE RUINED HER LIFE AND SHORTENED HER LIFESPAN. FOLLOW UP FROM 15-JUN-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO

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REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED ALONG WITH HER UTERUS, FALLOPIAN TUBES AND OVARIES DUE TO AN UNSPECIFIED REACTION. ADDITIONALLY, SHE STATED SHE BECAME SEPTIC DUE TO THIS PROCEDURE. THESE EVENTS WERE CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE. SEPSIS IS UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE OTHER EVENT IS LISTED. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ESSURE WAS REMOVED APPROXIMATELY 2 YEARS AFTER ITS INSERTION. ALTHOUGH THE EXACT REASON FOR THE PROCEDURE WAS NOT SPECIFIED; SINCE PATIENT RELATED IT TO ESSURE, CAUSALITY CANNOT BE EXCLUDED. REGARDING THE REPORTED SEPSIS, LIMITED INFORMATION WAS PROVIDED. HOWEVER, BASED ON THE AVAILABLE INFORMATION, IT CANNOT BE EXCLUDED THAT THIS EVENT OCCURRED AS A COMPLICATION OF ESSURE'S REMOVAL SURGERY. DUE TO THE SERIOUS INJURY (SEPSIS) AND SURGICAL INTERVENTION REPORTED; THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY, THE NON-SERIOUS EVENTS BIG SCAR FROM ALL THE SURGERIES AND SURGICAL MENOPAUSE WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 10-SEP-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED ALONG

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043277	BAYER	6/22/2015	6/30/2015

Event Information:

Event Date (B3): 5/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B40019

Single Use:
Implant Date (E6): 2/10/2014
Explant Date (E7): 5/29/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN AND HAD MANY HEALTH PROBLEMS. AFTER I DID, SWELLING, BLOATING, INFECTIONS, PELVIC INFLAMMATORY DISEASE, SEVERE PAIN AND CRAMPS IN STOMACH.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00415	BAYER HEALTHCARE LLC	6/22/2015	7/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61992

Single Use: Y
Implant Date (E6): 5/12/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/23/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C61992. IT WAS REPORTED THAT TWO UNITS WERE CONCERNED. FIRST ESSURE INSERT WAS WELL PLACED. FOR THE SECOND ESSURE INSERT, AT REMOVAL AFTER INSERT RELEASE, DELIVERY CATHETER BROKE AND STAYED ATTACHED INTO FALLOPIAN TUBE. THE SURGEON SUCCEEDED IN REMOVING THE BROKEN PIECE WITHOUT CAUSING ANY DAMAGE. THE EVENT OCCURRED IN THE OPERATING ROOM DURING PLACEMENT WHICH WAS PERFORMED WITHOUT ANESTHESIA, UNDER MEOPA. BILATERAL PLACEMENT WAS PERFORMED WITH THE CONCERNED ESSURE INSERTS. PLAIN ABDOMEN X-RAY SHOWED THAT THE TWO INSERTS WERE A PRIORI WELL PLACED. THERE WERE NO CONSEQUENCES FOR THE PATIENT FOLLOWING THE PROCEDURE. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP (B)(6) 2015: FOLLOW UP INFORMATION RECEIVED FROM THE PHARMACIST. ESSURE WAS INDICATED FOR PERMANENT BIRTH CONTROL. ESSURE PLACEMENT WAS DONE IN LITHOTOMY POSITION BY NATURAL WAYS. NO OTHER NEW MEDICAL INFORMATION WAS PROVIDED. NCA REFERENCE NUMBER FROM (B)(6) (#(B)(4)) WAS ADDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: AS OF (B)(6) 2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C61992 (PRODUCTION DATE (B)(6) 2014 AND EXPIRATION DATE (B)(6) 2017) AND

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CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WAS CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, AT REMOVAL AFTER INSERT RELEASE, DELIVERY CATHETER BROKE AND STAYED ATTACHED INTO FALLOPIAN TUBE. PHYSICIAN WAS ABLE TO REMOVE THE BROKEN PIECE AND THERE WERE NO CONSEQUENCES FOR THE PATIENT. THE REPORTED EVENT IS LISTED ACCORDING TO TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, A PRODUCT TECHNICAL ANALYSIS WAS REQUESTED FOR FURTHER EVALUATION OF THE EVENT; HOWEVER SINCE IT WAS REPORTED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH PATIENT HAD NO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WAS CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 29-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ES

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00417	BAYER HEALTHCARE LLC	6/22/2015	7/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68792

Single Use: Y
Implant Date (E6): 5/19/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C68792. IT WAS REPORTED THAT DURING ESSURE INSERTION; THE DELIVERY CATHETER BROKE IN HYSTEROSCOPE AND ESSURE BECAME UNUSABLE. ESSURE INSERTION WAS IMPOSSIBLE ON LEFT SIDE DUE TO TOO MUCH UPSTREAM MANIPULATIONS. BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER DEVICE. NO CAUSAL RELATIONSHIP WITH PATIENT COULD HAVE EXPLAINED THE EVENT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(6). FINAL ASSESSMENT: FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT

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THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C68792 (PRODUCTION DATE(B)(6) 2014 AND EXPIRATION DATE (B)(6) 2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WAS CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE DELIVERY CATHETER BROKE IN HYSTEROSCOPE; ESSURE BECAME UNUSABLE. THIS EVENT IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, AS THE REPORTED EVENT OCCURRED IN ASSOCIATION WITH A DIFFICULT ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT AS NEITHER A QUALITY DEFECT WAS CONFIRMED NOR AN ADVERSE EVENT WAS REPORTED AT THIS POINT IN TIME. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 08-SEP-2015 NO FURTHER INFORMATION WAS OBTAINED DESPITE FOLLOW-UP ATTEMPTS. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00429	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61992

Single Use: Y
Implant Date (E6): 5/12/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 26-MAY-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN A MARKET RESEARCH ACTIVITY FOR ESSURE (FALLOPIAN TUBE INSERT), STUDY NUMBER: (B)(6). ESSURE WAS INSERTED ON (B)(6) 2015. AT THE TIME OF ESSURE THE PLACEMENT, THE DELIVERY SYSTEM WAS DEFECTIVE. THE PHYSICIAN HAD DIFFICULTIES TO REMOVE IT AND WHEN IT WAS DONE, SYSTEM WAS UNWOUND. A PLAIN ABDOMEN X-RAY WAS IMMEDIATELY DONE ((B)(6) 2015) AND SHOWED IMPLANTS WELL PLACED; BUT THERE WAS A SPACE BETWEEN THE 2 METALLIC PARTS ON IMPLANT WHICH POSED PROBLEM DURING PLACEMENT. THE PATIENT WENT BACK TO PHYSICIAN'S OFFICE 10 DAYS LATER AND COMPLAINED OF PAIN EPISODES. ANTI-INFLAMMATORY DRUG TREATMENT WAS INITIATED AS TREATMENT. NOTHING TO REPORT, SINCE THAT DAY. THE PHYSICIAN CONSIDERED THE EVENTS RELATED TO ESSURE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS WERE PROVIDED ON 18-JUN-2015:. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO REPORTED PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. THE REPORTED PRODUCT QUALITY ISSUE COULD NOT BE INVESTIGATED IN FURTHER DETAIL DUE TO LACK OF SAMPLE RETURN. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION NOR A TECHNICAL BATCH INVESTIGATION IS

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POSSIBLE. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT, WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN A MARKET RESEARCH ACTIVITY FOR ESSURE (FALLOPIAN TUBE INSERT). AT THE TIME OF PLACEMENT, THE DELIVERY SYSTEM WAS DEFECTIVE, THE PHYSICIAN HAD DIFFICULTIES TO REMOVE IT AND WHEN IT WAS DONE, THE SYSTEM WAS UNWOUND. THE ABDOMINAL X-RAY PERFORMED IMMEDIATELY AFTER SHOWED THAT THERE WAS A SPACE BETWEEN THE 2 METALLIC PARTS OF IMPLANT (INTERPRETED AS DEVICE BREAKAGE). DEVICE BREAKAGE IS LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). THE ESSURE IS A FLEXIBLE IMPLANT DEVICE THAT ALLOWS THE INSERT TO BEND AND FLEX BACK WHEN ENCOUNTERING ANATOMICAL ISSUES SUCH AS STENOTIC FALLOPIAN TUBES, A UTERINE WALL, FIBROIDS, ENDOMETRIAL FLUFF, OR A TUBAL SPASM. HANDLING ERRORS, DEVIATIONS FROM THE INSTRUCTIONS FOR USE OR NON-PRODUCT RELATED ANATOMICAL ISSUES CAN CAUSE THE SHAPE ALTERATION OF ESSURE. IN THIS PARTICULAR CASE, THE SPACE BETWEEN THE 2 METALLIC PARTS WAS NOTICED IMMEDIATELY AFTER A DIFFICULT INSERTION. ALTHOUGH A HANDLING ERROR MAY HAVE OCCURRED, CONSIDERING THE NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP BETWEEN THE BREAKAGE AND ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE. ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION IT COULD HAVE LED TO IT UNDER LESS FORTUNATE CIRCUMSTANCES. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-NOV-2015 WITH AN UPDATE TO THE FINAL PTC (PTC GLOBAL NUMBER: (B)(4)) INVESTIGATION RESULT: FINAL ASSESSMENT: BATCH NUMBER: C61992. PRODUCTION DATE: JUN-2014. EXPIRATION DATE: 30-JUN-2017. FOR CASES WHERE A DEVICE FAILURE DURING IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00430	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628326

Single Use: Y
Implant Date (E6): 6/26/2009
Explant Date (E7): 5/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. SHE EXPERIENCES PAIN (NOS) ON LEFT SIDE OF ABDOMEN. THE REASON OF THE PAIN COMPLAINTS AND THE KIND OF PAIN ARE UNKNOWN. GYNECOLOGIST WANTED TO ASK ACCOUNT MANAGER IF THE ESSURE COULD BE REMOVED NOW. FOLLOW UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN ON (B)(6) 2015: THE PATIENT'S AGE WAS UPDATED; SHE WAS (B)(6) YEARS OLD AT THE TIME OF ESSURE INSERTION. ESSURE, LOT NUMBER 628326, WAS INSERTED ON (B)(6) 2009.

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THE REPORTER MENTIONED AS COMPLICATIONS DURING THE PROCEDURE THAT THERE WAS A MIRENA (LEVONORGESTREL) IN CAVUM; PARTIALLY ADJACENT IN MYOMETRIUM. FURTHERMORE, THERE WERE ADHESIONS IN THE LEFT TUBA CORNER. ESSURE INSERTION IN LEFT TUBE WAS PAINFUL. A HYSTEROSALPINGOGRAM (HSG) WAS DONE 3 MONTHS LATER AND SHOWED NO CLOSED TUBA OSTIA. THEREFORE, IT WAS NOT CONSIDERED RELIABLE AND PATIENT WAS STERILIZED. ADDITIONALLY, IT WAS REPORTED SHE EXPERIENCED PAIN ON LEFT SIDE, NEXT TO NAVEL. ON (B)(6) 2015 ESSURE WAS REMOVED VIA HYSTEROSCOPY; IT WAS ENTIRELY LOOSE IN CAVUM UTERI (NO ESSURE PARTIALLY IN TUBE). CASE UPGRADED TO INCIDENT. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). BATCH NUMBER 628326 (PRODUCTION DATE NOV-2008; EXPIRATION DATE NOV-2011). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A LACK OF EFFICACY (NO OCCLUSION). THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY MEDICAINLA PRODUCT AND IS ALSO NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: ABDOMINAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 280 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO EXPERIENCED PAIN ON LEFT SIDE OF ABDOMEN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE UNDERWENT A HYSTEROSCOPY AND ESSURE WAS FOUND LOOSE IN CAVUM UTERI, THIS DEVICE WAS REMOVED. ADDITIONALLY, PHYSICIAN REPORTED AS COMPLICATION DURING ESSURE INSERTION THE PRESENCE OF A MIRENA (LEVONORGESTREL IUS) PARTIALLY ADJACENT IN MYOMETRIUM (REGARDED AS DEVICE DISLOCATION). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN MIRENA'S AND ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, IT WAS REPORTED PATIENT'S 3-MONTH CONTROL HYSTEROSALPINGOGRAM REVEALED TUBAL PATENCY. PHYSICIAN PERFORMED STERILIZATION, BUT NO FURTHER INFORMATION WAS PROVIDED ABOUT ESSURE EXPULSION AT THAT TIME. LATER, PATIENT UNDERWENT A HYSTEROSCOPY DUE TO PAIN, AND THE DEVICE WAS FOUND IN UTERUS. ALTHOUGH THE EXACT MECHANISM OF THIS DEVICE EXPULSION IS UNKNOWN; PHYSICIAN MENTIONED THAT AT THE TIME OF ESSURE PROCEDURE, THE PATIENT HAD ADHESIONS IN LEFT UTERINE CORNER AND A DISLOCATED MIRENA; THESE CONDITIONS MAY HAVE RENDERED ESSURE INSERTION DIFFICULT, AND CONTRIBUTED TO ITS SUBSEQUENT EXPULSION TO UTERUS. GIVEN THE ABOVE MENTION INFORMATION AND CONSIDERING EVENT'S NATURE CAUSALITY WITH THE SUSPECT PRODUCTS CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. A REVIEW OF THE MANUFACTURING BATCH RECORD WAS CONDUCTED AND PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT

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CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00432	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/22/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(4) ON 22-AUG-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 TO PREVENT PREGNANCY. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: CERAZETTE (DESOGESTREL), DOMPERIDONE (DOMPERIDONE), FEXOFENADINE HYDROCHLORIDE (FEXOFENADINE HYDROCHLORIDE), LORATADINE (LORATADINE), LAMICTAL (LAMOTRIGINE), IBUPROFEN (IBUPROFEN) AND PARACETAMOL (PARACETAMOL). THE CONSUMER STATED THAT SHE SAW HER GP IN 2010 AFTER A FEW MONTHS OF HAVING THE IMPLANT DUE TO A CHANGE IN HER MENSTRUAL CYCLE. HER PERIODS WERE MORE FREQUENT AND HEAVIER BLEEDING WITH BLOOD CLOTS AND THE PERIOD WAS LONGER THAN 5 DAYS, WHICH WAS HER NORMAL LENGTH. SHE HAD NOT SUFFERED FROM HEAVY PERIODS PREVIOUSLY AND SHE DID NOT HAVE CLOTS. SHE HAD NOT BEEN TAKING ANY FORM OF HORMONAL CONTRACEPTIVE BEFORE HAVING THE IMPLANT. SHE HAD TO USE TWO FORMS OF SANITARY PROTECTION DUE TO THE HEAVINESS OF HER PERIOD. SHE WAS FEELING LIGHT HEADED DURING HER PERIOD. HER GP REFERRED HER TO HAVE A BLOOD TEST AND AN ULTRASOUND. SHE WAS PRESCRIBED MEDICATION TO LESSEN THE BLEEDING. THE ULTRASOUND CAME BACK NORMAL, WITHOUT FIBROIDS; ONE OF HER OVARIES WAS UNABLE TO BE FOUND. THE OTHER OVARY WAS NORMAL. HER PERIODS CHANGED AGAIN IN 2013; SHE HAD TWO PERIODS CONSECUTIVELY IN 10 DAYS OF HER PERIOD, STARTED WITH A HEAVIER BLOOD LOSS, WENT INTO A LIGHTER FLOW AND THEN HARDLY ANY BLOOD FLOW. ON THE NEXT DAY IT STARTED ALL OVER AGAIN WITH A HEAVIER FLOW. THEN, IT STOPPED. IN (B)(6) THIS YEAR, SHE VISITED HER DOCTOR AND INTERNAL SCAN TO CHECK HER OVARIES WAS PERFORMED. AGAIN THAT CAME BACK AS NORMAL, BUT IT WAS NOTED THAT THERE WAS FREE FLUID AND SCARING. HER BLOOD TEST CAME BACK NORMAL FOR HORMONE LEVELS. SHE WAS

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PRESCRIBED WITH PROGESTERONE TO SEE IF THAT WOULD HELP. HER PERIODS WERE LATER; APPROXIMATELY SHE HAD A 32 / 33 MENSTRUAL CYCLE. BEFORE THE IMPLANT SHE HAD A 28 DAY CYCLE, WITH A 5 DAY PERIOD. AFTER THE IMPLANT SHE SUFFERED FROM VAGINAL BLEEDING FOR A DAY THEN IT STOPPED. ON DAY, SHE EXPERIENCED A HEMORRHAGE WITH LARGE BLOOD CLOTS. THIS LASTED A FEW DAYS AND SHE THOUGHT IT WAS NORMAL AFTER HAVING THE IMPLANTS. SHE HAD BEEN SUFFERING FROM A VARIETY OF SYMPTOMS SINCE THE IMPLANTS; SOME OF THEM WERE INCREASING IN SEVERITY AS TIME GOES ON. SHE HAD MANY BLOOD TESTS AND IT ALWAYS SHOWED A SLIGHTLY ELEVATED WHITE BLOOD CELL COUNT; SHE HAD NO INFECTION. PERIODICALLY SHE BROKE OUT IN A STRANGE RASH WHICH LOOKS LIKE A FEW BLISTERS CLUMPED TOGETHER, HER GP HAD NEVER SEEN THIS BEFORE. SHE ALSO HAD HIVES AND ANOTHER IDENTIFIABLE RASH. SHE WAS PRESCRIBED WITH HIGH DOSES OF ANTI-HISTAMINES AS WELL AS A CREAM, TO WHATEVER WAS CAUSING THIS ALLERGIC RESPONSE. SHE DEVELOPED NEW SYMPTOMS LIKE RESTRICTED PELVIC MOVEMENT; SHE WAS UNABLE TO TILT HER PELVIS TO STAND UP DUE TO PAIN IN LEFT PELVIS, GROIN AND SHE WAS UNABLE TO WEIGHT BARE ON HER LEFT LEG TO STAND. BUT SHE WAS ABLE TO WALK PAIN FREE BUT JUST FELT TIGHTNESS IN THAT AREA. SHE WAS ADVISED TO INCREASE THE ANTI-INFLAMMATORY TABLETS. SHE HAD TO INSTALL GRAB RAILS IN HER BATHROOM. THIS LASTED 5 DAYS. HER VISION SUDDENLY CHANGED IN (B)(6) 2014 SHE HAD BLURRED VISION AND DIFFICULTY IN FOCUSING, DURING THE EYE TEST SHE WAS TOLD THAT SHE HAD INCREASED PRESSURE BEHIND HER LEFT EYE, DUE TO INCREASED FLUID. SHE WAS BEEN REFERRED TO THE EYE CLINIC AT THE HOSPITAL AND SHE DID NOT HAVE ANY MEMBERS OF MY FAMILY WITH GLAUCOMA. EARLIER OF THIS YEAR SHE HAD INCREASED PELVIC PAIN AND A URINALYSIS WAS PERFORMED AND SHOWED A TRACE OF BLOOD IN URINE. IN THE COURSE OF THE WEEK SHE HAD INCREASED TO A MODERATE AMOUNT OF BLOOD IN URINE. SHE SAW HER DOCTOR AND WAS REFERRED TO AN UROLOGIST AND A BLOOD KIDNEY FUNCTION TEST WAS DONE AND WAS NORMAL. SHE HAD NEVER SUFFERED SO MANY AILMENTS AND BEEN PRESCRIBED SO MANY DIFFERENT TABLETS BEFORE HAVING THE ESSURE IMPLANT. SHE WAS CONVINCED THAT THE ESSURE WAS CAUSING THESE SYMPTOMS AS SHE HAD A VARIETY OF TESTS AND THEY COME BACK AS NORMAL, SO HER CELLS AND TISSUE WERE HEALTHY AND NORMAL, SOMETHING WAS CAUSING IT. THE ESSURE WAS THE CHEAPEST OPTION THAN HAVING SURGERY, BUT SHE THOUGHT IT WAS PROVING TO BE MORE EXPENSIVE, DUE TO THE SCANS AND TESTS AND SEEING A VARIETY OF CONSULTANTS AND DOCTORS. THE ESSURE IMPLANTS WERE AN ALIEN IN HER BODY AND SHE THOUGHT THESE SYMPTOMS WERE HER BODY'S REACTION TO IT. PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE REPORTED EVENTS ARE OF BROAD NATURE AND THE MAJORITY OF EVENTS WAS CONSIDERED UNRELATED TO THE PRODUCT BY COMPANY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION. CORRECTION ON 05-JUN-2015: AFTER A COMPANY INTERNAL REVIEW CASE WAS REGARDED AS INCIDENT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 10-JUN-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PELVIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 333

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CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER VIA REGULATORY AUTHORITY (HA). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL DISTENSION, MENSTRUAL CYCLE ABNORMAL, PRE-MENOPAUSAL SYMPTOMS, NAUSEA PROPHYLAXIS, BLOOD IN URINE, PELVIC PAIN FEMALE, PELVIC RESTRICTED MOVEMENT, BLURRED VISION, FACIAL HAIR GROWTH, RASH RECURRENT, MIGRAINE, LEG MUSCLE TREMOURS AND GENERAL PHYSICAL CONDITION ABNORMAL. ALL THE EVENTS WERE CONSIDERED SERIOUS BY THE REGULATORY AUTHORITY. THE EVENTS ABDOMINAL DISTENSION, MENSTRUAL CYCLE ABNORMAL, PELVIC PAIN FEMALE AND RASH RECURRENT ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE; WHILE THE REMAINING EVENTS ARE UNLISTED. IN THIS PARTICULAR CASE, THERE WAS A POSITIVE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED PELVIC PAIN, RASHES, ABDOMINAL DISTENSION AND CHANGES IN CONSUMER'S MENSTRUAL CYCLE. GIVEN THIS INFORMATION AND CONSIDERING THESE EVENTS ARE POSSIBLE ADVERSE REACTIONS DURING ESSURE THERAPY, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING PELVIC RESTRICTED MOVEMENT, PATIENT RELATED THIS EVENT TO HER PAIN. THEREFORE, A CAUSAL RELATIONSHIP TO ESSURE CANNOT BE EXCLUDED. FOR THE REMAINING EVENTS; ESSURE IS A METALLIC NON-DRUG RELEASING IMPLANT WITH A LOCAL ACTION IN THE FALLOPIAN TUBES. CONSIDERING THIS INFORMATION AND EVENTS NATURE, CAUSALITY WITH ESSURE IS CONSIDERED UNLIKELY. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT. HOWEVER, AFTER A COMPANY INTERNAL REVIEW OF ENTRY RULES FOR ESSURE CASES, IT WAS AMENDED TO INCIDENT (IN LINE WITH HA'S ASSESSMENT); SINCE CONSUMER DESCRIBED CHRONIC USE OF ANTI-INFLAMMATORY DRUGS (MEDICAL INTERVENTION REQUIRED) AND THE USE OF GRAB RAILS IN THE BATHROOM (INDICATING A CHRONIC RESTRICTION IN MOBILITY; WHICH COULD BE REGARDED AS A PERMANENT IMPAIRMENT). THE PERFORMED PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 31-JUL-2015: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA HEALTH AUTHORITY (B)(4). CONSUMER REPORTED THAT IN 2009 WHEN SHE HAD THE ESSURE IMPLANTS IT WAS SAID THAT THE COILS WERE MADE OF THE SAME MATERIAL THAT IS USED IN A HEART TRANSPLA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00433	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): 12/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/19/2013
Explant Date (E7): 5/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT SINCE INSERTION SHE HAS BEEN HAVING CHRONIC FATIGUE, EXCRUCIATING JOINT PAIN IN HER ANKLES, KNEES, HIPS, HER HANDS WERE SWOLLEN, SHE SOMETIMES COULDN'T EVEN GET OUT OF BED DUE TO JOINT PAIN AND FATIGUE. SHE COULDN'T THINK CLEARLY, GOT CONFUSED, FORGETFUL, COULDN'T CONCENTRATE. CONSUMER HAS BEEN TESTED FOR RHEUMATOID ARTHRITIS, LYMES, GOUT, OSTEO-ARTHRITIS, HAD HER THYROID CHECKED AND ALL OF THEM WERE NEGATIVE. SHE HAS NOT BEEN TESTED FOR FIBROMYALGIA, HAS NOT HAD HER VITAMIN B12. VITAMIN D LEVELS WERE NOT TESTED AND SHE HAS NOT HAD ANY NICKEL ALLERGY TESTING. SHE HAD A DEPO SHOT PRIOR TO INSERTION, THAT PUSHED BACK THE INSERTION DATE DUE TO THE SEVERE BLEEDING FROM THE DEPO FOR 4 OR 5 MONTHS. CONSUMER ALSO MENTIONED THAT HER MENSES HAVE BEEN VERY HEAVY AND SHE HAS NEEDED A TAMPON AND A SUPER HEAVY PAD DUE TO BLEEDING AND CLOTS, AND LAST MONTH WAS THE WORST, PASSING HUGE CLOTS, HORRIBLE BLEEDING. SHE WOULD HAVE AN APPOINTMENT ON (B)(6) 2015 WITH HER GYNECOLOGIST. SHE HAS BEEN CONTINUING WITH ESSURE. CORRECTION (B)(6) 2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT "SHE COULDN'T THINK CLEARLY" WAS RECODED TO (B)(4) LLT "INABILITY TO THINK CLEARLY". THE CASE WAS UPGRADED TO SERIOUS. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 PTC INVESTIGATION RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE

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UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ADDITIONALLY, THE FOLLOWING CORRECTION WAS PERFORMED AFTER A COMPANY INTERNAL REVIEW: PATIENT WAS (B)(6) YEARS OLD. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: ON (B)(6) 2015, ESSURE WAS REMOVED VIA HYSTERECTOMY. CONSUMER STATED THAT SHE HAD PROBLEMS FROM DAY ONE OF THE INSERTION WITH HORRIBLE CRAMPING AND BLEEDING. SHE HAD 2 MEDICAL DOCTORS WHO TOLD HER SHE HAS A COBALT ALLERGY, SIMILAR TO A NICKEL ALLERGY. SHE WAS TOLD SHE HAS UNDIFFERENTIATED CONNECTIVE TISSUE DISEASE. SHE HAS BEEN TAKING STEROID SHOTS IN HER HANDS AND FEET DUE TO SWELLING. SHE HAS PRE-EXISTING GLAUCOMA, HAS BEEN ON PREDNISONE SINCE (B)(6) 2015, TAPERING DOWN THE DOSE, SHE WAS VERY AFRAID OF ALL THE STEROIDS AFFECTING HER GLAUCOMA. SHE HAS ANOTHER 30 DAYS OF IT AT 5 MG. ALSO ON TLAQUENIL FOR JOINT INFLAMMATION. ONSET DATE OF EVENTS: (B)(6) 2013. EVENTS WERE ONGOING. FOLLOW UP FROM (B)(6) 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODEL HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE COULDN'T THINK CLEARLY. LATER IT WAS INFORMED SHE PRESENTED HORRIBLE CRAMPING SINCE PLACEMENT AND UNDERWENT HYSTERECTOMY TO REMOVE THE ESSURE DEVICES. THESE EVENTS, INTERPRETED AS MENTAL IMPAIRMENT AND ABDOMINAL PAIN ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. MENTAL IMPAIRMENT IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE ABDOMINAL PAIN IS LISTED. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE, HOWEVER, MENTAL IMPAIRMENT IS NOT EXPECTED. IN THIS CASE, THE CONSUMER COULDN'T THINK CLEARLY, GOT CONFUSED, FORGETFUL, COULDN'T CONCENTRATE. LATER IT WAS INFORMED SHE HAD HORRIBLE CRAMPING AND THEN HYSTERECTOMY WAS PERFORMED TO REMOVE THE DEVICES. ALTHOUGH THE PATIENT HAD NOT RECOVERED FROM THE EVENTS AFTER HYSTERECTOMY, GIVEN THE NATURE OF THE EVENT, A CONTRIBUTORY ROLE OF ESSURE FOR ABDOMINAL PAIN CANNOT BE TOTALLY EXCLUDED. HOWEVER, CONSIDERING ESSURE DEVICES ACT LOCALLY IN FALLOPIAN TUBES, CAUSAL RELATIONSHIP BETWEEN MENTAL IMPAIRMENT AND ESSURE USE IS VERY UNLIKELY. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT, AFTER FOLLOW UP INFORMATION, THIS CASE

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WAS UPGRADED TO INCIDENT, SINCE HYSTERECTOMY WAS PERFORMED TO REMOVE THE DEVICES. OTHER NON-SERIOUS EVENTS WERE INFORMED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00434	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): 2/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71766

Single Use: Y
Implant Date (E6): 2/24/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 5/11/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER B71766 (EXPIRATION DATE SEP-2016) ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION. PREGNANCY WAS DENIED. HEALTHCARE PROFESSIONAL (HCP) ATTEMPTED TO INSERT FIRST ESSURE IN RIGHT TUBE AND ROLLED BACK, SAW BLACK MARK AND ON 2ND ROLL BACK IT WOULD NOT RELEASE. SHE ATTEMPTED TO INSERT ANOTHER COIL IN RIGHT TUBE AND ON 2ND ROLL BACK THE COIL ALSO DID NOT RELEASE AT FIRST TRIED REMOVING, THEN IT WAS RELEASED AND SOME OF COILS WAS IN TUBE. SHE REMOVED THE ESSURE OUT OF THE TUBE BUT IS AFRAID THAT SHE MIGHT HAVE DAMAGED THE TUBE. SHE THEN WENT TO LEFT TUBE AND ATTEMPTED TO INSERT ESSURE. ESSURE RELEASED BUT THE COILS SEEM TO BE IN A U SHAPE IN TUBE AND ONLY 3 COILS WERE TRAILING INTO UTERUS AND IT WAS LEFT IN PLACE. ESSURE WAS CONTINUED ON LEFT SIDE, AS REPORTED. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: ROLLBACK TO INITIAL HARD STOP; DEPRESS BUTTON; PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS

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GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. AS OF (B)(4) 2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015. PTC GLOBAL NUMBER (B)(4). BATCH NUMBER B71766 (PRODUCTION DATE 12-SEP-2013; EXPIRATION DATE 30-SEP-2016). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: ROLLBACK TO INITIAL HARD STOP; DEPRESS BUTTON; PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. WE TYPICALLY INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. AS RECEIVED, MICRO-INSERT OF SYSTEM 1 WAS DETACHED AND BROKEN. MICROINSERT OF SYSTEM 2 WAS DEPLOYED AND DETACHED. THE SYSTEM 3 WAS RECEIVED WITHOUT MICRO-INSERT. ALL IFU STEPS WERE COMPLETED ON THREE SYSTEMS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. WE ALSO CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. THE PROVIDED COMPLAINT SAMPLES WERE INVESTIGATED. NO QUALITY DEFECT OR DEVICE MALFUNCTION COULD BE CONFIRMED AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. OPERATIVE REPORT PROVIDED BY THE PHYSICIAN ON (B)(4) 2015: CASE

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UPGRADED TO INCIDENT. PATIENT'S HISTORICAL CONDITION INCLUDED MENORRHAGIA. ESSURE PROCEDURE WAS PERFORMED IN THE OPERATING ROOM UNDER MONITORED ANESTHESIA AND PARACERVICAL BLOCK WITH 0.25% MARCAINE AND 1% LIDOCAINE. UTERINE SOUNDING LENGTH WAS 8 CM, UTERUS WAS RETROVERTED. CERVIX WAS DILATED TO 6 CM. AFTER INTRODUCTION OF THE HYSTEROSCOPE, THE ENDOMETRIUM WAS NOTED TO BE SPONGY IN APPEARANCE WITH SUGGESTION OF MULTIPLE SMALL POLYPS. THE VISUALIZATION OF THE LEFT TUBE WAS EASY. THE RIGHT TUBAL OSTIUM WAS A LITTLE MORE DIFFICULT TO VISUALIZE DUE TO SHAGGY ENDOMETRIUM. RIGHT TUBAL OSTIUM WAS EASILY CANNULATE, PHYSICIAN ADVANCED TO CATHETER TO THE BLACK MARKER AND THEN THE WHEEL WAS DRAWN BACK TO PULL BACK CATHETER, BUT IT DID NOT SEEMED TO THREAD BACK IN THE PROPER FASHION AND PHYSICIAN WAS UNABLE TO VISUALIZE THE GOLD KNOB. HE REMOVED THE ESSURE STENT AS HE WAS CONCERNED THE DEVICE WOULD NOT DEPLOY PROPERLY. A SECOND ESSURE WAS OPENED AND ANOTHER ATTEMPT TO INSERT ESSURE IN THE RIGHT TUBE WAS PERFORMED, THE CATHETER DID NOT DISENGAGE FROM THE STENT AND HE COULD NOT REMOVE THE CATHETER ITSELF. WHEN HE TRIED MOST OF THE COIL CAME BACK INTO THE ENDOMETRIAL CAVITY. THE PHYSICIAN HAD TO PLACE A HYSTEROSCOPIC GRASPERS THROUGH THE OPERATING CHANNEL AND GRAB A HOLD OF THE COILS AND APPLY SOME TRACTION. HE WAS ABLE TO REMOVE THE ENTIRE COIL THOUGH IT DID BREAK INTO TWO PIECES. BOTH ENDS WERE IDENTIFIED. A THIRD ESSURE WAS OPENED AND LEFT TUBAL OSTIUM WAS CANNULATED WITH THIS. AFTER PLACEMENT OF THE ESSURE STENT IN THE LEFT TUBAL OSTIUM, THE ESSURE STENT WAS OBSERVED TO POSSIBLY BE MALPOSITIONED. THREE TRAILING COILS WERE NOTED AND THE PHYSICIAN HAD THE IMPRESSION THAT THE DISTAL END OF THE DEVICE PERHAPS CURLED BACK ON ITSELF AT THE TUBAL OSTIUM THOUGH IT WAS DIFFICULT TO VISUALIZE. HE STATED THE INSERT MIGHT HAVE COME OUT INTO THE UTERINE CAVITY AS WELL BUT THERE WERE NOT ENOUGH TRAILING COILS TO SAFELY REMOVE THE STENT. PHYSICIAN LOOKED BACK AT THE RIGHT TUBAL OSTIUM BECAUSE HE WAS CONCERNED THAT THERE COULD BE SOME BLEEDING GIVEN THE TWO ATTEMPTS AND THE NECESSARY REMOVAL OF THE IMPROPERLY PLACED SECOND STENT. HE CONTACT THE PATIENT'S HUSBAND AND LET HIM KNOW THAT WANTED TO PROCEED WITH A LAPAROSCOPY TO LOOK FOR ANY SIGNS OF RIGHT TUBAL DAMAGE OR INTERNAL BLEEDING AND ALSO TO COMPLETE THE STERILIZATION PROCESS BY DOING A BILATERAL TUBAL FULGURATION. BEFORE THE TUBAL FULGURATION A THERMACHOICE BALLOON (ENDOMETRIAL ABLATION) WITH D5W IN 8-MINUTE TREATMENT CYCLE WAS PERFORMED. THERE WAS A LITTLE BIT OF ACTIVE BLEEDING NOTED FROM APPEARED TO BE THE POSTERIOR VAGINAL FORNIX WHERE THE PARACERVICAL BLOCK HAD BEEN APPLIED. THEN, A LAPAROSCOPY WAS PERFORMED. BOTH FALLOPIAN TUBES WERE IDENTIFIED AND FOLLOWED AT THEIR FIMBRIAL ENDS. THE TUBES WERE BOTH FULGURATED IN A WIDE SWATHE IN THE MIDLINE AND THEN DIVIDED IN THE MIDDLE OF THE FULGURATED AREA. LAPAROSCOPIC FINDINGS INCLUDED NORMAL OVARIES, NORMAL UTERUS AND NORMAL FALLOPIAN TUBES BILATERALLY. AFTER ALL THE PROCEDURES PERFORMED, THE UTERINE MANIPULATOR WAS REMOVED AND THERE WAS A LITTLE BIT OF BLEEDING NOTED IN THE VAGINA WITH REMOVAL OF THE MANIPULATOR. THIS WAS WIPED AWAY WITH SPONGE STICKS AND NO FURTHER ACTIVE BLEEDING WAS NOTED. THE PATIENT RECEIVED 1GM OF INTRAVENOUS ANCEF PREOPERATIVELY AND 30MG OF INTRAVENOUS TORADOL AT THE CONCLUSION OF THE PROCEDURE. SHE TOLERATED THE PROCEDURE WELL AND WAS TAKEN TO THE RECOVERY ROOM AWAKE AND IN STABLE CONDITION. FOLLOW UP FROM (B)(4) 2015: UPDATED PTC RESULT WAS RECEIVED. NO MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD 2 ATTEMPTS OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION IN RIGHT FALLOPIAN TUBE. IN THE SECOND ATTEMPT THE CATHETER DID NOT DISENGAGE FROM THE STENT AND PHYSICIAN HAD TO REMOVE IT WITH GRASPERS. THE REMOVAL WAS SUCCESSFUL, HOWEVER THE COIL BREAK INTO TWO PIECES. ADDITIONALLY, IN THE LEFT SIDE ESSURE STENT WAS OBSERVED TO POSSIBLY BE MALPOSITIONED. DUE TO A CONCERN ON RIGHT TUBAL DAMAGE OR INTERNAL BLEEDING THE PHYSICIAN PERFORMED A LAPAROSCOPY. BOTH TUBES WERE FOUND NORMAL DURING THE SURGERY AND WERE FULGURATED. THE REPORTED EVENTS ARE LISTED IN ESSURE REFERENCE SAFETY INFORMATION. IN THIS CASE, PATIENT HAD A SHAGGY ENDOMETRIUM

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WHICH CONTRIBUTED TO THE REPORTED INSERTION DIFFICULTIES; HOWEVER CONSIDERING THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, THE SERIOUS EVENT BLEEDING IN VAGINAL FORNIX WHERE PARACERVICAL BLOCK HAD BEEN APPLIED WAS REPORTED, THIS EVENT WAS CONSIDERED AS RELATED TO ESSURE, SINCE IT WAS A COMPLICATION OF LOCAL ANESTHESIA PERFORMED DURING PREPARATION FOR DEVICES PLACEMENT. ALTHOUGH NO INJURY TO THE FALLOPIAN TUBES WAS CONFIRMED AT LAPAROSCOPY; SINCE AN INTERVENTION WAS REQUIRED, THIS CASE WAS REGARDED AS AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00435	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/21/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. IT WAS REPORTED THAT THE PATIENT HAD 2, 5 RIGHT OVIDUCT WINDINGS (WHICH WAS GOOD ACCORDING TO THE REPORTER). SHE EXPERIENCED LEFT OVIDUCT HALF WINDING AND PAIN IN 2014. ON (B)(6) 2014 LEFT OVIDUCT WAS REMOVED. ON THE SAME DAY THE PATIENT UNDERWENT A HYSTEROSALPINGOGRAM WHICH WAS LOOKING GOOD. PATIENT HAD RECOVERED AND WAS FREE FROM COMPLAINS AT TIME OF THIS REPORT. NO CLINICAL ASSESSMENT HAD BEEN GIVEN. FOLLOW UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY

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CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LEFT OVIDUCT HALF WINDING, WHICH WAS REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION FOR THE OCCURRENCE OF THE EVENT WAS PROVIDED. CONSIDERING THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 06-AUG-2015: LOT NUMBER WAS NOT AVAILABLE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00437	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C40056

Single Use: Y
Implant Date (E6): 3/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(6)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C40056. THE CONSUMER STATED THAT SINCE SHE HAD ESSURE INSERTED, SHE HAD BEEN HOSPITALIZED DUE TO A SEVERE ABDOMINAL PAIN, HEADACHE, CRAMPS IN HER LEGS, WITH DIAGNOSE OF ACUTE SALPINGITIS AND OOPHORITIS. SHE MADE THE COMPLAINT TO HAVE ESSURE REMOVED FROM HER BODY. ALL EVENTS WERE CONSIDERED RELATED TO ESSURE. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2015 FROM PHYSICIAN. IT WAS REPORTED THAT AFTER ESSURE WAS INSERTED THE PATIENT EXPERIENCED AN INFLAMMATORY PROCESS AND THE PATIENT WAS HOSPITALIZED. THE PATIENT RECOVERED AND WAS DISCHARGED. THE PATIENT INSISTED SHE WANTED ESSURE TO BE REMOVED. AT THE TIME OF THIS REPORT INTERVENTION WAS PENDING TO BE PERFORMED. REGARDING THE CAUSAL RELATIONSHIP THE PHYSICIAN DOES NOT GIVE A CLEAR RELATIONSHIP, BUT IT COULD BE POSSIBLE THAT THE PROCEDURE OF INSERTION CAUSED THE INFLAMMATION, IN THIS CASE PELVIC INFLAMMATORY DISEASE. NO FURTHER INFORMATION WAS AVAILABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED VIA HEALTH AUTHORITY AND REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS HOSPITALIZED DUE TO ACUTE SALPINGITIS AND OOPHORITIS / PELVIC INFLAMMATORY DISEASE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING

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INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS IN THE FIRST 4 WEEKS AFTER THE INSERTION PROCEDURE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED AND NO TEMPORAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND THE EVENT WAS GIVEN. THE PATIENT RELATED IT TO THE DEVICE AND THE PHYSICIAN STATED THAT IT COULD BE POSSIBLE THAT THE PROCEDURE OF INSERTION CAUSED THE INFLAMMATION. GIVEN ITS NATURE, A CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE SERIOUS INJURY AND HOSPITALIZATION REPORTED THIS CASE WAS REGARDED AS AN INCIDENT, IN LINE WITH HEATH AUTHORITY ASSESSMENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 16-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT C40056; MFG DATE: 3/2014;

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00438	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 683285

Single Use: Y
Implant Date (E6): 9/21/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(6)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 WITH LOT NUMBER 683285. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED DEVICE DISLOCATION, DEVICE BREAKAGE, ALLERGY CAUSED BY NICKEL IN THE GENITAL AREA, WITH INFECTIONS, STINGING, BAD ODOUR AND IRRITATION. ADDITIONALLY, SHE REPORTED CHANGES IN THE MENSTRUATION (FROM THREE TO EIGHT DAYS), SEVERE MENSTRUAL PAIN INCLUDING KIDNEY AREA AND VITAMIN D DEFICIENCY. A SURGERY (SUBTOTAL HYSTERECTOMY AND SALPINGECTOMY) WILL BE DONE TO REMOVE DEVICES IN THE FOLLOWING DAYS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEVICE BREAKAGE AND DISLOCATION. DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION, WHILE THE OTHER EVENT IS LISTED AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. ALTHOUGH THE EXACT MECHANISM AND TIMING OF THE EVENTS WAS UNKNOWN, GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN OTHER REPORTABLE INCIDENT DUE TO THE REPORTED DEVICE BREAKAGE, AS ALTHOUGH NO DEATH OR SERIOUS HEALTH DETERIORATION WAS MENTIONED BY THE CONSUMER THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED SINCE THIS IS A HEALTH AUTHORITY CASE.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 16-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: BATCH NUMBER 683285. MFG DATE:

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00439	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7): 5/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO AN ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR CONTRACEPTION IN 2005 BY ANOTHER PHYSICIAN. ON (B)(6) 2015 SHE PRESENTED WITH PELVIC PAIN. THE PATIENT HAD AN X-RAY OF THE LOWER SPINE BY HER PRIMARY CARE PHYSICIAN RELATED TO BACK PAIN. ON THE X-RAY IT NOTED IT APPEARED TO NOT BE IN THE APPROPRIATE POSITION. ON (B)(6) 2015 THE PATIENT HAD A DIAGNOSTIC LAPAROSCOPY. BOTH COILS WERE REMOVED. IT APPEARED IT HAD PERFORATED AND WAS COMING OUT OF THE UTERUS. ON (B)(6) 2015 THE PATIENT CAME BACK IN FOR POST OP APPOINTMENT AND WAS FINE. FOLLOW-UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PATIENT UNDERWENT AN X-RAY WHICH RESULT SHOWED ESSURE WAS NOT IN THE APPROPRIATE POSITION. SHE HAD A DIAGNOSTIC LAPAROSCOPY AND BOTH COILS WERE REMOVED. IT APPEARED IT HAD PERFORATED AND WAS COMING OUT OF THE UTERUS. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF UTERINE PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENT BACK PAIN WAS REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 08-SEP-2015: ESSURE HEALTHCARE PROVIDER GENERAL QUESTIONNAIRE. PATIENT´S DEMOGRAPHIC INFORMATION WAS PROVIDED. HER MEDICAL HISTORY INCLUDED GRAVIDA 2, PARA 2. REPORTING PHYSICIAN ONLY REMOVED ESSURE (OTHER ONE INSERTED IT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00440	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38209

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C38209, INSERTION ATTEMPTED. IT WAS STATED THAT THE PHYSICIAN DID NOT GO INTO THE OSS DURING ATTEMPTED PLACEMENT OF INSERT BUT WENT INTO THE FUNDUS AND HAD TO KEEP REMOVING THE DEVICE WHICH KEPT BREAKING. IT CAME OUT BUT IN A LOT OF PIECES. DID NOT GET IT ALL OUT WITH GRASPERS. PROCEDURE WAS COMPLETED WITH OTHER DEVICES. LAPAROSCOPY WAS DONE TO RETRIEVE REMAINING COIL. FOLLOW-UP INFORMATION WAS RECEIVED ON 04-JUN-2015. PATIENT'S INITIALS WERE PROVIDED. ON (B)(6) 2015 ESSURE LOT NUMBER C38209 WAS IMPLANTED. IT WAS REPORTED THAT IT DID NOT DEPLOY IN CORRECT LOCATION. UNIT BROKE WHEN REMOVING WITH GRASPER. BILATERAL PLACEMENT WAS ACHIEVED AND THE PATIENT HAD NO INJURY. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP FROM 16-JUN-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. (B)(4). BATCH NUMBER C38209, PRODUCTION DATE: (B)(4) 2014, EXPIRATION DATE: 31-MAR-2017. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF

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THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT PHYSICIAN DID NOT GO INTO THE OSS DURING ATTEMPTED PLACEMENT OF INSERT BUT WENT INTO FUNDUS, DID NOT DEPLOY IN CORRECT LOCATION AND HAD TO KEEP REMOVING THE DEVICE WHICH KEPT BREAKING, UNIT BROKE WHEN REMOVING WITH GRASPER (INTERPRETED AS DEVICE BREAKAGE). IT CAME OUT BUT IN A LOT OF PIECES, DID NOT GET IT ALL OUT WITH GRASPERS. THE EVENT DEVICE BREAKAGE WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE AND A LAPAROSCOPY WAS PERFORMED IN ORDER TO RETRIEVE REMAINING COIL. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION (WHETHER LAPAROSCOPY OR HYSTEROSCOPY WAS PERFORMED) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 21-AUG-2015: QUESTIONNAIRE WAS PROVIDED WITH NO NEW INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00441	BAYER HEALTHCARE LLC	6/23/2015	6/23/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91769

Single Use: Y
Implant Date (E6): 12/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. IT WAS REPORTED THAT HSG SHOWED DOUBLE PATENCY. IN (B)(6) 2015, PATIENT HAD HAD SURGERY TO REMOVE BOTH TUBES AND NO ESSURE COILS WERE FOUND IN FALLOPIAN TUBES. BOTH COILS WERE IN ABDOMEN. FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SIX MONTHS AFTER PLACEMENT HAD

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SURGERY TO REMOVE BOTH TUBES AND NO ESSURE COILS WERE FOUND IN FALLOPIAN TUBES. BOTH COILS WERE IN ABDOMEN. THESE EVENTS, INTERPRETED AS SALPINGECTOMY AND DEVICE DISLOCATION, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY) MAY BE REQUIRED. ALSO, DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES TO PERITONEAL CAVITY. IN THIS CASE, THE PATIENT UNDERWENT A SALPINGECTOMY FOR UNKNOWN INDICATION AND DURING THE PROCEDURE IT WAS FOUND OUT THAT THE DEVICES WERE NOT IN FALLOPIAN TUBES. THE DEVICES WERE IN ABDOMEN. ALTHOUGH IN THIS CASE THE INTERVENTION'S INDICATION WAS NOT PROVIDED, CONSIDERING THEIR NATURE AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION (PERFORATION QUESTIONNAIRE) RECEIVED ON 24-JUL-2015 FROM PHYSICIAN: THE PATIENT WAS (B)(6) AT TIME OF THE EVENT. SHE IS OBESE AND WAS NOT PREGNANT AT TIME OF THE REPORT. HER MEDICAL HISTORY INCLUDES DEPRESSION AND ASTHMA. SHE HAS NO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043254	BAYER	6/23/2015	6/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE BIRTH CONTROL AND IT HAS CAUSED ME RASHES, LOWER ABDOMEN BLOATING AND LOTS OF PAIN AND DISCOMFORT. THIS PRODUCT IS AWFUL AND I THINK IT SHOULD BE REMOVED FROM THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043259	CONCEPTUS	6/23/2015	6/30/2015

Event Information:

Event Date (B3): 6/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/22/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE COILS INSERTED IN (B)(6) 2011. A REP FROM CONCEPTUS WAS PRESENT DURING IMPLANTATION AND ENSURED THAT THE COILS WERE CORRECTLY PLACED. BY THE TIME I RETURNED TO HAVE THE HSG TEST DONE THREE MONTHS POST IMPLANT, I WAS STILL STRUGGLING WITH STABBING PAIN WHERE THE COILS WERE PLACED AND EXHAUSTION. I WAS TOLD THAT THE PLACEMENT WAS CORRECT AND THAT I WAS NOW STERILE. FOR THE PAST YEAR, MY SYMPTOMS HAVE GROWN WORSE AND HAVE INCREASED TO INCLUDE: EXTREME EXHAUSTION, MIGRAINE HEADACHE, A BLISTER LIKE RASH ON MY CHEST, SHOULDERS AND UPPER THIGHS, HEAVY BLEEDING AND CLOTTING DURING MY PERIOD, JOINT PAIN AND SWELLING, LOWER BACK PAIN AND SWELLING, TINGLING AND NUMBNESS IN HANDS AND FEET AND NERVE PAIN. I HAD TESTS DONE ON MY THYROID, HAD LIQUID FROM THE RASH TESTED ETC WITH NO ANSWERS. I WENT TO THE OB/GYN AND THEY FOUND THAT THE COIL HAD MIGRATED FARTHER INTO MY FALLOPIAN TUBES, THAT I HAD CERVICAL AND ENDOMETRIAL POLYPS, THAT MY HEMATOCRIT LEVEL WAS LOW AND THAT I HAD AN ATYPICAL PAP SMEAR. WITH THE EXCEPTION OF MY HEMATOCRIT LEVEL, I HAVE NEVER HAD ANY GYNECOLOGICAL PROBLEMS PRIOR TO THE INSERTION OF ESSURE. I AM NOW FACED WITH HAVING TO HAVE HYSTEROSCOPY AS WELL AS HAVING THE COILS AND MY FALLOPIAN TUBES REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00431	BAYER HEALTHCARE LLC	6/23/2015	7/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/2/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR CONTRACEPTION. REPORTER STATED THAT SHE ATTEMPTED TO PLACE INSERT IN FIRST TUBE BUT IT WAS IN SPASM SO SHE INSERTED THE COIL IN THE OTHER TUBE WHICH WENT FINE. SHE WENT BACK TO THE FIRST TUBE AND WAS ABLE TO INSERT IT BUT IT NEVER RELEASED AND STAYED CONNECTED AND BROKE. THERE WAS A PORTION OF THE PLASTIC SHEATH STILL ATTACHED TO THE COIL. SHE ALSO STATED THAT DURING THE PROCEDURE, THE INTERNAL CATHETER STRETCHED OUT AND DETACHED INTO THE PATIENT. THE PHYSICIAN ALSO PULLED OUT "AS MUCH AS SHE COULD". THE ESSURE COILS REMAIN IN PLACE. THE PHYSICIAN ALSO REPORTED THAT THE PATIENT HAD A TUBAL SPASM DURING THE PROCEDURE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A

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GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE COIL NEVER RELEASED AND STAYED CONNECTED AND BROKE. THERE IS A PORTION OF THE PLASTIC SHEATH STILL ATTACHED TO THE COIL (DEVICE BREAKAGE). DURING THE PROCEDURE, SHE EXPERIENCED A TUBAL SPASM AND THE INTERNAL CATHETER STRETCHED OUT AND DETACHED INTO PATIENT. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 10-SEP-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00436	BAYER HEALTHCARE LLC	6/23/2015	7/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06518

Single Use: Y
Implant Date (E6): 5/7/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN OTHER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C06518, INSERTION ATTEMPTED ON UNSPECIFIED DATE AND THE DEVICE DID NOT DEPLOY CORRECTLY. IT WAS REPORTED THAT THERE WAS SOME RETAINED PLASTIC LEFT BEHIND IN THE PATIENT (MAYBE A PLASTIC RING) AND CALLER SAID THE PHYSICIAN SAID IT WAS OKAY AND INSERTED ANOTHER COIL. FOLLOW UP (B)(6) 2015: FOLLOW UP INFORMATION RECEIVED FROM A NON-HEALTHCARE PROFESSIONAL FROM THE MEDICAL CENTER WHO PROVIDED CONSUMER'S DATA AS (B)(6). PATIENT WAS NOT PREGNANT. ESSURE WAS INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION. ONE COIL DIDN'T DEPLOY PROPERLY. WHEN THE HCP (HEALTH CARE PROFESSIONAL) ATTEMPTED TO TAKE IT OUT, THE PLASTIC RING THAT WAS PART OF THE DEVICE, CAME OFF AND STAYED IN THE PATIENT. HCP CHOSE TO LEAVE IT AND USED ANOTHER DEVICE FOR THE SAME TUBE. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON (B)(6) 2015: NO NEW CLINICAL INFORMATION. FOLLOW-UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER AND/OR MICRO-INSERT AND/OR INTRODUCER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT.

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MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THERE WAS SOME RETAINED PLASTIC LEFT BEHIND IN THE PATIENT (MAYBE A PLASTIC RING). THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE AND THE DEVICE DID NOT DEPLOY CORRECTLY. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 01-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSU

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00442	BAYER HEALTHCARE LLC	6/23/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON(B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT HSG (HYSTEROSALPINGOGRAM) WAS REVIEWED AND TUBES WERE OCCLUDED BUT COIL MAY BE SEPARATED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS

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TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HYSTEROSALPINGOGRAM (HSG) SHOWED TUBES WERE OCCLUDED BUT COIL MAY BE SEPARATED. THIS EVENT, INTERPRETED AS SUSPICION OF DEVICE BREAKAGE, IS NON-SERIOUS AND PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE, MOST OFTEN DURING DIFFICULT INSERTIONS. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. THE EXACT MECHANISM OF THE EVENT WAS NOT REPORTED NEITHER WAS THE TIME INTERVAL BETWEEN INSERTION AND THE HSG. HOWEVER, CONSIDERING THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE SUSPICION OF DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00443	BAYER HEALTHCARE LLC	6/24/2015	6/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE STATED THAT SHE SUFFERED FROM EXTREME INFLAMMATION OF LIPS AND FINGERS, STOMACH RASHES, SEVERE HIP, JOINT AND BOTTOM OF FEET PAIN AFTER SITTING OR LYING DOWN, SHARP PELVIC AND HEADACHE PAIN, BOILS ON THIGHS AND LEGS THAT SHE HAD TO CUT; OPEN DRAINED AND PUT IN ANTIBIOTICS. SHE HAD BEEN PUT ON ANXIETY, DEPRESSION, GERD, (VITD AND INFLAMMATION MEDICATIONS). CREAMS FOR RASHES DID NOT WORK. SHE HAD CONSTANT EXTREME HOT SWEATY FLASHES, HIGH BLOOD PRESSURE, HEAVY BLEEDING THAT GOES FOR WEEKS AT A TIME. HER DOCTOR WHO INSERTED ESSURE PUT HER BACK ON BIRTH CONTROL PILLS TO SUPPOSEDLY HELP THE BLEEDING. SHE ALSO EXPERIENCED SICK FEELING AND EXTREME FATIGUE. SHE HAS 3 SMALL KIDS AND SAID THAT ESSURE WAS ROBBING HER FROM THEM, BECAUSE SHE WAS SICK FEELING AND WAS TIRED TO DO WHAT SHE NEED TO WITH THEM. SHE SAID THAT SHE NEVER EXPERIENCED THE EVENTS BEFORE ESSURE. DOCTORS TOLD HER THAT ALL ISSUES WERE NOT ESSURE RELATED; THEY DID NOT BELIEVE HER. ON AN UNSPECIFIED DATE, SHE HAD A HYSTERECTOMY; REMOVED TUBES, UTERUS AND CERVIX. SHE IMMEDIATELY FELT A DIFFERENCE IN HOW SHE FELT. INFLAMMATIONS, HIP, FEET AND JOINT PAIN WERE GONE. RASHES ARE GOING AWAY. SHE WAS STILL RECOVERING BUT SHE FELT BETTER RECOVERING WITH GAS PAIN AND THROUGH 3 PREGNANCIES THAN ANY 1 DAY HAVING ESSURE IN HER BODY. FOLLOW UP FROM (B)(4) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE

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HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RASHES (STOMACH RASHES/RASHES); HEAVY BLEEDING AND SEVERE HIP/ JOINT PAIN. SHE WAS SUBMITTED TO A HYSTEROSALPINGECTOMY; AFTER THIS SURGERY HER JOINT PAIN DISAPPEARED AND HER RASHES WERE RECOVERING. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. RASH AND GENITAL BLEEDING ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE JOINT PAIN IS UNLISTED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. ADDITIONALLY, ABDOMINAL, PELVIC PAIN, UNCHARACTERIZED PAIN AND ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE EVENTS WAS NOT PROVIDED; CONSIDERING CONSUMER STATED SHE DID NOT HAVE THIS ISSUES PRIOR TO ESSURE THERAPY AND AS THE EVENTS IMPROVED WITH DEVICE REMOVAL, CAUSALITY CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS REQUIRED, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

AFTER INTERNAL REVIEW ON 07-JUL-2015: THE EVENT CONSTANT EXTREME HOT SWEATY FLASHES WAS SPLIT AND THE MEDDRA EVENT TERM HYPERHIDROSIS WAS ADDED. FOLLOW-UP FROM 04-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE.

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043262	BAYER	6/24/2015	6/30/2015

Event Information:

Event Date (B3): 6/22/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PT BECAME PREGNANT WITH ESSURE IN PLACE DESPITE APPROPRIATE APPEARING PLACEMENT AND NORMAL 3 MONTH F/U HSG SHOWING TUBAL BLOCKAGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043356		6/24/2015	7/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): MALFUNCTION	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 841531

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT PROCEDURE DONE 3 YEARS AGO IN 2012, NO SERIOUS SIDE EFFECTS AS OF YET BUT THERE HAS BEEN A COMPLETE LOSS OF SEXUAL DRIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043357	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 8/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 844600

Single Use:
Implant Date (E6): 8/18/2011
Explant Date (E7): 7/31/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

A FEW MONTHS AFTER GETTING THE IMPLANTS, I STARTED EXPERIENCING EXTREME PAIN IN MY LOWER ABDOMEN. IT WAS MORE PROMINENT ON THE RIGHT HAND SIDE, BUT STILL AFFECTED MY LEFT AS WELL. I WOULD HAVE TO CALL IN TO WORK AT TIMES, AS I COULD BARELY GET OUT OF BED, LET ALONE CARE FOR MY SMALL CHILD IN SUCH PAIN,WHICH HAD ME DOUBLED OVER. I HAD GONE TO MY DOCTOR THAT PLACED THE ESSURE AND HE WAS ADAMANT THAT NONE OF THE ISSUES THAT STARTED AFTER THE IMPLANTS, WERE CAUSED BY THE IMPLANTS THEMSELVES. HE DID TESTS, ULTRASOUNDS AND EXAMS, AND NOTHING WAS EVER THE CAUSE. HE THOUGHT THERE MAY HAVE BEEN CYSTS THAT WERE CAUSING THE PAINS, BUT NOTHING WAS FOUND DURING MY TESTS AND PROCEDURES. HE EVENTUALLY SUGGESTED RIPPING OUT THE COILS FROM MY TUBES FROM THE LITTLE SECTIONS THAT WERE STICKING OUT, WHICH ACTUALLY FRIGHTENED ME SO MUCH, THAT I COULDN'T BEAR TO GO BACK TO SEE HIM. I WENT TO SEE ANOTHER GYN, WHO HAD EXPERIENCED SIMILAR SIDE EFFECTS/PAINS. HE AGAIN STARTED THE WHOLE ROUTINE ALL OVER AGAIN, WITH TESTS, ULTRASOUNDS AND OTHER EXAMS. AGAIN NOTHING WAS FOUND TO BE THE CAUSE. I MENTIONED THAT I HAD NEVER HAD ANY OF THESE SYMPTOMS BEFORE I HAD ESSURE PLACED AND HE GAVE ME THE OPTION TO TRY REMOVAL OF MY TUBES IN ORDER TO REMOVE THE ESSURE AND HOPEFULLY ALL OF THE PET FIBERS WITH MY TUBE REMOVAL. ESSURE WAS PLACED ON (B)(6) 2011 AND REMOVED FROM MY BODY (B)(6) 2014. SINCE REMOVAL OF MY TUBES AND THE ESSURE DEVICES, I HAVE HAD NONE OF THE SAME PAINS OR DISCOMFORT. FROM ABOUT (B)(6) 2011 THROUGH (B)(6) 2013, I HAD EXPERIENCED SUCH PAIN AND AM NOW FREE OF SAID PAINS, SINCE THE DEVICES WERE REMOVED. THIS SHOULD NO LONGER BE ON THE MARKET, AS I LATER FOUND THOUSANDS OF WOMEN WHO HAD SUFFERED THE SAME EFFECTS AS ME PLUS MORE. THEY SAY THE SUCCESS RATE IS 98 SOMETHING PERCENT, WHICH I FEEL IS A COMPLETE LIE. I FEEL THAT THESE DOCTORS WHO

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HAVE PERFORMED THE PROCEDURES ARE INTENTIONALLY KEEPING FACTS AND REPORTS FROM THE FDA AS THEY ARE LIKELY GETTING A BUMP BACK OR WHATEVER ITS CALLED FOR PUSHING THIS PROCEDURE ON THEIR PATIENTS, AS WAS THE CASE WITH ME. I WANTED TO AVOID HAVING SURGERY AND WANTED TO AVOID HAVING ADDITIONAL CHILDREN, WHEN I REQUESTED A TUBAL OR SOME SORT OF LONG TERM BIRTH CONTROL, I WAS TOLD BY MY DOCTOR THIS IS THE SAFEST AND MOST EFFECTIVE PROCEDURE WHICH WOULD NOT BE SURGICAL. BECAUSE OF THIS, I ENDED UP HAVING MY TUBES REMOVED ANYWAY. SO MUCH FOR NOT HAVING A SURGERY. ESSURE RUINED MY LIFE FOR 3+ YEARS AND I AM NOW HAPPY TO REPORT I AM LIVING A HAPPY HEALTHY ESSURE FREE LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043358	BAYER/CONCEPTUS ESSURE	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/1/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED. SINCE THEN I HAVE HAD MULTIPLE STROKES IN BOTH SIDES OF MY BRAIN. MULTIPLE TIAS. MULTIPLE HEMORRHAGES. I HAVE HAD EXTREMELY HEAVY PERIODS SINCE THE DEVICE WAS IMPLANTED, AND HAVE SINCE BEEN INVESTIGATED FOR A HOARD OF OTHER SERIOUS MEDICAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043359	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 6/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 6/1/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

INCREASED PAIN AND HEAVY BLEEDING AFTER HAVING ESSURE IMPLANTED. INCREASE IN LOW BACK PAIN AS WELL AS PELVIC PAIN AND TENDERNESS. INCREASED BLOATING AND FATIGUE. DECREASED LIBIDO AND SOME PAIN DURING SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043360	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN (B)(6) ONE OF THE COILS IS MISSING AND THE OTHER IS HURTING VERY BAD. I GO IN FOR A HYSTERECTOMY ON (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043361		6/24/2015	7/2/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/16/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN 2009. I HAVE A HAD COMPLICATIONS WITH PERIODS, I'VE HAD BLOATING WITH PAIN ALSO SEVERE PAIN WHERE THE IMPLANTS ARE TROUBLE WITH WEIGHT GAIN, PROBLEMS WITH BEING ABLE TO EAT VERY MUCH BECAUSE I NEVER FEEL HUNGRY, MY EYE SIGHT HAS GOTTEN HORRIBLE, I'VE GOTTEN CERVICAL CANCER CELLS CUT OUT FOR THREE YEARS NOW WHICH I NEVER HAD ANY PROBLEMS WITH CELLS IN THE PAST, MY TEETH ARE GOING BAD AND I HAVE NO INSURANCE SO UNABLE TO DO ANYTHING ABOUT ANY OF IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043362	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/26/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

REDUCED TO NO SEX DRIVE, HORMONAL IMBALANCES, DEPRESSION, MOOD SWINGS, VISION AND DENTAL ISSUES, ACNE, FORGETFULNESS "BRAIN FOG", ARM AND LEG NUMBNESS AND TINGLING, HAIR LOSS, LOWER BACK PAIN, ABD PAIN AND CRAMPING, BLEEDING, GASTRO ISSUES, LOSS OF ENERGY, SHAKING AN UNSTEADY HANDS, INCREASED SWEATING, BLADDER ISSUES. RX MEDS: ESSURE STILL IMPLANTED. OTC MEDS: NONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043363	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 6/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/11/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE THE PLACEMENT OF ESSURE, I'VE HAD MANY ISSUES. HAIR LOSS, FALLING OUT IN CLUMPS, PSORIASIS ON MY SCALP. SWELLING OF THE EYES WITH DRY SKIN AROUND THE LIDS AND UNDERNEATH. WEIGHT GAIN, HORRIBLE PERIODS. CRAMPING WORSER THAN NORMAL. TESTING DONE WITH OUT OF POCKET COSTS. PAIN ON LEFT SIDE CONSTANTLY, EVEN WORSE DURING OVULATION. EXHAUSTED, DEPRESSION, NO ENERGY, MOOD SWINGS. VISIONS CHANGES WHERE ITS HARD TO EVEN DRIVE AT NIGHT. INSOMNIA. PAIN IN HIPS AND LEGS. SWELLING, SHORTNESS OF BREATH. SCHEDULED FOR A HYSTERECTOMY (B)(6) 2015 WHICH I'M SURE WILL HAVE MORE OUT OF POCKET EXPENSES. SINGLE MOTHER AND CAN'T AFFORD ALL OF THESE COPAYS TO GET MY LIFE BACK. NEED HELP! OTC MEDS: TYLENOL WHEN PAIN GET TOO BAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043375	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 5/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B66025 & B93875

Single Use:
Implant Date (E6): 5/27/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT ON (B)(6) 2014. SINCE THEN I HAVE HAD SEVERE PELVIC PAIN DAILY, SWEATS, WEIGHT GAIN, HAIR LOSS, HEADACHES, LOSS OF SEX DRIVE, NUMBING PAIN DOWN THE BACK OF MY LEGS AND PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043376	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 4/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/16/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2013 I DECIDED TO GET ESSURE PERMANENT BIRTH CONTROL. SINCE THE IMPLANTATION I HAVE HAD NOTHING BUT PROBLEMS. I CONSTANTLY HAVE CRAMPING, WEIGHT GAIN, EXTREME BLOATING THAT LOOKS LIKE I'M PREGNANT, HORRIBLE HEADACHES AND IRREGULAR PERIODS. I DO NOT HAVE INSURANCE SO I HAVE TO LIVE WITH THESE EVERYDAY WITHOUT MEDICAL ATTENTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043377		6/24/2015	7/2/2015

Event Information:

Event Date (B3): 5/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/1/2010
Explant Date (E7): 5/21/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2010. SINCE THAT TIME I HAD ERRATIC HEAVY BLEEDING, SEVERE ABDOMEN PAIN, SKIN RASH, LEG PAIN, BACK PAIN, ETC. I FINALLY HAD AN ULTRASOUND THAT FOUND A TUMOR WHICH WAS MORE THAN LIKELY THE CAUSE FOR SOME OF THE BLEEDING. HOWEVER, ALL THE OTHER SYMPTOMS WHICH ARE NOT TUMOR SYMPTOMS WENT AWAY WHEN THE ESSURE COILS WERE REMOVED WITH MY FALLOPIAN TUBES. MY OBGYN CONCLUDED THE OTHER EFFECTS WERE FROM THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043378	CONCEPTUS/BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 5/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/23/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

FAILED ESSURE. HAD IT PLACED IN 2008 GOT PREGNANT IN 2010, 2011X3 AND CURRENTLY PREGNANT (2015) ALSO HAVE HAD LOW TO NO ENERGY, WEIGHT GAIN, HAIR LOSS, GALL BLADDER ISSUES, PAIN, BLOATING, EMOTIONAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043385		6/24/2015	7/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN 2013 A COUPLE MONTHS AFTER MY FOURTH BABY WAS BORN IN (B)(6) OF THAT YEAR. SINCE THE PROCEDURE I'VE HAD SEVERE, PIERCING PAIN IN MY ABDOMEN ON BOTH THE LOWER LEFT AND RIGHT HAND SIDE. THE PAIN COMES AND GOES BUT AT TIMES IT IS EXCRUCIATING AND I FIND IT DIFFICULT TO CARRY OUT MY DAY BECAUSE OF IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043386		6/24/2015	7/2/2015

Event Information:

Event Date (B3): 10/31/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/31/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE THE ESSURE DEVICE WAS PLACED I HAVE HAD SERIOUS ISSUES WITH BLEEDING NOT ONLY DURING MY PERIODS THAT NOW LAST 10-14 DAYS BUT ALSO BLEEDING IN BETWEEN PERIODS. THE ARE HEAVY AND I HAVE LOSS OF ENERGY AND HAVE GAINED 20 LBS SINCE THE PRODUCT WAS PLACED. I WAS TOLD INITIALLY BY MY OB/GYN THAT SYMPTOMS WERE ONLY TEMPORARY AND WOULD SUBSIDE BUT THEY HAVE ONLY INCREASED IN SEVERITY. SHE HAS SAID THAT I SHOULD TRY TAKING BIRTH CONTROL WHICH I WAS TOLD THIS PRODUCT WOULD REPLACE THE NEED FOR. THIS LESS INVASIVE PROCEDURE HAS MADE MY LIFE A LIVING HELL. I WISH I WOULD HAVE JUST BEEN ALLOWED TO HAVE THE MORE INVASIVE SURGICAL PROCEDURE AND BE DONE WITH IT BECAUSE PRIOR TO PLACEMENT OF THIS PRODUCT I HAD ABSOLUTELY NO ISSUES WITH MY MENSTRUAL CYCLE AND AM NOW LEFT WITH THIS IRREVERSIBLE NIGHTMARE. I NO LONGER HAVE INSURANCE AND NOW CAN NOT CHOSE TO CHANGE THE DAMAGE. I DO NOT UNDER ANY CIRCUMSTANCE FEEL THAT THIS DEVICE SHOULD BE PLACED IN ANOTHER HUMAN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043387	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 8/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2008 I HAD THE ESSURE PROCEDURE DONE AS A FORM OF PERMANENT BIRTH CONTROL. I WAS (B)(6) AT THE TIME AND AFTER MY 3 MONTH WAITING PERIOD I HAD THE DYE TEST DONE AND WENT OFF THE PILL, AFTER THAT I WENT INTO FULL BLOWN MENOPAUSE AND 2 YEARS LATER HAD TO START TAKING MEDS FOR THAT. FOR THE PAST FEW YEARS I HAVE HAD PAIN IN MY LEFT HIP. RECENTLY I HAD AN MRI DONE AND IT DIDN'T SHOW ANY PROBLEMS WITH MY HIP. BUT MY PAIN IS REAL. I WAS A RUNNER BUT NOT ANY LONGER, THE PAIN IS TOO BAD FOR THAT. WALKING IS OUT AS WELL NOW BECAUSE OF PAIN. WHAT KNOW MORE ON SEE WAS A CYST THE SIZE OF A GOLF BALL, I HAD AN ULTRASOUND (B)(6) 2015 AND WILL KNOW MORE ON THAT IN A FEW DAYS. I HAVE LEARNED THAT IS A SIDE EFFECT OF THE ESSURE THAT I DIDN'T KNOW ABOUT, NOR THE HIP PAIN. I HAVE LOSS OF LIBIDO AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043389		6/24/2015	7/2/2015

Event Information:

Event Date (B3): 8/8/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/8/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) OF 2005. SINCE THEN I HAVE GAINED (B)(6), LOSS OF HAIR, FACIAL HAIR GROWING, AND SEVERE CRAMPING AND VERY HEAVY MENSTRUAL CYCLES. I HAVE HAD NUMEROUS TESTS DONE AND AN EXPLORATORY SURGERY. THEY HAVE FOUND THAT I HAVE A HORMONE IMBALANCE DUE TO THE ESSURE BLOCKING THE RELEASE OF THE EGG FROM MY BODY. IF I HAD NEVER HAD IT PLACED I WOULD NOT BE LIVING IN PAIN AND NOW DEALING WITH DAILY HEALTH COMPLICATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043390		6/24/2015	7/2/2015

Event Information:

Event Date (B3): 6/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEALTHY MOTHER OF THREE, WHO DECIDED TO GET THE ESSURE IMPLANT PROCEDURE DONE AFTER MY 3RD CHILD ON (B)(6) 2010. I HAVE BEEN, SINCE THE PROCEDURE, EXPERIENCING LOWER BACK PAIN, HAIR LESS, PELVIC PAIN, OVARY PAIN, MIGRAINES, INCREASE OF WEIGHT, BLURRED VISION, DRY MOUTH WITH METALLIC TASTE, MOOD SWINGS THAT ARE UNEXPLAINABLE. I NEED TO GET THIS COILS OUT OF MY BODY BEFORE I LOSE MY JOB, MY HUSBAND AND MY FAMILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043391	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): 3SS305
Lot #(E4): B27983

Single Use:
Implant Date (E6): 8/1/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE PROCEDURE DONE (B)(6) 2013 I HAVE HAD NON STOP PROBLEMS. I BLEED FOR 6 MONTHS STRAIGHT. I CALLED MY DR. ABOUT IT AND I WAS TOLD THIS IS NORMAL. IT WAS FAR FROM NORMAL. I HAVE SEVERE CRAMPING BEFORE AND DURING MY PERIOD. HEADACHES 5 OR 6 DAYS A WEEK. I AM BLOATED AND SWOLLEN AND IT DOESN'T MATTER WHAT I DO TO FIX IT OR PREVENT IT. I CAN NOT LOSE WEIGHT. I HAVE ALWAYS BEEN ABLE TO LOSE AND NOW I CAN'T. DURING THE LAST 2 MONTHS I HAVE STARTED TO HAVE MORE ISSUES. I HAVE A PAIN IN MY LOWER LEFT SIDE, NEAR MY OVARIES, ALL THE TIME. SOMETIMES IT'S REALLY PAINFUL AND OTHERS IT'S JUST NOTICEABLE. WHEN THIS STARTED I ALSO STARTED HAVING PAIN IN MY LEFT SIDE DURING SEX. I HAVE NEVER HAD THAT BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043394		6/24/2015	7/2/2015

Event Information:

Event Date (B3): 6/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/31/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE THE ESSURE IMPLANTS WERE PLACED (B)(4) 2015 I HAVE HAD A CONTINUOUS YEAST INFECTION THAT WILL NOT GO AWAY WITH TREATMENT, OTHER INFECTIONS IN CHEST, KIDNEYS, CONSTANT PAIN, CRAMPING, BICATING, FATIGUE, ITCHING/HIVE LIKE RASH, HAIR LOSS AND WEIGHT GAIN. I AM LOOKING INTO HAVING THEM REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043396		6/24/2015	7/2/2015

Event Information:

Event Date (B3): 12/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS TOLD BY MY DOCTOR ABOUT A NON INVASIVE FORM OF BIRTH CONTROL AND WAS IMPLANTED WITH ESSURE (B)(6), 2014. SINCE MY SURGERY I HAVE HAD CRAMPING IN MY ABDOMEN, HEADACHES, HEAVY BLEEDING, ABDOMINAL PAIN, AND SEVERE BACK PAIN. THE SYMPTOMS HAVE WORSENED OVER TIME. I HAVE BEEN TO COUNTLESS DOCTORS AND NONE OF THEM CAN FIND ANY OTHER REASON FOR MY PAIN OTHER THAN ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043397	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 11/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A36516

Single Use:
Implant Date (E6): 11/21/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2012. SINCE THEN, I HAVE BEEN DIAGNOSED WITH FIBROMYALGIA, INSOMNIA AND ANXIETY DISORDERS. I WENT FROM TAKING NO MEDICATIONS TO 5 PILLS A DAY. I HAVE TRIED TO GO TO A PHYSICIAN TO GET THIS REMOVED AND NO ONE WILL HELP ME SINCE I AM NOT IN SEVERE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043398	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/11/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN (B)(6) 2010 AND HAVE NOTICED SINCE THEN I GET FREQUENT MIGRAINES WHICH I HAVE HAD TESTING DONE AND TAKE MEDICATION FOR. I HAVE HORRIBLE MENSTRUAL CRAMPS THAT I HAVE NEVER HAD BEFORE WITH CLOTS SIZE OF GOLF BALLS AND LARGER. EXCESSIVE BLEEDING WITH MENSES. I HAVE GAINED WEIGHT THAT I CAN'T SEEM TO GET OFF WITH DIET AND EXERCISE. I AM TIRED ALL THE TIME AND PRIOR TO ESSURE I VERY RARELY WAS SICK, NOW IT SEEMS I AM ALWAYS GETTING SICK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043399	ESSURE BIRTH CONTROL	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 1/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) OF 2011. I HAD CONSTANT HEAVY MONTHLY CYCLES, BLOATING, HIVES DUE TO WHAT I BELIEVE WAS A REACTION TO THE NICKEL, CONSTANT ABDOMINAL PAIN, OVARIAN CYST, SEVERAL BAD URINARY TRACT INFECTIONS THAT ALSO AFFECTED MY KIDNEYS, WEIGHT GAIN THAT COULD NOT BE EXPLAINED AND COULD NOT BE LOST NO MATTER HOW HARD I TRIED. I ALSO SUFFERED FROM SEVERE DEPRESSION DUE TO ALL ISSUES WHILE HAVING THIS PRODUCT IN MY BODY. I FINALLY HAD THIS DEVICE REMOVED (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043402	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 5/19/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTS
Device Type (E2): ESSURE IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/19/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE PELVIC, BACK, HIP PAIN, HEADACHES, HEAVY BLEEDING AND STOMACH ISSUES INCLUDING BUT NOT LIMITED TO COLITIS. I DIDN'T HAVE ANY OF THESE ISSUES UNTIL AFTER I RECEIVED THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043423	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 1/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/8/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM A PT WHO HAD THE ESSURE IMPLANT PLACED IN (B)(6) OF 2008. I HAVE BEEN HAVING PROBLEMS FOR QUITE SOMETIME NOW AND EVERY TIME I GO TO MY OBGYN THEY TELL ME THAT EVERYTHING LOOKS OKAY. I DO NOT UNDERSTAND WHY I HAVE BEEN HAVING BAD PAINS IN MY LOWER LEFT SIDE OF MY STOMACH, WHY WHEN I GET UP IN THE MORNINGS AND STRETCH I HAVE A STABBING PAIN IN MY LOWER LEFT PART OF MY STOMACH, I HAVE REALLY BAD BLOATING PROBLEMS. I CANNOT DO CERTAIN SEXUAL POSITIONS, YES I HAVE ONLY HAD ONE PARTNER IN THE LAST (B)(6). I HAVE MORNING SICKNESS EVERY MORNING. I WENT TO MY DOCTORS OFFICE ON (B)(6), 2015 SO I COULD GET CHECKED AGAIN. I HAVE TO GO BACK FOR AN ULTRASOUND TO CHECK MY ESSURE. I DID NOT HAVE ANY OF THESE SYMPTOMS BEFORE I HAD THE ESSURE IMPLANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043424	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 12/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/15/2014
Explant Date (E7): 5/18/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED (B)(6) 2014. AFTER HAVING THIS DONE. I HAD DAILY MIGRAINES, LONG AND PAINFUL PERIODS, AND PAIN DURING SEX. I HURT SO BAD THAT I HAD A HYSTERECTOMY (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043425	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 1/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTS
Device Type (E2): ESSURE IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/6/2015
Explant Date (E7): 6/24/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2015. I WAS (B)(6) WHEN IT WAS IMPLANTED. PRIOR TO THIS I HAD A BABY IN (B)(6) 2014. AFTER MY BABY WAS BORN I HAD MY PERIOD SIX WEEKS AND A PERIOD MONTHLY AFTER THAT. I WAS FINE ACTIVE, LOSING WEIGHT AND MOTIVATED. ONCE ESSURE WAS PLACED IN THE FIRST DAY THROUGH THE 4TH DAY, I HAD CRAMPING THAT REQUIRED STRONG MEDICATION TO BE TAKEN IN ORDER TO CONTROL THE PAIN. I WAS ALSO GIVEN A DEPO THE SAME DAY WHEN ESSURE WAS PLACED WHICH WAS (B)(6) 2015. I BEGAN HAVING JOINT PAIN AND RASHES. WHEN THE END OF THE MONTH CAME IN (B)(6) AND THEN THE END OF THE MONTH OF (B)(6) CAME AND BEGINNING OF (B)(6) CAME, I DID NOT GET A PERIOD. I MISSED TWO PERIODS! I DECIDED TO GO TO THE OBGYN AND HE SAID IT WAS PROBABLY A DEPO SHOT REACTION. I EXPLAINED I HAD THE DEPO SHOT GOT HSG TESTING AND ACCORDING TO THEM THE COILS WHERE IN PLACE. MY PERIOD LASTED SIX WEEKS UNTIL (B)(6). CAME AGAIN NO PERIOD BUT MY CRAMPING BLOATING AND PAINS ARE PERSISTENT AS IF MY PERIODS ARE GOING TO COME. I CAN BARELY EAT DUE TO THE BLOATING I FEEL AND HOW SICK MY STOMACH FEELS. I CALLED MY DOCTOR AGAIN BECAUSE BY MAY THE EFFECTS OF THE DEPO SHOT HAD BEEN OUT OF MY SYSTEM YET I STILL HAD PERIOD ISSUES. HE THEN TOLD ME IN THAT APPOINTMENT I HAD A HORMONE ISSUE. HE NEVER DID BLOOD WORK TO DETERMINE THIS. I EXPLAINED TO HIM I ALWAYS USED ALL SORTS OF BIRTH CONTROL PRIOR TO THIS DEVICE AND NEVER HAD AN ISSUE. I CHANGED DOCTORS AND I CAN'T BE SEEN UNTIL (B)(6). I WENT TO MY PRIMARY DOCTOR AND SHE TOLD ME I GAINED FIFTY POUNDS FROM (B)(6). I HAVE NEVER THIS BIG IN MY LIFE. MY LEGS ARE ALSO SWOLLEN. ALL THESE ISSUES BEGAN AFTER ESSURE. CONSTANT HEADACHES CRAMPING BLOATING AND NO LIFE. I NEVER KNOW WHEN I WILL BEGIN GUSHING BLOOD DUE TO MY PERIOD AND WHEN IT ARRIVES, IT LASTS MORE THAN A MONTH WITH EXTREME PAIN AND EXTREME HEAVINESS. A MONTH IN WHICH I BARELY CAN GET OUT OF BED IN PAIN TO

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

SHARE WITH MY CHILDREN. I JUST FOUND OUT THESE COILS ARE MADE OF NICKEL. I NEVER GOT TESTED PRIOR TO INSERTION TO CHECK MY NICKEL ALLERGIES SO I HAVE AN APPOINTMENT FOR THAT AS WELL. MY POINT IS SOMETHING THAT INTERFERES WITH OUR DAILY LIFE AND WELL BEING SHOULD NOT BE PLACED RANDOMLY. SINCE ESSURE, I AM NOT MYSELF, I SHOULD HAVE BEEN TESTED PRIOR TO INSERTION FOR NICKEL ALLERGIES. MY BODY HURTS, MY HAIR FALLS, MY BLOATING AND HEADACHES ARE BAD MY KIDS CANNOT HAVE FUN WITH MOM BECAUSE FOR THE PAST SIX MONTHS MOM IS SICK CONSTANTLY. I NEVER HAD A PRIOR ISSUE WITH HORMONES. THEREFORE HORMONES CAN'T BE THE CAUSE OF ALL MY ISSUES LIKE THE DOCTOR ASSUMED. MY PRIMARY DOCTOR DOES BLOODWORK YEARLY. I'VE ALWAYS BEEN A HEALTHY PERSON. UNTIL ESSURE.!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043426	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 4/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/16/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2013, I DECIDED TO GET ESSURE PERMANENT BIRTH CONTROL. SINCE THE IMPLANTATION, I HAVE HAD NOTHING BUT PROBLEMS. I CONSTANTLY HAVE CRAMPING, WEIGHT GAIN, EXTREME BLOATING THAT LOOKS LIKE I'M PREGNANT, HORRIBLE HEADACHES AND IRREGULAR PERIODS. I DO NOT HAVE INSURANCE, SO I HAVE TO LIVE WITH THESE EVERYDAY WITHOUT MEDICAL ATTENTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043427	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE SOMETIME IN (B)(6) 2011 BUT I NEVER HAD THE DYE TEST TO CHECK IF THE COILS WERE IN THE RIGHT PLACE. I'M NOT SURE HOW LONG AFTER, I STARTED HAVING MISSING OR IRREGULAR PERIODS WITH SEVERE STOMACH BLOATING TO THE POINT WHERE I THOUGHT I WAS PREGNANT. I ALSO HAVE LEFT SIDE PELVIC PAIN AND LOWER BACK PAIN. I DISCUSS THIS WITH MY DOCTOR AND SHE RAN ALL KINDS OF BLOOD TEST AND SAID EVERYTHING CAME BACK GOOD. AFTER TIME HAD PASSED AND I'M STILL EXPERIENCING THE SYMPTOM I DECIDED TO (B)(4) ESSURE AND CAME ACROSS A WHOLE BUNCH OF WOMEN WITH ESSURE THAT IS OR HAVE EXPERIENCED THE SAME SYMPTOMS THAT I DESCRIBED. SO I WENT BACK TO MY DOCTOR AND SHE IS MAKING AN APPOINTMENT FOR ME TO GET THE HSG TEST SOMETIME IN (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043428	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): 1/19/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/19/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I WAS IMPLANTED WITH ESSURE IN (B)(6) 2009, I HAVE NOTHING BUT ISSUES WITH MY HEALTH. MY PERIODS ARE EXCRUCIATING AND I NOW SUFFER FROM OVARIAN CYSTS. I HAVE CONSTANT PAIN INCLUDING PELVIC, STOMACH AND LOWER BACK PAIN. I ALSO EXPERIENCE FREQUENT DIZZY SPELLS AS WELL AS MIGRAINE HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043429	BAYER	6/24/2015	7/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2012, AFTER WHICH I BEGAN HAVING HEALTH PROBLEMS, SUCH AS WEIGHT GAIN/ABDOMINAL BLOATING, FATIGUE, IRREGULAR PERIODS, PAIN ON MY LEFT SIDE IN MY ABDOMEN, CONSTIPATION, AND HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043366	BAYER	6/25/2015	7/2/2015

Event Information:

Event Date (B3): 6/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/12/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE IMPLANTED IN (B)(6) 2012. SINCE THEN, I'VE EXPERIENCED SEVERE PAIN, WHICH I THOUGHT WAS MY GALLBLADDER. BLOATING IN MY ABDOMEN AND FATIGUE (BEYOND NORMAL).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043367	BAYER	6/25/2015	7/2/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/16/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE COMPLETED ON (B)(6) 2011, IMMEDIATELY FOLLOWING THE PROCEDURE I HAD AN ALLERGIC REACTION AND WAS GIVEN A LARGE AMOUNT OF (B)(6). I HAD BROKEN OUT IN HIVES ALL OVER MY CHEST, NECK AND BACK. I WAS THEN RELEASED AND HAD NO MAJOR SIDE AFFECTS TO NOTE. ALTHOUGH I DO BREAK OUT IN HIVES EVERY SO OFTEN FOR WHAT SEEMS TO BE NO REASON AT ALL. MY MOTHER HAS A NICKEL ALLERGY AND I HAVE NEVER BEEN TESTED FOR ALLERGIES. RECENTLY AFTER MY WEIGHT WAS DONE TO (B)(6), I HAD A SIGNIFICANT WEIGHT GAIN WITH NO ABILITY TO LOSE IT WITHOUT AN INCREASE IN CALORIES. CRAMPING AND IRREGULAR PERIODS. FATIGUE, DIAGNOSED WITH ANXIETY AND BEING TREATED WITH TWO MEDICATIONS FOR DEPRESSION. HEART PALPITATIONS, SHORTNESS OF BREATH, STOMACH BLOATING. MY DOCTOR HAS NEVER ADDRESSED THE ESSURE AS A POSSIBLE CAUSE FOR ANY OF MY RECENT SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043368		6/25/2015	7/2/2015

Event Information:

Event Date (B3): 12/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE CAUSED SEVERE BLEEDING, PAIN. WHICH LEAD TO FINDING OUT THE PRODUCT DAMAGED MY UTERUS AND LED TO A FULLY HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043369	BAYER HEALTHCARE LLC	6/25/2015	7/2/2015

Event Information:

Event Date (B3): 10/10/2008 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE. AFTERWARDS, I HAD HORRENDOUS PAIN AND CRAMPING. I BLED MORE THAN I HAVE EVER BLED IN MY LIFE. I HAD WEIGHT GAIN AND MIGRAINE HEADACHES. WHEN I CONTACTED MY DOCTOR AND TOLD HIM I WANTED IT OUT, HE SAID HE COULDN'T TAKE IT OUT AND HE DIDN'T THINK MY SYMPTOMS HAD ANYTHING TO DO WITH THE ESSURE. I ENDED UP GOING TO ANOTHER DOCTOR AND SHE PUT ME BACK ON BIRTH CONTROL PILLS TO TRY TO HELP WITH THE PAIN, CRAMPING AND HEAVY BLEEDING. TAKING BIRTH CONTROL DEFEATED THE PURPOSE OF HAVING THE ESSURE PROCEDURE DONE. I DO NOT WANT TO HAVE THE ESSURE IN MY BODY ANY LONGER. IT IS A HEALTH RISK TO ANY WOMAN WHO HAS IT DONE. THE SIDE EFFECTS OUTWEIGH ANY POSITIVES ABOUT IT. PLEASE DO NOT ALLOW DOCTORS TO CONTINUE TO USE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043370		6/25/2015	7/2/2015

Event Information:

Event Date (B3): 2/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/8/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN TO THE HOSPITAL OVER AND OVER SINCE 2008 WHEN I ORIGINALLY HAD THE ESSURE COILS IMPLANTED. I HAVE HAD THREE MISCARRIAGES AND PERIODS LASTING AS LONG AS 3-4 WEEKS. I HAVE HAD SEVERAL MONTHS WHERE I HAVE HAD TWO AND THREE PERIODS. I HAVE EXTREME PAIN IN MY LOWER ABDOMEN AND BACK CONSTANTLY. IT HAS BECOME UNBEARABLE TO HAVE INTERCOURSE. I WANT THOSE COILS REMOVED BEFORE ANYTHING WORSE OCCURS. I ALSO HAVE A NICKEL ALLERGY AND IT WAS NOT DISCLOSED TO ME THAT THE COILS HAD NICKEL, CAUSING ME TO BREAK OUT IN RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043371	BATYER	6/25/2015	7/2/2015

Event Information:

Event Date (B3): 6/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN, IN 2010. I HAVE VERY SEVERE PAINS WHEN I'M ABOUT TO START MY PERIOD AND WHILE ON MY PERIOD. I'VE NOTICED IF I MOVE CERTAIN WAYS IT WILL PUNCH OR FEEL LIKE A STABBING PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043372		6/25/2015	7/2/2015

Event Information:

Event Date (B3): 9/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE AND NOW I HAVE BEEN EXPERIENCING BACK PAIN, I'M TIRED ALL THE TIME, I HAVE NO MOTIVATION TO DO ANYTHING, I GOT HEADACHES ALL THE TIME AND I GAINED WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043373		6/25/2015	7/2/2015

Event Information:

Event Date (B3): 12/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/30/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(6) 2013, SINCE THEN I HAVE HAD EXTREMELY HEAVY MENSTRAL CYCLES, PAIN IN MY LEGS, PAIN AT IMPLANTATION SPOT, HEADACHES AND DEPRESSION AND EXTREME FATIGUE. I USED TO HAVE ENERGY, I USED TO BE ABLE TO RUN MILES AND WORK 8 HOUR DAYS. MY QUALITY OF LIFE HAS BEEN EXTREMELY EFFECTED. I AM NOT ALLERGIC TO NICKEL AND HAVE NEVER HAD ANY MAJOR HEALTH ISSUES. I CHOSE A DOCTOR WHO HAS PERFORMED OVER 1,000 ESSURE PROCEDURES ACCORDING TO THEIR WEBSITE AND HAD FULL CONFIDENCE HE WAS ABLE TO IMPLANT IT ACCORDING TO THEIR TRAINING. THIS IS VERY SERIOUS AND READING THAT OTHERS HAVE HAD THE SAME ISSUES IS TROUBLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043434	BAYER	6/25/2015	7/2/2015

Event Information:

Event Date (B3): 6/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/11/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD ESSURE DEVICE FOR 2 WEEKS AND EVER SINCE, HAVE HAD CONSTANT PAIN AND BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043442	BAYER	6/25/2015	7/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ENSURE PROCEDURE IN 2012, I AM NOW DIAGNOSED WITH CERVICAL DYSPLASIA, HAD TO HAVE CRYOTHERAPY. I HAVE BLEEDING BETWEEN MY PERIODS, INCREASED ANXIETY DURING PMS, AND EXCESSIVE WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043443	BAYER	6/25/2015	7/6/2015

Event Information:

Event Date (B3): 12/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/16/2013
Explant Date (E7): 5/5/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE PROCEDURE PERFORMED IN (B)(6) 2013. THEREAFTER , I SUFFERED HEAVY BLEEDING, PERIODS EVERY 15-20 DAYS LASTING 10 DAYS AT A TIME, SEVERE ABDOMINAL PAIN, CHRONIC FATIGUE, HEADACHES, ANXIETY, DEPRESSION. I SPOKE WITH MY INTERNIST AND MY GYN ABOUT THE SYMPTOMS. WE SWITCHED MEDICATION, WE DID ENDOMETRIAL BIOPSIES, WE DID TRANSVAGINAL ULTRASOUNDS, ALL WITH NO RESULT. (B)(6), I HAD A TOTAL HYSTECTOMY UNDER THE ASSUMPTION I LIKELY HAD ENDOMETRIOSIS. MY GYN REMOVED MY UTERUS, FALLOPIAN TUBES AND CERVIX, BUT HE FOUND NO ENDOMETRIOSIS DURING THE SURGERY. THE PATHOLOGY REPORT SHOWED A NORMAL RESULT. THERE IS NO OTHER EXPLANATION FOR THESE SYMPTOMS STARTING AFTER MY ESSURE PROCEDURE. I AM AN OTHERWISE EXTREMELY HEALTHY WOMAN. MY MEDICAL RECORDS FROM MY INTERNIST, MY GYN AND MY THERAPIST WOULD ALL CORROBORATE MY SYMPTOMS AND THOSE SYMPTOMS COINCIDING WITH THE ESSURE PROCEDURE AND LASTING UP UNTIL MY HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043444	BAYER	6/25/2015	7/6/2015

Event Information:

Event Date (B3): 10/7/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/1/2005
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE PROCEDURE (B)(6) 2005. SINCE THAT TIME I HAVE HAD SIDE EFFECTS THAT I DID NOT KNOW WHAT TO ATTRIBUTE THEM TO, UNTIL I BEGAN READING ABOUT OTHER WOMEN AND THEIR SIDE EFFECTS WITH THIS PROCEDURE. THE SIDE EFFECTS HAVE GOTTEN WORSE IN THE LAST FEW YEARS. SIDE EFFECTS THAT PELVIC PAIN AROUND OVULATION; STOMACH BLOATING; TROUBLE LOSING WEIGHT; BACK PAIN; MIGRAINES; VERTIGO; LACK OF ENERGY; HEAVY PERIODS WITH CRAMPING AND CLOTTING; DIAGNOSED WITH UNSPECIFIED ANEMIA AFTER I HAD THE ESSURE PROCEDURE, I EXPERIENCED BAD PELVIC PAIN RIGHT AWAY. AFTER HAVING TWO HYSTEROSALPINGOGRAPHY 3 AND 6 MONTHS POST PROCEDURE, I HAD MY MEDICAL PROCEDURE AND THAT IT WAS NOT SUCCESSFUL IN PREVENTING A PREGNANCY BECAUSE I HAVE ONLY ONE FALLOPIAN TUBE. THIS WAS AFTER I HAD THE PROCEDURE DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043445	BAYER HEALTH	6/25/2015	7/6/2015

Event Information:

Event Date (B3): 12/13/2013 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4): 626221
Lot #(E4): ESS305

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A HYSTERECTOMY IN (B)(6) OF 2013. MY DOCTOR INFORMED ME ONE OF THE ESSURE METAL COILS WAS "FLOATING AROUND" (HAD COME LOOSE) INSIDE ME. HE DIDN'T KNOW WHAT IT WAS UNTIL HE REMOVED IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043446	BAYER	6/25/2015	7/6/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

KIDNEY STONES, FATIGUE, ABDOMINAL PAIN, INSOMNIA, BLOATING FROM ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043447	BAYER HEALTH	6/25/2015	7/6/2015

Event Information:

Event Date (B3): 9/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/28/2013
Explant Date (E7): 9/5/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2013 I HAD THE ESSURE PLACED. IT WAS VERY PAINFUL GOING IN AND APPROXIMATELY A MONTH INTO IT I STARTED BLEEDING AND I WAS IN PAIN CONSTANTLY. I WENT BACK FOR THE FOLLOW UP TEST IN (B)(6) 2013 AND CONTINUED TO BLEED. THE PAIN OF CHECKING PLACEMENT; DEATH WOULD HAVE BEEN A BETTER CHOICE. WHEN I SAW MY DOCTOR AND EXPLAINED THE PROBLEMS I WAS HAVING WITH THE PRODUCT AND BLEEDING WAS A CONCERN BECAUSE I WAS BECOMING WEAK, HE ADVISED OUR ONLY OPTION TO CORRECT THE PROBLEMS AT HAND WERE TO HAVE A HYSTERECTOMY. NEEDLESS TO SAY (B)(6) I HAD MY HYSTERECTOMY TO FIX THE PROBLEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043469	BAYER	6/26/2015	7/6/2015

Event Information:

Event Date (B3): 12/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/14/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PUT IN FALL 2007. IN (B)(6) 2009, I HAD SEVERE ABDOMINAL PAIN AND SWELLING. DOCTOR PERFORMED EXPLORATORY SURGERY. HE FOUND FALLOPIAN TUBE TWISTED UP LIKE A COIL WITH CYST ATTACHED. DOCTOR REMOVED FALLOPIAN TUBE. SINCE THEN I HAVE CONTINUED TO SUFFER FROM HEAVY, CLOTTING PERIODS, PAIN DURING INTERCOURSE, BLADDER SENSITIVITY, HOT FLASHES AND LOW VITAMIN D.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043470		6/26/2015	7/6/2015

Event Information:

Event Date (B3): 6/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4): *
Catalog # (E4): *
Lot #(E4): *

Single Use:
Implant Date (E6): 6/15/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD ESSURE COILS FOR ABOUT TWO YEARS. WHEN I HAD THE PROCEDURE DONE, I FELT EVERYTHING. I WAS GIVEN NO TYPE OF ANESTHESIA. SINCE I HAD THE PROCEDURE, I AM IN EXTREME PAIN ALL OF THE TIME. THIS PAIN IS WORSENED WHEN MENSTRUATING AND DURING ANY PHYSICAL ACTIVITY, ESPECIALLY INTERCOURSE. I ASKED THE DOCTOR WHO PUT THEM IN TO REMOVE THEM. I AGREED, MY HEALTH INSURANCE COVERED THE REMOVAL AND THE SURGERY DATE WAS SET. THE MORNING OF MY SURGERY, THE DOCTOR CALLED AND CANCELLED, STATING THAT THE COMPANY WHO MAKES THE ESSURE COILS WOULD NO LONGER BACK HIM AS A PROVIDER OF THEIR PRODUCT IF HE WENT THROUGH WITH MY SURGERY TO REMOVE THEM. THAT WAS ABOUT A YEAR AND A HALF AGO. I AM STILL IN PAIN EVERY DAY. MY PERIODS HAVE BEEN BECOMING MORE AND MORE ERRATIC AND PAINFUL. I HAVE TRIED GOING TO OTHER DOCTORS AND HOSPITALS AND EVERYONE JUST TELLS ME TO TAKE SOMETHING FOR THE PAIN BUT I DON'T WANT TO BE ON PAIN KILLERS FOR THE REST OF MY LIFE. I JUST WANT TO HAVE THE ESSURE COILS REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043481		6/26/2015	7/6/2015

Event Information:

Event Date (B3): 6/4/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE STERILIZATION DEVICE
Device Type (E2): ESSURE STERILIZATION DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/4/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2009, I RECEIVED ESSURE STERILIZATION INSERTS VIA AN OUTPATIENT PROCEDURE IN MY GYNECOLOGIST'S OFFICE. WITHIN A YEAR TO YEAR AND A HALF OF HAVING THE PROCEDURE COMPLETED I BEGAN TO NOTICE FATIGUE, INTERMITTENT ABDOMINAL AND BACK PAIN AND A HOST OF SYMPTOMS I HAD NOT EXPERIENCED ON A REGULAR BASIS PRIOR TO THE PROCEDURE. BY 2014, I HAD SEEN BY PRIMARY CARE DOCTORS, GASTROENTEROLOGISTS, NEUROLOGY SPECIALISTS, OPHTHALMOLOGIST AND PULMONARY SPECIALIST FOR ISSUES RANGING FROM NUMBNESS AND TINGLING, EYE PAIN AND VISION BLURRINESS, HEADACHES, BURNING SENSATION IN HANDS AND LEGS TO CHRONIC CONSTIPATION, CHRONIC COUGH, JAW PAIN, TROUBLE BREATHING AND INSOMNIA. I HAVE RECEIVED A WEALTH OF POSSIBLE DIAGNOSIS INCLUDING MS, NEUROPATHY, ASTHMA AND MOST RECENTLY FIBROMYALGIA (FOR WHICH I HAVE NOW BEEN PRESCRIBED DAILY MEDICATION). I HAVE HAD A MULTITUDE OF TESTS (INCLUDING MRI, LUNG FUNCTION, NERVE CONDUCTION, COLONOSCOPY, ENDOSCOPY, ETC) AND HAVE SPENT YEARS LIVING WITH PAIN FOLLOWING THE INSERT OF THE ESSURE COILS. I BELIEVE ALL HEALTH CONCERNS ADDRESSED PREVIOUSLY ARE IN DIRECT RELATION TO HAVING THE ESSURE COILS PLACED WITHIN MY BODY. THIS PRODUCT IS NOT SAFE AS PRESENTED AND SHOULD BE REMOVED FROM PRODUCTION AND CONSUMER AVAILABILITY (MY OPINION).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043485	BAYER	6/26/2015	7/6/2015

Event Information:

Event Date (B3): 4/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/16/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD VERY HAD SIDE EFFECTS FROM THE ESSURE PERMANENT BIRTH CONTROL I RECEIVED IN 2013. I HAVE HAD DEPRESSION, HEAVY BLEEDING, FREQUENT HEADACHE AND ABDOMINAL PAIN THAT HAS GOTTEN WORSE AS TIME PASSES. ALSO MY PERIODS ARE VERY UNPREDICTABLE. I WOULD HAVE NEVER GOTTEN THIS PROCEDURE HAD I KNOWN THESE WERE POSSIBLE SIDE EFFECTS. I WOULD APPRECIATE ANY HELP WITH THIS. IF I COULD HAVE THEM REMOVED I WOULD BUT I CANNOT AFFORD TO AND I HAVE READ THAT IT IS NOT SAFE TO HAVE THEM REMOVED. I HAVE ALSO HAD VERY FLUCTUATING WEIGHT PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043438	BAYER	6/27/2015	7/2/2015

Event Information:

Event Date (B3): 8/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/3/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE ESSURE I BECAME PREGNANT AND HAD CHILD 2 YEARS LATER SUFFERED FROM HEAVY BLEEDING OVARIAN CYST HAD TO GET HYSTERECTOMY PELVIC PAIN, BACK PAIN, WEIGHT GAIN, DEPRESSION, CHRONIC DAILY MIGRAINE AND PAIN DURING INTERCOURSE. PREGNANT AFTER 2 YEARS BABY BORN WITH HEALTH PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043472	BAYER	6/27/2015	7/6/2015

Event Information:

Event Date (B3): 6/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/26/2014
Explant Date (E7): 4/15/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED 3 MONTHS AFTER HAVING MY LAST CHILD AT THE END OF (B)(6) 2014. ROUGHLY ONE MONTH AFTER ESSURE WAS IMPLANTED, I STARTED TO DEVELOP STRANGE AND PROBLEMATIC SYMPTOMS. THE BEGINNING SYMPTOMS INCLUDED SEVERE PELVIC PAIN, SEVERE BLEEDING FOR 2 MONTHS, STABBING HEAD PAINS, EAR PAIN, TINNITUS AND HEADACHE, HORRIBLE LIGHTHEADEDNESS, DIZZINESS AND PANIC ATTACKS THAT INCLUDED NAUSEA AND VOMITING ON OCCASION, AND CHRONIC FATIGUE. IN THE FOLLOWING MONTHS, I CONTINUED TO GAIN WORSENING SYMPTOMS INCLUDING THE PREVIOUS NOTED AND, AUTO IMMUNE LIKE SYMPTOM, JOINT PAIN, BREATHING ISSUES, HEART PALPITATIONS, CHRONIC CHEST PAIN WITH A CRACKING STERNUM, STOMACH, AND OTHER GI ISSUES, MEMORY AND CONCENTRATION PROBLEMS, MOOD SWINGS, DEPRESSION, HOPELESSNESS, SADNESS, FEELING TOXIC OR POISONED, A METALLIC TASTE IN MY MOUTH, AND STRANGE SMELLS LIKE BURNING HAIR, OR CHLORINE, AND TEETH SENSITIVITY/PAIN AND DECAY. THERE ARE THINGS I'VE LEFT OUT IN SURE. I HAVE IN ATTEMPTS TO FIGURE OUT WHAT WAS HAPPENED TO ME SEEN MY OBGYN THAT IMPLANTED THE ESSURE. I ALSO SAW OTHER OBGYNS, MULTIPLE DRS AND INTERNISTS, MULTIPLE SPECIALISTS INCLUDING 2 CARDIOLOGISTS, AN ENT, A RHEUMATOLOGIST, A GI, A CHIROPRACTOR, A BREAST SURGEON, HAD 30+ ER VISITS, CARDIAC STRESS TEST, CARDIAC NUCLEAR TEST, NUCLEAR HIDESCAN, 20+ CHEST X-RAYS, MULTIPLE CT SCANS, MRI, MAMMOGRAM, AND IT SEEMS ENDLESS BLOOD TESTS FOR CARDIAC REASONS AND TESTING FOR LYME, LUPUS, AND RA. I HAD MULTIPLE DDIMER TEST RETURN QUITE ELEVATED EACH TIME. I HAVE BEEN PRESCRIBED A GROCERY LIST OF MEDICATIONS TO TREAT SYMPTOMS, INCLUDING BETA BLOCKERS, CALCIUM CHANNEL BLOCKERS, SEVERAL DIFFERENT ANTI-ANXIETY MEDICATIONS, VALIUM, PAIN KILLERS, BIRTH CONTROL (TO STOP THE 2 MONTHS OF BLEEDING), AND ANTI-DEPRESSANTS. I HAD A HYSTERECTOMY ON (B)(6) 2015 TO REMOVE THE ESSURE COILS. I

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AM CURRENTLY SUFFERING SEVERAL SYMPTOMS STILL THAT I DID NOT HAVE BEFORE ESSURE. IN MY BELIEF ALL OF THE ABOVE IS DIRECTLY CAUSED FROM THIS DEVICE, AS I SUFFERED NONE OF THESE SIDE EFFECTS PRIOR TO BEING IMPLANTED. I SUFFER FROM THIS DAILY. IT'S RUINED MY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043463		6/28/2015	7/6/2015

Event Information:

Event Date (B3): 6/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE IN 2011. IN 2012 I BEGAN HAVING THE FOLLOWING PROBLEMS: FLOODING MENSTRUAL CYCLES, CYSTS AND FIBROIDS IN OVARIES, ANEMIA, VITAMIN D DEFICIENCY, IRREGULAR CYCLES, PAIN IN LOWER ABDOMEN, BACK ACHES. REPEATED TRIPS TO DIFFERENT DOCTORS FOR ABOVE PROBLEMS. WENT TO OBGYN IN 2013 THROUGH 2014 COMPLAINING OF THE ABOVE SYMPTOMS AND THAT I THOUGHT THE ESSURE PROCEDURE WAS THE CAUSE. THE DOCTOR DISMISSED ESSURE BEING THE CAUSE. TRIED ME ON BIRTH CONTROL PILLS WITH NO SUCCESS. (B)(6) 2015, A MEDICAL DOCTOR DID BLOOD WORK THAT DETERMINED SEVERE IRON ANEMIA AND VITAMIN D DEFICIENCY. OBGYN DOCTORS IN 2013 AND 2014, TRIED ME ON DIFFERENT BIRTH CONTROL PILLS. IN 2014, A DIFFERENT OBGYN SUGGESTED A HYSTERECTOMY BECAUSE BIRTH CONTROL WAS NOT HELPING MY CYCLES AND ESSURE CANNOT BE REMOVED. I DID NOT GET THE HYSTERECTOMY PROCEDURE. STILL HAVING MANY MENSTRUAL PROBLEMS THAT MAKE IT HARD TO GO ANYWHERE FOR THE FIRST 3 DAYS OF MY CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043464	BAYER	6/28/2015	7/6/2015

Event Information:

Event Date (B3): 12/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/21/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE IMPLANTS SINCE 2006. HAVE HAD NUMEROUS SIDE EFFECTS, STABBING PAIN IN ABDOMEN. PAINFUL BREAST, CONSTANT YEAST INFECTIONS, HIGH BLOOD PRESSURE, DX OF PMDD, SWELLING OF LEG, ANKLES, ABDOMEN, RESTLESS LEG SYNDROME, HEAVY MENSTRUAL CYCLE, BLOOD CLOTS THE SIZE OF GOLF BALLS, NO LIBIDO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043465		6/28/2015	7/6/2015

Event Information:

Event Date (B3): 12/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/28/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE DONE (B)(6) 2012. OUT PATIENT SURGICAL FACILITY UNDER GENERAL ANESTHESIA. PREGNANCY 4 MONTHS POST SURGICAL-HEALTHY BIRTH OF CHILD, FREQUENT INDESCRIBABLE PAIN IN UTERUS AND OVARY AREA SOMETIMES INTO THE ABDOMEN AND RIGHT HIP AREA, HEAVIER MENSTRUAL CYCLES, INCREASED YEAST INFECTIONS, CONSTANT DISCOMFORT IN UTERINE AREA WITH BLOATING, PAIN IN UTERUS AFTER SEXUAL INTERCOURSE NAUSEOUS IN MORNING AND SOMETHING THROUGHOUT THE DAY, BURNING OR TEARING FEELING IN UTERINE/OVARY AREA EITHER LAYING DOWN OR STANDING, OCCASIONAL SEVERE INDESCRIBABLE PAIN IN UTERUS/ABDOMEN ENOUGH TO MAKE ME DOUBLE OVER AND STOP EVERYTHING AND NOT ABLE TO WALK OR MOVE, ABNORMALLY INCREASED VAGINAL DISCHARGE. NO TESTING AT ALL TO DATE, WAS PREGNANT BY THE TIME THE CONFIRMATION TEST WAS DUE. WILL BE REQUESTING AN XRAY OF SOME TYPE TO DETERMINE LOCATION OF COILS. NOT SURE IF THEY ARE IN PROPER POSITION OR IF THE TUBES WERE OCCLUDED. ADVIL FOR PAIN WHEN NECESSARY, OVER THE COUNTER AND RX MEDICATION FOR VAGINAL DISCOMFORT DUE TO YEAST INFECTIONS WHEN NEEDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043466	BAYER	6/28/2015	7/6/2015

Event Information:

Event Date (B3): 6/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/10/2013
Explant Date (E7): 12/31/2013
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DISABLED FROM BAYER'S PRODUCT ESSURE PERMANENT BIRTH CONTROL COILS. PERMANENT NERVOUS SYSTEM DYSFUNCTION CAUSED BY EXCESSIVE INFLAMMATION. DIAGNOSED WITH POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME. THIS PRODUCT HAS COMPLETELY RUINED MY LIFE. I'VE LOST MY FAMILY AND HEALTH TWO YEARS AGO. MY SYMPTOMS ARE EXCESSIVE TACHYCARDIA AND IRREGULAR BEATS UPON STANDING. BLOOD POOLS, SHORTNESS OF BREATH, DIZZINESS, FAINTING, UNABLE TO STAND FOR ANY LENGTH OF TIME, ANXIETY, DEPRESSION, CHRONIC FATIGUE, NAUSEA, MIGRAINES, GASTROINTESTINAL ISSUES, REMOVAL OF UTERUS AND TUBES, WEIGHT PAIN, JOINT PAIN, SEVERE CHEST PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043471		6/28/2015	7/6/2015

Event Information:

Event Date (B3): 5/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESSURE
Catalog # (E4): ESS305
Lot #(E4): 717518

Single Use:
Implant Date (E6): 5/27/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE (B)(6) 2010. IT WAS THE WORST EXPERIENCE EVER. THE PROCEDURE WAS BRUTAL. I NEVER SAID ANYTHING TO MY DOCTOR, HE HYPED ESSURE UP SO MUCH. HE DELIVERED MY SON IN 2007 AND I RESPECTED HIM. I HAVE HAD EXCRUCIATING PERIODS SINCE AND ABDOMINAL PAIN OFTEN. I'VE BEEN TO THE DOCTORS THEY'VE DONE ALL KINDS OF TESTS AND SAY EVERYTHING IS FINE. IT'S NOT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043234	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 9/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN AND CRAMPING. ABNORMAL STOOL. FATIGUE. DEPRESSION. MISCARRIAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043235	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 6/18/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE LOWER ABDOMINAL PAIN, JOINT PAIN, MIGRAINES, HAIR LOSS, SKIN ISSUES, EXTREMELY PAINFUL CRAMPS AND HEAVY BLEEDING DURING AND BETWEEN MENSTRUAL CYCLES, MISSED MENSTRUAL CYCLES, PAINFUL INTERCOURSE, BLOATING AND WEIGHT GAIN OVER 80 LBS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043236	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 5/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE GETTING THIS DEVICE I HAVE SEVERE CRAMPING AND PAIN. I HAVE TO TAKE 3 DIFFERENT STOMACH MEDICATION. 1 FOR IBS AND THEY ARE STILL NOT SURE WHAT CAUSING THE PAIN I HAVE. THEY SAY GERD ACID REFLUX IBS ANOREXIA AND GASTRITIS AND ETC.... I WAS DIAGNOSED WITH DEGENERATIVE DISC DISEASE AND HAVE PAIN SO BAD THAT I CAN NOT TURN MY HEAD. I HAVE PAIN IN ALL OF MY JOINTS. MY HANDS HURT SO BAD I CAN'T USE THEM. I AM CURRENTLY LOOK AT KNEE SURGERY. I HAVE JUST HAD ROSTER COMB INJECTIONS AND THEY ARE NOT HELPING. I CATCH A COLD AND 2 DAYS LATER I HAVE PNEUMONIA AND HAVE TO TAKEN 2 ROUNDS I'VE LEVAQUINE BECAUSE NOTHING ELSE WORKS. ITS THE STRONGEST ANTIBIOTIC THEY CAN GIVE YOU OVER THE COUNTER. I HAVE ALLERGIES NOW AND NEVER IN MY ENTIRE LIFE HAD THEM. I HAVE HAD KIDNEY INFECTIONS SO MUCH THAT MY RIGHT KIDNEY IS FULL IF SCAR TISSUE. I HAD TO HAVE A SCOPE AND BIOBSY DONE AND THEY COULD NEVER FIND WHAT WAS WRONG. ALL TRDT CAME BACK NORMAL. SO I WAS PUT ON MACROBID FOR 6 MONTHS BECAUSE I AM NOW IMMUNE TO BACTUIM.... MY SKIN IS HORRIBLE. I HAVE DARK MARKS ALL OVER MY FACE AND LOOK LIKE I'M GOING THREW PUBERTY AGAIN. I HAVE BEEN ON MEDS FOR ACNE AND NOTHING HELPS. THE BLOATING AND SWELLING US UNREAL. I LOOK LIKE I'M 8 MONTHS PREGNANT. I CAN BOY LOOSE WEIGHT AND HAVE GAIN 50 POUNDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043237	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I GOT THE ESSURE PLACED, I HAVE HAD CONSTANT MIGRAINES. THEY HAVE GOTTEN WORSE, SO BAD THAT THEY LAST ANYWHERE FROM 12-15 DAYS. NOTHING HELPS THEM. I HAVE BEEN TO A NEUROLOGIST AND FROM A NEURO STANDPOINT THERE IS NOTHING WRONG. I HAVE BEEN TO AN ENDOCRINOLOGIST AND HE TOLD ME FIRST THAT I HAVE THYROID PROBLEMS. AFTER COUNTLESS TESTS THAT WAS FOUND NOT TRUE. THEN HE SAID I HAD A PITUITARY TUMOR WHICH WAS ALSO FOUND TO BE NOT TRUE AFTER BLOOD WORK AND MRI'S. THEN HE SAID THAT I HAVE LOW CORTISOL WHICH AGAIN HAS BEEN FOUND NOT TRUE. EVEN THO ALL OF THIS IS FOUND UNTRUE HE STILL HAS ME ON THYROID MEDS BECAUSE HE DOESN'T KNOW WHAT COULD BE CAUSING MY PROBLEMS. I HAVE SEVERE ANXIETY WHICH I NEVER HAD BEFORE. NO MEDS WORK FOR IT. I HAVE SEVERE NAUSEA, AND DIZZINESS WITH AN UNKNOWN CAUSE ACCORDING TO MY DR. I HAVE SEVERE PAIN IN MY RIGHT SIDE OF MY STOMACH. I HAVE NO SEX DRIVE. WHEN I DO HAVE SEX WITH MY HUSBAND ITS ONLY ONCE A MONTH BECAUSE I HAVE NO SEX DRIVE AND EVEN THEN I CAN'T GET PLEASURE AND I CAN'T ORGASM. I WAS NEVER LIKE THIS BEFORE. BEFORE THE ESSURE, I WAS A LOVING MOTHER TO FOUR WONDERFUL CHILDREN AND MARRIED TO A WONDERFUL MAN. NOW I'M ALL THE TIME HAVING PAINS, SICK TO MY STOMACH, CONSTANTLY DIZZY, MIGRAINES. I HAVE GAINED SO MUCH WEIGHT IN MY STOMACH THAT I CONSTANTLY LOOK PREGNANT. NO MATTER WHAT I DO I CAN NOT LOSE IT. ESSURE HAS RUINED MY LIFE. IT HAS HURT MY FAMILY AND MY MARRIAGE. I WANT THIS DEVIL THING OUT OF ME. I'M SICK OF BEING IN PAIN, NOT BEING ABLE TO PLAY WITH MY CHILDREN OR TAKE CARE OF THEM BECAUSE OF NO ENERGY, MIGRAINES, NAUSEA, DIZZINESS.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043238	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 8/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PARTIAL HYSTERECTOMY TO REMOVE PRODUCT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043239	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 11/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). AS SOON AS I HAD THE ESSURE I FELT DIFFERENT CRAMPING BLEEDING BACK PAIN , HEADACHES OR MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN SHOCKS, NERVE PAIN, BRAIN FOG AND CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, DEPRESSION (SADNESS/SUICIDAL THOUGHTS), BLACK OUT SPELLS/ FAINTING, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), MOOD DISORDERS, CRAMPING, SHARP/STABBING PELVIC PAIN, ABNORMAL MENSES, PAINFUL OVULATION (MITTELSCHMERZ), NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS (DYSMENORRHEA), PAINFUL INTERCOURSE (DYSPAREUNIA), BLEEDING BETWEEN PERIODS (METRORRHAGIA), EARLY MENOPAUSE, URGENT/FREQUENT URINATION, BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP, CHRONIC PELVIC PAIN. FACE PAIN (TIGRINA NEURALGIA), WEIGHT ISSUES, SEVERE BLOATING, VISION PROBLEMS FLOATERS, BLURRED VISION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043240	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 4/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE HAVING THE ESSURE PROCEDURE, I'VE HAD CHRONIC PAIN IN MY LOWER RIGHT SIDE, NAUSEOUS EVERYDAY, HOT FLASHES, NIGHT SWEATS, DIZZINESS, LOWER BACK PAIN, VOMITING, DIARRHEA, TIRED ALL THE TIME, AND THE WORST MENSES I'VE EVER HAD IN MY LIFE AND I'M (B)(6) OLD. I'VE GONE TO MY PCP COMPLAINING ABOUT VARIOUS SYMPTOMS, HAD BLOOD WORK DONE, AND NOW HAVE TO GET AN UPPER AND LOWER GI DONE. AFTER THAT I WILL HAVE TO HAVE MY UTERUS AND FALLOPIAN TUBES REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043242	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 1/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A FULL LAPAROSCOPIC HYSTERECTOMY ON (B)(6) 2015, I WAS DIAGNOSED WITH ANEMIA-ACUTE BLOOD LOST, FIBROIDS, ADENOMYOSIS, CHRONIC PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043243	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043244	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 3/31/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODS LASTED FOR 9 MONTHS AFTER INSERTION, URINE SMELL HAS CHANGED, ITCHY IN VAGINAL AREA, PAIN IN OVARIES, PERIODS COME MORE OFTEN THAN THEY SHOULD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043245	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVERY TIME I HAVE SEX WITH MY WIFE I GET CUTS ON MY PENIS, IT SWELLS UP, I GET A RASH ON MY PENIS AND IT ONLY HAPPENS WHEN I HAVE SEX WITH HER. I AM ALLERGIC TO NICKEL AND ESSURE HAS NICKEL, THIS DEVICE HAS RUINED OUR ENTIRE LIVES. IT NEEDS TO BE RECALLED. ENOUGH IS ENOUGH!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043246	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD CYST, FORMED A NICKEL ALLERGY, MISCARRIAGE, FATIGUE, MOOD SWINGS, BLOATED ALL THE TIME, DIGESTIVE PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043247	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 7/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, CONSTANT PAIN, UNSTOPPABLE BLEEDING. ONE COIL WASN'T PLACED RIGHT AND ENDED UP IN RAVELING ITSELF AND ATTACHED TO MY STOMACH LINING AN INCH BELOW MY BOWEL. ONLY ENDED UP HAVING IT FOR 4 MONTHS AND THEN ENDED UP HAVING TO HAVE SURGERY WHICH WAS WHAT I DIDN'T WANT TO HAPPEN TO HAVE MY TUBES REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043248	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 5/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAVE HAD ESSURE SINCE 2009. MY PERIODS HAVE BECOME HEAVIER, AN LONGER. I HAVE BEEN EXPERIENCING BLURRY VISION, AND MY STOMACH CONSTANTLY IS UPSET, ALMOST LIKE MORNING SICKNESS, EXCEPT IT LAST MOST OF THE DAY, WEAKNESS, DIZZINESS, ALSO I HAD A BOIL OUTBREAK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043249	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 10/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WITH IN 24 HOURS OF HAVING THE DEVICE PLACED I HAD A FEVER, NAUSEA, AND HORRIBLE CRAMPING. THE CRAMPING GOT WORSE THOUGH THE NAUSEA WENT AWAY AFTER ABOUT A WEEK. I THEN EXPERIENCED, BACK PAIN, PAINFUL AND HEAVY MENSTRUAL CYCLES, MIGRAINES, JOINT PAIN, FATIGUE, PAIN AND BLEEDING AFTER SEX, HAIR LOSS, METAL SENSITIVITY, AND FREQUENT URINATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043250	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 3/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043251	BAYER	6/29/2015	6/29/2015

Event Information:

Event Date (B3): 9/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SO RIGHT NOW I HAVE ABDOMINAL PAIN, CHRONIC FATIGUE, MEMORY LOSS, SEVERE MENSTRUAL CYCLE, TEETH SENSITIVITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043285	BAYER	6/29/2015	6/30/2015

Event Information:

Event Date (B3): 9/13/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN IN UNDESCRIBABLE PAIN IN MY ABDOMEN AND PELVIC AREA FOR YEARS. I HURT IN MY HIPS AND LOWER BACK AND I QM IN A CONSTANT PAIN. I FEEL LIKE THERE IS SOMETHING MOVING INSIDE MY STOMACH AS IF I AM PREGNANT. ALL OF THIS STARTED ABOUT 2 MONTHS AFTER HAVING ESSURE PLACES. IT HAS PROGRESSIVELY GOTTEN WORSE. AT TIMES, IT IS ALMOST UNBEARABLE. MY MONTHLY CYCLE IS THE WORST. I CRAMP SO SEVERELY THAT I GET PHYSICALLY SICK, I PASS HUGE BLOOD CLOTS AND I HAVE A VERY HEAVY FLOW. CRAMPING STARTS ABOUT A WEEK BEFORE I DO AND LAST ABOUT A WEEK AFTER I STOP. I ATTRIBUTE ALL OF HIS TO ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043286	BAYER	6/29/2015	6/30/2015

Event Information:

Event Date (B3): 12/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, DEPRESSION, CHEST PAIN WHILE LAYING ON BACK AND LEFT SIDE,TIRED, BACK PAIN, STOOL CHANGES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043287	BAYER	6/29/2015	6/30/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE IMPLANTED (B)(6) 2013. APPROXIMATELY 7 MONTHS LATER I DEVELOPED CHRONIC AND SEVERE AT TIMES BILATERAL HIP/PELVIC PAIN, HAIR LOSS, CHRONIC FATIGUE WITH JOINT PAIN. NUMBNESS AND TINGLING IN EXTREMITIES. PSORIASIS. I HAD A FULL WORK UP IN (B)(6) 2014 AND ALL TESTS NEGATIVE. SAW A CHIROPRACTOR AND ORTHOPEDIST WHO SAW NOTHING ON X-RAY. ONE ORTHOPEDIST SAID I HAD LEFT HIP BURSITIS AND GAVE ME CORTISONE SHOTS. PAIN CONTINUED INTO MY GROIN AREA BILATERALLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043288	BAYER	6/29/2015	6/30/2015

Event Information:

Event Date (B3): 5/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE SURGICALLY INSERTED ON (B)(6) 2009. SINCE THEN I'VE BEEN IN AND OUT OF ER, GYNECOLOGIST, HOSPITALS WITH SEVERE STABBING PAIN IN MY LOWER ABDOMINAL AREA DUE TO ESSURE. OVER THE YEARS IT'S GOTTEN WORSE BUT WITH FEW DOCTORS THAT WILL REMOVE THEM OR EVEN SEE ME I'VE LIVED WITH HORRIBLE PAIN, BODY CRAMPS, SWEATS, WEIGHT GAIN, HEADACHES, TEETH ROTTEN, HEAVY BLEEDING SINCE MY SURGERY TO IMPLANT ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043289	BAYER	6/29/2015	6/30/2015

Event Information:

Event Date (B3): 4/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THIS DEVICE WAS INSERTED, I HAD HORRIBLE PERIODS,THE MOST HORRID PMS EVER, AND EVENTUALLY A SHARP RIGHT SIDE PELVIC PAIN THAT IS ALWAYS THERE NOW. IT IS HARD TO GET COMFORTABLE TO SLEEP AT NIGHT BECAUSE IT IS SO UNCOMFORTABLE. DURING MY PERIOD, I FEEL A SHARP PAIN SHOOTING FROM MY HIP (RIGHT SIDE) DOWN MY LEG. DURING PMS I FEEL LIKE MY WHOLE BODY ACHES-LIKE I HAVE THE FLU. I ALSO HAVE TERRIBLE LOWER BACK PAIN. WENT TO DR. LAST WEEK..UTERUS IS ENLARGED..I HAVE ULTRASOUND SCHEDULED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043566	BAYER	6/29/2015	7/8/2015

Event Information:

Event Date (B3): 10/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/14/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE MEASURE DEVICE IMPLANTED ON (B)(6) 2014. SIX WEEKS LATER I HAD THE HSG TEST PERFORMED, THAT WAS A POSITIVE RESULT (TUBES FULLY BLOCKED). SIX MONTHS LATER I BECAME PREGNANT, WHICH RESULTED IN A MISCARRIAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043569		6/29/2015	7/8/2015

Event Information:

Event Date (B3): 3/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/13/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER RECEIVING THE ESSURE DEVICE I STARTED HAVING VERY PAINFUL MENSTRUAL CYCLES. THE CRAMPS WERE UNBEARABLE. I HAD VERY BLEEDING TO THE POINT I WOULD HAVE TO WEAR A TAMPON AND A PAD SO THAT I WOULD NOT BLEED THROUGH MY CLOTHING. I THEN HAD SECOND SURGERY UTERINE ABLATION TO HELP WITH THESE PROBLEMS. AFTER THAT SURGERY I STILL HAVE BAD CRAMPS AND THE BLEEDING HAS RETURNED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043574	CONCEPTUS	6/29/2015	7/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 789032

Single Use:
Implant Date (E6): 8/12/2011
Explant Date (E7): 5/18/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE IMPLANT DEVICE PUT IN (B)(6) 2012 (WILL HAVE TO CHECK EXACT DATE). MY MENSTRUAL CYCLE INSTANTLY BEGAN GETTING HEAVIER, MY CRAMPS BECAME UNBEARABLE AFTER 2 YEARS, WENT TO EMERGENCY ROOM (B)(6) 2015, WHICH LEAD TO A TOTAL HYSTERECTOMY DUE TO MY OVARIES HAVING MULTIPLE CYSTS CAUSING THE PAIN. I NEVER HAD THESE SYMPTOMS PRIOR TO ESSURE, I HAVE A PICTURE OF THE HUGE, BLOODY CYST COVERING MY RIGHT OVARY, MY OB/GYN SAID IT WAS PROBABLY DUE TO THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043578		6/29/2015	7/8/2015

Event Information:

Event Date (B3): 9/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANT PUT IN AND WAS IN PAIN FROM HAVING THEM FOR TWO YEARS BEFORE THE FIGHT WITH MY DOCTOR TO HAVE THEM TAKEN OUT. MAIN REASON FOR THEM COMING OUT WAS RIGHT ONE WAS BENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043290	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 10/11/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I AWOKE FROM THE PROCEDURE, I KNEW THE COILS WERE THERE. I SAID THEY PINCHED AND BURNED AND CONTINUED TO DO SO FOR THE ENTIRE TIME I HAD THEM. I WAS TOLD THAT I COULDN'T FEEL THEM... I HAD A UNEXPLAINED RASH ACROSS MY ABDOMEN A FEW MONTHS LATER. I CONTINUED TO FEEL THE PINCHING AND BURNING ESPECIALLY DURING OVULATION AND DURING MENSTRUAL CYCLE. FOR THE NEXT SEVERAL YEARS, MY CYCLES WERE INCREASINGLY PAINFUL AND HEAVY BLEEDING, BEGAN HAVING BLOOD CLOTS AS WELL. GAINED WEIGHT GRADUALLY, STAMINA/ ENERGY DECLINED. CONTINUALLY LOWER BACK AND PELVIC PAIN. VERY SENSITIVE SCIATICA PAIN, OFTEN SHOOTING DOWN MY LEG TO MY FOOT. WENT TO MANY CHIROPRACTOR VISITS. INCREASED BLEEDING/CLOTTING DURING CYCLES, CYCLES BECAME MORE IRREGULAR AND FREQUENT, PAIN DURING INTERCOURSE. WAS GIVEN MEDICINE TO REDUCE BLOOD FLOW, WHICH DID HELP MANAGE BLOOD FLOW BUT DID NOT REDUCE PAIN NOR IMPROVE ANEMIA. CONTINUALLY BATTLED HEADACHES, MIGRAINES AND VERTIGO. ESSURE WAS REMOVED VIA TAH/BS ON (B)(6) 2015. UTERUS FOUND TO BE ENLARGED. FOUND SEVERAL POLYPS AND APPROXIMATELY 10 FIBROIDS, LARGEST BEING 2.5 CM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043291	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GAINED 65 LBS LOST MOST OF MY HAIR AND STARTED TO LOOK ABOUT 6 MONTHS PREGNANT ABOUT A YEAR AND A HALF AFTER GETTING THE ESSURE. MY PERIODS BECAME VERY HEAVY AND PAINFUL AND CAME TWICE A MONTH. I GOT SORES IN MY HEAD AND DANDRUFF THAT FELT LIKE MY SCALP WAS ON FIRE. I ALSO STARTING HAVING ACNE ON MY FACE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043292	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 8/15/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BAD HEADACHES, JOINT PAIN, MAJOR BACK AND PELVIC PAIN, HEAVY MENSTRUAL BLEEDING/CLOTTING, FATIGUE,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043293	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 10/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BACK PAIN, HEAVY PERIOD, HEADACHES, HAIR LOSS, CRAMPS, PAIN DURING INTERCOURSE, UNABLE TO ORGASM, FATIGUE, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043294	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 7/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN BOTH SIDES, NUMBNESS IN LEGS, DIZZINESS, HAIR LOSS, VISION IMPAIRMENT, UNEXPLAINED RASHES, ITCHING, LOSS OF SEX DRIVE, PAINFUL INTERCOURSE, SWELLING, EXTREME FATIGUE, HEAVY PERIODS, PAINFUL CRAMPING IN ABDOMEN, CHEST PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043295	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE 2010 I HAVE BEEN EXPERIENCING THE FOLLOWING SYMPTOMS: FATIGUE, BLOATING, INABILITY TO LOSE WEIGHT (EVEN WITH DIET AND EXERCISE), SEVERE PAIN ALTERNATING ON EITHER SIDE OF MY BODY WHERE THE COILS WOULD BE LOCATED, EXTREMELY HEAVY PERIODS, MY PERIOD WAS COMING EVERY 2 WEEKS, MEMORY ISSUES, JOINT PAINS, UNEXPLAINED BRUISING, LEG TWITCHING, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043296	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 10/10/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, FATIGUE, SHARP SHOOTING PAINS IN ABDOMEN, UNBEARABLE STABBING PAINS BEFORE MENSTRUATION, ABNORMAL PERIODS, LEG, BACK AND PELVIC PAIN..DEPRESSION, IRRITABILITY, UNEXPLAINED BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043297	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 11/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT AND LEFT SIDE PELVIC PAIN, RIGHT HIP PAIN RADIATING DOWN MY ENTIRE LEG, HUGE BLOOD CLOTS DURING PERIOD, CONTRACTION LIKE PAIN AND SEVERE INTENSE HEAVY BLEEDING, METAL LIKE TASTE, INTENSE PREGNANT LIKE BLOATING, GASTROINTESTINAL ISSUES, WEIGHT GAIN THAT WILL NOT DROP NOT MATTER WHAT, DEPRESSION, ANXIETY, HOSPITALIZED FOR FAINTING, LOSS OF SPEECH AND COORDINATION. HUGE BLOOD FILLED MASSES FOUND ON ULTRASOUNDS. BREAST PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043298	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 4/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT'S BEEN A LITTLE OVER SIX MONTHS SINCE MY PROCEDURE. MY SYMPTOMS HAVE CONTINUALLY PROGRESSED. SIGNIFICANT FATIGUE, DEBILITATING HEADACHES, SEVERE MOOD SWINGS, HORMONE IMBALANCE, LACK OF FOCUS/MENTAL CLARITY, IRREGULAR MENSTRUAL CYCLES WITH CLOTS RESEMBLING TISSUE, SEVERE BLOATING AND CONTINUED WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043299	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE ON (B)(6) OF 2011. THIS MEDICAL DEVISE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMERLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) OF 2011. THIS IS A LIST OF THE SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: CRAM PIC, SHARP PELVIC PAIN, ABNORMAL MENSES, HOT FLASHES, NIGHT SWEATS, MENORRHAGIA, MITTELSCHMERZ, LOSS OF LIBIDO, DYSMENORRHEA, POLYMENORRHEA, JOINT AND LEG PAIN, NAUSEA, VOMITING, BLOATING, METALLIC TASTE IN MOUTH, DIZZINESS,TINGLING IN HANDS, FORGETFULNESS, ANXIETY, MOOD SWINGS, WEIGHT GAIN, POLYCYSTIC OVARIAN SYNDROME, INSULIN RESISTANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043300	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 3/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043301	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOOD CLOTS, HEAVY BLEEDING, DIZZINESS, NIGHT SWEATS, PELVIC PAIN, HEADACHES, IRREGULAR PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043302	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE CONSTANT PELVIC PAIN, MAINLY ON THE LEFT SIDE. HEAVY BLEEDING WITH BLOOD CLOTS DURING PERIOD, MIGRAINES BEFORE AND DURING PERIOD, BLOATING, CRAMPING, GASTROINTESTINAL PROBLEMS, NUMBNESS IN HANDS JOINT PAIN, BACK PAIN MUSCLE SPASMS EYE TWITCHING, PAIN DURING INTERCOURSE. FREQUENT BLADDER AND YEAST INFECTIONS. NEVER HAD ONE BEFORE ESSURE... SEVERE FATIGUE, BLURRY VISION, ANXIETY, HAIR LOSS, TOOTH DECAY, MOOD SWINGS!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043303	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I WAS ALLERGIC TO IT. I HAD ALLERGIC REACTION ON MY UTERUS FROM IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043304	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). REMOVAL OF THE FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043305	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 2/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CONSTANT PELVIC PAIN, MAINLY ON THE LEFT SIDE. HEAVY BLEEDING WITH BLOOD CLOTS DURING PERIOD, MIGRAINES BEFORE AND DURING PERIOD, BLOATING, CRAMPING, GASTROINTESTINAL PROBLEMS, NUMBNESS IN HANDS JOINT PAIN, BACK PAIN MUSCLE SPASMS EYE TWITCHING, PAIN DURING INTERCOURSE. SEVERE FATIGUE, BLURRY VISION, ANXIETY, HAIR LOSS, MOOD SWINGS, HIVES, BODY RASH. VITAMIN D DEFICIENCY, HIATAL HERNIA WITH NISSEN FUNDOPLICATION (REPAIRED JULY 2014), GALLBLADDER DISEASE (GALLBLADDER REMOVED (B)(6) 2015), GANGLION CYSTS (FIRST SURGERY TO TREAT IT (B)(6) 2015).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043306	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5043306 #(B)(4). HAVE SINCE HAD A DAVINCI ASSISTED HYSTERECTOMY WITH BILATERAL SALPINGECTOMY FOR SYMPTOM MANAGEMENT WITH ENDOMETRIOSIS BEING FOUND ON PATHOLOGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043307	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY MENSTRUATION. CHRONIC PAIN BELOW THE BELLY BUTTON . BLEEDING BRIGHT RED BLOOD AFTER CERTAIN ACTIVITIES. STABBING PAIN IN MY UTERUS. LOW LIBIDO. SWOLLEN\ BLOATED BELLY. AFTER EXPERIENCING THESE SYMPTOMS , I WENT TO GET HSG WHICH REVEALED THE RIGHT COIL HAD MIGRATED AND WAS PERFORATING MY UTERUS. AS A RESULT, I HAD SURGERY DONE TO GET REMOVAL (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043308	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, CONFUSION/BRAIN FOG, MUSCLE WEAKNESS, JOINT PAIN, INTENSE GROIN PAIN, HIP PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043309	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 11/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043310	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE PAIN IN MY ABDOMINAL AREA MORE SO ON THE LEFT SIDE, SEVERE BLOATING MY STOMACH IS HUGE AND STAYED LIKE THIS, BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043311	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/2/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I HAD PROCEDURE I STARTED HAVING MIGRAINE HEADACHES, IN 2011 STARTED BLEEDING ALMOST EVERYDAY AND HAVING SEVERE ABDOMINAL PAINS AND SWELLING. IN (B)(6) 2013 I HAD A PARTIAL HYSTERECTOMY, REMOVED UTERUS AND CERVIX, WHICH STOPPED THE BLEEDING BUT DID NOT STOP THE ABDOMINAL PAIN AND SWELLING. I HAVE BEEN IN PRETTY MUCH CONSTANT PAIN SINCE 2011.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043312	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC FATIGUE PAIN IN HIPS AND ELBOWS. LOW CHRONIC BACK PAIN. SWEATING. PAINS IN MY SIDE. SCRATCHING FEELING DOWN THE INSIDE OF MY UTERUS. MAJOR MIGRAINES. DIZZINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043313	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 4/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT WAS A VERY PAINFUL PROCEDURE, I STOPPED HAVING A MENSTRUAL PERIOD RIGHT AFTER THE PROCEDURE. I CONTACTED THE DR WITH CONCERNS AND WAS TOLD IT HAD NOTHING TO DO WITH THE PROCEDURE, I EXPLAINED ABOUT THE CONSTANT LOWER ABDOMINAL PAIN, AND BACK PAIN, EXTREME FATIGUE AND BLOATING, MY ORGANS FEEL LIKE THEY ARE ON FIRE, SEVERE HEADACHES, HOTFLASHES, MOOD SWINGS, I HAVE BEEN IN AND OUT OF THE ER AND HAVE HAD FULL BODY SCANS AND BEEN TO NUMEROUS DR AND NOBODY CAN TELL ME ANYTHING. I FEEL LIKE I WASN'T INFORMED ABOUT THIS PROCEDURE, NOR DID I REALIZE THE RISKS OR COMPLICATIONS. THIS PROCEDURE HAS RUINED MY LIFE, AND I HAVE NOT FELT RIGHT SINCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043314	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 4/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODS 2-3 WEEKS LONG HORRID CONTINUED UNTIL MY SURGERY SCHEDULES (B)(6), 2015, BLADDER STOPPED FUNCTIONING OUT OF BLUE HAD A DEVICE INTERIM STEM THERAPY STIMULATOR PLACED 3 MONTHS AFTER ESSURE PLACEMENT , OVARIAN CYSTS WITH OVARIAN TORSION NEEDED SURGERY ALSO SURGERY FOR MENORRHAGIA WITH A THERMACHOICE ABLATION ON (B)(6), 2011. (B)(6), 2011 HAD FIRST STROKE ALSO DIAGNOSED WITH BLOOD DISORDER MTHFR. (B)(6), 2014 SECOND STROKE FOLLOWING 10 DAYS OF 2 DIFFERENT HOSP STAY AND 6 MONTHS OF PHYSICAL THERAPY . (B)(6) 2015 ALLERGIC TO NICKEL WHICH IS IN THE ESSURE COILS, DNC (B)(6) 2015 . THROUGH ALL THIS BLOATING , MIGRAINES, RASHES OF DRY SKIN ON MY BODY , SCALP LESIONS . (B)(6), 2015 AT THE AGE OF (B)(6) HYSTERECTOMY TO REMOVE ESSURE COILS. I HAVE ALL MEDICAL RECORDS FOR ALL THESE HEALTH ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043315	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVING TO HAVE A HYSTERECTOMY DO TO ESSURE AND THE EFFECTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043316	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD DEPRESSION AND ANXIETY ISSUES IN THE PAST BUT NO OTHER HEALTH ISSUES. I HAVE HAD NO ISSUES WITH DEPRESSION SINCE I WAS (B)(6). I GOT ESSURE BACK IN (B)(6) 2013 . BIGGEST MISTAKE I'VE EVER MADE. SINCE I'VE RECEIVED THE ESSURE I HAVE SUFFERED FROM HORRIBLE HEADACHES THAT SOMETIMES CAUSE ME TO BLACK OUT, MASSIVE PELVIC PAIN, HOT FLASHES, MOOD SWINGS, BRAIN FOG/ MEMORY LOSS, DEPRESSION, AND WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043317	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 1/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MENSTRUAL CYCLE BECAME VERY IRREGULAR. BLEEDING BECAME MUCH HEAVIER WITH EXCESSIVE CLOTTING. PERIODS LAST LONGER AND THERE IS NO REGULAR CYCLE. SEVERE CRAMPING ALSO STARTED OCCURRING. EXCESSIVE PAIN WHEN REMOVING OR INSERTING TAMPONS. INCREASED DEPRESSION AND ANXIETY. EXCESSIVE LOSS OF HAIR AND DIZZINESS. I ALSO EXPERIENCE PAIN DURING AND AFTER SEX. I ALSO HAVE RECURRING MIGRAINE HEADACHES THAT MY PRIMARY DR IS UNABLE TO DIAGNOSE A CAUSE FOR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043318	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE STARTED HAVING OF PERIODS USE TO BE REGULAR FLOW NOW LIGHT ALL SYMPTOMS OF PREGNANCY BLOATING, CRAMPS, FATEGUED, NEASIUSE, SORE BOOBS, MOODY, LOWER BACK PAIN,HEADACHES WHICH I NEVER GOT ANY OF THE ABOVE BEFORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043319	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT IS (B)(6) 2015, I HAVE HEADACHES NECK PAIN CAN'T SLEEP THROUGH THE NIGHT CAN SLEEP ON MY STOMACH MY ARMS ARE NUMB FOOT AND LEGS ARE SWOLLEN MY VISION IS BLURRED MY MENSTRUAL STOPPED 2 MONTHS AGO I HAVE BACK PAIN I WAS TOLD I HAVE STONE IN MY GALLBLADDER 5 MONTHS AGO AND 2 HERNIATED DISC I'M ITCHY ALL THE TIME NO SEX DRIVE MY FEET HURT AND STILL HAVE SKIN PROBLEMS MY BREAST FEEL FUNNY AND WHEN I TRY TO STRAIGHTEN MY BACK AND NECK I GET THIS UNEDGE FEELING IN MY CHEST AND BACK AND WAS TOLD BY DOCTOR I HAVE URETRINE PROLAPSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043320	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER ONE YEAR OF THE PROCEDURE I STARTED GETTING EXTREME PAINS AND BLOATING THAT WILL NOT DIMINISH. MY CRAMPING IS SO BAD THAT OVER THE YEARS I HAVE STARTED TAKING SOMAS FOR THE PAIN...IBUPROFEN NO LONGER IS EFFECTIVE. I WAKE UP WITH INTENSE CRAMPS EVERY MORNING AND I HAVE GAINED 20 LBS THAT I AM NOT ABLE TO LOSE NO MATTER HOW MUCH I DIET AND EXERCISE. I WOULD RATHER HAVE A FULL HYSTERECTOMY THAN TO CONTINUE TO DEAL WITH THIS INTENSE PAIN ON A DAILY BASIS. I HAVE BEEN TO THE EMERGENCY ROOM TWICE DUE TO THE EXTREME PAIN...NO ONE BELIEVES ME THAT THE PAIN IS CAUSED BY THE ESSURE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043321	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GET MY PERIOD EVERY OTHER WEEK, HAVE BEEN GETTING IT LIKE THIS FOR THE PAST FEW MONTHS; BUT SINCE (B)(6) 2014, I GET BLOATED TO THE POINT WHERE I LOOK PREGNANT... MIGRAINES IN THE BACK OF MY HEAD.. LOSS OF APPETITE, I WAS (B)(6) WHEN I GOT ESSURE, NOW I CAN BARELY MAINTAIN (B)(6). I HAVE SEVERE ABDOMINAL PAIN MOST DAYS..

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043322	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2014, I HAD A CONSULTATION APPOINTMENT WITH THE SURGICAL COORDINATOR, (B)(6), AT (B)(6)'S HEALTH TO DISCUSS THE IMPLANTATION OF THE ESSURE DEVICE. THE IMPLANTATION WAS SCHEDULED FOR (B)(6) 2014 WITH (B)(6), MD, AND I WAS GIVEN A PRESCRIPTION FOR DIAZEPAM 10 MG (3 COUNT), NAPROXEN SODIUM 550 MG (30 COUNT), PROMETHAZINE 25 MG (20 COUNT), AND OXYCODONE 5 MG (20 COUNT). I WAS TOLD TO BRING THE DIAZEPAM AND OXYCODONE TO THE PROCEDURE WITH ME, AS I WOULD TAKE THEM PRIOR TO THE PROCEDURE, AND TO CONTINUE TAKING FOLLOWING THE PROCEDURE. THE PROCEDURE TOOK PLACE AS SCHEDULED ON (B)(6) 2014. HOWEVER, AFTER BEING PREPPED FOR THE PROCEDURE, I WAS INSTRUCTED THAT DR. (B)(6) WAS IN LABOR AND DELIVERY WITH ONE OF HER OTHER PATIENTS, AND (B)(6), MD, WOULD INSTEAD PERFORM THE PROCEDURE. I WAS TOLD THAT AFTER BEING PREPPED, THE PROCEDURE ITSELF WOULD TAKE TEN TO FIFTEEN MINUTES, AND THEN I WOULD BE REQUIRED TO STAY UP TO FORTY FIVE MINUTES TO ENSURE THAT I WAS RECOVERING APPROPRIATELY. I HAD A FRIEND PREPARED TO DRIVE ME HOME. AS THE PROCEDURE BEGAN, I WAS INSTRUCTED THAT A PHARMACEUTICAL REPRESENTATIVE FOR ESSURE WAS THERE AND WOULD BE SITTING IN WHILE THE ESSURE WAS IMPLANTED. DR. (B)(6) BEGAN THE PROCEDURE AND PLACED ONE COIL WITHOUT DIFFICULTY. HOWEVER, THE SECOND COIL WAS VERY DIFFICULT TO PLACE AND SHE TRIED NUMEROUS TIMES. SHE STATED THAT MY FALLOPIAN TUBE WAS CURVED AT THE POINT WHERE THE ESSURE SHOULD BE PLACED, AND SHE WAS UNSUCCESSFUL IN PLACING IT. SHE THEN TRADED PLACES IN LABOR AND DELIVERY WITH DR. (B)(6) , SO THAT SHE COULD ATTEMPT THE IMPLANTATION. DR. (B)(6) WAS ABLE TO GET THE COIL PLACED, BUT NOT AFTER MUCH DIFFICULTY AS WELL. THE PHARMACEUTICAL REPRESENTATIVE OFFERED VERBAL ADVICE TO BOTH DOCTORS ON HOW TO ATTEMPT PLACEMENT. I WAS IN A SEVERE AMOUNT OF VISIBLE DISCOMFORT DURING THE

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PROCEDURE, AND THREW UP IMMEDIATELY FOLLOWING. THE SURGICAL COORDINATOR INSTRUCTED MY FRIEND TO KEEP A CLOSE WATCH ON ME THAT NIGHT AS I WAS FEELING SO SICK. I RECEIVED MY ESSURE IDENTIFICATION CARD, WITH REF AND LOT NUMBERS: ESS305 / B66021. THERE HASN'T;T BEEN ANYTHING FILED WITH THE FDA UNDER THIS LOT NUMBER, THOUGH THE PHARMACEUTICAL REPRESENTATIVE WITNESSED THE COMPLICATIONS ABOVE. UPON REQUESTING A COPY OF MY MEDICAL RECORDS (B)(6) 2015, I NOTED THE FOLLOWING IN MY CHART FOR (B)(6) 2014: NO COMPLICATIONS. MY HCG CONFIRMATION TEST WAS PERFORMED BY DR. (B)(6) IN (B)(6) 2014 AND I WAS TOLD THAT MY TUBES WERE OBSTRUCTED AND I WAS STERILE. IN (B)(6) 2014, I SOUGHT (B)(6) (PCP) MEDICAL ADVICE ON OVERWHELMING FATIGUE, FREQUENT AND CUMBERSOME JOINT AND MUSCLE PAIN, AND HEADACHES. THESE PROGRESSIVELY GOT WORSE THROUGH OUR COURSE OF TREATMENT LEADING UP TO THE PRESENT DAY. MY BLOOD WORK SHOWED A POSITIVE ANA RESULT; THEREFORE, SHE RECOMMENDED THAT I SEE A RHEUMATOLOGIST. WHILE UNDER HER CARE, AND NOW UNDER THE CARE OF HER SUPERVISOR AS OF (B)(6) 2015, DR. (B)(6), MD, I HAVE TRIED NUMEROUS DIFFERENT PRESCRIPTION MEDICATIONS (SEE MEDICINE LIST) AND EVEN MORE OVER THE COUNTER SUPPLEMENTS TO ADDRESS SYMPTOMS THAT ONSET AFTER THE PLACEMENT OF THE ESSURE. DR. (B)(6) DIAGNOSED ME WITH FIBROMYALGIA THOUGH I DO NOT HAVE THE PRESSURE POINTS OFTEN PREFERRED IN A DIAGNOSIS, AS I HAD THE OTHER SYMPTOMS OF CONSTANT AND WIDESPREAD JOINT PAIN, DEBILITATING FATIGUE, AND HEADACHES. HE HAS NO EXPLANATION FOR MY HEADACHES AND MIGRAINES, FOR WHICH HE RECOMMENDED THAT I SEE A NEUROLOGIST, AS WELL AS FOR FREQUENT UTIS, PAIN DURING SEXUAL INTERCOURSE, CRAMPING AND ABDOMINAL PAIN, INABILITY TO SLEEP, WEIGHT FLUCTUATION, HOT FLASHES, AND NIGHT SWEATS. I AM CURRENTLY SCHEDULED FOR FOLLOW-UP VISITS EVERY SIX MONTHS TO DETERMINE ONGOING COURSE OF TREATMENT, AS NO TREATMENTS TO THIS POINT HAVE BEEN SUCCESSFUL. SINCE THE PLACEMENT OF THE ESSURE 14 MONTHS AGO, I HAVE SEEN MY PCP 11 TIMES. (B)(6) HAVE PRESCRIBED 13 MEDICATIONS, AS WELL AS RECOMMENDING MANY OVER THE COUNTER SUPPLEMENTS, EXERCISE, STRETCHING, ETC. I SAW (B)(6), MD OF THE ARTHRITIS CENTER OF (B)(6), ON (B)(6) 2014. I WAS RECOMMENDED BY MY PCP, (B)(6), DUE TO BLOOD WORK SHOWING A POSITIVE ANA WHICH COULD POTENTIALLY INDICATE LUPUS. DR. (B)(6) PERFORMED BLOOD WORK AND DID NOT FIND ANY INDICATIONS OF LUPUS BUT DID FIND A VITAMIN D DEFICIENCY, WHICH SHE TREATED WITH 50,000 IU OF VITAMIN D SUPPLEMENTS WEEKLY. I FOLLOWED UP WITH DR. (B)(6) ON (B)(6) 2014, (B)(6) 2015, AND I CURRENTLY HAVE A FOLLOW-UP APPOINTMENT SCHEDULED WITH DR. (B)(6) FOR (B)(6) 2015. AT EACH OF THESE PREVIOUS VISITS, DR. (B)(6) HAS BEEN UNABLE TO CONFIRM A DIAGNOSIS, STATING THAT I AM A "MYSTERY" TO HER WITH ALL OF MY POSITIVE SYMPTOMS. THOUGH I DO NOT HAVE BLOOD WORK TO SUPPORT A LUPUS DIAGNOSIS, I HAVE ALL OF THE SYMPTOMS OF LUPUS. BECAUSE OF THIS, DR. (B)(6) HAS STARTED ME ON A PLAQUENIL TRIAL (A DMARD THAT IS USED IN THE TREATMENT OF LUPUS OR RA). PLAQUENIL TAKES MONTHS TO BUILD UP IN THE PATIENT'S BLOOD AND THEREFORE I HAVE NOTT SEEN ANY POSITIVE CHANGES YET, BUT PLAQUENIL ALSO HAS DANGEROUS SIDE EFFECTS INCLUDING VISION LOSS, AND I HAVE TO BE CONSISTENTLY MONITORED BY AN OPHTHALMOLOGIST TO ENSURE NO CHANGES TO MY FIELD OF VISION. I AM CURRENTLY SCHEDULED FOR FOLLOW-UP VISITS EVERY FOUR MONTHS TO DETERMINE ONGOING COURSE OF TREATMENT, AS NO TREATMENTS TO THIS POINT HAVE BEEN SUCCESSFUL. SINCE TREATMENT WITH DR. (B)(6) STARTED, I HAVE SEEN HER 3 TIMES, AND SHE HAS PRESCRIBED 8 MEDICATIONS, AS WELL AS RECOMMENDING MANY OVER THE COUNTER SUPPLEMENTS. I SAW (B)(6), MD OF UNIVERSITY OF (B)(6) ON (B)(6) 2015, FOR RECURRENT URINARY TRACT INFECTIONS (UTI). THOUGH I HAD UTIS BEFORE THE PLACEMENT OF THE ESSURE, THEIR FREQUENCY AND INTENSITY GREW AFTER THE PLACEMENT OF THE ESSURE. I NOW HAVE CONSTANT DIFFICULTY STARTING MY URINE STREAM EVEN WHEN I DO NOT HAVE A UTI. DR. (B)(6) ORDERED A CT SCAN AND A CYSTOSCOPY FOR (B)(6) 2015, TO LOOK FOR POTENTIAL CAUSES, B6T WAS UNABLE TO ATTRIBUTE THE UTIS TO ANYTHING FOUND. SHE PRESCRIBED A LONG-TERM COURSE OF ANTIBIOTICS TO HELP LESSEN THE FREQUENCY OF MY UTIS. I AM CURRENTLY SCHEDULED FOR FOLLOW-UP VISITS EVERY SIX MONTHS TO DETERMINE ONGOING COURSE OF TREATMENT, AS NO TREATMENTS TO THIS POINT HAVE BEEN SUCCESSFUL. I SAW (B)(6), MD OF (B)(6) CENTER IN (B)(6) ON (B)(6) 2015, AT THE

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RECOMMENDATION OF DR. (B)(6). I REPORTED SYMPTOMS OF HEADACHES 3-4 TIMES A WEEK AND MIGRAINES 1-2 TIMES A WEEK FOR THE PAST YEAR, WITH ONLY RELIEF COMING FROM 100 MG OF TRAMADOL. DR. (B)(6) EXPLAINED THAT, BASED ON MY SYMPTOMS, THESE WERE ALL MIGRAINES, THOUGH SOME WERE ADMITTEDLY LESS SEVERE. PRIOR TO (B)(6) 2014, HEADACHES WERE VERY INFREQUENT, AND I HAD LESS THAN FIVE MIGRAINES IN MY ENTIRE LIFE. HE RECOMMENDED A MAINTENANCE MEDICATION AS WELL AS A VITAMIN SUPPLEMENT TO LESSEN THE FREQUENCY OF THE SYMPTOMS, BUT DID NOT HAVE AN EXPLICIT CAUSE FOR MIGRAINES. BECAUSE OF THE DIFFICULTIES IN LIVING WITH CHRONIC PAIN AND FATIGUE, I SOUGHT MENTAL HEALTH COUNSELING FROM (B)(6), IN (B)(6). SINCE THE ONSET OF TREATMENT ON (B)(6) 2015, WE HAVE MET 7 TIMES. BECAUSE OF THE CHRONIC PAIN AND FATIGUE, I BEGAN SEEING (B)(6), IN (B)(6) ON (B)(6) 2015. I HAVE HAD MONTHLY MASSAGES TO EASE PRESSURE ON JOINTS AND MUSCLES SINCE. SYMPTOMS CURRENTLY EXPERIENCED INCLUDE: MUSCLE WEAKNESS; MUSCLE PAIN; CONSTANT FATIGUE; JOINT PAIN; MUSCLE CRAMPS; MUSCLE SPASMS; CONSTIPATION; TINGLING IN FINGERTIPS; SHOOTING PAIN FROM FINGERTIPS TO SHOULDER (LEFT SIDE ONLY); INABILITY TO SIT, STAND OR LAY IN ONE POSITION FOR LENGTH OF TIME; TOSSING AND TURNING IN SLEEP; TROUBLE STAYING ASLEEP; HEADACHES/MIGRAINES (MULTIPLE TIMES A WEEK); LACK OF SEXUAL DESIRE; PAIN DURING SEXUAL INTERCOURSE; VAGINAL DISCHARGE/ODOR; ITCHING/BURNING AROUND GENITALIA; FREQUENT UTIS; DIFFICULT STARTING URINE STREAM; PAIN DURING URINATION; NIGHT SWEATS; HOT FLASHES; DISCHARGE FROM NIPPLES; HAIR LOSS; DIFFICULT BREATHING/FEELING OF NOT BEING ABLE TO GET ENOUGH AIR; MEMORY PROBLEMS; BRAIN;; JOINTS POPPING; INABILITY TO SUPPORT HANDS OR ARMS ABOVE HEAD; INCREASED MOOD SWINGS, ANXIETY, AND DEPRESSION; SKIN RASHES AND BUMPS; DIZZINESS; INSOMNIA; IRREGULAR/FREQUENT PERIODS (EVERY 2-3 WEEKS); HEAVY PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043323	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT WON'T LET ME PICK A DATE. I HAD SYMPTOMS AFTER 3 MONTHS. PAINFUL MORE FREQUENT PERIODS. PAIN OR SPOTTING AFTER SEX. IRREGULAR PERIODS. PAIN SHOOTING DOWN LEGS. PELVIC PAIN ON BOTH SIDE LIKE SHOOTING CRAMPS N SHARP PAIN RANDOMLY WEEKLY EVEN DAILY. MORE MIGRAINES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043324	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5043324 #(B)(4). FRAGMENTS REMAINING FROM SURGERY TO REMOVE THIS HORRIBLE PRODUCT STILL CAUSING THE SAME ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043325	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, HAIR LOSS, BAD BLOATING, HEAVY BLEEDING DURING PERIOD, PAINFUL WHEN HAVE SEX, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043326	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN DURING SEX. SPOTTING AFTER SEX. TEETH BEGAN TO BREAK AND FALL OUT. FATIGUE ALL THE TIME. PAIN IN MY LOWER BACK AND UPPER LEGS. NO SEX DRIVE. HAIR LOSS. REALLY BAD ACNE AND BREAK OUTS ON MY FACE NECK AND BACK. PAINFUL MENSTRUAL CYCLE. ABNORMALLY HEAVY BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043327	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I'VE HAD MANY SIDE EFFECTS BEGINNING BACK IN SUMMER OF 2012. METAL TASTE IN MOUTH, COLD SWEATS, EXTENDED PERIODS AND HEAVY BLEEDING CAUSING ER VISITS. CYSTS. DEPRESSION AND OTHER EMOTIONAL ISSUES. DIZZINESS. FOGGY MEMORY, CRAMPING IN MY HEAD (ICY FEELING/ TINGLES OR SHOCKING SENSATION). BOILS THAT LASTED MORE THAN A YEAR ON MY BODY. IN MY HEAD THROUGHOUT MY SCALP CHEST AND A NEW RASH NOW ON THE BODY AND BREASTS. BLOATED BELLY WITH A FEELING OF EXCESSIVE PRESSURE DURING PERIODS. UNEXPLAINED FATIGUED. VITAMIN DEFICIENCY MAINLY D. MUSCULAR WEAKNESSES, UNUSUAL DISCHARGE, WEAKEN IMMUNITY (LONGER HEALING TIME FOR AVERAGE INJURY OR ILLNESS).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043328	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY HEAVY AND PAINFUL PERIODS, ALL OVER JOINT PAIN, ABDOMINAL PAIN, MIGRAINES, DENTAL PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043329	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 5/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, ACNE, WEIGHT GAIN, TOOTH DECAY, HORRIBLE PAIN IN LOWER ABDOMEN, TUMOR ON RIGHT OVARY, CYSTS ON MY LEFT OVARY, ALREADY HAD MY RIGHT OVARY REMOVED, INTERCOURSE IS VERY PAINFUL, HIP PAIN, HEADACHES, FATIGUE, 1 MISCARRIAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043330	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 6/30/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5043330 #(B)(4). PLEASE NOTE: MY WIDESPREAD PAIN IS TWO-FOLD. I HAVE BOTH EXTREME JOINT AND FLU-LIKE MUSCLE SORENESS PAIN THROUGH OUT, PLUS SIGNIFICANT LOWER BACK AND COCCYX PAIN. SITTING IS EXTREMELY DIFFICULT, AS WELL AS, WALKING OR ANY TYPE OF PHYSICAL ACTIVITIES. I EXPERIENCE STIFFNESS IN THE MORNINGS, WHERE WALKING IS ALMOST NON-EXISTENT. PAIN CONTAINS THROUGHOUT THE DAY, WORSE WITH ANY LEVEL OF ACTIVITY, AND SLEEPING IS DIFFICULT. I ALSO SUFFER PAIN FROM LIGHT TOUCH, LIKE SHOWER WATER OR A GENTLE HUG, AND PAINFUL HEADACHES, AND MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043331	BAYER	6/30/2015	6/30/2015

Event Information:

Event Date (B3): 1/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BESIDES SEASONAL ALLERGIES I'M A VERY HEALTHY PERSON. I DO NOT TAKE ANY OTHER MEDICATIONS BESIDES IRON AND CALCIUM VITAMINS. I HAVE REGULAR PERIODS BUT SINCE HAVING THE ESSURE I HAVE RANDOM SPOTTING, FREQUENT YEAST INFECTIONS, LOWER BACK PAIN AND SOME CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043548	BAYER	6/30/2015	7/8/2015

Event Information:

Event Date (B3): 3/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN AND I STARTED HURTING AND KEPT BLEEDING FOR FIVE MONTHS AND I HAD TO HAVE SURGERY AND A DNC TO CUT IT OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043549		6/30/2015	7/8/2015

Event Information:

Event Date (B3): 11/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/30/2011
Explant Date (E7): 3/1/2012
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE BACK IN 2011 AT THE AGE OF (B)(6) AFTER THAT I BEGAN HAVING PROBLEMS WITH PAIN AND COULDN'T PICK MY KIDS UP OR MOVE FOR MANY MONTHS UNTIL I HAD TO HAVE A HYSTERECTOMY 6 MONTHS LATER I STILL HAVE PROBLEMS MANY YEARS LATER ALL CAUSED FROM THIS DEVICE I AM GOING THROUGH MENOPAUSE AT THE AGE OF (B)(6) WHICH IS HORRIBLE IF ONLY I WOULD HAVE KNOWN THE SYMPTOMS OF THIS I WOULD HAVE NEVER TAKEN THIS ROUTE...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043550	BAYER	6/30/2015	7/8/2015

Event Information:

Event Date (B3): 9/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/5/2014
Explant Date (E7): 9/10/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED (B)(6) 2014. I WAS OK AT FIRST THEN ON (B)(6) 2014 I BEGAN MY PERIOD. IT WAS VERY HEAVY, LOTS OF CLOTTING AND CRAMPS SOMETHING TERRIBLE. WELL TO MY SURPRISE I WOULDN'T STOP BLEEDING. IN (B)(6) 2014 I WAS HOSPITALIZED TO RECEIVE A BLOOD TRANSFUSION. MY BLOOD COUNT WAS 6.4. I HAD SEVERE BREAKOUTS BECAUSE I AM ALLERGIC TO THE NICKEL. WHICH I WAS UNAWARE I DIDN'T HAVE A NICKEL TEST NOR WAS I WARNED. I HAD AN INFECTION IN MY CERVIX AND IT WASN'T STD. I HAD A GREEN DISCHARGE BECAUSE MY BODY WAS INFECTED. (B)(6) STILL BLEEDING, NON STOP. I FINALLY GOT THESE DEVILS REMOVED VIA HYSTERECTOMY. SIX MONTHS OF PURE HELL. I AM (B)(6) IT WAS THE WORST MISTAKE EVER GETTING THESE. RX MEDS: LEVROTHYROXINE 300MCG. OTC MEDS: VIT B12, VIT D.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043551		6/30/2015	7/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/20/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE SEVERE BACK & PAIN ON BOTH SIDES OF MY PELVIS THAT CAUSES ME NOT TO BE ABLE TO STAND OR WALK AROUND LONG PERIODS OF TIME. EVEN WHEN I'M LAYING DOWN I EXPERIENCE THESE PAINS. I NEVER EXPERIENCED THESE PAINS UNTIL I HAD THE PROCEDURE DONE IN (B)(6) 2010. I HAVEN'T HAD TOO MANY DOCTOR VISITS BECAUSE I HAVE NO INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043555		6/30/2015	7/8/2015

Event Information:

Event Date (B3): 11/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2013 AFTER MY 3RD CHILD AND I HAVE HAD MAJOR BACK PAIN IN MY LOWER BACK AND IN MY PELVIS. WHEN I HAVE MY MENSTRUAL CYCLE I BLEED SO HEAVY AND HAVE SUCH BAD CRAMPING I HAVE TO STAY IN BED FOR ALMOST 2 DAYS. WHEN I AM NOT ON MY PERIOD I GET SHARP PAINS IN MY PELVIS. IT ALSO HURTS TO HAVE SEX WITH MY HUSBAND WHICH HAS NEVER HAPPENED BEFORE I HAD THE ESSURE PUT IN. I DO NOT HAVE MEDICAL INSURANCE SO I AM NOT ABLE TO GO TO THE HOSPITAL WHEN THIS HAPPENS SO I JUST HAVE TO SUFFER THROUGH THE PAIN. OVER THE LAST 6-8 MONTHS I HAVE HAD TO HAVE MY FRIENDS COME OVER TO HELP ME WATCH MY CHILDREN SINCE THE PAIN HAS GOTTEN WORSE WHEN I AM ON MY PERIOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043571		6/30/2015	7/8/2015

Event Information:

Event Date (B3): 6/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GETTING THE ESSURE MULTIPLE, ABDOMINAL PAIN AND HEAVY BLEEDING. WHEN I GO TO THE DOCTOR THEY SAID THERE'S NOTHING THEY CAN DO. SEVERE BACK PAIN AS WELL WHEN THE BLEEDING STOPPED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043573	BAYER	6/30/2015	7/8/2015

Event Information:

Event Date (B3): 9/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6): 8/10/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE FALLOPIAN TUBE IMPLANTS IN (B)(6) 2012. HAD THE FOLLOW-UP PROCEDURE TO CHECK THAT FALLOPIAN TUBES WERE BLOCKED IN (B)(6) 2012. THAT TEST SHOWED ONE TUBE WAS NOT BLOCKED. HAD ANOTHER FOLLOW-UP PROCEDURE TO RE-CHECK THE UNBLOCKED FALLOPIAN TUBE IN (B)(6) 2013. THAT TEST SHOWED THAT BOTH FALLOPIAN TUBES WERE NOW BLOCKED. BECAME PREGNANT IN (B)(6) 2014. BABY BORN (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043333	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 5/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMEN PAIN, FEELING SICK, DIZZINESS, LIGHT HEADEDNESS, CONSTANT MIGRAINES, LIGHT PERIODS FOR ABOUT A MONTH STRAIGHT, CAN'T GET MOTIVATED OR BE HAPPY, MOOD SWINGS LIKE CRAZY, APPETITE CHANGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043334	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 6/7/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALL OVER BODY ACHES/PAIN, SEIZURES. MUCH MORE THAT ARE STILL ON GOING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043335	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 2/2/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS NEVER INFORMED THAT THE ESSURE DEVICES HAD NICKEL I HAVE A NICKEL ALLERGY THAT CAUSES SEVERE INFLAMMATION AND PAIN. SEVERE BLOATING, EXTREMELY ABNORMALLY HEAVY PERIODS, VERY LARGE BLOOD CLOTS(NO HISTORY OF BLOOD CLOTS OR HEAVY PERIODS. OVERLY FREQUENT PERIODS AND BOUTS OF UNEXPLAINED BLEEDING. (FROM 3 PERIODS A YEAR TO 3 A MONTH). DEPRESSION AND ANXIETY ATTACKS, MY DR. IS NOW PUTTING ME ON A HYSTERECTOMY LIST .... THANKS A LOT ESSURE FOR NOTHING BUT PURE HELL.....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043336	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE ON (B)(6) 2010 IN A SURGERY CENTER. I WAS UNDER ANESTHESIA FOR ANOTHER PROCEDURE AND WAS ADVISED I COULD ALSO HAVE ESSURE PLACED AT THE SAME TIME. THE PROCEDURE WENT WELL, I WENT BACK AFTER 3 MONTHS FOR THE TEST (ALTHOUGH INSURANCE DID NOT COVER IT AND I WAS NOT TOLD THAT). IN 2012, MY SYMPTOMS BEGAN. HERE IS A LIST OF ALL OF THE SIDE EFFECTS I EXPERIENCED IN THOSE 3 YEARS: CRAMPING, SHARP/STABBING PELVIC PAIN, HOT FLASHES, EXCESSIVE BLEEDING DURING PERIODS, NIGHT SWEATS, LOSS OF LIBIDO, BREAST TENDERNESS, BACK PAIN, ALL OVER BODY ACHES, CONSTIPATION, SEVERE BLOATING, SEVERE HEARTBURN, BOWEL ISSUES, HEADACHES, TINGLING SENSATIONS, NUMBNESS, BRAIN FOG, MOOD SWINGS, HIGH BLOOD PRESSURE, INABILITY TO MAINTAIN BLOOD SUGAR LEVELS, CHEMICAL AND FOOD SENSITIVITIES, ALLERGY TO NICKEL, HEIGHTENED ALLERGIES, GLUTEN SENSITIVITY, HIVES/RASHES, ACNE, SKIN ITCHING, SWELLING OF LEGS/FEET, HAIR LOSS, DENTAL ISSUES, WEIGHT GAIN, VISION PROBLEMS, EXCESSIVE SWEATING. DUE TO THE SEVERE BLEEDING DURING MY PERIODS, PELVIC PAIN, AND THE DEVELOPED ALLERGY TO NICKEL, I HAD A HYSTERECTOMY ON (B)(6) 2015. AFTER MY SURGERY I WAS ALSO DIAGNOSED WITH ADENOMYOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043337	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 6/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN IN CONSTANT PAIN FROM MY LOWER BACK ALL THE WAY DOWN TO MY TOES. I'VE HAVE A CONSTANT METAL TASTE IN MY MOUTH. I'M BLOATED TO THE POINT OF LOOKING 5/6 MONTHS PREGNANT. I'VE IRREGULAR PERIODS. I'VE DISCOVERED I HAVE A NICKEL ALLERGY. MY VISION IS DRASTICALLY WORSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043338	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 2/13/2007 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WELL, I GET RASHES THAT LASTS FOR MONTHS THAT STARTED 6 MONTHS AFTER HAVING THE ESSURE PUT IN. ABOUT A YEAR INTO THIS, I LOST HAIR SO NOW I HAVE VERY THINNING HAIR ON THE TOP OF MY HEAD IN THE FRONT. I NOW HAVE HORRIBLE MIGRAINES A COUPLE WEEKS THROUGH THE MONTH EVERY MONTH OFF AND ON. I NOW GET LOWER BACK PAIN ALL THE TIME. I GET STABBING PAIN IN MY LOWER FRONT SIDES. AND I DO NOT ENJOY HAVING INTERCOURSE. ALMOST ALWAYS AFTER SEX I'M IN SO MUCH PAIN AS IF I CAN'T CATCH MY BREATH AND IF SOMEONE IS WITH BOTH HANDS JUST SQUEEZING MY LOWER STOMACH AND ALMOST AS IF IT'S ON FIRE AT THE SAME TIME. THEN THERE IS ALL THE OTHER SIDE EFFECTS THAT THEY PROMISE THIS BIRTH CONTROL DID NOT HAVE. REALLY REALLY HEAVY PERIODS, RUINED CLOTHES, MY BED AND JUST EMBARRASSING MOMENTS. THERE'S THE OVER WEIGHT NOW I'M GONE FROM 5 TO A 0 TO NOW 11 IN ONE YEAR. I CANT LOOSE THIS WEIGHT. I'VE ALWAYS BEEN HEALTHY, NEVER NEVER HAD PROBLEMS LIKE THESE TIL I GOT THE ESSURE PUT IN. IT AFFECTS ME IN EVERY WAY THAT OTHER BIRTH CONTROLS SAID THEY WOULD AFFECT A WOMEN AND THAT'S WHY I STAYED AWAY FROM OTHER BIRTH CONTROLS. OH AND AS FAR AS HAVING ANY MOTIVATION - NONE. I HAVE TO TALK AND FIGHT MYSELF TO GET OUT OF BED AT TIMES AND OR TO JUST GET OUT OF THE HOUSE. THE WHOLE IDEA OF HAVING TO GET DRESSED AND TAKE SHOWERS JUST SOUNDS LIKE TOO MUCH WORK. THAT'S CRAZY FOR ANYONE TO FEEL THAT WAY. I'VE NEVER FELT SO DAMN LAZY IN MY LIFE. I AM A PERSON WHO WOULD GO, GO, GO ALL THE TIME, NOTHING COULD STOP ME OR GET IN MY WAY. I LOVE TO GET MY HANDS DIRTY. ANYTHING NEW I CAN TRY OR LEARN, I'M THERE. NOW I CAN CARE LESS. I AM NOT ME. NOT ANY MORE, THANKS TO THE ESSURE. OH AND ALSO GETTING SICK ALL THE TIME NOW TO NEVER BEING SICK. EVERYONE AROUND ME WOULD BE SICK AND MAD AT ME FOR NEVER CATCHING A FEVER OR A COLD. BUT NOW YUP, I GET A COLD EVERY TIME SOMEONE AROUND ME HAS ONE. I

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KNOW MY PROBLEMS ARE THE CAUSE OF THE BIRTH CONTROL ESSURE AND THE CHANCE I GET TO GET THESE OUT, I AM. THE DATE I PUT ABOVE IS THE DAY MY DAUGHTER WAS BORN I CAN'T REMEMBER IF I HAD THE ESSURE PUT IN THE YEAR OF OR THE NEXT FOLLOWING YEAR WHICH WOULD BE 2008.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043339	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 2/1/2005	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST OF ALL AFTER ESSURE PLACEMENT I GOT PREGNANT WITH MY 5TH CHILD WHO HAS HAD ALLERGIES AND SEIZURES FROM DAY ONE. NONE OF MY OTHER CHILDREN HAVE SEIZURES. THERE IS A CYST THAT IS IN HIS HEAD THAT HAS BEEN THERE FOR AS LONG AS I KNOW, SINCE HIS FIRST MRI , THAT IS STILL IN THE SAME LOCATION NOW SAME SIZE FOR LAST 7 YEARS. MY SON HAS BEEN ON MEDICATION FOR THIS LONG. I' M NOT SURE IF ONE OF THE COILS MIGRATED INTO HIM AS A FETUS. I MYSELF HAVE CONSTANT CRAMPING AND BLOATING, WITH THE WEIGHT GAIN IN MY ABDOMINAL AREA. I BELIEVE THAT ESSURE HAS CAUSED ME TO GO INTO EARLY MENOPAUSE. I HAVE JOINT PAIN IN ALL OF MY JOINTS THAT STARTED AFTER ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043340	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 6/7/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE COILS PLACED I HAVE HAD EXTREME JOINT PAIN, HUGE BLOOD CLOTS DURING MY PERIOD, SHARP SIDE PAINS, PELVIC PAIN, FATIGUE, BEEN DIAGNOSED WITH FIBROMYALGIA, HYPOTHYROIDISM, VITAMIN B DEFICIENCY, VITAMIN D DEFICIENCY, BLOATING, CONSTIPATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043341	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 4/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN MAKING THE CONNECTION WITH AUTOIMMUNE AND INFLAMMATION CAUSED BY PET FIBERS, I HAVE DISPLAYED SYMPTOMS OF LUPUS AND HAD SHINGLES TWICE (I'M ONLY (B)(6)). I HAVE SINCE FOUND OUT BOTH COILS HAVE MIGRATED AND POSSIBLY PERFORATED MY OVARIES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043342	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 4/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). STRETCHING, FELT PAINS IN IMPLANTATION AREA. NEXT DAY EXTREME VERTIGO, NEXT WEEK PAINS IN UTERUS ACCOMPANIED BY HAIR LOSS, PAINS IN GUT AND GENERAL FEELING OF UNWELLNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043343	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 10/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE NOW HAD A TOTAL HYSTERECTOMY ((B)(6) 2015), WHICH INCLUDES: FALLOPIAN TUBES, UTERUS, AND CERVIX. HORRIBLE PAIN NOW FROM SURGERY, BUT I ALREADY FEEL A LITTLE BETTER WITH ESSURE OUT OF MY BODY. ESSURE DEFINITELY HAD A (B)(6) IMPACT ON MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043344	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 5/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WIDESPREAD PAIN. CHRONIC FATIGUE. AUTOIMMUNE DISEASE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043345	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 1/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DVT, PE, FATIGUE, SHORTNESS OF BREATH, MENSES HAS BEEN TWICE A MONTH AND VERY HEAVY AND PAINFUL, CRAMPING, BACK PAIN, JOINT PAIN, DEPRESSION, INCREASED ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043346	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 4/25/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UPDATE (B)(6) 2015: I HAD AN APPOINTMENT WITH MY GYNECOLOGIST AND DUE TO ALL THE SIDE EFFECTS I AM HAVING WITH ESSURE, SHE IS SCHEDULING ME FOR A HYSTERECTOMY IN (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043347	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MEDICAL CONDITION: HYPO THYROID. PERIOD ISSUES: 2X PER MONTH 7 DAYS EACH TIME. HAVE TO WEAR DIAPERS AT NIGHT. BACK PAIN. NO PERIOD SINCE (B)(6) 2014. ONGOING ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043348	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 3/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PANIC ATTACKS, TACHYCARDIA, BLOATING, SWELLING OF THE LEGS AND HANDS AND FEET RASHES, LOSS OF SEX DRIVE, ABDOMEN CRAMPING, PAINFUL INTERCOURSE, SHARP PAINS IN LEFT AND RIGHT SIDE ENDOMETRIOSIS, HAD TO HAVE A LAPAROSCOPY AND D AND C AND GETTING READY TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6) AND I HAVE ENLARGED BLOOD CELLS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043349	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 8/1/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED FEELING ABDOMINAL PAIN SHORTLY AFTER ESSURE WAS IMPLANTED. MY PERIODS BECAME IRREGULAR. AS OF A YEAR AND HALF AGO MY PERIODS ARE EXTREMELY HEAVY AND PAINFUL. I HAVE FIBROIDS ON MY UTERUS AND A CYST ON MY OVARY. I HAVE PELVIC PAIN AND LOWER ABDOMINAL PAIN. ALL OF WHICH I HAVE NEVER HAD BEFORE. I HAVE PAINFUL INTERCOURSE BECAUSE OF THE FIBROIDS AND THEY ALSO CAUSE ME TO BLEED BETWEEN MY PERIODS. MY PERIODS LAST 10 TO 14 DAYS AND I HAVE IT TWICE A MONTH WHICH MEANS I ONLY GET 7 10 DAYS BETWEEN EACH CYCLE. I GET HEADACHES ALMOST DAILY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043350	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PANIC ATTACKS, BRAIN FOG, HEART PALPITATIONS, STABBING PAINS IN BODY, VISION, PAINFUL AND BLEEDING HAVING INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043351	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 11/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2014. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: I HAVE HAD ONGOING PAIN AT THE IMPLANTATION SITE. THE SKIN ON MY FINGERNAILS BECAME WEAK AND WOULD BE SUBJECT TO REPEATED TEARS AND SPLITS, AND THE REST OF MY SKIN BROKE OUT IN ONGOING CYSTIC ACNE (WHICH WAS OF A DIFFERENT DEGREE OF SEVERITY THAN ON JUST TESTOSTERONE ALONE, AND EVEN IN THE FEW DAYS SINCE THE REMOVAL OF THE DEVICE, MY SKIN IS STARTING TO CLEAR UP AND HEAL). I GAINED 20 POUNDS IN THE SIX MONTHS I HAD ESSURE (MY WEIGHT HAD OTHERWISE BEEN CONSISTENT FOR THE PAST FIVE YEARS). MY SHORT-TERM MEMORY WAS NEGATIVELY AFFECTED BY THIS DEVICE. MY JOINTS THROUGHOUT MY BODY WERE CONSTANTLY INFLAMED AND PAINFUL. I HAVE BEEN SEEN BY APPROXIMATELY 7 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: FIBROMYALGIA. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: HYSTERECTOMY, SALPINGECTOMY. THE DEVICE WAS REMOVED ON (B)(6) 2015. I AM UNCERTAIN IF THE DEVICE WAS RETURNED TO THE MANUFACTURER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043352	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 5/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PELVIC PAIN. LOWER BACK PAIN. TWO HARD LUMPS HAVE APPEARED. I'M DIZZY AND DISORIENTED. SOME MEMORY LOSS AND SHORTNESS OF BREATH. SHOOTING PAINS IN MY RIGHT SIDE. NECK CRAMPS AND HEADACHE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043353	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 5/13/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5043353 #(B)(4). AM NOW SITTING IN THE HOSPITAL WITH EXTREMELY ELEVATED LIVER ENZYMES. WHICH I HAVE HAD ELEVATED LIVER ENZYMES BEFORE MY HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043354	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 8/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE, I HAVE BEEN EXPERIENCING EXCESSIVE SWEATING, HOT FLASHES, JOINT PAIN, FREQUENT HEADACHES, MIGRAINES, BRAIN FOG, BLOATING, SWELLING OF LIMBS, GAS, HEARTBURN, HEAVY BLEEDING DURING PERIODS, IRREGULAR PERIODS, CLOTTING DURING PERIODS, EXTREME FATIGUE, INFLAMED SINUSES, UNABLE TO LOSE WEIGHT, CRYING SPELLS, MOOD SWINGS, RINGING/CLICKING IN EARS, SCALP AND SKIN RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043392	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE HAS EFFECTED ME AND OTHER WOMEN LIKE ME FOR YEARS. FROM HAIR LOSS, CHRONIC FATIGUE, EYE SIGHT CHANGES, CHRONIC HIVES, CRAMPING, SEVERELY HEAVIER MENSTRUAL CYCLES, PELVIC AND BACK PAIN, ANEMIA FROM SUCH HEAVY CYCLES, MIGRAINES, DEPRESSION FROM ALL THE SIDE EFFECTS AND HOW THEY HAVE IMPACTED MY DAILY LIFE, AND MANY MORE SYMTOMS. WHILE MY GENERAL PRACTITIONER AGREES THAT THE NICKEL BASED COILS ARE WHAT'S CAUSING MY HEALTH ISSUES, MY IMPLANTING OBGYN ASSURED ME THAT EVEN THOUGH MY CONCERN WITH CERTAIN METALS MAY CAUSE ME HARM "THAT IF THE BUTTON ON MY JEANS DIDNT CAUSE ME TO BREAK OUT, THEN THERE SHOULD BE NO ISSUE". TWO MONTHS AFTER IMPLANTATION MY HIVES STARTED AND HAVE NOT LESSENED, TO THE POINT THAT OVER THE COUNTER ALLERGY MEDICATION (BENEDRYL, ALLERGRA, ETC) DO NOT EASE THE HIVES. THEN, THE MASSIVE HAIR LOSS, RESULTING IN BALDING. MIGRAINES EVERY DAY, WORSENING WHEN MY CYCLE ARRIVED. I TAKE BENEDRYL AND EXCEDRIN EVERY DAY. THIS DEVICE DOESNT SEEM TO BE SAFE FOR MOST OF ITS PATIENTS, ESPECIALLY THE ONES SUFFERING DAILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043393	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MENORRHAGIA, NICKEL ALLERGY, ALLERGIC REACTIONS, PRURITIS, ABLATION, HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043395	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 4/15/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING CHRONIC AND DEBILITATING PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043400	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 5/7/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC AND BACK PAIN. JOINT PAIN. ABDOMINAL PAIN , LEG PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043401	BAYER	7/1/2015	7/1/2015

Event Information:

Event Date (B3): 8/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PLACED 2012. EXPERIENCED EXTREME PAIN DURING INSERTION AND ALMOST PASSED OUT. RIGHT COIL WOULD NOT RELEASE. HAD TO BE PULLED OUT AND COLLAPSED FALLOPIAN TUBE. THEN ANOTHER COIL WAS FORCED THROUGH. I WAS IN PAIN UNTIL I WAS BUCKLED OVER. WENT IN AND FOUND THAT THE COIL HAD PUNCTURED THROUGH MY RIGHT TUBE. HAD TO GO THOUGH A BILATERAL SALPINGECTOMY TO REMOVE BOTH COILS AT (B)(6). PAIN AND DISCOMFORT CONTINUED. I HAVE CONSTANT BLOOD LOSS, DEBILITATING PAIN SO INTENSE I AM LEFT UNABLE TO WALK, HIGH BLOOD PRESSURE, BREAST TENDERNESS, HEADACHES, BLADDER, AND BOWEL ISSUES. I AM NOW NEEDING A HYSTERECTOMY AT THE AGE OF (B)(6) TO CONTINUE TO REMOVE SCAR TISSUE, UTERUS, AND ONE OVARY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043421	BAYER	7/1/2015	7/2/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN.HAVING REALLY BAD PELVIC PAIN, ALSO BACK PAIN REALLY BAD HEAD ACHES SEX ALSO HURTS AND MY MENSTRUAL SEXUAL HAS BEEN HORRIBLE NOT EVERY MONTH BUT SOME MONTHS ARE SO BAD NO MATTER WHAT I USE I BLEED THREW!!! THIS IS HORRIBLE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043706		7/1/2015	7/9/2015

Event Information:

Event Date (B3): 4/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 629140

Single Use:
Implant Date (E6): 4/8/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I HAD THE ESSURE IMPLANT, I EXPERIENCE PAIN ON THE LEFT SIDE OF THE ABDOMEN. PAINFUL, EXCESSIVE BLEEDING WITH PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043707		7/1/2015	7/9/2015

Event Information:

Event Date (B3): 2/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE AND NOW I HAVE HEADACHES ALL THE TIME AND I HURT AND I BLEED FOR OVER A MONTH. EVERY TIME I START MY PERIOD AND I GO FOR A MONTH OR LONGER AND THEN I'M OFF FOR ONLY LIKE 2 WKS AND THEN I START AGAIN. I HATE THE ESSURE, NO ONE NEEDS THIS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00444	BAYER HEALTHCARE LLC	7/2/2015	7/2/2015

Event Information:

Event Date (B3): 3/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/16/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR FROM (B)(4) ON (B)(4) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(4) 2009, (B)(4) 2011, AND (B)(4) 2012. ON (B)(4) 2012, FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED ONE ELECTIVE ABORTION, 2 ECTOPIC PREGNANCY AND 2 CHILDREN. THE PATIENT'S DRUG HISTORY INCLUDED COMBINED PILL (ORAL CONTRACEPTIVE NOS). THE PATIENT'S CONCURRENT CONDITION INCLUDED TUBAL STENOSIS. ON (B)(6) 2009, ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT STERILIZATION. NSAID WAS USED AS PREMEDICATION. UTERINE DISTENSION WAS PERFORMED. CONDITION OF UTERINE CAVITY WAS NORMAL. PROCEDURE TOOK 8 MINUTES. OSTIUM WAS VISIBLE ONLY ON RIGHT SIDE. IT WAS NOT EASY TO INTRODUCE THE CATHETER ON LEFT SIDE DUE TO PERCEPTION OF OBSTACLE AND POOR VISUALIZATION. PATIENT EXPERIENCED PAIN DURING AND AFTER PROCEDURE. ESSURE WAS PLACED ONLY ON RIGHT SIDE; LEFT HORN DID NOT ALLOW THE ESSURE PLACEMENT ON LEFT (LEFT HORN STENOSIS CONSECUTIVE TO 2 ECTOPIC PREGNANCY OBJECTIVIZED BY HYSTEROSALPINGOGRAPHY AND CLINIC AT THE TIME OF ESSURE PLACEMENT) PAIN, CRAMPS AND BLEEDING WERE DENIED AS POSTOPERATIVE EFFECTS. AFTER INSERTION AND BEFORE CONFIRMATION TEST, COMBINATION PILL WAS USED AS CONTRACEPTION. ON (B)(6) 2009, RADIOGRAPHY WAS DONE AND INSERTS WERE NOT SYMMETRIC. HSG

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(HYSTEROSALPINGOGRAM) WAS ALSO DONE AND INSERT ON RIGHT SIDE WAS IN PLACE. BILATERAL OCCLUSION WAS REPORTED. ON (B)(6) 2011, AN ONGOING UTERINE PREGNANCY WAS DIAGNOSED. SHE HAD GOOD EVOLUTION OF PREGNANCY. IN (B)(6) 2011, A FEMALE (B)(6) WITH (B)(6) WAS BORN; SHE WAS WELL. PARTIAL TUBAL PERFORATION OF RIGHT ISTHMIC PORTION WAS FOUND. ON (B)(6) 2012, LAPAROSCOPY WITH 2 FILSHIES CLIP PLACEMENT WAS DONE. ADDITIONAL INFORMATION RECEIVED ON 03-APR-2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 26-JUN-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: FALLOPIAN TUBE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 204 CASES. PREGNANCY WITH CONTRACEPTIVE DEVICE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 2139 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD A PREGNANCY APPROXIMATELY 2 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE DELIVERED A HEALTHY BABY. PREGNANCY IS A NON-SERIOUS EVENT AND LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS PARTICULAR CASE, PATIENT HAD A LEFT UTERINE HORN STENOSIS DUE TO 2 PREVIOUS ECTOPIC PREGNANCIES AND ONLY ONE ESSURE WAS INSERTED. ALTHOUGH, ESSURE UNILATERAL PLACEMENT COULD BE AN ALTERNATIVE EXPLANATION FOR THE REPORTED DEVICE FAILURE (PREGNANCY); SINCE THE HSG, PERFORMED PRIOR TO PREGNANCY ONSET, SHOWED BILATERAL OCCLUSION CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, PATIENT HAD A PARTIAL TUBAL PERFORATION OF RIGHT ISTHMIC PORTION DIAGNOSED AFTER DELIVERY AND WAS SUBMITTED TO A LAPAROSCOPY. ALTHOUGH THE EXACT MECHANISM OF THIS EVENT WAS UNKNOWN (IF RELATED TO THE DIFFICULTIES DURING ESSURE INSERTION OR IF OCCURRED DURING PREGNANCY), GIVEN ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE PERFORMED INTERVENTION THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00445	BAYER HEALTHCARE LLC	7/2/2015	7/2/2015

Event Information:

Event Date (B3): 11/14/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/14/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2008 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2008 WHICH QUALIFIES THIS CASE AS AN INCIDENT.. STUDY DESCRIPTION: STUDY (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6) PATIENT HAS AS MEDICAL HISTORY PARITY 3, SALPINGITIS AND MENSTRUAL PAIN. THE DATE OF HER LAST MENSTRUAL PERIOD WAS (B)(6) 2008 AND, AS CURRENT CONTRACEPTION, SHE USES CONDOMS. ACCORDING TO HEALTH CARE PROFESSIONAL, PATIENT HAD ESSURE INSERTED IN (B)(6) 2008 ON CONSULTATION. NSAID (NONSTEROIDAL ANTI-INFLAMMATORY DRUGS) WERE USED AS PREMEDICATION. NO INITIAL ANESTHESIA WAS APPLIED DURING INSERTION. UTERINE DISTENTION WITH HYSTEROSCOPY WAS POSSIBLE AND THE VISUALIZATION OF BOTH OSTIUM WAS DONE. THE CONDITION OF PATIENT'S UTERINE CAVITY WAS NORMAL AND HER UTERUS WAS NOT RETROVERTED. PHYSICIAN STARTED THE INSERTION ON RIGHT SIDE AND INFORMED THAT OSTIUM WAS IN THE FIELD OF VISION DURING PLACEMENT. IT WAS EASY TO INTRODUCE THE CATHETER INTO BOTH TUBES AND THE PLACEMENT WAS SUCCESSFUL (EXTERNALLY VISIBLE COIL IN THE UTERINE CAVITY: 1 ON EACH SIDE; NO PET FIBERS VISIBLE). PROCEDURE TOOK 4 MINUTES. IN ADDITION, PHYSICIAN REPORTED THAT 2 INSERTS WERE USED AND STATES THAT PATIENT EXPERIENCED PAIN DURING PASSAGE THROUGH THE CERVIX AND AFTER PROCEDURE. SHE DID NOT PRESENT VASOVAGAL SYNCOPE REACTION. NO OTHER PROCEDURE WAS PERFORMED AT THE SAME TIME. ON (B)(6) 2008 DURING CONSULTATION, SHE HAD AS

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POSTOPERATIVE EFFECTS BLEEDING AND PAIN/CRAMPS. DUE TO INTENSE PELVIC PAIN EPISODES PERSISTENT 10 DAYS POST ESSURE PLACEMENT, SHE REQUESTED IMPLANTS REMOVAL. IN (B)(6) 2008, BILATERAL SALPINGECTOMY WAS PERFORMED. PATIENT USED POSTOPERATIVE ANALGESICS. ADDITIONALLY, REPORTER CONSIDERED THAT THE PROCEDURE FINAL RESULT HAS FAILED AND INFORMED THAT PATIENT WAS UNSATISFIED DUE TO PAIN EPISODES AND SALPINGECTOMY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: PROCEDURAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 168 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE SUBJECT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY(STUDY NUMBER (B)(6)). SHE EXPERIENCED BLEEDING AND INTENSE PELVIC PAIN EPIDOSES (PAIN/CRAMPS) PERSISTENT 10 DAYS AFTER FALLOPIAN TUBE OCCLUSION INSERT (ESSURE) PLACEMENT. THE DEVICES WERE REMOVED BY SALPINGECTOMY. ALL EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR; IN THIS CASE GIVEN THE CLOSE TEMPORAL RELATION BETWEEN THE EVENTS AND ESSURE PROCEDURE CAUSALITY WITH THE STUDY DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR DEVICES REMOVAL. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00446	BAYER HEALTHCARE LLC	7/2/2015	7/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/29/2008
Explant Date (E7): 10/28/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(4) 2008 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(4). THE PATIENT'S MEDICAL HISTORY INCLUDED POOR COOPER IUD INTOLERANCE, MENSTRUAL PAIN AND 02 CHILDREN. SHE DENIED CURRENT CONTRACEPTION. HER LAST MENSTRUAL PERIOD WAS ON (B)(6) -2008 AND HER BETA HCG WAS NEGATIVE. ON (B)(6) -2008 THE PATIENT HAD ESSURE 305 (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT STERILIZATION; BENZODIAZEPINE WAS USED AS PREMEDICATION; AND IV SEDATION WAS USED DURING THE PROCEDURE. UTERINE DISTENTION WAS DONE. THE CONDITION OF UTERINE CAVITY WAS NORMAL AND THE PATIENT DID NOT HAVE RETROVERTED UTERUS. PHYSICIAN HAD VISUALIZATION OF LEFT AND RIGHT OSTIUMS; THE PROCEDURE WAS STARTED ON LEFT SIDE. IT WAS EASY TO INTRODUCE THE CATHETER INTO THE TUBES (BOTH). AT THE END OF PROCEDURE SHE HAD 2 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND ON RIGHT SIDE. THE PHYSICIAN USED 2 INSERTS. THE PROCEDURE TOOK 8 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. THE PATIENT COMPLAINED OF PAIN DURING PLACEMENT, DURING PASSAGE THROUGH THE CERVIX. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. THE PATIENT WAS VERY SATISFIED WITH THE PROCEDURE AND ANOTHER PROCEDURE AT THE SAME TIME WAS NOT PERFORMED. ON AN UNSPECIFIED DATE THE PATIENT EXPERIENCED NICKEL INTOLERANCE AND

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"MALAISE AND NOT WELL-BEING" SENSATION. CLINICAL EXAMINATION WAS STRICTLY NORMAL. ON (B)(4) 2008 IMPLANTS WERE WITHDRAWN BY LAPAROSCOPY FOLLOWING PATIENT'S REQUEST. NO INFLAMMATORY ASPECT OF THE PELVIS. FALLOPIAN TUBES WERE MACROSCOPICALLY NORMAL. WITHDRAWAL WAS PERFORMED WITHOUT ANY DIFFICULTY. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ALLERGY TO METALS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE SUBJECT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY (STUDY NUMBER: (B)(4)). SHE HAD FALLOPIAN TUBE OCCLUSION INSERT (ESSURE) INSERTED AND EXPERIENCED NICKEL INTOLERANCE; THE DEVICES WERE REMOVED BY LAPAROSCOPY. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; HOWEVER GIVEN THE REPORTED EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE INTERVENTION REPORTED, THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00448	BAYER HEALTHCARE LLC	7/2/2015	7/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2008 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2009 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6) THE PATIENT'S MEDICAL HISTORY INCLUDED 2 CHILDREN. THE PATIENT'S DRUG HISTORY INCLUDED COMBINED PILLS. THE PATIENT LAST MENSTRUATION PERIOD BEFORE THE INSERTION PROCEDURE WAS (B)(6) 2008. ON (B)(6) 2008, ESSURE WAS INSERTED IN THE OPERATING ROOM IN THE HOSPITAL. THE PATIENT'S UTERINE CAVITY CONDITION WAS NORMAL. THE PROCEDURE STARTED ON LEFT SIDE. THE PHYSICIAN DID NOT CONSIDER EASY TO INTRODUCE THE CATHETER INTO BOTH TUBES; ON THE RIGHT SIDE THERE WAS POOR VISUALIZATION AND ON LEFT THE DIFFICULTY WAS NOT SPECIFIED. AT THE END OF PROCEDURE SHE HAD 2 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE. THE PATIENT EXPERIENCED PAIN DURING AND AFTER THE PROCEDURE. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. NO OTHER PROCEDURE WAS DONE AT THE SAME TIME OF THE INSERTION. THE PROCEDURE TOOK 15 MINUTES AND ONLY PLACEMENT OF LEFT SIDE WAS SUCCESSFUL; ABSENCE OF VISIBILITY WAS THE REASON FOR THE UNILATERAL PLACEMENT. DURING CONSULTATION ON (B)(6) 2009, THE PATIENT REPORTED THAT SHE DID NOT USED POSTOPERATIVE ANALGESICS; SHE ALSO REPORTED THAT SHE HAD POSTOPERATIVE EFFECTS LIKE PAIN/CRAMPS. SHE USED COMBINED PILLS AS BACK-UP CONTRACEPTION. AT THIS CONSULTATION, HSG

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(HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED THAT THE LEFT INSERT WAS NOT IN PLACE AND OCCLUSION DID NOT OCCUR. THE FINAL RESULT WAS CONSIDERED AN ESSURE FAILURE DUE TO ABDOMINAL MIGRATION. PHYSICIAN SUSPECTED OF PERFORATION IN LEFT SIDE. ON AN UNSPECIFIED DATE, LAPAROSCOPY PROCEDURE WAS DONE AND MIGRATION OF LEFT INSERT INTO AMPULLA OF UTERINE TUBE WAS OBSERVED; A TUBAL LIGATION WAS PERFORMED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 322 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING LAPAROSCOPY, IT WAS FOUND OUT THAT THERE WAS A MIGRATION OF THE LEFT INSERT INTO AMPULLA OF UTERINE TUBE. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE INSERTION WAS DIFFICULT, PATIENT EXPERIENCED PAIN DURING AND POST PROCEDURE. AT CONFIRMATION TEST (HSG) THE TUBAL OCCLUSION IN THE LEFT SIDE WAS NOT ACHIEVED AND THE INSERT WAS NOT IN GOOD POSITION. PHYSICIAN SUSPECTED OF PERFORATION. A LAPAROSCOPY WAS PERFORMED AND THE LEFT INSERT HAD MIGRATED TO AMPULLA AND A TUBAL LIGATION WAS DONE. CONSIDERING EVENT'S NATURE, CAUSALITY WITH DEVICE IS ASSESSED AS RELATED. SINCE INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00449	BAYER HEALTHCARE LLC	7/2/2015	7/2/2015

Event Information:

Event Date (B3): 4/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/9/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). STUDY DESCRIPTION: (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. (B)(6). THE PATIENT USED COMBINED PILLS AS HISTORICAL DRUG. HER MEDICAL HISTORY INCLUDED MENSTRUAL PAIN. HER LAST MESNTRUAL PERIOD WAS ON (B)(6) 2009. ON (B)(6) 2009, ESSURE WAS INSERTED IN THE OPERATING ROOM UNDER GENERAL ANESTHESIA. PATIENT DID NOT RECEIVE PREMEDICATION. THE UTERINE CAVITY CONDITION WAS NORMAL, THE PATIENT DID NOT HAVE RETROVERTED UTERUS. PHYSICIAN HAD VISUALIZATION OF LEFT AND RIGHT OSTIUMS; THE PROCEDURE WAS STARTED ON LEFT SIDE. THE PHYSICIAN CONSIDERED EASY TO INTRODUCE THE CATHETER INTO THE TUBES. AT THE END OF PROCEDURE SHE HAD 5 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 2 ON RIGHT SIDE; EXTREMITY INTERNAL COIL OF INSERT WERE VISIBLE IN THE UTERINE CAVITY AND NO PET FIBERS WERE VISIBLE IN THE UTERINE CAVITY. THE PHYSICIAN USED 2 INSERTS, 1 ON EACH SIDE. THE PROCEDURE TOOK 5 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. THE PATIENT DID NOT EXPERIENCE PAIN DURING OR AFTER THE PROCEDURE. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS ALSO DENIED. NO OTHER PROCEDURE WAS DONE AT THE SAME TIME OF THE INSERTION. THE PATIENT WAS VERY SATISFIED WITH THE PROCEDURE. DURING CONSULTATION ON (B)(6) 2009, THE PATIENT REPORTED THAT SHE DID NOT USE POSTOPERATIVE ANALGESICS; NO PAIN OR BLEEDING WERE EXPERIENCED. SHE USED COMBINATION PILL AS BACK-UP CONTRACEPTION. AT THIS CONSULTATION,

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RADIOGRAPHY WAS DONE AND SHOWED ASYMMETRIC INSERTS, THE DISTANCE OF PROXIMAL PORTIONS OF DEVICES WAS MORE THAN 4 CM. AN ULTRASOUND WAS ALSO PERFORMED AND SHOWED 4 MARKERS WELL PLACED IN LEFT SIDE BUT NOT ON THE RIGHT SIDE; THE LEFT INSERT WAS SEEN FROM THE CAVITY TO THE HORN BUT NOT SEEN ON RIGHT SIDE. A HSG (HYSTEROSALPINGOGRAM) WAS ALSO DONE AND SHOWED THE INSERT IN PLACE ON LEFT SIDE; ON RIGHT SIDE A MIGRATION OF THE RIGHT INSERT OF 3 CM REMOTE FROM THE UTERINE HORN WAS NOTED. BILATERAL OCCLUSION DID NOT OCCUR. THE IMAGE WAS INTERPRETABLE AND IN CONCLUSION, ONLY THE LEFT SIDE INSERT HAD A GOOD POSITION. PHYSICIAN CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS FAILURE OF ESSURE DEVICES DUE TO ABDOMINAL MIGRATION. THERE WAS A REQUIREMENT OF SECONDARY LAPAROSCOPY. THE PATIENT WAS UNSATISFIED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 08-APR-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY (B)(4) AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 26-JUN-2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE SUBJECT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY (B)(6). SHE HAD FALLOPIAN TUBE OCCLUSION INSERT (ESSURE) INSERTED AND AT HYSTEROSALPINGOGRAM (HSG) A MIGRATION OF THE RIGHT INSERT WAS FOUND. A COELIOSCOPY WAS REQUIRED AS TREATMENT. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED DEVICE MIGRATION IS NOT KNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043705	BAYER	7/2/2015	7/9/2015

Event Information:

Event Date (B3): 5/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY AFTER THE PROCEDURE WAS DONE, MY PERIODS STARTED TO BECOME LONGER. I WAS ALSO DIAGNOSED WITH A FIBROID AFTER THE PROCEDURE WAS DONE. PRIOR TO THIS I HAD NEVER HAD ANY HEALTH PROBLEMS. IN THE FOLLOWING MONTHS, I BEGAN TO HAVE PAINFUL PERIODS THAT I HAD TO BEGIN TAKING PAIN RELIEVER FOR. I HURT REALLY BAD ON THE RIGHT AND LEFT OF MY STOMACH WHERE THE ESSURE IS INSERTED. IT HAS AFFECTED MY SELF ESTEEM, AND MY EVERYDAY LIFE ACTIVITIES. AS A RESULT OF THE ESSURE CAUSING IRREGULAR, LONGER, PAINFUL PERIODS, I HAVE BECOME VERY INSECURE, AND SELF CONSCIOUS CAUSING ME NOT WANTING TO BE AROUND MY CO-WORKER, FAMILY, FRIENDS, SOCIAL EVENTS, GO GROCERY SHOPPING, OR OUT IN THE PUBLIC AT ALL. NOT TO MENTION MY SEX LIFE IS ALMOST NON EXISTENT BECAUSE OF THE EMBARRASSING SMELL AND THE PAIN IT CAUSES. IT'S CAUSING ME TO HAVE CONTINUOUS BACTERIA INFECTIONS, AND YEAST INFECTIONS THAT GO AWAY FOR SHORT PERIODS OF TIME AND RETURN. I'M FORCED TO WEAR PANTY LINERS DAILY BECAUSE I'M PARANOID ABOUT MY PERIOD DECIDING TO SHOW UP, AND THEY IRRITATE MY VAGINA MAKING IT SENSITIVE TO THE TOUCH AND RAW. WHENEVER I EXPLAIN MY PROBLEMS/CONCERNS TO THE DR, THEY ALWAYS SAY IT'S NOT THE ESSURE THAT'S CAUSING MY CONDITIONS. THEREFORE, THEY PROCEED TO SUGGEST HAVING A HYSTERECTOMY, NOVASURE, ETC., TO RESOLVE MY ISSUES, NONE OF WHICH I APPROVE OF. I'M DRAINED, AND I JUST WANT THE ESSURE REMOVED; SO THAT I CAN HAVE MY LIFE BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043920	BAYER HEALTHCARE LLC, MILPITAS, CA	7/2/2015	7/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/30/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I'VE HAD THE ESSURE COILS IMPLANTED IN MY TUBES I'VE DEALT WITH ABDOMINAL PAIN. NEVER HAD THESE PROBLEMS BEFORE, ALSO MY MENSTRUAL CYCLE IS HEAVIER THAN EVER. THE PAIN COMES OUT OF NOWHERE AND IT'S NOTHING I CAN DO BUT LAY DOWN AND THAT REALLY DOESN'T HELP EITHER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043921	BAYER	7/2/2015	7/13/2015

Event Information:

Event Date (B3): 8/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/12/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE PLACEMENT, I HAVE HAD NUMEROUS HEALTH PROBLEMS. BEFORE HAVING THIS DONE, I WAS CONSIDERED HEALTHY. I NOW SUFFER FROM MIGRAINES, REPEATED CHEST PAINS (SENDING ME TO THE ER), NEUROPATHY, FIBROMYALGIA, WEIGHT GAIN, BLADDER INCONTINENCE, SEVERE SIDE/BACK PAIN, EXCESSIVE BLEEDING DURING MENSTRUAL CYCLES, FATIGUE, AND DEPRESSION. I'VE BEEN SEEN IN THE EMERGENCY ROOM 2-3 TIMES FOR THE CHEST PAINS, ADMITTED ONCE, AFTER NUMEROUS TESTS, NO KNOWN CAUSE. I'VE BEEN TO THE EMERGENCY ROOM AND HOSPITALIZED NUMEROUS TIMES FOR THE MIGRAINES, NEUROPATHY, AND FIBROMYALGIA, WHERE AGAIN THEY CANNOT FIND CAUSE OF ORIGIN. I'VE SEEN NUMEROUS SPECIALISTS FOR ALL THE ABOVE. NONE OF THIS WAS AN ISSUE UNTIL I HAD ESSURE! I DIDN'T GIVE IT MUCH THOUGHT UNTIL I SPOKE WITH NUMEROUS OTHER WOMEN WHO HAVE HAD THE SAME ISSUES AFTER GETTING ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043894	BAYER	7/3/2015	7/13/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY ESSURE WAS PUT IN (B)(6) 2014. SINCE THEN, I HAVE HAD SEVERE CRAMPING, HEAVY IRREGULAR BLEEDING AND DOUBLE CYCLES. I'VE HAD CONSTANT MIGRAINES SINCE (B)(6) 2015. I HAVE BLOATING IN MY ABDOMEN AREA THAT MAKE ME LOOK PREGNANT (NOT PREGNANT). I HAVE ENDOMETRIOSIS AND OVARIAN CYSTS, AND IN MY OPINION AND FEELING, HAVE BECOME MUCH WORSE. I CANNOT SLEEP LIKE NORMAL, OR WAKE UP RESTED. THIS HAS BEEN HAPPENING FOR 8 MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043916	BAYER	7/3/2015	7/13/2015

Event Information:

Event Date (B3): 7/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/4/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PERMANENT BIRTH CONTROL PROCEDURE IN (B)(6) 2014. PROCEDURE WAS DONE IN DOCTORS OFFICE. SINCE THAT TIME I HAVE HAD SEVERAL HEALTH ISSUES BOTH NEW AND THE WORSENING OF EXISTING CONDITIONS, INCLUDING RAPID WEIGHT GAIN, HAIR GROWTH, MOOD SWINGS, SEVERE DEPRESSION, CHRONIC FATIGUE, JOINT PAIN, CRAMPS, PAIN AND SWELLING IN ABDOMINAL REGION, SPOTTING, DIZZINESS, SEVERE MIGRAINES, NAUSEA, CONSTIPATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043923	BAYER HEALTHCARE LLC, MILPITAS, CA	7/3/2015	7/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/4/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IMPLANT IN (B)(6) 2013. SINCE THEN I HAVE EXPERIENCED PROLONGED PERIODS OF BLEEDING, SEVERE CRAMPING, AND A METALLIC TYPE TASTE IN MY MOUTH. THERE ARE DAYS MY CYCLE IS SO HEAVY THAT I BLEED THROUGH BOTH A TAMPON AS WELL AS A PAD. I ALSO HAVE STARTED HAVING MIGRAINES. I HAVE BEEN TOLD I CAN'T HAVE THE DEVICE REMOVED AS IT IS CONSIDERED ELECTIVE SURGERY OR I MUST PAY FOR IT OUT OF POCKET. OR IF I COMPLAIN ENOUGH, I MAY BE ABLE TO HAVE A HYSTERECTOMY. HOW CAN SOMETHING THAT IS COVERED TO BE INPUTTED INTO MY BODY NOT BE COVERED TO BE REMOVED. THIS PRODUCT NEEDS TO BE PULLED FROM THE MARKET OR THERE NEEDS TO BE MANDATORY TESTING FOR ADVERSE REACTIONS TO NICKEL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043925	BAYER HEALTH	7/3/2015	7/13/2015

Event Information:

Event Date (B3): 8/6/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/6/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE THAT DID NOT WORK (RIGHT FALLOPIAN TUBE DID NOT BLOCK). UPON CONFIRMATION TESTING NO BLOCKAGE WAS SEEN. AFTER THE PROCEDURE I CONTINUED TO HAVE BACK PAIN, PAINFUL INTERCOURSE, HEAVY CRAMPING AND BLEEDING. I HAD TO HAVE ADDITIONAL SURGERY (TUBAL LIGATION) TO ENSURE I DID NOT GET PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043926	CONCEPTUS INCORPORATED	7/3/2015	7/13/2015

Event Information:

Event Date (B3): 7/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 623319

Single Use:
Implant Date (E6): 5/25/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2007, TO PREVENT ANYMORE PREGNANCIES, AND AFTER I GOT IT DONE I'VE NOTICED LOTS OF BACK PAIN, PROLONGED MENSTRUAL CYCLES, HEAVY BLEEDING, VERY PAINFUL WHILE BEING INTIMATE, BLEEDING ON RANDOM DAYS WHEN I'M NOT DUE FOR MY CYCLE, THERE ARE DAYS I JUST CRAWL INTO FETAL POSITION JUST TO BARE WITH THE PAIN, I'VE BEEN SUFFERING WITH ALL THIS FOR 8 YEARS, I'VE SEEN MY GYNECOLOGIST FOR HELP WITH MY CYCLE BUT THAT DIDN'T WORK, I NEED TO KNOW WHAT IS GOING ON WITH THIS ESSURE, I'VE RECENTLY SPOKE WITH THE DOCTOR WHO INSERTED THE ESSURE AND HE SAID THERE ARE TWO WAYS TO NOT HAVE TO DEAL WITH THIS PAIN, 1. HE CAN GO IN AGAIN AND TRY TO REMOVE THE ESSURE BUT THEN THERE'S A CHANCE I CAN HEMORRHAGE, 2. GET A HYSTERECTOMY, I'M (B)(6) OLD AND TWO CHILDREN! IF I WOULD'VE KNOWN THIS WOULD BE THE SIDE EFFECTS I WOULD'VE JUST GOTTEN MY TUBES TIED, BUT SINCE THE DOCTOR ASSURED ME THIS WAS A GREAT PROCEDURE TO HAVE, I DID IT, AND NOW LOOK !!! I HAVE THE ESSURE CARD HE PROVIDED FOR ME WITH A LOT NUM ON IT, I CAN BE REACHED EITHER BY PHONE OR EMAIL, MY CELL # (B)(6). PLEASE LET ME KNOW, THANK YOU.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043929	BAYER HEALTH	7/3/2015	7/13/2015

Event Information:

Event Date (B3): 7/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/31/2007
Explant Date (E7): 3/9/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE DEVICE IMPLANTED ON (B)(6) 2007 AND AFTER THAT I STARTED HAVING SYMPTOMS SURFACING. HAD TO SEE DIFFERENT DRS AND AN ALLERGY DR. WAS PRESCRIBED A LOT OF DIFFERENT MEDICATIONS THAT I NEVER TOOK BECAUSE I'M NOT MEDICATING MY BODY. THE DR THAT PLANTED THE DEVICE NEVER TOLD ME THAT IT WAS A PERMANENT DEVICE, I THOUGHT I WAS ABLE TO GET IT TAKEN OUT AS I PLEASED TO HAVE ANOTHER CHILD IF I WANTED TO. THE SYMPTOMS THAT STARTED SURFACING IS/WAS MAJORLY BAD HEADACHES THAT PUT ME IN BED, PAIN DURING SEX, CONSTANT BLEEDING AT ONE POINT, RASHES FROM MONTH TO MONTH THAT I HAD TO GO TO THE HOSPITAL FOR, NICKEL ALLERGY, MASSIVE TIREDNESS AND BEING IN BED A LOT FOR BARELY KEEPING MY EYES OPENED, HAVING TO GET POLYPS REMOVED FROM MY CERIX (PRECANCEROUS CELLS), I'M STILL HAVING MAJOR PAIN DURING SEX WITH MY PARTNER, I'VE DEALT WITH RELATIONSHIP PROBLEMS CAUSE OF THE DEVICE AND MANY OTHER BAD THINGS HAS HAPPENED TO ME. THE DEVICE IS A BIG MISTAKE AND HAS RUINED MY LIFE! I'VE ALSO GAINED MASSIVE AMOUNTS OF WEIGHT OVER THE YEARS FROM IT AS WELL THAT I'M STILL TRYING TO WORK OFF.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043893	BAYER	7/4/2015	7/13/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2011 AFTER DOING MUCH RESEARCH FOR BIRTH CONTROL AND THOUGHT IT WAS THE SAFEST WAY TO GO. AFTER HAVING THE ESSURE IMPLANTED I WAS IN CONSTANT SEVERE PAIN. AT FIRST I THOUGHT IT WOULD JUST GO AWAY BUT IT ONLY GOT WORSE. I HAD VERY HEAVY BLEEDING WHERE STANDING UP WOULD LEAD TO SUCH HEAVY LEAKING AND DRAINING THAT IT OFTEN CAUSED QUITE A MESS. IT WAS PRETTY SCARY SO I WENT TO THE PLANNED PARENTHOOD TO GET CHECKED OUT AND THEY WERE CONCERNED IT MIGHT HAVE CANCER IN THE UTERUS. SO I GOT MY UTERUS SCRAPED TO DISCOVER THAT THERE WAS THANKFULLY NO CANCER. BUT THE PROBLEM DID NOT GET ANY BETTER. I HAD NUMEROUS VISITS TO THE DOCTOR DUE TO THE PAIN AND BLEEDING WITH THEM NOT FINDING ANYTHING WRONG WITH ME. I HAVE SEVERE ABDOMINAL AND BACK PAIN. SOME DAYS IT IS HARD TO GET OUT OF BED AND MOVE AROUND. WHEN I WENT TO VISIT MY MOTHER IN 2013 THE PAIN WAS SO INTENSE I WENT TO SEE ANOTHER DOCTOR IN (B)(6) WHO DECIDED TO DO ANOTHER CANCER SCRAPE WHICH CAME BACK NEGATIVE. I CHOSE THE ESSURE PROCEDURE BECAUSE AFTER ALL THE RESEARCH I DID IT SEEMED TO BE THE SAFEST METHOD AND THE ONE WITH THE LEAST AMOUNT OF SIDE EFFECTS AND COMPLICATIONS. I AM SORRY I EVER GOT IT DONE AND IF I COULD GO BACK AND CHANGE THINGS I WOULD NOT DO IT AGAIN. I AM IN PAIN EVERY DAY NOW AND THIS WOULD NEVER HAVE BEEN SO IF I NEVER HAVE GOTTEN THAT PROCEDURE DONE. INTERCOURSE HAS BECOME SO PAINFUL SINCE THE PROCEDURE THAT I DO NOT EVEN WANT TO HAVE IT ANY MORE AND IT IS GREATLY AFFECTING MY MARRIAGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043917	BAYER	7/4/2015	7/13/2015

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER ESSURE IMPLANTED DEVELOPED MIGRAINES AND WILL TAKE MEDICINE NOW AS LONG AS ESSURE IS IN ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043918	BAYER	7/4/2015	7/13/2015

Event Information:

Event Date (B3): 10/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/10/2013
Explant Date (E7): 12/17/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) I HAD THE ESSURE PROCEDURE DONE, MY DR ASSURED ME THIS WAS A SAFE, EASY, EFFECTIVE PERMANENT BIRTH CONTROL WITH NO SIDE EFFECTS. AFTER MY FOLLOW-UP APPOINTMENT TO ENSURE THAT THE TUBES WERE FULLY BLOCKED I WAS TOLD IT WAS SAFE TO GET OFF MY BIRTH CONTROL. I SUFFERED FROM SEVERE BLEEDING AND CRAMPS FOR 14 MONTHS STRAIGHT. I WENT BACK TO MY DR MULTIPLE TIMES, AT ONE POINT THEY EVEN PUT IN A MIRENA IUD TO CONTROL THE BLEEDING WHICH DID NOT HELP. ALONG WITH THE SEVERE BLEEDING AND CRAMPS IN THAT 14 MONTHS I HAD HUGE BLOOD CLOTS, CONSTANT BLOATING AND STOMACH PAIN, WEIGHT GAIN, DEPRESSION AND ABSOLUTE LOSS OF SEXUAL DRIVE WHICH RUINED MY MARRIAGE. FINALLY AFTER 14 MONTHS I WENT TO A SPECIALIST BECAUSE MY DR WAS UNABLE TO CONTROL MY BLOOD LOSS AND I WAS FORCED INTO A HYSTERECTOMY AT THE AGE OF (B)(6), THAT WAS THE ONLY CURE FOR THE BLEEDING. HOWEVER A HYSTERECTOMY CANNOT FIX MY DEPRESSION, SEX DRIVE, OR MY MARRIAGE SO I WILL NEVER BE THE SAME AFTER USING THIS PRODUCT! PLEASE REMOVE THIS PRODUCT SO THAT NO MORE WOMEN HAVE TO ENDURE THIS NIGHTMARE. WITHIN THE FIRST 6 MONTHS I HAD TO HAVE AN IUD PUT IN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043932	BAYER	7/4/2015	7/13/2015

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/1/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER ESSURE IMPLANTION DEVELOPED MIGRAINES AND WILL TAKE MEDICINE NOW AS LONG AS ESSURE IS IN ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043940	ESSURE	7/5/2015	7/13/2015

Event Information:

Event Date (B3): 10/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): PERMANENT BIRTH CONTROL SYSTEM
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B21574

Single Use:
Implant Date (E6): 10/24/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED IN (B)(6) 2013. WAS TOLD MY MENSTRUAL CYCLE WOULD STOP OVER TIME. FROM THE FIRST TIME I HAD SEXUAL INTERCOURSE WHICH WAS 6 WEEKS AFTER IMPLANT UNTIL PRESENT DAY, I BLEED EVERY TIME I HAVE SEX. FROM 3-7 DAYS BEFORE I START I GET EXCRUCIATING, STOPS ME IN MY STEPS CRAMPS, THAT LAST FROM 20S TO A MINUTE OR 2. WHEN I START IT IS EXCESSIVE BLEEDING FOR 2 DAYS, I HAVE TO USE SUPER PLUS TAMPONS AND CHANGE THEM HOURLY AND USE OVERNIGHT PADS, WHICH I BLEED THROUGH AND RUIN AT LEAST ONE PAIR OF PANTIES AND PANTS A MONTH. I PASS NICKLE TO KIWI SIZED BLOOD CLOTS THE FIRST TWO DAYS. MY (B)(6)DAUGHTER CAME IN THE BATHROOM ONE TIME AND WAS MORTIFIED, STILL TO THIS DAY SHE WON'T BARGE INTO THE BATHROOM IF I'M IN THERE. THE 3RD DAY I DROP TO SUPER TAMPONS AND EXTRA LONG PADS AND THEN THE FOURTH DAY IT'S REGULAR TAMPONS AND USUALLY I DON'T BLEED THROUGH TO PAD AND THEN FIFTH DAY I WEAR A PAD JUST IN CASE. AND IF THAT'S NOT ENOUGH, I SWELL UP AND AM ALL BLOATED WHICH I NEVER NOTICED BLOATING BEFORE THE INSERTION OF THE ESSURE. RX MEDS: LEVOTHYROXIN, AMLODIPINE, DO NOT TAKE LIKE I SHOULD SUMARIPTAN, MELEXOCAM. OTC MEDS: EXCEDRIN MIGRAINE, EXCEDRIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043941		7/5/2015	7/13/2015

Event Information:

Event Date (B3): 5/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD THE ESSURE NOW FOR 2 MONTHS AND I'M STILL IN TERRIBLE PAIN! MY BACK IS SWELLING, AND MY ABDOMEN HURTS! I HAVE NO ENERGY AT ALL! I'M IN SO MUCH PAIN THAT I CAN'T EVEN TAKE CARE OF MY TWO BABIES! MY HUSBAND HAS BEEN HERE TO HELP THANK GOD BUT I WAS NEVER WARNED ABOUT THESE HORRIBLE SIDE EFFECTS! I READ ABOUT OTHER WOMEN AND THEIR HORRIBLE STORIES ABOUT THE ESSURE, ALSO DEATHS! I'M VERY TERRIFIED AND NEED TO KNOW WHAT TO DO.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00450	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/9/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). PATIENT HAS AS MEDICAL HISTORY PARITY 3, 1 CAESARIAN AND MENSTRUAL PAIN. AS CURRENT CONTRACEPTION SHE USES CONTRACEPTIVE IMPLANTS AND THE DATE OF HER LAST MENSTRUAL PERIOD WAS (B)(6) 2008. PATIENT HAD ESSURE INSERTED ON (B)(6) 2008. INITIAL GENERAL ANESTHESIA WAS APPLIED DURING PROCEDURE, UTERINE DISTENSION WAS DONE AND HYSTEROSCOPY WAS POSSIBLE. PATIENT'S UTERINE CAVITY WAS NORMAL AND HER UTERUS WAS NOT RETROVERTED. PHYSICIAN STARTED THE INSERTION ON LEFT SIDE AND INFORMED THAT OSTIUM WAS IN THE FIELD OF VISION DURING PLACEMENT. IT WAS EASY TO INTRODUCE THE CATHETER INTO BOTH TUBES AND THE PLACEMENT WAS SUCCESSFUL (EXTERNALLY VISIBLE COIL IN THE UTERINE CAVITY: 4 ON LEFT AND 2 ON RIGHT). PROCEDURE TOOK 5 MINUTES. IN ADDITION, PHYSICIAN REPORTED THAT 2 INSERTS WERE USED (1 ON EACH TUBE) AND STATES THAT PATIENT DID NOT PRESENT VASOVAGAL SYNCOPE. NO OTHER PROCEDURE WAS PERFORMED AT THE SAME TIME OF INSERTION. PATIENT TOOK POST-OPERATIVE ANALGESICS AND DID NOT USE ANY CONTRACEPTIVE METHOD. SHE DID NOT EXPERIENCE BLEEDING. AS COMPLICATION, INVESTIGATOR REPORTED INCAPACITATING BILATERAL PAIN AND INFORMED THAT PLAIN ABDOMINAL X-RAY, PELVIC ULTRASOUND, HYSTEROSCOPY (ESSURE NOT SEEN) AND PELVIS LAPAROSCOPY WERE NORMAL. BILATERAL SALPINGECTOMY WAS PERFORMED. ADDITIONALLY, REPORTER

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CONSIDERED THAT THE PROCEDURE FINAL RESULT HAS FAILED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ABDOMINAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 280 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS INVOLVED IN A OBSERVATIONAL COMPANY-SPONSORED STUDY AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE EXPERIENCED BILATERAL INVALIDATING PAIN (INTERPRETED AS ABDOMINAL PAIN). PATIENT UNDERWENT SOME RELEVANT TESTS AND IT WAS REPORTED THAT ESSURE WAS NOT SEEN (INTERPRETED AS DEVICE DISLOCATION) UPON HYSTEROSCOPY. A BILATERAL SALPINGECTOMY WAS PERFORMED. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, PATIENT EXPERIENCED INCAPACITATING BILATERAL PAIN AFTER AN UNKNOWN TIME OF ESSURE INSERTION. WITH REGARDS TO THE EVENT DEVICE DISLOCATION, THE EXACT DATE AND MECHANISM WERE NOT KNOWN. BASED ON THE INFORMATION PROVIDED AND GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00451	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/3/2009
Explant Date (E7): 5/18/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6)-2009 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6)-2009 AND (B)(6)-2012 . ON (B)(6)-2009 FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE (B)(4) IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 01 CHILD AND MENSTRUAL PAIN. MEDICATION AT TIME OF INSERTION INCLUDED COMBINED PILL. HER LAST MENSTRUAL PERIOD BEFORE INSERTION OCCURRED ON (B)(6)-2009. ON (B)(6)-2009 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS EASILY IMPLANTED FOR PERMANENT STERILISATION. ANALGESICS AND NSAID (NON-STEROIDAL ANTI-INFLAMMATORY DRUG) WERE USED AS PREMEDICATION. UTERINE CAVITY WAS WITHIN NORMAL CONDITIONS AND SHE DID NOT HAVE RETROVERTED UTERUS. VISUALIZATION OF OSTIUM WAS GOOD BILATERALLY. THE PROCEDURE WAS STARTED ON RIGHT SIDE. AT THE END OF PROCEDURE SHE HAD 6 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 2 COILS ON RIGHT SIDE. THE PHYSICIAN USED 2 INSERTS. THE PROCEDURE TOOK 4 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. PATIENT PRESENTED PAIN DURING INSERTION AND AFTER THE PROCEDURE. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. THE PATIENT WAS VERY SATISFIED WITH THE PROCEDURE AND NO ADDITIONAL PROCEDURE WAS PERFORMED AT THE SAME TIME. POSTOPERATIVE ANALGESICS WAS USED. COMBINATION PILL WAS USED DURING THE 3 MONTHS AFTER ESSURE INSERTION. ON (B)(6)-2009 THE PATIENT

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EXPERIENCED PAIN/CRAMPS AT 3 MONTHS. BLEEDING WAS DENIED. RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS WERE NOT SYMMETRIC POSITIONED AND DISTANCE BETWEEN PROXIMAL PORTION WAS MORE THAN 4 CM. FOUR MARKERS WERE WELL PLACED ON THE LEFT SIDE ONLY. HSG WAS NOT DONE. ULTRASOUND WAS PERFORMED AND INSERT WAS SEEN FROM THE CAVITY TO THE HORN ON THE LEFT SIDE. FINAL RESULT OF PROCEDURE WAS CLASSIFIED AS "FAILURE" DUE TO INTRAPERITONEAL MIGRATION OF THE RIGHT IMPLANT (PROBABLE PERFORATION DUE TO IMPORTANT PUSH OR SIMPLE MIGRATION). PHYSICIAN REPORTED THAT PAIN AT TIME OF INSERTION REINFORCED THE PERFORATION DIAGNOSIS. PATIENT WAS NOT VERY SATISFIED. ON (B)(6)-2009 LAPAROSCOPY WAS PERFORMED AND THE IMPLANT WAS FOUND IN OMENTUM. IMPLANT COLLECTED AND COAGULATION WAS OBSERVED: SECTION BY LAPAROSCOPY. TUBAL LIGATION PERFORMED. POST-PROCEDURE FOLLOW-UPS WERE STOPPED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6)-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER 2015-011343. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6)-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: UTERINE PERFORATION . THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 145 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. INTRAPERITONEAL MIGRATION OF RIGHT IMPLANT (PROBABLE PERFORATION) WAS OBSERVED DURING LAPAROSCOPY. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION WITH ESSURE USE MAY OCCUR MOSTLY DURING INSERTION. IN THIS CASE, THE INSERTION WAS EASY BUT PATIENT EXPERIENCED PAIN DURING AND AFTER PLACEMENT. THE CONFIRMATION TEST (ULTRASOUND) SHOWED THE RIGHT INSERT WAS NOT IN GOOD POSITION. ONE WEEK LATER, A LAPAROSCOPY WAS THEN PERFORMED AND THE IMPLANT WAS FOUND IN OMENTUM AND REMOVED. GIVEN AVAILABLE INFORMATION AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED. SINCE LAPAROSCOPY WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00452	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 4/4/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/4/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2008 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2009 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION:(B)(6) IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED TWO CHILDREN. SHE HAD AN IUD FOR CONTRACEPTION. ON (B)(6) 2008, THE FIRST ATTEMPT TO INSERT ESSURE WAS PERFORMED. PATIENT'S BETA HCG WAS NEGATIVE. BENZODIAZEPINE WAS USED AS PREMEDICATION. UTERINE CAVITY CONDITION INCLUDED HYPERTROPHIC ENDOMETRIUM; UTERUS WAS NOT RETROVERTED. OSTIUM VISUALIZATION WAS ONLY POSSIBLE ON THE LEFT SIDE. THE PROCEDURE TOOK 10 MINUTES. THERE WAS A PERCEPTION OF OBSTACLE IN THE RIGHT SIDE. IUD WAS IN PLACE AND WAS REMOVED FOR ESSURE PLACEMENT; HOWEVER ESSURE INSERTION ON RIGHT SIDE WAS IMPOSSIBLE. INVESTIGATOR CONSIDERED TUBAL OBSTRUCTION AS THE REASON FOR UNILATERAL PLACEMENT AND REQUESTED A HYSTEROGRAPHY. ON (B)(6) 2009, ANOTHER ATTEMPT TO INSERT RIGHT ESSURE WAS PERFORMED. IV SEDATION FAILED SO GENERAL ANESTHESIA WAS PERFORMED. UTERINE CONDITION WAS NORMAL. PROCEDURE TOOK 10 MINUTES. THERE WAS PERCEPTION OF OBSTACLE ON RIGHT SIDE, INSERT WAS WITHDRAWN AND THERE WAS A SENSATION OF PERFORATION. STERILIZATION WAS PERFORMED BY LAPAROSCOPY (CLIP PLACED ON RIGHT SIDE). PATIENT EXPERIENCED PAIN DURING AND AFTER THIS ATTEMPT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL

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COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: UTERINE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. DURING ESSURE INSERTION, THE PHYSICIAN HAD THE PERCEPTION OF AN OBSTACLE AT THE RIGHT SIDE AND, WHILE WITHDRAWING THE INSERT, HAD A SENSATION OF PERFORATION. PATIENT EXPERIENCED PAIN. THE PROCEDURE WAS STOPPED AND STERILIZATION WAS PERFORMED BY LAPAROSCOPY. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, THE INSERTION WAS STOPPED AS PLACEMENT WAS DIFFICULT ON THE RIGHT SIDE DUE TO PERCEPTION OF AN OBSTACLE. IT REMAINS UNCLEAR WHETHER A PERFORATION OCCURRED OR WHETHER THERE WAS ONLY THE SENSATION OF A PERFORATION BY THE PHYSICIAN. NEVERTHELESS, CONSIDERING THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION (LAPAROSCOPY) WAS REQUIRED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00455	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 7/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/20/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON 12-AUG-2009 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). PATIENT'S MEDICAL HISTORY INCLUDED 2 CHILDREN. SHE WAS ON COMBINED PILL AT INSERTION AND MENSTRUAL PAIN WAS ALSO NOTED. HER LAST MENSTRUAL PERIOD OCCURRED ON (B)(6) 2009. ON (B)(6) 2009, ESSURE WAS EASILY INSERTED. OSTIUM WAS VISUALIZED. PROCEDURE DURATION WAS 6 MINUTES. BETA HCG WAS NEGATIVE. BENZODIAZEPINE WAS USED AS PREMEDICATION AND IV SEDATION WAS USED. UTERINE CONDITION WAS NORMAL AND HER UTERUS WAS NOT RETROVERTED. THREE COILS WAS SEEN EXTERNALLY IN THE UTERINE CAVITY IN BOTH SIDES AFTER PROCEDURE. TWO ESSURE INSERTS WERE USED. PATIENT PRESENTED PAIN DURING AND AFTER PROCEDURE. VASOVAGAL REACTION WAS DENIED. NO OTHER PROCEDURE WAS PERFORMED AT THE SAME TIME OF INSERTION. SUCCESSFUL PLACEMENT ACHIEVED. COMBINATION PILL WAS USED AS BACK-CONTRACEPTION. ON (B)(6) 2009, RADIOGRAPHY WAS PERFORMED AND INSERTS WERE NOT SYMMETRIC AND THE DISTANCE OF PROXIMAL PORTIONS WAS NOT LESS THAN 4 CM. HYSTEROSALPINGOGRAM (HSG) WAS ALSO PERFORMED AND SHOWED RIGHT INSERT IN PLACE AND LEFT INSERT WAS NOT IN PLACE. BILATERAL OCCLUSION WAS REPORTED. AND CONCLUSION WAS THAT LEFT INSERT WAS NOT IN GOOD POSITION. FINAL RESULT OF THE PROCEDURE WAS NOTED AS 'FAILURE' AND PATIENT WAS SATISFIED. SUSPICION OF

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ABDOMINAL MIGRATION WAS NOTED. BY HSG, LEFT INSERT SEEMED TO BE INTRA-ABDOMINAL. ON (B)(6) 2009, LAPAROSCOPY WAS PERFORMED AND ELECTRICAL COAGULATION OF THE LEFT TUBE WAS PERFORMED. IT WAS ALSO NOTED THAT THERE WAS NOT VISIBLE INSERT IN THE ABDOMINAL CAVITY. NO FURTHER INFORMATION WAS PROVIDED. ADDITIONAL INFORMATION RECEIVED ON 08-APR-2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER:(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY (B)(4) AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 26-JUN-2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. (B)(4) IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY AND HAD ESSURE INSERTED. PATIENT PRESENTED PAIN DURING AND AFTER PROCEDURE AND UPON FOLLOW UP, HYSTEROSALPINGOGRAM WAS PERFORMED AND THE RESULT SHOWED LEFT INSERT SEEMED TO BE INTRA-ABDOMINAL. SUSPICION OF ABDOMINAL MIGRATION OF LEFT INSERT WAS REPORTED. A LAPAROSCOPY WAS PERFORMED BUT THERE WAS NOT VISIBLE INSERT IN THE ABDOMINAL CAVITY. INSERT MIGRATION IS SERIOUS EVENT DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MIGRATION IS OFTEN USED SYNONYMOUSLY WITH PERFORATION. IT IS SOMETIMES USED TO IMPLY THAT A COMPLETE PERFORATION OCCURRED NOT IMMEDIATELY, BUT OVER TIME, E.G. WHEN AN UNDIAGNOSED PARTIAL PERFORATION DURING INSERTION GRADUALLY LEADS TO A COMPLETE PERFORATION. OFTEN MIGRATION IS REPORTED WHEN THE EXACT TIME POINT OF PERFORATION IS NOT KNOWN. SOMETIMES MIGRATION THROUGH THE FALLOPIAN TUBE IS SUSPECTED BY THE REPORTER, BECAUSE THE ESSURE INSERT IS FOUND IN THE ABDOMEN AND NO APPARENT PERFORATION CAN BE IDENTIFIED. THEREFORE, BASED ON THE INFORMATION PROVIDED AND POSSIBLE MECHANISM OF MIGRATION, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A LAPAROSCOPY WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00456	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 7/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/20/2009
Explant Date (E7): 8/31/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON 20-APR-2009 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON 31-AUG-2009 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY , ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6) THE PATIENT'S MEDICAL HISTORY INCLUDED 02 CHILDREN, CURETTAGE, HYPERTENSION ARTERIAL, AND HYPERTHYROIDISM. SHE DENIED MENSTRUAL PAIN. SHE USED COMBINED PILL AS CONTRACEPTIVE. HER LAST MENSTRUAL PERIOD WAS ON (B)(6) 2009. ON (B)(6) 2009, THE PATIENT HAD ESSURE 305 (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT STERILIZATION. UTERINE DISTENTION WAS DONE. CONDITION OF UTERINE CAVITY WAS ATROPHIC AND THE PATIENT DID NOT HAVE RETROVERTED UTERUS. OSTIUM WAS VISUALIZED ONLY ON RIGHT SIDE. THE PROCEDURE WAS STARTED ON LEFT SIDE. IT WAS DIFFICULT TO INTRODUCE THE CATHETER INTO THE TUBES DUE TO PERCEPTION OF OBSTACLE ON THE LEFT SIDE AND POOR VISUALIZATION ON BOTH; LEFT SYSTEM WAS PLACED WITHOUT OSTIUM VISUALIZATION. AT THE END OF PROCEDURE SHE HAD 2 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 4 COILS ON RIGHT SIDE. THE PHYSICIAN USED 2 INSERTS. THE PROCEDURE TOOK 7 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. THE PATIENT COMPLAINED OF PAIN DURING PLACEMENT ON THE LEFT SIDE, DURING PASSAGE THROUGH THE CERVIX. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. THE PATIENT WAS VERY SATISFIED WITH THE PROCEDURE AND ANOTHER PROCEDURE AT THE SAME TIME WAS NOT PERFORMED.

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COMBINATION PILL WAS USED AFTER PLACEMENT AND BEFORE CONFIRMATION TEST. ON (B)(6) 2009, AT 3-MONTH VISIT, POSTOPERATIVE BLEEDING WAS REPORTED. ON THE SAME DAY, RADIOGRAPHY WAS PERFORMED AND SHOWED THAT INSERTS WERE NOT SYMMETRIC AND THE DISTANCE (PROXIMAL PORTIONS) WAS <4 CM. AT 3D ULTRASOUND INSERTS WERE SEEN FROM THE CAVITY TO THE HORN AND THERE WAS NOTHING TO REPORT. A HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED UNILATERAL OCCLUSION WITH LEFT HORN PERMEABILITY AND ESSURE OUTSIDE OF TUBAL LIGHT. A SECOND CONFIRMATION EXAMINATION WAS DONE ON (B)(6) 2009 WITH SIMILAR FINDINGS. ON (B)(6) 2009, PATIENT WAS SUBMITTED TO A LAPAROSCOPY AND ESSURE WAS REMOVED. DURING THE SURGERY, IMPLANT WAS SEEN 2CM OUTSIDE OF SEROUS UTERINE, AND THERE WAS PERFORATION OF LEFT UTERINE HORN DUE TO ESSURE IMPLANT. IMPLANT ABLATION WAS EASY BY TRACTION. THERE WAS NO BLEEDING AND IMPLANT WAS COMPLETE. TWO FILSHIE CLIPS WERE PLACED. INVESTIGATOR CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A DEVICE FAILURE DUE TO ABDOMINAL MIGRATION AND PATIENT WAS NOT VERY SATISFIED. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-APR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: UTERINE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 145 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE SUBJECT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY (STUDY NUMBER: (B)(4)). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT 3-MONTH EXAMINATION, ESSURE WAS FOUND IN WRONG POSITION. SHE WAS SUBMITTED TO A LAPAROSCOPY, WHICH SHOWED A LEFT UTERINE HORN PERFORATION. ESSURE WAS REMOVED. ADDITIONALLY SHE EXPERIENCED BLEEDING (REGARDED AS GENITAL BLEEDING). THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, ESSURE WAS INSERTED WITH DIFFICULTY AND WITHOUT OSTIUM VISUALIZATION IN THE LEFT SIDE; THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED PERFORATION. THEREFORE, BASED ON THE AVAILABLE INFORMATION, THIS EVENT WAS CONSIDERED AS RELATED TO THE SUSPECT INSERT/PROCEDURE. REGARDING GENITAL BLEEDING CAUSALITY WITH ESSURE CANNOT BE EXCLUDED DUE TO ITS CLOSE TEMPORAL RELATIONSHIP WITH DEVICE INSERTION. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00457	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 9/4/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/18/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2009 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 2 CHILDREN, MENSTRUAL PAIN AND MOLAR PREGNANCY; SHE USED COMBINED PILLS AS CONTRACEPTIVE METHOD AND HER CONCURRENT CONDITION INCLUDED FALLOPIAN TUBE STENOSIS. HER LAST MENSTRUAL PERIOD WAS ON (B)(6) 2009. ON (B)(6) 2009 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT STERILIZATION. NSAID (NONSTEROIDAL ANTI-INFLAMMATORY DRUG) WAS USED AS PREMEDICATION. HYPNOTIC ANESTHESIA AND UTERINE DISTENTION WERE PERFORMED. CONDITION OF UTERINE CAVITY WAS NORMAL. PROCEDURE TIME TOOK 13 MINUTES. OSTIUMS ON BOTH SIDES WERE NOT VISIBLE DURING PROCEDURE. IT WAS NOT EASY TO INTRODUCE CATHETER INTO BOTH TUBES DUE TO PERCEPTION OF OBSTACLE. ESSURE WAS ONLY PLACED ON RIGHT SIDE (WITH 3 TRAILING COILS IN THE UTERINE CAVITY) DUE TO OSTIAL STENOSIS ON LEFT. PATIENT EXPERIENCED PAIN DURING AND AFTER INSERTION. PAIN/CRAMPS AND BLEEDING WERE DENIED AS POSTOPERATIVE EFFECTS. SHE USED COMBINATION PILLS DURING THE 3 MONTHS PRIOR TO THE CONFIRMATION TEST. ON (B)(6) 2009 HSG (HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED PROXIMAL LEFT TUBAL OCCLUSION AND RIGHT TUBAL PERMEABILITY. INSERT ON THE RIGHT WAS VISIBLE BUT MIGRATION TOWARD FIMBRIAE (ROLLED UP

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ASPECT OF THE INSERT, NOT LOCATED ON THE LEFT UTERINE HORN AREA). INVESTIGATOR CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS ESSURE FAILURE AND A CELIOSCOPY, STERILIZATION AND RIGHT INSERT REMOVAL WERE PERFORMED. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 322 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE SUBJECT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD FALLOPIAN TUBE OCCLUSION INSERT (ESSURE) INSERTED AND AT HYSTEROSALPINGOGRAM (HSG) INSERT ON THE RIGHT WAS VISIBLE BUT WITH MIGRATION TOWARD FIMBRIAE. THIS INSERT WAS REMOVED BY CELIOSCOPY. THE REPORTED EVENT, REGARDED AS DEVICE DISLOCATION, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE DEVICE DISLOCATION IS NOT KNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN INCIDENT, DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00458	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 8/31/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/24/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) PATIENT WHO WAS INVOLVED IN AN (B)(6), STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2009 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6) PATIENT'S MEDICAL HISTORY INCLUDED THREE CHILDREN, 1 ELECTIVE ABORTION AND MENSTRUAL PAIN. MEDICATION AT TIME OF INSERTION INCLUDED MINIPILLS. HER LAST MENSTRUAL PERIOD BEFORE INSERTION OCCURRED ON (B)(6) 2009. HCG (HUMAN CHORIONIC GONADOTROPIN) TEST WAS NEGATIVE. ON (B)(6) 2009, ESSURE WAS INSERTED (PROCEDURE TOOK 8 MINUTES). BENZODIAZEPINE WAS USED AS PREMEDICATION AND IV SEDATION AS ADDITIONAL ANESTHESIA. UTERINE CAVITY WAS WITHIN NORMAL CONDITIONS. HER UTERUS WAS NOT RETROVERTED. VISUALIZATION WAS GOOD BILATERALLY. LEFT CATHETERIZATION WAS DIFFICULT. RIGHT SIDE INSERTION WAS EASY. BOTH ESSURE DEVICES WERE PLACED. PATIENT PRESENTED PAIN DURING INSERTION AND SHE DENIED PAIN AFTER THE PROCEDURE. NO ADDITIONAL PROCEDURE WAS PERFORMED AT THE SAME TIME. ON (B)(6) 2009, RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS SYMMETRIC POSITIONED AND DISTANCE BETWEEN PROXIMAL PORTION WAS LESS THAN 4 CM. FOUR MARKERS WERE WELL PLACED. HYSTEROSALPINGOGRAM (HSG) WAS ALSO PERFORMED AND SHOWED RIGHT INSERT IN GOOD POSITION BUT LEFT INSERT DOUBTFUL. OCCLUSION WAS ONLY OBSERVED IN THE LEFT SIDE. FINAL RESULT OF PROCEDURE WAS CLASSIFIED AS "FAILURE". LAPAROSCOPY WAS REPORTED AS COMPLICATION. DURING THIS PROCEDURE, THE IMPLANT WAS FOUND OUT IN SUBSEROSA AND FALLOPIAN

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TUBE WAS PERMEABLE (PERFORATION). ELECTROCOAGULATION AND DIVISION WAS THEN PERFORMED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6)2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PATENCY). (B)(4) FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE, A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: FALLOPIAN TUBE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 204 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) PATIENT WHO WAS INVOLVED IN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMPLANT WAS SUBSEROSAL AND FALLOPIAN TUBE WAS PERMEABLE (PERFORATION). THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. IN THIS CASE, THE INSERTION ON THE LEFT WAS DIFFICULT AND PROCEDURAL PAIN WAS REPORTED. DURING HYSTEROSALPINGOGRAM PERFORMED 6 MONTHS AFTER PLACEMENT, RIGHT DEVICE WAS IN GOOD POSITION BUT LEFT WAS DOUBTFUL. THERE WAS OCCLUSION ONLY IN THE LEFT SIDE. A LAPAROSCOPY WAS THEN PERFORMED AND IT WAS FOUND OUT THAT THE (RIGHT) IMPLANT WAS SUBSEROSAL AND THE FALLOPIAN TUBE WAS PERMEABLE. THE INSERT WAS NOT REMOVED AND ELECTROCOAGULATION AND DIVISION WERE PERFORMED. ALTHOUGH THE EXACT DATE AND MECHANISM OF PERFORATION ARE NOT KNOWN, GIVEN ITS NATURE, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE USE. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL PROCEDURE WAS REPORTED. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00459	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 11/29/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/27/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). PATIENT'S MEDICAL HISTORY INCLUDED MENSTRUAL PAIN. HER LAST MENSTRUAL PERIOD OCCURRED ON (B)(6) 2009. ON (B)(6) 2009, ESSURE WAS INSERTED. GENERAL ANESTHESIA WAS USED. UTERINE CONDITIONS WERE NORMAL. HER UTERUS IS NOT RETROVERTED. OSTIUM VISUALIZATION WAS NOT POSSIBLE IN BOTH SIDES; HOWEVER THE INSERTION WAS SUCCESSFUL WITH ONE INSERT USED IN EACH SIDE. CERVIX DILATATION WAS PERFORMED WITH DILATOR. PATIENT USED POSTOPERATIVE ANALGESICS. SHE CAME BACK DUE TO ATROCIOUS PAIN. MAJOR POST-OPERATIVE PAIN BEGAN AFTER INSERTS PLACEMENT (48 HOURS LATER). HOSPITALISATION OCCURRED WITH PERFALGAN, NSAID AND MORPHINE. HYSTEROSALPINGOGRAPHY (HSG) AND PELVIC ULTRASOUND WERE PERFORMED AND SHOWED INSERTS WERE WELL PLACED. LAPAROSCOPY AT DAY 21 AFTER ESSURE PLACEMENT FOR BILATERAL SALPINGECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE

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TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PROCEDURAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 168 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO WAS INVOLVED IN OBSERVATIONAL COMPANY-SPONSORED STUDY, HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND TWO DAYS AFTER PLACEMENT EXPERIENCED MAJOR POST PROCEDURE PAIN. THIS EVENT IS SERIOUS DUE REQUIRED INTERVENTION AND MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION. PELVIC PAIN IS EXPECTED DURING OR FOLLOWING ESSURE INSERTION. IN THIS CASE, THE INSERTION WAS DIFFICULT DUE TO POOR VISUALIZATION BUT BILATERAL PLACEMENT WAS ACHIEVED. THE PATIENT RETURNED 48 HOURS LATER WITH MAJOR POST-OPERATIVE PAIN. SHE WAS HOSPITALIZED, ULTRASOUND AND HYSTEROSALPINGOGRAM WERE DONE AND SHOWED THE DEVICES WERE IN GOOD POSITION. A COUPLE OF WEEKS AFTER INSERTION, BILATERAL SALPINGECTOMY WAS PERFORMED. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP THE EVENT IS ASSESSED AS RELATED TO ESSURE USE. SINCE REQUIRED INTERVENTION WAS REPORTED, THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 10-DEC-2015 FROM INVESTIGATOR: LAPAROSCOPY REPORT: TWO TUBAL RESECTIONS 8 CM AND 6.5 CM LENGTH WERE PERFORMED WITH SYSTEMATIC SPECIMEN COLLECTION. THE MICROSCOPIC INVESTIGATION FOUND THE FOLLOWING: RAMIFIED FIMBRIAE OF ON

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00482	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 12/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/11/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2008 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2010, (B)(6) 2011 AND (B)(6) 2013. FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). PATIENT HAD AS MEDICAL HISTORY 1 CHILDREN AND MENSTRUAL PAIN. SHE USED CONTRACEPTIVE IMPLANTS FOR CONTRACEPTION AND THE DATE OF HER LAST MENSTRUAL PERIOD, BEFORE ESSURE PLACEMENT, WAS (B)(6) 2008. PATIENT HAD ESSURE INSERTED ON (B)(6) 2008. NO ANESTHESIA WAS APPLIED DURING PROCEDURE, UTERINE DISTENSION WAS DONE AND HYSTEROSCOPY WAS POSSIBLE. PATIENT'S UTERINE CAVITY EXAMINATION SHOWED ENDOMETRIAL HYPERTROPHY AND HER UTERUS WAS NOT RETROVERTED. PHYSICIAN STARTED THE INSERTION ON LEFT SIDE AND INFORMED THAT OSTIUM WAS IN THE FIELD OF VISION DURING PLACEMENT. IT WAS EASY TO INTRODUCE THE CATHETER INTO BOTH TUBES AND PLACEMENT WAS SUCCESSFUL (EXTERNALLY VISIBLE COIL IN THE UTERINE CAVITY: 1 ON LEFT AND 6 ON RIGHT). PROCEDURE TOOK 5 MINUTES. THE PATIENT EXPERIENCED PAIN DURING PLACEMENT INTO BOTH TUBES AND AFTER INSERTION. SHE DID NOT PRESENT VASOVAGAL SYNCOPE. NO OTHER PROCEDURE WAS PERFORMED AT THE TIME OF INSERTION. PATIENT DID NOT TAKE POST-OPERATIVE ANALGESICS AND USED CONTRACEPTIVE IMPLANT AS BACK-UP CONTRACEPTION DURING THE 3 MONTHS POST INSERTION. ON (B)(6) 2008, AT POSTOPERATIVE CONSULTATION, PATIENT REPORTED BLEEDING. SHE HAD X-RAY AND

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ULTRASOUND (2D) PERFORMED WHICH SHOWED THAT RIGHT INSERT WAS IN A GOOD POSITION BUT LEFT INSERT WAS NOT IN THE CORRECT POSITION. ON (B)(6) 2009, A HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND SHOWED GOOD INSERT POSITION AND BILATERAL OCCLUSION. INVESTIGATOR CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A SUCCESS AND PATIENT WAS VERY SATISFIED. ON (B)(6) 2010, AT FOLLOW-UP CONTACT, PATIENT REPORTED PROFUSE MENSTRUATION. ON (B)(6) 2011 SHE INFORMED AN AGGRAVATION OF PROFUSE MENSTRUATION AND WAS NOT VERY SATISFIED WITH ESSURE PROCEDURE. ON (B)(6) 2013, A HYSTERECTOMY WAS REPORTED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: MENORRHAGIA. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 106 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY (STUDY NUMBER: (B)(6)). SHE EXPERIENCED PROFUSE MENSTRUATION AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND WAS SUBMITTED TO A HYSTERECTOMY. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, THE PATIENT COMPLAINED OF GENITAL BLEEDING DURING HER FIRST FOLLOW-UP VISIT (3-MONTHS AFTER ESSURE PLACEMENT). LATER; AT 1 YEAR AND 2 YEARS FOLLOW-UP, SHE STATED HE HAD PROFUSE MENSTRUATION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE REPORTED INTERVENTION (HYSTERECTOMY), THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00483	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 4/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/5/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2010 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2011 AND (B)(6) 2013. ON (B)(6) 2013 FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN OTHER REPORTABLE INCIDENT. STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). PATIENT'S MEDICAL HISTORY INCLUDED ONE ELECTIVE ABORTION, ONE CHILD, COMBINED PILLS (ALSO USED AS BACK UP CONTRACEPTION DURING THREE MONTHS AFTER ESSURE PROCEDURE) AND MENSTRUAL PAIN. HER LAST MENSTRUAL PERIOD, BEFORE ESSURE PLACEMENT, OCCURRED ON (B)(6) 2010. ON (B)(6) 2010, A FIRST ATTEMPT TO INSERT ESSURE WAS PERFORMED. UTERINE CONDITION WAS NORMAL AND BOTH OSTIUM WERE VISUALIZED. IT WAS NOT EASY TO INTRODUCE CATHETER IN TUBES DUE TO POOR VISUALIZATION ON LEFT SIDE AND SPASM ON RIGHT SIDE. BILATERAL PLACEMENT WAS NOT ACHIEVED. THE PROCEDURE TOOK 12 MINUTES. PATIENT EXPERIENCED POST PROCEDURAL PAIN. ON (B)(6) 2011, A NEW ESSURE INSERTION ATTEMPT WAS DONE. IT WAS EASY TO INTRODUCE CATHETER INTO THE TUBES AND BILATERAL PLACEMENT WAS ACHIEVED. THERE WERE 2 COILS VISIBLE IN UTERINE CAVITY ON LEFT SIDE AND 3 ON RIGHT AT THE END OF THE PROCEDURE. THE PROCEDURE TOOK 5 MINUTES AND PATIENT PRESENTED POST PROCEDURAL PAIN. ON (B)(6) 2011, RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS SYMMETRIC, WITH DISTANCE OF PROXIMAL PORTIONS < 4 CM AND 4 MARKERS WELL PLACED. DURING CONSULTATION ON (B)(6) 2011 PATIENT COMPLAINED OF BLEEDING. ON (B)(6) 2011 A

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HYSTEROSALPINGOGRAM WAS PERFORMED AND REVEALED INSERTS IN PLACE WITH BILATERAL OCCLUSION. INVESTIGATOR CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A SUCCESS. ON (B)(6) 2012, PATIENT EXPERIENCED MENSTRUATIONS HEAVIER FOR 8 DAYS, LOSS OF TWO PARTS (DIFFICULT EXAMINATION BUT IT SEEMED TO WORK). ON (B)(6) 2013, PATIENT REPORTED STOMACH ACHES, PAINFUL MENSTRUATION PERIODS AND HEADACHES. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED POSTOPERATIVE BLEEDING. ADDITIONALLY, SHE HAD A LOSS OF TWO PARTS (REGARDED AS DEVICE BREAKAGE). THE REPORTED DEVICE BREAKAGE IS LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC) AND WAS CONSIDERED NON-SERIOUS; WHILE THE OTHER EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, CAUSALITY BETWEEN THE REPORTED BLEEDING AND THE SUSPECT INSERT CANNOT BE EXCLUDED IN THIS CASE. REGARDING THE REMAINING EVENT, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS/REMOVALS. IN THIS PARTICULAR CASE, ALTHOUGH LIMITED INFORMATION WAS PROVIDED AND THE EXACT MECHANISM OF THE REPORTED EVENT IS NOT KNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 26-JAN-2016: (B)(4). CONTROL EXAMINATION VIA PLAIN ABDOMEN X-RAY PERFORMED IN (B)(6) 2011 SHOWED WELL PLACED ESSURE INSERTS, IN ASSOCIATION WITH BLEEDING. HYSTEROGRAPHY WAS PERFORMED AND THE REPORT MENTIONED NORMAL CAVITY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00484	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/6/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON 29-NOV-2013 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). ON (B)(6) 2008, ESSURE WAS EASILY INSERTED (8 MINUTES PROCEDURE). NSAID WAS USED AS PREMEDICATION. UTERINE CONDITION WAS NORMAL. BOTH OSTIUM WERE VISUALIZED. PATIENT PRESENTED PAIN DURING AND AFTER PROCEDURE. VAGINAL RING WAS USED AS BACK UP CONTRACEPTION. PATIENT´S LAST MENSTRUAL PERIOD OCCURRED ON (B)(6) 2008. ON (B)(6) 2009, RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS SYMMETRIC, DISTANCE BETWEEN PROXIMAL PORTIONS < 4 CM AND 4 MARKERS WELL PLACED. GOOD INSERT POSITION WAS REPORTED. IT WAS STATED THAT SHE WAS DEPRESSED FOR THREE WEEKS AS SHE WAS NOT PSYCHOLOGICALLY PREPARED TO NOT HAVE CHILDREN ANYMORE. SHE FELT OLD. THE PATIENT WAS CONTACTED ON (B)(6) 2011, SHE FELT SO WELL THAT SHE DID NOT ASKED FOR GYNAECOLOGICAL CONSULTATION FOR TWO YEARS. SHE WAS CONTACTED AGAIN ON (B)(6) 2013 AND AN INFECTION AND SALPINGECTOMY WAS REPORTED. NO FURTHER INFORMATION WAS PROVIDED. ADDITIONAL INFORMATION RECEIVED ON 09-APR-2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO

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LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 29-JUN-2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: SALPINGITIS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INFECTION. THIS EVENT, SEEN AS SALPINGITIS, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SALPINGITIS OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE FALLOPIAN TUBES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS WITHIN 4 WEEKS AFTER INSERTION PROCEDURE. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. APPARENTLY, THE INFECTION OCCURRED FIVE YEARS AFTER INSERTION. NEVERTHELESS, CONSIDERING ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY WITH SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. SINCE SALPINGECTOMY WAS REPORTED, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00485	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 7/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/8/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2014 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). CONCOMITANT CONDITION INCLUDED NULLIPAROUS AND PATIENT'S CONCURRENT CONDITION INCLUDED AMENORRHEA. SHE DENIED MENSTRUAL PAIN AND AT TIME OF INSERTION, SHE WAS TAKING COMBINED PILLS. ON (B)(6) 2009 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS EASILY IMPLANTED FOR PERMANENT STERILISATION. HYDROXYZINE WAS USED AS PREMEDICATION AND GENERAL ANESTHESIA WAS APPLIED. UTERINE CAVITY WAS WITHIN NORMAL CONDITIONS AND SHE DID NOT HAVE RETROVERTED UTERUS. UTERINE DISTENTION WAS DONE. VISUALIZATION OF OSTIUM WAS GOOD BILATERALLY. THE PROCEDURE WAS STARTED ON LEFT SIDE. AT THE END OF PROCEDURE SHE HAD 1 COIL EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 2 COILS ON RIGHT SIDE. THE PHYSICIAN USED 2 INSERTS. THE PROCEDURE TOOK 6 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. PATIENT PRESENTED PAIN DURING INSERTION AND SHE DENIED PAIN AFTER THE PROCEDURE. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. THE PATIENT WAS SATISFIED WITH THE PROCEDURE AND NO ADDITIONAL PROCEDURE WAS PERFORMED AT THE SAME TIME. SHE DENIED THE USE OF POSTOPERATIVE ANALGESICS, AND SHE DID NOT EXPERIENCED POSTOPERATIVE PAIN/CRAMPS. COMBINATION PILL WAS USED DURING THE 3 MONTHS AFTER ESSURE

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INSERTION. ON (B)(6) 2009 SHE EXPERIENCED BLEEDING AT 3 MONTHS. RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS SYMMETRIC POSITIONED AND DISTANCE BETWEEN PROXIMAL PORTION WAS LESS THAN 4 CM. FOUR MARKERS WERE WELL PLACED. GOOD INSERT POSITION ON BOTH SIDES. HSG (HYSTEROSALPINGOGRAM) AND ULTRASOUND WERE NOT DONE. FINAL RESULT OF PROCEDURE WAS CLASSIFIED AS SUCCESS. ON (B)(6) 2014 THE PATIENT EXPERIENCED HAEMORRHAGIC MENSTRUAL PERIODS REQUESTING TRANSFUSION DUE TO IRON DECREASE. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: MENORRHAGIA. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 106 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING AT 3 MONTHS AFTER PLACEMENT. FIVE YEARS LATER, SHE HAD HAEMORRHAGIC PERIODS REQUESTING TRANSFUSION. THESE EVENTS, SEEN AS GENITAL HAEMORRHAGE AND MENORRHAGIA, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, THE PLACEMENT WAS EASY AND PATIENT EXPERIENCED PROCEDURAL PAIN. AT 3 MONTHS CONTROL, SHE COMPLAINED OF BLEEDING . AFTER FIVE YEARS, THE PATIENT HAD HEMORRHAGIC MENSTRUAL PERIODS WHICH REQUESTED TRANSFUSION DUE TO DECREASED BLOOD IRON. GIVEN AVAILABLE INFORMATION AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN THE REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED AND SINCE A MEDICAL INTERVENTION (BLOOD TRANSFUSION) WAS NECESSARY, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00486	BAYER HEALTHCARE LLC	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/27/2009
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2010 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON 23-MAY-2014 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 3 CHILDREN, 3 CESAREAN SECTIONS, CURETTAGE AND MENSTRUAL PAIN. HER LAST MENSTRUAL PERIOD BEFORE ESSURE PLACEMENT WAS ON (B)(6) 2009. ON (B)(6) 2009 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED UNDER GENERAL ANESTHESIA. UTERINE DISTENSION WAS PERFORMED. OSTIUM FROM BOTH SIDES WAS VISUALIZED AND WAS EASY TO INTRODUCE THE CATHETER INTO THE TUBES. BILATERAL PLACEMENT ACHIEVED. ON BOTH SIDES, 3 COILS OF INSERTS WERE VISIBLE IN THE UTERINE CAVITY. THE PROCEDURE TOOK 17 MINUTES. A POLYP ABLATION WAS PERFORMED AT THE SAME TIME OF INSERTION. AFTER PROCEDURE, PATIENT USED CONDOM AS BACK CONTRACEPTION. ON (B)(6) 2009, RADIOGRAPHY WAS DONE AND INSERTS WERE SYMMETRIC. ULTRASOUND WAS ALSO PERFORMED AND INSERTS WERE SEEN FROM THE CAVITY TO THE HORN. NO HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED. INVESTIGATOR CONCLUDED ON GOOD INSERT POSITION AND CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A SUCCESS. IN (B)(6) 2010, AT PHONE CONTACT, PATIENT COMPLAINED OF DIGESTIVE BLOATING AFTER CYCLE. SHE WAS CONTACTED AGAIN ON (B)(6) 2011 AND COMPLAINED OF INTESTINAL SWELLING, DIARRHEA/CONSTIPATION BEFORE AND AFTER MENSTRUAL PERIODS. INVESTIGATOR STATED

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THESE EVENTS WERE NOT FAVORABLE TO ESSURE. ON (B)(6) 2014, AT NEW PHONE CONTACT, PATIENT STATED SHE REQUESTED BILATERAL SALPINGECTOMY, WHICH WAS PERFORMED IN 2012. PTC INVESTIGATION RESULT WAS RECEIVED ON 08-APR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY (B)(4) AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 29-JUN-2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: ABDOMINAL DISTENSION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. (B)(4) IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(4) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE EXPERIENCED DIGESTIVE BLOATING/INTESTINAL SWELLING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT AND REQUESTED A BILATERAL SALPINGECTOMY; WHICH WAS PERFORMED 3 YEARS AFTER DEVICES INSERTION. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. AFTER ESSURE INSERTION, ABDOMINAL GAS AND BLOATING MAY OCCUR. THEREFORE, CAUSALITY BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED IN THIS CASE. SINCE AN INTERVENTION WAS PERFORMED THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043487	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 1/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT UTI'S, PELVIC PAIN, CLOTTING WHEN ON MENSTRUAL CYCLE, HEAVY PERIODS, ANXIETY, FAINTING SPELLS, CONSTANTLY HAVING BV, MOOD SWINGS, WEIGHT GAIN IN RAPID TIME, JOINT PAIN IN WRIST, TINGLING SENSATION AND PAIN DOWN RIGHT LEG, PAINFUL INTERCOURSE, CHRONIC FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043488	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES. NAUSEA. PELVIC PAIN, WEAKNESS, TINGLY LIMBS, DIVERTICULITIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043489	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC EXCRUCIATING PAIN ON LEFT SIDE, EXCRUCIATING MENSTRUAL CYCLES, HEAVY BLEEDING AND CLOTTING, NIGHT SWEATS, INSOMNIA, VOMITING, UNABLE TO WORK AND CARE FOR MY FAMILY REGULARLY, MIGRAINES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043490	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GOT ESSURE IN (B)(6) 2012 OR (B)(6) 2013. MY LADY PARTS HURT BAD FOR 2 DAYS. AFTER THAT EVERYTHING SEEM NORMAL. COUPLE MONTHS LATER MY PERIOD STARTED AND IT WAS AND STILL IS HEAVY WITH SERVAL BLOOD CLOTS THAT ARE A SIZE OF A PENNY AND SOMETIMES I CAN PUSH THEM OUT. AND THEY ARE BIG. I HAVE STABBING PAINS IN MY RIGHT SIDE WHEN MY TUBE IS THEY COME AS GO AS THEY PLEASE. IT BRINGS ME TO MY KNEES. REAL BAD CRAMPS (NEVER HAD THOSE B4.) A COUPLE TIMES I HAVE FELT WHAT SEEMS TO BE KICK.. AND NIPPLES GET REAL SENSITIVE. I HAVE A LITTLE PAIN IN LEFT SIDE TUBE. DID NOT GO BACK TO GET TEST DUE TO INSURANCE WOULDN'T PAY AND I DON'T HAVE (B)(6).. CALLED THE DOCTOR MANY TIMES FOR THE NURSES TO TELL ME IT'S NORMAL SO I STOP CALLING. I HAVE IT ALMOST 3 YEARS. PERIOD IS SAME HEAVY BADLY SOMETIMES DARK AND ALWAYS HAVE BIG CLOTS. I DON'T EVEN STOP WHEN I'M TAKING A SHOWER. USUALLY I WOULD STOP FOR COUPLE HOURS. NOT ANYMORE. I HAVE BE GETTING HEADACHES IN LAST 2 MONTHS REALLY BAD. TO WHERE I CAN'T STAND TO BE AROUND NOISE. AND SEND MY KIDS TO THEIR BEDROOM. I STILL HAVE ESSURE. I'M AFRAID TO GO TO DOCTOR. PLUS MY DOCTOR WOULDN'T EVEN SAY ANYTHING ABOUT REMOVING IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043491	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE DEVELOPED A BURNING, ITCHING RED SKIN RASH ON MY NECK AND ARMS. I HAVE GAINED 50 LBS. I HAVE BEEN SO BLOATED THAT I LOOK 8 MONTHS PREGNANT. I HAVE CONSTANT HEADACHES, NAUSEA AND CAN NOT LOSE WEIGHT. MY HAIR IS FALLING OUT AND WILL NOT GROW. I HAVE PAIN IN MY PELVIC AREA. I AM GETTING MY PERIOD EVERY 3 WEEKS AND HAVE HEAVY BLEEDING AND HEAVY CLOTTING. I STAY TIRED AND SORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043492	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY PAINFUL PERIODS, PAINFUL INTERCOURSE, STABBING PAINS IN LEFT AND RIGHT PELVIC REGIONS, EXTREME BLOOD LOSS DURING PERIODS, ANEMIA, FIBROIDS TUMORS, ENLARGED UTERUS, LOWER BACK PAIN, HAIR LOSS, BRAIN-FOG/CONFUSION, WORSENING OF ANXIETY AND DEPRESSION, RANDOM BOUTS OF BLURRY VISION, AND EXTREME BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043493	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 7/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, PAIN IN LOWER BELLY, CONSTANT CRAMPING, SEVERE HEADACHES , LEG PAIN, FEET SWELLING, BACK PAIN. SHARP PAINS IN HIPS. WEIGHT FLUCTUATION. SEVERE BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043494	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 2/6/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN THROUGHOUT WHOLE BODY. BURNING OF THE SKIN AND FELT LIKE MY INSIDE WERE ON FIRE. COULD NOT TOUCH MY SKIN IT WAS SO PAINFUL. LOWER BACK PAIN. SHARP PAIN IN MY PELVIC AREA. TOOTH DECAY AND BREAKING. FEEL LIKE I ALWAYS HAVE A FEVER. VERY LIGHT HEADED. BLOODWORK SHOWED AUTOIMMUNE DISEASE. WITHIN A YEAR I WAS ALSO DIAGNOSED WITH FIBROMYALGIA. CHRONIC FATIGUE. I HAVE BEEN SICK WITH THESE SIDE EFFECTS FOR 7 YEARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043495	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER PROCEDURE, PAINFUL MENSTRUAL CYCLES, HEAVY BLEEDING, HEADACHES, PELVIC PAIN, ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043496	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GALLBLADDER PROBLEMS INCLUDING EMERGENCY SURGERY, GI PROBLEMS TO INCLUDE FREQUENT BOWEL MOVEMENTS AND CONSTANT DIARRHEA. FATIGUE. DEPRESSION AND ANXIETY. WORSENING MENSTRUAL CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043497	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 7/2/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN WITH MOVEMENT. FEELS LIKE SOMETHING INSIDE ME IS TEARING. SEVERE CRAMPS WITH PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043498	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 12/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY LARGE OVARIAN CYSTS NOTED. CONTINUE TO HAVE TERRIBLE BURNING PELVIC PAIN. CHRONIC UTI'S, ALL OVER BODY PAIN, RASH TO PALM OF HANDS AND SOLES OF FEET, LOW BACK PAIN AND TERRIBLE MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043499	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCRUCIATING AND DEBILITATING PELVIC AND ABDOMEN PAIN, PAIN IN BACK AND HIPS, CONSTANT MIGRAINES, NUMBNESS IN HANDS ARMS AND LEGS. BLEEDING WHEN URINATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043500	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 4/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED ON (B)(6) AND EVERYTHING WAS GOOD UNTIL I HAD THE HSG TESTING DONE ON (B)(6), 2015. AFTER HE PROCEDURE I EXPERIENCED EXTREME CRAMPING WHICH I THOUGHT WAS NORMAL. HOWEVER, SINCE THE HSG PROCEDURE I HAVE HAD 3 MENSTRUAL CYCLES THAT LAST ABOUT 6 DAYS. THEY ARE GONE FOR A WEEK THEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043501	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 2/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED TO GET MIGRAINES ALL THE TIME, 12 TO 15 A MONTH. ALSO IT HURTS TO HAVE SEX NOW. WEIGHT GAIN ESPECIALLY IN MY STOMACH AREA. SEVERE PAIN IN MY PELVIC AREA. HAIR LOSS. BLINDNESS OFF AN ON IN MY RIGHT EYE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043502	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN MY LEFT SIDE ALONG MY LEFT LEG AND IN GROIN AREA, NAUSEA, HEADACHES, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043503	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 1/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ITCHING AND RASH ALL OVER MY BODY, BLOOD BLISTERS, NAUSEA, STOMACH BLOATING, MASS LOCATED IN THE LOWER LEFT HAND-SIDE ON ABDOMEN THAT EXERTS PAIN, FOOD AVERSIONS, VERY GASSY, SEVERE HEADACHES, LIVER ENZYMES ARE OFF, ZINC LEVELS ARE NOW LOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043504	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 11/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, WEIGHT GAIN, HEAD ACHE, HAIR LOSS, LOTS OF BLEEDING, HIPS HURTING, HURTS SO BAD TO HAVE INTERCOURSE WITH MY HUSBAND I FEEL LIKE THERE IS SOMETHING INSIDE ME ALL THE TIME LIKE FISH HOOKS TRYING TO PULL BACK THE OTHER WAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043505	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 2/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, NEED TO NAP 2-3 TIMES A DAY, GROIN AND HIP PAIN THAT IS CHRONIC. PSORIASIS, HAIR LOSS, AT FIRST INCREASED WEIGHT AND NOW WITH CONSTANT NAUSEA AND EXTREME WEIGHT LOSS ALL OVER MUSCLE ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043506	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5043506 #(B)(4). I ALSO HAVE SEVERE MIGRAINES SINCE A FEW WEEKS AFTER IT WAS PLACED. I TAKE SO MANY MEDS FOR THESE SIDE EFFECTS, I FEEL LIKE MY LIVER AND KIDNEYS ARE BEING DAMAGED. ADD URINARY INCONTINENCE TO THE WHOLE THING TOO. VITAMIN D DEFICIENCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043507	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 2/7/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M ALWAYS TIRED, LEG PAINS WHILE DRIVING, ANXIETY, PAINFUL MENSTRUATION, RASHES, HAIR LOSS, ANGER, AND ITS RUINING MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043508	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCRUCIATING PAIN AFTER PROCEDURE, AFTER ADVISED MINIMAL PAIN WOULD BE EXPERIENCED. CONSTANT CRAMPING. HEADACHES, TOOTH DECAY, PELVIC SWELLING, EVENTUAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043509	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 11/1/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME DEBILITATING HEAVY BLEEDING, MOOD SWINGS, SHARP PAIN ON LEFT BACK SIDE, DIZZINESS, LIGHTHEADED NESS, ALL ONGOING SINCE I HAD THE ESSURE INSERTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043510	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 3/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I'VE HAD THIS DEVICE MY BONES HAVE ACHED TO THE POINT WHERE I CANNOT WALK. I'VE EXPERIENCED BLEEDING FROM DAY ONE ALONG WITH THE STABBING PAIN AND THE HORRIBLE MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043511	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS INSERTED IN 2013...I SUFFERED SEVERE BLEEDING FOR OVER A YEAR FROM THE DAY THEY WERE INSERTED, THE PAIN ON BOTH MY LEFT AND RIDE SIDE ARE WORSE THEN LABOR! I WENT TO A NEW OB WHO ENDED UP PERFORMING A PROCEDURE TO CORTIRZE MY UTERUS TO STOP THE BLEEDING, WHEN DOING SO HE FOUND 1 MIGRATED ESSURE, HE WAS ABLE TO REMOVE IT. SINCE THEN THE RIGHT SIDE PAIN HAS GONE AWAY BUT THE LEFT IS UNBEARABLE!! I HAVE BEEN IN THE HOSPITAL MANY MANY TIMES DUE TO THE LEFT SIDE STABBING PAIN. MY ABDOMEN HAS SEVERE BLOATING, AND I SUFFER FROM ONGOING BLEEDING, THE PAIN ON MY LEFT SIDE FEELS LIKE I AM BEING STABBED AND THAT SOMEONE IS TWISTING MY OVARY. I ALSO GET SUDDEN SEVERE PAIN THAT SHOOTS ACROSS FROM LEFT TO RIGHT THAT FEELS LIKE ELECTRICITY ...THIS HAS RUINED MY EVERYDAY LIFE!!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043512	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE SHARP, STABBING PAINS IN MY SIDE WHEN I TURN, SIT UP FROM A LAYING POSITION, RUN. ETC. MY HAIR IS FALLING OUT. DEPRESSION, ANXIETY. SERIOUS BLOATING THAT MAKES ME LOOK 6 MONTHS PREGNANT. MEMORY LOSS EXTREME FATIGUE. BLEEDING ON AND OFF EVERY COUPLE OF DAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043513	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WON'T LET ME CHANGE DATE BUT HAS BEEN SINCE 6 MONTHS AGO. SEVERE MIGRAINES THAT ENDED ME IN EMERGENCY ROOM WITH HIGH BLOOD PRESSURE, ABDOMINAL PAIN, BACK PAIN, NAUSEA, FEEL FULL ALL THE TIME WHEN I ATTEMPT TO EAT, PRESSURE FRONT AND BEHIND HEAD, PERIODS ARE AWFUL CLOTS LOTS OF THEM PERIODS ALSO HAVE LOTS OF BLEEDING CHANGE PADS EVERY 30 MINUTES, JOINT PAIN ESPECIALLY ELBOWS AND KNEES, MY LEFT ARM HAS GONE NUMB AS WELL AS MY RIGHT ARM! MY MRI SHOWED INFLAMMATION ON MY LEFT FALLOPIAN TUBE AND ALSO SHOWS FLUID IN IT (STILL OPEN)! I AM SUPER TIRED AT ALL TIMES NO...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043514	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWO NEW THINGS FROM THIS WONDERFUL LITTLE DEVICE: WHILE AT WORK, I STOOD UP AND BASICALLY HEMOREAGED. I LIFTED MY PANT LEG TO FIND I HAD BLED INTO MY SOCKS FROM MY VAGINA AND I HAD A TAMPON IN. WHEN I WENT TO THE RESTROOM, I PASSED A CLOT ABOUT 2 TO 3 INCHES IN DIAMETER. I WAS ON NO MEDICATIONS AND I TESTED FOR A POSSIBLE MISCARRIAGE, BUT THIS WAS NEGATIVE. ABOUT 2 WEEKS LATER WENT TO THE ER WITH SEVERE ABDOMINAL PAIN, NAUSEOUS, AND DIZZY SPELLS. HAD A SEVERE UTI AND KIDNEY INFECTION. ON NO MEDICATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043515	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 3/12/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS RUSHED TO THE HOSPITAL WITH WHAT WAS BELIEVED TO BE A MASSIVE CYST ON MY OVERIES. THEY WERE THE SIZE OF GRAPFRUITS. PER DETAILED ULTRASOUND IT WAS CONFIRMED THE ESSURE DEVICE WERE NOT PROPERLY PLACED. I HAD SURGERY TO REMOVE FALLOPIAN TUBES COMPLETELY TO SAVE MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043516	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 1/5/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING MIGRAINES. THEN IT TURNED INTO MIGRAINES WITH STROKE LIKE SYMPTOMS. I WAS ON MY PERIOD FROM THE DAY I GOT THE DEVICE UNTIL 4 WEEKS AFTER SURGERY. I'M STILL HAVING MY PERIOD TWICE A MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043517	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CHRONIC PELVIC PAIN. I HAVE LOWER BACK PAIN. I ALSO AM STARTING TO GET MUSCLE SPASMS. I HAVE MIGRAINE HEADACHES. MY CRAMPS ARE PAINFUL THAN BEFORE. MY JOINTS ARE MESSING UP. MY VISION IS GETTING WORSE. I CAN'T RUN WALK JUMP STRETCH ANYTHING TO WITH EXERCIZES. I CAN'T CARRY MY YOUNGEST CHILD! I CAN'T LAY ON MY SIDES OR BE ON MY STOMACH TO LONG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043518	BAYER	7/6/2015	7/6/2015

Event Information:

Event Date (B3): 5/20/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE NON STOP PERIODS. BACK PAIN. STABBING PAIN. AND DEVICE MOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043519	BAYER	7/6/2015	7/7/2015

Event Information:

Event Date (B3): 4/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN DEBILITATING AT TIMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043520	BAYER	7/6/2015	7/7/2015

Event Information:

Event Date (B3): 9/3/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD REALLY BAD WEIGHT GAIN HAIR LOSS FATIGUE. CRAMPING PELVIC PAIN. THE CRAMPS ARE SO BAD AT TIMES I CAN'T STAND UP I'M BENT OVER IN BED CRYING. I NOW HAVE PERIODS THAT LAST 7-9 DAYS WHEN MY PERIOD WOULD LAST 2-4 DAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043521	BAYER	7/6/2015	7/7/2015

Event Information:

Event Date (B3): 3/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATELY FOLLOWING THE PROCEDURE MY HEART RATE DROPPED. IT TOOK OVER 30 MINUTES TO GET IT TO GO BACK UP. I WENT HOME AND SLEPT MAJORITY OF THE DAY. WHEN I WOKE UP I HAD TWITCHING IN MY LEFT EYE LID AND LEG. ONE WEEK AFTER INSTALLING ESSURE I GOT A YEAST INFECTION IT TOOK A PRESCRIPTION TO GET RID OF IT. NOW, I GET THEM ABOUT EVERY OTHER WEEK. I ALSO HAVE EXTREME PAIN IN MY RIGHT PELVIC AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043522	BAYER	7/6/2015	7/7/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DATE OF ONSET WILL NOT LET ME CHANGE TO 2010. BECAME PREGNANT AFTER HSG CONFIRMATION OF BLOCKED FALLOPIAN TUBES. SINCE IMPLANTED, DIAGNOSED WITH PMDD, HYPERTENSION, VITAMIN D DEFICIENCY. SUFFERED WITH ANXIETY ATTACKS, MOOD SWINGS, DEPRESSION, DYSMENORRHEA, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043523	BAYER	7/6/2015	7/7/2015

Event Information:

Event Date (B3): 5/7/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN SEVERE PAIN. HEAVY BLEEDING. RASH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043524	BAYER	7/6/2015	7/7/2015

Event Information:

Event Date (B3): 4/9/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4), 5 YEARS OF HEAVY MENSTRUAL CYCLES, PAINFUL INTERCOURSE, BLOATING, TEETH DETERIORATING, JOINT INFORMATION, CERVICAL DISC DISEASE, SHARP STABBING PAINS IN LOWER ABDOMEN, ENDOMETRIOSIS, ADENOMYOSIS RESULTING IN A HYSTERECTOMY AT (B)(6). THE PHOTO ATTACHED SHOWS 2 WEEKS PRIOR TO HYSTERECTOMY ON THE LEFT, AND 12 DAYS AFTER HYSTERECTOMY ON THE RIGHT. SHOWING HOW MUCH THE DEVICE CAUSED ME TO BLOAT, AND BE PAINFULLY UNCOMFORTABLE, VS THE IMMEDIATE RELIEF ONCE IT WAS REMOVED. I BECAME LESS BLOATED EVERYDAY, AND CONTINUE TO FEEL BETTER SINCE HAVING THIS DEVICE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043525	BAYER	7/6/2015	7/7/2015

Event Information:

Event Date (B3): 4/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A FULL HYSTERECTOMY LEAVING ONLY MY OVARIES; I'M (B)(6). I HAD BLISTERS FROM ALLERGIES TO NICKEL 3 TUBAL PREGNANCIES AN HORRIBLE BLEEDING HAIR LOSS, WEIGHT GAIN, MIGRAINES CYSTS. WHEN THEY REMOVED MY UTERUS, THEY FOUND A COIL IN THE WALL OF IT AND THE OTHER WAS ALMOST OUT OF THE TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043526	BAYER	7/6/2015	7/7/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED OUT WITH ONE TUBE NOT CLOSING THEN HEAVY BLEEDING TWO CYCLES A MONTHS, STRANGE HIVES , HAIR LOSS AND COME TO FIND OUT THE RIGHT COIL MIGRATED AND EMBEDDED AND WRAPPED AROUND MY UTERUS AND I HAD TO HAVE A FULL HYSTERECTOMY AT (B)(6)!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043905	BAYER	7/6/2015	7/13/2015

Event Information:

Event Date (B3): 11/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20193380

Single Use:
Implant Date (E6): 11/17/2009
Explant Date (E7): 12/17/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACED IN MY TUBES IN (B)(6) 2009 IN ORDER TO NO LONGER HAVE CHILDREN. IN ADDITION, ONLY ONE SIDE WAS BLOCKED I COULD STILL GET PREGNANT I HAD TO RETURN FOR THE DYE TEST AGAIN TO FIND OUT IF I COULD GET PREGNANT. THE SECOND DYE TEST SHOWED I WAS NOT ABLE TO GET PREGNANT. AFTER THE ESSURE WAS IMPLANTED I HAD CONSTANT PELVIC PAIN. I CONTINUOUSLY TOLD THE DOCTOR WHO PERFORMED THE PROCEDURE. HE IGNORED MY COMPLAINTS AND CONTINUOUS VISITS TO HIS OFFICE FOR THE PAIN. I BEGAN TO BLEED HEAVILY AND STEADILY FOR ALL BUT APPROXIMATELY 1 WEEK A MONTH FOR YEARS. I HAD PAIN AFTER THE ESSURE WAS IMPLANTED AND THE ENTIRE TIME THAT I HAD THE ESSURE COILS INSIDE ME, IT KEPT ME FROM DOING THE THINGS I HAD PREVIOUSLY ENJOYED BECAUSE OF THE PAIN. I WOULD CONSTANTLY HAVE TO TAKE BREAKS AT WORK DUE TO THE PAIN. FINALLY, I WENT TO ANOTHER DOCTOR AND HAD THE ABLATION PROCEDURE WHICH DECREASED MY BLEEDING FOR A FEW MONTHS AND THE BLEEDING CONTINUED. I HAD TO HAVE A HYSTERECTOMY AND THE DOCTOR TOOK OUT MY TUBE WHICH CONTAINED THE ESSURE COILS. THE ESSURE WAS SUPPOSED TO KEEP ME FROM TAKING TIME OFF FROM WORK, NOT CAUSE ME PAIN, AND WAS SUPPOSED TO KEEP ME FROM HAVING A HYSTERECTOMY. IT DID NONE OF WHAT IT WAS SUPPOSED TO DO. THE ESSURE COILS FAILED ME AS DID BAYER. I WAS NOT AWARE OF THE RISKS, IF I WOULD HAVE KNOWN I WOULD NOT HAVE HAD THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043933	ESSURE	7/6/2015	7/13/2015

Event Information:

Event Date (B3): 5/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/9/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PRODUCT WAS IMPLANTED IN MY FALLOPIAN TUBES, THE DAY OF THE PROCEDURE I WAS GIVEN A MEDICINE THAT CAUSED MY HEAD TO FEEL LIKE IT EXPLODED, I WAS SENT TO HAVE A CT SCAN DONE THE FOLLOWING DAY, THE ESSURE PROCEDURE CAUSED CONTINUAL BLEEDING FOR 6 MONTHS UNTIL THE OB/GYN HAD TO GIVE ME A MEDICATION TO STOP BLEEDING ALL TOGETHER. THIS CAUSED ME TO MISS 4 MONTHS OF HAVING A PERIOD WHEN IT RETURNED IT IS HEAVIER THAN IT HAS EVER BEEN, CLOTTING IS THICK, IT IS EXTREMELY PAINFUL, I AM NOW FORCED TO SOMETIMES MISS WORK OR BE IN MISERABLE PAIN. I HAVE HAD SEVERE BACK PAINS AND HAVE NEVER BEEN SO DISAPPOINTED. IF I HAD TO DO IT ALL OVER AGAIN I WOULD NEVER DO THIS PROCEDURE OR RECOMMEND THIS PROCEDURE TO ANY FEMALES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043934		7/6/2015	7/13/2015

Event Information:

Event Date (B3): 4/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE TUBAL
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE EXPERIENCED SEVERE PELVIC PAIN, MULTIPLE MENSTRUAL CYCLES IN THE SAME MONTH, LOWER ABDOMINAL PAIN, I'VE BEEN DEALING WITH THE PAIN SINCE 2009 AFTER I HAD THE ESSURE TUBAL DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043935		7/6/2015	7/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE EXPERIENCED TERRIBLE ABDOMINAL PAIN AND BACK PAIN SINCE I HAD ESSURE PUT IT. I HAVE ALSO EXPERIENCED HEAVY BLEEDING AND HEAVY CRAMPING DURING MENSTRUAL CYCLE EACH MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043936	CONCEPTUS	7/6/2015	7/13/2015

Event Information:

Event Date (B3): 6/18/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626598

Single Use:
Implant Date (E6): 6/18/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(6) 2008 AFTER THE BIRTH OF MY SECOND CHILD. NOT LONG AFTER HAVING THE ESSURE INSERTED I BEGAN HAVING LONG (8+ DAYS) HEAVY MENSTRUAL CYCLES WITH PALM SIZE BLOOD CLOTS. I ALSO BEGAN TO DEVELOP RIGHT LOWER PELVIC PAIN. AS A RESULT I BECOME ANEMIC. IT IS ALSO VERY PAINFUL DURING INTERCOURSE. AS A RESULT OF THE LONG PERIODS AND PAIN DURING INTERCOURSE I AM VERY LIMITED WITH INTERCOURSE WITH MY SPOUSE. I HAVE MADE THESE ISSUE KNOWN TO MY OB-GYN ON NUMEROUS OCCASIONS. I WAS GIVEN THE OPTIONS OF A HYSTERECTOMY, HOWEVER, I HAVE DECLINED AT THIS TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043937	BAYER	7/6/2015	7/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE (B)(6) AND HAVE DEVELOPED A BAD NICKEL ALLERGY THAT STARTED RIGHT AFTER. HAVE BEEN TRYING TO FIGURE OUT WHY I CONSTANTLY HAVE RASHES ON HANDS AND FACE, AND I HAVE BEEN AVOIDING DIETARY NICKEL AS WELL AS CONTACT WITH NICKEL. OCCURRED TO ME RECENTLY THAT IT MUST BE INTERNAL, AND SYMPTOMS STARTED A MONTH AFTER ESSURE. I ALSO HAVE PELVIC PAIN WHEN I OVULATE AND EXTREMELY HEAVY PERIODS, WHICH I DID NOT HAVE PRIOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043938		7/6/2015	7/13/2015

Event Information:

Event Date (B3): 8/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/5/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD THE DEVICE IN PLACE SINCE AUGUST 2008. I HAVE EXTREME PAIN WITH NUMBING ON THE RIGHT (FROM HIP TO TOES), DURING MY CYCLE. I HAVE TROUBLE HAVING BOWEL MOVEMENTS, NO MATTER THE FECAL CONSISTENCY. I HAD A HISTORY OF MIGRAINES, WHICH HAS SINCE DOUBLED WITHIN THE SAME TIME FRAME. PAINFUL INTERCOURSE DURING AND AFTER. MENSTRUAL CYCLES BEGAN AT AGE 11, RANGING FROM 3-4 DAYS TOTAL. SINCE THE DEVICE I RANGE FROM 9-12 DAY CYCLES. ABRUPT SNEEZING NOR COUGHING CAN NOT BE DONE WHILE SITTING ON MY BOTTOM. IF I AM STANDING DURING ONE OF THE OCCURRENCES, I MUST IMMEDIATELY TOPPLE OVER TO STOP THE SHARP PAIN THAT SHOOTS THROUGH MY VAGINAL CAVITY. I GET MENSTRUAL LIKE PAINS THAT HAVE A LONG LASTING PERIOD LIKE CONTRACTIONS, BUT DO NOT OCCUR DURING MY CYCLE. THESE PAINS COMPLETELY PARALYZE ME FOR THE DURATION OF THE PAIN (I CAN NOT BREATHE, SPEAK, NOR MOVE) UNTIL IT HAS PASSED. THE DEVICE HAS KIND OF TRICKED MY BODY INTO THINKING ITS PREGNANT, SO I HAVE DAILY MORNING SICKNESS WITHOUT ACTUALLY VOMITING. I AM EXTREMELY FATIGUED. WHEN I COMPLAINED OF THIS TO MY PHYSICIAN, I WAS TOLD, "WE HEAR THE SAME THING FROM A LOT OF OTHER WOMEN THAT HAVE THE ESSURE. THOSE ARE NORMAL SIDE EFFECTS." NAPROXEN FOR PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00453	BAYER HEALTHCARE LLC	7/6/2015	7/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/3/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON 03-JUL-2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON 15-NOV-2011. STUDY DESCRIPTION: STUDY (B)(6) IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). ON (B)(6) 2009 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT CONTRACEPTION. HER LAST MENSTRUAL PERIOD WAS ON (B)(6) 2009. THE PROCEDURE TOOK 15 MINUTES. UTERINE DISTENSION WAS DONE DURING PROCEDURE. OSTIUM OF BOTH SIDES WAS VISUALIZED AND IT WAS EASY TO INTRODUCE THE CATHETER INTO THE TUBES. IT WAS REPORTED THAT EXTERNAL COIL RUPTURED. HOWEVER, BILATERAL PLACEMENT WAS REPORTED. PATIENT EXPERIENCED PAIN DURING PROCEDURE. AFTER INSERTION, CONDOM WAS USED AS CONTRACEPTION. ON (B)(6) 2009, RADIOGRAPHY WAS DONE AND SHOWED THAT INSERTS WERE SYMMETRIC. HSG WAS ALSO PERFORMED AND SHOWED THAT INSERTS WERE IN PLACE (GOOD POSITION) WITH BILATERAL OCCLUSION. ON (B)(6) 2011 (AT 2 YEAR FOLLOW UP VISIT), PATIENT HAD ENDOMETRIUM POLYP AND ENDOMETRIUM ABLATION WAS SCHEDULED. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-APR-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO

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CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 26-JUN-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING PLACEMENT, EXTERNAL COIL RUPTURED. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS PARTICULAR CASE, THE EXACT CIRCUMSTANCES OF BREAKAGE WERE NOT INFORMED. THE INSERTION WAS EASY BUT PATIENT EXPERIENCED PAIN. CONSIDERING THE EXTERNAL COIL RUPTURED DURING INSERTION, CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00454	BAYER HEALTHCARE LLC	7/6/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/18/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2009, (B)(6) 2009 AND (B)(6) 2010. ON (B)(6) 2009 FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN OTHER REPORTABLE INCIDENT. STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6) PATIENT HAD AS MEDICAL HISTORY 2 CHILDREN, 1 CAESARIAN, CURETTAGE AND MENSTRUAL PAIN. AS CURRENT CONTRACEPTION SHE USED MACRODOSE PROGESTAGENS AND MINIPILLS. SHE HAD A FIRST ATTEMPT OF ESSURE INSERTION ON (B)(6) 2009. THE DATE OF HER LAST MENSTRUAL PERIOD WAS (B)(6) 2009. NON-STEROIDAL ANTI-INFLAMMATORY DRUG AND ANALGESICS WERE USED AS PREMEDICATION. NO INITIAL ANESTHESIA WAS APPLIED DURING PROCEDURE. UTERINE DISTENTION WITH HYSTEROSCOPY WAS POSSIBLE AND THE VISUALIZATION OF BOTH OSTIUM WAS DONE. THE CONDITION OF PATIENT'S UTERINE CAVITY (ENDOMETRIUM) WAS NORMAL AND HER UTERUS WAS RETROVERTED. INVESTIGATOR STARTED THE INSERTION ON LEFT SIDE AND INFORMED THAT OSTIUM WAS IN THE FIELD OF VISION DURING PLACEMENT. THE INSERTION OF CATHETER ON LEFT SIDE WAS EASY AND THE PLACEMENT WAS SUCCEEDED WITH 4 EXTERNALLY VISIBLE COILS IN THE UTERINE CAVITY. HOWEVER, THE INSERTION ON THE RIGHT SIDE WAS DIFFICULT DUE TO SPASM AND PLACEMENT DID NOT SUCCEED. PATIENT EXPERIENCED PAIN DURING PASSAGE THROUGH CERVIX, DURING PLACEMENT OF DEVICES IN BOTH TUBES AND AFTER THE PROCEDURE. PROCEDURE TOOK 20 MINUTES. SHE DID NOT

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HAVE VASOVAGAL SYNCOPE. NO OTHER PROCEDURE WAS PERFORMED AT THE SAME TIME OF INSERTION. ON (B)(6) 2009, PATIENT HAD A SECOND INSERTION ATTEMPT, ESSURE WAS INSERTED ON RIGHT SIDE UNDER GENERAL ANAESTHESIA. ANALGESICS, BENZODIAZEPINE AND STEROIDAL ANTI-INFLAMMATORY DRUG WERE USED AS PREMEDICATION. UTERINE DISTENSION WAS DONE AND HYSTEROSCOPY WAS POSSIBLE. THE OSTIUM WAS IN THE FIELD OF VISION DURING PLACEMENT; THE CATHETER WAS EASILY INSERTED AND 5 EXTERNALLY COILS WERE SEEN IN THE UTERINE CAVITY. PROCEDURE TOOK 8 MINUTES. PATIENT DID NOT EXPERIENCE PAIN AFTER PROCEDURE. SHE DID NOT HAVE VASOVAGAL SYNCOPE AND WAS VERY SATISFIED. ADDITIONALLY, ON THE SAME DAY, INVESTIGATOR PERFORMED AN ABLATION FRAGMENT INNER COIL USING HYSTEROSCOPY BEFORE THE ESSURE PLACEMENT AND STATED IT DID NOT MAKE THE INSERTION MORE DIFFICULT. ON (B)(6) 2009, AT CONSULTATION, PATIENT DID NOT REPORT PAIN/CRAMPS OR BLEEDING AND DID NOT TAKE POST-OPERATIVES ANALGESICS. RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS SYMMETRIC WITH DISTANCE OF PROXIMAL PORTION LESS THAN 4 CM (4 MARKERS WELL PLACED). HYSTEROSALPINGOGRAM WAS ALSO PERFORMED AND SHOWED BOTH INSERTS IN PLACE AND BILATERAL OCCLUSION. NO ULTRASOUND WAS PERFORMED. ADDITIONALLY, REPORTER CONSIDERED THAT THE PROCEDURE FINAL RESULT HAS SUCCEEDED AND INFORMED THAT PATIENT WAS VERY SATISFIED. IT WAS ALSO REPORTED THAT, IN THE 12 MONTHS FOLLOW-UP, THERE WAS NOTHING TO BE NOTICED; PATIENT HAD MASTODYNIA. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 1026 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY (STUDY NUMBER: 18097). SHE HAD AN INITIAL ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ATTEMPT; WHICH FAILED IN RIGHT SIDE DUE TO TUBAL SPASM. LATER, DURING A SECOND INSERTION ATTEMPT INVESTIGATOR STATED HE PERFORMED AN ABLATION OF A FRAGMENT INNER COIL USING HYSTEROSCOPY. THE REPORTED EVENT, INTERPRETED AS DEVICE BREAKAGE, IS LISTED ACCORDING TO PRODUCT TECHNICAL (PTC) ANALYSIS AND WAS CONSIDERED NON-SERIOUS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS OR REMOVALS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED, NEVERTHELESS CONSIDERING THE REPORTED EVENT'S NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY OTHER NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS AN OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE; AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00460	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 1/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/29/2010
Explant Date (E7): 2/24/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON 29-JAN-2010 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON 24-FEB-2010 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. (B)(4). THE PATIENT'S MEDICAL HISTORY INCLUDED 5 CHILDREN, ONE CESAREAN SECTION, CURETTAGE AND MENSTRUAL PAIN. SHE USED COMBINED PILLS AS CONTRACEPTIVE. HER LAST MENSTRUAL PERIOD WAS ON (B)(6)-2010. ON (B)(6)-2010, ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT STERILIZATION WITHOUT ANESTHESIA. NSAID (NONSTEROIDAL ANTI-INFLAMMATORY DRUG) WAS USED AS PREMEDICATION AND A UTERINE DISTENSION WAS DONE; THERE WAS SYNECHIAE IN UTERINE CAVITY. ONLY THE RIGHT SIDE OSTIUM WAS VISIBLE. THE INSERTION OF CATHETER WAS NOT EASY DUE TO PRE-OSTIAL OBSTACLE. PATIENT EXPERIENCED PAIN DURING PROCEDURE. AFTER INSERTION, SHE USED COMBINED PILL AS CONTRACEPTION. PLAIN ABDOMEN X-RAY WAS DONE AT SAME DAY OF INSERTION AND SHOWED THE INSERTS WERE NOT SYMMETRIC; THE POSITION OF LEFT INSERT WAS DOUBTFUL AND IT HAD A WRAP FORM. RIGHT INSERT WAS IN GOOD POSITION. INVESTIGATOR CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A FAILURE AS INSERT FOLDED UP IN THE FALLOPIAN TUBE (INSERT WRAPPED). ON (B)(6)-2010, PATIENT HAD PAIN/CRAMPS AS POSTOPERATIVE EFFECTS. ON THE SAME DATE, A TUBAL LIGATION WAS DONE BY CELIOSCOPY AFTER LEFT INSERT WAS REMOVED. PTC INVESTIGATION RESULT RECEIVED ON 02-APR-2015 PTC GLOBAL NUMBER (B)(4). FINAL

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ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6)-2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: DEVICE PHYSICAL PROPERTY ISSUE. (B)(6). BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE SUBJECT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD A DIFFICULT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND A X-RAY, PERFORMED IMMEDIATELY AFTER THE PROCEDURE, REVEALED LEFT INSERT HAD A WRAP FORM, INVESTIGATOR STATED IT FOLDED UP IN THE FALLOPIAN TUBE. A CELIOSCOPY WAS PERFORMED AND THIS DEVICE WAS REMOVED. THE REPORTED EVENT, REGARDED AS DEVICE SHAPE ALTERATION, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. IN THIS PARTICULAR CASE, PATIENT HAD UTERINE SYNECHIAE WHICH MAY HAVE CONTRIBUTED TO THE REPORTED INSERTION DIFFICULTY AND DEVICE FOLDING. NEVERTHELESS, CONSIDERING THE REPORTED EVENT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED FOR DEVICE REMOVAL, THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00461	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 12/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/8/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN FRANCE ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2010 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT USED CERAZETTE AS HISTORICAL DRUG. HER MEDICAL HISTORY INCLUDES ONE CESAREAN LABOR; SHE ALSO HAD A CURETTAGE DONE. THE PATIENT LAST MENSTRUATION PERIOD BEFORE THE INSERTION PROCEDURE WAS (B)(6) 2008. ON (B)(6) 2008, ESSURE WAS INSERTED IN THE OUTPATIENT OPERATING ROOM; ANESTHESIA WAS NOT USED DURING THE PROCEDURE. THE PATIENT'S UTERINE CAVITY CONDITION WAS NORMAL, AND HER UTERUS WAS RETROVERTED. THE PROCEDURE WAS STARTED ON LEFT SIDE. THE PHYSICIAN CONSIDERED EASY TO INTRODUCE THE CATHETER INTO LEFT TUBE AND DIFFICULT IN THE RIGHT TUBE DUE TO PERCEPTION OF OBSTACLE AND POOR VISUALIZATION. AT THE END OF PROCEDURE SHE HAD 2 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 2 ON RIGHT SIDE; THE PHYSICIAN USED 2 INSERTS, 1 ON EACH SIDE. THE PROCEDURE TOOK 25 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. THE PATIENT EXPERIENCED PAIN DURING AND AFTER THE PROCEDURE. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. NO OTHER PROCEDURE WAS DONE AT THE SAME TIME OF THE INSERTION. THE PATIENT WAS SATISFIED WITH THE PROCEDURE. DURING CONSULTATION ON (B)(6) 2008, THE PATIENT REPORTED THAT SHE USED POSTOPERATIVE ANALGESICS; SHE ALSO REPORTED THAT SHE

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HAD POSTOPERATIVE EFFECTS LIKE PAIN AND BLEEDING. SHE USED MINIPILL CERAZETTE AS BACK-UP CONTRACEPTION. AT THIS CONSULTATION, RADIOGRAPHY WAS DONE AND SHOWED ASYMMETRIC INSERTS. AN ULTRASOUND WAS ALSO PERFORMED AND SHOWED ONLY THE LEFT DEVICE VISIBLE FROM THE CAVITY TO THE HORN. A HSG (HYSTEROSALPINGOGRAM) WAS NOT DONE. IN CONCLUSION, THE LEFT INSERT WAS IN GOOD POSITION BUT THE RIGHT WAS NOT. THE FINAL RESULT WAS CONSIDERED AN ESSURE FAILURE DUE TO ABDOMINAL MIGRATION. PHYSICIAN DETAILS THE REASON OF THE FAILURE AS RIGHT ESSURE WITH PERFORATION OF RIGHT UTERINE HORN CERTAINLY DUE TO PERFORATION BY FALSE PASSAGE DURING PLACEMENT. ON (B)(6) 2009, THE PATIENT HAD RIGHT ESSURE ABLATION WHICH HAD PERFORATED HORN WITHOUT INTRA-ABDOMINAL MIGRATION (ESSURE PROXIMAL EXTREMITY WAS IN HORN), THE ABLATION OCCURRED WITH NO DIFFICULTY AND A RIGHT SALPINGECTOMY WAS PERFORMED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: UTERINE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 145 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A PERFORATION OF RIGHT UTERINE HORN CERTAINLY DUE TO PERFORATION BY FALSE PASSAGE DURING PLACEMENT OCCURRED. ALSO, THE PATIENT EXPERIENCED POST-PROCEDURAL BLEEDING. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. ALSO, BLEEDING IS AN EXPECTED EVENT DURING OR FOLLOWING ESSURE INSERTION. IN THIS PARTICULAR CASE, THE INSERTION WAS DIFFICULT DUE TO POOR VISUALIZATION AND PERCEPTION OF OBSTACLE, WHICH MIGHT HAD CONTRIBUTED TO PERFORATION OF RIGHT UTERINE HORN. THE PERFORATION PROBABLY WAS THE REASON FOR THE POST-OPERATIVE BLEEDING AND PAIN. GIVEN POSITIVE TEMPORAL RELATIONSHIP AND THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. SINCE ESSURE REMOVAL AND SALPINGECTOMY PER LAPAROSCOPY WERE PERFORMED, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00462	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/29/2008
Explant Date (E7): 3/17/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN FRANCE ON (B)(6) 2008 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2010 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY NUMBER: (B)(6). STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 4 CHILDREN AND MENSTRUAL PAIN. ON (B)(6) 2008 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT CONTRACEPTION. UTERINE DISTENSION WAS PERFORMED. PROCEDURE TOOK 4 MINUTES. BOTH OSTIUM (LEFT AND RIGHT) WERE VISUALIZED. IT WAS NOT EASY TO INTRODUCE THE CATHETER ON LEFT SIDE DUE TO PRE-OSTIAL OBSTACLE. BILATERAL PLACEMENT OCCURRED WITH 7 COILS IN THE UTERINE CAVITY ON LEFT SIDE AND 4 COILS ON RIGHT SIDE. PATIENT EXPERIENCED PAIN DURING AND AFTER PROCEDURE. AFTER INSERTION, COMBINATION PILL WAS USED AS CONTRACEPTION. ON (B)(6) 2009 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND REVEALED THAT INSERTS WERE IN PLACE (GOOD POSITION) WITH BILATERAL OCCLUSION. AT THE SAME DAY, PATIENT COMPLAINED OF CHRONIC POST-OPERATIVE PAIN/CRAMP. ALTHOUGH GOOD POSITION WAS REPORTED BASED ON HSG; IT WAS ALSO REPORTED THAT ESSURE WAS REMOVED BY LAPAROSCOPY AND HYSTEROSCOPY ON (B)(6) 2009 DUE TO PAIN AND MIGRATION. DURING THE INTERVENTION, THE PATIENT HAD CLIPS APPLICATION ON BOTH UTERINE TUBES. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE

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NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1.ABDOMINAL PAIN: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 280 CASES. 2. DEVICE DISLOCATION: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 322 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS INVOLVED IN A OBSERVATIONAL COMPANY-SPONSORED STUDY AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS NOT EASY TO INTRODUCE THE CATHETER ON LEFT SIDE DUE TO PRE-OSTIAL OBSTACLE. PATIENT EXPERIENCED PAIN DURING AND AFTER PROCEDURE AND REPORTED CHRONIC POST-OPERATIVE PAIN/CRAMPS AT 3 MONTHS VISIT. ALSO, MIGRATION WAS INFORMED. THE PAIN AND MIGRATION LED TO ESSURE REMOVAL EIGHT MONTHS LATER, VIA LAPAROSCOPY AND HYSTEROSCOPY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN/CRAMPS AND DEVICE MIGRATION MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, HYSTEROSALPINGOGRAM WAS PERFORMED AND THE RESULT SHOWED INSERTS IN GOOD POSITION WITH BILATERAL OCCLUSION. IN THE SAME DATE, THE PATIENT INFORMED ABOUT THE CHRONIC PAIN. ALTHOUGH THE GOOD POSITION ON HSG, IT WAS REPORTED THAT THE DEVICES MIGRATED. CONSIDERING POSITIVE TEMPORAL RELATIONSHIP AND THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE WAS REMOVED BY LAPAROSCOPY AND HYSTEROSCOPY. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 15-DEC-2015: ESSURE WAS INSERTED ON (B)(6) 2008. THE DEVICES WERE REMOVED ON (B)(6) 2009. THE PATIENT HAD POST-PROCEDURE PAIN SINCE (B)(6) 2008. SHE WAS HOSPITALIZED FROM (B)(6) 2009 FOR INSERTS REMOVAL BY HYSTEROSCOPY AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00463	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/7/2009
Explant Date (E7): 9/17/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2010 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 2 CHILDREN, CURETTAGE, AND MENSTRUAL PAIN. HER DRUG HISTORY INCLUDED COMBINED PILL (ORAL CONTRACEPTIVE NOS). THE PATIENT LAST MENSTRUATION PERIOD BEFORE THE INSERTION PROCEDURE WAS (B)(6) 2009. ON (B)(6) 2009, ESSURE WAS INSERTED IN THE OPERATING ROOM; GENERAL ANESTHESIA WAS APPLIED DURING THE PROCEDURE. THE PATIENT'S UTERINE CAVITY CONDITION WAS NORMAL, AND HER UTERUS WAS NOT RETROVERTED. THE PROCEDURE WAS STARTED ON RIGHT SIDE. THE PHYSICIAN CONSIDERED EASY TO INTRODUCE THE CATHETER INTO BOTH TUBES. AT THE END OF PROCEDURE SHE HAD 2 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 5 ON RIGHT SIDE; THE PHYSICIAN USED 2 INSERTS, 1 ON EACH SIDE. THE PROCEDURE TOOK 5 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. THE PATIENT EXPERIENCED PAIN AFTER THE PROCEDURE. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. NO OTHER PROCEDURE WAS DONE AT THE SAME TIME OF THE INSERTION AND THE PATIENT WAS SATISFIED WITH THE PROCEDURE. ON (B)(6) 2009, RADIOGRAPHY WAS DONE AND SHOWED SYMMETRIC INSERTS. AN ULTRASOUND WAS ALSO PERFORMED AND SHOWED BOTH DEVICES VISIBLE FROM THE CAVITY TO THE HORN. A HSG (HYSTEROSALPINGOGRAM) WAS NOT DONE. IN CONCLUSION, BOTH INSERTS WERE IN GOOD POSITION. THE FINAL RESULT WAS SUCCESSFUL. DURING CONSULTATION ON (B)(6) 2009, THE PATIENT REPORTED THAT SHE DID NOT USE POSTOPERATIVE ANALGESICS; SHE ALSO REPORTED THAT SHE HAD POSTOPERATIVE EFFECTS LIKE BLEEDING. SHE USED TRINORDIOL AS BACK-UP CONTRACEPTION. DURING CONSULTATION ON (B)(4)2010, IT

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WAS REPORTED THAT THE PATIENT HAD PAIN AS COMPLICATION. ON THE SAME DAY, A LAPAROSCOPY WAS DONE AND SHOWED GOOD ASPECT OF THE ESSURE DEVICES; BILATERAL SALPINGECTOMY WAS PERFORMED. PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015 (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PELVIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(6) PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS INVOLVED IN A OBSERVATIONAL COMPANY-SPONSORED STUDY AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PATIENT EXPERIENCED PAIN AFTER THE PROCEDURE, POSTOPERATIVE EFFECTS LIKE BLEEDING (REGARDED AS GENITAL BLEEDING) AND PAIN (REGARDED AS PELVIC PAIN). PAIN AND BLEEDING WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BOTH EVENTS MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. CONSIDERING POSITIVE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE BILATERAL SALPINGECTOMY WAS PERFORMED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00464	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/18/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6)-2010 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6)-2010 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 03 CHILDREN, ECTOPIC PREGNANCY, SALPINGOTOMY, AND MENSTRUAL PAIN. MEDICATION AT TIME OF INSERTION INCLUDED HORMONAL IUD. ON (B)(6) 2010 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS IMPLANTED FOR PERMANENT STERILISATION. VISUALIZATION OF OSTIUM WAS GOOD ON THE RIGHT SIDE AND NOT GOOD ON THE LEFT. LEFT AND RIGHT CATHETERIZATION WERE DIFFICULT DUE TO PERCEPTION OF OBSTACLE. THE PROCEDURE WAS STARTED ON RIGHT SIDE. AT THE END OF PROCEDURE SHE HAD 4 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE RIGHT SIDE. THE PROCEDURE TOOK 21 MINUTES AND BILATERAL PLACEMENT WAS NOT ACHIEVED. INSERT PLACEMENT FAILURE ON LEFT SIDE DUE TO TUBAL OBSTRUCTION. NO APPOINTMENT FOR CONTRALATERAL PLACEMENT WAS PERFORMED. PATIENT PRESENTED PAIN DURING INSERTION AND AFTER THE PROCEDURE. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. THE PATIENT WAS NOT VERY SATISFIED WITH THE PROCEDURE. IUD ABLATION (REMOVAL) WAS PERFORMED AT THE SAME TIME. SHE DENIED THE USE OF POSTOPERATIVE ANALGESICS, AND SHE DID NOT EXPERIENCED POSTOPERATIVE PAIN/CRAMPS AND BLEEDING. CONDOM WAS USED AFTER ESSURE INSERTION. ON (B)(6) 2010 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED RIGHT HORN PERFORATION AND BILATERAL PERMEABILITY. FINAL RESULT OF PROCEDURE WAS CLASSIFIED AS "FAILURE". TUBAL LIGATION BY LAPAROSCOPY WAS PERFORMED. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT

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WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6)2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: UTERINE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6)FEMALE PATIENT, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE HYSTEROSALPINGOGRAM SHOWED RIGHT HORN PERFORATION. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION WITH ESSURE USE MAY OCCUR MOSTLY DURING INSERTION. IN THIS CASE, THE INSERTION WAS DIFFICULT ON BOTH SIDES DUE TO PERCEPTION OF OBSTACLES. ON THE LEFT, PLACEMENT WAS NOT ACHIEVED AND PATIENT COMPLAINED OF PAIN DURING AND POST PROCEDURE. THE CONFIRMATION TEST (HYSTEROSALPINGOGRAM) SHOWED RIGHT HORN PERFORATION AND THEN, A LAPAROSCOPY FOR TUBAL LIGATION WAS PERFORMED IN THE SAME DAY. GIVEN AVAILABLE INFORMATION AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED. SINCE A LAPAROSCOPY WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00465	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/25/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2009 AND (B)(6) 2011. ON (B)(6) 2011 FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: (B)(6). PATIENT´S MEDICAL HISTORY INCLUDED FIVE CHILDREN (1 CESAREAN) AND MENSTRUAL PAIN. SHE WAS ON MINIPILLS AND AMENORRHEA. HER UTERUS WAS NOT RETROVERTED. ON(B)(6) 2009, ESSURE WAS EASILY INSERTED IN TWO MINUTES. NSAID WAS USED AS PREMEDICATION. UTERINE CONDITION WAS NORMAL AND VISUALIZATION WAS POSSIBLE BILATERALLY. THE NUMBER OF EXTERNALLY VISIBLE COILS IN THE UTERINE COILS WAS THREE IN THE LEFT SIDE AND ONE IN THE RIGHT SIDE. PATIENT PRESENTED PAIN DURING INSERTION. NO OTHER PROCEDURE WAS PERFORMED AT THE TIME OF INSERTION. ON (B)(6) 2009, PAIN AND BLEEDING WERE DENIED. BACK CONTRACEPTION USED WAS MINIPILLS. ULTRASOUND WAS PERFORMED AND INSERTS WERE SEEN FROM THE CAVITY TO THE HORN. CONCLUSION WAS GOOD INSERTS POSITION. FINAL RESULT OF THE PROCEDURE WAS CONSIDERED SUCCESSFUL AND PATIENT WAS SATISFIED. AT 12 MONTHS VISIT, IT WAS REPORTED PELVIC PAIN, IRREGULAR MENSTRUATION AND WEIGHT LOSS. LOWER ABDOMINAL PAIN THROUGHOUT THE YEAR, NOT SYSTEMATICALLY AT MENSTRUATION TIMES. TWO YEARS LATER, AN INFECTION WAS REPORTED. SHE UNDERWENT A REMOVAL OF FALLOPIAN TUBES UP TO 60% DUE TO INFLAMMATION. NO FURTHER INFORMATION WAS PROVIDED. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY

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MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(6). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(6) PREFERRED TERM: SALPINGITIS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(6) PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO WAS INVOLVED IN OBSERVATIONAL COMPANY-SPONSORED STUDY, (B)(6). PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED FALLOPIAN TUBE INFLAMMATION (INFECTION). THIS EVENT, SEEN AS SALPINGITIS, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SALPINGITIS OCCURS WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE FALLOPIAN TUBES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS, INCLUDING SALPINGITIS AFTER INSERTION PROCEDURE (WITHIN 4 WEEKS). IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. APPARENTLY, THE INFLAMMATION OCCURRED TWO YEARS AFTER INSERTION AND IT WAS NOT RELATED TO INSERTION PROCEDURE. HOWEVER DUE TO LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION AND CONSIDERING LOCAL ACTION OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WITH SUSPECT DEVICE USE CANNOT BE TOTALLY EXCLUDED. SINCE THIS EVENT LED TO SALPINGECTOMY, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00467	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 3/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/5/2011
Explant Date (E7): 4/27/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2011 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2011 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 02 CHILDREN. SHE USED MINIPILLS AND WAS IN AMENORRHEA AT TIME OF ESSURE INSERTION. ON (B)(6) 2011 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED UNDER IV SEDATION. UTERINE DISTENTION WAS DONE; UTERINE CAVITY WAS WITHIN NORMAL CONDITIONS. VISUALIZATION OF OSTIUM WAS GOOD BILATERALLY. LEFT CATHETERIZATION WAS DIFFICULT DUE TO SPASM. RIGHT SIDE INSERTION WAS EASY. AT THE END OF PROCEDURE THERE WAS 1 COIL EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 3 ON RIGHT SIDE. THE PROCEDURE TOOK 10 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. PATIENT PRESENTED PAIN AFTER THE PROCEDURE AND USED POSTOPERATIVE ANALGESICS. ON (B)(6) 2011, DURING CONSULTATION, PATIENT REPORTED POSTOPERATIVE PAIN/CRAMPS AND BLEEDING. RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS WERE NOT SYMMETRIC POSITIONED; THE DISTANCE BETWEEN THEIR PROXIMAL PORTIONS WAS MORE THAN 4 CM. FOUR MARKERS WERE WELL PLACED ON THE RIGHT SIDE AND NOT WELL PLACED ON THE LEFT. ACCORDING TO INVESTIGATOR THERE WAS AN OBVIOUS PERFORATION ON PLAIN ABDOMEN; HE CONSIDERED THE FINAL RESULT OF PROCEDURE AS A FAILURE DUE TO ABDOMINAL MIGRATION. ON (B)(6) 2011 A LAPAROSCOPY WAS

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PERFORMED AND SHOWED PERFORATION ON THE LEFT AND SUBSEROSAL PERFORATION IN RIGHT SIDE. DEVICES WERE REMOVED, AND ELECTRIC RESECTION ON THE 2 TUBES WAS PERFORMED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: FALLOPIAN TUBE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 204 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT RADIOGRAPHIC CONTROL, INSERTS WERE NOT IN GOOD POSITION. SHE WAS SUBMITTED TO A LAPAROSCOPY; WHICH REVEALED PERFORATION ON THE LEFT SIDE AND SUBSEROSAL PERFORATION IN RIGHT SIDE. THE INSERTS WERE REMOVED. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A COMPLETE PERFORATION OCCURS, ESSURE CAN BE FOUND IN THE ABDOMINAL CAVITY AS IT PERFORATES THE WHOLE FALLOPIAN TUBE WALL. IN THIS PARTICULAR CASE, ESSURE INSERTION WAS DIFFICULT; THIS MAY HAVE CONTRIBUTED TO THE REPORTED EVENT AND ALTHOUGH ITS EXACT MECHANISM WAS NOT REPORTED; CAUSALITY WITH THE SUSPECT INSERT/INSERTION PROCEDURE CANNOT BE EXCLUDED. ADDITIONALLY IT WAS REPORTED PATIENT EXPERIENCED BLEEDING AND PAIN AFTER ESSURE INSERTION. SINCE A LAPAROSCOPY WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00468	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 6/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2011 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2011 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED THREE CHILDREN, THREE CESAREAN SECTIONS, AND MENSTRUAL PAIN. SHE USED MINIPILLS AS CONTRACEPTIVE AND WAS IN AMENORRHEA AT THE TIME OF ESSURE INSERTION. ON (B)(6) 2011, ESSURE WAS SUCCESSFULLY INSERTED. NSAID (NONSTEROIDAL ANTI-INFLAMMATORY DRUG) WAS USED AS PREMEDICATION. UTERINE CAVITY WAS UNDER NORMAL CONDITIONS. VISUALIZATION WAS POSSIBLE FOR BOTH OSTIUM. PATIENT PRESENTED PAIN DURING AND AFTER PROCEDURE, WHICH TOOK 3 MINUTES. ON (B)(6) 2011, RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS SYMMETRIC WITH PROXIMAL PORTIONS DISTANCE NOT < 4 CM AND 4 MARKERS NOT WELL PLACED. AT ULTRASOUND THE INSERTS WERE NOT SEEN FROM THE CAVITY TO THE HORN; HYSTEROSALPINGOGRAM (HSG) WAS DOUBTFUL. INVESTIGATOR CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A FAILURE (FAILED TO ASSERT THE OBSTRUCTION OF THE TUBES; INSERTS ON DISTANCE FROM THE CORNS); AND HAD A DOUBT ON A SPASM. A LAPAROSCOPY WAS PERFORMED AND IN FACT THE 2 INSERTS WERE WELL PLACED DURING THE SURGERY. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY

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QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY (STUDY NUMBER: (B)(6)). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND INSERTS WERE IN DOUBTFUL POSITION AND PHYSICIAN WAS FAILED TO ASSERT THE OBSTRUCTION. SHE WAS SUBMITTED TO A LAPAROSCOPY, WHICH REVEALED INSERTS WERE IN PLACE. THE REPORTED EVENT, REGARDED AS SUSPICION OF DEVICE DISLOCATION, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE REPORTED DISLOCATION WAS NOT CONFIRMED DURING LAPAROSCOPY; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED AND AS AN INTERVENTION WAS REQUIRED; THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00469	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/11/2011
Explant Date (E7): 6/30/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2011 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). STUDY DESCRIPTION: STUDY (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY.. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 03 CHILDREN AND 01 ELECTIVE ABORTION. SHE DENIED MENSTRUAL PAIN. MEDICATION AT TIME OF INSERTION INCLUDED COMBINED PILL. HER LAST MENSTRUAL PERIOD BEFORE INSERTION OCCURRED ON (B)(6) 2010. BETA HCG WAS NEGATIVE. ON (B)(6) 2011 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS EASILY IMPLANTED FOR PERMANENT STERILISATION. BENZODIAZEPINE AND NSAID (NON-STEROID ANTI-INFLAMMATORY DRUG) WERE USED AS PREMEDICATION. UTERINE CAVITY WAS WITHIN NORMAL CONDITIONS AND THE PATIENT DID NOT HAVE RETROVERTED UTERUS. UTERINE DISTENTION WAS DONE. VISUALIZATION OF OSTIUM WAS GOOD BILATERALLY. THE PROCEDURE WAS STARTED ON LEFT SIDE. AT THE END OF PROCEDURE SHE HAD 4 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND ON RIGHT SIDE. THE PHYSICIAN USED 2 INSERTS. THE PROCEDURE TOOK 5 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. PAIN DURING INSERTION AND PAIN AFTER THE PROCEDURE WERE DENIED. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. THE PATIENT WAS VERY SATISFIED WITH THE PROCEDURE AND NO ADDITIONAL PROCEDURE WAS PERFORMED AT THE SAME TIME. SHE DENIED THE USE OF POSTOPERATIVE ANALGESICS, AND SHE DID NOT EXPERIENCED POSTOPERATIVE PAIN/CRAMPS AND BLEEDING. COMBINATION PILL WAS USED AFTER PLACEMENT AND BEFORE

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CONFIRMATION TEST. ON (B)(4) 2011 RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS SYMMETRIC POSITIONED AND DISTANCE BETWEEN PROXIMAL PORTION WAS LESS THAN 4 CM. FOUR MARKERS WERE WELL PLACED. HSG AND ULTRASOUND WERE NOT DONE. FINAL RESULT OF PROCEDURE WAS CLASSIFIED AS SUCCESS. ON UNSPECIFIED DATE SHE EXPERIENCED PAIN. THE ONSET OF PAIN WAS REPORTED AS FOLLOWING MONTHS AFTER INTERVENTION. ON (B)(6) 2011 ESSURE WAS REMOVED UNDER LAPAROSCOPY (STRICTLY NORMAL ASPECT OF THE FALLOPIAN TUBES). PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: PELVIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 337 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS INVOLVED IN A OBSERVATIONAL COMPANY-SPONSORED STUDY AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. THIS EVENT (REGARDED AS PELVIC PAIN) WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, PATIENT EXPERIENCED PAIN DURING THE FOLLOWING MONTHS AFTER ESSURE INSERTION. NO ALTERNATIVE EXPLANATION WAS REPORTED. BASED ON THE INFORMATION PROVIDED AND GIVEN ITS NATURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE WAS REMOVED UNDER LAPAROSCOPY. ACCORDING TO PRODUCT TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00470	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/28/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2010 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2011 AND (B)(6) 2012. ON (B)(6) 2011 FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED THREE CHILDREN, DIABETES, ASTHMA AND MENSTRUAL PAIN. THE PATIENT'S CONCURRENT CONDITION INCLUDED RETROVERTED UTERUS, ADENOMYOSIS. MEDICATION AT TIME OF CONSULTATION WAS COMBINED PILLS. HER LAST MENSTRUAL PERIOD OCCURRED ON (B)(6) 2010. ON (B)(6) 2010, ESSURE WAS EASILY INSERTED. BOTH SIDES WERE VISUALIZED. PATIENT PRESENTED PAIN DURING AND AFTER PROCEDURE AND ALSO VASOVAGAL SYNCOPE. PROCEDURE WAS SUCCESSFUL. COMBINATION PILL WAS USED AS BACK UP CONTRACEPTION. PATIENT USED POSTOPERATIVE ANALGESICS. SHE PRESENTED POSTOPERATIVE EFFECTS LIKE PAIN/ CRAMPS AND BLEEDING. ON (B)(6) 2010, RADIOGRAPHY WAS PERFORMED AND INSERTS WERE SYMMETRIC, DISTANCE OF PROXIMAL PORTIONS WAS < 4 CM AND 4 MARKERS WERE WELL PLACED. ULTRASOUND WAS ALSO PERFORMED AND INSERTS WERE SEEN FROM THE CAVITY TO THE HORN. ON (B)(6) 2011, INFECTED ESSURE WAS REPORTED, INCREASED PAIN AND INCREASED BLEEDING/ MENSTRUAL PERIODS. HOSPITALIZATION OCCURRED IN (B)(6) 2011. ON (B)(6) 2012, PATIENT STOPPED FOLLOW UP DUE TO HYSTERECTOMY. NO FURTHER INFORMATION WAS PROVIDED. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: PTC

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(PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PELVIC INFECTION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 06 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. UPON ONE YEAR FOLLOW UP (2011), PHYSICIAN REPORTED INFECTED ESSURE (INTERPRETED AS PELVIC INFECTION) WHICH RESULTED IN HOSPITALIZATION. IN 2012, HYSTERECTOMY WAS PERFORMED. THE EVENT INFECTED ESSURE IS SERIOUS DUE TO HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ESSURE MICRO-INSERTS ARE SUPPLIED STERILE AND PLACED UNDER HYSTEROSCOPIC GUIDANCE IN THE PROXIMAL FALLOPIAN TUBE. HOWEVER, AS WITH ALL TRANS-CERVICAL PROCEDURES, ESSURE PLACEMENT CAN CAUSE INFECTION DUE TO A BACTERIAL CONTAMINATION DURING INSERTION. IN THIS PARTICULAR CASE, ALTHOUGH TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED INFECTION WAS WEAK, SINCE INVESTIGATOR RELATED THIS EVENT TO THE SUSPECT DEVICE, COMPANY CONSIDERS CAUSALITY CANNOT BE EXCLUDED. SINCE HOSPITALIZATION AND SURGICAL INTERVENTION WERE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO PRODUCT TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00471	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 8/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 5/20/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2010 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2011 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). PATIENT HAD NO RELEVANT MEDICAL HISTORY AND USED HORMONAL IUD AS CURRENT CONTRACEPTION. THE DATE OF HER LAST MENSTRUAL PERIOD WAS (B)(6) 2010. ESSURE WAS INSERTED. NO ANESTHESIA WAS APPLIED DURING PROCEDURE, UTERINE DISTENSION WAS DONE AND HYSTEROSCOPY WAS POSSIBLE. PATIENT'S UTERINE CAVITY EXAMINATION WAS NORMAL AND HER UTERUS WAS NOT RETROVERTED. PHYSICIAN STARTED THE INSERTION ON LEFT SIDE AND INFORMED IT WAS EASY TO INTRODUCE THE CATHETER INTO BOTH TUBES AND THE PLACEMENT WAS SUCCESSFUL (EXTERNALLY VISIBLE COIL IN THE UTERINE CAVITY: 1 ON BOTH SIDES). PROCEDURE TOOK 6 MINUTES. PATIENT EXPERIENCED PAIN DURING PASSAGE THROUGH THE CERVIX AND DURING ESSURE PLACEMENT IN BOTH TUBES. SHE DID NOT PRESENT PAIN AFTER PROCEDURE OR VASOVAGAL SYNCOPE. NO OTHER PROCEDURE WAS PERFORMED AT THE SAME TIME OF INSERTION. PATIENT DID NOT TAKE POST-OPERATIVE ANALGESICS AND DID NOT USE CONTRACEPTIVE METHODS DURING THE 3 MONTHS POST ESSURE PLACEMENT. SHE DID NOT EXPERIENCE PAIN/CRAMPING BUT EXPERIENCED BLEEDING/METRORRHAGIAS. ON (B)(6) 2011, A PELVIC ULTRASOUND (2D) WAS PERFORMED AND SHOWED GOOD INSERT POSITION ON RIGHT SIDE BUT LEFT INSERT WAS NOT SEEN FROM THE CAVITY TO HORN (DOUBTFUL INSERT

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POSITION). ESSURE IN LEFT SIDE WAS FOLDED IN UTERINE CAVITY. AN OUTPATIENT HYSTEROSCOPY SHOWED LEFT ESSURE INSERT WAS EXTERIORIZED WITH MORE THAN 8 COILS INSIDE THE CAVITY. HYSTEROSCOPY AND CELIOSCOPY WERE PERFORMED AND LEFT ESSURE INSERT WAS WITHDRAWN; A CLIP WAS PLACED IN LEFT FALLOPIAN TUBE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 322 CASES BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT CONTROL EXAMINATION, ESSURE IN LEFT SIDE WAS FOLDED IN UTERINE CAVITY AND EXTERIORIZED WITH MORE THAN 8 COILS INSIDE THE UTERINE CAVITY. THIS DEVICE WAS WITHDRAWN BY HYSTEROSCOPY AND CELIOSCOPY. THE REPORTED EVENT, REGARDED AS DEVICE DISLOCATION, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED DISLOCATION IS UNKNOWN, GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. SINCE A CELIOSCOPY WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00472	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 3/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/19/2010
Explant Date (E7): 4/12/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2011 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2011 AND (B)(6) 2012. ON (B)(6) 2011 FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(6), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 2 CHILDREN, COCKETT SYNDROME, AND 2 SALPINGITIS AND HER DRUG HISTORY INCLUDED MINIPILL (ORAL CONTRACEPTIVE NOS). THE PATIENT LAST MENSTRUATION PERIOD BEFORE THE INSERTION PROCEDURE WAS (B)(6) 2010. ON (B)(6) 2010, ESSURE WAS INSERTED IN THE OPERATING ROOM; NO ANESTHESIA WAS APPLIED DURING THE PROCEDURE. THE PATIENT'S UTERINE CAVITY CONDITION WAS NORMAL, AND HER UTERUS WAS NOT RETROVERTED. THE PROCEDURE WAS STARTED ON THE LEFT SIDE. THE PHYSICIAN CONSIDERED EASY TO INTRODUCE THE CATHETER INTO BOTH TUBES. AT THE END OF PROCEDURE SHE HAD 2 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 1 ON THE RIGHT SIDE. THE PATIENT EXPERIENCED PAIN DURING AND AFTER THE PROCEDURE. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. NO OTHER PROCEDURE WAS DONE AT THE SAME TIME OF THE INSERTION. THE PROCEDURE TOOK 10 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. DURING CONSULTATION ON (B)(6) 2011, THE PATIENT REPORTED THAT SHE USED POSTOPERATIVE ANALGESICS; SHE ALSO REPORTED PAIN/CRAMPS AS POSTOPERATIVE EFFECTS. SHE USED MINIPILL AS BACK-UP CONTRACEPTION. AT THIS CONSULTATION, A TRANSVAGINAL ULTRASOUND WAS

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DONE AND SHOWED ONLY THE LEFT DEVICE VISIBLE FROM THE CAVITY TO THE HORN, IT WAS ALSO FOUND OUT A HYDROSALPINX ON RIGHT AND LEFT SIDES. ADDITIONALLY, INVESTIGATOR STATED A PROBLEM OCCURRED IN ONE TUBE, ONE ESSURE MOVED AND AN INFECTION/SALPINGITIS OCCURRED. BILATERAL SALPINGECTOMY AND HYSTERECTOMY WERE PERFORMED. THE ESSURE PROCEDURE WAS CONSIDERED A FAILURE AND PATIENT WAS NOT SATISFIED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERMS: 1. SALPINGITIS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 34 CASES. 2. DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 325 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE (B)(4) PTS. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT FOLLOW-UP CONSULTATION A HYDROSALPINX (INFECTION/SALPINGITIS) WAS DIAGNOSED. ADDITIONALLY, IT WAS FOUND ONE ESSURE MOVED. SHE WAS SUBMITTED TO A SURGICAL PROCEDURE. THE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. HYDROSALPINX IS THE RESULT OF DAMAGES IN FALLOPIAN TUBES WHICH BECAME FILLED WITH A STERILE FLUID, BLOCKED AND ENLARGED. THE MOST OFTEN CAUSES OF HYDROSALPINX ARE PELVIC INFLAMMATORY DISEASE (SALPINGITIS), PREVIOUS SURGERIES OR ADHESIONS. IN THIS CASE THE PATIENT HAD A HISTORY OF 2 PREVIOUS SALPINGITIS, WHICH COULD BE ALTERNATIVE EXPLANATIONS FOR THE REPORTED HYDROSALPINX. NEVERTHELESS, THE INVESTIGATOR MENTIONED AN INFECTION/SALPINGITIS 1 YEAR POST INSERTION. CONSIDERING ESSURE LOCAL ACTION IN THE FALLOPIAN TUBES (ACTING AS A FOREIGN BODY); A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. REGARDING THE REPORTED DEVICE MIGRATION, PATIENT'S HYDROSALPINX MAY HAVE BEEN CONTRIBUTED TO ITS OCCURRENCE AND DUE TO ITS NATURE, THIS EVENT WAS CONSIDERED AS RELATED TO ESSURE. SINCE SURGICAL PROCEDURE WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00487	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 1/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 28-JAN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ADDITIONAL INFORMATION RECEIVED ON 30-JAN-2015. ON (B)(6)-2015, THE PATIENT EXPERIENCED POSSIBLE NICKEL ALLERGY REACTIONS, ACNE, WEIGHT GAIN, BLOATING, BROKEN TEETH AND HAIR LOSS. PTC INVESTIGATION RESULT WAS RECEIVED ON 18-FEB-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. BROKEN TEETH ARE NOT A KNOWN FAILURE MODE RELATED TO ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 08-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE

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TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW UP INFORMATION (GENERAL QUESTIONNAIRE) RECEIVED ON 08-JUN-2015 FROM PHYSICIAN: THE PATIENT DID NOT HAVE ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES. SHE WAS NOT POST-PARTUM AT TIME OF THE INSERTION PROCEDURE. THE INSERTION PROCEDURE WAS CONSIDERED EASY WITH VISUALIZATION OF TUBAL OSTIUM. THE PHYSICIAN APPLIED LOCAL AND GENERAL ANESTHESIA; CERVICAL DILATATION AND SOUNDING WERE NOT DONE. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES AND THERE WERE NO MORE THAN 1500CC OF FLUID LOSS. THE HSG (HYSTEROSALPINGOGRAM) TEST WAS DONE TO CONFIRM ESSURE PLACEMENT. ON AN UNSPECIFIED DATE, ESSURE WAS REMOVED. THE REMOVAL WAS A PATIENT REQUEST; SHE WAS NOT HOSPITALIZED. NO OTHER RELATED DIAGNOSTIC TESTS WERE DONE. PHYSICIAN MENTIONED THAT PERFORATION DID NOT OCCUR (INFORMATION NOT CLEARLY REPORTED). REMOVAL METHOD: LAPAROSCOPY; SALPINGECTOMY AND LAPAROTOMY. DURING THE SURGERY, THE DEVICES WERE IN NORMAL PLACEMENT. NO PATHOLOGY TEST WAS DONE. PHYSICIAN STATED THAT THE PATIENT'S BLOATING WAS MUCH BETTER AFTER ESSURE REMOVAL. FOLLOW UP INFORMATION RECEIVED ON 23-JUN-2015 THE PTC ASSESSMENT WAS UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED POSSIBLE NICKEL ALLERGY REACTIONS. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. PATIENT UNDERWENT A LAPAROSCOPY, SALPINGECTOMY AND LAPATOMY IN ORDER TO REMOVE ESSURE. GIVEN THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO REQUIRED INTERVENTION, THIS CASE WAS UPGRADED TO INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00488	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 4/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26967

Single Use: Y
Implant Date (E6): 4/21/2015
Explant Date (E7): 4/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(4) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2015, LOT NUMBER C26967, FOR PERMANENT CONTRACEPTION. DURING THE PLACEMENT PROCEDURE HCP (HEALTH CARE PROFESSIONAL) NOTICED A FLUID DEFICIT. PROCEDURE WAS ABORTED AND TUBAL LIGATION PERFORMED. NO PERFORATION NOTED AT TIME OF TUBAL LIGATION. THE ESSURE DEVICE WAS NOT OPENED. FOLLOW UP RECEIVED ON (B)(4) 2015: REPORTER STATED THAT THE ESSURE PROCEDURE WAS ABORTED BECAUSE THE PATIENT HAD A FLUID DEFICIT DURING THE HYSTEROSCOPY. THE DOCTOR VISUALIZED THE 2 TUBAL OSTIA. THE ESSURE PACKAGE WAS OPENED BUT NOT USED. BECAUSE OF THE FLUID DEFICIT, THE DOCTOR CONVERTED THE ESSURE PROCEDURE TO A LAPAROSCOPIC TUBAL LIGATION. PTC INVESTIGATION RESULT WAS RECEIVED ON 06-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C26967 (PRODUCTION DATE 28-FEB-2014 AND EXPIRATION DATE 28-FEB-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN,

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POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 08-JUN-2015 FROM PHYSICIAN: PATIENT HAD COMPLICATIONS FROM HYSTEROSCOPY AND NOT FROM ESSURE. SHE WAS THREE MONTHS POST PARTUM AT TIME OF ATTEMPTING INSERTION. CERVICAL DILATATION AND GENERAL ANESTHESIA WERE USED. IT WAS DIFFICULT TO VISUALIZE TUBAL OSTIUM. THERE 1900 ML OF FLUID LOSS DURING INSERTION AND THE PROCEDURE TOOK MORE THAN 20 MINUTES. IT WAS UNABLE TO PLACE ESSURE DUE TO SUSPECTED RUPTURED OF UTERUS DURING HYSTEROSCOPY. PERFORATION AND HOSPITALIZATION WAS DENIED. LAPAROSCOPY WAS PERFORMED. THERE WERE NO OTHER COMPLICATIONS. REPORTER DID NOT RELATE EVENTS TO ESSURE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO HAD A ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND IT WAS REPORTED FLUID LOSS DURING HYSTEROSCOPY 1900ML (CONSIDERED AS SYSTEMIC LEAKAGE). IT WAS UNABLE TO PLACE ESSURE DUE TO SUSPECTED RUPTURED OF UTERUS DURING HYSTEROSCOPY, BUT PERFORATION AND HOSPITALIZATION WERE DENIED. THE EVENT SYSTEMIC LEAKAGE IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SYSTEMIC LEAKAGE OF FLUIDS MAY OCCUR DURING DIFFICULT AND PROLONGATED ESSURE INSERTIONS. THE PHYSICIAN REPORTED THAT PATIENT HAD COMPLICATIONS FROM HYSTEROSCOPY AND NOT FROM ESSURE. HOWEVER, SINCE THE EVENT WAS RELATED TO ESSURE INSERTION PROCEDURE, COMPANY CONSIDERS THE REPORTED EVENT AS RELATED TO ESSURE USE. IN THIS CASE, TUBAL LIGATION WAS PERFORMED DUE TO FAILED INSERTION AS CONTRACEPTIVE METHOD AND A LAPAROSCOPY WAS PERFORMED. THIS CASE WAS UPGRADED TO INCIDENT DUE TO REQUIRED INTERVENTION PERFORMED. AN UPDATED PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 11-SEP-2015 COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO HAD A ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND IT WAS REPORTED FLUID LOSS DURIN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00489	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A78083

Single Use: Y
Implant Date (E6): 12/15/2014
Explant Date (E7): 5/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 08-JUN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. IT WAS REPORTED THAT ESSURE WAS INSERTED IN OPERATING ROOM, WITHOUT ANESTHETICS. RIGHT INSERTION WENT DIFFICULT, BUT SHE HAD NO COMPLAINTS. ON (B)(6) 2015, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED A PERFORATION OF RIGHT OVIDUCT, BUT PATIENT STILL HAD NO COMPLAINTS. ON (B)(6) 2015, LAPAROSCOPY WAS DONE AND RIGHT DEVICE WAS REMOVED; IMMEDIATE LAPAROSCOPIC STERILIZATION WITH CLIPS WAS DONE. PATIENT HAD NO COMPLAINTS AND WAS DOING WELL. THE OUTCOME OF THE EVENTS WAS RECOVERED / RESOLVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE

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WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND RIGHT INSERTION WENT DIFFICULT BUT SHE HAD NO COMPLAINTS. AN HYSTEROSALPINGOGRAM WAS PERFORMED AND THE RESULT SHOWED A PERFORATION RIGHT OVIDUCT. THIS EVENT, SEEN AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. IN THIS CASE, THE REPORTED EVENT WAS DIAGNOSED ABOUT 5 MONTHS AFTER ESSURE INSERTION. PATIENT UNDERWENT A LAPAROSCOPY AND RIGHT DEVICE WAS REMOVED. THE MECHANISM OF PERFORATION WAS NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 30-JUL-2015: NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. FOLLOW- UP INFORMATION RECEIVED ON 16-AUG-2015: PATIENT'S DEMOGRAPHIC INFORMATION WAS PROVIDED. HER MEDICAL HISTORY INCLUDED GRAVIDA 3 AND PARA 2 (1 SPONTANEOUS ABORTION). ON (B)(6) 2014

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00492	BAYER HEALTHCARE LLC	7/7/2015	7/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA A BAYER EMPLOYEE IN UNITED STATES ON (B)(6) 2014. IT DESCRIBES THE OCCURRENCE OF PREGNANCY WITH ESSURE IN PLACE IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. REPORTER DID NOT HAVE FURTHER INFORMATION BESIDE THAT PATIENT WOULD COME INTO PHYSICIAN'S OFFICE THE FOLLOWING WEEK OF THIS REPORT ((B)(6)-2014). FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6)2014. PATIENT HAD ESSURE PLACED 3 YEARS PRIOR TO THIS REPORT BY ANOTHER FACILITY, AND CALLED THE PHYSICIAN OFFICE FOR FOLLOW UP AND INFORMED THEM SHE WAS PREGNANT. SHE WAS SCHEDULED TO BE SEEN THE FOLLOWING WEEK OF THIS REPORT. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON (B)(6) 2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) -2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE. NO BATCH NUMBER WAS REPORTED.

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WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE LIMITED AVAILABLE INFORMATION. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6)-2015: THE REPORTER STATED THEY DID NOT DO THE INSERTION SO SOME OF THE INFORMATION THEY DID NOT HAVE. THEY TOOK CARE OF THE PATIENT DURING PREGNANCY. SHE ALREADY DELIVERED (BABY'S OUTCOME WAS NOT PROVIDED). PATIENT'S INITIALS AND DATE OF BIRTH WERE PROVIDED. THIS REPORT REFERS TO AN ADULT FEMALE PATIENT. FURTHER INFORMATION WILL BE PROVIDED. FOLLOW UP INFORMATION (PREGNANCY QUESTIONNAIRE) RECEIVED ON (B)(6) 2015 FROM PHYSICIAN: THE PATIENT WAS (B)(6) AT TIME OF THIS REPORT. SHE WAS GRAVIDA 7 AND PARA 4 WITH 2 MISCARRIAGES. HER PAST MEDICAL HISTORY INCLUDES DEPRESSION AND CHRONIC PAIN; SHE ALSO HAS ALLERGIES CODEINE AND SHELLFISH. HER PAST SURGICAL HISTORY INCLUDES D AND C (DILATATION & CURETAGGE), CHOLECYSTECTOMY AND CESAREAN SECTION. HER CURRENT MEDICATIONS WERE NORCO, PROAIR, VALIUM, GABAPENTIN AND ZOLOFT. THE PATIENT DENIED TOBACCO, ALCOHOL, OR ILLICITS. THE REPORTER WAS NOT THE PHYSICIAN WHO INSERTED ESSURE DEVICES IN PATIENT. THE EXPECTED DATE OF DELIVERY WAS (B)(6) 2015; HER LAST MENSTRUAL PERIOD WAS (B)(6) 2014, BUT THE PHYSICIAN WAS UNCERTAIN ABOUT THIS DATE. ON (B)(6) 2014, THE PATIENT PRESENTED TO THE EMERGENCY DEPARTMENT STATING THAT SHE BELIEVES SHE WAS PREGNANT. THE PATIENT STATED SHE HAD THE ESSURE PROCEDURE DONE IN (B)(6)2011. THE PATIENT ALSO REPORTED THAT SHE LOST FOLLOW-UP. SHE STATED THAT SHE TOOK A HOME PREGNANCY TEST THAT WAS NOTED TO BE POSITIVE AND THUS NOW PRESENTS TO EMERGENCY DEPARTMENT FOR FURTHER EVALUATION AND TREATMENT. SHE DENIED ANY VAGINAL BLEEDING. SHE DID COMPLAIN OF NAUSEA WITH NO EVIDENCE OF EMESIS AS WELL AS BREAST TENDERNESS. THERE WERE NO OTHER ALLEVIATING, MODIFYING, OR PRECIPITATING FACTORS. A PREGNANCY TEST (SERUM) WAS DONE AND SHOWED POSITIVE RESULT. ON THE SAME DAY A BETAHCG WAS DONE AND THE RESULT WAS 58367,4 MLU/ML. AN OBSTETRICAL ULTRASONOGRAPHY WAS DONE DUE TO FETAL VIABILITY AND PAIN AND SHOWED FETAL HEART MOTION AND AGE OF 8 WEEKS AND 1 DAY; THERE WAS ALSO AN AREA OF ALTERED ECHOGENICITY WITHIN THE UTERUS, SUGGESTIVE OF FIBROID FORMATION; A 2 CM LEFT OVARIAN CYST WAS PRESENT, THE OVARIES APPEARED OTHERWISE UNREMARKABLE. DURING THE EXAMINATION (OF EYES, NECK, HEART, LUNGS/CHEST, ABDOMEN, EXTREMITIES, NEUROLOGIC, SKIN AND PSYCHIATRIC) NO ABNORMALITIES WERE OBSERVED. THE PATIENT WAS SEEN AND EXAMINED BY THE PHYSICIAN. AFTER A THOROUGH HISTORY AND FOCUSED PHYSICAL EXAM, LABORATORY STUDIES INCLUDING CBC, SERUM PREGNANCY TEST, URINALYSIS, AND PELVIC ULTRASOUND IS OBTAINED. REVIEW OF THE PATIENT'S LABORATORY STUDIES REVEALS A BLOOD TYPE OF A POSITIVE, BETA IS 58,367. URINALYSIS WAS UNREMARKABLE. WHITE BLOOD CELL COUNT 8.5, HEMOGLOBIN 12.5, HEMATOCRIT 37.7, AND PLATELET COUNT IS 329. PELVIC ULTRASOUND DEMONSTRATES AN INTRAUTERINE PREGNANCY. THE PATIENT WAS ADVISED TO TAKE PRENATAL VITAMINS AS WELL AS DISCONTINUE HER VALIUM. SHE WAS ENCOURAGED TO RETURN TO THE EMERGENCY DEPARTMENT IF SHE HAS ANY NEW OR WORSENING SYMPTOMS. THE PATIENT WAS DISCHARGED HOME IN HEMODYNAMICALLY STABLE CONDITION. ON (B)(6) 2015, THE PATIENT DELIVERED LIVE BIRTH VIA CESAREAN (REPEATED ELECTIVE AND DUE TO OLIGOHYDRAMNIOS); THE PATIENT WAS (B)(6) PREGNANT AT TIME OF THE DELIVERY. THE BABY WAS IN STABLE CONDITION AT TIME OF THE DELIVERY; HE WEIGHT (B)(6). THE APGAR SCORE WAS 9 AT 1 MINUTE AND 9 AT 5 MINUTES. THE DELIVERY HAD NO COMPLICATIONS. THE BABY RECEIVED ERYTHROMYCIN IN BOTH EYES AND VITAMIN K. ALTHOUGH THE PHYSICIAN MENTIONED THAT ESSURE DEVICES WERE NOT REMOVED, DURING THE SURGERY (C-SECTION LABOR) A BILATERAL PARTIAL SALPINGECTOMY WAS DONE FOR STERILIZATION. FOLLOW-UP RECEIVED ON (B)(6) 2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PREGNANCY WITH ESSURE IN PLACE WAS DIAGNOSED. SHE GAVE BIRTH TO A HEALTHY BABY

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VIA CESAREAN SECTION DUE TO OLIGOHYDRAMNIOS. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE. PREGNANCY IS LISTED IN ESSURE REFERENCE SAFETY INFORMATION, WHILE OLIGOHYDRAMNIOS IS UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS PARTICULAR CASE, THE PATIENT LOST HER FOLLOW UP AND APPARENTLY DID NOT HAD THE CONFIRMATION TEST PERFORMED. THEN, SHE GAVE BIRTH TO A LIVE AND HEALTHY BABY VIA CESAREAN SECTION DUE TO OLIGOHYDRAMNIOS. OLIGOHYDRAMNIOS REFERS TO AMNIOTIC FLUID VOLUME THAT IS LESS THAN EXPECTED FOR GESTATIONAL AGE. THIS MAY BE CAUSED PER LEAKAGE OR RUPTURE OF MEMBRANES. ALTHOUGH IN THIS CASE THE PREGNANCY MAY BE RATHER A CONSEQUENCE OF NON-COMPLAINT USE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. IN ADDITION, CONSIDERING THAT A MECHANICAL INTERFERENCE OF THE ESSURE DEVICE IN THE AMNIOTIC SAC CANNOT BE TOTALLY EXCLUDED, THE OLIGOHYDRAMNIOS WAS CONSIDERED AS RELATED TO ESSURE AND THEREFORE THIS CASE WAS UPGRADED TO INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043527	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 3/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PCOS SEVERE BACK PAIN, BLOATING, NUMBNESS IN ARMS AND LEGS, SEVERE BLEEDING AND EXTREME PAIN DURING PERIODS!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043528	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 3/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD TO HAVE A HYSTERECTOMY AND SALPINGECTOMY DUE TO MIGRATION AND PERFORATION FROM ESSURE COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043529	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVER HIP PAIN WHERE I CAN'T MOVE. MY PERIODS ARE COMPLETELY HORRIBLE TERRIBLE CRAMPS. HEADACHES, MOOD SWINGS, TERRIBLE ACNE. I SEEM TO GET BRUISES OUT OF NO WHERE. AND PAIN IN BETWEEN PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043530	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CONSISTENTLY HAVE PAIN IN MY LOWER ABDOMEN. ONLY AT MID CYCLE BUT EVERY MONTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043531	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 10/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WOKE UP IN SEVERE PAIN JUST LIKE AFTER THE ESSURE PROCEDURE. I WENT TO 6 ERS AND 3 DRS. TO BE TOLD I HAD KIDNEY INFECTION, CYST . BECAUSE NO DRS WANTED TO BE RESPONSIBLE FOR REMOVING THE COILS SINCE THEY DIDN'T PUT THEM IN. FINALLY AFTER 3 MONTHS OF SEVERE PAIN AND BEING DIAGNOSED WRONG . FOUND A HOSPITAL THAT ACTUALLY CARED. HAD THE FIRST SURGERY TO SEE IF THE COILS COULD BE FIXED. RIGHT COIL IN UTERUS AND LEFT COIL BUSTING OUT OF TUBE. SO I HAD TO BE SCHEDULED FOR A HYSTERECTOMY AT THE AGE OF (B)(6)!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043532	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 9/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY MENSTRUAL CYCLE, EXTREME PAIN IN LOWER BACK AND LEFT SIDE MUSCLE SPASMS. DIZZY SPELLS THAT I COMPARE TO MOTION SICKNESS THAT HAS LASTED 12 HOURS +. BLOATING, HAIR LOSS AND WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043533	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS PLACED IN 2009/2010. I HAVE BEEN HAVING LOTS OF ISSUES OVER LAST 3 YEARS. THINKING IT WAS HORMONAL I HAD LABS ALL CHECKED AND ALL CAME BACK NORMAL. I HAD MY LEFT OVARY REMOVED WITH FALLOPIAN TUBE AND COIL DUE TO A HUGE DERMOID CYST BUT I CONTINUE TO HAVE CRAMPING, IRREGULAR CYCLES, HEADACHES, JOINT PAIN AND STIFFNESS, CHRONIC FATIGUE, WEIGHT GAIN AND INABILITY TO LOSE IT. ALSO MEMORY LOSS AND BRIAN FOG. SHORT TERM MEMORY LOSS. ABDOMINAL PAIN AND DISCOMFORT DURING INTERCOURSE. DECREASED LIBIDO, NIGHT SWEATS AND HOT FLASHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043535	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN LOWER ABDOMEN. HEAVY BLEEDING. BLOOD CLOTS THE SIZE OF SILVER DOLLARS. NO PERIOD OR PERIOD FOR MONTHS ON END. ELECTRICAL ZAPS IN LOWER ABDOMEN. BLEEDING DURING INTERCOURSE. PCOD. OVARIAN CYSTS. HEADACHES. NAUSEA. LACK OF ENERGY. DIZZY SPELLS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043536	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 4/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I HAD GOTTEN THE ESSURE, THERE WERE NO PROBLEMS BESIDES THE PAIN OF IT ACTUALLY BEING PUT IN. IT HURT WORSE THAN THE ACTUAL LABOR/CHILD BIRTHING I WENT THROUGH WITH ALL THREE OF MY CHILDREN. FOR ALMOST A YEAR, NO WORRISOME SYMPTOMS. BESIDES THE EXTREMELY HEAVY PERIODS, SEVERE CRAMPING, HAVING THE FEELING OF JUST GIVEN BIRTH AND PELVIC PAINS. THEN, THE SYMPTOMS BEGAN AT ABOUT A YEAR AFTER INSERTION. THE DAY BEFORE MY PERIOD, I FEEL LIKE DEATH SO MUCH AS TO WHERE I CAN'T EVEN GET OUT OF BED. I CAN'T EVEN SEE PARTIALLY SOMETIMES. SEX IS SOMETIMES TOO PAINFUL TO EVEN CONTINUE. MY LEFT LOWER ABDOMEN AND LEFT HIP REGION IS CONSTANTLY IN PAIN. I HAVE NUMBNESS AT TIMES, TINGLING, EXCRUCIATINGLY SHARP PAINS AS IF BEING HIT WITH A SHARP OBJECT IN THAT REGION. I CONSTANTLY FEEL AS THOUGH I AM FIGHTING THE FLU OR A HEAD COLD. NAUSEA, VOMITING, FATIGUE ALMOST EVERYDAY. HEADACHES STARTED TO OCCUR WHICH TURNED INTO MIGRAINES WITH BLURRY VISION AND DIZZINESS. I AM MOTHER OF THREE AND ALSO A SUBSTITUTE TEACHER AND CAN HAVE NONE OF THE NEUROLOGY THINGS GOING ON WHEN I AM TRYING TO STAY ON THE RIGHT TRACK AS A MOTHER AND A TEACHER. AND SO, I PLEADED WITH MY DOCTOR TO PLEASE PLEASE PLEASE LISTEN! HE FINALLY SENT ME TO A RHEUMATOLOGIST AND ALSO A NEUROLOGISTS IN WHICH THEY ARE STILL RUNNING TESTS. SO FAR I HAVE BEEN DIAGNOSED WITH INCOMPLETE LUPUS, RHEUMATOID ARTHRITIS AND AN AUTO IMMUNE DISEASE. I BELIEVE IN MY HEARTS OF HEARTS THAT IT IS THE ESSURE. I BELIEVE THAT YOUR BODY IS CONSTANTLY TRYING TO FIGHT OFF SOMETHING IT DOES NOT AGREE WITH AND THEREFORE, PUTTING YOUR SYSTEM INTO OVERDRIVE, YOU START TO OCCUR THESE SYMPTOMS. MY DOCTOR HAS AGREED TO DO A FULL HYSTERECTOMY TO RELIEVE ME OF SOME PAIN. BUT, BECAUSE OF ESSURE, I AM STUCK WITH DEBILITATING AND POSSIBLY LIFE TIME DISEASES.

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Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043552	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/18/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OVER THE COURSE OF THE PAST 12 YEARS I HAVE SUFFERED MANY MEDICAL ISSUES THAT FOR A LONG TIME I COULD NOT PINPOINT THE CAUSE NOR COULD ANY DOCTOR. WORST OF THESE HAS BEEN HEADACHES. HEADACHES THAT WENT ON FOR DAYS AND INVOLVED MUSCLE SPASMS OF THE NECK AND UPPER BACK WITH NO RELIEF. FINALLY I HAD TO START GOING TO THE ER FOR HELP. TRYING VARIOUS MEDICATIONS AND PHYSICAL THERAPY, CHIROPRACTOR AND MUSCLE MASSAGE. I HAVE SEEN A NEUROLOGIST FOR VARIOUS SYMPTOMS INCLUDING THE HEADACHES. OTHER SYMPTOMS I HAVE EXPERIENCED ARE INSOMNIA, BODY ACHES AND PAIN, HEART PALPITATIONS, BRAIN FOG, DIZZINESS, DRY EYES, FACE PAIN AND TEETH/GUM PAIN, EXCESSIVE SWEATING INCLUDING NIGHT SWEATS, FATIGUE, GASTROINTESTINAL ISSUES INCLUDING , EXCESSIVE GAS, HEART BURN AND CONSTIPATION, IRREGULAR PERIODS, YEAST INFECTIONS, TINGLING NUMBNESS IN HANDS AND ARMS, BRAIN SHOCKS, TINNITUS, ACNE, HIGH BLOOD PRESSURE AND REYNAUD'S SYNDROME. I HAVE HAD MRI'S, X-RAYS, BLOOD TESTS OF ALL KINDS, PHYSICAL THERAPY MORE THAN ONCE, NUMEROUS TRIPS TO A CHIROPRACTOR AND WEEKLY MASSAGE AND AS OF RIGHT NOW I AM SEEING A PAIN MANAGEMENT DOCTOR WHO HAS NOT BEEN ABLE TO ALLEVIATE MY PAIN FOR MORE THAN A WEEK. ONE OF MY ESSURE COILS WAS MISSING FROM LEFT FALLOPIAN TUBE WHEN I UNDERWENT SURGERY IN (B)(6) 2015 TO HAVE THEM REMOVED. AFTER MORE X RAY BEING TAKEN IT WAS DISCOVERED TO BE LODGED IN THE LEFT SIDE HIGH IN MY HIP BONE AREA CURLED IN ON ITSELF. I HAD FURTHER SURGERY IN (B)(6) 2015 TO HAVE THIS REMOVED. IT CAME OUT IN THREE PIECES. I ALSO FOUND OUT THAT I HAVE A PROLAPSE UTERUS, FIBROIDS AND ENDOMETRIOSIS WHICH SEEMS IS COMMON IN WOMEN WHO HAVE ESSURE. BECAUSE OF PET FIBERS I WILL PROBABLY SUFFER WITH SOME OF MY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

SYMPTOMS THE REST OF MY LIFE. I HAD THEM INSERTED IN A HOSPITAL OR AND HAD THE FOLLOW UP HSG TEST DONE 3 MONTHS LATER WITH 100% BLOCKED. I DID MY PART BUT ESSURE FAILED ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043553	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 11/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN STABBING PAIN IN RIGHT SIDE. MY SIDE CONSTANTLY ACHES AND RADIATES DOWN TO MY FEET IN MY PELVIC AREA RIGHT WHERE THE ESSURE IS LOCATED. CONTINUOUS PERIODS, 2 A MONTH. VERY PAINFUL PERIODS NOW. MORE LETHARGIC, LESS SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043554	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE CRAMPS, NAUSEA, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043556	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 9/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I NOW HAVE TERRIBLE PERIODS WITH MAJOR CLOTTING AND LOSS OF BLOOD. SOME HAIR LOSS AND STOMACH THAT HAS BEEN PERMANENTLY BLOATED SINCE THE INSERTION OF THE ESSURE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043558	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MAJOR BLEEDING (EVERY 2 WEEKS), CRAMPING, BLOATING, LONG PERIODS (SOMETIMES 6 WEEKS), HEADACHES, MAJOR WEIGHT GAIN, PAINFUL SEX, EXTREME FATIGUE AND INSOMNIA. I AM ALLERGIC TO NICKEL AND WAS NOT TOLD IT CONTAINED NICKEL. ADENOMYOSIS. HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043560	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 3/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING DURING MENSTRUAL PERIOD GOT INCREASINGLY HEAVIER, STARTED PASSING LARGE BLOOD CLOTS (SOME THE SIZE OF A TAMPON), EXCRUCIATING PAIN DURING MENSTRUAL PERIOD, PAIN DURING INTERCOURSE, OVERALL TENDERNESS IN ABDOMEN/GENITAL AREAS, DEPRESSION, WEIGHT GAIN. DEVELOPED ENDOMETRIOMA AND REQUIRED TO SCHEDULE A FULL HYSTERECTOMY TO SOLVE ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043561	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN (B)(6) OF 2014 A MONTH AFTER GETTING THE ESSURE COILS PLACED I STARTED HAVING REALLY BAD DEPRESSION AND ANXIETY. ALSO PELVIC PAIN AND CONSTANT BLEEDING FOR OVER 3 MONTHS STRAIGHT. I HAD TO BE PUT ON SEVERAL ANTIDEPRESSANTS AND GO TO COUNSELING. I'VE ALSO GAINED 50LBS SINCE THEY WERE PLACED. AND WHEN I WENT TO GO MAKE SURE THEY WERE PROPERLY PLACED MY LEFT ONE IS NOT PROPERLY PLACED. THE OBGYN WHO PUT THEM IN REFUSED TO REMOVE THEM. I'M ALSO CURRENTLY EXPERIENCING HORRIBLE MIGRAINES WITH NO PREVIOUS HISTORY OF HEADACHES. MY VISION HAS ALSO BEEN DETERIORATING, BEFORE ESSURE I HAD 20/20 VISION. NOW I WEAR PRESCRIPTION GLASSES. I'M VERY DISSATISFIED WITH THIS PRODUCT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043568	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE GETTING ENSURE IN 2016. HAVE HAD EXTREME PELVIC CRAMPS INCLUDING SHARP SHOOTING PAINS. EXTRA HEAVY PERIODS WITHIN CLOTS. PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043572	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES...STOMACH PAINS AND CRAMPING...SHARP PAIN IN LEFT LOWER ABDOMEN..BLEEDING AND PAIN AFTER SEX...VERY TIRED...MOODINESS...DEPRESSION...HEARTBURN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043576	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, CHRONIC BLOATING, HAIR LOSS, UNEXPLAINED WEIGHT GAIN, HEART PALPITATIONS, GASTRO INTESTINAL ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043581	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 3/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE FIRST COUPLE OF DAYS AFTER GETTING ESSURE WERE FINE, BUT THEN IT GOT WORSE. FATIGUE, HIP AND ANKLE PAIN, RIDICULOUSLY BLOATED TUMMY, MOOD SWINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043586	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN THAT LEAVES ME HELPLESS (UNABLE TO GET OUT OF BED OR BRINGS ME TO MY KNEES WHEN THE SUDDEN STABBING PAIN HAPPENS), SERIOUS MOOD SWINGS (CRYING ONE MINUTE, LAUGHING THE NEXT TO SCREAMING THEREAFTER), HAIR LOSS, BODY ACHES, BACK PAIN, CONTINUED BLEEDING, VAGINAL DISCHARGE, BLOATING, WEIGHT GAIN, HEADACHES, CONSTANT FATIGUE (FEELS LIKE I NEVER SLEEP NO MATTER HOW MUCH SLEEP I ACTUALLY GET).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043588	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 12/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GET HIVES OFTEN THAT BOTH ITCH AND BURN. JOINT PAIN AND NUMBNESS. A LOT OF BLOATING THAT MAKES ME LOOK LIKE I AM 9 MONTHS PREGNANT. PROBLEMS WITH MY TEETH LIKE DECAY. TIRED ALL THE TIME WITH VITAMIN D AND B12 DEFICIENT. I GET SICK A LOT MORE THAN I EVER DID BEFORE. SUFFER FROM DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043589	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPS, PELVIC PAIN, PAINFUL INTERCOURSE, BACK PAIN, HEADACHES, DIZZINESS, VISION CHANGES, HEAVY BLEEDING, BREAST PAIN, AND LACTATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043590	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 12/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAVE EXPERIENCED MULTIPLE SIDE EFFECTS AND SYMPTOMS SINCE RECEIVING THIS PROCEDURE. I SUFFER CHRONIC DAILY MIGRAINES, INABILITY TO MAINTAIN DAILY ESSENTIAL VITAMINS, UNABLE TO REGULATE POTASSIUM, CALCIUM, AND FOLIC ACID LEVELS EVEN WHILE ON MEDICINE, FAINTING SPELLS, DIZZY SPELLS, MUSCLE WEAKNESS, MUSCLE SPAMS, NUMBNESS AND TINGLING OF FINGERS, TOES, AND JAW, SHORT TERM MEMORY LOSS, EXTREME FATIGUE, ABDOMINAL PAIN, IRRITABILITY, MOOD SWINGS, VISION IMPAIRMENT, DEPRESSION, AND THE WORST OFFENDER BEING A CYST IN THE CENTER OF MY BRAIN BETWEEN THE PITUITARY AND PINEAL AREAS OF THE BRAIN! THESE ARE JUST SOME OF THE THINGS I SUFFER FROM DAILY! I WAS IMPLANTED IN 2012 AND JUST STARTED EXPERIENCING ALL OF THIS IN (B)(6) OF 2014! BEFORE THIS I WAS HEALTHY AND ATHLETIC EXCEPT DURING MY PREGNANCIES WHEN I WAS DIAGNOSED WITH HYPEREMESIS GRAVIDARUM. I HAVE 2 KNOWN ALLERGIES TO LATEX AND BERRIES. MY BLOOD PRESSURE IS CONSTANTLY LOW AROUND 86/60 AND MY POTASSIUM IS CONSISTENTLY SITTING AT A 3 AND LOWER DESPITE BEING ON 10 MEQ 4 TIMES DAILY. AND THEY FOUND THE CYST IN (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043591	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 11/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED OUT AS JUST ELONGATED PERIODS AND BAD ACNE, BUT LED TO A CYST REMOVAL SURGERY; DEBILITATING PAIN IN MY GROIN/LOWER ABDOMEN; MONTH LONG PERIODS WITH ONLY A FEW DAYS OF RELIEF BETWEEN; THICK, HEAVY PERIODS; COLLAPSING RANDOMLY; DIZZY SPELLS; INSOMNIA; FORGETFULLNESS; BRAIN FOG; HAIR FALLING OUT ON MY HEAD; PUBIC HAIR GROWING BEHIND MY KNEES AND IN THICK PATCHES ON MY THIGHS; FACIAL HAIR; WEIRD RASHES ON MY ARMS AND LEGS THAT WOULD COME WITH NO WARNING AND GO AWAY ON THEIR OWN; TEETH CRUMBLING; STROKE LIKE SYMPTOMS; ALLERGIES TO MY JEWELRY; FATIGUE; DEPRESSION; EXTREME MIGRAINES THAT IMPACTED MY VISION; LACK OF SEX DRIVE; SHARP PAIN DURING INTERCOURSE; MOODINESS; LACK OF MOTIVATION; WEAKER IMMUNE SYSTEM; REDUCED TO TEARS IN FRONT OF THE DOCTOR FROM SO MUCH PAIN WHEN SHE WOULD DO MY PELVIC EXAMS; ENDING WITH A HYSTERECTOMY IN THE SUMMER OF 2014. I WAS TO THE POINT WHERE I WAS TAKING A VICADEN ABOUT ONCE A WEEK JUST TO GET COMFORTABLE ENOUGH TO SLEEP FOR A FEW HOURS. AFTER MY HYSTERECTOMY, I NEVER EVEN GOT THE PAIN MEDS FILLED OUT BECAUSE SO MUCH OF MY PAIN WAS ALREADY ALLEVIATED. MOST OF MY SYMPTOMS HAVE GONE AWAY AT THIS POINT. MY HAIR'S GROWN BACK IN, MY SKIN'S CLEARED UP, MY MIGRAINES HAVE SETTLED DOWN, AND WHILE A LOT OF MY MEMORY IS STILL FUZZY, MY FOCUS IS BACK AND I CAN THINK AGAIN. I DON'T HAVE THE PAIN ANYMORE AND CAN ENJOY TIME WITH MY HUSBAND ONCE MORE. MY KIDS HAVE TOLD ME THEY'RE HAPPY I'M NOT SICK ANYMORE AND CAN PLAY AGAIN.

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Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043592	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER THE IMPLANTATION OF THE DEVICE IN (B)(4) 2009 I HAVE HAD A MYRIAD OF HEALTH ISSUES BOTH DIAGNOSED AND COMPLETE MYSTERIES. PELVIC PAIN AND TENDERNESS, ABDOMINAL SWELLING AND BLOATING, SYSTEMIC PAIN AND INFLAMMATION, DIZZINESS, COGNITIVE ISSUES, EXTREME FATIGUE, NUMBNESS AND TINGLING IN MY EXTREMITIES, INCONTINENCE, AS WELL AS NIPPLE DISCHARGE AND PAINFUL GASTRO- RELATED ISSUES. I HAVE BEEN DIAGNOSED WITH FIBROMYALGIA, IBS, GASTRITIS, GERD, STOMACH ULCERS, GALACTORRHEA, PYELONEPHRITIS, VERTIGO, DEPRESSION, ANXIETY, OCULAR MIGRAINES, CARPEL TUNNEL, ULNAR NEUROPATHY AND DYSAUTONOMIA. THAT IS THE SHORT LIST. I HAVE HAD SEVERAL SURGERIES AS WELL AS ENDURED MANY HOSPITALIZATIONS. I SEE MY PRIMARY CARE PHYSICIAN A NEUROLOGIST, A GASTROENDEROLIGIST AND A CHIROPRACTOR REGULARLY. I HAVE BEEN TO MANY MANY SPECIALIST, I WAS EVEN SENT TO AN ONCOLOGIST BECAUSE MOST EVERYTHING HAD BEEN RULED OUT AND NO ONE KNEW WHAT WAS WRONG WITH ME. IT WOULD BE NEARLY IMPOSSIBLE TO INCLUDE MY MEDICAL AND LAB DATA AS IT IS SO EXTENSIVE. IT TOOK APROXIMATLY 12-18 MONTHS FOR THE PROBLEMS/SYMPTOMS TO WORSEN TO THE POINT THAT THEY WERE EFFECTING MY DAILY LIFE. I HAVE RECENTLY DISCOVERED THAT MOST OF THE ABOVE IS ENDURED BY MANY WOMEN THAT WERE IMPLANTED WITH THE ESSURE DEVICE. I BELIEVE THAT THE NICKEL, AS WELL AS THE PET FIBERS THAT ARE IN ESSURE ARE THE CAUSE OF MANY OF MY HEALTH CONDITIONS. I WAS NEVER TESTED FOR NICKEL HYPERSENSITIVITY/ALLERGY BEFORE IMPLANTATION. MY GYNOCOLOGIST HAS SCHEDULED ME FOR A HYSTERECTOMY TO REMOVE THE DEVICE IN JUNE (2015) AND ANY AND ALL TISSUE THAT MAY HAVE COME IN CONTACT WITH IT. DURING REMOVAL, SHE WILL BE ABLE TO ASSESS ANY INTERNAL DAMAGE AND INFLAMMATION, AND BE ABLE TO TELL IF THEY WERE PLACED CORRECTLY, ARE INTACT OR HAVE MIGRATED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

TRYING TO STAY WITH DOCUMENTED FACTS BUT I CAN NOT NEGLECT TO EXPRESS HOW ALL OF THE ABOVE CONDITIONS HAVE MADE MY DAILY LIFE ALMOST UNMANAGEABLE. CONSTANT PAIN, HOURS IN A BATHROOM, LOSING VISION WHILE I'M DRIVING, FALLING AND HURTING MYSELF, THE FATIGUE AND WEAKNESS, TRYING TO FIND ANSWERS AND GIVING UP WHEN THERE WERE NONE TO BE FOUND, ONLY TO START THE SEARCH AGAIN WHEN SOMETHING THAT I COULD NOT MANAGE HAPPENS LIKE HIGH FEVERS, INFECTIONS, INTENSE PAIN. I ALSO HAVE TO INCLUDE EMBARRASSMENT, HUMILIATION, ALIENATION, DESPERATION, DISAPPOINTMENT, AND THE HOPELESSNESS THAT ACCOMPANIES ALL OF THE ABOVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043594	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 7/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NIGHT SWEATS, BACTERIAL VAGINITIS, MORE YEAST INFECTIONS, PELVIC PAIN, CRIPPLING ABDOMINAL CRAMPS AND BURNING, FREQUENT HEADACHES, PERIODS BECAME IRREGULAR (LATE, EARLY, LONGER, SHORTER). PRIOR TO ESSURE, I'D ALWAYS HAD A 28 DAY CYCLE, NEVER LATE UNLESS PREGNANT. NOW I'M 26, 25, 23, 20 AND 32. METALLIC TASTE IN MY MOUTH, DIZZINESS, NIPPLE DISCHARGE W/O STIMULATION, LOWER BACK PAIN, MY RIGHT THIGH UNDER MY CHEEK CONSTANTLY ACHES SINCE ABOUT A WEEK AFTER THE PROCEDURE, I FEEL POKING/PRICKS ON EITHER SIDE (WHERE THE COILS ARE), FORGETFUL, AND JUST THIS PAST YEAR I'VE HAD BREAKOUTS IN DIFFERENT PLACES, SEVERE BODY ACHES AT NIGHT (ABDOMEN, LOWER BACK AND LEGS). I'VE HAD SEVERAL FILLINGS PLACED IN MY TEETH, 4 TEETH EXTRACTED DUE TO SEVERE DECAY AND 3 CHIPS REPAIRED. THE DENTAL WORK IS ON GOING. (PRIOR TO ESSURE I'VE ALWAYS HAD GREAT DENTAL EXAMS AND HEALTHY TEETH AND GUMS). THESE PAST FEW MONTHS I'VE BEEN EXPERIENCING PAINFUL PERIODS (PRIOR TO ESSURE TO, I ONLY HAD MINOR BREAKOUTS ON MY FACE, CRAVINGS AND MINOR BACK ACHE) NEVER HAVE I EVER SUFFERED SEVERE PMS SYMPTOMS OR CRAMPS NOT EVEN SLIGHT ONES. EXCESSIVE VAGINALLY DISCHARGE BOTH ODOR AND ODORLESS. (B)(6) 2014 I HAD A MISCARRIAGE AFTER JUST BARELY REALIZING I WAS PREGNANT (ABOUT 6 WEEKS). HEARTBURN IS ALMOST DAILY. I SIGNED UP TO PREVENT FUTURE PREGNANCIES NOT BECOME CRIPPLE TO THESE DEVICES. I'VE ALWAYS BEEN ACTIVE AND ATHLETIC AND MOST DAYS I FEEL LIKE I'M AGING RAPIDLY. MY WEIGHT IS UP AND DOWN, MY ABDOMEN IS ALWAYS BLOATED AND I'M FLATULENT MOST OF THE TIME. MY MOODS ARE UP AND DOWN BECAUSE MY "FEEL GOOD" DAYS ARE UP AND DOWN. I WANT THESE THINGS OUT AND I WANT MY LIFE AND HEALTH BACK. PLEASE, HELP US.. (ALL ESSURE VICTIMS)!

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043604	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 12/13/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I IMMEDIATELY STARTED BLEEDING VAGINALLY FOR ABOUT 6 MONTHS. MY DR COULDN'T STOP THE BLEEDING SO SHE PRESCRIBED SEVERAL HIGH DOSES OF BIRTH CONTROL PILLS. FOR LAST 8 YEARS I'VE HAD SYMPTOMS SUCH AS RECURRENT YEAST INFECTIONS, FATIGUE, PELVIC FLOOR PAIN, BRAIN FOG, MEMORY PROBLEMS, HEAVY PERIODS PASSING BIG CLOTS, EYE VISION PROBLEMS, AND DENTAL DECAY. I'VE VISITED SEVERAL DOCTORS LOOKING FOR ANSWERS BUT NOBODY HAS BEEN ABLE TO FIGURE OUT MY SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043605	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT TIMES I WILL HAVE SO MUCH PAIN I DROP DOWN TO MY KNEES. SOME TIMES IT KEEPS ME FROM SLEEPING DUE TO SHARP PAINS. ALSO MY TEETH HAVE BEEN GETTING BAD. I AM ALLERGIC TO NICKLE AND WELL I HAVE BEEN GETTING RASHES OFF AND ON. HAIR LOSS THE BLOATING OFF AND ON. I CANT LOSE WEIGHT NO MATTER WHAT I DO. I DONT HAVE THE ENERGY I USED TO HAVE. DIZZY ALL THE TIME ANYMORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043606	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STOMACH PAIN, UNUSUAL BLEEDING, HEAVY PERIODS, HEADACHE, NAUSEA AND LEG DISCOLORATION LIKE A RASH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043607	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THERE IS NO SET DATE TO START WITH WHEN SIDE EFFECTS STARTED. ESSURE PLACED IN (B)(6) OF 2009. THE LIST OF SIDE EFFECTS ARE: LOSS OF SEX DRIVE!, MY BELLY AREA ALWAYS FEELS HEAVY AND ANNOYING, BLOATING OF THE BELLY, HAIRLOSS, VERY DRY SKIN AND ESPECIALLY MY HANDS THEY CRACK ALL THE TIME AND ALWAYS NEED TO HAVE LOTION WITH, EVERY FEW MONTHS I GET A ITCHY RASH ALL OVER AND SHED SKIN. THIS WAS REALLY BAD IN (B)(6) OF 2011. I HAD TO USE TOPICAL CREAMS FOR THE UNBEARABLE ITCH AND WAS ON PRETNISONE. MY WHOLE BODY WAS SHEDDING SKIN. MY TEETH ARE GETTING WORSE AND HAVE THE TASTE OF METAL A LOT. ALSO TINGLING HANDS AND GOING NUMB LATER IN THE EVENING. ENERGY LEVEL IS NOT WHERE I WANT TO BE, YES I DO GO TO THE GYM TO WORK OUT. I WOULD SAY ONE OF THE WORST ONES TO ME IS THE WAY MY BELLY AND LOWER AREA FEELS. I HAVE A UNDERSTANDING HUSBAND, BUT I FEEL HORRIBLE ABOUT HAVING NO SEX DRIVE AT ALL. IT IS IMPORTANT TO STAY CONNECTED TOGETHER AND I FEEL ESSURE TOOK THAT AWAY. BECAUSE OF INSURANCE AND WHAT WE HAVE TO PAY OUT OF OUR OWN POCKET I HESITATE TO GO SEE A GYNECOLOGIST BECAUSE WE CANT EFFORT IT RIGHT NOW. AS SOON AS I CAN I WANT MY HAPPY LIFE AND BODY BACK. THIS DEVICE MEANS I HAVE A SPRING MADE OF HARMFUL NICKEL IN MY BODY AND PET FIBERS. I REALLY WISH I NEVER HAD THIS IMPLANTED, IT HAS TAKEN A LOT OF SPECIAL MOMENTS AWAY FROM ME. PLEASE EDUCATE ON THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043608	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC EXCRUCIATING PAIN ON LEFT SIDE, EXCRUCIATING MENSTRUAL CYCLES, HEAVY BLEEDING AND CLOTTING, NIGHT SWEATS, INSOMNIA, VOMITING, UNABLE TO WORK AND CARE FOR MY FAMILY REGULARLY, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043609	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES.NAUSEA.PELVIC PAIN, WEAKNESS, TINGLY LIMBS, DIVERTICULITIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043610	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STOMACH PAIN, UNUSUAL BLEEDING, HEAVY PERIODS, HEADACHE, NAUSEA AND LEG DISCOLORATION LIKE A RASH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043611	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 12/13/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I IMMEDIATELY STARTED BLEEDING VAGINALLY FOR ABOUT 6 MONTHS. MY DR COULDN'T STOP THE BLEEDING SO SHE PRESCRIBED SEVERAL HIGH DOSES OF BIRTH CONTROL PILLS. FOR LAST 8 YEARS I'VE HAD SYMPTOMS SUCH AS RECURRENT YEAST INFECTIONS, FATIGUE, PELVIC FLOOR PAIN, BRAIN FOG, MEMORY PROBLEMS, HEAVY PERIODS PASSING BIG CLOTS, EYE VISION PROBLEMS, AND DENTAL DECAY. I'VE VISITED SEVERAL DOCTORS LOOKING FOR ANSWERS BUT NOBODY HAS BEEN ABLE TO FIGURE OUT MY SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043612	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THERE IS NO SET DATE TO START WITH WHEN SIDE EFFECTS STARTED. ESSURE PLACED IN (B)(6) OF 2009. THE LIST OF SIDE EFFECTS ARE: LOSS OF SEX DRIVE!, MY BELLY AREA ALWAYS FEELS HEAVY AND ANNOYING, BLOATING OF THE BELLY, HAIRLOSS, VERY DRY SKIN AND ESPECIALLY MY HANDS THEY CRACK ALL THE TIME AND ALWAYS NEED TO HAVE LOTION WITH, EVERY FEW MONTHS I GET A ITCHY RASH ALL OVER AND SHED SKIN. THIS WAS REALLY BAD IN (B)(6) OF 2011. I HAD TO USE TOPICAL CREAMS FOR THE UNBEARABLE ITCH AND WAS ON PRETNISONE. MY WHOLE BODY WAS SHEDDING SKIN. MY TEETH ARE GETTING WORSE AND HAVE THE TASTE OF METAL A LOT. ALSO TINGLING HANDS AND GOING NUMB LATER IN THE EVENING. ENERGY LEVEL IS NOT WHERE I WANT TO BE, YES I DO GO TO THE GYM TO WORK OUT. I WOULD SAY ONE OF THE WORST ONES TO ME IS THE WAY MY BELLY AND LOWER AREA FEELS. I HAVE AN UNDERSTANDING HUSBAND, BUT I FEEL HORRIBLE ABOUT HAVING NO SEX DRIVE AT ALL. IT IS IMPORTANT TO STAY CONNECTED TOGETHER AND I FEEL ESSURE TOOK THAT AWAY. BECAUSE OF INSURANCE AND WHAT WE HAVE TO PAY OUT OF OUR OWN POCKET I HESITATE TO GO SEE A GYNECOLOGIST BECAUSE WE CANT EFFORT IT RIGHT NOW. AS SOON AS I CAN I WANT MY HAPPY LIFE AND BODY BACK. THIS DEVICE MEANS I HAVE A SPRING MADE OF HARMFUL NICKEL IN MY BODY AND PET FIBERS. I REALLY WISH I NEVER HAD THIS IMPLANTED, IT HAS TAKEN A LOT OF SPECIAL MOMENTS AWAY FROM ME. PLEASE EDUCATE ON THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043613	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/13/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY MENSTRUATION, EXCESSIVELY LARGE CLOTS, BACK PAIN, MENTAL FOG, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043614	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 2/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DAY I GOT ESSURE I HAD SEVERE PELVIC PAIN BUT PRIOR TO GETTING ESSURE MY DR KNEW I HAD A NICKEL ALLERGY AND SHE TOLD ME THERE WAS NO NICKEL IN ESSURE AND NOW A YEAR LATER ITS MOVING INTO MY UTERUS AND IM HAVING A LOT OF ISSUES STILL SEVERE PELVIC PAIN, I HEADACHE FOR 9 MONTHS STRAIGHT AND NOW I HAVE VERTIGO I HAVE TO HAVE A HYSTERECTOMY TO REMOVE EVERYTHING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043615	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 1/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT UTI'S, PELVIC PAIN, CLOTTING WHEN ON MENSTRUAL CYCLE, HEAVY PERIODS, ANXIETY, FAINTING SPELLS, CONSTANTLY HAVING BV, MOOD SWINGS, WEIGHT GAIN IN RAPID TIME, JOINT PAIN IN WRIST, TINGLING SENSATION AND PAIN DOWN RIGHT LEG, PAINFUL INTERCOURSE, CHRONIC FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043616	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 8/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAINS OFF AND ON. RANDOM OUT OF THE BLUE. SEVERE BLEEDING UP TO 20 DAYS OUT OF THE MONTH. LOW BACK JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043617	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 1/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVERYTHING WAS GOING FINE, UNTIL LAST SUMMER, WHEN ALL THE SYMPTOMS OF PAIN, FATIGUE, LACK OF ENERGY, BACK PAIN, HAIR LOSS AND WEIGHT GAIN. I'M TIRED OF IT BUT I DON'T HAVE THE MONEY TO GET THEM REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043618	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT TIMES I WILL HAVE SO MUCH PAIN I DROP DOWN TO MY KNEES. SOME TIMES IT KEEPS ME FROM SLEEPING DUE TO SHARP PAINS. ALSO MY TEETH HAVE BEEN GETTING BAD. I AM ALLERGIC TO NICKLE AND WELL I HAVE BEEN GETTING RASHES OFF AND ON. HAIR LOSS THE BLOATING OFF AND ON. I CANT LOSE WEIGHT NO MATTER WHAT I DO. I DONT HAVE THE ENERGY I USED TO HAVE. DIZZY ALL THE TIME ANYMORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043619	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 7/25/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ON MY RIGHT SIDE. FELT A "KNOT" NEAR MY RIGHT OVARY. IT HAS NEVER STOPPED SINCE THAT DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043620	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BREAKING OUT IN HIVES ALL OVER MY BODY, I ALSO HAVE SEVERE CRAMPING IN MY OVARY AREA AND MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043621	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SKIN RASHES, ALLERGIC REACTION TO NICKEL. ONGOING HAIR LOSS, BLOATING, HEAVY PERIODS W/BLOOD CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043622	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 12/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SHARP STABBING PAIN, DISCHARGE, BACK AND LEG PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043623	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 12/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP STABBING PAIN PELVIC, DISCHARGE, BACK AND LEG PAIN, HEARTBURN, HEADACHES, MIGRAINES, DIZZINESS, TINGLING SENSATIONS IN MY HEAD, ANXIETY, MOOD SWINGS, UNEXPLAINED EASILY BRUISING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043624	BAYER	7/7/2015	7/7/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO HAVE MY FALLOPIAN TUBES AND ESSURE COILS REMOVED. THE ESSURE COILS CAUSED A RANDOM PINCHING SENSATION IN BOTH MY TUBES. I ALSO HAD EXTREME BLOATING, WEIGHT GAIN, AND UNEXPLAINED FEVERS WITH THIS DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00473	BAYER HEALTHCARE LLC	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 5/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/28/2011
Explant Date (E7): 6/14/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2011 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION RECEIVED ON 10-MAY-2011 AND 07-OCT-2011. ON 07-OCT-2011 THE CASE WAS UPGRADED TO INCIDENT. STUDY DESCRIPTION: STUDY (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 01 CHILD, 02 ELECTIVE ABORTIONS, AND MENSTRUAL PAIN. MEDICATION AT TIME OF INSERTION INCLUDED COMBINED PILL. HER LAST MENSTRUAL PERIOD BEFORE INSERTION OCCURRED ON (B)(6) 2011. ON (B)(6) 2011 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS EASILY IMPLANTED. ANALGESICS AND NSAID (NON-STEROID ANTI-INFLAMMATORY DRUG) WERE USED AS PREMEDICATION. THE CONDITION OF UTERINE CAVITY (ENDOMETRIUM) WAS HYPERTROPHIC AND SHOWED ADENOMYOSIS. UTERUS WAS NOT RETROVERTED. VISUALIZATION OF OSTIUM WAS GOOD BILATERALLY. THE PROCEDURE WAS STARTED ON LEFT SIDE. AT THE END OF PROCEDURE SHE HAD 1 COIL EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND 6 COILS ON RIGHT SIDE. THE PROCEDURE TOOK 11 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. NO ADDITIONAL PROCEDURE WAS PERFORMED AT THE SAME TIME. VASOVAGAL SYNCOPE WAS DENIED. PATIENT PRESENTED PAIN DURING INSERTION AND AFTER THE PROCEDURE. SHE USED POSTOPERATIVE ANALGESICS. MINIPILL WAS USED AFTER PLACEMENT AND BEFORE CONFIRMATION TEST. ON (B)(6) 2011, DURING CONSULTATION, PATIENT REPORTED POSTOPERATIVE PAIN/CRAMPS AND BLEEDING. RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS WERE NOT SYMMETRIC POSITIONED; THE

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DISTANCE BETWEEN PROXIMAL PORTIONS WAS LESS THAN 4 CM AND FOUR MARKERS WERE WELL PLACED. AT ULTRASOUND RIGHT INSERT WAS SEEN FROM THE CAVITY TO THE HORN IN GOOD POSITION. LEFT SIDE WAS NOT IN GOOD POSITION. INVESTIGATOR CONSIDERED THE FINAL RESULT OF PROCEDURE AS FAILURE DUE TO ABDOMINAL MIGRATION, PROBABLE TUBAL PERFORATION. ON (B)(6) 2011 A LAPAROSCOPY UNDER GENERAL ANESTHESIA WAS PERFORMED AND SHOWED INSERTS WERE NORMALLY PLACED (NO PERFORATION).TOTAL SALPINGECTOMY ON THE RIGHT SIDE AND PARTIAL SALPINGECTOMY ON THE LEFT WITH REMOVAL OF THE 2 INSERTS WAS DONE. ADDITIONAL INFORMATION RECEIVED ON 03-APR-2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY (B)(4) AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: FALLOPIAN TUBE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. (B)(4) IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT CONTROL CONSULTATION, THERE WAS A SUSPICION OF ABDOMINAL MIGRATION, PROBABLE TUBAL PERFORATION OF ONE DEVICE. A LAPAROSCOPY WAS PERFORMED AND REVEALED INSERTS IN NORMAL POSITION (NO PERFORATION); THE DEVICES WERE REMOVED. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, ALTHOUGH THE REPORTED PERFORATION WAS NOT CONFIRMED DURING LAPAROSCOPY; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED; AND SINCE AN INTERVENTION WAS PERFORMED; THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY, PATIENT EXPERIENCED GENITAL BLEEDING AFTER ESSURE PROCEDURE. THIS EVENT WAS CONSIDERED SERIOUS, ANTICIPATED; AND DUE TO THE POSITIVE TEMPORAL RELATIONSHIP REGARDED AS PROBABLY RELATED TO THE SUSPECT INSERT/INSERTION PROCEDURE. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00474	BAYER HEALTHCARE LLC	7/7/2015	7/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/29/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6)-2009 AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6)-2011 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(4) SUCCESS II, ESSURE (B)(4) IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 2 CHILDREN WITH 2 ELECTIVE ABORTIONS AND MENSTRUAL PAIN. SHE USED COMBINED PILL AS CONTRACEPTION. HER LAST MENSTRUAL PERIOD WAS ON (B)(6) 2009. AT THE TIME OF ESSURE INSERTION, THE PATIENT WAS IN AMENORRHEA, SHE USED 2 SUCCESSIVE PILL PACKS AND HER BETA HCG TEST WAS (B)(6). ON (B)(6)-2009, ESSURE WAS INSERTED IN THE OPERATING ROOM (OUTPATIENT); NO ANESTHESIA WAS APPLIED DURING THE PROCEDURE. THE PATIENT'S UTERINE CAVITY CONDITION WAS NORMAL, AND HER UTERUS WAS NOT RETROVERTED. THE PROCEDURE WAS STARTED ON THE LEFT SIDE. THE PHYSICIAN CONSIDERED EASY TO INTRODUCE THE CATHETER INTO BOTH TUBES. AT THE END OF PROCEDURE, 2 COILS WERE EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE LEFT SIDE AND NONE ON THE RIGHT SIDE. THE PROCEDURE TOOK 4 MINUTES AND BILATERAL PLACEMENT WAS SUCCESSFUL. THE PATIENT EXPERIENCED PAIN DURING THE PROCEDURE. VASOVAGAL SYNCOPE WAS DENIED. NO OTHER PROCEDURE WAS DONE AT THE SAME TIME OF ESSURE INSERTION. DURING POSTOPERATIVE CONSULTATION, THE PATIENT REPORTED THAT SHE DID NOT USE POSTOPERATIVE ANALGESICS; AND DID NOT EXPERIENCED POSTOPERATIVE EFFECTS. SHE USED COMBINATION PILL AS BACK-UP CONTRACEPTION. ON (B)(6)-2010, RADIOGRAPHY WAS

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DONE AND SHOWED SYMMETRIC INSERTS. INVESTIGATOR CONCLUDED INSERTS HAD GOOD POSITION AND CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A SUCCESS. IN 2010 (DATE NOT SPECIFIED), THE PATIENT REPORTED WEIGHT GAIN OF 18 KG AND PAINFUL BLEEDING. IN 2011, SHE REPORTED A HYSTERECTOMY WAS DONE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6)-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY (B)(4) AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(6). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6)-2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: GENITAL HAEMORRHAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES (B)(4) IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(4) PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE EXPERIENCED PAINFUL BLEEDING AFTER ESSURE PLACEMENT AND WAS SUBMITTED TO A HYSTERECTOMY. THE REPORTED EVENT, REGARDED AS GENITAL BLEEDING, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, THE EVENT WAS REPORTED AT 1-YEAR FOLLOW-UP. LATER, THE PATIENT STATED SHE WAS SUBMITTED TO A HYSTERECTOMY. ALTHOUGH LIMITED INFORMATION WAS PROVIDED; GIVEN THE EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; COMPANY CONSIDERS CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE INTERVENTION REPORTED (HYSTERECTOMY), THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00475	BAYER HEALTHCARE LLC	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 9/29/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/25/2009
Explant Date (E7): 9/29/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2012 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 2 CHILDREN AND ONE CESAREAN SECTION. SHE USED CONTRACEPTIVE IMPLANTS AND HER LAST MENSTRUAL PERIOD BEFORE ESSURE INSERTION WAS ON (B)(6)2009. ON (B)(6) 2009 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED. OSTIUM FROM BOTH SIDES WERE VISUALIZED AND WAS EASY TO INTRODUCE THE CATHETER INTO THE TUBES. BILATERAL PLACEMENT OCCURRED WITH 4 COILS SEEN IN THE UTERINE CAVITY ON LEFT SIDE AND 3 ON RIGHT SIDE. THE PROCEDURE TOOK 6 MINUTES. PATIENT EXPERIENCED PAIN ON RIGHT SIDE DURING INSERTION AND PAIN AFTER PROCEDURE. INVESTIGATOR CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS FAILURE DUE TO UTERINE OR VAGINAL EXPULSION. ON (B)(6) 2009, LAPAROSCOPY WAS DONE DUE TO PELVIC PAIN. PERFORATION OF THE UTERINE FUNDUS WAS SEEN. ESSURE WAS REMOVED AND TUBAL LIGATION WAS DONE. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT

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SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: UTERINE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6)FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE EXPERIENCED PELVIC PAIN DURING AND AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PROCEDURE. AS THIS PAIN PERSISTED; SHE WAS SUBMITTED (4 DAYS AFTER ESSURE INSERTION) TO A LAPAROSCOPY; WHICH REVEALED A PERFORATION OF THE UTERINE FUNDUS. ESSURE WAS REMOVED AND A TUBAL LIGATION WAS PERFORMED. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, GIVEN THE CLOSE TEMPORAL RELATIONSHIP BETWEEN ESSURE PROCEDURE AND THE REPORTED UTERINE PERFORATION; CAUSALITY WITH THE ESSURE AND ITS INSERTION PROCEDURE CANNOT BE EXCLUDED. DUE TO THE REQUIRED INTERVENTION, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00476	BAYER HEALTHCARE LLC	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 3/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/16/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR FROM (B)(4) ON (B)(4) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(4) 2009, (B)(4) 2011, (B)(4) 2012. ON (B)(4) 2012, FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED ONE ELECTIVE ABORTION, 2 ECTOPIC PREGNANCY AND 2 CHILDREN. THE PATIENT'S DRUG HISTORY INCLUDED COMBINED PILL (ORAL CONTRACEPTIVE NOS). THE PATIENT'S CONCURRENT CONDITION INCLUDED TUBAL STENOSIS. ON (B)(6) 2009, ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT STERILIZATION. NSAID WAS USED AS PREMEDICATION. UTERINE DISTENSION WAS PERFORMED. CONDITION OF UTERINE CAVITY WAS NORMAL. PROCEDURE TOOK 8 MINUTES. OSTIUM WAS VISIBLE ONLY ON RIGHT SIDE. IT WAS NOT EASY TO INTRODUCE THE CATHETER ON LEFT SIDE DUE TO PERCEPTION OF OBSTACLE AND POOR VISUALIZATION. PATIENT EXPERIENCED PAIN DURING AND AFTER PROCEDURE. ESSURE WAS PLACED ONLY ON RIGHT SIDE; LEFT HORN DID NOT ALLOW THE ESSURE PLACEMENT ON LEFT (LEFT HORN STENOSIS CONSECUTIVE TO 2 ECTOPIC PREGNANCY OBJECTIVIZED BY HYSTEROSALPINGOGRAPHY AND CLINIC AT THE TIME OF ESSURE PLACEMENT) PAIN, CRAMPS AND BLEEDING WERE DENIED AS POSTOPERATIVE EFFECTS. AFTER INSERTION AND BEFORE CONFIRMATION TEST, COMBINATION PILL WAS USED AS CONTRACEPTION. ON (B)(6) 2009, RADIOGRAPHY WAS DONE AND INSERTS WERE NOT SYMMETRIC. HSG

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(HYSTEROSALPINGOGRAM) WAS ALSO DONE AND INSERT ON RIGHT SIDE WAS IN PLACE. BILATERAL OCCLUSION WAS REPORTED. ON (B)(6) 2011, AN ONGOING UTERINE PREGNANCY WAS DIAGNOSED. SHE HAD GOOD EVOLUTION OF PREGNANCY. IN (B)(6) 2011, A FEMALE (B)(6) WITH (B)(6) WAS BORN; SHE WAS WELL. PARTIAL TUBAL PERFORATION OF RIGHT ISTHMIC PORTION WAS FOUND. ON (B)(6) 2012, LAPAROSCOPY WITH 2 FILSHIES CLIP PLACEMENT WAS DONE. ADDITIONAL INFORMATION RECEIVED ON 03-APR-2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 26-JUN-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: FALLOPIAN TUBE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 204 CASES. PREGNANCY WITH CONTRACEPTIVE DEVICE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 2139 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD A PREGNANCY APPROXIMATELY 2 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE DELIVERED A HEALTHY BABY. PREGNANCY IS A NON-SERIOUS EVENT AND LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS PARTICULAR CASE, PATIENT HAD A LEFT UTERINE HORN STENOSIS DUE TO 2 PREVIOUS ECTOPIC PREGNANCIES AND ONLY ONE ESSURE WAS INSERTED. ALTHOUGH, ESSURE UNILATERAL PLACEMENT COULD BE AN ALTERNATIVE EXPLANATION FOR THE REPORTED DEVICE FAILURE (PREGNANCY); SINCE THE HSG, PERFORMED PRIOR TO PREGNANCY ONSET, SHOWED BILATERAL OCCLUSION CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, PATIENT HAD A PARTIAL TUBAL PERFORATION OF RIGHT ISTHMIC PORTION DIAGNOSED AFTER DELIVERY AND WAS SUBMITTED TO A LAPAROSCOPY. ALTHOUGH THE EXACT MECHANISM OF THIS EVENT WAS UNKNOWN (IF RELATED TO THE DIFFICULTIES DURING ESSURE INSERTION OR IF OCCURRED DURING PREGNANCY), GIVEN ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE PERFORMED INTERVENTION THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00477	BAYER HEALTHCARE LLC	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 2/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/30/2009
Explant Date (E7): 4/4/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION RECEIVED ON (B)(4) 2011 AND (B)(4) 2012. ON (B)(4) 2012, FOLLOW-UP INFORMATION RECEIVED QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 2 ELECTIVE ABORTION, ECTOPIC PREGNANCY AND 5 CHILDREN. HER LAST MENSTRUAL PERIOD WAS ON (B)(6) 2009. ON (B)(6) 2009, ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT STERILIZATION. UTERINE DISTENSION WAS PERFORMED. THE PROCEDURE TOOK 12 MINUTES. OSTIUM FROM BOTH SIDES WERE VISUALIZED AND IT WAS EASY TO INTRODUCE THE CATHETER INTO THE TUBES. AFTER INSERTION, 3 COILS WERE SEEN IN UTERINE CAVITY FROM LEFT SIDE AND 2 FROM RIGHT SIDE. PATIENT EXPERIENCED PAIN ON LEFT SIDE DURING PLACEMENT AND PAIN AFTER PROCEDURE. BILATERAL PLACEMENT ACHIEVED. ON (B)(6) 2010, RADIOGRAPHY WAS DONE AND SHOWED THAT INSERTS WERE SYMMETRIC AND IN GOOD POSITION. AN ULTRASOUND WAS ALSO PERFORMED AND INSERTS WERE SEEN FROM THE CAVITY TO THE HORN. HSG WAS NOT PERFORMED. AT THIS TIME, PATIENT COMPLAINED OF PAIN/CRAMPS. ON (B)(6) 2011, PATIENT COMPLAINED OF LEFT PAIN, PAINFUL INTERCOURSE AND PAINFUL AND LONGER MENSTRUATIONS. ON (B)(6) 2012, HYSTERECTOMY WAS PERFORMED. ADDITIONAL INFORMATION RECEIVED ON 09-APR-2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 26-JUN-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PELVIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 337 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN IN THE LEFT SIDE. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE USE. IN THIS CASE, THE INSERTION WAS EASY BUT PATIENT HAD PAIN ON THE LEFT SIDE DURING AND AFTER PROCEDURE. SHE COMPLAINED OF PAIN AND CRAMPS AT 3 MONTHS CONTROL AND ONE YEAR LATER SHE PRESENTED LEFT PAIN, PAINFUL INTERCOURSE AND PAINFUL AND LONGER MENSTRUATIONS. THEN, TWO YEARS AFTER PLACEMENT, HYSTERECTOMY WAS PERFORMED. CONSIDERING AVAILABLE INFORMATION AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE HYSTERECTOMY WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00478	BAYER HEALTHCARE LLC	7/7/2015	7/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/7/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2012 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 2 CHILDREN AND CONTRACEPTIVE (MINIPILLS) USE. HER LAST MENSTRUAL PERIOD AT THE TIME OF ESSURE INSERTION WAS ON (B)(6) 2009. ON (B)(6) 2009 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS SUCCESSFULLY INSERTED. UTERINE DISTENSION WAS PERFORMED. THE PROCEDURE TOOK 7 MINUTES. OSTIUM FROM BOTH SIDES WAS VISUALIZED AND WAS EASY TO INTRODUCE THE CATHETER INTO THE TUBES. ON LEFT SIDE, 2 COILS OF INSERT WERE VISIBLE IN THE UTERINE CAVITY AND ON RIGHT SIDE 5 COILS. THE PATIENT EXPERIENCED PAIN DURING AND AFTER PROCEDURE. AT CONSULTATION, ON (B)(6) 2009, PATIENT COMPLAINED OF PAIN/CRAMPS. A RADIOGRAPHY WAS DONE AND INSERTS WERE SYMMETRIC AND IN GOOD POSITION. NO ULTRASOUND OR HYSTEROSALPINGOGRAM WERE PERFORMED. INVESTIGATOR CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A SUCCESS. THREE YEARS AFTER ESSURE PLACEMENT; PATIENT HAD A PREGNANCY WITH FALLOPIAN TUBES ABLATION FOLLOWED BY ELECTIVE ABORTION; INVESTIGATOR STATED ONE OF ESSURE MIGRATED IN THE FALLOPIAN TUBES. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR

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INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1. DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 322 CASES. 2. PREGNANCY WITH CONTRACEPTIVE DEVICE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 2139 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD A PREGNANCY 3 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND WAS SUBMITTED TO FALLOPIAN TUBES ABLATION FOLLOWED BY AN ELECTIVE ABORTION. INVESTIGATOR STATED ONE OF ESSURE MIGRATED IN THE FALLOPIAN TUBES. ALL EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. PREGNANCY IS NON-SERIOUS; WHILE THE REMAINING EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. ADDITIONALLY, IF DEVICE MOVEMENT (MIGRATION OR EXPULSION) OCCURS DURING ESSURE THERAPY, ITS CONTRACEPTIVE EFFICACY MAY BE COMPROMISED, RESULTING IN PREGNANCIES. IN THIS PARTICULAR CASE, DURING CONTROL EXAMINATION, ESSURE WAS IN GOOD POSITION; LATER A PREGNANCY AND DEVICE MIGRATION WERE DIAGNOSED. ALTHOUGH THE EXACT MECHANISM OF THE REPORTED EVENTS IS NOT KNOWN (IF MIGRATION PRECEDED PREGNANCY OR VICE-VERSA); CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00479	BAYER HEALTHCARE LLC	7/7/2015	7/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/15/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2009 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(4) 2012 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY ENQUETE SUCCESS II, ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 3 CHILDREN AND MENSTRUAL PAIN. PATIENT'S LAST MENSTRUAL PERIOD WAS ON (B)(6) 2009. ON (B)(6) 2009 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT CONTRACEPTION UNDER GENERAL ANESTHESIA. UTERINE DISTENSION WAS PERFORMED. THE PROCEDURE TOOK 7 MINUTES. OSTIUM FROM BOTH SIDES WERE VISUALIZED AND WAS EASY TO INTRODUCE THE CATHETER INTO THE TUBES. BILATERAL PLACEMENT ACHIEVED. ON LEFT SIDE, 2 COILS OF INSERT WERE VISIBLE IN THE UTERINE CAVITY AND ON RIGHT SIDE 2 COILS OF INSERT. AFTER INSERTION, SHE USED COMBINATION PILL. ON THE SAME DAY, AFTER ESSURE PLACEMENT; PATIENT WAS SUBMITTED TO TRASOBTURATOR TAPE STRESS URINARY INCONTINENCE TREATMENT; ACCORDING TO INVESTIGATOR THIS PROCEDURE DID NOT MAKE THE ESSURE PLACEMENT MORE DIFFICULT. ON (B)(6) 2009 DURING CONSULTATION, PATIENT COMPLAINED OF PAIN/CRAMPS. ON (B)(6) 2009, ULTRASOUND WAS DONE AND INSERTS WERE IN GOOD POSITION (SEEN FROM THE CAVITY TO THE HORN). INVESTIGATOR CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A SUCCESS AND PATIENT WAS VERY SATISFIED. AT 12 MONTH AND 2 YEARS FOLLOW-UP, PATIENT WAS DISSATISFIED. INVESTIGATOR REPORTED REJECTION WITH AT THE SAME TIME

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WEIGHT GAIN AND SWELLING. ESSURE INSERTS HAD TO BE WITHDRAWN WITH PRESENCE OF A GYNECOLOGIST AND AN UROLOGIST, URINARY STRIPS HAD TO BE WITHDRAWN TOO. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-APR-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 29-JUN-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PATIENT-DEVICE INCOMPATIBILITY. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 10 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION IN ASSOCIATION WITH PLACEMENT OF A TAPE FOR STRESS URINARY INCONTINENCE TREATMENT. LATER, SHE EXPERIENCED REJECTION. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; IT IS UNCLEAR IF THE REPORTED REJECTION REFERS TO INTOLERANCE TO THE TAPE USED FOR URINARY INCONTINENCE TREATMENT OR TO ESSURE COMPONENTS. HOWEVER, SINCE INVESTIGATOR STATED DEVICES REMOVAL WAS NECESSARY; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED AND THIS CASE WAS THUS, CONSIDERED AN INCIDENT (REQUIRED INTERVENTION). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00480	BAYER HEALTHCARE LLC	7/7/2015	7/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/28/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2010 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). ADDITIONAL INFORMATION WAS RECEIVED ON 17-DEC-2012 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: STUDY (B)(4), ESSURE ESS305 IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE® PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). PATIENT HAD AS MEDICAL HISTORY 3 CHILDREN AND APPENDICECTOMY. SHE USED COMBINED PILL FOR CONTRACEPTION AND THE DATE OF HER LAST MENSTRUAL PERIOD WAS (B)(6) 2010. SHE HAD ESSURE INSERTED ON (B)(6) 2010. NO ANESTHESIA WAS APPLIED DURING PROCEDURE, UTERINE DISTENSION WAS DONE AND HYSTEROSCOPY WAS POSSIBLE. PATIENT'S UTERINE CAVITY WAS NORMAL AND HER UTERUS WAS NOT RETROVERTED. TUBAL OSTIUM WAS IN THE FIELD OF VISION DURING PLACEMENT. IT WAS EASY TO INTRODUCE THE CATHETER INTO BOTH TUBES AND THE PLACEMENT WAS SUCCESSFUL (EXTERNALLY VISIBLE COIL IN THE UTERINE CAVITY: 4 ON LEFT AND 1 ON RIGHT). PROCEDURE TOOK 2 MINUTES. THE PATIENT EXPERIENCED PAIN DURING THE PASSAGE THROUGH THE CERVIX, DURING PLACEMENT INTO BOTH TUBES AND ALSO AFTER PROCEDURE. SHE DID NOT PRESENT VASOVAGAL SYNCOPE AND NO OTHER PROCEDURE WAS PERFORMED AT THE TIME OF INSERTION. PATIENT DID NOT TAKE POST-OPERATIVE ANALGESICS AND USED COMBINATION PILL AS CONTRACEPTIVE METHOD DURING THE 3 MONTHS POST INSERTION. SHE DID NOT HAVE POSTOPERATIVE PAIN/CRAMPING OR BLEEDING. ON (B)(6) 2010, A X-RAY WAS PERFORMED AND INSERTS WERE NOT SYMMETRIC AND THEIR PROXIMAL PORTIONS WERE NOT LESS THAN 4 CM. AT ULTRASOUND (2D), RIGHT INSERT WAS NOT SEEN

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FROM THE CAVITY TO THE HORN. NO HYSTEROSALPINGOGRAM WAS PERFORMED. INVESTIGATOR CONCLUDED ON GOOD INSERTION POSITION AND CONSIDERED THE FINAL RESULT OF THE PROCEDURE AS A SUCCESS HOWEVER, IT WAS REPORTED THAT THREE MONTHS AFTER ESSURE PLACEMENT; PATIENT WAS SUBMITTED TO ABLATION OF FALLOPIAN TUBES BECAUSE ONE OF ESSURE INSERTS WAS NOT WELL PLACED. ADDITIONAL INFORMATION RECEIVED ON 09-APR-2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 26-JUN-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE DISLOCATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 322 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE WAS SUBMITTED TO FALLOPIAN TUBES ABLATION, 3 MONTHS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT, BECAUSE ONE OF ESSURE INSERTS WAS NOT WELL PLACED. THE REPORTED EVENT, REGARDED AS DEVICE DISLOCATION, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED DISLOCATION IS UNKNOWN, GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. SINCE A SURGERY WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00481	BAYER HEALTHCARE LLC	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 1/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/23/2008
Explant Date (E7): 4/5/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2008 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2013 WHICH QUALIFIES THIS CASE AS AN INCIDENT. STUDY DESCRIPTION: (B)(6). PATIENT´S MEDICAL HISTORY INCLUDED THREE CHILDREN, SPONTANEOUS ABORTION AND LEFT BREAST ABSCESS. HER LAST MENSTRUAL PERIOD OCCURRED ON (B)(6) 2008 AND HER UTERINE CONDITION INCLUDED SYNECHIAE. NSAID WAS USED AS PREMEDICATION. ON (B)(6) 2008, ESSURE WAS EASILY INSERTED ON BOTH SIDES (8 MINUTES PROCEDURE). BOTH OSTIUM WERE VISUALIZED. PATIENT PRESENTED PAIN. BILATERAL PLACEMENT WAS ACHIEVED. ON THREE MONTHS VISIT ((B)(6) 2009), PATIENT REPORTED BLEEDING. RADIOGRAPHY WAS PERFORMED AND SHOWED INSERTS SYMMETRIC, DISTANCE (PROXIMAL PORTIONS < 4 CM) AND 4 MARKERS WELL PLACED. AN ULTRASOUND WAS ALSO PERFORMED AND INSERTS WERE SEEN FROM THE CAVITY TO THE HORN. GOOD INSERT POSITION WAS REPORTED. AT TWO YEARS FOLLOW UP CONTACT ((B)(6) 2010), HAEMORRHAGE EPISODES AND ANEMIA WERE REPORTED. IT WAS ALSO REPORTED THAT ON (B)(6) 2011 HYSTERECTOMY AND THERMOCOAGULATION WERE PERFORMED. NO FURTHER INFORMATION PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 PTC GLOBAL NUMBER (B)(4) FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT

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THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: GENITAL HAEMORRHAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4)CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HAEMORRHAGE EPISODES AT 2 YEARS. THIS EVENT, SEEN AS GENITAL HAEMORRHAGE, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, THE PLACEMENT WAS EASY AND PATIENT EXPERIENCED PROCEDURAL PAIN. AT 3 MONTHS CONTROL, SHE COMPLAINED OF BLEEDING. TWO YEARS LATER, THE PATIENT HAD HAEMORRHAGE EPISODES AND ANEMIA. THEN, HYSTERECTOMY AND THERMOCOAGULATION WERE PERFORMED. GIVEN POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN THE REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED AND SINCE HYSTERECTOMY WAS INFORMED, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043625	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 11/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BASICALLY FROM THE CHRONIC INFLAMMATION MY BODY WASN'T RIGHT. CHRONIC FATIGUE. LOW BLOOD PRESSURE. DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043626	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS, CONSTANT PERIODS. PAIN IN OVARIES. CYST. LEGS HURTING. BACK HURTING. KIDNEYS HURTING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043627	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 9/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) FOUR YEARS AFTER IMPLANTATION, AND AFTER INCREASING SYMPTOMS (INCLUDING BRAIN FOG/MEMORY LOSS, HEART PALPITATIONS, AND POOR IMMUNE SYSTEM), I HAD A TOTAL HYSTERECTOMY (REMOVAL OF TUBES - WITH COILS INTACT - UTERUS AND CERVIX) AND SAW IMPROVEMENT OR ELIMINATION OF ALL SYMPTOMS. SO SIX-MONTHS POST-OP, I'M LEFT WITH CONTINUED HAIR THINNING AND - THANKS TO THE LEGAL PROTECTION OF THIS DEVICE - A WHOPPING MEDICAL BILL THAT WILL TAKE ME MANY YEARS TO FULLY PAY OFF. BUT I AM 100% CONVINCED THAT ESSURE WAS THE CAUSE OF ALL THOSE SYMPTOMS I LISTED HERE AND IN MY ORIGINAL REPORT, AND I AM GLAD IT'S GONE. I JUST WISH THIS WOULD BE TAKEN OFF THE MARKET SO OTHER WOMEN COULD BE SPARED FROM THIS TOXIC DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043628	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN (CANNOT LOSE WEIGHT DESPITE DIETARY CHANGES AND EXERCISE), BLOATING, EXTREME MOOD SWINGS, LOSS OF FOCUS AND CONCENTRATION, DENTAL ISSUES FROM DECAYED TEETH TO BROKEN MOLARS, PAIN IN RIB CAGE, VITAMIN D DEFICIENCY, PERI-MENOPAUSE, GAS, BLOATING, LOWER ABDOMINAL PAIN, LOWER BACK PAIN, SWELLING IN LEGS AND FEET, MIGRAINES, CHEST PAIN, INSOMNIA, DEPRESSION, ANXIETY, CHRONIC HEADACHES, CYSTS ON OVARIES, HOT FLASHES, NAUSEA, LOSS OF SEX DRIVE, CHRONIC FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043629	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 9/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH THE MIGRAINES THEN THE ABDOMEN PAIN AND BACK PAIN. LEFT SHOULDER AND NECK PAIN THAT COMES AND GOES. THEN GROIN PAIN. FATIGUED. LOW ENERGY. INCREASED ANXIETY. BODY SHAKES. LEGS JUMP FOR NO REASON. CYSTS ON OVARIES THE SIZE OF GRAPEFRUIT'S THAT WOULD RUPTURE ABOUT A YEAR AGO. PAINFUL INTERCOURSE. HURTS TO SIT DOWN. SHARP SHOOTING PAINS IN MY VAGINA. PAINS ON MY LEFT AND RIGHT SIDE OF ABDOMEN. HAIR LOSS. FREQUENT URINATION. PAINFUL URINATION. PAINFUL BOWEL MOVEMENT. SHARP SHOOTING PAINS IN VAGINA. SOMETIME BURNING SENSATION. LOSS OF ENERGY. MOOD SWINGS. BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043630	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 4/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BECAME PREGNANT AND SHORTLY AFTER HAD A MISCARRIAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043631	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). METALLIC TASTE IN MY MOUTH, LOSS OF LIBIDO, INSOMNIA, BRAIN FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043632	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 12/29/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THE COILS IMPLANTED I HAVE STEADILY GAINED WEIGHT. A TOTAL OF 70 POUNDS SO FAR. I CANNOT LOSE IT. I HAVE DULL PAIN MOST OF THE TIME IN MY ABDOMEN THEN SHARP PAINS RANDOMLY. MY GENERAL HEALTH HAS STEADILY DECLINED SINCE THEN AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043633	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 1/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ISSUES WITH IT SINCE IT WAS PLACED IN (B)(6) 2013. I HAVE HAD ISSUES WITH EXTREME HEADACHES, HAIR LOSS, ABDOMINAL PAIN, LOWER BACK PAIN, MUSCLE SPASM, LOSS OF SLEEP, AND I HAD TO HAVE EMERGENCY GALLBLADDER SURGERY ON (B)(6) 2014 BECAUSE MY GALLBLADDER WAS FILLED WITH SLUSH AND INFLAMED SO THEY HAD TO TAKE IT OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043634	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY SKIN IMMEDIATELY BROKE OUT INTO AN ALLERGIC REACTION (RASH) 2 WEEKS AFTER IMPLANTED, I HAVE A NICKEL ALLERGY AND WAS NEVER TESTED PRIOR TO IMPLANTATION, I BLED FOR 4 MONTHS STRAIGHT AFTER IMPLANTATION AND I STILL BLEED EVERY 3 WEEKS, I HAVE SEVERE MEMORY LOSS, AND I AM GAINING WEIGHT LIKE CRAZY AND DO NOT EVEN EAT A LOT, I HAVE SHARP STABBING PAIN WHEN I GET UP FAST FROM A SITTING POSITION, I HAVE A DULL PAIN IN MY ABDOMEN DAILY, I AM TIRED ALL THE TIME NO MATTER HOW MUCH REST I GET, MY SKIN IS VERY DRIED OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043635	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 5/20/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TOLD BY DOCTOR I HAVE YEAST INFECTION. INNER THIGHS AND UNDER MY BREAST. I HAVE HEADACHES. CAN'T SLEEP. THERE IS ALWAYS A BROWN LINING ON MY PANTIES AT THE END OF THE DAY BECAUSE I LEAK FLUID WHEN I SNEEZE OR COUGH AND FOWL ODOR. I WAS TOLD BY DOCTOR I HAVE UTERINE PROLAPSE. FEET SWOLLEN. SKIN CONDITIONS ON MY THIGHS ARMS...NUMBNESS ON MY ARM AND HANDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043636	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 1/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ISSUES WITH IT SINCE IT WAS PLACED IN (B)(6) 2013. I HAVE HAD ISSUES WITH EXTREME HEADACHES, HAIR LOSS, ABDOMINAL PAIN, LOWER BACK PAIN, MUSCLE SPASM, LOSS OF SLEEP, AND I HAD TO HAVE EMERGENCY GALLBLADDER SURGERY ON (B)(6) 2014 BECAUSE MY GALLBLADDER WAS FILLED WITH SLUSH AND INFLAMED SO THEY HAD TO TAKE IT OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043637	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY SYMPTOMS BEGAN TWO YEARS AGO BUT THE CALENDAR WON'T LET ME CHANGE THE DATE. SYMPTOMS OF JOINT PAINS, SWELLING OF EXTREMITIES, ENLARGED ABDOMEN, PELVIC PAIN, CHRONIC PAIN IN HIPS THAT RADIATES DOWN MY LEG, WEIGHT GAIN, TIREDNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043638	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 1/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED WITH SEVERE CRAMPS AND EXTENDED MENSTRUAL CYCLE. THEN HEADACHE, MIGRAINE, TEETH DECAYING, SEVERE BLOATING, WHOLE BODY ACHE, HAIR FALLING OUT, HAIR GROWING ON MY FACE. ON (B)(6), 2014 I HAD A MISCARRIAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043639	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 1/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED WITH SEVERE CRAMPS AND EXTENDED MENSTRUAL CYCLE. THEN HEADACHE, MIGRAINE, TEETH DECAYING, SEVERE BLOATING, WHOLE BODY ACHE, HAIR FALLING OUT, HAIR GROWING ON MY FACE. ON (B)(6) 2014 I HAD A MISCARRIAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043640	BAYER	7/7/2015	7/8/2015

Event Information:

Event Date (B3): 3/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN IN LOWER ABDOMINAL REGION, SKIN RASHES, ALL OVER BODY ITCHINESS, CYSTIC ACNE, CONSTANT BACTERIAL VAGINAL INFECTIONS, CONSTANT YEAST INFECTIONS, EXCESSIVE WEIGHT GAIN OVER 50 POUNDS IN 6 MONTHS OF HAVING ESSURE PLACED, HEADACHES, DIZZINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044160	BAYER HEALTHCARE LLC	7/7/2015	7/16/2015

Event Information:

Event Date (B3): 8/11/2014 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): C06466

Single Use:
Implant Date (E6): 8/11/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WENT TO AN OUT-PATIENT SERVICE AT (B)(6) HOSP TO GET THE ESSURE PROCEDURE FOR PERMANENT BIRTH CONTROL. I WAS TOLD THERE WOULD BE MILD CRAMPING AFTER THE PROCEDURE FOR A FEW HOURS AND WAS PRESCRIBED IBUPROFEN FOR PAIN. THE CAMPING LASTED LONGER THAN EXPECTED AND SOON STARTED TO CAUSE LOWER BACK PAIN AS WELL. I HAVE BEEN TO MY PRIMARY PHYSICIAN FOR UNEXPLAINED SYMPTOMS. I HAVE A HISTORY OF BACTERIAL DIAGNOSIS AND UNDERSTAND THE SYMPTOMS FROM EXPERIENCE. I WOULD HAVE SWOLLEN LYMPH NODES OR SWELLING ON THE LEFT SIDE. MY DOCTOR WOULD RUN SOME TEST FOR CHLAMYDIA AND GONORRHEA AND TREAT THOSE CONDITIONS. RESULT WILL ALWAYS COME BACK NEGATIVE. IN WHICH I KNEW THEY WOULD. MY MENSTRUAL CYCLE HAS CHANGED WITH HEAVIER FLOW. I NEVER HAVE CRAMPS BUT SINCE THE INSTALLMENT OF THE DEVICE I CRAMP WEEKS BEFORE MY CYCLE STARTS. THESE CRAMPS RANGE FROM MILD TO SEVERE. I WAS NOT MADE AWARE OF THE OPTIONS FOR REMOVAL AND AT THIS POINT WILL BE DISCUSSING THOSE OPTIONS WITH MY PHYSICIAN. MY HUSBAND HATES THAT WE MADE THE DECISION FOR ME TO GET THE DEVICE AND WISHED HE WOULD HAVE GOTTEN A VASECTOMY INSTEAD. I HAVE DONE A LOT OF RESEARCH LOOKING FOR OTHERS WHICH SYMPTOMS SIMILAR TO MINE AFTER THE PROCEDURE. I HAVE ALSO EXPERIENCED SEVERE SWELLING IN THE LEFT KNEE CAP WHICH HINDERED ME FROM WORK FOR A FEW DAYS. JUST WOKE UP ONE MORNING AND COULD NOT WALK ON THE LEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044165		7/7/2015	7/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WELL WHEN I FIRST GOT THE ESSURE I WAS OK THE FIRST 2 DAYS. AFTER THE 2ND DAY I WAS IN A LOT OF PAIN IN MY LOWER BACK AND MY PMS IS LONGER THEN EVER. SOMETIMES I GO 2 WEEKS. I HAVE A HARD TIME HAVING SEX WITH MY HUSBAND ; IT'S VERY VERY PAINFUL. I DON'T WANT TO BE TOUCHED. I HAVE VERY BAD PAINS IN MY LOWER STOMACH AND I BREAK OUT IN A VERY BAD RASH ON MY STOMACH. IT HAS BEEN VERY BAD FOR ME AS A WOMAN. I HAVE NO LIFE. I WISH TO GET THIS UNDONE ONE DAY SOON. (B)(4)

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044167		7/7/2015	7/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2008, I HAD ESSURE INSERTED AFTER THE BIRTH OF MY DAUGHTER IN (B)(6). A YEAR LATER I STARTED HAVING LOWER ABDOMINAL PAINS, STABBING, BURNING, CRAMPING PAINS. THESE PAINS WERE NOT ASSOCIATED WITH MY MENSTRUAL CYCLE. SHORTLY AFTER THOSE PAINS STARTED, I STARTED GETTING YEAST INFECTIONS THEN URINARY INFECTIONS AND BACTERIAL VAGINOSIS. THE LIST GOES ON TO OVARIAN CYSTS TO NOW HAVING IRREGULAR MENSTRUAL CYCLES AND PASSING BLOOD CLOTS THE SIZE OF A GOLF BALL. I WENT TO THE DOCTOR REGULARLY WHEN THIS FIRST STARTED UNTIL I BECAME IMMUNE TO THE ANTIBIOTICS AND DISCOVERED OTC MEDS THAT WORKED JUST THE SAME. I HAVE HAD BEYOND NUMEROUS X-RAYS, ULTRASOUNDS, CT SCANS ETC. EVERY OBGYN I'VE BEEN REFERRED TO KEEPS TELLING ME IT'S JUST MY AGE AND THESE ONGOING PAINFUL SYMPTOMS DON'T APPLY TO THE ESSURE PROCEDURE. I'M (B)(6). THIS HAS BEEN GOING AND GETTING WORSE FOR THE PAST 7 YEARS NOW. HOW MUCH MORE DO I HAVE TO ENDURE AND SUFFER? I HAVE 2 CHILDREN THAT DEPEND ON ME AND THERE ARE MORE TIMES THAN I CAN COUNT WHEN THEY HAVE TO HELP TAKE CARE OF ME BECAUSE I CAN'T EVEN GET OUT OF THE BED. I'VE DONE MY RESEARCH AND ALL MY SYMPTOMS ARE RELATED AND CAN BE REVERSED AND OR ELIMINATED. BUT DOCTORS TELL ME NO. I'M MISERABLE AND WAS HEALTHY UNTIL THIS PROCEDURE AND NEVER HAD THESE PROBLEMS. NOW THEY ARE GETTING WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044168		7/7/2015	7/16/2015

Event Information:

Event Date (B3): 7/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/20/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE DONE IN 2009 AND HAVE PAIN EVER SINCE. MY LIFE HAS CHANGED. I DON'T HAVE A SEX LIFE WITH MY HUSBAND ANY MORE DUE TO THE SIDE EFFECTS AND I STAY IN PAIN. CAN'T PLAY WITH MY KIDS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00466	BAYER HEALTHCARE LLC	7/7/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/22/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS STUDY CASE REPORT WAS RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON 22-MAR-2011 AND REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(6). ADDITIONAL INFORMATION RECEIVED ON 20-JUN-2011. STUDY DESCRIPTION:(B)(6) IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 02 CHILDREN. HER LAST MENSTRUAL PERIOD BEFORE INSERTION OCCURRED ON (B)(6) 2011. ON (B)(6) 2011 ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED FOR PERMANENT STERILISATION. ANALGESICS AND NSAID (NON-STEROID ANTI-INFLAMMATORY DRUG) WERE USED AS PREMEDICATION. UTERINE CAVITY WAS WITHIN NORMAL CONDITIONS AND THE PATIENT HAD RETROVERTED UTERUS. UTERINE DISTENTION WAS DONE. VISUALIZATION OF OSTIUM WAS GOOD BILATERALLY. THE PROCEDURE WAS STARTED ON RIGHT SIDE. IT WAS EASY TO INTRODUCE THE CATHETER INTO THE TUBES. AT THE END OF PROCEDURE SHE HAD 4 COILS EXTERNALLY VISIBLE IN THE UTERINE CAVITY ON THE RIGHT SIDE. BILATERAL PLACEMENT WAS NOT ACHIEVED. ABSENCE OF INSERT RELEASE AND REMOVAL OF FRAGMENT OF LEFT INSERT THAT BROKE WITH PLIERS WERE REPORTED. THE PROCEDURE TOOK 12 MINUTES. PATIENT PRESENTED PAIN DURING INSERTION AND SHE DENIED PAIN AFTER THE PROCEDURE. VASOVAGAL SYNCOPE WAS DENIED. THE PATIENT WAS SATISFIED AND NO ADDITIONAL PROCEDURE WAS PERFORMED AT THE SAME TIME. NEW APPOINTMENT FOR CONTRALATERAL PLACEMENT WAS SCHEDULED. ON (B)(6) -2011 SHE WENT FOR ESSURE INSERTION ATTEMPT ON THE LEFT SIDE. AMENORRHEA WAS REPORTED. ANALGESICS AND NSAID (NON-STEROID ANTI-INFLAMMATORY DRUG) WERE

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USED AS PREMEDICATION. UTERINE CAVITY WAS WITHIN NORMAL CONDITIONS. IT WAS DIFFICULT TO INSERT CATHETER INTO THE TUBES DUE TO PERCEPTION OF OBSTACLE. SHE EXPERIENCED PAIN DURING ESSURE PLACEMENT. SUCCESSFUL PLACEMENT WAS NOT ACHIEVED. NEW APPOINTMENT FOR CONTRALATERAL PLACEMENT WAS NOT SCHEDULED. VASOVAGAL SYNCOPE DURING THE PROCEDURE WAS DENIED. THE PATIENT WAS VERY SATISFIED WITH THE PROCEDURE AND NO ADDITIONAL PROCEDURE WAS PERFORMED AT THE SAME TIME. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-APR-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 26-JUN-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON THE RIGHT SIDE. ON THE LEFT, THERE WAS ABSENCE OF INSERT RELEASE AND A REMOVAL OF BROKEN INSERT FRAGMENT WITH PLIERS WAS NECESSARY. THESE EVENTS, SEEN AS DEVICE DEPLOYMENT ISSUE AND DEVICE BREAKAGE, ARE NON-SERIOUS. BREAKAGE IS LISTED ACCORDING TO TECHNICAL ANALYSIS AND DEPLOYMENT ISSUE IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE AND DEPLOYMENT ISSUE. IN THIS PARTICULAR CASE, THE INSERTION ON THE RIGHT SIDE WAS EASY BUT ON THE LEFT SIDE WAS NOT POSSIBLE DUE TO THE REPORTED EVENTS. ANOTHER ATTEMPT OF INSERTION ON THE LEFT SIDE WAS PERFORMED, HOWEVER, IT ALSO FAILED. CONSIDERING THE REPORTED EVENTS OCCURRED DURING INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ACCORDING TO TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENTS TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00490	BAYER HEALTHCARE LLC	7/7/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64477

Single Use: Y
Implant Date (E6): 5/28/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN FRANCE ON 08-JUN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C64477, IMPLANTED ON (B)(6) 2015. IT WAS REPORTED THAT THE INSERT NOT RELEASED AFTER INSERTION OF THE IMPLANT. REPEATED SOFT TRACTIONS, LEADING TO COILS BREAKAGE, IMPLANT CHECKED IN PLACE AT THE END OF THE PLACEMENT. NO CAUSE LINKED TO THE PATIENT. GOOD CONDITIONS FOR THE PLACEMENT. BILATERAL INSERTION PERFORMED WITH THE CONCERNED IMPLANT. FOLLOW-UP ON 15-JUN-2015: NCA REFERENCE NUMBER RECEIVED FROM THE (B)(4), (B)(4). FOLLOW UP INFORMATION (SPECIFIC QUESTIONNAIRE) RECEIVED ON 25JUN2015: ESSURE TYPE ESS305. BREAKAGE DESCRIPTION: LACK OF FULL RELEASE OF THE IMPLANT, STUCK IN THE DELIVERY CATHETER, AFTER SEVERAL ATTEMPTS TO WITHDRAW, BREAKAGE OF THE IMPLANT AT ITS PROXIMAL PART. RECOMMENDATIONS FOR USE WERE FOLLOWED BUT IT WAS IMPOSSIBLE TO COMPLETE THE RELEASE. BROKEN PIECES WERE NOT RETRIEVED. NO LESION FOR THE PATIENT BUT BREAKAGE COULD HAVE LED TO TUBE STRIPPING, IN LESS FAVORABLE CONDITIONS. OUTCOME UNKNOWN; CONTROL VISIT SCHEDULED IN (B)(6) 2015. NO MEDICAL OR SURGICAL HISTORY, NO ALLERGY. HYSTEROSCOPY REPORT DATED (B)(6) 2015: NORMAL UTERINE CAVITY, OSTIA WELL VISUALIZED. INSERTION OF ESSURE IN THE LEFT TUBE WITH 5 OUTER COILS. DURING THE INSERTION OF THE IMPLANT, ON THE RIGHT SIDE, DIFFICULT RELEASE, STUCKED COIL. AFTER SEVERAL ATTEMPTS OF SOFT TRACTIONS, BREAKAGE OF THE COIL, LEADING TO RELEASE THE INSERTION KIT. INTRATUBAL POSITION OF THE IMPLANT WAS CHECKED. REMOVAL OF THE HYSTEROSCOPE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE INSERT NOT RELEASED AFTER INSERTION OF THE IMPLANT.

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REPEATED SOFT TRACTIONS, LEADING TO COILS BREAKAGE (DEVICE BREAKAGE). THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 12-AUG-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER:(B)(4). LOT NUMBER C64477 (PRODUCTION DATE 13-JUN-2014; EXPIRATION DATE 30-JUN-2017). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00491	BAYER HEALTHCARE LLC	7/7/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26973

Single Use: Y
Implant Date (E6): 6/5/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 08-JUN-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C26973, IMPLANTED FOR PERMANENT CONTRACEPTION ON (B)(6) 2015. SHE WAS NOT PREGNANT. IT WAS REPORTED THAT THE PLACEMENT WAS SUCCESSFUL IN RIGHT SIDE; HOWEVER ON LEFT SIDE, INNER COIL WAS HALFWAY OUT INTO THE UTERINE CAVITY; PHYSICIAN WAS TRYING TO REMOVE IT WHEN IT BROKE OFF; SO PART OF THE COIL WAS STILL IN PATIENT'S LEFT TUBE. THE EVENT WAS ONGOING. ESSURE WAS CONTINUED AND THE PATIENT WAS OTHERWISE OKAY. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-JUN-2015. (B)(4). BATCH NUMBER C26973 (PRODUCTION DATE 03-MAR-2014; EXPIRATION DATE 31-MAR-2017). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE AND A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION

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WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) SUCCESSFULLY INSERTED IN RIGHT FALLOPIAN TUBE. IN LEFT FALLOPIAN TUBE HOWEVER; THE INNER COIL WAS HALFWAY OUT INTO THE UTERINE CAVITY; WHEN PHYSICIAN TRIED TO REMOVED IT; THE COIL BROKE OFF; PART OF IT WAS STILL IN PATIENT'S TUBE. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED NON-SERIOUS. ONCE ESSURE IS PLACED, HYSTEROSCOPIC INSERT REMOVAL SHOULD NOT BE PERFORMED UNLESS 18 OR MORE TRAILING COILS ARE SEEN INSIDE THE UTERINE CAVITY. ATTEMPTED REMOVAL WITH LESS THAN 18 TRAILING COILS MAY RESULT IN FRACTURED INSERT, FALLOPIAN TUBE PERFORATION OR OTHER INJURY. IN THIS PARTICULAR CASE, CONSIDERING THE REPORTED BREAKAGE OCCURRED IN THE CONTEXT OF AN ATTEMPT OF ESSURE REMOVAL DUE TO DEVICE MALPOSITION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, DUE TO DEVICE BREAKAGE. AS ALTHOUGH PHYSICIAN STATED PATIENT WAS OKAY, SHE MIGHT HAVE SUFFERED A SERIOUS HEALTH DETERIORATION UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 03-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00493	BAYER HEALTHCARE LLC	7/7/2015	8/3/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 3033

Single Use: Y
Implant Date (E6): 6/8/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 6/29/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 09-JUN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. PHYSICIAN WAS INSERTING ESSURE TO THE PATIENT AND ACCORDING TO HER SHE HAD DONE ALL THE STEPS CORRECTLY AND IN RIGHT ORDER. HOWEVER, THE IMPLANT DID NOT GET LOOSE FROM THE INSERTER WHILE IT WAS STUCK IN PATIENT'S FALLOPIAN TUBE FROM THE OTHER END. IMPLANT NEEDED TO BE CUT AND PART OF IT REMAINED IN PATIENT. THEREFORE NEW INSERTION WAS NOT TRIED AND A LAPAROSCOPIC STERILIZATION IS PLANNED. FOLLOW-UP RECEIVED ON 18-JUN-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C51066; PRODUCTION DATE: 16-APR-2014; EXPIRATION DATE: 30-APR-2017. FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-

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INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY MICRO-INSERT BREAKING DURING THE PROCEDURE AND DETACHMENT DIFFICULTY IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. IN ADDITION, THE AE CASE REFERS TO DEVICE MISUSE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE, THE IMPLANT DID NOT GET LOOSE FROM THE INSERTER WHILE IT WAS STUCK IN PATIENT'S FALLOPIAN TUBE. PHYSICIAN HAD TO CUT THE INSERT WITH SCISSORS, PART OF IT REMAINED IN THE PATIENT. THE REPORTED EVENTS WERE CONSIDERED NON-SERIOUS AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL; IN THIS PARTICULAR CASE ESSURE INSERTION WAS COMPLICATED BY A DEVICE DEPLOYMENT ISSUE. CONSIDERING THAT IT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-JUL-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C51066; PRODUCTION DATE: 16-APR-2014; EXPIRATION DATE: 3

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00494	BAYER HEALTHCARE LLC	7/7/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51077

Single Use: Y
Implant Date (E6): 6/5/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO (B)(6) FEMALE PATIENT. SHE HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION (WITH LOT NUMBER C51077) FOR PERMANENT CONTRACEPTION ON (B)(6) 2015. IT WAS REPORTED THAT THE DEVICE GOT STUCK IN THE TUBE, AS THE PHYSICIAN WAS RETRACTING THE CATHETER, THE INNER COIL GOT STRETCHED OUT, IT WOULD NOT DETACH, AND PHYSICIAN TOOK HYSTEROSCOPIC SCISSORS AND CUT IT. THE PATIENT WAS OKAY; ESSURE WAS CONTINUED. FOLLOW-UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT BATCH NUMBER C51077; PRODUCTION DATE 25-APR-2014; EXPIRATION DATE 30-APR-2017 DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: 1) ROLLBACK TO INITIAL HARD STOP. 2) DEPRESS BUTTON. 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE

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TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE AND A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE THE DEVICE BECAME STUCK IN THE TUBE. THE INNER COIL GOT STRETCHED WHEN PHYSICIAN RETRACTED THE CATHETER AND AS IT WOULD NOT DETACH; THE PHYSICIAN HAD TO CUT IT WITH HYSTEROSCOPIC SCISSORS. THE REPORTED EVENTS WERE CONSIDERED NON-SERIOUS AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL; IN THIS PARTICULAR CASE CONSIDERING THAT THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH PHYSICIAN STATED PATIENT WAS OKAY, THE EVENTS MIGHT HAVE LED TO SERIOUS DETERIORATION IN HEALTH UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 21-JUL-2015 IT WAS REPORTED THAT THE DELIVERY CATHETER BROKE AND THE COIL DID NOT DEPLOY. IT WAS STUCKED IN HER LEFT FALLOPIAN TUBE; IT WAS TOO FAR DOWN. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043641	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/11/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEIZURES, BLOOD CLOT IN LUNG, EXCESSIVE BLEEDING, HAIR LOSS, MUSCLE SPASMS, JOINT GAVE OUT, BROKEN BONE, CONSTANT FATIGUE, FREQUENT BLADDER INFECTION, MANY OTHER ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043642	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 3/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS LASTING 10+ DAYS. STABBING ABDOMINAL PAINS. PERIOD CYCLES EXTREMELY IRREGULAR SOMETIMES UP TO SIX WEEKS APART, SOMETIMES ONLY TWO WEEKS APART. SEVERE MOOD SWINGS AND DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043643	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS BLEEDING HEAVILY FOR 14 MONTHS WAS TOLD THAT WAS NORMAL BEGAN GAINING WEIGHT DEPRESSION AMONGST THE MANY OTHER SIDE EFFECTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043644	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 4/15/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I HAD ESSURE PUT IN ON (B)(6) 2015 I HAVE NOTHING BUT PROBLEMS. I HAVE SEVERE MUSCLE SPASMS IN MY LEGS, CONSTANT BACK PAIN. I HAVE LOSS CONTROL OF MY BLADDER AND LEAK FROM TIME TO TIME. I ALSO HAVE BLOOD IN MY URINE. I HAVE NOT HAD PERIOD. IM CURRENTLY 16 DAYS LATE AND NOT PREGNANT. I HAVE MODERATE JAW PAIN AND MY FILLINGS AND MY TEETH ARE FALLING OUT. I HAVE HEADACHES ALMOST EVERY NIGHT. MY SLEEP IS ALL MESSED UP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043645	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 9/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, FATIGUE, HEAVY BLEEDING WITH HUGE CLOTS, SEVERE RIGHT SIDE PAIN, BLOATING LOOK LIKE I WAS 6 MONTHS PREG., AUTO IMMUNE, CONSTANT SICKNESS, MIGRAINES, DISCHARGE NON STOP. MOOD SWINGS. DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043646	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, PAIN, NONSTOP BLEEDING, PAIN, PASSING CLOTS, DEPRESSION WORSEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043647	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BLEEDING BLOATING SWELLING PAIN.. WHOLE BODY TURN RED .. HEAT FLASHES. JOINT PAIN. DEPRESSION ...HEADACHE, BACK PAIN, METAL TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043648	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SEVERE PAIN WHEN SNEEZING OR GET UP QUICKLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043649	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 8/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BAD MIGRAINES AND HEADACHES, ABDOMINAL PAIN, BACK PAIN, SWELLING OF ABDOMINAL AREA, HURTFUL INTERCOURSE, PERIOD CYCLE ALL OFF.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043650	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 4/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). 1 THING IS ONLY ONE SIDE WAS INSERTED DUE TO THE OTHER BEING BLOCKED AND THE DR COULDN'T GET THE SIDE IN. I HAVE BEEN BLEEDING SINCE DAY ONE AND IT'S ALMOST BEEN 2 MONTHS. I HAVE STOMACH CRAMPS ALL THE TIME AND I GET REALLY BAD LEG CRAMPS AT NIGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043651	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAD MY ESSURE IMPLANTED IN (B)(6) OF 2013. THE PROCEDURE ITSELF WASN'T LONG. I TOOK A XANEX PRIOR TO AND FELT EVERY PAIN THERE WAS TO FEEL WHILE THEY WERE GETTING IMPLANTED. I BLED FOR JUST SHY OF 2 1/2 MONTHS. RIGHT BEFORE I HAD TO GO BACK FOR THE HSG TEST THE DR STOPPED TAKING MY INSURANCE, SO I HAVE NOT HAD IT TESTED. RETURNED TO NORMAL. I'VE NEVER STOPPED HURTING SINCE THE DAY OF IMPLANTATION. MY PERIODS ARE ALMOST UNBEARABLY PAINFUL AND I PASS HUGE CLOTS. SEX IS PAINFUL AND ALMOST ALWAYS CAUSES BLEEDING. ITS LIKE I CAN FEEL MY PARTNER HIT THE COILS AND IT HURTS. I HAVE LOST WEIGHT SO I DONT THINK THAT IS A SIDE EFFECT BUT I AM EXPERIENCING HAIR LOSS. IM (B)(6) WITH A FAMILY FULL OF THICK HAIRED PEOPLE. IM CURRENTLY TRYING TO FIND A DR WHO WILL HELP ME OUT OF THIS MESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043652	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 11/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL AND BACK PAIN, JOINT PAIN, BLOATING, HAIR LOSS, FATIGUE, WEIGHT GAIN, DENTAL ISSUES RECTAL BLEEDING. (B)(6) 2015 SURGERY REMOVING COILS AND TUBES FRAGMENTS AND COIL LEFT IN MY UTERUS NEXT SURGERY (B)(6) 2015. NICKEL ALLERGY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043653	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ABDOMINAL PAIN THAT FEELS LIKE LABOR CONTRACTIONS, ITCHY HIVES CAUSED FROM NICKEL, PREGNANCY LOOK, BRAIN FOG, LOSS OF HAIR, DEPRESSION, ANXIETY, NIGHT SWEATS WAKE UP SOAKED, NUMBNESS IN HANDS AND FINGERS THAT COMES AND GOES, LOWER BACK PAINS THAT COME AND GO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043654	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 12/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED IN (B)(6) 2011. I BLED FROM MY VAGINA EVERY TWO WEEKS AND EVERY TIME I WAS INTIMATE WITH MY HUSBAND FOR A WHOLE YEAR. I WAS TOLD THIS IS "NORMAL." OVER THE NEXT YEAR, I BEGAN TO HAVE SPASMS IN MY LOWER ABDOMEN LIKE A BABY KICKING. I ALSO STARTED TO DEVELOP BAD HEADACHES AT LEAST ONCE PER WEEK. IF I MOVED TO FAST OR GOT UP ANYWAY BUT STRAIGHT I WOULD FEEL A BAD PINCHING PAIN FOR 30 SECONDS TO A MIN THEN IT WOULD SUBSIDE. IT STARTED TO BECOME PAINFUL IN MY 3RD YEAR AFTER IMPLANTATION TO BE INTIMATE WITH MY HUSBAND ESPECIALLY IF I ORGASMED. MY TEETH HAD ALSO STARTED TO CHIP AND DECAY WITH NO REASONING. MY DENTIST DOES NOT HAVE AN EXPLANATION STILL. I BEGAN TO FEEL PINCHING PAINS MUCH MORE FREQUENTLY IN (B)(6) 2014. THE PAIN BECAME LESS AND LESS TOLERABLE UNTIL ALL AT ONCE IN (B)(6) 2014, I BENT DOWN TO GRAB SOME DIRTY LAUNDRY AND IT FELT LIKE SOMETHING WAS STABBING THROUGH MY LOWER ABDOMEN ON THE RIGHT SIDE FROM THE INSIDE. I WENT TO MY OBGYN AND HE PROCEEDED TO RUN ALL SORTS OF TESTS ON ME UNTIL HE COULD NOT FIND ANY REASONABLE EXPLANATION FOR MY PAIN AND THE (B)(6) I HAD GAINED IN ONE MONTH. I AM NORMALLY (B)(6) AND HAVE HAD THE SAME OBGYN FOR ALMOST 9 YEARS THROUGH TWO PREGNANCIES. FINALLY AFTER A LOT OF PAINFUL TESTS AND SUFFERING FROM THIS DEVIL DEVICE FOR MONTHS, HE AGREED TO REMOVE THEM. I NOW HAVE ADENOMYOSIS AND HE HAD TO CUT OUT ENDOMETRIOSIS. I HAVE NEVER HAD ANY OF THESE ISSUES UNTIL ESSURE. ALTHOUGH THE ESSURE HAS BEEN REMOVED I STILL HAVE ADENOMYOSIS AND MY PERIODS ARE EXCRUCIATING. I HAVE NEVER EXPERIENCED ANYTHING NEAR THE PAIN I FEEL WHILE MENSTRUATING OTHER THAN BEING IN ACTIVE LABOR.

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Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043655	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SERVER CRAMPS, BUTT CRAMPS, LEG CRAMPS, HEAVY BLEEDING ON MY PERIOD A LOT OF FATIGUE, MY WEIGHT GAIN IS RIDICULOUS. HEADACHES, LEG PAINS, MY LEFT LEG GIVES OUT. I FAINT, I GET DIZZY A LOT, MY STOMACH IS VERY BLOATED. ITCHY LEGS, RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043656	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BURNING IN MUSCLES. SEVERE WEAKNESS. HEART PALPITATIONS. THYROID NODULES. OVARY CYSTS. HAIR LOSS. ACNE. WEIGHT GAIN. BODY SWELLING. THICK SALIVA. FIBROMYALGIA. HASHIMOTOS DISEASE. PARATHYROID NODULE. HIGH AND LOW VITAMIN D LEVELS. IN WHEELCHAIR. HOT STABBING PAIN THROUGHOUT ENTIRE BODY. MUSCLE FLUTTERS SPASMS. WHITE BLOOD CELL COUNT HIGH. DIZZINESS. FALLING. NAUSEA AND VOMITING. CONSTIPATION. DIARRHEA. PAINFUL JOINTS. ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043657	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CHRONIC JOINT PAIN, FATIGUE, CHRONIC ABDOMEN PAIN, OVARIAN CYSTS, TROUBLE PELVIC PAIN TWO WEEKS A MONTH,BLOOD CLOT PERIODS, HAND AND FOOT NUMBNESS/TINGLING. HEADACHES, AUTOIMMUNE DISEASES, FIBROMYALGIA, KIDNEY PROBLEMS, LABS SHOWN + FOR "LUPAS" AND ALWAYS HAVE RARE BACTERIA AND TRACES OF BLOOD... DEPRESSION,SADNESS. DOCTOR'S NOT GIVING ANY ANSWERS OR RELIEF, THEN PASS YOU OFF TO SPECIALIST AND MORE CONFUSION... I WOULD LOVE TO HAVE THEM OUT...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043658	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CHRONIC HEADACHES, WEIGHT GAIN, BREAST TENDERNESS, SHORTER MENSTRUAL CYCLES WITH HEAVIER BLEEDING AND CRAMPS, ANXIETY ATTACKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043659	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 12/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE HEADACHES, PAINFUL INTERCOURSE, VAGINAL BLEEDING, PELVIC PAIN. HAVE PROVIDED LAB DATA. THREE ULTRASOUNDS PROVIDED EVIDENCE SEVERAL OB\GYN VISITS AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043660	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEART RACING, ANXIETY, HAIR FALLING OUT, SEVERE PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043661	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 4/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JUST A COUPLE WEEKS AFTER MY ESSURE PROCEDURE I STARTED HAVING NIGHT SWEATS, SWEATY HANDS, MEMORY LOSS, WEIGHT LOSS (30+LBS), FATIGUE, MIGRAINES, BODY RASH (MOSTLY HANDS AND FEET) ABDOMINAL PAIN, LOWER BACK PAIN, BAD PERIODS AND I HAVE SINCE BEEN DIAGNOSED WITH PELVIC CONGESTION SYNDROME. I LIVE WITH ALL OR MOST OF THESE SYMPTOMS EVERYDAY. I HAVE HAD BLOOD WORK AND SCANS TO CHECK IF COILS ARE IN PLACE AND EVERYTHING ALWAYS COMES BACK FINE. I CANT EVEN WORK FULL-TIME. ITS TO HARD ON ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043662	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 1/12/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON ANTI-BIOTICS AGAIN FOR ANOTHER UTI. ANOTHER ER VISIT FOR SEVERE PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043663	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 1/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD SEVERE BACK PAIN. PELVIC AND SIDE PAIN. SOMETIMES COULD NO WALK FROM PAIN. WAS IN THE HOSPITAL A LOT DUE TO PAIN. THAT TO HAVE HYSTERECTOMY AND IN (B)(6) 2014 WENT FOR THAT AND THE DR HIT THE BOWEL. SO HAD TO WAIT ANOTHER 6 MONTH (B)(6) 2015 FOR SECOND GO AT HYSTERECTOMY. SO WAS IN MORE PAIN FOR THAT TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043664	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DONT REMEMBER EXACT DATE. BUT I TOOK IT. I HAD SO MUCH ISSUES. GAINED WEIGHT, HEAVY BLEEDING, BACK HURT, MOOD SWINGS, DEPRESSION, CONTINUED FIBROIDS SO I HAD A TOTAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043665	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ITCHY RED RASH, NIGHT SWEATS, HORMONAL SWINGS, PREGNANCY SYMPTOMS, IRREGULAR PERIODS, THINNING HAIR, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043666	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 7/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BEGINNING WITH HIVES ALL OVER MY BODY, THAT LED TO NIGHT SWEATS AND CHRONIC RIGHT PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043667	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN OVER 150 POUNDS IN A YEAR. ALWAYS BLOATED. BAD MIGRAINE HEADACHES. IN THE MORNING CAN'T WALK DUE TO STIFFNESS IN JOINTS. ITCHY SKIN. HAIR LOSS. ABDOMINAL PAIN. IRREGULAR PERIODS MOOD SWINGS. BACK PAIN. METAL ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043668	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 8/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVER BLOATING AND NOW I HAVE ENDOMETRIOSIS AND CONSTANT BLEEDING CONSTANT PAIN ON MY RIGHT SIDE MOSTLY IN MY OVARY AREA CONSTANT MUSCLE PAIN HURT BACK GAIN WEIGH N CANT LOOSE IT. ALWAYS TIRED LOSING TONS OF HAIR EVERYDAY CONSTANT DISCHARGE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043669	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CONSTANT PELVIC PAIN, BLOATING FEELING ALL THE TIME, HEADACHES, BACK ACHE, METAL TASTE IN MOUTH CONSTANTLY, FREQUENT URINATION (FEELING OF HAVING A UTI WITHOUT UTI PRESENT) NUMBERS IN LEGS SHARP STABBING PAINS IN OVARIES. RECENT DIAGNOSIS OF PCOS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043670	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 12/1/2002 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAD ESSURE IMPLANTED IN EITHER 2002 AS PART OF AN (B)(6). NOT LONG AFTER, I EXPERIENCED CRAMPING, BACK PAIN, EXTREMELY HEAVY PERIODS WHICH WENT FOR WEEKS AND MONTHS AT A TIME, LARGE BLOOD CLOTS IN MENSTRUAL BLOOD, WHICH HAVE NOW CEASED DUE TO EARLY MENOPAUSE. IN 2004 I WAS DIAGNOSED WITH A RARE CHRONIC AUTO-IMMUNE DISEASE (SYSTEMIC SCLEROSIS AKA SCLERODERMA). I HAVE ALSO SINCE BEEN DIAGNOSED WITH FIBROMYALGIA, CHRONIC FATIGUE AND SJOGRENS. I STILL EXPERIENCE SEVERE CRAMPING, LOWER BACK PAIN, BLOATING, PAIN HAVING SEX, BLEEDING AFTER SEX, OVARIAN CYSTS, A FEELING OF A HEAVY, FULL, DRAGGING UTERUS WHICH FEELS LIKE MY INSIDES ARE FALLING OUT, URINARY URGENCY, EXTREME FATIGUE, STABBING, SHARP PAINS AND A PERSISTENT DULL ACHE IN THE PELVIC AREA, ENTEROCELE, CYSTOCELE AND RECTOCELE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043671	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HARD TIME BREATHING AND LEFT SIDE WENT NUMB.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043672	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD ESSURE IMPLANTED IN ME I HAVE HAD IRREGULAR PERIODS ALONG WITH THE MOST EXCRUCIATING PAIN I HAVE EVER FELT. I AM UNABLE TO HAVE REGULAR BOWEL MOVEMENTS AS WELL AS URINATE NORMAL. MY EMOTIONS FLUCTUATE ALL THE TIME, I BREAK OUT IN PIMPLES MY SKIN HAS DEVELOPED THESE DARK SPOTS AND MOST OF ALL THE PAIN IS UNBEARABLE. IT HAS STOPPED ME FROM BEING ME. I MISS MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043673	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN ABDOMINAL AREA, HEADACHE, EXTREMELY FATIGUED, STROKE IN (B)(6), MEMORY LOSS, VERTIGO, NUMBNESS IN HANDS AND FEET, FALLING SUDDENLY, ANXIETY AND PTSD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043674	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 3/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). PAIN HEAVY PERIOD HEAD ACHE BACK PAIN LEG PAIN PUFFY STOMACH BOWEL ISSUES TIRED NAUSEOUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043675	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). IT STARTED WITH VERY PAINFUL MENSTRUAL CYCLES AND EXCESSIVE BLEEDING. I AM NOW SEEING A DOCTOR THAT SPECIALIZES IN PAIN MANAGEMENT TILL I GET A HYSTERECTOMY. DURING MY PERIOD I BLEED SO HEAVY THAT I HAVE TO INCREASE MY IRON AND KEEP TRACK OF HOW MUCH BLOOD I AM LOOSING. I AM IN SO MUCH PAIN THAT WE HAVE HAD TO HIGHER ON THE NANNY BECAUSE I CAN NOT CARE FOR MY 3 YOUNG CHILDREN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043676	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). PELVIC PAIN, HEADACHES, SPOTTING AND CONTINUE DISCHARGE, BLOATING, HORMONAL CHANGES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043677	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). EXCESSIVE WEIGHT GAIN (B)(6) LBS IN LESS THAN A YEAR. FEET, LEG, HIP AND BACK PAIN. HEAVY PERIODS AND PAINFUL PERIODS GOING THROUGH SUPERS IN AN HOUR. ANXIETY ATTACKS AND DIZZINESS WHILE ON MY PERIOD TO THE POINT I CAN'T GET OUT OF BED. PAINFUL SHARP PAINS IN MY LOWER ABDOMEN. SWELLING OF MY FEET LEGS AND HANDS. BLURRY VISION AT TIMES. PAINFUL INTERCOURSE. HEADACHES. NUMBNESS IN ARMS, LEGS AND FEET QUICKLY. HIGH BLOOD PRESSURE. BECAME DIABETIC. VERY WEAK. FATIGUE. SWOLLEN/BLOATED BELLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043678	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 6/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I HAD MY DEVICE PUT IN ON (B)(6) 2011. STARTING THE 30TH, I WAS HAVING SEVERE CRAMPING, HEAVY MENSTRUAL CYCLE. STARTING A MONTH LATER, I BEGAN GETTING OVARIAN CYSTS AND SEVERE WEIGHT GAIN. TO THIS DAY I'M ON MEDS TO STOP MY CYCLES BUT STILL WITH THE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043679	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 1/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE BEING IMPLEMENTED WITH ESSURE IN (B)(4) 2015 I HAVE HAD DAILY PAIN. SEVERE BLOATING, SEVERE PELVIC PAIN, STABBING PAINS IN LEFT AND RIGHT SIDE WHERE TUBES ARE, BURNING PAIN IN PELVIC AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043680	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 10/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I BEGAN HAVING A SEVERE ALLERGIC REACTION ALL OVER MY BODY THAT RESULTED IN WHELPS. THESE WHELPS RAN FROM MY FACE, NECK, SHOULDERS, LEGS, HANDS. THEY BECAME SI INTENSE, I CHECKED INTO URGENT CARE AND WAS GIVEN AN EPIPEN. SEVERAL MONTHS LATER I STARTED EXPERIENCING SEVERE ABDOMINAL AND PELVIC PAINS. UPON EXPERIENCING THESE PAINS I WAS GIVEN A TRANSVAGINAL SCOPE WHICH SHOWED PLACEMENT OF DEVICE AND SUBSEQUENT CYSTS. ALMOST A YEAR LATER I HAVE A SEVERE BLOATED STOMACH THAT CONTINUES TO GROW AND UNEXPLAINED WEIGHT GAIN OF 20 PDS. IN THE PAST YEAR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043681	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 11/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE IN (B)(6) 2011 HAVE HAD HORRIBLE MIGRAINES, SUPER TIRED, PERIODS ARE HORRIFIC, HORRIBLE CRAMPING, HEAVY, HEAVY BLEEDING WITH BLOOD CLOTS. HORRIBLE STOMACH AND BACK PAIN. HAD TO HAVE GALL BLADDER REMOVED. MORE DEPRESSED AND ANXIETY WAY HIGHER. HAVING NO WANTING FOR SEX OR MY HUBBY , TEETH ARE HORRIBLE AND BREAKING OUT OF NO WHERE. I'VE GAINED 50 POUNDS AND CAN'T LOOSE THE WEIGHT ,EASY BRUISING , HAIR LOSS LIKE CRAZY , DOUBLE KIDNEY INFECTION. IT'S BEEN HELL. JUST WANT MY LIFE BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043682	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DURING PLACEMENT, EXPERIENCED INTENSE PAIN AND CRAMPING. BLEEDING FOR SEVERAL WEEKS AFTER. AFTER PLACEMENT, UNTIL NOW - CONSTANT CRAMPING, INFECTIONS AND PAIN DURING INTERCOURSE. TREMENDOUS BACK PAIN, SWOLLEN BELLY AND SHARP SHOOTING PAINS IN GUT. CRAMPS ARE CONSTANT, NEVER GO AWAY - BUT DO GET WORSE, AND WAY WORSE AT TIMES. INTENSE, HEAVY BLEEDING DURING MY MONTHLY CYCLE AS WELL AS IRREGULAR BLEEDING AT OTHER TIMES DURING THE MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043693	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 3/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATELY AFTER THE DEVICE WAS INSERTED I WAS VOMITING, LEG PAIN WEAKNESS FATIGUE HEADACHE, PELVIC PAIN, PRESSURE, RECURRENT BACTERIAL VAGINOSIS, LONGER AND HEAVY PERIODS. CLOTS, PREGNANCY, ARTHRITIS, TOOTH PROBLEMS. BACK PAIN, RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043694	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ABDOMINAL PAIN, BLOATING, VERY HEAVY PERIODS, RASHES, HEADACHES AND JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043696	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 8/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD ESSURE SINCE (B)(6) OF 2008, GRADUALLY HAVING SIDE EFFECTS THAT I WOULD JUST BLOW OFF. UNTIL LAST, (B)(6) MY (B)(6) YEAR ANNIVERSARY OF ESSURE PLACEMENT, I WENT TO GO GET A PERM (WHICH I'VE DONE BEFORE), MY HAIR FELL OUT, MY SCALP WAS SCORCHED, TWO DAYS AFTER THAT I COULDN'T SEE, I WENT TO EYE DOCTOR WHOM SAID AFTER A FEW TESTS, THAT I WAS BLIND 3/4 IN RIGHT EYE, I LOST MY CDL CLASS B, PERMIT ANDAMP; ALSO HAD TO GET A RESTRICTION ON MY DRIVERS LICENCE. AT FIRST I WAS BLAMING THE PERM CHEMICALS, BUT I WAS WRONG MORE THEN THREE DIFFERENT DOCTORS, TOLD ME NO THE PERM WOULD NOT HAVE CAUSED THIS. THEN MY SIDE EFFECTS REALLY STARTED SPIRALLING OUT OF CONTROL, STARTED HAVING (MS SYMPTOMS), AFTER MORE TESTS IT HAS BEEN DETERMINED THAT I DO NOT HAVE MS. HERE ARE THE SIDE EFFECTS I HAVE TO ESSURE: LOSS VISION, MORE SENSITIVE TO HAIR PRODUCTS, OFF ANDAMP; ON HAVING TROUBLE WALKING, PAIN IN LEGS ANDAMP; HIPS, PAIN IN ARCH OF RIGHT FOOT (FEELS LIKE MUSCLE TISSUE TEARING), TINGLING ANDAMP; NUMBNESS FROM FINGERTIPS TO MID SHOULDER (BOTH ARMS), SHARP PAIN IN SHOULDER BLADE (BOTH SIDES), MIGRAINES ANDAMP; HEADACHES (EVERYDAY) , 16-18 HOUR SLEEP COMAS (FATIGUE), NAUSEA (EVERYDAY), MOODINESS (EVERYDAY), NECK STIFFNESS, LOWER, AND MID BACK PAIN, ELECTRIC SHOCK PAIN IN BOTH BREAST AREAS (AT DIFFERENT TIMES, EVEN ON DIFFERENT DAYS), MY TEETH ARE BECOMING VERY POOR, METAL TASTE IN MOUTH, HIVES SHOWING UP ON RIGHT EAR, RIGHT ARM, AND ON BELLY UNDER BELLY BUTTON (ALL THREE AT DIFFERENT TIMES, EVEN YEARS APART) ITCHING SO PAINFUL, PERIODS ARE JUST STARTING TO ACT UP SINCE (B)(6) OF THIS YEAR, HAVING PREGNANCY SYMPTOMS, THEN WHEN I START MY PERIOD, I HAVE STUFF HANGING OUT OF MY VAGINA (IT IS SO GROSS, ANDAMP; FREAKS ME OUT), BOTH OF MY EYES TWITCH IN THE OUTER CORNERS, FIRST IT MY RIGHT EYE FOR MONTHS, THEN IT STARTED ON MY LEFT EYE JUST A MONTH AGO, I'VE ALSO HAD

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KNIFE SHARP DRAGGING PAIN IN MY LOWER ABDOMINAL AREA; BACK IN (B)(6) 2014, I COULD NOT MOVE WITH OUT FEELING THAT KNIFE BLADE PAIN, I WAS SO SCARED TO DEATH. I WOULD JUST LAY ON MY BED AND HOLD VERY STILL UNTIL THE PAIN WAS GONE, I ALSO GET THESE SMALL KICKS IN MY LOWER ABDOMINAL AREA (FLUTTERS) BUT MINE FEELS LIKE A BABY KICKING (I'VE HAD THREE CHILDREN), I'VE HAD TWITCHING IN MY FACE , ON CHEEKBONE AND RIGHT UNDER MY BOTTOM LIP, I WAKE UP WITH AN ODOR IN MY PANTIES, NOT STINKY, KIND OF SWEET BUT YUCKY MIXED TOGETHER, ITS CLEAR LIKE WATER, BUT ITS NOT SWEAT, MY MAIN SIDE EFFECT BESIDES GOING BLIND, AND LOSING MY HAIR, IS MY MEMORY LOSS, I CAN'T REMEMBER ANYTHING, I LOOSE MY STUFF BECAUSE I DON'T KNOW WHERE I'VE PLACED, I'VE FORGOTTEN HOW TO USE A COMPUTER SOMETIMES, NAMES OF PEOPLE I'VE KNOWN FOR YEARS, I FORGET WHAT PEOPLE TELL ME, DATES, BUT THEN THERE ARE OTHER DAYS I WILL REMEMBER RANDOM STUFF FROM THE PAST. BESIDES ME THINKING THE PERM CAUSED MY BLINDNESS, AND MY HAIR TO FALL OUT, I THOUGHT I WAS SHOWING SIGNS OF EARLY ALZHEIMER'S BUT DOCTORS ONCE AGAIN TOLD ME NO. THEY CAN'T DISCOVER WHAT IS CAUSING THESE FLARE UPS I NEVER WOULD HAVE THOUGHT OF ESSURE, UNTIL I STARTED DOING RESEARCH ON IT. THAT WAS DURING THE END OF TIME I WAS GETTING DESPERATE WITH THIS MYSTERY OF MY HEALTH PROBLEMS. I'VE LOST TWO JOBS DUE TO MY SIDE EFFECTS, BUT I STILL WORK MY OTHER TWO JOBS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043702	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I JUST LEFT THE LOCAL EMERGENCY ROOM. I AWOKE AT 4:30 A.M. TO EXTREME CRAMPING AND BLEEDING. JUST 3 DAYS PRIOR, I FELT A STABBING PAIN IN THE AREA OF MY OVARIES. THIS HAS HAPPENED MULTIPLE TIME SINCE HAVING ESSURE IMPLANTED IN EARLY 2008. AFTER THE PAIN, I STARTED BLEEDING WITH NO PAIN, WHICH IS VERY UNUSUAL FOR MY MENSTRUAL CYCLE. ON DAY 2, THE PAIN BEGAN. IT WAS BAD, BUT I WAS CONTROLLING IT WITH IBUPROFEN. THIS MORNING, THE PAIN WAS UNBEARABLE. I COULDN'T KEEP THE IBUPROFEN DOWN. I WENT TO THE ER IN EXTREME PAIN, VOMITING, AND COVERED IN SWEAT. IT TOOK 3 PAIN INJECTIONS AND 3 NAUSEA INJECTIONS TO SUBSIDE MY CONDITION. I HAD A CT SCAN AND BLOOD WORK. THEY FOUND NOTHING, AND STATED I COULD HAVE PASSED A KIDNEY STONE. THE SAME THING HAPPENED LAST YEAR, AND I WENT TO MY GYNECOLOGIST. SHE FOUND NOTHING WRONG, AND TRIED BIRTH CONTROL PILLS FOR THE 5TH TIME. I HAVE ALSO ALREADY HAD CYSTS REMOVED FROM BOTH OVARIES, ALONG WITH ENDOMETRIOSIS. THE SYMPTOMS CONTINUE TO WORSEN. MY MENSTRUAL CYCLE IS HIGHLY IRREGULAR AND ALWAYS PAINFUL. I AM WORKING TO HAVE THE DEVICE REMOVED. MY ABDOMEN HAS BEEN SWOLLEN FOR YEARS, AS WELL. I HAVE TRIED EVERYTHING POSSIBLE AND CAN'T GET THE SWELLING DOWN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043703	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 2/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). 5 DAYS AFTER HAVING ESSURE IMPLANTED I STARTED HAVING SEVERE LEVEL 10 STABBING PAINS IN MY LOWER STOMACH. THIS SOMETIMES LASTS FOR 10 MINUTES SOMETIMES 2-3 WEEKS. MY PERIODS ARE HORRIBLE, CRAMPING AND BLEEDING EVERY 12-16 DAYS. IN THE LAST 4 YEARS I HAVE EXPERIENCED. BLOATING TO WHERE I LOOK PREGNANT, JOINT PAINS. BURNING IN ARMS, HANDS AND FEET. TINGLING IN HANDS, ARMS, AND FEET. TOOTH DECAY AND LOST TEETH. BRUISING ALL OVER MY BODY FOR NO REASON. THE TASTE OF SALTY METAL IN MY MOUTH CONSTANTLY. FATIGUE ALL THE TIME. CONTINUOUS FOGGY HEAD. RASHES. LOWER BACK PAIN. PAIN DURING INTERCOURSE. COMPLETE LOSS OF SEX DRIVE. CONSTANT PAIN. THROWING UP ON A DAILY BASIS. TREMORS AND CONSTANT SHAKING. HOT FLASHES ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043708	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 8/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5043708 #(B)(4). RE: REPORT ID (B)(4) SUBMITTED (B)(6), 2015. CORRECTIONS AND ADDITIONS IN CAPS: (B)(6); DATE OF IMPLANTATION WAS (B)(6), 2014; A PELVIC AND TRANSVAGINAL ULTRASOUND DONE (B)(6), 2015 DUE TO SEVER LOWER LEFT ABDOMINAL PAIN. PATHOLOGY REPORT CONFIRMED MICROSCOPIC ENDOMETRIOSIS IN SOFT TISSUE SURROUNDING ESSURE COILS AND INFLAMMATION OF THE FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043709	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWOLLEN ANKLES, PAIN IN LOWER JOINTS, PAIN IN ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043710	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN ALL THE TIME, ABNORMAL BLEEDING, PAINFUL PERIODS, HEAVY BLEEDING, MOOD SWINGS, BV, REOCCURRING YEAST INFECTIONS, ENLARGED UTERUS, ENLARGED OVARIES, WEIGHT GAIN, METAL TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043711	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 2/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN ON R SIDE IN ABDOMINAL REGION. BLEEDING AND PAINFUL INTERCOURSE. BLEEDING ALL THE TIME. HSG PERFORMED AND STATES ANGULATION OF MARKER SHOWING POSSIBLE FRACTURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043712	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 6/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD BAD HEADACHES, SERIOUS IMMOBILIZING PELVIC AND ABDOMINAL PAIN. SHARP STABBING FEELING. I CAN FEEL MY FALLOPIAN TUBES WHEN I SIT, WALK, LAY DOWN. EXHAUSTION, PAIN DURING AND AFTER INTERCOURSE. CONSISTENT YEAST INFECTIONS. BACK TO BACK AT TIMES. BLOATING THAT CAUSE PAIN TO A POINT WHERE I LOOK AS IF IM PREGNANT. SPOTTING, DIZZINESS, FATIGUE. LOST COUNT OF HOW MANY TIMES I'VE BEEN TO THE EMERGENCY ROOM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043713	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEPRESSION, HAIR LOSS, BLOTTING, HEAVY PERIOD, RASHES, HEADACHES, WEIGHT GAIN, MOOD SWINGS, ABDOMEN PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043714	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 11/15/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MASSIVE ABDOMINAL PAIN, EXCESSIVE BLEEDING, BACK PAIN, CYSTIC ACNE, RASHES, BLOATING, WEIGHT GAIN, MOOD SWINGS, IRREGULAR MENSTRUAL CYCLES, DEPRESSION, MEMORY LOSS, HAIR FALLING OUT, HIVES, SKIN CONDITIONS, HORMONAL IMBALANCE, GUM ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043715	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 2/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MAJOR MIGRAINE, DIZZINESS, FATIGUE, AND PAINS THAT FEEL LIKE LABOR PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043716	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT ALL STARTED IN (B)(6) 2013 AFTER I HAD THE PROCEDURE DONE. MY DOCTOR HAD TROUBLE PLACING THE COIL ON THE RIGHT SIDE AND FOR A WHOLE YEAR AFTERWARDS (UNTIL (B)(6) 2014) I HAD CONSTANT PAIN TO THE POINT I WAS TAKING PAIN PILLS TO GET RID OF IT AND EVEN THEN IT WOULD ONLY BE TEMPORARY RELIEF. NOW, EVERY TIME I GET MY PERIOD THE PAIN COMES BACK FOR THE DURATION OF THE PERIOD, AND FOR THE LAST 2 DAYS OF EVERY CYCLE, I HAVE THIS NASTY FOUL-SMELLING BROWN DISCHARGE. IT'S NOT BLOOD, OR IF IT IS, IT IS VERY DRIED BLOOD AND IT MAKES MY VAGINA ITCH AND BECOME SENSITIVE. ESSURE HAS ALSO CAUSED ME TO BLOAT EXCESSIVELY IN MY STOMACH AREA, EVEN AFTER I LOST 50 LBS AFTER MY SECOND CHILD. I CANNOT GET RID OF MY STOMACH AREA, AND I AM CONSTANTLY BLOATED NO MATTER WHAT. ALSO, ESSURE HAS MESSED WITH MY EMOTIONAL STATE BADLY AS I AM DEPRESSED A LOT OF THE TIME. ONE MORE THING, MY LEFT LEG GOES NUMB EVERY SINGLE WEEK FOR SEVERAL DAYS OUT OF THE WEEK. IT IS ALWAYS A DIFFERENT DAY OF THE WEEK, BUT IT GOES NUMB TO THE POINT I HAVE TO WALK 24/7 TO GET RELIEF. I NEVER HAD ANY OF THESE SYMPTOMS PRIOR TO ESSURE. I AM CONFIDENT I HAVE A NICKEL ALLERGY TO THIS DEVICE, BUT I HAVE NOT BEEN TESTED FOR THE ALLERGY. I HAVE VISITED THE ER ONCE FOR MY LEG PAIN ((B)(4), 2015), BUT THE PHYSICIAN DID NOT DO ANYTHING FOR MY LEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043717	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE FIBROMYALGIA, CELIAC DISEASE, I CAN'T WEAR EARRINGS FOR LONG PERIODS OF TIMES IN MY LOBES WITHOUT MY EARS SWELLING AND GETTING INFECTED, MY JOINTS HURT, I BURN REALLY EASY OUT IN THE SUN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043718	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 12/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AS SOON AS I WAS IMPLANTED I COULD FEEL A DIFFERENCE ESPECIALLY THE DAY AFTER BACK PAIN STARTED , CRAMPING STARTED, SEVERE PAIN ON MY LEFT SIDE PELVIC AREA, BLOATING STARTED, SEVERE SKIN OUTBREAK, STARTED GETTING VERY MOODY, BAD FATIGUE, LIMITED ACTIVITIES WITH MY CHILDREN. BEEN VERY EMOTIONAL, WORSENING PERIODS....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043719	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE COILS INSERTED I HAVE CHRONIC BACK PAIN, CHRONIC MIGRAINES, DIAGNOSED WITH FIBROMYALGIA, HEAVY PAINFUL CLOTTING PERIODS, PASS HUGE CLOTS, DAYS LEADING UP TO MY PERIOD I'M N BED WITH SUCH SEVERE PAIN I CANT DO ANYTHING BUT LAY IN BED, DEPRESSION, PTSD, ARTHRITIS, PELVIC PAIN, CRAMPING, CONSTANT UTI'S, DERMATITIS ON MY INNER THIGHS, ANXIETY, FACE BREAKS OUT SEVERELY, HAIR LOSS, PAINFUL SEXUAL INTERCOURSE, SEVERE WEIGHT GAIN!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043720	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 4/20/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE WEIGHT GAIN. PELVIC PAIN. LOWER BACK PAIN. PHYSICAL THERAPY. HIGH BLOOD PRESSURE. HEAVY PERIODS. BLOOD CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043721	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2013, IT WAS OUT, IN, AND I NEED IT OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043722	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 12/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABNORMAL (NON-STOP) VAGINAL BLEEDING SINCE IMPLEMENTATION, CAUSING ANEMIA, SEVERE ABDOMINAL PAIN, HAIR LOSS, BRAIN FOG, FATIGUE, LOSS OF SEX DRIVE, MIGRAINES, ABDOMINAL SWELLING, WEIGHT GAIN, CONSTIPATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043723	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, FATIGUE , MIGRAINES, WEIGHT GAIN, LOSS OF SEX DRIVE, SUICIDE,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043724	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SHARP/STABBING PELVIC PAIN, OVARIAN CYSTS, BACTERIAL VAGINOSIS, DISCHARGE (ODOUR/NON ODOUR), ENDOMETRIOSIS (INVESTIGATING FURTHER AS WE SPEAK), HOT FLASHES, CYSTS IN THE VAGINAL OPENING (BARTHOLIN'S CYSTS), NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, PAINFUL INTERCOURSE (DYSPAREUNIA), EARLY MENOPAUSE, INCONTINENCE, URGENT/FREQUENT URINATION, ITCHING/BURNING/STABBING/STINGING OF THE VAGINAL ENTRANCE (VULVOYNIA), BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/TWITCHING/FLUTTERING, BACK/JOINT/CHEST/LEG/BREAST/NECK/SPINE/HIP, CHRONIC PELVIC PAIN, ALL OVER BODY ACHES/PAIN, NAUSEA/GAS/CONSTIPATION/DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN HAS INCREASED, BOWEL ISSUES, HEADACHES/MIGRAINES GOTTEN WORSE EVEN TO BE ADMITTED TO HOSPITAL, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, NERVE PAIN, BRAIN FOG - CLOUDINESS/FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, DEPRESSION (SADNESS/SUICIDAL THOUGHTS), RINGING IN THE EARS (PULSATILE TINITUS), DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), MOOD DISORDERS (DIAGNOSED WITH BIPOLAR DISORDER SINCE HAVING ESSURE), PTSD (POST TRAUMATIC STRESS DISORDER), NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN (PARESTHESIA), NERVE PAIN, SHAKINESS, DIZZINESS, SKIN IRRITATION/ITCHING GOTTEN SO BAD I'M SCRATCHING SOMETHING CHRONIC, HEART PALPITATIONS GOTTEN WORSE, SWELLING OF LEGS OR FEET, HAIR LOSS OR CHANGES, DENTAL ISSUES, INSOMNIA, WEIGHT ISSUES (LOSS/GAIN), NUMBNESS IN JAWS, SWELLING OF LEGS/FEET, MUSCLE SPASMS, VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION), EXCESSIVE SWEATING, DRY SKIN/HAIR/EYES, SEVERE BLOATING, SWOLLEN GLANDS.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043725	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY THICK SALIVA. FEET AND HANDS COLD. BODY ODOR EVEN RIGHT AFTER SHOWER. SHARP STABBING PAINS. NAUSEA AND VOMITING. DIZZINESS. CONSTIPATION. ANXIETY. DEPRESSION. EXTREME WEAKNESS AND PAIN CAUSING ME TO BE IN WHEELCHAIR. THICK NAILS. EVERYDAY HEADACHES. EXTREME JOINT PAIN. BED RIDDEN. FOGGINESS AND FORGETFULNESS IN BRAIN. FIBROMYALGIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043726	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 11/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6)-2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THE ONSET OF MY COMPLAINT STARTED ON IMMEDIATELY. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: FATIGUE, JOINT PAIN, FEELING OF "ALIENS CLAWING AT MY INSIDES," INTERMITTENT CRAMPING IN THESE MONTHS FOLLOWING THE PROCEDURE. NOT ONLY DO I HAVE THESE SYMPTOMS FOLLOWING THE IMPLANTATION OF ESSURE, BUT IT DID NOT WORK AS IT WAS SUPPOSED TO. FOLLOWING THE CONFIRMATION TESTS AT 3 MONTHS AND AGAIN AT 6 MONTHS POST IMPLANTATION, RADIOLOGY RESULTS INDICATE THAT THE ESSURE COIL DID NOT SCAR THE RIGHT FALLOPIAN TUBE AND IS NOT FUNCTIONAL AS BIRTH CONTROL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043727	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DUE TO MY ONGOING PROBLEMS WITH ESSURE I HAD TO HAVE A HYSTERECTOMY. I HAD GAINED 65LBS. LOOKED 7 MONTHS PREGNANT, LOST MOST OF MY HAIR, HAD SORES IN MY HEAD AND ACNE START ALL OVER MY FACE ALONG WITH RASHES ON MY ARMS AND LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043728	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, BACK PAIN, PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043729	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 2/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I GOTTEN THE ESSURE PUT IN I HAVE HAD BAD BLEEDING ALL THE TIME. I FOUND OUT AFTER HAVING ESSURE PUT IN THAT I HAVE IBS AND INTERSTITIAL CYSTITIS. I AM SO SWOLLEN IN THE BELLY . I AM CRAMPING ALL THE TIME. I CAN'T SLEEP BECAUSE OF THE PAIN I AM DEALING WITH. I AM HAVING A LOT OF MEMORY LOSS, MORE EACH DAY. I GET LIGHT HEADEDNESS. I AM TWITCHING SO BAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043730	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE RIGHT AFTER MY FIFTH CHILD, RIGHT AWAY I STARTED HAVING PAIN AND CRAMPING THAT I WAS TOLD WOULD GO AWAY WITH TIME, IT DID NOT, IT GOT WORSE AND WAS ACCOMPANIED WITH STABBING PAINS AND CRAMPING, ALSO BLOATING IRREGULAR BLEEDING, HEAD ACHES. I HAVE WAITED TWO AND A HALF YEARS AND FINALLY DECIDED THAT I CAN'T LIVE WITH THIS PAIN ANYMORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043731	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN , GAINED WEIGHT, NAUSEA, PAIN AFTER AND WHEN I'M HAVING SEX, HEADACHES, I FEEL SAD , TIRED, SENSITIVE BREAST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043732	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 4/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HYPOTHYROIDISM AND PTSD. I HAVE STARTED BLOATING PAINFULLY AFTER MEALS TO THE POINT WHERE I LOOK PREGNANT. IT IS EXTREMELY PAINFUL AND CAN LAST ANYWHERE FROM HALF AN HOUR TO TWO HOURS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043734	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/31/2012 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH THE ESSURE DEVICE IN MY GYNECOLOGISTS OFFICE. NOT ONLY DID I HAVE IMMENSE PAIN, I'VE HAD NOTHING BUT ADVERSE EFFECTS SINCE THEN, BUT MY DOCTOR REFUSED TO SEE ME, AND MY MEDICAL RECORDS FROM MY IMPLANTING DOCTOR AS WELL AS OTHER DOCTORS I WENT TO SEEKING HELP ARE FALSIFIED. YES, I DO HAVE PROOF AND DOCUMENTATION OF MY ALLEGATIONS. MY UNBORN CHILD THAT I CONCEIVED AFTER A CONFIRMATION HSG TEST THAT CLAIMED I WAS 100% OCCLUDED, WAS MISCARRIED EARLY IN MY PREGNANCY, WHICH IS WHY I USED THE CHECK MARK ON THE BOX THAT SAYS DEATH. MY UNBORN CHILD DIED AS A RESULT OF THIS DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043735	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD HEADACHES, DIZZY, METAL TASTE, SHARP PAIN IN AREA AS COIL ON MY LEFT, HOT FLASHES, FEVERS AND WENT TO DOC AND I WAS NOT ILL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043736	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 11/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CAUSED TILTING OF UTERUS, ENDOMETRIOSIS, INFECTION OF LEFT TUBE, BRAIN FOG, EXTREME LOW PELVIC PAIN, JOINT PAIN/ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043740	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 5/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CONSTANT SEVERE PAIN, RASHES, BREAKOUTS, ALSO HAVE A LARGE MASS IN MY RIGHT OVARY. I AM TYPE 1 DIABETIC HAVE DEGENERATIVE DISC SEVERE MIGRAINES AND SEVERE ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043741	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 6/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE NOTICED THE FLOW OF MY PERIOD VERY HEAVY, LOWER ABDOMEN PAIN, MIGRAINES, DIZZINESS FORGETFULNESS, DEPRESSION THESE THINGS THAT ARE AFFECTING MY EVERY DAY ACTIVITIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043743	BAYER	7/8/2015	7/8/2015

Event Information:

Event Date (B3): 3/22/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY TUBES PINCHED AND HURT NON STOP AFTER GETTING THIS. THEN CAME BACK PAIN. JOINT PAIN. LOSS OF ENERGY FROM BEING IN PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043733	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 11/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ESSURE SINCE (B)(6) 2007. I WAS NOT TOLD OF ANY ADVERSE POSSIBLE SIDE EFFECTS, SO WHEN THEY ALL BEGAN, I DID NOT MAKE THE CONNECTION TO ESSURE. DUE TO THE ABUSIVE NATURE OF MY IMPLANTING DOCTOR, AND THE TRAUMA THAT I EXPERIENCED DURING MY IMPLANTATION "PROCEDURE" (NO PAIN MEDS, WIDE AWAKE, IN HIS CLINIC) AND FOLLOWING HSG TEST, I STOPPED SEEING THAT DOCTOR AND HAD DIFFICULTY TRUSTING ANY OTHERS TO HELP ME FIGURE OUT WHAT WAS HAPPENING TO MY BODY IN THE YEARS TO COME. IT STARTED OFF AS SEVERE ITCHING AND SWELLING OF MY HANDS SHORTLY AFTER I WAS IMPLANTED. MY FEET AND ANKLES ALSO BEGAN TO SWELL UP. I TRIED SPECIAL DIETS WHICH DID NOTHING TO HELP. SHORTLY LATER, THE INTENSE VAGINAL ITCHING WITHOUT DISCHARGE OR ODOR BEGAN. IN 2009 I BEGAN BREAKING OUT IN HIVES, WELTS AND RASHES. I ALSO DEVELOPED DERMATOGRAPHISM AT THIS TIME. THIS IS WHEN I BEGAN TAKING ALLERGY MEDICATIONS TO GET THROUGH THE DAYS. IN 2012 I WAS SEEN BY MANY DOCTORS AND SPECIALISTS WHEN I HAD AN AUTOIMMUNE ATTACK ON MY BRACHIAL PLEXUS. I WAS DIAGNOSED WITH PARSONAGE-TURNER SYNDROME, AN AUTOIMMUNE CONDITION, CAUSED BY ALL THE INFLAMMATION IN MY BODY. I STILL HAVE PARALYSIS AND ATROPHY IN MY RIGHT SHOULDER FROM THAT ATTACK. IN 2013, ALONG WITH ALL THE OTHER SIDE EFFECT STILL PLAGUING MY BODY, I DEVELOPED DISHYDROTIC ECZEMA WITH INTENSE ITCHING, BLISTERING AND SKIN LOSS ON MY HANDS AND FEET. AT THIS TIME, I INCREASED THE ALLERGY MEDICATION IN AN ATTEMPT TO MAINTAIN THE FLESH ON MY BODY. ONCE MAKING THE CONNECTION OF THIS TYPE OF ECZEMA AND AN EXPOSURE TO NICKEL, I BEGAN TO SEEK OUT HOW I COULD BE COMING IN CONTACT WITH NICKEL AND I WAS HORRIFIED TO FIND OUT THAT IT IS FROM THE ESSURE DEVICE. IN (B)(6) OF 2015 I TESTED (B)(6) TO A NICKEL AND GOLD ALLERGY. I HAD BILATERAL SALPINGECTOMY ON (B)(6) 2015 WITH COIL REMOVAL. ON (B)(6) 2015, ONE WEEK AFTER THE SURGERY, I BECAME

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EXTREMELY SICK WITH BLOATING, FEVER AND RIB PAIN. I WENT THE ER WHERE A CT SCAN REVEALED METAL FRAGMENTS LEFT INSIDE MY UTERUS. THE SIDE EFFECTS HAVE BECOME WORSE AFTER THE SURGERY ON (B)(6). ALLERGY MEDICATION MIGHT BE HELPING BUT NOT ENOUGH, AS STOPPING THE BLISTERING AND MAINTAINING THE SKIN ON MY HANDS AND FEET ARE MUCH MORE DIFFICULT AT THIS TIME. THE SWELLING IN MY HANDS AND FEET ARE CONSTANT. THE HIVES AND DERMATOGRAPHISM IS AT IT'S WORSE. I ALSO NOW HAVE SIDE, BACK AND ABDOMINAL PAIN THAT WAS NOT THERE BEFORE THE SURGERY. OUTSIDE OF THESE PHYSICAL SIDE EFFECTS I ALSO HAVE HAD NO INTEREST IN SEX SINCE HAVING ESSURE, DEAL WITH DEPRESSION ON A REGULAR BASIS, HAVE PTSD AND RIGHT AFTER HAVING ESSURE IMPLANTED, HAVE STRUGGLED WITH WEIGHT GAIN THAT NO AMOUNT OF DIET OR EXERCISE HAS BEEN ABLE TO REGULATE. MY IMPLANTING DOCTOR PRESENTED ESSURE PERMANENT BIRTH CONTROL TO ME. IT WAS NOT ME WHO INQUIRED OF HIM. HE AND HIS PRACTICE HAD A LOT OF EXPENSIVE ESSURE EQUIPMENT INSIDE OF THEIR OFFICE TO PAY FOR. MY HEATH WAS FOR SALE AND I DID NOT KNOW IT. THIS DEVICE WAS PRESENTED AS MY SAFEST OPTION SINCE I ALREADY HAD 3 CESARIAN SECTIONS. PREGNANCY WOULD BE RISKY AS WOULD ANOTHER SURGERY TO DELIVER A BABY. NO NEED TO REQUIRE A VASECTOMY OF MY HUSBAND, ESSURE WAS SAFE AND NON SURGICAL. THE GREATEST INJUSTICE IS THAT I WILL NOW REQUIRE AT LEAST TWO SURGERIES TO REMOVE THIS DEVICE FROM MY BODY. ADDING THESE TO MY 3 CESARIAN SECTIONS. I AM NOW SCHEDULED FOR YET ANOTHER SURGERY. I WILL BE LOOSING MY UTERUS AND CERVIX ON (B)(6) OF 2015. DUE TO THE FACT THAT THE SURGERY ON (B)(6) CAUSED THE DEVICES TO BREAK, IT IS POSSIBLE THAT THIS NEXT SURGERY WILL NOT ACTUALLY BE EFFECTIVE AT REMOVING ALL OF THE FRAGMENTS FROM MY BODY. ESSURE, AND THE POISONS THAT ARE IN IT, MAY NEVER REALLY BE ENTIRELY REMOVED FROM MY BODY. MY REPRODUCTIVE ORGANS AND MY HEALTH BELONG TO ME! NOT THE FDA, NOT (B)(4), NOT CONCEPTUS, NOT MY DOCTORS. THIS PRODUCT NEEDS TO BE RECALLED AND REMOVED FROM THE MARKET. THERE WILL BE NO JUSTICE FOR ME OR THE TENS OF THOUSANDS OF OTHER WOMAN WHO ARE BEING INJURED BY THIS "MEDICAL DEVICE" UNTIL THIS HAPPENS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043737	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 3/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDAMW5043737 #(B)(4). ON (B)(6), 2014 I DID HAVE TO HAVE A BILATERAL SALPINGECTOMY WITH DANDAMP;C TO REMOVE THE ESSURE DEVICE. ALSO ALMOST ALL SYMPTOMS ARE GONE. MOST OF MY BACK ANDAMP; HIP PAIN WAS GONE THE SAME DAY OF REMOVAL. COINCIDENCE... I THINK NOT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043738	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 2/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODIC SHARP STABBING PAINS FROM THE LEFT FALLOPIAN TUBE AREA THROUGHOUT THE MONTH DEBILITATING UTERINE CONTRACTIONS (9+ ON THE PAIN SCALE), COLD SWEATS, NAUSEA/VOMITING, SHARP DROPS IN BLOOD PRESSURE, SHAKING ABOUT 4-5 DAYS AFTER THE START OF MY PERIOD. ACCORDING TO THE PATHOLOGY REPORT AFTER A HYSTERECTOMY ON (B)(6) 2015 TO REMOVE THE UTERUS, FALLOPIAN TUBES, AND CERVIX - THERE WAS SIGNIFICANT ADENOMYOSIS WHERE THE FALLOPIAN TUBES MEET THE UTERUS - LIKELY CAUSING THE DEBILITATING PAIN AND CONTRACTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043739	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 12/9/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4), 3 MISCARRIAGE'S, SEVERE PAIN IN LOWER ABDOMEN AND LEGS, GALLBLADDER ISSUES, SEVERE SLEEPLESS, SEVERE CRAMPING, POST PARTUM DEPRESSION, DEPRESSION, BLOOD TRANSFUSION DO TO MISCARRIAGE, MOOD SWINGS, MOVEMENT OF ESSURE, FAILED ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043742	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 5/8/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE PLACED IN (B)(6) OF 2012, AND ANKLES AND FEET HAVE BEEN SWELLING SINCE 2013. GRADUALLY GETTING WORSE AND WORSE OVER THE YEARS. WENT TO THE DOCTOR AND DID A URINE SAMPLE. KIDNEY INFECTION WITHOUT ANY SYMPTOMS OR SIGNS OF A UTI; 3 DIFFERENT ANTIBIOTICS IN A MONTH AND A REFERRAL TO A UROLOGIST. KIDNEY ULTRASOUND AND 24 HOUR URINE SAMPLE TO BE DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043744	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CRAMPING, SHARP/STABBING PELVIC PAIN, ABNORMAL MENSES, PERIOD STOPS, ADENOMYOSIS, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), PAINFUL OVULATION (MITTELSCHMERZ), NIGHT SWEATS, LOSS OF LIBIDO, PAINFUL PERIODS (DYSMENORRHEA), BLEEDING BETWEEN PERIODS (METRORRHAGIA), LONG MENSTRUAL CYCLES (POLYMENORRHEA), LACK OF MENSTRUAL CYCLE (AMENORRHEA), BREAST PAIN/TENDERNESS, PAIN IN JOINTS, LEG, BREAST, HIP, KNEES, ALL OVER BODY ACHES/PAIN, SEVERE, METALLIC TASTE IN MOUTH, NEUROLOGICAL, MENTAL HEALTH, HEADACHES AND MIGRAINES, TINGLING SENSATIONS, NUMBNESS, BRAIN FOG AND CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, DEPRESSION, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), TREMORS/SHAKINESS, ANEMIA/ IRON DEFICIENCY/LOW FERRITIN, VITAMIN D DEFICIENCY, VITAMIN B-12 DEFICIENCY, ALLERGIES/SENSITIVITIES, HEIGHTENED ALLERGIES/ ALLERGIC REACTIONS, ALLERGIC REACTIONS, CYSTS, BOILS, ACNE, SWELLING OF LEGS OR FEET, HAIR LOSS OR CHANGES, DENTAL ISSUES, INSOMNIA, THYROID DISEASE (HYPOTHYROID WORSE SINCE ESSURE), WEIGHT ISSUES (GAIN), SLEEP APNEA IS WORSE. SWELLING OF LEGS/FEET, VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION), DRY SKIN/HAIR/EYES, SEVERE BLOATING

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043745	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 9/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER ESSURE WAS INSERTED I HAD PAIN THAT I EXPECTED, BUT THE PAIN CONTINUES. I HAVE PAIN WHEN I COUGH, SNEEZE, BEND, INTERCOURSE (DURING AND AFTER) AND INCREASED SEVERITY OF CRAMPS DURING MY PERIOD. I WAS DIAGNOSED WITH MENORRHAGIA (EXCESSIVE BLEEDING) DURING MY PERIODS SINCE ESSURE WAS PLACED. MY DR. STATES ITS FROM NOT BEING ON THE PILL, I DISAGREE. THESE MENTRUAL CYCLES POST ESSURE ARE HORRIFIC. I HAVE FOUR CHILDREN WHEN I WAS OFF THE BIRTH CONTROL PILL PRIOR THE PERIODS WERE NOWHERE NEAR THE VOLUME OF THESE POST ESSURE PERIODS. I HAVE HAD BOILS THAT POP UP AND LAST A MONTH OR MORE REGULARLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043746	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 5/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT SIDE STARTED HURTING LIKE A STABBING PINCHING PAIN. SEX WAS SO PAINFUL. LOST A LOT OF HAIR. GAINED 30 POUNDS AND CAN'T LOSE IT. NO ENERGY WHAT SO EVER. THIS HAS RUINED MY LIFE THE LAST 4 YEARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043747	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 12/4/2014 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT AFTER THE PROCEDURE I WAS ALREADY IN ALOT OF PELVIC PAIN. GOOD THING I WAS PUT UNDER. FROM THAT POINT ON I HAD CONSTANT PAIN FROM CRAMPING, STABBING, RADIATING TO MY BACK, I COULDN'T HAVE SEX, OR EVEN STICK A TAMPON IN. MY BLOOD STARTED TO LOOK LIKE A THICK TAR WITH CLOTS IN IT. I WAS CONSTANTLY VOMITING OR NAUSEOUS. STARTED LOSING MY HAIR AND I WOULD GET HOT FLASHES SO BAD THAT I WANTED TO PASS OUT OR FELT LIKE MY BRAIN WAS GOING TO FRY SO I WOULD TAKE 4-6 SHOWERS A DAY. I WOULD GET DIZZY, HAVE MIGRAINES, BLURRED VISION, AND PAIN SHOOTING DOWN MY LEGS. AS WELL AS CRAMPING IN MY MUSCLES. I WAS UNABLE TO WALK, OR DRIVE. I LOST SENSATIONS IN MY FINGER AND TOES AND COULDN'T FEEL WATER TEMPERATURE. SUICIDAL THOUGHTS WHICH LEAD TO A BREAK UP BETWEEN MY CHILDREN'S DAD AND I. NOW I HAVE CPS INVOLVED AND HAVE TO BE MONITORED 24HRS IF I AM WITH MY KIDS. THIS HAS LED MY FAMILY TO TAKE OFF WORK TO HELP ME KEEP MY KIDS AND TAKE CARE OF THEM SINCE I WAS SO SICK. I HAD MY APPENDIX REMOVED, AS WELL AS BLADDER INFECTIONS, KIDNEY INFECTIONS, ENLARGED ABDOMINAL LYMPH NODES AS WELL AS ELEVATED LIVER ENZYMES. I WAS LOSING MY MEMORY, HAD NO SEX DRIVE, HAD DEPRESSION AND ANXIETY. HAD A METAL TASTE IN MY MOUTH AS WELL AS ITCHING AND BLOATING. GAINED WEIGHT I COULDN'T LOSE NO MATTER HOW HARD I TRIED. NEVER STOPPED BLEEDING. HAD TO PUT ME ON NARCOTICS FOR PAIN AS WELL AS MUSCLE RELAXERS. BUILT UP A TOLERANCE THAT LED DRS TO ACCUSE/ASSUME I WAS A DRUG ADDICT OR HAVING WITHDRAWS. HAD TO HAVE A HYSTERECTOMY WHICH I BLED OUT IN RECOVERY AND WAS RUSHED BACK TO THE OPERATING ROOM. AFTER DISCHARGED FROM THE HOSPITAL I HAD TO RETURN DUE TO A FEVER, VOMITING, FAINTING, AND PAIN. STAYED 1WEEK IN THE HOSPITAL. HAVE TROUBLE WITH MY BLADDER AND CONSTANTLY HAVING THE URGE TO GO PEE OR GO PEE, STILL HAVING ABDOMEN PAIN WHICH HAS LED ME IN AND OUT OF THE HOSPITAL.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

HAVE TO TAKE A IRON SUPPLEMENT DUE TO MY BLOOD LOSS. STILL DIZZY AND LIGHT HEADED. CONSTIPATED AND FEEL AS THOUGH MY FOOD IS GETTING STUCK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043748	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 2/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BREAKING OUT IN BOILS EVERY MONTH AND IT SO BAD THAT I DON'T LIKE TO GO ANYWHERE, I'M EMBARRASSED. AND U CAN TELL U I DON'T CARE OF MY LOOKS OR WHAT OTHER THINK BUT IT SO GROSS AND IT ON MY BACK AND IT SEEMS WHEN U SWEAT IT WORSE. MY BODY IS ACHE MY JOINTS, MY BACK, MY FEET, HURT OFF AND ON. MY STOMACH I SWEAR I COULD FEEL SOMETHING MOVING KICKING OR FLUTTERING FEELING AND I'M NOT PREGNANT. I CAN BE FINE THEN 5 MIN FROM GOING TO BATHROOM OR EATING OR EVEN AFTER SEX I LOOK (B)(6) PREGNANT. MY HAIR IS FALLING OR BREAKING APART. ON OCCASION I GET SHAPE PAIN IN MY VAGINA AND MY COLON. OR STRAIGHT DOWN MY LEG WITH A BURNING SENSATION THAT FEELS LIKE MENTHOL. I HAVE NEVER HAD ANY BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043749	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 5/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ESSURE COILS HAVE MIGRATED AND ARE CAUSING SEVER PELVIC PAIN. METAL TOXIN IN MY BODY. ABDOMINAL SWELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043750	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 9/11/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMEN PAIN LOWER LEFT WAS THE WORST, SEVERE RASHES THAT CAUSED HOSPITALIZATION, BECAME VERY LOW ON IRON AND HAD TO GET INFUSIONS, HAIR FELL OUT, MIGRAINES, DEPRESSION, BACTERIAL INFECTION THAT CAUSED HOSPITALIZATION, MOOD SWINGS, HEAVY PAINFUL CLOTTED MENSTRUAL CYCLE THAT WERE NEVER REGULAR AND MORE WHICH LEAD ME TO HAVE A HYSTERECTOMY RECENTLY IN (B)(6) 2015. SENSE THEN ALL ISSUES HAVE SUBSIDED AND I FEEL MUCH BETTER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043751	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 5/23/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, HIP BACK PAIN, SLEEP AMNIA, HAIR LOSS, ENDLESS LIST. DENTAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043752	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 4/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING, EXCESSIVE MENSTRUATION, LOWER BACK PAIN, MEMORY LOSS, MIGRAINE, MUSCLE WEAKNESS, MUSCLE FATIGUE, APHASIA, EXTREME FATIGUE, WEIGHT GAIN, ACNE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043753	BAYER	7/8/2015	7/9/2015

Event Information:

Event Date (B3): 3/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BREAK OUTS. SEVERE HEAVY MENSTRUAL, I FEEL CONTINUOUS PAIN IN MY VAGINAL AREA. I STAY BLOATED, VERY TIRED. EVER SINCE I HAD THESE PUT IN, I FEEL HORRIBLE. GOING NEXT WEEK TO SEE ABOUT HAVING SURGERY TO REMOVE THEM. I WANT MY LIFE BACK!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043930	BAYER	7/8/2015	7/13/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER REPORTS HAVING ESSURE IMPLANTED IN 2010, ONE YEAR LATER SHE WAS FORCED TO HAVE A FULL HYSTERECTOMY. CALLER STATES SHE HAD A HISTORY OF FIBROIDS BUT ONCE THE ESSURE WAS IMPLANTED THE TUMORS GREW AND PROLIFERATED CAUSING HER TO HAVE A HYSTERECTOMY. CALLER REPORTS A YEAR AGO SHE CONTRACTED A BLADDER INFECTION. IT WAS FOUND THAT ONE OF THE ESSURE COILS WAS NOT REMOVED AND HAS MIGRATED TO AN UNKNOWN LOCATION IN THE CALLER'S BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044151		7/8/2015	7/16/2015

Event Information:

Event Date (B3): 2/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4): 626679

Single Use:
Implant Date (E6): 2/1/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

MY SON WAS BORN (B)(6) 2005 AND I ASKED MY DOCTOR TO TIE MY TUBES. SHE WOULDN'T LISTER TO ME AND TOLD ME TO WAIT. THREE YEARS LATER, I ASKED HER AGAIN TO TIE MY TUBES BECAUSE I WAS DONE HAVING CHILDREN. SHE CONVINCED ME TO GO A DIFFERENT ROUTE. SHE TOLD ME ABOUT ESSURE PROCEDURE. SHE SAID IT WAS PAINLESS AND LESS RECOVERY TIME. WHEN I HAD THE PROCEDURE, WHEN SHE INSERTED THE RIGHT SIDE EVERYTHING WENT FINE. WHEN SHE INSERTED THAT LEFT SIDE IT HURTS SO BAD. SHE HAD TO TAKE IT OUT AND REINSERT IT. SHE TOLD ME I WOULD HAVE SOME DISCOMFORT. I REMEMBER CALLING SEVERAL TIMES LETTING HER KNOW THAT I HAD A LOT OF PAIN ON MY LEFT SIDE. WHEN I WENT IN FOR MY 3 MONTH CHECK UP ON THE PROCEDURE, THEY SAID EVERYTHING WAS FINE. IT IS NOW 2015 AND I STILL HAVE PAIN ON MY LEFT SIDE. I HAVE GONE TO SEVERAL DOCTORS AND HAD SEVERAL SCANS, MRIS, X-RAYS YOU NAME IT. NO ONE CAN TELL ME WHY I HAVE PAIN. I AM UNABLE TO EXERCISE A LOT, BECAUSE I WILL BE IN A LOT OF PAIN. I HAVE PAIN AFTER SEX, I HAVE PAIN AFTER LONG PERIODS OF SITTING. THERE IS NO MEDICATION REALLY THAT TAKES THIS PAIN AWAY. I HAVE TRIED IBUPROFEN, TYLENOL, HEATING PADS, ICE PACKS AND PAIN PATCHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044152	BAYER	7/8/2015	7/16/2015

Event Information:

Event Date (B3): 4/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 789033

Single Use:
Implant Date (E6): 4/5/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY ESSURE IMPLANTS PUT IN (B)(6) OF 2011 AND AT FIRST EVERYTHING WAS FINE. ABOUT 3 MONTHS AFTER IT WAS PUT IN I STARTED MY PERIOD AND I BLED FOR 3 MONTHS STRAIGHT. I WENT BACK TO MY DOCTOR AND WAS PUT ON BIRTH CONTROL PILLS TO REGULATE MY PERIODS. I STARTED HAVING HORRIBLE MIGRAINE HEADACHES, MY LEFT SIDE ALWAYS HURTS DURING MY PERIODS AND EVEN WHEN I'M NOT ON MY PERIOD. IT'S HARD TO HAVE SEX BECAUSE IT HURTS SO BAD AND FEELS LIKE MY OVARIES ARE BEING RIPPED OUT. I HAVE CONSTANT DIZZY SPELLS AND ALWAYS FEEL TIRED. WHEN I BROUGHT THIS TO MY DOCTOR'S ATTENTION I WAS TOLD IT WAS BECAUSE I WAS OVERWEIGHT. SINCE THE PROCEDURE I HAVE LOST 40 LBS AND I'M STILL EXPERIENCING THESE SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044153	CONCEPTUS/BAYER	7/8/2015	7/16/2015

Event Information:

Event Date (B3): 7/8/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PUT IN 2014. HAVE HAD HEAVY PERIODS, PAIN, PAINFUL INTERCOURSE, RANDOM STABBING PAINS IN PELVIC AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044154		7/8/2015	7/16/2015

Event Information:

Event Date (B3): 7/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/17/2004
Explant Date (E7): 2/5/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER RECEIVING THE ESSURE IMPLANTS IN 2004, I BEGAN EXPERIENCING EXTREME PAIN AND CRAMPING EVERY MONTH. I WOULD ALSO HAVE EXCESSIVE BLEEDING EACH MONTH LASTED FOR WEEKS AND WEEKS. MY DOCTOR RECOMMENDED HAVING A HYSTERECTOMY SINCE 2006 BUT BECAUSE THIS IS AN EXTREME CHANGE TO MY BODY. I DECIDED NOT TO HAVE IT DONE. I HAVE BEEN GOING BACK AND FORTH TO THE DOCTOR FOR YEARS BECAUSE OF THE PAIN. IN 2010 TO RELIEVE SOME OF THE PAIN I HAD MY FIRST SURGERY, A MYOMECTOMY TO REMOVE THE FIBROIDS CAUSED BY THE SEVERE BLEEDING. THE MYOMECTOMY DID NOT CURE THE PAIN AND/OR THE EXCESSIVE BLEEDING. AFTER SEVERAL DOCTOR VISITS AND NO RELIEF, I FINALLY DECIDED TO HAVE A HYSTERECTOMY AND HAVE THE COILS REMOVED IN (B)(6) 2015. SINCE THEN I HAVE HAD NO PAIN OR EXCESSIVE BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044171	BAYER	7/8/2015	7/16/2015

Event Information:

Event Date (B3): 5/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/17/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAD THE ESSURE PROCEDURE DONE I HAVE HAD SEVERE MIGRAINES, URINE HAS A STRONG ODOR, BACK PAIN, LOWER ABDOMEN PAIN, FATIGUE, WEIGHT GAIN, SWOLLEN AND MY STOMACH IS BLOATED ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044173		7/8/2015	7/16/2015

Event Information:

Event Date (B3): 7/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/7/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2011 I HAD THE ESSURE PROCEDURE DONE IN A PRIVATE DOCTOR'S OFFICE EVER SINCE I'VE HAD THE PROCEDURE DONE I'VE HAD BAD PAIN ON THE LEFT SIDE OF MY FALLOPIAN TUBE, THE COIL ON MY LEFT SIDE IS LOST SOME WHERE ELSE, I'VE HAD TWO PREGNANCIES, HAIR LOST, BACK PAIN AND PAIN DURING SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044174	BAYER	7/8/2015	7/16/2015

Event Information:

Event Date (B3): 11/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 11/22/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTED EXPERIENCING INCREDIBLY HEAVY PERIODS, INTENSE CRAMPING, CONSTANT PAIN, FREQUENT MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00495	BAYER HEALTHCARE LLC	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 6/1/2005
Explant Date (E7): 7/16/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 10-JUN-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2002 FOR PERMANENT CONTRACEPTION. SHE HAS BEEN EXPERIENCING EXCESSIVE BLEEDING ABOUT EVERY 12 TO 14 DAYS, ONE OF THE ESSURE COILS HAS MOVED INTO UTERUS, HAVING EXTREME PELVIC AND STOMACH PAIN, MIGRAINE HEADACHES FOR YEARS (SINCE ABOUT 2004). SHE DID NOT KNOW IT MIGHT BE RELATED TO ESSURE UNTIL SHE SAW THAT OTHER WOMEN HAVING SAME EXPERIENCE. HER HEALTHCARE PROFESSIONAL (HCP) ATTEMPTED TO DO A NOVASURE PROCEDURE ON (B)(6)-2015 BUT WAS UNABLE SINCE ONE ESSURE COIL IS IN THE UTERUS. A D&C (DILATATION AND CURETTAGE) WAS PERFORMED INSTEAD. HCP RECOMMENDED HYSTERECTOMY. EVENTS WERE ONGOING AND ESSURE NOT REMOVED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 18-JUN-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE.

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NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE BLEEDING. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION IS AVAILABLE. CONSUMER UNDERWENT A DILATATION AND CURETTAGE. GIVEN ITS NATURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-AUG-2015 WITH ADDITIONAL INDOEMARION ON 23-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEET

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00496	BAYER HEALTHCARE LLC	7/9/2015	7/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER'S SISTER IN THE UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE WANTED TO KNOW WHAT WAS THE PROCEDURE OF TAKING THE ESSURE OUT OF SOMEONE'S BODY BECAUSE ESSURE WAS ALMOST KILLING HER SISTER. SHE WAS ASKING WHAT CAN THEY DO TO GET THAT REMOVED BEFORE SHE HEMORRHAGES TO DEATH. SHE WAS IN THE HOSPITAL, HEMORRHAGING FROM THE COIL SHARDS BLISTERING INTO HER BODY. SHE STATED THAT HER SISTER WAS ABOUT TO DIE BECAUSE OF THE PROCEDURE. SHE WAS GOING TO SUE THE COMPANY FOR WHATEVER THEY'RE WORTH ESPECIALLY IF HER SISTER DIES. IT WAS CUTTING HER INSIDE. THE COIL HAS RESTED INSIDE HER SISTER, IT HAS MIGRATED AND SPLINTERED. SHE HAS METAL SHARDS, IT'S KILLING HER. IT WAS REPORTED THAT THE ADVERSE EVENT WAS ONGOING. NO FURTHER INFORMATION WAS PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A

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QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 26-JUN-2015: CONSUMER'S SISTER DECLINE TO PROVIDE CONSUMER'S CONTACT AND ANY FOLLOW-UP INFORMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEMORRHAGING FROM THE COIL SHARDS BLISTERING INTO HER BODY (SEEN AS PELVIC HEMORRHAGE). IT WAS CUTTING HER INSIDE (SEEN AS PELVIC ORGAN INJURY) AND THE COIL HAS RESTED INSIDE, IT HAS MIGRATED (SEEN AS DEVICE DISLOCATION) AND SPLINTERED (SEEN AS DEVICE BREAKAGE). THIS EVENT PELVIC HEMORRHAGE IS SERIOUS DUE TO HOSPITALIZATION AND LIFE-THREATENING (AS REPORTED), AND IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC ORGAN INJURY IS SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED. DEVICE DISLOCATION IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED. DEVICE BREAKAGE IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. IN THIS CASE, IT WAS NOT REPORTED WHETHER CONSUMER WILL UNDERGO A SURGERY IN ORDER TO REMOVE ESSURE. ALTHOUGH IT WAS UNKNOWN WHETHER THE EVENTS OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. SINCE CONSUMER WAS HOSPITALIZED, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. CONSUMER WAS GOING TO SUE THE COMPANY, THEREFORE, FURTHER INFORMATION WILL BE OBTAINED THROUGH THE NORMAL LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00497	BAYER HEALTHCARE LLC	7/9/2015	7/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007 FOR BIRTH CONTROL. CONSUMER STATED THAT SHE STARTED HAVING SEVERE BACK PAIN, HAIR LOSS, WEIGHT GAIN, PAIN DURING SEX, DEPRESSION AND EVENTUALLY DUE TO COMPLICATIONS SHE NEEDED A HYSTERECTOMY. SHE ASSESSED THE EVENT OUTCOME AS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS); HOWEVER, SHE DID NOT SPECIFY IT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT

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A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO EXPERIENCED SEVERE BACK PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT. ADDITIONALLY, SHE STATED EVENTUALLY SHE NEEDED A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND BACK PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEITHER TEMPORAL RELATION BETWEEN ESSURE INSERTION AND THE EVENT NOR AN ALTERNATIVE EXPLANATION WAS GIVEN. NEVERTHELESS, CONSIDERING EVENT'S NATURE CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT IN A CONSERVATIVE APPROACH. AS ALTHOUGH IT IS UNCLEAR IF THE REPORTED HYSTERECTOMY WAS ACTUALLY PERFORMED; THE CONSUMER STATED THIS INTERVENTION WAS NEEDED DUE TO ESSURE. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 27-JUL-2015: NEW REPORTER WAS ADDED AND CASE BECAME POTENTIAL LEGAL CASE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS LEGAL CASE REPORT; REFERS TO A FEMALE CONSUMER WHO EXPERIENCED SEVERE BACK PAI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00498	BAYER HEALTHCARE LLC	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/6/2015
Explant Date (E7): 2/20/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5041126) IN UNITED STATES ON 11-JUN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2015. ACCORDING TO THE CONSUMER SHE HAD SEVERE PAIN AND CRAMPING IN HER PELVIS FROM THE START. THEN, OTHER SYMPTOMS STARTED SHORTLY AFTER, INCLUDING LEG PAIN, HIP PAIN, HEADACHES, MAJOR FATIGUE, OFF AND ON BLEEDING, WEIGHT LOSS AND LOSS APPETITE. SHE FELT LIKE SHE WAS GIVING BIRTH EVERYDAY; SOME DAYS WERE SO BAD SHE COULD NOT GET OUT OF BED. SHE MISSED 15 DAYS OF WORK AND MADE 2 TRIPS TO ER (EMERGENCY ROOM) AND 1 CT (COMPUTERIZED TOMOGRAPHY) SCAN. SHE AND HER DOCTOR DECIDED TO REMOVE THE COILS AND TUBES TO PREVENT MORE COMPLICATIONS AND ANY MORE SEVERE PAIN. ON (B)(6)-2015, SURGERY WAS DONE AND ESSURE AND BOTH TUBES WERE REMOVED. SHE WAS MISSING 2 WEEKS OF WORK TO RECOVER FROM SURGERY. TRIMADOL WAS REPORTED AS CONCOMITANT MEDICAL PRODUCT. FOLLOW-UP RECEIVED ON 18-JUN-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED

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ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN AND CRAMPING IN PELVIS AND OFF AND ON BLEEDING (INTERPRETED AS GENITAL BLEEDING). BOTH TUBES AND ESSURE WERE REMOVED ONE AND A HALF MONTH AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE CONSUMER HAD SEVERE PAIN AND CRAMPING IN PELVIS FROM THE START. THEREFORE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ALSO, AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, OFF AND ON BLEEDING STARTED SHORTLY AFTER INSERTION. THEREFORE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED SURGICAL INTERVENTION FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 28-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00499	BAYER HEALTHCARE LLC	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B82482

Single Use: Y
Implant Date (E6): 6/10/2015
Explant Date (E7): 6/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B82482, PLACED INTO ONE TUBE (SIDE UNKNOWN), ON (B)(6)-2015 AND A FEW MINUTES LATER, SHE STARTED HAVING EXTREME PAIN AND HAD TO BE SENT TO ER (EMERGENCY ROOM). THE PHYSICIAN LATER REMOVED TUBE. LEEP (LOOP ELECTROCAUTERY EXCISION PROCEDURE) WAS ALSO PERFORMED. THE PATIENT WAS OKAY (END OF ADVERSE EVENT REPORTED AS (B)(6)-2015). ESSURE WAS NOT CONTINUED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6)-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD (B)(4) (PRODUCTION DATE (B)(6)-2013 AND EXPIRATION DATE (B)(6)-2016) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. FOUR FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH TWO CASES REFER ALSO TO A SIMILAR TYPE OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A

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TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6)-2015: IT WAS REPORTED THAT ONE INSERT WAS ALREADY PLACED WHEN SHE COMPLAINED OF TOO MUCH PAIN. PHYSICIAN COULD NOT PLACE SECOND INSERT; PATIENT WAS TAKEN TO ER FOR PAIN AND A SALPINGECTOMY WAS PERFORMED TO REMOVE TUBE AND ESSURE. IT WAS ALSO REPORTED THAT IT LOOKED LIKE INSERT WAS BEING PUSHED OUT INSTEAD OF OUTER SHEATH RETRACTING BACK. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO EXPERIENCED EXTREME PAIN FEW MINUTES AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT. SHE WAS SENT TO THE ER, AND UNDERWENT A SALPINGECTOMY. AFTER THIS PROCEDURE SHE WAS OKAY. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. PAIN AND CRAMPING MAY OCCUR DURING AND FOLLOWING ESSURE PLACEMENT PROCEDURE. IN THIS PARTICULAR CASE, THE INSERTION WAS DIFFICULT (IT LOOKED LIKE INSERT WAS BEING PUSHED OUT INSTEAD OF OUTER SHEATH RETRACTING BACK) AND ONLY ONE INSERT WAS PLACED. PATIENT WAS TAKEN TO ER FOR PAIN AND A SALPINGECTOMY WAS PERFORMED TO REMOVE TUBE AND ESSURE. CONSIDERING THE REPORTED PAIN OCCURRED IN CLOSE ASSOCIATION WITH ESSURE INSERTION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE REQUIRED INTERVENTION, THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 10-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00500	BAYER HEALTHCARE LLC	7/9/2015	7/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW5041238) IN UNITED STATES ON 11-JUN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT SHE EXPERIENCED SIDE EFFECTS AFTER ESSURE PROCEDURE: RASHES, MIGRAINES, FAINTING, VARICOSE VEIN ON UTERUS CAUSING MAJOR PAIN, VOMITING, URINARY TRACT INFECTION (UTI) AND CHEST PAINS. SHE STATED SHE WAS HOSPITALIZED FOR MANY TEST TO BE RAN, CAT SCAN, ETC. HOSPITAL RULED OUT TO HAVE DEVICES REMOVED FOR HEALTH CONCERN REASONS. SURGERY REMOVAL IS NOT COVERED BY HER HEALTH INSURANCE AND SHE MUST PAY IT. CONSUMER ASSESSED THE EVENT OUTCOME AS INTERVENTION REQUIRED; HOWEVER SHE DID NOT SPECIFY IT. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO

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A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RASHES AND UTI'S (URINARY TRACT INFECTIONS). SHE STATED SHE WAS HOSPITALIZED TO UNDERGO TESTS DUE TO SIDE EFFECTS AFTER ESSURE PLACEMENT. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. RASH IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE UTI IS UNLISTED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED RASH WAS NOT PROVIDED; CONSIDERING THIS EVENT OCCURRED AFTER ESSURE THERAPY, CAUSALITY CANNOT BE EXCLUDED. REGARDING URINARY TRACT INFECTION (UTI); ITS PATHOGENESIS IN WOMEN BEGINS WITH COLONIZATION OF THE VAGINAL INTROITUS BY UROPATHOGENS FROM THE FECAL FLORA, FOLLOWED BY ASCENSION VIA THE URETHRA INTO THE BLADDER. GIVEN THIS INFORMATION, CAUSALITY BETWEEN THE REPORTED UTI'S AND ESSURE IS CONSIDERED UNLIKELY. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. SINCE HOSPITALIZATION WAS REQUIRED, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP RECEIVED ON 14-JUL-2015: CONSUMER GENERAL QUESTIONNAIRE RETURNED BACK BLANK. NO NEW CLINICAL INFORMATION RECEIVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00501	BAYER HEALTHCARE LLC	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 5/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 5/21/2015
Explant Date (E7): 6/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT STERILIZATION ON (B)(6) 2015. SHE WAS NOT PREGNANT. AFTER THE INSERTS WERE PLACED, THE PATIENT INFORMED THE DOCTOR THAT SHE HAD A NICKEL ALLERGY. PHYSICIAN STATED PATIENT WAS COUNSELLED IN ADVANCE OF THE PROCEDURE AND SHE DID NOT LIST ANYTHING FOR ALLERGIES. ON (B)(6) 2015 SHE COMPLAINED OF BLEEDING, PAIN, HEADACHES AND BLOATING. ON (B)(6) 2015 SHE WAS REFERRED TO SURGEON FOR ESSURE REMOVAL. ON (B)(6) 2015 PATIENT UNDERWENT A HYSTEROSCOPIC BILATERAL PARTIAL SALPINGECTOMY, TO REMOVE INSERTS AND TUBAL OCCLUSION. TREATMENT OF ADVERSE EVENT WAS REPORTED AS SURGERY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT

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THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO EXPERIENCED BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PROCEDURE. SHE WAS SUBMITTED TO BILATERAL SALPINGECTOMY AND THE DEVICES WERE REMOVED. THE REPORTED EVENT, REGARDED AS POST PROCEDURAL BLEEDING, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING AND FOLLOWING ESSURE INSERTION PROCEDURE GENITAL BLEEDING AND SPOTTING MAY OCCUR. IN THIS CASE, THE EVENT WAS REPORTED 4 DAYS AFTER ESSURE INSERTION. THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WAS REQUIRED FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 23-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMAL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043754	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BECAME VERY ILL WITH A HEADACHE. AND IT CONTINUES DAILY SINCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043755	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE MIGRAINES, MOOD SWINGS, SEVERE ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043756	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 11/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY FLOW. PAINFUL CRAMPS. BLOATING. SEVERE ACNE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043757	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A SURPRISE PREGNANCY AT (B)(6). I HAD WHAT I WOULD CALL A PRETTY NORMAL PREGNANCY FOR SOMEONE MY AGE UP TO THE BIRTH. I HAD TO HAVE AN EMERGENCY C SECTION AS THE BABY STARTED SHOWING SIGNS OF DISTRESS. THREE DAYS AFTER THE BIRTH, I RETURNED TO THE HOSPITAL WITH SEVERE PAIN IN MY ABDOMINAL REGION, HIGH FEVER, REDNESS, SWELLING AND RIPPLING. I HAD EMERGENCY SURGERY FOR AN ANAEROBIC INFECTION. THEN A SECOND AS THE INFECTION RETURNED. I WAS IN ICU FOR 21 DAYS AND WHEN I WENT HOME, IT WAS WITH HOME CARE 4 TIMES PER WEEK AND A WOUND VAC AND WOUND CENTER CARE ONCE A WEEK FOR OVER 4 ADDITIONAL MONTHS. DURING THAT TIME, MY OBGYN DECIDED TO PLACE THE ESSURE COILS. ON THE DAY OF THE PROCEDURE, WHILE THE DOCTOR HAD THE CAMERA INSERTED, HE SAID I DID NOT HAVE A RIGHT FALLOPIAN TUBE SO HE WOULD ONLY BE INSERTING IN THE LEFT ONE. I WAS TOLD THE PROCEDURE WOULD BE PAINLESS BUT EVEN WITH A VALUM PROVIDED BY MY DOCTOR TO TAKE PRIOR TO THE PROCEDURE, IT HURT. I ASKED ABOUT THE LACK OF MY RIGHT TUBE AND THE DOCTOR SAID THERE WASN'T ANY SCAR TISSUE SO I MUST HAVE BEEN BORN WITH ONLY MY LEFT FALLOPIAN TUBE AND THAT IS WAS RARE ENOUGH TO CONCEIVE LATE IN LIFE BUT ESPECIALLY WITH ONLY MY LEFT TUBE. LET ALONE THAT I HAD 3 OLDER CHILDREN APPARENTLY CONCEIVED WITH ONLY MY LEFT TUBE. IMMEDIATELY FOLLOWING THE PROCEDURE, I HAD SEVERE CRAMPING. I WAS TOLD I SHOULD EXPECT MILD CRAMPING. I FELT LIKE I WAS IN LABOR AGAIN AND WITH AN OPEN WOUND! MY DOCTOR TOLD ME THAT IT WAS RECOMMENDED THAT AN ULTRASOUND BE PERFORMED 3 MONTHS AFTER INSERTION OF ESSURE BUT THAT IT WAS NOT NECESSARY AND THAT MEDICAID, WHICH I WAS ON, WOULD NOT PAY FOR IT ANYWAY. I HAVE SINCE HAD NUMEROUS ISSUES. CONTINUED SEVERE CRAMPING, BACK PAIN, STABBING PAINS IN THE RIGHT SIDE OF MY NECK, A VERY PERSISTENT RASH THAT COMES AND GOES IN DIFFERENT PLACES THAT DOES NOT GO AWAY WHEN

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TREATED WITH ANTIBIOTICS, ANTIFUNGAL OR STEROIDAL CREAMS, SEVERE SHARP PAINS IN MY LOWER LEFT SIDE, PAIN IN MY RIGHT LOWER RIBCAGE, DEBILITATING HEADACHES, ALARMINGLY LONG AND HEAVY FLOW PERIODS, BLOOD CLOTTING, PAIN AND SPOTTING WITH SEX, THYROID IMBALANCE, FLUCTUATING BLOOD SUGARS, BLURRED VISION, INCONTINENCE, FATIGUE, INSOMNIA, INABILITY TO CONCENTRATE OR MULTI TASK, COMMON UTIS, I HAVE ALWAYS BEEN ALLERGIC TO PENICILLIN BUT NOW HAVE A CEPHALOSPORIN ALLERGY AS WELL, UMBILICAL HERNIA, HEEL SPUR, SUDDEN GROWTH OF FACIAL HAIRS, LOSS OF SEX DRIVE, EXCESSIVE VAGINALLY DISCHARGE, I'LL LET YOU KNOW IF I LEFT ANYTHING OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043758	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/1/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE HEAVY BLEEDING CAME FIRST, FOLLOWED BY THE STABBING PAINS IN MY LOWER ABDOMEN AND SIDES. THESE PAINS ARE SO BAD SOMETIMES THEY DOUBLE ME OVER TO THE FLOOR. IT FEELS LIKE SOMEONE IS STABBING ME WITH A HOT KNIFE. HEADACHES AND TERRIBLE MOOD SWINGS HAPPENED NEXT. I'VE ONLY EXPERIENCED THE METAL TASTE A FEW TIMES. I GAINED SO MUCH WEIGHT I ACTUALLY HAD TO GO TO MY PHYSICIAN FOR HELP. I DIDN'T REALIZE THIS COULD BE FROM THE ESSURE UNTIL A FRIEND OF MINE TOLD ME ABOUT HER SYMPTOMS AND HOW SHE HAD SURGERY AND FEELS 100% BETTER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043759	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 8/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE IN 2010. WHEN THE DOCTOR STARTED THE PROCEDURE EVERYTHING WAS FINE UNTIL HE GOT TO THE LEFT SIDE. ONCE HE STARTED IN THE LEFT SIDE, THE PAIN BECAME SO UNBEARABLE I WAS CRYING. THE DOCTOR DECIDED AT THAT TIME THAT I WOULD HAVE TO WAIT AND HAVE THE LEFT COIL PUT IN SURGICALLY. I HAD TO WAIT A COUPLE WEEKS AND THEN HAD THE LEFT SIDE PUT IN. ABOUT (B)(6) OF 2011, I STARTED TO EXPERIENCE SEVERE UTIS AND PAINFUL INTER COURSE. I WAS GIVEN EVERY MEDICATION THAT YOU CAN HAVE FOR UTIS AND NOTHING WAS CLEARING IT UP. I HAD AN ULTRASOUND DONE AND OTHER LAB WORK DONE. THE DOCTOR FOUND ENDOMETRIOSIS AND A CYST ON MY LEFT OVARY THE SIZE OF A GOLF BALL. I WAS SENT INTO SURGERY TO REMOVE THE ENDOMETRIOSIS AND THE CYST. THE DOCTOR HAD TO REMOVE THE LEFT FALLOPIAN TUBE AND LEFT OVARY. HE HAD TO SCRAPE OFF ALL THE ENDOMETRIOSIS. I HAVE SINCE BEEN EXPERIENCING PAINFUL INTER COURSE, MIGRAINE AND WEIGHT GAIN. CURRENTLY I HAVE RIGHT HIP PAIN AND JOINT PAIN SO BAD THAT I CAN'T FUNCTION BY THE END OF THE DAY. I AM UNABLE TO LOOSE WEIGHT AND CURRENTLY TAKE MEDICATION FOR ANXIETY. I HAVEN'T EVER HAD WEIGHT ISSUES OR ANXIETY. I AM CONSTANTLY BLOATED WITH GAS AND NOTHING RELIEVES IT. I HAVE VERY LOW ENERGY LEVELS AND AM TIRED ALL DAY EVEN AFTER AN 8 HOUR NIGHTS SLEEP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043760	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 5/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HYSTERECTOMY DUE TO ISSUES WITH ESSURE PERFORATION FALLOPIAN TUBE. HEAVY BLEEDING, PAINFUL INTERCOURSE, JOINT PAIN, HEADACHES, SEVERE PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043761	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN 2005. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2005. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. PELVIC PAIN, JOINT PAIN, PANIC ATTACKS, ANXIETY ATTACKS, BLOATING, SWOLLEN LEGS AND FEET, NUMBNESS IN MY HIPS AND PELVIC AREA, HAIR LOSS, UTERINE CYSTS, EXCESSIVE BLEEDING DURING MENSTRUATION, ANEMIA, I AM NOW IRON DEFICIENT, NO ENERGY, DRY SKIN, DEPRESSION, MUSCLE PAIN, IRRITABLE BOWEL, LEG CRAMPS, ENDOMETRIOSIS, UTERINE FIBROIDS, UTERINE INFLAMMATION, PAINFUL OVULATION, NIGHT SWEATS, LOSS OF LIBIDO, PAINFUL INTERCOURSE, A SEVERE CASE OF INCONTINENCE, SEXUAL DISFUNCTION, NUMEROUS YEAST INFECTIONS, MANY UTI'S, BREAST PAIN, ABDOMINAL FLUTTERS, BACK PAIN IS AWFUL, BODY ACHES, NAUSEA, VOMITING, CONSTIPATION, HEARTBURN, HEADACHES, DIZZINESS, NERVE PAIN, FORGETFULNESS, MY EARS RING, TREMORS, HIGH BLOOD PRESSURE, WEIGHT GAIN, BRUISES, ARTHRITIS, HEART PALPITATIONS, MANY DENTAL ISSUES, INSOMNIA, GALLBLADDER ISSUES, ADRENAL ISSUES, BLURRED VISION, AND DRY EYES. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE. D N C , AND AN ABLATION THE DEVICE IS STILL INSIDE OF ME AT THIS TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043762	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SINCE GETTING ESSURE I HAVE NOTICED THAT I HAVE MIGRAINES MORE FREQUENTLY, LOW LIBIDO, HOT FLASHES, JOINT PAINS, MUSCLE SORENESS, VITAMIN DEFICIENCIES INCLUDING VITAMIN D AND POTASSIUM, OVARIAN CYSTS, AND EXCRUCIATING PELVIC PAIN, HEAVY AND PAINFUL MENSTRUAL CYCLES, AND CHRONIC RECURRING BACTERIAL VAGINOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043763	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 10/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING, CRAMPING, HEADACHES, LOSS OF LABIDO, WEIGHT GAIN, BLOATING, DEPRESSION, PELVIC PAIN, ITCHING, TIRED, DISLODGEMENT OF DEVICE, TUBAL REMOVAL, HOSPITALIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043764	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIZZINESS, CONSTANT STOMACH ISSUES, NO SEX DRIVE, BACK PROBLEMS, NO ENERGY, WEIGHT GAIN, HIGH BLOOD PRESSURE, DIARRHEA, MOOD SWINGS, STOMACH PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043765	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 7/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING PROBLEMS 2 YEARS AFTER I HAD THE ESSURE DONE. I AM NOW EXPERIENCING IRREGULAR BLEEDING, EXTREME PELVIC PAIN THAT KEEPS ME IN BED, HEADACHES, FATIGUE AND LOTS MORE. I AM NOW BEING CONSIDERED FOR SURGERY TO GET THESE THINGS REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043766	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE PROCEDURE DONE IN (B)(6) OF 2014 SINCE THEN I HAVE HAD ONGOING PELVIC PAIN, HEAVY PERIODS, HEADACHES, SWEATS, OVARIAN CYST AND HAVE GAINED 30 POUNDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043767	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/19/2000 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ON RIGHT SIDE STARTED RIGHT AFTER PLACEMENT. INCREASED HEADACHES. EXTREMELY ITCHY HIVES/RASH ALL OVER MY ARMS/SHOULDERS. POSSIBLE CERVICAL CANCER. EXTREME FATIGUE. DIZZINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043768	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 5/27/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN STARTED IN UTERUS. THOUGHT I WAS PREGNANT, NEGATIVE TEST. WOKE UP ONE MORNING AND IT WAS WORSE. WENT TO EMERGENCY CLINIC. THEY FOUND A 4CM CYST. I'VE NEVER HAD THEM BEFORE ESSURE. ESSURE WILL BE REMOVED SOON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043769	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 664666 MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN (B)(6) 2010. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: SINCE HAVING ESSURE INSERTED 4 YEARS AGO, I HAVE HAD IRREGULAR MENSTRUAL CYCLES. I HAVE HAD WEEKS OF SPOTTING IN BETWEEN CYCLES. I HAVE ALSO HAD UNUSUALLY LONG CYCLES THAT INCLUDE VERY HEAVY BLEEDING AND BLOOD CLOTS. I HAVE OVULATION PAIN ON ONE SIDE THAT CAN LAST UP TO 4 DAYS. IN ADDITION TO MENSTRUAL ISSUES, I'VE ALSO DEVELOPED FOOD ALLERGIES, SPECIFICALLY TO ALL GRAINS. I HAVE AN AUTOIMMUNE RESPONSE IF I EAT ANY GRAINS, INCLUDING WHEAT, CORN, OATS, RICE, AND BARLEY. I ALSO HAVE ISSUES WITH EXTREME ADRENAL FATIGUE. I HAVE SWITCHED MY EATING HABITS TO ONLY LEAN PROTEIN, FRESH FRUITS, AND FRESH VEGETABLES TO ALLEVIATE THE AUTOIMMUNE RESPONSE TO EATING GRAINS OR OTHER PROCESSED FOODS. IT HAS HELPED AND I FINALLY BEGAN TO LOSE WEIGHT, BUT NOW IT'S STOPPED AGAIN AND I'M EXHAUSTED FOR NO REASON. I'VE ALSO DEVELOPED SEVERE CLINICAL DEPRESSION, WHICH HAS NEVER BEEN AN ISSUE FOR ME. I HAVE BEEN SEEN BY 3 DOCTORS, AND I KEEP SEEKING NEW DOCTORS THAT CAN GET TO THE BOTTOM OF THESE ISSUES. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: FOOD ALLERGIES: ALL GRAINS INCLUDING WHEAT, CORN, OATS, RICE, AND BARLEY. SEVERE CLINICAL DEPRESSION, IRREGULAR MENSTRUAL PERIODS, MID-CYCLE MENSTRUAL SPOTTING, MENSTRUAL CLOTTING, URINARY INCONTINENCE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043770	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 10/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, LOSS OF SEXUAL DRIVE, JOINT PAIN, HEADACHES AFFECTING VISION, CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043771	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN LOWER ABDOMINAL, BLEEDING, CRAMPING, FATIGUE, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043772	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I ORIGINALLY SIGNED A TUBAL LIGATION PAPER AFTER I HAD MY 6TH CHILD IN (B)(6) 2012. MY TUBAL LIGATION DATE WAS SET FOR (B)(6) 2013. ONCE I ARRIVED AT THE HOSPITAL AND WAS READY TO BE PUT TO SLEEP THE DR. CAME IN AND EXPLAINED THAT HE WOULD BE DOING THE ESSURE PROCESS. I HAD NO TIME TO RESEARCH THIS PRODUCT NOR DID I KNOW WHAT IT WAS. I WAS TRUSTING THAT MY DR. WAS DOING A TUBAL LIGATION. AFTER ABOUT 20 DAYS OF HAVING ESSURE IN ME, I BEGAN TO LOSE AN ABUNDANCE OF HAIR, WAS CRAMPING OUT OF CONTROL, BLEEDING SO BAD I HAD TO GO TO THE DR. HE OF COURSE JUST SAID THAT MY HORMONES WERE PROBABLY OUT OF WHACK AND THAT IT SHOULD SUBSIDE ITSELF. I THEN GAINED ABOUT 60 POUNDS OVER THE COURSE OF THE NEXT 4 MONTHS. I WAS REFERRED BY MY PCP TO SEEK A SURGICAL PROCEDURE BECAUSE I WAS "OVERWEIGHT". I DID NOT! FOR THE LAST 2 YEARS I BEGAN TO HAVE HORRIBLE MIGRAINES THAT MADE ME NAUSEOUS AND UNABLE TO EVEN FUNCTION DAILY WITH MY CHILDREN. I HAVE LOST ALL URGE TO HAVE SEX WITH MY PARTNER. I HAD BEGAN TO HAVE REALLY BAD CRAMPING LIKE LABOR CONTRACTIONS DURING MENSTRUATION, MY LEFT ARM CONTINUES TO GO NUMB A RANDOM TIMES, AND I CONSTANTLY FORGET WHAT I WAS DOING OR NEED CONSTANT REMINDERS. I FINALLY HAD ENOUGH AND CRIED OUT TO MY PCP WHO THEN ORDERED A PELVIC ULTRASOUND, THEN I TOOK THOSE RESULTS TO MY OBGYN THAT DID IMPLANTATION. HE SCHEDULED FOR ME TO HAVE THE FLAT PANEL XRAYS WHERE WE FOUND OUT THAT ONE OF MY COILS (LEFT ESSURE) HAD MIGRATED AND IS NOWHERE TO BE FOUND. I ALSO HAD PELVIC CT SCAN, ABDOMINAL CT SCAN, AND STILL NOWHERE TO BE FOUND.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043773	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/3/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PELVIC PAIN. JOINT PAIN. FATIGUE. BLEEDING. NAUSEA. PAIN DURING SEX ALL FOR THE LAST 5 YEARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043774	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 11/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES. MIGRAINES. STOMACH PAIN. ACNE. FORGETFULNESS. OVARIAN CYSTS. BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043775	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 2/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN AND REALLY BAD CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043776	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING ESSURE IMPLANTED, SHORTLY AFTER I WOULD EXPERIENCE EXTREMELY SHARP CRAMPS, POKING FEELING IN MY TUBES WHEN BENDING OVER, ACHING IN MY OVARIES, FEELING ANEMIC, NAUSEA, TASTING METAL IN MY MOUTH, LOW ON ENERGY, AND JUST OVERALL BAD FEELING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043777	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/10/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). FIRST MIGRAINE EVER WHILE LAYING ON THE COUCH. I COULDN'T LIFT MY HEAD AND WAS UNCONTROLLABLY CRYING. THE MIGRAINE LASTED FOR ABOUT 10 MIN AND EVER SINCE HAVE HAD WEEKLY HEADACHES BUT NOT AS EXTREME AS THE FIRST. HEADACHES CAN LAST FROM MINUTES TO HOURS THEY CAN BE AS FREQUENT AS DAILY OR AS FAR APART AS WEEKLY. I ALSO HAVE CHRONIC CONSTIPATION SINCE (B)(6) 2010 WHEN THE ESSURE PROCEDURE TOOK PLACE. I HAVE BEEN TO THE DOCTOR AND HOSPITAL ON SEVERAL OCCASIONS FOR THE ABOVE STATED SYMPTOMS. MY SYMPTOMS LIST HAS GROWN SIGNIFICANTLY SINCE THE FIRST YEAR OF THE ESSURE PROCEDURE. MY SYMPTOMS INCLUDE HAIR LOSS, SHORTNESS OF BREATH, DIZZINESS, INDIGESTION, LIGHTHEADEDNESS, NEAR FAINTING, VOMITING, EYE TWITCHES, LOWER RIGHT FACE CRAMPING, WEIGHT GAIN, INCREASED LEG, ARM AND BACK PAIN, TINGLING AND NUMBNESS, IRRITABILITY, WEAKNESS, AND FATIGUE, ABDOMINAL PAIN, CRAMPING, ABDOMINAL TWITCHING, THE FEELING AS IF MY ABDOMEN IS GOING TO TARE WHEN I SNEEZE, WHEN I COUGH HARD, HEAVY BLEEDING, CLOTTING, CRAMPING AND PAIN DURING MENSTRUATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043778	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 11/5/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE SHARP PAINS, EXTREME BLOATING, CRAMPS THROUGHOUT STOMACH AND LEGS ALL MONTH LONG, VERY HEAVY AND PAINFUL PERIODS. I AM SCHEDULED TO HAVE ESSURE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043779	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WELL I HAVE HAD AN OVARY AND TUBE REMOVED AND NOW I'M HAVING NUMBNESS IN MY LEG AND FOOT AND MY BACK HURTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043780	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHORTLY AFTER DEVICE WAS PLACED I WAS FEELING TIRED AND I GAINED WEIGHT. I BEGAN HAVING THYROID PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043781	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 8/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOSS USE OF SWALLOWING, HAD NUMEROUS ALLERGIC REACTIONS. BECAME ALLERGIC TO EVERYTHING ALMOST. DEVELOPED SEVERE MENTAL ILLNESSES. DIAGNOSED WITH CHRONIC PAIN AND MULTIPLE CYST'S ON MY OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043782	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY LONG PERIODS. NUMBNESS AND TINGLING DOWN MY LEFT SIDE. PAIN AND BLOATING IN MY ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043783	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE FIRST SYMPTOM I EXPERIENCED WAS MY HAIR FALLING OUT AT A RAPID PACE. I NOTICED IT IN (B)(6) 2014. THE SECOND WAS ABOUT 6 MONTHS AGO. I WAS GETTING OUT OF MY CAR AND A FELT A SHARP STABBING PAIN IN MY RIGHT SIDE AND WHAT FELT LIKE A WARM SENSATION. IT WAS SO PAINFUL I DROPPED TO MY KNEES AND COULDN'T MOVE FOR NEARLY A MINUTE. I MADE AND APPOINTMENT TO BE SEEN BY THE DR THAT PUT THE COILS IN. HE WAS NOT ABLE TO SEE WHAT CAUSED THE PAIN BUT TOLD ME TO COME BACK IF IT CONTINUES AND WAS NOT BETTER WITH THE PAIN MEDS HE GAVE ME. OVER THE NEXT 6 MONTHS DURING OVULATION MY TUBES FELT LIKE THEY ARE BURNING ME FROM THE INSIDE OUT. THIS LASTS AN ENTIRE WEEK OR LONGER. DURING MY PERIOD I EXPERIENCE ALL PREGNANCY SYMPTOMS AND SHARP CRAMPING PAINS. I HAVE THE MOST TROUBLE WITH THE NAUSEA. THIS LAST PERIOD I WAS CONFINED TO MY BED FOR 4 DAYS WITH DEBILITATING BACK PAIN AND SHOULDER PAIN AS WELL AS NAUSEA, HEADACHE, CRAMPS, AND A PAIN ON MY RIGHT SIDE (THAT STILL CONTINUES), AND LIGHT BLEEDING. THE BACK PAIN HAS CONTINUED SINCE MY LAST PERIOD AND OCCASIONAL NAUSEA HAS REAPPEARED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043784	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). PALMS OF HANDS AND BOTTOM OF FEET BEGAN ITCHING UNCONTROLLABLY. THEN EVERY TIME I SCRATCHED, MY SKIN WELTED AND LEFT RED SWOLLEN SCRATCH MARKS. I COULDN'T STOP SCRATCHING. I WENT TO AN URGENT CARE AND WAS PRESCRIBED STEROIDS. THAT WORKED, UNTIL THE MEDICINE TREATMENT WAS COMPLETED, THEN MY SKIN WELTED UP AGAIN AND I ITCHED ALL OVER MY BODY. I WENT TO AN ALLERGIST AND THEN I WAS PUT ON 4X THE RECOMMENDED DAILY DOSE OF ZYRTEC, ZANTAC, HYDROXYZINE, BENADRYL, AND SINGULAIR TO CONTROL THE ITCHING. THE DOCTOR SAID IT WILL PROBABLY GO AWAY OVER TIME, BUT IT'S BEEN 9 MONTHS, WITH NO IMPROVEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043785	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/3/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAINED 55 POUNDS, HYPERTRIGLYCERIDEMIA, EXPERIENCING MAJOR DEPRESSION, METAL TASTE IN MY MOUTH, MAJOR HAIR LOSS, BACK AND JOINTS PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043786	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 8/22/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING PAIN IN MY LOWER ABDOMEN DAILY. THIS CONTINUED AND STILL CONTINUES. SINCE THEN I DEVELOPED ENDOMETRIOSIS THAT LED TO ABLATIONS AND SCAR TISSUE REMOVAL, MAJOR BLEEDING THAT NEVER OCCURED PRIOR. IRREGULAR PERIODS. SOME BLEEDING LASTING FOR MONTHS. MANY ABNORMAL PAP WITH CIN3 CELLS THAT LED TO A PARTIAL HYSTERECTOMY IN (B)(6) 2011. I AM STILL HAVING SHARP PAIN DAILY!! TO THE POINT IT WILL DOUBLE ME OVER. ON BOTH SIDES. SINCE THE PROCEDURE I HAD DEVELOPED SEVERAL PAINFUL OVARIAN CYSTS. DYSPLASIA. UTERINE FIBROIDS. EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA) I STILL HAVE VERY PAINFUL OVULATION. I GET BACTERIAL VAGINOSIS ALL THE TIME. UNEXPLAINED BODY ACHES. FREQUENT DIARRHEA FOR ABOUT 5 YEARS NOW, DIAGNOSED AS IBS. MOOD SWINGS. SORES ON MOUTH FACE, ETSC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043787	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER GETTING ESSURE WHICH WAS (B)(6) 2013, I BEEN HAVING A LOT OF ISSUES WHICH STARTED WITH FEVERS, HEADACHES, IRREGULAR PERIODS, NAUSEA, SEVERE ACNE, DEPRESSION, HOT FLASHES, CHRONIC FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043788	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DESDE QUE ME PUSIERON ESSURE TENGO SANGRADO QUE ME DURAN 2 MESE IENDO A EMERGENCIA ME DAN DOLORES FUERTE MI ESTANDOACUTE;MAGO SE INFLA TENGO CALAMBRE EN EL ESTANDOACUTE;MAGO NANDAACUTE;USEA OCASIANDOACUTE;N EN MI PARTE ANDIACUTE;NTIMA SANGRADO FUERTE QUE SE ME CAE AL PISO (B)(6) GRANDE ARDOR A ORINAL

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043789	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/14/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE SWELLING IN ABDOMEN AREA, CONTINUOUS BLEEDING, SEVERE CONSTANT PAIN, OVARY REMOVAL, WEIGHT GAIN, SEVERE FATIGUE, HAIR LOSS, ACNE, NICKEL ALLERGY, CONTINUOUS TREATMENT FOR ENDOMETRIOSIS RESULTING IN HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043790	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2006, I RECEIVED THE ESSURE TUBAL IMPLANTS AT FIRST THINGS SEEMED FINE. SEVERAL MONTHS LATER I BEGIN DEVELOPING THE FOLLOWING SYMPTOMS: A SHARP, NAGGING PAIN MY LOWER ABDOMEN. AN ALLERGY TO TAPE AND A SENSITIVITY TO DAIRY. BODY RASH ANDAMP; "BREAKOUTS" (NEVER HAD THEM BEFORE). CHRONIC ITCH - I FEEL LIKE I AM HAVING AN ALLERGIC REACTION, MY SKIN ITCHES CONSTANTLY. KIDNEY ISSUES AND CHRONIC UTI, CHRONIC YEAST INFECTIONS AND BV, INTERMITTENT LEFT LEG NUMBNESS, DEGENERATIVE JOINTS AND BONE LOSS, CHRONIC BACK ISSUES, CHRONIC HIP AND KNEE ISSUES, CHRONIC INFLAMMATION IN THE ABDOMEN, RAPID WEIGHT GAIN, ANXIETY, PTSD, HEAVY, CLOTTING PERIODS THAT LAST DAYS, PAIN DURING INTERCOURSE, VULVAL INFLAMMATION, CONSTANT WATERY DISCHARGE, BLEEDING AFTER SEX, BLEEDING (FULL ON BRIGHT RED W/ CLOTS) BETWEEN PERIODS, BREAST PAIN (AND NON-CANCEROUS LUMPS, RESULTING IN SURGERY TO REMOVE LUMPS), IBS LIKE SYMPTOMS, RAPID EMPTYING, MOOD SWINGS, DIMINISHED BRAIN FUNCTION. CHRONIC HEADACHE ANDAMP; MIGRANE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043791	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PAINFUL PERIODS SINCE UNTIL PRESENT, LEGS PAIN, A METAL TASTE WITCH IS TAKING MY SENSE OF TASTE AND SMELL...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043792	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL BLOATING, EXCESSIVE GAS, SPASTIC COLON, MOOD SWINGS, WEIGHT GAIN, BRAIN FOG, PAIN AFTER SEX, ANXIETY, DEPRESSION, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043793	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE IMPLANTED IN (B)(6) 2010. INFORMED THE IMPLANTING DOCTOR OF MY METAL ALLERGY AT MY PRE-OP APPT AND HE STILL IMPLANTED ME. AFTER I HAD THE DYE TEST PERFORMED IN (B)(6) 2010 MY PERIOD BEGAN TO BECOME EXTREMELY PAINFUL. IN THE FOLLOWING MONTHS THE PAIN CONTINUED TO GET WORSE AND THEN MY CYCLES BECAME ERRATIC. I BEGAN GOING ANYWHERE FROM 10 DAYS TO 40 DAYS IN BETWEEN START DATES FOR MY CYCLE. WITHIN THE NEXT YEAR I BEGAN TO HAVE PAIN DURING INTERCOURSE, MORE ERRATIC CYCLES, HEAVY BLEEDING, ANXIETY, METAL TASTE IN MY MOUTH, CRAMPING THAT MADE ME UNABLE TO MOVE, BLEEDING BETWEEN PERIODS, WEIGHT GAIN, WEIGHT LOSS, BLOATING, PAIN IN BACK AND LEGS, SHARP STABBING PAINS IN MY ABDOMEN AND CYSTS FOR THAT HAVE BEEN ALMOST THE FULL SIZE OF MY OVARIES. I HAVE NUMEROUS ULTRASOUNDS TO LOOK FOR FIBROIDS. PLACED ON LOGESTRAL OF CYCLE REGULARITY, SERTRALINE FOR ANXIETY, AND NOW HAVE A CONSULTATION WITH A OBGYN 100 MILES AWAY FROM HOME TO HAVE SURGERY TO REMOVE MY TUBES AND THE ESSURE COILS. I HAVE SEEN 3 DIFFERENT DOCTORS. ONE WHO IMPLANTED THE DEVICE, ONE WHO TOLD ME IT WAS ALL BECAUSE OF MY BOWELS AND FINALLY ONE WHO HAS TRIED METHODS TO HELP AND HAS DECIDED HAVING MY TUBES REMOVED OR HAVING A HYSTERECTOMY PREFORMED WILL BE MY ONLY OPTIONS TO STOP MY PAIN AND SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043794	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 10/14/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AWOKE FROM A NAP WITH THE RIGHT SIDE OF MY FACE PARALYZED. THIS WAS FOLLOWED THREE WEEKS LATER BY INTENSE PAIN ON THE RIGHT SIDE OF MY HEAD THAT CONTINUED STEADILY UNTIL 2010. I STILL HAVE PAIN AND PARALYSIS TO THIS DAY. I HAD NO MEDICAL CONDITIONS PRIOR TO THIS EVENT. I HAVE A TEAM OF NEUROLOGISTS WHO CAN FIND NO OTHER CAUSE FOR THIS. MEDICATIONS AND TREATMENTS THAT ARE USED FOR BELLS' PALSY HAVE NOT WORKED IN MY CASE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043795	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/5/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE A LOT OF PELVIS PAIN, LOWER BACK PAIN, HEAVY PERIODS, PAIN AFTER HAVING INTERCOURSE, THYROID AFTER THE IMPLANT OF ESSURE...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043796	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY HEAVY PERIODS LAST 10 DAY'S BLOATING, GAS MOVEMENT IN STOMACH. HIGH SED RATE. TIRED ALWAYS. BODY ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043797	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, STOMACH PAIN, BACK PAIN, PELVIC PAIN, GLUTEN ALLERGY, LACTOSE ALLERGY, PERIOD LOSS, MOOD SWINGS AND HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043798	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SHARP/STABBING PELVIC PAIN, HOT FLASHES, NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS (DYSMENORRHEA), PAINFUL INTERCOURSE (DYSPAREUNIA), BLEEDING BETWEEN PERIODS (MENORRHAGIA), EARLY MENOPAUSE, INCONTINENCE, LONG MENSTRUAL CYCLES (POLYMENORRHEA), YEAST INFECTIONS, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP, CHRONIC PELVIC PAIN, FACE PAIN (TRIGEMINAL NEURALGIA), ALL OVER BODY ACHES/PAIN, GASTROINTESTINAL, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, NEUROLOGICAL, MENTAL HEALTH, HEADACHES OR MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN SHOCKS, NERVE PAIN, BRAIN FOG ANDNDASH; CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, DEPRESSION, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), MOOD DISORDERS, VITAMIN D DEFICIENCY, DENTAL ISSUES; INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043799	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, DIZZINESS, NAUSEA, CRAMPING, HIVES, BLOATING, SHARP STABBING PAIN, COIL CAME OFF TUBE A LANDED ON TOP OF RECTUM - SHARP RECTUM PAIN. HAD TO HAVE FALLOPIAN TUBES REMOVED. STII SICK. SEEKING HYSTEROTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043800	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT BLEEDING AND PAIN!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043801	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD UNBEARABLE PAIN, LIKE MISCARRIAGE CRAMPS, DIZZINESS, NAUSEA AND IT HAD LASTED FOR A WEEK SO I WENT TO ER AND THIS LIKE MANY TIMES BEFORE THE DOCTOR DIAGNOSED IT AS ABNORMAL UTERINE BLEEDING. I STILL HAVE THESE PAINS BUT CAN'T AFFORD ANY MORE MEDICAL BILLS TO BUILD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043803	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD UNBEARABLE PAIN, LIKE MISCARRIAGE CRAMPS, DIZZINESS, NAUSEA AND IT HAD LASTED FOR A WEEK SO I WENT TO ER AND THIS LIKE MANY TIMES BEFORE THE DOCTOR DIAGNOSED IT AS ABNORMAL UTERINE BLEEDING. I STILL HAVE THESE PAINS BUT CAN'T AFFORD ANY MORE MEDICAL BILLS TO BUILD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043804	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED GRADUALLY, WEIGHT GAIN, PAIN ON BOTH SIDES OF LOWER ABDOMEN. MORE RIGHT THEN LEFT. BLOAT JUST CAME OUT OF NO WHERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043805	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INFLAMED LIPS, FINGERS, RASHES, BOILS ON LEGS AND THIGHS THAT HAS TO BE CUT AND DRAINED, ANTIBIOTICS, PAIN IN HIPS, JOINTS, BOTTOM OF FEET AFTER SITTING OR LAYING AWHILE, ANXIETY, GERD, HIGH BLOOD PRESSURE, HEAVY BLEEDING, SHARP PELVIC AND HEADACHE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043806	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN, CRIPPLING AT TIMES. UNABLE TO PERFORM JOB DUTIES AS A NURSE AT TIMES. ABDOMINAL WEIGHT GAIN, EXTREME MOOD CHANGES, NIGHT SWEATS, HOT FLASHES, EDEMA IN EXTREMITIES, CYSTS, MENTAL FOGGINESS, FORGETFULNESS, EXTREME IRRITABILITY, EXTREME FATIGUE. PAIN. PAIN. PAIN. PAIN IN OVARY, VAGINAL PAIN, PAINFUL INTERCOURSE, HEADACHES, JOINT PAIN, OVERALL FEELING LIKE CRAP. RIGHT SIDED OVARIAN PAIN BEGAN WITHIN TWO WEEKS OF PLACEMENT AND HAS GRADUALLY GOTTEN WORSE. PAIN IS NOW CONSTANT INSTEAD OF RANDOM. LOOKING AT REMOVAL OPTIONS, POSSIBLE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043807	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, BLOATED BELLY, WEIGHT GAIN, HAIR LOSE, THYROID PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043808	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, AND CRAMPING, AND SEVERE UTERINE BLEEDING, STARTED HAVING SEVERE MIGRAINES, AND STOMACH PAINS, ALONG WITH NAUSEA. MY MOODS BECAME UNSTABLE WITH SEVERE CHANGES. ALSO UNEXPLAINED RASHES ON INSIDE OF THIGHS AND ARMS, CHEST, BACK. SEVERE ACNE ON FACE, CHEST, AND BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043809	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, BLOATED BELLY, WEIGHT GAIN, HAIR LOSE, THYROID PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043810	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CONSTANT PELVIC PAIN, HEAVY LONG LASTING (10 TO 12) DAYS OF BLEEDING , HAIR LOSS, FATIGUE, DEPRESSION, WEIGHT GAIN, BACK PAIN, BOWEL ISSUES, BLOATING. I NEVER FEEL GOOD. I WORK OUT, AND EAT HEALTHY BUT I FEEL HORRIBLE , PAIN ALL THE TIME, SOMETIMES IT'S DEBILITATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043811	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 9/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HAD ESSURE IMPLANTED AND WITHIN 3 DAYS I BEGAN FEELING STABBING SHARP PAINS, VERY LARGE CLOTS SOAKING THREW PADS AND CONTRACTION LIKE PAIN ON MOSTLY RIGHT SIDE. TOLD DOC MANY TIMES AND HE REFUSED TO BELIEVE MY SYMPTOMS WERE FROM ESSURE. HAD TO SUFFER 3 MORE MONTHS FOR HSG TEST TO SHOW RIGHT COIL BROKE AND MIGRATED DOWN . HAD TO WAIT FOR DOC TO HEAR BACK FROM CONCEPTUS ABOUT WHAT HE SHOULD DO. (B)(6) 2013 FINALLY HAD TO HAVE SURGERY TO REMOVE DAMAGED COIL AND TUBE, DOC WAS SCARED TO DO IT AO HE CALLED ANOTHER DOC INTO HELP. SHORTLY AFTER RIGHT WAS REMOVED I NOTICED MORE PAIN AND CRAMPING AND PERIODS GOT MUCH WORSE. I'VE CALLED MANY TIMES ASKING FOR HELP WITH THIS TO BE TOLD ITS MOST LIKELY SOMETHING ELSE NOT ESSURE. I WAS FINE BEFORE ESSURE. I NEED THE LEFT SIDE OUT. I CANT CONTINUE MUCH LONGER LIKE THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043812	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, PAIN DURING SEX, ENDOMETRIOSIS, BV, DEPRESSION, MIGRAINE, HOT FLASHES, HAIR LOSS, ANXIETY, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043813	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED DEVELOPING CYSTS ON LEFT OVARY WITH SEVERE PAIN. DR'S KEPT TREATING ME AD POSSIBLY KIDNEY STONES AT URGENT CARE BUT FINALLY SENT ME TO ER FOR IV AND THEY DID A CT SCAN AND FOUND CYSTS. I WAS GIVEN BIRTH CONTROL PILLS BY MY OBGYN (DR. (B)(4)) TO TRY TO LIMIT GROWTH IN HOPES THAT THEY WOULD SHRINK OR BURST ON THEIR OWN. SEX BECAME UNBEARABLE SO I RETURNED TO DR AND I STILL HAD CYSTS. TRIED ANOTHER BIRTH CONTROL PILL, BUT SYMPTOMS OF PAIN AND CRAMPING CONTINUED ALONG WITH INCREASED ACNE, MEMORY LOSS, BRAIN FOG, MOOD SWINGS, AND DEPRESSION. DR THEN ORDERED ULTRASOUND AND FOUND 4CM CYST. THEY SCHEDULED SURGERY FOR A FEW DAYS LATER TO REMOVE CYST. HE ENDED UP TAKING MY OVARY AND TUBE (ALONG WITH ESSURE COIL). AFTER REMOVAL, I HAD A TOUGH RECOVERY FOR ABOUT A WEEK. THEN I STARTED FEELING BETTER. I TRULY BELIEVE THAT THE ESSURE COILS HAD MORE TO DO WITH THE CYSTS THAN THE DR WOULD TELL ME. EVER SINCE I RECEIVED THEM I'VE HAD ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043814	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN HAVING SWELLING AND IRRITATION AROUND MY EYES. AN UNEXPLAINED RASH THAT WAS ON MY UPPER ARMS SPREAD TO MY FOREARMS. I ALSO EXPERIENCED JOINT PAIN, EXCRUCIATING LOWER BACK PAIN, NUMBNESS AND TINGLING IN MY LEFT LEG, FATIGUE, HEADACHES, AND OVARIAN PAIN. MY BLOOD WORK REVEALED ELEVATED INFLAMMATION, ELEVATED LIVER ENZYMES, AND ELEVATED LEUKOCYTES, AND AN ALLERGY TO NICKEL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043815	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BODY ACHES, HEAD ACHES, LETHARGIC, CONSTANT DIARRHEA, YELLOW EYES, HAIR LOSS, TOTAL LOSS OF SEX DRIVE, PAIN WITH INTERCOURSE, MOOD SWINGS, DEPRESSION, RASHES, UNCONTROLLABLE VOMITING, BACK PAIN, KIDNEY PAIN. STOMACH PAIN, WEAK AND BREAKING TEETH, NUMBNESS IN HANDS, ARMS, LEGS, FEET. SWELLING, JOINT PAIN. TIRED ALL THE TIME, BUT UNABLE TO SLEEP. RESTLESS LEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043816	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 5/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STOMACH ISSUES, STABBING PAINS, PAIN DURING INTERCOURSE, TERRIBLE CRAMPING, BLOATING AND SWELLING, WEIGHT GAIN, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043817	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). WENT IN, WAS PUT TO SLEEP AND HAD COILS INSERTED. WOKE UP, WENT HOME, CHECKED 3 MONTHS LATER, SAW SCAR TISSUE, THAT WAS IT. SINCE THEN FEEL HORRIBLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043818	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT STABBING PELVIC PAIN, SERIOUS BLOATING AND LOWER ABDOMINAL PAIN, LOWER BACK PAIN, MIGRAINES, NAUSEA, WEIGHT GAIN, DEPRESSION. WAS RECENTLY TOLD ESSURE CONTAINS NICKEL, NOT SURE IF IT'S TRUE, BUT I'M ALLERGIC TO NICKEL AND WAS NEVER TOLD ABOUT THIS ASPECT. I HAVE BEEN ABSOLUTELY MISERABLE SINCE I HAD THE PROCEDURE DONE IN (B)(6) 2014. FOLLOWING UP WITH AN OBGYN TO HOPEFULLY GET THESE AWFUL DEVICES REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043819	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 9/22/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SERIOUS ABDOMINAL CRAMPING, MIGRAINES THAT LASTED FOR DAYS, SEVERE MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043820	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 5/16/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HIGH BLOOD PRESSURE, CONSISTENT SWEATING, CHRONIC HEADACHES, LOWER BACK PAIN, STROKE - LIKE SYMPTOMS, NUMBING IN FACE, TINGLING IN FINGERS, BLOATING, BRAIN FOG, WEIGHT GAIN, SHARP PAINS IN PELVIC AREA, NAUSEA, RASH AND HIVES ALL OVER, LIGHT-HEADED, NECK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043821	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 8/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BLOATING, STOMACH FLUTTERING, INABILITY TO LOSE WEIGHT, SEVERE CRAMPING, UNUSUAL PERIODS, SHARP PAINS IN LOWER ABDOMINAL AREA, HEMOCHROMATOSIS WAS DISCOVERED AND DIAGNOSED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043822	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 2/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BREAKING OUT IN HIVES. MY MOOD DROPPED SEVERELY. MY FACE STARTED BREAKING OUT IN PIMPLES. I WAS BECOMING VERY TIRED EASILY. MY HAIR STARTED SHEDDING. I DIDN'T KNOW WHAT WAS HAPPENING. I FIGURED MY BODY WAS FREAKING OUT BECAUSE I WAS NO LONGER ON BIRTH CONTROL PILLS ANYMORE. I HAD ESSURE COIL PUT IN (B)(6) 2007, TUBES TIES END OF (B)(6) 2007. AS TIME WENT ON, I TRIED EATING BETTER, TAKING SUPPLEMENTS FOR MY HAIR AND SKIN TO COUNTER ACT WHAT I COULD. IN 2010 AFTER A COUPLE YEARS HAVING MY PCP TEST ME FOR DIFFERENT THINGS, MY RIGHT BREAST STARTED LEAKING. I HAD A SHINGLE LIKE RASH ON MY BACK BEHIND MY BREAST. MY RIGHT ARM FATIGUED EASILY AND I COULDN'T USE IT. I COULDN'T THINK OR SPEAK RIGHT. MY PCP ORDERED AN MRI OF MY BRAIN AND UPPER SPINE AND NECK. THIS IS WHEN I WAS TOLD RESULTS INDICATED MULTIPLE SCLEROSIS. BRAIN FOG, FATIGUE, DIZZINESS, BALANCE PROBLEMS, SPEECH PROBLEMS, SEROUS STOMACH ISSUES THAT I NEVER HAD BEFORE. THEN SKIN ISSUES GOT WORSE, BUMPS ON MY SCALP, AROUND MY BIKINI AREA, NEW CYST LIKE BUMPS ON LEGS AND ARMS. TASTE IN MY MOUTH, BAD BREATH, MY DEODORANT SEEMED TO STOP WORKING, NO DEODORANT SEEMED TO WORK TO STOP SWEAT OR BODY ODOR. JUST A FEW WEIRD THINGS THAT YOU DONT REALLY TALK ABOUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043823	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE, I HAVE DEVELOPED AN UNDERACTIVE THYROID, HIP/PELVIC PAIN, ARTHRITIS IN L4-L5 THAT CAUSES SCIATIC NERVE PAINS, A NUMBNESS IN RIGHT THIGH THAT FEELS LIKE LEG IS ON FIRE, STOMACH PROBLEMS, EXTREMELY HEAVY BLEEDING ON PERIODS, SPOTTING BEFORE AND AFTER PERIODS, PERIODS THAT LAST WITH SPOTTING AND HEAVY BLEEDING FOR (SO FAR) UP TO 3 WEEKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043824	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BECAME ALLERGIC TO SOY AND SEVERAL OTHER FOOD TYPES AS WELL AS HOT FLASHES, PAIN, SWELLING IN MY ABDOMEN AND HEAD ACHES THAT BECAME MIGRAINES, DIZZINESS, FATIGUE AND NAUSEA. TO GETTING (B)(6) BECAUSE OF THE COPPER DEVICE. WAS TOLD BY A RN THAT SHE BELIEVES ITS BECAUSE OF ESSURE AND SINCE REMOVAL LAST SUMMER, I AM HYPER SENSITIVE TO ANY HOSPITAL SOAPS, SCRUBS AND TO ANY STERILE STRIPS AND EVEN (B)(6). TO CONSTIPATION AND PAINFUL PERIODS AND YEAST INFECTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043825	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE, I HAVE DEVELOPED AN UNDERACTIVE THYROID, HIP/PELVIC PAIN, ARTHRITIS IN L4-L5 THAT CAUSES SCIATIC NERVE PAINS, A NUMBNESS IN RIGHT THIGH THAT FEELS LIKE LEG IS ON FIRE, STOMACH PROBLEMS, EXTREMELY HEAVY BLEEDING ON PERIODS, SPOTTING BEFORE AND AFTER PERIODS, PERIODS THAT LAST WITH SPOTTING AND HEAVY BLEEDING FOR (SO FAR) UP TO 3 WEEKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043826	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATE AND CONSTANT PAIN, FATIGUED, BLOATED, DEPRESSED, FIBROIDS, DYSFUNCTIONAL UTERINE BLEEDING, SEVERE CRAMPS (MEDICATED WITH HYDROCODONE).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043827	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATE AND CONSTANT PAIN, FATIGUED, BLOATED, DEPRESSED, FIBROIDS, DYSFUNCTIONAL UTERINE BLEEDING, SEVERE CRAMPS (MEDICATED WITH HYDROCODONE).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043828	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE HEADACHES DAILY, WEIGHT GAIN, SHARP PELVIC PAIN, (WORSE THAN LABOR PAIN), HAIR LOSS, ANXIETY, PANIC ATTACKS, DEPRESSION, BODY ACHES (LIKE BEING 100 YEARS OLD), TEETH FALLING APART, NO ENERGY, HEAVY PERIODS (BLOOD CLOTS EVERY MONTH).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043829	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HAIR LOSS, SEVERE CRAMPING DURING MENSTRUAL, EXTREMELY HEAVY PERIODS, CHRONIC PELVIC PAIN, SEVERE BREAST TENDERNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043830	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 3/9/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN AND WEIGHT GAIN AND EXTREMELY AGITATED HAD MY DR PUT ME ON ANXIETY MEDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043831	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE PLACEMENT, I DEVELOP MULTIPLE SKIN RASHES ON MY THIGH, UNDERARMS, AND BACK. I ALSO SUFFER FROM SEVERE HEADACHES, DEPRESSION, SEVERE MOOD SWINGS, INSOMNIA, GENERALIZED BODY PAIN (FEELS LIKE I'VE BEEN IN A CAR ACCIDENT) ON A DAILY BASIS. MAJOR HAIR LOSS, WEIGHT GAIN, AND SEVERE ABDOMINAL INFLAMMATION AND PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043832	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THIS DATE APPROXIMATELY I HAVE HAD ONGOING CONSTANT UPSET STOMACH, MIGRAINES SO BAD THAT THEY WOULD LAST UP TO 2 WEEKS AND I WOULD BE PUKING, NON STOP TIREDNESS, ALL OVER BODY PAIN TO THE POINT OF TEARS AND NOT BEING ABLE TO TAKE CARE OF MY CHILDREN AT TIMES, SWELLING IN THE LOWER PART OF MY BRAIN THAT CANNOT BE ATTRIBUTED TO ANYTHING WHICH IN TURN CAUSES MORE MIGRAINES AND VISION PROBLEMS. I HAVE GAINED A LOT OF WEIGHT, HAVE HAD PROBLEMS WITH HOT AND COLD FLASHES FOR NO REASON, EXTREMELY BAD BOUTS OF DEPRESSION, INSOMNIA.... AGAIN ALL FOR SOME UNKNOWN REASON. MY HAIR HAS BECOME THINNER, IT JUST SLOWLY KEEPS FALLING OUT. I AM CONSTANTLY BLOATED, HAVE ABDOMINAL CRAMPING ALL THE TIME AND DURING MY CYCLE THE PAIN GETS SO EXTREME I CAN DO NOTHING BUT CRY. CLOTTING AND BLEEDING DURING MY CYCLE IS EXTREMELY HEAVY AND CLOTS ARE HUGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043833	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP STABBING PAIN IN MY TUBES AREA. FELT LIKE HAVING A BABY TO NEEDLES VERY PAINFUL. MY PERIOD COMES AND GOES NOW NEVER EXPECTED. I'M A PETITE WOMEN AND I GET BLOATED LIKE I'M PREGNANT BREAST TENDERNESS. MY LOWER ABDOMEN HURT 18 TO 20 DAYS OUT OF THE MONTH. I THOUGHT I WAS PREGNANT TWICE BECAUSE OF BLOATING AND I ALREADY HAVE 4 KIDS. I WANTED MY TUBES TIED BUT MY DOCTOR WAS GOING OUT OF TOWN FOR (B)(6) WHEN MY DAUGHTER WAS BORN AND HE SAID HE WOULD RECOMMEND THE ESSURE DOES THE SAME THING. I WOULD NOT DONE IT. I WOULD HAVE JUST TOOK PILLS IF I KNEW WHAT I KNOW NOW. NOW I CAN'T GET THEM REMOVED BECAUSE OF FUNDS SO IT'S PAIN I HAVE TO LIVE WITH AND SO MY KIDS HAVE TO WATCH ME GO THROUGH IT. I WOULDN'T RECOMMEND IT TO NO ONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043834	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 9/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE JOINT/MUSCLE PAIN AND STIFFNESS ALL OVER, NUMBNESS AND TINGLING IN HAND/ARMS/LEGS/FEET, EASILY BRUISING AND ITCHY ALL OVER MY BODY, RASH, HEADACHES, BRAIN FOG (CANT CONCENTRATE OR FIND MY WORDS), FATIGUE, NO ENERGY, DAILY FATIGUE, DEPRESSION, FIBROMYALGIA, SEVERE BLOATING, DAILY CRAMPING, PERIOD EVERY 2-4 MONTHS, HEAVY BLEEDING WITH HUGE CLOTS AND CRAMPING, CONSTANT SPOTTING, PAINFUL SEX AND BLEEDING AFTERWARDS, SHARP STABBING PELVIC PAIN, BLADDER PRESSURE, LEAKING URINE, NO ENERGY, HYPOGLYCEMIA, NIGHT SWEATS, LACK OF DESIRE, HEADACHES, ANXIETY, HEART PALPITATIONS, ELEVATE BLOOD COUNTS, DIZZINESS, WEIGHT GAIN, MUSCLE SPASMS IN FEET AND CALVES, OVERALL ILL FEELING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043835	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). PELVIC PAIN. DIZZY. RASHES. NO ENERGY, TIRED ALL THE TIME. HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043836	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 10/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD SEVERE ABDOMEN PAIN AND RECTUM PAIN. I WENT TO MY FAMILY DOCTOR AND SHE THEN SENT ME TO A GYNECOLOGIST (NOT THE SAME DOCTOR WHO PREFORMED THE ESSURE SURGERY). THE GYNECOLOGIST EVALUATED ME AND DECIDED I NEEDED MY LEFT OVARY AND FALLOPIAN TUBE REMOVED. ON THE DAY OF THAT SURGERY HE ENCOUNTERED THAT THE ESSURE DEVICE HAD EXPELLED OUT OF MY LEFT FALLOPIAN TUBE AND EMBEDDED BETWEEN MY UTERUS AND COLON. HE HAD TO CALL IN AN ADDITIONAL SURGEON TO HELP PULL IT OUT OF MY COLON AND HOPE THAT IT DID NOT PUNCTURE THE COLON. I WAS OFF WORK, SEVERAL DAYS OFF AND ON. PRIOR TO THIS SURGERY, ENCOUNTER SEVERAL MEDICAL BILLS, WAS DENIED SHORT TERM DISABILITY FOR THE TIME OFF FOR RECOVERY AND I CONTINUALLY STRESS ABOUT THE RIGHT SIDE DEVICE STILL IMPLANTED IN MY BODY. I HAVE DOCTOR'S LETTERS STATING WHAT I HAVE MENTIONED ABOVE BUT DO NOT KNOW HOW TO INSERT - PLEASE CONTACT ME AT (B)(6) ON HOW I CAN INCLUDE ALL MY BACKGROUND INFORMATION. THANKS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043837	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT SHARP SHOOTING PAINS IN SIDES OF ABDOMEN. SEVERE PAIN DURING OVULATION. LONGER, HEAVIER PERIODS, EXTREME FATIGUE, DRY SKIN PROBLEMS, INCLUDING PSORIASIS ON MY SCALP. DIFFICULTY SLEEPING, MOOD SWINGS, DEPRESSION, PAIN DURING SEX. JOIN PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043838	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HEADACHES, FATIGUE, MUSCLE ACHES, FEVERS. ALMOST DAILY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043839	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 9/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVER CRAMPING. EXTREME PAIN IN MY LOWER BACK, ABDOMEN, UPPER LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043840	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT HAD HORRIBLE PERIODS EVER SINCE ESSURE WAS PUT IN, RASHES, HAIR FALLING OUT, BRUISING, PAINFUL INTERCOURSE, HIGH ANXIETY BEFORE PERIODS. I AM PAYING (B)(6) PLUS TRAVEL EXPENSES TO HAVE IT REMOVED WITHOUT HAVING TO HAVE A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043841	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER ESSURE, MY PERIODS BECAME EXTREMELY HEAVY WITH HUGE CLOTS. NEVER HAD BEFORE. DIDN'T WANT TO LEAVE THE HOUSE. HAD AN ABLASION DONE WITH ISSUES STILL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043842	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 9/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TESTED ME FOR CANCER, THEN DOCTOR REALIZED THAT THE ESSURE IMPACTED THROUGH THE FALLOPIAN TUBES. I NEEDED A HYSTERECTOMY DUE TO ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043843	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 1/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THREE MONTHS AFTER ESSURE WAS PLACED THE DYE WAS INJECTED TO SEE IF IT WORKED. SHORTLY AFTER I HAD MY PERIOD. TECH SAID IT'S JUST SPOT IT SHOULD STOP. GOT HOME STILL BLEEDING. HAD MY PERIOD FOR 8 TO 14 DAYS. WERE HEAVIER HAD TO WEAR TAMPON AND PAD AND ALSO HAD CLOTS PASS AS WELL. BEFORE ESSURE BLEEDING WAS NOT SO HEAVY AND PERIODS LASTED UP TO 4-5 DAYS. I HAVE SLE LUPUS AND WHEN ESSURE WAS PLACED I WAS ON HIGH DOSES OF PREDNISONE. IF I GOT A BROCHURE ON ESSURE OR KNEW MORE ABOUT PROBABLY WON'T HAVE DONE IT BUT I TRUSTED MY DOCTOR. THREE MONTHS AFTER DYE I WAS DIAGNOSED WITH FIBROMYALGIA. I ALSO HAVE SEVERE PELVIC PAIN. PAIN WAS SO BAD I COULD STAND FOR LONG PERIOD OF TIME. I HAVE ALLERGIES MOST MEDICINE AS WELL THAT I WAS NOT ALLERGIC TO BEFORE ESSURE. I HAD TO HAVE A HYSTERECTOMY TO REMOVE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043844	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 2/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, PELVIC PAIN, HIP PAIN, BACK PAIN, DIZZINESS, STOMACH PROBLEMS, DIGESTION PROBLEMS, GLUTEN ALLERGY, LACTOSE ALLERGY, DEPRESSION, ANXIETY, HAIR LOSS, PERIOD LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043845	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SWELLING IN THE STOMACH. BAD PAIN SINCE I HAD THE STENTS PUT IN MY TUBES. MY MONTHLY CYCLE IS A LOT WORSE ON BLEEDING AND CRAMPS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043846	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS NEVER ASKED IF I HAD ANY METAL ALLERGIES (WHICH I DO) PRIOR TO BEING PUT IN ME, INSTEAD OF GETTING MY TUBES TIED. SINCE THEN I HAVE HAD NUMEROUS SIDE EFFECTS THAT I KNOW ARE DIRECTLY RELATED TO THIS DEVICE. CRAMPING; ABDOMINAL, TOES, FEET, HANDS, AND CALVES, SHARP/STABBING PELVIC PAIN. ABNORMAL MENSES 24/7 TAMPONS : (I WILL DIE FROM TOXIC SHOCK IS THE ONGOING SAD JOKE BETWEEN MY OLDER CHILDREN AND I) CONSTANT SPOTTING, DISCHARGE (ODOR/NO ODOR), HOT FLASHES, UTERINE INFLAMMATION, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), PAINFUL OVULATION (MITTELSCHMERZ), NIGHT SWEATS, LOSS OF LIBIDO ~ HAVEN'T HAD AND NO DESIRE FOR SEX FOR WELL OVER 3 YRS NOW. I USE TO HAVE SEX 3-4 TIMES A WEEK! HOT FLASHES, BLEEDING/SPOTTING AFTER SEX PAINFUL PERIODS (DYSMENORRHEA), PAINFUL INTERCOURSE (DYSPAREUNIA), BLEEDING BETWEEN PERIODS (MENORRHAGIA), EARLY MENOPAUSE ???, INCONTINENCE, LONG MENSTRUAL CYCLES (POLYMENORRHEA), SEXUAL DYSFUNCTION (UNABLE TO ORGASM OR FEEL PLEASURE), YEAST INFECTIONS (CANDIDA), URGENT/FREQUENT URINATION, UTI (URINARY TRACT INFECTION), BLADDER INFECTION, CERVICITIS/VAGINITIS (SWELLING, INFLAMMATION, INFECTION OF THE CERVIX OR VAGINA), ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE, (VULVODYNIA), BREAST PAIN/TENDERNESS ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, PAIN, BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP, CHRONIC PELVIC PAIN, ALL OVER BODY ACHES/PAIN, NAUSEA, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES. HEADACHES OR MIGRAINES ~ (I HAVE HEADACHES EVERY SINGLE DAY FOR THE LAST FEW YEARS, I LIVE WITH THEM AND FUNCTION UNLESS THEY ARE MIGRAINES WHICH ARE FREQUENT) DIZZINESS, TINGLING SENSATIONS, NUMBNESS, NERVE PAIN, BRAIN FOG AND CLOUDINESS, FORGETFULNESS, ANXIETY, MOOD SWINGS ~ SEVERE I SCARE MYSELF AT TIMES AND NEED TO GO TO MY ROOM AND SHUT MY DOOR AS I

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KNOW IT IS NOT ME NOR MY POOR CHILD...SHE DOESN'T UNDERSTAND THOUGH...NOT AT 5! STROKE SYMPTOMS, DEPRESSION, RINGING IN EARS (PULSATILE TINNITUS), BLACK OUT SPELLS/ FAINTING, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS) MOOD DISORDERS, NUMBNESS IN THIGH (MERALGIA PARESTHETICA), NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN (PARESTHESIA), TREMORS/SHAKINESS, ANEMIA/ IRON DEFICIENCY, BLOOD CLOTS, HIGH BLOOD PRESSURE AND LOW BLOOD PRESSURE I AM NEVER NORMAL, UNEXPLAINED/EASILY BRUISING, CHRONIC FATIGUE SYNDROME...I COULD SLEEP ALL DAY EVERY DAY!, ALLERGIES/SENSITIVITIES, METAL ALLERGIES (NICKEL). HEIGHTENED ALLERGIES/ ALLERGIC REACTIONS, GLUTEN SENSITIVITY, ALLERGIC REACTIONS, HIVES, RASHES, CYSTS, BOILS, ACNE, SKIN IRRITATION/ITCHING (I HAVE SCARS ON MY LEGS FROM DIGGING WHILE I SLEEP. I USE FORKS SOME TIMES AS NOTHING MAKES ME FEEL COMFORT) SWELLING OF LEGS OR FEET, HAIR LOSS OR CHANGES. DENTAL ISSUES, INSOMNIA, THYROID DISEASE (HYPOTHYROID/HYPERTHYROID), SEROMA, GALLBLADDER ISSUES. WEIGHT ISSUES (GAIN~ I LOOK AND FEEL 7 MONTHS PREGNANT FOR 3 YEARS) SLEEP APNEA SWOLLEN GLANDS UNEXPLAINED FEVERS. MUSCLE SPASMS VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION) EXCESSIVE SWEATING DRY SKIN/HAIR/EYES. SEVERE BLOATING! HUNDREDS OF RED SPOTS/FRECKLES ON MY STOMACH...THEY WERE NOT THERE BEFORE NOW THEY ARE ALL OVER MY LARGE GUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043847	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 7/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CONSTANT ABDOMINAL PAINS, HORRIBLE MIGRAINES, OUT OF CONTROL MOOD SWINGS, BLEEDING, DEPRESSION, SUICIDAL THOUGHTS AND ACTIONS. ADMITTED INTO HOSPITAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043848	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 12/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD ESSURE PLACED ON (B)(6) 2013 I HAD NOTHING BUT PROBLEMS. I HAD CONSTANT ABDOMINAL PAIN, BLOATING, FATIGUE, AND BLEEDING. I BLED FOR 4 MONTHS STRAIGHT AFTER PLACEMENT. THEN IF I BENT OVER, EXERCISED, OR MOVED I WOULD BEGIN BLEEDING. MY PERIODS WENT FROM (PRIOR TO ESSURE) BEING VERY LIGHT, WITH NO CRAMPING, AND LASTING AT THE MOST 4-5 DAY, TO (AFTER ESSURE) EXTREMELY HEAVY WITH LARGE BLOOD CLOTS, VERY PAINFUL CRAMPING, AND LASTING 7 OR MORE DAYS. THE PAIN FROM ESSURE WAS SO EXTREME THAT MANY DAYS ALL I COULD DO WAS LAY IN BED BECAUSE NORMAL DAILY ACTIVITIES WERE TOO PAINFUL. FINALLY I COULDN'T TAKE IT ANYMORE AND ON (B)(6) 2014 I HAD ESSURE REMOVED ALONG WITH MY FALLOPIAN TUBE AND HAD AN ABLATION TO PREVENT FUTURE HEAVY BLEEDING. SINCE THE REMOVAL OF ESSURE ALL PAIN AND OTHER SYMPTOMS HAVE GONE AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043849	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 8/31/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ON RIGHT LOWER ABDOMEN AND PAIN IS WORSE IN CERTAIN SITTING POSITIONS. LOWER BACK PAIN, MORE PERSISTENT THAN NORMAL. LOSS OF HAIR. PAIN IN HIPS/JOINTS. WORSENING EYESIGHT WITHIN MONTHS OF IMPLANT. I ALSO BREASTFED MY DAUGHTER FOR 1 YEAR AFTER IMPLANT AND SHE HAS SEVERE FOOD ALLERGIES AND ECZEMA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043850	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 4/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLOATING, SKIN DISCOLORATION, MIGRAINES, DIZZINESS, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043851	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 10/10/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNDERWENT HYSTERECTOMY AND BILATERAL SALPINGECTOMY ON (B)(6) 2015. HEADACHES, BACK PAIN, FATIGUE, PELVIC PAIN AND CRAMPS, NIGHT SWEATS AND JOINT PAIN CEASED ALMOST IMMEDIATELY. I HAVE MY LIFE BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043853	BAYER	7/9/2015	7/9/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN SEVER PERIODS EVERY TWO WEEKS. HAVING TO GET HYSTERECTOMY IN A MONTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043852	BAYER	7/9/2015	7/10/2015

Event Information:

Event Date (B3): 12/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INCREASED CRAMPING AND HEAVIER PERIODS, PROGRESSING OVER TIME TO BECOMING BEDRIDDEN UNABLE TO STAND UPRIGHT DUE TO DEBILITATING PAIN, INCREASED BLOOD PRESSURE, DEVELOPED METABOLIC SYNDROME, WEIGHT GAIN, HAIR LOSS, BRITTLE TEETH, JOINT PAIN, SLEEP APNEA, CHRONIC FATIGUE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043854	BAYER	7/9/2015	7/10/2015

Event Information:

Event Date (B3): 7/7/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, SHARP PAIN IN LOWER STOMACH, HEADACHES, TINGLING HANDS AND FEET, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043855	BAYER	7/9/2015	7/10/2015

Event Information:

Event Date (B3): 7/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DOCTOR PLACED ONE COIL IN. ONE OF MY TUBES WAS BLOCKED NATURALLY. I HAVE SEVERE BLOATING, FATIGUE, SEVERE PAIN DURING SEXUAL INTERCOURSE AND PAIN WHILE ON THE MENSTRUAL CYCLE. SEVERE BACK PAIN. AND SEVERE MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043856	BAYER	7/9/2015	7/10/2015

Event Information:

Event Date (B3): 12/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE STOMACH PAIN, CRAMPING, OVARION CYSTS, RASH, HAIR GROWTH IN NEW PLACES, PAINFUL PERIODS, PAINFUL INTERCOURSE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043857	BAYER	7/9/2015	7/10/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). HAD PAIN IN UTERUS, WENT TO ER AND WAS TOLD THE CLAMP HAD MIGRATED INTO MY UTERUS. HAD A HYSTERECTOMY TWO WEEKS LATER TO REMOVE THEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043858	BAYER	7/9/2015	7/10/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).I HAVE GOTTEN ESSURE PUT IN (B)(6) 2012 AN FOR THE FIRST YEAR I HAD NO PROBLEMS BUT BY THE SECOND YEAR I HAVE HAD SEVERE PAIN. I HAVE HAD BAD ABDOMINAL PAIN, BACK PAINS I HAVE GAINED WIEGHT, I GET VERY BAD HEAD ACHES MY HAIR IS THINNING OUT AN I'M ONLY 24 YEARS OLD .THE PAIN I GET IS UNBEARABLE IT'S GETS SO BAD IT HAS ME IN TEARS I CAN'T WAIT TO GET RIDE OF ESSURE CAUSE HAVING IT IS A LIVING HELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043859	BAYER	7/9/2015	7/10/2015

Event Information:

Event Date (B3): 6/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). BLOATED ABDOMEN 24 HOURS A DAY, HEAVY MENSTRUATION, NO LONGER REGULAR, COMES 2 OR 3 TIMES A MONTH WITH A FOUL ODOR, CRAMPING LIKE A CONTRACTION GOING INTO LABOR PAINS, MIGRAINE HEADACHES, SKIN RASHES, PEELING OF SKIN ON HANDS AND FEET, HEART PALPITATIONS, SHORTNESS OF BREATH, ANXIETY ATTACKS, HAIR LOSS, BRAIN FOG, LOSS OF MEMORY, DENTAL ISSUES NEVER HAD ANY BEFORE ESSURE, RESTLESS LEG, NUMBNESS IN HANDS AND FEET, PELVIC PAIN, PAIN DURING AND AFTER INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043860	BAYER	7/9/2015	7/10/2015

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SENSE ESSURE I HAVE BEEN EXTREMELY WEAK, TIRED, SLEEP ISSUES, CONCENTRATION PROBLEMS, MIGRAINS ALL THE TIME. BLOATING SORE BREASTS, SORE MUSCLES AND JOINTS. BACK PAIN, HAIR WON'T GROW MUCH, EVER COUPLE MONTH I FEEL LIKE I'M PREGNANT BECAUSE I GET ALL THE SYMPTOMS LIKE NAUSEOUS AND THROWING UP I GET DIZZY AND SMELLS BOTHER ME A LOT AND MANY FOODS.THIS LASTS FOR 6 WEEKS AT A TIME AND MAKES IT VERY DIFFICULT TO CARE FOR MY 4 KIDS. I'VE BEEN UNHAPPY BECAUSE OF DEALING WITH ALL THIS PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044386	BAYER	7/9/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2013 I HAD THE ESSURE BIRTH CONTROL PLACED TO PREVENT PREGNANCY AND POSSIBLY HELP WITH HEAVY BLEEDING DURING PERIODS. THE PROCEDURE ITSELF WAS QUITE PAINFUL AND I SPOTTED HEAVILY FOR TWO WEEKS AFTER THE PROCEDURE AND THEN MODERATELY TO LIGHTLY FOUR WEEKS AFTER THAT. I ALSO EXPERIENCED CRAMPING, SOME SEVERE, AND FATIGUE DURING THAT PERIOD OF TIME. I DISCUSSED THE SYMPTOMS WITH MY DOCTOR AND SHE ADVISED ME THAT THE SYMPTOMS SHOULD SUBSIDE OVER TIME. DURING MY FIRST PERIOD AFTER THE PLACEMENT I BLED HEAVIER THAN I CAN EVER REMEMBER BLEEDING AND HAD CRAMPS SO SEVER I WOULD CROUCH DOWN UNTIL THEY SUBSIDED. AGAIN I WAS ADVISED BY MY DOCTOR THAT THESE SYMPTOMS SHOULD SUBSIDE AND TO GIVE THE DEVICE MORE TIME. I THEN BEGAN TO EXPERIENCE FAIRLY RAPID WEIGHT GAIN AND MOOD SWINGS WITH HEADACHES. WITH EACH PERIOD FOR THE REMAINDER OF 2014 THE SYMPTOMS INCREASED AND IN (B)(6) MADE AN APPOINTMENT WITH A NEW DOCTOR IN THE STATE THAT WE HAD MOVED TO. AFTER SPEAKING WITH HER IN LENGTH ABOUT THE PROBLEMS WE DECIDED IT BEST TO HAVE A PARTIAL HYSTERECTOMY TO STOP THE ISSUES. IN (B)(6) 2015 I HAD A PARTIAL HYSTERECTOMY AND SINCE HAVE HAD NONE OF THE TERRIBLE SYMPTOMS THAT WERE PREVIOUSLY EXPERIENCED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044387	BAYER	7/9/2015	7/21/2015

Event Information:

Event Date (B3): 2/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT DONE IN 2013 I HAVE BEEN HAVING LOTS OF HEALTH PROBLEMS DUE TO THE IMPLANT SUCH AS BACK PAIN, PELVIC PAIN, VERY BAD HEADACHES, NAUSEA, ABNORMAL PAP. I NEVER HAD ANY OF THESE PROBLEMS BEFORE I HAD THIS DONE. ALL OF MY PAP SMEARS WERE NORMAL I NEVER HAD ANY OF THESE PROBLEMS BEFORE. I WAS TOLD THIS WAS THE BEST THING TO GET DONE INSTEAD OF SURGERY AFTER I HAD MY 3RD CHILD NOW I'M NOT SO SURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044388		7/9/2015	7/21/2015

Event Information:

Event Date (B3): 7/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 904753

Single Use:
Implant Date (E6): 6/8/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE PROCEDURE IN (B)(6) 2011 AFTER HAVING MY SON. I HAD CRAMPING, LOTS OF WEIGHT GAIN, PAINFUL INTERCOURSE, BACK PAIN/SPASMS, PAINFUL MENSTRUAL CYCLE, AND LOST ENERGY SINCE HAVING IT IN. I WOULD ONLY TAKE TYLENOL/IBU PROFEN, HOT BATHS, AND USE A HEATING PAD TO EASE THE PAIN. I TRIED TO IGNORE IT AND A FRIEND THAT ALSO GOT IT DONE 2 WEEKS AFTER ME STARTED HAVING SIMILAR PROBLEMS SO WHEN I CAME UP WITH THE FUNDS TO GO TO DOCTOR IN (B)(6) 2015 HE AGREED TO TAKE IT OUT BUT I HAVE TO PAY HIS FEE FIRST AND WITH A SON HAVING SPECIAL NEEDS THAT IS HARD TO DO AT THIS TIME; PLEASE HELP MYSELF AND OTHERS GET RID OF THE PAIN THIS DEVICE HAS CAUSED AND PREVENT OTHERS FROM HAVING TO GO THROUGH IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044389		7/9/2015	7/21/2015

Event Information:

Event Date (B3): 7/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/30/2013
Explant Date (E7): 2/3/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2013. I IMMEDIATELY HAD BLEEDING AND CRAMPING. I SPOKE TO MY DR AND SHE TRIED PUTTING ME ON 4 DIFFERENT TYPES OF HORMONE PILLS TO HELP THE BLEEDING. NOTHING WORKED ONE ACTUALLY MADE IT TO WHERE I FELT LIKE I COULDN'T BREATHE AND I HAD TO GO TO THE HOSPITAL. I MISSED WORK MANY TIMES BECAUSE IT WAS JUST TOO PAINFUL TO SIT UP OR WALK. MY DR KEPT TELLING ME I WOULD EVENTUALLY STOP CRAMPING AND BLEEDING. I WENT BACK 3 MONTHS TO DO THE PROCEDURE WHERE THEY MAKE SURE THAT THE PLACEMENT WAS DONE CORRECTLY AND IT WAS, BUT THE PAIN AND BLEEDING WOULD JUST NOT STOP. I SOUGHT DIFFERENT OPINIONS FROM 2-3 OTHER DOCTORS AND AFTER AN ULTRASOUND THEY DECIDED THAT I SHOULD GET A HYSTERECTOMY DONE. I WAS ONLY (B)(6) AT THE TIME. I HAD 5 HEALTHY IDS AND NO OTHER MEDICAL ISSUES UP TO THIS POINT. THEY TOLD ME THAT THE HYSTERECTOMY WOULD STOP THE BLEEDING AND THE CRAMPING AND I WOULD BE BACK TO NORMAL. THAT WAS NOT THE TRUTH. I HAD A HYSTERECTOMY IN (B)(6) 2014. I DID STOP BLEEDING BUT CONTINUED TO HAVE THE SHARP, PAIN, ON MY LEFT SIDE. THEN AL IN MY PELVIC AREA. THE PAIN IS SO SEVERE THAT I STILL CONTINUE TO MISS WORK, I WAKE UP AT NIGHT WITH THE PAIN JUST LIKE I DID BEFORE THE SURGERY. I DEAL WITH PAIN THE VERY FIRST MOMENT I WAKE UP UNTIL I GO TO BED AT NIGHT AND SOMETIMES DURING THE NIGHT. I WAS HEALTHY AND LIVING A NORMAL LIFE UNTIL I HAD THE ESSURE PROCEDURE DONE. I AM DEPRESSED, ANGRY, SAD AND IN PAIN NOW DEALING WITH THIS. I NO LONGER LIVE A NORMAL LIFE. IT IS VERY DEPRESSING FOR ME TO BE (B)(6) HAVING HAD A HYSTERECTOMY. I WOULD HIGHLY RECOMMEND THAT NO ONE ELSE GETS THIS PROCEDURE DONE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044397	BAYER HEALTH	7/9/2015	7/21/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ENSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEAVY BLEEDING HEADACHES TASTE IN MOUTH THAT WONT GO AWAY I KEEP UTI AND SEVERE PAIN ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044398	BAYER CORP	7/9/2015	7/21/2015

Event Information:

Event Date (B3): 9/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/27/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN PUT ON THE ESSURE (B)(6) 2014. AND ABOUT 2 MONTH LATER THE PROBLEMS STARTED. SYMPTOMS: SURPRISINGLY PUNCHY PAIN, CRAMPING, SWELLING, BLEEDING. THE BIGGEST PROBLEM IS BLEEDING. BLEEDING WILL START THE NEXT DAY OR IN THE EVENING WHEN THERE IS SEX. THAT'S WHY I'M NOT HAD SEX WITH MY HUSBAND APPROX. 9 MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043861	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 2/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE TO PREVENT FROM HAVING MORE CHILDREN, MY IMPLANT DR. KNEW I HAD A NICKEL ALLERGY AND TOLD ME THERE WAS NO NICKEL IN THE COILS, NOW A YEAR LATER I FIND OUT THAT I HAVE 2 COILS ON MY LEFT SIDE AND THEIR NOT EVEN IN MY TUBE. ONE IS POKING OUT OF MY TUBE AND THE OTHER IS POKING INTO MY OVARY. MY RIGHT SIDE IS MIGRATING INTO MY UTERUS, I NOW SUFFER FROM AUTOIMMUNE DISEASE FROM HASHIMOTO THYROIDITIS, I HAVE TO GET THIS UNDER CONTROL BEFORE I CAN HAVE MY HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043862	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). EXTREME BLOATING. HEAVY BLEEDING THAT LED TO ME BECOMING ANEMIC. SEVERE BACK PAINS DURING PERIODS. DOCTOR OFFERED TO PERFORM ABLATION OR TAKE BIRTH CONTROL PILLS TO HELP REGULATE CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043863	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 4/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STILL HAVING. CRAZY PAINS. RADIATES FROM MY BACK TO MY FRONT. SOME DAYS CAN HARDLY WALK. EXPERIENCING HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043864	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 12/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). EXTREMELY PAINFUL UPON INSERTION IN THE OFFICE. EXCESSIVE HEMORRHAGING, IRREGULAR, PAINFUL CRAMPING PERIODS. BRAIN FOG, EXTENSIVE CHANGING HORMONAL IMBALANCES, CONFUSION, MENTAL, EMOTIONAL AND PHYSICAL. SEVERE AND EXCRUCIATING CRAMPING OF LEGS, CHRONIC PAIN, JOINT SWELLING OF FEET, HANDS, KNEES, ELBOWS. I HAVE SEEN 11 DRS. SINCE THE ESSURE WAS IMPLANTED D/T VARIOUS COMPLICATIONS THAT STARTED FROM DAY ONE AND STILL CONTINUE TO THIS DAY. I TAKE NUMEROUS MEDICATIONS NOW FOR THE SWELLING AND PAIN OF MY JOINTS, WITH NO PARTICULAR SPECIFIC DIAGNOSIS. I HAD A HYSTERECTOMY (B)(6) 2015 TO REMOVE THE ESSURE. THE PAST 18 MONTHS OF MY LIFE HAS BEEN NOTHING BUT PURE (B)(4), AND THAT IS PUTTING IT MILDLY. I WAS A FIGURE COMPETITOR, HEALTH CONSCIOUS INDIVIDUAL WHO WORKED OUT AND TRAINED TWICE A DAY PREPARING FOR FIGURE COMPETITIONS, COMPLETELY HEALTHY UNTIL THAT DAY, (B)(6) 2013 OF THE IMPLANTATION OF ESSURE..

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043865	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 9/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEFT HIP WAS SORE, PAIN WAS ON AND OFF FOR AROUND 1 MONTH. FELT AS THOUGH I HAD SLEPT ON A CONCRETE FLOOR. THEN THE PAIN/SORENESS TURNED TO EVERY DAY SINCE. SHARP ABDOMINAL PAINS ABOUT TWICE A MONTH SINCE INSERTION. MUSCLE FATIGUE BECAME NOTICEABLE ABOUT A MONTH AFTER THE INSERTION. THE AMOUNT OF WEIGHT I WAS LIFTING AT THE GYM DETERIORATED TO 1/2 THE AMOUNT I WAS ABLE TO BEFORE. SLEEPINESS AT ALL TIMES OF THE DAY. I HADN'T BEEN THAT TIRED SINCE PREGNANCY. I COULD FALL ASLEEP STANDING UP I BELIEVE. WEIGHT GAIN OF 16 POUNDS IN 3 MONTHS EVEN THOUGH THERE WAS NO CHANGE IN DIET OR EXERCISE. FIRST PERIOD AFTER INSERTION AND EACH ONE THERE AFTER LASTS 7-8 DAYS AND IS EXTREMELY HEAVY WITH LARGE CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043866	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 12/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN TO THE ABDOMEN. INSOMNIA. WEAK BLADDER. WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043867	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 4/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I STARTED HAVING MIGRAINE HEADACHES AT LEAST 4-6 A MONTH. I KEPT TELLING MY GYNECOLOGIST THAT MY LOWER BACK IS HURTING AND SO WAS MY LOWER STOMACH. I BEGAN TO BLEED. AND TEST AFTER TEST I ULTIMATELY EVEN END UP HAVING A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043868	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 6/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EQUIPMENT MALFUNCTIONED DURING INSERTION. DEVICE HAD TO BE CUT OFF OF THE EJECTOR. LATER HAD TO HAVE COILS REMOVED BY SURGERY AND NOW HAVE HAD 2 PERIOD CYCLES PER MONTH SINCE. THEY ARE ALSO VERY PAINFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043869	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 11/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN LOWER BACK. RASHES AND SWELLING IN HANDS . HAIR LOSS. UNABLE TO LOSE WEIGHT. SHARP PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043870	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD THE ESSURE FOR 6 YEARS AND I'VE EXPERIENCED EXTREME HAIR LOSS, HORRIBLE CRAMPING. EXCESSIVELY LONG PERIODS, FACIAL HAIR GROWTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043871	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 8/15/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS IMPLANTED, I BEGAN GETTING HEAVY AND PAINFUL MENSTRUAL CYCLES, MIGRAINES BEGAN WITHIN A COUPLE MONTHS, MEMORY PROBLEMS, BLOATING, WEIGHT GAIN, SEVERE DEPRESSION AND MOOD SWINGS, WHICH I HAVE TIL THIS PRESENT DAY. I ALSO HAVE CHRONIC BACK PAIN AND NUMBNESS AND TINGLING OF MY EXTREMITIES, WHICH CAUSED ME TO HAVE TWO DISCS IN MY CERVICAL SPINE FUSED, ONLY TO HAVE ALL THE SYMPTOMS COME BACK TWICE AS BAD RECENTLY. ALONG WITH PAINFUL INTERCOURSE, LOSS OF SEXUAL DESIRE, AND MOOD SWINGS SO BAD THAT THEY CAUSE PROBLEMS WITH ALL RELATIONSHIPS. I'VE BEEN FORCED TO SPEND MOST OF MY TIME ALONE, AS THE EASIEST WAY OF PREVENTING LOSING MY TEMPER ON PEOPLE FOR LITTLE THINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043872	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 12/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, BLEED OR SPOT AFTER SEX, LOW DRIVE FOR SEX, FATIGUE, DEPRESSION, ANXIETY, BLOATING, MIGRAINE AND SO MUCH MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043873	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 11/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT WAS EARLY IN THE MORNING AND I WOKEN UP FROM A DEAD SLEEP TO SHARP PAINS IN MY RIGHT SIDE. THAT WAS JUST THE FIRST TIME. THE SECOND HAPPENED TWO MONTHS LATER AND IT WAS THE SAME SHARP PAIN. THE THIRD TIME IT HAPPENED I WAS AT WORK AND HAD TO BE SENT HOME EARLY DUE TO THE FACT THAT I COULD STAND UP STRAIGHT OR WALK. BY THE TIME OF (B)(6) 2014 I HAD TO QUIT WORK DUE TO MANY HEALTH ISSUES THAT MADE WORKING DIFFICULT. RANGING FROM TERRIBLE PAINS TO OUT OF NO WHERE LOSS OF ENERGY. TRYING TO KEEP UP WITH MY THREE KIDS WAS NO ISSUE BEFORE ESSURE BUT ONE MORE BABY AND ESSURE LATER AND I CAN BARELY MAKE IT THROUGH THE DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043874	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE OF (B)(6) 2012 NON STOP PAIN IN MY GIRL AREA AROUND MY TUBES. IT GETS BAD WHERE IT'S HARD TO WORK, PLAY WITH MY KIDS AND HAVE SEX WITH MY HUSBAND. SINCE I GOT THIS I HAVE SEEN A LOT OF DOCTORS AND THE TWO DOCTORS THAT DID MY C SECTION AND THE ONE WHO PUT ESSURE IN ME AS DAMAGE MY INSIDE THAT I'M A HIGH RISK OF HAVING SURGERY IN MY GIRL AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043875	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 3/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I GOT THE ESSURE IN 2013 BECAUSE THE DOCTOR SAID IT WAS THE BEST WAY TO GO. I'VE GAINED OVER THIRTY POUNDS HAVE A LOT OF PELVIC PAIN, IRREGULAR PERIODS THAT LAST MORE THAN 2 WEEKS, SOMETIMES I LOOK LIKE I'M 3 MONTHS PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043876	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 12/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT BLEEDING, CONSTANT HEADACHES, BREAK OUTS, EMOTIONAL, VERY LOW SEX DRIVE, ALWAYS TIRED, NO ENERGY. SEVERE WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043877	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY BACK HURTS ALL THE TIME BY MY PELVIC BONES, THE RISK OF HAVING A HYSTERECTOMY IS GREAT. THIS SHOULD BE TAKEN OFF AND TAKEN OUT OF ALL WOMAN. THIS IS NOT RIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043878	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BACK PAIN, HEADACHE EVERY DAY, MISCARRIAGE IN 2011, DIZZINESS, TIRED ALL THE TIME, IRREGULAR PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043879	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 7/13/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS STARTED 2 WEEKS AFTER THEY WERE PLACED. SHORTNESS OF BREATH, DIZZINESS, HEART PALPITATIONS, FATIGUE AND COULDN'T SLEEP. WEIGHT GAIN (BLOATING SEVERE). BRAIN FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043880	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 1/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INTENSE PELVIC PAIN, SHARP PAINS IN LEFT SIDE AND DOWN LEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043881	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM THE MOMENT IT WAS INSERTED INTO FALLOPIAN TUBES I HAD EXTREME PAIN AND SINCE HAVING REMOVED HAVE HAD EXTREME BLEEDING. HAD TO HAVE AN ABLATION TO STOP BLEEDING AND HAVE LARGE CYSTS GROWING ON OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043882	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 10/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE BACK PAIN EVERY DAY. PAINFUL INTERCOURSE, AND HEAVY IRREGULAR BLEEDING EVERY MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043883	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 11/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PUT IN (B)(6) 2010. OVER THE PAST 5 YEARS I HAVE HAD MORE THAN A FEW SIDE AFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043884	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY EXPERIENCE IS AN EVER GOING ONE - ABNORMAL PERIODS, HOT FLASHES CONSTANTLY, PAINFUL (EXCRUCIATING) PERIODS AND OVULATION, NIGHT SWEATS (I MAY AS WELL BE IN A FREAKING POOL!!), LOSS OF LIBIDO, SHARP SHOOTING PAINS IN MY VAGINA, BLOATING LIKE I AM 5 MONTHS PREGNANT, HEARTBURN, ANEMIA, UNEXPLAINED BRUISING, HEIGHTENED ALLERGIES, VISION PROBLEMS, AND THE HEADACHES. THE PAINFUL OVULATION AND PERIODS ARE ABSOLUTELY TERRIBLE - THERE ARE DAYS I CANNOT EVEN GET OUT OF BED. THE HEADACHES ARE THE WORST THING I HAVE EXPERIENCED IN MY LIFE..... I HAVE HAD CT SCANS, MRIS, EEGS, AND BEEN TO NUMEROUS NEUROLOGISTS AND THERE ARE NEVER ANY ANSWERS. THEY CAN TELL ME WHAT IT IS NOT, BUT NOT WHAT IT IS! ALSO, THE BACTERIAL VAGINOSIS THAT IS CAUSED BY COPPER AND NICKEL (BOTH OF WHICH ARE INCLUDED IN THESE COILS) - I HAVE HAD A TREMENDOUS AMOUNT OF INFECTIONS SINCE BEING IMPLANTED WITH THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043885	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD PELVIC PAIN, ABNORMAL MENSES, BREAST TENDERNESS, HAIR LOSS, IBS, ENLARGED ABDOMEN, ITCHING, BV, FIBROIDS, ABNORMAL PAP SMEARS, SKIN DISORDER, INCONTINENCE AND THE LIST GOES ON. SOMEONE NEEDS TO GET THIS OFF THE MARKET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043886	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 10/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, CYSTS ON MY OVARIES, I HAD TO GET AN ABLATION BECAUSE OF HEAVY PERIODS. PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043887	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 6/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE MIGRAINES, BODY ACHES ALL OVER, HANDS AND FOREARMS GO NUMB AND TINGLE, TEETH CONTINUOUSLY BREAKING OFF..

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043888	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 12/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HAIR LOSS. MORE FREQUENT MIGRAINES SEVERE PAIN BEFORE AND AFTER PERIODS. EXTREMELY HEAVY PERIODS. HEMOGLOBIN LEVELS GOING LOW DUE TO HEAVY PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043899	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 5/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEBILITATING CRAMPING. I NEVER, EVER HAD ANY CRAMPS BEFORE THE ESSURE WAS IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043915	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 5/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, PAIN IN STOMACH, LOSS OF HAIR, HEADACHE, VERY HEAVY MENSTRUAL CYCLE, PAIN IN JOINTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043924	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 8/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, BLOATING, HEADACHES, DIZZY, CONSTANTLY FEELING SICK, SHARP PAINS, KIDNEY INFECTION, FREQUENT UTI'S, OVARIAN CYSTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043950	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 1/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ENDOMETRIOSIS OVARIAN CYST WEIGHT GAIN LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043951	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 8/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE ABDOMEN PAINS THAT HAPPENS DAILY. I'VE HAD TO HAVE AN URINARY ABLATION. I HAVE EXTREMELY EXCESSIVE BLOATING, MOOD SWINGS AND HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043952	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DELIVERED A (B)(6) STILLBORN BABY ON (B)(6) 2015. I HAD THE ESSURE PLACED IN (B)(6) 2013. THEY HAD AN HSG THAT SHOWED THE ESSURE DID NOT PROPERLY FORM THE SCAR TISSUE AND MY TUBE WAS STILL OPEN. I STARTED TAKING DEPOT SHOTS. I HAD NO CLUE I WAS PREGNANT, UNTIL A FEW DAYS BEFORE, WHICH WAS ON A WEEKEND, AND WAS GOING TO CALL THE OB ON MONDAY. SUNDAY EVENING, I STARTED BLEEDING PROFUSELY, WENT TO THE ER, AND DELIVERED A (B)(6) GESTATION BABY WHO WAS STILL BORN. AS OF SUNDAY EVENING SHE WAS VERY ACTIVE. MY OB TOLD ME THAT THE ESSURE WAS DISLODGED AND WAS STICKING OUT ENOUGH IN MY ABDOMINAL SPACE THAT IT RUPTURED MY PLACENTA, WHICH LED TO FETAL DEMISE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043953	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DELIVERED A (B)(6) STILLBORN BABY ON (B)(6) 2015. I HAD THE ESSURE PLACED IN (B)(6) 2013. THE HAD AN HSG THAT SHOWED THE ESSURE DID NOT PROPERLY FORM THE SCAR TISSUE AND MY TUBE WAS STILL OPEN. I STARTED TAKING DEPOT SHOTS. I HAD NO CLUE I WAS PREGNANT, UNTIL A FEW DAYS BEFORE, WHICH WAS ON A WEEKEND, AND WAS GOING TO CALL THE OB ON (B)(6). (B)(6) EVENING, I STARTED BLEEDING PROFUSELY, WENT TO THE ER, AND DELIVERED A (B)(6) WHO WAS STILL BORN. AS OF (B)(6) EVENING SHE WAS VERY ACTIVE. MY OB TOLD ME THAT THE ESSURE WAS DISLODGED AND WAS STICKING OUT ENOUGH IN MY ABDOMINAL SPACE THAT IT RUPTURED MY PLACENTA, WHICH LED TO FETAL DEMISE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043955	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 11/18/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECENTLY IN (B)(6) 2013 HAD THE ESSURE PROCEDURE DONE. I WENT TO MY 3 MONTH CHECK UP TO FIND OUT THAT ONLY ONE SIDE OF MY FALLOPIAN TUBES WERE BLOCKED. I WAS NEVER CONTACTED AFTERWARDS BUT TOLD THAT THE OTHER SIDE WOULD CLOSE WITHIN THE NEXT COUPLE MONTHS. I NOW, 1 1/2 YEARS LATER, AM PREGNANT. NOT ONLY AM I FINDING OUT THIS SHOCKING, BUT AT THE SAME TIME EXCITING NEWS, BUT ALSO FINDING OUT THAT THE ESSURE COIL IS NO LONGER LOCATED IN MY FALLOPIAN TUBE. I HAVE BEEN INFORMED THAT DURING MY ULTRASOUND, TO CHECK AND MAKE SURE I DIDN'T HAVE AN EPTOPIC PREGNANCY, THEY SAW THAT THE DEVICE IS NOW FLOATING IN MY UTERUS, ALONG WITH ME BEING PREGNANT! SO WHAT DOES THAT MEAN?? APPARENTLY, THERE ARE NO REPORTED CASES OF A PREGNANCY WITH THE ESSURE DEVICE IN THE UTERUS. SO HOW I AM SUPPOSED TO MOVE FORWARD? I HAVE BEEN GIVEN NO INFORMATION THAT CAN HELP ME AND MY FAMILY MAKE A SAFE DECISION? ABORTING THE PREGNANCY IS NOT AN ISSUE, BUT AT THE SAME TIME, THERE IS THE UNKNOWN IF I CARRY THE CHILD. MY DOCTORS HAVEN'T BEEN ABLE TO GIVE ME ANSWERS TO ANY QUESTIONS I HAVE HAD. ONE HAD SAID I WILL BE FINE TO CARRY THE CHILD, WHERE REPORTED CASES OF WOMEN GETTING PREGNANT WITH THE IUD HAVE BEEN SUCCESSFUL. OTHERS SAY I RISK THE CASE OF GETTING AN INFECTION, WHERE IF THIS HAPPENS, THE PREGNANCY WILL HAVE TO BE TERMINATED AND COULD POSSIBLY BE FATAL TO ME. I STILL HAVE TWO SMALL CHILDREN AT HOME TO THINK OF AS WELL AS A HUSBAND. IF IM AT RISK OF LOSING MY OWN LIFE- I WOULD LIKE TO KNOW THESE THINGS NOW. THE THOUGHT OF SOMETHING HAPPENING TO MYSELF OR MY UNBORN BABY IS UNBEARABLE. THERE HAS TO BE SOMEONE OUT THERE WITH ANSWERS AND/OR A WAY TO GET THIS PRODUCT OFF THE MARKET.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043958	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 4/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DEVICE WAS IMPLANTED IN (B)(6) 2010, I BEGAN EXPERIENCING VERY HEAVY PERIODS AND REQUIRED A UTERINE ABLATION ON (B)(6) 2011. I CONTINUED TO HAVE INTERMITTENT PELVIC PAIN. IN (B)(6) 2015 I SOUGHT HELP FOR PELVIC PAIN THAT WAS UNRELENTING. A CT SCAN SHOWED A THIRD COIL LOCATED OUTSIDE MY FALLOPIAN TUBES. I HAD A HYSTERECTOMY ON (B)(6) 2015 WHERE BY DISSECTION BY THE PATHOLOGIST SHOWED THE 3RD COIL IN MY UPPER UTERUS, HE ALSO NOTED MULTIPLE FALLOPIAN TUBE CYSTS. THIS FAULTY DEVICE DID NOT DEPLOY CORRECTLY IN 2010 AND MY PHYSICIAN DID NOT RELEASE IT WAS LEFT BEHIND. THIS FAULTY DEVICE HAS CAUSED ME TO NEED BOTH A UTERINE ABLATION AND A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043959	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 2/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN PAIN ALL THE TIME EVEN AFTER IT WAS REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043966	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 2/13/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL PERIODS, HEAVY BLEEDING, PASSING BLOOD CLOTS, HAIR LOSE, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043972	BAYER	7/10/2015	7/10/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BECAME PREGNANT WHILE RELYING ON ESSURE, COMPLICATIONS FROM THE DEVICE LED TO THE DEATH OF THE INFANT GIRL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043954	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 6/9/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD EXTREME PAIN IN MY LOWER ABDOMEN. I HAVE EXTREM HEAVY BLEEDING WITH MY PERIOD. WHEN IM WALKING MY LEFT THIGH GOES NUMB FOR SOME REASON. I HAVE 5-6 MIGRAINS A MONTH AND I HAVE NEVER HAD THIS MANY IN ONE MONTH. I HAVE HAD 3 MISCARRIAGES SINCE I HAD THIS PUT IN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043956	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 2/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE ABDOMINAL CRAMPING SINCE BEING PLACED WITH ESSURE. OFTEN THE PAIN IS SO BAD I AM UNABLE TO WALK AND AM CRIPPLED OVER. SERIOUS BACK PAIN SO BAD THAT QUITE OFTEN I'M UNABLE TO MOVE AROUND OR SLEEP. I HAVE GAINED 80LBS SINCE ESSURE PLACEMENT AND HAVE BEEN UNABLE TO LOSE ANY OF IT AND I KEEP GAINING. DESPITE STRICT DIETING AND DAILY RIGOROUS EXERCISE. I NOW HAVE MODERATE TO SEVERE HEADACHES EVERYDAY. MY PERIODS HAVE BECOME IRREGULAR ACCOMPANIED WITH PARALYZING PAIN. I HAVE ALSO HAD FALSE POSITIVE PREGNANCY TEST RESULTS SINCE ESSURE PLACEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043957	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 7/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2015 I HAD A BILATERAL SALPINGECTOMY BY ROBOTIC PROCEDURE TO REMOVE ESSURE DEVICES. PATHOLOGY REPORT STATED THE RIGHT ESSURE DEVICE WAS IN FALLOPIAN TUBE. LEFT FALLOPIAN TUBE DID NOT CONTAIN THE ESSURE DEVICE. A CT SCAN WAS DONE PRIOR TO SURGERY IN WHICH THE LEFT DEVICE WAS SEEN, BUT IN SURGERY THEY VISUALLY WERE NOT ABLE TO SEE THE DEVICE. THE LEFT ESSURE DEVICE HAS COMPLETELY PERFORATED MY FALLOPIAN TUBE, AND HAS MIGRATED TO AN UNKNOWN AREA. IN 3 MONTHS I WILL HAVE ANOTHER SPECIAL CT SCAN DONE TO POSSIBLY "TAG" LOCATION, ANOTHER ROBOTIC SURGERY TO REMOVE DEVICE AND AT THE SAME TIME A LIVE XRAY TO MAKE SURE ALL PIECES REMOVED. OTHERS SYMPTOMS I'VE HAD FOR THE PAST YEAR ARE CHRONIC PELVIC PAIN, CHRONIC FATIGUE, BRAIN "FOGGINESS", AND FREQUENT ILLNESSES, SUCH AS COLDS, FLU, AND BRONCHITIS. I WAS IMPLANTED WITH THE ESSURE DEVICE (B)(6) 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043960	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 10/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE SAME DAY OF THE IMPLANT I KNEW SOMETHING WAS WRONG. I WAS IN UNBEARABLE PAIN. I CALLED THE DOCTOR THE NEXT DAY AND SHE REQUESTED ME TO TAKE OVER THE COUNTER PAIN MEDICATION. THE DIDN'T CEASE SO I WENT TO ANOTHER DOCTOR TO GET AN X-RAY AND SHE FOUND THAT MY LEFT TUBE HAD BEEN PUNCTURED BY THE ESSURE. THE COIL SPRING IN MY RIGHT HAD MIGRATED SOMEWHERE. IMMEDIATELY AFTER THE NEW DOCTOR PRESCRIBED NORCO FOR MY PAIN AND SCHEDULED ME FOR SURGERY. ME BEING FRIGHTENED I DIDN'T WANT A TOTAL HYSTERECTOMY. SO IN TURN I HAD ONE TUBE REMOVED AND THE DOCTOR SAID TO BE TOTALLY PAIN FREE I WOULD HAVE TO HAVE THE TOTALLY HYSTERECTOMY. I AM A STILL IN PAIN,MOOD SWINGS, SLEEPLESS NIGHT, VERY FORGETFUL AND A LOT OF CONFUSION DAILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043961	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 4/13/2009	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, ECZEMA, FIBROMYALGIA, PERIODS HEAVY W/SHARP PAIN IN LOWER RIGHTSIDE, NEUROLOGIC REFLEXES DETERIORATING, LETHARGIC, IBS SYMPTOMS WORSE,MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043962	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE (B)(6) 2014 I HAVE DEALT WITH CRAMPING SO BAD I GO INTO FETAL POSITION. MY PERIODS ARE SO HEAVY I USE A WHOLE BOX OF TAMPONS (SUPER) FOR ONE CYCLE (MENORRHAGIA). I GET HOT FLASHES ALL THE TIME. MY PANIC/ANXIETY ATTACKS HAVE DOUBLED SO BAD THAT I BEGIN TO SWEAT AND CANT BREATHE, SENT TO THE ER. BODY ACHES OFTEN. EXHAUSTION DUE TO HEAVY PERIOD. PAIN WHILE HAVING INTERCOURSE. BREAST PAIN. FALSE PREGNANCY SYMPTOMS. BLOATING CONSTANTLY. UTI SIDE EFFECTS. SHARP PELVIC PAIN/STABBING, DISCHARGE (ODOR), DYSMENORRHEA, POLYMENORRHEA, SEXUAL DYSFUNCTION (UNABLE TO ORGASM OR FEEL PLEASURE), URGENT/FREQUENT URINATION, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, VULVODYNIA, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, HEARTBURN BOWEL ISSUES NEUROLOGICAL, MENTAL HEALTH HEADACHES OR MIGRAINES, MOOD SWINGS, DEPRESSION (SADNESS/SUICIDAL THOUGHTS), POSSIBLE RAYNAUDANDRSQUO'S SYNDROME (HANDS TURNING BLUE), HEART PALPITATIONS, INSOMNIA, WEIGHT ISSUES (GAIN), MUSCLE SPASMS, BLOOD IN URINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043963	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 3/7/2003	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED (B)(6) 2005, I HAVE A GRADE 1 INSERTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043964	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD THEM PLACED AFTER MY DAUGHTER WAS BORN IN 2010. I GET HEAVY PERIODS AND EXCESSIVE BLOOD CLOTS AND BLEEDING DURING SEX. PELVIC PAIN HEADACHES, REALLY BAD CRAMPS. LOW IRON. I HAVE SEEN TWO DIFFERENT DOCTORS BOTH SAY THE SAME THING. THAT IT'S MY WEIGHT. I CAN'T LOSE WEIGHT. HAVE TRIED EVERYTHING. I GET SO BLOATED LOOKS LIKE I'M STILL PREGNANT. MY FEET SWELL UP. ALL MY BLOOD WORK COMES BACK NORMAL EXCEPT MY IRON. I'M TIRED ALL THE TIME I CAN'T SLEEP AT NIGHT. AND WHEN I DO I DON'T WANT TO GET UP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043965	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 9/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY PERIOD FOR TWO WEEKS, HEAVY BLEEDING AND CRAMPING, BACK PAIN, NAUSEA, FATIGUE, AND I'VE CONTINUE TO BLEED FOR TWO WEEKS AT A TIME SINCE (B)(6) 2014

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043967	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 12/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVEN'T HAVE A PERIOD EVER SINCE, I'M CURRENT TAKING MEDICATION TO GET ME BACK ON MY CYCLE. I HAVE A INFLAMMATION ON MY ABDOMEN. GAIN WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043968	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE STABBING PAIN IN MY ABDOMEN MY PERIODS ARE HELL I CAN'T MOVE WHEN I START IT FEELS LIKE SOMEONE IS STABBING ME I GET BOILS NEVER HAD THEM BEFORE I GOT ESSURE I AM SWOLLEN MY FACE HAS CHANGED SO MUCH SINCE I GOT IT DONE ITS SWOLLEN I WANT IT OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043969	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, HEAVY PERIODS FOR SEVEN DAYS, BAD CRAMPS, HYPERTHYROID, FIBROMYALGIA, BACK PAIN, PAIN IN MY ARMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043970	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 11/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE IN (B)(6) OF 2011 AFTER GIVING BIRTH TO MY SON. THIS MEDICAL DEVICE IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. I DID NOT RECEIVE A CARD WITH A LOT NUMBER OR MODEL NUMBER AT THE TIME OF IMPLANT. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. IMMEDIATELY AFTER HAVING ESSURE INSERTED I BEGAN TO EXPERIENCE SYMPTOMS THAT AT THAT TIME I BLAMED ON POST PART-TUM DEPRESSION. I WOULD LATER COME TO REALIZE THAT THESE EFFECTS WERE NOT GOING TO GO AWAY. SINCE HAVING ESSURE I HAVE EXPERIENCED MASSIVE MOOD SWINGS, UNEXPLAINED WEIGHT GAIN THAT I AM UNABLE TO LOSE, FATIGUE, CRAMPS AND BLOATING, SEVERE DRY SKIN (PSORIASIS) , BRAIN FOG SO SEVERE THAT I HAVE FORGOTTEN WHERE I WAS, WHAT I AM DOING AND ALMOST WHO I AM. DURING MY MENSTRUAL CYCLE I BLEED VERY HEAVY, AND HAVE SEVERE CRAMPS. I HAVE BEEN TO THE DOCTOR AND VISITED THE EMERGENCY ROOM, ONLY TO BE TOLD THAT I AM DEPRESSED. NO AMOUNT OF EXERCISE, EATING RIGHT, OR HEALTH CHOICES I MAKE SEEM TO MAKE A DIFFERENCE IN THE WAY I FEEL. ESSURE IS STILL INSIDE OF ME, BUT I AM SEEING MY PCP (B)(6) 2015 TO TALK ABOUT HAVING A HYSTERECTOMY TO GET THIS DEVICE REMOVED. ESSURE HAS RUINED MY LIFE, AND I AM READY TO GET IT BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043971	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 11/21/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS DEVICE NEEDS TO BE PULLED FROM THE MARKET! TOO MANY WOMEN ARE SUFFERING AND HAVE HAD TO HAVE HYSTERECTOMIES BECAUSE THEY WERE TOLD THIS WAS SAFE AND EASY AND LITTLE TO NO SIDE EFFECTS.. WE WERE TRYING TO BE RESPONSIBLE ADULTS AND NOW WE ARE FORCED TO LOSE OUR LADY PARTS. I JUST WENT TO DOCTOR AND TOLD MY UTERUS IS ENLARGED.I AM DOING FURTHER TESTS TO SEE IF I WILL NEED A HYSTERECTOMY. MY DOCTOR NO LONGER IMPLANTS THESE DEVICES BECAUSE SHE HAS PATIENTS THAT HAD THESE MIGRATED ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043973	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 1/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONE OF THE COILS CAME OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043974	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 6/7/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAINS, SEVERE BLOATING, BLEEDING. HORRIBLE PAIN. CYSTS EVERY MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043975	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 7/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING ESSURE PUT IN PLACE ABOUT 3 MONTHS LATER MY HAIR STARTED FALLING OUT REALLY BAD, I WASN'T SURE WHY? THEN AFTER 6 MONTHS MY PERIODS BECAME SO HEAVY THAT A WOULD BLEED THROUGH A SUPER TAMPON WITH IN 15 MINUTES, HAVE BLOOD CLOTS AND EXTREME CRAMPS THAT FEELS LIKE I'M IN LABOR. ALSO PAINFUL OVULATION AND A FEW TIMES A MONTH I GET SHARP STABBING PAINS THAT COME OUT OF NO WHERE. ALSO HAVE JOINT PAIN IN MY HIPS THAT I NEVER HAD BEFORE, AND BRAIN FOG VERY FORGETFUL. WHEN I HAVE MY MENSTRUAL CYCLE I HAVE EXTREME FATIGUE AND DIARRHEA THE WHOLE TIME DURING AND BEFORE, THINK THAT'S ALL FOR NOW. HAVING IT REMOVED IN A FEW WEEKS MY TUBES AND THE COILS, AND CAN NOT WAIT TO GET IT OUT AND GET MY LIFE BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043976	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD PAIN IN MY LEFT HIP AREA FOR SEVERAL MONTHS. WENT TO HAVE MY HSG AND IT SHOWED THE ENTIRE LEFT TUBE WAS OPEN AND THE COIL HAD MIGRATED. SINCE THE TEST, SEVERE PAIN HAS INCREASED AND WILL BE DISCUSSING REMOVAL TOMORROW

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043977	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 6/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RECENTLY HAD LOWER ABDOMEN PAIN. LOWER BACK PAIN. HARD TO URINATE. NOW FEELING BLOATED. MY ESSURE COILS ARE BOTH IN MY UTERUS AND ARE TANGLED TOGETHER IN ONE BIG KNOT FULL HYSTERECTOMY NEEDED. HAVE TO CUT ME OPEN INSTEAD IF LAPAROSCOPIC DUE TO THE COILS BE ENTANGLED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043978	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 6/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PUT IN AFTER HAVING MY LAST CHILD IN 2011. I'VE BEEN FEELING DIFFERENT EVER SINCE. I WENT TO MY OB/GYN SHORTLY AFTER THE PROCEDURE WAS DONE COMPLAINING OF MAJOR JOINT/BODY/LEG PAIN, I COULD HARDLY GET OUT OF BED IN THE MORNING BECAUSE OF THE PAIN, ALWAYS TIRED, AND I WAS UNABLE TO USE MY HAND DUE TO A VERY PAINFUL CYST THAT POPPED UP ON MY RIGHT INDEX FINGER. HE DID BLOOD WORK AND SINCE MY RA FACTOR WAS HIGH, HE SENT ME TO A RA SPECIALIST ((B)(6), 2011) WHO COULD NOT DIAGNOSE ME WITH RA. THE RA SPECIALIST REFERRED ME TO A SURGEON TO HAVE THE CYST REMOVED FROM MY FINGER. I HAVE ALSO DEVELOPED A CYST IN MY VAGINA (YOU CAN SEE IT HANGING OUT) AND NOW ON MY WRIST. I'M STILL HAVING BODY PAIN THAT INTERFERES WITH DAILY ACTIVITIES!! I'VE ALSO BEEN VERY AWARE OF MY OVARIES SINCE THE PROCEDURE. IF I STRETCH A CERTAIN WAY, COUGH, SNEEZE, OR MOST OF THE TIME OUT OF THE BLUE, I GET SHARP PULLING PAINS ON BOTH SIDES. IT FEELS LIKE MY TUBES ARE ABOUT TO RIP APART! IT TAKES MY BREATH AWAY!!! I DON'T REALLY LIKE SEX ANYMORE BECAUSE WELL IT HURTS AND MY DESIRE IS LOW. I GET A VERY SHARP PAIN IN MY ANUS WHEN HAVING SEX AND SOMETIMES JUST WHILE I'M SITTING AROUND THE SHARP PAIN HITS. HEADACHES AND HOT FLASHES ARE BECOMING MORE COMMON AND MY PERIODS ALMOST DON'T EXIST. JUST ONE HEAVY CRAMP FILLED DAY THEN LIKE 1-2 DAYS OF VERY LIGHT SPOTTING. I GET VERY NAUSEATED (TO THE POINT I RANDOMLY THROW UP) AND BREAST PAIN BEFORE AND DURING MY PERIODS. ALSO, MY VAGINA HAS A HEAVY COIN SMELL AND MY HUSBAND SAYS IT TASTE LIKE A PENNY. MY VAGINA AND MY EYES ARE VERY DRY. I FEEL THE NEED TO URINATE ALL THE TIME. I HAVE BEEN HAVING HEART PALPITATIONS/CHEST PAIN SINCE MY ESSURE WAS PLACED. I HAD EKG AND OTHER TESTS RUN ON MY HEART AND WAS DIAGNOSED WITH ASTHMA. MY FOOD ALLERGY SYMPTOMS HAVE HEIGHTENED AND HAVE DIGESTION ISSUES WHEN I EAT ANYTHING DAIRY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043979	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 12/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I HAD THIS PROCEDURE I'VE EXPERIENCED PAIN, WEIGHT GAIN, INABILITY TO LOSE WEIGHT, HEADACHES, JOINT PAIN, ABDOMINAL PAIN, SWELLING, NIGHT SWEATS AND INCREASED DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043980	BAYER	7/10/2015	7/13/2015

Event Information:

Event Date (B3): 11/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST I GOT A (B)(6) OUT BREAK, THEN IN 2008 I WAS DIAGNOSED WITH FIBROMYALGIA THEN IN 2009 I WAS DIAGNOSED WITH LUPUS. I'VE HAD HIP PAIN, JOINT PAIN, UNEXPLAINED FEVERS, ANEMIA, SEVERE ABDOMINAL PAIN, PAINFUL CRAMPS WHICH I'VE NEVER HAD BEFORE. EXTREME WEIGHT GAIN, PAINFUL SEX, AND CRAZY DISCHARGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044243	BAYER	7/10/2015	7/20/2015

Event Information:

Event Date (B3): 3/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/25/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED FOUR YEARS AGO. I HAVE CONSTANT RIGHT SIDE PELVIC PAIN AS ESSURE IS IN MY MUSCLE. I HAVE HAD ABNORMAL BLEEDING, WEAKNESS AND ABNORMAL VAGINAL DISCHARGE. MY BLOOD PRESSURE IS ELEVATED A LOT DUE TO PAIN. I ALSO HAVE A PERMANENT RASH ON MY BODY. RX MEDS: HYDROCODONE, IBUPROFEN 600MGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044244	CONCEPTUS	7/10/2015	7/20/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVELOPED IBS AND SEVERE BLOATING, AS WELL AS SEVERE MIGRAINES AFTER IMPLANT OF ESSURE. OTC MEDS: NONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044248	BAYER	7/10/2015	7/20/2015

Event Information:

Event Date (B3): 6/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/17/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN THE PAST YEAR AND A HALF I HAVE BEEN EXPERIENCING SERIOUS SIDE EFFECTS FROM THE ESSURE PROCEDURE I HAD DONE FOUR YEARS AGO. EXTREME PELVIC PAIN, LEG DISCOMFORT, BACK PAIN AND EXTREME BLOATING AND WEIGHT GAIN. EVERYDAY IS A DAY ASSOCIATED WITH PAIN AND FEELING UNCOMFORTABLE. I CANNOT HAVE INTERCOURSE WITH MY HUSBAND DUE TO THE PAIN ASSOCIATED WITH THE ESSURE IMPLANT. I GET SEVERE PAIN ON THE RIGHT AND LEFT SIDE OF MY PELVIC AREA AND BLOATING TO THE POINT I HAVE BEEN ASKED THREE TIMES IF I AM PREGNANT. I HAVE NOT CHANGED MY DIET AND MY REGULAR EXERCISE ROUTE. I WENT FROM WEIGHING (B)(6). PLEASE HELP THE WOMEN THAT ARE GOING THROUGH THIS "PROFANITY" WITH ESSURE AND GET IT TAKEN OFF THE MARKET. I PRAY THAT I WILL BE ABLE TO GET THESE COILS REMOVED SOON AS THEY ARE TEARING APART MY HEALTH AND LIFE. I KNOW BEFORE I GOT THE ESSURE PROCEDURE DONE I DID NOT HAVE ANY OF THE LISTED SIDE EFFECTS I AM EXPERIENCING NOW WITH ESSURE IN ME. RX MEDS: LEVOTHYROXINE. OTC MEDS: ALEVE, NAPROXEN, EXTRA STRENGTH TYLENOL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044249	BAYER HEALTHCARE LLC	7/10/2015	7/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/15/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

INTENSE BLEEDING, BLOOD CLOTS, AND SEVERE PAIN IN MY ABDOMINAL REGION. PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044250	BAYER	7/10/2015	7/20/2015

Event Information:

Event Date (B3): 1/29/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/29/2009
Explant Date (E7): 6/29/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IN 2009. AFTER ESSURE I DEVELOPED AN ALLERGY (DERMOGRAPHISM OR URTICARIA FACTITIA). I HAD JOINT PAIN, BACK PAIN, TIREDNESS, EXCESSIVE SWEAT, I COULD BARELY WALK, LACK OF ENERGY, DEPRESSION. I HAD STRUGGLED FOR YEARS WITH DOCTORS. NOW I'M ESSURE FREE AND I'M ALREADY FEELING BETTER. RX MEDS: FEXOFENADINE (ALLEGRA). OTC MEDS: NO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044251	BAYER	7/10/2015	7/20/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/31/2010
Explant Date (E7): 6/24/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN ME IN 2010. ONCE I DID I STARTED TO GET UTI'S EVERY COUPLE OF MONTHS IT SEEMED LIKE, WHICH I WAS NOT GETTING BEFORE. WHEN I STARTED TO HAVE SEX I COULD FEEL THE PRODUCT FROM THE OUTSIDE. SOMETIMES MY TUBES WOULD SWELL UP AND THEY WOULD CAUSE ME SO MUCH PAIN. I ENDED UP HAVING TO HAVE MY TUBES REMOVED BECAUSE THEY WOULD CAUSE SO MUCH PAIN. I WOULD GO TO THE EMERGENCY ROOM AND ASK DOCTORS TO LOOK INTO IT BUT THEY WOULD ALWAYS RESPOND WITH "THERE IS NO WAY THAT YOU CAN FEEL THEM." OR "ESSURE HAS NO BEARINGS ON HOW YOU FEEL."

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044260	BAYER	7/11/2015	7/20/2015

Event Information:

Event Date (B3): 4/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE BIRTH CONTROL IN (B)(6) 2000. SINCE THE PROCEDURE, I HAVE EXPERIENCED SEVERAL ISSUES. I EXPERIENCED PROLONGED BLEEDING DAILY FROM (B)(6) 2011. AFTER THAT, I HAD A D AND C TO CORRECT THE BLEEDING. I WAS VERY FATIGUED AND FRAIL, WHICH AFFECTED (B)(6). ON (B)(6)2014 I DEVELOPED ADDITIONAL ISSUES WHICH RESULTED IN A PARTIAL HYSTERECTOMY. I HAVE ENDURED PELVIC PAIN WHICH HAS AFFECTED MY MARRIAGE INTIMACY WITH MY HUSBAND. WE HAVE NOT BEEN INTIMATE SINCE THE HYSTERECTOMY IN 2014. I AM IN CONSTANT PAIN FROM PELVIC TO LOWER BACK PAIN DAILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044262	BAYER	7/11/2015	7/20/2015

Event Information:

Event Date (B3): 5/5/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/5/2006
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN 2006. IN (B)(6) 2011, I HAD TO HAVE A PRESACRAL NEURECTOMY TO DEAL WITH THE CONSTANT AND DEBILITATING ABDOMINAL PAIN. THIS WAS ONLY DUE TO ESSURE. WHEN THEY WERE PERFORMING MY PRESACRAL NEURECTOMY, THEY VISUALLY INSPECTED MY UTERUS FOR SIGNS OF ENDOMETRIOSIS AND FOUND NONE. THERE WERE NO OTHER ISSUES, NO FIBROIDS, NO LESIONS, JUST DEBILITATING ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044263		7/12/2015	7/20/2015

Event Information:

Event Date (B3): 2/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): 58565
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/21/2011
Explant Date (E7): 10/10/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2011 I INITIALLY WENT TO THE GYN FOR A CONSULTATION FOR HAVING MULTIPLE OVARIAN CYST AND BLEEDING 2-3 WEEKS PER MONTH FOR A YEAR AFTER MY MENSTRUAL CYCLE. I WANTED A HYSTERECTOMY AT THE TIME. I WAS INFORMED OF THE RISK AND COMPLICATIONS ALONG WITH THE SIDE EFFECTS OF GETTING A HYSTERECTOMY. I THEN WAS TOLD ABOUT THE ESSURE DEVICE BY MY GYN DOCTOR AND ENSURED THAT THE ESSURE DEVICE PLACEMENT AND A ENDOMETRIAL ABLATION WOULD HELP SOLVE MY ISSUE I WAS HAVING AND THAT I WOULD FEEL MUCH BETTER AFTER THE PROCEDURE WAS CONDUCTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00502	BAYER HEALTHCARE LLC	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 2/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) ON (B)(6) 2015. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. IT WAS REPORTED THAT PHYSICIAN DID AN ABLATION AT THE SAME TIME DURING ESSURE INSERTION AND EVER SINCE SHE HAD TROUBLES. ACCORDING TO THE CONSUMER, DOCTOR DID THE ABLATION BECAUSE OF HSG TEST. IN (B)(6) 2013, SHE HAD A HYSTERECTOMY. SHE STATED THAT BEFORE THAT, ONE OF THE COILS FELL OUT AND PERFORATED HER UTERUS. THEY WERE NOT ABLE TO FIND THE COIL ON X-RAY AND SO THEY DO NOT KNOW WHERE IT WAS. THIS HAPPENED SOME TIME IN 2012. THE REASON WHY PHYSICIANS KNEW THAT THIS HAD HAPPENED WAS BECAUSE THEY WENT IN TO REMOVE HER FALLOPIAN TUBES. FOLLOW UP INFORMATION RECEIVED ON 19-JUN-2015: ACKNOWLEDGEMENT RECEIVED FROM THE (B)(6) HEALTH AUTHORITY; THE REFERENCE NUMBER PROVIDED WAS (B)(4). FOLLOW-UP RECEIVED ON 24-JUN-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT

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PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE OF THE COILS FELL OUT AND PERFORATED HER UTERUS. SHE WAS SUBMITTED TO A HYSTERECTOMY. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, CONSUMER STATED ONE OF ESSURE COILS PERFORATED HER UTERUS AND WAS NOT FOUND ON X-RAY; ACCORDING TO HER PHYSICIANS DISCOVERED THIS WHEN THEY WERE DOING A SALPINGECTOMY. ADDITIONALLY SHE UNDERWENT A HYSTERECTOMY MONTHS AFTER ESSURE INSERTION. ALTHOUGH THE EXACT MECHANISM OF THE EVENT IS UNKNOWN, CONSIDERING ITS NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 21-JUL-2015: DESPITE SEVERAL ATTEMPTS FOR FOLLOW-UP, NO RESPONSE RECEIVED, CASE CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABAS

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00503	BAYER HEALTHCARE LLC	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2015. IT WAS REPORTED THAT 6 DAYS LATER HER HEALTH BEGAN TO DECLINE. SHE EXPERIENCED THE WORSE HEADACHES AND BACK PAIN. SHE WAS VERY UNCOMFORTABLE. SHE HAD A GREAT DEAL OF PRESSURE IN HER PELVIC AREA. SHE HAS BEEN TO EMERGENCY ROOM 7 TIMES IN A MONTH. HER BP (BLOOD PRESSURE) WAS VERY HIGH. SHE STATED THAT THOSE PROBLEMS DEVELOPED AFTER ESSURE. SHE WAS A NURSING MOM AND THOSE PROBLEMS AFFECTED HER DAILY LIVING. HOSPITALIZATION WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON 18-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE

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AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED GREAT DEAL OF PRESSURE IN MY PELVIC AREA. THIS EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS GIVEN. IT WAS REPORTED THAT CONSUMER HAS BEEN TO EMERGENCY ROOM 7 TIMES IN A MONTH AND CONSUMER REPORTED HOSPITALIZATION AS EVENT OUTCOME. THEREFORE, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 11-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00504	BAYER HEALTHCARE LLC	7/13/2015	7/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014 FOR CONTRACEPTION. IT WAS REPORTED THAT DURING PLACEMENT PROCEDURE, PATIENT EXPERIENCED PELVIC PAIN. ON (B)(6) 2015, HSG WAS DONE AND SHOWED A SEPARATION OR UNRAVELING OF DISTAL OUTER COIL FROM THE DISTAL INNER COIL ON THE LEFT SIDE. IT ALSO APPEARED EXTRINSIC TO FALLOPIAN TUBE. ON RIGHT SIDE, THE DISTAL TUBAL MARKER WAS NOTED IN THE SUB ENDOMETRIAL MYOMETRIUM. HOWEVER, THE FALLOPIAN TUBE WAS OCCLUDED PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY

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TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HSG SHOWED ON THE RIGHT SIDE, THE DISTAL TUBAL MARKER WAS NOTED IN THE SUB ENDOMETRIAL MYOMETRIUM AND ON THE LEFT, THERE WAS A SEPARATION OR UNRAVELING OF DISTAL OUTER COIL FROM THE DISTAL INNER COIL. THE FIRST EVENT, SEEN AS DEVICE EMBEDMENT, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE OTHER EVENT, SEEN AS DEVICE BREAKAGE IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF DEVICE BREAKAGE AND PARTIAL PERFORATION HAVE BEEN REPORTED. IN THIS CASE, THE PATIENT HAD PAIN DURING INSERTION PROCEDURE AND THE CONFIRMATION TEST PERFORMED 10 MONTHS LATER SHOWED A SEPARATION OR UNRAVELING OF DISTAL OUTER COIL FROM THE DISTAL INNER COIL ON THE LEFT SIDE. ON RIGHT SIDE, THE DISTAL TUBAL MARKER WAS NOTED IN THE SUB ENDOMETRIAL MYOMETRIUM. HOWEVER, THE FALLOPIAN TUBE WAS OCCLUDED. GIVEN THE AVAILABLE INFORMATION AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN THE REPORTED EVENTS AND ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 28-JUL-2015 IT WAS REPORTED THAT PATIENT DID NOT EXPERIENCE PAIN DURING THE PROCEDURE, BUT HAD PELVIC PAIN AT A LATER TIME AND THAT WAS THE REASON SHE RETURNED FOR HSG. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043981	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 5/25/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME BACK PAIN, ABDOMINAL PAIN AND PRESSURE, CRAMPING AND BLOATING. ULTRASOUND SHOWED 2 CYSTS GROWING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043993	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 3/30/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEPRESSION WORSEN, FATIGUE, NAUSEOUS, BLOATED TO MAKE ME LOOK 7 MONTHS PREGNANT WEIGHT GAIN, SERVE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043994	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HIVES ALL OVER MY BODY. STOMACH IS BLOATED ALL THE TIME, WITH PAIN ON THE RIGHT SIDE. JOINT INFLAMMATION (KNEES, ARM AND HANDS). MY EYES HAVE BECOME VERY DRY AND PAINFUL. CYST ON MY RIGHT OVARY. NUMBNESS ON MY LEGS WHEN I LAY DOWN OR A PAINFUL TINGLY FEELING. DIAGNOSED WITH SJOGREN'S AND MY ANA TEST CAME BACK POSITIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043995	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 11/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAINS, GALL BLADDER ISSUES RESULTING IN REMOVAL OF GALL BLADDER. SEVERE PELVIC PAIN, CYSTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043996	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 5/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN DOC VISITS ER VISIT PELVIC AND INTENSE CRAMPS NAUSEA AND BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043997	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE MAJOR BLOATING.. PAIN CONSTANTLY... HEADACHE... DIZZINESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043998	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 11/28/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGY TO NICKEL AND OTHER METALS. HIVES RANDOMLY AND FEVERS RANDOMLY. A DOMINANT PAIN. PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5043999	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 5/22/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, BLOATING, NAUSEA, STM PAIN,HOT FLASHES, DIARRHEA, GAS, DEPRESSION, STRESS,ANXIETY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044000	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 11/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAINS, GALL BLADDER ISSUES RESULTING IN REMOVAL OF GALL BLADDER. SEVERE PELVIC PAIN, CYSTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044001	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVER CRAMPS, EXTREMELY HEAVY 3 DAY CYCLES, LOWER BACK PAIN THAT RADIATES DOWN MY LEG, BROKEN SLEEP DUE TO SEVERE PAIN. I'VE HAD IT GOING ON 4YRS IN (B)(6) 2015. BAD HEADACHE , SEVERE ABDOMINAL PAIN, LARGE CLOTS THAT FALL OUT, FEELS LIKE I'M URINATING ON MYSELF WHEN A FLOW COMES. USES A WHOLE (B)(4) OF OVERNIGHT PADS WITH WINGS. CYCLES SO BAD, I'M SCARED TO LAUGH OR COUGH HARD, TO AVOID MAKE A MESS. HORRIBLE, HORRIBLE, HORRIBLE. I JUST WANT MY TUBED REMOVED OR THE CYCLE TO STOP FOREVER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044002	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 7/26/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MISPLACED COILS. PERFORATED ORGAN. TOTAL HYSTERECTOMY AT (B)(6). HORMONAL UNBALANCE. MIGRAINES. PELVIC PAIN. ABORTION. EXTREME FATIGUE. DIZZINESS. SKIN RASH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044003	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 7/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN MY TUBE AREA, SHARPER PAIN DURING MY PERIOD, WEAKNESS AND TIREDNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044004	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 1/6/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, LARGE CLOTTING, EXCESSIVE BACK AND HIP PAIN, PELVIC PAIN ESPECIALLY DURING CYCLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044005	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 11/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKEL ALLERGY, SEVERE JOINT PAIN AND SWELLING, BRAIN FOG, WEIGHT GAIN THAT I CAN NOT LOOSE, VITAMIN D LEVEL HIGH STARTED 50,000 UNITS WEEKLY, SED RATE HIGH SEE RHEUMO DR NEXT MONTH TO SEE WHAT'S NEXT! EACH DAY IT TAKES ME AT LEAST UNTIL LUNCH TIME TO GET OUT OF THE BED FLY FUNCTIONING. I HAVE LOST MY LIFE WITH MY KIDS I CAN'T DO ANYTHING WITH THEM BC I KNOW THE RESULT BLOOD CLOT RECENTLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044006	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, NO ENERGY, HEAVY PERIODS, IRREGULAR PERIODS, POLYCISTIC OVARIAN SYNDROME

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044007	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 2/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PERIOD HAS BEEN CRAZY SINCE GETTING ESSURE , TO THE POINT I EVEN ATTEMPTED AN ABLATION, WOKE UP HALF WAY THOUGH IN PAIN, DOCTOR COULD NOT CONT. BECAUSE OF TOO MUCH SCAR TISSUE IN MY UTERUS, ALSO I HAVE WHAT PEOPLE CALL AN E-BELLY, BLOATED 16 TO 20 HOURS A DAY, I WANT THIS ESSURE OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044008	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 10/1/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY BAD A CRAMPS WORSE THEN LABOR PAINS, NO MORE SEX DRIVE, TINGLING IN LEGS HAND FEET, PAIN DURING SEX, EYE SIGHT, HEARING LOSS, DEPRESSION, ANXIETY, TIRED, CAN'T FOCUS, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044010	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE IMPLANTED IN 2009 I HAVE SUFFERED WITH HEAVY CLOT FILLED PAINFUL PERIODS THAT SMELLED OF METAL, I HAD MY GALLBLADDER REMOVED, AND CURRENTLY SUFFER FROM WHAT MY DR. BELIEVES IS ENDOMETRIOSIS. DURING MY CYCLE THE PAIN FROM SAID ENDOMETRIOSIS TRAVELS DOWN MY LEG AND CAUSE MY LEG TO GIVE OUT. ASIDE FROM THIS, I HAVE MOOD SWINGS LIKE I'VE NEVER HAD BEFORE AND ABDOMINAL PAIN AND BLOATING. ALSO, THE SAID ENDOMETRIOSIS BOTHERS ME WAY BEFORE MY CYCLE AND LONG AFTER, ALMOST UNTIL MY NEXT. THIS LIMITS MY ABILITY TO PLAY WITH MY CHILDREN B/C IT IS EXTREMELY TENDER TO THE TOUCH, LIMITS MY INTIMACY AND EXERCISING ABILITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044011	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN STARTED. I HAVE HAD A LOT JOINT PAIN IN VARIOUS PARTS OF MY BODY, BACK PAIN, AND LOWER STOMACH PAIN. I HAVE BEEN TESTED FOR FIBROMYALGIA, LUPUS, LYMES, I'VE DONE PHYSICAL THERAPY AND BEEN ON ALL DIFFERENT KINDS OF PAIN MEDS AND MUSCLE RELAXERS TO NOW BE GETTING AN ULTRASOUND TO SEE IF IT'S MY ESSURE AS ALL MY OTHER TESTS COME BACK NORMAL!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044012	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/10/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING SEVERE BACK PAIN AND SEVERE STOMACH PAIN ON RIGHT SIDE, HEAD ACHS, STABBING PAIN IN STOMACH, SEVERE MENSTRAL BLEEDING,HAIR LOSS, HAD TO GO TO ER FOR THIS AND ALL TEST CAME BACK NORMAL, TOLD NEED TO CHECK INTO ESSURE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044013	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SOON AFTER THE DEVICE WAS IMPLANTED, I HAVE HAD CHRONIC PAIN IN MY ABDOMEN, BLOATING, HEAVY BLEEDING OUTSIDE OF MY MENSTRUAL CYCLE, HEADACHES, RASHES, PAIN DURING AND AFTER SEX, BLEEDING AFTER SEX. THESE SYMPTOMS STARTED WHEN IT WAS IMPLANTED AND HAVEN'T STOPPED SINCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044014	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE DEVICES PLACED IN 2012 FOR PERMANENT CONTRACEPTION. IN THE 3 YEARS SINCE, I HAVE PROGRESSIVELY BEEN EXPERIENCING ADVERSE SIDE EFFECTS. SIGNIFICANT WEIGHT GAIN (40LBS IN APPROXIMATELY 11 MONTHS), PELVIC/OVARIAN PAIN, SEVERE BLOATING, HEADACHES, MIGRAINES, OVULATION PAIN, WIDESPREAD JOINT PAIN, DIFFICULTY CONCENTRATING, EXTREME FATIGUE, MALAISE, CHRONIC INFLAMMATION, RESTLESS LEG SYNDROME, RECURRENT UTI, PROBLEMS WITH TEETH/GUMS, HAIR LOSS, VITAMIN D DEFICIENCY, IRON DEFICIENCY ANEMIA, AND SKIN RASHES. IN THE LAST YEAR, THE SYMPTOMS HAVE WORSENED CONSIDERABLY. I HAVE DAILY PELVIC PAIN, AND THE JOINT PAIN IN MY HANDS, WRISTS AND KNEES IS BECOMING DEBILITATING. I AM CONCERNED THAT THE DEVICES MAY BE CAUSING LONG TERM DAMAGE, AND I AM MEETING WITH MY DOCTOR TO DISCUSS HAVING A TOTAL HYSTERECTOMY AT THE AGE OF 37 TO ENSURE THE DEVICES ARE COMPLETELY REMOVED WITHOUT BREAKAGE. DUE TO THE INCREASE IN PELVIC PAIN, I AM CONCERNED THAT THE DEVICES MAY HAVE MIGRATED OR BROKEN, AND I WILL BE HAVING TESTS TO DETERMINE PRESENT COIL LOCATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044015	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, NUMBNESS IN MY THIGHS, MIGRAINES, NUMBNESS IN MY FEET, CONSTANT DISCHARGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044016	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 7/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, FATIGUE, IRRETABLE, BLOATING, FEELING FULL ALL THE TIME, LOSS OF APPETITE, PELVIC PAIN, IRREGULAR BLEEDING, ENDOMETRIOSIS, ENDOMIOSIS, HYSTERECTOMY, HAD TO BE PUT ON LUPTON FOR ENDOMETRIOSIS, NO SEX DRIVE, PAINFUL TO HAVE SEX, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044017	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 9/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AUTOIMMUNE DISEASES, EXTREME FATIGUE, DAILY MIGRAINES, FEET HAND SWELLING, PSORIASIS, HIVES, EXTREMELY PAINFUL BLOATING, BOWEL PROBLEMS, PAINFUL SEX, RANDOM PELVIC PAIN, MUSCLE PAIN, JOINT STIFFNESS, DENTAL ISSUES, HEAVY DISCHARGE, FOUL ODOR, ABNORMAL PERIODS, BLURRED VISION, DIZZY SPELLS, INSOMNIA, SHOULDER AND ARM PAIN, KIDNEY PAIN, BACK AND NECK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044018	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 1/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED IN (B)(6) 2014 AFTER HAVING MY LAST CHILD. I WAS PUT COMPLETELY UNDER IN AN O.R. I WAS TOLD IT WAS JUST AS EFFECTIVE AS A TUBAL. I WAS NOT TOLD THAT THERE COULD BE ANY SIDE EFFECTS. I WAS ALSO NOT TESTED FOR A NICKEL ALLERGY. I BECAME PREGNANT (B)(6) 2015 WHILE STILL HAVING ESSURE IN PLACE. I HAVE SINCE DEALT WITH VERY BAD DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044019	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 4/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WASN'T FEELING GOOD FOR A COUPLE WEEKS AND ONE DAY I WAS SITTING DOWN AND WHEN I WENT TO STAND UP ALL OF A SUDDEN A GOT SHARP PAINS IN MY PELVIC AREA. I COULDN'T MOVE FOR A COUPLE DAYS. I HAVE BEEN HURTING SINCE THEN I WENT BACK TO THE DOCTOR WHO PLACED THE ESSURE IN ME AND HE TOLD ME IT HAD NOTHING TO DO WITH ESSURE BUT COULD NOT TELL ME WHAT WAS WRONG. I HAVE SINCE THEN SEEN LIKE 3 DOCTORS AND BEEN TO THE EMERGENCY ROOM A NUMBER OF TIMES BECAUSE THE PAIN GETS SO UNBEARABLE THAT I CAN'T EVEN MOVE. I WANT TO CRY ALL THE TIME. I HAVE 2 CHILDREN AND I CAN'T DO THINGS WITH THEM LIKE I SHOULD BECAUSE I AM ALWAYS HURTING! I HAVE ALSO HAD BREAKOUTS DOWN IN THE LOWER REGION SINCE AND THE DOCTORS DON'T KNOW WHAT THEY ARE FROM AS WELL AS GETTING SEVERE MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044020	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 3/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). REALLY BAD HEADACHES, NERVE PROBLEMS, IT'S CAUSING ME TO GAIN WEIGHT, CHEST PAINS ALOT COMES AND GOES BECAUSE OF THE ESSURE DIZZINESS "TRIED" ALL THE TIME BECAUSE OF THIS TOO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044021	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2008, I MADE THE DECISION TO GET ESSURE. I WAS (B)(6) WITH 3 KIDS I THOUGHT IT WAS RIGHT FOR ME. THE FIRST FEW WEEKS WERE FINE. NOTHING OUT OF THE ORDINARY. I WANT TO SAY ABOUT 26 DAYS AFTER I LOST A HUGE BALL OF RUBBERY STUFF AS DISCHARGE. I CALLED MY DR IMMEDIATELY AND HE SAID IT WASN'T THE ESSURE BECAUSE IT WAS NICKEL COULD NOT BE RUBBER! BUT DIDN'T SEEM TO CARE THAT SOMETHING CAME OUT OF ME. A WEEK AFTER THAT I STARTED GETTING SEVERE LOWER ABDOMINAL PAIN WHERE I'D BE IN THE DEREK POSITION FOR ABOUT AN HOUR. MY STOMACH WOULD BLOAT SO BAD I LOOKED PREGNANT BUT AFTER A FEW HOURS IT GOES DOWN! I EVENTUALLY WENT TO THE E.R. BECAUSE THE PAIN WAS SO BAD AND THEY SAID I WAS VERY INFLAMED AND IF THEY KNEW WHAT ESSURE WAS THEY'D BE ABLE TO TELL ME IF THAT WAS THE CAUSE BUT SINCE THEY DIDN'T THEY LEFT IT AT A 50 50. THEY ALSO TOLD ME I COULD BE ALLERGIC TO THE ITEMS IN MY BODY AND TO SEE MY GYNO. MY INSURANCE WAS CANCELLED AND OF COURSE THEY WOULDN'T SEE ME. FAST FORWARD 7 YEARS LATER ,STILL HORRIBLE CRAMPS BUT NOW I HAVE VAGINAL PRESSURE HORRIBLE AND IRREGULAR PERIODS TO THE POINT I MISS WORK. I'VE GAINED 15 LBS THAT I CAN'T GET RID OF. I HAVE DEPRESSION AND NO ENERGY AND I'M (B)(6). I JUST WANT MY OLD LIFE BEFORE ESSURE BACK! THESE SHOULD NOT BE LEGAL AND THEY NEED TO BE STOPPED!! NO ONE SHOULD HAVE TO GO THROUGH THE PAIN I EXPERIENCE AND A DAILY BASIS! SEX HURTS BEING OUTSIDE IS MISERABLE! SOMEONE PLEASE HELP US!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044022	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 4/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD CRAMPS LIKE I'M HAVING CONTRACTIONS, FATIGUE, MY ANXIETY HAS WORSEN, DEPRESSION SHAPE PAIN IN MY RIGHT SIDE, NAUSEA, MIGRAINES, PAINS IN MY LEGS, DIARRHEA, BLOATING,GAS, CONSTANT COMPLAINTS TO DR ABOUT MY STOMACH AND SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044023	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 1/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLEEDING AND BASEBALL SIZE CLOTS, MIGRAINES, BLOATING, UTERUS DAMAGE ENDED UP WITH HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044024	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 9/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE GAINED TOO MUCH WEIGHT LIKE 20PDS I'M ALWAYS BLOATED CONSTIPATED SINCE THEN I HAVE PAIN IN MY PELVIC AREA THAT COMES AND GOES , I GET MIGRAINES REAL OFTEN, I GET LOWER BACK PAINS OFTEN, MY PERIODS CHANGE EVERY MONTH WITH A LOT OF CRAMPS SOMETHING I NEVER HAD BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044025	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DAILY HEADACHES/MIGRAINES, NICKEL ALLERGY, CYSTS, PAIN, IRREGULAR PERIODS, HEAVY CYCLES WITH HEAVY CLOTS, LEFT SIDE PAIN, LOW BACK PAIN, NO SEX DRIVE, INABILITY TO ORGASM, BRAIN FOG, MEMORY LOSS, IRRITABILITY, METALLIC TASTE IN MOUTH, DENTAL ISSUES TO THE POINT OF HAVING A FULL SET OF DENTURES WITHIN ONE YEAR OF PLACEMENT, HOT FLASHES, DIZZINESS, NAUSEA, VOMITING, MOOD SWINGS, RINGING IN EARS, HIVES/SKIN RASHES, BLURRED/UNFOCUSED VISION, ANXIETY/PANIC ATTACKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044026	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 10/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DAILY MIGRAINES, HAIR LOSS, DEPRESSION, BLOATING, PAIN, CRAMPING, HEAVY PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044027	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/17/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE A LOT OF PAIN RIGHT WHERE THE ESSURE IS AT A LOT OF BLOATING RIGHT AFTER I GOT THE ESSURE I BROKE OUT IN HIVES AND RASH I ALWAYS FEEL WEAK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044028	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 3/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE STARTED TO EXPERIENCE SEVERE WEIGHT GAIN, MEMORY LOSS, DENTAL PROBLEMS, ITCHING, MIGRAINE HEADACHES THAT WILL LAST FOR DAYS, HEAVY PERIODS, DEPRESSION, SUICIDAL THOUGHTS, PAIN IN JOINTS, FALLING ASLEEP JUST LIKE THAT, SHARP PAINS IN CHEST AND ABDOMINAL PAIN, METALLIC TASTE IN MY MOUTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044029	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 4/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, HEAVY BLEEDING, WAS DIAGNOSED WITH ADENOMYOSIS IN (B)(6) OF 2014. PUFFY ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044030	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 5/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD STOMACH ISSUES FOR ABOUT SIX YEARS NOW. I NEVER THOUGHT IT WOULD BE THIS. I WENT TO ER BECAUSE I HAD SEVERE PAIN ON LEFT SIDE LIKE A KNIFE OR SOMETHING. I TOLD DOCTOR AND HE SAID NOTHING SHOWED UP ON XRAY AND I WAS RELEASED. MY SIDE CONSTANTLY IS IN PAIN. INFLAMMATION OF BELLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044031	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). PAIN ON RIGHT SIDE OF ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044032	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 5/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD STOMACH ISSUES FOR ABOUT SIX YEARS NOW. I NEVER THOUGHT IT WOULD BE THIS. I WENT TO E.R. BECAUSE I HAD SEVERE PAIN ON LEFT SIDE LIKE A KNIFE OR SOMETHING. I TOLD DOCTOR AND HE SAID NOTHING SHOWED UP ON XRAY AND I WAS RELEASED. MY SIDE CONSTANTLY IS IN PAIN. INFLAMMATION OF BELLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044033	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCRUCIATING PELVIC PAIN, MIGRAINES, NAUSEA, HAIR LOST EXCESSIVE BLEEDING IN BETWEEN PERIODS AND NOW BLEEDING THAT WON'T STOP. PAINFUL SEXUAL INTERCOURSE, FATIGUE AND ALSO JOINT PAIN. EVERYDAY I HAVE CHILLS AND I KNOW I FEEL SICK AFTER I HAVE THIS DEVICE INSERTED IN MY BODY .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044034	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/13/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVING BAD PERIODS, LOWER BACK PAIN, HIP BONE JOINTS ACHE AND NUMBNESS DOWN LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044035	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 4/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING EVERYDAY, PAIN IN ABDOMEN ESPECIALLY WHEN SNEEZING. HEART PALPATIONS. HEADACHES, NO SEX DRIVE BLEEDING CONTINUOUSLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044036	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, FATIGUE, SHARP HIP PAINS, BACK PAINS/SPASMS, HEADACHES, MISSED PERIODS FOR 3 MONTHS OR MORE AT A TIME, CONSTIPATION, WEIGHT GAIN, HAIR LOSS, EYE SIGHT HAS GOTTEN WORST, LOST LIBEIDO, TIRED 24/7, MOODY, ACNE, LOW IRON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044037	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE. MIGRAINES. PELVIC PAIN. BOWELS ARE HARD TO HAVE AND HURT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044038	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAIN,ABDOMINAL PAIN, BLOATING, SEVERE GAS, WEIGHT GAIN, VISION PROBLEMS, MUSCLE CRAMPING, FATIGUE, HIP PAIN, BOWEL PROBLEMS, BLOOD IN URINE, HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044039	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 8/15/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, JOINT PAIN, NO ENERGY, MOODY NESS, HAIR LOSS, WEIGHT GAIN, DEPRESSION, SKIN RASH, PERIODS SO BAD I HAVE MISSED WORK AND LOST JOBS BECAUSE OF THEM BEING SO BAD I HAVE TO STAY AT HOME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044040	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAVE HAD ESSURE IMPLANTED, I HAVE HORRIBLE JOINT PAIN, IT GETS WORSE AS TIME GOS BY. MY HIPS ARE SO SORE I CAN HARDLY MOVE SOMETIMES. ALSO UNCONTROLLABLE BLOATING MAINLY IN MY STOMACH AREA, I LOOK 8 MONTHS PREGNANT ALL THE TIME, THIS HAPPENED WITHIN 3 MONTHS AFTER GETTING THEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044041	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 3/19/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4) I WAS IMPLANTED IN (B)(6) 2008, BARELY SIX WEEKS AFTER MY SON WAS BORN, I WAS CONVINCED THIS WAS THE BEST OPTION AND NEVER TESTED FOR A NICKEL ALLERGY. FROM DAY ONE I EXPERIENCED DYSFUNCTIONAL BLEEDING, NO SEX DRIVE, PAIN IN MY JOINTS, HAIR LOSS, SEVERE PELVIC PAIN, BLEEDING DURING/AFTER SEX, PAINFUL SEX, I HAD MY HSG IN (B)(6) 2011 AND WAS TOLD EVERYTHING WAS OKAY, I HAD MY GALLBLADDER REMOVED IN (B)(6) 2011, NUMEROUS ER VISITS, OVARIAN CYSTS, HYSTERECTOMY IN (B)(6) 2014, DIAGNOSED AFTER SURGERY WITH CHRONIC CERVICITIS, MY RIGHT COIL MIGRATED AND PUNCTURED MY FALLOPIAN TUBE, THEY ALSO REMOVED AN OVARIAN CYST DURING MY HYSTERECTOMY, I STILL SUFFER FROM CHRONIC PAIN EVERYDAY. I AM IN THE PROCESS OF FINDING OUT WHY I SUFFER FROM SO MUCH PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044042	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 11/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, CLOTTING, MIGRAINE, ARTHRITIS, ACNE, BLOATING, STABBING ABDOMINAL PAINS, LOSS OF LIBIDO, HYPERTHYROIDISM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044043	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 5/13/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, DEPRESSION, HEAVY BLEEDING WITH IRREGULAR CYCLES, BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044044	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 7/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, EXCRUCIATING PAIN IN ABDOMEN, UNEXPLAINED VAGINAL BLEEDING FOR 3-4 WEEKS AT A TIME, PAINFUL INTERCOURSE, EXTREME WEIGHT LOSS, HAIR LOSS, TEETH DECAYING AND FALLING OUT, URINARY TRACT INFECTIONS, UNEXPLAINED RASH ON ARMS AND STOMACH, ABDOMEN SWELLING. BED RIDDEN FOR OVER A MONTH DUE TO EXTREME WEAKNESS, HEAVY BLEEDING AND EXCRUCIATING PAIN. MY HUSBAND HAS TO HELP ME JUST TO GO TO THE BATHROOM. IN THE LAST MONTH EVERYTHING HAS GOTTEN A LOT WORSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044045	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 4/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT'S BEEN AN ONGOING ILLNESS, NOT A ONE TIME EVENT. AND IT'S STEADILY GETTING WORSE. I HAVE TERRIBLY LONG AND PAINFUL PERIODS. SOMETIMES I BLEED FOR UP TO 10 DAYS STRAIGHT, WITH BLEEDING IN BETWEEN PERIODS. HORRIBLE CRAMPING DURING PERIODS AND SHARP STABBING PAINS THAT COME AND GO AT RANDOM TIMES. I ALSO SEEM TO HAVE CHRONIC VAGINAL INFECTIONS, DISCHARGE THAT SMELLS METALLIC, AND PAIN AFTER SEX OR ORGASM. MY HAIR HAS BEEN THINNING EVER SINCE THE DEVICE WAS INSERTED. I'VE LOST SO MUCH OVER THE YEARS, YOU CAN EASILY SEE MY SCALP ON TOP OF MY HEAD. CHRONIC FATIGUE. FREQUENT HEADACHES. GUM AND TEETH PROBLEMS, DESPITE GOOD ORAL HYGIENE. EYESIGHT HAS DIMINISHED AND I NOW REQUIRE READING GLASSES. CHRONIC PELVIC PAIN WITH OR WITHOUT BLEEDING. I FEEL LIKE I'M DYING A VERY SLOW DEATH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044046	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 3/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN, NEAR FAINTING AND NAUSEA DURING AND DIRECT AFTER PLACEMENT OF THE ESSURE DEVICE. SINCE PLACEMENT UP UNTIL NOW: MENORRHAGIA, IRREGULAR MENSTRUAL BLEEDING WITH CLOTS, PROLONGED MENSTRUAL BLEEDING (UP UNTIL 3 MONTHS CONTINUOUS NON-STOP HEAVY BLEEDING). ALLERGIC REACTIONS, INFECTIONS THROUGHOUT BODY (VAGINA, THROAT, MOUTH, SKIN). ABDOMINAL PAIN, PAIN DURING SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044047	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 8/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHORTLY AFTER HAVING ESSURE IMPLANTED, I BEGAN EXPERIENCING EXTREMELY PAINFUL MENSTRUAL PERIODS. THERE WAS EXTREME PAIN IN MY PELVIC AREA, RADIATING DOWN TO MY KNEES. THE PAIN WOULD BE SO BAD THAT I WOULD BE UNABLE TO GET OUT OF BED FOR THE FIRST TWO DAYS OF MY PERIOD. THIS PAIN STILL OCCURS WITH EVERY PERIOD. I HAVE ALSO DEVELOPED CHRONIC JOINT AND MUSCLE PAIN THAT IS CONTINUOUS. OTHER THINGS THAT HAVE OCCURRED SINCE HAVING ESSURE THAT WERE NOT PRESENT PRIOR TO ESSURE ARE: LOSS OF HAIR, WEIGHT GAIN (OVER 50LBS), BLOATING, TINNITUS, HEADACHES, CHRONIC NECK AND BACK PAIN, CHRONIC PELVIC PAIN, DEPRESSION, MENTAL FOG, AND ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044048	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE HAVING THE ESSURE INSERTED I HAVE HAD NOTHING BUT PROBLEMS, INCLUDING STOMACH PAINS, NIGHT SWEATS, BAD MIGRAINES, UNEXPLAINED FEVERS OFTEN AND THE WORST ONE I'VE HAD IS ALL MY HAIR IS FALLING OUT. I'VE HAD BLOOD WORK DONE FOR MY HORMONES AND SUCH BUT EVERYONE TELLS ME THAT THEY ALL COME BACK NORMAL BUT I KNOW MY BODY AND I KNOW THAT I AM SUFFERING FROM THIS DEVICE AND I'M TRYING TO HAVE IT REMOVED ASAP!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044049	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWOLLEN BLOATED STOMACH, CAN'T SLEEP ON MY BACK, LACK OF SEX, MIGRAINES, BACKACHE, TOO MUCH FLOOD FROM PERIODS, ALLERGIES, HEMORRHOIDS, CONSTIPATION, AND LOST OF HAIR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044050	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS IS AN UPDATE TO MY PREVIOUS REPORTS. I HAD BEEN LOSING P E T FIBERS WITH MY MENSTRUAL AND WAS STILL SUFFERING FROM PAIN, AND TWO HEAVY MENSTRUAL A MONTH. I JUST HAD A HYSTERECTOMY USING DA VINCI TO REMOVE MY UTERUS, TUBES AND CERVIX ON (B)(6) 2015 TO REMOVE FRAGMENTS. NO PIECES WERE FOUND SO WE DO NOT KNOW IF I HAD PREVIOUSLY LOST THEM ALL WITH MY MENSTRUAL OR IF THEY HAVE LEFT THE ABDOMINAL WALL. I STILL SUFFER FROM THE HEADACHES AND JOINT PAIN AMONGST OTHER THINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044051	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 2/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT INSERTION THERE WERE COMPLICATIONS, NO MENSTRUAL CYCLE FOR 9 MONTHS, OVARIES BECAME CYSTIC, SEVERE ABDOMINAL PAIN, SEVERLY PAINFUL PERIODS, 50 LBS WEIGHT GAIN IN 9 MONTHS, SEVERE BACK PAIN, SEVERE PELVIC PAIN, ALL THIS ON GOING FOR YEARS, HAD SURGERY TO REMOVE COILS AND DISCOVERED THEY HAD MIGRATED AND PERFORATED THROUGH MY TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044052	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 12/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2014 TWISTED TUBE - EMERGENCY SURGERY TO RETAIN DYING OVARY. CHRONICS STABBING PAIN IN ABDOMEN, HARD TO EVEN WALK AT TIME. LIMITED DAILY FUNCTIONS. PLANNED SURGERY TO REMOVE TUBES AND COILS (B)(6) 2015. ONE COIL WAS REMOVED IN THE RIGHT TUBE - IT WAS 7" LONG, NOT THE 1 INCH IT WENT IN AS. THE PATHOLOGY DID NOT FIND THE 2ND TUBE. DYE PROCEDURE TO LOCATE MISSING TUBE AFTER PAIN HAD BECOME EVEN WORSE REQUIRING NARCOTICS TO GET THRU THE DAY. RADIOLOGY SHOWED IT IN THE UTERUS. WE THOUGHT SURGERY TO REMOVE FROM UTERUS WOULD BE SUFFICIENT UNTIL FINAL RADIOLOGY REPORT CITED ADDITIONAL FRAGMENTS FROM THE OTHER COIL EMBEDDED IN TISSUE. HYSTERECTOMY LEAVING OVARIES (B)(6). PAIN PRIOR WAS DEBILITATING- BEYOND ANYTHING I'VE DEALT WITH, NO OPTION IF I WANTED A LIFE OUTSIDE MY PAIN. HAD A FEW VISITS TO ER FOR PAIN MANAGEMENT, COULD NOT COPE WITH LEVEL OF PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044053	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 7/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2014. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. CRAMPING, SHARP/STABBING PELVIC AND OVARIAN PAIN, ABNORMAL MENSES, OVARIAN CYSTS, CHRONIC BACTERIAL VAGINOSIS, EXCESSIVE DISCHARGE, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION, LOSS OF LIBIDO, PAINFUL PERIODS, PAINFUL INTERCOURSE (DURING ANDAMP; AFTER) , LONG MENSTRUAL CYCLES, SEXUAL DYSFUNCTION (UNABLE TO FEEL PLEASURE DUE TO PAIN DURING INTERCOURSE), ITCHING/BURNING/STINGING/STABBING AT VAGINAL ENTRANCE, ABDOMINAL SPASMS/FLUTTERS/TWITCHES, BACK/HIP/JOINT PAIN, CHRONIC PELVIC PAIN, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEADACHES AND MIGRAINES IN MORE FREQUENT PERIODS, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CLOUDINESS, FORGETFULNESS, CONFUSION), MOOD SWINGS, MAJOR HAIR LOSS, MASSIVE AND UNCONTROLLABLE WEIGHT GAIN I HAVE BEEN SEEN BY TWO DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS CHRONIC BACTERIAL VAGINOSIS, HEMORRHAGIC CYSTS. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: LATERAL SALPINGO-OOPHORECTOMY AND I WILL ALSO BE SEEING MY OBGYN ON (B)(6) 2015 TO UNDER GO SEVERAL TESTS ANDAMP; TO DISCUSS HAVE A TOTAL HYSTERECTOMY. THE DEVICE IS STILL INSIDE OF ME. HOPEFULLY FOR NOT MUCH LONGER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044054	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 5/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NECK/SPINE PAIN, LIMBS TINGLING, JOINT PAIN, CHEST PAIN, DIZZY, HEART RUTHENIUM, NO ENERGY, ALLERGIES, SKIN RASHES, BLED CLOTS ALWAYS BLEEDING, PAINFUL INTERCOURSE, POTS, FIBROMYALGIA, GLEICH SYNDROME, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044055	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE DEVICE IMPLANTED BECAUSE AFTER MY SON WAS BORN, I HAD POST PARDUM CARDIOMYOPATHY SO IT WAS RECOMMENDED I HAVE NO MORE CHILDREN. THIS WAS THE LEAST INVASIVE OPTION AVAILABLE TO ME AT THE TIME. FOR THE FIRST COUPLE OF YEARS I SHOWED NO SIGNS OR DIDN'T REALIZE I HAD SIGNS OF PROBLEMS. SINCE LATE LAST YEAR, I HAVE NOTICED (WHICH I HAD NOTICED PRIOR AS WELL BUT DIDN'T ATTRIBUTE IT TO POTENTIALLY BEING ESSURE) WAS EXTREME FATIGUE, BLOATING AND RAPID WEIGHT GAIN, NUMBNESS IN MY HANDS AND FEET, HEAVY PAINFUL PERIODS, JOINT PAIN. MORE RECENTLY I HAVE ADDED DIZZINESS, HEADACHES, ALLERGIES PLUS ALL OF THE ABOVE ARE GETTING WORSE AS TIME GOES ON. MY CARDIOLOGIST HAS CLEARED MY HEART FAILURE FROM BEING THE CAUSE, AS I HAVE NO ISSUES WITH MY HEART SINCE MY SON WAS BORN. MY GENERAL DOCTOR CLEARED MY THYROID AND RAN EXTENSIVE BLOOD TESTING THAT ALL CAME BACK NORMAL. MY OB AGREES THAT BASED ON THE CURRENT REPORTED SIDE EFFECTS THAT ESSURE CAN BE THE SOLUTION, I AM SCHEDULED FOR A ROBOTIC HYSTERECTOMY BILATERAL SALPINDECTOMY ON SEPT 1ST. THIS IS NOT FIBROMYALGIA OR ANYTHING ELSE. MY SYMPTOMS ARE SIMPLY WORSENING ESPECIALLY THE BLOATING AND JOINT PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044056	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 6/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I ALSO HAVE A LOT OF HAIR LOSS. THIS ONLY HAPPENED AFTER ESSURE WAS IMPLANTED INSIDE ME, I WOULD SAY I'VE LOST AT LEAST 25% OF MY HAIR. IT WAS FULL AND THICK, NOW IT IS THIN AND BRITTLE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044057	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 5/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I FIRST GOT THE ESSURE, I BLED FOR LIKE 5 MONTHS, I BLED SO BAD THAT BOTH TIMES FOR MY TEST TO MAKE SURE THEY WERE BLOCKED THEY HAD TO CANCEL DUE TO THE AMOUNT OF BLOOD, I HAVE BEEN TO THE EMERGENCY ROOM MULTIPLE TIMES DUE TO THE ESSURE, I HAVE HAD INFECTIONS IN MY TUBES, LOWER BACK PAIN, STOMACH PAIN, WEAKNESS, WEIGHT GAIN, PAIN DURING AND AFTER SEX, MULTIPLE CYSTS ON MY OVARIES, INFECTION IN MY UTERUS, KIDNEY INFECTIONS, MY TUBES HAVE BEEN SWOLLEN JUST A LOT OF PAIN. I AM SET UP FOR SURGERY TO GET MY TUBES TAKEN OUT ON (B)(6) 2015 AT 3:30 PM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044058	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 7/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WITH IN A MONTH OF THE PROCEDURE I GOT A RASH ON MY TORSO AND STARTED TO EXPERIENCE OTHER SIDE EFFECTS OVER THE YEARS HERES A COMPLETE LIST; EXCESSIVE BLEEDING, HORRIBLE AND UNCONTROLLABLE MOOD SWINGS, I'VE GAINED 70LBS DISCHARGE WITH ODOR, CYST BESIDE VAGINAL OPENING THAT SMELL LIKE ROAD KILL WHEN IT DRAINS, OVARIAN CYST IVE HAD TO HAVE 3 TEETH PULLED AND NEED 3 MORE PULLED, FLUTTERS IN MY BELLY, SEVERE CRAMPING THAT HAS SENT ME TO THE ER SHARP STABBING PELVIC PAIN MISCARRIAGE HOT FLASHES AND NIGHT SWEATS, PAINFUL OVULATION, PAINFUL (STINGING) PERIODS, PAINFUL INTERCOURSE, URGENT/FREQUENT URINATION, ITCHING/STINGING/BURNING/STABBING PAIN AT THE OPENING OF VAGINA, BREAST PAIN/TENDERNESS, FACE/JAW PAIN, SEVER BLOATING, HEARTBURN, HEADACHES, BRAIN FOG, DIZZYNESS, ANXIETY/PANIC ATTACKS, DEPRESSION, RINGING IN THE EARS UNEXPLAINED BRUISING CYST/BOILS/ACNE, SWELLING IN MY LEGS AND FEET, INSOMNIA, PAIN IN MY JAW, MUSCLE SPASMS IN MY EYE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044059	BAYER	7/13/2015	7/13/2015

Event Information:

Event Date (B3): 2/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED IN (B)(6) 2009 CAUSED HEAVY BLEEDING, CLOTS AND PAINFUL PERIODS. I HAD AN ABLATION DONE IN (B)(6) 2011 DUE TO THE HEAVY PAINFUL BLEEDING. THE ABLATION HELPED WITH THE HEAVY BLEEDING BUT NOT WITH THE PAINFUL PERIODS. I STILL HAD A PERIOD JUST NOT HEAVY. EVERY MONTH THE PAIN JUST KEPT GETTING WORSE AND WORSE. I COMPLAINED TO MY OBGYN AND SHE JUST BLEW ME OFF AND OFFERED NO HELP. I HAVE HAD THE FOLLOWING SYMPTOMS. CYST ON OVARIES, ITCHING, HAIR LOSS, DRY SKIN HEADACHES, BLOATING JOINT ISSUES, SHARP STABBING PAIN, BACTERIAL VAGINOSIS, HOT FLASHES, NIGHT SWEATS, URGENT URINATION, METALLIC TASTE, BOWEL ISSUES, MEMORY PROBLEMS, COILS MIGRATED, ONE WAS EMBEDDED IN THE UTERUS AND THE OTHER ONE PERFORATED THE TUBE AND ATTACHED TO THE FATTY PART OF THE COLON. I HAD CYSTS ON BOTH OVARIES. I HAD A COMPLETE HYSTERECTOMY ON (B)(6) 2015. SOME OF THE SYMPTOMS I STATED ABOVE HAVE GONE AWAY. THIS DEVICE NEEDS TO BE REMOVED FROM THE MARKET. THIS COULD OF KILLED ME OR DONE MORE SERIOUS DAMAGE IF I DIDN'T HAVE THEM REMOVED WHEN I DID.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044412	BAYER	7/13/2015	7/21/2015

Event Information:

Event Date (B3): 4/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627757

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THE INSERTION OF THE DEVICE TOOK TWICE AS LONG AS IT SHOULD HAVE AND HE HAD TO USE THREE COILS AS ONE FAILED BEFORE IT WAS IN PLACE. THE ESSURE DEVICE FELL OUT OF MY FALLOPIAN TUBE AND BROKE INTO TINY PIECES THAT THE DOCTOR SAID HE DIDN'T THINK HE GOT THEM ALL. THIS CAUSED ME GREAT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044060	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD NO OTHER ILLNESSES, ALLERGIES OR MEDICAL CONDITIONS IN THE LAST 5 YEARS. I WAS IMPLANTED (B)(6) 2010. ROUGHLY 3 YEARS LATER I GAINED 40 LBS OUT OF NO WHERE. CANNOT SEEM TO LOOSE IT NO MATTER HOW MUCH I DIET AND EXERCISE. THE MOST I HAVE MANAGED TO LOOSE IS 8 LBS BUT GAINED IT RIGHT BACK. RIGHT AFTER IMPLANTATION I EXPERIENCED HORRIBLE ACID REFLUX I DEAL WITH ALMOST NONSTOP. MY PERIODS WENT FROM BEING COMPLETELY PREDICTABLE TO COMPLETELY UNPREDICTABLE. EXTREMELY HEAVY OR LIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044061	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 7/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN AND CRAMPING, EXTREME BLEEDING DURING PERIODS, EXTREME BLOATING DURING AFTER AN BEFORE MY PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044062	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD BEEN HAVING L FLANK PAIN FOR MONTHS, LATE PERIODS, BLOATING, HEADACHES AND FATIGUE. HAD AN EXAM, UA, X-RAY, CT SCAN, AND A VAGINAL ULTRASOUND WITH NO DIAGNOSIS. I HAVE BEEN HEALTHY UP TO THAT POINT. MD SUGGESTED AND DID AN EXPLORATORY LAP AND FOUND ENDOMETRIOSIS AND I ENDED UP HAVING A HYSTERECTOMY (TUBES, UTERUS AND CERVIX).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044063	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 2/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE PUT IN, IMMEDIATELY I WAS COMPLAINING OF PAIN. HE SAID THAT WOULD GO AWAY. IT HAS NOT, ALONG WITH A NON STOP PERIOD WITH EPISODES OF BREAKTHROUGH BLEEDING. GOT 3 MONTH TEST TO SEE THEY CORRECTLY INSERTED ANN DR SAID THEY LOOK GOOD ALTHOUGH HE POINTED OUT THE RIGHT TUBE WAS ALMOST TOO SMALL TO INSERT? I FEEL LIKE I AM GOING TO DIE DAILY. I HAVE BEEN TAKING MOTRIN DAILY AS MY DR DISMISSED MY PAIN. FOUR MOS LATER, IM STILL BLEEDING SOMETIMES LIKE NIAGRA FALLS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044064	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 5/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD NON STOP BLEEDING AND CHRONIC PAIN EVER SINCE HAVING THEM PLACED. LOWER ABDOMINAL SWELLING AND SEVERE STABBING PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044065	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 3/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HEADACHE, EXTREME FATIGUE, BLOATING BLURRED VISION, NUMBNESS IN HANDS AND FEET, HAIR LOSS, BRAIN FOG, MEMORY LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044066	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 9/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DAY I GOT THE ESSURE DEVICE PUT IN ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044067	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 8/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED IN 2007. IMMEDIATELY FELT DRAINED BUT NEVER LINKED THE ESSURE TO THIS FEELING SINCE I HAD 4 KIDS AND JUST ASSUMED I WAS GOING TO BE EXHAUSTED CHASING THEM. ANOTHER THING I NOTICE EARLY ON WAS A METALLIC TASTE IN MY MOUTH. I WOULD BRUSH MY TEETH AND USE MOUTH WASH AND THE TASTE WOULD COME BACK IN MINUTES. I STILL DIDN'T HAVE REASON TO LINK IT TO ESSURE BECAUSE I HAD A CAVITY AT THE TIME. HOWEVER, EVERYTIME I WOULD HAVE A CAVITY FIXED THEY WOULD FIND ANOTHER ONE AND THIS HAS CONTINUED FOR THE NEXT 8 YEARS. MY TEETH HAVE SLOWLY BECOME DISCOLORED (AND SOME TURNED ALMOST BLACK IN SOME PLACES) AND SOME HAVE EVEN BROKEN AND WERE FORCED TO BE REMOVED. TRIED TO KEEP UP WITH IT BUT WITH INSURANCE DEDUCTIBLES AND MONEY ISSUES I COULD ONLY DO WHAT I COULD AFFORD. AS TIME WENT ON, I STARTED NOTICING A DULL ACHE IN MY LOWER LEFT ABDOMEN. AT THE BEGINNING, I ASSUMED IT WAS OVULATION AND WOULD TAKE IBUPROFEN TO EASE DISCOMFORT. IN 2012, HOWEVER, THE PAIN STARTED TO BECOME SEVERE. ALMOST FELT LIKE CONTRACTIONS AT TIMES. I ENDED UP IN THE EMERGENCY ROOM ON (B)(6) 2012 AND THEY RAN LAB WORK AND DID A CAT SCAN AND DIAGNOSED ME WITH DIVERTICULITIS AND PRESCRIBED ME WITH PAIN MEDS AND ANTIBIOTICS. THE ANTIBIOTICS HELPED THE CONTRACTION PAIN BUT THE DULL ACHE NEVER COMPLETELY WENT AWAY. I FOLLOWED UP WITH GASTROENTEROLOGIST AND GYNECOLOGIST REFERENCE TO THIS PAIN. GASTROENTEROLOGIST CONFIRMED WITH A COLONOSCOPY THAT I DO HAVE DIVERTICULOSIS AND A COLON OF A (B)(6) MALE IN (B)(6) 2013. HOWEVER, THE SEVERE CRAMPING THAT WAS ALWAYS TREATED AS DIVERTICULITIS WAS NOT ALWAYS ABLE TO BE CONFIRMED WITH BLOOD WORK. DOCTORS WOULD SAY THAT I DIDN'T SHOW A HIGH LEVEL OF CELLS THAT WOULD CONSTITUTE DIVERTICULITIS BUT THERE WAS NO OTHER EXPLANATION. THE GYNECOLOGIST DID INTERNAL EXAM AND PREGNANCY TEST WHEN I SAW HIM AND SINCE

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EVERYTHING APPEARED TO BE FINE HE AGREED THAT IT MUST BE MY DIVERTICULITIS CAUSING THIS PAIN AND HAD NO REASON TO BELIEVE IT WOULD BE ANY PROBLEMS WITH ESSURE. MEANWHILE MY LOW ENERGY LEVEL AND LACK OF SEX DRIVE DESTROYED MY MARRIAGE. WE ENDED UP SEPARATING IN (B)(6) 2014. AFTER SEEING A NEWS CAST IN (B)(6) 2015 I IMMEDIATELY CONTACTED MY GYNECOLOGIST AND ASKED IF IT WAS A POSSIBILITY THAT ESSURE COULD BE THE CAUSE OF ALL MY ISSUES. HE AGREED TO HAVE ME COME IN AND DO AN ULTRASOUND. ULTRASOUND SHOWED THAT THE COILS WERE IN THE CORRECT PLACE BUT THAT I HAD 5 FIBROID CYSTS AND ADENOMYOSIS. WE ALSO TALKED ABOUT THE FACT THAT I MAY HAVE AN ALLERGY TO NICKEL DUE TO THE FACT THAT YELLOW GOLD WOULD BREAK ME OUT NOW AND THEN (WHICH CAN OCCUR WITH NICKEL ALLERGIES) AND HE EXPLAINED THAT THE ESSURE WAS MADE OF NICKEL. WE THEN DISCUSSED A HYSTERECTOMY TO REMOVE EVERYTHING BESIDE THE OVARIES. I HAVE NO PLAN TO HAVE ANY MORE KIDS SO I AGREED TO THE HYSTERECTOMY. HYSTERECTOMY WENT WELL WITH VERY LITTLE COMPLICATIONS. HE WAS ABLE TO REMOVE MY UTERUS AND CERVIX AND TUBES VIA THE DAVINCI AND ADVISED THAT THEY HAD TO REMOVE SOME OF MY COLON FROM MESH THAT WAS IN PLACE FROM A PREVIOUS HERNIA AND SCRAPE ENDOMETRIOSIS OFF MY COLON BUT WAS RELEASED THE NEXT DAY. WHEN CULTURE CAME BACK IT DID NOT SHOW THE ENDOMETRIOSIS WHICH MY DR EXPLAINED HAPPENS SOMETIMES, BUT IT DID SHOW THE CYSTS AND SHOWED THAT MY UTERUS WAS ENLARGED. THE FOLLOWING MONDAY I WAS ADMITTED BACK IN THE HOSPITAL WITH LOW BLOOD PRESSURE AND INFECTION HOWEVER I WAS ALREADY NOTICING THE METALLIC TASTE IN MY MOUTH WAS GONE. I STAYED TIL THAT THURSDAY AND SINCE MY RELEASE I HAVE NOTICED THAT THE SWELLING AND LOWER LEFT SIDE ABDOMINAL PAIN IS GONE AND MY TEETH ARE NOT AS SENSITIVE HOWEVER STILL NEED A LOT OF WORK. I PHYSICALLY FEEL LIKE A BRAND NEW PERSON. MY DOCTOR, FAMILY, FRIENDS AND CO-WORKERS HAVE EVEN STATED THAT THE GREYISH SKIN TONE I HAD ACQUIRED HAS BEEN REPLACED WITH A HEALTHIER SKIN TONE. I AM WRITING THIS BECAUSE I LIVED SICK FOR 8 YEARS AND I DIDN'T EVEN REALIZE THAT IT COULD OF BEEN TAKEN CARE OF SOON AND POSSIBLY COULD OF SAVED MY MARRIAGE. I ALSO WANT TO MAKE SURE THAT OTHERS THAT ARE LIVING WITH THIS CAN BE HELPED IF THEY DON'T REALIZE THAT THE ESSURE COULD BE THE MAJOR CAUSE. I HAVE READ A LOT SINCE REALIZING THIS AND I AM SO DISAPPOINTED TO BELIEVED THAT THE TRIAL OF THIS DEVICE MY NOT OF BEEN DONE CORRECTLY. I KNOW THAT THERE ARE ALWAYS POSSIBILITIES OF SIDE EFFECTS WITH ANYTHING PUT IN THE BODY BUT WHEN I WAS LOOKING INTO THE ESSURE ORIGINALLY NONE OF THESE SIDE EFFECTS WERE MENTIONED WHICH KEPT ME FROM LOOKING FURTHER INTO IT WHEN I WAS FEELING SO ILL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044068	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 3/21/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE REMOVED,WHICH CAUSED ME TO LOOSE BOTH OF MY FALLOPIAN TUBES .

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044069	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 4/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE DEVICE I HAVE EXPERIENCED SEVERE AND FREQUENT MIGRAINES, PAINFUL SEX, HAIR LOSS, LOST OF BALANCE, DENTAL ISSUES, DIZZINESS, NAUSEA AND VOMITING, HEAVY PERIODS, SEVERE CRAMPING, HOT FLASHES, HIVES/SKIN RASH, CHRONIC HEMMROIDS, BLOATING, GAS AND MEMORY ISSUES. ONE OF THE COILS CAME OFF OF MY TUBES AND RESTED ON MY RECTUM. I ENDED UP HAVING TO HAVE MY TUBES REMOVED IN 2014. AFTER STILL EXPERIENCING ISSUES AND I ENDED UP HAVING A TOTAL HYSTERECTOMY IN (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044070	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 3/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM (B)(6) AND HAD THE ESSURE PROCEDURE DONE SO I WOULDN'T HAVE TO UNDER GO SURGERY SO I WOULD BE ABLE TO TAKE CARE OF MY CHILDREN AFTERWARDS. WELL THAT BEING SAID I HAVE HAD BAD HORRIBLE CRAMPS, HEAVY BLEEDING, BAD MIGRAINE HEADACHES, HORRIBLE JOINT PAIN, OVARIAN CYST, PANIC ATTACKS FROM THE PAIN IN MY ABDOMINAL AREA, DEPRESSION, NUMBNESS AND TINGLING IN MY FACE AND ARMS THAT DOESN'T GO AWAY, AND WAS NEVER TESTED FOR ALLERGY TO NICKEL HAVE BAD ITCHING AROUND MY ABDOMINAL AREA BEEN TO THE ER SEVERAL TIMES FOR UNCONTROLLABLE ABDOMINAL PAIN. HAD MANY TEST RAN AND FAMILY DR IS TELLING ME TO GET THE OB TO DO A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044071	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 8/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING RASH AND SEVERE ABDOMINAL PAIN. SUPER CRAMPS AND PELVIC PRESSURE. MIGRAINE HEADACHE, BACK PAIN, AND JUST NOT FEELING GOOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044072	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAIN IN MY LOWER LEFT CHEST WITH INHALE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044073	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MINOR CRAMPING ON A DAILY BASIS. EXHAUSTION DAILY. BLEEDING SUBSIDED AFTER 3 WEEKS. DOCTOR'S MEDICAL REPORT SAYS "CONCERN FOR MISFIRE OF DEVICE, THEREFORE HYSTEROSCOPIC GRASPER USED TO REMOVE COIL, SEGMENT BY SEGMENT, UNDER DIRECT VISUALIZATION, WITH MUCH DIFFICULTY. LONG THIN INNER COIL WAS FULLY STRETCHED OUT TO POINT IT PROTRUDED OUT ON CERVIX AND INTO VAGINA WHEN SCOPE REMOVED. SCOPE REPLACED, COIL REMOVED IN 5-6 SEGMENTS, BUT TINY PIECE REMAINED VISUALIZED AT OSTIA DILATORS, TENACULUM, AND SPECULUM REMOVED, HEMOSTATIC"

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044074	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING VERY BAD PELVIC PAIN, BLOATING, HEAVY PERIODS, AND MIGRAINE HEADACHES, AND CHANGES IN MY SKIN. ALL SYMPTOMS CONTINUED EVEN WITH TRYING DIFFERENT MEDICATIONS AND PHYSICAL THERAPIES. ESSURE WAS REMOVED VIA A BILATERAL SALPINGECTOMY (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044075	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THE ESSURE USED I HAVE HAD CHRONIC UTI AND STREP B INFECTIONS WITH CONSTANT KIDNEY PAINS. NEVER HAD ISSUES LIKE THIS BEFORE. I FIND THE PAIN TO BE CONSTANT. I JUST HAD A ULTRASOUND ON KIDNEYS AND BLADDER AND THERE WAS NO FINDINGS. SCHEDULED FOR ANOTHER TEST IN (B)(6) PRAYING FOR ANSWERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044076	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED EXPERIENCING IRREGULAR HEAVY BLEEDING MORE THAN ONCE A MONTH (HADN'T HAD ANY AT ALL FOR APPROXIMATELY 2 YEARS AFTER HAVING DEVICE PLACED), EXTREME FATIGUE, ABDOMINAL PAIN, FREQUENT MIGRAINES AND HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044077	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 4/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPS, FATIGUE, NAUSEA, HEAVY PERIODS, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044078	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING OCCURRING ISSUES SINCE I HAD THE DEVICE PLACED IN 2009. I HAVE HAD EXTREME MEMORY LOSS, SEVERE PAIN, ABNORMAL PERIODS, MIGRAINES, BODY RASHES, COMPLETE LOSS OF SEX DRIVE, IRRITABILITY, DIAGNOSED SINCE DEVICE WAS PLACED WITH HYPOGLYCEMIA, SWELLING OF MY STOMACH, DIZZINESS, INSOMNIA, NUMBNESS OF MY LEGS, SHOOTING PAINS IN MY HIPS AND BACK THAT GO THROUGH MY ENTIRE BODY, AND HAVE BEEN UNABLE TO WORK SINCE SYMPTOMS HAVE GOTTEN MORE SEVERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044079	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 5/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN DIAGNOSED WITH CHRONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044080	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 10/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER LEFT PAIN, SEVERE CRAMPS WITH PERIODS, HEAVY BLEEDING, BLOATING, PAINFUL INTERCOURSE, HASHIMOTO'S THYROIDITIS, ECZEMA, FATIGUE, IRREGULAR PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044081	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 10/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING THESE PLACED THE PREVIOUS THURSDAY I STARTED HAVING UTI SYMPTOMS ENDED UP IN ER WITH A KIDNEY INFECTION. IN (B)(6) I HAD THE SAME THING HAPPEN. IN (B)(6) I ENDED IN THE ER WITH COMPLEX CYSTS ON MY OVARIES. I'M IN CONSTANT PAIN IN MY ABDOMEN AND BACK WITH A CONSTANT METAL TASTE IN MY MOUTH. I HAVE ON AVERAGE 15-20 MIGRAINES A MONTH. NUMBNESS IN MY FACE AND RIGHT ARM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044082	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 10/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JUST REALLY HEAVY BLEEDING. PASSING BLOOD CLOTS. TOOTH PROBLEMS. DUE TO METAL POISONING. BLOATING. SHARP PAINS IN MY LOWER SIDE AND BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044083	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN I LOOK PREGNANT, SHARP PAINS IN MY STOMACH AREA, HORRIBLE MIGRAINES EVERY DAY, IRREGULAR PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044084	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 4/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASHES, CRAMPING, BRUISING, HEADACHES, PELVIC PAIN, NUMBNESS, TINGLING IN LOWER EXTREMITIES, IRREGULAR PERIODS, TEETH PAIN AND BLEEDING GUMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044085	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY HEAVY AND LONG PERIODS. 40+ LB WEIGHT GAIN, ONGOING PELVIC PAIN WHICH NOW LEADS TO A FULL HYSTERECTOMY WHICH IS SCHEDULED FOR (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044086	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 12/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN, BRAIN FOG, SEVERE PERIODS, FATIGUE, HOT FLASHES, MOOD SWINGS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044087	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 9/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS FOR 3 WEEKS EVERY MONTH. HAD TO GO BACK ON BIRTH CONTROL PILLS TO CONTROL THE HEAVY BLEEDING

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044088	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 1/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WORSENING PERIODS TO INCLUDE EXTREME CRAMPING, CLOTTING AND ACNE. MOOD SWINGS, HEADACHES, VERTIGO, POLYCYSTIC OVARY SYNDROME, PMDD, WEIGHT GAIN, UNABLE TO LOSE WEIGHT, FACIAL HAIR GROWTH, IRREGULAR PERIODS, PHANTOM PREGNANCY SYMPTOMS, HAIR LOSS, IBS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044089	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 9/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). I BEGAN TO FLUCTUATE WEIGHT, GOING FROM AN AVERAGE (B)(6) IN A MATTER OF MONTHS. AS OF NOW IM AT THE HEAVIEST IN MY LIFE AT (B)(6). MY SKIN BEGAN TO ITCH AND HAVE SMALL BUMPS. I HAD EXTREMELY PAINFUL INTERCOURSE AND WOULD BLEED AFTERWARDS. I WAS DIAGNOSED WITH BACTERIAL VAGINITIS, IN 2014. I HAVE DEVELOPED CYSTS ON MY OVARIES AND MY PERIODS ARE COMPLETELY IRREGULAR. I WILL GO WITHOUT A PERIOD FOR UP TO 5 MONTHS, WITH SIGNS MIMICKING PREGNANCY FOLLOWED BY PERIODS LASTING 1 TO 3 MONTHS. I AM AT TIMES ANEMIC AND HAVE BEEN DIAGNOSED WITH A VIT D DEFICIENCY. MY BELLY BLOATS AND SOME DAYS I LOOK 4 MONTHS PREGNANT. MY TEETH HAVE BECOME VERY BRITTLE AND FILLED WITH CAVITIES. I HAVE PAIN IN BOTH SIDES OF MY HIPS, MORE SO ON MY LEFT SIDE. THE PAIN CAUSES SHOOTING NERVE PAIN DOWN MY LEGS AND INTO MY UPPER BACK. MY HAIR HAS THINNED. I HAVE ALSO BECOME QUITE DEPRESSED AT TIMES MORE SO DO TO MY LACK OF ENERGY ESPECIALLY DURING MY PERIOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044090	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 12/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PELVIC PAIN, 24/7 MIGRAINES, DEPRESSION, FATIGUE, INSOMNIA, BRAIN FOG, MEMORY LOSS, PAINFUL INTIMACY, HEAVY BLEEDING, IRREGULAR CYCLES, MULTIPLE HOSPITAL VISITS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044091	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 10/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I NOW HAVE BLOOD PRESSURE PROBLEMS. HORRIBLE PERIODS, ANXIETY PROBLEMS AND MY HAIR FALLS OUT A RIDICULOUS AMOUNT

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044092	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 3/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PERIOD WAS 2 MONTHS LATE. LAST PERIOD WAS FULL OF CLOTS AND MEAT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044093	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING SEVERE ABDOMINAL PAIN, PAINS IN MY SIDES, CHEST PAIN, MIGRAINES, AND SEVERE ABDOMINAL PAIN WHENEVER I BEND OVER, OR REACH FOR SOMETHING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044094	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN, HEAVY PERIODS. WEIGHT GAIN. HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044095	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS. VERY, VERY, HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044096	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS. VERY VERY HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044097	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN BLOATING RASHES

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044098	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 10/18/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING ESSURE PLACED, I EXPERIENCED PAIN RADIATING DOWN MY LEG. WHEN DOCTORS DID AN X-RAY, THEY DISCOVERED THAT ONE OF MY ESSURE COILS HAD MIGRATED OUT OF MY FALLOPIAN TUBE AND WAS DANGLING IN MY ABDOMEN. I HAD SURGERY AND THEY REMOVED THAT PARTICULAR FALLOPIAN TUBE. OVER THE YEARS SINCE THEN, I HAVE CONTINUED TO HAVE ABDOMINAL PAIN. I BELIEVE THAT THE PAIN IS CAUSED BY THE OTHER COIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044099	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE HEADACHES, ARM, SHOULDER, NECK NUMBNESS, SCIATICA, ABDOMINAL PAIN, LEG PAIN, JOINT PAIN, BRAIN FOG, HEAVY PERIODS, PUSTULES ON ARMS AND HANDS. ON GOING SPECIALIST APPOINTMENT AND PHYSICAL THERAPY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044100	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING PAIN, HEADACHES, WEIGHT GAIN, STRANGE RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044101	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 5/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WOULD NEVER HAVE ANYONE GET THIS .THEY PUT ME TO SLEEP WHEN I WOKE I HAD A LOT OF PAIN. I STILL HAVE PAIN TO THIS DAY WISH I DID IN GET IT ALONG WITH MY PERIOD ARE ALL OVER THE PLACE .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044102	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 11/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHEST PAIN, PANIC ATTACKS. PLEURISY, KIDNEY DISEASE, JOINT PAIN, NAUSEA, ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044103	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 10/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PANIC ATTACKS, ANXIETY, DEPRESSION, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044104	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, VERY HEAVY PERIODS SOMETIMES LAST 10 DAYS AND HAVE IT 2 TIMES A MONTH. BAD CRAMPING. LOWER BACK AND HIP PAIN. MOOD SWINGS. DIZZINESS. LOW IRON AND VITAMIN D, FORGETFULNESS AND SJÖGREN'S SYNDROME

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044105	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 2/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING FOR WEEKS AT A TIME, PELVIC PAIN, BLOATING, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044106	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAINS IN OVARY AREA

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044107	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 11/20/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DOUBLE OVER IN PAINS. HUGE CLOTS AND EXCESSIVE BLEEDING. CHANGE IN WEIGHT ESPECIALLY STOMACH AREA. ITCHY AT TIMES. SEX PAINFUL AT TIMES. SEXUAL DESIRE LOWERED. SOMETIMES FEELS LIKE LEAKING. MULTIPLE ISSUES. TEETH ISSUES. HAD ULTRASOUND AFTER INSERTING AND GOT THE PAINS AND SWELLING OF LEFT SIDE OF STOMACH. DOCTOR SAID WAS NOTHING TO WORRY ABOUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044108	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 1/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER GETTING ESSURE I EXPERIENCED HEAVY BLEEDING OR SPOTTING NON STOP FOR 5 MONTHS. MY HAIR STARTED FALLING OFF. I STARTED GETTING ACNE ON MY FACE AND BACK, SOMETHING I NEVER HAD ISSUES WITH BEFORE ESSURE. I GAINED MASSIVE WEIGHT AND SOMETIMES AM SUPER BLOATED. CRAMPS ON MY LEFT SIDE CONSTANTLY. DEPRESSION, I WAS ALWAYS A HAPPY PERSON AND NEVER DEALT WITH DEPRESSION WHATSOEVER UNTIL AFTER ESSURE. I SOMETIMES GET ITCHY SKIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044109	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 8/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME BLOATING, PAIN IN ABDOMEN, HORRIBLE HEADACHES, HORRIBLE BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044110	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 4/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS IS THE DAY I MISSED MY FIRST MENSTRUAL CYCLE BUT STILL HAD EXTREME CRAMPS WITHOUT THE ACTUAL PERIOD. TO THIS DAY I STILL EXPERIENCE MAJOR CRAMPING EVEN WHEN IT ISN'T TIME FOR MY MENSTRUAL CYCLE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044111	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 8/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST OF ALL I WASN'T PUT UNDER ANY ANESTHESIA AND THE PROCEDURE WAS QUITE PAINFUL. I HAVE HEART PALPITATIONS NOW. THE MOST FRUSTRATING THING IS AFTER THE DEVICE WAS IMPLANTED I BEGAN BLEEDING VERY HEAVY DURING MY PERIOD. I HAVE BEEN DIAGNOSED WITH ENDOMETRIOSIS. I NEVER HAD ANY ISSUES WITH THAT PRIOR TO THE IMPLANTATION

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044112	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 7/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANTLY IN PAIN.. MY BACK, STOMACH AND JOINTS... MY HAIR FALLS OUT IN CHUNKS ALL DAY LONG... EXTREMELY FATIGUED NO ENERGY... I HAVE HAD ALOT OF EAR TROUBLE... GET VERY SAD AND DEPRESSED BECAUSE MY LIFE HAS NOT BEEN THE SAME...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044113	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 2/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE DEVICE PLACED, ONE OF THE COILS MIGRATED INTO MY ABDOMEN AND PUNCTURED THROUGH MY UTERUS FROM THE OUTSIDE. THE OTHER COIL RECESSED PART WAY BACK INTO MY UTERUS. I HAD A SURGERY TO HAVE THE FIRST COOL REMOVED AND A CLIP PUT IN ITS PLACE. THE SECOND COIL REMAINED IN PLACE. I HAD EXTREME WEIGHT GAIN, PAIN BLEEDING, TROUBLE WITH SEXUAL AROUSAL, PAIN DURING INTERCOURSE, EXCESSIVE BLOATING, I LOST MY MILK SUPPLY, (MY DAUGHTER WAS 3 MONTHS OLD AT THE TIME), HAD CHRONIC UTERINE INFECTIONS, AND WAS UNABLE TO FUNCTION NORMALLY. (B)(6) 2014 I HAD A HYSTERECTOMY TO REMOVE THE REMAINING COIL AND THE FRAGMENTS LEFT BEHIND FROM THE FIRST COIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044114	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 11/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NEWLY DEVELOPED FOOD ALLERGIES, EXTREME FATIGUE, IRON DEFICIENCY, VITAMIN D DEFICIENCY, MIGRAINES, WEIGHT LOSS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044115	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, HOT FLASHES, EXTREME NIGHT SWEATS, HAIR LOSS, DEPRESSION, WEIGHT GAIN/SWELLING, AND SEVERE JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044116	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MAJOR BLOATING, HEADACHES, BACK PAINS, SHARP PAINS IN MY GROWING, HEAVY PERIODS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044117	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING, HEAVY BLEEDING. DIZZINESS,HEADACHE, WEIGHT GAIN, HIGH BLOOD PRESSURE, LOSS OF HAIR. MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044118	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER GETTING ESSURE PLACED WHEN I GET CRAMPS FOR MY TIME OF THE MONTH IT MAKES MY WHOLE LEFT LEG SEIZE UP AND ACHES ALL THE WAY TO MY ANKLE. SEVERE BLOATING NON STOP I LOOK 5 MONTH'S PREGNANT CONSTANT HEADACHES AND STABBING PAINS IN MY VAGINA. CYSTS ON MY OVARIES THAT WERE NEVER THERE BEFORE AND A HEMORRHAGIC CYST AND CONSTANT ER VISITS FOR VAGINAL UTERUS AND OVARIAN PAINS AND ISSUES

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044119	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 3/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, IRREGULAR PERIODS WITH CHUNKS AND PIECES OF BLOOD, HAIR LOSS, BLOATING, LOSS OF SEX DRIVE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044120	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING PELVIC PAIN, EXTREME BLOATING, IRREGULAR CYCLES, MULTIPLE CYSTS ON OVARIES, POLYP FOUND IN THE UTERUS. ELEVATED LEVELS OF TESTOSTERONE, OTHER BLOOD WORK RETURNED NORMAL RANGES. ULTRASOUND DONE PRIOR TO ESSURE IMPLANTATION SHOWED HEALTHY UTERUS AND OVARIES, NOW SHOWS MULTIPLE CYSTS ON OVARIES AND POLYP IN UTERUS. INABILITY TO LOSE WEIGHT NO MATTER HOW HARD I TRIED TO LOSE IT. CONSTIPATION ISSUES, VISUAL ISSUES, HAIR LOSS, HORMONAL ISSUES, AND ANXIETY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044121	BAYER	7/14/2015	7/14/2015

Event Information:

Event Date (B3): 6/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAINS CAUSING ME TO GO TO THE DR WHO THEN SENT ME TO THE ER FOR EMERGENCY SCAN TO RULE OUT APPENDICITIS AND KIDNEY STONE. PAINS WERE FROM HAVING THE COILS INSIDE. AS SUFFERED FOR ALMOST 2 YEARS BEFORE MY DR FINALLY AGREED TO DO THE HYSTERECTOMY AND TO REMOVE THE COILS AS WELL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00505	BAYER HEALTHCARE LLC	7/14/2015	7/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 621679

Single Use: Y
Implant Date (E6): 12/26/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN REPORTED THE DEVICE WAS FOUND BY ULTRASOUND TO BE LOCATED IN THE ENDOMETRIUM AND APPEARING TO PIERCE MYOMETRIUM. PATIENT WAS COMPLAINING OF INCREASED VAGINAL BLEEDING. SHE IS S/P (AS REPORTED) ENDOMETRIAL ABLATION. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION

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RECEIVED ON (B)(6)-2015 AND ON (B)(6)-2015 THE CASE (B)(4) WAS IDENTIFIED AS DUPLICATE FROM THIS CASE AND WAS DELETED FROM CENTRAL. ALL INFORMATION WAS TRANSFERRED TO THIS CASE. THE PATIENT'S INITIAL AND DATE OF BIRTH WERE UPDATED (SHE WAS 46 YEARS OLD). PREGNANCY WAS DENIED. ESSURE 205 WAS INSERTED ON (B)(6) 2006 FOR STERILIZATION. ON (B)(6) 2007, HSG WAS DONE BUT RESULTS WERE UNKNOWN. ON (B)(6) 2015 SHE WENT TO THE HCP OFFICE WITH BLEEDING AND AN ULTRASOUND WAS DONE AND SHOWED THAT THE RIGHT COILS HAD EXPELLED FROM THE RIGHT FALLOPIAN TUBE AND WAS WEDGED IN MYOMETRIUM. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015. CASE UPGRADED TO INCIDENT. PATIENT'S DEMOGRAPHIC INFORMATION WAS PROVIDED. HER MEDICAL HISTORY INCLUDED GRAVIDA 2, PARA 2, CERVICAL DYSPLASIA, HTN (HYPERTENSION), CERVICAL CONIZATION, CURETTAGE AND ABLATION IMMEDIATELY PRIOR TO ESSURE. ON (B)(6) 2006, ESSURE LOT NUMBER 621679 WAS INSERTED. PATIENT WAS NOT POST-PARTUM AT TIME OF INSERTION. IT WAS APPLIED DURING INSERTION: CERVICAL DILATATION, SOUNDING AND GENERAL ANESTHESIA. INSERTION WAS CONSIDERED DIFFICULT: DEBRIS ADJACENT TO RIGHT TUBAL OSTIA WAS REPORTED. VISUALIZATION WAS EASY AT LEFT SIDE AND DIFFICULT AT RIGHT SIDE. THERE WAS NO MORE THAN 1500 CC OF FLUID LOSS DURING HYSTEROSCOPY. ON (B)(6) 2007, A HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND SHOWED NO SPILLAGE ON RIGHT SIDE AND SPILLAGE ON LEFT SIDE. VASECTOMY WAS REPORTED AS BACK UP CONTRACEPTION. ON (B)(6) -2015, A 3-D PELVIC ULTRASOUND (TRANSVAGINAL) WAS PERFORMED AND SHOWED ESSURE IN INCORRECT POSITION. PATIENT WAS EXPERIENCING BLEEDING AND PAIN. PERFORATION AND PREGNANCY WERE DENIED. ON (B)(6) 2015, TOTAL LAPAROSCOPIC HYSTERECTOMY WITH LEFT SALPINGECTOMY WAS PERFORMED. PATHOLOGY REPORT INCLUDED "COILED METAL HARDWARE IN LUMEN OF BOTH TUBES". INFECTION WAS DENIED. PATIENT RECOVERED. REPORTER STATED THAT EVENTS WERE PROBABLY RELATED TO ESSURE. RIGHT DEVICE WAS EMBEDDED IN MYOMETRIUM, PATIENT HAD PELVIC PAIN IN RIGHT LOWER QUADRANT. DEVICES WERE NO LONGER PRESENT. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO EW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THE AE CASE REFERS ALSO TO A LACK OF EFFICACY (HSG SPILLAGE). A LACK OF EFFICACY MAY OCCUR WITH THE USE OF ANY MEDICINAL PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. ADDITIONALLY, THE AE CASE REFERS TO OFF LABEL USE AND TREATMENT NONCOMPLIANCE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT . IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE WAS FOUND BY ULTRASOUND TO BE LOCATED IN THE ENDOMETRIUM AND APPEARING TO PIERCE MYOMETRIUM/WEDGED IN MYOMETRIUM (INTERPRETED AS DEVICE EMBEDMENT). THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, IT WAS REPORTED THAT INSERTION WAS CONSIDERED DIFFICULT AND SHE MENTIONED THAT

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VASECTOMY WAS REPORTED AS BACK-UP CONTRACEPTION, WHICH MEANS THAT SHE DID NOT USE ANY BACK-UP CONTRACEPTION (TREATMENT NONCOMPLIANCE). SHE UNDERWENT A TOTAL LAPAROSCOPIC HYSTERECTOMY WITH LEFT SALPINGECTOMY. GIVEN THE REPORTED EVENT'S NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, OTHER NON-SERIOUS EVENTS WERE ADDED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044447		7/14/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 628440

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HEADACHES, LOWER BACK PAIN, SORE THROAT, FUNNY TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044448	BAYER HEALTHCARE LLC	7/14/2015	7/21/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26967

Single Use:
Implant Date (E6): 4/10/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

UPON ADVISEMENT BY DR, THE ESSURE DEVICE WAS IMPLANTED. I HAVE EXPERIENCED MENSTRUAL BLEEDING THAT HAS NOT STOPPED SINCE THE IMPLANTATION OF THE DEVICE. RX MEDS: LISINOPRIL, METFORMIN, AMBIEN, NORVASC, METOPROLOL, HYDROCHLOROTHIAZIDE, NEXPLANON, WOUND VAC, PROZAC, PERCOCET, LIDOCAINE, IMITREX, ZOFRAN. OTC MEDS: TYLENOL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044449	CONCEPTUS/BAYER	7/14/2015	7/21/2015

Event Information:

Event Date (B3): 5/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE COIL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/14/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I EXPERIENCED AN ADVERSE EVENT ON A MEDICAL DEVICE CALLED ESSURE, MANUFACTURED BY CONCEPTUS/BAYER. AT THE AGE OF (B)(6), I HAD THE DEVICE IMPLANTED IN BOTH FALLOPIAN TUBES ON (B)(6) 2010 BY MY OBGYN,(B)(6) OF (B)(6). AS REQUIRED, I HAD A SONOGRAM PERFORMED THREE MONTHS LATER TO MAKE SURE THAT SCAR TISSUE HAD BLOCKED THE FALLOPIAN TUBES. THE SONOGRAM REVEALED THAT THE COIL ON THE LEFT SIDE HAD MIGRATED INTO THE ABDOMINAL CAVITY. ON (B)(6) 2010 DR. (B)(6) PERFORMED A TUBAL LIGATION LAPAROSCOPICALLY ON THE LEFT SIDE ONLY. AT THAT TIME SHE ATTEMPTED TO REMOVE THE COIL THAT HAD MIGRATED OUT OF THE FALLOPIAN TUBE, BUT IT HAD LODGED IN THE OMENTUM AND ATTEMPTS TO REMOVE IT LAPAROSCOPICALLY COULD, SHE FELT, LEAD TO BLEEDING THAT WOULD REQUIRE MORE EXTENSIVE SURGERY. RATHER THAN OPEN UP THE ABDOMINAL CAVITY TO REMOVE THE COIL, SHE LEFT IT IN. RX MEDS: NONE. OTC MEDS: DAILY VITAMIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00506	BAYER HEALTHCARE LLC	7/15/2015	7/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61993

Single Use: Y
Implant Date (E6): 3/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/7/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; THE LOT NUMBER USED WAS C61993. PHYSICIAN REPORTED THAT DURING THE INSERTION PROCEDURE THE DEVICE DID NOT CAME OUT PROPERLY AND BROKE. BILATERAL PLACEMENT OF ESSURE WAS NOT SUCCESSFUL, ONLY ONE DEVICE WAS INSERTED. THE PATIENT HAD NO INJURIES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE INSERTION PROCEDURE THE DEVICE DID NOT CAME OUT PROPERLY AND BROKE. BILATERAL PLACEMENT OF ESSURE WAS NOT SUCCESSFUL, ONLY ONE DEVICE WAS INSERTED. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 16-JUL-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PTC. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT C61993. PRODUCTION DATE: 0

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00507	BAYER HEALTHCARE LLC	7/15/2015	7/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68797

Single Use: Y
Implant Date (E6): 3/23/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/10/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; THE LOT NUMBER USED WAS C68797. PHYSICIAN REPORTED THAT DURING THE INSERTION PROCEDURE THE DEVICE DID NOT CAME OUT PROPERLY AND BROKE. BILATERAL PLACEMENT OF ESSURE WAS NOT SUCCESSFUL, ONLY ONE DEVICE WAS INSERTED. THE PATIENT HAD NO INJURIES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE INSERTION PROCEDURE THE DEVICE DID NOT CAME OUT PROPERLY AND BROKE. BILATERAL PLACEMENT OF ESSURE WAS NOT SUCCESSFUL, ONLY ONE DEVICE WAS INSERTED. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON 28-JUL-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFOR

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00508	BAYER HEALTHCARE LLC	7/15/2015	7/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C13142

Single Use: Y
Implant Date (E6): 3/23/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/10/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; THE LOT NUMBER USED WAS C13142. PHYSICIAN REPORTED THAT THE DEVICE DID NOT COME OUT PROPERLY AND BROKE. BILATERAL PLACEMENT OF ESSURE WAS NOT SUCCESSFUL, ONLY ONE DEVICE WAS INSERTED. THE PATIENT HAD NO INJURY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE BROKE DURING THE PROCEDURE. SHE HAD NO INJURY. THE REPORTED EVENT WAS CONSIDERED NON-SERIOUS AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, PHYSICIAN STATED THE DEVICE DID NOT CAME OUT PROPERLY AND BROKE; ONLY ONE ESSURE WAS INSERTED. CONSIDERING THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 16-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT:

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044122	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 2/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPS, HEAVY PERIODS, HUGE BLOOD CLOTS, RASHES, WEIGHT GAIN, FATIGUE, BRAIN FOG,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044123	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 9/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING ACUTE PAIN IN THE PELVIC REGION CONCENTRATED MAINLY IN THE AREA WHERE THE FALLOPIAN TUBES ARE LOCATED BUT SPREADING THROUGH BOTH FRONT AND BACK AND DOWN INTO MY HIPS. I FIRST ATTRIBUTED THIS TO HAVING THE LYMPH NODES IN MY GROIN REMOVED (DUE TO CANCER) BUT IT MAINLY HURTS IN THE TUBE AREA. OTHER SIDE EFFECTS: HAIR LOSS, BRAIN FOG, EVEN MORE PAINFUL PERIODS (IT'S GOTTEN WORSE), HUGE BLOOD CLOTS PASSED DURING PERIOD, SWOLLEN FEET, TINGLING SENSATIONS IN FEET AND HANDS, NUMBNESS IN FEET AND HANDS, LOSS OF LIBIDO AND WHEN I DO HAVE SEX, IT'S VERY PAINFUL, CRAMPING, STABBING PAINS IN PELVIC AREA, VAGINAL INFECTIONS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044124	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 5/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY MENSTRUAL BLEEDING ACCOMPANIED BY SEVERE CRAMPING AND PASSING OF BLOOD CLOTS. THIS HAS BEEN A MONTHLY OCCURENCE SINCE IMPLANTATION IN (B)(6) 2008. I ALSO REGULARLY EXPERIENCE MIGRAINES, BLOATING THROUGHOUT THE MONTH, BACK PAIN, AND JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044125	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 10/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIES CRAMPS BLOATING PAIN DURING SEX SOMETIMES CONTINUES BLEEDING. SPOTTING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044126	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 2/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, NAUSEOUS, HEAVY BLESSING, SHARP PAINS IN FALLOPIAN TUBES, LOWER BACK PAINS, LEGS HURT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044127	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 11/30/2007	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN, MIGRAINE, MENTRUAL EVERY 2 WEEKS, WEIGHT GAIN, DENTAL PROBLEMS AND MUCH MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044128	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 1/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY PAINFUL MENSTRUAL CYCLES, OVARIAN CYSTS, CHRONIC PELVIC PAIN, HEAVY BLEEDING, ERRATIC CYCLES, WEIGHT GAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044129	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 6/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEFT SIDED PAIN WITH NO DIAGNOSIS, HAIR LOSS, HEAVY PAINFUL PERIODS, PAINFUL INTERCOURSE AT TIMES,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044130	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING SEVERE ACNE, SEVERE CRAMPS, REALLY BAD MENSTRUAL CYCLES AND BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044131	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 11/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PERIOD SKIPS MONTHS AND ARE 2 WEEKS LONGER. I'VE BEEN BREAKING OUT IN HIVES SENSE THE END OF (B)(6). PAIN ON MY LEFT SIDE THAT COMES AND GOES THEY THROUGH OUT THE DAY. MIGRAINES, WEIGHT GAIN, HAIR LOSS, SEVERE HEART BURNS, HEAVIER PERIOD, LACK OF INTIMACY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044132	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOOD CLOTS DURING EVERY PERIOD (QUARTER SIZE AND LARGER). HORRIBLE BREAST TENDERNESS. CRAMPS THAT FEEL LIKE CONTRACTIONS. EXTREME BLOATING/SWELLING IN THE STOMACH AREA. PELVIC PAIN. DISCHARGE (ODOR/NO ODOR). EXCESSIVE BLEEDING DURING PERIOD. PAINFUL OVULATION . LOSS OF LIBIDO. ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE. DIZZINESS. TINGLING SENSATIONS. NUMBNESS. BRAIN SHOCKS. BRAIN FOG AND CLOUDINESS, FORGETFULNESS. MOOD SWINGS. DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS). NUMBNESS/TINGLING IN EXTREMITIES. SHAKINESS. SKIN IRRITATION/ITCHING. INSOMNIA. WEIGHT ISSUES. SWELLING/NUMBNESS IN JAWS/LIPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044133	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 6/1/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE ALSO DEVELOPED AUTO-IMMUNE SYMPTOMS AS WELL AS SEVERE ABDOMINAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044134	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN BLEEDING HAS BEEN GOING ON SINCE (B)(6) 2014. MISSED PERIODS, MIND FOG, WEIGHT GAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044135	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, HEADACHES, EXTREME BACK PAIN, LEG PAIN, PELVIC PAIN, HEAVY PERIODS, LATE PERIODS, FATIGUE, MOODINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044136	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 4/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE STOMACH PAIN, OVARIAN CYSTS THAT HAVE SENT ME TO THE ER FROM PAIN, ALLERGIES AND RASHES THAT I NEVER HAD BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044137	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 3/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN THE BEGINNING MY DR LIED BY TELLING ME I WAS COMPLETELY REMOVABLE WITH NO SIDE EFFECTS. THIS WAS HER RECOMMENDATION DUE TO MY ALLERGIES WITH OTHER BIRTH CONTROLS. STARTED AS HORRIBLE CRAMPING DURING PERIODS, THEN CAME THE BLOATING, HAIR LOSS, AND THEN THE CONSTANT CRAMPING, PAINFUL INTERCOURSE, LOSS OF LIBIDO, RASHES, SHARP ABDOMINAL PAINS, PAINFUL B/MS AND NOW I SUFFER FROM ALL OF THAT CONSTANTLY. MOST DAYS THE PAIN IS SO MUCH THAT I DON'T HAVE AN APPETITE, SLEEPING IS IMPOSSIBLE, IT HURTS TO WALK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044138	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 12/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIC TO PENICILLIN. HEAVY BLEEDING 15 DAY PERIOD. 20 DAY CYCLE. EXTREME LOWER BACK CRAMPS. LOTS OF CLOTTING. SHARP STABBING PAINS IN ABDOMEN DAILY. EXCRUCIATING PAIN WHEN I SNEEZE IN SAME AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044139	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 12/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM FATIGUED ALL DAY LONG. I HAVE HORRIBLE ABDOMINAL PAIN ALONG WITH BACK PAIN. SKIN RASHES, HAIR LOSS. I'M ALSO A BREASTFEEDING MOTHER FOR THE 3RD TIME AND HAVE A REDUCED MILK SUPPLY. I WAS IN THE HOSPITAL AT ONE POINT ON XMAS EVE FOR ODD YET EXCRUCIATING STOMACH PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044140	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 8/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN FROM THE MINUTE I WAS IMPLANTED. ABNORMAL PERIODS. BURNING AND STINGING VAGINA. PERSISTENT RIGHT SIDED ABDOMINAL PAIN. LOSS OF HAIR. 20LB WEIGHT GAIN. UNCONTROLLABLE MOOD SWINGS. YELLOWING EYES. INTERSTITIAL CYSTITIS. NUMEROUS DOCTORS VISITS. NUMEROUS MEDICATIONS TAKEN AND ULTIMATELY A HYSTERECTOMY AT THE AGE OF (B)(6) IN ORDER TO REMOVE THIS EVIL DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044141	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY SHARP PAINS IN LOWER ABDOMEN, HEAVY BLEEDING AND CLOTTING, SEVERE SWELLING OF ABDOMEN, OCCASIONAL LIGHT SPASMS IN LOWER ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044156	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 3/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN IN MY TUBES AND BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044159	BAYER	7/15/2015	7/15/2015

Event Information:

Event Date (B3): 6/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TO ADD TO MY PREVIOUS REPORT, I'M NOW EXTREMELY VITAMIN D DEFICIENT. MY LEVEL WAS ONLY 7. I ALSO NOW HAVE HYPERPARATHYROIDISM, HIGH LIVER ENZYMES. I'M NOW BEING TESTED FOR LUPUS AND RHEUMATOID ARTHRITIS. I'M IN SO MUCH PAIN DAILY. BONE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044379	CONCEPTUS	7/15/2015	7/21/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 5/1/2013
Explant Date (E7): 8/1/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY AFTER THE IMPLANTATION SURGERY, WHILE STILL IN THE HOSPITAL, PATIENT HAD A FEVER. SHE WAS NEVERTHELESS RELEASED ON 1 PAIN PILL. THE FEVER PERSISTED FOR WEEKS. THE DOCTOR WHO IMPLANTED THE DEVICE NEVER RETURNED HER CALLS. SHE FINALLY CONSULTED WITH HER REGULAR FAMILY DOCTOR WHO DIAGNOSED SEPSIS. SHE WAS PLACED ON STRONG ANTIBIOTICS AND EVENTUALLY GOT WELL. NONETHELESS A NEW SET OF ILLNESSES CROPPED IN. SHE EXPERIENCED EXCRUCIATING ABDOMINAL PAIN, DYSPAREUNIA, WEIGHT GAIN (ABOUT (B)(6)) AND INCONTINENCE; HER BLADDER HAD BEEN DAMAGED. IN (B)(6) 2014, SHE HAD THE DEVICE REMOVED. BUT ONLY PART OF IT CAME OUT BECAUSE IT WAS DEEPLY ENTRAPPED WITHIN HER TISSUE. IN (B)(6) 2015, SHE HAD ANOTHER SURGERY, THIS TIME TO REMOVE THE SCAR TISSUE AROUND THE URETHRA BECAUSE IT WAS BLOCKING THE SMOOTH FLOW OF URINE. SHE IS PRESENTLY SUPPOSED TO HAVE ANOTHER SURGERY BECAUSE THE URETHRA IS COMPLETELY BLOCKED AND SHE IS UNABLE TO URINATE. CONSEQUENTLY A FOLEY CATHETER CAN'T BE INSERTED. PATIENT IS VERY FATIGUED AND DISABLED. SHE'S UNABLE TO TAKE CARE OF HERSELF. SHE SAYS HER HUSBAND LEFT HER BECAUSE OF HER CONDITION. HER DAUGHTER IS AWAY IN THE ARMY. SO THERE'S NO ONE AROUND TO HELP HER BEFORE, DURING AND AFTER THE SURGERY. CONSEQUENTLY SHE CAN'T SCHEDULE THE SURGERY. IN VIEW OF THE AFOREMENTIONED, PATIENT IS ASKING HOW THE FDA GOT TO APPROVE THIS DEVICE AND WHY IT'S STILL IN THE MARKET DESPITE ALL THE NUMEROUS NEGATIVE REVIEWS FROM WOMEN. SHE WOULD LIKE THIS COMPLAINT TO BE MADE PUBLIC IN ORDER TO INFORM OTHER WOMEN. PATIENT WOULD LIKE THE DEVICE TO BE TAKEN OFF THE MARKET BECAUSE SHE BELIEVES THE FDA IS THERE TO PREVENT SUCH MISHAPS FROM HAPPENING TO OTHER WOMEN.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044528		7/15/2015	7/22/2015

Event Information:

Event Date (B3): 6/6/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/6/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2008, I WAS PUT TO SLEEP BY MY OB/GYN DR. (B)(6) TO HAVE THE ESSURE (OR AS I CALL IT (PROFANITY)) IMPLANTED IN ME. MY LIFE HAS BEEN A LIVING (PROFANITY) EVER SINCE THAT DAY. FIRST LET ME START BY SAYING I AM ALLERGIC TO CONTRAST DYE. I NEVER RECEIVED THE 3 MONTH CONFIRMATION PLACEMENT TEST. I HAVE A CONSTANT, SHARP, POKING FEELING WITH RANDOM BOUTS OF BLEEDING. MY PERIODS LAST ANYWHERE FROM 2-6 WEEKS. I CANNOT LEAVE THE HOUSE BECAUSE THERE ARE TIMES WHEN I STAND UP, NUMEROUS BLOOD CLOTS START POURING DOWN MY LEGS. MY HAIR IS FALLING OUT. I CAN'T REMEMBER ANYTHING, AND MY PREVIOUSLY PERFECT TEETH ARE NOW DETERIORATING AND BREAKING OFF. NEVER IN MY LIFE HAVE I EVER BEGGED TO HAVE A SURGERY, BUT I HAVE PRAYED EVERY NIGHT TO FIND A DOCTOR THAT WOULD DO A HYSTERECTOMY SO MY (PROFANITY) CAN END, BUT WITH MY INSURANCE (B)(6) I'M PRETTY SURE THAT WON'T HAPPEN. I JUST HOPE ANOTHER (B)(6) WOMAN DOESN'T HAVE TO LIVE LIKE I AM. THANKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044531		7/15/2015	7/22/2015

Event Information:

Event Date (B3): 7/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SHARP PAIN, LOTS OF LONG TERM PERIODS AND HEAVY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044534	BAYER	7/15/2015	7/22/2015

Event Information:

Event Date (B3): 7/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/15/2007
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN (B)(6) OF 2007. SINCE THEN I HAVE HAD THREE PREGNANCIES TO WHICH I HAVE TWO CHILDREN. I ABORTED THE OTHER. I HAVE HAD EXTREME BLOATING, PAIN IN THE LOWER ABDOMEN THAT RECURS OFTEN. MY PERIODS ARE NOW PAINFUL TO THE POINT WHERE I CANNOT GET OUT THE BED. I AM OFTEN DEPRESSED AND NO LONGER ENJOY LIFE AS I DID PRIOR TO ESSURE. IT IS PAINFUL TO HAVE PRESSURE ON MY STOMACH. I SOMETIMES BLEED HEAVILY FOR LONG PERIODS OF TIME. MY HAIR IS FALLING OUT. I HAD TO STOP WORKING BECAUSE OF THE EXTREME BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044535		7/15/2015	7/22/2015

Event Information:

Event Date (B3): 3/18/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 3/18/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN I WAS (B)(6) MY PARTNER AND I DECIDED WE DID NOT WANT TO HAVE ANY MORE KIDS. I WENT TO MY OB WHO REFERRED ME TO (B)(6) TO GET THE ESSURE PROCEDURE WHICH WAS COMPLETED ON (B)(6) 2009; I GOT A TEST COMPLETED 3 MONTHS LATER TO VERIFY THAT THE ESSURE WAS PLACED CORRECTLY. IN (B)(6) OF 2009, I TOLD MY OB ABOUT THE PAIN AND STARTED TO HAVE AND HEAVY PERIOD WHICH I WAS TOLD IT HAS AN ASSOCIATION OF ME NOT HAVING A PERIOD OF 5 YEARS DUE TO THE BIRTH CONTROL. SHE ALSO OFFERED ADD'L BIRTH CONTROL AS THE PILL OR THE SHOT WHICH AT THE TIME I WOULD ADVISE MY DOCTOR ABOUT THE ISSUES, AND SHE WOULD SAY OKAY WE WILL KEEP AN EYE AND SEE IF IT GETS WORSE. I ALSO SAW MY PRIMARY IN OCCASION WHO ALSO ADVISED IT WAS NORMAL TO BE MORE SENSITIVE DUE TO AGE AND PERIOD CYCLES. IN (B)(6), I HAD REAL BAD LOWER BACK AND THIGH PAIN I WAS UNABLE TO GET UP FROM BED FOR 3 DAYS STRAIGHT I DID NOT GO TO WORK FOR 2 WEEKS. I DECIDED TO MAKE AN APPOINTMENT WITH A CHIROPRACTOR TO TRY TO FIX THE PROBLEM OF MY LOWER BACK THAT WAS JUST CONSTANT AND DURING THE MONTH IT IS FINE BUT WHEN I GET MY PERIOD IT IS HORRIBLE CRAMP AND MY LEFT THIGH HURTS AND FALL SLEEP I HAVE HEAVY PERIOD THAT SADLY I HAD TO LEAVE WORK TO CHANGE CLOTHING. I AM UNABLE TO DO EXERCISE AND OTHER THINGS THAT I WAS ABLE TO DO; I WOULD BE THE PERSON IN MY HOME THAT COULD REARRANGE, CARRY HEAVY THINGS, DRIVE FOR MORE THAN IN HALF HOUR WITHOUT STOPPING. I HAD MY YEARLY CHECK UP ON (B)(6) 2015 WHEN IN THE MIDDLE SHE WAS NOT PLEASED WITH MY TENDERNESS. I ADVISED IT WAS GETTING WORSE TO EVEN HAVE SEXUAL INTERCOURSE DUE TO THE PAIN AGAIN. DOCTOR ADVISED IT COULD BE NUMEROUS THINGS NOT ONCE MENTION ABOUT A PROBLEM WITH ESSURE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044536		7/15/2015	7/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN BACK IN 2014, IN (B)(6) AFTER BEING PERSUADED BY MY PHYSICIAN. AFTER A FEW MONTHS I STARTED COMPLAINING OF PAIN AND SAID IT WAS IN THE RIGHT PLACE. SHE THEN LEFT ME IN THE CARE OF A NEW PHYSICIAN, BECAUSE OF UNK REASON SHE LEFT THE PRACTICE. I COMPLAINED TO THE NEW PHYSICIAN AND HE DID AN ULTRASOUND AND SAID IT WAS IN THE RIGHT PLACE AND DIDN'T KNOW WHY I WAS HAVING PAINS. I THEN REQUESTED TO HAVE A SECOND OPINION IN (B)(6) 2015, SAW A DIFFERENT PHYSICIAN AND HE DIDN'T DO ANY TEST OR ANYTHING. HE AGREED TO REMOVE IT AND I WENT IN TO HAVE IT REMOVED AND MY FALLOPIAN TUBES IN (B)(6) 2015. AFTER THE REMOVAL MY PHYSICIAN CAME IN AND SAID IT WAS IN THE CORRECT PLACE AND HE DIDN'T UNDERSTAND WHY I HAD PAIN. A FEW WEEKS LATER, AFTER THE REMOVAL, I NO LONGER HAD ANY PAIN. HAVING THE ESSURE PUT IN AND REMOVED WAS DEVASTATING. I AM NO LONGER ABLE TO HAVE CHILDREN AND MY HUSBAND AND I WERE PERSUADED INTO HAVING THE ESSURE PLACED EVEN THOUGH WE DID WANT MORE CHILDREN. THE REASON IT WAS IMPLANTED IS BECAUSE I DIDN'T HAVE REGULAR PERIODS AND AFTER BEING ON BIRTH CONTROL OFF AND ON MY PERIODS NEVER BECAME REGULAR. I WAS ONLY (B)(6) I WANTED MORE CHILDREN AND NOW MY DAUGHTER IS AN ONLY CHILD BECAUSE I CAN NO LONGER GET PREGNANT WITHOUT IN VITRO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044537		7/15/2015	7/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/20/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DONE (B)(6) 2013. I AM UNSURE WHETHER ESSURE IS THE SOURCE OF MY ISSUES, BUT I HAVE BEEN HAVING ODD MEDICAL AND PSYCHOLOGICAL ISSUES BEGINNING IN (B)(6) 2014. UNTIL I READ AN ARTICLE ON NPR YESTERDAY ABOUT AN INVESTIGATION INTO ESSURE. I THOUGHT ESSURE HAD CAUSED ME TO ENTER PERIMENOPAUSE BECAUSE I STARTED GETTING MIGRAINE HEADACHES AND VERY INTENSE PMS - ANXIETY AND DEPRESSIVE SYMPTOMS. I'M ALSO HAVING JOINT PAIN AND WEIRD WEIGHT FLUCTUATIONS WHICH UNTIL READING THE ARTICLE YESTERDAY, WOULD NEVER HAVE ASSOCIATED WITH ESSURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00509	BAYER HEALTHCARE LLC	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 10/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): FALLOPIAN TUBE OCCLUSION INSERT
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 838566

Single Use: Y
Implant Date (E6): 7/18/2011
Explant Date (E7): 1/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A CLINICAL STUDY CASE REPORT RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE SUBJECT WHO WAS INVOLVED IN A INTERVENTIONAL COMPANY-SPONSORED STUDY, (B)(4). STUDY DESCRIPTION: USE OF TRANSVAGINAL ULTRASOUND TO CONFIRM ESSURE MICRO-INSERT PLACEMENT IN WOMEN: DEMONSTRATION OF EFFECTIVENESS. SUBJECT NUMBER: (B)(4). THE SUBJECT'S MEDICAL HISTORY INCLUDED 3 PREVIOUS PREGNANCIES WITH 3 VAGINAL BIRTHS. ON (B)(6) 2011, SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 838566, INSERTED. ON (B)(6) 2014 SHE STARTED EXPERIENCING PELVIC CRAMPING, CONSIDERED AS SEVERE AND NOT RELATED TO ESSURE BY THE INVESTIGATOR. ON (B)(6) 2015 SHE WAS SUBMITTED TO A HYSTERECTOMY AND BILATERAL SALPINGECTOMY AND RECOVERED FROM THE EVENT. FOLLOW-UP INFORMATION RECEIVED FROM INVESTIGATOR ON 26-JUN-2015: THE SUBJECT DEVELOPED ABNORMAL UTERINE BLEEDING AND REQUESTED NOVASURE. FOLLOWING THE NOVASURE, SHE EXPERIENCED DAILY PELVIC CRAMPING, SEVERE AT TIMES WHICH RESULTED IN THE SUBJECT REQUESTING A HYSTERECTOMY. PATHOLOGY RESULTS WERE CONSISTENT WITH INFLAMMATORY PAIN RELATED TO THE NOVASURE ABLATION. ACCORDING TO THE INVESTIGATOR THE EVENT WAS NOT CONSIDERED SERIOUS AS IT WAS NOT RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE SUBJECT WHO WAS INVOLVED IN AN INTERVENTIONAL COMPANY SPONSORED STUDY (B)(6). SHE EXPERIENCED PELVIC CRAMPING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND WAS SUBMITTED TO A HYSTERECTOMY WITH BILATERAL SALPINGECTOMY. SHE RECOVERED AFTER THIS TREATMENT. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IT IS LISTED ACCORDING TO THE INVESTIGATOR'S BROCHURE. AFTER ESSURE INSERTION, PELVIC PAIN AND ABNORMAL GENITAL BLEEDING MAY OCCUR. IN THIS PARTICULAR CASE, THE INVESTIGATOR STATED

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PATIENT HAD ABNORMAL UTERINE BLEEDING AND WAS SUBMITTED TO AN ENDOMETRIAL ABLATION. AFTER THIS PROCEDURE, SHE EXPERIENCED PELVIC CRAMPING. SHE UNDERWENT A HYSTERECTOMY AND RECOVERED FROM THIS EVENT. THE INVESTIGATOR CONSIDERED PATIENT'S PAIN WAS NON-SERIOUS AND NOT RELATED TO ESSURE. HOWEVER, CONSIDERING BLEEDING AND PAIN ARE POSSIBLE ADVERSE EVENTS DURING ESSURE THERAPY AND AS THE DEVICES WERE IN SITU AT THE TIME OF THEIR ONSET; COMPANY CONSIDERS CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED (IN DISAGREEMENT WITH INVESTIGATOR'S ASSESSMENT). SINCE INTERVENTIONS WERE REQUIRED FOR BLEEDING AND PAIN TREATMENT; THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 26-AUG-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00510	BAYER HEALTHCARE LLC	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/14/2014
Explant Date (E7): 3/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER STATED THAT INSERTION OCCURRED (B)(6). WITHIN 3 WEEKS OF THE PROCEDURE, SHE BEGAN HAVING SHOOTING PAINS UP HER BACK, HEAVY VAGINAL DISCHARGE, YEAST INFECTIONS, BLEEDING AFTER INTERCOURSE, PANIC ATTACKS, AND DIZZY SPELLS TO WHERE SHE COULD NOT DRIVE. SHE WAS UNABLE TO TAKE CARE OF HER CHILDREN BECAUSE OF HER CONDITION. SHE RETURNED TO HER PHYSICIAN WHO INFORMED HER THAT IT COULD NOT BE THE ESSURE THAT WAS CAUSING HER PROBLEMS, BUT SHE WAS A PERFECTLY HEALTHY WOMAN WITH NO OTHER HEALTH ISSUES BEFORE ESSURE. HER PHYSICIAN TOLD HER THAT ESSURE COULD NOT BE REMOVED AND THE ONLY WAY WOULD BE TO PERFORM A HYSTERECTOMY. MONTHS WENT BY AND THE SYMPTOMS CONTINUED. AROUND THE FOURTH MONTH AFTER ESSURE, IN (B)(6) 2015, SHE BEGAN HAVING A FLUTTERING IN HER UTERUS AND THAT WAS WHEN SHE KNEW SHE NEEDED TO GET THE IMPLANTS REMOVED. ON (B)(6) 2015, ESSURE WAS REMOVED AND A TUBAL LIGATION WAS DONE. AFTER THAT, HER SYMPTOMS AND PAIN STOPPED. PTC INVESTIGATION RESULT WAS RECEIVED ON 24-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR

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CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AROUND THE FOURTH MONTH AFTER INSERTION SHE BEGAN HAVING A FLUTTERING IN HER UTERUS/PAIN. ESSURE WAS REMOVED AND HER SYMPTOMS STOPPED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR AFTER ESSURE INSERTION. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT, POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THAT HER SYMPTOMS STOPPED AFTER ESSURE REMOVAL, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION FROM CONSUMER ON 22-JUL-2015: CONSUMER WAS (B)(6) AND WAS NOT PREGNANT. SHE REPORTED THAT THREE WEEKS AFTER INSERTION SHE HAD SHOOTING PAINS UP BACK, DIZZY; SHE WAS DISORIENTATED; SHE COULD NOT DRIVE BECAUSE OF PANIC ATTACKS; SHE SAI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00511	BAYER HEALTHCARE LLC	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 6/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D30798

Single Use: Y
Implant Date (E6): 6/18/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 8/11/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 18-JUN-2015 WHICH REFERS TO A (B)(6) PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER D30798 (EXPIRATION DATE 28-NOV-2017) INSERTION ATTEMPTED ON (B)(6) 2015.

IT WAS REPORTED THAT DURING PLACEMENT IN THE OPERATING ROOM, BREAKAGE OF DELIVERY CATHETER EXTREMITY AT THE TIME OF ESSURE INSERT RELEASE OCCURRED. BILATERAL PLACEMENT WAS NOT PERFORMED (PROCEDURE WAS STOPPED). FULL DEVICE WAS KEPT (HANDLE+INSERT). NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. PROCEDURE CONDITIONS: AS USUALLY, LIQUID PHASE HYSTEROSCOPY.

LAPAROSCOPY WAS SUGGESTED.

PTC INVESTIGATION RESULT WAS RECEIVED ON 07-JUL-2015.
THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4)
FINAL ASSESSMENT:

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FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 7/01/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD D30798 (PRODUCTION DATE 03-NOV-2014 AND EXPIRATION DATE 28-NOV-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT.

MEDICAL ASSESSMENT:
THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

FOLLOW-UP RECEIVED ON 10-JUL-2015:
PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. (B)(6).
INFORMATION RECEIVED STATES THAT BREAKAGE WAS DIAGNOSED DURING PLACEMENT.

ACCORDING TO REPORTER, THE BREAKAGE AT GREEN RELEASE CATHETER LEVEL OCCURRED AT THE MOMENT OF ESSURE INSERT RELEASE. DELIVERY CATHETER EXTREMITY BROKE AND WAS STUCK INTO THE INSERT AND INTO FALLOPIAN TUBE. BOTH DELIVERY CATHETER EXTREMITY AND INSERT WERE REMOVED (THE INSTRUCTIONS IN THE IFU WERE FOLLOWED).

IN ADDITION, IT WAS REPORTED THAT IT WAS MEDICALLY NECESSARY TO REMOVE ESSURE INSERT. PATIENT DID NOT REQUEST REMOVAL.

REMOVAL METHOD: HYSTEROSCOPIC.

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THE BROKEN PIECES WERE RETRIEVED FROM FALLOPIAN TUBE WITH BLEEDING.

HEALTH CARE PROFESSIONAL INFORMED THAT NO INJURY OCCURRED AND STATES THAT BREAKAGE COULD NOT HAVE LED TO SERIOUS INJURY UNDER LESS FORTUNATE CIRCUMSTANCES.
PATIENT HAS RECOVERED FROM FALLOPIAN BLEEDING.

NO FURTHER INFORMATION WILL BE PROVIDED.

CASE CONSIDERED TO BE CLOSED.

THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA.
IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 14-JUL-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE BREAKAGE. (B)(4). BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT.

COMPANY CAUSALITY COMMENT:

THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED A BREAKAGE OF DELIVERY CATHETER EXTREMITY AT THE TIME OF ESSURE INSERT RELEASE.

THIS EVENT IS NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, BILATERAL PLACEMENT WAS NOT PERFORMED (PROCEDURE WAS STOPPED). ON THE SAME DAY, ESSURE INSERT WERE REMOVED HYSTEROSCOPICALLY. ACCORDING TO THE PHYSICIAN, NO INJURY OCCURRED. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES.

PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

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ADDITIONALLY, SERIOUS EVENT (FALLOPIAN TUBE BLEEDING) WAS REPORTED.

NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

UPDATED PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 27-AUG-2015 UPON RECEIPT OF DEVICE SAMPLE (ONE DEVICE WAS RECEIVED ON 11-AUG-2015). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: (

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00512	BAYER HEALTHCARE LLC	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 6/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/7/2014
Explant Date (E7): 8/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN NETHERLANDS ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR DEFINITIVE CONTRACEPTION. PATIENT'S MEDICAL HISTORY INCLUDED PARA1 (VAGINAL DELIVERY). SHE HAD A TRANSVAGINAL ECHO WHICH SHOWED NORMAL UTERUS AND ANNEXAE. ON (B)(6) 2014, ESSURE WAS EASILY INSERTED BILATERALLY IN 3 MINUTES AND 50 SECONDS. TWO WINDINGS WERE VISIBLE ON BOTH SIDES. ON (B)(6) 2014, AN EXTRA CONTROL WAS PERFORMED BECAUSE OF PAIN AFTER PILL STOP. GYNECOLOGICAL EXAMINATION WAS NORMAL (I.E. LAB, ECHO. NO PARTICULARS; DEVICES BILATERAL IN SITU). DIFFERENTIAL DIAGNOSIS WAS OVULATION. ON (B)(6) 2014, PATIENT DID NOT HAVE COMPLAINTS ANYMORE. FOLLOW-UP ECHO SHOWED RIGHT ESSURE DEVICE IN SITU AND THERE WAS A SUSPICION OF LEFT CURLED DEVICE. NEGATIVE PREGNANCY TEST WAS ALSO REPORTED. ON (B)(6) 2014, HSG (HYSTEROSALPINGOGRAM) AND RX LIST: TUBAL BILATERALLY CLOSED RIGHT DEVICE IN SITU (EXTRAVASATION), LEFT CURLED DEVICE. SOME SUSPICIONS WERE REPORTED: FIRST ECHO ((B)(6) 2014) PRESUMABLY LEFT DEVICE NOT PROPERLY INTERPRETED, RELATIONSHIP WITH 1X PAIN (?); TUBAL CLOSED ON HYSTEROSALPINGOGRAM (HSG); TRUSTWORTHY (?); WHAT WITH ABNORMAL POSITION LEFT DEVICE, LAPAROSCOPY NECESSARY (?). ON (B)(6) 2015, THE REPORTING PHYSICIAN WANTED TO HAVE THE ULTRASOUND AND HSG REVIEWED DUE TO PATIENT'S CYCLICAL ABDOMINAL PAIN AND AS IN ULTRASOUND IMAGE IT SEEMED THAT THE ESSURE WAS NOT SITUATED WELL. THE IMAGES WERE REVIEWED AND THE CONCLUSION WAS THAT A THING WAS NOT GOOD. ON (B)(6) 2015, ECHO AND HSG WERE CONDUCTED AGAIN. ON THE ECHO, IT SEEMED INDEED A KIND OF CURL IN THE LEFT COIL. AFTER A DYNAMIC HSG WAS MADE, BY USE OF THE BULLET FORCEPS TO MOVE THE UTERUS BACK AND FORTH, WHICH IN THE FIRST INSTANCE WAS NOT DONE, IT WAS CLEAR THAT THE

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COIL HAD PERFORATED THE FALLOPIAN TUBE HALFWAY. INCIDENTALLY, THE TUBE SEEMED TO BE CLOSED AT THE BEGINNING (OF THE TUBE). BECAUSE OF THE PERFORATION, THUS A REASON TO NOT ASSUME THE RELIABILITY OF THE ESSURE. AFTER THIS CONSULTATION IT WAS DECIDED THAT PATIENT SHOULD COME BACK FOR A LAPAROSCOPY TO REMOVE THE COIL, AND IMMEDIATELY PERFORM A TUBECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A PRODUCT ISSUE. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HSG (HYSTEROSALPINGOGRAM) SHOWED LEFT COIL HAD PERFORATED THE FALLOPIAN TUBE HALFWAY. PHYSICIAN WILL PERFORM A LAPAROSCOPY IN ORDER TO REMOVE THE COIL AND FALLOPIAN TUBE. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, ESSURE INSERTION WAS REPORTED AS EASY. AT 3 MONTHS CONTROL, PHYSICIAN SUSPECTED LEFT ESSURE WAS CURLED; LATER A FALLOPIAN TUBE PERFORATION WAS DIAGNOSED WITH DYNAMIC HSG. ALTHOUGH THE EXACT MECHANISM OF THIS PERFORATION WAS UNKNOWN, GIVEN ITS NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE AN INTERVENTION (LAPAROSCOPY) WILL BE REQUIRED FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 29-JUL-2015: REPORTER INFORMED THAT SHE WILL WAIT FOR THE LAPAROSCOPY RESULT (PLANNED TO THE END OF (B)(6) 2015) TO COMPLETE THE PERFORATION QUESTIONNAIRE. IN ADDITION, ESSURE EXPERT ASSESSMENT OF THE ESSURE IMAGES AND CD-ROM WAS PRO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044191	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 8/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER RIGHT AND LEFT ABDOMEN PAIN HEAVY PERIODS NONSTOP FOR WEEKS HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044192	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 3/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOST A OVARY AN HAD TO HAVE DERMOID CYST. REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044193	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 1/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS WAS DONE IN THE OFFICE AND I WAS GIVEN SOME VALIUM TO RELAX ME - I WASN'T ANXIOUS AT ALL AND HAVE A VERY HIGH TOLERANCE FOR PAIN. DURING THE PROCEDURE, I FELT EVERYTHING. THE MOMENT THAT HE PUT THAT FIRST COIL IN MY FALLOPIAN TUBE, IT STARTED SPASMING AND IT WAS THE MOST HORRIBLE PAIN THAT I HAVE EVER FELT IN MY LIFE, EVEN AFTER CHILDBIRTH. I BAWLED AND BAWLED AND IT TOOK ABOUT 20 MINUTES FOR THE SPASMING TO STOP AND THEN HE CONTINUED (ALL THE WHILE HE KEPT HIS INSTRUMENTS IN THERE. HE CONTINUED TO DO THE 2ND TUBE,THAT WASN'T NEAR AS BAD AS THE FIRST BUT WAS HORRIBLE PAIN. IT HAS BEEN 4 1/2 YEARS AND I HAVE PRETTY MUCH HAD A VERY HEAVY PERIOD ABOUT 20 TO 25 DAYS PER MONTH. I WOULD FIRST SPOT AND THEN AS EACH DAY WENT, THE FLOW OF MENSTRUAL BLOOD WOULD INCREASE AND THERE WAS ABOUT 2 TO 3 DAYS THAT IT WAS SO HEAVY THAT A SUPER PLUS TAMPON WOULD BE FULL WITHIN 2 HOURS - THEREFORE I WAS CHANGING MY TAMPON EVERY 2 HOURS, ROUND THE CLOCK FOR 2 TO 3 DAYS. THEN IT WOULD SLOWLY TAPER OFF AND THEN I MIGHT HAVE 1 OR 2 DAYS WITHOUT ANY BLOOD, BUT DURING THAT TIME I HAVE CLEAR MUCOUSY DISCHARGE. I HAD TO ALWAYS WEAR A PAD - I GOT 'DIAPER RASH' MANY MANY TIMES, IT WAS SO PAINFUL. I HAVE ALSO HAD LEFT SIDED PAIN - THOUGHT IT WAS MUSCULAR BUT THE DOCS DON'T SEEM TO KNOW WHAT THE PROBLEM IS OR WHAT TO DO ABOUT IT. JUST THIS PAST (B)(6) 2015 THEY HAD DID A CT SCAN OF MY PAINFUL ABDOMEN AND FOUND A 3.5 MM CYST ON MY LEFT OVARY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044194	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 2/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD CHRONIC RHINITIS SINCE (B)(6) OF 2013. HORRIBLE ALLERGIES YEAR ROUND THAT I'VE NEVER HAD BEFORE. MENSTRUAL CYCLES THAT ARE OUT OF WHACK. THEY CAN LAST 7 TO 14 DAYS AND SOMETIMES COMES TWICE A MONTH. I HAVE TO WEAR A COMBO OF PADS AND TAMPONS BECAUSE THE BLEEDING IS EXCESSIVE TO THE POINT WHERE IT'S 8 TO 10 TIMES A DAY THAT I NEED TO CHANGE. I ALSO GET HORRIBLE STOMACH PAIN AND THE DOCTORS THINK IT'S JUST MENSTRUAL CRAMPS OR POOR DIET. I HAVE NEVER HAD MENSTRUAL CRAMPS PRIOR TO ESSURE AND I HAVE IMPROVED MY DIET AND STILL HAVE THE PAIN. MY DOCTORS KEEP GIVING ME ANTIBIOTICS FOR THE RHINITIS BECAUSE THEY THINKS IT'S BACTERIAL BUT HAVE NOT DONE A CULTURE TO TEST THAT OUT. THE ANTIBIOTICS DO NOTHING! I HAVE TAKEN THEM FOR 2 WEEKS AND THEN ANOTHER ROUND OF 3 WEEKS. I AM ALSO ON FLONASE WHICH ALSO DOES NOTHING. I GET LITTLE RED DOTS AT NIGHT ALL OVER MY LEGS AND THE DOCTOR THINKS IT'S JUST ALLERGIES. I WAS TOLD TO TAKE BENADRYL FOR THIS AND IT DOES NOT WORK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044195	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 12/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED TO SUFFER FROM PAIN IN MY OVARIES. CONSTANT HEADACHES. DEPRESSION AND ANXIETY AND PANIC ATTACKS. CRAMPING WHICH I'D NEVER HAD BEFORE. FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044196	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 6/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE STOMACH CRAMPING. HUGE BLOOD CLOTS. CANNOT TIGHT MY STOMACH MUSCLES WITH STABBING PAIN. EXTREME LOW IRON. FATIGUE. MIGRAINES. WEIGHT GAIN. DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044197	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALMOST RIGHT AFTER I HAD ESSURE PLACED I NOTICED A LOT OF BLOATING AND ABNORMAL BLEEDING. MONTHS AFTERWARDS I STARTED GAINING WEIGHT FOR NO REASON. I'VE GAINED A TOTAL OF 35LBS IN THE LAST 30 MONTHS. MY PERIODS ARE VERY HEAVY AND SOMETIMES IRREGULAR. I HAVE PELVIC PAIN ALMOST ON A DAILY BASIS, HEADACHES, FATIGUE. I'VE DEVELOPED A RASH ON MY FACE THAT I NEVER HAD BEFORE PLACEMENT. NEXT MONTH I'M GETTING A TOTAL HYSTERECTOMY TO REMOVE MY UTERUS AND TUBES. I AM VERY DISSATISFIED WITH ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044198	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 5/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, MIGRAINE, STABBING PAIN IN BOTH SIDES OF LOWER ABDOMINAL AREA TO THE POINT OF NOT BEING ABLE TO MOVE, SWELLING, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044199	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 6/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PERIODS LAST FOR 3 WEEKS AT A TIME, THE CRAMPS ARE HORRID AND TAKE MY BREATH AWAY AND I START TO BLEED WHEN EVER MY HUSBAND AND I HAVE SEX IT ALSO HURTS TO HAVE SEX MOST TIMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044200	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 2/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE RASH. MY SKIN IS ALWAYS ITCHY. NO MATTER WHAT I USE IT FEELS LIKE SOMETHING IS CRAWLING ON ME AND ITS NEVER ANYTHING THERE. MY CYCLES ARE HORRIBLE. THEY COME AND GO AS THEY PLEASE. IM ALWAYS LATE. LAST LONGER THAN THE NORMAL AND THE BLOOD CLOTS ARE SCARY SO MANY OF THEM. MY HORMONES ARE ALSO ALL OVER THE PLACE I CAN GO FROM HAPPY OR SAD IN SECONDS. IM ALWAYS ANGRY. DONT HAVE ENERGY TO DO ANYTHING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044201	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 6/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE HEADACHE, HEART PALPITATIONS, DIZZINESS, NAUSEA, LEG PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044202	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 5/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEFT SIDE PELVIC PAIN AFTER INSERTION, SEVERE BLOATING, HEAVY PERIODS WITH CLOTTING, NERVE PAIN LEFT SIDE, STABBING PELVIC PAIN LEFT AND RIGHT SIDE, DEVELOPMENT OF CYSTS AFTER PROCEDURE, PAIN W/PERIODS AND LASTING OVER 2 WEEKS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044203	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE PLACEMENT OF THIS DEVICE WAS HORRIFIC, DONE IN A CLINIC, WHERE THE DOCTOR GAVE ME SO MUCH MEDICINE, I WAS UNABLE TO MOVE OR SPEAK DURING THE PROCEDURE. THE DYE TEST THREE MONTHS LATER WAS EVEN MORE PAINFUL. EVER SINCE I HAVE HAD THIS DEVICE, I HAVE STRUGGLED WITH HEADACHES, ANXIETY, DEPRESSION, HEART PALPITATIONS, PAIN IN MY TUBES, CRAMPING, HEAVY PERIODS, BRAIN FOG, FORGETFULNESS, WORSENING EYE SIGHT, TOOTH DECAY, LOSS OF LIBIDO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044204	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 2/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN BREAKING OUT IN HIVES ALL OVER MY BODY. THEY CONTINUE TO REOCCUR DAILY. ALSO AROUND THIS TIME SWELLING AND PAIN OF MY JOINTS BEGAN. MY PERIODS ARE MORE FREQUENT, TERRIBLY PAINFUL WITH VERY HEAVY BLEEDING AND LARGE CLOTS. I ALSO HAVE A CONSTANT TENDERNESS/SORENESS IN MY STOMACH THAT I HAVE NEVER HAD BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044205	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OVER A PERIOD OF SEVERAL MONTHS WHICH BEGAN APPROXIMATELY 2 YEARS AFTER PLACEMENT OF ESSURE: RASH, ABDOMINAL PAIN AND SWELLING TO THE POINT THAT I COULDN'T STAND OR WALK FOR MORE THAN A FEW MINUTES AT A TIME, SHARP STABBING PAINS IN ABDOMEN, PAINFUL TO HAVE ANYTHING LAY ON MY STOMACH/ABDOMEN (EVEN MY OWN ARM), LOWER BACK PAIN, HIP PAIN WHICH MADE IT DIFFICULT TO GET UP AFTER SITTING FOR ANY LENGTH OF TIME AND DIFFICULT TO WALK AT TIMES, MEMORY ISSUES(BRAIN FOG), MORE FREQUENT MENSTRUAL PERIODS, GENERAL FEELING OF MALAISE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044206	BAYER	7/16/2015	7/16/2015

Event Information:

Event Date (B3): 3/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STILL ALL ONGOING.... HAIR LOSS WEIGHT GAIN PAIN DAILY HEAVY PERIODS A LOT OF LARGE BLOOD CLOTS STABBING PAIN ON BOTH SIDES PLUS MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044494		7/16/2015	7/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD SEVERE BACK PAIN, SEVERE ABDOMINAL PAIN, HEAVY BLEEDING WHEN I'M ON MY CYCLE, WAS HOSPITALIZED DUE TO A BLOOD CLOT IN MY UTERUS. MY PAIN HAS BEEN CONTINUOUS; NONSTOP. I HATE I EVER HAD THE ESSURE PLACED INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044499	BAYER	7/16/2015	7/22/2015

Event Information:

Event Date (B3): 4/13/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4): NA
Lot #(E4): 12270711

Single Use:
Implant Date (E6): 4/13/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN,LEG PAIN AND VARICOSE VEIN, HAIR LOSS, RASH AND ITCHING, PAINFUL INTERCOURSE, SEVERE MENSTRUAL CRAMPS, HEAVY BLEEDING LASTING MORE THAN 1 DAY, SWOLLEN UTERUS DURING MENSTRUAL CYCLE, MIGRAINES, BLOOD CLOTS DURING MENSTRUAL CYCLE, NAUSEA, LOWER BACK PAIN AND SEVERE CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044603	BAYER	7/16/2015	7/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/7/2012
Explant Date (E7): 7/31/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DECIDED TO HAVE THE ESSURE PROCEDURE DONE. ONCE IT WAS DONE I BEGAN HAVING ISSUES SUCH AS EXTREME WEIGHTLOSS, CRAMPING, NAUSEA, NOT SLEEPING, NOT EATING. I COULDN'T KEEP GOING LIKE THIS SO I WENT TO THE DOCTOR TO FIND OUT WHAT WAS GOING ON WITH ME. NO ONE COULD TELL ME. I RACKED UP TONS OF MONEY ON DR BILLS TRYING TO FIGURE IT OUT. UPON NOT BEING ABLE TO FIND OUT I FINALLY WENT TO MY OB AND I TOLD HIM I WANTED THEM TAKEN OUT BECAUSE THEY WERE MAKING ME SICK. HE SAID THE ONLY WAY TO REMOVE THEM WAS TO DO A HYSTERECTOMY. I TOLD HIM TO DO WHAT NEEDED TO BE DONE BECAUSE I WASN'T GOING TO LIVE MY LIFE BEING IN CONSTANT PAIN AND SICKNESS. UPON REMOVAL I HAVEN'T HAD ANY ISSUES SINCE. RX MEDS: PROZAC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044608	BAYER HEALTHCARE LLC	7/16/2015	7/24/2015

Event Information:

Event Date (B3): 8/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/26/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER NEVER EXPERIENCING BLOATING BEFORE, I HAVE EXPERIENCED SEVERE ABDOMINAL BLOATING FOR ALMOST TWO YEARS SINCE MY ESSURE HAS BEEN IN PLACE. AT TIMES, MY ABDOMEN GET SO LARGE IT APPEARS THAT I AM 5-6 MONTHS PREGNANT. THAT BLOAT CAN VANISH THE NEXT DAY. THIS ALL COINCIDES WITH INSERTION OF THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044609	BAYER HEALTHCARE LLC	7/16/2015	7/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL PUT IN (B)(6) 2011. SINCE THEN I HAVE PAIN IN MY ABDOMEN AND LOWER BACK WITH HEAVY BLEEDING AND VERY PAINFUL CRAMPING ON MY PERIOD. I HAVE ATTACKS THAT I CAN'T WALK OR MOVE. I'M IN SUCH PAIN. I CALL ATTACKS BECAUSE I DON'T KNOW WHAT TO CALL THEM. I HAVE GONE TO THREE DIFFERENT DOCTORS AND NO ONE CAN TELL ME WHAT IS CAUSING THE PAIN. I DID LOOK UP THE SIDE EFFECTS ON THE IMPLANT AND I HAVE A LOT OF THEM. I WOULD LIKE TO REMOVE BUT I HAVE A HYSTERECTOMY AND I'M TOO YOUNG FOR THAT. RX MEDS: SEROQUEL, ZOLOFT, LAMICTAL, ATIVAN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00513	BAYER HEALTHCARE LLC	7/17/2015	7/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PATIENT WAS WITH A LOT OF COMPLAINTS, INCLUDING PAIN. DOCTOR PERFORMED HYSTERECTOMY ON PATIENT AND REMOVED HER TUBES. FOLLOW UP (B)(6) 2015: THE SALES REPRESENTATIVE CALLED BACK TO PROVIDE ADDITIONAL INFORMATION RECEIVED FROM THE PHYSICIAN. PATIENT'S INITIALS WERE ADDED. ESSURE WAS INSERTED ON (B)(6) 2014 AND THE PATIENT WAS TAKEN INTO OPERATING ROOM ON (B)(6) 2014 FOR A SALPINGECTOMY. SHE ALSO HAD HYSTERECTOMY WITH ANOTHER HEALTHCARE PROFESSIONAL IN THE AREA AROUND (B)(6) 2015. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY . THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT . IN SUMMARY, THERE IS

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED A LOT OF COMPLAINTS, INCLUDING PAIN. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE USE. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. THE PATIENT HAD PAIN AND UNDERWENT A SALPINGECTOMY TWO WEEKS AFTER INSERTION. EIGHT MONTHS AFTER INSERTION SHE UNDERWENT A HYSTERECTOMY. REPORTER DID NOT INFORM WHETHER ESSURE WAS REMOVED WITH SALPINGECTOMY OR ONLY LATER WITH THE HYSTERECTOMY. GIVEN THE AVAILABLE INFORMATION, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS PERFORMED THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 28-SEP-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00514	BAYER HEALTHCARE LLC	7/17/2015	7/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. ON UNSPECIFIED DATE SHE HAD THE DEVICES REMOVED DUE TO PAIN AND A POSSIBLE NICKEL ALLERGY. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD THE DEVICES REMOVED DUE TO PAIN (INTERPRETED AS PELVIC PAIN) AND A POSSIBLE NICKEL ALLERGY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO

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MEDICAL SIGNIFICANCE AND THEY ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. ALSO, PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THIS DEVICE IS IMPLANTED. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. THE TIME INTERVAL BETWEEN ESSURE INSERTION, THE ONSET OF THE EVENTS AND THE REMOVAL OF THE DEVICES WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THESE EVENTS, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REPORTED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 29-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCL

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044207	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HELL. MESSED UP PERIODS, HEADACHES, PAINFUL SEX, LOW SEX DRIVE, CONSTANT PAIN, BLOOD CLOTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044208	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 4/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE ABDOMINAL PAIN,MIGRAINE HEADACHES,JOINT PAIN,METAL TASTE IN MOUTH,PAIN DURING INTERCOURSE, MISCARRIAGE, BRAIN FOG,DIGESTIVE ISSUES, ABDOMINAL BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044209	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 12/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN HAVING DEBILITATING PAINS A DAY OR TWO BEFORE MY MENSTRUAL CYCLE, THEN TWO OR THREE DAYS INTO THE ACTUAL CYCLE. DURING THIS TIME I WOULD BECOME EXTREMELY ILL, LIGHTHEADED, AND IN TERRIBLE PAIN. I BECAME PREGNANT IN (B)(6) 2014, BUT HAD A MISCARRIAGE AT (B)(6). I BECAME PREGNANT AGAIN (B)(6) 2015, AND I'M CURRENTLY PREGNANT. I AM IN CONSTANT PAIN, UNABLE TO STAND FOR LONG PERIODS OF TIME. THE PAIN SHOOTS UP MY BACK AND DOWN MY LEGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044210	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 4/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE I SUFFERED FROM HEAVY BLEEDING LASTING 5-8 DAYS, WEIGHT GAIN, HIGH BLOOD PRESSURE, SEVERE MIGRAINES, BAD CIRCULATION, JOINT PAIN, BACK PAIN, PANIC ATTACKS, ANXIETY, SEVERE LOWER ABDOMINAL PAIN ON LEFT SIDE THAT WOULD RADIATE DOWN MY LEFT LEG DURING OVULATION, PELVIC PAIN, HAIR LOSS, DRY SKIN, TOOTH DECAY AND DETERIORATION, LOSS OF DENTAL FILLINGS, INCONTINENCE, HOT FLASHES AND MOOD CHANGES TO NAME A FEW. HAD SURGERY TO REMOVE SCAR ADHESIONS AND FINALLY HYSTERECTOMY ON (B)(6) 2015

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044211	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 1/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN WITH INTERCOURSE, GRAVES DISEASE, PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044212	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE, I'VE EXPERIENCED MIGRAINE HEADACHES, CLOUDED VISION, BLURRED VISION, LOSS OF VISION, HEART CONDITION, STROKE, HEAVING BLEEDING, CRAMPING, BLOATING, STOMACH INFECTIONS, BACK PAIN, LEG, ARM JOINT PROBLEMS, MUSCLE SPASMS. SEVERAL HOSPITALIZATION, HYSTERECTOMY, REMOVAL OF GALLBLADDER, BLOOD CLOTS RESULTING IN LIFETIME BLOOD THINNERS. WEIGHT GAIN, LOSE OF SPEECH DUE TO STROKE. GASTROINTESTINAL PROBLEMS, HYPERACTIVE THYROID, ANXIETY, DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044213	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 1/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCRUCIATING PAIN IN LOWER LEFT ABDOMEN. PAIN CAME AND WENT BUT GOT STRONGER AS MONTHS WENT BY. FELT LIKE SOMEONE WAS STABBING ME. AT TIMES IT FELT LIKE SOMETHING WAS PULLING INSIDE ME. FINALLY GOT A DOCTOR TO AGREE THAT IT COULD BE ESSURE. HAD PARTIAL HYSTERECTOMY IN (B)(6) 2012 AND HAVE NEVER HAD THE PAIN AGAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044214	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 8/15/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY HEAVY AND PAINFUL PERIODS, STOMACH PAIN, BACK PAIN, RASHES, PAINFUL SEX, ANEMIC, VITAMIN D, K DEFICIENCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044215	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/16/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A COIL MIGRATED AND ATTACHED ITSELF TO MY UTERUS. THE COILS AND MY FALLOPIAN TUBES WERE SURGICALLY REMOVED THAT DAY. THANKFULLY, THE DEVICE DID NOT PUNCTURE ANY OTHER ORGANS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044216	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 2/24/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN, EXTREME BLOATING, EXCRUCIATING MIGRAINES, STABBING PAINS, TIREDNESS, LACK OF SEX DRIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044217	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 2/27/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSISTENT LEFT-SIDED PELVIC PAIN BEGINNING 24 MONTHS AFTER THE PLACEMENT OF ESSURE. TESTS INCLUDED BLOOD TESTS, ULTRASOUNDS AND CT IMAGING. NO PRE-EXISTING CONDITION AT THE TIME OF THE ONSET OF PAIN. PAIN IS NOW CONSIDERED CHRONIC AND HAS PERSISTED FOR 8+ YEARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044218	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN HAVING VERY IRREGULAR PERIODS WITH EXTREMELY HEAVY BLEEDING. I HAD TO GO TO THE EMERGENCY ROOM ON ONE OCCASION DUE TO BLEEDING AND PAIN. I NEVER HAD ANY ISSUES WITH MY PERIOD PRIOR TO ESSURE. I HAVE SINCE HAD A TOTAL HYSTERECTOMY DUE TO ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044219	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 4/3/2013 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEFT COIL PERFORATED MY FALLOPIAN TUBE RESULTING IN AN UNWANTED PREGNANCY WHICH I HAD TERMINATED (THIS HORRIFIC SITUATION THAT I WAS FORCED IN RESULTED IN A DECISION THAT HAUNTS ME DAILY). I'VE HAD SURGERY TO REMOVE MY RIGHT FALLOPIAN TUBE AND ESSURE COIL, COSTING ME OVER $8,000. MY LEFT COIL COULD NOT BE FOUND AND REMOVED SO I AM NOW LOOKING AT A CT SCAN AND FURTHER SURGERY. ON TOP OF THIS, I HAVE BEEN DEALING WITH THE FOLLOWING SYMPTOMS: DEPRESSION, BLOATING, LOSS OF SEX DRIVE, CRAMPING, INCREASED IRRITABILITY, LOSS OF CONCENTRATION, "BRAIN FOG," TWITCH IN BELLY (LIKE BABY KICKS).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044220	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BROKE OUT IN RASH AND FOUND OUT I WAS 13 WEEKS PREGNANT. WAS TOLD RASH WAS DUE TO PREGNANCY ONLY TO STILL HAVE RASH 11 WEEKS POST PARTUM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044221	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN THAT CAUSED TWO HOSPITALIZATIONS. ALL TEST WERE NORMAL BUT PAIN COULD NOT BE TREATED WITH OUT IV MEDICATION DURING EMERGENCY VISITS. 2 YEARS OF DEALING AND I AM FACED WITH THE COILS CAUSING CYST THAT REOCCUR AND BURST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044222	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 9/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BECAME PREGNANT 6 YEARS AFTER RECEIVING THIS DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044223	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, ABDOMINAL PAIN, HEADACHES, MUSCLE PAIN, HAIRLOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044224	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 5/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL SWELLING. SWELLING IN PELVIC AREA. PELVIC PAIN. FATIGUE. BREAST TENDERNESS. HEADACHES. MOOD SWINGS. BRAIN FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044225	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLOATING, LEFT ABDOMINAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044226	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 4/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT THE TIME OF INSERTION I WAS IN SO MUCH PAIN, DESPITE AN A SEDATIVE ADMINISTERED PRIOR TO THE PROCEDURE. AT THE FIRST INSERTION I WAS WRITHING IN PAIN, CLUTCHING THE TABLE AND MOANING. A NURSE CAME OVER TO SPEAK TO ME AND ASK WHY I WAS SO UPSET. I EXPLAINED HOW PAINFUL IT WAS AND SHE ADMINISTERED MORE PAIN MEDICATION THROUGH MY IV. THE DR ATTEMPTED TO INSERT THE SECOND COIL BUT I WAS IN SO MUCH PAIN I WAS UNABLE TO REMAIN STILL. HE SAID THAT HE HAD TO CONTINUE, THAT HE COULD FORCE IT AND WENT AHEAD, DESPITE MY CRYING AND INSERTED THE SECOND COIL. I COULD HARDLY KEEP MYSELF ON THE TABLE I WAS IN SO MUCH PAIN. AFTER IMPLANTATION I REQUIRED ASSISTANCE TO WALK TO RECOVERY, AS I WAS WEAK AND SHAKING SO BAD I COULD HARDLY WALK. BEFORE I WAS DISCHARGED I WAS GIVEN A PRESCRIPTION FOR 10 HYDROMORPHONE TABLETS FOR PAIN. FOR TWO DAYS I WAS UNABLE TO FUNCTION IN MY DAILY LIFE OR CARE FOR MY CHILDREN. I WAS FORTUNATE TO HAVE FAMILY CARE FOR ME, AS I WAS UNABLE TO DO IT MYSELF. I SPENT A WEEK SLOWLY RECOVERING, BUT DID NOT FEEL 'RIGHT' FROM THE START AND WITHIN A FEW DAYS BEGAN TO RUN A LOW GRADE FEVER. I RETURNED TO WORK FOR TWO DAYS AND WAS UNABLE TO CONTINUE, SAW A DR AND WAS DIAGNOSED WITH AN INFECTION. I REQUIRED ANTIBIOTICS FOR 10 DAYS, I BELIEVE. RECOVERY FROM THE INFECTION WAS SLOW AND IT WAS ANOTHER 2 WEEKS BEFORE I FELT MYSELF AGAIN ALTHOUGH I CONTINUED TO HAVE DISCOMFORT IN MY ABDOMEN FROM THAT POINT ON. A LIST OF SYMPTOMS THAT HAVE GRADUALLY BEGUN TO PLAGUE ME SINCE ESSURE INCLUDE: ABDOMINAL DISCOMFORT AND PAIN LOWER BACK DISCOMFORT AND NO PAIN. BOTH OF THESE BEGAN AS DISCOMFORT AND HAVE PROGRESSED OVER TIME TO DAILY PAIN THAT AFFECT MY LIFESTYLE. I USED TO GO TO THE GYM AND RUN 5 KM 5 DAYS A WEEK. I AM UNABLE TO DO EITHER ANY LONGER BECAUSE OF THE CONSTANT PAIN. I HAVE GRADUALLY BEGUN TO EXPERIENCE JOINT PAIN THAT

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DOES NOT SUBSIDE. I HAVE INCREASINGLY FOGGY MENTAL CLARITY...TO THE POINT THAT I STRUGGLE FOR COMMON VOCABULARY WORDS AND CONSTANTLY LOSE MY TRAIN OF THINKING. THIS AFFECTS MY JOB, AS I AM A SCHOOL TEACHER. I HAVE CHRONIC FATIGUE, MOST DAYS IT LEAVES ME UNABLE TO GET PAST DINNER WITHOUT REQUIRING A NAP TO RECHARGE. AGAIN, I WAS AN AVID GYM GOER WITH ENERGY TO BURN. NOW I OFTEN DO NOT HAVE THE ENERGY TO MAKE IT THROUGH COOKING DINNER FOR MY FAMILY. I HAVE NOT CHANGED MY DIET IN ANY SIGNIFICANT WAY AND HAVE GAINED (B)(6) LB IN TWO YEARS. IN FACT, I HAVE SOUGHT THE ASSISTANCE OF A DIETICIAN TO HELP ME FIGURE OUT WHY I EAT CLEAN, HEALTHY AND HAVE GOOD HABITS AND YET GAIN AN UNHEALTHY AMOUNT OF WEIGHT. I EXPERIENCE DAILY ABDOMINAL BLOATING. WHEN I WAKE IN THE MORNING I HAVE A RELATIVELY FLAT ABDOMEN (GIVEN THE FACT THAT I'VE HAD 2 C-SECTIONS AND HAVE NOW GAINED (B)(6) LB AND AMP; BY BED TIME I AM SO BLOATED THAT I LOOK PREGNANT. MY SKIN/COMPLEXION HAS CHANGED DRASTICALLY. I USED TO HAVE CLEAR WONDERFUL SKIN. NOW I EXPERIENCE ACNE THAT IS ACTUALLY PAINFUL, CYSTIC IN NATURE. MY SKIN IS ALSO DRY, DESPITE THE FACT THAT I MOISTURIZE AND DRINK ON AVERAGE 120 OZ OF WATER EACH DAY. MY HAIR HAS BECOME DRY AND IS THINNING. I HAVE HAD AT LEAST 3 OCCASIONS WHERE I'VE EXPERIENCED SHARP, ALMOST CUTTING PAIN IN MY ABDOMEN THAT HAS LITERALLY RENDERED ME UNABLE TO MOVE FOR A TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044227	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 2/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED AS A STIFF BACK. PROGRESSED TO THE POINT THAT I COULD NOT BEND OVER AND HAD TO HAVE HELP GETTING UP FROM A SITTING POSITION. HAVE BEEN IN CONSTANT PAIN IN MY BACK AND HIPS EVER SINCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044228	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 3/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, BLOATING, SPOTTING, CLOTS, OVARIAN CYSTS, FOLLICLES ON OVARIES, IBS AND GALLBLADDER ISSUES, CONSTANT PAIN IN ABDOMEN, CAN'T EAT DAIRY ANYMORE, HIGH CHOLESTEROL

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044229	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 9/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MULTIPLE STROKES IN (B)(6) 2010. I HAVE HAD SEVERAL TIA'S. HAEMORRHAGED MULTIPLE TIMES, REQUIRING TRANSFUSIONS. I HAVE MIGRAINE HEADACHES. AMONG OTHER SERIOUS HEALTH ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044230	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 9/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NOT LONG AFTER IMPLANT I STARTED HAVING PAIN IN MY LOWER ABDOMEN ON THE LEFT SIDE MOSTLY BUT ALSO ON THE RIGHT. I STARTED HAVING SEVERE HEADACHES AND AFTER RECTANGULAR TRIPS TO THE ER I WAS DIAGNOSED WITH MIGRAINES. I'VE HAD VAGINAL INFECTIONS THAT DIDN'T COME FROM STIS NOR YEAST OF BV. MY BODY AND JOINTS ACHE. HEAVY MENSTRUAL CYCLE. ALSO IT WENT FROM 5-7 DAYS TO NOW 8-10+ DAYS. BLEEDING IS EXTREMELY HEAVY. DENTAL PROBLEMS. HIGH BLOOD PRESSURE. LAPAROSCOPIC PROCEDURES. DIFFERENT MEDICATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044231	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 3/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, SWELLING, FATIGUE, FOGGY MEMORY, PAIN, MIGRAINES, DEPRESSION , SEVERE MOOD SWINGS, IT'S PAINFUL TO HAVE SEX, NO INTEREST IN SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044232	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 3/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAS ESSURE PLACED FROM PLACEMENT UNTIL SALPINGECTOMY SLIGHLT BETTER EXTREME PAIN, NAUSEA VOMITING BLOATING, HEADACHES AND EXTREME TIREDNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044233	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 10/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOR TWO DAYS AFTER IMPLANTATION I HAD SEVERE CRAMPING, WHICH EVENTUALLY WENT AWAY. AFTERWARD MY PERIODS CHANGED DRASTICALLY, GOING FROM 5-7 DAYS EVERY 29 DAYS TO 21 DAYS EVERY 45 DAYS. MY DOCTOR ATTRIBUTED THIS TO DEPO PROVERA. ON (B)(6) 2015 I HAD MY HYSTEROSALPINGOGRAM PERFORMED. MY RIGHT ESSURE WENT COMPLETELY TO THE END OF MY FALLOPIAN TUBE BUT SHOWN AS BLOCKED. MY LEFT ESSURE APPEARED TO HAVE PERFORATED MY TUBE AND WAS SHOWN AS UNBLOCKED. MY DOCTOR ADVISED ME THAT I WOULD NEED TO TAKE BIRTH CONTROL TO PREVENT PREGNANCY. I REFUSED AND REQUESTED TO STILL BE STERILIZED. ON (B)(6) 2015 I HAD A BILATERAL SALPINGETOMY. MY SURGEON REPORTED TO ME THAT MY LEFT ESSURE PERFORATED MY UTERUS AND WAS LEFT INSIDE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044234	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 5/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED, WOKE UP SICK NEXT MORNING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044235	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/17/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEXUALLY PAINFUL A LOT CRAMPS PERIODS TURNED INTO NO PERIOD MENOPAUSE FELT TIRED ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044236	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 1/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOTS OF URINARY PROBLEMS INCLUDING BLADDER AND URETHRA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044237	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 7/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PELVIC PAIN, CHRONIC HIP PAIN, ULCERATIVE COLITIS, REFLUX, RASH, PAINFUL MENSTRUAL CYCLES, PAINFUL OVULATION, SEPSIS, BACK PAIN, MIGRATION, EMBEDDED IN UTERUS, CHRONIC FATIGUE, HINT PAIN, INFLAMMATION,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044238	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M HAVING PELVIC PAIN ON THE LEFT SIDE, LOWER BACK PAIN, MISSED AND IRREGULAR PERIODS, AND STOMACH BLOATING TO THE POINT WHERE I THINK I'M PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044239	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 10/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). COILS WERE IMPLANTED HAD SEVERE PAIN AS SOON AS MEDS FROM SURGERY WORE IT OFF . PAIN ALL THE TIME SHARP STABBING PAIN,WEIGHT GAIN ,BLOATING IN ABDOMEN ,DIZZY FEELING ,BRAIN FOGS WHERE I WOULD FORGET THINGS . I WAS NOT ABLE TO GET OUT OF BED BECAUSE OF PAIN AND LOW ENERGY. INTERCOURSE WAS SO PAINFUL WAS NOT ABLE TO HAVE IT .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044240	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 8/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I GOT THE DEVICE INSERTED I HAVE HAD NOTHING BUT COMPLICATIONS. I GET RANDOM BLEEDING SEVERE PAIN WHERE I CANT EXERCISE. PAINFUL SEX AND I GET PAIN THAT STOPS ME IN MY TRACKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044241	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 8/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONE COIL WENT MISSING RESULTING IN SURGERY TO FIND IT. IT WAS FOUND TO BE TUNNELING ITS WAY THOROUGH MY UTERUS. THAT ONE WAS REMOVED. DURING THAT SURGERY, MY BLADDER WAS PERFORATED RESULTING IN A CATHETER FOR A WEEK AFTER SURGERY AND I ALSO HAD MAJOR ISSUES WITH THE ANESTHESIA. THE ENTIRE TIME I HAD THIS; I WAS HAVING ABD PAIN AND EXTENSIVE BLEEDING DURING PERIODS. AFTER THE MISSING COIL WAS REMOVED, I NEEDED AN ABLATION JUST TO STOP THE BLEEDING. I HAD BLEED HEAVILY FOR 7 WEEKS STRAIGHT BEFORE THE ABLATION WAS DONE. I STILL HAVE A COIL IN MY LET SIDE AND STILL HAVE LEFT SIDED PAIN, MY HAIR IS FALLING OUT, WEIGHT GAIN, SWELLING ON THAT SIDE, NUMBNESS IN MY LEG ON THAT SIDE AND SEVERAL OTHER ISSUES THAT WERE NOT THERE BEFORE THEY WERE IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044252	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 5/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT AFTER SURGERY I STARED A RASH IN ARMS, FACE, NECK AND LEGS. I HAD BLISTERS ON MY SCALP AND BEHIND MY EARS. MY FINGER KNUCKLES WERE SWOLLEN. RIGHT AFTER THE SURGERY, THE SECOND AND THIRD NIGHT, I WOKE UP UNABLE TO BREATH. MY THROAT WAS CLOSED. I HAD TO GASP FOR AIR, IT FELT LIKE A ANAPHYLACTIC ATTACK. THIS HAPPENED TWO MORE TIMES DURING THE FIRST MONTH AFTER THE SURGERY. I HAD A SWOLLEN ABDOMEN LIKE AN EIGHT MONTH PREGNANT WOMAN. I ALSO SUFFERED FROM SEVERE CRAMPS AND EXTREMELY HEAVY PERIODS WHERE BLOOD WOULD JUST GUSH OUT AFTER A SEVERE CRAMP. I HAD BACK PAIN AND SWOLLEN FEET. AFTER TAKING MY OVER THE COUNTER ALLERGY MEDICINE I WOULD HAVE SHORTNESS OF BREATH AND THE HIVES IN MY BODY WOULD GROW IN SIZE AND START ITCHING. I BECAME ALLERGIC TO ALLERGY MEDICINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044253	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 7/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH LONG, HEAVY MENSTRUAL CYCLES, LASTING UP TO 3 WEEKS. FOR A WEEK RIGHT AFTER I GOT THE ESSURE I HAD EXTREMELY BAD STOMACH PAIN, SO MUCH I HAD TO LEAVE WORK. I STILL GET THOSE PAINS FROM TIME TO TIME. I CAN NOT LOSE WEIGHT AT ALL. I'VE TRIED ALL SORTS OF WAYS, I'VE NEVER WEIGHED THIS MUCH. I PASSED REALLY LARGE BLOOD CLOTS, SO MUCH THAT I'VE HAD TO CHANGE CLOTHES SEVERAL TIMES. AS WELL AS LEAVING TO GO TO DOCTOR BECAUSE I THOUGHT I WAS GOING TO PASS OUT. WORST DECISION I'VE EVER MADE, I SHOULD HAVE GONE THE TRADITIONAL ROUTE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044254	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS, SEVERE CRAMPS, DECREASE IN ENERGY, TOTAL HYSTERECTOMY ON (B)(6) 2015, PATHOLOGY REPORTS CAME BACK WITH CERVICITIS, ENDOMETRITIS, AND ACUTE AND CHRONIC HYPERPLASIA WITH CONFIRMED C1N3.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044255	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT CRAMPING PAIN. SOMETIMES HAVE SHARP STABBING PAIN. SWOLLEN BELLY, LOOK PREGNANT BUT AM NOT. TIRED ALL THE TIME. HEADACHES EVERYDAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044271	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, EXTREME WEIGHT GAIN, HEAVY BLEEDING, PAINFUL CRAMPING, EYE TWITCHING, LEG PAIN, BACK PAIN, BRAIN FOG, EXTREME BLOATING, PELVIC TENDERNESS, NUMBING IN ARMS AND LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044279	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 10/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESSIVE URINARY TRACT INFECTIONS. THEY GET REALLY BAD RIGHT AWAY. HAIR LOSS, JOINT PAIN, WEIGHT GAIN ETC ETC ETC. HORRIBLE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044280	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 5/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN PELVIC AREA, WENT TO GYNO AND HE FOUND CYSTS IN OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044281	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 4/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING AND PROLONG PERIOD. CONSTANT PELVIC PAIN. TINGLING SENSATION IN LEFT ARM. RIGHT KNEE PAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044282	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 12/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE PUT IN (B)(6) AND PAIN STARTED (B)(6). TO MAKE LONG STORY SHORT AFTER CALLING MY DOCTOR, ER VISITS, GOING TO SEE MY DOCTOR, CT SCAN, AND FINDING A NEW DOCTOR BECAUSE OLD ONE DIDN'T BELIEVE I HAD TO HAVE A HYSTERECTOMY BECAUSE ESSURE HAD PERFORATED MY UTERUS AND TUBE ON MY RIGHT SIDE AND POKING ME IN MY BLADDER AND MY PELVIS. THE PAIN I WAS FEELING WAS A STABBING PAIN OVER AND OVER AND OVER AGAIN. I LIVED IN A FETAL POSITION MOST OF THE TIME AND COULDN'T BARELY TAKE CARE OF MY (B)(6). THE WORST PAIN I HAVE EVER FELT!! AFTER HYSTERECTOMY AND ESSURE REMOVAL THE PAIN IN GONE!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044283	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE IMPLANT (B)(6) - HEAVY IRREGULAR PERIODS STARTED IN (B)(6) - FOLLOWED BY YEARS OF SYMPTOMS THAT PROGRESSIVELY WORSENED - AROUND (B)(6), SYMPTOMS BECAME UNBEARABLE - (B)(6) HAD HYSTERECTOMY (REMOVED CERVIX, TUBES, UTERUS) OVARIES REMAINED. YEARS OF SYMPTOMS: CONSTANT METAL TASTE IN MOUTH. SEVERE ALLERGIC REACTIONS (DOCTORS COULD NEVER DETERMINE CAUSE) - RANDOM RASHES ON FACE, INNER THIGHS, TORSO, UNDERARMS. SEVERE STAPH SORES ON LOWER TORSO/PUBIC AREA. UNBEARABLE MENSTRUAL CYCLES, IRREGULAR, EXTREMELY HEAVY FOR MORE THAN 2-WEEKS AT A TIME. SEVERE INFLAMMATION OF ABDOMEN. CONSTANT BURNING SENSATION INTERNAL (LOWER ABDOMEN) DURING OVULATION - SEVER LOWER BACK / SCIATIC PAIN DURING OVULATION. SEVERE WEIGHT GAIN. DEPRESSION. LIMITED PHYSICAL ACTIVITY DUE TO CONSTANT PAIN, ESPECIALLY DURING MENSTRUAL CYCLE (AGAIN, 2-3 WEEKS AT A TIME). VERY PAINFUL INTERCOURSE. OVARIAN CYST (RUPTURE ON MULTIPLE OCCURRENCES RESULTING IN ER VISITS). HAIR LOSS. FACIAL HAIR GROWTH. OVERALL QUALITY OF LIFE DIMINISHED FOR ALMOST 7 YEARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044284	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 11/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER ABDOMINAL PAIN ON BOTH SIDE INCLUDING BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044285	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN AND SPASMS. IRREGULAR PERIODS. BLEEDING THROUGHOUT THE MONTH. PAINFUL SEXUAL INTERCOURSE. BLEEDING AFTER SEXUAL INTERCOURSE ACCOMPANIED BY SEVERE CRAMPING. WEIGHT GAIN (20+ LBS). INABILITY TO LOOSE WEIGHT WITH RIGOROUS EXERCISE AND STRICT DIETING. IRRITABILITY. HIP JOINT PAIN AND LOWER BACK PAIN (NEITHER WAS PRESENT PREVIOUSLY). HAIR GROWTH ON CHEST AND FACE. HOT FLASHES. STABBING PAIN AND BURNING IN MY LOWER ABDOMEN JUST TO THE LEFT AND RIGHT OF CENTER. URINARY INCONTINENCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044286	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE. LOWER ABDOMEN SWELLING AND BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044287	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SHARP PAINS ON FALLOPIAN TUBES, BACK PAIN, NECK PAIN, JOINT PAINT, NERVE DAMAGE AND PAIN IN TOP OF LEGS, PAINFUL INTERIORS, SOAR BOOBS AND NIPPLE, YEAST INFECTIONS, LETHARGIC, DEPRESSION, LOSS OF LIBIDO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044288	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HARD TIME BREATHING, TINGLING IN JOINTS, HEART FLUTTERING, PAIN DURING INTERCOURSE, WEIGHT GAIN, HAIR LOSS, SKIN IRRITATION, DENTAL ISSUES, FORGETFULNESS, SLEEP APNEA, BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044289	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 3/3/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED ITCHING A LOT. I HAD CHRONIC BACK PAIN. ENDED UP HAVING TO HAVE BACK SURGERY. NEVER WOULD HEAL. HEADACHES. FINALLY HAD A HYSTERECTOMY AND HAD THE ESSURE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044290	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 2/6/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD STOMACH CRAMPS, HEADACHES, NAUSEA, VOMITING, STOMACH/PELVIC PAIN, BACK PAIN, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044291	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GALLERY BLADDER ISSUES, BLADDER ISSUES, MEMORY FOG, PAIN IN BOTH HIPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044293	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 8/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I EXPERIENCED HAIR LOSS, WEIGHT GAIN, BLOATING IN MY STOMACH, SEVERE MENSTRUAL CYCLE WITH LARGE CLOTS, SEVERE MIGRAINES AND DIZZINESS, PAIN AND NUMBNESS IN MY LEGS, HIGH BLOOD PRESSURE, ORGANS FUSING TOGETHER, AND ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044294	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 1/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING SHARP PAIN ON RIGHT PELVIC AREA. PAIN DURING INTERCOURSE. BACK PAIN IN LOWER BACK. DAYS WHERE I COULD NOT GET UP AND WALK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044295	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 3/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN THAT WILL NOT GO AWAY EVEN WITH MEDICATION. MIGRAINE AND BACK AND HIP PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044296	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 3/6/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING. PAIN IN MY SIDES. CONTRACTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044297	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE THIS ONGOING PAIN IN MY LOWER BACK ON MY RIGHT SIDE. AT FIRST I THOUGHT IT WAS PAIN FROM BLADDER INFECTION BUT I HAVE NO BLADDER INFECTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044298	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 3/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKEL ALLERGY - HAD HIVES AND RASH ALL OVER BODY ITCHING 24/7 HAD TO UNDERGO SURGERY TO HAVE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044299	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 3/11/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASHES. THINNING HAIR. HEAVY PERIODS. LOWER BACK PAIN LEG PAIN HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044300	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 6/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE,MOOD SWINGS,DEPRESSION, SEVERE TOOTH DECAY, LOW IRON, LOW THYROID, IRREGULAR PERIODS, PAINFUL PERIODS, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044301	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 9/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PELVIC PAIN. CONTINOUS HIVES. HEADACHES. VISION CHANGES. FATIGUE, METAL TASTE IN MOUTH, ACNE, INSOMNIA, SWOLLEN LEGS, RINGING IN EARS, LOSS OF PERIOD, CHANGE IN BOWELS, BLOATING IN STOMACH, BRAIN FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044302	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 11/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE EXACT DAY IT WAS PLACED IN MY BODY WAS (B)(6) 2011. MORE SIDE EFFECTS, MEMORY LOSS/ FORGETFULNESS, ACNE, HAIR LOSS, LACK OF PERIOD, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044303	BAYER	7/17/2015	7/17/2015

Event Information:

Event Date (B3): 2/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN, EXCESSIVE BLEEDING, UNCONTROLLABLE WEIGHT GAIN, MIGRAINES, ANEMIA, 2 BLOOD TRANSFUSIONS, PARTIAL HYSTERECTOMY TO REMOVE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044304	BAYER	7/17/2015	7/20/2015

Event Information:

Event Date (B3): 1/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM STILL BLEEDING EVERY TWO WEEKS WITH SPOTTING IN BETWEEN . I FEEL TIRED AND HAVE HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044305	BAYER	7/17/2015	7/20/2015

Event Information:

Event Date (B3): 6/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, STABBING LOWER ABDOMEN PAIN, MASSIVE BLOOD CLOTS WHEN MENSTRUATING, FATIGUE, HEADACHES, CHANGES IN MOOD, BLOATING, WEIGHT GAIN, SWELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044306	BAYER	7/17/2015	7/20/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ESSURE SINCE 2002 I GET HEADACHES EVERY DAY LOWER BACK PAIN CONSTIPATION HAD MY GALL BLADDER REMOVED WEIRD MENSTRUAL PERIODS BLOATING WEIGHT GAIN NUMBNESS DOWN MY THIGH ALONG WITH BURNING AND THE LIST GOES ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044307	BAYER	7/17/2015	7/20/2015

Event Information:

Event Date (B3): 6/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT FATIGUE, EXTREME JOINT PAIN, SHARP EXCRUCIATING PAINS IN ABDOMEN, RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044308	BAYER	7/17/2015	7/20/2015

Event Information:

Event Date (B3): 8/31/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AS SOON AS I GOT IT I BEGAN ITCHING ALL OVER AND STILL CONTINUES TO THIS DATE. I HAVE SHARP STABBING PAIN IN MY FALOPIAN TUBES ON AND OFF. IT'S SO SEVERE THAT IT BRINGS ME TO MY KNEES SOMETIMES. IM ALWAYS CRAMPING. MY PERIODS HAVE CHANGED. I'M EITHER 2 WEEKS LATE OR A LOT OF THE TIME I GET 2 PERIODS IN ONE MONTH. I BLEED HEAVIER THAN BEFORE ESSURE. I GAINED 40 LBS. RIGHT AFTER I HAD ESSURE PLACED AND CANNOT LOOSE IT, AND CONSTANTLY FEELING BLOATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044602	BAYER	7/17/2015	7/24/2015

Event Information:

Event Date (B3): 7/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 1/10/2011
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2011 I HAD ESSURE DONE, SINCE THEN MY CYCLES ARE HORRIBLE. SEVERE PELVIC PAINS, BODY PAINS, PAIN DURING INTERCOURSE, HEADACHES, MOOD SWINGS, VERY BLOATED AND VERY FATIGUED. I WENT TO OBGYN, HAD ULTRA-SOUND DONE AND EXAM. NOW I HAVE TO MAKE A DECISION ON EITHER PARTIAL HYSTERECTOMY OR REMOVAL OF MY TUBES WHERE ESSURE IS INSERTED. I WAS A HEALTHY PERSON, NEVER HAD ISSUES LIKE THESE BEFORE ESSURE WAS DONE. THIS IS NOWHERE NEAR FAIR THAT I HAVE TO HAVE THIS DONE. WHEN ESSURE WAS INTRODUCED TO ME I WAS NOT INFORMED THAT I WAS GOING TO SUFFER LIKE THIS. I WAS JUST TOLD YOU WILL HAVE SOME DISCOMFORT AFTER PROCEDURE BUT IT SHOULD NOT LAST LONG AND CAN TAKE IBUPROFEN FOR THIS. ALSO I WAS NEVER TESTED TO MAKE SURE I WASN'T ALLERGIC TO NICKEL WHICH I THINK THAT SHOULD HAVE BEEN DONE REGARDLESS. MY HEALTH IS DECLINING DUE TO THE ESSURE BIRTH CONTROL. RX MEDS: NAPROXEN 325 FOR PAIN. OTC MEDS: VITAMIN D 50,000 UNIT ONCE A WEEK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044605	BAYER	7/17/2015	7/24/2015

Event Information:

Event Date (B3): 11/3/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2006. HAVE HAD PAIN DURING DAILY ACTIVITIES ON THE LEFT SIDE CONTINUALLY. OVULATION IS EXTREMELY PAINFUL AND MY BODY MAY BE REJECTING THE METAL IN THE DEVICE. RX MEDS: AMBIEN, XANAX FOR SLEEPING. OTC MEDS: IBUPROFEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044610	BAYER HEALTHCARE LLC	7/17/2015	7/24/2015

Event Information:

Event Date (B3): 7/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 7/15/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE WHICH WAS INSERTED (B)(6) 2013. SINCE THEN I HAVE HAD SEVERE BUCKLING OVER PAIN, CRAMPING, WORSENING MENSTRUAL CYCLES (PASSING HALF DOLLAR SIZED CLOTS, SATURATING OVERNIGHT PAD EVERY 2 HOURS), FATIGUE, AND WEIGHT GAIN THAT HAS ONLY OCCURRED SINCE HAVING THE DEVICE INSERTED. I MADE MY PROVIDER AWARE THAT I HAVE A SENSITIVITY TO NICKEL WHICH HE SAID SHOULDN'T BE A PROBLEM WITH THIS DEVICE. NOW AT (B)(6) I AM HAVING TO UNDERGO A HYSTERECTOMY AND SALPINGECTOMY. RX MEDS: TOPIRAMATE - MIGRAINES, OTC MEDS: NONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044630	ESSURE	7/17/2015	7/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN 2012. LAST YEAR I STARTED HAVING A LOT OF CRAMPING, NOT JUST DURING MY MENSTRUAL CYCLE, BUT WHEN I HAD INTERCOURSE AND IT HURT TO HAVE SEX AND WOULD START BLEEDING AND CRAMPING AFTER. I AM NOW DEVELOPING CYSTS IN MY OVARIES AND NEVER HAD THAT PROBLEM, SO THAT COULD BE PART OF MY CRAMPING PROBLEM. MY LOW BACK AS HURT MOST OF MY LIFE, BUT THE PAIN HAS GOTTEN WORSE AND MORE FREQUENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044631	BAYER	7/17/2015	7/24/2015

Event Information:

Event Date (B3): 12/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 12/9/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL DEVICE IMPLANTED IN MY FALLOPIAN TUBES IN (B)(6) 2013. I IMMEDIATELY EXPERIENCED TREMENDOUS PAIN THAT LASTED FOR 6 MONTHS OR MORE. I STILL HAVE CRAMPING EVEN WHEN NOT ON MY MENSTRUAL CYCLE. AFTER 2 MONTHS OF NON-STOP BLEEDING, I WENT BACK TO THE DOCTOR WHO ADMINISTERED THE IMPLANTS AND INFORMED HIM OF THE PAIN AND BLEEDING. HE PLACED ME ON PROGESTERONE WHICH DID NOT STOP THE BLEEDING. I BLED NON-STOP FOR AN ADDITIONAL 4 MONTHS. I CAN NO LONGER DO SIT UPS AS A FORM OF EXERCISE BECAUSE I HAVE SHARP STABBING PAIN WHERE THE IMPLANTS ARE WHEN I TRY TO DO SIT UPS. EVERY MONTH WHEN I OVULATE, IT IS SO PAINFUL THAT I HAVE THROWN UP BECAUSE OF THE INTENSITY OF THE PAIN. MY ABDOMEN ALSO BLOATS WHEN I OVULATE. THE PAIN IS OFTEN DEBILITATING AND I HAVE TO STAY IN BED UNTIL MY BODY IS DONE OVULATING. I NOW SPOT BEFORE MY MENSTRUAL CYCLE EVEN STARTS, MY CRAMPING IS MORE SEVERE THAN BEFORE I HAD THE IMPLANTS, MY CYCLE IS LONGER, AND THE BLEEDING IS MUCH HEAVIER. INTERCOURSE IS NOW PAINFUL. AND I HAVE GAINED 50 POUNDS SINCE RECEIVING THE IMPLANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044633	CONCEPTUS/BAYER	7/17/2015	7/24/2015

Event Information:

Event Date (B3): 7/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 12266007

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS IMPLANTED IN (B)(6) 2004, I HAVE HAD SEVERE PAIN IN HIP, BACK AND JOINTS REQUIRING EPIDURAL INJECTIONS, STEROID INJECTION AND SURGERY IN 2009. NUMBNESS IN FEET AND HANDS. SURGERY FOR INCONTINENCE IN 2011. PAINFUL INTERCOURSE, AND SHARP STABBING PAIN IN ABDOMINAL AREA, VERY PAINFUL OVULATION. I HAVE SLEEP ISSUES, CHRONIC FATIGUE AND DENTAL ISSUES. BREAK OUT AND UNEXPLAINED RASHES AND NO SEX DRIVE. OTHER ISSUES INCLUDE HAIR LOSS, SEVERE NIGHT SWEATS, EXCESSIVE SWEATING. CONTINUE TO DEAL WITH ISSUES EVERYDAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044635		7/17/2015	7/24/2015

Event Information:

Event Date (B3): 7/17/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE IMPLANTED AND HAS SEVERE HEADACHES, BLOATING, FATIGUE, BLEEDING AFTER INTERCOURSE, SEVERE CRAMPING, SEVERE BACK PAIN, SEVERE TUBAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044637		7/17/2015	7/24/2015

Event Information:

Event Date (B3): 5/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE DEVICE
Device Type (E2): ESSURE DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 6/10/2011
Explant Date (E7): 5/27/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

REAL BAD PAINS, HEAVY PERIODS, LOWER BACK PAINS, AND SOMETIMES DURING SEX. I HAD A HYSTERECTOMY ON (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044638		7/17/2015	7/24/2015

Event Information:

Event Date (B3): 1/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): 6784270991
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

HELLO MY NAME IS (B)(6). I HAVE HAD THE ESSURE FOR 3 YEARS NOW. I HAVE HAD NOTHING BUT PROBLEMS FROM IT. I HAVE THE WORST CRAMPS IN MY LOWER STOMACH THAT MAKE ME CURL UP INTO A BALL OR LAY LIKE A BABY WITH MY KNEES TUCKED IN. I HAVE ALSO HAD THE WORST HEADACHES IN THE WORLD FOR DAYS AT A TIME. THEY SOMETIMES GET SO BAD THAT I GET REALLY HOT AND FEEL LIKE I AM GOING TO PASS OUT. THEY ALSO MAKE ME SICK TO MY STOMACH AND MAKE ME THROW UP (THE CRAMPS GET THAT BAD SOMETIMES TOO). I SOMETIMES HAVE TO GO AND SIT IN MY KITCHEN FLOOR WITH A COLD WASHCLOTH ON THE BACK OF MY NECK AND I PUT MY FACE OVER THE VENT IN THE FLOOR, TO LET THE COLD AIR HIT ME IN THE FACE. WHEN I GET THE HEADACHES I SOMETIMES CAN'T EVEN FUNCTION. I FEEL THE COILS ON BOTH SIDES. AND WHEN I SIT DOWN IT FEELS LIKE SOMETHING IS STABBING ME. I HAD GONE TO THE DOCTOR ABOUT THIS. AND TOLD HIM THAT I HAD BEEN TAKING IBUPROFEN AND MOTRIN FOR A 6 WEEKS. ALL THE DOCTOR TOLD ME IS THAT HE IS NOT GOING TO GIVE ME ANYTHING FOR PAIN, BECAUSE IT CAN BE ADDICTIVE. AND THAT MY PROBLEMS CAN'T BE FROM THE ESSURE BECAUSE IT HAS NO HORMONES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044309	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIODS CONSIST OF EITHER VERY HEAVY FLOW FOR LONG PERIODS OF TIME TAKING ME HOME FROM WORK BECAUSE OF THE PAIN TO ALMOST A YEAR WITHOUT A PERIOD. LOTS OF UNEXPLAINED PAIN, BLOATING, IN MY ABDOMEN. HAIR LOSS. SEVERE DANDRUFF. SEVERE IMMUNE DEFICIENCY, CONSTANTLY SICK. THRUSH, YEAST INFECTIONS. URINARY TRACK INFECTIONS. PAINFUL INTERCOURSE. UNEXPLAINABLE RASHES (I NEVER HAD RASHES BEFORE) WEIGHT GAIN. LYMPH NODES ON THE SIDE OF MY BODY THAT ESSURE IS ON ARE SWOLLEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044310	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 2/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 3 DAYS AFTER THE PROCEDURE I STARTED FEELING LIKE SOMETHING SHARP WAS STABBING ME IN MY LOWER ABDOMEN EVERY TIME I LAID ON MY BACK OR TURNED A CERTAIN WAY. AFTER ABOUT A MONTH I STARTED FEELING SICK ALL THE TIME AND I HAD A STABBING PAIN IN MY LOWER ABDOMEN ALL THE TIME. THE DOCTOR DID THE DYE TEST TO MAKE SURE THEY WERE IN PLACE AND SAID MY TUBES WERE BLOCKED IN (B)(6) 2013. IN (B)(6) 2014 I WAS REFERRED TO ANOTHER GYNECOLOGIST DUE TO THE SEVERE PAIN AND CONSTANT UTERUS INFECTION, MUCOUS DISCHARGE AND HEAVY BLEEDING. THEY DID AN ULTRA SOUND AND FOUND MY LEFT TUBE WAS FILLED WITH FLUID. I HAD BOTH TUBES REMOVED BECAUSE THE LEFT COIL HAD PROTRUDED OUT OF MY TUBE. THE RIGHT SIDE WAS HALF WAY IMBEDDED IN MY UTERUS AND THEY COULDN'T GET IT ALL BECAUSE IT BROKE. THEN I HAD AN ABLATION DONE 6 MONTHS LATER BECAUSE THE BLEEDING WAS GETTING WORSE. THEN ON (B)(6) 2015 I HAD A FULL HYSTERECTOMY BUT LEFT MY OVARIES TO GET THE REST OF ESSURE OUT. THE DOCTORS ALSO ADVISED ME IN (B)(6) 2015 I HAVE A SEVERE CASE OF A BLADDER DISEASE CALLED INTERSTITIAL CYSTITIS WHICH IS CAUSED FROM TOXINS IN THE BODY. I GOT ESSURE BECAUSE IT HAD NO HORMONES AND I WAS ON LIFE SUPPORT IN 2010 FOR BOTH LUNGS FILLED WITH BLOOD CLOTS DUE TO 4 TYPES OF BLOOD CLOTTING DISORDERS I HAVE SUCH AS PROTEIN S DEFICIENCY, PROTEIN C DEFICIENCY AND 2 TYPES OF MTHFR. NOW BECAUSE OF ESSURE MY SKIN HAS TURNED VERY SENSITIVE TO TOUCH AND I'VE HAD SEVERAL RASHES ALL OVER MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044311	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 10/26/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN WHERE THEY PLACED THE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044312	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST PERIOD SINCE INSERTION OF DEVICE AND EVERY PERIOD THERE AFTER HAVE BEEN IRREGULAR AND INCLUDE PAINFUL CRAMPING. PRIOR TO INSERTION OF DEVICE, MY PERIODS WERE EVERY 28 - 30 DAYS LASTING 3-4 DAYS AND VERY LIGHT. NOW PERIODS ARE VERY IRREGULAR, CAN BE SUPER LIGHT OR SUPER HEAVY, CAN LAST 2 DAYS OR 10 DAYS OR SKIP A MONTH. HAVE HAD EXCESSIVE WEIGHT GAIN (40 POUNDS) IN A SHORT PERIOD OF TIME (6 MONTHS) WITH NO SIGNIFICANT CHANGES IN EATING OR EXERCISE HABITS. HAVE MADE SIGNIFICANT CHANGES IN LAST 4 MONTHS TO BOTH EATING AND EXERCISE HABITS WITH NO SUCCESS IN LOSING THE WEIGHT. CONSTANTLY FATIGUED ALL THE TIME. CHANGES IN SKIN AND HAIR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044313	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 7/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED EXPERIENCING SEVERE ABDOMINAL PAINS AND PROLONGED MENSTRUAL CYCLES THAT LAST ANYWHERE FROM 1 TO 3 MONTHS BECAME VERY FATIGUED STARTED GETTING SEVERE MIGRAINES AND SHARP STABBING PAINS IN THE LEFT SIDE OF MY CHEST MY HAIR AS STARTED THING AND MY TEETH ARE CRUMBLING IN SPOTS I ALSO COMPLETELY LOST MY SEX DRIVE TO THE POINT I DIDN'T EVEN NOTICE IT WAS GONE MY HUSBAND HAD TO POINT IT OUT TO ME I OCCASIONALLY HAVE HOT FLASHES AND COLD SWEATS THAT HAVE YET TO BE EXPLAINED AS WHY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044314	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 10/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN. STARTED WHEN THE ESSURE WAS PLACED IN THE LEFT FALLOPIAN TUBE. IT FELT AS IF I WAS CONSTANTLY BEING STABBED ON THE LEFT SIDE OF MY BODY. I WAS TOLD BY THE DOCTOR THAT THE LINING OF MY FALLOPIAN TUBE IS THIN AND THE DEVICE WAS ESSENTIALLY STABBING THE LINING, BUT THAT IT SHOULD GET BETTER WITH TIME. I ALSO EXPERIENCE THE EXTREME BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044315	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 5/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT WAS EXTREMELY PAINFUL HAVING THEM INSERTED, I HAD IT DONE AT MY DOCTORS OFFICE. SINCE IMPLANTED I HAVE HAD PAIN WHERE THEY ARE IN MY BODY. ESSURE FEELS LIKE IT IS POKING MY INSIDES, SEX IS PAINFUL, IF I BEND OVER FOR TOO LONG WHERE THEY ARE HURTS, I'VE HAD BACK PAIN AND MY JOINTS ARE STIFF I HAVE A HARD TIME WALKING UP STAIRS AND STANDING UP WHEN I AM SITTING ON THE FLOOR. MY PERIOD IS IRREGULAR, I HAVE HAD MY PERIOD THE SAME DAY EVERY MONTH FOR 25 YEARS, UNTIL ESSURE. I HAVE MIGRAINES THAT I CAN'T GET RID OF EVEN WITH MIGRAINE MEDS OR PAIN MEDS. MY ABDOMEN HURTS MOST OF THE TIME. I HAVE A SWOLLEN BELLY, YES IT'S FROM ESSURE, I WEIGHED LESS 6 WEEKS BEFORE I HAD ESSURE IMPLANTED WHEN I HAD MY CHILD. I SPOT HERE AND THERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044316	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 5/6/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN IN PELVIC REGION, HEAVY IRREGULAR PERIODS; WEIGHT GAIN, BLOATED ABDOMEN, HEADACHES EVERY DAY AND OCCASIONAL MIGRAINES; FATIGUE, CONSTANT PAIN ALL OVER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044317	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 1/10/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS WAS MY FIRST OF WHAT WOULD BECOME MANY URINARY TRACT INFECTIONS; I ALSO HAD 2 PELVIC INFECTIONS (NEVER HAD THESE ISSUES UNTIL ESSURE)... FATIGUE, BLOATING, HEAVY VAGINAL BLEEDING,L ABNORMAL VAGINAL BLEEDING, PAIN WITH INTERCOURSE, LOSS OF LIBIDO, HEADACHES, NAUSEA ALL DAY EVERYDAY, PELVIC PAIN, SHARP STABBING PAIN ON RIGHT SIDE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044318	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN THE SUMMER OF 2007 I HAD ESSURE AND THEN BLED SO HEAVILY THAT I BECAME SO ANEMIC OVER TIME THAT I HAD TO HAVE BLOOD TRANSFUSIONS AND INFUSIONS...MISSING WORK AND FAMILY LIFE. I ALSO BECAME EXTREMELY DEPRESSED FROM LACK OF BLOOD AND ALMOST LOST MY FAMILY AND WANTED TO DIE. AFTER TREATMENT TO IMPROVE MY HEMOGLOBIN FROM A 5 TO AN 11.5 (17.5 PRIOR TO ESSURE) I BECAME PREGNANT AND ADVISED TO ABORT BECAUSE THERE WAS NO INFO ABOUT OUTCOMES OF A CHILD BORN WITH ESSURE. IT WAS A NIGHTMARE! I HAVE NEVER FELT THE SAME SINCE HAVING THIS PROCEDURE....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044319	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 2/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HORRIBLE MOOD SWINGS ONE MINUTE FINE THEN NEXT SNAPPING TERRIBLE MONTHLY CYCLES WERE I USE TO ONLY GO 3 OR 4 DAYS LIGHT TO MEDIUM FLOW NOW TO 12 TO 14 DAYS OF SUPER HEAVY FLOW AND TERRIBLE CRAMPING AND BACK PAIN CONSTANT BLOATING AND SOMETIME SEVERE STABBING PAIN TO WERE I CAN'T STAND UP STRAIGHT NOT TO MENTION THE HORRIBLE HAIR LOSS EVERYDAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044320	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 8/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESSIVE WEIGHT GAIN 50+ LBS, HIP PAIN, HIGH BLOOD PRESSURE, FATIGUE, LACK OF ENERGY, LOSS OF SEX DRIVE, PAINFUL SEXUAL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044321	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 6/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PERIODS BECAME EXTREMELY HEAVY AND PAINFUL. I FEEL CONSTANT PRESSURE AND ABDOMINAL BLOATING. I ALSO HAVE DEVELOPED OVARIAN CYSTS AND EXTREMELY PAINFUL OVULATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044322	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 10/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE PAIN WHEN HAVING PUT IN WAS SO UNBEARABLE. ABOUT A MONTH AFTER HAVING IT PUT IN, I STARTED HAVING ANXIETY. THEN AFTER ALL THAT EVERY YEAR SOMETHING NEW HAS HAPPENED TO ME. FROM GAINING WEIGHT TO HAVING INFECTION IN MY PRIVATE PARTS. NOW I HAVE FIBRO AND SLEEP PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044323	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWELLING OF INTESTINAL WALLS, MISCARRIAGE, NO PERIODS, MIGRAINES, HAIR LOSS, MASSIVE WEIGHT GAIN, BLOATING, DEPRESSION, ACHES, UNCONTROLLABLE CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044324	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD SURGERY ON (B)(6) 2015 TO REMOVE THE COIL IN MY UTERUS. MY DOCTOR REMOVED IT VAGINALLY. I DID NOT HAVE AN HYSTERECTOMY. I AM STILL IN PAIN WHEN MY MENSTRUAL COMES ON. I AM SCHEDULED FOR A CT SCAN (B)(6) 2015. I HAVE TO SAY THIS OVER AND OVER. I NEVER EXPERIENCED THIS TYPE OF PAIN WHEN MY PERIOD CAME ON UNTIL AFTER ESSURE WAS IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044325	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 1/8/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY ESSURE IMPLANT PLACED IN (B)(6) 2008. I HAVE BEEN HAVING PROBLEMS SINCE. I HAVE BAD PAINS IN MY LOWER LEFT SIDE OF MY STOMACH, WHEN I WAKE UP IN THE MORNINGS I HAVE MORNING SICKNESS I ALSO HAVE STABBING PAIN IN MY LOWER LEFT PART OF MY STOMACH WHEN I STRETCH LAYING FLAT ON MY BACK, I CAN NOT PREFORM CURTAIN SEXUAL POSITIONS BECAUSE OF THE PAIN, I HAVE BAD BLOATING I LOOK PREGNANT AND I AM NOT, I AM MISERABLE ALL THE TIME AND I NEVER HAD THESE PAIN OR PROBLEMS BEFORE MY ESSURE WAS PLACED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044326	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 2/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, BACK PAIN, JOINT PAIN, WEIGHT GAIN, HEAVY PERIODS, LONG PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044327	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 3/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVERY PERIOD WITH THIS, ESSURE, EVERY OTHER PERIOD SINCE IT WAS PLACED , IT FEELS AS IF THE COIL IS MOVING. IT MAKES ME LOOK AS IF I AM 6-8 MONTHS PREGNANT. THE FIRST TWO DAYS OF MY PERIOD I AM STUCK IN THE FETAL POSITION. I GET CONSTANT MIGRAINES, WHICH I NEVER HAD PREVIOUS. THE ONLY OPTION IN MICHIGAN IS A HYSTERECTOMY. ONLY SOME DOCTORS WILL MESS WITH ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044328	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 12/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THESE ARE ALL OF THE ISSUES I HAVE ACQUIRED SINCE HAVING ESSURE PLACED IN 2006: SHARP PAIN ON MY LEFT SIDE, DISCHARGE ALL THE TIME - HEAVY BLEEDING AFTER SEX, CONSTANT BLADDER INFECTIONS, MISCARRIAGE, JOINT PAIN, METAL TASTE IN MOUTH, SEVERE BLOATING, BOWEL ISSUES, EASILY BRUISED AND LASTS WEEKS, CHRONIC FATIGUE, MIGRAINES, BRAIN FOG FORGETS THINGS EASILY, MOOD SWINGS, RINGING IN EARS, HEIGHTEN ALLERGIES, GLUTEN SENSITIVITY, BOILS, ADULT ACNE, EXTREME ITCHING ON HANDS, LEGS AND STOMACH, INSOMNIA,THYROID DISEASE, BLURRED VISION, UNEXPLAINED FEVERS, DRY SKIN, WEIGHT LOSS/GAIN, INCONTINENCE, AN ENLARGED UTERUS I AM CURRENTLY SCHEDULED FOR A PARTIAL HYSTERECTOMY TO REMOVE THE COILS AND PET FIBERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044329	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 4/16/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SEVERE PELVIC PAIN ALL THE TIME HORRIBLE BLEEDING, PAINFUL OVULATION, NIGHT SWEATS HOT FLASHES, LOSS OF LIBIDO PAINFUL INTERCOURSE ON RIGHT SIDE BLEEDING AFTER INTERCOURSE SEXUAL DISFUNCTION DUE TO THE HORRIBLE PAIN URGENT FREQUENT URINATION ALL OVER BODY ACHE PAINS SEVERE PAIN IN RIGHT SIDE OF BACK HIP AND LEG CHRONIC PELVIC PAIN BLOATING BOWEL ISSUES NERVE PAIN DEPRESSION NUMBNESS IN RIGHT THIGH HIGH BLOOD PRESSURE VITAMIN D DEFICIENCY SWELLING IN LEGS AND FEET MUSCLE SPASMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044330	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAIN, SPOTTING, SWELLING FEET, HEADACHE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044331	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 1/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD SEVERAL RINGWORM TYPE RASHES ON VARIOUS PLACES OF MY BODY A WEEK AFTER GETTING ESSURE PLACED. I AM ALSO CURRENTLY EXPERIENCING SHORT-TERM MEMORY LOSS, BRAIN FOGGINESS, IRREGULAR MENSTRUAL CYCLES (I GET ONE EVERY 2 WEEKS!) MOODS SWINGS, LACK OF LIBIDO, I OCCASIONALLY EXPERIENCE TOOTHACHES AFTER HAVING ESSURE PLACED AS WELL. I'VE ONLY HAVE THIS DEVICE FOR 6 MONTHS AND I'VE EXPERIENCED TOO MANY ADVERSE SIDE EFFECTS SINCE HAVING IT PLACED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044332	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 5/13/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANOTHER MISCARRIAGE, APPROXIMATELY 6 WEEKS ALONG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044333	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 3/2/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE IMPLANTED. BLED FOR 3 MONTHS. STILL IN PAIN. ERRATIC PERIODS. LOST MY TEETH. DARK SPOTS ON SKIN. EXTREME ABDOMINAL SWELLING. HAIR LOSS. INCREASED SVT WITH HEART RATE OVER 225. RASHES. I NEED DENTURES NOW. OCULAR MIGRAINES. FATIGUE. ALL STARTED AFTER ESSURE PLACEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044334	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN FINALLY DIAGNOSED IN (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044335	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAIN. WHILE WORKING OUT I HAVE VERY SHARP PAINS IN MY LOWER STOMACH AREA. WHILE WALKING I GET PAINS THAT WILL STOP ME IN MY TRACKS. NO ENERGY. BLOATED STOMACH. BLEEDING FOR LONG TIME PERIODS. THINNING HAIR. DEPRESSION. THE PAIN IS THE BIGGEST PROBLEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044336	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 2/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS IMPLANTED (B)(6) 2011, STARTED HAVING PROBLEMS 3 MONTHS LATER, HAD TO HAVE A HYSTERECTOMY (B)(6) 2015 DUE TO ALL OF THE SIDE EFFECTS I WAS HAVING LISTED BELOW : CHRONIC DRY EYES, HAIR LOSS, JOINT PAIN, HEAVY BLEEDING, DAILY CRAMPING, EXTENDED MENSTRUAL CYCLES, MIGRATION OF COILS STARTING TO OCCUR(WAS MOVING OUT OF LEFT TUBE INTO UTERUS), CHRONIC INFLAMMATION, ARTHRITIS, WEIGHTS GAIN, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044337	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 4/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT INSERTION DR HAD HARD TIME, SEVERE PAIN, ONE WAS NOT BLOCKED, CYST , DIZZY, CRAMPS, MUSCLE DAMAGE, PAIN FULL SEX, BACTERIAL INFECTIONS, NUMBNESS, SOB, FATIGUE, DIGESTIVE ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044338	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE MEMORY LOSS, PAIN IN SIDES,LACK OF SEX DRIVE AND LOSS OF A PREGNANCY DUE TO ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044339	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 3/10/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A HYSTERECTOMY BECAUSE OF SIDE EFFECTS FROM ESSURE EXTREME BLOATING, ABDOMINAL PAIN, WEIGHT GAIN, HORRIBLE MOOD SWINGS AND ABNORMAL LAB RESULTS LOW VITAMIN D.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044340	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL BLOATING, I LOOK LIKE IM PREGNANT. SEVERE LOWER BACK AND ABDOMINAL PAIN. MENSTRUAL HEAVY WITH BIG BLOOD CLOTS. ALWAYS TIRE, NO ENERGY, VERY FORGETFUL LATELY. HAIR LOSS, SEVERE ACNE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044341	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ABDOMINAL PAIN SINCE THE IMPLANT IN 2014. MY BONES HAVE ACHED , MY MUSLES HAVE CRAMPED. MY STOMACH HAS BEEN BLOATED LIKE I'VE BEEN PREGNANT THIS WHOLE TIME. MY PERIODS ARE WORSE AND HORRIBLE. HEADACHES CONSTANTLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044342	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 1/11/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). APPROXIMATELY THREE MONTHS AFTER HAVING ESSURE IMPLANTED, I BEGAN HAVE DEBILITATING HEADACHES, CONSISTENT JOINT PAIN, IRREGULAR AND HEAVIER THAN NORMAL PERIODS, EXCESSIVE WEIGHT GAIN/BLOATING AND EXTREME IRRITABILITY. NONE OF THESE SYMPTOMS WERE PRESENT WITH ANY SORT OF CONSISTENCY PRIOR TO IMPLANTATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044343	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY, PALPITATIONS, HEADACHES, DEPRESSION, ACID REFLUX, HAIR LOSS, VITAMIN LOSS, SHORTNESS OF BREATH, ALLERGIES, CHRONIC PELVIC PAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044344	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 11/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS HAVING SEVERE ALLERGIC REACTION TO THE NICKEL THAT ESSURE IS MADE OF. I WAS BREAKING OUT IN RASHES/ HIVES ALL OVER MY BODY. I ENDED AT THE EMERGENCY ROOM DUE TO HIVES GOING INTO MY EYES. OVER TIME MY BODY JUST STARTED SHUTTING DOWN. MY IMMUNE SYSTEM WAS HORRIBLE. PARTS OF MY BODY STARTED SHUTTING DOWN. I STARTED GOING TO MY DOCTOR WITHIN THE FIRST YEAR OF HAVING ESSURE DONE AND I WAS COMPLAINING ABOUT ISSUES I WAS EXPERIENCING BUT HE INSISTED THAT IT COULDN'T EVER BE ESSURE, SO INSTEAD HE TOLD ME THAT I WAS PRE MENOPAUSAL..... I WAS ONLY (B)(6) OLD!!!!!!!! IT TOOK ME 5 YEARS BEFORE I FINALLY FOUND A DOCTOR TO LISTEN TO ME AND HELP ME. I WAS ONLY SUPPOSE TO HAVE THE ESSURE REMOVED BUT WHEN I GOT INTO SURGERY I WAS BLEEDING TO BAD SO I HAD TO HAVE BOTH OF MY FALLOPIAN TUBES REMOVED. ESSURE COSTED ME PARTS OF MY LIFE THAT I WILL NEVER GET BACK OR TIME I'VE HAD TO TAKE OFF FROM WORK!!! ESSURE ENDED UP BEING TWO SURGERIES !!!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044345	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE PERIODS WITH HUGE CLOTS AND DEBILITATING PAIN. FOGGY HEAD. DEPRESSION. STABBING PAINS. FATIGUE. WEAKNESS. PAIN PAIN...PAIN!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044346	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 10/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THIS PUT IN, I HAVE HAD SEVERE CRAMPING ALL THE TIME!!! SWOLLEN BELLY LOOKS LIKE I'M PREGNANT AT TIMES, IRREGULAR PERIODS, SOME SO HEAVY I CAN HARDLY STAND IT!!! I GET SUCH SEVERE CRAMPING I'VE GONE INTO THE ER NUMEROUS TIMES...AND THE DOCTOR NUMEROUS TIMES ALSO! I WAS/AM GOING THROUGH MAJOR BRAIN FOG...AND SINCE I HAD THESE INSERTED, I'VE BEEN DIAGNOSED WITH HYPOTHYROIDISM, SLEEP APNEA, SEVERE HEARTBURN , ADHD, GENERALIZED ANXIETY DISORDER ALONG WITH DEPRESSION AND MOODINESS SO BAD, I HAD TO GET A DIVORCE!!! MY STOMACH IS SO SWOLLEN ALL THE TIME AND BLOATED AND GASSY!!! I WAS SCHEDULED TO HAVE A HYSTERECTOMY LAST (B)(6), HOWEVER, I WENT THROUGH MY DIVORCE, LOST MY JOB AND HAD TO MOVE, SO SINCE THEN, I'VE BEEN TRYING TO GET BACK ON MY FEET, SO I CAN BE STABLE ENOUGH TO HAVE IT DONE!! I HAVE ALSO BEEN DIAGNOSED RECENTLY WITH REYODS SYNDROME AND VERY POOR CIRCULATION....EVERYTHING KEEPS GOING WRONG...THESE DEVICES NEED TO BE PULLED OFF THE SHELVES AND OUT OF OUR BODIES....I ALSO HAD A MISCARRIAGE 2 MONTHS AGO DUE TO MY ESSURE!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044347	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 11/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS ORIGINALLY TOLD NO SURGERY AND THEN ENDED UP HAVING SURGERY ANYWAY. HAVING CONSTANT ABDOMINAL PAIN. EXCESSIVE BLOATING ALL THE TIME. METALLICA TASTE VERY FREQUENT. HAVING EXCESSIVE BLEEDING. LOWER BACK PAIN. PAIN WITH INTERCOURSE. SHARP STABBING PAIN WITH CERTAIN MOVEMENTS IN MY ABDOMEN. BEEN TO OB DOCTOR SEVERAL TIMES AND TO HOSPITAL. GAVE UP ON GOING TO DOCTOR AND BEEN IN PAIN EVER SINCE I GOT THE EASIER PUT IN. THE WORST THING I EVER DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044348	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 3/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN 2013. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THE ONSET OF MY COMPLAINT STARTED IN 2014; THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. CRAMPING, SHARP/STABBING PELVIC AND OVARIAN PAIN (LEFT SIDE), ABNORMAL MENSES, OVARIAN CYST. EXCESSIVE DISCHARGE, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION, LOSS OF LIBIDO, PAINFUL PERIODS, PAINFUL INTERCOURSE (DURING AND AFTER) , LONG MENSTRUAL CYCLES, SEXUAL DYSFUNCTION, ITCHING/BURNING/STINGING/STABBING AT VAGINAL ENTRANCE, BACK/HIP/JOINT PAIN, CHRONIC PELVIC PAIN, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEADACHES AND MIGRAINES IN MORE FREQUENT PERIODS, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CLOUDINESS, FORGETFULNESS, CONFUSION), MOOD SWINGS, MAJOR HAIR LOSS, LOSS OF TEETH, BRITTLE TEETH, LETHARGIC, MASSIVE AND UNCONTROLLABLE WATER WEIGHT GAIN I HAVE BEEN SEEN BY DOCTORS. THEY HAVE DIAGNOSED ME WITH THE FOLLOWING CONDITIONS-LUPUS BUT BEEN TEST THREE DIFFERENT TIMES AND NOW THEY SAY I DON'T HAVE IT. ALL ORGANS TESTED AND FINE. CANT FIND OUT WHY I KEEP GETTING FALSE THEN POSITIVE BLOOD TESTS FOR LUPUS. SPENT NUMEROUS TIMES AND LOTS OF MONEY ON DOCTORS AND THEY CAN'T FIGURE IT OUT. THIS IS AFFECTING ME AND MY FAMILY. I'M NOT MYSELF SINCE I HAD THE ESSURE PUT IN. IT HAS AFFECTED ME TREMENDOUSLY IN A NEGATIVE WAY. MY DAYS ARE ALWAYS CHALLENGING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044349	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 1/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING BACK PAIN JOINT PAIN HIP PAIN HEADACHES MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044350	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 8/8/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, SKIN ALLERGIES, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044351	BAYER	7/18/2015	7/20/2015

Event Information:

Event Date (B3): 7/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE, ABDOMINAL PAIN, DIZZINESS, PAINFUL INTERCOURSE, NO SEX DRIVE, FATIGUE, BLOATING, DIARRHEA/CONSTIPATION, BRAIN FOG, LABOR LIKE CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044352	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 5/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, HEAVY BLEEDING, ACNE, JOINT PAIN, HAIR LOSS, SWELLING, BLOATING, LOSS OF SEX DRIVE, ITCHY RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044353	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 8/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASH ON LEG THAT PERSISTS DESPITE MULTIPLE TREATMENT ATTEMPTS. LEFT PELVIC PAIN THAT REMAINS UNDIAGNOSED DESPITE SEVERAL RADIOLOGIC STUDIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044354	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 6/17/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT BLOATING, HEADACHES, IBS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044355	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 4/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASHES, WEIGHT GAIN, HEADACHES, ALLERGY TO NICKEL, CONSTANT INFECTIONS, WILL HAVE TO HAVE A HYSTERECTOMY, ALWAYS FEELING BAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044356	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 5/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BASICALLY, BEGINNING SOON AFTER IMPLANTATION, MY MONTHLY CYCLES STARTED CHANGING. AT ONSET, I WOULD FEEL DIZZY, LIGHTHEADED AND DISORIENTED. I CONSTANTLY FELT A PULLING SENSATION AND BROUGHT THAT UP AT ANNUAL PREVENTATIVE APPOINTMENTS. EARLY IN 2015, I STARTED TO NOTICE BILATERAL FOOT PAIN OFF AND ON. I CONTRIBUTED IT TO AGING. IN (B)(6) 2015, I HAD AN EPISODE OF SUDDEN PELVIC PAIN AND NAUSEA, AS IF I WAS HAVING A BLADDER INFECTION. STOOL SAMPLES, URINE AND LABS WERE RUN. MY FOLLOWUP IS THIS FRIDAY. FOLLOWING THAT EPISODE, THE PULLING SENSATION HAS WORSENED. I HAVE STARTED HAVING MORE FREQUENT FOOT PAIN. LEG HEAVINESS STARTED IN ALONG WITH RANDOM BODY TWITCHES AND SPELLS OF EXTREME FATIGUE. DURING THE SPELLS OF FOOT PAIN, HEAVINESS AND TWITCHING, I FEEL DISORIENTED MUCH SIMILAR TO HOW I FEEL AT ONSET OF PERIOD. AFTER RESEARCHING AND SEEING THE LARGE AMOUNT OF AUTOIMMUNE DISORDERS INDUCED BY THIS DEVICE, I AM SCHEDULED TODAY TO TALK WITH A DIFFERENT PHYSICIAN FOR RECOMMENDATIONS ON REMOVAL. I AM MORE THAN READY TO GET THIS THING OUT OF MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044357	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 2/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INCREDIBLE AMOUNT OF WEIGHT GAIN EVEN THOUGH MY DIET HAS NOT CHANGED. A HUGE DESTINED STOMACH THAT NEVER GOES AWAY. MORE PAINFUL PERIODS LIKE I HAVE NEVER HAD BEFORE. THE FATIGUE IS OFF THE CHARTS AND MIGRAINE HEADACHES PUT ME OUT OF COMMISSION FOR SEVERAL DAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044358	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 3/27/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN,OVARIAN CYSTS, MUTIPLE KIDNEY PROBLEMS,MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044359	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 6/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SERIOUS PAIN AND CRAMPING FOLLOWED BY HEAVY MENSTRAL CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044360	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 2/16/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JUST BACK PAIN AND LOTS OF LOWER BELLY PAIN SINCE I GOT THE ESSURE DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044361	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 7/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIAGNOSED WITH ADENOMYOSIS BY OB. PERIOD EVERY 12 DAYS. SEVERE ABDOMINAL PAIN AND FEELING IF CONSTANT "HEAT" FROM LOWER ABDOMEN ALMOST ALL THE TIME SINCE 2010. BURSITIS IN LEFT HIP SINCE 2010. SEVER FATIGUE. PUT ON COPD INHALER. EXTREMELY HEAVY PERIODS(NEVER HAD PROBLEMS), BOILS ALL OVER BREASTS AND ABDOMINAL AREA THAT LEAVE SCARS. HIVES ON ABDOMINAL AREA. CONSTANT, EXTREME LOWER BACK PAIN TO WHERE I CAN'T STAND UP STRAIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044362	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 11/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY, PAIN IN KNEES, PAIN IN FEET, PAIN IN BACK TO SIDES, HEAVY MENSTRUAL CYCLES, PAIN WHEN URINATING, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044363	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GAINED 20LBS WHICH I CAN'T LOSE, BLOATING, ABDOMINAL PAIN, LYMPHEDEMA IS WORSE, MY SKIN CONDITION IS 10X WORSE, VERY PAINFUL PERIODS, PAINFUL SEX, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044364	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 3/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALL OVER JOINT PAIN, SKIN RASHES, LEFT SIDE SHARP SHOOTING PAIN, PAIN DURING INTERCOURSE, ABNORMAL PERIODS AND HEAVIER THAN NORMAL PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044365	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 7/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN WHILE COUGHING, PAIN DURING SEX, WEIGHT GAIN, BACK ACHE, SEVER HIP PAIN, FATIGUE, SEVERE SINUS PAIN, MIGRAINES, BLOATING

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044366	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 6/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL INTER COURSE, EXTREME PAIN DURING MENSTRUAL CYCLES, OVARIAN CYST THAT ENDED UP RUPTURING ON (B)(6) 2013. SEVERE PELVIC PAIN IN RIGHT GROIN AREA EXTREMELY FATIGUE AND HEART BURN WITH CONSTANT BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044367	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 9/30/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DATE IS APPROXIMATE. HEAVY BLEEDING, PELVIC PAIN. MY LEFT COIL PERFORATED MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044368	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS DEVICE HAS CAUSED INFLAMMATION, WEIGHT GAIN, PAINFUL JOINTS, MIGRAINES, BRAIN FOG, SKIN PIGMENT ISSUES, HEAVY BLEEDING, CRAMPS, MOOD SWINGS, INSOMNIA, LACK OF ENERGY, HEARTBURN, CONSTANT FEELING OF MY HANDS BEING ASLEEP, VISION ISSUES, HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044369	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 8/6/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASHES, BACK AND PELVIC PAIN, FATIGUE, DIZZY SPELLS, CHEST PAIN, NERVE DAMAGE, GASTROINTESTINAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044370	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 3/4/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NAUSEOUS, EXTREME RIGHT HIP AND SIDE PAIN, HEADACHES, LOSS OF LIBIDO, MOOD SWINGS, DEPRESSION, EXTREME BODY ACHES AND TIGHTNESS, WEIGHT GAIN, SEVERE BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044371	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN WHILE COUGHING, PAIN DURING SEX, WEIGHT GAIN, BACK ACHE, SEVER HIP PAIN, FATIGUE, SEVERE SINUS PAIN, MIGRAINES, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044372	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 3/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALL OVER JOINT PAIN, SKIN RASHES, LEFT SIDE SHARP SHOOTING PAIN, PAIN DURING INTERCOURSE, ABNORMAL PERIODS AND HEAVIER THAN NORMAL PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044373	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 6/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DOCTOR RECOMMENDED A UTERINE ABLATION BECAUSE OF SEVERE BLEEDING. I WAS TOLD THAT I NEEDED A FORM OF BIRTH CONTROL BECAUSE OF THE ABLATION. THEY RECOMMENDED ESSURE. I HAD BOTH PROCEDURES DONE ON (B)(6) 2014 UNDER GENERAL ANESTHESIA AT THE HOSPITAL. THEY PLACED THE ESSURE FIRST AND THEN DID THE ABLATION. IT IS MY UNDERSTANDING THAT AN ABLATION SHOULD NOT BE DONE IF YOU HAVE ESSURE AND STATES THAT IN THE ESSURE PAPERWORK, BUT IT WAS DONE ANYWAY. FROM THE MOMENT I WOKE UP I WAS IN SEVERE PAIN. THE LOWER RIGHT SIDE WAS THE WORST. THEY SAID THIS WAS NORMAL AND WOULD GET BETTER EVENTUALLY, IT DID NOT. IN (B)(6) OF 2014 I STARTED TO HAVE EPISODES OF HEAVY BLEEDING AND WENT BACK TO MY DOCTOR. THEY RAN TESTS AND SAID IT WAS A DELAYED REACTION THAT WAS NORMAL. I CONTINUED TO HAVE THESE BLEEDING EPISODES, ONE IN (B)(6), ONE IN (B)(6) AND ONE IN (B)(6). I WENT BACK TO MY DOCTOR AND COMPLAINED ABOUT IT AS WELL AS OTHER SYMPTOMS. EXTREME FATIGUE, SEVERE HEADACHES, CRAMPING LIKE I WAS IN LABOR, SHARP, STABBING PAIN IN MY LOWER RIGHT SIDE, HAIRLOSS, FLU LIKE SYMPTOMS AND RASHES. THE DID BLOOD WORK, ULTRASOUNDS AND A UTERINE BIOPSY, ALL OF WHICH WERE NORMAL. MY DOCTOR WOULD NOT LISTEN TO MY COMPLAINTS AND HIS EXACT WORDS WERE, "SINCE YOU DON'T WANT ANYMORE PERIODS, WE CAN JUST DO A HYSTERECTOMY." I WENT TO A DIFFERENT DOCTOR FOR ANOTHER OPINION AND SHE RECOMMENDED THAT HYSTERECTOMY WOULD HELP ME. THAT MY BODY IS REJECTING THE ESSURE AND CAUSING ME PROBLEMS. I WAS DIAGNOSED TODAY WITH DEPRESSION AND PUT ON MEDICATION FOR IT. I WAS ALSO PRESCRIBED HEAVY PAIN MEDICATION TO HELP WITH PAIN UNTIL THE SURGERY CAN TAKE PLACE. SINCE THE ESSURE COILS HAVE BEEN PLACED I HAVE BEEN IN PAIN AND SICK. IT HAS EFFECTED MY HEALTH AND QUALITY OF LIFE AND I WILL BE GLAD TO HAVE THEM REMOVED. I WOULD NOT RECOMMEND THEM TO ANYBODY.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044374	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 4/22/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). COILS HAVE MIGRATED TO MY UTERUS. THEY WERE SEEN THERE IN A CT SCAN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044375	BAYER	7/19/2015	7/20/2015

Event Information:

Event Date (B3): 1/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BACK PAIN BEFORE AND DURING MENSTRUAL CYCLE, EXTREMELY HEAVY BLEEDING AND CLOTTING DURING MENSTRUAL CYCLE . HAIR LOSS , MOOD SWINGS MORE RECURRENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044654	BAYER	7/19/2015	7/24/2015

Event Information:

Event Date (B3): 6/27/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): B93881

Single Use:
Implant Date (E6): 6/27/2014
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

THROUGH THE YEAR AFTER THE DEVICE WAS INSERTED, I'VE NOTICED MENSTRUAL IRREGULARITIES, SPOTTING FOR THE FIRST TWO WEEKS BEFORE THE HEAVIER 3-4 DAYS. I DO SUFFER FROM MIGRAINES 1-2 OVER MONTH, AND A TERRIBLE ALLERGY REACTION TO MY FACE. I THOUGHT IT WAS WHAT I WAS EATING, BUT CHANGED MY DIET, LESS CAFFEINE DRINKS AND HAVE FOUND THAT MY FACE STILL SUFFERS FROM BREAK OUTS. LAST, I ALSO HAVE ABDOMINAL AND BACK PAIN DURING THE COLD MONTHS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044655		7/19/2015	7/24/2015

Event Information:

Event Date (B3): 4/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/1/2009
Explant Date (E7): 6/2/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I DECIDED TO GET MY TUBES TIED IN 2009, AFTER THE BIRTH OF MY 4TH CHILD. MY OB/GYN DR. (B)(6) OFFERED THE ESSURE IMPLANTS. HE DIDN'T WARN ME OF THE SIDE EFFECTS AND HE COMPLETELY GLORIFIED THIS PRODUCT, SAYING THIS WAS A VERY SIMPLE PROCEDURE AND WITH MINIMAL PAIN. SO I AGREED TO DOING THE ESSURE. THE PROCEDURE WAS COMPLETELY HORRIBLE. IT WAS EXTREMELY PAINFUL TO WHERE I HAD TEARS COMING OUT OF MY EYES. THE COUPLE OF PILLS THEY GAVE ME BEFORE HAND DID ABSOLUTELY NOTHING FOR THE PAIN. AFTER THE PROCEDURE, I WAS HAVING A LOT OF BLEEDING. I HAD EXTREMELY HEAVY AND PAINFUL PERIODS AND I WOULD BLEED FOR UP TO 3 WEEKS AT A TIME. DR. (B)(6) SAID THAT IT HAD TO DO WITH THE OVARIAN CYSTS I HAD. NOT ONCE DID HE MENTION THAT IT COULD HAVE ANYTHING TO DO WITH THE ESSURE PRODUCT. AFTER A FEW MONTH OF THE PROBLEMS WITH PAIN AND BLEEDING. I WENT BACK IN TO DR. (B)(6) OFFICE ASKING HIM FOR HELP WITH THE PAIN AND BLEEDING. HE REQUESTED THAT I HAVE A HYSTERECTOMY SO THAT I WOULDN'T HAVE THE ISSUES ANYMORE. SO ON (B)(6) 2010, I HAD A HYSTERECTOMY. AFTER THE HYSTERECTOMY, I CONTINUED TO HAVE PAIN IN MY LOWER ABDOMEN THAT GOT SO PAINFUL SOMETIMES IT WOULD DROP ME TO MY KNEES. I THEN WENT BACK TO (B)(6) AND WAS TOLD THAT IT WAS THE CYSTS BURSTING. SO I JUST ENDURED THE PAIN AND WENT ON WITH MY LIFE. STARTING THIS YEAR 2015, THE PAINS WOULD COME AND STAY LONGER. ON (B)(6), I WAS IN EXTREME PAIN THAT I HAD TO STAY I BED ALL WEEKEND. WITH THE PAIN SO LOW IN MY LOWER LEFT ABDOMEN, I THOUGHT IT WAS MY APPENDIX, SO I WENT INTO THE ER AT (B)(6), THE DR'S 3 DIFFERENT ULTRASOUNDS AND SAID MY APPENDIX WAS FINE AND THAT I DID HAVE OVARIAN CYSTS, BUT THEY COULDN'T UNDERSTAND WHERE THE PAIN WAS COMING FROM SO THEY DID A CT SCAN. THE CT SCAN SHOWED I HAD STILL HAD THE ESSURE IN MY BODY, BUT THEY SURE IF THAT'S WHAT WAS CAUSING THE PAIN. SO I HAD TO WAIT ONE MORE WEEK TO GO AND SEE A DOCTOR

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BECAUSE MY INSURANCE DIDN'T START TILL (B)(6). THEY WANTED ME TO GO BACK THE NEXT DAY IF I STILL HAD PAIN AND THAT THEY WOULD MAYBE HAVE TO DO AN EXPLORATORY SURGERY, BUT WITH NO INSURANCE MY BILL WAS (B)(6), SO I DECIDED TO TOUGH IT OUT TILL (B)(6). I WENT IN TO SEE DR. (B)(6). SHE GAVE ME A STAT REFERRAL TO A OB/GYN. I WENT AND SAW DR. (B)(6) WHO SAID WE NEED TO GO IN AND TAKE THE ESSURE OUT. I HAD THE SURGERY ON (B)(6) 2015. DR. (B)(6) OPENED ME UP AND FOUND THAT WHEN I HAD MY HYSTERECTOMY THAT DR. (B)(6) HAD CUT MY FALLOPIAN TUBE EXPOSING THE ESSURE WHICH ADHERED TO OTHER TISSUE WHICH WAS CAUSING THE PAIN. DR. (B)(6) REMOVED THE RIGHT OVARY AND FALLOPIAN TUBE WITH THE ESSURE. SINCE I HAVE HEALED FROM THE SURGERY, I HAVE HAD NO MORE PAIN IN MY ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00515	BAYER HEALTHCARE LLC	7/20/2015	7/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64472

Single Use: Y
Implant Date (E6): 6/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C64472, IMPLANTED ON (B)(6) 2015. DURING PLACEMENT, IN THE OPERATING ROOM, DEVICE BROKE AT THE FIFTH COIL LEVEL ON TUBAL ORIFICE AREA. THERE WAS NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS PERFORMED, BUT THE SURGEON WAS NOT SURE ABOUT METHOD'S EFFICACY AS INSERT WAS PARTIAL. FOLLOW-UP RECEIVED ON 10-JUL-2015: INFORMATION RECEIVED STATES THAT BREAKAGE WAS DIAGNOSED VIA HYSTEROSCOPY DURING PLACEMENT. THE INSTRUCTIONS IN THE IFU WERE FOLLOWED. HEALTH CARE PROFESSIONAL REPORTED THAT ESSURE INSERT WAS NOT REMOVED AND STATES THAT IT WAS NOT MEDICALLY NECESSARY TO REMOVE IT. THE BROKEN PIECES WERE RETRIEVED FROM UTERUS AND PATIENT EXPERIENCED NO INJURY. ACCORDING TO THE REPORTER, THE BREAKAGE COULD NOT HAVE LED TO SERIOUS INJURY UNDER LESS FORTUNATE CIRCUMSTANCES. NO FURTHER INFORMATION WILL BE PROVIDED. CASE CONSIDERED TO BE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE DEVICE BROKE AT THE FIFTH COIL LEVEL ON TUBAL ORIFICE AREA. THIS EVENT, REGARDED AS DEVICE BREAKAGE, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, A PRODUCT TECHNICAL ANALYSIS WILL BE PERFORMED TO FURTHER INVESTIGATE THE EVENT. HOWEVER, CONSIDERING IT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD

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TO DEATH OR SERIOUS HEALTH DETERIORATION, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 27-AUG-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE W

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00516	BAYER HEALTHCARE LLC	7/20/2015	7/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C40061

Single Use: Y
Implant Date (E6): 6/2/2015
Explant Date (E7): 6/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 22-JUN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE GENERIC REIMBURSEMENT PROGRAM. THE PATIENT'S MEDICAL HISTORY INCLUDED PARA II AND CAESAREAN SECTION (2010). NO UTERINE ABNORMALITIES OR UTERINE SURGERIES IN ANAMNESIS. ON (B)(6) 2015 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C40061, INSERTION ATTEMPTED. THE INSERTION WAS NOT PERFORMED POSTPARTUM, NOT DURING BREAST-FEEDING, NOT AFTER CURETTAGE AND NOT POST ABORTION. IT WAS REPORTED THAT, DURING THE PROCEDURE, ESSURE DID NOT RELEASE FROM DEVICE AFTER THE FOLLOWED PROCEDURE. BROKE OFF AND REMAINING PART WAS REMOVED WITH FORCEPS. A NEW ESSURE INSERTION HAS ALREADY BEEN PERFORMED AND ESSURE WAS CORRECTLY INSERTED ON BOTH SIDES. ESSURE WAS STILL INSERTED. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SOLICITED MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE ESSURE DID NOT LET GO OF DEVICE AFTER FOLLOWED PROCEDURE (INTERPRETED AS DEVICE DEPLOYMENT ISSUE) AND ESSURE BROKE OFF (DEVICE BREAKAGE). THESE EVENTS ARE NON-SERIOUS. DEVICE DEPLOYMENT ISSUE IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE DEVICE BREAKAGE IS UNLISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THE PRESENT CASE, THE EVENTS OCCURRED DURING THE ESSURE INSERTION PROCEDURE. THEREFORE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. A NEW ESSURE INSERTION WAS PERFORMED AND ESSURE WAS CORRECTLY INSERTED ON BOTH SIDES. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID

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NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 20-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00517	BAYER HEALTHCARE LLC	7/20/2015	7/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. THE PATIENT'S HYSTEROSALPINGOGRAM (HSG) FOR PROCEDURE WAS PERFECT PLACEMENT AND OCCLUSION ON AN UNKNOWN DATE IN 2014. THE PATIENT WROTE A LETTER TO THE PHYSICIAN AND STATED THAT ON (B)(6) 2015 SHE HAD HER RIGHT OVARY AND TUBE REMOVED. SHE HAD A WEIGHT GAIN OF (B)(6), PELVIC PAIN, IRREGULAR CYCLES, FATIGUE, BLOATING, HEADACHES, JOINT PAIN, VAGINAL PAIN AND IRRITATION. PATIENT REFUSED TO ALLOW HER NAME TO BE PROVIDED TO COMPANY AT THIS TIME. FOLLOW-UP INFORMATION RECEIVED ON 22-JUN-2015 NO NEW CLINICAL INFORMATION RECEIVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 01-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4), AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY . THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL

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EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. IT WAS REPORTED THAT AN HYSTEROSALPINGOGRAM WAS PERFORMED AND THE RESULT SHOWED PERFECT PLACEMENT AND OCCLUSION. PATIENT HAD HER RIGHT OVARY AND TUBE REMOVED. CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO REQUIRED INTERVENTION, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 01 OCT 2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00518	BAYER HEALTHCARE LLC	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 1/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C40061

Single Use: Y
Implant Date (E6): 1/23/2015
Explant Date (E7): 3/16/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER C40061). PHYSICIAN REPORTED THAT THE ESSURE INSERTION WAS UNCOMPLICATED WITH ONE WINDING IN BOTH SIDES DUE TO A BIT THICKER ENDOMETRIUM, HE DECIDED FOR A HSG (HYSTEROSALPINGOGRAM). SINCE INSERTION PATIENT HAD CONTINUOUS PAIN ON LEFT SIDE UNDER ABDOMEN. NO FEVER OR OTHER COMPLAINTS. IN 2015, LABORATORY TESTS AND X-ABDOMINAL OVERVIEW SHOWED NORMAL VIEW, NORMAL ESSURE SHAPE. AS THE COMPLAINTS PERSISTED IT WAS DECIDED FOR A LAPAROSCOPIC TUBECTOMY. ON (B)(6) 2015, AN UNCOMPLICATED LAPAROSCOPY WITH TUBECTOMY WAS PERFORMED; NO PERFORATION. HEREAFTER, NO PAIN COMPLAINTS ANYMORE. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD (B)(4) (PRODUCTION DATE 31-MAR-2014 AND EXPIRATION DATE 31-MAR-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN,

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POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 3 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH 2 CASES REFER ALSO TO A SIMILAR TYPE OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 16-JUL-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ABDOMINAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO EXPERIENCED PAIN ON LEFT SIDE UNDER ABDOMEN SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A LAPAROSCOPIC SALPINGECTOMY AND RECOVERED FROM THE PAIN. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, GIVEN THE CLOSE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED EVENT AND AS IT RECOVERED WITH DEVICES REMOVAL; CAUSALITY CANNOT BE EXCLUDED. DUE TO THE REQUIRED INTERVENTION, THIS CASE WAS CONSIDERED AN INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044420	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 10/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD SEVERE MIGRAINES AND PELVIC PAIN THAT STARTED ALL AROUND THE SAME TIME. I'VE NEVER HAD PAIN LIKE THIS BEFORE IN MY LIFE. I'VE BEEN TO SEVERAL DOCTORS AND NONE CAN FULLY EXPLAIN WHAT IS GOING ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044421	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ESSURE DEVICE WAS PUT IN ON (B)(6) 2013. WHILE IN RECOVERY MY LEFT SIDE WAS IN SO MUCH PAIN I WAS SCREAMING, I WENT HOME AND HAD MASSIVE BLEEDING, THE DR SAID IT WAS NORMAL, MULTIPLE TIMES I WENT TO THE DR COMPLAINING OF THE PAIN THE BLEEDING LASTED WELL OVER A YEAR, I WENT TO ANOTHER OB WHO PERFORMED AN ABLATION IN THE HOSPITAL AND ENDED UP FINDING A MIGRATED COIL FROM MY RIGHT SIDE. THE MASSIVE PAIN I AM IN EVERYDAY OF MY LIFE IS ON THE LEFT NOW ONLY. THE PAIN GOES INTO MY LEG. INTERCOURSE IS SO SO SO PAINFUL AND I BLEED FOR DAYS AFTER WITH MASSIVE PAIN. EVERYDAY I FEEL LIKE THERE IS SOMETHING SHARP STABBING ME AND I FEEL LIKE THE LEFT ONE CAME OUT OR IS COMING OUT. AFTER MANY MANY DR AND ER VISITS I AM CURRENTLY SEEING THE CHIEF OF OBGYN IN (B)(6) HOSPITAL ON (B)(6), AND WE ARE IN DISCUSSION OF A HYSTERECTOMY, HOWEVER IT IS MORE DIFFICULT BC IT'S ONLY MY LEFT SIDE RIGHT NOW BC THE ESSURE IS NO LONGER ON MY RIGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044422	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 11/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED BLEEDING AND IT WOULD NOT STOP. IT HAD A STRANGE COLOR. NOT MY NORMAL PERIOD. WENT ON FOR MONTHS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044423	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS UNTIL DR FELT GAVE ME NO OTHER OPTIONS FOR BIRTH CONTROL, SAID IT WAS A SIMPLE IN OFFICE, OUTPATIENT PROCEDURE THAT WAS PAINLESS AND NO SIDE AFFECT EXCEPT FOR MILD CRAMPING AFTER INSERTS. THAT WAS FAR FROM THE TRUTH. I HAVE BEEN IN HORRIBLE PAIN EVER SINCE, I HAVE BEEN FORCED TO UNDERGO A HYSTERECTOMY AND AM STILL IN CONSTANT PAIN. I FEEL LIKE MY LIFE HAS CHANGED IN SO MANY WAYS FROM THIS DEVICE AND I'M AFRAID THAT I'M NEVER GOING TO NOT BE IN PAIN.. I'M PRETTY SCARED. I WANT THE PAIN GONE, I WANT A INTIMATE RELATIONSHIP WITH MY HUSBAND OF NOW (B)(6). AND I REALLY WANT NO OTHER WOMEN OR FAMILIES TO ALLOW THEMSELVES TO FALL VICTIM TO THIS DEVICE OR THE HANDS OF THEIR DOCTOR. SO MUCH MORE TO SAY BUT SINCE. ... ESSURE MADE ME SICK AND ON TOP OF BEING A MOTHER I AM ALSO THE MOM TO A SPECIAL NEEDS BABY WITH DOWN SYNDROME. SO PLEASE BARE WITH ME AND IF YOU WOULD LIKE MORE INFORMATION THEN I'D BE HAPPY TO SEND YOU MORE DETAILS VIA EMAIL AT A LATER TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044424	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK, JOIN, MUSCLE PAIN, HAIR LOSS, COIL MIGRATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044425	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 10/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD SEVERE MIGRAINES AND PELVIC PAIN THAT STARTED ALL AROUND THE SAME TIME. I'VE NEVER HAD PAIN LIKE THIS BEFORE IN MY LIFE. I'VE BEEN TO SEVERAL DOCTORS AND NONE CAN FULLY EXPLAIN WHAT IS GOING ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044426	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 5/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHY DOES MY REPORT STILL SAY PENDING? MY REPORT DAY IS WRONG IT'S SAYING THE DATE I GOT IT IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044427	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 1/15/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE PROCEDURE ITSELF WAS EXTREMELY PAINFUL AND I MISSED 2 DAYS OF WORK. I HAVE EXPERIENCED HEAVY PERIODS LASTING 2- 3 MONTHS AND NOW I HAVE PERIODS WITH SEVERE PAIN AND CLOTTING TWICE A MONTH. I HAVE SHARP STABBING PAINS IN MY PELVIC AREA AND FATIGUE. I HAVE VAGINAL BURNING THAT IS NOT A YEAST INFECTION AND I BELIEVE IT TO BE A REACTION TO THE TOXIC MATERIALS IN THIS DEVICE. I AM SCHEDULED FOR A HYSTERECTOMY ON (B)(6) 2015 THANKS TO THIS PRODUCT. MY HSG SHOWS ONE OF MY COILS LOOKS TWISTED AND BENT, MY NEW DOCTOR SUSPECTS IT HAS PERFORATED THE TUBE AND MAY BE BROKEN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044428	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 10/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAVE HAD THE ESSURE IMPLANTED I HAVE HAD A LOT OF PAIN DUE TO IT. I HAD TO HAVE A HYSTERECTOMY ON (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044429	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 4/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN SWELLING, HAVING SHARP PAIN, HAIR LOSS, MAJOR WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044430	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THE ESSURE PROCEDURE DONE I HAVE HAD SEVERE MOOD SWINGS. I HAVE ALSO SUFFERED WITH PAIN IN MY LOWER RIGHT ABDOMEN, THE PAIN CAN BE PRETTY SEVERE AT TIMES. ANOTHER EFFECT I HAVE HAD SINCE HAVING THE ESSURE PROCEDURE, IS INTERMITTENT BLEEDING AFTER INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044431	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 8/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE I HAVE HAD LOWER LEFT ABDOMINAL PAIN AND TENDERNESS, PAINFUL INTERCOURSE, FATIGUE, JOINT PAIN, HEAVY AND LONG MENSTRUAL CYCLES AND BRAIN FOG AND HAVE BEEN DIAGNOSED WITH ENDOMETRIOSIS. I HAVE ALWAYS BEEN HEALTHY AND HAVEN'T HAD ANY PHYSICAL AILMENTS UNTIL AFTER I HAD THE ESSURE PLACEMENT. HAVE HAD ULTRASOUNDS AND MRI DONE WITH NO DIAGNOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044432	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE PAIN IN ABDOMEN AREA,TWO MENSTRUAL PERIODS A MONTH, LOOKS LIKE I AM SIX MONTHS PREGNANT (WE CALL THIS EBELLY), HAIR FALLS OUT, INSOMNIA, HURTS WITH INTERCOURSE, BEEN TO HOSPITAL SEVERAL TIMES FOR THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044433	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/5/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR FALLING OUT JOINT PAINS HEART FLUCTUATES FROM TIME TO TIME BRAIN FOG I CAN'T REMEMBER ANYTHING. CONSTIPATION BUTT PAINS ON MY RIGHT AND TAIL BONE NASTY TASTE IN MY MOUTH. NAUSEA GAS BREAKING OUT IN VAGINA. SEVERE PAINS IN LOWER STOMACH TO THE POINT I CAN NOT FUNCTION!! BIG BELLY I LOOK PREGNANT. HARD TO HEEL. LONG PERIOD CRAMPING SEVERELY BLOOD CLOTS . PAIN IS EXTREMELY SEVERE. U T I... ALL THE TIME. SLEEPY. BLEED DURING SEX . DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044434	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, HEAVY PERIODS, LOW LIBIDO, CYST ON OVARIES, WEIGHT GAIN, JOINT PAIN, SEVERE CRAMPING, LOWER BACK PAIN, BACTERIA VAGINOSIS, PAIN DURING SEX, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044435	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 11/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) SEVERE BACK PAIN, MENSTRUAL CYCLE ALL OUT OF CONTROL. SOME MONTHS WILL SPOT ALL MONTH OTHERS WILL NOT HAVE A PERIOD OR IT WILL BE REALLY HEAVY AND LAST A LONG TIME. NEVER HAD THESE ISSUES BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044436	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 2/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I HAD THE DEVICE PLACED ON (B)(6) 2007. SINCE PLACEMENT I HAVE HAD SEVERE BACK PAIN, GROIN PAIN, BREAKOUTS WITH HIVES, WEIGHT GAIN, INABILITY TO LOSE WEIGHT, WATER RETENTION, MIGRAINES, THE FAMOUS EBELLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044437	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 12/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY HEALTH STARTED DECLINING BIG TIME AFTER MY FIRST REPORT. I STARTED HAVING ABDOMINAL CRAMPS ABOUT 3 WEEKS OUT OF THE MONTH, HAIR LOSS, HIVES, EXCRUCIATING BACK AND PELVIC PAIN, DIGESTIVE PROBLEMS AND JOINT PAIN, ALONG WITH THE PROBLEMS I WAS ALREADY HAVING. ON (B)(6) 2015, ONLY 10 MONTHS AFTER I GOT ESSURE AND 5 WEEKS BEFORE MY (B)(6), I HAD A TOTAL HYSTERECTOMY. DURING SURGERY MY DOCTOR SAW THAT THE LEFT COIL HAD PERFORATED MY TUBE, WHICH SHOULD ACCOUNT FOR A LOT OF THE PAIN I WAS IN. LESS THAN A WEEK AFTER SURGERY MY HIVES AND JOINT PAIN WENT AWAY. THE BACK PAIN HAS IMPROVED A LOT AND HAS ONLY OCCURRED 2 TIMES IN THE PAST 4 MONTHS, WHILE BEFORE IT WAS A FEW TIMES A WEEK. I'VE ONLY HAD 2 UTIS IN 4 MONTHS WHICH IS DEFINITELY AN IMPROVEMENT BECAUSE I HAD ONE AT LEAST ONCE A MONTH WHEN I HAD ESSURE. I DON'T HAVE TO WEAR PADS ALL THE TIME BECAUSE I DON'T LEAK URINE ANYMORE. BEFORE SURGERY I THOUGHT I WAS SO TIRED ALL THE TIME BECAUSE OF MY KIDS BUT SINCE MY HYSTERECTOMY I HAVE SO MUCH MORE ENERGY AND DON'T HAVE TO TAKE NAPS DAILY TO BE ABLE TO FUNCTION AND CARE FOR ME KIDS, LIKE I HAD TO BEFORE. THE ONLY THING THAT HASN'T IMPROVED IS MY DIGESTIVE PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044438	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 12/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, HOT FLASHES, PERIOD HAS STOPPED, STABBING PELVIC AND ABDOMINAL PAIN, FEMININE ODOR, NIGHT SWEATS, FREQUENT URINATION, PAINFUL INTERCOURSE, LOSS OF LIBIDO, YEAST INFECTIONS, BACK AND JOINT PAIN, BLOATING, HEARTBURN, NAUSEA, BOWEL ISSUES, MIGRAINES, METALLIC TASTE IN MOUTH, MOOD SWINGS, ANXIETY ATTACKS, WORSENING OF DEPRESSION, DIMINISHED BRAIN FUNCTION, DECREASED ENERGY, INSOMNIA, EXCESSIVE SWEATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044450	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVELOPED AN ALLERGIC REACTION TO NICKEL, HAVE HAD HIVES ON AND OFF FOR NO REASON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044451	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN BAD ENOUGH THAT ITS DIFFICULT TO GET UP IN THE MORNINGS ALSO HARD TO GET UP FROM A SITTING POSITION. FORGETFULNESS. BRAIN FOG. SHORT TERM MEMORY LOSS. DENTAL HEALTH VERY BAD TOOTH DETERIORATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044452	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE EXTREMELY PAINFUL, HEAVY MENSTRUAL CYCLES THAT ARE IRREGULAR AND UNPREDICTABLE. THESE BEGAN AFTER THE ESSURE COILS WERE IMPLANTED. EVERY CYCLE CONTINUES TO GET WORSE TO THE POINT I CAN'T SLEEP THROUGH THE NIGHT THE FIRST THREE NIGHTS OF MY PERIOD DUE TO AN UNCONTROLLABLY HEAVY FLOW. I AM ALSO EXPERIENCING SIGNIFICANT WEIGHT GAIN, HAIR LOSS, DENTAL ISSUES, SCALP BLISTERS, SPOTTING BETWEEN CYCLES, BLEEDING AFTER INTERCOURSE, AND EXTREME CRAMPING BOTH DURING MY PERIOD AS WELL AS DURING OVULATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044453	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER ABDOMEN PAIN. LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044454	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 8/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THIS DEVICE IMPLANTED IN (B)(6) 2013. ALMOST IMMEDIATELY I STARTED SUFFERING SEVERE PAIN AND AMP; CRAMPING ON MY LEFT SIDE AROUND OVULATION TIME AND DURING MY MENSTRUAL CYCLE, THAT CAN SOMETIMES BECOME DEBILITATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044455	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 5/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER ESSURE I BEGAN TO HAVE PELVIC PAIN. JOINT PAIN. SEVERE HEADACHES. MULTIPLE ER TRIP FOR THE MIGRAINES. CHRONIC FATIGUE. CRAMPING EVEN WHEN NOT HAVING PERIOD. WEIGHT GAIN. HOT FLASHES, NIGHT SWEATS. MOOD SWINGS HIGH BLOOD PRESSURE. VITAMIN D DEFICIENCY. DEPRESSION, STOMACH PAINS AFTER EATING. ACID REFLUX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044456	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 8/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, MEMORY LOSS, LOWER BACK PAIN AND EXTREME BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044457	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 5/7/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, CRAMPING, HEAVIER PERIODS, SEVERE PAIN AT IMPLANTATION SITE, CYSTS, FATIGUE, MENTAL FOG, ANEMIC, SEVERE ABDOMINAL PAIN, DEBILITATING HEADACHES, NAUSEA, ALLERGIC RESPONSE TO NICKEL, WEIGHT GAIN, NIGHT SWEATS, JOINT PAIN, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044458	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 11/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ISSUES LOSING WEIGHT, STABBING PAINS IN PELVIC REGION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044459	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 12/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE COILS PLACED UNDER ANESTHESIA AND WAS TOLD THAT THERE WOULD BE NO PAIN OR SIDE EFFECTS EXCEPT PERHAPS SOME SPOTTING. WHEN I WOKE UP, I WAS IN PAIN BUT ASSUMED THIS WAS NORMAL. THREE DAYS LATER, I KNEW SOMETHING WASN'T RIGHT AND CALLED MY DOCTOR BUT HE ASSURED ME THAT THE PAIN HAD NOTHING TO DO WITH THE INSERTS. WITHIN DAYS OF HAVING THEM IMPLANTED, I STARTED HAVING WEIRD RASHES PARTICULARLY IN THE ABDOMINAL AREA. A MONTH LATER, I HAD THE FIRST OF MANY EYE INFECTIONS. MY GYN SAID IT HAD NOTHING TO DO WITH ESSURE. AFTER GOING TO HIM SEVERAL TIMES ABOUT THE PAIN AND BEING TOLD IT HAD NOTHING TO DO WITH THE PROCEDURE, I QUIT TRYING AND WAITED FOR THE FOLLOW-UP HSG TEST AT WHICH TIME I WAS TOLD THAT THE TUBES WERE IN PLACE, FULLY OCCLUDED AND I WAS SET. SINCE HE WAS SO ADAMANT, I ASSUMED THAT HE WAS CORRECT. FOR THE FOLLOWING 18 MONTHS, MY HEALTH STEADILY DECLINED. JOIN SWELLING AND PAIN, MUSCLE SPASMS, HEAVY BLEEDING, INFECTIONS THAT WERE UNEXPLAINED, AND A HORRIBLE SEARING HOT PAIN IN MY ABDOMEN. I FINALLY FOUND A DOCTOR OF INTERNAL MEDICINE WHO WAS ALARMED BY MY SYMPTOMS AND ORDERED SEVERAL SPECIAL BLOOD TESTS WHICH SHOWED MY BODY HAD REACTED TO THE INSERTS WITH A SYSTEMIC INFLAMMATORY CASCADE. HIS STATEMENT TO ME WAS, "THESE THINGS ARE GOING TO KILL YOU IF YOU DON'T GET THEM OUT." HE PULLED SOME STRINGS AND TWO WEEKS LATER, I HAD A HYSTERECTOMY (LEAVING OVARIES) DURING WHICH IT WAS DISCOVERED THAT ONE OF THE INSERTS HAD PERFORATED THE UTERUS AND HAD BECOME SCARRED INTO THE OMENTUM. AFTER REMOVAL, THE SEARING PAIN IN MY ABDOMEN WAS GONE IMMEDIATELY. IT TOOK ALMOST THREE YEARS FOR THE JOINT SWELLING AND MUSCLE PAIN TO GO AWAY COMPLETELY. THE RASHES AND INFECTIONS CEASED WITHIN THREE MONTHS OF REMOVAL.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044460	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD THIS DEVICE IN ME SINCE 2008. FOR THE LAST FEW YEARS I'VE BEEN HAVING SEVERE MENSTRUAL CRAMPS AND LARGE BLOOD CLOTS WHEN GOING TO THE BATHROOM DURING MY TIME OF THE MONTH. I'VE NEVER HAD THIS PROBLEM BEFORE I HAD THE DEVICE PUT IN. I AM ALSO SUFFERING FROM HAIR LOSS. I WENT FROM A FULL SET OF THICK COARSE HAIR TO DRY BRITTLE HAIR WITH SCALP SHOWING ESPECIALLY NOTICEABLE WHEN HAVING MY HAIR IS TIED UP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044461	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WIDESPREAD JOINT PAIN - FOOT AND ANKLE PAIN, DIFFICULTY WALKING FOR FIRST 15 MINUTES UPON WAKING, HIP PAIN, LOW BACK AND THORACIC BACK PAIN, "BRAIN FOG", HEAVY, FREQUENT PERIODS, SEVERE HEADACHES, RIGHT SIDE FLANK PAIN, NAUSEA. CONSULTS AND TESTING WITH RHEUM, PCP, ALLERGIST, OBGYN, ALL NEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044462	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WIDESPREAD JOINT PAIN - FOOT AND ANKLE PAIN, DIFFICULTY WALKING FOR FIRST 15 MINUTES UPON WAKING, HIP PAIN, LOW BACK AND THORACIC BACK PAIN, "BRAIN FOG", HEAVY, FREQUENT PERIODS, SEVERE HEADACHES, RIGHT SIDE FLANK PAIN, NAUSEA. CONSULTS AND TESTING WITH RHEUM, PCP, ALLERGIST, OBGYN, ALL NEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044463	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ONE OF TWO ESSURE WAS MISSING DURING A PRE-OP ULTRASOUND FOR AN ABLATION. ENACT SIDE IS UNCOMFORTABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044464	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 12/25/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN, SLEEP PROBLEMS, ABDOMINAL PAIN, CRAMPING, IRREGULAR BLEEDING, PAINFUL INTERCOURSE, DEPRESSION, STOMACH ISSUES, SKIN RASH, DIAGNOSED WITH AUTO IMMUNE DISEASES AND MULTIPLE MEDICAL ISSUES SINCE THIS SURGERY. MY ENTIRE WORLD AND THAT OF MY LOVED ONES HAS COMPLETELY CHANGED SINCE BEING IMPLANTED. I NO LONGER ENJOY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044465	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 3/5/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME ABDOMINAL PAIN. FELT LIKE SOMETHING POKING ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044466	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 12/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, CHRONIC BACK PAIN, CHRONIC JOINT PAIN, CHRONIC HEADACHES, CRAMPING, BLOATING, HEARTBURN, TINGLING IN FEET, MOOD SWINGS, NICKEL ALLERGY, BRAIN FOG, ELEVATED BLOOD ANTIBODY RESULT (GOING TO RHEUMATOLOGIST FOR FURTHER INFORMATION - TITER OF 1:320).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044467	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN TO FEEL REALLY TIRED AND MY THYROID LEVELS WERE ALL OVER THE PLACE. I ALSO EXPERIENCED EXTREMELY HEAVY PERIODS, LOW IRON, VITAMIN D DEFICIENCY, MY HAIR FELL OUT, CONSTANT JOINT PAIN, FAILING EYESIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044468	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 10/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT MADE ME TEETH CRACK AND FALL OUT. MADE ME EXTREMELY FATIGUED TO THE POINT I COULDN'T PERFORM MY DUTIES AS A MOTHER OR WIFE. ESSURE GAVE ME DEBILITATING HEADACHES AND WHOLE BODY ACES. IT GAVE ME HORRIBLE PELVIC PAIN WHICH WAS CAUSED FROM MY ESSURE MIGRATING AND "PIRIFIATED(?)-TORE-MY" TUBE AND UTEROUS.. SINCE HAVING IT REMOVED I FEEL 100% BETTER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044469	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 4/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING ESSURE IMPLANTED IN (B)(6) 2013, I HAVE MANY DIFFERENT SIDE EFFECTS STARTING WITH WEIGHT GAIN/ NOT BEING ABLE TO LOSE WEIGHT, COMPLETE LOSS OF ENERGY, CONSTANT PAIN AND CRAMPING, WHAT FEELS LIKE RIPPING IN MY UTERUS, AND THE WORSE OF THEM ALL ON (B)(6) 2015, I FOUND OUT THAT MY COILS HAD MIGRATED OUT OF MY TUBE AND I WAS PREGNANT, I HAD THE DYE TEST WHICH SHOWED 100 PERCENT BLOCKAGE ON BOTH SIDES 6 WEEKS AFTER I HAD THEM IMPLANTED, NOW ON (B)(6) 2015, I WILL FIND OUT IF I HAVE TO HAVE A HYSTERECTOMY, AND FOR THE RECORD I AM ONLY (B)(6) YEARS OLD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044470	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 12/24/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY COILS PLACED (B)(6) 2007. BY (B)(6), I LANDED MY FIRST TRIP TO THE EMERGENCY ROOM WITH SEVERE ABDOMINAL PAIN. BY (B)(6) 2008 I WAS DIAGNOSED WITH FIBROMYALGIA AND CHRONIC MYOFASCIAL PAIN SYNDROME. I ALSO FOUND OUT AFTER THE PROCEDURE WAS DONE THAT THE PRODUCT CONTAINED NICKEL. I AM VERY ALLERGIC TO NICKEL AND BROKE OUT IN MANY UNEXPLAINED RASHES. THIS PROCESS CONTINUED UNTIL A HYSTERECTOMY IN 2012. I ALSO HAD A POSITIVE PREGNANCY TEST DURING THE COURSE OF USING ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044471	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST SET FELL OUT OF FALLOPIAN TUBES AND WERE DISCOVERED IN MY UTERUS. SECOND SET HAS MIGRATED FROM MY FALLOPIAN TUBED AND ARE NOW PROTRUDING INTO MY UTERUS, SO ITS LIKELY THEY WILL FALL OUT INTO MY UTERUS AGAIN. WEIGHT GAIN, ABDOMINAL BLOATING, THYROID DISFUNCTION, ABNORMAL MENSTRUAL PERIODS AND SEVERE CRAMPING, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044473	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD EXTREME CONSTIPATION AND BLOATING THAT CAUSES ME TO LOOK 5-6 MONTHS PREGNANT. I HAVE ABDOMINAL PAIN FREQUENTLY. I'VE SUFFERED FROM EXTREME ACNE AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044474	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 8/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I HAD ESSURE IMPLANTED I HAD CONSTANT MENSTRUAL BLEEDING. MY MENSTRUAL CYCLE WAS NORMAL BEFORE THE PROCEDURE BUT WOULDN'T STOP AFTERWARD. MY DOCTOR HAD ME TRY HIGH DOSES OF IBUPROFEN WHICH DIDN'T WORK THEN PUT ME ON BIRTH CONTROL PILLS. THIS DEFEATED THE WHOLE PURPOSE OF HAVING ESSURE. AFTER 3 MONTHS MY PERIOD STABILIZED WITHOUT BIRTH CONTROL FOR ABOUT 6 MONTHS THEN I GOT MY PERIOD AFTER 2 WEEKS. THIS BRINGS US TO THE PRESENT TIME. MY MAIN CONCERN IS CHRONIC PAIN IN MY BACK, HIPS, AND NECK AREA THAT STARTED IN (B)(6) 2014. I WENT TO THE CHIROPRACTOR FOR 6 MONTHS WITH MINIMAL RELIEF. I THEN WENT TO MY PRIMARY PHYSICIAN AND HAD BLOOD WORK, BRAIN MRI, AND XRAYS DONE. EVERYTHING CAME BACK NORMAL BUT I HAD HIGH LEVELS OF CYCLIC CITRULLINE PEPTIDE (NORMAL IS ANDLT;20 AND MINE WAS 22) IN MY BLOOD WORK AND WAS REFERRED TO A RHEUMATOLOGIST. STARTING IN NOVEMBER I ALSO STARTED HAVING BOUTS OF VERTIGO THAT OCCUR FOR NO REASON. I HAVE EXPERIENCED IT STANDING, SITTING DOWN, AND LAYING IN BED GOING TO SLEEP. I AM A HEALTHY (B)(6) AND NEVER HAD THESE ISSUES BEFORE ESSURE. WHEN I HAVE HAD BACK PAIN IN THE PAST IT HAS GONE AWAY WITHIN 2 WEEKS OF SEEING THE CHIROPRACTOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044475	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 11/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL JOINTS, CONSTANT NAUSEA, PINCHING IN THE LOWER ABDOMEN, CONSTANT BLOATING(EXTREME). INABILITY TO MOVE MY BODY FLEXIBLY (TOO PAINFUL). FEEL LIKE I'M 100 YEARS OLD. LOSS OF ANY SEXUAL APPETITES (TOTALLY GONE).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044476	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 1/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PELVIC PAIN, BLOATED, SWOLLEN ARMS AND LEGS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044477	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 3/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE PLACES I HAVE A PINCHING PAIN ON MY LEFT LOWER SIDE. AFTER DEALING WITH THE PAIN FOR ABOUT A MONTH I WENT TO THE DOCTOR. THE LEFT COIL IS IRRITATING A NERVE WHICH IS CAUSING THE PINCHING PAIN. I AM SCHEDULED TO HAVE BOTH MY COILS AND MY TUBES REMOVED IN (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044478	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 7/15/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABOUT A MONTH AFTER THESE THINGS WERE PUT IN. HAS MADE MY LIFE SO HARD. ALWAYS IN PAIN, EACH MONTH IT IS WORSE THEN THE MONTH BEFORE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044479	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 2/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GALLBLADDER REMOVAL (B)(6). SHARP STABBING PAINS WHEN STRETCHING, SNEEZING, AND RANDOMLY PAINFUL INTERCOURSE. PAINFUL MENSTRUAL CYCLES. UP TO 6 WEEKS BETWEEN MENSTRUAL CYCLES . WEIGHT GAIN. ALLERGIES STARTED IN (B)(6). MOOD SWINGS. DIAGNOSED BIPOLAR THEN SWITCHED TO PMDD, NEVER BEEN A ISSUE BEFORE (B)(6) 2009. BATTLED DEPRESSION. ANXIETY. METALLIC TASTE IN MOUTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044480	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 5/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIAGNOSED WITH SEVERE INFLAMMATION WITH NO SPECIFIED CAUSE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044481	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME INTENSE PAIN IN THE LOWER ABDOMEN OCCURRING IRREGULARLY AT FIRST THEN INCREASING TO CONTINUOUS OVER THE NEXT FEW MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044482	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 11/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVER PAIN IN MY LEFT AND RIGHT SIDES, FATIGUE, NAUSEA, LOWER BACK PAIN, NECK PAIN, HEADACHES, JOINT PAIN, WEIRD RASHES THAT COME AND GO, MEMORY PROBLEMS THAT MAKE ME FEEL LIKE I'M IN A FOG. SEVERE BLEEDING WITH IN THE LAST YEAR THROUGH OUT THE MONTH. PERIODS ARE NOT NORMAL ANY LONGER. I FINALLY HAD AN INTERNAL ULTRA SOUND THAT SHOWED FIBROID TUMORS IN MY UTERUS AND LEFT TUBE IS VERY INFLAMED AND FILLED WITH LIQUID. MY REFERRAL TO A GYNECOLOGIST HAS TAKEN A WHILE BUT SCHEDULED FOR FIRST WEEK IN (B)(6) TO DISCUSS OPTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044483	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE PLACED ON (B)(6) 2015 AND A WEEK AFTER I START EXPERIENCING PAIN LIKE NEVER BEFORE. ABDOMINAL PAIN, SHARP PAINS IN MY STOMACH AND LEFT SIDE, ALSO A SHARP PAIN ON THE RIGHT SIDE OF MY VAGINA THAT COME AND GOES ALL THE TIME, CONSTANT HEADACHES,Y LEFT EYE IS ALWAYS TWITCHING, I'M BLOATED. AND MY PERIODS ARE WORSE THAN EVER. I JUST WANT ESSURE REMOVED BECAUSE IT IS NOT GOOD FOR ANY WOMEN! JUSTICE PLEASE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044484	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 10/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD SEVERE PAIN AFTER PLACEMENT. I STARTED BLEEDING IMMEDIATELY AFTER PLACEMENT. I BLED EVERY DAY UNTIL I HAD THE ESSURE REMOVED IN (B)(6) 2012. I HAD SEVERE PAIN THAT WOULD START AT MY OVARIES AND SHOOT DOWN TO MY TOES. THIS PAIN WAS DAILY. THE PAIN WOULD INTERFERE WITH MY SLEEP AND WITH DRIVING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044485	BAYER	7/20/2015	7/20/2015

Event Information:

Event Date (B3): 11/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDAMW5044485 #(B)(4). I BLED FOR 6 1/2 MONTHS NOT 8 1/2 MONTHS..

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044472	BAYER	7/20/2015	7/21/2015

Event Information:

Event Date (B3): 5/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD GOTTEN ESSURE IN (B)(6) OF 2005 IN HOPES OF IT BEING EASIER WAY OF A PERMANENT CONTRACEPTIVE THROUGHOUT THE YEARS STABBING PAINS IN MY OVARIES AND UTERUS WERE CONSTANT. BLEEDING BECAME MORE AND MORE AS WELL AS IRREGULAR PERIODS THAT WOULD LAST ANYWHERE FROM 1-6 WEEKS WITH BLOOD CLOTS THAT GREW TO THE SIZE OF A LARGE CHICKEN EGG. THE PAIN GOT WORSE WITH EACH PERIOD TO THE POINT OF FEELING LIKE I WAS GIVING BIRTH AGAIN EACH MONTH! THE BLEEDING WAS SO HEAVY AT TIMES I COULD NOT GO ANYWHERE DUE TO LEAKING EVERYWHERE WHEN I MOVED! I HAVE HAD MEMORY LOSS BLOATING TO THE POINT THAT I LOOK 7 MONTHS PREGNANT. DOCTORS TRIED EVERYTHING THEY COULD TO FIX THE ISSUES I WAS HAVING RESULTING IN A HYSTERECTOMY ON (B)(6) 2015

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044486	BAYER	7/20/2015	7/21/2015

Event Information:

Event Date (B3): 8/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE GOT SOME SHARP PAIN THAT SHOOT DOWN MY LEFT LEG. IF I STAND MORE THAN 5 MIN BOTH MY LEGS GO NUMB. I HAVE A CONSTANT HEADACHE. LATE PERIODS. HEAVY BLEEDING. NONE OF THIS STARTED TILL AFTER I GOT ESSURE!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044703	BAYER	7/20/2015	7/27/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4): NA

Single Use:
Implant Date (E6): 5/1/2008
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

SIDE EFFECTS FROM ESSURE COILS. I AM HAVING SYMPTOMS OF VERTIGO, HIVES, PAIN, HEAVY MENSTRUAL CRAMPING, AND NON-STOP HEAVY BLEEDING, MIGRAINES, NUMBNESS IN LIMBS, RESTLESSNESS, INSOMNIA, SOMETIMES FEEL DELUSIONAL, NIGHT SWEATS, RASHES, RAPID HEART BEAT WITH PANIC ATTACKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044704		7/20/2015	7/27/2015

Event Information:

Event Date (B3): 12/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE THE ESSURE GOT PUT IN I'VE BEEN HAVING PELVIC PAIN, BUT THOUGHT IT WOULD GO AWAY. NO I'VE BEEN GETTING A BAD RASH ON MY STOMACH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044707	BAYER	7/20/2015	7/27/2015

Event Information:

Event Date (B3): 7/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/31/2009
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN 2006. ABOUT 4 YEARS AGO MY HEALTH STARTED TO DETERIORATE IN A NUMBER OF DIFFERENT WAYS FROM VISION ISSUES, TO HAIR LOSS, HORMONAL, EXTREME BLOATING, GASTRO ISSUES, RASHES, AND PAIN. MENSTRUAL AND PERIOD ISSUES WITH MY LONGER PERIOD LASTING 3 WEEKS! I HAVE BEEN SEEN BY A NUMBER OF SPECIALIST AND A NUMBER OF TESTS RUN ON ME WITH NO CONCRETE DIAGNOSIS. I HAVE AN APPOINTMENT FRIDAY (B)(6) TO EXPLORE THE REMOVAL OF THE COILS. THERE ARE NO WORDS I HAVE TO DESCRIBE HOW THE PAST FEW YEARS BEEN SUCH A STRUGGLE. I WANT TO REGAIN MY GENERAL POSITIVE OVERALL HEALTH. I FEEL TOTALLY MISLED THAT NO DOCTOR EVER EXPLORED THE ESSURE AS THE ROOT CAUSE OF MY ISSUES. AS A SINGLE WOMEN THERE WERE MANY DAYS I HAVE BEEN SO FATIGUED AND DIZZY THAT I COULD BARELY FUNCTION. I TRUSTED MY DOCTOR AND WAS NEVER INFORMED OF ANY MAJOR SIDE EFFECT LIKE THOSE I'VE EXPERIENCED. THIS PRODUCT SHOULD NEVER HAVE BEEN APPROVED WITHOUT EXTENDER STUDIES AVAILABLE. IN MY CASE MY SYMPTOMS STARTED AROUND THE 5 YEAR MARK AND HAVE PROGRESSIVELY GOTTEN WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044748	ESSURE	7/20/2015	7/27/2015

Event Information:

Event Date (B3): 10/10/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 10/10/2012
Explant Date (E7): 1/3/2014
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN ME A MONTH IN A HALF AFTER MY DAUGHTER WAS BORN. THEY TOLD ME THIS PROCEDURE WAS BEST BECAUSE I WOULD GO INTO SURGERY AND THEY SAID IT WAS IRREVERSIBLE. AFTER I HAD THE ESSURE FOR ONE MONTH, I FOUND OUT I WAS PREGNANT WITH MY LAST CHILD. I TOLD THEM IF THEY COULD TAKE THE ESSURE OUT. THEY SAID NO, BECAUSE I HAD TO HAVE AN ABORTION BUT I DIDN'T WANT TO HAVE AN ABORTION. MY PREGNANCY WAS HIGH RISK.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00519	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/6/2012
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON (B)(6) 2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER (B)(4), RECEIVED AT FDA ON (B)(6) 2013). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED SHARP PAINS, BLOATING, DIZZINESS, ANXIETY, HEART PALPITATIONS, MISSED MENSTRUAL CYCLES, HEAVY MENSTRUAL CYCLES, SEVERE CRAMPS, DEPRESSION, NAUSEA, VOMITING, HEADACHES, SHARP PAINS IN HER HIPS AND HER BACK, SEVERE EXHAUSTION, AND SEVERE WEIGHT GAIN, ALLERGIC REACTIONS TO NICKEL. FDA REPORT TYPE WAS "INJURY", REPORTED OUTCOME OF EVENTS WAS "HOSPITALIZATION" NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2012, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. ON (B)(6) - 2013, CONSUMER REPORTED SINCE IMPLANTATION IN 2013, START DATE OF EVENTS REPORTED AS (B)(6)-2013 (ALSO REPORTED IMPLANTATION DATE (B)(6) - 2012) SHE HAS HAD MULTIPLE SIDE EFFECTS THAT SHE HAS NEVER HAD BEFORE, INCLUDING SHARP PAINS, BLOATING, DIZZINESS, ANXIETY, HEART PALPITATIONS, MISSED MENSTRUAL CYCLES, HEAVY MENSTRUAL CYCLES, SEVERE CRAMPS, DEPRESSION, NAUSEA, VOMITING, HEADACHES, SHARP PAINS IN HER HIPS AND HER BACK, SEVERE EXHAUSTION, AND SEVERE WEIGHT GAIN, ALLERGIC REACTIONS TO NICKEL. SHE TOLD THE DOCTOR THAT SHE WAS ALLERGIC TO NICKEL, AND SHE WAS TOLD THAT SHE WOULD NOT HAVE NO EFFECTS FROM IT, ALTHOUGH SHE HAS SYMPTOMS NOW. AFTER INFORMING THE DOCTOR WHO PERFORMED THE PROCEDURE. SHE WAS TOLD THAT EVERYTHING LOOKS NORMAL ON HER ULTRASOUND YET SHE IS STILL FEELING ALL OF THIS PAIN. THE ESSURE IS SAID TO HAVE NO KNOWN SIDE EFFECTS, YET SHE HAS SIDE EFFECTS. THE ONLY THING SHE SEES CAN BE DONE NOW WAS A

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HYSTERECTOMY, WHICH IS A SURGERY THAT SHE AVOIDED IN THE FIRST PLACE BY GETTING THE ESSURE PLACEMENT. THIS IS NOT ACCEPTABLE. ESSURE NEED TO BE TAKEN OFF THE MARKET. FOLLOW-UP RECEIVED ON (B)(6) -2015: INFORMATION RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)). SHE STATED THAT HER SYMPTOMS STARTED SINCE ESSURE PLACEMENT ON 2012 AND CONSISTED OF HIGH BLOOD PRESSURE, BLOATING, FATIGUE, EYE TWITCHES, MUSCLE CRAMPS, MUSCLE SPASMS, BACK PAIN, SHARP PAINS IN LOWER STOMACH, PULLING SENSATION IN LOWER STOMACH, LONG PERIODS, HEAVY PERIODS, MISSING PERIODS, WEIGHT GAIN/UNABLE TO LOSE WEIGHT, DEPRESSION (BECAUSE OF WEIGHT GAIN AND CONSTANTLY BEING ASKED HOW FAR ALONG SHE WAS OR IF SHE WAS HAVING A BOY OR A GIRL) AND PAINFUL INTERCOURSE. CONSUMER ALSO REPORTED THAT SHE COULDN'T DO NORMAL THINGS WITH HER CHILDREN BECAUSE OF THESE SYMPTOMS, STRESS WITHIN HER RELATIONSHIP BECAUSE OF THESE ISSUES. IN ADDITION, SHE INFORMED THAT, ON 2015, SHE HAD A HYSTERECTOMY PERFORMED AND STATED THAT IT HAS RESOLVED MANY ISSUES WITHIN DAYS. THE SERIOUSNESS CRITERION "REQUIRED INTERVENTION" WAS REPORTED; HOWEVER IT WAS NOT SPECIFIED FOR WHICH EVENT. CASE UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO EXPERIENCED SHARP PAINS IN HER LOWER STOMACH SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, LOWER ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE CONSUMER REPORTED LOWER STOMACH PAIN IN ADDITION TO OTHER NON-SERIOUS EVENTS. ACCORDING TO HER, THESE EVENTS STARTED AFTER ESSURE INSERTION AND MANY OF THEM RECOVERED WITH DEVICES REMOVAL BY HYSTERECTOMY. CONSIDERING THIS INFORMATION, A CAUSAL RELATIONSHIP WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REQUIRED INTERVENTION (HYSTERECTOMY) FOR EVENT'S TREATMENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 02-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00520	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 620734

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 11/21/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(6)2014 VIA COMPANY INTERNET SITE. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AT AGE (B)(6) AND EXPERIENCED BLEEDS DURING SEX, HAS BLOOD CLOTS THE SIZE OF QUARTERS COMING OUT ALL OVER HER HUSBAND DURING SEX, PAINFUL CRAMPS, HAIR LOSS, WHEN SHE HAS SEX IT HURTS SO BAD, GETS RASHES ALL OVER HER BODY, MAJOR SWELLING ALL OVER, NO SLEEP BECAUSE IT FEELS LIKE HER TUBES ARE GOING TO EXPLODE. NO INFORMATION WAS GIVEN ON CONSUMER'S DRUG HISTORY, CONCOMITANT MEDICATION. THE CONSUMER'S MEDICAL HISTORY/CONCURRENT CONDITIONS INCLUDED BEING HEALTHY, HAVING FOUR KIDS. ON AN UNSPECIFIED DATE IN 2006, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED ESSURE HAS DESTROYED HER LIFE, SHE IS NOT THE SAME PERSON. SHE BLEEDS DURING SEX, HAS BLOOD CLOTS THE SIZE OF QUARTERS COMING OUT ALL OVER HER HUSBAND DURING SEX. PAINFUL CRAMPS, HAIR LOSS. WHEN SHE HAS SEX IT HURTS SO BAD THAT SHE JUST WANTS TO CRY. SHE GETS RASHES ALL OVER HER BODY, MAJOR SWELLING ALL OVER, NO SLEEP BECAUSE IT FEELS LIKE HER TUBES ARE GOING TO EXPLODE. SHE DOES NOT WANT TO GO OUTSIDE AND PLAY WITH HER CHILDREN. ESSURE HAS RUINED HER LIFE, HER MARRIAGE, HER WOMANHOOD. SHE GOT TO GET ALL HER FEMALE PARTS TAKEN OUT TO FEEL NORMAL AGAIN, TO ENJOY THE SMALL THINGS OF LIFE AGAIN. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: THE LOCAL HEALTH AUTHORITY WAS ADDED AS REPORTER UNDER THE REFERENCE NUMBER (B)(4). IN 2006 SHE HAD THE ESSURE BIRTH CONTROL IMPLANTED. SHE STATED THAT SHE HAS HAD NOTHING BUT ISSUES WITH THAT. SHE EXPERIENCED BLEEDING, PAINFUL SEXUAL INTERCOURSE, HAIR FALLING OUT, BLOATING, SHE LOOKED LIKE SHE WAS 6 MONTHS PREGNANT; WEIGHT HAS GONE UP SO MUCH AND BACK DOWN AND

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BACK UP. IT WAS REPORTED THAT SHE GOT TO HAVE ALL HER LADY PARTS TAKEN OUT BECAUSE ONE OF THE DEVICES HAS TORN THRU AND HAS MANAGED TO GO TO ANOTHER BODY PART WHERE IT SHOULD NOT BE. HER MOOD SWINGS HAVE BEEN HORRIBLE, TO THE POINT WHERE SHE HAS THOUGHT ABOUT ENDING HER LIFE; THE PAIN WAS HORRIBLE. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014 FROM SOCIAL MEDIA: THE CONSUMER REPORTED SHE EXPERIENCED PAIN, BLEEDING CLOTS THE SIZE OF QUARTER OR BIGGER, SHE WAS NOT HAVING SEXUAL RELATIONS, LOOSING HAIR, SWELLING LIKE 5 MONTHS PREGNANT, ISSUED WITH HEART, LIVER AND INSIDE HER ON FIRE ALL THE TIME. SHE STATED ESSURE HAS RUINED HER LIFE. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2014: UNSUCCESSFUL FOLLOW-UP ATTEMPT. THE CASE IS POTENTIAL LEGAL CASE. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) -2014: UNSUCCESSFUL FOLLOW-UP ATTEMPT. FOLLOW-UP RECEIVED ON (B)(6) 2015: INFORMATION RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY ((B)(4)) STATES THAT SHE HAD ESSURE MODEL 205 (LOT NUMBER 620734) PLACED IN 2008 (DISCREPANT INFORMATION). FROM THE TIME SHE WOKE UP IN 2014 (UNSPECIFIED DATE) SHE HAS BEEN IN PAIN. CONSUMER ALSO REPORTED GAINING OVER 100 POUNDS, BLOOD CLOTS THE SIZE OF GOLF BALLS, HAIR HAS FALLEN OUT, EYE LASHES DISAPPEARED AND NO SEX DRIVE. CONSUMER INFORMED THAT WHEN SHE DID HAVE SEX IT WAS SO PAINFUL AND SHE WOULD BLEED FOR DAYS AFTER SEX. SHE HAD TO HAVE 2 ABLATIONS DONE BECAUSE THE DOCTORS COULD NOT FIGURE OUT WHY SHE WAS IN SO MUCH PAIN. IN ADDITION, CONSUMER REPORTED THAT SHE GOT PREGNANT TWICE (BOTH ENDING IN DEATH OF FETUS). SHE HAD SEVERAL PANIC ATTACKS BECAUSE OF THE PAIN AND REPORTS HEART ISSUES AND CYST ON HER OVARIES THE SIZE OF QUARTERS OR BIGGER. ACCORDING TO CONSUMER, ESSURE MIGRATED THROUGH HER TUBES AND END UP WRAPPED AROUND OTHER ORGANS AND STATES NOW THAT THE DEVICES ARE OUT SHE FEELS 100% BETTER. ESSURE WAS EXPLANTED ON (B)(6) 2014 AND ALL HER SIDE EFFECTS WERE GONE. CONSUMER STATES THAT THE SWELLING ALL OVER HER BODY AND THE PAIN THAT SHE WAS IN EVERY DAY WERE CAUSED BY ESSURE. CASE UPGRADED TO INCIDENT. CONSUMER'S SECOND PREGNANCY CASE NUMBER IS (B)(4). PTC INVESTIGATION RESULT RECEIVED ON (B)(4) 2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: CASE CONSIDERED CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT TWICE AFTER ESSURE INSERTION, BOTH PREGNANCIES ENDED IN DEATH OF THE FETUS. ADDITIONALLY, ONE OF THE DEVICES HAS TORN THRU (ESSURE MIGRATED THROUGH HER TUBES) AND END UP WRAPPED AROUND THE ORGANS AND SHE HAD BLEED DURING SEX/ BLOOD CLOTS THE SIZE OF QUARTERS COME OUT ALL OVER HER HUSBAND, BLOOD CLOTS THE SIZE OF GOLF BALLS AND HORRIBLE MOOD SWINGS, TO THE POINT WHERE SHE HAS THOUGHT ABOUT ENDING HER LIFE (REGARDED AS DEPRESSION SUICIDAL). SHE WAS SUBMITTED TO 2 ABLATIONS AND HAD ESSURE REMOVED. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL

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IMPORTANCE AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT FOR DEPRESSION SUICIDAL AND FETAL DEATH, WHICH ARE UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE INCLUDING FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED ABOUT HSG. THE PATIENT STATED ON ESSURE MIGRATED THROUGH HER TUBE. THIS FALLOPIAN TUBE PERFORATION COULD BE AN ALTERNATIVE EXPLANATION FOR THE REPORTED DEVICE FAILURE (PREGNANCY). HOWEVER, SINCE ITS MECHANISM IS UNKNOWN (IF PERFORATION OCCURRED BEFORE OR AFTER PREGNANCY ONSET), CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING FETAL DEATH, LIMITED INFORMATION WAS PROVIDED, HOWEVER CONSIDERING THE VAST MAJORITY OF SPONTANEOUS ABORTIONS OCCURS IN THE FIRST TRIMESTER OF PREGNANCY DUE TO FETAL CHROMOSOMAL ABNORMALITIES, CAUSALITY WITH ESSURE IS CONSIDERED UNLIKELY. FOR THE OTHER EVENTS, CONSUMER STATED ALL HER SIDE EFFECTS WERE GONE AFTER ESSURE REMOVAL. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED; AND DUE TO THE REQUIRED INTERVENTIONS FOR EVENTS TREATMENT (ABLATION AND ESSURE REMOVAL) THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00521	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 958708

Single Use: Y
Implant Date (E6): 8/21/2012
Explant Date (E7): 9/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PERMANENT BIRTH CONTROL SYSTEM, LOT NUMBER 958708, INSERTED ON (B)(6) 2012. IN AROUND (B)(6) 2014, SHE BECAME PREGNANT AND GAVE BIRTH ON (B)(6) 2015. AT THE TIME OF THE COMPLAINT, SHE WAS REQUIRING SURGERY TO REMOVE THE COILS BECAUSE THEY HAD MIGRATED SOMEWHERE IN HER ABDOMEN. X-RAYS HAD BEEN TAKEN OF THE DISPLACED COILS WITHIN THE USER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AND DELIVERED AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, IT WAS STATED SHE WAS REQUIRING SURGERY TO REMOVE ESSURE COILS BECAUSE THEY HAD MIGRATED SOMEWHERE IN HER ABDOMEN. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG) TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED ABOUT THE HSG; THE CONSUMER STATED ESSURE COILS HAVE MIGRATED TO HER ABDOMEN, HOWEVER LIMITED INFORMATION WAS PROVIDED ABOUT THIS EVENT. ALTHOUGH THE MECHANISM OF THE REPORTED DEVICE MIGRATION IS UNKNOWN (IF IT OCCURRED BEFORE OR AFTER PREGNANCY ONSET); CONSIDERING PREGNANCY OCCURRED APPROXIMATELY 2 YEARS AFTER ESSURE INSERTION, CAUSALITY BETWEEN THE EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS

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CASE WAS CONSIDERED AN INCIDENT, SINCE AN INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL (ACCORDING TO THE CONSUMER). A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-AUG-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT I

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00522	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D30798

Single Use: Y
Implant Date (E6): 6/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON 23-JUN-2015. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER D30798, INSERTED ON (B)(6) 2015. ESSURE WAS INSERTED IN THE OPERATING ROOM, UNDER GENERAL ANESTHESIA. DURING THE PROCEDURE, IT WAS DIFFICULTY TO MOVE UP THE ESSURE INSERT, ON REMOVAL IT WAS NOTICED THAT THE INSERT WAS BROKEN. THERE WAS NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. FOLLOWING THE EVENT, ANOTHER ESSURE DEVICE WAS OBTAINED. BILATERAL INSERTION WAS QUICKLY AND EASILY PERFORMED WITH THIS OTHER DEVICE. THE VISUALIZATION WAS GOOD, AND NO OTHER DIFFICULTY OCCURRED. FOLLOW-UP INFORMATION RECEIVED ON 02-JUL-2015 THE PATIENT'S WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). DURING ESSURE PROCEDURE, THERE WAS GOOD VISUALIZATION OF THE OSTIUM. INSERTION ATTEMPT: FEELING OF A STOP OF THE INSERT DURING INSERTION. REMOVAL WAS PERFORMED. THE INSERT WAS BROKEN WHEREAS THE SURGEON DID NOT FORCE. BREAKAGE WAS FOUND DURING PLACEMENT AND OCCURRED ON THE INNER COIL OF THE INSERT. THE INSTRUCTIONS IN THE IFU WERE FOLLOWED. INSERT WAS REMOVED ON (B)(6) -2015 (SAME DAY OF INSERTION) VIA HYSTEROSCOPY METHOD. IT WAS MEDICALLY NECESSARY TO REMOVE ESSURE; ESSURE WAS NOT REMOVED BECAUSE OF PATIENT REQUEST. THE BROKEN PIECES WERE RETRIEVED BEFORE INSERTION. INSERT WAS CHANGED AND NEW INSERTION WAS EASY. THE REPORTER STATED THERE WAS NO INJURY FOR THE PATIENT; ACCORDING TO HIM BREAKAGE COULD NOT HAVE LED TO SERIOUS INJURY UNDER LESS FORTUNATE CIRCUMSTANCES. NO FURTHER INFORMATION WILL BE PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE IT WAS

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DIFFICULT TO MOVE UP THE ESSURE INSERT, ON REMOVAL IT WAS NOTICED THAT THE INSERT WAS BROKEN. BILATERAL INSERTION WAS PERFORMED WITH OTHER DEVICE. THIS EVENT, REGARDED AS DEVICE BREAKAGE, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, THE BREAKAGE OCCURRED IN ASSOCIATION WITH A DIFFICULTY ESSURE PROCEDURE, THUS CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE PATIENT HAD NO INJURY, THE COMPANY CONSIDERS THE REPORTED DEVICE BREAKAGE COULD HAVE LED TO SERIOUS HEALTH DETERIORATION UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 12-AUG-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). LOT NUMBER D30798 (PRODUCTION DATE 03-NOV-2014; EXPIRATION DATE 28-NOV-2017). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00523	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/4/2009
Explant Date (E7): 4/26/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE CONSUMER VIA REGULATORY AUTHORITY (MW# 5041429) IN UNITED STATES ON(B)(6) -2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON(B)(6) 2009. A YEAR AFTER ESSURE INSERTION, CONSUMER STARTED PRESENTING PAIN AND HEAVIER PERIODS. SHE STATED THAT WAS STILL ON BIRTH CONTROL TO GET PERIODS, BECAUSE THEY WERE STILL HEAVY. IT KEPT ONGOING UNTIL 2012 WHEN HER PHYSICIAN NOTICED A COIL OF THE ESSURE HAD WENT THROUGH HER RIGHT TUBE. HYSTERECTOMY AND PARTIAL REMOVAL OF RIGHT FALLOPIAN TUBE AND REMOVAL OF THE COILS WAS PERFORMED ON (B)(6) 2012. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS WERE PROVIDED ON (B)(6) 2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THREE YEARS, HER PHYSICIAN NOTICED THAT A COIL OF THE ESSURE WENT THROUGH HER RIGHT TUBE. THIS EVENT, SEEN AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. IN THIS CASE, ONE YEAR AFTER PLACEMENT PROCEDURE, THE PATIENT PRESENTED PAIN AND HEAVIER PERIODS. TWO YEARS LATER, HER PHYSICIAN NOTICED THAT A MICRO-INSERT WENT THROUGH HER RIGHT FALLOPIAN TUBE. HYSTERECTOMY AND PARTIAL REMOVAL OF RIGHT FALLOPIAN TUBE WITH COILS REMOVAL WERE THEN PERFORMED. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 01 OCT 2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00524	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 855628

Single Use: Y
Implant Date (E6): 8/9/2011
Explant Date (E7): 6/3/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW# 5041960) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER 855628 INSERTED ON (B)(6) -2011. ABOUT ONE YEAR AFTER THEM BEING IMPLANTED SHE STARTED HAVING SEVERE SIDE EFFECTS. SHE SUFFERED FROM EXTREME PAIN WHILE OVULATING EACH MONTH AND HAD TROUBLE WITH EVERYDAY TASK. THE OVULATING PAIN WOULD LAST FOR ABOUT A WEEK SOMETIMES LONGER. THEN SHE WOULD BE UNCOMFORTABLE AND EXTREMELY BLOATED ONLY TO THEN HAVE EXTREME PAIN AGAIN THE WEEK BEFORE HER PERIOD. THE EXTREME PAIN WOULD BE ABOUT 3 WEEKS OUT OF THE MONTH. THE PAIN WAS MAKING HER DEPRESSED AND IRRITABLE ALL THE TIME. SHE ALSO GAINED 30 POUNDS SINCE HAVING THE ESSURE IMPLANTED. A MRI (NUCLEAR MAGNETIC RESONANCE IMAGING) WAS PERFORMED AND SHOWED ESSURE DEVICES WERE STILL CORRECTLY IN PLACE. CONSUMER HAD TUBES REMOVED WITH THE ESSURE DEVICES ON (B)(6) 2014. THE SURGERY WENT WELL, BUT THE FIRST MENSTRUAL CYCLE AFTER HAVING THEM REMOVED SHE HAD HEAVY BLEEDING. TO DATE SHE WAS STILL EXPERIENCING EXTREMELY HEAVY CYCLES, BLOOD CLOTS THROUGHOUT HER CYCLE AND SHE ALSO DEVELOPED OVARIAN CYSTS SINCE ESSURE REMOVAL. SHE WAS ABOUT TO HAVE AN ENDOMETRIAL ABLATION TO SEE IF SHE GETS ANY RELIEF OF MY HEAVY MENSTRUAL CYCLES. SHE WAS ALSO DEALING WITH ANEMIA. CONSUMER ASSESSED EVENT OUTCOME AS DISABILITY OR PERMANENT DAMAGE; HOWEVER SHE DID NOT SPECIFY IT. FOLLOW-UP RECEIVED ON (B)(6) -2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(6) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: 855628; PRODUCTION

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DATE: (B)(6) 2011; EXPIRATION DATE: APR-2014. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREMELY BLOATED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, ABOUT ONE YEAR AFTER ESSURE INSERTION, SHE STARTED HAVING SEVERE SIDE EFFECTS. IT WAS REPORTED THAT A MRI (NUCLEAR MAGNETIC RESONANCE IMAGING) WAS PERFORMED AND THE RESULT SHOWED ESSURE DEVICES WERE STILL CORRECTLY IN PLACE. CONSUMER HAD TUBES REMOVED WITH THE ESSURE DEVICES. GIVEN THE EVENT'S NATURE, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO REQUIRED INTERVENTION, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 01 OCT 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00525	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/9/2009
Explant Date (E7): 9/16/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (B)(4) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 FOR BIRTH CONTROL. CONSUMER STATED THAT SHE EXPERIENCED SEIZURES, WEIGHT GAIN, FATIGUE, FOOD ALLERGIES, CONSTANT PERIODS AND GRAPEFRUIT SIZE BLOOD CLOTS. SHE ALSO HAD MASS FIBROIDS THROUGHOUT UTERUS; THE BIGGEST ONES GROWING AROUND ESSURE DEVICES. SHE CONSIDERED THAT THE EVENTS WERE RELATED TO ESSURE. SHE RECEIVED THERMOFIT AS CONCOMITANT MEDICATION. ON (B)(6) 2014 ESSURE WAS REMOVED. AN INJURY (HOSPITALIZATION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 01-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE

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AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD GRAPEFRUIT SIZE BLOOD CLOTS. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE, THE EXACT TIMING BETWEEN ESSURE INSERTION AND EVENT ONSET WAS NOT REPORTED HOWEVER GIVEN THE NATURE OF THE EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. CONSUMER ALSO REPORTED SHE HAD SEIZURES. THIS EVENT IS UNLISTED FOR ESSURE AND WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION (HOSPITALIZATION WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS). CAUSES OF SEIZURES INCLUDE HEAD TRAUMA, BRAIN TUMORS, STROKE, INTRACRANIAL INFECTION, CEREBRAL DEGENERATION, CONGENITAL BRAIN MALFORMATIONS, HYPOGLYCEMIA, NONKETOTIC HYPERGLYCEMIA, HYPONATREMIA, HYPOCALCEMIA, RENAL FAILURE WITH UREMIA, HYPERTHYROIDISM, CEREBRAL ANOXIA, WITHDRAWAL STATE AND INTOXICATION. IN THE PRESENT CASE, THE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND ONSET OF THE EVENT WAS NOT REPORTED. CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT, AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, THIS EVENT WAS ASSESSED AS UNRELATED TO ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. ESSURE WAS REMOVED 5 YEARS AFTER INSERTION (INTERVENTION IMPLIED) THEREFORE THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 02 OCT 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00526	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE REPORTED THAT DUE TO ESSURE COILS SHE EXPERIENCED MASSIVE BLOOD CLOTS, WAS IN SO MUCH BACK PAIN AND PELVIC PAIN, AND MIGRAINES. SHE MENTIONED THAT SHE ENDED UP HAVING A HYSTERECTOMY TO END THE NIGHTMARE SHE WAS IN. THE CONSUMER MENTIONED THE SERIOUSNESS CRITERIA REQUIRED INTERVENTION AS EVENT OUTCOME BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL

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ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MASSIVE BLOOD CLOTS. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE, THE EXACT TIMING BETWEEN ESSURE INSERTION AND EVENT ONSET WAS NOT REPORTED HOWEVER GIVEN THE NATURE OF THE EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 02 OCT 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLO-UP WILL BE PURSUED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00527	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/31/2012
Explant Date (E7): 12/31/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5042061) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. SHE REPORTED THAT 6 MONTHS AFTER ESSURE WAS INSERTED SHE STARTED TO FEEL THAT THING WERE NOT RIGHT WITH HER BODY. SHE WENT TO HER PHYSICIAN AND DID SOME TESTS (BLOOD, XRAYS) AND NOTHING WAS FOUND. SHE MENTIONED THAT WENT TO AN ALLERGIST AND FOUND THAT SHE HAD MANY ALLERGIC REACTIONS SHE DID NOT HAVE PREVIOUSLY; SHE WAS TESTED POSITIVE FOR NICKEL ALLERGY, BUT THIS ALLERGY SHE HAD ALWAYS HAD. THE CONSUMER PROVIDED AN ESSURE EXPLANT DATE OF (B)(6)-2013. SHE STATED THAT BEFORE HER BILATERAL SALPINGECTOMY HER SYMPTOMS WERE: CRAMPING, STABBING PELVIC PAIN, HOT FLASHES, NIGHT SWEATS, BLEEDING AND SPOTTING AFTER SEX, PAINFUL INTERCOURSE, AND FREQUENT YEAST INFECTIONS; SWELLING OF THE VAGINA, ITCHING, BURNING AND STINGING OF VAGINAL ENTRANCE, ABDOMINAL SPASMS AND TWITCHING; BACK, JOINT, LEG AND HIP PAIN; NAUSEA; GAS AND CONSTIPATION; SEVERE BLOATING AND SWELLING OF THE ABDOMINAL AREA; HEARTBURN; HEADACHES AND MIGRAINES; CONSTANT DIZZINESS; BRAIN FOG, CLOUDINESS AND FORGETFULNESS; ANXIETY ATTACKS; MOOD SWINGS; DEPRESSION; CONSTANT RINGING IN EARS, HEIGHTENED ALLERGIES AND ALLERGIC REACTIONS, HIVES AND RASHES; CYSTS AND BOILS IN VAGINAL AND RECTAL AREA; SWELLING OF THE LEGS AND FEET; HAIR LOSS AND WELTS IN SCALP; TEETH SENSITIVITY; BLURRED VISION AND FLOATERS; DRY SKIN AND EYES. AFTER HER BILATERAL SALPINGECTOMY, HER SYMPTOMS WERE: VAGINAL DISCHARGE; CRAMPING; STABBING PELVIC PAIN; URGENT AND FREQUENT URINATION; BLEEDING AND SPOTTING AFTER SEX; PAINFUL INTERCOURSE; FREQUENT YEAST INFECTIONS; SWELLING OF THE VAGINA, ITCHING, BURNING AND STINGING OF VAGINAL ENTRANCE; BACK, JOINT,

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LEG AND HIP PAIN; NAUSEA; GAS AND CONSTIPATION; SEVERE BLOATING AND SWELLING OF THE ABDOMINAL AREA; HEARTBURN; HEADACHES AND MIGRAINES; CONSTANT DIZZINESS; TINGLING AND NUMBNESS IN ARMS; DEPRESSION; CONSTANT RINGING IN EARS; HEIGHTENED ALLERGIES AND ALLERGIC REACTIONS, HIVES AND RASHES; CYSTS AND BOILS IN VAGINAL AND RECTAL AREA; SWELLING OF THE LEGS AND FEET; HAIR LOSS AND WELTS IN SCALP; TEETH SENSITIVITY; BLURRED VISION AND FLOATERS; DRY SKIN AND EYES; SEVERE BLOATING AND SWELLING OF THE ABDOMEN. THE CONSUMER MENTIONED THE SERIOUSNESS CRITERIA REQUIRED INTERVENTION BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON (B)(6) 2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MANY ALLERGIC REACTIONS/ HEIGHTENED ALLERGIES. SHE WAS SUBMITTED TO A BILATERAL SALPINGECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE CONSUMER HAD A PREVIOUS NICKEL ALLERGY AND STARTED TO EXPERIENCING HEIGHTENED ALLERGIES AFTER ESSURE INSERTION IN ADDITION TO OTHER NON-SERIOUS EVENTS SUCH AS PAIN AND BLOATING. ALTHOUGH, ACCORDING TO HER, HER ALLERGIES AND SYMPTOMS PERSISTED AFTER SALPINGECTOMY; SINCE LIMITED INFORMATION WAS PROVIDED ABOUT THIS PROCEDURE (IF ESSURE WAS COMPLETELY REMOVED) CAUSALITY BETWEEN THE EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE INTERVENTION REPORTED, THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION (CLARIFICATION ABOUT EVENT'S OUTCOME AFTER SALPINGECTOMY) IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 22-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE CONSUMER WHO HAD ES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00528	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW# 5041996) IN UNITED STATES ON 23-JUN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED THAT SHE EXPERIENCED BLEEDING FOR OVER A YEAR, BECAME ANEMIC AND HAD TO HAVE A HYSTERECTOMY AS ONE COIL WAS MISSING. NOTHING WAS WRONG WITH HER BEFORE ESSURE AND NOTHING WRONG AFTER EVERYTHING WAS TAKEN OUT. SHE ALSO EXPERIENCED PAIN. CONCOMITANT MEDICATION INCLUDED WOMEN´S ONE A DAY VITAMIN. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 01-JUL-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE

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TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE BLEEDING (SEEN AS GENITAL BLEEDING). IT WAS REPORTED THAT ONE COIL WAS MISSING (SEEN AS DEVICE DISLOCATION). A HYSTERECTOMY WAS PERFORMED. BOTH EVENT ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALSO, GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN. IT WAS REPORTED THAT CONSUMER BLEED FOR OVER A YEAR AND BECAME ANEMIC. NO ALTERNATIVE EXPLANATION WAS PROVIDED. GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00529	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/3/2012
Explant Date (E7): 3/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW# 5041504) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. CONSUMER WASN'T INFORMED THE DEVICE CONTAINED NICKEL, NOR GIVEN ANY TYPE OF SENSITIVITY TEST FOR IT. THE FIRST ADVERSE EFFECT SHE NOTICED WAS THAT SHE WOULD SET OFF ANTI-THEFT DEVICES UPON ENTERING/EXITING STORES, WHICH WAS EMBARRASSING. SHE WAS TOLD BY IMPLANTING DOCTOR THAT HER PERIODS WOULD BECOME LIGHTER AS A RESULT. THEY DID NOT. SHE HAD TO LEAVE WORK SEVERAL TIMES TO CHANGE CLOTHES BECAUSE THEY WERE SO HEAVY, SOMETHING SHE HADN'T HAD TO DO IN ABOUT 20 YEARS. SHE ALSO EXPERIENCED BLEEDING FROM URETHRA. HER SKIN WAS EXTREMELY DRY, WHERE AS IT USED TO BE OILIER, RESULTING IN SOME SORT OF DERMATITIS OR ADULT ACNE, ALTHOUGH NOTHING THE DERMATOLOGIST PRESCRIBED HER SEEMED TO HELP. SHE HAD DIGESTIVE ISSUES THAT SEEMED TO START AFTER SHE HAD ESSURE IMPLANTED, ALTHOUGH GASTROLOGIST COULD NOT FIND THE EXACT CAUSE OF HER PROBLEMS. SHE EXPERIENCED PELVIC PAIN ON A DAILY BASIS AND HAD A FEW UTIS (URINARY TRACT INFECTIONS) TOO. HER IRON, HEMOGLOBIN AND FERRITIN LEVELS WERE LOW THAT SHE HAD TO RECEIVE IV IRON INFUSIONS. CONSUMER ASSESSED THE CASE AS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOWEVER SHE DID NOT SPECIFY IT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(6). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES.

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SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER PERIODS WERE SO HEAVY, HER IRON, HEMOGLOBIN AND FERRITIN LEVELS SO LOW THAT SHE HAD TO RECEIVE INTRAVENOUS IRON INFUSIONS. SHE ALSO HAD BLEEDING FROM URETHRA AND SEVERAL URINARY TRACT INFECTIONS. THE HEAVY PERIODS, INTERPRETED AS MENORRHAGIA, IS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION. THE URETHRAL HEMORRHAGE AND URINARY TRACT INFECTIONS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THE MENORRHAGIA IS LISTED AND WHILE THE OTHER TWO SERIOUS EVENTS ARE UNLISTED. BLEEDINGS MAY OCCUR WITH ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER WAS TOLD BY HER PHYSICIAN THAT HER PERIODS WOULD BECOME LIGHTER BUT THEY DID NOT THEY WERE HEAVY. HER IRON, HEMOGLOBIN AND FERRITIN LEVELS WERE LOW. SO SHE HAD TO RECEIVE INTRAVENOUS IRON INFUSIONS. CONSIDERING THE NATURE OF THIS EVENT, THE POSITIVE RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS CONSIDERED RELATED TO ESSURE. HOWEVER, CONSIDERING THE LOCALIZED ACTION OF ESSURE, IT IS NOT EXPECTED THAT IT WOULD CAUSE URETHRAL HEMORRHAGE AND/OR URINARY TRACT INFECTIONS. THEREFORE, THESE TWO EVENTS ARE CONSIDERED UNRELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO THE REQUIRED MEDICAL INTERVENTION. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 27-OCT-2015 THE REQUIRED NUMBERS OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00530	BAYER HEALTHCARE LLC	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/13/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW5041523) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) -2008. THE CONSUMER STATED THAT SINCE INSERTION SHE STARTED EXPERIENCING MULTIPLE SYMPTOMS THAT SHE BELIEVED WERE TIED TO ESSURE. SHE HAD GAINED AN INCREDIBLE AMOUNT OF WEIGHT/ SHE NEVER WEIGHTED SO MUCH, INCLUDING BEING FULL TERM PREGNANT. SHE HAD MOOD SWINGS, DEPRESSION WHICH LED TO HOSPITALIZATION, EXHAUSTION, HEADACHES, AND CHRONIC BACK PAIN AND JOINT PAIN. THE BACK PAIN WAS THE POINT THAT SHE HAD SEEN A PAIN MANAGEMENT SPECIALIST AND HAD MULTIPLE PROCEDURES DONE TO LITTLE AVAIL. SHE SAID THAT COULD NOT STAND FOR MORE THAN 5 MINUTES WITHOUT EXPERIENCING EXCRUCIATING BACK PAIN. SHE TOOK TYLENOL ARTHRITIS. AN INJURY (DISABILITY OR PERMANENT DAMAGE) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO

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BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEPRESSION AND CHRONIC BACK PAIN. DEPRESSION WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND CHRONIC BACK PAIN WAS CONSIDERED SERIOUS DUE TO DISABILITY. BOTH ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER REPORTED THAT SHE COULD NOT STAND FOR MORE THAN 5 MINUTES WITHOUT EXPERIENCING EXCRUCIATING BACK PAIN. NO ALTERNATIVE EXPLANATION FOR THE OCCURRENCE OF THE EVENTS WERE PROVIDED. CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO HOSPITALIZATION AND DISABILITY. ADDITIONALLY, NON-SERIOUS EVENTS WERE ADDED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 29-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUB

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044487	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONOLOGICAL PAIN, EXCESS BLEEDING AND BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044488	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 8/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A LITTLE OVER A YEAR FROM INSERTION OF THE ESSURE DEVICE I STARTED HAVING CRAMPING, BLEEDING, HEADACHES, WEIGHT GAIN AND PAIN DURING INTERCOURSE. I WENT TO MY PCP WHO ALSO PERFORMS ALL OF MY PAP SMEARS AND THEY JUST TOLD ME THAT ALL OF THOSE SIDE EFFECTS WERE NORMAL WITH BIRTH CONTROL. ALL OF THESE SYMPTOMS HAVE CONTINUED 3 YEARS LATER AND I'M NOW SEEING REPORTS OF THESE COILS CAUSING HEALTH PROBLEMS, ALLOWING WOMEN TO GET PREGNANT AND PERFORATING ORGANS. IM SCARED THAT SOMETHING IS HAPPENING TO ME!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044489	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BECAME PREGNANT, BEFORE THE PREGNANCY. SEVERE PAIN, LIGHT HEADEDNESS, DIZZYNESS, MIGRAINES. PAINFULLY LONG MENSTRUAL CYCLES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044490	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALMOST IMMEDIATELY AFTER HAVING ESSURE IMPLANTED IN MY TUBES, I BEGIN EXPERIENCING PAIN AND DISCOMFORT. I WAS TOLD ESSURE WOULD NOT CAUSE THIS PAIN. 3 MONTHS AFTER I WAS IMPLANTED I WAS INFORMED THAT THE RIGHT COIL WAS NOT THERE. MY DR. SAID THAT IT MUST HAVE FALLEN OUT BUT DID NOT VERIFY THAT IT WASN'T SOMEWHERE ELSE IN MY BODY. SHE SAID THAT WE COULD PUT A NEW ONE IN, BUT AT THIS POINT I WAS HAVING SEVERE CRAMPING ON MY LEFT SIDE DURING OVULATION AND MY MENSTRUAL CYCLE. SHE SAID AGAIN IT WASN'T ESSURE, BUT AT THAT POINT I DIDN'T AGREE WITH HER. EACH MONTH AFTER THAT, THE PAIN BEGAN TO WORSEN ON MY LEFT SIDE UNTIL I WAS CONVINCED THERE WAS SOMETHING WRONG. I HAD BEEN EXPERIENCING DEBILITATING MIGRAINES, INABILITY TO LOSE WEIGHT, HAIR LOSS, PAIN DURING INTERCOURSE, AND FATIGUE. IN (B)(6) 2014 I WENT TO A NEW DR AND EXPRESSED MY CONCERNS ABOUT ESSURE. SHE ALSO TOLD ME THAT ESSURE WOULD NOT BE CAUSING MY PROBLEMS EVEN THOUGH IT WAS MY LEFT SIDE IN PAIN AND THE LEFT SIDE THAT STILL HAS A COIL. AFTER AN ULTRASOUND WHERE I WAS TOLD THAT MY LEFT OVARY AND SIDE WERE UNUSUALLY TENDER, IT STILL COULDN'T BE ESSURE. SHE SUGGESTED THAT IT WAS PROBABLY SOMETHING GASTRIC. AS THE PAIN CONTINUED, I DECIDED TO GO TO MY PRIMARY DR INSTEAD OF AN OBGYN TO AGAIN EXPRESS MY CONCERNS. I WAS TOLD AT THAT VISIT, IN (B)(6) 2014, THAT I WAS PREGNANT. MY DR IMMEDIATELY SENT TO THE HOSPITAL TO HAVE AN ULTRASOUND COMPLETED TO ENSURE IT WASN'T A TUBAL PREGNANCY. IT WASN'T. I FOUND A NEW OBGYN WHO WAS SURPRISED THAT MY ORIGINAL DR DID NOT MAKE SURE MY RIGHT COIL WASN'T LODGED SOMEWHERE ELSE AND WE DECIDED IMMEDIATELY TO INCLUDE A FOLLOW-UP XRAY IN THE HOSPITAL AFTER DELIVERY TO LOOK FOR IT. WE ALSO DECIDED THAT I WOULD HAVE A TUBAL LIGATION IMMEDIATELY AFTER DELIVERY. WHILE MY EARLIER SYMPTOMS CONTINUED, I DID HAVE A RELATIVELY HEALTHY PREGNANCY. I DID DEVELOP A

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

RASH ON MY STOMACH THAT I HAD NEVER PREVIOUSLY HAD AND DID WONDER IF I HAD DEVELOPED AN ALLERGY TO THE NICKEL IN THE ACTUAL COIL. MY SON WAS BORN AT 36 WEEKS AND 6 DAYS, SO ABOUT 3 WEEKS EARLY. THE NEXT MORNING I HAD A TUBAL LIGATION DONE. AFTER SURGERY I WAS IN EXTREME PAIN ON MY LEFT SIDE AND BECAME EXTREMELY SICK. AFTER PASSING OUT AND FALLING OUT OF MY BED TO THE FLOOR, MY DR HAD AN XRAY COMPLETED. IT WAS DETERMINED THOUGH THAT AND BLOOD WORK THAT I HAD INTERNAL BLEEDING. I HAD TO UNDERGO A SECOND SURGERY THE NEXT MORNING IN WHICH MY DR FOUND THAT MY LEFT TUBE HAD TORN AT THE BASE AND I HAD A BLOOD CLOT THE SIZE OF A SOCCER BALL IN MY STOMACH. WHILE SHE DID NOT REMOVE THE COIL FROM MY LEFT SIDE AT THAT TIME, IT IS TOO COINCIDENTAL THAT IT WAS THAT SIDE THAT TORE. SHE SAID THAT SHE HAD NEVER SEEN A TUBE THAT TORE AT THE BASE THE WAY MINE DID. AFTER DELIVERY, THE RASH ON MY STOMACH CONTINUES AS WELL AS TENDERNESS AND PAIN ON MY LEFT SIDE. I HAVE ALSO HAD EXTREME MIGRAINES WHERE MY SPEECH WAS IMPAIRED. MY HAIR IS CONTINUING TO THIN OUT. MY SON WAS BORN (B)(6) 2015. IT'S BEEN ALMOST 3 MONTHS AND I STILL FEEL EXTREME CRAMPING ON MY LEFT SIDE. I WAS UNABLE TO HOLD MY SON FOR ALMOST 72 HOURS AFTER SURGERY BECAUSE I WAS IN SO MUCH PAIN. BECAUSE OF THIS I WAS UNABLE TO BREASTFEED HIM AS HE WAS ALREADY USED TO FORMULA BY THE TIME I WAS ABLE TO TRY TO NURSE HIM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044491	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN PROGRESSIVELY WORSE OVER TIME BECOMING LIKE LABOR. HEAVY BLEEDING TO THE POINT I COULD NOT LEAVE MY HOME. SYMPTOMS LED TO HYSTERECTOMY. HAD TO HAVE A TUBAL DONE AFTER ONE IMPLANT FELL OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044492	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/24/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PREGNANT TWICE. SEVERE ABDOMINAL PAIN. HEAVIER PERIODS, NAUSEA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044493	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/6/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MENSTRUAL CYCLE THAT LASTS FOR THREE WEEKS AT A TIME, WITH VERY VERY HEAVY BLEEDING. HAIR LOSS, JOINT PAIN, TOOTH LOSS, ABDOMINAL PAIN, BACK PAIN, MENTAL FOGGINESS, VERY TIRED AND SEVERE BLOATING. I CAN ALSO FEEL BOTH COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044497	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 7/11/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NOW STARTED GETTING PAIN IN LEFT ARM AND HAND. GET TINGLING AND NUMBNESS THAT IN ARM AND HAND. CAN'T SLEEP AT NIGHT DUE TO THE PAIN .

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044503	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 7/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). -PAIN IN REPRODUCTIVE AREA. -HAIR LOSS. -SCALP IRRITATION AND RASH. -SKIN IRRITATION/RASH THAT COMES AND GOES. -TASTE AND SMELL OF METAL. -STOMACH BLOATING. -STOMACH PAIN. -SHARP PAIN DURING INTERCOURSE. -SHARP PAIN FROM OVARIES, UTERUS, CERVIX AND VAGINA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044505	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 3/3/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME HEADACHES,MIGRAINES,CHANGE IN MENSTRUAL CYCLE,CONSTANT SPOTTING,EXTREME CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044506	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 10/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NAUSEA, VOMITING, HEADACHE, ABDOMINAL PAIN, CRAMPING, IRREGULAR MENSTRUAL CYCLES, HAIR LOSS, MOOD ALTERATION, EARLY ONSET MENOPAUSE, FATIGUE, PELVIC PAIN, PELVIC FLUTTERING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044513	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ESSURE SINCE (B)(6) 2010 AND I HAVE GAINED SO MUCH WEIGHT SINCE THEN. (B)(6). I ALSO HAVE A LOT OF BACK PAIN. I AM VERY DEPRESSED AND HAVE A LOT OF ANXIETY TOO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044514	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 11/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOST A COIL. IT CAME OUT THE SAME WAY IT WENT IT. HAD SEVER CRAMPING AND BLEED EVER SINCE. THEN IN (B)(6) OF 2010 I WAS TAKEN TO THE ER FOR SHARP STABBING PAIN IN MY LOWER ABDOMINAL AREA. HAD A RUPTURED OVARIAN CYST AND LOST THE SECOND COIL. STILL HAVE METAL FRAGMENTS IN MY TUBES AND DEAL DAILY WITH BLOATING. SHORTLY AFTER GETTING ESSURE I STARTED HAVING PAIN EVERYWHERE. WAS DIAGNOSED WITH DEPRESSION AND FIBROMYALGIA. WORST MISTAKE OF MY WAS GETTING ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044515	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN HAVING CONTRACTIONS ABOUT 4 TIMES A DAY SINCE THE IMPLANTATION OF ESSURE. THE CONTRACTIONS ARE PAINFUL AND MAKE ME DOUBLE OVER IN PAIN. MY PERIODS ARE EXTREMELY HEAVY, AND I ALWAYS HAVE LARGE BLOOD CLOTS. I'VE ALSO GAINED ABOUT (B)(6). I'VE ALWAYS BEEN UNDER WEIGHT. I DEVELOPED AN ALLERGY TO THE SUN RIGHT AFTER IMPLANTATION, AND AS A PERSON WITH OLIVE SKIN WHO HAS ALWAYS TANNED, THIS IS OBVIOUSLY A SIDE-EFFECT OF ESSURE. WHEN I'M IN THE SUN I GET BUMPS COVERING ANY PART OF ME THAT IS EXPOSED, USUALLY MY ARMS. I WAS DIAGNOSED WITH AN ALLERGY TO THE SUN. I NEVER HAD ANY OF THESE ISSUES BEFORE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044516	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING UNUSUAL PERIODS, GAINED ABOUT (B)(6), LOW VITAMIN D, TROUBLE WITH MY THYROID, PAIN IN BREAST, AND CRAMPING REALLY LOW IN THE STOMACH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044517	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP STOMACH/PELVIC PAIN, RAPID WEIGHT GAIN((B)(6)-MOSTLY IN MY STOMACH), JOINT PAIN IN MY LEGS, RASHES ON MY FACE, HANDS AND NECK DUE TO ALLERGIC REACTION FROM THE NICKEL FROM THE COILS, EXTREMELY HEAVY PERIODS, EXTREME FATIGUE, LOSS OF SEX DRIVE, BLURRY VISION, HAIR LOSS, INFLAMMATION THROUGHOUT MY BODY-ESPECIALLY MY STOMACH, SWOLLEN HANDS, LEGS AND FEET. HAVE GONE TO THE DOCTOR MANY TO TRY TO RESOLVE THESE PROBLEMS AS THEY DID NOT BEGIN UNTIL I HAD ESSURE PUT IN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044518	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 3/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DR AT THE CLINIC WHERE I RECEIVED THE ESSURE IMPLANTS (DR (B)(6) MEDICAL CENTER (B)(6)) PUSHED THE ESSURE ON ME OVER THE TUBAL THAT I WANTED BECAUSE IT WAS AN IN CLINIC PROCEDURE. IN THE PRE PROCEDURE I WAS NOT ASKED WHETHER OR NOT LOCAL ANESTHESIA AFFECTED ME. DURING THE PROCEDURE AFTER MAXING OUT THE DOSAGE OF LOCAL ANESTHESIA (LIDOCAINE) I WAS INFORMED THAT I WOULDN'T OF BEEN A CANDIDATE FOR THE PROCEDURE IF THEY HAD KNOWN THAT IT DIDN'T WORK. I TOLD THEM THAT THEY DIDN'T ASK. THE PAIN I EXPERIENCED WAS EQUAL TO THAT OF CHILD BIRTH WHEN TRYING TO PLACE THE RIGHT COIL PROPERLY. THE FIRST TIME THEY COULDN'T PLACE THE COIL PROPERLY SO THEY PULLED IT OUT AND ATTEMPTED TO PLACE THE SECOND COIL. IT TOOK OVER FORTY FIVE MINUTES. I HAVE BEEN IN PAIN EVER SINCE. CRAMPING. SEVERE SHARP/STABBING PELVIC PAIN. ABNORMAL MENSES. OVARIAN CYSTS. FALLOPIAN TUBE CYSTS. BACTERIAL VAGINOSIS. DISCHARGE WITH ODOR. ENDOMETRIOSIS. PID (PELVIC INFLAMMATORY DISEASE). CYSTS AT THE VAGINAL OPENING (BARTHOLIN'S CYST). PMDD (PREMENSTRUAL DYSPHORIC DISORDER). UTERINE INFLAMMATION. EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA). LARGE CLOTS (BIGGER THAN A HALF DOLLAR COIN) DURING PERIOD. PAINFUL OVULATION (MITTELSCHMERZ). NIGHT SWEATS. LOSS OF LIBIDO. HOT FLASHES. BLEEDING/SPOTTING AFTER SEX. PAINFUL PERIODS (DYSMENORRHEA). PAINFUL INTERCOURSE (DYSPAREUNIA). YEAST INFECTIONS (CANDIDA). URGENT/FREQUENT URINATION. UTI (URINARY TRACT INFECTION). CERVICITIS/VAGINITIS (SWELLING, INFLAMMATION, INFECTION OF THE CERVIX OR VAGINA). ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE (VULVODYNIA). BREAST PAIN/TENDERNESS. ABDOMINAL PAIN. BACK, JOINT, LEG, BREAST, SPINE, HIP PAIN. CHRONIC PELVIC PAIN. ALL OVER BODY ACHES/PAIN. EXTREME JOINT PAIN. HEARTBURN. HEADACHES. DIZZINESS. TINGLING SENSATIONS. NUMBNESS. NERVE PAIN. BRAIN FOG AND DASH; CLOUDINESS, FORGETFULNESS.

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ANXIETY/PANIC ATTACKS. DEPRESSION FROM PAIN. DIMINISHED BRAIN FUNCTION MEMORY CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS. NUMBNESS IN THIGH (MERALGIA PARETHETICA). NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET). SENSATION OF BURNING AND PRICKLING OF SKIN. UNEXPLAINED/EASILY BRUISING. ANEMIA. CHRONIC FATIGUE. CYSTS, ACNE. HEART PALPITATIONS. COILS/DEVICE ISSUES SHARP STABBING PAIN. SWELLING OF LEGS/FEET. HAIR LOSS/THINNING OF HAIR. INSOMNIA . ITP (IDIOPATHIC THROMBOCYTOPENIA PURPURA) . MUSCLE SPASMS. VISION PROBLEMS (BLURRED VISION). BLOATING. BLOOD IN URINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044519	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 1/4/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY HEAVY BLEEDING TO WHERE I WAS BLEEDING THROUGH CLOTHES. JOINT PAIN, CONSTANT PELVIC PAINS, DAILY HEADACHES, BP ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044538	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 8/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SERIOUS BLEEDING WHEN HAVING SEX, STRAINING BOWEL MOVEMENTS, AND RANDOM TIMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044539	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/7/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER BACK AND PELVIC PAIN, HEADACHES, NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044540	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 10/31/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATELY AFTER I HAD ESSURE IMPLANTED IN MY FALLOPIAN TUBES I EXPERIENCED SEVERE ITCHING/RASH, PELVIC PAIN AND BLEEDING. AFTER THAT SUBSIDED, AND WITHIN A FEW MONTHS MY HAIR BEGAN TO FALL OUT, I HAD CONSTANT PELVIC PAIN, HEADACHES, SWELLING AND INFLAMMATION AND WEIGHT GAIN. AS TIME WENT ON, MORE AND MORE SYMPTOMS BECAME OBVIOUS. BY THE TIME I HAD ESSURE IMPLANTED FOR 6 YEARS I DEALT WITH ONGOING STABBING PELVIC PAIN, SEVERE HEADACHES, SEVERE SWELLING OF THE HANDS, FEET, LEGS AND ANKLES, VAGINAL ODOR, METAL TASTE IN MY MOUTH, CONSTANT HOT FLASHES AND NIGHT SWEATS, EXCESSIVE BLEEDING DURING PERIODS, AND VERY PAINFUL PERIODS. IN 2014 I ENDED UP HAVING A TOTAL HYSTERECTOMY, HAD A TUMOR IN MY UTERUS, AND HAD FIBROIDS ON BOTH FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044541	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 4/21/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR FALLING OUT HORRIBLE STABBING CRAMPS , MUSCLES ACHE ALL OVER BODY TERRIBLE HEADACHES METAL TASTE IN MOUTH BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044542	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ARTHRITIS AND LOWER BACK PAIN ALMOST DAILY; NEUROPATHY; FACIAL HAIR; LESSENED VISION WITH FLOATERS; HAIR LOSS AND THINNING; UTI'S; KIDNEY STONE 8 MM; PELVIC PAIN; STOMACH FLUTTERS; WEAK HIPS; SCIATICA; SWOLLEN AND PAINFUL LEGS, FEET, ANKLES. WAS IMMOBILE AT ONE POINT. TEETH AND JAW PAIN; SWOLLEN; "NUMBER"; AND TINGLING HANDS, ARMS AND FEET; RASH; VERTIGO; SED RATE STAYS HIGH AROUND 73; BLOOD PRESSURE STAYS HIGH, ENDED UP WITH 3RD PILL, MULTIPLE SINUS INFECTIONS. WEIGHT GAIN. FATIGUE. SWOLLEN STOMACH. DEGENERATIVE DISC DISEASE WORSENED FAST; ACNE; VAGINAL CRAMPS; PAIN DURING SEX; LOSS OF LIBIDO; CONSTIPATION; INSOMNIA; NO PERIOD; BODY SPASMS; DISCHARGE; HOT FLASHES;. DEPRESSION; ANXIETY;. INCONTINENCE; SEXUAL DYSFUNCTION; URGENT URINATION; EARS STOPPED UP; WEAKENED IMMUNE SYSTEM; ANEMIA WORSENED; CYST/BOILS; THYROID ISSUES; HEARTBURN/GAS; CHEMICAL/FOOD SENSITIVITIES; BREAST TENDERNESS; CHRONIC ADRENAL FATIGUE; BODY SPASMS; HARD TO STRAIGHTEN RIGHT LEG AT TIMES, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044543	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 1/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STOMACH SPASMS, SEVERE PAIN ON RIGHT SIDE, BLOATING, UNEXPLAINED WEIGHT GAIN, LOSS OF LIBIDO, IRREGULAR PERIODS, SYMPTOMS OF HAVING A PERIOD FOR HALF A MONTH AT A TIME AND CHANGES IN UNABLE TO REACH ORGASM. I NEVER EXPERIENCED ANY PROBLEMS IN THE PAST PRIOR TO THIS DEVICE. I FEEL MISERABLE AND FATIGUED THE MAJORITY OF THE MONTH. CHRONIC BLOATING ALL OF THE TIME AND SHARP PAINS IN SIDE PRIOR TO BEGINNING MENSTRUAL CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044544	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC NAUSEA/VOMITING, CONSTANT BLOATING, PERSISTENT LOWER BACK PAIN AND PELVIC PAIN, INCREASED MIGRAINES, EXCESSIVE LOSS OF ENERGY, PAINFUL/HEAVY MENSTRUAL CYCLES EVERY 2-3 WEEKS, PAINFUL INTERCOURSE, HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044545	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 5/9/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE IMPLANTED IN MAY 2013, HAVE HAD CRAMPING EVER SINCE. PAIN WITH SEX, PAIN WHEN MAKE QUICK MOVEMENTS, BLOATING, WEIGHT GAIN...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044546	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 5/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, DIZZINESS, RUNNY EYES, RASHES JUST TO NAME A FEW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044547	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 8/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN AND CRAMPS IN UTERUS. SWELLING IN ABDOMEN. WEIGHT GAIN THAT CANT BE LOST EVEN WITH WORKOUTS AND DIET. FREQUENT HEADACHES. DIAGNOSED WITH ANXIETY AFTER HAVING ESSURE PUT IN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044548	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNDERWENT HYSTERECTOMY ABOUT 3 WEEKS AGO WITH A DOCTOR WHO BELIEVED MY PAIN WAS FROM ESSURE. SINCE SURGERY I HAVE HAD NO PAIN IN THE LOCATION THAT WAS BOTHERING ME BEFORE, NO RASHES OR BOILS, AND MY BELLY BLOAT THAT I THOUGHT WAS JUST WEIGHT GAIN HAS BEEN GONE! I'VE LOST OVER 20 POUNDS IN 3 WEEKS. I FEEL LESS TIRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044549	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEFORE ESSURE I DID NOT HAVE ANY PAIN PELVIC DURING MY PERIOD NOR FEW DAYS BEFORE OR AFTER. AFTER FEW MONTHS OF ESSURE I START HAVING SEVERE CRAMPING AND CONTRACTIONS LIKE PAIN ON MY RIGHT PELVIC AREA, THE PAIN GOES ALL THE WAY TO MY LEG AND BACK, OVER THE TIME IS HAS BEEN GETTING WORST TO THE POINT OF NOT ABLE TO SLEEP WELL OR FUNCTION DURING THE DAY, THIS PAIN START ABOUT TWO WEEKS BEFORE MY PERIOD AND IT GOES AWAY DURING MY PERIOD. THE PAIN IS SO STRONG THAT SOME TIMES FEELS LIKE I AM IN LABOR. I HAVE GAIN A LOT OF WEIGHT, AND I HAVE PERIODS OF MIGRAINES THAT I DID NOT HAVE BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044550	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 6/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD INTENSE ABDOMINAL PAIN FOLLOWING MY PROCEDURE. IN THE SIX WEEKS FOLLOWING MY PROCEDURE, MY PAIN WAS SO INTENSE THAT I COULDN'T SIT UP. I WAS ASSURED THAT THIS WAS DUE TO THE SPASMING OF MY FALLOPIAN TUBES, A SIDE EFFECT THAT DOESN'T HAPPEN OFTEN BUT WOULD GO AWAY. AFTER THAT SIX WEEK PERIOD, THIS PAIN DID LESSEN, BUT NEVER COMPLETELY LEFT. I STILL HAVE TIMES WHEN THE PAIN HITS ME SO HARD THAT I DOUBLE OVER AND AM INCAPACITATED. I HAVE SINCE HAD THE COILS REMOVED AND AM ALSO SCHEDULED FOR A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044551	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 10/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT A MIGRAINE THAT LASTED 16 DAYS IMMEDIATELY AFTER IMPLANTATION AND HAVE HAD THEM 2 OR 3 DAYS A WEEK SINCE. I ALSO HAD A 4.5 MONTH PERIOD AND HAVE BEEN EXPERIENCE MODERATE TO SEVERE CRAMPING ACCOMPANIED BY A STABBING SENSATION. I HAVE HAD INFECTIONS THROUGHOUT MY BODY CONSTANTLY SINCE IMPLANTATION AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044552	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 9/10/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE DEVICES IN (B)(6) 2012, AFTER THE BIRTH OF MY 4TH CHILD. I BLED FOR 2 MONTHS, THEN IN (B)(6) OF 2013 I STOPPED HAVING MENSTRUAL CYCLES FOR 6 MONTHS. IN THAT TIME I STAYED LOSING HANDFULS OF HAIR, GAINING WEIGHT RAPIDLY, HAVE BECOME VERY EMOTIONAL. I HAVE SINCE STARTED MY CYCLES AGAIN, MOST MONTHS, AND THEY ARE VERY HEAVY AND VERY PAINFUL. I HAVE CHRONIC JOINT PAIN, HEADACHES, FORGETFULNESS, SEVERE FATIGUE AND ALLERGY SYMPTOMS THAT I'VE NEVER HAD BEFORE. MIGRAINES AT LEAST TWICE A WEEK. NONE OF THIS WAS HAPPENING BEFORE ESSURE. I NEED THEM OUT BUT CAN'T GET INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044553	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE COILS BUSTED THROUGH MY TUBES AND GREW INTO MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044554	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 1/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED (B)(6) 2012. SINCE THAT TIME MY PERIODS HAVE BEEN HORRIBLE. BLEEDING EXTREMELY HEAVY WITH CLOTS AND VERY BAD CRAMPING. IN (B)(6) 2014, I EXPERIENCED 4 MONTHS OF BLEEDING. WHEN I FINALLY STOPPED BLEEDING, I WAS STILL CRAMPING ALL THE TIME. I ALSO NOTICED THAT I WAS BLOATED ALL THE TIME TOO, NO MATTER WHAT I ATE OR DRANK. I STARTED HAVING HEADACHES THAT WOULD COME WITH MY PERIODS AND LAST THE WHOLE TIME MY PERIOD DID. SEX WAS PAINFUL. THEN, (B)(6) 2015 I STOPPED HAVING A PERIOD FOR ABOUT 4 MONTHS. THE CRAMPING AND BLOATING AND HEADACHES ALL REMAINED EVEN THOUGH I WAS NOT HAVING A PERIOD. I NOW HAVE ALL THESE SYMPTOMS EVERYDAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044555	BAYER	7/21/2015	7/21/2015

Event Information:

Event Date (B3): 11/26/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, STABBING PELVIC PAIN, ABNORMAL MENSTRUAL, HOT FLASHES, NIGHT SWEATS, BLEEDING AFTER SEX, PAINFUL INTERCOURSE, LOSS OF PLEASURE, WORSEN MENSTRUAL, BREAST PAIN AND TENDERNESS, ABNORMAL SPASMS FLUTTERING, PID, GAS, ABNORMAL BLOATING, WORSEN MIGRAINE, DIZZINESS, BRAIN FOG, SHORT TERM MEMORY LOSS, HEART PALPITATIONS, INSOMNIA, MUSCLE CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044787	BAYER	7/21/2015	7/29/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 626904

Single Use:
Implant Date (E6): 6/8/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE BIRTH CONTROL IMPLANT CALLED ESSURE PLACED IN MY FALLOPIAN TUBES AFTER MY SECOND CHILD IN 2008. SINCE THEN IT HAS CAUSED ME MORE HARM THAN GOOD. I HAVE DEALT WITH NUMEROUS TESTS, BLOODWORK, XRAYS, MEDICATIONS, PHYSICAL THERAPY, AND SO MUCH MORE OVER THE PAST 7 YEARS. I HAVE BEEN FROM ONE SPECIALIST TO THE NEXT WITH SYMPTOMS INCLUDING, RAPID WEIGHT GAIN, HEADACHES, MEMORY LOSS, PCOS, BACK PAIN, ABDOMINAL PAIN, ALL OVER PAIN LIKE HAVING A SUNBURN ON MY SKIN, NUMBNESS OF HANDS AND FEET, SEVERE EDEMA, HIGH BLOOD PRESSURE, LOSS OF BLADDER AND BOWEL FUNCTION, RINGING IN MY EARS, METALLIC TASTE IN MY MOUTH, MUSCLE SPASMS, HEAVY MENSTRUATION LASTING MORE THAN 7 DAYS, INABILITY TO WALK DUE TO SEVERE SWELLING, RASHES, ITCHING, SWEATING ALL THE TIME, INSOMNIA, PELVIC AND KIDNEY PAIN, BRUISING FOR NO REASON, INCREASED THIRST, HAIR LOSS, BLOATING OF THE ABDOMEN LOOKING LIKE I AM 6 MONTHS PREGNANT, SKIN SENSITIVITY, CYSTOCELE AND RECTOCELE, JOINT PAIN, DEPRESSION, URINARY TRACT INFECTIONS, BLOOD IN URINE, NO LIBIDO, NO FEELING DURING INTERCOURSE, AND CHRONIC FATIGUE EVERY MONTH SINCE 2008 WHEN THE IMPLANT WAS PLACED BY MY OB/GYN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044788		7/21/2015	7/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD REALLY BAD PAIN; COULDN'T SIT ON MY BUTT. I WAS BLEEDING TO DEATH. I HAD TO HAVE IT REMOVED. THE PAIN WAS UNBEARABLE AND I COULDN'T STOP BLEEDING, I WAS UNABLE TO HAVE SEX WITH IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044789		7/21/2015	7/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAVE HAD THE ESSURE INSERTED I NOTICE I HAVE BEEN EXPERIENCING HEAVY MONTHLY BLEEDING, HEADACHES, ACHES AND PAINS IN ABDOMINAL AREA. I HAVE IT TO PREVENT PREGNANCY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00531	BAYER HEALTHCARE LLC	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/15/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR PERMANENT CONTRACEPTION. ON (B)(6) 2015, ULTRASOUND SCAN WAS DONE AND LEFT SIDE INSERT WAS NOT VISUALIZED. ON (B)(6) 2015, PATIENT WAS COMPLAINING OF FATIGUE, HEADACHES AND WEIGHT GAIN. IT WAS REPORTED THAT PATIENT NEVER HAD HSG (HYSTEROSALPINGOGRAM) DONE. THE OUTCOME OF THE EVENTS LEFT SIDE INSERT WAS NOT VISUALIZED, FATIGUE, HEADACHES, AND WEIGHT GAIN WAS NOT RECOVERED / NOT RESOLVED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4)-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL

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INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON (B)(6) 2015: INFORMATION RECEIVED STATES THE (B)(6) FEMALE PATIENT HAS AS MEDICAL HISTORY MIGRAINES WITHOUT AURA AND PENICILLIN ALLERGY (HIVES). SHE DENIES SMOKING OR ALCOHOL INTAKE AND HER FAMILY HISTORY INCLUDED HYPERTENSION, CANCER AND DIABETES. THE PATIENT IS GRAVIDA 6, PARA 6 (1 C-SECTION FOR BREECH PRESENTATION AND ALL OTHER DELIVERIES WERE VAGINAL) AND HAS NO ABORTION. ALSO, SHE HAD A NORMAL SPONTANEOUS DELIVERY AND, IN (B)(6) 2013, WAS SEEN FOR HER POST-PARTUM VISIT FOLLOWED BY ESSURE PLACEMENT 1 WEEK LATER. HER CONCOMITANT MEDICATION ARE IMITREX, IBUPROFEN, PROVERA, DIFLUCAN AND VITAMIN D AND HER DRUG HISTORY INCLUDES ADIPEX-P. PATIENT HAD A FOLLOW-UP ON WHICH SHE WAS ON THE DEPO-PROVERA INJECTIONS, SHE WAS ADVISED A HYSTEROSALPINGOGRAM TO BE DONE 3 MONTHS FOLLOWING THE PROCEDURE, WHICH SHE DID NOT DO. SHE WAS SEEN AGAIN IN (B)(6) 2013 FOR SOME ABNORMAL BLEEDING AND, AT THAT TIME, SHE WAS STILL USING DEPO-PROVERA INJECTIONS. SHE WAS ALSO REMINDED TO DO THE HYSTEROSALPINGOGRAM POST ESSURE PROCEDURE BUT THIS EXAM WAS NOT DONE. SHE RETURNED FOR ANNUAL EXAM ON (B)(6) 2014 AND, AT THE TIME, SHE HAD NO COMPLAINTS. SHE WAS ALSO REMINDED THAT, THE HYSTEROSALPINGOGRAM WAS NOT DONE. ON (B)(6) 2015, PELVIS COMPLETE ULTRASOUND AND TRANSVAGINAL ULTRASOUND WERE PERFORMED AND SHOWED RIGHT ESSURE DEVICE IN THE RIGHT ADNEXAL REGION AND LEFT SIDED DEVICE WAS NOT VISUALIZED. THE PATIENT WAS SEEN AGAIN IN (B)(6) 2015 WITH A COMPLAINT OF AMENORRHEA, DYSMENORRHEA (FOR PAST 3 MONTHS NOT RELIEVED WITH HEATED PADS OR MOTRIN) AND PELVIC PAIN (FOR PAST 6 WEEKS CONSTANT) ON WHICH IS MOSTLY LOCATED IN THE RIGHT LOWER QUADRANT FOR THE PAST FEW WEEKS. ON EVALUATION, PELVIC ULTRASOUND WAS ESSENTIALLY NEGATIVE OF ANY FINDINGS EXCEPT FOR THE EVIDENCE OF THE COIL IN THE RIGHT TUBE; THE COIL ON THE LEFT SIDE COULD NOT BE LOCATED. ON ONE ASSESSMENT, THERE WAS A QUESTIONABLE COIL PRESENCE IN THE PELVIC AREA; HOWEVER, THIS WAS NOT DOCUMENTED WITH OTHER EVALUATIONS. PELVIC PAIN WAS TREATED WITH PROVERA TABLET AND PATIENT STATED THAT SHE WAS RECENTLY PRESENTING IRREGULAR MENSTRUAL CYCLES. ON (B)(6) 2015, PELVIS X-RAY WAS DONE. MULTIPLE VIEWS OF PELVIS REVEALED SINGLE ESSURE DEVICE WAS OVERLAPPING THE RIGHT PELVIS (EXPECTED LOCATION OF THE RIGHT FALLOPIAN TUBE). THE SECOND ESSURE DEVICE OVERLAPPED THE UPPER SACRUM (THIS WOULD BE MORE SUPERIOR THAN EXPECTED FOR THE LEFT FALLOPIAN TUBE). NO ADDITIONAL FOREIGN BODY APPRECIATED. NO FRACTURE IDENTIFIED. THE PATIENT HAD CALLED BACK AND, APPARENTLY, SHE HAS BEEN COMPLAINING OF SEVERE PELVIC PAIN ASSOCIATED WITH SO MANY OTHER DIFFERENT PROBLEMS, WHICH SHE FEELS THEY WERE ALL ATTRIBUTED TO THE METAL THAT IS IN THE TUBAL COIL. SHE HAS HAD DIFFERENT COMPLAINTS OF DIFFERENT KINDS AND SHE STATED THAT THIS METAL IS POISONING HER BODY. ALSO, SHE HAS METAL ALLERGY TO IT. HEALTH CARE PROFESSIONAL DISCUSSED WITH PATIENT ON THE EVALUATION AND SHE SEEMED TO BE DETERMINED THAT ESSURE IS REALLY HER MAIN PROBLEM AND WANTS THIS DEVICE OUT OF HER, SO CONSULTED ABOUT THE SURGERY EVALUATION. PATIENT DOES NOT WANT ANY CUTTING OF THE TUBES TO REMOVE THE METAL. SHE WANTS EVERYTHING TO BE REMOVED, SO IT WAS DISCUSSED THE REMOVAL OF BOTH FALLOPIAN TUBES. SINCE THE COIL ON THE LEFT SIDE COULD NOT BE LOCATED BY ABDOMINAL/PELVIC CT SCANS NOR BY ULTRASOUND AND, THE RIGHT TUBE (WITHIN THE COIL IN IT) WILL BE REMOVED, HER PELVIS WOULD ALSO BE INVESTIGATED FOR ANY REMAINING MATERIAL RELATED TO THE METAL OF THE ESSURE COIL. PATIENT CONSENTED TO AN EXPLORATORY LAPAROTOMY AND REMOVAL OF BOTH TUBES. IN ADDITION, PATIENT'S PHYSICAL EXAMINATION, PERFORMED ON (B)(6) 2015, WAS PROVIDED: PATIENT'S ABDOMEN WAS SOFT, OBESE WITH SOME TENDERNESS VAGUELY IN THE LOWER ABDOMEN. HER PELVIC ANALYSES SHOWED EXTERNAL GENITALIA WITHIN NORMAL LIMITS, VAGINA CLEAR AND CERVIX WITH NO EVIDENCE OF ANY LESION. THE UTERUS AND THE ADNEXA WERE DIFFICULT TO EVALUATE DUE TO THE PATIENT'S BODY HABITUS. SHE IS HAVING THE SURGERY ON (B)(6) 2015. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: THE SURGERY WAS DONE ON (B)(6) 2015. SHE HAD FOLLOW-UP ON (B)(6) 2015 AND HER STAPLES REMOVED. SHE WAS DOING WELL, WITH NO PROBLEMS.

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FOLLOW-UP RECEIVED ON (B)(6) 2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. FOLLOW-UP FROM (B)(6) 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ON ULTRASOUND PERFORMED TWO YEARS AFTER INSERTION LEFT SIDE INSERT WAS NOT VISUALIZED. ACCORDING TO FOLLOW UP INFORMATION, SHE ALSO EXPERIENCED ABNORMAL BLEEDING AND STATED THAT ESSURE METAL WAS POISONING HER BODY. THESE EVENTS, INTERPRETED AS DEVICE DISLOCATION, GENITAL HAEMORRHAGE AND METAL POISONING, ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, THE EXACT LOCATION OF THE DEVICE WAS NOT REPORTED. HSG (HYSTEROSALPINGOGRAM) WAS NEVER DONE AND IN ULTRASOUND PERFORMED TWO YEARS AFTER INSERTION, THE LEFT ESSURE WAS NOT VISUALIZED. CONSIDERING THE AVAILABLE INFORMATION AND NATURE OF DISLOCATION, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED LATER, ABNORMAL BLEEDING AND METAL POISONING WERE INFORMED. THE BLEEDING, GIVEN ITS NATURE IS ASSESSED AS RELATED TO ESSURE USE. ALTHOUGH ESSURE RELEASES NICKEL, THE AMOUNT IS NOT ENOUGH TO CAUSE METAL POISONING. THUS, THIS EVENT IS ASSESSED AS UNRELATED TO ESSURE. ALSO, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PHYSICIAN IN FOLLOW UP INFORMATION, BILATERAL SALPINGECTOMY WITH DEVICE REMOVAL AND LAPAROTOMY EXPLORATORY WERE PERFORMED. THEREFORE THIS CASE WAS UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00532	BAYER HEALTHCARE LLC	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(6)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. THE CONSUMER, WHO WAS (B)(6) AT THE TIME OF THIS REPORT, STATED THAT SHE HAD ESSURE INSERTED AFTER HER SECOND DAUGHTER WHO WAS CONCEIVED WHILE MIRENA IUD (SEE CASE (B)(4)). SHE HAD A TROUBLE PREGNANCY AND HAD HER 6 WEEKS EARLY AND WAS TOLD THAT PROBABLY SHE WOULD NOT SURVIVE ANOTHER PREGNANCY. BECAUSE OF THIS, SHE HAD ESSURE PLACED. SHORTLY AFTER ESSURE, SHE DEVELOPED BACTERIAL INFECTIONS, YEAST INFECTIONS, SEVERE CRAMPS DAILY, HEAVY AND PAINFUL MENSTRUAL CYCLE, NUMBNESS IN VAGINA AREA, HOT FLASHES, LACK OF SEX DRIVE AND LACK OF ABILITY TO GET WET PRETTY MUCH A COMPLETE HORMONAL SHIFT. SHE HAS BEEN THROUGH LOTS OF TESTS AND POSSIBILITIES OF WHAT ALL THE PROBLEMS COULD BE BEFORE BLAMING ESSURE. ALL FINGERS WERE POINTING AT THE IMPLANT AFTER 3 YEARS OF GUESSING GAME AND SEARCHING FOR THE PROBLEM. AN INJURY (SERIOUS IMPORTANT MEDICAL EVENTS) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE

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HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON (B)(6) 2015: CONSUMER´S DATE OF BIRTH WAS UPDATED. SHE STATED THAT SHE HAD TO HAVE A HYSTERECTOMY TO REMOVE ESSURE. AFTER REMOVAL, THE PROBLEMS THAT WERE CAUSED BY ESSURE WERE GONE. CASE WAS UPGRADED TO INCIDENT. FOLLOW-UP RECEIVED ON (B)(6) 2015: NO NEW INFORMATION. PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES ON (B)(6) 2015. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO EXPERIENCED SEVERE CRAMPS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT. SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE CONSUMER STATED THE EVENT STARTED SHORTLY AFTER ESSURE INSERTION, AND AFTER REMOVAL THE PROBLEMS CAUSED BY ESSURE WERE GONE. THEREFORE, A CAUSAL RELATIONSHIP WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS UPGRADED TO INCIDENT DUE TO REQUIRED INTERVENTION, SINCE THE CONSUMER REPORTED SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 09-OCT-2015 FROM NURSE: THE PATIENT HAS NOT BEEN SEEN SINCE (B)(6) 2014, SO THERE WAS NO INFORMATION REGARDING HYSTERECTOMY OR PROCEDURE TO REMOVE ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044556	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 3/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BLEEDING VAGINALLY AT A VERY RAPID PACE. I WOULD FILL UP A SUPER TAMPON AS WELL AS A MAXI PAD IN LESS THAN 30 MINUTES. THIS HAD LASTED MORE THAN TEN DAYS AND NOW SEEMS TO BE A CONSTANT THING EVERY MONTH. I ALSO STARTED GETTING EXTREMELY PAINFUL STABBING LIKE PAINS IN MY LOWER ABDOMEN AND A CHRONIC PAIN IN MY LOWER BACK THAT STILL HAS NOT WENT AWAY. I ALSO FIND THAT AFTER INTERCOURSE THE PAINS GET MUCH WORSE. THIS IS STILL GOING ON TODAY, (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044557	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 11/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED MISSING PERIODS. MAJOR LOWER BACK AND RIGHT HIP JOINT PAIN FEELS LIKE IT'S OUT OF PLACE. HORRIBLE CRAMPS. GOT PRESCRIBED PAIN PILLS. UPSET STOMACH BEFORE PERIODS, THEN NEVER COME. NAUSEOUS AND BAD BOWEL MOVEMENTS USUALLY 2-3 DAYS BEFORE START DATE. HEAVY BLEEDING WHEN MY PERIODS USED TO BE LIGHT AND MAYBE ONE DAY OF MODERATE BLEEDING. VERY IRRITABLE BEFOREHAND ALSO, NEVER USED TO BE LIKE THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044558	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 10/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONTINUED BLEEDING SINCE I GET A DAY OR TWO WITH NO SPOTTING BUT THEN I CONTINUE TO BLEED. VERY UNCOMFORTABLE WHEN I WALK OR CARRY MY CHILDREN. IF I RUB IT IT IS SENSITIVE TO TOUCH AND PAINFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044559	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 7/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONTINUOUS UNEXPLAINED BREAK OUTS, CHRONIC PELVIC PAIN (RIGHT SIDE), RECURRING BACTERIAL VAGINOSIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044560	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THE PROCEDURE, I EXPERIENCE UNEXPLAINED RASHES, ABDOMINAL PAIN, DEPRESSION, ANXIETY, CHANGES IN HAIR AND NAILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044561	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANEMIA, SEVERE FATIGUE, WEIGHT GAIN, HEART PALPITATIONS, MUSCLE STIFFNESS, SEVERE ABDOMINAL PAIN ON BOTH RIGHT AND LEFT SIDE, PAIN AFTER INTERCOURSE, SEVERE HEAVY BLEEDING DURING MENSTRUAL CYCLE, CONSTANT ABDOMINAL CRAMPING, DIARRHEA, BLOATING, MEMORY LOSS, FEELING LIKE IN A FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044562	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 12/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE WAS INSERTED IN MY TUBES NOT ONLY DID MY LEFT SIDE FAIL BUT SINCE I HAVE HAD SEVERE PAINS ON MY LEFT SIDE AND IT CAUSES MY BLOOD PRESSURE TO RISE BECAUSE OF PAIN. SINCE ESSURE I HAVE ALSO HAD TWO PERIODS A MONTH FOR SEVERAL MONTHS. I CAN'T LOSE WEIGHT EVEN WITH WORKING OUT AND CLEAN EATING. I ALSO HAVE A NICKEL TASTE IN MY MOUTH ALWAYS AND GET HEADACHES OFTEN AND FATIGUE ALWAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044563	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 7/25/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M ALSO A REGISTERED NURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044564	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 7/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPS. HEADACHES. FEVERS. CHILLS. JOINT PAIN. MUSCLE PAIN. WEIGHT LOSS. HAIR LOSS. BLOOD CLOTS. HEAVY MENSTRUATION. FAINT. DIZZYNESS. UTI. INFECTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044565	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 7/6/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOOD PRESSURE INSTABILITY. UNEXPLAINED MIGRAINES LEADING TO EMERGENCY ROOM TRIPS. UNEXPLAINED NAUSEA. STABBING PELVIC PAIN. THE FEELING OF GIVING BIRTH DURING CYCLES. UNBEARABLE PAIN IN PELVIC AREA AND OVARY AREA DURING CYCLES. BLADDER LEAKAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044566	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 1/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN AND VAGINAL PRESSURE, BLOATING, PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044567	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 2/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ONSET OF MY COMPLAINTS STARTED ALMOST IMMEDIATELY FOR SOME OF MY SIDE EFFECTS; CRAMPING, ABDOMINAL PAIN, MENORRHAGIA, LOSS OF LIBIDO, INCONTINENCE, ALL OVER BODY ACHES, HEADACHES, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING HEARTBURN, BOWEL ISSUES, BRAIN FOG, MOOD SWINGS, WEIGHT ISSUES, EXCESSIVE SWEATING. THESE ISSUES HAVE CAUSED ME NOT TO BE ABLE TO TAKE CARE OF MY TWO YOUNG CHILDREN. IT HAS CAUSED ISSUES WITH MY HUSBAND AND HOME LIFE. PRETTY MUCH ESSURE HAS RUINED MY LIFE AND I WANT IT REMOVED!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044568	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 7/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIC TO ORAL PREDNISONE, STEROID INJECTIONS, IBUPROFEN, BACLOFEN, DICLOFENAC, ETODOLAC, ROBAXIN. NON STOP MUSCLE SPASMS, NERVE DAMAGE IN BACK (ARTHRITIS), SPONDYLOSIS HAS SPED UP. I AM NOW ON NERVE MEDICATION AND HAVE HAD MULTIPLE INJECTIONS AS WELL AS EVERY THERAPY POSSIBLE TO DEAL WITH THE PAIN. RASHES ALL OVER BACK AND BELLY. SWELLING IN BELLY, HIPS AND BACK. WEIGHT GAIN. NON STOP PELVIC PAIN I HAD TO HAVE ULTRASOUNDS FOR AND A MRI WHICH FOUND A MASS FROM SCAR TISSUE. BLEEDING BETWEEN PERIODS. GIANT CLOTS DURING MONTHLY CYCLE. MISCARRIAGE. LOW VITAMIN D. I HAVE BEEN DIAGNOSED WITH IBS AS WELL. AFTER HAVING A COLONOSCOPY AT (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044569	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 5/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING , CONSTANT MIGRAINES, IRREGULAR BLEEDING AND CLOTS , ABDOMINAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044570	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 7/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE PLACEMENT OF ESSURE, I HAVE GAINED 24 POUNDS OF WEIGHT ESP IN MY ABDOMEN WITH DEFINITIVE BLOATING AT NIGHT. UNCONTROLLABLE PAIN AS IF LABOR PAINS SINCE (B)(6) 2014, UNABLE TO WORK OUT DUE TO SWELLING DOWN LEGS AND JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044571	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 9/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BLEEDING A FEW MINUTES AFTER THE DEVICES WERE IMPLANTED AND CONTINUED TO BLEED WITH IT BECOMING HEAVIER AND LASTING UNTIL I HAD A SECOND SURGERY (UTERINE ABLATION) IN (B)(6) 2013. BACK AND PELVIC PAIN STARTED THE DAY OF SURGERY AS WELL AND CONTINUE EVEN NOW. EXTREME FATIGUE BEGAN TWO WEEKS AFTER THE DEVICES WERE IMPLANTED AND HAS SLOWLY STARTED TO GET A BIT BETTER SINCE (B)(6) 2014 WHEN I HAD TO GET A HYSTERECTOMY TO REMOVE ALL BUT MY OVARIES TO STOP THE BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044572	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 7/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M IN PAIN EVERYDAY. MY LEFT SIDE HURTS SO MUCH THAT IT FEELS LIKE SOMEONE IS STABBING ALL THE WAY TO MY BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044573	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 6/10/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN STARTED IMMEDIATELY THE COILS WOULD NOT GO IN EASY. AND I PROTESTED AND THE DR INSISTED. AFTER 2 WEEKS THE PAIN WAS SO BAD THE DR ORDERED A LAPAROSCOPIC SURGERY TO LOCATE THEM. ONE HAD MOVED BUT STILL IN PLACE. AFTER AN ER VISIT A WEEK LATER SHOWED THE LEFT HAD MOVED AGAIN. ANOTHER LAPAROSCOPIC FOUND THEM "PERT USING" INTO MY UTERUS. A SECOND DR FINALLY ASSISTED IN REMOVAL OF THE ESSURE COILS. ONLY OPTION WAS A HYSTERECTOMY IN LATE 2008. I WAS (B)(6). I WAS NOT TOLD ESSURE WAS PERMANENTLY PLACED. I WANTED MORE CHILDREN. BEFORE ESSURE I WAS HEALTHY, I'M ALWAYS SICK AND IN PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044574	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 5/11/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). METALLIC TASTE IN MOUTH, CONSTANT CRAMPING, ABNORMAL BLEEDING/SPOTTING. OVARIAN CYSTS AND PELVIC PAIN. NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044575	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 7/25/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE LAST YR HAS BEEN H"*#, I'VE BEEN THROUGH SO MUCH PAIN IN MY LOWER PELVIC AREA I'M CONSTANTLY ON PAIN MEDICATION, I HAVE ITCHY SCALP, BOILS ON MY VALVA AREA, HEART FLUTTERS, BACK PAIN, SEVERE FATIGUE, NAUSEA, HEADACHES, MOUTH SORES, CONSTANT ITCHY SKIN, CLOUDY MEMORY, NIPPLE PAIN, SHARP STABBING PAINS IN MY PELVIC. IRRITABILITY, UNABLE TO SLEEP AT NIGHTS, UNSTABLE BOWEL MOVEMENTS. I EITHER POO 4X A DAY OR NOT AT ALL FOR A WEEK. NOSE BLEEDS. HEAVY AND PAINFUL MENSURATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044576	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT WOULD NOT LET ME CHANGE DATE. SHOULD BE (B)(6) 2014. I HAVE GAINED (B)(6), HAVE BEEN NAUSEATED, HAVE HAD SEVERE MIGRAINES, PELVIC PAIN, PAINFUL MENSTRUATION, PAINFUL INTERCOURSE, FATIGUE, AND A CHEMICAL PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044577	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOR ABOUT 6 MONTHS OR MORE I HAVE HAD MORE THAN 1 PERIOD A MONTH. I HURT IN MY LOWER BACK TO MY HIPS DAILY. I AM CONSTANTLY FATIGUED, HAIR LOSS, ACNE. I AM BEYOND MOODY. I HAVE BEEN DIAGNOSED WITH A OVERSIZED UTERUS WITH POSSIBLE ENDOMETRIOSIS. I AM SET TO HAVE LAPAROSCOPIC SURGERY SOON TO FIND OUT. WEIGHT GAIN WITH NO EXPLANATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044578	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 12/10/2002 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I STARTED HAVING PAIN IN MY NECK THEN MY JOINTS. I THEN STARTED HAVING LOWER ABDOMINAL PAINS AND PAINS IN MY HANDS. I AM BLOATED ALL THE TIME AND WEIGHT GAIN IS RIDICULOUS. MY HAIR THINNED OUT SOMEWHERE ALONG THE WAY AND THE MENTAL CLARITY IS GONE. MY MEMORY IS SHOT. I ALSO STOPPED HAVING A PERIOD AT (B)(6) AND WENT INTO MENOPAUSE. THERE ARE THINGS HAPPENING TO MY BODY ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044579	BAYER	7/22/2015	7/22/2015

Event Information:

Event Date (B3): 5/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN HAVING ALMOST IMMEDIATE STABBING PAINS RIGHT AFTER THE PROCEDURE, I HAVE BEEN IN PAIN SINCE WITH STABBING PAIN THAT IS LOCATED NEAR MY OVARIES, I LIVE IN CONSTANT PAIN DAILY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00533	BAYER HEALTHCARE LLC	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C22919

Single Use: Y
Implant Date (E6): 4/17/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C22919 FOR CONTRACEPTION. IN AN UNSPECIFIED DATE THE PATIENT EXPERIENCED PAIN. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C22919; PRODUCTION DATE: 13-FEB-2014; EXPIRATION DATE: 28-FEB-2017. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN ON (B)(6) 2015 PATIENT WAS PLACED ESSURE IN FEW MONTHS BACK AND SHE WAS HAVING PROBLEMS. SHE WAS SCHEDULED FOR HYSTERECTOMY ON (B)(6) 2015. HER PAIN NEVER REALLY RESOLVED. CASE UPGRADED TO INCIDENT. FOLLOW-UP FROM (B)(6) 2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. PTC INVESTIGATION RESULT WAS UPDATED WITHOUT MAJOR CHANGES ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. THIS EVENT, SEEN AS PELVIC PAIN, WAS PREVIOUSLY CONSIDERED AS NON-SERIOUS. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS UPGRADED TO SERIOUS DUE TO PLANNED REQUIRED INTERVENTION. THE EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE. IN THIS CASE, THE PATIENT HAD PAIN AND LATER IT WAS INFORMED THAT THIS PAIN NEVER RESOLVED AND HYSTERECTOMY WAS SCHEDULED TO THE FOLLOWING DAY OF THIS REPORT. CONSIDERING AVAILABLE INFORMATION AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. INITIALLY THIS CASE WAS REGARDED AS NON-INCIDENT. AFTER THE RECEIPT OF THE INFORMATION CONCERNING THE REQUIRED INTERVENTION, IT WAS UPGRADED TO INCIDENT. THE PERFORMED PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. DESPITE FOLLOW-UP ATTEMPTS NO FURTHER INFORMATION WAS OBTAINED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 21-JUL-2015. IT WAS REPORTED THAT THE PATIENT HAD A HYSTERECTOMY BUT THEY DID NOT HAVE ANY OTHER INFORMATION. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00534	BAYER HEALTHCARE LLC	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER SUFFERED SIDE EFFECTS INCLUDING NAUSEA, DIZZINESS, FATIGUE, MILD HEADACHES, LACK OF BALANCE, LACK OF CONCENTRATION, OCCASIONAL PAIN AFTER MOVING. THESE SYMPTOMS WERE SEVERE ENOUGH FOR HER TO BE UNABLE TO WORK FOR 9 MONTHS UNTIL REMOVAL OF THIS DEVICE. THIS THEREFORE RESULTED IN DISMAL FROM WORK. SHE WAS UNABLE TO COMPLETE SIMPLE TASKS SUCH AS SHOPPING. FOLLOWING THE REMOVAL OF THIS DEVICE AND HER FALLOPIAN TUBES USING BILATERAL SALPINGECTOMY, ON (B)(6) 2015, SHE WAS FEELING MUCH BETTER. SHE STATED THAT THE MOST SEVERE EVENTS WERE DIZZINESS, FATIGUE, NAUSEA AND LACK OF BALANCE. SHE BELIEVES THIS WAS DUE TO THE NICKEL CONTAINED WITHIN ESSURE AND STATED THAT KNOWING THAT HER SKIN REACTS ON CONTACT TO NICKEL, SHE WOULD NOT HAVE FOLLOWED THE DOCTORS ADVICE TO HAVE THESE IMPLANTS. FOLLOW UP (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF

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A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ALLERGY TO METALS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND REPORTED THAT KNOWING HER SKIN REACTS ON CONTACT TO NICKEL, SHE WOULD NOT HAVE THESE IMPLANTS. SHE UNDERWENT A BILATERAL SALPINGECTOMY AND ESSURE DEVICES WERE REMOVED. THIS EVENT, INTERPRETED AS NICKEL ALLERGY, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. GIVEN THE EVENT'S NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. ADDITIONALLY, OTHER EVENTS WERE REPORTED AND CONSIDERED AS SERIOUS SINCE CONSUMER STATED THAT THESE SYMPTOMS WERE SEVERE ENOUGH FOR HER TO BE UNABLE TO WORK FOR 9 MONTHS AND ALSO UNABLE TO COMPLETE SIMPLE TASKS. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00535	BAYER HEALTHCARE LLC	7/23/2015	7/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER IN UNITED STATES ON 25-JUN-2015 WHICH DESCRIBES A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ON AN UNSPECIFIED DATE THE CONSUMER BECAME PREGNANT WITH ESSURE IN PLACE (DEVICE INEFFECTIVE) SINCE IT HAD BROKEN AND CAME OUT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF (B)(6) 2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE

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WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE AE CASE REFERS ALSO TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCURE WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015. NO NEW CLINICAL INFORMATION PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT WITH ESSURE IN PLACE. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS REPORTED THAT THE CONSUMER BECAME PREGNANT WITH ESSURE IN PLACE SINCE IT HAD BROKEN (INTERPRETED AS DEVICE BREAKAGE) AND CAME OUT (INTERPRETED AS DEVICE EXPULSION). THE EXACT TEMPORAL RELATIONSHIP BETWEEN THESE EVENTS WAS NOT REPORTED. THE DEVICE BREAKAGE AND EXPULSION COULD HAVE CONTRIBUTED FOR THE OCCURRENCE OF PREGNANCY HOWEVER IT IS NOT KNOWN WHETHER THEY OCCURRED PRIOR TO CONCEPTION. CAUSALITY BETWEEN THE PREGNANCY AND ESSURE CANNOT BE TOTALLY EXCLUDED (DEVICE INEFFECTIVE). THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 17-JUL-2015 NO NEW CLINICAL INFORMATION PROVIDED. FOLLOW-UP DATED (B)(6) 2015: UPON FOLLOW UP WITH THE REPORTER; SHE CONFIRMED THAT CASE THIS CASE WASN'T ABOUT A FRIEND BUT IT WAS A CALL ABOUT HERSELF. WITH THIS INFORMATI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00536	BAYER HEALTHCARE LLC	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 2/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED BY COURTESY FROM (B)(6) ON 25-JUN-2015 FROM A CONSUMER IN UNITED STATES. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A ADULT (>=18Y & <65Y) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS WERE PROVIDED). THE CONSUMER DID NOT PROVIDE INFORMATION SINCE LOT NUMBER WAS NOT AVAILABLE TO HER. ON AN UNKNOWN DATE, IN 2011, THE CONSUMER BEGAN A CO-SUSPECT DRUG HUMIRA (ADALIMUMAB) FOR CROHN'S DISEASE. THE CONSUMER HAD TWO MISCARRIAGES BETWEEN THE YEARS 2009 AND 2011 BEFORE HUMIRA USE. SHE HAS A GIRL CHILD WHO IS (B)(6), TWO BOYS AGED (B)(6) RESPECTIVELY, ANOTHER GIRL CHILD WHO IS (B)(6) AND THEN THE TWIN BOYS. THE CONSUMER'S MOTHER HAD THREE CHILDREN INCLUDING THE TWINS AFTER SHE BEGAN HUMIRA. THE CONSUMER ALSO HAD POLYPS (STARTED 2011). SHE WAS NON-SMOKER, ABSTAINS FROM ALCOHOL, DRUG ALLERGY PENICILLIN AND HAD 4 PREVIOUS NORMAL PREGNANCIES. IN 2011 SHE HAD A COLONOSCOPY (BEFORE HUMIRA USE), BIG LONG SPOT IN LARGE INTESTINE SUGGESTING CROHNS. POLYPS PRESENT TOO. IN (B)(6) 2014 HEMOGLOBIN WAS 7.0 (SECOND HEMOGLOBIN LEVEL DRAWN AFTER ONE UNIT OF BLOOD TRANSFUSION). OTHER COLONOSCOPY IN (B)(6) 2014 WHICH SHOWED THAT CROHN'S DISEASE WAS STILL ACTIVE. THE CONSUMER STATED THAT SHE HAD ESSURE BIRTH CONTROL SIX WEEKS AFTER HER FOURTH CHILD WAS BORN AND SHE ALSO STATED THAT SHE STILL GOT PREGNANT WITH HER TWINS (DRUG EXPOSURE DURING PREGNANCY). IN THE LAST WEEK OF (B)(6) 2014, THE CONSUMER COULD NOT BREATHE AND HAD PREMATURE CONTRACTIONS. HENCE, SHE HAD BEEN ADMITTED TO THE HOSPITAL FOR A WEEK. SHE HAD BLOOD WORK DONE AND IT WAS FOUND THAT HER HEMOGLOBIN WAS SEVEN. THE CONSUMER STATED THAT SHE DID NOT HAVE ANY VAGINAL OR RECTAL BLEEDING AT THAT TIME. SHE HAD BEEN GIVEN ONE UNIT OF RED BLOOD CELL TRANSFUSION FOR THE EVENT HEMOGLOBIN LEVEL

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DECREASED. A REPEAT BLOOD TEST AFTER THE SINGLE UNIT OF BLOOD TRANSFUSION REVEALED THAT THE DECREASE IN HER HEMOGLOBIN LEVEL PERSISTED. HENCE, THE CONSUMER HAD BEEN GIVEN TWO MORE UNITS OF RED BLOOD CELL TRANSFUSION BEFORE SHE HAD BEEN DISCHARGED FROM THE HOSPITAL. IN (B)(6) 2014, THE PREMATURE CONTRACTIONS AND HEMOGLOBIN LEVEL DECREASED RESOLVED. ON AN UNKNOWN DATE WITH UNKNOWN EGA (ESTIMATED GESTATIONAL AGE) THE CONSUMER DELIVERED VIA AN UNKNOWN METHOD. IT WAS NOT REPORTED IF SHE RECEIVED SEDATION OR ANESTHETIC DURING DELIVERY. NO MATERNAL MEDICAL PROBLEMS OR COMPLICATIONS DURING DELIVERY OR POSTPARTUM PERIOD WERE REPORTED. THE TOTAL MATERNAL WEIGHT GAIN WAS NOT REPORTED. NEONATAL BIRTH WEIGHT, LENGTH, SEX AND APGAR SCORES WERE NOT REPORTED. IT WAS NOT REPORTED IF NEONATAL COMPLICATIONS, CONGENITAL ANOMALIES OR BIRTH DEFECTS WERE IDENTIFIED. ONCE HER TWINS WERE BORN, SHE HAD A TUBAL LIGATION. IN (B)(6) 2014, THE CONSUMER EXPERIENCED BLOOD IN STOOLS, STOOL URGENCY AND WATERY STOOLS. IN (B)(6) 2014, AFTER DELIVERING HER TWINS, THE PATIENT HAD BLOOD IN STOOLS, STOOL URGENCY AND WATERY STOOLS. IN (B)(6) 2014, THE EVENT COULD NOT BREATHE RESOLVED. IN (B)(6) 2014, THE CONSUMER EXPERIENCED ACTIVE CROHN'S DISEASE AND ON THIS SAME MONTH SHE HAD A COLONOSCOPY DONE WHICH REVEALED THAT HER CROHN'S DISEASE WAS STILL ACTIVE. HENCE, HUMIRA DOSE HAD BEEN INCREASED TO WEEKLY DOSING FROM BIWEEKLY DOSING. ON AN UNKNOWN DATE, SHE STATED THAT SHE WAS TIRED ALL THE TIME DUE TO DEALING WITH HER SIX CHILDREN. THE CONSUMER DENIED ANY OTHER MEDICAL HISTORY AND CONCOMITANT MEDICATIONS. ESSURE BIRTH CONTROL WAS ALSO CONSIDERED AS A SUSPECT DRUG. THE REPORTER CAUSALITY ASSESSMENT BETWEEN THE EVENTS AND ESSURE WAS MENTIONED AS NOT REPORTED. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF DRUG EFFECT. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BEGAN A CO-SUSPECT DRUG HUMIRA FOR CROHN'S DISEASE. SHE GOT PREGNANT WITH TWINS, EXPERIENCED PREMATURE UTERINE CONTRACTIONS AND HAD HEMOGLOBIN LEVEL DECREASED. SHE DELIVERED VIA AN UNKNOWN METHOD. IT WAS NOT REPORTED IF NEONATAL COMPLICATIONS, CONGENITAL ANOMALIES OR BIRTH DEFECTS WERE IDENTIFIED. ONCE HER TWINS WERE BORN, SHE HAD A TUBAL LIGATION. PREGNANT WITH TWINS WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE PREMATURE UTERINE CONTRACTIONS WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND IS UNLISTED. HEMOGLOBIN LEVEL DECREASED WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE

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INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, IT WAS NOT REPORTED WHETHER ESSURE CONFIRMATION TEST WAS PERFORMED. CONSUMER HAD NO HISTORY OF PREMATURE DELIVERY. CONSIDERING A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY INCLUDING THE PREMATURE UTERINE CONTRACTIONS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. CONCOMITANT DISEASE CROHN'S DISEASE AND TWIN PREGNANCY MIGHT HAVE CONTRIBUTED TO OCCURRENCE OF HEMOGLOBIN LEVEL DECREASED, THEREFORE A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT DUE TO HOSPITALIZATION. ADDITIONALLY, OTHER SERIOUS EVENTS (UNRELATED TO ESSURE) WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00537	BAYER HEALTHCARE LLC	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C22911

Single Use: Y
Implant Date (E6): 3/8/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 25-JUN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C22911 INSERTED ON (B)(6) 2015 FOR STERILIZATION. AT THE FOLLOW-UP HYSTEROSALPINGOGRAM (HSG), IT WAS NOTED THAT THERE WAS A SPILLAGE OF DYE OUTSIDE OF THE FALLOPIAN TUBE. THE ESSURE COIL WAS ALSO LOCATED OUTSIDE OF THE FALLOPIAN TUBE. THE CURRENT STATUS OF THE PATIENT WAS NOT PROVIDED TO THE SALES CONSULTANT. HOWEVER, SHE WAS CURRENTLY SCHEDULED TO HAVE TO IMPLANT SURGICALLY REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C22911 (PRODUCTION DATE 08-FEB-2014 AND EXPIRATION DATE 28-FEB-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A LACK OF EFFICACY MAY OCCUR WITH THE USE OF ANY MEDICINAL PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT CONFIRMATION TEST (HSG) ESSURE COIL WAS LOCATED OUTSIDE OF THE FALLOPIAN TUBE. THE REPORTED EVENT, INTERPRETED AS DEVICE DISLOCATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, INCLUDING DISLOCATION TO DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY. ALTHOUGH, IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF THE EVENT IS UNKNOWN, CONSIDERING ITS NATURE AND CLOSE TEMPORAL RELATION WITH ESSURE INSERTION (DIAGNOSED AT CONFIRMATORY HSG); CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE, ACCORDING TO THE PHYSICIAN, A SURGICAL INTERVENTION WAS SCHEDULED FOR DEVICE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 06-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CAS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00538	BAYER HEALTHCARE LLC	7/23/2015	7/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF. SHE IS FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS WERE PROVIDED). CONSUMER STATED THAT SHE WAS CALLING ABOUT THE ESSURE. SHE HAD HIGH NICKEL CONTENT IN HER BLOOD AND WAS INTERESTED IN TREATMENT OF THE NICKEL IN THE BLOOD. SHE HAS GONE TO ANOTHER DOCTOR, AND GAVE AN ORDER OF BLOOD TEST FOR NICKEL. IN (B)(6) 2015, THE NICKEL LEVEL IN HER BLOOD WAS 3.1. ANOTHER TEST WAS DONE IN (B)(6) 2015 BUT THEY DID NOT HAVE THE RESULTS. EIGHT MONTHS AGO, IN (B)(6) 2014, SHE HAD THE AUTOIMMUNE DISEASE, IT WENT AFTER THE NICKEL, THEN AFTER HER. IT WAS TRIGGERED BY SOMETHING SHE WAS ALLERGIC TO. CONSUMER REPORTED THAT HAS HAD 5 AUTOIMMUNE DISEASES, IT WAS HEREDITARY. FIRST SHE HAD NICKEL RASH, THEN RHEUMATOID ARTHRITIS. HER JOINTS STARTED SWELLING, AND FIBROMYALGIA. IT WAS ALL DIAGNOSED BY THE RHEUMATOLOGIST. SHE HAD CHRONIC FATIGUE SYNDROME, MENIERE'S SYNDROME, EARS RINGING AND SCREECHING. SHE COULD NOT REMEMBER ALL OF THEM. SHE ALSO HAD SPASMS AND CRAMPING ON HER HANDS AND FEET. AFTER SEEING IN THE NEWS ABOUT ESSURE, SHE JUST WANTED TO REPORT IT. ON A DATE NOT REPORTED, THE CONSUMER HAD THE ESSURE REMOVED. SHE WOULD LIKE TO HAVE PLASMAPHERESIS, CHELATING THERAPY. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015 FROM CONSUMER: SHE CONTACTS THE COMPANY AND MADE A COMMENT ABOUT AFRAID OF LITIGATION. THIS CASE WILL BE CONSIDERED POTENTIAL LEGAL CASE. FOLLOW-UP RECEIVED ON (B)(6) 2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER

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REFERENCE NUMBER FOR THE PTC REPORT IS (B)(6) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, POTENTIAL LEGAL AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HIGH NICKEL CONTENT IN HER BLOOD (NICKEL LEVEL IN HER BLOOD WAS 3.1). THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS CASE, NO MEDICAL HISTORY ABOUT NICKEL ALLERGY BEFORE INSERTING ESSURE WAS REPORTED. SHE HAD THE ESSURE REMOVED. CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REMOVAL OF ESSURE. ADDITIONALLY, OTHER SERIOUS EVENTS (UNRELATED TO ESSURE) AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 02 OCT 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00539	BAYER HEALTHCARE LLC	7/23/2015	7/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 12277837 (INVALID)

Single Use: Y
Implant Date (E6): 8/24/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6)2015. SHE HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 12277837, INSERTED ON (B)(6) 2005. CONSUMER REPORTED THAT SHE HAD ESSURE COILS PLACED AND HAD NON-STOP BLEEDING/PAIN PROBLEMS, THAT BROUGHT HER TO A HYSTERECTOMY IN 2008, LEAVING HER OVARIES AND FALLOPIAN TUBES. IN ADDITION, ACCORDING TO CONSUMER'S SURGICAL PATHOLOGY REPORT, THERE WAS A 1.5 CM TWISTED METAL WIRE PRESENT WITHIN THE LEFT CORNU, REVEALING A SIMILAR METAL REMNANT WITHIN THE RIGHT CORNU. CONSUMER WAS WONDERING, IF SHE STILL HAS HER FALLOPIAN TUBES AND THE ESSURE COILS MEASURE 1.5", WHERE WERE THE REST OF THE COILS WITH THE PET FIBERS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT NUMBER 12277837 IS INVALID. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A PRODUCT QUALITY ISSUE. NEITHER VALID

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BATCH NUMBER NOR A COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE AE CASE REFERS TO BATCH NO. 12277837, WHICH IS INVALID ACCORDING TO THE RQU. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO VALID BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO EXPERIENCED NON-STOP BLEEDING AND PAIN PROBLEMS AFTER ESSURE INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY PRESERVING HER FALLOPIAN TUBES AND OVARIES. THE PATHOLOGY REPORT REVEALED A 1.5CM TWISTED METAL WIRE WITHIN LEFT UTERINE CORNU AND SIMILAR METAL REMNANT WITHIN THE RIGHT CORNU. CONSUMER WONDERED WHERE WERE THE REST OF THE COILS (REGARDED AS SUSPICION OF DEVICE BREAKAGE). THE REPORTED EVENTS ARE LISTED, ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; EXCEPT FOR DEVICE BREAKAGE WHICH IS LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, ALTHOUGH LIMITED INFORMATION WAS PROVIDED; CONSIDERING EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING CONSUMER'S SUSPICION OF DEVICE BREAKAGE, ESSURE INSERT HAS APPROXIMATELY 4 CM IN LENGTH (WITH 36 COILS). WHEN THE INSERT IS PROPERLY PLACED, IT SPANS IN THE UTERO-TUBAL JUNCTION WITH 3 TO 8 TRAILING COILS VISIBLE IN THE UTERINE CAVITY (THUS, A PORTION OF THE COIL REMAIN IN THE REGION OF UTERINE CORNUA). IF ESSURE REMOVAL IS NECESSARY, LINEAR SALPINGOTOMY OR SALPINGECTOMY SHOULD BE PERFORMED; IN ADDITION, A CORNUAL RESECTION MAY BE REQUIRED. IN THIS CASE, CONSUMER STATED HER FALLOPIAN TUBES WERE PRESERVED DURING HYSTERECTOMY. CONSIDERING ESSURE LOCATION, THE PATHOLOGY REPORT MENTIONED BY THE CONSUMER WOULD BE THE RESULT EXPECTED DUE TO THE TYPE OF SURGERY PERFORMED (ONLY A PORTION OF THE DEVICE LOCATED IN UTERINE CORNUA AND THE REMNANT PORTIONS PROBABLY STAYED IN FALLOPIAN TUBES). FOLLOW-UP INFORMATION WILL BE REQUESTED TO CLARIFY IF THIS WAS THE MECHANISM OF THE EVENT; HOWEVER BASED ON THE AVAILABLE INFORMATION CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE AN INTERVENTION WAS REQUIRED FOR EVENT'S TREATMENT. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 24-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE (FDA-2014-N-0736-1707), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEM

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00540	BAYER HEALTHCARE LLC	7/23/2015	7/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 975385

Single Use: Y
Implant Date (E6): 9/4/2012
Explant Date (E7): 1/8/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW5042110) IN UNITED STATES ON (B)(6) -2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 WITH LOT NUMBER 975385. CONSUMER STATED THAT AFTER PROCEDURE SHE HAD CRAMPING AND BLEEDING AND A PAIN IN LOWER LEFT ABDOMEN THAT CONTINUED. WHILE AT HER 3 MONTHS CHECK OF THE ESSURE PLACEMENT SHE EXPLAINED THE PAIN THAT SHE WAS HAVING TO HER DOCTOR AND SHE WAS SAID THAT IT SOUNDED LIKE A MUSCLE THAT WAS CAUSING THE PAIN. HOWEVER, THE PAIN IN HER LEFT ABDOMEN CONTINUED TO HURT AND SHE STARTED TO HAVE OTHER PROBLEMS LIKE CONSTANT HEADACHES, BOWEL PROBLEMS, CHRONIC PELVIC PAIN, TOTAL LACK OF SEX DRIVE, TINGLING IN LEGS AND ARMS, PAIN DURING INTERCOURSE, FEELING WORN OUT AND TIRED ALL OF THE TIME, ABDOMEN WAS SWOLLEN AND TENDER, AND IT ALSO WOULD HURT TO EXERCISE AS WELL AS EVEN TO SIT DOWN TOO FAST. SHE WENT TO EMERGENCY ROOM FOR HORRIBLE PELVIC PAIN TO FIND OUT WHAT WAS GOING ON. AFTER MANY TESTS AND ULTRASOUNDS, DOCTORS COULD NOT EXPLAIN WHY SHE WAS FEELING THIS WAY. ON AN UNSPECIFIED DATE, SHE VISITED ANOTHER DOCTOR AND ANOTHER ULTRASOUND WAS DONE AND AN ENLARGED UTERUS WITH FIBROIDS WAS DIAGNOSED. ON (B)(6) 2015 A LAVH HYSTERECTOMY WAS DONE (EVERYTHING WAS REMOVED EXCEPT HER OVARIES) AND SINCE THEN, CHRONIC PELVIC PAIN THAT WAS IN HER LOWER LEFT ABDOMEN AND THE PAIN DURING INTERCOURSE RESOLVED. THE OTHER PROBLEMS THAT SHE WAS EXPERIENCING WERE SLOWLY GOING AWAY. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(6). FINAL ASSESSMENT: LOT NUMBER 975385 PRODUCTION DATE: 4/2012 EXPIRATION DATE: 4/2015. SINCE NO PRODUCT WAS RETURNED TO

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US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN IN LOWER LEFT ABDOMEN, CHRONIC PELVIC PAIN/HORRIBLE PELVIC PAIN AND BLEEDING (INTERPRETED AS GENITAL BLEEDING). THE CONSUMER UNDERWENT A HYSTERECTOMY AND ESSURE REMOVAL. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. ALSO, ABDOMINAL AND PELVIC PAIN MAY OCCUR. IN THE PRESENT CASE, THESE EVENTS STARTED AFTER ESSURE INSERTION. AFTER HYSTERECTOMY AND ESSURE REMOVAL THE PAIN IN LOWER LEFT ABDOMEN, AND CHRONIC PELVIC PAIN/HORRIBLE PELVIC PAIN RESOLVED AND THE BLEEDING WAS GOING AWAY. SHE ALSO HAD FIBROIDS, WHICH COULD HAVE HAD A CONTRIBUTORY ROLE IN THE OCCURRENCE OF THE EVENTS. HOWEVER, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00541	BAYER HEALTHCARE LLC	7/23/2015	7/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/4/2012
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (B)(4) IN UNITED STATES ON (B)(6) 2015. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. CONSUMER STATED SHE HAD UTERINE ABLATION PERFORMED FOR SEVERE BLEEDING. IN ADDITION, SHE REPORTED SEVERAL HOSPITAL VISITS, ULTRASOUNDS LATER AND STATED SHE HAD A HYSTERECTOMY DONE. ESSURE EXPLANT DATE WAS PROVIDED AS (B)(6) 2015. TWO DAYS BEFORE THE TIME OF THE REPORT TO THE REGULATORY AUTHORITY (IMPLYING (B)(6) 2015) CONSUMER HAD ANOTHER EMERGENCY ROOM VISIT WITH X-RAYS SHOWING THE INTENSE FLANK PAIN WAS SITE OF COIL ON LEFT. RIGHT COIL WAS NOT FOUND IN X-RAY. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO EXPERIENCED SEVERE BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A UTERINE ABLATION AND HAD A HYSTERECTOMY. THREE MONTHS AFTER THIS SURGERY, SHE WENT TO THE ER AND X-RAYS SHOWED HER INTENSE FLANK PAIN WAS SITE OF COIL ON LEFT. RIGHT COIL WAS NOT FOUND. THE REPORTED EVENTS, REGARDED AS GENITAL BLEEDING AND FLANK PAIN DUE TO DEVICE DISLOCATION, ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED SERIOUS. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, ALTHOUGH LIMITED INFORMATION WAS PROVIDED (NO INFORMATION GIVEN ABOUT BLEEDING ONSET OR CONCOMITANT CONDITIONS), CONSIDERING EVENT'S NATURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT; DISCREPANT INFORMATION WAS PROVIDED. CONSUMER PROVIDED AN ESSURE EXPLANT DATE AND STATED SHE HAD A HYSTERECTOMY. HOWEVER, HER X-RAY, PERFORMED AFTER THIS SURGERY, REVEALED A COIL ON LEFT. ALTHOUGH THE EXACT MECHANISM OF THIS EVENT IS UNKNOWN, CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED BASED ON THE INFORMATION AVAILABLE. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REPORTED SURGICAL INTERVENTIONS (ABLATION AND HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 07-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044580	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 7/7/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SYMPTOMS BEGAN AFTER INSERTION (B)(6) 2008. EXTREME PINCHING PAIN ALONG C SECTION LINE AND BOTH SIDES, APPENDIX AREA HEIGHT. BELLY SWELLING, SHORTNESS OF BREATH, FOGGINESS, BLURRED VISION, FEELINGS OF BEING PREGNANT, OFF SCHEDULE PERIODS. HAD TO GO FOR PREGNANCY TEST IN 2010 BEFORE I GOT MARRIED DUE TO MORNING SICKNESS 2 MISSED PERIODS BREAST TENDERNESS. EXTREME WEIGHT GAIN EVEN WITH DIET PILLS, WATER PILLS, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044581	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 8/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE HEADACHES, SHAKING, LOWER BACK PAIN, BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044582	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 10/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD CHRONIC BLEEDING FOR WEEKS AND WAS UNABLE TO GET OUT OF BED WITHOUT BEING IN A SEVERE AMOUNT OF PAIN. I HAD A LOT OF ABDOMINAL CRAMPING AND FLUTTERING IN MY LOWER ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044583	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 7/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, WEIGHT GAIN, CAN'T LOOSE WEIGHT, NO SEX DRIVE, PAIN IN PELVIC AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044585	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 8/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2015 I HAD A HYSTERECTOMY KEEPING OVARIES. THEY FOUND ENDOMETRIOSIS, ENLARGED UTERUS, COIL MIGRATION AND EMETRIOSIS ETC. 12 WEEKS POST OP, MY BELLY HAS GONE DOWN, HAIR STOPPED FALLING OUT, METAL TASTE GONE, MEMORY FOG SUBSIDED, NO HEADACHES, SMALL WEIGHT LOSS, RASHES GONE FEW ISSUES REMAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044586	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 10/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CONSTANT JOINT PAIN,I'M ALWAYS BLOATED, PELVIC PAIN, ABDOMINAL PAIN, MENSTRUAL CYCLE TWICE A MONTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044587	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 10/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN BLOATING, SEVERE PROLONGED CRAMPING, BLEEDING, SEX IS EXTREMELY PAINFUL, I CAN FEEL THE COIL ON MY RIGHT SIDE MOVING, NO LONGER HAVE REGULAR PERIODS. EXERCISING NOW HURTS AS IT PULLS ON MY RIGHT SIDE . PAINFUL, MIGRAINE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044588	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 10/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NAUSEA AND AMP; VOMITING. ALWAYS HAVE PAINS IN MY PELVIC AREA/HIPS. BACK PAINS. CAN'T HAVE SEX BECAUSE IT HURTS WAY TOO MUCH. HORRIBLE MIGRAINES. NO ENERGY. LOSS OF APPETITE. DEPRESSED, MISERABLE AND STRESSED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044589	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 12/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN AS SLIGHT JOINT PAIN. SLOWLY PROGRESSED. PELVIC PAIN, INCREASED PELVIC PAIN THAT BECOMES UNBEARABLE AROUND THE TIME OF MY PERIOD. FATIGUE. EXTREME AMOUNTS OF FATIGUE. I GET ONE GOOD WEEK A MONTH. MEMORY LOSS/BRAIN FOG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044590	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1, #FDA MW5044590, #(B)(4). HAD HYSTERECTOMY ON (B)(6) 2015. MY UTERUS WAS GREATLY ENLARGED AND THE LEFT TUBE WAS PERFORATED BY THE COIL WHICH CAUSED A LOT OF INFLAMMATION. HAD TUBES, CERVIX AND UTERUS REMOVED. RETAINED OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044593	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 10/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING, HEAVY BLEEDING, ABDOMINAL BLOATING, BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044594	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I RECEIVED THIS DEVICE (B)(6) 2012. I RECEIVED MY HSG TEST IN (B)(6) 2013. WAS CONFIRMED BLOCKED. BEFORE THIS I NOTICED A LOT OF CRAMPING DURING MY PERIODS. LABOR PAINS TO BE EXACT. AND STILL HAPPEN TO THIS DAY. BLOATING IS AN ISSUE. THERE ARE DAY WHERE I LOOK 9 MONTHS PREGNANT. I DO HAVE PHOTOS. I HAVE HAD HEADACHES A LOT SINCE THIS DEVICE WAS IMPLANTED ALSO. I AM NOT ONE TO GET HEADACHES OFTEN. I ALSO GAINED (B)(6) AFTER IMPLANTATION. LOST (B)(6) BUT HAVEN'T BEEN ABLE TO LOSE ANYMORE. I WENT ON BIRTH CONTROL (LOW DOSE) TO SEE IF IT WOULD TAKE AWAY SOME OF THE PAIN AND REDUCE BLEEDING DURING MY CYCLES. I ALSO BLEED IN BETWEEN CYCLES. SPOTTING FOR A WEEK AT A TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044597	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINS IN BOTH MY SIDES DEBILITATING STABBING PAIN THAT DOES NOT GO AWAY INCREASED BLEEDING WHEN I STAND UP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044598	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PAINFUL IRREGULAR PERIOD. LARGE CLOTS. PAINFUL INTERCOURSE. ABDOMINAL PAIN. PELVIC PAIN. BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044621	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 3/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RACING HEART, PALPITATIONS, NIGHT SWEATS, THYROID ISSUES, LOSS OF HAIR, ANEMIA, HEAVY MENSTRUAL PERIODS TO THE POINT OF HEMORRHAGING , BLOOD CLOTS, SWELLING OF THE ABDOMEN, ANXIETY, HEADACHES 4-5 TIMES A WEEK, INABILITY TO LOSE WEIGHT, PASSING OUT, LOW HEMOGLOBIN AND EXTREMELY LOW IRON AND FERRITIN LEVELS TO THE POINT OF HAVING A HYSTERECTOMY IN (B)(6) 2015. SINCE THE SURGERY 10 WEEKS AGO, ALMOST ALL OF THESE HAVE GONE AWAY OR IMPROVED ALREADY. HAIR HAS STOPPED FALLING OUT ALMOST COMPLETELY, NO HEADACHES, NO BRUISING, NO IRREGULAR HEARTBEATS/PALPITATIONS OR PASSING OUT. MY THYROID LEVELS ARE ALREADY ALMOST UP TO NORMAL LEVELS AGAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044622	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WENT TO HAVE A CT SCAN DONE AND FOUND OUT HAD MULTIPLE CYSTS ON LEFT OVARY AND FLUID IN LEFT FALLOPIAN TUBE. HAVE BEEN HAVING SHARP STABBING PAIN IN LEFT SIDE. NEED TO GET ANOTHER ULTRASOUND DONE TO SEE IF ANY CHANGES, THEN DOCTOR WILL DECIDE IF I NEED SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044623	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 7/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS HAVING MILD SYMPTOMS BEFORE THIS DATE ABOVE, BUT AFTER THIS, MY LIFE HAS NEVER BEEN THE SAME. IT STARTED WITH EXTREME DIZZINESS AND NAUSEA. I PASSED OUT AND HAD VIOLENT VOMITING. SINCE 2010, I HAVE ONLY HAD 3 MONTH SPAN WITH NO DIZZINESS. I WENT TO SEVERAL ENTS WITH NO AVAIL, THEY COULD NOT HELP ME. SINCE THIS TIME, I HAVE HAD A COUPLE MRI'S LOOKING FOR TUMORS, ABNORMAL PERIODS, EXCESSIVE BLEEDING DURING PERIOD, EARLY MENOPAUSAL SYMPTOMS, SOME INCONTINENCE, ALL OVER BODY ACHES, CONTINUED DIZZINESS, SEVERE BLOATING, BOWEL ISSUES, BRAIN FOG, MOOD SWINGS, IRON DEFICIENCY (TAKING SUPPLEMENTS) , VITAMIN D DEFICIENCY (TAKING SUPPLEMENTS), THYROID ISSUES (ON MEDS), HORMONAL ISSUES (ON TESTOSTERONE AND PROGESTERONE), AUTOIMMUNE DISORDER/HEIGHTENED ALLERGIES (ALLERGIC TO ALMOST EVERYTHING), INFLAMMATION, EXTREME WEIGHT GAIN, SWELLING, HAIR LOSS, ADRENAL FATIGUE AND VISION ISSUES. MY BODY IS LITERALLY TURNING ON ITSELF!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044624	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 11/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM ABOUT A WEEK OR TWO AFTER BEING IMPLANTED WITH ESSURE I HAVE HAD NOTHING BUT PROBLEMS OVER THE COURSE OF ALMOST 6 YEARS. SEVERE AND CRIPPLING CRAMPING LASTING WEEKS AT A TIME, SEVERE BLEEDING LASTING WEEKS AT A TIME, SEVERE CYSTIC ACNE, WEIGHT GAIN, MY HAIR IS FALLING OUT AND GETTING THINNER. FROM THOSE SIDE EFFECTS, I HAVE ALSO NOW DEVELOPED TYPE 2 DIABETES (BECAUSE OF THE WEIGHT GAIN), I HAVE A DRS APPOINTMENT WITH AN ENDOCRINOLOGIST IN 5 DAYS ABOUT THYROID PROBLEMS AND A POSSIBLE DIAGNOSIS OF POLY CYSTIC OVARIAN SYNDROME. BEFORE ESSURE I WAS HEALTHY, AT A HEALTHY WEIGHT, NO ISSUES, BUT WITHIN WEEKS OF BEING IMPLANTED WITH ESSURE, MY HEALTH HAS GONE DOWNHILL. I AM ONLY (B)(6) YEARS OLD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044625	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 5/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). COMPLETE LOSS OF LIBIDO, HIP, KNEE AND BACK PAIN, PAIN RADIATING DOWN LEGS AND AROUND TO BACK, DISRUPTION ON BOWEL MOVEMENTS, CONSISTENT BRAIN FOG, AND EXTREME FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044626	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RECENT FOLLOW-UP BLOOD PANELS AND HORMONE PANELS ARE ALL STILL NORMAL. ONE MONTH AGO, I EXPERIENCED A SHARP, SUDDEN BURST/POP NEAR MY LEFT COIL. A RECENT ULTRASOUND WITH AN EXPERIENCED TECH NOW SHOWS THE COIL HAS PERFORATED MY FALLOPIAN TUBE, PENETRATED MY UTERUS AND IS NOW LODGED IN THE WALL OF MY UTERUS. THE COIL IS NO LONGER EVEN IN MY TUBE. I HAVE BEEN ADVISED TO USE "BACKUP BIRTH CONTROL." THE ULTRASOUND ALSO SHOWS OTHER BILATERAL CYSTS, FIBROIDS AND A HEMORRHAGIC CYST NEAR THE LEFT OVARY, PRESUMABLY NEAR THE PERFORATION. MY LOWER ABDOMEN CONTINUES TO BE SWOLLEN DAILY, MAKING ME LOOK ABOUT 5 MONTHS PREGNANT, AND GETS PROGRESSIVELY LARGER THROUGHOUT THE DAY. AT (B)(6) AND (B)(6), IT IS VERY NOTICABLE AND THE HARD PRESSURE OF MY PELVIC AREA IS PHYSICALLY UNCOMFORTABLE DAILY. THE LEFT COIL CONTINUES TO STAB ME ALL DAY, EVERY DAY AND IT IS VERY PAINFUL. I AM SCHEDULED FOR A PARTIAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY, PROVIDED I CAN COME UP WITH (B)(6) IN THE MEANTIME FOR THE HOSPITAL TO PROCEED WITH SCHEDULING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044627	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/6/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING ILLNESS AND MEDICAL TESTING, ACHES, PAINS, TINGLING SENSATIONS, DIZZY SPELLS, CHEST PAINS, NO ENERGY, AND MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044628	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 12/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). REMOVAL OF BOTH FALLOPIAN TUBES DUE TO INFLAMMATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044634	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ITS IMPLANTATION I HAVE STRUGGLED WITH SERIOUS PAIN IN MY UTERUS AND TUBES. NUMBNESS IN MY LIMBS, RASHES, CHRONIC ITCHING AND IRREGULAR PERIODS. SOME PERIODS IN THE FIRST FEW YEARS AFTER IMPLANTATION WOULD BE SO PAINFUL AND SO MUCH BLOOD VOLUME THAT I CALLED MY IMPLANTING DOCTOR TO REPORT AND WAS LAUGHED AT. NIGHT SWEATS AND FEVERS ARE COMMON. AS THE YEARS HAVE GONE ON I HAVE HAD ISSUES WITH INFLAMMATION THAT HAS NOW MOVED INTO MY JOINTS CAUSING MORE PAIN. DURING THE CONSULTATION WITH THE IMPLANTING DOCTOR I TOLD HIM I WAS ALLERGIC TO ALL EARRINGS AND ANYTHING THAT CONTAINED NICKEL AND HE LAUGHED AND SAID IT WAS SUCH A SMALL AMOUNT THAT THERE WAS NO CHANCE OF REACTION BUT REACTIONS ARE ALL I HAVE HAD SINCE THEN. I AM CURRENTLY PLANNING ON IT BEING REMOVED TO GET MY HEALTH BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044648	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THERE ARE STOMACH PAINS NOT ASSOCIATED WITH MY CYCLE. I HAVE A BLOATED STOMACH MOST DAYS AND AMP; PAIN WHEN I TRY TO EXERCISE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044652	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 4/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, DIARRHEA, BACTERIAL VAGINOSIS, RECURRENT URINARY TRACT INFECTIONS, BRAIN FOG, CRAMPING, SHARP STABBING PELVIC PAIN, CLOTTING DURING MENSTRUAL, DISCHARGE, HOT FLASHES, NIGHT SWEATS, LOSS OF LIBIDO, PAINFUL MENSTRUAL, INCONTINENCE, YEAST INFECTIONS, BREAST PAIN, ABDOMINAL SPASMS, BACK AND LEG PAIN, NAUSEA, DIZZINESS, ANXIETY, MOOD SWINGS, SENSATION OF BURNING IN HIP/PELVIC REGION, HIVES AND RASHES, ALLERGIC REACTIONS, ELEVATED DHEA, DENTAL ISSUES, WEIGHT GAIN, SWOLLEN GLANDS, VISION PROBLEMS, HAIR GROWTH IN NEW PLACES, AND SWELLING OF HANDS, LEGS AND FEET.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044653	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 7/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WOKE UP WITH HIVES THAT CONTINUED 24 HOURS PER DAY ALMOST EVERY DAY UNTIL ESSURE REMOVAL WITH HYSTERECTOMY IN (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044656	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THERE ARE STOMACH PAINS NOT ASSOCIATED WITH MY CYCLE. I HAVE A BLOATED STOMACH MOST DAYS AND AMP; PAIN WHEN I TRY TO EXERCISE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044657	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 2/3/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE PAIN AND BLOATING SINCE IMPLANTED. I STARTED LOSING MY HAIR. MY FIBROMYALGIA HAS INCREASED SINCE ALSO. MY DEPRESSION HAS INCREASED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044658	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 12/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE STABBING PAIN IN MY LEFT OVARY, IF I TURN A CERTAIN WAY OR MOVE TO QUICKLY SOMETIMES I WILL HAVE THE STABBING PAIN TO WHERE I'M SCARED TO MOVE, I AM ON MY PERIOD 3 WEEKS OUT OF THE MONTH, I HAVE MIGRAINES, AND WEIGHT GAIN. I HAD GONE TO THE ER FOR THE STABBING PAIN AND THEY DID A CT SCAN AND SAID I HAVE CYSTS ON MY OVARIES AND I NEVER HAD THE PROBLEM BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044659	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP STABBING PAIN ON MY LEFT SIDE, LASTED FOR 5 HOURS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044660	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 12/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, EXTREME PAIN DURING MENSTRUAL CYCLE, PASSING CLOTS DURING CYCLE, WEIGHT GAIN, HEADACHES, DIZZINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044661	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/24/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN LIKE SOMEONE STABBING AND TURNING SCREWING IT. BAD PERIODS. PAIN FULL HIPS. PAIN IN TUMMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044662	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 9/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING BOWEL ISSUES, AS IN LOOSE STOOLS ALL THE TIME. PAIN DURING INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044663	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 10/27/2014 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOUND OUT I WAS PREGNANT WITH THE ESSURE STUCK IN MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044664	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 12/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IRREGULAR BLEEDING. TOTAL OF 3 COILS, ONE ON THE LEFT 2 ON THE RIGHT PID.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044665	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 9/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXHAUSTION AND INABILITY TO FOCUS WERE THE FIRST OF MY SYMPTOMS. I SAW MY DOCTOR ABOUT IT AND THEY REFERRED ME TO A PSYCHOLOGIST WHO PLACED ME ON WELLBUTRIN. SINCE THEN, I'VE HAD ONE CYST UNDER MY BREAST, DIAGNOSED WITH MY SECOND CASE OF GARDNERELLA, SEVERELY HEAVY MENSES, AND A CYST ON MY OVARY. I ALSO HAVE BEEN HAVING REGULAR HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044666	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 5/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAIN, NUMBNESS IN RIGHT FOOT, TINGLING IN BODY, BRAIN FOG, DEPRESSION, HAIR LOSS, BLOATING IN STOMACH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044667	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 2/11/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MYSTERY PARALYZING CRAMPS DURING SEX, EXTREME BLOATING, LIGHT HEADED, BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044668	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 7/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING MY ESSURE PUT IN, I HAVE GAINED A TOTAL OF 45 POUNDS I WOULD SAY, I AM IN TERRIBLE ABDOMINAL PAIN, NO PERIODS (WHICH I HAVE BEEN TOLD IS FINE) EARLY TERM MISCARRIAGE, INSOMNIA, ANXIETY, BLOATING, BACK PAIN, RASHES THAT COME AND GO. REALLY REALLY BAD MEMORY PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044669	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES ARE MUCH MORE FREQUENT AND MUCH WORSE. HAIR LOSS, LOWER BACK PAIN, SHOOTING VAGINAL PAIN, DISCHARGE, ODOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044670	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 1/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN. CONSTANT FEELING OF BEING MENSTRUAL, NAUSEA, HEADACHES, DIZZY SPELLS, BACK PAIN,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044672	BAYER	7/23/2015	7/23/2015

Event Information:

Event Date (B3): 6/6/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE, I'VE HAD SEVERE CRAMPING, PAINFUL HEAVY BLEEDING THROUGHOUT THE MONTH.. WAS NEVER TOLD OF ANY SEVER SIDE EFFECTS AND THAT IT WAS A NON SURGICAL PROCEDURE. I WAS PUT TO SLEEP IN A HOSPITAL FOR IMPLANTS. I'VE HAD SEVERAL DR VISITS AND HAVE ONLY ONE TUBE BUT TWO COILS.. I WAS NEVER TESTED FOR NICKEL OR TITANIUM ALLERGIES PRIOR TO IMPLANTS. SINCE IMPLANTS I BREAK OUT IN RASHES, SEVERE HEADACHES. ALSO FOUND OUT I'M ALLERGIC TO NICKEL...PLEASE TAKE IT OFF THE MARKET...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044671	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 1/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIC REACTION, HEADACHE, BLOATING, CRAMPS, HEAVY AND IRREGULAR PERIOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044673	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 7/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I HAD MY ESSURE PUT IN,(2011) IT WAS VERY VERY PAINFUL ESPECIALLY ON MY LEFT SIDE. INSTEAD OF 20 MINUTES PROCEDURE IT ENDED UP 1 1/2 HOURS LONG AND WAS WIDE AWAKE WHILE DOING THIS. 3 MONTHS LATER I HAD DYE TEST DONE (ALLERGIC TO CONTRAST DYE SO USED SOMETHING ELSE) AND FOUND THAT IT WAS NOT SUCCESSFUL AS SEEMS MY LEFT COIL WAS HALF WAY OUT. SO SCHEDULED TO HAVE TUBES TIED IN (B)(6) 2011 AND FOUND OUT THAT MY LEFT COIL FELL ONTO MY INTESTINES AND LEFT IT IN THERE ALONG WITH MY RIGHT COIL INTACT IN MY RIGHT TUBE. AFTER WHILE FOR SEVERAL MONTHS BEEN DEALING PAIN ON LEFT SIDE OVARY AND HAD CYST BURSTS SEVERAL TIMES TO MAKE MORE BLEEDING. EACH MONTH MY PERIOD BE ON TIME BUT AGAIN PAINFUL AND EXTREMELY HEAVY BLEEDING EACH MONTH. FINALLY LAST YEAR (2014) IN (B)(6) I HAD ENDED UP WITH HYSTERECTOMY WITH UTERUS, LEFT OVARY AND TUBE, CERVIX REMOVED. ALSO FOUND I HAVE FIBROIDS, ENDOMETRIOSIS AND OTHERS ALL OVER THE PLACE. BUT THE COILS STILL INSIDE MY RIGHT TUBE AND THE ONE ON LEFT STILL ON MY INTESTINE AS THE DOCTOR THINKS IT NO NEED TO WORRY AND LEFT IT IN THERE. INSTEAD OF ONE NIGHT STAY AT HOSPITAL I ENDED UP 2 NIGHTS DUE TO BAD REACTION TO ANESTHESIA. EXTREMELY LOW IRON COUNTS AND ALLERGIES TO NARCOTICS. ON 3RD DAY I WAS SENT HOME BUT ALL AMBULANCE NEXT MORNING DUE TO EXTREME LOW BLOOD PRESSURE, IRON LOW, AND PAIN. THE ER DOCTOR ORIGINALLY THOUGHT HAD BLOOD CLOT BUT IT WAS NEGATIVE. SINCE THEN I'M DOING OK BUT DEALING PAIN ON RIGHT OVARY NOW IT DEVELOPING CYSTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044674	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 3/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY PAINFUL INSERTING ESSURE. HAD SPASMS IN TUBES/CERVIX. HAD SEVERE PAIN. SINCE HAVING IT INSERTED I HAVE DEVELOPED MULTIPLE CYSTS AND FIBROIDS. HORMONE IMBALANCE HYPOTHYROIDISM, 50+ POUND WEIGHT GAIN, BLOATING, SWELLING IN MY LOWER SPINE, EXCESSIVE MENSTRUAL BLEEDING, HAIR LOSS, IBS, VITAMIN DEFICIENCY, HAD TO GO TO PAIN MANAGEMENT DOCTORS AND PHYSICAL THERAPY HAVE ON GOING PRESCRIPTION FOR CODEINE SULFATE AND MELOXICAM. I HAVE A NICKEL ALLERGY. MY SKIN TURNS GREEN WITH METAL NOW. HAVE TO HAVE A HYSTERECTOMY TO REMOVE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044675	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A FEW MONTHS AFTER I HAD MY IMPLANTS PUT IN, I STARTED HAVING SEVERE LOWER ABDOMINAL PAIN. I THOUGHT IT WAS JUST CRAMPING SO I IGNORED IT OR TOOK ADVIL TO HELP WITH THE PAIN. AS THE MONTHS WENT BY I KEPT HAVING PAIN, I WENT AND SAW MY DOCTOR REGARDING THE PAIN AND I WAS TOLD THAT THERE WAS NO WAY IT COULD BE THE ESSURE. I TOOK HIS WORD FOR IT AND LEFT. AROUND (B)(6) 2014 I WENT BACK TO MY DOCTOR EXPLAIN TO HIM THAT THE PAIN IS NOT ONLY STILL THERE BUT IT HAS GOTTEN A LOT WORSE, I HAVE A CONSTANT STABBING PAIN AT ALL TIMES TO THE POINT THAT I HAVE TO TAKE SLEEPING MEDS EVERY NIGHT JUST TO STAY ASLEEP AND I WAKE UP EVERY MORNING AND THE FIRST THING I HAVE TO DO IS TAKE SOMETHING TO HELP WITH THE PAIN. I KEEP GETTING TOLD THAT I HAVE CYST BUT I HAVEN'T HAD ANY PROBLEMS WITH CYST IN 14 YEARS AND THIS HORRIBLE PAIN DIDN'T START UNTIL A FEW MONTHS AFTER THE IMPLANTS WERE PUT IN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044676	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 2/7/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN THE DR WAS PLACING THE COIL INTO MY TUBES HE WAS AN ISSUE WITH MY LEFT TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044677	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 10/8/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DAY I HAVE IT IMPLANTED ,THE DOCTOR PERFORATED MY LEFT FALLOPIAN TUBE THAT CAUSES A PERITONITIS . IT CAUSE ME HAIR LOSS, BLOATING, PELVIC PAIN, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044678	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 8/9/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT ITCHING ON BODY, HEAD ITCHES, EARS SOMETIMES BURN AND HIVES ON MY LEGS AND BACK. HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044679	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 10/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALL DIFFERENT PROBLEMS, FROM SEVERE PAIN IN THE PELVIC AREA, TO HORRIBLE MIGRAINES. METAL TASTES IN MY MOUTH. PAIN DURING SEX. PAINS IN MY LOWER BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044680	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 12/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN ON MY LEFT SIDE AND THE FROM OF MY LEGS. DIZZINESS, BAD HEADACHES, SWELLING 5 TIMES MY NORMAL SIZE, HARD TO BREATHE, HEAVY PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044681	BAYER	7/23/2015	7/24/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, DEPRESSION, WEIGHT GAIN, BLOATING, LEG/JOINT PAIN, OVARIAN CYST, BRAIN FOG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044871	BAYER	7/23/2015	7/30/2015

Event Information:

Event Date (B3): 4/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/12/2013
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE GAINED WEIGHT SINCE IMPLANTATION OF ESSURE COIL. I HAVE HAD CONSTANT BLOATING WAS PAIN ASSOCIATED WITH THIS. I HAVE CRAMPS WHEN I OVULATE, WHICH DIDN'T HAPPEN UNTIL AFTER ESSURE. I GET SHARP/STABBING PELVIC PAIN AT TIMES. I HAVE CERVICAL DYSPLASIA, WHICH I DID NOT HAVE PRIOR TO ESSURE. I HAVE NIGHT SWEATS WHICH I NEVER DID. I HAVE STABBING AT THE VAGINAL ENTRANCE AT TIMES. I HAVE CONSTANT BREAST PAIN/TENDERNESS/STABBING PAINS. I HAVE JOINT AND HIP PAINS. I NOW HAVE HEARTBURN ALL THE TIME TO GO WITH THE BLOATING. I NOW GET MIGRAINES. I HAVE BEEN HAVING DIZZINESS OFTEN LATELY. I HAVE BRAIN FOG, CLOUDINESS, FORGETFULNESS AND SHORT TERM MEMORY LOSS. I DIDN'T HAVE ANY OF THOSE PRIOR TO ESSURE. I HAVE HEART PALPITATION/SKIPPED BEATS NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044682	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING (ON HEAVY DAYS GO THROUGH A TAMPON EVERY HOUR). PASSING BLOOD CLOTS, SEVERE CRAMPING/PELVIC PAIN. LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044683	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPS AND BLEEDING. IT MAKES ME FEEL HORRIBLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044684	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 9/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).SINCE HAVING ESSURE PLACED I HAVE UNEXPLAINED RASHES AND ITCHING DAILY THAT WILL NOT GO AWAY, FREQUENT HEADACHES, VERY HEAVY PERIODS WITH HUGE CLOTS AND WITH BAD CRAMPING, LIGHTHEADED ALL THE TIME, HEART PALPATATIONS AND CHEST PAIN, DIARREAH WHICH I HAD A COLONOSCOPY FOR, INSOMNIA I HAVE VISITED MULTIPLE DR'S WITH NO ANSWERS AND WITH NO INSURANCE I HAVE TO JUST LIVE WITH ALL THESE SYMPTOMS WHICH HAVE CAUSED ME TO BECOME DEPRESSED THESE DEVICES HAVE REEKED HAVOC ON MY BODY AND DESTROYED MY LIFE! I WAS A HAPPY HEALTHY PERSON BEFORE I HAD THESE PUT IN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044685	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOUND OUT IM HIGHLY ALLERGIC TO NICKEL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044686	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 10/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PSEUDOTUMOR CEREBRI, INABILITY TO LOSE WEIGHT, BLOATING, ABDOMINAL PAIN, SEXUAL DYSFUNCTION, MIGRAINES, BRAIN FOG, FACIAL NUMBNESS, HEART PALPITATIONS, IRRATIONAL MOOD SWINGS, ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044687	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER RIGHT PAIN AND CRAMPING AND BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044688	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SERVE PAIN IN LEFT SIDE THAT DROPS ME TO MY KNEE. HEAVY BLEEDING. RASH FROM THE NICKEL HEADACHE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044689	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT PELVIC PAIN-ONGOING, MULTIPLE MONTHLY PERIOD WITH HEAVY BLEEDING, SEVERE CRAMPING RIGHT BEFORE AND DURING PERIODS, LARGE BLOOD CLOTS, VAGINAL TISSUE DISCHARGE, BACK PAIN, FREQUENT HEADACHES/MIGRAINES, WEIGHT GAIN, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044690	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 3/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ALWAYS BEEN A FUN LOVING FULL OF ENERGY PERSON WITH VERY LITTLE MOOD SWINGS. I'VE ALWAYS WEIGHT ABOUT THE SAME AND EVER SINCE HAVING THIS PUT IN ME I'VE BEEN VERY MOODY TRIED MORE OFTEN, NO ENERGY GAIN 15LBS ALWAYS PAIN IN THE PELVIC AREA, FEEL LIKE I'M PREGNANT. TAKEN AT LEAST 5 TEST. DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044691	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DUE TO THE ESSURE, I HAVE MIGRAINES DAILY, EXTREME PELVIC PAIN (LIKE SOMEONE IS STABBING ME WITH A KNIFE), BLOATING, PELVIC SPASMS THAT MAKES ME FEEL AS IF I AM PREGNANT, EXTREME IRRITATION IN THE VAGINAL AREA, SHORTNESS OF BREATH, EXTREMELY HEAVY MENSTRUAL CYCLES (SEVERAL BLOOD CLOTS) AND AN AMOUNT EXCESSIVE VAGINAL SECRETIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044692	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 4/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, SEVERE ABDOMINAL PAIN, MANSTRUL CYCLE LASTING UP TO 21 DAYS WITH HEAVY BLEEDING, DECAYING OF TEETH, HEADACHES, SWELLING, AND PAINFUL SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044693	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY BAD ABDOMINAL PAIN, CONSTANT BLEEDING WHEN HAVING INTER COURSE ALSO HURTS DURING INTER COURSE, MIGRAINES, DIZZYNESS, AND MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044694	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON GOING RASHES ON BODY, MIGRAINES, EXTREME FATIGUE, SHARP PAINS IN ABDOMEN AS WELL AS BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044696	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CONSTANT PELVIC PAIN ON MY LEFT SIDE. MY PERIODS ARE EXTREMELY HEAVY I HAVE A METAL TASTE IN MOUTH ALWAYS I HAVE CONSTANT MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044698	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 11/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AUTOIMMUNE SYMPTOMS; JOINT PAIN, CHRONIC FATIGUE, HAIR LOSS, ITCHING PATCHES ON SKIN, HEADACHES, FLU-LIKE BODY ACHES, UNEXPLAINED FEVER, INTOLERANCE TO COLD, RAYNAUDS SYNDROME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044699	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 1/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OVARIAN CYSTS, SEVERE ABDOMINAL PAIN, ESCRUTAITING PAIN DURING AND AFTER INTERCOURSE, ALLERGIC REACTION TO AMOXICILLIN. END RESULT A PARTIAL HYSTERECTOMY (B)(6) 2014 (OVARIES LEFT).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044700	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 12/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2014 I STARTED HAVING CRAMPING IN MY ABDOMEN AND BACK, HEADACHES, BACK PAIN, HEAVY BLEEDING, AND DEPRESSION. SINCE THEN THESE THINGS HAVE ONLY WORSENED TO THE POINT WHERE IT BECOMES HARD TO TAKE CARE OF MY 2 KIDS WHO ARE (B)(6). I HAVE BEEN TO COUNTLESS DOCTORS WHO HAVE ALL TOLD ME THAT I AM IN GOOD HEALTH AND THEY HAVE NO EXPLANATION FOR THE PAIN I AM FEELING. I KNOW THAT ESSURE HAS CAUSED EVERYTHING I'M EXPERIENCING AND I JUST WANT MY LIFE BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044702	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 10/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I FIRST GOT THE ESSURE EVERYTHING WAS FINE, BUT AS TIME WENT ON I STARTED GETTING HORRIBLE PERIOD CRAMPS WHEN I WAS ON MY MENSTRUAL CYCLE. I EVEN GET THESE PAINS WHEN IT'S NOT THAT TIME OF THE MONTH. THE PAINS ARE WORSENING TO WHERE THEY MAKE ME HURT SO BAD I DON'T EVEN WANT TO GET OUT OF BED. THE PAINS ARE HORRIBLE THAT I CHANGE MY MOOD AND GET ANGRY. I ALSO HAVE NIGHT SWEATS ALMOST EVERY NIGHT, I WAKE UP JUST SWEATING LIKE CRAZY. SOMETIMES, EVEN DURING THE DAY I GET THESE SWEATS AND IT'S JUST GETTING REALLY ANNOYING. IF I WOULD HAVE KNOWN ALL THESE SIDE EFFECTS WOULD HAPPEN, I NEVER WOULD HAVE GOTTEN THE ESSURE PUT IN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044705	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 2/7/2007	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HEADACHES, MIGRAINES, THROWING UP, HAD MY GALLBLADDER REMOVED AND THEN WAS DIAGNOSED WITH DIVERTICULITIS, HAVE HAD SEVERE MENSTRUAL CYCLE, EXCESSIVE BLEEDING AND CLOTS, DIAGNOSED WITH CHRONIC FATIGUE SYNDROME. I ALSO HAVE SEVERE MOOD SWINGS, CRYING AND DEPRESSED, PLANTAR FASCITIS,HEEL SPUR, NAUSEA, SEVERE BLOATING, DRY BRITTLE HAIR, UNEXPLAINED RASHES AND ACNE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044706	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE IN (B)(6) OF 2013. THIS HAPPENED JUST 5 WEEKS AFTER I HAD MY LAST SON. BEFORE BEING IMPLANTED, I DISCUSSED MY CONCERNS ABOUT THE NICKEL IN THE PRODUCT AND ME BEING ALLERGIC TO NICKEL. I WAS TOLD IT WAS LIKE A HEART STENT AND WOULD BE FINE. SINCE DAY 3 OF IMPLANTATION, MY HEALTH HAS DECLINED. I HAVE HAIR LOSS, MEMORY LOSS, BRAIN FOG, BLOATING, PAIN, EXTREMELY HEAVY MONTHLY PERIODS THAT LAST LONGER THEN NORMAL, PAINFUL INTERCOURSE, MOOD SWINGS, AND PAIN IN MY JOINTS. I HAVE ALSO NOTICED I AM MORE SENSITIVE TO METALS AND BREAK OUT VERY EASILY. I WAS NOT TOLD AFTER THE PROCEDURE THAT ONE OF MY COILS WAS NOT PLACED CORRECTLY. I FOUND OUT AT MY HSG FOLLOW UP THAT NOT ONLY IS ONE OF MY COILS IMPROPERLY PLACED, BUT I HAVE A FRAGMENT. MY HEALTH CONTINUES TO DECLINE DAILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044716	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE SWELLING, SITTING AND PULLING OF GENITAL AREAS AFTER SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044717	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 9/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS AWAKE WHEN THEY PUT THE ESSURE INTO MY TUBES AND IT WAS EXTREMELY PAINFUL AND FOR THE NEXT 2 DAYS I COULD HARDLY GET OFF THE COUCH. SINCE GETTING ESSURE IN I CONSTANTLY HAVE LOWER BACK AND PELVIC PAIN. MY PERIOD IS HEAVY AND IS ALL BLOOD CLOTS VERY STICKY AND GROSS. MY MENSTRUAL CRAMPS ARE UNBEARABLE MOST TIMES. I HAVE PAIN THAT SHOOTS FROM MY PELVIC AREA UP THROUGH MY BELLY BUTTON AND THE PAIN NEVER SEEMS TO GO AWAY. I GET NASTY MIGRAINES NOW. LACK OF ENERGY AND I CAN'T SEEM TO LOOSE WEIGHT EVEN THOUGH I'M EATING HEALTHY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044718	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED (B)(6) 2013. I HAVE BEEN HAVING SEVERE BLEEDING. I WOULD BLEED FOR 2 OR 3 WEEKS THEN STOP FOR A WEEK JUST TO START BACK UP. I AM ALWAYS TIRED AND SUFFER FROM PALPITATIONS. I AM VITAMIN D DEFICIENT. I AM STUCK AT THE SAME WEIGHT I WAS WHEN I GOT ESSURE PLACED EVEN THOUGH I EXERCISE LIKE CRAZY. THE INFLAMMATION AROUND MY BELLY IS CRAZY. MY HAIR KEEPS FALLING OUT AND CAN'T HAVE SEX WITH MY HUSBAND DUE TO PAIN. I SUFFER FROM A LOT OF STOMACH ISSUES. AND CONSTANTLY HAVE NAUSEA

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044719	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 12/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD SEVERE CRAMPING WHERE BIRTH CONTROL WAS PLANTED. IT HAPPENS OFTEN. BUT THIS PARTICULAR NIGHT I COULD BARELY MOVE. I WASN'T ABLE TO GO TO THE ER BECAUSE I DON'T HAVE MEDICAL INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044720	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 12/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JUST A FEW SHORT MONTHS AFTER BEING IMPLANTED WITH THE ESSURE DEVICE, I STARTED EXPERIENCING PELVIC PAIN. I GET RANDOM SHARP, STABBING PAINS IN MY PELVIC AREA, MOST DOMINANT ON THE RIGHT SIDE. OTHER ISSUES I NOW HAVE (AND DID NOT BEFORE) AFTER GETTING ESSURE INCLUDE: GROIN PAIN (RIGHT SIDE) THAT SHOOTS DOWN TO KNEE, MIGRAINES, IRREGULAR PERIODS, OLIGOMENORRHEA, FATIGUE, MITTELSCHMERZ, BRAIN FOG, SEVERE BLOATING, BARTHOLIN'S CYST AND JOINT PAIN. I HAVE SEEN MY DOCTOR (MORE THAN ONCE) AND ALL TESTS COME BACK NORMAL WHICH IS WHY I SUSPECT ESSURE FOR ALL OF THESE PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044721	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 5/2/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE PAIN SINCE INSERTION THAT HAS NOT SUBSIDED. I HAVE FAINTED SINCE ESSURE, I NOW HAVE TACHYCARDIA, I HAVE A RASH ON MY FACE CHEST AND THIGHS, I ITCH ALL OVER. I FEEL VIBRATIONS INSIDE MY BODY AND I ALSO NOW HAVE INTESTINAL ISSUES ON MY RIGHT SIDE WERE THE PAIN IS. I HAD A LAPAROSCOPY SURGERY ONLY TO FIND SCARING ON MY RIGHT TUBE AND LARGE INTESTINE WERE THE PAIN IS. I HAVE SEVERE BLOATING AND EXTREME PAIN WHEN MENSTRATING I HAVE LARGE BLOOD CLOTS. I HAVE ALLERGIES NOW WHEN I NEVER HAVE. I WOULD NEVER GET SICK BEFORE AND NOW THIS YEAR I HAVE BEEN SICK OVER 5 TIMES ONCE EVEN WITH PNEUMONIA THIS PAST MONTH. MY VITAMIN D LEVEL IS AT A 7 WHICH IS EXTREMELY LOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044722	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 2/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEG EDEMA, WEIGHT GAIN, EXTREME FATIGUE, ALLERGY TO METAL IN THE DEVICE, EXTERNAL STENOSIS OF THE BOTH ILIAC VEINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044723	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NON STOP BLEEDING, EXTREME CRAMPING , BLOATNESS , ENLARGED UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044724	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS FINE UNTIL I GOT THE ESSURE. SINCE I GOT IT I HAVE SEVERE MIGRAINES, FAINTING, WEIGHT LOSS, SEVERE PELVIS PAINS AND DIAGNOSIS OF ENDOMETRIOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044725	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 3/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERFORATED FALLOPIAN TUBES. REQUIRING 2 SURGERIES TO REPAIR ALL DAMAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044726	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 2/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, POKING HEADACHES, STOMACH PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044727	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN BACK PAIN NAUSEA LOSS OF BALANCE MIGRAINES HEADACHES LOSS OF HAIR NUMBNESS ON UPPER LEFT THIGH DIZZINESS FATIGUE BLOATING I LOOK LIKE I'M PREGNANT! MY BODY IS SORE MY FEET HURT MY NERVOUS SYSTEM FEELS ABSOLUTELY HORRIBLE I HAVE BACK SPASMS. I CAN'T LAY ON MY SIDES OR STOMACH. INTERCOURSE HURTS AND MOSTLY PAINFUL. LIGHT HEADED. LOWER BACK PAIN. CHRONIC PELVIC PAIN. DEPRESSION. JOINTS HURT MY RIGHT KNEE HURTS SO BAD. CAN'T EXCERSIZE I START TO HAVE PAIN REALLY BAD. CAN'T GO FOR WALKS. I CAN'T CARRY MY LITTLE BOY MY STOMACH STARTS TO HURT. I CANT STRETCH IT FEELS LIKE THE COILS ARE RIPPING WHEN I STRETCH. BASICALLY I FEEL LIKE I'M AN OLD LADY I'M ONLY (B)(6)! I HAVE TO GET UP SLOW OR ELSE I'M IN PAIN MY HEALTH HAS GONE TO SHIT BECAUSE OF THIS DEVICE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044728	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING SKIN ISSUES DEPRESSION ANXIETY LOW TO NO SEX DRIVE CRAMPS HIP AND BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044729	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 1/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I HAD ESSURE PLACED I BLED NON STOP! I HAD CONSTANT ABDOMINAL PAIN AND SHARP STABBING PAIN WHEN I BENT OVER. I HAD HEADACHES EVERYDAY, OVER TIME I STARTED HAVING LOWER BACK PAIN, SEX LIFE WAS RUINED AND GETTING RASHES. I GAINED 40+ POUNDS WHILE I HAD ESSURE. I DIDN'T WANT TO GET OFF THE COUCH ALL DAY, I WAS MISERABLE! I HAD NO LIFE BASICALLY. COULDN'T PLAY WITH MY KIDS OR TAKE THEM OUT TO DO STUFF. FINALLY IN MAY/JUNE 2014 I WENT TO SEE MY OB-GYN AND HE SAID HE WOULD DO A HYSTERECTOMY ON (B)(6) 2014. SO AT (B)(6) OLD I HAD TO HAVE A HYSTERECTOMY (BODY PARTS REMOVED!!). I MAY HAVE BEEN DONE HAVING KIDS WHEN I GOT ESSURE BUT IN NO WAY, SHAPE, OR FORM DID I WANT MY LIFE RUINED AND TO LOSE PART OF WHAT MAKES ME A WOMAN!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044730	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE PROCEDURE TOOK MUCH LONGER THA PLANNED. I WAS NEVER TOLD I WOULD NEED A RIDE HOME. I WANT ABLE TO TAKE ANY PAIN RELIEF MEDICATION DURING THE PROCEDURE. I WATCHED AS THE DOCTOR INSERTED BOTH COILS. ON MY LEFT SIDE, THE DOCTOR SAID "OPPS". THE COIL WENT TOO FAR IN, NO TRAILING COILS WERE VISIBLE. I HAVE HAD HORRIBLE PAIN ON THAT SIDE SO SEVERE I COULDN'T MOVE. WEIGHT GAIN, ENDOMETRIOSIS, JOINT PAIN. I HAVE WANT THEM REMOVED BUT CANNOT AFFORD IT. I'VE HAD SURGERY FOR THE ENDOMETRIOSIS AND HAD THE COIL PLACEMENT CHECKED. THE LEFT SIDE COIL HIS MIGRATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044731	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 10/23/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING FOR WEEKS AT A TIME, INTENSE STABBING PAIN IN LOWER LEFT ABDOMEN, MIGRAINE HEADACHES, CONSTANTLY BLOATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044732	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FREQUENT HEADACHES(3 TO 4 TIMES A WEEKLY), WEIGHT GAIN, STOMACH SWELLING, HEAVY MENSTRUAL FLOW, IRREGULAR MENSTRUAL CYCLE (I WOULD HAVE MY PERIOD FOR 10 TO 14 DAYS, VERY HEAVY FLOW, BE OFF MY PERIOD FOR 7 TO 10 DAYS AND BE ON AGAIN FOR 10 TO 14 AGAIN, THE LONGEST LASTING 19 DAYS), SEVERE CRAMPING (FEELS LIKE LABOR CONTRACTIONS) FATIGUE, JOINT PAIN, IRRITABILITY, HAIR LOSS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044733	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 10/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN, JOINT PAIN, METALLIC TASTE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044734	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 3/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVERYTHING BEGAN ON THE DAY IT WAS IMPLANTED. I HAD SEVERE CRAMPING AND BLEED FOR 2WKS. DR. SAID I SHOULD BLEED FOR A DAY OR TWO. THEN THE ABDOMINAL PAIN BEGAN AND FATIGUE. NOW, A LITTLE OVER 2YRS LATER ITS GETTING WORST. ALONG WITH THE CRAMPING AND FATIGUE I NOW GET BAD MIGRAINES, JOINT PAIN, BACK PAIN, BAD MOOD SWINGS, EXTREME TIREDNESS, HARD TO FOCUS, BRAIN FOG, BLOATING AND CAN NOT LOOSE WEIGHT. I GOT ESSURE AT MY 3MONTH CHECK UP AFTER GIVING BIRTH TO MY HEALTHY SON AND I STILL HAVEN'T LOST THE WEIGHT. I WAS AN ACTIVE (B)(6) SIZE 8 BEFORE AND NOW I AM (B)(6) AND A SIZE 14. I HAVE BEEN NURSING THE ENTIRE TIME AND STILL HAVEN'T LOST 1LB. I HAVE BEEN IN THE HOSPITAL ANDAMP; DOCTORS OFFICE FOR THE MIGRAINES, FATIGUE, ANDAMP; PAIN. I HAVE NOT TAKEN ANY MEDICATION DUE TO BREASTFEEDING AND BELIEFS. I HAVE NO OTHER ILLNESSES OR HEALTH CONDITIONS OTHER THAN PLANTAR FASCIATISIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044735	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TENDER ABDOMEN, PAIN DURING INTERCOURSE, CONSTANT BLEEDING, JOINT PAIN HEADACHES, FATIGUE, OCCASIONALLY RASHES POP UP, THE LIST GOES ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044736	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 9/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE GETTING THE ESSURE IN (B)(6) OF 2012, I HAVE EXPERIENCED EXTREME BLEEDING 3 WEEKS OUT OF THE MONTHS, CHRONIC PELVIC PAIN, HAIR LOSS, CONSTANT BLOATING AND WEIGHT GAIN, VERY HEAVY MENSTRUAL CYCLES AND SEVERE DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044737	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED TO HAVE SEVERE MIGRAINES, EXTREMELY HEAVY PERIODS, BLOOD CLOTS THE SIZE OF A CHILD'S FIST DURING MY PERIODS WHERE I WAS CLOSE TO HEMORRHAGING, NIGHT SWEATS, MOODINESS, FATIGUE, CRAMPING IN MY LOWER BACK THAT WAS UNEXPLAINABLE, ALONG WITH MY LOWER ABDOMEN, ALSO WEIGHT GAIN THAT I COULD NOT LOSE, ALONG WITH BECOMING ANEMIC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044738	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO GET ALL MY TOP TEETH PULLED OUT BECAUSE THEY KEPT BREAKING AND FALLING OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044739	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, NAUSEA, LIGHTHEADEDNESS, VOMITING AFTER SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044740	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 7/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WITHIN 2 WEEKS OF HAVING THE DEVICE IMPLANTED I STARTED EXPERIENCING MIGRAINES. WENT TO THE ER SEVERAL TIMES OVER THE PAST 4 YEARS FOR SEVERE MIGRAINES. I HAVE DEVELOPED HEAVY PERIODS WITH LARGE CLOTS. CRAMPING DURING PERIOD THAT MAKES ME VOMIT FROM THE PAIN. I HAVE EXPERIENCED SWELLING OF MY ABDOMEN. I WENT FROM A SMALL STOMACH TO LOOKING PREGNANT. I EXPERIENCE SEVERE PAIN DURING SEX TO THE POINT WHERE MY HUSBAND AND I HAVE DIVORCED OVER THIS ISSUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044741	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME BLOATING, PAINFUL PERIODS, BACK PAIN, SEVERE WEIGHT GAIN, HEADACHES, METAL TASTE IN MOUTH, JOINT PAINS, SEVERE MOOD SWINGS, UNUSUAL LARGE AMOUNTS OF HEAVY BLEEDING, HAIR LOSS, DEPRESSION, SEVERE ALLERGIC REACTIONS THAT OCCUR NOW THAT HAS NEVER OCCURED BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044742	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 1/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, JOINT SWELLING, BACK PAIN, STOMACH PAINS, WEIGHT GAIN, REALLY BAD CRAMPS THRU MONTHLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044743	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 12/7/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO GET A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044744	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 2/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE REOCCURRING RASHES ON MY VAGINA, BUTTOCKS, BACK AND BETWEEN MY LEGS. I HAVE SEVERE PAIN NEAR MY FALLOPIAN TUBES, DURING SEX, CERTAIN MOMENTS CAUSE PAIN. SEVERE HEADACHES, WEIGHT GAIN, BLOATING, ACCUMULATED FLUIDS. ALSO DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044745	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING PROBLEMS IMMEDIATELY AFTER. I BEGAN WAKING UP WITH HEADACHES I COULDN'T GET RID OF. EXTREME PELVIC PAIN, PAINFUL SEX, INSOMNIA, HOT FLASHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044746	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 4/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE IMPLANTED ON (B)(6) 2013. MY OBGYN WAS SKEPTICAL BECAUSE OF MY AGE ((B)(6)) MY OBGYN WOULDN'T PROCEED WITH TUBAL LIGATION ON CUTTING MY TUBES, SO WE DISCUSSED ESSURE. ESSURE WAS SUPPOSED TO BE LESS INVASIVE, LESS TIME OFF WORK TO RECOVER AND PERMANENT FIX. I HAD SOME DISCOMFORT FOR 2 MONTHS AFTER PROCEDURE WHERE THE COILS WERE PLACED AND FELT FATIGUED, CRAMPING, AND INTENSE THROBBING PAIN WHERE COILS WERE PLACED THAT WOULD HURT AT RANDOM TIMES. IT DIDN'T MATTER IF I WAS SITTING, STANDING, LAYING DOWN OR EXERCISING. MID-SEPTEMBER CAME AROUND MY BODY SETTLED DOWN AND ADJUSTED AND I WAS FINE UNTIL (B)(6). (B)(6) 2014 I STARTED EXPERIENCING ABNORMAL SYMPTOMS STARTING WITH A MISSED PERIOD, FREQUENT URINATION, BLADDER INFECTIONS, DIZZY SPELLS, NAUSEA, WEIGHT GAIN, SEVERE BLOATING WHERE I LOOKED PREGNANT, SEVERE CONSTIPATION, SEVERE ABDOMINAL CRAMPING LIKE MY INSIDES WERE BEING TWISTED AND TORN APART AS WELL AS CRAMPING IN PELVIC REGION LIKE MY UTERUS WAS STRETCHING. I WENT TO MY OBGYN (B)(6) 2014 AND SHE DID A VAGINAL EXAM AND URINE TEST AND CAME BACK NEGATIVE. SHE DIAGNOSED IT AS HORMONAL IMBALANCE. MY SYMPTOMS BECAME WORSE WITH SEVERE ABDOMINAL CRAMPING TO THE POINT WHERE I COULDN'T WALK, THROBBING PAIN IN PELVIC REGION WHERE COILS COULD HAVE BEEN PLACED AND 2" BELOW, AND SEVERE CONSTIPATION FOR 6 DAYS AND I WENT INTO AN URGENT CARE CLINIC (B)(6) 2014 AND THEY DIAGNOSED IT AS SEVERE CONSTIPATION AND BLOCKAGE IN MY INTESTINES AS WELL AS BLOOD IN MY STOOL, AND HIGH LEVELS OF PROTEIN. I WAS ON LAXATIVES, ANEMA AND STOOL SOFTENERS FOR 1 WEEK AND NOT MUCH RELIEF AND AGAIN MY SYMPTOMS BECAME EVEN WORSE WITH ABDOMINAL PAIN, FLANK PAIN , UTI, AND PREVIOUS SYMPTOMS LISTED PRIOR. I WENT TO A DOCTOR (B)(6) 2014 AND SHE RAN A URINE TEST AS I STILL HAD NOT STARTED MY PERIOD AND SHE REQUESTED AN X-RAY AND

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DIAGNOSED ME WITH A UTI , AND THE X-RAY SHOWED I HAD BLOCKAGE IN MY INTESTINES AS WELL AS FOUND 3 COILS, 2 IN MY FALLOPIAN, ONE ON EITHER SIDE AND ONE BELOW FALLOPIAN TUBES BUT THOUGHT NOTHING OF IT WHEN WE LOOKED AT IT BECAUSE WE WERE FOCUSED ON THE BLOCKAGE IN MY INTESTINES. MY DOCTOR PRESCRIBED ME WITH SOME ANTIBIOTICS FOR MY UTI. MY SYMPTOMS STILL REMAINED ALL OF THEM LISTED PRIOR BUT THIS TIME HIGH FEVER LESS THAN 24 HOURS LATER LEAVING HER OFFICE AND EXPERIENCED HIGH FEVER FOR 6 DAYS OF 101-103, SEVERE ABDOMINAL CRAMPING WHERE I COULDN'T MOVE, AND I BROKE OUT IN A RASH HEAD TO TOE AND MY SYMPTOMS BECAME WORSE AND I WOUND UP IN THE ER (B)(6) 2014. I WENT TO THE ER AND THEY LOOKED AT MY X RAY AND PERFORMED A CT SCAN AS WELL AS DID BLOOD WORK. MY DOCTORS CAME IN AND SAID THAT WHAT THEY COULD CONCLUDE FROM MY CT SCAN, X RAY AND URINE TESTS IS THE 3RD COIL HAD BROKEN OFF AND WAS PERFORATING MY UTERUS CAUSING ALL OF MY SYMPTOMS. MY DOCTORS TOLD ME TO CALL MY OBGYN RIGHT AWAY AND TO SCHEDULE SURGERY TO HAVE IT REMOVED IMMEDIATELY. I CALLED MY OBGYN AND WE MADE AN APPOINTMENT TO REMOVE IT. ON (B)(6), I HAD THE FAULTY COIL REMOVED USING LAPAROSCOPIC SURGERY.THE COIL WAS BENT, UNTWINED, AND DAMAGED.
(B)(6) 2014 WENT TO OBGYN FOR BLEEDING AND PELVIC PAIN. I HAD AN OVARIAN HEMORRHAGIC CYST AND NEEDED TO BE REMOVED IMMEDIATELY BY LAPAROSCOPIC SURGERY. I WENT INTO THE HOSPITAL IMMEDIATLY AFTER SEEING THE OBGYN AND STAYED OVERNIGHT AT THE HOSPITAL AND THEY SCHEDULED SURGEY TO REMOVE THE CYST THE NEXT DAY.
(B)(6) 2015 WENT TO OBGYN FOR PELVIC PAIN AND DID AN ULTRASOUND WHICH REVEALED ANOTHER CYST. IT WENT AWAY ON ITS OWN
(B)(6) 2015 WENT TO OBGYN AGAIN FOR PELVIC PAIN AND ONCE AGAIN A CYST HAD FORMED. IT WENT AWAY ON ITS OWN
(B)(6) 2015 WENT TO OBGYN FOR CONSTIPATION, BLOATING AND BLADDER ISSUES. URINE TEST CAME BACK NEGATIVE BUT STOOL WAS BACKED UP IN MY INTESTINES AND MIRALAX WAS PRESCRIBED.
(B)(6) 23 2015 WENT TO OBGYN FOR PELVIC PAIN, BLOATING, SEVERE STABBING PAIN WITH CRAMPS, VAGINAL BLEEDING. URINE TEST, BLOOD TEST,AND PELVIC ULTRASOUND EXAM WERE ADMINISTERED. THE RESULTS WERE INCONCLUSIVE AND WAS TOLD TO GO TO ER IF BLEEDING AND CRAMPING BECAME WORSE. I WAS REFERRED TO A GI DOCTOR TO BETTER CONCLUDE RESULTS. THE OBGYN FELT LIKE MY ISSUES WERE DUE TO ESSURE AND REQUESTED I SEE A GASTROINTESTINAL TO GET A BETTER UNDERSTANDING INTERNALLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044747	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/7/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HIGH BLOOD PRESSURE, MIGRAINES, HIVES, HEAVY PERIODS FOR 7 DAYS, PELVIC PAIN, BLOATING, CHEST PAINS ON THE LEFT SIDE, ACID REFLUX, HEIGHTENED ALLERGIC REACTIONS, CONSTANT HEADACHES. I HAVE X-RAY FOR MY PELVIS AND ULTRASOUND, DOCTOR SAID I HAVE CORRECT PLACEMENTS BUT MY LEFT SIDE WHERE I HAVE PELVIC PAINS, THE COILS ARE BENT, THE RIGHT SIDE I HAVE TWO DARK MASSES. I HAVE BEEN TAKING, HIGH BLOOD PRESSURE MEDS, ACID REFLUX MEDS, ANTIBIOTICS, BECAUSE I HAVE BEEN HAVING CONSTANT INFECTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044749	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THESE SIDE EFFECTS HAVE BEEN ON-GOING SINCE A FEW MONTHS ABOUT 5-8 MONTHS AFTER GETTING THE ESSURE PRODUCT PLACEMENT. I HAVE BAD LEFT SIDE PAIN TO THE POINT I CAN BARELY STAND AND VERY PAINFUL INTERCOURSE WHICH HAS CAUSED LARGE AMOUNTS OF PROBLEMS WITH MY PARTNER, (THE FATHER OF MY CHILDREN). I HAVE STOMACH BLOATING AND JUST THE FEELING OF BEING SWOLLEN IN MY ABDOMEN AREA. I HAVE HAD MY GALL BLADDER REMOVED BECAUSE I HAD 1 GALL STONE AND THE AMOUNT OF PAIN I WAS HAVING IN MY STOMACH, SIDE, AND ABDOMEN AREA THEY BELIEVED IT WAS FROM A BAD GALL BLADDER. THE PAIN CONTINUED AFTER THAT PROCEDURE AND ONLY SEEMED TO GET WORSE. I MISSED COUNTLESS DAYS OF WORK AND FAMILY OUTINGS BECAUSE I WAS ALWAYS IN PAIN. THE PAIN MOVED FROM MY LEFT SIDE AROUND THROUGH MY BACK AND WHEN IT WAS COLD IT WAS TWICE A BAD. FINALLY LAST YEAR I RECEIVED AND TUBAL REMOVAL WHERE ONLY 1 AND 1/2 COILS WAS FOUND IN MY TUBES. THE DR DID END UP FINDING THE OTHER HALF OUTSIDE OF MY TUBE. SINCE THE REMOVAL MY SWELLING HAD WENT DOWN AND I NO LONGER HAVE PAIN DURING INTERCOURSE WHICH ALMOST COST ME MY RELATIONSHIP AND FAMILY, IM NOT LONGER IN EVERYDAY ALL DAY PAIN. THE ONLY THING THAT I HAVE TO DEAL NOW IS THE IBS I ACQUIRED AND NOT BEING ABLE TO EAT ANYTHING OUTSIDE MY HOUSE BECAUSE NOW I GET TREMENDOUS PAIN BECAUSE I NO LONGER HAVE GALL BLADDER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044750	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 6/17/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER GETTING ESSURE, I BLED PROFUSELY FOR FIVE MONTHS WHICH LED TO HAVING THE NOVASURE ABLATION. ALTHOUGH THAT STOPPED THE BLEEDING COMPLETELY, THE PAIN NEVER DOES. THE PAIN IS IN MY TUBE AREA, LOWER BACK, HIPS, AND MIGRAINES. I AM LOSING MY HAIR AND BRUISING FOR NO REASON. I BECOME EXTREMELY BLOATED AT NIGHT. I CAN BARELY EAT BECAUSE I BECOME INSTANTLY SICK. THE PAIN IS INDESCRIBABLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044751	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 9/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE SEVERE BLEEDING DURING PERIODS, CRAMPING, BACK PAIN ALL THE TIME, HIP PAIN, CHEST PAIN. HEADACHES, LIGHT HEADEDNESS. NAUSEA OCCASIONALLY. SEVERE BLOATING AS IF I'M PREGNANT. AND SO MUCH MORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044752	BAYER	7/24/2015	7/24/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVING VERY BAD STOMACH PAIN, FEELS LIKE I AM BEING STABBED OVER AND OVER AGAIN, BLOATING, PAINFUL SEX TO WHERE I CRY, PAIN ALL THE TIME. NO ENERGY, BACK PAIN, NIGHT SWEATS AND HAVE NO URGE TO HAVE SEX. PLUS MORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044917	BAYER CORP	7/24/2015	7/31/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 678817

Single Use:
Implant Date (E6): 9/21/2010
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD 5 YRS OF PROBLEMS CAUSED BY ESSURE. LAST YEAR HAS BEEN THE WORST OF MY LIFE STRUGGLE OF PAIN, IN TERMS OF ASSET PROBLEMS AND ASSISTANCE TO DRUGS. A YEAR AGO I BEGAN TO HAVE UNIMAGINABLY HARD LOW BACK AND PELVIC PAIN. PAIN "BEAMED" THIGH AND THE BLADDER WAS FEELING THE PRESSURE. IN ADDITION, MY BREASTS WERE SO SORE THAT I COULD NOT EVEN SLEEP AT NIGHT WITHOUT SPORTS JACKETS. SOUGHT MEDICAL ATTENTION SEVERAL TIMES (INTERNAL MEDICINE PHYSICIAN, GENERAL PRACTITIONER, WORK PLACE PHYSICIAN, GYNECOLOGIST). MY BACK WAS FILMED AND THE CAUSE IS NOT FOUND. I HAD TO BE ON SICK LEAVE FOR LONG PERIODS OF TIME. IN (B)(6) 2015, THE ESSURE IMPLANT CAME OUT WITH MENSTRUAL CYCLE. I ORDERED MYSELF LUMBAR SPINE A YEAR AGO, CAPTURED IMAGES AND EVEN A LAYMAN. I NOTICED THAT ALREADY THEN THE SECOND IMPLANT IS NOT INSERTED. IN (B)(6) I WENT SECTION, WHICH WAS INTENDED TO REMOVE THE SECOND ESSURE IMPLANT AND AT THE SAME TIME MAKE ME STERILE. AFTER THE SURGERY, I READ SECURITIES, THAT THE IMPLANT HAS NOT BEEN AWAY, AS IT WAS INTO THE MYOMETRIUM. FOR NOW I DON'T KNOW IF THERE IS ANY PIECES OF OUTGOING IMPLANT OR I DON'T EXACTLY KNOW WHERE THE OTHER ONE IS. PAIN AND MANY OTHER SYMPTOMS ARE STILL EVERYDAY PROBLEMS. SYMPTOMS I HAVE BEFORE ESSURE: SWELLING, ANTIQUE (I DO NOT FEEL REFRESHED), APPETITE (I CANNOT START ANY), SKIN DISORDERS (ACNE PIMPLES), BREAST TENDERNESS, TOOTH BLOOD LEAKAGE, RINGING IN THE EARS, ALLERGY (CONSTANT RUNNY NOSE AND SNEEZING), CYSTS IN BREASTS, GROIN PAIN, HAIR LOSS, VERY PAINFUL MENSTRUATION, LEUKOCYTE VALUES ARE HIGH, GOITER. MANY OF THESE SYMPTOMS WAS DIAGNOSED BY DOCTOR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044918	BAYER	7/24/2015	7/31/2015

Event Information:

Event Date (B3): 4/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 4/11/2012
Explant Date (E7): 7/22/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE - HAD IT PLACED IN (B)(6) OF 2012, AND I HAVE HAD CONTINUOUS PAIN LOWER RIGHT IN MY ABDOMINAL PELVIC AREA. IT'S SO PAINFUL IT FEELS AS THOUGH MY APPENDIX HAS BURST. I HAVE SUFFERED CONTINUOUSLY. I HAVE MIGRAINES, BACKED UP FLUID, EXCESSIVE HEAVY PERIOD SMELL, PAIN DURING INTERCOURSE, WEIGHT GAIN, ETC. IT HAPPENED ONCE I HAD ESSURE PLACED. I SUFFER EVERYDAY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00542	BAYER HEALTHCARE LLC	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 2/27/2015
Explant Date (E7): 5/7/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 23-APR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR STERILIZATION. PATIENT STARTED PRESENTING PELVIC PAIN, ITCHING, AND HEADACHES. SHE BLAMED THE IMPLANT, AND SHE WANTED IT REMOVED. AN ULTRASOUND WAS PERFORMED AND RESULTED NORMAL, IT WAS PROPERLY PLACED. A CBC (COMPLETE BLOOD COUNT), AND CMP (COMPREHENSIVE METABOLIC PANEL) TESTS WERE ALSO PERFORMED. PATIENT WAS GAVE CELEBREX. EVENT WAS ONGOING AND ESSURE WAS NOT REMOVED. FOLLOW-UP INFORMATION WAS RECEIVED ON 28-APR-2015: IT WAS STATED THAT THE PHYSICIAN HASN'T REMOVED THE ESSURE DEVICES YET, SO THEY DID NOT KNOW IF THERE WOULD BE ANY FRAGMENTS LEFT BEHIND. THEY DID NOT HAVE THE LOT NUMBER. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 01-MAY-2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR

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COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION (GENERAL QUESTIONNAIRE) RECEIVED ON 29-JUN-2015 FROM PHYSICIAN: THIS CASE REFERS TO A (B)(6) OBESE PATIENT. SHE WAS NOT POST-PARTUM AT TIME OF THE INSERTION. DURING ESSURE INSERTION PROCEDURE, CERVICAL DILATATION AND PARACERVICAL BLOCK WERE APPLIED; NO SOUNDING AND NO ANESTHESIA WERE USED. THE INSERTION PROCEDURE WAS CONSIDERED EASY WITH EASY VISUALIZATION OF TUBAL OSTIUM. THERE WERE NO MORE THAN 1500CC OF FLUID LOSS. THE PATIENT WAS USING DEPO PROVERA AS BACK UP CONTRACEPTION. ON (B)(6) 2015, AN ULTRASOUND WAS DONE AND SHOWED THE COILS WERE IN PLACE. ON (B)(6) 2015, ROBOTIC BILATERAL IMPLANT REMOVAL WITH BILATERAL SALPINGECTOMY AND HYSTEROSCOPY WERE DONE. THE REMOVAL OF DEVICES WAS REQUESTED BY THE PATIENT AND THE PHYSICIAN CONCURRED. DURING THE SURGERY THE DEVICES WERE ADHERED IN THE TUBES AND FRAGMENTED ON REMOVAL; AN INTRAOPERATIVE X-RAY SHOWED THE FRAGMENTS WHICH WERE REMOVED PRIOR TO FINISH THE SURGERY. THE PHYSICIAN STATED THAT ESSURE CONTRIBUTED TO THE PATIENT'S CONDITION DUE TO NICKEL SENSITIVITY BUT NO ALLERGY. THE PATIENT'S SYMPTOMS RESOLVED ALMOST ENTIRELY AFTER SURGERY. THE OUTCOME WAS REPORTED AS EXCELLENT. THE PATIENT HAS MINIMAL PAIN AND NO FURTHER ITCHING OR HA (UNDERSTOOD AS HEADACHE). THE PHYSICIAN MEDICALLY CONFIRMED THE EVENTS AND DETAILS PREVIOUSLY REPORTED. THE CASE WAS UPGRADED TO INCIDENT. FOLLOW UP INFORMATION RECEIVED ON 01-JUL-2015: UPDATED PTC (PRODUCT TECHNICAL COMPLAINT). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A PRODUCT QUALITY ISSUE. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT THE REMOVAL OF DEVICES WAS REQUESTED BY THE PATIENT AND DURING THE SURGERY THE DEVICES WERE ADHERED IN THE TUBES AND FRAGMENTED ON REMOVAL. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED APPROXIMATELY 2.5 MONTHS AFTER ITS INSERTION DUE TO NICKEL SENSITIVITY. DURING THE SURGERY ESSURE DEVICES FRAGMENTED ON REMOVAL. THE REPORTED EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, ALLERGIC REACTIONS TO ESSURE MAY HAPPEN, AND ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, PATIENT HAD PRURITUS, HEADACHE AND PAIN WHICH RECOVERED AFTER DEVICES REMOVAL. CONSIDERING THE ABOVE MENTION INFORMATION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING ESSURE BREAKAGE; PHYSICIAN STATED THE DEVICES WERE VERY ADHERED IN THE FALLOPIAN TUBES; THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED EVENT, AND AS IT OCCURRED IN ASSOCIATION WITH ESSURE REMOVAL IT WAS CONSIDERED AS RELATED TO THE SUSPECT INSERT. THIS CASE WAS REGARDED

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AS AN INCIDENT DUE TO THE REQUIRED INTERVENTION FOR DEVICES REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00544	BAYER HEALTHCARE LLC	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 5/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS000HV

Single Use: Y
Implant Date (E6): 4/6/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER CS000HV, INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION. ON (B)(6) 2015 PATIENT COMPLAINED OF PAIN. HEALTH CARE PROFESSIONAL WAS WORRIED SO DID FLAT X-RAY ON (B)(6) 2015 WHICH SHOWED COIL PRESENT ON LEFT SIDE BUT NO COIL WAS SEEN ON RIGHT SIDE. PHYSICIAN STATES THAT THOUGHT BILATERAL PLACEMENT WAS ACHIEVED AT TIME OF ESSURE INSERTION. THE PHYSICIAN WAS AWAY FOR 10 DAYS AND PATIENT WAS IN EXTREME PAIN, SO SHE WENT TO ANOTHER DOCTOR WHO DID TOTAL HYSTERECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: (B)(4). BATCH NUMBER (B)(4). PRODUCTION DATE: 03-NOV-2014. EXPIRATION DATE: 28-NOV-2017. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO

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BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER ONE MONTH EXPERIENCED EXTREME PAIN (INTERPRETED AS PELVIC PAIN). SHE UNDERWENT A TOTAL HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE THE PAIN STARTED ONE MONTH AFTER INSERTION. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENT WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION (GENERAL QUESTIONNAIRE) RECEIVED ON 27-JUL-2015: THE PATIENT HAS NO RELEVANT MEDICAL HISTORY. SHE HAS NO PREVIOUS GYNECOLOGICAL PROBLEMS OR CONCURRENT CONDITIONS. THE PATIENT WAS NOT POSTPARTUM AT TIME OF ESSURE INSERTION. DURING THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00545	BAYER HEALTHCARE LLC	7/27/2015	7/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/22/2013
Explant Date (E7): 2/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE ((B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT SINCE ESSURE WAS DONE SHE HAS HAD PROBLEMS WITH ANXIETY, DEPRESSION, MIGRAINES 3 OR MORE TIMES A WEEK, PAIN IN HER SIDE, AND ITCHING OF THE SKIN. IN 2014 SHE HAD TO HAVE A TUBULIZATION BECAUSE ONE TUBE WAS STILL OPEN. ON (B)(6) 2015 SHE HAD HER TUBES AND ESSURE REMOVED. DURING PRE-OPERATIVE APPOINTMENT, THE CONSUMER FOUND OUT THAT ONE THE PAPER ON HER HBG (HEMOGLOBIN) TEST STATED THAT THE RIGHT MICRO INSERT WAS NORMAL BUT THE LEFT MICRO INSERT WAS MEDIAL TO THE FEET OF THE TUBE AND OUTSIDE OF ENDOMETRIAL CAVITY WITH THE DISTAL PORTION PARTIALLY OVERLYING THE LEFT UTERINE CORNU. HER X-RAY SHOWED THAT ONE OF THEM WAS NOT EVEN IN HER TUBE, IT WAS IN HER UTERINE WALL AND THE OTHER WAS POLING THROUGH. SINCE HER SURGERY, SHE FELT 100% BETTER AND ALSO HAS NOT HAD A MIGRAINE SINCE THEN. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST

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FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A LACK OF EFFICACY AS IT WAS REPORTED THAT ONE TUBE IS STILL OPEN. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY MEDICINAL PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE INSERTION SHE HAS HAD PROBLEMS (NON-SERIOUS EVENTS ADDED). SHE HAD HER TUBES AND ESSURE REMOVED ABOUT 1 YEAR AND 3 MONTHS AFTER ESSURE INSERTION. DURING PRE-OPERATIVE APPOINTMENT, IT WAS OBSERVED THAT THE RIGHT MICRO INSERT WAS NORMAL BUT LEFT WAS MEDIAL TO FEET OF TUBE AND OUTSIDE OF ENDOMETRIAL CAVITY WITH DISTAL PORTION PARTIALLY OVERLYING THE LEFT UTERINE CORNU (POLING THROUGH THE UTERINE WALL) AND THE OTHER IT WAS IN HER UTERINE WALL. THIS EVENT, INTERPRETED AS DEVICE EMBEDDED, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM THE REPORTED EVENT WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 02 OCT 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UPS WILL BE PURSUED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00546	BAYER HEALTHCARE LLC	7/27/2015	7/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE ((B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS WERE PROVIDED). CONSUMER REPORTED THAT SHE HAD TO HAVE TWO MAJOR SURGERIES TO REMOVE FROM HER TUBES. THE LEFT SIDE PERFORATED HER TUBE AND STUCK TO HER BOWEL AND CAUSED HER PAIN, SHE LOST WAGES FROM BEING OFF WORK. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LEFT SIDE PERFORATED HER TUBE AND STUCK TO HER BOWEL. THIS EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION AND TRAUMATIC INTESTINAL PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN TUBE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION, WITH POSSIBLE INJURY TO THE BOWEL. IN THE PRESENT CASE, NO INFORMATION WAS PROVIDED REGARDING THE INSERTION PROCEDURE OR THE EXACT TIMING BETWEEN INSERTION AND THE PERFORATION. HOWEVER, GIVEN THE NATURE OF THE EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. SINCE THE CONSUMER REPORTED TWO MAJOR SURGERIES TO REMOVE ESSURE FROM HER TUBES, THIS CASE WAS REGARDED AS INCIDENT (REQUIRED INTERVENTION). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 02 OCT 2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UPS WILL BE PURSUED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00547	BAYER HEALTHCARE LLC	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/23/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (# MW5042226) IN UNITED STATES ON 29-JUN-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT SINCE ESSURE INSERTION SHE SUFFERED FROM JOINT PAINS, REALLY BAD HEADACHES, VERY HEAVY PERIODS, AND BAD CRAMPS. OVER THE WEEKEND ON (B)(6) 2015, SHE WAS IN SO MUCH PAIN SHE WAS RUSHED TO THE EMERGENCY ROOM AND AFTER DOING A LOT OF BLOOD WORK AND OTHER TEST, THEY FOUND OUT THAT SHE WAS PREGNANT AND IT MIGHT BE IN THE TUBES. SHE HAD TO GO THROUGH MORE PAIN BECAUSE OF THIS FAULTY PRODUCT. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED

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QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE WAS PREGNANT AND IT MIGHT BE IN THE TUBES. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ECTOPIC PREGNANCIES HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE THE INSERT IN PLACE. IN THIS PARTICULAR CASE, ABOUT 1 YEAR AND 8 MONTHS AFTER ESSURE INSERTION, SHE DISCOVERED THAT SHE WAS PREGNANT. AN ECTOPIC PREGNANCY WAS SUSPECTED. CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED, AND IT WAS THEREFORE CONSIDERED AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 14-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER W

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00548	BAYER HEALTHCARE LLC	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A96184

Single Use: Y
Implant Date (E6): 6/20/2014
Explant Date (E7): 8/12/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042243) IN UNITED STATES ON 29-JUN-2015, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER A96184, INSERTED ON (B)(6) 2014. CONSUMER REPORTED THAT, TWO WEEKS AFTER HAVING ESSURE COILS IMPLANTED, SHE EXPERIENCED SEVERE NAUSEA, LOWER ABDOMINAL PAIN, BLOATING AND BLEEDING. ACCORDING TO HER, THESE SYMPTOMS CONTINUED UNTIL SHE HAD THE COILS REMOVED ON (B)(6) 2014 AND, ONCE THE COILS WERE REMOVED, ALL OF THESE SYMPTOMS DISAPPEARED. IN ADDITION, THE SERIOUSNESS CRITERION "REQUIRED INTERVENTION" WAS REPORTED; HOWEVER IT WAS NOT SPECIFIED FOR WHICH EVENT. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: BATCH NUMBER A96184. PRODUCTION DATE: 2/2013. EXPIRATION DATE: 2/2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS

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HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICES WERE REMOVED AND SHE RECOVERED FROM THIS EVENT. THE REPORTED EVENT, REGARDED AS GENITAL BLEEDING, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, TWO WEEKS AFTER ESSURE PLACEMENT, CONSUMER STARTED EXPERIENCING BLEEDING, BLOATING, AND LOWER ABDOMINAL PAIN. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION AND AS THE EVENTS RECOVERED WITH DEVICES REMOVAL, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE ESSURE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED). A PRODUCT TECHNICAL COMPLAINT ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 09-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT R

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00549	BAYER HEALTHCARE LLC	7/27/2015	7/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C35240

Single Use: Y
Implant Date (E6): 6/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 30-JUN-2015. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; THE LOT NUMBER USED WAS C35240. DURING INSERTION PROCEDURE, THE DEVICE DID NOT DEPLOY PROPERLY. THE PLASTIC PIECE OF THE DEVICE WAS LEFT INSIDE AND COIL DID NOT DEPLOY WHEN PLACED. BILATERAL PLACEMENT OF DEVICES WAS ACHIEVED AND THE PATIENT HAD NO INJURY.. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A PLASTIC PIECE OF THE DEVICE WAS LEFT INSIDE DURING THE PROCEDURE. PATIENT HAD NO INJURY. THE REPORTED EVENT, REGARDED AS DEVICE BREAKAGE, WAS CONSIDERED NON-SERIOUS AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, THE DEVICE DID NOT DEPLOY PROPERLY AND A PLASTIC PIECE REMAINED INSIDE. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED IN ORDER TO CLARIFY THE EVENT. NEVERTHELESS, CONSIDERING IT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015. (B)(4). LOT NUMBER C35240 (PRODUCTION DATE 06-MAR-2014; EXPIRATION DATE 31-MAR-2017). FINAL ASSESSMENT FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044753	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CHRONIC PELVIC PAIN, VERTIGO, BLOATING, BRAIN FOG AND MANY MANY MORE THINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044754	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN IN LOWER ABDOMINAL AREA. HEAVY ONSET OF PERIODS, WITH CRAMPS THAT ARE SO BAD THAT I CAN'T DO ANYTHING THE 1ST AND 2ND DAYS OF PERIOD. CHANGE IN EMOTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044755	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, FATIGUE, HEAVY MENSTRUAL CYCLE, PELVIC CRAMPS, UNEXPLAINED THYROID ENLARGEMENT, BRUISING, LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044756	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 3/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JUST STOPPED BLEEDING HAD BEEN BLEEDING WHEN THEY INSERTED IT IN ME STOPPED BLEEDING (B)(6) OF 2013 AND SINCE THEN STARTED HAVING VERY LOW BACK PAINS IN LOWER ABDOMINAL PAIN THEN MY BLEEDING STARTED BACK UP IN (B)(6) SOMETIME IN 2013 AND STILL HAVE THE SAME PROBLEM NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044757	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, CHRONIC FATIGUE, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044758	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 9/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING THE COILS DONE. I WAS IN PAIN FOR AN ENTIRE YEAR. CRAMPS WERE SO BAD I COULDN'T MOVE HAD TO CURL IN A BALL. THE BLEEDING WAS SO HEAVY AND LASTED 10 DAYS SOMETIMES 14. WHERE I COULDN'T EVEN LEAVE THE HOUSE BECAUSE I COULDN'T CONTROL IT OR PROTECT MYSELF. I HAD TO USE HOSPITAL PADS JUST TO SIT OR SLEEP. VERY BIG CLOTS THAT HURT WHEN THEY CAME OUT. I JUST RECENTLY STARTED HAVING NORMAL CYCLES WHERE A PAD WILL PROTECT ME AND THE FLOW ISN'T SO BAD. BUT IT'S BEEN 4 YEARS. I'VE HAD BACK PAIN FOR THE LAST 2 YEARS. JUST KEPT TAKING IBUPROFEN. BUT NOW IT'S TO THE POINT WHERE NOTHING WILL HELP THE PAIN. I CAN'T HAVE SEX WITH MY HUSBAND BECAUSE THE PAIN IS SO BAD. I CRY AND BLEED EVERY TIME. ITS BEEN LIKE THAT FOR THE LAST 4 YEARS. THIS WAS DEFINITELY THE WORST DECISION OF MY LIFE. I JUST WANT THEM TO BE REMOVED AND THE PAIN TO BE GONE. I'VE VISITED THE EMERGENCY ROOM A FEW TIMES FOR THE BLEEDING. THEY JUST SENT ME HOME. COULDN'T DO ANYTHING FOR ME. I JUST STARTED SEEING MY DOCTOR ON A REGULAR BASIS FOR BACK PROBLEMS AND EXPLAINED THE WAY MY CYCLES WERE. I AM ONLY (B)(6) AND SHOULDN'T HAVE THIS MANY PROBLEMS. HELP NEEDED!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044759	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 9/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLOATING, HEAVY BLEEDING, PELVIC PAIN, WEIGHT GAIN, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044760	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 11/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PROCEDURE AT THE END OF 2010. WHEN THEY WERE DONE THEY TOLD ME THAT I WOULD BE IN PAIN FOR A COUPLE DAYS AND THAT WOULD BE ALL. I HAVE HAD CHRONIC PELVIC PAIN AND LOWER BACK PAIN SINCE THAT DAY. MY PERIODS ARE EITHER VERY HEAVY AND PAINFUL OR VERY LIGHT AND LAST ALL MONTH. I HAVE ALSO HAD SIDE EFFECTS LIKE: HAIR LOSS, WEIGHT GAIN, CRAMPING, SEVERE BLOATING, EXCESSIVE DISCHARGE, CONSTANT FATIGUE. I AM HAVING A PARTIAL HYSTERECTOMY IN (B)(6) OF 2015. I FINALLY FOUND A DOCTOR THAT BELIEVED ME!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044761	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 3/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ON MY OVARIES ALL THE TIME, LONGER AND MORE FREQUENT CYCLES, SERVE HEADACHES, DENTAL ISSUES, PAINFUL SEX, BLEEDING AFTER SEX, LOW LIBIDO, RASHES, NAUSEOUS, FATIGUE, BACK PAIN, MEMORY PROBLEMS, BRAIN FOR AND BRAIN ZAPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044762	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 12/15/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKEL ALLERGY. PELVIC PAIN, BACK PAIN, WEIGHT GAIN, UNEXPECTED STOMACH PINCHING, SEEING WHITE SPOTS, BRAIN SPASMS, HAIR FALLING OUT, INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044763	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 11/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DOCTOR PROMISED THAT ESSURE PLUGS WILL BE THE BEST WAY FOR ME TO NO LONGER HAVE KIDS INSTEAD OF CUTTING MY TUBES. I HAD TWINS AT THE AGE OF (B)(6) AND I WAS SCARED TO HAVE MORE KIDS. SO I LISTEN TO MY DOCTOR AND GOT TO ESSURE PLUGS . I NEVER HEARD OF ESSURE BEFORE BUT MY DOCTOR SOUNDED REALLY SURE ABOUT THEM . HE SAID I WILL NOT FEEL ANY PAIN AFTER I WAKE UP NOR WILL I BE BLEEDING . THE MOMENT I WOKE UP I WAS IN EXTREME PAIN. AS I WALK TO THE BATHROOM TO PEE, THERE WAS BLOOD ALL ON THE FLOOR FROM MY ROOM TO THE BATHROOM IN THE HOSPITAL. SINCE (B)(6) 2012 I'VE BEEN IN SO MUCH PAIN AND BEEN LIVING IN "PROFANITY". I AM ALWAYS BLOATED I HAVE BEEN DEPRESSED THAT I CANNOT LONGER FUNCTIONING LIFE. I'VE BEEN A COLLEGE STUDENT SINCE GRADUATING HIGH SCHOOL AND AFTER ESSURE I FELL OFF TREMENDOUSLY. I CAN NO LONGER FOCUS AND MY MEMORY IS REALLY BAD. MY TEETH NEED A LOT OF WORK DONE TO THEM. I HAVE CONSTANT PAIN IN MY RIGHT OVARY. I MOVED FROM WHERE I RECEIVED THE ESSURE AND MY CURRENT DOCTOR HAS NO CLUE ABOUT ESSURE PROBLEMS SO HE SAYS ALL MY SYMPTOMS ARE NOT RELATED TO ESSURE. MY INITIAL DOCTOR SAID IF I EVER RECEIVED PAIN THAT HE MIGHT DO A HYSTERECTOMY ON ME I AM ONLY (B)(6) AND I FEEL I AM TOO YOUNG FOR ONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044764	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 12/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED IN (B)(6) 2012, SINCE THEN I HAVE HAD EXTREME MOODSWINGS AND ANXIETY. ALSO, I NO LONGER HAVE MY PERIOD AND SUFFER FROM NIGHT SWEATS AND FROM HORRIBLE MIGRAINES. I HAVE LOST A TREMENDOUS AMOUNT OF WEIGHT. I ALSO HAVE BLEEDING AFTER INTERCOURSE ALONG WITH HAVING BLOOD CLOTS BETWEEN THE SIZE OF DIMES AND NICKELS AFTER INTERCOURSE. I HAVE SEVERE STABBING PAINS IN MY LOWER ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044765	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP ALMOST STABBING PAIN IN MY LEFT OVARY OR FALLOPIAN TUBE, BLOATED STOMACH, WEIGHT GAIN, CYSTIC ACNE, CYSTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044766	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BAD STOMACH PAIN MIGRAINES BACK PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044767	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 1/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, ENDOMETRIOSIS. BLEEDING FOR MONTHS STRAIGHT. NIGHT SWEETS, FEVERS, FIBROIDS, CYST, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044768	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 7/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4), MY CYCLES BECAME VERY HEAVY, WHICH MADE ME STAY ON MY CYCLE FOR 3-4 MONTHS. I ALWAYS HAVE CRAMPS, PELVIC PAIN AND JUST WEAK SOME DAYS. MY STOMACH IS ALWAYS BLOATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044769	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 2/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY HEAVY PERIODS, LARGE CLOTS PASSED, PELVIC PAIN, BACK PAIN, HEADACHES, DIZZINESS, INCONTINENCE, FREQUENT URINATION, CONSTIPATION, PANIC ATTACKS, INSOMNIA, ABDOMINAL MUSCLE SPASMS, EXCESSIVE WEIGHT GAIN, BLOATING, TOOTH DECAY, GUM DISEASE, HEART BURN, JOINT PAIN, PAINFUL PERIODS, MUSCLE SPASMS, VISION CHANGES AND EYE TWITCHING, FOOD ALLERGIES, HIP PAIN, PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044770	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MAJOR HEADACHES, WEIGHT GAIN, MOOD SWINGS, ACNE, ENDOMETRIOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044771	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 9/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INTENSE PAIN, NON-STOP BLEEDING, INCREASED WHITE BLOOD CELL COUNT, BLOATING, HEAVY PERIODS, BLISTERS IN VAGINA, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044772	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, MIGRAINES, JOINT PAIN, REAL BAD ABDOMINAL PAIN, EXCESSIVE BLEEDING, COIL EXPLOITED OUT MY VAGINA, CONSTANT BACK PAIN, RASHES, HAIR LOSS, WEIGHT GAIN, PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044773	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 5/2/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAINS IN THE STOMACH. I CANNOT LAY ON MY STOMACH WITHOUT PAIN. BIG ABDOMIN LOOKS SWOLLEN AND DOESN'T GO DOWN AT ALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044774	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 6/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GET MY PERIOD TWICE A MONTH, EXTRA HEAVY FLOW, HUGE BLOOD CLOTS SIZE OF GOLFBALL, LOW IRON, DIZZY, FORGETFULNESS, AND WEAKNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044775	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 1/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I THOUGHT EVERYTHING WAS GOING SMOOTH EVEN RECOMMENDED IT TO PEOPLE. SINCE THEN I'VE GAINED AT LEAST (B)(6) HAVE HAD CONSTANT BACK PAIN. I SWEAR I CAN FEEL "IT" AND MY LEFT LEG CONSTANTLY GOES NUMB. I HAVEN'T HAD MENSTRUAL CRAMPS SINCE I WAS (B)(6) BUT AFTER HAVING THE PROCEDURE I GET THEM ABOUT 3 DAYS BEFORE AND DURING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044776	BAYER	7/27/2015	7/27/2015

Event Information:

Event Date (B3): 10/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I ENDURED THESE SYMPTOMS ALONG WITH SEVERE PAIN FOR 5 YEARS. THEN IN (B)(6) 2013, THE PAIN WAS SO TERRIBLE I COULDN'T WALK AND HAD AN EMERGENCY CT SCAN. AFTER THE SCAN, I WAS SENT TO SEE AN OB GYN FOR FOLLOW UP AND A VAGINAL ULTRASOUND. THE ULTRASOUND REVEALED THE DEVICE HAD MIGRATED. MY SURGEON BELIEVED IT TO BE IMBEDDED IN MY UTERUS AND SCHEDULED AN EMERGENCY HYSTERECTOMY. WHILE PERFORMING THE HYSTERECTOMY, SHE HAD TO PERFORM EXPLORATORY SURGERY BECAUSE THE DEVICE HAD ACTUALLY PERFORATED MY UTERUS AND WAS FOUND RESTING BETWEEN THE UTERUS AND COLON. THIS NORMALLY 2 HOUR SURGERY TOOK NEARLY 4 HOURS DUE TO THE MIGRAINE AND PERFORATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00543	BAYER HEALTHCARE LLC	7/27/2015	7/28/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B09701

Single Use: Y
Implant Date (E6): 8/5/2013
Explant Date (E7): 6/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5040354) IN UNITED STATES ON 22-MAY-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER STATED THAT SINCE INSERTION, SEXUAL INTERCOURSE WAS EXTREMELY PAINFUL AND SHE GOT INFECTIONS. SEXUAL PAIN ONLY STARTED AFTER SHE HAD ESSURE. SHE ALSO EXPERIENCED PELVIC PAIN AND BLOATING AND SHE WAS AFRAID TO HAVE SEX. AN INJURY (SERIOUS IMPORTANT MEDICAL EVENTS) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP WILL BE REQUESTED. FOLLOW-UP RECEIVED ON 29-MAY-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER

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BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON 29-JUN-2015 FROM CONSUMER. THIS CASE WAS UPGRADED TO INCIDENT. CONSUMER'S DATE OF BIRTH WAS PROVIDED. THIS REPORT REFERS TO A 40 YEARS OLD FEMALE CONSUMER. IT WAS REPORTED THAT DUE TO ESSURE LOT NUMBER B09701, SHE HAD TO UNDERGO A SALPINGECTOMY ON (B)(6) 2015. THE SURGERY WAS A SUCCESS AS FAR AS REMOVAL OF BOTH FALLOPIAN TUBES AND ALL OF THE ESSURE INTACT WITH NO FRAGMENTS LEFT BEHIND. IT WAS ALSO DETERMINED SHE HAD ENDOMETRIOSIS AND ONE FIBROID. SHE HAS NEVER HAD OR BEEN DIAGNOSED WITH EITHER OF THOSE UNTIL SHE HAD THE ESSURE. FOLLOW-UP RECEIVED ON 01-JUL-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: B09701; PRODUCTION DATE: MAR-2013; EXPIRATION DATE: 31-MAR-2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN AMONG OTHER NON-SERIOUS EVENTS. PELVIC PAIN WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE (SALPINGECTOMY WAS PERFORMED) AND ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS EVENT IS LISTED. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE PELVIC PAIN STARTED SINCE THE INSERTION. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND ITS NATURE, THIS EVENT IS CONSIDERED RELATED TO ESSURE. THIS CASE WAS UPGRADED TO INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP ON 24-SEP-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00550	BAYER HEALTHCARE LLC	7/27/2015	7/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN THE UNITED STATES ON 22-AUG-2013. IT DESCRIBES THE OCCURRENCE OF PREGNANCY AND DEVICE INEFFECTIVE IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER'S MEDICAL HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATIONS WERE NOT REPORTED. ON AN UNSPECIFIED DATE IN 2008, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION-INSERT) INSERTED. LOT NUMBER WAS NOT REPORTED. IN 2013, THE CONSUMER WAS 5 MONTHS PREGNANT. HER DOCTOR WAS AWARE OF THIS AND SHE WAS CONCERNED ABOUT BEING PREGNANT WITH ESSURE. AT THE TIME OF THIS REPORT, THE OUTCOME OF THE EVENTS PREGNANCY AND DEVICE INEFFECTIVE WAS UNKNOWN. THE REPORTER CAUSAL RELATIONSHIP WAS NOT REPORTED. ADDENDUM: THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO ARGUS ON (B)(6) 2013. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED. FOLLOW UP INFORMATION RECEIVED ON 01-JUL-2015 FROM CONSUMER: THE CONSUMER REPORTED SHE BECAME PREGNANT WITH HER THIRD CHILD WHILE THE COILS WERE STILL IN ONLY TO FIND THAT THEY MIGRATED INTO HER UTERINE WALL. SHE WAS IN CONSTANT PAIN AND DISCOMFORT FOR YEARS AFTER IMPLANTATION. SHE COULD NOT AFFORD TO HAVE THE DEVICES REMOVED UNTIL THE BLEEDING BECAME SO BAD THAT SHE HAD TO HAVE A HYSTERECTOMY IN 2014 TO END THE NIGHTMARE SHE WAS LIVING. CONSUMER STATED THAT SHE WANTS TO BE COMPENSATED FOR HER MISERY AND PAIN BECAUSE IF SHE KNEW ALL THE SIDE EFFECTS PRIOR TO IMPLANTATION, SHE WOULD NOT HAVE CHOSEN THIS METHOD OF STERILIZATION. THIS CASE WAS UPGRADED TO INCIDENT. FOLLOW-UP RECEIVED ON 14-JUL-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY

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(PREGNANCY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE EXPERIENCED BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND STATED ESSURE HAD MIGRATED INTO HER UTERINE WALL (REGARDED AS DEVICE EMBEDMENT/PARTIAL UTERINE PERFORATION). ALL REPORTED EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE; EXCEPT FOR THE REPORTED PREGNANCY WHICH IS NON-SERIOUS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG) TO DETERMINE IF TUBAL OCCLUSION IS PRESENT. IN THIS CASE, NO INFORMATION WAS PROVIDED ABOUT HSG (IF IT WAS PERFORMED OR NOT). THE REPORTER STATED ESSURE WAS MIGRATED INTO HER UTERINE WALL, AND DUE TO BLEEDING SHE WAS SUBMITTED TO A HYSTERECTOMY FOR DEVICES REMOVAL. IN THIS CASE; SINCE IT IS UNCLEAR THE EXACT MECHANISM AND DATE OF PERFORATION (WHETHER IT OCCURRED PRIOR OR AFTER PREGNANCY) AN ESSURE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED AND DUE TO THEIR NATURE ALL EVENTS WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. THIS CASE WAS REGARDED AS INCIDENT, SINCE AN INTERVENTION (HYSTERECTOMY) WAS REQUIRED FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 13-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044935	BAYER	7/27/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS; HHS)
Brand Name (E1): ESSURE; ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6) 2013. AS OF SOME TIME LAST YEAR I HAVE BEEN HAVING ON AND OFF PELVIC PAIN. LAST YEAR (B)(6) 2014 I WENT AND HAD A TRANSVAGINAL ULTRASOUND. THE REPORT CAME BACK THAT "LEFT ESSURE DEVICE WITH TORTUOUS COURSE, SUGGESTIVE OF PERFORATION INTO THE MYOMETRIUM." SINCE THEN I HAVE BEEN SUFFERING WITH THE PAIN MORE CONSTANTLY. I WENT TO MY DOCTOR TODAY AND NOW I HAVE TO HAVE ULTRASOUND AND MY DOCTOR IS TALKING SURGERY AND A POSSIBLE HYSTERECTOMY. I AM HIGHLY UPSET WITH THE OUTCOME WITH THE ESSURE IMPLANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044940	BAYER	7/27/2015	8/3/2015

Event Information:

Event Date (B3): 7/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 919013

Single Use:
Implant Date (E6): 1/5/2012
Explant Date (E7): 7/10/2015
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN (B)(6) 2012. I HAD PAIN IN MY PELVIC AREA, LEGS, BACK, DURING SEX, AND LIMITED RANGE OF MOTION. I HAD A CONTANT SWOLLEN STOMACH. IN (B)(6) OF THIS MONTH I HAD A PARTIAL HYSTERECTOMY AND IT WAS DISCOVERED THAT ONE OF THE COILS MIGRATED FROM THE TUBE TO THE MUSCLE IN MY UTERUS. NOT ONLY WAS IT CAUSING PAIN AND INFLAMATION I COULD HAVE ALSO BECOME PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044777	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 6/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, CHRONIC PELVIC PAIN, CHEST PALPATIONS, ANXIETY, INSOMNIA, PAIN WITH INTERCOURSE, LACK OF PERIODS, ODOR WHEN ON PERIODS, BLOATING, JOINT PAIN, SEVERE BACK PAIN, PAINFUL CRAMPING, DIARRHEA, CONSTIPATION, MOOD SWINGS, DEPRESSION, HOT FLASHES, LOSS OF HAIR, METALLIC TASTE, LIST GOES ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044778	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 7/18/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MAJOR CRAMPS, LOTS OF BLEEDING. ABDOMINAL PAIN, LEG PAIN. PAIN SO GREAT AT TIMES IT MAKES ME NAUSEOUS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044779	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 2/19/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERIOD BLEEDING GOT WORSE HEAVIER AND CONSTANT WOULD GET LIKE A 2 DAY BREAK THEN BACK HEAVY AGAIN. ALWAYS TIRED AND EMOTIONAL HAD HORRIBLE THOUGHTS IN MY HEAD VERY IRRITABLE. STOMACH PAINS AND BLOATED ALL THE TIME. MADE MY LOWER BACK HURT AND MY HEADACHE MORE OFTEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044780	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 6/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THE ESSURE I'VE HAD VERY BAD MIGRAINE HEADACHES,DEPRESSION,PAIN ABOVE MY PRIVATE AREA DURING MENSTRUAL CYCLE AND INTERCOURSE,MOOD SWINGS THAT EVEN MY OWN FAMILY DOESN'T WANT TO BE AROUND ME. I'VE LOST MOTIVATION, GAINED WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044782	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT TO THE BATHROOM TO CHANGE OUT MY TAMPON, AND I FOUND THE ESSURE COIL CAUGHT IN MY TAMPON, I ALREADY HAD MY PERIOD FOR THE MONTH OF JUNE WITH HEAVY BLOOD CLOTS IN THE STOOL AND ON MY TAMPON. AND NOW THE COIL CAME OUT, WENT TO E.R. TO MAKE SURE THEIR WASN'T ANY FRAGMENTS, I HAVE PICTURES OF THE COIL IN MY TAMPON, I JUST CAN'T POST THEM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044784	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 1/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IRREGULAR PERIODS, ABDOMINAL PAIN,HAIR LOSS, HEADACHES, SEX DRIVE STOPPED COMPLETELY DUE TO PAIN, WEIGHT GAIN, SWELLING,LACK OF ENERGY, HIGH ANXIETY OF GETTING PREGNANT, CRAMPS EVERY DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044792	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 7/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DR. (B)(6) INSISTED THAT THIS WAS THE BEST BIRTH CONTROL. HE TOLD ME MY INSURANCE WOULD PAY FOR THE CHECK UP, BUT THAT WAS A LIE. I'VE BEEN IN SEVERE PAIN FOR YEARS WITH TERRIBLE BACK PAIN, AND REALLY HEAVY AND PAINFUL MENSTRUAL CYCLES. I SWELL FOR NO REASON. GAS PAINS ARE RIDICULOUS. I CAN HARDLY WALK WHEN I'M ON MY PERIOD. NOR CAN I LAY DOWN. I'VE EXPERIENCED SEVERAL PANIC ATTACKS AND CHEST PAINS. I CAN HARDLY WORK. I CAN'T PLAY WITH MY CHILDREN. THIS PAIN IS EVERY DAY THOUGH. NOT JUST ON MY CYCLE. I LIVE WITH THE PAIN. I'M EXTREMELY ANEMIC. MY HAIR FELL OUT. MY FEET SWELL AND I'VE GAINED SO MUCH WEIGHT I BARELY RECOGNIZE MYSELF. I CAN'T REALLY EXERCISE DUE TO THE PAIN. IT'S RIDICULOUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044795	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 1/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE FIRST TIME I THOUGHT IT COULD BE MY ESSURE. I WAS BLEEDING SO BAD I ALMOST PASSED OUT BUT HAD CALLED FOR 911 I WAS GIVEN FLUIDS BY IV AND GIVE A SCRIPT FOR PROVERA PILL FORM. THAT I USED FOR 9 MONTHS I HAD ON GOING MENTAL HEALTH ISSUES BIPOLAR, MAJOR ANXIETY. I'M ON DISABILITY BECAUSE OF MY BIPOLAR NOW AND MY HOSPITALIZATIONS. I'VE HAD PAIN SO BAD PMS I'VE HAD TO GO TO THE HOSPITAL BECAUSE I FEEL SOMETHING IS WRONG. I'VE HAD TWO DIFFERENT TIMES I'VE HAD POSITIVE PREGNANCY TESTS AND BEEN A WEEK LATE AND NO PREGNANCY. I FEEL I WAS NOT PROPERLY INFORMED OF WHAT THIS DEVICE WAS. I HAVE A NICKEL ALLERGY SINCE I WAS LITTLE. I'M HOPEFUL TO HAVE THIS REMOVED ASAP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044805	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, JOINT PAIN, MOOD SWINGS, LACK OF DESIRE FOR INTERCOURSE, TERRIBLE BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044806	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 11/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE IMPLANTS DONE. LOTS OF PAIN AND BLEEDING EVER SINCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044807	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 6/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER ESSURE DONE 2011 I HAVE SUFFERED LOTS OF DIFFERENT KINDS OF INFECTIONS, BLEEDING AND SPOTTING, PELVIC PAIN, BACK PAIN, PAINS IN MY ABDOMEN. HEARTBURNS, 2 DIFFERENT HERNIA, BLOATING, WEIGHT GAIN ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044808	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 6/22/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, MIGRATED DEVICES, HEAVY BLEEDING, HAIR LOSS, DEPRESSION, FATIGUE, WEIGHT GAIN, MISSED PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044809	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 6/13/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, CRAMPING, MOOD SWINGS, LOSS OF LIBIDO, PELVIC PAIN, BREAST TENDERNESS, DISCHARGE, YEAST INFECTIONS, VAGINALLY PAIN AND BURNING, WEIGHT GAIN, NERVE PAIN IN LEGS AND BACK ALONG WITH NECK, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044818	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE 9-10 DAY PERIODS, STARTING WITH SPOTTING FOR 3-4 DAYS, HEAVY BLEEDING FOR 2 DAYS, NORMAL BLEEDING FOR A DAY OR TWO, THEN 2-3 OF SPOTTING. I HAVE HAD MORE CRAMPING DURING MY HEAVY DAYS THAN EVER SINCE THE PROCEDURE. I HAVE ALSO HAD FATIGUE MORE THAN NORMAL. I HAVE TALKED ABOUT THESE CONCERNS WITH MY OB/GYN A COUPLE TIMES, AND THEY SUGGESTED THAT I GO ON THE PILL TO CONTROL MY PERIOD. I HAVE BEEN VERY HESITANT, BECAUSE I GOT ESSURE TO BE MY ONLY FORM OF BIRTH CONTROL. I GOT IT SO THAT I DIDN'T HAVE TO BOTHER WITH TAKING A PILL DAILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044819	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 6/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN BLEEDING SINCE I HAD IT PLACED 3 WEEKS AGO. EXTREME BLOATING, HEADACHES, ITCHING ALL OVER BODY, EXTREME PELVIC PAIN, BACK PAIN, JOINT PAIN, AND MUSCLE PAIN, FEELING SICK ALL THE TIME AND WANTING TO SLEEP ALL THE TIME, HAVING TO TAKE TRAMADOL FOR THE PAIN, I AM IN SEEN MY DOCTOR TWICE AND MY FAMILY DOCTOR ONCE FOR THE PROBLEMS I HAVE HAD SO FAR, WAITING FOR SURGERY DATE TO HAVE ESSURE REMOVED DUE TO ALL THE PROBLEMS I AM HAVING EVER SINCE IT WAS PUT INSIDE ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044832	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 9/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BLEED FOR A MONTH IN (B)(6) 2009 AND THEN FOUND OUT I HAD A CYST THE SIZE OF A GOLF BALL SO I HAD TO HAVE IT SURGERY REMOVED. AFTER THAT I HAVE NOT HAD A PERIOD SINCE,I DEAL WITH HORRIBLE PAIN ALL THE TIME,SOME DAYS TO WERE I CAN'T EVEN GET UP AND WALK. THE PAIN IS ON BOTH SIDES OF MY OVARIES AND GOES AROUND TO MY BACK. I'VE GAIN (B)(6) LBS SINCE I'VE HAD THIS,I'VE TRY EVERYTHING TO LOSE WEIGHT AND NOTHING WORKS. THEY SAY THE ONLY WAY TO REMOVE THE COILS IS TO HAVE A HYSTERECTOMY BUT THE DR WHO DID THIS TO ME SAYS I'M TO YOUNG TO HAVE A HYSTERECTOMY. I AM (B)(6) YRS OLD AND I WANT MY LIFE BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044833	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 7/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN, BOWEL ISSUES, PAINFUL MENSTRUATION, SWELLING, FATIGUE, NUMBNESS THAT CONTINUED FROM 2008 TO 2014, END RESULT BEING A HYSTERECTOMY THAT INCLUDED REMOVAL OF CERVIX, UTERUS, FALLOPIAN TUBES, AND LEFT OVARY. DURING MY HYSTERECTOMY MY DOCTOR FOR MY LEFT FALLOPIAN TUBE AND LEFT OVARY TO BE OVERLAPPING AND TWISTED TOGETHER IN (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044834	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I FIRST NOTICED THE FATIGUE. I THOUGHT AT FIRST THAT IT REMINDED ME OF THE FIRST TRIMESTER PREGNANCY EXHAUSTION. I WROTE IT OFF AND TOLD MYSELF I NEEDED MORE SLEEP. BUT IT NEVER WENT AWAY. OVER THE FOLLOWING MONTHS I FOUND MYSELF SITTING ON THE COUCH MORE AND MORE AND DREADING GETTING OUT OF BED AND PLAYING WITH MY KIDS LESS AND LESS. BY THE END OF THE YEAR, I FOUND MYSELF THINKING OR FANTASIZING EVEN MY DEATH. I ADMITTED WHAT WAS GOING ON TO FRIENDS AND THEY HAD ME REACH OUT FOR HELP. I'VE STARTED WALKING AFTER DINNER AND TRYING TO GO TO A YOGA CLASS DURING THE DAY AND JUST SORT OF FORCING MYSELF TO GET OFF THE COUCH AND BE ACTIVE. I'M STILL EXHAUSTED AND I'M CONTINUING TO GAIN WEIGHT BUT IT'S SLOWED DOWN AND I'M NOT FEELING SUICIDAL BUT STILL DEFINITELY BATTLING DEPRESSION. I'VE HEARD THAT SOMEONE HAS COMMIT SUICIDE AFTER ESSURE AND I CAN SAY THAT IF I HADN'T REACHED OUT TO FRIENDS WHEN I DID MY CHILDREN MIGHT NOT HAVE THEIR MOTHER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044835	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 3/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DAILY SEVERE PAIN IN JOINTS, PELVIS, ABDOMEN, ORGANS. CONSTANT BLOATING AND CRAMPING. LONGER MORE SEVERE MENSTRUAL CYCLES. CHRONIC MIGRAINES. DEPRESSION. INABILITY TO WORK DUE TO THESE COMPLICATIONS AND MORE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044836	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 5/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN, ABNORMAL PERIODS, CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044837	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 3/3/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I TRIED TO CLICK OTHER SERIOUS AND NON-SERIOUS (SINCE SOME SYMPTOMS ARE SERIOUS, AND SOME ARE NOT TOO SERIOUS), BUT IT WILL ONLY LET ME CLICK NON-SERIOUS. CAN YOU CHANGE IT TO OTHER SERIOUS, PLEASE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044838	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 4/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCRUCIATING PAIN IN MY TUBES. IT WAS LIKE THE CRAMPS YOU GET DURING CHILD BIRTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044839	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN IN PELVIS. CRAMPING THAT FELLS LIKE CONTRACTIONS. CAN'T LOSE WEIGHT. I HAVE IBS. LOW SEX DRIVE. LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044840	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 6/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, DEPRESSION, WEIGHT GAIN, INFLAMMATION, BRAIN FOG, IRREGULAR PERIODS, AND COIL MIGRATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044842	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 4/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS HAVING SEVERE ABDOMINAL AND PELVIC PAINS. I WENT TO THE E.R. TO FIND I WAS PREGNANT AND HAD THESE ESSURE COILS IMPLANTED. I ALSO HAD TO HAVE HYSTERECTOMY AFTER DELIVERY OF THE CHILD DUE TO THE COILS MIGRATING TO AND EMBEDDING INTO MY UTERINE WALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044843	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 10/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE BACK PAIN ALONG WITH OVARIAN PAIN, HEAVIER MENSTRUAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044844	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 2/22/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER IMPLANTATION, I BLED FOR 3 MONTHS CONTINUOUSLY. SINCE IMPLANTATION, I HAVE SUFFERED FROM LONG, IRREGULAR PAINFUL MENSES. I HAVE ALSO HAD TRANSIENT PELVIC PAIN, CLEAR VAGINAL DISCHARGES, TINGLING IN MY HANDS/FEET, JOINT PAIN IN KNEES/CALVES/FOREARMS AND HANDS, AND HEAD/BACK ACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044845	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 1/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING THE SURGERY, I STARTED HAVING TERRIBLE BLEEDING (DOUBLE PERIODS), NUMBNESS AND TINGLING ON MY UPPER TORSO, PELVIC CRAMPS AND NO SEX DRIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044846	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 10/1/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MUSCLES STARTED KNOTTING UP IN LEGS, MUSCLE SPASMS IN LEG, IRREGULAR PERIODS(GOING ON 7 MONTHS WITHOUT ONE NOW), WEIGHT GAIN, SEVERE HEADACHES CONSTANTLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044847	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 9/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY HEAVY BLEEDING EVERY 2 WEEKS THAT CAUSED ME TO BE VERY ANEMIC. CURRENTLY ON BIRTH CONTROL BUT STILL VERY HEAVY BLEEDING. PAINFUL CRAMPS IN THE F. TUBE AREA. LOW BACK PAIN AND EXCESSIVE TIREDNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044848	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING FOR WEEKS AT A TIME WITH LITTLE BREAK IN BETWEEN PERIODS, SEVERE CRAMPING, CRYOABLATION IN (B)(6) 2015 TO FIX PROBLEM. ESSURE IMPLANTED (B)(6) 2013 AND (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044849	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY/ LONG MENSTRUAL CYCLES WITH CLOTS, ABDOMINAL CRAMPS, BACK PAINS WHEN ABDOMINAL CRAMPS, ANXIETY ATTACKS, BLOATED STOMACH, HAIR LOSS, BAD LEG CRAMPS, DEPRESSION, RASHES ON FACE,DARK SPOTS ON FACE, LIGHTHEADEDNESS, FATIGUE, S.O.B.,FAINTING, PAINFUL INTERCOURSE, PELVIC INFLAMMATORY DISEASE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044850	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, SHARP ABDOMINAL PAINS, INCREASINGLY EXTREEMLY HEAVY PERIODS, OVARIAN CYSTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044851	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 1/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE ESSURE, I HAVE HAD HORRIBLE CRAMPING AND BELLY SWELLING EVERY MONTH WHEN I GET MY PERIOD. THE PAST 6 MONTHS HAVE GOTTEN UNBEARABLE. BUT THE MAJOR CONCERN FOR MY HEALTH IS BEING DIAGNOSED WITH RHEUMATOID ARTHRITIS IN (B)(6) 2012 WHICH DOES NOT RUN IN MY FAMILY AND THE INFLAMMATION IS CONSTANT. I DO NOT HAVE "FLARE UPS" SO TO SPEAK (WHICH BAFFLES DOCTORS). I NOW HAVE A "DESTROYED FOOT" DUE TO THE RA AND I AM FILING FOR DISABILITY. I TAKE 2 MEDICATIONS THAT WEAKEN MY IMMUNE SYSTEM AND CAUSE MIGRAINES NOW TO TRY AND PREVENT IT FROM SPREADING TO MY OTHER JOINTS. TODAY (B)(6) 2015, I JUST HAD A HYSTERECTOMY THIS MORNING TO GET THE COILS REMOVED TO TRY AND RELIEVE MY SYMPTOMS. I NEVER HAD THESE PROBLEMS BEFORE I HAD THESE IMPLANTED. THERE HAVE BEEN SEVERAL ER VISITS DUE TO HORRIBLE CRAMPING AND BLEEDING...THEY JUST HAVE SAID LIKE A RECORD THAT IT IS A BAD PERIOD THIS MONTH AFTER TEST AFTER TEST COMES BACK FINE. I JUST AM GLAD TO HAVE THIS ESSURE OUT OF MY BODY!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044852	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 6/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WOKE UP SUNDAY, (B)(6) 2015 AT 5:00AM WITH ABDOMINAL PAIN. I FELT NAUSEOUS, MY RIGHT SIDE HURT, I COULDN'T STAND UPRIGHT. THE SIGNS MIMICKED APPENDICITIS. I WENT TO THE ER. THEY RAN BLOOD AND ORDERED A CT SCAN WITH CONTRAST. THE ER DR. CAME IN AND SAID "WELL, IT'S NOT YOUR APPENDIX. THE DEVICE IN YOUR TUBE HAS SLIPPED AND HAS PUNCTURED YOUR UTERUS. I WILL FIND YOU A OBGYN AND YOU NEED SURGERY TOMORROW". SO SURGERY WAS ON (B)(6) 2015 AT 6:00 PM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044853	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 7/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS, SEVERE CRAMPING ON AND OFF MY PERIOD, HUGE BLOOD CLOTS, MIGRAINES, LEGS HURTING, BACK PAIN, INSOMNIA, TINGLING, NUMBNESS, NO SEX DRIVE, SEVERE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044854	BAYER	7/28/2015	7/28/2015

Event Information:

Event Date (B3): 8/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS DIAGNOSED WITH LUPUS AT (B)(6) WHEN I HAD MY FIRST PREGNANCY I FOUND OUT HOW MY BODY COULDN'T HANDLE PREGNANCY. SO AFTER HER BIRTH I TRIED MERINA, THAN SHOTS, THEN PILLS AND EACH TIME I HAD A BAD REACTION, SO WHEN I GOT PREGNANT THE SECOND TIME AND IT WAS EVEN WORSE, SO I WANTED A TUBAL BUT THAT DIDN'T HAPPEN AT THE HOSPITAL WHEN I HAD THE BABY. AT MY 6W I TALKED WITH MY DOCTOR AND HE STRONGLY SUGGESTED THIS DEVICE, TOLD ME IT WAS HORMONE FREE AND WAS MADE OF SURGICAL STEEL AND DID NOT CONTAIN NICKEL SO I AGREED TO THIS. AFTERWARDS I GOT WORSE WITH MY HEALTH ISSUES. I WAS THAN DIAGNOSED WITH VITAMIN D DEFICIENCY, ANEMIA/IRON DEFICIENCY, HIGH BLOOD PRESSURE, HYPOGLYCEMIA, FIBROMYALGIA. AND I HAVE SO MANY SIDE EFFECTS TO YET BE DIAGNOSED WITH WHY I'M HAVING SUCH AS SHARP/STABBING PELVIC PAIN, ABNORMAL MENSES, DISCHARGE, HOT FLASHES, PELVIC INFLAMMATORY DISEASE, UTERINE INFECTION, LOSS OF LIBIDO, SPOTTING AFTER SEX, YEAST INFECTIONS, URGENT/FREQUENT URINATION, UTI, ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE, BREAST PAIN/TENDERNESS, BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP PAIN,ALL OVER BODY ACHES/PAIN, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, HEADACHES OR MIGRAINES, DIZZINESS, NUMBNESS, TINGLING SENSATIONS, BRAIN SHOCKS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, DEPRESSION, RINGING IN EARS, PTSD, BIPOLAR DISORDER, SHAKINESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00551	BAYER HEALTHCARE LLC	7/28/2015	7/29/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20227514

Single Use: Y
Implant Date (E6): 4/30/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5040472) IN UNITED STATES ON 22-MAY-2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. CONSUMER REPORTED THAT SHE HAD THE ESSURE DEVICE PLACED IN 2010 AND SINCE THEN SHE HAS EXPERIENCED MANY SIDE EFFECTS. SHE USED TO HAVE NO CRAMPING IN HER BODY, NOW SHE HAS PAIN THAT SHOOTS DOWN HER RIGHT LEG AND UP HER BACK. SHE NO LONGER BLED WITH HER CYCLE IN A HEALTHY MANNER. SHE SAT ON THE TOILET AND HUGE CLOTS OF BLOOD FALL FROM HER BODY. SHE WAS NO LONGER ABLE TO WEAR ANY SORT OF METAL JEWELRY WHETHER PURE GOLD OR NOT HER SKIN TURNED GREEN. A MONTH AGO, SHE WAS UNABLE TO STAND FOR APPROXIMATELY 18 HOURS DUE TO PAIN IN HER UTERUS AFTER INTERCOURSE. SHE WENT TO THE DOCTOR AND THEY WERE UNABLE, AFTER AN ULTRASOUND, TO LOCATE THE RIGHT COIL, BUT THE LEFT ONE HAS MIGRATED AND IMPLANTED ITSELF INTO HER UTERUS. CONSUMER BLED FOR 3 WEEKS AFTER HAVING THE PROCEDURE DONE. THE DOCTOR WHO DID IT TOLD HER THAT IT WAS FINE. THEY WERE RECOMMENDING A HYSTERECTOMY TO REMOVE HER UTERUS BEFORE MORE DAMAGE WAS DONE TO HER BODY. SHE WOULD BE MEETING WITH A SURGEON ON A DATE NOT REPORTED. NO ADDITIONAL DETAILS WERE PROVIDED. THE SERIOUSNESS CRITERIA INTERVENTION REQUIRED WAS MENTIONED IN THE SECTION EVENT OUTCOME IN THE SOURCE DOCUMENT BUT IS WAS NOT ASSIGNED AND/OR SPECIFIED TO ONE OF THE EVENTS IN THE NARRATIVE. PTC INVESTIGATION RESULT WAS RECEIVED ON 03-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE

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UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON 01-JUL-2015 FROM CONSUMER. THIS CASE WAS UPGRADED TO INCIDENT. CONSUMER'S DATE OF BIRTH WAS PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE CONSUMER. SHE DENIED ANY PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES AND ANY OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. ESSURE LOT NUMBER 20227514 WAS IMPLANTED 6 MONTHS AFTER PREGNANCY. SHE HAD NO SEX AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. IN (B)(6) 2010 HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND OCCLUSION WAS CONFIRMED. ON UNSPECIFIED DATE SHE STARTED EXPERIENCING SEVERE CLOTTING DURING CYCLES, PAIN THAT SHOT THROUGH HER LOWER BACK, DOWN TO RIGHT LEG; SHE WAS ABLE TO FEEL THE COILS DURING YOGA POSES THAT AFTERWARD WOULD CAUSE CONSIDERABLE PAIN FOR HOURS VERY ACUTELY WHERE THE COILS WERE PLACED. IT GOT WORSE AS THE YEARS WENT BY (SHE HAD THEM FOR 5 YEARS), UNTIL FINALLY ONE DAY SHE WAS UNABLE TO STAND UP STRAIGHT AFTER INTERCOURSE. SHE MISSED DAYS OF WORK DUE TO PAIN. SHE WAS UNABLE TO URINATE DURING THAT TIME OF NOT BEING ABLE TO STAND AND THE PRESSURE OF PAIN WAS NOT ALLOWING TO. ON (B)(6) 2015 ESSURE DEVICES WERE REMOVED VIA MICROSURGERY. HYSTERECTOMY OR SALPINGECTOMY WAS NOT NECESSARY. THERE WAS NO INFECTION AFTER SURGERY. IT WAS STATED THAT BOTH COILS WERE IN THE "RIGHT PLACE" BUT THE LEFT COIL HAD BENT BACK OVER ITSELF. SHE RECOVERED FROM THE ESSURE REMOVAL PROCEDURE. IT WAS REPORTED THAT THE ESSURE COILS CAUSED THE PAIN AND UNUSUAL CYCLES THAT SHE EXPERIENCED. SHE STATED SHE HAS NEVER HAD CLOTS OR PAIN THAT SHOT THROUGH HER BODY, NEVER HAD PAIN AFTER INTERCOURSE THAT PROHIBITED FROM STANDING UPRIGHT, NEVER BEEN SO ALLERGIC TO METAL OR NOT ABLE TO DO YOGA POSES BECAUSE OF PAIN IN HER ABDOMEN FOR HOURS AFTER, UNTIL ESSURE. THE SYMPTOMS/PAIN RESOLVED AFTER SURGERY. SHE REPORTED THAT SHE EVEN BLEED NORMALLY DURING HER CYCLES. SHE DID NOT WANT THE PHYSICIAN TO BE CONTACTED (MAYBE WHEN THE LAWSUIT COMES). NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 08-JUL-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: 20227514; PRODUCTION DATE: DEC-2009; EXPIRATION DATE: DEC-2013. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE AE CASE REFERS ALSO TO A DEVICE PHYSICAL PROPERTY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED

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BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, POTENTIAL LEGAL AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLED FOR 3 WEEKS AFTER HAVING THE PROCEDURE DONE (AFTER ESSURE INSERTION). SHE EXPERIENCED HUGE CLOTS OF BLOOD FALL FROM HER BODY (SEEN AS GENITAL BLEEDING) AND WAS UNABLE TO STAND FOR APPROXIMATELY 18 HOURS DUE TO PAIN IN HER UTERUS AFTER INTERCOURSE. SHE WENT TO THE DOCTOR AND THEY WERE UNABLE TO LOCATE THE RIGHT COIL (SEEN AS DEVICE DISLOCATION), BUT THE LEFT ONE HAS MIGRATED AND IMPLANTED ITSELF INTO HER UTERUS (SEEN AS DEVICE EMBEDDED). UPON RECEIPT OF FOLLOW-UP INFORMATION, IT WAS REPORTED THAT THE ESSURE DEVICES WERE REMOVED VIA MICROSURGERY AND NEITHER HYSTERECTOMY NOR SALPINGECTOMY WERE NECESSARY. BOTH COILS WERE IN THE CORRECT PLACE BUT THE LEFT COIL HAD BACK OVER ITSELF. THEREFORE, THE EVENTS SEEN AS DEVICE DISLOCATION AND DEVICE EMBEDDED WERE DELETED. SHE ALSO EXPERINCED ABDOMINAL PAIN, ALLERGIC TO METAL AND WAS ABLE TO FEEL COILS DURING YOGA POSES (SEEN AS MEDICAL DEVICE DISCOMFORT). ALL EVENTS, EXCEPT FOR THE EVENT UTERINE PAIN, ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALL THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. IN THIS CASE, CONSUMER EXPERIENCED THESE EVENTS AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE EVENTS AND BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE INTERVENTION WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00552	BAYER HEALTHCARE LLC	7/28/2015	7/29/2015

Event Information:

Event Date (B3): 7/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NZ

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): BZ1772

Single Use: Y
Implant Date (E6): 7/2/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER BZ1772, INSERTED ON (B)(6) 2015. PHYSICIAN INSERTED ESSURE COIL ON LEFT OSTIUM SUCCESSFULLY UNDER GENERAL ANESTHESIA. RIGHT OSTIUM ESSURE INSERTION WAS ATTEMPTED; HOWEVER, PHYSICIAN INFORMED THAT AFTER RELEASING THE DEVICE, NO COIL WAS SEEN (NO RESISTANCE WAS FELT). HEALTH CARE PROFESSIONAL SUSPECTED A FAULTY DEVICE WITH NO DEPLOYMENT OF ESSURE COIL. THREE MORE INSERTION ATTEMPTS WERE UNSUCCESSFUL. PHYSICIAN THEN PROCEEDED WITH LAPAROSCOPY WHICH REVEALED ESSURE PERFORATION OF FOUR MICRO-INSERTS IN FALLOPIAN TUBE. LAPAROSCOPY ALSO CONFIRMED THAT DEVICE DID NOT FAIL AND THE ADVERSE EVENT RESULTED FROM USER ERROR. FOLLOW UP INFORMATION (PERFORATION QUESTIONNAIRE) RECEIVED ON (B)(6) 2015: THE PATIENT MEDICAL HISTORY INCLUDES 2 C-SECTIONS (PARITY 2) AND A CERVICAL CONIZATION. HER CONCOMITANT DISEASES ARE ATOPIC DERMATITIS AND NICKEL ALLERGY. PHYSICIAN WAS NOT AWARE OF PREVIOUS GYNAECOLOGICAL INTERVENTION OR CURETTAGE, PREVIOUS IUS/IUD, MYOMECTOMY OR ADNEXAL SURGERY. ESSURE WAS INSERTED ON (B)(6) 2015. THE PHYSICIAN DID NOT KNOW IF THE PATIENT WAS POST-PARTUM; SHE WAS NOT BREAST-FEEDING AT TIME OF THE INSERTION. PRIOR TO THE INSERTION PROCEDURE THE PATIENT HAD NO ABNORMAL UTERINE FINDINGS. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES AND THERE WERE NO MORE THAN 1500CC OF FLUID LOSS. DURING THE PROCEDURE, CERVICAL DILATATION WAS PERFORMED (NO SOUNDING); THE PATIENT WAS UNDER GENERAL ANESTHESIA. THE VISUALIZATION OF TUBAL OS WAS CONSIDERED EASY ON LEFT SIDE AND MODERATELY EASY ON RIGHT SIDE. THE INSERTION WAS CONSIDERED MODERATELY EASY ON RIGHT SIDE, CORRECT PLACEMENT WITH 8 COILS, AND SOME RESISTANCE WAS MEET; AT LAPAROSCOPY

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(LSC) IT WAS FOUND THAT THE ESSURE TIP WAS CLOSE TO TUBAL SEROSA, NON-PERFORATED ON THE RIGHT; BUT ESSURE DISTAL TIP SEEN SUBSEROSAL (PENETRATION OF TUBAL MUCOSA SUSPECTED, HOWEVER IRRELEVANT AS SEROSA INTACT). ON THE LEFT SIDE A COMPLETE PERFORATION AT OR SHORT BEHIND LEFT TUBO UTERINE JUNCTION OCCURRED; IT WAS VERY EASY, THE FIRST MM OF TUBAL OSTIUM SEEN ORTHOGRADE AND INSERTION OF ESSURE TIP WITHOUT RESISTANCE. THE PLACEMENT OF 4 DEVICES WAS EASY, BUT WRONGLY ASSUMED FAILURE TO DEPLOY IMPLANT (INSTEAD INADVERTENT LOSS INTO ABDOMINAL CAVITY); CONSIDERATION OF OPTIONS, ACQUISITION OF REPLACEMENT ESSURE CATHETERS, AND REPEAT STUDY OF MANUAL ALL TOOK EXTRA TIME. THE PATIENT DID NOT HAVE COMPLAINTS IMMEDIATELY AFTER INSERTION. THE PERFORATION WAS DIAGNOSED DURING OPERATION (LAPAROSCOPY) ON DAY OF INSERTION; THE PERFORATION OCCURRED BEFORE THE DEVICE DEPLOYMENT. TUBAL LIGATION WAS COMPLETED WITH LAPAROSCOPIC BIPOLAR TUBAL LIGATION AND BILATERAL PARTIAL FULL THICKNESS SALPINGECTOMY. ESSURE ON RIGHT SIDE WAS LEFT IN THE CORRECT POSITION. ON THE LEFT SIDE ALL 4 DEVICES WERE REMOVED; 1 FROM MESO-SIGMOID (COILS PARTLY EXPANDED) PLUS 3 DEVICES FROM POUCH OF DOUGLAS, THESE 3 UN-EXPANDED. PHYSICIAN MENTIONED THAT THE DEVICES REMOVAL WAS NOT MEDICALLY NECESSARY. THE PATIENT RECOVERED WELL (DAYSTAY), THE PROBLEM WAS RESOLVED INTRAOPERATIVE.. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A LAPAROSCOPY PERFORMED SHOWED PERFORATION OF FOUR ESSURES MICRO-INSERTS IN FALLOPIAN TUBE. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF DEVICE INSERTION OR REMOVAL. IN THIS CASE, THE LEFT INSERT WAS PLACED WITH NO DIFFICULTIES. THE RIGHT SIDE WAS ATTEMPTED, BUT PHYSICIAN AFTER DEPLOYMENT DID NOT SEE ANY COIL. THEN, HE TRIED 3 MORE TIMES WITHOUT SUCCESS AND THEREAFTER PROCEEDED WITH LAPAROSCOPY WHICH REVEALED PERFORATION OF 4 MICRO-INSERTS IN FALLOPIAN TUBE. THE ESSURE DEVICES WERE REMOVED AND PATIENT RECOVERED. CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 25-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: RE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044982		7/28/2015	8/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD USED THE ESSURE TO NOT GET PREGNANT. I ENDED UP CRAMPING ALL THE TIME AND LATER HAD TO HAVE MY UTERUS REMOVED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00553	BAYER HEALTHCARE LLC	7/29/2015	7/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 11/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO HERSELF. SHE IS AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS WERE PROVIDED). THE CONSUMER REPORTED COMPLAINTS OF PREMATURE MENOPAUSE, AT NIGHT LYING AWAKE, EXCESSIVE SWEATING, CONSTANT FATIGUE, PAINFUL LOWER BACK AND LEGS. FURTHER CONSUMER SAID THAT SHE RECEIVED MEDICATION THAT NORMALLY PEOPLE WHO HAVE EPILEPSY RECEIVE (NOS). SEVERAL TIMES BEEN BACK AFTER INSERTING ESSURE, ESSURE WAS REMOVED IN (B)(6) 2013. CONSUMER RECEIVED LUCRIN AGAINST ABDOMINAL PAINS, ACCORDING TO CONSUMER THIS WORSENED THE SYMPTOMS. CONSUMER STILL HAD CONSIDERABLE COMPLAINTS. CONSUMER HAD SLEPT POORLY, WAS CONSTANTLY TIRED AND HAD A LOT OF PAIN IN THE LOWER BACK. CONSUMER HAS HAD LITTLE BENEFIT FROM ACUPUNCTURE, SINCE STOPPING ACUPUNCTURE COMPLAINTS HAVE INCREASED AGAIN. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE

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KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS REPORTS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ABDOMINAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 288 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO AN ADULT FEMALE CONSUMER WHO EXPERIENCED ABDOMINAL PAINS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACEMENT. THE DEVICE WAS REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE ESSURE REMOVAL WAS REPORTED (INTERVENTION IMPLIED). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW-UP INFORMATION WILL BE REQUESTED SINCE THIS CASE WAS RECEIVED VIA HEALTH AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00554	BAYER HEALTHCARE LLC	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 6/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/7/2013
Explant Date (E7): 9/12/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA REGULATORY AUTHORITY IN (B)(6) ON 02-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. IMMEDIATELY AFTER INSERTION, CONSUMER DEVELOPED SEVERE PAIN IN ABDOMEN. SHE WAITED A COUPLE OF DAYS, BUT THE PAIN GOT WORSE SO SHE WENT TO CONSULT THE GENERAL PRACTITIONER SEVERAL TIMES. SHE ALSO RE-VISITED THE HOSPITAL. CONSUMER HAD CONTINUOUS ABDOMINAL PAIN, SOMETIMES WITH SEVERE ACHES. SHE ALSO HAD SEVERE TIREDNESS AND STATES THAT SHE DID NOT HAVE THESE COMPLAINTS PRIOR TO ESSURE INSERTION. EXPLORATORY SURGERY SHOWED THAT THE COILS WERE LOCATED IN SITU. GYNECOLOGIST SUGGESTED REMOVING THE FALLOPIAN TUBES AND UTERUS AND, ON (B)(6) 2013, SURGERY WAS PERFORMED. THE SEVERE PAIN IS RESOLVED NOW, BUT SHE STILL HAS MINOR ABDOMINAL COMPLAINTS. NO FURTHER INFORMATION WAS PROVIDED, NOR CAN BE OBTAINED SINCE THE CASE WAS REPORTED TO (B)(6). CASE CONSIDERED TO BE CLOSED. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A

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QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 16-JUL-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PROCEDURAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 168 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE ABDOMINAL PAIN IMMEDIATELY AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, CONSUMER STATED THAT SHE DID NOT EXPERIENCE THIS EVENT PRIOR TO ESSURE INSERTION. IT WAS REPORTED THAT THE COILS WERE LOCATED IN SITU AND SHE HAD HER FALLOPIAN TUBES AND UTERUS REMOVED. AS THE EVENT OCCURRED IMMEDIATELY AFTER ESSURE INSERTION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION CAN BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00555	BAYER HEALTHCARE LLC	7/29/2015	7/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA REGULATORY (B)(6) WHICH REFERS TO HERSELF. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS WERE PROVIDED). CONSUMER REPORTED THAT IMMEDIATELY AFTER INSERTION CONSUMER GOT MENOPAUSAL SYMPTOMS SUCH AS SWEATING AT NIGHT, A LOT OF ITCH AND CONSTIPATION. AFTER 3 MONTHS CONSUMER WENT FOR CONTROL AT THE GYNECOLOGIST. CONSUMER HAD TAKEN THE PILL IN THE MEANTIME AND COULD NOT HAVE THESE MENOPAUSAL SYMPTOMS, ACCORDING TO THE GYNECOLOGIST. CONSUMER THEN STOPPED TAKING THE PILL AND WAS THEN NO LONGER MENSTRUATING. CONSUMER ALSO REPORTED THAT HER STOMACH SWELLED, SHE COULD ALWAYS FEEL THE COILS SITTING AND HAD PAIN IN HER LEGS. CONSUMER WENT BACK TO THE GYNECOLOGIST, CONVINCED THAT THE COMPLAINTS CAME FROM THE NICKEL. CONSUMER MANAGED TO REDUCE THE REACTION ON NICKEL IN HER OWN WORDS THROUGH AN ADJUSTED DIET, THIS REDUCED THE SWOLLEN STOMACH AND THE MENOPAUSAL SYMPTOMS. SHE HAS STILL DECIDED TO LET REMOVE THE FALLOPIAN TUBES. SHE KNEW THAT SHE WAS ALLERGIC TO NICKEL, BUT THE DOCTOR NEVER TALKED ABOUT THIS BEFORE INSERTION OF ESSURE. GYNECOLOGIST INSISTED IT COULD NOT COME THROUGH NICKEL, BECAUSE THIS MATERIAL WAS ALSO USED IN MEDICAL DEVICES FOR THE HEART. THE COILS AND FALLOPIAN TUBES WERE REMOVED ON (B)(6) (UNSPECIFIED). NO ADDITIONAL INFORMATION WAS PROVIDED. CASE CLOSED. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS

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CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 16-JUL-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: (B)(6). THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(6) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT ((B)(6)) REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A LOT OF COMPLAINTS WHICH CAME FROM THE NICKEL. THIS EVENT, SEEN AS NICKEL ALLERGY, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING. IN THIS PARTICULAR CASE, IMMEDIATELY AFTER INSERTION, CONSUMER HAD A LOT OF ITCH AND OTHER NON-SERIOUS EVENTS. CONSUMER WAS CONVINCED THAT THE COMPLAINTS CAME TO NICKEL SINCE SHE WAS ALLERGIC TO THAT METAL. THEN, ESSURE COILS AND FALLOPIAN TUBES WERE REMOVED. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. AS AN INTERVENTION WAS REQUIRED THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION CANNOT BE REQUESTED. TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00556	BAYER HEALTHCARE LLC	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 8/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/26/2014
Explant Date (E7): 1/20/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY IN (B)(4) ON 02-JUL-2015 WHICH REFERS TO HERSELF. SHE IS A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER REPORTED THAT THE INSERTION WAS VERY PAINFUL. ACCORDING TO THE PRODUCT INFORMATION THE CONSUMER EXPECTED THAT SHE WOULD BE ABLE TO LEAVE THE HOSPITAL AFTER 10 MINUTES. DUE TO THE PAIN COMPLAINTS SHE HAD TO STAY IN THE HOSPITAL FOR 4-5 HOURS. THESE PAIN-COMPLAINTS PERSISTED AND ACCORDING TO THE CONSUMER THE COMPLAINTS NEVER LEFT. THE PAIN WAS ESPECIALLY LOCATED IN THE LOWER ABDOMEN. BECAUSE THE COMPLAINTS INCREASED BADLY SHE CONTACTED THE HOSPITAL BY PHONE 4 TIMES. SHE WAS INVITED FOR CONSULT EVERY TIME. CONSUMER WAS EXAMINED BY SEVERAL DISCIPLINES, THERE WAS SUSPICION OF APPENDICITIS OR PYELONEFRITIS. COMPLAINTS COULD NOT HAVE BEEN CAUSED BY ESSURE. NO DIAGNOSIS COULD BE MADE AND THE CONSUMER WAS SENT HOME WITH PAINKILLERS. BESIDES SEVERE COMPLAINTS IN HER ABDOMEN CONSUMER EXPERIENCED RASH. IN (B)(6) 2014 THE PAIN COMPLAINT GOT SO WORSE THAT CONSUMER WAS REFERRED TO THE HOSPITAL BY THE GENERAL PRACTITIONER ON DUTY. SHE WAS HOSPITALIZED OVERNIGHT AND HAD VARIOUS EXAMINATIONS. NEXT DAY CONSUMER WAS SENT HOME BECAUSE NO DIAGNOSIS COULD BE MADE. IN (B)(6) 2014 THE CONSUMER VISITED HER GYNAECOLOGIST. BECAUSE THE COMPLAINTS OCCURRED IMMEDIATELY AFTER INSERTION OF ESSURE, THE GYNECOLOGIST WAS OF THE OPINION THAT THIS COULD BE THE CAUSE OF THE COMPLAINTS. ON (B)(6) 2015 BOTH FALLOPIAN TUBES AND UTERUS WERE REMOVED. INFLAMMATION OF UTERUS AND FALLOPIAN TUBES WAS DIAGNOSED. GYNECOLOGIST SUSPECTED THAT THE NICKEL ALLERGY COULD BE THE REASON. AFTER REMOVAL OF THE ESSURE ALL COMPLAINTS RESOLVED. DUE TO THE COMPLAINTS CONSUMER WAS NOT ABLE TO WORK FOR MONTHS. NO FURTHER

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INFORMATION WAS PROVIDED. CASE CLOSED. FOLLOW UP 09-JUL-2015: FOLLOW UP INFORMATION RECEIVED FROM GYNECOLOGIST. ESSURE WAS INSERTED BY ANOTHER GYNECOLOGIST IN (B)(6) 2014. OVIDUCTS AND UTERUS WERE REMOVED BY THE REPORTER VIA THERAPEUTIC LAPAROSCOPY. ON (B)(6) 2015 FROM START PERSISTING PAIN RIGHT ABDOMINAL COMPLAINTS AT PATIENT. AFTER LAPAROSCOPY FREE FROM COMPLAINTS. NICKEL ALLERGY WAS REPORTED THAT TIME. NO ADDITIONAL DETAILS WERE PROVIDED. CASE CLOSED. FOLLOW-UP RECEIVED ON 09-JUL-2015: FOLLOWING INTERNAL REVIEW FROM INFORMATION RECEIVED ON 09-JUL-2015 IT WAS NOTED THAT AN INTERPRETATION MISTAKE WAS MADE WITH TRANSLATION OF THE SOURCE DOCUMENT. INFORMATION REVIEWED STATES THAT, FROM START, PATIENT EXPERIENCED PERSISTING PAIN RIGHT ABDOMINAL COMPLAINTS. ON (B)(6) 2015, OVIDUCTS AND UTERUS WERE REMOVED BY GYNECOLOGIST VIA THERAPEUTIC LAPAROSCOPY. FOLLOW-UP RECEIVED ON 14-JUL-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 16-JUL-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: ABDOMINAL PAIN LOWER. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. ALLERGY TO METALS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS HOSPITALIZED DUE TO CONTINUING SEVERE LOWER ABDOMINAL PAIN. SHE WAS SUBMITTED TO A BILATERAL SALPINGECTOMY AND HYSTERECTOMY; WHICH REVEALED INFLAMMATION OF UTERUS AND FALLOPIAN TUBES. ACCORDING TO HER; HER PHYSICIAN SUSPECTED NICKEL ALLERGY COULD BE THE REASON FOR THE EVENTS; WHICH RECOVERED AFTER THE SURGERY. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE OR HOSPITALIZATION; AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND USUALLY RESOLVE AFTER DEVICE REMOVAL. ADDITIONALLY, ABDOMINAL, PELVIC PAIN AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER HAD ABDOMINAL PAIN AND RASH, WHICH STARTED IN CLOSE ASSOCIATION WITH ESSURE INSERTION AND RECOVERED AFTER DEVICES REMOVAL. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS REQUIRED, THIS CASE WAS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED

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ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FOLLOW-UP INFORMATION WILL BE REQUESTED, SINCE THIS CASE WAS RECEIVED VIA REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00557	BAYER HEALTHCARE LLC	7/29/2015	7/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/11/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY IN NETHERLANDS ON 02-JUL-2015 FOLLOWING TELEVISION BROADCASTING. IT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 FOR STERILIZATION. THE INSERTION WAS PAINFUL. ONE OF THE COILS (RIGHT) BURST/BROKE, DUE TO THIS A PART OF THE END CAME IN THE UTERUS. PATIENT EXPERIENCED A LOT OF COMPLAINTS BECAUSE OF THIS, PATIENT MENTIONED THAT SHE EXPERIENCED PAIN ON THE RIGHT WHEN SEATED AND THAT SHE EXPERIENCED A LOT OF FLUX, PATIENT ALSO MENTIONED TO HAVE REPORTED THIS TO THE GYNECOLOGIST. PATIENT FELT THE PRESENCE OF THE COILS AND HAD A LOT OF PHYSICAL COMPLAINTS. IN THE EMAIL OF THE PATIENT CONTRADICTORY INFORMATION WAS REPORTED REGARDING THE EXECUTION OF THE HSG (HYSTEROSALPINGOGRAM) 3 MONTHS LATER ((B)(6) 2011; NO RESULT WAS PROVIDED). EVENTUALLY THE COILS AND THE OVIDUCTS WERE REMOVED BY A GYNECOLOGIST (DIFFERENT THAT THE TREATING GYNECOLOGIST). THE PAIN BECAME LESS BY THIS, BUT IS NOT FULLY GONE. A PIECE OF THE COIL WAS ADHERED IN THE UTERUS, THIS COULD ALSO NOT BE REMOVED. PATIENT STILL HAS PAIN COMPLAINTS AT THIS MOMENT. PATIENT MENTIONED THAT THE GYNECOLOGIST (DIFFERENT THAN THE TREATING GYNECOLOGIST) CHECKED HER FILE AND MENTIONED THAT A PICTURE WAS MADE IN THE HOSPITAL ON WHICH THE COMPLICATION (A POSSIBLE PERFORATION) WAS SEEN, THIS WAS NEVER SHARED WITH PATIENT. NO FURTHER INFORMATION CAN BE OBTAINED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS WERE PROVIDED ON 15-JUL-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY

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TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 16-JUL-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: DEVICE BREAKAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. UTERINE PERFORATION. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE INSERTION WAS PAINFUL. ONE OF THE COILS (RIGHT) BURST/BROKE. THE COILS AND THE OVIDUCTS WERE REMOVED. A PIECE OF THE COIL WAS ADHERED IN THE UTERUS AND A SUSPICION OF PERFORATION WAS CONSIDERED. THE EVENT DEVICE BREAKAGE IS LISTED (ANTICIPATED) ACCORDING TO THE PRODUCT TECHNICAL ANALYSIS (PTC), WHILE THE EVENT SUSPICION OF UTERINE PERFORATION IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BOTH ARE SERIOUS DUE TO MEDICAL IMPORTANCE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALSO, UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE AND THE SUSPICION OF UTERINE PERFORATION MAY HAVE OCCURRED DURING REMOVAL OF ESSURE. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO INTERVENTION REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PERFORMED PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION CAN BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00558	BAYER HEALTHCARE LLC	7/29/2015	7/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 02-JUL-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014 FOR PERMANENT STERILIZATION. PHYSICIAN REPORTED THAT PATIENT HAD ESSURE PROCEDURE ABOUT A YEAR AGO (IN 2014) AND THEN, MORE RECENTLY, HAD A NOVASURE PROCEDURE DONE. DOCTOR SAID THAT INADVERTENT PULLED OUT A PORTION OF THE COIL WHILE DOING A NOVASURE PROCEDURE. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 07-JUL-2015: PHYSICIAN STATED THAT PATIENT HAD ESSURE PLACED APPROXIMATELY 1 &#55321;EARS AGO, AND THE HYSTEROSALPINGOGRAM REVEALED TUBAL OCCLUSION. ABOUT 2 MONTHS AGO ((B)(6) 2015), HEALTH CARE PROFESSIONAL PERFORMED A NOVASURE PROCEDURE AND, WHEN HE WAS REMOVING THE INSTRUMENTS, PART OF THE LEFT TUBAL COIL WAS DISLODGED AND HE CUT PART OF THE COIL OFF. AN ULTRASOUND WAS ORDERED LAST WEEK ((B)(6) 2015) AND 7-8MM REMAINED IN THE TUBE, AND SOME ARE IN THE UTERUS. PHYSICIAN WONDERS IF PATIENT CAN RELY ON THE ESSURE FOR CONTRACEPTION. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER

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ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE AND A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND APPROXIMATELY ONE AND HALF YEAR LATER PHYSICIAN INADVERTENT PULLED OUT A PORTION OF THE COIL WHILE DOING A NOVASURE PROCEDURE. A CONTROL ULTRASOUND WAS PERFORMED AND SHOWED 7-8MM OF ESSURE REMAINED IN THE TUBE, AND SOME ARE IN THE UTERUS. THESE EVENTS, REGARDED AS DEVICE BREAKAGE DUE TO UNINTENTIONAL ESSURE REMOVAL, ARE NON-SERIOUS. DEVICE BREAKAGE IS LISTED ACCORDING TO TECHNICAL ANALYSIS WHILE THE OTHER EVENT IS LISTED. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE, MOST OFTEN DURING DIFFICULT INSERTIONS. ALSO, PERFORMING INTRAUTERINE PROCEDURES WITHOUT DIRECT VISUALIZATION MAY RESULT IN TRAILING COILS OF INSERT BEING ENSNARED IN ANOTHER DEVICE. WHEN DEVICE IS WITHDRAWN, THE INSERT MAY BE REMOVED. IN THE PRESENT CASE, THE DEVICE BREAKAGE OCCURRED DURING A NOVASURE PROCEDURE, WHEN DOCTOR INADVERTENT PULLED OUT A PORTION OF ESSURE COIL. THEREFORE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 30-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED.

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00559	BAYER HEALTHCARE LLC	7/29/2015	7/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18717

Single Use: Y
Implant Date (E6): 6/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER C18717). PHYSICIAN REPORTED THAT DID NOT FEEL COMFORTABLE AFTER DEPLOYMENT OF THE ESSURE BECAUSE THE COILS WERE ALL TANGLED UP AND SHE SAW A PIECE OF METAL PROTRUDING OUT OF THE TUBAL OSTIAS. DOCTOR REMOVED THE INSERT AND COULD NOT PLACE ANOTHER DEVICE/BILATERAL PLACEMENT WAS NOT ACHIEVED. NO INJURY OCCURRED. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 07/07/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE

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INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C18717 (PRODUCTION DATE 05-FEB-2014 AND EXPIRATION DATE 28-FEB-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF THE COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND AFTER DEPLOYMENT, THE PHYSICIAN SAW A PIECE OF METAL PROTRUDING OUT OF THE TUBAL OSTIAS. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL INVESTIGATION. DURING DIFFICULT INSERTIONS OR REMOVALS, ESSURE DEVICE BREAKAGE MAY OCCUR. IN THIS CASE, AFTER DEPLOYMENT OF ESSURE MICRO-INSERT, THE COILS WERE ALL TANGLED UP AND SHE SAW A PIECE OF METAL PROTRUDING OUT OF THE TUBAL OSTIAS. PHYSICIAN REMOVED THE INSERT AND COULD NOT PLACE ANOTHER ONE (BILATERAL PLACEMENT NOT ACHIEVED). CONSIDERING THE REPORTED EVENT HAS OCCURRED ASSOCIATED TO INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 03-AUG-2015: PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. HYSTEROSCOPIC WAS USED TO REMOVED COILS. PATIENT RECOVERED FROM EVENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WH

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00560	BAYER HEALTHCARE LLC	7/29/2015	7/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** NZ

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C35394

Single Use: Y
Implant Date (E6): 6/26/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR FEMALE STERILIZATION (LOT NUMBER C35394 WITH EXPIRATION DATE IN MAR-2017). PHYSICIAN REPORTED THAT ESSURE WAS INSERTED VIA A STORZ TROPHY HYSTEROSCOPE, POSITIONED IN TUBAL OSTEA AND WHEEL WOUND BACK TO RETRACT INTRODUCER CATHETER, BUTTON DEPLOYED BUT WHEN WHEEL RETRACTED FOR THE SECOND TIME THE CATHETER WOULD NOT SEPARATE FROM THE MICRO-INSERT (ESSURE IMPLANTS DIFFICULT TO RELEASE FROM INTRODUCER). THE RETRIEVED CATHETER REVEALED A VERY ELONGATED INTRODUCER GUIDEWIRE AND GREEN SHEATH AND NO MICROINSERT VISIBLE. SURGEON RETRIEVED BROKEN PIECES OF THE INTRODUCER WIRE AND GREEN PLASTIC AND ABANDONED PROCEDURE. THIS PATIENT HAS 1 MICROINSERT IN SITU. THERE WAS NO INJURY TO THE PATIENT. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 02-JUL-2015: THE PATIENT WAS (B)(6) AT TIME OF THE EVENTS.. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE SURGEON RETRIEVED BROKEN PIECES OF THE INTRODUCER WIRE AND GREEN PLASTIC. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE, MOST OFTEN DURING DIFFICULT INSERTIONS. IN THE PRESENT CASE, WHEN WHEEL RETRACTED FOR THE SECOND TIME THE CATHETER WOULD NOT SEPARATE FROM THE MICRO-INSERT (ESSURE IMPLANTS DIFFICULT TO RELEASE FROM INTRODUCER). THE RETRIEVED CATHETER REVEALED A VERY ELONGATED INTRODUCER GUIDEWIRE AND GREEN SHEATH AND NO MICROINSERT VISIBLE. SURGEON RETRIEVED BROKEN

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PIECES OF THE INTRODUCER WIRE AND GREEN PLASTIC AND ABANDONED PROCEDURE. SINCE THE DEVICE BREAKAGE OCCURRED DURING INSERTION PROCEDURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

DEVICE BREAKAGE QUESTIONNAIRE RECEIVED ON 04-AUG-2015 THE PATIENT'S INITIAL WAS UPDATED. IT WAS REPORTED THAT BREAKAGE WAS DIAGNOSED DURING PLACEMENT. THE IMPLANT BROKE; WHEEL FAILED TO WIND BACK AND THE ESSURE COILS STRETCHED AND BROKE. THE BREAKAGE OCCU

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00561	BAYER HEALTHCARE LLC	7/29/2015	7/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** NZ

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C35394

Single Use: Y
Implant Date (E6): 5/28/2015
Explant Date (E7): 5/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR STERILIZATION (LOT NUMBER C35394). ESSURE INSERTED VIA A STORZ TROPHY HYSTEROSCOPE, POSITIONED IN TUBAL OSTEA AND WHEEL WOUND BACK TO RETRACT INTRODUCER CATHETER AND BUTTON DEPLOYED. BUT WHEN WHEEL RETRACTED FOR THE SECOND TIME THE CATHETER WOULD NOT SEPARATE AND THE ESSURE COIL STRETCHED AND BROKE OFF, LEAVING SOME MATERIAL IN THE UTERUS, GREEN PLASTIC AND BROKEN METAL WHICH WAS RETRIEVED BY THE SURGEON. A SECOND MICRO-INSERT WAS TRIED AND A SIMILAR RESULT OCCURRED BUT MICRO-INSERT WAS DELIVERED AND WAS IN SITU. INTRODUCER CATHETERS RETRIEVED WERE CATHETER MINUS THE MICRO-INSERT AND THE SECOND MINUS THE MICRO-INSERT AND AN ELONGATED GUIDEWIRE. THREE ESSURE CATHETERS WERE USED IN ALL AND 2 IMPLANTS ARE IN SITU. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: THE PATIENT WAS (B)(6) YEARS OLD AT TIME OF THE INSERTION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING A DIFFICULT INSERTION, ESSURE BROKE OFF LEAVING MATERIAL IN THE UTERUS (GREEN PLASTIC AND BROKEN METAL) WHICH WAS RETRIEVED BY SURGEON. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS OR REMOVALS, ESSURE DEVICE BREAKAGE MAY OCCUR. IN THIS CASE, ESSURE WAS POSITIONED IN TUBAL OSTEA AND WHEN THE WHEEL RETRACTED FOR THE SECOND TIME, THE CATHETER WOULD NOT SEPARATE AND THE ESSURE COIL STRETCHED AND BROKE OFF, LEAVING SOME MATERIAL IN THE UTERUS (GREEN PLASTIC AND BROKEN METAL). THIS MATERIAL WAS

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THEN RETRIEVED PER PHYSICIAN. A SECOND MICRO-INSERT WAS ATTEMPTED AND A SIMILAR RESULT OCCURRED BUT MICRO-INSERT WAS DELIVERED AND WAS IN SITU. CONSIDERING THE REPORTED EVENT HAS OCCURRED ASSOCIATED TO INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 04-AUG-2015: ESSURE WAS REMOVED BY GRASPERS VIA UTERUS AT DAY OF INSERTION ATTEMPT. NO INJURY TO THE PATIENT WAS REPORTED. SHE WAS RECOVERED AND DEVICE WAS NOT AVAILABLE. PTC INVESTIGATION RESULT WAS RECEIVED ON 17-AUG-20

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044855	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 5/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT LOWER ABDOMINAL PAIN ON THE RIGHT SIDE RIGHT WHERE MY TUBES ARE. NO PERIOD SINCE HAVING THE PROCEDURE DONE. I'VE HAD ULTRASOUNDS, CT SCANS, BLOOD WORK, AND PELVIC EXAM ALL OF WHICH HAVE CAME BACK FINE. I CAN'T LOSE WEIGHT AND ALWAYS FEEL AS IF I'M BLOATED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044856	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONE FELL OUT A MONTH AFTER HAVING PROCEDURE DONE. BLOATING, HEAVY MENSTRUALS, HEADACHES, BAD CRAMPS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044873	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 8/31/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SEVERE HEADACHES, WEIGHT GAIN, FATIGUE, VITAMIN D DEFICIENCY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044874	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 6/25/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WENT TO ER TODAY MY BODY IS REJECTING THE ESSURE EVEN THOUGH I HAVE NO NICKEL ALLERGY. MY CERVIX IS IRRITATED AND SWOLLEN ALMOST SHUT AND THE COILS ARE ALMOST OUT OF MY TUBES WHERE MY BODY IS REJECTING IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044875	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY CYCLES,DEPRESSION,BODY ACHES,FATIGUE,GAINED WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044876	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 4/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS NOT TOLD OF ALL THE METALS AND PET FIBERS IN THIS DEVICE. I ALSO WAS NOT INFORMED OF THE FACT ESSURE SHOULD NOT BE PLACED IN A PARTIAL TUBE!!!! I'M A CANCER SURVIVOR AND WELCOMED STERILIZATION WITH LITTLE RISK! I NOW HAVE SEVERE CHRONIC ABDOMINAL PAIN, CONSTANT ABDOMINAL PAIN. EXTREMELY ABNORMAL PERIODS; HEAVY, CRAMPING, FOUL ODOR, DARK LARGE BLOOD CLOTS. FATIGUE. EASY BRUISING, MOOD SWINGS. FOUL SMELLING DISCHARGE. HAIR LOSS, BLOATING FEELING LIKE MY INSIDES ARE SWOLLEN. METALLIC TASTE, MIGRAINES. PAINFUL INTERCOURSE, LOSS OF LIBIDO. PLACED IN A PARTIAL TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044877	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 6/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLED FOR A MONTH STRAIGHT. I'M STILL BLEEDING. GUSHING BLOOD NOT SPOTTING. I CAN'T MOVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044879	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 6/26/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIZZY SPELLS ,MAJOR WEIGHT LOSS, HAIR LOSS, BAD ABDOMEN PAINS , WORSE PERIODS, MOOD SWINGS CAUSED FROM PAIN WHICH LEADS TO DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044882	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY, BOILS, IRREGULAR PERIODS, HEADACHES, MIND FOG, WEIGHT GAIN, HAIR LOSS, RASH ON CHEST, BLOATINESS, SHARP PAINS IN ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044883	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 7/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD CHRONIC FATIGUE ,JOINT ACHES AND SWELLING .DIGESTIVE ISSUES ,BOWEL PROBLEMS,CHRONIC PELVIC PAIN . PERIODS STOPPED . PAINFUL INTERCOURSE .DEVELOPED CHRONIC SKIN PROBLEMS ,ALLERGIES TO EVERY FOOD WITH EXCEPTION OF A FEW . WILL BE HAVING A TOTAL HYSTERECTOMY TO HAVE THESE REMOVED ON (B)(6)... THESE IMPLANTS CAUSED A SLOW INFLAMMATION THAT BECAME CHRONIC AND SYSTEMIC ITS WRECKED MY IMMUNE SYSTEM AND CAUSE HOSPITALIZATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044884	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 11/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE DAY ONE I BEEN HAVING A REALLY BAD RASH BY MY LEG ANOTHER THING IS PAINFUL ARMS FEET NUMB LEG HAIR LOSS WEIGH GAIN TIRED ALL THE TIME

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044885	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 12/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6). I BECAME SO ILL MY FAMILY DOCTOR DID AN EMERGENCY CT SCAN SO I DIDN'T HAVE TO WAIT IN THE WAITING ROOM I FOUND OUT THE COIL AFTER OVER A YEAR SHIFTED INTO MY UTERUS AND I HAD BECOME 12 WK PREGNANT. I SPENT TIME IN ER TO BECOME HYDRATED AND MANY VISIT TO HIGH RISK OBGYN AND CARDIOLOGIST AS WELL AS TIME IN THE ICU MISSED A LOT OF WORK SINCE THEN I CONTINUE TO HAVE BAD CRAMPS BACK PAIN AND BLADDER PROBLEMS. I HAD THE TEST AND WAS TOLD IT WAS 100% BLOCKED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044887	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 3/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN PROGRESSIVELY WORSE FELLING LIKE LABOR PAIN. EXTREMELY HEAVY PERIODS. LEADING TO HYSTERECTOMY. PATHOLOGY SHOWED UTERUS WAS THREE TIMES THE SIZE OF NORMAL. WITH FIBROID GROWTH AND CYST ON OVARY. ONE IMPLANT BECAME DISLODGED AND WAS IN THE BOTTOM OF MY UTERUS. HAD SURGERY TO REMOVE IT AND TUBAL ON THAT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044888	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 6/16/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAIR LOSS, METAL TASTE, OVARY CYST BUSTED, DEPRESSION, ANXIETY, MRSA, CERVICAL CANCER, NEUROLOGICAL DAMAGE, NERVE DAMAGE, PAIN ALL THE TIME IN LEGS , ARMS, SHOULDERS, BLOATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044889	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 1/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE ESSURE I HAVE TERRIBLE LOWER BACK PAIN, ABDOMINAL PAIN LIKE IF I'M GETTING STABBED, I BLEED A LOT DURING MY MENSTRUAL CYCLE, PAIN IN MY BREAST, I DID NOT HAVE ANY OF THESE SYMPTOMS BEFORE THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044890	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 8/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I IMMEDIATELY WOKE FROM GETTING ESSURE IN HORRIBLE PAIN THAT NEVER WENT AWAY I ALSO WOKE BLEEDING WHICH ALSO NEVER STOPPED UNTIL MY HYSTERECTOMY IN (B)(6) OF 2014 I ALSO STARTED GETTING RASHES FROM JEWELRY, HORRIBLE NIGHT SWEATS, WEIGHT GAIN, EXTREME BLOATING, MOOD SWINGS, CHRONIC FATIGUE, BRAIN FOG, AND OTHER MENOPAUSE LIKE SYMPTOMS WHICH ALL VANISHED AFTER HYSTERECTOMY TO REMOVE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044891	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 6/26/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD A HYSTERECTOMY TO REMOVE ESSURE SECOND SURGERY ON (B)(6). BEEN THROWING UP FOR 2 DAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044892	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 4/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2015 I HAD AN TOTAL HYSTERECTOMY LEAVING OVARIES IN PLACE. ESSURE HAD ME IN SO MUCH PAIN SO MY SURGERY WAS SCHEDULED RIGHT AWAY. I DIDN'T SIGN UP FOR A HYSTERECTOMY, I SIGNED UP FOR A "SAFE NO PAIN PROCEDURE" THAT HAS RUINED MY LIFE! I LOST MY JOB BECAUSE I NEEDED ABOUT 4-6 WEEKS OFF AFTER MY SURGERY.. I AM SO DISAPPOINTED!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044893	BAYER	7/29/2015	7/29/2015

Event Information:

Event Date (B3): 6/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM FILING ON BEHALF OF A (B)(6) OLD CAUCASIAN FEMALE (B)(6) NONSMOKER WHO UNDERWENT THE ESSURE STERILIZATION PROCEDURE IN (B)(6) 2013. THE DEVICE ON THE LEFT MIGRATED OUT OF THE FALLOPIAN TUBE--LOCATION UNKNOWN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044880	BAYER	7/29/2015	7/31/2015

Event Information:

Event Date (B3): 4/5/2015 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD A MISCARRIAGE. LOT OF PAIN AND BLOOD. I HAD A SONOGRAM, CT SCAN , MRI, BLOOD WORK. I AM IN SHOCK AND VERY DEPRESSED. I DIDN'T EVEN KNOW I WAS PREGNANT. HAVING HYSTERECTOMY (B)(6) 2015 DUE TOO ESSURE DEVICE FAILURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045041	BAYER	7/29/2015	8/5/2015

Event Information:

Event Date (B3): 2/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 2/26/2015
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE DEVICE (B)(6) 2015, SHORTLY AFTER, I BECAME BLOATED, MY HAIR STARTED TO FALL OUT. ON (B)(6), I STARTED MY CYCLE AND STOP IN (B)(6) 2015, CALLED DOCTOR. THEN ON (B)(6) STARTED SECOND CYCLE. BY (B)(6) I BECAME WORRIED AND I WAS HAVING PAIN, CLOTTING, CRAMP AND HEAVY BLEEDING. WENT TO DOCTOR ON (B)(6) 2015 AND THEY PUT ME ON A HORMONE BIRTH CONTROL PILL (MEDROXYPROGESTERONE) WHEN I CONTINUE TO BLEED. I WENT BACK TO THE DOCTOR ON (B)(6) 2015 AND WAS PUT ON LUTERA BIRTH CONTROL. I WAS TOLD THE ONLY OTHER OPTION AFTER THAT IS A HYSTERECTOMY. I NEVER MENSTRUATED PAST A WEEK UNTIL I GOT ESSURE. SINCE ESSURE, I HAVE HAIR LOSS, DEBILITATING HEADACHES, WEIGHT GAIN (BLOATING), LONGER HEAVY PAINFUL MENSES, AND RASHES. PUT ON BIRTH CONTROL TO STOP BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045043	BAYER	7/29/2015	8/5/2015

Event Information:

Event Date (B3): 8/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6): 8/8/2012
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

AS A SAMPLE, EXPERIENCED VAGINAL BLEEDING 31/52 WEEKS IN 2014. EMERGENCY ROOM VISITS. EMOTIONAL SIDE EFFECTS. EXCRUCIATING PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045044	CONCEPTUS, INC.	7/29/2015	8/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD THE ESSURE SINCE 2010. THIS DEVICE CAUSES ME MUCH PAIN. I FEEL LIKE I AM BEING STABBED FROM THE INSIDE OUT. I ALSO FEEL A BURNING SENSATION. AFTER SEX I CRAMP VERY BADLY FOR DAYS. MY MENSTRUAL CRAMPS HAVE ALSO BECOME MORE PAINFUL. I ALSO HAVE A LOT OF PAIN AND A VERY TENSE HARD FEELING IN MY SIDE WHEN I COUGH TOO HARD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044895	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, CRAMPS, JOINT PAIN, HEAVY MEN CYCLES, FATIGUE AND NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044896	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN MY GYNECOLOGIST WAS INSERTING THE ESSURE COIL INTO MY LEFT FALLOPIAN TUBE HE HAD TROUBLE. AS THE TIME AND DAYS WENT I WAS CRAMPING MORE AND MORE EVERYDAY. SINCE (B)(6) 2013, I CRAMP ON MY LEFT SIDE DAILY, I CAN'T HAVE INTERCOURSE BECAUSE OF THE PAIN. I CAN'T LAY COMFORTABLY ON MY LEFT SIDE BECAUSE OF THE TENDERNESS AND PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044897	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WOKE UP LOOKING 7 MONTHS PREGNANT I AM NOT PREGNANT NOT DO I WISH TO BE THEY ARE SAYING IT IS GAS BUT MYSELF AND OTHERS WITH ESSURE ARE ALL HAVING THE SAME ISSUE I'VE NEVER JUST WOKE UP LIKE THIS IT HURTS!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044898	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 6/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAINS IN ABDOMEN, BREAST HURT AS IF I WERE PREGNANT, BODY ACHES INSIDE AND OUT, SEVERE BLOATING/ WEIGHT GAIN,HEARTBURN/ACID RE-FLUX, SUPER MIGRAINES, DAILY HEAD ACHES, NUMBNESS BOTH ARMS ALL THREW FINGER TIPS/ RIGHT ELBOW HURTS SUPER BAD. BRAIN FOG/ MEMORY LOSS, MOOD SWINGS, RINGING IN EARS AT TIMES PLUGGED EARS. VITAMIN D DEFICIENCY, FOOD ALLERGIES, NICKEL ALLERGIES, SWELLING OF ANKLES AND FEET, HAIR LOSS, DRY SKIN, SHORTNESS OF BREATH, NECK SHOULDER AN BACK LOWER BACK PAIN(RIGHT NOW AS I SIT HERE) MOVING CYCLE,FATIGUE, I GOT SOMETHING MOVING IN MY STOMACH LIKE BABY IN THERE. JOINT PAIN SPECIALLY MY ANKLES. I STARTED GETTING CHEST PAIN RECENTLY RASHES ON ARMS INTERCOURSE HAPPENS LIKE TWICE A MONTH, LOSS OF BALANCE, APPEARS I HAVE FIBROMYALGIA. SUPER ANXIETY!!!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044899	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 5/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED GETTING HIVES ON MY BODY, I HAD INSOMNIA AND HORRIBLE MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044900	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BURNING SENSATION IN MY OVARIES. HEAVY MENSTRUATION. WEIGHT GAIN. BLOATING. PAINFUL INTERCOURSE JUST RECENTLY STARTED ALSO WITH BLEEDING ACCRUING. HEADACHES. ANXIETY. CRAMPS. MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044901	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 8/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WENT FOR 2ND HSG TO LOCATE COILS, ON ONE THE MARKER IS BROKE AND THE OTHER IS MIA . PLEASE TAKE THIS OFF THE MARKET AS I HAVE TO GO FOR A COMPLETE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044902	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 6/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BACK PAIN, LOWER ABDOMINAL PAIN, SEVERE NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044903	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 6/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKEL ALLERGY, BLOATING, EXTREME INFLAMMATION, LOWER BACK PAIN, MIGRAINES, NO ENERGY, NAUSEA, CHEST PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044904	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 7/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DOCTOR TOLD ME WAS A SAFE PROCEDURE BUT AFTER THE INSERT OF THE ESSURE I PASS OUT BECAUSE OF THE PAIN,AFTER THAT I BEEN EXPERIENCING BACK PAIN, HIP PAIN, PAINFUL INTERCOURSE, SHARP STAVING IN MY PELVIC AREA AND ITCHY BUMPS IN MY ARMS, IN THE PAST YEAR I ALSO HAD TO VAGINAL INFECTIONS AND A LOT OF HEADACHES AND MOOD SWINGS. I HAVE TO ADD THAT II JUST HAVE ONE COIL INSERT BECAUSE THE DOCTOR COULDN'T PUT THE OTHER ONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044905	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 7/17/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DOCTOR TOLD ME WAS A SAFE PROCEDURE BUT AFTER THE INSERT OF THE ESSURE I PASS OUT BECAUSE OF THE PAIN, AFTER THAT I BEEN EXPERIENCING BACK PAIN, HIP PAIN, PAINFUL INTERCOURSE, SHARP STAVING IN MY PELVIC AREA AND ITCHY BUMPS IN MY ARMS, IN THE PAST YEAR I ALSO HAD TO VAGINAL INFECTIONS AND A LOT OF HEADACHES AND MOOD SWINGS. I HAVE TO ADD THAT I JUST HAVE ONE COIL INSERT BECAUSE THE DOCTOR COULDN'T PUT THE OTHER ONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044906	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 3/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE INSERTION OF THE ESSURE I BEGAN HAVING SEVERE SHARP PAIN IN MY LOWER LEFT ABDOMINUM WITH BLOATING. MY DR BELIEVED IT WAS OF NO CONCERN. MONTHS LATER DURING THE HSG XRAY IT SHOWED THE LEFT ESSURE COIL HAD DISLODGED AND MOVED UP INTO A DIFFERENT PART OF MY BODY. FEARING IT MAY HAVE PUNCTURED OTHER ORGANS I HAD SURGERY TO REMOVE THE DISLODGE COIL AND MY LEFT TUBE WAS CLAMPED INSTEAD. SURGERY WAS 4 DAYS AGO SO STILL IN PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044927	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 5/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN HAVING BAD HEADACHES WITH NAUSEA, ALSO I'VE NOTICE MY UPPER PALATE IN MY MOUTH GOING NUMB.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044928	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 6/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, CHRONIC FATIGUE, IRREGULAR AND HEAVY MENSTRUAL CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044929	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 6/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, CHRONIC FATIGUE, IRREGULAR AND HEAVY MENSTRUAL CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044930	BAYER	7/30/2015	7/30/2015

Event Information:

Event Date (B3): 8/26/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, PINCHING, LOWER BACK PAIN, MIGRAINES, ANXIETY, DEPRESSION, BRAIN FOG, VITAMIN D DEFICIENCY, B12 DEFICIENCY, NICKEL ALLERGY, RASHES, ECZEMA, CERVICAL SPINE PAIN, FACET SYNDROME C-4, C-5, C-6, JOINT PAIN (HIPS, SHOULDERS, WRISTS), CARPEL TUNNEL SYMPTOMS, NUMBNESS IN LEGS AND HANDS, ABNORMAL BLEEDING, PROLONGED PERIODS (8 WEEKS AT A TIME), CYSTS, ADHESIONS, ADENOMYOSIS (NEW), CONNECTIVE TISSUE DISORDER, DETACHED LABRUM OF LEFT SHOULDER WITHOUT EVENT - SPONTANEOUS DETACHMENT NECESSITATING SHOULDER RECONSTRUCTION WITH 4 ANCHORS (STILL NOT RECOVERED FULL RANGE OF MOVEMENT), CYSTS IN HIP JOINT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044946	BAYER	7/31/2015	7/31/2015

Event Information:

Event Date (B3): 2/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING PAIN EVERY TIME I'D HAVE SEXUAL INTERCOURSE. MY PERIODS ARE HORRIBLE WITH PAIN, BLOOD CLOTS AS THOUGH I'M HAVING A MISCARRIAGE. SOMETIMES WHEN I'M WALKING I FEEL A SCRATCHING FEELING IN AND AROUND MY OVARIAN AREA. I CAN BE LAYING DOWN AND FEEL SOMETHINGS JUST NOT RIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044947	BAYER	7/31/2015	7/31/2015

Event Information:

Event Date (B3): 7/21/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE PROCEDURE I START FEELING SO MUCH PAIN AND I HAVE HEMORRHAGE. THE DOCTOR SENT ME METRONIDAZOLE BECAUSE HE SAID I GOT AN INFECTION. THEY JUST PUT ONE COIL IN THE LEFT SIDE BECAUSE MY PAIN WAS TERRIBLE AT THE POINT THAT I PASS OUT. SINCE THAT DAY MY HIPS, BACK IS KILLING ME PLUS I GOT LIKE A RASH ON MY ARMS. WHEN I SNEEZE I FEEL THE COIL PINCHING INSIDE. THIS THING IS A KILLER DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045114	BAYER	7/31/2015	8/5/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ANXIETY; PANIC ATTACKS; SEVERE WEIGHT GAIN +30 LBS IN 6 MONTHS - CANNOT TAKE IT OFF AND I HAD GASTRIC BANDING; HEAVY, LONG PERIODS 6+ WEEKS THEN SKIP 4-5 MONTHS; UTI'S; HARI LOSS; ITCHY EYES AND EYELASH LOSS; LARGE BROWN PATCH ON LEG; LITTLE RED DOTS (RUBY POINTS) ALL OVER; EARLY MENOPAUSE; PELVIC PAIN. ALL OCCURING 3 YRS AFTER INSERTED IN 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044949	BAYER	8/1/2015	8/3/2015

Event Information:

Event Date (B3): 3/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE PAIN STARTED THE DAY IT WAS PUT IN. THEN SEEMED TO EASE UP A LITTLE THE SECOND MONTH. BUT SINCE THEN THE PAIN AND HEAVY BLEEDING HAS GOTTEN WORSE EVERY MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044950	BAYER	8/1/2015	8/3/2015

Event Information:

Event Date (B3): 2/6/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATE CRAMPING, SEVERE LEFT ABDOMINAL PAIN, HEADACHES AFTER PLACEMENT. NOW THAT I HAVE HAD ESSURE IMPLANTED FOR 8 YEARS THE SYMPTOMS HAVE GOTTEN 10 TIMES WORSE AND NOW INCLUDE NUMBNESS IN FACE, HANDS, FEET, BRAIN FOG, MULTIPLE FIBROIDS, SEVERE AND PAINFUL BLOATING, IBS, TEETH CRUMBLING, EXCRUCIATING PAIN IN MY ENTIRE ABDOMEN, A VAGINAL BACTERIAL INFECTION THAT REOCCURS EVERY 2 MONTHS, BLURRED VISION, MEMORY LOSS, POST NASAL DRIP THAT DOES NOT GO AWAY, SEVERE ALLERGIC REACTIONS TO NICKEL EVERY 4-6 MONTHS AND NOW A FUTURE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045116	BAYER	8/2/2015	8/5/2015

Event Information:

Event Date (B3): 9/29/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 872994

Single Use: Y
Implant Date (E6): 9/29/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

UNDERWENT ESSURE STERILIZATION PROCEDURE ON (B)(6) 2011. FOUND OUT IN (B)(6) 2012 THAT RIGHT INSERT WAS NOT POSITIONED PROPERLY. OVER TIME DEVELOPED NUMEROUS SYMPTOMS; FLUID RETENTION: BEFORE ESSURE - SOMETIMES SEVERE IN RIGHT FOOT/ANKLE. AFTER ESSURE - PROGRESSIVELY WORSE, MOSTLY SEVERE IN FEET/ANKLE, SOMETIMES IN KNEES/THIGHS, ARMS, FINGERS. NUMBNESS IN OUTER THIGHS (NEUROPATHY): BEFORE ESSURE - NONE. AFTER ESSURE - PROGRESSIVELY WORSE, STARTED LENGTHWISE IN OUTER THIGHS, SOMETIMES ABOVE KNEES. NUMBNESS IN TOES/FEET/FINGERS/HANDS: BEFORE ESSURE - SOMETIMES LAST 2 FINGERS, RARE OCCASION FEET FALL ASLEEP. AFTER ESSURE - FINGERS/HANDS EXTREMELY NUMB ON WAKING UP, TOES NUMB AT TIMES THROUGHOUT DAY. IBS: BEFORE ESSURE - UNDER CONTROL. AFTER ESSURE - SOME FLARE UPS WITH SEVERE CRAMPING AND A LOT OF PRESSURE NEAR INSERTS. CRAMPS: BEFORE ESSURE - SOME MINOR WITH MONTHLY CYCLE. AFTER ESSURE - A LOT OF CRAMPS BEFORE/DURING/AFTER CYCLE WITH A LOT OF PRESSURE NEAR INSERTS. HEADACHES: BEFORE ESSURE - SOME SINUS PRESSURE HEADACHES. AFTER ESSURE - PAIN STARTING IN BACK OF NECK UP THROUGH HEAD BEFORE/DURING/AFTER MONTHLY CYCLE. VAGINAL DISCHARGE: BEFORE ESSURE - ON RARE OCCASION. AFTER ESSURE - MORE FREQUENT CLEAR DISCHARGE WITH MINOR SMELL. MONTHLY CYCLE: BEFORE ESSURE - CONTROLLED BY ORTHO NOVUM 7/7/7 - ON TIME AND LIGHT, HEAVY ON RARE OCCASION. AFTER ESSURE - VARIES - ON TIME/LATE 3 WEEKS/EARLY 10 DAYS, HEAVIER, SOMETIMES SEVERE BLEEDING. TONGUE: BEFORE ESSURE - NO ISSUES. AFTER ESSURE - SWOLLEN WITH IMPRINTS OF TEETH ON THE SIDE. SUGAR LEVELS: BEFORE ESSURE - NO ISSUES. AFTER ESSURE - HIGHER BLOOD SUGAR LEVELS, POSSIBLE PRE-DIABETES. BRAIN: BEFORE ESSURE - RARE CONCENTRATION ISSUES. AFTER ESSURE - PROGRESSIVE CONCENTRATION ISSUES. HEART BEFORE ESSURE - SOME HEAVINESS DUE TO FLUID RETENTION. AFTER ESSURE - RACING ON OCCASION, MORE HEAVINESS

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DUE TO TAKING MORE FLUID RETENTION. EARS: BEFORE ESSURE - RARE OCCASION OF RINGING. AFTER ESSURE - MORE FREQUENT OCCASION OF RINGING. MUSCLES: BEFORE ESSURE - SOME CRAMPS IN CALVES DUE TO FLUID RETENTION. AFTER ESSURE - KNOTS IN BUTT, ARMS TIRED WHEN UP IN AIR, MORE CRAMPS IN CALVES DUE TO FLUID RETENTION. BLOATING BEFORE ESSURE - MINOR ON OCCASION. AFTER ESSURE - PROGRESSIVELY WORSE MOST OF THE TIME. TROUBLE SLEEPING: BEFORE ESSURE - ON RARE OCCASION. AFTER ESSURE - MOST NIGHTS TAKES ABOUT 1 HOUR TO FALL ASLEEP, AT TIMES UP PERIODICALLY TO URINATE. BACK PAINS: BEFORE ESSURE - RARE OCCASION PAIN IN MIDDLE OF BACK. AFTER ESSURE, PAIN IN MIDDLE OF BACK, NUMBNESS IN MIDDLE OF BACK, LOWER BACK PAIN. SHOULDERS BEFORE ESSURE - SOME KNOTS IN SHOULDERS. AFTER ESSURE - MORE KNOTS IN SHOULDERS. HIPS: BEFORE ESSURE - NO ISSUES. AFTER ESSURE - PAIN IN BOTH HIPS, FATIGUE: BEFORE ESSURE - NO ISSUES. AFTER ESSURE - TIRED MORE EASILY, WANT TO CRASH/SLEEP AFTER A WORKOUT OR STRENUOUS ACTIVITY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045158	BAYER	8/2/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 7/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER SEVERAL YEARS TRYING TO NARROW DOWN WHY MY HEALTH WAS PRETTY MUCH GOING DOWN HILL IT WAS ESSURE COILS. I HAD MIGRAINES THAT LANDED ME IN THE EMERGENCY ROOM, JOINT PAIN, TOOTH DECAY, UNEXPLAINED INJURY TO MY ANKLES AND KNEES BACK; SHOULDER PAIN. INSOMNIA, DIZZY SPELLS, STOMACH PAINS PELVIC PAINS, PAIN THROUGH MY LEFT SIDE, BLOATING, VERY HEAVY BLEEDING WITH LARGE SIZE CLOTS, BRAIN FOG, DEPRESSION, ANXIETY, TROUBLE FUNCTIONING ON A DAILY BASIS AND WAS UNABLE TO HELP A SICK CHILD. GANGLION CYST, ARTHRITIS, RA SYMPTOMS, AUTOIMMUNE ISSUES, LOW VITAMIN D AND BLOOD CELL COUNT IRREGULAR.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00562	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 4/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C22913

Single Use: Y
Implant Date (E6): 3/27/2015
Explant Date (E7): 4/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT CONTRACEPTION ON (B)(6) 2015. ON (B)(6) 2015 THE PATIENT EXPERIENCED PAIN AND WENT TO ER (EMERGENCY ROOM) FOR CT SCAN AND ULTRASOUND WHICH SHOWED THAT THE LEFT PLACEMENT WAS FINE BUT RIGHT PLACEMENT WAS IN ENDOMETRIAL CAVITY. ESSURE WAS NOT REMOVED. THE EVENT WAS ONGOING BUT PATIENT WAS OTHERWISE OKAY. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 23-APR-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 24-APR-2015: THE ESSURE LOT NUMBER USED WAS C22913. IT WAS REPORTED THAT THE DEVICE FOUND IN ENDOMETRIAL CAVITY WAS REMOVED WITH GRASPERS. ANOTHER ESSURE WAS INSERTED ON 22-APR-2015. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 01-MAY-2015. (B)(4).THE PTC ASSESSMENT WAS UPDATED UPON LOT NUMBER RECEIPT. FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 05-JUN-2015: NO NEW INFORMATION WAS RECEIVED. FOLLOW-UP INFORMATION WAS RECEIVED ON 06-JUL-2015 VIA ESSURE HEALTH CARE PROVIDER PREGNANCY QUESTIONNAIRE. THIS CASE WAS UPGRADED TO INCIDENT. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, GYNECOLOGICAL PROBLEMS OR PROCEDURES AND ANY OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. GENERAL ANESTHESIA WAS APPLIED DURING ESSURE INSERTION PROCEDURE. THE INSERTION WAS CONSIDERED EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. ON (B)(6) 2015 ESSURE WAS REMOVED BY HYSTEROSCOPY WITH GRASPERS AND ANOTHER ESSURE DEVICE WAS PLACED IN RIGHT TUBE. HYSTERECTOMY OR SALPINGECTOMY WAS NOT NECESSARY. SHE RECOVERED FROM THE REMOVAL PROCEDURE. THE SYMPTOMS/PAIN RESOLVED AFTER SURGERY. ON (B)(6) 2015 AN ULTRASOUND WAS PERFORMED. PATIENT WAS IN EXCELLENT HEALTH. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 13-JUL-2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE EXPERIENCED PAIN AND WENT TO EMERGENCY ROOM FOR CT SCAN AND ULTRASOUND WHICH SHOWED THAT THE LEFT PLACEMENT WAS FINE BUT RIGHT PLACEMENT WAS IN ENDOMETRIAL CAVITY - EXPULSION OF DEVICE FROM RIGHT TUBE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THIS EVENT WAS DIAGNOSED ABOUT 7 DAYS AFTER ESSURE INSERTION. SHE HAD ESSURE REMOVED BY HYSTEROSCOPY WITH GRASPERS. HYSTERECTOMY OR SALPINGECTOMY WAS NOT NECESSARY. GIVEN THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT DUE TO THE REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00563	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76528

Single Use: Y
Implant Date (E6): 7/2/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PURCHASING AGENT ON BEHALF OF A MEDICAL DOCTOR IN UNITED STATES ON 06-JUL-2015. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2015; THE LOT NUMBER USED WAS B76528 (EXPIRATION DATE OCT-2016). DURING THE INSERTION PROCEDURE, THE UNIT MISFIRED AND BROKE UP INTO MANY PIECES. THE PIECES HAD TO BE REMOVED FROM THE PATIENT. AS FAR AS THE PURCHASING AGENT KNEW, NO ADDITIONAL TREATMENT WAS REQUIRED. FOLLOW UP INFORMATION RECEIVED ON 07-JUL-2015: THE PATIENT WAS NOT PREGNANT AT TIME OF THE INSERTION. ESSURE WAS INSERTED FOR PERMANENT STERILIZATION. ACCORDING TO THE OFFICE MANAGER, DURING FIRST COIL DEPLOYMENT, THE UNIT WAS DEPLOYED AND CAME APART INTO SEVERAL PIECES AND ALL OF THEM WERE COLLECTED. IT WAS REPORTED THAT THE PATIENT WAS OKAY. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-JUL-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). LOT NUMBER B76528 (PRODUCTION DATE 02-OCT-2013; EXPIRATION DATE 31-OCT-2016). FINAL ASSESSMENT FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE

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FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING AND PREMATURE DEPLOYMENT IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE THE UNIT MISFIRED AND BROKE UP INTO MANY PIECES. THE PIECES HAD TO BE REMOVED FROM THE PATIENT. PATIENT WAS OKAY. THE REPORTED EVENTS, REGARDED AS A DEVICE DEPLOYMENT ISSUE FOLLOWED BY DEVICE BREAKAGE, WERE CONSIDERED NON-SERIOUS. DEVICE BREAKAGE WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. THE OTHER EVENT IS ALSO LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

THIS IS A CORRECTION TO THE INITIAL REPORT SUBMITTED AUGUST 3, 2015, THE 'DATE RECEIVED BY MANUFACTURER" HAS BEEN UPDATED FROM 06/06/2015 TO THE CORRECT DATE OF 07/06/2015. DATE WAS REPORTED ACCURATELY IN 'DESCRIBE EVENT OR PROBLEM' OF INITIAL REPORT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00564	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 3/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (#MW5041670) IN UNITED STATES ON 06-JUL-2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER REPORTED THAT SHE EXPERIENCED CHRONIC PELVIC PAIN AND HEAVY PERIODS AFTER THE ESSURE PLACEMENT IN 2008. THESE SYMPTOMS BEGAN IN 2011/2012. SHE UNDERWENT A HYSTERECTOMY ON (B)(6) 2015 AND THEY FOUND HER RIGHT FALLOPIAN TUBE WAS PERFORATED BY THE ESSURE COIL. ESSURE REMOVAL DATE WAS REPORTED AS (B)(6) 2015. NO ADDITIONAL INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 15-JUL-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR

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FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 3-4 YEARS LATER EXPERIENCED CHRONIC PELVIC PAIN. SHE UNDERWENT HYSTERECTOMY AND ESSURE REMOVAL 7 YEARS AFTER INSERTION AND IT WAS FOUND THAT HER RIGHT FALLOPIAN TUBE WAS PERFORATED BY THE ESSURE COIL. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THE PERFORATION ARE UNKNOWN. CONSUMER HAD CHRONIC PELVIC PAIN, UNDERWENT A HYSTERECTOMY AND THE PERFORATION WAS FOUND. THE PERFORATION LIKELY HAD A CONTRIBUTORY ROLE IN THE OCCURRENCE OF PELVIC PAIN. GIVEN THE NATURE OF THE REPORTED EVENTS, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENT WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY/ ESSURE REMOVAL). A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

THIS IS A CORRECTION TO THE INITIAL REPORT SUBMITTED AUGUST 3, 2015, THE 'DATE RECEIVED BY MANUFACTURER" HAS BEEN UPDATED FRPM 06/06/2015 TO THE CORRECT DATE OF 07/06/2015. DATE WAS REPORTED ACCURATELY IN 'DESCRIBE EVENT OR PROBLEM' OF INITIAL REPORT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00565	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/26/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (#MW5042267) IN UNITED STATES ON 06-JUL-2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER REPORTED THAT SHE THE ESSURE PLACED IN 2014 AND HAS HAD VAGINAL BLEEDING, SEVERE BLOATING, EXCRUCIATING PELVIC PAIN, LOTS OF HAIR LOSS, AND MIGRAINE HEADACHES SINCE HAVING THIS PLACED. SHE HAD TIMES WHERE HER LEGS WENT NUMB WHERE SHE BLED ENOUGH TO FILL A PAD EACH HOUR AND HAD BEEN UNABLE TO WORK. SHE HAD THE HYSTEROSALPINGOGRAM TEST TO CHECK PLACEMENT AS WELL IF HER TUBES WERE THEN BLOCKED AND IT SHOWED THAT ONE OF HER COILS HAS MIGRATED AND SHE WAS HAVING A TOTAL HYSTERECTOMY TO REVERSE THIS PROCEDURE IN 2015 (NO DETAILS MENTIONED). CONSUMER HAD NOT HAD A SINGLE SYMPTOM UNTIL THE DAY THE ESSURE WAS PLACED. PERCOCET WAS ADDED AS A CONCOMITANT DRUG. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 15-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS

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CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE UNDERWENT A HYSTEROSALPINGOGRAM TEST IN ORDER TO CHECK PLACEMENT AS WELL IF HER TUBES WERE THEN BLOCKED AND THE RESULT SHOWED ONE OF COILS MIGRATED. SHE WAS HAVING A TOTAL HYSTERECTOMY TO REVERSE THIS PROCEDURE. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MIGRATION IS OFTEN USED SYNONYMOUSLY WITH PERFORATION. IT IS SOMETIMES USED TO IMPLY THAT A COMPLETE PERFORATION OCCURRED NOT IMMEDIATELY, BUT OVER TIME, E.G. WHEN AN UNDIAGNOSED PARTIAL PERFORATION DURING INSERTION GRADUALLY LEADS TO A COMPLETE PERFORATION. OFTEN MIGRATION IS REPORTED WHEN THE EXACT TIME POINT OF PERFORATION IS NOT KNOWN. SOMETIMES MIGRATION THROUGH THE FALLOPIAN TUBE IS SUSPECTED BY THE REPORTER, BECAUSE THE ESSURE INSERT IS FOUND IN THE ABDOMEN AND NO APPARENT PERFORATION CAN BE IDENTIFIED. THEREFORE, BASED ON THE INFORMATION PROVIDED AND POSSIBLE MECHANISM OF MIGRATION, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

THIS IS A CORRECTION TO THE INITIAL REPORT SUBMITTED AUGUST 3, 2015, THE 'DATE RECEIVED BY MANUFACTURER" HAS BEEN UPDATED FROM 06/06/2015 TO THE CORRECT DATE OF 07/06/2015. DATE WAS REPORTED ACCURATELY IN 'DESCRIBE EVENT OR PROBLEM' OF INITIAL REPORT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00566	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B04948

Single Use: Y
Implant Date (E6): 10/14/2013
Explant Date (E7): 4/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042314) IN UNITED STATES ON 06-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBERS B04948 AND 1365832, INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT SHE HAS HAD CHRONIC PAIN IN HER ABDOMEN, FATIGUE AND SWOLLEN ABDOMEN. ULTRASOUND SHOWED HER DEVICE MIGRATED INTO HER UTERUS AND, ACCORDING TO CONSUMER, SHE WAS HAVING A FULL HYSTERECTOMY TO REMOVE THE DEVICES AT THE DAY OF THE REPORT (EXPLANT DATE: (B)(6) 2015). FOLLOW-UP RECEIVED ON 15-JUL-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: B04948; PRODUCTION DATE: FEB-2013; EXPIRATION DATE: 29-FEB-2016. LOT NUMBER 1365832 IS INVALID. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 9 FURTHER AE CASE

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REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED VALID BATCH, OF WHICH (B)(4) CASES REFER ALSO TO SIMILAR TYPES OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. IN ADDITION, THE AE CASE REFERS TO THE LOT NUMBER 1365832, WHICH IS INVALID ACCORDING TO THE RESPONSIBLE QUALITY UNIT (RQU). THE BATCH DOCUMENTATION OF THE REPORTED VALID BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND U/S SHOWED HER DEVICE MIGRATED INTO HER UTERUS. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE REQUIRED INTERVENTION AND MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MIGRATE OUT OF FALLOPIAN TUBES. IN THIS PARTICULAR CASE, U/S SHOWED THAT THE DEVICE MIGRATED INTO HER UTERUS AND SHE WAS HAVING A FULL HYSTERECTOMY TO REMOVE THE MICRO-INSERTS. CONSIDERING THE NATURE OF EVENT, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION CANNOT BE REQUESTED. TWO BATCH NUMBERS WERE REPORTED. BATCH NUMBER 1365832 WAS CONSIDERED AS INVALID. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

THIS IS A CORRECTION TO THE INITIAL REPORT SUBMITTED AUGUST 3, 2015, THE 'DATE RECEIVED BY MANUFACTURER" HAS BEEN UPDATED FROM 06/06/2015 TO THE CORRECT DATE OF 07/06/2015. (B)(4).

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00567	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 755529

Single Use: Y
Implant Date (E6): 4/11/2011
Explant Date (E7): 2/16/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (#MW5042295) IN UNITED STATES ON 06-JUL-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 (LOT NUMBER 755529). CONSUMER REPORTED THAT ESSURE IMPLANTED EARLY 2011 AND AFTER 3 MONTHS STARTED HAVING SEVERE ABDOMINAL AND PELVIC PAIN, DIGESTIVE ISSUES, ENERGY LOSS, AND CONSTANT AND SEVERE MENSTRUAL BLEEDING. GASTROINTESTINAL WAS SUSPECTED CAUSE AND SHE WAS SEEN BY TWO DIFFERENT GASTROINTESTINAL SPECIALISTS AND A GENERAL SURGEON WHO GAVE HER 4 LOWER ENDOSCOPIES, TWO UPPER ENDOSCOPIES, AND A CAPSULE ENDOSCOPY. SHE ALSO HAD TO SEE PAIN MANAGEMENT AS SHE WAS ON SOME PRETTY POWERFUL PAIN KILLERS JUST TO FUNCTION AND WAS DIAGNOSED WITH PEPTIC ULCERS AND POSSIBLE JEJUNOILEITIS. CONSUMER MENTIONED THAT BEFORE ESSURE, SHE WAS COMPLETELY HEALTHY. FINALLY AN EMERGENCY ROOM DOCTOR HELPED HER AND GOT A REFERRAL FOR HER TO A GYNECOLOGIST SPECIALIST IN 2015. SHE HAD A LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY WITH A BILATERAL SALPINGECTOMY TO REMOVE BOTH ESSURE COILS ON (B)(6) 2015 AND WHAT THEY HAD AFFECTED. HER PATHOLOGY REPORT REVEALED NUMEROUS CYSTS COVERING HER FALLOPIAN TUBES AND ONE CYST ON AN OVARY. SINCE HER HYSTERECTOMY, SHE HAS NOT HAD ANY PAIN AT ALL OR DIGESTIVE ISSUES, HER HAIR WAS NO LONGER FAILING OUT AND HER ENERGY LEVEL WAS RECOVERING. HER QUALITY OF LIFE HAS BEEN RETURNED TO HER. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: BATCH NUMBER 755529. PRODUCTION DATE: 6/2010. EXPIRATION DATE: 6/2013. SINCE NO PRODUCT WAS RETURNED TO US FOR

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INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH ONE CASE REFERS ALSO TO SIMILAR TYPES OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER 3 MONTHS STARTED HAVING SEVERE ABDOMINAL PAIN. SHE WAS DIAGNOSED WITH PEPTIC ULCERS. FOUR YEARS AFTER INSERTION SHE UNDERWENT HYSTERECTOMY AND SALPINGECTOMY TO REMOVE ESSURE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. ABDOMINAL PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE REMAINING EVENT IS UNLISTED. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. PEPTIC ULCERS ARE DEFECTS IN THE GASTRIC OR DUODENAL MUCOSA THAT EXTEND THROUGH THE MUSCULARIS MUCOSA. RISK FACTORS INCLUDE H. PYLORI INFECTION, DRUGS SUCH AS NONSTEROIDAL ANTI-INFLAMMATORY, LIFESTYLE FACTORS SUCH AS TOBACCO USE, SEVERE PHYSIOLOGIC STRESS, HYPERSECRETORY STATES, AND GENETIC FACTORS. CONSIDERING PEPTIC ULCER'S PATHOPHYSIOLOGY AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, THIS EVENT WAS ASSESSED AS UNRELATED TO ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY AND SALPINGECTOMY TO REMOVE ESSURE). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 14-OCT-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00568	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042261) IN UNITED STATES ON 06-JUL-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. CONSUMER REPORTED THAT SHE HAD ESSURE IMPLANTED IN 2006 AND, ACCORDING TO HER; THE DEVICE WAS ONLY SUCCESSFULLY IMPLANTED ON ONE SIDE. TWO MONTHS LATER, SHE HAD REVISION PROCEDURE WHEN THE ONE IMPLANTED WAS REMOVED AND A NEW ONE WAS INSERTED ALONG WITH THE SIDE THAT DID NOT HAVE DEVICE INITIALLY INSERTED. CONSUMER INFORMED THAT FOR THE LAST 2 YEARS SHE HAS BEEN EXPERIENCING EXCRUCIATING PAIN CAUSED BY THE ESSURE. SHE ALSO REPORTED THAT SHE IS NOT SEEKING A SECOND OPINION BY AN OBSTETRICIAN/GYNECOLOGIST SPECIALIST IN HOPES TO REMOVE THE DEVICE. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS

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REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ACCORDING TO HER, THE DEVICE WAS ONLY SUCCESSFULLY IMPLANTED ON ONE SIDE. SHE HAD REVISION PROCEDURE WHEN THE ONE IMPLANTED WAS REMOVED. THIS EVENT, CONSIDERED AS DEVICE MEDICAL REMOVAL, WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THIS CASE WAS REPORTED WITH LIMITED INFORMATION. ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE ADDED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 15-OCT-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00569	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/22/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (#MW5042352) IN UNITED STATES ON 06-JUL-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007. CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN 2007 AND SHORTLY AFTER SHE HAD HEAVY PERIODS AND PAINFUL CRAMPS. SHE HAS HAD ABDOMINAL PAIN HOSPITALIZED AND 2 SURGERIES IN 2012. SHE HAD HER RIGHT TUBE REMOVED BECAUSE IT WAS BENT AND BLOOD VESSEL WRAPPED AROUND IT CAUSING PAIN. SHE WAS STILL IN CONSTANT ABDOMINAL PAIN ALMOST DAILY. SHE HAS BEEN DIAGNOSED WITH ANEMIA WHEN SHE ASKED HER DOCTOR IN 2007 IF IT WAS SAFE TO PLACE THIS BECAUSE OF THE NICKEL SINCE SHE HAD REACTIONS TO NICKEL, HE SAID IT WAS FINE AND ESSURE HAD VERY MINIMAL AMOUNT OF NICKEL. SHE SUFFERED DAILY WITH HEAVY BLEEDING FILLING PADS AND TAMPONS WITH STILL LEAKING ON HER CLOTHES AND CRAMPS SO SEVERE THAT SHE COULD NOT FUNCTION. SHE HAS BEEN DIAGNOSED WITH MIGRAINES IN 2009. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 15-JUL-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE

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KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD RIGHT TUBE REMOVED BECAUSE IT WAS BENT AND BLOOD VESSEL WRAPPED AROUND IT (INTERPRETED AS FALLOPIAN TUBE DISORDER) AND EXPERIENCED PAINFUL CRAMPS (SO SEVERE) AND ABDOMINAL PAIN (CONSTANT). THE EVENT FALLOPIAN TUBE DISORDER WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND THE OTHER EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION. ONLY PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED PAIN DUE TO THE OCCURRENCE OF FALLOPIAN TUBE DISORDER. IT WAS NOT SPECIFIED WHAT EXACTLY OCCURRED AT RIGHT FALLOPIAN TUBE. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO HOSPITALIZATION AND REQUIRED INTERVENTION. ADDITIONALLY, ANOTHER SERIOUS EVENT (HEAVY BLEEDING FILLING PADS AND TAMPONS WITH STILL LEAKING ON HER CLOTHES) AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 15-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00570	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/12/2011
Explant Date (E7): 4/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA REGULATORY AUTHORITY (CASE# MW5042357) IN UNITED STATES ON 06-JUL-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 FOR PERMANENT BIRTH CONTROL. PHYSICIAN REPORTED THAT ESSURE COILS HAD PERFORATED ONE TUBE AND MIGRATED OUT OF THE OTHER EMBEDDING 2CM INTO UTERUS. ON (B)(6) 2015 ESSURE WAS EXPLANTED. FOLLOW UP 15-JUL-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO

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HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ESSURE COILS PERFORATED ONE TUBE AND THE OTHER ESSURE MIGRATED OUT OF TUBE EMBEDDING 2CM INTO UTERUS. BOTH EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. MIGRATION IS OFTEN USED SYNONYMOUSLY WITH PERFORATION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF BOTH EVENTS WERE NOT KNOWN, HOWEVER GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. IN THIS CASE, ESSURE WAS EXPLANTED, THUS THIS CASE WAS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 15-OCT-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00571	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/12/2011
Explant Date (E7): 4/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 06-JUL-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. PHYSICIAN REPORTED THAT ESSURE WAS PLACED ON (B)(6) 2011 AND STATES THAT PAIN AND ISSUES BEGAN WITHIN 6 MONTHS RELATING TO ESSURE. HEALTH CARE PROFESSIONAL REPORTED HIGH BLOOD PRESSURE, SEVERE TUBAL PAIN, HEAVY BLEEDING/PASSING CLOTS, MIGRAINES, WEIGHT GAIN, HAIR LOSS, LOSS OF LIBIDO, MOOD SWINGS AND MANY OTHER ISSUES. ON (B)(6) 2015, ESSURE DEVICE WAS EXPLANTED. IN ADDITION, THE SERIOUSNESS CRITERION "REQUIRED INTERVENTION" WAS REPORTED. HOWEVER, IT WAS NOT SPECIFIED FOR WHICH EVENT. PTC INVESTIGATION RESULTS WERE PROVIDED ON 15-JUL-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL

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ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WITHIN 6 MONTHS EXPERIENCED SEVERE TUBAL PAIN AND HEAVY BLEEDING (PASSING CLOTS). THESE EVENTS, SEEN AS ADNEXA UTERI PAIN AND GENITAL BLEEDING, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, SEVERE TUBAL PAIN, HEAVY BLEEDING (PASSING CLOTS) AND OTHER NON-SERIOUS ISSUES BEGAN 6 MONTHS AFTER PLACEMENT. ESSURE MICRO-INSERTS WERE THEN REMOVED. GIVEN POSITIVE TEMPORAL RELATIONSHIP AND THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. IT WAS INFORMED THAT ESSURE WAS REMOVED (INTERVENTION REQUIRED WAS IMPLIED) SO THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00572	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71766

Single Use: Y
Implant Date (E6): 2/14/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY FDA MAUDE (#MW5042368) IN UNITED STATES ON 06-JUL-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 (LOT NUMBER B71766). DURING HYSTEROSALPINGOGRAM TEST, ESSURE WAS FOUND TO BE TOO FAR INTO THE FALLOPIAN TUBES AND THE PROXIMAL END MARKER ON THE LEFT COIL APPEARED BROKEN OR SEPARATED FROM INNER COIL, ASSOCIATED PAIN WAS RESULTED IN THE LOCALIZED AREA. SINCE INSERTION, MENSTRUAL CYCLE HAS CONSISTED OF HEAVY BLEEDING WITH HEMORRHAGING, SOFT BALL SIZED BLOOD CLOTS AND PERIODS LASTING UP TO FOURTEEN DAYS. OVULATION ALSO CAUSED EXTREME LOWER BACK AND ABDOMINAL PAIN. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 14-JUL-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: B71766; PRODUCTION DATE: 12-SEP-2013; EXPIRATION DATE: 30-SEP-2016. FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO

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REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 08-JUL-2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING HYSTEROSALPINGOGRAM, ESSURE WAS FOUND TO BE TOO FAR INTO THE FALLOPIAN TUBES (DEVICE DISLOCATION) AND THE PROXIMAL END MARKER ON THE LEFT COIL APPEARED BROKEN OR SEPARATED FROM INNER COIL (DEVICE BREAKAGE). DEVICE DISLOCATION IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE DEVICE BREAKAGE IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS OR REMOVALS, ESSURE BREAKAGE MAY OCCUR. ALSO, THERE IS A RISK THAT THE MICRO-INSERTS COULD MOVE INTO THE FALLOPIAN TUBES. CONSIDERING THEIR NATURE, CAUSALITY BETWEEN THE REPORTED EVENTS AND ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. OTHER NON-SERIOUS EVENTS WERE INFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-56111	BAYER HEALTHCARE LLC	8/3/2015	8/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/22/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (#MW5042352) IN UNITED STATES ON 06-JUL-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007. CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN 2007 AND SHORTLY AFTER SHE HAD HEAVY PERIODS AND PAINFUL CRAMPS. SHE HAS HAD ABDOMINAL PAIN HOSPITALIZED AND 2 SURGERIES IN 2012. SHE HAD HER RIGHT TUBE REMOVED BECAUSE IT WAS BENT AND BLOOD VESSEL WRAPPED AROUND IT CAUSING PAIN. SHE WAS STILL IN CONSTANT ABDOMINAL PAIN ALMOST DAILY. SHE HAS BEEN DIAGNOSED WITH ANEMIA WHEN SHE ASKED HER DOCTOR IN 2007 IF IT WAS SAFE TO PLACE THIS BECAUSE OF THE NICKEL SINCE SHE HAD REACTIONS TO NICKEL, HE SAID IT WAS FINE AND ESSURE HAD VERY MINIMAL AMOUNT OF NICKEL. SHE SUFFERED DAILY WITH HEAVY BLEEDING FILLING PADS AND TAMPONS WITH STILL LEAKING ON HER CLOTHES AND CRAMPS SO SEVERE THAT SHE COULD NOT FUNCTION. SHE HAS BEEN DIAGNOSED WITH MIGRAINES IN 2009. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT RECEIVED ON 15-JUL-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE

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KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD RIGHT TUBE REMOVED BECAUSE IT WAS BENT AND BLOOD VESSEL WRAPPED AROUND IT (INTERPRETED AS FALLOPIAN TUBE DISORDER) AND EXPERIENCED PAINFUL CRAMPS (SO SEVERE) AND ABDOMINAL PAIN (CONSTANT). THE EVENT FALLOPIAN TUBE DISORDER WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND THE OTHER EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION. ONLY PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED PAIN DUE TO THE OCCURRENCE OF FALLOPIAN TUBE DISORDER. IT WAS NOT SPECIFIED WHAT EXACTLY OCCURRED AT RIGHT FALLOPIAN TUBE. BASED ON THE INFORMATION PROVIDED, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO HOSPITALIZATION AND REQUIRED INTERVENTION. ADDITIONALLY, ANOTHER SERIOUS EVENT (HEAVY BLEEDING FILLING PADS AND TAMPONS WITH STILL LEAKING ON HER CLOTHES) AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044951	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 3/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4.)I HAD THE ESSURE DEVICE PLACED ON THE DATE ABOVE. I BLED FOR TEN MONTHS STRAIGHT. I PASSED CLOTS BIGGER THAN MY HAND. I WAS IN CONSTANT LOW TO MID LEVEL PAIN THAT WOULD OCCASIONALLY SPIKE TO SUCH PAIN THAT I COULD NOT MOVE. I VISITED THE EMERGENCY ROOM AT LEAST 7 TIMES WHILE I HAD THE ESSURE. I CALLED MY DOCTOR WHEN I BEGAN PASSING LARGE CLOTS AND THE NURSE ON CALL SAID THAT WAS FINE. I VISITED MY DOCTOR WHEN THE BLEEDING DIDN'T STOP AND SHE GAVE ME BIRTH CONTROL PILLS. I HAD THE ESSURE REVERSED ON (B)(6) 2014. I HAD TO TAKE OUT A (B)(6) LOAN TO DO SO. I'VE NOW DEVELOPED RECURRENT CYSTS ON BOTH OVARIES AND MY RIGHT KIDNEY. THE MOST RECENT CYST WAS DETECTED ON FRIDAY AND THEY SAID IT IS A COMPLEX CYST THAT MUST BE MONITORED IN CASE SURGICAL REMOVAL IS REQUIRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044952	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 3/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD CONSISTENT OVARIAN CYST RUPTURES. FLUID LEAKING FROM MY OVARIES. I HAVE GAINED A VERY LARGE AMOUNT OF WEIGHT. MY HAIR IS FALLING OUT. I HAVE NEVER ENDING METALLIC TASTE IN MY MOUTH. SEVERE STOMACH PAIN THAT NEVER GOES AWAY. SEVERE ITCHING AND RASH ON STOMACH WHERE MY OVARIES ARE AND THEN I HAVE PUS POCKETS APPEAR AND RUPTURE IN SAME PLACE. NEVER ENDING BODY PAIN LEG AND ARM CRAMPS. VISION CHANGES. SEVERE HEADACHES. CRAWLING SKIN EXTREME FACIAL AND BODY TWITCHING. HANDS MOUTH AND FEET TURN BLUE. CONSTANT SWOLLEN STOMACH. ANXIETY. AGITATION. MOOD SWINGS EXTREME NIGHT SWEATS INTOLERANCE TO HOT AND COLD TEMPERATURES. UNEXPLAINED FEVERS ESPECIALLY AT NIGHT. CONSTANT COLD AND FLUE SYMPTOMS EVEN THOUGH I DONT HAVE EITHER ONE. CONSTANT COUGH. SENSITIVITY TO SMELLS. SORE AND RECEDING GUMS . INSOMNIA. TINGLING AND NUMBNESS IN EXTREMITIES. EXTREME BRAIN FOG AND FORGETFULNESS. INTOLERANCE TO MEDICATIONS. EXTREME FATIGUE. SKIN PROBLEMS HOT BURNING RASHES. CLEAR FLUID FILLED BLISTERS THAT APPEAR ON FINGERS FEET AND BACK OF NECK. DEGENERATIVE BONE DISEASE. COATED TONGUE. ALLERGIES TO INSECT BITES THAT I WASN'T ALLERGIC TO BEFORE. CANT LOOSE WAIT JUST KEEP GAINING EVERY YEAR SINCE IT WAS PUT IN ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044953	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 1/16/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, DIZZINESS, SEVERE MIGRANT, BACK PAIN, HIVES, INFLAMMATION, PAIN INTERCOURSE, PERFORATION TUBE INFECTION, BACTERIA AND LIVER ABSCESSES, APPENDIX, CONSTIPATION,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044954	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 5/4/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT TO MY OB/GYN COMPLAINING OF CONTINUAL ABDOMINAL PAIN. ALL OF THE TESTING WAS NEGATIVE FOR ENDOMETRIOSIS OR OTHER AILMENTS THAT WOULD CAUSE PAIN. MY DOCTOR SAID I NEEDED TO GET A SPINAL NERVE ABLATION DUE TO PAIN. I BELIEVE NOW THIS WAS CAUSED BY ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044955	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 6/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INTENSE CRAMPING PAIN SIMILAR TO GIVING BIRTH. DAILY CRAMPING PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044956	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 5/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE IMPLANTED, MY HEALTH HAS CONTINUALLY GOTTEN WORSE. SYMPTOMS/SIDE EFFECTS I HAVE EXPERIENCED INCLUDE: PALPITATIONS,ANXIETY,DEPRESSION,MEMORY LOSS, FORGETFULNESS, EASILY BRUISED,SPIDER VEINS, WEIGHT GAIN,BACTERIAL VAGINOSIS, YEAST INFECTIONS,ACNE, BOILS, DRY SKIN, EXCESSIVE SWEATING,HAIR LOSS,IMMUNE ISSUES, INCREASED SEVERITY OF RHEUMATOID ARTHRITIS AND FIBROMYALGIA, SWELLING OF LEGS, FEET AND HANDS, SWOLLEN GLANDS,ABDOMINAL SPASMS,MUSCLE SPASMS, CHARLIE HORSES,DIZZINESS, BRAIN SHOCKS,SEVERE MIGRAINES, TINGLING, ITCHING, BURNING, PAINFUL NUMBNESS, FOUL DISCHARGE, SPOTTING AND PAINFUL INTERCOURSE, CYST LIKE LUMPS ON VAGINA, PAINFUL OVULATION AND MENSES TIME, CHRONIC PELVIC PAIN, THE FEELING OF CONTRACTIONS, SHARP STABBING PELVIC PAIN, UNABLE TO ORGASM, LOSS OF LIBIDO,BACK PAIN, BODY ACHES AND PAIN, HIP PAIN, JOINT PAIN, BLOATING, CONSTIPATION, DIARRHEA, BOWEL IRREGULARITY, GASTRITIS, GERD, NAUSEA, SOMETIMES VOMITING, FREQUENT URINATION, INCONTINENCE, HAVE TO FORCE TO EMPTY BLADDER, DENTAL ISSUES, FEVERS, INSOMNIA, METALLIC TASTE,NIGHT SWEATS, VITAMIN D AND B12 DEFICIENCY, WEIGHT GAIN, CHRONIC FATIGUE SYNDROME,, RHEUMATOID ARTHRITIS, FIBROMYALGIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044957	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 10/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT THIS TIME, I STARTED HAVING CRAMPS IN MY LEFT PELVIC AREA THAT COINCIDED WITH OVULATION. THE CRAMPS WERE INTERMITTENT UNTIL (B)(6) WHEN AN EXCRUCIATING PAIN WENT SHOOTING THROUGH THE SAME AREA, BRINGING ME TO MY KNEES. THE PAIN WAS SO INTENSE FOR ABOUT 15 MINUTES THAT IT WAS HARD TO BREATHE. I WENT TO MY OB/GYN THE NEXT DAY, AND HE DETERMINED I'D HAD A CYST RUPTURE. THERE WAS NO CYST ON MY LEFT OVARY BEFORE THE ESSURE. I HAVE HAD A CYST ON MY RIGHT OVARY (SMALL) SINCE A MISCARRIAGE IN 1996.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044958	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 3/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BACK PAIN, JOINT PAIN,FATIGUE, MUSCLE WEAKNESS, SPOTTING ALL MONTH, SOMETIMES NO MENSTRUAL CYCLE, LAST A LOT LONGER THEN BEFORE ESSURE, FREQUENTLY/URGENCY URINATION. STOMACH BLOATING TROUBLE LOSING WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044959	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 6/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED (B)(6) 2012. I HAVE HAD MULTIPLE ISSUES, BUT NO DOCTOR CONTRIBUTES TO ESSURE. IN FACT, I REALLY BELIEVE A LOT OF MY ISSUES WERE DUE TO AGE (I AM (B)(6)) AND ALSO I HAD GASTRIC BYPASS SURGERY PRIOR TO ESSURE. ANYWAY, MY PERIODS WERE VERY REGULAR FOR THE YEARS POST OP, BUT DID LEAN TOWARD THE HEAVIER SIDE. BUT NOTHING I COULD NOT HANDLE. OUT OF NOWHERE, THIS LAST PERIOD LASTED FOR 2 WEEKS, VERY HEAVY AND PAINFUL. I WENT TO THE DOCTOR AND SHE ORDERED AN ULTRASOUND WHICH SHOWED A COMPLEX OVARIAN CYST ON AN OVARY AND ALSO POLYPS INSIDE THE UTERUS. DUE TO THE BLEEDING AND THICKNESS OF THE WALL, THEY COULD NOT SEE FOR SURE, SO THEY RECOMMENDED I TAKE LYSTEDA FOR A FEW DAYS, WHICH DID STOP THE BLEEDING, THEN GO ON PROGESTERONE FOR 5 DAYS TO INDUCE ANOTHER PERIOD TO CORRECT MY CYCLE THEN AT THE NEXT PERIOD IN (B)(6) OR SO, ON THE 5TH TO 9TH DAY OF THAT PERIOD COME IN FOR ANOTHER ULTRASOUND BECAUSE MY WALL WILL BE THINNED OUT. WELL, I FINISHED MY PROGESTERONE LAST WEEK AND HAD A PERIOD THAT WAS PAINFUL AND HEAVY AGAIN SO I CALLED THEM TODAY (THREE DAYS OF CLOTTED PERIOD) AND THEY SAID TO TAKE THE LYSTEDA AGAIN AND THEY WANT TO SCHEDULE A D+C TO EXAMINE EVERYTHING FURTHER AND SCRAPE MY UTERINE WALLS. I REALLY DO LIKE MY PRACTICE AND TRUST THEM. SO I AM NOT NAY SAYING THEIR CREDIBILITY. UGH. ANOTHER MAJOR ISSUE I HAVE HAD WHICH HAS RECENTLY GOTTEN WORSE OVER THE YEARS IS JOINT PAIN, ESPECIALLY IN MY HANDS. I WAS TESTED FOR RA AND THOUGHT IT WAS A VITAMIN D DEFICIENCY, BUT IT WAS CORRECTED AND THE STIFFNESS IN MY JOINTS HAVE BEEN PROGRESSIVE AND I AM SEEING A RHEUMATOLOGIST IN AUGUST. THEY CAN'T FIGURE OUT WHY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044960	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 6/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED (B)(6) 2012. I HAVE HAD MULTIPLE ISSUES, BUT NO DOCTOR CONTRIBUTES TO ESSURE. IN FACT, I REALLY BELIEVE A LOT OF MY ISSUES WERE DUE TO AGE (I AM (B)(6)) AND ALSO I HAD GASTRIC BYPASS SURGERY PRIOR TO ESSURE. ANYWAY, MY PERIODS WERE VERY REGULAR FOR THE YEARS POST OP, BUT DID LEAN TOWARD THE HEAVIER SIDE. BUT NOTHING I COULD NOT HANDLE. OUT OF NOWHERE, THIS LAST PERIOD LASTED FOR 2 WEEKS, VERY HEAVY AND PAINFUL. I WENT TO THE DOCTOR AND SHE ORDERED AN ULTRASOUND WHICH SHOWED A COMPLEX OVARIAN CYST ON AN OVARY AND ALSO POLYPS INSIDE THE UTERUS. DUE TO THE BLEEDING AND THICKNESS OF THE WALL, THEY COULD NOT SEE FOR SURE, SO THEY RECOMMENDED I TAKE LYSTEDA FOR A FEW DAYS, WHICH DID STOP THE BLEEDING, THEN GO ON PROGESTERONE FOR 5 DAYS TO INDUCE ANOTHER PERIOD TO CORRECT MY CYCLE THEN AT THE NEXT PERIOD IN AUGUST OR SO, ON THE 5TH TO 9TH DAY OF THAT PERIOD COME IN FOR ANOTHER ULTRASOUND BECAUSE MY WALL WILL BE THINNED OUT. WELL, I FINISHED MY PROGESTERONE LAST WEEK AND HAD A PERIOD THAT WAS PAINFUL AND HEAVY AGAIN SO I CALLED THEM TODAY (THREE DAYS OF CLOTTED PERIOD) AND THEY SAID TO TAKE THE LYSTEDA AGAIN AND THEY WANT TO SCHEDULE A D+C TO EXAMINE EVERYTHING FURTHER AND SCRAPE MY UTERINE WALLS. I REALLY DO LIKE MY PRACTICE AND TRUST THEM. SO I AM NOT NAY SAYING THEIR CREDIBILITY. UGH. ANOTHER MAJOR ISSUE I HAVE HAD WHICH HAS RECENTLY GOTTEN WORSE OVER THE YEARS IS JOINT PAIN, ESPECIALLY IN MY HANDS. I WAS TESTED FOR RA AND THOUGHT IT WAS A VITAMIN D DEFICIENCY, BUT IT WAS CORRECTED AND THE STIFFNESS IN MY JOINTS HAVE BEEN PROGRESSIVE AND I AM SEEING A RHEUMATOLOGIST IN AUGUST. THEY CAN'T FIGURE OUT WHY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044961	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 9/12/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY CLOTTED PERIODS, BACK PAIN, JOINT PAIN, ANXIETY, INSOMNIA, BLOATING, URINARY PROBLEMS, HAD TO HAVE DANDAMP;C DUE TO LINING NOT SHEDDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044962	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 3/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME ABDOMINAL PAIN, MAJOR BLOATING, EXTREME HAIR LOSS, ABNORMAL BLOOD CLOTTING MENSES, RECTAL BLEEDING, ANEMIA, BONE FATIGUE, DEPRESSION, ANXIETY, FOGGY MEMORY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044963	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 4/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS ADVISED BY OB/GYN THAT ESSURE WOULD BE THE BEST OPTION FOR PERMANENT BIRTH CONTROL FOR ME. I WAS INFORMED IT WAS FAST/EASY, VIRTUALLY PAINLESS, AND PERMANENT. IT WAS NONE OF THESE, IN MY CASE. THE PROCEDURE WAS HORRIFIC. NEARLY 3 HOURS OF CONSTANT CONTRACTING AND PAIN. IT TOOK NEARLY 2 HOURS TO GET LEFT COIL INSERTED. THE RIGHT COIL WENT QUICKER, AT JUST AROUND 10 MINUTES. AFTER PROCEDURE, I EXPERIENCED A VAGEL RESPONSE, UNABLE TO MOVE ANY OF MY JOINTS, AND COULD NOT BREATHE. ABOUT 30 MINUTES LATER I WAS ABLE TO SIT UP AND GET DRESSED. I WAS EXHAUSTED AND STILL CRAMPING. I WAS NOT GIVEN THE DEPO SHOT UNTIL THE FOLLOWING WEEK. 3 WEEKS AFTER IMPLANT, I STARTED BLEEDING AND EXPERIENCING PAIN/PRESSURE IN MY RIGHT SIDE. I CALLED NURSE WHO SAID IT'S POSSIBLY FROM DEPO SHOT. AFTER ANOTHER 2 WEEKS OF BLEEDING (FRESH BRIGHT RED BLOOD) I CALLED AND DEMANDED TO BE SEEN. I WENT IN ON (B)(6) TO DISCUSS MY SYMPTOMS. IMPLANT DOC SAID HE WAS CONCERNED DUE TO THE WAY THE PROCEDURE ITSELF WENT. THAT HE CONSULTED WITH HIS PARTNER AND THEY PLANNED TO SCHEDULE A 3D ULTRASOUND FOR FOLLOWING WEEK. HOWEVER, 2 DAYS LATER, ON (B)(6), I USED THE RESTROOM AND AS I PULLED OUT MY TAMPON, I SEE A HUGE BLOOD CLOT WITH ONE OF THE COILS ATTACHED. I WAS UNABLE TO REACH MY OB, SO VISITED ER TO MAKE SURE I WASN'T BLEEDING INTERNALLY. THEY DID US AND VAG US, DETERMINED I WAS NOT BLEEDING INTERNALLY, HOWEVER, COULD NOT CONFIRM THE LOCATION OF REMAINING COIL. I CALLED OB ON MONDAY MORNING, ((B)(6)) AND EXPLAINED SITUATION. HE WAS OBVIOUSLY CONCERNED DUE TO THE WHOLE PROCEDURE AND OFFERED TO PERFORM REMOVAL SURGERY "AT NO COST". I OPTED FOR 2ND OPINION FROM ANOTHER DOCTOR, AS MY CONFIDENCE IN IMPLANT DOC WAS DIMINISHED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

NEW DOCTOR ADVISED MY UTERUS WAS PROLAPSED, AS WELL, AND ADVISED LAVH SURGERY WOULD BE REQUIRED TO REMOVE REMAINING COIL AND SOLVE PROLAPSED UTERUS. SURGERY WAS (B)(6) 2015, 63 DAYS AFTER IMPLANT OF ESSURE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044964	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 12/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD CHRONIC PELVIC AND LOWER BACK PAIN THAT DID NOT END. AS WELL AS CONSTANT VAGINAL BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044965	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 2/12/2009 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PIERCING PAIN IN BOTH SIDES. MISCARRIAGE 3 YEARS LATER. HAIR LOSS, BLOATING, HORRIBLE PAIN, PAINFUL INTERCOURSE, ANOTHER MISCARRIAGE AND RUPTURED FALLOPIAN TUBE. REMOVAL OF BOTH FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044966	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 2/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE PROCEDURE (WITHIN 2 WEEKS AND SINCE THAT PERIOD), I HAVE EXPERIENCED PROFOUNDLY HEAVY BLEEDING DURING MY MENSTRUAL CYCLES. DURING THE FIRST TWO DAYS OF EACH CYCLE, I CANNOT EVEN STAND UP BECAUSE THE BLOOD IS EQUAL TO THAT OF A MISCARRIAGE. IN ADDITION, I SUFFER FROM SEVERE AND FREQUENT MIGRAINES (AT LEAST 6-7 PER MONTH). I HAVE ALSO SUFFERED SEVERE BLOATING AND DESPITE WEIGHT LOSS, MY STOMACH DISTENDS AS IF I AM 5 MONTHS PREGNANT, WHICH DID NOT OCCUR WITH ANY OF MY FIVE PREGNANCIES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044967	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 6/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, BLEEDING, PAIN OVULATING, CHRONIC PELVIC PAIN, CHRONIC JOINT PAIN, HEADACHES/MIGRAINES/EYE TWICHING, FLOATERS. CHRONIC FATIGUE, BLOATING, WEIGHT GAIN, HOT FLASHES, SHARP/STABBING PELVIC PAIN, SPOTTING BLEEDING AFTER SEX, LOSS OF LIBIDO, UNABLE TO ORGASM, ITCHING BURNING STINGING STABBING OF VAGINAL ENTRANCE, URGENT FREQUENT URINATION, BREAST PAIN/TENDERNESS. ABDOMINAL FLUTTERINGS. HIP PAIN, BACK, ARM, HAND, LEG, NECK AND FEET PAINS. FACE PAIN TEETH PAIN, NAUSEA, GAS, DIARRHEA, METALLIC TASTE IN MOUTH, HEARTBURN. BRAINSHOCKS, ANXIETY, PANIC ATTACKS, DEPRESSION, BRAIN FOG, DIZZINESS, VERY HIGH BLOOD PRESSURE, ALLERGIES FACE SWELLING/HEIGHTENED HAYFEVER SYMPTOMS, CYSTS, FOOD ALLERGIES, SKIN ITCHING, METAL ALLERGIES CANT WEAR JEWELLERY ANYMORE, DERMATITIS, HAIR LOSS, INSOMNIA, FEVERS/CHILLS, SWEATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044968	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 4/7/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDA MW5044968 #(B)(4). HAD A HYSTERECTOMY ON (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044971	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 4/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWELLING OF HANDS, FEET, AND LEGS. PELVIC PAIN, ABNORMAL BLEEDING, CYST ON OUTSIDE OF VAGINA, BOIL ON BACK OF EAR, BLEEDING DURING INTERCOURSE, EXCESSIVE FATIGUE, DIZZINESS, FORGETFULNESS, VERTIGO, DEPRESSION, ANXIETY ATTACKS, NUMBNESS OF THE FACE, TINGLING IN HANDS AND FEET, JOINT PAIN, HIP PAIN, HEADACHES, PREGNANCY SYMPTOMS, WEIGHT GAIN, CRAMPING OF HANDS AND FEET, BRAIN FOG, MEMORY LOSS, HIVES,UTI, BACTERIAL VAGINOSIS, YEAST INFECTIONS, BREAST TENDERNESS ALL THE TIME, PAINFUL OVULATION, HOT FLASHES, FOUND OUT ALLERGIC TO NICKEL, BURSITIS IN BOTH KNEES, UNABLE TO STAND FOR LONG PERIODS OF TIME, VITAMIN D DEFICIENCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044973	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 11/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ENDOMETRIOSIS, CHRONIC PELVIC PAIN, CONSTANT VAGINAL BLEEDING, BLOATING, HYPER THROID, WEIGHT GAIN/LOSS, MIGRAINES, LIGHT HEADNESS, SLEEP PROBLEMS, CHRONIC PAIN, EXTREME CRAMPING, SVT, FATIGUE, MUSCLE APATHY AND BLURRY VISION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044981	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 3/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING DURING MENSTRUATION, INTENSE PAIN IN ABDOMINAL AREA, WEIGHT GAIN, MIGRAINE WERE MADE WORSE, BODY ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044983	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 3/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS INSERTED WITH ESSURE (B)(4) 2012 WAS EXPERIENCING HEAVY BLEEDING THE DAY AFTER. PROBLEMS STARTED WITH BLEEDING THE FIRST YEAR OF INSERTION , NON STOPPED. CRAMPING WAS NEXT ONGOING PROBLEM . THEN THE PELVIC PAIN WITH IN THE FIRST YEAR. STARTING OF THE SECOND YEAR I HAVE EXPERIENCED THE FOLLOWING , GYNECOLOGICAL: DISCHARGE, HOT FLASHES, NIGHT SWEATS, PAINFUL OVULATION, LOSS OF LIBIDO, SPOTTING AFTER SEX, PAINFUL PERIODS , PAINFUL INTERCOURSE , YEAST INFECTIONS, BREAST TENDERNESS , ABDOMINAL SPASMS/FLUTTERING. PAIN: BACK , JOINT, BREAST, HIP. GASTROINTESTINAL: NAUSEA, CONSTIPATION, SEVERE BLOATING , METALLIC TASTE IN MOUTH. NEUROLOGICAL: HEADACHES AND MIGRAINES , DIZZINESS, TINGLING SENSATIONS , NUMBNESS, NERVE PAIN , BRAIN FOG, ANXIETY , PANIC ATTACKS , MOOD SWINGS, DEPRESSION, RINGING IN EARS, FAINTING, TINGLING IN EXTREMITIES. BLOOD ISSUES: IRON DEFICIENCY. ALLERGIES: NICKEL, SKIN IRRITATION. HEART : HEART PALPITATIONS. OTHER: HAIR LOSS, WEIGHT ISSUES , SWOLLEN GLANDS , MUSCLE SPASMS , VISION PROBLEMS , EXCESSIVE SWEATING , DRY SKIN / HAIR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044984	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 9/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GOT BAD MIGRAINES SO BAD I COULD NOT FUNCTION. THEN STARTED NOTICING THIS PAST YEAR I'VE BEEN HAVING BAD DEPRESSION MOOD SWINGS MY MENSTRUAL CYCLE IS GETTING MORE AND MORE UNBEARABLE AS MONTHS GO BY. I HAVE BEEN GETTING CRAMPS THIS PAST MONTH WHEN I'M NOT CLOSE TO MENSTRUAL CYCLE AND IT GETS SO BAD I HAVE TO STOP WHAT I'M DOING TO LET IT PASS AND THEN CONTINUE WHAT I'M DOING. I HAVE HAD IN THE PAST YEAR AND GETTING MORE FREQUENT DIZZY SPELLS I FEEL LIKE I'M GONNA PASS OUT. AT TIMES I FEEL LIKE MY HEART IS GONNA STOP BEATING WHILE I'M AT REST. RECENTLY I HAVE NOTICED MORE PAINS IN MY BACK SHOULDERS NECK FEET HANDS TO WHERE I CAN'T ENJOY MY DAY WITHOUT PAIN. I HAVE A (B)(6) YEAR OLD AND A (B)(6) YEAR OLD AND I CAN'T ENJOY PLAYING WITH THEM WITHOUT ANY TYPE OF PAIN. I HAVE GOOD DAYS WHEN IT'S NOT TOO BAD AND I HAVE BAD DAYS WHERE I DON'T KNOW WHO I AM ANYMORE. I WAS BORN WITH CHRONIC KIDNEY DISEASE AND WAS TOLD THIS PROCEDURE WAS THE BEST FOR ME AND MY HEALTH BUT LATELY IT'S SEEMS LIKE IT WAS THE WORST. I WAS FINE TILL I HAD THIS DONE AND WAS TOLD NO SIDE EFFECTS JUST CRAMPING AFTER THE PROCEDURE AND I WOULD BE FINE. I HAVE SINCE MOVED TO A DIFFERENT STATE I HAVE NO MEDICAL INSURANCE AND CAN NOT SEE A DOCTOR TO GET THIS TAKEN CARE OF. I CAN'T WORK. I HAVE NOT BEEN ABLE TO GET MY MEDICATIONS FOR MY BLOOD PRESSURE OR MY THYROID AND I DON'T KNOW IF I HAVE ANYTHING NEW WRONG WITH ME SINCE ITS BEEN 3 YEARS SINCE I HAVE SEEN A DOCTOR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5044985	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 9/25/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HEADACHE BACK PAIN LOWER ABDOMEN PAIN NAUSEA HEAVIER PERIODS MORE THEN 7 DAYS SOMETIMES 2 A MONTH DEPRESSED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045010	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 6/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DISCOVERED A THYROID NODULE. WENT TO SEE A DOCTOR AND WAS FOUND TO HAVE THYROIDITIS AND HYPO,HYPER THYROID. SINCE THEN I HAVE BEEN DIAGNOSED WITH HASHIMOTO'S THYROIDITIS, SLEEP APNEA AND I HAVE HAD IRREGULAR AND PAINFUL PERIODS, RECENTLY THESE HAVE TURNED INTO NON EXISTENT PERIODS WITH ONLY DARK BROWN SPOTTING AND PASSING OF BLOOD CLOTS SPORADICALLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045011	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PLACEMENT 2 WEEKS LATER INTENSE ABDOMINAL PAIN BLOATING UNABLE TO URINATE DIZZY NAUSEAS REQUIRED HOSPITALIZATION HAS IT REMOVED THEY LEFT ONE SPRING IN MY RIGHT ABDOMEN THAT WAS FLOATING AND I WAS STILL VERY ILL HAD THAT ONE REMOVED AND SURPRISE WENT TO HAVE POST OP XRAY AND SPRING WAS NOW FLOATING ON LEFT SIDE OF ABDOMEN AGAIN ANOTHER SURGERY. HAVE SINCE NEEDED GALLBLADDER REMOVAL DUE TO ADHESIONS ONGOING BLADDER INFECTIONS AND VAGINAL INFECTIONS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045012	BAYER	8/3/2015	8/3/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BREAST PAIN/TENDERNESS WITH EVERY PERIOD. VAGINITIS. SHARP/STABBING PELVIC PAIN THAT HAPPENS RANDOMLY. TESTED TWICE FOR CERVICAL CANCER ONE CAME OUT POSITIVE WHICH LEAD TO ME GETTING MY CERVIX SCRAPPED TO CHECK AGAIN FOR CAME OUT NEGATIVE. UTI. SEVERE BLOATING BEFORE PERIODS. WEIGHT GAIN OF 30+ LBS SINCE BEING PUT IN, REGARDLESS OUT WORKING OUT AND DIETARY CHANGES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055276		8/3/2015	8/11/2015

Event Information:

Event Date (B3): 1/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): A45116

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MASSIVE WEIGHT GAIN, SEVERE CRAMPING, DIARRHEA, INSOMNIA, HEAVY BLEEDING, UTI, ANXIETY, DEPRESSION, PANIC ATTACKS, HAIR LOSS, SEVERE FATIGUE, SKIN IRRITATION, SEVERE MIGRAINES, RESTLESS LEGS, DIZZINESS, METALLIC TASTE IN MOUTH, NUMBNESS IN HANDS/LEGS, MAJOR BLOATING, BAD VISION, PAINFUL INTERCOURSE, SHORTNESS OR BREATH, SEVERE ACNE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00573	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY FDA MAUDE (#MW5042370) IN UNITED STATES ON 06-JUL-2015. IT REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER REPORTED THAT HER DOCTOR PLACED ESSURE AND SHE WENT THREE MONTHS LATER AND HAD TEST TO CONCLUDE BLOCKAGE. SHE IMMEDIATELY HAD UNEXPLAINED WEIGHT GAIN, RASHES, HAIR LOSS, PAIN, BLOATING. A YEAR LATER HAD SEVERE NON-STOP PAIN, DEBILITATING CHRONIC FATIGUE AND PAIN ON A DAILY BASIS. IN 2013 SHE WAS ELECTROCUTED AND THE ESSURE COILS KEPT THE CURRENT INSIDE OF HER INSTEAD OF IT LEAVING. SHE WAS AT THE HOSPITAL FOR SEVERAL DAYS RECOVERING FROM BURNS. CONSUMER HAD CONTINUED PAIN AND AS DIAGNOSED WITH FIBROMYALGIA AND CHRONIC FATIGUE SYNDROME. TWENTY TWO EMERGENCY ROOM VISITS LATER A DOCTOR LISTENED TO HER. SHE HAD A BILATERAL SALPINGECTOMY TO REMOVE TUBES AND COILS. LEFT COIL WAS INTACT IN FALLOPIAN TUBE AND THE RIGHT SIDE HAD PERFORATION. ALSO HER TUBES WERE NECROTIC AND BLACK FROM THE ALLERGIC REACTION TO THE NICKEL. SHE RECOVERED FROM THAT EMERGENCY SURGERY TO HAVE A SECOND TWO MONTHS LATER. HYSTERECTOMY BY EMERGENCY SURGERY TO REMOVE AN OVERSIZED UTERUS. THE PATHOLOGY REPORT STATED ADENOMYOSIS AND NECROSIS OF UTERUS. SHE JUST HAD AN APPENDECTOMY RULED SUSPICIOUS BC (INTERPRETED AS BECAUSE) HER APPENDIX WAS HUGELY ENLARGED BUT NO INFECTION. HER DOCTOR SEEMED TO BELIEVE IT WAS CAUSED BY STRAY PET FIBERS FROM THE ESSURE DEVICES. ALL SURGERIES WERE EMERGENCY, NO TIME TO PREPARE AND SHE ALMOST LOST LIFE ON THE OPERATING TABLE DURING HER SECOND SURGERY. SHE WAS ADMITTED FOR 16 DAYS DUE TO COMPLICATIONS AND SIDE EFFECTS OF ESSURE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 15-JUL-2015. THIS ADVERSE EVENT REPORT IS

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RELATED TO A PTC. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALLERGIC REACTION TO NICKEL. SHE WAS SUBMITTED TO A BILATERAL SALPINGECTOMY. DURING THE SURGERY, A PERFORATION WAS FOUND IN RIGHT FALLOPIAN TUBE. ADDITIONALLY, CONSUMER REPORTED BURN (AFTER BEING ELECTROCUTED), ADENOMYOSIS (REQUIRING HYSTERECTOMY) AND AN ENLARGED AND INFLAMED APPENDIX (REQUIRING SURGERY). THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY NICKEL ALLERGY AND FALLOPIAN TUBE PERFORATION ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY; WHICH MAY INDUCE ALLERGIC REACTIONS IN PATIENTS WITH NICKEL SENSITIVITY. IN THIS CASE, THE CONSUMER WAS SUBMITTED TO A SALPINGECTOMY MORE THAN ONE YEAR AFTER ESSURE PLACEMENT. ACCORDING TO HER, DURING THE SURGERY HER TUBES WERE FOUND NECROTIC AND BLACK DUE TO NICKEL ALLERGY AND ESSURE ON RIGHT SIDE HAD PERFORATED. MAJOR INCONSISTENCES WERE FOUND IN CONSUMER'S REPORT, SUCH AS THE TIMING BETWEEN NICKEL ALLERGY MANIFESTATIONS AND ESSURE INSERTION. ADDITIONALLY, FALLOPIAN TUBE NECROSIS IS NOT AN EXPECTED COMPLICATION OF NICKEL ALLERGY. FALLOPIAN TUBE NECROSIS USUALLY HAS AN ACUTE ONSET WITH SERIOUS COMPLICATIONS SUCH AS PERITONITIS; WHICH WERE NOT REPORTED IN THIS CASE. DESPITE THE LACK OF DETAIL AVAILABLE, THE ABSENCE OF MEDICAL CONFIRMATION AND REPORT INCONSISTENCIES TO PERFORM A COMPREHENSIVE CAUSALITY ASSESSMENT; THE INTERVENTION (SALPINGECTOMY) REPORTED BY THE CONSUMER, IS REGARDED AS A SERIOUS INJURY BY THE COMPANY. THEREFORE, THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

INTERNAL COMMUNICATION RECEIVED ON 07-DEC-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00574	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 12/5/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042395) IN UNITED STATES ON 06-JUL-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) BIRTH CONTROL DEVICE IMPLANTED IN 2007. CONSUMER STARTED HAVING ADVERSE REACTIONS SOON AFTER ESSURE INSERTION, WHICH INCLUDED LOW BACK PAIN, BOWEL ISSUES (INCLUDING DIARRHEA), LOSS OF BLADDER FUNCTION AND SEVERE ABDOMINAL PAINS THAT LASTED OVER MONTHS. FINALLY, IN (B)(6) 2014, SHE WAS ADMITTED TO THE HOSPITAL AFTER 3 EMERGENCY ROOM VISITS IN 10 DAYS WHERE HER OBSTETRICIAN/GYNECOLOGIST DID A LAPAROSCOPIC BILATERAL SALPINGECTOMY BECAUSE THE ESSURE COIL ON THE RIGHT SIDE HAD PERFORATED HER FALLOPIAN TUBE AND WAS STUCK TO HER COLON. ADDITIONALLY, CONSUMER INFORMED PAROXITINE AS CONCOMITANT MEDICATION. THE SERIOUSNESS CRITERION "OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)" WAS REPORTED. HOWEVER, IT WAS NOT SPECIFIED FOR WHICH EVENT. PTC INVESTIGATION RESULT WAS RECEIVED ON 15-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS

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CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS SUBMITTED TO A BILATERAL SALPINGECTOMY, 7 YEARS LATER, BECAUSE ESSURE COIL ON THE RIGHT SIDE HAD PERFORATED HER FALLOPIAN TUBE AND WAS STUCK TO HER COLON. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE PERFORATION OF THE UTERUS, FALLOPIAN TUBES AND INTERNAL BODILY STRUCTURES MAY OCCUR DURING ESSURE THERAPY DUE TO INSERT MIGRATION OR DURING INSERTION PROCEDURE (HYSTEROSCOPY OR ESSURE PLACEMENT). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE EVENT IS UNKNOWN; GIVEN ITS NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, OTHER NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE AN INTERVENTION (SALPINGECTOMY) WAS REQUIRED FOR EVENT'S TREATMENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 15-OCT-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00575	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/18/2014
Explant Date (E7): 4/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (B)(4) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. SHE REPORTED SYNTHROID AS CONCOMITANT MEDICATION. SHE REPORTED THAT SHE HAD SEVERE BACK PAIN AFTER ESSURE INSERTION FOR ABOUT 2 WEEKS. SHE THOUGHT SHE HAD JUST PULLED A MUSCLE ON THAT SIDE. ON 2015, SHE HAD THE HSG (HYSTEROSALPINGOGRAM) TEST DONE AND IT SHOWED THAT ONE OF THE COILS HAD MIGRATED OUT OF HER FALLOPIAN TUBE AND FELL BACK BEHIND HER UTERUS. ON (B)(6) 2015, SHE HAD SURGERY TO FIND AND REMOVE IT. FOLLOW UP 15-JUL-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HYSTEROSALPINGOGRAM (HSG) SHOWED ONE OF THE COILS HAD MIGRATED OUT OF HER FALLOPIAN TUBE AND FELL BACK BEHIND HER UTERUS. SHE UNDERWENT SURGERY TO FIND AND REMOVE IT 4 MONTHS AFTER INSERTION. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, THE HSG SHOWED ONE OF THE COILS HAD MIGRATED OUT OF THE TUBE AND FELL BACK BEHIND THE UTERUS. GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENT WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SURGERY TO FIND AND REMOVE THE COIL). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 12-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00576	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/24/2009
Explant Date (E7): 3/30/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER (ADULT (>=18Y AND <65Y) VIA REGULATORY AUTHORITY (CASE# MW5042327) IN UNITED STATES ON 06-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. SHE REPORTED THAT TAKE DILANTIN AS CONCOMITANT MEDICATIONS. CONSUMER STATED THAT THE INSERTION OF ESSURE WAS VERY PAINFUL AND OVER THE NEXT FEW YEARS SHE HAD LOW BACK PAIN, HEAVY PERIODS AND LONG PERIODS AND NO SEX DRIVE. SHE DID NOT RELATE THESE EVENTS TO ESSURE; HER PHYSICIAN THOUGHT THEY WERE DUE TO BEING PRE-MENOPAUSAL. SHE HAD ESSURE REMOVED IN (B)(6) 2015 AND THREE DAYS POST OP HER CHRONIC BACK PAIN WAS GONE. PTC INVESTIGATION RESULT WAS RECEIVED ON 15-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER

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BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LOW BACK PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSUMER STATED THAT SHE HAD ESSURE REMOVED AND THREE DAYS POST OPERATION, HER BACK PAIN WAS GONE. CONSIDERING THE INFORMATION RECEIVED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REMOVAL OF ESSURE. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00577	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06519

Single Use: Y
Implant Date (E6): 9/17/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 06-JUL-2015 WHICH REFERS TO (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014; THE LOT NUMBER USED WAS C06519. PHYSICIAN REPORTED THAT THE PATIENT WENT TO HIS OFFICE ON (B)(6) 2015 AND HANDED A PIECE OF METAL - A METAL PART AND STATED THAT IT WAS FROM THE ESSURE COIL. THE PIECE OF METAL EXPELLED FROM HER VAGINA. THE PATIENT SAID THIS WAS THE SECOND TIME THIS HAPPENED. THE PATIENT WAS OTHERWISE FINE - SHE HAD NO OTHER COMPLAINTS. PATIENT NEVER WENT FOR HSG (HYSTEROSALPINGOGRAM) SO THE PHYSICIAN WAS TELLING HER TO HAVE HSG TEST DONE. THE PHYSICIAN DID AN ULTRASOUND AND HE SAID HE COULD SEE THE ESSURE COILS. PTC INVESTIGATION RESULT RECEIVED ON 28-JUL-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. IN ADDITION, THE AE CASE REFERS TO TREATMENT NONCOMPLIANCE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND APPROXIMATELY ONE YEAR LATER; SHE HANDED HER DOCTOR A PIECE OF METAL - A METAL PART WHICH WAS EXPELLED FROM HER VAGINA. THE REPORTED EVENTS, REGARDED AS SUSPICION OF DEVICE BREAKAGE FOLLOWED BY DEVICE EXPULSION, WERE CONSIDERED NON-SERIOUS. DEVICE BREAKAGE IS LISTED ACCORDING TO TECHNICAL ANALYSIS AND DEVICE EXPULSION IS LISTED IN THE ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, THE PATIENT STATED SHE EXPELLED METALS FROM HER VAGINA TWO TIMES; SHE BELIEVED THESE METALS WERE ESSURE PARTS. HER PHYSICIAN PERFORMED AN ULTRASOUND AND HE COULD SEE THE ESSURE COILS; A HYSTEROSALPINGOGRAM (HSG) WAS REQUESTED. CONSIDERING AVAILABLE INFORMATION AND THEIR NATURE, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO SUSPICION OF DEVICE BREAKAGE, AS ALTHOUGH PATIENT HAD NO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 21-SEP-2015 VIA HEALTH CARE PROFESSIONAL QUESTIONNAIRE. PATIENTS INITIALS, WEIGHT AND HEIGHT WERE PROVIDED. CONCOMITANT CONDITION INCLUDED OVERWEIGHT (B)(6). ON UNSPECIFIED DATE SHE EXPERIENCED MENORRHAGIA AND WENT FO

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00578	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68117

Single Use: Y
Implant Date (E6): 6/4/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; THE LOT NUMBER USED WAS C68117 (EXPIRATION DATE JUN-2017). THE INSERTION OF ESSURE INSERTS INTO RIGHT FALLOPIAN TUBE; THE PROCEDURE PERFORMED WITHOUT INCIDENT. AT DELIVERY CATHETER REMOVAL AT TUBAL LEVEL, RELEASE OF PROXIMAL FRAGMENT OF THE INSERT (5 COILS) INTO UTERINE CAVITY OCCURRED. VISUALIZATION OF INSERT EXTREMITY AT TUBAL OSTIUM LEVEL WAS ZERO OUTER TRAILING COILS. CLINICAL CONSEQUENCES REPORTED WERE: SOFT CURETTAGE WITH CURETTE WAS REQUIRED LEADING TO FRAGMENT EXTRACTION. NO OUTER TRAILING COILS IN UTERINE CAVITY. IT WAS REPORTED THAT THE PROCEDURE WAS LONGER THAN USUAL. IT WILL BE NECESSARY TO PERFORM HYSTEROSALPINGOGRAPHY INSTEAD OF SIMPLE X-RAY WITHIN 3 MONTHS TO CONFIRM CORRECT TUBAL OCCLUSION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT DELIVERY CATHETER REMOVAL, RELEASE OF PROXIMAL FRAGMENT OF THE INSERT (5 COILS) IN UTERINE CAVITY (SEEN AS DEVICE BREAKAGE). THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 27-AUG-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00579	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 5/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE IS A SOLICITED CASE REPORT RECEIVED FROM A PHYSICIAN FROM (B)(6) ON 21-MAY-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 FOR DEFINITIVE CONTRACEPTION. THE PATIENT CONSULTED THE PHYSICIAN DUE TO A 6 WEEKS PREGNANCY. HE REVIEWED HER 3 MONTHS CONTROL PLAIN ABDOMEN; WHICH SHOWED RIGHT ESSURE OFF CENTER AND TWISTED. SHE UNDERWENT AN ELECTIVE ABORTION ON (B)(6) 2015. ADDITIONALLY, THE PHYSICIAN STATED THE RIGHT ESSURE WAS FOUND IN UTERUS, PROBABLY DUE TO PERFORATION OF FALLOPIAN TUBE. HE RELATED ALL EVENTS TO ESSURE. FOLLOW UP 18-JUN-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCURE WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE AE CASE REFERS ALSO TO A PRODUCT ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 10-JUL-2015: INFORMATION RECEIVED FROM GYNECOLOGIST STATES THAT A PATIENT WHO HAS AS MEDICAL HISTORY GRAVIDA 4, PARA 2, 1 ELECTIVE ABORTION, 1 SPONTANEOUS ABORTION AND NO HISTORY OF C-SECTION OR ECTOPIC PREGNANCY, DOES NOT HAVE PREVIOUS GYNECOLOGICAL INTERVENTION, PREVIOUS IUS/IUD, RELEVANT HISTORY OR CONCURRENT CONDITIONS AND DID NOT HAVE ESSURE CARD (AS REPORTED); HAD ESSURE (BATCH NUMBER AND EXPIRATION DATE UNKNOWN) INSERTED ON 2009. ACCORDING TO HEALTH CARE PROFESSIONAL, INSERTION WAS PERFORMED DURING FOLLICULAR PHASE AND PATIENT HAD BEEN FITTED WITH ESSURE BY ANOTHER PHYSICIAN. LOCAL ANALGESIA WAS APPLIED DURING INSERTION AND PROCEDURE WAS DESCRIBED AS EASY. THE VISUALIZATION OF TUBAL OS WAS UNKNOWN. THERE WERE NO ABNORMAL UTERINE FINDINGS PRIOR TO INSERTION AND THERE WERE NO COMPLAINTS IMMEDIATELY AFTER INSERTION. PATIENT USED ALTERNATIVE CONTRACEPTION FOR 3 MONTHS AFTER ESSURE INSERTION. ON (B)(6) 2011, ESSURE CONFIRMATION TEST VIA X-RAY AND ULTRASOUND WERE DONE. GYNECOLOGIST REVIEWED PLAIN ABDOMEN X-RAY IMAGES WHICH WERE ASYMMETRIC AND PATIENT WAS ADVISED TO RELY ON ESSURE. NO SECOND CONFIRMATION TEST WAS PERFORMED. ON UNSPECIFIED DATE, PHYSICIAN CONFIRMED THAT PATIENT WAS PREGNANT AND INFORMED THAT SHE PLANNED TERMINATING THE PREGNANCY. ON (B)(6) 2015, ESSURE INCORRECT POSITION WAS DIAGNOSED VIA X-RAY, ULTRASOUND AND LAPAROSCOPY. COMPLETE PERFORATION OCCURRED (UNILATERAL RIGHT); LEFT WAS IN CORRECT POSITION. NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS PERFORATED AND PATIENT PRESENTED WITH NO SYMPTOMS. PREGNANCY GESTATIONAL WEEK: 6 WEEKS OF AMENORRHEA. IT IS UNKNOWN WHETHER PERFORATION OCCURRED BEFORE DEPLOYMENT OR WITH COIL DEPLOYMENT. IN ADDITION, HEALTH CARE PROFESSIONAL REPORTED THAT ESSURE WAS NOT IN SITU AFTER DIAGNOSIS OF PREGNANCY AND STATES THAT, ON (B)(6) 2015, IT WAS REMOVED (RIGHT IMPLANT ONLY). REMOVAL METHOD: LAPAROSCOPY. ACCORDING TO REPORTER, RIGHT ABDOMINAL IMPLANT WAS "PLACED" ON UTERUS (AS REPORTED) AND PROBABLE FALLOPIAN TUBE PERFORATION AT THE TIME OF ESSURE PLACEMENT OCCURRED. ALSO ACCORDING TO PHYSICIAN, THE REMOVAL WAS MEDICALLY NECESSARY AND REQUESTED BY PATIENT. THERE WERE NEITHER PATHOLOGY RESULTS NOR SIGNS OF INFECTION OR INFLAMMATION. NO OTHER NEW MEDICAL INFORMATION WAS PROVIDED. CASE CONSIDERED TO BE CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 14-JUL-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: PREGNANCY: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. FALLOPIAN TUBE PERFORATION: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE (B)(4) REVEALED CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SOLICITED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD A PREGNANCY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION; SHE UNDERWENT AN ELECTIVE ABORTION. IN ADDITION, IT WAS REPORTED THAT RIGHT UNILATERAL PERFORATION OCCURRED. THE REPORTED EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UTERINE AND FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ESSURE USE. IN THIS PARTICULAR CASE, THE FIRST CONFIRMATION TEST PERFORMED SHOWED THE INSERTS ASSYMETRICS BUT SHE WAS ADVISED TO RELY ON ESSURE. PREGNANCY WAS DIAGNOSED APPROXIMATELY 6 YEARS AFTER ESSURE INSERTION; AND ACCORDING TO FOLLOW UP INFORMATION, THE CONFIRMATION TEST PERFORMED 4 YEARS AFTER THE FIRST ONE SHOWED COMPLETE PERFORATION ON THE RIGHT SIDE (PROBABLY RELATED TO INSERTION PROCEDURE). THEN, THE RIGHT ESSURE COIL WAS REMOVED VIA LAPAROSCOPY. ALTHOUGH THE PERFORATION PROBABLY OCCURRED DURING DEVICE PLACEMENT, IT IS NOT KNOWN FOR SURE. ALSO, IT IS UNCLEAR IF PREGNANCY FOLLOWED THE PERFORATION OR NOT; THEREFORE CAUSALITY BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. AS ESSURE WAS LATER

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REMOVED VIA LAPAROSCOPY (REQUIRED INTERVENTION) THIS CASE WAS UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00580	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68120

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/27/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 09-JUL-2015 WHICH REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED; THE LOT NUMBER USED WAS C68120. PHYSICIAN REPORTED THAT THE DEVICE WAS NOT RELEASED AND STAYED ATTACHED TO DELIVERY CATHETER AND PARTIALLY BROKE AT REMOVAL (ONE INSERTION FAILURE ON LEFT SIDE). BILATERAL INSERTION WAS PERFORMED (THE LEFT SIDE AND RIGHT SIDE INSERTIONS WERE PERFORMED WITH ONE KIT). PTC INVESTIGATION RESULT RECEIVED ON 31-JUL-2015. (B)(4). LOT NUMBER C68120 (EXPIRATION DATE 30-JUN-2017; PRODUCTION DATE 19-JUN-2014). FINAL ASSESSMENT: FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE PRODUCT WAS RETURNED TO US FOR THIS COMPLAINT, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE RETURNED PRODUCT. WE TYPICALLY INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. AS RECEIVED, ALL IFU STEPS WERE COMPLETED. THE DEVICE WAS RETURNED

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WITHOUT MICRO-INSERT. THE CATHETER LARGE TIGHT PITCH COIL FOUND TO BE STRETCHED. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. WE ALSO CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. THE RETURNED COMPLAINT SAMPLE WAS INVESTIGATED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE ONE DEVICE WAS NOT RELEASED AND STAYED ATTACHED TO DELIVERY CATHETER AND PARTIALLY BROKE AT REMOVAL. THE REPORTED EVENTS, REGARDED AS A DEVICE DEPLOYMENT ISSUE FOLLOWED BY DEVICE BREAKAGE, WERE CONSIDERED NON-SERIOUS. DEVICE BREAKAGE WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. THE OTHER EVENT IS LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 02-NOV-2015. NO FURTHER INFORMATION OBTAINED DESPITE FOLLOW-UP ATTEMPTS. (B)(4). THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00581	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76526

Single Use: Y
Implant Date (E6): 5/21/2015
Explant Date (E7): 8/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 08-JUL-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; WITH LOT NUMBER B76526. PATIENT WAS NOT PREGNANT. ON (B)(6) 2015, THE PATIENT CONTACTED PHYSICIAN'S OFFICE COMPLAINING OF CHEST PAIN AND SHORTNESS OF BREATH. SHE WAS ADMITTED INTO A HOSPITAL ON (B)(6) 2015. THE PATIENT EXPERIENCED CRAMPING AND PAIN IN LOWER LEFT QUADRANT, PELVIC ULTRASOUND SHOWED NOTHING WRONG. A CT SCAN WAS ALSO DONE AND ADENOPATHY WAS DIAGNOSED. THE PATIENT WAS DISCHARGED FROM HOSPITAL ON THE NEXT DAY. ON (B)(6) 2015 PATIENT WENT BACK TO DOCTOR'S OFFICE AND SAID SHE THOUGH ESSURE CAUSED ADENOPATHY. THE PHYSICIAN PERFORMED ULTRASOUND AND TEST SHOWED ESSURE HAD GOOD PLACEMENT. ON (B)(6) 2015, DIAGNOSTIC MEDIA STENOSCOPY WAS PERFORMED AND DIAGNOSIS OF SARCOID AND INFLAMMATION IN THE MEDIASTINUM (IN THE CHEST) WAS MADE. THE PATIENT STATED SHE WANTS ESSURE REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 15-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD B76526 (PRODUCTION DATE 01-OCT-2013 AND EXPIRATION DATE 31-OCT-2016) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT

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THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS HOSPITALIZED DUE TO CRAMPING/PAIN IN LOWER LEFT QUADRANT, CHEST PAIN AND SHORTNESS OF BREATH 6 DAYS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS DISCHARGED AND LATER DIAGNOSED WITH SARCOID. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND MEDICAL IMPORTANCE. THEY ARE UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT FOR CRAMPING/PAIN IN LOWER LEFT QUADRANT, WHICH IS LISTED. SARCOIDOSIS (ALSO KNOWN AS SARCOID) IS A MULTISYSTEM INFLAMMATORY DISEASE OF UNKNOWN ETIOLOGY THAT MANIFESTS AS NONCASEATING GRANULOMAS, PREDOMINANTLY IN THE LUNGS AND INTRATHORACIC LYMPH NODES. ITS MAIN SYMPTOMS INCLUDE DYSPNEA, CHEST PAIN AND ARTHALGIAS. IN THIS CASE, PATIENT STARTED EXPERIENCING CHEST PAIN AND DYSPNEA 2 DAYS AFTER ESSURE PLACEMENT. A CT SCAN SHOWED ADENOPATHY AND SHE WAS LATER DIAGNOSED WITH SARCOID. GIVEN SARCOID PATHOPHYSIOLOGY, AND CONSIDERING IT AS AN ALTERNATIVE EXPLANATION FOR PATIENT THORACIC SYMPTOMS, CAUSALITY WITH ESSURE IS CONSIDERED VERY UNLIKELY. REGARDING THE REPORTED LOWER LEFT QUADRANT PAIN, LIMITED INFORMATION WAS PROVIDED. IT IS UNCLEAR IF THIS EVENT REFERRED TO ARTHRALGIA OR OCCURRED AS A CONSEQUENCE OF ADENOPATHY (AND WAS THUS RELATED TO SARCOID) OR IF IT REFERRED TO LOWER ABDOMINAL PAIN RELATED TO ESSURE PROCEDURE. ALTHOUGH THE DEVICES WERE IN GOOD POSITION AT ULTRASOUND; CONSIDERING EVENT'S NATURE AND ITS CLOSE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED BY NOW. SINCE HOSPITALIZATION WAS REQUIRED, THIS CASE WAS REGARDED AS AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE RECEIVED ON 25-AUG-2015: PATIENT'S WEIGHT AND HEIGHT WERE ADDED. HER BODY MASS INDEX (BMI) WAS (B)(6). PAST MEDICAL HISTORY INCLUDED C-SECTION. SHE WAS NOT POSTPARTUM AT TIME OF ESSURE INSERTION. THE DEVIC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00582	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 7/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/6/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT STERILIZATION. DURING THE INSERTION PROCEDURE, THE PHYSICIAN FELT IT GIVE AND HE DEPLOYED ANYWAY, HE DEPLOYED AFTER PERFORATION. THE PHYSICIAN STATED THAT IT ALL HAPPENED SO QUICKLY; THE MICRO-INSERT WAS FLOATING IN PATIENT'S PELVIS. THE PHYSICIAN CHECKED THE PATIENT LAPAROSCOPICALLY BECAUSE HE LOST THE MICRO-INSERT AND PATIENT WAS ALREADY INTUBATED. THE PHYSICIAN ENDED UP DOING A BTL (UNDERSTOOD AS BILATERAL TUBAL LIGATION), LOOKING FOR THE MICRO-INSERT. HE ALSO DID AN X-RAY; HE COULD SEE THE MICRO-INSERT AND IT APPEARED THAT IT WAS IN THE OMENTUM. THE PATIENT DID NOT HAVE ANY PAIN AND SHE WAS SCHEDULED FOR FOLLOW-UP VISIT ON (B)(6) 2015. PATIENT WAS INSTRUCTED TO CALL DOCTOR IF SHE DEVELOPS PAIN. THE PATIENT WAS UPSET. AT TIME OF THE REPORT, ESSURE DEVICE WAS CONTINUED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY

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ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING PLACEMENT DOCTOR DEPLOYED ESSURE AFTER PERFORATION AND IN X-RAY IT APPEARS THAT IT WAS IN OMENTUM. THIS EVENT, SEEN AS UTERINE PERFORATION POST PROCEDURAL, IS SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE OR FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS CASE, THE PHYSICIAN THOUGHT IT WOULD BE POSSIBLE AND DEPLOYED THE MICRO-INSERT AFTER PERFORATION ANYWAY. HE STATED THAT IT HAPPENED VERY QUICKLY. THE MICRO-INSERT WAS FLOATING IN PATIENT'S PELVIS AND THEN THE PHYSICIAN PROCEEDED TO A LAPAROSCOPY TO SEEK FOR THE MICRO-INSERT. IN THE END, THE DEVICE WAS NOT FOUND AND A BILATERAL TUBAL LIGATION WAS DONE. AFTERWARDS, X-RAY WAS PERFORMED AND APPARENTLY THE ESSURE COIL WAS IN THE OMENTUM. CONSIDERING THAT THE REPORTED EVENT OCCURRED DURING INSERTION PROCEDURE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION (LAPAROSCOPY) WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 20-OCT-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFES TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00583	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 10-JUL-2015. IT DESCRIBES THE OCCURRENCE PREGNANCY IN A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. CONSUMER REPORTED THAT SHE HAD HER SON IN (B)(6) 2007; ON THE DAY AFTER HER SIX WEEK CHECKUP SHE HAD ESSURE INSERTED. SHE HAS BEEN HAVING REAL BAD COMPLICATIONS EVER SINCE SHE HAD IT, SHE EXPERIENCED REAL BAD PAIN. SHE MENTIONED FOR THE LAST THREE MONTHS WHEN SHE HAD SEX SHE COULD FEEL IT MOVING ON ONE SIDE; ON HER LEFT SIDE. SHE HAD A COMPLICATION; SHE WAS HURTING FOR 2.5 WEEKS ON HER LEFT SIDE. SHE HAD AN ULTRASOUND ON (B)(6) 2015. ON (B)(6) 2015 SHE WENT TO HER DOCTOR AND HE SAID SHE WAS PREGNANT OUTSIDE OF THE TUBE ON THE LEFT SIDE. FOLLOW-UP INFORMATION RECEIVED ON 23-JUL-2015 NO RESPONSE WAS OBTAINED AFTER FOLLOW-UP ATTEMPTS. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO BECAME PREGNANT OUTSIDE OF THE TUBE ON THE LEFT SIDE, APPROXIMATELY 7.5 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN A PREGNANCY OCCURS AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. IN THIS PARTICULAR CASE; THE CONSUMER MENTIONED HER PREGNANCY WAS OUTSIDE THE TUBE; HOWEVER SHE DID NOT SPECIFY ITS EXACT LOCATION (IF INTRA OR EXTRA-UTERINE). ALTHOUGH LIMITED INFORMATION WAS PROVIDED, COMPANY CONSIDERS AN EXTRA-UTERINE PREGNANCY

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CANNOT BE EXCLUDED BASED ON THE AS REPORTED TERM. THEREFORE, THIS EVENT WAS CONSIDERED AS RELATED TO THE SUSPECT INSERT AND CASE WAS REGARDED AS INCIDENT. FOLLOW-UP INFORMATION WILL NOT BE REQUESTED, HOWEVER A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 05-AUG-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE W

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00584	BAYER HEALTHCARE LLC	8/4/2015	8/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** AS

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B04953

Single Use: Y
Implant Date (E6): 7/6/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/14/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM HOSPITAL VIA REGULATORY AUTHORITY TGA ((B)(4)) AND VIA AMSL IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER B04953 WITH EXPIRATION DATE IN FEB-2016). THE HOSPITAL REPORTED THAT DOCTOR TRIED TO DEPLOY ONE ESSURE CATHETER AND WOULD NOT DEPLOY, ATTEMPTED A SECOND ESSURE CATHETER FROM THE SAME BOX THIS WOULD ALSO NOT DEPLOY. TWO SEPARATE DEVICES FROM THE SAME BATCH NUMBER FAILED TO DEPLOY. THE SECOND BOX WAS OPENED AND THE PROCEDURE WAS COMPLETED SUCCESSFULLY. PATIENT HAD NO INJURY. NO ADDITIONAL INFORMATION WAS PROVIDED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 04-AUG-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: DEVICE DEPLOYMENT ISSUE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 268 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS.. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE TWO SEPARATE DEVICES FROM THE SAME BATCH FAILED TO DEPLOY. ANOTHER DEVICE WAS USED AND BILATERAL PLACEMENT WAS COMPLETED SUCCESSFULLY. THE REPORTED EVENT, REGARDED AS A DEVICE DEPLOYMENT ISSUE, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL, IN THIS PARTICULAR CASE LIMITED INFORMATION WAS PROVIDED, HOWEVER

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CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ALTHOUGH NO INJURY, PERMANENT DAMAGE OR REQUIREMENT OF INTERVENTION WAS REPORTED IN THIS CASE; IT WAS CONSIDERED AS OTHER REPORTABLE INCIDENT IN LINE WITH HEALTH AUTHORITY'S ASSESSMENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 13-AUG-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). LOT NUMBER B04953 (PRODUCTION DATE FEB-2013; EXPIRATION DATE 29-FEB-2016). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045013	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 6/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, RECURRING BLADDER INFECTIONS, HEAVY BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045014	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 2/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT HIP PAIN, HEAVY PERIODS, MIGRAINE HEADACHES, BACK PAIN, WEIGHT GAIN, DEPRESSION, ANXIETY, PAINFUL SEX, CONSTANT URINATION, NIGHT SWEATS, PAINFUL CRAMPING, PHANTOM KICKS, HOT FLASHES, NUMBNESS AND TINGLING IN HANDS AND FEET, EASILY BRUISE, JOINT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045015	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 1/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BREAST PAIN/TENDERNESS, BLEEDING FROM RIGHT NIPPLE, SEVERE BLOATING, HEADACHES, DIZZINESS, BLURRED VISION, BRAIN SHOCKS/FORGETFULNESS, MOOD SWINGS, TINGLING SENSATIONS, RASH ON FACE, VITAMIN D DEFICIENCY, HAIR LOSS AND CHANGES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045016	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 3/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OK SO I HAD THE ESSURE PLACED BACK IN (B)(6) (2015) AND EVER SINCE MY BODY HASN'T BEEN THE SAME. I WAS NOT TOLD ABOUT ANY SIDE EFFECTS. I WASN'T TOLD ABOUT THE COILS BEING MADE OF METAL AND NICKEL. I EXPERIENCED A TERRIBLE MISCARRIAGE. BEFORE THAT MY PERIOD WOULD STOP THEN IT WILL PICK UP THE MONTH OF (B)(6) I BLED FOR THE WHOLE MONTH. IM ALWAYS NAUSEOUS, LIGHTHEADED. I'VE DEALT WITH WEIGHT GAIN IN THE BELLY. I SUFFER FROM HEADACHES FROM TIME TO TIME. STABBING PAINS ALWAYS ON THE LEFT SIDE. IM ALWAYS FATIGUED UGH IT'S JUST BAD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045017	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS DIAGNOSED WITH INTERSTITIAL CYSTITIS AFTER HAVING THE ESSURE. ALSO HAD CRAMPS AND ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045018	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 5/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DAY LISTED IS CLOSE TO INSERTION DATE. PAIN AND BLEEDING FIRST 4 MONTHS. 2 YEARS LATER PREGNANCY SYMPTOMS BUT NO PREGNANCY. CRAMPING, LOSS OF PERIODS I'VE HAD NONE SINCE (B)(6) 2009. ABDOMINAL PAIN, SWELLING, BLOATING, BACK PAIN, LEGS/FEET/FINGERS SWELLING, WEIGHT GAIN, BREAST TENDERNESS FORCING UNWANTED MAMMOGRAMS, MOODINESS, MOOD SWINGS, SHORTNESS OF BREATH, CHEST PAINS, MUSCLE SPASMS, PAINFUL INTERCOURSE, LOSS OF LIBIDO, EXTREME EXHAUSTION, BLURRED AND FAILING VISION, FEELING OF BEING POKED BY METAL IN BOTH SIDES, LOSS OF CONCENTRATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045019	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 6/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE PROCEDURE WENT FINE. I WAS AWAKE DURING THE INSERTION OF THE COILS, THEY GAVE ME MEDICINE TO CALM ME DOWN TO MAKE IT EASIER. AFTER THE PROCEDURE, WHICH ONLY TOOK AROUND FIVE MINUTES OR SO, I HAD INTENSE CRAMPING AND BLEEDING. (THIS WAS EXPECTED TO LAST A FEW DAYS ANDAMP; I THOUGHT NOTHING OF IT.) HOWEVER, MY BLEEDING AND LIGHT CRAMPING CONTINUED FOR OVER SIX MONTHS. I WENT BACK AND FORTH TO THE OBGYN EXPLAINING MY CONCERNS. THEY TOLD ME IT WAS NORMAL, AND TOLD ME TO TAKE A DOUBLE DOSE OF BIRTH CONTROL PILLS TO CONTROL THE BLEEDING. (THIS SEEN CRAZY TO ME, AND I DIDN'T UNDERSTAND HOW IT WAS NORMAL TO BE BLEEDING SO HEAVY FOR SO LONG). IT WAS VERY HEAVY BLEEDING AND CONTINUED WELL AFTER THE DOUBLE DOSE OF BIRTH CONTROL THEY PRESCRIBED TO STOP THE BLEEDING. I WENT BACK TO THE DOCTORS AND THEY TOLD ME TO STOP WORRYING ABOUT IT. I HAD HORRIBLE CRAMPING, WAS FILLING A TAMPON AN HOUR, AND BLEEDING NON-STOP. FINALLY, AFTER OVER SIX MONTHS OF THIS AND BRUISING EASILY AND BECOMING DIZZY I WENT TO A NEW DOCTOR. HE PUT ME ON HORMONES THAT EVENTUALLY HELPED CONTROL THE BLEEDING. MY PROBLEMS WITH ESSURE WAS NOT DONE YET. AFTER RECEIVING ESSURE, MY PERIODS WERE LONGER ANDAMP; HEAVIER WITH SPOTTING BETWEEN CYCLES. THE CRAMPING WAS RIDICULOUS AND HURTFUL. I HAD NOTICED THAT I HAD BEEN BRUISING VERY EASILY, HAVING DIZZY SPELLS, A LOT MORE TIRED, AND MY IMMUNE SYSTEM SEEMED LOWER. I WAS GETTING SICK EASIER. I USED TO BE ABLE TO FIGHT OFF COLDS A LOT FASTER. THE FIRST YEAR OF HAVING ESSURE, I GOT PNEUMONIA THREE TIMES IN A ROW. I NEVER HAD IT BEFORE. I NEVER THOUGHT TO LINK THE TWO UNTIL I KEPT GETTING SICK EASIER. I KNEW FOR SURE MY INTENSE PERIODS WERE THE CAUSE OF ESSURE. THE DOCTORS WOULDN'T TAKE ME SERIOUSLY, AND KEPT PRESCRIBING BIRTH CONTROL TO TAKE ON TOP OF THE ESSURE. I DIDN'T UNDERSTAND WHY I WOULD HAVE TO TAKE BIRTH CONTROL WHEN THE

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WHOLE POINT OF THE ESSURE WAS SUPPOSED TO ELIMINATE HAVING TO TAKE BIRTH CONTROL TO BEGIN WITH. ESSURE CAUSED MANY SIDE EFFECTS THAT THEY DO NOT WARN YOU ABOUT. THEY NEVER TOLD ME THERE WAS A CHANCE THAT I WOULD BLEED FOR SIX MONTHS AFTER THE IMPLANTATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045020	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 2/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 6 MONTHS AFTER INSERTION I BEGAN HAVING A RASH ON MY LEGS WITH PURPURA AND VASCULITIS. I ALSO WAS EXPERIENCING DEPRESSION AND STARTED ON WELLBUTRIN XL. IN (B)(6) 2009 I WAS DIAGNOSED WITH HIDRADENITIS SUPPURATIVA AND CAPILLARITIS. IN 2010, I BEGAN HAVING IRREGULAR PERIODS WITH PAINFUL CRAMPS, WORSENING STRESS INCONTINENCE AND SPOTTING WITH BMS. THE BLEEDING CONTINUED AND IN (B)(6) 2011 I BEGAN BIRTH CONTROL PILLS TO HELP CONTROL THE BLEEDING. CONTINUED TO BLEED FOR THE NEXT SEVERAL MONTHS NON-STOP. (B)(6) 2011 HAD A COLPOSCOPY SHOWING A PROLIFERATIVE ENDOMETRIUM. DISCUSSED AN ABLATION OR MIRENA AT THIS TIME. BLEEDING CONTINUED UNTIL (B)(6) 2012 WHEN I HAD AN ABLATION AND HYSTEROSCOPY. AT THIS PINT I WAS WEARING A TAMPON AND ON OVERNIGHT PAD AND CHANGING THEM EVERY 1-1.5 HOURS WITH LARGE CLOTS AND SOAKING THROUGH MY CLOTHES. ALSO, VERY PAINFUL CRAMPS. IN (B)(6) 2012 I WAS DIAGNOSED WITH UVEITIS THAT LASTED FOR 3 MONTHS. AT THIS TIME HUMIRA WAS ORDERED. BLEEDING WAS STILL PROFUSE AFTER THE ABLATION. IN (B)(6) 2013 I HAD BEEN BLEEDING FOR 3MONTHS. I HAD A TRANSVAGINAL ULTRASOUND AND WAS DIAGNOSED WITH ADENOMYOSIS. AT THIS TIME THEY COULD SEE THE LEFT COIL BUT NOT THE RIGHT. IN (B)(6) 2013 I DEVELOP PUSTULES ON MY HANDS AND FEET. I WAS DIAGNOSED WITH PSORIASIS (WHICH WAS LATER SAID TO BE A CLASS EFFECT OF THE HUMIRA). IN (B)(6) 2013 I HAD A MIRENA IMPLANTED. AN ENDOMETRIAL BIOPSY SHOWED SIMPLE HYPERPLASIA WITH ATYPIA. I REPORTED THAT I HAD BEEN BLEEDING SINCE (B)(6) 2013. I HAD TO START METHOTREXATE FOR THE PSORIASIS WHICH WAS SO BAD THAT I HAD TO HAVE AN ACCOMMODATION AT WORK TO NOT BE INVOLVED IN PATIENT CARE. I AM AN ICU NURSE. THIS ACCOMMODATION LASTED 6 MONTHS. IN (B)(6) 2014 I STARTED STELLARA AFTER IT WAS DETERMINED THAT THE PSORIASIS WAS FROM THE HUMIRA. IN (B)(6) 2014 MY ENODMETRIAL BIOPSY SHOWED POLYPOID FRAGMENTS WITH

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DYSSYNCHRONOUS ENDOMETRIUM WITH STROMAL NECROSIS = SIMPLE HYPERPLASIA WITHOUT ATYPIA. MY FOLLOW-UP BIOPSIES HAVE BEEN UNCHANGED. THROUGHOUT THIS TIME I HAVE REMAINED ON ANTI-DEPRESSANTS. I ALSO HAVE A VERY POOR MEMORY THAT HAS HAD ME SO CONCERNED THAT I HAVE TALKED WITH MY PCP ABOUT IT OVER THE PAST FEW YEARS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045021	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 9/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, DISCHARGE ORDER/NO ORDER, YEAST INFECTION , BREAST PAIN/TENDERNESS, ALL OVER BODY ACHES/PAIN, SEVERE BLOATING, HEARTBURN, HEADACHES/MIGRAINES, NUMBNESS, NERVE PAIN, BRAIN FOG, MOOD SWINGS, RINING IN THE EARS, HIGH BLOOD PRESSURE , VITAMIN D AND B-12 DEFICIENCY, FOOD ALLERGIES , SWELLINGS OF LEGS OF FEET, HAIR LOSS OR CHANGES, INSOMNIA, MUSCLE SPASMS , DRY SKIN/HAIR/EYES, ITCHING, BURNING, STONING, STABBING OF VAGINAL ENTRANCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045022	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 6/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (INSERT DATE). (B)(6) 2012 THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY MODEL NUMBER IS ESS305 OR ESS205. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2013. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. -EXTREME PELVIC PAIN. -NAUSEA. -EXTREME PAIN DURING INTERCOURSE. -FORCED TO LEAVE MILITARY AFTER 14 YEARS OF SERVICE DUE TO INABILITY TO WORK. I HAVE BEEN SEEN BY 3 DOCTORS. THE DEVICE WAS REMOVED ON (B)(6) 2014 AND THE PAIN HAS NOT STOPPED. THE DEVICE WAS NOT RETURNED TO THE MANUFACTURER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045023	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 2/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE HAD NUMEROUS SIDE EFFECTS THAT I NEVER ASSOCIATED WITH ESSURE UNTIL NOW. THIS IS THE LIST OF ALL THE SIDE EFFECTS THAT STARTED AFTER THE INSERTION OF ESSURE. SEVERE CRAMPING, SHARP/STABBING PELVIC PAIN, CYSTS, CONSTANT DISCHARGE WITH ODOR, HOT FLASHES, PELVIC INFLAMMATORY DISEASE, MENORRHAGIA (EXCESSIVE BLEEDING DURING PERIOD), PASSING OF BLOOD CLOTHS, MITTELSCHMERZ (PAINFUL OVULATION), NIGHT SWEATS, DYSMENORRHEA (PAINFUL PERIODS), DYSPAREUNIA (PAINFUL INTERCOURSE), FREQUENT/URGENT URINATION , VULVODYNIA (BURNING, STINGING, STABBING OF VAGINAL ENTRANCE), BACK, JOINT, BREAST AND NECK PAIN, CHRONIC PELVIC PAIN, ALL OVER BODY ACHES, NAUSEA, GAS , CHRONIC CONSTIPATION, SEVERE BLOATING, CONSTANT HEADACHES, DIZZINESS, TINGLING SENSATION ON HANDS, NUMBNESS ON FINGERS, BRAIN FOG ANDNDASH; CLOUDINESS, FORGETFULNESS, MEMORY LOSS , MOOD SWINGS, RINGING IN EARS, HAIR LOSS, INSOMNIA, WEIGHT GAIN, SWELLING OF JAW, VISION PROBLEMS (BLURRED, FLOATERS), DRY SKIN, EYES, EXCESSIVE SWEATING, CHRONIC FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045024	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 3/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CONSTANTLY BLED UP UNTIL ABOUT A MONTH AGO. BUT EVERY TIME ME AND MY HUSBAND ARE INTIMATE I BLEED TO THE POINT THAT MY HUSBAND IS COVERED IN BLOOD AND MY HEAD IS CLOUDY AND I'VE GOTTEN VERY FORGETFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045025	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 3/12/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE IN (B)(6) 2006. I HAVE HAD EXTREME CRAMPING SINCE THEN, HEAVY BLEEDING WAS PUT ON DEPO AND STILL SPOTTED FOR 4 MONTHS STRAIGHT. I HAD A UTERINE ABLATION STILL HAD CRAMPING AFTER THIS. IN (B)(6) 2014 I HAD A HYSTERECTOMY DUE TO THESE SIDE EFFECTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045026	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 8/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD SEVERE ABDOMINAL CRAMPING, SHARP ABDOMINAL PAINS THAT START AT MY BELLY BUTTON AND SHOOT ALL THE WAY THROUGH MY CERVIX, FATIGUE, DIZZINESS, OVARIAN CYSTS, NUMBNESS OFF AND ON IN LEGS, AND HOT FLASHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045027	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING ALL THE TIME. SHARP PAINS FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045028	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY HEALTH CHANGE COMPLETELY AFTER ESSURE . I LIVE IN PAIN 24/7.... AFTER ESSURE I DEVELOPED FIBROMYALGIA . I WAS ALSO ALWAYS HEAVY BLEEDING CAUSING ME TO BE EXTREME ANEMIC. I'D HAVE MAJOR PAIN RESULTING IN A HYSTERECTOMY. HEADACHES ,BACK ACHES ..... CRAMPING AND PAIN IN PELVIC AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045029	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 5/5/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE STABBING PAINS IN UTERUS. EXCESSIVE HAIR LOSS. EXTREMELY HEAVY MENTRUAL FLOW. TOOTH DECAY. HOT FLASHES. BACTERIAL VAGINOSIS. LOSS OF LIBIDO. NIGHT SWEATS. BLEEDING AFTER SEXUAL INTERCOURSE. YEAST INFECTIONS. ITCHING / BURNING OF VAGINAL ENTRANCE. CONSTANT BREAST PAIN. SEVERE BLOATING. NAUSEA. GAS. HEARTBURN. HEADACHES (SEVERE MIGRAINE LIKE). BRAIN SHOCKS. BRAIN FOGGINESS. MEMORY LOSS. PANIC ATTACKS. HORRIBLE MOOD SWINGS. DIZZINESS. CHRONIC FATIGUE SYNDROME AND INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045030	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 9/16/2003 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MASSIVE CRAMPING, UNEXPLAINED VAGINAL BLEEDING, NEW ALLERGIC REACTIONS TO FOODS, IBS, BLOATING, DEPRESSION, SUICIDE ATTEMPTS, UNEXPLAINED SKIN RASHES, HEADACHES, HAIR LOSS, COLON POLYPS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045046	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 6/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT INTO THE OFFICE FOR A SIMPLE PROCEDURE THAT TURNED MY LIFE UPSIDE DOWN FROM THE MINUTE IT WAS IMPLANTED. THE DEVICE MALFUNCTIONED DURING THE PROCEDURE; WHEREIN, I "NOT" HAVE 3 COILS IN ME. OVER THE COURSE OF THE PAST TWO YEARS, I HAVE THE FOLLOWING SYMPTOMS: EXTREMELY HEAVY, PAINFUL PERIODS, MULTIPLE PERIODS A MONTH, SHARP PAINS IN MY STOMACH, CRAMPING THAT CRIPPLES ME, CONSTANT HEADACHES, SEVERE SWEATING (WHEREIN I AM FORCED TO WEAR PANTIE LINERS IN MY SHIRTS), BLOATING, EXCESSIVE WEIGHT GAIN, (EVEN THOUGH I WORK OUT AND EAT HEALTHY), MY GALLBLADDER WAS REMOVED DUE TO GALLSTONES, EXTREMELY EXHAUSTION, DOCTOR THOUGHT IT WAS LOW TESTOSTERONE, NOTHING HAS HELPED. I AM SO TIRED ON SOME DAYS, I CAN'T GET OUT OF BED. BACK ACHES, HOT FLASHES, LOW GRADE UNEXPLAINED FEVERS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045047	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 3/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE EXPERIENCE ENLARGE UTERUS, HEAVY BLEEDING, IRREGULAR PERIOD, STABBING PAINS IN MY VAGINA AND PELVIC AREA , NEEDLE LIKE FEELING AROUND MY BELLY BUTTON, TERRIBLE MIGRAINES, BRAIN FOG, BLOATING OF THE STOMACH, INFLAMMATION IN MY LOWER BACK WITH NO BACK INJURIES. RIGHT SIDE OF MY BODY SWELLS UP. JOINTS ACHE ALL OVER. PAIN WHILE HAVING INTERCOURSE EITHER DURING OR AFTERWARDS. BOWEL MOVEMENTS BLOCKAGE, HAVE NO ENERGY. ALL OF THIS I NEVER EXPERIENCE BEFORE ESSURE. I WAS HEALTHY BEFORE I HAD THIS DONE. NEVER HAD A FEVER BEFORE OR EAR ACHE NEVER HAD A COLD. SO PLEASE TELL ME WHY I HAVE ALL THESE SIDE EFFECTS?

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045050	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 7/1/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD TWO CYST ON MY RIGHT OVARY THAT HAS BUSTED. I HAVE HAD HPV , ALSO I HAVE HAD METAL TASTE IN MY MOUTH NONE STOP, HAIR LOSS, MUSCLE TONE LOSS, MEMORY LOSS, DEPRESSION, ANXIETY, NERVE DAMAGE , WEIGHT GAIN, ATTEMPTED SUICIDE TWICE, (B)(6) NOW, INSOMNIA, AND THE LIST GOES ON. I HAVE HAD THEM FOR 10 YEARS AND MY HEALTH HAS DECLINED BADLY. I AM (B)(6) YEARS OLD. ALSO I HAVE NEUROPATHY TOO. TWO THINGS HAVE A CHANCE OF KILLING ME THAT IS THE NEUROPATHY AND (B)(6). ALSO AUTOIMMUNE DISEASES TO MENTAL HEALTH ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045051	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 5/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BECAME PREGNANT ALONG WITH SEVERAL PREVIOUS SERIOUS SIDE EFFECTS FROM THE INITIAL IMPLANT DATE. (B)(6) 2008.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045052	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 4/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN THE BEGINNING I BLED AFTER THE PROCEDURE FOR A YR AND HALF. I STILL HAVE HORRIBLE CRAMPING AND THAT GETS WORSE WHEN I'M ON MENSTRUAL. I HAVE BEEN TO THE HOSPITAL FOR THESE PAINS AND ITS SHOWING THE COIL IS MIGRATING OUT OF MY TUBE. I HAVE HORRIBLE HOT FLASHES WHICH I HAVE NEVER HAD BEFORE. I HAVE MIGRAINES ON A DAILY BASIS. THANKS ESSURE FOR MAKING MY LIFE A NIGHTMARE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045053	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 2/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED MENSTRUAL CYCLE HAD SHARP STABBING PAIN WERE FEELS LIKE MY OVARIES OR FALLOPIAN TUBES ARE LOCATED AND HEAVY MENSTRUAL BLEEDING ALONG WITH DIME TO NICKEL SIZED BLOOD CLOTS AND THIS HAS PROCEEDED TO HAPPEN SINCE THEN WITH EVERY MENSTRUAL CYCLE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045054	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I HAVE HAD THIS PUT IN IN 2011 I HAVE HAD MANY ISSUES. PAIN VERY BAD DURING PERIOD AND SEX AND SOMETIMES JUST PAIN FOR NO REASON. MY BODY GOES NUMB ALL THE TIME. MY HAIR IS FALLING OUT. I HATE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045055	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M LOSING MY HAIR, EYEBROWS, AND EYELASHES. I HAVE TO TAKE BIRTH CONTROL WITH THE ESSURE BECAUSE MY PERIODS ARE SO HEAVY AND HORRIBLE. I NEVER EVER HAD PROBLEMS WITH MY PERIOD. NOW I HAVE STABBING PAINS, BLEED/SPOT MOST OF THE MONTH, AND HUGE BLOOD CLOTS THAT I E NEVER SEEN COME OUT OF ME. I'VE HAD FULL BLOOD PANELS DONE VERY RECENTLY AND I'M ALWAYS HAVING MY THYROID CHECKED BECAUSE MY DOCTORS CAN'T FIGURE OUT WHAT'S WRONG WITH ME. ALSO, IN THE PAST YEAR MY THINKING HAS GOTTEN MORE CLOUDY, AND I HAVE THE HARDEST TIME REMEMBERING SIMPLE THINGS. THERE ARE CHUNKS OF TIME I WON'T REMEMBER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045056	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD BAD CRAMPING, BACK PAIN, NAUSEA, AND SOME BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045057	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 6/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PROCEDURE WAS DONE (B)(6) 2014 I WAS FINE UNTIL I GOT MY PERIOD SINE I WAS BREASTFEEDING SO I WASN'T GETTING ONE UNTIL (B)(6) THAT'S WHEN IT STARTED HEAVY PERIOD I NEVER HAD ONE JUST LIKE IT REALLY HAD BACK PAIN HIP LEG PAIN I COULDN'T MOVE IT HURT SO BAD I'M BLOATED MOST OF THE TIME I LOOK PREGNANT, ACHES ALL OVER BODY, RIGHT SCIATIC PAIN, FATIGUE, MIGRAINES BEFORE AND DURING PERIOD, SOMETIMES PAIN DURING INTERCOURSE, DISCHARGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045058	BAYER	8/4/2015	8/4/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE INITIAL PLACEMENT OF THE DEVICE CAUSED EXTREME PAIN AND NAUSEA. THE PROCEDURE AND RECOVERY LASTED WELL OVER AN HOUR. FOLLOW UP HSG AFTER 4 MONTHS SHOWED ONE TUBE OCCLUDED AND THE SECOND ESSURE COIL WAS GONE. THE COIL IN PLACE IS ON THE LEFT SIDE. I EXPERIENCE EXTREME PAIN ON THE LEFT SIDE DURING OVULATION AND THE PAIN/CRAMPING DURING MY PERIODS HAS BECOME SEVERE. BEFORE ESSURE I EXPERIENCED NO PAIN DURING OVULATION AND MY PERIODS WERE NOT PAINFUL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00585	BAYER HEALTHCARE LLC	8/4/2015	8/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 6/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN RECENTLY REMOVED ESSURES FROM A PATIENT AT HER REQUEST. ONE DEVICE THAT STILL STUCK OUT IN THE CAVUM WAS CONCRETION. THE PHYSICIAN'S QUESTION WAS WHETHER THESE CONCRETIONS COULD CONCERN CORROSION OR LIME PRECIPITATION. FOLLOW-UP INFORMATION WAS RECEIVED ON 13-JUL-2015. IT WAS REPORTED THAT THE COILS WERE GIVEN TO THE PATIENT. PATIENT WAS STERILIZED ELSEWHERE. REPORTER DOES NOT HAVE BATCH NUMBERS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED FROM THE PHYSICIAN ON 16-JUL-2015: PATIENT WAS (B)(6) . SHE HAD ESSURE INSERTED IN 2009. THE REASON FOR ESSURE REMOVAL, ON (B)(6) 2015, WAS REPORTED AS REQUEST BECAUSE OF COMPLAINTS THAT STARTED AFTER INSERTION. ITCH, URTICARIA, JOINT COMPLAINTS. THE PHYSICIAN STATED IT WAS STILL TOO EARLY TO ASSESS IF THE PATIENT RECOVERED FROM THE EVENTS AFTER ESSURE REMOVAL. PTC INVESTIGATION RESULT RECEIVED (B)(6) 2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT BASED UPON REVIEW OF THE SUBMITTED PHOTOS, IT IS VERY DIFFICULT TO DETERMINE THE EXACT IDENTITY OF THE WHITE DEPOSIT MATERIAL. IT IS LIKELY THE WHITE DEPOSIT MATERIAL IS TISSUE FROM THE UTERINE CAVITY WHICH HAS ATTACHED TO THE INSERT. IT IS VERY UNLIKELY THIS SUBSTANCE IS AN ARTIFACT FROM THE MANUFACTURING PROCESS. SINCE NO PRODUCT HAS BEEN RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO REQUESTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVAL, APPROXIMATELY 6 YEARS AFTER ITS INSERTION, DUE TO URTICARIA AND JOINT COMPLAINTS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY URTICARIA (HIVES) IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, AND HIVES (URTICARIA) THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, PATIENT HAD ITCH AND URTICARIA, WHICH STARTED AFTER DEVICES INSERTION. ALTHOUGH THE PHYSICIAN WAS UNABLE TO INFORM IF PATIENT RECOVERED AFTER DEVICES REMOVAL; CONSIDERING EVENT'S NATURE AND THE POSITIVE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING JOINT COMPLAINTS, LIMITED INFORMATION WAS PROVIDED. HOWEVER, GIVEN ESSURE LOCAL ACTION AT FALLOPIAN TUBES, CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED UNLIKELY. SINCE ESSURE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FOLLOW-UP INFORMATION (EVENTS OUTCOME) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 06-OCT-2015 NO FURTHER INFORMATION WAS RECEIVED. CASE CONSIDERED CLOSED. (B)(4). THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDR

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045132		8/4/2015	8/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT STATED THAT HER BODY REJECTED THE ESSURE PRODUCT WHICH CAUSED SEVERE INFECTIONS AND AT FIRST, A PARTIAL HYSTERECTOMY. ON (B)(6) 2013 THE PATIENT'S UTERUS AND PART OF BOTH FALLOPIAN TUBES WERE REMOVED. ON (B)(6) 2013, (B)(6) HAD TO HAVE THE REMAINDER OF HER LEFT TUBE AND OVARY REMOVED DUE TO INFECTIONS. ON (B)(6) 2015, THE REMAINDER OF HER RIGHT TUBE AND OVARY WERE REMOVED. THIS LAST SURGERY RESULTED IN A COMPLETE HYSTERECTOMY. (B)(6) STATES THAT SHE HAS SUFFERED CONSTANT INFECTIONS AND PAIN SINCE THE DEVICE WAS PLACED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045064	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAINS,MAINLY PELVIC PAIN, PAINFUL PERIODS,SKIN RASH,BLURRED VISION AND MUSCLE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045067	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 2/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SOON AFTER I WAS IMPLANTED I STARTED SUFFERING EXTREME FATIGUE, CYSTIC ACNE AND DEPRESSION GOT REAL BAD. WEIGHT GAIN AND PAIN IN MY RIGHT SIDE. HAD TEST DONE FOR THYROID, SLEEP STUDY DONE AND HAD ER VISIT FOR ALL TO COME BACK NORMAL. ABOUT 2 YEARS AGO STARTED HAVING OVER ACTIVE BLADDER TO BE OUT ON MEDS TO HELP IT. MY HORMONES WERE WAY ELEVATED TO THE POINT MY LIVER MADE MY BODY GO TOXIC. HAD TO COME OFF ALL MEDS TO TRY TO RESTART MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045071	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I TOLD DR THAT SOMETHING DIDN'T FEEL RIGHT 3 MONTHS AFTER PUTTING IN ESSURE; DIDN'T LISTEN. NOW I AM ALWAYS TIRED, MOOD SWINGS, PAINS ALL THE TIME, BLEEDING ALL THE TIME, NOW ALSO HAVE 2 GREAT BIG CYSTS, SEX HURTS ALSO, AND NOW LOOKING TO GET A HYSTERECTOMY AT THE AGE OF (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045073	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 1/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS HESITANT AT FIRST RECEIVING ESSURE BECAUSE I WAS TOLD THE PROCEDURE WOULD BE DONE IN MY OBGYN OFFICE. INSTEAD, I WAS TOLD I HAD TO GO TO THE LOCAL HOSPITAL. I WOKE UP IN RECOVERY IN SEVERE PAIN. I WAS SORE IN MY PELVIC AREA FOR ABOUT A WEEK. ABOUT 2-4 MONTHS LATER, I WAS BACK AT MY OBGYN DUE TO SEVERE PAIN THROUGHOUT MY BODY AND CHRONIC UTI'S. I HAVE SUFFERED FROM NUMBNESS IN MY BODY WHERE I CAN'T EVEN EXIT THE BED. SEVERE BACK PAINS, SWELLING IN FEET, CONSISTENT MIGRAINES, MOOD SWINGS, AND I'VE HAD AT LEAST 12 UTI'S WITHIN 2 YEARS. I WAS PRESCRIBED PAIN MEDS FOR PAIN BUT I COULDN'T WORK WITH TAKING THEM. WITH THE UTI, I WAS TREATED 4 TIMES FIRST WITH AN ORAL PRESCRIPTION AND THEN THE GEL AFTERWARDS. AFTER BEING TIRED OF THE RIDICULOUS CO PAY EACH TIME, I NOW JUST GO TO THE PHARMACY AND PURCHASE OVER THE COUNTER MEDS. WHEN GOING BACK TO GET THE HSG TEST DONE, IT TOOK SEVERAL OF TIMES BEFORE THE DOCTOR INFORMED ME THAT HE COULDN'T TELL IF ESSURE WAS PROPERLY INSTALLED AND THAT HE WOULD NEED TO SPEAK TO THE DOCTOR WHO PERFORMED THE OPERATION. SINCE THEN, I HAVE NOT HEARD ANYTHING FROM OBGYN ABOUT THE ISSUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045075	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 6/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RHEUMATOID ARTHRITIS , MRI SCAN DETERMINED INFLAMMATION AND DETERIORATION IN BONES IN SPINE. INFLAMMATION IN WRISTS AND HANDS. PAIN IN LOWER BACK, WRISTS AND HANDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045077	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 12/27/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MANY SYMPTOMS LISTED AS SECONDARY FOR ESSURE. WEIGHT GAIN, DEPRESSION, HAIR LOSS, MIGRAINES, SEVERE ABDOMINAL BLOATING, LIGHT HEADEDNESS, ACUTE YEAST INFECTIONS, LOWERED SEX DRIVE, JOINT PAIN AND OTHERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045079	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 7/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE COIL HAS MIGRATED AND IS CAUSING EXCRUCIATING PAIN IN MY BACK, CERVIX AND SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045082	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 7/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE COIL HAS MIGRATED AND IS CAUSING EXCRUCIATING PAIN IN MY BACK, CERVIX AND SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045083	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 3/24/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM NOT SURE THE EXACT DATE I WAS IMPLANTED, BUT I DO KNOW IT WAS (B)(6) OF 2011. I DO NOT HAVE MY MEDICAL RECORDS YET, BUT I WILL GET THEM. SINCE THE DAY I WAS IMPLANTED I HAVE HAD MANY COMPLICATIONS DUE TO THE ESSURE. I DID NOT REALIZE IT WAS FROM ESSURE UNTIL MANY YEARS LATER, IT WAS SEPTEMBER OF 2014 WHEN I REALIZED IT WAS FROM ESSURE. THE LIST OF MY SIDE EFFECT IS VERY LONG, AND MORE SIDE EFFECTS GET ADDED TO MY LIST EVERY DAY. I WILL NOW GIVE MY LIST OF SIDE EFFECTS AS OF NOW THAT I HAVE. CRAMPING; SHARP/STABBING PELVIC PAIN; SHARP/STABBING BREAST PAIN; ABNORMAL MENSES; PERIOD STOPS; OVARIAN CYSTS; BACTERIAL VAGINOSIS; DISCHARGE (ODOR/NO ODOR); HOT FLASHES; PAINFUL OVULATION (MITTELSCHMERZ); NIGHT SWEATS; LOSS OF LIBIDO; BLEEDING/SPOTTING AFTER SEX; PAINFUL PERIODS (DYSMENORRHEA); PAINFUL INTERCOURSE (DYSPAREUNIA); EARLY MENOPAUSE; INCONTINENCE; LONG MENSTRUAL CYCLES (POLYMENORRHEA); SEXUAL DYSFUNCTION (UNABLE TO ORGASM OR FEEL PLEASURE); LACK OF MENSTRUAL CYCLE (AMENORRHEA); YEAST INFECTIONS (CANDIDA); URGENT/FREQUENT URINATION; UTIANDRSQUOS; (URINARY TRACT INFECTIONS); CERVICITIS/VAGINITIS (SWELLING, INFLAMMATION, INFECTION OF THE CERVIX AND/OR VAGINA); VULVODYNIA (ITCHING, BURNING, STINGING, STABBING OF THE VAGINAL ENTRANCE); BREST PAIN/TENDERNESS; ABDOMINAL SPASMS/TWITCHING/FLUTTERING; FOUL SMELL OF THE VAGINA; METALIC SMELL OF THE VAGINAL REGION; DRY VAGINA; BACK, JOINT, LEG, BREAST, NECK, SPINE, SHOULDER, HIP PAINS; SWELLING OF THE LEGS AND FEET; CHRONIC PELVIC PAIN; ALL OVER BODY ACHES; NUMBNESS OF LIMBS; TINGLING SENSATIONS; NERVE DAMAGE AND PAIN; NAUSEA; VOMITING; GAS; CONSTIPATION; DIARRHEA; SEVERE BLOATING/PAINFUL BLOATING; METALIC TASTE IN MOUTH; HEARTBURN; BOWEL ISSUES; IMBALANCE OF WEIGHT (GAIN/LOSS); APPETITE CHANGES; HEADACHES/MIGRAINES; DIZZINESS; TINGLING SENSATIONS; NUMBNESS; NERVE PAIN; BRAIN FOG

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(CLOUDINESS/FORGETFULNESS); MOOD SWINGS/DISORDER; RINGING IN EARS (PULSATILE TINNITUS); TREMORS/SHAKINESS; DIMINISHED BRAIN FUNCTION (BRAIN FOG, FORGETFULNESS, CLOUDINESS, SHORT TERM MEMORY LOSS); NUMBNESS IN THIGHS (MERALGIA PARETHETICA); NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET); PARETHESIA (SENSATIONS OF BURNING, STINGING, TINGLING OR PRICKING OF THE SKIN); LOSS OF FOCUS OR CONCENTRATION; LOSS OF HOPE; FEELINGS OF DREAD; MEMORY LAPSES; UNEXPECTED TEARS; VITAMIN D DEFICIENCY; IRON DEFICIENCY; ELEVATED BLOOD COUNTS; CHRONIC FATIGUE; DEFICIENCY OF ENERGY; CHEMICAL AND FOOD ALLERGIES; METAL ALLERGIES; CYSTS, BOILS IN SKIN; ACNE; BROKEN COILS; DENTAL/TEETH ISSUES; SLEEPING PROBLEMS (CANT STAY ASLEEP OR TAKES NAPS DAILY); SWEARS DURING SLEEP DUE TO PAIN; SWELLING OF LEGS/FEET; INSOMNIA; DEGENERATIVE DISK DISEASE (OR DEGENERATIVE BONE DISEASE); WEIGHT ISSUES (GAIN/LOSS); SWELLING/NUMBNESS IN JAWS/LIPS; UNEXPLAINED FEVERS; MUSCLE SPASMS; VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION); DRY SKIN/HAIR/EYES; SEVERE BLOATING/PAINFUL BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045085	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 3/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN IN LOWER BACK AND PELVIC PAIN DURING PERIOD. HEAVY BLEEDING WITH HUGE CLOTS. REPEATED UTI'S AND YEAST INFECTIONS. BLEEDING BETWEEN PERIODS. DEPRESSION, ANXIETY, IBS, TMJ, GALLBLADDER ISSUES, MIGRAINES. SHARP PAIN IN RIGHT SIDE AFTER SEX OR AROUSAL. NUMBNESS IN EXTREMITIES. ITCHING OR SKIN CRAWLING SENSATION. CONSTIPATION. FEELING DRAINED AND JUST OVERALL ILL FEELING. HEART PALPITATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045086	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 6/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RHEUMATOID ARTHRITIS, MRI SCAN DETERMINED INFLAMMATION AND DETERIORATION IN BONES IN SPINE. INFLAMMATION IN WRISTS AND HANDS. PAIN IN LOWER BACK, WRISTS AND HANDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045088	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 6/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE HAS CAUSED PAINFUL PERIODS, HEAVY BLEEDING, PELVIC PAIN, AN ER VISIT, PAINS DOWN MY THIGHS, FATIGUE, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045089	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 2/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, OCCASIONAL HIVES AND SKIN IRRITATIONS , BLADDER PROBLEMS, MENSTRUAL CRAMPS GOT WORSE NOT ONLY WHEN PERIOD IS DUE BUT ALL THE TIME, BLEEDING GOT WORSE WITH SPOTTING OF DARK BLOOD IN BETWEEN PERIODS, HEADACHES/MIGRAINES, KIDNEY PROBLEMS, PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045092	BAYER	8/5/2015	8/5/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE BEGINNING OF HEAVIER PERIODS AND CRAMPING DURING PERIODS. ANEMIA AND OTHER SYMPTOMS BEGAN BUT DID NOT AFFECT DAILY LIFE. MIGRAINES AND OTHER SYMPTOMS BEGAN IN (B)(6) OF 2010 THAT BEGAN TO AFFECT JOB AND HOME, AND BY (B)(6) 2011, EXPERIENCED SEVERE SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045060	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 3/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL AND PELVIC PAIN, WEIGHT GAIN, WORSE AND MORE FREQUENT MIGRAINES, EXTREME MOOD SWINGS, LOSS OF SEX DRIVE, ANXIETY, HEAVY AND PAINFUL PERIODS (AWFUL PMS), LOW BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045061	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 8/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MINE IMPLANTED IN ABOUT (B)(6) 2009. I HAD NO PROBLEMS AND NO REAL PAIN DURING IMPLANT. ABOUT ONE MONTH LATER, I STARTED HAVING SEVERE AND CONSTANT PELVIC PAIN. MY SYMPTOMS PROGRESSED AND I BEGAN HAVING SEVERE HEADACHES 24 HOURS A DAY. I ALSO HAD BACK PAIN. IT GOT TO THE POINT, WHERE I DEMANDED THEY BE REMOVED EVEN AFTER BEING TOLD IT WOULD LIKELY REQUIRE A HYSTERECTOMY. I HAD A SIX HOUR SURGERY, AND I LOST ONE TUBE. I HAVE BEEN SYMPTOM FREE SINCE REMOVAL. MY DOCTOR SENT ME TO SEVERAL OTHER DOCTORS BEFORE REMOVAL TO MAKE SURE THAT I DID NOT HAVE ANY OTHER ISSUES. NO OTHER DOCTOR FOUND ANYTHING WRONG WITH ME. I WAS VERY HEALTHY WITH NO OTHER ILLNESSES AT THE TIME OF IMPLANT. I HAD THE IMPLANT ABOUT 3 MONTHS AFTER MY LAST CHILD WAS BORN. I HAVE NEVER BEEN DIAGNOSED WITH A NICKLE ALLERGY. I HAVE SENSITIVITY TO SOME EARRINGS, BUT NOBODY EVER SUGGESTED A NICKLE TEST. I AM ALLERGIC TO NUMEROUS PRESCRIPTION MEDICATIONS INCLUDING KELFEX, SULFA, CODEINE, PENICILLIN, AND I AM ALSO ALLERGIC TO CERVIDIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045062	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 4/3/2008	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT IN TO HAVE ESSURE COILS IMPLANTED. I FELT EVERYTHING, IT WAS TORTURE. MY BLOOD PRESSURE SKYROCKETED AND I WAS ALMOST ADMITTED. I FELT PAIN CONSISTENTLY IN MY PELVIC REGION FOR OVER A YEAR. I WAS DEPRESSED BECAUSE I WAS IN SO MUCH PAIN I COULDN'T LIVE MY LIFE. I BEGGED MY DOCTOR TO REMOVE THE COILS AND SHE AGREED. I HAD THEM REMOVED IN (B)(6) 2009. I FELT BETTER IMMEDIATELY, NO PAIN IN MY PELVIC AREA AFTER REMOVAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045063	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING, PELVIC PAIN, WEIGHT GAIN, JOINT PAIN, HAND SWELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045065	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 2/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, JOINT PAIN,MOOD SWINGS, CHRONIC ABDOMINAL PAIN, HOT FLASHES, COLD SWEATS, FATIGUE,BLOATING, MIGRAINES, NNP SEX DRIVE, FORGETFULNESS, MEMORY LOSS, VISION IMPAIRMENT, NERVE PAIN, NUMBNESS AND TINGLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045066	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, HIP PAIN, BLOAT, PAINFUL PRESSURE IN LOWER ABDOMEN AND CROTCH AREA, HAIR LOSS, WORSTING ANXIETY, MOOD SWINGS, LOSS OF SEX DRIVE, LOWER BACK PAIN, INFECTION, HYSTERECTOMY, BRAIN FOG, MEMORY LOSS, PAIN DURING SEX, EXCESSIVE SWEATING, BREAST PAIN, DETERIORATION IN RIGHT HIP

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045068	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 6/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE HAS CAUSED PAINFUL PERIODS, HEAVY BLEEDING, PELVIC PAIN, AN ER VISIT, PAINS DOWN MY THIGHS, FATIGUE, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045069	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I HAD THE PROCEDURE DONE, I HAVE HAD WEIGH GAIN, MAJOR CRAMPING DURING AND AFTER CYCLE, SWELLING, HEART PROBLEMS, LOSE OF SEX DRIVE WHICH LEAD TO A DIVORCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045070	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 1/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHORTLY AFTER MY PROCEDURE, I HAD 8 WEEKS OF VERY PAINFUL CRAMPS, NOT TO MENTION THE RIVER OF BLOOD AND BIG BLOOD CLOTS I WAS PASSING. STARTED HAVING SOME BAD HEADACHES, LOTS OF CRAMPING IN MY BACK, I'M STAYING BLOATED,GET LIGHT HEADED ALL THE TIME. MY PERIODS ARE CRUCIAL. SOMETIMES PUTTING ME IN MY BED CAUSE OF THE PAIN OF THE CRAMPING. I HAVE TO WEAR 2 SUPER ABSORBENT PADS AT A TIME AND CAN'T USE TAMPONS CAUSE IT'S TOO PAINFUL. I HAVE ABSOLUTELY NO ENERGY, AND I HAVE 3 CHILDREN 3 YEARS AND YOUNGER TO LOOK AFTER. I HAVE BEEN STAYING NAUSEOUS AND THIS LAST WEEKENDS ROUND WITH THE VOMITING WAS SO HORRIBLE. I WOULDN'T WISH THAT ON ANYONE. I WENT BACK TO THE OBGYN AND THEY TOLD ME THAT I WAS IN MY HEAD ABOUT THE ESSURE MAKING ME SICK AND TRIED TO SAY MAYBE ORGAN PROLAPSE WAS CAUSING MY PAIN. WENT TO MY NORMAL PCP AND HE MADE ME FEEL LIKE I WAS JUST ASKING FOR MEDICINE. BUT NO HELP WITH THE PAINS AND PROBLEMS I'M HAVING. NOT EVEN TEST. ANYTHING. I ALWAYS FEEL BAD AND CAN'T GET THE DOCTORS TO TAKE ME SERIOUSLY. I'M AT MY WITS END. I DREAD NEXT WEEK CAUSE IT'S THAT TIME OF THE MONTH AGAIN AND I REALLY DON'T WANT TO START MY PERIOD CAUSE I KNOW THE THINGS I WILL BE GOING THREW THOSE DAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045072	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT LOWER BACK PAIN, NICKEL ALLERGY, DRY SKIN/SKIN IRRITATION, INSOMNIA, SEVERE BLOATING/INFLAMMATION, IRON DEFICIENCY, PMDD, DIZZINESS, HEADACHES/MIGRAINES, INCONTINENCE, BREAST PAIN, EXCESSIVE BLEEDING DURING PERIODS, CRAMPING, SHARP/STABBING PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045074	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FREQUENT OUTBREAK IN HIVES ON HANDS. LOWER LEFT SIDE ABDOMINAL PAIN, PAINFUL OVULATION, HAIR LOSS, HEART PALPITATIONS, EXTREME FATIGUE, BRAIN FOG, LACK OF APPETITE, DENTAL PROBLEMS, JOINT PAIN, NECK AND LOWER BACK PAIN, SHAKINESS, FAINTNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045076	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 12/24/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED GETTING VERY ILL AND WEAK. VOMITING EVERYDAY. NOT SLEEPING. STOMACH PAINS. MONTHS LATER I LEARNED I WAS PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045078	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 4/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UPDATE: HAD A TOTAL HYSTERECTOMY ON (B)(6) 2015. PATHOLOGY REPORT FOUND ADENOMYOSIS AND A FIBROID. CURRENTLY GOING THROUGH TESTING TO DETERMINE IF I HAVE RA OR LUPUS OR IF I HAVE FIBROMYALGIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045080	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, WEIGHT GAIN, THINNING HAIR, JOINT PAIN, SHARP ABDOMINAL PAINS, DARK CIRCLES UNDER EYES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045081	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 1/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM SUFFERING OF HAIR LOSS , MIGRAINE HEAD ACHES AND BLOOD PRESSURE THAT I HAVE ENDED UP IN EMERGENCY ROOM FOR ! I GET CONSTANT MIGRAINES THAT I CAN'T FUNCTION WHAT SO EVER . I WENT TO EMERGENCY ROOM W THIS AND ALSO COULDN'T MOVE MY LEFT ARM MY BLOOD PRESSURE WAS SUPER HIGH .. I ALSO HAVE JOINT PAIN ON LEGS.. I NOW SUFFER OF ANXIETY ATTACKS WHEN NOT ONCE HAD I HAD THIS I FEEL LIKE I WANT TO JUMP OUT OF MY SKIN.. MY MENSTRUAL PERIODS ARE SO INSANE I NOW GET THEM 2 TIMES A MONTH .. I ALREADY KNOW WHEN I'M ABOUT TO START SINCE I HAVE SEVERE CRAMPS W NO FLOW AT ALL JUST CLOTS CLOTS CLOTS NO FLOW .. I'LL START MAYBE 4 DAYS LATER W FLOW AND CLOTS AND W A LOT OF BACK PAIN N BELLY PAIN .. MY HAIR IS INSANE I CAN MAKE A WIG IT JUST FALLS OFF INSANELY .. IT'S DEPRESSING TO SEE THIS . I ALSO HAVE NO ENERGY TO DO ANYTHING NOT TO PLAY W MY KIDS OR EVEN INTERACT W THE HUBBY... I HAD A MRI ULTRASOUND DONE AS WELL AND SHOWS MY LEFT SIDE FALLOPIAN TUBE HAS A OPENING AND SHOWS SEVERELY INFLAMED !!! I ALSO HAVE A CYST .. W ALL THIS NOW I'M ABOUT TO HAVE A HYSTERECTOMY (B)(6)!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045084	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 5/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, BLOATING, FATIGUE, DIZZINESS, ANXIETY, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045087	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). PELVIC PAIN, HIP PAIN, BLOAT, PAINFUL PRESSURE IN LOWER ABDOMEN AND CROCH AREA, HAIR LOSS, WORSTING ANXIETY, MOOD SWINGS, LOSS OF SEX DRIVE, LOWER BACK PAIN, INFECTION, HYSTERECTOMY, BRAIN FOG, MEMORY LOSS, PAIN DURING SEX, EXCESSIVE SWEATING, BREAST PAIN, DETERIORATION IN RIGHT HIP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045090	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 5/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED ESSURE IN 2007. I COMPLAINED ABOUT BAD MENSTRUAL CRAMPS AND HEAVY BLEEDING. MY DOC. PUT ME ON THE BIRTH CONTROL PILL. I QUIT TAKING IT FOR AWHILE AND LIVED WITH THE PROBLEMS. FOR THE PAST ALMOST 6 YEARS MY PROBLEMS HAVE BEEN SEVERE. I HAVE TO MISS WORK DUE TO THE CRAMPING AND BLOOD CLOTS THAT GUSH OUT AND ARE SO LARGE. I HAVE CONSTANT PAIN IN MY PELVIS. MAINLY ON THE RIGHT SIDE. I HAVE MADE TRIPS TO THE URGENT CARE FOR THESE PROBLEMS IN THE PAST. LAST YEAR IN (B)(6) I COULDN'T TAKE IT SO AGAIN I MADE AN APPOINTMENT WITH MY DOC. SHE SENT ME FOR A ULTRASOUND. MY UTERUS LINING IS ABNORMAL 20MM. I HAD FIBROIDS. THERE IS SOMETHING IN THE RIGHT SIDE OF MY UTERUS THAT LOOKED LIKE A IUD SAID THE TECH. BUT I HAVE NEVER HAD AN IUD. SHE SAID IT DID NOT LOOK LIKE MY ESSURE. THERE WAS NO MENTION OF MY LEFT COIL. MY DOC. SAID THAT MAYBE SHE WASN'T EXPERIENCED ENOUGH SO EVERYTHING WAS PROBABLY FINE. I DO NOT FEEL FINE. I HAD A DNC TO REMOVE THE THICK LINING AND FIBROIDS IN (B)(6) 2014. SINCE THEM I FEEL WORSE NOT BETTER MY PERIODS HAVE ALSO BEEN IRREGULAR FOR THE PAST 3 YEARS COMING EVERY 3 WEEKS. CRAMPS THAT FEEL LIKE LABOR CONTRACTIONS. IT HAS LOWERED MY SEX DRIVE BECAUSE OF THE BLEEDING AND PAIN. I HAVE ANOTHER ULTRASOUND THIS MONTH AND I AM GOING TO BEG THE TECH. TO TRY AND FIND THE COILS NOW THAT I KNOW HOW MANY PEOPLE HAVE HAD THERE COILS MIGRATE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045091	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PROLONGED BLEEDING DURING MENSTRUATION CYCLE, ABDOMINAL AND PELVIC PAIN , FATIGUE, NAUSEA AND HEADACHES, EXTREMELY BLOATED, PAIN DURING INTERCOURSE, UNWANTED PREGNANCY, HAIR LOSS, EMOTIONAL DISTRESS, BROKEN DEVICE, BELL'S PALSY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045095	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 5/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED ESSURE IN 2007. I COMPLAINED ABOUT BAD MENSTRUAL CRAMPS AND HEAVY BLEEDING. MY DOC. PUT ME ON THE BIRTH CONTROL PILL. I QUIT TAKING IT FO E AWHILE AND LIVED WITH THE PROBLEMS. FOR THE PAST ALMOST 6 YEARS MY PROBLEMS HAVE BEEN SEVERE. I HAVE TO MISS WORK DUE TO THE CRAMPING AND BLOOD CLOTS THAT GUSH OUT AND ARE SO LARGE. I HAVE CONSTANT PAIN IN MY PELVIS. MAINLY ON THE RIGHT SIDE. I HAVE MADE TRIPS TO THE URGENT CARE FOR THESE PROBLEMS IN THE PAST. LAST YEAR IN (B)(6) I COULDN'T TAKE IT SO AGAIN I MADE AN APPOINTMENT WITH MY DOC. SHE SENT ME FOR A ULTRASOUND. MY UTERUS LINING IS ABNORMAL 20MM. I HAD FIBROIDS. THERE IS SOMETHING IN THE RIGHT SIDE OF MY UTERUS THAT LOOKED LIKE A IUD SAID THE TECH. BUT I HAVE NEVER HAD AN IUD. SHE SAID IT DID NOT LOOK LIKE MY ESSURE. THERE WAS NO MENTION OF MY LEFT COIL. MY DOC. SAID THAT MAYBE SHE WASN'T EXPERIENCED ENOUGH SO EVERYTHING WAS PROBABLY FINE. I DO NOT FEEL FINE. I HAD A DNC TO REMOVE THE THICK LINING AND FIBROIDS IN (B)(6) 2014. SINCE THEM I FEEL WORSE NOT BETTER MY PERIODS HAVE ALSO BEEN IRREGULAR FOR THE PAST 3 YEARS COMING EVERY 3 WEEKS. CRAMPS THAT FEEL LIKE LABOR CONTRACTIONS. IT HAS LOWERED MY SEX DRIVE BECAUSE OF THE BLEEDING AND PAIN. I HAVE ANOTHER ULTRASOUND THIS MONTH AND I AM GOING TO BEG THE TECH. TO TRY AND FIND THE COILS NOW THAT I KNOW HOW MANY PEOPLE HAVE HAD THEIR COILS MIGRATE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045096	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 1/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE DEVICE PUT IN IN (B)(6) 2010. AT FIRST EVERYTHING WAS OK BUT THEN ABOUT (B)(6) 2014 MY MONTHLY CYCLE STARTED BEING OFF TRACK. I STARTED GETTING REALLY BAD CRAMPS. MY CRAMPS WERE SO BAD I WOULD DOUBLE IN HALF. THE PAIN IN MY LOWER BACK GO REAL BAD AS WELL. I STARTED BLEEDER WORSE AND HAVING BLOOD CLOTS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045097	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 6/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS HAVING INCREASED PAIN THAT FELT LIKE HOT POKERS IN MY BELLY. MY BELLY BUTTON BEGAN TO LEAK FLUID FROM A TROCHAR SITE. I HAD TO BE ADMITTED WITH A SEVERLY ELEVATED WHITE COUNT. I STAYED ONE NIGHT IN THE HOSPITAL FOR ANTIBIOTICS. I LEFT WITH A COLOSTOMY BAG ON MY BELLY BUTTON UNTIL I SAW AN ADDITIONAL SURGEON THE FOLLOWING WEEK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045098	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 6/4/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DUE TO MULTIPLE SIDE EFFECTS OF ESSURE I HAD A ROBOTIC ASSISTED FULL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045099	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 6/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS RUSHED INTO THE ER WITH TERRIBLE 10 OUT OF 10 PAIN. THE DRAINAGE FROM MY BELLY BUTTON HAD BEGUN TO COME OUT CONSTANTLY. IT ALSO CHANGED FROM CLEAR TO BROWNISH FLUID. MY BPS WERE AT 80/60 AND I NEEDED 5L OF O2 TO KEEP MY SATS @ 90. I HAD A CT SCAN W/ DYE CONTRAST AND THEY FOUND A 20X20X2 FLUID FILLED TUMOR POST OP HYSTERECTOMY. I WAS RUSHED INTO EMERGENCY SURGERY AT 5PM ON (B)(6) 2015. THE TUMOR WAS ACTUALLY 30/24/4. I WAS TO STAY IN THE HOSPITAL FOR 2 NIGHTS ON VANCOMYCIN. MY DOCTOR PUT ME ON BED REST FOR 4 WEEKS. I HAVE LOST WAGES FOR ABOUT A MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045100	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 7/3/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOUND OUT I AM PREGNANT. I HAVE ALSO HAD MULTIPLE ISSUES SINCE I GOT THE DEVICE 5 YEARS AGO, INCLUDING, RASHES, HEAVY BLEEDING, LONGER PERIODS, AND ABDOMINAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045101	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 9/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED BREAKING OUT IN HIVES FROM HEAD TO TOE. ABDOMINAL PAIN, UNCONTROLLED WEIGHT GAIN, PAINFUL INTERCOURSE, AND CHRONIC FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045102	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 9/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2015 I HAD TO HAVE A HYSTERECTOMY TO REMOVE ESSURE DUE TO THE CHRONIC PROBLEMS IT WAS CAUSING. THE PATHOLOGY REPORT INDICATED THAT I HAD CHRONIC INFLAMMATION OF THE TUBES, UTERUS AND CERVIX. I ALSO HAD SEVERAL FIBROIDS. I HAVE ALSO BEEN DIAGNOSED WITH HASHIMOTO'S THYROIDITIS AND CHRONIC EPSTEIN BARR VIRUS. WITHIN 6 MONTHS OF GETTING ESSURE BACK IN 2010 I STARTED HAVING JOINT PAIN IN BOTH MY HANDS AND WRISTS, SINCE MY ESSURE REMOVAL IT HAS NOT GOTTEN ANY BETTER, NOW I HAVE TO GO TO A RHEUMATOLOGIST. ALL OF THESE HAVE SOMETHING IN COMMON, THEY ARE AUTO IMMUNE RELATED ALL DUE TO THE AUTO IMMUNE RESPONSE TRIGGERED BY THE IMPLANTATION OF THE COILS. I NOW HAVE TO TRY AND ACCEPT WHILE I HAVE NO MORE ABDOMINAL PAIN, I STILL HAVE THE CHRONIC ISSUES FROM AUTO IMMUNE DISEASES THAT WILL NEVER GO AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045103	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 5/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN WHEN OVULATING, TIRED ALL THE TIME, PAIN IN MY SIDE CONSTANTLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045104	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).PAINS IN LOWER ABDOMEN (OVARY AREA). SEVERE HAIR LOSS. BRUISE VERY EASILY (NEVER HAVE BEFORE). PAINFUL MENSTRUAL CYCLE. SUPER HEAVY MENSTRUAL CYCLES. WEIGHT GAIN. INABILITY TO LOSS ANY WEIGHT EVEN WHILE WORKING OUT ON A VERY REGULAR BASIS. VERY EMOTIONAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045105	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 10/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, BACK PAIN, MEMORY LOSS, DIZZINESS, ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045106	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 7/24/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY NIGHTMARE STARTED ON (B)(6) 2008. WENT IN FOR REGULAR PAP SMEAR AND MY GYNECOLOGIST EXCITEDLY TOLD ME ABOUT THIS 10 MINUTES IN OFFICE PROCEDURE FOR PERMANENT BIRTH CONTROL. I TOLD HIM I WAS ALREADY IN MY 40'S AND ME AND MY HUSBAND ALWAYS USED A CONDOM, I ALSO MENTIONED MY HUSBAND WOULD BE BACK IN A FEW DAYS, JUST IN TIME FOR OUR (B)(6) ANNIVERSARY. DR SAID WHAT ON AMAZING GIFT I WOULD BE GIVING MY HUSBAND AND WHAT A BOOST TO OUR INTIMACY. I WAS SADLY SOLD AND SIGNED UP FOR ESSURE PROCEDURE FOR THE VERY NEXT DAY. IT WAS WEIRD BC I COULDN'T UNDERSTAND WHEN I GOT THERE WHY I WAS OFFERED A VALIUM BC I WASN'T NERVOUS SINCE DR SAID IT WOULD BE PAINFREE. NURSE INSISTED AND I OBLIGED. THE PROCEDURE DID NOT TAKE 10 MINUTES BUT SO MUCH LONGER WITH ME CRYING AND SHAKING THE ENTIRE TIME. IT WAS AS IF A WIRE HANGER WAS INSERTED INSIDE OF ME AND TWISTED AROUND OVER AND OVER. THE RIGHT SIDE WAS AWFUL BUT WHEN HE DID MY LEFT, I SIMPLY JUST THOUGHT I WAS GOING TO DIE. THE PAIN WAS UNIMAGINABLE! WHEN HE WAS DONE MY LEGS WOULDN'T STOP SHAKING AND FROM THAT DAY FORTH MY LIFE WOULD CHANGE FOREVER. PAIN NEVER SUBSIDED, KEPT GETTING PROGRESSIVELY WORSE AND BLEEDING WAS NONENDING. FROM VERY NEXT DAY, I KNEW SOMETHING WAS VERY VERY WRONG. UPON CALLING MY DR, I WAS TOLD MY DR WAS AWAY ON VACATION AND I COULD TALK TO DR (B)(6) WHO WAS LEFT IN CHARGE. THIS LADY WAS A MONSTER, A ROCK, NO FEELINGS, NO COMPASSION. SHE KEPT SAYING THAT MY SYMPTOMS WERE NOT RELATED TO ESSURE WHICH WAS DONE DAY PRIOR, NOT MUCH THAT COULD BE DONE EXCEPT MORE AND MORE PAIN MEDICINE. I ENDED UP IN THREE DIFFERENT HOSPITALS WITHIN 5 DAYS. THEY ALL PERFORMED VAGINAL ULTRASOUNDS AND ALL SHOCKED AT WHAT FILMS SHOWED BUT EACH ONE WOULD CONTACT DR (B)(6) AND SHE WOULD HAVE ME RELEASED. ONE NURSE ACTUALLY CRIED FOR ME. I REMEMBER MY HUSBAND, WHO I HAD NEVER SEEN CRY,

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CRYING AND BEGGING TO SAVE MY LIFE. AT ONE HOSPITAL DURING THE ULTRASOUND, WHEN HANDPIECE WAS PULLED OUT OF MY VAGINA THE BLOOD SHOT UP AND ACTUALLY SPLASHED ON THE CEILING. EVERYONE FELT SO SORRY BUT NO ONE HELP ME. THEY ALL INSISTED I HAD TO WAIT FOR MY REGULAR DOCTOR. I CANT BELIEVE IM STILL ALIVE BUT SOMEHOW 6 DAYS AFTER MY NIGHTMARE STARTED, MY DOCTOR RETURNED. I REMEMBER GOING INTO OFFICE, BENT OVER WITH MY HUSBAND HOLDING ME AND JUST ASKING HIM TO RELEASE MY RECORDS TO SEE IF SOMEONE WOULD TRY TO SAVE ME. DR LOWERED HIS HEAD AND SHOOK HIS HEAD, APOLOGIZED AND TOLD ME HE WOULD DO ANYTHING TO HELP ME BUT I NEEDED TO GO INTO EMERGENCY SURGERY THAT VERY DAY. ULTRASOUNDS SHOWED A PROGRESSION OF THIS TWISTED MASS ON MY LEFT SIDE THAT HAD GONE FROM THE SIZE OF A MARBLE ON 1ST FILM TO THE SIZE OF A BASEBALL ON 3RD FILM TAKEN WITHIN 4 DAYS OF ESSURE INSERTION. SEEMS COIL ON MY LEFT SIDE HAD PUNCTURED MY OVARY AND STARTED TWISTING AND TOOK FALLOPIAN TUBE AND PART OF MY COLON WITH IT, FORMING A HUGE MASS. THEY ENDED UP REMOVING BOTH FALLOPIAN TUBES, MY LEFT OVARY AND PART OF MY COLON. UNFORTUNATELY FOR ME THE NIGHTMARE WAS FAR FROM OVER. I WAS NEVER AGAIN ABLE TO ENJOY SEX WITH MY HUSBAND BECAUSE PAIN WAS UNBEARABLE, HAVE NOT GONE A SINGLE DAY WITHOUT USING AT LEAST 3 PADS FROM CONSTANT BLEEDING AND ALTHOUGH NOW YEARS LATER THE PAIN IS VERY FAINT, IT NEVER COMPLETELY SUBSIDES. EVERY DOCTOR SINCE HAVE TRIED TO PUT ME ON BIRTH CONTROL TO CONTROL BLEEDING AND MEDICINE FOR DEPRESSION. I REFUSED BOTH. INITIALLY I DID TRY TO SUE BUT EVERY TIME I HAD TO RELIVE WHAT HAPPENED I WOULD FALL DEEPER AND DEEPER INTO A DEPRESSION. THAT AND THE FACT THAT PERSON WHO ALMOST LET ME DIE, DR (B)(6), COULD NOT BE SUED BC SHE NEVER TOUCHED ME! UNFORTUNATELY I WAS TOO WEAK TO FIGHT. TODAY IM (B)(6) AND PROBABLY THE ONLY WOMAN IN THE WORLD LOOKING FORWARD TO MENOPAUSE SO I CAN SPEND 1 FULL DAY WITHOUT BLEEDING. MY HUSBAND ENDED UP CHEATING AND HOW CAN I BLAME HIM SINCE I SIMPLY WAS UNABLE TO HAVE SEX. YES I WENT THRU A DIVORCE BUT MORE BECAUSE (B)(6) DESERVES TO BE HAPPY AND I DONT KNOW IF I WILL EVER BE ABLE TO HAVE THAT PART OF MY LIFE BACK. I JUST PRAY TO GOD THAT THEY DISCONTINUE THIS PRODUCT BECAUSE NOW I KNOW IM ONE OF THE LUCKY ONES AND WAY WORSE CASES OUT THERE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045107	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 7/7/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN BLEEDING HEADACHES WEEPY SAD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045108	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN 2011 RIGHT AFTER MY THIRD CHILD WAS BORN I DECIDED TO GET THE ESSURE. I DIDN'T EXPERIENCE ANY SYMPTOMS UNTIL A YEAR LATER, FOR THE LAST THREE YEARS MY SYMPTOMS HAVE INCLUDED... DEBILITATING HEADACHES ALMOST EVERYDAY, EXTREME ABDOMINAL PAIN, BLEEDING DURING AND AFTER INTERCOURSE, PAIN DURING AND AFTER INTERCOURSE, NUMBNESS AND TINGLING IN HANDS, FEET, ARMS, LEGS, BURNING SENSATION IN ABDOMEN, WEIGHT LOSS, WEIGHT GAIN, BLOATING, FATIGUE, MOOD SWINGS, UNEXPLAINED BRUISING, DIZZINESS AND HERE RECENTLY I'VE DEVELOPED AN ALLERGY TO DAIRY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045110	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 1/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ESSURE DEVICES WERE IMPLANTED 4 MONTHS AFTER THE BIRTH OF MY CHILD. THE IMPLANTATION PROCEDURE WENT WELL, I EXPERIENCED SOME MILD CRAMPING AND LIGHT SPOTTING AS EXPECTED. ONE MONTH AFTER THEY WERE IMPLANTED, I BEGAN EXPERIENCING: HEADACHES, DIZZINESS, JOINT PAIN, HORMONAL IMBALANCE, SEVERE PMS, EXTENSIVE OVULATION PAIN, EXTENSIVE PAIN DURING PERIOD, EXTREMELY HEAVY BLEEDING, HAIR LOSS, AND SCALP IRRITATION/PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045111	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 2/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BECAME PREGNANT AFTER CONFIRMATION HSG TEST THAT MY TUBES WERE CLOSED. I CURRENTLY EXPERIENCE HAIR LOSS, WEIGHT GAIN, DEPRESSION, ACHES AND PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045122	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 5/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDA MW 5045122 #(B)(4). (B)(6) 2015 - PATHOLOGY REPORT FROM (B)(6) SHOWED ACUTE CHRONIC BACKGROUND INFLAMMATION, CHRONIC CERVICITIS WITH NO SIGNS OF INFECTION, ESSURE DEVICE BREACHING LEFT FALLOPIAN TUBE, EXTENSIVE ADENOMYOSIS, AND RETROPERITONEAL FIBROSIS OBLITERATING BOTH URETERS, REQUIRING BILATERAL PELVIC URETEROLYSIS. THE LEFT OVARY, FALLOPIAN TUBE, UTERUS, CERVIX, AND BOWEL WERE FUSED TOGETHER WITH DENSE ADHESIONS. OVARIES WERE COMPLETELY NORMAL WITH NO CYSTS, AND CYSTOSCOPY WAS ALSO COMPLETELY NORMAL. UTERUS WAS NORMAL IN SIZE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045124	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 8/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP STABBING PAINS IN MY STOMACH, PELVIC AREA; HEADACHES, EXTREME PAIN WHEN ON MENSTRUAL, HAIR LOSS, HUGE STOMACH NUMBNESS, BACK PAIN, PROBLEMS USING THE BATHROOM, AND MUCUS DISCHARGE FROM MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045125	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 6/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) I STARTED GETTING VERY SEVERE ABDOMINAL PAINS, AND VAGINAL PAINS. IT FELT AS THOUGH I WAS IN LABOR WITH A BABY EVEN THOUGH I WAS NOT. I WAS DOUBLED OVER AT WORK ON (B)(6) AND COULD NOT WALK, WENT INTO THE ER AND THAT FOLLOWING (B)(6) 2015 HAD TO GO IN FOR SURGERY AND HAVE MY FALLOPIAN TUBES REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045140	BAYER	8/5/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WIRE PERFORATED RIGHT FALLOPIAN TUBE AND UTERUS, POSSIBLE CONTACT WITH BOWEL. WIRE IS BROKEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055330	ESSURE	8/5/2015	8/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4): 863494
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE THEN ABOUT TWO YEARS AGO I BEGAN TO LOOSE MY HAIR, I BEGAN TO BE VERY FATIGUED ALL THE TIME I EVEN TRIED ENERGY SUPPLEMENTS AND NOTHING WORKED. I AM NOT IN CHRONIC PAIN WHEN I WALK, MY LEGS AND FEET SWELL ALL THE TIME. I AM BEGINNING TO GET RASHES ALL OVER MY BODY CONSISTENT WITH THE NICKEL ALLERGY. I CAN'T HAVE SEX BECAUSE IT HURTS TOO BAD. I AM CONSTANTLY NAUSEOUS SO MUCH TO THE POINT I WENT TO HAVE A BLOOD TEST DONE BECAUSE I THOUGHT I WAS PREGNANT. MY DOCTOR NEVER DID A ALLERGY TEST ON ME. I HAVE THIS HORRIBLE FEELING THAT MY OVARIES ARE SWOLLEN SOME HOW BECAUSE IT HURTS REALLY BAD IN THAT AREA. I DONT HAVE MEDICAL COVERAGE SO IT'S HARD FOR ME TO SEE A DOCTOR. I'M AT A LOSS BECAUSE I DON'T KNOW WHAT TO DO BUT ONE THING I DO KNOW IS I HAVE BECOME VERY DEPRESSED AND THIS IS NOT THE USUAL ME AND I SEE NOW THAT I HAVE THE SAME SIMILAR SYMPTOMS AS A LOT OF OTHER WOMEN WHO HAVE HAD THIS PROCEDURE DONE AND THEY ARE LOOSING THEIR ENTIRE UTERUS AND HAVING TO HAVE HYSTOS AND REMOVE ALL THERE FEMALE ORGANS AND I'M TERRIFIED TO DEATH. PLEASE HELP I DON'T KNOW WHAT TO DO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055331	BAYER	8/5/2015	8/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE PROCEDURE DONE IN 2006. FIRST I GAINED A LOT OF WEIGHT, SEVERE ABDOMINAL AND BACK PAIN, ABNORMAL BLEEDING, AND RECENTLY FOUND OUT MY ESSURE MIGRATED INTO MY PELVIS AND I'M GETTING A HYSTERECTOMY ON (B)(6). I'VE BEEN IN PAIN FOR OVER A YEAR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055337	BAYER	8/5/2015	8/13/2015

Event Information:

Event Date (B3): 6/24/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/24/2004
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL DEVICE IMPLANTED IN (B)(6) 2004. I BEGAN HAVING ISSUES IN 2005 WHEN I, LITERALLY OVER NIGHT WAS HIT WITH LIFE ALTERING FATIGUE. TO THIS DAY, 10 YEARS LATER, I STILL HAVE SEVERE FATIGUE THAT PREVENTS ME FROM DOING THINGS I REALLY WANT TO DO. IN 2009, I WAS HIT WITH A RASH OF NEW SIDE EFFECTS, WHICH INCLUDED THE FOLLOWING: DEBILITATING HEADACHES, BLOOD PRESSURE DROPS, JOINT PAIN, LOSS OF MOTOR SKILLS IN HANDS (RIGHT HAND MAINLY), REDUCTION IN MUSCLE STRENGTH, INSOMNIA, DEPRESSION, FEVERS, DIZZINESS AND GENERAL PAIN. IN 2012, THE REST OF MY SYMPTOMS JOINED THE LIST, THAT INCLUDE: CHEST PAIN, SERIOUS DIGESTIVE ISSUES, BLOATING (LOOKING ABOUT 6-8 MONTHS PREGNANT), DIARRHEA, CONSTIPATION, SHARP STABBING PAIN IN RIGHT OVARY. FALLOPIAN TUBE AREA THAT LASTS ANYWHERE FROM MERE MINUTES TO DAYS, BACK PAIN, LEG CRAMPS, BLEEDING A COUPLE WEEKS PRIOR TO MONTHLY CYCLE, SEVERE NECK PAIN, NAUSEA, MENTAL FOG FEELING, LOSS OF FEELING IN EXTREMITIES WHILE LYING DOWN OR SITTING, HAND TREMORS, SENSITIVITY TO GLUTEN, ITCHY ALL THE TIME, HEART PALPITATIONS, WEIGHT GAIN WITH NO CHANGE IN EATING OR EXERCISE HABITS (WEIGHT THAT CANNOT BE LOST), BLURRED VISION, MUSCLE ACHES, AND A FEW I PROBABLY MISSED. I EXPERIENCE MOST OF THE ABOVE MENTIONED SYMPTOMS ON A DAILY BASIS. I HAVE NOT BEEN WITHOUT A HEADACHE IN OVER 6 YEARS!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045146	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A CSECTION (B)(6) 2014 AT (B)(6) WEEKS FRATERNAL TWINS! (NOT SURE HOW TO CATEGORIZE THIS) GOT ESSURE 6 WEEKS AFTER MY DAUGHTER WAS BORN (B)(6) 2009. DOCTORS TOLD ME WOULD HAVE TO WAIT UNTIL THEIR DELIVERY TO FIND OUT WHAT HAPPENED AND HOW I GOT PREGNANT. WAS TOLD I HAD A SMALL TEAR IN ONE TUBE. I DON'T KNOW ANYTHING ELSE ON DETAILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045153	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/12/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEED FOR 3 MONTHS ON AND OFF 3 WEEKS AFTER I GOT THE ESQUIRE PROCEDURE. PERIODS HAVE NOT BEEN THE SAME. MY HAIR STARTED FALLING OUT. I'M AM CURRENTLY BALD AT THE FRONT TO THE MIDDLE OF MY HEAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045155	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 2/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045156	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/12/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEED FOR 3 MONTHS ON AND OFF 3 WEEKS AFTER I GOT THE ESQUIRE PROCEDURE. PERIODS HAVE NOT BEEN THE SAME. MY HAIR STARTED FALLING OUT. I'M AM CURRENTLY BALD AT THE FRONT TO THE MIDDLE OF MY HEAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045157	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A C SECTION (B)(6) 2014 AT 34+1 WEEKS FRATERNAL TWINS! (NOT SURE HOW TO CATEGORIZE THIS) GOT ESSURE 6 WEEKS AFTER MY DAUGHTER WAS BORN (B)(6) 2009. DOCTORS TOLD ME WOULD HAVE TO WAIT UNTIL THEIR DELIVERY TO FIND OUT WHAT HAPPENED AND HOW I GOT PREGNANT. WAS TOLD I HAD A SMALL TEAR IN ONE TUBE. I DON'T KNOW ANYTHING ELSE ON DETAILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045162	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD HORRIBLE PAINS IN THE OVARY REGION, ON THE RIGHT SIDE, (THE GYN COULD NOT GET THE LEFT SIDE IN) LIKE SOMETHING WAS POKING ME. I STILL HAD BLEEDING AFTER THE ABLATION, I SWITCHED GYNS WITHIN A YEAR OF THE ESSURE IMPLANT AND MY NEW GYN SCHEDULED ME FOR A PARTIAL HYSTERECTOMY. REMOVAL OF THE UTERUS AND TUBE TO REMOVE THE ESSURE. WHEN HE OPENED ME UP, THE ESSURE COIL HAD MIGRATED INTO MY UTERUS AND WAS POKING THROUGH CAUSING A SMALL AMOUNT OF INTERNAL BLEEDING. THE COIL IS NOW GONE, BUT SINCE HE REMOVED IT FROM MY UTERUS HE LEFT THE TUBE, I STILL HAVE VERY BAD PAINS IN THAT TUBE, ALMOST CONSTANT BURNING OR CRAMPING IN IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045163	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 6/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ON (B)(6) I STARTED GETTING VERY SEVERE ABDOMINAL PAINS, AND VAGINAL PAINS. IT FELT AS THOUGH I WAS IN LABOR WITH A BABY EVEN THOUGH I WAS NOT. I WAS DOUBLED OVER AT WORK ON (B)(6) AND COULD NOT WALK, WENT INTO THE ER AND THAT FOLLOWING MONDAY ON (B)(6) 2015 HAD TO GO IN FOR SURGERY AND HAVE MY FALLOPIAN TUBES REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045164	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/19/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PLACED IN (B)(6) 2006 AFTER THE BIRTH OF MY 2ND CHILD. IN (B)(6) OF 2007, I WAS ADMITTED INTO THE HOSPITAL DUE TO SEVERE ABDOMINAL PAIN FOR OVER 12 HOURS. DOCTORS COULD NOT FIND THE SOURCE OF THE PAIN AND RELEASED ME AFTER 24 HOURS. (B)(6) 2007 AFTER MISSING MY CYCLE, IT WAS DISCOVERED THAT I WAS PREGNANT. AFTER VISITING WITH ANOTHER PHYSICIAN AND A CONFERENCE CALL WITH CONCEPTUS AND THE PHYSICIAN AND GETTING NO POSITIVE ANSWERS FOR THE SAFETY OF MYSELF AND/OR MY FETUS, I DECIDED I WANTED TO ABORT THE PREGNANCY AS MY 2 CHILDREN DESERVED THEIR MOTHER. AFTER THE DNC WAS COMPLETE, THE DOCTOR ORDERED SEVERAL X-RAYS TO BE DONE AND ONLY 1 COIL HAS BEEN LOCATED. TO THIS DATE, I STILL HAVE NO ANSWERS OF WHERE THE OTHER COIL IS. LATER THAT YEAR, I DID HAVE A TUBAL LIGATION TO PREVENT ANY FURTHER PREGNANCIES. SINCE THAT TIME I HAVE GAINED OVER 30 LBS, LARGE AMOUNTS OF HAIR LOSS, CONSTANT DIARRHEA, CONSTANT FATIGUE, BLOATING, HEADACHES, HIP PAIN, PELVIC PAIN, LEG ACHES AND THROBS, EXTREME MOODINESS, DEPRESSION, ANXIETY ATTACKS, ABNORMAL HAIR GROWTH ON NECK AND BREASTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045165	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SIDE EFFECTS STARTED WITH MIGRAINES THAT WOULD NOT GO AWAY, AROUND THE SAME TIME, ON AND OFF HIVES AND SEVERE BLOATING AND CONSTIPATION ISSUES. BY (B)(6), MIGRAINES GOT WORSE, PERIODS BECAME HEAVIER AND CRAMPS BECAME MUCH WORSE. BY APRIL, BEGAN HAVING 2 PERIODS A MONTH WITH SEVERE CRAMPS AND HEAVY BLEEDING. STILL HAVING PAINFUL CYCLES, MIGRAINES TO THE POINT OF THROWING UP, RESTLESS NIGHTS, MOOD SWINGS, PAINFUL INTERCOURSE, CONSTIPATION ISSUES, TO NAME A FEW. HAD LAB WORK DONE TO RULE OUT THYROID ISSUES AND CAME BACK NORMAL. CHANGED MY DIET, NOTHING CHANGED SYMPTOM WISE. I DO HAVE A NICKEL ALLERGY WHICH I RECENTLY FOUND OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045166	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN IN PELVIC AREA, LEGS, FEET, BACK, HIPS, HEAD, VITAMIN D, B12 DEFICIENT, HORMONE LEVELS UP AND DOWN, HAIR LOSS, NIGHT SWEATS, PAIN DURING SEX, NO SEX DRIVE, TIREDNESS, DEPRESSION, ANXIETY, TINGLING IN MY FEET AND HANDS, RINGING IN MY EARS, EYE PROBLEMS, FORGETFULNESS AND MANY MORE!! ESSURE HAS TAKEN MY LIFE AWAY FROM ME!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045167	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I FOUND OUT I WAS PREGNANT ON (B)(6) 2012 DUE TO LOWER ABDOMINAL PAIN. GAVE BIRTH TO MY DAUGHTER (B)(6) 2013. ESSURE WAS PUT IN (B)(6) 2009. ABNORMAL PERIODS, BACTERIAL INFECTION, MASSIVE ABDOMINAL PAIN FOR THE PAST 6 MONTHS, WEIGHT FLUCTUATION, HEADACHES, AND NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045168	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 2/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WOKE UP IN HORRIBLE PAIN, HAD TO MAKE AN E.R. VISIT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045169	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/26/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN OVARIES,PELVIC AREA,HIPS,JOINTS. EXTREME SWELLING IN ABDOMEN. NUMBNESS IN FINGERS, TOES AND LEG. LOSS OF MEMORY, OCCASIONAL VERTIGO, IRRITABILITY

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045170	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 9/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD HEADACHES DAILY THAT NEVER GO AWAY WITH ANY TYPE OF MEDICATION, I HAVE AT LEAST 3 WEEKLY MIGRAINES, I HAVE BLURRED VISION, RINGING IN EARS, NUMB ARMS AND LEGS, SEVERE BACK AND ABDOMINAL PAIN, PAINFUL SEX, BLOATING, DISTENDED BELLY, TINGLING ALL OVER, NAUSEA, DIZZINESS, HEAD FOG, EXTREMELY HEAVY PERIODS, LARGE BLOOD CLOTS, LONG PERIODS, URINARY TRACT ISSUES, PRESSURE IN ABDOMEN. THESE ISSUES ARE BAD ENOUGH TO AFFECT MY DAILY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045171	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMPLANTED WITH ESSURE DEVICE IN 2006. I HAD SEVERE CRAMPING AND HEAVY BLEEDING WITH MENSTRUATION. IN 2010 I BEGAN HAVING SEVERE PAIN IN MY RIGHT SIDE. AFTER 2 ER VISITS, ULTRASOUNDS, X-RAYS, AND A CT SCAN IT WAS DETERMINED THAT I HAD A 3RD COIL THAT HAD MIGRATED, CAUSING MY PAIN. IT REQUIRED A HYSTERECTOMY TO RESOLVE THE PAIN. I WAS HOSPITALIZED FOR 3 DAYS AND REQUIRED A BLOOD TRANSFUSION DUE TO BLOOD LOSS DURING SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045172	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 10/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVER MIGRAINES, ABDOMINAL PAIN, SEVER BACK PAIN, HAIR FALLING OUT, URINARY TRACT INFECTIONS, HEAVY MENSTRUAL PERIODS, SEVER CRAMPING !

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045173	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 3/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ER VISIT DUE TO SEVERE MIGRAINE AND FEELING OF BLOOD VESSELS BUSTING THROUGH OUT MY HEAD. DIZZINESS, BRAIN FOG, EXTREME FATIGUE, NUMBNESS IN HANDS AND LEGS. HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045174	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/29/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC FATIGUE, ABDOMINAL PAIN, RASH, JOINT PAIN, LONG MENSTRUAL CYCLE, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045175	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/24/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESSIVE LONG PERIODS AND CRAMPING. WOUND UP WITH CYCLES LASTING 3 WEEKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045176	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD NUMEROUS PROBLEMS SINCE GETTING ESSURE TO INCLUDE HEADACHES, STOMACH PAINS, HEAVIER PERIODS, AND DEPRESSION. I ALSO HAVE PROBLEMS WITH PAIN ON MY LEFT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045177	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD NUMEROUS PROBLEMS SINCE GETTING ESSURE TO INCLUDE HEADACHES, STOMACH PAINS, HEAVIER PERIODS, AND DEPRESSION. I ALSO HAVE PROBLEMS WITH PAIN ON MY LEFT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045178	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER#:(B)(4). ELEVATED CRP LEVELS WITHOUT POSITIVE BLOOD TESTING FOR AUTOIMMUNE DISEASE OR INFLAMMATORY MARKERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045179	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 6/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER FIRST SURGERY TO GET RID OF ESSURE, I WAS LEFT WITH FRAGMENTS, HAD TO HAVE UTERUS AND CERVIX REMOVED. ALLERGIC TO NICKEL, WEIGHT GAIN, JOINT PAIN, BACKACHE, DENTAL PROBLEMS, LOSS OF HAIR, BRAIN FOG, METALLIC TASTE IN MY MOUTH, EYE RASH, BLOATING, ABDOMINAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045180	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 10/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOTS OF PAIN WHILE IT WAS BEING PUT IN. MY OBGYN DONE IT IN HIS OFFICE. NOW I SUFFER FROM WEIGHT GAIN, HAIRLOSS, MOOD SWINGS, LOWER BACK PAIN, IRREGULAR PERIODS, PAIN DURING SEX, HARDLY ANY SEX DRIVE, I HAVE MANY MORE JUST TO MANY TO LIST

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045181	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 12/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN HAVING REALLY BAD PAIN IN MY BACK, STOMACH, HEADACHE AND WEIGHT GAIN THE PAIN I FEEL IS SO BAD SOMETIMES I CAN'T GET UP FROM MY BED I'M ALWAYS DEPRESS HARDLY DO THINGS I JUST WISH I COULD SPEND MORE TIME WITH MY FAMILY MY BABIES BUT I'M ALWAYS SO DEPRESS AND I WISH I COULD JUST REMOVE IT BUT DON'T HAVE THE MONEY I'M JUST TRYING TO REPORT THIS SO PEOPLE DON'T HAVE TO GO THRU THIS AND FAMILY CAN BE HAPPY AND STAY STRONG

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045182	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 6/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN HAVING INCREASE MIGRAINE HEADACHES; BEFORE MAY BE ONCE A YEAR; NOW I'M AT ABOUT 2 PER MONTH, I'VE STARTED TO HAVE HEAVY MENSTRUATIONS BEFORE 2-3 DAYS, NOW 7-8 DAYS, ALSO PELVIC PAIN, LOW SEX DRIVE, DEPRESSION, CARPAL TUNNEL SYNDROME, I'VE HAD BILATERAL CARPAL TUNNEL RELEASE. DEPRESSION, BLURRED VISION, SOUR TASTE TO MOUTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045183	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, DEPRESSION, GOT PREGNANT. MY BABY WAS BORN WITH LOW MUSCLE TONE. DEVELOPMENTAL DELAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045184	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 9/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I JUST SPOKE WITH MY SURGEON AND HE TOLD ME THAT HE ALSO FOUND ADENOMYOSIS. COMMON WITH ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045185	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SCHEDULED HYSTERECTOMY (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045186	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 2/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PLANTAR FASCIITIS, ARTHRITIS, PAINS: HAND, UPPER ARM, SHOULDER, LOWER AND UPPER BACK, NECK, HEADACHES, FIBROMYALGIA, HIGH BLOOD PRESSURE, DIABETIC, LOWER ABDOMINAL PAIN AND TENDERNESS IN MY PELVIC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045187	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAINFUL CRAMPING FOR 4 DAYS ACCOMPANIED BY MENSTRUAL HEMORRHAGING. LARGE BLOOD CLOTS. SEVERE HEADACHES AND MIGRAINES. JOINT (MAINLY IN KNEES) PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045188	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . I AM ALLERGIC TO NICKLE. I HAVE HAD SEVERE ABDOMINAL PAIN , JOINT PAIN, NAUSEA, SWELLING OF HANDS AND FEET, BLOOD CLOTS, ANXIETY, INSOMNIA AND DEPRESSION, UNEXPLAINED SKIN RASHES, BLEEDING AND PERIODS IRREGULAR. I HAVE HAD 2 HEAVY PERIODS PER MONTH, PAIN AND BLEEDING AFTER SEX. SYMPTOMS BEGAN IMMEDIATELY AFTER THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045189	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING AFTER ANDAMP; BEFORE SEX. PERIODICALLY STOMACH CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045190	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAIN, FLUID FLOWING THROUGH TUBES. STILL DOING ONGOING TESTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045191	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 9/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED IN (B)(6) OF 2010 EVERYTHING SEEMED OK. I BECAME PREGNANT WITH COMPLICATIONS. I HAD HIM A MONTH EARLY AND HAD A TUBAL. SINCE THEN I HAVE BEEN VERY FUZZY HEADED AND FORGETFUL. MY PERIODS ARE EXTREMELY LONG HEAVY AND PAINFUL. I HAVE MANY HUGE CLOTS DURING AND AFTER MY PERIOD. MY HIPS CONTINUALLY ACHE AND AT TIMES RADIATE DOWN MY LEGS. ALWAYS HAVE A DULL ACHE DOWN IN MY LOWER ABDOMEN AND I BELIEVE THE DR CUT THE DEVICE WHEN GIVING ME A TUBAL. I NEVER HAD AN X RAY TO CONFIRM PLACEMENT BEFORE SURGERY AND NOT EDUCATED AND LEFT IN THE DARK ABOUT THE WHOLE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045192	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/21/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PROBLEMS STARTED WITHIN ONE WEEK AFTER INSERTION. DIZZINESS, FOGGY HEAD, BLACKOUTS, MIGRAINES, WEIGHT GAIN, STOMACH PAIN. FOUR ER VISITS, HUNDREDS OF TESTS AND AMP; EVERYTHING NORMAL. THE ONLY DIFFERENCE IN MY BODY WAS ESSURE. I FELT LIKE I WAS BEING SLOWLY POISONED. FINALLY AFTER 4 MONTHS, CONVINCED MY DOCTOR TO TAKE THEM OUT. ENDED UP HAVING A SALPINGECTOMY AND WAS FINE THE NEXT DAY!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045193	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 12/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING SHARP/STABBING PELVIC PAIN, OVARIAN CYSTS, BACTERIAL VAGINOSIS ,CONSTANT DISCHARGE (ODOR), HOT FLASHES, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION , NIGHT SWEATS, SPOTTING AFTER SEX ,PAINFUL PERIODS, PAINFUL INTERCOURSE ,YEAST INFECTIONS (CANDIDA) BACTERIAL VAGINOSIS, URGENT/FREQUENT URINATION, UTI (URINARY TRACT INFECTION), BLADDER INFECTION, ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE,BREAST PAIN/TENDERNESS ABDOMINAL SPASMS/ TWITCHING/FLUTTERING,PAIN BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP CHRONIC PELVIC PAIN, FACE PAIN, ALL OVER BODY ACHES/PAIN,GASTROINTESTINAL NAUSEA, VOMITING, DIARRHEA SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, NEUROLOGICAL, MENTAL HEALTH ,HEADACHES AND MIGRAINES, DIZZINESS, TINGLING SENSATIONS NUMBNESS, BRAIN SHOCKS, NERVE PAIN, BRAIN FOG "ANDNDASH";CLOUDINESS, FORGETFULNESS ANXIETY/PANIC ATTACKS MOOD SWINGS, DEPRESSION, RINGING IN EARS, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS) MOOD DISORDERS, PTSD, NUMBNESS IN THIGH,NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET) SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN, NERVE PAIN, TREMORS/SHAKINESS, DIZZINESS, BLOOD ISSUES, ANEMIA/ IRON DEFICIENCY, VITAMIN D DEFICIENCY, UNEXPLAINED/EASILY BRUISING, VITAMIN B-12 DEFICIENCY, ELEVATED BLOOD COUNTS, CHRONIC FATIGUE SYNDROME, ALLERGIES/SENSITIVITIES CHEMICAL AND FOOD SENSITIVITIES, METAL ALLERGIES (NICKEL,) HEIGHTENED ALLERGIES/ ALLERGIC REACTIONS FOOD ALLERGIES, RASH, SKIN IRRITATION/ITCHING, HEART PALPITATIONS, HAIR LOSS PROBLEMS WEIGHT ISSUES (LOSS/ GAIN) SWOLLEN GLANDS, MUSCLE SPASMS, EXCESSIVE SWEATING DRY SKIN/HAIR/EYES, AND SEVERE BLOATING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045194	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I ENDED UP PREGNANT AFTER I HAD THE TEST AND IT SAID, MY TUBES WERE OCCLUDED. I GET INTENSELY HEAVY PERIODS WITH CLOTTING. I CAN FEEL THEM, THEY CAUSE PAIN, TWINGE AND EXTREME BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045195	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 6/4/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS CALLED IN BY MY DOCTOR DURING THAT TIME BECAUSE I HAD JUST HAD A SON (B)(6) SO I WAS SUPPOSE TO GET A TUBAL INSTEAD , BUT HE STATED THAT IT WOULD STILL BE MONTHS ON DOWN THE LINE FOR ME TO GET MY TUBAL DONE , BUT A NEW BIRTH CONTROL METHOD JUST CAME OUT ON THE MARKET WHICH WAS CALLED ESSURE , NOW WHAT HE DID EXPLAIN TO ME THAT IT WAS VERY PERMANENT AND IF I WAS SURE ABOUT NOT HAVING ANY MORE CHILDREN WHICH I STATED YES I AM SURE . BUT WHAT HE FAILED TO TELL ME WAS THE LONG TERM DAMAGE THAT IT WOULD CAUSE ME , LIKE HEAVY CRAMPING ,BLEEDING EVERYDAY WHEN IT WASN'T TIME FOR MY CYCLE AND THE EXCUSE I WOULD GET IS YOUR BODY HAS TO GET REGULATED TO THIS NEW BIRTH CONTROL , HEAVY BLEEDING THE SIZE OF GOLF SIZE BALLS THEN HAVING LOWER BACK PAIN STILL THAT I HAVE TO THIS DAY AS WE SPEAK . HAVING GYNECOLOGICAL ISSUES FOR 7 YEARS SWELLING OF MY LEGS AND FEET RUNNING BACK AND FOURTH TO THE HOSPITAL JUST TO MAKE SURE I DIDN'T HAVE BLOOD CLOTS FORMING IN MY LEGS , ITS HARD NOT TO BE ABLE TO ATTEND TO YOUR CHILDREN BECAUSE I CANT MOVE OUT THE BED , MIGRAINES WHICH I AM ON MED FOR THE FATIGUE AND MAJOR WEIGHT GAIN , I TALKED WITH MY NEW OBGYN AND SHE STATED THAT IT WAS IN BEST INTEREST THAT I HAVE A COMPLETE HYSTERECTOMY (2010) BECAUSE OF MY INTENSE PELVIC PAIN . IF I HAD KNOWN THAT ESSURE WAS GOING TO AFFECT MY LIFE THE WAY THAT IT DID MISSING OUT ON ACTIVITIES WITH MY CHILDREN AND FAMILY BECAUSE MY ENERGY LEVEL WAS SO LOW AND HAD NO DESIRE TO PERFORM SEXUALLY BECAUSE IT WAS VERY PAINFUL NO I WOULD NOT HAVE CONSENTED TO IT , THE DOCTOR DID NOT DO OR PERFORM ANY TYPE OF TEST ON ME TO SEE IF I WAS ALLERGIC TO THIS DEVICE HE JUST GAVE ME A CARD AND SAID KEEP ON ME AT ALL TIMES , AND HIM BEING MY DOCTOR I TRUSTED HIM .

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045196	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ESSURE SINCE (B)(6) 2009. SINCE THEN I HAVE HAD PROBLEMS WITH MY CYCLE. IT COMES EVERY 3 MONTHS AND WHEN IT DOES IT CLOTS AND SEVER PELVIC PAIN. I ALSO AM HAVING PROBLEMS WITH HIGH BLOOD PRESSURE NOW. AT TIMES I AM UNABLE TO MOVE BECAUSE OF THE PAIN. IT FEELS LIKE SOMETHING IS STRETCHING AND PULLING ON MY INSIDES. COIL IN MY LEFT TUBE HAS BEEN BELIEVED TO HAVE MIGRATED SINCE IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045197	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 10/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THE ESSURE PUT IN I HAVE SUFFERED SEVERE MOOD SWINGS EMOTIONAL INSTABILITY, HORMONE IMBALANCE AND BACK PAIN. THE BACK PAIN WAS LIVEABLE WITH UP UNTIL ABOUT A TWO YEARS AGO. NOW IT'S EXTREME AND OFTEN. PUTTING ME OUT OF WORK FOR A WEEK AT A TIME. ESPECIALLY DURING MY CYCLE. THE EMOTIONAL/HORMONE IMBALANCE HAS INCREASED AS WELL IN THE LAST YEAR. CAUSING SEVERE DEPRESSION AND HORRIBLE MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045198	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 5/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING LOWER BACK PAIN WITH SHARP ABDOMINAL PAIN, RASH ON BOTH ARMS, FOGGY BRAIN VERTIGO, HAIR LOSS, MOOD SWINGS, JOINT PAIN, SEVERE CRAMPING WITH BLOOD CLOTS, CAN'T SLEEP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045199	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT MIGRAINES, SEVERE BLOATING, BACK PAIN, METAL TASTE, ALWAYS TIRED, NAUSEOUS ALL THE TIME, I BREAK OUT IN HIVES ON MY CHEST, NECK, AND FACE WHICH DIDN'T START TILL ENSURE WAS PLANTED IN ME... MASSIVE WEIGHT GAIN CANNOT KEEP IT OFF EVEN STARTED DIETING AND WORKING OUT WITH NO POSITIVE RESULTS. INJAVE ABDOMINAL PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045200	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABNORMAL VAGINAL BLEEDING, PAINFUL INTERCOURSE, SWOLLEN BELLY, MIGRAINES, MEMORY ISSUES, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045201	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 6/3/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED GETTING DIAGNOSED WITH DEPRESSION,ANXIETY,BIPOLAR,RYNAUDS,FIBROMYALGIA,MIGRAINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045202	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 2/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE JOINT PAIN IN MY SHOULDERS, HIPS, KNEES, FINGERS. I HAVE ABDOMINAL PAIN AND IT IS SO MUCH WORSE WHEN I SNEEZE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045203	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 3/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS PLACED (B)(6) 2012. IN (B)(6) 2012 I BROKE OUT IN AN EXTREME RASH FROM HEAD TO TOE. I WENT TO MY PRIMARY CARE DOCTOR AND WAS PLACED ON STEROIDS, ANTI FUNGAL, ANTI BACTERIA, STEROID CREAMS, ANTI ITCH MEDICATION. I WAS SENT TO A DERMATOLOGIST FOR ALLERGY TESTING AND WAS PLACED ON A GLUTEN FREE DIET FOR OVER A YEAR AND A HALF. I HAVE TAKEN ZANTAC, AND BENADRYL OR CLARITIN IN HIGH DOSES TO KNOCK DOWN THE RASH SYMPTOMS WHEN THEY GET TO BE SO STRONG THAT I CANT TAKE IT. I HAVE HAD THE RASH NOW SINCE (B)(6) 2012. I HAVE BEEN TO NUMEROUS DOCTORS TO TRY AND FIGURE OUT WHAT IS WRONG, DIFFERENT DIETS, DIFFERENT CREAMS AND NOTHING IS STOPPING THE RASH. I ALSO HAVE EXPERIENCED EXTREME BACK PAIN. I HAVE ALWAYS BLAMED IT ON MY BACK BUT IT IS NOT THE SAME. THE PAIN IS OFF TO THE SIDES ON MY BACK NOT IN MY SPINE. THE BACK PAIN CAN GET SO EXTREME THAT I CANT GET OUT OF BED. IN APRIL MY FAMILY AND I WENT ON A SMALL HIKE. THE NEXT DAY, EASTER, I COULDN'T GET OUT OF BED BECAUSE OF THE BACK PAIN. I WAS DOWN FOR THREE DAYS. AGAIN, I BLAMED IT ON MY BACK ISSUES. I HAVE WENT BACK TO THE ONCOLOGIST THAT PUT THE COILS IN AND AM SCHEDULED TO HAVE THEM REMOVED (B)(6) BUT NOW AM FACED WITH THE MEDICAL BILLS TO HAVE THEM REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045204	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKEL ALLERGY, SEVERE IRON DEFICIENCY ANEMIA, SEVERE VITAMIN D DEFICIENCY, CONSTANT BACTERIAL VAGINOSIS, VERY HEAVY PERIODS AND SEVERE CRAMPING, CONSTANT PELVIC PAIN, LACK OF SEX DRIVE, PAINFUL INTERCOURSE, SEVERE BLOATING, CHRONIC FATIGUE, FEELING LIKE I HAVE THE FLU ALL THE TIME, BOWEL ISSUES, CONSTANT HEADACHES, TINGLING IN HANDS, WEIGHT GAIN, NIGHT SWEATS, ANXIETY AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045205	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM NOW STARTING TO GET SEVERE PAIN IN THE BACK OF MY SKULL TOWARDS THE TOP OF MY HEAD. IT HAS HAPPENED RANDOMLY OVER THE PAST 3 DAYS. WHEN IT HAPPENS MY ENTIRE NECK GOES LIMP. I CAN'T CONTROL IT AT ALL. THIS HAS NEVER HAPPENED BEFORE IN MY LIFE. (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045206	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWO COILS ON LEFT TUBE, PELVIC PAIN, LONG MENSTRUAL CYCLE, HEAVY CYCLES, BLEEDING IN BETWEEN CYCLES, PAIN DURING SEX, SPOTTING AFTER SEX, DISCHARGE, JOINT PAIN, DEGENERATIVE DISC DISEASE, MIGRAINES, VITAMIN D DEFICIENCY, ANEMIA, AND HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045207	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 3/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE DONE AT MY SIX WEEK CHECK UP AFTER HAVING MY 3RD CHILD. I WAS IN THE HOSPITAL GOING TO HAVE A TUBAL AND THE DR CAME IN TOLD ME HE WOULDN'T DO A TUBAL BECAUSE IT IS AN AT RISK, UNNECESSARY PROCEDURE. HE THEN TOLD ME I CAN GET ESSURE DONE. I WENT IN HAD THE PROCEDURE DONE A FEW MONTHS LATER I STARTED MY PERIOD IT WAS HORRIBLE. I WAS DOUBLED OVER IN PAIN I BLED HORRIBLY AND I HURT IN MY HIPS MY BACK MY LOWER STOMACH. I HAD NEVER IN MY LIFE HAD A PERIOD LIKE THAT. EVER SINCE THE PROCEDURE MY PERIODS ARE STILL THAT WAY. I STAY IN CONSTANT PAIN ALL DAY EVERY DAY, LOWER BACK, HIP PAIN LOWER STOMACH PAIN. IN THE PAST TWO YEARS I HAVE BEEN HOSPITALIZED TWICE FOR UTI AND KIDNEY INFECTION AND I HAVE NEVER BEEN HOSPITALIZED FOR THAT EVER BEFORE. I ALSO STARTED HAVING SEVERE MIGRAINES BOUT TWO MONTHS AFTER THE PROCEDURE AND STILL HAVE THEM TODAY. MY FAMILY DOCTOR SAID SHE DOESN'T SEE WHY I AM HAVING THEM. I ALSO BELIEVE I MAY BE ALLERGIC TO NICKEL. I CAN NOT WEAR EARRINGS OR JEWELRY THAT CONTAIN IT. AND I WAS NOT TOLD THE ESSURE CONTAINED NICKEL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045208	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 10/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DYSFUNCTIONAL UTERINE BLEEDING, FEMALE GENITAL ORGAN SYMPTOMS, DYSURIA, ABDOMINAL PAIN, DYSMENORRHEA, CYST OF OVARY, MENSTRUATION FINDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045209	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 5/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NUMMING, PAIN, ITCHING RED SPOTS BODY PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045210	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 4/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER MY ESSURE PROCEDURE, I HAD NO BAD SYMPTOMS TILL ABOUT A YEAR LATER. MY HAIR WAS COMMING OUT IN CLUMPS, I WAS DIZZY AND DIAGNOSED WITH VESTIBULAR NEURITIS, RINGING IN MY EARS, HORRIBLE ABDOMINAL PAIN, EXCRUCIATING BACK PAIN TO THE POINT I COULD HARDLY WORK, POOR DENTAL, BAD SWEATING, BLOATING, POOR VISION. I HAD A HYSTERECTOMY ON (B)(6) AND MOST OF MY SYMPTOMS ARE GONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045211	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/26/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN PELVIC AREA BOTH SIDES. HORRIBLE CRAMPING. HEAVY PERIODS. MULTIPLE PERIODS A MONTH. SPOTTING ALL MONTH. MIGRAINES. NO SEX DRIVE AT ALL. WEIGHT GAIN. DEPRESSION. "FLUTTERING" EFFECT IN STOMACH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045212	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I SUFFER FROM CHRONIC SINUS INFECTIONS. I HAVE SUCH BAD INFLAMMATION AROUND MY EYES, I CAN NO LONGER WEAR CONTACTS. I HAVE HAD CONTINUOUS FATIGUE AND GET SICK EASIER. I HAVE ALSO SUFFERED FROM FREQUENT NOSEBLEEDS SINCE HAVING ESSURE IMPLANTED. ALL MY LABS WERE NORMAL SO I KNOW THERE ARE NO OTHER UNDERLYING HEALTH CONDITIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045213	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 3/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD NIGHT SWEATS, CONSTANT HEADACHES, JOINT PAIN, MUSCLE ACHES, BRAIN FOG, INSOMNIA, NECK PAIN, INTESTINAL PROBLEMS (DIARRHEA, CONSTIPATION, SEVERE ABDOMINAL PAINS), UTERINE CRAMPING AND PAIN, HAIR LOSS, AND WEIGHT GAIN/INABILITY TO LOSE WEIGHT SINCE HAVING THE ESSURE PLACED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045214	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use:
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6):
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING. BLOATING. HEAVY BLEEDING. CYCLES LASTING FOR 2 WEEKS, 3 DAYS OFF AND CYCLE RETURNS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045215	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONTINUOUS BLEEDING, CRAMPING, FEVER. CALLED OB SAID WAS NORMAL CALLED ESSURE SAID NORMAL THIS CONTINUED FOR TWO YEARS. HEAVY BLEEDING, BLOATING, RASHES, BLOOD IN URINE, PASSING CLOTS, FATIGUE, PAIN, FEVER OF 104, CHILLS SWEATS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045216	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 5/25/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME STOMACH PAIN. PAINFUL PERIODS. STABBING PAIN IN ABDOMEN WHEN WALKING OR FIRST STANDING UP. MOOD SWINGS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045217	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 2/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, NAUSEA, CONSTANT ABDOMINAL CRAMPING, SHARP ABDOMINAL PAINS, CYST ON OVARIES, UNUSUAL PERIODS, MOOD SWINGS, MUSCLE SORENESS, INSOMNIA, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045218	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 2/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP 1 #FDA MW5045218 #(B)(4). ON (B)(6) 2015 I UNDERWENT A TOTAL HYSTERECTOMY SALPINGECTOMY, LEAVING MY OVARIES. IT IS ONE WEEK TO THE DATE OF MY SURGERY. I AM NOW (B)(6) YEARS OLD AND HAD TO UNDERGO A MAJOR SURGERY TO RELIEVE THE SYMPTOMS I BELIEVE WE'RE ASSOCIATED WITH THE ESSURE. I AM HAPPY TO DAY THAT SO FAR I AM HEALING WELL AND SIDE EFFECTS HAVE GONE AWAY DO TO THE SURGERY (NO LONGER WILL HAVE A MENSTRUAL CYCLE). I NEVER WOULD HAVE CONSIDERED HAVE A HYSTERECTOMY AT SUCH A YOUNG AGE. HOWEVER THE SYMPTOMS I WAS HAVING WERE CHANGING MY LIFE FOR THE WORST. I CAN SAY THAT MY ATTITUDE AND IRRITABILITY HAS DECLINED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045219	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC CRAMPING, SEVERE BACK PAIN, SEVERE SWOLLEN LEGS AND ANKLES, BRAIN FOG, FORGETFULNESS, MOOD SWINGS, HEARTBURN, HEART PALPITATIONS, SHORT OF BREATHE, EXCESSIVE SWEATING, PAIN IN EXTREMITIES

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045220	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOSS OF MEMORY, UNEXPLAINED RASHES, FREQUENT URINATION, UNKNOWN VAGINAL DISCHARGE, LOSS OF VISION ESPECIALLY DURING MENSES, HEART PALPITATIONS, DIGESTIVE ISSUES SUCH AS DIARRHEA AND OR EXTREME CONSTIPATION. BLEEDING GUMS, TOOTH SENSITIVITY, WEIGHT GAIN. EVERYDAY MALAISE AND IN PAIN EVERY DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045221	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 9/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE PLACED IN 2008 AND BY MID 2012, I WAS A VERY SICK PERSON. PREVIOUSLY, I WAS A LITTLE OVERWEIGHT, BUT IN GENERAL GOOD HEALTH. BY 2012, I HAD GERD, GASTRITIS, OBESE, DIABETES, SEVERELY VITAMIN DEFICIENT, EXPERIENCING HAIR LOSS, UNEXPLAINED BRUISES, VERICOSE VEINS, SLEEP APNEA, UNUSUALLY PAINFUL MENSES, SEVERE MOOD SWINGS, DEPRESSION/ANXIETY, PCOS, NERVE PAIN AND NUMBNESS, HOT FLASHES/NIGHTS SWEATS, BRAIN FOG, GENERAL BODY ACHES, GLUTEN SENSITIVITY, MORE SEVERE SEASONAL ALLERGIES, SWELLING OF THE FEET AND HANDS, SEVERE DERMATITIS ON THE SCALP. MEETING WITH DOCTOR TO DETERMINE THE POSITIONS OF ESSURE AND DISCUSSING REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045222	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 3/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WORSENING IN CHRONIC BACK PAIN, SEVERE ABDOMINAL CRAMPS, SIGNIFICANT WEIGHT GAIN, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045223	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, EXTREME LOW BACK PAIN DURING PERIOD, THROBBING ON MY LOW RIGHT SIDE OF ABDOMEN, JOINT PAIN, DURING MRI MY INSIDES WERE HEATING UP, MIGRAINES, FLU/FEVER WITH EACH PERIOD, SEVERE ACNE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045224	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 9/10/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD ESSURE IMPLANTS SINCE (B)(6) 2007.. MY FIRST PROBLEM STARTED (B)(6) 2007.. I BLEED FOR 5 MONTHS STRAIGHT..THE LAST TWO YEARS HAVE BEEN THE ABSOLUTE WORSE.. I PRAY EVERY MORNING BEFORE MY FEET HIT THE FLOOR FOR THE LORD TO GIVE ME THE STRENGTH TO GET THROUGH THE DAY.. I AM A MOTHER OF 4 SONS AND A WIFE OF 25 YEARS. I HAVE NEVER ENDURED THIS MUCH DAILY PAIN IN MY LIFE.. MY BODY ACHES ALL OVER CONSTANTLY.. I FEEL LIKE I'M BURNING ON THE INSIDE.. I HAVE CHRONIC LEFT PELVIC AND HIP PAIN, NUMBNESS AND TINGLING THROUGHOUT MY HANDS, LEGS, AND FEET.. MY LEGS GET VERY WEAK AND HEAVY THE LONGER I'M ON THEM AND FEEL AS IF THERE GOING TO COLLAPSE FROM UNDER ME.. I HAVE TO SIT RIGHT AWAY.. SEVERE BLOATING AND BURNING SENSATION IN MY ABDOMEN.. PAINFUL INTERCOURSE, IRREGULAR BLEEDING AND MONTHLY CYCLES, CLOTTING, AND FOUL DISCHARGE AT TIMES. MIGRAINES LAST SEVERAL DAYS. I'M SO FATIGUED THAT I JUST HAVE NO ENERGY ANYMORE AND GIVE OUT OF BREATHE EASILY. SO MANY THINGS HAVE GONE WRONG AND I FEEL DEPRESSED AND WORRIED ALL THE TIME ABOUT WHAT IS GOING ON WITH MY HEALTH, AND HOW HARD IT IS TO GET THROUGH EACH DAY IN PAIN.. IT IS NOT FAIR. I DID NOT SIGN UP FOR PREMATURE AGING AND MY BODY TO BE POISONED.. I HAVE A FAMILY THAT NEEDS THEIR MOM AND WIFE.. PLEASE TAKE US SERIOUS.. WE ARE MOTHERS WHO ONLY TRIED TO PREVENT FROM HAVING MORE CHILDREN, AND NOT HAVE OUR HEALTH DESTROYED.. ESSURE IS ONE BC THAT NEEDS TO DEFINITELY BE RECALLED.. ASAP!!!! THANK YOU..

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045225	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 10/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALL TREATMENT WAS THROUGH KAISER INCLUDING PLACEMENT OF ESSURE. BELOW I WILL IDENTIFY SOME BUT NOT ALL INFORMATION AS I NEED ACCESS TO MY KAISER RECORDS. PLEASE READ BELOW. IN ADDITION TO THIS I WAS PLACED OUT OF WORK FOR SEVERAL MONTHS RESULTING IN LOSS OF INCOME. HEALTH PROBLEMS: BEFORE DERMATITIS I WAS BELIEVED TO HAVE LUPUS, DERMATITIS. BODY ACHES. UPI. DIZZINESS. ACUTE STRESS DISORDER. ANXIETY DISORDER. ECZEMA. CYSTIC ACNE ANDNDASH; UNSURE IF RELATED TO ESSURE (NEVER HAD ACNE BEFORE). INSTRUCTED TO USE: AMOXICILLIN 500 MG ORAL CAP. PHENOL (CEPASTAT) 14.5 MG MM LOZENGE. INSTRUCTED TO USE: ZYRTEC 10MG 1-4 TABS A DAY OR (B)(6). DIAZEPAM (VALIUM) 2 MG ORAL TAB. VENLAFAXINE (EFFEXOR XR) 37.5 MG ORAL 24HR SR CAP. (B)(6) TWICE DAILY TO BIOPSY SITES. PREDNISONE 10MG 1 TAB FOR 3 MORE DAYS, 1 TABLET EVERY OTHER DAY FOR 5 DAYS, THEN STOP. CLOBETASOL (TEMOVATE) 0.05 % TOP OINT. LAB WORK: 2 BIOPSIES. ORDERS: ALT, SERUM [(B)(6) CPT(R)], ANA [(B)(6) CPT(R)], CBC NO DIFF [(B)(6) CPT(R)], CREATININE, SERUM [(B)(6) CPT(R)], ERYTHROCYTE SEDIMENTATION RATE, AUTOMATED [(B)(6) CPT(R)], GLUCOSE, RANDOM [(B)(6) CPT(R)], LIPID PANEL [(B)(6) CPT(R)], REFERRAL HEALTH EDUCATION [(B)(6) CUSTOM], REFERRAL PSYCHIATRY [(B)(6) CUSTOM] , RHEUMATOID FACTOR, SERUM [(B)(6) CPT(R)], TSH [(B)(6) CPT(R)] , URIC ACID, SERUM [(B)(6) CPT(R)], CHLAMYDIA/GC, SWAB AMPLIFIED PROBE TECHNIQUE [(B)(6) CUSTOM], GYN CYTOLOGY [(B)(6) CUSTOM] , VACC ADMIN, FIRST IM OR SUBQ VACCINE TOXOID [(B)(6) CPT(R)], VACC TDAP (ADACEL) [(B)(6) CPT(R)] , CULTURE, URINE [(B)(6) CPT(R)] , URINALYSIS, AUTOMATED WO MICRO [(B)(6) CPT(R)], URINALYSIS, AUTOMATED WO MICRO [(B)(6) CPT(R)] , URINALYSIS, MICROSCOPIC ONLY [(B)(6) CPT(R)], ALDOLASE [(B)(6) CPT(R)] , ANA [(B)(6) CPT(R)] , BORRELIA BURGDORFERI ANTIBODY [(B)(6) CPT(R)], CHLAMYDIA PSITTACI ANTIBODY [(B)(6) CPT(R)] , CREATINE KINASE [(B)(6) CPT(R)] , DIGITAL PHOTO, IMAGING [(B)(6) CUSTOM], DOUBLE STRANDED DNA ANTIBODY [(B)(6) CPT(R)] ,

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JO-1 ANTIBODY [(B)(6) CPT(R)] , PARVOVIRUS B19 IGG AND IGM [(B)(6) CUSTOM], PUNCH BIOPSY, SKIN [(B)(6) CPT(R)] , SSA AND SSB ANTIBODY [(B)(6) CUSTOM], SURGICAL PATHOLOGY [(B)(6) CUSTOM].

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045226	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 9/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THREW ME INTO MENOPAUSE EARLY, 40+ WEIGHT GAIN, PELVIC PAIN, MEMORY LOSS, LOW SEX DRIVE, MOOD SWINGS, HIVES/SKIN ERUPTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045227	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 6/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SINCE DEVELOPED AN ADDISON'S DISEASE, AUTOIMMUNE DISEASE WHICH I WAS DIAGNOSED WITH (B)(6) OF 2014. I HAVE BEEN HOSPITALIZED WITH ADDISON'S CRISES OR ADDISON'S RELATED ILLNESS 3 TIMES IN THE LAST YEAR. I HAVE HAD MANY OTHER SIDE EFFECTS SINCE ESSURE, INCLUDING BUT NOT LIMITED TO THE FOLLOWING: ABNORMAL MENSTRUATION (I BLEED MOSTLY BLACK BLOOD WHICH I HAVE NEVER HAD BEFORE), SEVERE PELVIC PAIN, PAINFUL INTERCOURSE, DECREASED LIBIDO, NUMBNESS AND TINGLING OF HANDS, FEET AND HEAD, NIGHT SWEATS (SOAKING IN SWEAT), SEXUAL DYSFUNCTION, LEG PAIN AND CRAMPING, SEVERE BLOATING (I LOOK LIKE I'M PREGNANT ALL THE TIME), DEPRESSION, DIZZINESS, FAINTING AND BLACK OUTS, FATTY LIVER, SLEEP APNEA, BLURRED VISION, HAIR LOSS, WEIGHT GAIN, BRAIN SHOCKS, BRAIN FOG, FORGETFULNESS, CYSTS. BODY ACHES AND PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045228	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). CHRONIC ABDOMINAL PAIN LOWER AND UPPER. VOMITING, HEADACHE, NAUSEA, ACID REFLUX, SORE NECK AND SHOULDER PAIN, THYROID NODULES, COATING ON TONGUE. CRAMPING AND SHARP STABBING PAINS IN LOWER ABDOMINAL SINCE. ESSURE PLACEMENT IN 2009.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045229	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL PERIODS WORSENING OVER TIME. MENSTRUAL CYCLE LASTING LONGER, HEAVIER, HEAVY CLOTTING. HEADACHES. MOODSWINGS. EMOTIONAL. RESTLESS SLEEP. PAIN IN PELVIC REGION SIMILAR TO STABBING FEELING. WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045230	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 3/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIAGNOSED WITH DEGENERATIVE DISK DISEASE. MIGRAINES WITH NAUSEA FEW TIMES A WEEK. INCREASE IN SCIATIC NERVE PAIN, WENT FROM TINGLING TO SHARP BURNING PAIN. LOWER BACK PAIN WAS LEFT SIDE AND NOW IS ENTIRE LOWER BACK. MUSCLE SPASMS IN BACK HAS INCREASED IN SEVERITY AND MORE OFTEN. PRESCRIPTIONS ARE NOT HELPING WITH PAIN ANYMORE, AND I WAS TAKEN OFF OTHER PILLS AND STARTED ON THESE SO I DONT HAVE A TOLERANCE FOR THEM. HAVING SHARP ABDOMINAL/SIDE PAIN. HAVE REFERRAL TO NEUROLOGIST WITH APPT IN (B)(6) 2015. HAD EEG DONE AND THEY CANT SEE WHAT'S CAUSING MIGRAINES. SEVERE CRAMPS WITH MENSTRUAL CYCLE. THEY WERE SAME TIME EVERY MONTH BUT AM CURRENTLY A WEEK LATE. WEIGHT GAIN OF ABOUT 50 POUNDS IN LAST YEAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045231	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 5/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WELL I GOT THE ESSUER DONE A FEW MONTHS AFTER MY DAUGHTER WAS BORN. AT ALMOST A MONTH LATER, MY BONES STARTED TO HURT; I WAS LIKE OK, I UNDERSTAND CAUSE SOMETIMES MY KNEES GIVE ME PROBLEMS. WELL, I REALIZED MY HAIR STARTED TO FALL OUT IN HAND FULLS, I WENT TO THE HOSPITAL IN THE PAST TWO YEARS MORE THAN 10 TIMES. I HAVE HAD SEVERE PAIN BUT I MEAN LIKE STABBING ACHING PAIN TO WHERE IT FEELS LIKE SOME ONE HAS TAKEN A KNIFE OR A JIGSAW AND STABBING THE INSIDE OF MY UTERUS WITH IT; I HAVE HAD BACK PAIN TO WHERE IT FEELS LIKE I AM IN LABOR BUT I'M NOT. IT HURTS SO MUCH TO HAVE INTERCOURSE WITH MY HUSBAND AND IT IS SO BAD I HAVEN'T HAD INTERCOURSE WITH MY HUSBAND IN ALMOST A YEAR BECAUSE OF THIS SO CALLED WONDERFUL PRODUCT OF Y'ALLS, WHAT IS IT CALLED, OH YES IT IS THE ESSURE! THE PRODUCT THAT THEY SAY IS SO WONDERFUL AND THE PERFECT BIRTH CONTROL. HAHAHAHA. TRY AGAIN, ITS THE WORSE THING Y'ALL HAVE EVER CAME OUT WITH! WELL I FOLLOWED UP WITH MY OB/GYN LIKE THE HOSPITAL TOLD ME TO, SO I DID. WELL I TOLD HER ABOUT THE SEVERE ABDOMINAL PAIN THAT I HAVE BEEN HAVING AND EVERYTHING THAT HAS BEEN GOING ON WITH ME BECAUSE MY MENSTRUALS WERE SO HORRIBLE, SHE PUT ME ON BIRTH CONTROL PILLS; THEY DIDN'T WORK WELL. SINCE THEN, HAVE BEEN OFF OF THEM AND I STILL HAVE EVERY LITTLE PROBLEM OUT THEIR SINCE I HAVE BEEN ON THIS SO CALLED WONDERFUL PRODUCT THE ESSURE! THESE ARE THE SYMPTOMS THAT I HAVE HAD SINCE I GOT THIS MONSTER THE ESSURE IN! I AM HAVING THE SYMPTOMS OF: I HAVE GYNECOLOGICAL: SHARP/STABBING PELVIC PAIN, ABDOMINAL MENSES, OVARIAN CYST, SPOTTING, DISCHARGE, ADENOMYOSIS , HOT FLASHES, PAINFUL OVULATION, NIGHT SWEATS, SPOTTING AFTER INTERCOURSE (SOMETIMES), SEVERE PAINFUL INTERCOURSE, BLEEDING BETWEEN PERIOD, SEXUAL DYSFUNCTION, ITCHING, BURNING OF VAGINAL ENTRANCE, BREAST PAIN / TENDERNESS, ABDOMINAL SPASMS, TWITCHING (ALL THE TIME), PAIN (BACK,

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JOINT ,LEG, BREAST, NECK, SPINE, HIPS), CHRONIC PELVIC PAIN, ALL OVER BODY ACHES AND PAIN, GASTROINTESTINAL, SEVERE NAUSEA, VOMITING, GAS, CONSTIPATION, SEVERE BLOATING (I LOOK LIKE I'M 7 MONTHS PREGNANT), METALLIC TASTE IN MY MOUTH, BOWEL ISSUES, NEUROLOGICAL/MENTAL HEALTH, SEVERE MIGRAINES, SEVERE DIZZINESS, TINGLING SENSATION, NERVE PAIN, BRAIN FOG / FORGETFULNESS, ANXIETY/ PANIC ATTACKS, SEVERE MOOD SWINGS, DEPRESSION/ SADNESS, DIMINISHED BRAIN FUNCTION/ SHORT TERM MEMORY LOSS, CONFUSION, FORGETFULNESS, PTSD, NUMBNESS / TINGLING IN EXTREMITIES / HAND, FEET, SHAKINESS, DIZZINESS, BLOOD ISSUES, UNEXPLAINED / EASILY BRUISING, HYPOGLYCEMIA, ALLERGIES / SENSITIVITIES, CYST / ACNE, SKIN IRRITATION / ITCHING, OTHER HAIR LOSS, SWELLING OF FEET / LEGS, DENTAL ISSUES, HORRIBLE INSOMNIA, WEIGHT ISSUES, MUSCLE SPASMS, VISION PROBLEMS EXCESSIVE SWEATING, DRY SKIN / EYES, SEVERE BLOATING (I LOOK LIKE I AM 7 MONTHS PREGNANT). THESE ARE ALL THE HORRIBLE, HORRIBLE ISSUES I AM HAVING EVER SINCE I PUT THE SO CALLED WONDERFUL PRODUCT OF BIRTH CONTROL! IT'S MORE LIKE THE WORST PRODUCT THAT THEY EVER CAME OUT WITH. THEY REALLY NEED TO TAKE THIS THING OFF THE MARKET. THERE ARE OVER MORE THEN 20,000 WOMEN WHO KNOW WHAT I AM TALKING ABOUT! I HOPE AND PRAY THAT Y'ALL TAKE THIS KILLING PRODUCT OFF THE MARKET! I AM SCHEDULED THIS MONTH TO SEE A DIFFERENT OB/GYN (SINCE MY OLD ONE WON'T LISTEN TO ME) TO SEE IF I CAN GET THIS HORRIBLE KILLING ESSURE OUT OF ME, SO I CAN BE E-FREE! INSTEAD OF E-HELL!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045232	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 5/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN HAVING AN EXTREMELY HEAVY PERIOD EACH MONTH FOLLOWED BY SPOTTING AND BLOOD CLOTS THROUGHOUT THE MONTH UNTIL MY NEXT PERIOD. BROWN DISCHARGE WITH BLOOD CLOTS THROUGHOUT THE MONTH. I HAVE BLOATING AND SWELLING OF THE HANDS AND LEGS, MAKING IT DIFFICULT TO STAND OR WALK FOR LONG PERIODS OF TIME. CONSTANT PAIN IN THE ABDOMEN AREA AND I BEGAN TO LOSE MY HAIR, WHICH WAS SO SEVERE IT REQUIRED SHOTS IN MY HEAD TO TRY TO STIMULATE NEW HAIR GROWTH. I CONTINUE TO LOSE MY HAIR AND NOW HAVE A DRY FLAKY SCALP. LOSS OF LIBIDO, PAINFUL INTERCOURSE, MOOD SWINGS, DEPRESSION, FORGETFULNESS, VERTIGO, HIVES, RASH AND ITCHINESS ALL OVER MY BODY. SENSITIVITY TO SMELLS, BACK AND NECK PAIN AND I DEVELOPED A STABBING PAIN THAT BRINGS ME TO MY KNEES ON THE LEFT SIDE OF MY ABDOMEN. I FEEL LIKE I AM BEING STABBED AND GET A SHOCK THROUGHOUT MY BODY. METALLIC TASTE IN MY MOUTH, GAS, DIFFICULTY WITH BOWEL MOVEMENTS, PAINFUL BLOATING PAIN IN ABDOMINAL ARE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045233	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 4/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I FIRST NOTICED A RASH, REDNESS, SWELLING, IN MY HANDS, FEET, LEGS. THEN AS THE WEEKS WENT ON I HAD A RASH ON MY BACK, STOMACH AREA, AND LAST MY FACE. I BLEED FROM THE PROCEDURE LIKE I WAS ON MY MENSTRUAL CYCLE. I ASKED MY DOCTOR WHAT IT WAS AND SHE TOLD ME I HAD DERMATOGRAPHIA AND PRESCRIBED ME ALLERGY MEDICATION. I CONTINUED TO HAVE THE ABOVE SIDE EFFECTS. IN JUNE I EXPERIENCED LIGHT HEADED, DIZZINESS, NAUSEA MOOD SWINGS, AND DEPRESSED THOUGHTS. I ALSO WENT TO THE ER FOR THEM TO PRESCRIBE ME MORE MEDICATION (METHYLPREDNISOLONE)

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045234	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MEMORY LOSS/BRAIN FOG, LACK OF MOTIVATION, SNORING, SLEEP APNEA, DEPRESSION, FATIGUE, WEIGHT GAIN, JOINT PAIN, PELVIC PAIN, ADRENAL FATIGUE, TEETH PROBLEMS, LOSS OF PERIODS, CHANGE IN SEX DRIVE, DECLINING VISION - EYE SIGHT PROBLEMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045235	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE IMPLANT I HAVE DAILY PELVIC PAIN (SEVERE MENSTRUAL-LIKE TO CONTRACTION -LIKE) AND BACK PAIN. I CONTINUE TO HAVE HAIR LOSS, WEIGHT GAIN. I HAVE IRREGULAR AND EXTREMELY PAINFUL PERIODS. I HAVE BEEN HAVING PERIODS FOR 27 YEARS. NEVER THIS PAINFUL UNTIL (B)(6) 2015, DATE OF IMPLANT. I WAS A HEALTHY ACTIVE YOUNG FEMALE WITH NONE OF THESE PROBLEMS UNTIL ESSURE. NOW I LIVE ON DAILY OTC ADVIL/TYLENOL AND USE A HEATING PAD FOR THE PAIN. THE MEDS DO NOT EVEN TOUCH THE PAIN. I HAVE 2 CHILDREN AND I AM A MEDICAL PROVIDER AND WILL NOT TAKE NARCOTIC PAIN MEDICATION. THE SOLUTION IS NOT TO MASK THE SIDE EFFECTS WITH MEDICATION. THE SOLUTION IS TO REMOVE THE DEVICE FROM THE MARKET BEFORE THE SERIOUS SIDE EFFECTS BECOME TOO FREQUENT. DEATH CANNOT BE FIXED WITH PAIN MEDICATION. MORE SO DEATH IS JUST NOT "ALL IN YOUR HEAD."

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045236	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 3/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THE ESSURE PROCEDURE I HAVE HAD EXCESSIVE AMOUNT OF PAIN WITH MENSTRUATION AND BLEEDING SO BADLY THAT AFTER AN HOUR I AM SOAKED THROUGH A SUPER TAMPON AND A PAD ONTO MY CLOTHING. I HAVE ALSO BEEN PASSING GOLF BALL SIZED CLOTS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045237	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/15/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HYSTERECTOMY EVERYTHING REMOVED EXCEPT OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045238	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC HIP JOINT PAIN IN THE MID BACK MORE ON RIGHT SIDE. PAINFUL CRAMPS/STABBING PAINS NOT DURING PERIOD.. ON RIGHT SIDE ALSO. HEART PALPITATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045239	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 3/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

MEDWATCHER #(B)(4). REALLY BAD CRAMPING WHICH I CAN FEEL IN MY LOWER BACK TO THE FRONT OF MY UPPER PELVIS AREA. CRAMPING IS UNBEARABLE FROM FRONT TO BACK. THESE CONTINUE TO COME EVERY MONTH OR SO AND THE LONGER I'VE HAD THE DEVICE THE WORSE THE CRAMPING HAS GOT. ALSO SINCE THE DEVICE WAS PUT IN I'VE HAD MIGRAINES MORE FREQUENTLY EVERY SO MANY MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045240	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MENSTRUAL CYCLES STARTED TO BECOME VERY HEAVY - SOMETIMES TWICE IN ONE MONTH - THEY ARE VERY FREQUENT (EVERY 20 - 23 DAYS) AND ARE DEBILITATING. I'VE ALSO GAINED A LOT OF WEIGHT AROUND MY BELLY AREA AND AM VERY BLOATED MOST DAYS. I'VE STARTED GETTING SEVERE HEADACHES AND AM EXTREMELY CONSTIPATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045241	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE STABBING PAIN IN MY LOWER RIGHT PELVIC REGION, WHICH I BELIEVE IS DIRECTLY RELATED TO A MIGRATED ESSURE COIL (SEE X-RAY). I AM ALSO EXPERIENCING EXCESSIVE BLOOD FLOW DURING PERIODS, LOSS OF LIBIDO, HEMATURIA, KIDNEY CYSTS, COGNITIVE AND MEMORY LAPSES. I AM ACTIVELY SEEKING A SURGEON WHO CAN REMOVE THE MIGRATED COIL TO RELIEVE MY PAIN WHICH OCCURS WHEN I CHANGE POSITION- SITTING TO STANDING, BENDING OVER AND SO ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045242	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

MEDWATCHER #(B)(4). I HAVE HAD LITE CRAMPS OFF AND ON FOR THE PAST 8 YRS. I ALSO HAVE NOT BEEN ABLE TO LOSE WEIGHT AND MY STOMACH HAS BLOATING THAT IS SO BAD THAT IT APPEARS THAT I'M PREGNANT. I HAVE HEADACHES THAT LAST DAYS AT A TIME. MOOD SWINGS ARE HARD TO MANAGE AT TIMES AND FOGGY HEADED AT TIMES. WITHIN THE LAST YEAR I HAVE STARTED TO GET RASHES UNDER SOME OF THE RINGS THAT I WEAR AND THEY ITCH, BURN, AND CRACK OPEN. WEAK AND FATIGUE A LOT OF TIMES AND IT TENDS TO GET WORSE DURING MY PERIOD. THE BLEEDING IS ALSO EXTREMELY HEAVY EVERY MONTH THAT HAS FOLLOWED THE ESSURE. THERE TIMES THAT I CAN NOT FEEL MY FINGERS AND TOES BECAUSE OF MY ARMS AND LEG GOING TO SLEEP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045243	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 4/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ITCHY SKIN, TINGLING LIPS, ALLERGIC REACTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045244	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE LOWER ABDOMEN PAIN ON MY RIGHT SIDE. ALSO DURING MY MENSTRUAL I PASSING BLOOD CLOTS THE SIZE OF HALF DOLLARS AND ITS PAINFUL. ALSO DOCTOR HAS FOUND THAT ONE OF THE DEVICES IS DISPLACED. AND IS NEEDING TO REMOVE IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045245	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 11/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DEVELOPED PAIN ALL OVER MY BODY AND WAS LATER DIAGNOSED BY THE (B)(6) CLINIC AS HAVING FIBROMYALGIA. ALSO MIGRAINES, INCREASED BLOOD PRESSURE, INFLAMMATORY ARTHRITIS, ANEMIA, VIT D DEFICIENCY, SEVERE ANXIETY, OVARIAN CYSTS, GROIN PAIN, AND INSOMNIA ALL DEVELOPED AFTER HAVING ESSURE PLACED IN MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045246	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 7/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: I
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): I
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER MY ESSURE WAS PUT IN, I STARTED TO EXPERIENCE MEDICAL ISSUES SUCH AS: SEVERE CHEST PAIN DIFFICULTY BREATHING FAINTING SPELLS... WENT TO AN AFTER HOURS CLINIC AND THEY DIAGNOSED ME WITH GERD AFTER RUNNING AN MRI... START TO EXPERIENCE SEVERE ALLERGIC REACTIONS... AFTER SEEING AN ALLERGIST AND BEING TESTED FOR AUTOIMMUNE DISEASES DISCOVERED MY TYPESET LEVELS WERE EXTREMELY HIGH. I HAD TO SEE A HEMATOLOGIST BECAUSE MY IRON LEVELS WERE TOO LOW AFTER HAVING A BONE MARROW BIOPSY DONE TO TEST FOR OTHER DISEASES WHICH CAME BACK NEGATIVE BUT SHOWS THAT I HAD LOW IRON AND NO RED BLOOD CELLS IN MY BONE MARROW! I HAVE GAINED EXCESSIVE WEIGHT, HAIR LOSS, EXTREME FATIGUE, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5045247	BAYER	8/6/2015	8/6/2015

Event Information:

Event Date (B3): 12/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: N
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 2011 A FEW MONTHS AFTER IT WAS PLACE MY HANDS STARTED TO ITCH ALOT AND MY FOOT I ALSO FAINTED 2012 I STARTED TO NOTICE KNEE PAIN AND SEVERE BODY PAIN WITH MY PERIODS 2013 SEVERE VAGINAL PAIN SHARP PAINS 2014 I STARTED BREAKING OUT WITH HUGE BLISTERS ALL OVER MY BODY THEY STARTED ATTACKING MY JOINT AREA MY ELBOWS FELT LIKE THEY WAS ON FIRE AND VERY SWOLLEN AND ITCHY TODAY I LIVE WITH SEVERE ITCHING AND BODY PAIN AND I HAVE DIZZY SPELLS ALOT

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055343	BAYER	8/6/2015	8/13/2015

Event Information:

Event Date (B3): 7/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): FALOPIAN TUBE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/15/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

INTRACTABLE PAIN AND UNKNOWN IF TUBAL OCCLUSIONS IS PRESENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055344	BAYER	8/6/2015	8/13/2015

Event Information:

Event Date (B3): 2/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): FALOPIAN TUBE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/14/2014
Explant Date (E7): 2/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

MIGRATION OF ESSURE DEVICE WITH UTERINE PERFORATION ENDING IN NON-STERILIZATION CONFIRMED BY RADIOLOGY. DATES OF USE: (B)(6) 2014 - (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055353	BAYER	8/6/2015	8/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED IN 2009. SINCE THEN I HAVE HAD PAIN AND CRAMPING IN MY PELVIS AND HIPS, BOUTS OF FEELING SICK TO MY STOMACH, PAIN DURING AND OR AFTER SEX, MORE IRREGULAR PERIODS, CHRONIC LOWER BACK PAIN, FREQUENT HEADACHE OR MIGRAINES, AND WHEN I COUGH ESPECIALLY, OR ITCH MY LEFT SIDE I LOSE FEELING DOWN MY LEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055371		8/7/2015	8/13/2015

Event Information:

Event Date (B3): 8/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PRODUCT HAS CAUSED ME TO HAVE DISCOMFORT, PAIN AND EXCESSIVE MENSTRUAL CYCLES WITH WEAK KNEES AND PAIN WITH INTERCOURSE. OTC MEDS: IBUPROFEN AND EXCEDRIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055372	CONCEPTUS	8/8/2015	8/13/2015

Event Information:

Event Date (B3): 8/8/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 508104

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IN 2005 AFTER TRAUMATIC EXPERIENCE OF HAVING A VERY PREMATURE BABY. I WAS ADMITTED TO HOSPITAL THE SAME EVENING WITH HORRENDOUS CRAMPING, PAIN AND HEAVY BLEEDING. SINCE HAVING I HAVE HAD FAR HEAVIER AND MORE PAINFUL PERIODS, MOOD SWINGS, AND VERY BAD OVULATING PAIN, OFTEN CRIPPLING SHARP STABBING PAIN IN THE AREA OF MY RIGHT OVARY. IN THE YEARS FOLLOWING MY LOWER BACK HAS BECOME PAINFUL AND OFTEN LEFT ME IMMOBILE FOR DAYS, SOMETIMES WEEKS. SINCE 2013 MY BACK PAIN HAS BECOME SO DEBILITATING THAT I WAS UNABLE TO WALK WITHOUT A WALKING STICK. IN (B)(6) 2013, AN MRI SHOWED BULGING AND HERNIATED DISK DISEASE. I HAVE ALSO HAD PROBLEMS EMPTYING MY BLADDER. MY PERIODS AND MID CYCLE PAIN HAVE BECOME SO BAD THAT I HAVE BEEN REFERRED TO GYNECOLOGY TO DISCUSS MY REQUEST FOR A FULL HYSTERECTOMY (WITH SUPPORT FROM MY GP). I HAVE SUFFERED WITH CERVICAL CHANGES REQUIRING CAUTERIZATION, AND VERY LARGE NABOTHIAN CYSTS REGULARLY RETURNING FOR THE LAST TWO YEARS AND HAVING TO BE DRAINED. I HAVE ALSO BEEN DIAGNOSED WITH FIBROMYALGIA IN THE LAST YEAR DUE TO CRIPPLING PAINS IN MANY AREAS OF MY BODY AND FATIGUE. I BELIEVE MOST OF THESE PROBLEMS, IF NOT ALL ARE AS A DIRECT RESULT OF HAVING THE ESSURE COILS IN 2005. RX MEDS: HAPOCTICN, LYRICS, NORTRIPTYLINE. OTC MEDS: VITAMIN D, CALCIUM WITH MAGNESIUM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055387		8/10/2015	8/14/2015

Event Information:

Event Date (B3): 9/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HOW IT HAPPENED, I WANTED TO BE OFF THE PILL SO I WENT TO MY DOCTOR SHE GAVE ME OPTIONS SO I TOOK ESSURE BECAUSE IT WOULD BE THE RIGHT THING FOR ME TO DO. WHEN I HAD IT DONE RIGHT AFTER I WAS OUT, I WAS STILL IN PAIN A BURNING SENSATION ON MY OVARIES. TOOK MEDS DIDN'T WORK. EVERY MONTH I HAD TO GO THRU THE SAME THING. PAIN AND DISCOMFORT. HAD VERY BAD PERIOD CRAMPS, HEADACHES. PERIOD ALL MONTH. DIDN'T WANT TO HAVE SEX BECAUSE I WAS ON MY PERIOD ALL THE TIME AND IT HURT! I'M DONE WITH THIS!!

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00586	BAYER HEALTHCARE LLC	8/11/2015	8/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C40057

Single Use: Y
Implant Date (E6): 4/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 8/11/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 26-JUN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C40057. ADDITIONAL INFORMATION RECEIVED ON 05-AUG-2015. IT WAS REPORTED THAT THE DISTAL END OF ESSURE SPLIT (COMPLICATION OF DEVICE INSERTION). PATIENT WAS STABLE. DEVICE WAS INSERTED BILATERALLY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING PLACEMENT THE DISTAL END OF ESSURE SPLIT. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED MAINLY DURING DIFFICULT INSERTIONS. IN THIS CASE, THE INSERTION WAS COMPLICATED DUE TO SPLIT OF ESSURE DISTAL END. PATIENT WAS STABLE AND THE DEVICES WERE INSERTED BILATERALLY. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. (B)(4). FINAL ASSESSMENT FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INS

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00587	BAYER HEALTHCARE LLC	8/11/2015	8/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AFTER HAVING ESSURE IMPLANTED SHE STARTED HAVE VERY HEAVY AND IRREGULAR PERIODS. HER DOCTOR PERFORMED AN ABLATION WHICH SHE LATER LEARNED SHOULD NOT BE PERFORMED WITH ESSURE. SHE EXPERIENCED EXCESSIVE HAIR LOSS, CONSTANT NAUSEA WHICH LED TO HAVE AN ENDOSCOPY PERFORMED. THE RESULTS SHOWED SHE HAD SEVERE STOMACH INFLAMMATION. THIS STARTED RIGHT AFTER SHE HAD THE ESSURE IMPLANTS PUT IN; SHE EXPERIENCED EXCESSIVE WEIGHT GAIN, ABDOMINAL CRAMPING AND BLEEDING AFTER INTERCOURSE. SHE CONTACTED HER DOCTOR WHO DID NOT THINK THEY WERE ESSURE RELATED; HOWEVER, SHE HAS NEVER EXPERIENCED A SINGLE ONE OF THEM UNTIL HAD THEY IMPLANTED. SHE WAS NOW HAVING HER TUBES AND COILS REMOVED IN WHICH SHE WILL BE MISSING 3 DAYS OF WORK WITHOUT PAY. THE CONSUMER MENTIONED THE SERIOUSNESS CRITERIA DISABILITY OR PERMANENT DAMAGE BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL

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FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL CRAMPING AND VERY HEAVY IRREGULAR PERIODS. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO DISABILITY (CONSUMER MENTIONED IT AS EVENT OUTCOME, HOWEVER SHE DID NOT SPECIFY IT) AND MEDICAL IMPORTANCE, RESPECTIVELY, AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BLEEDING AND PAIN/CRAMPING MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSUMER WAS NOW HAVING HER TUBES AND COILS REMOVED. GIVEN THEIR NATURE AND CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP RECEIVED ON 21-OCT-2015: NO FURTHER INFORMATION COULD BE OBTAINED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00588	BAYER HEALTHCARE LLC	8/11/2015	8/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN REPORTED THAT RECENTLY HE DID AN UTERUS EXTIRPATION IN A PATIENT WITH COMPLAINTS. THE PATHOLOGIST WAS STILL WORKING ON FURTHER ANALYSIS. THE PATIENT WAS STERILIZED ELSEWHERE AND REPORTER DID NOT HAVE LOT NUMBER. FOLLOW UP INFORMATION RECEIVED ON 16-JUL-2015 FROM PHYSICIAN: THE PATIENT WAS (B)(6) AT TIME OF THE REPORT. SHE HAD ESSURE DEVICES INSERTED IN 2010. THE PHYSICIAN REPORTED THIS PATIENT HAD CONCREMENTS ON BOTH DEVICES. THE PATIENT COMPLAINED OF ABDOMINAL PAIN NAMELY BOTTOM RIGHT. ON (B)(6) 2015, ESSURE WAS REMOVED. THE PHYSICIAN MENTIONED THAT IT APPEARS THE PATIENT RECOVERED AFTER ESSURE REMOVAL HOWEVER HE STATED THAT WAS STILL A LITTLE BIT SHORT FOR FOLLOW UP. FOLLOW-UP FROM 03-AUG-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. (B)(4). FINAL ASSESSMENT: BASED UPON REVIEW OF THE SUBMITTED PHOTOS, IT IS VERY DIFFICULT TO DETERMINE THE EXACT IDENTITY OF THE WHITE DEPOSIT MATERIAL. IT IS LIKELY THE WHITE DEPOSIT MATERIAL IS TISSUE FROM THE UTERINE CAVITY WHICH HAS ATTACHED TO THE INSERT. IT IS VERY UNLIKELY THIS SUBSTANCE IS AN ARTIFACT FROM THE MANUFACTURING PROCESS. SINCE NO PRODUCT HAS BEEN RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICROINSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. . MEDICAL

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ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO FEMALE PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN NAMELY BOTTOM RIGHT (THE EVENT UTERUS EXTIRPATION WAS DELETED). THIS EVENT WAS CONSIDERED SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, PATIENT HAD AN UTERUS EXTIRPATION. NO ALTERNATIVE EXPLANATION WAS AVAILABLE. GIVEN THE EVENT'S NATURE, CAUSALITY BETWEEN THE REPORTED EVENT AND SUSPECTED INSERT CANNOT BE EXCLUDED. DUE TO REQUIRED INTERVENTION, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENT WAS ADDED. FURTHER INFORMATION (EVENT OUTCOME) HAS BEEN REQUESTED. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 09-OCT-2015: DESPITE FOLLOW UP ATTEMPTS, NO FURTHER INFORMATION WAS OBTAINED. (B)(4). THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055394	BAYER	8/11/2015	8/17/2015

Event Information:

Event Date (B3): 5/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/24/2013
Explant Date (E7): 7/8/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS PLACED WITH ESSURE IN 2013 WITH PAIN FROM DAY OF IMPLANTATION AND THERE AFTER ON RIGHT SIDE. DUE TO THIS ONGOING PAIN MY RIGHT TUBE AND COIL WERE REMOVED A FEW WEEKS LATER. AFTER THIS PROCEDURE, I CONTINUED TO HAVE PAIN. ER VISITS CRAMPING, HORRIBLE MENSES, THIS ALSO AFFECTED MY SEX LIFE. I FOUND A NEW DOCTOR IN (B)(6) 2015. DR EXPLAINED ALL MY PROBLEMS I HAD BEEN HAVING FOR THE PAST TWO YEARS. WE DISCUSSED A FEW OPTIONS THE BEST FOR ME WAS TO REMOVE ESSURE. THIS REQUIRES ME TO HAVE MY TUBES REMOVED; HOWEVER, THE COIL THAT WAS TO BE REMOVED BACK IN 2013 WAS LEFT IN MY UTERUS. SO THIS COIL THAT WAS IN MY TUBE HAD NOT BEEN IN MY TUBE IT PERFORATED MIGRATED INTO MY UTERUS. THEREFORE I HAD TO HAVE A HYSTERECTOMY. ON (B)(6) 2015 LEAVING MY OVARIES. IT IS VERY SAD WHEN A WOMAN HAS TO GIVE UP SOMETHING YOU ARE BORN WITH EVEN IF YOU ARE DONE HAVING CHILDREN. PLEASE TAKE A LOOK INTO THIS PRODUCT SO NO MORE WOMEN MAY HAVE TO GO THROUGH THE SAME PROBLEMS. THAN YOU (B)(6).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00589	BAYER HEALTHCARE LLC	8/12/2015	8/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** AS

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 12267443

Single Use: Y
Implant Date (E6): 4/28/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA NEWS ARTICLE IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED SHE RECENTLY HAD HER ESSURE REVERSED AFTER SUFFERING FROM PAIN, FATIGUE AND EXTREME SMELL SENSITIVITY - THOUGH SHE WAS INITIALLY TOLD IT COULD ONLY BE DONE BY HYSTERECTOMY. SHE BELIEVED THE DEVICE GAVE HER HEAVY METAL POISONING; SHE STATED SHE HAD NO LIFE FOR THE PAST FOUR YEARS. FOLLOW UP INFORMATION RECEIVED ON 15-JUL-2015 FROM CONSUMER VIA UNITED STATES HEALTHY AUTHORITY MAUDE EVENT REPORT ((B)(4)): ON (B)(6) 2005, THE CONSUMER HAD ESSURE INSERTED (THE ESSURE MODEL WAS AMENDED TO ESS205). THE LOT NUMBER USED WAS 12267443. THE CONSUMER REPORTED SHE HAD AUTO IMMUNE ISSUES AND LEFT HIP PAIN SINCE THE IMPLANTATION OF ESSURE BIRTH CONTROL DEVICES. SHE ALSO STATED THAT CURRENTLY SHE WAS TREATING WITH NATURAL SUPPLEMENTS DUE TO SENSITIVE NATURE OF THE BODY AFTER ESSURE; SHE REPORTED MANY MEDICATIONS DID NOT WORK OR CAUSED MASSIVE COMPLICATIONS. THE CONSUMER MENTIONED THE SERIOUSNESS CRITERIA DISABILITY OR PERMANENT DAMAGE BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW UP 11-AUG-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4) FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY (B)(4) AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 12-AUG-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PELVIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 40 CASES. (B)(4) IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED; NEWS MEDIA CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REVERSED DUE TO PAIN. SHE BELIEVED ESSURE GAVE HER HEAVY METAL POISONING. ADDITIONALLY, SHE STATED SHE HAD AUTOIMMUNE ISSUES SINCE ESSURE PLACEMENT. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE THE OTHER EVENTS ARE UNLISTED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. ALTHOUGH, IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM ESSURE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE A METAL POISONING. THEREFORE THE REPORTED HEAVY METAL POISONING WAS CONSIDERED UNRELATED TO ESSURE. FOR AUTOIMMUNE ISSUES, CONSIDERING ESSURE LOCAL ACTION AT FALLOPIAN TUBES AND THE NATURE OF THIS EVENT, CAUSALITY IS CONSIDERED VERY UNLIKELY. REGARDING CONSUMER'S PAIN; SINCE ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY, CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, AS ALTHOUGH THE EXACT METHOD FOR ESSURE REVERSAL WAS NOT REPORTED; WHEN REMOVAL OF THE MICRO-INSERT IS NECESSARY, AN INTERVENTION IS USUALLY REQUIRED. ADDITIONALLY NON-SERIOUS EVENT WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00590	BAYER HEALTHCARE LLC	8/12/2015	8/12/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** AS

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA NEWS ARTICLE IN (B)(6) ON 14-JUL-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED SHE DID BECOME PREGNANT - THREE TIMES - RESULTING IN TWO TERMINATIONS AND A BABY. THIS CASE REFERS TO THE THIRD PREGNANCY. THE OTHER TWO PREGNANCIES CASES WERE CREATED UNDER REFERENCES (B)(4) (FIRST AND SECOND PREGNANCY RESPECTIVELY). AFTER FIRST AND SECOND PREGNANCIES, THE CONSUMER BECAME PREGNANT AGAIN. SHE WAS TOO DEPRESSED TO CONTINUE WITH HER THIRD PREGNANCY AND SUCCESSFULLY SUED HER GYNECOLOGIST FOR NEGLIGENCE AND BREACH OF CONTRACT BECAUSE HE ASSURED HER THE DEVICE WAS WORKING AFTER THE FIRST PREGNANCY AND FAILED TO ADVISE HER TO USE FURTHER CONTRACEPTION. ON UNSPECIFIED DATE SHE GOT RID OF THE ESSURE, BY HYSTERECTOMY, BUT THE PAIN LINGERS, SHE STATED THAT FELT SO BLESSED THAT SHE HAD THREE HEALTHY KIDS, BUT SHE FEELS FOR THE TWO SOULS.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT THREE TIMES WITH ESSURE. THIS CASE REFERS TO THE THIRD PREGNANCY. SHE GOT RID OF THE ESSURE, BY HYSTERECTOMY, BUT THE PAIN LINGERS. BOTH EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, SHE WAS TOO DEPRESSED TO

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CONTINUE WITH HER THIRD PREGNANCY WHICH RESULTED IN TERMINATION. A HYSTERECTOMY WAS PERFORMED, BUT THE PAIN CONTINUES. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. FOLLOW UP WILL NOT BE POSSIBLE BECAUSE ADVERSE EVENT WAS REPORTED IN A NEWS ARTICLE.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 25-AUG-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00591	BAYER HEALTHCARE LLC	8/12/2015	8/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C96076

Single Use: Y
Implant Date (E6): 12/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF (B)(6)-YEAR-OLD IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014; THE LOT NUMBER USED WAS C96076. CONSUMER REPORTED THAT DURING ESSURE PLACEMENT THE LEFT SIDE WAS PLACED FINE BUT THE RIGHT SIDE COIL BENT AND MAYBE BROKE, BUT SHE WAS NOT SURE. ON (B)(6) 2015, SHE DID THE CONFIRMATION TEST ANYWAY AND THE RIGHT SIDE WAS NOT OCCLUDED SO SHE HAD A BILATERAL TUBAL LIGATION SURGERY DONE ON (B)(6) 2015. FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: LOT C96076 IS INVALID. FAILURE MODE / MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT

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NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE AND A LACK OF EFFICACY. A LACK OF EFFICACY MAY OCCUR WITH THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER A VALID BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. NO VALID BATCH NUMBER WAS REPORTED. THE AE CASE REFERS TO THE LOT NUMBER C96076, WHICH IS INVALID ACCORDING TO THE (B)(4). WITHOUT A VALID BATCH INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ON THE RIGHT SIDE, ESSURE COIL BENT AND MAYBE BROKE. THIS EVENT, SEEN AS DEVICE BREAKAGE AND DEVICE USE ERROR, IS NON-SERIOUS. BREAKAGE IS LISTED ACCORDING TO TECHNICAL ANALYSIS. DEVICE USE ERROR IS ALSO LISTED. DEVICE BREAKAGE HAS BEEN REPORTED MOSTLY DURING DIFFICULT ESSURE INSERTIONS OR REMOVALS. IN THIS CASE, DURING ESSURE PLACEMENT ON THE LEFT SIDE THE INSERT WAS WELL PLACED BUT ON THE RIGHT SIDE THE DEVICE BENT AND MAYBE BROKE. THE CONFIRMATION TEST WAS PERFORMED A FEW MONTHS LATER AND THE RIGHT FALLOPIAN TUBE WAS NOT OCCLUDED. THEN A TUBAL LIGATION WAS PERFORMED. CONSIDERING THE EVENTS OCCURRED PROBABLY DURING PLACEMENT PROCEDURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE THE TUBAL LIGATION WAS PERFORMED TO ENSURE CONTRACEPTION AND THE DEVICE BREAKAGE COULD HAVE LED TO A SERIOUS INJURY UNDER LESS FORTUNATE CIRCUMSTANCES, THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT. TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 23-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00592	BAYER HEALTHCARE LLC	8/12/2015	8/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/6/2015
Explant Date (E7): 6/8/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA MEDIA COVERAGE FROM A (B)(6)-YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2015. CONSUMER STATED HER PROCEDURE WAS PROMISED 20 MINUTES AND IT WAS 3 HOURS. 63 DAYS LATER SHE UNDERWENT A HYSTERECTOMY. ONE COIL CAME OUT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-

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MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE COIL CAME OUT. SHE WAS SUBMITTED TO A HYSTERECTOMY 63 DAYS AFTER ESSURE PLACEMENT. THE REPORTED EVENT, INTERPRETED AS DEVICE DISLOCATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ALTHOUGH, IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF THE EVENT IS UNKNOWN, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A HYSTERECTOMY WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO ACTIVE FOLLOW-UP WILL BE PURSUED; SINCE THIS CASE WAS RECEIVED VIA (B)(4).

Manufacturer Narrative (H10):

FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0579, AWARENESS DATE 14

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00593	BAYER HEALTHCARE LLC	8/12/2015	8/12/2015

Event Information:

Event Date (B3): 4/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B16009

Single Use: Y
Implant Date (E6): 9/9/2013
Explant Date (E7): 4/7/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6) 2015 WHICH DESCRIBED A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. ON (B)(6) 2014, THE PATIENT EXPERIENCED PREGNANCY WITH ESSURE, MORE THAN ONE YEAR AFTER PLACEMENT OF THE IMPLANTS THAT WAS CONTROLLED BY RADIOGRAPHY AND ULTRASONOGRAPHY IN (B)(6) 2013. AN ELECTIVE ABORTION WAS PERFORMED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015 FROM PHYSICIAN: THE PATIENT WAS (B)(6) YEARS OLD AT TIME OF THE REPORT. THE PHYSICIAN CONFIRMED PATIENT'S PREGNANCY. AT TIME OF THE REPORT, ESSURE DEVICES HAVE NOT BEEN REMOVED. NO MORE INFORMATION AVAILABLE BECAUSE THE PHYSICIAN THAT COMPLETED THE QUESTIONNAIRE DID NOT PERFORM THE PLACEMENT. FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). BATCH NUMBER B15009 PRODUCTION DATE: 4/2013 AND EXPIRATION DATE: 4/2016. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. FINAL RISK CLASSIFICATION RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT AS IT MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE

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REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON (B)(6) 2015: INFORMATION RECEIVED STATES THAT AN ULTRASOUND WAS PERFORMED FOLLOWING ESSURE PLACEMENT (NO RESULTS PROVIDED). ON (B)(6) 2015, PATIENT WAS SEEN FOR MEDICAL EXAMINATION (NO FURTHER INFORMATION PROVIDED). FOLLOW UP INFORMATION (PREGNANCY QUESTIONNAIRE) RECEIVED ON (B)(6) 2015 FROM PHYSICIAN: THE ESSURE BATCH NUMBER REPORTED BY PHYSICIAN WAS B16009. THE PLACEMENT OF ESSURE WAS PERFORMED DURING FOLLICULAR PHASE (FIRST DAY OF THE LAST MENSTRUATIONS WAS (B)(6) 2013). AN OBSERVATION OF THE UTERUS BEFORE PLACEMENT PROCEDURE WAS PERFORMED AND SHOWED SYNECHIA OF THE UPPER PART OF THE ENDOCERVIX. THE CONTRACEPTION USED BEFORE CONFIRMATION OF EFFICIENCY OF ESSURE WAS CERAZETTE (STARTING ON (B)(6) 2013 AND STOPPED ON (B)(6) 2013). A TEST FOR CONFIRMATION OF ESSURE WAS PERFORMED BY RADIOGRAPHY ON (B)(6) 2013 AND BY 3D TRANSVAGINAL ULTRASONOGRAPHY ON (B)(6) 2013. THE CONFIRMATION TEST DID CONFIRM THE OBSTRUCTION. THE PATIENT RECEIVED THE INFORMATION THAT ESSURE WAS EFFICIENT ON BASIS OF THE CONFIRMATION TEST. THE PHYSICIAN CONFIRMED THE PREGNANCY AND STATED THE IMPLANTS WERE IN PLACE AT THE TIME OF DIAGNOSIS OF PREGNANCY; HE ALSO REPORTED THE PATIENT'S WISH REGARDING THE PREGNANCY WAS INTERRUPTION. ESSURE IMPLANTS WERE REMOVED ON (B)(6) 2015 BY LAPAROSCOPY. OBSERVATION ABOUT LOCALIZATION AND CONDITION OF THE IMPLANTS SHOWED THE RIGHT ESSURE TRANSFIXING THE UTERINE HORN AND THE LEFT ESSURE IN PLACE. CASE UPGRADED TO INCIDENT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 CERAZETTE WAS STARTED IN (B)(6) 2013 AND WAS STOPPED AT THE END OF (B)(6) 2013. NO FURTHER INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY AND REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD A PREGNANCY WITH ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) MORE THAN 1 YEAR AFTER DEVICE PLACEMENT. SHE UNDERWENT AN ELECTIVE ABORTION. LATER, DURING A LAPAROSCOPY SURGERY FOR ESSURE REMOVAL, RIGHT ESSURE WAS FOUND TRANSFIXING THE UTERINE HORN. THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THE PRESENT CASE, TUBAL OCCLUSION WAS CONFIRMED 3 MONTHS AFTER ESSURE PLACEMENT BY X-RAY AND ULTRASOUND. LATER; A UTERINE PERFORATION WAS DIAGNOSED DURING A LAPAROSCOPIC SURGERY FOR ESSURE REMOVAL. THIS PERFORATION COULD HAVE BEEN A CONTRIBUTORY ROLE IN ESSURE FAILURE (PREGNANCY). HOWEVER, SINCE PHYSICIAN STATED ESSURE INSERTS WERE IN PLACE AT THE TIME OF PREGNANCY DIAGNOSIS; A CAUSAL RELATIONSHIP BETWEEN THE EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT; HOWEVER, UPON RECEIPT OF FOLLOW-UP INFORMATION, A SURGICAL INTERVENTION FOR ESSURE REMOVAL WAS REPORTED. THEREFORE, THIS CASE WAS UPGRADED TO INCIDENT. AN UPDATED PRODUCT TECHNICAL ANALYSIS (LOT NUMBER AMENDED AT FOLLOW-UP) IS BEING SOUGHT.

Manufacturer Narrative (H10):

CORRECTION PERFORMED ON 12-AUG-2015 CONCERNING FOLLOW-UP INFORMATION RECEIVED ON 16-JUL-2015: THE EVENT LEFT ESSURE WAS TRANSFIXING THE UTERINE HORN WAS AMENDED TO RIGHT ESSURE WAS TRANSFIXING THE UTERINE HORN. UPDATED PRODUCT TECHNICAL COMPLAINT (PTC) IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00594	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/26/2014
Explant Date (E7): 4/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA LAY PRESS FROM AN ADULT FEMALE CONSUMER IN UNITED STATES ON (B)(4) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON UNSPECIFIED DATE AND HAD TO HAVE A HYSTERECTOMY AT (B)(6) YEARS. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 22-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 10-AUG-2015: REPORTED WAS RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY (CASE # MW5043472). ON (B)(6) 2014, ESSURE WAS INSERTED, THREE MONTHS AFTER HAVING

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HER LAST CHILD. ROUGHLY ONE MONTH AFTER ESSURE WAS IMPLANTED, SHE STARTED TO DEVELOP STRANGE AND PROBLEMATIC SYMPTOMS. THE BEGINNING SYMPTOMS INCLUDED SEVERE PELVIC PAIN, SEVERE BLEEDING FOR 2 MONTHS, STABBING HEAD PAINS, EAR PAIN, TINNITUS AND HEADACHE, HORRIBLE LIGHTHEADEDNESS, DIZZINESS AND PANIC ATTACKS THAT INCLUDED NAUSEA AND VOMITING ON OCCASION, AND CHRONIC FATIGUE. IN THE FOLLOWING MONTHS, SHE CONTINUED TO GAIN WORSENING SYMPTOMS INCLUDING THE PREVIOUS NOTED AND AUTO IMMUNE LIKE SYMPTOM, JOINT PAIN, BREATHING ISSUES, HEART PALPITATIONS, CHRONIC CHEST PAIN WITH A CRACKING STERNUM, STOMACH, AND OTHER GASTROINTESTINAL ISSUES, MEMORY AND CONCENTRATION PROBLEMS, MOOD SWINGS, DEPRESSION, HOPELESSNESS, SADNESS, FEELING TOXIC OR POISONED, A METALLIC TASTE IN HER MOUTH, AND STRANGE SMELLS LIKE BURNING HAIR OR CHLORINE AND TEETH SENSITIVITY/PAIN AND DECAY. SHE HAD 30+ ER (EMERGENCY ROOM) VISITS, CARDIAC STRESS TEST, CARDIAC NUCLEAR TEST, NUCLEAR HIDESCAN, 20+ CHEST X-RAYS, MULTIPLE CT SCANS, MRIS, MAMMOGRAM, AND IT SEEMS ENDLESS BLOOD TESTS FOR CARDIAC REASONS AND TESTING FOR LYME, LUPUS AND RA. SHE HAD MULTIPLE DDIMER TEST RETURN QUITE ELEVATED EACH TIME. SHE WAS PRESCRIBED A LIST OF MEDICATIONS TO TREAT SYMPTOMS, INCLUDING BETA BLOCKERS, CALCIUM CHANNEL BLOCKERS, SEVERAL DIFFERENT ANTI-ANXIETY MEDICATIONS, VALIUM, PAIN KILLERS, BIRTH CONTROL (TO STOP THE 2 MONTHS OF BLEEDING), AND ANTI-DEPRESSANTS. ON (B)(6) 2015, A HYSTERECTOMY WAS PERFORMED TO REMOVE THE ESSURE COILS. SHE WAS STILL SUFFERING SEVERAL SYMPTOMS. IN HER BELIEF ALL OF THE ABOVE WAS DIRECTLY CAUSED FROM THIS DEVICE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE A HYSTERECTOMY AT (B)(6) YEARS. ACCORDING TO FOLLOW UP INFORMATION RECEIVED VIA REGULATORY AUTHORITY, ROUGHLY ONE MONTH AFTER INSERTION SHE EXPERIENCED SEVERE PELVIC PAIN AND SEVERE BLEEDING FOR 2 MONTHS (SEEN AS GENITAL BLEEDING), IN ADDITION, SHE PRESENTED AUTOIMMUNE LIKE SYMPTOM. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT AUTOIMMUNE LIKE SYMPTOM WHICH IS UNLISTED. PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR WITH ESSURE USE. IN THIS CASE, SHE HAD THE PAIN AND BLEEDING ONE MONTH AFTER INSERTION. CONSIDERING CLOSE TEMPORAL RELATIONSHIP AND THEIR NATURE, THESE EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. REGARDING AUTO IMMUNE LIKE SYMPTOM, LIMITED INFORMATION HAS BEEN PROVIDED; HOWEVER, GIVEN ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND SUSPECT INSERT IS VERY UNLIKELY. AS ESSURE REMOVAL WAS REQUIRED (VIA HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00595	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): 2/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C55829

Single Use: Y
Implant Date (E6): 2/4/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS WERE PROVIDED). PHYSICIAN REPORTED THAT PATIENT EXPERIENCED PELVIPERITONITIS. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. PTC INVESTIGATION RESULT WAS RECEIVED ON 08-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON 15-JUL-2015 FROM PHYSICIAN: PATIENT'S INITIALS AND DATE OF BIRTH WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. IN (B)(6) 2015 ESSURE LOT NUMBER C55829 WAS IMPLANTED.

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INSERTION CONDITIONS WERE GOOD AND BILATERAL PLACEMENT WAS PERFORMED. ON (B)(6) 2015, AT DAY 8 FOLLOWING ESSURE INSERTION, SHE EXPERIENCED PELVIPERITONITIS. THERE WAS NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. ACCORDING TO THE PHYSICIAN CLINICAL CONSEQUENCES WERE SIMPLE AFTER SURGERY REVISION. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO EXPERIENCED PELVIPERITONITIS 8 DAYS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE REPORTED EVENT IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE AND WAS REGARDED AS SERIOUS, DUE TO MEDICAL IMPORTANCE. PERITONITIS IS DEFINED AS INFLAMMATION OF THE SEROSAL MEMBRANE THAT LINES THE ABDOMINAL CAVITY AND THEIR ORGANS; IT IS MOST OFTEN CAUSED BY INTRODUCTION OF AN INFECTION INTO THE OTHERWISE STERILE PERITONEAL CAVITY. WOMEN MAY EXPERIENCE SECONDARY PERITONITIS FROM A PELVIC INFLAMMATORY DISEASE, WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT, THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS PARTICULAR CASE, THE EXACT CAUSE OF PATIENT'S PERITONITIS WAS NOT PROVIDED AND IT IS UNCLEAR IF THIS EVENT WAS A CONSEQUENCE OF AN UPPER GENITAL TRACT INFECTION; HOWEVER CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE SERIOUS INJURY REPORTED, THIS CASE WAS CONSIDERED AN INCIDENT. AN UPDATED PRODUCT TECHNICAL ANALYSIS (LOT NUMBER REPORTED UPON FOLLOW-UP) AND FURTHER INFORMATION (EVENT'S ETIOLOGY) ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 30-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00596	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) ON 25-NOV-2014 WHICH WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. SHE STATED THAT WAS EXPERIENCING PAIN IN HER OVARIES, FALLOPIAN TUBES AND WAIST EVER SINCE ESSURE INSERTION. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED BY CONSUMER ON 11-DEC-2014 THE CONSUMER STATED THAT SHE HAD THE TEST PROCEDURE DONE IN 2009 TO MAKE SURE THAT HER TUBES WERE BLOCKED AND SHE WAS TOLD THAT THEY WERE BLOCKED. SHE WAS STILL HAVING PAIN IN HER OVARIES. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER (B)(4) AND THE (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE EVENTS WERE REPORTED WITH AN OCCURRENCE OVER 6 YEARS. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER

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TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 25-JUN-2015: CONSUMER STATED THAT SHE HAD PAIN SOMETIMES IN STOMACH NEAR HIP WHERE WIRES ARE AND SOMETIMES IN UTERUS WHEN SHE IS ON HER MENSTRUAL AND ALSO WHEN IT RAINS REALLY BAD. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 17-JUL-2015 CONSUMER SAID THAT SHE HAD ESSURE INSERTED AND IT BROKE OFF IN HER. SHE ALSO STATED THAT SHE HAD BEEN PREGNANT AND DID NOT KNOW IT AND SHE HAD A MISCARRIAGE. SHE HAD REALLY BAD PAIN AND CLOTS. NO FURTHER INFORMATION WAS PROVIDED. CASE UPGRADED TO OTHER REPORTABLE INCIDENT. PTC INVESTIGATION RESULT RECEIVED ON 24-JUL-2015 PTC (B)(4) FINAL ASSESSMENT THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE AND A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP DATED 24-JUL-2015: UPON FOLLOW UP WITH THE REPORTER; SHE CONFIRMED THAT CASE (B)(4) WASN'T ABOUT A FRIEND IT WAS A CALL ABOUT HERSELF. SHE STATED SHE HAD A MISCARRIAGE LAST MONTH ((B)(6) 2015); AND THIS WASN'T SUPPOSED TO HAPPEN BECAUSE SHE HAD THE TEST AFTER THE ESSURE. SHE WAS IN THE HOSPITAL RECENTLY BECAUSE SHE HAD A BREAST INFECTION; SHE WAS TREATING WITH AN ANTIBIOTIC AND A CREAM. SHE ALSO REPORTED SHE HAD HER PERIOD THREE TIMES LAST MONTH. WITH THIS INFORMATION, (B)(4) WAS IDENTIFIED AS DUPLICATE OF THIS CASE. (B)(4) WILL BE DELETED FROM BAYER DATABASE AND THE FOLLOWING INFORMATION WAS ADDED TO THIS REMAINING CASE: ON AN UNSPECIFIED DATE THE CONSUMER BECAME PREGNANT WITH ESSURE IN PLACE (DEVICE INEFFECTIVE) SINCE IT HAD BROKEN AND CAME OUT. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE

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INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 6/29/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT QUALITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE AE CASE REFERS ALSO TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. DURING INTERNAL REVIEW OF INFORMATION FROM 24-JUL-2015 (FROM DELETED CASE); THE EVENT ESSURE CAME OUT WAS ADDED UNDER MEDDRA PT DEVICE EXPULSION. FOLLOW UP 11-AUG-2015: NO NEW CLINICAL INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE INSERTION AND HAD A MISCARRIAGE. SHE STATED ESSURE BROKE OFF IN HER. ADDITIONALLY, SHE HAD CLOTS (REGARDED AS GENITAL BLEEDING) AND WENT TO THE HOSPITAL DUE TO BREAST INFECTION. MISCARRIAGE AND BREAST INFECTION ARE UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE OTHER EVENTS ARE LISTED. ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC), DEVICE BREAKAGE IS LISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS PARTICULAR CASE, CONSUMER STATED SHE HAD TUBAL OCCLUSION CONFIRMED. LATER, SHE INFORMED ESSURE BROKE OFF IN HER AND CAME OUT. THIS DEVICE BREAKAGE COULD HAVE BEEN A CONTRIBUTORY ROLE IN ESSURE FAILURE. HOWEVER, SINCE EVENT'S ONSET IS UNKNOWN, AN ESSURE'S CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING MISCARRIAGE IT IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY, OCCURRING IN UP TO 20% OF CLINICALLY RECOGNIZED PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION. CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THE REPORTED EVENT WAS CONSIDERED AS UNRELATED TO THE SUSPECT INSERT. FOR THE EVENT CLOTS; LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING ITS NATURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. CONSUMER ALSO REPORTED BREAST INFECTION; WHICH DUE TO ITS NATURE WAS CONSIDERED AS UNRELATED TO ESSURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PTC ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-NOV-2015: THIS CASE IS A POTENTIAL LEGAL CASE NOW. CONSUMER STATED THAT ESSURE WAS INSERTED IN 2008. SHE HAS BEEN EXPERIENCING PAIN IN HER PELVIS AND HAD A TEST THAT REVEALED ONE OF THE COILS CAME LOOSE AND IS IN HER UTERUS. SHE A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00597	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/13/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042707) IN UNITED STATES ON 15-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. THE CONSUMER REPORTED THAT ESSURE WAS IMPLANTED AND WITHIN A MONTH SHE HAD NAUSEA, SEVERAL HEADACHES, FATIGUE, CONTINUED SLEEP PROBLEMS, WEIGHT GAIN AND BLOATED BELLY. SHE STATED THAT SHE HAD A "HYSTO" AND THE COIL HAD PROTRUDED THRU. NO OTHER INFORMATION WAS GIVEN. THE CONSUMER MENTIONED THE SERIOUSNESS CRITERIA OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON 21-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR

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COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND COIL HAD PROTRUDED THRU. THIS EVENT, INTERPRETED AS UTERINE PERFORATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF UTERINE PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. IT WAS REPORTED THAT A "HYSTO" (SEEN AS HYSTERECTOMY) WAS PERFORMED. THEREFORE, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-NOV-2015: CONSUMER REPORTED SHE GOT ESSURE IN (B)(6) 2011. SHE HAD FATIGUE, NAUSEAS AND HEADACHES. SHE IS (B)(6) AND RECENTLY HAD A HYSTERECTOMY. BACK PAIN AND ABDOMINAL PAIN WERE HORRIBLE . SHE ALWAYS WANTING TO FALL ASLEEP. COMP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00598	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): 5/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/14/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042680) IN UNITED STATES ON 15-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. THE CONSUMER REPORTED SHE HAS BEEN IN PAIN FROM THE MOMENT ESSURE WAS IMPLANTED IN HER FALLOPIAN TUBE. SHE STATED THAT WAS HOSPITALIZED 2 TIMES AND CURRENTLY WAS SEEKING TO HAVE THE COIL REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 24-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY

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CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO EXPERIENCED PAIN FROM THE MOMENT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS IMPLANTED IN HER FALLOPIAN TUBE. SHE STATED SHE WAS HOSPITALIZED TWO TIMES. THIS EVENT, REGARDED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE CONSUMER STATED THE EVENT STARTED AFTER ESSURE INSERTION. THEREFORE, A CAUSAL RELATION WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE HOSPITALIZATION WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 02-OCT-2015 FROM CONSUMER. DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE CONSUMER. ON UNSPECIFIED DATE HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED. ON UNSPECIFIED DATE SHE EXPERIENC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00599	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/16/2010
Explant Date (E7): 12/18/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042802) IN UNITED STATES ON 15-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. THE CONSUMER REPORTED HER PERIODS PROGRESSIVELY BECAME MORE PAINFUL WITH HEAVIER BLEEDING CAUSING LARGE BLOOD CLOTS TO PASS. EVERY MONTH PRIOR TO HER MENSTRUAL CYCLE SHE WOULD ENDURE A 2 DAY MIGRAINE HEADACHE THAT PREVENTED HER FROM DAILY ACTIVITY. SHE STATED THAT THE CRAMPING FROM HER PERIODS BECAME UNBEARABLE. AFTER TRYING SEVERAL PRESCRIPTION MIGRAINE MEDICATIONS FROM HER PRIMARY DOCTOR HER PHYSICIAN RECOMMENDED A HYSTERECTOMY IN 2014. THE PROCEDURE WAS SCHEDULED TO BE LAPAROSCOPIC, BUT DUE TO THE LEFT COIL PUNCTURING HER FALLOPIAN TUBE THEY HAD TO GO IN ABDOMINALLY TO REMOVE THE SEVERE ENDOMETRIOSIS. SHE WAS NEVER DIAGNOSED NOR HAD DIFFICULTY WITH ENDOMETRIOSIS UNTIL AFTER ESSURE. SHE HAD EVERYTHING REMOVED IN (B)(6) 2014 EXCEPT THE RIGHT OVARY; THE LEFT OVARY WAS REMOVED DUE TO THE DAMAGE AND SHE WAS BEING TREATED FOR AN ENDOMETRIAL CYST ON HER RIGHT OVARY WHICH CAUSED SEVERE PAIN AND CRAMPING DAILY. PTC INVESTIGATION RESULT WAS RECEIVED ON 21-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD LEFT COIL PUNCTURING MY FALLOPIAN TUBE AND PERIODS PROGRESSIVELY BECAME MORE PAINFUL / CRAMPING FROM MY PERIODS BECAME UNBEARABLE. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, CONSUMER UNDERWENT A HYSTERECTOMY ABDOMINALLY DUE TO SEVERE ENDOMETRIOSIS. THE EXACT DATE AND MECHANISM OF FALLOPIAN TUBE PERFORATION WERE NOT KNOWN. GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION PERFORMED. ADDITIONALLY, ANOTHER SERIOUS EVENT (OVARY (THE LEFT WAS REMOVED DUE TO THE DAMAGE - UNRELATED TO ESSURE) AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 28-AUG-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CON

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00600	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): 5/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 915889

Single Use: Y
Implant Date (E6): 3/21/2012
Explant Date (E7): 12/22/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A CLINICAL STUDY CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6)2015 WHICH REFERS TO AN ADULT (>=18Y & <65Y) FEMALE PATIENT WHO WAS INVOLVED IN A INTERVENTIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: USE OF TRANSVAGINAL ULTRASOUND TO CONFIRM ESSURE MICRO-INSERT PLACEMENT IN WOMEN: DEMONSTRATION OF EFFECTIVENESS. PATIENT NUMBER: (B)(6). ON (B)(6) 2012, ESSURE WAS INSERTED; THE LOT NUMBER USED WAS 915889. AN ADEQUATE VISUALIZATION OF THE RIGHT AND LEFT TUBAL OSTIA WAS ACHIEVED. AT LEAST ONE ESSURE MICRO-INSERT PASSED THROUGH THE CHANNEL OF THE SCOPE AT ANY TIME DURING THE PROCEDURE. ORAL MEDICATIONS WAS USED AS ANESTHESIA METHOD. PRIOR TO THE PROCEDURE, SUBJECT RECEIVED NAPROXEN 500MG. ON THE SAME DAY OF INSERTION, AN URINE PREGNANCY TEST WAS PERFORMED AND THE RESULT WAS NEGATIVE. HER LAST MENSTRUATION WAS ON (B)(6) 2012. ON (B)(6) 2012, THE PATIENT EXPERIENCED INTERMENSTRUAL BLOOD LOSS. THE INVESTIGATOR CONSIDERED THE EVENT RELATED TO STUDY AND THE PATIENT ALSO EXPERIENCED ABDOMINAL PAIN. ON (B)(6) 2014, A NOVASURE PROCEDURE WAS DONE FOR MENORRHAGIA. THE PROBE LENGTH WAS 8 CM; THE CERVIX LENGTH WAS 4 CM AND THE CAVUM LENGTH WAS 4 CM. THE PROCEDURE WAS CONSIDERED UNCOMPLICATED. AFTER THE PROCEDURE, THE PATIENT CONTINUED WITH THE HEAVY INTERMENSTRUAL BLOOD LOSS. ON (B)(6) 2014, A LAPAROSCOPIC HYSTERECTOMY WAS PERFORMED. DURING THE PROCEDURE, THE UTERUS AND ADNEXA WERE WITH NORMAL ASPECTS; THE INSPECTION OF ABDOMEN SHOWED NO ADHESIONS OF OTHER PATHOLOGIES. DURING INSPECTION OF ABDOMEN, SMOOTH LIVER AND NO ADHESIONS OF OTHER PATHOLOGIES WERE VISIBLE. THE PHYSICIAN PERFORMED A BOTH SIDES TUBECTOMY (NOT LOOSED IN TUBA CORNER), AND AFTER THAT BOTH SIDES ROTUNDA WERE TAKEN WITH HELP OF LIGASURE AND LIGAMENTA OVARIA PROPRIAE; BOTH SIDES

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OF PARAMETRIA AND VASCULAR SYSTEM WHICH WAS DISSECTED WAS GONE THROUGH WITH LIGASURE. THE PHYSICIAN PERFORMED A MOBILIZATION SIGMOID DUE TO SEVERAL ADHESIONS AND OPENING BLADDER PERITONEUM FROM LATERAL AND DISSECTION OF THE BLADDER, HERE MULTIPLE ADHESIONS WERE NOTICED. A BLEEDING IN THE VAGINA BACKSIDE WAS COAGULATED WAS OBSERVED. SUBSEQUENTLY REMOVAL OF UTERUS IN TOTAL BY UTERUS MANIPULATOR WAS DONE. THE FINAL INSPECTION SHOWED A GOOD HEMOSTASIS. THE WOUND CLASS WAS CONSIDERED CLEAN CONTAMINATED. CONCLUSION OF THE PROCEDURE: UNCOMPLICATED LAPAROSCOPIC UTERUS EXTIRPATION WITH TAKING OF TUBA. OVARY LEFT IN SITU. AFTER-TREATMENT/OUTPATIENT FOLLOW-UP: TELEPHONIC CONSULT 2 WEEKS FOR PATIENT AMD CHECK-UP IN 6 WEEKS. THE PATIENT RECOVERED FROM EVENT AFTER ESSURE DISCONTINUATION. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015. LOT NUMBER WAS CONFIRMED TO 915889 (PRODUCTION DATE OCT-2011; EXPIRATION DATE OCT-2014). FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(4). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING (B)(4) PREFERRED TERM: METRORRHAGIA. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 8 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, CLINICAL STUDY CASE REPORT REFERS TO A FEMALE SUBJECT WHO WAS INVOLVED IN A INTERVENTIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4) AND EXPERIENCED INTERMENSTRUAL BLOOD LOSS. THIS EVENT IS SERIOUS DUE TO HOSPITALIZATION AND LISTED IN THE INVESTIGATOR'S BROCHURE FOR ESSURE. IN THIS CASE, THIS EVENT OCCURRED ABOUT 56 DAYS AFTER ESSURE INSERTION. INVESTIGATOR CONSIDERED THIS EVENT RELATED TO STUDY DEVICE. SUBJECT UNDERWENT AN UNCOMPLICATED LAPAROSCOPIC UTERUS EXTIRPATION WITH TAKING OF TUBA. CONSIDERING THE EVENT NATURE AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, COMPANY AGREES WITH INVESTIGATOR'S ASSESSMENT AND CONSIDERS THE REPORTED EVENT AS RELATED TO STUDY DEVICE. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION AND HOSPITALIZATION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00601	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64469/C68790

Single Use: Y
Implant Date (E6): 7/16/2015
Explant Date (E7): 7/16/2015
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 8/17/2015

Event Description (B5):

OTHER REPORTABLE INCIDENT (MALFUNCTION: DEVICE BREAKAGE). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN OTHER HEALTH PROFESSIONAL IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. IT WAS REPORTED THAT DURING INSERTION, END PIECE OF DELIVERY CATHETER BROKE AND STAYED ATTACHED TO THE FIRST INSERT (LOT NUMBER C64469). THIS FIRST INSERT WAS REMOVED AND WAS KEPT AT THE PHARMACY. THE PHYSICIAN TRIED TO PLACE A SECOND ESSURE INSERT (LOT NUMBER C68790) BUT THE SAME PROBLEM HAPPENED: END PIECE OF DELIVERY CATHETER BROKE AND STAYED ATTACHED TO THE SECOND INSERT. THE SECOND ESSURE INSERT WAS LEFT IN PLACE. FOLLOW-UP INFORMATION WAS RECEIVED ON (B)(6) 2015. AT INSERTION OF THE FIRST INSERT (C64469) ON THE LEFT SIDE, END PIECE OF DELIVERY CATHETER BROKE AND STAYED ATTACHED TO THE INSERT INTO THE PATIENT. DEVICE WAS REMOVED WITH GRIPPING PLIER. NEW ATTEMPT WAS MADE WITH ANOTHER ESSURE INSERT (C68790) AND THE SAME PROBLEM OCCURRED, BUT THE INSERT STAYED PLACED. A THIRD INSERT WAS USED FOR RIGHT SIDE INSERTION WHICH WENT WELL. NO CLINICAL CONSEQUENCES FOR THE PATIENT. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: AS OF (B)(6) 2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE INTRODUCER TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT IT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C64469 (PRODUCTION DATE 09-JUN-2014 AND EXPIRATION DATE 30-JUN-2017); C68790 (PRODUCTION

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DATE 23-JUN-2014 AND EXPIRATION DATE 30-JUN-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THESE LOTS WERE PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF DAMAGE OR BREAKAGE OF THE INTRODUCER IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCHES WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING INSERTION, END PIECE OF DELIVERY CATHETER BROKE AND STAYED ATTACHED TO THE FIRST INSERT AND ALSO TO THE SECOND INSERT. THESE EVENTS, SEEN AS DEVICE BREAKAGE, ARE NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

UPDATED PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 01-SEP-2015 UPON RECEIPT DEVICE SAMPLE (TWO DEVICES WERE RECEIVED ON 17-AUG-2015). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00602	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): 7/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18705

Single Use: Y
Implant Date (E6): 4/10/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 17-JUL-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C18705, INSERTED ON (B)(6) 2015 FOR STERILIZATION. ON (B)(6) 2015 A FOLLOW UP HSG (HYSTEROSALPINGOGRAM) CONFIRMATION ON ESSURE WAS PERFORMED AND SHOWED THAT THE TUBES WERE BLOCKED, BUT THE TIP OF ONE OF THE DEVICES (LEFT) WAS BROKEN IN 2 PIECES. ESSURE WAS NOT REMOVED. FOLLOW-UP INFORMATION WAS RECEIVED ON 22-JUL-2015: PHYSICIAN STATED THAT BOTH INSERTS WERE IN PROPER LOCATION WITH BILATERAL OCCLUSION. STRETCHING OF PROXIMAL COILS WAS REVIEWED AND THE PHYSICIAN WAS ADVISED TO CONTACT RADIOLOGIST AND DETERMINE IF THAT WAS WHAT THE RADIOLOGIST WAS SEEING. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED FROM PHYSICIAN ON 22-JUL-2015: PHYSICIAN STATED PER RADIOLOGIST THE INSERT IS >50% IN THE UTERINE CAVITY (PROXIMAL PLACEMENT) AND DISTAL MARKERS ARE SEPARATED NOT PROXIMAL. ACCORDING TO THE REPORTER PATIENT HAD NO COMPLAINTS. FOLLOW-UP RECEIVED ON 01-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C18705; PRODUCTION DATE: 27-JAN-2014; EXPIRATION DATE: 31-JAN-2017. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR

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IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. IN THIS CASE IT IS UNCLEAR IF THE INSERT IS ACTUALLY BROKEN, OR IF THE INSERT HAS BEEN STRETCHED OR BENT AND APPEARS TO BE BROKEN SINCE IN MANY CASES ONLY THE RADIOPAQUE MARKERS ARE VISIBLE ON HSG IMAGES, WHICH LEADS SOME RADIOLOGISTS TO ASSUME THE DEVICE IS BROKEN. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT 3-MONTH CONTROL HYSTEROSALPINGOGRAM (HSG) ONE OF THE DEVICES (LEFT) WAS BROKEN IN 2 PIECES. ACCORDING TO THE RADIOLOGIST, ESSURE DISTAL MARKERS WERE SEPARATED NOT PROXIMAL AND THE INSERT WAS >50% IN THE UTERINE CAVITY. THE REPORTED EVENTS WERE REGARDED AS SUSPICION OF DEVICE BREAKAGE AND AS DEVICE DISLOCATION (ESSURE PROTRUDING INTO UTERINE CAVITY). DEVICE DISLOCATION IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE; WHILE THE OTHER EVENT IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. IN THIS PARTICULAR CASE, CONTROL HSG REVEALED BILATERAL TUBAL OCCLUSION; HOWEVER THE DEVICE WAS DISLOCATED AND REPORTER SUSPECTED IT COULD BE BROKEN. CONSIDERING EVENTS' NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO SUSPICION OF DEVICE BREAKAGE, AS ALTHOUGH PATIENT HAD NO INJURY THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

INTERNAL COMMUNICATION RECEIVED ON 27-OCT-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00603	BAYER HEALTHCARE LLC	8/13/2015	8/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM SPAIN WAS DERIVED FROM MEDICAL LITERATURE ON 04-AUG-2015, ARTICLE ENTITLED "HYSTEROSCOPIC TREATMENT OF HYDROSALPINX PRIOR TO IN VITRO FERTILIZATION - EMBRYO TRANSFER (IVF - ET)". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE IN WHOM ESSURE WAS USED FOR HYDROSALPINX PRIOR TO IN VITRO FERTILIZATION AND LATER SHE BECOME GEMELAR PREGNANT VIA IN VITRO FERTILIZATION. SHE HAD PRETERM DELIVERY AT 35 WEEK OF GESTATION. TRADE NAME WAS REPORTED AS ESSURE. CASE REPORT: THIS FEMALE PATIENT WAS INVOLVED IN A PROSPECTIVE, SINGLE-ARM, CLINICAL STUDY TO ASSESS HYSTEROSCOPIC TREATMENT OF HYDROSALPINX PRIOR TO IN VITRO FERTILIZATION - EMBRYO TRANSFER (IVF - ET). THE HYSTEROSCOPIC PLACEMENT OF THE ESSURE MICROINSERT WAS PERFORMED UNDER LOCAL ANESTHESIA. THIS PATIENT BECOME GEMELAR PREGNANT VIA IN VITRO FERTILIZATION. SHE HAD PRETERM (35 WEEKS OF GESTATION) CESAREAN DELIVERY OF TWO HEALTHY INFANTS. NONE OF THEM HAD POSTPARTUM COMPLICATIONS. AUTHORS COMMENTS: THIS DATA SHOW THAT TUBAL PROXIMAL OCCLUSION WITH ESSURE MICROINSERT IS A SAFE, MINIMALLY INVASIVE AND EFFECTIVE THERAPEUTIC ALTERNATIVE IN INFERTILE PATIENTS WITH ULTRASOUND VISIBLE HYDROSALPINGES. CONSIDERING THE ONGOING PREGNANCY RATE, IN THE FUTURE THE TRANSCERVICAL APPROACH MAY BE CONSIDERED FIRST THERAPEUTICAL OPTIONS. ABSTRACT: INTRODUCTION: NOWDAYS THE NEGATIVE EFFECT OF THE HYDROSALPINGES IN IN VITRO FERTILIZATION - EMBRYO TRANSFER (IVF ET) OUTCOMES, REDUCING THE IMPLANTATION RATE AND INCREASING THE MISCARRIAGE RISK, ARE WELL KNOWN. ANY SURGICAL INTERVENTION INTERRUPTING THE COMMUNICATION WOULD IMPROVE THE PREGNANCY RATE, SPECIALLY IF THE HYDROSALPINX IS LARGE ENOUGH TO BE VISIBLE ON ULTRASOUND. LAPAROSCOPIC SALPINGECTOMY OR PROXIMAL OCCLUSION HAVE BEEN DEMONSTRATED TO BE AN EFFECTIVE OPTION, BUT THEY ARE INVASIVE, MAY DISTURB OVARIAN

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BLOOD SUPPLY AND ARE ASSOCIATED WITH SEVERAL COMPLICATIONS IN PATIENTS WITH INTRA-ABDOMINAL ADHESIONS. THE ESSURE MICROINSERT IS THE FIRST AND ONLY APPROVED TRANSCERVICAL METHOD FOR FEMALE STERILIZATION. HYSTEROSCOPIC APPROACH MAY BE A THERAPEUTIC ALTERNATIVE, SPECIALLY IF LAPAROSCOPY WAS FELT TO BE CONTRAINDICATED. MATERIAL AND METHODS: PROSPECTIVE, SINGLE-ARM, CLINICAL STUDY. ELEVEN WOMEN (MEAN AGE: 34,6 YEARS; RANGE : 31-38 YEARS) WITH UNILATERAL (N : 3) OR BILATERAL HYDROSALPINGES (N : 8) WERE INCLUDED. IN ALL CASES HYDROSALPINGES WERE VISIBLE ON ULTRASOUND AND THE LAPAROSCOPIC TREATMENT WAS CONTRAINDICATED BECAUSE INTRA-ABDOMINAL ADHESIONS OF VARIOUS ETIOLOGIC CAUSES (PELVIC ENDOMETRIOSIS 7; PELVIC INFLAMMATORY DISEASE 3; GENITAL TBC 1). THE HYSTEROSCOPIC PLACEMENT OF THE ESSURE MICROINSERT WAS PERFORMED UNDER LOCAL ANESTHESIA. A MEAN NUMBER OF THREE COILS WERE LEFT PROTRUDING INTO THE UTERINE CAVITY. TRANSVAGINAL ULTRASOUND WAS PERFORMED THREE MONTHS POSTPROCEDURE TO EVALUATE SUCCESSFUL PLACEMENT OF THE MICROINSERT. IVF WAS STARTED AFTER A MEAN OF 6,4 MONTHS (RANGE 3 - 11) FOLLOWING ESSURE PROCEDURE. RESULTS: ALL PROCEDURES WERE PERFORMED WITHOUT ANY INTRAOPERATIVE OR POSTOPERATIVE COMPLICATIONS. IN ALL PATIENTS THE POSTPROCEDURE ULTRASOUND CONFIRMED SUCCESSFUL PLACEMENT OF THE MICROINSERT. TWO PATIENTS ARE NOW IN IVF ET TREATMENT. FIVE PATIENTS DID NOT BECOME PREGNANT. ONE OF THEM EXPERIENCED A FIRST TRIMESTER MISCARRIAGE IN A SPONTANEOUS PREGNANCY THAT OCCURRED TWO MONTHS AFTER THE ESSURE INSERTION. FOUR PATIENTS (PREGNANCY RATE: 44.44 %) BECAME PREGNANT IN THE FIRST IVF ET TREATMENT, TWO OF THEM HAD PREVIOUS UNSUCCESSFUL IVF ET TREATMENTS. IN THIS GROUP OF PREGNANT WOMEN ONE EARLY MISCARRIAGE OCCURRED AND THREE WERE ONGOING PREGNANCIES (ONE SINGLE AND TWO MULTIPLE). TWO PATIENTS HAVE ALREADY DELIVERED: THE SINGLE PREGNANCY HAD A NORMAL PREGNANCY COURSE AND A SPONTANEOUS TERM VAGINAL DELIVERY; THE GEMELAR PREGNANCY HAD A PRETERM (35 WEEKS OF GESTATION) CESAREAN DELIVERY OF TWO HEALTHY INFANTS. NONE OF THEM HAD POSTPARTUM COMPLICATIONS. THE THIRD ONE IS A TRIPLET PREGNANCY OF 30 WEEKS. DISCUSSION: THIS DATA SHOW THAT TUBAL PROXIMAL OCCLUSION WITH ESSURE MICROIN-SERT IS A SAFE, MINIMALLY INVASIVE AND EFFECTIVE THERAPEUTIC ALTERNATIVE IN INFERTILE PATIENTS WITH ULTRASOUND VISIBLE HYDROSALPINGES. CONSIDERING THE ONGOING PREGNANCY RATE, IN THE FUTURE THE TRANSCERVICAL APPROACH MAY BE CONSIDERED FIRST THERAPEUTICAL OPTIONS. SEVERAL STUDIES HAVE PROPOSED THE POSTOPERATIVE RADIOLOGICAL OR HISTEROSCOP-ICAL CONFIRMATION OF TUBAL OCCLUSION. AUTHORS DATES SHOW THAT ASSESSMENT BY TRANSVAGINAL ULTRASOUND OF THE CORRECT POSITION OF THE MICROINSERT MAY BE ENOUGH. MORE STUDIES ARE NEEDED TO DEFINE SEVERAL TECHNICAL DETAILS, LIKE THE IDEAL NUMBER OF COILS REMAINING IN THE UTERINE CAVITY OR THE BEST TIME PERIOD BETWEEN THE INSERTION AND IVF TREATMENT. OTHER CASES FROM SAME ARTICLE: 2015-393922, 2015-393940, 2015-393941, 2015-393942, 2015-393943, AND 2015-393945. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO A FEMALE PATIENT IN WHOM ESSURE WAS USED FOR HYDROSALPINX (OFF LABEL USE) PRIOR TO IN VITRO FERTILIZATION AND LATER SHE BECOME GEMELAR PREGNANT (THERAPEUTIC EFFECT UNEXPECTED) VIA IN VITRO FERTILIZATION (CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE). SHE HAD PRETERM DELIVERY AT 35 WEEK OF GESTATION (CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED). CESAREAN DELIVERY OF TWO HEALTHY INFANTS WAS PERFORMED. HYDROSALPINGES OCCUR WHEN THE FALLOPIAN TUBES ARE BLOCKED AND FILL WITH STERILE FLUID. THEY MAY BE A TUBAL FACTOR OF INFERTILITY AND THEIR PRESENCE DECREASES THE SUCCESS RATE OF IN VITRO FERTILIZATION (IVF) DUE TO OBSTRUCTION TO SPERM MIGRATION AND RETROGRADE FLOW OF TUBAL CONTENTS INTO THE ENDOMETRIAL CAVITY (WHICH CREATES A HOSTILE ENVIRONMENT TO IMPLANTATION OF AN EMBRYO). GIVEN THE NATURE OF THE REPORTED OFF LABEL USE AND CESAREAN DELIVERY, THEY WERE CONSIDERED AS UNRELATED TO ESSURE THERAPY. PATIENT'S PREGNANCY WAS CONSIDERED AS RELATED TO ESSURE, SINCE A CONTRIBUTORY ROLE OF THE INSERT IN THIS PREGNANCY OCCURRENCE (DUE TO AN UNEXPECTED THERAPEUTIC RESPONSE/ IMPROVEMENT OF INFERTILITY DUE TO HYDROSALPINX) CANNOT BE EXCLUDED. MOST OF PREMATURE

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BIRTHS OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES. A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THIS CASE WAS THUS, CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

THIS CASE REPORT FROM SPAIN WAS DERIVED FROM MEDICAL LITERATURE ON 04-AUG-2015, ARTICLE ENTITLED "HYSTEROSCOPIC TREATMENT OF HYDROSALPINX PRIOR TO IN VITRO FERTILIZATION - EMBRYO TRANSFER (IVF - ET)". IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE IN WH

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055549	ESSURE	8/13/2015	8/20/2015

Event Information:

Event Date (B3): 2/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IN 2011 AND AFTER RECEIVING IT. IT CAUSED HEAVY BLEEDING AND SEVERE CRAMPING. IT WAS SO BAD, THAT ON (B)(6) OF THIS YEAR. I RECEIVED AN HYSTERECTOMY. THERE WAS NOTHING ELSE THEY COULD DO FOR ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055550	BAYER	8/13/2015	8/20/2015

Event Information:

Event Date (B3): 2/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/5/2009
Explant Date (E7): 6/11/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PERMANENT BIRTH CONTROL IMPLANTED IN 2008. IN THE (B)(4) OF 2014, I BEGAN HAVING ALLERGIC REACTIONS TO A SEALANT USED ON MY EYELASH EXTENSIONS (PTFE) WHICH REQUIRED PREDNISONE TO CLEAR UP DUE TO MY EYES SWELLING SHUT. I ALSO STARTED HAVING QUITE A LOT OF BLEEDING BETWEEN MY PERIODS AT THIS TIME. THE PROBLEM WITH MY EYES CONTINUED INTO THE WINTER OF 2015 WHICH REQUIRED A REFERRAL TO AN ALLERGIST ALONG WITH ALLERGY TESTING. THE TESTING SHOWED ALLERGIES TO GOLD, NICKEL AND EYE SHADOWS THAT I HAVE USED FOR YEARS. THESE OVERSHADOWS ALL CONTAINED PTFE. MY BLEEDING GOT WORSE AND WORSE AND I EVENTUALLY HAD TO HAVE A HYSTERECTOMY. I FOUND OUT AT THAT TIME THAT THE COILS USED IN THE ESSURE IMPLANTS ARE COATED IN PTFE. I BELIEVE MY MEDICAL ISSUES WERE CAUSED BY THE ESSURE IMPLANTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055551	CONCEPTUS INCORPORATED	8/13/2015	8/20/2015

Event Information:

Event Date (B3): 8/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 962097

Single Use: *
Implant Date (E6): 8/13/2012
Explant Date (E7): 1/6/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE IMPLANTS WERE IMPLANTED IN (B)(6) 2011 AND BLEEDING ENSUED FOR OVER 90 DAYS THEN SEVERE CRAMPING HEADACHES, LOWER BACK PAIN AND THE PROCEDURE DID NOT TAKE ON THE SIDE. IN THE 2 YRS LEADING UP TO MY HYSTERECTOMY, I BLEED FOR MONTHS AT A TIME, COULD NOT HAVE INTERCOURSE, AND WAS MOSTLY IN BED FOR THE TIME UNTIL I HAD THE REMOVAL. THAT SIDE IT HAD FLOATED INTO MY UTERUS AND WAS CONNECTING TO MY WALL CAUSING MORE BLEEDING. AS I HAD PROCEDURE DONE ON A MILITARY INSTALLATION. I HAD TO WAIT MONTHS FOR THEM TO CLEAR IT THROUGH THE RED TAPE. I HAD TO PCS (MOVE/TRANSITION) TO ANOTHER PLACE AND ENDED UP HAVING A PARTIAL HYSTERECTOMY DUE TO THIS PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055606	CONCEPTUS INCORPORATED USA	8/13/2015	8/20/2015

Event Information:

Event Date (B3): 8/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 962097

Single Use: *
Implant Date (E6): 8/13/2012
Explant Date (E7): 1/6/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE IMPLANTS WERE IMPLANTED IN (B)(6) 2012 AND BLEEDING ENSUED FOR OVER 90 DAYS THEN SEVERE CRAMPING, HEADACHES, LOWER BACK PAIN AND THE PROCEDURE DID NOT TAKE ON ONE SIDE. IN THE 2 YEARS LEADING UP TO MY HYSTERECTOMY I BLED FOR MONTHS AT A TIME, COULD NOT HAVE INTERCOURSE, AND WAS MOSTLY IN BED FOR THE TIME UNTIL I HAD THE REMOVAL. THAT SIDE IT HAD FLOATED INTO MY UTERUS AND WAS CONNECTING TO MY WALL CAUSING MORE BLEEDING. AS I HAD PROCEDURE DONE ON A MILITARY INSTALLATION. I HAD TO WAIT MONTHS FOR THEM TO CLEAR IT THROUGH THE RED TAPE. I HAD TO PCS (MOVE/TRANSITION) TO ANOTHER PLACE AND ENDED UP HAVING A PARTIAL HYSTERECTOMY DUE TO THIS PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055609	BAYER	8/13/2015	8/20/2015

Event Information:

Event Date (B3): 8/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/22/2009
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE HAS CAUSED MANY DIFFERENT COMPLICATIONS IN MY LIFE. MY MENSTRUAL CYCLE HAS WENT FROM 2-3 DAYS TO 2 WEEKS, WITH BIG BLOOD CLOTS, SEVERE BACK PAIN, INCREASED MIGRAINES AND PAINFUL SEXUAL INTERCOURSE. I WANT TO HAVE THIS REMOVED AS A SIMPLE TAMPON EVEN HURTS. I WISH MY DOCTOR WAS ABLE TO ADVISE HOW MUCH PAIN I WOULD BE IN BECAUSE I WAS ADVISED THAT IT WOULD GO AWAY IN A FEW MONTHS, WELL IT HAS BEEN ALMOST 6 YEARS AND THINGS ARE WORSE. PLEASE TAKE THIS PRODUCT OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055603	BAYER	8/14/2015	8/20/2015

Event Information:

Event Date (B3): 7/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED 3 YEARS AGO AND 6 MONTHS LATER I STARTED HAVING BLEEDING THAT NEEDED MEDICATION TO STOP. STABBING PAIN ON LEFT SIDE AND PAIN ON MY JOINTS. MIGRAINES AND TIREDNESS, SWELLING OF ABDOMEN AND WEIGHT GAIN. DEPRESSION. I HAD TO HAVE MY FALLOPIAN TUBES ALONG WITH THE ESSURE IMPLANTS REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055585	BAYER	8/15/2015	8/20/2015

Event Information:

Event Date (B3): 12/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2009 I HAD ESSURE PUT IN BUT WHILE LATER I WAS HURTING REAL BAD IN MY UTERUS, STILL AM TO THIS DAY. I WAS IN THE HOSPITAL TWICE, HAVE HORRIBLE BACK PAIN AND HAVE LOST SOME OF MY HAIR AND IT HAS GONE THIN WITH TERRIBLE MIGRAINES THAT I AM ON 2 DIFFERENT MEDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055604		8/15/2015	8/20/2015

Event Information:

Event Date (B3): 8/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/4/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6). I AM A MOTHER OF TWO ONLY (B)(6). I HAVE HAD THE ESSURE COILS FIVE WEEKS AFTER HAVING MY SON WHO JUST TURNED TWO AT THE END OF (B)(6). FOR THE LAST YEAR AND A HALF TO YEAR I HAVE HAD SO MANY COMPLICATIONS STARTING WITH BV, HORRIBLE PERIODS, TO NOW I'M ON BLOOD THINNERS XARELTO 36 MG A DAY FOR A BLOOD CLOT IN MY LEFT OVARIAN VEIN THAT GOES TO MY HEART AND LUNGS. I WAS HOSPITALIZED FOR ALMOST A WEEK AND WAS GETTING TRIPLE DOSES OF BLOOD THINNER SHOTS IN MY BELLY. I NOW HAVE HAD TO BY PERSONAL INSURANCE TO MAKE SURE I DON'T WHITTLE AWAY. THE DOCTORS HAVE DONE MULTIPLE CT SCANS, DOPPLER ULTRASOUNDS, AND INTERNAL ULTRASOUNDS THEY FOUND A DARK SPOT IN LIVER LAST WEEK (B)(6) 2015 THAT CAME BACK NEGATIVE BUT NOW HAVE FORMED TWO NEW CYST THAT ARE FILLING UP IN MY RIGHT OVARY. ALL THEY DO FOR ME IS GIVE ME A SCRIPT FOR PAIN PILLS EVERY OTHER WEEK. LET'S NOT TALK ABOUT HOW OLD AND WORN OUT I AM FOR BEING (B)(6). I WOULD DO ANYTHING TO JUST BE (B)(6) MOTHER AGAIN. I CAN'T EVEN ENJOY ACTIVITIES OUTSIDE WITH MY CHILDREN FOR TOO LONG BECAUSE THE THINNERS MAKE ME SO WEAK. ALL THE COMPLICATIONS HAVE EVEN ALMOST CAUSED ME TO LOSE MY JOB. WHICH WE ALL KNOW THAT IS HOW I SUPPORT MY FAMILY. PLEASE HELP US GET THIS WORD OUT BECAUSE DOCTORS ARE LOOKING RIGHT PASSED THE ACTUAL PROBLEM. I HAVE ENTIRE FOLDER FILLED WITH ALL MY TEST DONE SINCE 2013-2014-2015.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00604	BAYER HEALTHCARE LLC	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/11/2010
Explant Date (E7): 5/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW5043069) IN (B)(6). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT WITHIN 12 HOURS OF RECEIVING ESSURE, SHE BROKE OUT IN HIVES AND RASH THAT CONTINUED TO WORSEN OVER 2 WEEKS. SHE TRIED CREAMS AND OTHER MEDICATIONS TO RELIEVE AND ELIMINATE THE RASH AND NOTHING WORKED. THE DOCTOR WHO DID THE PROCEDURE SAID THAT A REMOVAL OF ESSURE COULD BE TRIED, BUT IF HE WAS NOT ABLE TO REMOVE THEM, SHE WOULD HAVE A HYSTERECTOMY. HOWEVER, ON (B)(6) 2010 PHYSICIAN WAS ABLE TO REMOVE THE COILS AND WITHIN 12 HOURS OF HAVING THEM OUT, CONSUMER'S RASH WENT AWAY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON (B)(6) 2015: (B)(4) FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 05-AUG-2015 NO NEW CLINICAL INFORMATION PROVIDED.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RASH, WHICH RECOVERED AFTER INSERTS REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, CONSUMER STATED HER RASH APPEARED 12 HOURS AFTER ESSURE INSERTION AND RESOLVED WITH DEVICES REMOVAL (INTERVENTION PERFORMED APPROXIMATELY 3 WEEKS AFTER ESSURE PLACEMENT). CONSIDERING THIS POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENT HIVES WAS REPORTED. SINCE ESSURE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION (CONSUMER GENERAL QUESTIONNAIRE) RECEIVED ON 21-OCT-2015: THE CONSUMER WAS (B)(6) AT TIME OF THE ESSURE PROCEDURE. SHE HAD NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES, SHE HAD NO CONCURRENT CONDITIONS. SHE HAD A MISCARRIAGE 2 MO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00605	BAYER HEALTHCARE LLC	8/17/2015	8/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2007
Explant Date (E7): 5/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. SERIOUS INJURY. REQUIRED INTERVENTION AND MALFUNCTION THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW5043072) IN UNITED STATES ON 20-JUL-2015. SHE HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007 FOR PERMANENT BIRTH CONTROL. THE CONSUMER STATED THAT BEFORE ESSURE SHE NEVER HAD PROBLEMS WITH MONTHLY PERIODS. AFTER GETTING ESSURE, SHE WAS NEVER THE SAME. SHE HAD A PERIOD EVERY 2 WEEKS AND THEY WERE SO HEAVY THAT SHE WOULD GET LIGHTHEADED AT TIMES. SHE ALSO HAD AT LEAST ONCE A YEAR EXTREME PAIN IN HER LOWER ABDOMEN THAT SHE WENT TO THE EMERGENCY ROOM. THERE WAS NEVER A REASON. ON (B)(6) 2015 ESSURE WAS REMOVED AND A COMPLETE HYSTERECTOMY WAS DONE (FALLOPIAN TUBES AND UTERUS WERE REMOVED). ONLY A TINY PORTION OF THE DEVICE WAS FOUND AND WAS STILL IN HER. IN SOMETIME BETWEEN 2007-2015 ESSURE BROKE AND WERE EXPELLED FROM HER BODY WITHOUT HER KNOWING. PTC INVESTIGATION RESULT WAS RECEIVED ON 24-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH

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INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY AND A REPORTED PRODUCT QUALITY ISSUE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME PAIN IN HER LOWER ABDOMEN. SHE WAS SUBMITTED TO A HYSTERECTOMY. DURING THIS SURGERY ONLY A TINY PORTION OF ESSURE WAS FOUND; SHE STATED BETWEEN 2007-2015 ESSURE BROKE AND WAS EXPELLED FROM HER BODY WITHOUT HER KNOWING. DEVICE BREAKAGE IS LISTED ACCORDING TO TECHNICAL ANALYSIS. ALSO, THE OTHER EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER STATED HER SYMPTOMS STARTED AFTER ESSURE INSERTION. ADDITIONALLY, ACCORDING TO HER ESSURE BROKE AND WAS EXPELLED. THIS COULD HAVE BEEN A CONTRIBUTORY ROLE IN CONSUMER'S PAIN. ALTHOUGH THE EXACT MECHANISM OF THE EVENTS IS UNKNOWN, CONSIDERING THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE AN INTERVENTION (HYSTERECTOMY) WAS REQUIRED FOR DEVICES REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP ON 29-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT : THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00606	BAYER HEALTHCARE LLC	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 4/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/15/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW5043136) IN UNITED STATES ON 20-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2011. THE CONSUMER REPORTED THAT FROM THE START SHE KNEW SOMETHING WAS WRONG. SHE HAD BEEN AT THE HOSPITAL AND TO HER FAMILY PHYSICIAN SEVERAL TIMES DUE TO PAIN, SWELLING AND HEAVY BLEEDING. SHE STATED SHE LIVES IN PAIN EVERY DAY. SHE WANTED TO HAVE ESSURE REMOVED BUT NO ONE WAS WILLING TO DO IT. THE PHYSICIAN SAID HE DID NOTHING WRONG. SHE HAS TALKED TO SEVERAL LAWYERS BUT NONE WOULD HELP SAYING IT'S A CONFLICT OF INTEREST BECAUSE THEIR WIVES USE. SHE STATED SHE LOST SEVERAL JOBS BECAUSE OF TAKING TIME OFF FROM WORK DUE TO PAIN. DISABILITY OR PERMANENT DAMAGE WAS MENTIONED IN FDA FORM BUT NOT ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 24-JUL-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED

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STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT . IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 03-AUG-2015, NO NEW CLINICAL INFORMATION PROVIDED. FOLLOW UP 05-AUG-2015: PTC INVESTIGATION RESULTS WERE RE-OPENED (B)(4)) WITHOUT MAJOR CHANGES. NO NEW INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BEEN AT THE HOSPITAL SEVERAL TIMES DUE TO PAIN AND HEAVY BLEEDING. THE REPORTED EVENTS, REGARDED AS PELVIC PAIN AND GENITAL BLEEDING, ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS PARTICULAR CASE, THE CONSUMER RELATED THE EVENTS TO ESSURE INSERTION. ADDITIONALLY, SHE REPORTED DAILY PAIN, WITH NEED OF MEDICAL INTERVENTION (SHE WENT TO THE HOSPITAL SEVERAL TIMES) AND IMPAIRMENT OF HER REGULAR ACTIVITIES (SHE STATED SHE LOST JOBS DUE TO PAIN). CONSIDERING THE ABOVE MENTION INFORMATION AND IN THE LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE DISABILITY AND HOSPITALIZATION REPORTED; THIS CASE WAS CONSIDERED AN INCIDENT. IN ADDITION THE NON-SERIOUS EVENT SWELLING WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00607	BAYER HEALTHCARE LLC	8/17/2015	8/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26966

Single Use: Y
Implant Date (E6): 7/20/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C26966 FOR CONTRACEPTION. SHE WAS NOT PREGNANT. IT WAS REPORTED THAT ONE ESSURE COIL WENT IN FINE. THE OTHER COIL ON OTHER SIDE AS IT WAS RELEASING PART OF RELEASE DEVICE GOT BROKEN OFF INTO COIL. WHEN HCP WENT TO PULL OUT WITH GRASPERS, IT PULLED OUT THE INNER COILS WITH FILAMENTS ON IT AND THEN WAS PULLING ESSURE OUT SO HCP STOPPED REMOVING COIL AND IT IS STILL IN PATIENT. SHE IS DECIDING IF SHE WILL DO SURGERY. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 FROM PHYSICIAN: PATIENT DATA WAS UPDATED. SHE WAS (B)(6) YEARS OLD. PHYSICIAN HAD A RESIDENT PRESENT FOR TRAINING AND IT WAS THE RESIDENT WHO PERFORMED ESSURE PROCEDURE UNDER DOCTOR'S SUPERVISION. THE RESIDENT PULLED BACK ON ESSURE RELEASE PREMATURELY. THE DOCTOR THINKS THIS MIGHT POSSIBLY BE RELATED TO THE INNER COIL GETTING STUCK ON THE RELEASE CATHETER. THE RESIDENT INADVERTENTLY PULLED OUT INNER COIL. THE DOCTOR DID GO AHEAD AND PERFORM STERILIZATION VIA SURGERY ON PATIENT. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: PHYSICIAN REPORTED THE MICRO INSERT DEPLOYED AND WHEN RETRIEVAL WAS DONE THE INNER COIL CAME BACK PARTIALLY WITH A BROKEN OFF PIECE OF THE RELEASE CATHETER. BILATERAL PLACEMENT OF ESSURE WAS NOT ACHIEVED. THE PATIENT HAD NO INJURIES. PTC INVESTIGATION RESULT RECEIVED ON (B)(6) 2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS

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TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE A PART OF RELEASE DEVICE GOT BROKEN OFF INTO COIL. THE PROCEDURE WAS STOPPED AND PHYSICIAN PERFORMED STERILIZATION VIA SURGERY (REGARDED AS AN ALTERNATIVE CONTRACEPTIVE MEASURE DUE TO UNSUCCESSFUL ESSURE INSERTION). THE REPORTED EVENT WAS CONSIDERED NON-SERIOUS AND IS LISTED ACCORDING TO TECHNICAL INVESTIGATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, ESSURE INSERTION WAS PERFORMED BY A RESIDENT IN TRAINING. THE PROCEDURE WAS DIFFICULT AND ESSURE WAS RELEASED PREMATURELY. THIS MAY HAVE CONTRIBUTED TO THE REPORTED DEVICE BREAKAGE, AND AS THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION; THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP ON 29-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT : THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00608	BAYER HEALTHCARE LLC	8/17/2015	8/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 20-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED THAT ESSURE BROKE INSIDE OF HER AND SHE BECAME PREGNANT (DEVICE INEFFECTIVE) AND MISCARRIED. SHE WANTS TO REMOVE ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON 03-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE AND A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH

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SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATED THAT ESSURE BROKE INSIDE OF HER AND SHE BECAME PREGNANT AND MISCARRIED. PREGNANCY AND MISCARRIAGE ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE DEVICE BREAKAGE IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. THEREFORE A CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED PREGNANCY CANNOT BE EXCLUDED. REGARDING MISCARRIAGE (SPONTANEOUS ABORTION), IT IS THE MOST COMMON COMPLICATION OF EARLY HUMAN PREGNANCY, OCCURRING MAINLY DURING THE FIRST TRIMESTER OF PREGNANCY. THIS IS CONSIDERED TO BE DUE TO A HIGH NUMBER OF ABNORMAL EMBRYOS PRESENTING WITH EITHER CHROMOSOMAL AND/OR GROSS MORPHOLOGICAL ABNORMALITIES. CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. ALTHOUGH IT WAS NOT REPORTED WHEN DEVICE BREAKAGE OCCURRED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00609	BAYER HEALTHCARE LLC	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 6/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C35383

Single Use: Y
Implant Date (E6): 3/13/2015
Explant Date (E7): 8/17/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 20-JUL-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT STERILIZATION. ON (B)(6) 2015, SHE HAD A MODIFIED HSG (HYSTEROSALPINGOGRAM) WHICH REVEALED A BROKEN/FRACTURED COIL IN THE RIGHT FALLOPIAN TUBE. PATIENT WAS HAVING PELVIC DISCOMFORT THAT WAS BEING TREATED WITH MOTRIN. SHE IS SCHEDULED FOR ESSURE REMOVAL ON (B)(6) 2015. FOLLOW-UP INFORMATION RECEIVED ON 22-JUL-2015 PHYSICIAN SAID THAT THREE MONTH TEST SHOWED MICRO-INSERT WAS FRACTURED. PATIENT IS SCHEDULED FOR SURGICAL (LAPROSCOPIC) REMOVAL OF FRACTURED MICRO-INSERT ON (B)(6) 2015. PATIENT IS STILL HAVING PAIN. FOLLOW-UP RECEIVED ON 03-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. NEITHER BATCH

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NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD A MODIFIED HSG (HYSTEROSALPINGOGRAM) WHICH REVEALED A BROKEN COIL IN THE RIGHT FALLOPIAN TUBE - COIL WAS FRACTURED. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND LISTED ACCORDING TO PTC RESULTS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DEVICE BREAKAGE WAS DIAGNOSED ABOUT 3 MONTHS AFTER ESSURE INSERTION. A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ESSURE REMOVAL WILL BE PERFORMED. ADDITIONALLY, NON-SERIOUS EVENT PELVIC DISCOMFORT WAS REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-AUG-2015 FROM PHYSICIAN - QUESTIONNAIRE RECEIVED: THIS CASE WAS UPGRADED TO INCIDENT. THE PATIENT'S CONCURRENT CONDITIONS INCLUDED NORMAL WEIGHT (B)(6). THERE WAS NO DEVIATION FROM THE INSERTION PROCEDURE. THE DOCTOR W

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00610	BAYER HEALTHCARE LLC	8/17/2015	8/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE PATIENT WAS AWAITING SURGERY FOR REQUESTED ESSURE REMOVAL. THE RIGHT INSERT WAS IN THE TUBE WITH OCCLUSION BUT THE LEFT WAS EXPELLED INTO THE UTERINE CAVITY WITH PATENCY. PATIENT WAS ELECTING TO HAVE THE INSERTS REMOVED AND SUBSEQUENT BILATERAL TUBAL LIGATION (BTL). PATIENT WAS EXPERIENCING SOME NAUSEA AND AFTER READING THINGS ON THE INTERNET, ATTRIBUTED HER SYMPTOMS TO ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER

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TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LEFT INSERT WAS EXPELLED INTO THE UTERINE CAVITY. SHE REQUESTED ESSURE REMOVAL, WHICH ACCORDING TO THE PHYSICIAN, WOULD BE PERFORMED ON THE DAY OF THIS REPORT. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT DATE OF THE EVENT WAS UNKNOWN, GIVEN ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENT NAUSEA WAS REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE AN INTERVENTION WILL BE PERFORMED FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP ON 28-OCT-2015: NO FURTHER INFORMATION COULD BE OBTAINED. CASE CLOSED. COMPANY CAUSALITY COMMENT : THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LEFT I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00611	BAYER HEALTHCARE LLC	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 12/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A45106

Single Use: Y
Implant Date (E6): 10/26/2012
Explant Date (E7): 6/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT FEMALE CONSUMER IN UNITED STATES ON 02-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 OR 2012. THE HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED 3 MONTHS LATER AND THE RESULTS WERE FINE. RIGHT AFTER THE PROCEDURE SHE STARTED TO EXPERIENCE REACTIONS DUE TO ESSURE; SHE HAD NO PRIOR HISTORY OF SUCH EVENTS. SHE HAS NOW A REACTION TO EGGS, EXPERIENCING STOMACH PROBLEMS AND REPORTING THAT SHE CANNOT GO TO THE BATHROOM FOR AT LEAST FIVE HOURS AND HAS A LOT OF PAIN. SHE USED TO HAVE REGULAR PERIODS, BUT NOW THEY ARE IRREGULAR, WITH BLEEDING THREE DAYS AND THEN STOPPING AND THEN BLEEDING TWO DAYS AND THEN STOPPING FOR A WEEK; SHE WAS STARTED ON ORAL BIRTH CONTROL PILLS IN THE BEGINNING OF (B)(6) 2014 TO REGULATE HER PERIOD, BUT THEY DID NOT WORK AND WERE DISCONTINUED IN THE LAST WEEK OF (B)(6) 2015. SHE ALSO KEEPS GETTING BUMPS ON HER SINCE THE PROCEDURE AND HER HEALTHCARE PROVIDER THINKS THAT SHE MAY HAVE A NICKEL ALLERGY; SHE REPORTED THAT SHE WAS NEVER TOLD THAT THE COILS CONTAINED NICKEL. SHE FEELS SICK ALL THE TIME, HAS SHARP PAINS/CONSTANT PAIN AND FEELS LIKE SOMEONE IS STABBING HER IN THE STOMACH WHEN SHE MOVES, TWISTS OR STRETCHES. ACCORDING TO HER, THE PHYSICIAN WHO DID THE PROCEDURE DOES NOT THINK THAT HER EVENS ARE RELATED TO ESSURE, BUT HER PRIMARY PHYSICIAN BELIEVES THAT THIS IS POSSIBLE SINCE HER SYMPTOMS STARTED SOON AFTER INSERTION. REGARDING ONLY THE PAIN, BOTH PHYSICIANS ARE UNSURE ABOUT THE CAUSE. SHE ASKED HER INSERTING PHYSICIAN FOR AN X-RAY TO CHECK IF THE INSERTS HAVE MOVED, BUT HE PERFORMED A CLINICAL EXAM INSTEAD AND REPORTED THAT SHE COULD CHECK IT VIA PAP SMEAR. SHE WANTS TO HAVE HER DEVICES REMOVED, BUT SHE COULD NOT FIND A DOCTOR WHO WOULD CHECK THE LOCATION OF COILS AND REMOVE THEM. PTC INVESTIGATION RESULT WAS RECEIVED ON 18-FEB-

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2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 10-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. FOLLOW-UP RECEIVED ON 24-JUN-2015: INFORMATION RECEIVED FROM NURSE STATES THAT A NON-PREGNANT PATIENT WHO HAD ESSURE INSERTED ON (B)(6) 2012 FOR PERMANENT STERILIZATION, DEVELOPED A NICKEL ALLERGY AND WILL HAVE SURGERY ON (B)(6) 2015 TO REMOVE ESSURE MICRO-INSERTS. REPORTER SAID PATIENT STARTED TO COMPLAIN OF ALLERGY SYMPTOMS ON (B)(6) 2014 AND, ON (B)(6) 2015, NICKEL ALLERGY WAS CONFIRMED. FOLLOW UP 02-JUL-2015: DUPLICATE PTC RESULTS WERE PROVIDED WITHOUT CHANGES. NO NEW INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 21-JUL-2015 FROM THE CONSUMER: CONSUMER DATA WAS UPDATED. SHE WAS (B)(6) AT THE TIME OF ESSURE INSERTION. ESSURE WAS INSERTED ON (B)(6) 2013. SHE HAD A BAD NICKEL ALLERGY THAT WAS MAKING HER SICK AND FELT LIKE ESSURE WAS CONSTANTLY STICKING HER. SHE DEVELOPED AN EGG ALLERGY SOON AFTER ESSURE INSERTED. SHE WAS EATING THINGS WITH EGG AND SHE BECAME SO SICK, VOMITING AND COULD NOT GO TO THE BATHROOM FOR ABOUT 4 TO 5 HOURS. SHE DEVELOPED A RASH ALL OVER WITHIN 6 WEEKS OF ESSURE BEING INSERTED. THE RASH WOULD COME AND GO. THEY COULD NOT FIGURE IT OUT SO NURSE TOLD HER TO GO TO STORE AND BUY JEWELRY WITH NICKEL IN IT AND SHE BROKE OUT FROM IT. THE BUTTON ON HER PANTS EVEN LEFT A MARK ON HER SKIN UNDER THE BUTTON. IT HAD NICKEL IN IT. SHE SAW ANOTHER DOCTOR AND HE SAID THE RASH WAS STAPH BUT DID NOT DO A CULTURE. DOCTOR WHO INSERTED THE ESSURE SAID IT HAD TO BE REMOVED DUE TO NICKEL. SHE RECEIVED ANTIBIOTICS AS TREATMENT. ESSURE COILS AND TUBES WERE REMOVED LAPAROSCOPICALLY ON (B)(6) 2015. THE RASH WAS ALMOST GONE AND NOW SHE CAN EAT EGGS; HER BODY FEELS FINE NOW. CASE UPGRADED TO INCIDENT. FOLLOW UP INFORMATION (GENERAL QUESTIONNAIRE) RECEIVED ON 28-JUL-2015 FROM HEALTH CARE PROVIDER: THE PHYSICIAN CONFIRMED ALL EVENT AND DETAILS PREVIOUSLY REPORTED. THE PATIENT MEDICAL HISTORY INCLUDE ALLERGIES TO SULFA AND ERYTHROMYCIN. SHE HAS NO PREVIOUS GYNECOLOGICAL PROBLEM OR PROCEDURES. ESSURE LOT NUMBER WAS A45106 (EXPIRATION DATE 31-AUG-2015). PATIENT WAS NOT POSTPARTUM AT TIME OF ESSURE INSERTION. DURING THE PROCEDURE, CERVICAL DILATION WAS DONE (17 FRENCH DILATOR PASSES EASILY), AND SOUNDING SHOWED 8CM OF LENGTH. NO GENERAL ANESTHESIA WAS APPLIED; IT WAS USED VALIUM AND HYDROCODONE. THE PROCEDURE WAS CONSIDERED EASY BY PHYSICIAN, WITH EASY VISUALIZATION OF BOTH OSTIA. DURING THE HYSTEROSCOPY, THERE WAS MORE THAN 1500CC OF FLUID LOSS. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. THE PATIENT USED ORTHOTRICYCLEN AS BACK UP CONTRACEPTION. ON (B)(6) 2013 (DISCREPANT INFORMATION REPORTED), THE HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED THE TUBES OCCLUDED AND CORRECT PLACEMENT. ON (B)(6) 2015, A (B)(6) WAS DONE AND HAD NEGATIVE RESULT. ON (B)(6) 2015, AN X-RAY WAS DONE AND SHOWED THE DEVICES IN PLACE. ON THE SAME DAY AN EKG (ELECTROCARDIOGRAM) WAS ALSO PERFORMED FOR CHEST PAIN AND RIGHT ARM PAIN. PATIENT ALSO

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EXPERIENCED SHOULDER PAIN. THE PHYSICIAN REPORTED THAT OTC (UNDERSTOOD AS ORTHOTRICYCLEN) WAS USED AS TREATMENT TO REGULATE MENSTRUAL CYCLE. HOSPITALIZATION WAS NOT REQUIRED. ON (B)(6) 2015, THE DEVICES WERE REMOVED LAPAROSCOPICALLY, BILATERAL SALPINGECTOMY WAS NECESSARY; THE PROCEDURE WAS CONSIDERED MEDICALLY NECESSARY AND WAS ALSO PERFORMED DUE TO PATIENT'S REQUEST. DURING THE HYSTEROSCOPY NORMAL FINDINGS WERE OBSERVED. DURING SURGERY THE COILS WERE IN PROPER POSITION. THE PATHOLOGY SHOWED NO SIGNS OF INFECTION. THE PHYSICIAN STATED THE PATIENT'S CONDITION WAS DUE TO NICKEL ALLERGY CAUSED BY ESSURE. HE MENTIONED THE PATIENT WAS DOING MUCH BETTER SINCE REMOVAL OF DEVICES AND THE NICKEL ALLERGY SEEMED TO BE GONE; HER SYMPTOMS RESOLVED AFTER SURGERY. PTC INVESTIGATION RESULT RECEIVED ON 05-AUG-2015. PTC GLOBAL NUMBER (B)(4) LOT NUMBER A45106 (PRODUCTION DATE AUG-2012; EXPIRATION DATE 31-AUG-2015). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 06-AUG-2015: INFORMATION RECEIVED STATES THAT PATIENT HAD ESSURE, LOT NUMBER A45106 AND EXPIRATION DATE 31-AUG-2015, INSERTED ON (B)(6) . COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED NICKEL ALLERGY. THE ESSURE INSERTS AND HER FALLOPIAN TUBES WERE REMOVED BY LAPAROSCOPY. SHE RECOVERED AFTER THIS PROCEDURE. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, 6 WEEKS AFTER ESSURE PLACEMENT, THE PATIENT DEVELOPED A RASH. SHE ALSO HAD PAIN AND EGG INTOLERANCE. PHYSICIAN BELIEVED HER ISSUES WERE DUE TO A NICKEL ALLERGY CAUSED BY THE ESSURE DEVICES. CONSIDERING THIS INFORMATION, THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION FOR ESSURE REMOVAL WAS REPORTED UPON FOLLOW-UP. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055403	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING EXTREMELY HORRIBLE PERIODS, HIGH CHOLESTEROL, EXTREME BLOATING TO WHERE I LOOK PREGNANT, HIVES AND HAIR LOSS TO NAME A FEW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055404	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 6/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABNORMAL HEAVY BLEEDING REQUIRING EMERGENCY ROOM VISIT, DAYS OFF WORK AND ABLATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055405	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 7/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS IS ACTUALLY THE 4TH TIME IT HAS OCCURED SINCE ESSURE. SEVERE ABDOMINAL PAINS. LOOSING CONSCIOUS BLOOD PRESSURE DROPPED DRASTICALLY. VERTIGO IS UNBEARABLE. TESTOSTERONE DROPPED TO 29 LEVEL. MY THYROID IS HYPO ACTIVE NOW SEVERE CRAMPS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055406	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 10/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, BACK PAIN, PELVIC PAIN, SHOULDER PAIN, FATIGUE, WEIGHT GAIN, PAINFUL OVULATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055407	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE REALLY BAD MIGRAINES, PAIN IN MY LEFT SIDE BECOMES WORSE WITH MY PERIOD. NUMBNESS IN LEFT FINGERS. EXCESSIVE WEIGHT GAIN. PAIN IN HIP 1 WEEK BEFORE PERIOD THAT LASTS UNTIL MY PERIOD ENDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055408	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 6/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A HYSTERECTOMY ON (B)(6) 2015. I IMMEDIATELY WOKE UP FROM ANESTHESIA FEELING AMAZING. THE SWELLING IN MY BODY HAS GONE DOWN TREMENDOUSLY. I HAVE HAD 2 MIGRAINES SINCE SURGERY VS THE 4 TO 5 MIGRAINES A WEEK WHILE I HAD ESSURE IN MY BODY. MY STOMACH IS CONSIDERABLY FLATTER. MY EMOTIONS ARE NO LONGER DRAMATIC. WHILE MY HAIR IS STILL FALLING OUT, IT IS STARTING TO SLOW DOWN. I NO LONGER HAVE HORRIBLE BODY ACNE AND THE MYSTERIOUS BUMPS THAT HAVE POPPED UP SINCE ESSURE WAS IMPLANTED ARE NEARLY COMPLETELY GONE. I DO NOT NEED TO CHECK MY BLOOD SUGAR MORE THAN 2-3 TIMES A WEEK SINCE MY HYSTERECTOMY. I CAN SAY I FEEL NOTHING SHORT OF AMAZING SINCE MY HYSTERECTOMY!! THE PAIN OF SURGERY RECOVERY WAS SURPRISINGLY EASY AND PALES IN COMPARISON TO THE PAIN I ENDURED EVERY SINGLE DAY SINCE I HAD ESSURE IMPLANTED IN 2011.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055409	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 4/2/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, CRAMPING, HEADACHES, BLOATING, WEIGHT GAIN, BLACK OUTS, JOINT PAIN, BACK PAIN, HIP PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055410	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 4/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MASSIVE MIGRAINE, SWOLLEN STOMACH, LEG CRAMPS, HIP CRAMPS, VERY PAINFUL CRAMPS, LOWER BACK PAIN, LOW SEX DRIVE, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055411	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 3/27/2013	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M CONSTANTLY SICK, MASSIVE HEADACHES, MASSIVE CRAMPING DURING MENSTRATION THAT I NEVER HAD BEFORE, MASSIVE BLOOD CLOTS ABOUT THE SIZE OF A QUARTER, 3 PREGNANCIES THAT RESULTED IN MISCARRIAGES, PAIN IN MY ABDOMEN THAT I WAS TOLD WOULD GO AWAY BUT NEVER HAS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055412	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 8/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, HEAVY MENSTRUAL CYCLE, FATIGUE, DEPRESSION, WEIGHT GAIN, ABDOMINAL CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055413	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M ALLERGIC TO NICKEL WHICH I WAS NOT TOLD WAS IN THE DEVICE. IN 2 YEARS I HAVE SEEN 4 DOCTORS FOR HEADACHES, EXTREME FATIGUE, HIVES,CONSTANT PELVIC PAIN, MOSTLY DULL SOMETIMES SHARP. RASH LIKE BUMPS ON LOWER BACK, BLOATING, WEIGHT GAIN, JOINT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055414	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWO YEARS AFTER PLACEMENT I STARTED HAVING EXTREME MENSTRUAL BLEEDING LASTING WEEKS OUT OF NOWHERE. THIS WENT ON FOR SEVERAL MONTHS BEFORE I WAS TOLD TO GET NOVASURE ABLATION. HOWEVER I GOT THIS DONE IN (B)(6) 2012 AND HAVE HAD LOTS OF RANDOM PAINS IN ABDOMINAL AREA, I WOULD BLEED AFTER SEX, MY FIBRO LIKE PAINS HAVE INCREASED SIGNIFICANTLY, MY STOMACH IS SWOLLEN, AND OVER THE LAST YEAR I HAVE LOST LIBIDO, TIRED ALL THE TIME,INSOMNIA, AND MOOD ISSUES, I ALSO HAVE A CONSTANT CRAWLY SKIN FEELING, AND A SUN ALLERGY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055415	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY SYMPTOMS INCLUDE: FATIGUE, PAIN IN ABDOMEN, NUMBNESS IN TOES, WEIGHT GAIN, IRRITABILITY, MOOD SWINGS, CONSTIPATION, DISCHARGE, PAIN DURING INTERCOURSE, INABILITY TO STAY FOCUSED, HEAVY PERIODS, LOW SEX DRIVE, DYSPLASIA, CRAMPING, PAINFUL OVULATION, FLUTTERING IN ABDOMEN, HEADACHES, DEPRESSION, BLOOD CLOTS, ACNE, BACTERIAL VAGINOSIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055416	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE EXPERIENCED NO MENSTRUAL CYCLE SINCE (B)(6) 2012, SIGNIFICANT WEIGHT GAIN, HAIR LOSS/THINNING, HEADACHES/MIGRAINES, HOT FLASHES, MOOD SWINGS, MY ALLERGIES SEEM TO HAVE GOTTEN WORSE, PAIN IN THE LOWER PELVIC REGION ON BOTH SIDES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055417	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER BACK PAIN, MIGRAINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055418	BAYER	8/17/2015	8/17/2015

Event Information:

Event Date (B3): 7/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING WITH MY MENSTRUAL CYCLE; MORE THAN NORMAL, BLOOD CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055557	BAYER CORP	8/17/2015	8/20/2015

Event Information:

Event Date (B3): 2/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/18/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS DIAGNOSED WITH SINUS THROMBOSIS BACK IN 2004, THAT WITH THE MALPRACTICE OF MY DOCTORS, ALMOST KILLED ME. THE CAUSE OF MY CONDITION WAS (B)(6) BIRTH CONTROL PILLS. I AM THE MOTHER OF FOUR GIRLS AND DURING MY PREGNANCY I HAD TO TAKE FRAGMIN SHOTS. BECAUSE OF THIS I HAVE NOT BEEN ABLE TO USE HORMONAL BIRTH CONTROL. AFTER OUR YOUNGEST WAS BORN, MY HUSBAND AND I DECIDED TO HAVE ESSURE DONE. I HAD TO FIGHT OVER SIX MONTHS FOR THE DOCTORS TO ALLOW THIS PROCEDURE FOR ME (DUE TO YOUNG AGE I PRESUME). AFTER I WAS IMPLANTED WITH THE ESSURE DEVICE, I FELT OK FOR ABOUT 6 MONTHS, I HAD SOME MINOR PAINS BUT I JUST THOUGHT THEY WERE NORMAL REACTION TO HAVING THE COILS PUT IN. BUT NOW THAT THE PAIN HAS INCREASED I HAVE BEEN LEFT WONDERING. AT THIS MOMENT, I HAVE BEEN SUFFERING FROM TREMENDOUS AMOUNT OF STOMACH PAINS WITH SOME MENSTRUAL FLOW ABNORMALITIES. I HAVE HAD TO MISS WORK SEVERAL TIMES DUE TO THESE PAINS. THE DOCTORS HAVE EXAMINED ME, EVERYTHING SEEMS TO BE OK, AND THEY SAY IT'S NOT CAUSED BY ESSURE. I FEEL LIKE I HAVE BEEN LABELED 'CRAZY'. TO ADD INSULT TO MY INJURY, MY DOCTORS ARE REALLY PUSHING ME TO HAVE A (B)(6) WITH MY ESSURE. I REFUSE TO HAVE IT, ENOUGH IS ENOUGH! OTC MEDS: BURANA, PANADOL, LITALGIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055560	BAYER	8/17/2015	8/20/2015

Event Information:

Event Date (B3): 8/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE DONE ESSURE PROCEDURE IN 2013 AND SINCE THEN I HAVE SO MANY HEALTH PROBLEMS. I'M GOING FOR HYSTERECTOMY NOW SINCE I'M IN PAIN EVER SINCE I DID ESSURE. PLEASE STOP THIS COMPANY FROM HARMING CUSTOMERS. MY LIFE IS A DISASTER SINCE I DID THIS PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055561	CONCEPTUS	8/17/2015	8/20/2015

Event Information:

Event Date (B3): 6/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/21/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE IMPLANTED IN (B)(6) 2011 I HAVE HAD SEVERAL PROBLEMS INCLUDING WEIGHT GAIN, FATIGUE, DEPRESSION, ITCHING, SEVERE STOMACH PAIN, SWELLING, HAIR LOSS, GASTROINTESTINAL PROBLEMS. I HAVE ASKED THE DOCTOR TO REMOVE IT AND SHE WILL NOT SO I AM WAITING FOR A SECOND OPINION MEANWHILE I AM SUFFERING EVERYDAY. I WISH I KNEW THIS BEFORE GETTING IT DONE BECAUSE I WOULD NOT HAVE DONE IT. RX MEDS: ESSURE, PROTONIX, EFFEXOR. OTC MEDS: MULTI VITAMIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00612	BAYER HEALTHCARE LLC	8/18/2015	8/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68800

Single Use: Y
Implant Date (E6): 7/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 9/3/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 21-JUL-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C68800. IT WAS REPORTED THAT ESSURE WAS INSERTED WITH PART OF THE DELIVERY CATHETER STUCK IN THE INSERT. THE EVENT HAPPENED IN THE OPERATING ROOM. THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS PERFORMED. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. FOLLOW-UP RECEIVED ON 03-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C68800; PRODUCTION DATE: 30-JUN-2014; EXPIRATION DATE: 30-JUN-2017. FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 28-JUL-2015,

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, A PART OF THE DELIVERY CATHETER STUCK IN THE INSERT. THE REPORTED EVENT, REGARDED AS BREAKAGE OF ESSURE CATHETER, WAS CONSIDERED NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WILL BE REQUESTED IN ORDER TO CLARIFY THE EVENT. NEVERTHELESS, CONSIDERING IT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

UPDATED PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 14-OCT-2015. SAMPLE RECEIVED ON 03-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE PRODUCT WAS RETURNED TO US FOR THIS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00613	BAYER HEALTHCARE LLC	8/18/2015	8/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26938

Single Use: Y
Implant Date (E6): 9/22/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE WITH LOT NUMBER C26938. IT WAS REPORTED THAT ESSURE INSERT WAS NOT RELEASED INTO FALLOPIAN TUBE, IT BROKE. ANOTHER INSERT WAS USED. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON 03-AUG-2015. (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. AS OF 7/28/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE

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WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS HAVE BEEN REPORTED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 10-AUG-2015: PATIENT'S DEMOGRAPHIC INFORMATION WAS PROVIDED. THE BREAKAGE WAS DIAGNOSED DURING PLACEMENT. THE INSERTION INSTRUCTIONS WERE FOLLOWED. DURING ESSURE INSERTION, DEVICE WAS NOT RELEASED INTO FALLOPIAN TUBE. IT BROKE. ESSURE DEVICE WAS REMOVED DURING INSERTION ATTEMPT ON (B)(6) 2014. ANOTHER DEVICE WAS USED. THE PATIENT HAD NO INJURY. DEVICE WAS AVAILABLE. NO FURTHER INFORMATION WILL BE PROVIDED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN (B)(4). BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE ESSURE INSERT WAS NOT RELEASED INTO FALLOPIAN TUBE, IT BROKE. ANOTHER DEVICE WAS USED. THE REPORTED EVENT WAS CONSIDERED NON-SERIOUS AND IS LISTED ACCORDING TO TECHNICAL INVESTIGATION RESULTS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 01-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ES

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00614	BAYER HEALTHCARE LLC	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/21/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C35242

Single Use: Y
Implant Date (E6): 7/21/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 21-JUL-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. ADDITIONAL INFORMATION RECEIVED ON THE SAME DAY. THE PHYSICIAN PLACED ESSURE INTO THE RIGHT OSTIA WITH NO PROBLEM IN THE OFFICE. WHEN SHE WENT TO PLACE THE LEFT DEVICE, SHE HAD DIFFICULTIES WITH THE DEPLOYMENT AND MANEUVERING THE SCOPE AND DEPLOYING THE DEVICE. SHE LEFT PART OF THE GOLD RING, PART OF THE DELIVERY SYSTEM, THE OUTER COIL, AND PROBABLY THE INNER COIL AND THE PLASTIC COVERING INSIDE THE PATIENT. AN ULTRASOUND DONE IMMEDIATELY AFTER APPEARED IT WAS IN THE CORRECT PLACE. THE PHYSICIAN HAD TO STOP THE PROCEDURE DUE TO THE PATIENT WAS TOO UNCOMFORTABLE. SHE STATED THE PATIENT HAD A MIRENA IN PLACE AT THE TIME OF THE PROCEDURE, AND IT WAS LEFT IN PLACE FOR THE 3 MONTH BIRTH CONTROL USE. FOLLOW-UP INFORMATION RECEIVED FROM THE PHYSICIAN ON 28-JUL-2015: THE PHYSICIAN REPORTED THAT INSERTED ESSURE NORMALLY AND LEFT SIDE TOOK TO BLACK MARKER, ROLL BACK DIDN'T RETRACT PROPERLY AND MOVED THE DEVICE TO WHERE SHE THOUGHT THE GOLD MARKER WAS. OUTER CATHETER ROLLED BACK. TRIED TO SEE IF SHE COULD MOVE IT FURTHER. THEN DEPLOYED AND WHEN SHE SCROLLED BACK SOME RETRACTED BACK BUT NOT ALL, 4 OR 5 RINGS SHOWING, WITH PIECE OF GREEN CATHETER LEFT AND GOLD MARKER AND PIECE OF INSERTER COIL. SHE HAD TO CUT IT OFF TO SEPARATE IT. ULTRASOUND WAS DONE AND ABOUT 1.68CM COIL WAS SEEN. THE PHYSICIAN WOULD LIKE TO KNOW IF THERE WAS AN ISSUE WITH THE PIECES LEFT ATTACHED TO THE COIL. FOLLOW-UP FROM 03-AUG-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN

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POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: ROLLBACK TO INITIAL HARD STOP; DEPRESS BUTTON; PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO DEPLOYMENT DIFFICULTY. SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. IN THIS CASE THE DETACHMENT DIFFICULTY EVENT MAY HAVE CONTRIBUTED TO A CATHETER BREAKAGE EVENT, AS DESCRIBED IN THE COMPLAINT NARRATIVE. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE AND A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PATIENT HAD A MIRENA IN PLACE AT THE TIME OF THE PROCEDURE, AND IT WAS LEFT IN PLACE FOR THE 3 MONTH BIRTH CONTROL USE (CONSIDERED AN OFF LABEL USE OF DEVICE). PHYSICIAN LEFT PART OF THE GOLD RING, PART OF THE DELIVERY SYSTEM, OUTER COIL, PROBABLY THE INNER COIL AND THE PLASTIC COVERING INSIDE THE PATIENT. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, POSSIBLE DEVICE INSERTER CATHETER BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE. A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW UP ON 30-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED.
COMPANY CAUSALITY COMMENT : THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00615	BAYER HEALTHCARE LLC	8/18/2015	8/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006 FOR PERMANENT STERILIZATION. IT WAS REPORTED THAT IN 2010 PATIENT HAD A VAGINAL HYSTERECTOMY. RECENTLY, PATIENT WAS SEEN BY A PHYSICIAN. CT SCAN WAS DONE AND SHOWED ESSURE MICRO-INSERT HAS ERODED INTO RIGHT URETER; APPEARED TO BE AT UV JUNCTION. PATIENT WAS COMPLAINING ABOUT NIGHT SWEATS. THE OUTCOME OF EVENT WAS REPORTED AS ONGOING. INTERNAL CORRECTION ON (B)(6) 2015 BASED ON INFORMATION RECEIVED ON (B)(6) 2015 AFTER INTERNAL REVIEW, ESSURE MODEL 305 WAS CHANGED TO ESSURE MODEL 205 BECAUSE INSERTION OCCURRED IN 2006. FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER

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TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A CT SCAN SHOWED ESSURE MICRO-INSERT HAS ERODED INTO RIGHT URETER; APPEARED TO BE AT UV JUNCTION. THIS EVENT, SEEN AS URETERIC PERFORATION AND DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. INTERNAL ORGANS PERFORATION MAY OCCUR WITH ESSURE, DUE TO DEVICE MIGRATION OR DURING INSERTION PROCEDURE. IN THIS CASE, THE PATIENT HAD A VAGINAL HYSTERECTOMY 4 YEARS AFTER INSERTION AND RECENTLY, A CT SCAN WAS DONE AND SHOWED ESSURE MICRO-INSERT HAS ERODED INTO RIGHT URETER; APPEARED TO BE AT UV JUNCTION. ALTHOUGH THE EXACT DATE AND THE MECHANISM OF PERFORATION IN THE PRESENT CASE ARE NOT KNOWN, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. SINCE A HYSTERECTOMY WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 22-OCT-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00616	BAYER HEALTHCARE LLC	8/18/2015	8/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 748469

Single Use: Y
Implant Date (E6): 11/12/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY FDA MAUDE (#MW5043156) IN UNITED STATES ON 21-JUL-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. CONSUMER REPORTED THAT HAD THE ESSURE PROCEDURE DONE IN 2010 IN HER DOCTOR OFFICE AND A FEW DAYS AFTER THE PROCEDURE, SHE WOUND UP WITH A TERRIBLE VAGINAL INFECTION. HER PERIODS WERE HEAVIER THAN THEY WERE PRIOR TO THE PROCEDURE, LAST 8-10 DAYS ON AVERAGE. SHE HAD CONSTANT PAIN IN HER LEFT OVARY AND HAD TO GO TO THE EMERGENCY ROOM ON SEVERAL OCCASIONS DUE TO THE INTENSITY OF THE PAIN. SHE WAS TOLD THAT THE DEVICE WAS PLACED CORRECTLY AND THE DOCTOR WHO DID THE PROCEDURE WAS TOLD HER THE ONLY WAY TO RECTIFY THE ISSUES WAS WITH A HYSTERECTOMY, AND THE LEFT OVARY WOULD ALSO NEED TO BE REMOVED. SHE HAS HAD NO PRIOR HISTORY OF MIGRAINE HEADACHES UNTIL SHE HAD THIS PROCEDURE. SINCE THE PROCEDURE, SHE HAS HAD MIGRAINE HEADACHES AT LEAST 4-5 PER WEEK. THE DOCTOR STATED THE TWO WERE UNRELATED. FOLLOW-UP RECEIVED ON 03-AUG-2015: NO NEW INFORMATION. PTC INVESTIGATION RESULT RECEIVED ON 05-AUG-2015. PTC GLOBAL NUMBER(B)(4) LOT NUMBER 748469, FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE

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DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HAD TO GO TO THE EMERGENCY ROOM ON SEVERAL OCCASIONS DUE TO CONSTANT PAIN IN HER LEFT OVARY. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION LOWER ABDOMINAL AND PELVIC PAIN MAY OCCUR. IN THIS PARTICULAR CASE, THE CONSUMER RELATED THE EVENT TO ESSURE INSERTION. ADDITIONALLY, SHE DESCRIBED HER PAIN AS CONSTANT, WITH NEED OF MEDICAL INTERVENTION (SHE WENT TO THE ER SEVERAL TIMES). CONSIDERING THE ABOVE MENTIONED INFORMATION AND IN THE LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE REQUIRED MEDICAL INTERVENTION REPORTED; THIS CASE WAS CONSIDERED AN INCIDENT. IN ADDITION THE NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP ON 28-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT : THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (F

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055419	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING, HEADACHE, BLOOD CLOTS, PAIN IN RIGHT OVARY, BLOATED TO THE POINT I LOOK PREGNANT, WEIGHT GAIN AND CAN'T LOSE IT WHATEVER I TRY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055420	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 6/1/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, DIZZINESS, OCCASIONAL SHARP ABDOMINAL PAIN, CAVITIES, NOW BEING TREATED FOR LUPUS. THE BLOATING LOOKS LIKE AN 8TH MONTH PREGNANCY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055421	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 12/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). NON STOP BLEEDING, IRREGULAR PERIODS, PAIN JOINT SWELLING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055422	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WENT TO THE HOSPITAL FOR SHARP ABDOMINAL PAIN. ALL BLOOD WORK CLEAR. NO CLEAR REASON FOR PAIN. LASTED 2 WEEKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055423	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 6/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWO MONTHS OF PAIN AND NON-STOP BLEEDING AFTERWARDS. ANXIETY ISSUES STARTED FALL 2012. STRANGE RASHES WOULD COME AND GO STARTING (B)(6) 2014 ON MY THIGHS AND ARMS. TWO MOMENTS OF KNEE DROPPING SHARP PAINS IN RIGHT SIDE. NOTHING WOULD STOP THE ITCH. THINNING HAIR STARTED TO BE NOTICED (B)(6) 2014. ON (B)(6) 2015, VERY SHARP PAIN IN RIGHT SIDE, DROPPED TO MY KNEES, TURNED INTO DULL THROBBING CONSTANT PAIN. TOOK IBUPROFEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055424	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 6/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN. LOWER LEFT OVARY WAS DIAGNOSED WITH A HEMORRHAGIC CYST 1.5CM, POSSIBLE ENDOMETRIOSIS IF IT DOESN'T GO AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055425	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 8/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE NOTICED A SIGNIFICANT WEIGHT GAIN WITH MOST OF IT BEING AROUND MY ABDOMEN. I STARTED GETTING ACNE ON MY BACK AND CHEST. I DISMISSED THESE AS MAYBE SIMPLY A HORMONE IMBALANCE. I HOWEVER STARTED RECENTLY ON (B)(6), 2015 STARTED HAVING PELVIC PAIN THAT FET LIKE STABBING. I HAD NUMEROUS TESTS DONE ON (B)(6). SONOGRAM SHOWED NO OVARIAN CYSTS (WHICH I HAVE A HISTORY OF). A UTERINE FIBROID DID HOWEVER SHOW ON SONOGRAM. I WAS TOLD THE FIBROID SHOULDN'T BE THE CAUSE OF MY PELVIC PAIN. I'VE BEEN PRESCRIBED AN ANTIBIOTIC FOR 7 DAYS. IF THE PAIN DOESN'T GO AWAY WITH THAT TREATMENT I'M SUPPOSE TO CONTACT THE SURGEON WHO INSERTED MY DEVICES AND POSSIBLY BE CHECKED FOR ADHESIONS THROUGH LAPAROSCOPIC SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055426	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/20/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD A HYSTERECTOMY AND FOUND THAT A COIL HAD BROKEN THROUGH AND PUNCTURED MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055427	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, HEAVY BLEEDING, NAUSEA, CONSTANT FAT BLOATED BELLY THAT DOESN'T GO AWAY. EXTENSIVE CRAMPS AND EXTREME FEELING OF COILS TWISTING. NECK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055428	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 5/7/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PLACED IN ME IN 2008 AND I REMEMBER THAT MY PERIOD WAS FOR OVER 1 MONTH. I WENT FOR MY 3 MONTH CHECK UP AND WAS TOLD I WAS FINE AND ESSURE WAS PLACED SUCCESSFUL. BEFORE ESSURE MY PERIOD WAS ANYWHERE FROM 2-3 DAYS AND VERY LIGHT RIGHT AFTER ESSURE WHEN I STARTED HAVING MY PERIOD THEY HAVE BEEN FOR 5-7 DAYS VERY HEAVY, WHEN THEY ARE SHORTED THEY COME WITH A LOT OF CRAMPING, A LOT OF BLEEDING, MY ENTIRE BODY IS IN PAIN, FATIGUE AND BLOATED. SINCE ABOUT 2 YEARS NOW I HAVE BEEN FEELING FATIGUE EVERY DAY, EVERY DAY MY JOINTS ARE HURTING, HEADACHES, HEARTBURN, SWELLING ON LEGS, FEED, HANDS AND ARMS, WEIGHT GAIN, UNABLE TO LOOSE WEIGHT NO MATTER WHAT I AM DOING AND OTHER SYMPTOMS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055429	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE ON 2009. I'VE BEEN EXPERIENCE HEADACHES, PAINFUL SEX, HEAVY PERIODS, REALLY BAD CRAMPS, A SHARP STABBING PAIN IN MY ABDOMEN, LEFT LEG PAIN, I'M LOOSING MY HAIR, SPOTTING AFTER SEX. AND NOW I NEED A HYSTERECTOMY. THANKS ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055430	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 9/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER IMPLANTATION I HAD SEVERE PAIN IN GROIN AREA MUSCLE SPASMS AND PAIN IN LEGS, SHAKING IN HANDS AND WEAKNESS IN HANDS, BLURRY VISION, EXCESSIVE SWEATING, HEART PALPITATIONS, FOGGY BRAIN AND DIZZINESS, ACNE,EXTEND FATIGUE,SWELLING IN LEFT SIDE OF FACE AND NECK, NECK AND BACK PAIN, HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055431	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 2/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING RASHES TO COME AND GO ALL OVER MY BODY. THEY FEEL LIKE PAINFUL PIN PRICKING IN MY SKIN. I HAVE ALSO BEEN HAVING A LOT OF PAIN IN MY JOINTS...KNEES, TMJ, ELBOWS, ETC. I AM HAVING INSOMNIA. MY FINGERS FEEL NUMB A LOT. I HAVE BEEN HAVING EXTREME HEAD ACHES. I AM HAVING PAIN IN MY BACK IN MY LOWER STOMACH CONSTANTLY THAT FEELS LIKE EARLY STAGES OF LABOR...EVEN THOUGH I AM NOT PREGNANT. AT FIRST, MY PERIODS WERE EXTREMELY HEAVY WITH CLOTS. THIS HAPPENED A COUPLE OF MONTHS AFTER I HAD THE DEVICES IN PLACE. THE DOCTOR DID AN ABLATION AND THAT CLEARED UP. HOWEVER, NOW MY PERIODS COME AND THEY LAST FOR 2-WEEKS. THEY ARE NOT ENOUGH TO SHOW UP ON A PAD, BUT WHEN I WIPE, THERE IS BLOOD. I ALSO PASS CHUNKS OF STUFF THAT LOOKS LIKE THE MUCOUS PLUG DURING THIS TIME. AT TIMES, MY PAIN FEELS SO BAD THAT I DO NOT FEEL LIKE GETTING OUT OF BED. OTHER TIMES, IT MAKES ME FEEL WEAK AND SICK. I ALWAYS FEEL FATIGUED. ONE OTHER THING, I AM LOSING HAIR BAD AND I AM GAINING WEIGHT CONSISTENTLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055432	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 8/15/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALMOST IMMEDIATELY AFTER THE PROCEDURE I BEGAN HAVING BLOATING THAT ALWAYS HIT IN THE EVENING TIME. THEN IN (B)(6) 2015 I FOUND OUT I WAS PREGNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055433	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 11/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, HEAVY BLEEDING, UNSTABLE MENTALITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055434	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GOLF BALL SIZE CLOTS, EXTREME BLOATING FAINTING SPELLS, BREAST HURT LIKE LACTATING. CRAMPS FEEL LIKE I'M IN LABOR . THIS HAS GONE ON FOR 5 YEARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055435	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE I HAVE SHOOTING PAIN IN OLD OLD SCARS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055436	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 10/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE GETTING THE PROCEDURE DONE TOWARDS THE END OF 2012, I HAVE BEEN HAVING A LOT OF PHYSICAL PROBLEMS... I HAVE MAJOR LOWER BACK PAIN CONSTANT HEADACHES, HEAVY BLEEDING DURING MY PERIODS, NOT JUST BLEEDING, BIG CHUNKS OF STUFF COMING OUT THAT I DON'T EVEN KNOW WHAT IT IS... ALL THIS STARTED AFTER ESSURE... FOR THE LAST 3 MONTHS, MY LEFT ARM KEEPS GOING NUMB EVERY 10 MINUTES OR SO... IT IS CONSTANT AND WILL NOT STOP... IT HAS BEEN EVERYDAY... BEFORE THE PROCEDURE, I WAS PRETTY HEALTHY, NOW AT (B)(6), I FEEL LIKE A 70 YEAR OLD... I WISH THEY WOULD STOP IMPLANTING THIS DEVICE INTO INNOCENT WOMEN... I WISH TO HAVE MINE REMOVED, BUT DON'T HAVE INSURANCE AT THE MOMENT.. I ALWAYS FEEL TIRED AND FATIGUE... I WILL DO ANYTHING TO HAVE THIS REMOVED RIGHT NOW... THE PAIN I'M GOING THROUGH ON A DAILY BASIS IS UNBEARABLE... IF THERE WAS MORE ACCURATE RESEARCH AVAILABLE IN 2012, I WOULD HAVE NEVER GOT IT DONE! BIGGEST REGRET IN MY LIFE...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055437	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED ON (B)(6) 2014. I SPENT WEEKS AFTER WAKING UP SOAKED IN SWEAT. I CONTINUE TO HAVE IRREGULAR BLEEDING. IT IS NOW (B)(6) 2015 AND I BLEED ONCE EVERY OTHER WEAK. I CONTINUE TO FEEL FATIGUE SINCE SHORTLY AFTER PROCEDURE. I HAVE SEEN MY PRIMARY CARE DOCTOR TWICE SINCE PROCEDURE WITH COMPLAINTS OF FATIGUE, WEIGHT GAIN, JOINT PAIN, BREAST SIZE INCREASE AND PAIN. LABS HAVE SHOWN NO EXPLANATION TO MY SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055442	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). COIL ON RIGHT SIDE HAS MOVED PER XRAY, CONSTIPATION, HEADACHES, HEAVY BLEEDING, BACK PAIN, CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055443	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 1/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OVER THE LAST 6 MONTHS, I HAD BLOODWORK DONE TO SEE IF I HAD ARTHRITIS. ALL TESTS CAME BACK NEGATIVE. THESE ARE THE SYMPTOMS, I HAD BEEN EXPERIENCING PRIOR TO ESSURE REMOVAL. STABBING PAINS ON LOWER PELVIC AREA, EXTREME CRAMPING, FEELING OF CONTRACTIONS {AS IF I WAS IN LABOR}, SEVERE BLOATING {AS IF I WAS 4 MONTHS PREGNANT}, LACK OF ENERGY, HARD TIME FOCUSING { MIND FOG}, HEART PALPATIONS, DIZZINESS, PAINFUL INTERCOURSE, LOWER BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055444	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 3 WEEK MENSTRUAL CYCLES, EXTREME PAIN, NAUSEA. DISLODGED, TISSUE DISCHARGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055445	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IN THE HOSPITAL FROM 7-430 FOR WHO KNOWS WHAT REASON. SURGERY WAS ABOUT 9-11 AND I WAS IN PAIN AT THAT TIME. THE HOSPITAL WAS NICE THEY GAVE ME SOME PAIN MEDS WHILE I WAS THERE. MY DOCTOR REFUSED TO PRESCRIBE ME ANY THOUGH. I STARTED SWELLING REAL BAD DOWN THERE AND EVERY TIME I USE THE REST ROOM I SWELL MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055446	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 10/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST I STARTED HAVING BAD PAIN INTO MY RIGHT OVARY THEN MY LEFT THAT BASICALLY HASN'T WENT AWAY SINCE WITH NOTHING I TAKE.. MY HAIR HAS BEEN FALLING OUT I HAVE SHARP PAINS FROM MY VAGINAL DOWN INTO MY LEGS EVERYDAY. MY UTERUS IS NOW HARD FOR NO REASON I'VE BEEN CHECKED FOR ALL KINDS OF THINGS AND THE ONLY THING EVERYTHING ADS UP TO THE ESSURE EVEN MY DOCTOR SAID SO. NOW I CAN'T EVEN HAVE SEX WITHOUT IT HURTING BAD AND I HAVE NO SEX DRIVE. IT'S RUINED MINE MY HUSBAND AND MY CHILDREN'S LIVES BECAUSE I'M NOT THE PERSON I USE TO BE. NOW I'M (B)(6) AND I GOTTA HAVE A HYSTERECTOMY DONE SOON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055449	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 1/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, STABBING PAINS ON MY RIGHT SIDE, BURNING PAINS IN PELVIC REGION, BLOATING, PAINFUL INTERCOURSE, AND BRUISING EASILY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055451	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 6/25/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INTENSE CRAMPS, HEAVY BLEEDING, SEVERE RIGHT SIDES LOWER ABDOMEN PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055452	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. I WAS NOT GIVEN AN ESSURE CARD AND THEREFORE DO NOT HAVE MY LOT NUMBER OR MY MODEL NUMBER. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ALMOST IMMEDIATELY HOWEVER SYMPTOMS WORSENED IN (B)(6) 2015. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. CONTINUOUS CRAMPING IN THE LEFT SIDE FROM THE BEGINNING, ALWAYS FEELING LIKE I AM MENSTRUATING, VERY HEAVY FLOWS WHEN MENSTRUATING, RINGING IN EARS, CHRONIC FATIGUE, DIMINISHED BRAIN FUNCTION (BRAIN FOG, UNABLE TO COMMUNICATE EFFECTIVELY, CONFUSION, FORGETFULNESS AND SHORT TERM MEMORY LOSS), LOSS OF LIBIDO, PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE, OCCASIONAL SPOTTING DURING THE MONTH, INCREASED DISCHARGE, SHARP STABBING PELVIC PAIN, EXTREMELY PAINFUL OVULATION, MORE PAINFUL PERIODS, NERVE PAIN PARTICULARLY IN THE LOWER BACK AREA, SHOOTING PAINS DOWN LEGS, ALL OVER BODY ACHES AND PAINS, MIGRAINES, SEVERE BLOATING (LIKE I AM PREGNANT), HAIR LOSS, VISION PROBLEMS, SERIOUS WEIGHT GAIN, SWELLING OF LEGS AND HANDS AND MUSCLE SPASMS. I HAVE BEEN SEEN BY 1 DOCTOR, THE ONE THAT DID THE IMPLANTATION WHO HAS RECOMMENDED A HYSTERECTOMY. I HAVE NOT BEEN SPECIFICALLY DIAGNOSED WITH ANYTHING. THE DEVICE IS STILL INSIDE OF ME AND A HYSTERECTOMY IS BEING SCHEDULED. I AM CURRENTLY SEEKING A SECOND OPINION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055453	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 6/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2009. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THE ONSET OF MY COMPLAINT STARTED AROUND (B)(6) 2010. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE OVER THE PAST FIVE YEARS. NOT ALL HAPPENED AT THE SAME TIME SO I DIDN'T CONNECT ALL THE SYMPTOMS UNTIL RECENTLY. SYMPTOMS HAVE INCLUDED: INCREASED HEADACHES/MIGRAINES, BRAIN FOG, JOINT PAIN, BACK PAIN, EXTREME FATIGUE, PAINFUL PERIODS, PROLONGED PERIOD, MASSIVE/SEVERE BLOATING, UNEXPLAINED BLISTERS/LESIONS ON HANDS, HOT FLASHES, STABBING PAIN AT OPENING OF VAGINAL AREA, EXTREME TENDERNESS (SOMETIME PAIN) IN BREAST, LUMPS IN BREAST/ARMPIT THAT ARE PAINFUL AND GO AWAY AFTER A FEW WEEKS, UNCONTROLLABLE PAIN IN LEGS, SWELLING OF FEET, BRUISES OF UNKNOWN ORIGIN, EXTREME FATIGUE, WEIGHT GAIN, BLURRY VISION, NO ENERGY, SEVERE CONSTIPATION (ENEMA, LAXATIVES, SOFTENERS, FIBER, ETC DOESN'T WORK), MAJOR MOOD SWINGS, FORGETFULNESS, BAD TASTE IN MOUTH, SKIN ON BACK ITCHES ALL THE TIME, URGE TO URINATE ALL THE TIME/INABILITY TO HOLD URINE, MARBLE SIZE CYSTS AT VAGINAL OPENING (TWICE), DISCHARGE/ODOR FROM VAGINA, SHARP PAINS IN ABDOMEN (ALWAYS THINK I'M HAVING APPENDICITIS), SEVERE ALLERGIES (NEVER HAD AN ISSUE BEFORE), NUMBNESS/TINGLING ALONG MY SPINE, HAIR GROWTH ON CHIN. I HAVE BEEN SEEN BY MULTIPLE DOCTORS. NO DOCTORS CAN COME UP WITH A REASONABLE EXPLANATION FOR MY SYMPTOMS. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055454	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 3/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NO MENSTRUAL CYCLE FOR 9MO, THEN NON STOP MENSTRUAL CYCLE 4MO UNTIL HYSTERECTOMY, SEVERE ABDOMINAL CRAMPS, SEVERE BACK PAIN, FREQUENT HEADACHES/ MIGRAINES, HAIR LOSS, DRY SKIN, SLEEPLESSNESS, MOOD SWINGS, CONSTIPATION, NAUSEA, LOSS OF APPETITE, FATIGUE, DEPRESSION, GAS, BLOATING, MEMORY LOSS, FOGGY BRAIN, LOSS OF CONCENTRATION, RHEUMATOID ARTHRITIS, HOT FLASHES, NIGHT SWEATS, HORMONE IMBALANCE, BREAST TENDERNESS, EASY/ UNEXPLAINED BRUISING, FREQUENT UTI/ BLADDER INFECTIONS/ YEAST INFECTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055455	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 12/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PROCEDURE DONE IN 2009...STARTING FEELING CRAPPY 6 MONTHS AFTER. HAVE BEEN TO NUMEROUS DOCTORS TO NO AVAIL. JUST RECENTLY HEARD ON NEW ABOUT ALL THE PROBLEMS THIS DEVICE HAS BEEN GIVEN GIRLS. MY DOCTOR NEVER EVEN TOLD ME THIS ESSURE COULD BE THE ISSUE. I AM NOW SCHEDULED FOR DIFFERENT TESTS TO SEE WHERE THESE COILS ARE AND IF THEY HAVE MOVED. THE PAIN IS HORRIBLE AND EACH DAY IS DRAINING WITH PELVIC PAIN, BACK PAIN, MIGRAINES, JOINT PAIN ITS JUST NEVER ENDING. MY NEXT STEP IS TO GET THESE THINGS OUT OF ME. I CAN'T BELIEVE THE FDA HAS NOT LOOKED INTO THIS SOONER WITH ALL THE COMPLAINTS. THANK GOD I FOUND ALL TYPES OF INFORMATION ON THE WEB AND A (B)(6) FORUM WITH OVER (B)(6) WOMEN WITH COMPLAINTS AND NEVER ENDING ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055456	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, HAIR LOSS, LEG PAIN. CHEST PAIN. WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055457	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I SUFFER FROM GALACTORRHEA, HAIR GROWTH ON CHIN, FATIGUE, LACK OF ENERGY/MOTIVATION, NOT FEELING "RIGHT", HEADACHES/HEAD FOG, CHRONIC SINUS ISSUES, CAN'T LOSE WEIGHT/GAIN EASILY, OVERALL FEELING OF BEING SWOLLEN, ABDOMEN SWELLING/BLOAT, MILD DEPRESSION, HIGH BLOOD PRESSURE (BOTTOM), CRAMPING/SHARP/STABBING PAIN IN ABDOMEN AND LOWER BACK, CONSTANT TIGHTNESS/WEAKNESS IN UPPER BODY/NECK, ACHY/PRESSING/DULL PAIN IN BREASTS, PASS LARGE BLOOD CLOTS DURING PERIOD, UTI, JOINT PAIN, HAIR LOSS, PAINFUL OVULATION, EXCESSIVE DISCHARGE, TWINGEY NERVES, ARMS/HANDS WILL FALL ASLEEP, SEE STARS, DIZZY WHEN ON PERIOD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055483	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 8/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED THE ESSURE COILS ON (B)(6) 2013 AT (B)(6) HOSPITAL IN (B)(6) AS AN OUTPATIENT SURGERY. AT THE TIME I WAS A PATIENT OF (B)(6). DUE TO THEM BEING A CATHOLIC HOSPITAL THEY DID NOT PERFORM ANY TYPE OF STERILIZATION, I WAS REFERRED TO ANOTHER GROUP OUTSIDE OF THE(B)(6) PHYSICIANS AND HOSPITALS. I WAS TOLD THAT IT WAS A SIMPLE SURGERY AND QUICK RECOVERY. IT WAS EXPLAINED TO ME THAT THE COILS WERE LIKE THE SPRING INSIDE OF AN INK PEN THAT WERE INSERTED IN MY FALLOPIAN TUBES AND OVER THE NEXT THREE MONTHS THEY WOULD GROW SCAR TISSUE THAT WOULD BLOCK ANY EGGS FROM DROPPING, AND ME GETTING PREGNANT. AFTER THE SURGERY I WENT HOME WITH SOME CRAMPING AND MINOR BLEEDING. FAST FORWARD 8-9 MONTHS LATER....I BEGAN HAVING SEVERE ABDOMINAL CRAMPING, HEAVY BLEEDING DURING MY PERIOD, SHOOTING PAINS IN MY LOWER ABDOMEN THAT WOULD RADIATE TO MY LOW BACK, OVARIAN CYST, UTERINE FIBROIDS, CYST AND BOILS AROUND VAGINA AND RECTUM THAT HAD TO BE SURGICALLY REMOVED, BLOATING TO THE POINT I LOOK FIVE MONTHS PREGNANT OR GREATER, EXTREME FATIGUE, JOINT ACHES, WHOLE BODY ACHING AND NUMBNESS AND TINGLING IN MY ARMS AND LEGS, ABNORMAL HEAVY VAGINAL DISCHARGE, CHRONIC PELVIC PAIN AT THIS POINT. I HAVEN'T BEEN TO THE DOCTOR MUCH DUE TO NOT HAVING HEALTH INSURANCE. I AM NOW (B)(6) AND I KNOW MY BODY AND I KNOW THESE ESSURE COILS ARE CAUSING MY SYMPTOMS. I AM CURRENTLY GOING TO THE OBGYN HERE IN (B)(6). THEY ARE DOING ALL TYPES OF TESTS ON ME TO FIGURE OUT WHAT'S GOING ON. I KNOW WHAT'S GOING ON BUT I HAVE TO DO ALL THIS TO SATISFY INSURANCE TO HAVE A HYSTERECTOMY TO HAVE THE ESSURE REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055484	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MAJOR BLEEDING, PELVIC PAIN, BACK ACHES, HEADACHES, STOMACH DISCOMFORT, ITCHY BUMPS EVERYWHERE, LOSING HAIR, FATIGUE, WEIGHT GAIN, BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055485	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 9/18/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERFORATION TO BOWEL, DEBILITATING PELVIC AND VAGINAL PAIN, DEVELOPED NICKEL ALLERGY, SEVERE BLOATING AND CRAMPING, EXCESSIVE WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055486	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 4/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED THE ESSURE IN 2011. I WAS FINE UNTIL TWO YEARS AGO WHEN MY CYCLES STARTED TO GET WORSE. MY CRAMPS ARE CLOSE IN COMPARISON TO CONTRACTIONS THESE DAYS. I HAVE SHARP LOWER BACK AND ABDOMEN PAINS, SWEATING, ANXIETY ATTACKS, SEVERE HEADACHES, NAUSEOUSNESS, AND PAIN DURING INTERCOURSE. THIS BY FAR IS THE WORST PAIN I HAVE EVER EXPERIENCED. I NEVER HAD A PROBLEM DURING MY CYCLES AND NEVER CRAMPED UNTIL RECENT YEARS. I ALSO HAVE CYSTS GROWING ON MY OVARIES. I STRONGLY BELIEVE THAT ESSURE NEEDS TO BE TAKEN OFF THE MARKET. I WANT THE COILS REMOVED BUT I KEEP HEARING THAT THEY CAN'T BE REMOVED AND THAT I WILL HAVE TO GET A HYSTERECTOMY WHICH IS NOT AN OPTION FOR ME AT THIS POINT IN MY LIFE. THERE HAS TO BE SOMETHING THAT CAN BE DONE, NO ONE SHOULD HAVE TO ENDURE THE ISSUES THAT HAD BEEN PRESENTED WITH THIS DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055487	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/28/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ADENOMYOSIS. CYST AND A LOT OF PAIN FOR AT LEAST 3 WEEKS IN A MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055488	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 5/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD PREGNANCY IN 2011 WHICH LEAD TO A MISCARRIAGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055489	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ON LEFT SIDE WHERE COIL IS LOCATED. ABNORMAL ULTRASOUND, SURGERY RECOMMENDED TO REMOVE ESSURE (B)(6) 2014. I POSTPONED SURGERY DUE TO AN INSURANCE CHANGE, PLANNING ON GOING BACK IN NEXT MONTH DUE TO SEVERE ABDOMINAL PAIN NOW. I WAS NOT EVEN A CANDIDATE FOR ESSURE BECAUSE I DID NOT HAVE TWO TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055490	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 3/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER PLACEMENT, EXCESSIVE BLEEDING. DR ADVISED NOVA SURE FOR CAUTERIZE THE LINING OF THE UTERUS. ESSURE COOL ON THE RIGHT SIDE MIGRATED IN THE FIRST 3 MONTHS. 7 YEARS LATER AFTER YEARS OF PAIN AND COMPLAINTS, I SWITCHED DOCTORS AND IT WAS DISCOVERED THE RIGHT COIL PERFORATED THE TOLUENE AND LODGED IN THE LIGAMENT SURROUNDING THE UTERUS. A SOFTBALL SIZE MASS WAS ALSO FOUND INSIDE THE UTERUS. A COMBINATION OF THE TWO PROCEDURES RESULTED IN A MASS OF BLOOD CONTINUOUSLY GROWING. HAD THE BLOOD ESCAPED THE UTERUS, SEPTICEMIA COULD HAVE SET IN, RESULTING IN DEATH. AS A RESULT, A HYSTERECTOMY WAS REQUIRED. THANKFULLY OVARIES WERE LEFT IN PLACE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055491	BAYER	8/18/2015	8/18/2015

Event Information:

Event Date (B3): 7/28/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LAPAROSCOPIC TOTAL HYSTERECTOMY REMOVING TUBES, UTERUS, AND CERVIX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055706		8/18/2015	8/25/2015

Event Information:

Event Date (B3): 10/9/2014	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/9/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ENSURE IN (B)(6) 2014 AND NOW I HAVE SEVERE CRAMPS, BACK PAIN, AND BLOATING TO THE POINT I AM BED RIDDEN FOR A FEW DAYS A MONTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055707		8/18/2015	8/25/2015

Event Information:

Event Date (B3): 8/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 624469

Single Use: *
Implant Date (E6): 7/14/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE PROCEDURE AFTER THE PROCEDURE, I WAS FINE, BUT MONTHS DOWN THE ROAD I STARTED TO GAIN WEIGHT AND FEELING BLOATED. THEN I STARTED FEELING MORE LIKE CRAMPING ON MY LOWER ABDOMINAL AND MY BACK HURTS MORE OFTEN. I HAVE NOT FALLEN AT ALL OR CAUSE ANY BIG TRAUMA ON MY BACK. MY LOWER ABDOMINAL AREA HAVE NEVER HAD MAJOR SURGERY TO SAY IT COULD BE FROM INCISIONS. NOW AFTER 7 YEARS MY PERIODS ARE HEAVIER AND LONGER IT COULD LAST UP TO 3 WEEKS. AFTER THE PROCEDURE, MY PERIODS WERE KIND OF NORMAL, BUT THEN COUPLE OF MONTHS DOWN THE ROAD, THE BLEEDING WAS HEAVY FOR FIRST 3 DAYS THEN LIGHT THE REST OF THE DAYS AND LAST FOR 7 DAYS TOTAL, OR IT WOULD BE LIGHT THE WHOLE MONTH LIKE SPOTTING. MY POINT IS THAT NOW MY PERIODS ARE LONGER HEAVY AND CRAMPING IS LIKE AN EVERYDAY THING WAKE UP SORE. IF I DID A WORK OUT, MY BACK HURTS EVERY DAY. I AM MOST OF THE TIME BLOATED WITH MOOD SWING AND SWELLING ALL OVER MY BODY. I COULD GIVE YOU A LIST.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055708	BAYER	8/18/2015	8/25/2015

Event Information:

Event Date (B3): 8/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6): 12/12/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THE ESSURE HAVE CAUSED A SEVERE PAIN, CONSTANT BLEEDING, CYSTS ON MY OVARIES, BLOOD CLOTS AND AS OF TODAY I AM (B)(6) WITH MY 3RD CHILD. I AM DUE (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055711		8/18/2015	8/25/2015

Event Information:

Event Date (B3): 6/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTATION DEVICE
Device Type (E2): ESSURE IMPLANTATION DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/12/2006
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2006 I HAD THE ESSURE PUT IN TO PREVENT PREGNANCY IN (B)(6) OF 2007, I GAVE BIRTH TO MY SON I WAS TOLD THE SCAR TISSUE AROUND THE COIL DIDN'T FULLY HEAL. I LATER HAD A SCAN DONE AGAIN TO CONFIRM THE SCAR TISSUE STILL HASN'T HEALED. I GOT PREGNANT AGAIN IN 2011, BUT HAD TO TERMINATE THE PREGNANCY. THIS PAST (B)(6) OF 2015, I GAVE BIRTH TO A BABY BOY I SIGNED PAPERS TO HAVE A TUBAL LIGATION. I WAS INFORMED WHEN I WENT IN FOR MY F/U THAT MY TUBE WAS NEVER BLOCKED THAT THE COIL WAS IMBEDDED ON THE SURFACE OF MY UTERUS. I HAVE SINCE REALIZED THAT THIS COULD HAVE BEEN THE CAUSE FOR MY PAINFUL PERIODS AND SEXUAL INTERCOURSE BUT ALSO MANY HARMFUL THINGS COULD HAVE HAPPENED TO MY UTERUS THE FACT THAT THE COIL WAS NEVER IN MY TUBE HAS FRUSTRATED ME, I HAVE TWO BEAUTIFUL CHILDREN THAT I LOVE DEARLY BUT THE PURPOSE OF THE ESSURE WAS SO I COULDN'T HAVE ANY MORE CHILDREN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00617	BAYER HEALTHCARE LLC	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B94872

Single Use: Y
Implant Date (E6): 4/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 23-JUL-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014 FOR STERILIZATION (LOT NUMBER B94872). CONSUMER REPORTED SHE EXPERIENCED BLEEDING FROM (B)(6) 2014 TO (B)(6) 2015. SHE WENT TO HOSPITAL IN TOTAL OF 3 OR 4 TIMES BECAUSE OF PAIN AND DISCOMFORT. SHE DID AN ULTRASOUND BUT THE RESULTS WERE NOT MENTIONED. SHE WAS REFERRED TO GYM. CONSUMER REPORTED THAT SHE WANTED TO HAVE ESSURE REMOVED DUE TO PAIN AND DISCOMFORT. SHE COULD NOT WALK OR WORK AND HER DOCTOR SAID TO HER ABOUT HYSTERECTOMY. SHE STATED THAT SHE WAS WAITING ON DISABILITY FOR ESSURE REMOVAL AND HAS BEEN CONTINUING WITH THE DEVICES. NO ADDITIONAL INFORMATION WAS PROVIDED. AFTER INTERNAL REVIEW REGARDING INFORMATION OF 23-JUL-2015 THE FOLLOWING WAS ADDED: CONSUMER REPORTED TWO MONTHS AFTER ESSURE, SHE STARTED HAVING PAIN AND DISCOMFORT. HER PHYSICIAN SAID IT WAS PART OF PROCEDURE, TO LET IT RUN ITS COURSE. FOLLOW UP INFORMATION RECEIVED ON 28-JUL-2015: SHE ALSO REPORTED HER PHYSICIAN ONLY DOES HYSTERECTOMY. THERE IS ANOTHER DOCTOR, AND MAY BE ABLE TO JUST MAKE A LITTLE INCISION ON THE FALLOPIAN TUBE. FOLLOW UP 05-AUG-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT

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THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 3 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH ONE CASE REFERS ALSO TO SIMILAR TYPES OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED BLEEDING, PAIN AND DISCOMFORT. THESE EVENTS, SEEN AS GENITAL BLEEDING, PELVIC PAIN AND DISCOMFORT RESPECTIVELY, ARE SERIOUS DUE MEDICAL IMPORTANCE AND HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN, GENITAL BLEEDING AND DISCOMFORT MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE PATIENT WAS PRESENTING BLEEDING SINCE THE INSERTION PROCEDURE AND IT LASTED FOR 10 MONTHS. IN ADDITION, SHE INFORMED THAT WENT TO HOSPITAL IN TOTAL OF 3 OR 4 TIMES DUE TO PAIN AND DISCOMFORT. CONSIDERING THE AVAILABLE INFORMATION AND NATURE OF EVENTS, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE HOSPITALIZATION WAS INFORMED, THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 22-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00618	BAYER HEALTHCARE LLC	8/19/2015	8/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. THE DOCTOR REPORTED THAT PATIENT HAD ESSURE FOR SEVERAL YEARS AND WAS DONE BY DIFFERENT DOCTOR. THIS DOCTOR DID PERFORM A HYSTERECTOMY ON PATIENT ON AN UNKNOWN DATE BECAUSE PATIENT COMPLAINED OF PAIN AND HEAVY BLEEDING. NO ADDITIONAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON 05-AUG-2015 .(B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND

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SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED PAIN AND HEAVY BLEEDING. THE REPORTED EVENTS LED HER TO A HYSTERECTOMY. THESE EVENTS, SEEN AS PELVIC PAIN AND GENITAL BLEEDING ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR. IN THIS CASE, THE PHYSICIAN PERFORMED A HYSTERECTOMY BECAUSE PATIENT COMPLAINED OF PAIN AND HEAVY BLEEDING. CONSIDERING AVAILABLE INFORMATION AND THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE AND SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 04-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT R

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00619	BAYER HEALTHCARE LLC	8/19/2015	8/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91762

Single Use: Y
Implant Date (E6): 7/21/2015
Explant Date (E7): 7/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

OTHER REPORTABLE INCIDENT (BREAKAGE: MALFUNCTION). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C91762 INSERTED ON (B)(6) 2015. IT WAS REPORTED THAT ESSURE DEVICE FAILED TO DEPLOY AND BROKE OFF DURING ATTEMPT TO REMOVE. A NEW DEVICE WAS PLACED AND BILATERAL PLACEMENT WAS ACHIEVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, DEVICE FAILED TO DEPLOY AND BROKE OFF. THESE EVENTS, SEEN AS DEVICE DEPLOYMENT ISSUE AND DEVICE BREAKAGE, ARE NON-SERIOUS. DEPLOYMENT ISSUE IS LISTED, WHILE DEVICE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS OR REMOVALS, DEVICE BREAKAGE AND DEVICE DEPLOYMENT ISSUE MAY OCCUR. IN THIS CASE, ESSURE DEVICE FAILED TO DEPLOY DURING INSERTION AND BROKE OFF DURING ATTEMPT TO REMOVE. A NEW DEVICE WAS PLACED AND BILATERAL PLACEMENT WAS ACHIEVED. CONSIDERING THE REPORTED EVENTS OCCURRED ASSOCIATED TO THE INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 20-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00620	BAYER HEALTHCARE LLC	8/19/2015	8/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C22911

Single Use: Y
Implant Date (E6): 7/23/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) -YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE LOT NUMBER USED WAS C22911. PHYSICIAN REPORTED THAT DURING THE INSERTION PROCEDURE THE DEVICE WAS DEPLOYED IN PATIENT'S TUBE AND THEN CAME OUT INTO CAVITY - APART FROM THE PET FIBER (SEPARATED) AND IT WAS REMOVED WITH GRASPERS. THE PATIENT HAD NO INJURY AND BILATERAL PLACEMENT OF DEVICE WAS ACHIEVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT DEVICE WAS DEPLOYED IN TUBE AND THEN CAME OUT INTO CAVITY-APART FROM THE PET FIBER-SEPARATED (REGARDED AS DEVICE BREAKAGE). THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 17-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00621	BAYER HEALTHCARE LLC	8/19/2015	8/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER'S MOTHER IN (B)(6) 2015 WHICH REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER'S MOTHER REPORTED THAT SINCE INSERTION, HER DAUGHTER EXPERIENCED JOINT PAIN, BACK PAIN, HEADACHES, FATIGUE, PAIN IN HER RIGHT OVARY, AND BRUISING FROM HER HIPS TO HER TOES. SHE HAD A HYSTERECTOMY IN (B)(6) 2014, AND WAS TOLD THAT ONE DEVICE WAS NOT IN HER FALLOPIAN TUBE. SINCE HER HYSTERECTOMY, SHE HAD 4 (B)(6), CANNOT GET OUT OF BED AND FATIGUE. PTC INVESTIGATION RESULT WAS RECEIVED ON 05-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A

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CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE DEVICE WAS NOT IN HER FALLOPIAN TUBE (INTERPRETED AS DEVICE DISLOCATION). SHE UNDERWENT A HYSTERECTOMY; SINCE THIS SURGERY SHE EXPERIENCED (B)(4). THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY DEVICE DISLOCATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO THE UTERUS OR OUT OF THE BODY) OR DISLOCATION (INTO FALLOPIAN TUBE OR TO PERITONEAL CAVITY). ALTHOUGH, IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF THE EVENT IS UNKNOWN, GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. REGARDING THE REPORTED (B)(4); CONSIDERING THE NEGATIVE TEMPORAL RELATIONSHIP WITH ESSURE THERAPY (EVENT OCCURRED AFTER HYSTERECTOMY); IT WAS CONSIDERED AS UNRELATED TO THE SUSPECT INSERT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER INFORMATION WILL BE PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055492	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 3/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME WEIGHT LOSS, DIARRHEA, VOMITING, MUSCLE WEAKNESS, TREMORS, EARLY ONSET ARTHRITIS, ABDOMINAL PAIN, EXTREME BLOOD LOSS, HAIR LOSS, WEIGHT GAIN, DISTENDED BELLY, CYSTS ON BREASTS, LOW SEX DRIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055493	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 3/2/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE MIGRAINES, PELVIC PAIN, ENLARGED UTERUS, WEIGHT GAIN, SEVERE EXHAUSTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055494	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 2/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE IMPLANTED IN 2009. (B)(6) 2015 DURING A UTERINE BIOPSY THE DOCTOR PULLED OUT A COIL THAT MUST HAVE MIGRATED. SINCE THEN MY SYMPTOMS HAVE WORSENED SEVERELY. I HAVE DEBILITATING PAIN IN MY PELVIC AREA, LOWER BACK AND HIPS. CHRONIC FATIGUE, NAUSEA, HEADACHES, CONSTANT ITCHY SKIN, EXTREMELY SORE BREASTS, BLADDER ISSUES, BOWEL CHANGES, HEAVY AND PAINFUL PERIODS, LATEST ADDITIONAL IS A PERPETUAL "YEAST INFECTION".

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055495	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 7/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, MAJOR CRAMPS. PIERCING IN LEFT AND RIGHT SIDE LOWER PELVIC AREA. HAIR LOSS AND BACK PAINS. SWELLING OF LEGS AND FEET. FATIGUE AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055496	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 12/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, SEVERE PELVIC PAIN, CLOTTING, HEAVY PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055497	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 4/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING PELVIC PAIN BACK PAIN SEVERE HEADACHES NUMBNESS IN THIGHS SEVERE MOOD SWINGS RANGING FROM DEPRESSION TO ANGER BLURRY VISION WEIGHT GAIN STOMACH PAIN WORSENS WHEN BENDING OVER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055498	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 10/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, BLOAT, MIGRAINES, PELVIC PAIN, HAIR LOSS, CRAMPING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055499	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 3/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).I WAS AT WORK FELT DIZZY AND BP AND HEART RATE STARTED TO INCREASE FAST THEN BLACKED OUT. THIS HAS CONTINUED TO THIS VERY DAY. I HAVE GAINED A LOT OF WEIGHT, SEVER BACK/PELVIC PAIN VERY FATIGUE ALL THE TIME. AND BE GET VAGINAL YEAST INFECTION OUT OF NOW WHERE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055500	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 7/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS CRAMPS BLOATING FATIGUE DEPRESSION ANXIETY BACK PAIN ABDOMINAL PAIN METAL TASTE IN MOUTH DRAINAGE FROM EARS LIGHTHEADED WEIGHT GAIN PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055501	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 3/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IN A LOT OF PAIN RIGHT AFTER IMPLANTATION. I BLED FOR AN ENTIRE YEARS AFTERWARD RIGHT UP UNTIL I HAD MY TUBES REMOVED (B)(6) 2014. I STOPPED A WEEK LATER. IN (B)(6) 2013, I STARTED HAVING TROUBLE SWALLOWING AND HAD TO HAVE A PARTIAL THYROID GLAND REMOVAL. I CRAMPED CONTINUOUSLY AND STAYED BLOATED. I GAINED 40 LBS. I STAYED FATIGUED AND WAS DIAGNOSED WITH LOW VITAMIN D. I ALSO HAD SEVERE JOINT PAIN. FOR THE FIRST TIME IN MY LIFE, I EXPERIENCED MENORRHAGIA. SEXUAL INTERCOURSE WAS NOT ONLY PAINFUL, BUT NEARLY IMPOSSIBLE. I BEGAN A BATTLE WIT FREQUENT URINATION AND WAS SUBSEQUENTLY DIAGNOSED WITH A BLADDER DISEASE CALLED INTERCYSTITUAL CYSTITIS. I WAS ALSO DIAGNOSED WITH HAVING AN INFLAMED CERVIX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055502	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 12/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, HEAVY HORRIBLE PERIODS TWICE A MONTH, BLOATING, WEIGHT GAIN, CRAMPS, LOWER BACK PAIN, SEVERE HIP PAIN IN LEFT HIP, FATIGUE, HAIR LOSS. IT'S ALL BEEN DOWN HILL SINCE HAVING THIS ESSURE IN MY BODY. PERIOD HAVE LASTED 53 DAYS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055503	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 7/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BACK PAIN, FATIGUE, HEADACHES, BRAIN FOG, STABBING PAIN IN ABDOMEN AT TIMES, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055504	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 11/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED MONTHS PRIOR TO THIS. I HAD CONSTANT BLEEDING PROBLEMS FROM THE START. I WAS CURRENTLY BEING WORKED UP FOR A LIVER TRANSPLANT DUE TO PRIMARY BILIARY CIRRHOSIS. I BECAME PREGNANT AND DUE TO MY MEDICAL CONDITION HAD TO HAVE A D AND C ON (B)(6). ONCE HEALED, I CONTINUED TO HAVE BLEEDING AND DUE TO THAT, ISSUES WITH FINDING ONE OF THE COILS, AND MY LIVER CONDITION I HAD A TOTAL HYSTERECTOMY. I WASN'T ABLE TO HAVE IT DONE ROBOTICALLY OR LAPAROSCOPICALLY AS MY MD NORMALLY WOULD DO BECAUSE OF THE ANESTHESIA AND MY LIVER CONDITION. DUE TO THE TOTAL HYSTERECTOMY, I WAS THROWN INTO MENOPAUSE AND COULD NOT TAKE ANY HORMONE REPLACEMENT THERAPY BECAUSE OF MY LIVER. I WAS (B)(6). THIS IS THE VERY SHORT VERSION AS I REQUIRED MULTIPLE DOCTORS DUE TO THE DANGEROUS CONDITION ESSURE PUT ME IN WITH MY LIVER. I HAVE ALL AND ANY MEDICAL RECORDS NEEDED. THIS DEVICE CAUSED MY PHYSICAL DAMAGE (BLEEDING, PAIN, SURGERIES, RECOVERY,ETC), FINANCIAL DAMAGE AS I MISSED WORK FOR MULTIPLE DOCTOR APPOINTMENTS AS WELL AS RECOVERY FROM BOTH SURGERIES, AND EMOTIONAL DAMAGE (HAVING TO HAVE A MEDICAL ABORTION , ESPECIALLY SINCE YEARS BEFORE THIS WE WENT TO A PERINATAL DOCTOR ABOUT HAVING CHILDREN WITH MY LIVER DISEASE, AND HAVING TO DEAL WITH ALL THIS IN THE MIDDLE OF TRYING TO BE LISTED FOR A TRANSPLANT).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055505	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 5/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE TERRIBLE BLOATING, TO WHERE IT LOOKS LIKE I'M PREGNANT. SEVERE CRAMPS, HEAVY BLEEDING DURING MY PERIOD. I GET SHARP, STABBING PAINS IN MY RIGHT OVARY. LOTS OF HAIR COMES OUT EVEN I BRUSH MY HAIR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055506	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 7/20/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN BLEEDING SHARP PAINS IN ABDOMEN AND HEART AREA BLURRED VISION HEADACHES WEAKNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055507	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 10/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABNORMAL BLEEDING WITH HUGE CLOTS AND TERRIBLE CRAMPING/CONTRACTION LIKE PAIN IS HOW IT STARTED. SINCE THEN, I HAVE HAD HAD NON STOP BLEEDING, INCLUDING CLOTS ON A REGULAR BASIS, EXTREMELY FATIGUE, CONSTANT UTI'S, MEMORY LOSS, MIGRAINE, JOINT PAIN, HAIR LOSS, BLOATING, WEIGHT GAIN, DIZZINESS AND BLURRED VISION, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055508	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 8/21/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WANTED TO ADD, ANOTHER SIDE EFFECT THAT DEVELOP AFTER I WAS IMPLANTED IT STARTED 2011 IT CALLED HYPERADRENERGIC POTS, IT IS A FORM OF DYSAUTONOMIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055509	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 4/17/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE MY HAIR FALLS OUT IN HUGE AMOUNTS! A TON OF PAIN IN MY OVARIES. BEEN TO DOCTOR AND THEY JUST BLOW YOU OFF! MEMORY LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055510	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MISCARRIAGE, SEVERE HEADACHES, HEAVY BLEEDING, HEAVY CLOTTING WITH PERIOD, LOWER BACK NERVE PAIN, STABBING PAINS WHEN OVULATING, PAINFUL CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055511	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SLOWLY STARTED HAVING MEDICAL ISSUES. MIGRAINES WAS THE BIGGEST ONE THEN THE ABNORMAL PERIODS THAT WERE LONGER. BLEEDING AFTER SEX. FEELING FAINT AND DIZZY. NAUSEA ALL THE TIME. WEIGHT LOSS. THEN THE TREMORS IN MY HANDS AND THE NUMBNESS AND TINGLING IN MY HANDS AND FEET. I AM ALWAYS CONFUSED. I FORGET WORDS FREQUENTLY LIKE MY DAD WHO HAS ALZHEIMERS. I HAVE BOWEL ISSUES WHERE I WILL BE CONSTIPATED AND HAVE DIARRHEA IN THE SAME SITTING. I HAVE HUGE BRUISES THAT APPEAR OUT OF NOWHERE THAT I HAVE NO IDEA HOW I GOT. I HAVE PANIC ATTACKS NOW OVER NOTHING. I GET DEPRESSED AND CRY AT WORK FOR NO REASON AND IT HAS SEVERELY AFFECTED MY JOB. I'M SURPRISED THAT I STILL HAVE A JOB AT THIS POINT. I HAVE LOST SO MUCH HAIR AT MY TEMPLES THAT I'M SURPRISED THAT THERE'S ANY LEFT. I'VE ALWAYS HAD GOOD TEETH AND NOW THEY ARE ALL CRACKING. MY JOINTS WILL JUST ACHE FOR NO REASON. I WILL BLEED AFTER SEX EVEN THOUGH I HAD AN ABLATION TO REMOVE ALL THE TISSUE INSIDE MY UTERUS TO STOP THE HORRIBLE BLEEDING AFTER I GOT THE ESSURE. I ALWAYS HAD REGULAR PERIODS BEFORE BUT NOT AFTER THE ESSURE. AT NIGHT WHEN I TRY TO SLEEP I HAVE TO GO TO THE BATHROOM EVERY 5 MINUTES. NOW I ALSO WAKE UP COVERED IN SWEAT BUT I DON'T HAVE ANY HORMONES THAT SHOW THAT I AM BEGINNING MENOPAUSE SO IT'S NOT THAT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055512	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 4/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN 7 OUT OF 10 FROM IMPROPER PLACEMENT OF ESSURE. NAUSEA, VOMITING. HAVING TO HAVE SURGERY TO REMOVE UTERUS ANDAMP; FALLOPIAN TUBES DUE TO ESSURE PLACEMENT ANDAMP; PERFORATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055513	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 4/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CAUSED MIGRAINES WITHIN 3 DAYS AND NEVER HAD MIGRAINES, NOW THEY ARE VERY FREQUENT, EVEN AFTER STOPPED BIRTH CONTROL, SEVERE PAIN IN TUBE AND CERVIX AREA FOR A WEEK BEFORE, WEEK OF AND WEEK AFTER PERIOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055514	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 5/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE ESSURE PROCEDURE I'VE HAD NOTHING BUT HEALTH ISSUES. SEVERE PAIN IN MY ABDOMEN AND LOWER BACK! MEMORY LOSS, HEADACHES, VERTIGO, SWOLLEN AND BLOATED TO THE POINT THAT I LOOK PREGNANT AGAIN. I'M FATIGUE ALL THE TIME NO MATTER HOW MUCH I SLEEP. I ALSO BLEED SEVERELY WITH HUGE BLOOD CLOTS WHEN I'M ON MY PERIOD (WHEN MY BODY DESIDES TO HAVE ONE).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055515	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY LONGER THAN USUAL PERIODS, EXTREME CRAMPING, BLOOD CLOTS THE SIZE OF HALF DOLLARS, WEIGHT GAIN, FATIGUE, DEPRESSION, SEVERE SWELLING IN ABDOMEN, OVARIAN CYSTS, ENDOMETRIOSIS AND THICKENING IN MY UTERINE LINING AND INTERNAL BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055516	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE PROCEDURE IN (B)(6) 2013. BY (B)(6) 2013 I HAD GAINED 30 LBS. IN (B)(6) 2014, I STARTED GETTING SEVERE DIZZINESS WITH CRIPPLING HEADACHES. (B)(6) 2014, I STARTED BLEEDING VAGINALLY AND CONTINUED FOR 4 MONTHS. AFTER GOING TO THE EMERGENCY ROOM AFTER PASSING HUGE MASSES OF TISSUE AND SEEING MY DOCTOR WHO SAID I NEEDED A VAGINAL ULTRASOUND. I DIDN'T HAVE INSURANCE, SO I WAITED. WAS PUT ON BIRTH CONTROL PILLS TO STOP BLEEDING BUT IF I SKIP ONE DAY, I START BLEEDING AGAIN. STARTED HAVING JOINT PROBLEMS, PAIN AND TINGLING IN LEGS, SWELLING IN HANDS AND FEET. INFLAMMATION IN ABDOMEN THAT GETS WORSE THROUGHOUT THE DAY. SED NUMBERS ARE ELEVATED. REFERRED TO A RHEUMATOLOGIST BUT HAVE NO INSURANCE. SKIN RASHES THAT TAKE MONTHS TO GO AWAY BUT RETURN. CANNOT LOSE WEIGHT DESPITE CHANGING DIET AND EXERCISE. EXTREME FATIGUE. NOW BLADDER AND KIDNEY ISSUES. HAD VAGINAL ULTRASOUND AND WAS TOLD ESSURE IS PERFORATING MY ENDOMETRIUM AND IT NEEDS TO GET REMOVED. HAVE NO INSURANCE, SO DON'T KNOW WHAT TO DO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055517	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 1/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MONTHLY PERIODS ARE NOW EXTREMELY PAINFUL, HEAVY BLEEDING AND MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055518	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 9/29/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED EXPERIENCING MAJOR MOOD SWINGS, AND ENDED UP BEING HOSPITALIZED FOR A WEEK DUE TO THE STRESS OF IT. I HAVE ALSO HAD HEAVIER BLEEDING DURING MY PERIODS AS WELL AS PASSING VERY LARGE BLOOD CLOTS. THERE IS ALSO STABBING PAINS IN MY RIGHT LOWER ABDOMEN THAT WILL CAUSE ME TO DOUBLE OVER, THEY DO COME AND GO. MY WEIGHT HAS GENERALLY BEEN WELL MAINTAINED AND AFTER THIS PROCEDURE AND BEING ACTIVE, I HAVE NOT BEEN ABLE TO LOSE WEIGHT ESPECIALLY IN MY LOWER ABDOMEN AREA, (I DID ROLLER DERBY). TO THIS DAY MY MOODS DO CHANGE RATHER FREQUENTLY, AND IT IS NOT A NORMAL FOR ME UNTIL AFTER A YEAR OF HAVING THIS IMPLANTED IN ME. I ALSO DEVELOPED A FOOD SENSITIVITY TO EGGS, I NEVER HAD A PROBLEM BEFORE AND HAVE HAD ALLERGY TESTING TO CLARIFY THIS, AND IT IS JUST A SENSITIVITY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055519	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC FATIGUE, LOOSING MY HAIR, AS TIME WENT ON MY SYMPTOMS WERE WORSE AND GREW MORE SEVERE AND INLUDE: CONSTANT CONGESTION THAT NEVER GOES AWAY AND GOES INTO SINUS INFECTIONS AND BRONCHITIS, EAR INFECTIONS, SEVERE BLOATING, DRY SKIN AND HAIR, EYES: BLURRED VISION, DRY EYE ISSUES, FLOATERS, SEVERE HAIR LOSS, SWELLING OF MY LEGS AND OTHER PARTS OF MY BODY, CRAMPING, SHARP-STABBING PELVIC PAIN, SHOOTING PAIN DOWN INTO MY THIGHS, DISCHARGE, HOT FLASHES, NIGHT SWEATS/DAY SWEATS, LOSS OF LIBIDO, PAINFUL INTERCOURSE, YEAST INFECTIONS, URGENT AND FREQUENT URINATION; ITCHING, BURNING, STINGING STABBING OF VAGINAL ENTRANCE AND INSIDE, BREAST TENDERNESS AND PAIN ALL THE TIME, ABDOMINAL SPASMS, TWITCHING, FLUTTERING. ADDITIONAL PAIN INCLUDED: LOWER BACK PAIN, ALL OVER BODY ACHES, NAUSEA, GAS, CONSTIPATION, DIARRHEA, HEARTBURN, HEADACHES AND MIGRAINES, DIZZINESS, BRAIN FOG, NUMBNESS IN BODY, SEVERE PAIN SHOOTING DOWN INTO MY THIGHS, NERVE PAIN, RINGING IN THE EARS, SENSATION OF PRICKING OF MY SKIN BY A SHARP NEEDLE ALL OVER MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055520	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 3/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER ESSURE WAS PLACED, I BEGAN TO EXPERIENCE EXTREMELY HEAVY LONG PERIODS WITH HUGE CLOTS. I GAINED WEIGHT, BEGAN LOSING HAIR, PAIN DURING SEX, DURING MENSTRUAL CYCLES AND OVULATION, HEADACHES, BLOATING, FACIAL HAIR, ACNE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055521	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 7/11/2014	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING EVERY TWO WEEKS AND OVARIAN CYST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055522	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PLAYED (B)(6) WITH MY DAUGHTER AND STARTED HAVING SEVERE LOWER BACK PAIN ON THE LEFT SIDE THAT WOULD WRAP AROUND MY SIDE TO MY LOWER LEFT ABDOMEN. SAW A DOCTOR WHERE I WAS LIVING AND HE TOLD ME IT WAS PROBABLY JUST A PULLED MUSCLE. I WENT HOME AND ANYTIME I MOVE THE WRONG WAY OR SAT DOWN IN CERTAIN POSITIONS THE PAIN WOULD FEEL LIKE BEING STABBED TO THE POINT WHERE I COULDN'T HELP SWEARING! THE PAIN BECAME A DULL ACHE ON THE LEFT LOWER BACK AND STILL STABBING IN FRONT DEPENDING ON HOW I SAT. I MOVED IN (B)(6) 2015 AND STARTED NOTING BLOOD IN MY URINE GETTING WORSE AND WORSE EVERYDAY. I WENT TO A DOCTOR AND WHEN I GAVE A URINE SAMPLE IT LOOKED LIKE I HAD POURED COLA IN THE SAMPLE CONTAINER BECAUSE OF HOW MUCH BLOOD WAS PRESENT. THE DOCTOR SAID I HAD A UTI AND PUT ME ON ANTIBIOTICS. LATER F/U URINE SAMPLE SHOWED SMALL AMOUNT OF BLOOD BUT THE PAIN STARTED AGAIN ESPECIALLY WHEN USING THE STAIRS IN MY TOWN HOME. I EVENTUALLY COULDN'T HANDLE THE PAIN THAT CAME WITH THE USE OF STAIRS. THE DOCTOR RECOMMENDED THAT I NO LONGER SHOULD LIVE IN THE TOWNHOUSE DUE TO ISSUES FROM USING THE STAIRS. I THEN MOVED (B)(6) SECOND AND I HURT INCREDIBLY BAD DURING AND AFTER THE MOVE. SO I SCHEDULED AN APPOINTMENT WITH AN OB/GYN AND I SUGGESTED IT MAY BE FROM THE ESSURE IMPLANTS. SHE SCHEDULED ME FOR ULTRASOUND AND WHEN THE REPORT CAME BACK IT SHOWED FLUID IN MY UTERUS, SO SHE SUGGESTED I HAVE A D AND C DONE TO REMOVE THE FLUID. AFTER THE PROCEDURE SHE SAID MY UTERUS WAS SCARRED FROM THE ABLATION I HAD DONE AT THE SAME TIME I HAD THE ESSURE DONE. SHE STATED SHE WASN'T SURE IF SHE GOT ALL THE FLUID BECAUSE THE SCAR TISSUE WAS SO BAD THAT SHE COULD BARELY GET THE CAMERA INSIDE... PAIN CONTINUED AND AT F/U APPT SHE BASICALLY SAID I COULD TRY AND DEAL WITH THE PAIN OR GO AHEAD WITH THE HYSTERECTOMY. AFTER EVERYTHING I'VE BEEN THROUGH I

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OPTED FOR THE HYSTERECTOMY WHICH IS SCHEDULED FOR A FUTURE DATE. SINCE THE ESSURE WAS PLACED, BODY PAIN INCREASED, MIGRAINE HEADACHES STARTED, PAINFUL INTERCOURSE, IRREGULAR SPOTTING, MOODINESS, DEPRESSION, AND THE DEVELOPMENT OF A SECOND UTI. ONCE AGAIN THE PAIN IS SO UNBEARABLE THAT SOMETIMES I CAN BARELY GET OUT OF BED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055523	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 9/24/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY MENSTRUAL CYCLE, LOWER BACK PAIN, PAIN ON MY LEFT SIDE, PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055524	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 8/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE GETTING ESSURE, I HAVE HAD SEVERE BLOATING, HEAVY PERIODS, FATIGUE, HEADACHES, JOINT PAIN, INCREASED PALPITATIONS, PELVIC PAIN WHEN LEANING FORWARD/PUSHING/STRETCHING/WALKING AND INCREASED BREAST TENDERNESS AND ABNORMAL MENSTRUAL CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055525	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 8/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD ESSURE FOR GOING ON EIGHT YEARS NOW, AND FOR THE LAST THREE OR FOUR YEARS MY SIDE EFFECTS HAVE PROGRESSED. I'VE GONE FROM SHARP PAINS TO EXTREME PAINS IN MY PELVIC REGION. I'M TALKING BALLED UP FETAL POSITION PAINS. THERE'S ALSO PAINFUL INTERCOURSE, BLEEDING/SPOTTING FOR DAYS/WEEKS AT A TIME AND NUMBNESS IN MY LEGS, JUST TO NAME A FEW.... THIS PRODUCT SHOULD DEFINITELY BE TAKEN OFF THE MARKET!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055526	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 2/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, CHRONIC BLOATING, HEADACHES, ERRATIC AND PROLONG MENSTRUATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055527	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 7/9/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS MIGRAINES, RASHES, DIZZINESS CHANGE IN VISION, DEPRESSION, WEIGHT GAIN, INABILITY TO LOSE WEIGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055528	BAYER	8/19/2015	8/19/2015

Event Information:

Event Date (B3): 1/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE WAS IMPLANTED IN 2003, SYMPTOMS STARTED IN 2006 WITH ABSOLUTELY DEBILITATING FATIGUE. IN 2009, OTHER SYMPTOMS STARTED WHICH INCLUDED EXTREME, EXCRUCIATING HEADACHES, TREMORS, LOSS OF FEELING IN ARMS WHILE LYING DOWN, LOSS OF MOTOR SKILLS IN RIGHT HAND (ON AND OFF) AND BLOOD PRESSURE DROPPING SUDDENLY AND DRAMATICALLY. IN 2012 OTHER SET OF SYMPTOMS STARTED WHICH INCLUDED CHEST PAIN, EXTREME DIGESTIVE ISSUES, MAJOR BLOATING, DIARRHEA, CONSTIPATION, LEG CRAMPS, INSOMNIA, DEPRESSION, WEIGHT GAIN, SEVERE JOINT PAIN, SUDDEN UNEXPLAINED FEVERS, WEAKENED IMMUNITY AND ALL OVER GENERAL PAIN. AS EACH SYMPTOM BEGAN, THE OTHERS HAVE CONTINUED ON, SO TODAY I EXPERIENCE EVERY SINGLE ONE OF THE SYMPTOMS, MANY OF THEM ON A DAILY BASIS. I HAVE BEEN TO NUMEROUS, NUMEROUS DOCTORS AND OTHER THAN THE ESSURE DEVICE, THERE IS NO OTHER DIAGNOSIS FOR MY SYMPTOMS, PAINS AND ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055727	BAYER	8/19/2015	8/25/2015

Event Information:

Event Date (B3): 3/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): C22909

Single Use: *
Implant Date (E6): 3/17/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE PROCEDURE I BEGAN HAVING EXTREME PAIN IN MY PELVIS AND LOWER BACK, PRESSURE IN MY PELVIS AND LOWER BACK, HEAVY MENSTRUAL CYCLES THAT LAST 8-12 DAYS, FATIGUE AND WEAKNESS, PAIN DURING INTERCOURSE, OCCASIONAL BLEEDING FOLLOWING INTERCOURSE, AND BLOATING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00622	BAYER HEALTHCARE LLC	8/20/2015	8/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C55836

Single Use: Y
Implant Date (E6): 7/14/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 28-JUL-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR STERILIZATION (LOT NUMBER C55836). SHE WAS NOT PREGNANT. PHYSICIAN REPORTED THAT IT SEEMED TO BE A PROBLEM WITH ONE OF THE COILS. AS THE DOCTOR WAS DRAWING AND DIALING BACK AFTER PLACING ON LEFT SIDE, THEN 3-4 COILS SPRING OUT INTO THE ENDOMETRIAL CAVITY. HE COULD SEE THERE WAS LIKE A PARTIAL PIECE OF THE DEVICE, THERE WAS NO INNER COIL IN THAT TUBE. PHYSICIAN RIGHT PLACED THE RIGHT SIDE FINE WITH NO RESISTANCE. A NEW DEVICE PLACED EASILY IN THE LEFT SIDE. PTC INVESTIGATION RESULT WAS RECEIVED ON 05-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C55836 (PRODUCTION DATE 31-MAY-2017 AND EXPIRATION DATE 15-MAY-2014) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE CANNOT CONFIRM THIS QUALITY COMPLAINT; HOWEVER, BASED ON THE COMPLAINT DESCRIPTION PROVIDED, WE ARE ABLE TO CONCLUDE THAT A QUALITY ISSUE IS PLAUSIBLE. IT IS POSSIBLE DURING THE MANUFACTURING ASSEMBLY PROCESS A SMALL GAP WAS LEFT BETWEEN THE INNER COIL AND INNER CATHETER (THEY SHOULD BE BUTTED TOGETHER DURING ASSEMBLY). WHEN THE OUTER COIL OF THE MICRO-INSERT IS WOUND DOWN A SMALL

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PORTION OF THE COIL CAN BECOME TRAPPED IN THE GAP. IF A DEVICE HAS THIS ISSUE, WHEN THE PHYSICIAN PRESSES THE BUTTON TO RELEASE THE MICRO-INSERT, THE OUTER COIL MAY SEVER ITSELF AS IT IS BEING DEPLOYED FROM THE CATHETER. THIS SEVERING OCCURS INSIDE THE CATHETER PRIOR TO THE PIECES BEING DEPLOYED FROM THE CATHETER. THE SEVERING OF THE COILS INSIDE THE CATHETER DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PATIENT. THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE IN THE CONTEXT OF A COMPLICATED INSERTION. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT - BUT PLAUSIBLE. ACCORDING TO THE TECHNICAL ASSESSMENT A QUALITY DEFECT WAS NOT CONFIRMED BUT CONSIDERED PLAUSIBLE. ALTHOUGH THE TECHNICAL INVESTIGATION CONCLUDED A POTENTIAL CAUSAL RELATIONSHIP BETWEEN THE ISSUE REPORTED AND A QUALITY DEFECT, THE ASSIGNED FINAL RISK CATEGORY IV REFLECTS A DEFECT WHICH WOULD NOT POSE A HAZARD TO PATIENT'S HEALTH. BASED ON THE PROVIDED INFORMATION THE DEFECT TYPE CORRESPONDS TO THE FOLLOWING MEDDRA LLT: DEVICE BREAKAGE. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. A CAUSAL RELATIONSHIP BETWEEN THE POTENTIAL PRODUCT QUALITY ISSUE AND ADVERSE EVENTS CANNOT BE ASSESSED, AS NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, 3-4 COILS SPRING OUT INTO THE ENDOMETRIAL CAVITY ON THE LEFT SIDE; ACCORDING TO THE PHYSICIAN THERE WAS LIKE A PARTIAL PIECE OF THE DEVICE, THERE WAS NO INNER COIL IN THAT TUBE. THE REPORTED EVENT, REGARDED AS DEVICE BREAKAGE, WAS CONSIDERED NON-SERIOUS AND ASSESSED AS LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS DID NOT CONFIRM A QUALITY DEFECT BUT CONSIDERED IT PLAUSIBLE. ALTHOUGH THE TECHNICAL INVESTIGATION CONCLUDED A POTENTIAL CAUSAL RELATIONSHIP BETWEEN THE ISSUE REPORTED AND A QUALITY DEFECT, THE ASSIGNED FINAL RISK CATEGORY IV REFLECTS A DEFECT WHICH WOULD NOT POSE A HAZARD TO PATIENT'S HEALTH. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION (DEVICE BREAKAGE QUESTIONNAIRE) RECEIVED ON 02-SEP-2015 FROM PHYSICIAN: THE ESSURE (ESS305) WAS INSERTED ON (B)(6) 2015 BECAUSE PATIENT DESIRED STERILITY, LOT NUMBER C55836 AND EXPIRATION DATE MAY-2017. IT WAS REPORTED THAT THE INSTR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00623	BAYER HEALTHCARE LLC	8/20/2015	8/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627735

Single Use: Y
Implant Date (E6): 7/17/2009
Explant Date (E7): 7/23/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON (B)(6)-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5032525, RECEIVED AT FDA ON 31-OCT-2013). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED CONSTANT PELVIC PAIN, TORN FALLOPIAN TUBES, DEVICE MIGRATION, HEAVY CLOTTING AND CRAMPING, MUSCLE SPASMS, LOW POTASSIUM AND MAGNESIUM, NUMBNESS IN EXTREMITIES, SEVERE BLOATING, EXACERBATED DEPRESSION, ANXIETY, PTSD (POSTTRAUMATIC STRESS DISORDER), ENVIRONMENTAL ALLERGIES, BRAIN FOG, BLACKOUTS, JOINT STIFFNESS, HEART PALPITATIONS, MEMORY LOSS, HAIR LOSS, DEVICE EMBEDDED IN SURROUNDING TISSUES/ORGANS, HEADACHES, FATIGUE, AUTOIMMUNE DIAGNOSIS, SWELLING FEET AND LEGS, HIP PAIN, TINGLING SENSATIONS, URGENCY TO URINATE, BLURRED VISION, CHRONIC ILLNESS, FRAGILE NAILS, WEIGHT GAIN, DIGESTIVE ISSUES, TEETH ISSUES, ITCHY SKIN, VIBRATING SENSATION IN ABDOMEN. FDA REPORT TYPE WAS [?]INJURY', REPORTED OUTCOME OF EVENTS WAS 'REQUIRED INTERVENTION' NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6)-2009, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 627735, IMPLANTED. CONSUMER REPORTED HER COMPLAINTS ARE CONSTANT PELVIC PAIN, TORN FALLOPIAN TUBES, DEVICE MIGRATION, HEAVY CLOTTING AND CRAMPING, MUSCLE SPASMS, LOW POTASSIUM AND MAGNESIUM, NUMBNESS IN EXTREMITIES, SEVERE BLOATING, EXACERBATED DEPRESSION, ANXIETY, PTSD (POSTTRAUMATIC STRESS DISORDER), ENVIRONMENTAL ALLERGIES, BRAIN FOG, BLACKOUTS, JOINT STIFFNESS, HEART PALPITATIONS, MEMORY LOSS, HAIR LOSS, DEVICE EMBEDDED IN SURROUNDING TISSUES/ORGANS, HEADACHES, FATIGUE, AUTOIMMUNE DIAGNOSIS, SWELLING FEET AND LEGS, HIP PAIN,

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TINGLING SENSATIONS, URGENCY TO URINATE, BLURRED VISION, CHRONIC ILLNESS, FRAGILE NAILS, WEIGHT GAIN, DIGESTIVE ISSUES, TEETH ISSUES, ITCHY SKIN, VIBRATING SENSATION IN ABDOMEN. EVENT START DATE WAS REPORTED AS (B)(6)-2009. ESSURE WAS EXPLANTED ON (B)(6)-2013. NO FURTHER DETAILS WERE REPORTED. FOLLOW-UP RECEIVED ON 23-JAN-2014: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT RECEIVED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC) - INCIDENT REPORT. (B)(4). IF THE OUTCOME OF THE PTC INVESTIGATION CONFIRMS A QUALITY DEFECT OR A COUNTERFEIT, THIS WILL BE COMMUNICATED IN A FOLLOW-UP REPORT. FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN WI-03635, "PROCESSING ESSURE CASES IN (B)(4)" FDA EVALUATION: METHOD: MANUFACTURING REVIEW. RESULTS: NO RESULTS AVAILABLE SINCE NO EVALUATION PERFORMED. CONCLUSIONS: UNABLE TO CONFIRM COMPLAINT; 92 - DEVICE NOT RETURNED. MEDICAL ASSESSMENT: THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE FOR A QUALITY DEFICIT PER SE. THE EVENTS WERE REPORTED WITH AN OCCURRENCE OVER A PERIOD OF 3,5 YEARS AND ARE OF BROAD NATURE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 627735. NO BATCH SIGNAL COULD BE IDENTIFIED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE REVIEW OF THE LOT HISTORY RECORDS FOUND THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AT TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW UP INFORMATION RECEIVED ON 03-FEB-2014: ALL FOLLOW UP ATTEMPTS DONE. CASE CLOSED. FOLLOW UP INFORMATION RECEIVED ON 29-JUL-2015 FROM CONSUMER VIA REGULATORY AUTHORITY (CASE #MW5042877): ESSURE WAS INSERTED ON (B)(6)-2009 AND REMOVED ON (B)(6)-2013. SHE REPORTED THAT SHE HAD TO GET A HYSTERECTOMY DESPITE HAVING ESSURE COILS REMOVED IN 2013 BECAUSE OF DEVELOPMENT OF ADENOMYOSIS AND INCREASED COMPLICATIONS OF ENDOMETRIOSIS. AFTER SHE HAD CYSTS ON RIGHT OVARY AND IN RIGHT FALLOPIAN TUBE, AFTER HYSTERECTOMY HAD TO BE READMITTED DUE TO AN INFECTION OF UNKNOWN ORIGIN REQUIRING A 3 DAY HOSPITAL STAY WITH IV (INTRAVENOUS) ANTIBIOTICS. SHE MENTIONED XANAX AS CONCOMITANT MEDICATION. FOLLOW UP INFORMATION RECEIVED FROM THE DUPLICATE CASE 2013-140707 IDENTIFIED ON 31-JUL-2015: CONSUMER REPORTED VIA SOCIAL MEDIA THAT SHE WAS MISERABLE AND IT WAS HARD TO FUNCTION. SHE JUST KEPT GETTING WORSE INSTEAD OF GETTING BETTER. SHE HAD PAIN IN HER PELVIS AND LOWER BACK, CRAMPING AND ODD SICKNESS AFTER HAVING THE ESSURE MICRO-COIL IMPLANTED INTO HER FALLOPIAN TUBES AS PERMANENT BIRTH CONTROL. FOLLOW UP 31-JUL-2015: NEW REPORTERS ADDED FROM THE DUPLICATE CASE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED 4 YEARS AFTER ITS INSERTION. THE DEVICE UNDERWENT MIGRATION AND WAS EMBEDDED IN SURROUNDING TISSUES/ORGANS. ADDITIONALLY SHE REPORTED HEAVY CLOTTING, TORN FALLOPIAN TUBES, BLACKOUTS AND AUTOIMMUNE DIAGNOSIS. AFTER ESSURE REMOVAL SHE WAS HOSPITALIZED DUE TO AN INFECTION OF UNKNOWN ORIGIN BLACKOUTS, AUTOIMMUNE DIAGNOSIS AND INFECTION ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE OTHER EVENTS ARE LISTED. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THIS CASE DEVICE MIGRATION/EMBEDDEMENT IN SURROUNDING TISSUES/ORGANS WAS REPORTED AND ESSURE WAS REMOVED, SO THIS EVENT WAS CONSIDERED AS CAUSALLY RELATED TO ESSURE. FOR THE EVENT TORN FALLOPIAN TUBES, AS NO INFORMATION WAS PROVIDED ABOUT ITS CHARACTERISTICS, THE CAUSALITY CANNOT BE ASSESSED. REGARDING THE EVENT HEAVY CLOTTING, CONSUMER WAS DIAGNOSED WITH ENDOMETRIOSIS, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THIS EVENT; HOWEVER SINCE ABNORMAL GENITAL BLEEDINGS MAY OCCUR DURING ESSURE THERAPY, CAUSALITY CANNOT BE EXCLUDED. FOR BLACKOUTS, CONSIDERING ITS NATURE; CAUSALITY WITH ESSURE IS CONSIDERED

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UNLIKELY. THE REMAINING EVENT (INFECTION) WAS REPORTED AFTER A HYSTERECTOMY DUE TO ADENOMYOSIS/COMPLICATIONS OF ENDOMETRIOSIS, THUS IT WAS CONSIDERED UNRELATED TO ESSURE. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE ESSURE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055529	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 9/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TOTALLY HORRIBLE FROM DEBILITATING HEADACHES TO FEELING BLOATED . PELVIC PAIN THAT WAS SO BAD I COULDN'T WALK . INSOMNIA AND HAIR FALLING, INFLAMMATION AND NOW DIAGNOSE WITH FIBROMYALGIA. I WAS PERFECTLY FINE BEFORE ESSURE . AFTER ONE YEAR OF ESSURE IMPLANT EVERYTHING IN MY HEALTH CHANGE , I WAS BLEEDING EXTREMELY AND IN PUBLIC PLACES WAS THE WORST AND IT WAS VERY EMBARRASSING TO BLEED OUT EVERY WHERE IN FRONT OF EVERYONE . THIS DEVICE SHOULD BE REMOVE I HAVE SO BAD JOINT PAIN AND INFLAMMATION THAT I WILL UNDERGO SURGERY ON MY FOOT TO RELEASE A NERVE .

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055530	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WITHIN 2 MONTHS, FULL BODY URTICARIA PAINFUL AND BURNING. LED TO HASHIMOTOS, POLYGLANDULAR TYPE II, IBD, FIBRO, REYNOUDS, RLS, INSOMNIA, MAJOR DEPRESSIVE DISORDER. HAIR LOSS, SKIN THINNING, BRUISING, TURNING COLORS, FLUSHING, HEART PALPITATIONS. RUINED MY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055531	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I HAD THEM PUT IN I STARTED HAVING PAIN RIGHT AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055532	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 5/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN GETTING ESSURE PUT IN 2010...WHEN THEY CAME TO DO MY LEFT SIDE IT ESSURE WOULDN'T GO IN PROPERLY SO THEY PULLED IT OUT AND SAID IT HAD BENT ..SO THEY TRIED AGAIN..AS THEY TRIED AGAIN THE PAIN IN MY LEFT SIDE WAS EXTREME AND THEY HAD SAID IT WAS JUST CRAMPS.... I KNOW WHAT CRAMPS ARE BUT THEY WERE NOTHING LIKE THIS...SO THEY FINALLY PUT IT IN...AND SINCE THAT DAY I STILL HAVE EXTREME PAIN IN MY LEFT SIDE AND WHEN I GO FOR SCANS NOTHING SHOWS UP..ALSO WHEN I WENT FOR MY 3MONTH SCAN THE SCAN OPERATOR SAID I THINK THEY ARE IN THE RIGHT PLACE..SO THAT GAVE ME NO CONFIDENCE...AND STILL TO THIS DAY 5YEARS ON AND LOADS MORE SCANS STILL IN EXTREME PAIN....HAVE BEEN GIVEN THE COIL TO HELP WITH PERIODS AND PAIN...AND IT DOESN'T DO EITHER...AND PAIN STILL THERE EVERY DAY AND PAIN KILLERS TAKEN EVERY DAY... ESSURE I THINK NEEDS TO BE TAKEN OFF THE SHELVES AND RECALL EVERYONE WHO HAS IT.....I AM AT MY WITS END WITH THIS PAIN...ONLY SO MANY PAIN KILLERS YOU CAN TAKE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055533	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVELOPED LARGE OVARIAN CYST, INCREASED WEIGHT GAIN, HEADACHES, DAILY ABDOMINAL PAIN, LEG PAIN, NAUSEA, INCREASED ANXIETY/DEPRESSION, SEVER PAIN DURING MY PERIOD, VERY HEAVY BLEEDING DURING MY PERIOD, LARGE CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055534	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BLOATING, PAINFUL AND HEAVY PERIODS, SEVERE MOOD SWINGS, INSOMNIA, ANXIETY, PANIC ATTACKS, NO SEX DRIVE, PAINFUL INTERCOURSE, PELVIC PAIN, LOWER BACK PAIN, HAIR LOSS, WEIGHT GAIN AND INABILITY TO LOOSE WEIGHT, MIGRAINES, LOSS OF VISION, MUSCLE SPASMS, SHARP PAIN IN MY LADY PARTS, SENSITIVE SKIN, SENSITIVE BREASTS AND THE LIST CAN GO ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055535	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 10/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PERIOD STARTED AND LASTED FOR 3 MONTHS STRAIGHT NONSTOP VERY HEAVY, I HAD TO USE SUPER PLUS TAMPONS AND PADS EVERY SINGLE DAY. I HAVE BECOME A SEVERE ANEMIC DUE TO MY BLOOD LOSS. SINCE THEN MY PERIOD HAS NEVER BEEN THE SAME. IT COMES VERY OFTEN AND SUPER HEAVY, I ALSO PASS A LOT OF CLOTS AND THE PAIN CAN BE EXCRUCIATING AT TIMES. I CAN'T NOT LOSE ANY WEIGHT I JUST GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055536	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 9/1/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, CONSTANT BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055537	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 2/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOTTING, ABDOMINAL PAIN, BACK PAIN, JOINT PAIN, HEAVY PERIODS, BAD CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055538	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 1/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PALPITATIONS, HEAVY PERIOD LASTING LONGER THAN BEFORE PLACEMENT, CERVICAL PROLAPSE, MIGRAINES, BACK AND HIP PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055539	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). KEEP GAINING WEIGHT AND FEELING BLOATED ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055540	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN AREA OF IMPLANTS, SEVERE PAIN IN LOWER BACK TO THE POINT IT WAS DIFFICULT TO STAND OR SIT, CHANGES IN BOWEL HABITS FROM LOSE TO CONSTIPATION, CHANGES IN DIGESTION ABILITIES, HIVES, HEAVY PERIODS, MIGRANES, ACNE, WEIGHT GAIN, DEPRESSION, ANXIETY, ONSET OF FIBROIDS, AND LAB DATA SHOWS A COIL WAS SOME HOW BROKEN INTO 2 WHILE INSIDE MY BODY AND THAT IRRITATION OCCURED IN MY TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055541	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 7/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAVE DECIDED THAT I WANTED ALL MY WOMAN PARTS SAVED. I DECIDED TO DO A REVERSAL (B)(6) 2015. I HAVE NOTICE I DO NOT TAKE ANY TYLENOL OR ADVIL FOR MY MIGRAINES. IT HAS GONE AWAY. MY BLOATING HAS COME DOWN SOME. I DONT KNOW ABOUT MY CYCLES YET CAUSE I'M WAITING FOR MY NEXT CYCLE. I HAVEN'T HAD INTERCOURSE YET TO SEE ABOUT MY ABDOMINAL PAINS. HAVEN'T FELT SHARP PAINS WHEN I SQUAT. I STILL HAVE MEMORY LOSS.(FORGETFUL) HAIR HASN'T THICKEN UP YET. EVERYTHING IS STILL NEW I HAVE TO WAIT AND SEE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055563	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS,WEIGHT GAIN, PAINFUL PERIODS, HEAVY PERIODS, PERIODS EVERY 2 WEEKS, ABD PAIN, SIDE PAIN, DRY SKIN, DEPRESSION, HEADACHES, RINGING IN EARS, DIZZINESS, HOT FLASHES, HOT HANDS, INABILITY TO LOSE WEIGHT, INCREASED EMOTIONAL MOODS SWINGS, VOMITING, DIARRHEA, BODY ACHES, BLOATING. GI DOCTOR THOUGHT I HAD A BRAIN TUMOR. ONSET WAS (B)(6) 2007.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055564	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 6/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE COILS PLACED IN (B)(6) OF 2013 FROM THEN ON I HAVE HAD PELVIC PAIN AND PAINFUL INTERCOURSE IT'S A STABBING PAIN. I ALSO HAVE PAINFUL OVULATION

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055565	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/22/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CLUSTER HEADACHES, ABDOMINAL PAIN, BLEEDING 3 WEEKS OUT OF THE MONTH FOR 7 YEARS, TASTING METAL, FOUL ODOR LIKE ROTTING FLESH, DEPRESSION, WEIGHT GAIN, FOGGIEST OF MIND, MIGRAINE HEADACHES, STABBING PAINS LIKE I WAS GETTING CUT, NO LIBIDO, 3 INSERTED COILS INSTEAD OF 2 BECAUSE ONE MIGRATED INTO MY UTERUS AND WAS IN PIECES, ENDOMETRIOSIS, FIBROIDS. END RESULT WAS A COMPLETE HYSTERECTOMY WHICH HAS THROWN ME INTO EARLY MENOPAUSE WITH UNBEARABLE HOT FLASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055566	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OF THE 2 COILS THAT WERE PLACED, 1 MY BODY REJECTED AND CAME OUT THROUGH MY VAGINA. THE OTHER COIL MIGRATED AND MISPLACED ITSELF INTO MY UTERUS. THIS CAUSES EXCRUCIATING PAIN, CRAMPING, NAUSEA, BLEEDING, 10-15 DAY MENSTRUAL CYCLES, HEADACHES, INFECTIONS AND INSOMNIA. THIS WAS DISCOVER DISCOVERED THROUGH AN ULTRASOUND. THE RESULT IS A RECOMMENDED HYSTERECTOMY, WHICH OF COURSE SEEMS EXTREME FOR MY YOUNG AGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055567	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED TO GET BURNING SENSATIONS ALL OVER MY BODY. WHEN THEY WOULD APPEAR THEY WOULD TURN INTO RED LINES AND/OR RASHES. WITH AN INTENSE ITCHING. THIS WOULD GO ON FOR AN HOUR SOMETIMES. MY PERIOD WENT FROM A 3 DAY LIGHT FLOW TO A 7 DAY HEAVY FLOW WITH CLOTTING AND MASSIVE CRAMPS. SOME DAYS I COULDN'T EVEN GET OUT OF BED, SOME DAYS I WOULD HAVE TO TAKE A HEATING PAD TO WORK. I STARTED HAVING HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055568	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 9/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). COILS WERE INSERTED IN (B)(6) 2010, ONLY 2 MONTHS AFTER THE BIRTH OF MY SECOND DAUGHTER. I HAD THE NORMAL CRAMPING/PAIN INVOLVED WITH THE PROCEDURE, BUT BLED FOR ABOUT 2 MONTHS STRAIGHT AFTERWARD. A TOTAL OF ALMOST 4 MONTHS POST PARTUM BLEEDING ALL TOGETHER. I STILL HAD PAIN ON BOTH SIDES OF MY LOWER ABDOMEN AROUND 6 MONTHS LATER AND WENT BACK TO MY OB/GYN WHO DID INSERTION. MY PAIN AND PROBLEMS WERE THROWN UP TO FIBROMYALGIA AND POST POSTPARTUM DEPRESSION. NOTHING WAS DONE TO CORRECT THE PAIN I WAS STILL EXPERIENCING. I STILL HAVE THE COILS NOW IN 2015 AND HAVE EXPERIENCED IRREGULAR MENSTRUATION, PAINFUL CRAMPING, SHARP STABBING PAINS IN BOTH SIDES OF LOWER ABDOMEN, BUT MOSTLY ON THE LEFT SIDE. BLOATING THAT MAKES ME LOOK 8 MONTHS PREGNANT, AND RAPID WEIGHT GAIN. THE BLOATING IS ALWAYS THE WORST AT THE END OF THE DAY AND THE PAIN IS ALWAYS THE WORST AT THE END OF THE DAY. I HAVE INSOMNIA, HORRIBLE HAIR LOSS TO THE POINT WHERE A PONY TAIL IS NO THICKER THAN A PENCIL. I HAVE ALSO DEVELOPED SKIN UNCONTROLLABLE SKIN PROBLEMS THAT ITCH LIKE ALLERGIC REACTIONS AND LOOK LIKE ECZEMA IN RANDOM PLACES ON MY BODY. I ALSO NOW HAVE JOINT PAIN AS WELL AS AN ALLERGY ALL ANY AND ALL METAL JEWELRY. I CAN'T EVEN WEAR MY WEDDING RINGS ANYMORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055569	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, BACK PAIN, HAIR LOSS, CRAMPS, PAIN IN MY OVARIES, MOOD DISORDER, SKIN RASH, VITAMINS DEFICIENCY, BLOOD BETWEEN PERIODS, RECURRENT VAGINOSIS, VAGINAL ODOR DIFFERENT, TIREDNESS, HEADACHE ALMOST ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055570	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 4/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ALWAYS HAD NORMAL PERIODS 4-5 DAYS. VERY LIGHT AND NO CRAMPING. SINCE HAVING THE ESSURE I HAVE HAD IRREGULAR PERIODS, NON STOP SPOTTING AND HORRIBLE CRAMPS. I AM STILL ON BIRTH CONTROL PILLS TO HELP WITH THE EVERYDAY BLEEDING/SPOTTING. I STAY FEELING BLOATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055571	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 12/31/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE (B)(6) WHEN I HAD THE ESSURE IMPLANTED I AM CONSTANTLY ON AN EMOTIONAL TRAIN. MY PERIODS ARE LONGER AND HEAVIER, MY HAIR IS THINNING, I HAVE FACIAL ACNE THAT I DIDN'T HAVE EVER BEFORE, LOWER BACK PAIN, SPORADIC PAINS AROUND STOMACH AND LOWER BACK, HEADACHES, CONFUSION, MEMORY LOSE, HOT FLASHES, NIGHT SWEATS, PAINFUL OVULATION, PAINFUL MENSTRUALS, PAIN AFTER INTERCOURSE, SEVERE BLOATING, HEARTBURN, HEADACHES, ANXIETY, FORGETFULNESS, DIZZINESS, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055572	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY MONTHLY HAVE BEEN SO BAD I HAVE MISSED WORK AND ITS HARD TO TAKE CARE OF MY SON. WHEN IT THAT TIME OF THE MONTH I FEEL LIKE I HAVE NO ENERGY. I GET PALE, FEEL NAUSEATED, PAIN IN MY PELVIC AREA, HIPS AND BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055573	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED EXPERIENCING A SHARP, STABBING PAIN IN MY RIGHT PELVIC AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055574	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 4/11/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HOT FLASHES, NIGHT SWEETS, NAUSEA, VOMITING, MIGRAINES, FATIGUE, WEIGHT GAIN, HAIR LOSS, EXTREME SEVERE CRAMPS, HEAVY BLEEDING, LEG PAIN, SWELLING, RASHES, ACNE, POOR QUALITY OF LIFE. VERY HARD TO WORK A FULL TIME JOB BECAUSE OF ALL THE PAIN ASSOCIATED WITH ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055575	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, ABDOMINAL PAIN, FOGGY HEAD, DEPRESSION, BELLY WEIGHT GAIN, LOWER BACK PAIN, LOSS OF ENERGY, CHANGE IN PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055576	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 5/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, ABNORMAL MENSES, DISCHARGE (NO ODOR), HOT FLASHES, NIGHT SWEATS, LOSS OF SEXUAL INTEREST, SEXUAL DYSFUNCTION (CAN'T OBTAIN SATISFACTION), AMENORRHEA, VULVODYNIA, ABDOMINAL TWITCHING, BACK AND JOINT PAINS, BODY ACHES, MIGRAINES, ANXIETY ATTACKS, MOOD SWINGS, DEPRESSION, TINGLING IN HANDS, FOOD SENSITIVITIES, CYSTS AND BOILS, HAIR GROWTH IN NEW PLACES, DENTAL ISSUES, PSORIASIS OF THE SCALP, SUICIDAL THOUGHTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055577	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE IN (B)(6) 2009. SINCE THEN I HAVE HAD A SEVERE ALLERGIC REACTION CAUSING MY ENTIRE BODY TO BE BROKE OUT IN HIVES. I HAVE BEEN DIAGNOSED WITH PSORIASIS. I HAVE TERRIBLE PERIODS WITH CLOTS OF BLOOD THAT CAN LAST FROM 3 DAYS TO 3 MONTHS, NON-STOP. MY HAIR HAS FALLEN OUT. I ALWAYS HAVE A METALLIC TASTE IN MY MOUTH. MY TEETH, THAT HAVE BEEN WELL TAKEN CARE OF ARE CRUMBLING TO PIECES. I HAVE ALMOST EVERY VITAMIN DEFICIENCY. MY BONES AND JOINTS HURT ON A DAILY BASIS. I HAVE BEEN DIAGNOSED AS CHRONICALLY DEPRESSED. I HAVE HAD SEVERAL UTI'S, BLADDER INFECTIONS, AND KIDNEY STONES. AND, MOST RECENTLY (BUT NOT THE FIRST TIME), I HAD A LARGE CYST ON MY OVARY BURST FEELING LIKE LABOR PAINS AND SENDING ME TO THE HOSPITAL. I AM NOW SCHEDULED FOR A HYSTERECTOMY AT THE AGE OF (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055578	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M WRITING IN REGARDS TO ESSURE AND THE ISSUES IT HAS CAUSED MY FAMILY AND I. I WAS IMPLANTED IN 2011, AFTER HAVING MY 3RD CHILD. I WAS TOLD IT WAS A BETTER OPTION FOR ME THAN SURGERY TO TIE MY TUBES BECAUSE I HAD MY CHILDREN NATURALLY. I DIDN'T WANT TO HAVE SURGERY OR DEAL WITH RECOVERY WHILE CARING FOR A NEW BORN. AT FIRST, I THOUGHT IT WAS GREAT. I HAD LOTS OF JOINT PAIN, HEADACHES, NAUSEA, DIZZY SPELLS, AND MORE BUT NEVER CONNECTED THE ISSUES WITH ESSURE. I HAVE BEEN TESTED FOR RA, FOR THE SEVERE JOINT PAIN, BUT THE TESTS WERE NEGATIVE. I HAVE PAIN DURING AND AFTER SEX AND ALSO HAVE BLEEDING AT TIMES AS WELL. A FEW MONTHS AGO I BEGAN TO HAVE HEART PALPITATIONS AND DIFFICULTY BREATHING. AFTER SEVERAL TRIPS TO THE ER AND MY PHYSICIAN ALL MY TESTS HAVE COME BACK NORMAL. ALL TEST SHOW THAT I AM PERFECTLY HEALTHY AND SHOULD NOT BE EXPERIENCING THESE ISSUES. I KNOW ESSURE IS CAUSING THIS. I HAVE A LONG LIST OF SIDE EFFECTS I ATTRIBUTE TO ESSURE WHICH I WILL LIST NOW: CRAMPING, HEAVY BLEEDING/CLOTTING, HAIR LOSS, STABBING PELVIC PAIN, DISCHARGE, HOT FLASHES, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS, CONTRACTING OF THE UTERUS, ALL OVER BODY ACHES, NAUSEA, DIZZINESS, JOINT PAIN, METALLIC TASTE IN MOUTH, BLOATING, MOOD SWINGS, BRAIN FOG, RINGING IN EARS, EASILY BRUISED, METAL ALLERGY, HEIGHTENED ALLERGIES, HEART PALPITATIONS, GALLBLADDER ISSUES HAD TO HAVE IT REMOVED, VISION PROBLEMS, DRY SKIN/HAIR, NUMBNESS OF HANDS/FEET. I JUST RECENTLY WENT TO MY DOCTOR TO REQUEST TESTS TO SEE IF THE COILS ARE IN PLACE AND TO SEE OF I HAVE DEVELOPED ANY ISSUES WITH MY UTERUS/CERVIX/AND OR TUBES SO DO NOT HAVE THIS INFORMATION AT THIS TIME.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055579	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 11/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

FOLLOWUP# 4 MW5055579. (B)(4). ABDOMINAL SUPRACERVICAL HYSTERECTOMY/BILATERAL SALPINGECTOMY TO REMOVE ESSURE FROM MY BODY. WITHIN HOURS AND THEN DAYS FOLLOWING SURGERY, THE FOLLOWING ESSURE-RELATED SYMPTOMS SUBSIDED AND RESOLVED COMPLETELY: HEADACHE, BRAIN FOG, INABILITY TO CONCENTRATE, INFLAMMATION IN BELLY (LOST 7 INCHES IN 24 HOURS), CHRONIC JOINT PAIN AND INFLAMMATION (USED A CANE FOR TWO MONTHS, AND SUDDENLY, NONE OF MY JOINTS HURT AT ALL!), MY EYES ARE BRIGHT, I'M MORE ALERT, I CAN FALL ASLEEP NOW, AND WAKE UP FEELING RESTED, EVEN AFTER JUST 6-7 HOURS OF SLEEP. INSOMNIA RESOLVED, DIFFICULTY WAKING RESOLVED, ANXIETY, DEPRESSION, MOOD SWINGS - RESOLVED. CHRONIC ACNE - GONE. SWOLLEN FACE AND NECK - GONE. PAINFUL MOVEMENT OF HANDS AND EXTREMITIES - GONE. EVEN WITH THE PAIN OF AN ABDOMINAL INCISION AND A URETHRA/BLADDER INJURED BY THE CATHETER DURING AND RIGHT AFTER SURGERY, I HAVEN'T FELT BETTER IN 15 MONTHS THAN I FEEL TODAY. I WILL CONTINUE TO UPDATE AS MORE SYMPTOMS RESOLVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055580	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY MENSTRUAL CYCLE, PAIN IN VAGINAL AREA, CONSTANT PAIN WHEN ON MY CYCLE, CRAMPING, JUST A LOT OF UNEXPLAINED ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055581	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 9/17/2007	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN PELVIC AREA, STABBING PAIN IN ALTERNATE SIDES WHERE MY TUBES ARE. BLOATING TO THE POINT WHERE I AM ASKED IF I AM PREGNANT, TERRIBLE PERIODS, WITH LARGE CLOTS THAT ARE PAINFUL TO PASS, MOOD SWINGS, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055582	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SIGNIFICANT HAIR LOSS. I HAVE AN EXTREME VITAMIN D DEFICIENCY THAT I HAVE NEVER HAD. EXTREME LOSS OF ENERGY, BARELY ABLE TO STAY AWAKE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055593	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, ABNORMAL MENSES, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION, NIGHT SWEATS, LOSS OF LIBIDO, PAINFUL PERIODS, BLEEDING BETWEEN PERIODS, LONG MENSTRUAL CYCLES, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, LOWER BACK PAIN, METALLIC TASTE IN MOUTH, HEARTBURN, HEADACHES, ANXIETY, DEPRESSION, RINGING IN EARS, HIVES, ACNE, WEIGHT GAIN, MUSCLE SPASMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055594	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PAIN HAS BEEN DAILY. MY PAIN IS ON BOTH SIDES, BUT HURTS THE WORST ON THE LEFT. MY PAIN MIGRANTS FROM MY TUBES, PELVIC AREA, HIP, AND DOWN MY RIGHT LEG. NOTHING TAKES MY PAIN AWAY! SOME DAYS I HAVE A HARD TIME WALKING, TRY THIS WITH FOUR EAGER CHILDREN. SOME DAYS IT'S HARD TO DRIVE MY CAR FROM THE PAIN. I'M ALSO SUFFERING FROM OVARIAN CYST AND ENDOMETRIOSIS. Y OTHER SYMPTOMS HAVE BEEN EXTREME TIREDNESS, HAIR LOSS, FORGETFULNESS, AND JOINT PAIN. I ALSO HAVE EXTREME PAIN DURING INTERCOURSE. I'M ALSO EXPERIENCING A PERIOD EVERY TWO WEEKS. AT TIMES I'M UNABLE TO USE A TAMPON BECAUSE SOMETHING IS BLOCKING THE AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055611	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). REPEAT UTI.....LATER FOUND OUT A COIL HAD MIGRATED TO UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055612	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INCREASED MIGRAINES, EXTREME FATIGUE, BODY ACHES, EXTREMELY HEAVY BLEEDING DURING PERIODS (THIS STARTED IN 2013).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055614	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMPLANTED APPROX 5 YEARS AGO. SINCE THEN I HAVE: GAINED OVER 70LBS; INCONTINENCE; ZERO LIBIDO; DEPRESSION; HAIR LOSS; CONSTANT HEADACHES; UNEXPLAINED RASHES/BREAKOUTS; ACNE; CRAMPING; HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055618	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, HAIR LOST, PAINFUL INTERCOURSE, HIGH BLOOD PRESSURE,BLOATING, WEIGHT GAIN,LOW SEX DRIVE, GAS,OVARIAN CYST, UTI, BACTERIA VAGINITIS, AND HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055625	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: N
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WELL STARTED THE MONTH AFTER GETTING THE ESSURE PLACE STARTED HAVING PAINS DURING INTERCOURSE URINARY TRACT INFECTIONS ALL THE TIME ,PELVIC PAIN, MEMORY LOSS, SEVERE NECK AND HEAD PAIN. MIGRAINES TO THE POINT THAT MADE ME SICK AND NO MEDS WOULD WORK TO STOP THE HEADACHE, WEIGHT GAIN, METAL TASTE IN THE MOUTH, HAIR LOSS , AND TEETH PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055626	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE PELVIC PAIN THAT SHOOT DOWN MY LEG THAT HAS NOT GONE AWAY SINCE PLACEMENT OF THE ESSURE DEVICE IN (B)(6) 2014 AND MY CRAMPS DURING MY MONTHLY CYCLE HAS GOTTEN MORE AND MORE PAINFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055627	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 6/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN OVARY AREA ON INSIDES OF HIPS, HEAVY MENSTRUAL PERIODS, HEADACHES FREQUENTLY, ALLERGIES ALL YEAR LONG WHEN THEY HAD BEEN SEASONAL, LOSS OF SEX DRIVE, MEMORY LOSS IS THE WORST SYMPTOM FOR ME, HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055628	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN HAVING PELVIC PAIN CONSTANTLY. I HAVE NO ENERGY, I USED TO BE ACTIVE BEFORE ESSURE. CAN'T SLEEP. WEIGHT GAIN. DIAGNOSED WITH HIGH BLOOD PRESSURE BECAUSE OF MY WEIGHT. PAIN EVERYWHERE. BLOATED. DEPRESSED ALL THE TIME. NO SEX DRIVE. I'M ALLERGIC TO IT. MOODY ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055629	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 7/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT FELT LIKE I WAS HAVING CONTRACTIONS. PRESSURE IN MY PELVIC AREA FELT LIKE I WAS GOING TO DELIVER A BABY. I HAD HEADACHES, AND BACK PAINS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055630	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 5/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED LOSING MY HAIR AFTER THIS PROCEDURE. I HAD MY THYROID CHECKED OUT IN 2007 CAME BACK NEGATIVE. I'VE HAD CONSTANT STOMACH CRAMPS AND LOWER BACK PAINS. MY CYCLE IS HEAVY AND BLOOD CLOTS COME OUT. I AM NOT HAPPY WITH THIS PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055631	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 8/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN, CHRONIC PELVIC PAIN AND INFLAMMATION, SEVERE BLOATING, WEIGHT GAIN, HAIR LOSS, INCREASE IN DEPRESSION AND ANXIETY, INCREASED MIGRAINE ACTIVITY, PAINFUL INTERCOURSE, BLEEDING FOR THREE MONTHS AND OR DURING INTERCOURSE. HYSTERECTOMY ON (B)(6) 2014 THAT RESULTED IN CAUSING AN UMBILICAL HERNIA WHICH TURNED INTO A SOFTBALL SIZED ONE AND THEN YET ANOTHER SURGERY ON (B)(6) 2014. AND STILL DEALING WITH PAIN AND OTHER ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055632	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 10/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HIGH BLOOD PRESSURE (LAST CHECK 164/104) AND MY TYPE 2 DIABETES IS CONSTANTLY HIGH OR EXTREMELY LOW...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055633	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 2/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAPING, EXTREME BLOATING, HEAVY PERIODS, MOOD SWINGS, WEIGHT GAIN, HAIR LOSS, ABDOMINAL PAIN, PELVIC PAIN, RECTAL PAIN, PAINFUL SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055634	BAYER	8/20/2015	8/20/2015

Event Information:

Event Date (B3): 1/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT LOSS ((B)(6) LBS TO (B)(6) LBS), PELVIC/ABDOMINAL/HIP/BACK PAIN, DAILY MIGRAINES, PAINFUL HEAVY MENSES, PAINFUL INTERCOURSE, COSTOCHONDRITIS, SEVERE FATIGUE/BRAIN-FOG/MALAISE, NAUSEA/DIZZINESS, ACID REFLUX, STREP A, PERITONSILLAR ABSCESS, RENAL CYST, FIBROID, BOWEL AND BLADDER ISSUES, FREQUENT UTIS, HIGH RISK GLAUCOMA (NARROW ANGLES), VISION DETERIORATION, DRY EYE, DENTAL ISSUES, FIBROMYALGIA, SCIATICA, ACCELERATED OSTEOARTHRITIS, TINNITUS, METAL TASTE, SURGICAL AND INTERVENTIONAL PROCEDURES, ETC.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00624	BAYER HEALTHCARE LLC	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B21572

Single Use: Y
Implant Date (E6): 6/21/2013
Explant Date (E7): 6/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 28-MAY-2015 WHICH REFERS TO A (B)(6) NON-PREGNANT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR STERILIZATION. THE PATIENT REPORTED CHRONIC PELVIC PAIN; AND SHE IS SCHEDULED TO REMOVE BOTH DEVICES SURGICALLY ON (B)(6) 2015. ACCORDING TO THE PHYSICIAN, IT STARTED SHORTLY AFTER ESSURE WAS INSERTED. THE DEVICES WERE IN THE RIGHT LOCATION, THEY JUST HAVEN'T FOUND ANOTHER CAUSE. AT TIME OF THE REPORT, THE EVENT WAS ONGOING AND ESSURE DEVICES WERE CONTINUED. PTC INVESTIGATION RESULT WAS RECEIVED ON 02-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL

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RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 29-JUL-2015 THE PATIENT'S WEIGHT WAS (B)(6). PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS AND PROCEDURES AND CONCURRENT CONDITIONS WERE DENIED. ESSURE WAS INSERTED ON (B)(6) 2013 WITH LOT NUMBER B21572. IT WAS REPORTED THAT PATIENT WAS IN A POSTPARTUM (2 MONTHS) STATE AT TIME OF INSERTION. CERVICAL DILATION AND GENERAL ANESTHESIA WERE DENIED. PARACETAMOL, TORADOL AND VALIUM WERE USED AS ANALGESIA. INSERTION AND VISUALIZATION OF TUBAL OSTIUM WERE CONSIDERED EASY. FLUID LOSS WAS LESS THAN 1500CC AND PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. AFTER INSERTION, LO LOESTRIN WAS USED AS BACK CONTRACEPTION. AN IMAGING TEST WAS PERFORMED TO CONFIRM ESSURE PLACEMENT. ON (B)(6) 2013, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND BILATERAL OCCLUSION WAS CONFIRMED. ON (B)(6) 2015, PELVIC CT SCAN WAS DONE DUE TO PELVIC PAIN. FINDINGS INCLUDED: RETROVERTED UTERUS; BILATERAL ESSURE COILS GROSSLY IN PROPER LOCATION AND NO INFLAMMATORY CHANGES WERE FOUND. ON (B)(6) 2015 THE PATIENT WAS ADMITTED AND ESSURE WAS COMPLETELY REMOVED BY LAPAROSCOPY DUE TO HER REQUEST. SALPINGECTOMY WAS NECESSARY. DURING SURGERY, DEVICES WERE SEEN IN PLACE WITHOUT EVIDENCE OF PERFORATION. DISCHARGE WAS AT THE SAME DAY (HOSPITALIZATION WAS DENIED). PATIENT WAS SEEN 2 WEEKS AFTER SURGERY AND HER SYMPTOMS RESOLVED (SHE FELT 100% BETTER). CASE UPGRADED TO INCIDENT. FOLLOW UP 05-AUG-2015: PTC INVESTIGATION RESULTS WERE UPDATED (LOT NUMBER B21572 RECEIVED). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH . NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO STARTED EXPERIENCING CHRONIC PELVIC PAIN SHORTLY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE RECOVERED AFTER DEVICES REMOVAL BY LAPAROSCOPIC SALPINGECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, GIVEN THE CLOSE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED EVENT AND AS IT RECOVERED WITH DEVICES REMOVAL; CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT; HOWEVER UPON RECEIPT OF FOLLOW-UP INFORMATION, IT WAS REPORTED A SURGICAL INTERVENTION WAS REQUIRED FOR ESSURE REMOVAL. THEREFORE, THIS CASE WAS REGARDED AS AN INCIDENT. THE UPDATED PRODUCT TECHNICAL ANALYSIS (WITH LOT NUMBER) CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00625	BAYER HEALTHCARE LLC	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/18/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (B)(4) (CASE # (B)(4)) IN (B)(6) ON 29-JUL-2015 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. AFTER THE BIRTH OF HER THIRD CHILD IN 2012, SHE DECIDED THAT SHE WOULD LIKE TO BE STERILIZED AND, ON THE RECOMMENDATION OF HER GP (GENERAL PRACTITIONER), WAS REFERRED TO A DOCTOR WITH A VIEW TO HAVING THE ESSURE PROCEDURE. SHE WAS IMPLANTED WITH THE ESSURE DEVICE ON THE (B)(6) 2012, WITH A FOLLOW UP X-RAY TO CHECK CORRECT PLACEMENT, 3 MONTHS LATER. HER HEALTH PROBLEMS BEGAN IN (B)(6) 2012, BUT SHE DID NOT RELATE THEM TO ESSURE UNTIL EARLIER THIS YEAR. WITHIN A FEW MONTHS OF THE PROCEDURE, SHE STARTED TO EXPERIENCE LONG PAINFUL PERIODS WITH HEAVY BLEEDING, PAINFUL OVULATION, STOMACH ACHES, BLOATING AND GAS. THIS WAS FOLLOWED BY CHRONIC JOINT AND MUSCULAR PAIN AND EXTREME FATIGUE. IN THE PAST YEAR (2014) SHE HAS ALSO BEEN EXPERIENCING HAIR LOSS, ITCHY SKIN AND SKIN RASHES. AFTER MANY VISITS TO HER GP AND NUMEROUS BLOOD TESTS, WITH THE EXCEPTION OF LOW IRON, ALL RESULTS HAVE BEEN NORMAL AND NO CAUSE HAS BEEN FOUND. EARLIER THIS YEAR, SHE WAS FINALLY REFERRED BACK TO DOCTOR AND WILL BE HAVING A HYSTERECTOMY ON (B)(6) 2015. SHE FEELS SAD THAT SHE NOW FACE SURGERY AND WILL LOSE A PART OF HER BODY, PARTICULARLY WHEN ESSURE WAS SOLD TO HER ON THE BASIS THAT IT DID NOT REQUIRE SURGERY. SHE WAS ALSO SHOCKED TO DISCOVER THAT ESSURE CONTAINS PET FIBRES, AS SHE WAS TOLD THAT THE COILS WERE MADE OF NICKEL AND WAS NOT INFORMED THAT IT IS ACTUALLY THESE PLASTICS THAT CAUSE A LOCAL INFLAMMATION AND THE SUBSEQUENT FIBROSIS THAT BLOCKS THE FALLOPIAN TUBES. IT IS NOW HER UNDERSTANDING, AND LIKELY, THAT HER ILL HEALTH IS AN AUTOIMMUNE RESPONSE TO THE COILS. SHE HAS THEREFORE BEEN IN THE DARK AND AT A

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LOSS TO ESTABLISH THE CAUSE OF HER ILL HEALTH, WITH NO ONE LOOKING OUT FOR POSSIBLE SIDE EFFECTS, IT HAS TAKEN CONSIDERABLE TIME AND TAKEN A TOLL ON HER HEALTH TO REACH THIS POINT. PTC INVESTIGATION RESULT WAS RECEIVED ON 17-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LONG PAINFUL PERIODS WITH HEAVY BLEEDING. THE EVENT CODED AS HEAVY MENSTRUAL BLEEDING WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER STARTED TO EXPERIENCE THIS EVENT WITHIN A FEW MONTHS OF THE PROCEDURE. IT WAS REPORTED THAT SHE WILL BE HAVING A HYSTERECTOMY PERFORMED. THEREFORE, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-NOV-2015 FROM CONSUMER VIA REGULATORY AUTHORITY ((B)(4)): IN (B)(6) 2012, AT THE AGE OF (B)(6), CONSUMER DECIDED STERILISATION WOULD BE HER BEST OPTION. ESSURE WAS INSERTED ON (B)(6) 2012 UNDER GENERAL ANESTHESIA, WITH NO PROBLEM

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00626	BAYER HEALTHCARE LLC	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/15/2013
Explant Date (E7): 11/21/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042833) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED SHE WAS HOSPITALIZED BECAUSE ONE OF THE COILS SLIPPED INTO HER UTERUS AND HAD TO BE SURGICALLY REMOVED FIVE MONTHS BEFORE THE TIME OF HER REPORT. SHE STATED SHE NOW HAS UNBEARABLE PAIN FOR OVER A MONTH AND IS PREPARING TO HAVE THE TUBE REMOVED TO HAVE THE COIL REMOVED. ESSURE REMOVAL DATE WAS REPORTED AS (B)(6) 2013. PTC INVESTIGATION RESULT WAS RECEIVED ON 05-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO

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SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO WAS HOSPITALIZED BECAUSE ONE OF THE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) COILS SLIPPED INTO HER UTERUS AND HAD TO BE SURGICALLY REMOVED. ADDITIONALLY, SHE EXPERIENCED UNBEARABLE PAIN (REGARDED AS PELVIC PAIN). THE REPORTED EVENTS WERE CONSIDERED SERIOUS, DUE TO HOSPITALIZATION AND MEDICAL IMPORTANCE AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). ADDITIONALLY, ABDOMINAL AND PELVIC PAIN MAY OCCUR DURING ESSURE THERAPY. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE EVENTS WAS UNKNOWN, GIVEN THEIR NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WAS REQUIRED FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 26-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO WAS HOSPITALIZED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00627	BAYER HEALTHCARE LLC	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68119

Single Use: Y
Implant Date (E6): 4/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 30-JUL-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. DURING INSERTION, THE OSTIUM HAD NOT BEEN EASILY VISIBLE AS IT WAS COVERED WITH A VEIL, POSSIBLE A SYNECHIA. AT THE INSERTION PROCEDURE, THERE HAD BEEN NO VISIBLE TRAILING COIL. THE PHYSICIAN REPORTED A SUSPICION OF PERFORATION. IN (B)(6) 2015, PLAIN ABDOMEN X-RAY AT 3 MONTHS AFTER INSERTION WAS PERFORMED AND NOTED THAT THE DISTANCE BETWEEN INSERTS WAS TOO IMPORTANT: UPPER THAN 4 CM. A HSG (HYSTEROSALPINGOGRAM) WAS REQUESTED BY THE PHYSICIAN FOR CONFIRMATION. THE HSG SHOWED INSERT LIKE A LOOP. INSERT PLACEMENT COULD NOT CONFIRM TUBAL OCCLUSION BY FIBROSIS; NEVERTHELESS, THERE WAS NO TUBAL PATENCY ON HSG. THE PATIENT WAS INFORMED ABOUT RISK OF FAILURE IN VIEW OF LOCAL DIFFICULTY. A LAPAROSCOPY WAS TO BE PLANNED IN (B)(6). FOLLOW UP RECEIVED ON 31-JUL-2015: THE ESSURE LOT NUMBER IS C68119. FOLLOW UP 06-AUG-2015: NCA REFERENCE NUMBER FROM (B)(4) WAS RECEIVED: (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PHYSICIAN REPORTED A SUSPICION OF PERFORATION - DISTANCE BETWEEN INSERTS WAS UPPER THAN 4 CM ON PLAIN ABDOMEN X-RAY AT 3 MONTHS AFTER INSERTION. THIS EVENT, INTERPRETED AS SUSPICION OF UTERINE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING ESSURE INSERTION. IN THIS PARTICULAR CASE, DURING INSERTION THE OSTIUM HAD NOT BEEN EASILY VISIBLE AS IT WAS COVERED WITH A VEIL (POSSIBLE A SYNECHIA). PLAIN ABDOMEN X-RAY AT 3 MONTHS AFTER INSERTION SHOWED THAT THE

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DISTANCE BETWEEN INSERTS WAS TOO IMPORTANT, AND PHYSICIAN SUSPECTED OF PERFORATION. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENT WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WILL BE REQUIRED (LAPAROSCOPY WAS PLANNED). A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 28-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A TECHNICAL PRODUCT ISSUE AND A USABILITY ISSUE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00628	BAYER HEALTHCARE LLC	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B72583

Single Use: Y
Implant Date (E6): 10/17/2014
Explant Date (E7): 6/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF (B)(6) OLD VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER STATED AT TIME OF THE PROCEDURE SHE WAS NOT INFORMED OF ANY POSSIBLE SIDE EFFECTS. THE PROCEDURE WENT WELL; SHE EXPERIENCED PAIN FOR A WEEK OR SO AFTER. OVER THE NEXT FEW MONTHS, HER PERIOD BECAME HEAVIER WITH CLOTTING. IN (B)(6) 2015, SHE HAD THE COILS CHECKED AND WAS TOLD SHE COULD SAFELY USE THE DEVICE AS CONTRACEPTION AND SHE WOULD NOT BE ABLE TO GET PREGNANT. OVER THE FOLLOWING MONTHS, SHE STARTED TO GET THE FOLLOWING SYMPTOMS: CONSTANT PELVIC PERIOD TYPE PAIN; TIREDNESS; BRITTLE NAILS; BRITTLE DRY HAIR; SWELLING AND PAIN IN LEGS AND FEET; PAINFUL SEX; BLOATING; WEIGHT GAIN (APPROXIMATELY (B)(6)); NAUSEA; HEAVY CLOTTING PERIODS (BLEEDING FOR 5/6 DAYS THEN STOPPING FAR A DAY AND THEN BLEEDING AGAIN FOR A COUPLE OF DAYS); FREQUENT URINATION; BRAIN FOG; DIZZINESS; MOOD CHANGES; FEELING OF BEING PREGNANT; FLUTTERING IN STOMACH TO FEELING LIKE ABOUT TO GIVE BIRTH. IN (B)(6) 2015, SHE SAW GP (GENERAL PRACTITIONER) REGARDING THE PAIN AND PERSISTENT URINATION. SHE COMPLETED A URINE OUTPUT STUDY AND HAD AN ULTRASOUND. THE ULTRASOUND WAS EXTREMELY PAINFUL AND THE REPORT STATED ARISING FROM THE FUNDAL ENDOMETRIUM AND EXTENDING THROUGH THE MYOMETRIUM TO THE BORDER OF THE POSTERO-FUNDAL UTERUS A 23MM LENGTH ECHOGENIC LINEAR STRUCTURE SUGGESTIVE OF A FOREIGN BODY. SHE EXPLAINED SHE HAD THE STERILIZATION COILS IN PLACE BUT THE PHYSICIAN HAD NO IDEA WHAT SHE WAS TALKING ABOUT AND DID NOT THINK THAT IT COULD BE THEM. ON (B)(6) 2015, HER GP REFERRED HER TO GYNECOLOGY. ON (B)(6) 2015, SHE EXPERIENCED EXTREME PAIN AND THE GP ADMITTED HER TO HOSPITAL. ON ARRIVAL AT HOSPITAL THE CONSULTANT WHO HAD INSERTED THE COILS SAID

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STRAIGHT AWAY WE MUST GET THOSE COILS OUT, WE WILL DO A SALPINGECTOMY. ON (B)(6) 2015, SHE WAS GIVEN A PROSTAP INJECTION TO SEE IF THIS WOULD EASE THE CRAMPING PAIN. SHE WAS DISCHARGED FROM HOSPITAL AND WAS TOLD TO REST FOR 10 DAYS. NO OPERATION WAS PERFORMED AS NONE OF THE OTHER GYNECOLOGY CONSULTANTS WERE PREPARED TO TOUCH HER AS SHE HAD ESSURE IN PLACE. ON (B)(6) 2015, SHE CONTACTED THE HOSPITAL AS PAIN BAD AND FELT DIZZY, SPACED OUT AND SICK, AND WAS TOLD TO GO BACK TO GP. SHE SAW GP WHO DIAGNOSED A URINE INFECTION AND ADMITTED HER BACK TO GYNECOLOGY. ON (B)(6) 2015, SHE WAS DISCHARGED FROM HOSPITAL WITH AN APPOINTMENT WITH THE GYNECOLOGIST THE NEXT DAY. ON (B)(6) 2015, THE GYNECOLOGIST ADVISED THAT SALPINGECTOMY SHOULD BE DONE AS SOON AS POSSIBLE. ON (B)(6) 2015, SHE HAD A SALPINGECTOMY SURGERY. SHE WAS SIGNED OFF FOR 2 WEEKS AND ADVISED SHOULD BE OK WITHIN 2 TO 3 WEEKS. THE FOLLOW UP WOULD BE IN 4 WEEKS. ON (B)(6) 2015, SHE SAW THE GP AS SHE WAS FEELING VERY UNWELL. FURTHER INFECTION WAS DIAGNOSED AND SHE WAS GIVEN 2 DIFFERENT COURSES OF ANTIBIOTICS. ON (B)(6) 2015, SHE EXPERIENCED SICKNESS, DIZZINESS AND PAIN THAT SHE REFERRED AS REACTION TO ANTIBIOTICS. ON (B)(6) 2015, ORAL THRUSH WAS DIAGNOSED. ON (B)(6) 2015, THE GP REMOVED WHAT SUPPOSED TO BE THE DISSOLVABLE STITCHES. ON (B)(6) 2015, THE GP COMPLETED AN URGENT REFERRAL TO ENT (UNDERSTOOD AS EARS, NOSE, AND THROAT PHYSICIAN) DUE TO ORAL THRUSH NOT IMPROVING AFTER 4 WEEKS OF TREATMENT. ON (B)(6) 2015, IN THE ENT APPOINTMENT, SHE HAD BLACK HAIRY TONGUE DUE TO NOT BEING WELL. SHE HAD A GYNECOLOGIST APPOINTMENT AND THE CONSULTANT ADMITTED THAT SHE SHOULD NOT STILL BE BLOATED AND SIS NOT UNDERSTANDS THE PAIN. BEFORE DOING ANYTHING ELSE SHE WAS SENT FOR FURTHER BLOOD TEST, URINE TEST AN ULTRASOUND. SHE SHAD A REACTION TO THE PLASTER FROM THE BLOOD TEST WHICH SHE NEVER HAD BEFORE. SHE STATED THE ULTRASOUND WAS EXTREMELY PAINFUL INTERNAL AND EXTERNAL. SHE REPORTED THE ISSUES SINCE SALPINGECTOMY AS CONSTANT PELVIC PERIOD TYPE PAIN; TIREDNESS; BRITTLE DRY HAIR; PAINFUL SEX; BLOATING AND LOOKING LIKE PREGNANT; WEIGHT GAIN; NAUSEA; BRAIN FOG; DIZZINESS; MOOD CHANGES; FEELING OF BEING PREGNANT; FLUTTERING IN STOMACH TO FEELING LIKE ABOUT TO GIVE BIRTH. SHE STATED THAT THE FREQUENT URINATION IS THE ONLY THING WHICH HAS IMPROVED SINCE THE SALPINGECTOMY. SHE ALSO MENTIONED SHE HAD NOT A PERIOD SINCE THE PROSTAP INJECTION BUT WAS NOT DUE ANY FURTHER INJECTIONS. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 12-AUG-2015: CONSUMER PROVIDED HER DATE OF BIRTH. SHE STATED THAT STILL HAS THE REACTION; HOWEVER SHE DID NOT SPECIFY IT. SHE ALSO MENTIONED THAT A BILATERAL SALPINGECTOMY WAS PERFORMED AND THAT SHE WAS TREATED POST OP AND URINE INFECTIONS. SHE WAS SUFFERING FROM THE SAME SIDE EFFECTS AND WAS WAITING FOR A HYSTERECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON 17-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP DATED 06-AUG-2015: CASE (B)(4) WAS IDENTIFIED AS FOLLOW-UP OF THIS CASE. (B)(4) WILL BE DELETED FROM BAYER DATABASE AND THE FOLLOWING INFORMATION WAS ADDED: THIS CASE HAS BEEN

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IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4)). CONSUMER HAD ESSURE FITTED IN (B)(6) 2014 AND HAVE HAD NUMEROUS ISSUES SINCE INCLUDING CONSTANT PELVIC PERIOD PAIN; TIREDNESS; BRITTLE NAILS AND HAIR; SWELLING AND PAIN IN LEGS AND FEET; PAINFUL SEX; BLOATING; WEIGHT GAIN; NAUSEA; HEAVY CLOTTING IRREGULAR PERIODS; FREQUENT URINATION; BRAIN FOG; DIZZINESS. SHE HAD A BILATERAL SALPINGECTOMY IN (B)(6) 2015 TO REMOVE THE COILS BUT THIS HAS NOT SOLVED THE MAJORITY OF PROBLEMS. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: ABDOMINAL PAIN LOWER. (B)(4) BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME PAIN / CRAMPING PAIN, WHICH WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION. AN ULTRASOUND WAS PERFORMED AND THE RESULT SHOWED 23MM LENGTH ECHOGENIC LINEAR STRUCTURE SUGGESTIVE OF A FOREIGN BODY / ARISING FROM FUNDAL ENDOMETRIUM AND EXTENDING THROUGH THE MYOMETRIUM (SEEN AS UTERINE PERFORATION), CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. THESE EVENTS ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF UTERINE PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. WITH REGARDS TO THE EVENT EXTREME PAIN / CRAMPING PAIN, CONSUMER EXPERIENCED THIS EVENT 207 DAYS AFTER ESSURE INSERTION. SINCE TEMPORAL RELATIONSHIP IS POSITIVE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. IN THIS CASE, CONSUMER UNDERWENT A SALPINGECTOMY. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION REQUIRED. ADDITIONALLY, OTHER SERIOUS AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

TPRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT (PTC GLOBAL NUMBER (B)(4)) WAS UPDATED ON 14-DEC-2015: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00629	BAYER HEALTHCARE LLC	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 1/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/22/2013
Explant Date (E7): 2/6/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042897) IN UNITED STATES ON 29-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. THE CONSUMER REPORTED SHE HAD THE DEVICE PUT IN AND AFTER 15 DAYS OF HORRIBLE PAIN THAT GOT WORSE, ON (B)(6) 2013, A DIFFERENT PHYSICIAN REMOVED THE ESSURE TO FIND 2 ESSURE COILS IN HER RIGHT FALLOPIAN TUBE WHILE ONE IN THE LEFT. SHE STATED THAT STILL HAD PAIN SO THEY WENT IN AGAIN TO LOOK FOR OTHER CAUSES OF PAIN. AT TIME OF THE REPORT, SHE STILL HAD PAIN IN THE RIGHT SIDE OF HER ABDOMEN DURING INTERCOURSE AND DURING MENSTRUATION. SHE MENTIONED ZOLOFT AS CONCOMITANT MEDICATION. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A DEVICE MISUSE. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED

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STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HORRIBLE PAIN THAT GOT WORSE (SEEN AS PELVIC PAIN FEMALE). THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT SINCE THE INSERTION OF ESSURE. SHE HAD ESSURE REMOVED IN ORDER TO FIND 2 ESSURE COILS IN HER RIGHT FALLOPIAN TUBE. CONSIDERING THIS INFORMAITON, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED SURGICAL INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 06-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00630	BAYER HEALTHCARE LLC	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/20/2012
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042864) IN UNITED STATES ON 29-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. SHE HAD THE ESSURE COIL INSERTED AND HAD A TERRIBLE ALLERGIC REACTION. ALL THE MUSCLES IN HER BODY STIFFENED AND SHE COULD HARDLY WALK, ESPECIALLY AFTER SITTING STILL FOR A WHILE (EXAMPLE AFTER DRIVING OR WORKING AT MY DESK); SHE COMPLAINED TO HER DOCTORS AND THEY ALL INSISTED THIS WAS NOT THE CAUSE OF HER TROUBLE. FIBROMYALGIA WAS DIAGNOSED BECAUSE THEY COULD NOT FIGURE OUT THE CAUSE OF PAIN. SHE SWITCHED DOCTORS (CLINICS) AND THE NEW DOCTOR SENT HER TO A GYNECOLOGIST AND SHE DID A HYSTERECTOMY ON (B)(6) 2014. SHE STATED THE PAIN WAS GONE. SHE REPORTED THAT A TEST WAS NEVER DONE TO SEE IF SHE HAD AN ALLERGIC REACTION TO NICKEL OR WHAT THE DEVICE WAS MADE FROM. IT WAS THE WORST 2 YEARS EVER. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE

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KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALLERGIC REACTION AND PAIN. CONSUMER UNDERWENT A HYSTERECTOMY. BOTH EVENT ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. ALSO, UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED SURGICAL INTERVENTION. ADDITIONALLY, OTHER EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 22-SEP-2015 FROM CONSUMER: SHE WAS (B)(6)OLD, INCREASED BODY MASS INDEX, HISTORY OF PREGNANCY, DILATATION AND CURETTAGE IN (B)(6) 2004 AND THYROID REMOVAL IN (B)(6) 2014. HER MOTHER DIED OF OVARIAN CANCER AND SHE WAS ON B

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00631	BAYER HEALTHCARE LLC	8/21/2015	8/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. AFTER INSERTION OF ESSURE, SHE SUFFERED SEVERE SIDE EFFECTS. SHE HAD MAINLY CHRONIC PAIN IN PELVIC AREA, LOST 50% OF HER HAIR IN A YEAR; WAS COVERED IN RASH MOST DAYS AND WAS EXTREMELY TIRED. SHE SLEPT ABOUT 14HRS A DAY; HAD NO APPETITE AND HAD EXTREME PERIODS TO THE POINT SHE COULD NOT LEAVE HER HOUSE. SHE STATED THAT SHE IS LOSING BATTLE FOR REMOVAL AS SHE WAS BEING REFUSED. SHE REPORTED THAT ON INSERTION SHE WAS ASSURED THERE WERE NO SIDE EFFECTS AND AS HER BODY HAD REACTIONS TO SIMPLE THINGS IE.PARACETAMOL, SHE STATED THIS AT THE TIME AND THE DOCTOR REASSURED HER THERE WAS ABSOLUTELY NONE. SHE STATED THAT PREVIOUSLY SHE HAD THE MIRENA COIL (LEVONORGESTREL) AND THE ESSURE GAVE HER THE EXACT SAME SIDE EFFECTS; THE ONLY DIFFERENCE WAS THAT ESSURE COULD NOT BE REMOVED WITHOUT A HYSTERECTOMY. THE CONSUMER ALSO MENTIONED THAT THIS HAPPENED ON (B)(6) 2013 BUT SHE DID NOT SPECIFY AND/OR ASSIGN THE DATE TO ONE OF THE EVENTS. AT TIME OF THE REPORT, THE DEVICES WERE STILL IMPLANTED IN HER FALLOPIAN TUBES. SHE ALSO STATED THAT NO ONE WAS INJURED. CORRECTION REQUEST DONE ON 05-AUG-2015. RETURN TO SENDER WAS TICKED AS REQUESTED. PTC INVESTIGATION RESULT WAS RECEIVED ON 17-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER

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FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME PERIODS TO THE POINT SHE CANNOT LEAVE THE HOUSE - WITH ESSURE. SHE ALSO HAD MIRENA (LEVONORGESTREL) INSERTED AND EXPERIENCED THE SAME EVENT. THIS EVENT WAS CONSIDERED SERIOUS DUE TO DISABILITY AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND MIRENA. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED AND NO INJURY OCCURRED. GIVEN ITS NATURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE AND MIRENA CANNOT BE EXCLUDED. ALTHOUGH NO INJURY, PERMANENT DAMAGE OR REQUIREMENT OF INTERVENTION WAS REPORTED IN THIS CASE, THIS CASE WAS REGARDED AS INCIDENT IN LINE WITH REGULATORY AUTHORITY'S ASSESSMENT. ADDITIONALLY, NON-SERIOUS EVENTS OCCURRED WITH ESSURE AND MIRENA AS WELL. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 25-AUG-2015: DESPITE SEVERAL ATTEMPTS FOR FOLLOW-UP, NO RESPONSE WAS RECEIVED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055635	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING VERY PAINFUL SEX. PERIODS ARE EXTREMELY PAINFUL AND HEAVY. SHARP STABBING PAINS, GAINED WEIGHT AND CAN NOT LOSE WEIGHT. E-BELLY (EXTREME BLOATING AND PAIN).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055636	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 9/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PUT IN ON (B)(6) 2014. I HAD THE NORMAL PAIN AFTER THE PROCEDURE. AFTER ABOUT A WEEK I WAS GETTING EXCRUCIATING PAIN NEAR MY TAILBONE AREA. IT REALLY HURT TO SIT DOWN. I WENT TO A CHIROPRACTOR TO SEE IF SOMETHING WAS WRONG AND HE SAID EVERYTHING LOOKED OK TO HIM. I STARTED HAVING CRAMPING AND LOWER BACK PAIN THAT WOULD NOT GO AWAY. I WAS PRESCRIBED NARCOTICS TO HELP WITH THE PAIN BECAUSE IBUPROFEN WOULD NOT WORK. HEAT AND ICE DID NOT WORK AND THE PAIN MEDICATION THAT I WAS PRESCRIBED BARELY TOOK OFF THE EDGE. I WENT TO THE OBGYN WHO PERFORMED THE PROCEDURE AND WE DISCUSSED WHAT WAS WRONG WITH ME AND HE AGREED THAT THE ONLY THING THAT COULD BE CAUSING ME THE PAIN WAS THE ESSURE DEVICE. I HAD NO OTHER ONGOING ILLNESSES, ALLERGIES OR BIRTH PROBLEMS. I WAS FINE BEFORE I HAD THE ESSURE DEVICE PUT IN. THE DOCTOR REMOVED MY FALLOPIAN TUBES TO REMOVE THE ESSURE AND TO THIS DAY I NO LONGER HAVE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055637	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 9/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT HEADACHES, ONGOING PERIODS THAT LAST FOR WEEKS, METAL TASTE IN MOUTH, JOINT PAIN, PAIN ON RIGHT SIDE OF ABDOMINAL, CONFUSION, MOOD SWINGS (I'M NOT IN PRE MENOPAUSAL STAGE" WAS TESTED, PAINFUL SEX OCCASIONALLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055638	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 5/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE PUT IN I AM HAVING MANY HEALTH ISSUES. I HAVE ENDOMETRIOSIS, PELVIC PAIN, BACK PAIN, PAIN DURING INTER COURSE, 2 WEEK PERIODS, HEAVY PERIODS, AND HEAD ACHES. I AM SCHEDULED FOR A HYSTERECTOMY (B)(6) 2015. THIS DEVICE IS TERRIBLE AND HAS ALMOST WRECKED MY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055639	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY PAINFUL PROCEDURE, AFTER PROCEDURE, IRREGULAR PERIODS, BLOATING, HEAVY PERIODS, INFECTIONS, HIVES, HAIR LOSS, MASS ON OVARY, NOW REQUIRE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055640	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 6/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, VAGINAL PAIN, LOWER ABDOMINAL PAIN, LOWER BACK PAIN, LACK OF ENERGY, LACK OF SLEEP, DEPRESSION, PAIN DURING SEX, RASH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055641	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 7/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM THE TIME I GOT IT IMPLANTED I HAD A "MENSTROL" FOR 3 WEEKS OUT OF A MONTH 1 WEEK OFF, EXTREMELY HEAVY BLEEDING TO THE POINT OF SOAKING THRU A TAMPON IN LESS THEN 2 HOURS. SEVERE CRAMPING ALL MONTH LONG. METAL TASTE IN MY MOUTH ALL THE TIME. UNCONTROLLABLE MOODS. SEVERE ALLERGIES. HORMONAL ISSUES, LOSS OF WEIGHT, SEVERE FATIGUE, INSOMNIA, NAUSEA THAT ALL CONTINUED UNTIL THE DEVISES WERE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055642	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 3/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC YEAST INFECTIONS, BLEEDING/SPOTTING, ITCHING, BURNING AND STINGING, ABDOMINAL SPASMS, CHRONIC DISCHARGE, ABNORMAL MENSES, PAINFUL INTERCOURSE, FREQUENT URINATION, BREAST PAIN, SEVERE BLOATING, CHRONIC CONSTIPATION, WEIGHT GAIN, HEADACHES, BRAIN FOG, FORGETFULNESS, ANXIETY, MOOD SWINGS, ELEVATED BLOOD COUNTS, METAL ALLERGIES, HEART PALPITATIONS, HAIR LOSS, SWOLLEN GLANDS, DRY SKIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055643	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 2/28/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING MUSCLE PAIN, JOINT PAIN, AND SEVERE FATIGUE. CONSTANT BLOATING AND IBS SYMPTOMS. I HAD ABSOLUTELY NONE OF THESE BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055644	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 5/1/2002 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DOCTORS AT (B)(6) SUGGESTED ESSURE AS AN OPTION FOR PERMANENT CONTROL. I HAD PLANNED ON HAVING MY TUBES TIED. THEY ASSURED ME THAT IT WAS SAFE AND EFFECTIVE. I'M NOT SURE OF DATES, BUT EVENTUALLY I STARTED EXTREMELY HEAVY BLEEDING AND IT HAD A TERRIBLE METALLIC SMELL. THE BLEEDING WAS CONSTANT AND THE ODOR GOT SO BAD THAT I DIDN'T WANT TO USE PUBLIC RESTROOMS. I WENT BACK TO (B)(6) AND THEY DID NUMEROUS INTERNAL ULTRASOUNDS BUT COULDN'T GIVE ME AN ANSWER. I FINALLY WENT BACK TO MY OLD OB-GYN AND SHE SUGGESTED A UTERINE ABLATION (SP?). THIS IS WHERE SHE WOULD BURN THE LINING OF THE UTERUS SO THAT THE BLEEDING WOULD STOP. WHILE IN SURGERY, SHE FOUND ONE OF THE ESSURE COILS LYING IN MY UTERUS AND SAID THIS WAS THE REASON FOR THE BLEEDING. I WILL NEVER KNOW IF THE UTERINE ABLATION WAS A NECESSARY SURGERY. I THINK IF THE COIL HAD BEEN FOUND AND REMOVED IT WOULD HAVE SOLVED MY PROBLEM. FOR YEARS I'VE FELT A DECLINE IN MY HEALTH. MY LEGS HURT ALL THE TIME AND I HAVE NERVE PROBLEMS ON THE LEFT SIDE OF MY BODY. I'M TIRED ALL THE TIME. I CAN'T SAY FOR SURE THIS IS BECAUSE OF THE OTHER COIL. HOWEVER, LESS THAN TWO YEARS AGO I WENT TO THE ER FOR AN UNRELATED PAIN AND THE DOCTOR THERE ORDERED A CT SCAN. WHEN HE CAME TO TALK TO ME HE ASKED ME HOW MANY YEARS I HAD HAD THE COIL AND TOLD ME IT IS NOT IN MY TUBE AND HE SAID I SHOULD TRY TO GET IT REMOVED. HOWEVER, IT'S AS IF ALL THE DOCTORS ARE IN SOME KIND OF PACT OR SOMETHING AND NO ONE WANTS TO HELP ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055645	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 8/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DECIDED TO GET THE ESSURE CAUSE I WAS TOLD IT WAS SAFE BUT THE MIN I REALIZED WHEN I WAS OUT OF SURGERY THAT SOMETHING DIDN'T FEEL RIGHT. DEALT WITH BACK PAIN VERY HEAVY AND LONG PERIODS LACK OF SLEEP ANXIETY, DEPRESSION, DEVELOPED ENDOMETRIOSIS, PAINFUL SEX VERY TIRED ALL THE TIME, MAJOR UNHEALTHY WEIGHT LOSS THEN HAD TO GO THROUGH TO DIFFERENT SURGERIES TO GET THE COILS TO BE REMOVED AND ENDED UP LOOSING MY WHOLE WOMANHOOD BESIDES KEEPING ONLY ONE OVARY LEFT ON TOP OF SEARCHING OVER AND OVER AGAIN TO FIND A DOC TO HELP ME. NOW TO THIS DAY I MAY HAVE THE ESSURE OUT OF ME BUT MY BODY FEELS PERMANENTLY DAMAGED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055646	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TEETH DETERIORATING, MASSIVE BLOOD CLOTS, HAIR FALLING OUT, NO SEXUAL DESIRE, MARRIAGE FALLING APART, PERIODS LAST 10 DAYS TO 2 WEEKS. NUMEROUS OVARIAN CYSTS. CONSTANT LOWER ABDOMINAL PAIN. GAINED 70 LBS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055647	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 10/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN IN ABDOMEN, SEVERE CRAMPING AND POKING SENSATION. ONE COIL NOT VISIBLE ON TEST, LONGER AND HEAVIER MENSTRUAL CYCLES. SCHEDULED FOR HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055648	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 12/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BOTH OF MY PREGNANCIES WHERE HIGH RISK SO I THOUGH IT WAS BEST FOR ME TO DO SOMETHING SO I WOULDN'T GET PREGNANT AGAIN. WHEN I HAD PROCEDURE DONE MY DOCTOR WAS PUTTING FIRST COIL IN AND SHE HAD TO TAKE IT OUT BECAUSE THE COIL WAS DEFECTIVE AT THAT TIME I SHOULD OF JUST STOPPED THE PROCEDURE BUT DIDN'T SO SHE GOT A DIFFERENT PACKED OUT WITH NEW COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055649	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 8/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH LEG NUMBNESS AND PAIN, ESCALATED TO ANXIETY ISSUES, THEN FATIGUE AND BODY PAINS. CRAMPS PERIODS LASTING 2 WEEKS OR UP TO 16 DAYS. MEMORY FOG. DEPRESSION. MENOPAUSE SIGNS IM (B)(6). EXTREME WEIGHT LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055650	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 8/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP ABDOMINAL PAINS. .. CHRONIC ABDOMINAL PAIN.. DEPRESSION.. BOWEL PROBLEMS.. ITCHY SKIN .. RASHES .. ACNE .. TERRIBLE FORGETFULNESS .. BRAIN FOG.. RINGING IN EARS .. ONE DEVICE HAS MIGRATED SOMEWHERE IN MY BODY.. ABDOMINAL SWELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055651	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SHARP PELVIC PAIN, DISCHARGE, NIGHT SWEATS BREAST TENDERNESS, BACK PAIN, NAUSEA, GAS, CONSTIPATION, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, HEADACHES, MIGRAINES, DIZZINESS, RASH, SKIN IRRITATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055652	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 8/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH DULL PAIN IN ABDOMINAL AREA. PROGRESSED TO SEVERE ABS EXCRUCIATING SHARP PAIN IN ABDOMEN, LOWER BACK, AND LEG, ON RIGHT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055653	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 10/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, NAUSEA, MIGRAINE, HAIR LOSS, FATIGUE, LOWER BACK PAIN, HOT FLASHES, ABNORMAL MENSTRUATION, SHORTNESS OF BREATH WITH PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055654	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 6/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER BACK PAIN, PELVIC PAIN, AND PAIN ALL OVER MY BODY, STRANGE RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055655	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 6/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WELL SINCE I GOT THE ESSURE BACK IN 2010 I HAVE BEEN HAVING CRAMPS, BLEEDING MORE THAN NORMAL, THAT I DIDN'T HAVE AT FIRST. NOW I HAVE REAL BAD ALLERGIES THAT I HAVE TO TAKE MEDICINE FOR AND I HAVE TO GIVE MYSELF BREATHING TREATMENTS WITH ALBUTEROL DUE TO ALLERGIES. EVERY NOW AND THAN I WILL BREAK OUT WITH PATCHES OF LIKE RED AND ITCHY SPOTS ON MY BODY. I HAVE ANXIETY ATTACKS NOW AND HAVE TO TAKE XANAX. I HAVE BEEN TELLING MY DOCTOR FROM DAY ONE THAT I FELT LIKE SOMETHING WAS WRONG AND ALL HE TOLD ME WAS THIS WAS NORMAL AND MY ONLY OPTION WAS TO GET A HYSTERECTOMY. I NEVER HAD ANY OF THESE ISSUES UNTIL I GOT THE ESSURE. I HAVE BEEN HEALTHY ALL MY LIFE AND I FEEL THAT THIS IS SO WRONG THAT I HAVE TO GO THROUGH CONSTANT PAIN AND ALL THEY OFFER IS PAIN PILLS OR A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055656	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 7/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PROCEDURE WAS COVERED BY INSURANCE. THE PROCEDURE TOOK LONGER ON THE RIGHT SIDE BECAUSE MY UTERUS KEPT CONTRACTING. SINCE HAVING THIS PROCEDURE I HAVE HAD PAIN ON MY RIGHT SIDE WHERE IT WAS DONE. ABOUT A YEAR LATER I BEGAN HAVING SEVERE DIARRHEA. I HAD TO HAVE A COLONOSCOPY. THE RESULTS SHOWED NO PROBLEMS WITH MY COLON. TO THIS DAY I STILL HAVE THE PAIN, INTESTINAL ISSUES ALONG WITH FATIGUE AND JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055657	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 7/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE IMPLANTED SINCE (B)(6) 2013, HAVING ISSUES DEBILITATING STABBING PELVIC PAIN, SCIATICA PAIN, HAIR LOSS, ABNORMAL PERIODS, RASHES, BRAIN FOG, NUMBNESS IN LEGS, PAIN WITH OVULATION, PAIN WITH SEX. I RECENTLY HAD IMAGING DONE THAT SHOWS MY FALLOPIAN TUBE PERFORATED BY ESSURE; I HAD SURGERY TO REMOVE ESSURE AND PATHOLOGY REPORT CAME BACK WITH ENDOMETRIOSIS. I DON'T HAVE A HISTORY OF THIS; IT WAS CAUSED BY ESSURE. ALL MY PROBLEMS HAVE BEEN BECAUSE OF ESSURE!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055658	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 6/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE THE ESSURE DEVICE PUT IN ON (B)(6) 13 AT MY 6 WEEK CHECK UP AFTER HAVING MY 5TH CHILD. AFTER HAVING THIS DONE WITHIN THE FIRST 6 HOURS I HAVE HORRIBLE PAIN IN MY LEGS AND HIPS. I HAD TO HAVE HELP GETTING IN AND OUT OF BED FOR 2 WEEKS. MY HIPS FELT BUSTED. I ALSO NOTICED THAT I HAD HORRIBLE CRAMPS AND BURNING IN MY OVARIES. I HAD SOME SPOTTING THE DAY I LEFT MY DOCTORS OFFICE. DURING THE FIRST 2 WEEKS I WAS BLEEDING VERY HEAVY AND STARTED HAVING DIZZY SPELLS, FELLING SICK TO MY STOMACH, ANXIETY, WEIRD BITTER TASTE IN MY MOUTH, HORRIBLE MIGRAINE HEADACHES, AND CHRONIC PELVIC PAIN. 6 WEEKS AFTER HAVING THIS DONE I WAS STILL BLEEDING SO I WENT TO MY DR AGAIN. HE NOTICED THAT MY LEFT COIL WAS ABOUT 2 CM OUTSIDE IN MY UTERUS AND WAS RUBBING MY UTERUS CAUSING ME TO BLEED. I DEALT WITH THAT FOR 9 MONTHS. DURING THAT TIME AND TO DATE TODAY (B)(6) 2015 I HAVE LOST MASSIVE AMOUNTS OF HAIR, STILL HAVE HORRIFIC MIGRAINES, PAINFUL INTERCOURSE, HORRIBLE DIZZY SPELLS, I HAVE EXTREMELY HIGH BLOOD PRESSURE TO THE POINT THAT THE MEDICATION I'M ON DOESN'T REALLY HELP. I HAVE PAIN IN MY LOWER ABDOMEN ALL THE TIME. THE FEELING OF A HOT POCKET, OR FEELING LIKE MY TUBE ARE BEING PULLED. MOST OF THE TIME I'M IN HORRIBLE PAIN THAT I'M IN BED MOST OF THE TIME. I STILL DEAL WITH A BITTER TASTE IN MY MOUTH, I LOST HAIR IN WEIRD PLACES ALL OVER MY BODY. I'M DEALING WITH A SICK STOMACH DAILY. I DEAL WITH HORRIBLE BLOATING AND PRESSURE IN MY STOMACH, I HAVE A RASH THAT IS ON MY BACK AND CHEST THAT DOESN'T GO AWAY. I ALSO HAVE WHAT FEELS LIKE TREMORS THROUGHOUT MY BODY. THIS PROCEDURE DID NOTHING BUT TAKE MY LIFE FROM ME AND MY FAMILY.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055659	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 9/12/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). ON (B)(6) 2015, I WILL BE HAVING A HYSTERECTOMY ONLY LEAVING OVARIES IF POSSIBLE DUE TO COMPLICATIONS RELATED TO ESSURE INSERTS. SINCE PLACEMENT IN (B)(6) 2012 I HAVE BEEN DEALING WITH HEAVY BLEEDING, CONTRACTION LIKE CRAMPING, MIGRAINES, FATIGUE, WEIGHT GAIN, SERVERE LOWER BACK AND ABDOMINAL PAIN, RECURRING YEAST INFECTIONS AND MANY OTHER STABBING AGONIZING PAINS. FOR 3 YEARS I'VE BEEN IN PAIN AND IT ALL STARTED AFTER ESSURE. PLEASE LISTEN AND REMOVE THIS DANGEROUS DEVICE. I'M ONLY (B)(6) AND HAVING A HYSTERECTOMY...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055660	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE PUT INTO PLACE IN 2012. IN LAST YEAR, I'VE EXPERIENCED STRONG ABDOMINAL PAIN, AND LOWER BACK PAIN AND THE PAIN RADIATES FROM FRONT TO BACK. THE RIGHT OVARY HAS MORE STABBING PAIN AND I RECENTLY FOUND OUT THE COIL IS HANGING OUT A BIT FROM THE OVARY. I'D HAVE TO HAVE OVARIES REMOVED OR JUST GAVE A HYSTO. I ALSO HAVE TO TAKE LOTS OF TYLENOL, USE HEATING PAD ON BOTH ABS AND LOWER BACK. I NOW HAVE HEAVY PERIODS WITH LARGE CLOTTING AND BLEED THROUGH SUPER TAMPONS EVERY HOUR FOR 2 DAYS. I'M EXTREMELY ANEMIC AND GET TV INFUSIONS. EVEN THOUGH I HAVE 48 HOURS OF SUPER BLEEDING, THE CYCLE LASTS 8 DAYS. THEN I HAVE SPOTTING EVERY MONTH 1 WEEK AFTER CYCLE COMMENCES. THAT LASTS ABOUT 1 WEEK TOO. I'VE MISSED A LOT OF WORK IN LAST 12 MONTHS FROM THE DEBILITATING PAIN. I'M (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055661	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 12/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE IMPLANTATION, I HAVE GAINED WEIGHT, SUFFERED WITH FATIGUE, BODY ACHES, MIGRAINE LIKE HEADACHES, DIZZINESS, NAUSEA, FEELING OF GOING TO FAINT, HAIR LOSS, MOODINESS, LOSS OF SEX DRIVE, STABBING PAIN IN RIGHT SIDE NEAR PELVIC, PERIODS THAT ARE HEAVY AND LAST FOR WEEKS, INSOMNIA, ANXIETY, HEART PALPATIONS, VITAMIN D DEFICIENCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055662	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 12/11/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE ESSURE PROCEDURE I HAVE EXPERIENCED THE FOLLOWING SYMPTOMS. EXCESSIVE BLEEDING SO BAD I BLEED CLOTS THE SIZE OF QUARTERS AND GOLF BALLS, SEVERE BLOATING I LOOK 6 MONTHS PREGNANT WHEN I GET MY CYCLE, I ALSO EXPERIENCE TERRIBLE MIGRAINES, BACK PAIN THAT RUNS INTO MY THIGHS, PAIN DURING SEX, I CAN'T GET OUT OF BED OR WORK WHILE HAVING MY CYCLE DUE TO THE SEVERITY OF EXCRUCIATING PAIN I EXPERIENCE. I CURL UP IN A BALL CRYING IN MY BED BECAUSE I CAN'T SLEEP. I CAN'T DEAL WITH THE PAIN ANYMORE I JUST WANT THE PAINFUL BIRTH CONTROL OUT OF MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055663	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY WIFE HAD THIS PROCEDURE DONE AFTER THE BIRTH OF OUR SON. SINCE THEN, SHE HAS BATTLED FATIGUE, SEVERE AND FREQUENT MIGRAINES, PAINFUL SEX, DENTAL ISSUES, HAIR LOSS, LOSS OF BALANCE, DIZZINESS, NAUSEA AND VOMITING, HEAVY PERIODS, SEVERE CRAMPING, HOT FLASHES, HIVES/SKIN RASH, CHRONIC HEMMROIDS, BLOATING, GAS AND MEMORY ISSUES. ONE OF HER COILS CAME OFF AND TUBES AND RESTED ON HER RECTUM. SHE HAD HER TUBES REMOVED IN 2014 AND A TOTAL HYSTERECTOMY (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055664	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GOT ESSURE IN 2010. SINCE THEN I HAVE HAD SIGNIFICANT BLEEDING, HEADACHES, PAIN IN MY FALLOPIAN TUBE AREA, DIZZINESS,LIGHT HEADED, NAUSEA. THIS HAS BEEN SO BAD THAT IN (B)(6) 2014 I HAD BLEED SO HEAVY AND HAD A CONSTANT HEADACHE THAT WOULD NOT GO AWAY FOR WEEKS FINALLY I WENT TO THE ER AND WAS ADMITTED DUE TO A VERY LOW HEMOGLOBIN L AND I HAD TO GET A BLOOD TRANSFUSION. I AM NOW AND HAVE BEEN SINCE THE DATE CHRONICALLY ANEMIC, STILL HAVE HEADACHES DAILY, ACCOMPANIED BY LIGHT HEADED DIZZINESS AND PAIN. ALL THESE TOGETHER HAVE EFFECTED MY QUALITY OF LIFE TREMENDOUSLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055665	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I HAVE HAD THE ESSURE PROCEDURE I HAVE SUFFERED FROM SEVERE ABDOMINAL PAIN, HEADACHES, BLOATING, AND SEVERE MENSTRAL CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055666	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 3/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE ITS A HELL, ESSURE CHANGE MY LIFE ON PAIN, BLOATING MIGRAINES, BACK PAIN, OVARIES PAIN, HEMORRHAGES, LEG PAIN, BONES, VITAMIN D DEFICIENCE AND MY SEXUAL LIFE ITS HORRIBLE, ESSURE NEED TO BE OUT OF THE MARKET, I NEED TAKE ESSURE OUT OF MY BODY, BUT I DO NOT HAVE INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055667	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 3/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). COUNTLESS SURGERIES AND HEALTH PROBLEMS IN THE 10 YRS I HAVE HAD IT , SEVERE ALLERGIC REACTIONS , COUNTLESS HOSPITAL VISITS, AND LOTS OF TIME BEING CHRONICALLY ILL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055668	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 7/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, ANXIETY, AND WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055669	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 10/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OTHER PROBLEMS THAT I HAVE HAD SINCE ESSURE PLACEMENT ARE ARTHRITIC TYPE JOINT PAIN, MUSCLE CRAMPING, DIZZINESS, LACK OF SLEEP, HAVING TO TAKE MULTIPLE PRESCRIPTIONS FOR INFECTIONS AND RESULTANT PROBLEMS FROM THOSE INCLUDING 'C DIFF' TYPE DIARRHEA AND STOMACH ISSUES, MISSED WORK FOR OVER A WEEK DUE TO COMPLICATIONS FROM MEDICINES TAKEN DUE TO INFECTIONS. I HAVE LOST WORK AND THEREFOR LOST MONEY, LOST SLEEP, LOSS MENTAL CAPABILITIES, LOSS MEMORY, INCREASED PAIN, INCREASED ANXIETY, INCREASED WEIGHT, INCREASED MEDICAL BILLS, INCREASED HARM TO MY BODY, INCREASED ILL HEALTH ALL DUE TO THIS DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055670	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 3/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING AND HEAVY BLEEDING WITH MENSTRUAL CYCLE. PAIN DURING SEX AS WELL AS HEAVY BLEEDING OR SPOTTING. SPOTTING OR BLEEDING AT LEAST HALF OF EVERY MONTH. HAIR LOSS AND WEIGHT GAIN, BLOATING.....

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055671	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 7/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN AND DISCOMFORT . WENT TO OBGYN AND WAS TOLD THAT THE DEVICE WAS MOVING OUT OF PLACE ON ONE SIDE . THEN REFERRED TO A SURGEON WHO SUGGESTED I HAVE A PARTIAL HYSTERECTOMY .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055673	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 3/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE, PELVIC PAIN, CAN'T SIT FOR LONG PERIODS OF TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055674	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 9/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, CLOTTING DURING CYCLES. VERY PAINFUL CRAMPS BEFORE AND DURING CYCLES. PROLONGED BLEEDING, EXTRA CYCLES. SPOTTING. SHARP STABBING VAGINAL PAINS, PAINFUL OVULATION. ADENOMYOSIS, FIBROIDS, MOOD SWINGS, HAIR LOSS. RECURRING BACTERIAL VAGINOSIS, UTI'S. INSOMNIA, TEETH ISSUES, HEARTBURN, EXTREME FATIGUE, DEPRESSION, FORGETFULNESS, BRAIN FOG, HAIR GROWTH. METALLIC TASTE IN MOUTH, LOSS OF LIBIDO, PAINFUL SEX, TINGLING SENSATIONS, NUMBNESS, EASY TO CRY, EASILY ANGERED, PAINFUL JOINTS. EXTREMELY LOW IRON/ANEMIA, VITAMIN D DEFICIENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055675	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS DIAGNOSED WITH CELIAC DISEASE IN (B)(6) 2014. ALTHOUGH I HAVE REMAINED ON A GLUTEN-FREE, SOY FEE DIET, THE DIGESTIVE ISSUES, EXCESSIVE FLATULENCE, HAIR THINNING AND HEADACHES STILL REMAIN. I AM SCHEDULED TO HAVE ESSURE REMOVED VIA LAPAROSCOPY AS OF (B)(6) 2015. MY ESSURE REF# IS: (B)(4); LOT # 959215.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055676	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 5/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN THE SUMMER OF 2009 I GAVE BIRTH TO MY SECOND CHILD. BOTH OF MY CHILDREN WERE BORN PREMATURELY, ONE AT (B)(6) AND THE OTHER AT (B)(6). GIVEN THE DANGEROUS NATURE OF PREGNANCY TO MY BODY IT WAS RECOMMENDED THAT I NO LONGER HAVE CHILDREN. UNFORTUNATELY I WAS NOT ABLE TO HAVE MY TUBES TIED DURING THE C-SECTION OF MY SECOND CHILD DUE TO HIM BEING PREMATURE SO MY HUSBAND AND I ASKED MY OB WHAT OUR OPTIONS WERE TO AVOID FURTHER PREGNANCIES. THAT WAS WHEN IT WAS RECOMMENDED THAT I HAVE ESSURE INSERTED. MY HUSBAND AND I FELT THIS WAS A GOOD NON SURGICAL OPTION CONSIDERING ALL THAT MY BODY HAD BEEN THROUGH. WHEN MY OB COMPLETED THE PROCEDURE IT SEEMED TO GO FINE. A FEW MONTHS LATER I HAD THE HCG DYE TEST COMPLETED AND FOUND THAT ONLY ONE COIL WAS IN THE CORRECT LOCATION. AT THAT TIME I HAD ASKED MY DOCTOR IF THERE WAS ANY CONCERN WITH THIS AND HE SAID THAT I WOULD STILL BE ABLE TO GET PREGNANT BUT OTHER THAN THAT, ALL SHOULD BE FINE. FAST FORWARD TO (B)(6) OF 2015, I BEGAN TO HAVE TERRIBLE PAIN IN MY PELVIC REGION AND SEVERE BLOATING. I WENT TO MY PRIMARY CARE DOCTOR TO REPORT MY ISSUES AND THANKFULLY SHE ORDERED A CT SCAN. THE CT SCAN SHOWED THAT THE ESSURE HAD MOVED AND FURTHER TESTING NEEDED TO BE DONE SO AN ULTRASOUND WAS ORDERED. THE ULTRASOUND CONFIRMED THAT BOTH COILS HAD MOVED AND WERE IMPACTING MY UTERUS. THE CT STATED THAT ONE OF THE COILS HAD BROKEN AND APPEARED TO BE IN MY UTERUS. MY OB TOLD ME THE ONLY WAY TO RESOLVE THE ISSUES THAT I AM HAVING IS TO HAVE A HYSTERECTOMY. GIVEN THE FACT THAT THE DEVICE MOVED ON BOTH SIDES, SHOWS ME THAT IT DOESN'T MATTER WHETHER THE DEVICE IS INSERTED PROPERLY OR NOT, IT'S FAULTY AND SHOULD NOT BE ON THE MARKET!! PLEASE, IF YOU ARE CONSIDERING THIS AS YOUR PERMANENT BIRTH CONTROL, DON'T!!

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055677	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 4/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YESTERDAY I WENT TO THE HOSPITAL TO REQUEST MY RECORDS SPECIFIC TO THE DYE TEST PERFORMED IN 2011. UPON RETRIEVAL OF MY RECORDS, I DISCOVERED THAT I HAVE BEEN IMPLANTED WITH 3 COILS, WHEN I WAS ONLY SUPPOSED TO HAVE 2. ONE OF THE COILS WHICH APPEARS TO BE ATTACHED TO MY ABDOMEN NEAR MY HIP ON THE LEFT SIDE, WHICH IS NOWHERE IN THE PROXIMITY OF THE OBJECTIVE. AFTER DOING RESEARCH ON THE INTERNET, I DISCOVERED THAT THE COIL ON MY ABDOMEN AS WELL AS THE COIL ON MY RIGHT FALLOPIAN TUBE APPEAR TO EITHER BE BROKE OR BENT. AS A RESULT, I WILL REQUIRE AN ADDITIONAL SCREENING TO SEE IF THE COILS HAVE MOVED OR BEEN BROKEN FURTHER CAUSED BY CHILD BEARING. I WILL ALSO REQUIRE IMAGING TO SEE IF I POSSESS LOOSE FIBERS WHICH CAN CAUSE FURTHER HEALTH PROBLEMS. IN ADDITIONAL TO A FULL HYSTERECTOMY, IT IS PROBABLE THAT I REQUIRE TO BE TREATED BY A GENERAL SURGEON TO REMOVE THE COIL WHICH IS ORPHANED IN MY ABDOMEN. I HAVE NEVER EXPERIENCED SURGERY SO THIS IS UNCOMFORTABLE AND FRIGHTENING TO ME. I HAVE THREE CHILDREN AND THESE SURGERIES ARE GOING TO CAUSE ME TO BE UNABLE TO CARE FOR THEM AND WORK TO PROVIDE FOR THEM UNTIL I HEAL, FURTHERMORE, IF I DO NOT GET THE SURGERIES I COULD BE FACING PERMANENT HEALTH COMPLICATIONS OR DEATH. PLEASE TAKE THIS TERRIBLE PRODUCT OFF THE MARKET!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055678	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 10/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN IN ALL OF MY JOINTS AND MUSCLES, ABRUPT STOP IN MENSTRUATION WITHIN A COUPLE OF YEARS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055679	BAYER	8/21/2015	8/21/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE EMPLANED ON (B)(6) 2012 AND SINCE THEN IT HAS ALWAYS FELT WRONG, I HAVE BEEN TO THE DOCTOR SEVERAL TIMES REGARDING THIS AND WAS TOLD ITS NORMAL GIVE IT TIME , IT'S BEEN ALMOST 3 YEARS OF PURE HELL, I AM NOT ABLE TO BE WITH MY HUSBAND BECAUSE OF THE PAIN, IT'S SO UNBEARABLE TO FEEL LIKE I HAVE 50LBS OF PRESSURE IN MY UTERUS ALSO IT FEELS LIKE I HAVE A MEAT GRINDER IN BOTH SIDE WHERE THE DEVICES ARE , I HAVE HAD THE DUE TEST IT SAYS COMPLETELY BLOCKED , BUT MY SYMPTOMS ARE BECOMING MORE AND MORE ND GETTING WORSE , METAL TASTE IN MOUTH , NO ENERGY , DIZZINESS, FEELING FAINT. TINGLING AND NUMBNESS IN HANDS AND FEET THIS WAS AT NIGHT TIME BUT HERE IN THE LAST FEW WEEKS IT'S ALL DAY LONG, BURNING IN HANDS AND FEET , I BELIEVE I HAVE A COOL OUT OF PLACE BECAUSE I FEEL. POKING IN MY STOMACH THAT'S ALL IT CAN BE I CAN'T DO ANYTHING BUT SIT,90% OF THE TIME I CAN'T MOVE DUE TO CRAMPING PULLING AND PAIN IN MY PELVIC ARE THIS IS A ALL THE TIME FEELING . I AM A MOTHER AND I CAN'T EVEN DO THINGS WITH MY CHILDREN !! THIS DEVICE IS KILLING ME IT IS STEALING ME AWAY FROM MY FAMILY , I DON'T UNDERSTAND WHY BAYER WON'T DO THE RIGHT THING , THIS HAS STOLEN 3 YEARS FROM MY LIFE THAT I WILL NEVER GET BACK ! MOMENTS I WILL NEVER GET BACK , MEMORIES I CAN NOT REMAKE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055775	CONCEPTUS	8/21/2015	8/27/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A33567

Single Use: *
Implant Date (E6): 7/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED ON (B)(6), 2015. I HAVE BEEN BLEEDING DAILY FOR SEVEN WEEKS. THIS INFORMATION WAS NOT RELAYED TO ME BEFORE THE PROCEDURE. NOW I AM BEING TOLD THAT I COULD BLEED FOR FOUR MONTHS OR MORE. THIS SERIOUSLY AFFECTS THE QUALITY OF MY LIFE, AND I AM ALSO ON DEPO SHOTS WHICH STOP ME FROM BLEEDING. I DO NOT UNDERSTAND WHERE ALL THIS BLOOD IS COMING FROM. IT IS BROWN, BRIGHT RED, CLUMPY IT VARIES DAY TO DAY. IT IS TERRIBLE, AND I AM SICK OF IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055776	CONCEPTUS	8/21/2015	8/27/2015

Event Information:

Event Date (B3): 12/22/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/22/2009
Explant Date (E7): 5/6/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN MY TUBES IN 2009. SINCE THEN I HAVE HAD UNEXPLAINED RASHES AND SEVERE PELVIC PAIN. I HAVE HAD LONGER CYCLES. MAJOR BLOATING AND CONSTIPATION. STARTED GETTING MIGRAINES. FATIGUED ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055680	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 1/11/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD COILS INSERTED IN (B)(6) 2005. SHORTLY THEREAFTER STARTED TO EXPERIENCE PELVIC PAIN, LOWER BACK PAIN, IRREGULAR PERIODS AND ANXIETY. THIS HAS PROGRESSED OVER THE YEARS AND I HAVE DEVELOPED OSTEOARTHRITIS OF THE LOWER BACK WHICH HAS NOW SPREAD TO ALL PARTS OF MY SPINE WHICH I BELIEVE TO BE FROM CHRONIC INFLAMMATION RELATED TO THE COILS. I HAVE CHRONIC FATIGUE, AND WIDE SPREAD MUSCLE AND JOINT PAIN AND SEVERE ANXIETY. ALSO "BRAIN FOG" AND TROUBLE CONCENTRATING. POOR QUALITY OF LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055681	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 2/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ON LOWER LEFT SIDE OF MY BODY- UPPER THIGH, PELVIC AREA, BACK PAIN AND NUMBNESS IN BOTH LEGS, NUMBNESS IN BOTH ARMS AND HANDS, EXTREMELY PAINFUL MENSTRUAL CRAMPS, BLOOD CLOTS AND HEAVY BLEEDING DURING MENSTRUAL CYCLE, PERIOD OCCURRING EVERY 21-23 DAYS, CONSTANT URGE TO URINATE, CONSTANT URGE TO DEFECATE , POSSIBLE ADENOMYOSIS DIAGNOSIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055682	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 8/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNDERWENT HYSTERECTOMY REMOVING TUBES, UTERUS AND CERVIX ON (B)(6) 2015. THE RIGHT ESSURE INSERT WAS PERFORATED THROUGH THE PROXIMAL RIGHT TUBE AND THE LEFT WAS PARTIALLY PERFORATED THROUGH THE LEFT TUBE. THE UTERUS WAS SLIGHTLY ENLARGED AND GLOBULAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055683	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 4/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN THE ESSURE WAS IMPLANTED, IT TOOK SO LONG FOR THE DOCTOR TO GET IT IN THAT MY MEDS WORE OFF. IT WAS TERRIBLE PAIN. A MONTH LATER MY HAIR STARTED FALLING OUT ALITTLE AT A TIME. I STARTED TO FEEL TIRED ALL THE TIME. THAT FALL (2012) I BEGAN HAVING DENTAL PROBLEMS. I ENDED UP HAVING TO HAVE 8 TEETH PULLED AND HAVE HAD COUNTLESS ROOT CANALS, TEETH CRUMBLING AND MY ONCE PERFECT SMILE IS NOW FULL OF PARTIALS AND SEVERAL MORE TEETH THAT NEED TO BE PULLED. THE NEXT SPRING (2013) I STARTED HAVING WHAT SEEMED LIKE GALLBLADDER PROBLEMS BUT IT WAS NEVER FOUND ANYTHING WRONG WITH MY GALLBLADDER. AFTER COUNTLESS DOCTOR APPOINTMENTS I FINALLY LEARNED TO DEAL WITH THE SUDDEN BOWEL ISSUES AND ALMOST CONSTANT STOMACH PAIN. THE SUMMER OF 2014 BEGAN THE WORSE OF ALL MY SYMPTOMS. I STARTED GETTING THIS STRANGE WELL RASH ALL OVER MY BODY. IT WOULD COME AND GO WITHIN 24 HOURS. THEN THE JOINT PAIN STARTED. THE DEBILITATING JOINT PAIN. SOON ANY PHYSICAL ACTIVITY WOULD RESULT IN A NIGHT OF AGONIZING PAIN. THE FATIGUE GOT WORSE BECAUSE I WAS IN SO MUCH PAIN I COULDN'T SLEEP. MY MENSTRUAL CYCLE GOT WORSE AND WORSE ALSO. IT GOT TO WHERE I COULD NOT LEAVE THE HOUSE DURING MY PERIOD BECAUSE I BLED SO HEAVY. WEIGHT GAIN OF 50 LBS HAS HAPPENED IN THE PAST YEAR. MY DOCTOR AGREED TO TAKE ESSURE OUT AND DO AN ABLATION AFTER IT WAS OUT. WHEN SHE TOOK MY FALLOPIAN TUBES ONE COIL WAS IN MY TUBE BUT THE OTHER COIL WAS IN MY UTERUS. MY DOCTOR TOOK IT OUT OF MY UTERUS AND DID THE ABLATION. NOW 6 MONTHS LATER I STILL HAVE TERRIBLE WELPS, JOINT PAIN, FATIGUE, AND HAIR LOSS. I HAVE BEEN TESTED FOR COUNTLESS AUTOIMMUNE DISEASES AND ALL COME UP NEGATIVE. MY MOST RECENT TEST SHOWED THE MARKER FOR RHEUMATOID ARTHRITIS HIGH. ESSURE HAS RUINED MY LIFE. I WAS HEALTHY AND HAPPY BEFORE IT AND NOW MY QUALITY OF LIFE IS TERRIBLE. THIS NEEDS TO BE TAKEN OFF THE MARKET.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055684	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOLLOWING SYMPTOMS TO DATE INCLUDE: STOMACH BLOATING, STOMACH SHARP PAINS, BODY CONSTANTLY ACHING, CONSTIPATION, BACK ACHES, STABBING PAIN IN LOWER STOMACH, SWELLING IN LEGS AND FEET, RASHES ON BACK, LEGS AND FRONT, CYSTS, TERRIBLE CRAMPS, PERIODS EVERY OTHER WEEK AND SOMETIMES IN BETWEEN, EXCESSIVE BLEEDING, DIZZINESS, HOT FLASHES AND EXCESSIVE SWEATING, FATIGUE TO THE POINT OF PASSING OUT, EXCESSIVE WEIGHT GAIN, LOSS OF APPETITE, DIARRHEA SEVERAL DAYS A WEEK, NIGHT SWEATS, PAIN DURING INTERCOURSE, JOINT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055685	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 7/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN STARTED IN LOWER RIGHT SIDE OF MY ABDOMEN. IT WAS A BURNING AND STABBING PAIN THEN MOVED O MY ENTIRE ABDOMEN AND BLEEDING OCCURRED DURING INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055686	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 9/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE INSERTED 4 WEEKS POST PARTUM. I KNOW THE LEAFLET SAYS 6 WEEKS SO I'M NOT SURE WHY MY GYN DID IT EARLY AND IF THAT'S THE REASON FOR SO MANY ISSUES. IT WENT HORRIBLE. I WAS NOT GIVEN ANESTHESIA AND WASN'T GIVEN VALIUM. ABSOLUTELY NOTHING EXCEPT FOR MOTRIN. THE SHOTS IN MY CERVIX HURT SO BAD. WHILE THE CAMERA WAS BEING INSERTED I STARTED GETTING HORRIBLE PAIN IN MY NECK MY LOWER BACK. IT WAS SPASMING. IT FELT LIKE MY NECK AND BACK WERE GOING TO POP AND I COULD NOT STOP SHAKING. DOCTOR HAD TO PULL EVERYTHING BACKED OUT OF THE CERVIX. HE THEN ASKED IF I WAS EVER IN A CAR ACCIDENT. I SAID I WAS AROUND 10 TO 12 YEARS AGO. HE SAID HE NEVER SEEN ANYTHING LIKE THAT HAPPEN TO A PATIENT BEFORE. HE WAS ON MY CERVICAL SIGN AND THINKS IT MAY HAVE TRIGGERED THE SPASMS BUT WASN'T SURE. I STARTED FREAKING OUT. THE PAIN WAS UNBEARABLE AND I BEGAN SCREAMING. AFTER 5 MINUTES IT WENT AWAY. THEY PROPPED THE BED UP A LITTLE AND DECIDED TO TRY ONCE MORE. IF I BEGAN HURTING HE WOULD STOP AND NOT TRY AGAIN. THIS TIME NO SPASMS. WHEN THE COILS WERE INSERTED I GOT EXTREME CRAMPING THAT MADE ME WANT TO SLAP THE DOCTOR. WHEN IT WAS OVER I GOT UP AND WAS TOLD I WILL LEAK OUT SALINE BUT NO BLOOD. HOWEVER THERE WAS JUST A LITTLE BIT OF BLOOD. I PUT ON A PAD. I KNEW WHEN I WENT IN THAT I WAS BLEEDING SLIGHTLY LIKE THE END OF MY PERIOD. STARTED DRIVING HOME AND FELT GUSHES. THOUGHT IT WAS JUST SALINE COMING OUT. LOOKED DOWN AND NOPE BLOOD EVERYWHERE. I PULLED OVER. GRABBED A TOWEL TO PLACE UNDER ME AND ONE OF LOS DIAPERS AND STUFFED MY PANTIES. I LIVE AN HOUR AWAY FROM MY DR AND ANY CIVILIZATION! VERY SMALL TOWN. I RUN TO THE BATHROOM AND PULL OFF CLOTHES, AND PAD AND DIAPER. DIAPER WAS SOAKED AND HAD A CLOT THE SIZE OF MY FIST IN IT. THEN WHILE SITTING ON THE TOILET ANOTHER FIST SIZED CLOT. PLUS THE BLOOD WOULD NOT STOP. CALLED THE DR ON CALL. HE SAID I SHOULDN'T BE

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BLEEDING LIKE THAT BECAUSE NO CUTS OR INCISIONS WERE MADE. JUST THE SMALL PIN SIZE HOLE IN CERVIX. HE SAID I COULD GO TO THE EMERGENCY ROOM OR LAY DOWN AND SEE IF THE BLEEDING STOPS. I DECIDED TO LAY DOWN. AFTER 30 MIN THE BLEEDING EASED UP. TODAY IS BETTER. HEAVY BLEEDING AND CRAMPING BUT NOTHING LIKE WHAT I HAD. NURSE CALLED AND SAID BECAUSE THIS IS MY FIRST PERIOD IT WOULD BE BAD. THEY ARE OUT OF THEIR MINDS. WHATEVER HAPPENED YESTERDAY HAD ME BLEEDING CUPS OF BLOOD. I HAVE HAD NATURAL CHILD BIRTH, A C SECTION AND HAD GOT BIT BY A DOG ON THE FACE WHICH REQUIRED SEVERAL STITCHES. YOU ADD ALL THAT UP AND STILL THIS EXPERIENCE AND PAIN WAS THE WORST. THE HORRIBLE FEELING OF WHAT I THOUGHT WERE MY NECK AND BACK BREAKING AND CERVIX PAIN WAS UNBEARABLE. I DO NOT RECOMMEND THIS WITHOUT ANESTHESIA OR AT LEAST A VALIUM. IF I COULD GO BACK TO TOMORROW I WOULD NOT HAVE DONE IT. SOON FOLLOWING INSERTION (LIKE SAME DAY) I STARTED HAVING A FEELING OF FIRE RUNNING DOWN MY BUTT AND LEGS. THEN LATER IT WENT TO MY HANDS AND FEET. MIGRAINES 2X A WEEK. HEAVY PERIODS. EXTREME PAIN IN OVARY AREAS. I HAVE NERVE DAMAGE AND I THINK IT'S FROM PROBLEMS DURING THE PROCEDURE. THE GYN SHOULD NOT HAVE ATTEMPTED AGAIN AFTER THE FIRST FAIL. INSTEAD A ONE MINUTE BREAK AND BACK IN HE WENT. I GET WEIRD RASHES ON MY LOWER ABDOMEN NOW ALSO. I HAVE HAD TO GET STEROID EPIDURAL SHOTS AND PAY OUT OF POCKET AND IT'S STILL NOT FIXED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055687	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 4/2/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THE ESSURE PROCEDURE DONE IN 2009, I'VE STARTED HAVING MIGRAINES, FATIGUE, BLOATING AND PAIN ON BOTH SIDES OF MY LOWER ABDOMEN. I HAD AN ULTRASOUND DONE TO RULE OUT ANY OTHER ISSUES THAT MIGHT BE CAUSING MY PAIN AND IT CAME BACK CLEAR. SO I NEED TO HAVE THE ESSURE REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055688	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 10/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD AN ALLERGIC REACTION TO THE IMPLANT. IT CAUSED ME PAIN, HEAVY BLEEDING. NEUROLOGICAL PROBLEMS. I WAS UNABLE TO WORK DUE TO ALL THE SIDE EFFECTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055689	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 5/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NAUSEA, VOMITING, CHILLS, HOT FLASHES, DIZZINESS, VERTIGO, LIGHTHEADED, CRAMPS, LOWER BACK PAIN, ACHES, PAINFUL INTERCOURSE, EXTREMELY PAINFUL MENSTRUATION, WEAKNESS, NUMB EXTREMITIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055690	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 8/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ABDOMINAL PAIN. I THOUGHT IT WAS A BLADDER INFECTION. I WENT TO THE ER. THEY TESTED MY BLOOD AND URINE. I HAD A SLIGHT UTI. THE DOCTOR WAS CONCERNED ABOUT THE PAIN I WAS HAVING. WHEN HE FOUND OUT THAT I HAVE ESSURE COILS, HE LOOKED CONCERNED AND GAVE ME A PELVIC EXAM AND ULTRASOUND. I NOW HAVE PELVIC INFLAMMATORY DISEASE CAUSED BY THE ESSURE. HE SAID THEY NEED TO COME OUT ASAP. I'M ON ANTIBIOTICS THAT DO NOT SEEM TO WORK. I'VE BEEN GETTING SICKER DAY BY DAY. I FEEL LIKE I AM GOING TO DIE. I'VE MISSED A LOT OF WORK BECAUSE OF THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055691	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 6/13/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THIS REPORT I HAVE SINCE BEEN DIAGNOSED WITH INSULIN RESISTANCE AND HYPOTHYROIDISM. AND HAD TO HAVE AN ENDOSCOPY WHICH FOUND SEVERE INFLAMMATION, SCARRING AND POLYPS IN MY STOMACH. THESE DEVICES NEED TO BE TAKEN OFF OF THE MARKET AND ALL OF US WHO ARE SUFFERING FROM A BAD DEVICE NEED TO HAVE THEM REMOVED!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055693	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SUDDENLY I FEEL VERY TIRED, MY WHOLE BODY ACHE. ALL DAY MY BONES HURTS AND I FEEL SAD.. LIKE DEPRESSED. SOME TIMES MY LOWER BACK FEELS LIKE IF IT WILL BREAK. IT IS TERRIBLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055694	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, WEIGHT GAIN ,BRAIN FOG AND DIFFICULTY CONCENTRATING, WITH SEVERE MEMORY PROBLEMS, TO THE EXTENT OF HAVING DIFFICULTY COMPREHENDING WRITTEN TEXTS, REMEMBERING SHORT LISTS, REMEMBERING PEOPLE'S NAMES OR BASIC FACTS OR SEQUENCES THIS IS HIGHLY UNCHARACTERISTIC OF ME, AND THE ONSET WAS SUDDEN AND DRAMATIC, LETHARGY AND EXTREME FATIGUE, FEELING ALMOST AS IF I'VE BEEN DRUGGED AT TIMES, UNABLE TO STAY AWAKE WHILE WORKING, HAVING TO PULL OVER WHILE DRIVING, UNABLE TO WAKE IN THE MORNINGS, SLEEP DISRUPTIONS AND INSOMNIA, SEVERELY BLOATED BELLY, RECURRING PELVIC PAIN, SOMETIMES SHARP AND STABBING, SOMETIMES DULL AND ACHING, PAINFUL SEXUAL INTERCOURSE, INTOLERANCE TO COLD, DEBILITATING HEADACHES, DEPRESSION, ANXIETY, MOOD SWINGS, NUMBNESS IN HANDS AND FEET, LOSS OF CIRCULATION, BLURRED VISION, JOINT AND MUSCLE ACHES, SOMETIMES SO SEVERE I HAVE BEEN UNABLE TO WALK OR PERFORM BASIC PHYSICAL MOVEMENTS OR TASKS, DIZZINESS, FAINTING, SEVERE MENSTRUAL CRAMPS, HIGH CHOLESTEROL, AS A GENERALLY HEALTHY (B)(6) WOMAN, I'VE NEVER HAD THIS ARRAY OF SYMPTOMS BEFORE, (BLOATING, MOOD SWINGS, HEADACHES, FATIGUE).AND I DON'T HAVE PERIOD FOR 3 MONTHS, ALL OF THIS IS AFTER ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055695	BAYER	8/24/2015	8/24/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY MENSTRUAL CYCLES, HEADACHES, SEVERE PELVIC PAIN, BACKACHES, HORRIBLE CRAMPS, PAINFUL SEX, WEIGHT GAIN,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055799	BAYER	8/24/2015	8/28/2015

Event Information:

Event Date (B3): 8/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 4/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY WIFE HAD THE ESSURE IMPLANTED IN (B)(6) 2010 AND SINCE THAT TIME HAS EXPERIENCED PELVIC PAIN AND HEAVY MENSTRUAL CYCLE JUST TO NAME A FEW OF THE THINGS SHE HAS EXPERIENCED SINCE HAVING THIS DEVICE IMPLANTED. SHE HAD FOLLOW UP VISITS WITH THE DOCTOR AND THEY ASSURED HER THAT THE PAIN WOULD GO AWAY. THE PAIN HAS NOT GONE AWAY. IT HAS ONLY INTENSIFIED. IT IS SERIOUSLY IMPACTING HER HEALTH. I BELIEVE THE ESSURE IS CAUSING HER SERIOUS PROBLEMS AND NOW SHE HAS TO HAVE SURGERY TO RID HERSELF OF THIS DEVICE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00632	BAYER HEALTHCARE LLC	8/25/2015	8/25/2015

Event Information:

Event Date (B3): 6/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# MW5043952) IN (B)(6) 2015. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON 2013. ACCORDING TO THE REPORT, HYSTEROSALPINGOGRAM WAS PERFORMED (UNSPECIFIED DATE) AND SHOWED THE ESSURE DID NOT PROPERLY FORM THE SCAR TISSUE AND HER TUBE WAS STILL OPEN. CONSUMER STARTED TAKING DEPOT SHOTS. SHE HAD NO CLUE SHE WAS PREGNANT, UNTIL A FEW DAYS BEFORE, WHICH WAS ON A WEEKEND, AND WAS GOING TO CALL THE OBSTETRICIAN ON MONDAY ((B)(6)2015). SUNDAY EVENING ((B)(6) 2015), SHE STARTED BLEEDING PROFUSELY, WENT TO THE EMERGENCY ROOM, AND DELIVERED A BABY WHO WAS STILL BORN. AS OF SUNDAY EVENING ((B)(6) 2015) SHE WAS VERY ACTIVE, IT WAS TOLD THAT THE ESSURE WAS DISLODGED AND WAS STICKING OUT ENOUGH IN HER ABDOMINAL SPACE THAT IT RUPTURED HER PLACENTA, WHICH LED TO FETAL DEMISE ((B)(4)). ON (B)(6) 2015, PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). THE BAYER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS

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NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT TWO YEARS LATER. THEN, SHE STARTED TO BLEED PROFUSELY. SHE WENT TO EMERGENCY ROOM AND DELIVERED A BABY WHO WAS STILL BORN. ACCORDING TO HER, ESSURE WAS DISLODGED AND WAS STICKING OUT IN HER ABDOMINAL SPACE (SEEN AS DEVICE DISLOCATION) AND RUPTURED OF PLACENTA. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE. STILLBIRTH AND RUPTURE OF PLACENTA ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE PREGNANCY AND DISLOCATION ARE LISTED. IN THIS CASE, THE CONFIRMATION TEST SHOWED THE ESSURE DID NOT PROPERLY FORM THE SCAR TISSUE AND THE TUBE WAS STILL OPEN. IN ADDITION, IT WAS STATED THE DEVICES SHOULD BE DISLODGED. ALTHOUGH, IN THIS CASE, THE TUBAL PATENCY MAY HAVE OCCURRED AS A RESULT OF DEVICE DISLODGEMENT, DEVICE FAILURE CANNOT BE TOTALLY EXCLUDED AND THEREFORE THE PREGNANCY IS ASSESSED AS RELATED TO ESSURE USE. REGARDING STILLBIRTH, IN THE ABSENCE OF FATAL CONGENITAL ANOMALIES, STILLBIRTHS ARE MAINLY DUE TO MATERNAL EVENTS LEADING TO INADEQUATE OXYGEN SUPPLY TO THE FETUS. THUS A PROBLEM WITH THE PLACENTA IS A VIABLE CAUSE FOR STILLBIRTH. BASED ON THESE CONSIDERATIONS, A CONTRIBUTORY ROLE OF ESSURE IN THIS RUPTURE OF PLACENTA AND THEN IN STILLBIRTH CANNOT BE EXCLUDED. SINCE A SERIOUS COMPLICATION OF PREGNANCY RELATED TO DEVICE WAS REPORTED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 26-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00633	BAYER HEALTHCARE LLC	8/25/2015	8/25/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# MW5043952) IN UNITED STATES ON 21-JUL-2015. IT REFERS TO A FETUS WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) DURING PREGNANCY AND SUFFERED FETAL DEMISE (MOTHER CASE# (B)(4) / (B)(4)). ADDITIONAL INFORMATION RECEIVED ON 21-AUG-2015. ACCORDING TO THE INFORMATION PROVIDED, HYSTEROSALPINGOGRAM WAS PERFORMED (UNSPECIFIED DATE) AND SHOWED THE ESSURE DID NOT PROPERLY FORM THE SCAR TISSUE AND HER TUBE WAS STILL OPEN. CONSUMER STARTED TAKING DEPOT SHOTS. SHE HAD NO CLUE SHE WAS PREGNANT, UNTIL A FEW DAYS BEFORE, WHICH WAS ON A WEEKEND, AND WAS GOING TO CALL THE OBSTETRICIAN ON MONDAY ((B)(6)2015). SUNDAY EVENING ((B)(6) 2015), SHE STARTED BLEEDING PROFUSELY, WENT TO THE EMERGENCY ROOM, AND DELIVERED A BABY WHO WAS STILL BORN (GESTATIONAL AGE NOT PROVIDED). AS OF SUNDAY EVENING ((B)(6) 2015) SHE WAS VERY ACTIVE. ACCORDING TO THE REPORT, ESSURE WAS DISLODGED AND WAS STICKING OUT ENOUGH IN HER ABDOMINAL SPACE THAT IT RUPTURED HER PLACENTA, WHICH LED TO FETAL DEMISE. DUE TO UNAVAILABLE REPORTER CONTACT INFORMATION, NO FOLLOW UP CAN BE DONE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-AUG-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT

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OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY IN ASSOCIATION WITH A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FETUS WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) DURING PREGNANCY AND SUFFERED FETAL DEMISE. THIS EVENT IS SERIOUS DUE TO ITS FATAL NATURE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT CAUSE OF FETAL DEATH WAS NOT PROVIDED. IT WAS INFORMED THE MOTHER STARTED TO BLEED PROFUSELY, WENT TO EMERGENCY ROOM AND DELIVERED A BABY WHO WAS A STILLBORN. IT WAS ALSO STATED ESSURE WAS DISLODGED AND WAS STICKING OUT IN HER ABDOMINAL SPACE (INTERPRETED AS DEVICE DISLOCATION) AND RUPTURED HER PLACENTA. IN THE ABSENCE OF FATAL CONGENITAL ANOMALIES, STILLBIRTHS ARE MAINLY DUE TO MATERNAL EVENTS LEADING TO INADEQUATE OXYGEN SUPPLY TO THE FETUS. THUS, A PROBLEM WITH THE PLACENTA IS A VIABLE CAUSE FOR STILLBIRTH. BASED ON THESE CONSIDERATIONS, A CONTRIBUTORY ROLE OF ESSURE IN THIS RUPTURE OF PLACENTA AND THEN IN STILLBIRTH AND FETAL DEMISE CANNOT BE EXCLUDED. GIVEN THE FATAL NATURE OF EVENT, THIS CASE IS REGARDED AS INCIDENT. ACCORDING TO THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 26-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00634	BAYER HEALTHCARE LLC	8/25/2015	8/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# MW5043955) IN UNITED STATES ON 21-JUL-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. IT WAS REPORTED SHE WENT TO HER 3 MONTHS CHECK UP TO FIND OUT THAT ONLY ONE SIDE OF HER FALLOPIAN TUBES WERE BLOCKED. SHE WAS NEVER CONTACTED AFTERWARDS BUT SHE WAS TOLD THAT THE OTHER SIDE WOULD CLOSE WITHIN THE NEXT COUPLE MONTHS. ONE YEAR AND A HALF LATER, SHE BECAME PREGNANT. SHE ALSO FOUND OUT THAT THE ESSURE COIL WAS NO LONGER LOCATED IN HER FALLOPIAN TUBE DURING AN ULTRASOUND TO CHECK AND MAKE SURE SHE DID NOT HAVE AN ECTOPIC PREGNANCY. SHE HAD BEEN INFORMED THE DEVICE WAS FLOATING IN HER UTERUS, ALONG WITH HER BEING PREGNANT. THE CONSUMER WAS IN DOUBT IF SHE COULD CARRY THE PREGNANCY. ACCORDING TO HER, HER DOCTORS HAVE NOT BEEN ABLE TO GIVE HER ANSWERS TO ANY QUESTIONS SHE HAD. ONE HAD SAID SHE WILL BE FINE TO CARRY THE CHILD, WHERE REPORTED CASES OF WOMEN GETTING PREGNANT WITH THE IUD HAVE BEEN SUCCESSFUL. SHE MENTIONED THAT OTHER PHYSICIAN HAVE SAID THE RISK OF GETTING AN INFECTION, WHERE IF THIS HAPPENS, THE PREGNANCY WILL HAVE TO BE TERMINATED AND COULD POSSIBLY BE FATAL TO HER. SHE STATED SHE STILL HAS TWO SMALL CHILDREN AT HOME TO THINK OF AS WELL AS A HUSBAND AND THE THOUGHT OF SOMETHING HAPPENING TO HER OR HER UNBORN BABY IS UNBEARABLE. ON 13-AUG-2015, TECHNICAL INVESTIGATION WAS RECEIVED: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO

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CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT . IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT ONE YEAR AND A HALF LATER. IT WAS ALSO FOUND OUT THE DEVICE WAS FLOATING IN HER UTERUS (SEEN AS PARTIAL EXPULSION OF DEVICE), ALONG WITH HER BEING PREGNANT. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS CASE, THE CONFIRMATION TEST SHOWED JUST ONE TUBE BLOCKED. IN ADDITION, IT WAS STATED THE DEVICE WAS FLOATING IN HER UTERUS. ALTHOUGH THE TUBAL PATENCY MAY HAVE OCCURRED AS A RESULT OF DEVICE PARTIAL EXPULSION, DEVICE FAILURE CANNOT BE EXCLUDED AND THEREFORE, PREGNANCY IS ASSESSED AS RELATED TO ESSURE USE. THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT, SINCE THE PRESENCE OF DEVICE INTO UTERINE CAVITY MAY LEAD TO PREGNANCY COMPLICATION. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INVALID DATA**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00635	BAYER HEALTHCARE LLC	8/25/2015	8/25/2015

Event Information:

Event Date (B3): 6/8/2015 **Report Date (B4):** **Event Report Type (H1):** INVALID DATA **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# MW5043972) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO AN INFANT FEMALE PATIENT WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) DURING HER MOTHER PREGNANCY (MOTHER'S LINKED CASE (B)(4)). THE INFANT'S MOTHER BECAME PREGNANT WHILE RELYING ON ESSURE; COMPLICATIONS FROM THE DEVICE LED TO THE DEATH OF THE INFANT GIRL; (B)(6) 2015 WAS REPORTED AS EVENT DATE. ON 13-AUG-2015, TECHNICAL INVESTIGATION RESULT WAS RECEIVED PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE INFANT WHOSE MOTHER

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HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, BECAME PREGNANT PROBABLY DUE TO DEVICE FAILURE AND HAD COMPLICATIONS FROM DEVICE. THESE COMPLICATIONS LED THE INFANT TO DEATH. THIS EVENT IS SERIOUS DUE TO ITS FATAL OUTCOME AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, LIMITED INFORMATION REGARDING TO MOTHER'S PREGNANCY AND INFANT'S DEATH HAVE BEEN PROVIDED. CONSIDERING THAT A MECHANICAL INTERFERENCE OF DEVICE IN DEVELOPING PREGNANCY CANNOT BE TOTALLY EXCLUDED, THIS EVENT IS ASSESSED AS RELATED TO ESSURE USE AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055823	BAYER	8/25/2015	8/31/2015

Event Information:

Event Date (B3): 6/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7): 6/3/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I DECIDED TO GO WITH ESSURE FOR STERILIZATION AND SHORTLY AFTER IMPLANTATION, I BEGAN TO EXPERIENCE DEPRESSION, CONSTANT PAIN, ANEMIA, BRAIN FOG, VERY HEAVY PERIODS, IRREGULAR PERIODS (2 WEEKS A MONTH), AND IN 2012 SEVERAL CYSTS WERE FOUND. I WAS NEVER ASKED ABOUT AN ALLERGY TO ANY METAL IN THE IMPLANT OR TESTED FOR ONE BEFORE RECEIVING THE IMPLANT. PRIOR TO IMPLANTATION, I HAD REMOVED HAD A SINGLE CYST. A LARGEST CYST REQUIRED IMMEDIATE SURGERY AND MY RIGHT OVARY WAS REMOVED AT THAT TIME. I CONTINUED TO FEEL CONSTANT PAIN AND HAVE SWELLING ON ONE SIZE OF MY ABDOMEN. IN (B)(6) OF 2015, THE BLEEDING JUST NEVER STOPPED, I WAS VERY ANEMIC, AND THE PAIN INCREASED. I HAD TO HAVE A HYSTERECTOMY IN (B)(6) OF 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055830	BAYER	8/25/2015	8/31/2015

Event Information:

Event Date (B3): 8/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): BIRTH CONTROL METHOD
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/25/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE ESSURE COILS FOR EIGHT YEARS. EVER SINCE I GOT THEM I HAVE SHARP PAIN ON LEFT SIDE OF OVARY, MORE HEAVY BLEEDING ON MY MENSTRUAL AND PAIN IS GETTING WORSE WHILE ON MY PERIOD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055832	BAYER	8/25/2015	8/31/2015

Event Information:

Event Date (B3): 8/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE INSERTED ABOUT 5 YEARS AGO. I KNEW I NO LONGER WANTED KIDS AND WAS FINE WITH THE PERMANENT RESULTS OF THE PRODUCT. THE CRAMPING AFTER INSERTION LASTED ON AND OFF FOR ABOUT A YEAR. IT FINALLY SUBSIDED BUT AFTER THAT I OCCASIONALLY SUFFERED FROM HEMORRHAGIC CYSTS. I RECENTLY HAD A PAP SMEAR AND MY DOCTOR NOTICED EPITHELIAL CELLS WHERE THEY SHOULDN'T BE. I AM TOO YOUNG (B)(6) FOR CANCER SCREENINGS BUT I FOUND IT INTERESTING THAT A FRIEND OF MINE (WHO ALSO HAS ESSURE AND IS (B)(6)) IS HAVING THE EXACT SAME PROBLEM. SHE WILL START CANCER TESTING SOON. WE ALSO BOTH SUFFER FROM SEVERE MOOD SWINGS. I OFTEN FALL INTO DEPRESSION SINCE THE ESSURE PROCEDURE. I'LL BE CALLING MY DOCTOR TODAY TO DISCUSS POSSIBLE SOLUTIONS TO MY ISSUES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00636	BAYER HEALTHCARE LLC	8/26/2015	8/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B40019

Single Use: Y
Implant Date (E6): 2/10/2014
Explant Date (E7): 5/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043277) IN UNITED STATES ON 04-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014; THE LOT NUMBER USED WAS B40019. SHE REPORTED AFTER ESSURE SHE HAD SWELLING, BLOATING, INFECTIONS PELVIC INFLAMMATORY DISEASE, SEVERE PAIN AND CRAMPS IN STOMACH. SHE REPORTED (B)(6) 2015 AS EXPLANT DATE OF ESSURE. THE CONSUMER ALSO MENTIONED THE SERIOUSNESS CRITERION REQUIRED INTERVENTION BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. SHE ALSO MENTIONED VITAMIN D 10000 MG AS CONCOMITANT MEDICATION. FOLLOW-UP RECEIVED ON 18-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: B40019; PRODUCTION DATE: MAY-2013; EXPIRATION DATE: 31-MAY-2016 SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT

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INDICATIVE OF A QUALITY DEFICIT PER SE. (B)(4) FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, OF WHICH (B)(4) CASE REFERS ALSO TO A SIMILAR TYPE OF ADVERSE EVENTS. NO UNUSUAL PATTERN COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN (SEEN AS PELVIC PAIN) AND PELVIC INFLAMMATORY DISEASE. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR DURING ESSURE USE. CONSIDERING AVAILABLE INFORMATION AND EVENT'S NATURE, PELVIC PAIN IS ASSESSED AS RELATED TO ESSURE USE. ALTHOUGH THE ESSURE MICRO-INSERTS MAY BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT DURING INSERTION, THIS MOSTLY OCCURS IN THE FIRST WEEKS FOLLOWING THE ESSURE PLACEMENT. IN THIS CASE, THE ONSET DATE OF INFECTION WAS NOT PROVIDED, THEREFORE, CAUSALITY WITH ESSURE USE IS VERY UNLIKELY. SINCE EXPLANT DATE WAS PROVIDED, IT WAS IMPLIED THAT DEVICE REMOVAL WAS REQUIRED. THEREFORE THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP RECEIVED ON 13-NOV-2015: FOLLOW UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00637	BAYER HEALTHCARE LLC	8/26/2015	8/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043368) IN UNITED STATES ON 04-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE REPORTED ESSURE CAUSE SEVERE BLEEDING AND PAIN WHICH LEAD TO FIND OUT THE PRODUCT DAMAGED HER UTERUS LEADING TO A FULLY HYSTERECTOMY. FOLLOW-UP RECEIVED ON 18-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-

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MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN AND SEVERE BLEEDING AND STATED THE PRODUCT DAMAGED HER UTERUS AND LED TO FULLY HYSTERECTOMY. THESE EVENTS, SEEN AS GENITAL BLEEDING AND PELVIC PAN AND UTERINE DISORDER, ARE SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT THE UTERINE DISORDER WHICH IS UNLISTED. PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER INFORMED THAT ESSURE CAUSE SEVERE BLEEDING AND PAIN WHICH DAMAGED HER UTERUS. THIS DAMAGE THEN LED TO A FULLY HYSTERECTOMY. CONSIDERING AVAILABLE INFORMATION AND EVENTS' NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED (FULL HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FUP RECEIVED ON 13-NOV-2015: FOLLOW UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00638	BAYER HEALTHCARE LLC	8/26/2015	8/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043399) IN (B)(6)ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. CONCOMITANT MEDICATION INCLUDED WELLBUTRIN. SHE WAS IMPLANTED WITH ESSURE IN 2011. SHE EXPERIENCED CONSTANT HEAVY MONTHLY CYCLES, BLOATING, HIVES DUE TO WHAT SHE BELIEVES WAS A REACTION TO THE NICKEL, CONSTANT ABDOMINAL PAIN, OVARIAN CYST, SEVERAL BAD URINARY TRACT INFECTIONS THAT ALSO AFFECTED HER KIDNEYS, WEIGHT GAIN THAT COULD NOT BE EXPLAINED AND COULD NOT BE LOST NO MATTER HOW HARD SHE TRIED. SHE ALSO SUFFERED FROM SEVERE DEPRESSION DUE TO ALL ISSUES WHILE HAVING THE PRODUCT IN HER BODY. SHE FINALLY HAD THE DEVICE REMOVED IN 2014. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4) FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER

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BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT ABDOMINAL PAIN AND SEVERAL BAD URINARY TRACT INFECTIONS THAT ALSO AFFECTED HER KIDNEYS. SHE HAD THE DEVICE REMOVED 3 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. CONSTANT ABDOMINAL PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE THE EXACT TEMPORAL RELATIONSHIP BETWEEN ABDOMINAL PAIN AND ESSURE INSERTION WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE EVENT SEVERAL BAD URINARY TRACT INFECTIONS THAT ALSO AFFECTED HER KIDNEYS; URINARY TRACT INFECTION PATHOGENESIS IN WOMEN BEGINS WITH COLONIZATION OF THE VAGINAL INTROITUS BY UROPATHOGENS FROM THE FECAL FLORA, FOLLOWED BY ASCENSION VIA THE URETHRA INTO THE BLADDER. PATHOGENS CAN REACH THE KIDNEY BY ASCENDING FROM THE LOWER URINARY TRACT. CONSIDERING THE PATHOPHYSIOLOGY OF THE EVENT AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND ESSURE WAS ASSESSED AS UNRELATED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. SINCE ESSURE REMOVAL WAS REPORTED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP RECEIVED ON 13-NOV-2015: FOLLOW UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00639	BAYER HEALTHCARE LLC	8/26/2015	8/26/2015

Event Information:

Event Date (B3): 5/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B71764/880432

Single Use: Y
Implant Date (E6): 2/21/2014
Explant Date (E7): 5/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 04-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B71764 (LEFT) AND 880432 (RIGHT) IMPLANTED ON (B)(6) 2014. ON (B)(6) 2014 HYSTEROSALPINGOGRAM WAS PERFORMED AN SHOWED UTERINE CAVITY WAS NORMAL SIZE AND MORPHOLOGY, WITHOUT EVIDENCE OF FILLING DEFECT, SUBMUCOSAL FIBROID, SYNECHIAE OR CONGENITAL UTERINE ANOMALY; BILATERAL ESSURE DEVICES SHOWED NO EVIDENCE OF LEAKAGE BEYOND THE ESSURE LOCATION. UNREMARKABLE HYSTEROSALPINGOGRAM. IN AN UNSPECIFIED DATE THE PATIENT BECAME PREGNANT. AFTER ELECTIVE TERMINATION, PATIENT UNDERWENT A BILATERAL SALPINGECTOMY ON (B)(6) 2015. FOLLOW UP (B)(6) -2015: HCP CONTACT E-MAIL PROVIDED. NO NEW CLINICAL INFORMATION WAS RECEIVED. FOLLOW-UP RECEIVED ON 18-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: 880432; PRODUCTION DATE: JUL-2011; EXPIRATION DATE: JUL-2014. LOT NUMBER: B71764; PRODUCTION DATE: 11-SEP-2013; EXPIRATION DATE: 30-SEP-2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW

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TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE BATCH DOCUMENTATION OF THE REPORTED BATCHES WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH NUMBERS. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT. SHE HAS CHOSEN TO TERMINATE PREGNANCY AND AFTER ELECTIVE ABORTION, SHE UNDERWENT BILATERAL SALPINGECTOMY. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS CASE, HSG (HYSTEROSALPINGOGRAM) TEST WAS DONE THREE MONTHS AFTER PLACEMENT AND SHOWED BILATERAL OCCLUSION AND PROPER PLACEMENT. THEREFORE, THE POSSIBILITY OF DEVICE FAILURE CANNOT BE EXCLUDED. REGARDING SALPINGECTOMY, ITS NOT CLEAR IF IT WAS DONE TO ENSURE CONTRACEPTION OR TO REMOVE THE DEVICES. THUS, THE EVENT IS ASSESSED AS RELATED TO ESSURE USE AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH SIGNAL COULD BE IDENTIFIED AND THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PREGNANCY QUESTIONNAIRE WAS RECEIVED FROM THE PHYSICIAN ON 07-DEC-2015: THE PATIENT DID NOT HAVE CERVICAL CONIZATION, CURETTAGE, PREVIOUS IUS/IUD, MYOMECTOMY AND ADNEXAL SURGERY. PREVIOUS PROBLEMS OR PROCEDURES WERE DENIED. SHE HAD NO RELEVANT MEDICAL HIS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00640	BAYER HEALTHCARE LLC	8/26/2015	8/26/2015

Event Information:

Event Date (B3): 8/3/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68799

Single Use: Y
Implant Date (E6): 6/11/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 8/10/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE PHYSICIAN WAS INSERTING ESSURE IMPLANT TO THE PATIENT WHO HAD ONE ESSURE INSERTED ABOUT A MONTH AGO AND NOW INSERTED THE OTHER IMPLANT. THE CATHETER WENT SLOWLY TO THE TUBE; AFTER PUSHING DISCHARGE, PHYSICIAN STARTED SLOWLY PULL CATHETER AWAY. THE IMPLANT HAD NOT GOT LOOSE FROM THE CATHETER AND THE OTHER END WAS STUCK IN PATIENT'S TUBE. FINALLY MOST PART OF IMPLANT CAME OUT BUT A LITTLE PART OF IMPLANT REMAINED IN PATIENT. NEW INSERTION WAS NOT TRIED AND LAPAROSCOPIC STERILIZATION IS PLANNED. FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN ON (B)(6) 2015 IMPLANT TO THE RIGHT SIDE WAS INSERTED ON (B)(6) 2015 BUT THEN ENDOMETRIUM SWOLLEN AND INSERTION TO THE LEFT COULD NOT BE PERFORMED. ON (B)(6) 2015 VISIBILITY WAS GOOD AND IMPLANT WAS INSERTED TO THE LEFT SIDE NORMALLY BUT IMPLANT DID NOT GET LOOSE FROM THE INSERTING INSTRUMENT. IMPLANT STRETCHED UNTIL IT REND OFF. A LITTLE PART REMAINED DEEP IN LEFT TUBAL OPENING. IT WAS SO DEEP THAT IT COULD NOT BE CATCHED WITH FORCEPS (IN THE END IT WAS VISIBLE BY ULTRASOUND, 2,8MM). A NEW IMPLANT PAST TO THE PART WAS NOT DARED TO TRY. FILSIE-LAPAROSCOPY WILL BE PERFORMED TO THE PATIENT. LOT NUMBER WAS C68799. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE IMPLANT HAD NOT GOT LOOSE FROM THE CATHETER AND THE OTHER END WAS STUCK IN PATIENT'S TUBE. MOST PART OF IMPLANT CAME OUT BUT A LITTLE PART OF IMPLANT REMAINED IN TUBE (SEEN AS DEVICE BREAKAGE). THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE

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SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE INITIALLY WAS REGARDED AS OTHER REPORTABLE INCIDENT. ACCORDING TO FOLLOW UP INFORMATION, AN INTERVENTION WILL BE REQUIRED (LAPAROSCOPY). THUS, THIS CASE WAS UPGRADED TO INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 31-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. IN ADDITION, THE AE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00641	BAYER HEALTHCARE LLC	8/26/2015	8/26/2015

Event Information:

Event Date (B3): 5/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68119

Single Use: Y
Implant Date (E6): 2/6/2015
Explant Date (E7): 9/4/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 03-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE PLACEMENT PROCEDURE WAS REPORTED AS SUCCESSFUL BILATERAL PLACEMENT WITH NO INCIDENT ON THE LEFT SIDE AND A PLACEMENT A LITTLE MORE DIFFICULT ON RIGHT SIDE. IN (B)(6) 2015, THREE-MONTH POST-PLACEMENT CONFIRMATION TEST DONE BY PLAIN-ABDOMEN X-RAY UNDERLINED FOURTH MARKER NOT VISIBLE ON LEFT SIDE AND IMPLANT BENT ON RIGHT SIDE. SURGEON PRESCRIBED HYSTEROSALPINGOGRAM (HSG) THAT THE PATIENT ONLY UNDERWENT IN (B)(6) 2015 AS SHE HAD NO PAIN. IT SHOWED IMPLANT ON LEFT SIDE CUT IN TWO PARTS WITH ONE PART IN FALLOPIAN TUBE AND THE OTHER PART IN ABDOMEN AND NONE OF THE FALLOPIAN TUBES WERE BLOCKED. THE GYNECOLOGIST WAS TO PERFORM A LAPAROSCOPY ON (B)(6) 2015 TO REMOVE THE IMPLANT AND PROBABLY TO DO HYSTEROSALPINGECTOMY. FOLLOW-UP INFORMATION RECEIVED ON 03-AUG-2015: LOT NUMBER WAS C68119. NO OTHER NEW MEDICAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 07-AUG-2015: (B)(4). FOLLOW-UP RECEIVED ON 21-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE AND A LACK OF EFFICACY (PATENCY). (B)(4). FINAL ASSESSMENT: LOT NUMBER: C68119; PRODUCTION DATE: 18-JUN-2014; EXPIRATION DATE: 30-JUN-2017. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE OUTER COILS OF THE INSERT EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS

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PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE REPORTED IN THE CONTEXT OF A DIFFICULT DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE AND ADDITIONALLY TO A LACK OF EFFICACY. A LACK OF EFFICACY MAY OCCUR WITH THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH A PLACEMENT A LITTLE MORE DIFFICULT ON RIGHT SIDE AND IT WAS REPORTED THAT THREE-MONTH POST PLACEMENT, CONFIRMATION TEST WAS PERFORMED BY PLAIN ABDOMEN X-RAY AND THE RESULT SHOWED FOURTH MARKER NOT VISIBLE ON LEFT SIDE AND IMPLANT BENT ON RIGHT SIDE. AFTER THAT A HYSTEROSALPINGOGRAM WAS PERFORMED AND THE RESULT SHOWED IMPLANT ON LEFT SIDE CUT IN TWO PARTS WITH ONE PART IN FALLOPIAN TUBE AND THE OTHER PART IN ABDOMEN (INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY AND DEVICE BREAKAGE). NONE OF THE FALLOPIAN TUBES WERE BLOCKED. THE EVENT DEVICE DISLOCATION INTO ABDOMINAL CAVITY IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE DEVICE BREAKAGE IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. IN THIS PARTICULAR CASE, BOTH EVENTS WERE DIAGNOSED ABOUT 3 MONTHS AND 5 MONTHS RESPECTIVELY AFTER ESSURE INSERTION PROCEDURE, HOWEVER THE EXACT DATE AND MECHANISM FOR BOTH EVENTS WERE NOT KNOWN, HOWEVER GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION (LAPAROSCOPY AND PROBABLY HYSTEROSALPINGECTOMY) WILL BE REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 23-SEP-2015: NO FURTHER INFORMATION WAS OBTAINED DESPITE 2 FOLLOW-UP ATTEMPTS. CASE CLOSED. FOLLOW-UP INFORMATION RECEIVED FROM THE GYNECOLOGIST ON 30-SEP-2015: TUBAL STERILIZATION WITH ESSURE METHOD REPORT ON (B)(6) 2015: AT THE TIM

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055831	CONCEPTUS INCORPORATED, USA, BAYER	8/26/2015	8/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/30/2005
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD AN ESSURE DEVICE INSTALLED IN 2005. AT THIS TIME, I WAS NOT EXPLAINED BY THE DOCTOR ABOUT THE SIDE EFFECTS THAT THIS DEVICE CAN CAUSE. I HAVE SHARP PAIN IN MY LOWER ABDOMEN, NEAR MY VAGINA. THIS SHARP PAIN TAKES THE BREATH OUT OF ME BECAUSE IT PREVENTS ME FROM WALKING UNTIL THE PAIN GOES AWAY. I ALSO HAVE A SHARP PAIN IN MY LOWER BACK. I HAVE A LOT OF PAIN IN VAGINA. WHEN I HAVE INTERCOURSE WITH MY HUSBAND, I FEEL A SHARP PAIN AS WELL. MY VAGINA GETS VERY DRY. I HAVE BEEN SUFFERING WITH MIGRAINE HEADACHES SINCE AFTER THIS DEVICE WAS INSTALLED IN ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055849		8/26/2015	9/1/2015

Event Information:

Event Date (B3): 9/14/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/14/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS A (B)(6) YEAR OLD ACTIVE, HEALTHY WOMAN WHO WAS A MOM TO AN 18 YEAR OLD AND A NEW GRANDMA, SO I WAS DONE HAVING CHILDREN. WENT TO A WELL OB/GYN TO DISCUSS GETTING MY TUBES TIED. SHE TOLD ME ABOUT THIS NEW PERMANENT BIRTH CONTROL ESSURE THAT WAS SO AMAZING, ALMOST NO SIDE EFFECTS REPORTED, NO ESTROGEN, WIDELY STUDIED FOR 10 YEARS AND MOST WOMEN BACK TO WORK THE NEXT DAY. HAD IT DONE IN HER OFFICE, MOST PAINFUL PROCEDURE I'VE EVER HAD DONE AS SHE HAD TROUBLE GETTING THE INSERT INTO THE LEFT TUBE. I BEGAN TO HAVE PROBLEMS ALMOST IMMEDIATELY IN (B)(6) 2007 WAS MY FIRST MENSTRUAL CYCLE WHICH I ENDED UP IN THE EMERGENCY ROOM WITH LOWER PELVIC PAIN AND EXCESSIVE BLEEDING. I THOUGH I MIGHT HAVE BEEN HAVING A MISCARRIAGE BUT WAS TOLD TO GO HOME AND REST IF THINGS GOT WORSE TO CALL THE PHYSICIAN WHO DID THE PROCEDURE AND RETURN TO EMERGENCY ROOM. FROM THAT MONTH FORWARD, THINGS WOULD SLOWLY GET WORSE FOR ME. EVERY TIME I WOULD MENTION MY IMPLANT, NO DOCTOR HAD EVER HEARD OF IT AND KNEW NOTHING ABOUT IT. EVERY MONTH I WOULD GET A MIGRAINE WITH MY MENSTRUAL CYCLE AND SEVERE CRAMPS. IT SLOWLY, OVER THE NEXT 7 YEARS, WOULD GET WORSE AND WORSE. IN (B)(6) 2012, I STARTED HAVING CHRONIC HEADACHES CONSTANTLY THAT WOULD LAST MY ENTIRE MENSTRUAL CYCLE WHICH I WAS HAVING 2 TIMES A MONTH AT TIMES AND BLEEDING FOR 10 DAYS. I STARTED GOING TO ANOTHER OB/GYN TO SEE WHAT WAS GOING ON AND ONCE AGAIN NEVER HEARD OF ESSURE. TOLD HER I WAS HAVING HEADACHES, BLOATING, HEAVY BLEEDING, PAIN WITH INTERCOURSE, LOWER PELVIC PAIN, FELT STABBING PAINS INSIDE MY VAGINA. WAS TOLD I HAD FIBROIDS NOW AND TO CURE THE PROBLEMS I HAVE MENTIONED BEFORE, I WOULD NEED A PARTIAL HYSTERECTOMY BUT WAS NOT ABLE TO COMPLETE THE HYSTERECTOMY BECAUSE I HAD A STROKE. SO I LIVE EVERY DAY WISHING I HAD NEVER HAD THIS IMPLANT DONE. IT HAS CAUSED ME SO

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MANY ISSUES. I AM GOING TO LIST EVERYTHING THAT STARTED AFTER THE IMPLANT AND BEFORE MY STROKE. SEVERE CRAMPING, SEVERE LOWER ABDOMINAL PAIN, EXTREMELY HEAVY BLEEDING, SEVERAL PERIODS IN A MONTH, MIGRAINES, NAUSEA, HAIR LOSS, PAINFUL INTERCOURSE OR LACK OF DESIRE, STABBING SENSATIONS INSIDE VAGINAL AREA, USAGE OF OVER 100 TAMPONS AND OVER 36 MAXI PADS IN ONE CYCLE, FATIGUE, EXCESSIVE VAGINAL DISCHARGE, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055850	BAYER	8/26/2015	9/1/2015

Event Information:

Event Date (B3): 8/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 4/22/2014
Explant Date (E7): 8/21/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2014 I HAD THE ESSURE COILS PUT IN PLACE INSTEAD OF THE TRADITIONAL ROUTE OF GETTING MY TUBES TIED. WITHIN THE PAST YEAR I HAVE EXPERIENCED EXTREME LOWER ABDOMINAL PAIN. MAJOR BLOATING, AN INCREASE IN MIGRAINES, TROUBLE PASSING BOWELS. THIS IS JUST TO NAME A FEW. AFTER SPEAKING WITH MY DOCTOR IT WAS DETERMINED THAT THE BEST OPTION WAS TO REMOVE THE DEVICES WHICH MEANT TO REMOVE MY ENTIRE FALLOPIAN TUBES AS WELL AS SCREEN THE UTERUS FOR ANY PIECES THAT MAY HAVE COME OUT OF CONTACT. DURING THE SURGERY THEY FOUND THAT I HAD DEVELOPED ENDOMETRIOSIS. THIS IS SOMETHING I KNOW I DIDN'T HAVE BEFORE THE DEVICES WERE PUT INTO PLACE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055851		8/26/2015	9/1/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE SUMMER OF 2008; SHORTLY AFTER HAD ITCHING, BURNING, PAINFUL RASH ON BACK A COUPLE TIMES. I HAD NO IDEA IT WAS ESSURE RELATED, I DID NOT THINK OF IT AT THE TIME. NOW I BELIEVE IT WAS. I HAVE WEIGHT GAIN, SIGNIFICANT WEIGHT LOSS, MEMORY PROBLEMS, BLURRY/HAZING EYE SIGHT, HEADACHES, MIGRAINES, NUMBING AND TINGLING HANDS ARMS AND LEGS, BLOATING, HEAVIER MENSTRUAL CYCLES, PELVIC PAIN, LOWER BACK PAIN. SHOULD HAVE GONE TO EMERGENCY ROOM COUPLE TIMES AND NOW WISH I HAD, BUT I'M A FIGHTER. I HAVE EXTREME FATIGUE. I'M TIRED OF FEELING THIS WAY. I WAS HAPPY AND DOING SO WELL HEALTH WISE BEFORE ESSURE. I BELIEVE AND FEEL ESSURE HAS TRIGGERED ALL MY SYMPTOMS AND PROBLEMS. I WAS DIAGNOSED WITH ADENOMYOSIS RECENTLY. ANOTHER ISSUE I DID NOT HAVE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00642	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 3/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT BESIDES PREGNANCY, SHE WAS EXPERIENCING MIGRAINES EVERY DAY, JOINT PAIN, MAJOR HAIR LOSS, AND LOSS IN SEX DRIVE. AFTER HAVING HER SON 5 WEEKS EARLY, HE WAS IN THE NICK FOR 8 DAYS AND GOT TO COME HOME. HE WAS HAVING APNEA EPISODES, JAUNDICE ISSUES, AND NOT BEING ABLE TO EAT AND BREATHE AT THE SAME TIME. A FEW MONTHS LATER, SHE FOUND OUT SHE WAS PREGNANT AGAIN. SHE HAD ESSURE INSERTED BECAUSE SHE EXPERIENCES SEVERE HYPEREMESIS GRAVIDARUM THROUGHOUT HER ENTIRE PREGNANCIES. SO, AS SOON AS SHE STARTED TO GET SICK, SHE KNEW SHE WAS PREGNANT AGAIN. SHE ALSO GOT HER DAUGHTER 5 WEEKS EARLY AS WELL, BUT WITH HER, THERE WERE NO HEALTH ISSUES. SHE WAS JUST REALLY SMALL. DUE TO PREGNANCIES, SHE HAD THOUSANDS OF IVS AND 10 PICC LINES PLACED OVER THE LAST 7 YEARS. SHE WAS SUBMITTED TO A MORE INVASIVE TEST TO CONFIRM THE COIL PLACEMENT AND TURNED OUT THAT HER RIGHT TUBE WAS NOT FULLY BLOCKED. SHE EXPERIENCED CONTINUED PELVIC PAIN, MOOD SWINGS, BLOATING, MEMORY ISSUES, UNEXPLAINED RASHES AND VERY HEAVY MENSTRUAL PERIODS. CONSUMER HAD A THIRD COIL PLACED AGAIN AND THEN WITHIN A MATTER OF A COUPLE OF WEEKS THE PERIODS GOT EVEN HEAVIER AND MUCH MORE PAINFUL. AN ABLATION WAS DISCUSSED BECAUSE OF THE PAIN, BLEEDING, AND FIBROIDS WERE FOUND. THE PERIODS WERE SUPER HEAVY AND LASTING 3 WEEKS AND THAT SHE WOULD GET A COUPLE OF DAYS BREAK AND THEN IT WOULD START ALL OVER AGAIN. THE ABLATION HELPED WITH THE AMOUNT OF BLEEDING BUT SHE WAS STILL IN THE SAME 3 WEEK PATTERN THE PAIN CONTINUED TO WORSEN AND SO DID THE BLOATING. AN ULTRASOUND WAS PERFORMED AND SHOWED A VERY LARGE CYST ON HER OVARY. THE UTERUS

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WAS REMOVED BECAUSE THE BLEEDING WAS NOT GETTING BETTER. SHE CONTINUED TO HAVE PROBLEMS WITH CYSTS BURSTING ON A DAILY BASIS CAUSING A LARGE AMOUNT OF BLOATING. OVARIES WERE ALSO REMOVED. AT TIME OF THIS REPORT, CONSUMER WAS 4 WEEKS POST-OPERATIVE AND THINGS WERE GOING GREAT. COUPLE OF WEEKS AFTER ESSURE REMOVAL, HER HAIR WAS STARTING TO GROW BACK, HER JOINTS NO LONGER HURT, MIGRAINES SLOWED DOWN, FEELING OF KICKING IN HER UTERUS (LIKE A PHANTOM BABY KICK) WENT AWAY. ALL OF HER MAJOR PROBLEMS WENT AWAY WITH THE EXCEPTION OF THE OVARIAN CYSTS AND BLOATING DUE TO FLUID BUILD UP. SHE STATED THAT UTERUS, TUBES AND COILS WERE REMOVED, AS WELL AS THE LARGE CYST. PHYSICIAN STATED TO HER THAT HAD TO REMOVE AN EXCESSIVE AMOUNT OF FLUID FROM THE ABDOMEN AS WELL. DURING THIRD AND FOURTH PREGNANCIES (E-BABIES), SHE WAS VOMITING SO MUCH THAT SHE WAS WITH THE TEETH OF A "BELEMIC". CONSUMER ASSESSED EVENT OUTCOME AS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS); HOWEVER, SHE DID NOT SPECIFY IT. SHE ALSO ASSESSED EVENT DATE AS (B)(6) 2011; HOWEVER SHE ALSO DID NOT SPECIFY IT. PLEASE REFER TO CASE NUMBERS: 2015-394335, 2015-393281 AND 2015-393282. FOLLOW UP (B)(6) 2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONTINUED PELVIC PAIN, VERY HEAVY MENSTRUAL PERIODS/ BLEEDING AND OVARYAN CYSTS. SHE ALSO GOT PREGNANT AND HAD HER SON 5 WEEKS EARLY (SEEN AS PREMATURE LABOR AND DELIVERY). SHE UNDERWENT TO ENDOMETRIAL ABLATION TO TREAT THE HEAVY PERIODS AND LATER A HYSTERECTOMY WAS PERFORMED. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT THE PREMATURE LABOUR/DELIVERY AND OVARIAN CYSTS WHICH ARE UNLISTED. UNINTENDED PREGNANCIES AND PELVIC PAIN MAY OCCUR DURING ESSURE USE. CONSIDERING THERE ARE NO RECORDS REGARDING CONFIRMATION TEST, THE POSSIBILITY OF DEVICE FAILURE CANNOT BE EXCLUDED. REGARDING THE COMPLICATIONS OF PREGNANCY (PREMATURE LABOUR) A MECHANICAL INTERFERENCE OF THE DEVICES CANNOT BE TOTALLY EXCLUDED AND THEREFORE THE EVENT IS ASSESSED AS RELATED TO ESSURE USE. LASTLY, GIVEN AVAILABLE INFORMATION AND THE EVENT'S NATURE, CAUSALITY BETWEEN PELVIC PAIN AND HEAVY PERIODS AND ESSURE USE CANNOT BE EXCLUDED, WHILE THE OVARIAN CYST IS ASSESSED AS UNRELATED GIVEN THE ESSURE'S LOCAL ACTION IN TUBES. OTHER NON-SERIOUS EVENTS WERE INFORMED. AS REQUIRED INTERVENTIONS (HYSTERECTOMY AND ENDOMETRIAL ABLATION) RELATED TO DEVICE WERE MENTIONED, THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00643	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/7/2013
Explant Date (E7): 3/3/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 03-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. ESSURE WAS INSERTED AFTER SHE DELIVERED HER 5TH CHILD. IN 2013, WHILE ATTEMPTING TO HAVE THE HSG (HYSTEROSALPINGOGRAM) DONE SHE WAS TURNED AWAY DUE TO POSITIVE PREGNANCY TEST. IN 2013, SHE EXPERIENCED SEVERE CHRONIC FATIGUE AND DEPRESSION SYMPTOMS. IN 2014, SHE MISCARRIED AND CONTINUED SUFFERING CHRONIC FATIGUE AND DEPRESSION. SHE WAS UNAWARE AT THE TIME WHAT WAS HAPPENING TO HER AND NEEDED INTERVENTION TO GET HELP. SHE WAS PRESCRIBED MEDICATIONS AND SPENT THE NEXT 8 WEEKS GETTING BACK TO HER NORMAL ACTIVITY ROUTINES AND WAS ABLE TO FUNCTION AGAIN. STILL IN 2014, SHE HAD HER FIRST HSG AND DETERMINED ONLY ONE IMPLANT WAS PRESENT, SHE WAS TOLD THE OTHER ONE PROBABLY FELL OUT. SHE WAS CONCERNED ONE OF THE IMPLANTS WAS LOST INSIDE HER AND WAS TOLD THAT THEY COULD NOT SEE IT. SHE WANTED TO HAVE AN X-RAY TO MAKE SURE THE OTHER IMPLANT WAS NOT SOME OTHER PLACE INSIDE HER BUT LEARNED THAT THE MATERIAL OR NICKEL USED FOR THE MANUFACTURING COULD NOT BE VIEWED BY X-RAYS. SHE STATED THAT FELT LUCKY FOR NOT EXPERIENCING THE PHYSICAL PAIN AND THAT TWO THOUSAND FOURTEEN WAS THE WORST YEAR OF HER LIFE; SHE HAD NEVER EXPERIENCED THE DEPTH OF EMOTIONAL PAIN AND SUFFERED DUE TO THE SYMPTOMS SHE WAS EXPERIENCING. CONSUMER REPORTED THAT ON (B)(6) 2015, SHE ELECTIVELY HAD HER FALLOPIAN TUBES REMOVED AND OVER THE NEXT COUPLE OF MONTHS HER CHRONIC FATIGUE SYMPTOMS WENT AWAY. ANOTHER SIDE EFFECT SHE EXPERIENCED WAS A DERMATITIS TYPE RASH AND LESIONS ON HER SCALP THAT HAVE ALSO GONE AWAY AFTER REMOVAL SURGERY. AT TIME OF THE REPORT, SHE WAS STILL TREATING HER DEPRESSION IN AN EFFORT TO AVOID POTENTIAL RELAPSE

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SYMPTOMS. SHE STATED SHE WAS STILL PICKING UP THE PIECES FROM THE DAMAGES THAT WERE CAUSED EMOTIONALLY. SHE WAS STILL UNAWARE IF THERE MAY BE A LOST IMPLANT SOMEWHERE IN HER BODY. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHILE ATTEMPTING TO HAVE THE HSG (HYSTEROSALPINGOGRAM) PERFORMED, SHE WAS TURNED AWAY DUE TO POSITIVE PREGNANCY TEST. SHE MISCARRIED. IT WAS REPORTED THAT ONLY ONE IMPLANT WAS PRESENT, SHE WAS TOLD THE OTHER ONE PROBABLY FELL OUT (DEVICE EXPULSION). HER FALLOPIAN TUBES WERE REMOVED. ALL EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED, EXCEPT MISCARRIED, IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. SPONTANEOUS ABORTION IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY. IN THIS CASE, NO INFORMATION ON GESTATIONAL AGE IS PROVIDED. AS MOST SPONTANEOUS ABORTIONS OCCUR DURING THE FIRST 12 WEEKS, COMPANY CONSIDERS THIS EVENT AS UNRELATED TO SUSPECT INSERT. ALSO, IN THIS CASE, IT WAS NOT REPORTED THE EXACT DATE OF HYSTEROSALPINGOGRAM TEST AND CONSEQUENTLY THE CONFIRMATION OF PREGNANCY. CONSIDERING THAT CONSUMER GOT PREGNANT 3 MONTHS AFTER ESSURE INSERTION, COMPANY CONSIDERS AS RELATED TO SUSPECT INSERT. WITH REGARDS TO THE OTHER EVENT DEVICE EXPULSION, GIVEN ITS NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO FALLOPIAN TUBES REMOVAL. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 11-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00644	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626906

Single Use: Y
Implant Date (E6): 12/5/2008
Explant Date (E7): 3/17/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5036762) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. IT WAS REPORTED THAT SHE WAS AN ATHLETE AND KNEW HER BODY VERY WELL, WHEN SHE FIRST NOTICED THE FATIGUE SETTING IN, THEN THE BODY ACHES. THEN THE JOINT PAIN STARTED, LOWER BACK PAINS AND PAIN IN HIPS AND AFFECTING HER SCIATIC NERVE TO HER RIGHT LEG/SCIATIC NERVE IN LEGS PAIN. SHE WAS KICK BOXING AND HAD TO QUIT DUE TO NOT HAVING THE STAMINA TO TRAIN AND THE JOINT PAIN AND SEVERE MUSCLE FATIGUE SHE WAS EXPERIENCING. DURING THAT TIME, SHE WAS GETTING SEVERE UTI INFECTIONS THAT HAS LED TO SOME INCONTINENCE ISSUES. SHE ALSO EXPERIENCED IRREGULAR CYCLES, ABDOMINAL BLOATING, ABDOMINAL PAINS, KIDNEY PAIN, BLADDER INFECTIONS, HEART FLUTTERS, HEADACHES DAILY, SOMETIMES MIGRAINES, NECK PAIN, SPINAL PAIN, JAW PAIN, TEETH PAIN, THYROID ISSUES, HEAVY BLEEDING SOMETIMES GUSHING, BLOOD CLOTS DURING CYCLE, METAL TASTE IN MOUTH AND BLOOD, EAR ACHES WITH NO INFECTION WHEN HAVING JAW PAIN, DISCHARGE AND ODOR, TINGLING IN LEFT HAND, CRAMPING OF FINGERS, LIGHT HEADED, BRAIN FOG, ASTHMA ATTACKS, CRAWLING SKIN, NIGHT SWEATS, BLEEDING AFTER SEX, SPOTTING IN BETWEEN HEAVY FLOWS, NAUSEA, BAD PAP SMEARS THAT NEED TREATMENT FOR CANCER CELLS, SKIN CANCER REQUIRING MAJOR SURGERY. IT WAS ALMOST IMPOSSIBLE TO BE PHYSICAL DUE TO FATIGUE AND LOSS OF MUSCLE STRENGTH. ON (B)(6) 2014 LAVH (INTERPRETED AS LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY) WAS PERFORMED AND ESSURE WAS REMOVED. SHE WANTED TO KEEP HER OVARIES BUT THEY WERE DAMAGED TOO MUCH TO KEEP. HER OVARIES, TUBES AND UTERUS WERE FUSED TO HER COLON. HER DOCTOR NEEDED TO CALL IN THE GENERAL SURGEON TO SEPARATE HER ORGANS IN ORDER TO SAVE HER COLON. SHE HAD MANY OLD CYSTS AND NEW

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ONES, FILLED WITH ENDOMETRIOSIS FUSING HER ORGANS. SHE HAD LARGE FIBROIDS IN THE UTERUS AND CHOCOLATE POCKETS FILLED WITH OLD BLOOD THAT WOULD NOT SLOUGH OFF DURING MY CYCLE. SHE HAD UTI (INTERPRETED AS URINE TRACT INFECTION) TREATED PRIOR TO SURGERY AND HAVE HAD ANOTHER SINCE SURGERY. SHE NEVER HAD UTIS PRIOR TO ESSURE. SHE FELT REALLY GOOD AFTER SURGERY, WITH NO HEADACHES, BODY ACHES OR FATIGUE. SHE THEN HAD A PATCH TEST DONE WITH SOME OF THE ESSURE MATERIALS AND TWO HOURS AFTER THE PATCH WAS APPLIED SHE HAD A MAJOR HEADACHE, THEN WOKE UP WITH THE BODY ACHES AND FATIGUE. THE PATCH WAS REMOVED AFTER 48 HOURS AND THE SYMPTOMS REMAINED ANOTHER 24 HOURS; THEN DISAPPEARED. THREE MONTHS POST OP AND SHE STILL GET SEVERE KIDNEY INFECTIONS. SHE WAS PRESCRIBED ESTRADIOL DUE TO HYSTERECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). (B)(4) SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. CORRECTION <14-AUG-2015>: AFTER INTERNAL REVIEW, A NEW EVENT WAS ADDED (MENORRHAGIA). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING SOMETIMES GUSHING (INTERPRETED AS GENITAL BLEEDING) AND ABDOMINAL PAINS. BOTH EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER HAD MANY OLD CYSTS AND NEW ONES, FILLED WITH ENDOMETRIOSIS FUSING HER ORGANS. ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR OCCURRENCE OF THIS BLEEDING, HOWEVER A CONTRIBUTORY ROLE OF THE ESSURE INSERT IN THIS BLEEDING CANNOT BE TOTALLY EXCLUDED. ALSO, FOR THE EVENT ABDOMINAL PAINS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. CONSIDERING THAT THE CONSUMER UNDERWENT A LAVH (INTERPRETED AS LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY) AND ESSURE WAS REMOVED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, OTHER SERIOUS AND NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00645	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN UNITED STATES ON 03-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT BESIDES PREGNANCY, SHE WAS EXPERIENCING MIGRAINES EVERY DAY, JOINT PAIN, MAJOR HAIR LOSS, AND LOSS IN SEX DRIVE. AFTER HAVING HER SON 5 WEEKS EARLY, HE WAS IN THE NICK FOR 8 DAYS AND GOT TO COME HOME. HE WAS HAVING APNEA EPISODES, JAUNDICE ISSUES, AND NOT BEING ABLE TO EAT AND BREATHE AT THE SAME TIME. A FEW MONTHS LATER, SHE FOUND OUT SHE WAS PREGNANT AGAIN. SHE HAD ESSURE INSERTED BECAUSE SHE EXPERIENCES SEVERE HYPEREMESIS GRAVIDARUM THROUGHOUT HER ENTIRE PREGNANCIES. SO, AS SOON AS SHE STARTED TO GET SICK, SHE KNEW SHE WAS PREGNANT AGAIN. SHE ALSO GOT HER DAUGHTER 5 WEEKS EARLY AS WELL, BUT WITH HER THERE WERE NO HEALTH ISSUES. SHE WAS JUST REALLY SMALL. DUE TO PREGNANCIES, SHE HAD THOUSANDS OF IVS AND 10 PICC LINES PLACED OVER THE LAST 7 YEARS. SHE WAS SUBMITTED TO A MORE INVASIVE TEST TO CONFIRM THE COIL PLACEMENT AND TURNED OUT THAT HER RIGHT TUBE WAS NOT FULLY BLOCKED. SHE EXPERIENCED CONTINUED PELVIC PAIN, MOOD SWINGS, BLOATING, MEMORY ISSUES, UNEXPLAINED RASHES AND VERY HEAVY MENSTRUAL PERIODS. CONSUMER HAD A THIRD COIL PLACED AGAIN AND THEN WITHIN A MATTER OF A COUPLE OF WEEKS THE PERIODS GOT EVEN HEAVIER AND MUCH MORE PAINFUL. AN ABLATION WAS DISCUSSED BECAUSE OF THE PAIN, BLEEDING, AND FIBROIDS WERE FOUND. THE PERIODS WERE SUPER HEAVY AND LASTING 3 WEEKS AND THE SHE WOULD GET A COUPLE OF DAYS BREAK AND THEN IT WOULD START ALL OVER AGAIN. THE ABLATION HELPED WITH THE AMOUNT OF BLEEDING BUT SHE WAS STILL IN THE SAME 3 WEEK PATTERN THE PAIN CONTINUED TO WORSEN AND SO DID THE BLOATING. AN ULTRASOUND WAS PERFORMED AND SHOWED A VERY LARGE CYST ON HER OVARY. THE UTERUS WAS REMOVED

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BECAUSE THE BLEEDING WAS NOT GETTING BETTER. SHE CONTINUED TO HAVE PROBLEMS WITH CYSTS BURSTING ON A DAILY BASIS CAUSING A LARGE AMOUNT OF BLOATING. OVARIES WERE ALSO REMOVED. AT TIME OF THIS REPORT, CONSUMER WAS 4 WEEKS POST-OPERATIVE AND THINGS WERE GOING GREAT. COUPLE OF WEEKS AFTER ESSURE REMOVAL, HER HAIR WAS STARTING TO GROW BACK, HER JOINTS NO LONGER HURT, MIGRAINES SLOWED DOWN, FEELING OF KICKING IN HER UTERUS (LIKE A PHANTOM BABY KICK) WENT AWAY. ALL OF HER MAJOR PROBLEMS WENT AWAY WITH THE EXCEPTION OF THE OVARIAN CYSTS AND BLOATING DUE TO FLUID BUILD UP. SHE STATED THAT UTERUS, TUBES AND COILS WERE REMOVED, AS WELL AS THE LARGE CYST. PHYSICIAN STATED TO HER THAT HAD TO REMOVE AN EXCESSIVE AMOUNT OF FLUID FROM THE ABDOMEN AS WELL. DURING THIRD AND FOURTH PREGNANCIES (E-BABIES), SHE WAS VOMITING SO MUCH THAT SHE WAS WITH THE TEETH OF A "BULIMIC." CONSUMER ASSESSED EVENT OUTCOME AS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS); HOWEVER SHE DID NOT SPECIFY IT. SHE ALSO ASSESSED EVENT DATE AS (B)(6) 2011; HOWEVER SHE ALSO DID NOT SPECIFY IT. PLEASE REFER TO CASE NUMBERS: 2015-393256, 2015-393282 AND 2015-394335. CORRECTION <12-AUG-2015>: AFTER INTERNAL REVIEW OF INFORMATION RECEIVED ON 03-AUG-2015, A NEW EVENT WAS ADDED TO THE CASE. FOLLOW UP 11-AUG-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A MALE NEONATE WHO WAS EXPOSED TO ESSURE DURING PREGNANCY AND HER MOTHER HAD HIM 5 WEEKS EARLY (SEEN AS PREMATURITY). THE NEONATE WAS BORN WITH APNEA EPISODES, JAUNDICE ISSUES AND WAS NOT BEING ABLE TO EAT OR TO BREATHE. THESE EVENTS ARE ALL SERIOUS DUE HOSPITALIZATION AND MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREMATURITY IS A TERM FOR THE BROAD CATEGORY OF NEONATES BORN AT LESS THAN 37 WEEKS' GESTATION. THE COMPLICATIONS OF PRETERM BIRTH ARISE FROM IMMATURE ORGAN SYSTEMS THAT ARE NOT YET PREPARED TO SUPPORT LIFE IN THE EXTRAUTERINE ENVIRONMENT. IN THIS CASE THE MOTHER MENTIONED THAT HER SON WAS BORN 5 WEEKS EARLY AND HE WAS IN THE "NICK" FOR 8 DAYS (INTERPRETED AS HOSPITALIZED). HE HAD APNEA EPISODES, JAUNDICE ISSUES, AND WAS NOT BEING ABLE TO EAT AND BREATHE AT THE SAME TIME. CONSIDERING THE POSSIBILITY OF MECHANICAL INTERFERENCE OF THE DEVICES DURING PREGNANCY CANNOT BE TOTALLY EXCLUDED, THE PREMATURITY AND ITS COMPLICATIONS (THE OTHER EVENTS) ARE ASSESSED AS RELATED TO ESSURE USE. SINCE HOSPITALIZATION AND SERIOUS COMPLICATION OF PREGNANCY RELATED TO DEVICE WERE REPORTED, THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00646	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/10/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED DATE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 03-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. SHE REPORTED THAT SHE HAD REPEATED EMERGENCY ADMISSIONS FOR ABDOMINAL PAIN OF NO KNOWN CAUSE. SHE EXPERIENCED BLACK MENSTRUAL DISCHARGE ON A REGULAR BASIS; ABDOMEN WAS SWELLED UP LIKE AN APPLE. SHE STATED THAT NO PHYSICIAN WANTED TO TREAT OR REMOVE THE IMPLANTS. SHE HAD BEEN TESTED FOR EVERYTHING FROM CROHN'S TO COLON CANCER AND DIVERTICULITIS FOR HER ABDOMINAL PAIN. SHE HAD REPEATED ULTRASOUNDS. SHE REPORTED HAVING A KNOWN NICKEL ALLERGY AND NO ONE EVER DISCLOSED THIS DEVICE WAS MADE OF NICKEL. SHE ALSO REPORTED CHRONIC FATIGUE, HAIR FALLING OUT, LOW ENERGY, ACHING JOINTS, BAD COMPLEXION, CHRONIC INFECTED BOILS ON BUTTOCKS AND LEGS. SHE STATED SHE HAD PIECES OF COILS THAT COME OUT VIA URINE. THE CONSUMER ALSO MENTIONED THE SERIOUSNESS CRITERION REQUIRED INTERVENTION BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP INFORMATION RECEIVED ON 21-AUG-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO

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REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PIECES OF COILS COME OUT VIA URINE. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS SERIOUS PER REPORTER AND LISTED ACCORDING TO TECHNICAL ASSESSMENT. SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED MAINLY DURING DIFFICULT INSERTIONS. IN THIS CASE, THE PATIENT EXPERIENCED SEVERAL NON-SERIOUS EVENTS DURING ESSURE USE AND STATED THAT PIECES OF COILS COME OUT VIA URINE. ALTHOUGH THE EXACT MECHANISM AND CIRCUMSTANCES OF THIS BREAKAGE ARE NOT KNOWN, CONSIDERING EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 11-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00647	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 2/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B82471

Single Use: Y
Implant Date (E6): 2/4/2015
Explant Date (E7): 6/17/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA REGULATORY AUTHORITY (CASE# MW5043215) IN UNITED STATES ON 03-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; THE LOT NUMBER USED WAS B82471 (EXPIRATION DATE 31-OCT-2016). THE REPORTER MENTIONED VITAMIN C AS CONCOMITANT MEDICATION. DURING THE HYSTEROSCOPIC PLACEMENT THE ESSURE APPLICATOR WAS NOT FUNCTIONING PROPERLY (SHEATH DID NOT RETRACT AND DEVICE WAS NOT DEPLOYED). THE APPLICATOR WAS COMPARED TO A NEW AND USED APPLICATOR AND THE ESSURE INSERT APPEARED TO BE PRESENT IN THE APPLICATOR; THEREFORE, A NEW APPLICATOR WAS USED TO PLACE THE INSERT INTO THE LEFT TUBAL OSTIA (SUCCESSFUL PLACEMENT IN RIGHT TUBAL OSTIA WAS ALREADY PERFORMED). THE DEFECTIVE APPLICATOR WAS RETURNED TO THE MANUFACTURER. ON AN UNSPECIFIED DATE (IN 2015), THE HSG (HYSTEROSALPINGOGRAM) CONFIRMATORY TEST WAS PERFORMED AND SHOWED TWO ESSURE INSERTS ON THE LEFT AND ONE ON THE RIGHT. ON (B)(6) 2015, A DIAGNOSTIC LAPAROSCOPY WAS PERFORMED AND SHOWED ONE OF THE INSERTS ON THE LEFT PERFORATED THROUGH THE UTERINE CORNUA. THE DEVICE WAS REMOVED SUCCESSFULLY. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD B82471 (PRODUCTION DATE 11-OCT-2013 AND EXPIRATION DATE 31-OCT-

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2016) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE AND A USABILITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 4 MONTHS LATER A LAPAROSCOPY SHOWED ONE OF THE INSERTS ON THE LEFT PERFORATED THROUGH THE UTERINE CORNUA. THIS EVENT, INTERPRETED AS UTERINE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING ESSURE INSERTION. IN THE PRESENT CASE, DURING THE INSERTION PROCEDURE THE SHEATH DID NOT RETRACT AND PHYSICIAN THOUGHT THE DEVICE WAS NOT DEPLOYED. PHYSICIAN USED A NEW APPLICATOR TO PLACE THE INSERT INTO THE LEFT TUBAL OSTIA. THE HYSTEROSALPINGOGRAM CONFIRMATORY TEST WAS PERFORMED AND SHOWED TWO ESSURE INSERTS WERE PLACED ON THE LEFT, AND DIAGNOSTIC LAPAROSCOPY SHOWED ONE OF THE INSERTS ON THE LEFT PERFORATED THROUGH THE UTERINE CORNUA. THE UTERINE PERFORATION IN THIS CASE PROBABLY OCCURRED IN THE CONTEXT OF THE DIFFICULT INSERTION PROCEDURE. THEREFORE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (LAPAROSCOPY). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 14-OCT-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 4 MONTHS LAT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00648	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 844600

Single Use: Y
Implant Date (E6): 8/18/2011
Explant Date (E7): 7/31/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5043357) IN UNITED STATES ON 03-AUG-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER 844600 INSERTED ON (B)(6) 2011. A FEW MONTHS AFTER GETTING THE IMPLANTS, CONSUMER STARTED EXPERIENCING EXTREME PAIN IN HER LOWER ABDOMEN. IT WAS MORE PROMINENT ON THE RIGHT HAND SIDE, BUT STILL AFFECTED HER LEFT AS WELL. SHE WOULD HAVE TO CALL IN TO WORK AT TIMES, AS SHE COULD BARELY GET OUT OF BED, LET ALONE CARE FOR HER SMALL CHILD IN SUCH PAIN. UNSPECIFIED TESTS, ULTRASOUNDS AND EXAMS WERE PERFORMED AND NOTHING WAS EVER THE CAUSE. HER DOCTOR THOUGHT THERE MAY HAVE BEEN CYSTS THAT WERE CAUSING THE PAINS, BUT NOTHING WAS FOUND DURING TESTS AND PROCEDURES. ESSURE WAS REMOVED ON (B)(6) 2014. SINCE REMOVAL OF HER TUBES AND THE ESSURE DEVICES, SHE HAS HAD NONE OF THE SAME PAINS OR DISCOMFORT. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: LOT NUMBER 844600; PRODUCTION DATE: 3/2011; EXPIRATION DATE: 3/2014. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE

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DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME PAIN IN MY LOWER ABDOMEN, IT WAS MORE PROMINENT ON THE RIGHT SIDE BUT STILL AFFECTED HER LEFT AS WELL. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER UNDERWENT UNSPECIFIED TESTS, ULTRASOUNDS AND EXAMS AND NOTHING WAS FOUND. CONSUMER HAD HER TUBES AND ESSURE DEVICES REMOVED. CONSIDERING THE EVENT NATURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO PERFORMED SURGICAL INTERVENTION, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 20-OCT-2015: THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00649	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/22/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. SHE REPORTED A SALES REPRESENTATIVE FROM CONCEPTUS WAS PRESENT DURING THE IMPLANTATION AND ENSURED THAT THE COILS WERE CORRECTLY PLACED. BY THE TIME SHE RETURNED TO HAVE THE HSG (HYSTEROSALPINGOGRAM) TEST DONE THREE MONTHS POST IMPLANT, SHE WAS STILL STRUGGLING WITH STABBING PAIN WHERE THE COILS WERE PLACED AND EXHAUSTION; SHE WAS TOLD THAT THE PLACEMENT WAS CORRECT AND THAT SHE WAS NOW STERILE. FOR THE PAST YEAR (2014), HER SYMPTOMS HAVE GROWN WORSE AND HAVE INCREASED TO INCLUDE EXTREME EXHAUSTION; MIGRAINE HEADACHE; A BLISTER LIKE RASH ON HER CHEST SHOULDERS AND UPPER THIGHS; HEAVY BLEEDING AND CLOTTING DURING HER PERIOD; JOINT PAIN AND SWELLING; LOWER BACK PAIN AND SWELLING; TINGLING AND NUMBNESS IN HANDS AND FEET AND NERVE PAIN. SHE HAD TESTS DONE ON HER THYROID, HAD LIQUID FROM THE RASH TESTED ETC WITH NO ANSWERS. SHE WENT TO THE GYNECOLOGIST AND THEY FOUND THAT THE COIL HAD MIGRATED FARTHER INTO HER FALLOPIAN TUBES, THAT SHE HAD CERVICAL AND ENDOMETRIAL POLYPS. HER HEMATOCRIT LEVEL WAS LOW AND THAT SHE HAD AN ATYPICAL PAP SMEAR; WITH THE EXCEPTION OF HER HEMATOCRIT LEVEL SHE HAS NEVER HAD ANY GYNECOLOGICAL PROBLEMS PRIOR TO THE INSERTION OF ESSURE. SHE WAS FACING WITH HAVING TO HAVE A HYSTEROSCOPY AS WELL AS HAVING THE COILS AND HER FALLOPIAN TUBES REMOVED. THE CONSUMER ALSO MENTIONED THE SERIOUSNESS CRITERION REQUIRED INTERVENTION BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. SHE ALSO MENTIONED ZYRTEC AS CONCOMITANT MEDICATION. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4).

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FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD STABBING PAIN WHERE THE COILS WERE PLACED AND THE COIL HAD MIGRATED FARTHER INTO HER FALLOPIAN TUBES AMONG OTHER NON-SERIOUS EVENTS. THESE EVENTS, INTERPRETED RESPECTIVELY AS ADNEXA UTERI PAIN AND DEVICE DISLOCATION WERE CONSIDERED SERIOUS BY THE REPORTER. DEVICE DISLOCATION IS ALSO SERIOUS DUE TO ITS MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THESE EVENTS ARE LISTED. IN THIS PARTICULAR CASE, THE CONSUMER STATED THAT 3 MONTHS AFTER THE INSERTION OF ESSURE, SHE WAS STILL STRUGGLING WITH STABBING PAIN WHERE THE COILS WERE PLACED. APPROXIMATELY, THREE YEARS LATER, SHE WENT TO THE GYNECOLOGIST AND THEY FOUND THAT THE COIL HAD MIGRATED FARTHER INTO HER FALLOPIAN TUBE. SHE WAS FACING WITH HAVING TO HAVE A HYSTEROSCOPY AS WELL AS HAVING THE COILS AND HER FALLOPIAN TUBES REMOVED. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THAT THERE IS A KNOWN RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THE DEVICE DISLOCATION WAS REGARDED AS RELATED TO ESSURE. THE PRESENCE OF A FOREIGN BODY IN THE FALLOPIAN TUBES MAY CAUSE THIS PAIN. THEREFORE, THIS PAIN IS ALSO RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT BECAUSE A SURGICAL INTERVENTION WILL BE REQUIRED. THE TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 12-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00650	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043360) IN UNITED STATES ON 03-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. IT WAS REPORTED THAT ONE OF THE COILS IS MISSING AND THE OTHER IS HURTING VERY BAD [COIL]. SHE WENT IN FOR HYSTERECTOMY ON A NON REPORTED DATE. NO CONSUMER CONTACT INFORMATION PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY

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CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE COIL IS MISSING. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THE MICRO-INSERT CAN MOVE TOWARDS TO DISTAL PART OF FALLOPIAN TUBES OR MIGRATE INTO PERITONEAL CAVITY. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS STATED ONE COIL WAS MISSING AND OTHER WAS HURTING. SHE ALSO MENTIONED THAT SHE WENT IN FOR HYSTERECTOMY. ALTHOUGH THE EXACT DATE AND MECHANISM OF THIS DISLOCATION ARE NOT KNOWN, CONSIDERING ITS NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00651	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 6/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/11/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043363) IN UNITED STATES ON 03-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. EVER SINCE THE PLACEMENT OF ESSURE, CONSUMER STARTED EXPERIENCING HAIR LOSS, FALLING OUT IN CLUMPS, PSORIASIS ON HER SCALP, SWELLING OF THE EYES WITH DRY SKIN AROUND THE LIDS AND UNDERNEATH, WEIGHT GAIN, HORRIBLE PERIODS, CRAMPING WORSE THAN NORMAL, PAIN ON LEFT SIDE CONSTANTLY, EVEN WORSE DURING OVULATION, EXHAUSTED, DEPRESSION, NO ENERGY, MOOD SWINGS, VISIONS CHANGES WHERE IT'S HARD TO EVEN DRIVE AT NIGHT, INSOMNIA, PAIN IN HIPS AND LEGS, SWELLING, SHORTNESS OF BREATH. TYLENOL WAS USED WHEN PAIN GET TOO BAD. A HYSTERECTOMY IS SCHEDULED FOR 2015. FOLLOW UP 11-AUG-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER

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BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT EVER SINCE THE PLACEMENT OF ESSURE. NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND GIVEN ITS EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION (HYSTERECTOMY) WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 12-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00652	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2010
Explant Date (E7): 5/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. SHE REPORTED SINCE ESSURE INSERTION SHE HAD ERRATIC HEAVY BLEEDING; SEVERE ABDOMEN PAIN; SKIN RASH; LEG PAIN; BACK PAIN AND ETC. ON AN UNSPECIFIED DATE, SHE HAD AN ULTRASOUND DONE WHICH FOUND A TUMOR WHICH WAS MORE THAN LIKELY THE CAUSE FOR SOME OF THE BLEEDING. HOWEVER, ALL THE OTHER SYMPTOMS WHICH WERE NOT TUMOR SYMPTOMS WENT AWAY WHEN THE ESSURE COILS WERE REMOVED WITH HER FALLOPIAN TUBES ON (B)(6) 2015. HER GYNECOLOGIST CONCLUDED THE OTHER EFFECTS WERE FROM THE ESSURE PROCEDURE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE

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FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE ABDOMEN PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE CONSUMER EXPERIENCED THIS EVENT SINCE ESSURE INSERTION. ESSURE COILS WERE REMOVED WITH HER FALLOPIAN TUBES. NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING THE EVENT'S NATURE AND A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, OTHER SERIOUS EVENT (TUMOR, UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 12-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00653	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/16/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043367) IN UNITED STATES ON 03-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. SHE REPORTED IMMEDIATELY FOLLOWING THE PROCEDURE SHE HAD AN ALLERGIC REACTION AND WAS GIVEN A LARGE AMOUNT OF (HIDDEN INFORMATION IN DOCUMENT). SHE HAD BROKEN OUT IN HIVES ALL OVER HER CHEST, NECK AND BACK. SHE WAS THEN RELEASED AND HAD NO MAJOR SIDE EFFECTS TO NOTE. ALTHOUGH SHE DID BREAK OUT IN HIVES EVERY SO OFTEN FOR WHAT SEEMS TO BE NO REASON AT ALL. HER MOTHER HAS A NICKEL ALLERGY AND THE CONSUMER HAD NEVER BEEN TESTED FOR ALLERGIES. RECENTLY, SHE HAD A SIGNIFICANT WEIGHT GAIN WITH NO ABILITY TO LOSE IT WITHOUT AN INCREASE IN CALORIES. SHE ALSO HAD CRAMPING; IRREGULAR PERIODS; FATIGUE; SHE WAS DIAGNOSED WITH ANXIETY AND WAS BEING TREATED WITH TWO MEDICATIONS FOR DEPRESSION. SHE ALSO EXPERIENCED HEART PALPITATIONS; SHORTNESS OF BREATH AND STOMACH BLOATING. HER PHYSICIAN HAD NEVER ADDRESSED THE ESSURE AS A POSSIBLE CAUSE FOR ANY OF HER RECENT SYMPTOMS. THE CONSUMER ALSO MENTIONED THE SERIOUSNESS CRITERION REQUIRED INTERVENTION BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. SHE ALSO MENTIONED WELLBUTRIN AS CONCOMITANT MEDICATION. FOLLOW UP 11-AUG-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD AN ALLERGIC REACTION IMMEDIATELY FOLLOWING THE PROCEDURE. SHE RECEIVED TREATMENT BUT THE NAME OF THE DRUG WAS HIDDEN IN THE DOCUMENT. THE CONSUMER STATED SHE WAS RELEASED AND HAD NO MAJOR SIDE EFFECT. THE ALLERGIC REACTION WAS CONSIDERED SERIOUS DUE TO REQUIRED INTERVENTION BY THE REPORTER. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THIS EVENT IS LISTED. IN THIS PARTICULAR CASE, THE CONSUMER HAD AN ALLERGIC REACTION IMMEDIATELY AFTER THE ESSURE INSERTION PROCEDURE. SHE BROKE OUT IN HIVES ALL OVER HER CHEST, NECK AND BACK. SHE WAS GIVEN A LARGE AMOUNT OF AN UNSPECIFIED TREATMENT AND SHE WAS RELEASED WITH NO MAJOR SIDE EFFECTS. SHE STATED THAT SHE DID BREAK OUT IN HIVES EVERY SOMETIMES FOR NO REASON AT ALL. SHE ALSO MENTIONED THAT HER MOTHER HAS NICKEL ALLERGY BUT SHE WAS NEVER TESTED FOR ALLERGIES. CONSIDERING THE STRONG POSITIVE TEMPORAL RELATIONSHIP AND THE FACT THAT ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, THE ALLERGIC REACTION MAY BE RELATED TO POSSIBLE NICKEL SENSITIVITY. THEREFORE, THE ALLERGIC REACTION IS CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO THE REQUIRED MEDICAL INTERVENTION. TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 07-OCT-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA (B)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00654	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/22/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 03-AUG-2015 AND REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 FOR CONTRACEPTION. IN (B)(6) 2010, HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND SHOWED OCCLUSION ON THE RIGHT SIDE. LEFT SIDE, THE DEVICE WAS NOT PRESENT AND SPILLAGE WAS NOTED. BECAME PREGNANT IN 2014, DELIVERED A BABY THE END OF (B)(6) 2015 (HEALTHY). IN (B)(6) 2015, A SALPINGECTOMY WAS PERFORMED WITH THE INTENT OF REMOVING THE DEVICES AND TYING THE TUBES. NOT ABLE TO LOCATE EITHER DEVICE. X-RAY SHOWED DEVICES IN PELVIS. THE PATIENT HAD NO COMPLAINTS. SHE WANTS THEM OUT. TREATMENT PLAN IS TO BE DETERMINED. FOLLOW-UP INFORMATION RECEIVED ON 05-AUG-2015 PHYSICIAN WOULD LIKE TO KNOW IMPLICATIONS OF LEAVING THE ESSURE IN THE PELVIS OR IT THERE IS A RECOMMENDATION OF REMOVAL. SALPINGECTOMY WAS PERFORMED AND ESSURE DEVICES WERE NOT LOCATED. HYSTEROSCOPY ALSO PERFORMED AND ESSURE DEVICES NOT LOCATED. X-RAY SHOWED DEVICES NOT IN CORRECT LOCATION. FOLLOW-UP RECEIVED ON 14-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION

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AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HYSTEROSALPINGOGRAM (HSG) PERFORMED 4 MONTHS LATER SHOWED LEFT SIDE THE DEVICE WAS NOT PRESENT. SHE GOT PREGNANT MORE THAN 3 YEARS AFTER INSERTION AND THE BABY WAS BORN HEALTHY. TWO MONTHS AFTER DELIVERY SHE UNDERWENT A SALPINGECTOMY WITH THE INTENT OF REMOVING THE DEVICES AND TYING THE TUBES BUT THE DEVICES WERE NOT LOCATED AND AN X-RAY SHOWED DEVICES IN PELVIS. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. EVENT LEFT SIDE THE DEVICE WAS NOT PRESENT/ DEVICES IN PELVIS WAS INTERPRETED AS DEVICE DISLOCATION INTO PELVIC CAVITY. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE THE DISLOCATION WAS DIAGNOSED 4 MONTHS AFTER INSERTION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THE PRESENT CASE THE HSG SHOWED LEFT DEVICE WAS NOT PRESENT AND SPILLAGE WAS NOTED. IT WAS NOT REPORTED WHETHER THE PATIENT USED ANY FORM OF ALTERNATIVE CONTRACEPTION. THE DEVICE DISLOCATION MIGHT EXPLAIN THE OCCURRENCE OF PREGNANCY, HOWEVER GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON (B)(4) 2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00655	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 7/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/30/2013
Explant Date (E7): 12/11/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER IN THE UNITED STATES, ON BEHALF OF A FEMALE PLAINTIFF OF UNSPECIFIED AGE IN UNITED STATES ON 03-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR PERMANENT STERILIZATION. IT WAS REPORTED THAT IN LATE 2012, PLAINTIFF BECAME PREGNANT OF HER FIFTH CHILD AND WANTED A TUBAL LIGATION AT THE TIME OF DELIVERY. ON (B)(6) 2013, SHE UNDERWENT AN EMERGENCY CAESAREAN SECTION, BECAUSE HER UMBILICAL CORD HAD PROLAPSED AROUND HER FETUS. DUE TO THE EMERGENT NATURE OF THE DELIVERY, THE TUBAL LIGATION WAS NOT PERFORMED. ON (B)(6) 2013, DURING ESSURE INSERTION, PLAINTIFF IMMEDIATELY BEGAN REPORTING EXCRUCIATING ABDOMINAL PAIN. SHE ALSO EXPERIENCED INCREASED HEART RATE AND PROFUSE SWEATING. THE PROCEDURE WAS ABANDONED AFTER ONLY PLACING ONE THE TWO DEVICES. IT WAS STATED THAT ONLY THREE INTRAUTERINE COILS WERE PRESENT AFTER THE UNILATERAL PLACEMENT. NO NICKEL TEST WAS PERFORMED. ONE OR MORE PERFORATIONS OCCURRED, INCLUDING PLAINTIFF'S LEFT FALLOPIAN TUBE AND OTHER INTERNAL ORGANS. BETWEEN (B)(6) 2013 AND (B)(6) 2013, SHE EXPERIENCED UNCEASING AGONIZING PAIN DUE TO THE PRESENCE OF THE ESSURE DEVICE. AN X-RAY WAS PERFORMED DURING THE SURGERY TO VERIFY THAT THE DEVICE WAS SUCCESSFULLY REMOVED. IT SHOWED THAT A PIECE OF THE COIL WAS IN FACT LEFT BEHIND AND WAS OUTSIDE THE FALLOPIAN TUBE AND IT WAS CONSISTENT WITH A PERFORATION. USING THE X-RAY AND A HYSTEROSCOPY, THE PHYSICIAN CONCLUDED THAT PIECES OF THE ESSURE COIL WERE LEFT BEHIND; HOWEVER THEY COULD NOT LOCATE THEM AND DECIDED TO CONCLUDE THE SURGERY. AS A CONSEQUENT DECISION OF ESSURE INSERTION, PLAINTIFF SUFFERED INJURY WHEN THE ESSURE DEVICE FAILED, BROKE APART AND CAUSED PERFORATIONS, CAUSING HER TO SUFFER CHEST PAINS, ELEVATED BLOOD PRESSURE, RAPID BREATHING, EXCESSIVE SWEATING, CRAMPING, WEIGHT

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LOSS, ITCHING, RASHES, FLU LIKE SYMPTOMS, LIGHT HEADEDNESS, DIZZINESS, SEVERE HEADACHES, NAUSEA, A NICKEL TASTE, PAIN IN LEFT SIDE OF THE ABDOMEN, A BURNING SENSATION IN LOWER ABDOMEN, TINGLING AND NUMBNESS SENSATIONS IN HER HANDS AND LIPS, DIARRHEA, STOMACH PAIN, FATIGUE AND SURGERY INCLUDING REMOVAL OF HER FALLOPIAN TUBES AND A HYSTERECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF COMPLICATED DEVICE INSERTION AND REMOVAL. THE AE CASE REFERS TO A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 18-AUG-2015: NO NEW CLINICAL INFORMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, LEGAL AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD ONE OR MORE PERFORATIONS, INCLUDING PLAINTIFF'S LEFT FALLOPIAN TUBE AND OTHER INTERNAL ORGANS. SHE ALSO STATED THAT AN X-RAY WAS PERFORMED AND IT SHOWED THAT A PIECE OF THE COIL HAD IN FACT BEEN LEFT BEHIND/ BROKE APART (DEVICE BREAKAGE). THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. INTERNAL ORGANS PERFORATION MAY OCCUR WITH ESSURE, DUE TO DEVICE MIGRATION OR DURING INSERTION PROCEDURE. THE PERFORATION OF INTERNAL BODILY STRUCTURES OTHER THAN THE UTERUS AND FALLOPIAN TUBES (E.G. BOWEL, BLADDER, AND MAJOR BLOOD VESSELS) MAY OCCUR DURING HYSTEROSCOPY, AS WELL AS DURING DEVICE PLACEMENT; THIS RISK IS INHERENT WITH ANY HYSTEROSCOPIC PROCEDURE. DUE TO THE ANATOMICAL RELATIONSHIP BETWEEN BOWEL AND UTERUS, THE BOWEL IS THE MOST COMMONLY AFFECTED ORGAN. IN THIS CASE, IT WAS NOT SPECIFY THE EXACT ORGANS PERFORATED. AS THE PERFORATIONS (FALLOPIAN TUBE AND OTHER INTERNAL ORGANS) OCCURRED AT THE TIME OF ESSURE INSERTION PROCEDURE AND DEVICE BREAKAGE OCCURRED DURING REMOVAL, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. SINCE PLAINTIFF UNDERWENT A HYSTERECTOMY AND HAD HER

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FALLOPIAN TUBES REMOVED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ADDITIONAL INFORMATION WILL BE OBTAINED THROUGH THE NORMAL LITIGATION PROCESS. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00656	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/13/2013
Explant Date (E7): 7/30/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 03-AUG-2015 AND IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR PERMANENT CONTRACEPTION. PATIENT DID NOT GET HYSTEROSALPINGOGRAM (HSG) AND SHE BECAME PREGNANT IN (B)(6) 2014. SHE HAD A NORMAL PREGNANCY AND THEN ON (B)(6) 2015, A SALPINGECTOMY WAS PERFORMED ON BOTH TUBES. ONE ESSURE FOUND IN PELVIC SIDE WALL. ESSURE COILS REMOVED AND BILATERAL SALPINGECTOMY PERFORMED. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN ADDITION, THE AE CASE REFERS TO TREATMENT NONCOMPLIANCE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS

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REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT. AFTER DELIVERY, A SALPINGECTOMY WAS PERFORMED AND ESSURE WAS FOUND IN PELVIC SIDE WALL. THESE EVENTS, SEEN AS PREGNANCY AND DEVICE DISLOCATION, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS CASE, HSG (HYSTEROSALPINGOGRAM) TEST WAS NOT PERFORMED. ALTHOUGH IN THIS CASE PREGNANCY COULD BE RATHER THE RESULT OF NON-COMPLIANCE USE OR THE RESULT OF DEVICE DISLOCATION, IT IS NOT CLEAR IF THE CONCEPTION OCCURRED PREVIOUSLY OR AFTER THE DISLOCATION. THUS, THE POSSIBILITY OF DEVICE FAILURE CANNOT BE TOTALLY EXCLUDED. SINCE ESSURE REMOVAL (VIA BILATERAL SALPINGECTOMY) WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

HEALTHCARE PROVIDER GENERAL QUESTIONNAIRE RECEIVED ON 03-NOV-2015: PATIENT'S DEMOGRAPHY INFORMATION WAS PROVIDED. HER MEDICAL HISTORY INCLUDED CERVICAL DYSPLASIA AND LEEP (LOOP ELECTROSURGICAL EXCISION PROCEDURE). CONCOMITANT CONDITION WAS HYPOTHYROIDISM.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00657	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/3/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043438) IN UNITED STATES ON 03-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. CONSUMER REPORTED THAT, 2 YEARS AFTER THE ESSURE, SHE BECAME PREGNANT AND HAD A CHILD (BABY BORN WITH HEALTH PROBLEMS). CONSUMER SUFFERED FROM HEAVY BLEEDING, OVARIAN CYST, AND HAD TO GET HYSTERECTOMY. SHE ALSO REPORTED PELVIC PAIN, BACK PAIN, WEIGHT GAIN, DEPRESSION, CHRONIC DAILY MIGRAINE AND PAIN DURING INTERCOURSE. AS CONCOMITANT MEDICATION, CONSUMER USED TYLENOL. IN ADDITION, THE SERIOUSNESS CRITERION "OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)" WAS REPORTED. HOWEVER, IT WAS NOT SPECIFIED FOR WHICH EVENT. FOLLOW-UP RECEIVED ON 18-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE

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WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AND HAD A BABY BORN WITH PROBLEMS TWO YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED. SHE ALSO HAD HEAVY BLEEDING. OTHER NON-SERIOUS EVENTS WERE REPORTED. SHE HAD TO GET A HYSTERECTOMY. THE HEAVY BLEEDING, INTERPRETED AS GENITAL BLEEDING, AND THE PREGNANCY WITH CONTRACEPTIVE DEVICE ARE CONSIDERED SERIOUS EVENTS DUE TO THEIR MEDICAL IMPORTANCE. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THESE EVENTS ARE LISTED. IN THIS PARTICULAR CASE, THE PREGNANCY OCCURRED 2 YEARS AFTER THE INSERTION. CONSIDERING THAT THE PREGNANCY OCCURRED AFTER THE 3-MONTH WAITING PERIOD AND THAT THERE IS NO INFORMATION WHETHER THE ESSURE WAS INCORRECTLY PLACED, THE CAUSAL RELATIONSHIP BETWEEN THE ESSURE AND THE PREGNANCY CANNOT BE EXCLUDED (DEVICE INEFFECTIVE). THE CONSUMER ALSO REPORTED HEAVY BLEEDING. SINCE THE TEMPORAL RELATIONSHIP IS POSITIVE AND IT IS KNOWN THAT ESSURE MAY CAUSE ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES, THE HEAVY BLEEDING IS CONSIDERED RELATED TO ESSURE. THE CASE IS CONSIDERED INCIDENT DUE TO THE HYSTERECTOMY PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FUP RECEIVED ON 13-NOV-2015: FOLLOW UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00658	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 04-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. DIFFICULT INSERTION OF COIL INTO L TUBE WAS REPORTED. ON FOLLOW-UP HSG (HYSTEROSALPINGOGRAM), A BROKEN SMALL PIECE OF ESSURE WAS SEEN OUTSIDE OF TUBE IN THE PELVIC CAVITY AND PATIENT WAS SYMPTOMATIC (NOT SPECIFIED). PTC INVESTIGATION RESULT WAS RECEIVED ON 14-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE

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ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF DIFFICULT DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING HSG (HYSTEROSALPINGOGRAM), A BROKEN SMALL PIECE OF ESSURE WAS SEEN OUTSIDE OF TUBE IN THE PELVIC CAVITY. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED MAINLY DURING DIFFICULT INSERTIONS. IN THIS CASE, THERE WAS A DIFFICULT INSERTION INTO LEFT TUBE. THEN, ON FOLLOW UP HSG (HYSTEROSALPINGOGRAM), A BROKEN SMALL PIECE OF ESSURE WAS SEEN OUTSIDE OF TUBE IN THE PELVIC CAVITY AND PATIENT WAS SYMPTOMATIC (UNSPECIFIED). ALTHOUGH THE EXACT MECHANISM AND CIRCUMSTANCES OF THIS BREAKAGE ARE NOT KNOWN, CONSIDERING THE DIFFICULT INSERTION AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00659	BAYER HEALTHCARE LLC	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 8/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C55837

Single Use: Y
Implant Date (E6): 8/4/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 04-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C55837 FOR CONTRACEPTION AT THE SAME DATE OF THIS REPORT. SHE WAS NOT PREGNANT. IT WAS REPORTED THAT THE PHYSICIAN CANNULATED THE RIGHT TUBE, FOUND THE GOLD BAND, PULLED OUT, IT LOOKED LIKE PROPER PLACEMENT. ON EXAMINATION IT WAS DETERMINED THE DEVICE HAD BROKEN IN HALF AND PART OF THE MICRO INSERT WAS IN THE TUBE. THE PHYSICIAN HAD TO PULL THE INSERT OUT OF THE TUBE. NO ATTEMPT WAS MADE ON THE LEFT SIDE. PATIENT WAS TAKEN TO THE OR (OPERATING ROOM) FOR A SURGICAL TUBAL (SEEN AS TUBAL LIGATION). PTC INVESTIGATION RESULT WAS RECEIVED ON 14-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT.

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SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C55837 (PRODUCTION DATE 16-MAY-2014 AND EXPIRATION DATE 31-MAY-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A TECHNICAL PRODUCT ISSUE. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

DEVICE BREAKAGE QUESTIONNAIRE RECEIVED FROM PHYSICIAN ON 05-OCT-2015 (UPGRADED TO INCIDENT) PATIENT´S INITIAL AND DATE OF BIRTH WERE UPDATED (SHE WAS (B)(6) YEARS OLD). HER WEIGHT WAS (B)(6). ESSURE WAS INSERTED ON (B)(6)-2015. NO DEVIATION FROM THE INSER

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055756	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 10/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DURING THE PROCEDURE I STARTED BLEEDING AND THE PAIN WAS UNBEARABLE THE WAS SO MUCH BLOOD IT TOOK AT LEAST 30 MINS TO GET IT CONTROLLED WELL ITS BEEN ALMOST A YEAR SINCE I'VE HAD IT I EXPERIENCE MIGRAINS BLOATING AND HEAVY BLEEDING FOR THE PAST 2 WEEKS MY BLEEDING HAS GOTTEN WORSE AND I HAVE A PINTCHING FEELING IN MY ABDOMEN AREA WHEN I MOVE A CERTAIN WAY AND THEN MY BLEEDING GETTING HEAVIER I HAVE BEEN ON MY PERIOD FOR A YEAR NOW AND IM WONDERING IF YOU CAN GIVE ME SOME ANSWERS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055757	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 12/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN, HEAVY BLEEDING, BLOATING, HAIR LOSS, TUBE DIDN'T BLOCK COULDN'T RELY ON THIS AS BIRTH CONTROL. PHOTO IS NIGHT BEFORE SURGERY, 1 WEEK AFTER HYSTERECTOMY, 2 WEEKS POST OP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055758	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 2/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, TINGLING AND NUMBNESS IN HANDS, FEET AND FACE, ABDOMINAL PAIN, ABDOMINAL CONTRACTIONS AND CRAMPING, COGNITIVE DIFFICULTY INCLUDING SHORT TERM MEMORY LOSS AND PROBLEM SOLVING DIFFICULTIES, BALANCE INSTABILITY, DIZZINESS, SPEECH IMPAIRMENTS, FROZEN MOMENTS IN WHICH BODY DOESN'T MOVE, TREMORS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055759	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 1/2/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN HIPS AND DOWN LEGS. SHARP PAINS IN ABDOMINAL AREA. BLOATING AND SWELLING. IRREGULAR PERIODS. ISSUES HAVE ONLY INCREASED OVER TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055760	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 1/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2011 . THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2011. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. I AM ON MY PERIOD EVERY OTHER WEEK, WHICH IS EXTREMELY HEAVY AND ALL BLOOD CLOTS. IF I HAVE SEX ON MY "OFF WEEK", I BLEED/SPOT AFTERWARDS. I HAVE SHARP STABBING PAIN IN MY ABDOMEN, DISCHARGE, BLOATING, JOINT PAIN, MIGRAINES, AND HAIR LOSS. I HAVE NEVER EXPERIENCED THESE PROBLEMS BEFORE ESSURE. I HAVE A DOCTORS APPOINTMENT (B)(6) 2015 AND I AM HOPING THAT I CAN GET ESSURE REMOVED FROM MY BODY AS SOON AS POSSIBLE, SO I CAN GET BACK TO THE WAY MY LIFE WAS BEFORE ESSURE, HAPPY, HEALTHY, AND ACTIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055761	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 11/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN EXCRUCIATING PAIN IN ABDOMEN , THROWING UP , MIGRAINES , TOOTH PAIN , HAIR LOSS , BLOATING , EXTREME BLEEDING, CRAMPING , SKIN RASH ECT ECT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055762	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 6/30/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OVER TIME, STARTED NOTICING AN INCREASE IN MIGRAINE HEADACHES, INCREASING FATIGUE/MUSCLE PAIN AND PAINFUL INTERCOURSE. WAS FINALLY DIAGNOSED WITH FIBROMYALGIA AFTER A FEW YEARS - NONE OF THESE SYMPTOMS PRESENT BEFORE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055763	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 7/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE WAS COVERED BY INSURANCE. I HAVE VERY SEVERE BLOATING, CHIPPED TEETH, MORE HEAVY PERIODS THAN BEFORE DEVICE WAS IMPLANTED, FATIGUE AND BRAIN FOG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055764	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 8/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'M GETTING MORE LOWER BACK PAIN. MORE BACK SPASMS. AND I PULLED SOMETHING IN MY BACK THAT I ALSO FELT IN MY ARM. I STILL HAVE THE SAME SIDE EFFECTS JUST SOME OF THEM HAVE GOTTEN WORSE. I'VE NOTICED THAT I GET SHORTNESS OF BREATH WHEN EVER I BEND OVER OR DO ANYTHING PHYSICAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055783	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 10/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS IS AN UPDATE TO MY PRIOR REPORT/ I HAVE SENSE HAD A HYSTERECTOMY TO REMOVE THIS FROM MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055784	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 1/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED WITH SEVERE MIGRAINES ALL THE TIME, WHICH I NEVER REALLY HAD BEFORE, I WAS GETTING AT LEAST 10 OR MORE A MONTH, WHICH I AM STILL GETTING THEM BUT NOW HAVE TO HAVE 31 SHOTS OF BOTOX IN MY HEAD AND NECK EVERY 3 MONTHS TO CUT THE MIGRAINES DOWN TO 4 A MONTH NOW, I ALSO HAVE HAD RAPID WEIGHT GAIN, ALL MY LIFE I HAVE BEEN AROUND (B)(6) POUNDS EVEN AFTER 4 CHILDREN, BUT SINCE I HAD ESSURE PUT IN I GAINED (B)(6) POUNDS IN A YEAR!! DID NOT CHANGE MY EATING HABITS OR ANYTHING. I ALSO HAVE MAJOR BLOATING IN MY STOMACH AREA. I LOOK LIKE I'M 8 MONTHS PREGNANT. ANOTHER SIDE EFFECT HAS BEEN BRAIN FOG, IT HAS BEEN HAD TO REMEMBER THINGS AND TO FIND WORDS WHEN SPEAKING. I ASK YOU TO PLEASE TAKE ESSURE OFF THE MARKET. IT IS DANGEROUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055785	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 10/27/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE IMPLANTED I BEGAN TO IMMEDIATELY EXPERIENCE PELVIC PAIN ANDAMP; FLANK PAIN WHICH THE DOCTOR SAID IN NO WAY COULD BE CAUSED BY ESSURE. OVER THE YEARS THE PAIN HAS INCREASED EXPONENTIALLY TO WHERE MY DAILY LIFE IS EFFECTED AND MY ABILITY TO BE A GREAT MOTHER AND WIFE. OTHER SIDE EFFECTS: HAIR LOSS, DAILY HEADACHES, PAIN WITH INTERCOURSE, FATIGUE, SKIN RASH, WEIGHT GAIN, UTI'S, NAUSEA, SHARP STABBING PELVIC PAIN, OVARIAN CYSTS, TUBO OVARIAN ABSCESS, NIGHT SWEATS, HOT FLASHES, LOSS OF SEX DRIVE, EXTREMELY PAINFUL PERIODS, HEARTBURN, FREQUENT URINATION, SENSITIVE SKIN, BOWEL ISSUES, DIZZINESS, BRAIN FOG, MOOD SWINGS, TINGLING IN LEGS AND ARMS, GALLBLADDER ISSUES, SWOLLEN LYMPH NODES, EXTREMELY DRY SKIN. I WAS HOSPITALIZED FOR A WEEK ON IV ANTIBIOTICS FOR A 9CM ABSCESS. I HAD TO HAVE A TUBAL LIGATION AND AN ABLATION SINCE THE ESSURE DID NOT BLOCK MY TUBES. I AM SCHEDULED FOR A HYSTERECTOMY IN A WEEK TO REMOVE ESSURE DEVICE, TUBES, CERVIX ANDAMP; UTERUS. I HOPE TO KEEP MY OVARIES. ESSURE WAS RECOMMEND BY MY OBGYN (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055786	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE BEGAN TO THIN (STRETCH) AND THAN CUT IN TO MY UTERUS CAUSING ME TO HAVE A TOTAL HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055787	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE PUT IN A YEAR AGO. I THOUGHT THE SOUND OF BEING ABLE TO GET PERMANENT BIRTH CONTROL WITH "NO DOWN TIME" AND WITHOUT HAVE ANY ACTUAL SURGERY SOUNDED GREAT! GREAT, IT WASN'T. MOST OF MY SYMPTOMS STARTED A FEW DAYS FOLLOWING THE PROCEDURE. THE CRAMPING AND ABDOMINAL PAIN STARTED DAY ONE AND HASN'T WENT AWAY YET. SOME DAYS ARE BETTER THEN OTHERS. ITS THE HEADACHES THAT I CAN'T DEAL WITH. I AM CONSTANTLY TAKING SOMETHING FOR HEADACHES. THE AMOUNT OF TYLENOL/ADVIL I GO THROUGH A MONTH IS BEYOND RIDICULOUS. THE FLUTTERING FEELING I GET IN STOMACH JUST STARTED A FEW MONTHS AGO. I'M NOT SURE WHAT IT IS. I ALSO SUFFER FROM MENOPAUSE LIKE SYMPTOMS. PLEASE KEEP IN MIND I'M (B)(6). WHAT (B)(6) SHOULD HAVE TO DEAL WITH HOT FLASHES, EXTREME IRRITABILITY AND NIGHT SWEATS. I HONESTLY FEEL SOME DAYS I STRUGGLE TO EVEN FUNCTION. I WOULD HAVE NEVER PICKED ESSURE AS MY PERMANENT BIRTH CONTROL METHOD HAD I KNOWN I WOULD I WOULD BE DEALING WITH WHAT I AM NOW. WHAT SCARES ME EVEN MORE IS WHAT'S TO COME. IF THESE ARE SOME "SMALL" SYMPTOMS (AND I USE THAT TERM LIGHTLY) WHAT IN THIS WORLD COULD HAPPEN IN THE YEARS TO COME. I REGRET GETTING ESSURE. AND IF I HAD THE FUNDS I WOULD BE RUNNING TO FIND SOMEONE TO REMOVE IT FROM MY BODY. LOOKING BACK, HAVING SURGERY DOESN'T SEEM SO BAD TO ME ANY MORE COMPARED TO ESSURE. OTHER THINGS I HAVE NOTICED SINCE HAVING ESSURE PROCEDURE ARE LOSS OF HAIR, INCREASE IN ACNE, SHARP ABDOMINAL PAIN, DIZZINESS, LOWER BACK PAIN AND ON OCCASION NAUSEA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055788	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 11/28/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DURING INSERTION I HAD 3 COILS INSERTED BECAUSE ONE OF THE COILS WAS DEFECTIVE. WHEN I WAS TOLD ABOUT THIS AFTER THE MEDICATION I WAS GIVEN SO I WOULD NOT REMEMBER THE PROCEDURE WORE OFF, I ASKED MY DOCTOR IF SHE WOULD GO AND LOOK FOR IT WITH AND X-RAY AND SHE SAID IT WOULD TAKE MM PRECISE X-RAY MACHINERY AND THE COIL WOULD NOT CAUSE ANY PROBLEMS- WOULD NOT BE AN ISSUE IT WAS SO SMALL. MY DEVICE WAS PROVIDED BY MEDICAID BECAUSE THIS WAS THE ONLY OPTION I WAS GIVEN FOR PERMANENT BIRTH CONTROL. THE OUTCOMES OF THIS ADVERSE EVENT IS UNKNOWN AT THIS TIME. POSSIBLE PERFORATION AND OTHER SERIOUS INJURY IS STILL POSSIBLE. ABOUT A FEW WEEKS AFTER INSERTION (ABOUT (B)(6) 2008) I HAD TERRIBLE ABDOMINAL PAIN, BUT WAS NOT ABLE TO HAVE THIS CHECKED OUT BY A HEALTHCARE PROFESSIONAL BECAUSE I WAS IN NURSING SCHOOL AT THE TIME AND COULD NOT MISS CLASS OR LABS. (B)(6) 2009, I GAINED WEIGHT AND BECAME BLOATED IN MY ABDOMINAL AREA. I WEIGHTED THE MOST I EVER HAD AT (B)(6) POUNDS. I STARTED OUT AT ABOUT (B)(6). I BECOME BLOATED IN THE ABDOMINAL AREA GENERALLY DAILY. IN THE MORNINGS I START OFF WITH A FAIRLY FLAT STOMACH AND BY THE END OF THE DAY MY STOMACH CAN LOOK LIKE I AM 7 MONTHS PREGNANT. ON (B)(6) 2015 I NOTICED THAT I HAD BECOME EXTREMELY BLOATED AFTER EATING DINNER. I WENT INTO THE BATHROOM THAT NIGHT AND TOOK A PICTURE OF MY BELLY BECAUSE I WAS SHOCKED OF HOW BLOATED I WAS AND SHORTLY AFTER I HAD TO HAVE A BOWEL MOVEMENT. AFTER WHICH I BEGAN TO HAVE SHARP STOMACH, PELVIC AND LOWER BACK PAIN EXACTLY LIKE I HAVE HAD DURING LABOR (I HAVE HAD 3 CHILDREN WITH NON-MEDICATED VAGINAL BIRTHS). I WAS IN SUCH PAIN THAT IT BROUGHT ME TO MY HAND AND KNEES ON THE BATHROOM FLOOR WHERE I HAD DIFFICULTY BREATHING. THIS LASTED FOR NEARLY AN HOUR. I WAS STILL IN PAIN, BUT THE SHARP STABBING PAINS WERE MORE DULL AND I WAS ABLE TO CRAWL INTO BED AND LAY THERE TILL I

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FELL ASLEEP. THE NEXT DAY I FELT AN EXTREME AMOUNT OF PELVIC PRESSURE AND A SHARP O AND OFF PAIN IN MY LOWER RIGHT BACK AREA. THIS ONLY LAST FOR THAT NEXT DAY UNTIL ABOUT 3 WEEKS LATER I GOT EXTREMELY BLOATED AGAIN AND HAD THE SAME SHARP STABBING LOWER BACK, STOMACH, PELVIC AREA PAIN AS PREVIOUSLY MENTIONED. I WAS NOT ABLE TO GO TO THE DOCTOR OR HOSPITAL FOR AT THIS MOMENT I AM IN BETWEEN INSURANCES. THE ABDOMINAL BLOATING COMES AND GOES ON A DAILY BASIS. I ALSO TEND TO HAD SHARP PAINS AT THE AREA WHERE MY OVARIES ARE LOCATED WHEN I SNEEZE OR GET UP TO QUICKLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055789	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 4/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I PUT ESSURE IN 2010, A YEAR LATER I WAS PREGNANT AGAIN , I HAD TO INTERRUPT THE PREGNANCY AND THE DOCTOR MY TUBES TIED . SINCE I HAVE ESSURE , MY LIFE IS VERY DIFFICULT, I HAVE PAIN AND PELVIC INFLAMMATION , AND GAINED WEIGHT , I HAVE TROUBLE DOING EVERYDAY THINGS, I'M VERY TIRED, THE RELATIONSHIP AT HOME BECOMES DIFFICULT WITH MY CHILDREN AND MY HUSBAND , I CAN NOT HAVING SEX WITH MY HUSBAND FOR PELVIC PAIN , I WENT TO MY GYNECOLOGIST AND HE SAYS THAT I SHOULD GET A HYSTERECTOMY, RIGHT NOW IS MAKING ME ALL THE NECESSARY TESTS , THE DAY (B)(6) I HAVE THE NEXT APPOINTMENT , ACTUALLY I HAVE MUCH FEAR OF WHAT IS HAPPENING , I HAVE TWO YOUNG CHILDREN (5 AND 8 YEARS) AND I HAVE ONLY (B)(6) , THESE TOOK 3 MONTHS WITHOUT SEEING MY PERIOD NOW , THIS IS NOT STANDARD , PLEASE HEAR OUR VOICE, AND WE ARE MANY WOMEN WHO HAVE HAD ESSURE PROBLEM , TAKE IT OUT . AFTER MY APPOINTMENT WILL UPDATE MY REPORT , THANK YOU FOR ATTENTION AND HELP (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055790	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 2/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PUT IN AS AN ALTERNATIVE TO HAVING MY TUBES TIED. QUICKLY AFTER THE PLACEMENT I STARTED HAVING IRREGULAR HEAVY PERIODS. TYPICALLY THEY ARE FIVE DAYS ON AND A FEW DAYS OFF. I ALSO HAVE TERRIBLE HEADACHES AT LEAST 2-3 TIMES A DAY WHERE I NEVER HAD HEADACHES BEFORE. I STAY BLOATED, LOOKING PREGNANT DAILY, EVEN THOUGH I'M PHYSICALLY FIT AND EXERCISE DAILY. LAST, MY HAIR FALLS OUT IN CLUMPS. AGAIN, THIS HAS NEVER HAPPENED BEFORE I HAD ESSURE PLACED. THE SYMPTOMS AFFECT MY DAILY LIFE GREATLY AND I WISH I HAD NEVER PICKED THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055791	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 11/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE NICKLE ALLERGY; HYSTERECTOMY, ENDOMETRIOSIS, HAND NUMBING, SKIN RASHES, HEADACHES, CHEST PAIN, ABDOMINAL PAIN, HAIR LOSS, DRY EYES, WEIGHT LOSS AND GAIN, SWOLLEN LYMPH NODE, FATIGUE, PAIN IN JOINTS AND MUSCLES. DIAGNOSED WITH FIBROMYALGIA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055792	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 4/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD RECEIVED A GRANT FROM PUBLIC HEALTH TO HAVE ESSURE INSERTED (AS I HAD INSURANCE, BUT THE CO-PAY WAS HIGH AND I WAS TOLD BY MY PUBLIC HEALTH PROVIDER THAT I QUALIFIED). AT THE TIME OF INSERTION, I HAD GONE IN BY MYSELF AND WAS DRIVEN HOME. I HAD SEVERE CRAMPING FOR ABOUT 2 MONTHS AND HEAVY BLEEDING NONSTOP FOR ABOUT 3 WEEKS. I HAD THEN HAD EXTREME HEAVY BLEEDING A COUPLE TIME A MONTH, INCLUDING BLOOD CLOTTING. I HAD VAGINAL BACTERIA AND NUMEROUS YEAST INFECTIONS. I HAD SINUS INFECTIONS THAT I NEVER GOTTEN BEFORE. I BECAME DEPRESSED AND HAD SERIOUS PMS WITH SEVERE CRAMPING. IN (B)(6) 2014, I WENT TO THE DR AND WAS HAVING PAIN GOING DOWN MY LEG AND SEVERE CRAMPING AND HEAVY FREQUENT BLEEDING (OVER HALF THE MONTH WAS BLEEDING). I HAD HEADACHES AND WAS HAVING TROUBLES WALKING. I FOUND THAT I HAD CYSTS AND FIBROIDS AT THAT TIME. I HAD A HYSTERECTOMY ON (B)(6) 2014 WITH THE REMOVAL OF THE ESSURE, TUBES, UTERUS, AND CERVIX. I HAVE SINCE BEEN OVER 20 DIFFERENT MEDICATIONS FOR CRAMPING, ANXIETY ATTACKS AND HORMONAL TREATMENT. I GO IN TO A UROLOGIST SPECIALIST ON (B)(6) 2015 FOR A CT SCAN AND A BLADDER BIOPSY DUE TO CRAMPING AND PROBLEMS WITH URINATION. I HAVE SOME PROLAPSE, BUT NOT ENOUGH THAT SURGERY AT THIS TIME IS REQUIRED, BUT MAY IN THE FUTURE, AS I GET OLDER. I HAVE SEEN A OB/GYN, UROLOGIST SPECIALIST, AND AM UNDERGOING COUNSELING, AS WELL AS MY REGULAR FAMILY PHYSICIAN. I AM CURRENTLY TAKING VAGINAL VOLUME AND PROZAC (AS I WILL NOT TAKE YET ANOTHER PILL, BUT HOPE TO FIND OUT WHAT IS CAUSING MY PROBLEMS). THEY DID FIND ADENOMYOSIS AND CHRONIC INFLAMMATION AT THE TIME OF THE HYSTERECTOMY.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055793	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GOT ESSURE IN 2013; STARTED HAVING JOINT PAIN, WEIGHT GAIN, BACK PAIN, HEADACHES, FATIGUE, BLEEDING AFTER INTERCOURSE, HEAVY PERIODS WITH BIG CLOTS THAT LASTED ALMOST 10 DAYS (WHICH ALSO CAUSED ME TO MISS AT LEAST ONE DAY OF WORK DUE TO THE SEVERE CRAMPING), I STARTED GETTING SICK ALL THE TIME AND IT TOOK FOREVER (ALONG WITH SEVERAL ANTIBIOTICS) TO CLEAR IT UP BUT STILL NEVER FELT HEALTHY. I WOULD GET EAR INFECTIONS AND THE GLANDS ON MY NECK WERE ALWAYS SWOLLEN. CAME DOWN WITH PNEUMONIA SEVERAL TIMES (IN WHICH I NEVER HAD BEFORE) AND MY BLOOD WORK WOULD COME BACK ALWAYS INDICATING I HAD AN INFECTION EVEN IF I WASN'T FEELING SICK. I STARTED TO TAKE AN ANTI-INFLAMMATORY PROVIDED BY MY DOCTOR FOR THE JOINT AND BACK PAIN THAT I HAD ON A DAILY BASIS. I MET WITH A NEW OBGYN THE BEGINNING OF THIS YEAR; WE TRIED A SOME DIFFERENT MEDICATIONS BUT I CONTINUED HAVING THE HEAVY BLEEDING, CLOTS, ETC. DURING MY MENSTRUAL CYCLE. I HAD A VAGINAL ULTRASOUND DONE THE (B)(6) THIS YEAR SHOWING I HAD ADENOMYOSIS AND BACTERIAL VAGINOSIS . MY DOCTOR DETERMINED THAT IT WOULD BE BEST TO DO A HYSTERECTOMY LEAVING THE OVARIES. I HAD MY HYSTERECTOMY ON (B)(6) 2015; IT WAS SUPPOSED TO TAKE TWO HOURS AND ENDED UP TAKING FOUR AND A HALF. IT WAS ALSO SUPPOSED TO BE VAGINAL BUT DUE OTHER INTERNAL ISSUES HE HAD TO GO THROUGH THE STOMACH. I ENDED UP HAVING SEVERAL FIBROIDS, MY ESSURE COILS WERE STRETCHED OUT, AND MY CERVIX WAS PROLAPSING. I HAD MY YEARLY PAP SMEAR ON A REGULAR BASIS SINCE AGE 14 AND THEY HAVE ALWAYS CAME BACK NORMAL. AFTER ESSURE I HAVE HAD NOTHING BUT ISSUES AND MY PAPS WERE COMING BACK WITH BACTERIAL VAGINOSIS EVERY TIME; INDICATING I HAD SOME TYPE OF INFECTION GOING ON. THE DOCTOR WHO PERFORMED THE ESSURE DID NOT DO A NICKLE TEST ON ME OR EXPLAIN WHAT IT WAS MADE OF. I AM ALLERGIC TO NICKLE; CAUSING BURNING AND ITCHING IN THE AREA. MY DEVICE

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WAS PROVIDED BY MY INSURER; HOWEVER THEY DID NOT PAY FOR THE XRAY WITH DYE THAT YOU HAVE AT THREE MONTHS. I DID STILL HAVE THE XRAY DONE THOUGH ; WHICH I PAID OUT OF POCKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055794	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 4/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DOCTOR PUT COILS IN TUBES. DID MRI ONE WASN'T IN PLACE HAD TO GO BACK IN AND REPLACE IT. HAD MRI THEY SAID IT WAS FINE. START HAVING BACK PAIN WITHIN 3 MONTHS OF HAVING PROCEDURE DONE. THEN STARTED HAVING SEVERE PELVIC PAIN MY OB COULDN'T FIGURE OUT WHAT THE PROBLEM WAS SO SHE DID SOME RESEARCH AND CHECKS AND DECIDED SHE NEEDED TO DO HYSTERECTOMY. HAD HYSTERECTOMY DONE IN 2013 STILL HAVE ISSUES. CANT ALWAYS KEEP MY BLADDER UNDER CONTROL. BLADDER PROBLEMS CONSTANTLY. STILL PELVIC PAIN. MY DOCTOR REMOVED MY UTERUS WHICH WAS FULL OF INFECTION AND MY COIL WAS ON THE OUTSIDE OF MY TUBE. THE OTHER ONE HASN'T BEEN FOUND. HAVE LEG PROBLEMS BACK PROBLEMS PELVIC PROBLEMS, DEPRESSED, AND SICK OF BEING IN PAIN EVERYDAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055795	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 7/1/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC AREA PAIN, HIP PAIN, VAGINAL IRRITATION AND PAIN DURING SEX, NO SEX DRIVE, MEMORY NOT AS GOOD, BACK PAIN, MULTIPLE UTI'S AND YEAST INFECTIONS, SEVERE PAIN AFTER SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055796	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 11/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD EXTREME CRAMPING, INCREASED CRAMPING, HAIR LOSS, INCREASED MIGRAINES, EXTREMELY DEPRESSED, WEIGHT GAIN, LOSS OF INTEREST IN ACTIVITIES, NO APPETITE, METALLIC TASTE IN MY MOUTH, MEMORY LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055797	BAYER	8/27/2015	8/27/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EST DATE OF ONSET. HAD ITCHING BURNING RASH ON BACK COUPLE TIMES SHORTLY AFTER ESSURE. I DIDN'T REALIZE IT COULD'VE BEEN ESSURE. I'VE HAD WT GAIN, BLOATING, HEADACHES, MIGRAINES, NUMBING AND; TINGLING HANDS, ARMS, LEGS, EXTREME FATIGUE, SIGNIFICANT HAIR LOSS, MOODINESS. HEAVIER MENSTRUAL CYCLES (ESPECIALLY WITHIN LAST 2 YRS). PELVIC PAIN, CRAMPS DAILY, LOWER BACK PAIN DAILY (SOME DAYS MUCH WORSE). I SHOULD'VE WENT TO ER COUPLE TIMES BECAUSE PAIN WAS INTENSE. HAD SOMETHING COME OUT WHEN WIPED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055866	CONCEPTUS	8/27/2015	9/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): B02270

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN AS A FORM OF BIRTH CONTROL ((B)(6) 2013). SINCE THEN, I HAVE HAD CHRONIC PELVIC PAIN AND VAGINAL BLEEDING. I WENT TO A DIFFERENT DOCTOR (2ND DR, (B)(6) 2014) IN HOPE OF SOME RESOLVE. I WAS REFERRED TO PHYSICAL THERAPY TO HELP MANAGE THE PAIN. IN ADDITION, I HAD NON STOP BLEEDING FOR FIVE MONTHS. THE 2ND DOCTOR DID AN ABLATION PROCEDURE (NOVASURE, (B)(6) 2015) ON ME TO STOP THE BLEEDING. IT DID NOT WORK. I COULD NOT CONTINUE THE PHYSICAL THERAPY AFTER 2 MONTHS DUE TO FINANCES. I WENT TO A 3RD DOCTOR FOR SOME RELIEF. I WAS GIVEN MEDROXYPROGESTERONE ((B)(6) 2015) TO STOP THE BLEEDING. IT DID NOT HELP. I WAS GIVEN BIRTH CONTROL PILLS, IT HELPS SOME WITH THE BLEEDING. I STILL HAVE ABNORMAL BLEEDING AND PELVIC PAIN. SINCE ALL OF THIS, I BECAME DEPRESSED AND WAS GIVEN AMITRIPTYLINE AND REFERRED TO TALK THERAPY. I AM CURRENTLY AWAITING MY APPOINTMENT WITH A 4TH DOCTOR TO DISCUSS MY NEXT OPTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055867	BAYER	8/27/2015	9/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

JUST OVERALL HEALTH WENT DOWNHILL. EXTREME PAIN, RASH AND ITCHING, MOOD SWINGS, DIVORCE AND AN INABILITY TO GET OUT OF BED SOME DAYS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055876	BAYER HEALTHCARE LLC	8/27/2015	9/2/2015

Event Information:

Event Date (B3): 7/16/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): C76452

Single Use: *
Implant Date (E6): 7/16/2015
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DEVICE WAS DEPLOYED IN THE USUAL FASHION. THE INTERNAL SPRING RETRACTED OUT WITH THE INSERTION DEVICE PARTIALLY. ABLE TO REMOVE THE MAJORITY OF THE INTERNAL SPRING BUT THE EXTERNAL SPRING WAS LODGED IN THE TUBE WITH 3 COILS VISIBLE AT THE OS. DIAGNOSIS OR REASON FOR USE: STERILIZATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00660	BAYER HEALTHCARE LLC	8/28/2015	8/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN THE UNITED STATES ON 19-FEB-2014 VIA COMPANY INTERNET SITE. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A HYSTERECTOMY. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. CONSUMER REPORTED THAT ESSURE SHOULD BE RECALLED. BECAUSE OF THIS POS (UNSPECIFIED) SHE HAD A HYSTERECTOMY. NO FURTHER DETAILS WERE REPORTED AND ARE AVAILABLE. FOLLOW UP INFORMATION RECEIVED ON 02-JUL-2014: NO FURTHER INFORMATION COULD BE SOUGHT DUE TO LACK OF CONSUMER CONTACT INFORMATION. AFTER A COMPANY INTERNAL REVIEW THIS CASE WAS DOWNGRADED TO NON-INCIDENT (REASON FOR HYSTERECTOMY WAS NOT PROVIDED). FOLLOW-UP INFORMATION WAS RECEIVED ON 06-AUG-2015 AND 13-AUG-2015. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE ((B)(4)), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. CONSUMER STATED SHE HAD A HORRIBLE PAINFUL ESSURE INSERTION PROCEDURE, WHICH TAKE OVER AN 1 1/2 TO COMPLETE. WHAT WAS SUPPOSED TO BE A SMALL, PAINLESS, AND NONINVASIVE, LITTLE TO NO COST PROCEDURE HAS LANDED HER 4 SURGERIES, LEAVING HER WITH ONLY ONE OVARY AND TONS OF MEDICAL BILLS AND ALMOST DEATH BECAUSE OF ALL THAT. ALTHOUGH SHE WAS FEELING MUCH BETTER, SHE WAS NOW STRUGGLING WITH SOME SYMPTOMS THAT PROBABLY WOULD NOT GO AWAY. SHE IS A MOTHER OF 05 CHILDREN, WHO LOST THEIR MOTHER FOR 22 MONTHS BECAUSE OF THE PAIN AND SUFFERING FROM ESSURE. SHE SUFFERED FROM UNEXPLAINED RASHES, SEVERE JOINT PAIN, BACK PAIN, MISERABLE MENSTRUAL CYCLES, SHE WAS

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BLEEDING FOR 6 MONTHS AFTER ESSURE WAS IMPLANTED, WEIGHT GAIN DUE TO INFLAMMATION RESPONSE THROUGHOUT HER BODY, MIGRAINES, BACK PAIN, FATIGUE, AND MIGRATION OF HER LEFT COIL. CASE CONSIDERED INCIDENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN, BLEEDING (FOR 6 MONTHS) AND MIGRATION OF HER LEFT COIL. ACCORDING TO HER, SHE WAS SUBMITTED TO 4 SURGERIES, INCLUDING A HYSTERECTOMY. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. ALSO, THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION, MIGRATION OR OCCUR AS A RESULT OF A UTERINE/FALLOPIAN TUBE PERFORATION. IN THIS CASE, CONSUMER RELATED HER SYMPTOMS TO DEVICE INSERTION AND STATED SHE FELT BETTER AFTER THE ABOVE MENTION SURGERIES. GIVEN THIS INFORMATION AND IN THE LACK OF ALTERNATIVE EXPLANATIONS; CAUSALITY BETWEEN THESE EVENTS AND THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS UPGRADED TO INCIDENT, UPON RECEIPT OF NEW INFORMATION, SINCE DEVICE REMOVAL WAS REQUIRED (SURGERIES PERFORMED DUE TO THE EVENTS). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED ON A SOCIAL MEDIA AND DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

INTERNAL CORRECTION ON 24-NOV-2015. DATE OF FOLLOW-UP RECEIVED ON 06-AUG-2015 WAS AMENDED TO 09-AUG-2015.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00661	BAYER HEALTHCARE LLC	8/28/2015	8/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/17/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038066) IN UNITED STATES ON 06-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. ON (B)(6) 2014, ESSURE WAS INSERTED. SHE WAS PUT UNDER ANESTHESIA FOR THE PROCEDURE. SHE PRESENTED TREMENDOUS PAIN AND WAS SENT HOME WITH VICODIN. SHE HAD ABDOMINAL PAIN EVER SINCE. SHE WAS TAKEN TO THE EMERGENCY ROOM BY AMBULANCE FOR SEVERE ABDOMINAL CRAMPING AND DIARRHEA. SEVERAL TESTS, CT SCAN, BLOOD AND URINE TESTS WERE PERFORMED AND THEY DIDN'T KNOW WHAT WAS WRONG. SHE WAS PUT ON 7 DIFFERENT MEDICATIONS, INCLUDING 2 ANTIBIOTICS AND REFERRED TO A GASTROENTEROLOGIST. A COLONOSCOPY, THEN AN ENDOSCOPY AND THEN A SPECIAL X-RAY TEST WERE PERFORMED TO LOOK AT SMALL INTESTINE AND IT WAS FOUND SHE HAD A C-DIFF INFECTION, A VERY SERIOUS ONE TOO. SHE WAS STILL ON THE ROAD TO RECOVERY (SHE WAS BATTLING THIS INFECTION FOR 2 AND A HALF MONTHS). BEFORE ESSURE, SHE WAS A HEALTHY, ACTIVE WOMAN. SHE WAS COMPLAINING OF 2 PERIODS A MONTH, EXTREME ABDOMINAL PAINS DURING MENSES, HEADACHES SHE NEVER HAD, BAD ABDOMINAL PAIN ALL THE TIME, HER JOINTS AT HER HIPS HURT, SHARP PAINS IN LEFT OVARY (SHE DENIED CYSTS OR ENDOMETRIOSIS). SHE WAS SCHEDULED FOR AN ALLERGY TEST IN 2 MONTHS, BECAUSE SHE MAY BE HAVING AN ALLERGIC REACTION TO WHAT IT'S COMPOSED OF. CONSUMER REPORTED HOSPITALIZATION AS EVENT OUTCOME; HOWEVER SHE DID NOT SPECIFY IT. FOLLOW-UP INFORMATION RECEIVED ON 16-FEB-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER

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FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 11-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW UP 06-AUG-2015: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA HEALTH AUTHORITY FDA WEB DOCKET ((B)(4)). CONSUMER REPORTED THAT SHE WAS (B)(6), MOTHER OF FOUR AND SHE STATED THAT SINCE ESSURE WAS INSERTED SHE HAS BEEN A MEDICAL NIGHTMARE. SHE WAS A HEALTHY AND ACTIVE WOMAN PRIOR TO ESSURE. HER IMPLANTING DOCTOR AND SHE THOUGHT THIS DEVICE WOULD BE THE PERFECT FIT FOR HER SINCE SHE DID NOT WANT TO BE CUT ON. UPON WAKING AFTER THE PROCEDURE, SHE WAS IN TERRIBLE PAIN IN MY PELVIC REGION, ASKED FOR PAIN MEDICATION AND WAS GIVEN A PAIN KILLER AND A PRESCRIPTION TO TAKE HOME. THE PAIN HAS NEVER COMPLETELY GONE AWAY. FOR DAYS AFTER THE IMPLANT SHE WAS HYPER AWARE OF HER FALLOPIAN TUBES AND COULD ACTUALLY FELT SOMETHING IN THERE. A WEEK AFTER IMPLANT, STILL IN PAIN AND SHE DEVELOPED AN ALLERGY TO MILK. OR SO SHE THOUGHT. IT WAS ACTUALLY THE BEGINNING OF A REALTY BAD C-DIFF INFECTION. A MONTH AFTER IMPLANT SHE WAS TAKEN BY AMBULANCE TO THE HOSPITAL FOR SEVERE ABDOMINAL CRAMPING. THEY PUT HER THROUGH X-RAYS, CT SCAN, BLOOD WORK, COLONOSCOPY, ENDOSCOPE AND MORE X-RAYS. NOT ONE OF HER DOCTORS COULD FIGURE OUT HOW ON EARTH SHE HAD CONTRACTED A C-DIFF INFECTION AND SHE HAD TO PUT OFF HER HYSTEROSALPINGOGRAM TEST UNTIL THE INFECTION WAS MANAGED SHE HAD THE HSG IN (B)(6) 2014. SHE WAS 100% OCCLUDED AND THE PLACEMENT WAS CORRECT. IT TOOK 3 MONTHS AND 7 DIFFERENT MEDICATIONS TO BEAT THE INFECTION IN THOSE THREE MONTHS HER PERIODS BEGAN TO CHANGE, THEY BECAME HEAVIER, LONGER, EXTREMELY PAINFUL AND COMPLETELY IRREGULAR. HER DOCTOR TOLD HER THAT HAD NEVER HAD ANY PATIENT HAVING ISSUES WITH ESSURE, SO IT MUST BE SOMETHING ELSE. CONSUMER MENTIONED THAT SHE WAS IN BED, IN PAIN, FEELING HORRIBLE. AROUND 8 MONTHS AFTER IMPLANT SHE STARTED TO GAIN WEIGHT. NOT ONE OR TWO POUNDS, SHE QUICKLY WENT FROM (B)(6) TO BEING (B)(6) IN 5 MONTHS. AROUND THE SAME TIME, HER PERIODS STARTED COMING EVERY TWO WEEKS. HER PERIODS HAVE BECOME SO BAD THAT SHE BLEED THROUGH A TAMPON AND PAD IN A HALF HOURS TIME. I WILL GET AN ODD PRESSURE IN THE BOTTOM OF HER VAGINA AND IT FELT LIKE SOMETHING PUSHING OUT OF HER. SHE ALSO MENTIONED THAT SINCE GETTING THE DEVICE SEX HAS BECOME PAINFUL. SHE BLOATED TO WHERE IT WAS PAINFUL AND SHE LOOKED 7 MONTHS PREGNANT. SHE GET TERRIBLE HEADACHES, BROKE OUT IN RASHES AND SHE BEEN DIAGNOSED WITH RHEUMATOID ARTHRITIS JUST RECENTLY. HER HANDS AND FEET GO NUMB AND SWELL. CONSUMER HAS RECENTLY FOUND A GYNECOLOGIST WHO HAS MADE IT A POINT TO RUN VERY THOROUGH TESTS TO RULE OUT ANY OTHER POSSIBILITIES FOR HER DECLINING HEALTH, SO FAR EVERY SINGLE TEST HAS COME BACK NORMAL. HER NEW DOCTOR PREFORMED A SALINE ULTRASOUND TO LOCATE THE COILS AND CHECK FOR ANY OTHER THINGS THAT MIGHT BE CAUSING HER PAIN AND FAILING HEALTH. THE TEST FOUND AN OVARIAN CYST, FIBROIDS AND WHILE THEY WERE ABLE TO LOCATE HER LEFT IMPLANTED COIL, THE RIGHT ONE WAS NOT FOUND. SHE GOES BACK IN AUGUST TO DO ONE LAST ROUND OF TESTS BEFORE OPTING ON A COMPLETE HYSTERECTOMY. CONSUMER STATED THAT ESSURE HAS MADE HER LIFE MISERABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED A C-DIFF INFECTION (INTERPRETED AS CLOSTRIDIUM DIFFICILE INFECTION). THIS EVENT WAS CONSIDERED SERIOUS DUE TO

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HOSPITALIZATION AND IT IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO EXPERIENCED ABDOMINAL PAIN EVER SINCE; BAD ABDOMINAL PAIN ALL THE TIME, WHICH WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED. CONSUMER WILL UNDERGO A COMPLETE HYSTERECTOMY AND STATED THAT ESSURE HAS MADE HER LIFE MISERABLE. COLONIZATION OF THE INTESTINAL TRACT WITH CLOSTRIDIUM DIFFICILE OCCURS VIA THE FECAL-ORAL ROUTE AND IS FACILITATED BY DISRUPTION OF NORMAL INTESTINAL FLORA DUE TO ANTIMICROBIAL THERAPY. THE ORGANISM PRODUCES EXOTOXINS THAT BIND TO RECEPTORS ON INTESTINAL EPITHELIAL CELLS, LEADING TO INFLAMMATION AND DIARRHEA. CONSIDERING THE PATHOPHYSIOLOGY OF THIS REPORTED EVENT AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY WITH ESSURE WAS ASSESSED AS UNRELATED. WITH REGARDS TO THE OTHER EVENT, GIVEN ITS NATURE AND CONSIDERING THAT THE EVENT OCCURRED SINCE ESSURE INSERTION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. AN UPDATED PRODUCT TECHNICAL ANALYSIS IS EXPECTED. FURTHER INFORMATION COULD NOT BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00662	BAYER HEALTHCARE LLC	8/28/2015	8/28/2015

Event Information:

Event Date (B3): 7/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C22912

Single Use: Y
Implant Date (E6): 7/14/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C22912 IMPLANTED FOR PERMANENT STERILIZATION ON (B)(6) 2015. SHE WAS NOT PREGNANT. IT WAS REPORTED THAT THE INSERTION ON RIGHT SIDE HAD NO ISSUE. LEFT SIDE DID NOT INITIALLY DEPLOY. IT GOT STUCK HALFWAY OUT OF THE INSERTION DEVICE. THE PHYSICIAN HAD TO PULL OUT COIL AND REPLACE WITH ANOTHER ESSURE COIL. BILATERAL PLACEMENT WAS ACHIEVED. ON (B)(6) 2015 THE PATIENT REPORTED SEVERE PAIN. THE PAIN LASTED ONE WEEK. AT THAT POINT, THE LEFT TUBE WAS REMOVED ALONG WITH THE ESSURE COIL, DUE TO THE EXPULSION OF THE ESSURE COIL. ESSURE WAS ONGOING ON ONE SIDE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN / THE PAIN LASTED ONE WEEK. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, PATIENT EXPERIENCED THIS EVENT ONE DAY AFTER ESSURE INSERTION. IT WAS ALSO REPORTED THAT LEFT SIDE DID NOT INITIALLY DEPLOY. IT GOT STUCK HALFWAY OUT OF THE INSERTION DEVICE. SHE HAD HER LEFT TUBE REMOVED ALONG WITH THE ESSURE COIL DUE TO THE EXPULSION OF THE ESSURE COIL. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP AND GIVEN THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO PERFORMED SURGICAL INTERVENTION. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 01-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00663	BAYER HEALTHCARE LLC	8/28/2015	8/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/19/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 06-AUG-2015 WHICH REFERS TO A NON-PREGNANT (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT STERILIZATION. PHYSICIAN REPORTED THAT PATIENT WENT BACK IN OFFICE ON (B)(6) 2015, COMPLAINING OF CRAMPING. HEALTH CARE PROFESSIONAL (HCP) PERFORMED ULTRASOUND AND TEST SHOWED ONE COIL ON LEFT SIDE HAS PERFORATED. HCP CONSIDERING HYSTERECTOMY BUT PATIENT HAD NO INSURANCE. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION. APPROXIMATELY 3 MONTHS AFTER INSERTION, COMPLAINED OF CRAMPING AND THE ULTRASOUND SHOWED ONE COIL ON LEFT SIDE HAD PERFORATED. THE HCP WAS CONSIDERING HYSTERECTOMY BUT PATIENT HAD NO INSURANCE. THIS EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION, IS LISTED ACCORDING TO THE REFERENCE SAFETY FOR ESSURE. IN THIS PARTICULAR CASE, THE PERFORATION WAS DIAGNOSED VIA ULTRASOUND APPROXIMATELY 3 MONTHS AFTER INSERTION. NO DETAILS WERE PROVIDED REGARDING ESSURE INSERTION PROCEDURE. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND THAT FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ESSURE, THE PERFORATION IS CONSIDERED RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WILL BE REQUIRED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 27-AUG-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(6). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00664	BAYER HEALTHCARE LLC	8/28/2015	8/28/2015

Event Information:

Event Date (B3): 7/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY IN THE UNITED STATES, ON BEHALF OF A PLAINTIFF IN UNITED STATES ON 07-AUG-2015 WHICH REFERS TO A FEMALE PLAINTIFF OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) . ON OR ABOUT (B)(6) 2014, CONSUMER WAS SCHEDULED FOR A TUBAL LIGATION SURGERY. AT THE TIME OF THE SURGERY, PHYSICIAN ATTEMPTED TO IMPLANT THE ESSURE FEMALE BIRTH CONTROL DEVICE WITHOUT CONSUMER INFORMED CONSENT. UNBEKNOWNST TO CONSUMER, THE IMPLANTATION FAILED. ACCORDING TO REPORTED, ESSURE DEVICE DID NOT DEPLOY AND FAILED TO RELEASE IN THE SECOND RECOILING. FOLLOWING SURGERY, PHYSICIAN TOLD HER THAT "EVERYTHING WENT WELL" WITH HER TUBAL LIGATION AND DISCHARGED HER. CONSUMER EXPERIENCED AMONG OTHER THINGS, FEVER, CRAMPS, DISCHARGE AND A LOT OF PAIN AND DISCOMFORT. CONSUMER ATTEMPTED TO CONSULT WITH PHYSICIAN DUE TO HER SEVERE SYMPTOMS BUT HEALTH CARE PROFESSIONAL WAS NOT AVAILABLE FOR OVER THIRTY DAYS. CONSUMER ALSO REPORTED DISFIGUREMENT, SEVERE AND PERMANENT INJURY TO HER PERSON AND SEVERE AND ONGOING EMOTIONAL DISTRESS. SUBSEQUENTLY, PHYSICIAN INFORMED CONSUMER THAT HER SYMPTOMS AND PAIN WERE DUE TO THE SUBJECT ESSURE DEVICE THAT WAS UNSUCCESSFULLY IMPLANTED. HEALTH CARE PROFESSIONAL STATES SHE ATTEMPTED TO IMPLANT THE ESSURE DEVICE BUT WHEN IT DID NOT DEPLOY, SHE REMOVED HALF OF THE DEVICE BUT WAS UNABLE TO REMOVE THE OTHER HALF DURING THE SURGERY. THIS WAS THE FIRST TIME CONSUMER LEARNED THAT ESSURE WAS IMPLANTED AND ONLY PARTIALLY REMOVED ON THE DAY OF TUBAL LIGATION SURGERY. PHYSICIAN OFFERED CONSUMER A SECOND SURGERY TO REMOVE THE REMAINING PIECE OF THE ESSURE DEVICE HOWEVER, CONSUMER WAS AFRAID TO UNDERGO THE SURGERY WITH HER. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A

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PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE REPORTED IN THE CONTEXT OF COMPLICATED DEVICE INSERTION. THE AE CASE REFERS TO A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE PHYSICIAN ATTEMPTED TO IMPLANT THE ESSURE DEVICE BUT WHEN IT DID NOT DEPLOY, SHE REMOVED HALF OF THE DEVICE BUT WAS UNABLE TO REMOVE THE OTHER HALF (REGARDED AS DEVICE BREAKAGE). THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. ADDITIONALLY, OTHER SERIOUS EVENT (INJURIES/ INJURY/PHYSICAL INJURY/SEVERE AND PERMANENT INJURY/SERIOUS INJURY) AND NON-SERIOUS EVENTS WERE REPORTED. ADDITIONAL INFORMATION WILL BE OBTAINED THROUGH THE NORMAL LITIGATION PROCESS. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00681	BAYER HEALTHCARE LLC	8/28/2015	8/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51073

Single Use: Y
Implant Date (E6): 7/16/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015. IT REFERS TO A 34-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C51073 INSERTED ON (B)(6) 2015. DEVICE WOULD NOT DEPLOY AND THEN PART OF COIL DIDN'T OPEN AND ANOTHER PART SEPARATED. BILATERAL PLACEMENT WAS ACHIEVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A 34-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, DEVICE DID NOT DEPLOY AND THEN PART OF COIL DIDN'T OPEN AND ANOTHER PART SEPARATED. THIS EVENT, SEEN AS DEVICE BREAKAGE AND DEVICE DEPLOYMENT ISSUE, IS NON-SERIOUS. BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE DEPLOYMENT ISSUE IS LISTED. DURING DIFFICULT INSERTIONS OR REMOVALS, DEVICE BREAKAGE AND DEVICE DEPLOYMENT ISSUE MAY OCCUR. IN THIS CASE, THE DEVICE WOULD NOT DEPLOY AND THEN PART OF COIL DIDN'T OPEN AND ANOTHER PART SEPARATED. THEN, BILATERAL PLACEMENT WAS ACHIEVED. CONSIDERING THE REPORTED EVENTS OCCURRED ASSOCIATED TO A COMPLICATED INSERTION PROCEDURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 16-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00682	BAYER HEALTHCARE LLC	8/28/2015	8/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B76525

Single Use: Y
Implant Date (E6): 7/20/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B76525 IMPLANTED ON (B)(6) 2015. THE PHYSICIAN INSERTED THE DEVICE AND WHEN HE WENT TO REMOVE IT, PART OF GREEN CATHETER REMAINED IN THE PATIENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PLACEMENT PROCEDURE, THE PHYSICIAN INSERTED THE DEVICE AND WHEN HE WENT TO REMOVE IT, A PART OF GREEN CATHETER REMAINED IN THE PATIENT. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS OR REMOVALS, DEVICE BREAKAGE MAY OCCUR. CONSIDERING THE REPORTED EVENTS OCCURRED ASSOCIATED TO THE DEVICE INSERTION, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 26-AUG-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055914		8/28/2015	9/3/2015

Event Information:

Event Date (B3): 8/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/28/2013
Explant Date (E7): 8/17/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IN A LOT OF PAIN. I WENT TO THE DOCTOR. THEY EXAMINED ME AND THEY NOTIFIED ME THAT I HAD FLUID IN MY UTERUS AND ALSO AROUND MY BLADDER. THEY SAID THAT IF I DIDN'T HAVE SURGERY, THAT IT COULD TURN INTO CANCER. ALL OF THIS WAS CAUSED BY THE ESSURE THAT I HAD ABOUT 2 YEARS AGO ON (B)(6) 2015 BY DR (B)(6) OUT OF (B)(6). AN ULTRA SOUND ON (B)(6) 2015 WITH THE RESULT SHOWING THAT I HAD SOME FEMALE PROBLEMS AND HERNIA ON MY LEFT SIDE. A CAT SCAN ON (B)(6) 2015 WITH THE RESULT OF A GROWTH IN MY UTERUS. AN ULTRA SOUND BY DR (B)(6) IN (B)(6), ON (B)(6), 2015. THE RESULTS SHOWING FLUID IN MY UTERUS AND AROUND MY BLADDER. THE RESULTS WERE SENT OFF FOR A BIOPSY AND I WAS THEN SCHEDULED FOR SURGERY. I WENT IN FOR SURGERY ON (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055912		8/29/2015	9/3/2015

Event Information:

Event Date (B3): 8/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/20/2013
Explant Date (E7): 8/24/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE PROCEDURE PERFORMED ON (B)(6) 2013. ACCORDING TO THE DOCTOR, THE CASE WAS ROUTINE. I HAD SOME MILD CRAMPING FOR SEVERAL DAYS BUT HE DID INFORM ME THAT THIS WAS AN EXPECTED REACTION. I HAD THE FOLLOW-UP HSG TEST PERFORMED ON (B)(6) 2014. THE RADIOLOGIST REPORT STATES THAT THE ESSURE COILS WERE IN THE PROPER PLACES AND THAT THERE WAS TOTAL TUBAL OCCLUSION. I DID NOT EXPERIENCE ANY DISCOMFORT, BUT I DID NOTICE THAT MY CYCLES BEGAN TO FLUCTUATE A LITTLE BIT. I WOULD CYCLE BETWEEN 21 AND 29 DAYS AND THE DURATION WAS ABOUT 5 DAYS. TYPICALLY, THE FIRST 3 DAYS WOULD CONSIST OF HEAVY BRIGHT RED BLOODFLOW AND THE LAST 2 OR 3 DAYS WOULD BE VERY STICKY BROWN CLOTS. TWENTY MONTHS AFTER THE ESSURE COILS WERE PLACED, ON (B)(6) 2015 I BEGAN MY CYCLE AND IT WAS CONSISTENT WITH THIS PATTERN, EXCEPT THAT THE BROWN BLOOD FLOW WAS HEAVIER THAN NORMAL. ON (B)(6) 2015 I DECIDED TO CHECK MYSELF DIGITALLY. I INSERTED A FINGER INTO MY VAGINA TO SCOOP OUT THE BROWN CLOTS. I DID THIS ABOUT 3 TIMES AND THEN MY FINGER CAUGHT ON SOMETHING. I SWEPT MY FINGER AROUND MY VAGINA AGAIN AND WAS ABLE TO TOUCH THE METAL OBJECT I FELT AND REALIZED IT WAS PROTRUDING FROM MY CERVIX. I WAS ABLE TO INSERT A SECOND FINGER AND PINCHED THE OBJECT AND PULLED IT FROM MY CERVIX. IMMEDIATELY I KNEW IT WAS THE COIL, BUT IT WAS MISSING THE INNER INSERT. I SWEPT MY FINGERS AROUND MY VAGINA AGAIN AND WAS ABLE TO LOCATE THE INSERT. WITH MUCH DIFFICULTY, I WAS ABLE TO PINCH IT AND PULL IT FROM MY CERVIX. I CALLED MY GYNECOLOGIST THE NEXT MORNING AND HE WAS FLABBERGASTED. I MADE AN APPOINTMENT FOR A REPEAT HSG AND THAT WAS PERFORMED ON (B)(6) 2015. MY GYNECOLOGIST PERFORMED THE PROCEDURE WITH THE RADIOLOGIST THERE TO READ THE IMAGES. THEY CONCLUDED

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THAT THE COIL HAD COME FROM MY RIGHT FALLOPIAN TUBE, BUT IT WAS COMPLETELY OCCLUDED. THE LEFT COIL REMAINS IN PLACE. I ASKED MY GYNECOLOGIST TO SEND THE EXPELLED COIL AND INSERT TO PATHOLOGY FOR DOCUMENTATION PURPOSES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055913		8/29/2015	9/3/2015

Event Information:

Event Date (B3): 3/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/18/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

NOTICED BLOATING, UNEXPLAINABLE WEIGHT GAIN, DIFFICULTY LOSING WEIGHT, PROBLEMS CONCENTRATING, MEMORY ISSUES, ITCHING, PAINFUL JOINTS, AND LOWER BACK PAIN SINCE IMPLANTATION OF ESSURE IN 2013.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055888	BAYER	8/30/2015	9/3/2015

Event Information:

Event Date (B3): 8/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/25/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE (B)(6) 2014 AND NOW I CURRENTLY HAVE FLUID IN MY LEFT TUBE. AS A RESULT I NOW HAVE TO HAVE A HYSTERECTOMY. I HAVE EXPERIENCED NOTHING BUT PAIN AND PROBLEMS SINCE I GOT THE IMPLANT DONE. I HAVE COMPLAINED MULTIPLE TIMES TO MY DOCTORS AND HAVE BEEN TO THE E.R. MULTIPLE TIMES FOR THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055910	BAYER	8/30/2015	9/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE PRODUCT ESSURE FOR PERMANENT BIRTH CONTROL. A FEW MONTHS LATER, I STARTED COMPLAINING OF ABDOMINAL PAIN TO MY DR WHO REFERRED ME TO A UROLOGIST WHO COULD NOT EXPLAIN THE REASON FOR PAIN. MY DR WENT ON 4 MONTH MEDICAL LEAVE AND I WAS REFERRED TO THE EMERGENCY ROOM BY OBGYN FOR PAIN AND BLEEDING FROM MY VAGINA WHO REFERRED ME TO DIFFERENT UROLOGIST. THE LAST 7 WEEKS I HAVE BEEN IN THE EMERGENCY ROOM 7 TIMES AND DIAGNOSED WITH INFLAMED FALLOPIAN TUBES, CYST COVERING BOTH OVARIES AND LEFT OVARY INFLAMED, PELVIC INFLAMMATORY DISEASE AND CRIPPLING PAIN!. I HAVE SEEN OBGYN WHO RECOMMENDS HYSTERECTOMY TO REMOVE ESSURE. APPOINTMENT WITH DR TO SCHEDULE SURGERY (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00665	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-0047) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. THE CONSUMER STATED THAT SHE WAS NEVER INFORMED OF A POSSIBLE ALLERGIC REACTION AND IT WAS THEN SHE WOULD COME TO KNOW HOW MUCH ESSURE HAD AFFECTED HER. SHE BLED THE ENTIRE TIME VERY HEAVY AND SHE WAS TOLD THAT IF SHE DID NOT HAVE THE DEVICE REMOVED THAN SHE COULD BLEED TO DEATH. AFTER, SHE FOUND OUT THAT HER SKIN HAD GROWN TO THE ESSURE SO HAVING THE DEVICE REMOVED WOULD REQUIRE A HYSTERECTOMY. SHE STATED HER UTERUS WAS TAKEN AWAY FROM HER. HER DAMAGE WAS IRREVERSIBLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BLED THE ENTIRE TIME VERY HEAVY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY. THE REPORTED EVENT, INTERPRETED AS GENITAL BLEEDING, WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS IS A SOCIAL MEDIA CASE

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 03-SEP-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00666	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE#(B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A 42-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. THE CONSUMER REPORTED THAT AT TIME OF THE INSERTION PROCEDURE SHE WAS 42 WITH 6 KIDS AND THEREFORE WOULD LIKE A TUBAL LIGATION. IN OFFICE, THE PROCEDURE THAT WOULD TAKE ABOUT 10 MINUTES TOOK ALMOST 2 HOURS. SHE HAD HORRIBLE CRAMPS AND HER PERIOD WAS OLD BROWN DOTTY BLOOD, SHE FIGURED IT WAS THE PROCEDURE. AT HER 3 MONTH DYE TEST THE DOCTOR SAID ONE TUBE WAS BLOCKED BUT COULDN'T FIND THE OTHER COIL, THE PHYSICIAN SAID IT WOULD NOT HURT HER AND WOULD DO JUST SNIP THAT TUBE AND SHE WOULD BE FINE. SHE STARTED HAVING WEIRD THINGS GOING ON LIKE A MOLAR GOT LOOSE AND JUST FELL OUT AND SHE WAS LOSING HAIR; AND HER BODY ACHED AND SHE WAS GETTING A LOT OF WEIRD EYE FLOATERS AND KALEIDOSCOPE VISION. IN (B)(6) 2014, SHE WAS WORKING AND GOT HIT WITH A TON OF BRICKS, DROP YOU TO YOUR KNEES, ABDOMINAL PAIN AND SCIATIC PAIN, AND SHE WAS POOPING BLOOD CLOTS. IN THE NEXT MORNING SHE WENT TO THE ER AND CAT SCAN WAS PERFORMED AND FOUND ONE COIL WAS POKING OUT OF HER TUBE AND THE OTHER WAS EMBEDDED IN HER UTERUS. THE DOCTOR SAID THOSE HAD TO COME OUT AND SCHEDULE HER WITH A GYNECOLOGIST. SHE READ UP ON REMOVAL AND TALKED TO DOCTOR, SHE HAD HER OWN IDEA THAT SHE COULD PULL THEM OUT, THE CONSUMER BEGGED FOR HER NOT TO AND TOLD HER THAT WHATEVER ORGAN THEY WERE IN HAD TO BE RIVER (NOS) OR THEY BREAK AND SHE WOULD BE LEFT WITH FRAGMENTS AND PET FIBERS IN AND SHE ONLY WANTED TO HAVE SURGERY ONCE. THE PHYSICIAN DID IT HER

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WAY AND PROMISED SHE GOT IT ALL INTACT BUT SHE DID NOT SHOW THE CONSUMER ANY PATHOLOGY REPORT OR PIC PROVING THEY WERE GONE AND DREW HER PICTURE OF SURGERY AND SEND THE CONSUMER AWAY. THE CONSUMER REQUESTED ALL RECORDS AND SCANS AND THEY LEFT FRAGMENTS BEHIND AND THERE WAS ONE WHOLE COIL MISSING. SHE STATED SHE WAS STILL IN HORRIBLE PAIN HAD TO QUIT HER JOB. THE DAILY PAIN WAS UNBELIEVABLE; HER SECOND DOCTOR COULDN'T BELIEVE WHAT SHE WENT THROUGH AND DID A COMPLETE HYSTERECTOMY AND THERE WAS A HALF A COIL EMBEDDED IN HER UTERUS BUT STILL WAS SING (NOS) THAT OTHER COIL. SHE FELT SO MUCH BETTER AFTER ESSURE WAS OUT OF HER BODY; SHE REPORTED IT WAS SO BAD, SHE ITCHED ALL OVER ALL DAY EVERY DAY; BROKE OUT IN A RASH WEARING A BRA. SHE STATED THAT THEY THOUGHT SHE HAD CROHN'S DISEASE BECAUSE SHE WAS SO INFLAMED FROM ESSURE. SHE HAD 2 SURGERIES IN 4 MONTHS AND LOST ALL HER LADY PARTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A 42-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE MICRO-INSERT WAS POKING OUT OF HER TUBE AND OTHER WAS EMBEDDED IN HER UTERUS. APPARENTLY, DURING SURGERY FOR REMOVAL, FRAGMENTS WERE LEFT BEHIND. SHE ALSO EXPERIENCED POOPING BLOOD DOTS. THESE EVENTS, SEEN AS DEVICE EMBEDMENT, DEVICE DISLOCATION, DEVICE BREAKAGE AND HAEMATOTOCHEZIA RESPECTIVELY, ARE SERIOUS DUE MEDICAL IMPORTANCE (EXCEPT BREAKAGE WHICH IS NON-SERIOUS). DISLOCATION, EMBEDMENT AND BREAKAGE ARE LISTED, WHILE HAEMATOCHEZIA IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES (DISLOCATION). ALSO, A PARTIAL PERFORATION (DEVICE EMBEDMENT) OF FALLOPIAN TUBES OR UTERINE WALL MAY OCCUR. ADDITIONALLY, DURING DIFFICULT REMOVALS, DEVICE BREAKAGE HAS BEEN REPORTED. IN THIS CASE THE EXACT MECHANISM AND CHARACTERISTICS OF DISLOCATION, PARTIAL PERFORATION AND BREAKAGE ARE NOT KNOWN; HOWEVER, GIVEN THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. REGARDING HAEMATOCHEZIA, CONSIDERING ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY WITH SUSPECT INSERT IS VERY UNLIKELY. SINCE AN INTERVENTION WAS REQUIRED FOR ESSURE REMOVAL (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. IN ADDITION, THE AE CASE REFERS TO A USA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00667	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 06-AUG-2015 WHICH DESCRIBES A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) IN 2006. ADDITIONAL INFORMATION RECEIVED ON 11-AUG-2015. CONSUMER STATED THAT ESSURE AND NOVASURE WERE PERFORMED IN 2006. SHE HAD CONSTANT PAIN 8 WEEKS AFTER PROCEDURE AND SHE VISITED 3 DIFFERENT HOSPITALS BUT NOTHING COULD BE DIAGNOSED AND SHE WAS DISCHARGED WITH PAPERWORK REGARDING ABDOMINAL PAIN. TWO YEARS LATER, SHE GOT PREGNANT AND HAD SEVERE COMPLICATIONS WHICH LED TO A COMPLETE HYSTERECTOMY AT ALMOST 20 WEEKS PREGNANT. SHE LOST HER UTERUS AND BABY DIED AS WELL (CASE (B)(4)). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. AT 20 WEEKS OF GESTATION, SHE EXPERIENCED SEVERE COMPLICATIONS WHICH LEAD TO A COMPLETE HYSTERECTOMY. HER BABY DIED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY PREGNANCY IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS CASE, NO INFORMATION WAS PROVIDED ABOUT HSG. ADDITIONALLY, CONSUMER MENTIONED A NOVASURE PROCEDURE; WHICH IF PERFORMED CONCOMITANTLY WITH ESSURE COULD HAVE COMPROMISED AN HSG TEST.

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HOWEVER, AS PREGNANCY OCCURRED 2 YEARS AFTER ESSURE PLACEMENT; AN ESSURE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING THE REPORTED PREGNANCY COMPLICATIONS; THEY WERE NOT SPECIFIED. NEVERTHELESS, AS THEY OCCURRED DURING THE SECOND TRIMESTER OF GESTATION; A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED. THEREFORE, THIS EVENT WAS CONSIDERED AS RELATED TO THE SUSPECT INSERT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE SERIOUS INJURY FOR BOTH MOTHER AND FETUS. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-SEP-2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00668	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY ((B)(4)) IN UNITED STATES ON 06-AUG-2015 WHICH REFERS TO A FETUS WHOSE MOTHER OF UNSPECIFIED AGE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. THE MOTHER HAD SEVERE COMPLICATIONS WHICH LED TO A COMPLETE HYSTERECTOMY AT ALMOST (B)(6)WEEKS PREGNANT. THE FETUS DIED (MOTHER'S CASE (B)(4)). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER AND REFERS TO HER FETUS; WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERUS. AT (B)(6) WEEKS OF CONSUMER'S PREGNANCY, SHE WAS SUBMITTED TO A HYSTERECTOMY DUE TO SEVERE COMPLICATIONS (UNSPECIFIED) AND THE FETUS DIED. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO FATAL OUTCOME AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. THE COMPLICATIONS EXPERIENCED BY THE MOTHER WERE NOT SPECIFIED AND NO INFORMATION WAS PROVIDED ABOUT FETAL DISORDERS. NEVERTHELESS, CONSIDERING THE FETUS DIED DURING THE SECOND TRIMESTER OF GESTATION; A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED. THEREFORE, THE REPORTED EVENT WAS CONSIDERED AS POSSIBLY RELATED TO THE SUSPECT INSERT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6)2015: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00669	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-0386) IN (B)(6) ON 06-AUG-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR 6 YEARS. THE CONSUMER STATED THAT SHE SUFFERED AN EMOTIONAL ROLLER COASTER WHEN SHE HAD ESSURE IN PLACE. SHE HAD TO ENDURE MANY DAYS OF WORKING THROUGH THE SEVERE MIGRAINES AND VOMITING DUE TO DIZZINESS. ALL THE EVENTS RESOLVED AFTER HAVING A HYSTERECTOMY PERFORMED. THE CONSUMER CONSIDERED ALL EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND UNDERWENT HYSTERECTOMY. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR HYSTERECTOMY WAS NOT SPECIFIED, THE REPORTER REGARDED THE EVENT AS A CONSEQUENCE OF ESSURE USE. THUS, CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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INTERNAL CORRECTION ON 24-NOV-2015. DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 09-AUG-2015

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00670	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 06-AUG-2015 WHICH REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. CONSUMER REPORTED SHE WAS TOLD ESSURE WAS SAFE AND EFFECTIVE SO HER DOCTOR URGED HER TO GO WITH ESSURE OVER THE OPTION OF HAVING HER TUBES TIED. SHE STATED SHE BECAME SO ILL; SHE WAS IN AND OUT OF DOCTOR OFFICES AND LABELED AS A MYSTERY. HER SYMPTOMS DIDN'T ADD UP; SHE STATED THAT LOST 4 YEARS OF HER LIFE, FINALLY ENDING UP WITH A HYSTERECTOMY AT AGE (B)(6) WHEN HER TEAM OF PHYSICIANS FINALLY REALIZED ESSURE WAS THE CULPRIT. SHE COULD BARELY FUNCTION; HER KIDS DIDN'T HAVE A QUALITY LIFE FOR 4 YEARS WHICH WAS UNACCEPTABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ACCORDING TO HER; DUE TO THE DEVICE SHE LOST 4 YEARS OF HER LIFE, FINALLY ENDING UP WITH A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED SHE BECAME ILL, BUT LIMITED INFORMATION WAS GIVEN AND NO REASON FOR HYSTERECTOMY WAS PROVIDED. HOWEVER, SINCE CONSUMER RELATED THIS PROCEDURE TO ESSURE, A CAUSAL RELATIONSHIP WITH THE

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SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

INTERNAL CORRECTION ON 24-NOV-2015. DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 09-AUG-2015

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00671	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): 2/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009 FOR CONTRACEPTION. THE CONSUMER REPORTED THE INSERTION PROCEDURE WAS IN SURGERY CENTER AND SHE WAS PUT TO SLEEP AND ESSURE WAS IMPLANTED. SHE STATED THAT DIRECTLY AFTER THE PROCEDURE, SHE HAD SEVERE BLEEDING AND CRAMPING AND HER PHYSICIAN SAID SHE NEEDED TIME TO GET USED TO THE IMPLANTS. IN (B)(6) 2009 SHE HAD HSG (HYSTEROSALPINGOGRAM) DONE AND THE TUBES WERE CONSIDERED BLOCKED AND THE PHYSICIAN SENT HER A LETTER STATING THE PROCEDURE WAS SUCCESSFUL AND SHE COULD STOP THE CURRENT FORM OF BIRTH CONTROL. SHE REPORTED THAT SINCE THEN SHE HAD THE FOLLOWING SYMPTOMS: MENSTRUAL PERIODS TWICE A MONTH OR MORE, MUCH HEAVIER PERIODS THAN EVER BEFORE AND LOTS OF LARGE DOTS; SEVERE CRAMPING; PAIN WITH SEXUAL AROUSAL; PAIN WITH SEXUAL INTERCOURSE, BECAUSE OF THE PAIN INVOLVED WITH SEXUAL AROUSAL AND INTERCOURSE SHE HAD NO SEX DRIVE. SHE EXPERIENCED HAIR LOSS; CONSTANT FATIGUE; JOINT PAIN; INFLAMMATION; CONSTANT BLOATING TO WHERE SHE LOOK LIKE 6+ MONTHS PREGNANT; MEMORY FOG; STABBING PAINS IN HER UTERUS ALL THE TIME, DURING OVULATION AND MENSTRUATION (THIS WAS MADE MUCH WORSE). SHE ALSO HAD A CONSTANT FEELING OF PMS. SHE HAD SPOKEN TO HER NEW GYNECOLOGIST ABOUT ALL HER COMPLICATIONS AND SHE WAS GOING TO GIVE HER A HYSTERECTOMY (B)(6) 2015 BECAUSE OF THE PROBLEMS THAT SHE WAS HAVING AFTER ESSURE WAS PLACED. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DETECTED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO AN ADULT FEMALE

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CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DIRECTLY AFTER THE PROCEDURE, HAD SEVERE BLEEDING. AFTER HSG, SHE STARTED TO HAVE STABBING PAINS IN HER UTERUS ALL THE TIME. THESE EVENTS, SEEN AS GENITAL HAEMORRHAGE AND UTERINE PAIN, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING AND ABDOMINAL, PELVIC (UTERINE) AND UNCHARACTERIZED PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SHORTLY AFTER THE ESSURE INSERTION THE CONSUMER PRESENTED SEVERE BLEEDING AND CRAMPING. SOME MONTHS LATER, HSG WAS DONE AND SHOWED THE TUBES BLOCKED. SINCE THEN, SHE HAS BEEN EXPERIENCING STABBING PAIN IN HER UTERUS ALL THE TIME AMONG OTHER NON-SERIOUS EVENTS. SHE HAD HYSTERECTOMY SCHEDULED DUE TO PROBLEMS SHE WAS HAVING AFTER THE DEVICES PLACEMENT. CONSIDERING EVENT'S NATURE AND COMPATIBLE TEMPORAL RELATIONSHIP, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE AND SINCE AN INTERVENTION WILL BE REQUIRED THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00672	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 06-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT ESSURE PROCEDURE CAUSED HER HEAVY BLEEDING 3 WEEKS OUT OF THE MONTH FOR 7 STRAIGHT YEARS. ACCORDING TO HER, THE BLEEDING WAS SO BAD SHE HAD TO HAVE A CRYO ABLATION. IN ADDITION, CONSUMER INFORMED THAT THE UNBEARABLE CRAMPS LANDED HER IN THE HOSPITAL SEVERAL TIMES, HER DEPRESSION WAS/IS BEYOND WORDS, HER HEADACHES WERE EXCRUCIATING (SOME OF THE HEADACHES WERE CLUSTER HEADACHES), INTERCOURSE WAS PAINFUL AND WALKING WOULD BE PAINFUL. CONSUMER INFORMED THAT SHE FELT LIKE SOMETHING WAS STABBING HER ALL THE TIME AND STATES THAT NO DOCTOR WOULD LISTEN. AFTER BEGGING FOR 4 YEARS TO HAVE ESSURE REMOVED, HER TIME FINALLY CAME IN (B)(6) 2015. IT WAS THEN THAT THE SURGEON DISCOVERED FIBROIDS, OVARIAN CYSTS, ENDOMETRIOSIS AND SEVERAL METAL PIECES IN HER UTERUS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING 3 WEEKS OUT OF THE MONTH FOR 7 STRAIGHT YEARS (SEEN AS GENITAL BLEEDING) AND UNBEARABLE CRAMPS LANDED HER IN THE HOSPITAL SEVERAL TIMES / FELT LIKE SOMETHING WAS STABBING HER ALL THE TIME. THE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND HOSPITALIZATION, RESPECTIVELY, AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO

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REPORTED THAT DURING ESSURE REMOVAL, THE SURGEON DISCOVERED SEVERAL METAL PIECES IN HER UTERUS. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED. IN THIS CASE, IT WAS NOT REPORTED WHEN ESSURE BROKE. WITH REGARDS TO THE OTHER EVENTS, SHE STARTED EXPERIENCING AFTER ESSURE INSERTION. GIVEN THE EVENT'S NATURE AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO ESSURE REMOVAL, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED.

Manufacturer Narrative (H10):

INTERNAL CORRECTION ON 24-NOV-2015 DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 09-AUG-2015

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00683	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 11/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 14-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. ADDITIONAL INFORMATION RECEIVED ON 16-FEB-2015. CONSUMER WANTED TO GET HER TUBES TIED AFTER HER 5TH CHILD BUT WHEN SHE WENT TO HER OBSTETRICIAN/GYNECOLOGIST HEALTH CARE PROFESSIONAL (HCP) THEY PUSHED HER TO GET THE ESSURE. ON (B)(6) 2014 SHE GOT ESSURE. EVER SINCE IT WAS PLACED SHE HAS HAD SEVERE PELVIC PAIN, SOMETIMES IT STOPS AND THEN IT COMES BACK EVEN WORSE. SHE IS ALSO HAVING BLEEDING AND SOMETIME VOMITING. ON ABOUT (B)(6) 2015, SHE WENT BACK TO THE PLACING HCP AND TOLD HIM ABOUT THE PAIN. CONSUMER ALSO REPORTED THAT SHE DEVELOPED A HEMORRHAGIC CYST IN HER VAGINA AND THE HCP SAID THAT WAS FROM THE ESSURE PROCEDURE AND IT WOULD GO AWAY AND IT POPPED A WEEK LATER. SHE WANTED TO GO BACK FOR THE 3 MONTH HYSTEROSALPINGOGRAM TEST BUT EVEN THOUGH THEY TOLD HER IT WOULD BE COVERED; NOW THEY SAY SHE HAS TO PAY OUT OF POCKET. SHE DOES NOT HAVE THIS MONEY TO PAY SO SHE HAS NOT HAD THIS TEST DONE. SHE IS STILL HAVING DAILY PAIN AND TAKING TYLENOL, LORTAB, AND IBUPROFEN; IT HELPS BUT DOES NOT GET RID OF THE PAIN. CONSUMER IS CONTINUING TO BLEED A SMALL AMOUNT JUST ABOUT EVERY DAY OR EVERY OTHER DAY AND IS WORRIED SHE COULD HAVE A PERFORATION OR DEATH. SHE WANTED TO REPORT THIS. WHEN SHE GETS OFF WORK THIS AFTERNOON SHE IS GOING TO THE EMERGENCY ROOM. ESSURE DEVICES WERE NOT REMOVED. FOLLOW UP INFORMATION RECEIVED ON 26-FEB-2015: PTC (PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO

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VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE PATIENT REPORTED HAVING A CYST IN VAGINA, HOWEVER CYSTS ARE NOT A KNOWN FAILURE MODE RELATED TO ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE AE CASE REFERS ALSO TO A TREATMENT NONCOMPLIANCE AS IT WAS REPORTED THAT 3 MONTHS HSG WAS NOT PERFORMED. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 30-MAR-2015: NO NEW CLINICAL INFORMATION. FOLLOW-UP INFORMATION RECEIVED FROM THE CONSUMER VIA HEALTH AUTHORITY FDA MAUDE (MW5040846) ON 01-JUN-2015: CONSUMER STATED THAT THE ENSURE WAS HIGHLY RECOMMENDED AND SHE WAS TOLD IT WAS BETTER THAN THE TUBAL LIGATION AND EVER SINCE SHE HAVE HAD THE DEVICE PLACED SHE HAVE HAD DEBILITATING PAIN AND BLEEDING EVERY DAY. FOLLOW UP 11-JUN-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CLOSED. FOLLOW-UP RECEIVED ON 10-AUG-2015: INFORMATION RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5043548) STATES THAT SHE HAD THE ESSURE PUT IN AND STARTED HURTING AND KEPT BLEEDING FOR FIVE MONTHS. SHE HAD TO HAVE SURGERY AND A DILATATION AND CURETTAGE TO CUT IT OUT. IN ADDITION, THE SERIOUSNESS CRITERION "OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)" WAS REPORTED. HOWEVER, IT WAS NOT SPECIFIED FOR WHICH EVENT. FOLLOW-UP RECEIVED ON 18-AUG-2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SINCE DEVICE PLACEMENT SEVERE PELVIC PAIN AND ALSO HAVE BLEEDING/ CONTINUING TO BLEED A SMALL AMOUNT FOR FIVE MONTHS. SHE WAS WORRIED SHE COULD HAVE A PERFORATION. THESE EVENTS, SEEN AS PELVIC PAIN, GENITAL HAEMORRHAGE AND SUSPICION OF FALLOPIAN TUBE PERFORATION, ARE SERIOUS DUE MEDICAL IMPORTANCE. IN ADDITION, GENITAL HAEMORRHAGE IS SERIOUS DUE TO REQUIRED INTERVENTION. ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE, THESE EVENTS ARE LISTED. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. ALSO, DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP AND THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. UPON FOLLOW UP INFORMATION, THIS CASE WAS REGARDED AS INCIDENT DUE TO THE SURGERY PERFORMED TO TREAT THE BLEEDING THAT WAS POSSIBLY CAUSED BY ESSURE. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT, AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. DESPITE FOLLOW-UP ATTEMPTS, NO FURTHER INFORMATION WAS OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00684	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B60749

Single Use: Y
Implant Date (E6): 5/20/2015
Explant Date (E7): 7/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 23-JUN-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 BIRTH CONTROL. APPROXIMATELY 1 WEEK AFTER INSERTION PATIENT STATED SHE HAD RASH, ITCHING, GENERAL MALAISE, ABDOMINAL DISCOMFORT, AND CRAMPS. WAS SEEN IN OFFICE AND PHYSICIAN RECOMMENDED SHE FOLLOW UP WITH AN ALLERGIST TO DETERMINE IF SHE HAD A NICKEL ALLERGY. ON (B)(6) 2015 PATIENT FOLLOWED UP WITH PHYSICIAN, SHE HAD NOT BEEN SEEN BY AN ALLERGIST. ABOVE SYMPTOMS CONTINUE AND SHE WAS DEMANDING THAT THE ESSURE DEVICES BE REMOVED. FOLLOW-UP RECEIVED ON 02-JUL-2015: PTC RESULT. (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON

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THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 10-AUG-2015 SHE WAS (B)(6) AT TIME OF EVENT. HER WEIGHT WAS (B)(6) AND HEIGHT WAS 167.5CM (BMI (B)(6)). SHE HAD A HISTORY OF C-SECTION ((B)(6) 2014) AND THROMBOCYTOPENIA. ESSURE 305 WAS INSERTED ON (B)(6) 2015 WITH LOT NUMBER B60749. IT WAS INSERTED IN A POSTPARTUM STATE (5 MONTHS). CERVICAL DILATION, SOUNDING AND GENERAL ANESTHESIA WERE DENIED. IBUPROFEN WAS USED AS ANALGESIA. INSERTION AND VISUALIZATION OF TUBAL OSTIUM WERE CONSIDERED EASY. FLUID LOSS WAS LESS THAN 1500CC AND PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. AFTER PROCEDURE, SHE USED LOLOESTRIN FE AS BACK UP CONTRACEPTION. ON (B)(6) 2015, HSG (HYSTEROSALPINGOGRAM TEST) WAS DONE. RIGHT WIRE WAS LOCATED 1MM FROM CORNUA; SLIGHTLY MORE CURVED (ATRIAL WIRE R) MAKING EXACT DISTAL MEASUREMENTS DIFFICULT BUT APPROXIMATELY 4.1 CM FROM CORNUA. LEFT WIRE WAS 5MM AWAY FROM LEFT CORNUA; DISTAL PORTION APPROXIMATELY 4.5CM FROM CORNUA. ON AN UNSPECIFIED DATE, NICKEL ALLERGY WAS DISCOVERED AFTER INSERTION AND HOSPITALIZATION WAS DENIED. ON (B)(6) 2015, ESSURE WAS REMOVED VIA LAPAROTOMY (IT WAS MEDICALLY NECESSARY AND PATIENT REQUESTED). PARTIAL SALPINGECTOMY WAS DONE. PRE-OPERATIVE DIAGNOSIS WAS PELVIC PAIN SECONDARY TO ESSURE DEVICES. NO RELATED DIAGNOSTIC TEST WAS PERFORMED AFTER SURGERY. ACCORDING TO THE PHYSICIAN, THE CONDITION WAS CAUSED BY ESSURE. FOLLOW-UP RECEIVED ON 18-AUG-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: B60749; PRODUCTION DATE: 12-AUG-2013; EXPIRATION DATE: 31-AUG-2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A PRODUCT ISSUE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL ALLERGY. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING AND RASH. IN THIS CASE, THE PATIENT EXPERIENCED RASH, ITCHING AND OTHER NON-SERIOUS EVENTS 1 WEEK AFTER INSERTION. ACCORDING TO HER PHYSICIAN, THIS EVENT LED HER TO ESSURE REMOVAL VIA LAPAROTOMY AND PARTIAL SALPINGECTOMY. CONSIDERING EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS INFORMED THAT ESSURE REMOVAL WAS REQUIRED (VIA LAPAROTOMY AND PARTIAL SALPINGECTOMY), THEREFORE THIS CASE WAS UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00685	BAYER HEALTHCARE LLC	8/31/2015	8/31/2015

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893008

Single Use: Y
Implant Date (E6): 1/4/2012
Explant Date (E7): 7/14/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 10-JUL-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (B)(6) 2012 FOR PERMANENT STERILIZATION; THE LOT NUMBER USED WAS 893008. SHE REPORTED THAT SHE DEVELOPED A RASH FROM HEAD TO TOE IN LATE (B)(6) OF 2012. SHE HAS ALSO EXPERIENCED LOWER BACK PAIN SINCE THAT TIME. SHE HAS HAD SEVERAL APPOINTMENTS WITH HER PHYSICIAN. FOR THE RASH, SHE HAS TRIED STEROID MEDICATIONS AND CREAMS, ANTIFUNGAL MEDICATIONS, ANTIBACTERIAL MEDICATIONS, ALLERGY MEDICATIONS, ZANTAC, AND LAMISIL. SHE HAS HAD SKIN TESTING DONE BY A DERMATOLOGIST AND HAS TRIED A GLUTEN FREE DIET FOR ONE-AND-ONE-HALF YEARS. SHE REPORTED BEING ABLE TO KEEP THE RASH CONTROLLED WITH MEDICATIONS, BUT IT RECURS AFTER STOPPING TREATMENT. SHE WAS SCHEDULED TO HAVE THE ESSURE REMOVED ON (B)(6) 2015. SHE ALSO STATED THAT SHE IS FRUSTRATED BECAUSE HER PHYSICIAN INITIALLY INFORMED HER THAT IT WAS NOT THE ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: BATCH NUMBER 893008. PRODUCTION DATE: 8/2011. EXPIRATION DATE: 8/2014. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT

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REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WAS RECEIVED ON 10-AUG-2015 FROM PHYSICIAN THAT REMOVED ESSURE (UPGRADED TO INCIDENT): THE PHYSICIAN CLARIFIED THAT HE NOTIFIED THE PATIENT OF REPORTED REACTION AS POSSIBLE REACTION AS 0,01% AND THAT IF SYMPTOMS DID NOT IMPROVE AFTER REMOVAL OF ESSURE SHE SHOULD SEEK ADDITIONAL DIAGNOSTIC MEASURES. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. CONCOMITANT CONDITION INCLUDED OBESITY. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES. ON (B)(6) 2012 ESSURE LOT NUMBER 893008 WAS EASILY IMPLANTED. SHE WAS NOT ON POST-PARTUM STATE. ANALGESIA (LIDOCAINE 1% PARACERVICAL) WAS APPLIED DURING INSERTION. CERVICAL DILATATION AND SOUNDING WERE DENIED. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY, FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE TOOK 9MIN. SCOPE IN-TO-OUT TOOK 6 MIN. PAIN WAS REPORTED AS 01 ON 00 TO 10 SCALE. SHE DID NOT USE BACK-UP CONTRACEPTION. THE PATIENT DID NOT GET HSG IN SPITE OF MULTIPLE COMMUNICATIONS. DELAY FROM PLACEMENT TO HSG. PATIENT WAS NON-COMPLIANT. SKIN PROBLEMS WERE NOTED ON REVIEW OF SYSTEMS IN 2012. ON (B)(6) 2015 HSG WAS PERFORMED AND SHOWED THAT TUBES WERE BLOCKED AND THE COILS WERE IN CORRECT PLACEMENT. NORMAL TUBES, WITH NO SIGN OF INFECTION OR INFLAMMATION WERE REPORTED. ON 14-JUL-2015 ESSURE WAS REMOVED VIA LAPAROSCOPY; BILATERAL SALPINGECTOMY PERFORMED DUE TO PATIENT REQUEST. IT WAS NOT KNOWN IF MEDICALLY NECESSARY. THE TUBES WERE NORMAL, WITH NORMAL PATHOLOGY AND NORMAL FINDINGS, WITH NO EVIDENCE OF ANY ISSUE. AT THE TIME OF THIS REPORT, SIGNIFICANT SKIN RASH WAS REPORTED. SKIN TESTING WAS PERFORMED AND SHOWED POSITIVE FOR MANY ALLERGIES BUT THIS PHYSICIAN DID NOT HAVE THE RECORDS. THIS PHYSICIAN DID NOT TREAT HER FOR ANY RASH. AFTER REMOVAL, THE PHYSICIAN CONSIDERED RASH MIGHT BE IMPROVING. THE PHYSICIAN DID NOT KNOW IF THE IF THE ESSURE DEVICES CAUSED OR CONTRIBUTED TO THE CONDITION. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP 18-AUG-2015: PTC INVESTIGATION RESULTS WERE UPDATED AND PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: BATCH NUMBER 893008. PRODUCTION DATE: 8/2011. EXPIRATION DATE: 8/2014. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A TREATMENT NONCOMPLIANCE . THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED A RASH

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FROM HEAD TO TOE APPROXIMATELY ONE MONTH LATER. TO TREAT THIS RASH, THE PATIENT TRIED STEROID MEDICATIONS AND CREAMS, ANTIFUNGAL MEDICATIONS, ANTIBACTERIAL MEDICATIONS, ALLERGY MEDICATIONS, ZANTAC, AND LAMISIL. SHE HAS HAD SKIN TESTING DONE BY A DERMATOLOGIST AND HAS TRIED A GLUTEN FREE DIET FOR ONE-AND-ONE-HALF YEARS. SHE WAS ABLE TO KEEP THE RASH CONTROLLED WITH MEDICATIONS, BUT IT RECURRED AFTER STOPPING TREATMENT. THREE YEARS AND A HALF, AFTER INSERTION, THE PATIENT REQUESTED REMOVAL AND A BILATERAL SALPINGECTOMY VIA LAPAROSCOPY WAS PERFORMED. THE OUTCOME IS UNKNOWN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO REQUIRED SURGICAL INTERVENTION AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE, ESPECIALLY THOSE WITH A HISTORY OF METAL ALLERGIES. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED. TYPICAL ALLERGY SYMPTOMS REPORTED FOR ESSURE INCLUDE RASH, PRURITUS, AND HIVES. IN THE PRESENT CASE, THE PATIENT DEVELOPED THE RASH APPROXIMATELY A MONTH AFTER ESSURE INSERTION. SKIN TESTING WAS PERFORMED AND SHOWED POSITIVE FOR MANY ALLERGIES, BUT IT WAS NOT REPORTED IF SHE WAS ALLERGIC TO NICKEL. ALTHOUGH, THIS INFORMATION IS MISSING, CONSIDERING THAT SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED AND CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UPON FOLLOW UP INFORMATION, THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ADDITIONAL NON-SERIOUS EVENT WAS REPORTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED FRO CONSUMER ON 31-DEC-2015: CONSUMER STATED THAT SINCE HER SURGERY ALL OF HER CONDITIONS HAVE GONE AWAY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ES

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055837	BAYER	8/31/2015	8/31/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2015 X-RAY SHOWING ADDITIONAL COILS THAT FAILED TO DEPLOY DURING IMPLANTATION LEFT BEHIND. THEY ARE MANGKED TOGETHER, AND ONE APPEARS TO BE BROKEN. MEDICAL RECORDS STATE THAT THE COILS WERE REMOVED AND SENT BACK TO MANUFACTURER, WHICH IS ABSOLUTELY FALSE. CURRENTLY AWAITING APPROVAL FOR HYSTERECTOMY AT AGE (B)(6)

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055838	BAYER	8/31/2015	8/31/2015

Event Information:

Event Date (B3): 4/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST TIME HAVING HIVES COVERING MY ENTIRE BODY...HAVE HAD SEVERAL OUTBREAKS OVER THE YEARS BUT THIS WEEK OF (B)(6) 2015 HAS BEEN HORRIBLE. NOT ONLY DO I KEEP GETTING HIVES I'M HAVING NUMBNESS IN MY HANDS AND FEET. I WAKE UP TO HANDS THAT ARE TINGLING AND SWOLLEN TO NO FEELING AT ALL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055839	BAYER	8/31/2015	8/31/2015

Event Information:

Event Date (B3): 8/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YES MY DEVICES WAS PROVIDED BY MY INSURER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055840	BAYER	8/31/2015	8/31/2015

Event Information:

Event Date (B3): 8/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY HEAVY MENSTRUAL CYCLES, UNEXPLAINED PAIN, WEIGHT GAIN, THYROID ISSUES, VITAMIN D DEFICIENCY, IRREGULAR MENSTRUAL CYCLES, DEPRESSION, GALLBLADDER SURGERY, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055841	BAYER	8/31/2015	8/31/2015

Event Information:

Event Date (B3): 4/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SHARP/STABBING PELVIC PAIN, ABNORMAL MENSES, BACTERIAL VAGINOSIS, ENDOMETRIOSIS, UTERINE FIBROIDS, UTERINE INFLAMMATION, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), PAINFUL OVULATION (MITTELSCHMERZ), NIGHT SWEATS, LOSS OF LIBIDO, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS (DYSMENORRHEA), PAINFUL INTERCOURSE (DYSPAREUNIA), BLEEDING BETWEEN PERIODS (METRORRHAGIA), CANDIDA, UTI (URINARY TRACT INFECTION), BLADDER INFECTION, CERVICITIS/VAGINITIS, ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, BOWEL ISSUES, FOOD ALLERGIES, HIVES, RASHES, SKIN IRRITATION/ITCHING, HEADACHES OR MIGRAINES, DIZZINESS, BRAIN FOG -; CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, DENTAL ISSUES, INSOMNIA, EXCESSIVE SWEATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055907	CONCEPTUS	8/31/2015	9/3/2015

Event Information:

Event Date (B3): 10/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/28/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

DRS PROCEDURE, I HAVE BEEN SICK EVER SINCE THIS PROCEDURE TOOK PLACE, PAIN, BLEEDING, METAL TASTE IN MY MOUTH, DIZZY SPELLS ECT... FELL FORM DIZZY SPELL IN 2012. DIAGNOSIS: PREVENT PREGNANCY. MED - RECORDS, (B)(6) - DR (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055921	BAYER HEALTH	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 9/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/3/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE PROCEDURE AFTER MY SECOND CHILD. EVER SINCE I'VE HAD THE IMPLANTS I GET EXTREMELY BAD CRAMPS DURING MY PERIOD AND I HAVE LOTS OF PELVIC AND BACK PAIN ALL THE TIME WHEN NOT ON MY MENSTRUAL CYCLE. MY PERIODS ARE VERY "CLOTTY" AND MORE PAINFUL THAN THEY USED TO BE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055922	BEYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/31/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A20061

Single Use: *
Implant Date (E6): 12/7/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) OF 2012. THE DOCTOR TOLD ME HE WAS UNABLE TO GET THE SECOND COIL AROUND ALL THE WAY BUT THAT IT WOULD NOT BE AN ISSUE. SINCE THE ESSURE WAS IMPLANTED I HAVE EXPERIENCED MANY SIDE EFFECTS. I HAVE HAD EXCESSIVE ABDOMINAL SWELLING, RASHES AROUND MY PELVIS AREA AND LOWER BACK, MASS AMOUNTS OF HAIR LOSS, THE CONSTANT TASTE OF METAL, BODY ACHES, PERIODS MORE THAN ONCE A MONTH, HEAVY BLOOD FLOW DURING MY CYCLES, BLOOD CLOTS RELEASED DURING MY CYCLE THAT ARE THE SIZE OF HALF DOLLARS AND SWELLING IN MY ARMS THAT HAS CAUSED TRIPS TO THE HOSPITAL AND PAINFUL CYSTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055923	BAYER HEALTH	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 9/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTS
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/30/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6) 2009, I BLED CONSTANTLY FOR 8 MONTHS FOLLOWING THE PROCEDURE. THE DOCTORS TOLD ME THAT EVERY PATIENT WAS DIFFERENT AND GIVE IT TIME. SO AFTER ABOUT A YEAR I WENT TO AN OB DOCTOR AND EXPRESSED MY UNCOMFORTABLE FEELING IN MY LOWER STOMACH AND THE PAIN (WHICH FELT LIKE I WAS IN LABOR) WOULD HIT ME A COUPLE TIMES A WEEK. ONCE AGAIN, I WAS "JUST RECOVERING" AS THEY TOLD ME EVEN THOUGH MY PERIODS WERE SO HEAVY THAT I WAS WEARING DOUBLE THE PROTECTION A NORMAL WOMAN WOULD. I MOVED BACK INTO THE TOWN WHERE I HAD THE PROCEDURE DONE AND GOT A DIFFERENT OB. I EXPLAINED THAT FOR THE LAST 5 AND NOW ALMOST 6 YEARS MY CONCERN AND PAINFUL CONTRACTION-LIKE FEELINGS. HE PRESUMED TO TELL ME THAT THEIR OFFICE DIDN'T EVEN DO THE ESSURE BECAUSE THEY RESEARCHED ALL THE SIDE EFFECTS AND WOULD BE TOO MANY EXTRA APPOINTMENTS AND DIDN'T FEEL IT WAS SAFE SO THEY NEVER EVEN OFFERED IT. HE FINALLY GOT ME IN HIS OFFICE AND EXPLAINED THAT HE WAS PUTTING ME ON A BIRTH CONTROL TO HELP MY PERIODS AND HOPEFULLY I WOULD FEEL BETTER. NOW IT'S BEEN 6 MONTHS AND NOT LIFTING ANYTHING OVER 25 LBS HAS MADE SUCH A DIFFERENCE IN MY LIFE. FINALLY, AFTER 6 YEARS OF TORMENT, PAIN AND SEVERAL DOCTORS, I FINALLY GOT ONE TO HELP ME. I WAS TOLD IF THEY TRY TO REMOVE MY ESSURE IMPLANTS THAT IT WOULD CAUSE MORE HARM THAN GOOD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055924	BAYER HEALTH	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED AND HAVE HAD MASSIVE PERIODS SINCE THE IMPLANT AND ALSO HAVE REALLY BAD PAINS IN THE AREA THE IMPLANT IS AT. I HAVE TWO TO THREE PERIODS A MONTH NOW. I HAVE LOWER BACK PAIN CAUSED AS WHILE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055925	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 6/6/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANTS
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/6/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE MISPLACED, HAVE BEEN HURTING FROM PELVIC AREA. SWOLLEN LEGS. WEIGHT GAIN. HEADACHES. RASH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055926	BAYER HEALTH	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 11/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/12/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

BE DEVELOPING CYSTS. EXTREME MPS AND SEVERE CENTRAL PAIN SINCE IMPLANTATION. TWO YEARS AGO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055927	BAYER HEALTH	8/31/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN EARLY 2011 I ATTEMPTED TO HAVE THE ESSURE PROCEDURE, BUT THE DOCTOR WAS ONLY ABLE TO PUT THE COIL INTO MY LEFT TUBE, MY RIGHT TUBE WAS COVERED WITH SCAR TISSUE, SO I ENDED UP HAVING TO HAVE MY TUBES TIED ANYWAY, SO ON MY LEFT SIDE I HAVE BOTH THE ESSURE AND A CLAMP FROM THE TUBAL PROCEDURE. EVER SINCE I HAVE HAD PAIN DURING INTERCOURSE AND WHEN IT IS MY TIME OF THE MONTH I HAVE NUMBING IN MY LEFT LEG AND STABBING PAINS IN MY LEFT LOWER BACK. I HAVE BEEN TO THE DOCTOR SEVERAL TIMES ABOUT IT, AND THEY WANT TO DO A PARTIAL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055928	BAYER HEALTH	8/31/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED AND AT THE FOLLOW UP IT WAS FOUND THAT ONE WAS NOT IN MY TUBE AND THE OTHER HAD NOT WORKED. FOUND THAT I HAD ONE EMBEDDED IN MY UTERUS, THEREFORE A SURGERY TO REMOVE IT. HAD A 3RD SURGERY TO FIX TUBE THAT ESSURE DID NOT STAY IN. HAD HEAVY BLEEDING AND PAIN FOR MONTHS, AND HAD A 4TH SURGERY TO LOOK AND FOUND THAT THE ESSURE THAT WAS STILL IN MY OTHER TUBE HAD PERFORATED THROUGH MY TUBE, THEREFORE IT HAD TO BE REMOVED AS WELL. THE WHOLE TUBE HAD TO BE REMOVED. NOW TO THIS DAY I HAVE A LOT OF ABDOMINAL PAIN AND PROBLEMS FROM THESE IMPLANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055929	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS FOR PERMANENT STERILIZATION PROCEDURE DONE IN (B)(6) 2010. I HAVE HAD VERY PAINFUL INTERCOURSE SINCE THEN, PLUS MUCH HEAVIER PERIODS. NEITHER OF THESE SYMPTOMS WERE PRESENT BEFORE THE PROCEDURE. I ALSO HAD ANOTHER PREGNANCY RESULTING IN A (B)(6) BABY BOY BORN IN (B)(6) 2012.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055933	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED AFTER HAVING MY THIRD CHILD. DURING THE PROCESS OF GETTING IT IMPLANTED I EXPERIENCED LOT OF PAIN AND AFTER IT JUST KEPT GETTING WORSE. MY PERIODS WERE EXTREMELY HEAVY, I HAVE PAIN DURING INTERCOURSE, I EXPERIENCE SHARP STABBING PAINS THAT I'VE NEVER HAD BEFORE. I AM SCARED THAT I MADE A POOR CHOICE IN CHOOSING THE ESSURE, AND I AM ALSO WORRIED THAT I HAVE CAUSED PERMANENT DAMAGE TO MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055934	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/1/2008
Explant Date (E7): 8/31/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ONCE ESSURE WAS PLACED I WAS "FIT FOR DUTY" PRIOR TO THE PLACEMENT. I WAS IN THE (B)(6) AND HAD NO DOCUMENTED HEALTH PROBLEMS. AFTER HAVING ESSURE PLACED I HAVE, FIBROMYALGIA, ARTHRITIS, ASTHMA, VITILIGO, OBESITY, DEPRESSION, MIGRAINES, CHRONIC FATIGUE, INSOMNIA, PELVIC PAIN, BLADDER SPASMS, BACK SPASMS AND FULL HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055935	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HEART PALPITATIONS, ANEMIA, HEAVY BLEEDING, BECAME PREGNANT, AND HAD MY TUBAL LIGATION AGAIN IN 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055936	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER GETTING THE ESSURE DEVICE I HAD VERY SEVERE PELVIC AND VAGINAL PAIN. THIS STARTED 5 YEARS AND IS STILL AN ON GOING PROBLEM. IT HAS RUINED MY LIFE. MAKING LOVE WITH MY HUSBAND WAS EXTREMELY PAINFUL UNTIL IT BECAME UNBEARABLE WHICH HAD A GREAT AFFECT PSYCHOLOGY. I'VE BEEN THROUGH 3 GYNECOLOGISTS, PELVIC FLOOR PHYSICAL THERAPY, ULTRASOUND AND ALL KINDS OF PROBING. NOTHING RELIVED THE PAIN NOT EVEN HAVING SCAR TISSUE REMOVED. NO DOCTOR COULD GIVE ME AN ANSWER, BECAME A MYSTERY TO THEM AS WELL BECAUSE HOW LENGTHY AND SEVERE THE PAIN HAD BECOME AND DUE TO THE FACT NO MEDICAL PROCEDURE HAD BROUGHT ANY RELIEF. I AM NOW IN PROCESS OF REVIEWING MEDICAL HISTORY PERTAINING TO THE MATTER AT HAND. CURRENTLY CONSIDERING HAVING THEM REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055937	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 5/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/2/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ABOUT 2 MONTHS AFTER MY SON WAS BORN I GOT THE PROCEDURE WHERE THESE COIL LOOKING THONGS WENT IN MY TUBES. I CHOSE THIS METHOD BECAUSE IT WAS EASY AND FAST. MY FIRST PERIOD WAS REALLY HEAVY. LIKE REALLY REALLY HEAVY. I WOKE UP WITH MY BED SOAKED WITH BLOOD. ABOUT 2 MONTHS AFTER THAT I STARTED TO HAVE BACK PAIN. IT WOULD COME THE WEEK OF STARTING MY PERIOD. I COULDN'T ENJOY MY BABY. I WAS IN PAIN. I STARTED GETTING HEADACHES ALSO. I FELT LIKE A PULLING IN MY STOMACH AREA. THE WEEK OF MY PERIOD IS HORRIBLE. I TAKE PAIN PILLS MY DOC GAVE ME BUT OVER TIME I NEED STRONGER RELIEVER. BUT MY INSURANCE DOESN'T COVER IT. I NOW WISH I NEVER HAD THE PROCEDURE. I RATHER BE PREGNANT AGAIN THAN DEAL WITH THIS MONTHLY MESS. ABOUT 6 MONTHS AFTER PROCEDURE I SEEN MY DOCTOR. HE REFERRED ME TO OBGYN THAT DID THE PROCEDURE. MY DOCTOR SAID WITH ALL THE HEAVY BLEEDING I MIGHT NEED HARMONY PILLS. I WAS NOT COMFORTABLE TAKING THOSE SO I JUST DECIDED NOT TO SEE SPECIALIST. I JUST FIGURED IT WAS ALL PART OF THE HEALING PROCESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055939	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/30/2014
Explant Date (E7): 8/25/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED (B)(6) OF 2014 SINCE THEN I HAD ONGOING PAIN IN LEGS, FEET, PELVIC, AND INTERCOURSE PAIN. MY PERIODS BECAME 10 X WORSE CRAMPING, SEVERE FLOW TO A POINT OF ANEMIA. I ALSO ON MY LEFT TUBE IT CAME TO LIGHT THAT MY COIL HAS BROKEN IN HALF. IN AND OUT OF THE HOSPITAL AND DOCTORS OFFICE WITH INFECTIONS AND NOW I HAVE PID. MY LAST INFECTION IN MY ABDOMEN AND PELVIS WAS SO SEVERE I ALMOST DIED. I WAS SCHEDULED FOR URGENT HYSTERECTOMY TO REMOVE MY UTERUS AND TUBE TO GET THE DEVICE OUT OF ME. I AM NOW LAID UP AT HOME. OFF WORK TILL I HEAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055940	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/18/2009 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

WELL I HAD THE ESSURE IMPLANT BUT IT DIDN'T WORK AT ALL REAL BAD CRAMPS AND BACK ACHES. I HAD OTHER KIDS AFTER THE ESSURE WAS IMPLANTED. MY PERIODS WOULD BE VERY BAD, HEAVY, THE WORST CRAMPS EVER. I WENT FOR THE FOLLOW UP AS I WAS TOLD THAT MY TUBES WAS NOT CLOSE. THAT IT MAY HAVE SPIT THE COIL OUT. LIKE REALLY COME ON. NO SCAR TISSUE WHATSOEVER. SO MY INSURANCE RAN OUT AND THREE KIDS LATER...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055941	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/19/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN MY TUBES 19 DAYS AGO. I AM HAVING THEM REMOVED IN 2 DAYS. THE FIRST DAY OR TWO I EXPECTED TO BE SORE AND SOME MILD CRAMPING, BUT TO MY SURPRISE, I WAS IN MAJOR DEBILITATING PAIN AND ON TOP OF THE BLOATED AT LEAST 3 DRESS SIZES LARGER THAN I AM. I WAS SO HAPPY THAT I HAD JUST HAD A BABY IN (B)(6) AND LOST A LOT OF WEIGHT, BUT MUCH TO MY SURPRISE THAT WAS NOT THE WORST. I HAVE BLED EVER SINCE THE PROCEDURE AND I AM ON THE DEPO SHOT AND HAVEN'T EVER BLED WITH THE DEPO SHOT AND WAS NOT BLEEDING PRIOR TO THIS INCIDENT. I ALSO CANNOT DO ANYTHING. CANNOT PLAY TENNIS, RIDE MY BIKE, PICK UP MY LITTLE BABY, SIT COMFORTABLY FOR WORK, RUN, WORKOUT, SIT UPS. I CAN'T EVEN SHOWER BECAUSE THE WATER HURTS MY STOMACH TO HIT IT. IT IS PAINFUL TO EVEN TOUCH MY STOMACH SOFTLY. MY QUALITY OF LIFE IS NOT UP TO PAR SINCE I HATE PAIN KILLERS, BUT HAVE TO TAKE THEM BECAUSE IT LITERALLY FEELS LIKE GLASS OR RAZOR BLADES CUTTING INTO MY WHOLE ABDOMINAL REGION. IF I TRY TO TURN OR TO REACH FOR SOMETHING, NOT HAPPENING. MY MIND SAYS I CAN AND MY BODY WILL JERK AWAY FROM THE PAIN IN A SPASM TYPE WAY. THIS REALLY SUCKS AS I LIKED MY LIFE PERFECTLY BEFORE THIS AND IT WAS MADE TO SOUND BY READING THE PAMPHLET AND BOOK ON THIS PRODUCT THAT IT WOULD BE A GREAT CHOICE TO MAKE, BUT I REALLY GOT THIS DONE TO NOT HAVE CHILDREN. CAN'T GET PREGNANT ANYWAY IF YOU CAN'T HAVE SEX RIGHT? I HAVE A GREAT RELATIONSHIP WITH MY HUSBAND AND WE LIKE TO BE ABLE TO PLAY AROUND ANYTIME THAT WE FEEL LIKE IT, BUT SERIOUSLY THIS DEVICE HAS CAUSED ME SO MUCH PAIN, MY FAMILY SO MUCH PAIN AND IT NEEDS TO BE COMPLETELY REMOVED FROM SOCIETY. THE COMPANY SHOULD BE SUED. I COULD GO ON AND ON, BUT MY HIGH DOSES OF PAIN MEDS IS CAUSING ME TO BARELY BE ABLE TO THINK CORRECTLY. PLEASE LOOK FURTHER INTO THIS DEVICE. HAD I LOOKED AT ANY OF THE FORUMS THAT I HAVE NOW READ, I WOULD HAVE NOT HAD THE

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PROCEDURE DONE. I AM NOW HAVING MY TUBES CUT OUT IN 2 DAYS, BUT I WOULD HAVE TOTALLY HAD MY HUSBAND HAVE A VASECTOMY HAD I NOT THOUGHT THAT THIS WAS A BETTER ROUTE TO TAKE. ESSURE IS A HORRIBLE PRODUCT AND I THINK THAT IT IS DEADLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055943	UNK	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 7/16/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: *
Implant Date (E6): 7/16/2008
Explant Date (E7): 1/21/2011
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY DOCTOR TOLD ME ABOUT THE ESSURE PROCEDURE IN 2008. HAD NOTHING BUT COMPLICATION FOR 3 YEARS. STOMACH PAIN CONSISTENT DAILY. EVERY DAY GOING BACK AND FORTH TO THE DOCTOR. TAKING PRESCRIPTION PAIN MEDICINE TO HELP WITH THE PAIN. DID NOT WORK. FINALLY SHE SAID THE ONLY WAY SHE CAN GET THE METAL ROD OUT OF ME WAS TO HAVE A HYSTERECTOMY. SO IN 2011, I HAD A PARTIAL HYSTERECTOMY DONE. AFTER HAVING THE HYSTERECTOMY I HAD A COMPLICATION IN EXTENDING THE HOSPITAL STAY FOR 9 TO 10 DAYS DUE TO HAVING INFECTION THAT WENT INTO MY BLOOD STEM I HAD TO "HAHA" WITH A PIXIE LINE IN MY ARM AND GIVE MYSELF A DAILY ANTIBIOTICS FOR 2 WEEKS. IT WAS THE WORST THING THAT I COULD HAVE EVER BEEN THROUGH. CAN'T RECALL BUT I THINK I GOT THE ESSURE DONE IN (B)(6) 2008 IN THE HYSTERECTOMY OF (B)(6) 2011.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055944	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7): 10/8/2012
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICES PUT IN AND AFTERWARDS HAD LOT OF SEVERE PAIN AND HEAVY BLEEDING DURING MY MONTHLY PERIODS. MY PERIODS WENT FROM 4 DAYS OF LIGHT BLEEDING BEFORE THE ESSURE TO 2 WEEKS OF HEAVY BLEEDING WITH CLOTS THE SIZE OF GOLF BALLS, LITERALLY. I HAD ABDOMINAL SWELLING AND ASCITES AND BLOATING. I HAD TROUBLE CARING FOR MY CHILDREN AND MYSELF. EVENTUALLY I HAD THEM REMOVED BUT THEY HAD MIGRATED INTO MY UTERUS PARTIALLY AND I HAD TO HAVE A HYSTERECTOMY AND REMOVAL OF MY FALLOPIAN TUBES. IT WAS VERY TRAUMATIC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055945		8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD TO HAVE A HYSTERECTOMY DONE 5 DAYS AGO BECAUSE MY ESSURE COILS MOVED, MAKING ME HAVE SEVERE PAIN AND BLEED. SHREADS OF NICKEL AND PET FIBERS WERE FOUND IN MY UTERUS. I AM NOW OFF WORK FOR 2 MONTHS AND SUFFERING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055946		8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7): 8/24/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN (B)(6) OF 2014. I BLEED FOR MONTHS STRAIGHT RIGHT AFTER IMPLANT. BACK PAIN STARTED IMMEDIATELY AFTER IMPLANT WAS PUT IN. I COULDN'T HAVE SEX WITH MY HUSBAND BECAUSE EVERY TIME WE TRIED I BLED EVERYWHERE. I THEN HAD TO HAVE A HYSTERECTOMY ON (B)(6) 2015 AFTER I COULDN'T DEAL WITH THE PAIN ANYMORE AND I HAD A GIANT CYST ON MY RIGHT OVARY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055947	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 1/7/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/7/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE DEVICE IN 2008 AND EVER SINCE THEN I HAVE BEEN BACK AND FORTH TO THE DOCTOR JUST ABOUT EVERY MONTH FOR VAGINAL INFECTIONS (BACTERIA). I GET INFECTION SO BAD THAT I CAN'T AFFORD TO GO EVERY MONTH ANYMORE. BEFORE THE DEVICE I DIDN'T HAVE ANY ISSUES WITH MY BODY. I HAVE HAD A DOCTOR TO TELL ME THAT ISSUE IS THE DEVICE AND I JUST WANT HELP GETTING THE DEVICE REVERSED OUT OF MY BODY. EACH TIME I WENT TO THE DOCTOR I WAS TESTED ABNORMAL FOR VAGINAL INFECTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055948	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 5/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/30/2014
Explant Date (E7): 6/18/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS PERSUADED BY MY DOCTOR TO HAVE THE ESSURE PRODUCT AND PROCEDURE ALONG WITH AN IUD, THE MIRANA, PLACEMENT RATHER THAN A PARTIAL HYSTERECTOMY. THIS LEAD TO HAVING SEVERE CRAMPING, BLEEDING, AND THE IUD FLOATING UP FURTHER INTO MY UTERUS. THE IUD WAS LODGED AND ATTACHED TOO FAR UP IN MY UTERUS TO BE REMOVED. THE BLEEDING WAS SO SEVERE I HAD TO GO TO THE HOSPITAL DUE TO BLEEDING ALL OVER MY CLOTHS AND CHAIR AT WORK. I HAD SEVERAL APPOINTMENTS REGARDING THIS WHERE I MISSED ADD'L WORK. THEN I HAD TO HAVE THE HYSTERECTOMY WHERE MY UTERUS, OVARIES, AND TUBES WERE REMOVED. I WAS OUT OF WORK FOR 3 WEEKS AFTER THIS PROCEDURE. I WAS ALSO HOSPITALIZED AGAIN WITHIN THOSE THREE WEEKS DUE TO A REACTION TO AN ANTIBIOTIC WHICH IS NOW SOMETHING I HAVE TO CLOSELY MANAGE (C-DIFF) AS IT COULD CAUSE REOCCURRING ISSUES ANYTIME AN ANTIBIOTIC IS TAKEN. THIS STARTED IN (B)(6) OF 2014 WHEN THEY COMPLETED THE ESSURE PROCEDURE AND THE PLACEMENT OF THE IUD. THE CRAMPING BEGAN AROUND (B)(6) 2014 AND (B)(6) 2015 WAS WHEN THE HEAVY BLEEDING BEGAN. I WAS HOSPITALIZED FOR THE HYSTERECTOMY ON (B)(6) 2015 AND AGAIN ON (B)(6) 2015 DUE TO UNCONTROLLABLE VOMITING AND SEVERE STOMACH PAINS FROM THE C-DIFF WHICH WAS FROM AN ANTIBIOTIC GIVEN TO ME AT THE TIME OF THE RECENT SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055950		8/31/2015	9/4/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/1/2008
Explant Date (E7): 7/22/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I STARTED HAVING HEAVY MENSTRUAL BLEEDING, PAIN ON LOWER RIGHT SIDE, NAUSEA AND FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055952	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN (B)(6) 2013, AND HAVE HAD NOTHING BUT PROBLEMS. BUT DOCTORS KEEPS BRUSHING IT OFF. I KNOW IT IS ESSURE. I HAVE MASSIVE WEIGHT GAIN/AND LOSS. SERIOUSLY I CAN WAKE UP ONE DAY AND BE (B)(6) THE NEXT BE AS LOW AS (B)(6). IT'S CRAZY, I HAVE STABBING PAINS IN BOTH MY SIDES. AND OCCASIONAL HIP PAIN. MY PERIODS LAST FROM 1 DAY TO 3 WEEKS. JUST HOWEVER MY BODY IS FEELING THAT MONTH. AND WHEN I HAVE MY PERIODS I AM DYING. NO ONE SHOULD LOSE THAT MUCH AND STILL BREATHE. MY SEX LIFE HAS DWINDLED DRASTICALLY. ALL ESSURE HAS BEEN IS HELL AND I JUST WANT MY LIFE BACK. ALONG WITH SYMPTOMS IS BACK PAIN, IT'S EVERYDAY MIGHT I ADD IT'S SAD I'VE COME TO SOMEWHAT TOLERATE IT. IT NEEDS TO BE REMOVED SO NO OTHERS CAN SUFFER AS ALL OF US SISTERS HAVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055953	BAYER	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 10/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/5/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2010, I HAD THE ESSURE PROCEDURE DONE AND EVER SINCE I'VE HAD SEVERE SIDE AFFECTS WHICH INCLUDE: INTENSE CRAMPING, EXTREME WEIGHT GAIN, HEAVY BLEEDING, ANXIETY, DEPRESSION, HAIR LOSS AND INTENSE BACKACHES AND HEADACHES. IT HAS BEEN A HORRIFIC EXPERIENCE FOR THE SAFETY AND WELL BEING OF OTHER WOMEN THIS PRODUCT SHOULD BE TAKEN OFF THE MARKET AS SOON AS POSSIBLE. THIS HAS BASICALLY RUINED MY LIFE. DUE TO THE HEAVY BLEEDING I'VE EXPERIENCED I BECAME A CHRONIC ANEMIC AND HAD TO GET TWO BLOOD TRANSFUSIONS AND NOW NEED A HYSTERECTOMY. THIS PRODUCT IS HORRIBLE. CHRONIC ANEMIA DUE TO HEAVY BLEEDING BECAUSE OF THE ESSURE IMPLANTS. CURRENTLY TAKING NAPROXEN FOR CRAMPING AND BACKACHE. ALSO TAKING VERY HIGH DOSES OF IRON FOR ANEMIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055954		8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/10/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER MY 12 WEEK HYSTEROSALPINGOGRAM, I FOUND OUT THAT ONE OF THE ESSURE COILS HAD PERFORATED MY FALLOPIAN TUBE AND THAT I WOULD HAVE TO HAVE THE PROCEDURE DONE A SECOND TIME. I HAD IT DONE IN THE OFFICE AND HAVE SINCE HAD TO HAVE A HYSTERECTOMY. I AM UNSURE OF THE EXACT DATE OF MY FIRST PROCEDURE. I HAD A ESSURE PROCEDURE DONE IN (B)(6) 2007 AND ANOTHER PROCEDURE DONE LATER IN THE YEAR. MY HYSTERECTOMY WAS (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055955		8/31/2015	9/4/2015

Event Information:

Event Date (B3): 8/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE PLACED ABOUT 9 YEARS AGO, OVER THE YEARS I HAVE EXPERIENCED STOMACH ULCERS, HEAVIER MENSTRUATION, BAD CRAMPS, HEADACHES, PAIN DURING SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055956		8/31/2015	9/4/2015

Event Information:

Event Date (B3): 3/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/11/2009
Explant Date (E7): 3/12/2009
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE SMALL METAL TUBES IN MY FALLOPIAN TUBES. MY PHYSICIAN INFORMED ME THAT I WOULD HAVE NO PROBLEM WITH THEM. SHE TALKED ABOUT ALL THE WONDERFUL RESULTS OF THIS PRODUCT INCLUDING THE FACT THAT I WOULD NOT HAVE TO GO UNDER THE KNIFE LIKE WITH TUBAL LIGATION. WELL, IMMEDIATELY AFTER THE ESSURE WERE PLACED IN MY BODY, I HAD REACTIONS. I FELT TERRIBLE AND STARTED TO FEEL PAINS ALL OVER. I CONTACTED THE DOCTOR WHO TOLD ME THAT I HAD THE FLU. I TOLD HER THAT SOMETHING WAS VERY WRONG IN MY BODY. I AM ALLERGIC TO NICKEL WHICH IS WHAT THE PROBLEM WAS. I HAD TO GET A HYSTERECTOMY IN ORDER TO GET THE SMALL METAL COILS OUT. I WAS LEFT WITH ONLY A RIGHT OVARY. I HAD EXPERIENCED BLUE CELL NECROSIS. IN ORDER WORDS AS I UNDERSTAND IT, THE CELLS AROUND THE COILS WERE DEAD DUE TO THE NICKEL BEING ON THEM. THIS EXPERIENCE WAS VERY TRAUMATIC FOR ME. MY DOCTOR WENT ON VACATION RIGHT AFTER MY SURGERY AND HAS NOT SPOKEN TO ME ABOUT IT. I BELIEVE THAT SHE WAS NOT EXPERIENCED ENOUGH WITH PTS WHO HAD REACTIONS TO THIS PRODUCT. I FEEL LIKE I WAS BUTCHERED. IF SHE GOT MONEY AS I SUSPECT MANY OF THE PHYSICIANS DID TO PUSH THIS PRODUCT, IT SHOULD BE A CRIME BECAUSE I SIMPLY DO NOT UNDERSTAND HOW NO ONE CAUGHT THIS PROBLEM. THE DOCTOR ALSO RAN ANTIBIOTICS THROUGH MY ENTIRE BODY BECAUSE SHE WANTED TO BE SURE THAT ALL THE INFECTION WAS GONE. IT WAS A VERY TERRIBLE EXPERIENCE. THEY CLAIMED THAT I HAD ENDOMETRIOSIS WHICH WAS TOTALLY NOT TRUE. I NEVER HAD ANY PROBLEMS WITH MY FEMALE ORGANS AT ALL. I SIMPLY WANTED A BIRTH CONTROL METHOD THAT DID NOT REQUIRE SURGERY. I TRUSTED MY DOCTOR WHO SOLD ME A BAG OF BAD GOODS.

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Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055957	CONCEPTUS	8/31/2015	9/4/2015

Event Information:

Event Date (B3): 3/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESSURE
Lot #(E4): B09707

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WENT TO THE OFFICE TO HAVE THE ESSURE PLACED IN MY TUBES. THEY HAD COMPLICATIONS DUE TO THE ON ESSURE APPLICATOR OPENED UP WHILE IN MY TUBE BUT WOULD NOT RELEASE THE SPRING CAUSING EXTREME PAIN. THE DOCTOR HAD TO PULL THE SPRINGS THAT HAD OPENED UP OUT WHICH CAUSED A LOT OF PAIN BLEEDING AND COLLAPSED MY TUBE. I HAD TO WAIT A COUPLE WEEKS FOR IT TO HEAL AND GO BACK AND HAVE IT DOWN IN THE OPERATING ROOM. I HAD TO BE PUT TO SLEEP AND STILL WAS UNABLE TO HAVE THE ESSURE PLACED INTO THE TUBE THAT WAS DAMAGED. I HAD TO GET MY TUBES CUT AND TIED DUE TO THE MALFUNCTION OF THE IMPLANT. THIS CAUSED MORE TIME OFF FROM WORK DOUBLE BILLS AND A LOT OF PAIN AND EXCESSIVE BLEEDING. I DO NOT RECOMMEND TO ANYONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055960		8/31/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IN 2008, WAS TOLD PROCEDURE WAS SUCCESSFUL AND BOTH MY TUBES WERE BLOCKED. I BECAME PREGNANT THE FOLLOWING YEAR AND GAVE BIRTH TO A BEAUTIFUL HEALTH BABY GIRL. SINCE HAVING THIS PROCEDURE I'VE HAD OVARIAN CYSTS TIME AFTER TIME. THEN IN (B)(6) 2014, I WENT TO THE EMERGENCY ROOM THINKING I WAS HAVING MORE WHEN I WAS TOLD I WAS PREGNANT. THEY COULDN'T SEE A HEARTBEAT AND SAID THE BABY WAS (B)(6). I WENT BACK ONE MORE TIME AS THE PAIN WAS GROWING. THEN WENT TO MY OBGYN AT WHICH POINT I WAS TOLD I WAS PREGNANT IN MY TUBES AND NEEDED EMERGENCY SURGERY. BOTH MY TUBES AND MY DEAD BABY WAS TAKEN OUT OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00673	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY ((B)(4)) IN UNITED STATES ON 06-AUG-2015 WHICH REFERS TO AN ADULT FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT AFTER HAVING TO HAVE A TOTAL HYSTERECTOMY AT (B)(6) DUE TO ONE OF HER COILS MIGRATING INTO HER UTERUS SHE HAD DECLINING HEALTH, HER DEPRESSION ANXIETY AND PANIC ATTACKS HAVE GOTTEN WORSE; SHE SUFFERED INSOMNIA AND HAD ISSUES WITH HER THYROID. SHE STATED THAT ALL OF THIS MAY HAVE STARTED AFTER HER HYSTERECTOMY BUT THAT SURGERY WAS A DIRECT RESULT OF ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED HAD TO HAVE A TOTAL HYSTERECTOMY AT (B)(6) DUE TO ONE OF HER COILS MIGRATING INTO HER UTERUS. THE EVENT COILS MIGRATING INTO HER UTERUS, INTERPRETED AS DEVICE EXPULSION IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT AND THE LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT DUE TO THE SURGICAL REQUIRED INTERVENTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

INTERNAL CORRECTION ON 24-NOV-2015: DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 09-AUG-2015.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00674	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 06-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN 2009. CONSUMER STATED THAT WHEN SHE HAD ESSURE IMPLANTED IN 2009 SHE WEIGHED ABOUT (B)(6) LBS, WORKED OUT 5-6 DAYS A WEEK AND HAD REGULAR PERIODS WITH MINIMAL CRAMPING (THIS WAS WITHOUT USING ANY HORMONAL BIRTH CONTROL, SO THIS WAS HOW HER PERIODS WERE). A LITTLE OVER 2 YEARS AFTER IMPLANTATION, SHE STARTED TO EXPERIENCE HEART PALPITATIONS, DIZZINESS, DAILY NAUSEA, SLEEP DISTURBANCES AND PELVIC PAIN. AFTER A COUPLE OF YEARS OF THIS, SHE STARTED TO GET JOINT PAIN, MUSCLE WEAKNESS, MUSCLE PAIN, EXHAUSTION TO THE POINT WHERE SHE FELT LIKE SHE WAS MOVING THROUGH QUICK SAND EVERY DAY; SHE COULD NOT STAY UP PAST 8:30 PM BECAUSE SHE WAS SO TIRED. SHE HAD INCREASED PELVIC PAIN; PERIODS EVERY TWO WEEKS AND WAS PASSING BLOOD CLOTS THE SIZE OF FLATTENED TENNIS BALL. THEN FROM 2013 TO 2015 SHE GAINED RAPIDLY 100 LBS FROM HER STARTING WEIGHT (WITH EATING HEALTHY AND EXERCISING). MULTIPLE TESTS: MRI FOR MULTIPLE SCLEROSIS, RHEUMATOID TESTS TO TEST FOR ARTHRITIS BECAUSE OF HER CONSTANT JOINT PAIN, LYME DISEASE, STRESS TEST FOR HER HEART PALPITATIONS, THYROID TESTS, BLOOD WORK, ETC. ALL CAME UP WITH NOTHING. IT WASN'T UNTIL SHE HAD A STABBING PAIN IN MIDDLE LOWER PELVIS WHERE SHE CONSIDERED GOING TO THE EMERGENCY ROOM DID SHE START TO WONDER IF IT WAS ESSURE. AFTER MONTHS OF MORE TESTS AND MORE PAIN, SHE WAS FINALLY ABLE TO GET A HYSTERECTOMY TO HAVE ESSURE REMOVED. SHE WOKE UP FROM SURGERY WITH THE PAIN SHE HAD LIVED WITH FOR YEARS GONE. THE PATHOLOGY REPORT STATED CYSTS IN FALLOPIAN TUBES, UTERUS AND CERVIX, ADENOMYOSIS

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AND PELVIC CONGESTION (MORE THAN NORMAL BLOOD VESSELS TO UTERUS). AFTER REMOVAL, THE PAIN, DIZZINESS, STOMACH CRAMPS AND NAUSEA WERE GONE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED CASE REPORT IDENTIFIED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN (STABBING PAIN IN MIDDLE LOWER PELVIS). THIS EVENT IS SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE A COUPLE OF YEARS AFTER INSERTION, SHE STARTED TO PRESENT PELVIC PAIN. SHE HAD A STABBING PAIN IN MIDDLE LOWER PELVIS AND OTHER NON-SERIOUS EVENTS. THEN, SHE UNDERWENT HYSTERECTOMY TO GET ESSURE REMOVED AND AFTER THAT, THE PAIN HAD GONE (POSITIVE DECHALLENGE). CONSIDERING EVENT'S NATURE AND POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED (VIA HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00675	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4); AWARENESS DATE: 06-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. THE CONSUMER REPORTED SHE WAS IMPLANTED WITH THE DEFECTED DEVICE. THE PROCEDURE WAS DONE IN THE DOCTOR'S OFFICE AND WAS BEYOND EXCRUCIATING PAIN. THERE WAS DIFFICULTY PLACING THE LEFT SIDE DEVICE WHICH REQUIRED THE ASSISTANCE OF ANOTHER PHYSICIAN; WHAT WAS SUPPOSED TO BE A QUICK OFFICE PROCEDURE TURNED INTO NEARLY AN HOUR OF BLINDING PAIN AND NO PAIN MEDICATION. SHE REPORTED THAT SHE HAD NO PREVIOUS HEALTH ISSUES AND HER HEALTH DETERIORATED 12 MONTHS LATER; SHE WAS OVERCOME BY CHRONIC FATIGUE; BRAIN FOG; BLADDER ISSUES; PELVIC PAIN; BOWEL ISSUES JUST TO NAME A FEW. DOCTORS COULD NOT IDENTIFY THE SOURCE OF HER ISSUES, UNTIL SHE MADE THE CORRELATION BETWEEN HER SYMPTOMS AND THE ESSURE DEVICE ALTHOUGH HER DOCTOR COULD NOT GUARANTEE THAT A HYSTERECTOMY WOULD RESOLVE HER SYMPTOMS, THEY DETERMINED THAT IT WAS THE BEST SOLUTION IN HER CASE; AND WHEN THE DOCTOR CAME INTO HER ROOM AFTER THE PROCEDURE SHE IMMEDIATELY SAW A DIFFERENCE IN HER COLOR AND MENTAL CLARITY. SHE MENTIONED THAT FELT LIKE SHE DID PRIOR TO ESSURE WITHIN HOURS OF WAKING UP FROM HYSTERECTOMY. SHE ASKED FOR A NICKEL TEST TO BE PERFORMED ON HER UTERUS AND NICKEL WAS PRESENT; SHE HAD CHRONIC INFLAMMATION RESULTING IN ADHESIONS TO HER BOWEL AND 2 YEARS POST HYSTERECTOMY SHE WAS STILL SUFFERING WITH THE SIDE EFFECTS OF ADHESIONS AND INFLAMMATION. THE CONSUMER, WHO WAS (B)(6) AT THE TIME OF THIS REPORT, STATED THAT THIS FAULTY MEDICAL DEVICE TOOK 3 YEARS FROM HER LIFE. COMPANY CAUSALITY COMMENT: THIS NON-

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MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO EXPERIENCED PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY AND ACCORDING TO HER, AFTER THIS PROCEDURE SHE FELT LIKE SHE DID PRIOR TO DEVICE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED IN THE YEAR FOLLOWING ESSURE PLACEMENT AND APPARENTLY IMPROVED WITH DEVICE REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

INTERNAL CORRECTION ON 24-NOV-2015: DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 09-AUG-2015.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00676	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2011
Explant Date (E7): 6/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE: (B)(4), AWARENESS DATE 06-AUG-2015) IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. SHE SUFFERED MAJOR HEADACHES WITH BRAIN TINGLING WHICH SHE STILL HAS AT TIME OF THE REPORT. SHE DEVELOPED BOILS IN HER HEAD AND CHEST THAT DIDN'T GO AWAY FOR A YEAR THEN DEVELOPED OTHER PATCHY RASHES. SHE STATED THE DEPRESSION AND ANXIETY RUINED HER QUALITY OF LIFE. SHE DEVELOPED CYSTS AND HAD EXCESSIVE BLEEDING IT CAUSED HER TO LOSE HER JOB AND QUIT SCHOOL WITH LESS THAN A YEAR TO GRADUATION. HER CHILDREN SUFFERED THE LOSS OF HAVING THEIR MOTHER TO PROPERLY CARE FOR THEM. SHE HAD ESSURE REMOVED ON (B)(6) 2015 AND HER SKIN ISSUES HAVE DISAPPEARED LIKE MAGIC. AT TIME OF THE REPORT, HER BRAIN TINGLES CONTINUED; SHE STATED THAT THIS CAUSED DIZZINESS AND EXTREME HEADACHES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXCESSIVE BLEEDING AMONG OTHER NON-SERIOUS EVENTS. ESSURE WAS REMOVED. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS LISTED IN THE REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, ALTHOUGH THE ONSET DATE OF THE BLEEDING WAS NOT PROVIDED, A POSITIVE TEMPORAL RELATIONSHIP IS IMPLIED. CONSIDERING THIS COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN ESSURE AND THIS BLEEDING CANNOT BE EXCLUDED. THIS IS

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CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00677	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015.(REFERENCE: (B)(4), AWARENESS DATE 06-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED 5 YEARS BEFORE THE POSTING DATE (2010), SHORTLY AFTER THE BIRTH OF HER DAUGHTER. SHE REPORTED THE FIRST YEAR WITH ESSURE WAS GREAT, SHE HAD NO WORRIES ABOUT AN UNPLANNED PREGNANCY. AFTER ABOUT A YEAR, HER PERIODS STARTED GETTING EXTREMELY HEAVY; HER HAIR STARTED FALLING OUT; SHE STARTED GAINING WEIGHT (50 POUNDS TOTAL IN 5 YEARS) DESPITE RIGOROUS WORK OUT ROUTINES AND STRICT DIETS; SHE STARTED HAVING ABSENCE SEIZURES; MIGRAINE WITH AURA; HER SEX DRIVE DROPPED TO BECOME NONEXISTENT; SHE HAD NERVE PAIN IN DIFFERENT PARTS OF HER BODY; SHE COULD NO LONGER WEAR JEWELRY UNLESS IT WAS PURE GOLD OR SILVER; SHE WOULD CRAMP THE ENTIRE MONTH INSTEAD OF JUST AROUND THE TIME OF HER CYCLE; SHE HAD STABBING PAINS IN HER LOWER ABDOMEN; HER STOMACH WOULD BLOAT EVERY DAY TO THE POINT SHE LOOKED 8 MONTHS PREGNANT AND THEN IT WOULD GO DOWN EVERY NIGHT; SHE STARTED TO HAVE BRAIN FOG (SHE COULDN'T REMEMBER WHERE SHE WAS DRIVING TO, COULDN'T REMEMBER HOW TO MAKE COFFEE). SHE STATED THAT BECAME DEPRESSED. EACH AND EVERY SYMPTOM WAS CHECKED OUT BY NUMEROUS DOCTORS AND NO ONE COULD TELL HER WHAT WAS WRONG. THE MOST REASONABLE CONCLUSION WAS HYPOTHYROIDISM BUT HER BLOOD TESTS CAME BACK NORMAL. SHE REPORTED THAT THIS MADE HER GO INTO A DEEP DEPRESSION; SHE WAS (B)(6) (AT THE TIME OF REPORT) AND WONDERED WHAT QUALITY OF LIFE SHE COULD EXPECT AT 50 OR 60. SHE CONTACTED A NEW GYNECOLOGIST AND REQUESTED A HYSTERECTOMY. THE DOCTOR SAID SHE WASN'T SURE ESSURE WAS

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THE PROBLEM. AT TIME OF THE REPORT, THE CONSUMER WAS 2 MONTHS POST OP FROM A TOTAL HYSTERECTOMY AND ALL OF HER SYMPTOMS WERE GONE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER A YEAR SHE HAD CRAMP THE ENTIRE MONTH / STABBING PAINS IN HER LOWER ABDOMEN (INTERPRETED AS ABDOMINAL PAIN LOWER), ABSENCE SEIZURES (INTERPRETED AS PETIT MAL EPILEPSY), BRAIN FOG (INTERPRETED AS MENTAL IMPAIRMENT). SHE HAD A TOTAL HYSTERECTOMY PERFORMED APPROXIMATELY 5 YEARS AFTER INSERTION (IMPLIED ESSURE REMOVAL). SHE RECOVERED FROM ALL SYMPTOMS. THE ABDOMINAL PAIN IS LISTED WHILE THE PETIT MAL EPILEPSY AND MENTAL IMPAIRMENT ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THESE EVENTS OCCURRED DURING ESSURE USE. THE ABDOMINAL PAIN IS ASSESSED AS RELATED SINCE THE TEMPORAL RELATIONSHIP IS COMPATIBLE AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. IN CONTRAST, DESPITE THE COMPATIBLE TEMPORAL RELATIONSHIP, GIVEN THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT ESSURE WOULD CAUSE THESE EVENTS. THEREFORE, THE EVENTS PETIT MAL EPILEPSY AND MENTAL IMPAIRMENT ARE ASSESSED AS UNRELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

INTERNAL CORRECTION ON 24-NOV-2015: DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 09-AUG-2015.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00678	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 05-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED A AROUND 2 YEARS PREVIOUS TO THIS REPORT. SHE STATED THAT ABOUT 1.5 YEARS PREVIOUS TO THIS REPORT, SHE STARTED HAVING HEAVY PERIODS, VERY HEAVY, TERRIBLE CRAMPING, LOWER ABDOMINAL PAIN (WITHOUT PERIODS), BACK PAIN AND JOINT PAIN. SHE FELT LIKE AN OLD WOMEN. SHE WAS TESTED FOR LUPUS, RHEUMATOID ARTHRITIS, LYMES AND OTHER THINGS AND ALL WERE NEGATIVE. SHE WILL BE HAVING A HYSTERECTOMY IN (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DETECTED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO (B)(6) FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN. THIS EVENT IS SERIOUS DUE REQUIRED INTERVENTION AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR WITH ESSURE USE. IN THIS CASE THE CONSUMER HAD THIS PAIN APPROXIMATELY SIX MONTHS AFTER INSERTION AMONG OTHER NON-SERIOUS EVENTS AND HAD HYSTERECTOMY SCHEDULED. GIVEN EVENT'S NATURE AND COMPATIBLE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSME

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00679	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 06-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 FOR BIRTH CONTROL. CONSUMER STATED SHE IS MOTHER OF TWO AND HAD RECENTLY HAD A COMPLETE HYSTERECTOMY DUE TO COMPLICATIONS OF THE DEVICE. SHE REPORTED THE DEVICE WAS A DEFECTIVE PRODUCT AND IT NEEDS TO BE PULLED FROM THE MARKET SO THAT NO MORE WOMEN WILL SUFFER FROM DEBILITATING PELVIC PAIN AND A LIST OF NUMEROUS SIDE EFFECTS THAT INCLUDE BUT NOT LIMITED TO NEUROLOGICAL SYMPTOMS SUCH AS MIGRAINES; SPEECH PROBLEMS; VISION CHANGES; DEPRESSION AND ANXIETY AND A GENERAL FEELING OF BEING UNWELL. SHE STATED AS BEING POISONED OR LOSING YOUR MIND BECAUSE HEALTH CARE PROFESSIONALS WERE HAVING A HARD TIME DIAGNOSING THE SPECIFIC PROBLEM, AND THEN TO FIND OUT THAT IT IS ALL BEING CAUSED BY THE IMPLANTS AND THE MATERIALS THAT THEY ARE MADE OF. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD DEBILITATING PELVIC PAIN. SHE HAD RECENTLY UNDERGONE A COMPLETE HYSTERECTOMY DUE TO ESSURE COMPLICATIONS. THE EVENT DEBILITATING PELVIC PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER STATED THAT ESSURE SHOULD BE PULLED FROM THE MARKET SO NO MORE WOMEN WILL SUFFER FROM DEBILITATING PAIN. IT WAS ASSUMED THAT SHE WAS ALSO REFERRING TO HERSELF. ALTHOUGH NO DATES WERE PROVIDED, BUT IT IS IMPLIED THAT IT OCCURRED DURING

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ESSURE USE. CONSIDERING THE COMPATIBLE IMPLIED TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE PELVIC PAIN IS ASSESSED AS RELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). OTHER NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

INTERNAL CORRECTION ON 24-NOV-2015: DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 09-AUG-2015.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00680	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. ANTICIPATED. REQUIRED INTERVENTION. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 05-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE, AFTER HAVING HER LAST CHILD. CONSUMER WAS ASSURED THAT IT WAS MINIMAL DOWN TIME WITH NO HARMFUL SIDE EFFECTS. AFTER 2 YEARS OF PAIN, NOT BEING ABLE TO HOLD HER CHILDREN, HIGH BLOOD PRESSURE THAT DID NOT START UNTIL AFTER INSERTION, A HUGE BLOATED BELLY THAT LOOKED LIKE SHE WAS 9 MONTHS PREGNANT AND RANDOM SHOOTING PAINS IN ABDOMEN, SHE FINALLY GOT A HYSTERECTOMY AND GOT HER LIFE BACK. HER BLOOD PRESSURE HAS BEEN GREAT AND SHE DID NOT NEED MEDICATION SINCE SURGERY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RANDOM SHOOTING PAINS IN HER ABDOMEN. TWO YEARS AFTER THE ONSET OF THIS EVENT, AND AN UNSPECIFIED TIME AFTER ESSURE INSERTION, SHE UNDERWENT A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

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Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00686	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/15/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043470) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT SHE HAS HAD ESSURE COILS FOR ABOUT TWO YEARS AND INFORMS THAT WHEN SHE HAD THE PROCEDURE DONE, SHE FELT EVERYTHING (SHE WAS GIVEN NO TYPE OF ANESTHESIA). SINCE SHE HAD THE PROCEDURE, SHE IS IN EXTREME PAIN ALL OF THE TIME AND STATES THAT PAIN IS WORSENED WHEN MENSTRUATING AND DURING ANY PHYSICAL ACTIVITY, SPECIALLY INTERCOURSE. CONSUMER ASKED THE DOCTOR WHO INSERTED ESSURE TO REMOVE THEM AND THE SURGERY DATE WAS SET. THE MORNING OF HER SURGERY, THE DOCTOR CALLED AND CANCELLED IT. ACCORDING TO CONSUMER, THAT HAPPENED ABOUT A YEAR AND A HALF PRIOR TO THE REPORT AND SHE IS STILL IN PAIN EVERY DAY. HER PERIODS HAVE BEEN BECOMING MORE AND MORE ERRATIC AND PAINFUL. SHE HAS TRIED GOING TO OTHER DOCTORS AND HOSPITALS AND EVERYONE JUST TELLS HER TO TAKE SOMETHING FOR THE PAIN BUT SHE DOESN'T WANT TO BE ON PAIN KILLERS FOR THE REST OF HER LIFE. SHE JUST WANTS TO HAVE THE ESSURE COILS REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT

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REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THE PROCEDURE SHE IS IN EXTREME PAIN ALL OF THE TIME. SHE VISITED SEVERAL DOCTORS AND HOSPITALS AND RECEIVED PAIN MEDICATION. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE REPORTED EVENT CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE MEDICAL INTERVENTION WAS REQUIRED (LONG-TERM USE OF PAIN MEDICATION AND HOSPITAL VISITS). A SURGERY TO REMOVE ESSURE WAS SCHEDULED BUT IT WAS LATER CANCELLED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00688	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 12/15/2014
Explant Date (E7): 5/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043424) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. SHE REPORTED THAT AFTER HAVING ESSURE IMPLANTED SHE HAD DAILY MIGRAINES, LONG AND PAINFUL PERIODS, AND PAIN DURING SEX. SHE STATED IT HURT SO BAD THAT SHE HAD A HYSTERECTOMY PERFORMED ON (B)(6) 2015 WITH ESSURE REMOVAL. SHE MENTIONED PROZAC AS CONCOMITANT MEDICATION. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL

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QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAINFUL PERIODS/ HURT SO BAD AND PAIN DURING SEX AFTER HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE UNDERWENT A HYSTERECTOMY WITH ESSURE REMOVAL, 6 MONTHS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DYSMENORRHEA AND DYSPAREUNIA MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY AND ESSURE REMOVAL). BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00689	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/26/2011
Explant Date (E7): 2/29/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043549) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. CONSUMER STATED THAT AFTER INSERTION SHE BEGAN HAVING PROBLEMS WITH PAIN AND COULD NOT PICK HER KIDS UP OR MOVE FOR MANY MONTHS UNTIL SHE HAD HYSTERECTOMY ON (B)(6) 2012. SHE DESCRIBED THAT SHE STILL HAD PROBLEMS CAUSED FROM ESSURE. SHE WAS GOING THROUGH MENOPAUSE WHICH WAS HORRIBLE. FOLLOW-UP INFORMATION RECEIVED ON 20-AUG-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED,

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SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE PATIENT HAD PELVIC PAIN AFTER INSERTION, UNTIL SHE UNDERWENT HYSTERECTOMY A FEW MONTHS LATER. BASED ON CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 29-DEC-2015: PHYSICIAN INFORMED THAT WILL NOT FILL ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE. HOWEVER, PATIENT'S MEDICAL RECORDS WERE PROVIDED. ACCORDING TO INFORMATION RECEIVED, ON 21-OCT-2011, A (B)(6) FEMALE PATIENT WHO WA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00711	BAYER HEALTHCARE LLC	9/1/2015	9/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (FDA) IN UNITED STATES ((B)(4)) ON 11-AUG-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. THE CONSUMER STATED THAT WHEN SHE FIRST GOT ESSURE SHE THOUGHT IT WAS GREAT. SHE WAS IN A LITTLE BIT OF PAIN THE DAY SHE HAD IT IMPLANTED BUT NOTHING MAJOR. ON THE NEXT DAY, SHE WOKE UP WITH AN AWFUL HEADACHE. HER COLOR CHANGED TO A DARK GRAY. ACCORDING TO CONSUMER, HER LIFE WENT FROM HAPPY AND FULL OF LIFE, TO JUST EXISTING. SHE HURT EVERY TIME SHE WOULD MOVE AND COULD NOT TAKE CARE OF HER CHILDREN. CONSUMER DISCUSSED THE PAIN WITH HER DOCTOR AND ALSO COMPLAINED OF METALLIC TASTE IN HER MOUTH AND HOW QUICKLY THINGS HAD CHANGED. THE PHYSICIAN AGREED THAT THE ESSURE SHOULD BE REMOVED. SHE UNDERWENT A SURGERY IN THE NEXT WEEK AND ENDED UP HEMORRHAGING DURING SURGERY AND HAD AN EMERGENCY HYSTERECTOMY. ON THE NEXT MORNING, MOST OF ISSUES WERE GONE. FOR THE FIRST TIME IN 7 MONTHS SHE DID NOT EXPERIENCE HEADACHE AND FINALLY REMEMBER THINGS THAT SHE COULD NOT BEFORE. THE METALLIC TASTE WAS GONE, HER COLOR WAS BACK. AT TIME OF DISCHARGE SHE WAS FULL OF LIFE AGAIN. THE CONSUMER CONSIDERED THE EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IT HURT EVERY TIME SHE WOULD MOVE. DUE TO THE PAIN, SHE UNDERWENT A SURGERY TO REMOVE ESSURE. SHE ENDED UP HEMORRHAGING DURING SURGERY AND HAD AN

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EMERGENCY HYSTERECTOMY. THESE EVENTS ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, SHE EXPERIENCED THIS PAIN DURING ESSURE USE AND REQUESTED ITS REMOVAL. CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP AND CONSIDERING THAT ESSURE MAY CAUSE PAIN AND THAT THERE IS NO ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ALSO, AS THE HEMORRHAGING OCCURRED DURING THE ESSURE REMOVAL PROCEDURE AND NO ALTERNATIVE EXPLANATION WAS PROVIDED, THIS EVENT IS RATHER CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN T

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055859	BAYER	9/1/2015	9/1/2015

Event Information:

Event Date (B3): 9/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD ESSURE, I HAVE EXTREMELY HEAVY PERIODS, DEBILITATING PAIN IN MY PELVIC AREA, EXTREMELY BAD HEADACHES, LOWER BACK PAIN, CHEST PAIN, PAIN IN MY JOINTS, NECK AND LEGS. SOMETIMES, I CAN BARELY MOVE BECAUSE OF THE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055938	BAYER	9/1/2015	9/4/2015

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 7/1/2011
Explant Date (E7): 8/13/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN MY TUBES. I NOTICED SOMETHING WASN'T RIGHT. I GAVE THEM TIME TO HEAL. I HAVE HAD LOWER BACK PAIN. HEAVY PERIODS, MOOD SWINGS. I WAS ALSO HAVING LEFT LOWER ABDOMEN PAIN AND IT WAS SHOOTING DOWN MY LEFT LEG. I HAVE BEEN IN PAIN THE WHOLE TIME I HAD THEM IN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055976	BAYER	9/1/2015	9/8/2015

Event Information:

Event Date (B3): 8/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4): ESS305C06466

Single Use: *
Implant Date (E6): 8/11/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE IMPLANT AS A PERMANENT BIRTH CONTROL METHOD AND HAVE EXPERIENCED SEVERAL SIDE AFFECTS SINCE THE INSTALLATION. THERE WAS SEVERE CRAMPING AND BACK PAIN IMMEDIATELY FOLLOWING THE SURGERY. I REPORTED THIS PAIN TO THE PRESCRIBER WHO ADMINISTERED IT WITH NO RESPONSE. A FEW MONTHS INTO THE DEVICE I STARTED HAVING CRAMPING 2 WEEKS BEFORE AND 1 WEEK AFTER MY MENSTRUAL CYCLE. I HAVE NEVER CRAMPED BEFORE THIS DEVICE. I SUFFER FROM BACTERIAL INFECTIONS OCCASIONALLY HAS NOTICED THE MEDICATIONS PRESCRIBED DOES NOT CLEAR THE INFECTION. THERE SEEMS TO BE A RESISTANCE TO ANTIBIOTICS. I HAVE PRIDE IN MY HAIR AND THE THICKNESS OF IT. SINCE THE INSTALLATION OF THE DEVICE I BEGAN LOOSING A SIGNIFICANT AMOUNT OF HAIR. TODAY, (B)(6) 2015 I HAVE TO GO AHEAD AND GET MY HAIR CUT OFF DUE TO THE AMOUNT OF LOSS HAIR. I HAVE EXPERIENCED PAIN AND SWELLING IN THE ABDOMINAL AREA THAT IS UNEXPLAINABLE. MY DOCTOR HAS GIVEN ME MEDICINE FOR THE SWELLING AND WRONGLY DIAGNOSIS ME WITH (B)(6) OR (B)(6). THE TEST RESULTS ALWAYS COME BACK NEGATIVE. SHE ARGUES THAT THOSE DISEASES ARE THE ONLY THING THAT WILL CAUSE SWELLING IN THAT AREA. IT IS EMBARRASSING TO MAKE THESE TYPES OF VISITS TO THE MEDICAL OFFICE. AT HIS POINT I WILL BE DISCUSSING NEXT OPTIONS WITH MY PHYSICIAN. I WAS NEVER INFORMED THAT A HYSTERECTOMY IS THE ONLY OPTION TO REVERSE THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055977	BAYER	9/1/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/1/2004
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED AN ESSURE IMPLANT IN 2004. I'VE EXPERIENCED MINOR PAIN DURING INTERCOURSE AND MY MENSTRUAL CYCLE SOON AFTER THE PROCEDURE WAS DONE. I RECEIVED SONOGRAMS AND SCANS AND WAS TOLD THAT EVERYTHING LOOKED NORMAL AND THAT THE PAIN WOULD LESSEN OR GO AWAY. A FEW YEARS AFTER THAT I RELOCATED TO ANOTHER STATE. SINCE THEN THE PAIN HAS INCREASINGLY GOTTEN WORSE. I FINALLY GOT A SCAN A FEW YEARS BACK AND IT SHOWS THAT ONE OF THE ESSURE IMPLANTS HAS MOVED AND IS HANGING INTO MY UTERUS. THIS IS THE SOURCE OF MY PAIN, BUT THE ESSURE SPECIALIST I WENT TO WILL NOT DEFINITIVELY CONFIRM THAT. I AM NOW BEING TOLD THAT THE ONLY OPTION IS MAJOR SURGERY, A HYSTERECTOMY. I AM LOOKING FOR A NON-BIASED OBGYN FOR A 3RD OPINION. I AM A CONSULTANT, SO THE TIME I NEED TO TAKE OFF OF WORK IS UNPAID.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055979	BAYER HEALTH	9/1/2015	9/8/2015

Event Information:

Event Date (B3): 5/20/2009 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/20/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN. I CAN NO LONGER HAVE SEX WITHOUT PAIN, I AM ON BIRTH CONTROL FOR HEAVY CYCLES, AND EXPERIENCE GREAT PAIN WHEN MENSTRUATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055981	CONCEPTUS INC.	9/1/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20210352

Single Use: *
Implant Date (E6): 11/11/2005
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WENT TO MY DOCTOR REGARDING A TUBAL TO PREVENT FUTURE PREGNANCY. THIS WAS BACK IN 2005. I AM IN THE PROCESS OF OBTAINING MY MEDICAL RECORDS TO GET EXACT DETAILS REGARDING DATES, TIMES, AND FOLLOW UP APPOINTMENTS. I WAS TOLD BY MY DOCTOR THAT TUBALS WERE NO LONGER OFFERED AND SHE DISCUSSED WHAT SHE BELIEVED TO BE A SAFER AND LESS EXPENSIVE WAY TO HAVE A PERMANENT FORM OF BIRTH CONTROL. I WAS GIVEN INFORMATION (BROCHURE) TO EXPLAIN MORE ABOUT THE ESSURE DEVICE. INITIALLY I WAS FINE NO PROBLEMS. I DID, HOWEVER, SHORTLY AFTER HAVING THE PROCEDURE DONE SWITCH MY OB GYN FOR REASONS UNRELATED TO THE ESSURE DEVICE. MY FOLLOW UP PROCEDURE, HSG WAS CONDUCTED BY MY CURRENT OB. ABOUT A YEAR OR SO AFTER HAVING THE ESSURE DONE I BEGAN TO FEEL TERRIBLE. I BECAME FATIGUED, SIDE PAIN (MOSTLY ON THE LEFT SIDE), BACK PAIN, EXTREME ACNE, DEPRESSION, HEAVY BLEEDING, PASSING LARGE BLOOD CLOTS, AND I BEGAN TO HAVE TERRIBLE PMS WORSE THAT WHAT I HAD EVER EXPERIENCED. I TALKED TO MY DOCTOR AFTER I COULDN'T TAKE IT ANYMORE AND SHE SUGGEST I HAVE A PROCEDURE CALLED AN ENDOMETRIAL ABLATION OR A PARTIAL HYSTERECTOMY. I OPTED FOR THE SURGERY THAT WOULD GET ME BACK TO WORK SOONER. THIS HELPED ME FOR A WHILE AND THEN GRADUALLY IT SEEMED LIKE THE SYMPTOMS HAVE RETURNED STRONGER THAN EVER WITH EVEN MORE ISSUES ON TOP OF THEM. I BLAME ESSURE FOR MY WOES, AS MUCH AS I TRIED TO AVOID HAVING A HYSTERECTOMY, NOW AT AGE (B)(6) ON (B)(6) 2015 I WILL BE HAVING THE SURGERY TO REMOVE THIS GARBAGE FROM MY BODY. AS A SINGLE MOTHER OF THREE NOW DIVORCED I DON'T KNOW HOW I AM GOING TO PAY FOR MY MEDICAL EXPENSES BUT I JUST WANT TO BE BACK TO MYSELF. MY LIFE HAS BEEN HELL AND IT HAS AFFECTED ME IN SUCH A NEGATIVE WAY. SOME DAYS I CAN BARELY

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FUNCTION AND SOME DAYS ARE OKAY. I AM ASKING THAT YOU PLEASE GET THIS OFF THE MARKET AND HELP THE MANY WOMAN LIKE MYSELF GET OUR LIVES BACK!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055982	BAYER HEALTH	9/1/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ESSURE AND HAVE EXPERIENCED SOME OF THE PROBLEMS THAT WERE MENTIONED. I HAVE REALLY BAD CRAMPS ON MY RIGHT SIDE AND UNEXPLAINED BACK SPASMS ON THAT SIDE AS WELL. I'VE HAD AN ULTRASOUND AND X-RAYS RECENTLY SO IF YOU NEED COPIES OF THOSE I CAN GET THEM. MY DOCTOR STATED HE DIDN'T SEE ANYTHING WRONG WITH MY FALLOPIAN TUBES BUT HAS PRESCRIBED A PAIN KILLER, IBUPROFEN, AND A MUSCLE RELAXER TO HELP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055983	BAYER HEALTH	9/1/2015	9/8/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE BIRTH CONTROL. I'VE HAD IT FOR ALMOST 3 YEARS NOW. I'VE NOTICED HAVING HEAVY PERIODS, DISCOMFORT DURING AND AFTER SEX, ABDOMINAL CRAMPS DURING TIMES THAT I'M NOT ON MY PERIOD AND NOW I'M EXPERIENCING RASH LOOKING BUMPS ON MY ARMS, LEGS, AND LEFT SIDE OF CHEST. I'M NOW HOPING TO SEE AN ALLERGIST TO SEE WHAT'S GOING ON BECAUSE I HAVEN'T CHANGED ANYTHING I USE. SO I'M NOT SURE WHAT'S THE CAUSE AS OF NOW!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055986		9/1/2015	9/8/2015

Event Information:

Event Date (B3): 1/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/29/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE PERFORMED (B)(6) 2015. AFTER ABOUT 13 ATTEMPTS TO GET THE ESSURE PLACES THE DOCTOR FINALLY GAVE UP. SHE WAS ABLE TO GET ONE COIL IN THE TUBE, BUT THE TUBE SPADED AND THE COIL CAME OUT. SHE COULD NOT FIND THE COIL SO SHE TOLD ME THAT IT WOULD COME OUT OF ITS OWN. I HAD HEAVY BLEEDING FROM (B)(6). I WENT THROUGH OVER 100 PADS. I STARTED HAVING PROBLEMS ABOUT A MONTH AGO. I WENT TO THE DOCTOR AND SHE SENT ME FOR AN ULTRASOUND. THE ULTRASOUND SHOWED THAT THE COIL WAS STILL INSIDE OF ME. IT HAS GONE THROUGH THE BOTTOM OF MY UTERUS AND THE TOP OF MY CERVIX. I HAVE BEEN AND I AM STILL IN A LOT OF PAIN. THE PAIN IS CONTROLLED WITH MESS BUT I STILL HURT ALL THE TIME. I WILL HAVE TO HAVE SURGERY TO HAVE THE ESSURE COIL REMOVED. I AM NOT SURE WHEN MY SURGERY WILL BE. I AM WAITING ON THE DOCTOR TO CALL ME. THE DOCTOR SCRAPPED MY UTERUS WITH THE CAMERA EVERY TIME SHE WENT IN. SHE WAS GOING TO PUT ME IN THE HOSPITAL AND TIE MY TUBES THAT WAY BUT (B)(6) CAUGHT HER IN (B)(6) FRAUD. NOW SHE REFUSES TO EVEN SEE ME OR TO FIX THE PROBLEM THAT SHE HAS CAUSED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055987		9/1/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/24/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I GOT THE ESSURE IN 2012, MY BODY WAS DOING FINE AS THE YEARS GO BY I STARTED HAVING PROBLEMS HEAVY MENSTRUAL BLEEDING BLOOD CLOTS IRREGULAR PERIODS BACK ACHES HEADACHES NO PERIOD MISCARRIAGES ALL THESE SYMPTOMS STARTED AFTER I HAVE GOTTEN THE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055988		9/1/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

A LOT OF ABDOMINAL PAIN, HEAVY CRAMPING, HEAVY BLEEDING, BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055989		9/1/2015	9/8/2015

Event Information:

Event Date (B3): 9/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

GOT THE BIRTH CONTROL AND IMMEDIATELY STARTED TO HAVE BACK PAIN AND CRAMPS IN MY UPPER THIGHS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055990		9/1/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/1/2008
Explant Date (E7): 4/1/2009
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED RATHER THAN TRADITIONALLY HAVING MY TUBES TIED DUE TO THE SUGGESTION OF MY OBGYN IN 2008. I WAS (B)(6). IN LESS THAN SIX MONTHS, I HAVE SEVERE PAIN AND BLEEDING AND WENT TO THE EMERGENCY ROOM SEVERAL TIMES. MY OBGYN SAID IT WASN'T HIS ISSUE AND SENT ME TO MY PRIMARY CARE DR. MY PRIMARY CARE DR SENT ME TO A OBGYN PAIN SPECIALIST. I HAD THE FIRST SURGERY IN (B)(6). THEY DETERMINED THAT THE ESSURE HAD PUNCTURED MY FALLOPIAN TUBE AND COULD NOT BE REMOVED ON ITS OWN SAFELY. I HAD 10-20 INJECTIONS INTO MY ABDOMEN WEEKLY AFTER THAT TO MANAGE THE PAIN WHILE MY DR TRIED TO FIND A WAY TO REMOVE THE ESSURE SAFELY. I WAS ON PAIN MEDICATION AS WELL. I COULD NOT WORK AND LOST MY JOB. I WAS AT RISK OF INTERNAL BLEEDING AND ON (B)(6), I ULTIMATELY HAD TO HAVE A FULL HYSTERECTOMY. I HAVE ONLY OVARIES LEFT. I WAS (B)(6) YEARS OLD. FOR THE NEXT SEVERAL WEEKS, I COULD NOT DRIVE, WORK, TAKE CARE OF MY CHILDREN ETC. I AM ALSO NOW AT GREATER RISK OF EARLY ONSET MENOPAUSE AND BREAST CANCER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055991	BAYER	9/1/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE AND IT CAUSES ME TO CRAMP BADLY AND ALSO HEAVIER PERIODS. IT'S ALSO PAINFUL DURING INTERCOURSE I WOULD LIKE TO HAVE IT REMOVE BUT IT'S NOT REVERSIBLE THEY SAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055992		9/1/2015	9/8/2015

Event Information:

Event Date (B3): 11/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE IMPLANT. SINCE THE PROCEDURE, I HAVE HAD SEVERE BLEEDING DURING AND IN BETWEEN PERIODS. EXTREME BACK PAIN, ESPECIALLY DURING MY PERIOD. HAD TEST DONE AT THE HOSPITAL BUT COULDN'T FIND ANYTHING DIFFERENT OTHER THAN ESSURE. DOCTORS TOLD ME I JUST HAVE TO LIVE WITH IT AS THEY MAY BE SIDE EFFECTS. THE WHOLE EXPERIENCED HAS STRESSED ME OUT TO THE POINT I HAVE EXTREME HAIR LOSS KNOWN AS ALOPECIA DUE TO MY STRESS. BECAUSE OF THIS I NOW AM GOING BALD, BLEED CONTINUOUSLY AND HAVE BACK AND PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055993		9/1/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED ONLY IN RIGHT FALLOPIAN TUBE AND UNABLE TO INSERT IN LEFT TUBE. SEVERAL WEEKS LATER AN ATTEMPT WAS MADE TO INSERT INTO THE LEFT TUBE THAT WAS UNSUCCESSFUL. IMMEDIATE PAIN IN RIGHT FALLOPIAN TUBE AND A SERIES OF SEVERE LIFE THREATENING ILLNESSES TO FOLLOW RESULTING IN PANCREATITIS AND TUBE FEEDING AND PICC LINE FEEDING FOR SEVERAL MONTHS. SEVERE HEAVY VAGINAL BLEEDING MONTHLY REQUIRING THE USE OF 4 PADS AT A TIME. TWO YEARS AFTER THE IMPLANTS WAS INSERTED. I WAS FINALLY APPROVED FOR SURGICAL REMOVAL OF MY ENTIRE FALLOPIAN TUBE. THE PATHOLOGY REPORT CONFIRMED INTERNAL BLEEDING AND INFLAMMATION IN THE FALLOPIAN TUBE FROM THE ESSURE DEVICE. I HAVE BEEN ASYMPTOMATIC SINCE THE SURGERY AND HAVE GONE OFF 6 OF THE 7 MEDICATION I WAS TAKING DAILY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055994		9/1/2015	9/8/2015

Event Information:

Event Date (B3): 10/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IN TO GET THE ESSURE DEVICE IMPLANTED AND EVER SINCE THEN THERE HAS BEEN SERIOUS PELVIC PAIN, DAILY HEADACHES, PAIN WHILE HAVING SEX, WEIGHT GAIN, RINGING IN EARS, ON GOING YEAST INFECTIONS AND THE LIST GOES ON AND ON.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00687	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/5/2014
Explant Date (E7): 9/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043550) IN (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER REPORTED SHE WAS OK AT FIRST, AFTER ESSURE INSERTION, THEN IN 2014 SHE BEGAN HER PERIOD, IT WAS VERY HEAVY, WITH LOTS OF CLOTTING AND CRAMPS SOMETHING TERRIBLE. SHE REPORTED SHE WOULD NOT STOP BLEEDING AND THEN, ALSO IN 2014, SHE WAS HOSPITALIZED TO RECEIVE A BLOOD TRANSFUSION. HER BLOOD COUNT WAS 6.4; AND SHE HAD SEVERE BREAKOUTS BECAUSE SHE WAS ALLERGIC TO THE NICKEL, WHICH SHE WAS UNAWARE, SHE DID NOT HAVE A NICKEL TEST NOR WAS WARNED. SHE ALSO REPORTED AN INFECTION IN HER CERVIX AND IT WAS NOT (B)(6) (UNDERSTOOD AS (B)(6)), SHE HAD A GREEN DISCHARGE BECAUSE HER BODY WAS INFECTED. SHE WAS STILL BLEEDING NONSTOP. SHE FINALLY GOT THE DEVICES REMOVED VIA HYSTERECTOMY ON (B)(6) 2014. SHE MENTIONED AS PRESCRIBED MEDICATION LEVOTHYROXINE 300MCG AND OTCS VITAMIN B12 AND VITAMIN D. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE

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UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER ESSURE INSERTION, SHE BEGAN HER PERIOD. IT WAS VERY HEAVY WITH LOTS OF CLOTTING. SHE WOULDN'T STOP BLEEDING. SHE HAD SEVERE BREAKOUTS BECAUSE I AM ALLERGIC TO THE NICKEL. THE FIRST REPORTED EVENT IS SERIOUS DUE TO HOSPITALIZATION AND THE SECOND ONE IS SERIOUS DUE TO MEDICAL IMPORTANCE. THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR AND ALSO, ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS CASE, THE EVENTS OCCURRED AFTER ESSURE INSERTION. SHE HAD HER DEVICES REMOVED VIA HYSTERECTOMY. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO PERFORMED SURGICAL INTERVENTION. ADDITIONALLY, OTHER SERIOUS EVENTS (UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00690	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 789032

Single Use: Y
Implant Date (E6): 8/2/2011
Explant Date (E7): 5/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5043574) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 WITH LOT NUMBER 789032. THE CONSUMER REPORTED THAT HER MENSTRUAL CYCLE INSTANTLY BEGAN GETTING HEAVIER. HER CRAMPS BECAME UNBEARABLE AFTER 2 YEARS. SHE WENT TO EMERGENCY ROOM IN 2015, WHICH LEAD TO A TOTAL HYSTERECTOMY DUE TO HER OVARIES HAVING MULTIPLE CYSTS CAUSING THE PAIN. SHE SAID THAT SHE NEVER HAD THESE SYMPTOMS PRIOR ESSURE. SHE HAD A PICTURE OF THE HUGE, BLOODY CYST COVERING HER RIGHT OVARY. HER DOCTOR SAID TO HER THAT IT WAS PROBABLY DUE TO ESSURE. ON (B)(6) 2015, ESSURE WAS REMOVED. FOLLOW-UP INFORMATION RECEIVED ON 20-AUG-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF

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THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER 2 YEARS, CRAMPS BECAME UNBEARABLE. IN ADDITION, SHE PRESENTED OVARIES HAVING MULTIPLE CYSTS / HUGE, BLOODY CYST COVERING HER RIGHT OVARY. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. THE EVENT CRAMPS IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE OVARIAN CYST IS UNLISTED. ABDOMINAL PAIN AND CRAMPS MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER STATED THAT CRAMPS BECAME UNBEARABLE 2 YEARS AFTER INSERTION. SHE WENT TO EMERGENCY ROOM AND HAD HYSTERECTOMY DUE TO HER OVARIES HAVING MULTIPLE CYSTS (A HUGE BLOODY CYST WAS COVERING HER RIGHT OVARY). ALTHOUGH IN THIS CASE HER HUGE HEMORRHAGIC CYST COULD BE AN ALTERNATIVE EXPLANATION FOR ABDOMINAL CRAMPS, A CONTRIBUTORY ROLE OF THE DEVICE CANNOT BE TOTALLY EXCLUDED. THEREFORE, CAUSAL RELATIONSHIP BETWEEN UNBEARABLE CRAMPS AND ESSURE USE IS ASSESSED AS RELATED. SINCE ESSURE REMOVAL WAS REQUIRED (VIA HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 20-OCT-2015: CONSUMER WAS (B)(6). SHE HAD AS PREVIOUS SURGERY TONSILLECTOMY. SHE USES TOBACCO, ALCOHOL (UNREADABLE), DOES NOT USE DRUGS AND DOES NOT EXERCISE, HAS AS PREVIOUS PREGNANCIES GRAVIDA 3 AND PARA 2, HAD HER LAST PAP IN 2012

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00691	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): 1/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/6/2015
Explant Date (E7): 6/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043425) IN UNITED STATES ON 10-AUG-2015, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. CONCOMITANT MEDICATION INCLUDED ADVAIR MONTELUKAST. PRIOR TO INSERTION, SHE HAD HER BABY IN 2014. AFTER HER BABY WAS BORN, SHE HAD HER PERIOD SIX WEEKS AND A PERIOD MONTHLY AFTER THAT. SHE WAS FINE ACTIVE, LOSING WEIGHT AND MOTIVATED. ONCE ESSURE WAS PLACED IN THE FIRST DAY THROUGH THE 4TH DAY, SHE EXPERIENCED CRAMPING THAT REQUIRED STRONG MEDICATION TO BE TAKEN IN ORDER TO CONTROL THE PAIN. SHE WAS ALSO GIVEN A DEPO THE SAME DAY WHEN ESSURE WAS PLACED. HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED SHOWED THE COILS IN PLACE. SHE STARTED EXPERIENCING JOINT PAIN AND RASHES. SHE STATED DID NOT GET A PERIOD (SHE MISSED TWO PERIODS). THEN, HER PERIOD LASTED SIX WEEKS AND CAME AGAIN NO PERIOD BUT HER CRAMPING, BLOATING AND PAINS WERE PERSISTENT AS IF HER PERIODS ARE GOING TO COME. SHE COULD BARELY EAT DUE TO THE BLOATING SHE WAS FEELING AND HOW SICK HER STOMACH FELT. SHE WAS TOLD BY HER DOCTOR, SHE HAD A HORMONE ISSUE. BUT SHE STATED THAT NO BLOOD WORK WAS PERFORMED TO DETERMINE THIS. SHE GAINED FIFTY POUNDS, HER LEGS WERE ALSO SWOLLEN, AND SHE WAS EXPERIENCING CONSTANT HEADACHES, CRAMPING, BLOATING AND NO LIFE. SHE NEVER KNEW WHEN HER PERIODS WOULD COME AND WHEN IT ARRIVES, IT LASTS MORE THAN A MONTH WITH EXTREME PAIN AND EXTREME HEAVINESS. SHE NEVER WAS TESTED FOR NICKEL ALLERGIES PRIOR TO INSERTION. SINCE ESSURE, SHE WAS NOT HERSELF, HER BODY HURTS, AND HER HAIR FALLS, HER BLOATING AND HEADACHES WERE BAD. SHE WAS ALWAYS A HEALTHY PERSON UNTIL ESSURE. ON (B)(6) 2015, ESSURE WAS REMOVED. CONSUMER ASSESSED THE CASE WAS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS); HOWEVER SHE DID NOT SPECIFY IT. FOLLOW-

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UP INFORMATION RECEIVED ON 20-AUG-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT . IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CRAMPING/ PAIN (REGARDED AS ABDOMINAL CRAMPING). THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, ONCE ESSURE WAS PLACED IN THE FIRST DAY THROUGH THE 4TH DAY, SHE EXPERIENCED THIS EVENT. IT WAS REPORTED THAT AN HYSTEROSALPINGOGRAM WAS PERFORMED AND THE RESULT SHOWED THE COILS IN PLACE. ESSURE WAS REMOVED. BASED ON A COMPATIBLE TEMPORAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT, CAUSALITY CANNOT BE EXCLUDED. DUE TO DEVICE REMOVAL, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00692	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626221

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE WITH LOT NUMBER 626221. IT WAS REPORTED THAT IN 2013 CONSUMER HAD HYSTERECTOMY. HER DOCTOR INFORMED HER THAT ONE OF THE ESSURE COILS WAS FLOATING AROUND (HAD COME LOOSE) INSIDE HER. PHYSICIAN DID NOT KNOW WHAT IT WAS UNTIL HE REMOVED IT. SHE RECEIVED ZIAC AS CONCOMITANT MEDICATION. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4) FINAL ASSESSMENT: PRODUCTION DATE: 11/2007. EXPIRATION DATE: 10/2009. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY,

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THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE OF THE ESSURE COILS WAS FLOATING AROUND (HAD COME LOOSE) INSIDE HER. A HYSTERECTOMY WAS PERFORMED TO REMOVE THIS COIL. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THERE IS LIMITED INFORMATION. HOWEVER, CONSIDERING THE NATURE OF THIS EVENT AND IMPLIED TEMPORAL RELATIONSHIP, THE DEVICE DISLOCATION IS CONSIDERED RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, INCLUDING REVIEW OF BATCH DOCUMENTATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 06-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00693	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/13/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043569) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. CONSUMER STATED THAT AFTER ESSURE, SHE STARTED HAVING VERY PAINFUL MENSTRUAL CYCLES; THE CRAMPS WERE UNBEARABLE. SHE HAD VERY BLEEDING TO THE POINT SHE WOULD HAVE TO WEAR A TAMPON AND A PAD (NOT TO BLEED THROUGH HER CLOTHING). THEN SHE HAD A SECOND SURGERY UTERINE ABLATION TO HELP WITH THESE PROBLEMS. AFTER SURGERY, SHE STILL HAD BAD CRAMPS AND BLEEDING RETURNED. AN INJURY (DISABILITY OR PERMANENT DAMAGE) WAS MENTIONED AS EVENT OUTCOME BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP INFORMATION RECEIVED ON 20-AUG-2015: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD BLEEDING (INTERPRETED AS GENITAL BLEEDING) AFTER HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DUE TO THIS, SHE UNDERWENT AN UTERINE ABLATION. THIS EVENT WAS CONSIDERED SERIOUS BY THE REPORTER AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENT WAS REPORTED. REPORTER MENTIONED DISABILITY OR PERMANENT DAMAGE AS EVENT OUTCOME BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (UTERINE ABLATION). BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 23-NOV-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00694	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043578) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE REPORTED SHE WAS IN PAIN FROM HAVING THE DEVICES FOR TWO YEARS BEFORE THE FIGHT WITH HER DOCTOR TO HAVE THEM TAKEN OUT. SHE STATED THE MAIN REASON FOR THEM COMING OUT WAS THE RIGHT ONE WAS BENT. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY

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COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTORITY) REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS IN PAIN FROM HAVING THEM FOR TWO YEARS (INTERPRETED AS PELVIC PAIN), UNTIL SHE HAD THE DEVICES REMOVED. THE MAIN REASON FOR THEM COMING OUT WAS RIGHT ONE WAS BENT (SEEN AS DEVICE SHAPE ALTERATION) THESE EVENTS ARE SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE THE FACT THE DEVICE WAS BENT COULD HAVE CONTRIBUTED FOR THE INTENSITY OF PAIN. THEREFORE, CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE USE IS ASSESSED AS RELATED. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00695	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20193380 (INVALID)

Single Use: Y
Implant Date (E6): 11/17/2009
Explant Date (E7): 12/17/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 WITH LOT NUMBER 20193380 FOR CONTRACEPTION. CONCOMITANT MEDICATION USED: TRAZADONE. CONSUMER REPORTED THAT ESSURE COILS WERE PLACED IN ORDER TO NO LONGER HAVE CHILDREN. IN ADDITION, ONLY ONE SIDE WAS BLOCKED; SHE COULD STILL GET PREGNANT. ON AN UNSPECIFIED DATE, SHE HAD TO RETURN FOR THE DYE TEST AGAIN TO FIND OUT IF SHE COULD GET PREGNANT. THE SECOND DYE TEST SHOWED THAT SHE WAS NOT ABLE TO GET PREGNANT. AFTER THE ESSURE WAS IMPLANTED SHE HAD CONSTANT PELVIC PAIN AND SHE BEGAN TO BLEED HEAVILY AND STEADILY FOR ALL BUT APPROXIMATELY 1 WEEK A MONTH FOR YEARS. THE PAIN STARTED AFTER THE ESSURE WAS IMPLANTED AND THE ENTIRE TIME THAT SHE HAD THE ESSURE COILS INSIDE HER; IT KEPT HER FROM DOING THE THINGS SHE HAD PREVIOUSLY ENJOYED BECAUSE OF THE PAIN. SHE CONSTANTLY HAD TO TAKE BREAKS AT WORK DUE TO THE PAIN. SHE CONTINUOUSLY TOLD THE DOCTOR WHO PERFORMED THE PROCEDURE BUT HER COMPLAINTS WERE IGNORED. FINALLY, SHE WENT TO ANOTHER DOCTOR AND HAD THE ABLATION PROCEDURE WHICH DECREASED THE BLEEDING FOR A FEW MONTHS BUT THE BLEEDING CONTINUED. ON (B)(6) 2014, SHE HAD TO HAVE A HYSTERECTOMY AND THE DOCTOR TOOK OUT HER TUBE WHICH CONTAINED THE ESSURE COILS. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT #20193380 IS INVALID. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE

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WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO VALID BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THE DEVICE WAS IMPLANTED SHE HAD CONSTANT PELVIC PAIN / PAIN AFTER THE ESSURE AND THE ENTIRE TIME THAT SHE HAD IT AND SHE BEGAN TO BLEED HEAVILY AND STEADILY. SHE UNDERWENT AN ABLATION PROCEDURE BUT THE BLEEDING CONTINUED, AND 5 YEARS AFTER ESSURE INSERTION SHE HAD A HYSTERECTOMY WITH ESSURE REMOVAL. THESE EVENTS, INTERPRETED AS PELVIC PAIN AND GENITAL BLEEDING, ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN ESSURE AND THE REPORTED EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (ABLATION, HYSTERECTOMY WITH ESSURE REMOVAL). BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00696	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/10/2013
Explant Date (E7): 12/17/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043918) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR PERMANENT BIRTH CONTROL. SHE ALSO HAD MIRENA INSERTED. WHEN SHE HAD THE ESSURE PROCEDURE DONE, HER DOCTOR ASSURED HER THIS WAS A SAFE, EASY, EFFECTIVE PERMANENT BIRTH CONTROL WITH NO SIDE EFFECTS. AFTER HER FOLLOW-UP APPOINTMENT TO ENSURE THAT THE TUBES WERE FULLY BLOCKED SHE WAS TOLD IT WAS SAFE TO GET OFF HER BIRTH CONTROL. ON AN UNSPECIFIED DATE, SHE STARTED SUFFERING FROM SEVERE BLEEDING AND CRAMPS FOR 14 MONTHS STRAIGHT. SHE WENT BACK TO HER DOCTOR MULTIPLE TIMES, AT ONE POINT THEY EVEN PUT IN A MIRENA IUD TO CONTROL THE BLEEDING WHICH DID NOT HELP (THE FIRST 6 MONTHS SHE HAD TO HAVE AN IUD PUT IN.) ALONG WITH THE SEVERE BLEEDING AND CRAMPS IN THAT 14 MONTHS, SHE HAD HUGE BLOOD CLOTS, CONSTANT BLOATING AND STOMACH PAIN, WEIGHT GAIN, DEPRESSION AND ABSOLUTE LOSS OF SEXUAL DRIVE WHICH RUINED HER MARRIAGE. FINALLY AFTER 14 MONTHS (ON (B)(6) 2014) SHE WENT TO A SPECIALIST AND SHE WAS FORCED INTO A HYSTERECTOMY (AND ESSURE REMOVAL), WHICH WAS THE ONLY CURE FOR THE BLEEDING. HOWEVER A HYSTERECTOMY COULD NOT FIX HER DEPRESSION, SEX DRIVE OR HER MARRIAGE. FOLLOW-UP INFORMATION RECEIVED ON 20-AUG-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE BLEEDING / HUGE BLOOD CLOTS / BLOOD LOSS FOR 14 MONTHS. A HYSTERECTOMY WAS PERFORMED AND ESSURE INSERTS WERE REMOVED. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, AN UNSPECIFIED TIME AFTER ESSURE INSERTION, THE CONSUMER EXPERIENCED THIS BLEEDING FOR 14 MONTHS STRAIGHT. SHE WENT TO THE PHYSICIAN MULTIPLE TIMES AND ENDED UP PUTTING A MIRENA IUS TO CONTROL THIS BLEEDING BUT IT DID NOT HELP. SHE UNDERWENT A HYSTERECTOMY WHICH CURED HER BLEEDING. CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP, THE LACK OF ALTERNATIVE EXPLANATION AND THE FACT THAT IT IS KNOWN THAT ESSURE USE MAY CAUSE ABNORMAL GENITAL BLEEDING, THE BLEEDING IS ASSESSED AS RELATED TO ESSURE (NOT RELATED TO MIRENA, AS IT STARTED BEFORE ITS INSERTION). THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP 23-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00697	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/30/2013
Explant Date (E7): 9/5/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043447) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT ESSURE WAS VERY PAINFUL GOING IN AND, APPROXIMATELY A MONTH INTO IT; SHE STARTED BLEEDING AND WAS IN PAIN CONSTANTLY. SHE WENT BACK FOR THE FOLLOW UP TEST IN 2013 AND CONTINUED TO BLEED. CONSUMER ALSO REPORTED PAIN OF CHECKING PLACEMENT AND STATES THAT DEATH WOULD HAVE BEEN A BETTER CHOICE. SHE SAW HER DOCTOR AND EXPLAINED THE PROBLEMS SHE WAS HAVING WITH THE PRODUCT, ACCORDING TO HER, BLEEDING WAS A CONCERN BECAUSE SHE WAS BECOMING WEAK; PHYSICIAN ADVISED THE ONLY OPTION TO CORRECT THE PROBLEMS AT HAND WERE TO HAVE A HYSTERECTOMY. ON (B)(6) 2013, SHE HAD HER HYSTERECTOMY TO FIX THE PROBLEM. AS CONCOMITANT MEDICATION, CONSUMER USED NITROFUROTON HCTZ. IN ADDITION, THE SERIOUSNESS CRITERION "OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)" WAS REPORTED. HOWEVER, IT WAS NOT SPECIFIED FOR WHICH EVENT. FOLLOW-UP RECEIVED ON 20-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE

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UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A MONTH LATER SHE STARTED BLEEDING. SHE UNDERWENT A HYSTERECTOMY TO TREAT THIS BLEEDING. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, APPROXIMATELY A MONTH AFTER INSERTION SHE STARTED BLEEDING. SHE WAS CONCERNED WITH BLEEDING BECAUSE SHE WAS BECOMING WEAK. A HYSTERECTOMY WAS PERFORMED TO TREAT IT. CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP, THE LACK OF ALTERNATIVE EXPLANATION AND ALSO CONSIDERING THE FACT THAT ESSURE USE MAY CAUSE ABNORMAL GENITAL BLEEDING, THIS BLEEDING IS ASSESSED AS RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 07-DEC-2015: ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE WAS RECEIVED FROM PHYSICIAN. A (B)64) FEMALE PATIENT WHO HAD AS PREVIOUS GYNECOLOGICAL PROBLEM A MENORRHAGIA, HAD ESSURE INSERTED ON (B)(6) 2013 (DISCREPANT INFORMATION).

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00698	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/31/2007
Explant Date (E7): 3/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043929) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007 FOR BIRTH CONTROL. CONSUMER REPORTED THAT, AFTER SHE HAD ESSURE INSERTED, SHE STARTED HAVING SYMPTOMS SURFACING. SHE HAD TO SEE DIFFERENT DOCTORS AND AN ALLERGY PHYSICIAN AND WAS PRESCRIBED A LOT OF DIFFERENT MEDICATIONS THAT SHE NEVER TOOK BECAUSE SHE IS NOT MEDICATING HER BODY. THE PHYSICIAN WHO PLANTED THE DEVICE NEVER TOLD HER THAT IT WAS A PERMANENT DEVICE AND SHE THOUGHT SHE WOULD BE ABLE TO GET IT TAKEN OUT AS SHE PLEASED TO HAVE ANOTHER CHILD IF SHE WANTED TO. THE SYMPTOMS THAT STARTED SURFACING WERE MAJORLY BAD HEADACHES THAT PUT HER IN BED, PAIN DURING SEX, CONSTANT BLEEDING AT ONE POINT, RASHES FROM MONTH TO MONTH THAT SHE HAD TO GO TO THE HOSPITAL FOR, NICKEL ALLERGY, MASSIVE TIREDNESS AND BEING IN BED A LOT FOR BARELY KEEPING HER EYES OPENED AND HAVING TO GET POLYPS REMOVED FROM HER CERVIX (PRECANCEROUS CELLS). SHE IS STILL HAVING MAJOR PAIN DURING SEX WITH HER PARTNER AND SHE HAS DEALT WITH RELATIONSHIP PROBLEMS CAUSE OF THE DEVICE AND MANY OTHER BAD THINGS HAS HAPPENED TO HER. CONSUMER HAS ALSO GAINED MASSIVE AMOUNTS OF WEIGHT OVER THE YEARS FROM IT AS WELL THAT SHE IS STILL TRYING TO WORK OFF. ON (B)(6) 2015, ESSURE DEVICE WAS EXPLANTED. THE SERIOUSNESS CRITERION "REQUIRED INTERVENTION" WAS REPORTED BUT NOT SPECIFIED OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW-UP RECEIVED ON 20-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL

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NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO STARTED HAVING CONSTANT BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND NICKEL ALLERGY AFTER SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE ALSO HAD POLYPS REMOVED FROM HER CERVIX (PRECANCEROUS CELLS). ESSURE WAS EXPLANTED 7 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR POLYPS REMOVED FROM HER CERVIX (PRECANCEROUS CELLS) WHICH IS UNLISTED . AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. ALSO, PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE; SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED. CONSIDERING THE NATURE OF THE EVENTS CONSTANT BLEEDING AND NICKEL ALLERGY, AND COMPATIBLE TEMPORAL RELATIONSHIP CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE EVENT POLYPS REMOVED FROM HER CERVIX (PRECANCEROUS CELLS), IT WAS INTERPRETED AS CERVICAL DYSPLASIA. CERVICAL DYSPLASIA MAY REFER TO PREMALIGNANT SQUAMOUS CHANGES OF THE CERVIX ALSO KNOWN AS CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN). THE MAJOR CAUSE OF CIN IS CHRONIC INFECTION OF THE CERVIX WITH THE SEXUALLY TRANSMITTED (B)(6). CONSIDERING THIS EVENT'S PATHOPHYSIOLOGY AND ESSURE'S LOCAL EFFECT IN FALLOPIAN TUBES, THE EVENT WAS ASSESSED AS UNRELATED TO ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. SINCE ESSURE REMOVAL WAS REPORTED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 20-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00699	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/10/2013
Explant Date (E7): 12/31/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043466) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR BIRTH CONTROL. CONSUMER REPORTED PERMANENT NERVOUS SYSTEM DYSFUNCTION CAUSED BY EXCESSIVE INFLAMMATION. SHE WAS ALSO DIAGNOSED WITH POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME. HER SYMPTOMS ARE EXCESSIVE TACHYCARDIA AND IRREGULAR BEATS UPON STANDING, BLOOD POOLS, SHORTNESS OF BREATH, DIZZINESS, FAINTING, UNABLE TO STAND FOR ANY LENGTH OF TIME, ANXIETY, DEPRESSION, CHRONIC FATIGUE, NAUSEA, MIGRAINES, GASTROINTESTINAL ISSUES, WEIGHT GAIN, JOINT PAIN AND SEVERE CHEST PAIN. REMOVAL OF UTERUS AND TUBES WAS PERFORMED ON (B)(6) 2013. AS CONCOMITANT MEDICATION, CONSUMER USED ZEBETA BETA BLOCKER. IN ADDITION, THE SERIOUSNESS CRITERION "HOSPITALIZATION" WAS REPORTED. HOWEVER, IT WAS NOT SPECIFIED FOR WHICH EVENT. FOLLOW-UP RECEIVED ON 20-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLOOD POOLS. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER HAD HER UTERUS AND TUBES REMOVED. CONSIDERING THE EVENT'S NATURE OF THE EVENT, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO SURGICAL INTERVENTION PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, SHE ALSO EXPERIENCED SERIOUS EVENTS POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME, PERMANENT NERVOUS SYSTEM DYSFUNCTION AND EXCESSIVE INFLAMMATION. THESE EVENTS ARE UNRELATED TO SUSPECT INSERT BASED ON THE PATHOPHYSIOLOGY AND GIVEN ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES. NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP 23-NOV-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER W

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00700	BAYER HEALTHCARE LLC	9/2/2015	9/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/16/2013
Explant Date (E7): 5/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043443) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER HAD AN ESSURE PERFORMED AND THEREAFTER, SHE SUFFERED HEAVY BLEEDING; PERIODS EVERY 15-20 DAYS LASTING 10 DAYS AT A TIME; SEVERE ABDOMINAL PAIN; CHRONIC FATIGUE; HEADACHES; ANXIETY; AND DEPRESSION. SHE SPOKE WITH HER INTERNIST AND HER GYNECOLOGIST ABOUT THE SYMPTOMS; THEY SWITCHED MEDICATION, DID ENDOMETRIAL BIOPSIES, AND DID TRANSVAGINAL ULTRASOUNDS, ALL WITH NO RESULT. ON (B)(6) 2015, SHE HAD A TOTAL HYSTERECTOMY UNDER THE ASSUMPTION SHE LIKELY HAD ENDOMETRIOSIS. HER GYNECOLOGIST REMOVED HER UTERUS, FALLOPIAN TUBES AND CERVIX, BUT HE FOUND NO ENDOMETRIOSIS DURING THE SURGERY. THE PATHOLOGY REPORT SHOWED A NORMAL RESULT. THERE WAS NO OTHER EXPLANATION FOR THESE SYMPTOMS STARTING AFTER HER ESSURE PROCEDURE. SHE STATED THAT OTHERWISE SHE IS EXTREMELY HEALTHY WOMAN. HER MEDICAL RECORDS FROM INTERNIST, GYNECOLOGIST AND THERAPIST WOULD ALL CORROBORATE HER SYMPTOMS AND THOSE SYMPTOMS COINCIDING WITH THE ESSURE PROCEDURE AND LASTING UP UNTIL THE HYSTERECTOMY. THE CONSUMER MENTIONED A REQUIRED INTERVENTION BUT DID NOT SPECIFY TO WHICH EVENT. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS

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CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE ABDOMINAL PAIN AND HEAVY BLEEDING. A HYSTERECTOMY WAS PERFORMED ALONG WITH ESSURE REMOVAL AND SHE RECOVERED FROM THE SYMPTOMS. THE ABDOMINAL PAIN AND HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING) ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE CONSUMER STATED THAT SHE SUFFERED HEAVY BLEEDING AND SEVERE ABDOMINAL PAIN (AMONG OTHER NON-SERIOUS EVENTS) AFTER ESSURE INSERTION. INITIALLY ENDOMETRIOSIS WAS SUSPECTED. HOWEVER, SHE HAD A HYSTERECTOMY AND NO ENDOMETRIOSIS WAS FOUND DURING SURGERY. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, THE LACK OF ALTERNATIVE EXPLANATION AND CONSIDERING THAT ESSURE MAY CAUSE THE PAIN AND THE HEAVY BLEEDING, THESE EVENTS ARE CONSIDERED RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENT TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 20-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA (B)(6). IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055882	BAYER	9/2/2015	9/2/2015

Event Information:

Event Date (B3): 10/6/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YES, INSURANCE COVERED THE DEVICE. 6 MONTHS AFTER IMPLANT I DEVELOPED PANCREATITIS. URGENT FREQUENT URINATION, HEAVY AND PAINFUL PERIODS, HAIR LOSS, HEADACHES, ANXIETY, WEIGHT GAIN. AS THE YEARS GO ON, ITS BEEN 11 NOW, THESE SYMPTOMS INTENSIFIED WITH AN ONSET OF JOINT PAIN, TEETH FALLING APART, LACK OF SEXUAL DESIRE, DEPRESSION, PANCREATIC PAIN. IT NOW FEELS LIKE THE SYSTEMIC INFLAMMATION IS SQUEEZING MY INSIDES CAUSING CONSTANT PAIN ONLY HELPED BY NARCOTICS. MY MOODS ARE HORRIBLE, MY PAIN ITS HORRIBLE AND I CAN'T WORK. FOR 11 YEARS I HAVE HAD NO MORE THAN 2 HOURS OF SLEEP AT A TIME DUE TO FREQUENT URINATION. I CAN'T LOSE WEIGHT AND LOOK PREGNANT. ITS BEEN A HORRIBLE EXPERIENCE AND IS RUINING MY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055883	BAYER	9/2/2015	9/2/2015

Event Information:

Event Date (B3): 6/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BLEED 4-5 HEAVY PERIODS A MONTH. THE CRAMPS ARE SO BAD THAT I CAN'T MOVE. I HAVE BLOOD CLOTS I PASS WEEKLY NOW THAT I HAVE THE ESSURE. THE DOCTORS DON'T KNOW THAT'S GOING ON AND THIS PROBLEM HAS ONLY STARTED ONCE I GOT THE ESSURE IN. PLEASE HELP ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055884	BAYER	9/2/2015	9/2/2015

Event Information:

Event Date (B3): 11/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD HEAVY PERIODS. ALOT OF NUMBING MY ARMS AND HANDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055996	BAYER HEALTH	9/2/2015	9/8/2015

Event Information:

Event Date (B3): 8/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD GOTTEN THE ESSURE PLACED IN (B)(6) 2010. IN EARLY 2011 I STARTED HAVING REALLY BAD CRAMPING PAINS, EXCESSIVE BLEEDING, CONSTANT ABDOMINAL PAIN, LOWER BACK PAIN AND SHARP SHOOTING PAINS ALL OVER MY ENTIRE ABDOMINAL AREA. I WENT BACK TO THE DOCTOR AND HE RAN A BUNCH OF TESTS AND DETERMINED THAT I NEEDED TO HAVE A PARTIAL HYSTERECTOMY BECAUSE THE METAL IN THE ESSURE COILS CAUSED ME TO HAVE AN ALLERGIC REACTION AND THAT WAS THE ONLY WAY TO REMOVE IT. I HAVE ONLY 1 OVARY LEFT AND I'M DEVASTATED BECAUSE I'M ONLY (B)(6) AND HAVE BEEN STARTING TO GO THROUGH EARLY MENOPAUSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056006	BAYER HEALTH	9/2/2015	9/8/2015

Event Information:

Event Date (B3): 6/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/9/2010
Explant Date (E7): 6/25/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE IMPLANTS AND THEY CAUSE HEAVY BLEEDING DURING MY CYCLES. I ALSO HAD PAIN IN MY PELVIS AND LOW BACK. AT TIMES IT WAS HARD FOR ME TO WALK AROUND. I HAD SURGERY IN (B)(6) OF THIS YEAR TO HAVE THEM REMOVED. I FIRST GOT THE IMPLANTS IN (B)(6) 2010.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056008	CONCEPTUS INC	9/2/2015	9/8/2015

Event Information:

Event Date (B3): 10/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2008 I HAD THE ESSURE PROCEDURE DONE AFTER THAT I CONTINUOUSLY PASSED CLOTS MY DOCTOR TRIED DIFFERENT MEDS NOTHING WORKED. LEADING TO (B)(6) 2013 HAVING A COMPLETE HYSTERECTOMY. DUE TO THE ESSURE, MY LIFE HAS COMPLETELY CHANGED, MY SEX LIFE IS NOT THE SAME AND I'M VERY DEPRESSED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056009	CONCEPTUS INC	9/2/2015	9/8/2015

Event Information:

Event Date (B3): 6/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/10/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD SEVERE CRAMPS AND BLEEDING SINCE THE ESSURE DEVICE WAS IMPLANTED. ALSO HAVE HAD RECURRING BACTERIAL VAGINITIS INFECTIONS. MASSIVE BLOOD CLOTS DURING MY PERIOD. ABDOMINAL CRAMPS NOT BEING ON MY PERIOD. IRRITABLE BOWEL. FUNKY VAGINAL DISCHARGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056010	BAYER	9/2/2015	9/8/2015

Event Information:

Event Date (B3): 8/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/7/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IS KILLING ME. PLEASE RECALL IT. I WAS HEALTHY BEFORE ESSURE IMPLANT. NOW I'M HAVING CHEST PAIN, HIGH BLOOD PRESSURE, BLOATING, HEADACHES, WEAKNESS, INSOMNIA, SAD MOOD, NON STOP BLEEDING, HORRIBLE PELVIC AND ABDOMINAL PAIN, JOINTS AND MUSCLES PAIN, HAIR BREAK, PUFFINESS, NEED TO USE EYE GLASSES, PAINFUL SEX THAT PUT ME INTO MORE BLEEDING. I'M NOT BEING ABLE TO MAKE MY NORMAL DAY WITH MY BABY, MY KID, MY HUSBAND AND MY BUSINESS. THE CONFIRMATION TEST WAS INCOMPLETE BECAUSE OF THE BLEEDING. I'M IN THE PROCESS OF MORE TEST. I WENT TO ER DUE TO CHEST PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00701	BAYER HEALTHCARE LLC	9/3/2015	9/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 857591

Single Use: Y
Implant Date (E6): 8/1/2011
Explant Date (E7): 12/20/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 21-OCT-2013 WHICH REFERS TO HERSELF A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INCREASED BACK PAIN, FOOD SENSITIVITIES WITH REACTIONS, SEVERE PAIN DURING OVULATION, PERIODS WERE A LOT HEAVIER, PERIODS WERE A LOT MORE PAINFUL, CHRONIC URINARY TRACT INFECTIONS, CHRONIC YEAST INFECTIONS, AND ADENOMYOSIS / ABNORMAL THICKENING OF MY UTERINE WALL. NO INFORMATION GIVEN ON CONSUMER'S DRUG HISTORY, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. THE CONSUMER'S MEDICAL HISTORY INCLUDED DELIVERY IN APPROXIMATELY (B)(6) 2011. IN (B)(6) 2011 (THREE MONTHS POST PARTUM) THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR UNKNOWN INDICATION. IT WAS NOT REPORTED WHETHER ESSURE WAS USED PREVIOUSLY. THE CONSUMER WAS BREAST FEEDING POST INSERTION SO SHE DID NOT HAVE PERIODS. SHE STARTED HAVING INCREASED BACK PAIN AND FOOD SENSITIVITIES WITH REACTIONS. ONCE HER PERIOD HAS RESUMED, SHE HAD SEVERE PAIN DURING OVULATION AND HER PERIODS WERE A LOT HEAVIER AND A LOT MORE PAINFUL. SHE DEVELOPED CHRONIC URINARY TRACT INFECTIONS, AS WELL AS CHRONIC YEAST INFECTIONS. MOST RECENTLY, SHE WAS DIAGNOSED WITH ADENOMYOSIS CONSIDERED AN ABNORMAL THICKENING OF MY UTERINE WALL. WITH HER LAST PERIOD, SHE HAS HAD PAIN CONSTANTLY FOR TEN DAYS STRAIGHT. THE DOCTOR WHO INSERTED THE ESSURE HAS DROPPED THIS PATIENT BECAUSE THE DOCTOR SAID THERE WAS NOTHING MORE SHE COULD DO TO HELP THIS PATIENT. A MIDWIFE AT THE SAME PRACTICE WITH A NEW HCP (WHO IS A NURSE PRACTITIONER) STATED THAT THE PATIENT MAY REQUIRE A HYSTERECTOMY. IT WAS MENTIONED TO THE PATIENT THAT IF ESSURE WAS RELEASING NICKEL INTO HER BODY, IT MAY BE THE CAUSE OF HER PAIN AND "AGGRAVATING HER FEMALE SYSTEM". EVENTS ONSET DATES

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WERE UNKNOWN. IT WAS UNKNOWN WHETHER TREATMENT WAS GIVEN AND EVENTS WERE ONGOING. REPORTER CAUSALITY: THE RELATIONSHIP WAS NOT REPORTED. FOLLOW-UP RECEIVED ON 23-OCT-2013: NO NEW CLINICAL INFORMATION. FOLLOW-UP RECEIVED ON 07-NOV-2013: INFORMATION RECEIVED FROM CONSUMER STATES THAT SHE TESTED POSITIVE TO NICKEL AND ALSO THAT SHE HAS BEEN TWICE TO ER WITH SEVERE PELVIC PAIN WITHIN LAST TWO WEEKS. FUP INFORMATION WAS RECEIVED ON 27-NOV-2013: PTC NUMBERS ASSIGNED. FOLLOW-UP RECEIVED ON 18-DEC-2013: PATIENT INFORMATION WAS UPDATED. GYNECOLOGICAL PROBLEMS INCLUDES: SHE STATED AT AGE 14, SHE HAD ONE OVARIAN CYST RUPTURE. SHE UNDERWENT "LAPAROSCOPIC SURGERY TO CLEAN IT UP AND HAD AN APPENDECTOMY AT THE SAME TIME". SPOKE WITH CONSUMER WHO AT THE TIME OF THE CALL DECLINED TO PROVIDE CONSENT TO CONTACT ANY OF HER HEALTHCARE PROVIDERS. SHE STATES THAT THE ORIGINAL PHYSICIAN WHO PERFORMED THE IMPLANT REFUSED TO SEE HER TO DISCUSS WHAT SHE WAS EXPERIENCING WITH THE ESSURE AND REQUESTING THE ESSURE BE REMOVED. AS PREVIOUSLY REPORTED, THE ESSURE, LOT NUMBER (857591), WAS IMPLANTED IN (B)(6) 2011, 3 MONTHS POSTPARTUM. SHE WAS BREASTFEEDING AND ADVISED TO USE CONDOMS AS BACK UP CONTRACEPTION. AN HSG TEST TO CONFIRM OCCLUSION WAS PERFORMED (B)(6) 2011. FOOD SENSITIVITIES BEGAN "IMMEDIATELY" POST INSERTION. SHE REPORTS SHE COULD NOT EAT WHOLE GRAIN FOOD PRODUCTS OR DAIRY PRODUCTS WITHOUT EXPERIENCING SEVERE STOMACH CRAMPS AND NAUSEA. SHE STATED SHE DID NOT HAVE THESE FOOD SENSITIVITIES PRIOR TO ESSURE PLACEMENT. SHE'S HAD TO COMPLETELY ELIMINATE WHOLE GRAIN AND DAIRY PRODUCTS FROM HER DIET. BACK PAIN AND OVULATION PAIN BEGAN IN (B)(6) 2012 AND WORSENED THIS YEAR. IN (B)(6) 2013, SHE WAS SEEN IN AN EMERGENCY ROOM FOR THE PAIN. SHE WAS TREATED WITH IV PAIN MEDICATION. SHE HAD A CT SCAN PERFORMED TO "MAKE SURE SHE DIDN'T HAVE ANY OTHER ISSUES". SHE STATED THAT ONE OF THE "TECHS" INDICATED THE SCAN LOOKS LIKE "THE MARKER WAS BROKEN ON THE ESSURE" BUT SHE SAYS NONE OF HER PROVIDERS SAID ANYTHING ABOUT THIS. SHE WAS RELEASED FROM THE ER AFTER A FEW HOURS. ONE WEEK LATER, SHE HAD AN ULTRASOUND DONE. SHE WAS TOLD BY HER PROVIDERS THAT NOTHING CAN BE SEEN ON ULTRASOUNDS AND IT APPEARED THE ESSURE ARE IN THE RIGHT PLACE. ON (B)(6) 2013 SHE SAW HER FAMILY ALLERGIST WHO DID AN ALLERGY TEST FOR NICKEL. SHE WAS TOLD SHE "WAS SIGNIFICANTLY ALLERGIC TO NICKEL (ON A SCALE OF 0-3 SHE WAS A 2)". SHE WAS ADVISED TO GET THE ESSURE REMOVED. SHE HAD NO HISTORY OF YEAST INFECTIONS PRIOR TO ESSURE. SINCE 2012, SHE HAS A YEAST INFECTION ONCE A MONTH WHICH SHE TREATS WITH GARLIC AND PROBIOTICS. ONSET DATE OF UTI WAS (B)(6) 2013. SHE HAS HAD 6 IN TOTAL WHICH ARE TREATED WITH ANTIBIOTICS. THE MOST RECENT UTI WAS LAST WEEK FOR WHICH SHE WAS PRESCRIBED CLINDAMYCIN. ADENOMYOSIS WAS DIAGNOSED BY ULTRASOUND ON (B)(6) 2013. SHE STATES WILL BE HAVING A HYSTERECTOMY ON FRIDAY, (B)(6) 2013 FOR THIS. SHE WAS TOLD THEY ARE GOING TO TRY TO "PRESERVE THE OVARIES". ON (B)(6) 2013 SHE STATED SHE HAD AN ENDOMETRIAL BIOPSY PERFORMED ("ROUTINE PRIOR TO HYSTERECTOMY") WHICH SHOWED ENDOMETRITIS. TREATMENT PROVIDED CLINDAMYCIN (SAME TREATMENT SHE WAS TAKING FOR THE RECENT UTI). SHE IS PLANNING ON THE ESSURE BEING REMOVED WITH THE SURGERY ON (B)(6) 2013. CONSUMER AGAIN, REITERATED, SHE DID NOT WANT ANY OF HER HEALTHCARE PROVIDERS CONTACTED FOR MEDICAL INFORMATION. CONSUMER WAS PROVIDED WITH BAYER MEDICAL INFORMATION TOLL FREE NUMBER TO CONTACT AT HER CONVENIENCE. INTERNAL REVIEW FROM MDR COMMITTEE REVIEW MEETING DATED 13-JAN-2014: THE INCIDENT CATEGORY WAS CHANGED TO NON-INCIDENT. REASON: EVENT ADENOMIOSIS (INDICATION OF THE SCHEDULED PROCEDURE) IS UNRELATED TO ESSURE. PTC INVESTIGATION RESULT RECEIVED ON 22-JAN-2014. THE PTC (PRODUCT TECHNICAL COMPLAINT) GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN (B)(4)." MEDICAL ASSESSMENT THE MEDICAL EVENTS REPORTED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A

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TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW UP INFORMATION RECEIVED ON 11-AUG-2015: CONSUMER REPORTED WAS IMPLANTED WITH ESSURE AFTER HER DOCTOR ADVISED HER NOT TO HAVE MORE CHILDREN. IMMEDIATELY AFTER SHE HAD BACK PAIN, PAINFUL INTERCOURSE, AND STRUGGLED WITH GASTROINTESTINAL AND WEIGHT ISSUES. OVER THE NEXT TWO YEARS THE PAIN IN HER BACK SPREAD TO HER STOMACH, INCREASING SEVERELY TO THE POINT WHERE SHE COULD NOT GET OUT OF BED AND WAS BARELY ABLE TO BE INTIMATE WITH HER HUSBAND. SHE DEVELOPED A NICKEL ALLERGY AND COULD NOT WEAR THE WHITE GOLD WEDDING RINGS (WHITE GOLD IS GOLD DIPPED IN NICKEL TO TURN IT WHITE). THIS CAUSED HER TO SEEK OUT MEDICAL CARE AND REMOVAL OF THE IMPLANTS. WHEN SHE CONTACTED HER GYNECOLOGIST, SHE REFUSED TO MAKE AN APPOINTMENT, TELLING HER THEY WERE PERMANENT AND SHE WOULDN'T REMOVE THEM. LT TOOK HER EIGHT MONTHS AND NUMEROUS EMERGENCY ROOM TRIPS, AND THREE SEPARATE SPECIALISTS TO FIND A DOCTOR WILLING TO REMOVE THEM. ON (B)(6) 2013, SHE HAD A COMPLETE HYSTERECTOMY. HER COILS WERE INTACT WITH THE EXCEPTION OF ONE MARKER AND ONE COIL WAS A JUMBLED UP MESS. SHE REPORTED THAT NINETEEN MONTHS LATER, SHE CONTINUED TO SUFFER GASTROINTESTINAL ISSUES, CHRONIC PAIN, AND STRUGGLE TO LOSE WEIGHT. SHE ALSO STRUGGLE WITH SIDE EFFECTS OF THE HYSTERECTOMY. CASE CORRECTION REGARDING INFORMATION FROM 11-AUG-2015: THE CONSUMER REPORTED VIA FDA SITE; THE REFERENCE NUMBER FOR THIS REPORT IS (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND SHE TESTED POSITIVE TO NICKEL (ON A SCALE OF 0-3 SHE WAS A 2). THIS CASE IS NOT MEDICALLY CONFIRMED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS CASE, THIS OCCURRENCE CAUSED HER TO SEEK OUT MEDICAL CARE AND REMOVAL OF THE IMPLANTS. A COMPLETE HYSTERECTOMY WAS PERFORMED. HER COILS WERE INTACT WITH THE EXCEPTION OF ONE MARKER AND ONE COIL WAS A JUMBLED UP MESS (SEEN AS DEVICE DISLOCATION). GIVEN THE EVENT'S NATURE AND BASED ON A COMPATIBLE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN THE REPORTED EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO PERFORMED SURGICAL INTERVENTION, THIS CASE WAS UPGRADED TO INCIDENT. ADDITIONALLY, OTHER SERIOUS EVENT AND NON-SERIOUS EVENTS WERE REPORTED. AN UPDATED PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 17-DEC-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: 857591; PRODUCTION DATE: MAY-2011; EXPIRATION DATE: MAY-

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00702	BAYER HEALTHCARE LLC	9/3/2015	9/3/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/15/2007
Explant Date (E7): 11/2/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT FROM A CONSUMER IN UNITED STATES WAS IDENTIFIED ON (B)(6) 2013 ON AN INTERNET WEBSITE OF A TV STATION. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MIGRAINES, SEVERE BACK PAIN, AND PELVIC PAIN. FOLLOW-UP INFORMATION RECEIVED ON 11-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (FDA-2014-(B)(4) AND FDA-2014-(B)(4)). CASE IS NOW CONSIDERED INCIDENT. ON (B)(6) 2007, ESSURE WAS PERMANENTLY IMPLANTED. A YEAR LATER, CONSUMER HAD ALL KINDS OF COMPLICATIONS AND HORRIBLE SIDE EFFECTS, FROM HEAVY PERIODS, MISSED PERIODS, DEBILITATING MIGRAINES, ANXIETY, DEPRESSION, PANIC ATTACKS, EXCESSIVE BLOATING, PAINFUL INTERCOURSE TO BACK PAIN AND EXTREME PELVIC PAIN. SHE ALSO EXPERIENCED WITH ESSURE JOINT PAIN AND MUSCLE PAIN. IN 2013 SHE WAS DIAGNOSED WITH ENDOMETRIOSIS AND PID (PELVIC INFLAMMATORY DISEASE), HAD MANY TESTING DONE FROM PELVIC ULTRA SOUNDS IN THE ER (EMERGENCY ROOM) AS WELL AS ORDERED FROM HER PHYSICIAN. SHE WAS THEN TOLD THE BEST SOLUTION WAS A PARTIAL HYSTERECTOMY LEAVING MAYBE ONE OR TWO OVARIES. ON (B)(6) 2013, HYSTERECTOMY WAS PERFORMED AND ESSURE WAS REMOVED AND FINAL DIAGNOSE WAS ENDOMETRIOSIS AND PELVIC CONGESTION SYNDROME. SHE WAS LEFT WITH ONLY ONE OVARY. AFTER REMOVAL, SHE FELT BETTER FOR ABOUT 3 MONTHS. THEN SHE FELT SICK ALL OVER AGAIN AND MORE TESTS WERE PERFORMED AND SHE WAS DIAGNOSED WITH RHEUMATOID ARTHRITIS, FIBROMYALGIA AND RAYNAUDS SYNDROME. SHE CONTINUED WITH BACK, MUSCLE AND JOINT PAIN AND RECEIVED MEDICATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO

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A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN, PELVIC INFLAMMATORY DISEASE AND RHEUMATOID ARTHRITIS. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT RHEUMATOID ARTHRITIS WHICH IS UNLISTED. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE CONSUMER HAD EXTREME PELVIC PAIN AND OTHER NON-SERIOUS EVENTS ONE YEAR AFTER INSERTION. FIVE YEARS LATER, PELVIC INFLAMMATORY DISEASE (PID) WAS DIAGNOSED AND ESSURE WAS THEN REMOVED VIA HYSTERECTOMY. SHE FELT BETTER FOR THREE MONTHS. THEN, SHE WAS SICK AGAIN AND RHEUMATOID ARTHRITIS WAS DISCOVERED. GIVEN ITS NATURE AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN PELVIC PAIN AND ESSURE USE CANNOT BE EXCLUDED. ALTHOUGH ESSURE MICRO-INSERT MAY BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT DURING INSERTION, THIS MOSTLY OCCURS IN THE FIRST WEEKS FOLLOWING PLACEMENT. SINCE PID WAS DIAGNOSED 6 YEARS AFTER INSERTION, CAUSAL RELATIONSHIP WITH SUSPECT INSERT IS VERY UNLIKELY. IN ADDITION, CONSIDERING ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES AND NEGATIVE TEMPORAL RELATIONSHIP, RHEUMATOID ARTHRITIS IS ASSESSED AS UNRELATED TO ESSURE USE. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS REPORTED ESSURE REMOVAL WAS REQUIRED (VIA PARTIAL HYSTERECTOMY) AND THEREFORE THIS CASE WAS UPGRADED TO INCIDENT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS PROVIDED ON 10-SEP-2015. THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00703	BAYER HEALTHCARE LLC	9/3/2015	9/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 825626

Single Use: Y
Implant Date (E6): 3/19/2012
Explant Date (E7): 11/13/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 21-FEB-2014 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. FOLLOW-UP RECEIVED ON 21-FEB-2014 PATIENT'S INFORMATION WAS UPDATED. ON (B)(6) 2012 ESSURE WAS INSERTED WITH LOT NUMBER 825626. ON AN UNSPECIFIED DATE (MID-YEAR LAST YEAR), THE PATIENT STARTED HAVING PAIN. IN (B)(6) 2013 HYSTERECTOMY WAS PERFORMED. PATIENT HAD ASKED FOR COILS AND DOCTOR DID GIVE PATIENT COILS. DOCTOR AT THE TIME OF REMOVAL SAID THAT PLACEMENT WAS GOOD. CASE CORRECTION AND PTC INVESTIGATION RESULT RECEIVED ON 06-MAR-2014: UPON RECEIPT OF FOLLOW-UP INFORMATION ON 21-FEB-2014, THE CASE WAS UPGRADED TO SERIOUS AND A NARRATIVE WAS CREATED. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 21-FEB-2014 WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED PAIN . NO INFORMATION GIVEN ON PATIENT'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE PATIENT RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2012 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER 825626. ON AN UNSPECIFIED DATE (MID-YEAR LAST YEAR), THE PATIENT STARTED HAVING PAIN. IN (B)(6) 2013 HYSTERECTOMY WAS PERFORMED. PATIENT HAD ASKED FOR COILS AND DOCTOR DID GIVE PATIENT COILS. DOCTOR AT THE TIME OF REMOVAL SAID THAT PLACEMENT WAS GOOD. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN PAIN AND ESSURE WAS NOT REPORTED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER GLOBAL REFERENCE NUMBER FOR THE PTC REPORT WAS (B)(4). FINAL ASSESSMENT LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED;

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THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN WI-03635, "PROCESSING ESSURE CASES IN DEV@COM." MEDICAL ASSESSMENT THE MEDICAL EVENT REPORTED IS A POSSIBLE UNDESIRABLE EVENT WITH THE USE OF ESSURE AND NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. (B)(4) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 825626 BUT NONE OF THESE CASES REFER TO A SIMILAR TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS FOUND THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP INFORMATION WAS RECEIVED ON 04-MAR-2014. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. CONCOMITANT CONDITION INCLUDED OBESITY. SHE HAD 02 PREGNANCIES AND 02 LIVE BIRTHS. IT WAS REPORTED THAT SHE EXPERIENCED DUB (INTERPRETED AS DYSFUNCTIONAL UTERINE BLEEDING), DYSMENORRHEA AND CHRONIC PELVIC PAIN SINCE ESSURE INSERTION IN 2012. ON AN UNSPECIFIED DATE AN ULTRASOUND WAS PERFORMED AND SHOWED NORMAL PLACEMENT. A RIGHT OVARIAN CYST PAIN REQUIRED PAIN MEDICATION AND THE PATIENT REQUESTED HYSTERECTOMY TO HAVE ESSURES TO BE TAKEN OUT OF HER BODY. ON (B)(6) 2013 SHE UNDERWENT TAH, RSO (INTERPRETED AS TOTAL ABDOMINAL HYSTERECTOMY, RIGHT SALPINGO-OOPHORECTOMY). NORMAL PLACEMENT WAS NOTED DURING SURGERY WITH NO EVIDENCE OF PERFORATION OR SIGNS OF INFLAMMATION GROSSLY. UTERUS WEIGHED 195 G, ADENOMYOSIS AND BEGIN CYSTS RIGHT OVARY WERE REPORTED. AFTER REMOVAL, THE PATIENT'S SYMPTOMS/PAIN RESOLVED. THE PATIENT FELT MUCH BETTER. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 11-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (FDA REFERENCE NUMBER: (B)(4)). CONSUMER REPORTED THAT HER SYMPTOMS STARTED WITH FEET SWELLING AND PUTTING ON A FEW POUNDS. SO SHE DECIDED TO JOIN A GYM AND LOSE SOME WEIGHT FOR HER UPCOMING WEDDING. TWO MONTHS INTO WORKING OUT (3-5 DAYS A WEEK) HER HEART RATE WAS RACING, HER BLOOD PRESSURE WAS DROPPING AND NOT TO MENTION SHE IS GAINING MORE AND MORE WEIGHT EVEN THOUGH SHE HAS CUT CALORIES AND STARTED DOING INTENSE BOOT CAMPS. HER PHYSICIAN SENT HER TO DO A STRESS TEST BECAUSE SOMETHING WASN'T RIGHT. STRESS TEST SHOWED EVERYTHING TO BE NORMAL. CONSUMER STATES THAT THIS WENT ON FOR THE NEXT 7 MONTHS AND IS NOW THE NEW NORM FOR HER. CONSUMER STARTED HAVING VISION CHANGES TO WHERE SHE COULD HARDLY DRIVE HER CAR. SHE COULD NOT DETERMINE HOW FAR AWAY SHE WAS FROM OTHER VEHICLES (THIS WENT AWAY AFTER ESSURE REMOVAL). CONSUMER ALSO REPORTED BRAIN FOG AND STATES THAT SHE KNEW SHE HAD DONE THINGS, BUT SHE COULDN'T FIND WORDS TO EXPRESS HERSELF OF WHAT SHE HAD DONE MOST DAYS. IT IS LIKE SHE WAS IN A CONSTANT STATE OF BEING SO DRUNK BUT NEVER DRANK A DROP. HER HUSBAND TO BE THOUGHT SHE WAS GOING CRAZY (THIS TOO WENT AWAY AFTER ESSURE REMOVAL). IN ADDITION, CONSUMER REPORTED BRAIN SHOCKS, MEMORY LOSS, LOOKING 8 MONTHS PREGNANT, VIBRATIONS IN THE VAGINA AREA, HAIR LOSS, SEVERE ACNE, LOOKED LIKE SHE HAD AGED 20 YEARS IN A FEW SHORT MONTHS, HAIR FELT LIKE STRAW, EVERYDAY FEELING LIKE SHE HAD THE FLU, LOW GRADE TEMPERATURE AT ALL TIMES AND INFORMED THAT ALL WENT AWAY AFTER ESSURE REMOVAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN/ CHRONIC PELVIC PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. A HYSTERECTOMY WAS PERFORMED AND ESSURE DEVICES WERE REMOVED. SHE STATED THAT AFTER REMOVAL, SHE FELT MUCH BETTER. CONSIDERING THE EVENT'S NATURE AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP

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WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ACCORDING TO MEDICAL ASSESSMENT, THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00704	BAYER HEALTHCARE LLC	9/3/2015	9/3/2015

Event Information:

Event Date (B3): 1/1/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2004
Explant Date (E7): 2/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN THE UNITED STATES ON 19-FEB-2014 VIA COMPANY INTERNET SITE. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND REPORTED SHE DOES NOT OWN AN UTERUS ANYMORE BECAUSE OF ESSURE. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION. CONCURRENT CONDITIONS INCLUDE A SPECIAL NEEDS CHILD. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED SHE DOES NOT OWN A DOG OR AN UTERUS ANYMORE BECAUSE OF ESSURE PERMANENT BIRTH CONTROL. MAYBE NOW SHE WILL HAVE THE ENERGY TO CARE FOR HER SPECIAL NEEDS CHILD. NO FURTHER DETAILS WERE REPORTED. FOLLOW-UP 24-FEB-2014 FOUND ON THE COMPANY SITE IN THE INTERNET: CONSUMER REPORTED HER YEAR OF BIRTH (1981), AND THAT 12 DAYS BEFORE TIME OF REPORTING SHE HAD TO HAVE HER FALLOPIAN TUBES REMOVED (NEW EVENT ADDED) AND UTERUS REMOVED BECAUSE OF ESSURE. NO FURTHER DETAILS WERE REPORTED. FOLLOW-UP FROM 02-JUL-2014: FOLLOW-UP IS NOT POSSIBLE WITH THE CONSUMER DUE TO LACK OF CONTACT INFORMATION. FOLLOW-UP INFORMATION RECEIVED ON 11-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 ((B)(4)). CONSUMER STATED SHE WAS (B)(6) WHEN SHE HAD TO HAVE A HYSTERECTOMY BECAUSE OF THE NEARLY 100 CO-OCCURRING SYMPTOMS WHICH ORIGINATED AROUND THE SAME TIME AS IMPLANTATION WHEN SHE WAS (B)(6). BEFORE SHE WAS IMPLANTED, SHE WAS A THIN, ACTIVE AND HEALTHY YOUNG WOMAN WHO COULD DO ANYTHING AND DIDN'T NEED ANY KIND OF MEDICATION. AFTER ESSURE IMPLANTATION, SHE COULD BARELY DO ANYTHING AND NEEDED OVER

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THE COUNTER AND/OR PRESCRIPTION MEDICATIONS TO FUNCTION AT ALL. SHE COULD NOT CLIMB OUT OF BED. SHE WAS EXPERIENCING ANXIETY, DEPRESSION, WILD MOOD SWINGS WHICH ULTIMATELY ENDED HER FIRST MARRIAGE, CONSTANT MIGRAINES OR ABDOMINAL PAIN. SHE HAD TO HAVE UTERUS, FALLOPIAN TUBES, CERVIX, AND PART OF HER INTESTINE TO BE REMOVED. THE INFLAMMATION FROM ESSURE CAUSED DIGESTIVE ISSUES WHICH MAKE EATING AND EVACUATING HER BOWELS A STRUGGLE. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, WAS RECEIVED FROM COMPANY INTERNET SITE AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DO NOT OWN A UTERUS ANYMORE/HAD TO HAVE MY UTERUS REMOVED AND HAD TO HAVE MY FALLOPIAN TUBES REMOVED. THE REPORTED EVENTS WERE CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT, ARE LISTED IN REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THE INFORMATION RECEIVED FOR THIS SINGLE CASE, IT CANNOT BE EXCLUDED THAT THE EVENTS OCCURRED AS A CONSEQUENCE OF ESSURE, THEREFORE THEY WERE CONSIDERED RELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED.

Manufacturer Narrative (H10):

FOLLOW UP 09-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00705	BAYER HEALTHCARE LLC	9/3/2015	9/3/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 17-MAR-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FOOD AND DRUG ADMINISTRATION (FDA), THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5034433, RECEIVED AT FDA ON 10-FEB-2014). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED INFECTION THAT KEEPS COMING BACK, NON-STOP ALLERGIC REACTION, BLOATING, IRREGULAR PAINFUL PERIODS, AND TREMENDOUS AMOUNT OF PAIN SINCE (ESSURE PROCEDURE). FDA REPORT TYPE WAS 'INJURY', REPORTED OUTCOME OF EVENTS WAS 'OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)'. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, AND CONCOMITANT MEDICATION. THE CONSUMER WAS IN PERFECT HEALTH BEFORE ESSURE. SIX MONTHS BEFORE TIME OF REPORT, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. THE CONSUMER HAD A TREMENDOUS AMOUNT OF PAIN AND BLOATING SINCE (ESSURE PROCEDURE). AN INFECTION THAT KEPT COMING BACK, IRREGULAR PAINFUL PERIODS. AND A NON STOP ALLERGIC REACTION. THE CONSUMER WAS IN PERFECT HEALTH BEFORE ESSURE, AND EVER SINCE SHE HAVE BEEN MISERABLE. CONSUMER REQUESTED TO HAVE HER PROCEDURE DONE THE OLD FASHION WAY. AND HER DOCTOR TALKED HER INTO ESSURE. HE NEVER WARNED THE CONSUMER ABOUT THE POSSIBILITY OF AN ALLERGIC REACTION AND NEVER TESTED HER FOR SENSITIVITY. CONSUMER STATED THAT THERE WAS NO DOUBT THAT ESSURE HAD NO PLACE IN THE MARKET AND IT WAS A TOTALLY IRRESPONSIBLE PRODUCT. THE CONSUMER KNEW THAT EVERY DAY THIS THING WAS BEING OFFERED SOME ONE ELSE'S LIFE WAS BEING RUINED. SHE COULD NOT BELIEVE WITH ALL THE UPROAR PERTAINING TO THIS PRODUCT NOTHING HAD BEEN DONE YET. CONSUMER HAD NOTHING ELSE TO SAY, SHE COULD SPIT FIRE. FOLLOW-UP 22-APR-2014: CONSUMER ANSWERED TO FOLLOW-UP QUESTIONS ON

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PHONE. CONSUMER REPORTED THE INFECTION WAS LOCATED IN PELVIC REGION (LIKE BACTERIAL VAGINOSIS). IT STARTED ABOUT MONTH AFTER ESSURE WAS IMPLANTED. IT OCCURRED OFF AND ON. TREATMENT WITH ANTIBIOTICS HAD BEEN PRESCRIBED OVER THE PHONE. NO FURTHER DETAILS WERE REPORTED. FOLLOW UP 11-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE (#(B)(4)), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. CONSUMER REPORTED THAT AFTER ESSURE PLACEMENT SHE NOTICED A DECLINE IN HEALTH WHICH SLOWLY BUT STEADILY GOT WORSE OVER THE TWO YEAR PERIOD OF HAVING ESSURE. LT STARTED OUT AS A RASH, IMMEDIATELY THE VERY NEXT DAY SHE NOTICED AND FELT SHE WAS HAVING A REACTION TO ESSURE. OVER TIME THE RASH SUBSIDED. THE ONLY THING SHE DID WAS CUT DOWN ON FOODS AND STUFF THAT CONTAINED NICKEL. SHE HAD (CHRONIC) PAIN, EXCRUCIATING MENSTRUAL CYCLES, LOSS OF RANGE IN MOTION, REDUCTION IN MOBILITY, MEANING IT HURT TO STAND, TO LAY, TO SIT UP FROM LAYING, PRETTY MUCH EVERYTHING SHE DID HURT. HER QUALITY OF LIFE SEVERELY DECREASED. HUGE BLOOD CLOTS, HAIR LOSS, MASSIVE LIKE CRAZY MONTHLY GLOW. SHE WAS DEPRESSED, BLOATED AND MISERABLE, AND HER IMPLANTING DOCTOR TOLD HER SHE WAS WAY OFF BASE. SHE HAD TESTS DONE A CAT SCAN AND STUFF, HER PRIMARY CARE PROVIDER AND HER GYNECOLOGIST, BOTH AGREED IT WAS ESSURE CAUSING HER PROBLEMS. SHE HAD A HYSTO (INTERPRETED AS HYSTERECTOMY). SHE MENTIONED THAT THE PAIN FROM HER HYSTO FELT LIKE A WALK IN THE PARK IN COMPARISON TO THE PAIN SHE WAS IN BEFORE. AT THE TIME OF THE REPORT SHE WAS ABOUT 2 WEEKS IN, SHE WAS JUST CUT OPEN AND HAD THIS STUFF REMOVED. CONSUMER MENTIONED THAT SHE COULD RUN A MARATHON, THAT WAS HOW HIGH HER PAIN TOLERANCE IS NOW. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED TREMENDOUS AMOUNT OF PAIN SINCE ESSURE PROCEDURE, CHRONIC (INTERPRETED AS PELVIC PAIN), AND HUGE BLOOD CLOTS (INTERPRETED AS GENITAL BLEEDING). SHE ALSO REPORTED AN INFECTION IN PELVIC REGION (LIKE BACTERIAL VAGINOSIS), STARTED ABOUT MONTH AFTER ESSURE IMPLANTED OFF AND ON. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENTS TREMENDOUS AMOUNT OF PAIN SINCE ESSURE PROCEDURE, CHRONIC AND HUGE BLOOD CLOTS, THEY WERE ASSESSED AS RELATED TO ESSURE. REGARDING THE EVENT INFECTION IN PELVIC REGION (LIKE BACTERIAL VAGINOSIS), STARTED ABOUT MONTH AFTER ESSURE IMPLANTED OFF AND ON, GIVEN THE NATURE OF THE EVENT AND SINCE IT STARTED A MONTH AFTER INSERTION PROCEDURE (WEAK TEMPORAL RELATIONSHIP WITH THE PROCEDURE), CAUSALITY WITH ESSURE WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS UPGRADED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION, DUE TO REQUIRED INTERVENTION (HYSTERECTOMY).

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00706	BAYER HEALTHCARE LLC	9/3/2015	9/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/29/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038049) IN UNITED STATES ON 06-FEB-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. SINCE THE TIME IT WAS IMPLANTED, SHE WAS EXPERIENCING SEVERE MIGRAINES, 2-4 TIMES A WEEK, HOT FLASHES, NIGHT SWEATS, PELVIC PAIN, BACK PAIN, JOINT PAIN, FACIAL HAIR GROWTH AND NAUSEA. SHE WAS DIAGNOSED WITH RAYNAUD'S SYNDROME. SHE WAS ALSO EXPERIENCING SHOOTING PAINS THROUGH HIPS AND DOWN LEGS, BREAST PAIN, CHEST PAIN, WEIGHT LOSS, UNEXPLAINED RASHES AND THE SKIN ON THE PALMS OF HANDS WAS PEELING. CONSUMER REPORTED DISABILITY OR PERMANENT DAMAGE AS EVENT OUTCOME, HOWEVER SHE DID NOT SPECIFY IT. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-FEB-2015: THE BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). THE FINAL ASSESSMENT WAS: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. THE MEDICAL ASSESSMENT WAS: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 01-APR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. FOLLOW UP 11-AUG-2015: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA HEALTH AUTHORITY FDA DOCKET (#(B)(4)). CONSUMER REPORTED THAT SHE HAD ESSURE IMPLANTED IN (B)(6) 2012. SHE WAS A HEALTHY (B)(6) FEMALE. NO HISTORY OF ILLNESS OR REPRODUCTIVE PROBLEMS. AT HER 2 WEEKS POST IMPLANTATION CHECK-UP WITH HER GYNECOLOGIST SHE MADE HIM AWARE OF THE UNBEARABLE PAIN IN HER LOWER LEFT QUADRANT AND IN HER CHART WAS MARKED THAT PATIENT WAS OK. OVER THE NEXT TWO YEARS SHE HAD FREQUENT MIGRAINE HEADACHES, CHRONIC DEBILITATING PELVIC PAIN, JOINT PAIN, LOWER BACK PAIN, CHEST PAIN, RASHES, HIVES, PAINFUL AND HEAVY PERIODS, SHOOTING PAINS IN HER VAGINA, AND PAINFUL INTERCOURSE. SHE WAS ALSO DIAGNOSED WITH RAYNAUD'S AND SPASTIC PELVIC FLOOR SYNDROME. SHE WOULD LIKE TO AGAIN POINT OUT THAT BEFORE THE ESSURE PROCEDURE SHE HAD NO HEALTH ISSUES. ON (B)(6) 2015 SHE HAD TO HAVE A HYSTERECTOMY AND SHE WAS (B)(6). THE PATHOLOGY REPORT SHE RECEIVED GAVE HER THESE MOST NOTABLE FINDINGS ACUTE AND CHRONIC CERVICITIS, ADENOMYOSIS, MULTIPLE PERITUBAL CYSTS, AND NABOTHIAN CYST FORMATION. SINCE HER HYSTERECTOMY MOST OF HER HEALTH ISSUES HAVE IMPROVED. SHE DOES HOWEVER STILL SUFFER FROM RAYNAUDS. SHE MENTIONED THAT SHE WAS NOT ASKED IF SHE HAD ANY TYPE OF NICKEL OR ANY METAL ALLERGY AND WAS TOLD BY HER IMPLANTING DOCTOR THAT THE COILS WERE PLASTIC. NO ADDITIONAL DETAILS WERE PROVIDED. FOLLOW-UP RECEIVED ON 20-AUG-2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC DEBILITATING PELVIC PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE (DISABILITY OR PERMANENT DAMAGE WAS REPORTED AS EVENT OUTCOME) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, THE CONSUMER HAD UNBEARABLE PAIN IN HER LOWER LEFT QUADRANT 2 WEEKS POST IMPLANTATION. THEN, OVER THE FOLLOWING TWO YEARS, SHE DEVELOPED CHRONIC DEBILITATING PELVIC PAIN AND OTHER NON-SERIOUS EVENTS. SHE HAD TO HAVE A HYSTERECTOMY AND SINCE THEN MOST OF HER HEALTHY ISSUES HAVE IMPROVED (POSITIVE DECHALLENGE) GIVEN EVENT'S NATURE AND POSITIVE DECHALLENGE, CAUSALITY WITH ESSURE THERAPY CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, IN WHICH REQUIRED INTERVENTION RELATED TO DEVICE (HYSTERECTOMY) WAS REPORTED, THIS CASE WAS UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00707	BAYER HEALTHCARE LLC	9/3/2015	9/3/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA SOCIAL MEDIA IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (NO DETAILS REPORTED). CONSUMER REPORTED THAT SHE FELT LIKE HER PELVIS WAS BURNING ALL THE TIME. HER UTERUS FELT LIKE IT WAS ON FIRE, EVERYTHING, HER SIDE, IT WAS ON FIRE. THE PAIN RADIATED NOT JUST FROM HER PELVIS, IT RADIATED DOWN HER LEGS, AND HER HAIR STARTED FALLING OUT. FOLLOW-UP RECEIVED ON (B)(6) 2015: NO NEW INFORMATION. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS

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NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0171). IN 2010, THE CONSUMER HAD ESSURE INSERTED. ACCORDING TO HER, FROM THE MOMENT IT WAS PLACED HER BODY HAD BEEN REJECTING IT. SHE WENT TO DOCTORS, HAD EMERGENCY ROOM VISITS (COUNTLESS OF THEM), HOSPITAL STAYS. HER RELATIONSHIP ENDED BECAUSE SHE WAS CONSTANTLY IN PAIN. SHE WAS SUBMITTED TO THREE SURGERIES AND STILL HAS TO HAVE TWO MORE BECAUSE ESSURE HAS INFUSED HER ORGANS TOGETHER. CASE IS CONSIDERED INCIDENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE INSERTED AND SHE FELT LIKE HER PELVIS WAS BURNING ALL THE TIME, SHE WAS CONSTANTLY IN PAIN (HER PAIN RADIATED FROM PELVIS). ACCORDING TO HER SHE WAS SUBMITTED TO 3 SURGERIES AND WENT TO THE EMERGENCY ROOM/HOSPITAL SEVERAL TIMES. ADDITIONALLY, SHE STATED ESSURE HAS INFUSED HER ORGANS TOGETHER. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY PELVIC PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE CONSUMER REPORTED CONSTANT PELVIC PAIN AFTER ESSURE PLACEMENT. CONSIDERING EVENT'S NATURE AND THE SUGGESTIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT, LIMITED INFORMATION WAS PROVIDED AND ITS EXACT NATURE WAS NOT SPECIFIED (UNCLEAR IF IT REFERRED TO PELVIC ADHESIONS OR OTHER DISORDER). HOWEVER SINCE CONSUMER RELATED IT TO ESSURE, CAUSALITY CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE MEDICAL (ER VISITS AND HOSPITAL STAYS) AND SURGICAL INTERVENTIONS (NOT SPECIFIED) WERE REQUIRED FOR TREATMENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. NO FOLLOW-UP WILL BE PURSUED SINCE THIS CASE WAS RECEIVED VIA SOCIAL MEDIA.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00709	BAYER HEALTHCARE LLC	9/3/2015	9/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7): 8/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 11-AUG-2015 WHICH REFERS TO AN ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. ON AN UNSPECIFIED DATE THE PATIENT EXPERIENCED BLEEDING AND HCP (HEALTH CARE PROFESSIONAL) REMOVED BOTH DEVICES VIA HYSTEROSCOPY WITH GRASPERS IN THE OPERATING ROOM ON (B)(6) 2015. THE PATIENT DID NOT HAVE HER HSG TEST DONE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 20-AUG-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE AE CASE REFERS ALSO TO A TREATMENT NONCOMPLIANCE. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL

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ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING. THIS EVENT, REGARDED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, PATIENT DID NOT HAVE HER HSG TEST DONE. SHE HAD BOTH DEVICES REMOVED VIA HYSTEROSCOPY WITH GRASPERS. CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO SURGICAL INTERVENTION PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 23-SEP-2015: PHYSICIAN CONFIRMED THAT THIS WAS THE ONLY PATIENT THAT SHE REMOVED THE ESSURE FOR. NO NEW CLINICAL INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00710	BAYER HEALTHCARE LLC	9/3/2015	9/3/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ABOUT A YEAR AND A HALF FROM THE TIME OF THE REPORT ((B)(4) 2014). SHE REPORTED HAS BEEN DEALING WITH CHRONIC INFECTIONS SINCE. AT TIME OF THE REPORT, SHE WAS EXPERIENCING FOR FOURTH TIME SHE'S HAD SEPTICEMIA. SHE STATED THAT THESE SYMPTOMS STARTED A COUPLE OF WEEKS AFTER ESSURE INSERTION. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(6) FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC INFECTIONS (REGARDED AS PELVIC INFECTIONS), WHICH IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, AND HAD SEPTICEMIA, WHICH IS UNLISTED. THE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE. IN THIS CASE, THE EVENTS OCCURRED A COUPLE OF WEEKS AFTER ESSURE INSERTION. THE OCCURRENCE OF CHRONIC INFECTIONS MIGHT HAVE LED TO SEPTICEMIA. ALTHOUGH THIS CASE WAS REPORTED WITH LIMITED INFORMATION, CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP AND THAT A CONTRIBUTORY OF ESSURE INSERT IN OCCURRENCE OF THESE EVENTS IS LIKELY, CAUSALITY WITH SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. SINCE SEPSIS WITHIN 4 WEEKS AFTER INSERTION OF ESSURE IS A SERIOUS INJURY EVENT, THIS CASE WAS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-NOV-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056034	CONCEPTUS INCORPORATED	9/3/2015	9/9/2015

Event Information:

Event Date (B3): 4/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A36524

Single Use: *
Implant Date (E6): 4/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE THURSDAY, ON (B)(6) 2015 BY DR. (B)(6) IN (B)(6). IT WAS VERY PAINFUL AND I WAS IN AND OUT OF SLEEP OR CONSCIOUSNESS. DR. SAID SHE'D NEVER SEEN ANYONE HAVE THAT KIND OF REACTION TO THE SEDATION. SATURDAY I HAD BRIGHT RED SPOTTING THEN BLEEDING. THE FOLLOWING WEDNESDAY I WAS BLEEDING AND CRAMPING. ON (B)(6) THE PAIN WAS TOO BAD TO SLEEP. I DECIDED I WOULD CALL NURSE THE NEXT DAY. I (B)(6) PROBLEMS AFTER ESSURE TO TRY AND SEE IF THIS WAS NORMAL. THIS WAS THE FIRST TIME I'D READ ABOUT ALL THE PROBLEMS. I WOULD HAVE NEVER HAD IT DONE IF I HAD READ THIS BEFOREHAND. ON (B)(6), TOO PAINFUL TO SLEEP OR SHOWER. TEXTED NURSE WHO REPLIED DR. SAID I SHOULDN'T STILL BE HURTING/BLEEDING AND COULD I COME RIGHT IN. DR. SAID SHE'D NEVER HEARD OF ANY OF THE "HORROR STORIES" I'D JUST READ ABOUT. I HAD AN INFECTION. SHE PRESCRIBED ANTIBIOTICS, PAIN PILLS, AND PROGESTERONE. THREE MONTHS LATER WHEN I WENT BACK FOR MY DYE X-RAY CONFIRMATION PROCEDURE, IT SHOWED ONE OF MY COILS HAD MIGRATED FROM MY FALLOPIAN TUBE AND WAS IN MY UTERUS. I DO NOT KNOW IF IT IS "FLOATING AROUND" OR IF IT HAS GROWN INTO THE WALL OF UTERUS. I HAVE ALSO EXPERIENCED IRREGULAR MENSTRUAL CYCLES SINCE IMPLANTATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00708	BAYER HEALTHCARE LLC	9/4/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043442) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON 2012. CONSUMER REPORTED THAT SHE IS NOW DIAGNOSED WITH CERVICAL DYSPLASIA AND HAD TO HAVE CRYOTHERAPY. SHE HAS BLEEDING BETWEEN HER PERIODS, INCREASED ANXIETY DURING PREMENSTRUAL SYNDROME, AND EXCESSIVE WEIGHT GAIN. AS CONCOMITANT MEDICATION, CONSUMER USES NAPROXIN. IN ADDITION, THE SERIOUSNESS CRITERION "OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)" WAS REPORTED BUT NOT SPECIFIED OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW UP INFORMATION WAS RECEIVED ON 11-AUG-2015: CASE UPGRADED TO INCIDENT. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE (#(B)(4)), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. IN 2013 (PREVIOUSLY REPORTED AS 2012) ESSURE WAS IMPLANTED FOR STERILIZATION. SHE DID GO TO THE HSG (HYSTEROSALPINGOGRAM) TESTING AND WAS ADVISED ALL WAS GOOD. SINCE THEN, SHE STARTED EXPERIENCING SEVERAL SIDE EFFECTS, SUCH AS WEIGHT GAIN, HAIR LOSS, PELVIC PAIN, BLEEDING BETWEEN HER CYCLE, BLEEDING AFTER INTERCOURSE. SHE HAS ENDURED AN ABLATION POST ESSURE; THAT FOLLOWED WITH AN ABNORMAL PAP AT AGE (B)(6). SHE THEN UNDERWENT A COLPOSCOPY WHICH WAS FOLLOWED BY CRYOSURGERY. SHE WAS STILL HAVING CHRONIC PELVIC PAIN AND WAS SENT FOR ULTRASOUND FOR WHICH SHE WAS AWAITING RESULTS. SHE WAS IN A STATE OF CONSTANT FATIGUE. SHE WENT FROM RUNNING 5 MILES A DAY AND NOW WAS NOT BEING ABLE TO STAND ON HER FEET FOR 15 MINUTES WITHOUT NEEDING TO SIT DOWN. SHE WAS FEELING COMPLETELY AT A LOSS. PRIOR TO ESSURE, SHE WAS A HEALTHY WOMAN. DEPRESSION AND ANXIETY AS WELL AS PMDD (INTERPRETED AS PREMENSTRUAL DYSPHORIC

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DISORDER) WERE ALSO REPORTED. FOLLOW-UP INFORMATION RECEIVED ON 25-AUG-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS DIAGNOSED WITH CERVICAL DYSPLASIA. SHE ALSO HAD BLEEDING BETWEEN HER PERIODS AND UNDERWENT AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. CERVICAL DYSPLASIA IS AN UNLISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS LISTED. CERVICAL DYSPLASIA MAY REFER TO PREMALIGNANT SQUAMOUS CHANGES OF THE CERVIX ALSO KNOWN AS CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN). THE MAJOR CAUSE OF CIN IS CHRONIC INFECTION OF THE CERVIX WITH THE SEXUALLY TRANSMITTED (B)(6). CONSIDERING THIS EVENT'S PATHOPHYSIOLOGY AND ESSURE'S LOCAL EFFECT IN FALLOPIAN TUBES, THE EVENT WAS ASSESSED AS UNRELATED TO ESSURE. REGARDING THE EVENT BLEEDING BETWEEN HER PERIODS, AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. ALTHOUGH IN THE PRESENT CASE, THE CERVICAL DYSPLASIA MAY HAVE HAD A CONTRIBUTORY ROLE IN THE OCCURRENCE OF THIS BLEEDING, GIVEN THE NATURE OF THIS EVENT A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION STATING THE CONSUMER UNDERWENT AN ABLATION (REQUIRED INTERVENTION). ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 24-SEP-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00712	BAYER HEALTHCARE LLC	9/4/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 11-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER REPORTED THAT SINCE ESSURE IMPLANTED SHE HAS HAD OVER 75 ADVERSE SIDE EFFECTS, MOST SIDE EFFECTS DISAPPEARED AFTER RECEIVING A HYSTERECTOMY TO RID HER BODY OF ALL ESSURE AND EVERY BODY ORGAN THAT WAS DIRECTLY CONTAMINATED OR DAMAGED BY ESSURE. SHE HAS NEVER HAD ANY PRE ESSURE MEDICAL CONDITIONS NOR DID SHE VISITED A DOCTOR EXCEPT FOR HER ANNUAL EXAM. SINCE ESSURE WAS IMPLANTED SHE HAS HAD MANY MEDICAL ISSUES AND CONTINUE TO EVEN AFTER REMOVAL. SHE HAD MUSCLE FAILURE, ARTHRITIS CHRONIC FATIGUE, METAL TOXICITY, ASTHMA, ALLERGIES, CHRONIC INFLAMMATION AND CAUSE ENOUGH INTERNAL TURMOIL TO CAUSE ALL THE ORGANS TO FUSE TOGETHER. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO NA ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALLERGIES AND METAL TOXICITY. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. ALLERGY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE METAL TOXICITY IS UNLISTED. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING AND RASH. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. IN SPITE OF THE FACT OF ALLERGIES HAVE NOT IMPROVED AFTER HYSTERECTOMY, A CONTRIBUTORY ROLE OF ESSURE FOR THIS EVENT CANNOT BE TOTALLY EXCLUDED. ALTHOUGH ESSURE RELEASES NICKEL, THE AMOUNT IS

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NOT ENOUGH TO CAUSE METAL TOXICITY. THUS, THIS EVENT IS ASSESSED AS UNRELATED TO ESSURE. ALSO, NON-SERIOUS EVENTS WERE REPORTED. AS AN INTERVENTION WAS REQUIRED (HYSTERECTOMY) THIS CASE IS ASSESSED AS INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00713	BAYER HEALTHCARE LLC	9/4/2015	9/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-0034) IN (B)(6) ON 11-AUG-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE STATED THAT SHE LIVED FOR A FEW YEARS WITH THE PAIN, THE BLEEDING, THE DEPRESSION, THE BLOATING, AND THE MIGRAINES. SHE WAS ALSO DIAGNOSED WITH FIBROMYALGIA AFTER BEING IMPLANTED WITH ESSURE. ACCORDING TO HER, A CHRONIC PAIN CONDITION SHE WILL LIVE WITH THE REST OF HER LIFE. SHE HAD TO HAVE A HYSTERECTOMY AND SALPINGECTOMY AT THE (B)(6). MOST OF HER ISSUES WENT AWAY AFTER ESSURE REMOVAL BUT THE CHRONIC PAIN, FATIGUE, BARING FOG AND OTHER ISSUES OF FIBRO WILL BE WITH HER THE REST OF HER LIFE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING FOR A FEW YEARS AMONG OTHER NON-SERIOUS EVENTS. SHE UNDERWENT A HYSTERECTOMY AND SALPINGECTOMY. THIS EVENT, INTERPRETED AS GENITAL BLEEDING IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER STATED SHE LIVED FOR A FEW YEARS WITH BLEEDING. THE DATES OF ESSURE INSERTION AND REMOVAL AND THE ONSET DATE OF THE BLEEDING WAS NOT REPORTED. HOWEVER, CONSIDERING THE IMPLIED COMPATIBLE TEMPORAL RELATIONSHIP, AND LACK OF ALTERNATIVE EXPLANATION, CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE BLEEDING CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO SURGICAL REQUIRED INTERVENTION.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00714	BAYER HEALTHCARE LLC	9/4/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON A FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY IN UNITED STATES ON 11-AUG-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR ALMOST 9 YEARS. THE CONSUMER HAD A CHRONIC PELVIC PAIN AND MANY OTHER SIDE EFFECTS THAT SHE TRIED TO TREAT FOR YEARS - IT CAUSED HER MANY PAINFUL YEARS. A TOTAL HYSTERECTOMY WAS PERFORMED TO REMOVE ESSURE. THE CONSUMER CONSIDERED THE EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD CHRONIC PELVIC PAIN THAT SHE TRIED TO TREAT FOR YEARS. A TOTAL HYSTERECTOMY WAS PERFORMED TO REMOVE ESSURE. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER HAD CHRONIC PELVIC PAIN FOR YEARS. CONSIDERING THE IMPLIED COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00715	BAYER HEALTHCARE LLC	9/4/2015	9/4/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2013
Explant Date (E7): 6/1/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 11-AUG-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. PRIOR TO ESSURE INSERTION, THE CONSUMER WAS ACTIVE AND HEALTHY AND HAD REGULAR, MODERATELY LIGHT AND PAINLESS PERIODS. IMMEDIATELY AFTER INSERTION, SHE BEGAN EXPERIENCING EXTREMELY PAINFUL AND HEAVY PERIODS. WITHIN TWO WEEKS FROM THE TIME OF INSERTION, SHE WAS EXPERIENCING DRENCHING NIGHT SWEATS AND SEVERE HEADACHES. BY THREE WEEKS OUT, SHE GAINED 15 POUNDS IN A 3-WEEK TIME PERIOD. OVERALL, SHE PUT ON WEIGHT 20 POUNDS WHILE ESSURE WAS INSERTED. HER URINE HAD A FOUL ODOR AND SHE HAD A CONSTANT METALLIC TASTE IN HER MOUTH. AT TIMES, HER ABDOMEN WOULD BLOAT TO THE POINT WHERE SHE LOOKED LIKE SHE WAS PREGNANT IN HER THIRD TRIMESTER. ABOUT 3 MONTHS AFTER INSERTION, SHE WAS IN SO MUCH PAIN. THE CONSUMER SUFFERED INCREDIBLE BRAIN FOG, WHERE SHE WOULD HAVE DIFFICULTY COMPLETING THOUGHTS OR WHERE SHE WOULD USE A COMPLETELY INCORRECT WORD IN THE WRONG CONTEXT. SHE WAS STILL STRUGGLING WITH THIS. IN (B)(6) 2014 THE DOCTOR AGREED TO REMOVE ESSURE ONLY BECAUSE A DERMATOLOGIST TESTED THE CONSUMER AS POSITIVE FOR NICKEL ALLERGY. A LAPAROSCOPY WAS PERFORMED AND MOST OF THE EVENTS WERE GONE ALMOST IMMEDIATELY AFTER REMOVAL. FOLLOWING REMOVAL SURGERY, SHE HAD TO UNDERGO THREE MONTHS OF PHYSICAL THERAPY AS A RESULT OF COMPLICATIONS FROM THE LAPAROSCOPY. THE CONSUMER CONSIDERED ALL THE EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED

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CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS TESTED POSITIVE FOR NICKEL ALLERGY AND HAD DIFFICULTY COMPLETING THOUGHTS. ESSURE WAS REMOVED 6 MONTHS AFTER INSERTION, VIA LAPAROSCOPY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. NICKEL ALLERGY IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE; SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED. THEREFORE, GIVEN THE NATURE OF THE EVENT NICKEL ALLERGY, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE EVENT DIFFICULTY COMPLETING THOUGHTS; CONSIDERING THE NATURE OF THIS EVENT, ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, AND THE FACT THAT THE EVENT DID NOT RESOLVE AFTER ESSURE REMOVAL, CAUSALITY WITH ESSURE WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (LAPAROSCOPY WITH ESSURE REMOVAL). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00716	BAYER HEALTHCARE LLC	9/4/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED NOT TO HAVE ANYMORE CHILDREN. THE CONSUMER EXPERIENCED NUMB HANDS AND FEET, SEVERE BLOATING, SWOLLEN FEET, ANKLES AND HANDS, HEADACHES, EXTREME FATIGUE, ITCHING, CONSTANT URINATION, HEAVY PAINFUL MENSTRUAL CYCLES, JOINT PAIN AND MOODINESS. SHE WAS SCHEDULED FOR A LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY (LAVH) ON (B)(6) 2015 AND BELIEVED THE EVENTS WERE RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY MENSTRUAL CYCLES. SHE WAS SCHEDULED TO HAVE A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00717	BAYER HEALTHCARE LLC	9/4/2015	9/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 7/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)), AWARENESS DATE 11-AUG-2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. CONSUMER HAS SUFFERED FROM SEVERE PELVIC PAINS AND SEVERE PERIODS, DEPRESSION AND ANXIETY. SHE NEEDED TO HAVE A TOTAL HYSTERECTOMY ON (B)(6) 2015 AND STATES THAT SHE WANTED TO MAKE SURE THAT ESSURE WAS COMPLETELY REMOVED FROM HER BODY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PELVIC PAINS. SHE HAD A TOTAL HYSTERECTOMY 8 YEARS AFTER ESSURE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056063	BAYER	9/4/2015	9/10/2015

Event Information:

Event Date (B3): 12/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): WSS305
Catalog # (E4):
Lot #(E4): 654824

Single Use: *
Implant Date (E6): 12/7/2014
Explant Date (E7): 6/3/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE (B)(6) 2009. NO MENTION OF POSSIBLE SIDE EFFECTS NOR WAS I ASKED OF ANY METAL ALLERGIES (I WOULD HAVE SAID YES AND REFUSED THE PROCEDURE RIGHT THEN). REFERENCE NUMBER: (B)(4), LOT #654824. I BEGAN COMPLAINING ABOUT PELVIC PAIN AND PERIODS LASTING 2 WEEKS OUT OF EACH MONTH (WHICH DID NOT BEGIN UNTIL AFTER ESSURE IMPLANTATION). IN (B)(6) OF 2011, AFTER ANOTHER COMPLAINT OF PELVIC PAIN, CT SCANS REVEALED A 10CM MASS (NEVER HAD A TUMOR OR CYST PRIOR TO ESSURE IMPLANTATION) ATTACHED TO MY RT OVARY. IN (B)(6) OF 2012, THE TUMOR AND RT OVARY WERE REMOVED. PELVIC PAIN AND SWELLING CONTINUED, WITH MY GYNECOLOGIST TELLING ME THAT IT IS IMPOSSIBLE FOR ME TO HAVE PAIN IN THAT AREA SINCE THE OVARY WAS REMOVED. BETWEEN 2012 AND 2015 NUMEROUS CT AND ULTRASOUND WERE PERFORMED, BUT THE SOURCE OF THE PAIN WAS NOT VISIBLE. IN ADDITION TO CONSTANT PAIN, SWELLING, AND EXCESSIVE BLEEDING AND LONG PERIODS, I ALSO EXPERIENCED DIZZINESS. TWO MAJOR FALLS DOWN THE STAIRS RESULTED IN LONG-TERM INJURY. THE DATE OF THE 1ST I CAN'T REMEMBER, BUT THIS RESULTED IN CONSTANT PAIN WHEN SITTING OR STANDING THAT CONTINUES TO THIS DAY. THE SECOND FALL OCCURRED IN (B)(6) OF 2013 AND I LOST CONSCIOUSNESS AND HAVE NO MEMORY OF THE FALL. I RECEIVED A CONCUSSION AND NOW SUFFER FROM POST-CONCUSSION SYNDROME. THIS HAS COMPLETELY ALTERED MY LIFE AND MY ABILITIES. MEMORY AND CONCENTRATION ARE MOST SIGNIFICANTLY IMPACTED. I AM A GRAD STUDENT AND HAVE STRUGGLED IMMENSELY SINCE THIS INCIDENT. EVERYTHING IS MORE DIFFICULT THAN IT WAS BEFORE. GETTING BACK TO THE CONSTANT PAIN AND BLEEDING PROBLEMS, (B)(6) 2015 MY PERIOD BEGAN AND DID NOT STOP. THE PAIN INCREASED AND I BECAME ANEMIC AND EXTREMELY TIRED. THE DECISION WAS MADE, BASED ON CONSTANT PROBLEMS SINCE THE IMPLANTATION OF ESSURE, TO HAVE A HYSTERECTOMY. THIS WAS DONE ON (B)(6) 2015.

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BUT I HAD TO GO TO A DIFFERENT GYNECOLOGIST, AS THE ONE THAT DID MY ESSURE PROCEDURE ONLY DISMISSED MY COMPLAINTS. THE "ACKNOWLEDGED" SIDE EFFECTS OF ESSURE ARE FAR BEYOND WHAT ANY WOMAN SHOULD HAVE TO ENDURE. THEY ARE NOT MINIMAL AND THEY SIGNIFICANTLY IMPACT LIFE IN A VERY NEGATIVE WAY. THE ESCALATION OF THE "ACCEPTED" SIDE EFFECTS LEADING TO A HYSTERECTOMY IS UNACCEPTABLE. THIS IS A PRODUCT THAT SHOULD BE IMMEDIATELY TAKEN OFF THE MARKET AND BAYER SHOULD HAVE TO PAY FOR THE DAMAGES AND SUFFERING THAT WOMEN WITH ESSURE HAVE HAD TO ENDURE. EXACT DETAILS ON NUMBER OF TESTS AND DATES OF TESTS AS WELL AS NUMBER OF VISITS TO THE DOCTOR WAS NOT AVAILABLE. I CANNOT AFFORD THE COST FOR THE MEDICAL RECORDS. I NO LONGER HAVE ANY SICK LEAVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056065	BAYER	9/5/2015	9/10/2015

Event Information:

Event Date (B3): 5/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/8/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

CONSTANT PAIN AFTER THE ESSURE WAS IMPLEMENTED. ON THE VERGE OF LOSING MY FIANCE BECAUSE INTIMACY IS SO PAINFUL. I ALWAYS HAVE SHARP SHOOTING PAIN OUT OF NO WHERE. MY PERIODS ARE NOT NORMAL, SEEMS TO BE MORE CLOTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056067		9/6/2015	9/10/2015

Event Information:

Event Date (B3): 12/23/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 627404

Single Use: *
Implant Date (E6): 12/23/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IMPLANT AROUND (B)(6) 2008. WITHIN THE FIRST MONTH AND A HALF I EXPERIENCED A LOT OF CRAMPING AND BACK PAIN, WHICH I ASSUMED WAS FROM THE IMPLANT BEING PLACED OR THAT I HAD A UTI OR SOMETHING. I WENT TO THE BATHROOM ONE MORNING AND NOTICED THAT ONE OF THE IMPLANTS HAD COME OUT. I CALLED MY DOCTOR'S OFFICE THEY ADVISED ME TO COME IN AND THEY CONFIRMED IT WAS THE IMPLANT. I WAS SENT TO HAVE THE HSG TEST DONE. MY DOCTOR TOLD ME I WAS FIND AND MY TUBES WERE BLOCKED. I CONTINUE TO HAVE CRAMPING AND PAIN IN MY RIGHT SIDE. IN (B)(6) OF 2010, I BECAME PREGNANT. I CALLED MY DOCTOR'S OFFICE, WHO SAID THAT'S IMPOSSIBLE. THEY ADVISED ME TO COME IN AND HAVE A SONOGRAM DONE. I WAS TOLD I WAS 5 WEEKS AND 2 OR 3 DAYS PREGNANT. I WAS IN SHOCK. A FEW WEEKS LATER, I STARTED TO HAVE SOME BLEEDING AND DISCOVERED I HAD A MISCARRIAGE. NO ONE COULD TELL ME WHY I WAS PREGNANT IF I WAS SUPPOSED TO BE BLOCKED. I HAD TO HAVE A D AND C, AND I STARTED TAKING THE DEPO VERA SHOT TO PROTECT MYSELF. THE TIME AND MONEY SPENT TOOK A TOLL ON ME ESPECIALLY BECAUSE I SHOULD NOT BE GOING THROUGH THIS SINCE I HAD THIS ESSURE IMPLANT AND THE TESTING DONE TO CONFIRM ITS SECURITY. I BECAME PREGNANT AGAIN AND NOW HAVE A BEAUTIFUL (B)(6) GIRL. ALTHOUGH I DIDN'T WANT MORE KIDS, SHE'S THE ONLY GOOD THING THAT HAS COME FROM THIS, BUT I STILL HAVE TO PROVIDE FOR HER. THE ESSURE IMPLANT CAUSED ME QUITE A BIT OF PAIN. NOT JUST THE CRAMPING AND BACK PAIN. THE PAIN OF MISCARRIAGE, PREGNANCY, AND CHILDBIRTH ALL OVER AGAIN. I ALSO HAD TO HAVE ANOTHER TUBAL LIGATION PERFORMED IN (B)(6) 2014 AFTER MY BABY WAS BORN. I FELT TORMENTED BY THIS SO CALLED BULLET PROOF BIRTH CONTROL METHOD PHYSICALLY, MENTALLY AND EMOTIONALLY. I DON'T WISH THIS ON ANYONE ELSE. PLEASE TAKE THE ESSURE IMPLANT OFF THE MARKET.

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Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056068	BAYER	9/6/2015	9/10/2015

Event Information:

Event Date (B3): 10/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/29/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED IN 2012. SINCE THEN, VAGINAL BLEEDING FOR UP TO 13 WEEKS AT A TIME, MOOD CHANGES, EXTREME ABDOMINAL PAIN, ER VISITS OVER BLOOD LOSS, DIZZINESS, FAINTING, CHRONIC FATIGUE, HORMONAL EMOTIONAL IMBALANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056069	BAYER	9/6/2015	9/10/2015

Event Information:

Event Date (B3): 9/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/21/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD AN ESSURE PROCEDURE DONE. WHILE DOING THE PROCEDURE IN THE OFFICE THAT WAS DUE TO TAKE ABOUT TEN MINUTES, THE DOCTOR MADE A FALSE PASSAGE THROUGH MY CERVIX AND THE PROCEDURE TOOK FIVE HOURS. MOST OF THE FIVE HOURS WAS TRYING TO STOP BLEEDING. I THINK DOCTORS SHOULD HAVE BEEN TRAINED BETTER ON THE PROCEDURE. AFTER THE PROCEDURE, I WAS TOLD BY THE DOCTOR TO GO TO THE HOSPITAL FOR THE PAIN AND BLEEDING I WAS HAVING. THEY JUST GAVE ME PAIN KILLERS AND SENT ME HOME. ABOUT A MONTH AFTER THE PROCEDURE, I NOTICED WAS HAVING NON-STOP HEADACHES ALONG WITH SOME LOWER BACK PAIN. I ALSO STILL AFTER A YEAR LATER, BLEED ABOUT THREE WEEKS OUT OF THE MONTH WHEREAS IT WAS NORMAL FOR ME TO HAVE A FOUR DAY PERIOD. SEX HURTS NOW AND I DIDN'T HAVE THAT PROBLEM BEFORE THIS, EVEN AFTER THE BIRTH OF MY SON. LASTLY MY TASTE BUDS HAVE CHANGED. I THOUGHT IT WAS DUE TO ME GIVING BIRTH, BUT I HAVE TIMES WHEN I'VE EATING AND THE FOOD TASTES LIKE A CHEMICAL OR METAL AND I AM THE ONLY PERSON EATING THE FOOD THAT TASTES THIS. I FEEL ALL OF THESE SYMPTOM HAVE COME FROM THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 8/11/2015 **Report Date (B4): 8/27/2015** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): 893970

Single Use: *
Implant Date (E6): 2/24/2015
Explant Date (E7): 8/11/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL SYSTEM WAS EXPLANTED FROM A PATIENT AFTER APPROXIMATELY 6 MONTHS DUE TO ABDOMINAL PAINS. IT IS UNCLEAR IF THE DEVICE IS FAULTY AS ABDOMINAL PAIN IS A LISTED SIDE EFFECT. DEVICE WILL BE SENT TO THE MANUFACTURER FOR ADDITIONAL INVESTIGATION. MANUFACTURER RESPONSE FOR PERMANENT BIRTH CONTROL INTRAUTERINE DEVICE, ESSURE PERMANENT BIRTH CONTROL SYSTEM (PER SITE REPORTER): AS OF THIS REPORT, THE MANUFACTURER HAS OPENED AN INVESTIGATION INTO THE DEVICE. HOWEVER, NO OTHER DETAILS HAVE BEEN PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00718	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 11-AUG-2015 WHICH REFERS TO A ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED THAT SHE HAD ESSURE FOR A LITTLE OVER 18 MONTHS; IMMEDIATELY AFTER PLACEMENT SHE KNEW THAT SOMETHING WAS WRONG. SHE SUFFERED FOR A YEAR AND A HALF BEFORE TOTAL HYSTERECTOMY AT THE AGE (B)(6). SHE SAID THAT SHE STILL SUFFER FROM THE EFFECTS OF ESSURE; SUCH AS AUTOIMMUNE RESPONSE, WITHIN HER BODY, CONTINUAL BLADDER INFECTIONS AND KIDNEY PROBLEMS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND UNDERWENT HYSTERECTOMY AT (B)(6). AFTER THAT, SHE WAS STILL EXPERIENCING AUTOIMMUNE RESPONSE AND BLADDER INFECTIONS. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE. HYSTERECTOMY IS LISTED, WHILE AUTOIMMUNE DISORDERS AND BLADDER INFECTIONS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR HYSTERECTOMY WAS NOT SPECIFIED, THE REPORTER REGARDED THE EVENT AS A CONSEQUENCE OF ESSURE USE, THUS, COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN HYSTERECTOMY AND ESSURE THERAPY CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. REGARDING AUTOIMMUNE DISORDERS AND BLADDER INFECTIONS, CONSIDERING ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES AND THE FACT

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THAT THE PROBLEMS CONTINUED AFTER SURGERY FOR DEVICES REMOVAL (NEGATIVE DECHALLENGE), A CAUSAL RELATIONSHIP WITH SUSPECT MICRO-INSERT IS VERY UNLIKELY. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00719	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED THAT SHE EXPERIENCED EXCRUCIATING PAIN DURING INSERTION. SHE HAS A TILTED UTERUS AND DUE TO THIS, DOCTOR COULD NOT FIND THE OPENING OF RIGHT FALLOPIAN TUBE. WHEN HE FINALLY FOUND IT, HE COULD NOT INSERT ESSURE. HE PUSHED AND POKED AND MADE HER MOVE AROUND THE TABLE AND FORCED IT IN FINALLY. SHE WAS CRYING AND SWEARING IN THE OFFICE DURING INSERTION. SHE WAS IN PAIN FOR WEEKS. THE PAIN FINALLY DIED DOWN A BIT BUT AFTER 6 MONTHS THE NERVE PAIN AND HEADACHE STARTED. SHE VISITED DOCTORS AND WAS DIAGNOSED WITH OCCIPITAL NEURALGIA AND FIBROMYALGIA. SHE STARTED TO HAVE HORRIBLE PERIODS, GETTING 2 PERIODS A MONTH OR SKIPPING A MONTH TO HAVE 3 WEEKS OF BLEEDING THE NEXT. SHE WAS IN SO MUCH PAIN AND SLEEPING SO MUCH AND HAD EXHAUSTION TOO. HER MEMORY WAS SHOT AND SHE HAD CONSTANT BRAIN FOG AND LOST HER FEELING IN HER PINKIE FINGERS. HER DOCTORS TOLD HER THAT HER PROBLEMS WERE NOT CAUSED BY ESSURE. HER DOCTOR SENT HER FOR AN ULTRASOUND TO CHECK THAT SHE DID NOT HAVE OVARIAN CYSTS THAT WOULD BE THE CULPRIT, AND SHE WAS FINE OTHER THAN ESSURE. IN (B)(6) 2015, HYSTERECTOMY AND SALPINGECTOMY WERE DONE. SHE HAD SOME MINOR POST OPERATIVE ISSUES BUT SHE WAS HOPPING INTO THE OFFICE A MONTH LATER LIKE A NEW PERSON. AFTER SURGERY, ALL HER SYMPTOMS WERE GONE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS IN SO MUCH PAIN. SHE UNDERWENT

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A HYSTERECTOMY AND SALPINGECTOMY. THIS EVENT, INTERPRETED AS PELVIC PAIN, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, THE CONSUMER ALSO HAD FIBROMYALGIA WHICH COULD HAVE CONTRIBUTED FOR THE OCCURRENCE OF THIS PAIN. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY AND SALPINGECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDIT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00720	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 3/1/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN 2007. CONSUMER REPORTED THAT SHE HAD ESSURE PUT IN 2007 AND STARTED HAVING PROBLEMS VERY SOON AFTER. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED SHARP, STABBING AND CHRONIC PELVIC PAIN, BACTERIAL VAGINOSIS, CONSTANT SPOTTING, ADENOMYOSIS, UTERINE INFECTION, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), LONG MENSTRUAL CYCLE, BLEEDING/SPOTTING AFTER SEX, UTI (URINARY TRACT INFECTION), CERVICITIS (INFECTION OF CERVIX), CHEST PAIN, BRAIN SHOCKS, NERVE PAIN, BLACK OUT SPELLS, VITAMIN D DEFICIENCY, ADRENAL PROBLEMS, UNEXPLAINED FEVERS, VAGINITIS (INFECTION OF VAGINA), SWELLING OF CERVIX, INFLAMMATION OF CERVIX, SWELLING OF VAGINA, INFLAMMATION OF VAGINA, FAINTING, PID (PELVIC INFLAMMATORY DISEASE), CRAMPING, ABNORMAL MENSES, PERIOD STOPS, LACK OF MENSTRUAL CYCLE (AMENORRHEA), OVARIAN CYSTS, UTERINE CYSTS, DISCHARGE (ODOR/NO ODOR), ENDOMETRIOSIS, HOT FLASHES, UTERINE INFLAMMATION, POLYMENORRHEA, PAINFUL OVULATION, NIGHT SWEATS, LOSS OF LIBIDO, PAINFUL PERIODS (DYSMENORRHEA), PAINFUL INTERCOURSE (DYSPAREUNIA), BLEEDING BETWEEN PERIODS, INCONTINENCE, SEXUAL DYSFUNCTION (UNABLE TO ORGASM OR FEEL PLEASURE), YEAST INFECTIONS (CANDIDA), URGENT URINATION, FREQUENT URINATION, BLADDER INFECTION, ITCHING OF VAGINAL ENTRANCE , ABDOMINAL SPASMS, TWITCHING, FLUTTERING, MUSCLE SPASMS, BACK PAIN, JOINT PAIN, HIP PAIN, LEG PAIN, SPINE PAIN, NECK PAIN, ALL OVER BODY ACHES/PAIN, GASTROINTESTINAL, BOWEL ISSUES, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH,

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HEARTBURN, NEUROLOGICAL, MENTAL HEALTH, HEADACHES, MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN FOG, CLOUDINESS, ANXIETY, PANIC ATTACKS, MOOD SWINGS, MOOD DISORDERS, DEPRESSION (SADNESS, SUICIDAL THOUGHTS), RINGING IN THE EARS (PULSATILE TINNITUS), DIMINISHED BRAIN FUNCTION, CONFUSION, SHORT TERM MEMORY LOSS, NUMBNESS IN THIGH, IN EXTREMITIES (HANDS AND FEET), TINGLING IN EXTREMITIES, IN HANDS AND FEET, AND SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN (PARAESTHESIA), TREMORS/SHAKINESS, HIGH BLOOD PRESSURE, HEART PALPITATIONS, SWELLING OF LEGS OR FEET, HAIR LOSS, INSOMNIA, WEIGHT ISSUES (LOSS), WEIGHT ISSUES (GAIN), SLEEP APNEA, SWOLLEN GLANDS, VISION PROBLEMS (FLOATERS), BLURRED VISION, DECREASED VISION, EXCESSIVE SWEATING, BURNING OF VAGINAL ENTRANCE, STINGING, STABBING OF VAGINAL ENTRANCE (VULVODYNIA), BREAST PAIN, BREAST TENDERNESS, FORGETFULNESS, AND HAIR CHANGES. THE CONSUMER HAD ESSURE REMOVED IN (B)(6) 2014 AND INSTANTLY THE BLOATING AND INFLAMMATION WAS GONE. SHE DID FEEL WAY BETTER AFTER HAVING ESSURE REMOVED. HOWEVER, THERE WERE STILL SOME LINGERING ISSUES THAT SHE WAS DEALING WITH AND PROBABLY WILL FOR THE REST OF HER LIFE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP, STABBING AND CHRONIC PELVIC PAIN; PELVIC INFLAMMATORY DISEASE (PID); URINARY TRACT INFECTION (UTI); BLACK OUT SPELLS; DEPRESSION (SUICIDAL THOUGHTS) AND DIMINISHED BRAIN FUNCTION. SHE HAD ESSURE REMOVED 7 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. EVENTS PELVIC PAIN AND PELVIC INFLAMMATORY DISEASE ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE REMAINING EVENTS ARE UNLISTED. GIVEN THE NATURE OF THE EVENT PELVIC PAIN AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING PELVIC INFLAMMATORY DISEASE (PID); WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PID IN THE FIRST 4 WEEKS AFTER INSERTION. IN THE PRESENT CASE, NO INFORMATION SUGGESTING THIS CLOSE TEMPORAL RELATIONSHIP WITH THE INSERTION PROCEDURE WAS MENTIONED, AND ESSURE REMOVAL OCCURRED ONLY AFTER 7 YEARS. THEREFORE A CAUSAL RELATIONSHIP BETWEEN ESSURE AND PID WAS CONSIDERED VERY UNLIKELY (UNRELATED). CONSIDERING THE PATHOPHYSIOLOGY AND NATURE OF THE EVENTS URINARY TRACT INFECTION, BLACK OUT SPELLS, DEPRESSION (SUICIDAL THOUGHTS) AND DIMINISHED BRAIN FUNCTION, AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY BETWEEN ESSURE AND THESE REPORTED EVENTS WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE REMOVAL WAS REPORTED, IMPLYING THAT AN INTERVENTION WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00721	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0337; AWARENESS DATE: 11-AUG-2015). IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT SHE HAVE ALWAYS BEEN A VERY HEALTHY, HAPPY, ENERGETIC WOMAN. IN 2009, AFTER CAREFUL CONSIDERATION NOT TO HAVE ANY ADDITIONAL CHILDREN, SHE CONSULTED HER GYNECOLOGIST/OBSTETRICIAN AND DECIDED TO HAVE ESSURE INSERTED. SHE HAD THE PROCEDURE DONE IN THE DOCTOR'S OFFICE AND WAS ONLY GIVEN SOMETHING SIMILAR TO A VALIUM AND MAYBE SOME LIGHT PAIN MEDICATION. SHE WAS NOT SEDATED AND BY ALL ACCOUNTS THE PROCEDURE WENT WELL IN HER OPINION DUE TO HER DOCTOR BEING TRAINED WELL. SHE REMEMBERS THIS BEING PAINFUL. SHE DID NOT RECALL IMMEDIATE PROBLEMS FROM THE PROCEDURE AND SHE DID GO BACK FOR "DYE TESTING" AFTER 90 DAYS WHICH SHOWED TUBES TO BE BLOCKED. AS TIME PASSED CONSUMER STARTED HAVING EXTREMELY PAINFUL PERIODS, CRAMPING, HEAVY BLEEDING WITH CLOTS, BACK PAIN AND MANY UTI'S (URINARY TRACT INFECTIONS). THE FATIGUE STARTED COMING ON AND DRAINING HER LIFE OUT OF HER. SHE ALSO EXPERIENCED BRAIN FOG AND WAS CONSTANTLY TAKING PRESCRIPTION PAIN KILLERS FOR THE BACK AND ABDOMEN PAIN. TAKING THE PAIN PILLS BECAME A PROBLEM AND SHE HAD TO GET OUTPATIENT HELP FOR THAT. AS THE YEARS WENT ON THE SYMPTOMS CONTINUED AND MORE BIZARRE HEALTH ISSUES BEGAN. CONSUMER WENT FROM HAVING HEAVY PERIODS TO NONE AT ALL. SHE WOULD GO MONTHS WITHOUT A PERIOD, THEN MAYBE A COUPLE HEAVY PERIODS, AND REPEAT. SINCE SHE WAS IN EARLY 40'S A COUPLE DOCTORS DID NOT THINK IT WAS MENOPAUSE. WHEN THIS WENT ON A COUPLE YEARS SHE FINALLY SAW A NEW DOCTOR WHO TESTED HER

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BLOOD AND SHE WASN'T IN PERIMENOPAUSE, BUT FULL MENOPAUSE DUE TO HER FSH LEVELS. THINGS GOT SO BAD THAT SHE FINALLY FOUND A DOCTOR TO PERFORM A HYSTERECTOMY AT (B)(6). AT TIME OF THIS REPORT SHE WAS STILL HAVING HEALTH ISSUES AND HAD LOST HER JOB IN (B)(6) 2015. DUE TO HER MENTAL STATE AND DEBILITATING PAIN SHE DOES NOT ENJOY LIFE AS ONCE SHE DID. BY GETTING ESSURE SHE FEELS IT HAS FOREVER ROBBED NOT ONLY HER LIFE BUT THE LIFE OF HER CHILD. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEBILITATING ABDOMEN PAIN, HEAVY BLEEDING WITH CLOTS (REGARDED AS GENITAL BLEEDING) AND MANY UTI'S (URINARY TRACT INFECTIONS). SHE WAS SUBMITTED TO A HYSTERECTOMY AT (B)(6). THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY UTI IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. URINARY TRACT INFECTION (UTI) PATHOGENESIS IN WOMEN BEGINS WITH COLONIZATION OF THE VAGINAL INTROITUS BY UROPATHOGENS FROM THE FECAL FLORA, FOLLOWED BY ASCENSION VIA THE URETHRA INTO THE BLADDER. CONSIDERING UTI PHYSIOPATHOLOGY AND GIVEN ESSURE LOCAL ACTION AT FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND THE SUSPECT INSERT IS CONSIDERED UNLIKELY. REGARDING THE REMAINING EVENTS, AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE CONSUMER HAD A MENOPAUSAL TRANSITION/MENOPAUSE IN ASSOCIATION WITH THE EVENTS; THIS COULD BE AN ALTERNATIVE EXPLANATION FOR HER BLEEDING AND SOME OF OTHER NON-SERIOUS EVENTS SHE REPORTED (MENSTRUAL ABNORMALITIES). NEVERTHELESS, CONSIDERING EVENT'S NATURE A CONTRIBUTORY ROLE OF ESSURE CANNOT BE RULED OUT. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00722	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 11-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD ESSURE PROBLEM FREE FOR 3 YEARS. ACCORDING TO HER, ONE YEAR PREVIOUS TO THIS REPORT (2014), SHE HAD SURGICAL REMOVAL AND STATES THAT SINCE THEN SHE DOES NOT HAVE DAILY HEADACHES, PELVIC PAIN, ABDOMINAL PAIN, CHRONIC FATIGUE OR JOINT PAIN (ALL GONE). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER HAD A SURGERY TO REMOVE THE DEVICES AND SINCE THEN SHE HAS NO MORE PELVIC PAIN NEITHER OTHER NON-SERIOUS EVENTS (POSITIVE DECHALLENGE). THEREFORE, GIVEN EVENT'S NATURE AND POSITIVE DECHALLENGE, A CAUSAL RELATIONSHIP WITH ESSURE USE CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00723	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2012 AFTER HER 3RD CHILD WAS BORN. SHE REPORTED THAT BY (B)(6) 2012 SHE WAS HAVING SEVERE CRAMPING; HEADACHES; NAUSEA AND DIARRHEA. HER DOCTOR TOLD HER SHE WAS FINE. BY (B)(6) MORE ISSUES SHOWED UP ON TOP OF WHAT SHE WAS ALREADY HAVING; HER BODY ACHED SO BAD SHE COULD HARDLY MOVE; SHE WAS VOMITING; HER LOWER BACK ON THE LEFT SIDE HURT; HER CHEST HURT; HER LEFT ARM HURT AND WOULD GO NUMB; HER RELATIONSHIP WITH HER HUSBAND WAS AFFECTED, AND THE WORST FOR HER WAS SHE STOPPED SLEEPING AS SHE WAS TERRIFIED IF SHE WENT TO SLEEP THAT MIGHT NOT WAKE UP THE NEXT DAY. SHE STARTED TO GO TO THE ER; SHE WAS IN EXTREME PAIN AND FELT LIKE SHE WAS DYING. THE ER DOCTORS DIDN'T KNOW ANYTHING ABOUT ESSURE; HER IMPLANTING DOCTOR KEPT TELLING HER IT COULDN'T BE ESSURE. IN (B)(6) AN ER DOCTOR RECOMMENDED A DOCTOR SHE COULD SEE AND THIS DOCTOR KNEW RIGHT AWAY SHE WAS HAVING A REACTION TO THE ESSURE. SHE STATED THAT AT THE AGE OF (B)(6) SHE HAD A HYSTERECTOMY. DURING THE HYSTERECTOMY IT WAS DISCOVERED NOT ONLY WERE TUBES INFLAMED AND TWICE THE SIZE THEY SHOULD HAVE BEEN BUT HER LEFT TUBE HAD BEEN PERFORATED BY THE COIL. ALMOST 3 YEARS LATER SHE WAS DOING A LOT BETTER. SHE REPORTED THAT RIGHT AFTER THE PROCEDURE SHE FELT SO MUCH BETTER. BUT THE MENTAL RAMIFICATIONS OF WHAT SHE WENT THROUGH HAVE NOT GONE AWAY AND SHE WAS LEFT WITH MAJOR DENTAL ISSUES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE

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REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 2 MONTHS LATER, SHE STARTED EXPERIENCING BODY ACHE, SO BAD SHE COULD HARDLY MOVE, SHE WAS IN EXTREME PAIN. SHE MADE SEVERAL VISITS TO THE ER. AFTER 5 MONTHS, DURING THE HYSTERECTOMY, IT WAS FOUND THAT LEFT TUBE HAD BEEN PERFORATED BY THE COIL AND THAT TUBES WERE INFLAMED (TWICE THE NORMAL SIZE). RIGHT AFTER THE PROCEDURE SHE FELT SO MUCH BETTER, BUT THE MENTAL RAMIFICATIONS OF WHAT SHE WENT THROUGH HAVE NOT GONE AWAY. THE EVENTS, INTERPRETED AS FALLOPIAN TUBE PERFORATION AND SALPINGITIS ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF FALLOPIAN TUBE PERFORATION AND THE LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. REGARDING THE SALPINGITIS, SINCE THE TEMPORAL RELATIONSHIP IS COMPATIBLE AND THERE IS NO ALTERNATIVE EXPLANATION, THIS EVENT IS ALSO RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00724	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE ADULT CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED SHE WAS (AT TIME OF THIS REPORT) A HEALTHY (B)(6) THAT NEVER REQUIRED ANY DAILY MEDICATIONS. SHE WENT TO MY DOCTOR TO DISCUSS HAVING A TUBAL LIGATION DONE AND WAS TOLD BY HER GYNECOLOGIST THAT THIS PROCEDURE WAS NO LONGER AN OPTION AND THAT THE ESSURE PROCEDURE WAS THE EASIEST, SAFEST, MOST EFFECTIVE PROCEDURE AVAILABLE FOR PERMANENT BIRTH CONTROL. SHORTLY AFTER THE ESSURE INSERTION SHE BEGAN HAVING HEADACHES/MIGRAINES WEEKLY, HAIR LOSS, SKIN RASHES/BLISTERS, WEIGHT GAIN (HEAVIEST SHE HAD EVER BEEN), INSOMNIA, EXTREME MOOD SWINGS, MENTAL AND PHYSICAL EXHAUSTION, BLOATING, DIFFICULTY FOCUSING, DAILY DIARRHEA, A VIBRATING FEELING WHERE THE COILS SEEMED TO BE PLACED, AND STABBING PAINS IN ABDOMEN. AS A RESULT OF THESE SYMPTOMS, SHE WAS MISSING WORK OR LEAVING EARLY AND WAS UNABLE TO ENJOY TIME WITH HER FAMILY. AT THIS POINT SHE STARTED TO FEEL THAT SHE WAS MISLED BY HER DOCTOR ABOUT THE SAFETY OF THE ESSURE PROCEDURE. HER SYMPTOMS SEEMED TO FAR OUTWEIGH THE BENEFITS OF THE PROCEDURE; SHE LITERALLY FELT LIKE SHE WAS DYING A SLOW, PAINFUL DEATH. TWICE SHE WAS RUSHED TO THE EMERGENCY ROOM BECAUSE THE BLEEDING WAS SO SEVERE THAT SHE WAS DOUBLED OVER IN PAIN AND WAS PASSING HUGE BLOOD CLOTS. SHE WAS GIVEN HORMONE PILLS FOR 10 DAYS WHICH EVENTUALLY STOPPED THE BLEEDING. CONSUMER WENT TO HER GYNECOLOGIST MANY TIMES TO EXPRESS HER CONCERNS ABOUT THE ONGOING SYMPTOMS WHICH SEEMED TO INTENSIFY AS THE MONTHS WENT ON. THE GYNECOLOGIST ADVISED HER

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THAT SHE MIGHT BE IN EARLY MENOPAUSE OR HAVE ENDOMETRIOSIS. SHE EVEN REQUESTED THAT THE COILS BE REMOVED BUT THE DOCTOR INSISTED THAT IT WAS NOT THE COILS CAUSING HER SYMPTOMS. SHE WENT BACK TO THE DOCTOR THREE MONTHS AFTER THE ESSURE PROCEDURE TO HAVE THE RECOMMENDED HSG (HYSTEROSALPINGOGRAPHY) TEST COMPLETED WHICH WOULD CONFIRM THAT THE FALLOPIAN TUBES WERE BLOCKED. ONE TUBE WAS CONFIRMED BLOCKED BUT THE OTHER TUBE WAS NOT FULLY BLOCKED. THE DOCTOR ADVISED HER TO HAVE ANOTHER HSG TEST COMPLETED IN THREE MONTHS TO CHECK IF THE OTHER TUBE WAS BLOCKED. HER DOCTOR CONCEDED TO REMOVING THE COILS. SHE HAD AN INTERNAL AND EXTERNAL ULTRASOUND TO CONFIRM THE PLACEMENT OF THE COILS AS WELL AS A PELVIC X-RAY. THE RESULTS SHOWED ONE COIL WAS IN FALLOPIAN TUBE AND THE OTHER COIL HAD MIGRATED OUT OF THE TUBE. SHE UNDERWENT A TOTAL HYSTERECTOMY LEAVING BOTH OF OVARIES. AFTER SURGERY, SHE WAS TOLD THAT THE MIGRATED COIL WAS EMBEDDED IN UTERUS. AS SOON AS THE SURGERY WAS FINISHED, SHE NOTICED THAT THE SYMPTOMS WERE DIMINISHING. AT TIME OF THIS REPORT SHE NO LONGER HAD ANY OF THE SYMPTOMS THAT ACCORDING TO HER WERE CAUSED BY THE ESSURE COILS EXCEPT THE CONTINUED PROBLEM WITH WEIGHT GAIN AND THE DIFFICULTY LOSING THE EXTRA WEIGHT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD THE HYSTEROSALPINGOGRAM (HSG) PERFORMED 3 MONTHS AFTER INSERTION, SHOWED THAT ONE COIL MIGRATED AND WAS EMBEDDED IN UTERUS. SHE UNDERWENT A TOTAL HYSTERECTOMY AND LEFT HER OVARIES. SHE STATED SHE RECOVERED FROM THIS EVENT. THIS EVENT, INTERPRETED AS DEVICE EMBEDDED (PARTIAL PERFORATION) IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE HSG SHOWED A DEVICE EMBEDDED WHICH MAY HAVE CAUSED GENITAL BLEEDINGS AND ABDOMINAL PAIN THAT SHE HAD NEVER EXPERIENCED BEFORE ESSURE. CONSIDERING THIS NATURE OF THIS EVENT, THE FACT THAT SHE HAD NEVER EXPERIENCED THESE SYMPTOMS BEFORE AND THE LACK OF ALTERNATIVE EXPLANATION, DEVICE EMBEDDED IS ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00725	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0129, AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN THE FALL 2008. CONSUMER HAD ESSURE PROCEDURE IN 2008. EVERY YEAR SHE BECAME SICKER AND SICKER. EXCESSIVE BLEEDING, HORRIBLE PAINS IN THE LOWER PELVIC AREA. SHE BEGAN HAVING VARIOUS SYMPTOMS AND ILLNESSES BUT NO DOCTOR COULD MAKE A DIAGNOSIS. HER TEETH STARTED HAVING TROUBLE, GLANDS SWELLING IN NECK. SHE WENT THROUGH ALLERGY TESTS, COLONOSCOPY, VARIOUS ULTRA SOUNDS AND SONOGRAMS, PELVIC EXAMS ETC. NO PHYSICIAN COULD FIND ANYTHING. FINALLY, AFTER 2 YEARS OF BEING SICK, A PHYSICIAN LOOKED INSIDE AND PELVIC AREA WAS CEMENTED DOWN FROM OVERGROWTH OF TISSUE WHICH WAS SO BAD SHE HAD TO HAVE SURGERY ON COLON AS WELL AND HER URETER WAS ALSO DAMAGE. AFTER HAVING ALMOST ALL OF HER REPRODUCTIVE ORGANS REMOVED, SHE IS ALMOST 3 YEARS CLEAR AND ESSURE-FREE. SHE WAS NEVER A SICKLY PERSON UNTIL SHE HAD THE ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER 2 YEARS OF BEING SICK (PELVIC PAIN AND EXCESSIVE BLEEDINGS), THE PHYSICIAN THAT SAW HER NOTICED THAT THE PELVIC AREA WAS CEMENTED DOWN FROM OVERGROWTH OF TISSUE WHICH WAS SO BAD SHE HAD TO HAVE A SURGERY ON COLON (INTERPRETED AS ABDOMINAL ADHESIONS). HER URETER WAS DAMAGED (INTERPRETED AS URETERIC INJURY). SHE HAD ALMOST ALL HER REPRODUCTIVE ORGANS REMOVED. AT THE TIME OF REPORT SHE WAS 3

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YEARS FREE OF ESSURE AND ITS PROBLEMS. THE EVENTS ABDOMINAL ADHESIONS AND URETERIC INJURY ARE UNLISTED WHILE THE GENITAL BLEEDING IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER STATED THAT APPROXIMATELY 2 YEARS AFTER ESSURE INSERTION, SHE HAD ABDOMINAL ADHESIONS (COLON AND URETER) THAT WERE SO BAD THAT SHE HAD TO HAVE A SURGERY. IT WAS NOT REPORTED IF ESSURE WAS OUTSIDE THE FALLOPIAN TUBE. HOWEVER, SINCE THE PRESENCE OF ESSURE IN ABDOMEN COULD EXPLAIN THIS FINDING, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. AS THE INJURY IN THE URETER MIGHT BE A COMPLICATION OF ABDOMINAL ADHESIONS, THIS EVENT WAS ALSO CONSIDERED RELATED TO ESSURE. THE GENITAL BLEEDING IS CONSIDERED RELATED DUE TO THE NATURE OF THIS EVENT, LACK OF ALTERNATIVE EXPLANATION AND ALSO DUE TO THE FACT THAT SHE STATED THAT PRIOR TO ESSURE SHE WAS A HEALTH PERSON, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00726	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL. THE CONSUMER CHOSE ESSURE BECAUSE IT WAS SUPPOSED TO BE NON-SURGICAL WITH MINIMAL PAIN AND NO DOWNTIME. CONSUMER REPORTED THAT IF SHE KNEW ESSURE WAS MADE OF NICKEL SHE WOULD NEVER HAD IT DONE AS SHE HAS SENSITIVITY TO NICKEL. SHE REPORTED AFTER HAVING ESSURE, HER BODY STARTED SHAKING ALL OVER AND SHE WAS IN EXCRUCIATING PAIN. SHE MENTIONED A BAYER SALES REPRESENTATIVE WAS IN THE ROOM AT THE TIME AND SHE SENT THE NURSE TO GET A SHOT FOR HER TO TRY TO GET THE CONSUMER SOME RELIEF OF THE PAIN; UNTIL SHE FINALLY COULD GO HOME. SHE REPORTED HER PAIN CONTINUED AND SHE WENT BACK IN THE FOLLOWING WEEK TO SEE HER PHYSICIAN AGAIN; AN ULTRASOUND WAS DONE AND THEY FOUND OUT ONE OF HER FALLOPIAN TUBE WAS INFECTED. THE PHYSICIAN PUT HER ON ANTIBIOTICS AND OVER THAT WEEKEND HER PAIN GET WORSE AND SHE COULD NOT GET HER FEVER UNDER CONTROL. SHE WENT TO THE EMERGENCY DEPARTMENT AND SPENT FOUR DAYS ON THREE DIFFERENT IV (INTRAVENOUS) ANTIBIOTICS AND PAIN MEDICINE. SHE WENT FOR HER FOLLOW UP 3 WEEKS AFTER HAVING ESSURE INSERTED AND THE PHYSICIAN ASKED HOW SHE WAS FEELING; SHE STATED THAT COULD HAVE THE DEVICES PULLED OUT WITH HER HANDS IF POSSIBLE. THEN THE PHYSICIAN SCHEDULED A HYSTERECTOMY. FOUR WEEKS AFTER BEING IMPLANTED SHE HAD HER SURGERY; HER PHYSICIAN HAD TO REMOVE ONE OVARY BECAUSE OF THE DAMAGE ESSURE HAD DONE IT, ALONG WITH HER TUBES, UTERUS AND CERVIX; SHE STATED THAT WAS (B)(6). THE CONSUMER REPORTED THE ENTIRE TIME SHE HAD ESSURE SHE COULD

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NOT EAT; FUNCTION; TAKE CARE OF HER CHILD; DRIVE OR WORK. HER PHYSICIAN MENTIONED THAT, DURING THE SURGERY, HE COULD SEE THE INFECTION HAD ABSCESSED AND WAS THE SIZE OF A SOFTBALL; AND IT WAS LEAKING INFECTION INTO HER ABDOMEN. SHE STATED THAT HAD SURVIVED ONE BRAIN ANEURISM AND WAS DEALING WITH ANOTHER AT TIME OF THE REPORT. FAST FORWARD TWO YEARS LATER (AT TIME OF THE REPORT), SHE WAS ENTERING EARLY MENOPAUSE AT (B)(6); SHE HAD MULTIPLE GRADE 1 PROLAPSES WHICH SHE DID NOT HAD BEFORE HER HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND APPROXIMATELY A WEEK AFTER INSERTION, THE PHYSICIAN MADE AN ULTRASOUND AND FOUND THAT TUBE WAS INFECTED (INTERPRETED AS PYOSALPINX). SHE WAS TREATED FOR A WEEK WITH ANTIBIOTICS BUT PAIN GOT WORSE AND FEVER COULD NOT BE CONTROLLED. A FEW DAYS LATER, SHE WAS ADMITTED AND SPENT FOUR DAYS ON THREE DIFFERENT INTRAVENOUS ANTIBIOTICS AND PAIN MEDICINE. A MONTH AFTER INSERTION, DURING HYSTERECTOMY, THE PHYSICIAN NOTICED THAT THE INFECTION HAD ABSCESSED AND THE ABSCESS HAD RUPTURED (INTERPRETED AS RUPTURED ABSCESS). AT AGE OF (B)(6), SHE HAD ONE OVARY, ALONG WITH HER TUBES, UTERUS AND CERVIX REMOVED. OUTCOMES WERE NOT REPORTED. THE PYOSALPINX AND RUPTURED ABSCESS ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE PYOSALPINX WAS DIAGNOSED APPROXIMATELY A WEEK AFTER INSERTION. ALTHOUGH ESSURE SYSTEM IS STERILE, IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. CONSIDERING THIS INFORMATION AND THE SUGGESTIVE TEMPORAL RELATIONSHIP, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. CONSIDERING THAT THE RUPTURED ABSCESS MAY BE A COMPLICATION OF PYOSALPINX, THIS EVENT IS ALSO ASSESSED AS RELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED) AND THE PATIENT WAS HOSPITALIZED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00727	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED THAT SHE HAD ESSURE FOR 7 YEARS. DURING THIS PERIOD, SHE WAS DIAGNOSED WITH ACID REFLUX, CHRONIC DRY EYE, SEVERE ALLERGIES, DAILY CHRONIC PAIN THAT FELT LIKE BEING STABBED IN LOWER STOMACH AND PRICKLING PAIN IN LEGS AND FEET. SHE HAD MULTIPLE TESTS DONE OVER THE COURSE OF THE YEARS AND NO DOCTOR COULD FIND ANY REASON FOR SYMPTOMS BESIDES UNEXPLAINED INFLAMMATION. AFTER REMOVAL (DATE NOT SPECIFIED), ALL HER SYMPTOMS GREATLY IMPROVED OR DISAPPEARED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR 7 YEARS AND DURING THIS PERIOD EXPERIENCED DAILY CHRONIC PAIN THAT FELT LIKE BEING STABBED IN LOWER STOMACH, AMONG OTHER NON-SERIOUS EVENTS. ESSURE WAS REMOVED AND HER SYMPTOMS GREATLY IMPROVED OR DISAPPEARED. EVENT DAILY CHRONIC PAIN THAT FELT LIKE BEING STABBED IN LOWER STOMACH, INTERPRETED AS LOWER ABDOMINAL PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. CONSIDERING THE NATURE OF THIS EVENT, POSITIVE TEMPORAL RELATIONSHIP AND SINCE THE EVENT IMPROVED OR DISAPPEARED AFTER ESSURE REMOVAL, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REPORTED (INTERVENTION IMPLIED) THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 03-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00728	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 4/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/20/2015
Explant Date (E7): 7/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4) AWARENESS DATE 11-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED. CONSUMER IS MOTHER OF 3 CHILDREN AGES 4, 2 AND 6 MONTHS. HER 3RD CHILD WAS BORN VIA C-SECTION ON (B)(6) 2015 ESSURE WAS INSERTED ON (B)(6) 2015 FOR PERMANENT BIRTH CONTROL. THE PROCEDURE WAS NOT TOO BAD. SHE WAS ABLE TO LEAVE 30 MINUTES LATER WITH MILD CRAMPING AND BLEEDING. FIVE DAYS LATER CONSUMER WENT TO AN ER (EMERGENCE ROOM) PRESENTING FEVER, HIVES, CRAMPING, INSOMNIA AND EXHAUSTION. SHE INFORMED THAT SHE THOUGHT IT WAS DUE TO THE ESSURE BUT WAS TOLD 4 HOURS LATER AFTER NO TESTING THAT SHE JUST HAD WHATEVER BUG WAS GOING AROUND. EVER SINCE (B)(6) 2015 SHE EXPERIENCED SEVERE ITCHING INTERNALLY AND OUTWARDLY, HIVES COVERING HER BODY, BLOATING AS IF SHE WAS 6 MONTHS PREGNANT, HEADACHES, BACK PAIN, INSOMNIA, IRRITABILITY, BLEEDING THE ENTIRE TIME EVERY DAY AND EXTREME FATIGUE; CONSUMER WAS UNABLE TO CARE FOR HER CHILDREN PROPERLY, SHE WOULD NOD OFF CONSTANTLY AND HAD FITS OF RAGE. CONSUMER COULD NOT SLEEP DUE TO THE ITCHINESS, HIVES AND HEADACHES. SHE WAS NEVER HAPPY, ALWAYS MISERABLE TO BE AROUND. SHE WOULD NOT GO ANYWHERE SINCE SHE WAS SO UNCOMFORTABLE. AFTER TALKING WITH GYNECOLOGIST IT WAS DECIDED TO REMOVE ESSURE AND HER FALLOPIAN TUBES; ON (B)(6) 2015 THE DEVICE WAS REMOVED AND MANY OF SYMPTOMS INSTANTLY STOPPED. SHE HAD TO REMOVE THE TUBES. AT TIME OF THIS REPORT SHE STILL HAD TO FOLLOW UP TO MAKE SURE ALL FRAGMENTS WERE TAKEN OUT CORRECTLY, IF NOT A FULL HYSTERECTOMY WOULD BE THE NEXT STEP. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY

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CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THE PROCEDURE WAS BLEEDING THE ENTIRE TIME EVERY DAY (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT SALPINGECTOMY AND ESSURE REMOVAL 3 MONTHS AFTER INSERTION AND STILL HAD TO FOLLOW UP TO MAKE SURE ALL FRAGMENTS WERE TAKEN OUT (INTERPRETED AS SUSPICION OF DEVICE BREAKAGE). EVENT GENITAL BLEEDING IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENT BLEEDING THE ENTIRE TIME EVERY DAY, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING SUSPICION OF DEVICE BREAKAGE, LIMITED INFORMATION WAS PROVIDED. NO BREAKAGE WAS DESCRIBED DURING ESSURE REMOVAL PROCEDURE, AND THE EXACT REASON WHY SHE WAS NOT SURE ALL FRAGMENTS WERE TAKEN OUT WAS NOT SPECIFIED. HOWEVER, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (ESSURE REMOVAL AND SALPINGECTOMY) AND OTHER REPORTABLE INCIDENT DUE TO SUSPICION OF DEVICE BREAKAGE (MALFUNCTION). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00729	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE: 11-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN THE UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 FOR PERMANENT BIRTH CONTROL. CONSUMER IS A (B)(6) MOTHER OF 3 BOYS. ACCORDING TO HER, SHE HAS ALWAYS LIVED AN ACTIVE, HEALTHY LIFESTYLE. A YEAR AND A HALF AFTER ESSURE PLACEMENT SHE BEGAN HAVING SEVERE PAIN ON LOWER LEFT SIDE DURING MENSTRUAL CYCLE. HER PHYSICIAN SAID SHE DIDN'T FEEL THAT IT WAS CAUSED BY ESSURE. AS THE PAIN CONTINUED TO INCREASE IN SEVERITY AND DURATION SHE RETURNED TO HER PHYSICIAN. SHE FELT AT THAT TIME THAT IT COULD POSSIBLY BE THE ESSURE AND THEY DECIDED TO REMOVE THE LEFT FALLOPIAN TUBE IN ORDER TO REMOVE THE COIL. AT HER 2 WEEK POST-OPERATION APPOINTMENT, PHYSICIAN TOLD THE CONSUMER THAT THE PATHOLOGY REPORT SHOWED THAT THERE WAS NOT A METAL DEVICE IN TUBE. PHYSICIAN SAID IT SHOULDN'T HURT IF THE ESSURE WAS IN HER UTERUS. SHE ALSO SAID THAT CONSUMER COULD HAVE PASSED THE ESSURE DEVICE IN HER PERIOD AND THAT SHE MIGHT BE HAVING "PHANTOM PAIN". CONSUMER WAS ADVISED TO WAIT AND SEE IF THE PAIN CONTINUED. SHE STATED SHE HAD ENDURED TWO WEEKS OF RECOVERY AND WAS GOING TO HAVE TO DO ANOTHER 4 WEEKS OF LIMITED ACTIVITY FOR A SURGERY THAT SERVED NO PURPOSE. AS THE PAIN CONTINUED SHE CALLED HER DOCTOR WHICH STATED SHE REALLY DID NOT KNOW WHAT TO DO. CONSUMER WAS FINALLY ABLE TO FIND ANOTHER PHYSICIAN WHO DECIDED THE BEST COURSE OF TREATMENT WAS A HYSTERECTOMY AND SALPINGECTOMY TO REMOVE THE OTHER COIL AS WELL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO EXPERIENCED

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SEVERE PAIN ON HER LOWER LEFT SIDE DURING MENSTRUAL CYCLE AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A LEFT SALPINGECTOMY; PATHOLOGY REPORT SHOWED THERE WAS NOT A METAL DEVICE IN TUBE. AS HER PAIN CONTINUED TO INCREASE IN SEVERITY AND DURATION, SHE UNDERWENT A HYSTEROSALPINGECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, DYSMENORRHEA CAN OCCUR. IN THIS CASE, CONSUMER STARTED EXPERIENCING MENSTRUAL PAIN ON HER LEFT SIDE ONE AND HALF YEAR AFTER ESSURE PLACEMENT. DURING A LEFT SALPINGECTOMY NO DEVICE WAS FOUND ON THIS SIDE AT PATHOLOGY REPORT; IT IS UNKNOWN IF ESSURE WAS EXPELLED OR IF IT MIGRATED TO THE ABDOMINAL CAVITY. ALTHOUGH THE EXACT MECHANISM OF THE EVENTS IS UNKNOWN; CONSIDERING THEIR NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00730	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER (NURSE) OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. ACCORDING TO THE REPORTER, SHE WENT TO THE HOSPITAL FOR THE PROCEDURE AND WOKE UP IN OUTPATIENT SURGERY. SHE REPORTED IT WAS PAINFUL AND SHE STARTED HEAVILY BLEEDING IMMEDIATELY; SHE PASSED CLOTS BIGGER THAN THE PALM OF HER HAND. SHE STATED THAT IN THE NEXT DAY, SHE HAD TO LEAVE CLASS BECAUSE JUST WALKING FROM DOORWAY TO DOORWAY AND SITTING IN A DESK WAS TOO MUCH FOR HER BODY. SHE BLED DOWN HER LEGS AND ALL OVER HER CLOTHING IN PUBLIC BECAUSE THE AMOUNT OF BLEEDING WAS SO HEAVY. SHE STATED SHE'S GONE FROM BAD TO WORSE OVER THE YEARS. SHE EXPERIENCED PAIN; BRAIN FOG; INSOMNIA; THYROID ISSUES; HORMONAL IMBALANCES THAT LEAVE HER MOODY; LOW LIBIDO; BOWEL ADHESIONS; APPENDIX CAUGHT PET FIBERS AND SWELLED 4X THE SIZE, SHE HAD TO BE OPENED UP TO REMOVE SCAR TISSUE AND TO GET THE ORGAN REMOVED; STOMACH ULCERS THAT PERFORATED AND HEMORRHAGE AND HAD ANEMIA AS A RESULT, SHE HAD TO DO BLOOD TRANSFUSIONS AND IRON TRANSFUSIONS; PAINFUL AND HIGH RISK PREGNANCY; DEPRESSION; ANXIETY; METALLIC TASTE IN MOUTH; SEVERE SWELLING IN HIPS AND LEGS, SOME DAYS SO SIGNIFICANT SHE WAS UP 10-15 POUNDS; SEVERE WEIGHT GAIN; AND FATIGUE AMONG OTHERS ISSUES. SHE REPORTED IT WAS GETTING WORSE AND WORSE BECAUSE SHE HAD BEEN HUSHED TO BELIEVE THAT NONE OF THE SYMPTOMS COULD POSSIBLY BE RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE NURSE WHO HAD HEAVY BLEEDING AND PASSED CLOTS BIGGER THAN THE PALM OF HER

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HAND IMMEDIATELY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE BECAME PREGNANT; HAD A SURGERY BECAUSE HER APPENDIX CAUGHT PET FIBERS AND SWELLED 4X THE SIZE (REGARDED AS MIGRATION OF ESSURE TO ABDOMEN) AND EXPERIENCED ANAEMIA DUE TO STOMACH ULCERS THAT PERFORATED AND HAEMORRHAGE. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. PERFORATED STOMACH ULCERS WITH HEMORRHAGE AND ANEMIA ARE UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE OTHER EVENTS ARE LISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, THE REPORTED POST PROCEDURAL BLEEDING WAS CONSIDERED AS RELATED TO THE SUSPECT DEVICE. REGARDING THE REPORTED DEVICE MIGRATION AND PREGNANCY; LIMITED INFORMATION WAS PROVIDED. IT IS NOT KNOWN WHETHER ESSURE WAS MIGRATED FIRST AND THE PREGNANCY FOLLOWED, OR WHETHER IT WAS IN PLACE DURING THE CONCEPTION AND WAS MIGRATED LATER. HOWEVER, AS THE CONSUMER APPARENTLY GOT PREGNANT YEARS AFTER ESSURE INSERTION, A DEVICE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. FOR THE REMAINING EVENTS, GIVEN THEIR NATURE AND CONSIDERING ESSURE LOCAL ACTION AT FALLOPIAN TUBES, CAUSALITY IS CONSIDERED UNLIKELY. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, AS ALTHOUGH LIMITED INFORMATION WAS PROVIDED; CONSUMER STATED SHE HAD TO UNDERGO A SURGERY TO REMOVE SCAR TISSUE FROM HER APPENDIX (REGARDED AS SURGERY FOR ADHESIONS PRODUCED BY A MIGRATED ESSURE). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00731	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT CONSUMER HAD TO HAVE HYSTERECTOMY AT (B)(6) BECAUSE SHE WAS NOT TESTED FOR A NICKEL ALLERGY. SHE HAD A DECLINING OF HER HEALTH AND HAD EVERY IMAGINABLE SIDE EFFECT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DETECTED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO AN ADULT FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS NOT TESTED TO NICKEL ALLERGY AND THEN HAD TO HAVE HYSTERECTOMY AT (B)(6). THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY. IN THIS CASE, ALTHOUGH THE CHARACTERISTICS AND ONSET DATE OF THIS NICKEL ALLERGY HAVE NOT BEEN PROVIDED, CONSIDERING EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE THIS EVENT LED TO REQUIRED INTERVENTION (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00732	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE ADULT CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. ACCORDING TO THE CONSUMER WITHIN A YEAR TIME SHE WAS HAVING PROBLEMS. IT CAME TO THE POINT OF ALMOST LOSING HER HUSBAND. SHE WAS IN SO MUCH PAIN AND DIDN'T KNOW WHY. AS TIME WENT ON, HER MIND WAS NOT GOOD. SHE COULDN'T THINK STRAIGHT. SHE HAD NO IDEA IT WAS ESSURE UNTIL HAVING IT FOR 5 YEARS. SHE STATED THAT ESSURE MADE HER WANT TO KILL HERSELF. AT TIME OF THIS REPORT SHE WAS (B)(6) AND WAS ESSURE FREE. SHE HAD TO HAVE A HYSTERECTOMY TO HAVE THEM REMOVED. CONSUMER REPORTED THAT SHE FEEL LIKE A HUMAN NOW THAT SHE HAVE HAD THEM REMOVED. THE EVENTS WERE ASSESSED AS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS CASE REPORT, DETECTED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO AN ADULT FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SO MUCH PAIN. SHE ALSO WANTED TO KILL HERSELF. THESE EVENTS, SEEN AS PELVIC PAIN AND SUICIDAL DEPRESSION ARE SERIOUS DUE REQUIRED INTERVENTION AND MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. GIVEN PELVIC PAIN'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSAL RELATIONSHIP WITH ESSURE USE CANNOT BE EXCLUDED. ALTHOUGH LIMITED INFORMATION REGARDING THESE SUICIDAL DESIRE HAVE BEEN PROVIDED, CONSIDERING IT IS MOSTLY A COMPLICATION OF DEPRESSION, WHICH MAY

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OCCUR DURING ESSURE USE, CAUSALITY WITH ESSURE USE IS ASSESSED AS RELATED. SINCE ESSURE REMOVAL WAS REQUIRED (VIA HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. PTC ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00733	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 2/19/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/19/2009
Explant Date (E7): 4/7/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009 FOR BIRTH CONTROL. THE CONSUMER STATED SHE HAD A TILTED UTERUS. THE INSERTION PROCEDURE WAS DONE IN THE OPERATING ROOM; SHE HAD A LITTLE CRAMPING UPON WAKING AND SOME BLEEDING; SHE ENDED UP TAKING HALF OF THE NEXT WEEK OF. ABOUT 6 WEEKS AFTER HAVING ESSURE, SHE WAS IN A CHAIR AND TWISTED A BIT AND HAD HORRIBLE PAIN, FELT LIKE SHE GOT STABBED. THE HSG (HYSTEROSALPINGOGRAM) TEST WAS DONE AND IT WAS PAINFUL AND HORRIBLE. THEY HAD A SALES REPRESENTATIVE IN THE ROOM AND HE SAID EVERYTHING WAS BLOCKED. FROM THAT DAY SHE NEVER GAVE ESSURE ANOTHER THOUGHT. SHE BEGAN TO GET NIGHT SWEATS. ANOTHER SYMPTOM IN THE MIDDLE OF THE NIGHT WAS SHE WOULD WAKE UP FEELING REALLY NAUSEATED; SHE WOULD GET VERY PALE AND VERY SICK BUT NEVER THROW UP. THERE WAS NO PATTERN. OTHER TIMES SHE'D WAKE UP ITCHING; A MADDENING ITCHING ON HER SHOULDERS, IT WAS ALSO WHILE SLEEPING BUT NO RASH WAS VISIBLE, SHE STATED IT WAS COMING FROM THE INSIDE OUT. IN (B)(6) 2009, THE MONTH AFTER SHE WENT OFF THE PILL HER MONTHLY PMS (UNDERSTOOD AS PRE-MENSTRUAL SYNDROME) MIGRAINES INCREASED TO WAY MORE OFTEN. SHE COULD GET 15-20 HEADACHES A MONTH; SHE STARTED ACUPUNCTURE AND MONTHLY MASSAGES TO SEE IF IT WOULD HELP, HER NECK STARTING ACHING AND IT WOULD DRIVE HER NUTS AND TURN INTO MIGRAINE. SHE HAD TO CUT HER HOURS AT WORK AS SHE COULD NOT HANDLE THE PAIN. IN 2013, HER MOOD WENT SOUTH AS SHE FELT SOMETHING WAS WRONG AND SHE WAS NEAR HAVING A NERVOUS BREAKDOWN. IN 2014, SHE COULD

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BARELY EXERCISE; SHE ENDED UP WITH TWO SPRAINS. SHE HAD A BLOOD TEST DONE AND SEEMED NORMAL EXCEPT FOR LOW VITAMIN D; SHE TOOK TOPAZ FOR MIGRAINES AS SUGGESTED AND HAD BAD REACTIONS. SHE SAW A NEUROLOGIST AND TOLD HIM SHE ACHES ALL OVER AND HAD FIBROMYALGIA SYMPTOMS; HE GAVE HER TOPAMAX AND SUGGESTED LESS CAFFEINE, WHICH DIDN'T HELP AND SHE HAD FEVER FOR 5 DAYS. SHE ALSO REPORTED AN UNEXPLAINED BRUISE APPEARED ACROSS HER NOSE AND THEN IN HER BELLY; SHE EXPERIENCED HORRIBLE BLOATING WHICH SHE TRIED TO TREAT BUT HAD NO RELIEF. THEN HER MEMORY STARTED GETTING OFF, SHORT TERM WAS AFFECTED. IN THE SUMMER OF 2014, HER LOWER BACK STARTED ACHING; HER PMS WOULD BRING PAIN AND PERIOD TIME BECAME DREADFUL FOR PAIN. ON UNSPECIFIED DATE, SHE SAW HER X-RAYS AT HER CHIROPRACTOR AND ONE COIL WAS TOTALLY OUT OF PLACE AND LOOKED TO BE IN HER UTERUS; THE OTHER LOOKED IN PLACE BUT KINKED INTO A V SHAPE. ON (B)(6) 2015, SHE HAD A FULL UNNECESSARY HYSTERECTOMY; ONE OVARY WAS LEFT FOR SOME HORMONES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SOME BLEEDING AFTER THE PROCEDURE (INTERPRETED AS PROCEDURAL BLEEDING). SIX WEEKS AFTER INSERTION SHE HAD HORRIBLE PAIN, FELT LIKE SHE GOT STABBED (INTERPRETED AS PELVIC PAIN). SHE UNDERWENT AN HYSTERECTOMY 6 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENTS SOME BLEEDING AND HORRIBLE PAIN, FELT LIKE SHE GOT STABBED, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00734	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 AT (B)(6). IN (B)(6) OF 2015 THE CONSUMER STARTED HAVING LOWER LEFT PAIN IN PELVIS RUNNING UP LEFT SIDE INTO HER BACK. HER LEFT LEG HAD SHOOTING PAINS AND HER LEFT ARM WOULD GO NUMB. SHE HAD 2 ROUNDS OF BLOOD WORK, 2 ULTRASOUNDS, 1 COLONOSCOPY DONE BY A SPECIALIST, 1 CAT SCAN, AND 1 X-RAY. FINALLY THE CAT SCAN SHOWED SHE HAD AN ESSURE COIL MISSING OUT OF HER RIGHT TUBE. IT WAS NO WHERE TO BE FOUND. SHE INSISTED ON AN X-RAY AND THE COIL MIGRATED OUT OF HER RIGHT TUBE AND WAS IN THE LEFT SIDE OF PELVIS. NOW SHE HAVE TO HAVE A SURGERY TO REMOVE THE ESSURE COIL AND A FRAGMENT THAT BROKE OFF BEFORE THEY LODGE IN TISSUE OR ORGANS. SHE IS (B)(6) AND MAY BE FACING A HYSTERECTOMY. SHE IS SENSITIVE TO NICKEL AS WELL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A CT SCAN SHOWED ESSURE COIL WAS MISSING OUT OF RIGHT TUBE, THE COIL MIGRATED OUT OF RIGHT TUBE AND WAS IN LEFT SIDE OF PELVIS. ADDITIONALLY, SHE STATED ESSURE FRAGMENT BROKE OFF. THE REPORTED EVENTS WERE INTERPRETED AS DEVICE MIGRATION AND BREAKAGE. ONLY DEVICE MIGRATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION OR MIGRATION (INTO FALLOPIAN TUBE OR TO PELVIC CAVITY). IN THIS CASE, CONSUMER'S SYMPTOMS STARTED 5 YEARS AFTER ESSURE

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PLACEMENT AND LIMITED INFORMATION WAS PROVIDED TO CONCLUDE ON THE MECHANISM OF THE REPORTED EVENTS. NEVERTHELESS, CONSIDERING THEIR NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

T PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00735	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON UNSPECIFIED DATE SHE HAD ESSURE IMPLANTED FOR PERMANENT BIRTH CONTROL. SHE WAS INFORMED THAT EVERYTHING WENT SOOTHINGLY. A MONTH LATER, SHE HAD A CT SCAN FOR OTHER REASONS AND IT HAD SHOWED THAT ONE COIL WAS IMPROPERLY PLACED. SHE MADE AN APPOINTMENT WITH HER DOCTOR AND WAS TOLD THAT IT WAS FINE WHERE IT WAS AND THERE WAS NOTHING TO WORRY ABOUT. SHE WENT FOR HSG (HYSTEROSALPINGOGRAM) ALMOST 2 MONTHS LATE DUE TO NO ONE PUTTING IN THE ORDER OR WORKING ON GETTING IT SCHEDULED FOR HER. THE HSG WAS QUITE PAINFUL AND SHOWED THAT ONE OF HER COILS WAS MISSING. FURTHER X-RAYS FAILED TO FIND IT. SHE HAS BEEN EXPERIENCING PAIN ON THE SIDE WHERE THE COIL STILL WAS. SOME PAIN HAD BEEN NOTICED BEFORE ESSURE PLACEMENT BUT IT HAD INCREASED AFTER ESSURE INTENSELY. SHE FOUND A NEW DOCTOR AND HAS A TOTAL HYSTERECTOMY SCHEDULED FOR (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE MONTH LATER A CT SCAN SHOWED ONE COIL WAS IMPROPERLY PLACED. A FEW MONTHS LATER, A HYSTEROSALPINGOGRAM (HSG) SHOWED THAT ONE OF THE COILS WAS MISSING, FURTHER X RAYS ALSO FAILED TO FIND IT. CONSUMER WAS ALSO EXPERIENCING PAIN ON THE SIDE THE COIL STILL WAS. SHE WAS SCHEDULED FOR A HYSTERECTOMY. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD

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MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, CT SCAN AND HSG/X-RAY FINDINGS SUGGESTED ESSURE WAS EXPELLED IN THE MONTHS FOLLOWING INSERTION. CONSUMER ALSO REPORTED INCREASING PAIN IN CLOSE ASSOCIATION WITH ESSURE PROCEDURE. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND EVENTS NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00736	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. SOON AFTER THE PROCEDURE, SHE STARTED EXPERIENCING EXTREMELY PAINFUL PELVIC PAIN, LOWER BACK PAIN, PAIN DURING INTERCOURSE, MOOD SWINGS AND OTHER SYMPTOMS. SHE TRUSTED HER DOCTOR AND NOW SHE WAS DEALING WITH THE AFTERMATH OF ESSURE: A TOTAL HYSTERECTOMY. SHE LOST HER PARTNER OF 16 YEARS. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DETECTED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO AN ADULT FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SOON AFTER THE PROCEDURE, STARTED EXPERIENCING EXTREMELY PAINFUL PELVIC PAIN THIS EVENT IS SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SOON AFTER DEVICE INSERTION, THE CONSUMER PRESENTED EXTREMELY PAINFUL PELVIC PAIN AND OTHER NON-SERIOUS EVENTS. AT THE MOMENT OF THE REPORT SHE WAS DEALING WITH TOTAL HYSTERECTOMY. CONSIDERING EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. ALTHOUGH IT IS NOT CLEAR IF THE HYSTERECTOMY HAS ALREADY BEEN PERFORMED, AN INTERVENTION APPARENTLY IS BEING CONSIDERED. THUS, THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00737	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ACCORDING TO THE CONSUMER, SHE GOT ESSURE BECAUSE SHE WAS TOLD IT WAS AN EASY SAFE NON-SURGICAL PROCEDURE. SHE WAS NOT TOLD THERE WAS NICKEL IN IT. IF SHE HAD KNOWN, SHE WOULD NOT HAVE GOTTEN DUE TO THE FACT SHE WAS ALLERGIC TO IT. SHE HAD THE PROCEDURE DONE AND WITHIN 3-4 MONTHS SHE WAS IN SEVERE PAIN BARELY ABLE TO WALK. HER SYMPTOMS OVER THE MONTHS INCLUDED: HAIR LOSS, EXTREME NIGHT SWEATING, SEVERE HIP PAIN (SHE COULD NOT BEAR ANY WEIGHT ON IT WITHOUT FALLING OR CRYING WITH PAIN), 2 MENSTRUAL CYCLES A MONTH SOMETIMES WITH NO BREAK IN BETWEEN INCLUDING BLOOD CLOTS THE SIZE OF DIMES UP TO THE SIZE IF A GOLF BALL, SKIN RASH THAT INCLUDED ITCHING SO BAD SHE WANTED TO RIP HER SKIN OFF FOR RELIEF, STOMACH CRAMPING, TINGLING AND NUMBNESS FROM PELVIS DOWN TO HER TOES, PAINFUL SEXUAL INTERCOURSE, EXTREME BRAIN FOG, SEVERE MOOD SWINGS. SHE DID NOT HAVE A SINGLE ONE OF THOSE PROBLEMS BEFORE ESSURE. BY MONTH ELEVEN SHE HAD A BILATERAL SALPINGECTOMY WITH D&C (DILATION AND CURETTAGE). ALMOST IMMEDIATELY HER EXTREME HIP PAIN WENT AWAY. THE SIDE EFFECTS WERE ALL GONE WITHIN A FEW MONTHS OF REMOVAL. SHE STATED SHE LOST HER QUALITY OF LIFE AND A LOT OF TIME WITH HER 3 CHILDREN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN. SHE WAS SUBMITTED TO A BILATERAL SALPINGECTOMY AND DILATION/CURETTAGE. THIS EVENT WAS CONSIDERED SERIOUS DUE

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TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER HAD SEVERE PAIN AND OTHER NON-SERIOUS EVENTS (SUCH AS HIP PAIN AND MENSTRUAL CHANGES), WHICH STARTED WITHIN 3-4 MONTHS AFTER ESSURE INSERTION. THESE EVENTS RECOVERED WITH DEVICES REMOVAL BY BILATERAL SALPINGECTOMY (PERFORMED 11 MONTHS AFTER ESSURE PLACEMENT). CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00738	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE WAS EXPERIENCING CONSTANT PELVIC PAIN EVERY DAY AND BLOATING REALLY BAD. SHE WAS ALSO STRUGGLING TO KEEP HER RELATIONSHIP WITH HER SPOUSE BECAUSE SHE WAS UNABLE TO BE INTIMATE WITH HIM BECAUSE THE PAIN WAS UNBEARABLE. SHE FELT LIKE SHE WAS UNABLE TO DO MANY THINGS WITH HER KIDS AGES (B)(6). ESSURE REMOVAL SURGERY WAS SCHEDULED ON (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED CASE REPORT DETECTED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT PELVIC PAIN EVERYDAY AMONG OTHER NON-SERIOUS EVENTS. THIS EVENT IS SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, CONSIDERING EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED AND A SURGERY WAS SCHEDULED, THIS CASE IS REGARDED AS INCIDENT. PTC ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVI

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00739	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 6/23/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED ESSURE CAUSED INFLAMMATION IN HER ENTIRE BODY, NOT JUST HER TUBES WHICH RESULTED IN MUSCLE AND JOINT PAIN AS WELL AS CONSTANT FATIGUE AND COMPLETE LOSS OF SEX DRIVE. SHE SPENT HUNDREDS OF DOLLARS GOING TO HER PCP AND A SPECIALIST BECAUSE THEY THOUGHT SHE HAD AN AUTOIMMUNE DISEASE. SHE STATED THAT EVERY TEST CAME BACK NEGATIVE BUT NONE OF THE SYMPTOMS WENT AWAY. FINALLY AFTER TALKING WITH OTHER WOMEN THAT HAD ESSURE, SHE DID A LOT OF RESEARCH AND CAME TO THE CONCLUSION THAT ESSURE WAS MOST LIKELY RESPONSIBLE FOR HER DECLINE IN HEALTH. THEN, WHILE AT WORK, SHE STOOD UP AND FELT A GUSH OR BLOOD FROM BETWEEN HER LEGS. UPON FURTHER INVESTIGATION, IT APPEARED AS IF SHE HAD A MISCARRIAGE, SHE WAS NOT ABLE TO CONFIRM BECAUSE THIS WAS LATE ON A FRIDAY NIGHT AND COULD NOT ASK MY DOCTOR UNTIL MONDAY, BUT BY THE DETAILED DESCRIPTION, SHE BELIEVED THAT SHE HAD MISCARRIED. SHE STATED THAT LUCKILY SHE WAS ABLE TO GET THEM OUT BEFORE THEY MIGRATED, BUT HAVING ESSURE INSIDE HER BODY WAS THE MOST MISERABLE YEAR OR HER LIFE; IT AFFECTED HER WORK AS A POLICE OFFICER, IT AFFECTED HER LIFE WITH HER BOYFRIEND, AND IT PREVENTED HER FROM HAVING THE ENERGY TO PLAY WITH HER SON. ON (B)(6) 2015, SHE HAD A HYSTERECTOMY AND SINCE THEN SHE REGAINED HER ENERGY AND WAS ABOUT 90% PAIN FREE; HER SEX DRIVE HAS RETURNED 100% AND SHE FELT GREAT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN

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FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD INFLAMMATION IN HER ENTIRE BODY THAT RESULTED IN MUSCLE PAIN AND JOINT PAIN. ONE DAY, SHE HAD A GUSH OF BLOOD THAT SHE DISCUSSED WITH HER PHYSICIAN AND SHE BELIEVED SHE HAD MISCARRIAGE (IMPLIED PREGNANCY WITH ESSURE). SHE HAD A HYSTERECTOMY AND WAS ABOUT 90% PAIN FREE. THE EVENTS PREGNANCY WITH CONTRACEPTIVE DEVICE AND MISCARRIAGE ARE LISTED WHILE INFLAMMATION IN ENTIRE BODY IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, IT IS IMPLIED THAT INFLAMMATION OCCURRED WHILE ON ESSURE. ALTHOUGH THE ESSURE MECHANISM INVOLVES A LOCALIZED INFLAMMATION, IT WOULD NOT BE EXPECTED THAT IT COULD CAUSE AN INFLAMMATION IN THE WHOLE BODY. HOWEVER, SINCE THERE IS NO ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS CASE, THE ELAPSED TIME BETWEEN THE ESSURE INSERTION AND THE PREGNANCY IS NOT KNOWN. THERE ARE NO DETAILS REGARDING ITS INSERTION. THEREFORE, THE CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. ALTHOUGH GESTATIONAL AGE HAS NOT BEEN PROVIDED, SPONTANEOUS ABORTIONS OCCUR MOSTLY DURING THE FIRST 12 WEEKS OF PREGNANCY AND THE VAST MAJORITY OF THESE CASES ARE DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS, SO THE EVENT IS CONSIDERED AS UNRELATED TO ESSURE USE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00741	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED HER DOCTOR ASSURED HER THAT ESSURE WAS THE RIGHT CHOICE FOR HER; UNFORTUNATELY, HER LEFT COIL DID NOT TAKE AND WAS NEVER REMOVED. IT MIGRATED TO HER UTERINE WALL, CAUSING PAINFUL PERIODS, DAYS-LONG BOUTS OF NAUSEA AND VOMITING DURING HER PERIOD EACH MONTH AND PERSISTENT FATIGUE. SHE OPTED FOR A HYSTERECTOMY TO SOLVE THE PROBLEM. AFTER THE SURGERY, SHE FELT BETTER THAN SHE HAD IN 10 YEARS; SHE HAD FULL ENERGY BACK, NO MORE INSOMNIA AND NO MORE NAUSEA. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DETECTED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO AN ADULT FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE OF DEVICES MIGRATED TO HER UTERINE WALL. THIS EVENT, SEEN AS DEVICE EMBEDMENT, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE COILS MAY DISLOCATE AND EMBED INTO UTERUS OR FALLOPIAN TUBES. IN THIS CASE, THE LEFT DEVICE HAVE MIGRATED TO HER UTERINE WALL. SHE UNDERWENT AN HYSTERECTOMY AND AFTER THAT SHE FELT MUCH BETTER. CONSIDERING THIS INFORMATION AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00742	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE WAS ALLERGIC TO THE NICKEL AND HAD SYSTEMIC REACTIONS RESULTING IN THE NEED FOR A TOTAL HYSTERECTOMY. SHE SUFFERED FROM DEBILITATING MIGRAINES AND ALSO HAD ABDOMINAL PAIN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND REPORTED SHE WAS ALLERGIC TO THE NICKEL AND HAD SYSTEMIC REACTIONS, RESULTING IN THE NEED FOR A TOTAL HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE; IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED. IN THE PRESENT CASE, THE EXACT SYMPTOMS OF THE NICKEL ALLERGY WERE NOT REPORTED; CONSUMER MENTIONED SHE WAS ALLERGIC TO THE NICKEL AND HAD SYSTEMIC REACTIONS. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (TOTAL HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00744	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2008
Explant Date (E7): 9/11/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. THE CONSUMER REPORTED HER GYNECOLOGIST DID NOT TELL HER THE COILS WERE NICKEL PLATED AND SHE WAS HIGHLY ALLERGIC TO NICKEL. SHE ENDED UP HAVING TWO MISCARRIAGES AND ALSO FINDING OUT SHE HAD ENDOMETRIOSIS AND ANDOMETRIOSIS, AND A 4CM CYST ON HER LEFT OVARY AND A 3CM CYST ON HER RIGHT AND ALSO HAVING ONE RUPTURE. SHE DEALT WITH EXTREME PELVIC PAIN EVERY DAY, NO ENERGY, SEVERE MIGRAINES TO THE POINT THEY MADE HER VOMIT; SHE WAS BLOATED ALL THE TIME AND DEPRESSED; SHE ALSO STARTED LOSING HER HAIR. SHE ALSO MENTIONED HER LEFT COIL WAS EITHER BENT OR THE DOCTOR INSERTED TWO ON ONE SIDE WHICH CAUSED MAJOR PROBLEMS. ON (B)(6) 2014, SHE HAD A LAVH HYSTERECTOMY (LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY). THIS CASE REFERS TO THE FIRST PREGNANCY; SECOND PREGNANCY WAS REPORTED UNDER REFERENCE 2015-404535. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXTREME PELVIC PAIN EVERYDAY, GOT PREGNANT WITH ESSURE AND ENDED UP HAVING TWO MISCARRIAGES. SHE ALSO HAD ONE OVARIAN CYST RUPTURE. SHE UNDERWENT AN HYSTERECTOMY 6 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN AND PREGNANCY ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENTS ARE UNLISTED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE THE CONSUMER ALSO

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HAD ENDOMETRIOSIS, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THIS PAIN. HOWEVER, GIVEN THE NATURE OF THIS EVENT A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE. IN THE PRESENT CASE, LIMITED INFORMATION REGARDING THE PREGNANCY WAS PROVIDED. IT WAS NOT REPORTED WHETHER THE CONSUMER UNDERWENT A CONFIRMATION TEST, OR THE TIME INTERVAL BETWEEN ESSURE INSERTION AND THE PREGNANCY. HOWEVER, GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE MISCARRIAGE, IT IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY. THIS IS CONSIDERED TO BE DUE TO A HIGH NUMBER OF ABNORMAL EMBRYOS PRESENTING WITH EITHER CHROMOSOMAL AND/OR GROSS MORPHOLOGICAL ABNORMALITIES. IN THIS CASE, THE GESTATIONAL AGE WAS NOT PROVIDED. HOWEVER, GIVEN THE ABOVE MENTIONED INFORMATION AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THIS EVENT WAS CONSIDERED UNRELATED TO THE INSERT. A RUPTURED OVARIAN CYST IS A COMMON PHENOMENON. GIVEN THE NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP WITH ESSURE WAS CONSIDERED VERY UNLIKELY (UNRELATED). NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00745	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED DATE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT HER COILS MIGRATE AND PUNCTURE HER UTERUS. SHE LIVED WITH CONSTANT STABBING PAIN FOR THREE YEARS UNTIL A HYSTERECTOMY WAS DONE TO REMOVE ALL THE FRACTURED BITS OF THE COILS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER COILS MIGRATE AND PUNCTURE HER UTERUS. SHE STATED A HYSTERECTOMY WAS DONE TO REMOVE ALL THE FRACTURED BITS OF THE COILS. THE REPORTED EVENTS WERE INTERPRETED AS UTERINE PERFORATION AND DEVICE BREAKAGE. UTERINE PERFORATION WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION, MIGRATION OR OCCUR AS A RESULT OF A UTERINE PERFORATION. IN THIS CASE; LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENTS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00746	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED IN (B)(6) 2013. CONSUMER REPORTED THAT DURING PROCEDURE SHE FELT HORRIBLE PAIN; IT MADE HER SICK TO HER STOMACH AND TEARS BEGAN POURING DOWN HER FACE. DOCTOR TOLD HER THAT THE DEVICE MALFUNCTIONED WHILE INSIDE HER AND SHE HAD A DEVICE MISPLACED WHEREIN HE COULD NOT REMOVE WITHOUT ADDITIONAL DAMAGE. AFTER A WEEK, SHE WAS CALLED TO RESCHEDULE TO INSERT DEVICE AGAIN. THERE WAS MORE PAIN, HOWEVER, IT WENT AS DESIGNED AND SHE LEFT WITH 3 TOTAL COILS IN HER BODY. ONE MONTH AFTER PROCEDURE, A TEST WAS DONE AND CONFIRMED THAT HER TUBES WERE COMPLETELY CLOSED. THE FOLLOWING YEAR (2014), SHE STARTED NOTICING EXTREME FATIGUE, SPOTTING DURING THE MONTH (WHICH SHE NEVER HAD BEFORE), CRAMPING (NEVER HAD BEFORE) AND MANY OTHER UNEXPLAINED SYMPTOMS. SHE VISITED HER DOCTOR AND IT WAS DETERMINED THAT SHE HAD LOW TESTOSTERONE. SHE BEGAN RECEIVING THE PELLETS, THOUGH, THOSE QUICKLY SEEN TO FADE AND SHE WAS BACK TO SQUARE ONE. THERE WERE DAYS THAT SHE COULD NOT GET OUT OF BED. SHE EXPERIENCED MONTHS OF EXCESSIVE BLEEDING, HUGE CLOTS, 2 PERIODS A MONTH, EXCESSIVE SWEATING, WEIGHT GAIN (SHE GAINED OVER 30LBS IN 2 YEARS), ABDOMINAL IMMEDIATELY BLOATED (SHE LOOKED AS SHE WAS 7 MONTHS PREGNANT), PERIODS WERE MOST PAINFUL THING. SHE WAS BLEEDING THROUGH MULTIPLE TAMPONS, PADS AND THROUGH CLOTHES. SEX BECAME NOT ENJOYABLE BECAUSE OF THE PAIN AND BLEEDING. SHE ALSO HAD SHARP PAINS IN BACK. SHE WAS SCHEDULED TO HAVE A HYSTERECTOMY ON (B)(6) 2015. COMPANY CAUSALITY

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COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MONTHS OF EXCESSIVE BLEEDING/HUGE CLOTS. A HYSTERECTOMY WAS SCHEDULED. THIS EVENT, INTERPRETED AS GENITAL BLEEDING IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE BLEEDING WAS NOTICED THE FOLLOWING YEAR OF INSERTION. SINCE THE TEMPORAL RELATIONSHIP IS SUGGESTIVE AND NO ALTERNATIVE EXPLANATION WAS PROVIDED, THE GENITAL BLEEDING IS ASSESSED AS RELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00747	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012 FOR CONTRACEPTION. THE CONSUMER REPORTED SHE HAD THREE PREGNANCIES SINCE 2005, TWO OF WHICH WERE CONSIDERED HIGH-RISK AND WERE PHYSICALLY AND EMOTIONALLY EXHAUSTING; ALL THREE PREGNANCIES REQUIRED C-SECTION DELIVERIES AND THE RECOVERIES WERE NEARLY AS DIFFICULTY AS THE PREGNANCIES THEMSELVES. SHE STATED ESSURE SOUNDED LIKE THE PERFECT FIT BECAUSE IT DID NOT REQUIRE INVASIVE SURGERY, WHICH SHE DIDN'T WANT TO GO THROUGH AGAIN AFTER JUST GIVING BIRTH TO HER SON BY C-SECTION ON (B)(6) 2012. THE INSERTION WAS PERFORMED AS AN OUTPATIENT PROCEDURE AT A LOCAL HOSPITAL; UNDER ANESTHESIA. WHEN SHE AWOKE, HER GYNECOLOGIST EXPLAINED THAT SHE HAD SOME DIFFICULTY PLACING THE LEFT SIDE DEVICE, BUT THAT EVERYTHING APPEARED TO BE SUCCESSFUL. SHE EXPERIENCED SHARP, STABBING ABDOMINAL PAIN AND PROLONGED HEAVY BLEEDING THE MOMENT SHE WOKE UP FROM ANESTHESIA. AFTER INSERTION, SHE EXPERIENCED THE HEAVY BLEEDING AND STABBING ABDOMINAL PAIN FOR 6 WEEKS. WHEN THE BLEEDING FINALLY ENDED, SHE THOUGHT IT WOULD RESUME AS NORMAL BUT DURING THE TIME FROM INSERTION UNTIL THE TIME OF THE REPORT, EVERY MENSTRUAL CYCLE SHE HAD BECOME INCREASINGLY PAINFUL WITH SEVERE CRAMPING AND SEVERE BLOATING AND SWELLING OF HER ABDOMEN; SHE EXPELLED LARGE BLOOD CLOTS THE FIRST FEW DAYS OF HER CYCLE AS WELL IT HAS COME TO THE POINT WHERE THE PAIN AND HEAVY FLOW HAVE BEGUN TO INTERFERE WITH HER DALLY ACTIVITIES. DURING HER MENSTRUAL CYCLE, HER ENERGY LEVELS WERE COMPLETELY DEPLETED

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AND IT BECOMES DIFFICULTY TO DO THE THINGS SHE WANTED. SHE ALSO EXPERIENCED DURING THIS POST-INSERTION TIME PERIODIC SHARP STABBING PELVIC PAIN WHEN SHE SNEEZE HARD, OR IF WAS USING HER ABDOMINAL MUSCLES (FOR EXAMPLE, DURING EXERCISE). SHE WAS UNABLE TO HAVE THE HSG (HYSTEROSALPINGOGRAM) TEST TO CONFIRM PROPER PLACEMENT AND IN (B)(6) 2014, SHE FOUND OUT THAT SHE WAS PREGNANT ALMOST 2 YEARS AFTER HAVING ESSURE IMPLANTED. HER POST-ESSURE PREGNANCY WAS ABSOLUTELY THE WORST ONE YET. FROM THE VERY BEGINNING SHE HAD CONTINUOUS, PAINFUL CRAMPING AND CONTRACTIONS RIGHT UNTIL THE DAY SHE GAVE BIRTH ON (B)(6) 2015, BY ANOTHER C-SECTION. HER DAUGHTER WAS BORN SAFELY AND SHE MADE IT THROUGH THE PREGNANCY AND DELIVERY; BUT THE CONSUMER SUFFERED THROUGH EVERY MOMENT OF IT, AGAIN BOTH PHYSICALLY AND EMOTIONALLY, AS SHE HAD IN HER PREVIOUS PREGNANCIES. FOUR MONTHS POST-PARTUM, SHE EXPERIENCED ADDITIONAL SYMPTOMS INCLUDING PINCHING PAIN AND PRESSURE IN HER TAIL BONE AREA, AS WELL AS HER RIGHT LOWER PELVIC/HIP AREA, AND EVEN GREATER PAIN, BLOATING AND CLOTTING DURING HER MENSTRUAL CYCLES. ON (B)(6) 2015, AN HSG TEST WAS DONE TO CHECK PLACEMENT AND ON (B)(6) 2015 X-RAY WAS DONE (DURING AN UNRELATED IVP TEST TO CHECK FOR KIDNEY STONES). HER DOCTOR CONFIRMED THAT NEITHER ESSURE COIL WERE PROPERLY PLACED BOTH HAVE MIGRATED OUTSIDE OF THE FALLOPIAN TUBES; BOTH COILS WERE LOCATED IN AREAS THAT SHE HAD EXPERIENCED THE GREATEST AMOUNT OF LOWER BACK AND ABDOMINAL PAIN AS WELL. SHE STATED THAT NOW SHE WILL HAVE TO ENDURE ANOTHER SURGERY TO HAVE THE FALLOPIAN TUBES AND THE COILS REMOVED ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. AFTER DELIVERY VIA C-SECTION; A HYSTEROSALPINGOGRAM (HSG) SHOWED BOTH ESSURE DEVICES MIGRATED. ACCORDING TO HER, DEVICES AND FALLOPIAN TUBES REMOVAL IS SCHEDULED. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY C-SECTION IS UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG) TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, NO HSG WAS PERFORMED AND PATIENT BECAME PREGNANT ALMOST 2 YEARS AFTER ESSURE INSERTION. LATER A DEVICE MIGRATION WAS FOUND. ALTHOUGH PREGNANCY IN THIS CASE COULD BE CONSIDERED RATHER A CONSEQUENCE OF NON-COMPLIANT USE; SINCE IT IS NOT KNOWN WHETHER ESSURE WAS MIGRATED FIRST AND THE PREGNANCY FOLLOWED, OR WHETHER IT WAS IN PLACE DURING THE CONCEPTION AND WAS MIGRATED LATER A CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING C-SECTION, THE REASON FOR THIS PROCEDURE WAS NOT CLEARLY REPORTED; HOWEVER CONSUMER HAD 3 PREVIOUS C-SECTIONS, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THIS PROCEDURE. THEREFORE, IT WAS CONSIDERED AS UNRELATED TO ESSURE. ADDITIONALLY, CONSUMER HAD PROLONGED BLEEDING FOR 6 WEEKS AFTER ESSURE INSERTION (SERIOUS, LISTED EVENT) AND OTHER NON-SERIOUS EVENTS. THIS CASE WAS CONSIDERED AN INCIDENT; SINCE SURGICAL INTERVENTION WILL BE REQUIRED (SALPINGECTOMY SCHEDULED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 27-SEP-2015 AND ON 29-SEP-2015. CONSUMER STATED THAT ON COIL WAS DEEPLY EMBEDDED IN HER UTERUS AND HER DOCTOR COULD NOT REMOVE WITHOUT HER BLEEDING OUT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00748	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4): A57114
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/24/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 11-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; LOT NUMBER USED WAS A57114. THE PHYSICIAN REPORTED THAT THE OUTER COIL OF ESSURE CAME OFF OF THE INNER COIL WHILE PLACING IN FALLOPIAN TUBE. THE OUTER COIL WAS PULLED AWAY FROM INNER COIL LEAVING THE INNER COIL EXPOSED AND UNABLE TO BE PLACED IN THE FALLOPIAN TUBE. HOWEVER BILATERAL PLACEMENT OF DEVICE WAS ACHIEVED AND THE PATIENT HAD NO INJURY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT. HER PHYSICIAN STATED, DURING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PROCEDURE, WHILE HE WAS PLACING IN FALLOPIAN TUBE, THE OUTER COIL WAS PULLED AWAY FROM THE INNER COIL. PATIENT HAD NO INJURY. THE REPORTED EVENT, REGARDED AS DEVICE BREAKAGE, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: BATCH NUMBER A57114 PRODUCTION DATE: 9/2012 EXPIRATION DATE: 9/2015 THE ESSURE I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00749	BAYER HEALTHCARE LLC	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5032462) IN UNITED STATES ON 02-JAN-2014 WHICH REFERS TO HERSELF A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY ABNORMAL BLEEDING, ABNORMALLY LARGE OVARIAN CYST, LOWER ABDOMINAL PAIN, FAINTS, PAIN, LOSS OF SEX DRIVE, VAGINAL DISCOMFORT, DIZZY SPELLS, COLLAPSING, MINI STROKE LIKE SYMPTOMS, WEIRD TINGLING SENSATIONS IN HANDS AND FEET (PARTICULARLY THE RIGHT SIDE), SLEEP PROBLEMS EITHER EXTREMELY TIRED DESPITE SLEEPING A TON OR CANT SLEEP, CONSTANTLY DEPRESSED, LACK OF MOTIVATION, TERRIBLY FORGETFUL, BLURRED VISION, UNPREDICTABLE EXTREME BLOATING, NAUSEOUS, HIVES ON ARMS AND LEGS, AND CANNOT WEAR EARRINGS AS HER EARS START SWELLING AND ITCHING FIERCELY. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. IN 2011 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. WITHIN LESS THAN A YEAR, THE CONSUMER DEVELOPED HEAVY ABNORMAL BLEEDING. HER GYNECOLOGIST FOUND AN ABNORMALLY LARGE OVARIAN CYST THAT WOULD REQUIRE SURGERY. IN THE FEW MONTHS IT TOOK TO GET HER SET UP, SHE STARTED HAVING LOWER ABDOMINAL PAIN WHICH WAS THEN ATTRIBUTED TO THE CYSTS AND HAD A COUPLE OF FAINTS. IN 2012, SHE UNDERWENT SURGERY AND TESTS SHOWED THE REMOVED CYST WAS BENIGN. THE PAIN STARTED UP AGAIN A MONTH LATER, THE ABNORMAL HEAVY BLEEDING FOR WEEKS CONTINUED AND OTHER HEALTH ISSUES BEGAN SHOWING THEMSELVES. HOWEVER, HEALTH INSURANCE RAN OUT AND SHE HAVE SINCE SUFFERED WITH EXTREME PAIN, LOSS OF SEX DRIVE, VAGINAL DISCOMFORT, HEAVY BLEEDING, DIZZY SPELLS, COLLAPSING, MINI STROKE LIKE SYMPTOMS, WEIRD TINGLING SENSATIONS IN HANDS AND FEET (PARTICULARLY THE RIGHT SIDE),

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SLEEP PROBLEMS EITHER EXTREMELY TIRED DESPITE SLEEPING A TON OR CAN'T SLEEP, CONSTANTLY DEPRESSED, LACK OF MOTIVATION, TERRIBLY FORGETFUL, BLURRED VISION, UNPREDICTABLE EXTREME BLOATING, NAUSEOUS, HIVES ON ARMS AND LEGS, RECENTLY, CANNOT WEAR HER EARRINGS AS HER EARS START SWELLING AND ITCHING FIERCELY. THE EVENT OUTCOME PROVIDED WAS HOSPITALIZATION. SHE BELIEVED FIRMLY THAT SHE WAS SUFFERING FROM SIDE EFFECTS FROM ESSURE THAT WERE NEVER BROUGHT TO HER ATTENTION. SHE WAS INTENDING UPON GETTING A HYSTERECTOMY TO HAVE ESSURE REMOVED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS RELATED. **FOLLOW-UP RECEIVED ON 26-JAN-2014: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT RECEIVED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC) - INCIDENT REPORT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4) AND THE LOCAL NUMBER IS (B)(4). IF THE OUTCOME OF THE PTC INVESTIGATION CONFIRMS A QUALITY DEFECT OR A COUNTERFEIT, THIS WILL BE COMMUNICATED IN A FOLLOW-UP REPORT. FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN WI-03635, "PROCESSING ESSURE CASES IN DEV@COM." FDA EVALUATION CODES: METHOD: NO TESTING METHODS PERFORMED. RESULTS: NO RESULTS AVAILABLE SINCE NO EVALUATION PERFORMED. CONCLUSIONS: UNABLE TO CONFIRM COMPLAINT; DEVICE NOT RETURNED. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT INDICATIVE FOR A QUALITY DEFECT PER SE. THE MEDICAL EVENTS WERE REPORTED WITH AN OCCURRENCE OVER A PERIOD OF 2 YEARS AND ARE OF BROAD NATURE. THE MAJORITY OF THE REPORTED MEDICAL EVENTS WERE ASSESSED AS BEING NOT RELATED TO ESSURE OR CONSIDERED NOT ASSESSABLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP INFORMATION WAS RECEIVED ON 23-JAN-2014. CONSUMER'S DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE CONSUMER. CONCOMITANT CONDITION INCLUDED OBESITY (BMI (B)(6)). SHE DENIED ANY PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. SHE HAD 06 PREGNANCIES, 03 KIDS, 03 MISCARRIAGES, PREMATURE LABOR FOR MY LAST DAUGHTER WHEN SHE ENDED UP HAVING FLU AND HIGH BLOOD PRESSURE. RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS INCLUDED ASTHMA. AROUND (B)(6) 2010 ESSURE WAS INSERTED (PREVIOUSLY REPORTED AS 2011) 6-8 WEEKS AFTER HER LAST DELIVERY. SHE DIDN'T USE ANYTHING AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. HSG (HYSTEROSALPINGOGRAM) TEST WAS NOT PERFORMED SINCE HER INSURANCE RAN OUT. ON UNSPECIFIED DATE SHE EXPERIENCED BREAST PAIN MOSTLY IN NIPPLES, FEELS LIKE LACTATING AND FUNKY BLEEDING FOR 3 WEEKS WITH SPACING IN BETWEEN. OTHER SYMPTOMS STARTED AROUND (B)(6) 2011. SHE DIDN'T REALLY NOTICE THEM UNTIL (B)(6) 2012. IN (B)(6) 2012 SHE GOT REALLY DIZZY AND COLLAPSED, THINGS GOT NASTIER AND NASTIER AFTER THAT. SHE WENT TO THE DOCTOR WHERE THEY DISCOVERED AN OVARIAN CYST. SHE DOESN'T KNOW WHETHER OR NOT SHE CAN STAY ON HER FEET. THE OUTCOME WAS ONGOING. HER DOCTOR STATED THAT HER BLEEDING SHOULD HAVE CLEARED IN 3 MONTHS AND IT NEVER DID. ON UNSPECIFIED DATE THE CYST WAS LAPAROSCOPICALLY REMOVED. THEY WENT INTO HER BELLY BUTTON CUT CYST OFF THE OVARY. SHE STILL KEPT HER OVARIES. NO HOSPITALIZATION WAS REQUIRED. ESSURE DEVICES HAVE NOT BEEN REMOVED. SHE BELIEVES THE EVENTS WERE CAUSED BY ESSURE SINCE SHE WAS HEALTHY BEFORE IT WAS INSERTED. NO FURTHER INFORMATION WAS PROVIDED. **FOLLOW-UP RECEIVED ON 10-FEB-2014 ACCORDING TO THE CONSUMER, SHE WILL MEET A GENERAL DOCTOR AT THE END OF FEBRUARY. SHE WOULD LIKE TO FIND A GYNECOLOGIST AND HAVE ESSURE REMOVED. SHE WILL CALL BACK TO PROVIDE NEW INFORMATION ONCE THE REMOVAL PROCEDURE HAS BEEN SCHEDULED/PERFORMED. FOLLOW-UP INFORMATION RECEIVED ON 11-AUG-2015: THIS

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CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 ((B)(4)). CONSUMER REPORTED THAT AFTER THREE DIFFICULT PREGNANCIES AND THREE MISCARRIAGES, SHE DECIDED HER FAMILY WAS COMPLETE. HER YOUNGEST WAS ONLY ABOUT SIX MONTHS OLD AND SHE COULDN'T AFFORD THE DOWN TIME OF A TRADITIONAL TUBAL. CONSUMER REPORTED SHE GOT ESSURE DONE IN 2010, BUT BY THE END OF 2011 HER PERIODS WERE GETTING LONGER AND OFF. BY THE BEGINNING OF 2012, SHE WAS BLEEDING FOR WEEKS AT A TIME WITH ONLY A FEW DAYS BETWEEN. SHE ALSO REPORTED A MASSIVE ACNE BREAKOUT THAT WAS SO BAD HER CLOTHES WOULD BE DOTTED WITH BLOOD AND IT HURT WHEN PEOPLE TOUCHED HER BECAUSE SKIN WAS SO COVERED WITH ACNE. SHE WAS EXPERIENCING ABNORMALLY LARGE OVARIAN CYST. SHE WAS SCHEDULED A SURGERY IN JUNE. SHE STARTED HAVING SHARP STABBING PAINS IN HER LOWER LEFT ABDOMEN, DIZZY AND COLLAPSED. THE SURGERY CAME AND WENT, BUT THE BLEEDING CONTINUED AND THE PAIN INCREASED. AT HER SIX WEEK CHECKUP, HER DOCTOR ASSURED THE BLEEDING SHOULD CLEAR UP BY TWO MONTHS. SHE BLED FOR THREE WEEKS AT A TIME, HAD MISERABLE PERIODS WHERE SHE WOULD PASS LARGE CLUMPS, WAS SICK TO HER STOMACH, AND HAD CHRONIC DIARRHEA. SHE GOT A FEW DAYS REPRIEVE AND IT WOULD START UP AGAIN. THE PAIN, MILD AT FIRST, BECAME UNBEARABLE. SHE HAD A HIGH PAIN TOLERANCE BUT AFTER TWO YEARS OF DAILY AGONY, SHE NEEDED TO TAKE PAIN MEDS (WHICH I HADN'T NEEDED AFTER HER SURGERY) AT LEAST ONCE A WEEK SO SHE COULD ACTUALLY GET COMFORTABLE ENOUGH TO SLEEP. THE WEIRD COLLAPSING SPELLS BECAME MORE COMMON TO THE POINT SHE QUIT DRIVING FOR OVER A YEAR. HER HAIR STARTED TO FALL OUT, HER TEETH CRACKED AND BROKE, HER SKIN WOULD BREAK OUT IN HIVE RASHES WITHOUT ANY WARNING, SHE BECAME ALLERGIC TO HER JEWELRY, SHE COULDN'T REMEMBER ANYTHING, HER BRAIN FELT LIKE MUSH, SHE WAS DEPRESSED, SICK ALL THE TIME, SHE COULDN'T SLEEP BUT SHE WAS SO TIRED SHE COULD BARELY MOVE, INTERCOURSE RARELY HAPPENED AND WHEN IT DID, IT ALMOST ALWAYS HAD TO END EARLY CAUSE SHE WOULD BE IN SO MUCH PAIN AND START BLEEDING; HER MIGRAINES BECAME BLINDINGLY EXCRUCIATING AND MORE COMMON. SHE WENT TO A NEW GYNECOLOGIST AND WHEN SHE DID THE FIRST CHECKUP, THE CONSUMER CRIED FROM THE PAIN OF HER FINGERS. SHE PROPOSED A HYSTERECTOMY AND AFTER THE PROPER TESTS SHE REMOVED EVERYTHING BUT HER RIGHT OVARY. HER LEFT WAS TOO RIDDLED WITH CYSTS AND SWOLLEN TO SAVE. THE CONSUMER STATED IT WAS INSTANT RELIEF. SHE STATED THE HYSTERECTOMY SAVED HER LIFE. BEFORE THE SURGERY SHE COULD HARDLY HANDLE SITTING IN A CAR BECAUSE IT HURT SO BAD, AND AT THE TIME OF REPORT SHE COULD JET-SKI, QUAD AND DO THE THINGS THAT MADE HER HAPPY AGAIN. SHE HADN'T HAD A SINGLE PASSING OUT MOMENT, HER HAIR HAD GROWN BACK IN, AND IT TOOK A WHILE BUT SHE COULD EVEN WEAR SOME OF JEWELRY AGAIN. THE ONLY COST WAS THAT SHE HAD TO HAVE A HYSTERECTOMY, AT (B)(6). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF NOT REPORTED AGE WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED SHARP STABBING PAINS IN HER LOWER LEFT ABDOMEN, HEAVY ABNORMAL BLEEDING, ABNORMALLY LARGE OVARIAN CYST, AND MINI STROKE LIKE SYMPTOMS. A HYSTERECTOMY WAS PERFORMED ALONG WITH RIGHT OVARIAN REMOVAL. ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. OVARIAN CYST WAS ALSO SERIOUS DUE TO HOSPITALIZATION. THE LOWER PAIN IN ABDOMEN IS SERIOUS DUE TO REQUIRED INTERVENTION. PAIN IN LOWER ABDOMEN AND HEAVY ABNORMAL BLEEDING ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE ABNORMALLY LARGE OVARIAN CYST AND MINI STROKE LIKE SYMPTOMS ARE UNLISTED. AS THE TEMPORAL RELATIONSHIP BETWEEN HEAVY ABNORMAL BLEEDING AND PAIN IN LOWER ABDOMEN AND ESSURE USE IS SUGGESTIVE, CAUSALITY IS ASSESSED AS RELATED. CONSIDERING THE PATHOPHYSIOLOGY OF OVARIAN CYST AND MINI STROKE LIKE SYMPTOMS AND LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT ESSURE WOULD CAUSE THESE EVENTS. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). PRODUCT TECHNICAL COMPLAINT INVESTIGATION: BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT.

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Manufacturer Narrative (H10):

CASE CONSIDERED CLOSED ON 07-DEC-2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF NOT REPORTED AGE WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED SHARP STABBING PAINS IN HER LOWER LEFT

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055963	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ESSURE PROCEDURE WAS RECOMMENDED BY MY OBGYN SINCE IT WAS MINIMALLY INVASIVE. I WAS UNAWARE THE IMPLANT CONTAINED NICKEL OR IF AN ALLERGIC REACTION POSED A RISK. I'VE BEEN THROUGH A SERIES OF MEDICAL TESTING DUE TO PROGRESSIVE SYMPTOMS (NAUSEA, ABDOMINAL/BACK PAIN, SEVERE CHRONIC FATIGUE, FLU-LIKE SYMPTOMS, HEADACHES, DIZZINESS, TINNITUS, UTIS, UNINTENDED WEIGHT FLUX, STREP A, PERITONSIL ABSCESS, METALLIC TASTE, ETC.) WITHOUT AN DIAGNOSIS. THE MAIN VARIABLE PRIOR TO THE START OF MY SYMPTOMS WAS THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055964	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 6/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATE DIARRHEA, CRAMPING, METAL TASTE IN MY MOUTH, HAIR LOSS, RASH, BODY ACHES, EXCESSIVE TIREDNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055965	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO VISIT THE ER DUE TO PAIN IN THE LOWER LEFT SIDE OF PELVIS; I WAS DIAGNOSED WITH TWO DERMOID CYSTS , ONE THE LEFT AND THE OTHER ONE IN THE RIGHT OVARY . IN THE LEFT OVARY, I HAVE A CALCIFICATION . I HAVE MANY OTHER SIDE EFFECTS LIKE TENDER BREAST, PELVIC PAIN , BACK PAIN, CYSTS, VAGINAL SPOTTING, RASHES, JOINT PAIN, SWOLLEN FEET, DIZZINESS, NAUSEA, VOMIT, HIVES, LACK OF SLEEP, GAIN OF WEIGHT, HEAVY PERIODS, IRREGULAR PERIOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055966	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD SEVERE STOMACH CRAMPING WENT TO THE HOSPITAL. INTERNAL BLEEDING. PREGNANT. THE DOCTORS WANTED TO REMOVE MY CERVIX UTERUS FALLOPIAN TUBES, OVARIES, GALLBLADDER AND A PIECE OF MY INTESTINES FROM WHICH MY COIL HIT AND LEFT BRUISED. I WAS INFORMED THAT I WOULD DIE FROM HOW SICK I AM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055967	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 3/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE, MY JOINTS HAVE GOTTEN TO WHERE I CAN BARELY WALK FROM THE HIP DOWN ON DAYS. IF I SIT FOR TOO LONG, I CAN'T WALK FOR A FEW MINUTES WITH EXTENUATING PAIN, MASSIVE CHARLIE HORSE TYPE CRAMPS IN MY TUBES TO WHERE I DOUBLE OVER IN PAIN AND CAN'T MOVE UNTIL THEY WORK THEMSELVES OUT. BLEEDING THAT SHOULD SEND ME TO A HOSPITAL, SOAKING 2-3 SUPER + TAMPONS IN AN HOUR. NO LIBIDO AND MASSIVE PAIN DURING SEX WHEN I WANT IT. CONCENTRATION PROBLEMS. WEIGHT GAIN, SWELLING, MUSCLE PAIN, TENDON JOINT PAIN. NERVE PAIN THAT IS DEBILITATING IN MY LEGS, FEET, ARMS, SHOULDERS, AND NECK. SWELLING OF THE UTERUS THAT BECOMES LIKE A 7 MONTH PREGNANT WOMAN. MIGRAINES THAT CAUSE TIME AWAY AND MY ENERGY LEVELS ARE NULL AND VOID.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055968	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 12/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, EXTREME FATIGUE, HEADACHES, CONCENTRATION ISSUES, DEPRESSION, NUMBNESS IN ARMS, SEXUAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055997	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 7/31/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED A POSITIVE PREGNANCY TEST ON (B)(6). FROM THAT DAY UNTIL (B)(6), I HAVE HAD TO HAVE NUMEROUS ULTRASOUNDS, BILLS, CRAMPING..ETC. FOUND OUT (B)(6) THAT THE PREGNANCY STOPPED GROWING AT (B)(6). CURRENTLY HAVING TO INDUCE A MISCARRIAGE WHICH WILL INCLUDE PAIN AND EMOTIONAL SUFFERING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055998	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 11/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST NOTICED HAIR LOSS, HEART PALPATATIONS WHEN I WOULD BE RELAXING OR LAYING IN BED. SIX MONTHS LATER I STARTED HAVING ANXIETY/PANIC ATTACKS, MEMORY LOSS HARD TO CONCENTRATE OR THINK, HEAD HAS FEELING OF PRESSURE SOME DAYS, VERTIGO, MUSCLE CRAMPS, SPOTS ON MY HEAD THAT HURT TO THE TOUCH AND PATCHES ON MY SKIN THAT FEEL NUMB AND HURT TO TOUCH, HANDS AND ARMS GOING NUMB, HEADACHES, LARGE BLOOD CLOTS AND HEAVY BLEEDING DURING MENSTRUATION, LACK OF INTEREST IN SEX, PAIN DURING SEX, MOOD SWINGS, AGGRESSIVE AND ANGRY, LACK OF PATIENCE, EXTREME FATIGUE, LACK OF MOTIVATION, CAN NOT LOSE WEIGHT, TASTE OF METAL IN MY MOUTH, DIZZINESS, JOINT PAIN MORE SO RECENTLY, EXTREME BLOATING THAT IT HURTS, PAIN IN LOWER PELVIS ALONG WITH A BLOATED FEELING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5055999	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 8/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS PROVIDED BY MY INSURER. MY SURGEON WAS BEING TRAINED IN THE PROCEDURE, SO HE HAD A LOT OF DIFFICULTY PLACING THE COILS. THE PROCEDURE TOOK MUCH LONGER THAN EXPECTED, AND HE WAS ONLY ABLE TO PLACE ONE OF THE COILS. SINCE THE PLACEMENT, I HAVE HAD MODERATE TO SEVERE NAUSEA, CRAMPING, AND AT TIMES A FIERY PAIN IN MY ABDOMEN, ALONG WITH INFREQUENT STABBING PAINS IN MY PELVIC AREA. I'VE HAD A SONOGRAM WHICH DIDN'T SHOW ANY TROUBLE, AND THERE IS NO SIGN OF INFECTION FROM BLOOD WORK. THE PAIN IS WORST AT NIGHT AND IS AFFECTING MY SLEEP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056000	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE CRAMPING AND PAIN ESPECIALLY AT THE TIME OF MY PERIOD. I COULD/CAN ALWAYS FEEL THE COILS!!! IT'S SO UNCOMFORTABLE AND PAINFUL CONSTANTLY! MY PERIODS BECAME MORE FREQUENT, EVERY 2-3 WEEKS AND VERY HEAVY. I HAD AN ABLATION DONE TO STOP THE BLEEDING AND NOW I AM HAVING TO HAVE A HYSTERECTOMY DONE TO HELP WITH ALL MY PAIN AND BLOATING. THIS IS AWFUL!!! I AM ONLY (B)(6) AND I NEVER IMAGINED THIS IN MY LIFE!!!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056001	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES THAT LAST ALL DAY, BLOATING WHERE I LOOK LIKE I'M PREGNANT, BLURRED VISION, NAUSEA, PELVIC PAIN, BACK PAIN, JOINT PAIN, FATIGUE, NO ENERGY, HAIR LOSS, BALD PATCHES AT TEMPLE AREAS ON BOTH SIDES OF HEAD, MOODY, HOT FLASHES, FORGETFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056002	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON AROUND (B)(6) 2013. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON IN (B)(6) 2013. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. WEIGHT GAIN, RASHES, LOWER BACK PAIN, CRAMPING, LOW SEX DRIVE, IRREGULAR PERIODS, DEPRESSION, ANXIETY, POLY CYSTIC OVARIAN SYNDROME FLARE UP. I HAVE BEEN SEEN BY ONE DOCTOR. I HAVE BEEN TESTED FOR POLYCYSTIC OVARIAN SYNDROME, WAITING ON RESULTS. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056003	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 9/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I FOUND OUT WAS PREGNANT, DOCTOR DID TEST AND SAID IT IS GOING TO BE MISCARRIAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056004	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 7/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AS SOON AS I HAD ESSURE I STOPPED HAVING A PERIOD FOR 6 MONTHS, THEN MY PERIOD STARTED AND WOULDN'T STOP, SIMULTANEOUSLY I STARTED HAVING SERIOUS DIGESTIVE ISSUES, SKIN RASH THAT ITCHES, FATIGUE, BLOATING AND HEADACHES. I HAVE SEEN A GI FOR TWO YEARS HAVE HAD AN ENDOSCOPY AND COLONOSCOPY. THEY FOUND SOME INFLAMMATION BUT NOTHING MAJOR. I HAVE BEEN PUT ON NUMEROUS ANTIBIOTICS. IT ALL STARTED WHEN I GOT ESSURE. I EVEN HAD MY GALL BLADDER REMOVED BECAUSE THEY THOUGHT IT MIGHT BE CAUSING MY STOMACH PROBLEMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056005	BAYER	9/8/2015	9/8/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, HEAVY MENSES WITH LARGE CLOTTING, CHRONIC LOWER BACK PAIN, LOWER ABDOMINAL BLOATING, CHRONIC HEADACHES, CHRONIC FATIGUE, AND SIGNIFICANT WEIGHT GAIN. ALL SYMPTOMS HAVE INSIDIOUS ONSET. LEVEL OF PELVIC AND BACK PAIN HAS INCREASED TO A POINT THAT IT EFFECTS MY DAILY LIFE. I'VE SEEN 3 DOCTORS, NUMEROUS TESTING (BLOOD WORK, VAGINAL SONOGRAMS, CAT SCANS, PELVIC EXAMS) HAS BEEN DONE AND NO ONE CAN DETERMINE EXACTLY WHAT'S HAPPENING TO ME. CURRENTLY, MY DOCTOR IS LOOKING INTO AN ENDOMETRIOSIS DIAGNOSIS AS WELL. I HAVE RECENTLY BEEN DIAGNOSED WITH HYPOTHYROIDISM ALSO. MY CURRENT MEDICATIONS ARE: PAXIL, SYNTHROID, TOPAMAX, KLONOPIN, AND FIORICET. ESSURE DEVICE WAS IMPLANTED (B)(6) 2009 AND PAYMENT PROVIDED BY INSURANCE. OTHER THAN MIGRAINES, I WAS PERFECTLY HEALTHY PRIOR TO ESSURE IMPLANTATION AND DID NOT TAKE ANY MEDICATIONS. I WAS 22 AT THE TIME OF THE ESSURE PROCEDURE. I AM NOW (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056115	BAYER	9/8/2015	9/14/2015

Event Information:

Event Date (B3): 10/20/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/20/2008
Explant Date (E7): 1/5/2009
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056126		9/8/2015	9/14/2015

Event Information:

Event Date (B3): 10/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/28/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00740	BAYER HEALTHCARE LLC	9/9/2015	9/9/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A02660

Single Use: Y
Implant Date (E6): 9/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER A02660 INSERTED IN (B)(6) 2012 AFTER HAVING HER 6TH CHILD. A COUPLE HOURS AFTER THE ESSURE INSERTION PROCEDURE, SHE KNEW SOMETHING WAS WRONG. SHE CALLED THE DOCTOR AND TOLD THEM IT WAS HURTING PRETTY BAD. SHE WAS TOLD THAT THEY HAD A HARD TIME WITH ONE SIDE AND THAT SHE WOULD FEEL BETTER IN A FEW HOURS. MONTHS WENT ON WITH EXTREME BLEEDING, WHICH WAS SO BAD THAT SHE WOULD FILL A PAD IN 15 MINUTES. SHE WAS ASSURED BY HER DOCTOR THAT IT WAS NORMAL. IN THE END OF (B)(6) 2013 SHE HAD FINALLY HAD ENOUGH, SHE BLED FOR 27 DAYS JUST AS HEAVY AS DAY 1 AND A PARTIAL WAS SCHEDULED. IN (B)(6) 2013 SHE STAYED AT THE HOSPITAL AFTER PARTIAL WAS PERFORMED, AND WENT HOME STILL IN SEVERE PAIN. SHE GOT A CALL FROM HER DOCTOR; SHE TOLD HIM SHE WAS IN SOME REAL PAIN AND HE ASKED HER IF THE NURSES REMOVED HER PACKING THAT WAS LEFT INSIDE HER. SHE HAS HAD SEVERAL SURGERIES SINCE, INCLUDING A FULL HYSTERECTOMY, HYPOGASTIC NERVE COMPLEX, LAPAROSCOPIC PRESACRAL NEURECTOMY, ETC. AND STILL MORE SURGERIES TO COME DUE TO STILL BEING IN EXTREME PAIN. SHE STATED THAT SHE WILL GET A LAWYER. FOLLOW-UP RECEIVED ON 02-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT # PROVIDED A02660 IS INVALID. SINCE NO

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PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO VALID BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME BLEEDING; SHE BLEED FOR 27 DAYS AND SEVERE PAIN. SHE WAS SUBMITTED TO A HYSTERECTOMY. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS PARTICULAR CASE, THE EVENTS STARTED IN CLOSE ASSOCIATION WITH ESSURE INSERTION PROCEDURE AND 5 MONTHS AFTER DEVICES PLACEMENT, THE CONSUMER UNDERWENT A PARTIAL HYSTERECTOMY. HER PAIN PERSISTED AND A TOTAL HYSTERECTOMY WAS LATER PERFORMED. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00743	BAYER HEALTHCARE LLC	9/9/2015	9/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED SHE HAD BEEN TO THE HOSPITAL NUMEROUS OCCASIONS FOR A MISCARRIAGE, ABDOMINAL PAIN, SEVERE HEADACHES AND THE LIST GOES ON. SHE WAS CONSTANTLY IN A BATTLE WITH WEIGHT GAIN DUE TO INFLAMMATION OF THIS FOREIGN BODY AND DUE TO A NICKEL ALLERGY THAT WAS NEVER TOLD TO HER THAT THE PRODUCT WAS MADE OF IT OR WAS SHE TESTED BEFOREHAND; SHE BROKE OUT IN RASH AND HIVES RANDOMLY AND HAD BRAIN FOG AND BLURRED VISION, WHICH SHE NEVER HAD BEFORE ESSURE. SHE STATED EVERY TIME SHE WENT TO THE PHYSICIAN OR THE ER SHE WAS TOLD EVERYTHING WAS NORMAL. SHE ALSO STATED SHE NEEDED ASSISTANCE DUE TO CONSTANT PAIN. FOLLOW-UP RECEIVED ON 18-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)). THE CONSUMER WAS (B)(6) AT THE TIME OF REPORT. SHE REPORTED THAT SHE HAD ESSURE IMPLANTED BACK IN 2008 AND STATED THAT SHE WAS NEVER TESTED FOR A NICKEL ALLERGY. ABOUT 3 MONTHS AFTER HAVING ESSURE, SHE STARTED HAVING RASH ALL OVER HER ARMS, LEGS, STOMACH AND BACK (SHE THOUGHT IT WAS SOMETHING SHE ATE). SHE STARTED HAVING HEADACHES THAT WERE UNBEARABLE AND WENT TO THE EMERGENCY ROOM ONLY TO BE TOLD JUST AN ALLERGIC REACTION TO SOMETHING SHE PROBABLY ATE OR TOUCHED AND SINUSES FOR HER HEAD WHICH WASN'T THE CASE. SHE STATED SHE WAS TAKING CLARITIN TO BENADRYL ALL THE TIME AND WAS ASLEEP

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WHEN NOT AT WORK. IT WAS TAKING AWAY TIME WITH HER KIDS. THERE WERE TIMES THAT SHE JUST SCRATCHED AND POPPED TYLENOL ALL DAY TO TRY AND GET RID OF THE HEADACHES. OUT OF NOWHERE, HER PERIODS STARTED BEING LIKE A CATEGORY 5, HER BACK AND ABDOMINAL PAIN WERE LIKE SHE WAS IN LABOR, SHE PRESENTED FLOW THAT HAD HER CHANGE CLOTHES TWO TO THREE TIMES A DAY PLUS SHE WOULD BLOAT LIKE SHE WAS 5 MONTHS PREGNANT AND THAT LOOK NEVER WENT AWAY (STOMACH STILL BIG AT THE TIME OF REPORT). SHE EXPERIENCED LEG PAIN THAT HAD HER ALMOST IMMOBILE. AS THE TIME CONTINUE TO PASS SHE FLOSSED HER TEETH AND A PIECE BROKE OFF (SHE NEVER HAD THAT ISSUE BEFORE ESSURE). SHE ALSO MENTIONED SHARP PAINS CONSTANTLY STABBING IN HER SIDES THAT MADE HER ONLY WANT TO LIE DOWN IN BED. CONSUMER WENT TO THE EMERGENCY ROOM AGAIN AND WAS TOLD NOTHING WAS WRONG BUT TO GO TO HER PRIMARY CARE PHYSICIAN BECAUSE HER THYROID NUMBERS WAS HIGH. SHE WAS IN PAIN AND CONFUSED WITH ALL THESE AILMENTS AND STATED THAT SHE WAS AS HEALTHY AS POSSIBLE BEFORE ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD BEEN TO THE HOSPITAL NUMEROUS OCCASIONS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION FOR A MISCARRIAGE, ABDOMINAL PAIN AND SEVERE HEADACHES. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO HOSPITALIZATION. ONLY MISCARRIAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; CONSUMER ONLY MENTIONED A MISCARRIAGE. CONSIDERING MISCARRIAGE IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY, OCCURRING IN UP TO 20% OF CLINICALLY RECOGNIZED PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION DUE TO MATERNAL CONDITIONS OR FETAL CHROMOSOMAL ABNORMALITIES; CAUSALITY BETWEEN THIS EVENT AND ESSURE IS CONSIDERED UNLIKELY. REGARDING THE REMAINING EVENTS, AFTER ESSURE INSERTION ABDOMINAL PAIN AND HEADACHES MAY OCCUR. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE CONSUMER STATED SHE HAD BEEN TO THE HOSPITAL IN SEVERAL OCCASIONS. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00750	BAYER HEALTHCARE LLC	9/9/2015	9/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A (B)(4) MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. IN (B)(6) 2008, THE CONSUMER EXPERIENCED BLOATING AND SWELLING, AND SHE WAS TOLD THAT HER BODY WAS ADJUSTING TO THE IMPLANTS. SINCE THEN, SHE HAD SUFFERED WITH SEVERE SWELLING, HAIR LOSS, WILD PERIODS LASTING ALMOST ALL MONTH, BRUISING, KNOTS, INCONCLUSIVE BLOOD RESULTS, INCONCLUSIVE (B)(6) RESULTS (B)(6), LOSS OF LIBIDO, ETC. SHE WENT TO SEVERAL DOCTORS FOR NEUROLOGICAL DISORDERS, INTESTINAL ISSUES AND URINARY ISSUES, AND HAD INCONCLUSIVE RESULTS. SHE VISITED ER (EMERGENCY ROOM) 5 TIMES IN 2 WEEKS. THE CONSUMER HAD A SEVERE FAMILY HISTORY TO METAL (INTERPRETED AS ALLERGY TO METAL). SHE ALSO STATED THAT EVERY DAY WAS A STRUGGLE AND SHE WAS NO LONGER ABLE TO HOLD A JOB. SHE WAS IN CONSTANT PAIN AND WAS UNABLE TO SLEEP A FULL NIGHT WITHOUT PAIN - IT RADIATED CONSTANTLY ON THE LEFT SIDE AND SHE FELT LIKE SHE WAS IN LABOR ALWAYS. SHE LOOKED LIKE PREGNANT AND SHE HAD ALWAYS BEEN FIT AND ACTIVE. SHE WAS DEPRESSED AND ANXIOUS ALL THE TIME. SHE HAD 3 CHILDREN WHO SHE COULD NO LONGER PLAY WITH. SHE WAS SCHEDULED FOR HYSTERECTOMY IN (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PERIODS LASTING ALMOST ALL MONTH AND CONSTANT PAIN, RADIATED CONSTANTLY ON THE LEFT SIDE AND SHE FELT LIKE SHE WAS IN LABOR (INTERPRETED AS PELVIC PAIN). SHE WAS SCHEDULED TO HAVE A HYSTERECTOMY. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED

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IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENTS AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00751	BAYER HEALTHCARE LLC	9/9/2015	9/9/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/10/2010
Explant Date (E7): 3/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER IN UNITED STATES ON (B)(6) 2013 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP PAINS IN HER SIDES SHOOTING DOWN TO HER LEGS, SHARP PAINS IN HER SIDES SHOOTING DOWN TO HER LEGS, AND LEGS WOULD GO NUMB. THE CONSUMER'S MEDICAL HISTORY INCLUDED 5 CHILDREN. NO INFORMATION GIVEN ON CONSUMER'S DRUG HISTORY/CONCURRENT CONDITIONS. IT IS UNKNOWN WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. IN 2009 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL. IT WAS NOT REPORTED WHETHER ESSURE WAS USED PREVIOUSLY. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED SHARP PAINS IN HER SIDES SHOOTING DOWN TO HER LEGS AND LEGS WOULD GO NUMB. THE OUTCOME OF THE EVENTS WAS UNKNOWN. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 23-JAN-2014: CONSUMER'S BIRTH DATE WAS INFORMED. SHE WAS NOT PREGNANT. THE CONSUMER HAD MIRENA INSERTED ON (B)(6) 2010 (LOT NUMBER 664435) FOR STERILIZATION. CONSUMER HAD PAIN IN SIDES ABOUT ONE WEEK AFTER HER ESSURE PROCEDURE. SHE DESCRIBED IT AS A PINCHING PAIN AT FIRST. THE HEALTHCARE PROFESSIONAL BECAME AWARE AND INFORMED PATIENT THAT HER BODY WAS ADJUSTING TO THE PROCEDURE. SHE SAID THE PAIN HAS CONTINUED TO GET WORSE AND WORSE AND, AT THE TIME OF REPORT, WHEN SHE HAD THE PAIN, SHE WAS UNABLE TO WALK BECAUSE IT WAS SO BAD. SHE DESCRIBED IT AS A BAD, STABBING PAIN THAT SHOOTS DOWN HER LEGS. SHE ADDED THAT SHE HAS HAD HIVES A FEW TIMES TOO AND SHE CONSTANTLY HAS HAD HEADACHES SINCE THE PROCEDURE. SHE MENTIONED THAT SHE HAS HAD CONSTANT VAGINAL BLEEDING AS WELL. HEALTHCARE PROFESSIONAL PRESCRIBED JENCYCLA (DRUG ADMINISTRATION STARTED IN (B)(6) 2014) TO HELP MANAGE BLEEDING BUT IT WAS NOT WORKING. THE CONSUMER HAS

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ALREADY HAD A CAT SCAN AND ULTRASOUND DONE AND SHE WAS DIAGNOSED WITH OVARIAN CYSTS BUT THE PATIENT BELIEVED THAT HER HEALTH PROBLEMS WERE RELATED TO ESSURE. DOCTOR INFORMED HER THAT OVARIAN CYSTS WOULD NOT CAUSE SHOOTING PAINS TO DOWN HER LEGS. SHE HAD NO HISTORY OF ANY OF THESE PROBLEMS PRIOR TO ESSURE PROCEDURE. THE EVENTS AND ESSURE TREATMENT WERE ONGOING. THE REPORTING PERSON DOES NOT PROVIDE THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE TREATMENT. FOLLOW UP 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAS ALWAYS BEEN A HEALTHY, AND ENERGETIC MOTHER UNTIL AFTER HER 5TH CHILD WAS BORN AND SHE HAD THE ESSURE PROCEDURE. HER LAST CHILD WAS BORN IN (B)(6) 2009 AND (B)(6) 2010 SHE HAD ESSURE PLACED. RIGHT AWAY HER HEALTH AND BODY STARTED TO CHANGE. HER DOCTOR TOLD HER ESSURE COULD NOT BE THE CAUSE OF HER EXCESSIVE BLEEDING, HEADACHES, FATIGUE, HIVES, MODINESS, SHARP PAINS, AND NUMEROUS OTHER PROBLEMS. SHE BECAME DEPRESSED. IN (B)(6) 2014 THE CONSUMER FOUND A DOCTOR WHO REVERSED ESSURE AND DURING HER SURGERY HE DISCOVERED THAT THE COILS HAD PUNCTURED HER TUBES AND WERE EMBEDDED IN THE MUSCLE OF HER UTERUS AND THIS WAS WHAT WAS CAUSING HER EXTREME PAIN, AND EVERY OTHER DOCTOR WHO SHE WENT DUE TO THIS PAIN SAID THERE WAS NOTHING WRONG WITH HER. NOW SHE IS NO LONGER IN AS MUCH PAIN AS SHE WAS WITH THE ESSURE COILS AND SHE NO LONGER HAVE THE TERRIBLE BLEEDING AND CLOTTING THAT SHE HAD EVERY MONTH WITH ESSURE. SHE WAS HOWEVER, LEFT WITH A FRAGMENT OF THE COIL, AND OTHER LINGERING HEALTH ISSUES. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DETECTED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO AN ADULT FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING SURGERY TO REMOVE THE DEVICES, IT WAS FOUND THAT THE COILS HAD PUNCTURED HER TUBES AND WERE EMBEDDED IN THE MUSCLE OF HER UTERUS. THIS EVENT, SEEN AS UTERINE PERFORATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION WITH ESSURE USE MAY OCCUR MOSTLY DURING INSERTION OR VIA FALSE PASSAGE OVER TIME. IN THIS CASE, RIGHT AWAY FROM THE PLACEMENT, THE PATIENT HAD SHARP PAIN AND EXCESSIVE BLEEDING WITH CLOTS AMONG OTHER NON-SERIOUS EVENTS. FOUR YEARS AFTER INSERTION, A SURGERY WAS PERFORMED TO REMOVE THE DEVICES AND DURING THE PROCEDURE, IT WAS DISCOVERED THE COILS HAD PUNCTURED HER TUBES AND WERE EMBEDDED IN THE MUSCLE OF HER UTERUS AND THAT WAS THE CAUSE OF HER EXTREME PAIN. AFTER THE REMOVAL SHE RECOVERED FROM THE PAIN AND BLEEDING BUT A FRAGMENT OF COIL WAS LEFT IN HER, CAUSING UNSPECIFIED HEALTH ISSUES. ALTHOUGH IN THIS CASE, THE EXACT DATE AND MECHANISM OF THIS PERFORATION WERE NOT PROVIDED, GIVEN THE EVENT'S NATURE AND THE RECOVERY AFTER REMOVAL, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, IT WAS INFORMED THE EXTREME PAIN AND BLEEDING, INTERPRETED AS SYMPTOMS OF PERFORATION, LED TO ESSURE REMOVAL. THEREFORE, THIS CASE WAS UPGRADED TO INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 09-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00752	BAYER HEALTHCARE LLC	9/9/2015	9/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/19/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN THE UNITED STATES ON 28-AUG-2012 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO WAS IMPLANTED WITH ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED PERIOD STOPPED, PELVIC PAIN, DEEP BONE PAIN IN HIPS SHOOTS DOWN LEGS, INTERMITTENT SHARP PAINS IN HEAD, VISION ISSUES, TINGLING IN HEAD, HANDS, ARMS, AND LEGS, OCCASIONAL DIZZINESS, UTERUS FILLED WITH SCAR TISSUE, FIBROIDS, JOINT INFLAMMATION AND ESSURE MIGRATED OUT OF TUBES. CONSUMER REPORTED SHE HAD NO PRE-EXISTING CONDITIONS AND HAS NO PRIOR MEDICAL PROBLEMS. THERE IS SOME INDICATION THAT SHE IS CURRENTLY MENOPAUSAL. NO INFORMATION GIVEN PAST DRUGS AND CONCOMITANT MEDICATION. ON (B)(6) 2008 THE CONSUMER WAS IMPLANTED WITH ESSURE AND IN (B)(6) 2009 POST PROCEDURE HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED SHOWING OCCLUSION. CONSUMER REPORTED WITHIN MONTHS AFTER IMPLANTATION, PERIODS STOPPED COMPLETELY AND BEGAN HAVING PELVIC PAIN. PATIENT HAD ULTRASOUNDS AND BLOOD WORK AND THEY CAME HEALTHY AND NORMAL. THE CONSUMER CONTINUED TO SHOW MORE SYMPTOMS, PAIN BECAME WORSE, SOME DAYS SHE COULD BARELY STAND, SIT OR SLEEP DUE TO DEEP BONE PAIN IN HIPS THAT SHOOTS DOWN LEGS. SHE ADDITIONALLY REPORTED INTERMITTENT SHARP PAINS IN HEAD, VISION ISSUES, TINGLING IN HEAD, HANDS, ARMS, AND LEGS AND OCCASIONAL DIZZINESS. CONSUMER SAW A NEW PHYSICIAN THAT PERFORMED AN ULTRASOUND AND HER IMPLANTS COULD NOT BE SEEN FOR UNKNOWN REASONS AND UTERUS FILLED WITH SCAR TISSUE AND FIBROIDS THAT WERE NOT THERE IN 2010. CONSUMER HAD A BIOPSY AND HYSTEROSCOPY, PATHOLOGY RESULTS ARE PENDING, BUT SHE STATED "NEITHER COILS WAS SEEN IN FALLOPIAN TUBES". CONSUMER BELIEVES MIGRATED COILS ARE REASON FOR SEVERE PAIN AND JOINT INFLAMMATION BECAUSE SHE HAD NO PRE-EXISTING CONDITIONS. PATIENT BELIEVES ESSURE MIGRATED OUT OF TUBES. THE

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OUTCOME OF THE EVENTS WAS NOT REPORTED AND THE CAUSAL RELATIONSHIP BETWEEN THE EVENTS AND ESSURE WAS NOT REPORTED. ADDENDUM: THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO (B)(6) ON 09-OCT-2013. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED. FOLLOW UP INFORMATION RECEIVED ON 12-AUG-2015 FROM CONSUMER: THE CONSUMER REPORTED THE FOLLOWING VIA FDA SITE; THE REFERENCE NUMBER FOR THIS REPORT IS (B)(4). CONSUMER REPORTED SHE DECIDED TO HAVE ESSURE INSERTED SHE WAS (B)(6) AND HER FAMILY WAS COMPLETE. SHE HAD NO MEDICAL ISSUES; SHE WAS HEALTHY, ACTIVE AND STRONG. ON (B)(6) 2008, SHE WAS IMPLANTED WITH ESSURE. IT WAS DONE UNDER ANESTHESIA IN A HOSPITAL SETTING WITH A SALES REPRESENTATIVE IN THE ROOM. HER PROCEDURE WENT AS PLANNED, SHE HAD MILD CRAMPING FOR THE DAY, AND THEN SHE WAS FINE. OVER THE NEXT FEW DAYS SHE FELT WEAK AND TIRED AND FIGURED IT WAS THE ANESTHESIA; SHE BEGAN HAVING PAIN; DIZZINESS; HER CYCLE BECAME LONGER, HEAVY WITH MASSIVE CLOTS; SHE COULDN'T KEEP HERSELF PROTECTED. IN THE FIRST 7 MONTHS OF BEING IMPLANTED SHE HAD THREE CYCLES BEFORE HER CYCLE STOPPED COMPLETELY AND NEVER RETURNED. AFTER SEVERAL PHYSICIAN APPOINTMENTS TO FIND OUT WHAT WAS WRONG AND TESTS AFTER TESTS, SHE CONTINUED TO BE HEALTHY AND THE RESULTS WERE UNREMARKABLE. THE LONGER SHE HAD ESSURE IN HER THE MORE ILL HER BODY BECAME; SHE HAD BRAIN ZAPS THAT FELT LIKE SOMEONE WAS PUTTING A NAIL INTO HER HEAD, SHE COULDN'T GET A NEUROLOGIST TO LISTEN. HER HAIR WAS THINNING; SHE HAD SEVERE STABBING HIP PAIN; NERVES IN EYES WOULD THROB; SHE HAD BACK PAIN; SEVERE INFLAMMATION THROUGHOUT HER BODY; LONG TERM AND SHORT TERM MEMORY LOSS; NUMBNESS IN ARMS; NERVE PAIN DOWN HER LEGS INTO FEET; RESTLESS LEGS; INSOMNIA; PELVIC PAIN; PAIN DURING INTERCOURSE; BLOATING; ANXIETY; PAIN IN HER KIDNEY AREA; DRY BRITTLE NAILS; HORMONAL IMBALANCE; NECK PAIN; PALPITATIONS; VISION DETERIORATED; THICK MUCUS DISCHARGE; METAL TASTE; VAGINAL SMELL; STOMACH PAIN; OVARY SWELLING; ALLERGIES SHE NEVER HAD BEFORE; ITCHINESS; SKIN PAIN WHEN TOUCHED; HER HEAD HURT TO BRUSH HER HAIR; THICKENING OF THE UTERUS; DULL SKIN; TEETH SENSITIVITY; SHE COULDN'T SIT, LAY DOWN, COULDN'T MOVE BUT HAD TO KEEP MOVING BECAUSE TO STOP AND START WAS MORE PAINFUL; AND SINUS ISSUES. IN THE 4 1/2 YEARS SHE WAS IMPLANTED WITH ESSURE SHE HAD 5 ULTRASOUNDS - REGULAR AND VAGINAL, 2 ER TRIPS, 2 HSG TESTS, NUMEROUS BLOOD TESTS, CAT SCAN, HYSTEROSCOPY TO FIND ESSURE COILS - THEY COULD NOT BE SEEN THEY MIGRATED FURTHER INTO HER TUBES; BIOPSY AND A D&C, EVENTUALLY LEAD TO A HYSTERECTOMY IN (B)(6) 2013. DURING THE HYSTERECTOMY IT WAS FOUND THAT SHE HAD SEVERE SCAR TISSUE AND ADHESIONS THAT TETHERED, PULLED AND ATTACHED SEVERAL ORGANS TOGETHER, THEY HAD TO BE CUT APART. HER PHYSICIAN TOLD HER THAT INFLAMMATION CAN CAUSE THIS TO HAPPEN. IN THE SAME NIGHT OF THE HYSTERECTOMY, HER BRAIN FOG WAS GONE; WITHIN WEEKS HER PUFFINESS WAS GONE, HER MEMORY WAS RETURNING, BRAIN ZAPS WERE GONE, PAIN WAS GONE, HORMONAL IMBALANCE WAS GONE, HER SKIN WAS NORMAL, HIP PAIN WAS GONE. MOST OF THE ISSUES SHE HAD WHEN ESSURE WAS IN HER BODY WERE GONE. SHE STILL HAD INFLAMMATION FROM HER WAIST DOWN; CONSTANT INFLAMMATION IN HER SMALL INTESTINES AND STILL HAD NERVE PAR IN HER LEGS. SHE STATED THAT THERE IS NO WAY THAT ESSURE WAS NOT THE CAUSE OF HER HEALTH ISSUES WHEN SHE HAD NO PAIN OR MEDICAL ISSUES PRIOR. FOLLOW-UP RECEIVED ON 20-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH

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NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN / PAIN AND HAD ESSURE MIGRATED OUT OF TUBES / THEY MIGRATED FURTHER INTO HER TUBES. BOTH EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STARTED EXPERIENCING PELVIC PAIN IN THE FIRST 7 MONTHS AFTER ESSURE INSERTION. ABOUT 4 YEARS AND A HALF AFTER INSERTION, A HYSTEROSCOPY TO FIND ESSURE COILS WAS PERFORMED AND THE RESULT SHOWED ESSURE MIGRATION OUT OF TUBES. SHE HAD A HYSTERECTOMY PERFORMED AND IT WAS FOUND THAT SHE HAD SEVERE SCAR TISSUE AND ADHESIONS THAT TETHERED, PULLED AND ATTACHED SEVERAL ORGANS TOGETHER. CONSIDERING THE EVENT'S NATURE AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 17-OCT-2015: THE CONSUMER REPORTED THE FOLLOWING VIA FDA SITE; THE REFERENCE NUMBER FOR THIS REPORT IS (B)(4). CONSUMER HAD TWO SURGICAL HYSTEROSCOPIC PROCEDURES BECAUSE OF ESSURE. SHE EXPERIENCED A SERIOUS REACTION TO TH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00772	BAYER HEALTHCARE LLC	9/9/2015	9/9/2015

Event Information:

Event Date (B3): 3/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68790

Single Use: Y
Implant Date (E6): 3/4/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 7/27/2015

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 04-MAR-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C68790. DURING ESSURE PLACEMENT IN LEFT HORN, AT THE TIME OF THE IMPLANT RELEASE, MECHANISM GOT STUCK AND IT WAS IMPOSSIBLE TO REMOVE IMPLANT WITHOUT FORCING AND MAKE THE HORN BLEED. THE SURGEON FORCED ON DELIVERY SYSTEM TO REMOVE IT. THE EVENT OCCURRED IN THE OPERATING ROOM. THE PHARMACIST CONSIDERED THE EVENT SERIOUS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED FROM A NURSE ON 10-MAR-2015: PATIENT'S DATA, INCLUDING HER AGE, (B)(6) WERE PROVIDED. IT WAS UNKNOWN IF THERE WAS TRAINING OF THE SURGEON TO ESSURE PROCEDURE. THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS NOT PERFORMED BECAUSE THE PROCEDURE WAS STOPPED (PLACEMENT FAILURE). IN THE POSTOPERATIVE COURSE, THE CONSEQUENCE FOR THE PATIENT WAS THAT ONLY ONE INSERT WAS PLACED. COMPLETE ESSURE SYSTEM (INSERT AND HANDLE) WAS KEPT. DEVICE SIMILAR LISTING THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 18-AUG-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: DEVICE BREAKAGE: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PT. PTC INVESTIGATION RESULT WAS RECEIVED ON 06-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4).

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FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: ROLLBACK TO INITIAL HARD STOP; DEPRESS BUTTON; PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C68790 (PRODUCTION DATE 23-JUN-2014 AND EXPIRATION DATE 30-JUN-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP 12-AUG-2015: ONE DEVICE WAS RETURNED TO MANUFACTURER ON 27-JUL-2015 AND THE PTC RESULTS WERE UPDATED AND PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: ROLLBACK TO INITIAL HARD STOP; DEPRESS BUTTON; PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE ABLE TO CONDUCT AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. WE TYPICALLY INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. AS RECEIVED, ALL IFU STEPS WERE COMPLETED. THE DEVICE WAS RETURNED WITHOUT MICRO-INSERT. THE CATHETER LARGE TIGHT PITCH COIL FOUND TO BE STRETCHED AND BROKEN. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. WE ALSO CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT IS AN

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ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITATED DUE TO A PRODUCT ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. THE PROVIDED COMPLAINT SAMPLE WAS INVESTIGATED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN A (B)(6) FEMALE PATIENT WHO EXPERIENCED PAIN AND BLEEDING DURING INSERTION PROCEDURE. IT WAS IMPOSSIBLE TO REMOVE THE IMPLANT WITHOUT FORCING AND MAKING THE FALLOPIAN TUBE BLEED. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS, THE SAMPLE RETURNED WAS ANALYSED AND IT WAS NOTICED THAT THE CATHETER LARGE TIGHT PITCH COIL FOUND TO BE STRETCHED AND BROKEN. THE EVENTS PAIN AND BLEEDING, INTERPRETED AS PROCEDURAL PAIN AND PROCEDURAL BLEEDING WERE CONSIDERED SERIOUS BY THE REPORTED. ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, THESE EVENTS ARE LISTED AND THE DEVICE BREAKAGE IS UNLISTED. UNCHARACTERIZED PAIN AND BLEEDINGS MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, BOTH EVENTS OCCURRED DURING THE PROCEDURE TO INSERT ESSURE, AND WERE THEREFORE CONSIDERED RELATED TO ESSURE. IN THIS PARTICULAR CASE, THE DEVICE BREAKAGE WAS NOT REPORTED IT WAS NOTICED IN THE SAMPLE RECEIVED. HOWEVER, SINCE IN THIS CASE, ALL THE PROBLEMS OCCURRED DURING THE INSERTION, THE BREAKAGE IS ASSESSED AS RELATED TO ESSURE PROCEDURE. THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT, SINCE THE BREAKAGE DID NOT LEAD TO A SERIOUS DETERIORATION BUT COULD HAVE LED TO IT UNDER LESS FORTUNATE CIRCUMSTANCES. THE INITIAL PTC ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. AN UPDATED ANALYSIS IS EXPECTED. NO FOLLOW UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00779	BAYER HEALTHCARE LLC	9/9/2015	9/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REPORTER IN (B)(6) ON 06-AUG-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. THE REPORTER FROM A TV PROGRAM STATED THAT SHE WAS CONTACTED BY A PERSON WHOSE ONE IMPLANT CAME OUT DURING MENSTRUATION AND THE OTHER IMPLANT HAS DRIFTED IN MYOMETRIUM. FOLLOW-UP INFORMATION RECEIVED ON 14-AUG-2015. CASE IS NOW UPGRADED TO INCIDENT. THE REPORTER'S COLUMN HAS BEEN PUBLISHED AND IT INCLUDES FURTHER INFORMATION. THE CONSUMER IS (B)(6) FEMALE WHO HAS BEEN ESSURE STERILIZATION PERFORMED 5 YEARS AGO. LAST YEAR WAS THE WORST STRUGGLE OF HER LIFE: PAIN, PROBLEMS CAUSED BY MEDICATIONS AND GETTING FOR A HELP. THE CONSUMER HAD AN APPOINTMENT WITH A DOCTOR DUE TO STRONG LOWER BACK AND ABDOMINAL PAINS. THE PAIN RADIATED TO FRONT FEMURS AND SHE HAD PRESSURE FEELING IN URINARY BLADDER. MOREOVER HER BREASTS WERE SO SORE THAT SHE COULD NOT SLEEP WITHOUT SPORTS BRA. SHE WAS EXAMINED BY GENERAL PRACTITIONER, OCCUPATIONAL HEALTH PHYSICIAN, INTERNAL MEDICINE SPECIALIST AND ALSO GYNECOLOGIST BUT REASON FOR HER SYMPTOMS WAS NOT FOUND. HER SYMPTOMS WAS DEDUCED TO BE CAUSED BY HER BACK (IMAGE WAS TAKEN FROM THE BACK, EXACT METHOD NOT MENTIONED IN THE COLUMN). SHE GOT STRONG PAIN KILLERS WHICH CAUSED CONSTIPATION. SHE WAS IN SICK LEAVE SEVERAL TIMES. IN (B)(6) 2015 A TURN HAPPENED WHEN SHE NOTICED THAT ONE IMPLANT CAME OUT DURING MENSTRUATION. GYNECOLOGIST STATED TO HER BASED ON X-RAY TAKEN IN SPRING 2014 THAT IMPLANT HAS BEEN IN UTERUS. THE CONSUMER HAS REQUESTED A NEW X-RAY BECAUSE SHE WAS WORRIED ABOUT IF PART OF IMPLANT MIGHT STILL BE INSIDE HER. X-RAY HAS NOT PERFORMED DESPITE OF HER REQUEST. BECAUSE CONTRACEPTIVE EFFECT WAS NOT RELIABLE ANY MORE, HORMONAL INTRAUTERINE SYSTEM HAS

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INSERTED EVEN IF SHE DOUBTED. SHE HAD TO RETURN TO HOSPITAL AFTER A DAY BECAUSE OF FEVER. SHE GOT UTERINE INFECTION AND IT WAS NOTED THAT INTRAUTERINE SYSTEM IS NOT SUITABLE FOR HER. SHE WAS VERY SICK FOR MANY DAYS. IN (B)(6) 2015 THE CONSUMER WAS OPERATED WITH A PURPOSE TO REMOVE THE OTHER IMPLANT AND PERFORM A LAPAROSCOPIC STERILIZATION. AFTER OPERATION THE CONSUMER READ FROM HOSPITAL RECORDS THAT IMPLANT WAS NOT MANAGED TO REMOVE BECAUSE IT WAS PARTLY INSIDE THE MYOMETRIUM. NEXT STEP WILL BE HYSTERECTOMY. THE CONSUMER DOES NOT SAY THAT ESSURE WILL BE SUITABLE FOR NOBODY. SHE ONLY WANTED TO REMIND BY HER STORY THAT SYMPTOMS MIGHT BE VERY TOUGH FOR THOSE WHO SUFFERS FROM THEM. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION AND ONE IMPLANT HAD DRIFTED IN MYOMETRIUM. THIS EVENT, INTERPRETED AS DEVICE EMBEDDED (PARTIAL PERFORATION), IS CONSIDERED LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER HAD ONE IMPLANT THAT HAD DRIFTED IN MYOMETRIUM. A LAPAROSCOPIC STERILIZATION WAS PERFORMED IN ORDER TO REMOVE THE IMPLANT, BUT IT WAS NOT MANAGED TO REMOVE DUE TO THE LOCATION. THE NEXT STEP WOULD BE A HYSTERECTOMY. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, THE LACK OF ALTERNATIVE EXPLANATION AND CONSIDERING THE KNOWN RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THE DEVICE EMBEDMENT IS REGARDED AS RELATED TO ESSURE. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. ADDITIONALLY, OTHER EVENTS WERE REPORTED. FOLLOW UP INFORMATION CANNOT BE OBTAINED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00780	BAYER HEALTHCARE LLC	9/9/2015	9/9/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 13-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 FOR PERMANENT CONTRACEPTION. PHYSICIAN REPORTED THAT THE PATIENT BELIEVED THAT ESSURE WAS CAUSING BLEEDING AND PAIN SINCE INSERTION AND WAS SCHEDULED TO HAVE ESSURE REMOVED ON (B)(6) 2015. THE PHYSICIAN WOULD ALSO BE REMOVING FALLOPIAN TUBES AND DOING AN ENDOMETRIAL ABLATION AT SAME TIME. AT TIME OF THE REPORT, ESSURE HAD NOT BEEN REMOVED YET. FOLLOW-UP FROM (B)(6) 2015: NO NEW INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 13-AUG-2015: PATIENT HAD ESSURE PLACED IN 2010 AND HAS BEEN COMPLAINING OF EXCESSIVE BLEEDING AND PAINFUL INTERCOURSE. LAPAROSCOPY IS SCHEDULED FOR (B)(6) 2015. FOLLOW-UP INFORMATION RECEIVED ON 20-AUG-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR

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COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BELIEVED IT WAS CAUSING BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND PAIN (INTERPRETED AS PELVIC PAIN). SHE WAS SCHEDULED TO HAVE ESSURE REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. THE EXACT TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND EVENTS ONSET WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENTS, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 24-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00781	BAYER HEALTHCARE LLC	9/9/2015	9/9/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 9/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON 14-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED BY ANOTHER HEALTH PROFESSIONAL IN (B)(6) 2013 FOR PERMANENT STERILIZATION. PRIOR TO 2011, THE PATIENT HAD LAPAROSCOPY ON RIGHT SIDE FOR SALPINGO-OOPHORECTOMY. THE PHYSICIAN PLACED ESSURE COIL ON PATIENT'S RIGHT SIDE EVEN THOUGH SHE HAD NO TUBE. HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND SHOWED THAT RIGHT DEVICE APPEARED TO BE IN ABNORMAL POSITION. THE PATIENT SUFFERED FROM DYSPAREUNIA WHICH LED TO A HYSTERECTOMY IN (B)(6) 2014. THE HYSTERECTOMY WAS ALSO NOT PERFORMED BY THE CALLER'S PHYSICIAN. PATIENT RETAINED COIL IN LOWER PELVIS AFTER HYSTERECTOMY. THE REPORTER WOULD LIKE TO AVOID FURTHER SURGERY, IF POSSIBLE, AS PATIENT WAS NOT HAVING ANY PROBLEMS. THE PATIENT SAW THIS DOCTOR BECAUSE SHE WANTED DIFFERENT CARE AND SHE WAS CONCERNED ABOUT LEAVING COIL IN PELVIS; SHE WAS NOT HAVING ANY SYMPTOMS AT THE TIME OF THE REPORT. FOLLOW-UP INFORMATION RECEIVED ON 20-AUG-2015: HYSTERECTOMY WAS DONE ELSEWHERE. ON HSG, RIGHT DEVICE WAS IN ABNORMAL POSITION, LEFT DEVICE WAS IN PROPER POSITION AND THERE WAS UNILATERAL OCCLUSION. PATIENT HAD HYSTERECTOMY IN (B)(6) 2015 - IT WAS SAID THAT THE RIGHT INSERT WAS PARTIALLY PERFORATING THE UTERUS. ON (B)(6) 2015, CT (COMPUTERIZED TOMOGRAPHY) OF ABDOMEN AND PELVIS WAS PERFORMED SECONDARY TO ABDOMINAL PAIN, NAUSEA VOMITING AND DIARRHEA RECENTLY. ESSURE DEVICE WAS IN LOW PELVIS. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-AUG-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS

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COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO OFF LABEL USE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS SUBMITTED TO A HYSTERECTOMY, 4 MONTHS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION, DUE TO DYSPAREUNIA. BEFORE THIS SURGERY A HYSTEROSALPINGOGRAM (HSG) TEST WAS PERFORMED AND SHOWED THAT RIGHT DEVICE APPEARED TO BE IN ABNORMAL POSITION; DURING THE SURGERY IT WAS FOUND PARTIALLY PERFORATING THE UTERUS. LATER, A CT SCAN REVEALED A COIL WAS RETAINED IN PATIENT'S LOWER PELVIS. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ESSURE IS CONTRAINDICATED FOR PATIENTS WHO CAN HAVE ONLY ONE INSERT PLACED. IN THIS PARTICULAR CASE, THE PATIENT HAD A PREVIOUS SALPINGO-OOPHORECTOMY IN THE RIGHT FALLOPIAN TUBE. THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED EVENTS BY RENDERING ESSURE INSERTION DIFFICULT AND FACILITATING DEVICE MISPLACEMENT/PERFORATION. ALTHOUGH, IN THIS CASE, THE EXACT MECHANISM OF THESE FINDINGS WAS NOT KNOWN; CONSIDERING THEIR NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING DYSPAREUNIA, IT CAN OCCUR AFTER ESSURE INSERTION. IN THIS CASE, DUE TO THE SUGGESTIVE TEMPORAL RELATIONSHIP AND EVENT'S NATURE IT WAS CONSIDERED AS RELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE AN INTERVENTION FOR DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056046	BAYER	9/9/2015	9/9/2015

Event Information:

Event Date (B3): 1/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED DEVICE IMPLANT ON (B)(6) 2011. SOON AFTERWARDS I BLEED FOR 4 MONTHS STRAIGHT. SINCE THEN MY PERIODS ARE STILL IRREGULAR. I ALSO HAVE SEVERE BLOATING,PELVIC PAIN, HAIR LOSS AND IT HURTS WALKING, SEATING HAVING SEX, USING THE BATHROOM AND FORM OF SMOTACH MUSCLES I USE IT HURTS ALL DAY LONG . MY INSURANCE PAID FOR THIS DEVICE TO BE PUT IN BUT WON'T COVER IT TO BE REVERSED THEY SAY IT ELECTIVE. THE ONLY DOCTOR THAT WILL TAKE OUT IS THE DOCTOR WHO PUT IN BUT SHE WANT ONLY TO DO HYTERSRICTOMY. THIS IS EFFECTING MY LIFE PLEASE HELP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056047	BAYER	9/9/2015	9/9/2015

Event Information:

Event Date (B3): 3/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN PAIN ALL THE TIME. STABBING IN THE LOWER PART OF MY BELLY. FATIGUE. NO ENERGY. GAINED WEIGHT. OVARY CYSTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056048	BAYER	9/9/2015	9/9/2015

Event Information:

Event Date (B3): 8/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAVE GOTTEN THIS IMPLANTED IV HAD VERY BAD PELVIC PAIN, HEAVY PERIODS, LOSS OF HAIR, WEIGHT GAIN.. IM IN PAIN AT ALL TIMES, I BEEN IN AND OUT OF THE HOSPITAL, NOT KNOWING WHAT WAS WRONG..

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056050	BAYER	9/9/2015	9/9/2015

Event Information:

Event Date (B3): 9/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING MY LAST CHILD ME AND MY DOCTOR WENT OVER PREVENTIVE BIRTH CONTROLS SO I DIDN'T HAVE TO WORRY ABOUT HAVING ANOTHER CHILD, IT WAS BEST FOR ME DO TO HAVING LUPUS. I CHOOSE THE ESSURE BECAUSE I DIDN'T HAVE TO HAVE SURGERY TO HAVE THEM PLACED INTO MY TUBES, MY DOCTOR PUT 2 IN AT MY OFFICE VISIT, NOT LONG AFTER THE COILS WERE PLACED IN I STARTED HAVING SEVERE CRAMPING REALLY BAD PAIN DURING AND AFTER INTERCOURSE. I HAD MANY TESTS TO SEE IF THE COILS WERE WORKING AND IF THEY WERE CLOSING OFF, AS I CONTINUED TO HAVE SO MUCH PAIN AND DISCOMFORT MY DOCTOR HAD TO SET ME UP FOR SURGERY TO SEE WHY I WAS IN SO MUCH PAIN? AFTER WAKING FROM SURGERY I BECAME AWARE THAT ONE OF THE COILS HAD WENT ALL THE WAY THRU MY TUBE AND HAD PLANTED ONTO MY UTERUS, WHERE IT HAD TO BE CUT OUT. AND MY DOCTOR HAD TO THEN PLACE A RING AROUND MY TUBE. I CONTINUE TO HAVE SO MUCH PAIN AND AM NOT BEING ABLE TO HAVE INTERCOURSE WITHOUT BEING IN HORRIBLE PAIN. ANOTHER MAJOR PROBLEM SINCE THE ESSURE WAS PLACED INTO MY TUBES, I'VE BEEN SUFFERING FROM BAD MIGRAINES ABOUT 3 TO 4 TIMES A WEEK. I HAVE NOT BEEN THE SAME SINCE I HAD THE ESSURE WAS PLACED IN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056075	BAYER	9/9/2015	9/10/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER HAD ESSURE IMPLANTED IN (B)(6) 2008 AFTER THE BIRTH OF HER CHILD. SINCE THEN SHE HAS EXPERIENCED CHRONIC YEAST INFECTIONS, BACTERIAL INFECTIONS, PID, PELVIC PAIN AND AMBULATION DIFFICULTIES. SHE VISITED HER DOCTOR WHO ADVISED HER THAT SHE MIGHT BE HAVING A REACTION TO THE NICKEL IN THE ESSURE. SHE RECENTLY HAD A HYSTERECTOMY AND ALL HER PAIN AND SYMPTOMS WENT AWAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056152		9/9/2015	9/15/2015

Event Information:

Event Date (B3): 10/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/25/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE PLACED IN (B)(6) 2013. SINCE THEN, I HAVE EXPERIENCED MIGRAINES, WAS DIAGNOSED WITH FIBROMYALGIA 2 MONTHS AFTER, AND SUFFER FROM DIZZINESS AND FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056154		9/9/2015	9/15/2015

Event Information:

Event Date (B3): 4/4/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 4/4/2005
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2005 AND HAVE SUFFERED FROM ABNORMAL MENSTRUAL CYCLES, SEVERE PAIN IN UTERUS AND ABDOMEN ESPECIALLY WHEN OVULATING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00753	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT FROM A CONSUMER IN (B)(6) WAS IDENTIFIED IN THE INTERNET (SOCIAL MEDIA) ON (B)(6) 2013. THE REPORT REFERS TO THE REPORTING CONSUMER, A FEMALE OF UNSPECIFIED AGE, WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED PELVIC PAIN, HORRENDOUS BLEEDING, JOINT PAIN IN AREAS NOT ASSOCIATED WITH ESSURE, TOOK A TEST THAT WAS POSITIVE: PREGNANCY WITH ESSURE (DEVICE INEFFICIENCY), MISCARRIED, HAD YEAST INFECTIONS, BACTERIAL INFECTIONS, EXTREME FATIGUE, NAUSEA, ACID REFLUX, PAIN IN HIP BONE, SWELLING OF STOMACH, AND NICKEL TOXICITY POISONING. CONSUMER'S MEDICAL HISTORY / CONCURRENT CONDITIONS INCLUDED NICKEL ALLERGY AND EXTREME FATIGUE. NO INFORMATION WAS GIVEN ON CONSUMER'S PAST DRUGS, AND CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED SHE WAS ONE OF THE LADIES HAVING OR HAD ISSUES WITH ESSURE. SHE HAD (START DATES UNSPECIFIED) PELVIC PAIN, HORRENDOUS BLEEDING, JOINT PAIN IN AREAS NOT ASSOCIATED WITH ESSURE BUT NEVER HAD A PROBLEM BEFORE. IN (B)(6) 2012, SHE WAS 16 DAYS LATE, TOOK A TEST THAT WAS POSITIVE. FEW DAYS LATER, SHE MISCARRIED. CONSUMER STATED FROM THAT POINT ON EVERYTHING WAS WORSE. YEAST INFECTIONS AND BACTERIAL INFECTIONS. SHE ALWAYS HAD EXTREME FATIGUE BUT IT WAS GETTING WORSE. NAUSEA, ACID REFLUX PROBLEMS. PAIN IN HER HIP BONE. SWELLING OF HER STOMACH. IN (B)(6) 2013, SHE WENT TO HER DOCTOR WHO SET UP AN APPOINTMENT WITH GYNECOLOGIST, SHE WENT TO THAT APPOINTMENT AND A HYSTERECTOMY WAS SCHEDULED FOR (B)(6) 2013. THAT DAY HER COILS, TUBES, AND UTERUS CAME OUT AND THE NEXT MORNING, SHE HAD MORE ENERGY THAN SHE HAD IN 22 MONTHS. SHE ALSO WAS TESTED FOR NICKEL POISONING AS SHE HAD A DOCUMENTED NICKEL ALLERGY AND DOCTOR AND REPRESENTATIVE SAID THERE WAS NOT ENOUGH IN THE PRODUCT TO CAUSE

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HER HARM. SHE IS DETOXING FROM NICKEL TOXICITY POISONING, SOMETHING SHE THINKS WOULD NOT HAPPEN IF ESSURE WAS NOT IN HER BODY. CONSUMER IS FOUR MONTHS POST OPERATIVE AT TIME OF REPORTING AND WAS FEELING 'PRETTY DARN GREAT BESIDES HER ISSUES WITH DETOX AND POISONING'. NO FURTHER DETAILS WERE PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 30-MAY-2014: CASE CONSIDERED CLOSED. FOLLOW-UP RECEIVED ON 20-AUG-2014: INFORMATION RECEIVED FROM CONSUMER VIA INTERNET (SOCIAL MEDIA) STATES THAT, DUE TO MANY ALLERGIES, SHE IS NOW AN OWNER OF EPI PENS SOMETHING (AS REPORTED) WHICH SHE HAS NEVER NEEDED BEFORE. FOLLOW-UP INFORMATION RECEIVED ON 12-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0046). REPORTER STATED SHE IS CONSUMER'S FRIEND. CONSUMER HAD ESSURE REMOVED. SHE SUFFERED FROM DEBILITATING HEADACHES, DEVELOPED NUMEROUS ALLERGIES AND HAD HER WEIGHT DROPPED TO WHAT SHE PERCEIVED WAS AN UNHEALTHY LEVEL. SHE WAS AT TIMES QUITE EMOTIONAL. FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0278). CONSUMER REPORTED THAT SHE NEVER ONCE EXPECTED TO BECOME PREGNANT AND MISCARRY AND THEN, YEARS LATER, THINK ABOUT THE BABY. SHE ALSO NEVER EXPECTED TO BECOME SO SICK WITH ALLERGIES THAT THEY BECOME SO SEVERE SHE REACT TO EVERYTHING FOODS, MEDICINE, AND THE ENVIRONMENT. ACCORDING TO HER, ESSURE HAS INCREASED HER ALLERGIES IN EVERYTHING. IN ADDITION, CONSUMER INFORMED THAT HER BODY WENT INTO FREAK OUT MODE AND SHE LOST OVER 45LBS AND TOOK HER 6 MONTHS TO GET OVER 125LBS. SHE IS A BOUNCING YOYO WITH HER WEIGHT BECAUSE OF THE FOOD ALLERGIES. SHE IS NOW ALLERGIC TO THE SUN AND ALL BECAUSE ESSURE WAS IN HER BODY AND REAKED HAVOC (AS REPORTED) ON HER WHOLE ENTIRE SYSTEM. THE FATIGUE SHE FEELS DAILY IS A FATIGUE SHE CAN'T DESCRIBE TO DOCTORS AND THEY WILL NEVER UNDERSTAND. VITAMIN D IS VERY LOW AND HAS BEEN FOR MONTHS. SHE HAS A POSITIVE ANA RESULTS (AS REPORTED) WHICH MEANS AN AUTOIMMUNE PROBLEM. SHE HAS NO FAMILY WITH AUTOIMMUNE DIAGNOSIS. COMPANY CAUSALITY COMMENT: THIS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PREGNANCY WITH ESSURE AND MISCARRIED, HORRENDOUS BLEEDING AND HAD NICKEL TOXICITY POISONING. MISCARRIAGE, HORRENDOUS BLEEDING AND HAD NICKEL TOXICITY POISONING ARE SERIOUS EVENTS DUE TO MEDICAL IMPORTANCE: HORRENDOUS BLEEDING IS LISTED AND THE OTHER TWO UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCY WITH ESSURE IS NON-SERIOUS AND LISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE. PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE. IN THIS PARTICULAR CASE, NO SUCH CIRCUMSTANCE WAS REPORTED; CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE PREGNANCY CANNOT BE EXCLUDED. MISCARRIAGE IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY. RISK FACTORS INCLUDE MATERNAL AGE, SMOKING, LOW FOLATE LEVEL, UTERINE ABNORMALITIES, FETAL CHROMOSOMAL ABNORMALITIES, MATERNAL CHRONIC DISEASE AND MATERNAL INFECTIONS; THUS, THE EVENT MISCARRIED INITIALLY REGARDED AS RELATED TO ESSURE WAS AFTER A COMPANY INTERNAL REVIEW ASSESSED AS UNRELATED TO THE SUSPECT INSERT. THE ESSURE INSERT INCLUDES NICKEL-TITANIUM ALLOY. ALTHOUGH IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM THIS DEVICE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE A METAL POISONING. HOWEVER, SINCE IN THIS CASE THE CONSUMER BELIEVED SHE HAD A NICKEL TOXICITY POISONING DUE TO ESSURE AND UNDERWENT ESSURE REMOVAL, THIS EVENT WAS CONSIDERED RELATED TO ESSURE. ALSO, DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; THEREFORE CAUSALITY BETWEEN ESSURE USE AND HORRENDOUS BLEEDING CANNOT BE EXCLUDED. ALSO, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE INTERVENTION WAS REQUIRED (CONSUMER HAD A HYSTERECTOMY).

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Manufacturer Narrative (H10):

FOLLOW-UP FROM 09-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00754	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7): 3/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 23-OCT-2013 REFERRING TO HERSELF. THE CONSUMER HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LEFT SIDED LOWER BACK, SHARP STABBING PAIN FOR ABOUT 6 MONTHS AND LESS OVARIAN CYST PAIN SINCE ESSURE PLACEMENT. FOLLOW-UP INFORMATION RECEIVED ON 12-AUG-2015 FROM CONSUMER (CASE WAS UPGRADED TO INCIDENT): THIS INFORMATION WAS POSTED ON A FDA WEBSITE BY CONSUMER (REFERENCE NUMBERS FDA-2014-N-0736-0155 AND FDA-2014-N-0736-0015). CONSUMER HAD THE ESSURE PROCEDURE DONE IN 2005. ALTHOUGH HER PERIODS GOT MUCH HEAVIER, THE FOLLOWING 9 YEARS WITH ESSURE BIRTH CONTROL WAS PRETTY SUCCESSFUL. THEN ONE DAY IN 2013 SHE STARTED EXPERIENCING DEEP THROBBING PAIN IN HER LEFT OUTER THIGH (HIP TO KNEE) AND A CHRONIC BURNING PAIN IN HER LEFT BACK (NEAR KIDNEY) TOR 7 MONTHS. HER STOMACH WAS SO SWOLLEN THAT PEOPLE THOUGHT SHE WAS PREGNANT. EVEN AFTER ALL 3 PREGNANCIES SHE HAD A FLAT STOMACH. THE X-RAY SHOWED THE COIL LOOKED LIKE A FISH HOOK AND HER DOCTOR COMMENTED THE LEFT ONE DID NOT LOOK RIGHT AND AS SOON AS IT WAS REMOVED THE PAIN WENT AWAY AFTER HER COMPLETE HYSTERECTOMY, (B)(6) 2014, 3 MONTHS AFTER THE FIRST SURGERY WHICH LEFT FRAGMENTS. THEN 6 MONTHS LATER SHE WAS DIAGNOSED RAYNAUD'S DISEASE, RASHES, JOINT PAIN/ INFLAMMATION, INSOMNIA AND ANXIETY WHICH SHE BELIEVED WERE FROM THE TOXIC MATERIAL THAT MAKE UP THE PET FIBERS THAT WERE RELEASED IN HER BODY WHEN THE DOCTOR PULLED THEM OUT OF HER UTERUS. FOLLOW-UP RECEIVED ON 20-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A TECHNICAL PRODUCT ISSUE AND USABILITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4).

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FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A TECHNICAL PRODUCT ISSUE. THE AE CASE REFERS ALSO TO A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LEFT SIDED LOWER BACK (SHARP STABBING PAIN FOR ABOUT 6 MONTHS, CHRONIC BURNING PAIN IN HER LEFT BACK (NEAR KIDNEY) TOR 7 MONTHS). SHE UNDERWENT A FIRST SURGERY WHICH LEFT FRAGMENTS AND AFTERWARDS SHE UNDERWENT COMPLETE HYSTERECTOMY. A FEW MONTHS AFTER REMOVAL, SHE WAS DIAGNOSED WITH RAYNAUD'S DISEASE. THESE REPORTED EVENTS ARE INTERPRETED RESPECTIVELY AS BACK PAIN, DEVICE BREAKAGE AND RAYNAUD'S PHENOMENON. THE BACK PAIN AND DEVICE BREAKAGE ARE LISTED WHILE THE RAYNAUD'S PHENOMENON IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE PATIENT REPORTED CHRONIC BACK PAIN (7 MONTHS) AFTER ESSURE INSERTION. THE FIRST UNSPECIFIED SURGERY LEFT FRAGMENTS. THREE MONTHS LATER, SHE HAD A COMPLETE HYSTERECTOMY. SINCE IT IS KNOWN THAT ESSURE MAY CAUSE PAIN AND CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THIS BACK PAIN IS ASSESSED AS RELATED TO ESSURE. DUE TO THE NATURE OF THIS EVENT, ALTHOUGH IT WAS NOT REPORTED IF THE INSERTION OR REMOVAL WAS DIFFICULT, THE CAUSAL RELATIONSHIP BETWEEN THE ESSURE AND DEVICE BREAKAGE CANNOT BE EXCLUDED. IN CONTRAST, THE RAYNAUD'S SYNDROME IS ASSESSED AS UNRELATED DUE TO THE NEGATIVE TEMPORAL RELATIONSHIP, AND GIVEN THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, THE RAYNAUD'S PHENOMENON IS ASSESSED AS UNRELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED AND OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE THAT COULD HAVE LED TO A SERIOUS DETERIORATION IN HEALTH. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

LEGAL CLAIM RECEIVED ON 03-DEC-2015: ON (B)(6) 2005 SHE HAD THE ESSURE DEVICE IMPLANTED BECAUSE SHE WANTED PERMANENT BIRTH CONTROL. ON UNSPECIFIED DATE SHE BEGAN EXPERIENCING INFLAMMATION, BURNING SENSATIONS AND PAIN IN HER PELVIC AND BACK REGION DUE TO E

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00755	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/13/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT FROM A CONSUMER IN UNITED STATES WAS IDENTIFIED IN THE INTERNET ON 01-NOV-2013. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER COILS HAD MIGRATED, ITS IN ABDOMEN SOMEWHERE, SHE BECAME PREGNANT WITH ESSURE (DEVICE FAILED), AND DELIVERED VIA EMERGENCY C-SECTION. THE CONSUMER'S MEDICAL HISTORY INCLUDED TWO CHILDREN. NO INFORMATION WAS GIVEN ON CONSUMER'S DRUG HISTORY, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. IN 2008, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. THREE YEARS AFTER INSERTION (2011), CONSUMER WENT TO THE DOCTOR FOR PROBLEMS WITH HER MENSTRUAL PERIODS WAS DIAGNOSED WITH PREGNANCY (DEVICE FAILED). SIX MONTHS LATER, FEMALE BABY WAS DELIVERED VIA EMERGENCY C-SECTION, CONSUMER STATED 'AN UNEXPECTED BLESSING, HER E-BABY'. DOCTORS TOLD CONSUMER THAT HER COILS HAD MIGRATED, ITS IN HER ABDOMEN SOMEWHERE. REPORTER DID NOT ASSESS DRUG-EVENT RELATIONSHIP. NO FURTHER INFORMATION CAN BE OBTAINED. FOLLOW UP INFORMATION RECEIVED ON 27JAN2014 - PTC ASSESSMENT. PTC NUMBERS: GLOBAL (B)(4) AND LOCAL (B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL

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MEDICAL EVALUATION IS POSSIBLE. THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP 24-FEB-2014: IN A NEWS VIDEO CLIP, CONSUMER REPORTED HER EXPERIENCE USING A PERMANENT BIRTH CONTROL METHOD CALLED ESSURE. SHE DESCRIBED THAT IT HAD A GREAT EFFICACY RATE, IT WAS 99.98 PERCENT EFFECTIVE AT THAT TIME WHEN SHE HAD IT DONE. CONSUMER HERSELF BECAME PREGNANT. NO FURTHER DETAILS WERE REPORTED. FOLLOW-UP INFORMATION WAS RECEIVED ON 05-MAR-2014. THE CONSUMER STATED THAT WHAT REALLY MAKES SHE MAD IS NOT KNOWING HOW ESSURE IS GOING TO AFFECT HER E-BABY'S FUTURE REPRODUCTIVE HEALTH. NO FURTHER INFORMATION WAS PROVIDED. -FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY FROM UNITED STATES (REFERENCE NUMBER: MW5035132): IN (B)(6) 2008, THE CONSUMER WAS IMPLANTED WITH ESSURE SIX WEEKS AFTER THE BIRTH OF HER SECOND CHILD. HER HYSTEROSALPINGOGRAPHY WAS DONE FOUR MONTHS LATER (HER CYCLE DID NOT MATCHUP WITH AVAILABLE APPOINTMENTS AT THEE-MONTH MARK AS RECOMMENDED) AND SHE WAS TOLD SHE WAS 100% OCCLUDED AND COULD DISCONTINUE ORAL BIRTH CONTROL. IN 2010 SHE WAS EVALUATED BY ANOTHER OBSTETRIC/GYNECOLOGIST FOR CLOTTY, HEAVY, HEMORRHAGIC (AT TIMES) BLEEDING DURING HER PERIODS. SHE EXPRESSED HER CONCERN THAT ESSURE WAS THE CAUSE AS THAT WAS THE ONLY NEW THING SHE HAD DONE. THE DOCTOR DISMISSED HER CONCERN SAYING "ESSURE IS NON-HORMONAL AND HAS NO EFFECT ON YOUR BLEEDING". THE CONSUMER WAS PUT ON ORAL BIRTH CONTROL AFTER DOING AN ENDOMETRIAL BIOPSY. IN 2011, SHE DISCONTINUED THE ORAL BIRTH CONTROL AS HER BLEEDING HAD STARTED PRIOR TO THE END OF THE HORMONAL PILLS IN THE PACK. THE PILLS HAD NOT HELPED HER BLEEDING WHATSOEVER ANYWAY; IT WAS STILL HEAVY AND VERY CLOTTY. IN 2011, SHE DID NOT HAVE A PERIOD. SHE HAD BEEN WORKING OUT A LOT AND WATCHING HER DIET AND HAD LOST 35LBS. SHE THOUGHT HER BODY WAS ADJUSTING TO THE WEIGHT LOSS AND COMING OFF OF THE HORMONES. IN 2011, SHE RETURNED TO HER OBSTETRIC/GYNECOLOGIST AND THEY TOLD HER SHE WAS 13 WEEKS PREGNANT. HER PREGNANCY PROGRESSED NORMALLY, BEING OBSERVED WITH WEEKLY ULTRASOUNDS FOR MILD POLYHYDRAMNIOS AND HAD TWICE WEEKLY NON-STRESS TESTS DUE TO HER WEIGHT. HER BABY WAS BORN IN 2012. SHE UNDERWENT A LAPAROSCOPIC TUBAL LIGATION AND HERNIA REPAIR IN 2012. HER OBSTETRIC/GYNECOLOGIST FOUND THAT HER LEFT ESSURE COIL HAD COMPLETELY MIGRATED OUT OF THE FALLOPIAN TUBE AND WAS SCARRED INTO HER ABDOMINAL WALL. THE RIGHT ESSURE COIL HAD ALSO PERFORATED AND WAS PARTIALLY IN THE TUBE STILL, WITH THE FREE END MAKING CONTACT WITH HER COLON. IT WAS ELECTED TO REMOVE THAT ONE BUT DECIDED TO LEAVE THE LEFT COIL IN HER ABDOMEN. SINCE HER PARTIAL REMOVAL SHE STILL HAS HEAVY, HEMORRHAGIC, CLOTTY PERIODS. SHE HAS SINCE BEEN DIAGNOSED WITH MULTIPLE FIBROIDS, WHICH SHE DID NOT HAVE PRIOR TO ESSURE IMPLANTATION. FOLLOW UP INFORMATION RECEIVED ON 21-APR-2014: CONSUMER STATED THAT HER LAWYER ADVISED HER NOT TO SPEAK WITH BAYER. THIS IS A POTENTIAL LEGAL CASE NOW. FOLLOW-UP INFORMATION RECEIVED ON 14-AUG-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 ((B)(4)). CONSUMER STATED THAT PROCEDURE WAS QUICK, SIMPLE, NOT TOO PAINFUL (ALTHOUGH SHE WAS PUT TO SLEEP IN THE OPERATING ROOM) AND WAS BACK AT WORK THE NEXT DAY. THREE YEARS AFTER BEING CONFIRMED BLOCKED, SHE WAS THIRTEEN WEEKS PREGNANT. COMPANY CAUSALITY COMMENT: THIS LEGAL CASE REPORT REFERS TO A FEMALE CONSUMER OF NOT REPORTED AGE WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND BECAME PREGNANT. SHE DELIVERED VIA EMERGENCY C-SECTION. SHE ALSO EXPERIENCED LEFT ESSURE COIL HAD COMPLETELY MIGRATED OUT OF THE FALLOPIAN TUBE AND WAS SCARRED INTO HER ABDOMINAL WALL AND THE RIGHT ESSURE COIL HAD ALSO PERFORATED AND WAS PARTIALLY IN THE TUBE STILL, WITH THE FREE END MAKING CONTACT WITH HER COLON. THIS CASE IS NOT MEDICALLY CONFIRMED. DEVICE MIGRATION AND FALLOPIAN TUBE PERFORATION ARE LISTED IN THE REFERENCE SAFETY INFORMATION. DELIVERED VIA EMERGENCY C-SECTION' IS UNLISTED. ALL EVENTS ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR

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DURING ANY CONTRACEPTIVE USE. PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. THE FAILURE RATE MAY BE INCREASED DUE TO PATIENT NON-COMPLIANCE. IN THE PRESENT CASE, LEFT ESSURE COIL HAD COMPLETELY MIGRATED OUT OF THE FALLOPIAN TUBE AND THE RIGHT ESSURE COIL HAD PERFORATED. IT IS UNKNOWN WHETHER ESSURE COIL MIGRATED FIRST AND THE PREGNANCY FOLLOWED, OR IF IT WAS IN PLACE DURING CONCEPTION, AND MIGRATED LATER, DURING PREGNANCY. HOWEVER, THE POSSIBILITY OF CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. THE INDICATION OF EMERGENCY C-SECTION WAS NOT REPORTED. HOWEVER, DUE TO POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE IS ASSESSED AS RELATED. AS TEMPORAL RELATIONSHIP BETWEEN DEVICE MIGRATION AND FALLOPIAN TUBE PERFORATION AND ESSURE USE IS POSITIVE, CAUSALITY IS ASSESSED AS RELATED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. ACCORDING TO PTC REPORT, NO COMPLAINT SAMPLE WAS PROVIDED AND NO BATCH NUMBER WAS REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED THROUGH LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00756	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA PHARMACIST (CASE# MW5032103) IN UNITED STATES ON 12-NOV-2013 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN, SEVERE MIGRAINES, AUTOIMMUNES ISSUES, HAIR LOSS, SEVERE JOINT PAIN, DIZZINESS, EXTREME FATIGUE, INSOMNIA, SWALLOWING ISSUES, METAL TASTE IN MY MOUTH, STABBING PAINS IN MY SIDES, SEVERE HIP PAIN, VITAMIN DEFICIENCY, SEVERE MOOD SWINGS, SWELLING, COILS HAVE MIGRATED AND SUSPICION OF DEVICE BREAKAGE: ONE APPEARS BROKEN. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED PELVIC PAIN (FEW MONTHS AFER IMPLANTATION), SEVERE MIGRAINES, AUTOIMMUNES ISSUES, HAIR LOSS, SEVERE JOINT PAIN, DIZZINESS, EXTREME FATIGUE, INSOMNIA, SWALLOWING ISSUES, METAL TASTE IN MY MOUTH, STABBING PAINS IN MY SIDES, SEVERE HIP PAIN, VITAMIN DEFICIENCY, SEVERE MOOD SWINGS, SWELLING, COILS HAVE MIGRATED AND SUSPICION OF DEVICE BREAKAGE: ONE APPEARS BROKEN. ALL THE EVENTS ARE SERIOUS BECAUSE THEY RESULTED IN DISABILITY. THE PATIENT WAS TRYING TO FIND A DOCTOR TO REMOVE THE IMPLANTS. THE RELATIONSHIP BETWEEN PELVIC PAIN, SEVERE MIGRAINES, AUTOIMMUNES ISSUES, HAIR LOSS, SEVERE JOINT PAIN, DIZZINESS, EXTREME FATIGUE, INSOMNIA, SWALLOWING ISSUES, METAL TASTE IN MY MOUTH, STABBING PAINS IN MY SIDES, SEVERE HIP PAIN, VITAMIN DEFICIENCY, SEVERE MOOD SWINGS, SWELLING, COILS HAVE MIGRATED AND SUSPICION OF DEVICE BREAKAGE: ONE APPEARS BROKEN AND ESSURE WAS NOT REPORTED. PTC INVESTIGATION RESULT RECEIVED ON 27-JAN-2014: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT NO LOT NUMBER PROVIDED; THEREFORE, NO LOT

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HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN WI-03635, "PROCESSING ESSURE CASES IN DEV@COM." MEDICAL ASSESSMENT THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE FOR A QUALITY DEFICIT PER SE. THE CASE REFERS ALSO TO A SUSPECTED DEVICE BREAKAGE. THE EVENTS WERE REPORTED WITH AN OCCURENCE OVER A LONG PERIOD OF 6 YEARS AND ARE OF BROAD NATURE. THE MAJORITY OF THE REPORTED MEDICAL EVENTS WERE ASSESSED AS BEING NOT RELATED TO ESSURE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)). CONSUMER REPORTED THAT SHE WENT FROM A TYPICALLY HEALTHY PERSON TO A WOMAN WHO CAN BARELY GET OUT OF BED AND TAKE CARE OF HER NOW FIVE YEAR OLD DAUGHTER. ACCORDING TO HER, SHE NOW SUFFERS FROM MULTIPLE AUTOIMMUNE DISEASES THAT WILL LAST HER A LIFETIME. SHE HAD A HYSTERECTOMY AT THE AGE OF (B)(6) TO PREVENT ANY FURTHER DAMAGE FROM THE DEVICE. IN ADDITION, CONSUMER PROVIDED A LIST OF ALL THE SYMPTOMS THAT SHE WAS LEFT WITH AFTER ESSURE, WHICH INCLUDED: FEELING COLD WHEN OTHERS FEEL HOT, LOW BODY TEMPERATURE, HAIR LOSS (MOSTLY IN CROWN AREA OF HEAD), EXCESS HAIR GROWTH ON THE FACE, LOSS OF HAIR IN OUTER EYEBROW, HAIR IS ROUGH, COARSE DRY, BREAKING, BRITTLE, PAINFUL SKIN RASH (MAINLY ON BREASTS), BRUISES EASILY, ACNE, SKIN RASHES (ESPECIALLY "BUTTERFLY RASH" ON THE NOSE AND CHEEKS), SUN SENSITIVITY, DRY AND BRITTLE NAILS, SKIN AROUND NAILS THICKENING AND CRACKING, DRY EYES, BLURRED VISION, EYE DISCOMFORT OR PAIN, EYE TWITCHING, TINNITUS, DRY MOUTH, DIFFICULTY IN SWALLOWING (GET CHOKED OFTEN), MOUTH SORES, FULLNESS OR PRESSURE, CHOKING SENSATION IN THROAT, LUMP IN THE NECK, CHRONIC FATIGUE, INSOMNIA, EXHAUSTION AFTER MINIMAL EFFORT OR EXERCISE, PAIN AND TENDERNESS THROUGHOUT THE BODY, MUSCLE WEAKNESS, JOINT STIFFNESS, JOINT PAIN (MOST SEVERE IN FINGERS, WRISTS, KNEES, AND ANKLES), MUSCLE ACHES, BONE PAIN, EXTREME SENSITIVE TO COLD IN THE HANDS AND FEET, SWELLING IN HAND AND FEET (MOST OFTEN IN MORNINGS; FINGERS SWELL TO POINT OF BEING UNABLE TO BENT), WEIGHT GAIN, INABILITY TO LOSE WEIGHT, PALE AND FOUL-SMELLING STOOL, CONSTIPATION, IRRITABILITY, ANXIETY, BRAIN FOG, DIFFICULTY CONCENTRATING, FORGETFULNESS, NUMBNESS (ARMS/LEGS), WEAKNESS (ARMS/LEGS), TINGLING (ARMS/LEGS), MUSCLE TWITCHES (ARMS/LEGS), REDUCED SEX DRIVE, INCREASE IN SNORING (HAS HAD 2 SLEEPS STUDIES AND DO NOT HAVE SLEEP APNEA; ONLY RESTLESS LEG SYNDROME), SHORTNESS OF BREATH, TIGHTNESS IN THE CHEST, PROLONGED BLEEDING/HEALING (NOT ALL THE TIME), HYPOGLYCEMIA/LOW BLOOD SUGAR (BLOOD SUGAR PERIODICALLY DROPS; LOWEST TESTED WAS 42) AND SKIN CRAWLING/TINGLING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN (FEW MONTHS AFER IMPLANTATION), SEVERE MIGRAINES, STABBING PAINS IN MY SIDES AND COILS HAVE MIGRATED WHICH ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO EXPERIENCED AUTOIMMUNES ISSUES, HAIR LOSS, SEVERE JOINT PAIN (HIP, FINGERS, WRISTS, KNEES, AND ANKLES), DIZZINESS, EXTREME FATIGUE, INSOMNIA, DIFFICULTY IN SWALLOWING, GET CHOKED OFTEN, METAL TASTE IN MY MOUTH, VITAMIN DEFICIENCY, SEVERE MOOD SWINGS AND SWELLING WHICH ARE UNLISTED. SUSPICION OF DEVICE BREAKAGE: ONE APPEARS BROKEN IS UNLISTED IN THE REFERENCE SAFETY INFORMATION, BUT LISTED ACCORDING TO PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS. SHE UNDERWENT A HYSTERECTOMY. THIS CASE HAS LIMITED INFORMATION.

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CONSIDERING THE IMPLIED POSITIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN THE EVENTS PELVIC PAIN, SEVERE MIGRAINES, STABBING PAINS IN SIDES, COILS MIGRATED AND SUSPICION OF DEVICE BREAKAGE: ONE APPEARS BROKEN AND ESSURE CANNOT BE EXCLUDED. HOWEVER, FOR THE OTHER EVENTS, ALTHOUGH THE POSITIVE TEMPORAL RELATIONSHIP IS ALSO IMPLIED, IT IS UNLIKELY THAT ESSURE WOULD CAUSE THE EVENTS DUE TO THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES (UNRELATED). THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. OTHER NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PTC REPORT, NO COMPLAINT SAMPLE WAS PROVIDED FOR TECHNICAL INVESTIGATION AND NO BATCH NUMBER WAS REPORTED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP OF THE REPORTED ADVERSE EVENT TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

30-DEC-2015: CASE CLOSED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00757	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2009
Explant Date (E7): 10/14/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER VIA REGULATORY AUTHORITY FDA (CASE# MW5032160) IN UNITED STATES ON 11-DEC-2013 WHICH REFERS TO HERSELF (UNSPECIFIED AGE) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD UTERINE ENLARGEMENT RESULTING IN ADENOMYOSIS. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS CONCURRENT CONDITIONS, AND CONCOMITANT MEDICATION. ON (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2013 THE CONSUMER HAD UTERINE ENLARGEMENT RESULTING IN ADENOMYOSIS AND A TOTAL HYSTERECTOMY WAS PERFORMED ON (B)(6) 2013 AND ESSURE WAS REMOVED. REPORTER CAUSALITY: THE REPORTER ASSESSMENT WAS NOT REPORTED. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 14-JAN-2014: THE CONSUMER'S BIRTHDATE WAS PROVIDED. SHE WAS (B)(6)AT THE TIME OF FIRST SYMPTOM ONSET. SHE WAS (B)(6) HEIGHT AND (B)(6) WEIGHT (BMI: (B)(6)). SHE CONSIDERED HERSELF PERFECTLY HEALTHY BEFORE HAVING THE ESSURE INSERTED AND SHE DID NOT HAVE RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. SHE HAD THE ESSURE INSERTED IN (B)(6) 2009, AFTER HER LAST DELIVERY (DATED ON (B)(6) 2009). DEPO-PROVERA WAS ADMINISTERED ON THE SAME OF ESSURE INSERTION FOR BACKUP CONTRACEPTION. THE HYSTEROSALPINGOGRAPHY WAS PERFORMED IN 2010, SHOWING BOTH TUBES OCCLUDED. HEAVY BLEEDING, PELVIC PAIN, PAIN WITH INTERCOURSE, PAIN DURING HER CYCLES (PAIN NEVER LET UP) STARTED AFTER ESSURE'S INSERTION, AND FROM 2012 IT HAD BEEN REALLY BOTHERING. SHE HAD VISITED HER DOCTOR EVERY 6 MONTHS CONCERNING THESE SYMPTOMS AND TRIED BIRTH CONTROL. THE DIAGNOSIS OF ADENOMYOSIS WAS PROVIDED. ON (B)(6) 2013, THE CONSUMER UNDERWENT TO AN X-RAY TEST AND THE ESSURE COILS WERE SEEN TO BE BENT. THE CONSUMER WANTED TO HAVE THE ESSURE REMOVED IN ORDER FOR THE PAIN TO GO AWAY AND THE DOCTOR ALSO

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RECOMMENDED IT. ON (B)(6) 2013, THE CONSUMER HAD LAPAROSCOPIC HYSTERECTOMY (OVARIES WERE KEPT) AND ESSURE'S REMOVAL, BEING HOSPITALIZED DURING THE HYSTERECTOMY (TIME FRAME WAS NOT PROVIDED). DURING SURGERY, IT HAD BEEN FOUND THAT ESSURE INSERTS WERE STILL IN FALLOPIAN TUBES. PATHOLOGY RESULTS WERE IN POSSESSION OF HER PHYSICIAN. SHE HAD RECOVERED FROM THE ESSURE REMOVAL PROCEDURE. THE CONSUMER WAS FEELING BETTER/GREAT AT THE TIME OF REPORT AND HAD RECOVERED FROM PELVIC PAIN AND PAIN WITH INTERCOURSE. THE REPORTING CONSUMER HAS CONSIDERED THAT THE ESSURE CAUSED THESE ISSUES SINCE ALL SYMPTOMS STARTED AFTER INSERTION. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 26-JAN-2014: FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN WI-03635, "PROCESSING ESSURE CASES IN DEV@COM." METHOD: NO TESTING METHODS PERFORMED. RESULTS: NO RESULTS AVAILABLE SINCE NO EVALUATION PERFORMED. CONCLUSIONS: UNABLE TO CONFIRM COMPLAINT; DEVICE NOT RETURNED. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT INDICATIVE FOR A QUALITY DEFECT PER SE. THE REPORTED MEDICAL EVENTS WERE ASSESSED AS BEING NOT RELATED TO THE PRODUCT. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 23-JAN-2014: NO NEW INFORMATION PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 12-AUG-2015. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE (#(B)(4)), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015. ESSURE RUINED HER LIFE, HER MARRIAGE AND HER BODY. SHE WAS EXPERIENCING PAIN AS RESULT OF ESSURE. ACCORDING TO THE CONSUMER, REMOVING ESSURE WAS ONE OF THE BEST DECISIONS SHE HAS MADE FOR HER LIFE. FOLLOW-UP INFORMATION RECEIVED ON 22-AUG-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 ((B)(4)). AROUND CHRISTMAS 2010 WAS WHEN SHE BEGAN NOTICING A CHANGE IN HER WEIGHT, PMS AND CYCLES. SHE WAS RETAINING MORE AND MORE WEIGHT VERSE IT FALLING OFF AS IT DID WITH HER SON AND WAS GIVEN THE MIRENA AFTER HIM. SHE NOTICED A CHANGE BUT IT WAS NOT SIGNIFICANT ENOUGH FOR A CONCERN. SHE PUT IT OFF AS THE CHANGE AND ADJUSTMENT TO THE ESSURE SINCE IT WAS PLACED 4-6 MONTHS AGO. HER PERIOD HAD THAN SETTLE INTO A DIFFERENT DAY AND BECAME CONSISTENT AGAIN AT THAT POINT HER PERIOD START DATES WERE THE 11TH OF EACH MONTH FOR 5 TO 6 DAYS. AFTER PASSING THE CHANGE OFF TO HER BODY ADJUSTING TO THIS FOREIGN DEVICE, HER MOOD REALLY CHANGED. SHE WAS GAINING WEIGHT, SHE DIDN'T HAVE THE ENERGY TO COOK, CLEAN AND HAVE SEX. AFTER SHE HAD GOTTEN THE ESSURE PROCEDURE HER LIFE FELL APART; SHE WAS MEAN AND RUDE TO BABIES AND CONSTANT MODE CHANGES, LACK OF ENERGY, LACK OF SEXUAL DRIVE AND UNWILLINGNESS. AS SHE WAS STILL HAVING SEX, AROUND (B)(6) 2011 SHE BEGAN HAVING THE WEIRD FEELINGS SYMPTOMS AND SENSATION OF BEING PREGNANT. AS A WOMAN WHO UNDERWENT A STERILIZATION PROCEDURE SHE KNEW SHE COULD NOT BE PREGNANT SHE WAS JUST GOING CRAZY, BUT HER SYMPTOMS GOT STRONGER. SHE DECIDED TO TAKE A HOME PREGNANCY TEST AND IT WAS NEGATIVE, SO SHE WAITED A WEEK STILL NO PERIOD AND TOOK ANOTHER PREGNANCY TEST AND STILL NEGATIVE. AFTER THAT SHE DECIDED TO HAVE A ROUTINE PAP SMEAR. A THIRD PREGNANCY TEST WAS DONE AND IT WAS ALSO NEGATIVE. PHYSICIAN ASKED IF SHE EVER HAD THE HSG DONE AND SHE REPLIED NO, SO THE DYE TEST WAS DONE IN (B)(6) 2011 AND WAS 100% BLOCKED. SHE STATED THAT HER HCG HORMONES WERE NOT STRONG AND THEY WERE CAUSING FALSE NEGATIVES WHEN SHE WAS IN FACT PREGNANT. THE SAME THING HAPPENED TO HER SON (THE TESTER TOLD

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HER IT WAS NEGATIVE AND SHE HAD TO TAKE A SECOND TEST BEFORE A POSITIVE APPEARED). SHE DECIDED TO CALL HER DOCTOR TO SCHEDULE A PREGNANCY TEST AND THE PHYSICIAN THOUGHT SHE WAS CRAZY. LATER THAT MONTH HER PERIOD CAME AND IT WAS EXTREMELY HEAVY WITH FLESH PARTIAL OR BLOOD CLOTS IN IT, IN WHICH SHE BELIEVED WAS A MISCARRIAGE (NO MEDICAL SUPPORTING DOCUMENTS JUST HER KNOWING HER BODY). THE PAINS WERE CONSISTENT THEY STARTED TO COME EVERY DAY AT A POINT. EACH TIME SHE ATTEMPTED TO HAVE SEX IT WOULD HURT SO BAD. SHE HAD ISSUES WITH PASSING HER STOOL. SHE HAD EXTREME SHARP PAIN STREAK DOWN HER ABDOMEN DOWN THROUGH HER VAGINA AND RECTUM. HER RECTUM HURT SO BADLY THAT SHE WAS UNABLE TO SIT. SHE BEGAN BLOATING AND GAINING WEIGHT 10 POUNDS AT A TIME. SHE WENT TO THE PHYSICIAN REGARDING HER ISSUES BECAUSE SHE KNEW IT WAS ESSURE RELATED BECAUSE SHE FOUND THE ESSURE PROBLEM GROUP ON FACEBOOK AND OTHER WOMEN HAVE BEEN HAVING THE SAME ISSUES. SHE ALSO HAD PERIOD HEAVY, DUTY PADS WITHIN AN HOUR OR LESS, RECTUM PAINS, KNIFE STABBING FEELING IN ABDOMEN EACH MONTH, DEBILITATING SHARP PAINS IN ABDOMEN, SWOLLEN SORE TO THE TOUCH UTERUS, CONSTIPATION, PAINFUL SEX, HAIR FALLING OUT AND IMITABILITY. HER PAP WAS NOT NORMAL AND SHE HAD A BLADDER INFECTION AND WAS INSTRUCTED TO TAKE FLAGYL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UTERINE ENLARGEMENT RESULTING IN ADENOMYOSIS, HEAVY BLEEDING AND PELVIC PAIN. ESSURE INSERTS WERE REMOVED. HEAVY BLEEDING AND PELVIC PAIN ARE LISTED, WHILE UTERINE ENLARGEMENT AND ADENOMYOSIS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ADENOMYOSIS REFERS TO A DISORDER IN WHICH ECTOPIC ENDOMETRIAL TISSUE GROWS INTO THE UTERINE MUSCULATURE. RISK FACTORS FOR ADENOMYOSIS INCLUDE: PRIOR UTERINE SURGERY, MIDDLE AGE, AND CHILDBIRTH. IN THE PRESENT CASE, UTERINE ENLARGEMENT HAD PROBABLY OCCURRED AS A CONSEQUENCE OF ADENOMYOSIS. CONSIDERING THE PATHOPHYSIOLOGY OF ADENOMYOSIS, CAUSALITY WITH ESSURE IS UNLIKELY. IT IS ALSO UNLIKELY THAT ESSURE HAD CAUSED AN ENLARGEMENT OF UTERUS. CONSUMER ALSO REPORTED HEAVY BLEEDING AFTER ESSURE INSERTION THAT STARTED 4 YEARS BEFORE THE DATE OF THE REPORT. CONSIDERING HER DIAGNOSIS OF ADENOMYOSIS (A PLAUSIBLE ALTERNATIVE EXPLANATION), CAUSALITY BETWEEN THIS EVENT AND ESSURE USE CAN BE EXCLUDED. IN THIS CASE, THE CONSUMER STATED SHE WAS EXPERIENCING PAIN AS A RESULT OF ESSURE. ALTHOUGH THE TEMPORAL RELATIONSHIP IS UNCLEAR, CONSIDERING THAT ESSURE MAY CAUSE PELVIC PAIN, THIS EVENT IS ASSESSED AS RELATED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE INITIAL PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT QUALITY DEFECT. AN UPDATED ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

12/23/2015 - CASE CLOSED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00758	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 04-DEC-2013 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED HEAVY BLEEDING, IRREGULAR/WEIRD PERIODS EVER 41 DAYS, CHRONIC PAIN, NIGHT SWEATS, BAD PELVIC PAIN, ENDOMETRIOSIS, AND OVARIAN CYSTS. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT WAS NOT REPORTED WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. IN (B)(6) 2008 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SINCE SHE GOT THE ESSURE DONE SHE HAS HAD HEAVY BLEEDING, IRREGULAR/WEIRD PERIODS EVER 41 DAYS., CHRONIC PAIN, NIGHT SWEATS NOT SURE IF SHE WAS GOING THROUGH MENOPAUSE FROM THE ESSURE, AND BAD PELVIC PAIN. THE CONSUMER ALSO STATED THAT SINCE THE ESSURE SHE HAS BEEN TOLD SHE NOW HAVE ENDOMETRIOSIS AND OVARIAN CYST REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN HEAVY BLEEDING, IRREGULAR/WEIRD PERIODS EVER 41 DAYS, CHRONIC PAIN, NIGHT SWEATS, BAD PELVIC PAIN, ENDOMETRIOSIS, AND OVARIAN CYSTS AND ESSURE WAS REPORTED AS RELATED. THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO (B)(6) ON 03-JAN-2014. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED. FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)). CONSUMER REPORTED THAT BECAUSE OF ESSURE, SHE NOW HAS ENDOMETRIOSIS. SHE HAD A HYSTERECTOMY TO GET RID OF THAT AND SHE HAS INTERSTITIAL CYSTITIS WHICH A BLADDER CONDITION (AS REPORTED). IN ADDITION, CONSUMER REPORTED THAT SHE HAS CONSTANT OVARIAN CYSTS AND STATES THAT SHE JUST HAD SURGERY ON (B)(6) TO GET

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ANOTHER ONE REMOVED; SHE ALSO HAD TO GET AN ENDOMETRIAL ABLATION BECAUSE SHE WAS BLEEDING SO HEAVY 3 WEEKS OUT OF A MONTH. CONSUMER ALSO REPORTED PELVIC PAIN (THAT SHE STILL GO THROUGH). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING. SHE WAS BLEEDING SO HEAVY THAT IT WAS 3 WEEKS OUT OF A MONTH (SEEN AS GENITAL BLEEDING). SHE ALSO HAD OVARIAN CYST. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. BLEEDING IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE OVARIAN CYST IS UNLISTED. GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER EXPERIENCED THIS INTENSE BLEEDING AMONG OTHER NON-SERIOUS EVENTS SINCE ESSURE PLACEMENT. ALTHOUGH IN THIS CASE ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THE BLEEDING, CONSIDERING EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE TOTALLY EXCLUDED. THEREFORE, HEAVY BLEEDING IS ASSESSED AS RELATED TO ESSURE USE. STILL, ENDOMETRIOSIS IS A COMPATIBLE ALTERNATIVE EXPLANATION FOR THE OVARIAN CYSTS. BASED ON THIS CONSIDERATION AND ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE USE IS VERY UNLIKELY. THIS CASE WAS PREVIOUSLY REGARDED AS NON-INCIDENT. UPON MONITORING OF POSTING OF AN FDA DOCKET WEBSITE, IT WAS DETECTED THAT AN ENDOMETRIAL ABLATION WAS PERFORMED DUE TO BLEEDING. THUS, SINCE AN INTERVENTION WAS REQUIRED, THIS CASE WAS UPGRADED TO INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 05-NOV-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00759	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 13-JAN-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5032667, RECEIVED AT FDA ON 07-NOV-2013). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED SEVERE CRAMPING, PAIN, EDEMA AND IRREGULAR PERIODS, THE ESSURE DEVICE SHIFTED FROM THE FALLOPIAN TUBE TO LOW IN HER UTERINE WALL. FDA REPORT TYPE WAS INJURY', REPORTED OUTCOME OF EVENTS WAS 'HOSPITALIZATION' NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. IN 2008 , THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED SHE HAS LIVED WITH SEVERE CRAMPING, PAIN, EDEMA AND IRREGULAR PERIODS FOR THE PAST FIVE YEARS. NOW SHE IS SUFFERING FROM EXTREME PAIN AND AFTER HAVING A CT (COMPUTED TOMOGRAPHY) SCAN AND ULTRASOUND IT HAS BEEN DETERMINED SHE MUST HAVE A HYSTERECTOMY TO BE RID OF THE PAIN. HYSTERECTOMY INCLUDING HOSPITALIZATION WAS SCHEDULED FOR (B)(6) 2013 (REPORTED AS EVENT DATE BY CONSUMER ON 07-NOV-2013). THIS IS DUE TO THE ESSURE DEVICE SHIFTING FROM THE FALLOPIAN TUBE TO LOW IN HER UTERINE WALL. THE PRODUCT SHOULD BE PULLED AND THE MAKERS HELD RESPONSIBLE. SHE IS ONLY (AGE NOT REPORTED) AND LOOKING AT POSSIBLY GOING THROUGH MENOPAUSE DUE TO THIS HYSTERECTOMY. NO FURTHER DETAILS WERE REPORTED. PTC INVESTIGATION RESULT RECEIVED ON 27-JAN-2014 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN WI-

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03635, "PROCESSING ESSURE CASES IN DEV@COM." METHOD: NO TESTING METHODS PERFORMED. RESULTS: NO RESULTS AVAILABLE SINCE NO EVALUATION PERFORMED. CONCLUSIONS: UNABLE TO CONFIRM COMPLAINT; DEVICE NOT RETURNED. MEDICAL ASSESSMENT THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE FOR A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. AT TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED THIS WAS AN UNCONFIRMED QUALITY DEFECT. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT FOLLOW UP INFORMATION RECEIVED ON: 31-JAN-2014 CONSUMER DID NOT ANSWER TO CONTACT ATTEMPTS. CASE CLOSED. FOLLOW-UP INFORMATION HAS BEEN IDENTIFIED ON 13-AUG-2015 DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)): THE CONSUMER HAD NICKEL ALLERGY AND HAD 3 CHILDREN. AT THE TIME ESSURE WAS IMPLANTED, THERE WAS NO NICKEL WARNING. THE DOCTOR THE CONSUMER SAW DID NOT THINK THE PRODUCT CONTAINED NICKEL. THE PROCEDURE WAS SUPPOSED TO BE QUICK AND PAIN FREE, BUT IT WAS NOT. THEY HAD TO PAUSE BECAUSE OF UTERUS SPASMS AND THE CONSUMER WAS IN EXTREME PAIN. AFTER THE PROCEDURE, SHE BLED HEAVILY (NOT JUST SPOTTING), SO HEAVILY THE DOCTOR ENDED UP DOING A DNC (DILATION AND CURETTAGE). THE CONSUMER LIVED EVERY DAY FOR 5 YEARS IN AGONIZING PAIN, SHE FELT LIKE SOMEONE WAS CUTTING UP HER INSIDES WITH RAZOR BLADES. HER HAIR BEGAN FALLING OUT BY THE HANDFULS, HER SKIN STARTED TO BECOME ROUGHER AND SHE WOULD GO FOR MONTHS WITHOUT A PERIOD, AND THEN SHE WOULD HAVE IT EXTREMELY HEAVY, PASSING CLOTS THE SIZE OR HER FIST - THIS ORDEAL WOULD LAST FOR 3 MONTHS. INTIMACY WAS PAINFUL AS WELL. IN (B)(6) 2013, THE PAIN BECAME SO SEVERE THAT SHE COULD BARELY WALK. AN EMERGENCY CT SCAN INDICATED POSSIBLE MISPLACED DEVICE. HER DOCTOR WAS SKEPTICAL AND TRIED HORMONES AND FURTHER TESTING TO FIX THOSE ISSUES. A TRANSVAGINAL ULTRASOUND REVEALED A MISSING COIL, AND THE DOCTOR BELIEVED AT THAT TIME THAT THE COIL WAS EMBEDDED IN UTERUS AND SCHEDULED A TOTAL HYSTERECTOMY. THE CONSUMER WAS (B)(6) AT THIS TIME. THE SURGERY WAS DIFFICULT, AND IT WAS FOUND OUT THAT THE COIL WAS NOT EMBEDDED IN HER UTERUS, IT HAD PERFORATED THE UTERUS AND WAS LOOSE WITH ABDOMINAL CAVITY. AN EXPLORATORY SURGERY WAS PERFORMED AND THE MISSING COIL WAS LOCATED RESTING ON DESCENDING COLON. THE CONSUMER HAD A 3 DAY RECOVERY AT HOSPITAL. SHE WAS STILL SUFFERING FROM BRAIN FOG AND HAD AUTOIMMUNE ISSUES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THAT SHE BLED SO HEAVILY (INTERPRETED AS GENITAL BLEEDING) THE DOCTOR ENDED UP DOING A DILATION AND CURETTAGE. APPROXIMATELY 5 YEARS AFTER INSERTION IT WAS FOUND THAT THE DEVICE PERFORATED THE UTERUS AND WAS LOOSE WITH ABDOMINAL CAVITY, RESTING ON HER DESCENDING COLON (INTERPRETED AS UTERINE PERFORATION). SHE UNDERWENT A TOTAL HYSTERECTOMY AND EXPLORATORY SURGERY TO LOCATE THE COIL. SHE ALSO REPORTED AUTOIMMUNE ISSUES. UTERINE PERFORATION WAS CONSIDERED SERIOUS DUE HOSPITALIZATION, WHILE THE REMAINING EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENT BLED SO HEAVILY, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE, PERFORATION WAS DIAGNOSED APPROXIMATELY 5 YEARS AFTER INSERTION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING EVENT AUTOIMMUNE ISSUES, GIVEN THE PATHOPHYSIOLOGY OF THIS EVENT AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, IT WAS ASSESSED AS UNRELATED TO ESSURE. NON-

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SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION AND HOSPITALIZATION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00760	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5032832) IN UNITED STATES ON 13-JAN-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME BLOATING, ABDOMINAL PAIN THAT MAKES IT DIFFICULT TO WALK, SIDE WALL PAIN THAT MAKES IT DIFFICULT TO WALK, EXCESS SCAR TISSUE ATTACHING TO OTHER ORGANS, EXCESSIVE BLEEDING, NAUSEA, BOWEL ISSUES, PELVIC INFLAMMATION, NICKEL TOXICITY, TEETH ARE LOOSENING, EXTREME FATIGUE, DEPRESSION, MEMORY ISSUES, HIP AND THIGH NUMBNESS AND FLU-LIKE SYMPTOMS THAT DO NOT GO AWAY FOR A YEAR. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION RECEIVED. IN 2009 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER EXPERIENCED FLU-LIKE SYMPTOMS THAT DO NOT GO AWAY FOR A YEAR, EXTREME BLOATING, ABDOMINAL PAIN AND SIDE WALL PAIN THAT MAKES IT DIFFICULT TO WALK, EXCESS SCAR TISSUE ATTACHING TO OTHER ORGANS, EXCESSIVE BLEEDING, NAUSEA, BOWEL ISSUES, PELVIC INFLAMMATION, VITAMIN DEFICIENCIES DUE TO NICKEL TOXICITY, TEETH ARE LOOSENING, EXTREME FATIGUE, DEPRESSION, MEMORY ISSUES, HIP AND THIGH NUMBNESS, AND NICKEL TOXICITY. SHE STATES SHE WAS CLOSE TO LOSING ALL HER FEMALE ORGANS DUE TO ESSURE IMPLANT. ESSURE WAS ONGOING. NO OUTCOME WAS PROVIDED. NO CAUSALITY ASSESSMENT WAS GIVEN. CORRECTION ON 24-JAN-2014 FOLLOWING COMPANY INTERNAL CODING REVIEW. THE EVENT EXCESS SCAR TISSUE ATTACHING TO OTHER ORGANS CODED TO MEDDRA LLT SCAR WHICH LEADS TO PT SCAR, WAS RECODED TO MEDDRA LLT ADHESION WHICH LEADS TO PT ADHESION. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 23-JAN-2014: THE CONSUMER'S BIRTH DATE WAS INFORMED. SHE WAS (B)(6) AT THE TIME OF EVENTS ONSET AND SHE WAS (B)(6). HER RELEVANT

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GYNECOLOGICAL HISTORY INCLUDED MODERATE DYSPLASIA IN HER TWENTIES AND HAD THE TIP OF HER CERVIX BURNED OUT. SHE ALSO HAD LYSIS OF ADHESIONS IN 2000 DUE TO ADHESIONS TO HER INTESTINE AND LEFT OVARY. SHE DID NOT HAVE ANY OTHER RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITION. THE PATIENT HAD ESSURE INSERTED IN (B)(6) 2009. SHE HAD DELIVERED THREE TO FIVE MONTHS BEFORE THE INSERTION. AFTER THE INSERTION PROCEDURE, SHE HAS PERFORMED SEXUAL ABSTINENCE AS BACK-UP CONTRACEPTIVE METHOD. THE HYSTEROSALPINGOGRAPHY WAS PERFORMED 90 DAYS AFTER THE INSERTION AND THE TUBES WERE COMPLETELY BLOCKED. IN ADDITION TO PREVIOUSLY REPORTED EVENTS, SHE HAS HAD RESPIRATORY ISSUES AND SHE HAD A BACTERIAL LUNG INFECTION THAT PUT HER IN THE HOSPITAL. SHE HAS ALSO DEVELOPED FIBROMYALGIA A FEW MONTHS AFTER THE IMPLANTATION. FIVE MONTHS BEFORE THIS REPORTING, SHE WAS DIAGNOSED WITH OSTEOPOROSIS. SHE HAS NOT SEEN HER DOCTOR CONCERNING THESE SYMPTOMS, BUT SHE WAS TAKING TRAMADOL AS NEEDED. ON (B)(6) 2013, AN ULTRASOUND TEST SHOWED EVIDENCE OF BILATERAL TUBAL LIGATION. ADDITIONALLY, SHE INFORMED THAT MOST OF SYMPTOMS SHE HAS REPORTED STARTED SOON AFTER THE ESSURE WAS INSERTED AND THAT SHE WAS NOT HOSPITALIZED (DISCREPANCY NOTED AS SHE REPORTED BEING IN HOSPITAL DUE TO BACTERIAL LUNG INFECTION). THE REMOVAL OF THE ESSURE DEVICES WAS NOT PLANNED. THE CONSUMER BELIEVED MANY OF THE REPORTED ISSUES WERE CAUSED BY THE ESSURE AND THE SCAR TISSUE SHE HAS HAD IN THE PAST WAS ALSO CONTRIBUTING TO THE ISSUES. HER PHYSICIAN'S CONTACT INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 20-APR-2014 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). MEDICAL ASSESSMENT: THE REPORTED MEDICAL EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THE EVENTS WERE REPORTED WITH AN OCCURRENCE OVER A PERIOD OF ABOUT 4,5 YEARS AND ARE OF BROAD NATURE. NO BATCH NUMBER WAS REPORTED. NO COMPLAINT SAMPLE WAS PROVIDED FOR TECHNICAL INVESTIGATION. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER OR SAMPLE. AT TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. FOLLOW UP 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT 5 YEARS AFTER IMPLANT, SHE BEGAN TO EXPERIENCE SEVERE, RANDOM STABBING PAINS SPECIFICALLY AT HER IMPLANT SITE. SHE BEGAN TO SWELL AT RANDOM, OFF AND ON, DAILY TO LOOK 6 MONTHS PREGNANT. SHE ONLY WEIGHED (B)(6). SHE BEGAN TO BLEED FOR 7-10 DAYS AT RANDOM, 2-3 TIMES A MONTH. HER GUESS WAS EARLY MENOPAUSE, SO SHE HAD TESTS DONE. SHE QUICKLY BECAME MORE ILL. THE PAIN OF THE IMPLANTS WAS NOW 24/7. SHE STARTED HAVING HEART PALPITATIONS, HBP (HIGH BLOOD PRESSURE) EVEN TRANSFERRED FROM URGENT CARE TO THE HOSPITAL FOR FEAR OF STROKE OR HEART ATTACK. SHE COULD NOT BEND, PUSH, KNEEL, VACUUM, BATHE HER CHILD OR BARELY WALK FROM STABBING PAIN. HER FIBRO WAS PERMANENTLY FLARED, LOWER BACK ISSUES GREW IN SEVERITY, HER TEETH LOOSENED WITHOUT AN OUNCE OF DECAY, INCREASED ISSUES WITH NERVES, MUSCLES AND TISSUE OCCURRED ALL AT THE SAME TIME. SHE REQUESTED TO BE REFERRED TO A GYNECOLOGIST WHO WOULD REMOVE THE IMPLANTS THROUGH A HYSTERECTOMY. SEVEN MONTHS AFTER SEEKING HELP, A NEW ULTRASOUND SHOWED HER UTERUS (WHERE THE ESSURE COILS HAPPEN TO TOUCH) DEVELOPED A DISEASE CALLED ADENOMYOSIS. A HYSTERECTOMY WITH LYSIS OF ADHESIONS WAS DONE. CORRECTION REGARDING FOLLOW-UP RECEIVED ON 13-AUG-2015: THE CONSUMER STATED THAT GAVE BIRTH AT (B)(6) TO A (B)(6) BABY. IT WAS SUGGEST A BIRTH CONTROL, AS, IF SHE HAD MORE CHILDREN THEY PROBABLY WOULD NOT SURVIVE. DUE TO THE REPORTED EVENTS SHE UNDERWENT BLOOD WORK

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AND ULTRASOUND WHICH SHOWED NOTHING TO CREATE THESE SYMPTOMS. SHE WAS GIVEN BIRTH CONTROL AT (B)(6), BUT IT DID NOTHING. ONCE HER ESSURE IMPLANTS WERE REMOVED, THE STABBING PAIN WAS IMMEDIATELY GONE, SHE LOST THE RANDOMLY PREGNANT LOOK, HER HEART FEELS NORMAL, AND SHE DOES NOT USE HBP (HIGH BLOOD PRESSURE) MEDICINE. SHE WAS ABLE TO GARDEN, VACUUM, AND HER IMMUNITY SYSTEM WAS STILL IMPROVING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE INSERTED AND HAD EXCESSIVE BLEEDING, PELVIC INFLAMMATION, NICKEL TOXICITY, BACTERIAL LUNG INFECTION, HBP (HIGH BLOOD PRESSURE), ADENOMYOSIS, STABBING PAINS (PELVIC PAIN) AND SCAR TISSUE ATTACHING TO OTHER ORGANS. ESSURE IMPLANTS WERE REMOVED. AFTER THAT, STABBING PAIN WAS IMMEDIATELY GONE AND DID NOT NEED HIGH BLOOD PRESSURE MEDICINE ANYMORE. EXCESSIVE BLEEDING, PELVIC PAIN AND PELVIC INFLAMMATION ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENTS ARE UNLISTED. REGARDING GENITAL BLEEDING, IN THIS CASE THE CONSUMER WAS LATER DIAGNOSED WITH ADENOMYOSIS WHICH COULD HAVE CONTRIBUTED FOR THE BLEEDING. HOWEVER, GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. REGARDING PELVIC PAIN, CONSUMER ALSO HAD ADHESIONS WHICH COULD HAVE CONTRIBUTED FOR THE OCCURRENCE OF THE PAIN, HOWEVER GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. WHILE ESSURE IS STERILE IT MAY, DUE TO CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTION IN THE FIRST 4 WEEKS AFTER INSERTION. IN THIS CASE, NO INFORMATION SUGGESTING A CLOSE TEMPORAL RELATIONSHIP WITH THE INSERTION PROCEDURE WAS MENTIONED THEREFORE PELVIC INFLAMMATION WAS CONSIDERED UNRELATED TO ESSURE. CONSUMER UNDERWENT LYSIS OF ADHESIONS 9 YEARS PRIOR TO ESSURE INSERTION, THEREFORE EVENT SCAR TISSUE ATTACHING TO OTHER ORGANS WAS CONSIDERED UNRELATED TO ESSURE. IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED FROM THE DEVICE WOULD BE SUFFICIENT TO CAUSE METAL POISONING. THEREFORE, EVENT NICKEL TOXICITY WAS ASSESSED AS UNRELATED TO ESSURE. GIVEN THE PATHOPHYSIOLOGY OF BACTERIAL LUNG INFECTION, HBP AND ADENOMYOSIS, AND ESSURE'S LOCAL EFFECT IN FALLOPIAN TUBES, THESE EVENTS WERE ASSESSED AS UNRELATED TO ESSURE. THIS CASE WAS UPGRADED TO INCIDENT UPON RECEIPT OF INFORMATION STATING THE CONSUMER UNDERWENT HYSTERECTOMY. TECHNICAL ANALYSIS CONCLUDED BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00761	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 5/7/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/7/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5032752) IN UNITED STATES ON 13-JAN-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING PAIN, DEVELOPED NICKEL ALLERGY, HEADACHES, UNEXPLAINED WEIGHT GAIN, DIZZINESS, AND FATIGUE. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. OVER FIVE YEARS AGO CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER HAS BEEN IN EXCRUCIATING PAIN, DEVELOPED NICKEL ALLERGY, AND HAS BEEN SUFFERING FROM HEADACHES, UNEXPLAINED WEIGHT GAIN, DIZZINESS AND FATIGUE. SHE REPORTED THAT THE PAIN HAS GOTTEN SO BAD THAT NOW SHE IS BEING TOLD SHE NEEDS A HYSTERECTOMY BECAUSE DOCTORS DO NOT KNOW ANY OTHER WAY TO REMOVE THE IMPLANT. SHE CAN'T AFFORD FOR THE REMOVAL. REPORTER CAUSALITY WAS NOT REPORTED. FOLLOW UP INFORMATION RECEIVED ON 04-FEB-2014: SHE HAS HAD SEVERE PELVIC PAIN FOR SIX YEARS SINCE THE ESSURE WAS IMPLANTED AND RECENTLY FOUND OUT THAT SHE HAS A SEVERE NICKEL ALLERGY. SHE IS NOW FACING A HYSTERECTOMY AS A RESULT OF ESSURE, PAIN AND HER OVARIES ARE ENLARGED. SHE ALSO HAS SIGNIFICANT WEIGHT GAIN AND FATIGUE AND HEADACHES. FOLLOW UP 10-MAR-2014: NO RESPONSE FROM THE CONSUMER AFTER FOLLOW UP ATTEMPTS. CASE CLOSED. FOLLOW UP 24-APR-2014: NO PTC ASSIGNED FOLLOW-UP INFORMATION RECEIVED ON 13-AUG-2015 - FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)): THIS CASE WAS UPGRADED TO INCIDENT. THE CONSUMER WAS (B)(6) AND HAD 5 CHILDREN. ESSURE WAS INSERTED FOR BIRTH CONTROL. THE CONSUMER BEGAN TO HAVE PAIN AND HORRIBLE

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SYMPTOMS AS SOON AS IT WAS IMPLANTED. SHE BLED FOR MUCH LONGER THAN SHE WAS SUPPOSED TO AND THE CRAMPING WAS UNBEARABLE - IT HURT TO WALK. SHE WEIGHED (B)(6) WHEN ESSURE WAS INSERTED AND WAS WEIGHING (B)(6) AT THE TIME OF THE REPORT. SHE SUFFERED FROM SEVERE ANEMIA, HEAVY ABNORMAL BLOOD CLOT FILLED PERIODS, MIGRAINES, MUSCLE PAIN, EMPTY SELLA, ABDOMINAL PAIN AND EXCESSIVE BLOATING, TROUBLE SLEEPING, UNEXPLAINED NIGHT SWEATS, BREAST ISSUES, ADENOMYOSIS, ENDOMETRIOSIS, BOWEL ISSUES, MEMORY LOSS AND A CONSTANT RASH ON HER FINGER THAT BLED. ULTRASOUNDS, SCANS AND RADIOLOGICAL TESTS WERE PERFORMED (RESULTS NOT PROVIDED). THE CONSUMER STATED SHE HAD MULTIPLE SURGERIES AND STILL DID NOT HAVE MUCH RELIEVE. SHE WAS STILL SUFFERING DAILY AFTER TWO FAILED REMOVAL ATTEMPTS FROM ABDOMINAL BLOATING, ABNORMAL PERIODS, FATIGUE, DIZZINESS, BOWEL ISSUES, HEADACHES AND MEMORY LOSS. SHE ATTRIBUTED ALL EVENTS TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING PELVIC PAIN. ACCORDING TO FOLLOW UP INFORMATION IDENTIFIED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, SHE BLED FOR MUCH LONGER THAN SHE WAS SUPPOSED TO. THESE EVENTS, SEEN AS PEVIC PAIN AND GENITAL BLEEDING, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER STARTED TO EXPERIENCE PAIN AND SEVERAL OTHER NON-SERIOUS EVENTS AS SOON THE DEVICES WERE IMPLANTED. SHE BLED FOR MUCH LONGER THAN SHE WAS SUPPOSED TO AND THE CRAMPING WAS UNBEARABLE. ALTHOUGH ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THE EVENTS, A CONTRIBUTORY ROLE FROM ESSURE FOR THE REPORTED EVENTS CANNOT BE TOTALLY EXCLUDED. THUS, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON MONITORING FDA WEBSITE, IT WAS DETECTED THE CONSUMER HAD MULTIPLE SURGERIES AND TWO FAILED REMOVAL ATTEMPTS. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE WAS UPGRADED TO INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 09-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00762	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 3/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50700145

Single Use: Y
Implant Date (E6): 3/27/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 25-FEB-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5033724, RECEIVED AT FDA ON 02-JAN-2014). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 50700145, IMPLANTED ON (B)(6) 2013, AND SINCE THEN EXPERIENCED SEVERE ALLERGIES THAT DID NOT RESPOND TO ANY OVER THE COUNTER MEDICINE, SEVERE HEADACHES THAT DID NOT RESPOND TO REGULAR OVER THE COUNTER MEDICINE, PAIN THE LOWER ABDOMEN, SHARP PAIN WHEN I STRETCH IN CERTAIN DIRECTIONS, SEVERE LOWER BACK PAIN, FATIGUE, CONSTIPATION, AND WEIGHT GAIN EVEN WITH DIET AND EXERCISE. ON FDA FORM IT WAS REPORTED, REPORT TYPE WAS 'INJURY', OUTCOME OF EVENTS WAS 'REQUIRED INTERVENTION' CORRECTION: THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 24-FEB-2014 NOT ON 25-FEB-2014. FOLLOW UP RECEIVED ON 12-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA CASE NUMBER NOT RECEIVED, AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED FOR PERMANENT BIRTH CONTROL. SHE STATED THAT SHE WAS IN PAIN FROM THE VERY DAY IT WAS INSERTED AND SHE SAID THE PAIN SHOULD GO AWAY AFTER A COUPLE OF DAYS BUT IT DIDN'T. SHE KEPT CALLING TO LET HER KNOW OF HER PAIN BUT THE NURSE WHO TOOK HER CALLS SAID IT COULD JUST BE A CYST, OR APPENDIX. HER FEET BEGAN TO SWELL. SHE LOOKED PUFFY IN THE FACE AND, HER BODY WAS LOOKING INFLAMED WITHIN 8 WEEKS OF THE PROCEDURE. THE PAIN DID NOT GO AWAY. WHEN SHE RETURNED FOR HER 3 MONTHS

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ULTRASOUND THOUGHT THEY WOULD DO THE DYE TEST BUT THEY SAID THEY DID NOT HAVE TO. THE VAGINAL ULTRASOUND WAS PAINFUL, SHE WAS IN SO MUCH PAIN THAT THEY HAD TO STOP. SHE TOLD THE TECHNICIAN THIS WAS NOT NORMAL FOR HER TO HAVE PAIN BUT SHE SAID SHE WOULD TELL THE DOCTOR AND THAT WAS IT. FOR THE MONTHS TO COME. SHE WAS BLEEDING MORE, HAD MORE PELVIC PAIN, EXCESSIVE BLOATING, INFLAMMATION, SWOLLEN FEET AND HANDS. SHE BEGAN TO NOTICE MORE BLADDER INFECTIONS, INCONTINENCE AND VAGINAL ODOR. SHE DEVELOPED METALLIC TASTE IN HER MOUTH, HAD UNEXPLAINED DIARRHEA, SLEEPLESSNESS, UNEXPLAINED FEVERS, SINUS INFECTIONS, WEIGHT GAIN. THE QUALITY OF LIFE WAS LESS THAN SHE EVER EXPECTED OR IMAGINED AND NO DOCTOR BELIEVED THAT HER SYMPTOMS WERE RELATED TO ESSURE. SHE HAD ESSURE REMOVED SURGICALLY ALONG WITH HER FALLOPIAN TUBES. SHE REPORTED THAT SHE REGRET HAVING AGREED TO THE ESSURE PROCEDURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PAIN SINCE THE FIRST DAY OF INSERTION AND SHE STARTED BLEEDING MORE IN THE FOLLOWING MONTHS. SHE HAD ESSURE REMOVED SURGICALLY ALONG WITH HER FALLOPIAN TUBES. THESE EVENTS, INTERPRETED AS UNSPECIFIED PAIN AND GENITAL BLEEDING, ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR, THE CONSUMER EXPERIENCED CHRONIC PAIN SINCE DAY OF INSERTION AND IN THE FOLLOWING MONTHS SHE HAD BLEEDINGS WHILE ON ESSURE. CONSIDERING THE SUGGESTIVE TEMPORAL RELATIONSHIP OF BOTH EVENTS AND LACK OF ALTERNATIVE EXPLANATION, PAIN AND GENITAL BLEEDING ARE ASSESSED AS RELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00763	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 2/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 685787

Single Use: Y
Implant Date (E6): 8/6/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5033731) IN UNITED STATES ON 04-MAR-2014. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED OVARIAN CYSTS, PAINFUL AND IRREGULAR MENSTRUAL CYCLES AND HEADACHES. NO INFORMATION WAS GIVEN ON THE CONSUMER'S PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. SHE IS ALLERGIC TO METALS. ON (B)(6) 2010 SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED; THE LOT NUMBERS 685787 WAS PROVIDED. SINCE THE INSERTION SHE STARTED TO EXPERIENCE OVARIAN CYSTS, PAINFUL AND IRREGULAR MENSTRUAL CYCLES AND HEADACHES (CONSIDERED AS SERIOUS BY THE REPORTER). SHE HAD ULTRASOUNDS AND MANY OTHER VISITS WITH HER PHYSICIAN ABOUT THE POSSIBILITY OF ESSURE BEING THE ISSUE WITH NO LUCK; SHE INTENDS TO SEEK A SECOND OPINION. SHE DID NOT HAVE ANY OF THOSE SYMPTOMS BEFORE ESSURE WAS INSERTED. THE REPORTER'S CAUSALITY WAS NOT PROVIDED. FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 12-AUG-2015 INFORMATION WAS POSTED BY CONSUMER ON FDA SITE ((B)(4)). HER MEDICAL HISTORY INCLUDED 2 CHILDREN AND ALLERGY TO METALS. ESSURE WAS INSERTED IN (B)(6) 2010 AND IN (B)(6) 2011 HER SYMPTOMS BEGAN. BECAUSE OF THE PAIN, SHE WAS HAVING TO UNDERGO A HYSTERECTOMY AT THE AGE OF (B)(6). ACCORDING TO HER, (B)(6) 2015 WILL ADD ANOTHER PATIENT TO THE LIST OF WOMEN WHO HAVE HAD TO UNDERGO HYSTERECTOMY BECAUSE OF THE DAMAGE ESSURE HAS CAUSED. CASE UPGRADED TO INCIDENT. FOLLOW-UP RECEIVED ON 28-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: 685787; PRODUCTION DATE:

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OCT-2009; EXPIRATION DATE: OCT-2012. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN AND PAINFUL AND IRREGULAR MENSTRUAL CYCLES. ACCORDING TO HER, SHE WILL UNDERGO A HYSTERECTOMY DUE TO ESSURE. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABNORMAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE EVENTS STARTED 6 MONTHS AFTER ESSURE INSERTION. NO ALTERNATIVE EXPLANATION WAS PROVIDED. HOWEVER, GIVEN EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00764	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5034015) IN UNITED STATES ON 07-APR-2014 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE ABDOMINAL PAIN WHICH IS LOCATED IN THE LEFT QUADRANT AND WILL QUITE OFTEN RADIATE TO MY BACK, VERY IRREGULAR MENSTRUAL CYCLES THAT DID NOT BEGIN UNTIL AFTER HAVING THE PROCEDURE AND RECENTLY BEGAN BREAKING OUT INTO HIVES WITH NO REASON. FOLLOW-UP RECEIVED ON 14-AUG-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)). CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN (B)(6) OF 2006. SHE STARTED TO EXPERIENCE BACK PAIN BACK IN 2007 BUT DID NOT REALIZE THAT IT WAS DUE TO ESSURE. SHE HAS EXPERIENCED BLOATING, ABDOMINAL PAIN, BACK PAIN, HORRIBLE AGONIZING IRREGULAR PERIODS, FATIGUE, WEIGHT GAIN, AND BREAKING OUT IN HIVES. SHE TOOK NUMEROUS PREGNANCY TEST WHICH ALL CAME BACK NEGATIVE, HAD ALLERGY TESTS FOR NICKEL WHICH ALL CAME BACK NEGATIVE. IN ADDITION, CONSUMER INFORMED THAT SHE HAD THE HYSTEROSALPINGOGRAM EXAMINATION DONE 3 TIMES, BECAUSE THE FIRST 2 TIMES DID NOT SHOW THAT THE COILS WERE BLOCKED. SHE HAD TO BE PUT ON COURSES OF ANTIBIOTICS NUMEROUS TIMES DUE TO REPEATED INFECTIONS AND POSSIBLE MISCARRIAGES. CONSUMER ALSO REPORTED THAT SHE HAD TO HAVE THE COILS REMOVED VIA A HYSTERECTOMY AND STATES THAT SHE HAD TO HAVE HER UTERUS, CERVIX, AND WAS SUPPOSED TO BE BOTH OF HER FALLOPIAN TUBES DUE TO A PROLAPSED UTERUS AND RECTUM. ACCORDING TO HER, WHEN THE PATHOLOGY REPORT WAS DONE, IT SHOWED THAT SHE HAD ADENOMYOSIS (A CONDITION WHICH LEAVES BLOOD RETAINED FROM A PREVIOUS MENSTRUAL CYCLE AND

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CAUSES EXTREME CRAMPING, ABDOMINAL PAIN AND HUGE BLOOD CLOTS). HER DOCTOR DID NOT DO AS HE SAID HE WOULD DO AND SHE HAD TO HAVE A SECOND SURGERY DUE TO HER SYMPTOMS COMING BACK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD SEVERE ABDOMINAL PAIN WHICH WAS LOCATED IN THE LEFT QUADRANT AND POSSIBLE MISCARRIAGES AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY TO REMOVE THE COILS AND DUE TO PROLAPSED UTERUS AND RECTUM. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY ABDOMINAL PAIN IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, CONSUMER STATED SHE HAD HSG 3 TIMES AND IN 2 OF THEM THE TUBES DID NOT APPEAR BLOCKED. SHE REPORTED POSSIBLE MISCARRIAGES, HOWEVER LIMITED INFORMATION WAS PROVIDED. CONSIDERING MISCARRIAGE IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY, OCCURRING IN UP TO 20% OF CLINICALLY RECOGNIZED PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION (DUE TO MATERNAL CONDITIONS AND FETAL CHROMOSOMAL ABNORMALITIES); CAUSALITY WITH ESSURE IS CONSIDERED UNLIKELY. ADDITIONALLY, CONSUMER STATED SHE HAD ABDOMINAL PAIN WITH ESSURE. SHE UNDERWENT A HYSTERECTOMY AND PATHOLOGY REPORT SHOWED ADENOMYOSIS; WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THIS SYMPTOM. NEVERTHELESS, AS ABDOMINAL PAIN MAY OCCUR WITH ESSURE, A CONTRIBUTORY ROLE OF THE DEVICE CANNOT BE EXCLUDED. THE OTHER EVENTS (PROLAPSED RECTUM AND UTERUS) WERE CONSIDERED AS UNRELATED TO ESSURE DUE TO THEIR NATURE. THIS CASE WAS REGARDED AS AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED ON 10-SEP-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00773	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/18/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5038983) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. CONSUMER REPORTED SIDE EFFECTS FROM ESSURE THREE MONTHS AFTER IMPLANT. SHE STATES THAT SHE HAS NICKEL ALLERGY AND HER PHYSICIAN FAILED TO DISCLOSE INFORMATION REGARDING NICKEL IN DEVICE. CONSUMER HAS SEVERE RIGHT SIDED PAIN IN ABDOMINAL REGION AND STATES THAT THIS PAIN KEEPS HER IN BED FOR DAYS. CONSUMER ALSO REPORTS NAUSEA, PAINFUL SEXUAL INTERCOURSE, HEADACHES, JOINT ACHES, BLOATING, INTERMENSTRUAL BLEEDING, HEAVIER MENSES WITH CLOTS (AS BIG AS A COIN) AND MUSCLE SPASMS THAT LAST FOR DAYS. THE SPASMS ARE FELT ALL OVER CONSUMER'S BODY, IT BEGAN ON 2013 AND IT KEEPS GETTING WORSE AND WORSE. LASTLY, CONSUMER HAD ULTRASOUND DONE ON 2014 WHICH SHOWED HER FALLOPIAN TUBES ARE SAGGING DOWNWARDS. SHE WANTS DEVICE EXPLANTED AND HAS AN UPCOMING APPOINTMENT ON 2014. PTC INVESTIGATION RESULT RECEIVED ON 08-APR-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED MEDICAL EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE

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FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP FROM 10-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW-UP RECEIVED ON 12-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0324). A (B)(6) FEMALE CONSUMER REPORTED THAT SHE IS FORCED NOW TO BE ON REPLACEMENT HORMONES. ACCORDING TO HER, ESSURE WAS POISONING HER BODY MAKING HER SICK. SHE WAS IN HORRIBLE PAIN AND STATES THAT HER BODY WAS INFLAMED. HER MONTHLIES WERE VERY HEAVY AND SHE BLED THRU A PAD AN HOUR. THE PAIN WAS SO BAD SHE DIDN'T GET OUT OF BED FOR DAYS ON END. CONSUMER ALSO INFORMED THAT BEFORE ESSURE SHE HAD A WONDERFUL SEX LIFE, AND AFTER ESSURE THE PAIN WAS UNBEARABLE. SHE SUFFERED DEBILITATING MIGRAINES. ADDITIONALLY, CONSUMER STATED THAT SHE WENT THROUGH HORRENDOUS TESTING AND REPORTED THAT NOW, WITHOUT HER UTERUS AND HER OVARIES, SHE IS IN FULL BLOWN MENOPAUSE. FOLLOW UP INFORMATION RECEIVED ON 29-AUG-2015: THE PTC ASSESSMENT WAS UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE RIGHT SIDED PAIN IN ABDOMINAL REGION THAT KEEPS HER IN BED FOR DAYS/ HORRIBLE PAIN (INTERPRETED AS ABDOMINAL PAIN). SHE ALSO STATED THAT ESSURE WAS POISONING HER BODY AND THAT SHE WAS WITHOUT HER UTERUS AND OVARIES (INTERPRETED AS HYSTERECTOMY AND OOPHORECTOMY). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. ABDOMINAL PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. ABDOMINAL PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE, GIVEN THE NATURE OF THIS EVENT AND POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE EVENT ESSURE WAS POISONING HER BODY, THE INSERT INCLUDES NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. THE ENTIRE ALLOY SURFACE IS COVERED WITH A PROTECTIVE LAYER OF TITANIUM OXIDE WHICH SERVES TO MINIMIZE NICKEL ION RELEASE. ALTHOUGH IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM THIS DEVICE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE POISONING. THEREFORE, THIS EVENT WAS ASSESSED AS UNRELATED TO ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. UPON RECEIPT OF INFORMATION STATING THAT SHE WAS WITHOUT HER UTERUS, THIS CASE WAS UPGRADED TO INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT, BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00774	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/12/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5040270) IN UNITED STATES ON 18-MAY-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2012. ON AN UNSPECIFIED DATE, THE CONSUMER REPORTED THAT SHE EXPERIENCED MAJOR HEALTH ISSUES AFTER ESSURE DESCRIBED AS EXTREMELY HEAVY BLEEDING WITH LARGE CLOTS, AUTOIMMUNE DISEASE (FIBROMYALGIA), SEVERE HEADACHES, ITCHING, BLOATING, HORRIBLE CRAMPS, AND WEIGHT GAIN. DISABILITY OR PERMANENT DAMAGE WAS MENTIONED AS EVENT OUTCOME BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON 27-MAY-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION.

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THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 06-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. FOLLOW UP INFORMATION RECEIVED ON 14-AUG-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)): THE CONSUMER ALSO EXPERIENCED DEPRESSION; SHE STATED SHE WAS NOT ABLE TO WORK BECAUSE OF BEING SICK. SHE WAS 5 DAYS POST OP LAVH (INTERPRETED AS LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY). CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO EXPERIENCED EXTREMELY HEAVY BLEEDING WITH LARGE CLOTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR DURING AND FOLLOWING ESSURE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, CONSUMER STATED SHE DEVELOPED AN AUTOIMMUNE DISEASE (FIBROMYALGIA) (SERIOUS, UNLISTED EVENT). CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AND GIVEN ESSURE LOCAL ACTION AT FALLOPIAN TUBES, CAUSALITY IS CONSIDERED VERY UNLIKELY. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT. HOWEVER, UPON RECEIPT OF FOLLOW-UP INFORMATION, IT WAS UPGRADED TO INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). OTHER NON-SERIOUS EVENTS WERE ALSO REPORTED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION COULD NOT BE OBTAINED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 01-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00775	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW2040375) IN UNITED STATES ON 22-MAY-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR BIRTH CONTROL. CONSUMER STATED THAT SINCE INSERTION SHE HAD EXPERIENCED SEVERE PELVIC PAIN, SEVERE SKIN ALLERGY ISSUES, HEAVY IRREGULAR MENSES, HOT FLASHES, HEADACHES, FIBROMYALGIA RESULTING IN DEPRESSION BEING EXACERBATED. SHE ATTRIBUTED ALL OF THE EVENTS TO BE CAUSED BY ESSURE. SHE IS LIKELY TO HAVE A HYSTERECTOMY IN HER FUTURE TO REMOVE THE DEVICES. AN INJURY (REQUIRED INTERVENTION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT RECEIVED ON 29-MAY-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO

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SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 27-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. FOLLOW-UP INFORMATION RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 ((B)(4)). CASE IS NOW UPGRADED TO INCIDENT. CONSUMER UNDERWENT MAJOR SURGERY TO REMOVE ESSURE FROM HER BODY. HER DEVICES WERE PLACED CORRECTLY BY IMPLANTING PHYSICIAN, YET SHE EXPERIENCED ADVERSE EFFECTS SO SEVERE. SHE EXPERIENCED SYMPTOMS OF HEAVY METAL TOXICITY, SEVERE DEBILITATING PAIN, SHE LOST PERSONAL RELATIONSHIPS INCLUDING HER MARRIAGE. HER MIND AND BODY WILL NEVER FULLY RECOVER. EVEN AFTER REMOVAL, SHE WAS EXPERIENCING DEPRESSION. FOLLOW-UP RECEIVED ON 28-AUG-2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXPERIENCED SEVERE PELVIC PAIN SINCE INSERTION. SHE ALSO REPORTED SYMPTOMS OF HEAVY METAL TOXICITY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENT SEVERE PELVIC PAIN, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE EVENT HEAVY METAL TOXICITY, ALTHOUGH IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM THIS DEVICE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE A METAL POISONING. THEREFORE, THIS EVENT WAS ASSESSED AS UNRELATED TO ESSURE. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS UPGRADED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION STATING THE CONSUMER UNDERWENT SURGERY TO REMOVE ESSURE (INTERVENTION REQUIRED). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00776	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/8/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5040841) IN UNITED STATES ON 01-JUN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION ON (B)(6) 2013. SHE HAD BEEN IN PAIN SINCE SHE HAD THE DEVICE IMPLANTED (2 YEARS BEFORE THIS REPORT). CONSUMER STATED THAT SHE BLED EVERY DAY AND CURRENTLY HAD ENDOMETRIOSIS BECAUSE OF THE ESSURE. SHE ALSO COMPLAINED OF HAIR LOSS, SCIATICA PAIN, BODY RASH, NUMBNESS IN LEGS AND TOES, IRREGULAR PAINFUL BLEEDING, WEIGHT GAIN, BLOATING AND MIGRAINES. SHE COULD NOT TAKE THE PAINS ANYMORE AND WAS TIRED OF TAKING IBUPROFEN 800 MG 5 TIMES A DAY TO RELIEVE HER SYMPTOMS. CONSUMER HAD NEVER HAD ANY HEALTHCARE PROBLEMS PREVIOUSLY. THE REPORTER MENTIONED A REQUIRED INTERVENTION BUT DID NOT SPECIFY/ASSIGN TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON 09-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION, NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE

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DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 06-JUL-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. FOLLOW UP INFORMATION RECEIVED ON 06-JUL-2015 FROM CONSUMER AND CONSUMER'S HUSBAND VIA REGULATORY AUTHORITY (CASE# MW5042369 AND MW5042374 RESPECTIVELY): HE REPORTED THAT HIS WIFE HAS BEEN HAVING A LOT OF MEDICAL ISSUES SINCE SHE HAD THE ESSURE. EVERY TIME HE HAD INTERCOURSE WITH HER WHICH IS NOT OFTEN DUE TO HER PAINS, HE HAS CUTS ON HIS PENIS, SWELLING, REDNESS, AND PAIN THAT LASTS FOR A WEEK. THIS ONLY HAPPENS EVERY TIME THEY HAVE INTERCOURSE TOGETHER (HUSBAND'S CASE CREATED UNDER REFERENCE (B)(4)). THE CONSUMER STATED THAT CURRENTLY SHE HAS ESSURE. SHE RECENTLY DID A SCAN DUE TO HER NONSTOP SEVERE PELVIC PAIN THAT ROTATES AROUND HER BACK AND DOWN HER LEGS CONSTANTLY, AND IT SHOWED THAT A COIL WAS MISSING. SHE WAS DOING MORE SCANS TO SEE WHERE IT IS. SHE ALSO REPORTED OTHER SIDE EFFECTS FROM ESSURE: HAIR LOSS, HEAVY IRREGULAR BLEEDING, BLEEDING AFTER INTERCOURSE, PAIN WITH INTERCOURSE, RASHES ALL OVER HER BODY, PERFORATION INTO HER FALLOPIAN TUBE, WEIGHT GAIN, TOOTH SENSITIVITY, MIGRAINES, BLURRED VISION, NAUSEA, BRAIN FOG, NUMBNESS IN HER LEGS AND FEET. SHE STATED THAT IS IN PAIN ALL THE TIME AND EXPERIENCED EXTREME FATIGUE AND THAT THESE SYMPTOMS ARE DEBILITATING. FOLLOW-UP RECEIVED ON 14-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015, ((B)(4)). PATIENT, WHO IS ALSO A HEALTH PROFESSIONAL, AND HER HUSBAND REPORTED THAT SHE WAS PLACED WITH ESSURE ON (B)(6) 2013 (ACCORDING TO HUSBAND SHE HAS HAD ESSURE FOR 3 YEARS). FROM THE MOMENT, IT WAS PLACED SHE KNEW SOMETHING WAS WRONG. SHE HAD IN DEBILITATING PAIN/PAIN ALL THE TIME, STABBING PELVIC PAIN THAT WRAPPED AROUND HER BACK AND DOWN HER LEGS, NUMBNESS IN HER LEGS, HAIR LOSS, WEIGHT GAIN, BRAIN FOG, UNEXPLAINED RASHES, ABNORMAL HEAVY PERIODS, IRREGULAR PERIODS, PAIN WITH OVULATION, MIGRAINES AND FATIGUE ALONG WITH A LONG LIST OF MEDICAL ISSUES. HUSBAND ALSO STATES THAT A HYSTEROSALPINGOGRAM WAS DONE AND SHOWED PERFORATION ON PATIENT'S LEFT FALLOPIAN TUBE. ADDITIONALLY, IT WAS REPORTED THAT, WHEN THEY HAVE SEX, NOT ONLY IS SHE IN PAIN BUT HE GETS WEIRD RASHES ON HIS PENIS ALONG WITH SWELLING ON THE HEAD OF HIS PENIS AND MICROSCOPIC CUTS (HUSBAND CASE# (B)(4)). SHE UNDERWENT MAJOR SURGERY IN WHICH HER PATHOLOGY REPORT SHOWED THE PERFORATION TO THE TUBE AND ENDOMETRIOSIS (ACCORDING TO PATIENT, SHE HAS NEVER HAD NOR DOES SHE HAVE A FAMILY HISTORY OF THIS). PATIENT ALSO REPORTED THAT ESSURE HAS INJURED HER AND KEPT HER FROM DAILY ACTIVITIES FOR ALMOST 3 YEARS. IN ADDITION, PATIENT INFORMED THAT SINCE REMOVAL OF ESSURE HER PAINS ARE GONE, BUT SHE HAS OTHER EFFECTS IN WHICH NO PHYSICIAN CAN EXPLAIN. SHE IS CONSTANTLY DIZZY, WANTING TO PASS OUT, NAUSEOUS, AMONGST OTHER THINGS (ALL CAUSED BY ESSURE). PATIENT'S HUSBAND ADDITIONALLY REPORTED THAT THEY HAVE TWO SMALL CHILDREN. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLEED EVERYDAY/ HEAVY IRREGULAR BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND HAD PERFORATION INTO HER FALLOPIAN TUBE. SHE DID A SCAN AND IT SHOWS THAT A COIL IS MISSING (INTERPRETED AS DEVICE DISLOCATION). THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY. IN THE PRESENT CASE, SHE EXPERIENCED BLEEDING EVERY DAY. CONSIDERING THE IMPLIED POSITIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS CONSIDERED RELATED TO ESSURE. THE CONSUMER UNDERWENT A SCAN (NOT SPECIFIED IF CT SCAN OR ULTRASOUND SCAN) WHICH SHOWED ONE COIL WAS MISSING AND PERFORATION OF HER FALLOPIAN TUBE WAS FOUND IN HSG. IT IS NOT CLEAR FROM THE PROVIDED INFORMATION WHETHER THE SAME COIL THAT IS MISSING HAD ALSO PERFORATED OR IF IT

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REFERS TO THE CONTRALATERAL COIL. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE INCLUDING ESSURE INSERTION. IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THE PERFORATION AND DISLOCATION ARE UNKNOWN. GIVEN THE NATURE OF THE EVENTS FALLOPIAN TUBE PERFORATION AND DEVICE DISLOCATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ACCORDING TO FOLLOW UP INFORMATION, DETECTED DURING MONITORING OF FDA WEBSITE, SHE UNDERWENT A MAJOR SURGERY AND ESSURE WAS REMOVED. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE IS NOW REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 03-OCT-2015 FROM HUSBAND OF CONSUMER, IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00777	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/27/2015
Explant Date (E7): 5/7/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. CONSUMER REPORTED THAT, AFTER HAVING ESSURE IMPLANTED, SHE HAS HAD HEADACHES, ABDOMINAL PAIN, SKIN RASHES, LETHARGY AND HER THROAT FEELS LIKE IT IS CLOSING. SHE ALSO STATES THAT SHE HAS A NICKEL ALLERGY AND WAS MISLED ON THE AFFECTS IT WOULD HAVE ON HER. SHE RECEIVED PHENTERMINE AS CONCOMITANT MEDICAL PRODUCT. IN ADDITION, THE SERIOUSNESS CRITERION "OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)' WAS REPORTED. HOWEVER, IT WAS NOT SPECIFIED FOR WHICH EVENT. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE

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AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP (B)(6) 2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN (B)(4), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER WAS IMPLANTED WITH ESSURE AND IMMEDIATELY STARTED HAVING DEBILITATING SIDE EFFECTS WHICH INCLUDED ABDOMINAL PAIN, HEADACHES, JOINT PAIN, SKIN RASHES AND FATIGUE. SHE HAD ESSURE SURGICALLY REMOVED VIA SALPINGECTOMY ON (B)(6) 2015. SINCE THEN MOST OF HER SYMPTOMS HAVE IMPROVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING ABDOMINAL PAIN. SHE ALSO STATED THAT HER THROAT FEELS LIKE IT IS CLOSING. ESSURE WAS REMOVED VIA SALPINGECTOMY 3 MONTHS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE. ABDOMINAL PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. LIMITED INFORMATION WAS PROVIDED REGARDING EVENT HER THROAT FEELS LIKE IT IS CLOSING; IT IS UNCLEAR FROM THE AVAILABLE INFORMATION IF THE REPORTED EVENT WAS RELATED TO AN ALLERGIC REACTION OR TO AN UPPER RESPIRATORY/ GASTROINTESTINAL DISORDER. HOWEVER, GIVEN ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED UNLIKELY. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS PREVIOUSLY ASSESSED AS NON-INCIDENT BUT WAS UPGRADED TO INCIDENT UPON RECEIPT OF INFORMATION STATING THAT ESSURE WAS SURGICALLY REMOVED VIA SALPINGECTOMY (REQUIRED INTERVENTION). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: UPDATED PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00778	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 3/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2010
Explant Date (E7): 7/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA NEWS ARTICLE IN UNITED STATES ON 14-JUL-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE STATED THAT WAS IN PAIN ALL THE TIME. FOLLOW-UP FROM 24-JUL-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 12-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (FDA REFERENCE NUMBER (B)(4)). CONSUMER REPORTED THAT SHE WAS PERMANENTLY INJURED BY

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ESSURE. SHE STATES THAT SHE HAD NO LEFT FALLOPIAN TUBE AND INFORMED THAT THE LEFT COIL WAS FORCED IN AND PUSHED OUTSIDE OF HER UTERUS. SHE STARTED EXPERIENCING PAIN AT APPROXIMATELY 6 MONTHS AFTER IMPLANTATION ((B)(6) 2010). THE PAIN ON HER LOWER LEFT ABDOMINAL AREA WAS CONSTANT BUT IT WOULD GET UNBEARABLE WHEN SHE OVULATED. HER OTHER SYMPTOMS, THAT STARTED AFTER ESSURE, INCLUDED NAUSEA, VOMITING (THAT RESEMBLE MORNING SICKNESS), INCREASED ANXIETY (WITH FULL BLOWN PANIC ATTACKS), DENTAL PROBLEMS, EXTREMELY HEAVY PERIODS, AND HORRIBLE MENSTRUAL CRAMPS. CONSUMER ALSO REPORTED THAT SHE HAD NUMEROUS ULTRASOUNDS AND TWO HYSTEROSALPINGOGRAM TESTS AND YET DOCTORS COULDN'T TELL THAT SHE HAD NO FALLOPIAN TUBE. CONSUMER WAS IMPLANTED IN (B)(6) OF 2010. HER FIRST SURGERY TO REMOVE THE COILS WAS IN (B)(6) OF 2014 AND, THE DOCTOR THAT DID THE REMOVAL, LEFT METAL FRAGMENTS IN HER UTERUS, WHICH CAUSED HER TO HAVE A SECOND SURGERY. ON (B)(6) OF 2014 A TOTAL HYSTERECTOMY WAS PERFORMED. FOLLOW-UP RECEIVED ON 28-AUG-2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)INSERTED AND HAD LEFT COIL FORCED IN AND PUSHED OUTSIDE OF HER UTERUS. FIRST SURGERY TO REMOVE ESSURE WAS MADE REMOVED APPROXIMATELY 4 YEARS AFTER INSERTION. HOWEVER, THE PHYSICIAN LEFT METAL FRAGMENTS IN UTERUS AND SHE REQUIRED A SECOND SURGERY, A TOTAL HYSTERECTOMY. THE EVENTS, INTERPRETED AS UTERINE PERFORATION AND DEVICE BREAKAGE, ARE LISTED IN THE REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE UTERINE PERFORATION OCCURRED DURING INSERTION. ALTHOUGH, IT IS STATED THAT THE PHYSICIAN FORCED THE COIL IN, A CAUSAL RELATIONSHIP BETWEEN ESSURE PROCEDURE AND THE UTERINE PERFORATION CANNOT BE EXCLUDED. IT IS NOT CLEAR WHEN THE ESSURE BROKE. HOWEVER, CONSIDERING THE NATURE OF THIS EVENT, THE DEVICE BREAKAGE IS REGARDED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00782	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 8/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C35241

Single Use: Y
Implant Date (E6): 5/19/2015
Explant Date (E7): 9/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C35241 FOR CONTRACEPTION. ON (B)(6) 2015 HYSTEROSALPINGOGRAM (HSG) WAS DONE; BOTH SIDES WERE OCCLUDED. ON THE RIGHT SIDE, THE PROXIMAL TIP APPEARED TO BE INFERIOR TO THE UTERUS. PHYSICIAN SAID IT LOOKED LIKE THE DEVICE MAY HAVE FRACTURED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON (B)(6) 2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM, THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT, OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, THEY CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING

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FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT 3 MONTH HYSTEROSALPINGOGRAM (HSG), ON THE RIGHT SIDE, ESSURE PROXIMAL TIP APPEARED TO BE INFERIOR TO THE UTERUS. ACCORDING TO THE PHYSICIAN, IT LOOKED LIKE THE DEVICE MAY HAVE FRACTURED. THIS EVENT, INTERPRETED AS A SUSPICION OF DEVICE BREAKAGE, IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. HOWEVER, ACCORDING TO THE PRODUCT TECHNICAL INVESTIGATION, THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THE REVIEW OF THE MANUFACTURING BATCH RECORD CONFIRMED THE PRODUCT MET ALL RELEASE REQUIREMENTS. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THEREFORE, BASED ON AVAILABLE INFORMATION, THE QUALITY DEFECT CANNOT BE CONFIRMED AT THIS TIME. FOLLOW-UP INFORMATION IS BEING SOUGHT IN ORDER TO CLARIFY/CONFIRM THE EVENT.

Manufacturer Narrative (H10):

QUESTIONNAIRE - DEVICE BREAKAGE WITH ESSURE WAS RECEIVED ON 13-OCT-2015: PHYSICIAN REPORTED THAT A (B)(6) FEMALE PATIENT HAD ESSURE, LOT NUMBER C35241 AND MODEL NUMBER ESS305, INSERTED ON (B)(6) 2015. ON (B)(6) 2015, DURING HYSTEROSALPINGOGRAM CONFIRMATIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00784	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. REQUIRED INTERVENTION. ANTICIPATED. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER'S HUSBAND STATED THAT HIS WIFE HAD ESSURE PLACED A FEW YEARS BACK. SINCE THE DAY FOLLOWING THE PROCEDURE SHE HAS HAD PROBLEMS. IT STARTED WITH PAIN ON LEFT SIDE, MEMORY LOSS, BRAIN FOG, HAIR LOSS, JOINT PAIN, MIGRAINES, LOWER BACK PAIN AND VISION PROBLEMS. DURING THE TIME SHE HAD ESSURE, SHE ALSO DEVELOPED UTERINE FIBROIDS AND HEAVY BLEEDING. SHE WAS IN CONSTANT PAIN FOR 20 MONTHS. SHE HAD TO HAVE A TOTAL HYSTERECTOMY TO REMOVE ESSURE. THE DOCTOR FOUND THAT ONE OF THE COILS (LEFT SIDE) HAD PERFORATED HER FALLOPIAN TUBE. THEY WERE HOPING THAT ONCE ESSURE WAS OUT, THE HEALING COULD BEGIN. UNFORTUNATELY FOR HIS WIFE THAT WAS NOT THE CASE. ESSURE HAD ALREADY CAUSED TOO MUCH DAMAGE WITHIN HER BODY. SHE IS BEING TREATED FOR FIBROMYALGIA. ALSO, WITHIN THE LAST FEW MONTHS SHE HAS BEEN HAVING KIDNEY PROBLEMS AND HER BLOOD WORK CAME BACK WITH ELEVATED LEVELS FOR HER KIDNEYS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE OF THE COILS (LEFT SIDE) HAD PERFORATED HER FALLOPIAN TUBE. SHE ALSO EXPERIENCED HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A TOTAL HYSTERECTOMY TO REMOVE ESSURE. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE AND FALLOPIAN TUBE

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PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THIS PERFORATION WERE NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE, CONSUMER ALSO HAD FIBROIDS WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THE BLEEDING. HOWEVER, GIVEN THE NATURE OF THIS EVENT, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00785	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN 2007. CONSUMER STATED THAT IMMEDIATELY AFTER ESSURE INSERTION SHE HAD LOWER BACK PAIN WITH HER CYCLE AND ABNORMAL BLEEDING. IT WAS INITIALLY TOLERABLE BUT INCREASED OVER TIME. AFTER DETERIORATION OF HER LIFE, FAMILY AND WORK, SHE FELT AS THOUGH SHE WAS FALLING APART AND MUST JUST BE GETTING OLD. SHE ALSO HAD RECURRENT URINARY TRACT INFECTIONS (SHE RECEIVED ANTIBIOTICS FOR 7 DAYS), ECZEMA, INTENSE BACK PAIN, HIP PAIN CONSTANTLY, HAIR LOSS, BLOAT, WEIGHT GAIN AND SHE BLED FOR 14-DAYS OF EVERY 28-DAYS FOR 7-YEARS. IN 2012, IT WAS DISCOVERED THAT AN ESSURE COIL HAD MIGRATED INTO HER UTERUS. A SURGERY TO REMOVE COIL HYSTEROSCOPICALLY WAS DONE. IT FRAGMENTED. HER SYMPTOMS ESCALATED. SHE HAD LAPAROSCOPIC SURGERY 18-MONTHS AFTER TO ATTEMPT DIAGNOSIS OF HER SYMPTOMS, BUT IT WAS INCONCLUSIVE. IN 2014 AN ABDOMINAL HYSTERECTOMY WAS DONE. PATHOLOGY RESULTS SHOWED ADENOMYOSIS, WHICH ACCORDING TO CONSUMER, IT WAS A DIRECT RESULT OF THE CHRONIC INFLAMMATION THAT ESSURE WAS DESIGNED TO START BUT NEVER STOP. AFTER HYSTERECTOMY, ECZEMA, UTIS, BACK AND HIP PAIN RESOLVED. SHE WAS ALSO DIAGNOSED WITH SECONDARY HYPOTHYROIDISM. SHE WAS RECOVERING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN ESSURE COIL MIGRATED INTO HER UTERUS. DURING A HYSTEROSCOPIC ATTEMPT TO REMOVE THIS COIL, IT FRAGMENTED. CONSUMER WAS LATER SUBMITTED TO A DIAGNOSTIC LAPAROSCOPY AND

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HYSTERECTOMY. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (TO UTERUS OR OUT OF THE BODY) OR DISLOCATION (INTO FALLOPIAN TUBE OR TO PERITONEAL CAVITY). ALSO, IF HYSTEROSCOPIC ESSURE REMOVAL IS ATTEMPTED, THE INSERT MAY FRACTURE. IN THIS CASE, ESSURE EXPULSION TO UTERUS WAS DIAGNOSED 5 YEARS AFTER DEVICE PLACEMENT. NO INFORMATION WAS PROVIDED ABOUT ESSURE INSERTION PROCEDURE TO CONCLUDE ON THE MECHANISM OF THIS EVENT. NEVERTHELESS, CONSIDERING ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THE SAME ASSESSMENT IS GIVEN FOR THE REPORTED DEVICE BREAKAGE; SINCE IT OCCURRED IN ASSOCIATION WITH AN ESSURE REMOVAL ATTEMPT. ADDITIONALLY, THE SERIOUS EVENT SECONDARY HYPOTHYROIDISM (UNLISTED) WAS REPORTED AND CONSIDERED UNRELATED TO ESSURE DUE TO THE LOCAL ACTION OF THIS DEVICE INTO THE FALLOPIAN TUBES. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00786	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/5/2014
Explant Date (E7): 4/20/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE # (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014, LESS THAN A YEAR AFTER HAVING HER BABY. THE CONSUMER REPORTED THAT WITHIN THE FIRST COUPLE OF MONTHS WITH ESSURE INSERTED SHE GAINED ABOUT 30 LBS AND WENT UP 4 PANTS SIZES WITHOUT ANY CHANGE IN EATING HABITS OR DAILY ACTIVITY. DURING THE FOLLOWING MONTHS OTHER THINGS STARTED OCCURRING: PAIN IN BONES AND MUSCLES, HORRIBLE BLEEDING WITH HUGE BLOOD CLOTS, HEADACHES THAT LASTED FOR WEEKS, HIP PAIN, PELVIC PAIN, EXTREME HAIR LOSS, CYSTIC ACNE THAT NEVER WENT AWAY, INCONTINENCE, EXTREME FATIGUE, PANIC ATTACKS, INSOMNIA, EXTREME SWELLING OF HANDS LEGS AND FEET, NUMBNESS IN ALL THE ABOVE, RAPID TOOTH DECAY AND JAW PAIN. SHE WENT TO HER PHYSICIAN AND TOLD HER EVERYTHING SHE WAS EXPERIENCING; SHE RAN MULTIPLE TESTS AND SENT RESULTS TO HER GYNECOLOGIST. HE ALSO RAN SOME TEST AND ORDERED X-RAYS AND ULTRASOUND. SHE TOLD HIM NO MATTER WHAT SHE WANTED ESSURE OUT. HE REFERRED HER TO A DOCTOR FOR SURGERY AND ON (B)(6) 2015 SHE HAD ESSURE AND HER FALLOPIAN TUBES REMOVED. SHE STATED THAT SHE CAME OUT OF ANESTHESIA FEELING NORMAL AGAIN; ALL THE ACHES AND PAINS WERE GONE. SHE MENSTRUATED 1 WEEK AFTER SURGERY AND IT WAS NORMAL, NOT EXTREMELY HEAVY AND NO CLOTS. WITHIN 2 MONTHS OF SURGERY HER HAIR LOSS HAD STOPPED AND BEGAN GROWING AGAIN AND CYSTIC ACNE DISAPPEARED NOT LONG AFTER THAT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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INSERTED AND STARTED EXPERIENCING PELVIC PAIN. SHE HAD ESSURE AND HER FALLOPIAN TUBES REMOVED ONE YEAR AFTER INSERTION. AFTER SURGERY HER PAIN RESOLVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT, AND THE FACT THAT THE PAIN RESOLVED AFTER ESSURE REMOVAL, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SURGERY TO REMOVE ESSURE AND FALLOPIAN TUBES). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00787	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED IN 2010. CONSUMER STARTED HAVING PROBLEMS A COUPLE MONTHS AFTER ESSURE INSERTION. SHE EXPERIENCED SEVERE CRAPS IN HER BACK AND STABBING PAIN INSIDE. SHE HAD SEEN SEVERAL DOCTORS AND ER (EMERGENCE ROOMS) HOSPITALS AND WAS TOLD THAT EVERYTHING WAS FINE. ONE DAY SHE WENT TO ER BECAUSE SHE WAS IN SO MUCH PAIN. SHE UNDERWENT A SONOGRAM AND WAS TOLD THAT THE PAIN WAS BECAUSE ONE OF ESSURE COILS HAD GONE INTO HER UTERUS. THE GYNECOLOGIST/OBSTETRICIAN SUGGESTED TAKING THE COILS OUT AND TYING THE TUBES TO SEE HOW MUCH DAMAGE THERE WAS. SO, IN 2014 CONSUMER HAD HER TUBES TIED, BUT THE PAIN DID NOT GO AWAY AND AFTER TRYING DIFFERENT THINGS THE GYNECOLOGIST DECIDED TO PERFORM A HYSTERECTOMY AND LEAVING OVARIES. ON (B)(6) 2015 CONSUMER UNDERWENT A HYSTERECTOMY. IT WAS FIND OUT THAT SHE GOT 2 HERNIAS FROM SURGERY AND COUPLE DAYS AFTER BEING DISCHARGED CONSUMER WAS FEELING REALLY SICK. SO, SHE WENT BACK TO HOSPITAL; A BIG ABSCESS WAS DIAGNOSED AND SHE HAD TO BE HOSPITALIZED. THE ABSCESS HAD TO BE DRAINED, AFTER BEING IN THERE FOR A FEW DAYS AND BEING DRAINED THE CONSUMER WAS DISCHARGED ON ANTIBIOTICS. AT HOME, SHE SPENT A WEEK THROWING UP SICK. SHE WENT BACK TO HOSPITAL AND FIND OUT TWO MORE ABSCESSES WHICH WERE TOO SMALL TO DRAIN, SO SHE WAS TREATED WITH ANTIBIOTICS. SHE UNDERWENT 12 CT SCANS IN TWO AND HALF MONTHS AND IN (B)(6) 2015 HERNIA SURGERIES WAS PERFORMED. SHE ALSO REPORTED NIGHT SWEATS, BRAIN FOG, SWELLING, HEADACHES, INSOMNIA, AND NASTY TASTE OF

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METAL IN MOUTH. THE CONSUMER, WHO WAS (B)(6) AT TIME OF THIS REPORT, STATED THAT SHE DEVELOPED REALLY BAD ANXIETY FROM IT ALL AND THAT THE MOOD SWINGS ARE THE WORST OF IT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE OF ESSURE COILS HAD WENT INTO UTERUS (DEVICE EXPULSION). SHE WAS SUBMITTED TO A HYSTERECTOMY. AFTER THIS SURGERY, SHE WAS HOSPITALIZED DUE TO ABSCESS AND ALSO HAD 2 HERNIAS, WHICH WERE REPAIRED. ONLY DEVICE EXPULSION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR DISLOCATION TO PERITONEAL CAVITY. IN THIS CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED DEVICE EXPULSION IS NOT KNOWN; GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. REGARDING ABSCESS, SINCE IT OCCURRED IN CLOSE ASSOCIATION WITH HYSTERECTOMY, IT WAS CONSIDERED AS A COMPLICATION OF ESSURE REMOVAL PROCEDURE. FOR HERNIA, AS INCISIONAL HERNIAS ARE OFTEN DUE TO PATIENT RELATED FACTORS (AGE, OBESITY) IN ASSOCIATION WITH OPERATION/TECHNIQUE RELATED FACTORS, CAUSALITY WITH ESSURE IS CONSIDERED UNLIKELY. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED) A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00788	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. SHE EXPERIENCED EXCRUCIATING PAIN AFTER THE PROCEDURE DONE. SHE ALSO HAD CRAMPS THAT LASTED OVER 3 MONTHS AFTER THE PROCEDURE AND HAD TO TAKE PILLS ON A REGULAR BASIS. BEFORE ESSURE SHE WAS HEALTHY AND NEVER HAD ANY PROBLEMS. WITHIN THE LAST YEAR SHE HAS HAD CONSTANT HEADACHES, CHRONIC FATIGUE, BRAIN FOG, JOINT PAIN; BLEED FOR MONTHS AT A TIME, SHARP STABBING PAINS IN HER SIDE WHICH CAUSED HER TO MISS DAYS FROM WORK BECAUSE OF THE PAIN. GETTING ESSURE WAS ONE OF THE WORST MISTAKES SHE HAS EVER MADE. SHE WAS AT HOME RECOVERING FROM A HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED SHARP STABBING PAINS IN HER SIDE AND BLED FOR MONTHS AT TIME. THESE EVENTS, SEEN AS PELVIC PAIN AND GENITAL BLEEDING, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. IN THIS CASE, SHE EXPERIENCED EXCRUCIATING PAIN SOON AFTER THE PROCEDURE, ALSO HAD CRAMPS THAT LASTED OVER 3 MONTHS AFTER THE INSERTION AND WITHIN THE PREVIOUS YEAR SHE HAS HAD BLEEDING FOR MONTHS AT A TIME AND SHARP STABBING PAINS IN HER SIDE. THEN, SHE UNDERWENT AN HYSTERECTOMY. GIVEN THEIR NATURE AND COMPATIBLE TEMPORAL RELATIONSHIP, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE AND SINCE AN INTERVENTION WAS REQUIRED

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(HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PERUSED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00789	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 12/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/30/2014
Explant Date (E7): 5/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2014 SHE WENT TO HAVE THE NOVASURE AND HER DOCTOR ADVISED HER TO ALSO GET THE ESSURE TO PREVENT TUBAL PREGNANCY. SHE WAS TOLD IT WAS A SMALL AND PAINLESS PROCEDURE WITH NO SIDE EFFECTS. SHE EXPERIENCED HORRIBLE PAIN WHEN SHE WOKE UP. SHE HAD HEAVY BLEEDING AND CRAMPING FOR TWO WEEKS WITH NO RELIEF. AFTER THAT SHE HAD SEVERE PAIN IN LEFT SIDE, THE TOP OF BOTH OF HER LEGS HURT LIKE AN ABSCESSED TOOTH, HAD MIGRAINES, HER HAIR FELL OUT, SHE WAS DIZZY TO DRIVE AND WENT FROM A SIZE 4 TO A SIZE 10 IN LESS THAN 2 MONTHS, ALL IN HER BELLY FROM SWELLING, SHE HAD NO ENERGY AT ALL AND MISSED A LOT OF WORK BECAUSE OF THAT. AFTER A VAGINAL ULTRASOUND AND 4 ROUNDS OF ANTIBIOTICS HER IMPLANT DOCTOR SAID THAT IT WAS NOT AN INFECTION AND REFERRED HER TO A SURGEON. ON (B)(6) 2015 SHE UNDERWENT A TOTAL HYSTERECTOMY. THERE WAS ZERO DOUBT THAT THE ESSURE WAS HER PROBLEM. SHE WAS STILL HAVING ISSUES WITH HER BLADDER WHICH STEMS BACK TO THE ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD HEAVY BLEEDING FOR 2 WEEKS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE ALSO EXPERIENCED SEVERE PAIN ON HER LEFT SIDE. SHE UNDERWENT A TOTAL HYSTERECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING AND AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR.

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IN THIS CASE, THE EVENTS STARTED IN CLOSE ASSOCIATION WITH ESSURE INSERTION. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICES REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00790	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0085, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011, AFTER THE BIRTH OF HER SON. THE CONSUMER REPORTED THAT AFTER PLACEMENT HER DOCTOR CONFIRMED THE COILS WERE IN PLACE. SHE HAS BEEN EXTREMELY UNHEALTHY FOR THE PAST 4 YEARS. SHE HAD BEEN TO SPECIALIST BUT NOT ONE DOCTOR COULD FIND ANYTHING WRONG. SHE HAD LOST WEIGHT THEN GAINED IT RAPIDLY BACK, HAD A BLOATED TUMMY, CRACKED TEETH, MIGRAINES, POOR EYESIGHT, HAIR LOSS, JOINT PAIN, PAINFUL INTERCOURSE, NAUSEA/VOMITING, HIVES, CYST AND EARLY MENOPAUSE. SHE WENT TO THE ER (EMERGENCY ROOM) IN 2014 IN EXTREME PAIN. THE ESSURE CAME OFF HER TUBE AND WAS RESTING BETWEEN HER UTERUS AND RECTUM. SHE HAD SURGERY TO REMOVE THE COILS AND HER TUBES BUT THE SYMPTOMS NEVER REALLY LEFT; IN FACT THEY FLARED UP TO THE POINT WHERE SHE WAS NOW SCHEDULED FOR A HYSTERECTOMY ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND APPROXIMATELY 3 YEARS LATER IT WAS FOUND THAT ESSURE CAME OFF HER TUBE AND WAS RESTING BETWEEN HER UTERUS AND RECTUM. SHE HAD SURGERY TO REMOVE THE COILS AND HER TUBES. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR

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OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED; THE EXACT DATE OF THE EVENT WAS NOT REPORTED. APPROXIMATELY 3 YEARS AFTER ESSURE INSERTION, THE DEVICE WAS FOUND RESTING BETWEEN HER UTERUS AND RECTUM. DESPITE THE LIMITED INFORMATION, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SURGERY TO REMOVE ESSURE AND FALLOPIAN TUBES). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00791	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 4/30/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2012, FOR PERMANENT BIRTH CONTROL. CONSUMER DECIDED TO GET HER TUBES TIED AFTER HAVING HER THIRD BABY. HER OBSTETRICIAN SUGGESTED ESSURE AND MADE IT SOUND GREAT. AFTER GETTING IT SHE HAD SEVERE CRAMPING ALL THE TIME, PAINFUL PERIODS, HEADACHES ALL THE TIME, LOWER BACK PAIN. SHE HAD TO HAVE A PARTIAL HYSTERECTOMY ON (B)(6) 2015 AFTER HAVING ESSURE FOR TWO AND HALF YEARS. SHE WAS (B)(6) AT THE TIME OF HYSTERECTOMY. HER LEFT SIDE HAD MOVED AND WAS IN HER UTERUS. CONSUMER FELT SO MUCH BETTER AFTER HAVING ESSURE REMOVED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THAT SHE HAD SEVERE CRAMPING ALL THE TIME. SHE UNDERWENT A PARTIAL HYSTERECTOMY TWO AND A HALF YEARS AFTER INSERTION. THIS EVENT, INTERPRETED AS LOWER ABDOMINAL PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (PARTIAL HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT:

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00793	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): 1/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2005. THE CONSUMER REPORTED THAT OVER THE 8 YEARS THAT SHE WAS IMPLANTED HER BODY HAD A WEAKENED IMMUNE SYSTEM, HEAVY BLOOD CLOTS AND BLEEDING, CHRONIC PELVIC PAIN AND INFLAMMATION, JOINT SWELLING, FATIGUE. SHE REPORTED HER TUBES FELT AS IF THERE WAS A FIRE POKER IN THEM. SHE REPORTED THE DOCTORS DID ULTRASOUNDS AND X-RAYS AND SAID EVERYTHING LOOKED FINE. THE NOTED ONSET OF HER SIDE EFFECTS WAS AFTER 2 YEARS OF IMPLANTATION. SHE HAD HER TUBES REMOVED IN (B)(6) 2013. THE DOCTOR ATTRIBUTED THE PAIN SHE WAS SUFFERING TO THE COILS WITHOUT A DOUBT. SHE STATED THE DOCTOR AND THE NURSES IN HER SURGERY WERE SHOCKED TO FIND THAT THE COIL HAD PERFORATED THROUGH THE RIGHT TUBE; SHE STARTED FEELING BETTER WITHIN A DAY OR TWO OF SURGERY. LATER SHE HAD TO GET A FLUOROSCOPY SCAN OF HER UTERUS AS SHE HAD SOME TWINGES OF PAIN AND INFLAMMATION AFTER THE INITIAL SURGERY. THE FLUOROSCOPY SHOWED THAT THE ESSURE HAD BROKEN OFF DURING REMOVAL ON BOTH SIDES OF HER UTERUS AND THE ONLY OPTION FOR COMPLETE REMOVAL WAS A PARTIAL HYSTERECTOMY. IN (B)(6) 2014, AT AGE OF (B)(6), SHE HAD A PARTIAL HYSTERECTOMY. SHE STATED THAT ALL OF HER PAIN AND JOINT ACHES WERE GONE ESSURE WAS THE CULPRIT BEHIND MANY YEARS OF SUFFERING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND OVER THE 8

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YEARS SHE HAD A WEAKENED IMMUNE SYSTEM (INTERPRETED AS IMMUNODEFICIENCY) AND HEAVY BLOOD CLOTS/BLEEDING (INTERPRETED GENITAL BLEEDINGS). DURING SURGERY, IT WAS NOTED THAT THE COIL HAD PERFORATED THOUGH THE RIGHT TUBE (FALLOPIAN TUBE PERFORATION). SHE HAD HER TUBES REMOVED AFTER 8 YEARS AND SHE STARTED FEELING BETTER A DAY OR TWO AFTER SURGERY. HOWEVER, A FLUOROSCOPY SCAN PERFORMED AFTERWARDS SHOWED THAT THE ESSURE HAD BROKEN OFF DURING REMOVAL ON BOTH SIDES OF HER UTERUS (INTERPRETED AS DEVICE BREAKAGE). ALMOST A YEAR LATER, SHE HAD A PARTIAL HYSTERECTOMY FOR ESSURE COMPLETE REMOVAL. AFTER THAT, SHE RECOVERED FROM ALL PAIN AND JOINT ACHES. THE IMMUNODEFICIENCY IS UNLISTED WHILE THE GENITAL BLEEDING, FALLOPIAN TUBE PERFORATION AND ESSURE BREAKAGE DURING REMOVAL ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER EXPERIENCED A WEAKENED IMMUNE SYSTEM AND GENITAL BLEEDINGS DURING ESSURE USE. CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF INFORMATION, THE GENITAL BLEEDING, PERFORATION AND DEVICE BREAKAGE ARE ASSESSED AS RELATED TO ESSURE. IN CONTRAST, ALTHOUGH THE TEMPORAL RELATIONSHIP IS COMPATIBLE, CONSIDERING THE NATURE OF THIS EVENT AND THE LOCALIZED ACTION OF ESSURE, IT IS UNLIKELY THAT ESSURE COULD INTERFERE IN THE IMMUNE SYSTEM (UNRELATED). THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 08-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00794	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE PATIENT, WHO IS A HEALTH PROFESSIONAL, OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. THE PATIENT REPORTED SHE HAD ESSURE IMPLANTED AFTER THE MIRENA (LEVONORGESTREL) PERFORATED HER UTERUS. SINCE 2010, SHE HAS HAD AN ELEVATED C-REACTIVE PROTEIN LEVEL THAT HAS BEEN ESCALATING, AND WAS 10 AT TIME OF THE REPORT; WITH ZERO BEING NORMAL. SHE STATED THAT THIS INCREASES CARDIAC EVENT RISK, CREATED HOT FLASHES, AND RESULTED IN ACHY JOINTS. THE INFLAMMATION WAS DOCUMENTED IN HER MEDICAL RECORDS IN HER FEET, ELBOW, WRIST, HAND AND IN HER IT (INTERPRETED AS ILIOTIBIAL) BAND. ALTHOUGH HER DEVICES HAD NOT MIGRATED, SHE SUFFERED FROM EXTENSIVE SCARRING, AND HER UTERUS WAS NOT DEVIATED TO HER LEFT HIP. SHE STATED THAT THIS WAS PAINFUL, AND SHE WAS UNDERGOING A HYSTERECTOMY TO REMOVE THE DEVICES ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD MIRENA (LEVONORGESTREL) INSERTED AND IT PERFORATED HER UTERUS (INTERPRETED AS UTERINE PERFORATION). AFTER THAT SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS PAINFUL (INTERPRETED AS PELVIC PAIN), AND HAD ELBOW AND WRIST INFLAMMATION (INTERPRETED AS POLYARTHRITIS). SHE WAS SCHEDULED FOR A HYSTERECTOMY TO REMOVE ESSURE, 8 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. UTERINE PERFORATION AND PELVIC PAIN ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR BOTH MIRENA AND ESSURE, WHILE POLYARTHRITIS IS UNLISTED FOR BOTH PRODUCTS. UTERINE

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PERFORATION MAY OCCUR WITH ANY INTRAUTERINE DEVICE. THE RISK OF UTERINE PERFORATION MAY BE INCREASED WITH ABNORMAL UTERINE ANATOMY, IN WOMEN IN POSTPARTUM STATE AND LACTATING WOMEN AND WOMEN WITH A FIXED RETROVERTED UTERUS. IN THE PRESENT CASE NO SUCH CIRCUMSTANCES WERE REPORTED. GIVEN THE NATURE OF THE EVENT PERFORATED HER UTERUS, CAUSALITY WITH MIRENA CANNOT BE EXCLUDED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, SHE HAD EXTENSIVE SCARRING, WHICH COULD HAVE CONTRIBUTED FOR THE OCCURRENCE OF THE PAIN. HOWEVER, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. REGARDING THE EVENT POLYARTHRITIS, CONSIDERING THE PATHOPHYSIOLOGY OF THE EVENT AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND SUSPECT INSERT WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS RECEIVED ON 08-SEP-2015: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00795	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), CASE # (B)(4) AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER STATED WITHIN WEEKS OF RECEIVING THE ESSURE PROCEDURE, HER HEALTH BEGAN SLOWLY DETERIORATING. ACCORDING TO HER, IT TOOK HER OVER 2 YEARS AND A HANDFUL OF DOCTORS TO REALIZE THAT HER HEALTH ISSUES WERE RELATED TO ESSURE. SOME OF THE HEALTH ISSUES THAT CAME UP AS A RESULT OF ESSURE INCLUDED EXTREME PAIN IN ABDOMEN, ESPECIALLY WHEN BENDING DOWN OR COUGHING, SEVERE HORMONE IMBALANCE, IRRITABILITY, MOOD SWINGS, TROUBLE SLEEPING, LOSS OF LIBIDO, ANXIETY, FATIGUE, ACHING MUSCLES, ETC. THOSE SYMPTOMS INCREASED IN FREQUENCY AND SEVERITY UNTIL 2 YEARS LATER. SHE WAS UNABLE TO FUNCTION ANYMORE. SHE OPTED TO GO FOR A FULL REVERSAL, INCLUDING HAVING HER FALLOPIAN TUBES RECONNECTED AFTER REMOVAL OF ESSURE. WITHIN WEEKS OF THE REVERSAL, HER SYMPTOMS WERE DIMINISHING. IT'S BEEN OVER 2 YEARS SINCE SHE HAD THE COILS REMOVED AND SHE WAS HAPPY TO SAY THAT SHE MADE A GREAT RECOVERY. HOWEVER, SHE WAS STILL HAVING PAIN IN HER ABDOMEN WHEN COUGHING, PROBABLY DUE TO THE SCAR TISSUE IN HER TUBES. SHE WAS VERY CONCERNED ABOUT NOW POSSIBLY HAVING AN ECTOPIC PREGNANCY AND THE ISSUE OF FATALITY INVOLVED WITH THIS KIND OF PREGNANCY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD EXTREME PAIN IN ABDOMEN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICES WERE SURGICALLY REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS

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LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE THE EVENT STARTED WITHIN WEEKS OF ESSURE INSERTION AND IMPROVED WITH DEVICES REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00796	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. REQUIRED INTERVENTION. ANTICIPATED. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. CONSUMER REPORTED THAT ONE OF THE COILS DID NOT TAKE, AND MIGRATED OUT OF HER FALLOPIAN TUBE AND WAS EMBEDDED IN HER UTERINE WALL. SHE HAS ALREADY HAD THREE SURGERIES TO TRY TO REMEDY THE ESSURE FAILURE. SHE WAS SCHEDULED IN OCTOBER TO HAVE A TOTAL HYSTERECTOMY. SHE ALSO REPORTED SHE HAD THE PHYSICAL SIDE EFFECTS OF ABDOMINAL PAIN, BLOATING, AND HEADACHES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE COIL DID NOT TAKE, AND MIGRATED OUT OF HER FALLOPIAN TUBE AND IS EMBEDDED IN HER UTERINE WALL. SHE HAD 3 SURGERIES TO TRY TO REMEDY THIS EVENT, AND WAS SCHEDULED TO HAVE A TOTAL HYSTERECTOMY. THIS EVENT, INTERPRETED AS PARTIAL EXPULSION OF DEVICE AND DEVICE EMBEDDED (PARTIAL UTERINE PERFORATION), WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY). ALSO, UTERINE PERFORATION WITH ESSURE MAY OCCUR. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. THE EXACT DATE OF THE EVENT WAS NOT REPORTED. HOWEVER, CONSIDERING THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO

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REQUIRED INTERVENTION (ACCORDING TO THE CONSUMER, SHE HAD 3 SURGERIES) AND ANOTHER SURGICAL INTERVENTION WILL BE REQUIRED . A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00890	BAYER HEALTHCARE LLC	9/10/2015	9/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2007
Explant Date (E7): 4/28/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 04-MAR-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5029580, RECEIVED AT FDA ON 03-APR-2013). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PULMONARY EMBOLISM, SWELLING, MIGRAINES, IRREGULAR PERIODS, BLEEDING, CRAMPING, DIAGNOSED WITH FIBROMYALGIA, PAINFUL INTERCOURSE, WEIGHT GAIN, DIAGNOSED WITH GERD (GASTROESOPHAGEAL REFLUX DISEASE), DEVICE BREAKING DOWN INSIDE HER, DURING A DNC (DILATION AND CURETTAGE), A PIECE OF THE COIL WAS PULLED OUT, AND SHE IS IN EXTREME PAIN. ON FDA FORM REPORTED REPORT TYPE WAS 'INJURY', OUTCOME OF EVENTS WAS 'OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)'. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2007, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR PERMANENT BIRTH CONTROL. CONSUMER CALLED TO REPORT ADVERSE REACTIONS TO ESSURE PERMANENT BIRTH CONTROL SYSTEM. SHE HAD BEEN IN AND OUT OF HOSPITAL SINCE IMPLANTATION IN 2007 (REPORTED START DATE OF EVENT(S) WAS (B)(6) 2007), AND HAS EXPERIENCED MULTIPLE SYSTEMS INCLUDING SWELLING, MIGRAINES, BACK PAIN, PULMONARY EMBOLISM, IRREGULAR PERIODS, BLEEDING, CRAMPING, DIAGNOSED WITH FIBROMYALGIA, PAINFUL INTERCOURSE, TINGLING SENSATION ON RIGHT SIDE OF HER BODY AND WEIGHT GAIN. SHE STATED SHE HAS BEEN POT ON PROZAC (FLUOXETINE) AND WAS DIAGNOSED WITH GERD (GASTROESOPHAGEAL REFLUX DISEASE). SHE STATED THE DEVICE WAS BREAKING DOWN INSIDE HER, AND DURING A DNC (DILATION AND CURETTAGE) A PIECE OF THE COIL WAS PULLED OUT. THE CONSUMER STATED SHE IS IN EXTREME PAIN AND IS SCHEDULED TO HAVE A HYSTERECTOMY FOR DEVICE

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REMOVAL. ESSURE EXPLANT DATE WAS PROVIDED AS (B)(6) 2013. FOLLOW-UP RECEIVED ON 17-MAR-2014 AND ADDITIONAL INFORMATION IN 20-MAR-2014: NO NEW CLINICAL INFORMATION. CASE CONSIDERED TO BE CLOSED. FOLLOW UP RECEIVED ON 20-MAR-2014 WITH THE FINAL PTC (PTC GLOBAL NUMBER: (B)(4)) INVESTIGATION RESULT: FINAL ASSESSMENT: USABILITY ISSUES (UIS) ARE NOT ASSOCIATED WITH TECHNICAL DEFECTS OR ADVERSE EVENTS. UIS ARE TYPICALLY ACTS THAT LEAD TO A DIFFERENT RESULT THAN EXPECTED BY THE USER. EXAMPLES INCLUDE, BUT ARE NOT LIMITED TO, HANDLING ERRORS, DEVIATIONS FROM THE INSTRUCTIONS FOR USE, NON-PRODUCT RELATED ANATOMICAL ISSUES, OR OTHER CUSTOMER SATISFACTION ISSUES. PLEASE SEE REFERENCE (B)(4), "ESSURE USABILITY ISSUES". NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. FINAL RISK CLASSIFICATION: RISK CATEGORY IV MEDICAL ASSESSMENT: THE EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. IN THIS CASE A USABILITY ISSUE WHERE A COIL WAS PULLED OUT DURING A D&C PROCEDURE WAS REPORTED. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT BATCH NUMBER OR SAMPLE. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. INTERNAL CORRECTION FROM CODING ON 01-APR-2014: THE EVENT DURING A DNC A PIECE OF THE COIL WAS PULLED OUT WAS CONSIDERED AS NON-SERIOUS (PT: UNINTENTIONAL MEDICAL DEVICE REMOVAL). FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4)). CONSUMER REPORTED THAT SHE HAD ESSURE IMPLANTED A SHORT TIME AFTER SHE HAD HER SECOND CHILD. SHORTLY AFTER THAT, SHE WAS A MESS. SHE WAS ALWAYS IN PAIN WITH VISIT AFTER VISIT TO THE EMERGENCY ROOM. SHE SPENT MOST OF HER TIME IN BED AND MISERABLE. SHE COULDN'T PLAY WITH HER OWN CHILDREN AND WAS ALWAYS TOO SICK TO BE THERE FOR HER CHILDREN. SHE WAS ALWAYS IN PAIN OR BLEEDING, NOT TO MENTION ALL THE WEIGHT SHE GAINED. SHE WAS 2.5 YEARS ESSURE FREE AT THE TIME OF THIS REPORT, AND ALTHOUGH SHE WAS NOT BACK TO NORMAL, SHE WAS NOT SUFFERING DAILY LIKE SHE USED TO DO. THE INFLAMMATION IN HER BODY HAD DECREASED TREMENDOUSLY. SHE STATED THAT THERE IS NO WAY YOU COULD EVER TELL HER THAT ALL OF HER PROBLEMS WERE NOT DIRECTLY CONNECTED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PULMONARY EMBOLISM, SHE WAS ALWAYS BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND WAS IN EXTREME PAIN / ALWAYS IN PAIN (INTERPRETED AS PELVIC PAIN). CONSUMER REPORTED SHE WAS ESSURE FREE (INTERPRETED AS ESSURE REMOVAL) APPROXIMATELY 6 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. PULMONARY EMBOLISM IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE REMAINING EVENTS ARE LISTED. AFTER INTERNAL REVIEW, THE PREVIOUSLY REPORTED EVENT DURING A DNC A PIECE OF THE COIL WAS PULLED OUT WAS CONSIDERED NON-SERIOUS. IN ADDITION, NON-SERIOUS AND UNLISTED EVENT DEVICE BREAKING DOWN INSIDE HER WAS REPORTED. PULMONARY EMBOLISM IS USUALLY A COMPLICATION OF VENOUS THROMBOEMBOLISM AND ITS ETIOLOGY MAY INVOLVE HYPERCOAGULABLE STATES, IMMOBILIZATION, PREGNANCY, ORAL CONTRACEPTIVES AND ESTROGEN THERAPY, MALIGNANCY, HEREDITARY FACTORS AND ACUTE MEDICAL ILLNESS. CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AND ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES, CAUSALITY WITH ESSURE WAS ASSESSED AS UNRELATED. ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENTS ALWAYS BLEEDING AND EXTREME PAIN / ALWAYS IN PAIN, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS UPGRADED FROM OTHER REPORTABLE INCIDENT TO INCIDENT UPON RECEIPT OF INFORMATION STATING THE

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CONSUMER HAD ESSURE REMOVED (INTERVENTION IMPLIED). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 07-NOV-2015 FROM CONSUMER VIA SOCIAL MEDIA: THE CONSUMER STATED THAT ESSURE HAD POISONED HER AND THAT THE DAMAGE COULD NOT BE UNDONE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056143	BAYER	9/10/2015	9/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PELVIC PAIN, NUMBNESS AND TINGLING IN LEGS, DIZZINESS, STOMACH CRAMPS AND BACK PAIN. SEVERAL APPOINTMENTS. LAST APPT (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056145	BAYER	9/10/2015	9/15/2015

Event Information:

Event Date (B3): 12/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/12/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE IMPLANTED IN (B)(6) 2011 AFTER THAT, I HAD HEAVY BLEEDING 15 DAYS UNTIL BECOMING ANEMIC. HAD AN ABLATION DONE IN (B)(6) 2012 AND PAIN AFTERWARDS THAT NEVER GOT RESOLVED. I WENT SEVERAL TIMES TO MY OB/GYN DOCTOR AND GOT THE RUN AROUND NOT SURE IF THEY WERE AFRAID THAT MY SIDE EFFECTS WERE GETTING WORSE WITH THE ESSURE IMPLANT. I LEARNED HOW TO TAKE THE PAIN, I.E-INTIMACY, PLAYING WITH MY CHILDREN IN THE PARK ETC; UNTIL THIS YEAR IT IS BEING RESOLVED WITH SALPINGECTOMY WITH ESSURE COILS REMOVED FINALLY. I DID NOT WANT THIS TO HAPPEN AS NOBODY WOULD TELL ME ONE OF THE COILS IS NOT IN MY FALLOPIAN TUBE BUT IN MY UTERUS, SCHEDULED FOR SURGERY ON (B)(6) 2015. I HAVE BEEN BATTLING HIVES FOR 3-4 MONTHS, I AM ALLERGIC TO NICKEL WHICH NO ONE EVER TOLD ME IF I WAS ALLERGIC TO.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00765	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5036225) IN UNITED STATES ON 23-JUL-2014 REFERRING TO HERSELF. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DESCRIBES THE OCCURRENCE OF BEING PREGNANT WITH ESSURE (DEVICE INEFFECTIVE) AND NO ESSURE COIL IN LEFT TUBE. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT DRUGS AND CONCURRENT CONDITIONS. IN 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR TUBAL OCCLUSION. SHE HAD THE CONFIRMATION TEST DONE IN 2013 WHICH SHOWED HER TUBES WERE IN PLACE AND CLOSED. IN 2014 THE CONSUMER FOUND OUT SHE WAS PREGNANT. NO COIL WAS FOUND IN HER LEFT TUBE. NO ASSESSMENT WAS GIVEN. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 04-AUG-2014: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. FOLLOW-UP FROM 05-MAR-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE. FOLLOW UP 13-AUG-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN (B)(6) 2012 FOR BIRTH CONTROL. CONSUMER REPORTED THAT THERE WERE NO COMPLICATIONS WITH THE PROCEDURE ITSELF. SHE WENT IN (B)(6) 2013 TO HAVE THE TEST DONE TO PROVE HER TUBES WERE BLOCKED AND IT WAS CONFIRMED THAT THEY WERE BLOCKED. SHE STAYED ON BIRTH CONTROL FOR ABOUT 6 MONTHS AND IN (B)(6) 2014 SHE WAS HAVING PELVIC PAIN BUT DOCTORS WERE UNABLE TO EXPLAIN WHY AFTER AN ULTRASOUND. IN (B)(6) 2014 SHE FOUND OUT

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SHE WAS PREGNANT. UP UNTIL THAT POINT THE ONLY SIDE EFFECT SHE HAD WAS THE PELVIC PAIN BUT SHE WAS UNSURE IF THAT WAS RELATED TO THE ESSURE. SHE MISCARRIED IN (B)(6) 2014. CONSUMER HAD COSTLY ULTRASOUNDS, CT SCANS, AND A MRI WHICH SHOWED THAT THE COIL IN HER LEFT TUBE WAS NOT IN ITS PROPER PLACE. WHICH WAS THE TUBE SHE OVULATED FROM WHEN SHE GOT PREGNANT. SHE THEN STARTED BLEEDING CONTINUOUSLY FROM MAY UNTIL SEPTEMBER WHEN SHE HAD TO HAVE A DILATION AND CURETTAGE. SHE MENTIONED THAT SHE COULD EVEN EXPLAIN WHAT THIS HAS DONE TO HER EMOTIONALLY AND PHYSICALLY AND THE SCARS IT HAS LEFT HER FOR THE REST OF HER LIFE. SHE DID NOT WANT TO HAVE A HYSTERECTOMY AT (B)(6) BUT THAT MIGHT BE HER ONLY OPTION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO GOT PREGNANT AND MISCARRIED AFTER ESSURE INSERTION. A MRI SHOWED THE COIL IN HER LEFT TUBE WAS NOT IN ITS PROPER PLACE (NO COIL IN LEFT TUBE). AFTER THE MISCARRIAGE, SHE STARTED BLEEDING CONTINUOUSLY FOR 4 MONTHS, UNTIL SHE UNDERWENT A DILATION AND CURETTAGE. ALL EVENTS ARE LISTED EVENTS IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS CASE, CONSUMER'S TEST REVEALED TUBAL OCCLUSION; LATER ULTRASOUND, CT AND MRI SHOWED A POSSIBLE DEVICE DISLOCATION (EXACT INSERT LOCATION NOT PROVIDED). IT IS NOT KNOWN WHETHER ESSURE WAS DISLOCATED FIRST AND THE PREGNANCY FOLLOWED, OR WHETHER IT WAS IN PLACE DURING THE CONCEPTION AND WAS DISLOCATED LATER. HOWEVER, AS THE CONSUMER GOT PREGNANT ABOUT 1.5 YEARS AFTER ESSURE INSERTION, A DEVICE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING MISCARRIAGE, IT IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY, OCCURRING IN UP TO 20% OF PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION DUE TO MATERNAL CONDITIONS OR FETAL CHROMOSOMAL ABNORMALITIES. IN THIS CASE, CONSUMER MISCARRIED 1 MONTH AFTER PREGNANCY DIAGNOSIS; SUGGESTING THIS EVENT OCCURRED IN THE FIRST TRIMESTER OF GESTATION. THEREFORE, A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN THIS EARLY DEVELOPING PREGNANCY WAS CONSIDERED UNLIKELY. CONSUMER ALSO MENTIONED A PERSISTENT BLEEDING AFTER HER MISCARRIAGE; AS THIS EVENT LASTED MORE THAN EXPECTED TO BE CONSIDERED A MISCARRIAGE COMPLICATION AND SINCE ABNORMAL GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A DILATION AND CURETTAGE WAS REQUIRED AS BLEEDING TREATMENT, THIS CASE WAS REGARDED AS INCIDENT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00766	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 2/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/22/2011
Explant Date (E7): 10/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5036908) IN UNITED STATES ON 18-AUG-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. CONSUMER REPORTED THAT SINCE SHE HAD ESSURE IMPLANTED SHE HAS NOTICED SEVERAL DIFFERENT SIDE EFFECTS. SEVERE ABDOMINAL CRAMPING, SHARP STABBING PELVIC PAIN, VAGINAL DISCHARGE, EXCESSIVE BLEEDING DURING HER MENSTRUAL CYCLE, PAINFUL MENSTRUATION, PAINFUL INTERCOURSE, INCONTINENCE, ABDOMINAL SPASM, BACK PAIN, SEVERE BLOATING, METALLIC TASTE, HEARTBURN, HEADACHES, SWELLING AND TINGLING OF HANDS AND FEET, MOOD SWINGS, FORGETFULNESS, HIGH BLOOD PRESSURE, ACNE, HAIR LOSS, TEETH DECAY AND LOSS, WEIGHT GAIN, AND EXCESSIVE SWEATING. IN ADDITION A SERIOUSNESS CRITERIA (INJURY) WAS REPORTED; HOWEVER IT WAS NOT SPECIFIED FOR WHICH EVENT IT REFERS. FOLLOW-UP RECEIVED ON 19-SEP-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (REQUEST FOR CONFIRMATION OF QUALITY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS

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INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE AND THE MAJORITY OF EVENTS WERE CONSIDERED AS UNRELATED TO THE PRODUCT BY COMPANY. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THE AVAILABLE INFORMATION. FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)). CONSUMER REPORTED THAT WHILE SHE WAS PREGNANT WITH HER THIRD CHILD, SHE KNEW HER FAMILY WAS COMPLETE. SHE ASKED HER PHYSICIAN ABOUT ESSURE AND WAS TOLD ALL THE AWESOME BENEFITS OF GETTING AND HAVING ESSURE. HEALTH CARE PROFESSIONAL ASKED CONSUMER WHETHER SHE HAD AN ALLERGY TO NICKEL. CONSUMER EXPLAINED THAT JEWELRY WITH HIGH LEVELS ON NICKEL ALWAYS CAUSED HER TO HAVE A REACTION (RASHES AND BLISTERS). HOWEVER, PHYSICIAN SAID THAT WASN'T REALLY WHAT THEY WERE CONCERNED WITH. IN (B)(6) OF 2011 (PREVIOUSLY REPORTED AS (B)(6) 2011), SHE HAD ESSURE IMPLANTED. SHE WAS GIVEN A VALIUM AND A PAIN PILL PRIOR TO INSERTION AND STATED THAT IT WAS PRETTY UNCOMFORTABLE, BUT NOT HORRIBLE. SHE HAD A LITTLE CRAMPING AFTERWARDS, BUT STATED THAT IT WAS NOT UNBEARABLE. SHE WENT BACK FOR HER CONFIRMATION TEST AND WAS TOLD EVERYTHING LOOKED GREAT. OVER THE NEXT FOUR YEARS. SHE BEGAN TO CHANGE. ACCORDING TO HER, SHE BEGAN TO PUT ON WEIGHT AND COULD NOT LOSE IT. SHE BEGAN LOSING HAIR. ANY AND ALL MAKEUP MADE HER FACE ITCH LIKE CRAZY. SHE COULD NOT WEAR ANY JEWELRY WHATSOEVER BECAUSE IT WOULD BE EXTREMELY ACHY OR TURN HER SKIN GREEN WITHIN 10 MINUTES. HER TEETH THAT HAD FILLINGS BEGAN CRACKING AND FALLING OUT IN BITS AND PIECES. SHE BEGAN TO GET BOILS AND ABSCESSES IN ODD PLACES. HER MONTHLY MENSTRUAL CYCLE WAS HORRIBLE (SHE WAS BLEEDING SO HEAVILY THAT SHE HAD TO WEAR A SUPER PLUS TAMPON AND A HEAVY DUTY MAXI PAD THAT HAD TO BE CHANGED EVERY 30 MINUTES). SHE COULDN'T LEAVE HER HOUSE FOR 5 DAYS DURING HER CYCLE BECAUSE SHE WAS BLEEDING SO HEAVILY AND FELT HORRIBLE. SHE ALSO HAD HORRIBLE GAS PAINS AND BLOATING. CONSUMER HAD TO TAKE GASX LIKE THEY WERE VITAMINS AT SOME POINTS. SEX WITH HER HUSBAND WAS EXTREMELY PAINFUL AT TIMES AND SHE HAD NO DESIRE TO GO THROUGH WITH IT. SHE ALSO REPORTED THAT SHE EXPERIENCED BRAIN FOG EVERYDAY, WOULD FORGET FROM ONE MINUTE TO THE NEXT, COULD NOT FOCUS ON THINGS, WAS EXTREMELY TIRED AND STATED THAT SHE WOULD WAKE UP IN THE MORNING, DRINK COFFEE, AND GO SIT IN HER ARMCHAIR (SHE HAD NO ENERGY OR DESIRE TO DO ANYTHING). DURING THIS TIME, CONSUMER HAD NO IDEA WHAT WAS WRONG WITH HER. SHE WENT TO THE CLINIC IN TOWN TO GET TEST DONE BECAUSE SHE FELT HORRIBLE. ONCE SHE STARTED TELLING HER DOCTOR ALL THE SYMPTOMS SHE WAS EXPERIENCING AND REALIZED THE TIME FRAME. SHE STARTED RESEARCHING ESSURE ONLINE AND FOUND THE GROUP ON A SOCIAL MEDIA WHICH HAD A LIST OF ALL HER SYMPTOMS. SHE HAD ESSURE REMOVED IN (B)(6) OF 2014 AND STATED THAT IN THE LAST 10 MONTHS, HER LIFE HAD SLOWLY BECOME WHAT IT SHOULD. HER HAIR IS GROWING BACK AND SHE IS NO LONGER LOSING IT. SHE CAN WEAR MAKEUP AGAIN AND CAN WEAR JEWELRY NORMALLY. SHE HASN'T HAD A BOIL OR ABSCESS. HER MENSTRUAL CYCLE IS COMPLETELY NORMAL AND HER HEAVY DAYS ARE NORMAL HEAVY DAYS. SHE HASN'T HAD THE HORRIBLE GAS PAINS AGAIN. SEX IS ENJOYABLE AGAIN WITHOUT ANY PAIN. SHE CAN ORGANIZE AND REMEMBER SIMPLE TASKS AGAIN. SHE HAS ENERGY TO KEEP UP WITH HER VERY ACTIVE TEENAGERS AND (B)(6). ALSO ACCORDING TO HER, THE ONLY CHANGE IN HER LIFE WAS THE REMOVAL OF ESSURE AND, TO HER, THAT PROVED VERY CLEARLY THAT THEY WERE POISONING HER BODY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SHARP STABBING PELVIC PAIN SINCE INSERTION AND SHE STATED ESSURE WAS POISONING HER BODY (INTERPRETED AS METAL POISONING).

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ESSURE INSERTS WERE REMOVED ALMOST 4 YEARS AFTER INSERTION. SHE STATED THAT 10 MONTHS AFTER ESSURE REMOVAL SHE WAS SLOWLY RECOVERING, HOWEVER SHE DID NOT SPECIFY THE EVENTS. THE PELVIC PAIN IS LISTED WHILE THE METAL POISONING IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, BOTH EVENTS STARTED AFTER ESSURE INSERTION. PELVIC PAIN STARTED SINCE INSERTION. CONSIDERING THIS SUGGESTIVE TEMPORAL RELATIONSHIP AND THE NATURE OF THIS EVENT, THIS PAIN IS CONSIDERED RELATED TO ESSURE. THE ENTIRE NICKEL-TITANIUM ALLOY SURFACE IS COVERED WITH A PROTECTIVE LAYER OF TITANIUM OXIDE TO MINIMIZE NICKEL ION RELEASE. ALTHOUGH, IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM THIS DEVICE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE A METAL POISONING (UNRELATED). THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. AN INITIAL PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THAT SINCE NO PRODUCT WAS RETURNED AND NO LOT NUMBER WAS AVAILABLE FOR INVESTIGATION, THE COMPANY IS UNABLE TO CONFIRM ANY QUALITY DEFECT OR MALFUNCTION AT THE TIME OF THIS REPORT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING. AN UPDATED PTC IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00767	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 9/25/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/25/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) ON (B)(6) 2014 WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6). STUDY DESCRIPTION: ESSURE GENERIC ACTIVE ONLINE LISTENING. CONSUMER WAS EXPERIENCING ABDOMINAL PAIN. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULTS WERE PROVIDED ON 18.DEC.2014: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 14-AUG-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015

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(CASE# FDA-2015-N-2781-0547). CONSUMER REPORTED THAT SHE WAS IMPLANTED WITH ESSURE ON (B)(6) 2010. ACCORDING TO HER, SHE BEGAN HAVING PROBLEMS 2 HOURS AFTER IMPLANTATION AND HAS HAD THEM EVER SINCE. THE CHRONIC PAIN AND FATIGUE, COUPLED WITH EXTENDED MENSTRUAL CYCLES SENT HER BACK TO THE DOCTORS MULTIPLE TIMES OVER THE YEARS. THEY FINALLY DID EXPLORATORY SURGERY TO FIND THE REAL PROBLEM. THE END RESULT WAS NO OTHER ABNORMALITIES, BUT ABSCESSES FROM THE SURGERY AND ADHESIONS ON HER BOWELS FROM THE SUBSEQUENT SURGERIES. IN ADDITION, CONSUMER STATES THAT SHE HAS FINALLY FOUND A DOCTOR WHO AGREES THE COILS ARE DAMAGING HER BODY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD CHRONIC ABDOMINAL PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO AN EXPLORATORY SURGERY AND NO OTHER ABNORMALITIES WERE FOUND. AFTER THIS PROCEDURE, SHE HAD ABSCESSES. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY ABDOMINAL PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER STATED HER PAIN STARTED HOURS AFTER ESSURE INSERTION. SHE WAS SUBMITTED TO AN UNSPECIFIED EXPLORATORY SURGERY (IT SEEMS ESSURE WAS NOT REMOVED DURING THIS PROCEDURE). AN UNSPECIFIED TIME LATER SHE HAD ABSCESSES, WHICH SHE RELATED TO THIS PROCEDURE. ALTHOUGH LIMITED INFORMATION IS AVAILABLE IN THIS CASE; IT CANNOT BE EXCLUDED THAT THE REPORTED PAIN (WHICH REQUIRED SURGERY) WAS A CONSEQUENCE OF ESSURE THERAPY. THEREFORE, ALL EVENTS WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT (ABSCESS REGARDED AS A COMPLICATION OF AN ESSURE RELATED PROCEDURE). ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00768	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 3/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT POSTED ONLINE BY A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES AND RECEIVED BY BAYER ON 03-DEC-2014. THE CONSUMER WAS INVOLVED IN AN ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. SHE WAS HAVING A DIFFICULT DAY HEADACHE AND NAUSEATED. NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT RECEIVED ON 19-DEC-2014. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS NA ANTICIPATED EVENT. MEDICAL ASSESSMENT. THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 04-FEB-2015: ESSURE WAS INSERTED FOR BIRTH CONTROL. THE CONSUMER STATED SHE SUFFERED WITH HEADACHE, BACK PAIN, NAUSEA AND METAL TASTE IN MOUTH. SHE ALSO COMPLAINED OF STABBING PAIN ON RIGHT SIDE (AROUND THE RIB CAGE). FOLLOW-UP RECEIVED ON

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12-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0252). CONSUMER REPORTED THAT SHE HAD ESSURE BACK IN 2011. FIRST CONSUMER TOLD HER DOCTOR SHE FELT THEM, AND SHE SAID NO WAY. CONSUMER STARTED WITH TINGLING IN HER LEGS, THEN HEADACHES, LOSS OF SEXUAL DRIVE, TIREDNESS AND THEN IT STARTED TO GET WORSE, CONFUSION, DIZZINESS, NAUSEA, PAIN THROUGHOUT HER BODY AND IT WAS TO THE POINT WHERE SHE FELT THAT HER JOB OF 4 YEARS WAS IN JEOPARDY. HER LIFE WAS MISERABLE BECAUSE SHE FELT SHE HAD NO QUALITY OF LIFE AND EVERY PHYSICIAN THAT SHE SAW GAVE HER DIAGNOSIS FROM ARTHRITIS TO FIBROMYALGIA. CONSUMER TALKED TO HER MEDICAL DOCTOR WHO SAID IT COULD BE RELATED TO ESSURE AND THAT THEY WOULD HAVE TO SEE IT IN THE FUTURE. PHYSICIAN GAVE HER MEDICATION FOR PAIN, NAUSEA AND THE FIBRO (AS REPORTED). IN (B)(6) 2014, SHE FOUND A DOCTOR WHO LISTENED TO HER CONCERNS, SHE TOLD HIM THAT SHE HAD 3 C-SECTIONS DONE AND HAD A GALL BLADDER REMOVAL BEFORE ESSURE. THE PHYSICIAN FELT THAT ESSURE SHOULDN'T HAVE BEEN OFFERED AND THAT IT WAS CREATING MORE SCAR TISSUE AND ENHANCING THE PAIN WITH SEX (WHEN SHE DID HAVE IT) SO HE RECOMMENDED A HYSTERECTOMY. ON (B)(6) 2015, SHE HAD HYSTERECTOMY DONE AND 4 MONTHS LATER SHE HASN'T HAD A SYMPTOM: NO HEADACHES, NAUSEA OR PAIN. UPDATED PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-AUG-2015 WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS SOLICITED, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN WITH SEX. SHE UNDERWENT A HYSTERECTOMY 4 YEARS AFTER ESSURE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN AND DYSPAREUNIA MAY OCCUR AFTER ESSURE INSERTION. CONSIDERING THE NATURE OF THE REPORTED EVENT, AND SINCE THE PAIN RESOLVED AFTER HYSTERECTOMY, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. UPON RECEIPT OF FOLLOW-UP INFORMATION STATING THE CONSUMER UNDERWENT A HYSTERECTOMY, THIS CASE WAS UPGRADED TO INCIDENT DUE TO REQUIRED INTERVENTION. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 19-OCT-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00769	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/4/2013
Explant Date (E7): 2/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039005) IN UNITED STATES ON 15-JAN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ON (B)(6) 2014 THE CONSUMER STARTED EXPERIENCING EXPERIENCED SWELLING, MUSCLE WEAKNESS, TINGLING IN FACE, ARMS AND LEG, HIP PAIN, MULTIPLE BURSITIS, FOGGINESS, HEADACHES, RASH THAT COMES AND GO AND IRREGULAR PERIODS CAUSING BLOOD CLOTS. HAD UNDERGONE MULTIPLE TESTING TO RULE OUT CERTAIN DISEASE THAT WOULD CAUSE HER SYMPTOMS. ALL HAVE COME BACK NEGATIVE. THE LAST TESTING SHE HAD BEEN DONE WAS FOR NICKEL ALLERGY WHICH CAME BACK POSITIVE. BECAUSE OF THIS, SHE WILL HAVE TO HAVE A HYSTERECTOMY TO REMOVE THE COILS. THIS AFFECTED HER BY NOT BEING ABLE TO WORK FULL TIME. SHE WAS IN CONSTANT PAIN AND ALWAYS TIRED. INSTEAD OF FEELING LIKE SHE WAS 70 YEARS OLD. PTC INVESTIGATION RESULT RECEIVED ON 01-FEB-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE CONSIDERED RELATED BY COMPANY ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE AND WERE . NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER

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BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 16-MAR-2015 ESSURE WAS INSERTED ON (B)(6) 2013. AN INJURY (REQUIRED INTERVENTION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. CASE WAS UPGRADE TO SERIOUS. FOLLOW-UP WILL BE REQUESTED. FOLLOW-UP INFORMATION ON 13-AUG-2015: THIS FOLLOW-UP INFORMATION HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)): THE CONSUMER HAD THE CONFIRMATION TEST IN (B)(6) 2014; IT SHOWED BOTH TUBES BLOCKED. A MONTH LATER SHE BEGAN TO HAVE SWELLING IN HANDS, FEET, LEGS AND RIGHT ARM. SHE FIRST WENT TO HER DOCTOR WHO ATTRIBUTED THE PROBLEM TO ESSURE. TESTS AND BLOOD WORK CAME BACK FINE. THE CONSUMER STATED HER HEALTH BEGAN TO DETERIORATE: SHE HAD TINGLING IN HANDS AND FEET, LOSS OF FEELING ON THE RIGHT SIDE OF HER BODY, MOBILITY ON RIGHT SIDE WAS WEAK. SHE WENT TO PHYSICAL THERAPY, NEUROLOGIST, ORTHO DOCTOR - MUSCULAR SCLEROSIS WAS SUSPECTED, BUT CAT SCAN WAS NEGATIVE. SHE ALSO HAD PANIC ATTACKS, ANXIETY, VIRTU GO (AS REPORTED), WEIGHT GAIN, HIGH BLOOD PRESSURE, HEADACHES, EXTREME FATIGUE AND SHE FELT OLDER THAN SHE WAS. SHE EXPERIENCED NUMEROUS URINARY TRACT INFECTIONS, YEAST INFECTION, NO PERIOD AT TIMES, PERIODS THAT WERE EVERY TWO WEEKS, BLEEDING AFTER INTERCOURSE, BOILS AND BARTHOLOME CYST. SHE WAS TESTED LAST FOR A NICKEL ALLERGY THAT CAME BACK POSITIVE. SHE HAD A HYSTERECTOMY IN (B)(6) 2015 AND ALL HER SYMPTOMS HAVE GONE AWAY - SHE WAS 100% BETTER. THIS POST (POST# (B)(4)) WAS IDENTIFIED ON 29-AUG-2015 DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE. CONSUMER, WHO IS A SINGLE MOM, REPORTED THAT SHE HAD ESSURE IMPLANTED AFTER HER THIRD CHILD IN (B)(6) 2013. FOR THE FIRST 3 MONTHS SHE WAS FINE, THEN A MONTH AFTER HAVING THE HYSTEROSALPINGOGRAM TEST SHE WOKE UP WITH SWELLING AND PAIN IN HER RIGHT ARM. SHE WENT TO THE PHYSICIAN BUT NOTHING COULD BE FOUND. BY THE END OF THE WEEK, SHE HAD SWELLING IN BOTH LEGS AND DEVELOPED BURSITIS IN BOTH KNEES. SHE WAS SENT TO PHYSICAL THERAPY WHICH DIDN'T HELP. THEN, SHE WAS SENT TO A RHEUMATOLOGIST WHO TRIED CORTISONE SHOT THAT MADE IT WORSE. WITHIN THE NEXT COUPLE OF WEEKS HER HEALTH DETERIORATED. SHE HAD TINGLING AND NUMBNESS ON HER RIGHT SIDE OF THE BODY. SHE ALSO HAD SEVERE HEADACHES, ANXIETY, DEPRESSION, VERTIGO, DIZZY SPELLS, SWELLING OF THE HANDS AND FEET, NO PERIOD AT TIMES, BARTHOLOME CYST, BLEEDING DURING INTERCOURSE, SHARP PAIN IN HER RIGHT SIDE PELVIC, EXTREME FATIGUE, COULDN'T STAND FOR LONG PERIODS OF TIME (LOST TIME AT WORK BECAUSE SHE WAS UNABLE TO STAND), HIVES ON HER BODY (ALWAYS ITCHY), URINARY TRACT INFECTIONS AND YEAST INFECTIONS, CONSTANTLY PAIN IN RIGHT HIP, COULD NOT LOSE ANY WEIGHT (NO MATTER WHAT SHE TRIED), HER STOMACH WOULD SWELL AND HAD PREGNANCY SYMPTOMS ALL THE TIME. IN ADDITION, CONSUMER REPORTED THAT SHE WAS SEEN BY NUMEROUS SPECIALIST THOUGHT SHE HAD MULTIPLE SCLEROSIS, BUT MAGNETIC RESONANCE IMAGES CAME BACK FINE. THEY TRIED PHYSICAL THERAPY, MEDICINES, CORTISONE SHOTS WHICH FAILED TO WORK. THE LAST TEST THEY HAD HER HAS WAS A NICKEL ALLERGY TEST WHICH WAS SUPPOSED TO BE KEPT ON FOR 3 DAYS BUT LASTED A FEW SHORT HOURS. SHE WAS SO ALLERGIC SHE NEEDED TO REMOVE IT IMMEDIATELY. ON (B)(6) 2015 SHE HAD A HYSTERECTOMY AT THE AGE OF (B)(6). UPDATED PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 08-SEP-2015: UPDATED MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL ALLERGY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE

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SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE CONSUMER HAD A RASH AND TESTING FOR NICKEL ALLERGY CAME BACK POSITIVE. SHE WAS SUPPOSED TO BE KEPT ON FOR 3 DAYS BUT IT LASTED A FEW SHORT HOURS. SHE WAS SO ALLERGIC SHE NEEDED TO REMOVE IT IMMEDIATELY. ACCORDING TO HER; DUE TO THIS A HYSTERECTOMY WAS PERFORMED. CONSIDERING EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. SINCE DEVICES REMOVAL WAS REQUIRED; THIS CASE WAS CONSIDERED AN INCIDENT. NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THEREFORE, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00770	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B61397

Single Use: Y
Implant Date (E6): 4/4/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# MW5039117) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THAT THE ESSURE WAS MIGRATED. THE CONSUMER HAD SERIOUS CRAMPS AND BLEEDING FOR OVER 25 DAYS. IT WAS ALSO REPORTED THAT NO PHYSICIAN WANT TO TAKE THE COILS OUT. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 01-FEB-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 02-APR-2015: ON (B)(6) 2014, ESSURE DEVICES WERE INSERTED; THE LOT NUMBER USED WAS B61397. FOLLOW-UP RECEIVED ON 09-APR-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE

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UPDATED: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: B61397; PRODUCTION DATE: 26-AUG-2013; EXPIRATION DATE: 31-AUG-2016. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. ONE FURTHER AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH, BUT THIS CASE DOES NOT REFER ALSO TO A SIMILAR TYPE OF ADVERSE EVENTS. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)). CONSUMER REPORTED THAT SHE HAD A VAGINAL HYSTERECTOMY BECAUSE HER COIL MIGRATED INTO HER UTERUS AND WAS CAUSING HER PAIN, AMONGST OTHER THINGS SUCH AS BLEEDING FOR 15 DAYS AND ETC. SHE STATES THAT SHE UNDERSTANDS THAT ESSURE WAS MADE TO BE A PERMANENT BIRTH CONTROL AND SHE WOULD BE HAPPY IF IT WAS JUST THAT AND DIDN'T CAUSE HER THESE OTHER ISSUES. ACCORDING TO CONSUMER, FOR HER AT (B)(6), TO HAVE A HYSTERECTOMY ISN'T THE HEALTHIEST THING TO DO. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE COIL MIGRATED INTO HER UTERUS AND WAS CAUSING HER PAIN (INTERPRETED AS PELVIC PAIN). SHE ALSO HAD BLEEDING FOR OVER 25 DAYS (INTERPRETED AS GENITAL BLEEDING). CONSUMER UNDERWENT A VAGINAL HYSTERECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY). ALSO, DURING ESSURE USE, PELVIC PAIN, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE THE ESSURE COIL MIGRATED INTO HER UTERUS AND THE CONSUMER BELIEVED IT WAS CAUSING HER PAIN, AMONGST OTHER SYMPTOMS SUCH AS BLEEDING. GIVEN THE NATURE OF THESE EVENTS, CAUSALITY IS ASSESSED AS RELATED TO ESSURE USE. UPON RECEIPT OF INFORMATION STATING THAT THE CONSUMER UNDERWENT A VAGINAL HYSTERECTOMY, THIS CASE WAS UPGRADED TO INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS UPDATED. PTC GLOBAL NUMBER: (B)(4). LOT NUMBER B61397 (PRODUCTION DATE 26-AUG-2013; EXPIRATION DATE 31-AUG-2016). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION,

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00771	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/6/2010
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5039601) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. CONSUMER REPORTED THAT SHE SINCE THE ESSURE INSERTION, SHE HAS HAD HORRIBLE CRAMPS, WEIGHT GAIN, MIGRAINES, BACK PAIN, DEPRESSIONS, HIVES, CONFUSION AND MUCH MORE. PTC INVESTIGATION RESULT WAS RECEIVED ON 12-FEB-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON

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THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 11-MAY-2015 FROM CONSUMER VIA REGULATORY AUTHORITY (CASE#MW5039601). ESSURE WAS INSERTED ON (B)(6) 2010. FOLLOW UP INFORMATION RECEIVED ON 25-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. FOLLOW-UP RECEIVED ON 13-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4)). CONSUMER REPORTED THAT, THANKS TO ESSURE, SHE DOES NOT FEEL LIKE A COMPLETE WOMEN. SHE HAD TO HAVE A HYSTERECTOMY LEAVING ONLY HER OVARIES DUE TO THE DAILY STRUGGLE OF ESSURE. THE PAIN BECAME TOO UNMANAGEABLE, THE FATIGUE MADE LIVING VERY HARD, SHE GAINED WEIGHT, WAS IRRITABLE, BLED LIKE CRAZY, HAD CRAMPS SO BS (UNDERSTOOD AS BAD) SHE COULDN'T WALK. NOT TO MENTION THE MIGRAINES, MIND CONFUSION AND LOSS OF WANTING TO MAKE LOVE. IN (B)(6) OF 2015, CONSUMER HAD SURGERY TO REMOVE THE BIRTH CONTROL ESSURE FROM HER BODY AND STATES THAT, 7 MONTHS LATER; SHE IS FEELING ALMOST NORMAL AGAIN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLED LIKE CRAZY. SHE ALSO PRESENTED A PAIN THAT BECAME TOO UNMANAGEABLE. THESE EVENTS, SEEN AS PELVIC PAIN AND GENITAL BLEEDING, ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. GIVEN THEIR NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSAL RELATIONSHIP WITH ESSURE USE CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS ASSESSED AS NON-INCIDENT. UPON MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, IT WAS DETECTED THAT DEVICE REMOVAL WAS REQUIRED (VIA HYSTERECTOMY) AND SEVEN MONTHS LATER, SHE WAS FEELING ALMOST NORMAL AGAIN (RECOVERED). THEREFORE, THIS CASE WAS UPGRADED TO INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00783	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2003
Explant Date (E7): 7/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4); AWARENESS DATE: 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2003. HER MEDICAL HISTORY INCLUDED ONE CHILD. IN 2003 SHE HAD ESSURE IMPLANTED UNDER ANESTHESIA. IN 2007 SHE BECAME VERY ILL WITH JOINT PAIN, BURNING OF THE SKIN AND VERY FATIGUE. AFTER SEVERAL TEST SHE WAS DIAGNOSED WITH AUTOIMMUNE DISEASE, FIBROMYALGIA AND CHRONIC FATIGUE SYNDROME. SHE TOOK 4 DIFFERENT MEDICATIONS. IN (B)(6) OF 2015 SHE CAME ACROSS SYMPTOMS THAT WERE LISTED DUE TO ESSURE SIDE EFFECT. TESTS WERE DONE BY HER DOCTOR; HYSTEROSCOPY TEST SHOWED THAT ESSURE COILS HAD MOVED OUT OF FALLOPIAN TUBES AND WERE TANGLED TOGETHER IN UTERUS. THE COIL WAS ALSO UNRAVELED, DID NOT HAVE ANY TURNS. IT LOOKED LIKE A LONG PIECE OF WIRE. ONE COIL WAS ALSO BROKEN AND THE PIECE WAS POKING THROUGH HER FALLOPIAN TUBE. ON (B)(6) 2015 SHE HAD A FULL ABDOMINAL HYSTERECTOMY. AFTER SURGERY, HER FATIGUE WAS COMPLETELY GONE. HER JOINT PAIN IS NOW RELIEVED BY 70%. ACCORDING TO THE CONSUMER, ESSURE WAS CAUSING HER TO BE IN SEVERE PAIN AND SICK FOR 8 YEARS. FOLLOW-UP INFORMATION RECEIVED FROM THE PHYSICIAN ON 21-AUG-2015: IN 2007 THE CONSUMER STARTED EXPERIENCING SEVERE JOINT PAIN AND VERY FATIGUE. HER SKIN HURT TO THE TOUCH AND SHE HAD A BURNING SENSATION THROUGHOUT WHOLE BODY, ALSO HER TEETH WERE CRACKING AND SHE HAD SEVERAL TEETH REMOVED. AFTER SEEING SEVERAL DOCTORS, SHE WAS DIAGNOSED WITH FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, OSTEOPOROSIS AND AUTOIMMUNE DISEASE SHE HAD TO STOP WORKING AND WAS PUT ON DISABILITY (HER DAY CONSISTED OF BEING IN BED MOST IF THE

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DAY) HER SYMPTOMS WERE VERY SEVERE AND SHE USED TO RECEIVE 4 VICODEN/DAY AND ALSO 3 OTHER MEDICATION. IN 2015 HER GYNECOLOGIST PERFORMED SEVERAL TESTS WHICH REVEALED THAT ESSURE COILS WERE BROKEN AND HAD MIGRATED INTO HER UTERUS. THE COILS WERE ENTWINED AND TANGLED TOGETHER IN ONE BIG KNOT. ON (B)(6) 2015 SHE UNDERWENT A FULL ABDOMINAL HYSTERECTOMY. SIX WEEKS POST-SURGERY SHE HAD NO FATIGUE, NO JOINT PAIN AND WAS FEELING AMAZING. ACCORDING TO HER, THE SYMPTOMS WERE GONE ALMOST IMMEDIATELY AFTER SURGERY. ADDITIONAL INFORMATION PROCESSED AND RECEIVED ON 06-SEP-2015: PTC RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A PRODUCT TECHNICAL ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD AN HYSTEROSCOPY, APPROXIMATELY 12 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION, WHICH REVEALED THAT ESSURE COILS HAD MOVED OUT OF HER FALLOPIAN TUBES; ONE COIL WAS BROKEN AND THE PIECE WAS POKING THROUGH HER FALLOPIAN TUBE. SHE WAS SUBMITTED TO A HYSTERECTOMY. ADDITIONALLY, SHE WAS DIAGNOSED WITH AUTOIMMUNE DISEASE. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND TECHNICAL ANALYSIS, EXCEPT FOR THE REPORTED AUTOIMMUNE DISEASE. IN THIS CASE, CONSUMER HAD AN UNSPECIFIED AUTOIMMUNE DISEASE WITH ONSET 4 YEARS AFTER ESSURE PLACEMENT. GIVEN THIS WEAK TEMPORAL RELATIONSHIP AND CONSIDERING EVENT'S NATURE CAUSALITY WITH ESSURE IS CONSIDERED VERY UNLIKELY. REGARDING THE REMAINING EVENTS, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION, DISLOCATION OR OCCUR AS A RESULT OF A UTERINE/FALLOPIAN TUBE PERFORATION. IN THIS CASE, EVENT'S MECHANISM IS NOT KNOWN; HOWEVER GIVEN THEIR NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS SUCH AS FATIGUE AND PAIN WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED TO UNCONFIRMED QUALITY DEFECT (NO COMPLAINT SAMPLE OR LOT INFORMATION PROVIDED). THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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FOLLOW UP 07-JAN-2016: FOLLOW UP INFORMATION WAS RECEIVED FROM THE CONSUMER. CONSUMER REPORTED THAT 6 MONTHS POST-OPERATIVE FULL ABDOMINAL HYSTERECTOMY AND HER SYMPTOMS WERE GONE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE R

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00792	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2006
Explant Date (E7): 8/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0100 AND FDA-2014-N-0736-0015, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2006. SHE WAS IMPLANTED WITH THE ESSURE DEVICE IN6V 2006. IT WAS THE BEST OPTION FOR HER AT THE TIME BECAUSE SHE HAD A BAD PREGNANCY AND THE DOCTOR REFUSED TO GIVE HER A TUBAL LIGATION AT THE TIME OF DELIVERY. WITHIN THE FIRST YEAR SHE STARTED HAVING ISSUES THAT HER DOCTORS GAVE OTHER DIAGNOSES. THROUGH THE NEXT 8 YEARS SHE WAS DIAGNOSED WITH INTERSTITIAL CYSTITIS, PELVIC FLOOR DYSFUNCTION, FIBROMYALGIA, CHRONIC BACK PAIN CAUSED BY ARTHRITIS, SEVERE DEPRESSION, IRRITABLE BOWEL SYNDROME, DIVERTICULITIS AND MIGRAINES, INSOMNIA, SKIN RASHES, ISOLATED SPOTS OF NUMBNESS AND/OR A SCALDED BURNING FEELING OF THE SKIN, PUNGENT SMELLING NIGHT SWEATS, METALLIC TASTE IN MOUTH AND HER HAIR WAS FALLING OUT. SHE HAD HER FALLOPIAN TUBES AND PART OF UTERUS REMOVED IN (B)(6) OF 2014. SHE COULD NOT HAVE A COMPLETE HYSTERECTOMY BECAUSE OF THE PELVIC FLOOR DYSFUNCTION AND SHE WAS PROLAPSING SO SEVERELY. SINCE HAVING THEM REMOVED SHE HAD NO LONGER MIGRAINES. HER LOWER BACK AND JOINTS HAVE VIRTUALLY NO PAIN AND SHE HAD ONLY HAD ONE FLARE UP OF FIBROMYALGIA. SHE HAS LASTING EFFECTS, SHE WAS TOLD THAT HER ADRENAL SYSTEM WAS BAD BECAUSE OF THE STRESS PUT ON HER BODY AND SHE WAS DIAGNOSED WITH HYPOTHYROIDISM. SHE DID NOT HAVE THESE ISSUES BEFORE ESSURE DEVICE IMPLANTED. AN ABDOMINAL X-RAY WAS DONE SINCE REMOVAL PROCESS TO KNOW IF SHE MAY STILL HAVE COIL OR PET FIBER FRAGMENTS REMAINING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY

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CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CHRONIC BACK PAIN AND DIVERTICULITIS. SHE HAD HER FALLOPIAN TUBES AND PART OF UTERUS REMOVED IN (B)(6) 2014. THE CHRONIC BACK PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND DIVERTICULITIS IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. THE CHRONIC BACK PAIN IS LISTED WHILE THE OTHER EVENT IS UNLISTED. IN THIS PARTICULAR CASE, BOTH EVENTS OCCURRED DURING THE USE OF ESSURE. CONSIDERING THAT THE TEMPORAL RELATIONSHIP IS COMPATIBLE AND THERE IS NO ALTERNATIVE EXPLANATION, THE CHRONIC BACK PAIN IS ASSESSED AS RELATED. HOWEVER, THE DIVERTICULITIS IS ASSESSED AS UNRELATED BECAUSE ESSURE HAS A LOCALIZED ACTION IN THE FALLOPIAN TUBES AND IT IS UNLIKELY THAT IT WOULD CAUSE DIVERTICULITIS. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00797	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 8/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/30/2013
Explant Date (E7): 10/30/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. SHE SUFFERED SEVERE LOWER BACK PAIN THAT OCCURRED THE MORNING AFTER INSERTION. SHE RETURNED TO HER OB-GYN WITH LOWER BACK PAIN ISSUES AND WAS GIVEN MEDICATION FOR A SUSPECTED URINARY TRACT INFECTION WHICH SHE DID NOT HAVE AS THE PAIN DID NOT GO AWAY. SHE WAS FORCED TO UNDERGO THREE SEPARATE BACK PROCEDURES WITH NO ALLEVIATION OF PAIN. SHE DEVELOPED ABDOMINAL PAIN AROUND THE 6 MONTH MARK AND RETURNED TO HER IMPLANTING DOCTOR AND INFORMED HIM OF ABDOMINAL PAIN, BLOATED BELLY, AND SEVERE WEIGHT GAIN AND ASKED FOR HIM TO REMOVE THE IMPLANTS. SHE WAS SENT FOR BLOOD WORK AND A SONOGRAM WHICH SHOWED A CYST ON HER LEFT OVARY. THEN, A DIAGNOSTIC LAPAROSCOPY WAS PERFORMED AND SHE WAS FOUND TO HAVE MODERATE TO SEVERE ENDOMETRIOSIS WHICH SHE HAD NEVER BEEN DIAGNOSED WITH BEFORE. ON (B)(6) 2014, AFTER EXACTLY 14 MONTHS OF ESSURE, A LAVH-BSO (INTERPRETED AS LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY - BILATERAL SALPINGO-OOPHORECTOMY) WAS PERFORMED. HER BACK PAIN WAS IMMEDIATELY GONE UPON WAKING UP IN RECOVERY ROOM. AS OF (B)(6) 2015 HER BACK PAIN HAS NOT RETURNED. HER BLOATED BELLY WAS GONE ALSO. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LOWER BACK PAIN. THIS EVENT IS SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BACK PAIN MAY OCCUR DURING

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ESSURE USE. IN THIS CASE, SHE SUFFERED SEVERE LOWER BACK PAIN IN THE MORNING AFTER INSERTION. THEN, SHE WAS FORCED TO UNDERGO THREE SEPARATE BACK PROCEDURES WITH NO ALLEVIATION OF PAIN. 6 MONTHS LATER, SHE ALSO PRESENTED OTHER NON-SERIOUS EVENTS AND ENDOMETRIOSIS WAS DIAGNOSED. EXACTLY 14 MONTHS AFTER INSERTION, LAVH-BSO (HYSTERECTOMY) WAS PERFORMED AND HER BACK PAIN WAS IMMEDIATELY GONE. CONSIDERING EVENT'S NATURE, CLOSE TEMPORAL RELATIONSHIP AND PROMPT RECOVERY AFTER REMOVAL, CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED. SINCE INTERVENTION WAS REQUIRED (HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00799	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE SIGNED UP TO HAVE NO MORE CHILDREN AND NOT TO HAVE A HYSTERECTOMY AND BE LEFT WITH AUTOIMMUNE PROBLEMS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE A HYSTERECTOMY AND WAS LEFT WITH AUTOIMMUNE PROBLEMS. THE HYSTERECTOMY IS LISTED WHILE AUTOIMMUNE DISORDER IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE REASON FOR HYSTERECTOMY WAS NOT PROVIDED. DESPITE THE LACK OF INFORMATION, SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED AND THE REMOVAL OF ESSURE MAY REQUIRE A HYSTERECTOMY, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. IN THIS CASE, THE TEMPORAL RELATIONSHIP BETWEEN ESSURE AND THE AUTOIMMUNE DISORDERS IS NOT CLEAR. ALTHOUGH, NO ALTERNATIVE EXPLANATION IS AVAILABLE, SINCE ESSURE HAS A LOCALIZED ACTION IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT ESSURE WOULD CAUSE AUTOIMMUNE DISORDERS. THEREFORE, IT IS ASSESSED AS UNRELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00800	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE HAD A HYSTERECTOMY TO REMOVE ESSURE BECAUSE SHE WAS ALLERGIC TO IT. PHYSICIAN CUT ESSURE IN HALF DURING REMOVAL DUE TO NOT BEING IMPLANTED IN THE CORRECT PLACE (EVEN THOUGH HER HSG SAID THEY WERE). SHE NOW HAS SO MUCH SCARRING AND INFLAMMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD A HYSTERECTOMY TO REMOVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) BECAUSE SHE WAS ALLERGIC TO IT. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, CONSIDERING EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00801	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE HAD UNBEARABLE PAIN TO THE POINT OF BARELY BEING ABLE TO WALK, NONSTOP MENSTRUAL CYCLE FOR A SOLID STRAIGHT 2 YEARS. SHE COULD NOT LIFT HER LEG HIGH ENOUGH TO PUT HER FOOT IN A SHOE. SHE WAS DEPRESSED AND HAD NO DESIRE FOR SEX BECAUSE OF THE PAIN. THE WEIGHT GAIN WAS ALSO DEPRESSING (AS A MOTHER OF 4 SHE ALWAYS LOST BACK DOWN TO HER ORIGINAL WEIGHT FEW MONTHS AFTER DELIVERY, BUT NOT WITH ESSURE). ON AN UNSPECIFIED DATE, SHE WAS DIAGNOSED WITH RA (RHEUMATOID ARTHRITIS). NONE OF HER PROBLEMS WERE THERE BEFORE ESSURE. SHE FINALLY CONVINCED HER PHYSICIAN TO REMOVE ESSURE, AND IN 2012 SHE HAD HER SURGERY. HER LIFE IS BACKING TO NORMAL NOW. SHE IS STILL LIMITED TO DO SOME THINGS BECAUSE OF THE RA WHICH SHE BELIEVED WAS CAUSED FROM HAVING ESSURE FOR SO LONG. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD NONSTOP MENSTRUAL CYCLE FOR A SOLID STRAIGHT 2 YEARS, AND WAS DIAGNOSED WITH RA (RHEUMATOID ARTHRITIS). SHE UNDERWENT SURGERY TO REMOVE ESSURE, ON AN UNSPECIFIED TIME AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. NONSTOP MENSTRUAL CYCLE, INTERPRETED AS MENORRHAGIA, IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN

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THE NATURE OF THE EVENT NONSTOP MENSTRUAL CYCLE, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. IN RHEUMATOID ARTHRITIS (RA) AN AUTOIMMUNE REACTION LEADS TO SYNOVIAL HYPERTROPHY AND CHRONIC JOINT INFLAMMATION ALONG WITH THE POTENTIAL FOR EXTRA-ARTICULAR MANIFESTATIONS. IT IS THEORIZED TO OCCUR IN GENETICALLY SUSCEPTIBLE INDIVIDUALS. CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND ESSURE WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SURGERY TO REMOVE ESSURE). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00802	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0058, AWARENESS DATE 13-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED SHE SUFFERED FOR YEARS BEFORE SHE HAD TO HAVE TOTAL HYSTERECTOMY AT THE (B)(6). ESSURE CAUSED HER MANY ISSUES AND ALMOST A YEAR POST OP SHE WAS FEELING BETTER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ACCORDING TO HER; SHE SUFFERED FOR YEARS BEFORE SHE HAD TO HAVE TOTAL HYSTERECTOMY AT THE (B)(6). THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED SHE SUFFERED AND ESSURE CAUSED HER MANY ISSUES; THESE ISSUES WERE NOT SPECIFIED AND NO MEDICAL REASON FOR HYSTERECTOMY WAS GIVEN. ALTHOUGH LIMITED INFORMATION WAS PROVIDED IN THIS CASE; AS CONSUMER RELATED HER HYSTERECTOMY TO ESSURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00804	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED SHE WAS PERSONALLY BEING AFFECTED BY THE DEVICE NOT ONLY PHYSICALLY BUT ALSO EMOTIONALLY PERMANENTLY. SHE STATED SHE USED TO BE A HEALTHY PERSON WITH NO SURGERIES PERFORMED; SHE NEVER USED BIRTH CONTROL PILLS AND WANTED TO HAVE A PERMANENT SOLUTION TO AVOID PREGNANCY AFTER HAVING HER FOURTH CHILD. SHE REPORTED THAT ONCE SHE HAD THIS DEVICE IMPLANTED IN HER THINGS TOOK A 180 DEGREE TURN TO THE WORST TO THE POINT NOT ONLY HER PHYSICALLY HEALTH WAS AFFECTED BUT HER MENTAL AS WELL, TO KNOW THAT SHE USED TO BE HEALTHY FOR HER WHOLE LIFE AND THEN TO SEE HER HEALTH DETERIORATE WAS OVERWHELMING BECAUSE SHE KNEW SHE WAS NEGLECTING HER FAMILY. SHE REPORTED THAT ENDED UP WITH 3 SURGERIES IN LESS THAN 6 MONTHS TO HELP REMOVE PART OF THE SIDE EFFECTS THIS DEVICE CAUSED IN HER BODY AND IT LEFT A PERMANENT MARK OF BITTERNESS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO ENDED UP WITH 3 SURGERIES IN LESS THAN 6 MONTHS TO HELP REMOVE PART OF THE SIDE EFFECTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED HER HEALTHY DETERIORATE, BUT LIMITED INFORMATION WAS

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GIVEN. NO REASON OR DETAILS OF THE SURGERIES WAS PROVIDED. HOWEVER, SINCE CONSUMER RELATED THESE PROCEDURES TO SIDE EFFECTS FROM ESSURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00805	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/29/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0215, AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE, FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT FOR SIX VERY LONG YEARS ESSURE TOOK AHOLD OF HER LIFE AND RAN IT INTO THE GROUND. SHE SUFFERED FROM CHRONIC PAIN, IRREGULAR BLEEDING, MIGRAINES THAT LASTED FOR DAYS AND MOST OF THE TIMES WEEKS. SEX BECAME UNBEARABLE WITH SHARP SHOOTING PAIN, MEMORY WAS FOGGY AND MOST DAYS SHE STRUGGLED TO FIND SIMPLE WORDS THAT WOULDN'T COME OUT RIGHT. SHE HAD HORRIBLE UNEXPLAINABLE PAIN IN BREASTS WHICH MADE IT HARD TO WEAR A BRA OR WHEN SHE TOOK IT OFF IT WOULD SEND SHARP PAIN THROUGH HER BODY. CONSUMER HAD HORRIBLE WEIGHT GAIN, WENT FROM 120 TO (B)(6) AND COULDN'T GET THE WEIGHT OFF UNTIL THE INFLAMMATION IN ABDOMEN (MAKING SHE LOOK EIGHT MONTHS PREGNANT) SPREAD TO HER COLON AND SHE WAS DIAGNOSED WITH COLITIS AND COULDN'T KEEP FOOD DOWN. SHE THREW UP EVERYTHING SHE ATE AND STAYED SICK. CONSUMER HAD CONSTANT DIARRHEA FOR EIGHT MONTHS. HER MOODS WERE UNCONTROLLABLE. SHE WAS ALWAYS SLEEPY AND HAD ZERO ENERGY. SHE HAD METALLIC TASTE IN HER MOUTH THAT NEVER SEEMED TO GO AWAY WITH BRUSHING. THE NEVER KNOWING IF SHE WOULD START HER PERIOD OR NOT WAS A PAIN, HAVING IT TWO OR THREE TIMES IN ONE MONTH WAS RIDICULOUS. THE CHRONIC PAIN MADE LIFE UNBEARABLE, THE DEPRESSION IT CAUSED MADE HER WONDER IF SHE WOULD EVER GET HER LIFE BACK. ON (B)(6) 2015 SHE REGAINED SOME OF HER LIFE BUT LOST ALL OF HER FEMALE ORGANS EXCEPT ONE OVARY. SHE NEVER SIGNED UP FOR MAJOR SURGERY

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AS HER FORM OF BIRTH CONTROL AND NOW SHE PRAYS THAT HER ONE OVARY CONTINUES TO FUNCTION AND THAT HER LIFE WILL AT SOME POINT RETURN TO NORMAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CHRONIC PAIN (INTERPRETED AS PELVIC PAIN) AND IRREGULAR BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE STATED THAT SHE LOST ALL OF HER FEMALE ORGANS EXCEPT ONE OVARY (INTERPRETED AS HYSTERECTOMY). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENTS AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00809	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0272, AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. ESSURE WAS NOT THE SAFE AND EFFECTIVE BIRTH CONTROL IT IS MARKETED TO BE. IT TOOK A FULL HYSTERECTOMY AT AGE (B)(6) FOR HER TO HAVE HER QUALITY OF LIFE BACK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD TO HAVE A FULL HYSTERECTOMY TO HAVE HER QUALITY OF LIFE BACK. THE HYSTERECTOMY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE REASON FOR HYSTERECTOMY WAS NOT PROVIDED. DESPITE THE LACK OF INFORMATION, SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED AND THE REMOVAL OF ESSURE MAY REQUIRE A HYSTERECTOMY, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00814	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 9/29/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A 31 YEARS OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. AT TIME OF THE INSERTION, SHE HAD 2 CHILDREN AND 3 STEP-CHILDREN. THE CONSUMER REPORTED SHE WAS IN IMMEDIATE AND CONSTANT PAIN WHERE THE COILS WERE PLACED. SHE WAS TOLD THIS WAS NORMAL AFTER SHE HAD THEM PLACED. SHE REPORTED CONSTANT OVARIAN CYSTS, MUSCLE AND JOINT PAIN, MENSTRUAL TYPE CRAMPING EVERY DAY, SEVERE EXHAUSTION, LYMPH NODES WERE ALWAYS SWOLLEN, HER HAIR STARTED FALLING OUT IN CLUMPS, STABBING VAGINAL PAIN, MOTION SICKNESS, MAJOR METAL AND INDOOR ALLERGIC REACTIONS (SO MUCH SHE HAD TO FIND A NEW HOME FOR HER DOG), BRAIN FOG, ITCHY SCALP AND SKIN, DOCUMENTED BY OPTOMETRIST VISION LOSS, CHRONIC ALLERGIC CONJUNCTIVITIS IN EYES, STARTED USING RESTASIS BECAUSE HER EYES SLOWED TEAR PRODUCTION, CHEST PAINS, DEGENERATIVE DISCS, CARPAL TUNNEL, GLUTEN ALLERGIES, ANXIETY ATTACKS, SEVERE BLOATING (LOOKED 6 MONTHS PREGNANT), FLUTTERING IN THE ABDOMEN, BLEEDING SO PROFUSELY WITHIN A MONTH FROM UTERUS THAT HER DOCTOR HAD TO PUT HER ON HORMONES. SHE WAS DIAGNOSED WITH A NERVE SHEATH TUMOR IN 2015 THAT HAS BEEN GROWING FOR 2 YEARS ON HER CERVICAL SPINE AND IT WILL NEED TO BE REMOVED; SHE HAD IMAGING DONE 3 YEARS AGO AND IT WAS NOT VISIBLE AT THAT TIME. SHE HAD TO HAVE AN ENDOMETRIAL ABLATION IN 2013 BECAUSE THE HORMONES DID NOT HELP THE BLEEDING. THE ABLATION LEFT HER WITH AN INFECTION THAT TOOK 3 MONTHS TO HEAL AND SHE WAS ANEMIC AND LETHARGIC ALL OF 2013 AND MOST OF 2014. SHE FOUND A SURGEON WHO TOOK THE COILS OUT ON (B)(6) 2014. SHE WAS STILL LEFT WITH

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RHEUMATOID ARTHRITIS WHERE SHE HAD PAIN EVERY SINGLE DAY AND SHE STILL HAS A SWOLLEN UTERUS THAT WILL NEED TO BE REMOVED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED IMMEDIATE AND CONSTANT PAIN WHERE THE COILS WERE PLACED. THEN, HAD MENSTRUAL TYPE CRAMP EVERY DAY(PELVIC PAIN) AND WAS BLEEDING SO PROFUSELY (GENITAL BLEEDING) THAT SHE WAS ANEMIC AND LETHARGIC AND HAD AN ENDOMETRIAL ABLATION. THIS ABLATION LED TO A PELVIC (INFECTION) THAT TOOK 3 MONTHS TO HEAL. SHE ALSO PRESENTED: VISION LOSS, NERVE SHEATH TUMOR, RHEUMATOID ARTHRITIS, COELIAC DISEASE. ALL EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND INTERVENTION REQUIRED. PELVIC PAIN, BLEEDING AND PELVIC INFECTION ARE LISTED WHILE THE OTHER EVENTS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR DURING ESSURE USE. CONSIDERING EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, THESE EVENTS ARE ASSESSED AS RELATED TO ESSURE USE AND THE INFECTION, AS A CONSEQUENCE OF ENDOMETRIAL ABLATION DUE TO BLEEDING, IS ALSO CONSIDERED RELATED TO MICRO-INSERT. GIVEN THE ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, THE REMAINING EVENTS ARE ASSESSED AS UNRELATED TO ESSURE. SINCE MEDICAL INTERVENTION (ABLATION) AND ESSURE REMOVAL WERE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING. TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT:

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00815	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0268, AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER REPORTED ESSURE WAS INSERTED SHORTLY AFTER THE BIRTH OF HER THIRD CHILD. HER PROBLEMS BEGAN DURING THE PROCEDURE; THE RIGHT SIDE COIL WAS PLACED WITH NO PROBLEMS, HOWEVER WHEN PLACING THE LEFT COIL, SHE FELT AN EXCRUCIATING PAIN THAT CAUSED HER TO CRY OUT TO THE PHYSICIAN TO STOP IMMEDIATELY, THE PAIN WAS WORSE THAN LABOR CONTRACTIONS, AT THE END SHE WAS SOBBING IN SO MUCH PAIN; WHEN THE PHYSICIAN RETURNED, THE PAIN WAS LESS SHARP. FROM THE DAY OF INSERTION ON, SHE WAS MISERABLE WITH SHARP PAIN IN LOWER LEFT ABDOMEN, CRAMPING, BLEEDING, HEADACHES, ACHES AND PAINS THROUGHOUT HER BODY, EXTREME FATIGUE, AND OVERALL MALAISE. SHE STATED THAT THIS CONTINUED FOR MONTHS. SHE REPEATEDLY REPORTED HER SYMPTOMS TO HER DOCTOR AND HE SCHEDULED A SURGERY TO REMOVE THE COILS. SHE WAS TOLD AFTER THE SURGERY, THAT HE WAS UNABLE TO REMOVE THE LEFT COIL, SO HE JUST TOOK OUT THE WHOLE FALLOPIAN TUBE. HE STATED HE WAS ALSO UNABLE TO REMOVE THE RIGHT ONE AS WELL BUT SINCE SHE WASN'T COMPLAINING ABOUT PAIN ON RIGHT SIDE, HE DECIDED TO LEAVE IT, AND JUST CLAMPED HER FALLOPIAN TUBE. SHE LITERALLY CRIED FOR DAYS AS SHE STILL WAS LEFT WITH ONE OF THE COILS INSIDE HER BODY. THE SYMPTOMS STILL CONTINUED. HER DOCTOR THEN TRIED A DNC, THEN A UTERINE ABLATION. SHE STATED THAT, AT TIME OF THE REPORT SHE HAS UNEXPLAINED SYMPTOMS AND RECENTLY WAS DIAGNOSED WITH IDIOPATHIC INTRACRANIAL HYPERTENSION, A CONDITION THAT HAS BEEN LINKED TO SOME FORMS OF BIRTH

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CONTROL AND HOWEVER SHE COULD NOT HELP BUT TO WONDER IF ESSURE IS RESPONSIBLE FOR THIS AS WELL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THE DAY OF INSERTION SHE HAD SHARP PAIN IN LOWER LEFT ABDOMEN AND BLEEDING. SHE HAD A SURGERY TO REMOVE THE LEFT COIL AND SINCE THE PHYSICIAN WAS UNABLE TO REMOVE THE COIL, HE REMOVED THE WHOLE LEFT FALLOPIAN TUBE, THE RIGHT COIL WAS LEFT. SHE WAS ALSO DIAGNOSED WITH IDIOPATHIC INTRACRANIAL HYPERTENSION. SHE DID NOT RECOVER FROM THE EVENTS. THE EVENTS PAIN IN LOWER ABDOMEN AND BLEEDING (INTERPRETED AS GENITAL BLEEDING) ARE LISTED WHILE THE IDIOPATHIC INTRACRANIAL HYPERTENSION IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINCE THE PAIN IN LOWER ABDOMEN AND BLEEDING STARTED ON DAY OF INSERTION AND CONTINUED FOR MONTHS AND THERE IS NO ALTERNATIVE EXPLANATION, BOTH EVENTS ARE ASSESSED AS RELATED. HOWEVER, ALTHOUGH IT IS IMPLIED THAT THE IDIOPATHIC INTRACRANIAL HYPERTENSION OCCURRED DURING ESSURE USE, CONSIDERING THAT ESSURE HAS ONLY A LOCALIZED ACTION IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT THIS EVENT IS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00818	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN 2006. CONSUMER REPORTED THAT SHE WAS IMPLANTED WITH ESSURE IN 2006 AND WAS HOSPITALIZED WITH POLY NEPHRITIS AND HIGH BLOOD PRESSURE TWO WEEKS LATER. OVER THE YEARS SHE BECAME SICKER AND SICKER WITH ALL KINDS OF AUTOIMMUNE AND ALLERGIC TYPE ISSUES. AFTER 6 YEARS SHE HAD FIVE SURGERIES WHICH ONE WAS A FULL HYSTO. SHE CURRENTLY HAS 33 DIAGNOSES INCLUDING THREE CANCERS ALL SHE BELIEVED STEMMING FROM INFLAMMATORY PROPERTIES OF ESSURE. SHE HAS STILL BEEN HAVING RADIATION TREATMENTS AT THE MOMENT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS HOSPITALIZED WITH POLY NEPHRITIS (INTERPRETED AS PYELONEPHRITIS) AND HYPERTENSION. OVER THE YEARS SHE HAD ALLERGIC TYPE ISSUES (INTERPRETED AS HYPERSENSITIVITY). AT THE TIME OF REPORT SHE HAD THREE CANCERS AND OTHER 33 DIAGNOSES THAT SHE BELIEVED WERE CAUSED BY ESSURE. AFTER 6 YEARS SHE HAD UNDERGONE 5 SURGERIES WHICH ONE OF THEM WAS FULL HYSTO (INTERPRETED AS TOTAL HYSTERECTOMY). OUTCOMES WERE NOT PROVIDED. THE EVENTS OF PYELONEPHRITIS, HYPERTENSION AND CANCERS ARE UNLISTED WHILE THE HYPERSENSITIVITY IS LISTED. ALTHOUGH THE TEMPORAL RELATIONSHIP IS COMPATIBLE, CONSIDERING THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES IT IS UNLIKELY THAT ESSURE COULD CONTRIBUTE TO THE DEVELOPMENT OF PYELONEPHRITIS, HYPERTENSION AND CANCERS. IN CONTRAST, IN THIS CASE, THE ALLERGIC ISSUES WERE

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NOT SPECIFIED. HOWEVER, SINCE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, A CONTRIBUTORY ROLE OF ESSURE TO THE ALLERGIC ISSUES CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOUL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00819	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/4/2007
Explant Date (E7): 3/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. REQUIRED INTERVENTION. ANTICIPATED. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0300, AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED ON 04-OCT-2007. IT WAS REPORTED THAT ON (B)(6) 2015 ESSURE WAS REMOVED BECAUSE COIL WAS PERFORATING THROUGH HER TUBE LINING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, AND 7 YEARS AND A HALF LATER HAD IT REMOVED BECAUSE COIL WAS PERFORATING THROUGH HER TUBE LINING. THIS EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. THE EXACT DATE AND MECHANISM OF THIS PERFORATION WERE NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REPORTED, AN INTERVENTION WAS IMPLIED, THEREFORE THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00820	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 5/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER STATED THE SIDE EFFECTS FROM THIS PRODUCT WERE SEVERE AND DEBILITATING AT TIMES. SHE PERSONALLY ENDURED EXTREMELY PAINFUL INTERCOURSE WITH BLEEDING AFTERWARD. SHE HAD A MIGRAINE EVERY SINGLE DAY. HER MENSTRUAL CYCLES WERE 7 DAYS OF HEAVY BLEEDING (OVERNIGHT PADS IN 20 MINUTES), CONTAINED GOLF BALL SIZED CLOTS, AND CAME EVERY 12-14 DAYS. CONSUMER HAD SEVERE MOOD SWINGS. THE NEVER-ENDING PAIN IN HIPS, LOWER BACK, AND KNEES COMBINED WITH THE EXTREME NAUSEA MADE IT HARD TO GET OUT OF BED MOST DAYS. SHE REPORTED THAT ALL OF HER SYMPTOMS WERE DIRECTLY RELATED TO ESSURE AS SHE HAD HER TUBES AND ESSURE REMOVED ON (B)(6) 2015 AND HAVE HAD ABSOLUTELY ZERO PROBLEMS. HER CYCLES ARE BACK TO NORMAL, JOINT PAIN IS GONE AND SHE HAVEN'T EVEN BEEN NAUSEOUS ONCE. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DETECTED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO AN ADULT FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER MENSTRUAL CYCLES WERE 7 DAYS OF HEAVY BLEEDING, CONTAINED GOLF BALL SIZED CLOTS. THIS EVENT, SEEN AS MENORRHAGIA, IS SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, THE PATIENT EXPERIENCED THIS HEAVY MENSTRUAL BLEEDING AND OTHER NON-SERIOUS EVENTS AND STATED THAT AFTER ESSURE AND TUBES REMOVAL, SHE

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RECOVERED FROM THEM (POSITIVE DECHALLENGE). THEREFORE, CONSIDERING IMPLIED TEMPORAL RELATIONSHIP AND POSITIVE DECHALLENGE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE ESSURE AND TUBES REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT TECHNICAL ASSESSMENT IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00821	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/18/2009
Explant Date (E7): 9/30/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. THE CONSUMER REPORTED 4 MONTHS AFTER THE PROCEDURE SHE STARTED HAVING OVARIAN CYSTS WHICH SHE NEVER HAD BEFORE, AND OVER TIME THEY KEPT GETTING WORSE AND TURNED INTO HEMORRHAGIC OVARIAN CYSTS, THEN SHE HAD SEVERE ABDOMINAL PAIN, PELVIC PAIN, SEVERE MIGRAINES, ALLERGIC REACTIONS TO MEDICINES, DEPRESSION, HAIR LOSS, MOOD SWINGS, AND WEIGHT GAIN. SHE REPORTED IN THE LAST TWO YEARS PRIOR TO THE TIME OF THE REPORT, THE PAIN WAS SO SEVERE AND THE BLEEDING UNCONTROLLED; HER PHYSICIAN PLACED HER ON THE DEPO PROVERA SHOT TO HELP WITH THE BLEEDING AND IT ONLY GOT WORSE; THE INTERCOURSE BECAME EXCRUCIATING THAT HER MARRIAGE WAS FALLING APART; DISCUSSION ABOUT REMOVING HER OVARIES WAS BROUGHT UP SEVERAL TIMES. IN (B)(6) 2014 SHE WAS DIAGNOSED WITH ADENOMYOSIS. ON (B)(6) 2014, SHE HAD TO HAVE A PARTIAL HYSTERECTOMY LEAVING HER OVARIES. SHE STATED THE ESSURE WAS CAUSING THE CYSTS AND ALL THE OTHER ISSUES. SHE WAS SLOWING GETTING HER LIFE BACK. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 4 MONTHS AFTER THE PROCEDURE STARTED HAVING PELVIC PAIN/ PAIN WAS SO SEVERE AND HAEMORRHAGIC OVARIAN CYSTS. SHE WAS ALSO DIAGNOSED WITH ADENOMYOSIS. A PARTIAL HYSTERECTOMY WAS PERFORMED APPROXIMATELY 5 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE

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SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENTS ARE UNLISTED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THIS CASE THE CONSUMER ALSO HAD OVARIAN CYSTS AND ADENOMYOSIS, WHICH COULD HAVE HAD A CONTRIBUTORY ROLE IN THE OCCURRENCE OF THE PAIN. HOWEVER, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. REGARDING HAEMORRHAGIC OVARIAN CYSTS AND ADENOMYOSIS, CONSIDERING THE PATHOPHYSIOLOGY OF THESE EVENTS AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY BETWEEN THESE EVENTS AND SUSPECT INSERT WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (PARTIAL HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00822	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 6/1/2010
Explant Date (E7): 4/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. THE CONSUMER REPORTED THAT 3 MONTHS AFTER THE PROCEDURE, SHE HAD THE HSG (HYSTEROSALPINGOGRAM) TEST AND LEARNED THAT THE ESSURE COILS HAD MIGRATED INTO HER ABDOMEN. HER PHYSICIAN ASSURED HER THAT THERE WAS NO CONCERN, AND THAT SHE COULD PUT MORE ESSURE COILS IN WHICH THE CONSUMER REFUSED. IN NOVEMBER, SHE STARTED HAVING SYMPTOMS SHE THOUGHT IT WAS THE FLU, AT FIRST. THEN HER PHYSICIAN HAD HER TESTED FOR MONO. SHE WAS ACHY AND TIRED ALL THE TIME; SHE STARTED TO HAVE HEADACHES AND DIZZY SPELLS (SHE WAS TESTED FOR MS - MULTIPLE SCLEROSIS). SHE REPORTED THAT BY CHRISTMAS SHE HAD DIARRHEA EVERY DAY FOR 3 WEEKS, AND COULD ONLY EAT BLAND FOOD. IN (B)(6) SHE WAS TAKEN TO THE EMERGENCY ROOM WHEN SHE WAS TOO DISORIENTED TO FUNCTION. THEY RAN TESTS AND PUMPED HER FULL OF B12 AND SENT HER HOME. SHE WAS SENT TO NEUROLOGISTS AND ALLERGISTS, ENDOCRINOLOGISTS AND ONCOLOGISTS. EIGHTEEN MONTHS HAD GONE BY SINCE ESSURE HAD BEEN IMPLANTED AND SHE HAD BEEN SICK FOR 14 OF THEM. FINALLY A HEMATOLOGIST CAME INTO THE PICTURE AND HE DETERMINED THAT SHE WAS HAVING A SYSTEMIC RESPONSE. HE ASKED IF SHE HAD BREAST IMPLANTS - OR ANYTHING THAT COULD BE CAUSING HER BODY TO SHUT DOWN. THE CONSUMER REPORTED THAT THE WORST PART THIS ORDEAL ENDED 22 MONTHS AND 2 DAYS AFTER IT STARTED WHEN THE ESSURE COILS WERE LOCATED AND MOSTLY REMOVED FROM HER BODY IN A 4 HOUR SURGERY, WITH 2 SURGEONS THAT LEFT HER WITH AN 11 INCH SCAR. A PORTION OF HER UTERUS AND THE TISSUE

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TOUCHING THE COILS WERE ALSO REMOVED THAT DAY, AND SHE STARTED THE VERY LONG HEALING PROCESS. WITHIN 2 DAYS SHE WAS FEELING MUCH MORE LIKE SHE HAD BEFORE THE ESSURE COILS WERE IMPLANTED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COILS HAD MIGRATED INTO HER ABDOMEN (SEE AS DEVICE DISLOCATION). THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES INTO ABDOMINAL CAVITY. IN THIS CASE, DURING HSG PERFORMED THREE MONTHS AFTER PLACEMENT, IT WAS FOUND OUT THAT ESSURE COILS HAD MIGRATED INTO HER ABDOMEN. A COUPLE OF YEARS LATER, ESSURE COILS WERE LOCATED AND MOSTLY REMOVED FROM HER BODY IN A 4 HOUR SURGERY. SINCE THEN, SHE IS RECOVERING BUT AN 11 INCH SCAR WAS LEFT. ALTHOUGH THE EXACT DATE AND MECHANISM OF THIS DISLOCATION HAVE NOT BEEN INFORMED, CONSIDERING EVENT'S NATURE AND RECOVERY AFTER REMOVAL, CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00823	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0015 AND FDA-2014-N-0736-0149, AWARENESS DATE 12-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE PATIENT'S MEDICAL HISTORY INCLUDED 3 CHILDREN (BORN NATURALLY) AND NICKEL SENSITIVITY. CONSUMER STATED THAT SHE LOST 10 YEARS OF HER LIFE AFTER SHE GOT ESSURE. SHE WAS LED TO BELIEVE THAT HER SYMPTOMS WERE DUE TO POST-PARTUM AND AGE (SHE WAS 36 YEARS OLD AT THAT TIME). SHE WAS EXHAUSTED EVERYDAY, SEVERELY DEPRESSED AND WAS WITHDRAWN. ONE DAY SHE WOKE UP AND HEARD A PING IN HER RIGHT HIP AREA AND WAS PARALYZED WITH SUCH PAIN FROM RIGHT SIDE LOWER BACK/HIP AREA DOWN TO HER TOES. SHE WAS DRY HEAVING FROM THE AMOUNT OF PAIN. SHE WALKED WITH A LIMP AND WAS NEARLY TO LOST HER JOB AND WAS OUT OF WORK FOR MONTHS. SHE WAS MADE TO BELIEVE THAT SHE WAS CRAZY, THAT SHE WAS OLD AND THAT WAS WHY SHE WAS TIRED AND ALWAYS IN PAIN, ACHY MIGRAINES. SHE TOLD TO HER DOCTOR THAT SHE HAD NICKEL SENSITIVITY WHEN SHE WAS ASKED ABOUT ALLERGIES BUT SHE WAS TOLD IT DID NOT MATTER BECAUSE ESSURE WAS INSIDE AND BODY RESPONDS DIFFERENTLY. ON AN UNSPECIFIED DATE A HYSTERECTOMY WAS DONE AND AFTER THAT THE LIMP WENT AWAY AND THE PAIN IN HER HIPS SUBSIDED. SHE WAS STILL SUFFERING WITH NERVE PAIN FROM DAMAGE L3/L4. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN IN HIP AREA. SHE WAS SUBMITTED TO A HYSTERECTOMY AND THIS PAIN SUBSIDED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO

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MEDICAL IMPORTANCE AND IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND BACK PAIN MAY OCCUR. IN THIS CASE, THE CONSUMER REPORTED HIP AND BACK PAIN IRRADIATING TO TOES, WHICH COMPROMISED WALKING (SHE NEEDED A LIMP). SHE ALSO HAD AN UNSPECIFIED VERTEBRAL DAMAGE TO L3 AND L4. THIS CONDITION COULD BE AN ALTERNATIVE EXPLANATION FOR HER PAIN (SINCE CONSUMER'S PAIN DESCRIPTION SUGGESTED A RADICULOPATHY). HOWEVER, SINCE SHE STATED HIP PAIN IMPROVED WITH ESSURE REMOVAL, A CONTRIBUTORY ROLE OF THE SUSPECT DEVICE CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED ON 08-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00824	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED SHE ENDED UP HAVING A TUBAL DUE TO SIDE EFFECTS AND COMPLICATIONS SHE ENDURED AFTER HAVING ESSURE PLACED INCLUDING ONE OF THE COILS EMBEDDING IN HER UTERUS. SHE ALSO REPORTED SHE STILL HAS ONE COIL UN PLACE AND LIVE DAILY CONCERNED THAT THE COIL WILL MIGRATE AND CAUSE EVEN AN OUNCE OF THE PAIN AND TROUBLE THE FIRST MIGRATED CAUSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE ENDED UP HAVING A TUBAL DUE TO SIDE EFFECTS AND COMPLICATIONS INCLUDING ONE OF THE COILS EMBEDDING IN HER UTERUS. THIS EVENT, INTERPRETED AS DEVICE EMBEDDED (PARTIAL PERFORATION), IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF DEVICE EMBEDDED AND THE LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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THE PTC INVESTIGATION RESULT WAS PROVIDED ON 08-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYP

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00825	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. IN 2012 SHE STARTED HAVING MAJOR HEALTH PROBLEMS SUCH AS CHRONIC PAIN, BLEEDING, FATIGUE, CRAMPING, DISCHARGE, BACTERIAL VAGINOSIS, UTI'S, BREAST PAIN. THAT WAS JUST TO LIST A FEW OF THE CHRONIC SYMPTOMS. THERE WAS CONSTANT BACK PAIN THAT HAD TO BE MODERATED BY PAIN MEDICATION; SHE CONSTANTLY BROKE OUT IN HIVES, HAD HEARTBURN, A METALLIC TASTE IN HER MOUTH. MOOD SWINGS FROM HELL, A VITAMIN D AND IRON DEFICIENCY. THAT WAS ONLY SOME OF THE SIDE EFFECTS AND SYMPTOMS SHE SUFFERED THROUGH FOR THREE YEARS. SHE COULD NOT PLAY WITH HER CHILDREN, COULD NOT WORK, SHE COULD NOT DO THE SIMPLEST HOUSEHOLD CHORE WITHOUT HAVING TO STOP BECAUSE SHE WAS EITHER DIZZY OR IN TOO MUCH PAIN. SHE BLED EVERY SINGLE DAY FOR A YEAR AND GOT TOLD BY NUMEROUS DOCTORS THAT IT WAS ALL IN HER HEAD AND IT WAS NORMAL AND THAT WOMEN'S BODIES ARE CAPABLE OF BLEEDING FOR SUCH A LONG TIME LIKE THAT WITH NO ADVERSE EFFECTS. SHE WAS ON THE VERGE OF A NERVOUS BREAKDOWN WHEN SHE FINALLY FIGURED OUT THE PROBLEM WAS ESSURE. IT TOOK HER ANOTHER 6 MONTHS BEFORE SHE FOUND A DOCTOR WHO ACTUALLY LISTENED TO HER AND AGREED THAT ESSURE WAS CAUSING HER HEALTH PROBLEMS. SHE HAD TO HAVE A HYSTERECTOMY LEAVING ONLY HER OVARIES AT AGE 34. SHE WAS CURRENTLY TWO WEEKS POST OP AND THE MAJORITY OF HER HEALTH PROBLEMS WERE GONE WITHIN 3 DAYS OF HYSTERECTOMY. SHE DOES NOT HURT AND CAN PLAY WITH HER CHILDREN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING

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OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FIVE YEARS AFTER INSERTION SHE STARTED HAVING CHRONIC PAIN, BLEEDING AND UTI'S. SHE HAD TO HAVE A HYSTERECTOMY LEAVING ONLY HER OVARIES 3 YEARS AFTER THE ONSET OF EVENT. SHE DOES NOT FEEL PAIN ANYMORE. CHRONIC PAIN AND BLEEDING (INTERPRETED AS GENITAL BLEEDING) ARE LISTED WHILE UTI'S (INTERPRETED AS URINARY TRACT INFECTIONS) IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE EVENTS STARTED 5 YEARS AFTER INSERTION. CONSIDERING THIS TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATIONS, THE EVENTS BLEEDING AND CHRONIC PAIN ARE ASSESSED AS RELATED. HOWEVER, THE URINARY TRACT INFECTIONS ARE ASSESSED AS UNRELATED SINCE IT IS UNLIKELY THAT AN INFECTION DUE TO A BACTERIAL CONTAMINATION DURING INSERTION WOULD DEVELOP ONLY 5 YEARS AFTER ITS INSERTION (UNRELATED). THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED ON 08-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00828	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(6), AWARENESS DATE 12-AUG-2015). IT REFERS TO A (B)(6) YEARS OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. THE CONSUMER REPORTED HER DOCTOR WAS ONLY ABLE TO PLACE ONE COIL SINCE HER OTHER TUBE WAS BLOCKED; SHE STARTED BLEEDING SO HEAVY THAT A SUPER PLUS TAMPON WOULDN'T EVEN LAST 2 HOURS, IT WAS HORRIBLE; SO THEN HER DOCTOR PERFORMED AN ABLATION. SHE STATED THAT WAS THE MOST PAINFUL THING SHE HAD EVER BEEN THROUGH. ESSURE WAS PLACED IN HER FOR 4 YEARS AND HER SYMPTOMS INCLUDED: NIGHT SWEATS, HOT FLASHES, SHARP/STABBING PELVIC PAIN, LOSS OF LIBIDO, PAINFUL INTERCOURSE, URGED/FREQUENT URINATION, STABBING OF VAGINAL ENTRANCE, BREAST PAIN AND TENDERNESS, LOWER BACK AND JOINT PAIN, SEVERE BLOATING, BRAIN FOG, MOOD SWINGS, ANXIETY, RINGING IN EARS, NUMBNESS AND TINGLING IN ARM AND HANDS, SKIN IRRITATION AND ITCHING, HAIR LOSS AND TEXTURE CHANGE, AND INSOMNIA. AT TIME OF THE REPORT, THE CONSUMER WAS (B)(6) YEARS OLD AND WAS ESSURE FREE; SHE STATED HER LIFE COULDN'T BE ANY BETTER. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED BLEEDING SO HEAVY (INTERPRETED AS GENITAL BLEEDING) SO HER DOCTOR PERFORMED AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION). SHE ALSO HAD SHARP/STABBING PELVIC PAIN. SHE HAD ESSURE REMOVED 4 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN, ABNORMAL GENITAL

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BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENTS, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (ENDOMETRIAL ABLATION AND ESSURE REMOVAL). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED ON08-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00829	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4) AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN (B)(6) 2010. ADDITIONAL INFORMATION WAS RECEIVED ON 13-AUG-2015. CONSUMER REPORTED THAT SHE HAS HAD HAIR LOSS, ODD BLEEDING, PAIN, HEADACHES, A MISCARRIAGE IN (B)(6) 2015 AND A HYSTERECTOMY ON (B)(6) 2015 DUE TO ESSURE FAILED. SHE STATED THAT ESSURE CAUSED HER TO LOSE HER UTERUS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD ODD BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE ALSO HAD A MISCARRIAGE 4 YEARS AND A HALF AFTER INSERTION (IMPLYING A PREGNANCY WITH ESSURE). SHE UNDERWENT A HYSTERECTOMY APPROXIMATELY 5 YEARS AFTER ESSURE INSERTION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. GENITAL BLEEDING AND PREGNANCY ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE EVENT ODD BLEEDING AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE. PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE; THE FAILURE RATE MAY BE INCREASED DUE TO PATIENT NON-COMPLIANCE. IN THE PRESENT CASE, IT WAS NOT REPORTED WHETHER THE CONSUMER UNDERWENT A CONFIRMATION TEST POST INSERTION. HOWEVER, SINCE THE PREGNANCY OCCURRED MORE THAN 4 YEARS AFTER ESSURE INSERTION,

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CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED (DEVICE INEFFECTIVE). REGARDING MISCARRIAGE, IT IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY. THIS IS CONSIDERED TO BE DUE TO A HIGH NUMBER OF ABNORMAL EMBRYOS PRESENTING WITH EITHER CHROMOSOMAL AND/OR GROSS MORPHOLOGICAL ABNORMALITIES. IN THIS CASE, THE GESTATIONAL AGE WAS NOT REPORTED. HOWEVER, GIVEN THE PATHOPHYSIOLOGY OF THE EVENT AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THIS EVENT WAS ASSESSED AS UNRELATED TO THE INSERT. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00835	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. WITHIN TWO WEEKS AFTER INSERTION SHE WAS ADMITTED TO THE HOSPITAL WITH SEVERE PAIN AND SHE COULDN'T BREATHE. THE HOSPITAL ADMITTED HER OVERNIGHT FOR OBSERVATION AND HER DOCTOR WAS CALLED. HE TOLD HER THAT HER PELVIC PAIN, THE MIGRAINE, INABILITY TO BREATHE AND OTHER SYMPTOMS WERE ALL IN HER HEAD AND THERE WAS NOTHING WRONG WITH HER. A YEAR LATER SHE STARTED NOTICING THAT SHE HAD MORE FREQUENT MIGRAINES, ACHES IN LEGS AND LOWER BACK. AS TIME WENT ON MORE SYMPTOMS APPEARED AND SHE WENT TO HER GENERAL DOCTOR YEARLY SOMETIMES MORE OFTEN AND SHE WOULD RUN TESTS EVERYTHING CAME BACK NORMAL BUT HER SYMPTOMS PERSISTED. IN 2013, SHE BEGAN TO HAVE EXTREMELY HEAVY PERIODS THAT LASTED IN EXCESS OF 9 DAYS. ALONG WITH THOSE LONG HEAVY PERIODS WAS INTENSE PELVIC PAIN THAT HAD HER CURLED IN A BALL FOR DAYS. SHE SUFFERED WHAT FELT LIKE A MISCARRIAGE ON MORE THAN ONE OCCASION, BUT WAS SURE IT WASN'T POSSIBLE BECAUSE SHE HAD THE ESSURE COILS AND ALL TESTS THAT PROVED THEY WERE WORKING IN 2010. IN THE FOLLOWING YEAR SHE GAINED 24 LBS RAPIDLY. SHE BEGAN TO BLOW UP AND AT TIMES APPEARED TO BE 6-7 MONTHS PREGNANT. THE MIGRAINES WERE ALMOST DAILY. SHE HAD INTENSE PAIN AND SOMETIMES FELT LIKE SOMETHING WAS CATCHING IF SHE STOOD UP STRAIGHT SHE COULD FEEL A RIPPING SENSATION THAT BROUGHT HER TO HER KNEES IN PAIN. SHE BEGAN TO HAVE CHRONIC FATIGUE, BACK PAIN, LEG ACHES AND INSOMNIA. ULTRASOUND WAS PERFORMED AND SHOWED ONE OF HER COILS WAS MISSING AND THE SECOND COIL

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HAD MOVED AND WAS PERFORATING THROUGH THE UTERINE WALL. SHE HAD A HYSTEROSCOPY DONE TO REMOVE THE COIL PERFORATING HER UTERINE WALL, THE DOCTOR HAD TO PERFORM A LAPAROSCOPIC SURGERY DONE TO REMOVE THE DAMAGED FALLOPIAN TUBES AND UNFORTUNATELY THEY WERE UNABLE TO LOCATE THE SECOND ESSURE. HER DOCTOR WAS HOPING THAT IT PASSED AND WAS NOT FLOATING AROUND IN HER ABDOMEN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IN TWO WEEKS WAS ADMITTED TO THE HOSPITAL WITH SEVERE PAIN/ PELVIC PAIN AND SHE COULDN'T BREATHE. LATER, ULTRASOUND SHOWED ONE OF HER COILS WAS MISSING (INTERPRETED AS DEVICE DISLOCATION) AND THE OTHER COIL WAS PERFORATING HER UTERINE WALL. HYSTEROSCOPY WAS DONE TO REMOVE THE COIL PERFORATING UTERINE WALL, AND A LAPAROSCOPY WAS PERFORMED TO REMOVE HER DAMAGED FALLOPIAN TUBES. EVENTS SEVERE PAIN/ PELVIC PAIN AND COULDN'T BREATHE WERE CONSIDERED SERIOUS DUE TO HOSPITALIZATION, WHILE THE REMAINING EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. ALL EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR COULDN'T BREATHE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. DURING ESSURE USE THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THIS CASE ONE OF HER COILS WAS MISSING; THE EXACT LOCATION OF THIS COIL WAS NOT KNOWN. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE ONE OF HER COILS WAS PERFORATING UTERINE WALL. THE EXACT DATE AND MECHANISM OF THIS PERFORATION WERE NOT DESCRIBED. HOWEVER, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. CONSUMER REPORTED THAT LAPAROSCOPY WAS DONE TO REMOVE HER DAMAGED FALLOPIAN TUBES. ALTHOUGH THE EXACT NATURE OF THIS DAMAGE WAS NOT SPECIFIED, IT IS POSSIBLE THAT THIS WAS REFERRING TO A FALLOPIAN TUBE PERFORATION. THEREFORE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING COULDN'T BREATHE, DUE TO ITS NATURE THIS EVENT WAS ASSESSED AS UNRELATED TO ESSURE. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION AND HOSPITALIZATION. . TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00836	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2005 FOR PERMANENT BIRTH CONTROL. ONE YEAR AFTER PLACEMENT SHE HAD AN ABLATION PERFORMED BECAUSE HER PERIODS WERE VERY HEAVY. SHE HAD ALSO EXPERIENCED NIGHT SWEATS, BURNING SENSATIONS IN HER STOMACH, UNEXPLAINED RASHES, CHRONIC LEFT SIDED PELVIC PAIN, PAINFUL INTERCOURSE, FOGGINESS AND EXTREME BLOATING. SHE WAS NEVER TESTED FOR NICKEL ALLERGY. HER DOCTOR THOUGHT THAT MAYBE SHE HAD GASTROINTESTINAL PROBLEMS, BUT COMPUTED TOMOGRAPHY RULED THAT OUT. SHE STATED THAT ESSURE WAS NOT SAFE. PTC INVESTIGATIONAL RESULT RECEIVED ON 08-SEP-2015: GLOBAL PTC NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING

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MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE YEAR AFTER PLACEMENT SHE HAD AN ABLATION PERFORMED BECAUSE HER PERIODS WERE VERY HEAVY (INTERPRETED AS MENORRHAGIA). THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT THE HEAVY PERIODS STARTED DURING ESSURE USE, THE TEMPORAL RELATIONSHIP IS SUGGESTIVE. IN ADDITION, THERE IS NO ALTERNATIVE EXPLANATION FOR THIS BLEEDING. SHE PERFORMED AN ABLATION BUT IT WAS NOT INFORMED IF SHE RECOVERED FROM IT. BASED ON THIS INFORMATION, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THEREFORE, A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00837	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# (B)(4), AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. CONSUMER REPORTED THAT DURING PLACEMENT SHE SUFFERED PAIN TO NEAR FAINTING. AFTER PLACEMENT, SHE EXPERIENCED CONSTANT PAIN CAUSING HER TO STOP WORKING. THE PAIN REMAINED UNTIL THE REMOVAL OF ONE COIL BY REMOVAL OF ONE FALLOPIAN TUBE 6 MONTHS AFTER INSERTION. THE OTHER COIL FOUND TO BE MISSING. SHE ALSO HAD MENSTRUAL PROBLEMS LIKE SEVERE BLEEDING / ABNORMAL FORMING OF BLOOD CLOTS AND PROLONGED MENSTRUAL BLEEDINGS LASTING MONTHS THAT REQUIRED HORMONAL TREATMENT. SHE DEVELOPED ALLERGIC REACTIONS AND CHRONIC INFECTIONS IN SEVERAL PLACES OF HER BODY WHICH LESSENED BY THE USE OF ANTIHISTAMINE. SHE STATED THAT SHE NEVER HAD ANY MENSTRUAL PROBLEMS OR ALLERGIC REACTION AND CHRONIC INFECTIONS BEFORE ESSURE. SHE NEVER USED ORAL CONTRACEPTIVES AND NEVER BEEN PREGNANT BEFORE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER PLACEMENT, SHE EXPERIENCED CONSTANT PAIN. THE PAIN REMAINED UNTIL THE REMOVAL OF ONE COIL BY REMOVAL OF ONE FALLOPIAN TUBE 6 MONTHS AFTER INSERTION. THE OTHER COIL FOUND TO BE MISSING (INTERPRETED AS DEVICE DISLOCATION). THE EVENTS, INTERPRETED AS CHRONIC PAIN AND DEVICE DISLOCATION, ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CHRONIC PAIN STARTED AFTER ESSURE INSERTION AND STOPPED AFTER

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REMOVAL OF ONE OF FALLOPIAN TUBES. THE CONSUMER ALSO STATED THAT SHE NEVER EXPERIENCED THAT PAIN BEFORE ESSURE INSERTION. CONSIDERING THE SUGGESTIVE TEMPORAL RELATIONSHIP, THE FACT THAT SHE NEVER HAD THIS PAIN BEFORE, THAT IT STOPPED AFTER THE REMOVAL OF ESSURE ALONG WITH THE FALLOPIAN TUBE AND THAT THERE IS NO ALTERNATIVE EXPLANATION, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. DURING THE PROCEDURE THE DEVICE DISLOCATION OF THE OTHER COIL WAS NOTICED. CONSIDERING THE NATURE OF THIS EVENT AND LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS ALSO ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS PROVIDED ON 08-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICAL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00845	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 1/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 6/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0167, AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2007. CONSUMER RECEIVED ESCURE COILS 2 MONTHS AFTER HER DAUGHTER WAS BORN IN 2007. WITHIN 2 MONTHS HAVING THE DEVICES SHE STARTED HAVING PELVIC PAIN. SINCE THEN SHE HAD 3 ULTRASOUNDS DUE TO PELVIC PAIN (IN 2007, 2010, 2014) WHICH SHOWED A CYST ON LEFT TUBE. CONSUMER BEGAN HAVING MAJOR ISSUES WITH CHRONIC INFLAMMATION IN LEGS, SHOULDER INCLUDING MUSCLE SPASMS ALL BY THE END OF 2007. FROM 2007-2015 SHE HAVE HAD CHRONIC INFLAMMATION, WAS DIAGNOSED WITH TENDINITIS, FIBROMYALGIA, MUSCLE SPASMS, SEVERE BLOATING, HAIR LOSS, MIGRAINES, HEAVY MENSTRUAL CYCLES WITH MAJOR CRAMPING. SHE HAVE HAD INJECTIONS IN LEGS, FEET, NECK, SHOULDER AND HEAD AND A BREAST REDUCTION TO HELP WITH THE NECK AND SHOULDER PAIN. SHE JUST HAD A COMPLETE HYSTERECTOMY ON (B)(6) 2015 LEAVING HER OVARIES. ESSURE HAS CAUSED CHRONIC PAIN ALONG WITH DEPRESSION DUE TO THE PAIN AND HER LIFE HAS BEEN EXTREMELY HARD SINCE THE END OF 2007. PTC INVESTIGATIONAL RESULT RECEIVED ON (B)(6) 2015: GLOBAL PTC NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT:

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THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WITHIN 2 MONTHS STARTED HAVING PELVIC PAIN / CHRONIC PAIN. EIGHT YEARS AFTER ESSURE INSERTION, A HYSTERECTOMY WAS PERFORMED. SHE ALSO HAD NECK AND SHOULDER PAIN AND DUE TO THIS UNDERWENT A BREAST REDUCTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN / CHRONIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE NECK AND SHOULDER PAIN, SINCE THE CONSUMER UNDERWENT A BREAST REDUCTION TO HELP WITH HER SYMPTOMS, IT IS PROBABLE THAT SHE HAD GIGANTOMASTIA WHICH WAS CAUSING THE PAIN. GIVEN THE NATURE OF THIS EVENT AND PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00849	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0399, AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN 2009/2010 (DISCREPANT INFORMATION). SHE WAS IMPLANTED IN 2010 AND WAS TOLD THE PRODUCT WAS MADE FROM HEART STENT MATERIAL AND PERFECTLY SAFE. SINCE THEN, HER LIFE HAS BEEN FILED WITH CHRONIC HEALTH ISSUES IN WHICH NO DOCTOR HAS BEEN ABLE TO FIND ANY REASON AS TO WHY. PRIOR TO ESSURE IMPLANTATION, SHE WAS HEALTHY WITH NO MEDICAL CONDITIONS. SHE HAVE DELIVERED 4 BABIES, HER LAST ONE WAS DELIVERED IN (B)(6) OF 98. DUE TO THAT PREGNANCY BEING HIGH RISK HER DOCTOR HIGHLY RECOMMENDED ESSURE AND WAS IMPLANTED IN 2009. SINCE THEN, HER HEALTH HAS SLOWLY GOTTEN WORSE WITH NO KNOWN REASONS TO DATE. RIGHT AFTER PROCEDURE SHE HAD EXTREME DISCOMFORT, PAIN, CRAMPING, BLEEDING WHICH DOCTOR ADVISED WAS ALL NORMAL. SHE STARTED HAVING VERY PAINFUL OVULATIONS TO WHERE SHE WOULD BLEED DURING OVULATION AS WELL, NOT JUST SPOTTING. HER CYCLES BECAME IRREGULAR AND HEAVIER WITH CLOTTING, SO HER DOCTOR PUT HER ON THE PILL AGAIN TO KEEP HER REGULAR. HE ALSO SUGGESTED ABLATION BUT SHE DECLINED. AFTER BEING ON THE PILL FOR ABOUT 2 1/2 YEARS SHE THEN HAD TO COME OFF OF IT DUE TO AFFECTING BLOOD PRESSURE AND INCREASED WEIGHT GAIN. AFTER SHE WENT OFF THE PILL HER BP STABILIZED FOR A SHORT PERIOD OF TIME BUT SHE WAS THEN HAVING REALLY BAD ABDOMINAL PAIN PRETTY CONSISTENTLY. SHE ASKED HER DOCTOR IF THIS COULD BE RELATED TO ESSURE, HE SAID THAT IF SHE HAS AN ALLERGY TO NICKEL, IT WAS POSSIBLE AND STATED THAT THE ONLY WAY TO GET ESSURE OUT WAS BY DOING A COMPLETE HYSTERECTOMY. THEN, SHE STARTED HAVING MORE

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SYMPTOMS, EVEN MORE WEIGHT GAIN, HER SUGAR WAS NOW ELEVATING, SHE HAD VERY HIGH BLOOD PRESSURE, SWELLING, REALLY BAD ACNE, JOINT PAIN, MUSCLE WEAKNESS ETC. HER FAMILY PRACTICE DOCTOR SENT HER TO AN ENDOCRINOLOGIST TO RUN MORE TEST. ACCORDING TO THE ENDOCRINOLOGIST HER CORTISOL LEVELS WERE THROUGH THE ROOF AND SHE WAS SUSPECTING AN ADRENAL TUMOR. SHE CONDUCTED A TEST TO DETERMINE IF SHE HAD CUSHING'S SYNDROME AND ADDISON'S DISEASE. ALL TESTS CAME BACK NORMAL. SHE HAS SINCE THEN JUST LEARNED TO LIVE WITH SYMPTOMS. SHE TAKE AN AMINO ACID THAT IN SUPPOSED TO REGULATE THE BODY'S CORTISOL LEVELS AND WAS ON BLOOD PRESSURE MEDICATION. FOR THE PAST 3 YEARS THE AMOUNT OF VAGINAL YEAST AND BACTERIAL INFECTIONS HAVE INCREASED AND SHE CURRENTLY AT THE POINT TO WHERE SHE CONSTANTLY HAS THEM. HER DOCTOR KEEPS HAVING HER COME IN FOR CULTURES ON A MONTHLY BASIS JUST TO TELL HER THE SAME THING AS THE PREVIOUS MONTH. HE HAS GIVEN HER LONGER TREATMENTS AND TRIED DIFFERENT MEDICATIONS ALL TO WHICH GET RID OF THE INFECTIONS BUT WITHIN A WEEK THEY ARE BACK. MORE TESTS WERE DONE AND STATED THAT HER THYROID WAS SLOW, SO SHE WAS PUT ON NATURE THYROID, THIS HELPED TO FEEL BETTER FOR A FEW MONTHS, BUT THEN SHE SLIP BACK TO THE SAME SYMPTOMS. IT HAS HELPED WITH THE BRAIN FOG AND A LITTLE BIT OF THE CHRONIC FATIGUE BUT SHE WAS STILL NO WHERE NEAR FEELING AS GOOD AS PRE ESSURE. THIS HAS BEEN A HUGE LIFE CHANGER FOR HER; EVERY ASPECT OF HER LIFE HAS GOTTEN WORSE AND DEPRESSING. SHE HAD NO ENERGY TO GO ANYWHERE OR DO ANYTHING. DUE TO HER PERIODS BEING EVERY 2 WEEKS AND ALWAYS ON SUPPOSITORY MEDICATION FOR THE VAGINAL BACTERIAL INFECTIONS AND BATTING YEAST INFECTIONS SHE HAD AN ALMOST NONEXISTENT SEX LIFE. THIS WAS RUINING HER RELATIONSHIP. WHEN SHE SIT A CERTAIN WAY, BEND A CERTAIN WAY OR IF SHE LAY ON HER LEFT SIDE TOO LONG SHE GET A SHARP SHOOTING PAIN MY ABDOMEN. IRONICALLY, THERE WAS FIBROID GROWING AT THE BASE OF THE LEFT COIL. INTERCOURSE HAD ALSO BECOME UNCOMFORTABLE WHICH WOULD RESULT IN SPOTTING IN WHICH HER DOCTOR TOLD HER WAS NORMAL. SHE PROVIDED A LIST OF HER COMPLICATIONS: SHE ALSO HAD CHRONIC FATIGUE, JOINT PAIN, SWOLLEN ANKLES, FEET AND HANDS, INSOMNIA, DISCHARGE FROM HER BREAST WITH NORMAL PROLACTIN LEVELS, RASHES, SKIN TEXTURE CHANGES, TESTED POSITIVE FOR EBV (MONO) LAST OCTOBER, CHRONIC SWOLLEN GLANDS, CHRONIC INFLAMMATION, HEADACHES (MORE FREQUENT AS TIME GOES ON), PITYRIASE AND TREMORS ON HER LEFT HAND. ESSURE HAS MADE HER FEEL LIKE SHE HAD RAPIDLY AGED DUE TO ALL THE ALIMENTS, SHE FELT HER HEAD WAS IN A CLOUD ALL THE TIME AND SHE WAS SICK OF IT. HYSTERECTOMY IS SCHEDULED FOR (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND RIGHT AFTER PROCEDURE SHE HAD BLEEDING (INTERPRETED AS POST PROCEDURAL BLEEDING). SHE ALSO EXPERIENCED CRAMPING / BAD ABDOMINAL PAIN / SHARP SHOOTING PAIN IN ABDOMEN (INTERPRETED AS ABDOMINAL PAIN) AMONG NON-SERIOUS EVENTS. A HYSTERECTOMY WAS SCHEDULED BUT NOT PERFORMED YET. POST PROCEDURAL BLEEDING AND ABDOMINAL PAIN ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, SINCE THE BLEEDING OCCURRED RIGHT AFTER THE PROCEDURE AND THERE IS NO ALTERNATIVE EXPLANATION, THIS EVENT IS ASSESSED AS RELATED. ALSO, CONSIDERING THAT THE ABDOMINAL PAIN OCCURRED AFTER ESSURE INSERTION, NO ALTERNATIVE EXPLANATION WAS PROVIDED AND THAT SHE STATED SHE WAS HEALTHY PRIOR TO ESSURE, THIS ABDOMINAL PAIN IS RATHER ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PTC RESULTS WERE PROVIDED 08-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00853	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 1/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 7/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ESSURE HAS COMPLETELY CHANGED HER LIFE AND HER HEALTH AND NOT FOR THE BETTER. ALMOST IMMEDIATELY SHE BEGAN HAVING UNBEARABLE PAIN, BLEEDING, HAIR LOSS, FATIGUE, WEIGHT GAIN, JOINT AND BACK PAIN AND AS TIME WENT ON, THE SYMPTOMS KEPT MOUNTING AND EVERY DOCTOR SHE SAW DECIDED SHE WAS DEPRESSED AND NEEDED TO BE MEDICATED. THEY MADE HER FEEL AS THOUGH SHE WAS CRAZY. ON (B)(6) 2015 SHE FINALLY HAD A COMPLETE HYSTERECTOMY AFTER 7 1/2 EARS OF PURE HELL. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DETECTED DURING MONITORING OF POSTS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO AN ADULT FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ALMOST IMMEDIATELY AFTER PLACEMENT, EXPERIENCED UNBEARABLE PAIN AND BLEEDING. THESE EVENTS, SEEN AS PELVIC PAIN AND GENITAL BLEEDING, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SOON AFTER THE INSERTION SHE HAD UNBEARABLE PAIN, BLEEDING AND OTHER NON-SERIOUS EVENTS. AFTER 7 YEARS, SHE HAD HYSTERECTOMY PERFORMED CONSIDERING EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. TECHNICAL ASSESSMENT IS EXPECTED.

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Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00870	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2012
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0480, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN (B)(6) 2012. CONSUMER REPORTED: I WAS IMPLANTED WITH THE ESSURE IN (B)(6) 2012 ALSO HAVING THE NOVASURE ABLATION DONE AS WELL. IN (B)(6) OF 2012 I STARTED HAVING SEVERE CRAMP, HEAVY BLEEDING WITH CLOTS, BLOATING, AND SEVERE HEADACHES. I WENT BACK TO MY PHYSICIAN AND HE CONFIRMED THAT IT WAS NOT THE ESSURE THAT WAS CAUSING IT. I STARTED HAVING MULTIPLE (OVER 50+) ER (EMERGENCY ROOMS) VISITS. DURING THOSE VISITS I WAS TOLD I HAD SEVERE INTESTINAL INFLAMMATION WITH NO KNOWN CAUSE. FOR YEARS THIS WENT ON. AFTER 3 YEARS OF DEBILITATING PAIN, VOMITING, NAUSEA, HEADACHES, BLOATING, MULTIPLE DIFFERENT DRUGS NUMEROUS HOSPITAL STAYS, I WENT BACK TO MY PHYSICIAN AND WAS TOLD THE SAME THING: ITS NOT ESSURE. I WAS GIVEN PAIN MEDICATIONS AND BIRTH CONTROL PILLS TO HELP CONTROL THE BLEEDING THAT I HAD FOR 3 YEARS STRAIGHT. I WAS JUST ABOUT TO GIVE UP. IN (B)(6) OF 2014 I FOUND A FABULOUS PHYSICIAN THAT LISTENED TO ME AND AGREED THAT I NEEDED TO HAVE THEM REMOVED. IN (B)(6) 2015 I HAD A VAGINAL HYSTERECTOMY TO REMOVE MY TUBES, UTERUS AND CERVIX. I WAS SURE THAT I WOULD BE NORMAL AGAIN BECAUSE FOR THE PAST 3 YEARS ALL I HAVE HAD IS DOWN TIME. WELL, THE END OF (B)(6) I STARTED HAVING ABDOMINAL PAIN AGAIN. I HAD AN X-RAY DONE AND IT SHOWED THAT A COIL WAS LEFT BEHIND BECAUSE IT HAD RUPTURED OUT OF MY TUBE AND IN TO MY BOWEL. SECOND COIL REMOVAL SURGERY WAS IN (B)(6) 2015. I WAS REALLY HOPING THAT IT WOULD FIX MY PROBLEMS. WELL, IN (B)(6) OF 2015 I HAD MY WORST ATTACK EVER IN MY

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INTESTINES. I HAD TO HAVE EMERGENCY SURGERY TO REMOVE 20 IN OF MY INTESTINES AND TO FIX A FISTULA BETWEEN MY BOWEL AND MY VAGINAL CANAL. DURING THAT MONTH LONG HOSPITAL STAY I GOT A DIAGNOSES OF CROHN'S DISEASE. BEFORE ESSURE I WAS COMPLETELY HEALTHY. SINCE HAVING ESSURE IMPLANTED I NOW HAVE SERIOUS HEALTH ISSUES AND AUTO-IMMUNE DISORDERS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD DEBILITATING PAIN AND HEAVY BLEEDING WITH CLOTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE REQUESTED DEVICES REMOVAL; AFTER A HYSTEROSALPINGECTOMY HER PAIN PERSISTED AND AN X-RAY SHOWED A COIL WAS LEFT BEHIND (IT HAD RUPTURED OUT OF HER TUBE AND INTO HER BOWEL). SHE WAS SUBMITTED TO ANOTHER SURGERY TO REMOVE THE COIL. LATER, THE CONSUMER WAS HOSPITALIZED AND DIAGNOSED WITH CHRON'S DISEASE. ONLY CHRON'S DISEASE IS UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND ABDOMINAL, PELVIC OR UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE CONSUMER REPORTED AN ENDOMETRIAL ABLATION (NOVASURE) WAS PERFORMED ON THE SAME DAY OF ESSURE PLACEMENT; THIS MIGHT SUGGEST AN UNDERLYING CONDITION (SUCH AS CHRONIC MENORRHAGIA) WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR HER BLEEDING. REGARDING HER PAIN, SHE WAS DIAGNOSED WITH CHRON'S DISEASE, A CONDITION THAT CAN LEAD TO ABDOMINAL PAIN. NEVERTHELESS, CONSIDERING EVENTS NATURE AND THE POSITIVE TEMPORAL RELATIONSHIP WITH INSERTION (STARTED 1 MONTH AFTER THE PROCEDURE), A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. FOR THE PERFORATION MENTIONED BY THE CONSUMER (ESSURE RUPTURED OUT HER TUBE INTO HER BOWEL); THE PERFORATION OF THE UTERUS, FALLOPIAN TUBES AND INTERNAL BODILY STRUCTURES MAY OCCUR DURING ESSURE THERAPY DUE TO INSERT MIGRATION OR DURING INSERTION PROCEDURE. ALTHOUGH THE EXACT MECHANISM OF THIS EVENT WAS NOT KNOWN, GIVEN THE ABOVE MENTION INFORMATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. CHRON'S DISEASE WAS CONSIDERED AS UNRELATED TO ESSURE DUE TO THE LOCAL ACTION OF THE DEVICES IN FALLOPIAN TUBES AND GIVEN EVENT'S PATHOPHYSIOLOGY. OTHER NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED INCIDENT, SINCE DEVICES REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS PROVIDED ON 09-SEP-2015. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00872	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0529, AWARENESS DATE 14-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER'S HUSBAND REPORTED: I AM THE HUSBAND, WHO HAD TO WATCH HIS WIFE SUFFER FROM A DEVICE THAT WAS SUPPOSE TO MAKE OUR LIVES WORRY AND STRESS FREE BUT IT LEFT US IN PAIN. MY WIFE CONSTANTLY FELT LIKE SHE WAS IN LABOR. CONTRACTING, DIALATING, LACTATING, EMOTIONALLY WRECKED. SEX IS PAINFUL FOR HER. I HAD TO SIT BACK AND WATCH MY WIFE CHANGE BECAUSE OF THE PAIN AND SUFFERING CAUSED BY THESE COILS. MY WIFE IS TODAY 22 DAYS POST OPERATIVE VIA HYSTERECTOMY DUE TO COILS BEING LODGED IN HER UTERINE LINING. SHE IS (B)(6) AND STRONGER NOW THAN SHE EVER WAS WITH ESSURE. SHE RECOVERED IN ONE DAY FROM A FULL HYSTERECTOMY AND WAS SERIOUSLY NEGATIVELY EFFECTED AND SLOWLY DYING WHEN SHE HAD ESSURE INSIDE OF HER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE COILS WAS LODGED IN HER UTERINE LINING. THIS EVENT, SEEN AS DEVICE EMBEDMENT, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THERE IS A RISK THAT ESSURE MICRO-INSERT COULD DISLOCATE AND EMBED IN UTERINE WALL. IN THIS CASE, THE CONSUMER HAD INTENSE PAIN AND UTERINE CONTRACTIONS. THEN, SHE HAD A HYSTERECTOMY DUE TO COILS BEING LODGED IN HER UTERINE LINING. ALTHOUGH IN THIS CASE, THE EXACT MECHANISM OF EMBEDMENT HAS NOT BEEN INFORMED, GIVEN EVENT'S NATURE, CAUSALITY WITH ESSURE USE

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CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00874	BAYER HEALTHCARE LLC	9/11/2015	9/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0553, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008.THE CONSUMER'S MOTHER REPORTED HER DAUGHTER HAD ESSURE INSERTED IN (B)(6) 2008. SHE WAS A SINGLE MOTHER OF ONE DAUGHTER. SHORTLY THEREAFTER THE PROCEDURE SHE BEGAN DEVELOPING A MYRIAD OF PHYSICAL AND EMOTIONAL/MENTAL SYMPTOMS INCLUDING GASTRO, MENSTRUAL, VAGUE BODY ACHES AND PAINS, TICS, BRAIN ZAPS, DEPRESSION, ANXIETY, PANIC ATTACKS, PTSD, MERCURIAL MOOD CHANGES, HAIR LOSS, DENTAL, DIGESTIVE AND IRREGULAR HEARTBEAT PROBLEMS. SHE SOUGHT PROFESSIONAL HELP FOR BOTH HER PHYSICAL AND MENTAL CONDITIONS WITH NO IMPROVEMENT. BY (B)(6) 2008, SHE WAS MISSING WORK DUE TO HEALTH PROBLEMS. IN (B)(6) 2008 HER DAUGHTER WENT TO LIVE WITH THE REPORTER DUE TO HER MOTHERS DECLINING HEALTH. AS OF (B)(6) 2009 CONSUMERS WORK ABSENCES INCREASED AND THE PROFESSIONAL HEALTHCARE PRODUCED NO IMPROVEMENT; IN FACT, HER DETERIORATION CONTINUED. ON ONE OCCASION THE CONSUMER TOOK TOO MUCH MEDICATION AND WAS TAKEN TO THE HOSPITAL. SHE WAS DIAGNOSED WITH SEROTONIN SYNDROME. SHE HAD NOT BEEN EMPLOYED LONG ENOUGH TO EARN DISABILITY BENEFITS AND HAD NO HEALTH BENEFITS OR INCOME. TO THE PRESENT, SHE HAD SOUGHT HELP FROM AT LEAST 20 HEALTHCARE PROFESSIONALS IN ATTEMPTS TO GET BETTER. IN 2013, AS A RESULT OF OUR SEARCHES, THEY FOUND A PHYSICIAN AND MADE ARRANGEMENTS TO REMOVE THE ESSURE COILS. SINCE HER SURGERY, SHE HAS SLOWLY IMPROVED IN SOME AREAS BUT THE LASTING AFFECTS ENDURE. HER OVERALL HEALTH IS FAIR AT BEST; SHE STILL HAS EPISODES OF ILLNESS

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NECESSITATING ABSENCE FROM HER JOB. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED VAGUE BODY ACHES AND PAINS. THE DEVICES WERE REMOVED AND SHE IS SLOWLY RECOVERING. ADDITIONALLY, ONE DAY SHE TOOK TOO MUCH MEDICATION AND WAS TAKEN TO THE HOSPITAL; BEING DIAGNOSED WITH SEROTONIN SYNDROME. ONLY PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED AFTER ESSURE INSERTION AND IMPROVED WITH DEVICES REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, THE REPORTER STATED CONSUMER HAD EMOTIONAL DISORDERS WITH PANIC ATTACKS, DEPRESSION, ANXIETY. SHE WAS DIAGNOSED WITH SEROTONIN SYNDROME AFTER SHE TOOK TOO MUCH MEDICATION. SEROTONIN SYNDROME IS ASSOCIATED WITH INCREASED SEROTONERGIC ACTIVITY IN THE CENTRAL NERVOUS SYSTEM (CNS). IT IS SEEN WITH THERAPEUTIC MEDICATION USE, INADVERTENT INTERACTIONS BETWEEN DRUGS, AND INTENTIONAL SELF-POISONING. CONSIDERING ESSURE LOCAL ACTION AT FALLOPIAN TUBES AND GIVEN EVENT'S PATHOPHYSIOLOGY CAUSALITY IS CONSIDERED UNLIKELY. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE I

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056192	BAYER	9/11/2015	9/16/2015

Event Information:

Event Date (B3): 12/28/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/28/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER I GAVE BIRTH TO MY FOURTH CHILD I DECIDED TO GET ON A PERMANENT BIRTH CONTROL KNOWN AS ESSURE. AFTER HAVING THE BIRTH CONTROL INSERTED INSIDE OF ME I STARTED TO NOTICE HEAVIER VAGINAL BLEEDING THAN NORMAL WITH MY MONTHLY CYCLES, FREQUENT AND SEVERE HEADACHES, FATIGUE, AND SEVERE BACK PAIN THAT HAS TO BE HANDLED WITH PHYSICAL THERAPY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00798	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/27/2014
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0124, AWARENESS DATE 13-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHORTLY AFTER ESSURE WAS PLACED, THE CONSUMER STARTED EXPERIENCING PROLONGED PAINFUL PERIODS; CHRONIC ABDOMINAL PAIN; PAIN AND SWELLING IN HER JOINTS; VAGINAL BURNING AND SWELLING; DEPRESSION; ANXIETY AND HAIR LOSS. ONE OF HER COILS APPEARS TO BE BENT POSSIBLY BROKEN AND PERFORATED THE TUBE. ACCORDING TO HER, THERE WAS NO WAY TO KNOW FOR SURE WITHOUT SURGERY. SHE WAS SCHEDULED FOR A HYSTERECTOMY AT (B)(6) ON (B)(6) 2015 AS A RESULT OF THIS DEVICE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, AND ONE OF HER COILS WAS POSSIBLY BROKEN AND PERFORATED THE TUBE. SHE WAS SCHEDULED FOR A HYSTERECTOMY. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION; WHILE FALLOPIAN TUBE PERFORATION IS LISTED. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURES (E.G. HYSTEROSCOPY, CURETTAGE) INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. CONSUMER REPORTED A SUSPICION OF DEVICE BREAKAGE IN ADDITION TO FALLOPIAN TUBE PERFORATION AN UNSPECIFIED TIME AFTER ESSURE PLACEMENT. ALTHOUGH THE EXACT MECHANISM OF THESE EVENTS IS NOT KNOWN; GIVEN THEIR NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED.

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THIS CASE WAS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED AS EVENTS TREATMENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00803	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-2780736-0062, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT ESSURE HAS MADE HER VERY SICK. AFTER GETTING ESSURE SHE HAS HAD PAINFUL SEX, PELVIC PAIN, STABBING PAINS IN ABDOMINAL CAVITY, STABBING PAINS IN UTERUS AND VAGINA. SHE STARTED HAVING TWO HEAVY PERIODS A MONTH AND WHEN THE DOCTOR REFUSED TO BELIEVE IT WAS BECAUSE OF THE ESSURE, HE CHOSE TO DO AN ABLATION. CONSUMER HAS PAIN EVERYWHERE, BONES, MUSCLES, JOINTS. A TERRIBLE METALLIC TASTE IN MOUTH, TEETH AND HAIR ARE BRITTLE, AND A CONSTANT RINGING IN EARS. TWICE A MONTH, INSTEAD OF BLEEDING, SHE STILL HAS THE HORMONAL ISSUES WITH HER PERIOD. HER STOMACH IS BLOATED AND SHE IS ONLY (B)(6). THERE IS NO REASON FOR HER TO LOOK PREGNANT. CONSUMER ALSO HAS A RASH ON STOMACH AND THIGHS. SHE WAS SO SICK AND SO DEPRESSED THAT SHE TRIED TO END HER LIFE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS EXPERIENCING TWO HEAVY PERIODS A MONTH AND HAD AN ENDOMETRIAL ABLATION. SHE ALSO WAS SO DEPRESSED THAT SHE TRIED TO END HER LIFE. THESE EVENTS, SEEN AS POLYMENORRHOEA AND SUICIDE ATTEMPT, ARE SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SOME DEPRESSIVE FEELINGS AND EMOTIONAL DISTURBANCES REGARDING THE DEFINITIVE CONTRACEPTION WITH ESSURE HAVE BEEN REPORTED, HOWEVER; NEITHER MAJOR DEPRESSIVE, NOR SUICIDAL

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ATTEMPTS ARE EXPECTED. THUS, CAUSAL RELATIONSHIP BETWEEN SUICIDE ATTEMPT AND ESSURE USE IS VERY UNLIKELY. ALSO, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR DURING ESSURE USE. THEREFORE, GIVEN EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP POLYMENORRHOEA IS ASSESSED AS RELATED TO ESSURE USE. SINCE THIS EVENT LED TO REQUIRED INTERVENTION (ABLATION), THIS CASE IS REGARDED AS INCIDENT. IN ADDITION SOME DEPRESSIVE FEELINGS AND EMOTIONAL DISTURBANCES REGARDING THE DEFINITIVE CONTRACEPTION WITH ESSURE HAVE BEEN REPORTED, HOWEVER; NEITHER MAJOR DEPRESSIVE, NOR SUICIDAL ATTEMPTS ARE EXPECTED. THUS, CAUSAL RELATIONSHIP BETWEEN SUICIDE ATTEMPT AND ESSURE USE IS VERY UNLIKELY. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00806	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0162, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. THE CONSUMER REPORTED SHE BLED FOR 3-4 MONTHS AFTER ESSURE INSERTION AND AN ABLATION WAS PERFORMED IN 2010. SHE BEGAN DEVELOPING CYSTS AND ENDOMETRIOSIS; HER RIGHT OVARY ENLARGED TO THE SIZE OF A SOFTBALL AND CYST THE SIZE OF A BASEBALL ON TOP OF IT CAUSING UNIMAGINABLE PAIN. THE REMOVAL OF RIGHT TUBE AND OVARY WAS PERFORMED; WHICH HAD TO BE CUT IN PIECES TO EVEN BE REMOVED. SHE STATED THAT BEFORE ESSURE SHE HAD NO RELATED PROBLEMS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BLED FOR 3-4 MONTHS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO AN ABLATION. ADDITIONALLY, SHE DEVELOPED A CYST THE SIZE OF A BASEBALL IN HER RIGHT OVARY; WHICH WAS SURGICALLY REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY BLEEDING, REGARDED AS GENITAL BLEEDING, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER WAS DIAGNOSED WITH ENDOMETRIOSIS; WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR HER BLEEDING. HOWEVER, AS THIS EVENT STARTED AFTER ESSURE INSERTION AND SHE WAS SUBMITTED TO AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION) ON THE SAME YEAR OF DEVICE PLACEMENT; A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. FOR OVARIAN CYST; GIVEN ITS NATURE, CONSIDERING ENDOMETRIOSIS AS AN ALTERNATIVE

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EXPLANATION AND BASED ON ESSURE NON-HORMONAL, LOCAL ACTION AT FALLOPIAN TUBES, CAUSALITY IS CONSIDERED UNLIKELY. THIS CASE WAS REGARDED AS INCIDENT, SINCE AN INTERVENTION (ENDOMETRIAL ABLATION) WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED T

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00807	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT BECAUSE OF ESSURE SHE HAD TO HAVE A HYSTERECTOMY AT THE (B)(6). ESSURE CAUSED HER TO HAVE DAILY HEADACHES, MIGRAINES, RASHES, HIVES, DEPRESSION, WEIGHT GAIN, BLOATING, HEAVY PERIODS WHEN SHE WOULD HAVE THEM OR WOULD GO MONTHS AT A TIME WITHOUT HAVING A PERIOD, LEFT SIDE PAIN BY THE OVARIES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD LEFT SIDE PAIN BY THE OVARIES AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED AFTER ESSURE INSERTION. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00808	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0140, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. THE CONSUMER REPORTED THAT AFTER HAVING ESSURE INSERTED, SHE HAD STABBINGS PAINS, EXTREME BLEEDING, WEIGHT GAIN AND MANY PROCEDURES. SHE HAD BIOPSIES, D&C (INTERPRETED AS DILATION AND CURETTAGE), HYSTEROSCOPY, UTERINE ABLATION AND FINALLY A FULL HYSTERECTOMY. SHE STATED THAT NEVER ONCE HER PHYSICIAN INFORMED HER ANY OF THE SIDE EFFECTS OF ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THAT HAD EXTREME BLEEDING. SHE UNDERWENT BIOPSIES, D&C (INTERPRETED AS DILATION AND CURETTAGE), HYSTEROSCOPY, UTERINE ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION) AND FINALLY A FULL HYSTERECTOMY. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT, POSITIVE TEMPORAL RELATIONSHIP, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 08-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00810	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2010. THE CONSUMER EXPERIENCED CONSTANT BLEEDING AND ABNORMAL PAP. ABLATION AND LEEP (LOOP ELECTROSURGICAL EXCISION PROCEDURE) WERE PERFORMED. CYSTS DEVELOPED AS WELL AS ENDOMETRIOSIS. HER RIGHT OVARY BECAME ENLARGED WITH A CYST THAT WAS ALSO ENLARGED, AND BOTH NEEDED REMOVAL AS WELL AS RIGHT TUBE IN (B)(6) 2015. THE SURGERY CAUSED INFLAMED JOINT AND DISPLACEMENT, WHICH WAS CAUSING PAIN AND LIMITING ACTIVITIES EVEN WITH PHYSICAL THERAPY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT BLEEDING AND AN OVARIAN CYST THAT WAS SO ENLARGED IT WAS REMOVED. AN ABLATION WAS ALSO PERFORMED. THE SURGERY CAUSED DISPLACEMENT (INTERPRETED AS DEVICE DISLOCATION). THE DEVICE DISLOCATION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND THE GENITAL BLEEDING AND OVARIAN CYST ARE SERIOUS DUE TO REQUIRED INTERVENTIONS. ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE, THIS BLEEDING AND DEVICE DISLOCATION ARE LISTED WHILE OVARIAN CYST IS UNLISTED. IN THIS PARTICULAR CASE, THE EVENTS OCCURRED DURING ESSURE USE. ALTHOUGH THE TEMPORAL RELATIONSHIP IS COMPATIBLE, CONSIDERING THE NATURE OF EVENTS AND THE LOCALIZED ACTION OF ESSURE, THE CONSTANT BLEEDING AND DEVICE DISLOCATION COULD BE CAUSED BY ESSURE. HOWEVER, IT IS UNLIKELY THAT ESSURE WOULD CAUSE THE OVARIAN CYST (UNRELATED). THIS CASE IS

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REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00811	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0175, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008, FOR BIRTH CONTROL. THE CONSUMER REPORTED THAT IN 2015 A HYSTERECTOMY WAS REQUIRED TO RELIEVE THE PAIN, BLOATING, BRAIN FOG, GASTRIC PROBLEMS, AND MIGRAINES OF THIS DEVICE. SHE STATED THAT AFTER THE SURGERY ALL OF HER SYMPTOMS HAVE GONE. SHE REPORTED THAT SHE WAS NOT TOLD THE DEVICES HAD PET FIBERS IN IT AND THEY ARE EXCRUCIATING PAIN CAUSING DEVICES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING PAIN. SHE UNDERWENT A HYSTERECTOMY 7 YEARS AFTER ESSURE INSERTION. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT, THE LACK OF AN ALTERNATIVE EXPLANATION, AND SINCE THE PAIN RESOLVED AFTER HYSTERECTOMY, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT:

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00812	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 9/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4)2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. SINCE ESSURE INSERTION, THE CONSUMER HAD EXTREME BLOATING, HEAVY PAINFUL PERIODS, PELVIC PAIN ALL THE TIME. HER PAIN WAS SO BAD THAT HER DOCTOR TRIED DIFFERENT BIRTH CONTROL OPTIONS AND THEN FINALLY AN ABLATION. THE PELVIC PAIN IS STILL TERRIBLE. SHE WANT THEM OUT. SHE IS (B)(6) NOW. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY PAINFUL PERIODS AND PELVIC PAIN ALL THE TIME. SHE WAS SUBMITTED TO AN ABLATION. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND PELVIC PAIN MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER EXPERIENCED THE EVENTS SINCE ESSURE INSERTION. CONSIDERING THIS POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION); THE CONSUMER STATED IT WAS PERFORMED DUE TO HER PAIN. ENDOMETRIAL ABLATION IS USUALLY USED TO TREAT WOMEN WITH CHRONIC MENORRHAGIA. IT MAY ALSO BE USED FOR ACUTE ABNORMAL UTERINE BLEEDING. ALTHOUGH PAIN IS NOT AN INDICATION FOR AN ENDOMETRIAL ABLATION; CONSUMER ALSO REPORTED HEAVY MENSTRUAL BLEEDING; WHICH COULD BE AN INDICATION FOR THIS PROCEDURE. SINCE THIS

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INTERVENTION WAS REQUIRED AS EVENT'S TREATMENT; THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, THE NON-SERIOUS EVENT EXTREME BLOATING WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00813	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/5/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0416, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006 FOR BIRTH CONTROL. THE CONSUMER REPORTED THAT SHORTLY AFTER INSERTION, SHE STARTED EXPERIENCING EXCRUCIATING ABDOMINAL PAIN. THE PAIN GOT SO BAD SHE WAS UNABLE TO FUNCTION NORMALLY, HER DOCTOR SUSPECTED ENDOMETRIOSIS AND CHOSE TO PERFORM AN EXPLORATORY SURGERY. THERE WAS NO ENDOMETRIOSIS; AND AS DISCUSSED PRIOR TO SURGERY, HE PERFORMED A PRESACRAL NEURECTOMY TO RELIEVE HER PAIN. SHE STATED THAT HER OPTIONS BECAUSE OF ESSURE WERE TO HAVE A NERVE SEVERED OR HAVE HYSTERECTOMY AT (B)(6). AT TIME OF THE REPORT, SHE STILL EXPERIENCED PAIN AND HORRIBLE MENSTRUAL CYCLES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ABDOMINAL PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A PRESACRAL NEURECTOMY IN ATTEMPT TO RELIEVE THE PAIN; BUT IT PERSISTED. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL AND PELVIC PAIN MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER STATED SHE DEVELOPED EXCRUCIATING ABDOMINAL PAIN SHORTLY AFTER ESSURE INSERTION. AS TREATMENT HER PHYSICIAN SUGGESTED A HYSTERECTOMY OR A PRESACRAL NEURECTOMY (PSN). PSN IS A SURGICAL PROCEDURE TO INTERRUPT THE CERVICAL SENSORY NERVE FIBERS IN THE PELVIC AREA. IT IS USUALLY INDICATED FOR PRIMARY DYSMENORRHEA AND CHRONIC PELVIC PAIN. CONSIDERING

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THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND PAIN ONSET AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS REQUIRED AS EVENT'S TREATMENT, THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 07-OCT-2015 FROM CONSUMER VIA REGULATORY AUTHORITY (#MW5044262): A NEW REPORTER WAS ADDED. ESSURE WAS INSERTED ON (B)(6) 2006 AND IS ONGOING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPOR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00816	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2012
Explant Date (E7): 3/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. SHE INFORMED THE DOCTOR OF HER NICKEL ALLERGY AND WAS TOLD IT WOULD NOT IMPACT HER SINCE THE COILS WOULD BE WRAPPED IN SCAR TISSUE. LT SERIOUSLY CRIPPLED HER QUALITY OF LIFE. SHE EXPERIENCED INFLAMMATION THROUGHOUT HER BODY, CONSTANT STOMACH BLOATING, PAINFUL INTERCOURSE, CHRONIC FATIGUE AND ANXIETY ATTACKS. THE INFLAMMATION SHE EXPERIENCED WAS SO BAD SHE WAS DIAGNOSED WITH RHEUMATOID ARTHRITIS. ON (B)(6) 2015 SHE UNDERWENT A BILATERAL SALPINGECTOMY AND HAD THE COILS REMOVED. ALL THE SYMPTOMS LISTED ABOVE WERE GONE. IT WAS THE ESSURE THAT CAUSED HER PROBLEMS. SINCE THE REMOVAL OF ESSURE, HER DIAGNOSIS HAS BEEN CLEARED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD PAINFUL INTERCOURSE AMONG NON-SERIOUS EVENTS. THIS EVENT, INTERPRETED AS DYSPAREUNIA IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, IT IS IMPLIED THAT THE PAINFUL INTERCOURSE OCCURRED DURING ESSURE THERAPY. APPROXIMATELY 3 YEARS AFTER INSERTION, SHE UNDERWENT A BILATERAL SALPINGECTOMY WITH ESSURE REMOVAL AND ALL HER SYMPTOMS WERE GONE. CONSIDERING THE SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE

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EXPLANATION, THIS EVENT IS ASSESSED AS RELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00817	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0267, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED ESSURE MADE HER GAIN MORE THAN 60 POUNDS; HER HAIR FELL OUT AND SHE HAD NICKEL ALLERGY THAT WAS KNOWN AFTER ESSURE WAS IMPLANTED. SHE REPORTED THAT DUE TO WEIGHT GAIN SHE HAD HYPOTHYROIDISM AND SLEEP APNEA; SHE SUFFERED FROM CONSTANT STABBING PAIN IN HER PELVIC AREA, SEVERE MONTHLY BLEEDING AND THE ONLY WAY TO SOLVE THE ISSUES WAS A TOTAL HYSTERECTOMY AT AGE (B)(6). DURING THE SURGERY, HER DOCTOR NOTED EXTREME SCAR TISSUE THROUGH OUT HER FEMALE REPRODUCTIVE ORGANS AND ENDED UP HAVING TO LEAVE CERVIX DUE TO SCAR TISSUE ATTACHING IT TO HER BLADDER. SHE STATED THAT SINCE HER SURGERY SHE WAS DOWN ALMOST 8 POUNDS IN 11 DAYS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CONSTANT STABBING PAIN IN HER PELVIC AREA. SHE UNDERWENT A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, THE CONSUMER ALSO HAD PELVIC ADHESIONS WHICH COULD HAVE CONTRIBUTED TO THE OCCURRENCE OF THE PAIN. HOWEVER, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. NON-SERIOUS EVENTS WERE ALSO

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REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00875	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0539, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE FOR BIRTH CONTROL. CONSUMER STATED SHE CAN'T WORK TO TAKE CARE OF HER CHILDREN BECAUSE WAS EXPERIENCING TOO MUCH PAIN AND WAS IN AND OUT OF THE HOSPITAL ALL THE TIME. SHE COULD NOT PICK HER KIDS UP BECAUSE IT FELT LIKE HER INSIDES WERE RIPPING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN (SHE FELT LIKE HER INSIDES WERE RIPPING) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS EVENT, INTERPRETED AS PELVIC PAIN, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER REPORTED INTENSE PAIN WITH COMPROMISE OF HER DAILY ACTIVITIES AND WITH NEED OF HOSPITAL VISITS (UNCLEAR IF SHE WAS ADMITTED OR NOT). ALTHOUGH LIMITED INFORMATION WAS PROVIDED, SINCE CONSUMER RELATED HER PAIN TO ESSURE AND AS NO FOLLOW-UP WILL BE POSSIBLE; COMPANY CONSIDERS THIS EVENT AS RELATED TO THE SUSPECT INSERT. AS HOSPITALIZATION (SERIOUS INJURY) CANNOT BE FORMALLY EXCLUDED IN THIS CASE, IT WAS REGARDED AS AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00878	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE (B)(6) 2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2013. CONSUMER HAD ESSURE INSERTED TWO YEARS AGO. SHE HAS SUFFERED GREATLY AND DIDN'T REALIZE ESSURE WAS HER PROBLEM UNTIL ABOUT 8 MONTHS AGO. HER HAIR BEGAN TO FALL OUT, CYCLE WERE SO BAD THERE WERE DAYS SHE COULDN'T WORK, THE BACK AND PELVIC PAIN WERE SO BAD SHE COULDN'T FUNCTION TO TAKE CARE OF HER FAMILY OR WORK AND SHE STAYED TOTALLY EXHAUSTED. SHE HAD A LAPAROSCOPIC HYSTERECTOMY IN (B)(6) 2015 AT THE AGO OF (B)(6) TO REMOVE UTERUS, TUBES AND CERVIX. THE PHYSICIAN ENDED UP TAKING ONE OVARY BECAUSE OF SEVERE ENDOMETRIOSIS. AFTER SURGERY SHE HAS FELT LIKE A TOTALLY DIFFERENT PERSON. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND PRESENTED PELVIC PAIN. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER HAD PELVIC AND BACK PAIN AMONG OTHER NON-SERIOUS EVENTS. THEN, SHE HAD A LAPAROSCOPIC HYSTERECTOMY AT (B)(6) TO REMOVE UTERUS, TUBES AND CERVIX. ALTHOUGH ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION POR PAIN, GIVEN EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, A CONTRIBUTORY ROLE OF ESSURE FOR THE EVENT CANNOT BE TOTALLY EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED,

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THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 11-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00879	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0488, AWARENESS DATE 19-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED THAT BEFORE ESSURE PLACEMENT SHE TOLD HER PHYSICIAN SHE HAD NICKEL SENSITIVITY AND SHE ALWAYS HAD PAINFUL PERIODS. THE PHYSICIAN PERFORMED THE PROCEDURE AND PLACED MIRENA AS BACK UP BIRTH CONTROL. SHE STARTED HAVING SYMPTOMS WITHIN A MONTH OF PLACEMENT; SHE HAD VISION PROBLEMS, DOUBLE VISION, STARS. THEN DAILY HEADACHES STARTED STABBING PAIN IN THE PELVIC REGION. SHE WENT TO SEE AN OPTOMETRIST, OPHTHALMOLOGIST AND A NEUROLOGIST. SHE HAD TO HAVE AN MRI, RETINAL EVOKE TEST AND ALL OF WHICH CAME BACK FINE. SHE WENT BACK TO HER IMPLANTING PHYSICIAN WHO TOLD HER THAT HER HORMONES WERE THE CAUSE OF HER MEDICAL PROBLEMS, AT WHICH HE PRESCRIBED BIRTH CONTROLS PILLS AS WELL. SHE MADE A BLOOD WORK THAT CAME BACK NORMAL AND THEN SOUGHT A SECOND OPINION. HER NEW DOCTOR AGREED THAT THE ESSURE NEEDED TO BE REMOVED. SHE HAD A HYSTERECTOMY 14 MONTHS AFTER PLACEMENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD STABBING PAIN IN THE PELVIC REGION. SHE HAD A HYSTERECTOMY 14 MONTHS AFTER PLACEMENT. THIS EVENT, INTERPRETED AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, IT IS STATED THAT SHE STARTED HAVING SYMPTOMS 1 MONTH

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AFTER ESSURE INSERTION. THEN SHE HAD THIS PELVIC PAIN. CONSIDERING THE NATURE OF THIS EVENT, THE SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN ESSURE AND THIS EVENT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 11-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00880	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 8/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0580, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. CONSUMER STATED SHE HAD ESSURE IMPLANTED IN 2013 TO PREVENT ANY MORE PREGNANCIES BECAUSE HER LAST PREGNANCY WAS HORRIBLE FOR HER AND HER CHILD. ABOUT 2 MONTHS AFTER SHE HAD ESSURE IMPLANTED SHE BEGAN TO EXPERIENCE ADVERSE REACTIONS. SHE STATED THAT THE LIST OF THOSE ADVERSE REACTIONS WAS: GYNECOLOGIC: PAINFUL AND HEAVY PERIODS, PAIN WITH INTERCOURSE, EXCESSIVE BLOATING, CHRONIC LOWER BACK PAIN - SHE HAD AN ABLATION DONE (B)(6) 2014, WHICH WAS INEFFECTIVE. SHE HAD TO HAVE A HYSTERECTOMY (B)(6) 2015, AS AN END RESULT. GASTROINTESTINAL: CHRONIC NAUSEA AND VOMITING - SHE HAD A COLONOSCOPY/EGD DONE, WHICH WAS NEGATIVE AND THE DOCTOR COULD NOT TELL WHY SHE CONTINUED TO HAVE THESE SYMPTOMS - SHE TOOK ZOFRAN AND BENTYL AS DAILY MEDICATION WHICH SHE HAS NOT TAKEN SINCE SHE HAD HYSTERECTOMY. NEURO: MORE FREQUENT AND PAINFUL MIGRAINES - HAD A CT (COMPUTERISED TOMOGRAPHY) OF HEAD - MULTIPLE TRIALS OF MEDICINES, PRESENTLY TAKING ZONEGRAN BUT HAS NOT HAD A MIGRAINE SINCE SHE HAD HYSTERECTOMY. INTERNAL: DECREASED ENERGY, LETHARGY, DEPRESSION - SHE PRESENTLY TAKES VITAMIN B12. FOLIC ACID, AND VITAMIN D3. SHE HAS TRIED MULTIPLE ANTIDEPRESSANTS WHICH SHE CANNOT TOLERATE. SHE DID NOT CONTRIBUTE ALL OF HER NEWLY DEVELOPED HEALTH PROBLEMS TO ESSURE AT FIRST, BUT WHEN SHE DID A TIMELINE OF EVERYTHING, IT ALL STARTED AFTER SHE HAD ESSURE IMPLANTED. SHE STATED THAT SHE HAS MISSED OUT ON A LOT OF THINGS THAT HER CHILDREN HAVE

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DONE BECAUSE THE COILS STRIPPED HER OF HER HEALTH AND ENERGY. SHE USED TO COACH CHEERLEADING, SWIM, TAKE DAILY WALKS WITH HER CHILDREN, BE ABLE TO WORK FULL TIME AND MAINTAIN HER HOUSEHOLD WITHOUT DIFFICULTY, SHE USED TO BE HAPPY: UNTIL THE COILS WERE IMPLANTED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BEGAN TO EXPERIENCE HEAVY PERIODS. SHE UNDERWENT AN ENDOMETRIAL ABLATION WHICH WAS INEFFECTIVE, AND ENDED UP HAVING A HYSTERECTOMY 2 YEARS AFTER ESSURE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 11-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00881	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0506, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2011. CONSUMER REPORTED: I GOT ESSURE DONE IN 2011 AFTER MY SECOND CHILD WAS BORN. MILD DISCOMFORT FOR THE FIRST FEW WEEKS AFTER THEN I WAS FINE. A YEAR LATER I NOTICED I HAD GAINED 28 LBS. THEN I STARTED TO GET HORRIBLE JOINT PAIN. I'M ALSO AN EPILEPTIC WHO'S SEIZURES WERE UNDER CONTROL WITH MY MEDICATION. BUT MY SEIZURES STARTED TO GET FREQUENT, MY NEUROLOGIST HAD NO EXPLANATION WHY MY ANTI CONVULSION MEDICATION WAS ALL OF A SUDDEN INEFFECTIVE. IN 2013 I WAS CONFIRMED PREGNANT. ENDED UP IN THE EMERGENCY ROOM ONE NIGHT BLEEDING, I HAD MISCARRIED. AT THAT POINT I STARTED QUESTIONING ESSURE. IF IT WAS SO EFFECTIVE I SHOULD NOT HAVE GOTTEN PREGNANT ESPECIALLY AFTER BEING CONFIRMED BLOCKED AFTER THE PROCEDURE. IN (B)(6) OF 2014 I WENT IN TO MY OBSTETRICIAN ASKING FOR ESSURE REMOVAL DUE TO THE AMOUNT OF ABDOMINAL PAIN AND BLEEDING I CONTINUED TO HAVE. AFTER MY HYSTERECTOMY PHYSICIAN CAME IN MY ROOM AND SAID "NO WONDER YOU WERE IN PAIN, YOUR UTERUS WAS ENLARGED, AND YOUR LEFT COIL HAD MIGRATED AND WAS DANGLING FROM IT". AFTER SO MUCH TIME OF PAIN AND ISSUES NOT KNOWING WHAT THE PROBLEM WAS, I'M HAPPY TO SAY 9 MONTHS OF NOT HAVING ESSURE IN MY BODY MY JOINT PAIN IS BETTER, MY SEIZURES UNDER CONTROL AGAIN. AND NO ABDOMINAL PAIN. HOWEVER I DO NOW HAVE A METAL ALLERGY I CANNOT WEAR JEWELRY OF ANY KIND WITHOUT BREAKING OUT NOR CAN I CONSUME CANNED FOOD. LT ALSO MAKES ME BREAKOUT, AND I GET HORRIBLE SICK. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS

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AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT AND THEN MISCARRIED. SHE ALSO PRESENTED SEIZURE. LATER, SHE UNDERWENT HYSTERECTOMY DUE TO PAIN AND BLEEDING. DURING SURGERY, IT WAS FOUND THAT LEFT COIL MIGRATED AND WAS DANGLING FROM IT. THESE EVENTS, SEEN AS PREGNANCY, SPONTANEOUS ABORTION, SEIZURE, ABDOMINAL PAIN, GENITAL BLEEDING AND DEVICE DISLOCATION, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. THEY ARE LISTED, EXCEPT MISCARRIAGE AND SEIZURE WHICH ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCY MAY OCCUR IN WOMEN WITH ESSURE MICRO-INSERT. IN THIS CASE, IT WAS CONFIRMED THAT THE TUBES WERE BLOCKED. BUT, LATER, DURING HYSTERECTOMY, IT WAS FOUND THE LEFT COIL WAS MIGRATED. CONSIDERING IT IS NOT CLEAR THE EXACT DATE OF THIS DISLOCATION, THE POSSIBILITY OF DEVICE INEFFICACY CANNOT BE EXCLUDED. ALTHOUGH GESTATIONAL AGE HAS NOT BEEN PROVIDED, SPONTANEOUS ABORTIONS OCCUR MOSTLY DURING THE FIRST 12 WEEKS OF PREGNANCY AND THE VAST MAJORITY OF THESE CASES ARE DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS, THEREFORE CAUSAL RELATIONSHIP WITH ESSURE USE IS ASSESSED AS UNRELATED. GENITAL BLEEDING AND ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE THESE EVENTS LED HER TO HYSTERECTOMY. GIVEN EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. REGARDING SEIZURE, CAUSALITY BETWEEN THIS EVENT AND ESSURE USE IS VERY UNLIKELY SINCE ESSURE ACTS LOCALLY IN FALLOPIAN TUBES. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 11-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00882	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT AFTER ESSURE WAS PLACED HER PERIODS BECAME SO INCREDIBLY HEAVY, HER CRAMPS WERE UNBEARABLE AND SHE HAD PAIN AND HEAVINESS IN HER ENTIRE PELVIC REGION. SHE FINALLY HAD AN UTERINE ABLATION PERFORMED, AND STATED THAT THANKFULLY THE PERIODS STOPPED. HOWEVER, SHE STILL GOT BLOATING, CYSTIC ACNE, STRANGE FLUTTERING FEELING IN HER TUBES AND HER TEETH WERE STARTING TO CRUMBLE. SHE WANTED TO GET ESSURE OUT OF HER BODY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THAT HER PERIODS BECAME SO INCREDIBLY HEAVY THAT SHE HAD TO UNDERGO AN UTERINE ABLATION. THE EVENT RESOLVED AFTER THE PROCEDURE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (ENDOMETRIAL ABLATION). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00883	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0526, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT SHE WAS (B)(6) HAD PAIN AND HYSTERECTOMY. NO ADDITIONAL INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND PRESENTED PAIN. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS ONLY INFORMED SHE PRESENTED PAIN AND HYSTERECTOMY. THUS, CONSIDERING EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW-UP RECEIVED ON 10-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE I

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00884	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0576, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN 2014. CONSUMER REPORTED THAT SHE CHOSE ESSURE FOR BIRTH CONTROL. SHE WAS DEALING WITH TERRIBLE PAINS, HAIR LOSS, WEIGHT GAIN, LONGER PERIODS AND MORE. SHE HAD NO OTHER CHOICE THAN TO TAKE THE ROAD OF HYSTERECTOMY TO END THIS NIGHTMARE AT (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED TERRIBLE PAINS. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SHE WAS DEALING WITH TERRIBLE PAINS AMONG OTHER NON-SERIOUS EVENTS AND WILL HAVE AN HYSTERECTOMY AT (B)(6). CONSIDERING EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED ON 10-SEP-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. T

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00886	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 7/31/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0525, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. ESSURE WAS INSERTED AFTER THE CONSUMER HAD GIVEN BIRTH TO HER 3RD CHILD. IMMEDIATELY AFTER INSERTION SHE STARTED SUFFERING FROM SEVERE ABDOMINAL PAIN. SHE WAS CONFIRMED TO BE BLOCKED AFTER THE 3 MONTHS AND AS THE YEARS PASSED BY, HER SYMPTOMS WORSENED. SHE STARTED HAVING SEVERE PERIODS, JOINT PAINS, HURTING CONSTANTLY, MEMORY LOSS, HAIR LOSS, DENTAL PROBLEMS, SEVERE MIGRAINES, HIGH BLOOD PRESSURE, SEVERE WEIGHT GAIN, INFLAMMATION, FLUID RETENTION AND A NUMEROUS AMOUNT OF OTHER HEALTH PROBLEMS. SHE COULDN'T EVEN MAKE IT THROUGH A DAY WITHOUT SEVERAL MEDICATIONS. EVEN DAY TO DAY ACTIVITIES BECAME A STRUGGLE AND KEEPING A JOB WAS IMPOSSIBLE. ON (B)(6) 2015 THE CONSUMER HAD A BILATERAL SALPINGECTOMY TO REMOVE BOTH FALLOPIAN TUBES AND COILS. ALTHOUGH SHE WAS STILL IN THE HEALING PROCESS, SHE HAD FELT SOME IMMEDIATE RELIEF WITH SOME SYMPTOMS. FOR THE FIRST TIME ON (B)(6) 2015 SHE WAS ABLE TO WALK AROUND WITHOUT HER LEGS AND FEET SWELLING OR GOING NUMB AND SHE HAD MORE ENERGY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED SUFFERING FROM SEVERE ABDOMINAL PAIN/ HURTING CONSTANTLY. SHE UNDERWENT A BILATERAL SALPINGECTOMY TO REMOVE ESSURE 6 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL

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PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (BILATERAL SALPINGECTOMY TO REMOVE ESSURE). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS PROVIDED ON 11-SEP-2015. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00887	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0532, AWARENESS DATE 14-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE WAS IN PAIN ALL THE TIME, HAD HIGH BLOOD PRESSURE (WHAT WAS GONE NOW THAT SHE DOESN'T HAVE ESSURE ANYMORE) AND HEAVY MENSTRUAL CYCLE. SHE STATED THAT SHE JUST HAD A HYSTERECTOMY TO REMOVE ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PAIN ALL THE TIME (INTERPRETED AS PELVIC PAIN). SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY TO REMOVE ESSURE). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00902	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT, ANTICIPATED (SERIOUS INJURY: REQUIRED INTERVENTION). THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0513, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN 2008. SIX MONTHS AFTER ESSURE INSERTION THE CONSUMER STARTED HAVING ABDOMINAL PAIN, SWELLING OF HANDS AND FEET, STIFFNESS IN JOINTS, MORE PAIN ALL OVER. SHE WENT FROM HAVING AN ACTIVE AND HEALTHY LIFE TO ALWAYS BEING IN PAIN. ESSURE WAS REMOVED IN 2013, AND THEN IT WAS FOUND OUT THAT THE CONSUMER HAD RAYNAUD'S DISEASE, FIBROMYALGIA AND LUPUS. ALL THE EVENTS WERE CONSIDERED RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT 6 MONTHS AFTER ESSURE INSERTION. SHE HAD ESSURE REMOVED. BASED ON A POSITIVE TEMPORAL RELATIONSHIP AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO DEVICE REMOVAL. ADDITIONALLY, ANOTHER SERIOUS EVENT (LUPUS, UNRELATED TO SUSPECT INSERT) AND NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED I

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00903	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0015, #FDA-2015-N-2781-0510, AWARENESS DATE 14-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. SHE RECENTLY HAD TO HAVE A HYSTERECTOMY DUE TO COMPLICATIONS OF THE DEVICE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD TO HAVE A HYSTERECTOMY DUE TO COMPLICATIONS OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED ESSURE CAUSED HER COMPLICATIONS; WHICH WERE NOT SPECIFIED AND SHE HAD TO HAVE A HYSTERECTOMY. ALTHOUGH LIMITED INFORMATION WAS PROVIDED, IT CANNOT BE EXCLUDED THAT THIS SURGERY OCCURRED AS A CONSEQUENCE OF ESSURE. THEREFORE THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00904	BAYER HEALTHCARE LLC	9/12/2015	9/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0469, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT SHE WEIGHED (B)(6) AND STOOD 5 FEET AND 6 INCHES AND WANTED TO HAVE ESSURE INSERTED FOR CONTRACEPTION. SHE MENTIONED THAT THE "DOWN" WENT FROM 24 HOURS TO 3 YEARS. SHE HAD CRAMPS THAT JUST SEEMED TO GET PROGRESSIVE WORSE SHE COULD NOT BEND OVER TO EVEN TIE HER SHOES. TWO MONTHS LATER HER HUSBAND NOTICED THAT NOT ONLY WAS SHE CONSTANTLY UNCOMFORTABLE SHE WAS MOODY. SHE WAS BECOMING MORE AND MORE EMOTIONAL. HER KNEES STARTED HURTING TO THE POINT SHE COULD NOT EVEN WALK DOWN THE STAIRS TO WASH CLOTHES. NO X-RAY OR ULTRASOUND WAS ABLE TO FIND ANYTHING WRONG. SHE WOKE UP 1 YEAR TO HAVE ESSURE IMPLANTED TO HORRIBLE CRAMPS THINKING IT WAS JUST WHAT HAS BECOME OF HER MENSTRUAL CYCLE SINCE ESSURE AND GOT OUT OF BED TO FIND OUT THAT THERE WAS SERIOUS INFLAMMATION IN HER LOWER ABDOMEN AND BACK AND HER 2 LOWER DISCS WERE NO LONGER IN PLACE, THEY HAD BEEN PUSHED OUT. ALL WHILE SHE WAS SLEEPING. SHE ALSO HAD HIGH BLOOD PRESSURE, NERVE DAMAGE, A HEART ATTACK, HEADACHES, BACK PAIN, HORRIBLE VISION AND THE LIST GOES ON AND ON. SHE HAD HER FALLOPIAN TUBES REMOVED IN (B)(6) 2014 AND WAS CUT FROM HIP TO HIP TO MAKE SURE THE GYNECOLOGIST GOT IT ALL. IN (B)(6) 2015 SHE HAD RIGHT LOWER BACK PAIN AND STILL SICK ONLY TO FIND OUT IT EMBEDDED ITSELF IN HER UTERUS AND SHE CUT IT AND LEFT IT BEHIND. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT EMBEDDED RIGHT IN HER UTERUS AND SHE CUT IT AND LEFT IT BEHIND. SHE HAD HER FALLOPIAN TUBES REMOVED. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF UTERINE PERFORATION, MAINLY DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF EMBEDMENT WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 24-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056190	CONCEPTUS	9/12/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 508291

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING MY ESSURE IMPLANTS IN 2006, I SLOWLY BEGAN NOTICING CHANGES IN MY BODY. I AM TIRED ALL THE TIME, I HAVE JOINT PAIN SO BAD I WAS PUT ON MEDICATION FOR IT. MY HAIR IS THINNING AND DOESN'T GROW AND I HAVE HEART PALPITATIONS THAT SEEM TO BE GETTING WORSE BY THE DAY. I HAVE HEADACHES THAT NEVER SEEM TO END. I DID NOT HAVE THESE SYMPTOMS BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056191	BAYER	9/12/2015	9/16/2015

Event Information:

Event Date (B3): 9/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/30/2009
Explant Date (E7): 8/17/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD A HYSTERECTOMY AT AGE 33 DUE TO ESSURE. I WAS ALWAYS IN SUFFERING VERY PAINFUL PERIODS, PAINFUL SEX, HEADACHES, LEFT LEG PAIN, BODY RASHES SINCE THE DOCTOR TOOK ESSURE OUT I FEEL MUCH BETTER NO MORE PAIN THANK GOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00826	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2012
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0309, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2012. ACCORDING TO THE CONSUMER, PROCEDURE WAS PAINFUL, EVEN WITH THE PAIN MEDICATION; SHE FELT EVERYTHING. AFTERWARDS, SHE CONTINUED ON BIRTH CONTROL FOR A YEAR, AND THEN SHE HAD AN ABLATION. FOR TWO YEARS, SHE WAS IN CHRONIC PAIN. HER BELLY WAS BLOATED AND SHE GAINED WEIGHT, HAD HORRIBLE STABBING PAIN AND WAS MISERABLE. SHE SPENT TWO YEARS HURTING. IN (B)(6) 2014 SHE WAS IN THE ER; SHE WAS DOUBLED OVER IN PAIN. SHE HAD A HYSTERECTOMY IN (B)(6) 2015 (ASSUMED AS (B)(6) 2014). SHE DID NOT HAVE PAIN SINCE THE SURGERY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PAIN / HORRIBLE STABBING PAIN. SHE WAS SUBMITTED TO A HYSTERECTOMY AND RECOVERED FROM THIS EVENT. THIS EVENT, REGARDED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED AFTER ESSURE INSERTION AND IMPROVED WITH DEVICE REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE

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DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4) FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00827	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0072, AWARENESS DATE (B)(6) 2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE, FOR BIRTH CONTROL. CONSUMER REPORTED THAT FOR FIVE YEARS SHE SUFFERED FROM UNEXPLAINABLE SYMPTOMS, CONSTANT BLEEDING, USING BIRTH CONTROL TO CONTROL THE SYMPTOMS SHE WAS EXPERIENCING FROM HER BIRTH CONTROL. FIVE YEARS OF HER LIFE THAT SHE LOST. SIDE EFFECTS INCLUDED: WEIGHT GAIN, INCESSANT BLEEDING, IRON DEFICIENCY, VITAMIN D DEFICIENCY, DEPRESSION, ANXIETY, HEADACHES, ABDOMINAL PAIN, BACK PAIN, GENERALIZED JOINT PAIN, BLOATING, FATIGUE, BRAIN FOG, LOSS OF APPETITE, STRAINED RELATIONS, LOSS OF JOB, HAIR LOSS, NAUSEA, IBS (INTERPRETED AS IRRITABLE BOWEL SYNDROME),ETC. THE SIDE EFFECTS SHE WAS EXPERIENCING FROM ESSURE IMMEDIATELY CEASED AFTER REMOVAL BY HYSTERECTOMY AT THE AGE OF 34. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INCESSANT BLEEDING. ESSURE WAS REMOVED BY HYSTERECTOMY ON AN UNSPECIFIED TIME AFTER INSERTION. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THIS EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00830	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 5/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. THE CONSUMER REPORTED THAT WHILE THE DEVICES WERE IN SHE WAS IN PAIN DAILY WITH A STABBING PAIN IN WHAT SHE THOUGHT WERE HER OVARIES. AFTER 2 YEARS, THE DOCTORS AGREED TO REMOVE THEM. SHE HAD HER ESSURE COILS REMOVED (B)(6) 2015 AFTER HAVING THEM FOR THREE YEARS. THE FLEXIBLE COILS WERE BENT IN SUCH A WAY HER FALLOPIAN TUBES WERE ARCED UP CUTTING OFF CIRCULATION AND BLOOD FLOW TO HER TUBES CAUSING THE PAIN. HER DOCTOR TOLD HER HE HAD NO DOUBT ALL THE ISSUES SHE HAD HAD SINCE THE COILS WERE PLACED WERE DUE TO THE ESSURE. HE ALSO STATED HE HAD NEVER SEEN THE COILS DO THAT TO ANYONE AND DID A LOT OF RESEARCH AFTER HER PROCEDURE TO SEE IF HE COULD FIND ANYONE ELSE WITH THE SAME ISSUES WITH NO AVAIL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD DAILY STABBING PAIN IN WHAT SHE THOUGHT WERE HER OVARIES AMONG NON-SERIOUS EVENTS. AFTER 3 YEARS, SHE HAD ESSURE COILS REMOVED. THIS EVENT, INTERPRETED AS PELVIC PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT THE FLEXIBLE COILS WERE BENT IN A WAY HER FALLOPIAN TUBES WERE ARCED UP CUTTING THE BLOOD FLOW CIRCULATION TO HER TUBES. SINCE THIS SITUATION MAY CAUSE THE PELVIC PAIN, THE CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE IS ASSESSED AS RELATED. THIS CASE IS

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REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00831	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0290, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. SHE SUFFERED YEARS OF SEVERE PAIN, INABILITY TO LOSE WEIGHT, INFLAMMATION ALL OVER, DEPRESSION AND ANXIETY. AS SOON AS THE ESSURE COILS WERE REMOVED, SHE HAD NO MORE PAIN, LOST WEIGHT, HER DEPRESSION AND ANXIETY WERE GETTING BETTER BECAUSE SHE WAS ABLE TO DO MORE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SUFFERED YEARS OF SEVERE PAIN. ESSURE COILS WERE REMOVED, AND SHE HAD NO MORE PAIN. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT, THE LACK OF AN ALTERNATIVE EXPLANATION, AN SINCE THE PAIN RESOLVED AFTER THE DEVICE WAS REMOVED, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE REMOVAL WAS REPORTED, IMPLYING THAT AN INTERVENTION WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00832	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0295, AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. CONSUMER STATED THAT ESSURE WAS THE WORST MISTAKE SHE EVER MADE. SHE EXPERIENCED SO MUCH PAIN THAT SHE THOUGHT SHE WOULD DIE. SHE HAD A HYSTERECTOMY AT AGE 31. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SO MUCH PAIN THAT SHE THOUGHT SHE WOULD DIE. SHE UNDERWENT A HYSTERECTOMY. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. THE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND EVENT ONSET WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THIS EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00834	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/26/2013
Explant Date (E7): 3/21/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0316, AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER HAD ESSURE INSERTED ON (B)(6) 2013. SHE WENT THROUGH MOOD SWINGS, DEPRESSION, HAIR LOSS, FLUTTERS IN STOMACH AS IF SHE WAS PREGNANT, JOINT PAIN, NUMBNESS, FOGGINESS IN HEAD, HER SIGHT WAS ALTERED, HEAVY BLEEDING WITH BIG CLOTS PASSED, MADE IT VERY HARD TO FUNCTION. SHE STATED THAT SHE WAS A SINGLE MOTHER AND THE DEVICE CAUSED PROBLEMS WITH HER FAMILY AND COST HER FEMALE PARTS. HYSTERECTOMY WAS DONE ON (B)(6) 2014. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS, NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING WITH BIG CLOTS (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A HYSTERECTOMY ONE YEAR AFTER ESSURE INSERTION. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN T

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00847	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE (B)(6) 2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6)2012. ACCORDING TO HER, ESSURE INSERTION WAS A QUICK AND FAIRLY PAINLESS. THREE MONTHS LATER SHE HAD CONFIRMATION TEST PERFORMED AND EVERYTHING LOOKED GOOD. WITHIN A YEAR SHE HAD BACK PAINS AND STARTED TO GAIN WEIGHT CONSISTENTLY (HER BELLY WAS BIGGER THAN WHEN SHE WAS PREGNANT). EVERY TIME SHE WOULD HAVE SEX SHE BLED AND SHE GRADUALLY LOST HER DESIRE TO HAVE SEX ALL TOGETHER. IN (B)(6) 2014 SHE STARTED TO HAVE CRAZY HEAVY AND EXTREMELY LONG PERIODS. SHE NEVER HAD REGULAR PERIODS, SHE USUALLY ONLY GOT 2-3 A YEARS BUT EVEN THEY LASTED ONLY FOR A WEEK. AFTER FOUR MONTHS OF ALMOST CONSTANT BLEEDING SHE HAD NOVASURE ABLATION PERFORMED IN (B)(6) 2015 AND HAD NO BLEEDING SINCE HEALING. HER DOCTOR TOLD HER SHE WAS BLEEDING BECAUSE SHE WAS GETTING OLDER, BUT SHE HAD TURNED 30 AND SHE BELIEVES ESSURE WAS THE CAUSE OF IT. SHE ALSO EXPERIENCED A LOT OF HIP PAIN, RANDOM OCCASIONAL LOWER ABDOMINAL PAIN, AND CONSTANT CRAWLY FEELING IN HER SKIN, HAIR LOSS AND METAL ALLERGY, THAT MAY OR MAY NOT BE THE CAUSE OF THE CRAWLY FEELING. SHE HAS AN APPOINTMENT WITH HER GYNECOLOGIST IN (B)(6) 2015 AND SHE WILL REQUEST THE ESSURE REMOVAL VIA HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO EXPERIENCED HEAVY AND EXTREMELY LONG PERIODS 2 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. AFTER 4 MONTHS OF CONSTANT BLEEDING SHE WAS SUBMITTED TO AN ENDOMETRIAL ABLATION (NOVASURE) AND

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RECOVERED. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, THE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE EVENT WAS WEAK. HOWEVER, SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REPORTED ENDOMETRIAL ABLATION (REQUIRED INTERVENTION) FOR BLEEDING'S TREATMENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00850	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/14/2012
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0257, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. ADDITIONAL INFORMATION WAS RECEIVED ON 18-AUG-2015; WITH THE CASE # FDA-2014-N-0736-0699. CONSUMER STATED THAT ESSURE HAS RUINED HER LIFE. SHE STARTED OFF WITH BLEED FOR 3 MONTHS, THEN THE BLOATING THAT MAKES HER LOOK LIKE PREGNANT. SHE HAD SEVERE DEPRESSION, WEIGHT GAIN, SUICIDAL THOUGHTS, TIRED AND WEAKNESS. SHE DID NOT WANT TO BE AROUND NO ONE, HAD CONSTANT STABBING PAIN, HAD RED BUMPS ALL OVER BODY (RASH THAT TOOK OVER HER BODY), LOSS OF SEX DRIVE. THE CONSTANT PAIN WAS SO BAD SHE HAD TO LEAVE HER JOB. IT ALSO GAVE HER SEVERE BACK ISSUES. SHE HAD TO HAVE HER TUBES REMOVED IN (B)(6) 2014 AND SHE WAS TOLD IT WAS ALL OUT, BUT SHE WAS STILL HAVING ISSUES. HER DOCTORS RECOMMEND A HYSTERECTOMY AND LEAVE THE OVARIES IF ABLE; UNFORTUNATELY HER RIGHT OVARY WAS COVERED IN CYST THAT IT HAD TO BE REMOVED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CONSTANT STABBING PAIN (INTERPRETED AS PELVIC PAIN), SHE BLED FOR 3 MONTHS (INTERPRETED AS GENITAL BLEEDING), HAD SEVERE DEPRESSION, SUICIDAL THOUGHTS. SHE UNDERWENT A SALPINGECTOMY AND LATER A HYSTERECTOMY AND IT WAS FOUND THAT HER RIGHT OVARY WAS COVERED IN CYST AND IT HAD TO BE REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN AND GENITAL BLEEDING ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE

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REMAINING EVENTS ARE UNLISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. THEREFORE, GIVEN THE NATURE OF THE EVENT BLED FOR 3 MONTHS AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE CONSUMER HAD OVARIAN CYST, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THIS EVENT; HOWEVER, GIVEN THE NATURE OF THE EVENT A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. AFTER ESSURE INSERTION, A WOMAN MAY REGRET HER DECISION TO UNDERGO PERMANENT STERILIZATION AND EXPERIENCE MILD DEPRESSION; HOWEVER, NEITHER MAJOR DEPRESSION, NOR SUICIDAL IDEATION IS EXPECTED. DEPRESSION IS A HIGHLY PREVALENT DISORDER AND ITS PATHOGENESIS INVOLVES GENETIC, SOCIAL AND PSYCHOLOGIC FACTORS. CONSIDERING THE PATHOPHYSIOLOGY OF THE EVENT SEVERE DEPRESSION, SUICIDAL THOUGHTS AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES, THIS EVENT WAS ASSESSED AS UNRELATED TO ESSURE. ALSO, REGARDING EVENT RIGHT OVARY WAS COVERED IN CYST, GIVEN THE PATHOPHYSIOLOGY OF THIS EVENT AND ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00851	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0265, AWARENESS DATE 13-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2011. IN 2011 THE CONSUMER WAS CONVINCED BY HER DOCTOR THAT ESSURE WAS THE BEST FORM OF BIRTH CONTROL FOR HER. SHE HAS A LATEX ALLERGY AND SHE HAD A PE (INTERPRETED AS PULMONARY EMBOLISM) WITH HER FIRST PREGNANCY. HER OPTIONS WERE LIMITED. RECOVERY WAS FAST. THE 3 MONTH TEST SHOWED IT WORKED PROPERLY. ABOUT 6 MONTHS IT WAS IN, SHE WAS HAVING HORRIBLE PERIODS, INSANE CRAMP, HUGE CLOTS, EXTREME FATIGUE AND MOOD SWINGS. SHE HAD NO IDEA WHAT WAS CAUSING IT. AS TIME WENT ON, SHE BEGAN TO HAVE ODD BLOATING. SHE WOULD LOOK 8 MONTHS PREGNANT AFTER EATING. IN 2013 SHE SAW A NEW OBSTETRICIAN/GYNECOLOGIST WHO TOLD HER THAT ALL OF THIS COULD BE DUE TO ESSURE. CONSUMER COULD BE ALLERGIC TO THE METALS. THAT TEST CAME BACK NEGATIVE. THE OBSTETRICIAN/GYNECOLOGIST SWITCHED TO ANOTHER PRACTICE SOON AFTER AND CONSUMER NEVER SAW HER AGAIN. NO TRUE ANSWERS. HAD MANY TRIPS TO THE EMERGENCY ROOM. CONSUMER SAW A GASTROENTEROLOGY AND WENT THROUGH 2 COLONOSCOPIES AND UPPER GASTROINTESTINAL ENDOSCOPY, HIDA SCAN, BLOOD WORK, X-RAYS AND ULTRASOUNDS. EVERYTHING CAME BACK FINE. SHE WAS DIAGNOSED WITH LBS (INTERPRETED AS IRRITABLE-BOWEL SYNDROME). IN (B)(6) 2015 CONSUMER BEGAN TO WORK EXTREMELY HARD TO SHED SOME WEIGHT TO HELP EASE HER ISSUES. SHE LOST 551BS. SHE COULD BREATHE BETTER BUT HER SYMPTOMS DIDN'T CHANGE. SHE BEGAN TO FEEL A SHARP PAIN IN HER LOWER LEFT SIDE- NEAR HER OVARY. LOOKING BACK, SHE THINKS HER WEIGHT LOSS CAUSED A SHIFT IN HER LEFT COIL. SHE

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CONTINUED TO HAVE ALL OF HER SYMPTOMS AND IN LATE (B)(6) 2015 IT BECAME EXTREME. DURING AND AFTER SEX, SHE HAD SOME OF THE WORST PAIN OF HER LIFE. HER LEFT OVARY AREA FELT LIKE IT WAS BEING STABBED AND TWISTED. CONSUMER WENT TO THE DOCTOR 3 DAYS LATER BECAUSE THE PAIN WAS INTERMITTENTLY STILL THERE. SHE WAS SENT TO THE EMERGENCY ROOM. AGAIN NOTHING WAS REALLY FOUND. POSSIBLY A CYST THAT HAD ALREADY RUPTURED BUT THEY WEREN'T SURE. NO ONE EVER SEEMED TO HAVE AN ANSWER. HER HAIR WAS FALLING OUT AND HAD BECOME EMBARRASSINGLY THIN. SHE WAS ALWAYS SORE. SHE DREAD HER PERIOD BECAUSE SHE WAS CONFINED TO HER HOUSE. TAMPONS COULDN'T HOLD THE GIANT CLOTS THAT CONSTANTLY CAME OUT OF HER. SHE WENT THROUGH SO MANY PADS ALONG WITH TAMPONS. CONSUMER FOUND HER CURRENT OBSTETRICIAN/GYNECOLOGIST (WHO STILL DIDN'T THINK ESSURE CAUSED ANY OF THIS) AND SHE DID A LAPAROSCOPY. SHE SAID HER LEFT COIL WAS OK BUT WAS NOW EXPOSED AND WAS NOT WHERE SHE WOULD EXPECT IT TO BE. A WEEK AFTER THIS PROCEDURE HER PAIN WAS GETTING WORSE. THE PHYSICIAN CHOSE TO DO A CT NEXT TO SEE IF ANY DAMAGE WAS DONE DURING HER PROCEDURE. NO NEW DAMAGE WAS FOUND. AT FOLLOW UP, PHYSICIAN SAID. "COULD THIS BE CAUSING YOUR PAIN? YES. DO I THINK IT IS CAUSING YOUR PAIN? NO. ALL WE HAVE LEFT IS A FULL HYSTERECTOMY TO GET THE ESSURE OUT". SO AT (B)(6) CONSUMER WILL BE HAVING A FULL HYSTERECTOMY AND WILL ONLY BE KEEPING ONE OVARY. HER SURGERY IS SCHEDULED FOR (B)(6) 2015. SHE STATED SHE HATED WHAT ESSURE HAS DONE TO HER. SHE WAS POSITIVE THIS HELL WAS CAUSED BY ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER APPROXIMATELY 4 YEARS, DURING LAPAROSCOPY IT WAS NOTICED THAT LEFT COIL WAS EXPOSED AND WAS NOT WHERE SHE WOULD EXPECT IT TO BE (INTERPRETED AS DEVICE DISLOCATION). SHE ALSO HAD PAIN IN HER LOWER LEFT SIDE, NEAR HER OVARY AND THERE WAS A SUSPICION THAT SHE HAD A RUPTURED OVARIAN CYST. A FULL HYSTERECTOMY WAS SCHEDULED BUT NOT PERFORMED YET. THE DEVICE DISLOCATION IS LISTED WHILE THE RUPTURED OVARIAN CYST IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE DIAGNOSIS OF DEVICE DISLOCATION AND SUSPICION OF RUPTURED OVARIAN CYST OCCURRED DURING ESSURE USE. CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN ESSURE AND DEVICE DISLOCATION IS RELATED. HOWEVER, CONSIDERING THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT ESSURE WOULD CAUSE A RUPTURED OVARIAN CYST. THIS CASE IS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00852	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 4/14/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0397, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. CONSUMER HAD ESSURE INSERTED IN 2007 AFTER THE BIRTH OF HER SECOND CHILD. WITHIN TWO WEEKS OF RECEIVING ESSURE SHE HAD TO QUIT BREASTFEEDING HER DAUGHTER. SHE HAD CONSTANT BACK PAIN. BY YEAR TWO AFTER ESSURE PROCEDURE, HER SEX DRIVE WAS GONE, SHE WAS IN CONSTANT PAIN AND ON LARGE DOSES OF NARCOTICS. ONCE SHE GOT OFF THE NARCOTICS THE SEVERE PAIN WAS BACK, EVERY MINUTE OF THE DAY AND NIGHT. SHE HAD HORRIFIC MENSTRUAL CYCLES AND SHE COULD NOT LEAVE THE HOUSE FOR THE FIRST TWO DAYS SHE WAS ON HER PERIOD BECAUSE THE BLEEDING WAS SO HEAVY. CONSUMER'S HAIR WAS FALLING OUT IN CLUMPS AND HER DOCTOR THOUGHT SHE MUST HAVE FIBROMYALGIA. SHE GAINED 70 POUNDS BECAUSE EVERYTHING HURT, ALL THE TIME. SHE WAS ON ANTIDEPRESSANTS AND HER LIFE WAS FALLING APART AT THE SEAMS. ABOUT SIX MONTHS AGO A FRIEND MENTIONED THAT ESSURE COULD BE CAUSING SOME OF HER HEALTH ISSUES. CONSUMER WENT TO HER OB AND DID SOME TESTS. SHE HAD SEVERE NICKEL POISONING, HER UTERUS WAS "HARD AS A ROCK", AND TUBES WERE THREE TIMES THE NORMAL SIZE. SHE HAD A HYSTERECTOMY TO REMOVE ESSURE ON (B)(6) 2015. SINCE THEN SHE HAD LOST 45 POUNDS. HAIR STOPPED FALLING OUT. SHE DO NOT HURT ANYMORE AND SHE WAS OFF HER ANTIDEPRESSANTS. HER SEX DRIVE IS FINALLY NORMAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CONSTANT PAIN/ SEVERE PAIN/

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EVERYTHING HURT ALL THE TIME AND STATED SHE HAD SEVERE NICKEL POISONING. SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE APPROXIMATELY 8 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE HER DOCTOR SUSPECTED SHE HAD FIBROMYALGIA WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THE PAIN. HOWEVER, SINCE THIS EVENT RESOLVED AFTER ESSURE REMOVAL A CONTRIBUTORY ROLE OF THE DEVICE CANNOT BE EXCLUDED. REGARDING THE EVENT SEVERE NICKEL POISONING, THE INSERT INCLUDES NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. THE ENTIRE ALLOY SURFACE IS COVERED WITH A PROTECTIVE LAYER OF TITANIUM OXIDE WHICH SERVES TO MINIMIZE NICKEL ION RELEASE. ALTHOUGH IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM THIS DEVICE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE POISONING. THEREFORE, THIS EVENT WAS ASSESSED AS UNRELATED TO ESSURE. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY TO REMOVE ESSURE). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00905	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/23/2010
Explant Date (E7): 7/29/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0463, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED ON (B)(6) 2010. CONSUMER REPORTED THAT SHE HAD ESSURE IMPLANTED WHEN SHE WAS (B)(6). IN EARLY 2011 SHE STARTED HAVING SEVERE PANIC ATTACKS WOKE ONE MORNING AND HER WHOLE BODY WAS NUMB AND HER HEART WAS RACING WHEN THE AMBULANCE ARRIVED HER HEART RANGE WAS BETWEEN 150 AND 160. SHE HAD SEVERE PAIN IN HER SIDES, WEIGHT GAIN AND TIRED ALL THE TIME, WAS NEVER ASKED IF SHE WAS ALLERGIC TO ANY METALS. IN 2015 SHE GOT SOME ANSWERS SHE HAD A SEVERE ALLERGY TO NICKEL WHICH WAS WHY HER BODY WAS OUT OF WHACK AND HER STOMACH SWELLED. ON (B)(6) 2015 AT THE YOUNG (B)(6) SHE HAD TO HAVE A COMPLETE HYSTERECTOMY DUE TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE ALLERGY TO NICKEL APPROXIMATELY 5 YEARS AFTER INSERTION. SHE UNDERWENT A COMPLETE HYSTERECTOMY. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP, NATURE OF THIS EVENT AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN THIS ALLERGY TO NICKEL AND ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS

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REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00906	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0530, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014.SINCE THE PLACEMENT OF THE ESSURE, HER QUALITY OF LIFE HAS DECREASED DRAMATICALLY. HER DAUGHTER AND HUSBAND SUFFER GREATLY FROM THE CONSTANT FATIGUE AND PAIN IN HER LIFE. SHE CANNOT EVEN SIT ON THE FLOOR WITH HER DAUGHTER AND PLAY A BOARD GAME WITHOUT BEING IN EXCRUCIATING PAIN. SHE HAD TO QUIT A GRADUATE PROGRAM BECAUSE SHE WAS UNABLE TO FOCUS ON HER SCHOOLWORK AND FIND THE ENERGY TO FINISH THE PROGRAM. SHE MISSED COUNTLESS DAYS OF WORK BOUNCING FROM DOCTOR TO DOCTOR, TRYING TO FIND AN ANSWER TO HER PAIN. SHE WAS SCHEDULED FOR A HYSTERECTOMY IN (B)(6) 2015 WITH REMOVAL OF THE COILS, TUBES, UTERUS AND CERVIX. SHE ALSO HAD EVERY SYMPTOM OF LUPUS, BUT NO BLOOD WORK TO BACK IT UP. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, IT WAS REPORTED THAT SINCE THE PLACEMENT OF ESSURE, SHE STARTED EXPERIENCING THIS EVENT. A HYSTERECTOMY WITH REMOVAL OF THE COILS, TUBES, UTERUS AND CERVIX WAS SCHEDULED. BASED ON THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE

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WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, ANOTHER SERIOUS EVENT AND NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00907	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2015-N-2781-0479, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT SINCE INSERTION SHE HAS HAD A SEVERE ALLERGIC REACTION CAUSING HER ENTIRE BODY TO BREAK OUTING HIVES. SHE WAS DIAGNOSED WITH PSORIASIS. SHE HAD TERRIBLE PERIODS WITH CLOTS OF BLOOD THAT COULD LAST FROM 3 DAYS TO 3 MONTHS NON-STOP. HER HAIR WAS FALLING OUT, SHE ALWAYS HAD A METALLIC TASTE IN HER MOUTH AND HER TEETH WERE CRUMBLING TO PIECES. SHE HAD ALMOST EVERY VITAMIN DEFICIENCY. HER BONE AND JOINTS HURT ON A DAILY BASIS. SHE WAS DIAGNOSED AS CHRONICALLY DEPRESSED. SHE HAD SEVERAL URINARY TRACT INFECTIONS, BLADDER INFECTIONS AND KIDNEY STONES. SHE HAD A LARGE CYST ON HER OVARY AND A BURST FEELING LIKE LABOR PAINS THAT SENT HER TO THE HOSPITAL. SHE WAS SCHEDULED FOR A HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BURST FEELING LIKE LABOR PAINS. THIS EVENT, INTERPRETED AS PELVIC PAIN FEMALE, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STARTED EXPERIENCING THIS EVENT AFTER ESSURE INSERTION. A HYSTERECTOMY WAS SCHEDULED. NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON THE EVENT'S NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS

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CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00908	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE SUFFERED FROM METAL TOXICITY, ALLERGIC REACTIONS INCLUDING, BUT NOT LIMITED TO HAIR LOSS, HIVES, RASHES AND SENSITIVITIES TO FOODS, MEDICINES AND MATERIALS. SHE EXPERIENCED BLOATING BELLY, DARK CIRCLES UNDER HER EYES, EXTREME ACUTE PELVIC PAIN, EXCESSIVE BLEEDING, CRAMPING, MISCARRIAGE, DEPRESSION AND ANXIETY. SHE ALSO DEVELOPED FIBROMYALGIA AND HYPOTHYROIDISM, AND THESE EVENTS WERE ONGOING. SHE GOT ESSURE REMOVED VIA MAJOR SURGERY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME ACUTE PELVIC PAIN AND EXCESSIVE BLEEDING (INTERPRETED AS GENITAL BLEEDING). THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO GOT PREGNANT (SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED) AND HAD A MISCARRIAGE (SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED). IN THIS CASE, NO ALTERNATIVE EXPLANATION FOR THE OCCURRENCE OF THE EVENTS WERE PROVIDED. IT WAS REPORTED THAT ESSURE WAS REMOVED VIA MAJOR SURGERY. WITH REGARDS TO THE EVENTS EXTREME ACUTE PELVIC PAIN, EXCESSIVE BLEEDING AND PREGNANT, CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE EVENT MISCARRIAGE, SINCE NO INFORMATION ON

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GESTATIONAL AGE WAS PROVIDED AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENT AND NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 09-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00909	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2010
Explant Date (E7): 4/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2015-N-2781-0527, AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010.

SHE EXPERIENCED SEVERAL MEDICAL PROBLEMS, FINANCIAL AND EMOTIONAL.

IN (B)(6) 2015 SHE UNDERWENT A TOTAL HYSTERECTOMY.

COMPANY CAUSALITY COMMENT:

THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE WAS IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010 AND TOTAL HYSTERECTOMY WAS PERFORMED IN (B)(6) 2015.

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HYSTERECTOMY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. IN THIS PARTICULAR CASE, THE REASON FOR HYSTERECTOMY WAS NOT PROVIDED. DUE TO LACK OF INFORMATION AND CONSIDERING THE REMOVAL OF ESSURE MAY REQUIRE A HYSTERECTOMY; THE CAUSAL RELATIONSHIP WITH THE DEVICE CANNOT BE EXCLUDED.

THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED).

NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00910	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2015-N-2781-0542, FDA-2014-N-0736-0572 AND FDA-2014-N-0736-0015, AWARENESS DATE 14-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. HER SIDE EFFECTS GRADUALLY BECAME WORSE AND INCLUDED: DEBILITATING PELVIC PAIN / PAIN, BLOATING AND ABDOMINAL SWELLING, TINGLING IN HANDS AND FEET, HAIR LOSS, BRAIN FOG, DEPRESSION, LOSS OF QUALITY OF LIFE, IRREGULAR PERIODS, SKIN IRRITATIONS, RASH, WEIGHT GAIN, IRREGULAR MOOD SWINGS, UNUSUAL HEART PALPITATIONS AND CHRONIC INFLAMMATION IN HER FALLOPIAN TUBES. THE INFLAMMATION WAS STARTING TO AFFECT THE REST OF HER BODY; HER ESSURE COILS HAD SUCH A NEGATIVE EFFECT ON HER BODY. HER UTERUS, CERVIX AND FALLOPIAN TUBES WERE REMOVED TWO WEEKS BEFORE THIS REPORT (SHE WAS (B)(6) AT TIME OF SURGERY). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE WAS IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 AND EXPERIENCED FOLLOWING SERIOUS ADVERSE EVENTS: DEBILITATING PELVIC PAIN AND CHRONIC INFLAMMATION IN HER FALLOPIAN TUBES AMONGST OTHER NON-SERIOUS EVENTS. TWO WEEKS BEFORE THIS REPORT HER UTERUS, CERVIX AND FALLOPIAN TUBES WERE REMOVED. PELVIC PAIN AND FALLOPIAN TUBE INFLAMMATION ARE SERIOUS EVENTS DUE TO MEDICAL IMPORTANCE. PELVIC PAIN IS LISTED ACCORDING TO REFERENCE SAFETY INFORMATION AND FALLOPIAN TUBE INFLAMMATION IS UNLISTED. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, BOTH AS CONSIDERED RELATED TO ESSURE. AN INTERVENTION WAS

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REQUIRED THEN THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 10-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00911	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. ESSURE HAS CAUSED HER A GREAT DEAL OF PAIN, MISSED WORK, AND SEVERAL SURGERIES INCLUDING A FULL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY AND OOPHORECTOMY. BETWEEN THE PERFORATIONS, ALLERGIC REACTIONS, AND ADHESIONS. SHE HAS PICTURES OF PROPER PLACEMENT OF THE DEVICES AND THEN THE HSG (HYSTEROSALPINGOGRAM). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ESSURE HAS CAUSED HER A GREAT DEAL OF PAIN. SHE EXPERIENCED PERFORATIONS AND ALLERGIC REACTIONS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER UNDERWENT A FULL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY AND OOPHORECTOMY. SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED AND BASED ON THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WAS ADDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00912	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2013
Explant Date (E7): 3/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0567, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN (B)(6) 2013. CONSUMER REPORTED THAT SHE WAS IMPLANTED WITH THREE COILS INSTEAD OF TWO. SHE HAD NOTHING BUT PROBLEMS WITH ESSURE SINCE GETTING IT. WITHIN A MONTH OF GETTING ESSURE SHE HAD HEAVY BLEEDING DURING PERIODS, SEVERE PAIN AND CRAMPING, WAS UNABLE TO BE INTIMATE WITH HER HUSBAND DUE TO THE PAIN, HEADACHES, DIZZINESS, FATIGUE, BLOATING, AND NAUSEA. SHE HAD SURGERY TO REMOVE THE COILS IN (B)(6) 2014 AND THE DOCTOR SAW THAT THE RIGHT COIL WAS STICKING OUTSIDE OF HER TUBE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HER 3 ESSURE INSERTS (FALLOPIAN TUBE OCCLUSION INSERT) PLACED. NINE MONTHS LATER; DURING A SURGERY FOR DEVICES REMOVAL, RIGHT COIL WAS FOUND STICKING OUTSIDE OF HER TUBE. THIS EVENT, REGARDED AS FALLOPIAN TUBE PERFORATION, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF ESSURE. IN THIS CASE, CONSUMER HAD 3 ESSURES PLACED INSTEAD OF 2; THIS DEVICE MISUSE COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED PERFORATION. ALTHOUGH THE EXACT MECHANISM OF THIS EVENT IS NOT KNOWN, GIVEN ITS NATURE; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW UP 10-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00913	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0532, AWARENESS DATE 14-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER STATED THAT ESSURE RUINED HER LIFE. SHE HAD TO HAVE A HYSTERECTOMY AT AGE (B)(6) AND NOW SHE IS WORKING TOWARDS FIXING ALL THE PROBLEMS IT HAS CAUSED HER. IT EXACERBATED AUTOIMMUNE DISEASE LEAVING HER NEARLY CRIPPLED WITH PAIN AND INFLAMMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ACCORDING TO HER; SHE HAD TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6). ADDITIONALLY, SHE HAD AN EXACERBATED AUTOIMMUNE DISEASE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY HYSTERECTOMY IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS CASE, CONSUMER STATED ESSURE EXACERBATED AUTOIMMUNE DISORDER LEAVING HER WITH PAIN AND INFLAMMATION. THE EXACT ETIOLOGY OF HER DISEASE WAS NOT PROVIDED. HOWEVER; CONSIDERING ESSURE LOCAL ACTION AT FALLOPIAN TUBES AND GIVEN AUTOIMMUNE DISEASES NATURE, CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED UNLIKELY. REGARDING THE REPORTED HYSTERECTOMY; IF AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED ESSURE CAUSED HER PROBLEMS; WHICH WERE NOT SPECIFIED AND SHE HAD TO HAVE A HYSTERECTOMY. ALTHOUGH LIMITED INFORMATION WAS PROVIDED, IT CANNOT BE EXCLUDED THAT THIS SURGERY OCCURRED AS A CONSEQUENCE OF ESSURE. THEREFORE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00914	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0481, AWARENESS DATE 14-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013 IN THE HOSPITAL AND CAME HOME WITH LITTLE TO NO DISCOMFORT. SHE DID NOT HAVE A PERIOD FOR 6 MONTHS FOLLOWING THE PROCEDURE. SHE EXPERIENCED SEVERE CRAMPING, BREAST TENDERNESS, LEG NUMBNESS AND HAIR LOSS. IN THE 6TH MONTH SHE STARTED HER FIRST PERIOD. THE BLEEDING AND PAIN WERE HORRIBLE. SHE BEGAN TO GAIN WEIGHT RAPIDLY, HAIR CONTINUED TO FALL OUT, SKIN RASHES BEGAN, PAINFUL INTERCOURSE, CONSTANT PELVIC PAIN, INSOMNIA, NIGHT SWEATS AND MANY MORE ISSUES BEGAN. SHE HAD MRI'S, ULTRASOUNDS, LAB WORK AND PELVIC EXAMS AND WAS TOLD EVERYTHING WAS OK. SHE WAS STILL BLEEDING AND HAD NEVER STOPPED THROUGH THAT PROCESS. SHE WAS PUT ON MEDS TO STOP BLEEDING AND FOR PAIN. NOTHING HELPED. SHE WAS A PERFECTLY HEALTHY WOMAN WITH NO ISSUES BEFORE ESSURE DEVICE WAS IMPLANTED. FINALLY IN (B)(6) 2014 HER DOCTOR AGREED TO REMOVE HER TUBES BUT INSISTED ESSURE WAS NOT THE CAUSE. SHE HAD THE SURGERY AND WAS STILL FEELING BAD. SHE ENDED UP IN THE EMERGENCY ROOM AND HAD X-RAY DONE. THE ESSURE (THAT WAS SUPPOSED TO BE REMOVED) WAS IN HER BLADDER AND UTERUS. SHE HAD LARGE MASSES IN HER UTERUS AND LARGE CYSTS ON HER OVARIES PAIN OF SURGERY FOR NOTHING. SHE WENT TO A NEW DOCTOR WHO KNEW RIGHT AWAY THAT ESSURE WAS CAUSING HER PAIN FROM THE BEGINNING AND SHE UNDERWENT A HYSTERECTOMY IN (B)(6) 2015 TO FIX THE DAMAGE FROM THE ESSURE DEVICE. SHE LIVED IN PAIN WITH NO HELP FOR OVER A YEAR. SHE HAD 7 SCARS AND A LIFELONG REMINDER OF WHAT THAT HAS DONE TO HER AND HER

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FAMILY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 6 MONTHS FOLLOWING THE PROCEDURE SHE DID NOT HAVE A PERIOD. IN THE 6TH MONTH SHE STARTED HER FIRST PERIOD. SHE WAS STILL BLEEDING AND HAD NEVER STOPPED. SHE ALSO EXPERIENCED CONSTANT PELVIC PAIN. IT WAS REPORTED THAT HER DOCTOR AGREED TO REMOVE HER TUBES BUT INSISTED ESSURE WAS NOT THE CAUSE. SHE HAD THE SURGERY AND WAS STILL FEELING BAD. SHE ENDED UP IN THE EMERGENCY ROOM AND HAD X-RAY DONE. THE ESSURE WAS IN HER BLADDER AND UTERUS. A HYSTERECTOMY WAS PERFORMED IN ORDER TO FIX THE DAMAGE FROM THE ESSURE DEVICE. ALL THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF UTERINE PERFORATION AND BLADDER PERFORATION WERE NOT KNOWN. CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP IDENTIFIED ON 04-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (PO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00915	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0015 / FDA-2015-N-2781-0598, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR 3 YEARS. CONSUMER'S FATHER REPORTED THAT HIS DAUGHTER HAD SO MUCH PAIN. ESSURE PERFORATED HER FALLOPIAN TUBE AND SHE RECENTLY HAD SURGERY TO REMOVE IT. PATHOLOGY SHOWED SHE HAD ENDOMETRIOSIS. SHE WAS STILL EXPERIENCING UNEXPLAINED DIZZY SPELLS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE WAS IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR 3 YEARS AND EXPERIENCED PAIN AND FALLOPIAN TUBE PERFORATION. BOTH EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. PAIN AND FALLOPIAN TUBE PERFORATION MAY OCCUR DURING THE DEVICE THERAPY, SINCE BOTH EVENTS WERE REPORTED AFTER ESSURE PLACEMENT, CAUSALITY CANNOT BE EXCLUDED. CONSIDERING THAT SURGICAL REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS PROVIDED ON 11-SEP-2015. PTC GLOBAL NUMBER IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVO

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00916	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0497, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED. THE CONSUMER HAD ESSURE INSERTED AFTER HER LAST CHILD. SHE WAS FULL OF ENERGY AND LIFE. ABOUT 6 MONTHS AFTER INSERTION SHE STARTED TO HAVE PROBLEMS WITH HER HEALTH: HER MONTHLY CYCLES WHERE HORRIBLE TO GO THROUGH, SHE BEGAN TO GET MIGRAINE HEADACHES, HER STOMACH WAS VERY DISTENDED, SHE WAS ALWAYS FATIGUED AND UNABLE TO DO STRENUOUS ACTIVITY. HER LEFT COIL BECAME DISLODGED AND STARTED MIGRATING THROUGH HER BODY. THE COILS WERE REMOVED WITH A PARTIAL HYSTERECTOMY, AND SHE ALSO HAD TO GO THROUGH EXPLORATORY SURGERY TO FIND THE COIL THAT WAS FLOATING THROUGHOUT HER ABDOMINAL AREA. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD A PARTIAL HYSTERECTOMY AND HAD TO GO THROUGH AN EXPLORATORY SURGERY TO FIND THE COIL THAT WAS FLOATING THROUGHOUT HER ABDOMINAL AREA (INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY). THIS DISLOCATION IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT, COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN THIS DISLOCATION AND THE ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS

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REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 11-SEP-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00917	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0528, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED THAT EVER SINCE SHE GOT THE COILS SHE HAD RASHES, PAINFUL TINGLING IN HER SKIN, PAIN IN HER JOINTS, EXTREMELY BAD PAIN IN HER FEMALE ORGANS AND LOWER BACK PAIN ALMOST CONSTANTLY. SHORTLY AFTER HAVING ESSURE PLACED SHE HAD TO PERFORM AN ABLATION. HER PERIOD WAS NOT REGULAR AND WHEN IT DID COME IT WAS NOT A NORMAL FLOW. SHE WAS EXTREMELY FOGGY HEADED AND SHE WAS LIVING IN PAIN EVERY DAY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHORTLY AFTER ESSURE PLACEMENT SHE HAD TO PERFORM AN ABLATION. HER PERIOD WAS NOT REGULAR AND WHEN IT DID COME IT WAS NOT A NORMAL FLOW. THIS EVENT, INTERPRETED AS MENSTRUAL DISORDER, IS SERIOUS DUE TO REQUIRED ABLATION. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT ESSURE MAY CAUSE CHANGE IN BLEEDING PATTERNS AND THAT SHE HAD TO UNDERGO AN ABLATION SHORTLY AFTER ESSURE INSERTION, THE CAUSAL RELATIONSHIP BETWEEN THE MENSTRUAL DISORDER AND ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS REQUIRED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

FOLLOW UP 11-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00918	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0560, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (ESS205) INSERTED IN 2007. IN 2012, THE CONSUMER STARTED HAVING PROBLEMS WITH ABNORMAL BLEEDING, ABDOMINAL PAIN, BLOATING, AND NAUSEA. AFTER MANY DOCTORS AND E.R. (EMERGENCY ROOM) VISITS IT WAS FOUND OUT THAT ONE OF THE ESSURE COILS HAD MIGRATED FROM FALLOPIAN TUBE AND WAS EMBEDDED IN UTERUS. SURGERY HAD TO BE DONE TO TRY TO REMOVE THE COIL, HOWEVER, THE DOCTOR COULD NOT GET THE ENTIRE COIL OUT WITHOUT DOING ADDITIONAL DAMAGE TO SURROUNDING TISSUE/ORGANS, SO THE COIL WAS CUT AND A PORTION HAD TO REMAIN EMBEDDED. THIS HOWEVER DID NOT FIX ALL OF HER SYMPTOMS. SHE HAD A HYSTEROSALPINGOGRAM DONE AND THE REMAINING PIECE OF COIL HAD MIGRATED AGAIN, AND THE CONSUMER HAD A HYSTERECTOMY PERFORMED IN (B)(6) 2015. THERE WAS A COMPLICATION DURING SURGERY AND ONE OF HER OVARIES ALSO HAD TO BE REMOVED. ACCORDING TO PATHOLOGY REPORTS THERE WAS NO COIL TO BE FOUND IN UTERUS, FALLOPIAN TUBES, OVARY, OR CERVIX. TWO WEEKS AFTER HYSTERECTOMY, THE CONSUMER RUSHED TO THE HOSPITAL AND UNDERWENT AN EMERGENCY SURGERY TO REPAIR A PUNCTURED BOWEL. SHE WAS HOSPITALIZED FOR 5 DAYS AND WAS OFF OF WORK FOR 7 WEEKS. SHE THEN HAD PROBLEMS WITH HER BOWELS INCLUDING DIARRHEA, CONSTIPATION, NAUSEA, AND CRAMPING. SHE CONSIDERED ALL EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED.

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APPROXIMATELY 5 YEARS AFTER THE INSERTION, SHE STARTED HAVING ABNORMAL BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE FOUND OUT THAT ONE OF THE OILS WAS EMBEDDED IN UTERUS (INTERPRETED AS DEVICE EMBEDDED/PARTIAL PERFORATION). A SURGERY WAS PERFORMED TO TRY TO REMOVE, HOWEVER, THE DOCTOR COULD NOT GET THE ENTIRE COIL OUT AND A PORTION HAD TO REMAIN EMBEDDED. SHE PERFORMED A HYSTEROSALPINGOGRAM AND THE REMAINING PIECE HAD MIGRATED AGAIN (DEVICE DISLOCATION). THE CONSUMER UNDERWENT A HYSTERECTOMY, CERVIX AND FALLOPIAN TUBES REMOVAL. THE REMAINING COIL WAS NOT FOUND IN THE ORGANS REMOVED, ACCORDING TO THE PATHOLOGY REPORT. TWO WEEKS LATER, SHE UNDERWENT A SURGERY TO REPAIR A PUNCTURED BOWEL (INTERPRETED AS TRAUMATIC INTESTINAL PERFORATION). SHE WAS HOSPITALIZED FOR 5 DAYS. THE GENITAL BLEEDING IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. THE OTHER EVENTS ARE SERIOUS DUE TO REQUIRED INTERVENTION AND THE TRAUMATIC INTESTINAL PERFORATION IS ALSO SERIOUS SINCE IT LED TO HOSPITALIZATION. THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS AND THE SUGGESTIVE TEMPORAL RELATIONSHIP, THESE EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED ALSO DUE TO FACT THAT THE TRAUMATIC INTESTINAL PERFORATION LED TO HOSPITALIZATION. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 11-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00919	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# (B)(4)). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FOLLOWED UP WITH THE HSG TEST IN 2006. SHE HAD NO PROBLEMS UNTIL 2010 WHEN SHE BEGAN EXPERIENCING SEVERE PAIN ON HER RIGHT SIDE. AFTER SEVERAL TRIPS TO THE EMERGENCY ROOM, CT SCANS, MULTIPLE X-RAYS AND ULTRASOUNDS THE DOCTORS COULD FIND NOTHING WRONG WITH HER AND SENT HER HOME. SHE REQUESTED ALL HER MEDICAL RECORDS AND IMAGES AND UPON REVIEWING THE IMAGES SHE FOUND THAT SHE HAD 3 COILS (1 ON THE LEFT AND 2 PLACED ON THE RIGHT). IN (B)(6) 2011 SHE UNDERWENT A HYSTERECTOMY AND BILATERAL SALPINGECTOMY AND HAVE NOT HAD ANY PAIN SINCE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN ON MY RIGHT SIDE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, CONSUMER STARTED EXPERIENCING THIS EVENT 4 YEARS AFTER ESSURE INSERTION. SOME RELEVANT TESTS WERE PERFORMED AND THE DOCTORS COULD FIND NOTHING WRONG WITH HER. ALL HER MEDICAL RECORDS AND IMAGES WERE REQUESTED AND THE RESULTS SHOWED THAT SHE HAD 3 COILS (1 ON THE LEFT AND 2 PLACED ON THE RIGHT). A HYSTERECTOMY AND BILATERAL SALPINGECTOMY WERE PERFORMED. BASED ON A POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THE EVENT'S NATURE, A CAUSAL

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RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-SEP-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00920	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2015-N-2781-0556, AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2009. HER HAIR STARTED FALLING OUT, HANDS AND FEET SWELLING, HOT FLASHES. PREGNANT IN 2010 AFTER A CONFIRMED BLOCKED TEST. HER SYMPTOMS WORSENED. SEVERE LOWER BACK PAIN, NIGHT SWEATS, HIVES, ITCH, ANXIETY, DEPRESSION. HYSTERECTOMY LEAVING OVARIES. ONE COIL WAS EMBEDDED IN HER UTERUS (YET THAT SIDE BLOCKED DUE TO SCAR TISSUE) OTHER SIDE COIL WAS IN CORRECT POSITION (YET NOT BLOCKED). ESSURE DOES NOT WORK AND THEY MIGRATED. COMPANY CAUSALITY: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT. ONE COIL WAS EMBEDDED IN HER UTERUS AND OTHER SIDE COIL WAS IN CORRECT POSITION. A HYSTERECTOMY WAS PERFORMED LEAVING OVARIES. BOTH EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER GOT PREGNANT AFTER A CONFIRMED BLOCKED TEST. WITH REGARDS TO THE OTHER EVENT, THE EXACT DATE AND MECHANISM OF EMBEDMENT WERE NOT KNOWN. CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 07-JAN-2016: SHE REPORTED WAS IMPLANTED WITH ESSURE IN 2009; WITH A CONFIRMED BLOCKED TEST. SHE BECAME PREGNANT 2010. SHE ALSO REPORTED HAIR LOSS, SWOLLEN FEET, FATIGUE, HOT FLASHES, CHRONIC BACK PAIN, NIGHT SWEATS, HIVES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00921	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE # (B)(6), AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) YEAR-OLD IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007 AFTER THE BIRTH OF HER THIRD CHILD. CONSUMER REPORTED THAT SHE EXPERIENCED CRAMPING, SHARP / STABBING PELVI PAIN, ABNORMAL HEAVY CYCLES, CONSTANT SPOTTING, OVARIAN CYST (DERMOID), BACTERIAL VAGINOSIS, DISCHARGE WITH STRONG ODOR, EXCESSIVE BLEEDING DURING PERIOD, LOSS OF LIBIDO, BLEEDING / SPOTTING AFTER SEX, PAINFUL INTERCOURSE, PAINFUL PERIODS, URGENT URINATION, URINARY TRACT INFECTION, BACK PAIN, HEADACHES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, FORGETFULNESS, MOOD SWINGS, FAINTING, ITCHY SKIN, ITCHY UNDER THE SKIN AND HAIR LOSS. IN 2014, DOCTOR DECIDED THAT A FULL HYSTERECTOMY LEAVING THE OVARIES WAS THE BEST OPTION FOR HER, BUT TOMOGRAPHY SHOWED A DERMOID CYST IN HER LEFT OVARY EVEN THOUGH SHE HAD A SURGERY TO REMOVE IT IN 2009, SO LEFT OVARY WAS ALSO REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE WAS IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE AND REFERS TO A (B)(6) YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007 AND EXPERIENCED SERIOUS EVENTS SHARP/STABBING PELVIC PAIN, OVARIAN CYST (DERMOID), URINARY TRACT INFECTION AMONGST OTHER NON-SERIOUS EVENTS. SHE HAD A HYSTERECTOMY 7 YEARS AFTER PLACEMENT. PELVIC PAIN, SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WAS CONSIDERED RELATED TO ESSURE. AS HYSTERECTOMY WAS PERFORMED, EVEN THOUGH MANY YEARS POST INSERTION, THIS CASE IS REGARDED AS

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INCIDENT. OVARIAN DERMOID CYST AND URINARY TRACT INFECTION ARE UNLISTED EVENTS AND SERIOUS DUE TO MEDICAL IMPORTANCE. THEY WERE CONSIDERED UNRELATED TO THE DEVICE DUE TO ESSURE LOCAL ACTION IN THE FALLOPIAN TUBES. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00922	BAYER HEALTHCARE LLC	9/13/2015	9/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE # FDA-2015-N-2781-0536, AWARENESS DATE 14-AUG-2015). IT WAS RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR BIRTH CONTROL. THIS CASE REFERS TO CONSUMER'S FETUS. CONSUMER REPORTED SHE HAD A STILLBIRTH AT 4 MONTHS PREGNANCY. FOR MOTHER'S CASE PLEASE REFER TO CASE: (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER AND REFERS TO HER FETUS; WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERUS. THE MOTHER GAVE BIRTH TO THE STILLBORN AT (B)(6) MONTHS PREGNANT. THE REPORTED EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEITHER THE COMPLICATIONS EXPERIENCED BY THE MOTHER NOR FETUS STATUS WERE SPECIFIED. NEVERTHELESS, CONSIDERING THE EVENT OCCURRED DURING THE SECOND TRIMESTER OF GESTATION; A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THE REPORTED DEATH WAS, THUS CONSIDERED AS RELATED TO THE SUSPECT INSERT. THIS CASE WAS CONSIDERED AN INCIDENT, DUE TO FETAL DEATH. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00833	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# (B)(6), AWARENESS DATE (B)(6) 2015). IT REFERS TO AN ADULT FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. IN THE 3 1/2 YEARS THAT SHE HAD THE ESSURE DEVICE PLACED, SHE EXPERIENCED ABDOMINAL PAIN, EXTREME CRAMPING (10), STABBING IN CERVIX AND PELVIS, NIGHT SWEATS, LONG MENSTRUAL CYCLES ONLY 2 WEEKS APART, EXCESSIVE BLEEDING DURING CYCLE (FILING PAD AND SUPER TAMPON IN AN HOUR), NAUSEA, CONFUSION AND BRAIN FOG, MOOD SWINGS, BACK AND JOINT PAIN, FATIGUE, BLOATING, HEADACHES, NUMBNESS IN HANDS/FEET AND INSOMNIA. AT 37 SHE HAD A HYSTERECTOMY AND MOST OF THE SIDE EFFECTS SUBSIDED. SHE WAS STILL DEALING WITH NUMBNESS, INSOMNIA, BACK PAIN AND FATIGUE. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

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COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN, EXTREME CRAMPING. SHE WAS SUBMITTED TO A HYSTERECTOMY AND THE EVENT SUBSIDED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED AFTER ESSURE INSERTION AND IMPROVED WITH DEVICE REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT AND NO BATCH NUMBER WERE REPORTED, NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THEREFORE, A RELATIONSHIP OF A QUALITY DEFECT TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00838	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0365, AWARENESS DATE 12-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED THE PAIN, THE MOOD SWINGS AND DEPRESSION WERE THE WORST FEELING THAT A PERSON COULD ENCOUNTER. SHE STATED SHE WAS (B)(6) AND WILL BE HAVING A HYSTERECTOMY IN (B)(6) 2015 DUE TO COMPLICATIONS FROM ESSURE. FOLLOW-UP RECEIVED ON 20-AUG-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0675). NO NEW CLINICAL INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 03-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED

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"UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO EXPERIENCED PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, A HYSTERECTOMY WAS SCHEDULED DUE TO COMPLICATIONS FROM ESSURE. THE REPORTED EVENT, REGARDED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE AND IN THE LACK OF ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENT DEPRESSION WAS REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ACCORDING TO THE PRODUCT TECHNICAL ANALYSIS; NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00839	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2003
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0099, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2003. CONSUMER STATED THAT SHE DID NOT HAVE PROBLEMS INITIALLY BUT WITHIN A COUPLE OF YEARS SHE STARTED HAVING MEDICAL ISSUES. HEADACHES THAT OVER THE YEARS GOT WORSE. SHE HAD ITCHY PATCHES OF SKIN HAT HAD POPPED IN THE PAST FEW YEARS. SHE GOT ACNE THAT GOT WORSE AND PAINFUL, HAD MUSCLE SPASMS IN UPPER BACK, SHOULDER AND NECK, GASTROINTESTINAL PROBLEMS, KIDNEY STONES, UTI'S, MIGRAINES AND RAYNAUD'S SYNDROME. SHE ALSO STATED THAT SOME DAYS SHE COULD NOT GET OUT OF BED BECAUSE OF THE PAIN. IN (B)(6) 2015, DURING SURGERY, SHE FOUND THAT ONLY ONE TUBE HAD A COIL IN IT. SEVERAL X-RAYS WERE DONE AND WERE FOUND THAT THE MISSING COIL WAS LOCATED IN HER HIP BONE AREA. ANOTHER SURGERY WAS DONE TO REMOVE THIS COIL. SHE HAD 6 PROCEDURES ON HER NECK TO HOPEFULLY RELIEVE MUSCLES SPASMS AND NECK PAIN. AFTER SURGERY, SHE WAS STILL GETTING HEADACHES, ITCHY PATCHES OF SKIN AND TROUBLE WITH HER EYES. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 03-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF

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THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE EXPERIENCED PAIN AND KIDNEY STONES. APPROXIMATELY, 8 YEARS LATER, WHEN THE SURGERY WAS PERFORMED, ONLY ONE TUBE HAD THE COIL IN IT. AN X-RAY SHOWED THE COIL WAS LOCATED IN HER HIP BONE AREA, SO ANOTHER SURGERY WAS PERFORMED TO REMOVE THIS COIL. THE PAIN AND COIL LOCATED IN HIP BONE AREA (INTERPRETED AS DEVICE DISLOCATION) ARE SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE EVENT KIDNEY STONES IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND UNLISTED. IN THIS PARTICULAR CASE, THE CONSUMER STARTED EXPERIENCING THE EVENTS WITHIN A COUPLE OF YEARS OF ESSURE INSERTION. CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN THE PAIN AND DEVICE DISLOCATION CANNOT BE EXCLUDED. HOWEVER, ALTHOUGH THE TEMPORAL RELATIONSHIP BETWEEN KIDNEY STONES AND ESSURE IS ALSO COMPATIBLE, CONSIDERING THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT THE INSERTS WOULD CAUSE KIDNEY STONES. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT AND NO BATCH NUMBER WERE REPORTED, NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THEREFORE, A RELATIONSHIP OF A QUALITY DEFECT TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00840	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 10/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. DURING THE 4 YEARS SHE HAD ESSURE IN HER BODY, SHE EXPERIENCED PELVIC PAIN CONSTANTLY, OVARIAN CYSTS, ANXIETY, PANIC ATTACKS, NUMBNESS IN HANDS AND ARMS, SEVERE BACK PAIN, BACTERIAL VAGINOSIS, BLOOD CLOTS DURING 10-12 DAY BLEEDING CYCLES, HEAVY BLEEDING DURING PERIOD BETWEEN 10-12 DAYS LONG AND IRREGULAR CYCLE, PELVIC PAIN INTENSIFYING AROUND PERIOD AND OVULATION, BOWEL ISSUES, BREAST PAIN, HEARTBURN, CRAMPS IN LEGS, DEPRESSION, SEVERE BLOATING (6 MONTH PREGNANT LOOKING BLOATING), FATIGUE, SEVERE MIGRAINES, HOT FLASHES, INSOMNIA, SHARP STABBING PAIN IN AREA WHERE HER FALLOPIAN TUBES AND ESSURE COILS SHOULD BE, WEIGHT GAIN 60 LBS, RASH AROUND HER PELVIC AREA, DOWN HER THIGHS, ON HER ARMS AND ACROSS HER BREASTS, AND SEVERE JOINT PAIN. IN (B)(6) 2013 SHE HAD ESSURE COILS REMOVED. 99% OF THE SIDE EFFECTS DISAPPEARED. THE REMAINING SIDE EFFECT WAS THE 60 POUNDS WEIGHT GAIN THAT SHE WAS SLOWLY LOSING. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION

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AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE TIME SHE HAD THE DEVICE EXPERIENCED PELVIC PAIN CONSTANTLY. SHE HAD ESSURE REMOVED 4 YEARS AFTER INSERTION AND THE PAIN DISAPPEARED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT AND CONSIDERING THAT THE PAIN RESOLVED AFTER ESSURE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. SINCE ESSURE REMOVAL WAS REPORTED, THIS CASE WAS REGARDED AS INCIDENT (REQUIRED INTERVENTION IMPLIED). ACCORDING TO TECHNICAL ANALYSIS NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00841	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED SHE HAD ESSURE PLACED SEVERAL YEARS AGO AND HAD A HYSTERECTOMY IN 2014 DUE TO THE COMPLICATIONS FROM ESSURE. A YEAR LATER, SHE STILL HAS CHRONIC PAIN, HEADACHES, NUMBNESS, DEPRESSION, FATIGUE, BRAIN FOG, SENSITIVITY TO NOISE AND COLD. SHE STATED SHE CAN BARELY FUNCTION AT TIMES. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 03-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR

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A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND UNDERWENT A HYSTERECTOMY DUE TO COMPLICATIONS FROM ESSURE. SHE STATED THAT A YEAR AFTER HYSTERECTOMY, SHE STILL HAS CHRONIC PAIN. THIS EVENT, INTERPRETED AS CHRONIC PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, ALTHOUGH THE EXACT REASON FOR THE HYSTERECTOMY WAS NOT SPECIFIED, SINCE THE CONSUMER MENTIONED SHE STILL HAD CHRONIC PAIN A YEAR AFTER HYSTERECTOMY, IT WAS INTERPRETED THAT THIS EVENT LED TO THE PROCEDURE. THE FACT THAT THE EVENT PERSISTED ONE YEAR AFTER HYSTERECTOMY SUGGESTS THAT ESSURE WAS NOT THE ONLY RESPONSIBLE FOR THE CHRONIC PAIN. HOWEVER, GIVEN THE NATURE OF THIS EVENT, A CONTRIBUTORY ROLE OF ESSURE FOR ITS OCCURRENCE CANNOT BE TOTALLY EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). IN THIS CASE, NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00842	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED BECAUSE SHE NO LONGER WANTED KIDS. THE CONSUMER WOULD HAVE A TUBAL LIGATION DONE AND DID THE NECESSARY BLOOD WORK, TOOK A PREGNANCY TEST. SHE CONTACTED THE HOSPITAL FOR PRE-REGISTRATION LATER AND THE DOCTOR SUGGESTED ESSURE SINCE SHE HAD A CESAREAN AND WAS OVERWEIGHT, SHE WOULDN'T BE A GOOD CANDIDATE FOR TUBAL LIGATION. ON (B)(6) (YEAR NOT REPORTED), SHE WENT TO PHYSICIAN OFFICE AND TOOK A MIXTURE OF PILLS AND WAS PUT INTO A ROOM WITH HIM AS WELL AS HIS ASSISTANT. SHE REMEMBERED BEING DOPED UP WHILE SHE WATCHED HIM CLUMSILY POKE AT HER FALLOPIAN TUBES, IT FELT LIKE SHE WAS BEING PINCHED. HE WAS AS ABLE TO GET THE COILS IN, TOOK PICTURES AND LEFT THE ROOM; ANOTHER NURSE CAME IN AND GAVE HER A DEPO SHOT SO SHE WOULD BE ON BIRTH CONTROL DURING THE THREE MONTH WAITING. SHE REPORTED HER PERIODS CHANGED WITHIN THAT TIME, GOING FROM QUITE REGULAR 5-7 DAY, 29 APART TO 15-21 DAY, AND 20 APART. SHE STATED THAT IT WASN'T SUPER HEAVY, IT WAS JUST THERE. SHE CALLED THE DOCTOR AND HE SAID IT WAS THE DEPO THAT CAUSED HER PERIOD TO CHANGE; SHE HAD CRAMPING ON AND OFF DURING THAT TIME. THREE MONTHS LATER SHE WENT IN FOR HER HSG (HYSTEROSALPINGOGRAM), WHEN THE RADIOLOGIST BEGAN HE MENTIONED THAT HE NEEDED TO GET MORE DYE SINCE HER UTERUS SEEMED TO BE RATHER LARGE, SHE WAS QUICKLY ABLE TO SEE THAT HER COILS DID NOT LOOK LIKE THE STANDARD PICTURES THAT SHE SAW ON THE INTERNET. ONE COIL WAS ALL THE WAY DOWN THE TUBE WHILE THE OTHER BROKE THROUGH THE TUBE IT WAS PLACED IN. THE PHYSICIAN CONFIRMED

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THAT ONE TUBE WAS CLOSED WHILE THE OTHER WAS NOT; HE TOLD HER SHE WOULD NEED TO BE ON BIRTH CONTROL WHICH SHE DID NOT WANT SINCE THE WHOLE PURPOSE OF GETTING THIS WAS TO PREVENT PREGNANCY. SHE STATED THAT AFTER THAT SHE WAS AT A HIGHER RISK OF HAVING ISSUES, WITHIN TWO WEEKS SHE WAS AT THE HOSPITAL GETTING HER TUBES REMOVED BY A DIFFERENT DOCTOR. THE DOCTOR TOLD HER THAT ONE OF THE COILS WAS EMBEDDED IN HER UTERUS AND SHE WASN'T ABLE TO REMOVE IT, BUT SHE HAD ONE OUT AT LEAST AND HER PERIODS QUICKLY RETURNED TO NORMAL. SHE REPORTED SHE FELT BETTER 2 DAYS OUT FROM SURGERY. FOLLOW UP INFORMATION FROM 12-AUG-2015: FDA DOCKET NUMBER IS (B)(4). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HSG (HYSTEROSALPINGOGRAM) TEST SHOWED ONE COIL WAS ALL THE WAY DOWN THE TUBE AND THE OTHER BROKE THROUGH THE TUBE IT WAS PLACED IN. SHE WAS SUBMITTED TO A SURGERY TO REMOVE THE FALLOPIAN TUBES, BUT PHYSICIAN WAS UNABLE TO REMOVE ONE OF THE COILS WHICH WAS EMBEDDED IN CONSUMER'S UTERUS. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT FOR DEVICE BREAKAGE (UNLISTED). DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (TO UTERUS), MIGRATION (TO PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A UTERINE PERFORATION DURING INSERTION. IN THIS CASE, THE EVENTS WERE DIAGNOSED AT 3-MONTH HSG. ALTHOUGH THEIR EXACT MECHANISM IS UNKNOWN; CONSIDERING THEIR NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00843	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/5/2012
Explant Date (E7): 7/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. IN (B)(6) 2012, THE CONSUMER REPORTED SHE WAS PUT TO SLEEP AT THE OUTPATIENT BUILDING OF THE HOSPITAL FOR THE PROCEDURE. WITHIN A FEW DAYS OF BEING IMPLANTED SHE DEVELOPED AN INFECTION, SHE HAD PAIN, SWELLING, AND LIMITED MOBILITY. AN ULTRASOUND WAS DONE AND SHOWED AN ABSCESS. SHE WAS TREATED WITH ANTIBIOTICS BUT CONTINUED TO EXPERIENCE PAIN. THE DOCTOR SAID SHE DEVELOPED PID (UNDERSTOOD AS PELVIC INFLAMMATORY DISEASE). IN (B)(6) 2012, THE HSG WAS DONE. THE PROCEDURE WAS PAINFUL. THE TEST SHOWED BOTH TUBES WERE 100% BLOCKED. SHE CONTINUED TO HAVE PAIN IN PELVIC AREA, LEGS, AND LIMITED MOBILITY AT HER HIP. SHE HAD PAINFUL PERIODS AND DEVELOPED A SWOLLEN STOMACH. SHE WAS ABLE TO LOSE WEIGHT BUT HER STOMACH ALWAYS APPEARED AS IF SHE WAS PREGNANT. IN 2013, SHE STARTED HAVING EPISODES OF DIZZINESS. SHE WENT TO AN EAR NOSE AND THROAT SPECIALIST AND AFTER SEVERAL VISITS AND NUMEROUS TEST, THEY WERE UNABLE TO DIAGNOSE THE CAUSE OF THE BOUTS. SHE SUFFERED FOR WEEKS AT A TIME. AT THIS POINT, ALL WEIGHT LOSS ATTEMPTS WERE USELESS, SHE STAYED THE SAME WEIGHT NO MATTER HOW MUCH HER DIET IMPROVED AND SHE EXERCISED. IN 2014 SHE DISCUSSED THE CHRONIC PAIN, DIZZINESS AND INFLAMMATION WITH HER DOCTOR. HE AGREED THAT HER ISSUES COULD BE CONNECTED TO THE ESSURE. AFTER A YEAR OF RESEARCH AND SECOND OPINIONS SHE MADE THE DECISION TO HAVE HER UTERUS, FALLOPIAN TUBES, AND COILS REMOVED. THE PHYSICIAN PERFORMED THE OPERATION AND THE PATHOLOGY REPORT REVEALED THAT WHILE ONE DEVICE

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WAS IN PLACE, THE OTHER DEVICE WAS LODGED IN HER UTERINE MUSCLE. THE TUBE WAS NOTED AS BEING "GROSSLY UNREMARKABLE". ONE OF THE COILS MIGRATED FROM THE TUBE. THE CONSUMER STATED SHE HAD NO MEDICAL TRAINING. HOWEVER, SHE WOULD BE WILLING TO BET THAT A PIECE OF METAL STUCK IN HER UTERUS COULD, IN FACT, CAUSE THE ISSUES SHE WAS EXPERIENCING. WHEN HER LEG WAS BENT AT HER HIP SHE FELT LIKE SHE WAS BEING STABBED. AFTER THE SURGERY, IT WAS CONFIRMED THAT SHE WAS ACTUALLY BEING STABBED FROM THE INSIDE. SHE WAS (B)(6) AND HAD TO LOSE HER UTERUS AND FALLOPIAN TUBES DUE TO ESSURE. SHE SUFFERED FOR 3 YEARS BECAUSE OF THIS DEVICE. SHE WAS ONLY 3 WEEKS POST PROCEDURE (AT THE TIME OF REPORT) AND SHE HAD ALREADY SEEN A DIFFERENCE IN THE SWELLING OF HER STOMACH AND SHE COULD BEND HER LEG AT THE HIP AND NOT FEEL LIKE SHE WAS BEING STABBED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PID (INTERPRETED AS PELVIC INFLAMMATORY DISEASE) WITHIN A FEW DAYS OF ESSURE BEING IMPLANTED. IT WAS TREATED WITH ANTIBIOTICS BUT SHE CONTINUED TO EXPERIENCE PAIN. AFTER APPROXIMATELY 3 YEARS DUE TO CHRONIC PELVIC PAIN SHE UNDERWENT A SURGERY TO REMOVE HER UTERUS, FALLOPIAN TUBES AND ESSURE INSERTS. THE PATHOLOGY REPORT REVEALED THAT ONE INSERT WAS IN PLACE WHILE THE OTHER DEVICE WAS LODGED IN HER UTERINE MUSCLE (INTERPRETED AS DEVICE DISLOCATION). APPROXIMATELY 3 WEEKS POST PROCEDURE SHE DID NOT FEEL THE STABBING PAIN FROM INSIDE AND COULD BEND HER LEG AGAIN. THE PELVIC INFLAMMATORY DISEASE AND DEVICE DISLOCATION ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE PID STARTED A FEW DAYS AFTER INSERTION. ALTHOUGH ESSURE SYSTEM IS STERILE, IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. CONSIDERING THIS INFORMATION AND THE SUGGESTIVE TEMPORAL RELATIONSHIP, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THE DEVICE DISLOCATION WAS DIAGNOSED 3 YEARS AFTER ITS INSERTION. CONSIDERING THE NATURE OF THIS EVENT AND LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS ALSO ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED FROM CONSUMER VIA REGULATORY AUTHORITY (MW5044940) ON 20-OCT-2015: SHE HAD ESSURE PLACED ON (B)(6) 2012. SHE HAD PAIN IN HER PELVIC AREA, LEGS, BACK, DURING SEX AND LIMITED RANGE OF MOTION. SHE HAD A CONSTANT SWOLLEN STOMACH. THE MONTH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00844	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2013
Explant Date (E7): 7/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE # (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. THE CONSUMER REPORTED SHE HAD ESSURE INSERTED IN (B)(6) 2013 AND HAD HORRIBLE PAIN AND BLEEDING AFTERWARDS. SHE STATED THAT WHEN GETTING X-RAY TO CHECK THE PLACEMENT IN (B)(6) 2013, THE ESSURE WERE NOT IN HER FALLOPIAN TUBES; ONE WAS BEHIND HER UTERUS AND THE OTHER BY HER COLON. SHE WAS IN TERRIBLE PAIN FROM (B)(6) OF 2013 WHEN SHE HAD TO HAVE AN ABDOMINAL SURGERY TO REMOVE THE ESSURE. SHE STATED IT WAS A TRAUMATIC AND PAINFUL EXPERIENCE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 03-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO

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RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BLEEDING (INTERPRETED AS GENITAL BLEEDING) AFTERWARDS. THREE MONTHS AFTER INSERTION CONFIRMATION TEST SHOWED THAT ESSURE WERE NOT IN HER FALLOPIAN TUBES: ONE WAS BEHIND UTERUS THE OTHER BY HER COLON. SHE UNDERWENT SURGERY TO REMOVE ESSURE 4 MONTHS AFTER INSERTION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENT BLEEDING, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, THREE MONTHS AFTER INSERTION AN X-RAY SHOWED THE COILS WERE NOT IN HER FALLOPIAN TUBES; ONE WAS BEHIND HER UTERUS AND THE OTHER BY HER COLON. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SURGERY TO REMOVE ESSURE). THE PRODUCT TECHNICAL ANALYSIS CONSIDERED NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00846	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/5/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE # (B)(4), AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR BIRTH CONTROL. THE CONSUMER REPORTED SINCE THAT DAY SHE HAVE HAD NONSTOP PROBLEMS AND PAIN INCLUDING LOW BACK PAIN, ABDOMINAL PAIN, NONSTOP BLEEDING, DIZZINESS, FATIGUE, AND PETICHAE ALL OVER HER BODY TO NAME A FEW OF THE SYMPTOMS. SHE REPORTED SHE HAD BEEN IN TOO MUCH PAIN TO HAVE SEX AND HAVE NOT BEEN ABLE TO DO SO SINCE MAY. SHE STATED SHE IS ALSO A PERSONAL TRAINER AND HAVE DIFFICULTY WORKING OUT HERSELF. SHE SPENT MOST OF THE DAYS IN BED AND USED A HEATING PAD DAILY. THIS HAS DESTROYED HER LIFE AND SHE WAS FACING A HYSTERECTOMY IN TWO WEEKS. PTC INVESTIGATIONAL RESULT RECEIVED ON 08-SEP-2015: GLOBAL PTC NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY

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CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN AND NON-STOP BLEEDING (REGARDED AS GENITAL BLEEDING). SHE WILL BE SUBMITTED TO A HYSTERECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENTS STARTED SINCE ESSURE INSERTION. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE SURGICAL INTERVENTION WILL BE REQUIRED (HYSTERECTOMY SCHEDULED IN 2 WEEKS FROM THE TIME OF THIS REPORT). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00848	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE # (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE REPORTED THAT ESSURE STOLE HER UTERUS; SHE HAD HORRIBLE PAIN AND BLOATING. SHE HAD A HYSTERECTOMY PERFORMED AND EVEN AFTER THAT HER STOMACH WAS BIGGER THAN WHEN SHE WAS PREGNANT WITH TWINS AND STILL HURT DAILY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATIONAL RESULT RECEIVED ON 08-SEP-2015: GLOBAL PTC NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HORRIBLE PAIN (INTERPRETED AS ABDOMINAL PAIN). SHE UNDERWENT A HYSTERECTOMY BUT EVEN AFTER THAT IT STILL HURTS DAILY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO

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MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. THE FACT THAT THE EVENT PERSISTED AFTER HYSTERECTOMY SUGGESTS THAT ESSURE WAS NOT THE ONLY RESPONSIBLE FOR THE ABDOMINAL PAIN. HOWEVER, GIVEN THE NATURE OF THIS EVENT, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE TOTALLY EXCLUDED. NON-SERIOUS EVENT WAS ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). ACCORDING TO THE PRODUCT TECHNICAL ANALYSIS NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00855	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0367, AWARENESS DATE 13-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAS HAD TO SUFFER THROUGH SEVERAL MONTHS (ALMOST AN ENTIRE YEAR STRAIGHT) OF HEAVY BLEEDING, BRUISING EASILY, HAIR FALLING OUT, SEVERE PELVIC CRAMPING AND PAIN, UNPLEASANT SMELLS FROM HER VAGINA LINKED TO METAL TOXICITY, MIGRAINE HEADACHES EVERY SINGLE DAY THAT ARE DEBILITATING AND SO MUCH MORE SINCE SHE HAD ESSURE INSERTED. THE DOCTORS INSERTING HER ESSURE INSERTED TWO COILS ON HER LEFT SIDE AND ONE ON HER RIGHT. SHE HAD A BILATERAL SALPINGECTOMY TO REMOVE BOTH HER FALLOPIAN TUBES AND SUPPOSEDLY ALL THREE COILS. THE ONE FROM HER RIGHT FALLOPIAN TUBE HAD MIGRATED DOWN INTO HER UTERUS AND THE TWO IN HER LEFT SIDE HAD SUPPOSEDLY PROTRUDED THE TUBE. THE DOCTOR LEFT HALF A COIL IN THE LEFT UTERINE ARTERY AND FAILED TO TELL HER. AFTER CONTINUING TO EXPERIENCE DIFFICULTIES THAT WERE THE SAME AS BEFORE THE SURGERY SHE DEMANDED FROM HER DOCTOR A CT SCAN TO SEE IT THERE WAS ANYTHING LEFT, AS SHE KEPT TELLING HER THERE WAS NOT. FINALLY, THE CT SCAN SHOWED WHAT WAS LEFT, AND HER DOCTOR TOLD HER THAT THE HALF COIL WAS NO BIGGER THAN AN EYELASH. THE CONSUMER HAD A SECOND OPINION, AND A HYSTERECTOMY. SHE WAS 25 WHEN SHE HAD HER ESSURE COILS INSERTED AND HAD JUST TURNED (B)(6) WHEN SHE HAD HER HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)FEMALE PATIENT WHO HAD 3 ESSURE INSERTS PLACED (2 COILS ON LEFT SIDE AND 1 ON HER RIGHT). SHE HAD A BILATERAL SALPINGECTOMY AND THE ESSURE FROM

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HER RIGHT FALLOPIAN TUBE HAD MIGRATED DOWN INTO HER UTERUS AND THE TWO IN HER LEFT SIDE HAD SUPPOSEDLY PROTRUDED THE TUBE. ACCORDING TO HER, THE DOCTOR LEFT HALF A COIL IN THE LEFT UTERINE ARTERY (REGARDED AS DEVICE BREAKAGE) DURING THE SURGERY AND SHE UNDERWENT A HYSTERECTOMY TO REMOVE IT. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT FOR DEVICE BREAKAGE (UNLISTED). DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A FALLOPIAN TUBE PERFORATION DURING INSERTION. IN THIS CASE, CONSUMER HAD 2 ESSURES PLACED ON THE LEFT FALLOPIAN TUBE; THIS DEVICE MISUSE COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED COIL PROTRUSION. ALTHOUGH THE EXACT MECHANISM OF THE EVENTS IS NOT KNOWN, GIVEN THEIR NATURE; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICES REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00856	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED TO NOT HAVE TO WORRY ABOUT ANY MORE BABIES. SHE HAD NOTHING BUT PROBLEMS AND IT ALMOST DESTROYED HER. SHE HAS NEVER FELT SO HORRIBLE IN HER LIFE. SHE EXPERIENCED PROBLEM AFTER PROBLEM AFTER PROBLEM AND SURGERY AFTER SURGERY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD UNSPECIFIED PROBLEMS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND WAS SUBMITTED TO SURGERY AFTER SURGERY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED PROBLEMS AND SURGERIES DUE TO ESSURE, BUT LIMITED INFORMATION WAS GIVEN AND NO REASON OR DETAILS OF THE SURGERIES WAS PROVIDED. HOWEVER, SINCE CONSUMER RELATED THIS PROCEDURE TO ESSURE AND AS NO FOLLOW-UP WILL BE POSSIBLE; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00857	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 12/17/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00860	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS WERE PROVIDED ON 08-SEP-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00861	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00923	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 8/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C59250

Single Use: Y
Implant Date (E6): 8/14/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 15-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. ADDITIONAL INFORMATION RECEIVED ON 03-SEP-2015. PHYSICIAN HAD A DIFFICULT ESSURE PLACEMENT; HE BELIEVED THAT DEVICE MAY NOT HAVE DEPLOYED PROPERLY. HE TRIED TO REMOVE IT; HOWEVER THE PATIENT'S UTERUS WAS SO EDEMATOUS AT THAT TIME THAT VISIBILITY WAS POOR. PART OF THE IMPLANT WAS SEEN IN THE UTERUS AND HE TRIED TO REMOVE IT BUT IT WAS NOT POSSIBLE. THE PATIENT WAS IN PAIN. HE IS PLANNING TO PERFORM HYSTEROSCOPY ON FRIDAY (B)(6) 2015. IN ADDITION, ON 03-SEP-2015, PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A USABILITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: ROLLBACK TO INITIAL HARD STOP; DEPRESS BUTTON; PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO "DEPLOYMENT DIFFICULTY". SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. SINCE WE

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HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE PHYSICIAN BELIEVED THAT DEVICE MAY NOT HAVE DEPLOYED PROPERLY. HE TRIED TO REMOVE IT UNSUCCESSFULLY. A HYSTEROSCOPY IS PLANNED IN 2 WEEKS. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS ANTICIPATED ACCORDING TO PRODUCT TECHNICAL ANALYSIS (PTC). DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL, IN THIS PARTICULAR CASE PHYSICIAN STATED UTERINE VISIBILITY WAS POOR; THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED EVENT. CONSIDERING IT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION WILL BE REQUIRED (HYSTEROSCOPY PLANNED) DUE TO THE EVENT; THIS CASE WAS CONSIDERED AN INCIDENT. THE PTC CONCLUDED TO UNCONFIRMED QUALITY DEFECT (NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION). THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 06-JAN-2016 FROM MEDICAL ASSISTANT AND ON 07-JAN-2016 FROM PHYSICIAN (DOWNGRADED TO NON-INCIDENT). PATIENT'S INITIALS, DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. CON

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00924	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 2/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 15-AUG-2013 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN ALL THE TIME, UNABLE TO HAVE SEX DUE TO PAIN, AND STATES THAT RIGHT COIL WAS PUSHING OUT OF MY RIGHT TUBE. CONSUMER REPORTED AS MEDWATCH MW5030761. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. IN 2008 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. IT WAS NOT REPORTED WHETHER ESSURE WAS USED PREVIOUSLY. CONSUMER STATES THAT SHE HAD ESSURE PUT-IN IN 2008, AND THAT, BY 2010, SHE WAS IN PAIN ALL THE TIME AND WAS TOLD THAT SHE HAD GRAVES. IN 2012 SHE WAS UNABLE TO HAVE SEX DUE TO PAIN, AND ON 2013, HER DOCTOR DID A HYSTERECTOMY AND FOUND THAT HER RIGHT COIL WAS PUSHING OUT OF THE RIGHT TUBE AND HAD TO REMOVE IT ALONG WITH HER RIGHT OVARY AS WELL AS HER UTERUS. REPORTER CAUSALITY WAS NOT REPORTED. THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO (B)(6) ON 25-SEP-2013. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED. FOLLOW-UP INFORMATION RECEIVED ON 18-AUG-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(4) 2015 ((B)(4)). SHE STATED THAT ABOUT A WEEK AFTER INSERTION SHE I WAS TOLD SHE HAD AN INFECTION SEEMED LIKE NO BIG DEAL AT THE TIME. ABOUT A YEAR LATER SHE GOT WHAT THE FLU THAT SEEMED TO NOT WANT TO GO AWAY. AFTER SEVERAL WEEKS OF NOT FEELING WELL SHE WENT TO THE DOCTOR'S OFFICE FOR SOME TEST. AFTER TESTING SHE WAS TOLD SHE HAD GRAVES (INTERPRETED AS GRAVES'S DISEASE). SHE ALSO STARTED HAVING BAD PERIODS AND WAS TREATED FOR AUTOIMMUNE AND EVEN TESTED FOR

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FIBROMYALGIA AS A POSSIBILITY. SHE STARTED TRYING DIFFERENT MEDS FOR DEPRESSION AND OR ANXIETY. FAST FORWARD TO SUMMER/ FALL OF 2012 SHE STARTED HAVING LOTS OF PAIN WITH INTERCOURSE. AFTER SEVERAL MONTHS OF THIS SHE WENT BACK TO HER DOCTOR AND HE TALKED ABOUT HER OPTIONS AND ABOUT SOMETHING CALLED TUBAL SYNDROME AND HIS OPINION WAS HYSTERECTOMY (HE PLANNED TO REMOVE UTERUS AND ESSURE COILS AND WELL AS HER TUBES). HER SURGERY WAS IN (B)(6) 2013 AND DURING SURGERY THE DOCTOR FOUND THAT HER RIGHT ESSURE WAS STICKING OUT OF TUBE AND ATTACHED TO HER RIGHT OVARY; IT WAS ALSO ALL INFLAMED AND NEEDED TO COME OUT AS WELL. IT HAS BEEN 3 YEARS SINCE HER HYSTERECTOMY AND MOST OF HER ISSUES WERE GONE. SHE STARTED MENOPAUSE EARLY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. A WEEK AFTER INSERTION, SHE WAS TOLD SHE HAD AN INFECTION (INTERPRETED AS POST PROCEDURAL INFECTION). AFTER SOME TEST SHE WAS TOLD SHE HAD GRAVES (INTERPRETED AS GRAVE'S DISEASE). APPROXIMATELY, TWO YEARS AFTER INSERTION, THE CONSUMER STARTED EXPERIENCING PAIN ALL THE TIME (CHRONIC PAIN) AND SEVERAL MONTHS LATER, SHE HAD A HYSTERECTOMY AND REMOVAL OF FALLOPIAN TUBES AND COILS. DURING THE SURGERY THE PHYSICIAN FOUND THAT THE RIGHT ESSURE WAS STICKING OUT OF TUBE AND ATTACHED TO HER RIGHT OVARY (DEVICE DISLOCATION). THIS OVARY WAS INFLAMED (OOPHORITIS) AND WAS REMOVED TOO. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND THE CHRONIC PAIN IS ALSO SERIOUS DUE TO REQUIRED INTERVENTION. THE POST PROCEDURAL INFECTION, CHRONIC PAIN AND DEVICE DISLOCATION ARE LISTED WHILE THE OTHER EVENTS ARE UNLISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE INFECTION STARTED A WEEK AFTER INSERTION. CONSIDERING THIS SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS ASSESSED AS RELATED TO ESSURE PROCEDURE. ALSO, THE ESSURE ATTACHMENT IN RIGHT OVARY IS CONSIDERED RELATED DUE TO THE NATURE OF THIS EVENT AND SINCE THE INFLAMMATION IN THE RIGHT OVARY COULD BE A CONSEQUENCE OF THE COIL'S ATTACHMENT IN THE OVARY, THE OOPHORITIS IS ASSESSED ALSO AS RELATED TO ESSURE. IN CONTRAST, GIVEN THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT ESSURE WOULD CAUSE GRAVE'S DISEASE AND THUS UNRELATED TO ESSURE DESPITE THE COMPATIBLE TEMPORAL RELATIONSHIP. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 13-SEP-2015 (PTC RESULT) AND 15-SEP-2015: CONSUMER HAD HASHIMOTO'S. ALSO REPORTED THAT THE RIGHT COIL WAS PERFORATED THROUGH HER TUBE AND OVARY WAS KIND OF ATTACHED (PREVIOUSLY REPORTED AS STICKING OUT OF TUBE AND ATTACHE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00925	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A20064

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN THE UNITED STATES (B)(4) ON (B)(6) 2013 WHICH REFERS TO HERSELF A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED TREMENDOUS PAIN DURING INSERTION, UTERUS SPASMS DURING ESSURE INSERTION, LEFT FALLOPIAN TUBE WAS CLOSED OFF, BENT COIL / UNRAVELED COIL DURING ESSURE INSERTION, BLOOD HAD SPATTERED DURING INSERTION, UNABLE TO VERIFY IF COIL WAS IMPLANTED CORRECTLY (QUESTIONABLE PLACEMENT), HEAVY BLEEDING, PAIN IN PELVIC REGION, SEVERE HEADACHES, CREATININE LEVELS DECREASED, AND OVARIAN PAIN. THE CONSUMER'S DRUG HISTORY INCLUDED IUD AND SHE FOUND THAT IT WAS VERY PAINFUL EACH TIME SHE HAD A NEW IUD IMPLANTED. NO INFORMATION GIVEN ON CONSUMER'S MEDICAL HISTORY, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. IN 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER STATED THAT SHE SUFFERED A TREMENDOUS AMOUNT OF PAIN AND SHE ALSO WAS IN SURGERY OVER AN HOUR. DURING THE SURGERY THE FIRST COIL ON THE RIGHT SIDE HAS BEEN IMPLANTED PERFECTLY BUT HER UTERUS BEGAN TO SPASM. THE DOCTOR DID NOT WAIT FOR THE SPASM TO STOP AND ALTHOUGH HER LEFT FALLOPIAN TUBE WAS CLOSED OFF HE PROCEEDED TO PUSH THE COIL IN. THE FIRST COIL BENT. THE SECOND COIL UNRAVELED. THE THIRD COIL WAS IMPLANTED BUT BLOOD HAD SPATTERED ON THE CAMERA AND THE DOCTOR WAS UNABLE TO VERIFY IF IT WAS IMPLANTED CORRECTLY. ON THE SECOND DAY, AFTER IMPLANTATION, THE CONSUMER WENT INTO THE RESTROOM AND BEGAN TO HAVE HEAVY BLEEDING AND PAIN IN HER PELVIC REGION. THIS CONTINUED FOR 2 WEEKS AND SLOWED DOWN AND THEN THE SEVERE HEADACHES BEGAN. SHE STATED THAT SHE WENT IN FOR BLOOD WORK AND FOUND THAT HER CREATININE LEVELS DECREASED TREMENDOUSLY. SHE EVENTUALLY HAD SEVERAL IRON INFUSIONS. SHE CONTINUED TO

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HAVE OVARIAN PAIN, HEADACHES AND LOW CREATININE LEVELS. REPORTER CAUSALITY: THE RELATIONSHIP WAS NOT REPORTED. ADDENDUM: THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO ARGUS ON (B)(6) 2013. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED. FOLLOW-UP RECEIVED ON (B)(6) 2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0644). A (B)(6) YEAR OLD FEMALE CONSUMER REPORTED THAT ESSURE CAUSED SEVERE PELVIC PAIN, ABDOMINAL BLOATING (THAT WOULD WORSEN TOWARD THE EVENING RESULTING IN WHAT APPEARED LIKE A PREGNANT BELLY), INITIAL LOSS OF MENSTRUAL CYCLE (6 MONTHS+/- AFTER ESSURE PLACEMENT) FOLLOWED BY 45 DAY MENSTRUAL CYCLES WITH ABOUT TWO WEEKS OFF IN BETWEEN CYCLES, FATIGUE, DEPRESSION FROM THE ONGOING PAIN AND BODY CHANGES, RASHES, ANEMIA, MOOD SWINGS, EXTREME BREAST PAIN AND TENDERNESS. ACCORDING TO CONSUMER, ALL SYMPTOMS APPEARED ALMOST IMMEDIATELY AFTER ESSURE WAS PLACED. SHE ALSO REPORTED THAT SHE UNDERWENT TWO IRON INFUSIONS, AN ESOPHAGOGASTRODUODENOSCOPY, MULTIPLE ULTRASOUNDS, MULTIPLE ROUNDS OF PROVERA (IN AN ATTEMPT TO REGULATE CYCLE), VARIOUS BLOOD WORKS, AND MULTIPLE PELVIC EXAMS BEFORE HER GYNECOLOGIST PERFORM A HYSTERECTOMY TO REMOVE ESSURE (NO RESULTS PROVIDED). SHE IS 1 YEAR AND FOUR MONTHS POST HYSTERECTOMY AND ALL PREVIOUS SYMPTOMS HAVE DISSIPATED. SHE HAD A DEPO SHOT WHEN ESSURE WAS PLACED AND WAS CONFIRMED BLOCKED VIA HYSTEROSALPINGOGRAM THREE MONTHS AFTER ESSURE WAS PLACED. THREE ESSURE KITS WERE USED DURING THE IMPLANTATION BECAUSE THE DEVICES KEPT BREAKING AND BENDING. IN ADDITION, CONSUMER INFORMED THAT PATHOLOGY AND SURGICAL REPORT FROM HER HYSTERECTOMY CONFIRMED PROPER PLACEMENT OF ESSURE. HER PATHOLOGY REPORT SHOWED CHRONIC AND ACUTE INFLAMMATION THROUGHOUT HER UTERUS AND CYSTS IN HER FALLOPIAN TUBES. SHE HAD NO PRIOR ISSUES WITH IRREGULAR CYCLES, PELVIC PAIN, RASHES, BLOATING, DEPRESSION, OR FATIGUE PRIOR TO ESSURE. CONSUMER ALSO REPORTED THAT SHE HAS HAD ONE PREGNANCY AND ONE LIVE VAGINAL BIRTH. SHE HAD AN IUD FIVE YEARS PRIOR TO GETTING ESSURE AND HAD PREVIOUSLY RELIED ON BIRTH CONTROL PILLS. APPROXIMATELY 10 YEARS AGO SHE HAD AN ABNORMAL PAP WHICH REQUIRED A LOOP ELECTROSURGICAL EXCISION PROCEDURE AND SUBSEQUENTLY, HAD NO MORE ABNORMAL PAP SMEARS. ADDITIONALLY, CONSUMER REPORTED THAT SHE DOES NOT ROUTINELY TAKE MEDICATIONS, PRESCRIPTIONS OR OVER THE COUNTER AND SHE HAS NO FAMILY HISTORY OF GYNECOLOGICAL RELATED CANCERS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THIS INSERTION WAS VERY LONG AND DIFFICULT. THREE SETS OF DEVICES WERE USED: ONE DEVICE BENT, OTHER UNRAVELED AND THE THIRD WAS PLACED BUT BLOOD HAD SPATTERED ON THE CAMERA AND THE VISUALIZATION OF PROPER PLACEMENT WAS IMPAIRED. THE DEVICES KEPT BREAKING AND BENDING DURING THE PROCEDURE. AFTER PLACEMENT, SHE EXPERIENCED HEAVY BLEEDING AND SEVERAL OTHER NON-SERIOUS EVENTS. THESE BLEEDINGS, SEEN AS PROCEDURAL HAEMORRHAGE AND GENITAL BLEEDING RESPECTIVELY, ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING OR AFTER A DIFFICULT INSERTION, PROCEDURAL HAEMORRHAGE MAY OCCUR. ALSO, GENITAL BLEEDING AND MENSES PATTERN CHANGES ARE FREQUENT IN WOMEN WITH ESSURE IN PLACE. IN THIS CASE, THE BLEEDING LED TO ANEMIA, TWO BLOOD TRANSFUSIONS AND MULTIPLE CYCLES OF PROVERA IN AN ATTEMPT TO REGULATE HER CYCLE. THEN A HYSTERECTOMY WAS PERFORMED AND THE PREVIOUS SYMPTOMS HAVE DISSIPATED. THEREFORE, CONSIDERING COMPATIBLE TEMPORAL RELATIONSHIP, EVENT'S NATURE AND RECOVERY AFTER HYSTERECTOMY (ESSURE REMOVAL IMPLIED) CAUSAL RELATIONSHIP WITH ESSURE USE CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON DETECTION OF FOLLOW UP INFORMATION, REQUIRED INTERVENTION (HYSTERECTOMY) WAS INFORMED. HENCE THIS CASE WAS UPGRADED TO INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING. TECHNICAL ASSESSMENT IS EXPECTED.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 13-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00926	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5035907) IN UNITED STATES ON 02-JUN-2014. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING EVENTS: IN 2010 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON UNSPECIFIED DATE SHE EXPERIENCED BLURRED VISION, HEADACHE, ABDOMINAL PAIN, HIP PAIN, BACK PAIN, AND DEPRESSION. SHE WAS DIAGNOSED WITH INFLAMMATION OF THE CERVIX AND OVARIES A WEEK PRIOR TO THIS REPORT AND WAS ON 2-500MG ANTIBIOTICS TWICE A DAY PLUS HYDROCODONE FOR PAIN. SHE HAS NOT HAD ANY PREVIOUS MEDICAL ISSUES. SHE ALSO REPORTED FATIGUE. SHE DENIED CYSTS AND WAS NOT ON BIRTH CONTROL PRIOR TO HAVING THE PROCEDURE DONE. NO ASSESSMENT WAS GIVEN. FOLLOW-UP INFORMATION RECEIVED ON 17-JUN-2014 THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE. CASE CONSIDERED CLOSED. FOLLOW-UP INFORMATION RECEIVED ON 18-AUG-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0684). CONSUMER STATED THAT AT THE AGE OF (B)(6), SHE HAD A HYSTERECTOMY DUE TO THE PAIN. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN / PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, NO

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ALTERNATIVE EXPLANATION WAS PROVIDED. CONSUMER UNDERWENT A HYSTERECTOMY DUE TO THE PAIN. GIVEN ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 15-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00927	BAYER HEALTHCARE LLC	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056080	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 7/31/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP2 #FDA MW5056080, #(B)(4). ON (B)(6) 2016 DR. SAID WHEN THEY WENT IN, I HAD ENDOMETRIOSIS WITH A CYST ON MY RIGHT OVARY, MY LEFT OVARY, FALLOPIAN TUBE, WERE CONNECTED TO MY COLON WITH ENDOMETRIOSIS . ALSO HAD MILD CHRONIC INFLAMMATION OF THE CERVIX. THE OTHER THING I NOTICED AFTER HYSTERECTOMY, IS I NO LONGER HAD THE SINUS PROBLEMS I WAS HAVING SINCE (B)(6) OF 2015

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056081	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE IN 2010 AND OVER THE COURSE OF THE LAST FIVE YEARS I HAVE EXPERIENCED HEAVY ERRATIC PERIODS MIGRAINES PELVIC AND ABDOMINAL PAIN AND ALL OVER BODY AND JOINT PAIN DUE TO CHRONIC INFLAMMATION. I WAS TOLD THAT HORMONE BIRTH CONTROL WAS NO LONGER AN OPTION FOR ME DUE TO HEADACHES AND WAS MISGUIDED BY MY IMPLANTING DOCTOR THAT THE ESSURE CONTAINED NO NICKEL. MY HEALTH HAS DETERIORATED IN THE LAST FIVE YEARS. MY JOINTS ARE CHRONICALLY INFLAMED AND I CAN BARELY MAKE IT THROUGH MY WORK DAY. PRE IMPLANTATION MY HEADACHES WERE MANAGED WITH OVER THE COUNTER MEDICATION NOW THAT I HAVE ESSURE THE MIGRAINES CAUSE ME TO MISS WORK. I HAVE GAINED 70 POUNDS IN THE LAST FIVE YEARS AND MY QUALITY OF LIFE IS "PROFANITY" I GO TO WORK AND COME HOME. I DON'T HAVE THE ENERGY OR STRENGTH TO DO MUCH ELSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056082	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056083	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 7/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC NECK PAIN, DEPRESSION, ANXIETY. THIS WAS PROVIDED BY INSURANCE. SINCE THE ESSURE WAS PLACED I HAVE HAD HORRIBLY HEAVY PERIODS AND INTERMITTENT STABBING PAIN IN THE PELVIS WHICH HAS NOW BECOME CHRONIC AND CONSTANT. I HAVE TO HAVE A HYSTERECTOMY ON (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056084	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 9/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, SEVERE CRAMPS, PAIN IN MY CERVIX, DIZZINESS, HURTS WHEN I HAVE INTERCOURSE, PERIODS THAT LAST FOR WEEKS, NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056085	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 3/12/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INFLAMMATION OF THE FALLOPIAN TUBES. PELVIC PAIN. UTI AND YEAST INFECTIONS CONSTANTLY. HEAD ACHES, MUSCLE AND JOINT PAIN. STOMACH SWELLING. OVARIAN CYSTS. CURRENTLY: HYPERTHYROIDISM (GRAVES DISEASE) LUPUS (AUTO IMMUNE DISORDER. WIDE SPREAD PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056086	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 3/2/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS USING THE DEVICE TO PREVENT PREGNANCY AND NOW 10 YEARS LATER PREGNANT WITH MY DAUGHTER. NOT KNOWING AT THE TIME THAT I WAS PREGNANT I WAS EXPOSED TO X-RAY MACHINE . EXPRESS ABDOMINAL PAIN BACK PAIN HAIR LOSE. HEADACKES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056087	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 1/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVIER MORE PAINFUL PERIODS, PERIODS LAST IN LONG TIMES AND HAVING ANOTHER A COUPLE DAYS LATER, CRIPPLING MIGRAINES, UNBEARABLE PELVIC PAINS, MISSED PERIODS FOR MONTHS (NO PREGNANCY), INCREASED HAIR LOSS, PAINFUL INTERCOURSE, OVARIAN CYST (DIAGNOSED (B)(6) 2015), EXTREMELY EMOTIONAL, BAD MOOD SWINGS, LACK OF ENERGY, BLOATING, WEIGHT GAIN AND INABILITY TO LOSE, BRAIN FOG, FORGETTING SIMPLE THINGS (IT IS ACTUALLY TAKING ME QUITE A BIT OF TIME TO RECALL ALL OF MY SIDE EFFECTS AS THERE HAVE BEEN SO MANY OVER A SHORT TIME). THE DEVICE STILL REMAINS IN MY TUBES BUT I AM HOPING TO HAVE THEM REMOVED BEFORE SPRING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056088	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 9/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WELL SINCE I HAD ESSURE DONE. THIS FIRST 2 MONTHS I COULDN'T WALK WAS SO WEAK FROM MY LEGS . HAD HOT FLASHES THRU THE NIGHT. WAS VERY DRY WHEN HAVING INTERCOURSE. HAVE LOTS OF MIGRAINES. DURING MY PERIOD I GET VERY BAD CRAMPS HEAVY PERIOD THAT LAST A WEEK. AND EVERY MONTH I'M LATE ABOUT 20 DAYS. SPOT AFTER FINISHING MY PERIOD. THRU THE MONTH I GET REALLY SHARP PAIN IN MY UTERUS. I FEEL FATIGUE EVERY DAY I FEEL I HAD LOST MY SELF I FEEL SAD THAT I CAN'T BE GOOD FOR ALL FOUR OF MY KIDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056089	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 10/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING, MIGRAINES, BLOATING, SHARP PAINS, UTI'S. THIS IS ONGOING. HEAVY BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056090	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 10/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CONSTANT PAIN BLOATING HAIR LOSS AND WEIGHT GAIN I ALSO BLEED VERY HEAVILY AND HAVE HUGE CLOTS WITH MY PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056091	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 9/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE DONE (B)(6) 2011 AND THE DYE 3 MONTHS LATER AND IN (B)(6) 2011 STARTED HAVING SEVERE CRAMPS AND NAUSEA, HEADACHES I HAVE STOMACH PROBLEMS 4 IN A HALF YEARS LATER AND GOT APPT FOR GYNOCOLOGIST AND GI SPECIALIST DUE TO ESSURE I KNOW IT IS FROM THAT BC I DIDN'T HAVE ISSUES LIKE THAT BEFORE I GOT A FOREIGN OBJECT IN MY BODY I BLAME YOUR COMPANY FOR EVERY THING I STAY SICK ON MY STOMACH EVERYDAY I HAVE A LOT OF FATIGUE I CAN'T EVEN HOLD A JOB THANKS TO THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056092	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 8/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE IMPLANTS PLACED THREE YEARS AGO. MY DOCTOR GAVE LITTLE EXPLANATION, ONLY THAT IT WAS EASY, EFFECTIVE AND COVERED BY MY INSURANCE. I HAD THE PROCEDURE DONE IN THE OFFICE AND WAS ABLE TO GO BACK TO MY NORMAL ACTIVITIES WITHOUT RESTRICTIONS ALMOST IMMEDIATELY. I HAD LITTLE PAIN, JUST A DULL ACHE ON THE RIGHT SIDE OF MY LOWER BACK. TYLENOL AND MOTRIN SEEM TO ALLEVIATE THE PAIN. SINCE THAT TIME I HAVE HAD SLOWLY INCREASING RIGHT BACK/HIP PAIN. I WAS TOLD IT WAS SI JOINT PAIN AND I HAVE BEEN THROUGH MANY DIFFERENT TREATMENTS TO ALLEVIATE THE PAIN. AS THE YEARS GO ON IT ONLY INCREASES. I HAVE HAD 6 MONTHS OF PHYSICAL THERAPY, SI JOINT INJECTIONS UNDER FLUOROSCOPE, ACUPUNCTURE, MASSAGE THERAPY, AND VARIOUS MEDICATIONS TO RESOLVE OR COVER THE SYMPTOMS. I PURCHASED AN INVERSION TABLE TO HOPEFULLY HELP WITH THE PAIN AND IT TOO PROVIDED LITTLE RELIEF. I HAVE WEIGHT GAIN WITH ABDOMINAL BLOATING, DECREASED LIBIDO, SEVERE HIP AND BACK PAIN, FATIGUE AND DEPRESSION OVER THE PAST THREE YEARS AND THE ONLY COINCIDING EVENT IS THE PLACEMENT OF THE ESSURE IMPLANTS. MY LATEST SYMPTOMS ARE NUMBNESS AND TINGLING WITH MY RIGHT SIDE EXTREMITIES AND ABDOMINAL PAIN. I HAVE BEEN TO SEE MY PCP MULTIPLE TIMES OVER THIS SITUATION AND I HAVE BEEN DIAGNOSED WITH EVERYTHING FROM HYPOTHYROID TO DEPRESSION. ON MY LATEST ULTRASOUND THEY ARE UNABLE TO FIND THE COIL ON MY RIGHT SIDE. I AM MEETING WITH MY GYNECOLOGIST ON TUESDAY TO DISCUSS REMOVAL OF THE IMPLANTS, WHICH WILL INVOLVE A HYSTERECTOMY OR AT LEAST A PARTIAL HYSTERECTOMY. I HAVE READ OTHER STORIES VERY SIMILAR TO MINE AND I WANT TO EMPHASIZE TO MY SURGEON THE IMPORTANCE OF REMOVING THE ENTIRE COIL TO REDUCE THE POSSIBILITY OF FRAGMENTS REMAINING IN MY BODY. I SUSPECT I HAVE AN ALLERGY TO NICKEL AS I CAN NO LONGER EVEN WEAR EARRINGS WITHOUT IRRITATION AND UNFORTUNATELY NEVER HAD AN

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ALLERGY TEST PERFORMED PRIOR TO HAVING THE ESSURE PLACED. I WILL KEEP YOU POSTED AS TO WHAT HAPPENS IN THE FUTURE; HOPEFULLY THINGS START TO IMPROVE FROM THIS POINT!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056093	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 9/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IVE HAD THE INSERTS SINCE (B)(6) OF 2008. THE SIDE EFECTS BEGAN SEVERAL YEARS LATER WITH WEIGHT GAIN, EXTREME TIREDNESS, LOSS OF MEMORY, BLOATING, NOW I HAVE ARTHRITIS IN MY HANDS AND FEET , PAIN IN BACK AND OVARIES , PAINFUL PERIODS. I EAT VERY HEALTHY AND EXERCISE , THERE IS NO REASON AT MY AGE (B)(6) TO FEEL THIS WAY! YES MY INSURANCE COVERED IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056094	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE 9MM CYSTS ON MY OVERIES, SEVERE BACK AND ABDOMINAL PAIN, WEIGHT GAIN, BLOATING AND MOOD SWINGS \CHANGES. HAVE BEEN TO HOSPITAL MANY TIMES!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056095	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2015. TWO HOURS AFTER THE PROCEDURE I STARTED BLEEDING A LITTLE WHICH I WAS TOLD COULD HAPPEN. WELL, 8 DAYS LATER I WAS STILL BLEEDING. HEAVILY. I HAD HORRIBLE CRAMPS AND SHOOTING PAIN AND VERY LARGE CLOTS. THEN A FEW DAYS LATER IT STOPPED. I HAVE STARTED GETTING VERY SHARP, SHOOTING PAINS IN MY ABDOMEN EVERY SO OFTEN. I CONSTANTLY HAVE CRAMPING, EVEN WHEN I'M NOT ON MY PERIOD. I WOULD NORMALLY HAVE A REGULAR PERIOD THAT CAME EVERY 28 DAYS BUT NOW THEY ARE LATE AND CAN LAST UP TO 13 DAYS! I HAVE HAD TWO RANDOM RASHES ON MY ELBOWS AND ARMS. I HAVE NEVER HAD A RASH BEFORE SO IT WAS SURPRISING. I HAVE HEADACHES ALL THE TIME AND I'M NAUSEOUS A LOT. I GET, WHAT I'VE NOW HEARD IS CALLED, BRAIN SHOCKS. IT'S A HORRIBLE SHOOTING PAIN IN MY HEAD THAT WILL LAST A FEW SECONDS AND GO AWAY. AND ONE OF THE WORST "SIDE EFFECTS" I'VE HAD SINCE BEING ON ESSURE IS JOINT PAIN. THE PAIN IN MY FINGERS AND LOWER BACK IS CONSTANT AND DAILY. THERE ARE TIMES ITS HARD FOR ME TO DO THINGS LIKE COOK, OR CLEAN BECAUSE OF THE BACK PAIN AND HAVING TO USE MY HANDS. I HAVE NEVER HAD ISSUES LIKE THIS BEFORE. I COME FROM A VERY HEALTHY FAMILY AND HAVE NEVER EVEN BEEN TO THE HOSPITAL FOR ANYTHING. I HAVE 4 KIDS BETWEEN THE AGES OF 15 AND 5 MONTHS. I'M NOT THE MOM I KNOW I CAN BE. I'M ALWAYS IN PAIN AND ALWAYS TIRED NOWADAYS. I CAN'T GO SEE A DOCTOR BECAUSE MY INSURANCE RAN OUT AND I'M WAITING TO GET IT BACK. I'M HOPING WHEN I DO I CAN GET THESE THINGS REMOVED!! I REGRET EVER HAVING THEM PUT IN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056096	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 2/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STILL HAVING CHRONIC PAIN, SEVERE BLOATING, AFFECTING MY WORK AND ABILITY TO WORK FULL TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056097	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 8/24/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, METAL TASTE IN MOUTH, LEG CRAMPS, NUMBNESS, TINGLING IN LIMBS, MIGRAINES, SEEKING, SWELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056098	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 9/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVER LOWER BACK PAIN, EVERY MORNING I'M CRYING CAN HARDLY GET OUT OF BED. STOMACH PAINS I CAN'T LAY ON MY STOMACH AT ALL IT HURTS TO BAD. I CAN'T STAND OR WALK FOR A LONG TIME PELVIC AND HIP STARTS TO HURT. EVERY TIME I EAT OR DRINK ANYTHING I SWELL UP LIKE I'M 7 MONTHS PREGNANT. I SUFFER FROM HEAD ACHES, SEVER MOOD SWINGS. NO MATTER HOW MUCH SLEEP I GET I STILL FEEL EXHAUSTED. I CAN'T GO SHOPPING I GO INTO A PANIC ATTACK. DEPRESSION SO BAD I HAVE SUICIDAL THOUGHTS. WHEN EVER I'M MENSTRUAL I FLOW HEAVY GOING THROUGH SUPER (B)(6) THROUGH CLOTHES AND FLOW LONGER. I ALSO BEEN SUFFERING SEVER CONSTIPATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056099	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 8/1/2009 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED THIS EMAIL TODAY..... "GOOD AFTERNOON, FOUND THE EMAIL YOU ON THE INTERNET AFTER MUCH SEARCHING ON THE ESSURE PROBLEMS ... AND AFTER SO MUCH RESEARCH, SINCE FEW SITES TALKING ABOUT THE EVILS THAT CAUSE THIS DEVICE, I AM SURE THAT HE WAS THE CAUSE OF ONE OF THE BIGGEST LOSSES FOR MY FAMILY! IT ALL STARTED IN (B)(6) 2014, WHEN MY AUNT PERFORMED THE PROCEDURE WITH ESSURE. IN (B)(6), HE RETURNED TO THE HOSPITAL FOR EXAMINATIONS AND SEE IF HE WAS ALL RIGHT! THE DOCTOR WHO DID THE PROCEDURE AND ANALYZED THE EXAMINATIONS OF MY AUNT, SECURED ITS LIGATION AND WAS CLEAR IN SAYING THAT MY AUNT NEVER GET PREGNANT! IN (B)(6) THIS YEAR, SHE DISCOVERED SHE WAS PREGNANT TWO MONTHS! IT LED ALL OTHER MEDICAL EXAMINATIONS AND IT WAS FOUND THAT ONE OF HER FALLOPIAN TUBES HAD NOT BEEN COMPLETELY BLOCKED! AND YOUR DOCTOR WAS NEGLIGENT IN NOT PAYING ATTENTION TO THIS DETAIL AND GIVE YOU HIGH! WE ARE (B)(6) AND HERE THE METHOD IS NEW, AND DURING HER PREGNANCY NO DOCTOR INFORMED US THAT THE DEVICE COULD BE HARMFUL TO THE BABY! EVERYTHING WENT WONDERFULLY WELL, YOUR LAST VISIT WAS ON (B)(6) AND EVERYTHING WAS FINE WITH THE MOTHER AND THE BABY. OUR LITTLE ONE WAS PERFECT, WITH (B)(6) WEEKS! WE WAITED LOOKING FORWARD TO YOUR ARRIVAL AND ALL WAS READY! ON (B)(6), UPON WAKING, MY AUNT FELT A SMALL LOSS OF LIQUID! I HAD NO PAIN AND NO MORE EVIL! HE WAITED A BIT, HAD BEEN THROUGH THIS 22 YEARS AGO, HE KNEW HE HAD TIME. BEFORE LONG, SHE DECIDED TO GO TO THE HOSPITAL BECAUSE THE LIQUID DOES NOT STOP! THERE WAS PROMPTLY ANSWERED. THEY MADE AN ULTRASOUND AND SAW THAT THE BABY GIRL WAS SUFFERING BECAUSE HE HAD DONE A LITTLE STOOL AND FAILED TO LISTEN TO YOUR HEART! THEY MADE AN EMERGENCY CESAREAN SECTION. ALREADY REMOVED THE DRINKS WITHOUT THE WOMB OF LIFE! THEY TRIED TO RESUSCITATE HER, BUT THE EFFORT WAS IN VAIN ... CLINICAL

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EXAMINATIONS REVEALED THAT OUR LITTLE ONE WAS ALREADY DEAD MORE THAN 24 HOURS! THE MOTHER'S PLACENTA HAD NOT TAKEN OFF, THE UMBILICAL CORD HAD NOT HANGED HIM, HEART AND LUNG WERE OK! THE MOTHER HAD NO DIABETES OR HIGH BLOOD PRESSURE, OR ANY TYPE OF INFECTION THAT COULD HAVE CAUSED THE DEATH OF THE BABY! WE WERE UNGROUNDED, WITH NO DRINKS AND NO EXPLANATION! BUT THE DOCTOR WHO DID THE CESAREAN, LEFT US WITH A CRUEL DOUBT! SHE EXAMINED THE TUBES OF MY AUNT, IN FRONT OF MY UNCLE AND FOUND NEITHER DEVICES NOR FELT THE FIBROSIS THAT HE WOULD CAUSE WITH TIME! WE ARE CONCERNED WHERE HE IS! WE DID NOT HAVE THE COURAGE TO ASK AUTOPSY OF THE BABY! IT WAS ONE 'JUDIAANDCCEDIL;ANDATILDE;O' WHAT HAD HAPPENED TO HER! IT WAS NOT FAIR TO THAT PRINCESS, BE OPEN ONLY FOR AN ANSWER! IF HE'S WITH HER, EVER BEEN TO! UNFORTUNATELY NOTHING WILL BRING HER BACK TO US! BUT IF YOU'RE NOT IN IT, STILL ON MY AUNT, FLOATING IN IT AND CAN CAUSE YOU MORE HARM! THE PLACENTA WAS SENT FOR EXAMINATION, FOR THOSE WHO KNOW IT, WE FIND AN ANSWER TO THIS TRAGEDY! MY AUNT ALSO DO FURTHER TESTS TO LOOK FOR THE DEVICE INSIDE IT! NOTHING WILL BRING OUR LITTLE BACK! BUT WE NEED AN ANSWER TO AT LEAST TRY TO EASE OUR PAIN AND OUR SUFFERING! AND YESTERDAY, WHILE IN THE HOSPITAL, MY AUNT LEARNED OF ANOTHER CASE IN OUR CITY, WHERE A PREGNANT LADY ALSO UNDERGONE THE ESSURE PROCEDURE! WE HOPE, HEART, FIND AN ANSWER TO IT ALL! AND THUS BE ABLE TO FURTHER RAISE OUR FLAG AGAINST THE ESSURE! I CAME THROUGH THIS BECAUSE IT DOES NOT WANT TO MAKE THIS PUBLIC STORY YET! IT STILL HURTS QUITE ME! IMAGINE FOR PARENTS! JUST I WANTED TO VENT AND TELL THIS SAD STORY SO THAT ONE DAY NO ONE HAS TO GO THROUGH IT! THANK YOU, FOR NOW! SINCERELY, (B)(6)!'

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056100	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 7/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I EXPERIENCE FATIGUE, STABBING ABDOMINAL AND VAGINAL PAIN, HEAVY MENSES, SEVERE BLOATING, HOT FLASHES, CRAMPING, NIGHT SWEATS, LOSS OF LIBIDO, INCONTINENCE, URGENT URINATION, PROMINENT CERVIX, ABDOMINAL SPASMS, BOWEL ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056101	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 3/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAIN. BLOATING. PAIN IN TUBES PAIN WITH SEX. AFTER SEX. RIGHT LEG PAIN. ANXIETY. DEPRESSION. PERIODS ARE NOT RIGHT. OR DON'T HAVE IT ALL. STABBING SHARP PAINS IN UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056102	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 8/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH LABOR AND PMS SYMPTOMS AND PAINS WHEN I AM NOT PREGNANT. MY STOMACH GETS BLOATED. LATER I BROKE OUT WITH RASHES/ HIVES IN MY BACK, NECK, CHEST, STOMACH. I GET REALLY BAD DANDRUFF ON AND OFF. I GET REALLY LIGHT HEADED, ONCE I BLACKOUT AND HIT MY HEAD, HEADACHES, MUSCLE SPASMS, MY LEG BONES GET SPORADICALLY COLD WITH SHARP PAINS. MY FINGER JOINTS ARE STIFF EVERY MORNING. I GET SEVERE NIGHT SWEATS, WAKING UP SOAKED FROM HEAD TO TOE. I AM ALWAYS TIRED, BARELY HAVE ENERGY TO DO ANYTHING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056103	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE DEALT WITH EXTREME FATIGUE, SHARP AND CONSTANT DULL PELVIC PAIN, HEAVY BLEEDING AND CLOTTING, HAIR LOSS, SKIN RASHES, ETC. I'VE JUST HAD A RADICAL HYSTERECTOMY, WHERE THE DOCTOR TOLD ME THAT I ALSO HAVE DEVELOPED ENDOMETRIOSIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056104	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 6/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GET REGULAR REALLY SHARP PELVIC PAIN THAT FROM A SCALE OF 1-10 IT WOULD BE A 10+ LOST OF ENERGY I'M ALWAYS TIRED EVEN THOUGH I PUSH MYSELF TO GO OUT AND HAVE A LIKE I REALLY DO NOT ENJOY WHAT I'M DOING CAUSE I'M ALWAYS TIRED OUT OF ENERGY I'VE ALWAYS BEEN VERY ENERGETIC PERSON NOW I DON'T FEEL DOING ANYTHING BECAUSE I ALWAYS WAKE UP WITH HEADACHES THAT WON'T GO AWAY FOR HOURS I HATE TAKING ANY MEDICATION NOW I HAVE TO TAKE TYLENOL TO GET RID OF THOSE HEADACHES, I ALSO FEEL NUMBNESS ON MY RIGHT LEG AND SOMETIMES MY FINGER AND I FEEL SOMETHING WEIR ON MY LEFT MIDDLE FINGER SORT OF NUMBNESS AND PAIN LIKE IF I HAD A PULL MUSCLE I HAVE BEEN WORKING OUT FOR ABOUT 4 YEARS ALREADY AND I CAN'T GET RID OF MY BLOATED BELLY WHICH IS VERY UNPLEASANT TO HAVE SPECIALLY WHEN I'M ON MY PERIOD I LOOK ALMOST PREGNANT , CONSTANT METAL TASTE IN MY MOUTH THAT WON'T GO AWAY EVEN WITH MOUTH WASH

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056105	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 6/25/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SIDE EFFECTS BEGAN ALMOST IMMEDIATELY TO PRESENT DAY. CONSTANT BLEEDING, JOINT PAIN, SEVERE PAIN IN VAGINA AND STOMACH SHOOTING PAIN, NAUSEA, PAIN DURING INTERCOURSE, MEMORY PROBLEMS, WEAKENED IMMUNE SYSTEM, SKIN PROBLEMS ITCHY(RASH), ABDOMINAL PAIN AND PAIN IN AREA WHERE DEVICE IS LOCATED NEVER FEEL HEALED ON INSIDE. MY INSURANCE USED (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056106	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4), HIP TO HIP EXTREME PELVIC PAIN, INSIDES FEEL LIKE THEY ARE COMING OUT AFTER IM DONE URINATING, I HAVE A BLOOD CLOT IN A VERY SERIOUS VAIN THAT GOES TO OUR HEART AND LUNGS, TAKE XARELTO 20 MG DAILY, ON CANCER TYPE PAIN PILLS AND HAVEN'T BEEN DIAGNOSED WITH ANY TYPE OF ACTUAL ILLNESS, SINCE 2013 I WENT FROM (B)(6), HORRIBLE MENSTRUAL CRAMPS AND TONS OF BLOOD CLOT FILLED PERIODS, MIGRAINES, SHINGLES 8 TIMES LAST BREAKOUT WAS JUST TWO WEEKS AGO, TONS OF HAIR LOSS HAND FULLS DAILY, LIGHT HEADED, HOT/ COLD FLASHES, RASHES ON MY HEAD- HEAD HAS BEEN ITCHING FOR A MONTH DR SAYS NOTHING HE CAN DO FOR IT. INTERCOURSE AT TIMES IS UNBEARABLE FOR ME, (B)(6) AND FEEL CLOSE TO 90, EXTREME FATIGUE, PUKE ALMOST EVERYDAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056107	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO HAVE A HYSTERECTOMY, DUE TO ALL THE PAIN AND BLEEDING EVERY MONTH. I NOW ALSO HAVE FIBROMYALGIA, AND REALLY BAD DIZZIE SPELLS, LOWER BACK PAIN, HAIR LOSS, LOSS OF TEETH. I ALSO HAD LOTS OF PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056108	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO HAVE A HYSTERECTOMY, DUE TO ALL THE PAIN AND BLEEDING EVERY MONTH. I NOW ALSO HAVE FIBROMYALGIA, AND REALLY BAD DIZZIE SPELLS, LOWER BACK PAIN, HAIR LOSS, LOSS OF TEETH. I ALSO HAD LOTS OF PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056114	BAYER	9/14/2015	9/14/2015

Event Information:

Event Date (B3): 2/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INSURANCE PAID 100% FOR ESSURE. CYCLES BECAME HORRIBLE, WORSE I EVER EXPERIENCED. CHEST HAS REDNESS ALL THE TIME. CONSTANT HEADACHE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056203		9/14/2015	9/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2012 I HAD THE ESSURE IMPLANTS PLACED. I DID HAVE THE DYE TEST TO BE SURE THEY WERE IN THE CORRECT PLACE. I WAS TOLD EVERYTHING WAS FINE EVEN THOUGH I REPORTED HAVING PARALYZING PAIN CONSTANTLY. I'VE BEEN TO THE EMERGENCY ROOM NUMEROUS TIMES BECAUSE THE PAIN GETS SO BAD THAT I LITERALLY CANNOT MOVE. SINCE ESSURE MY FIBROMYALGIA HAS GOTTEN WORSE AND I WAS RECENTLY DIAGNOSED WITH LUPUS. I BREAK OUT IN SHINGLES FROM THE CONSTANT STRESS OF ALL THE INFLAMMATION. THESE IMPLANTS ARE DEBILITATING AND HAVE CAUSED SO MUCH MISERY THAT MY LIFE HAS CHANGED DRAMATICALLY IN THE WORSE WAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056210	BAYER	9/14/2015	9/17/2015

Event Information:

Event Date (B3): 3/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICES IMPLANTED (B)(6) 2015. ALONG WITH THIS I HAD AN ABLATION DONE. UNTIL THIS WEEK I WAS UNAWARE THESE 2 PROCEDURES SHOULD NOT HAVE BEEN DONE AT THE SAME TIME. SINCE HAVING ESSURE, I HAVE EXPERIENCED THE FOLLOWING: SEVERE LOWER BACK AND ABDOMINAL PAINS, HEADACHES, RASHES, BREAK THROUGH BLEEDING OF DIFFERENT COLORS (DARK BROWN TO BRIGHT RED), HAIR LOSS AND SEVERE FATIGUE. I AM SEEING A DOCTOR TOMORROW TO DISCUSS MY SITUATION AND WHAT CAN BE DONE TO PREVENT FURTHER SIDE EFFECTS NOW KNOWN RESULTING AFTER ESSURE. MY DOCTOR SAID THIS WAS THE BEST AND LEAST EVASIVE PROCEDURE TO PREVENT PREGNANCY. I HAVE A HISTORY OF SERIOUS PROBLEMS DURING PREGNANCY AND WAS ADVISED TO NOT HAVE ANY MORE CHILDREN. I TOOK MY DOCTORS ADVICE, THINKING HE HAD MY BEST INTEREST AT HEART. THIS WAS NOT THE CASE. KNOWING WHAT I KNOW NOW I WOULD RUN FROM HAVING ESSURE. MORE STUDIES NEED TO BE CONDUCTED AND UNTIL IT IS DEEMED 100% SAFE, IT NEEDS TO BE TAKEN OFF THE MARKET. IT IS RUINING MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00858	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 4/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00859	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 03-NOV-2015. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEP-2015 (FDA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00862	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/29/2015
Explant Date (E7): 7/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 ((B)(4), AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2015. CONSUMER REPORTED THAT SHE GOT THE ESSURE IMPLANTED ON (B)(6) 2015. IMMEDIATELY SHE STARTED HAVING ABDOMINAL CRAMPING, MAJOR LOWER BACK PAIN AND INDIGESTION. THE LOWER BACK PAIN FELT LIKE SHE WAS IN LABOR. SHE WENT BACK TO THE DOCTOR ON (B)(6) 2015 BECAUSE OF THE PAIN AND HER BODY NOT FEELING RIGHT. THEY DID AN EXAM AND GAVE HER AN ANTIBIOTIC. CONSUMER STARTED TO BLOAT; HER BELLY LOOKED LIKE SHE WAS PREGNANT. HER INDIGESTION AND LOWER BACK PAIN GOT WORSE, HER BRAIN GOT FOGGY, SHE WAS FORGETFUL, TIRED ALL THE TIME. SHE GOT HER PERIOD FOR 2 DAYS AND IT WAS BARELY ANYTHING (PERIODS USUALLY LAST 5 DAYS AND ARE VERY REGULAR; SHE GET IT THE SAME TIME EVERY MONTH LIKE CLOCKWORK). SHE WENT BACK TO THE DOCTOR ON (B)(6) 2015. ON (B)(6)2015 ESSURE COILS WERE REMOVED AND HER TUBES WERE TIED. AFTER THE PROCEDURE THE DOCTOR INFORMED HER THAT SHE HAS ADENOMYOSIS. CONSUMER STATED SHE WAS PERFECTLY HEALTHY BEFORE THE COILS WERE PLACED. SHE ONLY HAD ESSURE IN FOR 6 WEEKS. TODAY, 1 1/2 WEEKS LATER SHE FEEL SO MUCH BETTER THAN SHE DID. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD LOWER BACK PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICES WERE REMOVED AND SHE IMPROVED FROM THIS EVENT. BACK PAIN WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND BACK PAIN MAY OCCUR. IN

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THIS CASE, THE CONSUMER STATED HER PAIN STARTED IMMEDIATELY AFTER ESSURE INSERTION AND IMPROVED WITH DEVICE REMOVAL 6 WEEKS LATER. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00863	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 6/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 05-NOV-2015: THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00864	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 ((B)(4), AWARENESS DATE (B)(6)-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2008 ALONG WITH AN ABLATION. WITHIN A YEAR, SHE BEGAN EXPERIENCING PAIN IN LOWER ABDOMEN, BLOATING, EXCESSIVE WEIGHT GAIN, COMPLETE LOSS OF MENSTRUAL CYCLES AND PAINFUL INTERCOURSE. ADDING TO THESE AILMENTS AS TIME WENT ON, SWELLING OF THE HANDS, INCLUDING FINGERS, SWELLING OF THE FEET, PAINFUL MOVEMENT (I.E., BENDING, SITTING AND EVEN WALKING), WAS UNABLE TO RIDE HORSES, EVEN MORE PAINFUL INTERCOURSE FOLLOWED BY SPOTTING AND INCREASED PAIN TO THE POINT OF FEELING LIKE SOMEONE HAD A SERRATED KNIFE IN HER SIDES COATED WITH BENGY, LOSS OF MEMORY/ CONCENTRATION, MIGRAINES TO THE POINT OF NAUSEA AND SENSITIVITY TO LIGHT, BREAST TENDERNESS, LACK OF ENERGY, EXHAUSTION AND PREGNANCY MIMICKING SYMPTOMS. IT IS NOW 2015 AND THE SYMPTOMS ARE WORSENING. HER HUSBAND AND SHE ARE NOW IN MARRIAGE COUNSELING. BECAUSE OF THE PAIN, SHE HAD REFUSED TO PARTICIPATE IN SEXUAL ACTIVITIES. SHE HAD TRIED 5 DIFFERENT DIET METHODS, ONLY TO GAIN WEIGHT, EVEN WITH ADJUSTED DIET AND EXERCISE. SHE WAS FINALLY SCHEDULED FOR A HYSTERECTOMY ON (B)(6)-2015. SHE HAD BEEN SUBJECTED TO MUCH UNNECESSARY AND UNWANTED PAIN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 09-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WITHIN A YEAR, SHE BEGAN EXPERIENCING PAIN IN LOWER ABDOMEN AMONG NON-SERIOUS EVENTS. THIS PAIN IN LOWER ABDOMEN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER STARTED EXPERIENCING PAIN WITHIN A YEAR OF ESSURE USE. CONSIDERING THE NATURE OF THIS EVENT, THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. THE PRODUCT TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00865	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS PROVIDED ON 09-SEP-2015. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00866	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW-UP FROM 09-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00867	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-(B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON THE FIRST TIME THE DOCTOR TRIED TO INSERT ESSURE THE CONSUMER WAS SEDATED AND HER UTERUS WAS PERFORATED. SHE WENT BACK A MONTH LATER TO TRY AGAIN. THE FIRST KIT THE DOCTOR OPENED BROKE INSIDE HER TUBE. HE REMOVED IT AND OPENED A SECOND KIT. SHE WAS IN AGONY FROM THE MOMENT HE STARTED AND CRIED BECAUSE IT HURT OVER AND OVER. SHE SPENT 4 MONTHS IN PAIN AND NEVER STOPPED BLEEDING. THE COILS PERFORATED ONE TUBE AND THE OTHER FELL INTO HER UTERUS. IT CAUSED SO MUCH DAMAGE THAT SHE HAD TO HAVE HER FALLOPIAN TUBES REMOVED SURGICALLY AND SHE NOW FACE A TOTAL HYSTERECTOMY TO REMOVE THE PET FIBERS STILL ON HER BODY CAUSING RECURRENT INFECTIONS. HER HAIR FELL OUT AND SHE CONSTANTLY LOOKED 6 MONTHS PREGNANT AND IT ALWAYS HURT. SHE GOT SIGNIFICANTLY BETTER AFTER THE COILS WERE REMOVED IN 2014. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HER UTERUS PERFORATED DURING A FIRST ESSURE INSERTION ATTEMPT. ONE MONTH LATER; ANOTHER PROCEDURE WAS PERFORMED AND ONE DEVICE BROKE INSIDE CONSUMER'S TUBE. LATER, IT WAS FOUND THE COILS PERFORATED ONE TUBE AND THE OTHER FELL INTO HER UTERUS. SHE UNDERWENT A SALPINGECTOMY AND THE COILS WERE REMOVED. ACCORDING TO HER, SHE HAS PET FIBERS STILL ON HER BODY CAUSING RECURRENT INFECTIONS. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY UTERINE/FALLOPIAN TUBE PERFORATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN TUBE

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PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF ESSURE. THIS EVENT CAN BE SUSPECTED IF EXCESSIVE PAIN OR DISCOMFORT OCCURS DURING THE PROCEDURE. ALSO, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, PHYSICIAN TRIED TO INSERT ESSURE 2 TIMES. IN THE FIRST ATTEMPT A UTERINE PERFORATION OCCURRED. IN THE SECOND, ONE DEVICE BROKE AND CONSUMER HAD INTENSE PAIN; WHICH PERSISTED FOR 4 MONTHS WHEN A FALLOPIAN TUBE PERFORATION AND DEVICE EXPULSION WERE DIAGNOSED. GIVEN THIS POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING EVENTS NATURE; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT, ESSURE INSERT CONSISTS OF A SUPER-ELASTIC NITINOL OUTER COIL AND A STAINLESS STEEL INNER COIL WRAPPED IN POLYETHYLENE TEREPHTHALATE (PET) FIBERS. IN THIS CASE, DISCREPANT INFORMATION WAS PROVIDED. CONSUMER STATED THE BROKEN ESSURE WAS REMOVED; AS WELL AS THE PERFORATED AND EXPELLED DEVICES; THUS IT IS UNCLEAR HOW THE PRESENCE OF PET FIBERS IN HER BODY WAS DIAGNOSED. ADDITIONALLY, INFECTION WAS NOT SPECIFIED. ALTHOUGH LIMITED INFORMATION WAS PROVIDED, AS CONSUMER RELATED THE EVENTS TO ESSURE AND SINCE NO FOLLOW-UP IS POSSIBLE; COMPANY CONSIDERS CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 10-SEP-2015: THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00869	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW-UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICAL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00871	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/20/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT ON 09-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00873	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. SHE WAS IN SO MUCH PAIN THAT SHE COULDN'T WORK, PLAY WITH HER KIDS OR EVEN FUNCTION ON A DAILY BASIS. SHE EXPERIENCED SEVERE PELVIC AND LOWER BACK PAIN, EXCESSIVE BLOATING, PAINFUL MENSTRUAL CYCLES, MAJOR DEPRESSION, AND UNDERWENT A TOTAL HYSTERECTOMY AT THE AGE OF 34. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED SEVERE PELVIC PAIN AND MAJOR DEPRESSION. THESE EVENTS ARE SERIOUS DUE REQUIRED INTERVENTION AND MEDICAL IMPORTANCE. PELVIC PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE MAJOR DEPRESSION IS UNLISTED. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER PRESENTED SEVERE PELVIC PAIN, MAJOR DEPRESSION AND OTHER NON-SERIOUS EVENTS. THEN, SHE UNDERWENT A TOTAL HYSTERECTOMY AT THE AGE OF 34. GIVEN EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN PELVIC PAIN AND ESSURE USE CANNOT BE EXCLUDED. ALTHOUGH SOME DEPRESSIVE FEELINGS REGARDING THE DEFINITIVE CONTRACEPTION WITH ESSURE MAY OCCUR, CAUSAL RELATIONSHIP BETWEEN MAJOR DEPRESSION AND ESSURE USE IS VERY UNLIKELY. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PERSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00876	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2009
Explant Date (E7): 11/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0540, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. CONSUMER HAD ESSURE INSERTED IN (B)(6) 2009. SHE HAD THE FOLLOW-UP HSG TEST (HYSTEROSALPINGOGRAPHY) IN (B)(6) 2010 WHICH WAS CONFIRMED BLOCKED. SHE BEGAN HAVING HORRIFIC MENSTRUAL CYCLES THAT WOULD LAST TWO WEEKS AT A TIME WITH HEMORRHAGING CLOTS. HER IRON LEVELS WERE VERY LOW AND HER BODY BECAME ALL OUT OF WHACK. CONSUMER HAD SEVERE MENSTRUAL CRAMPING EVERYDAY OF THE MONTH, MIGRAINE HEADACHES, BACK PAIN. SHE WAS PUT ON BIRTH CONTROL PILLS TO HELP WITH THE BLEEDING WHICH RESULTED IN A PERIOD THAT LASTED A CONSTANT 90 DAYS. FIBROID HAD FORMED IN UTERUS. WHEN SHE WOULD BEND OVER SHE COULD FEEL A SHARP PINCHING FEELING IN LOWER RIGHT ABDOMEN AREA. SHE HAD TO HAVE A COMPLETE HYSTERECTOMY IN (B)(6) 2014 TO REMOVE EVERYTHING EXCEPT HER OVARIES. THE DOCTOR TOLD HER AFTER THE PROCEDURE THAT SHE COULD VISUALLY SEE WHERE THE ESSURE HAD PERFORATED THROUGH CONSUMER'S TUBE ON THE SIDE SHE WAS HAVING THE STABBING PAINS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING A SHARP PINCHING FEELING IN LOWER RIGHT ABDOMEN AREA. SHE UNDERWENT A HYSTERECTOMY 5 YEARS AFTER INSERTION AND DURING THE SURGERY DOCTOR COULD SEE THAT ESSURE HAD PERFORATED THROUGH HER TUBE ON THE SIDE SHE WAS HAVING THE STABBING PAIN. EVENT ESSURE HAD PERFORATED THROUGH HER TUBE IS SERIOUS DUE TO MEDICAL SIGNIFICANCE

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AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THIS PERFORATION WERE NOT REPORTED. THE PERFORATION WAS DIAGNOSED DURING HYSTERECTOMY 5 YEARS AFTER INSERTION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-SEP-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00877	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2015-N-2781-0163, AWARENESS DATE 13-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011, FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN 2011 AND HAD CONFIRMED PLACEMENT OF THE COILS WITH AN HSG (HYSTEROSALPINGOGRAM) TEST 3 MONTHS LATER. AFTER ESSURE SHE STARTED TO LOSE LARGE CLUMPS OF HAIR EVERY DAY, MIGRAINES AT LEAST 2 DAYS EVERY SINGLE WEEK, HAD PELVIC PAIN AND PRESSURE, SEVERE CRAMPS, EXTREMELY HEAVY, IRREGULAR PERIODS WITH LARGE CLOTS, AND WAS CONSTANTLY TIRED. AFTER EXPERIENCING THE HEAVY, IRREGULAR PERIODS I HAD TO GO ON BIRTH CONTROL PILLS FOR THE FIRST TIME IN HER LIFE. PRIOR TO ESSURE SHE ONLY USED CONDOMS FOR BIRTH CONTROL. THE PILLS DID LESSEN THE BLEEDING, BUT THE MIGRAINES STILL OCCURRED, THE PELVIC PAIN WAS STILL THERE, AND THEN SHE STARTED GETTING 2 CYCLES EVERY MONTH. SHE DID RESEARCH ON ESSURE AND FOUND THAT THE COMPONENTS MADE IN ESSURE ARE ENDOCRINE DISRUPTORS. WHEN HER GYNECOLOGIST DID BLOOD TESTING FOR HER HORMONE LEVELS SHE FOUND MOST WERE ELEVATED AND WANTED HER TO SEE A FEW DIFFERENT SPECIALISTS AND SHE SOUGHT A SECOND OPINION. IN (B)(6) 2014, AFTER 3 YEARS OF HAVING ESSURE AND 1 YEAR OF DEALING WITH 2 CYCLES A MONTH, SHE HAD A ROBOTIC HYSTERECTOMY REMOVING THE TUBES, UTERUS, AND CERVIX. SHE WAS ONLY (B)(6) YEARS OLD AT THE TIME OF THE SURGERY. HER COIL THAT WAS SUPPOSED TO BE IN HER RIGHT TUBE WAS NO LONGER THERE AND HAD MIGRATED. IT IS STILL MISSING BUT PRESUMED TO EITHER HAVE BEEN LOST DURING ONE OF HER HEAVIER PERIODS OR EMBEDDED IN HER CERVIX SINCE THAT WAS SEVERELY INFLAMED. AFTER

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RECEIVING SURGERY, SHE DOESN'T HAVE ANY PELVIC PAIN OR PRESSURE, DOESN'T HAVE MIGRAINES ANYMORE, HER HAIR STARTED TO SLOWLY GROW BACK, AND SHE HAD ENERGY BACK. SHE FELT LIKE SHE DID PRIOR TO ESSURE. SINCE SHE CHOSE ESSURE, SHE ENDED UP NEEDING MAJOR SURGERY, LOST PART OF HER WOMANHOOD, HAS SCARS ON HER STOMACH, AND 3 PAINFUL YEARS IN HER PAST. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED TO HAVE PELVIC PAIN AND PRESSURE/ 3 PAINFUL YEARS. THREE YEARS AFTER INSERTION SHE UNDERWENT HYSTERECTOMY AND SALPINGECTOMY. SHE STATED THAT THE COIL THAT WAS SUPPOSED TO BE IN HER RIGHT TUBE WAS NO LONGER THERE AND HAD MIGRATED (INTERPRETED AS DEVICE DISLOCATION). THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, THREE YEARS AFTER INSERTION IT WAS FOUND THAT THE COIL THAT WAS SUPPOSED TO BE IN HER RIGHT TUBE WAS NO LONGER THERE AND HAD MIGRATED. THE EXACT LOCATION OF THE DEVICE WAS NOT KNOWN. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. NON-SERIOUS EVENTS WERE ALSO REPORTED. A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00885	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 7/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-0736-0327 AWARENESS DATE 13-AUG-2015) IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2009. CONSUMER HAD ESSURE IMPLANTED IN 2009 (AT (B)(6)). SIDE EFFECTS SUCH AS INSOMNIA, FORGETFULNESS AND IRRITABILITY, ALONG WITH ALL THE HEALTH ISSUES, WEIGHT GAIN, BAD PERIODS, HORMONAL IMBALANCES, A NICKEL ALLERGY, AND WHEN TESTED HEAVY METAL TOXICITY. SHE HAD A FULL HYSTERECTOMY ON (B)(6) 2015 AT THE AGE OF (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED NICKEL ALLERGY AND WHEN TESTED, HEAVY METAL TOXICITY WAS DISCOVERED. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. NICKEL ALLERGY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE METAL TOXICITY IS UNLISTED. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY. IN THIS CASE, SHE PRESENTED NICKEL ALLERGY ALONG WITH OTHER NON-SERIOUS EVENTS. THEN, SHE HAD A FULLY HYSTERECTOMY. CONSIDERING THE ALLERGY'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. ALTHOUGH ESSURE RELEASES NICKEL, THE AMOUNT IS NOT ENOUGH TO CAUSE METAL POISONING. THUS, THIS EVENT IS ASSESSED AS UNRELATED TO ESSURE. SINCE INTERVENTION WAS REQUIRED (FULLY HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING. TECHNICAL ASSESSMENT IS EXPECTED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 11-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00888	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0327, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT HER FRIEND HAD TO HAVE A HYSTERECTOMY. NO ADDITIONAL INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE AN HYSTERECTOMY. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS GIVEN AND NO REASON FOR HYSTERECTOMY WAS PROVIDED. HOWEVER, SINCE CONSUMER RELATED THIS PROCEDURE TO ESSURE AND NO FOLLOW UP WILL BE POSSIBLE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 14-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00889	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ANTICIPATED INCIDENT - REQUIRED INTERVENTION. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4) AWARENESS DATE 13-AUG-2015). IT WAS REPORTED BY A HEALTH PROFESSIONAL AND IT REFERS TO A FEMALE PATIENT OF (B)(6) IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2013. THE PATIENT'S HISTORY INCLUDED GRAVIDA 4, PARA 3 AND 1 ABORTION. SHE WAS A NON-SMOKER IN GOOD GENERAL HEALTH, TOOK NO REGULAR MEDICATIONS AND HAD NO KNOWN DRUG ALLERGIES. HER GYNECOLOGICAL HISTORY WAS UNREMARKABLE EXCEPT FOR THE ESSURE PROCEDURE IN (B)(6) 2013. THERE WAS NO FOLLOWED UP HSG (HYSTEROSALPINGOGRAM) THREE MONTHS AFTER PLACEMENT AS RECOMMENDED DUE TO INSURANCE REASONS. THE PATIENT DEVELOPED GRADUALLY WORSENING PELVIC PAIN SHORTLY AFTER UNDERGOING THE ESSURE PROCEDURE, ACCOMPANIED BY INCREASED FATIGUE AND DYSPAREUNIA. IN (B)(6) 2015 THE PATIENTS SYMPTOMS BECAME INTOLERABLE AND SHE PRESENTED TO A LOCAL EMERGENCY DEPARTMENT FOR ASSESSMENT. AN HSG WAS INCLUDED DURING THAT WORK-UP AND REVEALED COMPLETE OCCLUSION OF THE RIGHT FALLOPIAN TUBE BY ESSURE, BUT THE LEFT IMPLANT HAD MIGRATED TO THE CONTRALATERAL LOWER PELVIS. THE LEFT TUBE WAS PATENT AND FREE SPILL OF DYE FROM THE LEFT TUBE WAS EVIDENT. SHE UNDERWENT AN UNCOMPLICATED HYSTEROSCOPY + LAPAROSCOPIC PARTIAL (RIGHT) SALPINGECTOMY ON (B)(6) 2015 TO REMOVE THE RIGHT ESSURE DEVICE INTACT. THE MIGRATED LEFT COIL COULD NOT BE VISUALIZED AT SURGERY DESPITE EXTENSIVE EXPLORATION. THE PATIENT HAD AN UNEVENTFUL POST-OPERATIVE COURSE AND WAS DISCHARGED HOME WITHIN 3 HOURS. FOLLOW-UP ABDOMINAL/PELVIC NON-CONTRAST CT (COMPUTERIZED TOMOGRAM) WAS ORDERED NEXT, AND THIS SHOWED A NORMAL UTERUS BUT THREE LINEAR

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SIGNAL DENSITIES CONSISTENT WITH THE ESSURE DEVICE (FRACTURED) WERE SCATTERED IN THE RIGHT LOWER QUADRANT. ONE OF THESE METALLIC PIECES WAS DESCRIBED AS FOLLOWS: A THIRD PUNCTATE, METALLIC DENSITY MEASURES 1-2MM IN DIAMETER, SIMILAR IN CALIBER TO THE OTHER FOREIGN BODIES ANTERIORLY, AND APPEARS TO BE LODGED WITHIN THE LUMEN OR WALL OF THE PROXIMAL SIGMOID COLON. AT THIS TIME, THE PATIENT WAS AWAITING ANOTHER CONSULTATION WITH COLORECTAL SURGERY SPECIALISTS FOR FURTHER MANAGEMENT, POSSIBLY INCLUDING PARTIAL BOWEL RESECTION TO RETRIEVE THE SPLINTERED AND MIGRATED LEFT ESSURE IMPLANT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PELVIC PAIN SHORTLY AFTER ESSURE INSERTION. APPROXIMATELY 2 YEARS LATER, SHE UNDERWENT A HYSTEROSCOPY AND LAPAROSCOPIC PARTIAL (RIGHT) SALPINGECTOMY. HOWEVER, THE LEFT IMPLANT HAD MIGRATED TO THE CONTRALATERAL LOWER PELVIS (INTERPRETED AS DEVICE DISLOCATION) AND COULD NOT BE RETRIEVED. A NON-CONTRAST CT (COMPUTERIZED TOMOGRAM) WAS ORDERED NEXT, AND SHOWED THREE LINEAR SIGNAL DENSITIES CONSISTENT WITH THE ESSURE DEVICE (FRACTURED) WERE SCATTERED IN THE RIGHT LOWER QUADRANT (INTERPRETED AS DEVICE BREAKAGE). THE PELVIC PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND DEVICE DISLOCATION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE, THESE EVENTS ARE LISTED WHILE THE DEVICE BREAKAGE IS UNLISTED. CONSIDERING THE NATURE OF THESE EVENTS, COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00891	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2014
Explant Date (E7): 7/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN (B)(6) 2014. CONSUMER REPORTED THAT IN (B)(6) 2015 SHE HAD HER HYSTEROSALPINGOGRAM PERFORMED DONE AND WITHIN 3 HOURS AFTER THE PROCEDURE SHE STARTED TO ITCH UNCONTROLLABLY ON HER FEET AND SHE BEGAN BLEEDING FROM HER VAGINA. THE BLOOD WAS WHILE SMALL AMOUNTS AND WAS NOT THE COLOR THAT SHE TYPICALLY GET WHEN SHE WAS ON HER PERIOD. IT WAS BRIGHT RED. AFTER AN HOUR OF ITCHING SHE TOOK BENADRYL AND IT HELPED CONTROL THE ITCH. HOWEVER FROM THAT DAY FORWARD SHE HAD TO TAKE BENADRYL OR OTHERWISE SHE WOULD ITCH UNCONTROLLABLY. WHILE THE ITCHING WAS CONTROLLED BY BENADRYL HER BODY STARTED TO EXPERIENCE OTHER PROBLEMS AS TIME WENT BY. SHE WAS CONSTANTLY FEELING NAUSEA, SHE WAS TIRED. SHE DEVELOPED TERRIBLE MIGRAINE HEADACHES, FOOD AVERSIONS AND MISSED HER PERIOD FOR TWO MONTHS. CONSUMER WENT TO THE DOCTORS ABOUT 2 WEEKS AFTER HAVING HER HSG TO DISCUSS HER HEALTH PROBLEMS. HE RAN SOME BLOOD WORK AND ORDERED A HEAD CT SCAN AND EVERYTHING CAME BACK NORMAL. AS TIME PROGRESSED SHE DEVELOPED YEAST INFECTIONS. SHE NOTICED AN OUTBREAK OF LITTLE RED SPOTS ALL OVER HER BOD (CHERRY ANGIOMAS), HER STOMACH STARTED LOOKING BLOATED AND SHE WAS SLOWLY GAINING WEIGHT FOR NO APPARENT REASON. SHE WAS CONFUSED BY THIS BECAUSE, HER 5' 2". (B)(6) LB FRAME WORKED OUT 6 OUT 7 DAYS AND SHE ATE VERY HEALTHY. SHE WENT TO AN ALLERGY SPECIALIST PER THE ADVISE OF HER PRIMARY IN (B)(6) AND HE PUT HER ON ALLEGRA AND ZYRLEX TO CONTROL HER ITCHING AND THE RASHES THAT HAD NOW DEVELOPED,

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RAN MORE BLOOD WORK AND DECIDE TO CONDUCT A TRUE PATCH TEST AND SAID SHE COULD NOT TAKE HER ALLERGY MEDS FOR A WEEK. THE WEEK THAT SHE WAS NOT ABLE TO BE ON HER ALLERGY MEDS WAS COMPLETE TORTURE. SHE ITCHED UNCONTROLLABLY AND RASHES RAN RAMPED ALL OVER HER BODY. SHE FELT LIKE SHE WAS CRAWLING OUT OF HER SKIN. ON THE DAY THAT HE WENT TO TAKE THE FIRST READING HER BODY REMAINED COMPLETELY RED AND HE WAS UNABLE TO GET A PROPER READING BECAUSE THE AREAS WHERE HE REMOVED THE TAPED WAS TERRIBLY INFLAMED. SO SHE HAD TO WAIT UNTIL THE 5TH DAY TO GET A PROPER READING. LUCKILY, ALL THE INFLAMMATION HAD DIED DOWN AND HE RATED HER BACK HAVING A 1 OUT OF A 6 REACTION TO GOLD. HE ALSO TOLD HER THAT HER ZINC LEVELS WERE LOW SHE DISCUSSED HER CONCERNS ABOUT HAVING ESSURE IN BODY AND THAT SHE HAD READ MAT POSSIBLY HER BODY WAS REACTING NEGATIVELY TO IT. THE DOCTOR COULD NOT DEFINITELY RULE OUT THAT HER BODY WAS REACTING TO ESSURE AND SUGGESTED THAT SHE REMOVED ESSURE IF SHE WAS UNCOMFORTABLE HAVING IT IN HER BODY. ON (B)(6) 2015 SHE HAD A TOTAL HYSTERECTOMY LEAVING HER OVARIES. SHE WAS NOW COMING UP ON TWO WEEKS AND SINCE THEN ALL OF HER SYMPTOMS HAVE DISAPPEARED AND SHE NO LONGER HAD TO TAKE ALLERGY MEDICINE. SO IN CONCLUSION, HER HEAD CT SCAN, HER LABS AND MEDICAL EXAMINES STATED, THAT FOR THE MOST PART SHE WAS FINE. HER PRIMARY DOCTOR AND THE ALLERGY SPECIALIST DIDN'T BELIEVE THAT ESSURE WAS CAUSING ANY OF HER PROBLEMS. CLEARLY THOUGH SHE WAS REACTING TO THE ESSURE BECAUSE NOW THAT IT HAS BEEN REMOVED FROM HER BODY SHE NO LONGER HAD ANY HEALTH ISSUES MENTIONED ABOVE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER 2015-032781. FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ABOUT 7 MONTHS AFTER ESSURE INSERTION, A HYSTEROSALPINGOGRAM WAS PERFORMED AND WITHIN 3 HOURS AFTER THE PROCEDURE SHE BEGAN BLEEDING FROM HER VAGINA. IT WAS REPORTED THAT HER BODY WAS REACTING TO ESSURE. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER HAD A TOTAL HYSTERECTOMY PERFORMED LEAVING HER OVARIES. SHE NO LONGER HAD TO TAKE ALLERGY MEDICINE. SINCE TEMPORAL RELATIONSHIP BETWEEN SUSPECT INSERT AND THE OCCURRENCE OF THE EVENTS IS POSITIVE AND GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00892	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0015 AND FDA-2014-N-0736-0077, AWARENESS DATE 13-AUG-2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN (B)(6) 2013. CONSUMER REPORTED THAT SHE HAD ESSURE PLACED AND HAD LITTLE STABBING PAINS ON BOTH SIDES OF HER LOWER ABDOMEN BUT SHE THOUGHT IT WAS JUST THE SCARRING PROCESS OF THE FALLOPIAN TUBES. THEN THE STABBING GOT WORSE. SHE HAD VERY BAD LOWER BACK PAIN, HER HAIR WAS COMING OUT A LOT IN THE SHOWER. HER IMPLANTING DOCTOR MOVED OUT OR HER INSURANCE SO SHE STAYED ON THE PILL FOR ABOUT A YEAR AND THEN GOT THE HYSTEROSALPINGOGRAM TEST DONE AND HER NEW DOCTOR SENT THE IMAGES TO BAYER FOR ONE OF THEIR RADIOLOGIST TO READ BECAUSE HE WAS NOT SURE WHAT TO MAKE OF THE TEST. THE BAYER RADIOLOGIST SAID IT LOOKED TO HIM THAT BOTH HER FALLOPIAN TUBES HAD BEEN PUNCTURED. SO THEY DECIDED ON A HYSTERECTOMY. HER DOCTOR FOUND OUT WHEN HE GOT IN THERE THAT THE COILS HAD WENT THROUGH THE TOP OF HER UTERUS ON BOTH SIDES AND THAT THERE WAS NO EVIDENCE THE COILS WERE EVER IN HER FALLOPIAN TUBES. ONE OF THE COILS WAS ADHERED TO HER BOWEL. IT WILL BE A YEAR THIS AUGUST THAT THEY WERE REMOVED AND SHE NO LONGER HAS LOWER BACK PAIN AND HER HAIR HAS STOPPED FALLING OUT. SHE FELT 100% BETTER. PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT

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TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BOTH OF HER FALLOPIAN TUBES HAD BEEN PUNCTURED, THE COILS HAD WENT THROUGH THE TOP OF HER UTERUS ON BOTH SIDES (SEEN AS FALLOPIAN TUBE PERFORATION). ONE OF THE COILS WAS ADHERED TO HER BOWEL (SEEN AS EMBEDDED DEVICE). THE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE EXACT DATE AND THE MECHANISM OF PERFORATION AND EMBEDMENT ARE NOT KNOWN. CONSUMER HAD A HYSTERECTOMY PERFORMED. A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00893	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 9/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/16/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0065, AWARENESS DATE 13-AUG-2015). IT REFERS TO A (B)(6) YEARS OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. ON (B)(6) 2012 SHE WAS IN A LOT OF PAIN AND CRAMPING AS IF SHE WAS IN LABOR AND BLEEDING EXTREMELY HEAVY. SHE WAS TOLD TO TAKE (B)(6). FOR THE NEXT 3 MONTHS SHE WENT TO THE DOCTOR AND WAS TOLD NOTHING WAS WRONG. DURING THAT TIME SHE EXPERIENCED EXTREME FATIGUE, BLEEDING, WEIGHT GAIN, PELVIC PAIN, BACK PAIN MOSTLY LOWER AND UPPER, NASTY METALLIC TASTE IN MOUTH, INTIMACY WAS UNBEARABLE. HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED TUBES BLOCKED BUT RIGHT SIDE MIGRATED, PERFORATED TUBE AND DESTROYED FALLOPIAN TUBE CAUSING EXTREMELY PAINFUL STABBING PAINS. IN (B)(6) 2013 THE DOCTOR AGREED TO TAKE ESSURE OUT. THE PAIN NEVER STOPPED. AT THE TIME OF THIS REPORT SHE WAS STILL DEALING WITH MANY SIDE EFFECTS FROM WHAT WAS LEFT ON THE RIGHT AND LEFT COIL. SHE WENT FROM A VERY HEALTHY PERSON TO A DEPRESSED AND SICK PERSON. DAILY SHE LIVES IN PAIN. SHE WAS (B)(6) AND BEGGING FOR A HYSTERECTOMY JUST TO HAVE SOME SORT OF HER LIFE BACK. IT WAS NOT JUST PHYSICAL; IT WAS EMOTIONALLY AND MENTALLY DESTRUCTIVE AS WELL. SHE CONTINUED TO SEARCH TO HAVE ESSURE TAKEN OUT. SHE HAS BEEN LIVING WITH ALL THAT AGONIZING PAIN AND BLEEDING FOR 3 YEARS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING EXTREMELY HEAVY (SEEN AS GENITAL

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BLEEDING, CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE). CONSUMER UNDERWENT A HYSTEROSALPINGOGRAM AND THE RESULT SHOWED TUBES BLOCKED BUT RIGHT SIDE MIGRATED, PERFORATED TUBE, DESTROYED FALLOPIAN TUBE (SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED) CAUSING EXTREMELY PAINFUL STABBING PAINS. THE DOCTOR AGREED TO TAKE ESSURE OUT. THE PAIN NEVER STOPPED. AT THE TIME OF REPORT SHE WAS DEALING WITH MANY SIDE EFFECTS FROM WHAT'S LEFT ON THE RIGHT AND THE LEFT COIL (INTERPRETED AS DEVICE BREAKAGE) (NON-SERIOUS AND LISTED). IN THIS CASE, THE EXACT DATE AND MECHANISM OF PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. WITH REGARDS TO THE EVENT DEVICE BREAKAGE, SINCE THIS EVENT MAY HAVE OCCURRED DURING ESSURE REMOVAL, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS PROVIDED ON 08-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICAL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00894	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2006
Explant Date (E7): 10/9/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4) AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED DATE IN UNITED STATES WHO HAD ESSURE (ESS205) INSERTED IN (B)(6) 2006. NOT LONG AFTER THE INSERTION, THE CONSUMER BEGAN TO EXPERIENCE MANY TERRIBLE SIDE EFFECTS THAT CONTINUED FOR SEVERAL YEARS UNTIL REMOVAL. THROUGHOUT THOSE SEVERAL YEARS, SHE VISITED A SPECIALIST FOR HER BOWEL ISSUES AND WENT TO THE EMERGENCY ROOM ON A COUPLE OF OCCASIONS FOR SHARP STABBING PAINS IN PELVIC AND VAGINAL AREA, BUT NO ONE COULD EVER TELL HER EXACTLY WHAT WAS CAUSING THE ISSUES. AT ONE POINT, SHE HAD TO HAVE A D&C (DILATION AND CURETTAGE) FOR ABNORMAL BLEEDING DURING CYCLES. OTHER SIDE EFFECTS INCLUDED ABNORMAL PERIODS AND BLEEDING, BLOATED BELLY, WEIGHT GAIN, HIP/JOINT PAIN, HOT FLASHES, MUSCLE SPASMS/TWITCHES, NAUSEA, EASY BRUISING, CRAMPING, DIZZINESS, FATIGUE, ANXIETY, MOOD SWINGS, AND HAIR LOSS. SHE DID NOT HAVE ANY OF THESE EVENTS PRIOR TO ESSURE INSERTION. SHE HAD AN ESSURE REVERSAL ON (B)(6) 2013. THE PELVIC PAIN AND HIP PAIN WERE GONE. SHE WAS NOT HAVING HOT FLASHES, MUSCLE SPASMS, NAUSEA, EASY BRUISING, CRAMPING, DIZZINESS, FATIGUE OR ANXIETY SINCE THEY' HAD BEEN REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND NOT LONG AFTER INSERTION, THE CONSUMER STARTED TO EXPERIENCE SHARP STABBING PAIN IN PELVIC AND ABNORMAL BLEEDINGS. BOTH EVENTS ARE SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE.

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CONSIDERING THE NATURE OF THESE EVENTS, THE SUGGESTIVE TEMPORAL RELATIONSHIP, THE LACK OF ALTERNATIVE EXPLANATION AND THE FACT THAT SHE DID NOT HAVE THEM PRIOR TO ESSURE, THE CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 08-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00895	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN 2012. CONSUMER REPORTED THAT SHE HAD ESSURE FOR 3 YEARS AND SUFFERED A HORRIFIC MISCARRIAGE AND HAD TO GOT TWO OPERATIONS AS A RESULT. SHE IS NOW (B)(6) AND HAD A COMPLETED HYSTERECTOMY. NO ADDITIONAL INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A HORRIFIC MISCARRIAGE THAT RESULTED IN TWO OPERATIONS. SHE UNDERWENT A TOTAL HYSTERECTOMY. ONLY THE IMPLIED PREGNANCY WITH ESSURE AND THE HYSTERECTOMY ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS CASE, THE ELAPSED TIME BETWEEN THE ESSURE INSERTION AND THE PREGNANCY IS NOT KNOWN. THERE ARE NO DETAILS REGARDING ITS INSERTION. THEREFORE, THE CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. ALTHOUGH GESTATIONAL AGE HAS NOT BEEN PROVIDED, SPONTANEOUS ABORTIONS OCCUR MOSTLY DURING THE FIRST 12 WEEKS OF PREGNANCY AND THE VAST MAJORITY OF THESE CASES ARE DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS, SO THE MISCARRIAGE IS CONSIDERED AS UNRELATED TO ESSURE THERAPY. IN THIS PARTICULAR CASE, THE REASON FOR HYSTERECTOMY WAS NOT PROVIDED. DESPITE THE LACK OF INFORMATION, SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED, THE CAUSAL

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RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). THE PRODUCT TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS WERE PROVIDED ON 08-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00896	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0456, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER MEDICAL HISTORY INCLUDED PARITY 2. CONSUMER REPORTED THAT SINCE INSERTION SHE HAD NOTHING BUT PROBLEMS. SHE WENT TO MULTIPLE SPECIALISTS FOR DIFFERENT ISSUES AND WAS ON NUMEROUS AMOUNTS OF MEDICATION. SHE FINALLY FOUND A DOCTOR THAT STATED ESSURE WAS CAUSING ALL OF HER PROBLEMS. SHE HAD BEEN LIVING IN PAIN FOR SO LONG. SHE HAD A HYSTERECTOMY SCHEDULED FOR (B)(6) 2015 TO REMOVE ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE WAS LIVING IN PAIN FOR SO LONG. SHE HAD A HYSTERECTOMY SCHEDULED TO REMOVE THE INSERTS BUT IT WAS NOT PERFORMED YET. THIS UNSPECIFIED PAIN IS SERIOUS DUE TO PLANNED REQUIRED INTERVENTION. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THERE IS AN IMPLIED COMPATIBLE TEMPORAL RELATIONSHIP, CONSIDERING THE NATURE OF THIS EVENT AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN THIS PAIN AND ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. THE PTC GLOBAL NUMBER IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00897	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE # FDA-2014-N-0736-0037, AWARENESS DATE (B)(6) 2015). IT REFERS TO A 39-YEAR-OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED THAT SHE WAS BEING WORKED UP FOR A LIVER TRANSPLANT FOR AN AUTOIMMUNE DISEASE AND PRIMARY BILIARY CIRRHOSIS. AFTER ESSURE INSERTION SHE BECAME PREGNANT. SHE UNDERWENT A MEDICALLY NECESSARY ABORTION, DILATATION AND CURETTAGE (D&C), DUE TO HEALTH CONCERNS FROM HER DISEASE. AFTER HEALING FROM THE D&C, NOT BEING SURE WHERE ONE OF THE COILS WAS, DOCTORS DECIDED SHE NEEDED A TOTAL HYSTERECTOMY. BECAUSE OF THIS SHE WAS THROWN INTO MENOPAUSE AND NOT ALLOWED TO TAKE ANY HORMONE REPLACEMENT THERAPY BECAUSE IT FILTERS THROUGH THE LIVER AND HER LIVER WAS NOT FUNCTIONING CORRECTLY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED AUTOIMMUNE DISEASE, PRIMARY BILIARY CIRRHOSIS, LIVER NOT FUNCTIONING CORRECTLY, SHE BECAME PREGNANT. THE PHYSICIAN WAS NOT SURE WHERE ONE OF THE COILS WAS (INTERPRETED AS DEVICE DISLOCATION) SO SHE UNDERWENT A TOTAL HYSTERECTOMY. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND THE DEVICE DISLOCATION IS ADDITIONALLY SERIOUS DUE TO REQUIRED INTERVENTION. THE PREGNANCY WITH ESSURE AND DEVICE DISLOCATION ARE LISTED EVENTS WHILE THE OTHERS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE ONSET DATE OF EVENTS IS NOT CLEAR BUT A POSITIVE TEMPORAL RELATIONSHIP IS

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IMPLIED. CONSIDERING THE NATURE OF THESE EVENTS AND THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, THE CAUSAL RELATIONSHIP BETWEEN THE PREGNANCY AND DEVICE DISLOCATION CANNOT BE EXCLUDED. HOWEVER, SINCE IT IS UNLIKELY THAT ESSURE WOULD CAUSE AUTOIMMUNE DISEASE, PRIMARY BILIARY CIRRHOSIS AND LIVER NOT FUNCTIONING CORRECTLY, THESE EVENTS ARE ASSESSED AS UNRELATED, DESPITE THE COMPATIBLE TEMPORAL RELATIONSHIP. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS PROVIDED ON 09-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICAL

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00898	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN (B)(6) 2011 AS A PERFECTLY HEALTHY (B)(6) YEAR OLD. BY (B)(6) 2013 THE PAIN WAS ON THE VERGE OF DEBILITATING. BY (B)(6) 2014 HAD A HYSTERECTOMY DUE TO PAIN, MIGRAINES, BLOATING, FIBROIDS, CYSTS AND ENLARGED UTERUS. A LITTLE OVER 1 YEAR WITHOUT ESSURE SHE WAS NO LONGER IN PAIN. NO MIGRAINES. NO BLOATING. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN WHICH WAS ON THE VERGE OF DEBILITATING. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT ABOUT 2 YEARS AND 5 MONTHS AFTER ESSURE INSERTION. A HYSTERECTOMY WAS PERFORMED. SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED AND BASED ON THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED SURGICAL INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 09-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00899	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2007. THE LEFT SIDE WENT IN WITH NO PROBLEM. THE RIGHT SIDE WENT IN AND CAUSED A SHARP PAIN IMMEDIATELY. THE PAIN WOULD GO AWAY, BUT IT ONLY INTENSIFIED FROM THAT DAY FORWARD. SHE HAS BEEN IN AND OUT OF DOCTOR OFFICES AND EMERGENCY ROOM FOR ALL OF THOSE YEARS. HER COMPLAINTS EVERY TIME WAS THE SAME: SEVERE MIGRAINE, BACK PAIN AND BURNING, LOWER PELVIC PAIN AND PRESSURE, WHICH WOULD ALWAYS INTENSIFY AROUND OVULATION. SHE EXPLAINED HER PAIN AS LIKE SOMEONE HAS STABBED HER ON RIGHT SIDE ON TOP OF OVARY AND HAS INSERTED A BALLOON OVER A 3-4 DAY PERIOD; FELT LIKE SOMEONE WAS FEELING THAT BALLOON UP JUST UNDER HER SKIN AND THEN WHEN IT IS FULL IT POPS AND THE PAIN DROPS HER TO HER KNEES. AT FIRST SHE WAS DIAGNOSED WITH LBS (INTERPRETED AS IRRITABLE BOWEL SYNDROME). THEN, SHE UNDERWENT STEROID INJECTIONS AND WAS TOLD SHE HAD ENDOMETRIOSIS AND CYSTS ON OVARIES. THEN, SHE WAS TOLD THAT SHE MIGHT BE SUFFERING FROM ABDOMINAL MIGRAINES. ON (B)(6) 2015 SHE UNDERWENT A TOTAL HYSTERECTOMY, BOTH OVARIES, CERVIX, AND APPENDIX INCLUDED. ALL OF HER SYMPTOMS WERE GONE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LOWER PELVIC PAIN AND PRESSURE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION

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FOR ESSURE. IN THIS CASE, CONSUMER UNDERWENT A TOTAL HYSTERECTOMY, BOTH OVARIES, CERVIX, AND APPENDIX INCLUDED. NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON THE EVENT'S NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 09-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00900	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0281, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED. THE CONSUMER HAD THE HSG (HYSTEROSALPINGOGRAM) DONE 3 MONTHS AFTER ESSURE WAS INSERTED, SHOWING THAT BOTH COILS WERE PROPERLY IN PLACE AND NO DYE HAD SEEPED THROUGH HER TUBES. EXACTLY ONE MONTH LATER SHE WAS RUSHED TO THE HOSPITAL FOR WHAT TURNED OUT TO BE INTERNAL BLEEDING DUE TO AN ECTOPIC PREGNANCY. SHE UNKNOWINGLY BECAME PREGNANT WHEN THE COILS SHIFTED, ONE PIERCING THE FALLOPIAN TUBE, THE OTHER PIERCING THE UTERUS. BECAUSE THE PREGNANCY RUPTURED SHE HAD BEEN INTERNALLY BLEEDING FOR 12 HOURS. HER CHILDREN WERE ONLY 2 YEARS OLD AND 6 MONTHS OLD AT THE TIME. SHE CONSIDERED ALL EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD AN ECTOPIC PREGNANCY. SHE UNKNOWINGLY BECAME PREGNANT WHEN THE COILS SHIFTED, ONE PIERCING THE FALLOPIAN TUBE, THE OTHER PIERCING THE UTERUS (SEEN AS EMBEDDED DEVICE). BECAUSE THE PREGNANCY RUPTURED SHE HAD BEEN INTERNALLY BLEEDING FOR 12 HOURS. THE EVENTS ECTOPIC PREGNANCY AND PREGNANCY RUPTURED IN FALLOPIAN TUBE ARE SERIOUS DUE TO HOSPITALIZATION AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE OTHER EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF

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THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. IN THIS CASE, A HYSTEROSALPINGOGRAM WAS PERFORMED 3 MONTHS AFTER ESSURE INSERTION AND THE RESULT SHOWED BOTH COILS WERE PROPERLY IN PLACE AND NO DYE HAD SEEPED THROUGH HER TUBES. ONE MONTH LATER SHE WAS RUSHED TO THE HOSPITAL AND AN ECTOPIC PREGNANCY WAS DIAGNOSED. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THEREFORE THIS CASE WAS REGARDED AN INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICAL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00901	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0426, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED. THE CONSUMER HAD ESSURE INSERTED A YEAR AFTER HER 3RD HEALTHY CHILD WAS BORN. AT THE 3 MONTH FOLLOW UP VISIT/DYE TEST, THE TUBES WERE CONFIRMED TO BE FULLY BLOCKED AND PERMANENTLY STERILE. AT THE ONSET OF THE FIRST PERIOD SHE WAS IN EXCRUCIATING PAIN SIMILAR TO LABOR AND COULD NOT LEAVE THE HOUSE DUE TO EXCESSIVE BLEEDING, AND THIS OCCURRED EVERY TIME SHE HAD HER CYCLE. SHE ALSO EXPERIENCED WEIGHT GAIN, FATIGUE, DIZZINESS, NIGHT SWEATS AND MORE. SHE WAS ALLERGIC TO NICKEL. WITHIN 6 MONTHS OF INSERTION THE CONSUMER WAS PREGNANT. A GENETIC SPECIALIST TOLD BABY HAD SEVERE ABNORMALITIES AND HEALTH DEFECTS. THE CONSUMER STATED THAT AS THE BABY WAS EXPOSED TO THE COMPONENTS OF ESSURE DURING THE FIRST 7 WEEKS OF DEVELOPMENT, WHICH CAUSED A NEAR MISCARRIAGE AND ABNORMAL DEVELOPMENT AFTER THAT POINT. SHE ENDED UP HAVING A HYSTERECTOMY (INTERPRETED ALSO AS A THERAPEUTIC ABORTION) TO REMOVE ESSURE AND STATED THAT HER SIDE EFFECTS MOSTLY GONE AFTER REMOVAL OF THE COILS. THE CONSUMER CONSIDERED ALL EVENTS RELATED TO ESSURE. THE CHILD CASE NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE BLEEDING (INTERPRETED AS GENITAL BLEEDING). WITHIN 6 MONTHS SHE WAS PREGNANT. THE CONSUMER STATED THAT AS THE BABY WAS EXPOSED TO THE

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COMPONENTS OF ESSURE DURING THE FIRST 7 WEEKS OF DEVELOPMENT, WHICH CAUSED A NEAR MISCARRIAGE, & ABNORMAL DEVELOPMENT. THE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR NEAR MISCARRIAGE, & ABNORMAL DEVELOPMENT, WHICH IS UNLISTED. IN THIS CASE, IT WAS REPORTED THAT AT 3 MONTH FOLLOW UP VISIT/DYE TEST, THE TUBES WERE CONFIRMED TO BE FULLY BLOCKED AND PERMANENTLY STERILE. AT THE ONSET OF THE FIRST PERIOD SHE COULD NOT LEAVE THE HOUSE DUE TO EXCESSIVE BLEEDING. CONSUMER GOT PREGNANT WITHIN 6 MONTHS OF INSERTION. A HYSTERECTOMY WAS PERFORMED IN ORDER TO REMOVE ESSURE. BASED ON THE EVENT'S NATURE, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS, EXCEPT FOR NEAR MISCARRIAGE, & ABNORMAL DEVELOPMENT, AND SUSPECT INSERT CANNOT BE EXCLUDED. CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THE REPORTED EVENT NEAR MISCARRIAGE, & ABNORMAL DEVELOPMENT WAS CONSIDERED AS UNRELATED TO THE INSERT. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00929	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2012
Explant Date (E7): 7/30/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 11-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00930	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS PROVIDED ON 11-SEP-2015. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOL

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00931	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00932	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2004
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00933	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627433

Single Use: Y
Implant Date (E6): 5/19/2009
Explant Date (E7): 8/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT NUMBER 627433, PRODUCTION

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00935	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00936	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 7/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW UP 15-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00937	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2011
Explant Date (E7): 6/12/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00939	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00940	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7): 10/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-SEP-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00941	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW UP 13-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00942	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00943	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 8/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 ((B)(4), AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED 3 YEARS PRIOR TO THIS REPORT. CONCOMITANT CONDITION INCLUDED FIBROID. SIX MONTHS LATER SHE STARTED HAVING IRREGULAR BLEEDING, CONSTANT STABBING PAIN THAT LASTED SECONDS ON HER LEFT ABDOMINAL SIDE AND PELVIC PAIN. HER BLEEDING WOULD NOT STOP UNTIL THE DOCTOR PRESCRIBED HORMONES. HER BELLY, NOW WELL KNOWN AS EMBELLISHED, WOULD BE DISTENDED AND BLOATED MOST OF THE TIME AND SHE GAINED 20 POUNDS THAT SHE COULD NOT SHAKE OFF WITH DIET OR EXERCISE. HER JOINTS HURT CONSTANTLY, SPECIFICALLY HER FINGERS, NECK, SHOULDERS AND KNEES. SHE FELT SICK MOST OF THE TIME, SLEEPY AND DEPRESSED. HER VISION WOULD VARY EVERY DAY AND SHE HAS NORMAL TO LOW BLOOD PRESSURE AND NOT DIABETIC. SOMETIMES SHE COULD NOT SEE WITH OR WITHOUT GLASSES. SEX DRIVE WAS LOW, COULD NOT CONCENTRATE AND HER PHYSICIAN THOUGHT THAT SHE HAD SYMPTOMS OF ADULT ADHD (INTERPRETED AS ATTENTION-DEFICIT HYPERACTIVITY DISORDER). SHE SUFFERED FROM MIGRAINE HEADACHES AND WAS HAVING THEM MORE OFTEN THAN EVER. DURING THOSE 3 YEARS SHE HAD PELVIC SONOGRAM, BIOPSIES, HER DOCTOR CHECKED HER HORMONES AND THYROID LEVELS AND EVERYTHING CAME BACK NORMAL. SHE WAS SUBMITTED TO BILATERAL SALPINGECTOMY WITH HYSTEROSCOPY IN (B)(6) 2015 TO HAVE THE ESSURE REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE WAS IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE AND REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED 3 YEARS PRIOR TO THIS REPORT

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

AND EXPERIENCED THE FOLLOWING SERIOUS EVENTS AMONGST OTHER NON-SERIOUS: CONSTANT STABBING PAIN LEFT ABDOMINAL SIDE, PELVIC PAIN AND IRREGULAR BLEEDING. THESE EVENTS ARE LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION AND CONSIDERED RELATED TO THE DEVICE IN THE ABSENCE OF PLAUSIBLE ALTERNATIVE EXPLANATION. CONSUMER WAS SUBMITTED TO BILATERAL SALPINGECTOMY WITH HYSTEROSCOPY IN (B)(6) 2015 TO HAVE THE ESSURE REMOVED. SINCE A SURGICAL INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 13-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00944	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2010
Explant Date (E7): 3/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-SEP-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00945	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 14-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00946	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00947	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/23/2013
Explant Date (E7): 8/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00948	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0664, AWARENESS DATE 18-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2008. CONSUMER REPORTED THAT IN 2007 HER GYNECOLOGIST TOLD HER THAT "WOMEN OF HER SIZE" ((B)(6)) WERE NOT CANDIDATES FOR TUBAL LIGATION AND THAT THIS DEVICE ESSURE WAS THE BEST CHOICE. IN 2008 THE ESSURE COILS WERE PLACED. SHE CAN REMEMBER THEM TELLING HER IN RECOVERY THAT THEY HAD A HARD TIME PLACING HER RIGHT SIDE COIL, BUT A REP FROM THE COMPANY WAS ABLE TO GET IT PLACED. AFTER THE ESSURE PLACEMENT HER WEIGHT BALLOONED TO (B)(6) AND HER PERIODS WERE EXTREMELY HEAVY AND PAINFUL, MAKING HER BORDERLINE ANEMIC, SHE LOST TIME FROM WORK AND SHE HAD HORRIBLE MIGRAINES WITH EVERY MENSTRUAL CYCLE. SHE UNDERWENT A GASTRIC BYPASS IN (B)(6) 2009. BECAUSE OF THE HEAVY MENSTRUATION AND UTERINE LINING THICKENING WITHOUT EXPLANATION, SHE UNDERWENT AN ABLATION PROCEDURE IN 2010. SHE STILL SUFFERS FROM MIGRAINES, NOW SHE IS FINDING OUT SHE IS ALLERGIC TO NICKEL WHICH SHE NEVER WAS BEFORE THE ESSURE WAS PLACED. SHE WOKE EVERY DAY WITH STIFF JOINTS, AND DEAL WITH CHRONIC TIREDNESS AS WELL. NONE OF THESE THINGS WERE TOLD TO HER, ESPECIALLY THE FACT THAT THERE ARE PET FIBERS IN THE DEVICE. SHE WOULD NOT HAS GOTTEN THESE COILS PLACED IF SHE HAD KNOWN THAT FACT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERIODS WERE EXTREMELY HEAVY. THIS EVENT WAS

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CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, AN ABLATION PROCEDURE WAS PERFORMED ABOUT 2 YEARS AFTER ESSURE INSERTION BECAUSE OF THE HEAVY MENSTRUATION. CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP AND BASED ON THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, OTHER EVENTS NON-SERIOUS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-SEP-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00949	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00950	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 10-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ES

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00951	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 8/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0677, AWARENESS DATE 18-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2013. CONSUMER HAD ESSURE INSERTED AND WENT THROUGH TWO YEARS OF DOWNWARD HEALTH PROBLEMS. SHE HAD WRIST STIFF, CRAMPING ALL THE TIME, TIRED ALL DAY, NAUSEA, LACK/NO SEX DRIVE, HORRIBLE CRAMPS AND PERIODS, MOOD SWINGS, DEPRESSION AND ALLERGY TO NICKEL. SHE HAD ENOUGH OF THIS PAIN SO ON (B)(6) 2015 SHE HAD ESSURE REMOVED ALONG WITH TUBES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HORRIBLE PERIODS AND CRAMPING ALL THE TIME / HORRIBLE CRAMPS. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, SHE HAD ESSURE REMOVED ALONG WITH TUBES. NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP BETWEEN THE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-SEP-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00952	BAYER HEALTHCARE LLC	9/15/2015	9/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 9/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE # FDA-2014-N-0736-0660 AND FDA-2014-N-0736-0724, AWARENESS DATE 18-AUG-2015). IT REFERS TO A 41 YEARS-OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2015. SHE REPORTED SHE IS MOTHER OF FOUR AND DECIDED SHE WAS DONE HAVING CHILDREN. SHE STATED SHE HAD BEEN IN AND OUT OF THE PHYSICIAN FOR WHAT EVERYONE TOLD HER IT WAS GERD, OR THE GALLBLADDER OR KIDNEY STONES AND ETC. SHE GAINED 30 POUNDS, HAD TERRIBLE PAINS IN HER SIDE, WHEN SHE COUGH SHE COULD FEEL THE COIL IN HER AND WHEN SHE WAS IN PAIN SHE COULDN'T USE A HEATING PAD BECAUSE SHE COULD FEEL IT HEAT UP AND HAD MORE PAIN. SHE SUFFERED FROM MIGRAINES HEADACHES, AND ONE LASTED 3 WEEKS STRAIGHT. SHE HAD METAL TASTE IN HER MOUTH ALL THE TIME, SHE EAT JUST ONCE A DAY IF THAT BECAUSE SHE WAS NAUSEOUS ALL THE TIME, SHE FELT LIKE SHE WAS GOING TO THROW UP EVERY DAY. SHE DESCRIBED HER PAIN GOES FROM HER HIP TO HER LEG AND TO HER TOES WHERE SHE COULD NOT WALK WITHOUT PAIN AND SHE GOT SPASM IN HER TUBAL AREA THAT WERE SO INTENSE THAT FELT LIKE A BABY WAS KICKING IN ITS EARLY STAGES. HER HANDS AND FINGERS ON RIGHT SIDE AND ARMS WENT NUMB, AND SHE WAS DEPRESSED, EXHAUSTED DAILY, HAD HEAVY BLEEDING, HER HAIR WAS FALLING OUT. SHE ALSO STATED THE NICKEL ALLERGY WAS INFECTING HER INSIDE OUT. SHE STATED SHE IS SCHEDULE TO HAVE A HYSTERECTOMY ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND

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EXPERIENCED PAIN IN HER TUBES AND HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING). THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. SHE STATED THAT SHE IS SCHEDULE TO HAVE A HYSTERECTOMY. BASED ON THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 16-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056162	BAYER	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 3/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I HAVE BEEN SCHEDULED FOR A PARTIAL HYSTERECTOMY (EVERYTHING BUT MY OVARIES) ON (B)(6). I AM HAVING HORRIBLE CRAMPS STILL HEAVY BLEEDING ON AND OFF. NOTHING HAS IMPROVED. SO NOW I'M HAVING TO GET A HYSTERECTOMY AT 24.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056163	BAYER	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN , MIGRATION , NICKEL ALLERGY, HEAVY BLEEDING , SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056164	BAYER	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 9/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056165	BAYER	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 1/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056166	BAYER	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 11/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056167	BAYER	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056168	BAYER	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 9/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESSIVE HAIR LOSS, EXCESSIVE DISCHARGE, HEADACHE, FATIGUE, IRREGULAR PERIOD, PELVIC PAIN, JOINT PAIN, BACK PAIN, FOGGY MEMORY, SUPER HEAVY CLOTTING PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056169	BAYER	9/15/2015	9/15/2015

Event Information:

Event Date (B3): 1/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN DURING OVULATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056247	BAYER	9/15/2015	9/18/2015

Event Information:

Event Date (B3): 1/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/28/2013
Explant Date (E7): 11/5/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY SON BORN ON (B)(6) 2012, BACK IN ALL MY CLOTHES BY (B)(6) 2013 WHEN I WENT BACK TO WORK. ESSURE PROCEDURE DONE ON (B)(6) 2013, SET OFF STORE ALARMS GOING IN AND COMING OUT OF 3 DIFFERENT STORES WITHIN A WEEK OF PROCEDURE. UNABLE TO FIT IN CLOTHES BY (B)(6) 2013 (WHILE STILL BREAST FEEDING AND EXERCISING MUCH MORE THAN I HAD WHILE ON MATERNITY LEAVE. WENT BACK 90 DAYS LATER FOR TEST. ONE SIDE WAS FINE BUT LEFT SIDE WAS NOT, WAS TOLD I NEEDED TO COME BACK TO 90 DAYS. DURING THE SUMMER OF 2014, I BEGAN HAVING SEVERE DIZZINESS AND STARTED GETTING CAR SICK EVEN WHILE DRIVING, ALSO NOTICED TINGLING IN FINGERS AND TOES; HAD SOME OF THAT WHILE I WAS PREGNANT WITH MY SON AND IT FELT VERY SIMILAR. WENT BACK IN (B)(6) 2013, LEFT SIDE WAS STILL NOT BLOCKED, MY OB WANTED TO DO A TUBAL ON THAT SIDE. WHEN I ASKED HER IF THE COIL COULD BE REMOVED SINCE I DIDN'T WANT A FOREIGN OBJECT IN MY BODY THAT WASN'T WORKING, SHE REPLIED "I DON'T KNOW I'VE NEVER BEEN ASKED THAT, " I IMMEDIATELY CALLED MY FORMER OB (THE ONLY REASON WHY I WAS NO LONGER A PT WAS HE LEFT HIS PRIVATE PRACTICE TO GO INTO MORE OF A RESEARCH ROLE AND NO LONGER HANDLED PREGNANCIES), WHEN I MET WITH HIM HE GAVE ME SEVERAL OPTIONS TO REMOVE BOTH COILS. I HAD BOTH FALLOPIAN TUBES REMOVED IN (B)(6) 2013. I CAN'T TELL YOU HOW EXACT, BUT I FELT BETTER INSTANTANEOUSLY ONCE THEY WERE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056248	BAYER	9/15/2015	9/18/2015

Event Information:

Event Date (B3): 9/20/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/18/2006
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IMPLANTED WITH ESSURE IN (B)(6) OF 2006, WAITED THE 3 MONTHS, HAD THE DYE TEST ALL IS SEALED. IMMEDIATELY MY CYCLES GOT LONGER, GOT WORSE, AND CRAMPS I NEVER HAD EXPERIENCED. CLOTTING AND JUST PAIN. BEGAN TO HAVE GOOD DAYS AND BAD DAYS. SHARP STABBING PAINS MOSTLY ON MY RIGHT SIDE. PAIN DURING SEX. CLUMPS OF WHAT APPEARS TO BE TISSUE WOULD COME OUT WHILE I WAS USING THE REST ROOM. MIGRAINES STARTED. THEY WOULD ALWAYS COME AT THE WORSE TIMES. MY LIFE WAS NO LONGER MY LIFE. I WAS GETTING FATTER. MY HUSBAND BEGAN TO CALL ME NAMES NOT UNDERSTANDING WHAT I WAS GOING THROUGH. MOOD SWINGS. HE BEGAN TO CALL ME BIPOLAR. WE SEPARATED AND I JOINED A GYM. WORKING HARD AND STILL GAINING WEIGHT. I WAS (B)(6) WHEN IMPLANTED. FINALLY AT (B)(6) I WENT TO THE DOCTOR. I HAD ENOUGH. I DIDN'T EVEN RECOGNIZE THE PERSON I WAS ANYMORE. DOCTOR SAID I DEVELOPED PCOS. CAUSES WEIGHT GAIN, MOOD SWINGS, HAIR GROWTH IN UNWANTED LOCATION, AND MORE. HE PUT ME ON BIRTH CONTROL TO CONTROL MY HORMONES, WAIT, BIRTH CONTROL, BUT I'M FIXED. THERE IS A REASON I GOT ESSURE, BUT I FOLLOWED DOCTOR'S RECOMMENDATIONS. LOST A LITTLE WEIGHT. IF I STAY ON IT THE MINUTE I GET OFF BRING ON THE FAT. I WANT MY LIFE BACK. I CAN'T AFFORD REMOVAL. I CAN'T STAND LOOKING IN THE MIRROR. EVEN SEX WITH MY PARTNER IS PAINFUL. STABBING PAIN THAT SENDS YOU IN TEARS DURING INTERCOURSE, THAT'S ATTRACTIVE. YEARS LATER, I'M STILL FIGHTING THE BATTLE. I HAVE 4 CHILDREN AND CANNOT GO INTO DEBT TO HAVE THIS DEVICE TAKEN OUT. I'M IN LIMBO NOT EVEN ABLE TO ENJOY MY LIFE. AS I SAID BEFORE THERE ARE GOOD DAYS AND BAD DAYS AFTER ALMOST 9 YEARS, I'M STARTING TO NOT REMEMBER NORMAL LIFE. EXCEPT IN PICTURES. TO BE HONEST I'M SCARED TO GO BACK TO THE DOCTOR WHAT IF THEY MIGRATED AND THAT'S CAUSING PAIN. THEN I LOOSE MORE OF WHO I AM. I'M LOST BECAUSE OF ESSURE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056249	BAYER	9/15/2015	9/18/2015

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 7/10/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2013. SINCE THEN, I HAVE PELVIC PAIN, EXTREME EXHAUSTION, HEADACHES AND DEPRESSION. IT HAS GOTTEN SO BAD THAT MY HUSBAND AND I ARE CURRENTLY SEPARATED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056250	BAYER	9/15/2015	9/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PAIN. SPOTTING BETWEEN PERIODS. ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056251	BAYER	9/15/2015	9/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/7/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

WITHIN 2 MONTHS AFTER BEING IMPLANTED ON (B)(6) 2014, I BEGAN EXPERIENCING WEIGHT GAIN (TO THE POINT WHERE I LOOKED 4-5 MONTHS PREGNANT), JOINT PAINS, BACK AND ABDOMINAL PAIN, HEAVY CYCLES WITH CLOTS, HEADACHES AND MOOD SWINGS. I DIDN'T REALIZE IT COULD BE RELATED TO ESSURE UNTIL I BEGAN RESEARCHING PROBLEMS AND IF ANYONE ELSE HAD ISSUES WITH IT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00953	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 958711

Single Use: Y
Implant Date (E6): 6/18/2012
Explant Date (E7): 8/19/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A CLINICAL STUDY CASE REPORT RECEIVED FROM A INVESTIGATOR IN UNITED STATES ON 31-MAY-2013. THIS (B)(6) NULLIGRAVID WOMAN WAS ENROLLED IN STUDY (B)(4), A PHASE 4 INTERVENTIONAL TRIAL EVALUATING EFFECTIVENESS OF TVU AS AN ALTERNATIVE APPROACH TO CONFIRM ESSURE MICRO-INSERT PLACEMENT IN WOMEN IN WHOM BILATERAL PLACEMENT WAS ACHIEVED, ON (B)(6) 2012. PATIENT NUMBER: (B)(6). CENTER NUMBER: (B)(6). MEDICAL AND SURGICAL HISTORY SHOWED THAT THE SUBJECT HAS HAD CHOLECYSTECTOMY IN 1999. THE SUBJECT IS NULLIGRAVID. THE FIRST DAY OF HER LAST MENSTRUAL PERIOD WAS ON (B)(6) 2012. AFTER CONFIRMATION OF A NEGATIVE PREGNANCY TEST, ESSURE MICRO-INSERT WAS INSERTED ON (B)(6) 2012 AND WAS COMPLETED WITH BILATERAL SUCCESSFUL PLACEMENT. THE SUBJECT UNDERWENT TRANSVAGINAL ULTRASOUND (TVU) ON THE 3-MONTH FOLLOW-UP VISIT, ON (B)(6) 2012. BOTH THE INSERTS WERE IDENTIFIED IN THE TVU SCAN AND WERE ASSESSED TO BE IN OPTIMAL LOCATION, IN BOTH THE TUBES. THE SUBJECT RATED THE COMFORT DURING THE PROCEDURE AS EXCELLENT, AND HER OVERALL SATISFACTION WITH THE PROCEDURE AS "VERY SATISFIED". ABOUT A YEAR POST-PLACEMENT, ON (B)(6) 2013, THE SUBJECT EXPERIENCED RIGHT LOWER QUADRANT PAIN OF SEVERE INTENSITY, ASSOCIATED WITH FEVER. CLINICAL IMPRESSION WAS ACUTE APPENDICITIS, AND THE SUBJECT WAS TAKEN TO THE OPERATING ROOM FOR EXPLORATORY LAPAROSCOPY. THE FINDINGS SHOWED NORMAL APPENDIX AND CYST ON THE RIGHT FALLOPIAN TUBE. APPENDECTOMY AND EXCISION OF THE CYST WERE PERFORMED. HER POSTOPERATIVE COURSE WAS UNEVENTFUL. SHE WAS GIVEN MEDICATIONS FOR PAIN, FLAGYL (METRONIDAZOLE) 500 MG EVERY 8 HOURS FOR 1 WEEK, AND LEVAQUIN (LEVOFLOXACIN) 500 MG ONCE DAILY FOR 1 WEEK. THE EVENT WAS ASSESSED AS NOT RELATED TO THE ESSURE MICRO-INSERT OR TO ANY OF THE STUDY PROCEDURES. AT THE 1-YEAR FOLLOW-UP, THE SUBJECT ASSESSED THE COMFORT OF WEARING AS EXCELLENT, AND OVERALL SATISFACTION WAS

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VERY SATISFIED. THE SUBJECT CONTINUES TO BE ENROLLED IN THE STUDY. THE FOLLOWING NON-SERIOUS AES WERE ALSO REPORTED DURING THE STUDY: VAGINAL INFECTION (B)(6) 2012), MILD INTENSITY, REMEDIAL DRUG THERAPY, RECOVERED/RESOLVED WITH TREATMENT, POSSIBLY RELATED TO THE STUDY PROCEDURE OR THE DEVICE; ENDO POLYP ((B)(6) 2012), MILD INTENSITY, NO ACTION TAKEN FOR THE EVENT, RECOVERED/RESOLVED WITHOUT TREATMENT, NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE; RIGHT OVARIAN CYST ((B)(6) 2012, ONGOING), MILD INTENSITY, NO ACTION TAKEN FOR THE EVENT, OUTCOME UNDETERMINED (CYST WAS STILL SEEN ON ULTRASOUND ON (B)(6) 2013), NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE; URINARY FREQUENCY ((B)(6) 2012), MILD INTENSITY, REMEDIAL DRUG THERAPY, RECOVERED/RESOLVED WITH TREATMENT, NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE; HOT FLASHES ((B)(6) 2012, ONGOING), MILD INTENSITY, NOT TREATED, EVENT CONTINUING, NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE; NIGHT SWEATS ((B)(6) 2012, ONGOING), MILD INTENSITY, NOT TREATED, EVENT CONTINUING, NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE; PELVIC PAIN ((B)(6) 2013, ONGOING), MODERATE INTENSITY, NO ACTION TAKEN FOR THE EVENT, OUTCOME UNDETERMINED (THE SUBJECT DID NOT HAVE AN OFFICE VISIT; THE EVENT COULD NOT BE EVALUATED), NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE; MALAISE ((B)(6) 2013, ONGOING), MILD INTENSITY, NO ACTION TAKEN FOR THE EVENT, OUTCOME UNDETERMINED (THE SUBJECT HAD NOT BEEN SEEN FOR FOLLOW-UP), NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE; BILATERAL KIDNEY STONES ((B)(6) 2013, ONGOING), MILD INTENSITY, ACTION TAKEN INCLUDED OTHER (EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY PERFORMED), EVENT CONTINUING AND NOT CONTROLLED WITH TREATMENT, NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE; VAGINAL BACTERIAL INFECTION ((B)(6) 2013), MILD INTENSITY, REMEDIAL DRUG THERAPY, RECOVERED/RESOLVED WITH TREATMENT, NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE; RIGHT FALLOPIAN TUBE CYST ((B)(6) 2013), MILD INTENSITY, ACTION TAKEN INCLUDED OTHER (CYST REMOVED), RECOVERED/RESOLVED WITH TREATMENT, NOT RELATED TO THE STUDY PROCEDURE OR THE DEVICE. ADDENDUM: THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO (B)(6) ON 08-APR-2014. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED. CORRECTION ON 03-JUN-2015 FOLLOWING RECONCILIATION WITH STUDY DATABASE: PATIENT WAS (B)(6) AT THE TIME OF THE EVENT. FOLLOW UP 11-JUN-2015: SAE REPORT RECEIVED FROM THE INVESTIGATOR. PATIENT NUMBER WAS UPDATED FROM (B)(6). BMI UPDATED. ON (B)(6) 2013 THE PATIENT EXPERIENCED SEPSIS. THE PATIENT HAD RIGHT LOWER QUADRANT PAIN, FEVER, ELEVATED WHITE BLOOD CELLS AND WAS ADMITTED TO HOSPITAL AND APPENDECTOMY WAS PERFORMED. SHE WAS TREATED WITH FLAGYL 1500MG ORAL AND LEVAQUIN 500MG ORAL AND ON (B)(6) 2013 SHE RECOVERED FROM THE EVENT. THE INVESTIGATOR CONSIDERED THE EVENT SEPSIS AS SEVERE AND UNRELATED TO ESSURE. THE ALTERNATIVE POSSIBLE EXPLANATION FOR SAE WAS GIVEN AS AN UNDERLYING DISEASE ACUTE APPENDICITIS. FOLLOW UP INFORMATION RECEIVED FROM THE INVESTIGATOR ON 19-AUG-2015: ESSURE LOT NUMBER WAS 958711. THE PATIENT DID NOT RECEIVE HORMONAL MANIPULATION TO PROMOTE ATROPHIC OR PROLIFERATE ENDOMETRIUM PRIOR TO ESSURE PLACEMENT PROCEDURE. SHE RECEIVED TORADOL 60MG INTRAMUSCULAR INJECTION AND NORCO 7.5/325MG TAB AND XANAX 0.25MG TAB DURING INSERTION PROCEDURE. THE VISUALIZATION OF THE LEFT AND RIGHT TUBAL OSTIA WAS ACHIEVED. AT LEAST ONE ESSURE MICRO-INSERT PASSED THROUGH THE CHANNEL OF THE SCOPE AT ANY TIME DURING THE PROCEDURE. TWO COILS WERE TRAILING IN BOTH SIDES AFTER INSERTION. ON (B)(6) 2014 THE PATIENT EXPERIENCED RT (RIGHT) SIDE ABDOMINAL PAIN, CONSIDERED AS NON-SERIOUS, MODERATE AND UNRELATED TO ESSURE BY THE INVESTIGATOR. AS TREATMENT, ESSURE WAS REMOVED BUT EVENT CONTINUED. ON (B)(6) 2015, A PERFORATION OF RT FALLOPIAN TUBE WAS FOUND; THIS EVENT WAS CONSIDERED AS NON-SERIOUS, SEVERE AND DEFINITELY RELATED TO ESSURE BY THE INVESTIGATOR. AFTER TREATMENT WITH SALPINGECTOMY; THE SUBJECT RECOVERED (EVENT STOP DATE: (B)(6) 2015). CASE UPGRADED TO INCIDENT. FOLLOW-UP INFORMATION RECEIVED ON 19-AUG-2015 FROM INVESTIGATOR: NO NEW CLINICAL INFORMATION. FOLLOW-UP INFORMATION RECEIVED ON 26-AUG-2015: THE SUBJECT HAS COMPLAINED OF RIGHT SIDE ABDOMINAL PAIN ON AND OFF SINCE THE ESSURE PLACEMENT ON (B)(6) 2012 AND REQUESTED REMOVAL OF THE ESSURES ON (B)(6) 2015.

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LAPAROSCOPIC BILATERAL SALPINGECTOMY WITH ESSURE REMOVAL WAS PERFORMED ON (B)(6) 2015. IT WAS FOUND DURING THE ESSURE REMOVAL THAT THE RIGHT FALLOPIAN TUBE WAS PERFORATED DURING THE ESSURE PLACEMENT ON (B)(6) 2012. ESSURE AND FALLOPIAN TUBES WERE SENT TO PATHOLOGY.. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE SUBJECT WHO WAS INVOLVED IN AN INTERVENTIONAL COMPANY SPONSORED STUDY (STUDY NUMBER: (B)(4)). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS HOSPITALIZED, 1 YEAR LATER, DUE TO ABDOMINAL PAIN. SHE WAS DIAGNOSED WITH ACUTE APPENDICITIS, WHICH WAS COMPLICATED BY SEPSIS. THE SUBJECT ALSO HAD RT SIDE ABDOMINAL PAIN SINCE ESSURE PLACEMENT AND REQUESTED DEVICES REMOVAL 3 YEARS LATER. SHE WAS SUBMITTED TO A LAPAROSCOPIC SALPINGECTOMY. DURING THIS SURGERY, A PERFORATION OF RT FALLOPIAN TUBE WAS FOUND. ONLY SEPSIS IS UNLISTED IN INVESTIGATOR'S BROCHURE. IN THIS PARTICULAR CASE, THE INVESTIGATOR ASSESSED SUBJECT'S SEPSIS AS NOT RELATED TO THE ESSURE AND CONSIDERED HER UNDERLYING ACUTE DISEASE (APPENDICITIS) AS AN ALTERNATIVE EXPLANATION. GIVEN EVENT'S PATHOPHYSIOLOGY AND CONSIDERING ITS WEAK TEMPORAL RELATIONSHIP WITH ESSURE PLACEMENT; COMPANY REGARDS IT AS UNRELATED TO ESSURE (IN LINE WITH THE INVESTIGATOR'S ASSESSMENT). REGARDING THE REMAINING EVENTS, INVESTIGATOR STATED THE RIGHT FALLOPIAN TUBE WAS PERFORATED DURING ESSURE PLACEMENT AND CONSIDERED THIS EVENT AS DEFINITELY RELATED TO ESSURE. AS THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE INSERTION; COMPANY AGREES WITH INVESTIGATOR'S ASSESSMENT. THIS CASE WAS INITIALLY CONSIDERED A NON-INCIDENT. HOWEVER, UPON RECEIPT OF FOLLOW-UP INFORMATION, IT WAS UPGRADED TO INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

INTERNAL COMMUNICATION RECEIVED ON 02-NOV-2015: NO FURTHER INFORMATION WAS OBTAINED DESPITE FOLLOW-UP ATTEMPTS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 19-NOV-2015: (PTC GLOBAL NUMBER: (B)(4)). FINAL ASSESSMENT: FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00954	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50678466

Single Use: Y
Implant Date (E6): 11/19/2014
Explant Date (E7): 5/19/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 19-MAY-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED CONFIRMED TESTING FOR A NICKEL ALLERGY. FOLLOW UP 27-MAY-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. FINAL RISK CLASSIFICATION RISK CATEGORY V MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 19-AUG-2015: NO NEW INFORMATION. FOLLOW UP INFORMATION RECEIVED ON 21-AUG-2015 FROM PHYSICIAN: CASE UPGRADED TO INCIDENT. ON (B)(6) 2014 SHE HAD ESSURE INSERTED FOR STERILIZATION, LOT NUMBER 50678466, EXPIRATION DATE 31-

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AUG-2015. PATIENT DEVELOPED A RASH ON HER BODY SOON AFTER ESSURE WAS IN PLACE. ON (B)(6) 2015, SHE WENT TO AN ALLERGIST AND HAD CONFIRMED TESTING FOR A NICKEL ALLERGY. ESSURE WAS REMOVED ON (B)(6) 2015. FOLLOW UP INFORMATION RECEIVED ON 28-AUG-2015: NO NEW INFORMATION REPORTED. FOLLOW-UP FROM 08-SEP-2015: PTC RESULT WAS UPDATED. NO MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CONFIRMED TESTING FOR A NICKEL ALLERGY. NICKEL ALLERGY IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING AND RASH. IN THIS CASE, SOON AFTER PLACEMENT THE PATIENT DEVELOPED A RASH ON HER BODY. SHE WAS TESTED SOME MONTHS LATER AND NICKEL ALLERGY WAS CONFIRMED. THEN, ESSURE WAS REMOVED. CONSIDERING CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS INFORMED THAT DEVICE REMOVAL WAS REQUIRED. THEREFORE, THIS CASE IS NOW REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION (INCLUDING A REVIEW OF PROVIDED BATCH NUMBER), THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00955	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/29/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO MIRENA (LEVONORGESTREL) INSERTED IN 2011 AT 20 MCG/24HR, CONT INTRA-UTERINE FOR HEAVY MENSTRUAL BLEEDING AND ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. ACCORDING TO THE PHYSICIAN, ESSURE PROCEDURE WENT NORMALLY. PATIENT CAME TO HOSPITAL ON (B)(6) 2015 BECAUSE OF ALLERGIC SYMPTOMS, CHOKING FEELING IN THROAT, DRY COUGH, VOMITING ON SATURDAY, SKIN SYMPTOMS: REDNESS ON LEGS AND FACE, PINCHING FEELING ON STOMACH AND BACK. IT WAS KNOWN THAT PATIENT HAS NICKEL ALLERGY. NO SWELLING IN THROAT AND NO PROBLEMS WITH BREATHING. PATIENT HAD TREATED HERSELF WITH ANTIHISTAMINE. THE PLAN IS TO REMOVE THE IMPLANTS LAPAROSCOPICALLY IF THE SYMPTOMS WON'T EASE. IT WAS ALSO TOLD THAT THE PATIENT HAD MIRENA INSERTED IN 2011 BECAUSE OF HEAVY MENSTRUAL BLEEDING. MIRENA WAS REMOVED ON THE THIRD DAY AFTER INSERTION BECAUSE OF SWELLING, FEVER AND ECZEMA. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A

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QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 FROM NURSE AT DERMATOLOGY AND ALLERGY DEPARTMENT: ESSURE IMPLANTS HAVE BEEN REMOVED AND THE PATIENT WAS GOING TO DERMATOLOGY AND ALLERGY DEPARTMENT FOR ALLERGY TESTING (TESTING IF SHE WAS ALLERGIC TO MIRENA AND ESSURE). OUTCOME WAS REPORTED AS UNKNOWN. THIS CASE WAS UPGRADED TO INCIDENT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: HYPERSENSITIVITY. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 18 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT.. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO EXPERIENCED CHOKING FEELING IN THROAT APPROXIMATELY 2 DAYS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE HAD NO SWELLING IN THROAT OR PROBLEMS WITH BREATHING. SHE TREATED HERSELF WITH ANTIHISTAMINE. ADDITIONALLY, SHE HAD OTHER ALLERGIC SYMPTOMS. ESSURE IMPLANTS WERE REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE. CHOKING FEELING IS UNLISTED ACCORDING ESSURE'S REFERENCE SAFETY INFORMATION; WHILE ALLERGIC REACTIONS TO ESSURE ARE LISTED. IN THIS PARTICULAR CASE, THE PATIENT HAD A PREVIOUS NICKEL ALLERGY AND EXPERIENCED ALLERGIC SYMPTOMS (INCLUDING REDNESS ON LEGS AND FACE) AFTER ESSURE PLACEMENT. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. ALTHOUGH PATIENT'S CHOKING FEELING IS NOT EXPECTED AS AN ALLERGIC REACTION FOR ESSURE; CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP BETWEEN THE EVENTS AND DEVICE INSERTION CAUSALITY CANNOT BE EXCLUDED. OTHER NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS INITIALLY CONSIDERED A NON-INCIDENT. HOWEVER, UPON RECEIPT OF FOLLOW-UP INFORMATION, IT WAS UPGRADED TO INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. ESSURE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. ADDITIONALLY, PHYSICIAN STATED PATIENT HAD A MIRENA (LEVONORGESTREL-IUS) INSERTED IN THE PAST. THIS IUS WAS REMOVED, 3 DAYS AFTER ITS INSERTION, DUE TO THE NON-SERIOUS EVENTS OF SWELLING, FEVER AND ECZEMA, WHICH WERE CONSIDERED BY THE COMPANY AS RELATED TO MIRENA DUE TO THE CLOSE TEMPORAL ASSOCIATION WITH IUS PLACEMENT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00956	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 20-AUG-2015, ARTICLE ENTITLED "PROVIDING RE-ESSURE-ANCE TO THE NICKEL ALLERGIC PATIENT CONSIDERING HYSTEROSCOPIC STERILIZATION". IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION. CASE REPORT: A (B)(6) FEMALE (GRAVIDA 3 PARA 3) WITH AN UNCOMPLICATED MEDICAL HISTORY AND NO KNOWN ALLERGIES HAD ESSURE INSERTED FOR PERMANENT STERILIZATION. SHE DENIED A HISTORY OF NICKEL ALLERGY, PELVIC INFECTIONS, PREVIOUS TUBAL LIGATION, OR OTHER TUBAL SURGERIES. THE PATIENT UNDERWENT UNCOMPLICATED ESSURE PLACEMENT IN THE OFFICE. WITHIN DAYS OF PLACEMENT, SHE DEVELOPED A PLEOMORPHIC, PRURITIC, URTICARIAL, MACULOPAPULAR RASH OVER THE PELVIS AND RETURNED TO OUR OFFICE OFFICE 10 WEEKS AFTER PLACEMENT FOR EVALUATION. OVER THE ENSUING WEEKS, THE RASH CLEARED AND THEN RE-APPEARED MULTIPLE TIMES OVER THE PELVIS AS WELL AS DISTANT SITES INCLUDING THE NECK AND AXILLA. SHE ALSO EXPERIENCED SEVERAL EPISODES OF FACIAL EDEMA. PRURITUS WAS CONTINUOUS AND ONLY MINIMALLY RELIEVED WITH DIPHENHYDRAMINE. ONSET OF EVENTS WAS < 2 WEEKS AFTER PLACEMENT OF ESSURE. FURTHER DIRECTED QUESTIONING ELICITED A HISTORY OF MULTIPLE REACTIONS TO JEWELRY, METAL BUTTONS ON CLOTHING, AND PIERCINGS. AN ALLERGIST CONFIRMED A NICKEL ALLERGY WITH PATCH TESTING. SHE COMPLETED A TRIAL OF ORAL PREDNISONE (40MG FOR 5 DAYS, THEN 20MG FOR 5 DAYS), WHICH PROVIDED ONLY TRANSIENT RELIEF. THE PATIENT REQUESTED SURGICAL REMOVAL AND REPEAT STERILIZATION. EIGHTEEN WEEKS AFTER PLACEMENT, DIAGNOSTIC LAPAROSCOPY CONFIRMED THAT BOTH INSERTS WERE PROPERLY PLACED IN THE FALLOPIAN TUBES WITHOUT PERFORATION OR MIGRATION. THE LEFT INSERT WAS IDENTIFIED WITHIN THE TUBE USING AN ATRAUMATIC GRASPER, WHICH WAS ADVANCED DISTALLY UNTIL THE INSERT WAS NO LONGER

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PRESENT. AT THIS LOCATION, THE TUBE WAS COAGULATED AND DIVIDED WITH A LIGASURE 5MM BLUNT TIP INSTRUMENT (COVIDIEN, (B)(4)). NEXT, A MARYLAND DISSECTOR AND A MONOPOLAR SCISSORS WERE USED TO TEASE APART THE TUBE UNTIL THE DISTAL END OF THE INSERT WAS VISUALIZED. THE INNER COIL WAS GRASPED AND EASILY REMOVED FROM THE TUBE. THE OUTER COIL WAS GRASPED WHERE IT ATTACHED TO THE INNER COIL AND WAS SLOWLY EXTRACTED IN A HAND OVER HAND TECHNIQUE UNTIL THE DEVICE WAS COMPLETELY REMOVED. AFTER INSERT REMOVAL, A SALPINGECTOMY WAS PERFORMED. THE SAME PROCESS WAS COMPLETED ON THE RIGHT. THE PATIENT WAS DISCHARGED ON THE DAY OF SURGERY WITH AN ORAL STEROID TAPER (ORAL PREDNISONE 40MG FOR 5 DAYS, THEN 20MG FOR 5 DAYS). AT BOTH TWO-WEEK AND SIX-WEEK POSTOPERATIVE FOLLOW UP APPOINTMENTS, THE PATIENT WAS FREE OF SYMPTOMS. AUTHORS COMMENT: SYSTEMIC CONTACT DERMATITIS (SCD) RESULTS WHEN A PREVIOUSLY SENSITIZED INDIVIDUAL IS EXPOSED TO THE ALLERGEN SYSTEMICALLY. BABOON SYNDROME, A FORM OF SCD, INCLUDES A CHARACTERISTIC PATTERN OF DIFFUSE, WELL-DEMARCATED ERYTHEMA OF THE BUTTOCKS, UPPER THIGH, AND AXILLA, AS SEEN IN OUR PATIENT. PRIOR TO THIS REPORT, THERE HAD BEEN NO HYSTEROSCOPIC REMOVALS REPORTED AFTER THE 12 WEEK PERIOD WHERE TUBAL OCCLUSION IS KNOWN TO OCCUR. OUR RESECTION WAS PRIOR TO THE PUBLICATION OF THIS REPORT, 18 WEEKS AFTER INSERTION, SO WE PERFORMED LAPAROSCOPIC REMOVAL. LAPAROSCOPIC REMOVAL IS GENERALLY DESCRIBED AS SALPINGOSOTOMY WITH ELECTROCAUTERY FOLLOWED BY TRADITIONAL SALPINGECTOMY ONCE THE DEVICES HAVE BEEN FREED FROM THE CORNUA. THE PATIENT'S DESIRE FOR STERILIZATION AND THE EXPERIENCE OF THE SURGEON WILL INDIVIDUALIZE THE APPROACH. ESSURE IS A POPULAR METHOD OF MINIMALLY INVASIVE STERILIZATION WITH A 5-YEAR EFFICACY OF 99.8% AND 96-99% PATIENT SATISFACTION. PLACEMENT IS WELL-TOLERATED IN THE OFFICE AND OFFERS A COST SAVINGS OVER LAPAROSCOPIC STERILIZATION, WHILE ALSO AVOIDING THE RISKS OF GENERAL ANESTHESIA. NICKEL ALLERGY IS THE MOST COMMON METAL ALLERGY WITH A PREVALENCE OF 18.8% OF FEMALES IN THE US. SELF- REPORTED NICKEL ALLERGY IS A POOR INDICATOR OF TRUE ALLERGY AS FEWER THAN 60% OF THOSE REPORTING WILL HAVE A PATCH CONFIRMED NICKEL ALLERGY. PATCH TESTING IS THE GOLD STANDARD FOR DIAGNOSING A NICKEL ALLERGY, BUT IT IS NOT A RELIABLE PREDICTOR OF CLINICALLY SIGNIFICANT REACTIONS. AUTHORS AGREE THAT NICKEL ALLERGY IS NOT A CONTRAINDICATION TO ESSURE PLACEMENT. ADDITIONAL CASES: 2014-068089 AND 2014-070630. COMPANY CAUSALITY COMMENT: THIS MEDICAL LITERATURE CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO DEVELOPED SYSTEMIC CONTACT DERMATITIS DUE TO NICKEL COMPONENT OF ESSURE DEVICE. THE INSERTS WERE SURGICALLY REMOVED, 18 WEEKS AFTER THEIR PLACEMENT, AND SHE RECOVERED FROM THE EVENT. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE DEVICE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 21-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00957	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 8/6/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR PERMANENT CONTRACEPTION. THE CONSUMER EXPERIENCED BLEEDING FOR 4 MONTHS AFTER ESSURE INSERTION. SHE WAS ADMITTED TO HOSPITAL ABOUT ONE MONTH AFTER ESSURE INSERTED ((B)(6) 2013) DUE TO BLEEDING EVEN WITH INTERCOURSE. EVEN IF SHE HAD SLOW SEX IT FELT LIKE PULLING HER INSIDES OUT (AS REPORTED). SHE WENT TO THE EMERGENCY ROOM SEVERAL TIMES DUE PAIN AND WAS TREATED WITH TRAMADOL. SHE HAD IRREGULAR SPOTTING STILL - SHE SPOTTED ON (B)(6) 2015 AND IT LASTED ONE DAY. SHE WAS IN CONSTANT PAIN AND CRAMPING, INCLUDING SEVERE AND CONSTANT STOMACH PAIN. SHE SAID SHE COULD ALSO BLEED WITH A BOWEL MOVEMENT AND SOMETIMES SHE WOULD SLEEP AND IT WOULD QUIT. SHE ALSO STATED SHE HAD AN OVARIAN CYST RUPTURE. THE CONSUMER WANTED ESSURE REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE MOTH LATER WAS ADMITTED TO HOSPITAL DUE TO BLEEDING. THIS BLEEDING OCCURRED FOR 4 MONTHS. SHE ALSO BLED WITH BOWEL MOVEMENT AND PRESENTED OVARIAN CYST RUPTURE. THESE EVENTS, SEEN AS GENITAL BLEEDING AND HAEMATOCHEZIA AND OVARIAN CYST RUPTURE, ARE SERIOUS DUE TO MEDICAL IMPORTANCE. GENITAL BLEEDING IS LISTED WHILE THE OTHER EVENTS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, GIVEN COMPATIBLE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY BETWEEN BLEEDING AND ESSURE USE IS ASSESSED AS RELATED AND SINCE THE CONSUMER WAS HOSPITALIZED DUE TO THIS BLEEDING, THIS CASE IS REGARDED AS INCIDENT. REGARDING

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HAEMATOCHEZIA AND OVARIAN CYST RUPTURE, CONSIDERING THAT ESSURE ACTS LOCALLY IN FALLOPIAN TUBES, CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND SUSPECT INSERT USE IS VERY UNLIKELY. OTHER NON-SERIOUS EVENTS WERE INFORMED. TECHNICAL ASSESSMENT AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00958	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64471

Single Use: Y
Implant Date (E6): 7/17/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 21-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015; LOT NUMBER USED WAS C64471. THE PHARMACIST REPORTED THE EVENT OCCURRED IN THE OPERATING ROOM AND DURING PLACEMENT; THE LEFT INSERT WAS NORMALLY INSERTED AND DURING RELEASE, LEFT INSERT BROKE AT THE FIFTH COIL LEVEL AND FLOATED IN CAVITY. THERE WAS NO CAUSE RELATED TO THE PATIENT THAT COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT OF ESSURE WAS NOT PERFORMED AND THE PROCEDURE OF INSERTION STOPPED. THE CONSEQUENCES REPORTED WERE: DOUBT ABOUT OBTURATION OF FALLOPIAN TUBE AND OPERATING TIME EXTENDED. FOLLOW UP INFORMATION RECEIVED ON 26-AUG-2015: THE (B)(4) NUMBER FOR THIS REPORT IS (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE, AT RELEASE, LEFT INSERT BROKE AT THE FIFTH COIL LEVEL AND FLOATED IN CAVITY. THE INSERTION PROCEDURE WAS STOPPED. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE, MOST OFTEN DURING DIFFICULT INSERTIONS. IN THE PRESENT CASE, THE LEFT INSERT WAS NORMALLY INSERTED BUT DURING RELEASE IT BROKE AT THE FIFTH COIL LEVEL. SINCE THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION

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THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 15-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: AS OF 9/02/2015, SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00959	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): 8/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS000W5

Single Use: Y
Implant Date (E6): 8/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 LOT NUMBER CS000W5 (SECOND UNIT WAS USED DURING PROCEDURE BUT LOT NUMBER WAS NOT PROVIDED) FOR CONTRACEPTION. SHE WAS NOT PREGNANT. DURING INSERTION, THE RIGHT SIDE WAS PLACED WITHOUT DIFFICULTY. LEFT SIDE, DEPLOYED DEVICE AND END OF DELIVERY CATHETER BROKE OFF AND WAS STUCK IN PATIENT. THE CATHETER WAS NOT REMOVED. ON (B)(6) 2015, THE HCP WAS PLANNING ON INSERTING A DEVICE IN THE RIGHT SIDE (AS REPORTED); FLAT PLATE X-RAY WAS DONE AND SHOWED THAT THERE WAS ALREADY A DEVICE IN THE RIGHT SIDE (DEVICES LOCATED IN BOTH SIDES). THE BROKEN CATHETER WAS REMOVED. NO ADDITIONAL DEVICES WERE INSERTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, END OF DELIVERY CATHETER BROKE OFF AND WAS STUCK IN PATIENT. SEVEN DAYS LATER, THE BROKEN CATHETER WAS REMOVED BY THE PHYSICIAN. THE REPORTED EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED; HOWEVER SINCE THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ALTHOUGH THE INTERVENTION FOR CATHETER REMOVAL WAS NOT SPECIFIED; SINCE PHYSICIAN STATED THE CATHETER WAS STUCK IN THE PATIENT, A SURGICAL PROCEDURE (HYSTEROSCOPY OR SURGERY) WAS PROBABLY REQUIRED. THEREFORE, THIS CASE WAS REGARDED AS INCIDENT. FOLLOW-UP INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: (B)(4). FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00960	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 20-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AROUND 2 OR 3 YEARS FROM THE TIME OF THIS REPORT. IN (B)(6) 2015, THE PATIENT WENT TO THE GYNECOLOGIST DUE TO PAIN COMPLAINTS; THE GYNECOLOGIST USED A HYSTEROSCOPE TO CHECK WHAT WAS GOING ON AND NOTICED THAT ONE ESSURE WAS IN THE UTERUS AND THE OTHER WAS STUCK OUT TOO FAR FROM THE OVIDUCT. THE ESSURE LOCATED IN THE UTERUS WAS REMOVED AND THE OTHER ESSURE WAS REMOVED WITH A TANG. BOTH WERE REMOVED DURING CHECK WITH THE HYSTEROSCOPE. THE GYNECOLOGIST WAS NOT COMPLETELY SURE IF THE ESSURE THAT WAS IN THE OVIDUCT WAS REMOVED COMPLETELY. IT APPEARED THAT A SMALL PIECE REMAINED BEHIND, BUT THE PHYSICIAN WILL NOT CHECK THAT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS SUBMITTED TO A HYSTEROSCOPY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION DUE TO PAIN COMPLAINTS. THE HYSTEROSCOPY SHOWED ONE ESSURE WAS IN THE UTERUS AND THE OTHER WAS STUCK TOO FAR OUT OF THE OVIDUCT. THESE INSERTS WERE REMOVED; HOWEVER PHYSICIAN WAS NOT SURE IF THE ESSURE IN OVIDUCT WAS REMOVED COMPLETELY; IT APPEARED THAT A SMALL PIECE REMAINED BEHIND. THESE EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION TO UTERUS OR DISLOCATION INTO FALLOPIAN TUBE OR TO PERITONEAL CAVITY. IN THIS PARTICULAR CASE, 2 TO 3 YEARS AFTER ESSURE INSERTION, ONE INSERT WAS FOUND EXPELLED TO UTERUS AND THE OTHER WAS DISLOCATED WITHIN THE FALLOPIAN TUBE AT HYSTEROSCOPY. ALTHOUGH THE EXACT MECHANISM OF THESE EVENTS IS UNKNOWN; GIVEN

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THEIR NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THE PHYSICIAN ALSO STATED HE REMOVED BOTH INSERTS DURING HYSTEROSCOPY; HOWEVER HE SUSPECTED ONE INSERT WAS NOT COMPLETELY REMOVED (REGARDED AS A SUSPICION OF DEVICE BREAKAGE). ONCE ESSURE IS PLACED, HYSTEROSCOPIC INSERT REMOVAL SHOULD NOT BE PERFORMED UNLESS 18 OR MORE TRAILING COILS ARE SEEN INSIDE THE UTERINE CAVITY. ATTEMPTED REMOVAL WITH LESS THAN 18 TRAILING COILS MAY RESULT IN FRACTURED INSERT, FALLOPIAN TUBE PERFORATION OR OTHER INJURY. ALTHOUGH DEVICE BREAKAGE WAS NOT CONFIRMED AT THE TIME OF THIS REPORT; IT WAS CONSIDERED AS RELATED TO THE SUSPECT INSERT AS IT WAS REPORTED IN ASSOCIATION WITH ESSURE REMOVAL. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS RETURNED AND NO BATCH NUMBER WAS PROVIDED IT WAS NOT POSSIBLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

PTC (PRODUCT TECHNICAL COMPLAINT) RESULT RECEIVED ON 11-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00961	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/29/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) CONSUMER IN UNITED STATES ON 19-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. SHE REPORTED SHE BLEED FOR ONE YEAR FOLLOWING THE INSERTION. SHE TOOK 10 DIFFERENT BIRTHS CONTROLS THAT DID NOT HELP HER. ON AN UNSPECIFIED DATE, SHE HAD AN ABLATION PERFORMED; SHE REPORTED THE PHYSICIAN PUT A HOLE IN HER UTERUS. AT TIME OF THE REPORT, SHE STATED SHE START TO BLEED 3-4 DAYS BEFORE SHE GOT HER PERIOD AND ALSO HAD CRAMPING. SHE REPORTED THAT HER HSG (HYSTEROSALPINGOGRAM) TEST SHOWED THE TUBES COMPLETELY BLOCKED. PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO BLED FOR ONE YEAR FOLLOWING THE INSERTION OF ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT). SHE WAS SUBMITTED TO AN ENDOMETRIAL ABLATION; ACCORDING TO HER PHYSICIAN PUT A HOLE IN HER UTERUS DURING THIS PROCEDURE. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, THE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE EVENT WAS POSITIVE AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED UTERINE PERFORATION; SINCE IT OCCURRED IN ASSOCIATION WITH THE ABLATION PROCEDURE; IT WAS CONSIDERED AS UNRELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REPORTED ENDOMETRIAL ABLATION (REQUIRED INTERVENTION) FOR BLEEDING'S TREATMENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 02-DEC-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00962	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/11/2011
Explant Date (E7): 2/4/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0636, AWARENESS DATE 19-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. ON (B)(6) 2015 ESSURE WAS REMOVED. THE DOCTOR LEFT FRAGMENTS OF ESSURE BEHIND IN HER UTERUS WHEN HE REMOVED THE DEVICE. SHE HAD HER COILS BREAK CAUSING HEAVY BLEEDING AND PAIN. SHE WAS GETTING READY FOR HER 2ND SURGERY, A HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ABOUT 3 YEARS AND 2 MONTHS AFTER ESSURE INSERTION, SHE HAD IT REMOVED. SHE HAD HER COILS BREAK, DR LEFT FRAGMENTS OF ESSURE BEHIND IN HER UTERUS WHEN HE REMOVED THE DEVICE CAUSING HEAVY BLEEDING AND PAIN. SHE WAS GETTING READY FOR HER 2ND SURGERY, A HYSTERECTOMY. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE REMOVAL WHICH CAUSED HEAVY BLEEDING AND PAIN, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 14-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00963	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 9/8/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0099, AWARENESS DATE 19-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED: I AM WRITING TO YOU TO LET YOU KNOW WHAT ESSURE DID TO ME. I WAS A HEALTHY STRONG WOMAN PRIOR TO HAVING ESSURE. SOON AFTER IMPLANTATION OF ESSURE I STARTED FEELING A SMALL PAIN HERE AND ANOTHER THERE. ONE DAY, WHILE AT WORK MY WHOLE BODY BEGAN TO HURT SO BAD THAT I WAS UNABLE TO WALK, TALK OR MOVE AND WAS RUSHED TO THE ER (EMERGENCY ROOM). AFTER NUMEROUS TESTS THAT NIGHT NOTHING WAS FOUND BE THE SOURCE OF THIS UNBEARABLE PAIN. SOON ER VISITS FOR THE UNEXPLAINED BODY PAIN BECAME THE NORM AND ALL VISITS FOR PAIN CONTROL ALL ENDED THE SAME WITH THE DOCTOR UNABLE TO LOCATE THE SOURCE AND LOOKING AT ME AS IF I WAS A PILL SEEKER OR WORSE AN ADDICT LOOKING FOR MY NEXT PILL. MY DOCTOR FINALLY DIAGNOSED ME WITH WHAT WAS BELIEVED TO BE FIBROMYALGIA. IN THE (B)(6) 2014, I CONSULTED THE DOCTOR WHO HAD IMPLANTED ME WITH THE DEVICE AND DESCRIBED THE SYMPTOMS I HAD BEEN EXPERIENCING. ON (B)(6) 2014 I HAD A COMPLETE HYSTERECTOMY. EVER SINCE I GOT ESSURE OUT OF MY BODY I CAN HONESTLY SAY I FEEL BETTER THAN I HAVE IN A REALLY LONG TIME BUT I STILL HAVE A LOT OF LONG-TERM EFFECTS THAT WILL NEVER COMPLETELY GO AWAY. THE ACHES I HAVE ARE STILL CONSIDERED FIBROMYALGIA, BUT I AM CURRENTLY BEING TESTED TO SEE IF I HAVE ANOTHER AUTO-IMMUNE DISEASE CALLED LUPUS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) INSERTED AND EXPERIENCED UNBEARABLE PAIN; HER WHOLE BODY BEGAN TO HURT. SHE WAS SUBMITTED TO A HYSTERECTOMY AND THE EVENT IMPROVED. CURRENTLY SHE IS BEING TESTED TO SEE IF SHE HAS ANOTHER AUTO IMMUNE DISEASE CALLED LUPUS. ONLY PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER STATED HER DOCTOR BELIEVED SHE HAD FIBROMYALGIA AND WAS ALSO TESTING HER FOR LUPUS. THESE CONDITIONS (CONSIDERED AS UNRELATED TO ESSURE DUE TO THEIR NATURE) COULD BE ALTERNATIVE EXPLANATIONS FOR CONSUMER'S PAIN. HOWEVER, AS SHE IMPROVED AFTER DEVICES REMOVAL BY HYSTERECTOMY; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00964	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/23/2010
Explant Date (E7): 9/23/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0679, # FDA-2014-N-0736-0810 AWARENESS DATE 19-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. ADDITIONAL INFORMATION WAS RECEIVED ON 28-AUG-2015. SINCE INSERTION, SHE FELT SICK ALL THE TIME, COULDN'T LOSE WEIGHT, EXPERIENCED MIGRAINE, VERTIGO, NAUSEA, PELVIC PAIN, CHRONIC FATIGUE, METALLIC TASTE ON MOUTH, PAIN ALL THE TIME, MUCH BLOATING AND MOOD CHANGES. IN (B)(6) 2014 SHE HAD ESSURE REMOVED AND SINCE THEN HER PAIN WAS GONE AND SHE LOST MORE THAN TEN POUNDS AND WAS FEELING FULL OF ENERGY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. SHE WAS SUBMITTED TO A HYSTERECTOMY AND HER PAIN WAS GONE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED AFTER ESSURE INSERTION AND IMPROVED WITH DEVICE REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00965	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0662, # FDA-2014-N-0736-0015, AWARENESS DATE 19-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. SHE LOST MONTHS OF HER LIFE DUE TO DEBILITATING PAIN, FATIGUE, ANXIETY, DECLINING HEALTH AND FINANCIAL STRAIN AFTER UNDERGOING THE ESSURE PROCEDURE. HER EXPERIENCE WITH ESSURE HAS ULTIMATELY RESULTED IN SURGERY COSTING THOUSANDS OUT-OF-POCKET TO REMOVE THE ESSURE DEVICES. SHE SUFFERED THROUGH MONTHS OF DOWN-TIME, MANY ER (EMERGENCY ROOM) AND DOCTORS VISITS, AND STRAIN ON HER FAMILY DUE TO THE DEBILITATING SIDE-EFFECTS SHE BEGAN EXPERIENCING AFTER INSERTION OF THE COILS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEBILITATING PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT AFTER UNDERGOING THE ESSURE PROCEDURE. SHE HAD ESSURE DEVICES REMOVED. GIVEN A SUGGESTIVE TEMPORAL RELATIONSHIP AND CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT

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TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00966	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0671, AWARENESS DATE 19-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. SHE EXPERIENCED CONSTANT PAIN AND 2 PERIODS A MONTH. SHE UNDERWENT A PARTIAL HYSTERECTOMY TO HAVE ESSURE REMOVED. POST-SURGERY SHE LOST 30 LBS AND DROPPED THE ANTI-DEPRESSANT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT PAIN. SHE WAS SUBMITTED TO A HYSTERECTOMY TO HAVE ESSURE REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED AFTER ESSURE INSERTION. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION THE NON-SERIOUS EVENT 2 PERIODS A MONTH WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00967	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 5/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0033, AWARENESS DATE 14-AUG-2015). IT REFERS TO A FEMALE CONSUMER ON UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN 2011. SHE STATED THAT PROCEDURE WAS VERY PAINFUL. FOUR MONTHS LATER SHE WAS HOSPITALIZED WITH AURA MIGRAINE. IN 2012 JOINT ISSUES SET IN AND NEEDED CORTISONE SHOTS IN BACK BAND SHOULDER. IN 2013 THE STABBING PAIN BEGAN ONE DAY WHEN SHE BENT DOWN TO PICK UP SOMETHING FROM THE FLOOR. SINCE THAT DAY, HER BELLY SWELLED SO MUCH THAT SHE LOOKED 8 MONTHS PREGNANT AND SHE STARTED SUFFERING FROM VERTIGO. IN 2014, SHE STARTED HAVING OF BACTERIAL VAGINOSIS; NECROTIC TISSUE WAS BEING EXPELLED OUT OF HER BODY AND THE SMELL WAS HORRIFIC. ON (B)(6) 2014 IT WAS DIAGNOSED THAT BOTH COILS MIGRATED INTO HER UTERUS AND A RARE STAGE 4 LARGE B CELL UTERINE LYMPHOMA IN THE AREAS OF THE COILS. SHE SPENT THE REMAINDER OF LAST YEAR IN AGGRESSIVE CHEMOTHERAPY 6 (5 DAY CONTINUOUS INFUSIONS - IN HOSPITAL EVERY 21 DAYS) THEN RADIATION. IN (B)(6) 2015, COMPLETE HYSTERECTOMY TO REMOVE EMBEDDED COILS WAS DONE; ONCE THE COILS WERE REMOVED NO MORE MIGRAINES, NO PRESSURE IN HER HEAD NO VERTIGO AND LESS JOINT PAIN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FOUR MONTHS AFTER INSERTION SHE WAS HOSPITALIZED WITH AURA MIGRAINE. ABOUT 3 YEARS LATER, BOTH COILS MIGRATED INTO HER UTERUS, NECROTIC TISSUE WAS BEING EXPELLED OUT OF MY BODY AND THE SMELL WAS HORRIFIC AND A RARE

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STAGE 4 LARGE B CELL UTERINE LYMPHOMA IN THE AREAS OF THE COILS WERE DIAGNOSED. ALL THESE EVENTS ARE SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR THE EVENT BOTH COILS MIGRATED INTO HER UTERUS (SEEN AS PARTIAL EXPULSION OF DEVICE) WHICH IS LISTED. IN THIS CASE, CONSUMER HAD TO UNDERGONE A COMPLETE HYSTERECTOMY IN ORDER TO REMOVE THE ESSURE COILS. ALTHOUGH THE EXACT DATE AND MECHANISM OF PARTIAL EXPULSION OF DEVICE WERE NOT KNOWN, CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, ALTHOUGH TEMPORAL RELATIONSHIP IS SUGGESTIVE, CONSIDERING THE PATHOPHYSIOLOGY AND THAT A CONTRIBUTORY ROLE OF ESSURE IS UNLIKELY GIVEN ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 13-SEP-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00968	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0796-0371, AWARENESS DATE 20-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT OVER 5 YEARS AGO, IT WAS PUSHED ON HER AS A SAFER EASIER ALTERNATIVE TO HAVING HER TUBES TIED. IT HAS CAUSED NOTHING BUT PROBLEMS. AFTER IT WAS IMPLANTED, SHE HAS EXPERIENCED A MYRIAD OF PROBLEMS RANGING FROM PELVIC PAIN, HEAVY TWO WEEK LONG PERIODS TO PASSING CLOTS THE SIZE OF BASEBALL'S. SHE ALSO EXPERIENCED BACK PAIN, PAINFUL INTERCOURSE, BLOATING BEYOND BELIEF, AND MORE. SHE WAS (B)(6) AND NOW FACING A HYSTERECTOMY TO GET THE THINGS OUT OF HER. NOT TO MENTION THE MISCARRIAGES SHE HAS HAD BECAUSE THE IMPLANTS WERE NOT EVEN PREVENTING PREGNANCY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. SHE GOT PREGNANT AND HAD MISCARRIAGES. A HYSTERECTOMY WAS PERFORMED. MISCARRIAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. ALL THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. ALSO, PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. THEREFORE A CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED EVENTS PREGNANCY AND PELVIC PAIN CANNOT BE EXCLUDED. SPONTANEOUS ABORTION IS THE MOST COMMON

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COMPLICATION OF EARLY PREGNANCY. RISK FACTORS INCLUDE MATERNAL AGE, PREVIOUS SPONTANEOUS ABORTION, SMOKING, LOW FOLATE LEVEL, UTERINE ABNORMALITIES, FETAL CHROMOSOMAL ABNORMALITIES, MATERNAL CHRONIC DISEASE (E.G. POLYCYSTIC OVARY SYNDROME AND THYROID DYSFUNCTION) AND MATERNAL INFECTIONS. IN THIS CASE, SINCE NO INFORMATION ON GESTATIONAL AGE WAS PROVIDED AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00969	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0274, AWARENESS DATE 20-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT NONE OF THEY SIGNED UP FOR THE POSSIBILITY OF LOSING BODY PARTS. ONE WOMAN GOING THROUGH A HYSTERECTOMY DUE TO A BIRTH CONTROL DEVICE WAS ONE TOO MANY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE UNDERWENT A HYSTERECTOMY DUE TO A BIRTH CONTROL DEVICE. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, SINCE REPORTER REGARDED THE EVENT AS A CONSEQUENCE OF ESSURE USE, COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00970	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/17/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AT A FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-0577) IN UNITED STATES ON 20-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. CONSUMER STATED THAT SHE EXPERIENCED PROBLEMS AFTER PROBLEMS AND FINALLY IN 2014 SHE GOT EVERYTHING TAKEN OUT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 AND HAD PROBLEMS AFTER PROBLEMS. IN 2014 SHE GOT EVERYTHING TAKEN OUT. THE REPORTED EVENT (INTERPRETED AS MEDICAL DEVICE REMOVAL) WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH THE PROBLEMS WERE NOT SPECIFIED, THEY OCCURRED AFTER ESSURE INSERTION AND RESULTED IN DEVICE REMOVAL. THEREFORE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL OCCURRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00971	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-0668) IN UNITED STATES ON 20-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN (B)(6) 2010. SINCE ESSURE INSERTION, HER MENTAL HEALTH DRASTICALLY CHANGED AND HER PHYSICAL HEALTH BEGAN TO DWINDLE SHORTLY AFTER. SINCE 2010 UNTIL NOW SHE GAINED 100 LBS, EXPERIENCED JOINT AND MUSCLE PAIN DAILY, MIGRAINES, MOOD SWINGS, HAIR LOSS, ECZEMA, SWELLING, LACK OF ENERGY, LOSS OF INTEREST, HYPOTHYROID, GALLBLADDER DISEASE, HIATAL HERNIA, GERD, POLYCYSTIC OVARIES, FATIGUE, STRESS, IRREGULAR MENSTRUATION, OBESITY, ESOPHAGITIS, VITAMIN D DEFICIENCY, SLEEP APNEA, OLIGURIA AND BRADYCARDIA. BECAUSE OF THOSE SYMPTOMS SHE WAS OFF AND ON ANTIDEPRESSANTS, SHE HAD HER GALLBLADDER REMOVED, HIATAL HERNIA REPAIRED WITH NISSEN FUNDOPLICATION, A GANGLION CYST REMOVED FROM HER WRIST AND A FULL HYSTERECTOMY TAKING EVERYTHING EXCEPT ONE OVARY. SHE WAS ON THYROID MEDICATION AND A VITAMIN D SUPPLEMENT. SHE STATED THAT NICKEL ALLERGY TESTING SHOULD BE A REQUIREMENT PRIOR TO IMPLANTATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED IRREGULAR MENSTRUALS. SHE HAD HER GALLBLADDER REMOVED, HIATAL HERNIA REPAIRED WITH NISSEN FUNDOPLICATION, A GANGLION CYST REMOVED FROM HER WRIST AND A FULL HYSTERECTOMY TAKING EVERYTHING EXCEPT ONE OVARY. IRREGULAR MENSTRUALS IS A LISTED EVENT IN THE

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REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE UNLISTED. ALL THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. THESE EVENTS OCCURRED SINCE ESSURE INSERTION. WITH REGARDS TO THE EVENT IRREGULAR MENSTRUALS, SINCE A TEMPORAL RELATIONSHIP IS IMPLIED AND GIVEN THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, BASED ON THE PATHOPHYSIOLOGY AND CONSIDERING THAT A CONTRIBUTORY ROLE OF ESSURE IS UNLIKELY GIVEN ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00972	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0672, AWARENESS DATE 20-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT THIS WAS THE WORST DEVICE EVER. SHE BLED FOR MONTHS AT A TIME, HORRIBLE PELVIC PAIN TO THE POINT WHERE SHE LOST HER JOB, NONSTOP CRAMPING. SHE WAS CONSTANTLY TIRED, NO ENERGY WHAT SO EVER COULD BARELY MOVE UNTIL SHE HAD THEM REMOVED ALONG WITH HER TUBES. SHE ALSO REPORTED THAT SHE COULD NOT HAVE SEX AT ALL, IT WAS TOO PAINFUL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HORRIBLE PELVIC PAIN/CRAMPING AND BLEEDING FOR MONTHS. THE DEVICES AND HER FALLOPIAN TUBES WERE REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED IN THIS CASE. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 15-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00973	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0501, AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD A TOTAL HYSTERECTOMY THIS YEAR (2015) DUE TO HEAVY BLEEDING, SEVERE CRAMPING, EXTREME HEADACHES, HYPERTENSION, AND LOTS OF WEIGHT GAIN. SHE WAS FOUND TO HAVE ANDYOMINOS, CYST AND POLYPS IN HER UTERUS. SINCE HER HYSTERECTOMY SHE HAS LOST 36 POUNDS, NO LONGER SUFFER FROM ALL THE ABOVE SYMPTOMS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD SEVERE CRAMPING AND HEAVY BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE UNDERWENT A HYSTERECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER HAD UTERINE POLYPS, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR HER BLEEDING. NEVERTHELESS, AS THE CONSUMER RECOVERED WITH DEVICES REMOVAL; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 14-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00974	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0703, AWARENESS DATE 21-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN (B)(6) 2012. SHE WAS IMPLANTED WITH ESSURE IN (B)(6) 2012. SHE NEEDED TO GET OFF BIRTH CONTROL DUE TO AGE AND INCREASE OF MIGRAINES. SHE CHOSE ESSURE FOR THE QUICK RECOVERY. SHE HAD THE PROCEDURE DONE. SHE HAD EPISODES OF FLU-LIKE SYMPTOMS AND SHE CAN BARELY GET OUT OF BED. HER PERIODS HAVE GOTTEN MORE FREQUENT (FROM 30 DAYS BETWEEN TO NOW 21 DAYS), THE DURATION OF THEM HAS LENGTHENED (FROM 4 DAYS TO 7), CLOTS ARE MORE FREQUENT AND LARGER IN SIZE, AND THE PELVIC PAIN HAS INCREASED. SHE ALSO HAD PAIN THAT SHOT TO HER ANUS AND DOWN HER LEGS INTO HER HIPS. HER HIPS GIVE OUT ON HER SOMETIMES WHEN SHE STANDS UP. SHE HAD PAIN ON BOTH SIDES IN THE MIDDLE OF HER BACK. SCIATICA NERVE ISSUES MOSTLY AROUND HER MONTHLY CYCLE. SHE HAS BEEN NOTICING ISSUES WITH HER STRENGTH IN HER HANDS AND GRIPPING THINGS. HER HYSTERECTOMY IS SCHEDULED IN ONE WEEK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN (B)(6) 2012. SHE EXPERIENCED SERIOUS PELVIC PAIN AMONGST OTHER NON-SERIOUS EVENTS AND HER HYSTERECTOMY IS SCHEDULED IN ONE WEEK. PELVIC PAIN MAY OCCUR DURING DEVICE THERAPY. DUE TO IMPLIED TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE

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EXPLANATION, THIS EVENT IS CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00975	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0704, AWARENESS DATE 21-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. SHE HAD TO HAVE A HYSTERECTOMY DUE TO THE PAIN AND SUFFERING IT CAUSED HER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED AND SHE HAD TO HAVE A HYSTERECTOMY DUE TO THE PAIN (INTERPRETED AS PELVIC PAIN). THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. IT IS CONSIDERED RELATED TO THE DEVICE. THIS CASE IS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00976	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0089, AWARENESS DATE 21-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT ESSURE WAS THE REASON WHY SHE HAD A HYSTERECTOMY AT (B)(6). IT BROKE DURING A REMOVAL ATTEMPT AND LEFT FRAGMENTS EMBEDDED IN THE UTERINE WALL. SHE WAS ALLERGIC TO NICKEL AND WAS NOT WARNED ABOUT IT. SHE WAS TOLD IT WOULD NOT POSE A PROBLEM. IT FLARED UP HER IMMUNE SYSTEM, CAUSING HER SYSTEMIC PAIN, INFLAMMATION, AND NOW SHE IS IN THE PROCESS OF BEING DIAGNOSED WITH MS (INTERPRETED AS MULTIPLE SCLEROSIS). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALLERGIC TO NICKEL. IT BROKE DURING A REMOVAL ATTEMPT (SEEN AS DEVICE BREAKAGE) AND LEFT FRAGMENTS EMBEDDED IN THE UTERINE WALL. IT FLARED UP HER IMMUNE SYSTEM AND SHE IS IN THE PROCESS OF BEING DIAGNOSED WITH MS (MULTIPLE SCLEROSIS). ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ALLERGIC TO NICKEL, DEVICE BREAKAGE AND LEFT FRAGMENTS EMBEDDED IN THE UTERINE WALL ARE LISTED WHILE THE OTHER EVENTS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER UNDERWENT A HYSTERECTOMY. CONSIDERING THAT ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY AND ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY, A CAUSAL RELATIONSHIP BETWEEN ALLERGY TO NICKEL AND SUSPECT INSERT CANNOT BE EXCLUDED. AS THE DEVICE

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BREAKAGE OCCURRED DURING ESSURE REMOVAL PROCEDURE AND CONSEQUENTLY LEFT FRAGMENTS WERE EMBEDDED IN THE UTERINE WALL, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, BASED ON THE PATHOPHYSIOLOGY AND GIVEN ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 14-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00977	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0461, # FDA-2014-N-0736 AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. SHE EXPERIENCED SEVERE BLEEDING, CRAMPS, HAIR LOSS, HEADACHES, ACNE, WEIGHT GAIN, BLEED VISION, SHORT TERM MEMORY LOSS. SHE WAS 34 AND HAD TO GET A TOTAL HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED. SHE EXPERIENCED SEVERE GENITAL BLEEDING AND PELVIC CRAMPING AMONGST OTHER NON-SERIOUS EVENTS. BOTH EVENTS MAY OCCUR DURING DEVICE THERAPY AND CONSIDERING LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, THEY ARE CONSIDERED RELATED TO ESSURE. SINCE AN INTERVENTION (HYSTERECTOMY) WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 14-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00978	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/17/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5033629) IN UNITED STATES ON 10-FEB-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN/ HURTING TOO BAD, BLOATING, BLEEDING, SWOLLEN OVARIES, VISION PROBLEMS, HAIR LOSS, CONSTIPATION, SHARP STABBING PAINS IN MY STOMACH, AND ESSURE ARE NOT IN THE CORRECT POSITION. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. ON (B)(6) 2011 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SINCE ESSURE INSERTION, THE CONSUMER HAS BEEN EXPERIENCING ON AND OFF PROBLEMS, INCLUDING PAIN, BLOATING, BLEEDING, SWOLLEN OVARIES, VISION PROBLEMS, HAIR LOSS, CONSTIPATION, SHARP STABBING PAINS IN STOMACH AND HURTING TOO BAD. SEVERAL ULTRASOUNDS WERE PERFORMED AND CLEARLY SHOWED THAT ESSURE IMPLANTS WERE NOT IN THE CORRECT POSITION. THE OUTCOME OF THE EVENT ESSURE ARE NOT IN THE CORRECT POSITION WAS NOT RECOVERED / NOT RESOLVED. THE OUTCOME OF THE EVENTS PAIN/ HURTING TOO BAD, BLOATING, BLEEDING, SWOLLEN OVARIES, VISION PROBLEMS, HAIR LOSS, CONSTIPATION, AND SHARP STABBING PAINS IN MY STOMACH WAS UNKNOWN. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS RELATED. FOLLOW UP INFORMATION RECEIVED ON 21-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0060, AWARENESS DATE 21-AUG-2015). THE CONSUMER IS (B)(6). SHE HAD ESSURE INSERTED IN (B)(6) 2011 AND SHE HAD MANY COMPLICATIONS; CYSTS, ABDOMINAL BLOATING, PAIN DURING INTERCOURSE, AND THE MOST SEVERE OCCURRED IN 2015, PARTS OF HER COIL CAME OUT BY VAGINA. HER PHYSICIAN DID AN X-RAY AND ESSURE

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SEEMED TO BE IN PLACE. SHE ALSO REPORTED SHE BECAME PREGNANT 3 MONTHS AFTER PART OF THE COIL CAME OUT, AND IT ENDED IN MISCARRIAGE. SHE STATED THAT ESSURE IS NOT SAFE AND SHE EXPERIENCED HAIR LOSS, WEIGHT GAIN ONLY IN THE ABDOMINAL CAVITY, NUMEROUS VAGINAL INFECTIONS AND PRECANCEROUS CELLS; ALL STEMMING FROM ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ULTRASOUNDS SHOWED ESSURE IMPLANTS WERE NOT IN THE CORRECT POSITION; ADDITIONALLY PARTS OF HER COIL CAME OUT BY VAGINA (REGARDED AS DEVICE BREAKAGE, FOLLOWED BY EXPULSION OF BROKEN PIECES). THREE MONTHS LATER, SHE BECAME PREGNANT AND HAD A MISCARRIAGE. ONLY DEVICE BREAKAGE AND MISCARRIAGE ARE UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, CONSUMER STATED ULTRASOUND SHOWED ESSURE WAS NOT IN CORRECT POSITION. ADDITIONALLY, ONE DEVICE BROKE AND PIECES WERE EXPELLED. THESE EVENTS COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED DEVICE FAILURE (PREGNANCY). THEREFORE, CAUSALITY BETWEEN THESE EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED MISCARRIAGE; CONSIDERING IT IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY, OCCURRING IN UP TO 20% OF CLINICALLY RECOGNIZED PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION (DUE TO MATERNAL CONDITIONS AND FETAL CHROMOSOMAL ABNORMALITIES); CAUSALITY WITH ESSURE IS CONSIDERED UNLIKELY. OTHER NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS AN OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE; AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 14-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00980	BAYER HEALTHCARE LLC	9/16/2015	9/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 6/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0355, AWARENESS DATE 21-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. CONSUMER REPORTED: I HAD ESSURE IMPLANTED IN (B)(6) 2009. I WAS TOLD THAT THE COILS WERE SURGICAL STAINLESS STEEL. IMMEDIATELY AFTER IMPLANT THE DEVICE CARD WAS GIVEN TO MY HUSBAND. LT WAS THEN THAT WE DISCOVERED THAT NICKEL IS A COMPONENT; I HAVE A NICKEL ALLERGY. MY DOCTOR HAD NOT BEEN TOLD THAT NICKEL WAS A COMPONENT. THE COMPANY WAS CALLED BY MY DOCTOR AND WE WERE THEN ASSURED THAT I WOULD MOST LIKELY NOT HAVE ANY ISSUES AND THAT MY TUBES WOULD SCAR SOONER. NO ONE EVER MENTIONED THE SKIN ISSUES: I HAVE BEEN TREATED FOR YEARS WITH UNEXPLAINED RASHES AND SKIN BREAKDOWN. I HAVE HAD DEBILITATING EXHAUSTION, MENTAL FOG, WORSENING PAIN, ALOPECIA AND WEIGHT ISSUES THAT DID NOT RESPOND TO DIETARY CHANGES AND EXERCISE. OVER THE PAST 16 MONTHS, DESPITE PREVIOUSLY HAVING HAD A UTERINE ABLATION, I SUFFERED FROM WORSENING MENORRHAGIA. I CONTACTED MY GYNECOLOGIST DUE TO THE DATA THAT SUPPORTED KNOWN ISSUES WITH ESSURE AND NICKEL ALLERGIES AND THE MENORRHAGIA. I WAS SCHEDULED FOR HYSTERECTOMY. THE WEEK BEFORE MY SCHEDULED HYSTERECTOMY, I PASSED WHAT I CAN ONLY DESCRIBE AS A FOREIGN BODY FROM MY VAGINA. I TOOK A PICTURE OF IT AND SAVED IT AS A SPECIMEN THAT WAS SUBMITTED ON THE DAY OF MY SURGERY. WHEN I POSTED THE PICTURE ON THE ESSURE PROBLEMS PAGE, I WAS TOLD BY MULTIPLE PEOPLE THAT HAD PASSED SIMILAR ITEMS THAT IT APPEARED TO BE A PET FIBER. I CANNOT PROVE THAT BUT IT IS DESCRIBED IN MY PATHOLOGY REPORT. UPON HAVING MY HYSTERECTOMY ON (B)(6) 2015 IT

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WAS DISCOVERED ON SURGICAL PATHOLOGY THAT I HAVE FALLOPIAN TUBE CANCER IN THE FIMBRAE OF THE RIGHT TUBE. PRIOR TO CHOOSING PERMANENT STERILIZATION I HAD BEEN ON ORAL BC (BIRTH CONTROL) SINCE I WAS (B)(6). THAT SHOULD HAVE OFFERED ME PROTECTION FROM THIS PARTICULAR CANCER. I AM (B)(6), WHICH IS NOT EXACTLY UNHEARD OF, BUT IS CONSIDERED YOUNG FOR CANCER OF THE FALLOPIAN TUBE. THIS FINDING REQUIRED ME TO HAVE A SECOND AND MUCH MORE EXTENSIVE SURGERY TO REMOVE MY OVARIES, ALL OF THE LYMPH NODES FROM THE PARA AORTIC THROUGH ALL OF THE PELVIC NODES, AND MY OMENTUM REMOVED ON (B)(6) 2015. TWO MAJOR SURGERIES IN THE SPAN OF JUST OVER FOUR WEEKS. I AM BLESSED THAT ALL OF THE SPECIMENS FROM THE SECOND SURGERY ARE NEGATIVE FOR MALIGNANCY. HOWEVER, DUE TO THE AGGRESSIVENESS OF MY CANCER I AM SCHEDULED TO BEGIN CHEMO ON (B)(6). I HAVE BEEN OUT OF WORK SINCE (B)(6) 2015. THERE ARE NO HUMAN STUDIES ON THE EFFECT OF NICKEL THAT I AM AWARE OF, BUT IN ANIMAL STUDIES IT HAS BEEN SHOWN TO CAUSE CANCER. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD MENORRHAGIA AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. AFTER A HYSTERECTOMY FOR DEVICES REMOVAL; SHE WAS DIAGNOSED WITH FALLOPIAN TUBE CANCER IN THE FIMBRAE OF THE RIGHT TUBE. ONLY MENORRHAGIA IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABNORMAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE CONSUMER REPORTED WORSENING MENORRHAGIA (DESPITE OF HAVING UTERINE ABLATION) AFTER ESSURE INSERTION. CONSIDERING EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT; PRIMARY FALLOPIAN TUBE CARCINOMA IS AN UNCOMMON TUMOR. ITS EXACT ETIOLOGY IS UNKNOWN; HOWEVER HORMONAL, REPRODUCTIVE, AND POSSIBLY GENETIC FACTORS THOUGHT TO INCREASE ITS RISK. CONSIDERING THIS INFORMATION AND AS ESSURE IS A NON-DRUG RELEASE DEVICE WITH MECHANICAL ACTION IN FALLOPIAN TUBES; CAUSALITY IS CONSIDERED UNLIKELY. IN ADDITION, THE NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 14-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056230	BAYER HEALTH	9/16/2015	9/17/2015

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER STATED THAT SHE HAS BEEN HAVING SEVERAL PROBLEMS WITH THE ESSURE AND HAS REQUESTED THAT IT BE REMOVED AND HAS BEEN TOLD THAT SHE CANNOT HAVE IT REMOVED BY ST MARY'S HOSPITAL. IT WAS PUT IN AT (B)(6) HOSPITAL AFTER SHE HAD HER LAST CHILD. COMPLAINTS OF; REAL BAD HEADACHES, SIDE AND ABDOMINAL PAIN, DEPRESSION, VAGINAL DISCHARGE WITH AN ODOR (ALL TESTS NEGATIVE), HAIR FALLING OUT, IRREGULAR PERIODS (TWICE A MONTH), CHEST PAIN (SAW A HEART SPECIALIST AND ALL TESTS NEGATIVE) AND TINGLING SENSATION ON LEFT SIDE IN ARM AND LEG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056302		9/16/2015	9/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAVE HAD THE ESSURE MY PERIODS ARE VERY FREQUENT AND HEAVY; EVERY 15-24 DAYS LASTING 7 DAYS AT A TIME. ON (B)(6) 2015 I HAD THE ENDOMETRIAL ABLATION DONE TO TRY AND SOLVE THIS PROBLEM. I WAS BLEEDING HEAVILY 2 WEEKS POST OP BUT HAVE NOT SINCE, YET. MY MEMORY IS TERRIBLE BOTH PAST AND PRESENT. IT'S NOT LIKE WHEN YOU FORGET SOMETHING AND LATER ARE LIKE "OH YEAH I FORGOT ABOUT THAT. IT'S MORE LIKE IT WASN'T EVER THERE IN THE FIRST PLACE. FOR EXAMPLE I TOOK MY MEDICINE TWICE THE OTHER DAY AND HAVE NO RECOLLECTION WHAT SO EVER OF EVEN TAKING IT ONCE. MY HAIR FALLS OUT AND IS VERY THIN. I TAKE FOLIC ACID, BIOTIN, AND USE A PRO-BIOTIC SHAMPOO AND NOTHING SEEMS TO HELP.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00979	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/27/2014
Explant Date (E7): 2/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0092, AWARENESS DATE 21-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2014. CONSUMER REPORTED THAT SHE HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2014. IMMEDIATELY AFTER THE PROCEDURE SHE STARTED TO HAVE PROBLEMS. SHE HAD CHRONIC PELVIC PAIN AND CONSTANT BLEEDING. SHE HAD BEEN ON THE DEPO SHOT BEFORE AND DURING THIS PROCEDURE FOR AROUND 2 YEARS AND HAD NEVER HAD HER MENSTRUAL CYCLE, BUT AFTER SHE HAD THIS PROCEDURE DONE SHE BLEED FOR 3 WEEKS, THEN SHE WOULD HAVE OCCASIONAL SPOTTING THEREAFTER. ONCE SHE DID HER 3 MONTH HSG TEST, SHE WAS TOLD THAT THE LEFT SIDE WAS BLOCKED BUT THE RIGHT SIDE HAD MIGRATED, BUT HE COULDN'T TELL WHERE IT WENT. THE HSG TEST WAS EXCRUCIATINGLY PAINFUL DURING AND AFTER. SHE WAS ALSO TOLD THAT SHE WOULDN'T HAVE ANY BLEEDING AFTER THE TEST WAS DONE BUT FOR A FEW MINUTES. SHE CONTINUED TO BLEED FROM THERE ON. SO FROM THE 3 MONTH TEST ON, SHE HAD SEVERAL SYMPTOMS SUCH AS CHRONIC, STABBING PELVIC AND ABDOMINAL PAIN RADIATING TO MY LOWER BACK AND HIPS. DEPRESSION AND FEELINGS OF HOPELESSNESS, SEVERE FATIGUE, MEMORY LOSS AND BRAIN FOG AND FEELING SLUGGISH, HIGH BLOOD PRESSURE. THAT'S JUST TO NAME A FEW. SHE WAS REALLY WORRIED ABOUT THE RIGHT ESSURE FLOATING AROUND IN HER BODY SOMEWHERE, ESPECIALLY KNOWING THAT IT COULD SCAR EVERYTHING IT TOUCHED. THE PHYSICIAN DECIDED TO DO AN MRI TO TRY TO FIND THE LOCATION OF MIGRATED ESSURE. THE REPORT CAME BACK SAYING THAT IT WAS LOCATED SOMEWHERE BETWEEN HER ABDOMINAL WALL AND HER BLADDER. SHE WAS ALREADY HAVING SEVERE PELVIC PAIN FROM THE

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ESSURE, SO SHE WAS WILLING TO DO A HYSTERECTOMY TO REMOVE THEM. SHE HAD A PARTIAL HYSTERECTOMY PROCEDURE DONE ON (B)(6) 2015. AFTER SHE WOKE UP FROM SURGERY, SHE WAS TOLD THAT IT WAS A GOOD THING THAT SHE WENT AHEAD AND HAD HER UTERUS REMOVED BECAUSE THE RIGHT ESSURE HAD LODGED INTO HER COLON AND THE LEFT ESSURE WAS BARELY HANGING OFF OF THE FALLOPIAN TUBE AND WAS EMBEDDED INTO HER UTERUS. SO, NEITHER ONE OF THEM WERE IN PLACE. SINCE THE ESSURE REMOVAL SHE HAD, AT THE TIME OF REPORT, A COLON BOWEL TYPE OF ISSUE THAT THE DOCTORS WERE STILL TRYING TO FIGURE OUT, BUT MOST LIKELY FROM THE ESSURE THAT WAS LODGED INTO HER COLON FOR MONTHS BEFORE REMOVAL. BUT OTHER THINGS HAVE GONE BACK TO NORMAL SUCH AS, A FEW MONTHS AFTER REMOVAL, HER BLOOD PRESSURE FINALLY WENT BACK TO NORMAL RANGES. SHE NO LONGER SUFFERED FROM SEVERE DEPRESSION OR EXTREME FATIGUE. AND SHE FELT LIKE SHE WAS MORE ALERT THAN SHE DID WHEN SHE WAS HAVING PROBLEMS WITH MEMORY LOSS AND BRAIN FOGGINESS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMMEDIATELY AFTER INSERTION SHE HAD CHRONIC PELVIC PAIN AND CONSTANT BLEEDING FOR 3 WEEKS (INTERPRETED AS POST-PROCEDURAL BLEEDING). AT 3-MONTH HYSTEROSALPINGOGRAM (HSG), IT WAS NOTICED THAT RIGHT ESSURE HAD MIGRATED. AFTER HSG TEST, SHE CONTINUED TO BLEED FROM THERE ON (INTERPRETED AS POST PROCEDURAL BLEEDING). SHE UNDERWENT A PARTIAL HYSTERECTOMY AND DURING SURGERY IT WAS NOTICED THAT THE RIGHT COIL HAD LODGED IN HER COLON (DEVICE DISLOCATION) AND LEFT COIL WAS EMBEDDED INTO HER UTERUS (DEVICE EMBEDDED). ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND PELVIC PAIN IS ALSO SERIOUS DUE TO REQUIRED INTERVENTION. ALL THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE TEMPORAL RELATIONSHIP BETWEEN ALL EVENTS AND ESSURE THERAPY OR ESSURE PROCEDURE IS COMPATIBLE. CONSIDERING THE SUGGESTIVE TEMPORAL RELATIONSHIP, NATURE OF EVENTS AND LACK OF ALTERNATIVE EXPLANATION, ALL THESE EVENTS ARE ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING

Manufacturer Narrative (H10):

CORRECTION <17-SEP-2015>: AFTER INTERNAL REVIEW, IT WAS NOTED THAT PTC RESULT WAS RECEIVED ON 15-SEP-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF TH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00981	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2010
Explant Date (E7): 6/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0580, FDA-2014-N-0736-0015 AND FDA-2014-N-0736-0744, AWARENESS DATE 21-AUG-2015 AND 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. IN (B)(6) 2012 SHE WAS DIAGNOSED WITH BREAST CANCER AT AGE OF (B)(6). SHE REPORTED THAT IN (B)(6) 2015 SHE ENDED UP IN THE ER THINKING SHE WAS HAVING A APPENDICITIS ATTACK; AFTER HER BLOOD WORK, HER WHITE BLOOD COUNT WAS 14,17 H (RANGE 3, 98-10,04), NEUTROPHIL 82,5H (RANGE 34.0 - 71.1), LYMPHOCYTE 10.4H (RANGE 19.3-51.7), EOSINOPHILS 0.4L (RANGE 0.7-5.8), NEUTROPHIL ABSOLUTE 11.70H (RANGE 1.56-6.13), MONOCYTES ABSOLUTE 0.84H (0.24-0.36), SHE STATED SHE HAD AN BAD INFECTION. THE PHYSICIAN ORDERED A CT (COMPUTERIZED TOMOGRAM) SCAN WITH CONTRAST WHICH SHOWED ONE OF THE DEVICES HAD SLIPPED AND PUNCTURED HER UTERUS AND SHE NEEDED AN EMERGENCY SURGERY. WHEN THE PHYSICIAN GOT IN THERE TO REMOVE THE DEVICE HER STOMACH WAS FULL OF PUS AND HAD TO BE WASHED OUT 7 - 8 TIMES. THE CONSUMER STATED THAT ON HER 1 WEEK CHECK-UP THE PHYSICIAN TOLD HER HE BELIEVED HE GOT IT ALL BUT COULDN'T SAY FOR SURE. SHE REPORTED THAT FOR THE LAST 5 YEAR SHE HAD SEVERAL SIDE EFFECTS NOT KNOWING AT THE TIME WHAT WAS GOING ON UNTIL AFTER THE DEVICE WAS REMOVED AND HER SIDE EFFECTS WENT AWAY. SHE COULD SLEEP 12 HOURS AND STILL BE TIRED ALL DAY. SHE THOUGHT SHE HAD GLUTEN ISSUE AND SHE DOESN'T HAVE NOT ANYMORE SHE CAN EAT ALL THINGS FLOUR/WHEAT, SHE WAS VERY MOODY (FLY OVER THE HANDLE AT THE SMALLEST THINGS), SHE WAS NEVER ABLE TO LOSE WEIGHT OR BEING INTIMATE WITH HER HUSBAND BECAUSE IT WAS VERY PAINFUL, SHE HAD

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MIGRAINES AND LEG CRAMPS. SINCE ESSURE WAS REMOVED ALL OF THESE SIDE EFFECTS WERE GONE. SHE MENTIONED THAT THE BREAST CANCER ISSUE NO ONE COULD EXPLAIN AND AFTER RESEARCHING THE DEVICE AND SHE LEARNED THAT THE PET FIBERS HAVE BEEN KNOWN TO CAUSE CANCER; AND ALSO HAS NICKEL ALLERGY AND SHE FOUND OUT THAT IS IN THERE AS WELL. SHE WAS NEVER TESTED BEFORE THE DEVICE WAS IMPLANTED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AND HAD AN BAD INFECTION. A CT (COMPUTERIZED TOMOGRAM) SCAN WITH CONTRAST WAS PERFORMED WHICH SHOWED ONE OF THE DEVICES HAD SLIPPED AND PUNCTURED HER UTERUS (INTERPRETED AS UTERINE PERFORATION). WHEN THE PHYSICIAN GOT IN THERE TO REMOVE THE DEVICE, HER STOMACH WAS FULL OF PUS. SHE THOUGHT SHE HAD GLUTEN ISSUE AND SHE DOESN`T HAVE NOT ANYMORE SHE CAN EAT ALL THINGS FLOUR/WHEAT (COELIAC DISEASE) AND SHE HAD BREAST CANCER. ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ALL EVENTS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR THE EVENT UTERINE PERFORATION WHICH IS LISTED. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF UTERINE PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, BASED ON THE PATHOPHYSIOLOGY AND CONSIDERING THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE WAS REMOVED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00982	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2015-N-2781-0506, AWARENESS DATE 21-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2011. CONSUMER REPORTED SHE GOT ESSURE DONE IN 2011, AFTER HER SECOND CHILD WAS BORN. SHE HAD MILD DISCOMFORT FOR THE FIRST FEW WEEKS AFTER THEN SHE WAS FINE. A YEAR LATER SHE NOTICED SHE HAD GAINED 28 LBS. THEN, SHE STARTED TO GET HORRIBLE JOINT PAIN. SHE IS ALSO EPILEPTIC WHO'S SEIZURES WERE UNDER CONTROL WITH HER MEDICATION. BUT HER SEIZURES STARTED TO GET FREQUENT, HER NEUROLOGIST HAD NO EXPLANATION WHY HER ANTI CONVULSION MEDICATION WAS ALL THE SUDDEN INEFFECTIVE. IN 2013 SHE WAS CONFIRMED PREGNANT. ENDED UP IN THE EMERGENCY ROOM ONE NIGHT WITH BLEEDING, SHE HAD A MISCARRIAGE. AT THAT POINT SHE STARTED QUESTIONING ESSURE. ESPECIALLY AFTER BEING CONFIRMED THE BLOCKED AFTER PROCEDURE. IN (B)(6) 2014 SHE WENT TO HER OBSTETRICIAN ASKING FOR ESSURE REMOVAL DUE TO THE AMOUNT OF ABDOMINAL PAIN AND BLEEDING SHE CONTINUED TO HAVE. SHE HAD A HYSTERECTOMY. AFTER HER HYSTERECTOMY SHE WAS INFORMED THAT HER UTERUS WAS ENLARGED AND HER LEFT COIL HAD MIGRATED AND WAS DANGLING FROM IT. AFTER SO MUCH PAIN AND ISSUES SHE IS HAPPY TO SAY 9 MONTHS OF NOT HAVING ESSURE IN HER BODY HER JOINT PAIN IS BETTER, HER SEIZURES UNDER CONTROL AGAIN AND NO ABDOMINAL PAIN, HOWEVER SHE DOES NOW HAVE A METAL ALLERGY. SHE CANNOT WEAR JEWELRY WITHOUT BREAKING OUT NOR SHE CAN CONSUMER CANNED FOOD. IT ALSO MADE HER BREAKOUT, AND SHE GOT HORRIBLE SICK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING

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MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN, CONTINUOUS BLEEDING AND HER SEIZURES STARTED TO GET FREQUENT. SHE GOT PREGNANT AND HAD A MISCARRIAGE. A HYSTERECTOMY WAS PERFORMED AND AFTER THAT SHE WAS INFORMED THAT HER UTERUS WAS ENLARGED AND HER LEFT COIL HAD MIGRATED AND WAS DANGLING FROM IT (INTERPRETED AS DEVICE DISLOCATION). ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. SEIZURES STARTED TO GET FREQUENT AND MISCARRIED ARE UNLISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. IN THIS CASE, ABOUT 1 YEAR AFTER ESSURE INSERTION SHE EXPERIENCED SEIZURES. PREGNANCY WAS CONFIRMED ABOUT 2 YEARS LATER AND ABDOMINAL PAIN AND CONTINUOUS BLEEDING 3 YEARS LATER. THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN. ALTHOUGH THE POSITIVE TEMPORAL RELATIONSHIP FOR THE EVENTS SEIZURES AND MISCARRIED ARE IMPLIED, A CONTRIBUTORY ROLE OF ESSURE IS UNLIKELY, THEREFORE A CAUSAL RELATIONSHIP CAN BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 15-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00983	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0227, AWARENESS DATE 21-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN 2014. CONSUMER REPORTED THAT SHE HAS HAD HER COILS PLACED JUST SHY OF A YEAR. FROM DAY ONE SHE HAS EXPERIENCED EXTREME BLOATING AND GAS. SHE CRAMP BADLY WHENEVER SHE HAD TO URINATE AND DEFECATE. HER PELVIC REGION WAS PAINFUL MOST DAYS, ESPECIALLY AFTER PHYSICAL ACTIVITY. HER PERIODS HAVE BECOME VERY LONG AND VERY HEAVY. HER SEX LIFE HAS GONE OUT THE WINDOW. HER HAIR WAS THINNING VERY BADLY. AND SHE WAS EXPERIENCED ADULT ACNE CONSISTENTLY AND NOT JUST DURING HER PERIOD. SHE JUST HAD A DNC (INTERPRETED AS DILATION AND CURETTAGE) AND CURRENTLY AWAITING RESULTS. SHE WILL BE SCHEDULING AN APPOINTMENT HER POST OP (OPERATIVE) APPOINTMENT TO HAVE HER FALLOPIAN TUBES REMOVED. UNLESS THE BIOPSY AND SCOPE RESULTS OF THE MASS IN HER UTERUS WAS INDEED A COIL. IF THIS IS THE CASE SHE WILL BE HAVING A HYSTERECTOMY. PUTTING HER THROUGH MENOPAUSE AT THE RIPE YOUNG AGE OF (B)(6). THIS HAS SHAKEN HER WHOLE LIFE UPSIDE DOWN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO EXPERIENCED VERY LONG AND VERY HEAVY PERIODS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A DNC (REGARDED AS DILATION AND CURETTAGE). THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER STATED SHE HAD A UTERINE MASS. SHE WAS WAITING THE BIOPSY RESULTS OF THIS MASS AFTER THE

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DNC TO KNOWN IF SHE WILL HAVE TO BE SUBMITTED TO A SALPINGECTOMY OR HYSTERECTOMY. UTERINE GROWTHS, SUCH AS POLYPS OR FIBROIDS, CAN LEAD TO MENORRHAGIA. IN THIS CASE THE EXACT NATURE OF CONSUMER'S MASS WAS NOT SPECIFIED AND SHE SUSPECTED IT COULD BE AN ESSURE COIL. ALTHOUGH LIMITED INFORMATION WAS PROVIDED IN THIS CASE; CONSIDERING MENORRHAGIA'S NATURE A CONTRIBUTORY ROLE OF ESSURE IN ITS OCCURRENCE CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE AN INTERVENTION (DILATION AND CURETTAGE) WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00984	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 1/1/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2004
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0516, # FDA-2014-N-0736-0015, AWARENESS DATE 21-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2004 SHORTLY AFTER HER YOUNGEST CHILD WAS BORN. SHE WAS NOT TESTED FOR A NICKEL ALLERGY AT THE TIME, AND SHE IS ALLERGIC TO NICKEL. ALMOST IMMEDIATELY AFTER BEING IMPLANTED, SHE STARTED TO GET SEVERE BACK PAIN THAT WOULD CAUSE HER LEGS TO GO NUMB WHILE HOLDING HER INFANT CHILD IF STANDING. REGULAR PAIN RELIEVERS LIKE ADVIL, TYLENOL, ALEVE WOULDN'T TAKE THE PAIN AWAY, SO SHE TRIED TRAMADOL AND OTHER STRONGER MEDS. SHE LIVED WITH DEBILITATING PAIN FOR 10 AND 1/2 YEARS. SHE NEVER HAD ISSUES WITH PAIN BEFORE ESSURE. SHE ALSO STARTED GAINING WEIGHT EXTREMELY RAPIDLY, DESPITE EXERCISING, WORKING WITH TRAINERS, AND NUTRITIONISTS. SHE WOULD EITHER MAINTAIN OR GAIN. SHE GAINED OVER 100 LBS. THEN THERE WERE THE RANDOM ZAPS OF PAIN IN HER ABDOMEN, IT FELT LIKE AN ELECTRICAL CURRENT ZAPPING YOU, AND WOULD TAKE YOUR BREATH AWAY. APPARENTLY THAT WAS THE FALLOPIAN TUBES SPASMING. NOT TO FORGET ABOUT HORRIBLE MENSTRUAL CYCLES, WITH HUGE CLOTS AND CRAZY AMOUNTS OF BLOOD FOR A 7 DAY PERIOD. THE PRESSURE OF FEELING LIKE YOUR PARTS WERE GOING TO LITERALLY DROP OUT OF YOU BEFORE THE ONSET OF THE VICIOUS PERIOD WAS WORSE THAN CARRYING AN OVER DUE BABY. ALLERGIES WORSENED EVERY YEAR. SHE WAS UP TO TAKING 4 ZYRTEC A DAY, IN ADDITION TO BENADRYL TO JUST TRY TO GET SOME RELIEF FROM THE ALLERGIES. SHE WAS ALSO TAKING NASAL SPRAYS AND EYE DROPS TO TRY TO GET THROUGH THE DAYS AT WORK. THEN SHE STARTED REACTING TO FOODS THAT SHE ATE.

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SHE HAD TO CARRY EPI-PENS IN CASE SHE COMES IN CONTACT WITH AVOCADOS, PEANUTS AND OTHER FOODS THAT SHE USED TO REGULARLY CONSUME. THE LACK OF ENERGY WAS HORRIBLE. ALL SHE WANTED TO DO WAS SLEEP. THE DOCTORS COULDN'T FIND ANYTHING MEDICALLY WRONG WITH HER. SHE WAS HEALTHY ACCORDING TO TEST. LUPUS, DIABETES AND OTHER AUTOIMMUNE DISEASES WERE DENIED. SHE MIGHT BE OVERWEIGHT, BUT HER CHOLESTEROL, TRIGLYCERIDES, BLOOD PRESSURE; BLOOD SUGARS WERE ALL WITHIN NORMAL RANGES. AT 10 AND 1/2 YEARS POST IMPLANTATION SHE HEADED INTO SURGERY AND HAD EVERYTHING EXCEPT HER OVARIES REMOVED. AT THAT POINT, SHE HAD ALREADY NOTICED THAT HER BACK DIDN'T SCREAM AT HER WHEN SHE TRIED TO GET UP AND MOVE. SHE WAS RELEASED FROM THE HOSPITAL THE NEXT MORNING PAIN FREE, WITHOUT MEDICATION IN HER SYSTEM. ALSO, SHE DIDN'T NEED THE BENADRYL OR THE ZYRTEC. HER ALLERGIES SUDDENLY DISAPPEARED; PERHAPS IT WAS SOMETHING IN THE COILS THAT HER BODY WAS REACTING TO. HER BACK PAIN WAS TOTALLY GONE, AND HER ENERGY LEVELS WERE THROUGH THE ROOF. THE SWELLING IN HER STOMACH WAS DOWN CONSIDERABLY FROM WHERE IT WAS BEFORE REMOVAL. SHE WAS LOSING WEIGHT. SINCE REMOVAL, SHE WAS FEELING SHE HAS GOTTEN HER LIFE BACK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BACK PAIN, DEBILITATING PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT ALMOST IMMEDIATELY AFTER BEING IMPLANTED. AT 10 AND 1/2 YEARS POST IMPLANTATION SHE HEADED INTO SURGERY AND HAD EVERYTHING EXCEPT HER OVARIES REMOVED. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND BASED ON THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00985	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0796-0371, AWARENESS DATE 21-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAS ESSURE AND WAS NOT GIVEN ANOTHER OPTION AT THE TIME. IT WAS PAINFUL FOR APPROXIMATELY 3 1/2 YEARS SHE WAS INSIDE HER. IT MOVED, AND ALSO FAILED AFTER SHE PASSED THE DYE TEST. IT FAILED BECAUSE NOT ONLY BOTH COILS MOVED BUT SHE BECAME PREGNANT. SHE THEN HAD TO GET AN ADDITIONAL SURGERY TO LATER HAVE HER TUBES TIED. THEN STILL HAD SEVERE PAIN BECAUSE THE DOCTOR REFUSED TO REMOVE THEM. SHE WENT TO ANOTHER DOCTOR WHO REMOVED THEM DURING THE NOVASURE PROCESS AND SHE WAS FINALLY OUT OF PAIN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE STATED BOTH COILS MOVED. SHE UNDERWENT A TUBAL LIGATION; LATER ESSURE DEVICES WERE REMOVED DURING A NOVASURE PROCESS (THE EXACT PROCEDURE FOR ESSURE REMOVAL WAS NOT SPECIFIED). THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, CONSUMER STATED ESSURE FAILED AFTER SHE PASSED HER DYE TEST BECAUSE THE

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COILS MOVED AND SHE BECAME PREGNANT. THIS DEVICE MOVEMENT COULD HAVE BEEN A CONTRIBUTORY ROLE IN ESSURE CONTRACEPTIVE FAILURE. THEREFORE, CAUSALITY BETWEEN THE EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT; SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 15-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00986	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 09-JUL-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION THREE OR FOUR MONTHS PREVIOUS TO THIS REPORT (IN 2015). INFORMATION STATES THAT PATIENT CAME BACK FOR THE HYSTEROSALPINGOGRAM. THE RESULT SHOWED THE RIGHT INSERT IN PROPER LOCATION WITH OCCLUSION. HOWEVER, THE LEFT INSERT WAS TOO PROXIMAL AND THE TUBE WAS PATENT. HEALTH CARE PROFESSIONAL HAD QUESTIONS ABOUT REMOVAL. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A LACK OF EFFICACY MAY OCCUR WITH THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH

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SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP 20-JUL-2015: PHYSICIAN WOULD LIKE TO HAVE INFORMATION ON ESSURE REMOVAL FOR THE PATIENT WITH MISPLACED COIL. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED FROM THE PHYSICIAN ON 24-AUG-2015: THE PHYSICIAN REPORTED THE SUSPICION OF LEFT ESSURE MISPLACEMENT AT TIME OF INITIAL PLACEMENT. THE PATIENT UNDERWENT LAPAROSCOPY. RIGHT SALPINGOSTOMY WAS DONE AND RIGHT ESSURE WAS REMOVED. HYSTEROSCOPY WAS PERFORMED AT SAME TIME AND THE LEFT ESSURE WAS HYSTEROSCOPICALLY REMOVED. THE LEFT ESSURE WAS CURLED UP IN ENDOMETRIUM; NEAR LEFT OSTIA. BILATERAL SALPINGECTOMY WAS REPORTED. ACCORDING TO THE REPORTER THE PATIENT DID WELL. NO COMPLICATIONS FROM SURGERY WERE REPORTED. FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS UPDATED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A LACK OF EFFICACY MAY OCCUR WITH THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN ADDITION, THE AE CASE REFERS TO A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING CONFIRMATION TEST PERFORMED THREE OR FOUR MONTHS LATER, LEFT INSERT WAS TOO PROXIMAL (MISPLACED COIL). THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MOVE INTO FALLOPIAN TUBES. IN THIS CASE, THE RESULT OF HYSTEROSALPINGOGRAM SHOWED THE RIGHT INSERT WAS IN PROPER LOCATION WITH OCCLUSION. HOWEVER, THE LEFT INSERT WAS TOO PROXIMAL AND THE TUBE WAS PATENT. ALTHOUGH THE EXACT DATE AND MECHANISM OF THIS DISLOCATION HAVE NOT BEEN PROVIDED (IT WAS SUSPECTED THAT IT OCCURRED DURING INSERTION), GIVEN EVENT'S NATURE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS INFORMED THAT INTERVENTION FOR ESSURE REMOVAL WAS REQUIRED. THEREFORE, THIS CASE IS NOW CONSIDERED AS INCIDENT. THE TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00988	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626161

Single Use: Y
Implant Date (E6): 5/26/2008
Explant Date (E7): 9/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN NETHERLANDS ON 20-JUL-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 DIRECTLY FOLLOWED BY A NOVASURE. THE PATIENT'S CONCURRENT CONDITION INCLUDED MANIC DEPRESSIVE. VERY SOON AFTER THE TREATMENTS PATIENT REMAINED HAVING COMPLAINTS SUCH AS PAIN AND BLEEDINGS. MEANWHILE, THE DOCTOR IS TALKING WITH PATIENT ABOUT FOLLOW-UP TREATMENT. AS IT LOOKS NOW THE UTERUS WILL BE REMOVED IN ITS ENTIRETY. PTC INVESTIGATION RESULT WAS RECEIVED ON 18-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY

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DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 27-AUG-2015 FROM GYNECOLOGIST: THE PATIENT WAS (B)(6) AT TIME ESSURE INSERTION PROCEDURE. THE ESSURE STERILIZATION WAS PERFORMED ON (B)(6) 2008, THE PROCEDURE WAS CONSIDERED UNCOMPLICATED. THE LOT NUMBER USED WAS 626161. THE FOLLOW-UP AFTER THREE MONTHS WAS DONE BY ECHO. DUE TO INTERMENSTRUAL BLOOD LOSS FIRST A DIAGNOSTIC HYSTEROSCOPY WAS PERFORMED IN 2011 WHICH SHOWED NO CAVITY ABNORMALITIES, ESSURE ON BOTH SIDES WERE NOT STICKING OUT. THEREFORE, THE PHYSICIAN CONDUCTED A NOVASURE ENDOMETRIAL ABLATION SUBSEQUENTLY. AFTERWARDS, HER BLOOD LOSS WITH INTERMENSTRUAL OR IRREGULAR PATTERN RETURNED. SO SHE WANTED A HYSTERECTOMY BECAUSE OF THE IRREGULAR FLOW AFTER NOVASURE, BUT EXPLICITLY ALSO ON BOTH SIDES TUBE WITH THE ESSURE REMOVED. THE PATIENT REPORTED SHE FELT THE VIBRATIONS OF THE ESSURE WHEN SHE FOR EXAMPLE, PASSES A REFRIGERATOR. THE PHYSICIAN STATED THE CONSUMER FIRST CAME WITH THE COMPLAINTS OF THE ESSURE ON (B)(6) 2015. THE PATIENT WANTED TO REMOVE HER ESSURE. SHE WILL HAVE A LAPAROSCOPIC HYSTERECTOMY BECAUSE OF PERSISTENT BLOOD LOSS AFTER NOVASURE ENDOMETRIAL ABLATION. THE PHYSICIAN REPORTED THAT HOSPITALIZATION IS SCHEDULED ON (B)(6) 2015 FOR NOW. PTC INVESTIGATION RESULT RECEIVED ON 01-SEP-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 11-SEP-2015 FROM PHYSICIAN: THE PHYSICIAN SENT THE PICTURES OF THE LAPAROSCOPIC HYSTERECTOMY ALONG WITH REMOVAL OF BOTH SIDES TUBE AND ESSURE INSERTS PERFORMED ON (B)(6) 2015. BOTH ESSURE COILS WERE POSITIONED PERFECTLY. GYNECOLOGIST COULD NOT SEE THE REASON FOR THE PAIN, ALSO NO ADHESION AROUND INTERNAL GENITALIA. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDINGS SPECIFIED AS BLOOD LOSS WITH INTERMENSTRUAL OR IRREGULAR FLOW. SHE PERFORMED A NOVASURE ENDOMETRIAL ABLATION BUT AS THIS BLEEDINGS RETURNED SHE ASKED FOR A HYSTERECTOMY AND ESSURE REMOVAL THAT WAS PERFORMED AFTER 7 YEARS. AFTER HYSTERECTOMY, THE GYNECOLOGIST COULD NOT SEE THE REASON FOR PAIN. THE EVENTS, INTERPRETED AS METRORRHAGIA AND UNSPECIFIED PAIN, ARE SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BLEEDINGS AND PAIN MAY OCCUR DURING AND FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT. AN UPDATED PRODUCT TECHNICAL COMPLAINT ANALYSIS IS EXPECTED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 17-DEC-2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00990	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0785, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER ON UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 AFTER THE BIRTH OF HER DAUGHTER. CONSUMER STATED THAT IN 2011, SHE WAS SICK AND FELT LIKE SHE HAD THE FLU. SHE WENT TO HER DOCTOR WHO SUGGESTED A BLOOD TEST WHICH SHOWED THAT SHE WAS PREGNANT. FEW MONTHS LATER, SHE DISCOVERED THAT THE BABY HAD WATER IN HIS HEAD, HYDROPHOLOUS AND ALSO CLUB FEET SPINA BIFIDA. SHE ALSO HAD CRAMPING, LOSS OF HAIR, BLOATING, SEVERE PERIODS THAT LAST 8 DAYS EVERY MONTH, ARTHRITIS IN THE KNEES, SEVERE HIVES AND RASHES DUE TO NICKEL, WEIGHT GAIN AND SO MANY MORE SYMPTOMS. SHE HAD BEEN IN AND OUT OF THE HOSPITAL BECAUSE OF ESSURE AND BECAUSE SO MANY NUMEROUS CYSTS. SHE FELT MISERABLE, SUFFERED AND LOST A LOT OF PRECIOUS TIME BECAUSE SHE HAD TO STAY IN BED. SHE LOST HER BABY AT (B)(6) (CASE (B)(4)). SHE STATED THAT SHE WAS ABOUT TO HAVE HER HYSTERECTOMY AT THE AGE OF (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND LOST HER BABY AT (B)(6). ADDITIONALLY, SHE STATED SHE WENT TO THE HOSPITAL SEVERAL TIMES BECAUSE OF ESSURE. SHE EXPERIENCED RASH DUE TO NICKEL AND UNSPECIFIED CYSTS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY CYSTS IS UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES

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OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS CASE, NO INFORMATION WAS PROVIDED ABOUT HSG. HOWEVER, AS PREGNANCY OCCURRED APPROXIMATELY 2 YEARS AFTER ESSURE INSERTION, A CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING THE REPORTED FETAL DEATH AT (B)(6), CONSUMER STATED THE FETUS HAD SPINA BIFIDA (MYELOMENINGOCELE) AND WATER IN HIS HEAD (PROBABLY HYDROCEPHALUS). THE ETIOLOGY IN MOST CASES OF MYELOMENINGOCELE IS MULTIFACTORIAL, INVOLVING GENETIC, RACIAL, AND ENVIRONMENTAL FACTORS, IN WHICH NUTRITION, PARTICULARLY FOLIC ACID INTAKE, IS A KEY. SPINA BIFIDA OFTEN OCCURS ALONG WITH MULTIPLE CONGENITAL ANOMALIES. IN THIS CASE, THE REPORTED FETUS ANOMALIES COULD BE ALTERNATIVE EXPLANATIONS FOR HIS DEATH. FOR CONSUMER'S NICKEL ALLERGY A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED; DUE TO EVENT'S NATURE AND CONSIDERING DEVICES COMPOSITION (ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY WHICH MAY CAUSE ALLERGIC REACTIONS). SINCE THE CYSTS WERE NOT SPECIFIED, CAUSALITY WITH ESSURE CANNOT BE ASSESSED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE ACCORDING TO THE CONSUMER, HOSPITALIZATION WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00991	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 05-JUL-2015 WHO WAS INVOLVED IN A ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE® GENERIC ACTIVE ONLINE LISTENING. CONSUMER HAD ESSURE INSERTED AND EXPERIENCED PAIN. FOLLOW UP 08-JUL-2015: CONSUMER REPORTED THAT SHE EXPERIENCED ANOTHER SPELL OF NUMBNESS IN THE THIGHS AND BOTTOM OF FEET AND RELATED THE EVENT TO ESSURE. NO ADDITIONAL DETAILS WERE PROVIDED. FOLLOW UP 10-JUL-2015: CONSUMER REPORTED THAT ESSURE CAUSED HER EXTREMELY SWOLLEN EVERYWHERE, MIGRAINE AND CLUMPS OF HAIR IN TUB. FOLLOW UP 15-JUL-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL

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QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 02-AUG-2015: CONSUMER STATED THAT SHE HAD NO DESIRE TO DO ANYTHING. FOLLOW UP INFORMATION RECEIVED ON 22-AUG-2015, 23-AUG-2015, 29-AUG-2015 AND TWO REPORTS FROM (B)(6) 2015 (UPGRADED TO INCIDENT): IT WAS REPORTED THAT ESSURE WAS HER PROBLEM AND AT THE TIME OF THE REPORT RECEIVED ON 29-AUG-2015, SHE WAS 3 DAYS POST OP SHE FEELS LIKE A DIFFERENT PERSON. ALSO CONSUMER INFORMED THAT ON DAY 3 OF NO ESSURE SHE SPENT THE DAY WITH NO PAIN, HEADACHES, AND FEELING IN EVERY PART OF HER BODY. SHE STATED THAT SHE WAS TOLD SHE HAD A DIFFERENT GLOW ABOUT HER WITHOUT THE PAIN OF ESSURE THAT WAS RUINING HER LIFE. SHE STATED THAT SHE WAS SO SAD IT HAD REQUIRED A HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED AND EXPERIENCED PAIN NOS. SHE UNDERWENT A HYSTERECTOMY AND 3 DAYS AFTER ESSURE REMOVAL SHE HAD NO PAIN. THE PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT IN THIS CASE, THE TEMPORAL RELATIONSHIP IS SUGGESTIVE AND THAT THERE IS NO ALTERNATIVE EXPLANATION, THE PAIN IS ASSESSED AS RELATED. UPON FOLLOW UP INFORMATION, THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00992	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 6/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/3/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. ANTICIPATED. SERIOUS INJURY. REQUIRED INTERVENTION. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0712, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER STATED SHE WAS HAVING SOME PROBLEMS AND HER DOCTOR RECOMMENDED AN UTERINE ABLATION BUT SAID SHE WOULD NEED A FORM OF BIRTH CONTROL AND SAID THAT ESSURE WOULD DO THE SAME THING AS IF HER TUBES WERE CUT. SINCE ESSURE PROCEDURE SHE EXPERIENCED PAIN IN HER LOWER RIGHT SIDE FROM DAY ONE. SIX MONTHS AFTER THE PROCEDURE, SHE HAD HEAVY BLEEDING, SEVERE HEADACHES, STRANGE RASHES, SEVERE FATIGUE; SHE WAS LOSING HER HAIR AND EYELASHES; CRAMPING THAT FEELS LIKE LABOR PAINS, AND A FLU-LIKE FEELING. THE SHARP PAINS IN HER RIGHT SIDE HAVE GOTTEN SO MUCH WORSE WITH EACH PASSING DAY AND SHE BLEED FOR WEEKS AT A TIME. SHE WAS SCHEDULED TO HAVE A COMPLETE HYSTERECTOMY ON (B)(6) 2015. THE LAST YEAR HAS BEEN VERY FRUSTRATING AND SCARY; HER QUALITY OF LIFE HAS SUFFERED. SHE WAS DEPRESSED, IN PAIN AND SICK. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS RECEIVED ON 14-SEP-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT

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REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD SHARP PAINS IN HER RIGHT SIDE AND HEAVY BLEEDING (SHE BLEED FOR WEEKS AT A TIME) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SCHEDULED TO HAVE A HYSTERECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER MENTIONED AN UTERINE ABLATION (UNCLEAR IF IT WAS PERFORMED BEFORE OR CONCOMITANTLY WITH ESSURE INSERTION); SUGGESTING A PREVIOUS ENDOMETRIAL DISORDER (WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR HER BLEEDING). HOWEVER, GIVEN EVENTS NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT; SINCE A SURGICAL INTERVENTION WILL BE REQUIRED (HYSTERECTOMY IS SCHEDULED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00993	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0711, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT HER KIDS LOST THEIR MOM FOR 3 YEARS. ONE COILED WENT INTO HER UTERUS AND WELL AS THE OTHER BREAKING. SHE HAD TO DEAL WITH HEADACHES, TIREDNESS, NAUSEA, WEIGHT GAIN, FORGETFULNESS, MOOD SWINGS. SEVERE BACK PAIN AND MANY OTHER SIDE EFFECTS. SHE JUST HAD TO UNDERGO A COMPLETE HYSTERECTOMY AND SHE WAS ONLY (B)(6). SHE HAD NO ENERGY FOR HER KIDS, ALWAYS TIRED OR IN PAIN. SHE WAS FEELING A LOT BETTER SINCE HER HYSTERECTOMY BUT SHE WAS NOT HAPPY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ONE COILED WENT INTO HER UTERUS (SEEN AS UTERINE PERFORATION) AND WELL AS THE OTHER BREAKING (SEEN AS DEVICE BREAKAGE). A COMPLETE HYSTERECTOMY WAS PERFORMED. UTERINE PERFORATION IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE DEVICE BREAKAGE IS UNLISTED. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. ALSO, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, IT WAS NOT REPORTED THE EXACT DATE AND MECHANISM OF BOTH EVENTS, HOWEVER GIVEN THEIR NATURE A CAUSAL

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RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 15-SEP-2015: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00994	BAYER HEALTHCARE LLC	9/17/2015	9/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-0710, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN 2010. CONSUMER REPORTED THAT FROM DAY ONE SHE HAD ESSURE INSERTED SHE WAS EXPERIENCING PAIN AND WAS TOLD IT WOULD PASS AND SHE WAS JUST SEEKING PAIN MEDICATION. THE PAIN NEVER PASSED AND SHE HAD TO LEARN TO COPE WITH NOTHING MORE THAN (B)(6). THE ESSURE ADDED MORE SCAR TISSUE AND ADDED TO ENDOMETRIOSIS PAIN. AT THE TIME OF REPORT, SHE WAS (B)(6) AND WAS HAVING TO GET A HYSTERECTOMY BECAUSE THIS WAS THE ONLY OPTION SHE HAD LEFT. ACCORDING TO THE CONSUMER, SHE WAS RIDICULED IN THE COURT ROOM AND LOST THE CUSTODY OF HER CHILDREN DUE TO THE AMOUNT OF PAIN SHE WAS SUFFERING SHE DID NOT HAVE THE ABILITY TO WALK, JUMP AROUND OR DO THE THINGS A MOTHER OF 4 SHOULD BE ALLOWED TO DO. SHE STATED SHE WAS LABELED AS DRUG ADDICT EVEN WITH DOCUMENTED PROOF THAT IT WAS ONLY (B)(6). SHE SAID THAT ESSURE WAS A DEFECTIVE PRODUCT. CONSUMER ALSO STATED THAT WITH ALL OF THAT SHE WAS BEING FORCED TO GET ANOTHER SURGERY TO REMOVE THE ESSURE. SHE MIGHT BE ABLE TO GET BACK ON HER FEET AFTER THE SURGERY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERTS) INSERTED AND EXPERIENCED CONSTANT PAIN SINCE THE DAY OF INSERTION. SHE TREATED IT WITH IBUPROFEN. DUE TO THE AMOUNT OF PAIN SHE WAS SUFFERING SHE DID NOT HAVE THE ABILITY TO WALK, JUMP AROUND OR DO THE THINGS A MOTHER OF 4 SHOULD BE ALLOWED TO DO.

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SHE STATED SHE WILL HAVE TO UNDERGO A HYSTERECTOMY BUT NO DATE WAS PROVIDED. THIS UNSPECIFIED PAIN IS SERIOUS DUE TO THE MEDICAL REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT THE PAIN STARTED THE DAY OF INSERTION AND THAT IT HAD HAS BEEN CONSTANT FOR FIVE YEARS, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT DUE TO LONG-TERM RESTRICTION OF ACTIVITIES OF DAILY LIFE CAUSED BY ESSURE-RELATED PAIN. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056194	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOOSING HAIR VERY BAD, HUGE WADS DAILY, BRUISING ALL OVER, NAUSEOUS DAILY. POSSIBLE ANEMIA. I ALSO HAVE SEVERE HIP PAIN AND NOW MY TOE FEELS LIKE IT HAS A RUBBER BAND AROUND IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056195	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING THE ESSURE PLACED IN 2011 MY PERIODS WENT FROM SOMEWHAT NORMAL TO SOAKING THROUGH A PAD AND TAMPON IN LESS THAN AN HOUR. OVERNIGHT I WAS FLOODING THE BED WITH BLOOD AND MY CRAMPS WERE OUT OF CONTROL. I WAS ALSO HAVING ISSUES WITH BLOOD CLOTS. SOME AS LARGE AS GOLF BALLS. IN (B)(6) 2012 I HAD THE NOVASURE DONE. THIS STOPPED THE PERIODS IN THE BEGINNING BUT SINCE THEN I STILL HAVE ISSUES WITH RANDOM BLOOD CLOTS. IN (B)(6) 2013 I WENT BACK TO THE OBGYN AND COMPLAINED OR SERIOUS INFLAMMATION IN MY HANDS, FEET, FACE AND STOMACH AS WELL AS SEVERE HAIR LOSS. I ASKED THE DR AT THAT TIME IF THERE WAS ANY WAY IT COULD BE MY THYROID AND HE JUST BLEW IT OFF AS IF IT WERE NO BIG DEAL. FOR THE LAST 2 YEARS I HAVE NOT GONE BACK, I STILL HAVE SEVERE INFLAMMATION ALL OVER AND MY HAIR STILL FALLS OUT AND NOW I HAVE STARTED BRUISING RANDOMLY. I WILL GO IN SOON TO BE CHECKED. I HAD NONE OF THESE ISSUES PRIOR TO ESSURE AND AFTER SOME RESEARCH ABOUT THE NICKEL AND PET FIBERS I AM THOROUGHLY CONCERNED THAT THIS IS ALL SOMEHOW CONNECTED

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056196	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 10/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEPRESSION, MOOD SWINGS, SKIN IRRITATION, BLOATING, MASSIVE WEIGHT GAIN, MIGRAINES, HAIR LOSS, MISSED OR MULTIPLE PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056197	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 9/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TIRED ALL THE TIME, SHARP STABBING PAIN ON RIGHT SIDE, HAIR LOSS, WEIGHT GAIN, HEAD ACHES, EXCESSIVE BLEEDING...ECT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056198	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 7/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS COVERED BY INSURANCE. I HAVE VERY HEAVY PERIODS AND CHRONIC BILATERAL PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056199	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 5/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING ESSURE IMPLANTS, I BLED UNTIL (B)(6) OF 2013. I WAS ON HORMONE E RELATE MENTIONED TO STOP IT AND SINCE THEN I HAVE CRAMPING, SOMETIMES SEVERE, I HAVE SHARP PAINS, HEADACHES, NAUSEA, I FEEL TIRED AND I HAVE HARD TIME CONCENTRATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056200	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 9/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UTERINE FIBROIDS, ENLARGED UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056201	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 7/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY INSURANCE HELPED PAY FOR MY ESSURE DEVICE THAT WAS IMPLANTED INTO MY BODY IN (B)(6) OF 2015. I HAVE HAD A 2.5 MONTH LONG HEAVY PERIOD AND CONSTANT HEADACHES SINCE I GOT THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056221	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 11/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT WAS COVERED. HAD INTERCOURSE I WAS HAVING SEVERE PAIN. THOUGHT IT WAS APPENDIX. WENT TO URGENT CARE. THEN ER DID MULTIPLE TESTING. AT ER THEY SAID DEVICE WASN'T PLACED RIGHT. FOLLOWED UP WITH MY GYNO SHE WOULD EVEN LOOK AT TEST RESULTS OR ANYTHING SAID I WAS FINE. SEVERE DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056222	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 3/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS COVERED BY INSURANCE. SINCE (B)(6) I HAVE EXPERIENCED WEIGHT GAIN, EXTREME FATIGUE AND IRREGULAR PERIODS. MY SEX DRIVE HAS COMPLETELY DISAPPEARED. (B)(6) COMES AROUND AND I START TO DEVELOP EXTREME PELVIC PAIN TO THE DEGREE THAT IT CAN ONLY BE BEST DESCRIBED AS BEING IN HARD LABOR AND TRYING TO LIVE LIFE DAILY. I HAVE ALSO NOW BEEN BLEEDING FOR TWO MONTHS. NOW AT THE AGE OF (B)(6) I'M HAVING A BILATERAL SALPINGNECTOMY DUE TO THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056223	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 6/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEFT LEG PAIN, METAL TASTE IN MOUTH, GUM PAIN, VERY BLOATED STOMACH, ANXIETY, PELVIC PAIN, BREAST TENDERNESS, OCCASIONAL PAIN WITH SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056225	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 7/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, TWO MENSTRUAL PERIODS A MONTH, BLOATED, MIGRAINE, BLURRY VISION, ABDOMINAL PAIN, LOWER BACK PAIN, WEIGH GAIN, ANEMIA, TIREDNESS AND MISCARRIAGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056226	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 7/28/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056228	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 12/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, BLOATING, HAIR LOSS, MOOD SWINGS, SEVERE BACK PAIN, SEVERE BLEEDING FOR MONTHS ON END, LARGE CLOTS WHILE BLEEDING, SEVERE CRAMPING, PELVIC PAIN, NO SEX DRIVE, RASHES, NAUSEA, DIARRHEA, TIRED ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056229	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 5/6/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVING LEG PAIN FOR THE LAST 7 YEARS AND NOW HAVE S SITU IMMUNE DISEASE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056231	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 6/21/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD AN ABDOMINAL HYSTERECTOMY TO REMOVE THE ESSURE COILS. THEY HAVE CREATED HAVOC ON MY LIFE. I WENT IN FOR A SONOGRAM ON (B)(6) AND IT WAS DETERMINED THAT IT WAS BEST THAT I HAVE A HYSTERECTOMY DUE TO MY PELVIC PAIN, STRESS URINARY INCONTINENCE, AND DYSMENOR. MY SURGERY WAS SCHEDULED TO LAST 2-3 HOURS IT LASTED 6-7 HOURS LONG. THE DOCTOR ADVISED ME THAT DURING THE SURGERY MY KIDNEYS REFUSED TO START AND SO SHE HAD TO DO SEVERAL DIFFERENT THINGS IN ORDER TO FINALLY GET THEM GOING. I NOW HAVE TO SEE A BLADDER SPECIALIST ALONG WITH A KIDNEY SPECIALIST. I NEED TO ALSO CORRECT THE DATE OF MY ESSURE PROCEDURE IT WAS CONDUCTED ON (B)(6) 2008. IN THE PATIENT PORTAL TO THE HOSPITAL IT STATES THAT THE REASON I HAD IT DONE IN THE HOSPITAL WAS BECAUSE I WANTED IT CONDUCTED IN A STERILIZED FIELD. AT NO TIME WAS I ASKED WHERE I WANTED IT DONE. I WAS TOLD BY MY DOCTOR TO REPORT TO THE HOSPITAL BECAUSE THAT IS WHERE IT WOULD BE DONE. I AM A WOMAN IN CONSTANT PAIN AND SUFFER BECAUSE OF THIS ISSUE. PLEASE TAKE THIS DEVICE OFF THE MARKET AND STOP WOMEN FROM SUFFERING ANY FURTHER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056232	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 3/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT FOR THE HSG TEST AND WAS CONFIRMED NOT BLOCKED ON MY RIGHT SIDE. I HAD A LAPAROSCOPY AND TUBE REMOVAL A MONTH LATER. A FEW WEEKS LATER, I STARTED HAVING BACK PAIN. THEN CAME THE KIDNEY STONES. THEN THE UTI THAT WOULDN'T GO AWAY. THEN PID (ALTHOUGH NEGATIVE FOR STDS). THEN THE HERNIATED DISC THAT REQUIRED EMERGENCY SURGERY BECAUSE IT WAS CRUSHING MY SCIATIC NERVE, CAUSING ME TO LOSE FUNCTION OF MY RIGHT LEG. THIS IS ALL BECAUSE THOSE COILS I THOUGHT WERE REMOVED WERE ONLY PARTIALLY REMOVED. I LEARNED THAT AFTER GETTING THE CT SCAN RESULTS DURING THE KIDNEY STONES EPISODE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056233	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 7/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME WORSENING OF ALLERGIES, ABDOMINAL PAIN, TINNITUS, JOINT PAIN (HIPS, KNEES, FEET, ACNE, RASHES, MOOD SWINGS, ANXIETY, BRAIN FOG, MEMORY LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056234	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 7/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ADDITION TO OTHER REPORT. EXTREME ABDOMINAL BLOATING AND WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056235	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 10/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, HEAVY BLEEDING DURING MY TEAM OF THE MONTH NOT NOAL FOR ME. BROWN RAISED BUMPS, DEPRESSION, ANXIETY, HUGE WEIGHT GAIN FOR NO REASON, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056236	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 4/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TRIGEMINAL NEURALGIA DUE TO NERVE DAMAGE CAUSED FROM ALLERGY TO DEVICE. PCOS. OVARIES COMPLETELY FILLED WITH CYST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056237	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING PERIODS, HEDVY PEIODS, SEVERE ITCHING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056238	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 9/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD PROCEDURE DONE (B)(6) 2015 AND WAS BLEEDING FROM VAGINA ON (B)(6) I HAD FELT LIKE I HAD TO PUSH A BABY OUT OF ME AND HAD SKIN COMING OUT OF ME IN BASEBALL SIZES SO I GO TO HOSPITAL AND HAS A CT SCAN WITH DYE AND THE DEVICES WERE IN MY UTERUS INSTEAD THEY SAID IF WE DONT DO EMERGENCY SURGERY YOU COULD DIE SO THEY COULD ONLY REMOVE ONE AND THE SURGERY WAS DONE ON (B)(6) THE OTHER PIECE FELL OUT WEEKS LATER AT HOME BUT BECAUSE THE DEVISE WAS DAMAGED IT MESSED AND CUT MY INSIDES ON ITS WAY OUT I AM NOW STILL HAVING PROBLEMS WITH CHRONIC PAIN AND BLOATING I HAVE BEEN BLEEDING SINCE MAY AND HAVE TO TAKE HORMONE PILLS CAUSE THE BLEEDING WONT STOP

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056239	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 6/26/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN, PELVIC PAIN, VAGINAL INFECTIONS, HEAD ACHES, BEING TIRED, EMOTIONAL, LOWER BACK PAIN, PAIN IN HIPS, DISSINESS, LIGHT HEADED, FORGETFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056240	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE EXPERIENCED CYCLES THAT LAST FOR MANY WEEKS WITH EXCESSIVE AMOUNTS OF BLEEDING. I'VE BEEN HAVING INFECTION LIKE SYMPTOMS BUT UPON GYNECOLOGICAL EXAMS AND TESTS IT'S BEEN PROVEN I HAVE NO INFECTIONS. NOW MY CYCLE HAS STOPPED ALTOGETHER, BUT I STILL AM DEALING WITH VAGINAL "INFECTION" LIKE SYMPTOMS. NONE OF THE ANTIBIOTICS THEY DOCTOR HAS PRESCRIBED FOR ME HAS WORKED BECAUSE THEY TESTS SHOW THERE ISN'T AN INFECTION AT ALL!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056241	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ANXIETY, HAIR FALLS OUT, SHARP PAIN IN MY LEFT SIDE, MOOD SWINGS AND WEIGHT GAIN. YES MY INSURE PROVIDED DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056242	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 9/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM AN ACTIVE (B)(6) WHITE FEMALE, WHO CURRENTLY IS ON NO MEDICATION, AND HAVE A HISTORY OF ONLY SUFFERING FROM OCCASIONAL (ONCE EVERY 6 MONTHS TO A YEAR) MIGRAINES WITH AURA. I WENT ON (B)(6) 2015 TO HAVE THE ESSURE IMPLANTED AS A METHOD OF STERILIZATION. MY FALLOPIAN TUBES BEGAN TO SPASM DURING THE PROCEDURE, WHICH WAS A FIRST FOR MY PHYSICIAN. SHE WENT BACK AND FORTH ON EACH TUBE AND FINALLY MANAGED TO JAM ONE COIL IN. I RETURNED A MONTH LATER ON (B)(6) 2015 TO HAVE THE SECOND COIL IMPLANTED, AND THIS TIME WAS GIVEN A DRUG TO CALM DOWN THE SPASMS. THE SECOND COIL WAS IMPLANTED SUCCESSFULLY. SINCE IMPLANTATION, I HAVE COMPLAINED OF SEVERE STABBING PAINS IN MY RIGHT SIDE THAT THEN RADIATES DOWN MY LEG ALL THE WAY TO MY FOOT. ALONG WITH THESE STABBING PAINS, AT THE END OF THE DAY MY ENTIRE LOWER ABDOMEN ACHES. I HAVE HAD IRREGULAR MENSES SINCE IMPLANTATION. THE FIRST MENSTRUAL CYCLE WAS EXTREMELY HEAVY, I WENT THROUGH SEVERAL (7-10) SUPER ABSORBENCY TAMPONS FOR 4 DAYS STRAIGHT. THE REMAINING MENSES HAVE BEEN SPORADIC, EXTREMELY LIGHT SPOTTING, WITH HARDLY EVEN ANYTHING. I HAVE EXTREMELY PAINFUL CRAMPING BOTH DURING OVULATION AND DURING MY PERIOD. SO MUCH TO THE POINT WHERE I NEED TO TAKE MANY TYLENOL, OR ALEVE TO ALLEVIATE THE PAIN, MINIMALLY. I AM BLOATED CONSTANTLY, EVEN THOUGH I DRINK PLENTY OF WATER AND EAT PLENTY OF FIBER. I TOOK A PHOTO ONE DAY JUST BECAUSE I COULD NOT BELIEVE THE SIZE OF MY STOMACH, I LOOKED SERIOUSLY 6 MONTHS PREGNANT, AND I AM EXTREMELY ACTIVE AND FIT EXERCISING RIGOROUSLY (OR USED TO BEFORE ESSURE) AT LEAST 5 DAYS A WEEK. MY MIGRAINES HAVE INCREASED FREQUENTLY WAKING ME UP AT NIGHT. I HAVE HAD DIARRHEA SINCE IMPLANTATION OF THE DEVICES, WITH NO RELIEF. I EXPERIENCE FREQUENT NAUSEA AS WELL. UNEXPLAINED RASHES HAVE BEEN PRESENT ON MY HIPS AND I CANNOT CONTRIBUTE THEM TO ANY NEW

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DETERGENTS, CLOTHES, OR ANYTHING ELSE. I HAVE MADE NO LIFESTYLE CHANGES OTHER THAN THE ESSURE DEVICE AND SUDDENLY I AM EXPERIENCING ALL OF THESE SYMPTOMS. AN ULTRASOUND PERFORMED (B)(6) 2015 SHOWED MY OVARIES TO BE IN GOOD CONDITION AND WITHOUT CYSTS, LEAVING MY PAIN UNEXPLAINED. UPON FURTHER EVALUATION, AN HSG WAS PERFORMED ON (B)(6) 2015 WHICH SHOWED THAT MY RIGHT COIL IS TWISTED AND DOES A LOOP-DE-LOOP AT THE LATERAL END OF THE COIL. I AM FEARFUL THAT THIS COIL HAS PUNCTURED MY FALLOPIAN TUBE. ACCORDING TO THE MANUFACTURER'S MANUAL, (CONCEPTUS) IF A COIL IS TWISTED OR COILED UP, IT IS CONSIDERED AN UNSATISFACTORY PLACEMENT, AND THE PATIENT SHOULD NOT BE INSTRUCTED TO RELY ON ESSURE FOR THEIR CONTRACEPTION. THE PATIENT SHOULD CONTINUE TO USE OTHER SOURCES OF CONTRACEPTION UNTIL FURTHER INVESTIGATION IS CONDUCTED ON THE UNSATISFACTORY PLACEMENT OF THE DEVICE. I HAVE CALLED MY PROVIDER TO DISCUSS THE PLACEMENT AND TWIST OF MY DEVICE AND HAVE BEEN TOLD ON NUMEROUS OCCASIONS THAT MY SYMPTOMS ARE UNRELATED TO ESSURE AND THAT EVEN IF THE COIL IS FOLDED BACK ON ITSELF OR DOES TWIST, THAT I AM COMPLETELY OCCLUDED AND CAN COUNT OF THE DEVICE FOR PROTECTION AGAINST PREGNANCY, EVEN THOUGH A (B)(6) STUDY HAS SHOWN THAT 1 IN 10 WOMEN WILL END UP GETTING PREGNANT WITH ESSURE DURING LONG-TERM STUDIES. MY PROVIDER REFUSES TO BELIEVE ESSURE IS CAUSE OF MY PROBLEMS YET I HAVE MADE NO OTHER LIFESTYLE CHANGES, HAVE NOT ADDED ANY MEDICATIONS OTHER ALEVE AND TYLENOL FOR OCCASIONAL MIGRAINES, AND I HAVE NOT INTRODUCED ANY OTHER MEDICAL DEVICES, THERAPIES, DIAGNOSES, OR LIFESTYLE CHANGES THAT WOULD WARRANT THESE SYMPTOMS. I WILL BE SEEKING REMOVAL OF THE ESSURE DEVICE UNFORTUNATELY BY WAY OF HYSTERECTOMY AND BILATERAL SALPINGECTOMY THROUGH A COMPLETELY NEW PROVIDER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056243	BAYER	9/17/2015	9/17/2015

Event Information:

Event Date (B3): 9/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BELLY AND GROIN PAIN, TERRIBLE CRAMPING STABBING, RIPPING PAIN IN GROIN. LOWER BACK CRAMPS, ACHY. NAUSEA, MIGRAINES, JOINT PAIN, RASHES, HIVES, NODULES IN HANDS, ARTHRITIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056360	BAYER	9/17/2015	9/23/2015

Event Information:

Event Date (B3): 2/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/2/2011
Explant Date (E7): 2/2/2012
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2011, I WAS IMPLANTED WITH THE ESSURE BIRTH CONTROL COILS. I EXPERIENCED IRREGULAR BLEEDING, INFECTION LIKE SYMPTOMS, EXTREME PELVIC PAIN, HEAVY MENSTRUAL BLEEDING, BACK PAIN, HEADACHES, SEVERE ACNE, ANXIETY AND MOOD SWINGS. IT WAS DISCOVERED THROUGH CT SCAN THAT ONE OF MY COILS HAD MIGRATED INTO THE RIGHT FALLOPIAN TUBE AND PUNCTURED THROUGH IT. AFTER DOCTOR CONSULTATION BOTH COILS AND FALLOPIAN TUBES WERE REMOVED LAPAROSCOPICALLY. I HAVE CONTINUED TO EXPERIENCE PAIN, MUSCLE WEAKNESS, RIGHT RIB PAIN, HEADACHES AND SEVERE MENSTRUAL CRAMPS AND BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056361	BAYER	9/17/2015	9/23/2015

Event Information:

Event Date (B3): 8/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/19/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE BAYER ESSURE COILS IMPLANTED IN MY FALLOPIAN TUBES. AFTER HAVING IT I STARTED TO NOTICE THINGS WEREN'T RIGHT. I HAVE HAD VERY HIGH ANXIETY, EXTREME BLEEDING THAT HAS NOT STOPPED SINCE I GOT THE ESSURE, HEADACHES, NECK PAIN, SHARP PELVIC PAINS, FATIGUE, NAUSEA, EXTREME DIZZINESS, MOOD SWINGS, TROUBLE WITH ANGER, MUSCLE SPASMS, VISION CHANGES, CRAMPS, WEIRD VAGINAL DISCHARGE, MEMORY LOSS, FEELING ZONED OUT, ACNE, AND RASHES. I WAS NOT WARNED BEFORE HAND THAT THIS COULD HAPPEN IF I WOULD HAVE BEEN WARNED I WOULD HAVE NEVER GOT IT!.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056363	BAYER	9/17/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE IN 2011. WHEN I WENT FOR THE TEST TO MAKE SURE THAT SCAR TISSUE HAD GROWN TO COVER THE COIL, ONE SIDE DID NOT TAKE. I WAITED ANOTHER THREE MONTHS, HAD SAME TEXT AND IT TOOK THEM. SHORTLY THEREAFTER, I STARTED HAVING HEAVY PERIODS, TO THE POINT, I HAD TO CARRY EXTRA CLOTHES AND ON SEVERAL OCCASIONS, HAD TO LEAVE WORK TO GO HOME AND CHANGE CLOTHES. I WAS MISERABLE. I ALSO HAD MAJOR HAIR LOSS AND FATIGUE. I WENT BACK TO OB TO DISCUSS MY HEAVY PERIODS. AT THE VERY FIRST APPT, HE SAID I NEEDED A HYSTERECTOMY. I COULD NOT EVEN BELIEVE WHAT HE WAS SAYING. I DID NOT HAVE PRE-CANCER OR ANY OTHER ISSUES THAN HEAVY BLEEDING. HE HAD BEEN MY DOCTOR FOR 20 YEARS, SO I HAD THE SURGERY. I HAVE GAINED SO MUCH WEIGHT, IT IS CRAZY, WELL OVER (B)(6) POUNDS. I BELIEVE THAT HAD I NOT HAD THE ESSURE. I WOULD NOT HAVE HAD HEAVY PERIODS AND WOULD NOT HAVE HAD THE CYST. A FEW WEEKS AGO, I CAME ACROSS AN ARTICLE ABOUT ESSURE AND STARTED READING WHAT HAD BEEN HAPPENING AND I COULD NOT BELIEVE IT. IT WAS MY CASE TO THE T. I ALSO HAVE GOT AUTOIMMUNE DISEASE HASHIMOTO, AND HAD LYMPH NODE SWELLING AND HAD TO BE PUT ON ANTIBIOTICS. I NEVER ASSOCIATED ANY OF THESE ISSUES WITH ESSURE UNTIL I READ ABOUT THIS HAPPENING TO SO MANY OTHER WOMEN. PLEASE TAKE THIS SERIOUS AND TAKE OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00987	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3): 7/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/11/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ATTORNEY IN THE UNITED STATES, ON BEHALF OF A PLAINTIFF FAMILY IN UNITED STATES ON 24-AUG-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR BIRTH CONTROL. THE INSERTION PROCEDURE WAS DONE UNDER GENERAL ANESTHESIA. A D&C (DILATION AND CURETTAGE) WAS ALSO DONE TO REMOVE REDUNDANT TISSUE CLOSE TO THE RIGHT TUBE OSTIUM, ALL OF WHICH WAS DONE UNDER GENERAL ANESTHESIA. THE PLAINTIFF WAS TOLD THAT SHE WOULD EXPERIENCE SHORT TERM SPOTTING, AND MILD CRAMPS. INSTEAD SHE HAD HEAVY BLEEDING AND SEVERE PAIN. AS A RESULT, SHE HAD ANOTHER SURGERY TO REMOVE THE ESSURE COILS, AND OPTED FOR A TUBAL LIGATION TO BE PERFORMED AT THE SAME TIME. ON (B)(6) PLAINTIFF UNDERWENT A HYSTEROSALPINGOGRAM CATHETER INTRODUCTION TO CHECK ON THE DEVICES. THE RADIOLOGY REPORT STATED THAT THE LEFT ESSURE COILS DEVICE WAS IN ITS PROPER PLACE AND OCCLUDED BUT RIGHT-SIDED ESSURE COIL DEVICE WAS NOT LOCATED WITHIN THE FALLOPIAN TUBE. A SECOND DEVICE WAS NOTED IN THE LEFT PELVIS AND MAY HAVE MIGRATED INTO THE PERITONEAL CAVITY. THE FACTS AND CIRCUMSTANCE OF THE CLAIM WERE DISCOVERED ON AFTER THE RADIOLOGY FOLLOW UP STUDY PERFORMED ON (B)(6) 2013. AS A DIRECT AND PROXIMATE RESULT OF THE DEFECTIVENESS OF THE ESSURE COIL PLAINTIFF SUFFERED HEMORRHAGE, HEADACHE, MENSTRUAL IRREGULARITIES, FATIGUE, WEIGHT FLUCTUATIONS, EXTREME STOMACH PAIN, IOSS OF SEXUAL DESIRE, AND DEPRESSION. AS THE DIRECT AND PROXIMATE RESULT OF THE NEGLIGENCE OF THE ABOVE-NAMED DEFENDANTS, AND EACH OF THEM, PLAINTIFF WAS HURT AND INJURED IN HER HEALTH, IN STRENGTH AND ACTIVITY, SUSTAINING INJURIES TO HER BODY AND SHOCK AND INJURIES AT HER NERVOUS SYSTEM AND PERSON WHICH INJURIES HAVE CAUSED AND CONTINUE TO CAUSE PLAINTIFF GREAT MENTAL, PHYSICAL, AND

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NERVOUS PAIN AND SUFFERING. PTC INVESTIGATION RESULT WAS RECEIVED ON 08-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT.. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS RECEIVED FROM A LAWYER ON BEHALF OF A FEMALE CONSUMER/PLAINTIFF WHO HAD SEVERE PAIN AND HEAVY BLEEDING/HEMORRHAGE AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. HER HYSTEROSALPINGOGRAM REVEALED HER RIGHT SIDED ESSURE COIL WAS NOT LOCATED WITHIN FALLOPIAN TUBE (COIL NOTED IN LEFT PELVIS AND MAY HAVE MIGRATED INTO THE PERITONEAL CAVITY). SHE WAS SUBMITTED TO A SURGERY TO REMOVE ESSURE COILS. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBE; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), MIGRATION (INTO FALLOPIAN TUBE OR TO PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A UTERINE/FALLOPIAN TUBE PERFORATION DURING DEVICE INSERTION. ALSO, ABNORMAL GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR WITH ESSURE. IN THIS PARTICULAR CASE, THE EVENTS WERE REPORTED WITHIN 3 MONTHS OF ESSURE INSERTION. GIVEN THIS POSITIVE TEMPORAL RELATIONSHIP AND EVENTS NATURE; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00995	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0716, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN (B)(6) 2013. CONSUMER REPORTED THAT HER DOCTOR KNEW THAT SHE WAS SENSITIVE TO METALS AND GENERALLY HAD VERY SENSITIVE SKIN. IN THE WEEKS AFTER GETTING ESSURE SHE FELT INTENSE BURNING AND SEVERE PELVIC PAIN. EIGHT WEEKS LATER, ON (B)(6) 2013, SHE HAD ESSURE REMOVED VIA BILATERAL SALPINGECTOMY (THE ESSURE COILS WERE PULLED OUT). THE RIGHT ONE BROKE DURING THE PROCEDURE BUT THE DOCTOR SWORE SHE GOT ALL THE PIECES OUT. AT 6 WEEKS POST-OPERATIVE, THE PAIN HAD COME BACK AND GOT WORSE AND WORSE OVER THE FOLLOWING YEAR. IT INTENSIFIED TO THE POINT WHERE HER ENTIRE BODY WAS IN PAIN, HER SKIN, JOINTS, AND NECK PAIN ACCOMPANIED THE SEVERE PELVIC PAIN, AND THE FATIGUE BECAME SO SEVERE THAT SHE OFTEN COULD NOT GET OUT OF BED. MULTIPLE VISITS AND MANUAL EXAMS CONFIRMED THAT HER UTERUS WAS EXTREMELY PAINFUL TO THE TOUCH. SHE WAS SCHEDULED FOR A TOTAL VAGINAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY. A MAGNETIC RESONANCE IMAGING PERFORMED 2 WEEKS BEFORE SURGERY CONFIRMED THAT METAL FRAGMENTS HAD EMBEDDED THEMSELVES IN THE UTERINE WALL. POST HYSTERECTOMY THE PELVIC PAIN REDUCED BY 80-90%, BUT THE SYSTEMIC JOINT PAIN REMAINED AND WORSENED. IN ADDITION, HER FATIGUE WAS JUST AS BAD IF NOT WORSE, AND SHE STARTED EXPERIENCING COGNITIVE SYMPTOMS INCLUDING DIZZINESS, TINNITUS, SPEECH PROBLEMS, SLURRED SPEECH, SEVERE FATIGUE, STUMBLING AND OTHER GAIT PROBLEMS, AND MORE. A BRAIN AND C-SPINE MRI SHOWED A LESION OR TUMOR IN THE BRAIN STEM AS WELL AS MULTIPLE

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HOT SPOTS IN THE BRAIN. SHE WAS SCHEDULED FOR A LUMBAR PUNCTURE ON (B)(6) 2015 TO CONFIRM OR RULE OUT MULTIPLE SCLEROSIS. SHE HAS STOPPED WORKING DUE TO THESE ISSUES WAS APPLYING FOR (B)(6). SHE WAS MOSTLY BEDRIDDEN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS RECEIVED ON 15-SEP-2015, (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD SEVERE PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A SALPINGECTOMY AND THE RIGHT ESSURE BROKE DURING THIS PROCEDURE. LATER, A MAGNETIC RESONANCE SHOWED ESSURE METAL FRAGMENTS HAD EMBEDDED THEMSELVES IN THE UTERINE WALL. SHE WAS SUBMITTED TO A HYSTERECTOMY. ADDITIONALLY, A MRI REVEALED LESION OR TUMOR IN HER BRAIN STEM (MULTIPLE HOT SPOTS IN THE BRAIN) AND THE CONSUMER WAS SCHEDULED FOR A LUMBAR PUNCTURE TO CONFIRM OR RULE OUT MULTIPLE SCLEROSIS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ONLY SUSPICION OF MULTIPLE SCLEROSIS AND BRAIN LESION/TUMOR ARE UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. IN THIS CASE, CONSUMER HAD PELVIC PAIN WEEKS AFTER ESSURE INSERTION. DURING A SALPINGECTOMY THE RIGHT DEVICE BROKE AND PIECES WERE FOUND EMBEDDED IN UTERINE WALL. CONSIDERING EVENTS NATURE AND GIVEN THEIR POSITIVE TEMPORAL RELATIONSHIP WITH ESSURE THERAPY; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS; CONSIDERING THEIR PATHOPHYSIOLOGY AND GIVEN ESSURE LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY IS CONSIDERED VERY UNLIKELY. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00996	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0719, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT ESSURE LEAD TO PELVIC PAIN, HEAVY, IRREGULAR, LONG LASTING PERIODS, ADENOMYOSIS, UTERINE PROLAPSE, OVARIAN CYSTS, BACK PAIN, WEIGHT GAIN, HAIR LOSS. IT WAS THE WORST THING SHE COULD HAVE EVER DONE. SHE ENDED UP WITH A TOTAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY IN JULY. SHE WAS ALSO ALLERGIC TO NICKEL, WHICH SHE WAS NOT AWARE OF WAS IN THE DEVICE WHEN IMPLANTED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO HAD UTERINE PROLAPSE, WHICH IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND UNLISTED. IN THIS CASE, CONSUMER REPORTED THAT ESSURE LEAD TO OCCURRENCE OF THESE EVENTS. SHE ENDED UP WITH A TOTAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY. NO ALTERNATIVE EXPLANATION WAS GIVEN. WITH REGARDS TO PELVIC PAIN, BASED ON THE EVENT'S NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO UTERINE PROLAPSE, ALTHOUGH THE CAUSE WAS NOT REPORTED, CONSIDERING ITS PATHOPHYSIOLOGY AND THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE

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EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 15-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00997	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0721, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN (B)(6) 2014. CONSUMER REPORTED THAT SHE HAD THE ESSURE IMPLANTED BY THE RECOMMENDATION OF HER DOCTOR. THE NEXT MONTH, IN (B)(6) 2014, AFTER IMPLANT SHE BEGAN TO FEEL ABDOMINAL PAIN, RANDOM RASHES, MAJOR FATIGUE AND ABNORMAL SKIN CHANGES. AFTER NUMEROUS TALKS WITH THE DOCTOR THEY SAID NOTHING WAS WRONG WITH HER. FINALLY, IT OCCURRED TO HER TO GET TESTED FOR NICKEL ALLERGY. AFTER HER TEST CAME BACK POSITIVE, THE GYNECOLOGIST SCHEDULED SURGERY. IT HAD BEEN OVER A YEAR OF PAIN WHEN A SIMPLE ALLERGY TEST COULD HAVE PREVENTED IT. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS RECEIVED ON 15-SEP-2015: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A

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QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ABDOMINAL PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. AFTER SHE WAS TESTED POSITIVE FOR NICKEL ALLERGY; HER PHYSICIAN SCHEDULED SURGERY. SHE STATED IT HAD BEEN OVER A YEAR OF PAIN. ALL EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND USUALLY RESOLVE AFTER DEVICE REMOVAL. ADDITIONALLY, ABDOMINAL, PELVIC PAIN AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE EVENTS STARTED IN CLOSE ASSOCIATION WITH ESSURE INSERTION. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN THIS CASE IT IS UNCLEAR IF CONSUMER ACTUALLY HAVE A SURGERY TO REMOVE ESSURE OR IF THE PROCEDURE WAS ONLY SCHEDULED. SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING AND NO FOLLOW-UP WILL BE POSSIBLE; COMPANY REGARDS THIS CASE AS INCIDENT (DUE TO THE POSSIBLE SURGICAL INTERVENTION). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00998	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 8/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-0718, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. CONSUMER REPORTED THAT SHE HAD ISSUES WITH THIS DEVICE. SHE HAD ESSURE PLACED AND IT WAS VERY PAINFUL AND UNPLEASANT EXPERIENCE IN HER DOCTOR'S OFFICE. SHE HAD PREVIOUSLY TOLD HER DOCTOR THAT SHE WAS ALLERGIC TO NICKEL AND HE TOLD HER THAT SHE WOULD HAVE NO ISSUES WITH THIS DEVICE BECAUSE THE MANUFACTURER USED A DIFFERENT ALLOY THAN STANDARD NICKEL. I WAS DOWN FOR 3 DAYS AFTER INSERTION. FROM HER DAY ONE UNTIL SHE HAD IT REMOVED VIA TOTAL HYSTERECTOMY LEAVING ONLY HER OVARIES IN (B)(6) 2014, SHE DEALT WITH DAILY PELVIC PAIN THAT GOT PROGRESSIVELY WORSE TO THE POINT IT HURT TO STAND UP STRAIGHT. HER ENERGY SLOWLY LEFT HER, SHE COULD NOT LOSE WEIGHT, SHE BEGAN TO HAVE MEMORY ISSUES, AND AT THE END SHE COULD BARELY TAKE CARE OF HER CHILDREN. SHE WENT TO DOCTOR AFTER DOCTOR TO FIND THE CAUSE AND ALL BLOOD WORK AND EXAMS CAME BACK AS NORMAL. SHE EVEN HAD TO SEE A GI (GASTROINTESTINAL) SURGEON BECAUSE IT WAS LIKE HAVING A BABY EVERY TIME SHE HAD A BOWEL MOVEMENT. IT WAS TO THE POINT THAT SHE HAD TO USE LIDOCAINE OINTMENT INSIDE HER RECTUM TO NUMB EVERYTHING SO SHE COULD NOT CRY EVERY TIME SHE WENT TO THE BATHROOM. IT WAS STILL PAINFUL BUT BEARABLE. THE JOINT PAIN, THE INCREASE IN MIGRAINES, THE BODY ACHES, MEMORY FOG, THE METAL TASTE IN HER MOUTH, THE PAIN DURING AND AFTER INTERCOURSE THAT WAS UNBEARABLE, THE STABBING PELVIC PAIN THAT HAPPENED WITH EVERY STEP SHE TOOK, THE UNEXPLAINED WEIGHT GAIN, THE PURE EXHAUSTION THAT WAS WITH HER EVERY DAY, THE NIGHT

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SWEATS, THE RANDOM UNEXPLAINED RASHES, THE HAIR LOSS, THE COLOR CHANGE IN HER HAIR TO WHITE AND GREY, THE BODY SWELLING, THE TEETH PROBLEMS, THE GENERAL MALAISE, THE TENDON ISSUES IN HER MAJOR JOINTS, ALL WERE NOT THERE PRIOR TO INSERTION OF THE ESSURE DEVICE. THEY ALL CAME ON WITHIN 6 MONTHS OF INSERTION AND GAINED STRENGTH AS TIME WENT ON TO MAKE HER LIFE A LIVING MISERY OF PAIN, DISCOMFORT, AND ULTIMATELY LEADING HER TO HAVING TO HAVE MAJOR SURGERY TO REMOVE IT FROM HER BODY, ALONG WITH A MAJOR ORGAN FOR A WOMAN. SHE STATED THAT SHE WAS ALMOST A YEAR OUT FROM HAVING ESSURE REMOVED AND HAD BEEN DIAGNOSED AT THE TIMED OF REPORT WITH AN AUTOIMMUNE DISEASE THAT HER BLOOD WORK THROUGH HER LIFE SHOWS IT BEGAN AFTER INSERTION OF THE DEVICE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEALT WITH DAILY PELVIC PAIN THAT GOT PROGRESSIVELY WORSE TO THE POINT IT HURT TO STAND UP STRAIGHT (INTERPRETED AS PELVIC PAIN). APPROXIMATELY 1 YEAR A HALF AFTER INSERTION, SHE HAD ESSURE REMOVED VIA TOTAL HYSTERECTOMY LEAVING ONLY HER OVARIES. A YEAR AFTER REMOVAL, SHE WAS DIAGNOSED WITH AN UNSPECIFIED AUTO-IMMUNE DISORDER. THE PELVIC PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE AUTO-IMMUNE DISORDER IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS UNLISTED. CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP BETWEEN THE ESSURE THERAPY AND PELVIC PAIN AND ALSO CONSIDERING THAT NO ALTERNATIVE EXPLANATION WAS PROVIDED, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. IN CONTRAST, CONSIDERING THE PHYSIOPATHOLOGY OF AUTO-IMMUNE DISORDERS AND THE LOCALIZED ACTION OF ESSURE IT IS UNLIKELY THAT IT WOULD CAUSE THE DEVELOPMENT OF THIS DISEASE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00999	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0728, # FDA2014N0736-0015, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. SHE HAD PERIOD FOR 3.5 YEARS, CONSTANT PAIN IN HER LEGS, HIPS, LOWER BACK, NECK AND ABDOMEN. SHE LOOKED 7 MONTHS PREGNANT. SHE EXPERIENCED HEADACHES ALWAYS, EVERY SINGLE DAY. THEY WERE SO BAD SHE HAS BEEN TO A NEUROLOGIST. SHARP PAINS WHEN SHE COUGHED OR SNEEZED, NO ENERGY EVER, NON-STOP ITCHING, ALWAYS AGITATED, DEPRESSED, NO SEX SINCE (B)(6) 2013 TO THE TIME OF THIS REPORT. ALL SHE WANTED TO DO WAS SLEEP. HER SKIN LOOKED HORRIBLE, DRY AND ITCH NON-STOP. SHE WENT TO A PAIN DOCTOR FREQUENTLY FOR HER BACK, HIPS AND LEGS. SHE HAD SWELLING IN HER LEGS MORE OFTEN THAN NOT. SHE NO LONGER HAS ANKLES ON MOST DAYS. HER FEET AND SKIN BURNS MOST OF THE TIME. SHE HAD BURSITIS AND USED TO GET LONG NEEDLES PUSHED THROUGH HER HIP INTO HER JOINT TO RELIEVE THE PAIN AND PRESSURE. HER MEMORY WAS GONE; VISION SEVERELY DECLINED IN THE LAST 2 YEARS. SHE HAD A PULSE IN HER EYELIDS THAT MAKES SHE FEEL LIKE SHE WAS GOING CRAZY AS WELL AS SEEING STARS WAY TO MANY TIMES. SHE SWEATS SO BADLY AT NIGHT. SHE FELT AS THOUGH SHE WAS BEING STABBED IN HER UTERUS WITH A KNIFE. SHE HAS BEEN SEEN FOR HER THYROID, TESTED FOR ARTHRITIS, STOMACH ISSUES IN UPPER AND LOWER GI TRACT, PHYSICAL THERAPY TO GET HER RIGHT HIP TO WORK AGAIN, COUNTLESS TIMES BY THE ORIGINAL OBGYN REGARDING SEVERE PELVIC PAIN AND BLEEDING. SHE WAS NOW HAVING ANXIETY ATTACKS. ON (B)(6) 2015 SHE UNDERWENT A SURGERY. SHE HAS NOT BLED SINCE SURGERY. ON (B)(6) 2015 THE BUMPS ON HER ARM, SWELLING IN HER FEET AND ANKLES

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AND CONSTANT ITCHING WERE GONE. HER EVERY DAY HEADACHES WERE GONE. SHE DOES STILL GET THE OCCASIONAL MIGRAINE BUT SHE WOULD TAKE 1 A WEEK OVER 1 EVERY DAY ALL DAY. SHE HAS ENERGY; HER 5 YEARS OLD DAUGHTER SAID SHE NO LONGER LOOK PREGNANT AND WAS NOT AS CRABBY. SHE HAS ONLY BEEN TO HER PAIN MANAGEMENT THERAPY 1 TIME SINCE SHE LEFT THE HOSPITAL. HER BURSITIS DISAPPEARED, WHICH MEANS NO MORE LONG NEEDLES IN HER HIP TO RELIEVE THE PAIN. THE INJECTIONS WERE GETTING IN HER NECK AND SHOULDERS ALSO NO LONGER NEEDED. HER LOWER BACK PAIN WAS NOWHERE NEAR AS BAD AS IT WAS. SHE WAS NOT WAKING UP IN THE MIDDLE OF THE NIGHT WITH HORRIBLE LEG PAINS JUST TO SMOKE A BOWL OF MARIJUANA. SHE WAS NOT TIRED THROUGHOUT HER DAY AT WORK AND SHE HAS SO FAR HAD 2 FULL WEEKS AT WORK. HER NIGHT SWEATS WERE GONE; HER FACE HAS CLEARED UP AGAIN. HER VISION WAS STILL BAD AND SHE STILL SEE STARS, BUT SHE STILL NEEDED TO DO A METAL DETOX. SHE WAS NOT DEPRESSED OR CRYING ALL THE TIME. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND SEVERE PELVIC PAIN. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER UNDERWENT A SURGERY. CONSIDERING THAT A POSITIVE TEMPORAL RELATIONSHIP IS IMPLIED AND GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION. ADDITIONALLY, SEVERAL NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 16-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01000	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0740; AWARENESS DATE:22-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. WITHIN HOURS, SHE STARTED TO HAVE EXTREME MIGRAINES. SHE STATED WAS NEVER TOLD THAT ESSURE WAS MADE OUT OF NICKEL. SHE IS HIGHLY ALLERGIC. WITH THIS SEVERE REACTION SHE WAS SOULY LIVING ON IBUPROFEN AND SHE COULD NOT LEAVE A ROOM WITHOUT SUNGLASSES. SHE EXPERIENCED PAIN, NOT ONLY FROM MIGRAINES, BUT FROM THE 36 OTHER SYMPTOMS THAT WERE CAUSED BY ESSURE. THIS AFFECTED HER AND HER CHILDREN. SHE WAS GIVEN PILLS TO BE SHOVED DOWN HER THROAT TO TRY TO COMPENSATE FOR THE PAIN THAT SHE WAS IN. SHE SPECIFIED THAT PAIN NOT ONLY A PHYSICALLY PAIN BUT ALSO MENTALLY. AT THE AGE OF (B)(6) SHE HAD A FULL HYSTERECTOMY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS RECEIVED ON 16-SEP-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT.

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BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED AFTER ESSURE INSERTION. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01001	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/16/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0714 / FDA-2014-N-0736-0816 / FDA-2014-N-0736-0015, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT SINCE ESSURE PROCEDURE SHE EXPERIENCED PAINFUL BLOATING AND CRAMPING SO SEVERE THAT IT HAS SENT HER TO THE EMERGENCY ROOM, INCONSISTENT IRREGULAR MENSTRUAL CYCLES, HAIR LOSS, BACK PAIN, HOT FLASHES, INSOMNIA AND SKIN ISSUES DUE TO A PRE-EXISTING NICKEL ALLERGY. SHE ALSO STATED THAT ESSURE HAD BEEN PHYSICALLY AND EMOTIONALLY DEBILITATING AND SHE WAS FACING A HYSTERECTOMY TO TRY AND GET HER LIFE BACK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING SO SEVERE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STARTED EXPERIENCING THIS EVENT SINCE ESSURE PROCEDURE. SHE WAS FACING A HYSTERECTOMY TO TRY AND GET HER LIFE BACK. NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON A POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THE EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED.

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ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 06-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS RE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01002	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2008
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0743, FDA-2014-N-0736-0752 AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER ON UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. WEEKS AFTER INSERTION, SHE STARTED SUFFERING FROM DEBILITATING JOINT PAIN TO THE POINT THAT WALKING OR DOING STAIRS WAS OFTEN DIFFICULT. FOR THE NEXT FIVE YEARS SHE SUFFERED WITHOUT ANY ANSWERS. THE INFLAMMATION IN HER BODY REACHED A PEAK IN 2012 AND SHE WAS DIAGNOSED WITH LUPUS AND WAS PUT ON TOXIC AUTOIMMUNE MEDICATIONS. SHE STATED THAT SHE WAS ROBBED OF YEARS WITH HER 3 CHILDREN, HUSBAND, HEALTH AND EVEN HER HAIR (SHE HAD TO WEAR A HAIR PIECE). SHE WAS ALWAYS SICK. SHE ALSO HAD LEG CRAMPS, BACK PAIN AND PAIN DURING INTERCOURSE. SHE COULD NOT LOSE WEIGHT AND WAS ALWAYS TIRED AND WITH NO ENERGY. SHE CONTACTED A DOCTOR WHO AGREED TO DO A HYSTERECTOMY DUE TO HER HEAVY PERIODS. IT HAS BEEN 5 MONTHS SINCE HER HYSTERECTOMY AND SHE DID NOT HAVE TO TAKE ANY MEDICATION FOR LUPUS SINCE THE DAY AFTER SURGERY. HER JOINT PAIN AND FLU LIKE SYMPTOMS WERE GONE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS RECEIVED ON 16-SEP-2015. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT

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REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO WAS SUBMITTED TO A HYSTERECTOMY DUE TO HEAVY PERIODS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE WAS DIAGNOSED WITH LUPUS. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY LUPUS IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER WAS DIAGNOSED WITH LUPUS. MENSTRUAL IRREGULARITIES, INCLUDING OLIGOMENORRHEA AND MENORRHAGIA ARE COMMON IN WOMEN WITH SYSTEMIC LUPUS ERYTHEMATOSUS. THIS COULD HAVE BEEN A CONTRIBUTORY ROLE IN CONSUMER'S BLEEDING. NEVERTHELESS, GIVEN EVENT'S NATURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING LUPUS, ALTHOUGH CONSUMER STATED SHE IMPROVED FROM THIS CONDITION WITH ESSURE REMOVAL; CONSIDERING LUPUS PHYSIOPATHOLOGY AND GIVEN ESSURE LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY IS CONSIDERED UNLIKELY. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01003	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0745, AWARENESS DATE 22-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED IN 2011. CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN 2011, UNDER THE IMPRESSION IT WAS THE SAFEST PERMANENT BIRTH CONTROL AVAILABLE. AFTER HER 3 MONTH CHECKUP AND A MISSING COIL AND A PERFORATED FALLOPIAN TUBE SHE FOUND HERSELF IN EMERGENCY SURGERY WITH A 4 MONTH OLD AND A 2 YEAR OLD. SURGERY COMPLETE AND THE SURGEON COULD NOT FIND THE MISSING COIL. HIS EXACT WORDS TO HER HUSBAND WERE THAT HE WAS JUST GOING TO LEAVE IT IN HER BODY, BECAUSE THE MANUFACTURE INFORMED THAT THEY IF THE COIL MIGRATED OUTSIDE THE FALLOPIAN TUBE, THEY WERE TO JUST LEAVE IT, BECAUSE THEY WILL NOT FIND IT. CONSUMER WAS IN HORRIFIC ABDOMINAL PAIN AND DEBILITATING JOINT PAIN FOR MONTHS. THE IMPLANTING DOCTOR SAID HER ONLY OPTION WAS A FULL HYSTERECTOMY. SHE FOUND A DOCTOR WILLING TO EXPLORE AND REMOVE THE COILS. SHE HAS NEVER FELT BETTER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER HER 3 MONTH CHECK UP, A MISSING COIL AND A PERFORATED FALLOPIAN TUBE WAS DIAGNOSED. A COMPLETE SURGERY WAS PERFORMED BUT THE SURGEON COULD NOT FIND THE MISSING COIL. CONSUMER WAS IN HORRIFIC ABDOMINAL PAIN AND DEBILITATING JOINT PAIN FOR MONTHS. THE IMPLANTING DOCTOR SAID HER ONLY OPTION WAS A FULL HYSTERECTOMY. THE EVENT FALLOPIAN TUBE PERFORATION IS LISTED IN THE REFERENCE SAFETY

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INFORMATION FOR ESSURE WHILE THE OTHER EVENT IS UNLISTED. BOTH ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, BASED ON THE PATHOPHYSIOLOGY AND CONSIDERING THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO COMPLETE SURGERY PERFORMED AND A PLANNED FULL HYSTERECTOMY. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 15-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01004	BAYER HEALTHCARE LLC	9/18/2015	9/18/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/29/2012
Explant Date (E7): 12/14/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0878 / FDA-2014-N-0736-0730 AWARENESS DATE 22-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2012. I HAD ESSURE INSERTED ON (B)(6) 2012. IT WAS WHEN MY NIGHTMARE STARTED. I STARTED HAVING BLEEDING 2 DAYS AFTER INSERTION OF COILS WITH SEVERE ABDOMINAL PAIN AND BACK PAIN, ALSO HAD A METAL TASTE IN MOUTH. I CALLED (B)(6) AND WAS ASSURED THAT THIS WAS NORMAL AND TO TAKE MOTRIN. AFTER MONTHS OF BLEEDING AND VARIOUS COMBINATIONS OF PRESCRIPTION MEDICATIONS TO TRY AND STOP BLEEDING , MY OBSTETRICIAN / GYNECOLOGIST ORDERED A D&C (DILATION AND CURETTAGE) ON (B)(6) 2012. HAD SURGERY AND WAS HOSPITALIZED FOR 4 DAYS ON (B)(6) 2012 DUE TO COMPLICATIONS POST-OPERATION CONSISTING OF CHEST PAIN, PNEUMONIA, URINARY TRACT INFECTION AND ACUTE RENAL FAILURE. STILL BLEEDING AFTER D&C. I WENT BACK TO EMERGENCY ROOM ON (B)(6) 2012 FOR SEVERE ABDOMINAL PAIN, BACK PAIN AND WAS MEDICATED AND RELEASED. HOSPITALIZED ON (B)(6) 2012 AFTER ULTRASOUND SHOWED LARGE CYST ON OVARY RELEASED 2 DAYS LATER AND SCHEDULED FOR HYSTEROSCOPY AND ENDOMETRIAL ABLATION SURGERY ON (B)(6) 2012. BEGAN HAVING SEVERE CLUSTER MIGRAINE HEADACHES AT THIS TIME ALSO. ABLATION STOPPED THE BLEEDING FOR A SHORT PERIOD OF TIME. HAVE HAD SEVERAL HOSPITALIZATIONS FOR MALIGNANT HYPERTENSION AND CLUSTER/MIGRAINE HEADACHES THAT LAST DAYS AT A TIME SEEM TO PEAK DURING MY CYCLE EVEN THOUGH I DON'T ACTUALLY BLEED LIKE A NORMAL PERIOD ANYMORE. HAD MRI OF HEAD ON (B)(6) 2014 SHOWING WHITE MATTER DISEASE GREATEST WITHIN THE LEFT FRONTAL LOBE FINDINGS MAY BE

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RELATED TO MIGRAINES GIVEN PATIENTS CLINICAL HISTORY. OTHER ETIOLOGIES MAY INCLUDE A DEMYELINATING DISORDER OR LESS LIKELY CHRONIC MICROVESSEL ISCHEMIA. AT THE TIME OF REPORT, I AM WAITING FOR REFERRAL AUTHORIZATION TO HAVE ESSURE REMOVED TO SEE IF THE HEADACHES AND HYPERTENSION ISSUES RESOLVE AFTERWARDS. I ALSO FORGOT TO MENTION THE 50 LBS OF WEIGHT GAIN. SHE MADE AN UPDATE TO HER STORY ON 20-AUG-2015: THE CONSUMER REPORTED: I HAD A COMPLETE HYSTERECTOMY ON (B)(6) 2014 AND THE LAST MIGRAINE I HAD WAS ON MY WAY INTO SURGERY. I WAS ONE OF THE FORTUNATE WOMEN TO HAVE FOUND A DOCTOR WHO CONCLUDED I WAS HAVING A SYSTEMATIC ALLERGIC REACTION TO A FOREIGN BODY AND HE IMMEDIATELY PROCEEDED WITH MY SURGERY. MY PATHOLOGIST REPORT SHOWED ADENOMYOSIS, ENDOMETRIOSIS AND BOTH COILS HAD BROKEN AND DISLODGED FROM THE INITIAL PLACEMENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED BLEEDING 2 DAYS AFTER COILS INSERTION (INTERPRETED AS GENITAL BLEEDING). A FEW MONTHS, AFTER INSERTION, SHE UNDERWENT A DILATION AND CURETTAGE TO TREAT THE BLEEDING. SHE STATED SHE HAD PNEUMONIA, URINARY TRACT INFECTION AND ACUTE RENAL FAILURE POST DILATION AND CURETTAGE COMPLICATIONS FOR WHICH SHE HAD TO BE HOSPITALIZED FOR 4 DAYS. SHE HAD TO BE HOSPITALIZED AGAIN FOR A LARGE CYST ON OVARY. SHE UNDERWENT AN ENDOMETRIAL SURGERY. SHE WAS HOSPITALIZED SEVERAL TIMES FOR MALIGNANT HYPERTENSION AND MIGRAINES. THE MRI SHOWED A WHITE MATTER DISEASE WITHIN THE LEFT FRONTAL LOBE. SHE UNDERWENT A HYSTERECTOMY APPROXIMATELY 2 YEARS AFTER INSERTION AND THE PATHOLOGY REPORT SHOWED THAT BOTH COILS WERE BROKEN AND DISLODGED FROM INITIAL PLACEMENT. AFTER HYSTERECTOMY, SHE NO LONGER HAD MIGRAINES. THE GENITAL BLEEDING, DEVICE BREAKAGE AND DEVICE DISLOCATION ARE SERIOUS DUE TO REQUIRED INTERVENTION, THE WHITE MATTER DISEASE WITHIN THE LEFT FRONTAL LOBE DUE TO ITS MEDICAL IMPORTANCE, WHILE THE OTHER EVENTS ARE SERIOUS DUE TO HOSPITALIZATION. THE GENITAL BLEEDING, DEVICE BREAKAGE AND DEVICE DISLOCATION ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION WHILE THE OTHER EVENTS ARE UNLISTED. IN THIS PARTICULAR CASE, SINCE THE BLEEDING STARTED AFTER ESSURE INSERTION AND THE PATHOLOGY REPORT SHOWED THAT ESSURE COILS WERE BROKEN AND DISLODGED FROM THE INITIAL PLACEMENT, IT CANNOT BE EXCLUDED THAT BROKEN ESSURE COILS COULD CONTRIBUTE TO GENITAL BLEEDING, DESPITE THE DIAGNOSIS OF ADENOMYOSIS AND ENDOMETRIOSIS THAT COULD ALSO EXPLAIN THE BLEEDING. CONSIDERING THE NATURE OF DEVICE BREAKAGE AND DISLOCATION, THESE EVENTS ARE ASSESSED AS RELATED TO ESSURE. HOWEVER, ALTHOUGH THE OTHER EVENTS OCCURRED DURING ESSURE THERAPY, CONSIDERING THE NATURE OF THESE EVENTS AND LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT ESSURE WOULD CAUSE PNEUMONIA, URINARY TRACT INFECTION, ACUTE RENAL FAILURE, LARGE CYST ON OVARY, WHITE MATTER DISEASE, MALIGNANT HYPERTENSION AND WHITE MATTER DISEASE WITHIN THE LEFT FRONTAL LOBE (UNRELATED). THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 16-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056474	BAYER	9/18/2015	9/25/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

STARTING AROUND 2012, I BEGAN TO HAE BODY ACHES, LOW GRADE FEVERS, JOINT PAIN, FATIGUE, MEMORY PROBLEMS, PAINFUL SEXUAL INTERCOURSE, LONGER PERIODS, A TIME WHERE MY PERIODS WERE HEAVIER THAN EVER IN MY LIFE, AND I SAW MY PCP BECAUSE I FELT SOMETHING WAS WRONG WITH ME AFTER I THOUGHT I WAS CONTINUALLY GETTING THE FLU! I SAW MY PCP SHE RAN TEST AND TOLD ME SHE WANTED TO REFER ME TO A RHEUMATOLOGIST FOR AN AUTOIMMUNE DISORDER AND SHE THINKS THAT IT IS LUPUS. I WENT TO THE RHEUMATOID PHYSICIAN SHE RAN ADD'L TEST AND DX RHEUMATOID ARTHRITIS AND FIBROMYALGIA. SHE STATED SHE WAS NOT SURE IF IT WAS LUPUS PER LAB TESTS. I WAS IN SO MUCH PAIN I MISSED DAYS OF WORK IN THE BEGINNING WHEN I THOUGHT I HAD THE FLU MANY TIMES I ALSO COULD NOT WORK DUE TO MONTH'S LONG FLARE UP OF PAIN AND DISCOMFORT FOR ABOUT A MONTH OR LONGER. I HAVE REPORTED PAIN, IRREGULAR BLEEDING, AND TENDERNESS IN MY ABDOMINAL TENDERNESS, ALONG WITH MY DX FIBROMYALGIA TO MY GYN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056475	BAYER	9/19/2015	9/25/2015

Event Information:

Event Date (B3): 9/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE TUBAL LIGATION
Device Type (E2): ESSURE TUBAL LIGATION
Model # (E4): NA
Catalog # (E4): NA
Lot #(E4): NA

Single Use: *
Implant Date (E6): 4/24/2008
Explant Date (E7): 9/19/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE TUBAL LIGATION PLACED IN 2008. BEEN HAVING HORRIBLE PAIN IN PELVIC, LOWER ABDOMEN, HIPS, AND LOWER BACK SINCE THE DEVICE HAD BEEN PLACED AND SYMPTOMS HAVE ONLY GOTTEN WORSE TO THE POINT OF NOT ONLY WANTING TO HAVE ESSURE REMOVED BUT FEEL IT IS IMMEDIATELY NECESSARY TO HAVE IT REMOVED. IT IS CONSTANT CHRONIC PAIN THAT CONTINUES TO ONLY GET WORSE WITH MENSTRUAL CYCLE BEFORE, DURING, AND AFTER. SINCE THE ESSURE WAS PLACED INTERCOURSE IS ALSO VERY PAINFUL TO WITH STAND. I'VE TRIED TO DEAL WITH THIS PAIN HOPING AND PRAYING AND WOULD EVENTUALLY SUBSIDE BUT, IT HASN'T IN THE TWO YEARS SINCE IT'S BEEN PLACED. MY LIFE HAS TOTALLY BEEN AFFECTED BY THIS DEVICE WITH THE UNCOMFORTABLE PAIN AND SUFFERING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056476	BAYER	9/19/2015	9/25/2015

Event Information:

Event Date (B3): 10/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/16/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE, EVER SINCE I GOT IT I HAVE HAD ISSUES, THE FIRST SIX MONTH I HAD PAINFUL INTERCOURSE, I GOT IT DONE IN 2013 AND I KEEP GETTING WEIRD SIDE EFFECTS LIKE THE OTHER REPORTS, BAD BACK PAIN EVERY DAY, SEVERE CRAMPING I NEVER HAD CRAMPS BEFORE ESSURE, HEAVY BLEEDING, HEADACHES ALMOST EVERY DAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056484	BAYER	9/20/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/20/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE I HAVE HAD THIS ESSURE DEVICE, I HAVE SUFFERED EXTREMELY HEAVY PERIODS. I HAVE HAD CRAMPING AND SEEM TO BLEED EVERY TWO WEEKS THOUGHT IT WOULD BE SAFER THAN ORAL BIRTH CONTROL AND NOW IN TERRIFIED I DON'T KNOW HOW TO TAKE IT OUT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-00989	BAYER HEALTHCARE LLC	9/21/2015	9/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012 STERILIZATION. HSG (HYSTEROSALPINGOGRAM) SHOWED BILATERAL BLOCKED TUBES AND DEVICES IN PROPER POSITION. ON AN UNSPECIFIED DATE, SHE STARTED HAVING INTERMITTENT BLEEDING. SHE ALSO HAD 3 YEARS OF POST COITAL SPOTTING. ULTRASOUND AND FLAT PLATE WERE DONE AND SUGGESTED THAT THE DEVICE HAD MIGRATED TOWARDS THE ENDOMETRIAL CAVITY, ALTHOUGH IT WAS STILL PARTIALLY IN THE TUBE; COMPARING IT WITH HSG, IT WAS SOMEWHAT LOW THEN. PHYSICIAN WAS ABLE TO REMOVE DEVICE INTACT HYSTEROSCOPICALLY AND DID A UNILATERAL LAP TUBAL. PHYSICIAN REPORTED POLYPS, SURROUNDING THE ESSURE DEVICE AS IT ENTERED THE OSTIA. ACCORDING TO HIM, MAYBE IT WAS AN INFLAMMATORY PROCESS CAUSING THE BLEEDING. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE MIGRATED TOWARDS THE ENDOMETRIAL CAVITY. THIS DEVICE WAS REMOVED BY HYSTEROSCOPY. THIS EVENT WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (PROXIMAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS CASE, THE PATIENT EXPERIENCED GENITAL BLEEDING; X-RAY AND ULTRASOUND SHOWED THE DEVICE WAS PROTRUDING INTO UTERUS. DURING A HYSTEROSCOPY FOR ITS REMOVAL; PHYSICIAN SAW POLYPS SURROUNDING THE ESSURE DEVICE. ACCORDING TO HIM, MAYBE THE BLEEDING WAS RELATED TO AN INFLAMMATORY PROCESS. THESE POLYPS COULD ALSO HAVE A CONTRIBUTORY ROLE IN THE REPORTED DEVICE DISLOCATION. NEVERTHELESS, CONSIDERING DEVICE DISLOCATION NATURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. FOLLOW-UP IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 13-NOV-2015 - ESSURE QUESTIONNAIRE PROVIDED: THE PATIENT WAS (B)(6). MEDICAL HISTORY INCLUDED GRAVIDA 2 AND PARITY 2. PREVIOUS GYNECOLOGICAL INTERVENTIONS WERE DENIED. ESSURE WAS INSERTED IN (B)(6) 2012. THE INSERTION WAS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01005	BAYER HEALTHCARE LLC	9/21/2015	9/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 9/4/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED IN 2009 FOR PERMANENT STERILIZATION BY ANOTHER DOCTOR. ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2015. SHE WAS NOT PREGNANT. SHE EXPERIENCED ABDOMINAL PAIN RELATED TO ESSURE COILS AND WANTED IT REMOVED. THE REPORTING PHYSICIAN WAS NOT CONVINCED THAT ABDOMINAL PAIN WAS RELATED TO ESSURE BUT DID REMOVE THE BILATERAL ESSURE ON (B)(6) 2015 THROUGH LAPAROSCOPY. PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS ALSO RECEIVED (RECEIPT DATE (B)(6) 2015). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO EXPERIENCED ABDOMINAL PAIN, WHICH SHE RELATED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). THE DEVICES WERE REMOVED BY LAPAROSCOPY. THE REPORTED EVENT WAS

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CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE PHYSICIAN WAS NOT CONVINCED THAT PATIENT'S ABDOMINAL PAIN WAS RELATED TO ESSURE. HOWEVER, SINCE NO ALTERNATIVE EXPLANATION IS AVAILABLE AND GIVEN EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICES REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

FOLLOW UP 03-DEC-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01006	BAYER HEALTHCARE LLC	9/21/2015	9/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/19/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON 24-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2015 IN AN UNCOMPLICATED PROCEDURE (SHE WAS 6 WEEK POSTPARTUM). ADDITIONAL INFORMATION FROM 11-SEP-2015 (PTC RESULT). ON (B)(6) 2015 THE PATIENT WAS COMPLAINING OF SEVERE PAIN AND REQUESTING REMOVAL OF HER DEVICES. THE PHYSICIAN ASKED IF HE COULD REMOVE THE DEVICES HYSTEROSCOPICALLY (AFTER L/S VISUALIZATION OF THE TUBES TO EVAL FOR PERFORATION) AND THEN PERFORM AN L/S SALPINGECTOMY FOR STERILIZATION. HE COULD PROBABLY GET SURGERY SCHEDULED BY FOLLOWING WEEK. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD SEVERE PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION.

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PHYSICIAN IS PLANNING TO PERFORM SURGERY FOR DEVICES REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE PATIENT CONTACTED THE PHYSICIAN COMPLAINING OF PAIN A FEW DAYS AFTER ESSURE INSERTION. SHE REQUESTED DEVICES REMOVAL AND PHYSICIAN IS PLANNING THE PROCEDURE BY FOLLOWING WEEK FROM THIS REPORT. CONSIDERING EVENT'S NATURE AND ITS CLOSE TEMPORAL RELATIONSHIP WITH ESSURE PLACEMENT; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

INTERNAL COMMUNICATION RECEIVED ON 07-DEC-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD SEVER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01007	BAYER HEALTHCARE LLC	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 8/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A84632

Single Use: Y
Implant Date (E6): 4/8/2013
Explant Date (E7): 8/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 25-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. ADDITIONAL INFORMATION RECEIVED ON 11-SEP-2015 (PTC RESULT). ESSURE MICRO INSERT WAS REMOVED AT TIME OF EMB (ENDOMETRIAL BIOPSY) ON (B)(6) 2015. THE DOCTOR USED A GYNECORE BRUSH. PRODUCT TECHNICAL COMPLAINT (PTC) WSA RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE ESSURE MICRO INSERT WAS REMOVED AT TIME OF EMB (ENDOMETRIAL BIOPSY) (INTERPRETED AS MEDICAL DEVICE REMOVAL AND THIS PROCEDURE WAS CONSIDERED AS OFF LABEL USE OF DEVICE). THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION,

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REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE ESSURE REMOVAL, THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 FROM PHYSICIAN - ESSURE QUESTIONNAIRE PROVIDED: THE PATIENT WAS (B)(6). ESSURE WAS INSERTED 10 WEEKS POSTPARTUM (LOT NUMBER A84632). CERVICAL DILATATION AND SOUNDING WERE NOT PERFORMED. PARACERVICAL BLOCK WAS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01008	BAYER HEALTHCARE LLC	9/21/2015	9/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 25-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE FOR PERMANENT STERILIZATION. ON UNSPECIFIED DATE A PICTURE WAS TAKEN, PRIOR TO PATIENT HAVING SALPINGECTOMY AND HYSTERECTOMY. THE PICTURE SHOWED THAT LOOKS LIKE ESSURE DEVICE PERFORATED THROUGH THE FALLOPIAN TUBE, ON THE SAME SIDE WHERE PATIENT WAS COMPLAINING OF PAIN. THIS DOCTOR DID NOT DO THE ESSURE PROCEDURE; HOWEVER, HE DID PERFORM THE SALPINGECTOMY AND HYSTERECTOMY. THE PATIENT WAS DOING FINE. PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE

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PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT A PICTURE WAS TAKEN AND THE RESULT SHOWED ESSURE DEVICE PERFORATED THROUGH THE FALLOPIAN TUBE. A SALPINGECTOMY AND HYSTERECTOMY WERE PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE) AND MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF FALLOPIAN TUBE PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION (UTERINE TUBAL PERFORATION QUESTIONNAIRE) HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 07-DEC-2105: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01009	BAYER HEALTHCARE LLC	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 8/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 25-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED IN 2010 FOR PERMANENT STERILIZATION. SHE WAS NOT PREGNANT. HSG (HYSTEROSALPINGOGRAM) TEST WAS NEVER DONE. PATIENT HAS HISTORY OF KIDNEY STONES. ON (B)(6) 2015 SHE WENT TO THE DOCTOR WITH COMPLAINTS OF DYSMENORRHIA AND METRORRHAGIA. THE CAT SCAN WAS ORDERED FOR HER KIDNEY STONES AND NOT ESSURE. SCAN TEST RESULTS SHOWED THAT THE ESSURE DEVICE WHICH APPEARS TO BE OUT OF THE FALLOPIAN TUBE WAS IN DISTAL ASPEC WITHIN FUNDUS OF THE UTERUS ON THE PROXIMAL AXIS. THE DOCTOR WAS PLANNING TO DO HYSTERECTOMY. AT THE TIME OF THIS REPORT, ESSURE WAS ONGOING. PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A

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QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT A SCAN TEST WAS PERFORMED AND THE RESULT SHOWED DEVICE WHICH APPEARS TO BE OUT OF THE FALLOPIAN TUBE, IN ITS DISTAL ASPECT, IS WITHIN FUNDUS OF THE UTERUS ON THE PROXIMAL AXIS (INTERPRETED AS DEVICE DISLOCATION). THE DOCTOR WAS PLANNING TO DO HYSTERECTOMY. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION (UTERINE TUBAL PERFORATION QUESTIONNAIRE) HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 30-NOV-2015 FROM PHYSICIAN. NO FURTHER INFORMATION PROVIDED REGARDING THE EVENTS. THE CT FINDINGS WERE NOT CONFIRMED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PAT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01010	BAYER HEALTHCARE LLC	9/21/2015	9/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 622308

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON 19-FEB-2014. THE REPORT REFERS TO THE REPORTING (B)(6) FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND NEVER HAD THE HSG (HYSTEROSALPINGOGRAM) CONFIRMATION TEST, EXPERIENCED HEAVY BLEEDING DURING HER CYCLES, SOME CYCLES WERE IRREGULAR, SOMETIMES DID NOT GET A CYCLE, SOMETIMES SHE HAD TWO CYCLES PER MONTH, BECAME PREGNANT (DEVICE INEFFECTIVE), MISCARRIED AT 7 WEEKS, HAD GINGIVITIS DURING PREGNANCY. CONSUMER EXPERIENCED A SECOND PREGNANCY ON ESSURE ONGOING AT TIME OF REPORTING, SEE BAYER CASE NUMBER (B)(4). NO INFORMATION WAS GIVEN ON CONSUMER HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IN (B)(6) 2007, THE CONSUMER HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 622308, INSERTED FOR PERMANENT BIRTH CONTROL. FOLLOWING PLACEMENT OF ESSURE, CONSUMER HAD A DEPO SHOT. CONSUMER NEVER HAD THE HSG (HYSTEROSALPINGOGRAM) CONFIRMATION TEST. SHE DID NOT HAVE THE THREE MONTH TEST DUE TO INSURANCE ISSUES AND WAS GIVEN A SECOND DEPO SHOT, AND WAS TOLD HER TUBES SHOULD BE BLOCKED. APPROXIMATELY THREE TO FOUR MONTHS AFTER INSERTION IN 2007, CONSUMER EXPERIENCED HEAVY BLEEDING DURING HER CYCLES, SOME CYCLES WERE IRREGULAR. SHE SOMETIMES DID NOT GET A CYCLE, AND SOMETIMES SHE HAD TWO CYCLES PER MONTH. THE CONSUMER BECAME PREGNANT IN 2007, AND MISCARRIED AT 7 WEEKS. CONSUMER BECAME PREGNANT AGAIN IN 2013, AND WAS DUE IN (B)(6) 2014 (SEE BAYER CASE NUMBER (B)(4)). CONSUMER WAS SCARED BEING PREGNANT WITH METAL INSIDE OF HER (DATE UNSPECIFIED). SHE HAD NICKEL ALLERGY TESTING THAT WAS NEGATIVE. SHE ALSO HAS EXPERIENCED SHARP STABBING PAINS IN HER LOWER ABDOMEN, A CONSTANT METALLIC TASTE IN HER MOUTH, HAD GINGIVITIS WHEN PREGNANT ON 2010 (DATE HAS TO BE CLARIFIED), AND HER DENTAL ISSUES

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HAVE GOTTEN WORSE WITH THE ACTUAL PREGNANCY (GUMS ARE SWOLLEN AT THE BOTTOM), IT WAS HARD FOR HER TO EAT, AND HER GUMS HURT. NO FURTHER DETAILS WERE REPORTED. FOLLOW-UP RECEIVED ON 10-MAR-2014: ALL FOLLOW-UP ATTEMPTS WERE DONE WITHOUT SUCESS. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-JUN-2014. ~ THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. LACK OF EFFECTIVENESS MAY OCCUR WITH THE USE OF ANY PRODUCT AS PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. BOTH OF THESE EVENTS ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE AND ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER 622308. NO BATCH SIGNAL CAN BE IDENTFIIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP RECEIVED ON 26-AUG-2015: THIS CASE WAS UPGRADED TO INCIDENT. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0780). CONSUMER REPORTED THAT SHE GOT ESSURE IN (B)(6) OF 2007 AT THE AGE OF (B)(6) AND STATES THAT SHE DID NOT HAVE HYSTEROSALPINGOGRAM PERFORMED (SHE COULD NOT AFFORD TO PAY OUT OF POCKET). SO SHE WAS GIVEN A 2ND DEPO SHOT AND TOLD THAT SHE SHOULD BE BLOCKED BY 6 MONTHS ANYWAY. AFTER ABOUT 7 OR 8 MONTHS, SHE STARTED HAVING HEAVIER PERIODS INCLUDING BLOOD CLOTS THE SIZE OF GOLF BALLS THAT LASTED LONGER. AS TIME WENT ON, THEY GOT IRREGULAR AND SHE STARTED HAVING PELVIC PAIN AND SHARP PAINS IN HER LEFT SIDE DURING HER CYCLES. AFTER 2 YEARS, SHE STARTED HAVING A METALLIC TASTE IN HER MOUTH, WEIGHT GAIN (THAT SHE COULD NOT LOSE NO MATTER WHAT SHE DID), ALCOHOL INTOLERANCE AND FREQUENT HEADACHES AND MIGRAINES. AFTER 3 YEARS, SHE BECAME PREGNANT AND MISCARRIED AT 6 WEEKS (PREVIOUSLY REPORTED AS 7 WEEKS). SHE WAS TOLD DURING AN ULTRASOUND THAT HER LEFT COIL LOOKED LOWER THAN IT SHOULD BE BUT THEY NEVER DISCUSSED HAVING AN HYSTEROSALPINGOGRAM TO CHECK IF SHE WAS BLOCKED OR NOT. AFTER ANOTHER 3 YEARS, SHE BECAME PREGNANT AGAIN; BY THE TIME SHE FOUND OUT SHE WAS ALREADY 8 WEEKS AND 4 DAYS ALONG. SHE HAD NO IDEA SINCE HER PERIODS GOT SO IRREGULAR. THIS TIME SHE HAD A HEALTHY BABY GIRL (SECOND PREGNANCY CASE# (B)(4)). IN ADDITION, CONSUMER REPORTED THAT HER PHYSICIAN WAS NOT CONCERNED ABOUT HER PAIN THAT SHE DESCRIBED, AND BRUSHED IT OFF AS NORMAL CRAMPING. SHE GOT A 2ND OPINION FROM A NEW PHYSICIAN AND HE DECIDED TO DO DIAGNOSTIC LAPAROSCOPY TO SEE WHAT WAS CAUSING HER PAIN AND HEAVY BLEEDING. WHEN HE DID THE SURGERY, HE SUCCESSFULLY REMOVED 1 ESSURE COIL AND, WHEN HE WENT TO GET THE 2ND ONE OUT, HE FOUND THAT THE LEFT COIL WAS NOT IN HER TUBE AT ALL, BUT EMBEDDED IN THE CORNUA OF HER UTERUS. HEALTH CARE PROFESSIONAL ALSO INFORMED IT WAS THE SIDE THAT WAS NOT BLOCKED AND WAS HOW SHE BECAME PREGNANT. SHE HAD TO HAVE A HYSTERECTOMY 2 MONTHS LATER IN (B)(6) 2014 DUE TO HER CONTINUED PAIN FROM THE EMBEDDED COIL. NOW, AFTER HYSTERECTOMY, CONSUMER FEELS 100 PERCENT BETTER AND FOUND OUT THAT THE SYMPTOMS SHE WAS HAVING MATCHED METAL TOXICITY INCLUDING THE ALCOHOL INTOLERANCE.

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COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT 3 YEARS AFTER ESSURE INSERTION AND SHE MISCARRIED AT 6 WEEKS. SHE ALSO HAD HER LEFT COIL LOOKED LOWER THAN IT SHOULD BE / LEFT COIL WAS NOT IN HER TUBE BUT EMBEDDED IN CORNUA OF HER UTERUS. A HYSTERECTOMY WAS PERFORMED. AFTER HYSTERECTOMY, CONSUMER FEELS 100 PERCENT BETTER AND FOUND OUT THAT THE SYMPTOMS SHE WAS HAVING MATCHED METAL TOXICITY INCLUDING THE ALCOHOL INTOLERANCE (SUSPICIOUS OF METAL TOXICITY). MISCARRIED AT 6 WEEKS AND SUSPICIOUS OF METAL TOXICITY WERE REGARDED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE UNLISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. THE OTHER EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED. SPONTANEOUS ABORTION IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY. UP TO 20% OF CLINICALLY RECOGNIZED PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION WILL UNDERGO SPONTANEOUS ABORTION. RISK FACTORS INCLUDE MATERNAL AGE, PREVIOUS SPONTANEOUS ABORTION, SMOKING, LOW FOLATE LEVEL, UTERINE ABNORMALITIES, FETAL CHROMOSOMAL ABNORMALITIES, MATERNAL CHRONIC DISEASE (POLYCYSTIC OVARY SYNDROME AND THYROID DYSFUNCTION, FOR EXAMPLE) AND MATERNAL INFECTIONS. BASED ON THIS AND DESPITE THE GIVEN TEMPORAL RELATIONSHIP MISCARRIED AT 6 WEEKS WAS REGARDED UNLIKELY RELATED (UNRELATED) TO ESSURE USE. WITH REGARDS TO THE OTHER EVENTS, CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS REQUIRED, THIS CASE WAS UPGRADED TO INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. AN UPDATED PRODUCT TECHNICAL ANALYSISIS EXPECTED.

Manufacturer Narrative (H10):

23-DEC-2015 - CASE CLOSED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01011	BAYER HEALTHCARE LLC	9/21/2015	9/21/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS, SOCIAL MEDIA CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED JUST ANOTHER HYSTERECTOMY. SHE STATED ESSURE WAS A CRUEL JOKE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2014: NO NEW INFORMATION PROVIDED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: CONSUMER STATED VIA SOCIAL MEDIA THAT HER NON SURGICAL PROCEDURE RESULTED IN 2 SURGERIES. SHE MENTIONED ESSURE PROBLEMS. FOLLOW UP

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INFORMATION RECEIVED ON (B)(6) 2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0806 AND FDA-201 4-N-0736-0015, AWARENESS DATE 26-AUG-2015). THE CONSUMER REPORTED SHE REPORTED THE PROCEDURE WAS THE MOST PAINFUL PROCEDURE SHE HAD EVER HAD, IT WAS EXCRUCIATING; SHE WAS SHAKING AND HYPERVENTILATING ON THE TABLE. THE PHYSICIAN HAD TO OPEN A SECOND KIT DUE TO ONE OF THE COILS FROM THE FIRST KIT BREAKING. AT HER HSG (HYSTEROSALPINGOGRAM) IT WAS FOUND THAT ONE TUBE WAS NOT BLOCKED, THEY TOLD HER THE COIL PROBABLY PERFORATED THE TUBE. THE PHYSICIAN WENT IN TO TIE THE TUBE AND REMOVE THE COIL BUT SHE COULD NOT LOCATE IT SO SHE PERFORMED A SALPINGECTOMY. THE MISSING COIL WAS NEVER FOUND AND SHE LEFT THE OTHER TUBE/COIL IN PLACE. ABOUT A YEAR LATER SHE STARTED EXPERIENCING TERRIBLE RASHES, HIVES AND UNCONTROLLABLE ITCHING; THE DOCTORS TREATED HER WITH ORAL AND TOPICAL STEROIDS, ORAL AND TOPICAL ANTIFUNGALS AND NOTHING WORKED. SHE WAS TOLD IT WAS CONTACT DERMATITIS OF AN UNKNOWN SOURCE AND TO JUST DEAL WITH IT. AT THE SAME TIME HER PERIOD WENT FROM EVERY 28 DAYS WITH REGULAR FLOW TO OUT OF CONTROL BLEEDING AND CLOTS. SHE WOULD HAVE HER PERIOD EVERY 2 WEEKS THEN MAYBE 6 WEEKS THEN EVERY WEEK; SHE WOULD BLEED THROUGH A SUPER PLUS TAMPON IN 30 MIN. AND IT WAS COMPLETELY IRREGULAR FOR THE NEXT 3 YEARS. SHE HAD PAINFUL CONSTANT CRAMPING, HER HAIR WAS FALLING OUT IN CLUMPS, SHE HAD EXTREME LOWER BACK PAIN, EXTREME SWEATING. IN THE (B)(6) 2014, SHE FOUND OUT THAT THE COILS CONTAIN NICKEL, WHICH SHE WAS ALLERGIC TO. NO DOCTOR EVER ASKED HER ABOUT NICKEL ALLERGY NOR WAS IN THE INFO SHE WAS GIVEN AT THE TIME OF THE ORIGINAL PROCEDURE. IN (B)(6) 2014, SHE HAD TO UNDERGO A TOTAL HYSTERECTOMY AND SALPINGECTOMY TO REMOVE THE COIL THAT WAS STILL IN THE TUBE/CORNUA AND THE MISSING COIL THAT HAD ENDED UP EMBEDDED IN HER UTERINE WALL. SHE STATED THAT AT THE AGE (B)(6) SHE HAD A HYSTERECTOMY AND HAS RISK OF PROLAPSE AND SHE WAS VERY ANGRY. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DURING THIS PROCEDURE PHYSICIAN HAD TO OPEN A SECOND KIT DUE TO ONE OF THE COILS FROM THE FIRST KIT BREAKING. AT HYSTEROSALPINGOGRAM ONE COIL COULD NOT BE LOCATED; LATER IT WAS DISCOVERED THE MISSING COIL THAT HAD ENDED UP EMBEDDED IN HER UTERINE WALL. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH SALPINGECTOMY. ONLY DEVICE EMBEDMENT (PARTIAL UTERINE PERFORATION) IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). ALSO, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED; MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE EVENTS IS UNKNOWN; GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01012	BAYER HEALTHCARE LLC	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 9/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE # (B)(4)) IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. SHE TOOK IBUPROFEN 5 MINUTES BEFORE PROCEDURE. PHYSICIAN COULD NOT GET COIL INTO THE TUBE AFTER NUMEROUS TIMES AND A LOT OF PAIN FINALLY PLACED IT AN HOUR LATER. SHE WAS FINE FOR ABOUT 2 YEARS THEN SHE STARTED TO DEVELOP SYMPTOMS OF FATIGUE, SLOWLY GETTING ABDOMINAL PAIN THAT WAS UNEXPLAINED, CYSTS ON OVARIES THAT WOULD GROW THE SIZE OF GRAPEFRUITS AND RUPTURE, HEAVY BLEEDING DURING MENSTRUAL CYCLE ALL WHICH WERE UNEXPLAINED. THEN 3 YEARS AGO IN 2013, SHE STARTED EXPERIENCING SEVERE STABBING PAIN IN RIGHT AND LEFT UPPER SIDES, SEVERE PELVIC PAIN, HAIR LOSS, SHE COULD NOT SIT DOWN WITHOUT SEVERE PAIN, METALLIC TASTE IN MOUTH, JOINT PAIN, MIGRAINES, LOSS OF CONCENTRATION, PAINFUL INTERCOURSE, PAINFUL URINATION, NAUSEA, DIZZINESS, BAD SMELL IN NOSE AND MUCH MORE. TESTS WERE PERFORMED INCLUDING BLOOD WORK UPS, EXPLORATORY LAPAROSCOPY FOR ENDOMETRIOSIS, CT SCANS OF THE ABDOMEN, ABDOMINAL ULTRASOUND, PELVIC ULTRASOUND, AND ENDOSCOPY. SHE WAS TREATED FOR SINUS INFECTION WHEN THERE WAS NO INFECTION PRESENT TO GET RID OF SMELL IN THE NOSE BUT NEVER WENT AWAY STILL SUFFERING FROM ALL SYMPTOMS. SHE HAS A SURGERY SCHEDULED FOR REMOVAL OF ESSURE DEVICE JUST TUBES AND DEVICE ON (B)(6). PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE

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NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2008. TWO YEARS POST INSERTION; SHE REPORTED THE FOLLOWING SERIOUS ADVERSE EVENTS AMONGST OTHER NON-SERIOUS EVENTS: ABDOMINAL AND PELVIC PAIN, OVARIAN CYSTS RUPTURE. OVARIAN CYST IS UNLISTED EVENT ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. GIVEN DEVICE LOCAL ACTION IN THE FALLOPIAN TUBES, THIS EVENT IS UNLIKELY RELATED TO ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR DURING DEVICE THERAPY (BOTH EVENTS ARE LISTED). CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, BOTH ARE CONSIDERED RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP 23-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056265	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 9/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY HSG TEST TODAY. THE TEST WAS NOT SUCCESSFUL DUE TO THE DYE GOING INTO MY VEINS IN MY UTERUS. I AM ALSO EXPERIENCING CLOTS, AND HEAVY BLEEDING. THEY HAD TO TRY THE TEST THREE TIMES BEFORE THEY DETERMINED THAT THEY WOULDN'T BE ABLE TO GET IT RIGHT AT ALL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056267	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 4/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DOCTOR PLACED THEM IN MY TUBES RESULTING IN EXTREME PAIN, SHE INSERTED 1 INTO A SCARRED TUBE. I HAD HEAVY BLEEDING WITH LARGE CLOTS FOR 3 WEEKS FALLOWING THE PROCEDURE. MY MENSTRUAL CYCLE WAS VERY IRREGULAR AFTER WORDS AND I COULD FEEL PAINFUL OVULATION. THEN I WOULD EXPERIENCE RANDOM BOUTS OF STINGING IN MY PELVIC REGION. FINALLY, ON (B)(6) 2015, I HAD A VERY SHARP, BURNING STABBING PAIN IN MY PELVIS THAT DROPPED ME, I COULD NOT MOVE FOR AWHILE, WHEN I WAS ABLE TO GET UP AND USE THE RESTROOM I HAD BEGIN SPOTTING, THE NEXT MORNING IN A 30 MINUTE WINDOW I SOAKED THROUGH A PAD AND MY CLOTHING AND BED. I HAD HEAVY BLEEDING ALL DAY THAT SATURDAY THE PAIN WAS SO UNBEARABLE I WENT TO THE ER WHO DID AN ULTRASOUND, THE ER DOCTOR SAID ONE OF MY COILS WAS IN MY UTERUS AND TO FOLLOW UP WITH MY GYNECOLOGIST. I SAW HER WEDNESDAY AND SHE DOESN'T THINK ESSURE COULD BE CAUSING THE PAIN AND WANTS ANOTHER ULTRASOUND THAT I CAN'T AFFORD BEFORE SHE WILL SPEAK WITH ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056268	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE VERY HEAVY PERIODS, MIGRAINE HEAD ACHES, SKIN RASHES AND LOWER BACK PAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056269	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 9/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A HYSTERECTOMY OVER A YEAR AGO AND WAS DIAGNOSED WITH FYBROMAYALGIA A FEW MONTHS AGO AND WAS JUST DIAGNOSED WITH RESTLESS LEG SYNDROME AND IRRITABLE BOWEL SYNDROME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056270	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 6/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, BLOATING, EXTREME MOOD SWINGS, FATIGUE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056271	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 9/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE DONE IN (B)(6) OF 2013 AFTER MY 4 CHILD SINCE THEN I'VE HAD MISCARRIED. MY STOMACH LOOKS LIKE 6 MONTHS PREGNANT. I STAY IN PAIN ALL DAY. I HAVE PERIOD 2 -3 TIME A MONTH. HEAVY BLEEDING AND BIG CLOTS. I GET UTI EVERY OTHER WEEK. PAINFUL SEX. SOMETIME I CAN BARELY EVEN WALK. WAS DONE WHEN I HAD (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056272	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 6/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (B)(6) 2014 EXTREME LOWER LEFT PELVIC PAIN. LASTED FOR SEVERAL DAYS. THEN HAD BLOATING AND ABDOMINAL FULLNESS FOR OVER A YEAR. (B)(6) 2015 PAIN OCCURRED AGAIN AND FOUND OUT IT WAS A COIL THAT RUPTURED THE FALLOPIAN TUBE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056273	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 9/16/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PUT IN 10 YRS AGO.. NOT LONG AFTER I DEVELOPED BAD ALLERGIES INDOOR AND OUT. IN THE LAST 3-5YRS MY PERIODS ARE LONGER (7 DAYS) AND THE BLEEDING IS OUT OF CONTROL . THEN I'VE GONE MONTHS W/OUT A PERIOD! I ALWAYS HAVE SHARP PAINS ON MY LEFT N RIGHT SIDES . SHARP PAINS IN MY VAGINAL AREA.; BURNING SENSATION ON BOTH SIDES AS WELL LIKE A BURNING INSIDE, TWITCHING SENSATION FROM MY OVARIES/TUBES AS WELL, THIS IS THE NORM FOR YRS NOW, I HAVE BEEN FEELING SEVERE UPS N DOWNS AROUND MY PERIODANDNBSP; AS WELL, FOGGY HEAD, LIGHTHEADED EPISODES, FEELINGS OF TICKLING ON MY SCALP AND SKIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056274	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 3/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS MEDICAL DEVICE SHOULD HAVE NEVER BEEN APPROVED. NO ONE SHOULD HAVE TO SUFFER FROM ALL THESE DIFFERENT MEDICAL ISSUES. IT HAS ALSO SENT ME THROUGH EMOTIONAL DISTRESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056275	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 6/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, DIZZYNESS, WEIGHT GAIN, FATIGUE, MOODINESS, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056276	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 12/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAIN IN STOMACH AREA. PAINFUL SEX, BLEEDING DURING AND AFTER SEX. BLEEDING BETWEEN PERIODS. HEAVY MENSTRAL WITH CLOTTING. AGGRESSIVE MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056277	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 3/11/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE DEVELOPED AN AUTOIMMUNE DISEASE DUE TO INFLAMMATORY RESPONSE OF THE MATERIALS ESSURE IS MADE OF. HAD I BEEN AWARE OF THE MATERIALS I WOULD NEVER HAVE AGREED TO HAVE THEM INSERTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056278	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 2/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANTLY BLOATED, CHRONIC PELVIC PAIN AN BACK PAIN, CONSTANT METALLIC TASTE IN MOUTH, FOUL VAGINAL ODOR, IRREGULAR HEAVY PERIODS, PAINFUL SEX, MEMORY LOSS, EYE PROBLEMS, I ALSO HAVE A NICKEL ALLERGY WHICH WAS STILL IMPLANTED WITH THE PRODUCT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056279	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 10/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WANTED A MORE PERMANENT WAY TO NOT HAVE MORE KIDS. MY INSURANCE COVER ESSURE AND MY DR RECOMMENDED IT. I EXPERIENCED WEIGHT GAIN AND ASKED ABOUT IT. A YEAR AFTER I WAS EXPERIENCING HEAVY BLEEDING, SO MY DR PUT ME BACK ON DEPOT PREVERA. I WAS HAVING A LOT OF CRAMPS SO I WENT BACK. HE KNEW I WAS NOT PLEASED ABOUT TAKING THE SHOT AGAIN, SO HE WENT IN AND BURNED MY UTERUS. I AM STILL GAINING UNEXPLAINED WEIGHT, IRRITABILITY, NO SEX DRIVE, MY HAIR IS SHEDDING MORE THAN NORMAL, AND I AM SO BLOATED IT HURTS AT NIGHT. HAVE JOINT PAIN, FLUTTER SPASMS IN MY STOMACH, DRY SKIN AND FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056280	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 6/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP CRAMPING, HEAVY AND IRREGULAR PERIODS, BLOATING, ABDOMINAL PAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056281	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 12/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREMELY HEAVY PERIODS WITH LARGE CLOTS, WOULD SOAK THROUGH TAMPON AND A PAD WITHIN AN HOUR, SORES ON SCALP, HAIR LOSS, JOINT PAIN, AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056282	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 11/27/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAS ESSURE PLACED IN (B)(6) 2009 AT MY DR'S OFFICE. THE COST WAS. COVERED BY INSURANCE. MY HEALTH RAPIDLY DECLINED IN THE YEARS FOLLOWING IMPLANTATION. I HAVE MANY ISSUES THAT I LINK TO ESSURE INCLUDING: IRREGULAR MENSTRUAL CYCLES, HEAVY BLEEDING, LARGE CLOTS, DEBILITATING MENSTRUAL CRAMPS, PELVIC PAIN, PAIN AFTER INTERCOURSE, AUTOIMMUNE ISSUES, JOINT PAIN, CHRONIC INFLAMMATION, MIGRAINES, "HIVEWWIGHT GAIN," BLOATING, LOSS OF LIBIDO, YEAST INFECTIONS (CHRONIC), GERD, ESOPHAGITIS, TINGLING IN HANDS, BRAIN FOG, MUSCLE SPASM, INSOMNIA, NIGHT SWEATS, DENTAL ISSUES, ADRENAL FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056284	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY INSURANCE COVERED ESSURE SO I HAD IT IMPLANTED IN (B)(6) 2014. THIS YEAR I STARTED NOTICING A LOT OF ISSUES AND JUST RECENTLY FOUND THAT MANY WOMEN WITH ESSURE HAVE REPORTED THE SAME ISSUES/SYMPTOMS. I'VE BEEN A HEALTHY PERSON BUT I FEEL MY HEALTH DECLINING. LIST OF SYMPTOMS: HEADACHES, FACIAL TINGLING, ITCHING IN THE ARMS, ABDOMINAL PAIN, FATIGUE, LEGS FEEL NUMB/HEAVY, WEIGHT GAIN, HAIR LOSS, CHEST PAIN, SHOCKS IN BRAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056285	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 9/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YES MY DEVICE WAS COVERED BY MY INSURER. IT WAS PLACED IN (B)(6) 2012. ABOUT 2 MONTHS LATER, I BEGAN HAVING INCREASING HEADACHES, FATIGUE, DECREASED SEX DRIVE, AND A LOT OF ABDOMINAL PAIN. AFTER THE 1ST HSG SCAN, THERE WAS STILL SOME FLOW SEEN ACROSS ONE FALLOPIAN TUBE. THREE MONTHS LATER, ANOTHER HSG WAS PERFORMED AND IT WAS NOTICED THAT THE COIL COULD NOT BE LOCATED. MORE TESTING WAS DONE AS MY PAIN WAS INCREASING. IT WAS HARD TO EVEN STAND FOR ANY PERIOD OF TIME OR HOLD MY SON ON THAT SIDE. EXPLORATORY LAP WAS DONE AND THE COIL HAD MIGRATED TO MY COLON. IT WAS REMOVED. THE PAIN RETURNED ABOUT 1 MONTH LATER EXCEPT THAT NOW IT ALSO HURT TO HAVE INTERCOURSE WITH MY HUSBAND. AFTER A CT SCAN FOR SEVERE PAIN TO THE POINT IT HURT TO WALK, THEY FOUND THAT WAS UTERUS WAS ENLARGED TO THAT OF A 4 MONTH PREGNANT PERSON. BIOPSIES AND ULTRASOUND WERE PERFORMED, IT WAS FOUND THAT I HAD DEVELOPED ADENOMYOSIS. OF NOTE, I HAD NEVER HAD ANY GYN PROBLEMS IN THE PAST. THEREFORE, MY DOCTOR AGREED THIS WAS FROM THE ESSURE DEVICE AND THE ONLY CHOICE I REALLY HAD WAS A HYSTERECTOMY WITH REMOVAL OF THE FALLOPIAN TUBES SO THAT THE OTHER COIL WOULD BE REMOVED. THIS WAS DONE IN (B)(6) OF 2014. THE INCISION GOT INFECTED AND I HAD TO BE READMITTED. RECOVERY WAS QUITE LONG. OF COURSE I HAVE NEVER BEEN THE SAME SINCE I WAS THROWN INTO EARLY MENOPAUSE. THIS YEAR, 2015, I BEGAN WITH PAIN AGAIN AND AFTER NOT BEING ABLE TO HARDLY WALK, I ENDED UP IN THE ER. THEY FOUND A 9CM MASS AND EXPLORATORY SURGERY WAS DONE. IT WAS AN ABSCESS AND CYST THAT WAS ENCASED IN SCAR TISSUE FROM THE PREVIOUS SURGERIES. THIS COULD HAVE KILLED ME HAD THE ABSCESS RUPTURED. SO NOW I SIT AND WONDER WHAT'S NEXT?

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Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056287	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 9/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING THEM PLACED ON (B)(6) 2013, WITHIN A MONTH I STARTED EXPERIENCING CONSTANT PELVIC PAIN, VAGINAL IRRITATION, HEAVY MENSTRUAL BLEEDING, FATIGUE, MIGRAINES, EMERGENT URINATION, DIZZINESS, CONSTIPATION, GENERAL WEAKNESS, PAIN DURING SEX, AND LEFT LEG NUMBNESS. WHEN ADDRESSED WITH THE DOCTOR I WAS INFORMED THAT ESSURE DOESN'T HAVE SIDE EFFECTS IT MUST BE SOMETHING ELSE, BUT THEY HAVEN'T BEEN ABLE TO FIND ANYTHING ELSE WRONG WITH ME THAT WOULD CAUSE THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056288	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 2/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEG, BACK, HIPS, ABDOMEN, HEADACHES AND MOOD SWINGS. HORRIBLE, HORRIBLE PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056290	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 9/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS PAINFUL TO IMPLANT, PAINFUL TO CONFIRM IT WORKED AND PAINFUL AFTER IMPLANTED. AFTER IT WAS IMPLANTED I EXPERIENCED RASHES AND CRACKED SORES ON SKIN, PELVIC PAIN, BACK PAIN, ABDOMINAL PAIN, SEVERE BLOATING, JOINT PAIN, MENSTRUAL CYCLE PAIN (ESP DURING OVULATION FOR UP TO 2 WEEKS), BLADDER LEAKAGE, INFLAMMATION, EDEMA (CONFIRMED EDEMA IN LUMBAR AND RETROSACRAL SOFT TISSUES AND QUADS CAUSING HIP IMPINGMENT), FACET CAPSULITIS, RED MARROW PROLIFERATION SUGGESTING CHRONIC ANEMIA AND EVEN A BULGED DISC AND DISC LOCATION AND BENT COCCYX WHICH WAS CAUSED BY THE PRESSURE FROM THE INFLAMMATION AND EDEMA. I CAN HARDLY GET OUT OF BED IN THE MORNING, CANNOT WIPE MYSELF IN THE MORNING FROM THE STIFFNESS AND CANNOT TAKE CARE OF MY TWO CHILDREN VERY WELL BECAUSE OF ALL THE SYMPTOMS AND CHRONIC PAIN. I WILL BE HAVING A HYSTERECTOMY TO HAVE THIS DEVICE REMOVED AS I HAVE NO OTHER OPTIONS TO STOP THE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056297	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING, HEADACHES, EXTREME BLOATING, HEAVY PERIODS, BLOOD CLOTS THE SIZE OF SOFTBALLS, NICKEL TASTE, TWITCHING ALL OVER BODY, EARS RINGING, EXCESSIVE PAIN, JOINT PAIN, FATIGUE, HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056298	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 3/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED (B)(6) 2010 (B)(6) COVERED MY IMPLANT. WITHIN 6 MONTHS AFTER HAVING IT IMPLANTED I WAS DIAGNOSED WITH ADENOMYOSIS. I HAVE BEEN HAVING EXTREMELY HEAVY PERIODS, BLOATING ALL THE TIME, VERY PAINFUL CRAMPING DURING MY PERIOD WHICH I HAVE NEVER HAD BEFORE IMPLANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056304	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 9/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOUND OUT BY SONOGRAM LEFT COIL HAS MIGRATED OUT OF THE TUBE AND INTO THE UTERINE CAVITY NOW I HAVE TO HAVE MY TUBES REMOVED AND THE COIL REMOVED. UNEXPECTED MEDICAL BILLS NOT MY FAULT

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056305	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TOWARDS THE END OF 2009 I HAD AN ESSURE IMPLANTATION VIA (B)(6). IT WAS ONLY A FEW MONTHS LATER THAT I BEGAN HAVING EXTREMELY PAINFUL PERIODS. I HAVE BEEN SUFFERING FROM INTENSE CRAMPING, CHRONIC FATIGUE, BLOATING, HEAVY PERIODS, JOINT PAIN, MIGRAINES, BACK PAIN AND HAVE GAINED CONSIDERABLE WEIGHT. MY MEMORY IS NOT AS SHARP AS IT ONCE WAS AND I OFTEN FEEL AS IF I AM WALKING AROUND IN A HAZE. I EXPERIENCE CRAMPING BEFORE, DURING AND AFTER MY PERIOD. I ALSO GET CRAMPS DURING INTERCOURSE. I OFTEN HAVE SEVERE MOOD SWINGS AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056307	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 1/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BODY PAIN, BACK PAIN, INCREASED BLEEDING DURING PERIODS, MIGRAINES, SWOLLEN DISTEND ABDOMEN, INCREASED BLOOD PRESSURE, SWOLLEN ANKLES, STABBING PAIN IN STOMACH, NO ENERGY, INSOMNIA, ONSET OF AUTOIMMUNE DISORDER BEHCETS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056308	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 8/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT FATIGUE. HEADACHES. MOOD SWINGS. HOT FLASHES. VERY PAINFUL MENSTRUATION. JOINT PAIN. BLOATING. BLURRED VISION. BRAIN FOGGINESS. NO LABS DONE SINCE HSG TO TEST OCCLUSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056309	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY INSURANCE COVERED ESSURE SO I HAD IT IMPLANTED IN (B)(6) 2014. THIS YEAR I STARTED NOTICING A LOT OF ISSUES AND JUST RECENTLY FOUND THAT MANY WOMEN WITH ESSURE HAVE REPORTED THE SAME ISSUES/SYMPTOMS. I'VE BEEN A HEALTHY PERSON BUT I FEEL MY HEALTH DECLINING. LIST OF SYMPTOMS: HEADACHES, FACIAL TINGLING, ITCHING IN THE ARMS, ABDOMINAL PAIN, FATIGUE, LEGS FEEL NUMB/HEAVY, WEIGHT GAIN, HAIR LOSS, CHEST PAIN, SHOCKS IN BRAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056310	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 5/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE IMPLANTED THIS YEAR AND IT SEEMED EVERYTHING WAS GOING FINE UNTIL JUST RECENTLY WHEN MY HAIR STARTED TO FALL OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056311	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). APPROXIMATELY 3-4 (2009/2010) YEARS AFTER GETTING ESSURE (INSERTION (B)(6) 2006) I EXPERIENCED FATIGUE, WEIGHT GAIN, BLOATING, IRREGULAR PERIODS, BACK PAIN, PELVIC PAIN. AT THE TIME OF INSERTION MY DEVICE WAS PROVIDED BY MY INSURER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056312	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 3/31/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INSURANCE COVERED THIS PROCEDURE . SEVERE DEPRESSION AND ANXIETY, NAUSEA, MUSCLE SPASMS. PELVIC PAIN, HEADACHES, BRAIN FOG, HEAVY BLEEDING THAT HAS NOT STOPPED SINCE DEVICE WAS PLACED, TIREDNESS, WEAKNESS, LETHARGIC, SLEEPY, MOOD SWINGS, PAIN WITH INTERCOURSE, RAPID HEART RATE, HIGH BLOOD PRESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056313	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY, PAINFUL PERIODS, WATER RETENTION/BLOATING, UNCONTROLLABLE WEIGHT GAIN, PAINFUL OVULATION, HOT FLASHES, NIGHT SWEATS, MOOD SWINGS, INSOMNIA, BLEEDING/CRAMPING BETWEEN PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056314	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 5/19/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESSIVE BLEEDING, CHRONIC PAIN, 2 HEAVY PERIODS A MONTH, BLOATED, SEVERE MIGRAINES, BLURRED VISION, PELVIC/ABDOMINAL PAIN, SEVERE LOWER BACK PAIN, JOINT PAIN, LEG PAIN, HEAVY WEIGHT GAIN, TIREDNESS, SEVERE ITCHING ALL OVER, METAL TASTE IN MOUTH, TENDER BREAST, PAIN WITH SEX, BIG CLOTTING WITH PERIODS, HEAVY VAGINAL DISCHARGE, DEPRESSION, MOOD SWINGS, INSOMNIA, STABBING PAINS IN VAGINA AND RECTUM, ANXIETY, TINGLING AND NUMBNESS ALL OVER BODY, HAIR LOSS, CHEST PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056315	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 4/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD (B)(6) AT THE TIME AND IT PAID FOR THIS TO BE DONE. SINCE THEN I HAVE GAINED A LOT OF WEIGHT, CONSTANT HEADACHE, SEVERE BACK PAINS, PELVIC PAINS, VERY HEAVY MENSTRUAL CYCLES INCLUDING HUGE BLOOD CLOTS, VISION PROBLEMS, GUM DISEASE AND TEETH PROBLEMS, MY SKIN AND BONES HURT TO THE TOUCH SOMETIMES AND MY BODY SWELLS (HANDS, FEET AND FACE). I HAVE HIGH BLOOD PRESSURE AND AM IN THE BEGINNING STAGES OF DIABETES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056316	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HEAVY MENSTRUAL BLEEDING, THAT LASTED FOR 3 WEEKS. IT WAS SO HEAVY THAT THEY HAD TO STOP MY MENSTRUAL CYCLE, BECAUSE I WAS GETTING DIZZY AND ALMOST PASSING OUT. SEVER ABDOMINAL PAIN AND CRAMPING . LOSS OF APPETITE, BUT GAINING OF WEIGHT, AND BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056317	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 5/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL MENSTRUAL CYCLE, HEADACHE, DIZZINESS, HEART PALPITATIONS, HAIR LOSS ALOPECIA, ENDOMETRIOSIS, ADENOMYOSIS, OVARIAN CYSTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056318	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 8/22/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING FOR THE FIRST 2-3 DAYS OF MY MENSTRUATION, CAN BARELY KEEP CONCENTRATION FROM DAY TO SAY, WAKE UP IN PAIN DAILY, CONSTANTLY TIRED, DRAINED MENTALLY AND EMOTIONALLY, UGH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056319	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 8/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAIN , CHEST PAIN, SHORTNESS OF BREATH, FATIGUE, WEIGHT GAIN, INFLAMMATION, VISION PROBLEMS (BLURRINESS), ACNE, HEART PALPATIONS, STABBING ABDOMINAL PAIN, SORENESS (ABDOMINAL AND VAGINAL).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056320	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 9/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2016 I HAD A HYSTERECTOMY UTERUS WITH CERVIX-BILATERAL FALLOPIAN TUBES. FINAL DIAGNOSIS: UTERUS HYSTERECTOMY: SQUAMOUS METAPLASIA, TUBULAR METAPLASIA, AND CHRONIC INFLAMMATION INVOLVING THE UTERINE CERVIX, PROLIFERATIVE ENDOMETRIAL, ADENOMYOSIS, SEROSOL ADHESIONS. RIGHT AND LEFT FALLOPIAN TUBES: ADHESION FORMATION, BILATERAL ESSURE COIL, GROSS DIAGNOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056321	BAYER	9/21/2015	9/21/2015

Event Information:

Event Date (B3): 5/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE IMPLANTED THIS YEAR AND IT SEEMED EVERYTHING WAS GOING FINE UNTIL JUST RECENTLY WHEN MY HAIR STARTED TO FALL OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056496		9/21/2015	9/25/2015

Event Information:

Event Date (B3): 2/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/25/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6), I HAD ESSURE PUT IN (B)(6) 2011. I HAVE HORRIBLE BACK PAIN, MIGRAINES, STOMACH PAIN, WEIGHT GAIN. CAN'T LOSE WEIGHT, PAINFUL SEX, BAD PERIODS, AND TIRED AND ALSO ALWAYS FEELING BLOATED FROM ESSURE. I HAVE HAD CYST ON MY OVARIES WENT TO HOSPITAL BECAUSE OF IT. I HAVE NEVER IN MY LIFE HAD CYST UNTIL AFTER ESSURE WAS PUT IN. I HAVE BACK PAIN MAKES IT HARD FOR ME TO GET HOUSE HOLD CHORES DONE. I ALWAYS DON'T FEEL MYSELF ANYMORE, ANY HEAD HURTS EVERYDAY TAKE MEDICATION FOR MIGRAINES. HAVE TRIED EVERYTHING TO LOSE WEIGHT BUT THE WEIGHT IS JUST IN MY LOWER STOMACH FEELS PREGNANT. I WANT THIS ESSURE OUT. ITS HORRIBLE SICK OF BEING IN PAIN AND DEPRESSED CAUSE OF THE WEIGHT, THE BACK PAIN, MY SEX LIFE, MY HAIR FEELS DIFFERENT AND MY BODY HURTS ALL THE TIME. SOMEONE HELP! I FEEL LIKE A TOTALLY DIFFERENT PERSON. I AM NOT ME ANYMORE. I CAN'T TAKE IT ANYMORE. ESSURE HAS RUINED BY LIFE. THIS MUST BE TAKEN OFF MARKET. SOMEONE NEEDS TO HELP PEOPLE LIKE MYSELF AND HELP THEM GET THIS TAKEN OUT. I JUST WANT TO GET RID OF THIS HORRIBLE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056498		9/21/2015	9/25/2015

Event Information:

Event Date (B3): 2/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 7/7/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IMPLANTS (B)(6) 2015. I DID THE FOLLOW UP DYE TEST AND BOTH TUBES WERE BLOCKED. IN (B)(6) 2015 I BECAME PREGNANT. AFTER AN ULTRASOUND, WE SAW THAT ONE OF THE IMPLANTS WAS GONE, THIS WAS AFTER DOING THE FOLLOW UP DYE TEST WITH BY OBGYN AND A RADIOLOGIST PRESENT, WHICH I ALSO SAW FOR MYSELF ON THE SCREEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056499		9/21/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/5/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVING HEADACHES, FATIGUE, DEPRESSION, PELVIC PAIN WITH INTERCOURSE AND WEIGHT FLUCTUATIONS. HEAVY AND IRREGULAR MENSTRUAL CYCLES WHEN I ATTEMPTED TO STOP MY BIRTH CONTROL PILL. I AM STILL TAKING MY BIRTH CONTROL PILL DUE TO THAT FACT. HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) 2007.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 8/21/2015 **Report Date (B4): 9/2/2015** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C22907

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

AN ESSURE IMPLANT FAILED TO FIRE FROM THE INTRODUCER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01013	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0849, AWARENESS DATE 26-AUG-2015). IT REFERS TO AN ADULT FEMALE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2012. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS WERE RECEIVED ON 15-SEP-2015. CONSUMER REPORTED: I HAVE 4 BOYS. I WAS A VERY ACTIVE MOM. THREE YEARS AGO I HAD ESSURE PLACED BECAUSE IT FELT LIKE IT WAS THE BEST OPTION FOR ME. NO DOWN TIME AND SPEEDY RECOVERY. MY CRAMPING NEVER WENT AWAY. IT INCREASED AS TIME WENT BY TO THE POINT THE PAIN WAS SO EXCRUCIATING I COULDN'T WALK AND WAS IN TEARS. I HAVE LOST SO MUCH HAIR. I HAVE MULTIPLE MIGRAINES AND HAVE BEEN TO THE EMERGENCY ROOM COUNTLESS TIMES. I HAVE BECOME VERY FORGETFUL, DIZZY, MY EYE VISION HAS GOTTEN WORSE. I HAVE BEEN DIAGNOSED WITH VERTIGO. I HAD ESSURE REMOVED IN (B)(6) 2015. AT AGE (B)(6) I HAD A HYSTO ONLY KEEPING MY OVARIES. THAT EXCRUCIATING CRAMPING GONE, THOSE MIGRAINES GONE, THE HAIR IS GROWING BACK, THE DIZZINESS GONE. MY FORGETFULNESS AND EYE VISION SEEM TO BE A PERMANENT THING. THOSE HAVE NOT CHANGED. I HAVE BECOME MORE ACTIVE NOT QUITE LIKE I WAS BEFORE. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL

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FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING/PAIN. SHE WAS SUBMITTED TO A HYSTERECTOMY AND HER CRAMPING WAS GONE. THIS EVENT, REGARDED AS LOWER ABDOMINAL PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED AFTER ESSURE INSERTION AND IMPROVED WITH DEVICE REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01014	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 6/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 6/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0854, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 AFTER HER DAUGHTER WAS BORN. ON (B)(6) 2015 SHE UNDERWENT A HYSTERECTOMY BECAUSE OF ALL THE MEDICAL PROBLEMS SHE HAD SINCE THEIR PLACEMENT. SHE WAS ONLY (B)(6), THAT WAS DEVASTATING TO HER. PTC INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD

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ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2008. ON (B)(6) 2015 SHE UNDERWENT A HYSTERECTOMY BECAUSE OF ALL THE MEDICAL PROBLEMS SHE HAD SINCE THEIR PLACEMENT. DURING DEVICE THERAPY, SURGICAL REMOVAL OF ESSURE MAY BE REQUIRED. CONSUMER PROVIDED VERY LIMITED INFORMATION, HOWEVER SHE MENTIONED MEDICAL PROBLEMS DUE TO DEVICE. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED AND THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01015	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0859, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. A FEW MONTHS LATER, SHE STARTED HAVING PROBLEMS. FIRST, WERE PREGNANCY SYMPTOMS, THEN PERIODS STARTED BEEN SO DIFFERENT, IT WAS NOT NORMAL. SHE STARTED BEEN BLOATING, HAVING LOT OF FATIGUE. BEFORE HAVING THE ESSURE, EVERYTHING WAS GOOD, SHE DIDN'T HAVE THOSE PROBLEMS. IT WAS HARD TO GET UP FROM BED AND BE ACTIVE. EIGHT MONTHS AFTER ALL THAT, SHE DECIDE TO HAVE THAT OUT OF HER, UNFORTUNATELY HAD TO HAVE HYSTERECTOMY. AT THE TIME OF THIS REPORT SHE WAS MUCH BETTER. IT WAS HER BACK AGAIN. HER HUSBAND WAS HAPPY TO HAVE HER BACK AGAIN AS HER KIDS DO. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE

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TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLOATING. SHE WAS SUBMITTED TO A HYSTERECTOMY; ACCORDING TO HER SHE WAS FEELING MUCH BETTER AFTER THIS SURGERY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL GAS AND BLOATING MAY OCCUR. IN THIS CASE, CONSUMER REPORTED MENSTRUAL ABNORMALITIES AND BLOATING AFTER ESSURE INSERTION, WHICH IMPROVED WITH DEVICE REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, THE NON-SERIOUS EVENT FATIGUE WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01016	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0835, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 FOR BIRTH CONTROL. THE CONSUMER CONCURRENT CONDITION INCLUDED NICKEL ALLERGY. CONSUMER REPORTED THAT SHE WAS SCHEDULED FOR AN ABLATION AND DOCTOR RECOMMENDED PLUGGING HER TUBES BECAUSE IF SHE GOT PREGNANT COULD BE FATAL FOR HER OR FOR THE FETUS. A FEW MONTHS AFTER ESSURE PLACEMENT SHE BEGAN TO SUFFER FROM RASHES, PELVIC AND JOINT PAIN, TINGLING ALL OVER, DIZZINESS AND WEIGHT GAIN. SHE WENT TO MULTIPLE DOCTORS AND PRESCRIPTION DRUGS TO ALEVIATE THE SYMPTOMS BUT NEVER CURED HER AILMENTS. IN 2015 SHE HAD A HYSTERECTOMY PERFORMED TO REMOVE ESSURE. SHE WAS DOING MUCH BETTER SINCE ESSURE REMOVAL, BUT WAS UPSET TO ALSO LOSE HER CERVIX, UTERUS AND TUBES. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2010 AND DEVICES HAD TO BE REMOVED IN 2015 DUE TO PELVIC PAIN (SERIOUS AND LISTED EVENT). PELVIC PAIN MAY OCCUR DURING DEVICE THERAPY. SINCE AN INTERVENTION WAS REQUIRED, CAUSALITY CANNOT BE EXCLUDED AND THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01017	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/3/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0807, AWARENESS DATE 26-AUG-2015). IT REFERS TO A (B)(4) YEARS OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. ADDITIONAL INFORMATION RECEIVED ON 15-SEP-2015 (PTC - PRODUCT TECHNICAL COMPLAINT). IT CAUSED RASHES ALL OVER HER BODY AND HER DOCTOR DETERMINED SHE WAS ALLERGIC TO NICKEL. THE RASHES LASTED FOR 5 MONTHS. SHE WAS TAKING 4 BENADRYL A DAY JUST TO QUIT ITCHING. SHE HAD A HYSTERECTOMY SCHEDULED IN (B)(6) 2014, BUT THE RASH SUDDENLY STOPPED COMING BACK. SHORTLY AFTER THEY STOPPED SHE STARTED HAVING PAIN IN HER ABDOMEN, BACK, AND PELVIC AREA. SHE STAYED SO DRAINED AND BLOATED ALL THE TIME. SHE KEPT A MIGRAINE ALL THE TIME. SHE NEVER HAD THE ENERGY TO DO ANYTHING WITH HER CHILDREN AND SOMETIMES ANY ENERGY TO GET OUT OF BED. SHE ALSO HAD A LOT OF PROBLEMS WITH IT MAKING HER GAIN WEIGHT. SHE STARTED HAVING 3 MENSTRUAL CYCLES A MONTH (B)(6) OF 2015 AND HER DOCTOR SCHEDULED A HYSTERECTOMY. SHE WAS HESITANT AT FIRST, BUT NOW SHE WAS SO GLAD SHE GOT IT. HER BELLY HAS GONE DOWN AND SHE WAS FEELING SO MUCH BETTER. ON (B)(6) 2015 SHE UNDERWENT A HYSTERECTOMY AND HAS NEVER FELT BETTER SINCE GETTING THE ESSURE. SHE WAS SO GLAD THE STRUGGLE WAS FINALLY OVER. PTC RESULT. PTC GLOBAL NUMBER: (B)(4). SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD.

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WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2013. SHE EXPERIENCED SERIOUS PELVIC PAIN THAT WAS CONSIDERED RELATED TO ESSURE AND REQUIRED A HYSTERECTOMY IN (B)(6) 2015. AFTER PROCEDURE, SHE RECOVERED FROM THE EVENT. PELVIC PAIN MAY OCCUR DURING DEVICE THERAPY AND SURGICAL PROCEDURE TO REMOVE ESSURE MAY BE REQUIRED. CONSIDERING POSITIVE TEMPORAL RELATIONSHIP, LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED AND SINCE A SURGICAL PROCEDURE WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01018	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0798, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. ALMOST IMMEDIATELY AFTER INSERTION, SHE BEGAN TO HAVE PAIN IN HER LOWER BACK AND SHARP PAINS IN HER GROIN. THE PAIN BECAME SO BAD SHE HAD TO FIND A NEW JOB THAT WAS MORE SEDENTARY. SHE BEGAN TO BECOME INACTIVE BY (B)(6) 2013. SHE WASN'T ABLE TO COOK SOME NIGHTS AND REALLY HASN'T BEEN ABLE TO DO HOUSE WORK. EVEN TO THE DAY OF REPORT (B)(6) 2015, HOUSE WORK SHE CAN'T DO MUCH OF. NOT ONLY DID THE PAIN AFFECT HER LIFE, BUT HER DAUGHTERS AS WELL. SHE FINALLY FOUND A DOCTOR TO LISTEN TO HER SYMPTOMS AND THAT SHE WAS ALLERGIC TO NICKEL IN HER EARS AND UNDERWENT A HYSTERECTOMY. PATHOLOGICAL FINDINGS WERE ADENOMYOSIS, ENDOMETRIOSIS AND CHRONIC CERVIXITIS. HER PERSONALITY BECAME VERY FLAT AFFECT. SHE WAS UNABLE TO ENJOY EVEN THE SMALL THINGS. THE PAIN AND OVERALL FEELING OF OVERALL SICK MADE HER INTO A SHELL OF HER FORMER SELF. SHE WAS LOSING HER HAIR MORE AND MORE EVERY DAY AND BECAME VERY CONSCIOUS OF THOSE CHANGES. NONE OF THOSE WERE SUSPECTED OR CAUSING ANY PROBLEMS UNTIL THE COILS WERE IMPLANTED AND SHE BEGAN HAVING PAIN. THE NICKEL CONTENT WAS NOT DISCLOSED TO HER OR THAT ANY POTENTIAL SIDE EFFECTS COULD COME UP FROM USE. POST HYSTERECTOMY AND COIL REMOVAL HER PAIN HAS ALL BUT COMPLETELY GONE AWAY. AT THE TIME OF REPORT, SHE WAS TWO MONTHS OUT BUT SHE WAS BACK TO BEING ABLE TO BE MORE ACTIVE. HER HAIR HAD BEGUN TO GROW BACK. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT

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TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO BEGAN TO HAVE PAIN IN HER LOWER BACK ALMOST IMMEDIATELY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE UNDERWENT A HYSTERECTOMY AND THE PATHOLOGY FINDINGS SHOWED ADENOMYOSIS, ENDOMETRIOSIS AND CERVICITIS. ALTHOUGH IN THIS PARTICULAR CASE, THE PATHOLOGY FINDINGS SHOWED ENDOMETRIOSIS, ADENOMYOSIS AND CERVICITIS, CONCOMITANT CONDITIONS THAT COULD EXPLAIN THE LOWER BACK PAIN, SINCE THE CONSUMER STATED THAT BACK PAIN STARTED ALMOST IMMEDIATELY AFTER INSERTION, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01019	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0869, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. ACCORDING TO THE REPORTER, ESSURE CAUSED SO MANY PROBLEMS WITH HER HEALTH. SHE ALREADY HAD 1 SURGERY AND MAY POSSIBLY NEED A SECOND SURGERY FROM ALL OF THE NEGATIVE EFFECTS IT HAS HAD ON HER BODY. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD MANY PROBLEMS

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WITH HEALTH AND HAD ONE SURGERY FROM ALL THE NEGATIVE EFFECTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, THE REPORTER MENTIONED MANY PROBLEMS AND NEGATIVE EFFECTS WITH ESSURE AND STATED ONE SURGERY WAS REQUIRED; BUT LIMITED INFORMATION WAS GIVEN AND NO REASON AND DETAILS OF THE SURGERY WAS PROVIDED. HOWEVER, SINCE THIS PROCEDURE WAS RELATED TO ESSURE AND AS NO FOLLOW-UP WILL BE POSSIBLE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01020	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0812, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2011. CONSUMER REPORTED: I HAD ESSURE DONE IN 2011 AND HAD TO HAVE THE OTHER SIDE REDONE IN 2012 AFTER MY HSG TEST SHOWED ONLY ONE SIDE WAS BLOCKED. I ALSO HAD AN ABLATION DONE WHEN THEY PLACED THE OTHER ESSURE IN 2012 BECAUSE MY PERIODS BECAME SO HEAVY. EVENT AFTER THE ABLATION I STILL CONTINUE TO HAVE HEAVY PERIODS AND DON'T EVENT GO A FULL MONTH BETWEEN PERIODS. I HAVE GAINED A LOT OF WEIGHT AND WEIGHT MORE NOW THAN WHEN I WAS PREGNANT WITH ALL FOUR OF MY KIDS. I GET HEADACHES ALL THE TIME WITH VERTIGO. MY STOMACH CONSTANTLY LOOKS LIKE I AM PREGNANT AND ALWAYS GETS MUCH WORSE AFTER EATING. I HAVE NEVER HAD A PROBLEM WITH ACNE BEFORE AND MY FACE IS NOW COVERED. I AM ALWAYS EXHAUSTED AND HAVE NO ENERGY. I HAVE LOW BACK PAIN AND SOMETIMES WILL GET WEIRD SHOOTING PAINS IN THE FRONT WHERE MY OVARIES ARE. I AM CONVINCED IT IS ALL FROM ESSURE SINCE ALL OF MY SYMPTOMS STARTED AFTER GETTING IT BUT DOCTORS ALL SAY IT IS POLYCYSTIC OVARIAN SYNDROME AND PUT ME BACK ON BIRTH CONTROL PILLS TO REGULATE MY HORMONES. ADDITIONAL INFORMATION RECEIVED ON 15-SEP-2015 (PTC - PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). PTC RESULT: FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS

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CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE ONE SIDE REDONE BECAUSE THE HYSTEROSALPINGOGRAM SHOWED ONLY ONE SIDE WAS BLOCKED. SHE HAD AN ABLATION (OFF LABEL USE) WHEN ESSURE PROCEDURE WAS REDONE BECAUSE HER PERIODS BECAME HEAVY (INTERPRETED AS MENORRHAGIA). THIS EVENT IS SERIOUS DUE TO REQUIRED SURGICAL INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER STATED ALL HER SYMPTOMS, INCLUDING MENORRHAGIA, STARTED AFTER ESSURE INSERTION. CONSIDERING THIS SUGGESTIVE TEMPORAL RELATIONSHIP, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED SINCE THE DIAGNOSIS OF POLYCYSTIC OVARIAN SYNDROME CAN EXPLAIN OTHER SYMPTOMS BUT NOT MENORRHAGIA. THIS CASE IS REGARDED AS INCIDENT SINCE A REQUIRED INTERVENTION WAS NECESSARY TO TREAT THE MENORRHAGIA ASSESSED AS RELATED TO ESSURE. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01021	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0769, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN (B)(6) 2010. ADDITIONAL INFORMATION RECEIVED ON 15-SEP-2015: PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS. CONSUMER REPORTED: I GOT ESSURE INSERTED IN (B)(6) 2010. THE IMPLANTATION PROCEDURE IS NOTHING LESS THAN TORTURE. I PASSED OUT DURING THE PROCEDURE AND AGAIN DURING HSG (HYSTEROSALPINOGRAPHY) TEST. I WAS HEALTHY BEFORE THEN. IN THE 5 YEARS SINCE, I DEVELOPED SYMPTOMS OF IMPENDING ILLNESS. I'VE HAD ECZEMA, CHEST PAINS, FATTY LIVER, HAIR LOSS, CHRONIC FATIGUE, BLURRED VISION, SEVERE BRAIN FOG, INABILITY TO LOSE WEIGHT WITH HEALTHY DIET AND EXERCISE, ITCHY PRIVATE PARTS, ABNORMAL CYCLES, PROLONGED MENSTRUATION, ANEMIA, MOOD SWINGS, WEIGHT GAIN FROM BIRTH CONTROL USED TO REGULATE CYCLES, EXCESSIVE CRAMPING AND SHARP PAIN NEAR OVARIES. I HAD A HYSTERECTOMY ON (B)(6) 2015 TO REMOVE ESSURE. I SUFFERED A SEVERE ALLERGIC REACTION AT THE INCISION SITES. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY

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DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PROLONGED MENSTRUATION. SHE WAS SUBMITTED TO A HYSTERECTOMY TO REMOVE THE DEVICE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER REPORTED PROLONGED AND ABNORMAL MENSTRUAL CYCLES WITH ANEMIA DURING ESSURE THERAPY. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01022	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. ADDITIONAL INFORMATION RECEIVED ON 15-SEP-2015 (PTC - PRODUCT TECHNICAL COMPLAINT). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-0821) IN UNITED STATES ON 26-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER'S HUSBAND REPORTED THAT SHE COULD NOT GET OUT OF BREATH AND HER ASTHMA ACTED UP MORE THAN USUAL. INTERCOURSE WAS PAINFUL, SHE EXPERIENCED MOOD SWINGS, HER HAIR WAS FALLING OUT, SHE GAINED WEIGHT AND AT AGE (B)(6) SHE HAD TO GET A HYSTERECTOMY SO SHE CAN GET RID OF ESSURE. PTC GLOBAL NUMBER: (B)(4). PTC RESULT: FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN

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FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAINFUL INTERCOURSE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER HAD TO GET A HYSTERECTOMY. BASED ON THE NATURE OF THE EVENT AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01023	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-0886, AWARENESS DATE ON 26-AUG-2015). IT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT SHE WAS SUFFERING FROM ESSURE FOR 10 YEARS. SHE HAD A HYSTERECTOMY IN (B)(6) 2015. SURGERY RESULT SHOWED THAT HER COIL WAS PUSHING THROUGH THE SIDE OF HER FALLOPIAN TUBE. SHE ALSO EXPERIENCED PAIN DURING ESSURE THERAPY. ADDITIONAL INFORMATION RECEIVED ON 15-SEP-2015 (PTC - PRODUCT TECHNICAL COMPLAINT). PTC GLOBAL NUMBER: (B)(4). PTC RESULT: FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD PAIN DURING ESSURE THERAPY.

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SHE HAD A HYSTERECTOMY TEN YEARS AFTER ESSURE INSERTION AND SURGERY RESULT SHOWED THAT HER COIL WAS PUSHING THROUGH THE SIDE OF HER FALLOPIAN TUBE (INTERPRETED AS FALLOPIAN TUBE PERFORATION). THIS FALLOPIAN TUBE PERFORATION IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT AND, THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THIS PERFORATION IS ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01024	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0801, AWARENESS DATE 26-AUG-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2006. CONSUMER REPORTED THAT SHE HAD ESSURE IMPLANTED IN 2006. SHE WAS SEEN IN THE ER (EMERGENCY ROOM) 4 MONTHS AFTER SHE HAD THEM IMPLANTED BECAUSE SHE STARTED BLEEDING AND IT WAS NOT HER PERIOD. SHE COULD HARDLY WALK AND IT FELT LIKE SHE WAS IN LABOR. PID (PELVIC INFLAMMATORY DISEASE) WAS DIAGNOSED. SHE SOON AFTER STARTED NOTICING SHARP PAINS SHOOTING DOWN HER VAGINA AND LOWER ABDOMEN. SHE STARTED GETTING MIGRAINES THAT WOULD LAST FOR DAYS SOMETIMES WEEKS. IF SHE TUM THE WRONG WAY IT FEET LIKE HER INSIDE ARE TWISTING. HER HAIR IS STILL FALLING OUT. SHE LOOK LIKE SHE WAS 6 MONTHS PREGNANT AND IT HAS BEEN 9 YEARS. SHE DEVELOPED AN EATING DISORDER BECAUSE OF THE INFLAMMATION IN THE STOMACH. SHE ALWAYS FELT FULL AND SHE COULD EAT. SHE HAS BEEN LEAVING WITH CHRONIC BACK PAIN FOR ALMOST A YEAR NOW. DOCTORS SAY SHE HAD INFLAMMATION IN MAY LOWER BACK. ESSURE NEEDS TO BE REMOVE BECAUSE NOBODY SHOULD HAVE TO LIVE WITH PAIN ON A DAILY BASIS. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE

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TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED BLEEDING AND IT WAS NOT HER PERIOD (INTERPRETED AS GENITAL BLEEDING). PID (PELVIC INFLAMMATORY DISEASE) WAS DIAGNOSED. BOTH EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS PARTICULAR CASE, PID WAS DIAGNOSED MORE THAN 4 WEEKS POST INSERTION, THEREFORE A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, SINCE GENITAL BLEEDING MAY OCCUR WITH ESSURE, CONSIDERING THE NATURE OF THE EVENT A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01025	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0773, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER ON UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. ADDITIONAL INFORMATION RECEIVED ON 15-SEP-2015 (PTC - PRODUCT TECHNICAL COMPLAINT). SHE STATED THAT SHE HAD HER TUBES REMOVED BECAUSE OF ESSURE. SHE WAS IN THE HOSPITAL FOR 5 DAYS TO FIND OUT THAT SHE HAD CYSTS DEVELOP AND BURST AND ALSO INFLAMMATION DUE TO AN ALLERGIC REACTION TO THE NICKEL. SHE EXPERIENCED A LOT OF LOSS FINANCIALLY AND EMOTIONALLY FROM THE ASSURE IMPLANTS. PTC GLOBAL NUMBER: (B)(4). PTC RESULT: FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD

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ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2010. CONSUMER REPORTED THAT HER TUBES WERE REMOVED DUE TO AN ALLERGIC REACTION TO THE NICKEL. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS PERFORMED, THIS CASE IS REGARDED AS SERIOUS AND INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01026	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 6/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0774, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012 AFTER HER 4TH CHILD. ADDITIONAL INFORMATION RECEIVED ON 15-SEP-2015 (PTC - PRODUCT TECHNICAL COMPLAINT). EARLIER THIS YEAR (2015) THE SYMPTOMS OF PELVIC PAIN, NAUSEA, FATIGUE, MENTAL FOGGINESS, DEPRESSION, BLOATING IN ABDOMEN WHERE SHE LOOKED AND FELT LIKE SHE WAS 6 MONTHS PREGNANT WORSENED TO THE POINT SHE THOUGHT SHE WAS LOSING HER MIND AND PREGNANT; ALL TESTS WERE NEGATIVE AND NORMAL. SHE WAS SO SICK AND SHE FELT THE MEDICAL COMMUNITY THOUGHT SHE WAS CRAZY. THE COIL ON THE LEFT SIDE COULD NOT BE SEEN ON ULTRASOUND OR MRI. ON (B)(6) 2015 SHE UNDERWENT A HYSTERECTOMY AND ALL THOSE SYMPTOMS WERE IMMEDIATELY GONE. SHE STILL DID NOT RECEIVE AN EXPLANATION OF WHAT HAPPENED TO THE LEFT COIL. PTC GLOBAL NUMBER: (B)(4). PTC RESULT: FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2012. EARLIER THIS YEAR (2015) PELVIC PAIN WORSENED AND THE COIL ON THE LEFT SIDE COULD NOT BE SEEN ON ULTRASOUND OR MRI (INTERPRETED AS DEVICE DISLOCATION). SHE WAS SUBMITTED TO A HYSTERECTOMY AND RECOVERED FROM HER SYMPTOMS. PELVIC PAIN AND DEVICE DISLOCATION MAY OCCUR DURING ESSURE THERAPY. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01027	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0842, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT ESSURE RUINED HER LIFE AND SHE WAS SCHEDULED TO PERFORM A HYSTERECTOMY ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED ON UNSPECIFIED DATE. IN (B)(6) 2015 SHE IS GOING TO HAVE A HYSTERECTOMY DUE TO ESSURE (NO CLINICAL EVENTS WERE REPORTED). DURING DEVICE THERAPY, SURGICAL REMOVAL OF ESSURE MAY BE REQUIRED. CONSUMER PROVIDED VERY LIMITED INFORMATION HOWEVER GIVEN THE IMPLIED TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED AND THIS CASE IS REGARDED AS INCIDENT SINCE AN INTERVENTION WILL BE REQUIRED (PERFORMED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 04-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01028	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-0858, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT ESSURE HAD AFFECTED HER LIFE IN THE FOLLOWING WAYS: SEVERE CRAMPING IN PELVIC AREA, HEAVY BLOOD FLOW THAT LASTED UP TO TWO WEEKS AT A TIME, PAIN IN ALL OF HER JOINTS ESPECIALLY HER BACK AND HIPS, MISSING TIME FROM HER KIDS BECAUSE OF THE PAIN, LEGS GOING NUMB AT RANDOM TIMES, DRASTIC MOOD SWINGS, BRAIN FOG, MEMORY LOSS OFTEN IN THE MIDDLE OF WHAT SHE WAS SAYING, WEIGHT GAIN PLUS BLOATING TO THE POINT HER CLOTHES WON'T FIT, HAIR FALLING OUT, IBS (INTERPRETED AS IRRITABLE BOWEL SYNDROME) DIAGNOSIS, INCONTINENCE PROBLEMS, BOILS, LOSS OF SEX DRIVE, PAINFUL INTERCOURSE WHEN SHE DID TRY, 3 MISCARRIAGES, AND A TOTAL HYSTERECTOMY AT THE YOUNG AGE OF (B)(6). SHE ALSO MENTIONED THAT FIBROIDS WERE FOUND IN HER UTERUS THAT WERE NOT THERE WHEN SHE DELIVERED HER DAUGHTER 3 MONTHS PRIOR TO THE PLACEMENT OF ESSURE. CONSUMER STATED ES SURE HAD LEFT HER WITH NOTHING BUT PROBLEMS THAT COULD NEVER BE REVERSED OR FIXED EVEN AFTER REMOVAL. THE OTHER LINKED PREGNANCY CASES ARE (B)(5) (SECOND PREGNANCY) AND (B)(4) (THIRD PREGNANCY). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEVERE CRAMPING IN PELVIC AREA, HEAVY BLOOD FLOW (INTERPRETED AS GENITAL BLEEDING), 3 MISCARRIAGES (IMPLIED PREGNANCY WITH ESSURE). SHE HAD A HYSTERECTOMY AT (B)(6). IN THIS

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PARTICULAR DATE, THE ONSET DATE OF EVENTS WAS NOT PROVIDED BUT IT WAS STATED THAT THEY OCCURRED DURING ESSURE THERAPY. CONSIDERING THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN ESSURE AND PELVIC CRAMP, GENITAL BLEEDING AND PREGNANCY WITH ESSURE (DEVICE INEFFECTIVE) CANNOT BE EXCLUDED. HOWEVER, ALTHOUGH GESTATIONAL AGE HAD NOT BEEN PROVIDED, SPONTANEOUS ABORTIONS OCCUR MOSTLY DURING THE FIRST 12 WEEKS OF PREGNANCY AND THE VAST MAJORITY OF THESE CASES ARE DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS, SO THE MISCARRIAGE IS CONSIDERED AS UNRELATED TO ESSURE, DESPITE THE COMPATIBLE TEMPORAL RELATIONSHIP. TWO OTHER CASES WERE CREATED FOR THE OTHER TWO MISCARRIAGES. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01029	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0890, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON UNSPECIFIED DATE. SHE EXPERIENCED SEVERE PAIN, BLOATING, DIGESTION PROBLEMS, DISCHARGE, INFECTIONS, ETC. DUE TO THE PROBLEMS SHE HAD THE ESSURE REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED AND EXPERIENCED SEVERE PAIN (INTERPRETED AS PELVIC PAIN) AMONGST OTHER NON-SERIOUS EVENTS. PELVIC PAIN MAY OCCUR DURING DEVICE THERAPY. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE AN IMPLIED INTERVENTION WAS REPORTED (SHE HAD THE ESSURE REMOVED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01030	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0884, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER ON UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT SHE EXPERIENCED INTENSE PELVIC PAIN, BLOATING, BACK PAIN, AND RASHES. ON AN UNSPECIFIED DATE, A SURGERY WAS DONE AND ESSURE WAS REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED AND EXPERIENCED INTENSE PELVIC PAIN (SERIOUS EVENTS) AMONGST OTHER NON-SERIOUS EVENTS. PELVIC PAIN MAY OCCUR DURING DEVICE THERAPY. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE SURGICAL PROCEDURE TO REMOVE ESSURE WAS REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01031	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0857, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER MEDICAL HISTORY INCLUDED 2 CHILDREN. CONSUMER REPORTED THAT SHE EXPERIENCED CONSTANT PAIN AND HEAVY BLEEDING WITH CHUNKS LIKE SHE HAD NEVER SEEN. IN 2013 SHE HAD A TOTAL HYSTERECTOMY AND RECOVERED FROM EVENTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2009, SHE REPORTED CONSTANT PAIN (INTERPRETED AS PELVIC PAIN) AND HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING). IN 2013 SHE HAD A HYSTERECTOMY AND RECOVERED FROM THE EVENTS. PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING DEVICE THERAPY. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP, LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION AND POSITIVE DECHALLENGE (SHE RECOVERED AFTER DEVICE REMOVAL), CAUSALITY CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01032	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 8/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0791, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012 FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT SINCE 3 WEEKS AFTER GETTING ESSURE SHE STARTED TO EXPERIENCE SEVERE CRAMPING, SHARP PELVIC PAINS, EXCESSIVE BLEEDING WITH PERIODS, BACTERAIL VAGINOSIS, YEAST INFECTIONS, LOW IRON, TWO PERIODS A MONTH, MIGRAINES, ENLARGED UTERUS, BRAI FOG, INSOMNIA, MOOD SWINGS, DEPRESSION, WEIGHT GAIN AND SEVERE BLOATING. TO FIX THIS, IN (B)(6) 2015 SHE HAD A HYSTERECTOMY PERFORMED, THAT LEFT NOTHING BUT HER OVARIES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2012 AND EXPERIENCED SHARP PELVIC PAIN 3 WEEKS AFTER GETTING ESSURE AMONGST OTHER NON-SERIOUS EVENTS. IN (B)(6) 2015, SHE WAS SUBMITTED TO HYSTERECTOMY. PELVIC PAIN MAY OCCUR DURING DEVICE THERAPY. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE SURGICAL PROCEDURE TO REMOVE ESSURE WAS REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01033	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/21/2014
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5039130) IN UNITED STATES ON 15-JAN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. THE CONSUMER STATED SHE WAS PRESENTING BAD PELVIC PAIN (SO BAD THAT MOST DAYS SHE COULD NOT GET OFF HER COUCH). SHE WAS ALSO EXPERIENCING MIGRAINES THREE TIMES A WEEK SINCE HAVING THE PROCEDURE DONE. SHE NEVER HAD THEM BEFORE. CONSUMER INFORMED THE DATE (B)(6) 2014; HOWEVER SHE DID NOT SPECIFY IT. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-FEB-2015: FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL

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NUMBER IS (B)(4). FOLLOW UP INFORMATION RECEIVED ON 02-APR-2015: ESSURE WAS INSERTED ON (B)(6) 2014. FOLLOW-UP RECEIVED ON 16-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. FOLLOW UP INFORMATION RECEIVED ON 27-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE # FDA-2014-N-0736-0874, AWARENESS DATE 27-AUG-2015). THE CONSUMER REPORTED ESSURE TOOK HER ENERGY TO PLAY WITH HER FOUR KIDS. IT MADE HER BLEED FOR TWO MONTHS BECAUSE IT WAS EMBEDDED IN HER UTERUS. SHE STATED SHE HAD A HYSTERECTOMY PERFORMED IN (B)(6) 2014 AND SINCE THEN HAD MORE ENERGY TO PLAY MORE WITH HER KIDS. AT TIME OF THE REPORT, SHE WAS (B)(6) YEARS OLD. THIS CASE WAS UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. ADDITIONAL INFORMATION WAS IDENTIFIED DURING MONITORING OF POSTINGS ON FDA HOSTED DOCKET WEBSITE. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD ESSURE EMBEDDED IN HER UTERUS. SHE HAD A HYSTERECTOMY APPROXIMATELY 2 MONTHS LATER. THIS EVENT, INTERPRETED AS DEVICE EMBEDDED (PARTIAL PERFORATION) IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO FURTHER INFORMATION WAS OBTAINED DESPITE FOLLOW-UP ATTEMPTS.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01034	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0809; AWARENESS DATE:26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER HAD THE ESSURE PLACED IN RIGHT TUBE BACK IN (B)(6) 2006 AFTER HER 6TH CHILD WAS BORN. SOON AFTER, SHE STARTED GETTING HORRIBLE ABDOMINAL PAIN, HEAVY BLEEDING, RAPID HAIR LOSS, BREAST TENDERNESS, JOINT PAIN, DIZZINESS, BLACK OUTS (SHE HAD STITCHES TWICE DUE TO FALLING A BROKEN TAIL BONE AND LOTS OF SCARS DUE TO FALLS), TEETH CRACKING/ BREAKING. SHE WAS SUBMITTED TO AN APPENDECTOMY AND SHE WAS INFORMED THAT SHE HAD A LOT OF SCARRING ON HER APPENDIX. THEN, A MONTH AND ONE DAY LATER, SHE HAD A PARTIAL HYSTERECTOMY TO REMOVE HER SWOLLEN UTERUS THAT WAS FULL OF ABRASIONS HOPING THAT IT WOULD STOP THE PAIN. IT STOPPED THE SEVERE BLEEDING AND HELPED WITH BLOOD COUNT. SHE WAS ON CONSTANT PAIN AND ALSO EXPERIENCED BRAIN FOG. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL

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FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN AND HEAVY BLEEDING. ACCORDING TO HER, SHE WAS SUBMITTED TO A HYSTERECTOMY TO REMOVE HER SWOLLEN UTERUS WHICH WAS FULL OF ABRASIONS HOPING IT WOULD HELP THE PAIN. HOWEVER, ONLY HER BLEEDING IMPROVED. ADDITIONALLY, SHE REPORTED BLACK-OUTS AND AN APPENDECTOMY. ONLY ABDOMINAL PAIN AND BLEEDING (REGARDED AS GENITAL BLEEDING) ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER REPORTED A SWOLLEN UTERUS. AN ENLARGED UTERUS MAY OCCUR DUE TO UTERINE FIBROIDS OR ADENOMYOSIS; BOTH CONDITIONS MAY PRESENT WITH BLEEDING AND COULD BE AN ALTERNATIVE EXPLANATION FOR THIS EVENT. NEVERTHELESS, CONSIDERING THE EVENTS STARTED SOON AFTER ESSURE INSERTION AND SINCE LIMITED INFORMATION WAS PROVIDED (EXACT NATURE OF UTERINE SWOLLEN WAS NOT SPECIFIED); CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, GIVEN THEIR NATURE AND CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY IS CONSIDERED UNLIKELY. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01035	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0824, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE HAS A PLETHORA OF ISSUES. SHE HAS NOT SEEN A DOCTOR FOR ALL OF HER NEW ISSUES POPPING UP. SHE HAD A SKIN DISEASE BECAUSE OF METAL TOXICITY. AMONG GYNECOLOGICAL ISSUES THAT LIST GOES ON FOR DAYS. SHE WAS HAVING A HYSTERECTOMY SOON TO REMOVE THESE COILS AND HER UTERUS THAT WAS PERMANENTLY DAMAGED AND HER FALLOPIAN TUBES AS WELL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A SKIN DISEASE BECAUSE OF METAL TOXICITY (INTERPRETED AS ALLERGY TO METALS). SHE WAS HAVING A HYSTERECTOMY SOON IN ORDER TO REMOVE THE COILS AND HER UTERUS THAT WAS PERMANENTLY DAMAGED AND HER FALLOPIAN TUBES AS WELL. METAL TOXICITY WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND WAS CONSIDERED LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE OTHER EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND UNLISTED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS CASE, IT WAS NOT SPECIFIED WHAT TYPE OF SKIN DISEASE THE CONSUMER HAD. IT WAS ALSO UNKNOWN WHAT TYPE OF DAMAGE

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OCCURRED IN HER UTERUS AND FALLOPIAN TUBES. CONSIDERING THAT ESSURE DEVICE MAY HAVE CONTRIBUTED TO OCCURRENCE OF THESE EVENTS, A CAUSAL RELATIONSHIP CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01036	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER REPORTED: I HAVE NEVER FELT THE PAIN I'VE HAD THIS PAST YEAR. I HAVE ALWAYS BEEN HEALTHY. THERE IS NO DOUBT IN MY MIND ESSURE WAS POISON FOR MY BODY. FROM THE MOMENT IT WAS INSERTED I WAS IN PAIN. OVER THE YEAR IT WAS WORSE I HAD PAIN EVEN WHEN NOT ON MY PERIOD. THE BLEEDING WAS INSANE. I FELT THAT MY INSIDES WERE BEING WRUNG OUT THOUGH MOST OF THE MONTH. LIVING ON 800 MG OF IBUPROFEN IS NO LIFE. ASIDE FROM THESE ISSUES ONE TUBE NEVER BLOCKED. SO WHEN AND IF I WAS ABLE TO BE WITH MY HUSBAND WE HAD TO USE A BACK UP BIRTH CONTROL ALTHOUGH I WAS SUPPOSED TO BE STERILE. WE ALSO HAD ISSUES IN OUR MARRIAGE BECAUSE I WAS IN PAIN OR BLEEDING MOST OF THE TIME. ALL TESTS I HAD ASSOCIATED WITH ESSURE WERE TORTURE. THE HSG (HYSTEROSALPINGOGRAPHY) TEST WAS TRULY TERRIFYING AND THE PAIN BEYOND GUT WRENCHING. I CRIED FOR HOURS DURING AND AFTER THE PROCEDURE. SUBSEQUENT ULTRASOUNDS AND BIOPSIES WERE ALSO AWFUL. I HAD A HYSTERECTOMY 2 WEEKS AGO. I AM FEELING AMAZING. I WOKE UP AND NOTHING HURT LIKE IT USED TO. I'VE LOST (B)(6) POUNDS IN 2 WEEKS, EVERYONE IS TELLING ME HOW AMAZING MY SKIN LOOKS AND HOW I LOOK SO DIFFERENT, IN A GOOD WAY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN AND BLEEDING. SHE WAS SUBMITTED TO A HYSTERECTOMY. THESE EVENTS, REGARDED AS PELVIC PAIN AND GENITAL BLEEDING, ARE

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LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER RELATED THE EVENTS TO ESSURE THERAPY AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. ADDITIONALLY, SHE STATED SHE FELT AMAZING AFTER THE HYSTERECTOMY. THUS; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01037	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 8/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0871, AWARENESS DATE 26-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. THE CONSUMER REPORTED THAT SHE HAD STABBING PAINS IN HER LEFT SIDE EVERY DAY SINCE ESSURE INSERTION. SHE STATED SHE WAS SUFFERING FROM CONTINUOUS FATIGUE, WEIGHT GAIN, HEADACHES/MIGRAINES AND INFLAMMATION. SHE ALSO REPORTED THAT HER DOCTOR NEVER ASKED HER ABOUT HAVING A NICKEL ALLERGY WHICH SHE HAD AND NOW SHE WAS DEALING WITH THE REACTION TO THE NICKEL IMPLANT DAILY. SHE WAS SCHEDULED TO MEET WITH AN OBGYN FOR A HYSTERECTOMY IN (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD STABBING PAINS IN HER LEFT SIDE EVERY DAY SINCE ESSURE INSERTION. THE HYSTERECTOMY WAS SCHEDULED BUT NOT PERFORMED YET. THIS EVENT, INTERPRETED AS ABDOMINAL PAIN LOWER, IS SERIOUS DUE TO THE PLANNED REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT, THE SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP OF ABDOMINAL PAIN LOWER WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 04-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01038	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2008
Explant Date (E7): 8/14/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-1014-N-0736-0860) IN UNITED STATES ON 26-AUG-2015 WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER HAS AN EXTENSIVE FAMILY HISTORY OF HYPERTENSION. BIRTH CONTROL PILLS WERE NOT AN OPTION; SHE HAD AN ALLERGIC REACTION TO THE NOVARING. SHE WAS BATTLING POST-INFECTIOUS IBS SINCE THE LATE 80S DUE AND WAS LOOKING FOR AN OPTION THAT WOULD MAKE HER PERIODS LESS PAINFUL, MAYBE LIGHTER FLOW, AND MAYBE CURB THE HORRIFIC MIGRAINES SHE HAD SINCE A CHILD. CONSUMER WAS IMPLANTED WITH THE ESSURE COILS IN (B)(6) 2008. ALL WENT WELL DURING INSERTION AND THE IMAGING DONE IN (B)(6) 2009 CONFIRMED THAT THE TUBES HAD SCARRED OVER AND NO OTHER BIRTH CONTROL PROTECTION WAS NECESSARY GOING FORWARD. SHE HAD NO ISSUES FOR A LONG TIME; HOWEVER WAS CONCERNED THAT NEVER HAD ANOTHER PERIOD AFTER THE IMPLANTS. FURTHERMORE, SHE WAS NOT GETTING HORRIFIC MIGRAINES AS OFTEN. FAST FORWARD 6 YEARS, AND SHE STARTED EXPERIENCING WEIGHT GAIN (40-50 LBS ON A (B)(6) FRAME), HIP PAIN AND SCIATIC ISSUES, FATIGUED, PAINS AND SWELLING IN DIFFERENT PARTS OF BODY, HOT FLASHES, NAUSEA, ITCHY PATCHES POPPING UP FOR NO APPARENT REASON. FINALLY, BEGINNING ABOUT 2 MONTHS BEFORE THIS REPORT, SHE STARTED EXPERIENCING HORRIFIC PAINS THAT FELT AS IF SOMEONE JUST KICKED HER IN THE GUT. ABOUT THREE WEEKS BEFORE THIS REPORT, SHE EXPERIENCED HORRIBLE THROBBING AND STABBING PELVIC PAIN. SHE GOT NO RELIEF FROM OTC PAIN KILLERS. AN IMAGING TEST WAS PERFORMED IN (B)(6) 2015, AND THE RADIOLOGIST SAID THAT THE UTERUS WAS FULL OF BLOOD THAT WAS

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NOT BEING EXPELLED, AND SHE WAS CONCERNED ABOUT THE RISK OF IT RUPTURING. ADDITIONALLY, IT APPEARED THAT THE RIGHT ESSURE COIL HAD MIGRATED OUT OF THE TUBE AND WAS PERFORATING THE UTERUS. WHILE PHYSICIAN WAS ABLE TO SUCCESSFULLY PERFORM THE D&C, DRAIN ALL OF THE POOLED BLOOD, SHE TOOK CLEAR PICTURES OF THE RIGHT ESSURE COIL NOT PLACED PROPERLY. HORMONAL STUDIES INDICATED CONSUMER WAS FULL MENOPAUSE ALREADY. ON (B)(6) 2015, CONSUMER HAD CERVIX, UTERUS, OVARIES, TUBES AND COILS REMOVED (HYSTERECTOMY PERFORMED). SHE STATED WAS ON SHORT TERM DISABILITY, AND FACING ALL OF THE PAIN AND RESTRICTIONS ASSOCIATED WITH RECOVERING FROM THE HYSTERECTOMY. SHE HAD A SWOLLEN BELLY POST-OP, AND WAS DEFINITELY SEEING THE SWELLING IN JOINTS AND MIDDLE REDUCING. SHE WAS EXPERIENCED NAUSEA AND WAS FORCED TO MOVE SLOWLY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AN IMAGING TEST WAS PERFORMED AND THE RADIOLOGIST SAID THAT THE UTERUS WAS FULL OF BLOOD THAT WAS NOT BEING EXPELLED AND THE RIGHT ESSURE COIL HAD MIGRATED OUT OF THE TUBE AND WAS PERFORATING THE UTERUS. BOTH EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE EVENTS WERE DIAGNOSED ABOUT 6 YEARS AND 8 MONTHS AFTER ESSURE INSERTION. THE UTERINE PERFORATION COULD HAVE LED TO UTERINE HEMORRHAGE. CONSUMER UNDERWENT A HYSTERECTOMY (CERVIX, UTERUS, OVARIES, TUBES AND COILS WERE REMOVED). CONSIDERING THE NATURE OF THE EVENTS AND A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE ADDED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01039	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0787, AWARENESS DATE 26-AUG-2015).IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT BECAUSE OF ESSURE SHE HAD A HYSTERECTOMY AT THE AGE OF (B)(6). ACCORDING TO HER, DURING ONE OF THE 4 SURGERIES SHE HAD DUE TO ESSURE, A COIL WAS FOUND EMBEDDED BETWEEN HER PSOAS MUSCLE AND HER BOWELS. AT THE TIME OF REPORT, SHE STATED SHE WILL NEED A 5TH SURGERY TO REMOVE THE REMAINING PIECES. CONSUMER ALSO REPORTED THAT ESSURE HAD COST HER A LOT OF PAIN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING ONE OF THE 4 SURGERIES SHE HAD DUE TO ESSURE, A COIL WAS FOUND EMBEDDED BETWEEN HER PSOAS MUSCLE AND HER BOWELS (INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY). SHE HAD A HYSTERECTOMY BUT SHE WILL NEED A FIFTH SURGERY TO REMOVE REMAINING PIECES (INTERPRETED AS DEVICE BREAKAGE). THE DEVICE DISLOCATION IS SERIOUS DUE TO REQUIRED INTERVENTION AND DEVICE BREAKAGE DUE TO PLANNED REQUIRED INTERVENTION. THE DEVICE DISLOCATION IS LISTED WHILE THE DEVICE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS, THE CAUSAL RELATIONSHIP BETWEEN THESE TWO EVENTS AND ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01040	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0767, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2008. CONSUMER REPORTED SHE HAD ESSURE IN 2008 AFTER HER SON WAS BORN. SHE STARTED HAVING PAIN IN HER LEFT SIDE ABOUT A YEAR AFTER AND KEPT GETTING WORSE. SHE HAS HAD CYSTS ON HER LEFT OVARY AND WAS TOLD THAT HER FALLOPIAN TUBE WAS SWOLLEN AND HAD FLUID IN IT. HER TUBES WERE REMOVED AND THE SCAR TISSUE WAS REALLY BAD. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2008. SHE REPORTED PAIN IN HER LEFT SIDE (INTERPRETED AS PELVIC PAIN) AND FLUID IN HER LEFT FALLOPIAN TUBE (INTERPRETED AS HYDROSALPINX). ON UNSPECIFIED DATE, HER TUBES WERE REMOVED (SALPINGECTOMY). BOTH EVENTS ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS PERFORMED (SALPINGECTOMY). NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01041	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/30/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 PERMANENT STERILIZATION. ON (B)(6) 2010, FIRST HSG (HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED SPILLAGE OF CONTRAST OF THE LEFT SIDE. RIGHT SIDE APPEARED TO BE OCCLUDED AND INTACT. NO MENTION OF DEVICE LOCATION. ON (B)(6) 2011, SECOND HSG WAS DONE AND BILATERAL OCCLUSION WAS REPORTED. PROXIMAL END OF DEVICE WAS AT UTJ (UTERINE TUBAL JUNCTION). CONTRAST SEEMED TO FILL THE CAVITY; NO FILLING DEFECTS. ON (B)(6) 2015, PHYSICIAN DID LAPAROSCOPY BECAUSE PATIENT COMPLAINED OF PAIN. PHYSICIAN FOUND THAT DEVICE WAS ACTUALLY PERFORATED ON LEFT SIDE AND WAS NOT IN THE FALLOPIAN TUBE. IT WAS NOT REMOVED AT THE TIME; PATIENT OPTED NOT TO HAVE IT REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT.

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BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO WAS SUBMITTED TO A LAPAROSCOPY DUE TO PAIN, 5 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING THIS SURGERY, THE DEVICE WAS FOUND PERFORATED ON LEFT SIDE AND WAS NOT IN THE FALLOPIAN TUBE. ESSURE WAS NOT REMOVED. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE PAIN DURING AND AFTER THE PROCEDURE. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF ESSURE PERFORATION WAS UNKNOWN; GIVEN EVENTS NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, AS ALTHOUGH ESSURE WAS NOT REMOVED; A SURGICAL INTERVENTION WAS REQUIRED (LAPAROSCOPY). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION (TUBAL PERFORATION QUESTIONNAIRE) RECEIVED ON 01-OCT-2015 FROM PHYSICIAN: THE PATIENT IS NON-SMOKER. SHE HAD NKDA (UNDERSTOOD AS NO KNOWN DRUG ALLERGIES). SHE HAD NO PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEM OR PROCEDURES. THE PA

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01042	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES VIA WEBSITE ON (B)(6)-2014 WHICH REFERS TO HERSELF. SHE IS A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 FOR INDICATION NOT REPORTED AND EXPERIENCED PAINS SINCE DAY 1. SHE STATED THAT WAS STILL SUFFERING FROM THIS DEVICE AND ESSURE WAS AWFUL. FOLLOW UP INFORMATION RECEIVED ON 27-AUG-2015 (UPGRADED TO INCIDENT). THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4)). THE CONSUMER REPORTED SHE HAD ESSURE IMPLANTED IN 2008 AND FROM DAY ONE SHE HAD COMPLICATIONS LIKE SEVERE PELVIC PAIN THAT HAPPENED IMMEDIATELY. SHE STATED THE LONGER ESSURE WAS IN MORE PROBLEMS BEGUN TO ADD UP; SHE HAD SEVERE CYCLES WITH LARGE BLOOD CLOTS, WEIGHT GAIN, HEADACHES, PELVIC PAIN, ABDOMEN PAIN, CRAMPS, CONSTANT BLOATING, YEAST INFECTIONS, SUPER PAINFUL INTERCOURSE, NO ENERGY, LOSS OF HAPPINESS, HAIR LOSS AND OTHER MILD ISSUES. IN EARLY 2015, SHE HAD HER TUBES AND COILS REMOVED (BILATERAL SALPINGECTOMY). SHE STATED SHE FELT MUCH BETTER HOWEVER, AT THE TIME OF REPORT, SOME SYMPTOMS HAD NOT RESIDED YET. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEVERE PELVIC PAIN SINCE DAY ONE OF INSERTION. APPROXIMATELY, SEVEN YEARS AFTER ESSURE INSERTION, SHE HAD A BILATERAL SALPINGECTOMY ALONG WITH COILS REMOVED. THE PELVIC PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT, THE SUGGESTIVE TEMPORAL

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RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. UPON FOLLOW UP INFORMATION, THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 19-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01043	BAYER HEALTHCARE LLC	9/22/2015	9/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES VIA TELEVISION PROGRAM ON 01-NOV-2013 REFERRING TO HERSELF. THE FEMALE CONSUMER OF UNSPECIFIED AGE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE JOINT PAIN, LIKE MY ENTIRE BODY AND EVERYTHING HURT ALL THE TIME. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION RECEIVED. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER STATED SHE HAD SEVERE JOINT PAIN, LIKE HER ENTIRE BODY AND EVERYTHING HURT ALL THE TIME. SHE HAD A HYSTERECTOMY DONE AND HER RELIEF WAS IMMEDIATE, WITHIN HOURS. NO CAUSALITY ASSESSMENT WAS GIVEN. FOLLOW-UP RECEIVED ON 27-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0892). CONSUMER EXPERIENCED DEBILITATING MIGRAINES THAT WENT ON FOR WEEKS AT A TIME AND STATES THAT, DUE TO HEAVY BLEEDING DURING HER PERIOD, SHE WOULD BE GOING THROUGH A SUPER TAMPON AND AN OVERNIGHT PAD WITHIN AN HOUR AND INFORMS THAT THIS WOULD GO ON FOR A WEEK TO 10 DAYS. IN ADDITION, CONSUMER REPORTED THAT HER PERIOD, WHICH HAD COME LIKE CLOCKWORK EVERY 28 DAY FOR 30 YEARS, NOW BECOME TOTALLY UNPREDICTABLE, COMING ANYWHERE FROM EVERY 18 TO 53 DAYS. CONSUMER ALSO EXPERIENCED EXTREME FATIGUE, BODY PAINS, ALL OVER HIVES, AUTOIMMUNE DISEASE, NAUSEA AND DIZZINESS AND REPORTED OVERALL LOSS OF QUALITY OF LIFE AND CAREER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EVERYTHING HURT ALL THE TIME / BODY PAINS. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO EXPERIENCED AUTOIMMUNE DISEASE, WHICH IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND UNLISTED. SHE EXPERIENCED OTHER NON-SERIOUS EVENTS. IN THIS CASE, CONSUMER UNDERWENT A HYSTERECTOMY. FOR THE EVENT EVERYTHING HURT ALL THE TIME / BODY PAINS, CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, BASED ON THE PATHOPHYSIOLOGY AND GIVEN ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056322	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 8/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN AT SITE OF IMPLANTS/DEVICES. HEAVY BLEEDING, FATIGUE, DENTAL ISSUES, BODY RASHES, SWEATS, IRREGULAR DISCHARGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056323	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 6/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE IMPLANTS PUT IN ON (B)(6) 2014. ALMOST INSTANTLY I KNEW I WAS HAVING G TROUBLE WITH THE IMPLANTS I BECAME CONSTIPATED FOR 5 FULL DAYS, AND AFTER THAT I HAD A VERY HARD TIME MAKING BOWEL MOVEMENTS. NOT CONSTIPATION FOR 4 MONTHS. DURING THAT TIME I WAS ALSO IN SEVERE PAIN. HAD MANY HEADACHES ALL THE TIME. WENT TO THE DOCTORS AND THE EMERGENCY ROOM SEVERAL TIMES AND WAS TOLD THAT NOTHING WAS WRONG WITH ME. I HAD A HYSTERECTOMY ON (B)(6) 2015. TODAY I STILL SUFFER FROM THE DAMAGE THE IMPLANTS LEFT BEHIND. I HAVE SEVERAL INFECTIONS AFTER MY SURGERY AND SCAR TISSUE THAT THE DOCTOR SAYS IS CAUSING MY PAIN . I DEAL WITH DEPRESSION NOW. I HAVE NEVER BEEN THIS SAD IN MY LIFE I WILL NOW SUFFER THE REST OF MY LIFE FROM THE ESSURE IMPLANTS AND I DON'T KNOW HOW IT WILL GET BETTER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056324	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 9/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANTLY IN ABDOMINAL PAIN, BLOATING, FATIGUE, HEADACHES, PAINFUL SEXUAL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056325	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 4/26/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OUT PATIENT SURGERY PROVIDED BY MY INSURER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056326	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 3/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE LOWER BACK PAIN, LEG PAIN, SWOLLEN AND PAINFUL KNEE, HEADACHES, HEART PALPITATIONS, FATIGUE, ANEMIA, HEAVY MENSTRUATION, BLOATING, JOINT PAIN , ITCHY SKIN ESPECIALLY LEGS. SYMPTOMS ONGOING. WAS COVERED BY INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056327	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 8/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLEEDING, DIZZINESS, HAIR LOSS, CRAMPING, LONGER PERIODS, SEVER MOOD SWINGS, MIGRAINES, BRAIN FOG, WEIGHT GAIN, EXTREME TIREDNESS, HEART PALPITATIONS, DENTAL PROBLEMS, BREAST PAIN, BLOATING, METAL TASTE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056328	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 6/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, CONSTANT URINARY TRACT INFECTIONS, NICKEL ALLERGY, VAGINAL INFECTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056329	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 8/13/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS LASTING 2 WEEKS WITH HEAVY CLOTS, JOINT PAIN, HAIR FALLING OUT, SWELLING/BLOATING OF ABDOMINAL AREA, SHARP STABBING PAINS IN ABDOMEN FOR NO REASON, HASHIMOTO THYROIDITIS, 1/2 THYROID REMOVED, GALLBLADDER STOPPED FUNCTIONING, GALLBLADDER REMOVED, FULL BODY HIVES IF DIDN'T TAKE ZYRTEC DAILY - ALLERGIST COULD FIND NO REASON FOR THE HIVES BUT I NEVER HAD A NICKEL ALLERGY TEST DONE (I DIDN'T KNOW ABOUT IT), HYSTERECTOMY MADE MANY SYMPTOMS IMPROVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056330	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MOOD SWINGS, ANXIETY, DEPRESSION , VISION ISSUES THAT BEGAN IN (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056331	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 9/21/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HIVES, SEVERE ITCHING, CONSTANT YEAST AND BACTERIAL VAGINAL INFECTIONS, VERY HEAVY BLEEDING WITH CLOTS, BLURRY VISION, SOME HAIR LOSS, FATIGUE, BLOATING, TOOTH LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056332	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOSS OF LIBIDO, IRREGULAR MENSTRUAL CYCLE, BREAST TENDERNESS THAT CONTINUED MONTHS AFTER I QUIT BREASTFEEDING, BACK PAIN, PAIN UNDER RIBCAGE ON BOTH RIGHT AND LEFT (NO GALLBLADDER ISSUES).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056333	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 11/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAVE HAD ESSURE IMPLANTED IN (B)(6) 2011, IT HAS BEEN A NIGHTMARE. THE FIRST SEVEN MONTHS WERE FINE, AND THAT'S WHEN I HAD MY FIRST EPISODE. THE PAIN WAS SO UNBEARABLE I WAS ABOUT TO TAKE MYSELF TO THE ER BECAUSE I HAD NO IDEA WHAT WAS GOING ON. IT WAS LATER THAT DAY THAT I FIGURED OUT IT WAS FROM THE TOXIC DEVICE I HAD INSERTED IN MY BODY. I AM MOST DEFINITELY NOT THE SAME PERSON I WAS PRIOR TO HAVING THIS EVIL DEVICE PUT IN ME. I CAN NOT WAIT UNTIL I AM ABLE TO GET IT REMOVED AND BE THE PERSON I WAS... TO BE THE MOTHER MY KIDS DESERVE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056334	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 9/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANTLY HEADACHES, ABNORMAL MENSTRUAL PERIOD, DEPRESSION,HAIR LOSS, CONSTANTLY NO REASON TIREDNESS,WEAKNESS, BACTERIAL VAGINOSIS,LOWER ABDOMINAL PAIN ON BOTH SIDES, OVARIAN CYST,KNEE PAIN, PERIOD STOP ,HOT FLASHES,EXCESSIVE BLEEDING DURING PERIODS,INCONTINENCE,VULVODYNIA,BREAST PAIN,SPINE PAIN, NECK PAIN,SEVERE BLOATING,BRAIN FOG FORGETFULNESS,MOOD SWINGS,SLEEP APNEA,MUSCLE SPASMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056335	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 10/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD CONTINUOUS HAIR LOSS SINCE THE FIRST 48 HOURS OF MY PROCEDURE ALONG WITH BLOATING SHARP PAIN IN LEFT SIDE OF ABDOMEN AND FORGETFULNESS. INSURANCE COVERED TOTAL COST OF IMPLANTATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056336	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 8/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I END UP PREGNANT. ALMOST A YEAR AFTER THE IMPLANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056337	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I MAJOR MIGRAINES, DEPRESSION, WEIGHT GAIN, HIVES, NAUSEA, LOSS OF APPETITE, PELVIC PAIN, HEAVY MENSTRUATION, SPOTTING, BLOOD CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056338	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 4/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, MIGRAINES, DIZZINESS, TINGLING, NUMBNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056339	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 9/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) ON (B)(6) 2016, LESS THAN 7 MONTHS AFTER HAVING ESSURE IMPLANTED, I HAD A TOTAL HYSTERECTOMY REMOVING BOTH FALLOPIAN TUBES, UTERUS AND CERVIX. DURING THE SURGERY, IT WAS LEARNED THAT THE FRACTURED COIL HAD PERFORATED THE RIGHT TUBE. ACCORDING TO BAYER AND MY IMPLANTING DOCTOR, THIS WOULDN'T HAPPEN BECAUSE THE SCAR TISSUE WOULD HOLD IT IN PLACE. OF COURSE THEY WOULD SAY THIS. I'M FOREVER GRATEFUL I ADVOCATED FOR MYSELF, FOUND A GREAT DOCTOR WHO LISTENED TO ME AND HAD THIS PRODUCT REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056340	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 11/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM (B)(6). EVER SINCE I HAVE GOTTEN IT, I HAVE HAD REAL BAD CRAMPS NON STOP TO THIS DAY AND I FEEL LIKE SOMETHING IS PINCHING ME. I HAVE JOINT AND MUSCLE PAIN ALL THE TIME. NOW A HEADACHE THAT WON'T GO AWAY, MY PERIODS HAVE BEEN HORRIBLE REAL BAD BLEEDING AND CRAMPS TO THE POINT WHERE I DONT WANNA MOVE .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056341	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 8/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE NOT STOPPED BLEEDING IN 23 DAYS, STOMACH IS BLOATED AND HAVE CRAMPS AND PAIN IN PELVIC AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056342	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP STABBING PAINS IN MY LEFT SIDE AROUND MY PELVIC AREA...FOUND OUT I WAS PREGNANT JUST 2012 THANKFULLY I HAD A HEALTHY BABY GIRL ....HAD A MISCARRIAGE (B)(6) 2014.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056343	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 12/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY SYMPTOMS STARTED WITHIN MONTHS OF HAVING ESSURE. HORRIBLE LOWER BACK PAIN, MUSCLE PAIN, JOINT PAIN, HEADACHES, HAIR LOSS, MEMORY LOSS, BRAIN FOGGINESS, VITAMIN DEFICIENCIES, INSOMNIA, MOOD SWINGS, DEPRESSION, ER VISIT AND CLINIC VISIT WITH A MONTH LONG PERIOD THAT ONLY STOPPED BY TAKING A BIRTH CONTROL PILL, INTERNAL AND EXTERNAL ULTRASOUNDS THAT REVEALED A VERY THICK UTERINE LINING FOR NO OTHER APPARENT REASON, NEEDED A UTERINE BIOPSY TO RULE OUT CANCER, CONSIDERABLE AMOUNT OF WEIGHT GAIN THAT DOES NOT SEEM TO COME OFF NO MATTER WHAT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056344	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER RECEIVING MY ESSURE I BEGAN TO HAVE EPISODES OF CHEST PAIN WHICH GRADUALLY GOT WORSE OVER TIME WHICH I WENT TO MY PRIMARY DR FOR WHO THEN SENT ME TO A GI SPECIALIST WHO FOUND DIGESTIVE ISSUES AND THEN REFERED ME TO A HEART DR. THE HEART DR FOUND NOTHING. AT THE SAME TIME I WAS ALSO EXPERIENCING OTHER IS THAT IS WAS SEEING MY PRIMARY FOR AND GETTING MULTIPLE TEST DONE FOR LIKE JOINT PAIN AND SWELLING, HEADACHES, BRUISING, AND BEING TIRED ALL THE TIME. I ALSO KEEP GETTING INFECTIONS THAT DO NOT WANT TO GO AWAY AND HAVE BEEN DIAGNOSED WITH ASTHMA DUE TO ALLERGIES. THE DR'S ARE FINDING NO EXPLANATION FOR MY PROBLEMS. I HAVE ALSO HAD ISSUES THAT HAVE NOT BEEN DISCUSSED WITH THE DR LIKE BACK PAIN AND BURNING, AND CONSTANT PAIN IN LEFT SIDE OF PELVIC AREA. I HAVE ALSO LOST SOME OF MY TEETH. I WAS PRETTY HEALTHY BEFORE ESSURE GOING TO DR MAYBE ONCE EVERY COUPLE MONTHS. I AM NOW THERE PRETTY MUCH ONCE A MONTH AT LEAST SOMETIMES 2 OR 3 TIMES A MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056345	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 8/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE (B)(6) 2013 I'VE EXPERIENCED THE FOLLOWING: PAIN ON LOWER RIGHT SIDE, HEADACHES , WEIGHT GAIN, EXTREME BLOATING, UNEXPLAINED VAGINAL DISCHARGE AND BLEEDING, UNEXPLAINED ITCHING AND RASHES, EXTREME FATIGUE, DEPRESSION, UNEXPLAINED FEELING OF FEVER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056346	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 2/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE IMPLANTED AND EVER SINCE THAT DAY I HAVE HAD SEVERE PAINS. I FEEL LIKE I CAN FEEL THE COILS IN ME. I HAVE HAD SIGNIFICANT HAIR LOSS. BLOATING AND EVEN WEIGHT FLUCTUATIONS. I'VE HAD MOOD CHANGES. MY LIBIDO IS WAY LOWER THAN NORMAL. I HAVE A PERIOD EVERY OTHER WEEK AND ITS MUCH HEAVIER THAN NORMAL. I'M IN PAIN EVERY DAY BUT SOME DAYS ARE WORSE THAN OTHERS. SOME DAYS ARE SO BAD I CANT EVEN MOVE.. MY INSURANCE PAID FOR ALL EXCEPT (B)(6). I WILL BE HAVING AN ULTRASOUND THIS WEEK TO CHECK AND SEE WHY THEY ARE HURTING ME TOO BAD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056347	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 9/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED THE IMPLANTATION AT (B)(6) HOSPITAL IN (B)(6) 2010 BY MY OB (B)(6). IT WAS COVERED UNDER MY (B)(6) PLAN. THE ONSET OF EVENTS BEGAN IN 2010 BUT THE REPORT WILL NOT ALLOW ME TO CHANGE THE DATE. CRAMPING, SHARP/STABBING PELVIC PAIN, PAINFUL PERIODS, PAINFUL INTERCOURSE, YEAST INFECTIONS, CERVICITIS/VAGINITIS (SWELLING, INFLAMMATION, INFECTION OF THE CERVIX OR VAGINA), ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE (VULVODYNIA), BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP, CHRONIC PELVIC PAIN, FACE PAIN (TRIGEMINAL NEURALGIA), ALL OVER BODY ACHES/PAIN, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, HEADACHES OR MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN SHOCKS, NERVE PAIN, BRAIN FOG ANDNDASH; CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, SEIZURES, STROKE SYMPTOMS, RINGING IN EARS, BLACK OUT SPELLS/ FAINTING, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), NUMBNESS IN THIGH, NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN, NERVE PAIN, TREMORS/SHAKINESS, DIZZINESS, UNEXPLAINED/EASILY BRUISING, MUSCLE SPASMS, VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION), DENTAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056348	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 5/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME BLEEDING INCLUDING BLEEDING PRACTICALLY 20+ DAYS OUT OF THE MONTH. LACKING SEX DRIVE DUE TO ALWAYS BLEEDING, INFECTIONS DUE TO BLEEDING SO MUCH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056349	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 3/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS , DENTAL ISSUES ,WEIGHT GAIN, HEAVY MENSTRUAL AND CRAMPING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056350	BAYER	9/22/2015	9/22/2015

Event Information:

Event Date (B3): 9/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH BILATERAL LOWER EXTREMITY EDEMA-INTERMITTENT, THIS CONTINUES. VERTIGO, BRAIN FOG, WEIGHT GAIN, LOWER ABDOMINAL FULLNESS, INCREASED EXCESSIVE MENSTRUAL BLEEDING WITH OCCASIONAL MID MONTH BREAKTHROUGH BLEEDING, FLUTTER DIRECTLY IN THE UTERUS AREA, SMOOTH MUSCLE TWITCHING (FEELS LIKE A BABY KICKING). ANXIETY EPISODES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056351	BAYER	9/22/2015	9/23/2015

Event Information:

Event Date (B3): 8/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT STATED THAT AFTER ESSURE PLACEMENT IN 2009, SHE BEGAN HAVING PROBLEMS IN 2011. AFTER BEING DIAGNOSED WITH COLON CANCER IN 2010, SHE BEGAN HAVING ABDOMINAL PAIN AND IRREGULAR PERIODS. FROM (B)(6) 2014 SHE HAD 6 MONTHS OF CONSTANT VAGINAL BLEEDING. SHE HAD A D AND C AND BIOPSY DONE IN (B)(6) 2015. IN (B)(6) 2015, SHE HAD AN EMERGENCY HYSTERECTOMY APPROACHED THROUGH HER ABDOMEN BECAUSE CANCER SURROUNDED THE IMPLANTED CLIP. THE CANCER PRESENT DID NOT METASTASIZE. IN (B)(6) OF 2015, 15 LYMPH NODES WERE REMOVED AND WERE BENIGN. AFTER HYSTERECTOMY, THE PATIENT HAD KIDNEY FAILURE, DEPRESSION, BOWEL OBSTRUCTION, DEHYDRATION, LOST (B)(6) LBS. IN 11 DAYS, HEADACHES AND PICC LINE PLACEMENT. PATIENT WAS HOSPITALIZED FOR 15 DAYS POST PROCEDURE. ON (B)(6) 2015, ONE LYMPH NODE FROM HER UNDERARM WAS REMOVED. SHE CURRENTLY HAS 6 SWOLLEN LYMPH NODES. DR. REQUESTED THAT PATIENT UNDERGO RADIATION TREATMENT EVERYDAY FOR 5 WEEKS AND SHE DECLINED. PATIENT STATES THAT THE DOCTOR IS CONVINCED THAT THE ESSURE WAS THE CAUSATIVE AGENT FOR HER ABDOMINAL CANCER. SHE IS CURRENTLY HAVING GENETIC TESTING DONE TO DETERMINE WHY TWO TYPES OF CANCER THAT ARE NOT RELATED WERE FOUND IN HER BODY. THE FIRST BEING COLON CANCER AND THE SECOND BEING ABDOMINAL CANCER CONCENTRATED AROUND THE IMPLANTED CLIP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056355	BAYER HEALTH	9/22/2015	9/23/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/1/2013
Explant Date (E7): 2/1/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER STATED SHE HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2013 AFTER SHE STARTED EXPERIENCING HEAVY BLEEDING, FOUL ODOR AND DYSPAREUNIA. SIX WEEKS AFTER THE PROCEDURE, SHE WENT TO SEE THE DOCTOR TO CHECK COIL PLACEMENT. SHE WAS TOLD THE COIL HAS DETACHED AND MIGRATED. AFTER DISCUSSIONS, SHE TOLD THE DOCTOR SHE WANTED IT REMOVED. IN (B)(6) 2014, SHE HAD A PROCEDURE DONE BUT WAS TOLD POST SURGERY THAT SHE HAD A PARTIAL HYSTERECTOMY. SHE WAS FURIOUS BECAUSE SHE WAS NOT TOLD THAT SHE WAS HAVING A PARTIAL HYSTERECTOMY. AN X-RAY WAS DONE AND SHE WAS INFORMED THE COIL IS STILL IN HER. SHE SAID SHE IS STILL EXPERIENCING DISCOMFORT, ABDOMINAL PAIN, CRAMPING AND BOWEL OBSTRUCTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056626	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): 7/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B94874

Single Use: *
Implant Date (E6): 7/10/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE ON (B)(6) 2014. SINCE THEN I'VE HAD NUMEROUS PROBLEMS THAT I BELIEVE ARE RELATED TO THE ESSURE COILS. NAUSEA, DIZZINESS, HEADACHES, JOINT PIAN, MEMORY PROBLEMS, HEAVY AND LONG PERIODS WITH OCCASIONAL BREAKS IN THE MIDDLE OF IT, LEG PAIN, TWITCHING IN MY RIGHT HAND, INSOMNIA, FATIGUE, NIGHT SWEATS AND HOT FLASHES, SEVERE MOOD SWINGS, SUDDEN WEIGHT LOSS, CRAMPS ON RIGHT SIDE ALL THE TIME AND WORSE WHEN I'M ON MY PERIOD, NICKEL ALLERGY THAT I NEVER HAD BEFORE, VAGINAL DISCHARGE ALL THE TIME, AND WORSENING DEPRESSION AND ANXIETY. THE RIGHT COIL WAS HARD TO PLACE AND I HAD TO HAVE TWO CONFIRMATION TESTS TO BE SURE IT WAS BLOCKED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056627	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/31/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

TWO YEARS AGO, I HAD ESSURE PUT IN TO PREVENT ANY FURTHER PREGNANCIES. ALMOST IMMEDIATELY, I STARTED HAVING A LOT OF PROBLEMS. I TALKED TO THE DR ABOUT IT AND TOLD HIM I WANTED THEM REMOVED. HE SENT ME A LETTER AND TOLD ME IT WAS NOT IN THE BEST INTEREST OF HIS CLINIC TO FURTHER PROVIDE ME WITH GYNECOLOGY CARE. SO FOR 2 YEARS I'VE BEEN DEALING WITH PAIN THAT DOUBLES ME OVER, LACK OF ANY KIND OF SEX DRIVE, MEMORY LOSS, CONFUSION, EXTREME FATIGUE, MANY BACTERIAL VAGINOSIS INFECTIONS, PAIN WITH INTERCOURSE, SKIN INFECTIONS, PAINFUL TO TOUCH, EXCESSIVE SCAR TISSUE FROM NICKLE ALLERGY WAS NEVER INFORMED THAT PRODUCT CONTAINED NICKLE AND HEAVY BLEEDING AND BLOOD CLOTS DURING MENSTRUATION. I WAS SCARED FOR A YEAR TO HAVE A PAP BECAUSE I REALLY THOUGHT I HAD CANCER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056628	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): 9/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED IN (B)(6) 2014. AROUND (B)(6), I STARTED HAVING SEVERE PAINS IN MY LOWER ABDOMINAL AREA. THEY WERE STRONG ACHING PAINS THAT ROTATED FROM THE FRONT TO MY LOWER BACK. AS SOON AS I NOTICED THERE WERE PROBLEMS, I CONTACTED MY PHYSICIAN TO HAVE THEM CHECK TO SEE IF THE ESSURE WAS IN PLACE. THE PHYSICIAN EXPRESSED TO ME THAT THE PAIN WOULD EVENTUALLY GO AWAY. SHORTLY AFTER, I STARTED HAVING HEART PAINS, SWELLING, CONSISTENT SHARP PAINS. RETURNED BACK TO THE DOCTOR AND AGAIN THE DOCTOR EXPRESSED IT WOULD GO AWAY. MY DOCTOR REQUESTED TO HAVE A MRI DONE IN (B)(6) 2015. ACCORDING TO THE DOCTOR THE DEVICE WAS STILL IN PLACE. HOWEVER, I DEVELOPED HIGH BLOOD PRESSURE AND MY HEART WAS ENLARGED. AS A RESULT, I WAS PLACED ON BLOOD PRESSURE PILLS AND PROVIDED PAIN PILLS TO HELP WITH THE PAIN (NAPROXEN 250MG, PROMETHAZINE 25MG, CYCLOBENZAPRINE 10MG, TRAMADOL 50MG, AND SO MANY MORE). THE DOCTORS JUST CONTINUED TO PRESCRIBE MEDICATIONS. THE PAIN WOULD SUBSIDE FOR A FEW HOURS, BUT COME BACK WORSE THAN BEFORE. AFTER A WHILE I STARTED ASKING IF THEY COULD REMOVE THE DEVICE. MY PHYSICIAN EXPRESSED THAT THEY COULD NOT REMOVE THE ESSURE DEVICE. AS TIME WENT ON, I STARTED GETTING IRRITATED, MOODY, HEADACHES, SHARP PAINS CONTINUED AND I STARTED TASTING METAL IN MY MOUTH. THE PAIN WOULD BE SO SEVERE AT NIGHT, IT WOULD WAKE ME AND I WOULD HAVE TO BALL UP TO TRY TO EASE THE PAIN. AGAIN I CONTINUED TO REPORT THESE SYMPTOMS. SINCE MY PHYSICIAN COULD NOT IDENTIFY AN ISSUE. I STARTED GOING TO THE HOSPITAL (B)(6). STILL THE DOCTOR COULDN'T FIND ANYTHING. "THEY RECOMMENDED MY REGULAR PHYSICIAN LOOK FURTHER INTO". I HAVE CONTINUED TO SUFFER FROM THESE SHARP PAINS, MOOD SWINGS, IRRITABILITY, SWELLING, HIGH BLOOD PRESSURE, BODY PAINS, TASTING METAL, AND HEADACHES. HERE IT IS (B)(6) 2015 NOTHING HAS CHANGED. I CONTINUE TO COMPLAIN, STACK MEDICAL BILLS

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AND TAKE MEDICATIONS TO LESSEN THE PAIN. HONESTLY, I CAN'T TAKE THE MEDICATION ALL THE TIME BECAUSE I HAVE FOUR SMALL CHILDREN. WHEN I'M HURTING IT EFFECTS EVERYONE BECAUSE I'M UNABLE TO MOVE. RETURNED BACK TO THE HOSPITAL AND DOCTOR (B)(6) 2015 AND (B)(6) 2015. I RETURNED FOR THE SAME SYMPTOMS, BUT ON SCALE OF 1 TO 10 IT WAS A 10. I HAD NUMBNESS ON MY RIGHT SIDE LEG TO FOOT. THE ER DOCTOR STATED "HAVE THE DEVICE REMOVED AS SOON AS YOU CAN, THE SYMPTOMS YOU ARE HAVING IS COMING FROM THE ESSURE". UNFORTUNATELY, I HAVE NOT BEEN ABLE TO LOCATE A DOCTOR THAT WILL REMOVE THIS DEVICE. BOTTOM LINE IS, I WAS NEVER INFORMED OF THESE SIDE EFFECTS. I WAS EXPLAINED TO THAT THE ESSURE WAS THE BEST METHOD TO GO WITH MINIMAL. SIDE EFFECTS AND A 99% EFFECTIVE RATE. HAD I BEEN EXPLAINED OR KNEW THAT I WOULD GO THROUGH THESE LIFE, CHANGING EVENTS, I WOULDN'T HAVE GOTTEN IT. NOTE: I DID NOT HAVE VITAMIN D ISSUES UNTIL I HAD THE ESSURE IMPLANTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056630	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): 8/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/16/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2013, I HAD THE ESSURE DEVICES IMPLANTED. SINCE THEN I'VE HAD THE FOLLOWING SYMPTOMS: PAIN ON THE LOWER RIGHT SIDE, HEADACHES, WEIGHT GAIN, EXTREME FATIGUE, EXTREME BLOATING, UNEXPLAINED VAGINAL DISCHARGE AND BLEEDING, UNEXPLAINED ITCHING AND RASHES, DEPRESSION AND UNEXPLAINED FEELING OF FEVER. I'VE SEEN MY DOCTOR ON SEVERAL OCCASIONS REGARDING THESE SYMPTOMS. HE HAS NO ANSWERS. I'VE NEVER HAD ANY OF THESE PROBLEMS BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056631	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): 4/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6): 3/15/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I BROKE OUT IN EXTREMELY ITCHY HIVES ALL OVER MY BODY. I BECAME NAUSEOUS WITH A HEADACHE. I WENT TO THE EMERGENCY ROOM AND MY BLOOD PRESSURE WAS (B)(6). I WAS GIVEN ANTIBIOTICS FOR ITCHING AND MEDICINE TO GET MY BLOOD PRESSURE LOWERED. I DIDN'T EAT OR USE ANYTHING DIFFERENT SO IT WAS UNEXPLAINED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056632		9/22/2015	9/30/2015

Event Information:

Event Date (B3): 3/3/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/3/2003
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE CAUSED WEIGHT GAIN, HEADACHES, FATIGUE AND PAIN IN PELVIC AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056635	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): 8/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/11/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS IN (B)(6) 2014. STARTED HAVING JOINT ISSUES IN (B)(6) 2014 WAS SUBSEQUENTLY DIAGNOSED WITH LUPUS IN (B)(6) 2015. THE LEFT IMPLANT PUNCTURED THROUGH THE FALLOPIAN TUBE CAUSING AN INFECTION IN (B)(6). I TOOK ANTIBIOTICS FOR THREE WEEKS BEFORE FINALLY BEING ADMITTED TO THE HOSPITAL IN (B)(6) FOR IV ANTIBIOTICS. I WENT INTO SURGERY TO REMOVE THE ABSCESS DURING MY STAY, BUT DUE TO THE SEVERITY OF THE INFECTION AND THE MASS THAT IS ASSUMED TO BE SCAR TISSUE, THE DOCTOR WAS NOT COMFORTABLE WITH PROCEEDING FURTHER. HE CLOSED THE INCISION, KEPT ME IN THE HOSPITAL FOR TWO ADDITIONAL DAYS ON ANTIBIOTICS AND SENT ME HOME WITH ANOTHER TWO WEEKS OF ANTIBIOTICS TO CLEAR THE INFECTION. I HAD A REPEAT CT SCAN IN (B)(6) THAT SHOWS I HAVE A MASS REMAINING IN THE AREA OF THE INITIAL INFECTION. IT IS ASSUMED BY MY DOCTOR THAT THIS IS SCAR TISSUE FROM THE ORIGINAL PUNCTURE CAUSED BY THE ESSURE IMPLANT. AT THIS POINT WE ARE WEIGHING MY OPTIONS WITH HYSTERECTOMY BEING A CONSIDERATION TO REMOVE THE IMPLANTS AND ALLEVIATE THE HEAVY MENSTRUAL CYCLES THAT I HAVE ALSO BEEN EXPERIENCING SINCE THE IMPLANTS. I SHOULD ALSO NOTE THAT I HAVE BECOME ANEMIC AS WELL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056636	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): 8/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/17/2009
Explant Date (E7): 1/31/2011
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I FIRST RECEIVED THE ESSURE PROCEDURE ON (B)(6) 2009 AND RIGHT FROM THE START I EXPERIENCED PAIN, CRAMPING NAD HEAVY BLEEDING. IT WAS NOT TWO WEEKS LATER THAT THE SEVERE MIGRAINES (NOTHING HELPED THE MIGRAINES) AND THE RASHES STARTED. THEN I STARTED TO LOSE FOCUS, COULD NOT THINK CLEARLY AND I BECAME VERY LETHARGIC. THEN I STARTED URINATING BLOOD. MY WEIGHT WAS GREATLY FLUCTUATING. I HAD TO GET AN ALLERGY TEST FOR MY DOCTOR TO BELIEVE THAT THESE SYMPTOMS WERE DUE TO THE ESSURE AND THE ALLERGY TEST WAS SO POSITIVE, THAT I STILL HAVE THE TWO SCARS FROM THE NICKEL AND COBALT TEST AREAS. I HAD IT REMOVED IN 2011 (THE ONLY WAY TO REMOVE IT IS A HYSTERECTOMY). IT IS NOW 2015 AND I AM STILL EXPERIENCING SEVERE MIGRAINES AND RASHES AND SEVERE STOMACH AND BACK PAIN, AND I STILL HAVE PROBLEMS WITH FATIGUE. I NOW BELIEVE THAT IT ALSO CREATED MY COLITIS. PLEASE STOP GIVING THIS TO WOMEN!!!! PULL IT NOW!!!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056638	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): 4/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 4/7/2014
Explant Date (E7): 9/12/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE AFTER I HAD MY DAUGHTER, THE PROCEDURE WAS DONE IN (B)(6). I HAD HEAVY BLEEDING AND SEVERE STOMACH CRAMPING FOR ABOUT 6 MONTHS AFTER HAVING MY BABY. I THEN MOVED BACK TO (B)(6) WHERE I SAW MY REGULAR OB/GYN AND HE IMMEDIATELY SCHEDULED ME FOR SURGERY. I AM NOW (B)(6) AND HAD TO GET A HYSTERECTOMY DUE TO THIS PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056639	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER ESSURE IMPLANT, OVER 10 YEARS AGO, I STARTED EXPERIENCING MIGRAINE HEADACHES DURING MENSTRUAL CYCLE AS WELL AS CLOTTING. I'M BEING TREATED FOR DEPRESSION AND LACK OF CONCENTRATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056640	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): 10/13/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/14/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN (B)(6) 2014. SINCE THEN IT'S BEEN A NIGHTMARE. I HAVE HAD MIGRAINES, PAIN EVERY MONTH WHEN OVULATING, DEPRESSION, WEIGHT GAIN, MY STOMACH HURTS MOST OF THE TIME. I WOULDN'T RECOMMEND THIS TO ANYONE, AND SEEING THAT THEIR STILL PUTTING THESE DEVICES IN PEOPLE IS AWFUL. THEY WILL DO ANYTHING FOR MONEY. I HAVE DONE A LOT OF RESEARCH, MANY WOMEN ARE GOING THROUGH THE SAME THING I AM AND IT'S AWFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056641	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE THE ESSURE BIRTH CONTROL. I'VE BEEN READING COMPLAINTS AND HAVE HAD THE SAME PROBLEMS. BLOATING, PELVIC PAIN, ABDOMINAL PAIN, DIGESTIVE ISSUES, DEPRESSION. I'VE HAD NUMEROUS TESTS DONE TO DETERMINE THE CAUSE AND HAVE NOT HAD ANY ANSWERS. I BELIEVE THAT THE PROBLEMS MAY BE FROM THE ESSURE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056642	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): 4/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 4/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THE PRODUCT IS ESSURE BIRTH DEVICE. A FEW WEEKS AFTER THE PROCEDURE. I BEGAN TO NOTICE PAIN IN THE PELVIC AREA ON THE LEFT AND RIGHT SIDE. THE PAIN MADE IT DIFFICULT TO WALK. I ALSO EXPERIENCED HEAVY MENSTRUAL CYCLE WHILE INCLUDES BLOOD CLOTS. I HAVE NEVER HAD A HEAVY CYCLE. SINCE THE SURGERY I HAVE LOWER BACK PAINS. IF I WOULD HAVE KNOWN ABOUT THESE SIDE EFFECTS, I WOULD NOT HAVE CONSIDERED THIS AS AN OPTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056643	BAYER	9/22/2015	9/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/1/2008
Explant Date (E7): 3/24/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE BIRTH CONTROL LEAD TO HYSTERECTOMY AFTER HAVING IT IMPLANTED. THE PAIN ON MY RIGHT SIDE CONTINUED TO GET WORSE. MY ORIGINAL GYNECOLOGIST WOULD DISMISS THE FACT THAT THE ESSURE COULD CAUSE THE PAIN. HAD ESSURE IMPLANTED IN 2008 AND SHE DID NOT MANDATE ME TO DO A FOLLOW UP "DYE" TEST TO CHECK IF THE ESSURE WAS PLACED PROPERLY. I SWITCHED GYNECOLOGIST AND HAD AN ULTRASOUND THAT CONFIRMED MY RIGHT TUBE WAS "NOT HAPPY" AND HAD RED ALL OVER THE ULTRASOUND INDICATING AN ISSUE. I HAD A HYSTERECTOMY IN 2014 (KEEPING MY OVARIES). DURING THE HYSTERECTOMY, IT WAS DISCOVERED THAT THE RIGHT ESSURE DEVICE HAD MIGRATED OUT OF THE TUBE AND I ACTUALLY HAD 2 ESSURE DEVICES IN MY LEFT TUBE. ALSO, I NOW HAVE CHRONIC HEADACHES. ALSO, I AM PERFECTLY HEALTHY EXCEPT FOR BEING DIAGNOSED WITH BLADDER CANCER (B)(6) 2011, 2 SURGERIES AND ONE INSTALLATION OF BCG TREATMENT, ALL CLEAR UNTIL (B)(6) 2014 AND (B)(6) 2015. NOT SURE WHAT CAUSED THE BLADDER CANCER, BUT CANNOT RULE OUT ISSUES WITH ESSURE. I HAVE NEVER SMOKED AND I AM AN ACTIVE (B)(6) FEMALE (WITH AN (B)(6) HEALTHY DAUGHTER). THIS SHOULD BE OFF THE MARKET.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01044	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 686082

Single Use: Y
Implant Date (E6): 5/28/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY IN UNITED STATES ON 11-JUN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 WITH LOT NUMBER 686082. SHE REPORTED THAT SHE HAD ESSURE INSERTED 5 YEARS AGO AND ALL THE SUDDEN SHE HAD MASSIVE PELVIC PAIN, NAUSEA, FATIGUE AND FEVER. SHE WAS IN THE EMERGENCY ROOM AT TIME OF REPORT BECAUSE ESSURE WAS AFFECTING HER BODY. SHE LOST DAYS AT WORK AND TIME WITH CHILD DUE TO BEING ILL. AN INJURY (REQUIRED INTERVENTION) WAS MENTIONED BUT NOT SPECIFIED AND /OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON 23-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: BATCH NUMBER 686082; PRODUCTION DATE: 11/2009; EXPIRATION DATE: 11/2012. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE

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BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 27-AUG-2015 AND 11-SEP-2015 (PTC RESULT UPDATED): THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0764). CONSUMER REPORTED THAT ESSURE HAS CAUSED HER MANY REACTIONS TO THE ACTUAL MAKE-UP OF THE PRODUCT RESULTING IN MASSIVE PELVIC PAIN, HAIR LOSS, ITCHY SKIN RASHES, DENTAL ISSUES, WEIGHT LOSS, MASSIVE ABDOMINAL BLOATING, CROHNS DISEASE, BREAST CYSTS AND OVARIAN CYSTS (WHICH RESULTED IN HER HAVING A FULL HYSTERECTOMY AT (B)(6)). IN ADDITION, CONSUMER INFORMED THAT HER PHYSICIANS HAVE PLACED BLAME FOR ALL HER SYMPTOMS ON ESSURE SINCE EVERY SINGLE SYMPTOM STOPPED AFTER IT WAS REMOVED. PTC RESULT UPDATED: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PLEASE NOTE THAT THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE INSERTED AND EXPERIENCED MASSIVE PELVIC PAIN. SHE ALSO HAD OVARIAN CYSTS AND CROHNS DISEASE. MASSIVE PELVIC PAIN IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE OTHER EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND UNLISTED. PELVIC PAIN MAY OCCUR WITH ESSURE USE. IN THIS CASE, THE PATIENT HAD ESSURE INSERTED 5 YEARS PREVIOUS TO THIS REPORT AND SUDDENLY SHE EXPERIENCED MASSIVE PELVIC PAIN. SHE UNDERWENT A FULL HYSTERECTOMY. GIVEN EVENT'S NATURE, AND IMPLIED POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, BASED ON THE PATHOPHYSIOLOGY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01045	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893970

Single Use: Y
Implant Date (E6): 2/24/2015
Explant Date (E7): 8/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 27-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 893970 (EXPIRATION DATE 01-NOV-2016), INSERTED FOR PERMANENT CONTRACEPTION ON (B)(6) 2015. ADDITIONAL INFORMATION RECEIVED ON 13-SEP-2015 (PTC RESULT) AND 15-SEP-2015. THE PATIENT WAS NOT PREGNANT BY THE TIME OF ESSURE INSERTION. IT WAS REPORTED THAT ESSURE WAS EXPLANTED FROM HER AFTER APPROXIMATELY 6 MONTHS DUE TO ABDOMINAL PAINS (ESSURE WAS REMOVED ON (B)(6) 2015). ACCORDING TO THE REPORTER, TT WAS UNCLEAR IF THE DEVICE WAS FAULTY. HOSPITALIZATION WAS REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: LOT NUMBER REPORTED 893970 IS INVALID. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED; 6 MONTHS AFTER ITS

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INSERTION, DUE TO ABDOMINAL PAINS. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, GIVEN THE CLOSE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 16-NOV-2015 AND 23-NOV-2015: ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE WAS RECEIVED WITHOUT FURTHER INFORMATION. REPORTER INFORMATION WAS UPDATED IN THE SECOND FOLLOW-UP, BUT NO NEW CLINICAL INFORMATION RECEIVED. FOLLOW-UP FR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01046	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 27-AUG-2015. ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVAL WAS REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 13-SEP-2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A PHYSICIAN WHO REPORTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVAL. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, MINIMAL INFORMATION WAS PROVIDED. NEVERTHELESS; CONSIDERING EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO THE POSSIBLE SURGICAL INTERVENTION FOR DEVICE REMOVAL; THIS CASE WAS CONSIDERED AN INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 26-OCT-2015: HEALTH CARE PROVIDER (HCP) FOLLOW-UP QUESTIONNAIRE WAS RECEIVED. PATIENT'S INITIALS, DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. SHE HAD NO PREVIOUS GYNECOLOGICAL INTERVENTIONS. PATIENT'S RELEVANT MEDICAL HISTORY WAS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01047	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C35241

Single Use: Y
Implant Date (E6): 4/7/2015
Explant Date (E7): 8/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 27-AUG-2015 WHICH DESCRIBES A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 LOT NUMBER C35241. IT WAS REPORTED THAT ESSURE WAS PLACED WITH 3 TRAILING COILS ON THE LEFT AND 8 TRAILING COILS ON THE RIGHT SIDE. THE PATIENT DID NOT HAVE HER HSG TEST DONE. ON AN UNSPECIFIED DATE, PREGNANCY WAS CONFIRMED. ON AN UNSPECIFIED DATE, PATIENT WAS TAKEN TO THE OPERATING ROOM AND HAD A DILATION AND CURETTAGE AND IT WAS DISCOVERED THAT ONE OF THE INSERTS HAD PERFORATED UTERUS AND WAS NEAR THE BOWEL. DEVICE WAS REMOVED, ALONG WITH HER APPENDIX. PTC INVESTIGATION RESULT WAS RECEIVED ON 13-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT C35241 (PRODUCTION DATE 06-MAR-2014 AND EXPIRATION DATE 31-MAR-2017) WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) / LACK OF EFFICACY IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE

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INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS RETROSPECTIVE PREGNANCY CASE REPORT. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A PREGNANCY CONFIRMED. SHE UNDERWENT A DILATION AND CURETTAGE (IMPLIED ABORTION). DURING THIS PROCEDURE, IT WAS DISCOVERED THAT ONE OF HER INSERTS HAD PERFORATED UTERUS AND WAS NEAR BOWEL. DEVICE WAS REMOVED ALONG WITH APPENDIX (INTERPRETED AS APPENDECTOMY). IT IS NOT CLEAR IF BOTH INSERTS WERE REMOVED. ALL EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND UTERINE PERFORATION IS ALSO SERIOUS DUE TO REQUIRED INTERVENTION. THE PREGNANCY AND UTERINE PERFORATION ARE LISTED WHILE THE UNSPECIFIED ABORTION AND APPENDECTOMY ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THE UTERINE PERFORATION AND THE LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. ALTHOUGH THE ONSET DATE OF PREGNANCY WAS NOT PROVIDED, SINCE IT WAS DIAGNOSED DURING ESSURE THERAPY, THE CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. LIMITED INFORMATION WAS PROVIDED REGARDING THE DILATION AND CURETTAGE AND APPENDECTOMY. SINCE THE GESTATIONAL AGE AND WHETHER IT WAS SPONTANEOUS OR ELECTIVE, THE CAUSAL RELATIONSHIP WITH ESSURE COULD NOT BE ASSESSED. ALSO, SINCE THE REASON FOR APPENDECTOMY WAS NOT PROVIDED IT IS NOT POSSIBLE TO ASSESS IF THIS PROCEDURE IS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A REVIEW OF MANUFACTURING BATCH RECORD CONFIRMED THAT THIS LOT MET ALL RELEASE REQUIREMENTS. HOWEVER, SINCE NO PRODUCT WAS RETURNED IT WAS NOT POSSIBLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

ESSURE HEALTH CARE PROVIDER UTERINE/ TUBAL PERFORATION QUESTIONNAIRE WAS RECEIVED ON 23-OCT-2015: PATIENT INFORMATION WAS UPDATED. HER REPORTED WEIGHT IS (B)(6), HER HEIGHT IS (B)(6). PREGNANCY HISTORY INCLUDED GRAVIDA 4, PARA 2, ABORTION 1 AND 1 SPONTANE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01048	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/11/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0841, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. CONSUMER REPORTED: I HAVE HAD ESSURE SINCE (B)(6) 2012. JUST THIS YEAR ALONE, I HAVE HAD MY PERIOD 20 TIMES. OTHER SYMPTOMS HAVE BEEN BLOATING, BRAIN FOG, HEAVY PERIODS, BLOOD CLOTS, HIVES ON MY BACK, FACE, AND NECK, DENTAL ISSUES, MOOD SWINGS, VAGINAL BLEEDING AFTER A BOWEL MOVEMENT, OVARIAN CYSTS, LOWER SEX DRIVE, AND LEFT SIDE OVARY PAIN. I HAVE POSSIBLE ADHESIONS AND ENDOMETRIOSIS OR PERFORATION. MY OBSTETRICIAN / GYNECOLOGIST WAS SCHEDULED TO DO A LAPAROSCOPIC SCOPE ON (B)(6) 2015. WHEN I RECEIVED MY SURGICAL PAPERWORK, SHE INCLUDED CUTTING OUT MY TUBES. WHEN I QUESTIONED HER ON REMOVING ESSURE WITH NO EXPERIENCE AND I SHOWED HER THE PHYSICIAN MANUAL THAT SAID THE ABLATION THEY DID LAST YEAR WAS AGAINST THE RECOMMENDATIONS SHE BECAME DEFENSIVE AND THEN REFUSED ANY SURGERY. I'VE BEEN A PERFECTLY HEALTHY WOMAN AND ESSURE IS RUINING MY LIFE. I NOW HAVE TO START ALL OVER AFTER TWO YEARS OF FIGHTING FOR REMOVAL WITH A NEW PHYSICIAN. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE

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HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO EXPERIENCED HEAVY PERIODS WITH CLOTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO AN ENDOMETRIAL ABLATION APPROXIMATELY 2 YEARS AFTER DEVICE PLACEMENT. SHE ALSO STATED SHE HAD A POSSIBLE ENDOMETRIOSIS OR PERFORATION (REGARDED AS UTERINE PERFORATION). ONLY ENDOMETRIOSIS IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER'S POSSIBLE ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR HER HEAVY PERIODS. HOWEVER; SINCE NEITHER ENDOMETRIOSIS NOR PERFORATION WERE CONFIRMED AT THE TIME OF THIS REPORT; A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REPORTED ENDOMETRIAL ABLATION (REQUIRED INTERVENTION) FOR BLEEDING'S TREATMENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01049	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2009
Explant Date (E7): 8/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0863, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. ADDITIONAL INFORMATION RECEIVED ON 19-SEP-2015 (PTC INVESTIGATION RESULT). CONSUMER REPORTED THAT IN THE YEARS THAT FOLLOWED INSERTION, SHE STARTED EXPERIENCING TROUBLE WITH PAINFUL INTERCOURSE, LOSS OF LIBIDO, NIGHT SWEATS, MIGRAINE, CHRONIC PELVIC ACHES, ONGOING FATIGUE, MUSCLE AND JOINT PAIN. AFTER SEVERAL YEARS OF VISITING DOCTORS, SHE WAS DIAGNOSED WITH FIBROMYALGIA. SHE UNDERWENT A HYSTERECTOMY IN (B)(6) 2015. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC ACHES. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT IN THE YEARS THAT FOLLOWED INSERTION. SHE UNDERWENT A HYSTERECTOMY. CONSIDERING THE NATURE OF THE EVENT AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01050	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4)). IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD ESSURE PLACED WHEN SHE WAS (B)(6) AND, 8 YEARS LATER, HAD TO HAVE A HYSTERECTOMY AT (B)(6). SHE STATES THAT SHE REALIZES SHE WAS SICK AFTER SHE HAD THIS SURGERY DONE (AS REPORTED, UNDERSTOOD AS ESSURE INSERTION). CONSUMER INFORMED THAT SHE EXPERIENCED PAIN AFTER THE SURGERY (WORSE THAN WHEN SHE GAVE BIRTH). SHE WAS TOLD THAT IT WAS NORMAL AND THAT WOULD ONLY LAST A COUPLE DAYS, BUT IT NEVER WENT AWAY. CONSUMER ALSO REPORTED THAT ESSURE MADE HER GAIN SO MUCH WEIGHT AND STATES THAT SHE NEVER HAD ANY ENERGY TO DO ANYTHING. SHE HAD CHRONIC PAIN, HORRIBLE PERIODS (SOMETIME 3 TIMES A MONTH) AND INFORMED THAT SHE WAS MISERABLE AND IT MADE GROW APART. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE

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TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD CHRONIC PAIN SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY, 8 YEARS AFTER DEVICE PLACEMENT. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED IN CLOSE ASSOCIATION WITH ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01051	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 2/16/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0768, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT SHE EXPERIENCED HORRIBLE PAIN, HORRIBLE BLEEDING AND CLOTS, HAIR LOSS, RASH, MEMORY PROBLEMS AND PAINFUL PERIODS. SHE HAD ESSURE REMOVED ON (B)(6) 2015 VIA COMPLETE HYSTERECTOMY, INCLUDING OVARIES. SHE IMMEDIATELY FELT A HUGE DIFFERENCE AFTER SURGERY. ACCORDING TO THE PATHOLOGY REPORT ONE COIL WAS EMBEDDED IN HER UTERUS, THE OTHER COIL HAD PERFORATED THE TUBE AND WAS ATTACHED TO THE FATTY TISSUE OF HER COLON AND HER CERVIX HAD CHRONIC BACTERIAL VAGINOSIS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS WERE RECEIVED ON 19-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED PRODUCT TECHNICAL ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE

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REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HORRIBLE BLEEDING AND CLOTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY, APPROXIMATELY 6 YEARS AFTER DEVICES PLACEMENT. PATHOLOGY REPORT SHOWED ONE COIL WAS EMBEDDED IN HER UTERUS; THE OTHER COIL HAD PERFORATED THE TUBE. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE THERAPY, THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION TO UTERUS, MIGRATION TO ABDOMEN OR OCCUR AS A RESULT OF A UTERINE/FALLOPIAN TUBE PERFORATION DURING INSERTION. DEVICE MOVEMENT CAN RESULT IN PAIN AND MENSTRUAL DISTURBANCES. IN THIS CASE, THE EXACT MECHANISM OF THE EVENTS WAS UNKNOWN. NEVERTHELESS, GIVEN THEIR NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01052	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1026; AWARENESS DATE: 29-AUG-2015). IT DESCRIBES A CASE OF A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD MIRENA (LEVONORGESTREL) AND ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER HAD ESSURE IMPLANTED AFTER GETTING PREGNANT WITH THE MIRENA DEVICE WITH HER FOURTH CHILD. SINCE IMPLANTING OF ESSURE, SHE EXPERIENCED HAIR LOSS, WEIGHT GAIN, HEART BUM, CONSTANT BACK PAIN, INSOMNIA, NIGHT SWEATS, HEADACHES AND COMPLETE HYSTERECTOMY JUST TO NAME A FEW OF ISSUES, SHE SAID. SHE STATED SHE LIVES IN CONSTANT PAIN DAILY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT ON 13-SEP-2015: BAYER PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, THEY WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, THEY WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE THEY HAVE NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE

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CONSUMER WHO BECAME PREGNANT WITH MIRENA (LEVONORGESTREL IUS). LATER, SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT BACK PAIN. SHE WAS SUBMITTED TO A HYSTERECTOMY. THESE EVENTS ARE LISTED IN MIRENA'S AND ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE. RISK OF UNINTENDED PREGNANCY DURING IUS (MIRENA) USE MAY BE INCREASED IN CASE OF ABNORMAL UTERINE ANATOMY OR INCORRECT LOCALIZATION OF THE IUS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE, A CAUSAL RELATIONSHIP WITH MIRENA CANNOT BE EXCLUDED. REGARDING CONSUMER'S BACK PAIN WITH ESSURE; AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND BACK PAIN MAY OCCUR. IN THIS CASE, THE CONSUMER RELATED HER PAIN TO ESSURE THERAPY. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01053	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4)) IN UNITED STATES , AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER HUSBAND REPORTED THAT HIS WIFE WAS IN SO MUCH PAIN. IN 2014 SHE HAD HER LAST SURGERY PERFORMED, HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED AND EXPERIENCED PAIN (INTERPRETED AS PELVIC PAIN). IN 2014, HYSTERECTOMY WAS PERFORMED. PELVIC PAIN MAY OCCUR DURING DEVICE THERAPY. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE SURGICAL PROCEDURE TO REMOVE ESSURE WAS REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 21-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01054	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 9/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626626

Single Use: Y
Implant Date (E6): 9/12/2008
Explant Date (E7): 11/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SOLICITED CASE REPORT WAS RECEIVED FROM A CONSUMER IN UNITED STATES ON 07-FEB-2014 VIA AN ESSURE GENERIC REIMBURSEMENT PROGRAM. THE REPORT REFERS TO THE REPORTING (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SKIN ALLERGIES, SOME THINGS THAT SHE CANNOT EAT OR DRINK, STARTED LOSING HAIR, AND RECEIVED IBUPROFEN FOR BAD MIGRAINE WHICH IS DAMAGING HER LIVER. CONSUMER ALSO HAD AN ELEVATED D-DIMER TEST. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2008, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 626626, INSERTED FOR STERILIZATION. CONSUMER WANTED TO GET THE CONTENT LIST OF THE ESSURE DEVICE SO SHE CAN BE TESTED FOR ALLERGIES. SHE WORKS FOR MATERIALS MANAGEMENT AND SHE KNOWS THERE IS A LIST OF WHAT IT IS MANUFACTURED FROM. SHE HAS THE LOT NUMBER TO SEE WHERE IT WAS MANUFACTURED. HER HCP (HEALTHCARE PROFESSIONAL) ASKED HER TO GET THE LIST. CONSUMER HAD BEEN HAVING DIFFERENT SIDE-EFFECTS THAT STARTED RIGHT AFTER SHE HAD THE ESSURE. SHE HAS SKIN ALLERGIES, ITCHING RANDOMLY, SOME THINGS THAT SHE CANNOT EAT OR DRINK. SHE STARTED LOSING HAIR. SHE STARTED TAKING IBUPROFEN SIX MONTHS AFTER IMPLANTATION ((B)(6) 2009) BECAUSE OF BAD MIGRAINE, AND IT IS DAMAGING HER LIVER. SHE HAD A LOT OF BLOOD WORK DONE, TESTED FOR A LOT OF THINGS. SHE HAD AN ELEVATED D-DIMER TEST. EVENT STOP DATE WAS REPORTED AS 'ONGOING'. PRODUCT WAS CONTINUED. SHE HAD FILED A REPORT WITH FDA (FOOD AND DRUG ADMINISTRATION, REGULATORY HEALTH AUTHORITY IN UNITED STATES) ABOUT THIS. NO FURTHER DETAILS WERE REPORTED. FOLLOW UP 18.NOV.2014: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER VIA SOCIAL MEDIA. CONSUMER SAID THAT SHE HAD MIGRAINES, PAIN AND WAS TIRED ALL THE TIME. FOLLOW UP 28.NOV.2014: PTC

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INVESTIGATION RESULTS PROVIDED FROM THE LOT NUMBER 626626. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. 6 FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE WITH THE REFERRED BATCH, BUT NONE OF THOSE CASES REFER ALSO TO A SIMILAR ADVERSE TYPE OF EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 06-JAN-2015 THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. FOLLOW-UP RECEIVED ON 30-AUG-2015 (UPGRADED TO INCIDENT): THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-0990). CONSUMER, WHO WAS A SINGLE MOTHER OF 3 KIDS, REPORTED THAT SHE WAS IMPLANTED WITH ESSURE IN (B)(6) 2008 AT THE (B)(6) AND 3 MONTHS AFTER HER 3RD CHILD WAS BORN. SHE STATED THAT, ALTHOUGH MOST OF HER SIDE EFFECTS SHE BRUSHED ASIDE AS HER HORMONES ADJUSTING TO JUST HAVING A BABY AND THE FACT THAT SHE WAS RECENTLY STERILIZED, HER SYMPTOMS STARTED ALMOST IMMEDIATELY. NIGHT SWEATS, MIGRAINES, BRAIN FOG, FATIGUE, INSOMNIA, JOINT PAIN, SWELLING IN HER EXTREMITIES, VISION PROBLEMS, UNEXPLAINED RASHES, CONSTANT URINARY TRACT INFECTIONS AND BLADDER INFECTIONS, DAILY HEART BURN, LOW VITAMIN D LEVELS, 75 LBS. WEIGHT GAIN, MASSIVE AMOUNTS OF HAIR LOSS, PAIN ON HER RIGHT SIDE, BACK PAIN, DENTAL ISSUES AND JUST THE FEELING LIKE SHE HAD A BAD CASE OF THE FLU DAILY. ON (B)(6) 2012, SHE HAD A HYSTERECTOMY (AT THE (B)(6)) AND STATES THAT SHE WAS 100 PERCENT BETTER WITHOUT IT. IN ADDITION, CONSUMER REPORTED THAT SHE HAD NEVER IN HER LIFE HAD HEALTH ISSUES BEFORE ESSURE AND SHE HADN'T EVEN BEEN TO A DOCTOR, BESIDES AN OBSTETRICIAN FOR THE PREGNANCIES, SINCE SHE WAS IN HER EARLY 20'S. SHE WAS ALWAYS HEALTHY, ACTIVE, HAPPY, AND FULL OF ENERGY, WORKED 2-3 JOBS AND WAS PTA (AS REPORTED) MOM. ACCORDING TO CONSUMER, HER LIFE CHANGED IN (B)(6) 2008, ESSURE MADE IT IMPOSSIBLE FOR HER TO PLAY WITH HER KIDS, COOK FOR THEM, CLEAN AND SHE NEARLY LOST HER JOB. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, STUDY CASE REPORT REFERS TO A FEMALE CONSUMER WHO WAS INVOLVED IN ESSURE GENERIC REIMBURSEMENT PROGRAM (STUDY ID: (B)(4)). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE SERIOUS EVENT IBUPROFEN IS DAMAGING HER LIVER AND PAIN IN HER RIGHT SIDE. THE IBUPROFEN IS DAMAGING HER LIVER, INTERPRETED AS DRUG-INDUCED LIVER INJURY, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND THE PAIN IN RIGHT SIDE IS SERIOUS DUE TO REQUIRED INTERVENTION. THE DRUG-INDUCED LIVER INJURY IS UNLISTED AND THE PAIN NOS IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN CONTRAST, THE DRUG-INDUCED LIVER INJURY IS LISTED FOR IBUPROFEN WHILE THE PAIN NOS IS UNLISTED. IN THIS PARTICULAR CASE, AS THE CONSUMER STATED THAT IBUPROFEN WAS DAMAGING HER LIVER AND GIVEN ESSURE'S LOCAL ACTION AT FALLOPIAN TUBES, THE REPORTED EVENT WAS CONSIDERED AS UNRELATED TO ESSURE THERAPY. FOR IBUPROFEN, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY CANNOT BE EXCLUDED. CONSIDERING THAT THE CONSUMER STATED THAT THE PAIN IN RIGHT SIDE STARTED ALMOST IMMEDIATELY AFTER ESSURE INSERTION AND CONSIDERING THAT NO ALTERNATIVE EXPLANATION WAS

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PROVIDED, THE CAUSAL RELATIONSHIP WITH ESSURE USE CANNOT BE EXCLUDED. HOWEVER, THE CAUSAL RELATIONSHIP BETWEEN THE PAIN AND IBUPROFEN CAN BE EXCLUDED SINCE THE PAIN STARTED BEFORE THE USE OF IBUPROFEN. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). AN INITIAL PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. NO FOLLOW UP INFORMATION COULD BE OBTAINED.

Manufacturer Narrative (H10):

UPDATED TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 30-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01055	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1007, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE STATED THAT SHE HAD A TOTAL HYSTERECTOMY BECAUSE OF ESSURE. REAL GREAT ITEM THAT RUINED HER LIFE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED AND SHE HAD TOTAL HYSTERECTOMY BECAUSE OF ESSURE. DURING DEVICE THERAPY, SURGICAL REMOVAL OF ESSURE MAY BE REQUIRED. CONSUMER PROVIDED VERY LIMITED INFORMATION HOWEVER GIVEN THE IMPLIED TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED AND THIS CASE IS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS PERFORMED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01056	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0921, AWARENESS DATE 28-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. CONSUMER REPORTED THAT IN 2011 SHE HAD AN ABLATION PERFORMED DUE TO CONSTANT BLEEDING. SHE ALSO EXPERIENCED CONSTANT BLOAT, PELVIC PAIN, HEADACHES, BLURRED VISION, RASHES AND CHRONIC FATIGUE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD AN ABLATION PERFORMED DUE TO CONSTANT BLEEDING. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING AND MENSES PATTERN CHANGES ARE FREQUENT IN WOMEN WITH ESSURE IN PLACE. IN THIS CASE, FOUR YEARS AFTER ESSURE INSERTION, THE CONSUMER HAD AN ABLATION PERFORMED DUE TO CONSTANT BLEEDING. SHE ALSO EXPERIENCED OTHER NON-SERIOUS EVENTS. GIVEN COMPATIBLE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE THIS EVENT LED TO A REQUIRED INTERVENTION (ENDOMETRIAL ABLATION), THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 20-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01057	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 8/20/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0837, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. CONSUMER REPORTED THAT SHE SUFFERED FOR TWO YEARS WITH SIDE EFFECTS FROM THE ESSURE. ACCORDING TO HER, BEFORE GETTING THE ESSURE SHE WAS A VERY HEALTHY WOMAN, ONCE SHE GOT THE ESSURE SHE WAS IN AND OUT OF DOCTORS TRYING TO FIGURE OUT WHAT WAS GOING ON WITH HER BODY. IT CAUSED HER TO BE BORDERLINE DIABETIC AND HER LIVER WAS FAILING. SHE ALSO BROKE OUT WITH ACNE ALL OVER HER FACE (WHICH WAS REALLY PAINFUL). SHE PUT ON A LOT OF WEIGHT AND HAD HER PERIOD FOR THREE OUT FOUR WEEKS A MONTH. HER PERIODS INCLUDED GOLF BALL SIZE BLOOD CLOTS THAT WOULD DOUBLE HER OVER IN PAIN. SHE HAD NO ENERGY TO GO TO WORK OR TAKE CARE OF HER FAMILY. ON 20-AUG-2015, SHE GOT ESSURE REMOVED AND STATES THAT SHE IMMEDIATELY FELT BETTER. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH

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INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PERIODS FOR THREE OUT FOUR WEEKS A MONTH WITH GOLF BALL SIZE BLOOD CLOTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH IMPROVEMENT. ADDITIONALLY, SHE REPORTED HER LIVER WAS FAILING. ONLY LIVER FAILING IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE EVENT STARTED AFTER ESSURE INSERTION AND IMPROVED WITH DEVICE REMOVAL; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT, GIVEN ITS NATURE AND CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY IS CONSIDERED UNLIKELY. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

AFTER INTERNAL REVIEW ON 24-SEP-2015, THE REPORTED EVENT BROKE OUT WITH ACNE ALL OVER FACE WHICH WAS PAINFUL WAS SPLIT AND THE MEDDRA PT PAINFUL SKIN WAS ADDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01058	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0794, AWARENESS DATE 27-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. ADDITIONAL INFORMATION RECEIVED ON 14-SEP-2015 (PTC - PRODUCT TECHNICAL COMPLAINT - WAS RECEIVED). HER DOCTOR TOLD HER AT TIME OF PROCEDURE THAT ESSURE WAS MADE OF PLASTIC AND COULD BE REMOVED WHENEVER SHE WANTED. SHE FOUND OUT AFTER INSERTION THAT ESSURE ARE MADE FROM NICKEL AND DOCTOR KNEW THAT SHE WAS ALLERGIC TO NICKEL. CONSUMER STATED THAT IN (B)(6) 2011 IT WAS CONFIRMED THAT TUBES WERE BLOCKED. SHE HAD 109 SIDE EFFECTS FROM ESSURE. HER LEFT COIL WAS BROKEN, SHE WAS LOSING HAIR, BREAKING OUT EVERYWHERE, HAD UNEXPLAINED BRUISING AND EXPELLED PET FIBERS. IN (B)(6) 2015, SHE HAD A MISCARRIAGE FROM ESSURE AND HER HUSBAND AND SHE ARE CURRENTLY WAITING TO FIND OUT IF SHE IS PREGNANT AGAIN (CASE (B)(4)). SHE IS MOTHER OF 4 KIDS (2 OF HER AND 2 OF HER HUSBAND) AND SHE COULD NOT DO SIMPLES THINGS BECAUSE OF THE PAIN. PTC INVESTIGATION RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE

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MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS AND LACK OF EFFICACY IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS/LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER LEFT COIL WAS BROKEN AND EXPELLED PET FIBERS. SHE GOT PREGNANT AND HAD A MISCARRIAGE. ALL EVENTS, EXCEPT MISCARRIAGE, ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE IS LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. THE EVENTS PREGNANCY AND MISCARRIAGE ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE WHILE THE OTHER EVENTS ARE NON-SERIOUS. IN THIS CASE, IT WAS NOT REPORTED WHETHER LEFT COIL WAS BROKEN DURING ESSURE INSERTION PROCEDURE. CONSUMER HAD A MISCARRIAGE ABOUT 4 YEARS AND 1 MONTH AFTER ESSURE INSERTION. CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THE EVENT MISCARRIAGE WAS CONSIDERED AS UNRELATED TO THE INSERT. WITH REGARDS TO THE OTHER EVENTS, GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS/LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01059	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2014
Explant Date (E7): 11/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0853, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF 30 (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014 AS WELL AS A UTERINE ABLATION. ADDITIONAL INFORMATION RECEIVED ON 19-SEP-2015 (PTC INVESTIGATION RESULT). CONSUMER REPORTED THAT SHE HAD A NICKEL ALLERGY SINCE THE BIRTH OF HER OLDEST CHILD IN 2006 THAT WAS IGNORED. SHE WOKE UP FROM PROCEDURE WITH SHARP STABBING LEFT PELVIC PAIN. THE PAIN CONTINUED, SEXUAL INTERCOURSE BECAME NEARLY IMPOSSIBLE, SHE STARTED TO EXPERIENCE PAINS THROUGHOUT HER BODY, JOINT SWELLING, WEIGHT GAIN AND BURNING / TINGLING SENSATIONS. THE DOCTOR TOLD HER THE COILS WERE IN PLACE WHICH SHE FOUND OUT 8 MONTHS LATER. THEY WERE INTACT BUT DEFINITELY ONE GOING UPWARDS AND ONE GOING DOWN. IN (B)(6) 2014 SHE PERFORMED A HYSTERECTOMY THINKING THAT THIS WOULD FIX THE PROBLEMS, BUT THE JOINT PAIN / SWELLING GOT WORSE, SHE HAD CONSTANT HEADACHES, HER TEETH BECAME EXTREMELY BRITTLE, SHE DEVELOPED VITAMIN D DEFICIENCY, HYPOTHYROIDISM, SHE HAD NO ENERGY AND A THYROID NODULE AND ANKYLOSING SPONDYLITIS WERE DIAGNOSED. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE

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DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE COILS WERE IN PLACE, BUT ONE GOING UPWARDS AND ONE GOING DOWN (INTERPRETED AS DEVICE DISLOCATION). ANKYLOSING SPONDYLITIS WAS DIAGNOSED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE EVENT DEVICE DISLOCATION IS LISTED IN THE REFERENCE SAFETY INFORMATION WHILE THE OTHER IS UNLISTED. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN. CONSUMER UNDERWENT A HYSTERECTOMY THINKING THAT THIS WOULD FIX THE PROBLEMS. CONSIDERING THAT THERE IS NO ALTERNATIVE EXPLANATION, GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, BASED ON THE PATHOPHYSIOLOGY AND CONSIDERING THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01060	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 8/12/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5039394) IN UNITED STATES ON 15-JAN-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD ESSURE 6 MONTHS AGO (UNSPECIFIED DATE) AND SHE HAS HAD SERIOUS PAIN IN HER ABDOMEN LOWER QUADRANT, PAIN WAS ACHY AND AT TIME SEVERE STABBING MADE HER NAUSEATED, DIZZY AND SWEATY. SHE HAS BEEN ON A DIET AND EXERCISE WHEN SHE GOT BLOATED HER STOMACH COULD GO FROM A 39 TO A 44, SO SHE MEASURED OFTEN, HER STOMACH WAS TENDER AND PAINFUL WHEN IT HAPPENED. PTC INVESTIGATION RESULT WAS RECEIVED ON 13-FEB-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL

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EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 28-APR-2015: ESSURE WAS INSERTED ON (B)(6) 2014, THE SAME DATE REPORTED AS EVENTS DATE. FOLLOW-UP RECEIVED ON 17-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. CASE CONSIDERED TO BE CLOSED. FOLLOW-UP RECEIVED ON 28-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1027). A (B)(6) FEMALE CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN 2013 (PREVIOUSLY REPORTED AS (B)(6)), THE INVASIVE IN AND OUT PROCEDURE ENDED UP WITH HER GETTING ANESTHESIA TO HAVE IT PLACED. AFTER PLACEMENT, SHE HAD HEAVY BLEEDING WITH LARGE CLOTS, PERIODS THAT LASTED 2-3 WEEKS AT A TIME OR MORE THAN ONE PERIOD IN A MONTH. SHE ALSO HAD EXTREME PAIN IN HER RIGHT LOWER QUADRANT, SO BAD SHE COULD NOT BEND OVER TO PICK UP ANYTHING ON HER RIGHT SIDE, NOT TO MENTION THE EXTREME BLOATING THAT STOPPED HER FROM BEING ABLE TO BEND AT ALL. AFTER A YEAR OF SUFFERING, SHE HAD A CHOICE TO GET ON BIRTH CONTROL TO HELP WITH HER PERIOD OR A HYSTERECTOMY. SHE HAD ESSURE PLACED BECAUSE SHE DIDN'T WANT BIRTH CONTROL PILLS OR SHOTS ANY MORE, ON TOP OF NOT HAVING ANY MORE CHILDREN. THE PAIN ON THE OTHER HAND WOULDN'T GO AWAY ON BIRTH CONTROL. SO, IN (B)(6) 2015 SHE HAD TO GET A HYSTERECTOMY AND STATES THAT SHE HAS NO MORE PAIN IN HER RIGHT SIDE. SHE IS RECOVERING FROM REMOVAL PROCEDURE. UPDATED PTC RESULT RECEIVED ON 14-SEP-2015: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER PLACEMENT SHE HAD PAIN IN HER ABDOMEN LOWER QUADRANT / EXTREME PAIN IN RLQ (RIGHT LOWER QUADRANT) AND HEAVY BLEEDING WITH LARGE CLOTS (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A HYSTERECTOMY APPROXIMATELY 2 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND ABDOMINAL PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE LACK OF AN ALTERNATIVE EXPLANATION, AND CONSIDERING THAT THE PAIN RESOLVED AFTER HYSTERECTOMY, CAUSALITY BETWEEN ESSURE AND THE REPORTED EVENTS CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE, INITIALLY REGARDED AS NON-INCIDENT, WAS UPGRADED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION STATING THE CONSUMER UNDERWENT A HYSTERECTOMY (REQUIRED INTERVENTION). SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY

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DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01061	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2004
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-0847, AWARENESS DATE 27-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2004. CONSUMER REPORTED THAT, AT THE TIME OF INSERTION, HER DOCTOR FELT ESSURE WAS THE BEST METHOD FOR HER, SINCE THERE WAS NO DOWN TIME AFTER THE PROCEDURE. ACCORDING TO CONSUMER, HER SECOND CHILD HAD A VERY ROUGH START IN LIFE AND WAS ALMOST TAKEN FROM HER AT 5 DAYS OLD. HE SPENT THE FIRST 6 MONTHS OF HIS LIFE IN THE NICU (NEONATAL INTENSIVE CARE UNIT), AND WENT HOME WITH A BROVIAC CATHETER IN PLACE FOR DAILY TPN INFUSIONS AND AN NG-TUBE FOR FEEDS. IN ADDITION, CONSUMER REPORTED THAT BIRTH CONTROL FAILED HER AND SHE HAD A THIRD CHILD WHICH WAS WHAT LEAD HER TO THE DECISION OF PERMANENT BIRTH CONTROL. SHORTLY AFTER ESSURE INSERTION, HER MENSTRUAL CYCLES BECAME HEAVIER (FROM 3-4 DAYS PRIOR TO IMPLANTATION TO 3-15 DAYS), OFTEN TIMES SO HEAVY THAT NOT EVEN 2 PADS WOULD PREVENT ACCIDENTS. WITHIN A COUPLE OF MONTHS, THE MIGRAINES BEGAN. SHE STARTED GOING TO NEUROLOGY TO FIGURE OUT WHAT WAS WRONG AND, WHEN SHE REALIZED THE MIGRAINES WERE AT THEIR WORST RIGHT AROUND HER PERIOD, SHE BROUGHT IT UP TO HER OBSTETRICIAN/GYNECOLOGIST. PHYSICIAN TOLD HER THAT THEY WERE PROBABLY "ME TRIAL" HEADACHES AND PRESCRIBED MIGRAINE MEDICATIONS. CONSUMER ALSO REPORTED THAT SHE WAS NOT A HUNDRED PER CENT SURE WHEN THE FOLLOWING SYMPTOMS BEGAN BUT STATED THAT THE DEPRESSION WAS KICKING HER INTO HIGH GEAR, WHEN SHE CONTEMPLATED SUICIDE NUMEROUS TIMES. CONSUMER EXPERIENCED FORGETFULNESS OF A TON OF STUFF, WEIGHT GAIN AND BLOATING (THAT HAVE

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MADE HER CONSCIENCE OF BODY IMAGE TO SUCH A DEGREE THAT SHE WOULDN'T EVEN LOOK AT HERSELF IN THE MIRROR). THERE WERE ALSO ISSUES WITH CHRONIC PAINS, SEVERE DEPRESSION, PINCHED NERVES IN HER BACK AND NECK (SHE HAS ALREADY HAD AN OPERATION TO FUSE TWO DISCS AND NEVER HAVING ANY TRAUMA TO HER BACK, EVEN THE NEUROSURGEON COULDN'T FIGURE OUT WHY SHE WAS UNABLE TO USE HER RIGHT HAND. AT THE TIME OF REPORT, SHE WAS FEELING THE SAME SYMPTOMS. ONLY THAT AT THAT TIME IT WAS AFFECTING BOTH ARMS WITH A VENGEANCE. SHE LOST HER JOB DUE TO MAJOR MOOD SWINGS; THE DEPRESSION AND CONSTANT PAIN HAVE BECOME UNBEARABLE AND SHE WAS CONSTANTLY AT DOCTORS APPOINTMENTS TO FIND SOME SORT OF RELIEF. SHE WAS NOT ABLE TO PLAY WITH HER KIDS OR DO MORE FOR THEM BECAUSE SHE WAS CONSTANTLY TIRED AND BECOMING WINDED REALLY FAST AND SHE COULDN'T DO THE HOBBIES SHE USED TO ENJOY BECAUSE HER BODY SIMPLE WOULDN'T ALLOW HER TO. LAST BUT NOT LEAST. SHE REPORTED THAT INTERCOURSE WAS PAINFUL AND OFTEN TIMES BLOODY (BECAUSE OF THIS, SHE SIMPLY DIDN'T WANT IT). SHE WAS SUPER MOODY AND SNAPPED AT PEOPLE OVER LITTLE THINGS (WHAT MAKES HER ALMOST IMPOSSIBLE TO BE AROUND FOR TOO LONG). SHE WAS ALSO SUPER EMOTIONAL OVER THE SMALLEST THINGS (THAT SHE REGULARLY CRIED OVER MINOR STUFF). SHE HAD BEEN DOING THE PRE-OPERATION WORKUP TO PREPARE FOR A HYSTERECTOMY WITH THE HOPE OF GETTING HER LIFE BACK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE HAD CONTEMPLATED SUICIDE NUMEROUS TIMES (INTERPRETED AS DEPRESSION SUICIDAL) AND HAD CONSTANT PAIN THAT WAS BECOMING UNBEARABLE. SHE MADE SEVERAL VISITS TO DOCTORS TO GET SOME RELIEF. AT THE TIME OF REPORT, ALMOST 11 YEARS AFTER ESSURE INSERTION, SHE HAD BEEN DOING THE PRE-OPERATION WORKUP TO PREPARE FOR A HYSTERECTOMY. THE DEPRESSION SUICIDAL IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND THE CONSTANT PAIN IS SERIOUS DUE TO PLANNED REQUIRED INTERVENTION. THE DEPRESSION SUICIDAL IS AN UNLISTED EVENT WHILE THE CONSTANT PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THERE IS LIMITED INFORMATION. THE ONSET DATE OF THESE EVENTS WAS NOT REPORTED, BUT SINCE THEY OCCURRED DURING ESSURE THERAPY, THE TEMPORAL RELATIONSHIP WITH ESSURE IS COMPATIBLE. CONSIDERING THE NATURE OF THESE EVENTS AND THE LOCALIZED ACTION OF ESSURE, THE CONSTANT PAIN WAS ASSESSED AS RELATED BUT THE DEPRESSION SUICIDAL IS ASSESSED AS UNLIKELY. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 19-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01062	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0982, AWARENESS DATE 28-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER MEDICAL HISTORY INCLUDED 3 CHILDREN. CONSUMER REPORTED THAT ESSURE PERFORATED HER TUBE AND UTERUS AND WAS NEAR HER BLADDER. SHE EXPERIENCED PAIN AND HAD TO PERFORM AN HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE PERFORATED HER TUBE AND UTERUS AND WAS NEAR HER BLADDER. THIS EVENT, SEEN AS UTERINE AND FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE AND FALLOPIAN TUBE PERFORATION ARE POTENTIAL COMPLICATIONS OF ESSURE USE. IN THIS CASE THE EXACT DATE AND MECHANISM OF THIS PERFORATION WAS NOT INFORMED. HOWEVER, CONSIDERING EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01063	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2008
Explant Date (E7): 4/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 17-DEC-2013 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5032203, RECEIVED AT FDA ON 07-OCT-2013). THE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND WAS NOT ABLE TO HAVE THE HSG (HYSTEROSALPINGOGRAM) DONE THREE MONTHS AFTER INSERTION, SHE EXPERIENCED HORRIBLE PAIN SO BAD SHE THOUGHT SHE WAS DYING, HAD 'CRIPPING' HEADACHES, STOMACH IS BLOATED THAT SHE LOOKS PREGNANT, SHE BLEEDS AND HAS CONSTANT PAIN WHEN SHE IS INTIMATE WITH HER HUSBAND, SHE HAS SHARP STABBING PAINS WHEN SHE COUGHS OR SITS OR STANDS, HAD SLIGHT DISTAL MIGRATION ON THE RIGHT SIDE AND HER UTERUS WAS THE SIZE OF A 12 WEEKS PREGNANT WOMAN. FDA REPORT TYPE WAS 'INJURY', REPORTED OUTCOME OF EVENTS WAS 'OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)'. NO INFORMATION WAS GIVEN ON CONSUMER'S PAST DRUGS, CONCOMITANT MEDICATION. AS FOR MEDICAL HISTORY, CONCURRENT CONDITIONS CONSUMER STATED SHE GOT PREGNANT IN 2007 WITH HER THIRD CHILD, HER LAST TWO WERE A YEAR AND A HALF APART AND SHE WAS DONE. SHE TOLD HER DOCTOR FROM THE BEGINNING THAT SHE WAS DONE HAVING CHILDREN AND SHE WANTED A TRADITIONAL TUBAL LIGATION. SHE WAS TOLD ABOUT ESSURE AND RESEARCHED IT HER ENTIRE PREGNANCY. SHE NEVER FOUND ANYTHING BAD ABOUT THE DEVICE (ACTUALLY IT WAS ALL GOOD) TOO GOOD TO BE TRUE SOME WOULD SAY. SHE DID NOT LISTEN TO HERSELF OR TO HER HUSBAND, WHO BEGGED HER NOT TO DO IT. SHE TRUSTED HER DOCTOR WHEN INDEED HER HEALTH AND SAFETY WAS NOT HER FIRST CONCERN. SHE HAD HER SON IN 2008. CONSUMER HAD ESSURE IMPLANTED IN 2008. CONSUMER STATED SHE WAS NOT TOLD THAT HER INSURANCE WOULD RUN OUT AND SHE WOULD NOT BE ABLE TO HAVE THE OH SO IMPORTANT, WHICH SHE WAS TOLD WAS NOT VERY

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IMPORTANT, HSG (HYSTEROSALPINGOGRAM) DONE. ABOUT A WEEK AFTER HER PROCEDURE, SHE WAS IN HORRIBLE PAIN SO BAD SHE THOUGHT SHE WAS DYING. SHE BRUSHED IT OFF AND WENT ON WITH HER LIFE. THINGS WERE FINE UNTIL ABOUT THREE YEARS LATER. SHE FINALLY HAD HER HSG DONE IN 2011. SHE WAS TOLD EVERYTHING WAS FINE WHEN IN FACT IT WAS NOT. SHE HAD 'CRIPPING' HEADACHES, HER STOMACH IS BLOATED THAT SHE LOOKS PREGNANT. SHE BLEEDS AND HAS CONSTANT PAIN WHEN SHE IS INTIMATE WITH HER HUSBAND. SHE HAS SHARP STABBING PAINS WHEN SHE COUGHS OR SITS OR STANDS AND THE LIST GOES ON AND ON. THIS HAS RUINED HER LIFE AND SHE DOES NOT HAVE THE INSURANCE TO HAVE IT REMOVED. SHE REQUESTED HER MEDICAL RECORDS FROM HER IMPLANTING DOCTOR AND WAS SHOCKED WHEN SHE READ THAT WHEN HER HSG WAS DONE, SHE HAD SLIGHT DISTAL MIGRATION ON THE RIGHT SIDE (WHY WAS SHE NEVER TOLD) WHY THE SECRETS. IT ALSO SAYS THAT HER UTERUS WAS THE SIZE OF A 12 WEEKS PREGNANT WOMAN, REALLY NOBODY FELT THE NEED TO TELL HER THIS EITHER. THIS WAS THE WORST DECISION SHE HAS NEVER MADE FOR HERSELF AND HER FAMILY. WHEN SHE FINALLY GETS INSURANCE, SHE WILL HAVE THIS EVIL DEVICE TAKEN OUT OF HER AND MAYBE THEN SHE CAN TRY TO GET HERSELF BACK TO THE PERSON SHE WAS BEFORE. SHE WOULD ALSO LIKE TO ADD THAT SHE WAS NEVER TESTED FOR A NICKEL ALLERGY AND SHE WAS NOT GIVEN HER ESSURE CARD AFTER THE PROCEDURE. REPORTER ASSESSED THE EVENTS WERE RELATED TO ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON 30-JAN-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN WI-03635, PROCESSING ESSURE CASES IN (B)(6). MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT INDICATIVE FOR A QUALITY DEFECT PER SE. THE MEDICAL EVENTS WERE REPORTED WITH AN OCCURRENCE OVER A LONG PERIOD OF 5 YEARS AND ARE OF BROAD NATURE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 28-AUG-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0945). THE CONSUMER HAD ESSURE IMPLANTED IN (B)(6) 2008, BARELY SIX WEEKS AFTER HER SON WAS BORN. SHE WAS CONVINCED THIS WAS THE BEST OPTION AND SHE WAS NEVER TESTED FOR A NICKEL ALLERGY. FROM DAY ONE SHE EXPERIENCED DYSFUNCTIONAL BLEEDING, NO SEX DRIVE, PAIN IN JOINTS, HAIR LOSS, SEVERE PELVIC PAIN, BLEEDING DURING/AFTER SEX AND PAINFUL SEX. SHE HAD HER HSG IN (B)(6) 2011 AND WAS TOLD EVERYTHING WAS OKAY. SHE HAD HER GALLBLADDER REMOVED IN (B)(6) 2011. SHE ALSO REPORTED NUMEROUS ER VISITS, OVARIAN CYSTS AND HYSTERECTOMY IN (B)(6) 2014, DIAGNOSED AFTER SURGERY WITH CHRONIC CERVICITIS. HER RIGHT COIL MIGRATED AND PUNCTURED HER FALLOPIAN TUBE; THEY ALSO REMOVED AN OVARIAN CYST DURING HYSTERECTOMY. SHE WAS STILL SUFFERING FROM CHRONIC PAIN EVERY DAY. SHE HAD BEEN PUT ON CYMBALTA BY HER RHEUMATOLOGIST AND HER DOCTOR WAS LEANING TOWARDS A FIBROMYALGIA DIAGNOSIS. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE RIGHT COIL MIGRATED AND PUNCTURED HER FALLOPIAN TUBE. ADDITIONALLY, SHE REPORTED UTERUS THE SIZE OF A 12 WEEK PREGNANT WOMAN; CRIPPING HEADACHES; STOMACH BLOATED THAT SHE LOOK PREGNANT; SHE BLEED AND HAS PAIN WHEN SHE IS INTIMATE WITH HER HUSBAND / (BLEEDING AND PAIN DURING/AFTER SEX); GALLBLADDER REMOVED AND OVARIAN CYSTS. SHE WAS SUBMITTED TO A HYSTERECTOMY. ALL REPORTED EVENTS ARE

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LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION, APART FROM THE EVENT UTERUS THE SIZE OF A 12 WEEK PREGNANT WOMAN AND GALLBLADDER REMOVED, WHICH ARE CONSIDERED UNLISTED. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE); INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE EVENT RIGHT COIL MIGRATED AND PUNCTURED HER FALLOPIAN TUBE IS UNKNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, THEY WERE CONSIDERED AS RELATED TO ESSURE DUE TO THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; EXCEPT FOR UTERINE ENLARGEMENT WHICH WAS CONSIDERED UNRELATED TO ESSURE DUE TO THE LOCAL ACTION OF THE DEVICE IN FALLOPIAN TUBES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01064	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-0883, AWARENESS DATE 27-AUG-2015). IT REFERS TO A NEARING (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. RECEIVED IN UNITED STATES ON (B)(6) 2015 AND REFERS CONSUMER REPORTED THAT SHE DECIDED TO BECOME STERILIZED AFTER HAVING HER FOURTH CHILD AND NEARING HER 40'S. WHEN SHE APPROACHED HER GYNECOLOGIST ABOUT TUBAL LIGATION SHE RECOMMENDED ESSURE AS A SAFER NON-SURGICAL ALTERNATIVE. CONSUMER SPECIFICALLY ASKED ABOUT MIGRATION DUE TO SOMEONE CLOSE TO HER HAVING MIRENA THAT HAD MIGRATED AND REQUIRED LAPAROSCOPIC ABDOMINAL REMOVAL (CASE NUMBER (B)(4)). CONSUMER WAS TOLD THAT EVEN THOUGH THE PAMPHLET WARNED ABOUT MIGRATION, IT REALLY COULDN'T HAPPEN DUE TO THE WAY THE SCARRING FORMS. AFTER TALKING IT OVER WITH HER HUSBAND, SHE DECIDED TO GO AHEAD WITH THE PROCEDURE IN OFFICE WITH ONLY LOCAL ANESTHESIA. ACCORDING TO HER, THE PROCEDURE WAS NOT QUICK AND EASY. ONE IMPLANT BROKE DURING IMPLANTATION AND HAD TO BE REPLACED WITH ANOTHER ONE FROM A SECOND PACKAGE. AT ONE POINT THE PAIN WAS LITERALLY SO GREAT, THAT SHE JUMPED U AND THE DOCTOR REASSURED HER SHE WAS ALMOST FINISHED AND EVERYTHING WAS OK. CONSUMER WAS NOT ABLE TO HAVE THE HYSTEROSALPINGOGRAM CONFIRMATION TEST DONE AT 3 MONTHS DUE TO NON-STOP BLEEDING. HER PERIOD FINALLY STOPPED AFTER 6 MONTHS. ONCE THE HSG TEST WAS PERFORMED IT WAS DISCOVERED THAT ONE IMPLANT HAD INDEED MIGRATED AND WAS IN HER ABDOMINAL CAVITY. HER FALLOPIAN TUBE WAS OPEN AND SHE WAS NOT STERILE. THE OTHER IMPLANT WAS IN PLACE AND SHOWED COMPLETE OCCLUSION. SHE EXPERIENCED MULTIPLE

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CHANGES IN HER BODY WITH EXCESSIVE WEIGHT GAIN, DEBILITATING JOINT PAIN, METALLIC TASTE IN MOUTH, HIGH BLOOD PRESSURE, HEART PALPITATIONS, CHRONIC PELVIC PAIN, HEAVY PERIODS, LARGE CLOTS DURING PERIOD, BRAIN FOG, PAIN DURING INTERCOURSE, CONSTANT BACK PAINS, HOT FLASHES, FLUCTUATIONS BETWEEN CONSTIPATION AND DIARRHEA, DIZZY SPELLS, EXTREME MOODINESS, DETERIORATION OF TEETH, JUST TO NAME A FEW THAT SHE NOTICED QUICKLY AFTER HAVING ESSURE IMPLANTED. SHE DECIDED SHE NO LONGER WANTED IT IN HER BODY. THE FACT THAT ONE WAS SHOWN TO BE IN HER ABDOMEN MADE THAT DIFFICULT. HER GYNECOLOGIST CALLED THE MANUFACTURER TO GET INFORMATION FOR PROPER REMOVAL WITH A MIGRATED IMPLANT AND WAS TOLD THERE WAS NO PROTOCOL FOR SUCH EVENT. HEALTH CARE PROFESSIONAL INFORMED HER THAT SHE COULD NOT HELP. AT THAT POINT, CONSUMER CALLED COUNTLESS DOCTORS TRYING TO FIND SOMEONE WHO COULD HELP HER. THE ONLY DOCTOR WHO WOULD ACCEPT HER CASE WAS AN ONCOLOGIST WHO WAS FAMILIAR WITH DIFFICULT GYNECOLOGICAL CASES. IT WAS DECIDED THAT THE BEST WAY TO REMOVE THE IMPLANTS WOULD BE A TOTAL HYSTERECTOMY WITH A BILATERAL SALPINGECTOMY AND THEY WOULD SEARCH FOR THE MIGRATED IMPLANT DURING SURGERY. THAT WAS NOT NECESSARY HOWEVER AS IT WAS DISCOVERED DURING SURGERY THAT INDEED BOTH IMPLANTS HAD MIGRATED BY THAT TIME AND WERE PERFORATING HER UTERUS. ACCORDING TO REPORTER, BOTH ESSURE IMPLANTS WERE STICKING THROUGH HER UTERUS AND STATED THAT DEVICE HAD MIGRATED AND HAD IMPALED HER. IN ADDITION, CONSUMER REPORTED THAT IF SHE HAD KNOWN THE TRUTH ABOUT MIGRATION, ABOUT THE MATERIAL THE DEVICE WAS MADE OF, THAT IT WOULD FOREVER CHANGE HER LIFE AND TAKE AWAY A YEAR OF HER LIFE, WHERE SHE HAD TO SIT AND WATCH EVERYTHING AND EVERYONE AROUND HER WHILE LIVING WITH DEBILITATING PAIN, OR THAT IT WOULD KILL HER SEXUAL DESIRE AND CAUSE PROBLEMS WITH HER HUSBAND; SHE WOULD NOT HAVE GOTTEN THE DEVICE. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE PROCEDURE WAS NOT QUICK AND EASY. ONE IMPLANT BROKE DURING IMPLANTATION AND HAD TO BE REPLACED BY ANOTHER ONE. SHE HAD PAIN AMONG OTHER NON-SERIOUS EVENTS QUICKLY AFTER HAVING ESSURE IMPLANTED. APPROXIMATELY 6 MONTHS AFTER ESSURE INSERTION, SHE HAD A HYSTEROSALPINGOGRAM HSG TEST PERFORMED IT WAS DISCOVERED THAT ONE IMPLANT HAD MIGRATED AND WAS IN HER ABDOMINAL CAVITY. SHE DECIDED TO HAVE ESSURE REMOVED AND DURING SURGERY IT WAS NOTICED THAT BOTH IMPLANTS HAD MIGRATED BY THAT TIME AND WERE PERFORATING HER UTERUS (INTERPRETED AS UTERINE PERFORATION). THE UTERINE PERFORATION IS SERIOUS DUE TO REQUIRED INTERVENTION WHILE THE DEVICE BREAKAGE IS NON-SERIOUS. THE UTERINE PERFORATION IS LISTED WHILE THE BREAKAGE DURING INSERTION IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS, THE COMPATIBLE TEMPORAL RELATIONSHIP AND FOR DEVICE BREAKAGE AND ALSO THE FACT THAT THE PROCEDURE WAS NOT EASY AND NOT QUICK, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL

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WAS REQUIRED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01065	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 8/7/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0766, AWARENESS DATE 28-AUG-2015). IT REFERS TO A FEMALE CONSUMER ON UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT SHE EXPERIENCED CHRONIC PELVIC PAIN, CHRONIC BACK PAIN, SHOOTING PAINS IN TUBES, LACK OF LIBIDO, BRAIN FOG AND JOINT ISSUES. ON (B)(6)2015, SHE HAD A HYSTERECTOMY AT (B)(6) (UTERUS, TUBES, CERVIX AND DEVICES WERE REMOVED). IMMEDIATELY, ALL HER ISSUES DISAPPEARED. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY

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CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN. SHE UNDERWENT A HYSTERECTOMY WITH ESSURE REMOVAL ON AN UNSPECIFIED TIME AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT, LACK OF A PLAUSIBLE ALTERNATIVE EXPLANATION AND CONSIDERING THAT THE EVENT RESOLVED AFTER HYSTERECTOMY AND ESSURE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY AND ESSURE REMOVAL). SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 23-OCT-2015: CONSUMER WAS IMPLANTED WITH ESSURE IN (B)(6) 2013. ALMOST IMMEDIATELY, SHE BEGAN HAVING CHRONIC PELVIC AND LOWER BACK PAIN, HER LIBIDO COMPLETELY DISAPPEARED AND SHE HAD JOINT ISSUES AND PRETTY BAD BRAIN FOG (PREVIOUSLY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01066	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0735-0814, AWARENESS DATE 28-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. ON AN UNSPECIFIED SHE STARTED EXPERIENCING EXCESSIVE BLEEDING, BLOATING, BLURRED VISION, AND HEADACHES. SHE WOULD BE GETTING HYSTERECTOMY ON (B)(6) 2015. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE BLEEDING. APPROXIMATELY 7 YEARS AFTER ESSURE INSERTION, SHE HAS A PLANNED HYSTERECTOMY. THE EXCESSIVE BLEEDING, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO PLANNED REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT THE BLEEDING STARTED DURING ESSURE THERAPY, THAT NO ALTERNATIVE EXPLANATION WAS PROVIDED, A CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01067	BAYER HEALTHCARE LLC	9/23/2015	9/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2012
Explant Date (E7): 8/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0876, AWARENESS DATE 27-AUG-2015). IT REFERS FEMALE CONSUMER OF UNSPECIFIED DATE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. SHE RECEIVED ESSURE IN (B)(6) 2012 AND EXPERIENCED MANY HORRIBLE, PAINFUL SYMPTOMS FROM ESSURE: SEVERE PELVIC PAIN, ABDOMINAL AND BACK PAIN, INSOMNIA, MIGRAINES, DIFFICULTY HEALING FROM BROKEN BONES AND OTHER INJURIES, BRITTLE TEETH, PAINFUL SEX, BLEEDING AFTER SEX, BLOATING, CONSTANT YEAST INFECTIONS, BACTERIAL VAGINOSIS, IRREGULAR AND INCONSISTENT PERIODS TO INCLUDE HEAVY BLEEDING AND MANY MORE SYMPTOMS. SHE HAD A PARTIAL HYSTERECTOMY (LEAVING OVARIES) IN (B)(6) 2014. DUE TO BACTERIA VAGINOSIS AND AID NOT HEAL PROPERTY FROM THE HYSTERECTOMY AND ENDED UP WITH SEVERE SCAR TISSUE SHE HAD TO HAVE A 2ND SURGERY IN (B)(6) 2015. AFTER THE 2 YEARS OF HELL WHILE SHE HAD ESSURE, AFTER THE HYSTERECTOMY, SHE WAS SO HOPEFUL FOR A FULL RECOVERY AND QUALITY OF LIFE, BUT INSTEAD SHE HAS GOTTEN WORSE. SHE STARTED HAVING SVT IN (B)(6) 2014 AND HAD TO UNDERGO HEART ABLATION AROUND (B)(6) 2015. SHE BEGAN HAVING SEVERE NAUSEA, CHEST ABDOMINAL, BACK PAIN AND SEVERE FATIGUE. IN (B)(6) 2015, SHE WAS DIAGNOSED WITH AORTIC INSUFFICIENCY WITH NEARLY 50% REGURGITATION CONFIRMED BY AN ECHO CARDIOGRAM (SHE HAD AN ECHO IN 2010 THAT SHOWED A PERFECT FUNCTIONING AORTIC VALVE). SHE WAS WORKING TO BE SEEN AT THE CLINIC TO HELP DIAGNOSIS OF POSSIBLE AUTOIMMUNE DISEASE AND CHRONIC INFLAMMATION CAUSED BY THE ESSURE COILS. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER

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REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PELVIC PAIN, BACTERIA VAGINOSIS, DIFFICULTY HEALING FROM BROKEN BONES AND OTHER INJURIES, POSSIBLE AUTOIMMUNE DISEASE AND SEVERE SCAR TISSUE. ALL THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. SEVERE PELVIC PAIN IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE UNLISTED. IN THIS CASE, CONSUMER UNDERWENT A PARTIAL HYSTERECTOMY ABOUT 2 YEARS AFTER ESSURE INSERTION. CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP BETWEEN SEVERE PELVIC PAIN AND SUSPECT INSERT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THE OCCURRENCE OF SCAR TISSUE COULD BE CONSIDERED AS A CONSEQUENCE OF HYSTERECTOMY PROCEDURE. WITH REGARDS TO THE OTHER EVENTS, CONSIDERING THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056368	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 4/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS ON (B)(6). THEY COVERED ALL COSTS OF THE PROCEDURE. I STARTED NOTICING CRAMPS, HEADACHES VERY EARLY AFTER INSERTION. IN THE LAST YEAR, I'VE EXPERIENCED FATIGUE, WEIGHT GAIN, NUMEROUS RUPTURED CYSTS, FORGETFULNESS, DIZZY SPELLS, CRAMPS, PELVIC PAIN AND VARICOSE VEINS ON MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056369	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 8/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ONGOING HORRIBLE BLEEDING AFTER HAVING ESSURE IN SINCE 2011. IN THIS PARTICULAR EVENT I BLEED FOR ALMOST 3 MONTHS AND HAD NUMEROUS OF DOCTOR VISITS. I ALSO HAVE ABNORMAL BLOAT AND PAINS THAT ARE CRIPPLING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056370	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 4/9/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PLACED IN 2004. SINCE THEN HAVE SUFFERED FROM MONTHLY SHARP STABBING PAIN ON LEFT SIDE NEAR OVARIES, CONSISTENT BLOATING, MIGRAINES, BRAIN FOG, BACK PAIN, BOWEL ISSUES, CONSTIPATION, BACTERIAL VAGINOSIS, PAINFUL MENSES / DEBILITATING CRAMPS, CONTINUAL ITCHING IN VAGINAL AREA, MID-SECTION RASHES, SENSITIVE/PRICKLING SKIN, INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056371	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 11/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CONSULTED A DR. FOR THE ONSET OF SEVERE JOINT PAIN AND WEIGHT GAIN WHICH HAS CONTINUED TO THIS DATE. I HAVE ALSO EXPERIENCED ABDOMINAL PAIN AND ABNORMAL DISCHARGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056372	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) 2009. YES THE DEVICE WAS PROVIDED BY MY INSURER. MY FIRST SIDE EFFECT WAS HEAVY BLEEDING AND BLOOD CLOTS WHICH HAS PROGRESSED TO INCLUDE UNPREDICTABLE PERIODS THAT LAST 4-14 DAYS, EXTREMELY PAINFUL INTERCOURSE ON 10 OCCASIONS (NOT ABLE TO WALK AFTER AND LEGS NUMB), SEVERE DAILY WRAPAROUND PAIN IN THE OVARY AREA, SEVERE CONSTANT CRAMPING IN MY UTERUS, EXCESSIVE BLOATING, SEVERE FATIGUE, SWELLING/ LACK OF FEELING OF JOINTS IN KNEES, HANDS AND FEET, HIVES, HAIR LOSS, FIBROMYALGIA (DIAGNOSED 2013).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056373	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 10/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE HEADACHES STARTED A WEEK AFTER I GOT IT IN. I OFTEN FEEL LAZY, NO ENERGY AT ALL. I HAVE BEEN SPOTTING FOR 3 MONTHS NOW AND I WENT TO THE DOCTOR 3 TIMES ALREADY. FIRST TOLD ME I HAD TO GET BACK ON THE PILL WHICH MADE NO SENSE TO ME BECAUSE THAT IS WHY I GOT THE ESSURE IN SO I WOULDN'T HAVE TO DEAL WITH ANY OTHER BIRTH CONTROL. SECOND DOCTOR TOLD ME I HAD DEPRESSION AND THE 3RD JUST PRESCRIBED ME MEDICINE FOR MY MIGRAINES WHICH DID NOT HELP ME!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056374	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WOULD LIKE TO ADD ALSO, THAT I DID START HAVING PAIN IN MY RIGHT SIDE WELL BEFORE COMING OFF BIRTH CONTROL PILLS. IT WAS ONLY WORSE AFTER COMING OFF THEM. I AM CONCERNED THAT THE COIL IN MY RIGHT TUBE IS MISPLACED AND HAS POSSIBLY MIGRATED. I DO HAVE AN ULTRASOUND ON THE (B)(6). AT THAT TIME I WILL FOLLOW UP ONCE AGAIN ON HERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056375	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT ESSURE IN (B)(6) 2013. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THE EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED (B)(6) 2014. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. HEAVY BLEEDING DURING MENSES, ABNORMAL MENSES, ANXIETY, DIZZINESS, FATIGUE, NAUSEA, WEIGHT GAIN, BOWL ISSUES, SWELLING OF FEET, JOINT PAIN, MEMORY ISSUES, SHARP PAINS IN ABDOMEN, FREQUENT URINATION, HEADACHES, MOOD DISORDER, SKIN IRRITATION/ITCHING, PELVIC PRESSURE, PAIN AND STABBING, VAGINAL BURNING, ABNORMAL VAGINAL DISCHARGE, ABDOMINAL SPASMS/TWITCHING FLUTTERING AND CRAMPING. I HAVE NOT BEEN SEEN BY A DOCTOR. THE DEVICE IS STILL INSIDE OF ME. THE DEVICE WAS NOT RETURNED TO BAYER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056376	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLEEDING, PELVIC PAIN, BACK PAIN, HEADACHES, PAIN DURING INTERCOURSE AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056377	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 7/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS B94874. (B)(4). THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2014. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. PAIN ON RIGHT SIDE NEAR COIL PLACEMENT. NAUSEA, MEMORY ISSUES, HEAVY AND LONG PERIODS, PAIN IN LEGS AND JOINTS, TWITCHING IN RIGHT HAND, DIZZINESS, HEADACHES, INSOMNIA, FATIGUE, NIGHT SWEATS/HOT FLASHES, VAGINAL DISCHARGE, SEVERE MOOD SWINGS, SUDDEN WEIGHT LOSS, NICKEL ALLERGY AFTER PROCEDURE, WORSENING DEPRESSION AND ANXIETY. I WILL BE SEEING A DOCTOR ON (B)(6) 2015. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056378	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 9/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOR THE LAST 3 YEARS, I BEEN SUFFERING OF WEIGHT GAIN ABOUT 45 POUNDS. EXTREMELY BACK PAIN, DEPRESSION. I STOP WORKING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056379	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 9/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM THE DAY I HAD THE DEVICE PLACED I HAD PROBLEMS WITH BLEEDING AND MOOD SWINGS. I BLED FOR 9 MONTHS STRAIGHT. I HAVE A COMPLETE LOSS OF LIBIDO, DEPRESSION, HAIR LOSS, BLOATING, WEIGHT GAIN, ANXIETY, AND ABDOMINAL PAIN (UPPER AND LOWER). FEELS LIKE BEING STABBED REPEATEDLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056380	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 9/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD THE ESSURE SINCE (B)(6) 2013 AND BLAMED MOST OF THE RELATED SYMPTOMS ON OTHER THINGS BUT IT ALL SEEMS TO BE LINKED TO ESSURE. HEADACHES, SORE JOINTS, HORRENDOUS MENSTRUAL CRAMPS, HEAVY MENSTRUAL BLEEDING, TAMPONS HURT, SEX HURTS, BAD TOOTH DECAY (NO HISTORY PRIOR), NO MORE REGULAR PERIODS, BLURRED VISION/DIZZY SPELLS, SERIOUS BLOATING NOT RELATED TO MENSTRUAL, WEIGHT GAIN... ALL OF THESE THINGS HAVE NO PRIORS TO ESSURE. ESSURE WAS PROVIDED BY INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056381	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAINS IN LOWER ABDOMEN, NUMEROUS UTIS, BLADDER INFECTIONS, EXTREME FATIGUE, MULTIPLE BV, HEAVY BLEEDING DURING AND AFTER INTERCOURSE, DEPRESSION, ANXIETY, FOGGINESS IN THOUGHTS, ALWAYS SICK WITH FLU LIKE SYMPTOMS, BREAST TENDERNESS, ACHES AND PAINS IN JOINTS AND MUSCLES, LOSS OF SLEEP, BACK PAINS, VAGINAL ODOR AND SWELLING, YEAST INFECTIONS, HIGH WHITE BLOOD CELLS AND BLOOD IN URINE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056382	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 1/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE WAS PROVIDED BY INSURER. MY PERIODS STARTING HAPPENING EVERY 2 WEEKS AND GOT WORSE WHEN I EXERCISE. I WAS SO HEAVY AT TIMES I WOULD BLEED THRU A TAMPON AN HOUR FOR THE FIRST FEW DAYS. I AM CONSTANTLY TIRED AND WHEN I WENT TO MY DOCTOR IN (B)(6) SHE SAID I WAS LOW IN VITAMIN D WHICH IS WEIRD BECAUSE I AM IN THE SUN WITH NO SUNSCREEN A COUPLE HOURS A DAY DUE TO THE FACT THAT I TRAIN FOR TRIATHLONS. ALONG WITH THIS I HAVE GAINED ABOUT (B)(6) POUND SINCE I HAVE HAD ENSURE PUT IN (B)(6) 2013. I ALSO HAVE BRAIN FOG I HAVE HAD BLOOD WORK DONE AND MY THYROID CHECK AND IT ALL CAME BACK NORMAL. I HAVE STARTED HAVING SHARP STABBING PAINS WHEN I GET UP SOMETIMES IT MAKES ME STOP IN MY TRACKS. I HAVE LOWER BACK PAIN AND I HAVE HAD MY BACK X-RAYED AND THERE IS NOTHING SHOWING UP TO INDICATE THERE IS SOMETHING WRONG WITH MY BACK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056383	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PELVIC PAIN, DISCHARGE, HOT FLASHES, PAINFUL OVULATION, SPOTTING AFTER SEX, INCONTINENCE, FREQUENT URINATION, BREAST PAIN, SPASMS IN PELVIC AREA (SOMETHING MOVING), 70 POUND WEIGHT GAIN, PANIC ATTACKS AT NIGHT, SEVERE BLOATING, MOOD SWINGS, TINGLING IN BODY/HANDS, BOWEL ISSUES, HAIR GROWTH, INSOMNIA, THYROID ISSUES, VISION BLURRED(BLOOD WORK COMPLETED), DRY SKIN ADRENAL PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056384	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 3/31/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, INCREASING IN FREQUENCY, INTENSITY AND DURATION; WEIGHT GAIN; INCREASINGLY LONGER, HEAVIER AND MORE FREQUENT PERIODS; JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056385	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 7/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SUDDEN ONSET OF JOINT PAIN, HORRIBLE PAIN IN PELVIS AND HIP. COMPLETE LOSS OF ENERGY. PAINFUL SEXUAL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056386	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON MEDICAID WHEN IT WAS PUT IN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056387	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 9/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONTINUOUS BLEEDING - NOT A PERIOD. AND HAS BE ONGOING FOR 14 DAYS OUT OF THE BLUE. HAD A DR. VISIT TODAY, SHE REFERRED ME TO A GYNO - WE'LL SEE WHAT THAT LEADS TO. MY DEVISE - I WAS PRESSURED INTO GETTING ESSURE BY MY DOCTOR INSTEAD OF A TUBAL STERILIZATION. THE DAY OF THE PROCEDURE I WAS ADMITTED TO THE ER. I HAD INTENSE VAGINAL BLEEDING, SO MUCH THAT I NEEDED 2 BAGS OF PLATELETS I HAD (B)(6) AT THE TIME OF THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056388	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 4/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE NEW OBGYN ORDERED AN ULTRA SOUND, BLOOD WORK AND PAP SMEAR. MY VITAMIN D IS EXTREMELY LOW, THE PERSON THAT PERFORMED THE ULTRA SOUND JUST KEPT STARING AT THE SCREEN. WHEN I ASKED WHAT SHE SAW SHE JUST SAID, "I'VE NEVER SEEN COULD BEFORE." SOMETHING TELLS ME THERE'S MORE TO IT. THE PAP CAME BACK INDICATING I NEED TO DISCUSS THE RESULTS WITH MY DOCTOR. THAT WILL HAPPEN IN TWO DAYS. THE PAIN IN MY LEFT SIDE IS BOTHERING ME EVEN MORE THAN BEFORE AND I'M EXHAUSTED 24/7. MY NEW DOC HAS REFUSED TO DO THE ESSURE PROCEDURE ON PATIENTS. OTHERS IN HER PRACTICE WILL...SHE WON'T. SHE DIDN'T EVEN ARGUE WITH ME WHEN I TOLD HER THE SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056389	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 9/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD TO HAVE SEVERAL THROAT ULTRASOUNDS DUE TO RANDOM GRAVES DISEASE DIAGNOSIS. I BLOAT EVERYDAY. I'M IN PAIN EVERY DAY. I'M SO TIRED I CAN'T EVEN GET UP ON TIME TO GET MY KIDS ON THE BUS ON TIME. AND I'M ALLERGIC TO NICKEL WHICH I WAS NOT TOLD AT TIME OF PLACEMENT THAT IT WAS MADE OF NICKEL. (B)(6) PAID FOR MY PROCEDURE. I WANT THESE COILS OUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056390	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 8/16/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEFT COIL WAS BROKE AND RIGHT COIL MIGRATED INTO UTERUS SHOWN ON HSG 5 MONTHS AFTER PLACEMENT (B)(6) 2008. ABDOMINAL PAIN, HEAVY BLEEDING THAT LASTED FOR WEEKS AT A TIME, BLEED MORE IN A MONTH THAN I DIDN'T BLEED, CONSTANT MIGRAINE HEADACHES, EXTREME FATIGUE, ABDOMINAL SWELLING, WEIGHT GAIN, UNEXPLAINABLE RASHES, ANXIETY AND DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056391	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 6/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE WAS NOT PROVIDED BY INSURER BUT WAS COVERED EXCEPT FOR OOP COPAY...SYMPTOMS INCLUDE BUT ARE NOT LIMITED TO PAINFUL PERIODS, OVARIAN CYSTS, ENDOMETRIOSIS, LARGE CLOTS DURING MENSES, CHRONIC FATIGUE, INSOMNIA, JOINT PAIN, HERNIATED CERVICAL DISC, BROKEN TEETH, ACNE, MOOD SWINGS, HAIR LOSS, WEIGHT GAIN, HYPOTHYROIDISM, FLOATERS IN MY VISION ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056392	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 1/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HEAVY PERIODS PAIN IN MY LEFT SIDE MIGRAINES TOOTH LOSS HAIR LOSS MEMORY LOSS AND BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056393	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 9/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY MENSTRUAL CYCLE IS HORRIBLE NEVER KNOW WHEN IM GONNA HAVE ONE AND I BLEED AND CLOT TERRIBLY! AFTER AND DURING INTERCOURSE I HAVE PAIN IN MY ABDOMEN AND LOWER BACK PAIN! ALSO I HAVE A MIGRAINES PROBABLY 4 TIMES A MONTH WHEN BEFORE I COULD NOT TELL YOU HOW A MIGRAINE FELT CAUSE I NEVER HAD THEM!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056394	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 11/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HIVES AND RASH AND DEPRESSION AND BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056395	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 6/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVER CRAMPING MOST ALL THE TIME ALONG WITH SHARP STABBING PAIN TO MY PELVIC AREA. I HAVE ABNORMAL PERIODS MOST MONTHS I HAVE 2 PERIODS A MONTH. SOME MOTHS I HAVE NO PERIODS. I CONSTANTLY HAVE A DISCHARGE THAT HAS NO ODOR. I HAVE HOT FLASHES AND NIGHT SWEATS. OVULATION IS A NIGHTMARE THE PAIN IS UNBEARABLE. I CAN'T HAVE SEX WITH MY HUBBY BECAUSE INTERCOURSE IS SO PAINFUL. I HAVE PAINFUL PERIODS. I BLEED IN BETWEEN PERIODS. I HAVE FREQUENT URINATION. I HAVE STINGING/ STABBING PAIN AT MY VAGINAL ENTRANCE. ALL OVER BODY ACHES. BACK, JOINT, LEG, BREAST, SPINE, HIP PAIN. BREAST PAIN AND TENDERNESS. GAS, NAUSEA, AND CONSTIPATION. SEVER BLOATING. I HAVE HEADACHES AND DIZZINESS. I HAVE PANIC/ANXIETY ATTACKS. I HAVE DEPRESSION AND MOOD SWINGS. I HAVE VITAMIN D AND B12 DEFICIENCIES. I HAVE NERVE PAIN. I FORGET THINGS. I HAVE HAIR LOSS. I HAVE DENTAL PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056396	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 5/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ESSURE PROCEDURE WAS COVERED BY (B)(6), AND WAS PLACED ON (B)(6) 2012. THE PROCEDURE WAS EXTREMELY PAINFUL, AS WAS THE HSG CONFIRMATION TEST, AND BOTH WERE FOLLOWED BY SEVERE CRAMPING FOR SEVERAL DAYS. I WAS HEALTHY WHEN I GOT ESSURE. SINCE THEN, I HAVE DEVELOPED MANY HEALTH PROBLEMS, MOST OF WHICH HAVE NOT BEEN OFFICIALLY DIAGNOSED BECAUSE I NO LONGER HAVE HEALTH INSURANCE, AND CAN'T AFFORD TESTING. MY DIAGNOSED PROBLEMS ARE PSORIATIC ARTHRITIS, PSORIASIS, SEVERE PERSISTENT ASTHMA, BURSITIS, VARICOSE VEIN IN LEG (WITH COMPLICATIONS), GERD, DEPRESSION. SYMPTOMS THAT I HAVE NOT BEEN ABLE TO GET DIAGNOSED FOR INCLUDE THE FOLLOWING: IRREGULAR, PAINFUL, HEAVY PERIODS WITH CLOTTING, HEAVY DISCHARGE , PAINFUL OVULATION, SEVERE DAILY BLOATING (PAINFUL, AND NOT HELPED BY DIET CHANGE), DAILY, SEVERE DIGESTIVE PROBLEMS (COLONOSCOPY RECOMMENDED), CYST-LIKE ACNE ON FACE, NECK, AND BEHIND MY EARS, SHARP PELVIC/ABDOMINAL PAINS, PAIN DURING INTERCOURSE, DECREASED LIBIDO, SWELLING IN LEGS, FEET AND ANKLES, CRAMPING AND PAIN IN LEGS AND FEET, MEMORY PROBLEMS (FORGETTING WORDS OR WHAT I'M DOING), BACK AND NECK PAIN, EXTREME RESPONSE TO ALLERGENS, SKIN RASHES AND ITCHING, BAD TASTE IN MOUTH, ANXIETY, PANIC ATTACKS, MOOD SWINGS/IRRITABILITY, BREAKING TEETH, FREQUENT URINATION, DIZZY SPELLS, HEART FLUTTERS, HEADACHES, EXTREME WEIGHT FLUCTUATIONS WITHOUT DIET/EXERCISE CHANGE, BLOOD LABS INDICATE POSSIBLE PROBLEMS WITH THYROID, LIVER, AND KIDNEYS. BEFORE ESSURE, I TOOK NO MEDICATION. SINCE ESSURE, I HAVE BEEN PRESCRIBED SIX DAILY MEDICATIONS, STEROID SHOTS, SHORT-TERM ORAL STEROIDS, AND MULTIPLE ROUNDS OF STRONG ANTIBIOTICS (FOR LUNG INFECTIONS). I ALSO HAVE TO TAKE A DAILY ALLERGY MEDICATION, LARGE DOSES OF CERTAIN VITAMINS, AND ADDITIONAL SUPPLEMENTS. EVEN WITH ALL OF THIS, I STRUGGLE EVERY DAY WITH MY SYMPTOMS.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056397	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 5/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ONE COIL THAT IS HALF IN MY TUBE AND HALF IN THE WALL OF MY UTERUS. I HAVE SERVIER CRAMPING SOME TIMES SO BAD I CAN'T WALK. VERY BAD MENSTRUAL CYCLES, HEADACHES THAT TAKE FOREVER TO GO AWAY, LOWER BACK PAIN, NUMBNESS IN HANDS AND FEET, VERY BAD ITCHING ON LEGS SOME TIMES SO BAD I LEAVE SCANS FROM ITCHING SO HARD. I DO HAVE A MILD NICKEL ALLERGY AND EVEN TOLD MY DR ABOUT IT BEFORE PLACEMENT OF ESSURE AND SHE SAID IT WOULDN'T AFFECT ME AT ALL. ALSO AFTER MY PLACEMENT IN (B)(6) OF 2012 I BLED FOR 3 MONTHS AFTER SO I WAS UNABLE TO GET THE CONFORMATION TEST DONE DUE TO INSURANCE RUNNING OUT BEFORE I STOPPED BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056398	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 8/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT HAS BEEN A YEAR SINCE I HAD THE ESSURE DONE I HAVE NEVER HAD HIP PAIN OR MY LEGS HURTING NEVER FELT LIGHT HEAD I WOULD GET HEADACHS ONCE IN A BLUE MOON NOW I GET THEM ALL DAY LONG I GET STABBING PAIN WHERE I GOT THE ESSURE AT MY BACK HURTS ALL THE TIME IT HURTS TO WALK I HAVE NOT HAD SEX FOR 2 YEARS AND I LOOK PREGNANT I PRAY THAT I CAN GET THESE OUT IM ONLY (B)(6) NEVER IN MY LIFE WOULD I THINK I WOULD HAVE TO LIVE IN PAIN ALL THE TIME I CANT DO NOTHING WITH MY KIDS I FEEL LIKE IM LETTING THEM DOWN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056399	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 4/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS PELVIS PAIN BLOATING A RASH ON MY LEG, PAIN IN BELLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056400	BAYER	9/23/2015	9/23/2015

Event Information:

Event Date (B3): 8/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT AND HEAVY BLEEDING FOR 8 MONTHS SOLID AFTER IMPLANTING ESSURE. MAYBE ONE DAY PER WEEK NOT EXPERIENCING HEAVY FLOW. DEVICE WAS PROVIDED BY MY OB/GYN IN THEIR OFFICE. CURRENTLY, IF I WORK OUT AT ALL HEAVY BLEEDING STARTS ALMOST IMMEDIATELY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056633		9/23/2015	9/30/2015

Event Information:

Event Date (B3): 5/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2014, I HAD THE ESSURE PROCEDURE AT (B)(6). A FEW MONTHS LATER, I STARTED FEELING FATIGUE, PAIN AND SLEEPLESSNESS. TO DATE, THOSE PROBLEMS HAVE NOT GONE AWAY. LIKE I ALWAYS TELL MY HUSBAND, "I DON'T FEEL LIKE MYSELF". SOMETHING IS DIFFERENT AND I ATTRIBUTE IT TO THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056634	BAYER	9/23/2015	9/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THANK YOU FOR TAKING THE TIME TO LISTEN TO MYSELF, AND EVERY OTHER WOMAN WHO'S LIVES HAVE BEEN TURNED UPSIDE DOWN AFTER HAVING THE ESSURE PROCEDURE. I DECIDED AFTER MY SECOND BORN THAT MY FAMILY WAS COMPLETE. MY HUSBAND AND I SAT DOWN AND DISCUSSED OUR OPTIONS FOR QUITE A FEW MONTHS. WHEN I FINALLY DECIDED TO GO THROUGH WITH A PERMANENT STERILIZATION, I MADE THE APPOINTMENT. I ORIGINALLY WENT IN TO TALK ABOUT A TUBAL LIGATION, HOWEVER, MY DOCTOR TOLD ME THAT THERE WAS THIS NEW PERMANENT PROCEDURE CALLED ESSURE. AT THE TIME, IT WAS AN OUTPATIENT PROCEDURE. MY DOCTOR SPOKE VERY HIGHLY OF THIS NEW PROCEDURE AND INSISTED IT WAS A SAFE AND EFFECTIVE PROCEDURE WITH LITTLE TO NO SIDE EFFECTS. SO, WE DECIDED TO GO THROUGH WITH AN ESSURE PROCEDURE ON DOCTORS RECOMMENDATION. WE MADE THE APPOINTMENT. I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2008. AS I LAID IN THE HOSPITAL BED BEING PREPPED FOR SURGERY, I SOBBED. THIS WAS A HUGH DECISION FOR ME. THIS CLOSED A CHAPTER IN MY LIFE. BUT I WAS AT PEACE WITH THE THOUGHTS THAT THIS WOULD BE A GOOD DECISION AND WE COULD ENJOY THE LIFE AND FAMILY WE HAVE CREATED. LITTLE DID I KNOW, I WAS ABOUT TO TURN MY LIFE UPSIDE DOWN. AFTER WAKING UP FROM THE PROCEDURE, I WAS ALREADY EXPERIENCING CRAMPING. THE DOCTOR TOLD ME IT WAS NORMAL FOR A COUPLE DAYS OF MILD CRAMPING. HOWEVER, HE DID NOT LISTEN TO ME WHILE I WAS TELLING HIM IT WAS SEVERE CRAMPING. I CALLED THE OFFICE A COUPLE DAYS LATER TO TELL THEM OF THE CRAMPING. THEY SAID IT SHOULDN'T BE THAT BAD AND MAYBE SOMETHING ELSE WAS GOING ON. OVER THE LAST SEVEN YEARS, I HAVE GONE TO DOCTORS AND TOLD THEM OF MY SYMPTOMS OF SEVERE CRAMPING, HEAVY PERIODS, TERRIBLE PRESSURE DURING MY PERIOD AS IF A BOWLING BALL IS DOWN THERE, SEVERE CRAMPING DURING OVULATION, SHARP PAINS DURING OVULATION, AND NAUSEA THAT LEADS TO ALMOST FAINTING, FEELING SHAKY

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AND HAVING LOW BLOOD SUGAR OFTEN, AND REALLY JUST NOT FEELING RIGHT, ETC. I EXPLAINED EACH AND EVERY APPOINTMENT THAT I REALLY BELIEVE ESSURE MAY BE TO BLAME, AS THESE SYMPTOMS ALL CAME UP AFTER HAVING THE ESSURE PROCEDURE DONE. APPOINTMENT AFTER APPOINTMENT NOBODY WOULD LISTEN TO WHAT I WAS SAYING. I WENT FROM DOCTOR TO DOCTOR TRYING TO GET JUST ONE TO LISTEN TO WHAT I WAS SAYING. THEY ALL SAID THE SAME THING, "IT COULD BE YOUR AGE," "YOUR BODY CHANGES THE OLDER YOU GET," "IT'S NOT ESSURE!," AND ANYTIME I BRING UP THE ESSURE, THEY REPEATEDLY TELL ME "ESSURE IS PERMANENT, SO IT CANNOT BE REMOVED!" I HAVE BEEN IN PAIN FOR CLOSE TO 8 YEARS NOW! I HAVE SUFFERED GREATLY AFTER HAVING THIS PROCEDURE FROM MY OWN PERSONAL PHYSICAL HEALTH, TO MY MENTAL HEALTH, TO MY INTIMATE RELATIONSHIP WITH MY HUSBAND. THE PAIN AND SUFFERING FROM THIS MAJOR LIFE DECISION IS MORE THAN ANY WOMAN SHOULD EVER HAVE TO GO THROUGH. FOR MYSELF, THIS WAS ONE OF THE HARDEST DECISIONS (PERMANENT STERILIZATION) I HAVE EVER MADE IN MY ENTIRE LIFE. I HAVE SUFFERED ENOUGH. IT IS MY GREAT HOPE THAT THIS WILL BE MADE RIGHT TO MYSELF, AND TO ALL OF THE OTHER WOMEN OUT THERE WHO ARE ALL GOING THROUGH THIS. THIS PROCEDURE IN ITSELF WAS VERY PAINFUL AND EVEN CAUSED BLEEDING. DOCTOR DISREGARDED MY COMPLAINT AND CARRIED ON WITH THE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056644	BAYER	9/23/2015	9/30/2015

Event Information:

Event Date (B3): 10/24/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 12533513

Single Use: *
Implant Date (E6): 10/24/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE WAS PLACED (B)(6) 2012. DURING PROCEDURE, FALLOPIAN TUBE SEIZED. PAIN WAS IMMENSE AFTER PROCEDURE AND MADE COMMENTS TO DOCTOR, SAID WAS NORMAL. STILL, 3 YEARS LATER HAVE PAIN ON SAME SIDE AS SEIZURE, WEIGHT GAIN, PAIN INCREASES AFTER ANY PHYSICAL ACTIVITY AND WORSE AT END OF DAY, CONSTANT BLOATING, INCREASE ISSUE WITH CONSTIPATION, HEADACHES (EVERYDAY), DIAGNOSED WITH ADENOMYOSIS, HEAVY MENSES WITH INCREASE IN PAIN AND BLOATING, EXHAUSTION, INCREASED FORGETFULNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056659	BAYER	9/23/2015	9/30/2015

Event Information:

Event Date (B3): 1/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/13/2012
Explant Date (E7): 1/21/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN MY FALLOPIAN TUBES IN 2012. I HAD TO HAVE THEM REMOVED, ALONG WITH MY TUBES, UTERUS AND CERVIX (TOTAL HYSTERECTOMY AND SALPINGECTOMY) IN (B)(6) 2015. DURING THE TIME THEY WERE IMPLANTED, I SUFFERED WITH UNUSUAL SYMPTOMS INCLUDING SEVERE MENSTRUAL PERIODS, BILATERAL ABDOMINAL PAIN , HEADACHES, ANXIETY AND DEPRESSION, WEAKENED TEETH AND GUMS, SKIN CONDITIONS, HAIR LOSS, RAPID WEIGHT GAIN, ABDOMINAL BLOATING, HAND TREMORS, DIGESTIVE ISSUES, CONSTANT VAGINAL INFECTIONS (VIRAL AND BACTERIAL), CONSTANT BACK AND NECK PAIN AND DEGENERATION OF SPINAL DISCS AND FACETS. SINCE THE SURGERY AND REMOVAL, SOME SYMPTOMS HAVE COMPLETELY GONE AWAY AND OTHERS HAVE PERSISTED URINARY ISSUES HAVE ALSO OCCURRED SINCE SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056660	CONCEPTUS, INC.	9/23/2015	9/30/2015

Event Information:

Event Date (B3): 5/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 825626

Single Use: *
Implant Date (E6): 5/10/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SIGNIFICANT AND CHRONIC SIDE EFFECTS INCLUDING SEVERE PAIN DURING OVULATION, EXCESSIVE HEAVY PERIODS WITH INTENSE CRAMPING AND BLOOD CLOTS, MIGRAINES, MEMORY LOSS/FORGETFULNESS, CHRONIC ABDOMINAL BLOAT AND DISTENTION, CHRONIC FATIGUE AND DECREASED ENERGY LEVEL, UNPRECEDENTED DIFFICULTY WITH WEIGHT LOSS/WEIGHT MANAGEMENT, CONSTANT ACHE AND "HEAVY" FEELING IN PELVIC AREA THAT INCREASES WITH ACTIVITY, RIPPING OR PULLING SENSATION IN PELVIC AREA WITH MOVEMENT, ABNORMAL PAP RESULTS, RESTLESS LEGS AND INVOLUNTARY MUSCLE SPASMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056661	BAYER	9/23/2015	9/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE HAS CAUSED ME YEARS FOR PAIN AND HEAVY BLEEDING. FINALLY IT GOT SO BAD THAT DOCTOR PERFORMED ENDOMETRIAL ABLATION, D&C AND OTHER PROCEDURES OVER 6 MONTH PERIOD TO TRY TO CORRECT SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056662	BAYER	9/23/2015	9/30/2015

Event Information:

Event Date (B3): 9/25/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/25/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WERE IMPLANTED (B)(6) 2007, SINCE THEN I HAVE HAD ANOTHER CHILD, PAINFUL SEX, DEPRESSION, MENSTRUATION COMING AT FREE WILL, HEAVY MENSTRUATION, DISCHARGE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01068	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0778, AWARENESS DATE 28-AUG-2015). IT REFERS TO (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. SHE STATED THAT ON (B)(6) 2012 SHE FOUND OUT THAT SHE WAS PREGNANT. AFTER MANY TESTS IT WAS DETERMINED THAT THE PREGNANCY WAS A MISCARRIAGE. SHE HAD SURGERY FOLLOWING THE DIAGNOSIS AND DURING SURGERY, DOCTOR DISCOVERED THAT ONE COIL WAS EMBEDDED IN HER ABDOMINAL WALL. HE PROCEEDED WITH D AND C AND REMOVED THE COIL. ON AN UNSPECIFIED DATE, SHE WENT FOR A CHECKUP AND IT WAS DISCOVERED THAT SHE WAS STILL PREGNANT. SHE HAD TO RECEIVE A MEDICATION THAT WOULD DISSOLVE THE PREGNANCY BECAUSE IT WAS FOUND IN HER FALLOPIAN TUBE. AFTER ALL OF THIS, SHE WAS HAVING VERY BAD REACTIONS WHICH LEAD TO A HYSTERECTOMY AND REMOVAL OF THE SECOND COIL. SHE STATED THAT SHE IS STILL HAVING REACTIONS DUE TO ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON 19-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS AND LACK OF EFFICACY IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS/LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, THIS PREGNANCY WAS A MISCARRIAGE AND SHE WAS SUBMITTED TO A DILATION AND CURETTAGE (D&C). DURING THIS PROCEDURE ONE COIL WAS FOUND EMBEDDED IN HER ABDOMINAL WALL AND REMOVED. LATER, SHE DISCOVERED SHE WAS STILL PREGNANT; PREGNANCY WAS IN HER FALLOPIAN TUBE AND SHE WAS TREATED WITH MEDICATIONS. AN UNSPECIFIED TIME LATER; SHE WAS SUBMITTED TO A HYSTERECTOMY DUE TO BAD REACTIONS WITH THE SECOND ESSURE COIL. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). WHEN A PREGNANCY OCCURS WITH ESSURE, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED ABOUT HSG. CONSUMER STATED ONE COIL WAS EMBEDDED, THIS COULD BE AN ALTERNATIVE EXPLANATION FOR ESSURE CONTRACEPTIVE FAILURE; HOWEVER DISCREPANT INFORMATION WAS RECEIVED (CONSUMER STATED ESSURE WAS REMOVED FROM THE ABDOMINAL WALL VIA D&C; HOWEVER D&C IS AN INTRAUTERINE PROCEDURE WITHOUT VISUALIZATION OF ABDOMINAL WALL) AND THE EXACT EVENT'S MECHANISM WAS UNKNOWN (IF IT OCCURRED BEFORE OR AFTER PREGNANCY ONSET). NEVERTHELESS, CONSIDERING THE ECTOPIC PREGNANCY OCCURRED 3 YEARS AFTER ESSURE INSERTION, CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS/LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01069	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (# FDA-2014-N-0736-0802, AWARENESS DATE 28-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) FOR OVER 2 YEARS (2013). CONSUMER REPORTED THAT SINCE INSERTION SHE EXPERIENCED HIP JOINT PAIN, HEART PALPITATIONS, NUMBNESS IN TOES AND FINGERS, HEAD STABBING PAIN, BRAIN FOG, WEIGHT GAIN, PELVIC PAIN AND ANXIETY. ALSO, AT THE TIME OF REPORT, SHE WAS LATE ON HER PERIOD. ON (B)(6) 2015 SHE WILL HAVE SURGERY TO REMOVE ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS

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NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE INSERTION SHE HAD PELVIC PAIN. APPROXIMATELY TWO YEARS AFTER ESSURE INSERTION, SHE HAS A SCHEDULED HYSTERECTOMY TO REMOVE ESSURE. THE PELVIC PAIN IS SERIOUS DUE TO PLANNED REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN PELVIC PAIN AND ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01070	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/14/2014
Explant Date (E7): 5/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (# FDA-2014-N-0736-0792, AWARENESS DATE 28-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER REPORTED THAT IMMEDIATELY AFTER INSERTION SHE EXPERIENCED CONSTANT STABBING PAIN AND BLEEDING. SHE ALSO HAD HORRIBLE HEADACHES AND STOMACH BLOAT. ON (B)(6) 2015 SHE HAD ESSURE REMOVED AND HAD IMMEDIATE RELIEF, SHE COULD DO THINGS AGAIN WITHOUT WORRYING IF SHE WOULD START BLEEDING. SHE ENDED UP HAVING A PERFORATED TUBE, ENDOMETRIOSIS AND OVARIAN CYST. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A PERFORATED TUBE (INTERPRETED AS FALLOPIAN TUBE PERFORATION) AND BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE HAD ESSURE REMOVED 9 MONTHS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THIS PERFORATION WERE NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THE EVENT PERFORATED TUBE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ALSO, AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENT BLEEDING, AND CONSIDERING THAT THIS EVENT RESOLVED AFTER ESSURE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. SINCE ESSURE REMOVAL WAS REPORTED, THIS CASE WAS REGARDED AS INCIDENT (REQUIRED INTERVENTION IMPLIED). SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01071	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2009
Explant Date (E7): 1/27/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0908, AWARENESS DATE 28-AUG-2015). IT REFERS FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. WHEN SHE WENT IN FOR THE PROCEDURE, SHE WAS TOLD BY THE DOCTOR THAT ONE OF THE COILS BROKE DURING IMPLANTATION AND THAT THE BROKEN PIECE COULD NOT BE FOUND. ABOUT A YEAR LATER, SHE STARTED NOTICING SOME MINOR STABBING PAIN IN HER SIDE AND WHEN SHE CONTACTED THE DOCTOR'S OFFICE SHE WAS TOLD THAT IT WAS NORMAL AS IT WAS MORE THAN LIKELY JUST HER BODY ABSORBING THE EGGS BACK INTO HER BODY DURING THE TIME OF HER NORMAL MENSTRUAL CYCLE. STARTING IN 2011, THE PAINS STARTED TO GET MORE AND MORE INTENSE AND IN SOME CASES CRIPPLING, CAUSING HER TO DOUBLE OVER IN PAIN. SHE WENT TO SEVERAL DOCTORS WHO'S TOLD HER THAT SHE WAS CRAZY BECAUSE ALL OF THE WOMAN THAT THEY HAD IMPLANTED NEVER COMPLAINED OF ANY ISSUES SHE DEALT WITH THE PAIN FOR MANY YEARS. HEADACHES, SEVERE STABBING PAINS, BACK PAIN, HIP PAIN, LACK OF ENERGY AND MANY OTHER ISSUES INCLUDING HAIR LOSS AND SEVERE DRY SKIN. SHE WAS ALSO LOST OUT ON A SEXUAL RELATIONSHIP WITH HER HUSBAND DUE TO THE SEVERITY OF THE PAIN THAT SHE WAS IN. ON (B)(6) 2015, LAPAROSCOPY WITH SALPINGECTOMY WAS DONE AND 7 MONTHS AFTER, SHE FELT LIKE PRIOR TO HAVING ESSURE IMPLANTED. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE OF THE COILS BROKE DURING IMPLANTATION. THE BROKEN PIECE COULD NOT BE FOUND. LATER, SHE EXPERIENCED STABBING PAIN IN HER SIDE AND WAS SUBMITTED TO A SALPINGECTOMY APPROXIMATELY 5 YEARS AFTER DEVICE PLACEMENT. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION (PAIN) AND PRODUCT TECHNICAL ANALYSIS (DEVICE BREAKAGE). AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. ALSO, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED; MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF THE EVENTS IS UNKNOWN; GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (SALPINGECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION IDENTIFIED ON 07-OCT-2015 FROM CONSUMER'S HUSBAND THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING THAT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01072	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1011, AWARENESS DATE 26-AUG-2015). CASE WAS RECEIVED IN UNITED STATES ON 28-AUG-2015 AND REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. ADDITIONAL INFORMATION RECEIVED ON 20-SEP-2015 (PTC INVESTIGATION RESULT). CONSUMER REPORTED THAT SHE HAD THE PROCEDURE IN 2012 AND, AFTER COUNTLESS PROBLEMS, WEIGHT GAIN, HAIR LOSS, ANXIETY, PAIN AND 2 CYSTS; SHE JUST HAD A HYSTERECTOMY. IN ADDITION, REPORTER INFORMED THAT HER RIGHT COIL DISAPPEARED AND HER DOCTOR FOUND IT AND SAID SHE WAS LUCKY THAT SHE DID NOT GET PREGNANT. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT RIGHT COIL DISAPPEARED (INTERPRETED AS DEVICE DISLOCATION). A HYSTERECTOMY WAS PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01073	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2011
Explant Date (E7): 7/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1012, AWARENESS DATE 28-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. CONSUMER REPORTED THAT SEVERE PROBLEMS BEGAN ALMOST IMMEDIATELY, INCLUDING FATIGUE, MIGRAINE HEADACHES, SEVERE PELVIC PAIN, SEVERE BACK PAIN, FORGETFULNESS, VITAMIN D DEFICIENCY, HIP PAIN, UNPREDICTABLE / IRREGULAR AND VERY HEAVY MENSTRUAL CYCLES SOME MONTHS AND OTHER MONTHS NO CYCLE AT ALL, DEPRESSION AND ANXIETY. ON (B)(6) 2015 SHE HAD A HYSTERECTOMY TO REMOVE ESSURE AND PROBLEMS SIGNIFICANTLY DIMINISHED OR WERE ENTIRELY GONE. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ALMOST IMMEDIATELY STARTED HAVING SEVERE PELVIC PAIN. SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE 4 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF A PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN ESSURE AND THE REPORTED EVENT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY TO REMOVE ESSURE). SINCE NO PRODUCT WAS RETURNED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01074	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/27/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0916, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. SHE HAD 3 CHILDREN AND WANTED HER TUBES TIED BUT THE HOSPITAL SHE USED WAS CATHOLIC, SO THEY WOULD NOT TIE HER TUBES. THE DAY OF THE PROCEDURE, SHE EXPERIENCED THE WORST PAIN SHE HAD EVER FELT IN HER LIFE; SHE WAS SCREAMING AND CRYING ON THE TABLE. SINCE THE PROCEDURE SHE EXPERIENCED SEVERE PELVIC PAIN MOSTLY ON LEFT SIDE, HER PERIODS WERE SO BAD SHE HAD TO USE A TAMPON AND PAD AT THE SAME TIME AND CHANGE THEM OFTEN. SHE GAINED 40 LBS AND AT THE END OF EVERY DAY SHE LOOKED 9 MONTHS PREGNANT (SHE DID NOT START OUT THAT BLOATED). SHE GOT FREQUENT HEADACHES AND HER HAIR WAS FALLING OUT BY THE HANDFULS. SOME DAY THE PAIN WAS SO BAD THAT SHE FELT IT IN HER HIPS AND RADIATING DOWN TO LEGS. SOME DAYS SHE DID NOT WANT TO GET OUT OF BED BUT SHE HAD 3 KIDS TO SUPPORT. SHE ALREADY WENT TO ER BECAUSE OF THE PAIN. A LAPAROSCOPIC SURGERY WAS DONE ON (B)(6) 2015. SHE WAS SCHEDULED TO HAVE A FOLLOW UP APPOINTMENT (B)(6) 2015 TO DISCUSS A HYSTERECTOMY THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE

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WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PELVIC PAIN MOSTLY ON LEFT SIDE. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE INSERTION WAS VERY PAINFUL AND SINCE THEN, SHE EXPERIENCED SEVERE PELVIC PAIN MOSTLY ON LEFT SIDE. SOME DAY, THE PAIN WAS SO BAD THAT SHE FELT IT IN HER HIPS AND RADIATING DOWN TO LEGS. SHE ALSO EXPERIENCED OTHER NON-SERIOUS EVENTS. THEN, A LAPAROSCOPIC PROCEDURE WAS PERFORMED. CONSIDERING CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (LAPAROSCOPIC SURGERY) THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01075	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (# FDA-2014-N-0736-0995, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT FOR 8 YEARS SHE HAD PELVIC PAIN, BACK PAIN, EXTREME FATIGUE, NICKEL ALLERGY, HAIR LOSS, INSOMNIA, DRY SKIN, BLOATING, WEIGHT GAIN, DIZZINESS, BRAIN FOG AND FORGETFULNESS. CONSUMER REPORTED THAT SHE KNOWS WAS ESSURE THAT CAUSED HER ALL THOSE THINGS BECAUSE IN 2014, AFTER HER HYSTERECTOMY, ALL OF IT LEFT HER BODY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN AMONG OTHER NON-SERIOUS EVENTS FOR 8 YEARS. AFTER HYSTERECTOMY, ALL OF IT LEFT HER BODY. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, CONSIDERING IMPLIED TEMPORAL RELATIONSHIP, EVENT'S NATURE AND RECOVERY AFTER REMOVAL (POSITIVE DECHALLENGE), CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING..

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 10-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01076	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0980, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED THAT SHE WAS A SINGLE, WORKING MOTHER OF FIVE WHEN SHE HAD ESSURE PLACED. IN THE FIRST TWO WEEKS, SHE PASSED CLUMPS OF TISSUE BIGGER THAN THE PALM OF HER HAND. THEY WERE PURPLE AND REMINDED HER OF RAW CHICKEN SKIN. SHE CALLED THE NIGHTTIME ON CALL DOCTOR WHO TOLD HER THAT THIS WAS NORMAL. THE PAIN NEVER WENT AWAY. SHE BLED FOR TEN MONTHS STRAIGHT AND HAD FREQUENT EPISODES WHERE HER ABDOMINAL PAIN WAS SO GREAT THAT SHE WOULD HAVE TO GO TO THE ER. SHE VISITED SEVERAL DOCTORS AND WAS TOLD BY EVERY MEDICAL PROFESSIONAL SHE MET THAT IT COULD NOT BE ESSURE CAUSING HER PAIN. SHE WAS OFFERED A UTERINE ABLATION, BIRTH CONTROL PILLS AND A HYSTERECTOMY TO TRY TO RELIEVE THE PAIN BUT SHE DID NOT WANT THOSE THINGS. AFTER A YEAR AND A HALF OF NEARLY MONTHLY EPISODES WHERE HER PELVIC PAIN WAS SO GREAT, A ESSURE REVERSAL WAS DONE. AFTER THE PAIN FROM SURGERY WORE OFF, SHE ENJOYED SIX PAIN FREE MONTHS AFTER ESSURE REVERSAL. BUT THEN THE PAIN RETURNED. SHE HAD A DYE TEST DONE, A CIS (AS REPORTED) RATHER THAN AN HSG WHICH SHOWED THAT HER FALLOPIAN TUBES HAD SCARRED DOSED. FOR THE LAST FOUR MONTHS WHEN SHE OVULATED, SHE HAD TERRIBLE PAIN. AT FIRST SHE THOUGHT IT MUST BE APPENDICITIS. AN ULTRASOUND AND TWO FOLLOW UPS WITH HER DOCTOR SHOWED THAT WHEN SHE OVULATE, SHE BLEED INTERNALLY. THIS WAS THOUGHT TO BE BECAUSE OF THE SCAR TISSUE. THE PAIN CAME BACK DURING HER MOST RECENT PERIOD AND THOUGH SHE

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STOPPED BLEEDING, THE PAIN PERSISTED. SHE SAW ANOTHER DOCTOR (THE ONLY ONE WHO BELIEVED THAT HER PAIN WAS CAUSED BY ESSURE) PRESCRIBED HER ANTI-INFLAMMATORY AND PAIN KILLERS. SHE WILL HAVE TO HAVE ADDITIONAL SURGERY IN A MONTH OR TWO TO ATTEMPT TO REMOVE HER SCAR TISSUE COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN (PAIN NEVER WENT AWAY). IN THE FIRST 2 WEEKS AFTER INSERTION, SHE PASSED CLUMPS OF TISSUE BIGGER THAN THE PALM OF HER HAND AND BLED FOR TEN MONTHS STRAIGHT (SEEN AS GENITAL BLEEDING). AFTER ONE YEAR AND HALF, ESSURE REVERSAL WAS DONE. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. IN THIS CASE, CONSIDERING CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE , CAUSALITY BETWEEN BLEEDING AND ESSURE USE CANNOT BE EXCLUDED. ALTHOUGH IN THIS CASE, THE PAIN HAS RETURNED 6 MONTHS AFTER ESSURE WITHDRAWN, GIVEN ITS NATURE, A CONTRIBUTORY ROLE FROM ESSURE TO THIS EVENT CANNOT BE TOTALLY EXCLUDED. THEREFORE, THIS EVENT IS ASSESSED AS RELATED TO ESSURE USE. SINCE ESSURE REVERSAL WAS DONE, IMPLYING THAT A DEVICE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01078	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 26-JUN-2013 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED COIL IN RIGHT DISLODGED AND PUNCHED THROUGH FALLOPIAN TUBE. NO INFORMATION GIVEN ON HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS UNKNOWN WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. IN 2012, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AT UNK. IT WAS UNKNOWN WHETHER ESSURE WAS USED PREVIOUSLY. HSG TEST WAS PERFORMED AND SHOWED COIL IN RIGHT DISLODGED AND PUNCHED THROUGH FALLOPIAN TUBE ON RIGHT SIDE. SHE WAS SUBMITTED TO A SURGERY TO CLAMP RIGHT TUBE BUT PHYSICIAN HAD TO REMOVE RIGHT TUBE BECAUSE THE COIL HAD PUNCHED THROUGH THE TUBE AND BEGAN TO WRAP AROUND THE TUBE. SHE IS CURRENTLY WITH ANOTHER PHYSICIAN DUE TO LEFT SIDE NOW. INCIDENT DATE: (B)(6) 2013. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN COIL IN RIGHT DISLODGED AND PUNCHED THROUGH FALLOPIAN TUBE AND ESSURE IS NOT REPORTED. [ADDENDUM: THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO (B)(6) ON 20-SEP-2013. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED.] FOLLOW-UP (LEGAL CLAIM) INFORMATION RECEIVED ON 02-SEP-2015: THIS CASE IS LEGAL CASE NOW. CASE CONSIDERED INCIDENT THE CONSUMER/PLAINTIFF WAS SUBMITTED TO A FIRST ESSURE (FEMALE BIRTH CONTROL DEVICE) INSERTION ATTEMPT IN OR AROUND (B)(6) 2012. PHYSICIAN ATTEMPTED TO IMPLANT THE DEVICE, BUT THE PROCEDURE WAS ABANDONED AFTER HE PERFORATED HER FALLOPIAN TUBE CAUSING BLEEDING. CONSUMER WAS ADMITTED TO HOSPITAL FOR 24 HOURS OBSERVATION DUE TO THE BLEEDING. SHE RETURNED TO THE PHYSICIAN IN (B)(6) 2012 FOR A SECOND ATTEMPT TO INSERT THE DEVICE. AT THIS TIME, ESSURE WAS INSERTED INTO THE TUBES. AFTER THE PROCEDURE, SHE STARTED EXPERIENCING

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SEVERE BLEEDING, AND CONSTANT, SEVERE DAILY PAIN. SHE CONTACTED THE DOCTOR MANY TIMES TO COMPLAIN ABOUT HER SYMPTOMS. IN (B)(6) 2012, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND SHOWED THAT LEFT MICRO-INSERT WAS PROPERLY LOCATED IN THE FALLOPIAN TUBE. THE RIGHT MICRO-INSERT, HOWEVER, WAS STRETCHED OR POSSIBLY BROKEN. IN (B)(6) 2013, DUE TO THE BROKEN ESSURE DEVICE (DEVICE FRACTURED INSIDE HER RIGHT TUBE DURING ONE PROCEDURE), CONSUMER UNDERWENT SURGERY TO REMOVE THE RIGHT FALLOPIAN TUBE AND THE BROKEN PIECES OF THE RIGHT MICRO-INSERT. SHE WAS EXPERIENCING THE SAME CONSTANT DAILY PAIN AND HEAVY BLEEDING DUE TO THE LEFT COIL. SINCE THE DEVICE WAS IMPLANTED, CONSUMER HAS ALSO SUFFERED FROM HEAVY BLEEDING, WEIGHT GAIN, DAILY PAIN, HEADACHES, ABDOMINAL PAIN, INFECTION, STOMACH ISSUES, INTENSE PELVIC PAIN, EMOTIONAL PAIN MENTAL AND EMOTIONAL AND MENTAL ANGUISH, PERSONAL INJURIES / PROFOUND INJURIES / PHYSICAL INJURIES AND CONTINUES TO SUFFER AT THIS TIME. SHE HAS BEEN SCHEDULED FOR ON OR ABOUT (B)(6) 2015 FOR A NEW SURGERY TO REMOVE THE LEFT MICRO-INSERT. FOLLOW-UP RECEIVED ON 10-SEP-2015: NO NEW INFORMATION PROVIDED. FOLLOW-UP FROM 16-SEP-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: FINAL ASSESSMENT - FAILURE MODE/MECHANISM - THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE OUTER COILS OF THE INSERT EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ELEVEN IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A TECHNICAL PRODUCT ISSUE. THE AE CASE REFERS ALSO TO USABILITY ISSUES. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS RECEIVED FROM A LAWYER ON BEHALF OF A FEMALE CONSUMER/PLAINTIFF. SHE WAS SUBMITTED TO AN ESSURE INSERTION ATTEMPT; DURING THIS PROCEDURE THE PHYSICIAN PERFORATED HER FALLOPIAN TUBE CAUSING BLEEDING AND SHE WAS HOSPITALIZED FOR OBSERVATION. TWO MONTHS LATER; ESSURE WAS SUCCESSFULLY IMPLANTED. HOWEVER, AT 3-MONTH CONTROL HSG (HYSTEROSALPINGOGRAM), THE RIGHT INSERT WAS FOUND POSSIBLY BROKEN (ACCORDING TO THE REPORTER DEVICE FRACTURED INSIDE RIGHT TUBE DURING ONE PROCEDURE). SHE UNDERWENT A SALPINGECTOMY. CURRENTLY, THE CONSUMER HAS DAILY PAIN AND HEAVY BLEEDING AND IS SCHEDULED FOR A SURGERY TO REMOVE THE LEFT COIL. ONLY DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. HOWEVER, ACCORDING TO PRODUCT TECHNICAL COMPLAINT ANALYSIS, THIS BREAKAGE IS ANTICIPATED EVENT. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF ESSURE AND CAN RESULT IN PAIN AND

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BLEEDING. ALSO, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, PHYSICIAN TRIED TO INSERT ESSURE 2 TIMES. IN THE FIRST ATTEMPT A FALLOPIAN TUBE PERFORATION OCCURRED. IN THE SECOND, ONE DEVICE BROKE. CONSIDERING THE EVENTS OCCURRED IN THE CONTEXT OF COMPLICATED ESSURE INSERTION ATTEMPTS; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, REPORTER STATED CONSUMER HAS PERSISTENT PAIN AND BLEEDING WHICH SHE RELATED TO THE REMAINING ESSURE COIL. AS NO ALTERNATIVE EXPLANATION WAS PROVIDED AND SINCE PAIN AND GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY; THESE EVENTS WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICES REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS

Manufacturer Narrative (H10):

FOLLOW UP 17-DEC-2015: THIS CASE WAS DUPLICATED OF THE CASE (B)(4) WHICH HAS BEEN MARKED FOR DELETION. ALL INFORMATION FROM THE DUPLICATE CASE HAS BEEN MOVED TO THIS CASE. CONSUMER STATED THAT THE COILS ARE DANGEROUS AND HAVE RUINED HER LIFE; SHE LIVE WIT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01079	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/17/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 15-JUL-2015. IT DESCRIBES THE OCCURRENCE PREGNANCY IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR CONTRACEPTION. ON (B)(6) 2015, THE PATIENT HAD A (B)(6) PREGNANCY TEST. ON UNSPECIFIED DATE, THE PATIENT HAD TWO HSGS (HYSTEROSALPINGOGRAM). PTC INVESTIGATION RESULT WAS RECEIVED ON 24-JUL-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR WITH THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A

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POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 02-SEP-2015: ESSURE HEALTH CARE PROVIDER PREGNANCY QUESTIONNAIRE WAS RECEIVED. INFORMATION RECEIVED FROM PHYSICIAN STATES THAT A (B)(6) FEMALE PATIENT WHO HAS AS PREVIOUS GYNECOLOGICAL INTERVENTION A CURETTAGE (DILATATION AND CURETTAGE) AND NO OTHER GYNECOLOGICAL PROBLEM OR PROCEDURE NOR ANY OTHER MEDICAL HISTORY OR CONCURRENT CONDITION AND HAS AS PREVIOUS PREGNANCIES GRAVIDA 3 AND PARA 3 (NO ABORTIONS OR ECTOPIC PREGNANCIES); HAD ESSURE (LOT NUMBER AND EXPIRATION DATE UNKNOWN) INSERTED ON (B)(6) 2013. PATIENT WAS POSTPARTUM AT THE TIME OF INSERTION. ACCORDING TO HEALTH CARE PROFESSIONAL, NO CERVICAL DILATATION, SOUNDING OR GENERAL ANESTHESIA WAS APPLIED DURING PROCEDURE. ANALGESIA WITH PERCOCET, TORADOL AND LIDOCAINE PARACERVICAL WAS DONE. PHYSICIAN CONSIDERED THE VISUALIZATION OF TUBAL OSTIUM EASY. HOWEVER, REPORTED THAT INSERTION WAS DIFFICULT AND DESCRIBED BILATERAL OSTIA WITH SCARRING VERSUS TUBAL SPASM. BOTH COILS TOOK FEW AMOUNT OF MANIPULATION (AS REPORTED). THERE WAS NO FLUID LOSS MORE THAN 1500CC DURING HYSTEROSCOPY AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. THERE WAS NO CAPABILITY FOR PICTURES AND NO IMAGING TEST WAS PERFORMED TO CONFIRM ESSURE PLACEMENT. AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION PATIENT USED DEPO. ON (B)(6) 2014, HYSTEROSALPINGOGRAM WAS PERFORMED AND SHOWED PERSISTENT CONTRAST VISUALIZATION LATERAL TO LEFT ESSURE DEVICE CONSISTENT WITH CONTRAST IN PERIPHERAL LEFT FALLOPIAN TUBE. ON (B)(6) 2014 NEW HYSTEROSALPINGOGRAM WAS DONE AND CONTRAST WAS VISUALIZED LATERAL TO THE LEFT ESSURE DEVICE, SUSPICIOUS FOR CONTRAST IN THE PERIPHERAL PORTION LEFT FALLOPIAN TUBE. RIGHT FALLOPIAN TUBE OCCLUSION. ON (B)(6) 2015, PREGNANCY URINE TEST WAS DONE AND, ON (B)(6) 2015, ULTRASOUND SHOWED (B)(6) PREGNANCY AND 23 CM SUBCHORIONIC HEMORRHAGE. FIRST DATE OF LAST MENSTRUAL PERIOD IS UNKNOWN AND THE EXPECTED DELIVERY DATE IS (B)(6) 2016. CURRENTLY, THERE ARE NO COMPLICATIONS AND PATIENT PLANS TO KEEP PREGNANCY. ESSURE REMOVAL IS PLANNED TO BE PERFORMED POSTPARTUM. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A POSITIVE PREGNANCY TEST. PREGNANCY IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, ABOUT 6 MONTHS AFTER ESSURE INSERTION, PATIENT UNDERWENT A HSGS (HYSTEROSALPINGOGRAM) AND THE RESULT SHOWED PERSISTENT CONTRAST VISUALIZATION LATERAL TO LEFT ESSURE DEVICE CONSISTENT WITH CONTRAST IN PERIPHERAL LEFT FALLOPIAN TUBE. ANOTHER HSG WAS PERFORMED AND CONTRAST WAS VISUALIZED LATERAL TO THE LEFT ESSURE DEVICE, SUSPICIOUS FOR CONTRAST IN THE PERIPHERAL PORTION LEFT FALLOPIAN TUBE. RIGHT FALLOPIAN TUBE OCCLUSION. PREGNANCY WAS DIAGNOSED ABOUT 1 YEAR AND 6 MONTHS AFTER ESSURE INSERTION. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN PREGNANCY AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT, SINCE A DEVICE REMOVAL (POSTPARTUM) WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION (PREGNANCY OUTCOME) IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01080	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 7/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 02-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR PERMANENT CONTRACEPTION. LOT NUMBER WAS NOT INFORMED. PATIENT REPORTED CRAMPING AND PELVIC PAIN. THE ONSET DATE OF EVENTS WAS REPORTED AS (B)(6) 2015. ON AN UNSPECIFIED DATE A DIAGNOSTIC LAPAROSCOPY WAS DONE AND SHOWED COILS OUT OF TUBES. ACCORDING TO THE REPORTER, ESSURE WAS CONTINUED. NO FURTHER INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT (PTC) RECEIVED ON 15-SEP-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT . IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED

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SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PATIENT WHO EXPERIENCED PELVIC PAIN AND CRAMPING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A DIAGNOSTIC LAPAROSCOPY, WHICH SHOWED COILS OUT OF TUBES. THESE EVENTS WERE CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE THERAPY THERE IS A RISK THE DEVICE COULD MOVE OUT OF THE FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION, MIGRATION OR OCCUR AS A RESULT OF A UTERINE PERFORATION DURING INSERTION. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, CONSIDERING EVENT'S NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT . IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 10-DEC-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT, REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO EXPERIENCED PELVIC PAIN AND C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01081	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GENERAL PRACTITIONER IN (B)(6) ON 04-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. IT WAS REPORTED THAT PATIENT FOUND OUT AFTER THE TREATMENT THAT THAT THERE WAS NICKEL IN THE COILS. THAT WAS THE REASON FOR PATIENT TO HAVE THE COILS REMOVED IN END OF (B)(6) 2015 WITH TUBECTOMY. THE PATIENT EXPERIENCED COMPLAINTS AT THAT MOMENT LIKE NAUSEA, ABDOMINAL PAIN AND INCREASED VAGINAL DISCHARGE. SHE INSISTED TO BE TREATED IN A SPECIFIC HOSPITAL (NIEUWEGEIN). THE REPORTER DID NOT WANT TO PROVIDE ADDITIONAL INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) COILS REMOVED; 2 MONTHS AFTER THEIR INSERTION, BECAUSE THERE WAS NICKEL IN THE COILS. THIS EVENT, INTERPRETED AS NICKEL SENSITIVITY, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, PHYSICIAN STATED PATIENT HAD NAUSEA, ABDOMINAL PAIN AND VAGINAL DISCHARGE. ACCORDING TO HIM, SHE HAD ESSURE REMOVED BECAUSE SHE DISCOVERED THE COILS HAD NICKEL (NO OTHER EVENTS, WHICH COULD BE RELATED TO NICKEL SENSITIVITY WERE REPORTED). ALTHOUGH LIMITED INFORMATION WAS PROVIDED IN THIS CASE; GIVEN THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE EVENT AND CONSIDERING ITS NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE

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EXCLUDED. THIS CASE IS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FURTHER INFORMATION CAN BE OBTAINED SINCE PHYSICIAN DENIED FURTHER CONTACT.

Manufacturer Narrative (H10):

FOLLOW UP RECEIVED ON 22-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REM

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01082	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE GENERIC REIMBURSEMENT PROGRAM. ON (B)(6) 2015 AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER D30804, WAS PERFORMED. IT WAS STATED THAT IMPLANT BROKE AT THE TIME OF INSERTION IN THE HYSTEROSCOPE, THERE WAS A PLACEMENT FAILURE DUE TO TECHNICAL REASON (IMPLANT RELEASE FAILURE AND BENDED IMPLANT TIP). IMPLANT WAS KEPT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND THE IMPLANT BROKE AT THE TIME OF INSERTION IN HYSTEROSCOPE. THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, PHYSICIAN HAD DEPLOYMENT DIFFICULTIES (THERE WAS A FAILURE TO RELEASE THE IMPLANT) AND ALSO A HANDLING ISSUE (ONE OF THE IMPLANT TIP BENDED). THIS SUGGESTS A DIFFICULT INSERTION, WHICH MAY HAVE CONTRIBUTED FOR DEVICE BREAKAGE. CONSIDERING THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-OCT-2015: NO FURTHER INFORMATION WAS OBTAINED DESPITE 2 FOLLOW-UP ATTEMPTS. FOLLOW-UP INFORMATION RECEIVED ON 26-OCT-2015 HER INITIALS AND AGE WERE RECEIVED. HER WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). PROBLEM WITH ESSURE RELEASE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01083	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0015, AWARENESS DATE: 28-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. CONSUMER STATED THAT PROCEDURE ON LEFT SIDE WAS COMPLETE WITHOUT ISSUE; THE RIGHT SIDE WAS A NIGHTMARE. THE PAIN WAS BEYOND ANYTHING SHE FELT BEFORE. DOCTOR TOLD HER THAT SHE MUST HAD SCAR ISSUE ON THAT SIDE. OVER FEW DAYS THE PAIN LET UP. ON AN UNSPECIFIED DATE, DYE TEST WAS DONE AND SHOWED THAT THE RIGHT COIL HAD ALREADY STARTED TO MIGRATE. THE DOCTOR SAID IT WENT A LITTLE DEEPER INTO THE TUBE BECAUSE OF THE ISSUES DURING PLACEMENT, BUT IT WAS OK BECAUSE THE TUBE WAS BLOCKED. OVER THE NEXT MONTHS, SHE HAD SEVERE CRAMPING AND BLEEDING. AN ABLATION WAS RECOMMENDED AND PROCEDURE WAS DONE. FOR NEXT FEW YEARS, SHE HAD MILD BLEEDING BUT WITH EXTREME CRAMPING. IT WAS DISCOVERED THAT SHE HAD A FIBROID TUMOR WHICH WAS GROWING AS A VINE AND WRAPPING ITSELF AROUND HER RIGHT TUBE. IN 2013, SHE WENT TO THE EMERGENCY VISIT AND SHE WAS TOLD THAT PAIN WAS DUE TO KIDNEY STONES. ON (B)(6) 2015, PELVIC ULTRASOUND AND TRANSVAGINAL ULTRASOUND WERE DONE. SHE WAS TOLD THAT SHE HAD A 10CM MASS INSIDE HER UTERUS AND THE COIL ON HER RIGHT SIDE PERFORATED THE TUBE AND SHOWED OUTSIDE HER RIGHT OVARY. A SURGERY WAS DONE IMMEDIATELY AND DURING SURGERY, DOCTOR FOUND THAT THE RIGHT COIL WAS LODGED INTO THE LIGAMENT SURROUNDING THE REPRODUCTIVE ORGANS. HE WAS UNABLE TO REMOVE IT AT THE TIME AS IT WAS BETWEEN TWO LARGE BLOOD VESSELS. THE REASON HE COULD NOT SEE INTO THE UTERUS WAS DUE TO MASSIVE AMOUNT OF SCAR TISSUE FROM THE ABLATION. HER CERVIX WAS THE

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SIZE OF A BASEBALL. A HYSTERECTOMY WAS RECOMMENDED. HER HYSTERECTOMY OCCURRED ON (B)(6) 2015 AND LATEST 3.5 HOURS. THE ABLATION SCAR TISSUE ENCOMPASSES HER CERVIX BLOCKING IT COMPLETELY. THE 10 CM MASS WAS A POOL OF BLOOD UNABLE TO LEAVE HER BODY; IT CONTINUED TO COLLECT AND HER ABDOMINAL AREA LOOKED AS SHE WAS 4 MONTHS PREGNANT. DUE TO CONDITION OF HER UTERUS, DOCTOR WAS UNABLE TO REMOVE EVERYTHING IN ONE PIECE. SHE WAS STABILIZED A COUPLE DURING SURGERY AND HE HAD TO DISSECT THE COIL FROM HER LIGAMENT. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. LATER, AN ULTRASOUND SHOWED RIGHT COIL PERFORATED HER TUBE; SHE WAS SUBMITTED TO A SURGERY AND RIGHT COIL WAS FOUND LODGED INTO THE LIGAMENT SURROUNDING HER REPRODUCTIVE ORGANS. ADDITIONALLY, SHE HAD MASSIVE AMOUNT OF SCAR TISSUE AFTER AN ABLATION FOR SEVERE BLEEDING. SHE UNDERWENT A HYSTERECTOMY DUE TO A 10CM MASS IN UTERUS WHICH WAS A POOL OF BLOOD UNABLE TO LEAVE HER BODY BECAUSE OF THE SCAR TISSUE (HER CERVIX WAS THE SIZE OF A BASEBALL). ONLY SCAR TISSUE, REGARDED AS UTERINE SYNECHIA, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, ESSURE INSERTION WAS DIFFICULT IN RIGHT FALLOPIAN TUBE AND ACCORDING TO THE CONSUMER, DOCTOR SAID IT WENT A LITTLE DEEPER INTO THIS TUBE. THIS COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED PERFORATION. ALSO, GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY. IN THIS CASE CONSUMER WAS DIAGNOSED WITH UTERINE FIBROIDS; THIS CONDITION COULD BE AN ALTERNATIVE EXPLANATION FOR HER BLEEDING. HOWEVER, CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP BETWEEN EVENTS AND ESSURE INSERTION AND GIVEN THEIR NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED UTERINE SYNECHIA, THEY WERE CONSIDERED AS UNRELATED TO ESSURE; AS THEY OCCURRED AS A COMPLICATION OF ENDOMETRIAL ABLATION. ADDITIONALLY, THE SERIOUS EVENT KIDNEY STONES (UNRELATED, UNLISTED) AND NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (SURGERIES PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01084	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/20/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0970, AWARENESS DATE 26-AUG-2015). CASE WAS RECEIVED IN UNITED STATES ON 28-AUG-2015 AND REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. ADDITIONAL INFORMATION RECEIVED ON 20-SEP-2015 (PTC INVESTIGATION RESULT). CONSUMER REPORTED THAT, WHEN THE HYSTEROSALPINGOGRAM TEST WAS DONE, THEY COULD NOT FIND ONE OF THE COILS. SHE THEN HAD A TUBAL. ACCORDING TO REPORTER, THEY WERE SUPPOSED TO REMOVE THE COILS WHEN THEY DID THE TUBAL, BUT DISCOVERED ONE HAD MIGRATED NEARBY BOWEL. CONSUMER RECENTLY STARTED ASKING ABOUT HER CONCERN WITH THE MIGRATED COIL AND THEY KEEP TELLING HER THEY WILL DISCUSS WITH THE PHYSICIAN AND THAT THEY WILL CALL HER BACK. THEY STILL, AFTER 2 MONTHS, HAVE NOT FOLLOWED UP, EVEN AFTER SHE CALLED AGAIN. CONSUMER THEN CALLED HER PRIMARY DOCTOR SO THAT SHE COULD GET A REFERRAL TO SEE ANOTHER PHYSICIAN. NOW IT HAS BEEN 2+ WEEKS AND HER PRIMARY HAS NOT CALLED HER BACK EITHER AND SHE WONDERS WHY THEY ARE AVOIDING THE ISSUE. IN ADDITION, CONSUMER REPORTED THAT THE FIRST THING SHE NOTICED (WITHIN A MONTH) WAS THAT HER HAIR STARTED FALLING OUT IN MASSIVE AMOUNTS. OTHER SIDE EFFECTS SHE HAD WERE EXTREME FATIGUE, LOW SEX DRIVE, WEIGHT GAIN, SHORT TERM MEMORY LOSS, FLUTTERS (LIKE WHEN YOU ARE PREGNANT), SHARP PAINS (THAT WERE WORSE AT FIRST, BUT SINCE HAVE GOTTEN BETTER), HARD TIME SLEEPING AT NIGHT, SLIGHT DEPRESSION AND ANXIETY (WHICH SHE NEVER HAD BEFORE) AND MOODINESS. THEN SHE STARTED GETTING NIGHT SWEATS AND HOT FLASHES. THEY DID SOME TESTS AND SHE IS NOW ON ESTROGEN, PROGESTERONE AND THYROID MEDICATIONS. THOSE

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SYMPTOMS HAVE GOTTEN BETTER AFTER SHE WAS PUT ON HORMONES. CONSUMER ALSO REPORTED THAT, FOR THE LAST YEAR, HER CYCLE HAS BEEN CRAZY AND THE LAST FEW MONTHS SHE WILL BLEED FOR 2 WEEKS, THEN NOTHING FOR A WEEK AND IT WILL START AGAIN. THEY KEEP CHANGING HER ESTROGEN AND PROGESTERONE DOSES BUT IT WAS NOT HELPING. SHE WAS NOTICING THE FEELING LIKE SOMETHING WAS CRAWLING ON HER, BUT WHEN SHE LOOKED NOTHING WAS THERE. SHE INFORMED THAT SHE READ SOMEWHERE THAT A CHANGE IN HORMONES CAN CAUSE THAT AND SHE WAS WONDERING IF HER CHANGE IN MEDICATION HAS MADE THAT WORSE. SHE WAS CONCERNED ABOUT ALL OF THE SIDE EFFECTS, BUT MOSTLY ABOUT THE MIGRATED COIL. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT WHEN THE HYSTEROSALPINGOGRAM TEST WAS DONE, THEY COULD NOT FIND ONE OF THE COILS / ONE HAD MIGRATED NEARBY BOWEL. SHE THEN HAD A TUBAL. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MIGRATION IS OFTEN USED SYNONYMOUSLY WITH PERFORATION. IT IS SOMETIMES USED TO IMPLY THAT A COMPLETE PERFORATION OCCURRED NOT IMMEDIATELY, BUT OVER TIME, E.G. WHEN AN UNDIAGNOSED PARTIAL PERFORATION DURING INSERTION GRADUALLY LEADS TO A COMPLETE PERFORATION. OFTEN MIGRATION IS REPORTED WHEN THE EXACT TIME POINT OF PERFORATION IS NOT KNOWN. SOMETIMES MIGRATION THROUGH THE FALLOPIAN TUBE IS SUSPECTED BY THE REPORTER, BECAUSE THE ESSURE INSERT IS FOUND IN THE ABDOMEN AND NO APPARENT PERFORATION CAN BE IDENTIFIED. THEREFORE, BASED ON THE INFORMATION PROVIDED AND POSSIBLE MECHANISM OF MIGRATION, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE PERFORMED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01085	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0999, AWARENESS DATE 28-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. SINCE 2010, SHE HAS BEEN SUFFERING SEVERE PAIN, HAIR LOSS, FATIGUE, WEIGHT GAIN AND A VARIETY OF OTHER HEALTH ISSUES THAT SHE NEVER HAD BEFORE THE DEVICE WAS IMPLANTED. IN 2014 SHE WENT TO THE EMERGENCY ROOM IN SEVERE PAIN. THE DOCTORS ASKED HER WHEN SHE HAD HER HYSTERECTOMY; SHE TOLD THEM SHE DID NOT EVER HAVE A HYSTERECTOMY AND THEY TOLD HER THAT RIGHT FALLOPIAN TUBE WAS GONE. IT WAS DISCOVERED THAT THE RIGHT ESSURE COIL HAD RIPPED OFF HER RIGHT FALLOPIAN TUBE AND WAS RESTING BETWEEN HER UTERUS AND HER RECTUM. IN THAT SAME YEAR BOTH FALLOPIAN TUBES WERE REMOVED. SHE HAD SOME RELIEF AFTER THE SURGERY, HOWEVER BY 2014 ALL SYMPTOMS RETURNED PLUS OTHERS. IN 2015 A TOTAL HYSTERECTOMY WAS DONE. SHE COULD NOT WORK FROM 2010 - 2014 DUE TO CONSTANT PAIN, MEMORY ISSUES AND BEING SICK ALL THE TIME. THERE WAS NO WAY SHE COULD HOLD ON A JOB. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD.

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WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FOUR YEARS LATER IT WAS FOUND THAT THE RIGHT ESSURE COIL HAD RIPPED OFF HER RIGHT FALLOPIAN TUBE AND WAS RESTING BETWEEN HER UTERUS AND RECTUM. IN THE SAME YEAR SHE UNDERWENT BILATERAL SALPINGECTOMY AND ONE YEAR LATER A HYSTERECTOMY. THIS EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THIS PERFORATION WERE NOT REPORTED. THE PERFORATION WAS DIAGNOSED 4 YEARS AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. SINCE NO PRODUCT WAS RETURNED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01086	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA 2014-N-0736-1016, AWARENESS DATE 28-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. IT WAS REPORTED THAT SHE HAS BEEN CONSTANTLY AND UNEXPLAINABLY SICK SINCE INSERTION. ON AN UNSPECIFIED DATE, SHE ENDED UP IN ER (EMERGENCY ROOM) AND THEY WERE ABLE TO DETERMINE THAT ONE OF HER COILS WERE MISSING. SHE ALSO SUFFERED OF HAIR LOSS, WEIGHT GAIN, BLOATING, BACK ACHES, OVARIAN CYST AND MIGRAINES. IN 2014 SHE HAD BOTH TUBES REMOVED AND A TOTAL HYSTERECTOMY IN 2015. SHE WAS BETTER, BUT SHE IS NOT THE SAME AS BEFORE. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER AN UNSPECIFIED TIME IT WAS FOUND THAT ONE OF HER COILS WAS MISSING. SHE UNDERWENT BILATERAL SALPINGECTOMY AND ONE YEAR LATER A HYSTERECTOMY. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE THE EXACT LOCATION OF THE DEVICE WAS NOT REPORTED, HOWEVER GIVEN THE NATURE OF THE EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION. SINCE NO PRODUCT WAS RETURNED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01087	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2014
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1013, AWARENESS DATE 26-AUG-2015). CASE WAS RECEIVED IN UNITED STATES ON 28-AUG-2015 AND REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. CONSUMER REPORTED THAT, IN (B)(6) 2015 (AFTER HAVING ESSURE PUT IN), SHE WAS CONSTANTLY IN AND OUT OF THE HOSPITAL. CONSUMER STARTED HAVING STROKE LIKE SYMPTOMS ALMOST 2 MONTHS AFTER THEY WERE PUT AND STATES THAT SHE STARTED GETTING HORRIBLE MIGRAINES AT THE SAME TIME. SHE ALSO BLED FROM THE TIME SHE GOT THEM UNTIL APRIL. CONSUMER WAS EVENTUALLY DIAGNOSED WITH AURORA MIGRAINES (AS REPORTED, UNDERSTOOD AS MIGRAINE WITH AURA). IN (B)(6) 2015 SHE HAD THEM REMOVED AND STATES THAT SHE HAS HAD NO MIGRAINES BUT SHE BLEEDS NOW AFTER INTERCOURSE. IN ADDITION, CONSUMER REPORTED THAT SHE STILL HAS A PIECE IN HER UTERUS AND INFORMED THAT HER DOCTOR LEFT THERE ON PURPOSE. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE

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DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE BLED (INTERPRETED AS GENITAL BLEEDING) FROM THE TIME SHE HAD ESSURE INSERTED FOR A FEW MONTHS. SHE WAS ALSO IN AND OUT OF HOSPITAL DUE TO MIGRAINES WITH AURA. APPROXIMATELY 3 MONTHS AFTER INSERTION, SHE HAD THEM REMOVED BUT THERE IS STILL A PIECE IN HER UTERUS (INTERPRETED AS DEVICE BREAKAGE). THE GENITAL BLEEDING IS SERIOUS DUE TO REQUIRED INTERVENTION AND MIGRAINES WITH AURA DUE TO HOSPITALIZATION. THIS BLEEDING IS LISTED WHILE MIGRAINES WITH AURA IS AN UNLISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO NEW FAILURE MODE FOR THE DEVICE (ANTICIPATED). IN THIS CASE, ALL EVENTS OCCURRED DURING ESSURE THERAPY. HOWEVER, CONSIDERING THE NATURE OF THESE EVENTS, THE GENITAL BLEEDING AND DEVICE BREAKAGE ARE ASSESSED AS RELATED TO ESSURE WHILE THE CAUSAL RELATIONSHIP WITH MIGRAINES WITH AURA IS RATHER ASSESSED AS UNLIKELY DUE TO THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01088	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/8/2010
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 13-JAN-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FOOD AND DRUG ADMINISTRATION (FDA), THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5032587, RECEIVED AT FDA ON 04-NOV-2013). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED MUSCLE PAIN, SWELLING OF HANDS, SWELLING OF LEGS AND ANKLES, STOMACH IS ALWAYS BLOATED, BAD CRAMPING, HEADACHES STARTING TO BE MORE FREQUENT AND MORE POWERFUL, HAVE NO ENERGY, AND EXTREMELY BAD JOINT PAIN. REPORT TYPE WAS INJURY. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2010, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. AFTER HAVING ESSURE IN 2010, THE CONSUMER HAD EXTREMELY BAD JOIN PAIN, MUSCLE PAIN, SWELLING OF HANDS, LEGS, ANKLES. CONSUMER'S STOMACH WAS BLOATED AND BAD CRAMPING. HEADACHES WERE STARTING TO BE MORE FREQUENT AND MORE POWERFUL. CONSUMER HAD ALWAYS BEEN ENERGETIC AND NOW SHE HAD NO ENERGY. CONSUMER FELT LIKE A [NO AGE PROVIDED] YEAR OLD AND SHE WAS ONLY [NO AGE PROVIDED]. FOLLOW-UP INFORMATION RECEIVED ON 29-AUG-2015 AND ADDITIONAL INFORMATION RECEIVED ON 21-SEP-2015 (PTC INVESTIGATION RESULT). THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0939 AND FDA-2014-N-0736-0015). ESSURE WAS PLACED IN (B)(6) 2010 AFTER HER THIRD CHILD. SHE STARTED TO HAVE PROBLEMS WITHIN A MONTH AFTER PROCEDURE; IT STARTED WITH FATIGUE WHICH SHE THOUGHT IT WAS JUST FROM HAVING A NEWBORN, BUT MORE SERIOUS SYMPTOMS STARTED SUCH AS

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HORRIBLE JOINT PAINT, LEG PAIN, MUSCLE PAIN, HIP PAIN, PELVIC PAIN, SEVERE CRAMPING EVERYDAY, HEADACHES, THINNING HAIR, BLOATING, BACK PAIN, TEETH PROBLEMS, STOMACH PROBLEMS, SICKNESS WITH FEVER AND BODY ACHES ALMOST EVERY WEEK. SHE THOUGHT SHE HAD LUPUS OR SOMETHING. FINALLY, AFTER REALIZING THAT THE ESSURE COILS WERE PROBABLY THE CULPRIT OF HER ISSUES, HER DOCTOR DECIDED TO PERFORM A PARTIAL HYSTERECTOMY IN (B)(6) 2014 REMOVING HER TUBES AND UTERUS. AFTER SURGERY, EVERY SINGLE SYMPTOM WENT AWAY AND HAS NOT RETURNED. CASE UPGRADED TO INCIDENT. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. A PARTIAL HYSTERECTOMY WAS PERFORMED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STARTED EXPERIENCING THIS EVENT WITHIN A MONTH AFTER ESSURE INSERTION PROCEDURE. CONSIDERING THE NATURE OF THE EVENT AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01089	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/31/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 18-FEB-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5033942, RECEIVED AT FDA ON 23-DEC-2013). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PMS (PREMENSTRUAL SYNDROME) AND PERIODS HAVE GOTTEN INCREASINGLY WORSE, PMS WEEK HAS BECOME SO PAINFUL SHE IS BEDRIDDEN, PMDD (PREMENSTRUAL DYSPHORIC DISORDER), PAINFUL CRAMPS AND BACK ACHES DURING PERIODS, ISSUES WITH PAINFUL CLOTS, EXTREMELY HEAVY FLOW, GOING THROUGH SUPER-PLUS TAMPONS IN ONE HOUR, ALLERGIC TO NICKEL, AND DEVICES IMPLANTED WITH TWO (COILS) SHOWING ON ONE SIDE, AND NO ONE THE OTHER, BOTH TOO HIGH AND INSERTION WAS FIVE WEEKS POSTPARTUM. FDA REPORT TYPE WAS INJURY, REPORTED OUTCOME OF EVENTS WAS 'DISABILITY OR PERMANENT DAMAGE' NO INFORMATION WAS GIVEN ON CONSUMER'S PAST DRUGS, CONCOMITANT MEDICATION. PATIENT'S HISTORY/CONCURRENT CONDITIONS INCLUDED A TILTED UTERUS, TWO PREGNANCIES, BEING POSTPARTUM. ON (B)(6) 2011, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. CONSUMER REPORTED HER DOCTOR SENT HER TO THE SAME DAY SURGERY CENTER AT THE HOSPITAL AND SHE WAS PUT COMPLETELY UNDER (NOT SPECIFIED) FOR THE INSERTION. HER INSERTION WAS FIVE WEEKS POSTPARTUM. HER DEVICES WERE IMPLANTED WITH TWO (COILS) SHOWING ON ONE SIDE, AND NO ON THE OTHER, BOTH TOO HIGH. SINCE THE PROCEDURE, PMS (PREMENSTRUAL SYNDROME) AND HER PERIODS HAVE GOTTEN INCREASINGLY WORSE. SHE IS AT THE POINT WHERE SHE EXPERIENCES PAINFUL CRAMPS AND BACK ACHES SEVERAL TIMES WEEKLY ALL THROUGHOUT HER CYCLE. PMS WEEK HAS BECOME SO PAINFUL SHE IS BEDRIDDEN, AND SHE CONSISTENTLY EXPERIENCES ISSUES WITH PAINFUL CLOTS, AND EXTREMELY HEAVY FLOW

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(GOING THROUGH SUPER-PLUS TAMPONS IN AN HOUR). SHE HAS BEEN DIAGNOSED WITH PMDD (PREMENSTRUAL DYSPHORIC DISORDER), WHICH SHE BELIEVES IS A DIRECT RESULT OF THE ESSURE. SHE IS ALLERGIC TO NICKEL TO THE POINT WHERE SHE CANNOT WEAR JEWELRY CONTAINING IT, AND SELF-PERFORMED NICKEL TESTS HAVE LEFT HER SKIN ITCHY AND BRUISED FOR DAYS. SHE WAS INFORMED THAT THE NICKEL CONTRAINDICATION HAD BEEN REMOVED, SO SHE WAS SAFE, OBVIOUSLY THIS WAS NOT THE CASE. HER DOCTOR KNEW HER UTERUS TO BE TILTED, HAVING MENTIONED THE PROBLEMS DETECTING HER BABIES HEARTBEATS DURING PREGNANCY BOTH TIMES, YET NEVER MENTIONED THAT ESSURE IS NOT RECOMMENDED FOR WOMEN WITH A TILTED UTERUS. FOLLOW-UP RECEIVED ON 03-MAR-2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THIS CASE ALSO REFERS TO A DEVICE DEPLOYMENT ISSUE (TWO COILS IN ONE FALLOPIAIN TUBE, NO COIL IN OTHER FALLOPIAN TUBE). NO COMPLAINT SAMPLE WAS PROVIDED FOR TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT BATCH NUMBER OR SAMPLE. AT THE TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. AWARENESS DATE 29-AUG-2015 (UPGRADED TO INCIDENT): THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-0955). THE CHANCES OF SUCCESSFUL ESSURE PLACEMENT ARE TOO GREAT, AND HER DOCTOR WAS LISTED ON ESSURE'S SITE AS AN APPROVED TRAINED DOCTOR. YET, SHE WAS LISTED IN HER MEDICAL FILE AS BEING STAGE 1 (TOO FAR IN TO BE RELIED UPON FOR CONTRACEPTION) AND WAS NEVER INFORMED OF THIS. IT WAS NOT A WORRY AT THE TIME OF REPORT, AS SHE HAD A HYSTERECTOMY AT THE AGE OF (B)(6) DUE TO EXTREME PAIN, BLEEDING AND CLOTTING. IN THE YEAR SINCE, SHE HAS TURNED FROM BEING BEDRIDDEN A WEEK OUT OF EVERY MONTH TO LIVING AN ACTIVE, HEALTHY LIFESTYLE UPDATED PTC RESULT WAS RECEIVED ON 14-SEP-2015: FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD EXTREME PAIN, BLEEDING AND CLOTTING AND PMS GOTTEN INCREASINGLY WORSE (INTERPRETED AS PREMENSTRUAL SYNDROME)TO THE POINT SHE WAS BEDRIDDEN ONE WEEK A MONTH . SHE HAD A HYSTERECTOMY AT (B)(6). A YEAR SINCE SHE BECAME ACTIVE AGAIN. THE EXTREME PAIN AND BLEEDING ARE SERIOUS DUE TO REQUIRED INTERVENTION AND THE PMS IS SERIOUS DUE TO A TEMPORARY DISABILITY (NOT PERMANENT). IN THIS PARTICULAR CASE, THE EVENTS OCCURRED WHILE ESSURE WAS INSERTED. IN ADDITION, THE CONSUMER STATED THAT THE PHYSICIAN CONSIDERED THE INSERTS WERE TOO FAR IN. GIVEN THIS INFORMATION, THE NATURE OF THESE EVENTS AND THE LACK OF ALTERNATIVE EXPLANATION, THESE EVENTS ARE ASSESSED AS RELATED TO

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ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01090	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/25/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 04-MAR-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5034024, RECEIVED AT FDA ON 23-JAN-2014). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED SO MUCH PAIN IN LEFT LEG TO THE VERGE OF TEARS/ LEG PAIN, VITAMIN D DEFICIENT, DEBILITATING MIGRAINES, DIAGNOSED WITH VERTIGO, STARTED SUFFERING FROM HORRIBLE PANIC/ANXIETY ATTACKS, VERY LOW HDL LEVELS, BACK PAIN, JOINT PAIN, GAINED A RIDICULOUS AMOUNT OF WEIGHT, DIAGNOSED WITH A.D.D. (ATTENTION DEFICIT DISORDER), SKIN IS SO DRY AND ITCHY, RED BUMPS AFTER I SHAVE, PERIODS ARE EXTREMELY PAINFUL, EXTREME AND PAINFUL STOMACH BLOATING, SHARP STABBING PAINS IN MY BELLY BUTTON AREA AND IN MY VAGINAL/RECTUM AREA, IT IS PAINFUL TO HAVE INTERCOURSE, MAJOR MOOD SWINGS, AND CONSTANT PAIN. ON FDA FORM REPORTED REPORT TYPE WAS INJURY, OUTCOME OF EVENTS WAS 'OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)' NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2009, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. CONSUMER REPORTED SHE WAS IMPLANTED IN 2009, AND IN 2009 SHE WAS IN SO MUCH PAIN IN HER LEFT LEG TO THE VERGE OF TEARS. SHE WENT TO THE DOCTOR AND WAS INFORMED OF BEING VITAMIN D DEFICIENT. AS TIME PASSED SHE STARTED SUFFERING FROM DEBILITATING MIGRAINES INCLUDING OCULAR MIGRAINES THAT SHE WAS SENT TO SEE AN EYE DOCTOR THAT SPECIALIZES IN PROBLEMS WITH THE RETINA. SHE HAD ON SEVERAL OCCASIONS TO GO TO DOCTOR OR HOSPITAL WITH WHAT FELT LIKE HEART ATTACK OR STROKE. THE LEFT SIDE OF HER BODY INCLUDING FACE STARTED GOING NUMB, SHE BROKE OUT IN A SWEAT AND HAD TROUBLE BREATHING, HER HAND STARTED

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TINGLING, AND SHE HAD HEADACHE THAT FELT LIKE SOMEONE HIT HER WITH A HAMMER. TEST RESULTS FROM THOSE INCIDENTS CAME BACK NORMAL. AS A RESULT INSTEAD SHE WAS DIAGNOSED WITH VERTIGO AND PARAESTHESIA. SHE STARTED SUFFERING FROM HORRIBLE PANIC/ANXIETY ATTACKS. SHE HAD BEEN SENT TO DIFFERENT TESTS THAT ALWAYS CAME BACK NORMAL. SHE HAD BEEN PRESCRIBED DIFFERENT TYPES OF MEDICATION FOR HER MIGRAINES AND VERTIGO. SHE HAD TAKEN A VERY HIGH DOSE OF VITAMIN D. SHE HAD BEEN DIAGNOSED WITH VERY LOW HDL LEVELS. SHE SUFFERED FROM BACK, LEG AND JOINT PAIN THAT HAD HER SOME DAYS JUST PRAYING FOR RELIEF. SHE GAINED A RIDICULOUS AMOUNT OF WEIGHT AFTER IMPLANTATION AND HER SKIN WAS SO DRY AND ITCHY. SHE GOT RED BUMPS AFTER SHE SHAVED THAT ITCHED SO BAD SHE WAS SCRATCHING ALL THE TIME LIKE A DOG WITH FLEAS WOULD. SHE HAD RECENTLY ALSO BEEN DIAGNOSED WITH A.D.D. (ATTENTION DEFICIT DISORDER) AND WAS NOW ON VYVANSE (LISDEXAMFETAMINE DIMESYLATE) WHICH HAD ALLEVIATED HER MIGRAINES BUT SHE STILL HAD DULL HEADACHES. HER PERIODS WERE EXTREMELY PAINFUL AND HEAVY TO THE POINT WHERE SHE HAD TO USE BOTH A TAMPON AND A PAD. SHE SUFFERED FROM EXTREME AND PAINFUL STOMACH BLOATING TO THE POINT WHERE SHE HAD TRIED TO CUT OUT ANY TYPE OF FOOD THAT SHE FELT WILL GIVE HER ISSUES. SHE GOT SHARP STABBING PAINS IN HER BELLY BUTTON AREA AND IN HER VAGINAL/RECTUM AREA. IT WAS PAINFUL TO HAVE INTERCOURSE. SHE HAD MAJOR MOOD SWINGS THAT WERE AFFECTING HER MARRIAGE. SHE FELT AT (NOT REPORTED) THAT SHE HAD THE BODY OF AN 80 YEAR OLD. SHE WAS IN CONSTANT PAIN AND SHE NEEDED TO FIND RELIEF. FOLLOW-UP INFORMATION RECEIVED ON 29-AUG-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0911). THE CONSUMER HAD THE ESSURE DEVICE IMPLANTED IN 2009. ALMOST IMMEDIATELY SHE STARTED HAVING PAIN ON THE LEFT SIDE OF HER BODY BUT MOSTLY HER LEFT KNEE AND LEG. SHE WENT TO HER GENERAL DOCTOR ABOUT A MONTH AFTER PROCEDURE AND SHE WAS DIAGNOSED WITH A VITAMIN D DEFICIENCY. FOR OVER FOUR YEARS SHE SUFFERED THROUGH DIFFERENT AILMENTS, FROM SEVERE MIGRAINES, NUMBNESS ON THE LEFT SIDE OF HER BODY, TINGLING IN HER EXTREMITIES ON THE LEFT SIDE OF BODY, GOING TO HOSPITAL FOR WHAT SHE FELT LIKE A STROKE, DIZZINESS, ANXIETY, HORMONAL PROBLEMS AND ETC. THERE WERE THE GYNECOLOGICAL ISSUES AS WELL; HAVING TO USE DOUBLE PROTECTION WHEN IT WAS THAT TIME OF THE MONTH. THE PAIN THAT SHE FELT WHEN TRYING TO BE INTIMATE WAS SOMETHING THAT SHE DID NOT WISH ON HER WORST ENEMY. ONE DAY, SHE HAD THE USUAL BACK PAIN AND LEFT LEG PAIN THAT SHE HAD, BUT THIS TIME WAS DIFFERENT; SHE FELT LIKE HER LEFT SIDE WAS PARALYZED. IT STARTED TO CAUSE PANIC IN HER AS SHE WAS HOME ALONE WITH HER YOUNGEST SON. SHE WOULD TRY AND PUT PRESSURE ON HER LEFT SIDE AND SHE WOULD FEEL SOMETHING IN HER PELVIC AREA AND EVERY TIME THAT SHE WOULD DO THAT I WOULD NOT FEEL HER LEGS BUT SHE WOULD FEEL THE PRESSURE IN THE PELVIC AREA. SHE HAD COILS REMOVED A FEW MONTHS LATER AND THE PAIN IN HER LEFT LEG WAS GONE IMMEDIATELY. THESE COILS CHANGED NOT ONLY HER LIFE BUT THAT OF HER HUSBAND AND HER CHILDREN AS WELL. SHE FELT BETTER FOR SURE, BUT SHE WILL NEVER BE THE WOMAN THAT SHE WAS BEFORE COILS. MAYBE SHE WAS JUST SUFFERING FROM DEPRESSION AND MAKING MORE OUT OF HER AILMENTS THAN THEY TRULY WERE. SHE CONSIDERED THE EVENTS RELATED TO ESSURE. CASE UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE

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TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD PAIN IN LEFT LEG AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY AND RECOVERED FROM THIS EVENT. LEG PAIN WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND LEG PAIN MAY OCCUR. IN THIS CASE, THE EVENT STARTED AFTER ESSURE INSERTION AND IMPROVED WITH DEVICE REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01091	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0913, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. IT WAS REPORTED THAT SINCE INSERTION SHE EXPERIENCED HEAVY BLEEDING WHICH LED TO AN ABLATION IN (B)(6) 2013, SEVERE FREQUENT ABDOMINAL PAINS, CRAMPING, SPASMS, PELVIC PAIN, HAIR LOSS, REDUCED LIBIDO, DIZZINESS, FREQUENT VERTIGO, FAINTING SPELLS, HEADACHES, JOINT PAINS, VITAMIN D DEFICIENCIES, ABDOMINAL BLOATING, EYE TWITCHING, FREQUENT URINATION, UTI'S, DRY SKIN, DRY EYES, SEVERE PERIODS, INFLAMMATION, CHRONIC FATIGUE. ON AN UNSPECIFIED DATE, COIL MIGRATED AND PERFORATED THROUGH UTERUS LEADING TO A TUBAL LIGATION IN (B)(6) 2013. COIL WAS STILL PERFORATED HER UTERUS AND SHE WILL BE HAVING A TOTAL HYSTERECTOMY IN (B)(6) 2015. PTC INVESTIGATION RESULT WAS RECEIVED ON 21-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE

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REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO WAS SUBMITTED TO AN ENDOMETRIAL ABLATION DUE TO HEAVY BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE STATED SHE WILL HAVE A HYSTERECTOMY IN THE FOLLOWING MONTH, BECAUSE ONE COIL MIGRATED AND PERFORATED THROUGH HER UTERUS. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE PAIN AND BLEEDING DURING AND AFTER THE PROCEDURE. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENTS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REQUIRED INTERVENTION FOR BLEEDING'S TREATMENT (ABLATION) AND SINCE A HYSTERECTOMY IS SCHEDULED FOR DEVICE REMOVAL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 05-NOV-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01092	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (# FDA-2014-N-0736-1002, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. CONSUMER EXPERIENCED FATIGUE, HEAVY PERIODS, MIGRAINES, JOINT PAINS AND CHRONIC HEMORRHOIDS. IN 2014 SHE HAD HER TUBES REMOVED AND IN 2015 SHE HAD A FULL HYSTERECTOMY PERFORMED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY PERIODS. THIS EVENT, SEEN AS MENORRHAGIA, IS SERIOUS DUE REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING AND MENSES PATTERN CHANGES ARE FREQUENT IN WOMEN WITH ESSURE IN PLACE. THUS, CONSIDERING IMPLIED TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. OTHER NON-SERIOUS EVENTS WERE INFORMED. SINCE AN INTERVENTION WAS REQUIRED (TUBES REMOVAL AND HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01093	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2004
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA A TELEVISION NEWS IN UNITED STATES ON 08-NOV-2013 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MOVING COILS, BLOATING, BACK PAIN, BELLY PAIN, HEADACHES, AND CYSTS. ADDITIONALLY, OTHER CASES WERE CREATED REPORTING EVENTS OCCURRED IN ANOTHER CONSUMERS WHICH WERE REPORTED IN THE SAME TELEVISION NEWS. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED MOVING COILS, BLOATING, BACK PAIN, BELLY PAIN, HEADACHES, AND CYSTS. THE OUTCOMES OF EVENTS WERE UNKNOWN. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN EVENTS AND ESSURE IS RELATED. FOLLOW-UP RECEIVED ON 29-AUG-2015: REPORTER INFORMATION WAS UPDATED. SHE RECEIVED THE ESSURE DEVICES IN (B)(6) 2004 AS A MINIMALLY INVASIVE PERMANENT BIRTH CONTROL OPTION. SHE WAS INFORMED THAT THE PROCEDURE WAS SAFE, HORMONE FREE AND THAT THERE WOULD BE NO DO EFFECTS AS SUCH. THE PROCEDURE IN AND OF ITSELF WENT VERY WELL AND SHE SUFFERED NO ADVERSE EFFECTS IN THE BEGINNING. SHE ACTUALLY WENT BACK TO WORK A FEW DAYS AFTER THE IMPLANTATION OF THE ESSURE DEVICES. HOWEVER A FEW MONTHS INTO 2005, SHE NOTICED THAT HER MOOD BEGAN TO CHANGE, SHE BECAME VERY DEPRESSED AND ANXIOUS, AND SHE SEEMED TO HAVE GAINED AN EXCESSIVE AMOUNT OF WEIGHT IN A SHORT AMOUNT OF TIME (50 POUNDS IN 3 MONTHS OR SO). ALSO SHE BEGAN EXPERIENCING SOME HAIR LOSS. HER HEALTH HAS TAKEN A STEADY DECLINE SINCE 2005, AND SHE NEVER HAD ANY REAL HEALTH PROBLEMS UNTIL AFTER SHE WAS IMPLANTED WITH ESSURE. IN 2007 SHE BEGAN EXPERIENCE EYE ALLERGIES, CORNEAL ABRASION AND HER PERIODS BEGAN

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TO BECOME IRREGULAR. SHE DID ASK HER DOCTOR ABOUT THE IRREGULAR PERIODS BEING CONNECTED TO ESSURE, AND AT THE TIME, THE DOCTOR THOUGHT IT WAS THE CAUSE, BUT SHE DID HAVE CONCERNS THAT ESSURE WAS THE PROBLEM. IN (B)(6) 2010, SHE EXPERIENCED A PERIOD THAT WAS SO BAD SHE HAD TO GO TO THE EMERGENCY ROOM DUE TO HEAVY BLEEDING, PAIN, DIZZINESS, NEAR-SYNCOPE AND PASSAGE OF BLOOD CLOTS. IN 2011, SHE BEGAN EXPERIENCING SKIN ISSUES (FLAKING, PEELING AND ITCHY SKIN), RASHES, BACK PROBLEMS GENERALIZED BODY PAIN, MUSCLE ACHES, ABDOMINAL BLOATING, LOWER EXTREMITY SWELLING, RINGING EARS, TINNITUS (PULSATILE) AND FATIGUE. IN 2012, THE EYE ALLERGIES AND CORNEAL ABRASIONS STARTED AGAIN AND HAVE NOT STOPPED. SHE CONTINUES TO SUFFER FROM REPEATED CORNEAL ABRASIONS IN HER RIGHT EYE THAT HAVE AFFECTED HER VISION. ALSO IN 2012, SHE EXPERIENCED BILIARY (GALLBLADDER) COLIC ISSUES, HAVING TO GO TO THE EMERGENCY ROOM AGAIN TO MAKE SURE SHE WAS OK. IT WAS CONFIRMED THAT SHE HAD GALLSTONES. FOR OVER A YEAR, SHE CONTINUED TO DEAL WITH SEVERE BILIARY COLIC, WHICH INCLUDED BUT NOT LIMITED TO NAUSEA, VOMITING, AND A FEELING OF GENERAL MALAISE. DUE TO THESE PROBLEMS, SHE MISSED MANY DAYS OF WORK BETWEEN 2012 AND FALL 2013. HER LAST PERIOD WAS IN (B)(6) 2014 AND SHE HAS NOT SEEN IT SINCE. SHE HAS TAKEN A PREGNANCY TEST WHICH CAME OUT NEGATIVE, SO THAT IS NOT THE ISSUE. SHE IS SCHEDULED TO HAVE THE ESSURE DEVICES REMOVED BY HER GYNECOLOGIST VIA LAPAROSCOPIC BILATERAL SALPINGECTOMY TO ALL OF THE ABOVE LISTED PROBLEMS. SHE IS HOPING THAT ALL OF THE COILS WILL BE ABLE TO BE REMOVED AND THAT NO FRAGMENTS WILL REMAIN AND THAT ALL OR MORE THAN MOST OF ANY PROBLEMS WILL BE RESOLVED. CONSUMER STATED THAT ESSURE ALLOW FOR A CLASS-ACTION LAWSUIT LO TAKE PLACE BECAUSE SO MANY WOMEN HAVE BEEN LIED TO BECOME PREGNANT WHICH IT IS SUPPOSED TO PREVENT) BECOME HURT BECAUSE OF THIS PRODUCT, LOST MARRIAGES, JOBS AND A FEW WOMEN HAVE LOST THEIR LIVES. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS A FOOD AND DRUG ADMINISTRATION (FDA) HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. FDA REFERENCE NUMBER FDA-2014-N-0736-0949. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING, PERIOD THAT WAS SO BAD WITH PASSAGE OF CLOTS. ALSO, SHE HAD MOVING COILS. THESE EVENTS, SEEN AS MENORRHAGIA AND DEVICE DISLOCATION, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING AND MENSES PATTERN CHANGES ARE FREQUENT IN WOMEN WITH ESSURE IN PLACE. IN THIS CASE, SIX YEARS AFTER INSERTION, SHE EXPERIENCED A PERIOD THAT WAS SO BAD SHE HAD TO GO TO THE EMERGENCY ROOM DUE TO HEAVY BLEEDING WITH PASSAGE OF CLOTS. SHE ALSO HAD SEVERAL OTHER NON-SERIOUS EVENTS. GIVEN COMPATIBLE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSAL RELATIONSHIP BETWEEN MENORRHAGIA AND ESSURE USE IS ASSESSED AS RELATED. REGARDING THE DISLOCATION, ALTHOUGH THE EXACT DATE AND MECHANISM OF THIS EVENT HAVE NOT BEEN PROVIDED, CONSIDERING ITS NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WILL BE REQUIRED (LAPAROSCOPIC BILATERAL SALPINGECTOMY IS SCHEDULED), THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01094	BAYER HEALTHCARE LLC	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0893, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER IN ON UNSPECIFIED DATE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. ADDITIONAL INFORMATION RECEIVED ON RECEIVED ON 20-SEP-2015 (PTC INVESTIGATION RESULT). SHE RECEIVED ESSURE IN THE SPRING OF 2013 AFTER HER DOCTOR RECOMMENDED THIS OVER A TUBAL LIGATION. SHE BECAME PREGNANT IN 2014. AFTER AN EMOTIONAL ROLLER COASTER, HER HUSBAND SHE DECIDED TO TERMINATE THE PREGNANCY. ON AN UNSPECIFIED DATE, DOCTOR REMOVED HER RIGHT FALLOPIAN TUBE AND ESSURE COIL. HE WAS UNABLE TO REMOVE HER LEFT COIL AS IT HAD MIGRATED OUT OF HER LEFT FALLOPIAN TUBE; HE WAS UNSUCCESSFUL IN LOCATING IT. A CT SCAN WAS DONE IN (B)(6) 2015 AND SHOWED THAT THE COIL HAD FRAGMENTED IN 3 PIECES; TWO IN THE FATTY TISSUE AROUND HER SMALL INTESTINES AND ONE IN THE WALL OF HER COLON. SHE IS TRYING TO FIND A SURGEON WHO WILL REMOVE THESE PIECES FROM HER. SYMPTOMS THAT SHE SUFFERED BECAUSE OR ESSURE INCLUDED: MENTAL TOG, SHORT TERM MEMORY LOSS, DEPRESSION, SEVERE ABDOMINAL BLOAT, EXCESSIVE SWEATING, LOSS OF ENERGY, LOSS OF LIBIDO, AND UNWANTED PREGNANCY. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT

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NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS AND LACK OF EFFICACY IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS / LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT. SHE DECIDED TO TERMINATE THE PREGNANCY. ON AN UNSPECIFIED DATE DOCTOR REMOVED HER RIGHT FALLOPIAN TUBE AND ESSURE COIL (MEDICAL DEVICE REMOVAL), BUT HE WAS UNABLE TO REMOVE HER LEFT COIL AS IT HAD MIGRATED OUT OF HER LETT FALLOPIAN TUBE / TWO IN THE FATTY TISSUE AROUND HER SMALL INTESTINES, ONE IN THE WALL OF HER COLON (SEEN AS DEVICE MIGRATION). IT WAS ALSO REPORTED THAT A COIL HAD FRAGMENTED INTO THREE PIECES (SEEN AS DEVICE BREAKAGE). ALL EVENTS, EXCEPT FOR DEVICE BREAKAGE, ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED. ALSO, THE EXACT DATE AND MECHANISM OF DEVICE MIGRATION WERE NOT KNOWN. IT WAS NOT KNOWN WHETHER ESSURE WAS IN-SITU DURING CONCEPTION OR NOT, THUS THE POSSIBILITY OF CONTRACEPTIVE FAILURE CANNOT BE TOTALLY EXCLUDED. BASED ON THE NATURE OF ALL EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS / LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056401	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 1/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS PROVIDED BY MY INSURER AND I AM ALLERGIC TO ASPIRIN. AFTER HAVING THE DEVICE IMPLANTED I BEGIN TO HAVE MIGRAINES, BLURRED VISION, PELVIC PAIN, AND SHARP PAINS IN RIGHT TUBE IF I MOVE TO FAST. I HAVE BEEN TO ER FOR PELVIC PAIN. I HAVE ALSO BEEN TO NEUROLOGIST FOR MIGRAINES AND BEEN PRESCRIBED GLASSES FOR STIGMATISM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056402	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 5/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SIDE EFFECTS HAVE BEEN MULTIPLE AND BEGAN ALMOST IMMEDIATELY FOLLOWING THE PROCEDURE. MOST IMPACTFUL AND PREVALENT RECURRING SIDE EFFECTS INCLUDE SEVERE PAIN DURING OVULATION, EXTRAORDINARILY HEAVY PERIODS WITH INTENSE AND CHRONIC CRAMPING AND PASSING OF BLOOD CLOTS. PELVIC DISCOMFORT - PAINFUL ACHE WITH "HEAVY" FEELING THAT INTENSIFIES WITH ACTIVITY, PULLING OR RIPPING SENSATION IN PELVIC AREA, BACK PAIN THAT WORSENS DRAMATICALLY DURING OVULATION AND MENSTRUATION, MARKED INCREASE IN FATIGUE AND GENERAL ENERGY LEVELS. FREQUENT BLINDING MIGRAINE HEADACHES, MEMORY LOSS/FORGETFULNESS. MARKED ABDOMINAL BLOAT - LOOKS LIKE I'M 3 MONTHS PREGNANT ALL THE TIME EVEN THOUGH I AM FIT AND ACTIVE, WEIGHT GAIN AND DIFFICULTY WITH WEIGHT MAINTENANCE, EVEN WITH NUTRITION AND MEDICAL OVERSIGHT FROM PCP. ABNORMAL PAP SMEARS SHOWING PRECANCEROUS INDICATORS, CHRONIC JOINT PAIN, RESTLESS LEGS., MOOD SWINGS/DEPRESSION MOST NOTABLY, THE HEAVY PERIODS, PAINFUL OVULATION AND PELVIC PAIN HAVE CONSIDERABLY IMPACTED MY LIFE AND ABILITY TO MAINTAIN THE LIFESTYLE, ACTIVITY AND OUTLOOK I HAVE ALWAYS HAD PRIOR TO THE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056403	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 9/24/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FORGOT TO ADD THAT SINCE (B)(6) 2015 I HAVE EXPERIENCING 2 HEAVY MENSTRUAL CYCLES A MONTH, SEEMS LIKE MY HAIR IS FALLING OUT WAY MORE THAN NORMAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056404	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 7/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DEVICE WAS COVERED BY MY INSURANCE BUT I AM ALLERGIC TO NICKEL AND MY DR TOLD ME I WOULD NOT HAVE A REACTION. I HAVE RASHES AND IF I WEAR ANY JEWELRY, NOW I SWELL UP AND GET BLISTER LIKE RASHES. CHRONIC PELVIC PAIN, SEVERE BLEEDING, BACK PAIN, SEVERE BLOATING AND WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056405	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 5/5/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, HEADACHES. ITCHY SKIN ON MY NECK AND CHEST. I HAVE BEEN TELLING MY ENDOCRINOLOGIST FOR A YEAR NOW ABOUT MY FATIGUE. HE DID A FULL PANEL OF BLOOD WORK. COULD NOT FIND ANYTHING WRONG. DID CHANGE MY DOSAGE OF SYNTHROID AND ADDED A T3 SUPPLEMENT. TOLD MY INTERNAL MEDICINE DOCTOR ABOUT MY HEADACHES AND SHE RECOMMENDED MAGNESIUM. IT DID NOT HELP. I TOLD MY DERMATOLOGIST ABOUT MY RED ITCHY SKIN ON MY NECK AND SHE GAVE ME A STEROID CREAM THAT DID NOT WORK. THIS HAS ALL BEEN IN THE LAST 12-18 MONTHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056406	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SERVER HEADACHES, IRREGULAR AND HEAVY BLEEDING SOME TIME TWO WEEK. AT A TIME OFF AND ON. PAIN IN MY PELVIC AREA, CRAMPING. SO TIRED ALL THE TIME. BLOATING AND BOWEL ISSUES. MOODY TENDERNESS IN MY BREAST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056407	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 12/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR BEGAN FALLING OUT (CLUMPS OF 100+HAIRS/DAY), INCREASED FATIGUE, INCREASED SORENESS, PAIN, HEAVY PERIODS 2 YEARS POST IMPLANTATION, IRREGULAR PERIODS/CYCLES, ANEMIA, INTERMITTENT BACK PAIN AND CRAMPING, INTERMITTENT IBS (I EAT A CLEAN DIET), BLEEDING/RECEDING GUMS, ITCHY SKIN (SCALP), SHINGLES OUTBREAKS (AT LEAST 3X/YEAR).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056408	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE HEADACHES, IRREGULAR AND HEAVY BLEEDING, SOME TIMES TWO WEEK. AT A TIME OFF AND ON. PAIN IN MY PELVIC AREA, CRAMPING. SO TIRED ALL THE TIME. BLOATING AND BOWEL ISSUES. MOODY, TENDERNESS IN MY BREAST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056409	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 3/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WOKE UP ONE MORNING AND COULDN'T MOVE OUT OF BED WITHOUT HELP I HAVE BEEN TOLD I SUFFER FROM HERNIATED DISCS ALSO PAIN IN MY HIP LEG AND KNEES BOTTOM OF FOOT GOES NUMB IN (B)(6) I STARTED LASHING OUT AT PEOPLE FOR NO REASON I SEE BLACK SPOTS IN MY RIGHT EYE I HAVE BEEN BLEEDING EVERY TWO WEEKS FOR MONTHS I BLEED AFTER SEX AND IS SOMETIMES PAINFUL LIKE A NEEDLE INSERTED IN ME NO HAVE A CONSTANT DISCHARGE AND SOME TIMES HAS A FOUL ODOR I GET HEADACHE OFTEN AND SOMETIMES MIGRAINES W HER I FEEL LIKE THROWING UP MY PROCEDURE WAS COVERED BY MY INSURANCE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056410	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 12/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD DEPRESSION, ANXIETY, WEIGHT GAIN (ABOUT 15LBS.) AND EXTREMELY ITCHY SKIN. MY DOSES OF ZOLOFT HAS BEEN INCREASED TO 150MG. JUST FINISHED A LARGE DOSE OF PREDNISONE FOR THE ITCHING. ALSO ADDED ATARAX 25MG AS NEEDED FOR ITCHING. I ALSO GET A SHARP PAIN IN MY LOWER RIGHT ABDOMEN DAILY. THE DEVICE WAS PROVIDED AND INSTALLED BY (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056411	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 9/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FOR THE LAST 4 YEARS I HAVE BEEN SUFFERING WITH SHARP AND CONSTANT PAIN IN STOMACH. I AM ALSO DEALING WITH HEAVY PERIODS THAT INCLUDE LARGE CLOTS. I HAVE CONSTANT VAGINAL DISCHARGE. I HAVE PAIN DURING SEX AND LOW LIBIDO. I AM ALSO DEALING WITH MILD DEPRESSION, BRAIN FOG, AND FORGETFULNESS. I HAVE CONSTIPATION AND BOWEL ISSUES. I SUFFER FROM HEART BURN AND ALSO HAVE ITCHY SKIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056412	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 7/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING ESSURE PLACED, I STARTED HAVING HEADACHES, HOT FLASHES, ABDOMINAL PAIN AND IRREGULAR MENSTRUAL CYCLES. I HAD THE HSG TEST DONE TO CONFIRM BLOCKAGE AND THE COIL IN MY LEFT FALLOPIAN TUBE MIGRATED BACK IN GO MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056413	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 1/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE INSERTION WAS HORRIBLE. I WAS AWAKE. THERE WAS A BIT OF DIFFICULTY IN IMPLANTING THE COIL IN MY TUBE. I HAVE AND HAD NO CURRENT ILLNESSES OR MEDICAL CONDITION . THE PROCEDURE WAS AT MY EXPENSE. NO LAB WAS DONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056414	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED IN 2008. NO PROBLEMS UP UNTIL ABOUT A YEAR AND HALF AGO. HEAVY MENSTRUAL PERIODS, BACKACHES, ANXIETY, PANIC ATTACKS, HAIR LOSS, NUMBNESS IN LEGS, FATIGUE, MOOD SWINGS, DEPRESSION, LOWER ABDOMINAL PAIN, AND SEVERE BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056415	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 6/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALL OF THESE HAVE BEEN GOING ON SINCE HAVING ESSURE PLACED IN (B)(6) 2012. MIGRAINES, NO MEDS WILL HELP, LAST USUALLY A DAY OR TWO, SHARP PAINS ON RIGHT SIDE AROUND HIP BONE AREA. MOOD SWINGS. TIRED MOST OF THE TIME. EXPANDED ABDOMEN BLOATED. SOME TIMES EXTREME BLOOD ON CYCLE AND SOMETIMES NOT VERY MUCH AT ALL. HUGE CLOTS AT TIMES THE SIZE OF GOLF BALLS AND A FEW THAT WERE THE SIZE OF A BASEBALL. UNEXPLAINED FEVERS BEFORE STARTING CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056416	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 7/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS TALKED INTO THIS BECAUSE I HAVE A HUGE FEAR OF SURGERY. THEY SAID THIS IS PERFECT FOR ME. I WENT IN THINKING IT WAS PAINLESS AND WOULDN'T AFFECT MY MENSTRUAL CYCLE. WAS WRONG; MY HUBBY COULD HEAR ME SCREAM FROM THE ROOM. IT WAS PAINFUL AND FOR THE RIGHT TUBE, THEY HAD TO USE TWO KITS. THEY GAVE ME A SHOT OF DEPO AND SENT ME HOME. DURING THE THREE MONTHS, I SUFFER FROM CRAMPS THAT WERE HORRIBLE, NO BLEEDING. AFTER THREE MONTHS, THEY CHECKED, SAID I WAS BLOCKED FOR THE PAST THREE YEARS. I'VE HAD SEVERE BLEEDING, CRAMPING, FATIGUE, HOT SWEATS, LOW PELVIS PAIN, AND PAIN DURING INTERCOURSE; BACK PAIN, NAUSEA AND THE LIST CONTINUES. IF I KNEW THIS, I WOULDN'T HAVE GOTTEN IT DONE. I'M IN AND OUT OF ER ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056417	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 6/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, HAIR LOSS, RANDOM MENSTRUAL PERIODS, ANXIETY, VERTIGO, MIGRAINES, WEIGHT GAIN, BACTERIAL VAGINOSIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056418	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 9/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN,HEAVY MENSTRUAL AND CRAMPING SPOTTING AFTER SEX, INSOMNIA, BLOATING, ALWAYS SICK WITH FLU LIKE SYMPTOMS, BREAST TENDERNESS, ACHES AND PAINS IN JOINTS AND MUSCLES, LOSS OF SLEEP EXTREME FATIGUE, ALL OF THESE THINGS HAVE NO PRIORS TO ESSURE. ESSURE WAS PROVIDED BY INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056419	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 5/16/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #(B)(4). SOON AFTER, I HAD IT DONE, I EXPERIENCE PAIN IN MY TUBES. SINCE THEN, I CONSTANTLY GET SHARP PAIN IN MY LEFT ABDOMEN. I HAD AN ULTRA SOUND DONE AT THE ER AND I WAS COVERED BY MY INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056420	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 6/6/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEFORE I GOT THE ESSURE PROCEDURE DONE I FELT FINE,I HAD NORMAL PERIODS AND NONE OF MY OTHER PROBLEMS ILL BE TELLING YOU ABOUT. AFTER I WOKE UP FROM GETTING ESSURE IMPLANTED I HAD A VERY BAD MIGRAINE THAT WOULD NOT GO AWAY...IT CONTINUED FOR DAYS THEN STOPPED AND COME BACK A FEW DAYS LATER. ALSO AFTER GETTING ESSURE I BLEED HEAVY FOR 2 WEEKS THEN STOPPED AND DIDN'T GET MY PERIOD FOR MONTHS THEN I WOULD GET IT BUT IT BECAME VERY HEAVY AND IRREGULAR. MY PERIODS NEVER HAVE HURT SO BAD OR BE SO HEAVY. I CONSTANTLY HAVE CHRONIC PELVIC PAIN NON STOP THAT GOES INTO MY LOWER BACK. I HAVE HAD A MASSIVE AMOUNT OF WEIGHT GAIN SINCE I HAD ESSURE PUT IN. MY WEIGHT GAIN I JUST AROUND MY STOMACH AREA. I CHANGED MY EATING HABITS AND STARTED TO EXERCISE NOTHING SEEMS TO HELP. ALSO IT HURTS TO HAVE INTERCOURSE WITH MY SIGNIFICANT OTHER. IF I TRY IT IS VERY PAINFUL AND I START TO BLEED. WITH ALL THESE SIDE EFFECTS MY DOCTOR THOUGHT IT WOULD BE A GOOD IDEA TO REMOVE ESSURE. MY DOCTOR THAT IMPLANTED THE DEVICE DID REMOVE ESSURE BUT HE WAS EDUCATED ON HOW TO REMOVE IT THE RIGHT WAY SO NOW THERE ARE PIECE OF ESSURE STILL IN MY TUBES WHICH IS CAUSING MY SIDE EFFECTS TO REMAIN. I AM HAVING A DIFFICULT TIME FINDING SOMEONE TO REMOVE THE REMAINING FRAGMENTS OF ESSURE SO MY SIDE EFFECTS GO AWAY. I WAS TALKED INTO GETTING THIS DEVICE BY MY EX-HUSBAND THAT WAS ABUSIVE IF IT WASN'T FOR THAT I WOULD OF NEVER GOT THIS DEVICE. IT IS CAUSING ME A LOT OF PAIN IN MANY DIFFERENT WAYS AND RUINING MY BODY AS WELL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056421	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 6/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, DAILY MIGRAINES, HEAVY MONTHLY PERIODS, SHARPS PAINS AT SITE OF COILS FEELS LIKE THEY HAVE MOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056422	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 6/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEAKY BLADDER, HEAVY PERIODS, SEVERE LOW ABDOMINAL CRAMPING, MOOD SWINGS, EXCESSIVE FATIGUE, PAINFUL INTERCOURSE, ABDOMINAL BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056423	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 8/27/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BECAME PREGNANT 6 MONTHS AFTER IMPLANTATION. I HAVE HAD REMOVAL OF ONE IMPLANT THAT MIGRATED TO THE OUTSIDE OF MY UTERUS. I ALSO HAD A BOWEL ADHESION. I HAVE ONGOING BODY ACHES AND PAINS, UNEXPLAINED PANCREAS ISSUES, INCREASED ALLERGIES, BELLY BLOAT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056424	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 12/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ESSURE WAS PUT IN BY DR. (B)(6). EVER SINCE I HAD THIS PROCEDURE DONE, I HAVE HAD SEVERE PELVIC PAIN, SEVERE CRAMPS, HEAVY HEAVY BLEEDING WHEN ON MY PERIOD, LARGE BLOOD CLOTS, I'M ALWAYS EXHAUSTED, CAN'T SLEEP VERY MUCH. IT'S HARD FOR ME TO FALL ASLEEP. I'VE NEVER REALLY HAD ANY CRAMPS WHILE ON MY PERIOD BUT NOW IT FEELS LIKE SOMEONE IS STABBING ME. I GO THROUGH A SUPER TAMPON EVERY TEN MINUTES AND MY PERIOD USED TO LAST ABOUT 5-7 DAYS BUT NOW IT LASTS ABOUT A WEEK AND A HALF. I'VE NEVER HAD ANY BLOOD CLOTS EITHER BUT NOW I DO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056425	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 9/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH THE MEDICAL DEVICE IMPLANT CALLED ESSURE ON APPROXIMATELY, (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY (B)(4), FORMALLY BY (B)(4). AT THIS TIME, I DO NOT HAVE THE INFORMATION CONTAINING THE LOT NUMBER OR MODEL NUMBER FOR THE ESSURE DEVICE USED DURING THE PROCEDURE WHEN THE ESSURE WAS IMPLANTED IN BOTH OF MY FALLOPIAN TUBES, (BOTH LEFT AND RIGHT TUBES). THIS INFORMATION WAS NEVER PROVIDED TO ME BY THE PHYSICIAN WHO PERFORMED THE PROCEDURE, IN-OFFICE, DURING MY 6 WEEK FOLLOW UP, POSTPARTUM APPOINTMENT. THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER, I DO NOT HAVE THE EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED APPROXIMATELY (B)(6) 2010. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: HEAVY BLEEDING; IRREGULAR MENSES; MENSES LASTING ON AVERAGE BETWEEN 25-45 DAYS; SEVERE CRAMPING; PELVIC PAIN; PAIN USING TAMPONS; PAINFUL INTERCOURSE; LACK/LOSS OF SEX DRIVE; JOINT PAIN; EXCESSIVE WEIGHT GAIN; SEVERE BLOATING; EXCESSIVE SLEEPINESS AND FATIGUE; HEADACHES AND MIGRAINES; MEMORY/BRAIN FOG (FORGETFULNESS, INABILITY TO CONCENTRATE, FOCUS, AND/OR STAY ON TASK); ANXIETY; DEPRESSION; IRRITABILITY; SWELLING AND INFLAMMATION IN HANDS, FEET, AND LEGS; WEAK TEETH AND/; INCREASED CAVITIES, BROKEN TEETH, RAPID TOOTH DECAY, LOSS OF MULTIPLE TEETH, SEVERE TOOTHACHES, AND NERVE PAIN IN JAW DUE TO RAPID ABSCESSES OF INFECTED TEETH AND/; SINCE 2011, I HAVE HAD 4 TEETH PULLED, AND 6 TEETH HAVE CRACKED OR HAVE BROKEN; FOR A TOTAL OF 10 TEETH WITH SERIOUS ISSUES AND COMPLICATIONS. I HAVE BEEN SEEN BY NINE (9) PHYSICIANS. I HAVE BEEN DIAGNOSED WITH FOLLOWING CONDITIONS: ENDOMETRIOSIS, ADENOMYOSIS, THICKENED ENDOMETRIAL TISSUES WHILE USING CONTINUOUS BIRTH CONTROL FOR THE MANAGEMENT OF PERIODS (I.E., CONTINUOUS USE OF NUVA RING, CHANGED AND REPLACED RING EVERY 28 DAYS), OVARIAN CYSTS,

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MENORRHAGIA, IRREGULAR MENSES, COLITIS, ADULT ADD, CHRONIC MIGRAINES/HEADACHES, AND CHRONIC JOINT PAIN, TOOTH EXTRACTIONS TO MULTIPLE TEETH, INCREASED AND RAPID TOOTH DECAY, AND ABSCESSED TEETH/NERVES. I HAVE HAD THE FOLLOWING SURGERIES DUE TO ESSURE: AND;C (DILATION AND CURETTAGE) AND LAPAROSCOPIC GYNECOLOGICAL (EXPLORATORY) SURGERY AT THIS TIME, THE ESSURE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056426	BAYER	9/24/2015	9/24/2015

Event Information:

Event Date (B3): 6/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY SIDE EFFECTS ARE AS FOLLOWS: CRAMPING, SHARP/STABBING PELVIC PAIN, HOT FLASHES, LOSS OF LIBIDO, BLEEDING/SPOTTING AFTER INTERCOURSE, PAINFUL PERIODS, PAINFUL INTERCOURSE, LONG MENSTRUAL CYCLES, ABDOMINAL FLUTTERING, SEVERE BLOATING, NAUSEA/VOMITING, DAILY MIGRAINES WITH VISION CHANGES, DIZZINESS, BRAIN FOG, ANXIETY, FORGETFULNESS, SKIN ITCHING, WEIGHT GAIN, BP CHANGES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056667	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 4/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 4/15/2010
Explant Date (E7): 4/21/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED IN EARLY 2010. BLED FOR 6 MONTHS AFTER. QUALITY OF LIFE GREATLY DIMINISHED DUE TO CHRONIC PELVIC PAIN, HEAVY, PAINFUL MENSTRUAL PERIODS. PAINFUL OVULATION. HAD UTERINE ABLATION COMPLETED WITHOUT RELIEF. TOTAL HYSTERECTOMY WITH REMOVAL OF OVARIES ON (B)(6) 2015. CONFIRMED ENDOMETRIOSIS IN PELVIC AND ABDOMINAL REGION VIA PATHOLOGY REPORT. ALL PROBLEMS EITHER FIRST APPEARED OR BECAME DRASTICALLY WORSE AFTER DEVICE PLACEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056669		9/24/2015	10/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN IN THE EMERGENCY ROOM MULTIPLE TIMES DUE TO PAIN FROM MY ESSURE COIL. THE PAIN REGULARLY INTERRUPTS MY DAILY FUNCTION AND ACTIVITIES. THE PAIN IS IMMENSE AND INDESCRIBABLE. I HAVE PAIN DURING INTERCOURSE NOW ALSO. THE PAIN IS ALWAYS THERE AND AT TIMES FLARES UP SO BAD THAT IT IS UNBEARABLE. NOTHING HAS COME BACK ABNORMAL FROM ANY TESTS SUGGESTING ANY OTHER HEALTH ISSUES. I AM COMPLETELY HEALTHY ASIDE FROM THIS ONE ISSUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056670	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 8/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PUT IN AROUND 3 YEARS AGO. I HAVE THE HSG TEST DONE AT MY 3 MONTH MARK AND EVERYTHING WAS PERFECT. THIS YEAR I STARTED HAVING PAIN IN MY SIDE AND MY DR RECOMMEND THAT I HAVE A HYSTERECTOMY. COME TO FIND OUT MY ESSURE COIL HAD MIGRATED OUT OF MY TUBE, INTO MY UTERUS AND WRAPPED BACK AROUND TO MY TUBE. IT WAS ALL TWISTED UP. THIS SHOULD BE TAKEN OFF THE MARKET. IT'S NO TELLING HOW MANY OTHERS THIS IS HAPPENING TO AND THEY DON'T KNOW IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056672	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 1/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/8/2010
Explant Date (E7): 1/28/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) OF 2010 UNDER THE ADVICE OF MY DOCTOR WHO TOLD ME IT WAS SAFE, NON INVASIVE AND 100 PERCENT EFFECTIVE WITH NO SIDE EFFECTS REPORTED. AFTER I GOT THE IMPLANT, I NOTICED A LOT OF WEIGHT GAIN AND A STRANGE METALLIC TASTE IN MY MOUTH AS WELL AS ODD PAINFUL PERIODS. I MENTIONED THIS TO THE DOCTOR WHICH WAS QUICKLY STATED DID NOT HAVE TO DO WITH THE IMPLANT. HOWEVER, IN (B)(6) 2014, I FOUND OUT I WAS PREGNANT (I HAD SWITCHED DRS) AND FOUND OUT IT WAS ECTOPIC. I WANTED TO WAIT BECAUSE I AM COMPLETELY PRO LIFE AND WANTED TO GIVE MY BABY A CHANGE HOWEVER UNDER THE STRICT ADVICE OF MY NEW DR, WE UNDERWENT SURGERY. ACCORDING TO MY DR AND THE PATHOLOGY PAPERS, MY PREGNANCY HAD RUPTURED AND BOTH MY TUBES HAD TO BE REMOVED. I WAS DEVASTATED. I DID NOT EXPECT ANOTHER CHILD AND WASN'T PLANNING ON IT, HOWEVER I WAS OVERJOYED WHEN I FOUND OUT I WAS EXPECTING. HOWEVER, DUE TO THIS PRODUCT I LOST MY BABY AND ALMOST MY LIFE. I AM STILL DEPRESSED ABOUT THIS AND HAVE LOST MOST INTIMACY FEELING BECAUSE OF MY DEPRESSION. THIS EXPERIENCE HAS CHANGED MY LIFE AND I PRAY NO ONE ELSE HAS TO GO THROUGH WHAT I WENT THROUGH. I AM STILL NOT SURE IF THEY ARE STILL IN MY BODY OR NOT, SO I LIVE WITH FEAR EVERYDAY THAT THEY HAVE MIGRATED SOMEWHERE THAT CTS CAN'T FIND.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056673	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 12/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627755

Single Use: *
Implant Date (E6): 10/15/2010
Explant Date (E7): 12/23/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED, THEN FOUND OUT I HAVE NICKEL AND TITANIUM ALLERGY, UVEITIS, FIBROMYALGIA, PELVIC PAIN, SWELLING, DEVICE MIGRATION, ABDOMINAL PAIN AND FIBROSIS CONFIRMED VIA LAB RESULTS FROM TISSUE REMOVED WITH ESSURE REMOVAL. I HAVE EXPERIENCED PANIC ATTACKS SINCE I GOT THEM, MIGRAINES, HEAVY BLEEDING, JUST AWFUL AWFUL AWFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056674	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2013 I HAD THE PRODUCT ESSURE PLACED. A YEAR LATER I BEGAN SHOWING SIGNS OF MS. I HAVE DAILY NUMBNESS AND TINGLING IN MY ARMS AND LEGS AND I AM EXTREMELY FATIGUED. I HAVE FREQUENT AND HEAVY PERIODS AND I CAN TASTE NICKLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056675	BAYER / CONCEPTIOUS	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 4/12/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6): 4/12/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT ESSURE PLACE AROUND (B)(6) 2010. IMMEDIATELY AFTER HAVING IT PLACES I WAS EXPERIENCING CRAMPS WHICH I WAS TOLD WOULD BE NORMAL. EVER SINCE ITS BEEN PLACED MY PERIODS HAVE BEEN COMPLETELY OUT OF WHACK. I DIDN'T HAVE A PERIOD AT ALL FOR OVER 9 MONTHS AFTER HAVING THE DEVICE IMPLANTED. I HAVE BEEN HOSPITALIZED A FEW TIMES FOR "STOMACH BUGS" YET NOTHING CAME BACK THROUGH TESTS. I WENT FROM HAVING NO PERIODS TO TOO MANY PERIODS AND THERE WERE TIMES WHERE I BLED FOR 2+ WEEKS. I AM CURRENTLY BEING TREATED FOR A HORMONE IMBALANCE YET MY HORMONES WERE NEVER TESTED, INSTEAD I WAS PUT ON BIRTH CONTROL. SINCE I'VE STARTED THE PILL, MY PERIODS HAVE REGULATED BUT THE FATIGUE AND BODY ACHES HAVE GOTTEN WORSE. I WISH I WOULD HAVE BEEN WARNED ABOUT THE SIDE EFFECTS. PLEASE GET THIS DEVICE OFF THE MARKET!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056676	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 9/14/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

BEFORE MY PERIOD, I GET MASSIVE CRAMPING, I HAVE IRREGULAR PERIODS, THEN ON SOME DAYS I WILL HAVE A ODD DISCHARGE (IT'S YELLOW/GREEN AND SMELLS). RIGHT AFTER THE PROCEDURE, WHAT EVER I ATE WOULD BE A VERY LOOSE STOOL. THAT WENT ON FOR SEVERAL MONTHS. I HAVE NO ENERGY TO COMPLETE THINGS THROUGH THE DAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056699	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED FOR PERMANENT BIRTH CONTROL. ONE OF MY COILS IS JUST GONE. THEY TOLD ME AT MY FOLLOW UP APPOINTMENT. WHEN I ASKED WHERE IS THE COIL THEY COULD NOT TELL ME. I HAVE SINCE HAD BAD MENSTRUAL CYCLE BLEEDING A LOT. HAVE HAD PAIN/VIBRATION IN ABDOMEN AREA. I HAD THEM PLACED (B)(6) 2013, AND EVER SINCE I HAVE BEEN BEYOND TIRED, AND GAINED (B)(6) POUNDS. WHICH IS OUT OF THE ORDINARY FOR ME. I HAVE BEEN DIZZY AS WELL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056726	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 6/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6). ON (B)(6) 2012, I RECEIVED THE ESSURE BIRTH CONTROL AND I HAVE HAD PROBLEMS WITH IT SUCH AS: PELVIC PAIN, BAD HEADACHES, NAUSEA, THROWING UP FOOD, HOT FLASHES, HEAVY BLEEDING, BLOATING, AND THINNING OF THE HAIR. IT GETS SO BAD THAT IT WILL PUT ME IN THE BED FOR 2-3 DAYS AT A TIME, I HAVE CALLED MY SON TO MY BEDSIDE AND TOLD HIM WHAT FAMILY MEMBER TO LIVE WITH IF SOMETHING HAPPENS TO ME. THIS HAS BEEN A NIGHTMARE!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056727		9/24/2015	10/1/2015

Event Information:

Event Date (B3): 9/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE AN ESSURE IMPLANT FOR THE LAST 4 YEARS. PERIODS ARE WORSENING, DAILY HEADACHES AND RANDOM OUTBREAKS OF HIVES, AND PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056728	BAYER CO	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 10/20/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE INSERTED INTO BOTH OF MY FALLOPIAN TUBES IN 2009, BEGAN TO HAVE SEVERE ABDOMINAL, PELVIC, HIP, LOWER BACK PAIN, BLOOD CLOTTING, SEVER OVARIAN PAIN, BURNING, STABBING, CONSTANT ABDOMINAL PAIN, BLOATING, HEADACHES, HORMONAL IMBALANCES, SEVER PMDD, SKIN CHANGES, ANEMIA, UNABLE TO REGULATE BODY TEMPERATURE, COMPLETE LOSS OF LIBIDO, COGNITIVE DIFFICULTIES, DEPRESSION (OBVIOUSLY).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056729	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE IMPLANTED MY OVERALL HEALTH HAS BEEN ON A SPIRAL DOWN FALL. I AM ONLY 28 YEARS OLD AND MOST DAYS DAY TO DAY CHORES SEEM ALMOST IMPOSSIBLE. I SUFFER FROM MIGRAINE SEVERAL TIMES A WEEK, HORRENDOUS BACK PAIN, SHARP STABBING ABDOMINAL PAIN, EMBARRASSING HAIR LOSS, IT HAS CAUSED WEIGHT GAIN, JOINT PAIN, FATIGUE, AND THE LIST GOES ON. I AM ALLERGIC TO NICKEL AND ITS IN THIS DEVICE, THE WORST PART ABOUT THAT IS I SPECIFICALLY ASKED MY DOCTOR WHAT KIND OF METAL IT WAS MADE OF FOR THIS VERY REASON AND I WAS LIED TO, HE TOLD ME SURGICAL STEEL. THERE ARE SO MANY INNOCENT WOMEN SUFFERING FROM THIS DEVICE, WE NEED OUR LIVES BACK!!! I HAVE DAYS WHERE GETTING OUT OF BED ALONE IS A TASK, ALL BECAUSE OF THESE IMPLANTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056730	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 1/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/11/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I OPTED FOR TUBAL LIGATION. WAS TOLD THE ESSURE WAS THE WAY TO GO WITH NO CUTTING AND WOULD BE ABLE TO RETURN TO NORMAL ACTIVITIES THE NEXT DAY. WELL THIS WAS SOMEWHAT TRUE BUT I NOW HAVE PAINFUL PERIODS WHERE I AM BENT OVER IN PAIN DU TO SEVERE CRAMPING RIGHT BEFORE, DURING AND RIGHT AFTER MY CYCLE. I HAVE LEG, BACK AND FOOT PAIN THAT COMES AND GOES BUT IT AT IT STRONGEST LEVEL OF PAIN. DURING MY CYCLE I HAVE HAD VISION CHANGES, HEAVIER CYCLES AND ALSO PAIN DURING INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056732	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 11/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/12/2013
Explant Date (E7): 10/14/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE IMPLANTED IN (B)(6) OF 2013, I HAVE SUFFERED FROM CONTINUAL ABDOMINAL PAIN AND BLOATING. I FINALLY HAD MY RIGHT FALLOPIAN TUBE AND OVARY REMOVED IN (B)(6) OF 2014. THE PAIN IS STILL PRESENT AND I AM IN THE PROCESS OF DISCUSSING A COMPLETE OR PARTIAL HYSTERECTOMY WITH MY DOCTOR. WE ARE HOPING TO AT LEAST BE ABLE TO KEEP MY LEFT OVARY. I HAVE LIVED IN PAIN FOR NEARLY TWO YEARS AFTER THIS WAS IMPLANTED. I HAVE BEEN TO NUMEROUS DOCTORS AND TO THE EMERGENCY ROOM WHEN THE PAIN GET TO BE MORE THAN I CAN HANDLE. STILL HAVE IMPLANT IN LEFT FALLOPIAN TUBE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056733		9/24/2015	10/1/2015

Event Information:

Event Date (B3): 10/5/2001 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/5/2001
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2010 I HAD THE ESSURE PROCEDURE DONE. SINCE THEN I HAVE BEEN TO MANY DIFFERENT DOCTORS AND SPECIALISTS TRYING TO DETERMINE THE CAUSE OF MY PAIN. THEY DO NOT SEE ANYTHING WRONG WITH ME. THEY HAVE NEVER CONSIDERED THE FACT THAT THE ESSURE DEVICE COULD BE THE CAUSE OF MY MANY PROBLEMS. MY MOST PAINFUL PROBLEM IS THE DAILY CRAMPING THAT I FEEL. IT IS NOT BASED ON MY MENSTRUATION CYCLE BECAUSE IT OCCURS EVERY SINGLE DAY ALL DAY. I WAS TOLD THAT I HAVE SPASMS OF MY PELVIC FLOOR MUSCLES. I DID PHYSICAL THERAPY BUT IT WAS A TEMPORARY CALMING OF THE MUSCLES AND THEN IT WOULD START UP AGAIN. ALONG WITH THAT I HAVE EXTREMELY PAINFUL PERIODS AND I SPOT BROWN BLACK BLOOD AT ODD TIMES OF THE MONTH. MY STOMACH IS SWOLLEN EVEN THOUGH (B)(6). I HAVE ALSO BEEN TOLD BY THE DOCTOR THAT MY UTERUS IS ENLARGED AND IT IS PAINFUL WHEN FELT DURING AN EXAMINATION. AT ONE POINT I HAD TO GO TO THE EMERGENCY ROOM FOR EXCESSIVE VAGINAL BLEEDING AND WAS DOUBLED OVER WITH CRAMPS AND WAS TOLD THAT I HAD HEMORRHAGIC BLEEDING AND THE REASON WAS UNKNOWN. I HAVE BEEN TO MANY DOCTORS AND SPECIALISTS AND THEY REALLY DON'T KNOW WHAT TO DO WITH ME. I HAVE SPENT THOUSANDS OF DOLLARS ON THE APPOINTMENTS, TESTS, PHYSICAL THERAPY. I HAVE MISSED MANY DAYS OF WORK DUE TO THE PAIN AND THE DOCTOR APPOINTMENTS AND TESTS. I HAVE SEVERAL ULTRASOUNDS DONE AS WELL AS A BIOPSY. THE DOCTORS HAVE SAID THAT THEY DO NOT SEE ANYTHING THAT COULD BE CAUSING MY PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056734	BAYER	9/24/2015	10/1/2015

Event Information:

Event Date (B3): 12/26/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/26/2007
Explant Date (E7): 12/28/2011
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WENT IN TO SEE MY OBGYN TO DISCUSS CHOICES OF PERMANENT BIRTH CONTROL DUE TO ME NOT WANTING ANY MORE CHILDREN. I HAD BEEN ON OTHER BIRTH CONTROL AND WAS TIRED OF GETTING THE SHOTS AND WANTED SOMETHING MORE PERMANENT. SO AFTER MEETING WITH MY OBGYN I DECIDED THE ESSURE WOULD BE MY CHOICE I WAS TOLD IT WAS SAFE I DID NOT NEED SURGERY IT WOULD BE DONE IN THE DOCTORS OFFICE AND ALL I WOULD NEED WAS PAIN KILLERS AN HOUR BEFORE MY PROCEDURE. THE DAY OF MY PROCEDURE (B)(6) 2011 IS SOMETHING I WILL NEVER FORGET THE PROCEDURE WAS SO UNCOMFORTABLE AND PAINFUL THE DOCTOR EVEN OFFERED TO STOP AND FOR ME TO COME IN FOR THE SECOND COIL. I HAD CRAMPING FOR SEVERAL DAYS WHICH I TOOK IBUPROFEN FOR COMFORT. I STAYED ON MY CURRENT BIRTH CONTROL FOR THE NEXT THREE MONTHS AND THEN IN FOR THE DYE AND X-RAY TEST TO MAKE SURE THAT THE PROCEDURE TOOK AND THAT SCARE TISSUE HAD BUILD UP IN MY FALLOPIAN TUBES TO PREVENT PREGNANCY. I RECEIVED CONFIRMATION A WEEK OR SO AFTER THE TEST THAT MY FALLOPIAN TUBES WERE BLOCKED AND THAT I COULD NOT GET PREGNANT. UNFORTUNATELY I CONTINUED TO HAVE CRAMPING AND PAIN ESPECIALLY DURING MY MENSTRUAL CYCLE. I CONTINUED TO DEAL WITH IT SINCE I FIGURED IT WAS BETTER THAN GETTING PREGNANT, I WAS ALSO TOLD THAT IT WOULD GET BETTER. TO MY SURPRISE IN (B)(6) OF 2011, I CAME UP PREGNANT AND SCARED. WE WAS NOT IN A POSITION TO BE READY FOR ANOTHER CHILD THAT IS THE REASON I TOOK STEPS TO PREVENT ME FROM BECOMING PREGNANT. I CHOSE TO HAVE AN ABORTION SHORTLY AFTER FINDING OUT I WAS EXPECTING AND ALSO DECIDED TO GO BACK ON BIRTH CONTROL FOR ADDED PROTECTION. I CHOSE THE 10YR IUD WHICH ENDED UP UNCOMFORTABLE AND CAUSE CRAMPING AND MENSTRUAL ISSUES SO I ASKED TO BE SWITCH TO THE MORENA IUD, WELL A COUPLE OF MONTHS AFTER THAT I STARTED TO HAVE SHARP CALVE PAIN IN MY RIGHT CALVE AND WENT INTO THE URGENT CARE TO

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FIND OUT I MIGHT HAVE A BLOOD CLOT I WAS TOLD TO GO DIRECTLY TO THE ER TO HAVE FURTHER TESTING DONE. I WAS ON BLOOD THINNERS FOR SIX MONTHS WAS TOLD THAT BIRTH CONTROL WAS NO LONGER A OPTION DUE TO THE BLOOD CLOT AND THAT THEY ALSO FOUND OUT THAT I AM HYPERCOAGULABLE WHICH MEANS I HAVE A PARTIAL GENE FOR CLOTTING WHICH MAKE IMPOSSIBLE FOR ME TO TAKE ANYTHING WITH HORMONES IN IT. I MET WITH A HEMATOLOGIST TO GO OVER BLOOD TEST RESULTS AN SHE TOLD ME I NEEDED TO LOSE WEIGHT, STOP SMOKING AN HAVE THE MORENA REMOVED IMMEDIATELY AN THAT IF I EVER GET ANOTHER BLOT CLOT I WOULD HAVE TO BE ON BLOOD THINNERS FOR THE REST OF MY LIFE. I STOPPED SMOKING COLD TURKEY THAT SAME DAY AND MADE AN APT TO SEE MY OB DOCTOR. SO AFTER MEETING WITH MY OBGYN DOCTOR I DECIDED THAT I WOULD SCHEDULE TO HAVE MY FALLOPIAN TUBES REMOVED THAT FOLLOWING (B)(6) 2011. SO THREE MONTH AFTER FINISHING MY BLOOD THINNERS I WAS PUT UNDER WHICH WHAT I WAS TRYING TO PREVENT SINCE I AM SCARED OF BEING PUT TO SLEEP. THE SURGERY WENT WELL HOWEVER WHEN I WOKE UP MY DOCTOR AS WELL AS A REPRESENTATIVE FROM ESSURE WAS AT MY BED SIDE. I WAS INFORMED THAT THE LEFT COIL HAD PUSHED ITS WAY OUT OF THE TUBE AN WAS HANGING ON THE OUTSIDE AND THAT THE RIGHT COIL HAD PUSHED ITS WAY OUT OF THE TUBE AND WAS HANGING ON THE OUTSIDE AND THAT THE RIGHT COIL HAD ALSO PUSHED ITS WAY OUT AND WAS STUCK ON THE OUTSIDE OF MY UTERUS I WAS GIVEN PICTURES AND SENT HOME TO RECOVER. I HAVE STRUGGLED WITH HEAD ACHES, AND NEVER ENDING HOT FLASHES MOOD SWINGS AND SEVERE CRAMPS ESPECIALLY DURING MY MENSTRUAL CYCLE. I TRIED REPORTING AND TALKING WITH LAWYERS AND WAS TOLD THERE WAS NOT ANYTHING I COULD DO. I FEEL THAT THIS IS NOT A SAFE FORM A BIRTH CONTROL AND SHOULD BE TAKEN OFF THE SHELF SO THAT NO OTHER WOMAN HAS TO ENDURE ANY SUFFERING TO THIS PRODUCT. AT THE TIME OF ALL OF THIS I WAS HEALTHY AND NOT ON MEDICATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01095	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2011
Explant Date (E7): 3/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0901, AWARENESS DATE 29-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. IT WAS REPORTED THAT ABLATION WAS DONE AT THE SAME TIME OF INSERTION. SHE THOUGHT THAT SHE SUFFERED FROM NICKEL ALLERGY; SHE SUSPECTED THAT SHE DEVELOPED IT FROM HAVING METAL IN HER BODY. SHE ALSO STATED THAT HER PERIOD WOULD ARRIVE EVERY 17-20 DAYS AND SHE GOT PERIOD FOR 3 WEEKS STRAIGHT (SHE WAS PUT ON BIRTH CONTROL PILL TO REGULATE HER PERIOD). SHE ALSO HAD UTERINE FIBROIDS (HYSTERECTOMY WAS RECOMMENDED), MIGRAINES DURING EVERY PERIOD, EXTREME BLOATING, SHE COULD NOT LOSE WEIGHT. SHE WAS TIRED, CRABBY, WAS DIAGNOSED WITH PMDD (PREMENSTRUAL DYSPHORIC DISORDER) AND INCREASED ANTI-DEPRESSANTS 4X USUAL DOSE. ON (B)(6) 2015 ESSURE WAS REMOVED AND HER STOMACH IMMEDIATELY WENT DOWN 4 INCHES. SHE HAD NO MORE MIGRAINES AND SHE FELT LIKE HER AGAIN, WITH SO MUCH MORE ENERGY. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME BLOATING (INTERPRETED AS ABDOMINAL DISTENSION). SHE UNDERWENT ESSURE REMOVAL APPROXIMATELY 3 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL BLOATING MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE LACK OF A PLAUSIBLE ALTERNATIVE EXPLANATION AND CONSIDERING THAT THE EVENT WAS RESOLVING AFTER ESSURE REMOVAL, A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. SINCE ESSURE REMOVAL WAS REPORTED, THIS CASE WAS REGARDED AS INCIDENT (REQUIRED INTERVENTION IMPLIED). SINCE NO PRODUCT WAS RETURNED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01096	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2009
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0015, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED DATE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. FIRST ALL SEEMED GOOD; OVER TIME SHE STARTED HAVING PELVIC PAIN FREQUENTLY. THEN SHE STARTED NOTICING SHE WOULD BLEED AFTER INTERCOURSE AND IT WAS PAINFUL TOO. SHE LOST HER LIBIDO AND WAS TIRED ALL THE TIME. THERE WAS NOT A DAY WHEN SHE WOULD NOT COMPLAIN OF PELVIC PAIN, HEADACHES OR NAUSEA. SHE WOULD GO TO THE DOCTOR AND THEY NEVER FOUND ANYTHING WRONG. IN JANUARY (2015) SHE HAD A HYSTERECTOMY AND RIGHT AWAY SHE STARTED FEELING BETTER. ABOUT A WEEK AFTER SURGERY SHE NO LONGER FELT NAUSEA AND IT WAS VISIBLY NOTICEABLE THAT HER INFLAMMATION HAD GONE AWAY. IT HAS BEEN NOW 6 1/2 MONTHS SINCE THE HYSTERECTOMY AND BILATERAL SALPINGECTOMY. SHE SEEMS TO HAVE MORE ENERGY AND HARDLY TAKES NAPS ANYMORE AND HER LIBIDO IS BACK. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH

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INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. A HYSTERECTOMY WAS PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER HAD A HYSTERECTOMY AND BILATERAL SALPINGECTOMY PERFORMED. BASED ON THE NATURE OF THE EVENT AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE ADDED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01097	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 4/20/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-0929, AWARENESS DATE: 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER ON UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE HAD ESSURE IMPLANTED AFTER HER (B)(6) WAS BORN AFTER HER 6 WEEK APPOINTMENT, SHE WAS NOT GIVEN ANY LIST OF COMPLICATIONS AND THE DOCTOR SAID THERE WERE NO SIDE EFFECTS. SHE WAS OKAY FOR PROBABLY THE FIRST YEAR AFTER THAT SHE STARTED SUFFERING FROM HEAVY BLEEDING, TWO PERIODS A MONTH EACH LASTING A FULL WEEK. SHE HAD TO USE A HEAVY TAMPON AND AN OVERNIGHT PAD AT THE SAME TIME AND CHANGE EVERY 2 HOURS. SHE ALSO SUFFERED FROM HEADACHES, HEAVY CRAMPING, DARK LINES UNDER HER EYES AND COLD AND HOT SWEATS. SHE EVEN THOUGHT SHE WAS GOING THROUGH DEPRESSION. SHE WAS SENT TO A CLINIC AND SHE WAS NOT EVEN DEPRESSED; IT WAS THE ESSURE. THERE WERE OTHER COMPLICATIONS; SHE COULD NOT THINK OF RIGHT OFF THE TOP OF HER HEAD, SHE HAD A BAD MEMORY. SHE HAD A HYSTERECTOMY ON (B)(6) 2015 AND SHE WAS STILL SUFFERING FROM HEADACHES EVERY DAY, IBS (IRRITABLE BOWEL SYNDROME), DIZZINESS, NAUSEA EVERY DAY. A MRI WAS DONE FOR HEAD AND THAT CAME BACK CLEAR. SHE WAS SENT TO A SPECIALIST BUT THEY HAVE NOT FOUND OUT WHY SHE WAS STILL SICK (HER MEMORY HAS GOTTEN WORSE). PTC INVESTIGATION RESULT WAS RECEIVED ON 21-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A

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LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HEAVY BLEEDING (TWO PERIODS A MONTH EACH LASTING A FULL WEEK) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER STATED THIS EVENT STARTED 1 YEAR AFTER ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01098	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 20222098 (INVALID)

Single Use: Y
Implant Date (E6): 4/16/2010
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 09-APR-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5035337, RECEIVED AT FDA ON 26-MAR-2014). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED CHRONIC AND PERSISTENT PELVIC PAIN, HEMORRHAGING WITH MENSTRUAL CYCLES, HAIR LOSS, SWELLING OF THE ABDOMEN, SEVERE HIP AND LOWER BACK PAIN, HEADACHES, VISION CHANGES, TERRIBLE PERSISTENT HEARTBURN, RECURRING YEAST AND BLADDER INFECTIONS, KIDNEY PROBLEMS, SERIOUS WEIGHT GAIN, MOODINESS, IRRITABILITY, DEPRESSION REQUIRING DAILY MEDICATION, LOSS OF LIBIDO, AND PAINFUL INTERCOURSE. ON FDA FORM REPORTED REPORT TYPE WAS "INJURY," OUTCOME OF EVENTS WAS 'DISABILITY OR PERMANENT DAMAGE' NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2010, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 20222098, IMPLANTED. CONSUMER REPORTED SINCE BEING IMPLANTED SHE HAS HAD CHRONIC AND PERSISTENT PELVIC PAIN, HEMORRHAGING WITH MENSTRUAL CYCLES, HAIR LOSS, SWELLING OF THE ABDOMEN, SEVERE HIP AND LOWER BACK PAIN, HEADACHES, VISION CHANGES, TERRIBLE PERSISTENT HEARTBURN, RECURRING YEAST AND BLADDER INFECTIONS, KIDNEY PROBLEMS, SERIOUS WEIGHT GAIN, MOODINESS, IRRITABILITY, DEPRESSION REQUIRING DAILY MEDICATION, LOSS OF LIBIDO, AND PAINFUL INTERCOURSE. NO FURTHER DETAILS WERE REPORTED. CONSUMER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP. FOLLOW-UP INFORMATION RECEIVED ON 29-AUG-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-

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N-0736-0971). THE CONSUMER HAD ESSURE IMPLANTED IN 2010. SINCE THEN, SHE HAS BEEN PLAGUED WITH DEBILITATING PAIN IN HER BACK, HIPS, KNEES, NECK AND SHOULDERS. SHE LOST AN ENORMOUS AMOUNT OF HAIR IN THIS TIME ALSO AND WAS EXTREMELY DEPRESSED, ANXIOUS AND JUST PLAIN MOODY. SHE HAD THE WORST MENSTRUAL CYCLES OF HER LIFE, MOST OF THE TIME PASSING CLOTS AS LARGE AS PING PONG BALLS. SHE WAS UNABLE TO PARTICIPATE IN HER CHILDREN'S DAIRY LIFE DUE TO HER PAIN AND MEDICATIONS SHE HAD BEEN ON AND WAS UNABLE TO GO TO WORK EVEN. AT THE AGE OR (B)(6), AFTER SUFFERING FOR 5 YEARS, SHE HAD HYSTERECTOMY TO REMOVE ESSURE. UNFORTUNATELY SOME OR THE DAMAGE WILL NEVER BE UNDONE. CASE UPGRADED TO INCIDENT. PTC INVESTIGATION RESULT WAS RECEIVED ON 21-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). LOT 20222098 IS NOT A VALID LOT NUMBER FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD HEMORRHAGE WITH MENSTRUAL CYCLE (PASSING CLOTS AS LARGE AS PING PONG BALLS) AND PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY TO REMOVE ESSURE. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER STATED THE EVENTS STARTED SINCE ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01099	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2014
Explant Date (E7): 8/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0926, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. SHE STATED THAT SHE GOT ESSURE PLACED AND STARTED TO HAVE SIDE EFFECTS RIGHT AWAY. WEIGHT GAIN, BLOATING, ANXIETY, HEADACHES, BRAIN FOG AND SHE WAS ALWAYS TIRED. THEN SHE STARTED TO EXPERIENCE JOINT PAIN, LOWER BACK PAIN THAT EVENTUALLY WOULD NOT EVENT LIFT HER BABY OFF THE GROUND. HER TESTOSTERONE LEVELS WERE LOW. SHE WAS NEVER TESTED FOR NICKEL ALLERGY BEFORE ESSURE INSERTION. SHE WAS 32 YEARS OLD AND IN (B)(6) 2015 SHE HAD A FULL HYSTERECTOMY PERFORMED. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD BACK PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND BACK PAIN MAY OCCUR. IN THIS CASE, THE CONSUMER STATED HER PAIN STARTED RIGHT AFTER ESSURE INSERTION. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01101	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0969, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER RECEIVED ESSURE AFTER HAVING HER 5TH CHILD. SINCE THEN HER HEALTH HAD STEADILY GONE DOWNHILL. SHE HAD SEVERE MIGRAINE, BLOATING, CONSTANTLY BLADDER AND KIDNEY INFECTIONS, HIGH BLOOD PRESSURE, WEIGHT GAIN, NO SEX DRIVE, NO ENERGY. SHE HAD A DILATATION AND CURETTAGE AND AN ABLATION PERFORMED, BUT SHE WAS STILL IN PAIN. SHE STATED SHE IS (B)(6) AND IS HAVING TO HAVE A HYSTERECTOMY DUE TO THESE HEALTH PROBLEMS. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

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COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. SHE WAS SUBMITTED TO DILATATION AND CURETTAGE (D&C) AND ENDOMETRIAL ABLATION WITHOUT IMPROVEMENT. SHE STATED SHE IS NOW HAVING TO HAVE A HYSTERECTOMY. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL AND PELVIC PAIN MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER STATED SHE HAD AN ABLATION AND D&C BUT SHE WAS STILL IN PAIN. ENDOMETRIAL ABLATION AND D&C ARE USUALLY USED TO TREAT WOMEN WITH CHRONIC MENORRHAGIA/ ABNORMAL UTERINE BLEEDING. ALTHOUGH PAIN IS NOT AN INDICATION FOR THESE PROCEDURES; LIMITED INFORMATION WAS PROVIDED IN THIS CASE AND NO ALTERNATIVE EXPLANATION FOR CONSUMER'S PAIN WAS PROVIDED. THEREFORE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED AND SINCE THESE INTERVENTIONS WERE REQUIRED; THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, THE SERIOUS EVENT KIDNEY AND BLADDER INFECTIONS (UNRELATED TO ESSURE DUE TO THEIR NATURE) AND OTHER NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01102	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0943, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE PATIENT (SHE IS A HEALTHCARE PROVIDER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. ADDITIONAL INFORMATION RECEIVED ON 21-SEP-2015 (PTC INVESTIGATION RESULT). SHE STATED THAT IN (B)(6) 2008 SHE WENT TO HER DOCTOR COMPLAINING OF HEAVY MENSTRUAL BLEEDING. AFTER A SONOGRAM, SHE WAS TOLD THAT SHE HAD SMALL FIBROSIS NOVASURE ENDOMETRIAL ABLATION WAS RECOMMENDED AS TREATMENT. AFTER ABLATION, DOCTOR RECOMMENDED ESSURE. SHE WAS TOLD THAT HER CONCERNS WERE VOICED REGARDING HER INABILITY TO WEAR NICKEL EARRINGS, JEAN SNAPS AND ETC. ESSURE WAS IMPLANTED IN (B)(6) 2008 AND AFTER PLACEMENT SHE HAD RASHES THAT WOULD COME AND GO, PELVIC PAIN THAT WAS VERY PAINFUL, BLADDER PRESSURE THAT SHE DESCRIBED AS FULL DRAGGING SENSATION, SHE ALWAYS FELT LIKE SHE HAD A URINARY TRACT INFECTION, METALLIC TASTE IN MOUTH AND EXCRUCIATINGLY PAINFUL SEX WITH PAIN THAT RADIATED TO HER HIP AND WOULD LAST FOR DAYS AFTERWARD. SOME DAYS SHE DID NOT WANT TO GET OUT THE BED AS THE PAIN WAS SO BAD AND RASHES WERE SO ITCHY AND IRRITATING. SHE SAID THAT SHE DID NOT HAVE THE OPTION TO STAY IN BED BECAUSE SHE IS A HEALTHCARE PROVIDER AND HAD CHILDREN TO TAKE CARE. IN (B)(6) 2014, DIAGNOSTIC LAPAROSCOPY AND HYSTEROSCOPY WERE DONE AND FOUND THAT HER RIGHT ESSURE COIL WAS NOT IN THE TUBE; IT WAS FOUND TOTALLY COVERED IN SCAR TISSUE IN HER UTERUS AND HER LEFT COIL WAS DANGLING FROM TUBE. BOTH TUBES WERE REMOVED BY BILATERAL SALPINGECTOMY AND SINCE REMOVAL, HER SYMPTOMS WERE GONE. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION

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AND FINAL ASSESSMENT: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN THAT WAS VERY PAINFUL. A DIAGNOSTIC LAPAROSCOPY AND HYSTEROSCOPY WERE DONE AND FOUND THAT HER RIGHT ESSURE COIL WAS NOT IN TUBE / IT WAS FOUND TOTALLY COVERED IN SCAR TISSUE IN HER UTERUS (INTERPRETED AS EMBEDDED DEVICE) AND LEFT COIL DANGLING FROM TUBE (INTERPRETED AS DEVICE DISLOCATION). BOTH TUBES WERE REMOVED BY BILATERAL SALPINGECTOMY. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, PATIENT EXPERIENCED PELVIC PAIN ABOUT 1 MONTH AFTER ESSURE INSERTION. THE OTHER EVENTS WERE DIAGNOSED ABOUT 6 YEARS AND 5 MONTHS AFTER INSERTION, HOWEVER THE EXACT DATE AND MECHANISM FOR DEVICE DISLOCATION AND EMBEDMENT WERE NOT KNOWN. CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01103	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0992, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. CONSUMER REPORTED THAT ESSURE RUINED HER LIFE AND STATED THAT HER SYMPTOMS INCLUDED HAIR LOSS, BACK PAIN, PELVIC PAIN, PAIN DURING INTERCOURSE, FORGETFULNESS, MONTHLY YEAST INFECTIONS, MIGRAINES, DAILY HEADACHES, (B)(6), PULMONARY EMBOLISM, JOINT PAIN, LIVER ISSUES, INCREASED WEIGHT GAIN AND THE LIST GOES ON. CONSUMER ALSO INFORMED THAT SHE ATTRIBUTED THIS TO GETTING OLDER BUT, AFTER REPEATED DOCTOR VISITS, SHE BEGAN TO NARROW DOWN THE ONSET OF WHEN HER SYMPTOMS STARTED: MONTHS AFTER INSERTION IN 2007. SHE HAD THEM REMOVED IN (B)(6) 2015 VIA HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND WAS SUBMITTED TO A HYSTERECTOMY TO REMOVE THE DEVICES. ADDITIONALLY, SHE WAS DIAGNOSED WITH (B)(6) AND PULMONARY EMBOLISM. ONLY PELVIC PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER'S PAIN STARTED MONTHS AFTER ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, LIMITED INFORMATION WAS PROVIDED. HOWEVER, GIVEN THEIR NATURE AND CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY IS CONSIDERED UNLIKELY. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED.

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THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 06-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY R

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01104	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1004, AWARENESS DATE 26-AUG-2015). CASE WAS RECEIVED IN UNITED STATES ON 29-AUG-2015 AND REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2006. CONSUMER REPORTED THAT, SINCE ESSURE PLACEMENT, SHE HAS BEEN DIAGNOSED WITH HYPERDERMINIS SUPPERIVE, ENDOMETRIOSIS, TUMORS AND CYSTS ON HER UTERUS AND OVARIES, EXTREME SWELLING OF HER UTERUS AND EXTREME AMOUNTS OF PAIN. SHE IS SCHEDULED FOR A HYSTERECTOMY ON (B)(6) 2015 BECAUSE OF ALL THESE ISSUES AND BECAUSE OF ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME AMOUNTS OF PAIN, HYPERDERMINIS SUPPERIVE, ENDOMETRIOSIS, TUMORS IN HER UTERUS, TUMORS IN HER OVARIES, CYSTS ON UTERUS, CYSTS ON OVARIES AND EXTREME SWELLING OF UTERUS WERE DIAGNOSED. THE EVENT EXTREME AMOUNTS OF PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE UNLISTED. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IT WAS REPORTED THAT SINCE ESSURE PLACEMENT, SHE EXPERIENCED ALL THESE EVENTS. A HYSTERECTOMY WAS SCHEDULED BECAUSE OF ALL THESE EVENTS AND BECAUSE OF ESSURE. BASED ON THE NATURE OF THE EVENT FOR EXTREME AMOUNTS OF PAIN, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, BASED ON THE PATHOPHYSIOLOGY AND CONSIDERING THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL

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RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01105	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/4/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0980, AWARENESS DATE 29-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE STATED THAT UPON RETURNING FOR HER PLACEMENT CHECKUP, SHE HAD A REACTION TO DYE TEST AND HER BLOOD PRESSURE WAS 70/33 AND SHE WAS SHIPPED STRAIGHT TO ER. SHE ALSO HAD SEVERE PELVIC PAIN, HIP PAIN, HAIR LOSS, MIGRAINES, DIZZINESS, FORGETFULNESS, HEAVY BLEEDING (LASTING 2 WEEKS OR MORE) AND WEIGHT GAIN. ON (B)(6) 2015, HYSTERECTOMY WAS DONE COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING HER CHECKUP VISIT, SHE A REACTION TO DYE TEST AND HER BLOOD PRESSURE WAS 70/33. ADDITIONALLY, SHE EXPERIENCED PELVIC PAIN AND HEAVY BLEEDING AND WAS SUBMITTED TO A HYSTERECTOMY. ONLY PELVIC PAIN AND BLEEDING ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT, ESSURE CONFIRMATION TEST (DYE TEST) MAY INDUCE A VASOVAGAL RESPONSE. IN THIS CASE, CONSUMER REPORTED HYPOTENSION IN ASSOCIATION WITH THE TEST WITH NEED OF AN ER VISIT, BUT MINIMAL INFORMATION WAS PROVIDED. NEVERTHELESS, THIS EVENT WAS CONSIDERED AS RELATED TO ESSURE; SINCE IT OCCURRED IN ASSOCIATION WITH CONFIRMATION TEST. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED.

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THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01106	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0951, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD VARIOUS SYMPTOMS A YEAR AFTER HAVING ESSURE PLACED. SHE GAINED 15 POUNDS DESPITE WORKING OUT EVERY DAY AND EATING GREAT. SHE GAINED A BALD SPOT ON THE TOP OF HER HAIR AND LOST HALF OF HER HAIR EVERYWHERE ELSE. SHE HAD BAD RAGES AND BLEEDING WHERE SHE WORE BAND AID AND JEWELRY. SHE ALSO GAINED STRETCH MARKS WITHOUT EVER HAVING CHILDREN. THEN SHE FOUND OUT HER LEFT COIL MIGRATED INTO HER UTERUS AND CERVIX. SHE HAD TO HAVE A HYSTERECTOMY AND HAVING EVERYTHING REMOVED EXCEPT HER OVARIES. AFTER REMOVAL, SHE THOUGHT SHE WAS GOING TO BE A LOT BETTER, BUT SHE REALIZED SHE HAS THYROID PROBLEMS FOR WHICH SHE HAS SEEN VARIOUS DOCTORS FOR THESE LAST 3 YEARS AND WILL ALWAYS CONTINUE FOREVER WITH LAB WORK ETC. ALSO, SHE HAS HAD TO SEE A DERMATOLOGIST FOR CORTISONE SHOTS AND SCALP SOLUTION TO TRY TO REGROW HER HAIR AND HAS HAD TO GO TO GASTROENTEROLOGIST FOR ULCER AND DIGESTIVE ISSUES WITH ALL THE STRESS FROM ALL OF THIS. PTC INVESTIGATION RESULT WAS RECEIVED ON 21-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS

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RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FOUND OUT HER LEFT COIL MIGRATED INTO HER UTERUS AND CERVIX. SHE UNDERWENT A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE THE LEFT COIL WAS FOUND MIGRATED INTO HER UTERUS AND CERVIX. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). SINCE NO PRODUCT WAS RETURNED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01107	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/26/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1029, AWARENESS DATE 29-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2004. IN 2011, SHE STARTED HAVING PROBLEMS WITH WEIGHT GAIN AND PAIN. IN 2013 PAIN GOT WORSE. ON (B)(6) 2014, SHE HAD A MISCARRIAGE OF TWINS AND HER PAIN LEVEL WENT THROUGH THE ROOF AND SHE WENT TO ER (EMERGENCY ROOM). SHE HAD MULTIPLE TESTS, X-RAYS AND SCAN DONE. AFTER MULTIPLE VISITS, HER PHYSICIAN FOUND THAT THE LEFT COIL WAS OUT OF PLACE AND WAS CAUSING THE EXCRUCIATING PAIN AND INFECTION. ON (B)(6) 2014, HYSTERECTOMY WAS DONE (SHE WAS (B)(6)) AND HER SURGERY WAS LONGER THAN NORMAL BECAUSE HER LEFT COIL MIGRATED FROM HER TUBE AND WAS EMBEDDED IN THE TOP LAYER OF MUSCLE IN HER UTERUS. HER UTERUS WAS FUSED CLOSED AND SCAR TISSUE HAD HER UTERUS AND TUBES MATTED TOGETHER. THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 21-SEP-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED

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THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A MISCARRIAGE TEN YEARS AFTER INSERTION (IMPLYING A PREGNANCY). SOON AFTER, IT WAS FOUND THAT THE LEFT COIL MIGRATED FROM LEFT TUBE AND WAS EMBEDDED IN THE TOP LAYER OF MUSCLE IN UTERUS (INTERPRETED AS DEVICE EMBEDMENT). SHE UNDERWENT A HYSTERECTOMY 10 YEARS AFTER INSERTION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR MISCARRIAGE WHICH IS UNLISTED. IN THE PRESENT CASE, ONE OF THE COILS WAS NOT PROPERLY LOCATED WHICH COULD HAVE CONTRIBUTED FOR THE OCCURRENCE OF PREGNANCY. HOWEVER, GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED (DEVICE INEFFECTIVE). MISCARRIAGE IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY. THIS IS CONSIDERED TO BE DUE TO A HIGH NUMBER OF ABNORMAL EMBRYOS PRESENTING WITH EITHER CHROMOSOMAL AND/OR GROSS MORPHOLOGICAL ABNORMALITIES. IN THIS CASE, THE GESTATIONAL AGE WAS NOT REPORTED. HOWEVER, GIVEN THE PATHOPHYSIOLOGY OF THE EVENT AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THIS EVENT WAS ASSESSED AS UNRELATED TO THE INSERT. REGARDING DEVICE EMBEDMENT (PARTIAL UTERINE PERFORATION); UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE THE PERFORATION WAS DIAGNOSED 10 YEARS AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). SINCE NO PRODUCT WAS RETURNED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01108	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1015, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER WAS ALLERGIC TO NICKEL. CONSUMER HUSBAND REPORTED THAT PROCEDURE WAS PAINFUL FOR HIS WIFE. AFTER 3 WEEKS SHE STARTED TO NOTICE WEIGHT GAIN AND PAIN DURING SEX. SHE ALSO STARTED HAVING HORRIBLE MIGRAINES AND ABDOMEN PAIN. IN (B)(6) 2013 SHE FELL AND BROKE HER ANKLE. DOCTOR TOLD THE NICKEL ON ESSURE WAS CAUSING HER BONES TO DETERIORATE. SHE LOOKED CONSTANTLY 7 MONTHS PREGNANT, HAD INCONSISTENT BLEEDING AND HORRIBLE CRAMPING. EVENTUALLY, SHE GOT PREGNANT THEN SHE MISCARRIED. ON AN UNSPECIFIED DATE SHE HAD A HYSTERECTOMY PERFORMED. DURING SURGERY SHE BEGAN TO BLEED OUT, ONE OF HER COILS HAD MIGRATED AND PUNCTURED AN ARTERY, BUT DOCTOR WERE ABLE TO SAVE HER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INCONSISTENT BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE BECAME PREGNANT THEN SHE MISCARRIED. A HYSTERECTOMY WAS PERFORMED AND DURING SURGERY BEGAN TO BLEED OUT, CANT STOP THE BLEEDING AND IT WAS REPORTED THAT ONE OF HER COILS HAD MIGRATED AND PUNCTUREDED AN ARTERY (SEEN AS DEVICE MIGRATION). MISCARRIED IS AN UNLISTED EVENT ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL

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IMPORTANCE. IN THIS CASE, IT WAS UNKNOWN WHETHER ESSURE WAS IN-SITU DURING CONCEPTION OR GOT PREGNANT AS CONSEQUENCE OF MIGRATION. THE OCCURRENCE OF BLEEDING DURING SURGERY (HYSTERECTOMY) COULD BE RELATED TO THIS PROCEDURE. CONSIDERING THE NATURE OF THE EVENTS, EXCEPT FOR MISCARRIAGE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE EVENT MISCARRIED, SINCE NO INFORMATION ON GESTATIONAL AGE WAS PROVIDED AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01109	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# F BUS-2015-US-072530 AWARENESS DATE 29-AUG-2015). THE (B)(6) CONSUMER HAD ESSURE IMPLANTED IN (B)(6) 2013. CONSUMER STATED THAT SHE WAS IN THE BEST SHAPE OF HER LIFE AND WAS COMPLETELY HEALTHY BEFORE SHE HAD THE ESSURE PROCEDURE DONE THE DEVICE WAS INSERTED IN THE OFFICE VIA A HYSTEROSCOPY WITHOUT GENERAL ANESTHESIA. SHE WENT IN TO HAVE THE PROCEDURE DONE AFTER ORALLY TAKING A MILD DOSE OF PAIN DRUGS TO GET HER READY FOR THE PROCEDURE. ACCORDING TO HER GIVING BIRTH TO HER TWO CHILDREN DID NOT EVEN COMPARE TO THE AMOUNT OF PAIN SHE EXPERIENCED DURING INSERTION. IT FELT INHUMANE AND THE DOCTOR AND NURSE NEVER ONCE ASKED HOW SHE WAS FEELING AND TOLERATING THE PROCEDURE AFTER THE PROCEDURE TOOK NEARLY ONE HOUR DUE TO THE FACT THAT ONE OF FALLOPIAN TUBES WAS ALREADY DOSED DUE TO ATROPHY (HER DOCTOR STATED THIS TO ME DURING THE PROCEDURE) SHE MANAGED TO SHOVE THE DEVICE IN THROUGH THE SCAR TISSUE THAT ALREADY EXISTED (DUE TO CONSUMERS AGE). AFTER IT WAS DONE, SHE SEEMED TO BE UNSURE OF PROPER PLACEMENT. ON THE SAME DAY THE CONSUMER UNDERWENT A VAGINAL ULTRASOUND TO IDENTIFY CORRECT PLACEMENT. THE US TECHNICIAN COULD NOT BE CERTAIN ON THE LOCATION OF THE DEVICES BUT CONCLUDED THEY WERE THERE. AT ABOUT 3 WEEKS POST ESSURE INSERTION SHE TO SWELL UP IN ABDOMEN LIKE SHE WAS 7 MONTHS PREGNANT; THIS HAPPENED DAILY AND NEVER WENT AWAY. THE HSG TEST THAT WAS DONE SEVERAL MONTHS LATER AND WAS EQUALLY AS PAINFUL. NONE OF THE SIDE EFFECTS SHE WAS SUFFERING FROM ON A CONTINUAL DAILY BASIS WERE EVER DISCLOSED TO HER. SHE WAS EXPERIENCING AUTOIMMUNE DISEASE AND CRIPPLING JOINT PAIN, HER BONES CRACK AND POP

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CONSTANTLY! SHE CAN NO LONGER WORKOUT AND EXERCISE, HER BODY GETS INFLAMED WHEN SHE DO. HER BODY THINKS EVERYTHING IS AN INTRUDER NOW, EVEN FOOD. SHE WAS UNDER SPECIAL DIET (AUTOIMMUNE PROTOCOL DIET PALEO) THAT CONSISTS OF NO DAIRY, NO GRAINS, NO SUGARS, NO SOY, NO NUTS AND SEEDS. SHE HAD NEVER HAD DIETARY ISSUES BEFORE HAVING ESSURE. ESSURE CAUSED HER TO SUFFER CHRONIC SYSTEMIC INFLAMMATION. SHE UNDERWENT TWO SURGERIES TO REMOVE THE DEVICES AND HAD LOST ALL HER REPRODUCTIVE ORGANS EXCEPT ONE OVARY. DEVICES FELL APART DURING REMOVAL, CAUSING HEAVY METAL TOXICITY. SHE HAVE JUST BEEN DIAGNOSED THROUGH EXTENSIVE TESTING TO HAVE HEAVY METAL POISONING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT ABOUT 3 WEEKS POST ESSURE INSERTION SHE STARTED TO SWELL UP IN ABDOMEN LIKE SHE WAS 7 MONTHS PREGNANT. DURING THE PROCEDURE TO REMOVE THE DEVICE, ESSURE FELL APART CAUSING METAL TOXICITY. SHE ALSO PRESENTED AUTOIMMUNE DISEASE. THESE EVENTS, SEEN AS ABDOMINAL DISTENSION, METAL POISONING AND AUTOIMMUNE DISORDER, ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. BLOATING IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE OTHER EVENTS ARE UNLISTED. ABDOMINAL BLOATING AND DISTENTION MAY OCCUR DURING ESSURE USE. IN THIS CASE, THREE WEEKS AFTER INSERTION, HER ABDOMEN SWOLLEN LIKE SHE WAS 7 MONTHS PREGNANT. GIVEN CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. REGARDING AUTOIMMUNE DISORDER, AS ESSURE ACTS LOCALLY IN FALLOPIAN TUBES, CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE IS VERY UNLIKELY. ALTHOUGH ESSURE RELEASES NICKEL, THE AMOUNT IS NOT ENOUGH TO CAUSE METAL POISONING. THUS, THIS EVENT IS ASSESSED AS UNRELATED TO ESSURE. SINCE INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01110	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0962, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. IN (B)(6) 2010, SHE WAS TOLD ESSURE WAS THE SAFEST STERILIZATION AND HAD IT IMPLANTED. SIX MONTHS LATER SHE STARTED HAVING EXTREME PELVIC PAIN, ACNE AND JOINT PAIN. NOT RELATING HER ISSUES TO ESSURE, DOCTORS GAVE HER MEDICATIONS AND PHYSICAL THERAPY. OVER THE LAST 5 YEARS, SHE HAD SEEN DOCTORS FOR MANY ILLNESSES. IN 2015, SHE BEGAN BLEEDING HEAVY WITH HER PERIODS FOR 5-10 DAYS AND HAVING PERIODS RANDOMLY 2-3 WEEKS APART. HER FERRITIN LEVELS DROPPED SIGNIFICANTLY AND HER DOCTOR STATED SHE NEEDED AN ABLATION. IN (B)(6) 2015, SHE HAD ESSURE REMOVED DUE TO PELVIC PAIN BY REMOVING HER TUBES AND ABLATION. ESSURE RIGHT TUBE BROKE DURING REMOVAL DUE TO ESSURE COIL MIGRATED TO HER UTERUS AND WAS EMBEDDED PARTIALLY IN UTERUS. HOWEVER, IN 2010, THE 3-MONTH FOLLOW UP AFTER ESSURE IMPLANT, HAD SHOWN HER ESSURE COIL WAS CORRECTLY IMPLANTED IN HER RIGHT TUBE AND NOT IN HER UTERUS. IN 2015, SHE HAD A SURGERY, DOCTOR ALSO FOUND ENDOMETRIOSIS IN HER UTERUS. SHE HAD NO FAMILY HISTORY OF ENDOMETRIOSIS. IN (B)(6) 2015, SHE WAS ADMITTED TO HOSPITAL FOR 6 DAYS WITH SMALL BOWEL OBSTRUCTION. IN (B)(6) 2015, SHE HAD TO HAVE COMPLETE HYSTERECTOMY DUE TO ENDOMETRIOSIS AND A MASS ON THE ENDOMETRIOSIS. DOCTOR FOUND HER ENDOMETRIOSIS IN AND OUTSIDE HER UTERUS AND ON THE WALL OF HER ABDOMEN WHICH MAY HAVE CAUSED HER SMALL BOWEL OBSTRUCTION. SHE WONDERED WHETHER ENDOMETRIOSIS WOULD HAVE FORMED IN HER UTERUS IF ESSURE COIL HAD NOT MIGRATED TO HER UTERUS AND EMBEDDED INTO

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IT. ENDOMETRIOSIS WAS FOUND IN HER UTERUS WHERE THE COIL HAD EMBEDDED INTO IT AND STATED THAT ENDOMETRIOSIS GREW FAST IN 8 MONTHS CONSUMING HER OVARIES, UTERUS AND ABDOMEN, LEADING TO SMALL BOWEL OBSTRUCTION AND COMPLETE HYSTERECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON 21-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SIX MONTHS AFTER THE INSERTION SHE WAS HAVING EXTREME PELVIC PAIN. APPROXIMATELY FOUR YEARS LATER SHE HAD ESSURE REMOVED ALONG WITH HER TUBES DUE TO PELVIC PAIN. DURING REMOVAL, ESSURE FROM RIGHT TUBE BROKE BECAUSE IT WAS EMBEDDED PARTIALLY IN UTERUS. SHE WAS ALSO HOSPITALIZED FOR 6 DAYS WITH SMALL BOWEL OBSTRUCTION AND A MONTH LATER SHE HAD TO PERFORM A TOTAL HYSTERECTOMY DUE TO ENDOMETRIOSIS THAT WAS GROWING IN UTERUS, OVARIES AND ABDOMEN. THE PELVIC PAIN AND ENDOMETRIOSIS ARE SERIOUS DUE TO REQUIRED INTERVENTION, THE EMBEDMENT DUE TO ITS MEDICAL IMPORTANCE, THE SMALL BOWEL OBSTRUCTION DUE TO HOSPITALIZATION AND DEVICE BREAKAGE IS NON-SERIOUS. THE PELVIC PAIN, DEVICE BREAKAGE DURING REMOVAL AND DEVICE EMBEDMENT ARE LISTED WHILE ENDOMETRIOSIS AND SMALL BOWEL OBSTRUCTION ARE UNLISTED EVENTS IN THE REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, THE PELVIC PAIN, DEVICE EMBEDMENT AND DEVICE BREAKAGE OCCURRED DURING ESSURE THERAPY. CONSIDERING THE NATURE OF THESE EVENTS, THEY WERE ASSESSED AS RELATED TO ESSURE. IN CONTRAST, THE ENDOMETRIOSIS WAS DIAGNOSED A FEW MONTHS AFTER ESSURE REMOVAL AND SMALL BOWEL OBSTRUCTION OCCURRED AFTER ESSURE REMOVAL. SHE HAS NO FAMILY HISTORY OF ENDOMETRIOSIS. ALTHOUGH, THE CONSUMER ATTRIBUTED THE ENDOMETRIOSIS TO THE ESSURE EMBEDMENT, CONSIDERING THE NATURE OF THIS EVENT, THE INCOMPATIBLE TEMPORAL RELATIONSHIP AND LOCALIZED ACTION OF ESSURE, ITS CAUSAL RELATIONSHIP WITH ESSURE IS UNLIKELY. SINCE THE SMALL BOWEL OBSTRUCTION MIGHT HAVE BEEN CAUSED BY THE ENDOMETRIOSIS IT WAS ALSO ASSESSED AS UNRELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01111	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 2/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 2/24/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-1022, AWARENESS DATE 29-AUG-2015).IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. IN ADDITION, CONSUMER REPORTED THAT THE COILS WERE IN PERFECT POSITION. THEY NEVER MIGRATED AND SHE INFORMED THAT SHE DID HER FOLLOW UPS. DURING THE SURGERY, HER OBSTETRICIAN/GYNECOLOGIST FOUND TISSUE HAD GROWN ON THE OUTSIDE OF HER TUBES STARTING AT THE COILS CAUSED BY ESSURE. ACCORDING TO REPORTER, THE DOCTOR CAME TO THIS CONCLUSION BECAUSE THE TISSUE WAS THICKER AT THE COILS AND FOUND SHE DID NOT HAVE ENDOMETRIOSIS. THE TISSUE HAD GROWN UP HER TUBES, ENCASED HER OVARIES AND CONNECTED TO HER ABDOMINAL WALL. SHE HAD AN OVARIAN CYST BURST EVERY TWO WEEKS FROM BEING IMPLANTING TO REMOVAL. IN 2009, SHE HEMORRHAGED FROM ONE OF THE CYSTS BURSTING AND DURING HER HYSTERECTOMY SHE HEMORRHAGED AGAIN CAUSING THE LOSS OF THE LEFT OVARY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXTREME PELVIC PAIN, OVARIAN CYST BURST EVERY TWO WEEKS SINCE ESSURE WAS IMPLANTED. TWO YEARS AFTER INSERTION, SHE HEMORRHAGED FROM ONE OF THE CYST BURSTING. APPROXIMATELY, 8 YEARS AFTER ESSURE INSERTION, SHE HAD A HYSTERECTOMY AND HAD TUBES REMOVED. DURING SURGERY, IT WAS FOUND THAT TISSUE HAD GROWN ON THE OUTSIDE OF TUBE, ENCASED OVARIES AND CONNECTED TO ABDOMINAL WALL (INTERPRETED AS PELVIC ADHESIONS). DURING HYSTERECTOMY, SHE HEMORRHAGED AGAIN AND THE LEFT

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OVARY HAD TO BE REMOVED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ADDITIONALLY, THE PELVIC PAIN AND PEVLIC ADHESIONS ARE ALSO SERIOUS DUE TO REQUIRED INTERVENTION. ALL EVENTS, EXCEPT FOR PELVIC PAIN ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, ALL EVENTS OCCURRED DURING ESSURE THERAPY. CONSIDERING THE PHYSIOPATHOLOGY OF PELVIC ADHESIONS AND ITS CO-LOCALIZATION WITH ESSURE INSERTS, IT CANNOT BE EXCLUDED THAT THIS EVENT IS RELATED TO ESSURE. CONSIDERING THE NATURE OF PELVIC PAIN, THE CONTEXT OF PELVIC ADHESIONS POSSIBLY RELATED TO ESSURE, THE PELVIC PAIN IS ALSO ASSESSED AS RELATED. SINCE THE HEMORRHAGE OCCURRED DURING AN ESSURE-RELATED HYSTERECTOMY, THE CAUSAL RELATIONSHIP BETWEEN THIS COMPLICATION AND ESSURE PROCEDURE CANNOT BE EXCLUDED. IN CONTRAST, DESPITE THE COMPATIBLE TEMPORAL RELATIONSHIP, GIVEN THE NATURE OF OVARIAN CYSTS AND ITS COMPLICATIONS (BURSTING AND HEMORRHAGE), IT IS UNLIKELY THAT ESSURE WOULD BE THE CAUSE. THEREFORE, THESE COMPLICATIONS WERE ASSESSED AS UNRELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01112	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4)). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED SHE EXPERIENCED EXTREMELY HEAVY PERIODS ALONG WITH EXCRUCIATING PELVIC PAIN. SHE OPTED FOR A FULL HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING PELVIC PAIN. SHE OPTED FOR A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENT WAS ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01113	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0985, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER WAS OVERWEIGHT. SHE REPORTED THAT AFTER ESSURE SHE STARTED TO HAVE PAIN AND HEAVY BLEEDING. FOR 4 YEARS SHE WAS SICK AND WORN OUT. IN 2015 SHE HAD TO PERFORM A HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED TO HAVE PAIN (INTERPRETED AS PELVIC PAIN) AND HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A HYSTERECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN AND ABNORMAL GENITAL BLEEDING MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE REPORTED EVENTS AND ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 07-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01129	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (CASE# FDA-2014-N-0736-1091, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER REPORTED THAT SHE CHOSE TO HAVE ESSURE PLACED AFTER HER THIRD CHILD BEING DELIVERED. GIVEN THAT SHE HAD BEEN OUT OF WORK FOR OVER 3 MONTHS, DUE TO PREGNANCY AND CHILDBIRTH, SHE DECIDED FOR THE METHOD THAT WAS PERMANENT AND FAST RECOVERY. ON (B)(6) 2013, CONSUMER HAD HYSTEROSALPINGOGRAM TEST CONFIRMING BLOCKED TUBES. SINCE THEN, SHE HAS SUFFERED FROM EXTREMELY HEAVY PERIODS WHICH SHE NEVER HAD PRIOR TO ESSURE. HER PERIODS LAST FROM 6 TO 9 DAYS AND THEY ALSO BECAME IRREGULAR GOING FROM A 30 DAYS BETWEEN PERIODS PRIOR TO ESSURE TO 45 TO 69 DAYS BETWEEN PERIODS. ACCORDING TO HER, SHE HAS CONTINUED WITH THE SAME DIET THAT ALLOWED HER TO LOSE ALL THE PREGNANCY WEIGHT. HOWEVER, SINCE ESSURE PLACEMENT SHE HAS GAINED 20 POUNDS. SEX IS EXTREMELY PAINFUL FOR DAYS AFTER AND SHE SUFFERS FROM CHRONIC LOWER BACK PAIN AND PELVIC PAIN. CONSUMER ALSO REPORTED THAT HER EXAMS ONLY SHOW THAT THE ESSURE IS IN PLACE. SHE IS SCHEDULED TO HAVE A HYSTERECTOMY ON (B)(6) 2014 (DISCREPANT INFORMATION). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO WAS EXPERIENCING PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, A HYSTERECTOMY WAS SCHEDULED. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND

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UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, GIVEN EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL (ALTHOUGH CONSUMER MENTIONED SET-2014 AS SURGERY DATE; COMPANY CONSIDERS A SURGERY WILL BE PROBABLY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01130	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015 (FDA-2014-N-0736-1052, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. SHE STATED THAT SHE PROBLEMS FROM CHRONIC ABDOMINAL PAIN, ABNORMAL PERIODS, WEIGHT GAIN, DEPRESSION, ANXIETY, HEAVY PERIODS, HEADACHES AND ETC. IN (B)(6) 2015 SHE HAD A HYSTERECTOMY AND HAD HER TUBES, UTERUS AND CERVIX REMOVED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC ABDOMINAL PAIN. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. THUS, CONSIDERING IMPLIED TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01131	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 2/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7): 8/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1023, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2005. DURING INSERTION, PHYSICIAN HAD TROUBLE GETTING THE LEFT COIL IN AND IT WAS DOWN BY HER UTERUS, HE CALLED THE MANUFACTURER AND THEY SAID TO LEAVE IT. DURING THE NEXT 10 YEARS SHE HAD MANY COMPLICATIONS SUCH AS PAIN, BLOATING, METAL TASTE IN MOUTH, HEADACHES AND ETC. THE ONLY WAY TO REMOVE THEM IS TO HAVE A HYSTERECTOMY, SO SHE FINALLY GOT THEM REMOVED IN AUG 2015. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ACCORDING TO HER, PHYSICIAN HAD TROUBLE GETTING THE LEFT COIL IN AND IT WAS DOWN BY HER UTERUS. TEN YEARS LATER, SHE HAD A HYSTERECTOMY TO REMOVE THE COILS. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL. IN THIS PARTICULAR CASE, CONSUMER REPORTED AN UNSPECIFIED INSERTION DIFFICULTY IN LEFT SIDE, AND ESSURE COIL REMAINED IN HER UTERUS (UNCLEAR IF IT WAS EXPELLED OR EMBEDDED). IN THE FOLLOWING YEARS SHE DEVELOPED PAIN AND THE DEVICES WERE REMOVED BY HYSTERECTOMY. CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. AS DEVICE REMOVAL WAS REQUIRED; THIS CASE WAS REGARDED AS INCIDENT. IN ADDITION NON-SERIOUS EVENTS

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WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01132	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4)). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT ESSURE HAS CAUSED HEARTACHE PAIN AND MISERY. ACCORDING TO REPORTER, IT IS THE FEELING EVERY MORNING WHILE YOU STRUGGLE TO COPE WITH THE PAIN THAT YOUR BODY IS BOYCOTTING. THE FEAR OF GOING OUT IN PUBLIC FROM THE PAIN, BUT ALSO, BECAUSE IT MAKES YOU GAIN WEIGHT IN YOUR STOMACH SO YOU LOOK 7 MONTHS PREGNANT. CONSUMER ALSO REPORTED HAIR LOSS, STRESS AND CONSTANT FATIGUE OVER SOMETHING THAT WAS GUARANTEED. IN ADDITION, CONSUMER REPORTED THAT SHE IS SCHEDULED FOR A HYSTERECTOMY BECAUSE OF ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO WAS EXPERIENCING PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, SHE WAS SCHEDULED FOR A HYSTERECTOMY BECAUSE OF ESSURE. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, GIVEN EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01133	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 ((B)(4)). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. CONSUMER REPORTED THAT AFTER INSERTION SHE STARTED EXPERIENCING CHRONIC PELVIC PAIN ALONG WITH CONTINUOUS OVARIAN CYSTS. SHE REMOVED HER LEFT OVARY DUE TO THE CYST. SHE ALSO PERFORMED CHOLECYSTECTOMY DUE TO CHRONIC INFLAMMATION AND APPENDECTOMY ALSO DUE TO CHRONIC INFLAMMATION. FINALLY SHE HAD BOTH OF HER TUBES REMOVED. ALL OF HER CHRONIC PAIN AND INFLAMMATION DISAPPEARED AFTER ESSURE REMOVAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED EXPERIENCING CHRONIC PELVIC PAIN. SHE ALSO REPORTED CONTINOUS OVARIAN CYSTS, CHRONIC INFLAMMATION OF APPENDICE, AND CHRONIC INFLAMMATION OF GALL BLADDER. SHE UNDERWENT SALPINGECTOMY AND ESSURE REMOVAL. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENTS ARE UNLISTED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE THE CONSUMER HAD OVARIAN CYSTS WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THE PAIN. HOWEVER, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THAT THE PAIN RESOLVED AFTER ESSURE REMOVAL, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. REGARDING EVENTS OVARIAN CYSTS, CHRONIC INFLAMMATION OF APPENDICE, AND CHRONIC INFLAMMATION OF GALL BLADDER, CONSIDERING THE PATHOPHYSIOLOGY OF THESE EVENTS AS ESSURE LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY

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WAS ASSESSED AS UNRELATED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SALPINGECTOMY AND ESSURE REMOVAL). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01134	BAYER HEALTHCARE LLC	9/25/2015	9/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 5/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1098, AWARENESS DATE 30-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) IN 2012. CONSUMER HAD ESSURE FOR THREE YEARS AND IN THOSE THREE YEARS SHE HAD CHRONIC MIGRAINES, WEIGHT GAIN, BLEEDING IN STOMACH, BECAME ANEMIC, LOW VITAMIN D, CHRONIC LOWER BACK PAIN, STOMACH PAINS (FELT LIKE LABOR PAINS), SEVERE DEPRESSION, ANXIETY AND HYPOTHYROIDISM. SHE UNDERWENT VARIOS TESTS THROUGHOUT THOSE THREE YEARS SUCH AS MRI OF HEAD, ENDOSCOPY, COLONOSCOPY, VAGINAL ULTRASOUND AND CONSTANT BLOOD TEST. SHE RECENTLY FOUND OUT THAT THE LEFT COIL MIGRATED OUT OF THE TUBE AND PUNCTURED HER UTERUS. SHE HAD A TOTAL HYSTERECTOMY IN (B)(6) 2015 AT (B)(6). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FOUND OUT THAT THE LEFT COIL MIGRATED OUT OF THE TUBE AND PUNCTURED HER UTERUS (INTERPRETED AS UTERINE PERFORATION). SHE ALSO EXPERIENCED BLEEDING IN HER STOMACH. SHE UNDERWENT A HYSTERECTOMY 3 YEARS AFTER ESSURE INSERTION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. UTERINE PERFORATION IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THE PERFORATION WERE NOT REPORTED. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING EVENT BLEEDING IN STOMACH, COMMON CAUSES ARE PEPTIC

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ULCERS, MALLORY-WEISS TEARS, AND ACUTE STRESS GASTRITIS. CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AND ESSURE LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PR

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056427	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAIN IN PELVIC AREA, INCREASED VAGINAL DISCHARGE, VERY HEAVY PERIODS AND PMS. BEFORE ESSURE PERIODS VERY LIGHT NO PMS SYMPTOMS. HEADACHES, 30LB WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056428	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 7/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PELVIC PAIN, PAIN DURING INTERCOURSE, CONSTANT BACTERIAL VAGINOSIS, CONSTANT YEAST INFECTIONS, MIGRAINES, METAL TASTE, AND HEAVY CRAMPING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056429	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 4/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MEDICAID. GOT ESSURE IN (B)(6) 2012 IN (B)(6) HOSPITAL AND THE PUT ME TO SLEEP. RIGHT AFTER A WOKE UP STAR FEELING SHARP PELVIC PAIN THAT SINCE THEN NEVER WENT AWAY. HAD MY PERIOD 2 TIMES IN 2 YEARS AND THEY WERE LONG PERIODS WITH EXTREMELY HEAVY BLEEDING. WENT TO CLINIC AND HOSPITAL FEW TIMES FOR MY SYMPTOMS. I START HAVING CHRONIC FATIGUE, NIGHT SWEATS, HOT FLASHES, STRONG MIGRAINES, MUSCLES AND BODY PAIN, LOWER BACK PAIN, JOINTS PAIN, PANIC ATTACKS AND RAPID PALPITATIONS, TIREDNESS, MOOD SWINGS, CHRONIC GASTRITIS, GALLBLADDER FAILURE WHICH LEAD ME TO A GALLBLADDER REMOVAL SURGERY. ABDOMINAL BLOATING,A LOT GASSES. BAD SMELL GASSES HARD TIME DIGESTING FOOD. METAL TASTE. VERY CHRONIC ALLERGY DERMATITIS CONTACT,TEETH START BREAKING HAD TO EXTRACT ALMOST ALL MY MOLARS. AMINORREHA,PAINFUL INTERCOURSE WITH BLEEDING AFTER INTERCOURSE. LOSS OF MY LIBIDO, BRAIN FOG. HAD A HYSTERECTOMY IN (B)(6) 2015 AFTER TO YEARS WITH THE COILS TO REMOVED THEM. AFTER THESE SOME SYMPTOMS DECREASED BUT NOT GONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056430	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 6/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DEVICE WAS NOT PAID FOR BY INSURANCE. I HAD THIS IMPLANT ON (B)(6) BY MY GYN. I EXPERIENCED OTHER MEDICAL EVENTS PRIOR TO (B)(6) 2015. (B)(6) 2014 I HAD INTENSE ABDOMINAL PAIN. A CAT SCAN REVEALED A PORTAL VEIN CLOT. THE DOCTOR HAD NO IDEA WHAT COULD HAVE CAUSED THIS VERY UNCOMMON DVT. IN (B)(6) 2014, I RETURNED TO THE ER WITH EXCRUCIATING ABDOMINAL PAIN IN THE EXACT SAME SPOT. A US REVEALED NO EVIDENCE OF A CLOT. (B)(6) 2015, I FOUND MYSELF BACK IN ER WITH EXCRUCIATING PAIN IN MY ABDOMEN IN EXACTLY THE SAME PLACE. A CAT SCAN ONLY REVEALED A LARGE AMOUNT OF STOOL. THEN ON (B)(6) 2015, I WENT TO ER WITH DIFFUSE ABDOMINAL PAIN. I WAS IN RENAL FAILURE SECONDARY TO DEHYDRATION (DESPITE THE FACT I HAD INGESTED TWO GALLONS OF WATER, A 16-OZ. (B)(6), AND 14-OZ. OF (B)(6) EARLIER THAT DAY). I WAS ADMITTED AND GIVEN 6 LITERS OF IV FLUIDS OVER THE COURSE OF 12 HRS. I ALSO PRESENTED WITH EXTREME LEG PAIN, BACK PAIN, BILATERAL UPPER FLANK PAIN. HOSPITALIST RULED OUT RABDO. CONSIDERED STATIN MIGHT BE CAUSING MUSCLE PAIN AND DC'ED SIMVASTATIN PENDING FOLLOW UP WITH MY REGULAR DOCTOR. I WAS DISCHARGED THE NEXT DAY, (B)(6) 2015. AFTER I HAD BEEN HOME 3 HOURS I HAD SUDDEN ONSET OF ABDOMINAL BLOATING. I HAD GAINED 16 LBS. IN 24 HOURS. I ASSUMED IT WAS FLUID OVERLOAD. I RETURNED TO THE ER THAT SAME NIGHT, (B)(6) 2015 WITH SHORTNESS OF BREATH. O2 SAT WAS RANGING FROM 84-88. CHEST X-RAYS REVEALED NO FLUID IN LUNGS. BLOOD TESTS WERE RUN. DOCTOR RULED OUT FLUID OVERLOAD AS CAUSE OF BLOATING AND SHORTNESS OF BREATH. INPATIENT OVERNIGHT ON O2. EXPERIENCED ATAXIA, BUT O2 SAT RETURNED TO NORMAL AND I WAS DISCHARGED (B)(6) 2015. I HAVE HAD DIARRHEA CONSISTENTLY 4-5 OUT OF 7 DAYS PER WEEK SINCE (B)(6) 2015. EVER SINCE THE (B)(6) 2015 HOSPITALIZATION I HAVE HAD FEWER AND FEWER NORMAL STOOLS WITH DIARRHEA EVEN MORE PROMINENT AND MORE OFTEN THROUGHOUT THE DAY. I AM STARTING TO GET TO THE

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POINT WHERE IT IS SO URGENT AND SO SUDDEN I SOMETIMES EXPERIENCE INVOLUNTARY FECAL INCONTINENCE BEFORE I GET TO THE RESTROOM. DIAGNOSED WITH LICHENSCLEROSIS - AN AUTOIMMUNE CONDITION IN (B)(6) 2013. I HAVE GAINED ANOTHER 3 LBS. ON TOP OF THE 16 I GAINED IN (B)(6). I HAVE BEEN EATING CONSIDERABLY LESS. MY NIGHT SWEATS AND HEAT FLASHES BEGAN IN (B)(6) 2015, AND CONTINUE TO INTENSIFY. MY MUSCLE PAIN PERSISTS DESPITE BEING OFF SIMVASTATIN SINCE (B)(6) 2015. MY ABDOMEN REMAINS DISTENDED 3 MONTHS LATER. NEVER HAVE I EVER HAD SUCH A ROUNDED, BULGING ABDOMEN AND I CAN'T REDUCE IT, DESPITE THE FACT THAT I WAS TEACHING (AND EXERCISING THROUGHOUT) A 90-MIN. AQUATIC STRENGTH AND CONDITIONING CLASS 4X A WEEK THROUGH MID-AUGUST. MY BALANCE HAS WORSENED. I AM SO FATIGUED I HAVE, ON MORE THAN ONE OCCASION, SLEPT FOR 24-HRS. STRAIGHT, ONLY GETTING UP TO USE THE BATHROOM. NO MATTER HOW MUCH SLEEP I GET, I NEVER FEEL RESTED. IN (B)(6) 2013, I DEVELOPED A DEEP, PRODUCTIVE COUGH THAT LASTED FROM (B)(6) 2013 TO (B)(6) 2014. IT DID NOT RESPOND TO ANY PRESCRIBED MEDICATION OR PRESCRIBED SYRUP. I EVEN MOVED 300 MILES AWAY AND IT STILL CONTINUED FOR ANOTHER 3 MONTHS. THE COUGH RETURNED (B)(6) 2014 AND PERSISTED UNTIL (B)(6) 2014. IT RETURNED (B)(6) 2015 AND LASTED ONE MONTH. I DEVELOPED URINARY STRESS INCONTINENCE SHORTLY AFTER RECEIVING THE IMPLANT. EVER SINCE THIS BLOATING EPISODE (B)(6) 2015, IT IS DIFFICULT TO MAKE IT TO THE TOILET WITHOUT STARTING TO LOSE CONTROL. AND I LEAK THROUGHOUT THE DAY SHORTLY AFTER I FIRST FEEL THE SENSATION TO URINATE. AND SUDDENLY OUT OF NOWHERE I EXPERIENCE VITREOUS SEPARATION IN MY LEFT EYE (A 9 OUT OF 10, ACCORDING TO OPHTHAMOLOGIST). DEVELOPED CATARACTS IN BOTH EYES. HAD TO HAVE A VITRECTOMY ((B)(6) 2014) AND CATARACT SURGERY ((B)(6) 2015). MY VISION HAS WORSENED DRAMATICALLY IN MY RIGHT (NON-SURGICAL) EYE. I HAVE NEVER HAD SO MANY UNUSUAL AND UNEXPLAINED HEALTH ISSUES IN MY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056432	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 8/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN. ABNORMAL PERIOD. SEVERE CRAMPING BLOATING SWELLING ON THE LEGS FACE AND HANDS. BACK PAIN

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056433	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 7/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN TO SEVERAL DOCTORS THEY CAN'T FIGURE OUT WHY I AM HAVING ABDOMINAL PAIN, MIGRAINES, LOWER BACK PAIN, ANXIETY (PANIC ATTACKS) INSOMNIA, FATIGUE, UNABLE TO LOOSE WEIGHT. WAS RECENTLY TESTED POSITIVE FOR LUPUS PANEL WAITING ON ANOTHER DOCTOR TO GET MY BLOOD RESULTS FROM ANOTHER DOCTOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056434	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 1/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMPLANTED IN THE DR OFFICE ON (B)(6) 2013. FULL HYSTERECTOMY LEAVING OVARIES ON (B)(6) 2015. ALL SYMPTOMS ARE GONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056435	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER MY FOURTH AND LAST BABY I WANTED A TUBAL LIGATION BUT WAS CONVINCED BY MY DOCTOR THAT I WAS A GOOD CANDIDATE FOR ESSURE. AFTER THEY EXPLAINED TO ME WHAT IT WAS AND ASSURED ME IT WAS SAFE AND THE BEST THING FOR ME I WENT ALONG WITH IT. I EXPERIENCED MINIMUM DISCOMFORT AND WAS SENT HOME A COUPLE OF HOURS LATER THE SAME DAY. FAST FORWARD TWO OR THREE MONTHS LATER I BEGAN TO EXPERIENCE MANY DIFFERENT ISSUES WITH MY BODY NEVER THINKING IT HAD ANYTHING TO DO WITH MY IMPLANTS. SEVERE MIGRAINES, NAUSEA, BACK PAIN, HIVES, TINGLING OF MY LEFT ARM AND LEG AS WELL AS MY FINGER TIPS AND NOSE! THESE WERE THE BEGINNING OF MY PROBLEMS TO FOLLOW UP WITH MEMORY LOSS, HAIR LOSS, ALOPECIA, ABDOMINAL PAIN WITH SEVERE BLOATING AND TENDERNESS,PAIN IN MY OVARIES BEFORE AND AFTER INTERCOURSE AND A VERY DISTINCT METALLIC TASTE IN MY MOUTH! IT HAS BEEN SIX YEARS NOW AND NO DOCTOR CAN TELL ME THE EXACT CAUSE TO MY ISSUES EXCEPT THAT I WAS STRESSED OUT AND NEEDED MORE REST AND SLEEP. AFTER GETTING A CAT SCAN MRI MY HEAD AND BRAIN IS FINE, I WAS ALSO DIAGNOSED WITH OUT OF THE BLUE ALOPECIA AND PRESCRIBED MEDICATION FOR THAT. I STILL LIVE WITH ALL OF MY ABOVE SYMPTOMS WITH NO ANSWERS I HAVE LEARNED TO LIVE WITH MY PAINS. DON'T WISH THIS ON ANYONE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056436	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SYSTEMIC SWELLING, MOOD SWINGS, BLOATING, AND NO MENCES. DEVICE WAS COVERED BY INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056437	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN SO BAD IN THE PELVIC AND ABDOMINAL AREAS THAT AT TIMES I'M UNABLE EVEN MOVE.. HAIR LOSS\THINNING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056438	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 7/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE DEVICE PUT IN AT THE END OF (B)(6) 2014. I IMMEDIATELY HAD INTENSE CRAMPING WHICH HAS CONTINUED. I FEEL AS THOUGH THERE IS A CONSTANT BURNING IN MY LOWER ABDOMEN. LOST ALL SEX DRIVE, BODY ACHES AND HAVE PUT 20 LBS IN LESS THAN 6 MONTHS WHICH I CAN NOT GET OFF. MY HAIR IS FALLING OUT AND I FEEL DEPRESSED. YES IT WAS COVERED BY MY INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056439	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 12/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE CALLED ESSURE FOR PERMANENT BIRTH CONTROL ON (B)(6) 2008 IN MY OB-GYN OFFICE. I RECEIVED A PATIENT IDENTIFICATION CARD SPECIFYING THAT THE DEVICE WAS MANUFACTURED BY (B)(4). AND I KNOW NOW IS MANUFACTURED BY (B)(4). MY LOT NUMBER IS ESS305 626678. I DON'T HAVE THE EXPIRATION DATE. MY SIDE EFFECTS AND SYMPTOMS EXPERIENCED AFTER THE IMPLANTED WAS LONGER MENSTRUAL PERIODS (3 -4 DAYS LONGER THAN USUAL), IN THE MIDDLE OF MY PERIODS I HAVE A DAY WITH OUT ANY BLEEDING, MENSTRUAL PERIODS ARE MORE HEAVY THAN BEFORE, PUTRIFIED ODOR WHILE URINATING, BACK PAIN. I KEEP MY HEALTH UNDER THE SUPERVISION OF MY GYNECOLOGIST AND OTHER FAMILY DOCTORS AND NURSE PRACTITIONERS AND QUIROS TRYING TO HELP EASY ALL THIS SYMPTOMS, SPECIALLY THE BACK PAIN THAT IS 24 HOURS 7 DAYS A WEEK. I NEED MEDICATIONS FOR THE BACK PAIN CONSTANTLY. I WENT THRU SURGERY ON (B)(6) 2015 TRYING TO EASY THE BACK PAIN. HAD SEVERAL X-RAYS TO BE SURE THE IMPLANTS WERE IN PLACE. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056440	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH SEVERE CRAMPING AND BACK PAIN DAILY, IRREGULAR MENSTRUAL CYCLES, SEVERE BLEEDING FOR ABOUT 6 MONTHS EVERY SINGLE TIME I HAD INTERCOURSE WHICH IS WHEN I WENT BACK TO A DIFFERENT GYNAECOLOGIST. I THEN WENT IN FOR EXPLORATORY PROCEDURE TO FIND OUT WHY I WAS BLEEDING SO MUCH AND HE FOUND THAT ONE OF THE COILS WAS PUNCTURING MY UTERUS; I THEN HAD SURGERY IN (B)(6) 2012 AND THEY REMOVED BOTH OF MY FALLOPIAN TUBES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056441	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, EXTREME BLEEDING, ABDOMINAL PAIN, CRAMPING, LOSS OF MEMORY, WEIGHT GAIN, HAIR LOSS, EXCRUCIATING PAIN,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056442	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 10/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED WITH FEELING THE IMPLANT ON MY LEFT SIDE. SOON AFTER MY PERIOD LASTED FOR 4 MONTHS. SINCE HAVING IT I'VE EXPERIENCED RASHES, HAIR LOSS, DENTAL PROBLEMS, ACHES, CRAMPS, ABDOMINAL PAIN, HEADACHES, AND HEAVY MENSTRUAL CYCLES JUST TO NAME A FEW. I ALSO CAN'T LEFT ANYTHING HEAVY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056443	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD UNEXPLAINED RASHES THAT DO NOT GO AWAY WITH STEROIDS OR CREAMS, HEAVY PERIODS THAT LAST 3 WEEKS, OFF FOR A COUPLE DAYS THEN IT STARTS AGAIN, HORRIBLE ACNE THAT WAS NOT PRESENT BEFORE, CRAMPING/PELVIC PAIN, HAIR LOSS, AS WELL AS FACIAL HAIR GROWTH, DEBILITATING MIGRAINES THAT DO NOT EASE WITH ANY MEDICATIONS, LOSS OF SEX DRIVE, MOOD SWINGS, HOT FLASHES, DRY EYE SYNDROME, VISION CHANGES, VITAMIN B12 AND D DEFICIENCIES, EXCESSIVE DISCHARGE, NO ENERGY, BRAIN FOG, JOINT PAIN, EXCESSIVE BLOATING (I LOOKED 5 MONTH PREGNANT) AND UNEXPLAINED WEIGHT GAIN. ALL OF THESE SYMPTOMS DID NOT APPEAR VERY STRONG UNTIL 2 YEARS AFTER INSERTION. I HAD A HYSTERECTOMY TO REMOVE THE ESSURE 3 1/2 YEARS AFTER INSERTION, WHICH WAS 7 MONTHS AGO, AND ALL MY SYMPTOMS ARE NOW GONE! SINCE MY HYSTERECTOMY I HAVE LOST 15LBS WITHOUT CHANGING MY EATING HABITS OR EXERCISE ROUTINE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056444	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 1/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ENDOMETRIOUS AND I HAVE CONSTANT BLEEDING WAS BLEEDING THAT LAST 6 - 7 WEEKS AT A TIME AND I HAVE TO BE PUT ON MEDICATION TO STOP THE BLEEDING... EVERYTIME I USE THE BATHROOM I'M LOSING SCARE TISSUE...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056445	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 6/22/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HORRIBLE PERIOD CRAMPS, HEAVY BLEEDING AND CLOTS, MY STOMACH SEEMS SWOLLEN AND HARD. I HAVE PAIN IN MY STOMACH ALMOST ALWAYS, I'M ALWAYS TIRED AND ITCHY .. YES INSURANCE PAID FOR THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056455	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 3/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC HIP AND BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056457	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 20 LBS WEIGHT GAIN, LOWER ABDOMEN PAIN CONSTANTLY, SWOLLEN ANKLES, LOWER MID BACK PAIN, NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056458	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 5/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NEVER HAD HEALTH ISSUES BEFORE. NOW I TAKE THYROID MEDICATION DAILY. I HAVE AWFUL PERIODS AND MOOD SWINGS. WEIGHT GAIN. TERRIBLE BACK PAINS. UNEXPLAINED BRUISES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056459	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ESSURE WAS FULLY COVERED BY MY INSURANCE. I WAS IMPLANTED IN (B)(6) 2012. IN (B)(6) 2013 MY HANDS AND FEET STARTED GETTING NUMB AND HAD EXTREME REACTIONS TO TEMPERATURE CHANGES. I ALSO HAD JOINT PAIN. I WAS DIAGNOSED WITH AN AUTOIMMUNE DISORDER. I NEVER ASSOCIATED ENSURE TO THIS, ALTHOUGH THERE IS NO AUTO IMMUNE DISORDER IN MY FAMILY HISTORY. SINCE THIS TIME, I HAVE SUFFERED FROM HAIR LOSS, CONSTANT BACTERIAL VAGINOSIS AND YEAST INFECTIONS, DRY RED FLAKY SKIN PATCHES, OPEN SORES ON MY BODY, MIGRAINES, ANXIETY AND MOST RECENTLY DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056461	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERFORATION OF RIGHT FALLOPIAN TUBE FOUND UPON LAPAROSCOPIC BILATERAL SALPINGECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056462	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 8/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON THE DATE OF IMPLANT I HAD A NUMBER OF COMPLICATIONS, DURING IMPLANT MY OBGYN PLACED MY LEFT COIL FIRST WITH LITTLE TO NO PROBLEMS AS FOR MY RIGHT COIL AND TUBE THAT WAS NOT THE CASE. AFTER IMPLANT OF THE RIGHT SIDE MY DOCTOR COULD NOT VIEW THE COIL AND STATED THAT EVERYTHING WILL BE OKAY SIMPLY TAKE THE BIRTH CONTROL PILL FOR THE NEXT THREE MONTHS. AFTER LEAVING THE OFFICE I WAS RUSHED TO THE ER DUE TO AN EXTREME AMOUNT OF BLOOD LOSS. I RECEIVED A VAST AMOUNT OF PAIN MEDS AND BLOOD CLOTTING MEDS, TO HELP GET THIS UNDER CONTROL THE DAY OF IMPLANT. I ALSO UNDERWENT AND ULTRASOUND AND SCAN TO INSURE NOTHING WAS WRONG, ALL WHILE EXPLAINING OVER AND OVER AGAIN TO EVERY DOCTOR WHAT ESSURE WAS AS NOT HAD EVER EVEN HEARD OF IT. I DID TAKE MY BIRTH CONTROL DURING THE TIME AS INSTRUCTED BUT CONTINUED TO EXPERIENCE A LOT OF PAIN. AFTER THE THREE MONTH WAIT I WENT INTO HAVE MY X-RAY DONE WITH DIE AND AT THAT POINT THEY STATED THERE WAS NO COIL LOCATED IN MY RIGHT TUBE AND IT WAS OPEN, THIS WAS THE WORST NEWS I COULD HAVE EVER GOTTEN. THE AMOUNT OF PAIN I WENT THROUGH TO ONLY FIND OUT I COULD STILL GET PREGNANT. I THEN CONTACTED MY DOCTOR TO SET UP AN APPOINTMENT ASAP. I WENT IN HE REVIEWED THE RESULTS AND ASKED DID I WANT TO HAVE IT PLACED AGAIN AND JUST WAIT ANOTHER THREE MONTHS. I REFUSED TO GO THROUGH THAT EXPERIENCE AGAIN. I ASKED THAT HE DO A TUBAL LIGATION, AND SET AN EMERGENCY ONE FOR THAT FOLLOWING MORNING. MY HUSBAND AND I WERE TOLD AFTER I GOT OUT OF RECOVERY THAT HE COULD NOT FIND THE MISSING COIL, AND TILL THIS DAY I EXPERIENCE EXTREME AMOUNTS OF PAIN ON MY RIGHT SIDE. AT TIMES I HAVE THESE PAINS FROM SIMPLY BENDING OVER TO TIE MY KIDS SHOES, TO WHEN I AM INTIMATE WITH MY HUSBAND. SINCE THE TUBAL I HAVE GONE INTO THE ER FOR CHRONIC PAIN AND CYSTS THAT HAVE FORMED ON MY OVARIES, MY RIGHT OVARY CYSTS ARE ALWAYS

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LARGER THAN THE ONES ON MY LEFT AND I HAD NEVER HAD THIS PROBLEM PRIOR TO HAVING THIS DEVICE IMPLANTED IN ME. MY CYCLES ARE NEVER CONSTANT AND ALWAYS PAINFUL. AND I AM ONLY (B)(6). AT THE TIME I WAS (B)(6) AND WENT THROUGH SO MUCH ALREADY. I LIVE WITH A FOREIGN OBJECT IN ME THAT CAN MIGRATE, ASIDE FROM THE ONE THAT WAS LOST ON DATE OF IMPLANT THAT WAS NOT ABLE TO BE FOUND DURING THE TIME OF MY TIBIAL LIGATIONS. WORKING THAT IF HAS MOVED AND CAN CAUSE UNKNOWN DAMAGE TO ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056463	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 4/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, SHARP STABBING PAIN WHEN WALKING, SEVERE MIGRAINS, BLOTING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056464	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 5/11/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER 2MONTHS OF GETTING ESSURE, I STARTED TO GET TINGLING IN ARMS AND LEGS. WENT TO A NEUROLOGIST AND HAD TESTS DONE. NO DIAGNOSIS WAS CONFIRMED. COULD NOT DETERMINE THE CAUSE. IN (B)(6) 2014, MY HAIR STARTED TO FALL OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056465	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DAY AFTER DEVICE WAS INSERTED, I'VE EXPERIENCED: CONSTANT BACK PAIN, FATIGUE, HAIR LOSS, PULLING SENSATION ON MY LOWER RIGHT ABDOMEN. (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056466	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 12/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE THE ESSURE WAS PLACED I HAVE BEEN EXPERIENCING EXCRUCIATING PAIN IN MY PELVIS, DIZZINESS, HEADACHES, JOINT PAIN, AND WEIGHT GAIN. I'VE TRIED EVERYTHING TO COMBAT THESE SYMPTOMS WITH NO RELIEF WHATSOEVER. IT IS CONTINUALLY AFFECTING MY LIFE AND MY ABILITY TO INTERACT WITH FAMILY AND FRIENDS. I HAVE EVEN HAD TO QUIT WORKING AS A RESULT. MY DEVICE WAS PROVIDED BY MY INSURANCE BLUE CARE OF TENNESSEE AS A SAFE ALTERNATIVE TO TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056467	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 7/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PLACED ON (B)(6) 2015. APPROXIMATELY TWO WEEKS LATER THE MIGRAINES STARTED. THESE AREN'T JUST REGULAR MIGRAINES, THESE LAST DAYS AND NOTHING HELPS. IN BETWEEN MIGRAINES I HAVE A CONTINUOUS DULL TO MID GRADE HEADACHE. I CAN FEEL THE COILS IN MY TUBES. I FEEL A POKING IN MY RIGHT TUBE CONTINUOUSLY AND IN MY LEFT IF I MOVE OR LAY THE WRONG WAY. I HAVE NAUSEA ALMOST ALL OF THE TIME. I HAVE REALLY BAD ACNE AND GREASY HAIR. I FEEL LIKE I'M IN HIGH SCHOOL AGAIN! MY SKIN ITCHES WHEN I GO OUT IN THE SUN. I HAVE DIARRHEA AND CONSTIPATION. THESE ARE JUST SOME OF THE SIDE EFFECTS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056468	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 2012-2013- WAS DIAGNOSED WITH POLYCYSTIC OVARIAN SYNDROME, FIBROID UTERINE TUMORS, WEIGHT FLUCTUATIONS, EXTREME HAIR LOSS, ANXIETY, BLURRED VISION, HEAVY FEELING IN THE LOWER ABDOMEN, LOSS OF PERIODS. 2014-2015 INCREASED PELVIC/LOWER ABDOMEN HEAVINESS AND PAIN, INCREASED PAINFUL CRAMPS DURING PERIOD, PINCHING FEELING ON LEFT OVARY WHICH HAS PROGRESSIVELY INCREASED, PAIN DURING SEX FOLLOWED WITH EXTREME BLOATING AND HEAVY FEELING IN LOWER ABDOMEN FOR SEVERAL DAYS... SINCE (B)(6) OF 2015-PELVIC INFLAMMATORY DISEASE, CERVICAL CYSTS, INTESTINAL INFECTION, AND CONGESTED PELVIC SYNDROME. INCREASED LOSS OF BALANCE AND BLURRED VISION, NUMBING FROM THE FOREARMS TO FINGER TIPS, NUMBING OF LEFT LEG FROM HIM TO TOES, JOINT PAIN FROM HIPS DOWN, JAW PAIN, TEETH DECAY AND BREAKAGE, INCREASED PAIN DURING PERIOD, INCREASED HEADACHES, FEELING OF FAINTING, CAN'T STAND FOR LONG PERIOD OF TIME, LOWER BACK PAIN IS DAILY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056469	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN WITH INTERCOURSE, PERIODS. CHRONIC BACK PAIN THAT RADIATES UP AND DOWN. CHRONIC FATIGUE, BLOATING, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056470	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING AND HIVES ALL OVER MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056471	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 10/14/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD TO HAVE MY RIGHT FALLOPIAN TUBE AND RIGHT OVARY REMOVED AFTER A YEAR OF PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056472	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE LEFT SIDE PAIN GET A WORSE COMES AND GOES WITH ACTIVITY, BLEEDING, PAINFUL SEX, JOINT PAIN, HAIR LOSS, MUSCLE PAIN, METALLIC TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056473	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PUT IN (B)(6) 2015. EVERY SINCE I'VE HAD SO MUCH PAIN,VERY BAD DIARRHEA, STABBING, CRAMPS, PAIN DURING SEX, AND A VERY BAD U.T.I THAT I CAN'T EVEN GET RID OF WITH MEDICATION . NOW MY DOCTOR IS GOING TO TRY AND TAKE THEM OUT (B)(6) 2015 AND HAS NEVER TAKE ESSURE OUT BEFORE AND WELL MORE THE LIKELY END UP LEAVING FRAGMENTS BEHIND LIKE SO MANY OTHER CASE'S.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056477	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 12/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TERRIBLE PERIODS, PAIN, BLOATING. THEN HAD ABLATION FOR THE BAD PERIODS. SUCCESSFUL HGC TEST (B)(6) 2012. PAIN CONTINUE VERY BAD. HAD HYSTERECTOMY (B)(6) 2012 ALMOST 1 YEAR AFTER INSERTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056478	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2013 I STARTED TO REALIZE FIRST THAT MY LOWER ABDOMEN AND CERVIX AREA STAYED TENDER AND SORE, I CONTINUE TO FEEL SHARP STABBING PAINS. IF I TURN WRONG OR SIT WRONG IT BECOMES PAINFUL. I STARTED HAVING BLINDING MIGRAINES THAT WOULD LAST SEVERAL DAYS, MY LIBIDO HAS DECREASED DRASTICALLY, MY HAIR IS THINNING, BRAKING AND HASN'T GROWN IN SEVERAL MONTHS, MY MENSTRUAL CYCLES ARE LIKE THEY NEVER WHERE BEFORE.. I HAVE EXCESSIVE BLEEDING, PAINFUL BLEEDING. I AM NOW ON A THYROID MEDICINE DUE TO MY LEVELS CHANGING, I HAVE EXPERIENCED EXCESSIVE ANXIETY AND DEPRESSION SINCE I'VE HAD THE PROCEDURE, I EXPERIENCE RANDOM NAUSEA AND DIZZINESS. ALL OF THESE ISSUES WERE NOT A PROBLEM FOR ME BEFORE I GOT THE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056481	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER MY SON PASSED AWAY, IN UTERO AT (B)(6) GESTATION, IN (B)(6) 2012, I SPOKE WITH MY DOCTOR ABOUT A PERMANENT FORM OF BIRTH CONTROL GIVEN MY HISTORY WITH OTHER FORMS OF CONTRACEPTION. HE SUGGESTED ESSURE. ON (B)(6) 2012, AFTER TWO ROUNDS OF THE DEPO PREVARA SHOT, I WAS IMPLANTED WITH THE DEVICE IN MY DOCTORS OFFICE. MY INSURANCE APPROVED OF THE PROCEDURE AND FULLY PAID THE DOCTOR FOR MY PROCEDURE. I WAS GIVEN A ROUND OF PAIN MEDICATION BEFORE THE PROCEDURE, WHICH DID NOT TAKE AFFECT AT ALL. DURING THE PROCEDURE, IT WAS DISCOVERED THAT MY UTERUS WAS ALMOST COMPLETELY TILTED UPSIDE DOWN, AND THAT MY LEFT FALLOPIAN TUBE WAS BENT AT A 90 DEGREE ANGLE. IT TOOK THEM 15 MINUTES TO SHOVE THE ESSURE COIL IN MY LEFT FALLOPIAN TUBE. I WAS SCREAMING AND IN TEARS DUE TO THE AMOUNT OF PAIN THIS CAUSED ME. SHORTLY AFTER THE PROCEDURE, I WAS IN A ROOM WITH 3 CHAIRS AND MY MOTHER BY MY SIDE. I SUDDENLY BECAME EXTREMELY HOT, AND FELT LIKE I WAS GOING TO VOMIT. I PASSED OUT. APPARENTLY, BECAUSE OF THE PAIN AND THE AMOUNT OF TIME THEY HAD TO HOLD MY VAGINA OPEN (ROUGHLY 25 MINUTES), IT HAD CAUSED MY BLOOD PRESSURE TO PLUMMET. THAT IS THE FIRST TIME THE DEVICE ALMOST KILLED ME. I WAS TOLD I WOULD ONLY EXPERIENCE MILD TO SEVERE CRAMPING AND NAUSEA FOR A FEW WEEKS. THIS WAS FALSE. I CONTINUED TO SUFFER PAIN AND NAUSEA, BUT ATTRIBUTED IT TO MY OVULATION AND MENSTRUAL CYCLE. FOR THE FIRST TIME IN MY LIFE, MY CYCLES WERE REGULAR. BUT THAT DIDN'T LAST VERY LONG. BY (B)(6) 2013, MY PAIN GREW MORE SEVERE. I NOTICED HAIR LOSS, BRAIN FOG, HEADACHES, EXTREME CRAMPING (MORE PRONOUNCED ON MY LEFT SIDE), INCREASED BLEEDING, GOLF BALL SIZED CLOTS, FATIGUE, MOOD SWINGS, AND SUFFERED MY FIRST MISSED PERIOD. AFTER THIS, I CONTINUED TO HAVE MISSED PERIODS. WHEN I WOULD START MY MENSTRUAL CYCLE, I WOULD BE IN SUCH EXCRUCIATING PAIN THAT I WOULD NOT BE

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ABLE TO PREFORM MY DAILY DUTIES. THE BLEEDING WOULD BE SO SEVERE THAT I WOULD GO THROUGH A MAXI PAD AN HOUR, AS WELL AS RUINING MANY OF MY CLOTHING AND BEDDING DUE TO THE EXCESSIVE BLEEDING. MY SEVERE PAIN WOULD LAST ALL DAY, EVERYDAY, AND NOT JUST WHEN I WAS ON MY CYCLE. I WAS UNABLE TO HAVE SEXUAL RELATIONS WITH MY HUSBAND, BUT MAYBE TWICE A MONTH, BECAUSE OF THE PAIN INTERCOURSE WOULD CAUSE ME IN (B)(6) 2014, I DISCOVERED I WAS PREGNANT. ON (B)(6) 2014 I SUFFERED A MISCARRIAGE AT (B)(6). FINALLY IN (B)(6) 2015, I FOUND A DOCTOR WHO WOULD LISTEN TO ALL OF MY SYMPTOMS, AND FIRMLY BELIEVED THAT MY HEALTH ISSUES AND PAIN WERE BECAUSE OF ESSURE. WE ALSO FOUND OUT THAT I WAS CONTINUOUSLY GETTING VAGINAL BACTERIAL INFECTIONS, AS WELL AS YEAST INFECTIONS. SHE ALSO ATTRIBUTED THIS TO ESSURE. MY GYN REFERRED ME TO A DOCTOR WHO SPECIALIZED IN SURGERY OF WOMEN WHO HAD HORRIBLE UTERINE ISSUES. AMONG OTHER ISSUES, MY SURGEON WAS 100% SURE THAT ESSURE WAS THE CAUSE OF MY MEDICAL PROBLEMS, AS WELL AS THE REASON WHY I MISCARRIED IN (B)(6). I HAD A TOTAL HYSTERECTOMY, INCLUDING FALLOPIAN TUBES, ON (B)(6) 2015. MY DOCTOR MADE SURE THAT ESSURE WAS REMOVED. SINCE THE REMOVAL, I HAVE BEEN PAIN FREE. MY HAIR IS STARTING TO COME BACK. I HAVE FINALLY STARTED TO FEEL LIKE MYSELF BEFORE I HAD THIS HORRIBLE DEVICE IMPLANTED IN ME. I WAS LIED TO BY MY DOCTOR AND (B)(4) IN REGARDS TO THE ACTUAL SIDE EFFECTS OF THIS DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056482	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/24/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PUT IN IN 2008. I HAD HORRIBLE STOMACH PAIN TWO MONTHS AGO THAT HAS NOT GONE AWAY IT FEELS LIKE A LOT OF PRESSURE ON MY PELVIC AND A STABBING PAIN WENT TO DOCTOR MY RIGHT COIL IS IN MY UTERUS. NOW I HAVE TO HAVE A HYSTERECTOMY NEXT TUESDAY! I'M SCARED TO DEATH! YES THIS WAS COVERED BY MY INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056485	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC BACK PAIN, HEADACHES, SWOLLEN ABDOMEN, FATIGUE, VERY HEAVY PERIODS, DEPRESSION, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056486	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, HAIR LOSS, METALLIC TASTE IN MY MOUTH, WEIGHT GAIN, HEAVY PERIODS, SKIN SENSITIVITY, PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056487	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 4/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ESSURE IMPLANT WAS RECOMMENDED BY MY OB/GYN AND IMPLANTED ON (B)(6) 2010. MONTHS AFTER MY SURGERY, I STARTED FEELING EXTREME FATIGUE, ANXIETY AND CONSTANT CRAMPING. OVER THE YEARS I HAVE EXPERIENCED THE FOLLOWING SYMPTOMS THE ARE CURRENT TO DATE: CRAMPING IN LOWER ABDOMEN, CONTINUOUS SHARP, STABBING PAINS ON BOTH LEFT AND RIGHT ABDOMEN, CONSTANT DISCHARGE, HOT FLASHES, PAINFUL OVULATION, NIGHT SWEATS, LOSS OF LIBIDO, PAINFUL AND IRREGULAR PERIODS, INCONTINENCE (DISCUSSED WITH NEW OB/GYN WITH NO RESOLVE), URGENT AND FREQUENT URINATION, ITCHING AND BURNING, BREAST PAIN AND TENDERNESS, ABDOMINAL SPASMS AND GHOST FLUTTERS, PACK AND JOINT PAIN, ARTHRITIS IN JOINTS, ALL OVER BODY ACHES, SEVERE BLOATING, METALLIC METAL TASTE IN MOUTH, HEARTBURN, WEEKLY MIGRAINES, DIZZINESS, TINGLING SENSATION IN FINGERS AND TOES, BRAIN FOG - CLOUDINESS, DIZZINESS, FORGETFULNESS, ANXIETY, MOOD SWINGS, UNEXPLAINED AND EASY BRUISING, HEART PALPITATIONS, SWELLING OF HANDS AND FEET, INSOMNIA, EXTREME WEIGHT GAIN (EVEN WITH EXERCISE AND HEALTHY EATING), SLEEP APNEA, SWELLING IN FACE AND LIPS, MUSCLE SPASMS, VISION ISSUES SUCH AS FLOATERS, BLURRED VISION, DRY SKIN, AND SEVERE FATIGUE. I HAVE BEEN TO MY PRIMARY DOCTOR MULTIPLE TIMES WITH A LIST OF THESE ISSUES, HAD BLOODWORK DONE, AND NO RESOLUTION. LEVELS ALWAYS COMING BACK NORMAL. NEW OB/GYN HAS BEEN NO HELP ON ISSUES EITHER. EXTREMELY FRUSTRATING!! I WANT MY LIFE BACK TO NORMAL FOR NOT ONLY MY FAMILY BUT MYSELF!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056489	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 1/16/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE IN (B)(6) 2013. IMMEDIATELY EXPERIENCED ABDOMINAL CRAMPING/SHARP PAINS AND CONTINUE TO PERIODICALLY GET THEM ON BOTH LEFT AND RIGHT SIDE. MY FIRST HSG CONFIRMED CORRECT PLACEMENT AND BLOCKAGE OF LEFT TUBE BUT RIGHT COIL HAD COME PART WAY OUT AND WAS NOT BLOCKING TUBE. MY SECOND HSG, DONE (B)(6) 2015 CONFIRMED BOTH COILS WERE IN AN UNKNOWN AREA, ONE POSSIBLY IN MY COLON. BOTH TUBES NO LONGER BLOCKED. SIDE EFFECTS SINCE INSERTION INCLUDE; BREAST TENDERNESS, LOWER BACK PAIN, SPOTTING, BOWEL ISSUES, FOGGY THOUGHTS, DIZZINESS, NAUSEA, LACK OF APPETITE, MOOD SWINGS, EVERY DAY HEAD PAIN/HEADACHES/MIGRAINES WITH VOMITING, PELVIC PRESSURE, COLON PRESSURE, FREQUENT URINATION, ABDOMINAL SPASMS, SKIN IRRITATION, FATIGUE, VAGINAL DISCHARGE/ODOR, BLOATING, SHARP PAIN IN LEGS, VAGINAL ITCHING/SKIN THINNING, TINGLING IN HANDS/FINGERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056490	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE DEVICE IMPLANTED IN 2009. SINCE THEN, I HAVE EXPERIENCED HOT FLASHES, HEAVY BLEEDING, MISSED PERIODS, ABNORMAL PERIODS, BLOOD CLOTS DURING PERIODS, BAD CRAMPING, SPOTTING, UTI/BLADDER INFECTIONS, YEAST INFECTION, VAGINAL ITCHING, NAUSEA, DIZZINESS, GASSY, HEART BURN, MOOD SWINGS, PLEURISY, CHEST PAIN, SHARP STABBING PAIN, STABBING PAIN AFTER AND DURING SEX, BLOATING, FATIGUE, LOSS OF ENERGY, NO SEX DRIVE, HEADACHES, RASHES, HAIR LOSS, HAIR GROWTH IN NEW PLACES, TEETH ISSUES, ITCHY SKIN/BREAST AND NIPPLES, LOWER BACK PAIN, PELVIC PAIN, LIMB NUMBNESS, TYPE2 DIABETES, HIGH BLOOD SUGAR, BREAK OUTS, THOUGHTS OF DEATH, DEPRESSION, OVARIAN CYST, WEIGHT GAIN, PREGNANCY SYMPTOMS, MUSCLE SPASMS, ALWAYS HUNGRY. THIS DEVICE WAS PROVIDE BY MY INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056491	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 8/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, LOWER BACK PAIN, BLOATING, HEAVY PAINFUL LONG PERIODS, FATIGUE, INSOMNIA, JOINT PAIN, MEMORY LOSS, DEPRESSION, WEIGHT GAIN, HAIR LOSS, HORMONAL CHANGES, SKIN RASH, CONFUSION, SELF DOUBT, AND HOPELESSNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056493	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 5/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY, DEPRESSION, VITAMIN D DEFICIENT, HAIR LOSS, WEIGHT GAIN, BLOATING, SKIN IRRITATIONS, CONSTIPATION, MIGRAINES, DIZZINESS, LIGHTHEADEDNESS, CRAMPING, ENDOMETRIOSIS, NIGHT SWEATS, PAINFUL PERIODS, LONG MENSTRUAL CYCLES, URGENT/FREQUENT URINATION, BREAST PAIN, ABDOMINAL SPASMS/TWITCHING/FLUTTERING, JOINT PAIN, PELVIC PAIN, NAUSEA, GAS, METALLIC TASTE IN MOUTH, HEARTBURN (DO NOT HAVE GALL BLADDER), BOWEL ISSUES, TINGLING SENSATIONS, NUMBNESS, BRAIN SHOCKS, BRAIN FOG, CLOUDINESS, MOOD SWINGS, STROKE LIKE SYMPTOMS, RINGING IN EARS, BRUISING EASILY, HYPOGLYCEMIA, ACNE, NEW HAIR GROWTH IN NEW AREAS, SLEEP PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056500	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 3/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BLOATING, HEAVY BLEEDING, SEVERE DEPRESSION INCLUDING HOSPITAL COMMITMENT TWICE, CRIPPLING HEADACHES, JOINT PAIN, SKIN PROBLEMS, DENTAL ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056510	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 3/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ESSURE WAS COVERED BY MY INSURANCE PROVIDER, (B)(6) WITH THE EXCEPTION OF MY CO-PAY. I HAD THE PROCEDURE FOR IMPLANTING ON (B)(6) 2013. AFTER THE 3 MONTH WAITING PERIOD, I HAD THE HSG TEST DONE BY (B)(6), AND WAS TOLD THAT ONE COIL WAS PROPERLY PLACE BUT THE OTHER HAD MIGRATED. A LATER MRI REVEALED THE COIL WAS OUTSIDE THE FALLOPIAN TUBE. I WAS GIVEN THE CHOICE TO INSERT A THIRD COIL OR CHOOSE A DIFFERENT BIRTH CONTROL METHOD, SUCH AS THE PILL. AFTER LITTLE CONSIDERATION, I ASKED TO HAVE BOTH COILS REMOVED IN (B)(6) 2013. REMOVAL WAS ALSO COVERED BY INSURANCE WITH THE EXCEPTION OF MY CO-PAY. DURING THE TIME IN WHICH I HAD ESSURE IN MY BODY, I REPORTED TO MY PHYSICIAN VIA EMAIL THROUGH THE (B)(6) THE EXTREME PAIN, HEAVY BLOOD FLOW DURING MENSTRUAL CYCLE, BLOATING AND WEIGHT GAIN, AND OTHER GENERAL SYMPTOMS THAT WERE TOLERABLE, BUT PRESENT ONLY AFTER ESSURE WAS IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056519	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 10/26/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ALL OVER MY BODY, PELVIC PAIN, IRREGULAR PERIODS, SKIN RASHES, HEADACHES, HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056522	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 8/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NAUSEOUS, CHEST PAIN, DIZZINESS, ARM AND BACK PAIN, HEADACHE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056523	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 7/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PELVIC PAIN ESPECIALLY AROUND TAIL BONE. FEELS LIKE I AM BEING KICKED DOWN THERE ALL THE TIME. THERE HAVE BEEN NUMEROUS MUSCLE SPASMS/ TREMORS IN BOTH UPPER AND LOWER ABDOMEN EVERYDAY. I HAVE SCIATICA AND THE TREMORS OR SPASMS IS MAKING THAT WORSE. I'VE HAD MIGRAINES IN THE PAST MAYBE ONCE A YEAR BUT SINCE THE PROCEDURE THEY ARE CONSTANT AND NOW IS AFFECTING MY VISION AND MEMORY. AM ON SO MANY MEDICATIONS NONE OF WHICH WORK ON THE PELVIC PAIN. WHEN PROCEDURE WAS DONE THE DOC SAID THAT THE LEFT COIL WAS PUT IN TOO FAR AND IF HE WERE TO PULL IT DOWN IT WOULD CAUSE MORE PAIN AND IRREVERSIBLE DAMAGE SO HE LEFT IT AS IS FELT EVERY PAIN AS THE MEDS THAT WERE GIVEN PRIOR TO PROCEDURE HAD NO AFFECT. PAIN IN THAT SIDE HAS NOT SUBSIDED AND FEELS LIKE CONSTANT CRAMPING. PERIODS HAVE BEEN MORE HEAVY AND LONGER LASTING WITH BIG CLOTS WHICH I NEVER HAD BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056524	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 3/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY HUSBAND AND I CHOSE ESSURE BECAUSE HORMONAL BC GAVE ME HORRIBLE MIGRAINES. MY HUSBAND HAS MALIGNANT HYPOTHERMIA, SO WE WANTED TO AVOID SURGERY FOR HIM. DURING THE IMPLANTATION, ONE OF THE COILS REMAINED ATTACHED TO THE CAMERA, AND WAS PULLED OUT CAUSING EXCESSIVE BLEEDING. FURTHER, THE COIL WAS NOT BLOCKED, PROVIDING NO PROTECTION. WHEN I WENT FOR THE DYE TEST A FEW WEEKS LATER, NOT ONLY WAS THE TUBE OPEN, BUT THERE WAS AN UNIDENTIFIABLE MASS IN MY UTERUS. MY DOCTOR FELT THIS WAS CAUSED BY THE TRAUMA OF THE BOTCHED IMPLANT, AND I NEEDED SURGERY TO REMOVE IT. I HAD CRAMPING, AND FATIGUE FOR A FEW MONTHS. I DEVELOPED A CHRONIC PAIN ON MY LEFT SIDE, AND HAD SEVERAL CYSTS DEVELOP ON MY OVARIES. WITHIN A YEAR, I HAD GAINED 20 LBS IN SPITE OF WATCHING MY FOOD INTAKE, AND REGULAR EXERCISE - I BEGAN EXPERIENCING INSOMNIA, IRRITABILITY, LOSS OF SEX DRIVE, AND CONFUSION. I LATER DEVELOPED HYPOTHYROIDISM. IN (B)(6) 2015, I HAD A SCAN TO DIAGNOSE THE PAIN ON MY LEFT SIDE. THE REMAINING COIL PRESENTED LIKE IT HAD BEGUN TO MIGRATE INTO MY UTERUS. I HAD A SECOND SURGERY TO REMOVE THE COIL AND BOTH TUBES. OH, AND MY HUSBAND HAD A VASECTOMY AFTER ALL - THAT'S THREE SURGICAL PROCEDURES CAUSED THIS NON INVASIVE DEVICE. I STILL EXPERIENCE PAIN, AND AM LIVING WITH THE EFFECTS OF HYPOTHYROIDISM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056525	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 10/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY SYMPTOMS STARTED SHORTLY AFTER IMPLANTED. MY SYMPTOMS WERE WEIGHT GAIN, HEAVY BLEEDING, CRAMPS, JOINT PAIN, HAIR LOSS, MORE THAN NORMAL. I AM VERY FATIGUED ALL THE TIME, NO SEX DRIVE, AN I GET IRRITATED VERY EASILY. I HAD AN EBLATION DONE TO HELP STOP THE BLEEDING, AND I AM PREMENOPAUSAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056526	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 8/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS INPLANTED IN (B)(6) 2013, CAUSED SERVER CONSTIPATION, HEADACHES, STOMACH PAIN, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056527	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/13/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED IN 2005. I BEEN UNDER SEVERAL DOCTORS CARE TO HELP DEAL WITH THE SIDE AFFECTS WHICH ARE DEBILITATING BACK PAIN. SEVERE ITCHING SPELLS THROUGH OUT THE YEARS UNTIL THE PRESENT. I LOST OVER HALF OF MY TEETH SINCE IMPLANTING. I LOST TWO INCHES OF HEIGHT (B)(6). HAIR LOSS . ABNORMAL ABDOMEN WEIGHT AND SEVERE PELVIC PAIN. MY BODY CONSTANTLY IS HOT THEN COLD HANDS AND FEET. ALL WHICH COULD NOT BE EXPLAINED BY MEDICAL DOCTORS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056528	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 4/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHE, CRAMPS BACK PAIN LEG CRAMP FORGETFULNESS, PAIN DURING SEX SPOTTING AFTER SEX NO PERIOD MOOD SWINGS AND MEDI-CAL PAID FOR IT AND HAIR LOSS JAW PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056529	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 9/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATELY FOLLOWING INSERTION OF ESSURE I STARTED HAVING SPASMS IN MY LEFT TUBE. BEFORE ESSURE I WAS HEALTHY. NOW I HAVE OSTEOPOROSIS, JOINT SWELLING, RASHES, NERVE PAIN, NUMBNESS, WEAKNESS, RAPID TOOTH DECAY, BLOATING, SEVER LOWER BACK PAIN, LESIONS ON SPINE AND LIVER, WEIGHT LOSS, HAIR LOSS. RECENT BLOOD WORK REVEALS ANEMIA, LOW PLATELETS, AND HEMOGLOBIN. I WAS SO HEALTHY BEFORE ESSURE AND SLOWLY OVER THE LAST 5 YEARS MY HEALTH HAS DECLINED. I HAVE TALKED WITH MY GYNO ABOUT THIS BUT HE JUST WON'T LISTEN. I TOLD HIM AS A CHILD MY MOM COULDN'T GET MY EARS PIERCED BECAUSE I WAS ALLERGIC TO THE METAL. WHY WOULD I NOT BE ALLERGIC TO THE METAL IN ESSURE? GYNECOLOGIST WON'T LISTEN. I FEEL LIKE I WILL BE DEAD BEFORE ANYONE WILL LISTEN. I'M ONLY (B)(6) I SHOULDN'T BE IN THIS SHAPE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056530	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 4/4/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DURING MY PERIOD I BEGAN PASSING BLOOD CLOTS THE SIZE OF GOLF BALLS. WITHIN WEEKS OF IMPLANTATION ((B)(6) 2013) MY HAIR BEGAN TO FALL OUT BY THE HAND FULLS, I HAVE MUSCLE TWITCHES, HIP/ JOINT PAIN, MIGRAINES AND HEADACHES. MY EMOTIONS FLY FROM ONE END OF THE SPECTRUM TO ANOTHER WITH NO WARNING. I GET SHARP STABBING PAINS IN MY ABDOMINAL AREA ON A REGULAR BASIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056531	BAYER	9/25/2015	9/25/2015

Event Information:

Event Date (B3): 4/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DURING MY PERIOD I BEGAN PASSING BLOOD CLOTS THE SIZE OF GOLF BALLS. WITHIN WEEKS OF IMPLANTATION ((B)(6) /2013) MY HAIR BEGAN TO FALL OUT BY THE HAND FULLS, I HAVE MUSCLE TWITCHES, HIP/ JOINT PAIN, MIGRAINES AND HEADACHES. MY EMOTIONS FLY FROM ONE END OF THE SPECTRUM TO ANOTHER WITH NO WARNING. I GET SHARP STABBING PAINS IN MY ABDOMINAL AREA ON A REGULAR BASIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056608	BAYER HEALTH	9/25/2015	9/30/2015

Event Information:

Event Date (B3): 4/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): P40241

Single Use: *
Implant Date (E6): 4/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER STATED THAT SINCE THE PROCEDURE WAS DONE SHE HAS HAD HEAVY BLEEDING TO THE POINT OF HEMORRHAGING. SHE ALSO BECAME PREGNANT AND HAD A DIFFICULT PREGNANCY SO THAT SHE HAD TO SEE A SPECIALIST. AFTER DELIVERY OF HER DAUGHTER SHE HAD BLEEDING AND THE DOCTOR GAVE HER AN ABLATION. SHE HAS ALSO HAD ABDOMINAL PAIN, CRAMPING, BACK PAIN, HEADACHES, HOT AND COLD SPELLS. ALSO COMPLAINING OF FEELING DEPRESSED ABOUT THINGS GOING ON WITH THIS DEVICE. ABLATION GIVEN FOR HEAVY BLEEDING AND NOW THE BLEEDING IS RECURRING AND THE DOCTOR SAYS THE REPORTER MAY NEED TO HAVE A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056610	BAYER	9/25/2015	9/30/2015

Event Information:

Event Date (B3): 2/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/25/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT STATED SHE HAD ESSURE IMPLANTED ON THE ABOVE DATE AND SINCE THEN SHE HAS BEEN SUFFERING FROM THE FOLLOWING HEALTH ISSUES: MIGRAINES, BENIGN BREAST TUMOR, HEART PALPITATION, AUTOIMMUNE DISEASE (FIBROMYALGIA), METALIC TASTE IN MOUTH FROM METAL ALLERGY, BRAIN FOG, WEIGHT GAIN, CHRONIC FATIGUE, LOCALIZED PAIN, NAUSEA, BOWEL ISSUES, DIZZINESS, HAIR LOSS, EXTREME BLOATING AND INFLAMMATION AROUND HER PELVIC AREA, BREAST PAIN AND TENDERNESS, ABNORMAL PERIODS, NEUROLOGICAL ISSUES, DENTAL PROBLEMS, NUMBNESS AND TINGLING SENSATIONS, JOINT AND BACK PAIN, GRINDING AND CRUNCHING OF TEETH, ANXIETY, AND PREMENSTRUAL DYSPHORIC DISORDER (PMDD). SHE WOULD LIKE TO KNOW WHAT FDA IS DOING WITH THIS PRODUCT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056611		9/25/2015	9/30/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER SAID ESSURE IMPLANTED IN HER EARLY THIS YEAR AND SINCE THEN SHE HAS BEEN " TEARING INSIDE OUT" ABNORMAL BLOOD CLOTS, PELVIC PAIN, ABNORMAL BLEEDING."THIS STUFF IS TEARING MY BODY UP". I WANT THIS STUFF OUT OF ME". HAVE BEEN BLEEDING FOR 8-9 MONTHS STRAIGHT, CAN NOT EVEN HAVE SEX WITH MY HUSBAND WITHOUT BLEEDING."THIS STUFF NEEDS TO BE OUT OF THE MARKET." HAD BLOOD TRANSFUSIONS DUE TO HEAVY BLEEDING AND WAS ADMITTED IN THE ICU.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056612	BAYER	9/25/2015	9/30/2015

Event Information:

Event Date (B3): 6/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT STATES THAT, EVER SINCE SHE HAD THE BIRTH CONTROL IMPLANTED SHE HAS BEEN MENSTRUATING NON STOP FOR THE PAST THREE MONTHS. SHE HAS ALSO BEEN EXPERIENCING CONSTANT FATIGUE, PERMANENT MIGRAINE AS WELL AS NAUSEA. SINCE THE DAY THE PROCEDURE WAS DONE SHE HAS NOT BEEN SEEN BY THE PHYSICIAN AND HE NEVER TOLD HER WHEN TO RETURN FOR A FOLLOW UP. SHE SAYS SHE IS VERY WORRIED WITH HER PRESENT CONDITION AND DOES NOT KNOW WHAT TO DO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056664	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 6/25/2012 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL
Device Type (E2): ESSURE COIL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/12/2012
Explant Date (E7): 6/21/2012
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS WERE SCHEDULED TO BE INSERTED IN (B)(6) 2012. URINE TEST AT (B)(6) HOSPITAL IN (B)(6) FOR PREGNANCY BEFORE PROCEDURE WERE NEGATIVE. PROCEDURE CONTINUED AS SCHEDULED. TWO WEEKS LATER I BEGAN TO FEEL ILL ALL THE TIME AND I THOUGHT MAYBE I WAS HAVING A REACTION TO THE COILS, SO I WENT BACK TO MY DOCTOR TO BE CHECKED OUT AND FOUND OUT THAT I WAS 6 WEEKS PREGNANT. SO IMMEDIATELY I ASKED ABOUT THE COILS AND IF THEY WOULD IN ANY WAY HAVE ANY TYPE OF AFFECT ON MY PREGNANCY. I WAS TOLD BY DR. (B)(6) THAT MY COILS "WOULD BEND OUT OF THE WAY AND THEY WOULD NOT CAUSE ANY HARM TO MY PREGNANCY." I WENT ON ABOUT MY EVERYDAY LIFE WITH MY OTHER 2 CHILDREN AND MY HUSBAND AS IF THINGS WOULD BE FINE. BECAUSE THAT'S WHAT A MEDICAL PROFESSIONAL TOLD ME, EVERYTHING WOULD BE FINE. I WAS AT 22 WEEKS WHEN I GOT UP IN THE MORNING TO GO TO THE RESTROOM. AS I CLIMBED OVER MY HUSBAND, THERE WAS A LOUD, POPPING SOUND, LIKE A BALLOON. IT FELT WEIRD IN MY STOMACH SO I DIDN'T MOVE. AFTER A FEW SECONDS I GOT OFF THE BED AND IMMEDIATELY HAD WATER TRICKLING DOWN MY LEGS. I PANICKED AND WENT TO THE ER AT (B)(6) AND WAS GIVEN A FERNING TEST TO SEE IF I WAS LEAKING AMNIOTIC FLUID. TEST CAME BACK NEGATIVE. WAS SENT HOME. BACK AGAIN THE NEXT DAY, STILL LEAKING, ANOTHER TEST, NO FERNING, SENT HOME. RETURNED AGAIN 2 DAYS LATER WITH CRAMPING AND FLUID LOSS STILL, WAS GIVEN AN ULTRASOUND AND WAS FOUND TO HAVE AN AMNIOTIC LEVEL OF 10. NORMAL IS AROUND 14. A CERCLAGE WAS PLACED TO TRY AND SAVE THE PREGNANCY. AN ULTRASOUND 2 DAYS LATER REVEALED THAT MY FLUID LEVEL HAD DROPPED TO A 4, AND THAT MY BABY WOULD NOT SURVIVE. BEING A CATHOLIC HOSPITAL THEY WOULD NOT REMOVE THE CERCLAGE TO PERFORM A D&C AND THAT WAS NOT WHAT I WANTED. I SIGNED OUT (B)(6) AND WAS ADMITTED TO (B)(6) HOSPITAL. THERE THE HIGH RISK TEAM ASSESSED ME AND DECIDED TO REMOVE THE CERCLAGE AND LET MY BODY DO

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THE REST. AS I WAS HAVING A PROCEDURE TO REMOVE THE CERCLAGE, WHICH WAS ONE OF THE MOST TRAUMATIZING THINGS I'VE EVER HAD TO GO THROUGH IN MY LIFE, THE HIGH RISK DOCTOR PERFORMING THE PROCEDURE STOPPED ABRUPTLY AND SAID "WHAT THE (PROFANITY) IS AN ESSURE COIL DOING IN HER VAGINAL TRACT?" THE COIL HAD NEVER IMPLANTED IN FALLOPIAN TUBE AND WAS FLOATING AROUND INSIDE OF MY UTERUS MY WHOLE PREGNANCY. THE COIL HAD PERFORATED THE AMNIOTIC SAC CAUSING IT TO RUPTURE AND CAUSING ME AND MY HUSBAND TO LOSE OUR BEAUTIFUL BABY GIRL DAPHNE. I WAS TOO FAR ALONG TO HAVE THE PREGNANCY REMOVED SO I HAD TO DELIVER HER ON MY OWN. I GAVE BIRTH TO HER ON (B)(6) 2012. SHE LIVED FOR ALMOST 15 MINUTES IN MY AND MY HUSBAND'S ARMS. SINCE SHE WAS TOO FAR ALONG TO HAVE THE PROCEDURE, WE HAD TO HAVE A FUNERAL FOR HER. I HAD TO BURY MY BABY BECAUSE OF A COIL. BECAUSE I TRUSTED MY DOCTOR TO KEEP ME AND MY BABY SAFE AND HE DIDN'T. I WAS NEVER MADE AWARE AT ANY TIME THAT THERE WERE ANY TYPES OF RISK INVOLVED IF I WERE TO BECOME PREGNANT. AND I AM ASSUMING THAT IS BECAUSE BAYER DID NOT ANTICIPATE THE POSSIBILITY OF IT HAPPENING. WELL, IT DID. AND THIS WAS THE OUTCOME. I NOW SUFFER FROM PTSD BECAUSE OF THE TRAUMATIZING NATURE IN WHICH THIS ALL HAPPENED. BAYER SHOULD BE HELD RESPONSIBLE FOR WHAT THEIR PRODUCT HAS DONE. NOT JUST TO ME, BUT TO ALL THE WOMEN WHO BELIEVED AND TRUSTED THEIR DOCTORS THAT THIS WAS OR IS A SAFE AND EFFECTIVE METHOD OF BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056665	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 9/21/2012 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/21/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE DEVICE (B)(6) 2012. I WAS NOT SCHEDULED FOR THE FOLLOW UP DYE TEST UNTIL THE FOLLOWING (B)(6) 2013, AFTER I SUFFERED A MISCARRIAGE. THERE WAS A SCHEDULING CONFLICT WITH RADIOLOGY AND I WAS NEVER RESCHEDULED FOR THE DYE TEST. I SUFFERED ANOTHER MISCARRIAGE IN (B)(6) 2014 AND HAD TO HAVE AN EMERGENCY DNC DONE. I FOLLOWED UP WITH THE DOCTOR WHO IMPLANTED THAT ESSURE DEVICE AND HE FINALLY SCHEDULED MY DYE TEST FOR (B)(6) 2014. AT THAT TIME I WAS NOTIFIED THAT ONLY ONE SIDE OF MY FALLOPIAN TUBES WAS CLOSED AND THAT I STILL STOOD A CHANCE OF GETTING PREGNANT. I HAVE DEBILITATING CRAMPS AND AM NAUSEOUS MORE TIMES OUT OF THE MONTH THAN NOT AND HAVE NOT HAD A REGULAR CYCLE SINCE 2012. I HAVE GAINED IN THE UPWARDS OF (B)(6) POUNDS THAT I AM UNABLE TO LOSE EVEN WITH DIET AND EXERCISE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056677		9/25/2015	10/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056678	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL DEVICE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 4/11/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM A WOMAN WHO HAD AN ESSURE DEVICE IMPLANTED AND HAVE SUFFERED SERIOUS SIDE EFFECTS SINCE, INCLUDING PAIN, WEIGHT GAIN, SWELLING, FEELING OF SORENESS, UNUSUALLY HEAVY BLEEDING DURING MENSTRUATION ACCOMPANIED WITH QUARTER-SIZE BLOOD CLOTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056679	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 11/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/22/2013
Explant Date (E7): 2/21/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2013, I HAD THE ESSURE COILS PLACED IN BOTH TUBES AND FOR IT BEING A SIMPLE DAY SURGERY I HAD IMMEDIATE CRIPPLING PAIN, WHICH MY OBGYN AT THE TIME DISMISSED AS NERVE DAMAGE FROM MY C-SECTION. AFTER ONGOING MOTRIN INTAKE AND MY OBGYN DISMISSING ME I EVENTUALLY WOUND UP IN THE ER AND FINALLY FOUND A NEW OBGYN THAT KNEW IT WAS MORE THAN WHAT I WAS TOLD. UPON GOING IN FOR A SCHEDULED HYSTERECTOMY, HE FOUND THAT THE LEFT COIL HAD PUNCTURED MY FALLOPIAN TUBE AND WAS CUTTING THROUGH THE BACK SIDE OF MY UTERUS, HE HAD TO REMOVE BOTH TUBES AND MY UTERUS. SINCE THEN, I HAVE HAD NUMEROUS SURGERIES TO HELP WITH CRIPPLING PAIN AND I HAVEN'T BEEN ABLE TO BE A WIFE NOR MOTHER, ITS BEEN ALMOST 2 YEARS AND IT STILL HAUNTS ME TO THIS DAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056680		9/25/2015	10/1/2015

Event Information:

Event Date (B3): 3/7/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/7/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ESSURE AND THE FIRST MONTH AFTER GETTING IT BACK IN 2007, IT FELT LIKE A SHARP PAIN IN MY VAGINA. I HAVE SHARP PAINS, MY BACK HURTS, I CAN'T HAVE SEX BECAUSE IT HURTS. I CAN'T HAVE IT CHECKED OUT ANY MORE BECAUSE NO INSURANCE BUT THE PAIN GETS WORSE OVER TIME. THE DOCTOR THOUGHT I WAS CRAZY BACK WHEN I GOT IT BUT SHE TRIED TO TELL MY "MOM I LOST IT, BUT I DID GO BEHIND HER AND BOTH WERE STILL THERE." I AM TIRED OF LIVING IN PAIN, I JUST WANT IT TAKEN OUT, BUT AT THIS TIME I CAN'T AFFORD IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056687	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 7/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/31/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2012 AND I WAS TOLD THAT MY PROCEDURE WAS A TOTAL SUCCESS THAT I WAS OCCLUDED 100%, WHICH IT NEVER WAS. THE DOCTOR MADE ME FEEL LIKE IT WAS. I WAS HAVING A LOT OF PAIN ON BOTH SIDES OF MY BREAST AND DISCOVERED A FEW MONTHS AFTER THAT I WAS GAINING WEIGHT AND ALSO DISCOVERED THAT I WAS PREGNANT 5 WEEKS AND I ALREADY HAD 4 CHILDREN MEANING THAT I WAS HAVING ANOTHER CHILD WHICH WILL BE BABY #5. I CALLED THE CERTIFIED DR WHO IMPLANTED BY DEVICE WHO WAS CERTIFIED BY ESSURE TO PERFORM ANY PROCEDURE AND HE TOLD ME HE DIDN'T KNOW HOW THIS HAPPENED. HE TOLD ME HE WAS CONTACTING THE SALES REP OF ESSURE TO SEE WHAT HAPPENED TO ME AND THEY WILL REVIEW MY HSG TEST, HE CONTACTED ME A FEW DAYS LATER TELLING ME THAT I WAS THE 1% FAILURE OF THIS PRODUCT. I WAS IN TOTAL SHOCK. I CONTACTED THE SALES REP THAT HANDLES ESSURE IN MY AREA AND SHE DIDN'T KNOW WHO I WAS, SHE THOUGHT PROBABLY I WAS SOMEONE FROM THE HOSPITAL WHERE I HAD BY PROCEDURE AND SHE SAID THAT IT WAS TAKEN CARE ALREADY, AND I WAS LIKE WHAT TAKEN CARE ALREADY, SHE WAS LIKE I'M NOT SUPPOSED TO TALK TO PTS. MY PREGNANCY WAS A ROLLER COASTER, I WAS ALWAYS IN A LOT OF PAIN ON MY RIGHT SIDE. DOCTOR COULD NOT HELP ME BECAUSE HE DIDN'T HAVE ANY EXPERIENCE WITH WOMEN GETTING PREGNANT WITH ESSURE. I WAS PRACTICALLY ON MY OWN DURING MY PREGNANCY. I FEEL THAT MORE EDUCATION IS NEEDED FROM DOCTORS AND PATIENTS, THE ONLY THINK I SUED TO HEAR WAS I NEVER HEARD ANYONE GETTING PREGNANT WITH ESSURE AND I HAD TO EXPLAIN TO EVERY PROFESSIONAL ABOUT THIS PROCEDURE BECAUSE IT SEEMED THAT NO DOCTORS KNEW WHAT ESSURE WAS. I'M VERY DISAPPOINTED THAT THE FDA COULDN'T ASSIST ME WITH INFO HOW ESSURE COULD AFFECT MY PREGNANCY. I HAD BY DAUGHTER IN (B)(6). SHE WAS BORN HEALTHY, BUT THE QUESTION WAS WHY DID I GET PREGNANT? WHY WAS I HAVING PAIN? I HAD BY HSG PROCEDURE DONE AGAIN TO

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LEARN THAT I WAS NEVER OCCLUDED. THE IMPLANTED DOCTOR WAS LYING TO ME. THIS IS WHAT THEY BEEN DOING TO MANY PATIENTS WHO OPTED FOR THIS PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056688	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 11/24/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/24/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD BRAIN FOG, HEART PALPITATIONS, FATIGUE, ANXIETY/DEPRESSION, VITAMIN DEFICIENCY, BREAST PAIN, ANEMIA SEXUAL DYSFUNCTION AND INSOMNIA. ALL OF THIS STARTED AFTER I HAD ESSURE PUT IN. I DIDN'T CONNECT ALL OF IT UNTIL I SAW IT ON (B)(6) AND A LIST OF SIDE EFFECTS THAT OTHER PEOPLE WHERE HAVING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056689	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 9/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN 2008 AND AT MY 3 MONTH CHECK ONE OF THE COILS HAD MIGRATED RENDERING THE IMPLANTS INEFFECTIVE AS BIRTH CONTROL. THE COIL HAS IMPLANTED ITSELF AT MY ABDOMEN AND I SUBSEQUENTLY HAD TO UNDERGO A TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056690	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 11/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/6/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE TUBAL LIGATION PROCEDURE IN (B)(6) 2014. SINCE THEN I HAVE EXPERIENCED HORRIBLE CRAMPS, STABBING OVARIAN PAIN, MIGRAINES, DIZZINESS AND PETITE MAL SEIZURES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056691	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 2/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/5/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT STERILIZATION PROCEDURE IN (B)(6) 2008. UPON LEAVING THE PHYSICIANS OFFICE, I EXPERIENCED A VAGUS NERVE INCIDENT, WHERE MY ENTIRE NERVOUS SYSTEM SHUT DOWN. FORTUNATELY, MY OBGYN'S OFFICE WAS IN THE HOSPITAL. I WAS RUSHED TO THE ER, WHERE I SPENT THE BETTER PART OF THE DAY. WITH NO FURTHER INCIDENTS, I WAS SENT HOME. WHEN I RETURNED TO MY DOCTOR FOR A FOLLOW-UP, I WAS TOLD THE VAGUS INCIDENT OCCURRED BECAUSE OF A REACTION I HAD TO THE DRUGS THEY GAVE ME TO MAKE ME RELAX. FOLLOWING THE PROCEDURE, I BLED HEAVILY FOR MORE THAN 50 DAYS. EVENTUALLY, MY DOCTOR PRESCRIBED BIRTH CONTROL PILLS (WHICH IS IRONIC BECAUSE THE PRIMARY REASON FOR HAVING THE PROCEDURE IN THE FIRST PLACE WAS IN ORDER TO STOP TAKING BIRTH CONTROL PILLS) TO CONTROL THE BLEEDING. BUT, IT TOOK NEARLY TWO MONTHS TO ACHIEVE THAT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056692	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 4/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED AFTER MY DAUGHTER BIRTH IN (B)(6) 2006. SINCE THEN I HAVE HAD MAJOR ISSUES WITH MAJOR AND AT TIMES DEBILITATING VAGINAL PAIN, PAINFUL AND HEAVY BLEEDING DURING MENSTRUAL CYCLES CAUSING SEVERE ANEMIA, AND COUNTLESS BOUTS WITH BV AND YEAST INFECTIONS. I ALSO HAVE HIP PAIN AND EXTREME BACK PAIN. PAIN DURING SEX. MOODINESS AND WEIGHT GAIN WITHOUT RESULT LOSING AFTER DIETING. SINCE I RECEIVED THIS DEVICE IT HAS BEEN NON-STOP (PROFANITY) OF PAIN TO THE POINT I HAVE ASKED TO HAVE IT REMOVED AND DUE TO ALL THE VAGINAL PROBLEMS DOCTORS STATES THAT A FULL HYSTERECTOMY WOULD BE THE ONLY OPTION. MY INSURANCE WILL NOT COVER UNLESS ALL OTHER MEASURES HAVE BEEN EXHAUSTED. SO, I AM LIVING IN PAIN DAILY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056693	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 3/4/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN MY GYNO'S OFFICE. I ALSO WENT BACK 3 MONTHS LATER AND HAD THE DYE TEST DONE TO MAKE SURE THAT IT WAS PLACED PROPERLY AND EVERYTHING WAS SEALED. I WAS TOLD THAT THE PROCEDURE WAS EFFECTIVE AND I COULD RELY ON IT AS MY FORM OF BIRTH CONTROL. THAT THE DYE TEST SHOWED 100% BLOCKED TUBES. THEREFORE, I STOPPED TAKING MY ORAL BIRTH CONTROL. MY HUSBAND AND I WERE SHOCKED TO FIND OUT THAT I WAS PREGNANT SOME MONTHS LATER. THIS PRODUCT SHOULD NOT BE MARKETED AS PERMANENT BIRTH CONTROL, AS IT IS NOT. I'VE FOLLOWED THE PROCEDURES EXACTLY, MAKING SURE TO GO BACK FOR THE DYE TEST BUT IT FAILED. THIS IS A COMPLETELY FALSE HOPE FOR WOMEN LOOKING FOR PERMANENT BIRTH CONTROL. THE FDA SHOULD NOT LET THIS PRODUCT REMAIN AVAILABLE IN THE CAPACITY IT IS BEING TOLD TO WOMEN IT IS FOR. IT IS NOT PERMANENT BIRTH CONTROL. MORE, UN-BIASED TESTING SHOULD HAVE BEEN PERFORMED. THE HEALTHCARE PROFESSIONALS OR DOCTORS NEED TO TAKE SOME OF THE BLAME TOO AS THIS PRODUCT WAS FORCEFULLY PROMOTED BY MY GYNO'S OFFICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056694	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 7/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 7/17/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN MY OVARIAN TUBES AFTER I HAD MY SECOND DAUGHTER (B)(6) 2015. ALTHOUGH I DID NOT WANT TO GET IT, MY DOCTOR ASSURED ME THAT A LOT OF HIS PTS HAD IT WITH NO COMPLAINTS. I DID NOT WANT TO HAVE ANY MORE KIDS SO I DECIDED SINCE IT WAS THE ONLY WAY TO PREVENT FUTURE KIDS I AGREED. AS SOON AS IT WAS INSERTED IN ME I NOTICED SIDE EFFECTS. IT IS SO PAINFUL TO THE POINT I CANNOT WALK OR SIT COMFORTABLY. I AM UNABLE TO WORK, OR HELP WITH MY KIDS SOMETIMES BECAUSE OF IT. I HAVE BEEN LOOKING TO GET IT REMOVED AS SOON AS THE 3 MONTH WAITING PERIOD EXPIRED AND I WAS STILL EXPERIENCES SEVERAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056695	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 9/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED AT (B)(6). THE FIRST PLACEMENT IN MY FALLOPIAN TUBE SNAPPED IN HALF AND HAD TO BE REMOVED AND INSERTED AGAIN. I WAS AWAKE AND FELT EVERYTHING. EVERYTHING WENT OKAY WITH THE RIGHT TUBE. IN THE FOLLOWING WEEKS I STARTED DEVELOPING PAIN AND CONTACTING MY DOCTOR WITH NO HELP. MY PLACEMENT SCAN SHOWED THE COIL ON THE RIGHT WAS FINE WHILE THE COIL ON THE LEFT PERFORATED MY FALLOPIAN TUBE AND WOUND UP ON ITSELF. I WAS THEN SCHEDULED FOR A LAPAROSCOPIC REMOVAL OF THE COIL. THE PAIN WAS BECOMING MORE SEVERE BY THE WEEK AND FINALLY ON (B)(6) 2014 WHILE GETTING OUT OF MY CAR I HAD SEVERE PAIN THAT MADE ME DOUBLE OVER AND ALMOST THROW UP IN MY FRONT YARD. I NOTIFIED THE MD ABOUT THIS AND SAID TO WAIT FOR THE SURGERY THAT I WAS PROBABLY JUST OVULATING. WHAT A BRUSH OFF! ALMOST 3 MONTHS LATER I WENT IN FOR THE COIL REMOVAL AND DURING THE PROCEDURE THEY DID A SALPINGECTOMY AND WERE UNABLE TO FIND THE COIL SO THEY PROCEEDED TO DO AN ENTIRE PELVIC EXPLORATORY LAPAROSCOPY AND STILL DID NOT FIND THE COIL. AN UNNECESSARY PROCEDURE IN MY OPINION. THE PAIN PERSISTED AND TO "MAKE ME FEEL BETTER" THE DR ORDERED CT SCAN TO FIND OUT WHERE THE COIL WAS EVEN THOUGH SHE INSISTED THAT I SHOULD BE FINE. THE CT SCAN SHOWED THAT THE COIL WAS NOW EMBEDDED IN MY UTERUS AND I WOULD NEED A HYSTERECTOMY TO HAVE IT REMOVED. I HAVE ASKED SEVERAL TIME FOR A HYSTERECTOMY AND MY MD WILL NOT PERFORM IT STATING THAT THE RISK IS GREATER THAN THE BENEFIT. EVERY MONTH I EXPERIENCE INCREASING PAIN AND EVERY MONTH I JUST WANT MY UTERUS REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056698	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE IN (B)(6) 2013. (B)(6) WAS THE INSURANCE I HAD AT THE TIME AND WOULD ONLY LET ME DO THE ESSURE AS A PERMANENT FORM OF BIRTH CONTROL. I REGRET THIS DECISION EVERYDAY. I AM NO LONGER ABLE TO BE INTIMATE WITH MY HUSBAND. SEX IS BEYOND PAINFUL AND IT IS REALLY PUTTING A STRAIN ON NOT ONLY MY RELATIONSHIP, BUT GIVING ME HORRIBLE SELF ESTEEM AS WELL. I HAVE CONSTANT HEADACHES, SOME THAT ARE DEBILITATING AND LEAVE ME IN BED NOT ABLE TO CARE FOR MY FAMILY. I AM LOSING ALL MY HAIR. I HAVE ALWAYS HAD THICK HAIR AND NOW IT IS BABY FINE. THE CONSTANT PELVIC PAIN FROM THIS DEVICE IS UNBEARABLE AND SEVERELY EFFECTS MY QUALITY OF LIFE. I NO LONGER FEEL LIKE A STRONG WOMAN. I FEEL DEFEATED AND HELPLESS. THIS DEVICE IS NOTHING TO HELP WOMEN. IT DESTROYS US! IT NEEDS TO BE RECALLED AND NEVER OFFERED AGAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056722	CONCEPTUS INCORPORATED	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 7/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 624475

Single Use: *
Implant Date (E6): 11/30/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IMMEDIATELY AFTER IMPLANT OF ESSURE CYCLE BECAME EXTREMELY PAINFUL AND VERY HEAVY, LOWER BACK PAIN EVERY DAY, SOMETIMES DEBILITATING, JOINT PAIN IN MULTIPLE PLACES, MIGRAINES, EXTREMELY LETHARGIC DAILY, DEPRESSION, WORSE RIGHT BEFORE CYCLES, GROWTH ON THYROID, MULTIPLE SURGERIES DUE TO SIDE EFFECTS OF ESSURE, TEETH ROTTEN AND CRUMBLING, LOSS OF HAIR, FEVERS FOR NO APPARENT REASON WHICH RESULTED IN LOSS OF WORK AND INCOME, MENTAL STRESS OVER MULTITUDE OF MEDICAL ISSUES CAUSING DURESS ON MY WELL BEING TO CARE FOR NOT ONLY MY CHILDREN BUT ALSO DISABLED MOTHER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056723	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 3/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE IMPLANT
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/15/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS ALWAYS A HEALTHY AND ACTIVE PERSON. I WAS LIKE 31 OR 32 WHEN I HAD IT DONE AND I AM NOW 39 YEARS OLD. SINCE HAVING THE ESSURE IMPLANT I EXPERIENCE IRREGULAR MENSTRUAL CYCLES, HEAVY MENSTRUAL BLEEDING ALONG WITH BIG BLOOD CLOTS, AND PAINFUL CRAMPING DURING MENSTRUAL CYCLE. WHICH, BEFORE THIS MY CYCLES WERE NORMAL WITH NO CRAMPING. I ALSO HAVE JOINT PAIN, BACK PAIN, AND HEADACHES NEARLY EVERYDAY. ALL OF THIS HAS SLOWLY BEEN GETTING WORSE SINCE HAVING THE PROCEDURE DONE. I ALSO SUFFER FROM CHRONIC FATIGUE, NUMBNESS IN MY HANDS, AND DEPRESSION. I HAD NEVER BEEN DEPRESSED UNTIL A FEW YEARS AGO. THE CYST I DEVELOPED WAS FOUND WHEN I HAD THE ONE YEAR CHECK UP AFTER HAVING IT DONE. BEING IRRITATED BY THIS I HAVE NOT HAD AN OB/GYN CHECK UP SINCE. I HAVE BEEN SEEING MY FAMILY DOCTOR AND EXPLAINING ALL OF THESE PROBLEMS TO HIM BUT NO BLOOD WORK HAS INDICATED ANYTHING IS WRONG. HE HAS NO SOLUTION AS TO HOW TO HELP ME WITH ALL OF THE SYMPTOMS I HAVE BEEN EXPERIENCING. I AM NOT SURE OF THE EXACT DATE THAT I HAD THIS DONE. I WOULD HAVE TO CONTACT THE DOCTOR WHO DID THE PROCEDURE WHICH I AM PLANNING TO DO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056725	BAYER	9/25/2015	10/1/2015

Event Information:

Event Date (B3): 3/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/31/2014
Explant Date (E7): 10/23/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED ON (B)(6) 2014. AFTER HAVING THE PROCEDURE DONE I HAD EXPERIENCED SEVERE CRAMPING AND IRREGULAR BLEEDING. I HAD A HYSTERECTOMY DUE TO THE DEVICE PENETRATING MY LEFT FALLOPIAN TUBE, THE PAIN AND RECOVERY WAS A HORRIBLE EXPERIENCE. I CAN NO LONGER HAVE CHILDREN DUE TO THE HYSTERECTOMY BEING IRREVERSIBLE, AS WHERE THE ESSURE WAS REVERSIBLE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056681		9/26/2015	10/1/2015

Event Information:

Event Date (B3): 9/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN 2004. PRIOR TO THAT I HAD BEEN DIAGNOSED WITH IBS AND FIBROMYALGIA IN 1989. FOLLOWING THE ESSURE PROCEDURE, I HAVE SINCE DEVELOPED CHRONIC ALLERGIES, I BREAK OUT IN HIVES RANDOMLY, OVARIAN CYSTS, HYPOTHYROIDISM AND NODULES, TMJ, CHRONIC MIGRAINES AND MITRAL AND TRICUSPID VALVE REGURGES. I EXPERIENCE IRREGULAR BLEEDING AND REMAIN ON BIRTH CONTROL PILLS AT (B)(6) NOW TO CONTROL THE CYSTS AND BLEEDING AS BEST AS POSSIBLE. HAVE HAD PELVIC PAIN ON AND OFF SINCE PROCEDURE TO WHICH MY OB/GYN CLAIMS IT'S LIKELY JUST PART OF MY FIBRO. I ALSO CANNOT TAKE MEDICATIONS WITHOUT THROWING SERIOUS SIDE EFFECTS TO THEM TO THE JOINT WHERE I AM RUNNING OUT OF MEDICATIONS, I CAN TAKE WHEN I AM SICK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056682		9/26/2015	10/1/2015

Event Information:

Event Date (B3): 11/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/14/2010
Explant Date (E7): 11/15/2010
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2010. AFTER EXPERIENCING A LOT OF PELVIC AND BACK PAIN, MY DOCTOR SAID IT WAS NORMAL AND I SOUGHT A SECOND OPINION. NEW DOCTOR DID AN ULTRASOUND AND WAS UNABLE TO FIND THE COILS. HE SCHEDULED A LAPAROSCOPIC SURGERY TO EXPLORE. ONE COIL WAS FOUND IN MY ABDOMEN, THE OTHER PERFORATED THROUGH MY FALLOPIAN TUBE AND EXTREMELY INFECTED. I WAS PUT ON ANTIBIOTICS FOR 1 MONTH AND THEN TAKEN BACK FOR A BILATERAL SALPINGECTOMY TO REMOVE MY TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056683		9/26/2015	10/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ITS BEEN ALMOST A YEAR SINCE MY ESSURE WAS PLACED, IN HAVING EXTREME PELVIC PAIN, FATIGUE, WEIGHT GAIN OF (B)(6) POUNDS RIGHT AFTER IT WAS PLACED, MY PERIODS ARE VERY HEAVY, I AM DEPRESSED AND TIRED ALL THE TIME SINCE AFTER ESSURE, I HAVE LOST HAIR AS WELL, IN HAVING PAIN WHEN HAVING INTERCOURSE. I NEVER HAD THESE KINDS OF SYMPTOMS BEFORE ESSURE. MY DOCTOR PUSHED IT ON ME, I WAS WANTING A TUBAL BUT HE INSISTED ESSURE WAS BETTER FOR ME. NOW I AM IN PAIN ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056684	CONCEPTUS	9/26/2015	10/1/2015

Event Information:

Event Date (B3): 9/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: *
Implant Date (E6): 9/14/2010
Explant Date (E7): 9/4/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE IMPLANTED AND STARTED HAVE A PUNCHING PAIN ON LEFT SIDE, BECAME CHRONIC PAIN OVER TIME. DIZZY, HAIR LOSS, CONFUSION (FOGGY MIND) AND MUCH MORE. ENDED UP HAVING A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056685	BAYER	9/26/2015	10/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE HAS CAUSED THESE PROBLEMS FOR ME. SEVERE MIGRAINES, EXCESSIVE BLEEDING, SEVERE BLOATING. I LOOK 6 MONTHS PREGNANT AND I'M NOT, SEVERE PAIN IN PELVIC AREA AND LOWER BACK INTO MY LEGS. I EXPERIENCE PAIN DURING SEX AND HAVE HAD SEVERAL URINARY TRACT INFECTIONS. THERE ARE DAYS I CAN'T GET OUT OF BED DUE TO THESE COMPLICATIONS WHICH RESULTED IN LOSS OF WORK. I NEVER EXPERIENCED ANY OF THESE PROBLEMS BEFORE ESSURE AND I AM 100% SURE THAT ESSURE IS THE CAUSE OF MY COMPLICATIONS AND BELIEVE ESSURE SHOULD BE RECALLED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056686		9/26/2015	10/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAVE BEEN EXPERIENCING SOME VERY SHARP PELVIS AND BACK PAIN, PAIN DURING SEX, SEVERE HEADACHES, PAIN WITH SUDDEN MOVEMENTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056707	BAYER	9/26/2015	10/1/2015

Event Information:

Event Date (B3): 4/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A78087

Single Use: *
Implant Date (E6): 4/10/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED AFTER MY FOURTH CHILD IN EARLY 2013. THE SURGERY WENT WELL. I WAS BACK TO WORK IN NO TIME. I DID HAVE MY FOLLOW UP TO SHOW THAT MY TUBES WERE BLOCKED IN (B)(6) OF 2013. HOWEVER, THE AFTER EFFECTS SINCE THEN HAS NOT BEEN SO GREAT. WEIGHT GAIN, HAIR LOSS, BLOATING, DEPRESSION, WEAKNESS, HEAVIER PERIODS, I COULD GO ON. DO NOT GET THIS IMPLANTED. I OPTED TO HAVE ANOTHER SURGERY (THERMACHOICE) TO CORRECT THE HEAVY PERIODS BECAUSE MY OBGYN WAS NOT GOING TO GIVE ME A HYSTERECTOMY. I WORK OUT 5-6 DAYS A WEEK WITH CARDIO AND WEIGHT TRAINING. IT HURTS SO BADLY THAT I CAN NOT WORK OUT LIKE I WANT. I CAN NOT LOSE WEIGHT LIKE I WANT EITHER. THIS BATTLE HAS BEEN NERVE WRECKING AND HOPEFULLY THE FDA WILL HAVE THIS DEVICE RECALLED ASAP. I AM NOW GOING BACK TO MY OBGYN TO SEE IF SHE WILL EVEN LISTEN TO ME TO HAVE THIS REMOVED FROM MY BODY. IF NOT, I'LL BE GOING TO ANOTHER DOCTOR UNFORTUNATELY. IM TIRED OF MY HAIR FALLING OUT EVERYDAY THE SIZE OF ORANGES. PLEASE RECALL THIS DEVICE FROM THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056708		9/26/2015	10/1/2015

Event Information:

Event Date (B3): 5/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/8/2010
Explant Date (E7): 5/21/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2010 IN (B)(6), I HAD THE ESSURE COILS PLACED IN MY FALLOPIAN TUBES TO PREVENT PREGNANCY. ALTHOUGH I WAS TOLD THERE WOULD BE MINOR CRAMPING, SIMILAR TO PERIOD CRAMPING, DURING/AFTER THE PROCEDURE, THAT WAS NOT WHAT I EXPERIENCED. THE PROCEDURE ITSELF WAS INCREDIBLY PAINFUL, LIKE GOING THROUGH CHILDBIRTH ALL OVER AGAIN. THE PAIN LESSENED OVER THE NEXT TWO DAYS, BUT IT NEVER WENT AWAY. I EXPERIENCED MILD PAIN ALL THE TIME, BUT IT BECAME SEVERE DURING BOWEL MOVEMENTS, WHILE HAVING SEX, LIFTING ANYTHING HEAVY, OR WHENEVER I JUST MOVED THE "WRONG" WAY. THAT SEVERE PAIN TOOK HOURS TO GO BACK TO "JUST" THE MILD PAIN THAT WAS CONSTANTLY PRESENT. MY YEARLY PELVIC EXAMS WERE ALSO INCREDIBLY PAINFUL. FINALLY IN (B)(6) 2013 I FOUND A DOCTOR THAT WAS WILLING TO LISTEN TO MY ISSUES AND SHE RECOMMENDED HAVING THE ESSURE COILS REMOVED. I WAS REFERRED TO AN OFF POST PROVIDER IN A (B)(6) HOSPITAL (MILITARY STATIONED IN (B)(6) AND HE SCHEDULED ME FOR SURGERY ON (B)(6) 2013. MY FALLOPIAN TUBES WERE REMOVED WITH THE ESSURE COILS AND, SINCE THEN, I HAVE NOT EXPERIENCED THE DEBILITATING PAIN THAT I HAD WHILE ESSURE WAS IN PLACE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056711	BAYER	9/27/2015	10/1/2015

Event Information:

Event Date (B3): 12/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/23/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2009 I HAD ESSURE PLACEMENT DONE, PERFORMED IN THE OFFICE BY MY OB/GYN. WHEN I WENT BACK FOR MY TEST (HYSTEROSALPINGOGRAM) TO MAKE SURE MY TUBES WERE FULLY OCCLUDED, IT WAS DETERMINED THAT ONE OF THE COILS HAD MIGRATED OUT OF MY FALLOPIAN TUBE AND HAD EMBEDDED IN MY UTERUS. MY DOCTOR SAID IT WASN'T A PROBLEM TO LEAVE THE COIL IN MY UTERUS, AND WE SET A DATE TO REDO THE FALLOPIAN TUBE THAT WAS MISSING THE COIL. I WENT BACK I BELIEVE IN (B)(6) 2010 AND HAD THE SECOND COIL REPLACED. WHEN I WENT BACK FOR MY 2ND HYSTEROSALPINGOGRAM, BOTH TUBES WERE FULLY OCCLUDED. BEGINNING IN THE SPRING OF 2010 AND CONTINUING FOR MORE THAN A YEAR, I HAD INTERMITTENT PAIN AND CRAMPING ON MY LEFT SIDE. SOME DAYS IT WAS SO PAINFUL, I WAS BEDRIDDEN AND HAD TO TAKE PAINKILLERS. THE PAIN WAS DEBILITATING AND LEFT ME UNABLE TO PROPERLY CARE FOR MY 3 CHILDREN. OVER THE SUMMER 2011, I HAD SURGERY AND SIGNED OFF ON 5+ DIFFERENT PROCEDURES PRIOR TO GOING UNDER ANESTHESIA. I SIGNED OFF ON TUBAL LIGATION OPERATION ROOM HYSTERECTOMY OPERATION CYST REMOVAL OPERATION ROOM OVARY REMOVAL OPERATION ROOM FALLOPIAN TUBE REMOVAL ETC. I ENDED UP HAVING MY LEFT FALLOPIAN TUBE AND LEFT OVARY REMOVED. MY DOCTOR STATED THAT THE BLOOD VESSELS AND CAPILLARIES IN THAT AREA WERE ENLARGED AND VARICOSE, THE DIAMETER OF PENCILS AND LARGER. SINCE THEN, I HAVE EXPERIENCED MORE PAIN. I AM CURRENTLY ON BIRTH CONTROL HORMONAL MEDICATION TO SUPPRESS OVULATION AND SEND MY OVARIES INTO HIBERNATION. I TAKE THE PILL ALL MONTH LONG TO AVOID HAVING A MONTHLY PERIOD. I HAVE GAINED WEIGHT DUE TO BEING ON THE PILL. I CONTINUE TO HAVE PAIN AND DISCOMFORT DUE TO THE ESSURE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056712	BAYER	9/27/2015	10/1/2015

Event Information:

Event Date (B3): 8/22/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 809009

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

DEPRESSION, ANXIETY, LEFT SIDE OF BODY HURTS, HOT FLASHES, MOOD UP AND DOWN, PAINFUL SEX.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01077	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 31-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION IN 2008. ADDITIONAL INFORMATION RECEIVED ON 15-SEP-2015 (PTC INVESTIGATION RESULT). THE CONSUMER WAS NOT PREGNANT BY THE TIME OF ESSURE INSERTION. AFTER THE PROCEDURE SHE STARTED EXPERIENCING BAD PERIODS. IN 2012 HER PHYSICIAN WANTED TO DO AN ABLATION WHICH COULD ONLY BE A HOT WATER ABLATION BECAUSE OF ESSURE COILS. THE CONSUMER AGREED AND DURING THE PROCEDURE THE PHYSICIAN DID NOT SEE THE ESSURE. THE PHYSICIAN, THEN, WENT AHEAD AND DID A SHOCK ABLATION TOO. THE CONSUMER REPORTED THAT SHE WAS OUT WHEN THE PHYSICIAN DECIDED TO DO THE SHOCK ABLATION AND SHE WAS ONLY INFORMED ABOUT THE DOUBLE ABLATION AFTER SHE WOKE UP. SHE STATED THAT SHE DID NOT CONSENT TO THIS. NOW, EVER SINCE THE ABLATION PROCEDURES, SHE HAD BEEN HAVING SEVERE, REALLY BAD LOWER ABDOMINAL PAIN. SHE ALSO REPORTED THAT HER OVARIES WERE COVERED IN CYSTS. SHE STATED SHE LOVED THE ESSURE PRODUCT AND IT DID NOT CAUSE HER PROBLEMS - THE ABLATIONS DID. SHE WAS GIVEN VICODIN AND IBUPROFEN FOR PAIN. SHE ALSO REPORTED THAT SHE CANNOT FUNCTION DURING THE DAY. HER ESSURE PHYSICIAN SUGGESTED SHE HAS A HYSTERECTOMY; HOWEVER SHE DID NOT WANT TO HAVE IT DUE TO HER YOUNG AGE. ON (B)(6) 2015 SHE HAD AN APPOINTMENT WITH A NEW PHYSICIAN WHO WOULD DO AN ULTRASOUND. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO

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LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHILE SHE WAS HAVING THE HOT WATER ABLATION, DOCTOR DID NOT SEE ESSURE COILS (SEEN AS DEVICE DISLOCATION). A HYSTERECTOMY WAS SUGGESTED BY HER PHYSICIAN. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 16-DEC-2015 FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01100	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0942, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. ADDITIONAL INFORMATION RECEIVED ON 21-SEP-2015 (PTC INVESTIGATION RESULT). CONSUMER REPORTED SHE WAS NEVER TESTED FOR NICKEL ALLERGY AND SHE WAS ALLERGIC. HER PERIODS BECAME VERY PAINFUL, SHE HAD CONSTANT BACTERIAL VAGINOSIS, HIGH CHOLESTEROL, THYROID PROBLEMS AND MIGRAINES. HER LEFT COIL MIGRATED TO INSIDE HER UTERUS WHILE THE RIGHT COIL APPEARED TO BE STILL IN THE TUBE. SHE LOOKED LIKE SHE WAS PREGNANT EVERYDAY FROM THE INFLAMMATION OF THE TOXIC FIBER AND METAL. SHE WAS SCHEDULED FOR A TOTAL HYSTERECTOMY TO HAVE ESSURE REMOVED. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE

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TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL ALLERGY AND HER LEFT COIL HAS MIGRATED TO INSIDE HER UTERUS (SEEN AS DEVICE EXPULSION). BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. ALSO, DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IT WAS NOT KNOWN THE EXACT DATE AND MECHANISM OF EXPULSION AND WITH REGARDS TO NICKEL ALLERGY, CONSUMER WAS NEVER TESTED FOR NICKEL ALLERGY. SHE WAS SCHEDULED FOR A TOTAL HYSTERECTOMY TO HAVE ESSURE REMOVED. BASED ON THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01114	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0154; AWARENESS DATE: 06-AUG-2015). IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER STATED THAT SHE HAS HAD ESSURE FOR 4 YEARS AND SINCE THE DAY OF THE PROCEDURE SHE HAD CHRONIC RIGHT SIDE PELVIC PAIN. SHE WENT TO DOCTORS AND ESSURE WAS IN A MUSCLE NOT EVEN IN HER TUBE. SHE VOMITED AND SUFFERED FROM WEIGHT LOSS. SHE WALKED BENT OVER AND HOLD HER STOMACH. FOLLOW-UP INFORMATION RECEIVED ON 30-AUG-2015 AND 16-SEP-2015 (PTC - PRODUCT TECHNICAL COMPLAINT - WAS RECEIVED). THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0928). ESSURE WAS INSERTED IN (B)(6) 2011 (SHE WAS (B)(6)). THE DAY OF THE PROCEDURE WAS THE ONSET OF RIGHT SIDE PELVIC PAIN. SHE BLED HEAVY FOR 1 YEAR. SHE HAS BEEN TO COUNTLESS DOCTORS FOR PELVIC PAIN; PELVIC EXAMS AND SEX WAS WHAT SHE AVOIDED DUE TO INCREASED PAIN. SHE WAS A VERY ANGRY PERSON DUE TO THE PAIN. ESSURE HAS RUINED HER LIFE; SHE LOST A LOT OF WEIGHT AND HER TEETH AND SKIN WERE DAMAGED. SHE SAID THAT ESSURE HURTS, NOT HELPS. SHE WAS SCHEDULE TO HAVE A SALPINGECTOMY WITH THE REMOVAL OF ESSURE DEVICES AND HYSTEROSCOPY IN (B)(6). CASE UPGRADED TO INCIDENT. PTC RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR

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ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE REFERS TO A (B)(6) FEMALE CONSUMER WHO BLED HEAVY FOR 1 YEAR AND HAD CHRONIC RIGHT SIDE PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE STATED ESSURE WAS IN A MUSCLE NOT EVEN IN HER TUBE (REGARDED AS DEVICE EMBEDMENT/PARTIAL PERFORATION). A SALPINGECTOMY IS SCHEDULED FOR DEVICES REMOVAL. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. ALSO, THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION, MIGRATION OR OCCUR AS A RESULT OF A UTERINE/FALLOPIAN TUBE PERFORATION. IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE PAIN AND BLEEDING DURING AND AFTER THE PROCEDURE. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF THE REPORTED DEVICE EMBEDMENT WERE NOT KNOWN, HOWEVER GIVEN EVENTS NATURE, A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE IS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR DEVICES REMOVAL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

INTERNAL CORRECTION ON 24-NOV-2015: DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 09-AUG-2015.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01115	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0894, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. AT TIME OF INSERTION, SHE SUFFERED SEVERE PAIN TO LACK OF PROPER PROCEDURE AND OF A BROKEN COIL. THIS PAIN NEVER SUBSIDED. AFTER RECEIVING THE IMPLANTS, SHE STAYED IN A GENERALLY IRRITATED MOOD DUE TO CONSTANT PAIN AND CONSTANT MENSTRUATION OVER THE NEXT SIX MONTHS. DURING THIS TIME SHE SUFFERED FROM HIGH BLOOD PRESSURE, HEART PALPITATION, ALLERGIC REACTIONS TO NICKEL, ALLERGIC REACTIONS TO PET FIBERS, LOSS OF ENERGY, EMOTIONAL DISTRESS, CONSTANT FEELING OF INADEQUACY AND LACK OF DESIRE FOR SEX (WHEN SHE WAS WILLING TO BE INTIMATE, IT WAS A DELICATE MATTER DUE TO POSITIONING OF THE COILS AND IRRITABLE PAIN IN HER BODY). AFTER SEARCHING FOR SEVERAL MONTHS, A SPECIALIST WAS FOUND. SHE WAS ONLY WILLING TO PERFORM A FULL HYSTERECTOMY DUE TO THE FACT THAT THE COILS HAD MIGRATED AND PROTRUDED THRU HER UTERUS. WITHIN THE FIRST WEEK AFTER SURGERY, SHE WAS A CHANGED PERSON. SHE WAS NOT, HOWEVER, BACK TO HER NORMAL SELF. PET FIBER ALLERGIES, HEART PALPITATIONS AND HIGH BLOOD PRESSURE ARE STILL AN ISSUE NEARLY SEVENTEEN MONTHS AFTER REMOVAL OF THE COILS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT TIME OF INSERTION, A BROKEN COIL OCCURRED. AFTER ESSURE INSERTION, SHE EXPERIENCED CONSTANT PAIN AND CONSTANT

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MENSTRUATION OVER THE NEXT SIX MONTHS. A FULL HYSTERECTOMY WAS PERFORMED DUE TO THE FACT THAT THE COILS HAD MIGRATED AND PROTRUDED THRU UTERUS (SEEN AS EMBEDDED DEVICE). BROKEN COIL IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE OTHER EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED. IN THIS CASE, ALL EVENTS OCCURRED AFTER ESSURE INSERTION PROCEDURE. THE EXACT DATE AND MECHANISM OF EMBEDMENT WERE NOT KNOWN. CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 01-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01116	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 6/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0938, AWARENESS DATE 30-AUG-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION IN 2012 (AFTER HER 3TH CHILD SHE DECIDED TO HAVE HER TUBES CUT AND TIED). THE CONSUMER REPORTED THAT SHE SIGNED CONSENT FOR TUBAL LIGATION AND THEN, AT THE HOSPITAL ON THE DAY OF HER SURGERY RIGHT WHEN SHE WAS IN PRE-OPERATIVE BED WITH IV, THE PHYSICIAN TOLD HER THAT THEY WERE NOT PERFORMING THAT TYPE OF PROCEDURE, THEY WERE DOING SOMETHING BETTER, PERMANENT TOO CALLED ESSURE. SHE WAS NEVER TOLD ABOUT THE NICKEL AND METALS ON THE DEVICE AND THE PHYSICIAN SAID THAT THERE WERE NO SIDE EFFECTS. RIGHT AFTER WOKEN UP FROM THE PROCEDURE SHE STARTED FEELING A LOT PELVIC PAIN WHICH NEVER WENT AWAY. SHE ALSO EXPERIENCED WEIGHT GAIN (ALMOST 40 POUNDS IN 2 YEARS), CHRONIC GASTRITIS, MIGRAINES, CHRONIC DIARRHEA AND LOT OF GASES, BELLY ACHE, A LOT OF BLOATING, PANIC ATTACKS, HOT FLASHES, AMENORRHEA, LETHARGY, BODY AND LOWER BACK PAIN, CONTACT DERMATITIS. SHE ALSO REPORTED FAILURE OF HER GALLBLADDER WHICH SHE HAD TO REMOVE. SHE REPORTED THAT ESSURE DESTROYED HER SEXUAL LIFE; HAVING SEX WAS TOO PAINFUL AND SHE ALWAYS BLED AFTER IT. SHE WENT TO MANY DOCTORS LOOKING FOR ONE TO HELP HER OUT, BECAUSE NO ONE BELIEVED HER. ON (B)(6) 2015, WHEN SHE WAS (B)(6), SHE HAD A TOTAL HYSTERECTOMY. SHE STATED THAT RIGHT AFTER THE SURGERY SHE FELT SO MUCH RELIEVE. IN (B)(6) 2015, A WEEK AFTER SURGERY, HER DERMATITIS DISAPPEARED. SHE REPORTED THAT AFTER 2 MONTHS, IN (B)(6) 2015, SHE WAS FEELING BETTER AND LOOKING FORWARD TO GET HER LIFE BACK. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS

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NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THE PROCEDURE STARTED FEELING A LOT OF PELVIC PAIN. SHE ALSO EXPERIENCED FAILURE OF GALLBLADDER WHICH SHE HAD TO REMOVE. THREE YEARS AFTER ESSURE INSERTION SHE UNDERWENT A HYSTERECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE REMAINING EVENT IS UNLISTED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING EVENT FAILURE OF GALLBLADDER, CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AS ESSURE LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01117	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0899, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. SHE WAS IMPLANTED WITH ESSURE AFTER THE BIRTH OF HER SECOND CHILD. AFTER THE SURGERY AND THE ESSURE IMPLANTATION A DYE TEST WAS DONE AND SHOWED THAT ESSURE WAS INEFFECTIVE AND WAS ALLOWING THE DYE FLUID TO PASS. OVER THE NEXT SEVERAL MONTHS SHE STARTED EXPERIENCING PAIN IN ABDOMEN AND SIDE ON A REGULAR BASIS. THIS PAIN INCREASED IN THE FORM OF CYSTS AND ABSCESSES AS WELL AS DEBILITATING PAIN. THE PAIN CONTINUED TO INCREASE EXPONENTIALLY OVER THE NEXT COUPLE OF YEARS AND RESULTED IN MULTIPLE HOSPITALIZATION AND VISITS, TO INCLUDE OVER A WEEK ON HIGH DRIP ANTIBIOTICS. SHE ALSO HAD FURTHER PAIN WITH SEXUAL INTERCOURSE, MENSTRUAL CYCLE AND EXTRANEOUS EXERCISES. SHE WAS SCHEDULE TO HAVE A HYSTERECTOMY; TO REMOVE FALLOPIAN TUBES, UTERUS AND CERVIX AS A RESULT OF DEVICE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN IN HER ABDOMEN AND SIDE AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, THIS PAIN RESULTED IN MULTIPLE HOSPITALIZATIONS AND SHE IS SCHEDULED FOR A HYSTERECTOMY. ADDITIONALLY, SHE HAD ABSCESSES (UNSPECIFIED) MONTHS AFTER ESSURE PLACEMENT. ONLY PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER'S PAIN STARTED MONTHS AFTER ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT

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CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT, THE EXACT LOCATION AND NATURE OF CONSUMER'S ABSCESS WERE NOT SPECIFIED. THUS, A COMPREHENSIVE CAUSALITY ASSESSMENT IS NOT POSSIBLE BASED ON THE AVAILABLE INFORMATION. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE HOSPITALIZATION WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01118	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 5/15/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0910, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. SHE HAD ESSURE PLACED IN 2013 AFTER HER THIRD BABY. SHE STARTED TO HAVE PERIODS EVERY TWO WEEKS. THEN SHE HAD A HSG (HYSTEROSALPINGOGRAM) TEST AND IT SHOWED THAT ONE OF HER TUBES WAS NEVER BLOCKED. ON AN UNSPECIFIED DATE, SHE HAD ANOTHER HSG TEST DONE AND IT SHOWED THAT A COIL MIGRATED AND WAS IN THE PELVIC AREA. ON (B)(6) 2015 SHE WAS MORE THAN JUST GETTING HER TUBES REMOVED. HER DOCTOR WENT IN AND FOUND OUT THAT THE COIL HAD EMBEDDED ITSELF IN AND WRAPPED AROUND HER UTERUS AND AT THE AGE OF 31 SHE HAD TO HAVE A WHOLE HYSTERECTOMY. WHEN SHE WOKE UP FROM RECOVERY, ALL OF HER SYMPTOMS SLOWLY WENT AWAY. HER BLOATING WAS GONE, HER RASHES NEVER CAME BACK. THREE MONTHS LATER HER HAIR STARTED GROWING BACK, HER PELVIC PAIN ON THE RIGHT SIDE WAS GONE AND OF COURSE THE HARSH PERIODS WERE GONE. SHE COULD NOT BELIEVE THAT THOSE COILS FROM ESSURE CAUSED ALL HER PAIN AND MENTAL EXHAUSTION FOR THE LAST TWO YEARS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND COIL MIGRATED AND WAS IN THE PELVIC AREA, THE COIL HAD EMBEDDED ITSELF IN AND WRAPPED AROUND UTERUS. SHE UNDERWENT A HYSTERECTOMY TWO YEARS AFTER INSERTION. THIS EVENT, INTERPRETED AS DEVICE EMBEDDED (PARTIAL UTERINE PERFORATION), IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT

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CASE HYSTEROSALPINGOGRAM SHOWED THAT A COIL MIGRATED AND WAS IN THE PELVIC AREA. DURING SURGERY, TWO YEARS AFTER ESSURE INSERTION, DOCTOR FOUND OUT THAT THE COIL HAD EMBEDDED ITSELF IN AND WRAPPED AROUND HER UTERUS AND SHE HAD A HYSTERECTOMY. GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01119	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0967, AWARENESS DATE 26-AUG-2015). CASE WAS RECEIVED IN UNITED STATES ON 30-AUG-2015 AND REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER REPORTED THAT AFTER PLACEMENT, SHE HAD MINOR CRAMPS AND DISCOMFORT. HER DOCTOR INFORMED HER THAT IT WAS NORMAL. SHE WENT BACK FOR HER CHECKUP AND DISCUSSED WITH HER DOCTOR THAT SHE WAS STILL CRAMPING AND HAD VERY SHARP PAINS LIKE SHE WAS BEING STABBED FROM TIME TO TIME. CONSUMER ALSO TOLD HEALTH CARE PROFESSIONAL THAT SHE WAS SPOTTING THE ENTIRE MONTH, AND STILL HER PHYSICIAN SAID NOT TO WORRY AND THAT IT WAS NORMAL. AT 3 MONTHS, CONSUMER WENT TO HAVE HER COILS CHECKS TO BE SURE THEY WERE IN PLACE AND BLOCKED. THE DOCTOR WHO PERFORMED THE TEST SAID THAT SHE WAS COMPLETELY BLOCKED AND EVERYTHING LOOKED GREAT. SHE CONTINUED SPOTTING, HAVING ABNORMAL MENSTRUAL CYCLES (HEAVY FOR 2 DAYS, NOTHING FOR 5 AND THEN WHAT SHE WOULD CONSIDER A NORMAL PERIOD FOR 4 DAYS) AND SHARP STABBING PAINS THE ENTIRE TIME. RANDOMLY, SHE STARTED HAVING BACTERIAL INFECTIONS THAT SHE HAS NEVER HAD BEFORE ESSURE (THE INFECTIONS CAME AND WENT FOR MONTHS). IN ADDITION, CONSUMER REPORTED THAT SHE HAD BEAUTIFUL LONG HAIR THAT WENT ALL THE WAY DOWN HER BACK AND, IN 2013, IT STARTED THINNING. SHE TRIED DIFFERENT REMEDIES TO MAKE SURE SHE HAD HEALTHY HAIR BUT, IN 2014, HER HAIR WAS BREAKING AND THINNING SO BADLY SHE HAD TO CUT IT OFF BECAUSE IT WAS SO DAMAGED. ACCORDING TO CONSUMER, SHE TAKES VERY GOOD CARE OF HER HAIR. ALSO IN 2014, HER OFFICE WAS NOT RUNNING SMOOTHLY AND SHE COULD NOT FIGURE OUT WHY. SHE HAD A HEART TO HEART

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WITH HER OFFICE ADMINISTRATOR AND SHE LET HER KNOW THAT SHE WAS NOT STAYING ON TASK. SHE KEPT JUMPING FROM ONE THING TO ANOTHER, FORGETTING WHAT SHE WAS DOING HALF WAY THROUGH IT AND JUST MOVING ON TO THE NEXT THING. SHE COULD NOT REMEMBER DETAILS FROM THE DAY BEFORE AND THAT IS NOT LIKE HER AT ALL. SHE WENT IN TO THE PHYSICIAN TO DISCUSS WHAT WAS GOING ON. THEY DESCRIBED THE ISSUE SHE WAS HAVING AS A BRAIN FOG. ONE DOCTOR PUT HER ON ADHD (ATTENTION DEFICIT HYPERACTIVITY DISORDER) MEDICINE. AFTER TAKING THAT, SHE WAS NOT SLEEPING AT NIGHT AND SHE KEPT FLUSHING THROUGHOUT THE DAY, SO THEY PRESCRIBED HER 2 MORE MEDICINES TO HELP WITH THOSE SIDE EFFECTS. SHE FEELS AS IF SHE WAS TAKING A MEDICINE TO HELP WITH THE FIRST MEDICINE AND ON AND ON. NOT THE WAY SHE WANTS TO LIVE. SHE STARTED HAVING HER LEFT EYE BLUR THROUGHOUT THE DAY. SOME MORNINGS, SHE WOULD WAKE UP AND HER EYE WAS SO BLURRY SHE COULD NOT SEE ANYTHING OUT OF IT EXCEPT FOG. OTHER DAYS, SHE COULD SEE FINE. CONSUMER HAD MANY PELVIC ULTRASOUNDS DUE TO PAIN (NO RESULTS PROVIDED) AND STATES THAT SHE HAS DEVELOPED A RASH ON HER UPPER BACK THAT IS CONSISTENT WITH A NICKEL ALLERGY. SHE IS HAVING JOINT PAIN IN HER HIPS, FINGERS AND KNEES. SHE HAS GAINED OVER 30LBS AND SHE EATS HEALTHY. WHEN SHE DOES DO ATTEMPT TO EXERCISE, SHE HURTS SO BADLY IN HER LOWER ABDOMEN THAT IT PUTS HER DOWN FOR DAYS. SHE GETS BADLY SHARP STABBING PAINS, CRAMPS AND BLOATING. ADDITIONALLY, CONSUMER REPORTED THAT ONE OF THE WORST THINGS IS THAT WHEN SHE WENT BACK TO THE DR. WHO IMPLANTED HER WITH ESSURE SHE LITERALLY LAUGHED IN HER FACE WHEN SHE TOLD HER THAT SHE FELT THIS WAS ESSURE RELATED. CONSUMER FOUND ANOTHER DR. AND CANNOT SAY THAT SHE WAS HUNDRED PERCENT CONVINCED THAT HER ISSUES WERE ESSURE RELATED, UNTIL MORE RECENTLY WHEN CONSUMER HAD TO DO A WALK IN APPOINTMENT BECAUSE SHE HAD SO MUCH PAIN THAT SHE WAS NAUSEOUS BECAUSE OF IT. PHYSICIAN SENT HER STRAIGHT OVER TO THE HOSPITAL TO HAVE ANOTHER ULTRASOUND WHICH SHOWED HER RIGHT COIL HAS PUNCTURED HER UTERUS. THEY COULD NOT SEE THE LEFT COIL. SHE WILL GO TO HER DR. ON (B)(6) 2015 BECAUSE SHE WANTS TO SET A HYSTERECTOMY SURGERY DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT RIGHT COIL HAS PUNCTURED HER UTERUS. CONSUMER WANTED TO SET A HYSTERECTOMY SURGERY DATE. THIS EVENT, SEEN AS UTERINE PERFORATION, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF UTERINE PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT PROVIDED RECEIVED ON 02-OCT-2015 : PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01120	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 7/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0917, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION WAS IDENTIFIED ON 20-SEP-2015. TWO AND A HALF YEARS AGO (2013) SHE WAS IMPLANTED WITH ESSURE IN A DOCTOR'S OFFICE. THE PROCEDURE ITSELF WAS VERY PAINFUL AND SHE WAS IN BED FOR TWO WEEKS AFTERWARD. SHE FELT THE ESSURE CLICK INSIDE HER AND FELT STABBING PAIN RIGHT AWAY. OVER A PERIOD OF MONTHS THE PAIN GOT BETTER, BUT NEVER WENT AWAY COMPLETELY. HER DOCTOR WOULD NOT EVEN ENTERTAIN THE POSSIBILITY OF ESSURE BEING THE CAUSE OF HER PAIN AND PROCEEDED WITH NEW TESTS AND DIAGNOSES. NONE OF WHICH EVER STOPPED THE PAIN THAT STARTED AT THE MOMENT SHE HAD ESSURE IMPLANTED. ABOUT SIX MONTHS AGO THE PAIN BECAME WORSE AND SHE DECIDED TO SEE A NEW DOCTOR. AFTER RULING OUT OTHER POSSIBILITIES, ONE DOCTOR ACKNOWLEDGED THAT THE PAIN COULD BE FROM ESSURE BUT GAVE NO GUARANTEE THAT IT WOULD STOP IF IT WAS REMOVED. SHE HAD NEVER REMOVED ESSURE BUT OFFERED TO TRY OR TO GIVE HER A HYSTERECTOMY (SHE DECIDED TO HAVE ANOTHER SURGEON WHO HAD MORE EXPERIENCE WITH REMOVING ESSURE WITHOUT HAVING A HYSTERECTOMY). ON (B)(6) 2015, SHE HAD ABDOMINAL SURGERY TO REMOVE THE ESSURE COILS AND TISSUES SURROUNDING THEM. HOWEVER, SHE WAS STILL SUFFERING FROM SURGERY. SHE NO LONGER HAD THE BURNING/STINGING/RADIATING/STABBING FEELING IN FALLOPIAN TUBES THAT BEGAN AT THE MOMENT SHE WAS IMPLANTED, NOR THE STABBING LOWER BACK PAIN. SHE STATED THAT THIS WAS SO MUCH FOR THERE BEING "NO WAY HER PAIN COULD BE CAUSED BY ESSURE". SHE STATED THAT SHE WAS

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NOT ALLERGIC TO NICKEL, ACCORDING TO THE PATCH TEST DONE RECENTLY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD BURNING/STINGING/RADIATING/STABBING FEELING IN FALLOPIAN TUBES (INTERPRETED AS ADNEXA UTERI PAIN). APPROXIMATELY TWO AND A HALF YEARS LATER, SHE HAD AN ABDOMINAL SURGERY TO REMOVE THE COILS AND TISSUE AROUND IT. AFTER THE SURGERY, THIS PAIN SUBSIDED. THE ADNEXA UTERI PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT THIS PAIN STARTED AT THE MOMENT SHE HAD ESSURE IMPLANTED AND THAT THE PRESENCE OF A FOREIGN BODY IN THE FALLOPIAN TUBES MAY CAUSE PAIN, AND CONSIDERING THAT THIS PAIN SUBSIDED AFTER ESSURE REMOVAL, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 10-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01121	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7): 8/19/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0919, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006 FOR BIRTH CONTROL. CONSUMER MEDICAL HISTORY INCLUDED 3 KIDS. SHE REPORTED THAT FOR THE FIRST 2 YEARS ESSURE WAS GREAT, BUT THEN SHE DEVELOPED 22 DIFFERENT SIDE EFFECTS THAT RANGE FROM RINGING IN HER EARS AND BLURRED VISION TO LEFT ABDOMINAL PAIN. SHE WAS ALWAYS IN PAIN AND FATIGUE. ON (B)(6) 2015 SHE HAD A FULL HYSTERECTOMY PERFORMED TO REMOVE ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN IN HER ABDOMEN AND SIDE AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (9 YEARS AFTER DEVICE PLACEMENT) TO REMOVE ESSURE. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER'S PAIN STARTED TWO YEARS AFTER ESSURE INSERTION. ALTHOUGH TEMPORAL RELATIONSHIP BETWEEN THE EVENT AND DEVICE INSERTION IS WEAK; SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01122	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0924, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. WITHIN 48 HOURS OF THE PROCEDURE SHE BECAME BEDBOUND WITH SEVERE PAIN AND COPIOUS BLEEDING. ELEVEN DAYS LATER, HER COILS WERE REMOVED VIA SALPINGECTOMY. UNFORTUNATELY, THAT WAS NOT THE END OF HER HISTORY WITH ESSURE. IT WAS AS IF THE DEVICE REBOOTED HER IMMUNE SYSTEM WITH A WHOLE HOST OF GLITCHES. THE MOST DEBILITATING SYMPTOMS WERE THE UNEXPLAINED VERTIGO AND THE INTERCOSTAL NEURALGIA, BOTH OF WHICH BRING HER TO THE FLOOR AND PREVENT HER FROM REGULARLY DRIVING. SHE ALSO EXPERIENCED JOINT PAIN ESPECIALLY IN HIPS, NECK AND LEFT ANKLE. HER HANDS LOCK UP, CRAMP, LOSE STRENGTH AND GO NUMB WITH MINIMAL USE. SHE HAD ALLERGIES AND SENSITIVITIES TO PERSONAL PRODUCTS (SHE MUST USE CHEMICAL FREE, ORGANIC, UNSCENTED PRODUCTS NOW AS ANYTHING ELSE GIVES HER A RASH AND FRAGRANCES TRIGGER ASTHMA EPISODES HER ASTHMA, WHICH WAS ALWAYS MODERATE AND WELL CONTROLLED ON LIMITED MEDS, WAS NOW DIFFICULT TO CONTROL. SHE HAD BEEN TO THE ER FOR BREATHING TREATMENTS, STEROIDS AND ANTIBIOTICS MULTIPLE TIMES OVER THE PAST TWO YEARS. PRIOR TO HER EXPERIENCE WITH ESSURE, THE LAST TIME SHE REQUIRED EMERGENCY TREATMENT FOR ASTHMA WAS OVER 6 YEARS AGO. SHE HAD INTENDED TO RETURN TO WORK AFTER HER YOUNGEST STARTED SCHOOL FULL TIME, BUT THAT BECAME IMPOSSIBILITY AFTER ESSURE (SHE HAD A TENDENCY TO BLACK OUT OR DOUBLE OVER FROM THE CRAMPS IN CHEST WALL MUSCLES, NOT TO MENTION HER ASTHMATIC REACTION TO CLEANING PRODUCTS OR AIR FRESHENERS)

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COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN AND COPIOUS BLEEDING (SEEN AS GENITAL BLEEDING). THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED SEVERE PAIN AND COPIOUS BLEEDING WITHIN 48 HOURS OF THE ESSURE PROCEDURE. HER COILS WERE REMOVED VIA SALPINGECTOMY 11 DAYS AFTER INSERTION. BASED ON A POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE EVENTS AND CONSIDERING THAT NO ALTERNATIVE EXPLANATION WAS PROVIDED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. IT WAS ALSO REPORTED THAT THE DEVICE REBOOTED HER IMMUNE SYSTEM WITH A WHOLE HOST OF GLITCHEX, WHICH IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND UNLISTED. BASED ON THE PATHOPHYSIOLOGY AND CONSIDERING THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 02-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01123	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0968 / FDA-2014-N-0736-0015, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER REPORTED THAT SINCE GETTING ESSURE INSERTED SHE HAS BEEN EXPERIENCING PAIN. SHE WOKE UP FROM PROCEDURE WITH EXCRUCIATING PAIN IN HER LEFT SIDE. DOCTOR PRESCRIBED TYLENOL. EVERY MONTH SHE GOT THE SAME PAIN. SHE LOST ENERGY, LOST HAIR, LOST TEETH AND NO MATTER WHAT SHE DID SHE COULD NOT GET RID OF THE BLOATED STOMACH. HER SELF ESTEEM HAS TAKEN A HIT. SHE FELT LIKE A FAILURE. SHE HAS SURGERY SCHEDULED TO REMOVE ESSURE ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THE INSERTION, HAS BEEN EXPERIENCING EXCRUCIATING PAIN ON HER LEFT SIDE. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SINCE THE CONSUMER HAD ESSURE INSERTED, SHE HAS BEEN EXPERIENCING PAIN. SHE WOKE UP FROM PROCEDURE WITH EXCRUCIATING PAIN IN HER LEFT SIDE AND HAD THE SAME PAIN MONTHLY. GIVEN CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WILL BE REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 02-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01124	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0986, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE TO KEEP FROM GETTING PREGNANT. CONSUMER REPORTED THAT SHE DID HER CONFIRMATION BLOCK TEST AND WAS CONFIRMED BLOCKED, BUT SHE ENDED UP GETTING PREGNANT ANYWAY. SHE LOST THE BABY AT (B)(6). FINALLY SHE HAD TO HAVE A HYSTERECTOMY DUE TO COMPLICATIONS. SHE WAS VERY DEPRESSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS RETROSPECTIVE PREGNANCY, CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT WITH ESSURE. SHE LOST HER BABY AT (B)(6) AND HAD TO PERFORM A HYSTERECTOMY DUE TO COMPLICATIONS. THE PREGNANCY WITH DEVICE IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE, THE SPONTANEOUS ABORTION AND UNSPECIFIED COMPLICATIONS ARE SERIOUS EVENTS DUE TO REQUIRED INTERVENTION. THE PREGNANCY WITH DEVICE IS LISTED WHILE THE SPONTANEOUS ABORTION AND UNSPECIFIED COMPLICATIONS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE ONSET DATE OF PREGNANCY WAS NOT PROVIDED, BUT IT IS STATED THAT SHE PERFORMED A CONFIRMATION BLOCK TEST AND BLOCKAGE WAS CONFIRMED. CONSIDERING THIS INFORMATION, IT IS NOT POSSIBLE TO EXCLUDE THE POSSIBILITY OF AN INEFFECTIVE DEVICE. IN THIS PARTICULAR CASE, LIMITED INFORMATION ABOUT THE PREGNANCY AND PATIENT WAS PROVIDED. HOWEVER, CONSIDERING THE GESTATIONAL AGE OF (B)(6), LACK OF ALTERNATIVE

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EXPLANATION AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF THE ESSURE DEVICE IN THE AMNIOTIC SAC CANNOT BE EXCLUDED, THE SPONTANEOUS ABORTION IS ASSESSED AS RELATED TO ESSURE AND THE CASE REGARDED AS INCIDENT. IN CONTRAST, SINCE THE COMPLICATIONS WERE NOT SPECIFIED, IT IS NOT POSSIBLE TO ASSESS IF THEY ARE RELATED TO ESSURE. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01125	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0987, AWARENESS DATE 26-AUG-2015). CASE WAS RECEIVED IN UNITED STATES ON 30-AUG-2015 AND REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. CONSUMER REPORTED THAT IN 2007, SHE WENT TO HER PHYSICIAN TO DISCUSS TUBAL LIGATION. THE PHYSICIAN RECOMMENDED ESSURE BECAUSE IT WAS THE LEAST INVASIVE AND REPORTER MENTIONED THAT HER BODY REJECTED AND EXPELLED HER IUD AND WOULD REJECT ESSURE BECAUSE IT WAS FOREIGN AS WELL. SHE WAS TOLD THAT SHE WOULD BE FINE. HOWEVER, HER BODY STARTED REJECTING ESSURE IMMEDIATELY. SHE WAS IN AND OUT OF THE DOCTORS AND EMERGENCY ROOMS DUE TO EXCESSIVE BLEEDING, PELVIC PAIN, HUGE WHITE BLOOD CLOTS, RED BLOOD CLOTS, HIVES ALL OVER HER BODY (UP UNTIL HER HYSTERECTOMY), PRESSURE IN HER UPPER ABDOMEN (WHICH FELT HERNIATED), SWELLING ALL OVER HER BODY INCLUDING HER STOMACH (WHICH SHE STILL HAS SOMEWHAT), BLEEDING WHEN EXERCISING (FELT LIKE SOMETHING WAS PUNCTURING), NO BLADDER CONTROL, JOINT PAIN AND, PROBABLY THE MOST SIGNIFICANT FEELING SHE HAD WAS HER BODY FELT LIKE IT WAS SHUTTING DOWN OR DESPERATELY TRYING TO FIGHT SOMETHING (NO ENERGY). CONSUMER HAD HER HYSTERECTOMY (VAGINAL LEAVING OVARIES) IN JULY 2014 AND STARTED IMMEDIATELY FEELING BETTER. HER HIVES WENT AWAY, HER SWELLING ALL OVER BODY (NECK, ARMS, LEGS) HAS GONE DOWN; HOWEVER THERE ARE A FEW LINGERING SYMPTOMS SUCH AS SLIGHT SWELLING AND DISCOMFORT IN HER ABDOMEN WHICH SHE IS SEEING HER PHYSICIAN FOR AT THIS TIME. IN ADDITION, CONSUMER REPORTED THAT HEALTH CARE PROFESSIONAL HAS NO RESOLUTION AS OF YET (CT SCAN, X-RAY, PELVIC SCAN ULTRASOUND).

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CONSUMER ALSO REPORTED THAT SHE HAS ONLY LISTED A FEW SIDE EFFECTS AND STATES THAT THERE ARE MANY MORE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE BLEEDING / HUGE WHITE BLOOD CLOTS / RED BLOOD CLOTS / BLEEDING WHEN EXERCISING. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSUMER UNDERWENT A HYSTERECTOMY. BASED ON THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01126	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0997, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2005. SHE STATED THAT HER BODY WAS BAD AS ESSURE CAUSED IMMUNE SYSTEM DISORDER AS WELL AS SEVERE CRAMPS AND BLEEDING. HER HAIR WAS FALLING OUT AND SHE HAD DEPRESSION AND WEAKNESS. SHE COULD NOT ENJOY HER LIFE BECAUSE OF THE PAIN SHE WENT THROUGH ON A DAILY BASIS. IN (B)(6) 2015 SHE HAD HYSTERECTOMY. SHE WAS STILL RECOVERING AT TIME OF THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEVERE CRAMPS (INTERPRETED AS ABDOMINAL PAIN) AND SEVERE BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A HYSTERECTOMY TEN YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL PAIN AND ABNORMAL GENITAL BLEEDING MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENTS AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01127	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1021, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER REPORTED THAT SHE EXPERIENCED CHRONIC PELVIC PAIN, CHRONIC / HEAVY PERIODS EVERY FEW WEEKS, JOINT PAIN IN HER WRISTS, LEGS, HIPS AND KNEES, LOWER BACK PAIN, BRAIN FOG, BLOATING, VISION CHANGES, HAIR LOSS, SWEATING, METAL TASTE IN MOUTH, DENTAL PROBLEMS, BAD ACNE, NO SEX DRIVE, PAINFUL INTERCOURSE, HEADACHES, ALLERGY TO NICKEL. SHE ALSO DEVELOPED TEMPOROMANDIBULAR JOINT DISORDER, TRIGEMINAL NEURALGIA AND HAD HER GALL BLADDER REMOVED IN (B)(6) 2013. IN (B)(6) 2014 SHE HAD A HYSTERECTOMY PERFORMED TAKING EVERYTHING EXCEPT HER OVARIES. SINCE THEN ALL HER SIDE EFFECT WERE GONE AND SHE FELT MUCH BETTER. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN AND HAD HER GALLBLADDER REMOVED. THESE EVENTS, SEEN AS PELVIC PAIN AND CHOLECYSTECTOMY, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. PELVIC PAIN IS LISTED WHILE CHOLECYSTECTMY IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. THUS, CONSIDERING IMPLIED TEMPORAL RELATIONSHIP, EVENT'S NATURE AND RECOVERY AFTER REMOVAL (POSITIVE DECHALLENGE), CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. IN ADDITION, SINCE MOST OF CHOLECYSTECTOMIES ARE PERFORMED DUE TO SYMPTOMS OR COMPLICATIONS RELATED TO GALLSTONES AND ESSURE ACTS LOCALLY IN FALLOPIAN TUBES,

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CAUSAL RELATIONSHIP BETWEEN SUSPECT INSERT AND THIS EVENT IS VERY UNLIKELY. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01128	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/8/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1095, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. TWO MONTHS AFTER INSERTION SHE HAD AN ALLERGIC REACTION, SHE FOUND OUT THAT SHE WAS ALLERGIC TO NICKEL. ESSURE WAS REMOVED ON (B)(6) 2015 ALONG WITH HER TUBES. AFTER SURGERY, HER SYMPTOMS WENT AWAY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND TWO MONTHS LATER HAD AN ALLERGIC REACTION TO NICKEL. SHE UNDERWENT SALPINGECTOMY AND ESSURE REMOVAL THREE MONTHS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE; SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED. THEREFORE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SALPINGECTOMY AND ESSURE REMOVAL). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01135	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 31-AUG-2015. IT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION ON AN UNSPECIFIED DATE. THE PATIENT WAS NOT PREGNANT. ON (B)(6) 2015 A SURGICAL LAPAROSCOPIC REMOVAL OF ESSURE WAS PERFORMED DUE TO PELVIC PAIN. PTC INVESTIGATION RESULT WAS RECEIVED ON 15-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) SURGICALLY REMOVED BY LAPAROSCOPY DUE TO PELVIC PAIN. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND

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UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE; CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-DEC-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01136	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/24/2009
Explant Date (E7): 7/27/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 31-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 FOR STERILIZATION. ADDITIONAL INFORMATION RECEIVED ON 15-SEP-2015 (PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT). ON (B)(6) 2015 THE PATIENT CALLED WITH COMPLAINTS OF BACK PAIN AND ABDOMINAL PAIN. SHE WAS REFERRED TO HER PRIMARY CARE. ON (B)(6) 2015, AFTER SEEING THE PRIMARY CARE, SHE CALLED BACK AND TOLD THE OFFICE THAT AN ABSCESS WAS FOUND IN HER TUBE. IN THE MEANTIME SHE WAS TREATED FOR INFECTION BECAUSE OF THE ABSCESS. ON (B)(6) 2015 SHE WAS HOSPITALIZED (NO DISCHARGE DATE PROVIDED) AND A COMPUTERIZED TOMOGRAM (CT SCAN) WAS PERFORMED; HOWEVER THE RESULTS WERE NOT PROVIDED. WHILE IN THE HOSPITAL NO SURGERY WAS PERFORMED BECAUSE THE INFECTION WAS STILL BEING TREATED. ON (B)(6) 2015 A NUCLEAR MAGNETIC RESONANCE IMAGING (MRI) WAS PERFORMED (NO RESULTS PROVIDED). ON (B)(6) 2015 SHE HAD A DRAIN PLACED. ON (B)(6) 2015 THE PHYSICIAN SCHEDULED HER SURGERY TO REMOVE THE PELVIC ABSCESS. ON (B)(6) 2015 THE PHYSICIAN ENDED UP DOING A TOTAL HYSTERECTOMY WITH THE ESSURE COILS REMOVED. THE POSTOPERATIVE DIAGNOSIS WAS TUBAL ABSCESS AND BILATERAL PERFORATION. THE PATIENT WAS FINE WITH NO COMPLICATIONS. IT WAS NOTED IN HER MEDICAL CHART THAT NO HYSTEROSALPINGOGRAM (HSG) WAS DONE. MOREOVER, A SECOND HOSPITALIZATION WAS REPORTED WITHOUT ANY DATE SPECIFIED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS

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CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT. SHE HAD AN ABSCESS IN HER FALLOPIAN TUBE AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. HER TREATMENT CONSISTED OF HOSPITALIZATION FOR AN INFECTION (BECAUSE THE ABSCESS) AND SURGERY (TOTAL HYSTERECTOMY). POSTOPERATIVE DIAGNOSIS REVEALED BILATERAL ESSURE PERFORATION. ALL EVENTS ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE ABSCESSES TYPICALLY RESULT FROM UPPER GENITAL TRACT INFECTIONS (COMPLICATION OF PELVIC INFLAMMATORY DISEASE). WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS PARTICULAR CASE, PATIENT WAS DIAGNOSED WITH A FALLOPIAN TUBE ABSCESS APPROXIMATELY 6 YEARS AFTER ESSURE INSERTION. THIS WEAK TEMPORAL RELATIONSHIP INDICATES THE EVENT WAS NOT RELATED TO ESSURE PROCEDURE. HOWEVER; AS BOTH INSERTS WERE FOUND PERFORATING PATIENT FALLOPIAN TUBES; IT CANNOT BE EXCLUDED THAT THIS PERFORATION COULD HAVE AGGRAVATED A POSSIBLE PELVIC INFECTION ACQUIRED BY THE PATIENT. THEREFORE, A CONTRIBUTORY ROLE OF ESSURE IN THE EVENTS CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, DUE TO THE SERIOUS INJURIES REPORTED (HOSPITALIZATION AND SURGICAL INTERVENTION WERE REQUIRED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. FOLLOW-UP INFORMATION (PATIENT CONCOMITANT CONDITIONS) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 28-DEC-2015: FOLLOW-UP ATTEMPTS HAVE BEEN DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT. SHE HAD AN ABSCESS IN HER FALLOPIAN

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01137	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/17/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 31-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015 FOR STERILIZATION. ADDITIONAL INFORMATION RECEIVED ON 02-SEP-2015. WHEN THE DEVICE WAS PLACED BY THE PHYSICIAN, THE OUTER COIL FRACTURED, AND CAME OUT WITH THE DELIVERY CATHETER. HE PLACED ONE SUCCESSFULLY, AND THE OTHER ONE FRACTURED. HE LEFT IT IN PLACE BECAUSE THERE WAS NO WAY TO REMOVE IT. ON (B)(6) 2015 A HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND ACCORDING TO THE PHYSICIAN IT HAD GOOD OCCLUSION AND GOOD LOCATION. THE FILM WAS REVIEWED AND BOTH OUTER AND INNER COIL FRACTURED AND ONLY A FRAGMENT OF THE DEVICE WAS LEFT IN THE PATIENT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING PLACEMENT PROCEDURE BOTH OUTER AND INNER COIL FRACTURED AND ONLY A FRAGMENT OF THE DEVICE IS LEFT IN THE PATIENT (INTERPRETED AS DEVICE BREAKAGE). THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, DURING INSERTION THE COIL FRACTURED, AND CAME OUT WITH THE DELIVERY CATHETER, ONLY A FRAGMENT OF THE DEVICE WAS LEFT IN THE PATIENT. SINCE THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

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Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CAS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01139	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/28/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1059, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER COMMENTED THAT SHE HAS EXPERIENCED AND CONTINUED TO EXPERIENCE ISSUES REGARDING THE ESSURE DEVICE NUMBER (B)(4). SHE WAS IMPLANTED IN (B)(6) 2012 AND IMMEDIATELY EXPERIENCED SEVERE ABDOMINAL PAIN, SWELLING/ INFLAMMATION ALONG WITH COUNTLESS KIDNEY, BLADDER INFECTIONS AND OVARIAN CYSTS. SHE ALSO HAS DEBILITATING HEADACHES, SWEATING AND VERY TENDER BREASTS. SHE HAS GAINED WEIGHT SINCE THE DEVICE WAS IMPLANTED AND IT HAS INTERFERED WITH HER QUALITY OF LIFE. SHE HAS HAD NUMEROUS VISITS TO DOCTORS AND EMERGENCY ROOMS. THE TESTS SHE HAS HAD DONE IN INCLUDED BLOOD TESTING, ULTRASOUNDS, CT SCANS, X-RAYS AND URINE CULTURES WHICH ALL COME BACK NORMAL. FINALLY SHE WAS ABLE TO FIND AN OBSTETRICIAN WHO TOOK HER SYMPTOMS SERIOUSLY AND HAD HER HYSTERECTOMY IN (B)(6) 2015 TO REMOVE HER UTERUS, TUBES AND CERVIX. SHE IS HOPING ONCE HER BODY IS ABLE TO RECUPERATE AND RETURN TO NORMAL THAT HER ISSUES AND SYMPTOMS WILL ABOLISH. AS THE MOMENT OF THE POST SHE STILL HAS THE HEADACHES, TENDER BEASTS AND ABDOMINAL PAIN. CONSUMER STATED THAT THIS DEVICE CAUSES WAY MORE ISSUES AND COMPLICATIONS TO OUTWEIGH THE RISKS TO BENEFITS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMMEDIATELY AFTER INSERTION, EXPERIENCED ABDOMINAL PAIN AND COUNTLESS KIDNEY AND BLADDER INFECTIONS. THESE EVENTS

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ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. ABDOMINAL PAIN IS LISTED WHILE KIDNEY AND BLADDER INFECTIONS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. ALTHOUGH IN THIS CASE THE PAIN REMAINED AFTER ESSURE REMOVAL, CONSIDERING CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, AN ESSURE'S CONTRIBUTORY ROLE FOR THIS EVENT CANNOT BE TOTALLY EXCLUDED. THEREFORE, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. CONSIDERING UROPATHOGENS FROM RECTAL FLORA ARE THE MOST FREQUENT CAUSE OF KIDNEY AND BLADDER INFECTIONS AND THE FACT THAT ESSURE ACTS LOCALLY IN FALLOPIAN TUBES, CAUSALITY BETWEEN THESE INFECTIONS AND ESSURE USE IS VERY UNLIKELY. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01140	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/28/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1057, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED THAT ESSURE TOOK HER YOUTH TOO YOUNG. NOT ONLY DID SHE BREAK OUT IN HIVES AND HAVE DELIBERATING PAIN. IT CAUSED HER TO HAVE 3 SURGERIES. THIS INCLUDES A HYSTERECTOMY AT THE AGE OF (B)(6). SHE STATED THAT THE PAIN IS NOT WORTH IT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD DELIBERATING PAIN (INTERPRETED AS PELVIC PAIN). SHE UNDERWENT A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENT WAS ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01141	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/28/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-1043, AWARENESS DATE: 01-SEP-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE STATED THAT SHE HAD ESSURE FOR 7 YEARS. IN THAT TIME SHE HAD GAINED WEIGHT (WHICH CAUSED PRE-DIABETES AND HIGH BLOOD PRESSURES), MASSIVE ABDOMINAL CRAMPING AND PELVIC INFLAMMATORY DISEASE. SHE WENT TO THE EMERGENCY ROOM AND THEY SAID IT WAS BECAUSE OF THE ESSURE COILS AND THEY HAD TO BE REMOVED AS SOON AS POSSIBLE. SHE WENT TO THE GYNECOLOGIST AT THAT DAY OF THE POST TO SCHEDULE THE SURGERY. CONSUMER STATED THAT SHE MAY HAVE TO HAVE A FULL HYSTERECTOMY AND SHE IS ONLY (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD MASSIVE ABDOMINAL CRAMPING (INTERPRETED AS ABDOMINAL CRAMPING) AND PELVIC INFLAMMATORY DISEASE. SHE WENT TO THE GYNECOLOGIST TO SCHEDULE THE SURGERY. THE ABDOMINAL CRAMPING AND PELVIC INFLAMMATORY DISEASE ARE SERIOUS EVENTS DUE TO THE PLANNED REQUIRED INTERVENTION. BOTH EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE CONSUMER HAD THESE EVENTS APPROXIMATELY 7 YEARS AFTER ESSURE INSERTION. CONSIDERING THIS TEMPORAL RELATIONSHIP, THE CAUSAL RELATIONSHIP BETWEEN LOWER ABDOMINAL PAIN AND ESSURE CANNOT BE EXCLUDED. HOWEVER, IT IS UNLIKELY THAT ESSURE

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WOULD CAUSE PELVIC INFLAMMATORY DISEASE AFTER SO MANY YEARS. THIS EVENT IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01150	BAYER HEALTHCARE LLC	9/28/2015	9/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/24/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0984, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. IT WAS REPORTED THAT SHE DID NOT GET THE NARCOTIC PRESCRIPTION AND FIRST COIL WAS IMPLANTED WITH NO PAIN MEDICATION; THIS WAS EXTREMELY PAINFUL, SO SHE REQUESTED IT FOR THE SECOND COIL. THROUGHOUT THE YEAR, SHE EXPERIENCED EXTREME BLOATING, A HARDNESS IN HER UTERUS AND HEAVY PERIODS THAT WOULD LEAVE HER IN BED FOR TWO DAYS BEFORE SHE ACTUALLY MENSTRUATED. SHE WAS EXPERIENCING SHORTNESS OF BREATH AND TIRING EASILY AFTER 1/2 HOUR OF PHYSICAL LABOR OR EXERCISE. SHE ATTRIBUTED MANY OF THESE SYMPTOMS TO AGING BUT KNEW THAT PAIN DURING OVULATION AND PAIN AFTER INTERCOURSE WERE DIRECTLY RELATED TO THE ESSURE IMPLANTS. COILS WERE REMOVED BY LAPAROSCOPIC AND HYSTEROSCOPICALLY WITH SALPINGECTOMY. WHEN SHE GOT THE HSG IT SHOWED THAT HER COILS WERE SECURED IN TUBES AND TUBES WERE COMPLETELY BLOCKED. DURING SURGERY, PHYSICIAN DISCOVERED THAT PART OF ONE OF THE COILS WAS INDEED IN HER UTERUS DESPITE THE HSG RESULTS. SO, PHYSICIAN CONCLUDED THAT HSG DID NOT SHOW ACCURATELY THE PLACEMENT OF THE COILS. THERE WERE ALSO BENIGN POLYPS ATTACHED TO THE PART OF THE COIL THAT WAS IN THE UTERUS. SHE STATED SHE WANTED BAYER/CONCEPTUS TO COMPENSATE HER FINANCIALLY FOR THE DEBT SHE HAD ACCRUED FOR ALL MEDICAL AND TRAVEL EXPENSES RELATED TO THIS PROBLEM AND A SUM FOR THE EMOTIONAL AND PHYSICAL HAVOC ESSURE HAD WRACKED ON HER BODY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON

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AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HEAVY PERIODS. SHE HAD A BILATERAL SALPINGECTOMY AND ESSURE INSERTS WERE REMOVED. ALTHOUGH THE HYSTEROSALPINGOGRAM SHOWED THAT ESSURE INSERTS WERE SECURED IN TUBES AND TUBES WERE COMPLETELY BLOCKED, DURING SURGERY, THE PHYSICIAN DISCOVERED THAT PART OF ONE OF THE COILS WAS INDEED IN HER UTERUS (INTERPRETED AS DEVICE EMBEDDED/PARTIAL PERFORATION). THE HEAVY PERIODS IS SERIOUS EVENTS DUE TO REQUIRED INTERVENTION AND PARTIAL PERFORATION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. BOTH EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF PARTIAL PERFORATION, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. SINCE A PARTIAL PERFORATION OCCURRED IN THIS PATIENT, IT CANNOT BE EXCLUDED THAT IT WOULD CAUSE HEAVY PERIODS. THEREFORE, THIS EVENT IS ALSO ASSESSED AS RELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056532	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 1/4/2010 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE DEVICE PLACED IN (B)(6) 2007. I HAD THE HSG DONE 8 WEEKS LATER AND IT CONFIRMED THAT BOTH FALLOPIAN TUBES WERE OCCLUDED. AFTERWARDS MY PERIODS BECAME IRREGULAR. I WAS TOLD BY MY DOCTOR THAT THEY WERE IRREGULAR BECAUSE OF MY WEIGHT AND I WAS DIAGNOSED WITH PRE-DIABETES. I WAS TOLD TO LOSE WEIGHT AND THEN MY CYCLE WOULD REGULATE ITSELF. IN (B)(6) OF 2010 I SUFFERED A DIZZY SPELL, WITH VOMITING AND HEADACHES. UPON BEING ADMITTED TO THE ER I WAS DIAGNOSED WITH VERTIGO. DURING THAT VISIT THEY WANTED TO DO AN MRI BUT I REFUSED IT BECAUSE NONE OF THE DOCTORS OR NURSES COULD EXPLAIN HOW THE ELECTROMAGNETIC FIELD WOULD EFFECT THE ESSURE COILS. (B)(6) OF 2011 I FOUND OUT I WAS PREGNANT WITH MY THIRD CHILD. THE DOCTOR THAT I WAS SEEING WAS NOT TRAINED TO PERFORM THE ESSURE PROCEDURE SO SHE WENT TO A CONFERENCE AND SPOKE WITH SOME ESSURE SALES REPRESENTATIVES. MY SON DIED AS A RESULT OF HER LACK OF KNOWLEDGE AT (B)(6). AFTER THE PREGNANCY MY PERIODS CONTINUED TO BE IRREGULAR. THE WOULD LAST ABOUT 30-35 DAYS EVERY OTHER MONTH. A NEW DOCTOR THEN DIAGNOSED ME WITH UTERINE POLYPS AND A SURGERY WAS SCHEDULED TO REMOVE THEM. DURING THE SURGERY IT WAS FOUND THAT THE ESSURE COILS HAD MIGRATED OUT OF MY FALLOPIAN TUBES AND WERE NOW LODGED IN MY UTERUS. THE VISIBLE COILS WERE REMOVED, THERE IS STILL ONE OF THE COILS LEFT LODGED IN THE LEFT WALL OF MY UTERUS. (B)(6) OF 2014 I WAS ADMITTED TO THE ER AND DIAGNOSED WITH AND ECTOPIC PREGNANCY. SURGERY WAS PERFORMED AND HALF OF MY LEFT OVARY WAS REMOVED, BOTH FALLOPIAN TUBES REMAINED IN TACK AND OPEN. (B)(6) OF 2015 I BECAME PREGNANT AGAIN. I AM CURRENTLY (B)(6).

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056533	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 4/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE HAD BECOME SO BAD I WAS HAVING A SEIZURE AND WAS SENT TO THE ER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056534	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 11/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOSS OF HAIR, PAIN, WEIGHT GAIN, BRAIN FOG, VERTIGO, PAIN IN JOINTS AND STIFFNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056535	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY IMPLANTS WERE DONE IN (B)(6) 2008. MY PERIODS BECAME PAINFUL AND HEAVY, 2 WEEK INTERVALS FOR TWO WEEKS AT A TIME. I HAD ENDED UP WITH DYSPLASIA AS WELL SO MY DOCTOR DID AN ABLATION AND LEEP PROCEDURE IN 2011. SINCE THEN I'VE HAD MANY ISSUES COME UP. PTSD, DEPRESSION, ALTERED MOODS, CRAMPING, SHARP PELVIC PAINS, ABNORMAL MENSES, PERIOD STOPS AND STARTS RANDOMLY, OVARIAN CYSTS, DISCHARGE, P.I.D., PAIN WHILE OVULATING, BACK HIP THIGH PELVIC RIB ABDOMINAL CHEST NECK AND CHRONIC BONE PAIN AND JOINT, INCONTINENCE, HOT FLASHES, COLD SWEATS, UNEXPLAINED FEVERS, CHRONIC INFECTION, BREAST TENDERNESS AND PAIN, NAUSEOUS, VOMITING, HEARTBURN, GAS, IBS, MIGRAINES LASTING TWO WEEKS OR MORE, NUMBNESS, TINGLING, BURNING OF EXTREMITIES, BRAIN FOG, CONFUSION, FORGETFULNESS, VITAMIN D DEFICIENCY, AUTO IMMUNE DISORDERS, ALLERGIES WENT FROM 3 OR 4 TO 33 SEVERE WITHOUT TESTING FOODS, NUTS OR METALS, HIVES, RASHES, ACNE, ITCHING, ECZEMA, CYSTS, BOILS, NEUROPATHY, SHINGLES, LABORED BREATHING, ASTHMA, HAIR FOLLICLES TENDER OR PAINFUL ON MY HEAD, LEG EDEMA, INSOMNIA, CHRONIC FATIGUE, WEIGHT GAIN, TMJ, VISION BLURRY OR LOSS, DRY SKIN, BLOATING, SENSITIVE TO TOUCH

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056536	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABOUT THREE YEARS AGO MY PERIODS WENT FROM ALMOST NOTHING TO INCREDIBLY HEAVY AND PAINFUL. I STARTED HAVING JOINT PAIN ALL OVER MY BODY AT ABOUT THAT SAME TIME. THEN ABOUT 10 MONTHS AGO I STARTED HAVING A VAGINAL DISCHARGE THAT, TO DATE, NO ONE HAS BEEN ABLE TO IDENTIFY. ALSO MY SEX DRIVE HAS TAKEN AN ENORMOUS TURN FOR THE WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056537	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 5/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FLUIDS IN LEFT TUBE. COIL IN STOMACH NOT TUBE. SPOTTING AND MAJOR CRAMPS. ALSO PAIN IN MY STOMACH. WEIGHT GAIN. YES, (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056538	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 6/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ABNORMAL PELVIC PAIN FOR YEARS NOW. THE PAIN BECAME SO BAD AFTER HAVING THESE IMPLANTS PUT IN THAT I AM NOW ON A SCRIPT FOR TIME RELEASED MORPHINE. I HAVE COUNTLESS SYMPTOMS INCLUDING: BRUISING, FEVERS, HYPOTHYROIDISM, SHAKING, HEADACHES, VISION LOSS, LOSS OF SENSATION ON RIGHT SIDE OFF MY BODY, EXHAUSTION AND MANY OTHERS. I AM CURRENTLY OUT OF WORK DUE TO THESE AILMENTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056539	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 6/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A LOT OF PAIN, SO MUCH HEAD PAIN, WHEN I HAVING SEX, A LOT OF BLEEDING, RASH IN THE LOWER ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056540	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 7/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING SEVERE LOWER BACK PAIN. NOW ALSO INCLUDING SEVERE HIP PAIN (JOINT PAIN) ALSO MY HIP FEELS LIKE ITS GOING TO CHARLEY HORSE; THIS EFFECT RADIATES DOWN MY WHOLE LEG. CRAMPING IN MY LOWER ABDOMEN, .FATIGUE, .IRRITABILITY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056541	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED IN (B)(6) 2011 AND HAD NO PROBLEMS UNTIL (B)(6) 2015. AT WHICH TIME I BEGAN HAVING HEADACHES, NO MENSTRUAL CYCLE FOR 3 MONTHS, WEIGHT GAIN AND THINNING HAIR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056542	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 4/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM ALLERGIC TO NICKEL. BEFORE GETTING THE DEVICE INSERTED, I ASK IF IT WOULD HARM ME BECAUSE I HAVE METAL ALLERGY AND MY PROVIDER TOLD ME THAT IT WAS MADE OF TITANIUM AND IT WOULD NOT BOTHER ME. SINCE HAVING THEM PLACED, I HAVE HAD BAD SKIN REACTIONS, CERVICAL PRE-CANCER, SWOLLEN LYMPH NODES, MIGRAINES, PAIN IN MY LEFT OVARY, HAIR LOSS, HYPOTHYROIDISM, MULTIPLE INFECTIONS, TIREDNESS AND OVERALL GENERAL ILL FEELING. I'M SURE THERE IS MORE THAT I HAVE LEFT OUT HERE IN MY STATEMENT AS I HAVE BRAIN FOG SINCE HAVING THIS DEVICE PUT IN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056543	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 3/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, SHARP/STABBING PELVIC PAIN, MISCARRIAGE, HOT FLASHES, PID (PELVIC INFLAMMATORY DISEASE), PMDD (PREMENSTRUAL DYSPHORIC DISORDER), NIGHT SWEATS, PAINFUL PERIODS (DYSMENORRHEA), UTI (URINARY TRACT INFECTION), BLADDER INFECTION, CERVICITIS/VAGINITIS (SWELLING, INFLAMMATION, INFECTION OF THE CERVIX OR VAGINA), ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE (VULVODYNIA) BREAST PAIN/TENDERNESS, BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP, ALL OVER BODY ACHES/PAIN, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEADACHES OR MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN FOG AND CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, SEIZURES, BLACK OUT SPELLS/ FAINTING, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), TREMORS/SHAKINESS, DIZZINESS, ANEMIA/ IRON DEFICIENCY/LOW FERRITIN, BLOOD CLOTS, SWELLING OF LEGS OR FEET, HAIR LOSS OR CHANGES, WEIGHT ISSUES (LOSS/ GAIN), SWELLING OF LEGS/FEET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056544	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 3/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY LEFT OVARY (AND POSSIBLY MY FALLOPIAN TUBES AND PART OF MY BOWELS) HAVE FUSED TO MY UTERUS BECAUSE THE SCAR TISSUE INCITED BY ESSURE HAS SPREAD FROM INSIDE MY FALLOPIAN TUBES TO OUTSIDE MY FALLOPIAN TUBES, UTERUS AND OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056545	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 8/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVEN'T STOPPED BLEEDING SINCE I HAD THIS DEVICE OVER A MONTH AGO. MIGRAINE HEADACHES, BACK PAIN, SCIATICA PAIN, HAIR LOSS, MOOD SWINGS, FORGETFULNESS, AND FATIGUE. I AM ALWAYS TIRED AND CAN'T FUNCTION DUE TO THE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056546	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE PROVIDED BY INSURER. BACK PAIN CONTINUOUS. ABLATION DONE IN 2011 TO ALLEVIATE PAIN TO NO AVAIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056547	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 5/13/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN 2009 I HAD ESSURE COILS PLACED. SHORTLY AFTER I STARTED WITH SEVERE MIGRAINES AND SHARP SHOOTING PAINS IN MY STOMACH. I ALSO EXPERIENCED PAIN IN MY PELVIC AREA ALONG WITH SWELLING. IN 2011 AN MRI WAS DONE DUE TO MIGRAINES, NOTHING FOUND. IN 2012 I WAS SEEN BY A RHEUMATOLOGIST DIAGNOSED WITH VITAMIN D DEFICIENCY AND IRON DEFICIENCY. IN 2014 I HAD MY GALL BLADDER REMOVED, SHARP SHOOTING PAINS STILL OCCURRED AFTER WITH FAINTING SPELLS. INBETWEEN ALL OF THIS I HAVE BEEN DIAGNOSED WITH SEVERAL BACTERIA VAGINOSIS INFECTIONS, NOT TO MENTION HAVE HAD SAME PARTNER FOR TEN YEARS. IN (B)(6) OF THIS YEAR I HAD TO HAVE PART OF MY CERVIX REMOVED DUE TO DISPLAGIA. LAST WEEK I WAS PUT ON HEART MEDICATION DUE TO THE FACT OF HEART PALPITATIONS. I AM ALSO BORDERLINE DIABETIC NOW. BEFORE 2009 I WAS AS HEALTHY AS COULD POSSIBLY BE, NEVER HAD HEALTH ISSUES. I AM ALWAYS FATIGUE AND MOODY. I HOPE THESE ISSUES ARE TAKEN INTO GREAT CONSIDERATION BECAUSE THIS IS NOT NORMAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056548	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I PUT THE ESSURE I STAR FEELING MY BODY ITCHING, HEADACHE, A LOT OF PAIN IN MY BODY, I WAS BLEEDING THE FIRST DAY BUT STOPS THE SECOND DAY NOW THE THIRD DAY I START BLEEDING AGAIN WITH A LOT OF CRAMPS, AND SINCE A PUT THIS MY STOMACH IS SO BLOODED, WITH A LOT OF GASES. I THINK THIS WAS A WRONG DECISION AND I WANT TO REMOVE THIS FROM MY BODY, BEFORE IS TOO LATE, PLEASE HELP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056549	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING HORRIBLE PERIODS WITH HUGE BLOOD CLOTS. I HAVE HORRIBLE CRAMPS TO WHERE I CAN'T GET OUT OF BED. LOWER BACK PAIN ALL THE TIME. SEVER BLOATING TO WHERE I LOOK PREGNANT. LOWER ABDOMEN HURTS ALL THE TIME. I'M SCHEDULED FOR HYSTERECTOMY (B)(6) 2015. I WANT ESSURE PULLED OFF THE MARKET AND THE PMA OFF TOO!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056550	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 1/18/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE DONE IN (B)(6) 2007 BECAUSE I HAD 3 CHILDREN AND I WAS HAPPY WITH THAT. I TOLD MY OBGYN THAT I WAS ALLERGIC TO STAINLESS STEEL AND ANY METALS. I TOLD THEM THAT I CAN'T WEAR A BELT, BUT THEY PUSHED ME TO GET THIS DONE AND SAID THAT MY ALLERGIES TO METALS WEREN'T AN ISSUE. I CAN'T EVEN WEAR JEWELERY UNLESS IT IS GOLD. SO (B)(6) 2007 I WENT BACK IN MY OBGYN SAID THAT IT WORKED AND I WAS GOOD TO GO. (B)(6) 2008 I FIND OUT I WAS PREGNANT AGAIN. SO YES I HAD ANOTHER CHILD WITH THIS INSIDE OF ME. MY ISSUES ARE SINCE THIS WAS DONE I HAVE HAD EXTREMELY HEAVY BLEEDING AND CLOTS. I BLEED FOR 8-10 DAYS SOMETIMES LONGER, WHEN BEFORE THIS MY PERIODS WERE 5 DAYS EVERY 28 DAYS AND NORMALLY THE FIRST DAY OR TWO WAS A LITTLE HEAVIER THAN THE REST. NOW I HAVE MY PERIOD LIKE I SAID FOR 8-10 DAYS IF NOT LONGER, THAN I STOP FOR A WEEK AND THEN IT STARTS AGAIN. I HAVE TO WEAR TAMPONS AND PADS AT THE SAME TIME OR I AM BLEEDING ALL OVER MY SELF WITH IN 20 MINUTES, WITH BOTH I CAN GO 30-45 MINUTES. I CAN NOT HOLD A JOB BECAUSE OF THIS, NOBODY WANTS TO HIRE ME OR IF THEY DO I LOSE IT WITHIN 3 MONTH BECAUSE THEY WILL NOT PUT UP WITH ME RUNNING TO THE BATHROOM EVERY 20-30 MINUTES. I AM IN CONSTANT PAIN, LIKE IT FEELS LIKE SOMETHING IS STABBING ME ON THE INSIDE. IN 2009, I HAD A DYE INJECTED IN ME BECAUSE THEY THOUGHT I HAD KIDNEY STONES AND THEY PERSON THAT READ MY RESULTS SAID THEY COULD SEE ONE COIL BUT THE OTHER ONE THEY HAD NO IDEA WHERE IT IS. I AM SUFFERING, MY HUSBAND IS SUFFERING AND ALL 4 OF MY CHILDREN ARE SUFFERING BECAUSE I CAN NOT HELP SUPPORT THEM FINANCIALLY. YES MY INSURANCE PAID FOR MY PROCEDURE BUT THEY WILL NOT COVER TO HAVE IT REMOVED. I WAS TOLD BY MY OBGYN THEY HAVE TO HAVE A "GOOD REASON" TO COVER IT AND ME PRACTICALLY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

BLEEDING TO DEATH ISN'T GOOD ENOUGH. AT LEAST I FEEL LIKE I AM BLEEDING TO DEATH. I HAVE HAD TEST TO MAKE SURE I AM NOT LOSING TOO MUCH BLOOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056551	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 2/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WRONG REPORT DATE, SORRY THAT WAS THE DATE GOT ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056552	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056553	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 3/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE. IN A DOCTORS OFFICE, NOT UNDER ANY DRUGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056554	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 3/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANTLY BLEEDING, HAIR FALLING OUT, CYST OR MASS ON MY OVARIES, HAIR FALLING OUT, CONSTANT BACK PAIN, PELVIC PAIN, SHARP STABS IN VAGINA, BLEEDING DURING AND AFTER SEX, ANXIETY, DEPRESSION, AND PASSING LARGE BLOOD CLOTS OUT VAGINA, AND ANEMIA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056555	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 6/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE SURGICALLY PLACED IN 2003. NEW HEAVY BLEEDING, CRAMPING, HEADACHES AND BLOATING AFTER DEVICE PLACEMENT. TALKED INTO ABLATION AND HAD SUCH WRITHING PAIN AFTER THAT I HAD TO STAY OVERNIGHT IN HOSPITAL AND THIS DID NOT RELIEVE THE MENSTRUAL ISSUES. THEN HAD LUMP IN BELLY AND HAD ENDOMETRIOMA THAT HAD TO BE SURGICALLY REMOVED. STILL HAVE CRAMPING, BLEEDING, PAIN, MIGRAINES, BLOATING. PRIOR TO THIS PROCEDURE, MY PERIODS WERE VERY LIGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056556	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 3/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD HEMMORAGING AND OVARIAN CYSTS RUPTURE INSIDE OF CAUSING SEVERE PAIN AND AN ER VISIT. WITHIN 6 MONTHS I GAINED 30 POUNDS. I HAD HORRIBLE BACK PAIN. MY HAIR STARTED TO FALL OUT. NOT KNOWING WHAT WAS WRONG, I TRIED SEVERAL WEIGHT LOSS PROGRAMS WITH THE ASSISTANCE OF A PHYSICIAN, DIETICIAN AND TRAINER AND NOTHING WORKED. THE BACK PAIN WAS SO BAD, I DECIDED TO GET A BREAST REDUCTION, THINKING THAT WOULD SOLVE MY PROBLEMS. WHEN THAT DIDN'T HELP MUCH, I CONTACTED AN ENDOCRINOLOGIST WHO TOLD ME MY SYMPTOMS SOUNDED LIKE CHRONIC FATIGUE. THE ENDOCRINOLOGIST ALSO PRESCRIBED LOW DOSE OF THYROID MEDICATION TO ASSIST IN MY HAIR LOSS, WEIGHT GAIN AND LOW LIBIDO. IT'S BEEN 3 YEARS OF GOING TO THE ENDOCRINOLOGIST AND TRYING DIFFERENT MEDICATIONS AND NOTHING IS WORKING. I EAT HEALTHY, EXERCISE REGULARLY, GET PLENTY OF REST, TAKE VITAMINS RECOMMENDED BY DOCTOR AND MY SYMPTOMS STILL REMAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056557	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LET ME START OUT BY SAYING I HAVE NEVER BEEN ABLE TO WEAR CHEAP OR FAKE JEWELRY ESPECIALLY NOT EARRINGS MY NECK AND MY FINGERS AND MY WRISTS MY ANKLES TURNED GREEN AND ITCH IF I WEAR FAKE JEWELRY IF I PUT EARRINGS IN MY EAR THAT ARE NOT STERLING SILVER OR GOLD MY EARS SWELL ITCH ACHE NOT JUST FOR THE TIME THAT I HAVE THEM IN BUT FOR DAYS AFTER I REMOVE THEM TOO IF I HOLD LOSE CHANGE IN MY HANDS MY PALMS ITCH LIKE CRAZY... AND WHY DOES MY BODY REACT THAT WAY TO CHEAP JEWELRY AND CHANGE? BECAUSE I HAVE A NICKEL SENSITIVITY OR ALLERGY.. WELL... THE ESSURE IS MADE UP OF A NICKEL TITANIUM ALLOY ... THAT, I WAS NEVER INFORMED OF AND IT WAS NOT IN THE PAPERWORK OR IN THE BROCHURE THE INFORMATIONAL PACKET OR THE SPEECH THAT THE DOCTOR GAVE ME AND MY HUSBAND EXPLAINING HOW BENEFICIAL THIS PROCEDURE WOULD BE FOR ME. I'VE BEEN TO DOCTOR AFTER DOCTOR MISDIAGNOSED WITH SO MANY STUPID THINGS LIKE CARDIOVASCULAR ISSUES PSORIASIS ECZEMA CYSTIC ACNE THE LIST GOES ON... I'VE EVEN BEEN TOLD IT'S ALL IN MY HEAD. WHEN I FIRST GOT THE COILS IN 2012 I BROKE OUT FULL BODY WITH RED RAISED HIVES ITCHY AND DROVE ME INSANE ALMOST LITERALLY MY DOCTORS GAVE ME A SLEW OF MEDICATIONS AND THE RASH WENT AWAY AFTER ABOUT A MONTH BUT THE ITCH HAS ALWAYS BEEN THERE STILL YEARS LATER EVERYWHERE I HAVE MANY MANY OTHER SIDE EFFECTS OR SYMPTOMS ILLNESSES WHATEVER YOU WANT TO CALL THEM SOME NOT SO BAD MANY FAR WORSE INCLUDING LSIL SEVERE CERVICAL DYSPLASIA LESIONS CERVICAL CANCEROUS CELLS OVARIAN CYSTS SEVERE ABDOMINAL PAIN SEVERE CRAMPING AND BLEEDING CHRONIC DAILY HEADACHES AND MIGRAINES MY HAIR IS FALLING OUT I HAVE SORES ALL OVER MY SCALP THAT ARE VERY PAINFUL IT HURTS TO WASH MY HAIR IT HURTS TO COMB MY HAIR OR BRUSH MY HAIR I FEEL LIKE I AM CONSTANTLY IN A FOG I CAN'T REMEMBER ANYTHING. I EXPERIENCED AND OR CONTINUE TO EXPERIENCE: VERTIGO, ANEMIA,

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INSOMNIA THAT GETS SO BAD I HAVE NIGHT TERRORS, UNCONTROLLABLE BLOOD SUGAR, NEUROLOGICAL ISSUES, PTSD, SEVERE DEPRESSION, SEVERE ANXIETY, PANIC ATTACKS, UNEXPLAINED FEVERS, CHILLS, ALLERGIC REACTIONS, METAL POISONING, HEART PALPITATIONS, IRREGULAR HEARTBEAT RHYTHM, VISION PROBLEMS. I HAVE HIGH BLOOD PRESSURE, AND LOW BLOOD PRESSURE SO I BLACK OUT. I HAVE TINGLING IN MY ARMS AND MY LEGS, MY FEET WERE NUMB FOR ALMOST A YEAR. I COULDN'T FEEL A FEW OF MY FINGERS FOR YEARS. NO MATTER HOW MUCH I DRINK MY BODY IS ALWAYS DEHYDRATED! MY WEIGHT IS ALL OVER THE PLACE I GAIN 20, LOSE 15, GAIN 30, LOSE 20 IT'S CRAZY! MY SKIN AND MY FINGERNAILS HAVE CHANGED IN A BAD WAY... CONSTANT INGROWN TOENAIL'S AND FINGERNAILS, IF THE NUMBNESS WASN'T PRESENT MY FEET KILLED ME WITH PAIN, I COULD BARELY WALK SOME MORNINGS, IT WOULD TAKE ME OVER 20 MINUTES TO WALK FROM MY BED TO THE LIVING ROOM OR KITCHEN. MY BIG TOES HURT THE MOST AND DAILY REGARDLESS, MY FEET AND HANDS CHANGE COLORS SOMETIMES A PURPLE /BLACK SOMETIMES A WHITE /GREY... DOCTORS SAY IT'S NOTHING. I HAVE HIP BURSITIS, TOOK MEDICATION FOR MONTHS THEN WHEN THEY WANTED TO STICK NEEDLES INTO MY HIP I QUIT GOING AND JUST DEAL WITH IT. I HAVE HAD 6 MOLARS SHATTER, ONLY 5 REMOVED SO FAR, I HAVE NO DENTAL INSURANCE SO I SUFFER W THE ONE BROKEN MOLAR STILL IN MY MOUTH. IT HURTS TO BRUSH MY TEETH AND IT HURTS TO EAT. I AM EITHER COMPLETELY WITHOUT EMOTION, OR OVERLY EMOTIONAL. I CRY EVERY DAY. I'M ANGRY A LOT WITH, A SOMETIMES OUT OF CONTROL RAGE, IT TAKES SO MUCH EFFORT FOR ME TO BE HAPPY. I WENT FROM EXTREMELY HAPPILY MARRIED TO MY BEST FRIEND, TO A MARRIAGE AND FRIENDSHIP DESTROYED!! I TRULY BELIEVE WITH ALL MY HEART THAT THIS IS THE UNDERLINING REASON WHY MY MARRIAGE HAS BEEN DESTROYED!!! I AM TIRED ALL THE TIME! I NEVER WANT TO DO ANYTHING! I MAKE EXCUSES NOT TO GO OUT CONSTANTLY WHEN I'M ASKED TO GO OUT. I HAVE ALMOST NO FRIENDS LEFT. I HAVE TO MAKE MYSELF GET OUT OF BED, TAKE A SHOWER, I HAVEN'T PUT MAKE UP ON OR DONE MY HAIR OTHER THAN FOR MY MODELING IN LONGER THAN I CAN REMEMBER. I PRETEND TO BE HAPPY, I FAKE A SMILE, I DON'T HAVE A DRIVE FOR LIFE ANYMORE! I'VE SEEN SEVERAL PSYCHOLOGISTS AND HAVE BEEN IN COUNSELING, BOTH PERSONAL AND FOR MY MARRIAGE. I'VE HAD YEARS OF TESTING, PROCEDURES, AND SURGERIES, ALL LEAVING ME STILL SICK, WITH MORE SIDE EFFECTS MORE FAILED ATTEMPTS AT FINDING THE PROBLEM. I'M GOING IN FOR MY NEXT HEART MONITOR SOON. I'VE BEEN SEEING A CARDIOLOGIST DUE TO THE LASTING AND AMPLIFIED EFFECT OF THESE COILS. I HAVE MORE PRESCRIPTIONS THAN I KNOW WHAT TO DO WITH, BUT THEY MAKE ME SICK SO I NEVER TAKE THEM. LAST MONTH I THREW AWAY CLOSE TO 30 PILL BOTTLES WITH MY NAME ON THEM. I HAD A PLASTIC TOTE FULL OF PRESCRIPTIONS. MY LIFE IS FALLING APART AND I FEEL LIKE I'M LOSING MY MIND, LITERALLY FEEL LIKE I'M GOING INSANE! I'VE EVEN ATTEMPTED TO ATTEMPT SUICIDE! THIS HAS ALL JUST BEEN TOO MUCH, I HAVE WITHDRAWN FROM MY FAMILY, FROM MY FRIENDS, FROM MY HUSBAND, SOME THINGS ARE JUST TO PERSONAL TO LIST BOTH SEXUAL AND BOWL PROBLEMS, LITERALLY MORE AND MORE OFTEN DAY AFTER DAY I STAY IN BED... THIS HAS GREATLY AFFECTED MY RELATIONSHIP WITH EVERYONE IN MY LIFE, INCLUDING MY CHILDREN! MY ATTITUDE, MY EMOTIONS, MY MENTAL STATE, MY PHYSICAL STATE, HAS SEVERELY DAMAGED EVERY RELATIONSHIP THAT I HAVE EVER HAD IN MY LIFE! IT'S TAKEN ME AWAY FROM MY CHILDREN, IT TOOK ME AWAY FROM MY HUSBAND.... IT TOOK US FROM EACH OTHER, AND IT KEEPS ME AWAY FROM MY FAMILY AND MY FRIENDS... I HAVE BEEN ROBBED OF MYSELF! MY BODY, MY MIND! I'M NOT MYSELF! AND EVEN THOUGH I CAN DECLARE TO EVERYONE AND ANYONE AT ANY TIME THAT I FEEL LIKE, THAT I HAVEN'T CHANGED, THAT I'VE BEEN THE SAME THAT I HAVE ALWAYS BEEN... I SEE THINGS NOW AND I KNOW I'M NOT THE SAME... BUT I ALSO KNOW THIS ISN'T MY FAULT! MY WORDS, MY ATTITUDE, MY ANGER, MY SADNESS, AND WHAT IS CALLED MY LAZINESS, THESE ARE NOT ME! THESE ARE NOT THINGS THAT I WAS!!! THESE ARE THINGS THAT THE ESSURE GAVE TO ME, IN EXCHANGE FOR CHOOSING TO NOT HAVING ANOTHER CHILD...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056558	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING FOR 4 MONTHS EXTREME PAIN IN ABDOMEN MOSTLY LEFT SIDE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056559	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 3/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE IMPLANTS I HAVE HAD SEVERE PAIN AND BLEEDING DURING MENSTRASION EVERY MONTH AS WELL AS EXCESSIVE BLEEDING. MIGRAINES AND PAINFUL SEX HAVE ALSO BEEN A REGULAR PROBLEM SINCE THE IMPLANTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056560	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING PAINS DIZZY SPELLS DECREASED EYE VISION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056561	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 10/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, HIVES, ABDOMINAL CRAMPS, HEAVY CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056562	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 3/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AS SOON AS I RECEIVED THIS DEVICE, I HAD HEAVY BLEEDING, PAINFUL CRAMPS, DIZZINESS, BLURRY VISION, PAIN DURING SEX. IT HAS BEEN GETTING WORSE. BUT SINCE THE LAST TWO MONTHS, I HAVE HAD TWO MISCARRIAGES. I WAS NOT SUPPOSE TO HAVE ANY MORE BABIES. THIS PRODUCT HAS MADE ME SICK EVERY DAY WHERE I CAN'T DO STUFF WITH MY FAMILY. I CAN'T CONCENTRATE ON MY SCHOOL WORK BECAUSE I GET BURNT VISION, HEADACHES, AND DIZZINESS. I FALL IN DEEP DEPRESSION MODES BECAUSE I CAN'T DO THE STUFF I USED TO OR BECAUSE I'M PREGNANT AND NOT KNOWING IF I CAN GET HURT BEING PREGNANT. EVEN LOSING A BABY IS HARD EMOTIONAL ROLLER COASTER EVEN WHEN YOU ARE DONE HAVING BABIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056563	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 2/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE PROCEDURE DONE AROUND 7 OR 8 MONTHS LATER I START TO FEEL WEAK CAN NO LONGER WALK , FEVER STARTS COLD SWEATS THEN MY HANDS START TO TURN BLUE /BLK ALONG WITH MY FEET THEN I START HAVING TROUBLE BREATHING. MY RESPIRATORY SYSTEM SHUTS DOWN. I'M UNRESPONSIVE I GET PUT ON LIFE SUPPORT AN INFECTIOUS DISEASE DR PUMPS ME WITH LARGE AMOUNTS OF STEROIDS HE SAVED MY LIFE. I STAYED IN THE HOSPITAL FOR A MONTH I LEFT THERE UNABLE TO WALK DUE TO MUSCLE WEAKNESS IT TOOK ME 4 TO 5 MONTHS TO WALK. I STILL HAD NO ANSWERS DR WAS UNSURE WHAT CAUSE WAS. I WENT TO A RHUMATOID SPECIALIST BECAUSE ONE THING WE KNOW I HAVE RAYNAUDS SYNDROME SHE DIAGNOSED ME WITH A TERMINAL AUTOIMMUNE DISEASE CALLED VASCULITIS. PUT ON METHOTREXATE FOR 4 YRS ONCE A WEEK AND STILL NOT FEELING WELL. I AM SUFFERING FROM FATIGUE PAIN HEADACHES SO MANY OTHER ISSUES. I KNOW HAVE DEVELOPED AN INTOLERANCE TO GLUTEN , WHEAT EGG MILK SOY PEANUTS AND SHRIMP ALONG WITH ALLERGIES TO TOILET PAPER, SHAMPOO DEODORANT AND I KEEP FINDING NEW THINGS AND THE SYMPTOMS ARE WORSE THAN EVER. ALL OF THIS IS DOCUMENTED. I BARELY HEARD ABOUT THIS A FEW DAYS AGO I'M VERY UPSET. I TOO HAVE A NICKEL METAL ALLERGY EVER SINCE I WAS A LITTLE GIRL. I WAS NOT TESTED BEFORE THE PROCEDURE WAS DONE. I NEED TO GET THESE COILS OUT. WHATEVER I HAVE TO LOOSE. OR I'M AFRAID I WILL HAVE ANOTHER LIFE THREATENING EVENT

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056564	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 5/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE PROBLEMS FROM THE FIRST DAY THEY PUT ME ESSURE I HAVE MANY HEALTH PROBLEMS, THE FIRST WAS I HAD MY PERIOD AND FOR THREE MONTHS AND WAS TOLD THAT REGULAR HERA THING I DO NOT THINK THAT IS NORMAL, MANY HEADACHES, FATIGUE, ACHES BACK, A LOT COLICKY PAIN, BLOOD CLOTS IN MY TIME, DEPRESSION, ANXIETY, FATIGUE, WEIGHT GAIN, VAGINAL INFECTIONS VERY FREQUENT,I NEED, I REMOVED ESSURE CAN NOT KEEP LIVING LIKE THIS, ALL THE TIME I FEEL VERY BAD

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056565	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE AN AUTO IMMUNE DISORDER AND BEING MONITORED FOR CERVICAL CANCER. IN ADDITION TO IBS. I SHOULD HAVE NEVER GOTTEN THIS DEVICE IN MY CONDITION. I HAD ONLY A FEW SYMPTOMS NOW I GOT JUST ABOUT 80% OF THE SYMPTOMS ON THE TRACKER OF SYMPTOMS. ONE BROKE OFF AFTER 4 DAYS AND CAME OUT. NOW I FACE A TUBAL AND OR HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056566	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 6/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE INSTALLED IN 2007. SINCE THEN I HAVE HAD MULTIPLE ONGOING ISSUES. IRREGULAR CYCLES, SEVERE CRAMPING, HEAVY BLEEDING, HEADACHES, DIGESTIVE ISSUES, DEPRESSION, SWELLING FEET AND HANDS, SKIN DISORDERS, JOINT PAIN AND MANY OTHERS. IN PAIN AS I SUBMIT THIS INFORMATION. IT HURTS TO WALK. THE PAIN NEVER GOOD AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056567	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 4/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CONTRACTED A UTERINE INFECTION DURING THE PROCEDURE, WHICH THREE ROUNDS OF ANTIBIOTICS FAILED TO CURE. MY ESSURE WAS FULLY COVERED BY INSURANCE. I HAVE HYPOTHYROIDISM BUT HAD NO OTHER ILLNESSES AT THE TIME. SINCE IMPLANTATION, I HAVE HAD PAIN WHEN SITTING; PAIN BEFORE BOWEL MOVEMENTS; PAIN DURING AND ESPECIALLY AFTER SEX; BLOATING AFTER SEX; CONSTANT GENITAL ITCHING; CHRONIC FATIGUE; LOSS OF SEX DRIVE AND SEXUAL FUNCTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056568	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 8/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE BREAST TENDERNESS, RECURRING VAGINITIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056569	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAIN. STOMACH BLOATING. DID PHYSICAL THERAPY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056570	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 10/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2015 AFTER A 26 DAY CYCLE I UNDERWENT A BILATERAL SALPINGECTOMY, D AND C, AND REMOVED A CYST. DOCTOR REPORTED THAT THE RIGHT SIDE COIL WAS ALMOST COMPLETELY OUT OF THE TUBE AND IN THE UTERUS. AFTER THE SURGERY I HAD A 4 DAY PERIOD (ONE WEEK AFTER SURGERY) THAT WAS NORMAL AMOUNTS AND NO CLOTS. NO BLEEDING SINCE THEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056571	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 12/5/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ITS BEEN A HORRIBLE EXPERIENCE. I'M IN CONSTANT PAIN ALL THE TIME. I HAVE REALLY BAD ABDOMINAL AND PELVIC PAIN , EXTREMELY PAINFUL BLOATING. SINCE ESSURE I HAVE YET TO FIND A WAY TO GET MY ENERGY BACK,CURE THE CONSTANT ANNOYING PAIN,BURNING, POKING,SPASMS IN SIDES AND MUCH MORE " UNEXPLAINED" HEATH PROBLEMS. BESIDES THE PAIN, I HAVE CONSTANT EMOTIONAL PROBLEMS, DEPRESSION,PANIC ATTRACTS. TIRED AND MY ENERGY TO EVEN GET THROUGH THE DAY IS VERY ROUGH. NOT TO MENTION HAVING TO DEAL WITH THE NAUSEOUSNESS, DIZZY SPELLS,BREATHING PROBLEMS FROM THE INFLAMMATION IN MY STOMACH, WHICH ALSO CAUSES ME TO NOT BE ABLE TO EAT, AND THE INSOMNIA AT NIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056572	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 12/4/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ADVERSE REACTION BEGAN WEEK OF (B)(6) 2008 AND INCREASED THROUGH AND UNTIL (B)(6) 2015. SYMPTOMS DEVELOPED WERE: CRAMPING, SHARP PELVIC PAIN, CONSTANT SPOTTING, DISCHARGE (NO ODOR), ALL OVER BODY ACHES, NAUSEA, METALLIC TASTE IN MOUTH, BOWEL ISSUES, MIGRAINES, TINGLING SENSATIONS THROUGHOUT BODY, THIGH NUMBNESS, DIZZINESS, BLURRED VISION, HEART BURN, BRAIN FOG, ANXIETY ATTACKS, MOOD SWINGS, SEVERE BLOATING, TREMORS, UNEXPLAINED FEVERS, METAL ALLERGIES, SKIN IRRITATIONS, HEART PALPITATIONS, FALLOPIAN TUBE CYSTS, SWELLING OF FEET, HAIR LOSS AND CHANGES, INSOMNIA, CONSTANT FATIGUE, SLEEP APNEA, NIGHT SWEATS, PAINFUL PERIODS, HEAVY PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056573	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER IMPLANTATION OF ESSURE I HAVE HAD MANY HEALTH PROBLEMS. I HAVE BEEN TO MANY DOCTORS WITHOUT ANY LUCK TO DETERMINE WHAT IS CAUSING THE SYMPTOMS I HAVE. I HAVE BEEN DEALING WITH BACTERIAL VAGINOSIS FOR 2 YEARS STRAIGHT. THE ANTIBIOTICS CURE IT FOR A COUPLE OF DAYS AND THEN IT RETURNS. THE PAIN IN MY UTERUS/TUBES COMES AND GOES EVERYDAY SOMETIMES PINCHING SOMETIMES STABBING. SEVERE FATIGUE CAUSING ME TO HAVE TO TAKE A NAP EVERYDAY JUST TO FUNCTION TO TAKE CARE OF MY OTHER CHILDREN ON TOP OF MY (B)(6). I HAD MY THYROID CHECKED TO SEE IF MY WEIGHT AND FATIGUE WAS DUE TO THAT. I HAVE ANEMIA THAT I DIDN'T HAVE BEFORE. HEADACHES. LOSS OF ANY LIBIDO WITCH IS CAUSING PROBLEMS IN MY MARRIAGE. DEPRESSION. SUICIDAL THOUGHTS. ANXIETY. METAL TASTE IN MY MOUTH. IRREGULAR AND HEAVY BLEEDING. I HAVE TO BE ON A BIRTH CONTROL PILL TO CONTROL BLEEDING. BODY JUST FEELS LIKE I'M TWICE MY AGE. I HAVE PAIN WITH SEX. I'VE BEEN TRYING TO GET A GYNECOLOGIST TO LISTEN TO MY CONCERNS WITHOUT LUCK. I HAVE BEEN KICKED OUT OF MY ORIGINAL GYNECOLOGIST OFFICE BECAUSE HE WAS SICK OF ME TRYING TO MAKE APPTS AND NOT HAVING ANY ANSWERS FOR ME. I WANT THESE REMOVED. I WANTED A TUBAL LIGATION BUT MY DR OFFICE DIDN'T HAVE ME SIGN THE PAPERS 30 DAYS IN ADVANCE SO MY INSURANCE WOULD COVER IT ALTHOUGH THEY KNEW THE WHOLE TIME THAT I WANTED A TUBAL LIGATION SINCE I WAS PREGNANT WITH MY 4TH CHILD. I WOULD NOT RECOMMEND ANYONE TO GET THIS DEVICE. I ABSOLUTELY HATE IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056574	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 1/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE PROCEDURE WAS DONE BY MY OBGYN. I'VE ALWAYS BEEN A HEALTHY. SINCE HAVING ESSURE I'VE HAD TO HAVE MY GALLBLADDER REMOVED, MORE OFTEN THEN NOT I'LL GET A PERIOD EVERY 2 WEEKS. THE CRAMPS ARE UNBEARABLY PAINFUL ANDAMP; INCREDIBLY HEAVY. I'VE ALSO HAD ALOT OF DENTAL PROBLEMS I DIDN'T REALIZE COULD BE LINKED TO THE DEVICE ALSO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056575	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, WEIGHT OUT OF CONTROL, SERIOUS PAIN IN PELVIS, PERIODS HORRIBLE BLEEDING, CLOTS, CRAMPS, MOOD SWINGS, TIRED ALL THE TIME, BODY ACHES ALL OVER. I DON'T FEEL LIKE MYSELF ANYMORE AND SO FAR I HAVEN'T GOT PREGNANT BECAUSE I GOT THIS STUPID DEVICE FOR A REASON AND IT SURELY WASN'T FOR THE HELL IT PUTS U THREW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056576	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WANTED TO ADD THE SIDE EFFECTS THAT ARE CONTRIBUTING TO MY ESSURE. I HAD IT DONE IN 2011. I HAD TO GO IN TWICE BECAUSE IT WOULD NOT TAKE THE FIRST TIME IN MY RIGHT TUBE DUE TO EXTREME SPAZZING. I HAVE HAD EXTREME BLEEDING SINCE. I BECAME PREGNANT ABOUT 9 MONTHS LATER. THE DR WAS WORRIED ABOUT MY UTERUS BECAUSE IT WAS VERY THIN. I WAS HIGH RISK. I ENDED UP HAVING AN EMERGENCY CSECTION A MONTH EARLY AND HAD A TUBAL AT THAT TIME. MY DR SAID HE REMOVED MY TUBES AND COILS. SINCE THEN I HAVE BEEN EXTREMELY FOGGY AND FORGETFUL, CONSTANT ABDOMINAL PAIN (SOMETIMES TO WHERE I FEEL I'M HAVING A PROLAPSE), MY HEART HAS BEGUN HAVING PALPITATIONS TO WHERE IT SCARES ME SEVERAL TIMES A DAY, I AM BLOATED AS WELL. FEELING LIKE I WAS PROLAPSING ABOUT A MONTH AGO I WENT TO MY DR AND ASKED HIM ABOUT IT AND WANTED TO SEE MY MEDICAL RECORDS. COME TO FIND OUT MY COILS WERE NEVER REMOVED AND ARE IMBEDDED IN MY UTERUS. THE DR DID NOT EVEN SEND MY TUBES TO PATHOLOGY. NOTHING WAS SENT. I WAS LIED TO. NOW HE FEELS I NEED A PARTIAL HYSTERECTOMY. I DONE KNOW WHAT TO DO AS I DO NOT WANT TO GO THROUGH ANOTHER OPERATION. I DO NOT KNOW IF MY DEVICE WAS PROVIDED BY MY INSURER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056577	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 11/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ITCHING ALL OVER BODY BUT NO VISIBLE HIVES OR DERMATITIS. BRAIN FOG, WEIGHT GAIN, FIBROCYSTIC BREAST, VITAMIN D DEFICIENCY, HIGHLY ALLERGIC TO NICKEL . INSURANCE COVERED THE IMPLANTATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056578	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 12/28/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PROCEDURE DONE IN (B)(6) OF 2010 IN MY GYN OFFICE (THEY HAD THE KIT THERE), (B)(6) OF 2010 I NOTIFIED MY GYN OF IRREGULAR BLEEDING AND PAIN WHEN ATTEMPTING TO HAVE INTERCOURSE. I ALSO BEGAN HAVING EXCESSIVE SWEATING, URINE LEAKAGE, WEIGHT GAIN (EVEN THOUGH I TRIED SEVERAL WEIGHT LOSS PLANS INCLUDING PHENTERMINE), HEADACHES, OCCASIONAL SHARP STABBING PAIN IN MY GROIN. FINALLY THE IRREGULAR BLEEDING LED TO ME HAVING A PARTIAL HYSTERECTOMY IN (B)(6) 2014 AS WELL AS A BLADDER TACK. MY TUBES WERE NOT REMOVED SO I DO NOT BLEED ANYMORE BUT I FEEL BLOATED CONSTANTLY AND STILL HAVE STABBING PAIN IN MY GROIN OCCASIONALLY IF I STRETCH MY LEGS OUT STRAIGHT OR LAY ON MY STOMACH. I WAS NEVER TESTED FOR A NICKEL OR METAL ALLERGY AND MY PRIMARY DOCTOR IS SUGGESTING I HAVE LAP BAND OR SOME OTHER SURGERY BECAUSE I AM NOW CONSIDERED OBESE. MY ANKLES SWELL CONSTANTLY AND I AM ALWAYS FATIGUED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056579	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 6/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE ESSURE I SUFFER FROM SHARP STABBING PELVIC PAIN BLOATING SEVERE CRAMPING EXCESSIVE BLEEDING DURING PERIOD BACTERIAL VAGINOSIS NIGHT SWEATS MOOD SWINGS PMDD DEPRESSION ANXIETY LOSS OF SEX DRIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056580	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (B)(6) APPROVED THE USE OF ESSURE AS A PREVENTIVE AFTER HAVING IT ADMINISTERED I'VE BEEN HAVING HEAVY BLEEDING, MUCUS DISCHARGE, OVER TIME I HAVE DEVELOPED A PAIN AND BURNING SENSATION IN PELVIC AREA, HAIR LOSS, MEMORY LOSS, JOINT PAIN, BLOOD CLOT, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056581	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE I HAD ESSURE PLACES I HAVE LOST EXTENSIVE AMOUNTS OF MY HAIR. I HAVE HAVE GOTTEN UNEXPLAINABLE RASHES. WHERE BEFORE ESSURE I HAD 2 TO 3 DAY PERIODS NOW I HAVE 3 WEEK LONG HEAVY PAINFUL PERIODS. MY BODY JUST HURTS ALL THE TIME JOINT PAIN. I HAVE NO ENERGY ANYMORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056582	BAYER	9/28/2015	9/28/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE WAS PROVIDED BY MY INSURANCE COMPANY. I HAVE THE FOLLOWING :SEVERE HEADACHES, MUSCLE ACHES, PELVIC PAIN, ABNORMAL CYCLE, BACK PAIN, SEVERE YEAST INFECTION, DISCHARGE, TREMORS, CHEST PAINS, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056758	BAYER	9/28/2015	10/2/2015

Event Information:

Event Date (B3): 5/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2013 I WAS TO GET MY TUBES TIED AND THE DOCTOR EXPLAINED THAT I WAS GETTING THE ESSURE. I GOT THE PROCEDURE DONE AND FROM THE BEGINNING I WAS HAVING VERY BAD ABNORMAL PELVIC PAINS. SO I WENT BACK TO MY OBGYN AND THEY DISCOVERED THAT A FOREIGN OBJECT WAS LEFT IN ME AFTER MY TUBES WERE TIED. SO I HAD TO GET ANOTHER SURGERY TO HAVE IT REMOVED. STILL AFTER THAN I HAVE ABNORMAL MENSTRUAL LASTING 12 TO 14 DAYS, I GAINED (B)(6), AND HAVING INTERCOURSE WITH MY HUSBAND IS PAINFUL. IT'S LIKE I HAVE NEVER ENDING CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056759	CONCEPTUS INC.	9/28/2015	10/2/2015

Event Information:

Event Date (B3): 6/6/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/6/2008
Explant Date (E7): 10/15/2008
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2008 I HAD OUTPATIENT SURGERY FOR A HYSTEROSCOPY ESSURE TUBAL LIGATION. EARLY IN THE MORNING OF (B)(6) 2008, I HAD A SEVERE PAIN ON ONE SIDE OF MY LOWER ABDOMEN SO SEVERE THAT I PASSED OUT. I REPORTED IT TO THE NURSE THE NEXT DAY, BUT NO ACTUAL WAS TAKEN. WHEN I HAD A DYE TEST ABOUT 3 MONTHS LATER, IT WAS DISCOVERED THAT THE ESSURE COIL HAD BEEN PUSHED OUT OF MY FALLOPIAN TUBE ON ONE SIDE INTO BY ABDOMEN. ON (B)(6) 2008, I HAD TO HAVE A SECOND SURGERY TO REMOVE THE ESSURE DEVICE FROM THE PERITONEAL CAVITY AND TO HAVE A LAPAROSCOPY BILATERAL TUBAL CAUTERIZATION . ONE OF THE ESSURE COILS IS STILL IN MY OTHER FALLOPIAN TUBE. I AM NOW CONCERNED AS TO WHETHER THIS DEVICE SHOULD BE REMOVED. MY OTHER CONCERN IS THAT I WAS NEVER WARNED THAT THE COIL COULD BE EJECTED INTO BY ABDOMEN. IT WAS IN FINE PRINT IN THE BROCHURE BUT NOT DISCUSSED DIRECTLY WITH ME. I WAS TOLD ESSURE WAS AN EASIER PROCEDURE, BUT THAT WAS NOT TRUE. AS THE ESSURE PROCEDURE WAS AN OUTPATIENT SURGERY UNDER ANESTHESIA, I SHOULD HAVE BEEN COUNSELED TO JUST HAVE A NORMAL TUBAL LIGATION IN THE FIRST PLACE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056760	BAYER	9/28/2015	10/2/2015

Event Information:

Event Date (B3): 11/21/2012 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/21/2012
Explant Date (E7): 11/27/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PRODUCT INSERTED IN (B)(6) 2012. MY OBGYN OFFICE DID NOT DO MY FOLLOW-UP UNTIL (B)(6) 2014, WHICH THEY TOLD THAT FROM THE LOOKS OF EVERYTHING, THE PRODUCT IS IN THERE CORRECTLY. (B)(6) 2014, I FOUND OUT THAT I WAS PREGNANT. WHEN I HAD THE BABY IN (B)(6) 2014, THROUGH A C-SECTION, THE DOCTOR SAID THAT THE ESSURE COIL INSERTED IN THE RIGHT BUT, WENT THROUGH THE TUBE AND WAS LAYING ON THE BOWEL. AT THAT TIME, HE CUT OUT THE COIL AND THEN DID A BILATERAL TUBAL STERILIZATION. THE LEFT COIL IS STILL INSERTED IN THE TUBE. I NOW HAVE A (B)(6) CHILD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056764	BAYER	9/28/2015	10/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED IN 2012. SOON AFTER I GAVE BIRTH TO MY SECOND CHILD. I HAD PAIN DURING IMPLANTATION AND FOR A WHILE AFTER AS TO BE EXPECTED. MY PERIODS BECAME MUCH HEAVIER AND I STARTED GETTING HEADACHES. I ASSUMED THIS WAS JUST BECAUSE OF MY AGE AND HORMONES AND LACK OF SLEEP. I HAD SEVERAL OTHER ISSUES AS WELL, SUCH AS PAIN, BLOATING, CRAMPING, HOWEVER, I CALKED EACH OF THESE UP TO THE REASONS I LISTED ABOVE. I LOST MY SEXT DRIVE AS WELL. I ASKED MY DOCTOR ABOUT THAT INCLUDING THOUGHTS ABOUT SEXUAL DYSFUNCTION AND I WAS TOLD WELL YOU'RE JUST TIRED. I BOUGHT THESE THINGS UP TO THE DOCTOR ON MORE THAN ONE OCCASION AND WAS TOLD THAT I WAS FINE OVER AND OVER AGAIN AND THE ISSUES WERE HAPPENING JUST BECAUSE OF MY AGE AND HORMONES AND THE FACT THAT I WAS TIRED ALL THE TIME. I FEEL LIKE I WAS MORE TIRED THAN I SHOULD HAVE BEEN. GRANTED, I AM A MOTHER OF TWO SO SOME TIREDNESS IS TO BE EXPECTED. BUT SOME DAYS I THINK IT WAS JUST EXCESSIVE. ONE OF THE WORST THINGS THAT HAS HAPPENED WAS IN THE SUMMER OF 2014. I STARTED GETTING MIGRAINES. THEY BECAME SO BAD THAT I TOOK MULTIPLE TRIPS TO THE ER. DURING THIS TIME I WAS TAKEN OUT OF WORK FOR SEVERAL WEEKS OF UNPAID MEDICAL LEAVE. I HAD SEVERAL TESTS DONE AND THERE WERE SEVERAL FOLLOW UP APPOINTMENTS MADE. WITH EACH OF THESE VISITS IT WAS FOUND THAT I HAD STRESS IN MY LIFE BECAUSE I WAS A MOTHER OF TWO AND WORKING AND THAT WAS ALL ANYONE COULD GIVE ME FOR AN ANSWER. THEREFORE THEY DENIED BY CLAIMS FROM THE MIGRATIONS SAYING THERE WAS REALLY NOTHING WRONG WITH ME. I ALSO HAVE LOST SEVERAL TEETH. THEY SAY THAT THIS WAS DUE TO SOFT ENAMEL AND IT SEEMS THAT THE TOOTH DECAYED RIGHT OUT SO THEY NEEDED TO BE PULLED, BUT I CERTAINLY TAKE CARE OF MY TEETH SO I HAVE A HARD TIME THINKING THAT IT IS JUST MY FAULT ALONE. ON TOP OF ALL OF THIS I HAVE HAD OTHER SYMPTOMS AS WELL, WEIGHT GAIN, PAIN ISSUES, NO SEX

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DRIVE, SEXUAL DYSFUNCTION, MOOD SWINGS, SEVERAL ITES, THE LIST GOES ON AND ON SO IT SEEMS. ALL THIS TIME I JUST THOUGHT EVERYTHING WAS MY FAULT AND THERE WASN'T TRULY ANYTHING WRONG WITH ME. I FELT COMPLETELY ASHAMED. I FOUND OUT APPROXIMATELY A WEEK AGO THAT SOME OF THESE ISSUES MAY ALL LEAD BACK TO THE ESSURE. IT IS TRULY THE ONLY THING THAT MAKES SENSE AT THIS POINT. CONSIDERING ALL THE TESTS THAT I HAVE HAD DONE AND THERE ARE STILL NO ANSWERS. AT THIS POINT, REALLY WHAT ELSE COULD IT BE? ALSO, HOW CAN IT BE PROVED THAT THIS GOES BACK TO THE ESSURE. I HAVE AN APPOINTMENT ON WEDNESDAY WITH THE DOCTOR WHO PUT THE ESSURE DEVICES IN SO I AM GOING TO SPEAK WITH HER ABOUT HOW I AM FEELING AND SEE IF THESE CAN BE REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056765	BAYER	9/28/2015	10/2/2015

Event Information:

Event Date (B3): 1/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/6/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PROBLEMS AND SYMPTOMS I'VE HAD AND/OR BEEN TESTED/TREATED FOR SINCE HAVING THE ESSURE PROCEDURE COMPLETED IN (B)(6) 2014. CRAMPING, SHARP/STABBING PELVIC PAIN, OVARIAN CYSTS, DISCHARGE (ODOR/NO ODOR), EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES PAINFUL PERIODS (DYSMENORRHEA), PAINFUL INTERCOURSE (DYSPAREUNIA). URGENT/FREQUENT URINATION, UTI (URINARY TRACT INFECTION), BLADDER INFECTION, ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE (VULVODYNIA) BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/TWITCHING/FLUTTERING PAIN IN BACK, JOINTS, CHEST,LEGS, BREAST, NECK, SPINE, HIPS CHRONIC PELVIC PAIN, ALL OVER BODY ACHES/PAIN, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING. METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, NEUROLOGICAL, MENTAL HEALTH, HEADACHES OR MIGRAINES, DIZZINESS TINGLING SENSATIONS, NUMBNESS, BRAIN SHOCKS, NERVE PAIN, BRAIN FOG - CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS MOOD SWINGS, SEIZURES DEPRESSION (SADNESS/SUICIDAL THOUGHTS) RINGING IN EARS (PULSATILE TINNITUS), BLACK OUT SPELLS/FAINTING DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), NUMBNESS IN THIGH (MERALGIA PARESTHETICA), NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN (PARESTHESIA), NERVE PAIN, TREMORS/SHAKINESS, DIZZINESS, UNEXPLAINED/EASILY BRUISING, RHEUMATOID ARTHRITIS INFLAMMATION, HEIGHTENED ALLERGIES/ALLERGIC REACTIONS, HIVES, RASHES CYSTS, BOILS, ACNE SKIN IRRITATION/ITCHING, SWELLING OF LEGS OR FEET HAIR LOSS OR CHANGES , HARD TO MANAGE THYROID DISEASE (HYPOTHYROID) DEGENERATIVE BONE DISEASE, GALLBLADDER ISSUES (REMOVAL),

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SWELLING/NUMBNESS IN JAWS/LIPS, SWELLING OF LEGS/FEET, MUSCLE SPASMS, VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION), EXCESSIVE SWEATING DRY SKIN/HAIR/EYES, SEVERE BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056776		9/28/2015	10/2/2015

Event Information:

Event Date (B3): 11/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/12/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN (B)(6) 2012 IN (B)(6) MEDICAL CLINIC, LOCATED IN (B)(6), AND HAVE BEEN IN CONSTANT PELVIC PAIN EVER SINCE. I WAS GIVEN NOTHING BUT EXAMS WITH INCONCLUSIVE RESULTS OR SUGGESTIONS TO TAKE PAIN MEDICINE. RECEIVED A DYE TEST IN (B)(6) 2014 TO CONFIRM BLOCKAGE. I WAS ABSTINENT BEFORE THEN. RECEIVED A BIOPSY IN (B)(6) 2015, WITH A NEGATIVE RESULT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056780	BAYER	9/28/2015	10/2/2015

Event Information:

Event Date (B3): 7/30/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 7/30/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2010 I MADE THE DECISION TO GET AN IMPLANT IN ME TO KEEP ME FROM HAVING MORE KIDS. SO THE IMPLANTS THAT WAS AVAILABLE WAS DISCUSSED WITH ME THROUGH MY DR (B)(6) AT (B)(6) HOSPITAL. I WAS JUST GETTING INTO THE IMPLANT AND THINGS STARTED TO CHANGE A LITTLE. I STARTED HAVING BAD BAD BAD MENSTRUAL CRAMPS WORSE THAN I HAD BEFORE IT WAS PUT IN, I STARTED HAVING TROUBLE WITH MY LOWER BACK, AND I ALSO HAD BAD BLOOD CLOTS. I NEVER THOUGHT THAT IT WAS THE IMPLANT TILL I RAN ACROSS A SCRIPT SHOWING THE SYMPTOMS FOR THE ESSURE IMPLANT. IMMEDIATELY I CONTACTED A WORKER TO SEE HOW I CAN GET THIS THING OUT OF ME. I'M A SINGLE MOTHER WITH A LOW INCOME JOB SO I NEVER TRIED TO SIGN UP FOR HEALTH INSURANCE CAUSE I KNEW I COULDN'T AFFORD THE PAYMENTS CAUSE I WAS BARELY MAKING IT WITH MY BILLS AND THE NEEDS OF MY KIDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056781	BAYER	9/28/2015	10/2/2015

Event Information:

Event Date (B3): 9/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): NONE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/23/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

CHRONIC PAIN EVER SINCE IMPLANTS, ESPECIALLY DURING OVULATION AND MENSTRUAL CYCLE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01138	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 5/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7): 8/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1034, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. WHILE PREGNANT WITH HER 2ND CHILD SHE DISCUSSED WITH HER PHYSICIAN ABOUT HAVING HER TUBES TIED AFTER DELIVERING HER BABY. HER PHYSICIAN TOLD ABOUT THE ESSURE PRODUCT. IN (B)(6) 2006 ESSURE WAS INSERTED. SHE DID NOT HAVE THE HSG (HYSTEROSALPINGOGRAM) DONE AFTER 3 MONTHS DUE TO BEING LAID OFF FROM HER JOB AND LOST INSURANCE. ACCORDING TO HER, EVEN HAD HER TUBES BLOCKED, THE EVENTS TOOK PLACE A YEAR AFTER BEING IMPLANTED WOULD HAVE HAPPENED ANYWAY. IN (B)(6) 2007, SHE WAS RUSHED TO THE ER AND ADMITTED TO THE HOSPITAL FOR 36 HOURS (ER PHYSICIANS, NURSES AND TECH'S HAD NO IDEA WHAT ESSURE WAS. EVEN AFTER SHOWING THE 10 CARD TO THEM THEY DISREGARDED IT). SHE WAS SUBMITTED TO MULTIPLE TESTS AND THE ATTENDING PHYSICIAN COULD ONLY CONCLUDE THAT MAYBE SHE PASSED A KIDNEY STONE. PRETTY SURE THAT WOULD HAVE SHOWN UP ON A TEST RESULT SINCE SHE WAS IN SO MUCH PAIN DURING ALL TESTS, SUCH AS ULTRASOUND, CT SCAN, X RAYS, ETC. IN (B)(6) 2007 AFTER MISSING HER PERIOD, SHE TOOK A PREGNANCY TEST TO FIND OUT THAT SHE WAS PREGNANT. ON (B)(6) 2007, SHE WAS HAVING A TRANSVAGINAL ULTRASOUND AND THE DOCTOR COULD ONLY SEE THE REFLECTION OF 1 COIL. ON (B)(6) 2007, SHE WAS ADMITTED TO HOSPITAL TO TERMINATE THE PREGNANCY. SINCE THAT DAY SHE WAS NOT BEING ABLE TO LIVE WITHOUT HAVING TO TAKE AN ANTI-DEPRESSANT; HER MARRIAGE ENDED, HER CHILDREN HAD TO LIVE DIFFERENT HOMES. HER HAIR WAS SO THIN FROM THE AMOUNTS OF HAIR LOOSE DAILY. SHE WAS NOT ABLE TO EAT WITHOUT

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HAVING TO GO STRAIGHT TO THE BATHROOM AFTERWARDS, INSOMNIA, SEVERE HIP AND LEG PAINS, EXTREMELY HEAVY PERIODS WITH A LARGE AMOUNT OF CLOTTING, WEIGHT GAIN WITHOUT CHANGING HER EATING HABITS, DEPRESSION, ANXIETY, MOOD SWINGS, SHORT TEMPER, ETC. ON (B)(6) 2015 DOCTOR FOUND THAT THE RIGHT COIL HAD PERFORATED FALLOPIAN TUBE AND WAS TWISTED IN THE FAT TISSUE SURROUNDING HER COLON ON THE LEFT SIDE OF HER BODY AND THE LEFT COIL HAD PERFORATED THAT TUBE AND WAS ATTACHED TO THE OUTSIDE OF THE TUBE ON LEFT SIDE. ESSURE WAS REMOVED AND HYSTERECTOMY WAS DONE IN (B)(6) 2015. SINCE SURGERY, HER HIPS AND LEGS DO NOT HURT, SHE HAD ONE BOWEL MOVEMENT EACH MORNING, SHE SLEPT LIKE A ROCK, SHE FOUND OUT PATIENCE AGAIN AND NOW SHE WILL BEGIN THE PROCESS TO ATTEMPT TO GET OFF OF THE ANTI-DEPRESSANTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER, WHO WAS HOSPITALIZED DUE TO PAIN 1 YEAR AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. FOUR MONTHS LATER SHE WAS DIAGNOSED WITH A PREGNANCY; WHICH SHE DECIDED TO TERMINATE. EIGHT YEARS LATER, IT WAS FOUND RIGHT ESSURE COIL HAD PERFORATED FALLOPIAN TUBE AND LEFT COIL HAD PERFORATED THAT TUBE AND WAS ATTACHED TO THE OUTSIDE OF THE TUBE. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH DEVICES REMOVAL. ALL EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE INCLUDING FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, CONSUMER DID NOT HAVE HER HSG. AN ULTRASOUND PERFORMED DURING PREGNANCY REVEALED ONLY ONE COIL. YEARS AFTER PREGNANCY TERMINATION A BILATERAL ESSURE PERFORATION WAS FOUND. THIS FALLOPIAN TUBE PERFORATION COULD BE AN ALTERNATIVE EXPLANATION FOR THE REPORTED DEVICE FAILURE (PREGNANCY). HOWEVER, SINCE ITS MECHANISM IS UNKNOWN (IF PERFORATION OCCURRED BEFORE OR AFTER PREGNANCY ONSET) AND AS PREGNANCY OCCURRED MORE THAN ONE YEAR AFTER DEVICES PLACEMENT; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE HOSPITALIZATION AND DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01142	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/28/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1070, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE HAD HYSTERECTOMY AND ALL HER SYMPTOMS WERE GONE 2 WEEKS LATER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HYSTERECTOMY PERFORMED. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE LIMITED INFORMATION WAS PROVIDED. IT WAS MENTIONED THAT THE CONSUMER HAD A HYSTERECTOMY. IN SPITE OF LACK OF DATA, CAUSALITY BETWEEN THE REPORTED EVENT AND SUSPECTED INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01143	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-1037, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE HAD ESSURE FOR 2 YEARS, DURING HER TWO YEARS OF COUNTLESS DOCTORS' VISITS, EMERGENCY ROOM VISITS, AND COUNTLESS OF DRUGS TO CEASE THE PAIN OR FLUSH ANY INFECTION OUT. FIRST OFF AS SOON AS THE ESSURE DEVICE WAS PLACED SHE WAS NAUSEOUS, DIZZY AND HAD A HORRIBLE MIGRAINE. SHE WAS TOLD THE HEADACHES AND CRAMPING WOULD GO AWAY (IT NEVER DID). HER FIRST HOSPITAL VISIT WAS FOR FLU LIKE SYMPTOM. SHE SUFFERED YEAR AND A HALF OF OCCASIONAL VOMITING AND DIARRHEA UNFORTUNATELY SOMETIMES AT THE SAME TIME. AFTER HAVING THESE SYMPTOMS AND THINKING THAT SHE HAS THE FLU A LOT. ALWAYS HAD HEAD COLDS THAT SHE THOUGHT WERE ALLERGIES AND IT WAS GIVING ALLEGRA D. TWO OTHER HOSPITAL VISITS WERE FOR ALLERGIC REACTIONS WHERE HER BODY WAS A RASH, ESPECIALLY HER CHEST AND LOW ABDOMINAL AREAS. SHE HAD ANOTHER VISIT FOR HORRIBLE STOMACH PAIN, HAD COUNTLESS OF TEST ULTRASOUND, UPPER GASTROINTESTINAL SCOPE, COLONOSCOPY, CT SCAN, MRI AND ABUNDANCE OF BLOOD DRAWN. ALL EXAMS COULD FIND WAS AN ULCER. A BLEEDING OPEN ULCER. THE PELVIC PAIN WAS SO BAD, SHE WAS DIAGNOSED WITH ENDOMETRIOSIS TWICE. HER CERVIX WAS SCOPED AND SCRAPPED OF ANY DEADLY MOLECULE SHE GAINED 45 POUNDS IN 6 MONTHS. FINALLY ABOVE ALL THINGS THAT MADE HER MISS WORK, VACATION, FAMILY EVENTS AND HER LIFE. THE CHRONIC PELVIC PAIN TOOK OVER HER MIND AND HER BODY. SHE EVEN THOUGHT TO TAKE HER OWN LIFE. ALMOST ACTED ON IT. THIS WAS A VERY SCARY AND PAINFUL TIME IN HER LIFE. NO ONE KNEW HOW TO HELP HER OR

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FIGURE OUT WHAT WAS WRONG SO FINALLY SHE ASKED HER PRIMARY CARE PHYSICIAN IF IT COULD BE HER ESSURE CAUSING ALL HER PELVIC DISCOMFORT. SHE WAS UNCERTAIN SINCE SHE WAS NOT THE ONE TO ADMINISTER THEM. SHE CALLED HER GYNECOLOGIST AND SET UP AN APPOINTMENT TO REMOVE THE ESSURE COILS. SHE CHOSE TO REMOVE HER FALLOPIAN TUBE DUE TO THE FACT SHE WAS ONLY (B)(6) AND DID NOT WANT TO EXPERIENCE MENOPAUSE. ON (B)(6) 2015 HER PELVIC PAIN WAS NO MORE. SHE DID HAVE SOME OPERATION PAIN BUT THE PAIN IN HER HEAD AND PELVIC AREA WAS GONE, SHE WAS ESSURE FREE, AND SHE WAS SLOWLY GAINING HER LIFE BACK. SHE DID NOT WISH ANY OF WHAT SHE WENT THROUGH ON ANY WOMAN BECAUSE ESSURE RUINED HER LIFE, HER BODY AND HER MIND. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD STOMACH PAIN. SHE WAS DIAGNOSED WITH A BLEED OPEN ULCER. SHE ALSO HAD CHRONIC PELVIC PAIN THAT LED HER TO EVEN THINK TO TAKE HER OWN LIFE. TWO YEARS AFTER INSERTION, SHE HAD HER FALLOPIAN TUBES REMOVED AND DID NOT PERFORM A HYSTERECTOMY. THE GASTRIC ULCER HAEMORRHAGE AND SUICIDAL IDEATION ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND CHRONIC PELVIC PAIN DUE TO REQUIRED INTERVENTION. THE PELVIC PAIN IS LISTED WHILE THE OTHER TWO EVENTS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THESE EVENTS OCCURRED DURING ESSURE USE. CONSIDERING THIS COMPATIBLE TEMPORAL RELATIONSHIP AND THE NATURE OF THESE EVENTS, THE PELVIC PAIN IS ASSESSED AS RELATED TO ESSURE. HOWEVER, ALTHOUGH ESSURE MIGHT CAUSE A MINOR DEPRESSION DUE TO REGRETTING THE DECISION OF ESSURE INSERTION, IT IS UNLIKELY THAT IT WOULD CAUSE A SUICIDAL THOUGHTS. ALSO, GIVEN THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT IT WOULD CAUSE A GASTRIC ULCER HAEMORRHAGE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01144	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/28/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1053, AWARENESS DATE 01-SEP-2015). THIS CASE REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006 AND SOON AFTER SHE STARTED DEVELOPING SYMPTOMS. IN 2013, SHE WENT TO A DIFFERENT DOCTOR THAT IMMEDIATELY THOUGHT HER ISSUES WERE BECAUSE OF ESSURE, HE NEVER BELIEVED IN THE PRODUCT AND WANTED TO DO A LAPAROSCOPY IMMEDIATELY TO FIND OUT. AT THAT TIME, HE REMOVED THE RIGHT OVARY AND TUBE (IMPLANT HAD PERFORATED TUBE AND DESTROYED OVARY) BUT LEFT IMPLANT WAS LEFT IN BECAUSE IT WAS WHERE IT WAS SUPPOSED TO BE. IN 2015 SHE WENT FOR A HYSTERECTOMY, SHE ONLY HAD LEFT OVARY, EVERYTHING ELSE WAS GONE. SHE FELT MUCH BETTER AFTER, SHE GOT HER ENERGY AND FOCUS IN LIFE BACK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED SYMPTOMS. SEVEN YEARS LATER, SHE HAD A LAPAROSCOPY AND HAD HER RIGHT OVARY AND TUBE REMOVED BECAUSE THE IMPLANT HAD PERFORATED THE FALLOPIAN TUBE AND OVARY. APPROXIMATELY 2 YEARS LATER, SHE HAD A HYSTERECTOMY AND LEFT FALLOPIAN TUBE REMOVAL, ONLY HER LEFT OVARY WAS LEFT IN. SHE FELT BETTER AFTER THAT. THE FALLOPIAN TUBE PERFORATION, OVARY PERFORATION AND HYSTERECTOMY ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THESE 3 EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, CONSIDERING THE NATURE OF THESE EVENTS, THE LACK OF ALTERNATIVE EXPLANATION AND THE FACT THAT SHE WAS FEELING

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BETTER AFTER ESSURE REMOVAL SUGGEST THAT THE CAUSAL RELATIONSHIP IS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 02-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01145	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1062, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE REPORTED THAT SHE WAS IMPLANTED WITH DESIRE AND IMMEDIATELY HAD ABDOMINAL PAIN ON A CONSISTENT BASIS. SHE ALSO REPORTED SEXUAL INTERCOURSE PAINFUL, CONSTANT BLEEDING AND WEIGHT GAIN. SHE FINALLY RECEIVED A HYSTERECTOMY AND STATED THAT SHE WAS ALLERGIC TO NICKEL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMMEDIATELY AFTER INSERTION SHE HAD ABDOMINAL PAIN ON A CONSTANT BASIS AND CONSTANT BLEEDING. SHE HAD A HYSTERECTOMY. THE ABDOMINAL PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND CONSTANT BLEEDING DUE TO ITS MEDICAL IMPORTANCE. BOTH EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS, THE SUGGESTIVE TEMPORAL RELATIONSHIP AND THE LACK OF ALTERNATIVE EXPLANATION, BOTH EVENTS ARE ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01146	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1071, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAS 2 ADHESIONS BY HER LIVER AND THEY HAVE TO STAY BECAUSE THEY DO NOT WANT TO INJURE HER LIVER. SHE STILL HAS AN EXTREMELY LARGE HIATAL HERNIA AND ONE OF HER TUBES HAD SCARRED TO HER BOWEL. SHE HAD UTERINE FIBROIDS AND OVARIAN CYSTS. BUT, ACCORDING TO HER, IN THE END EVERYTHING IS GONE AND THEY GOT ESSURE COILS OUT. NOW SHE IS IN MENOPAUSE WOOT (AS REPORTED). IN ADDITION, CONSUMER REPORTED 22 MONTHS OF PAIN, COUNTLESS EMERGENCY ROOM VISITS, NUMEROUS DOCTOR VISITS, TESTS, MULTIPLE DAILY MEDICATIONS, DEPO PROVERA SHOT AND A TOTAL HYSTERECTOMY INCLUDING TUBES AND OVARIES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN (INTERPRETED AS PELVIC PAIN). SHE UNDERWENT A TOTAL HYSTERECTOMY AND ESSURE WAS REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, THE CONSUMER ALSO HAD OVARIAN CYSTS AND UTERINE FIBROIDS WHICH COULD BE ALTERNATIVE EXPLANATIONS FOR THE PAIN. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENT, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE TOTALLY EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY, ESSURE REMOVAL). A PRODUCT

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TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01147	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1085, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN 2007. CONSUMER STATED THAT SHE HAD ESSURE FOR 7 YEARS. SHE HAD SKIN PROBLEMS, HAIR FALLING OFF AND BLOATING. AFTER SHE HAD THEM REMOVED IN (B)(6) 2014 SHE WAS BACK TO NORMAL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLOATING (INTERPRETED AS ABDOMINAL DISTENSION). SHE HAD ESSURE REMOVED 7 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL BLOATING MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE LACK OF A PLAUSIBLE ALTERNATIVE EXPLANATION AND CONSIDERING THAT THE EVENT RESOLVED AFTER ESSURE REMOVAL, A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. SINCE ESSURE REMOVAL WAS REPORTED, THIS CASE WAS REGARDED AS INCIDENT (REQUIRED INTERVENTION IMPLIED). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01148	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-1113) IN UNITED STATES ON 01-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN (B)(6) 2008. SINCE ESSURE PLACEMENT, HER SYMPTOMS HAVE SLOWLY PROGRESSED: SHE IS SUFFERING FROM EXTREMELY HEAVY PERIODS, EXCESSIVE HAIR LOSS AND WEIGHT GAIN, LOW SEX DRIVE, LOSS OF ENERGY AND MOTIVATION. SWOLLEN LEGS AND STOMACH, UNBEARABLE PAIN ON HER LEFT SIDE NEAR FALLOPIAN TUBE, COUNTLESS X-RAYS, COMPUTERISED TOMOGRAM SCANS, AND PAIN MEDICATION. NOT TO MENTION DEPRESSION AND ANXIETY. SHE IS SCHEDULED FOR A HYSTERECTOMY ON (B)(6). SHE IS OVERJOYED TO FINALLY HAVE AN EVICTION DATE OF THESE POISONOUS COILS. SHE IS AN ADVOCATE TO ALL WOMEN SUFFERING FROM THIS PAIN AND HELL. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UNBEARABLE PAIN ON HER LEFT SIDE NEAR FALLOPIAN TUBE. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SINCE DEVICE PLACEMENT, HER SYMPTOMS (THE PAIN AND OTHER NON-SERIOUS EVENTS) HAVE SLOWLY PROGRESSED AND SHE IS SCHEDULED FOR A HYSTERECTOMY. GIVEN EVENT'S NATURE AND SUGGESTIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN

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INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01149	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61995

Single Use: Y
Implant Date (E6): 8/31/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. PHYSICIAN INFORMED THAT, AFTER THE INSERTION, WHEN DELIVERY CATHETER WAS BEING REMOVED, IT BROKE AND HAD TO BE REMOVED WITH TWEEZERS. BILATERAL PLACEMENT WAS ACHIEVED AND NO PATIENT INJURY OCCURRED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHEN DELIVERY CATHETER WAS BEING REMOVED, THE DELIVERY CATHETER BROKE AND HAD TO BE REMOVED WITH TWEEZERS. THE EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW-UP RECEIVED ON 17-NOV-2015 WITH THE FINAL PTC (PTC GLOBAL NUMBER: (B)(4)) INVESTIGATION RESULT: FINAL ASSESSMENT: BATCH NUMBER - C61995. PRODUCTION DATE - 04-JUN-2014. EXPIRATION DATE - 30-JUN-2017. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01151	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/31/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1087, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER HAD ESSURE INSERTED AT DOCTORS OFFICE, AND WHAT WAS SUPPOSED TO BE A 20 MINUTES PROCEDURE LASTED OVER AN HOUR. SHE STATED IT WAS THE MOST HORRIFIC THING SHE HAD BEEN THROUGH SO FAR IN HER LIFE. AFTER SHE LEFT OFFICE, HER CHEST FELT HEAVY AND LIKE SHE COULDN'T BREATH. SHE WENT TO EMERGENCY ROOM, WHERE SHE FOUND OUT A COLLAPSED LUNG FROM TOO MUCH FLUID GOING PAST HER DIAPHRAM AND INTO HER CHEST CAVITY. SO, SHE WAS ADMITTED AND THE NEXT DAY THE WATER DRAINED FROM HER CHEST CAVITY. SHE KEPT COMPLAINING THAT HER RIGHT SIDE WAS IN HORRIBLE PAIN, SO THEY RUSHED HER DOWN TO CHECK OUT HER APPENDIX AND SAID EVERYTHING WAS FINE. SHE WENT DIRECTLY TO ANOTHER HOSPITAL AND THE SAME DOCTOR THAT DID THE ESSURE PROCEDURE WAS ON CALL AND HE DECIDED TO ADMIT HER AND TO TAKE OUT TUBES AND COILS. WELL WHEN HE GOT IN THERE, ONE OF THE COILS HAD RUPTURED HER UTERUS AND THE OTHER WAS MISPLACED. SO AFTER THAT SHE CONTINUED TO BLEED VERY HEAVILY AND SHE WAS ADMITTED AT LEAST 3-4 TIMES WITH INFECTION UNTIL FINALLY THE HOSPITAL DID A CT SCAN AND SHOWED FRAGMENTS OF THE ESSURE LEFT INSIDE HER BODY AND 150ML PUS POCKET WHICH WAS LEFT FROM FLUID RETAINED IN HER BODY. SO SHE WENT TO NEW GYN AND THE NEW DR SAID HER UTERUS LOOKED LIKE SHRAPNEL WAS LEFT INSIDE. SO SHE HAD TO END UP GETTING A TOTAL AND COMPLETE HYSTERECTOMY BECAUSE OF THIS SIMPLE IN OFFICE PROCEDURE. SHE WAS LITERALLY IN BED OR HOSPITAL FOR A YEAR. COMPANY CAUSALITY

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COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RIGHT SIDE WAS IN HORRIBLE PAIN, ONE OF THE COILS HAD RUPTURED HER UTERUS, OTHER COIL WAS MISPLACED, COLLAPSED LUNG FROM TOO MUCH FLUID GOING PAST HER DIAPHRAM AND INTO HER CHEST CAVITY (REGARDED AS PNEUMOTHORAX), INFECTION / 150ML PUS POCKET WHICH WAS LEFT FROM FLUID RETAINED IN BODY. THESE EVENTS ARE SERIOUS SINCE THEY RESULTED IN HOSPITALIZATION. SHE ALSO BLEED VERY HEAVILY AND FRAGMENTS OF THE ESSURE LEFT INSIDE MY BODY / UTERUS LOOKED LIKE SHRAPNEL WAS LEFT INSIDE (SEEN AS DEVICE BREAKAGE). THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE EVENTS PNEUMOTHORAX AND INFECTION ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. IN THIS CASE, CONSUMER UNDERWENT A TOTAL AND COMPLETE HYSTERECTOMY. ALTHOUGH A POSITIVE TEMPORAL RELATIONSHIP IS IMPLIED FOR ALL EVENTS, BASED ON THE PATHOPHYSIOLOGY AND CONSIDERING THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP BETWEEN PNEUMOTHORAX, INFECTION WITH SUSPECT INSERT CAN BE EXCLUDED. WITH REGARDS THE OTHER EVENTS, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01152	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1110, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. SHE REPORTED THAT SHE HAD ESSURE PLACED AND STATED THAT, WITH HER DIABETES THE NONSURGICAL OPTION WAS THE BEST. SHE REGRETTED HER DECISION EVERY DAY AFTER THAT. ACCORDING TO HER, SHE WENT TO MULTIPLE DOCTORS WHO SAID ESSURE COULD NOT BE THE PROBLEM. SO SHE CARRIED ON WITH THE PAIN, WEIGHT GAIN, LETHARGY, BRAIN FOG, FATIGUE, HEAVY BLEEDING, RASHES, MORE PAIN, LEG PAIN AND BACK PAIN. THEN THE PSYCHOLOGICAL EFFECTS: NOT BEING ABLE TO WORK, HELP WITH DINNERS MANY NIGHTS OR EVEN GET OUT OF BED. SHE FELT POISONED, JUST SICK IN EVERY INCH OF HER BODY AND SHE WAS BARELY IN HER (B)(6). IN ADDITION, CONSUMER INFORMED THAT SHE HAD MULTIPLE CAYVSCANS (AS REPORTED, UNDERSTOOD AS CAT SCANS) AND MRIS (MAGNETIC RESONANCE IMAGING) WITH NO ANSWERS, THEY SAID THEY APPEAR TO BE IN THE RIGHT PLACE SO THEY COULD NOT BE AFFECTING HER. IN 2015, SHE HAD A HYSTERECTOMY. SHE HAD CERVICAL CANCER REMOVED AND HAS HAD INFECTIONS SINCE SURGERY AND WAS STILL IN SO MUCH PAIN IN HER BACK AND GROIN DUE TO THESE. NOT TO MENTION THE BLOATING (THE EVER PREGNANT LOOK THAT FEELS SO SHAMEFUL, THE LOOKS AND QUESTIONS WHEN YOUR BABY IS 8 AND YOU LOOK LIKE YOUR STILL PREGNANT). CONSUMER ALSO REPORTED HEADACHES, RINGING IN HER EARS, VERTIGO, AND METALLIC TASTE IN MOUTH EVERY DAY. SHE HAD TWO SPLINTERS IN HER BODY FOR 9 YEARS THAT SHE FELT EVERY SINGLE DAY, ALL THE TIME; AND STATED THAT SHE WANTED TO TAKE A KNIFE TO HER SELF AND GET THEM OUT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS

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CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND PAIN. SHE MADE SEVERAL EXAMS INCLUDING MRI, CAT SCAN THAT SHOWED INSERTS WERE IN PLACE. AFTER NINE YEARS, SHE HAD A HYSTERECTOMY AND A CERVICAL CANCER REMOVED. SHE HAD INFECTIONS (INTERPRETED AS PELVIC INFECTIONS) AFTER SURGERY. THE UNSPECIFIED PAIN IS SERIOUS DUE TO A POSSIBLE REQUIRED INTERVENTION. THE GENITAL BLEEDING, CERVICAL CANCER AND PELVIC INFECTIONS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ALL EVENTS BUT CERVICAL CANCER ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, ALL THESE EVENTS OCCURRED DURING ESSURE USE. ALTHOUGH THE TEMPORAL RELATIONSHIP IS COMPATIBLE, CONSIDERING THE NATURE OF THESE EVENTS AND LOCALIZED ACTION OF ESSURE, THE PAIN AND GENITAL BLEEDING ARE ASSESSED AS RELATED. HOWEVER, THE CERVICAL CANCER AND THE PELVIC INFECTION FROM HYSTERECTOMY PERFORMED PROBABLY DUE TO THE CERVICAL CANCER ARE ASSESSED AS UNLIKELY RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01153	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1119, AWARENESS DATE 27-AUG-2015). CASE WAS RECEIVED IN UNITED STATES ON 01-SEP-2015 AND REFERS TO A (B)(6) FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. RIGHT AFTER GETTING IT, SHE BEGAN TO HAVE SHARP PAINS ON THE LEFT SIDE OF HER ABDOMEN. HER DOCTOR SAID HER BODY WAS PROBABLY JUST ADJUSTING. 3 MONTHS LATER, AT HER HYSTEROSALPINGOGRAM (HSG) X-RAY (AS REPORTED) IT WAS CONFIRMED THE LEFT COIL HAD MIGRATED AND PIERCED HER UTERUS. CONSUMER HAD TO HAVE SURGERY TO REMOVE IT AND HER LEFT TUBE WAS CLAMPED AT THAT POINT. IN ADDITION, SHE WAS FATIGUED ALL THE TIME AND STARTED TAKING DAILY VITAMIN, THINKING SHE WAS DEFICIENT. THEN SHE STARTED HAVING MIGRAINES DAILY, FEELING NAUSEA, LIGHT HEADED, DRY EYES, STOMACH BLOATING, GUMS HURTING, JOINT PAIN ALONG WITH SEVERE ABDOMINAL AND BACK PAIN. AT THE AGE OF (B)(6), SHE IS NO LONGER ABLE TO DO SOME OF THE BASIC THINGS LIKE WALKING WITHOUT HAVING PAIN. ADDITIONALLY, CONSUMER REPORTED THAT SHE DID ESSURE TO AVOID SURGERY AND YET, BECAUSE OF IT, SHE IS ON HER SECOND ONE. SHE HAD PAIN AND CONSTANT FATIGUE. ALL SHE HAS THE ENERGY TO DO AFTER WORK IS SLEEP. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 3 MONTHS AFTER PLACEMENT, AT CONFIRMATION TEST, IT WAS FOUND THAT LEFT COIL HAD MIGRATED AND PIERCED HER UTERUS. THIS EVENT, SEEN AS UTERINE PERFORATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION WITH ESSURE USE MAY OCCUR

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DURING ESSURE USE, MOSTLY DURING DIFFICULT INSERTIONS. IN THIS CASE, SOON AFTER PLACEMENT, THE CONSUMER HAD SHARP PAINS ON THE LEFT SIDE OF HER ABDOMEN. THEN, 3 MONTHS LATER, THE CONFIRMATION TEST (HSG) SHOWED THAT THE LEFT COIL HAD MIGRATED AND PIERCED HER UTERUS. CONSIDERING THE PERFORATION PROBABLY OCCURRED DURING INSERTION PROCEDURE AND GIVEN EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. AS ESSURE REMOVAL ON LEFT SIDE WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01154	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1120, AWARENESS DATE 01-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2002. CONSUMER REPORTED THAT PLACEMENT WAS UNEVENTFUL AND DEVICES WERE POSITIONED CORRECTLY AND STATES THAT THIS WAS PART OF THE TRIAL PROCESS. HOWEVER, THERE WAS MINIMAL FOLLOW-UP OTHER THAN TESTING TO CONFIRM TUBES WERE BLOCKED. SOMETIME AFTER INSERTION, HER MENSTRUAL CYCLE WENT HAYWIRE AND HER HEALTH STEADILY DECLINED. IN 2004, SHE WAS DIAGNOSED WITH A RARE CHRONIC AUTOIMMUNE DISEASE (SYSTEMIC SCLEROSIS). OVER THE FOLLOWING YEARS, SHE EXPERIENCED MAJOR HEAVY PERIODS, NONSTOP BLEEDING, SEVERE CRAMPING, LOWER BACK PAIN, ABDOMINAL BLOATING, PAIN HAVING SEX, BLEEDING AFTER SEX, OVARIAN CYSTS, FEELING OF A HEAVY, DRAGGING UTERUS, EXTREME FATIGUE, URINARY URGENCY, SEVERE CHRONIC PELVIC PAIN, STABBING PAIN IN THE BREAST AND PELVIS, AND A PERSISTENT DULL ACHE, DIAGNOSED FIBROMYALGIA, CHRONIC FATIGUE AND WENT THROUGH EARLY MENOPAUSE; ALL THANKS TO ESSURE. ON (B)(6) 2015, SHE UNDERWENT A TOTAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY TO REMOVE THE ESSURE DEVICES, A SURGERY SHE NEVER WOULD HAVE ELECTED TO HAVE UNLESS ABSOLUTELY NECESSARY. IN ADDITION, CONSUMER REPORTED THAT IN THE FOUR WEEKS FOLLOWING SURGERY, HER BLOATED ABDOMEN HAS GONE, FIBROMYALGIA PAIN REDUCED AND SHE HAS NOT SUFFERED FROM PELVIC CRAMPING, BREAST PAIN, LOWER BACK PAIN ETC. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND

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EXPERIENCED SEVERE CRAMPING AND NON STOP BLEEDING. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH SALPINGECTOMY TO REMOVE ESSURE. ADDITIONALLY, SHE WAS DIAGNOSED WITH SYSTEMIC SCLEROSIS. ONLY SYSTEMIC SCLEROSIS IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER HAD SYSTEMIC SCLEROSIS WHICH CAN ALSO LEAD TO CRAMPING. NEVERTHELESS, AS HER CRAMPING IMPROVED WITH ESSURE REMOVAL AND CONSIDERING EVENTS NATURE, CASUALTY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING SYSTEMIC SCLEROSIS, CONSIDERING THIS CONDITION IS A SYSTEMIC CONNECTIVE TISSUE DISEASE MANIFESTED BY VASCULAR AND IMMUNOLOGIC SYSTEM DISTURBANCES AND GIVEN ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY IS CONSIDERED UNLIKELY. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 07-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01155	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1066, AWARENESS DATE 01-SEP-2015). CASE WAS RECEIVED FROM CONSUMER'S FRIEND IN UNITED STATES AND REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER'S FRIEND REPORTED THAT, FOR YEARS SHE HAS WATCHED HER BEST FRIEND, WHO SHE GREW UP WITH, SUFFER GREATLY AFTER GETTING THE ESSURE BIRTH CONTROL. SHE HAS WATCHED HER HAVE AN UNEXPECTED CHILD AFTER GETTING ESSURE, SHE HAS WATCHED HER HAVE MULTIPLE SURGERIES, MULTIPLE IMAGES TO LOCATE THE FRAGMENTS THROUGHOUT HER ABDOMEN AND COLON. SHE HAS WATCHED HER HAVE TO GET A HYSTERECTOMY (2 WEEKS AGO; (B)(6) 2015) BECAUSE OF ESSURE AND STATES THAT HER FRIEND STILL HAS FRAGMENTS THROUGHOUT HER ABDOMEN. ACCORDING TO REPORTER, CONSUMER HAS SEEN MANY SPECIALISTS AND SURGEONS AND WAS TOLD THAT SHE HAS TO LIVE WITH THIS PAIN FOR THE REST OF HER LIFE BECAUSE THEY CANNOT BE SAFELY REMOVED. IN ADDITION, REPORTER INFORMED THAT SHE HAS WATCHED MANY OTHER FRIENDS SUFFER FROM ESSURE AS WELL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER, WHO HAD AN UNEXPECTED CHILD AFTER GETTING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). ADDITIONALLY, SHE WAS SUBMITTED TO MULTIPLE SURGERIES (UNSPECIFIED) TO LOCATE THE FRAGMENTS THROUGHOUT HER ABDOMEN AND COLON (REGARDED AS DEVICE BREAKAGE WITH DISLOCATION OF ESSURE FRAGMENTS INTO PERITONEAL CAVITY) ONLY DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-

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INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE INCLUDING FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED ABOUT HSG. THE CONSUMER WAS SUBMITTED TO UNSPECIFIED IMAGES AND FRAGMENTS OF ESSURE WERE FOUND IN HER ABDOMEN AND COLON. THIS DEVICE BREAKAGE/DISLOCATION COULD BE ALTERNATIVE EXPLANATIONS FOR THE REPORTED ESSURE FAILURE (PREGNANCY). HOWEVER, SINCE THEIR MECHANISM IS UNKNOWN (IF BREAKAGE OCCURRED BEFORE OR AFTER PREGNANCY ONSET); CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01156	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-1086) IN UNITED STATES ON 01-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED AND HAS HAD THE DEVICE REMOVED. REPORTER STATED THAT SHE RECENTLY LOCATED SOMEONE THAT HAS HAD THE DEVICE REMOVED IN HER CITY. SHE WAS CONTACTING HER AT THE DAY OF THE POST. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAS HAD THE DEVICE REMOVED. THIS EVENT, SEEN AS MEDICAL DEVICE REMOVAL, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY MAY BE REQUIRED. IN THIS PARTICULAR CASE, VERY LIMITED INFORMATION HAS BEEN PROVIDED. ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, CONSIDERING ITS NATURE; COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED AND DUE TO THE IMPLIED INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01157	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER MOTHER VIA REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-1035) IN UNITED STATES ON 01-SEP-2015 WHICH REFERS TO HER DAUGHTER FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED. ACCORDING TO REPORTER ESSURE HAS MADE HER DAUGHTER LIFE MISERABLE. AFTER HAVING HER THIRD CHILD, HER DAUGHTER AND HER HUSBAND MADE THE DECISION TO NOT HAVE ANY MORE CHILDREN. SHE TALKED WITH HER DOCTOR ABOUT HAVING HER TUBES TIED, BUT DOCTOR TALKED HER INTO HAVING THE ESSURE IMPLANTS PUT IN. AS SOON AS SHE HAD THE IMPLANT PUT IN, SHE IMMEDIATELY STATED HAVING NAUSEA AND PAIN IN HER STOMACH. SHE WAS ASSURED THAT IT WAS REACTIONS TO POST-SURGERY AND WOULD GO AWAY. SIX MONTHS LATER, IT WAS CLEAR THAT HER ISSUES WERE NOT POST-SURGERY AND DID NOT GO AWAY. SHE BEGAN HER LONG TWO YEARS OF DOCTORS, PAIN AND ILLNESS. THERE WERE MANY DAYS WHEN SHE COULD NOT EVEN GET OUT OF BED. SHE WOULD BE DOUBLED UP IN PAIN, CRYING. SHE FELT SO HELPLESS. SHE HAD A BABY AND TWO OLDER CHILDREN TO CARE FOR, BUT COULD NOT BECAUSE OF HER ILLNESS. SHE HAD NUMEROUS TESTS DONE: COMPUTED TOMOGRAPHY SCANS, ULTRASOUNDS, MAGNETIC RESONANCE IMAGING, INTERNAL ULTRASOUNDS, TRYING TO DETERMINE WHAT WAS CAUSING HER SYMPTOMS. HER MOM STATED THAT SHE WOULD HELP HER WITH THE CHILDREN, AS WOULD HER MOTHER-IN-LAW, AS MUCH AS THEY COULD IT WAS A NIGHTMARE FOR ALL OF THEM. SHE WANTED JUST BE A NORMAL MOTHER AND WIFE, BIN SHE COULD NOT. HER MOTHER CONTACTED HER DOCTOR AND REQUESTED THAT SHE REMOVE HER IMPLANTS. THE DOCTOR REFUSED INSISTING THAT CONSUMER ISSUES HAD TO BE

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SOMETHING ELSE. SHE SEARCHED AND SEARCHED FOR A GYNECOLOGIST THAT WOULD REMOVE THE IMPLANTS, NO ONE WANTED TO TOUCH IT. SHE KEPT SEARCHING UNTIL SHE FINALLY FOUND A DOCTOR THAT AGREED TO REMOVE THE IMPLANTS. WHEN THE DOCTOR CAME OUT AT THE DAY OF SURGERY, HE SAID THAT HE WAS ABLE TO REMOVE THE IMPLANTS, BUT HE HAD TO DO A PARTIAL HYSTERECTOMY TOO. THEY KNEW THIS WAS A POSSIBILITY, BUT WERE STUNNED TO FIND OUT THAT HER DAUGHTER, AT THE YOUNG AGE OF (B)(6), NO LONGER HAD HER FEMALE ORGANS. HOWEVER, THEY WERE HAPPY THAT THE IMPLANTS WERE OUT AND THEY DID NOT SHATTER AND DAMAGE OTHER ORGANS AS SOME WOMEN HAD EXPERIENCED. IT TOOK CONSUMER QUITE A WHILE TO RECOVER FROM HAVING THE IMPLANTS REMOVED AND THE HYSTERECTOMY. SHE STILL, TO THIS DAY, HAS OVARY PAIN AT TIMES AND THE EMOTIONAL IMPACT LOSING HER FEMALE ORGANS AT SUCH A YOUNG AGE, STILL DEPRESSES HER. JUST THIS WEEK, SHE WAS DIAGNOSED WITH A AUTO-IMMUNE DEFICIENCY THAT OTHER ESSURE PATIENTS HAVE SUFFERED FROM. YET ANOTHER ILLNESS AND ISSUE THAT WAS CAUSED BY ESSURE THAT SHE NOW HAS TO FACE. WHEN SHE SHOULD BE ENJOYING HER BEAUTIFUL CHILDREN AND LIFE, SHE SPENDS A LOT OF HER TIME IN THE DOCTOR'S OFFICE AND IS ON MANY MEDICATIONS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MANY DAYS WHEN SHE COULD NOT EVEN GET OUT OF BED, WOULD DOUBLED UP IN PAIN. A PARTIAL HYSTERECTOMY WAS PERFORMED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PAIN MAY OCCUR WITH ESSURE THERAPY. BASED ON THE NATURE OF THE EVENT AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP WITH SUSPECT INSERT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. SHE WAS ALSO DIAGNOSED WITH AUTO-IMMUNE DEFICIENCY, WHICH IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND UNLISTED. BASED ON THE PATHOPHYSIOLOGY AND GIVEN ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01158	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 7/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/2/2013
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1038, AWARENESS DATE 01-SEP-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. THE CONSUMER STATED THAT SHE WAS A SINGLE MOTHER OF TWO BY THE TIME OF ESSURE INSERTION. SHE WAS VERY ACTIVE AND HEALTHY AND AS SOON AS SHE WAS IMPLANTED WITH ESSURE SHE STARTED HAVING HEALTH PROBLEMS. SHE REPORTED IT STARTED WITH VOMITING AND LOWER ABDOMINAL PAIN. AFTER THREE MONTHS, IN (B)(6) 2013, SHE WAS TOO SICK TO ATTEND CLASSES, NOT TO MENTION THE DECREASE IN COGNITIVE FUNCTION. THE MIGRAINES LASTED DAYS AT A TIME AND HER BODY LOOKED AS IF SHE WAS PREGNANT. SHE BECAME EXTREMELY ANXIOUS AND EXPERIENCED EXTREME MOOD SWINGS. SHE HAD BEEN TO COUNTLESS SPECIALISTS AND WAS DIAGNOSED WITH AN AUTOIMMUNE DISEASE. JUST SHY OF HAVING ESSURE FOR TWO YEARS, SHE HAD A HYSTERECTOMY (IN 2015). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN LOWER AND AUTOIMMUNE DISEASE. THESE EVENTS ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. ABDOMINAL PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE AUTOIMMUNE DISORDER IS UNLISTED. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, AS SOON AS SHE HAD ESSURE IMPLANTED SHE STARTED TO HAVE ABDOMINAL PAIN LOWER AND OTHER NON-SERIOUS EVENTS. CONSIDERING SUGGESTIVE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. REGARDING AUTOIMMUNE DISEASE, LIMITED INFORMATION HAS

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BEEN PROVIDED; HOWEVER, GIVEN ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND SUSPECT INSERT IS VERY UNLIKELY. AS INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01159	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1055, AWARENESS DATE 01-SEP-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT WHEN THEY DID THE PROCEDURE SHE WAS IN THE DOCTOR OFFICE IN A LOT OF PAIN. SINCE SHE HAS HAD IT SHE HAS BEEN IN CONSTANT PAIN, MIGRAINES, LACK OF ENERGY, VITAMIN D CONSTANTLY LOW, AND MANY OTHER PROBLEMS. IT IS HARD FOR HER TO GET OUT AND DO ANYTHING WITH HER BOYS, SHE HATES THAT SHE MADE THE DECISION TO GET THIS DONE. SHE IS DEPRESSED ALL THE TIME BECAUSE OF THE FACT SHE COULD NOT DO ANYTHING WITH HER KIDS. SHE DID NOT EVEN HAVE A SEX LIFE IT HAS TAKEN THAT AWAY FROM HER ALSO WHICH CAUSED HER NOW EX-HUSBAND TO LEAVE HER BECAUSE HE DID NOT UNDERSTAND. SHE NEVER IMAGINED AT THE AGE OF (B)(6), SHE WOULD HAVE TO HAVE A HYSTERECTOMY BUT SHE DID THANKS TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD CONSTANT PAIN SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE MENTIONED A HYSTERECTOMY AT AGE OF (B)(6). THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER'S PAIN STARTED SINCE ESSURE PLACEMENT AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. IN THIS CASE, CONSUMER STATED SHE NEVER IMAGINED SHE

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WOULD HAVE TO HAVE A HYSTERECTOMY, AND THANKS TO ESSURE SHE DID. ALTHOUGH IT IS UNCLEAR IF THIS SURGERY WAS ACTUALLY PERFORMED; AS NO FOLLOW-UP WILL BE POSSIBLE, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01160	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51076

Single Use: Y
Implant Date (E6): 5/7/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 03-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER C51076). SCOPE TIME DURING ESSURE INSERTION WAS 20 MINUTES AND 2 TRAILING COILS WERE SEEN IN BOTH SIDES AFTER THE PROCEDURE. FOLLOWING HER ESSURE PROCEDURE ON (B)(6) 2015, THE PATIENT FOLLOWED UP WITH THE ESSURE CONFIRMATION TEST WHICH SHOWED THAT THE RIGHT MICRO-INSERT WAS NOT IN THE FALLOPIAN TUBE OR UTERINE CAVITY. IT WAS DETERMINED THAT THE ESSURE WAS ADHERED TO THE EPIPLOIC OF THE COLON (SUPERFICIAL, NOT EMBEDDED, BUT STARTED TO CONNECT WITH THE FATTY TISSUE THERE). THE PATIENT WAS TAKEN TO THE OPERATING ROOM AND THE DEVICE WAS REMOVED FROM THE SURFACE OF THE COLON. ON (B)(6) 2015 SHE WENT TO THE PHYSICIAN'S OFFICE FOR HER POST-OP VISIT. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C51076 (PRODUCTION DATE 25-APR-2014 AND EXPIRATION DATE 30-APR-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT

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QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER CONFIRMATION TEST REVEALED THE RIGHT MICRO-INSERT ADHERED TO THE EPIPLOIC OF THE COLON (SUPERFICIAL, NOT EMBEDDED, BUT STARTED TO CONNECT WITH THE FATTY TISSUE THERE). SHE WAS TAKEN TO THE OPERATING ROOM AND THE DEVICE WAS REMOVED. THIS EVENT, REGARDED AS DEVICE DISLOCATION INTO PERITONEAL CAVITY, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A UTERINE PERFORATION DURING INSERTION. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. PHYSICIAN STATED ESSURE INSERTION WAS SUCCESSFUL WITH 2 TRAILING COILS VISIBLE IN BOTH SIDES AFTER THE PROCEDURE. ALTHOUGH THE EXACT MECHANISM OF THE REPORTED DEVICE DISLOCATION IS UNKNOWN; CONSIDERING EVENT'S NATURE AND ITS CLOSE TEMPORAL RELATIONSHIP WITH ESSURE PROCEDURE; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01161	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 3131

Single Use: Y
Implant Date (E6): 7/31/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 03-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED BILATERALLY ON (B)(6) 2015. IT WAS REPORTED THAT PATIENT SUBSEQUENTLY HAD THEM REMOVED (DO NOT KNOW DATE OF REMOVAL) BECAUSE OF NICKEL ALLERGY. PHYSICIAN WAS TOLD THE PATIENT KNEW SHE HAD A NICKEL ALLERGY BUT NEVER MENTIONED IT TO THE DOCTOR. REPORTER WAS UNABLE TO ASCERTAIN WHAT SYMPTOMS LED TO THE PATIENT REQUESTING REMOVAL. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED ADVERSE EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED ADVERSE EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL

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ALLERGY. SHE SUBSEQUENTLY HAD ESSURE REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE; SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED. IN THE PRESENT CASE, THE PATIENT KNEW SHE WAS ALLERGIC TO NICKEL PRIOR TO ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION FOR ESSURE REMOVAL. SINCE NO PRODUCT WAS RETURNED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENT WAS CAUSED BY A POTENTIAL QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 17-NOV-2015 - QUESTIONNAIRE PROVIDED: THE PATIENT'S CONCURRENT CONDITIONS INCLUDED NORMAL WEIGHT ((B)(6)). SHE WAS NOT POST-PARTUM. ESSURE LOT NUMBER WAS C51069. DURING INSERTION, CERVICAL DILATATION, SOUNDING AND CERVICA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01162	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1044, AWARENESS DATE 02-SEP-2015). IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN 2006 FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT IN 2006 SHE DECIDED THAT SHE WANTED A PERMANENT BIRTH FORM CONTROL AND ESSURE WAS RECOMMENDED. SHE WAS TOLD BY HER GYNECOLOGIST THAT THEY HAD BEEN DOING IT FOR YEARS IN EUROPE WITH NO COMPLICATIONS. SHE AGREED TO HAVE THE PROCEDURE DONE EVEN THOUGH WAS AGAINST HER BETTER JUDGMENT. SHE COULD STILL HEAR HER NURSING SCHOOL INSTRUCTOR SAY YOUR BODY WILL TRY TO GET RID OF A FOREIGN BODY BUT HER DOCTOR SAID THEY HAD BEEN DOING THIS FOR YEARS WITHOUT ANY ISSUE. SHE IMMEDIATELY STARTED WITH SEVERE ACNE, AND THEN GAINED 30 POUNDS WITHIN 3-4 MONTHS. INFLAMMATION STARTED TO POP UP IN HER JOINTS AND THEN SHE CALLED IT THE CRAWL OUT OF HER SKIN PAIN. THAT IS BECAUSE SHE HURT SO BAD SHE JUST WANTED TO CRAWL OUT OF HER SKIN. SHE HURT ALL OVER, SHE STARTED GOING TO A CHIROPRACTOR, ACUPUNCTURIST, HAD A MASSAGE HERE AND THERE. SHE WENT TO MULTIPLE DOCTORS, SHE ALSO STARTED TO HAVE MANY OTHER ISSUES: TERRIBLE METALLIC TASTE IN MOUTH, HEAVY PERIODS WITH CLOTS THAT ENDED UP WITH ABLATION (B)(6) 2011, JOINT PAIN, BACK PAIN, FEVERS, HIVES/RASHES, FIBROMYALGIA, SHARP PELVIC PAINS, PAIN WITH INTERCOURSE, FATIGUE, BRAIN FOG, CLOUDINESS, FORGETFULNESS, NAUSEA, DIZZINESS, BLOATING, HAIR LOSS, DEPRESSION, ANXIETY, VITAMIN D DEFICIENCY, RECEDING GUMS, HEART BURN, HEART PALPITATIONS AND CONSTIPATION. SHE ENDED UP WITH A HYSTERECTOMY (B)(6) 2014 DUE TO BEING IN SO MUCH PELVIC PAIN. HER DEVICE WAS ALSO

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BROKEN. SHE HAD ADENOMYOSIS, PARATUBAL CYSTS, LEIOMYOMA, INFLAMMATION AND HEMORRHAGE IN TUBE. SHE HAD LOST SO MUCH FROM THAT HYSTERECTOMY: LOW LIBIDO, DIMINISHED OR ABSENT ORGASM AND DIMINISHED SENSATION AND PLEASURE. SHE BELIEVES THE INITIAL THOUGHT OF THE PRODUCT WAS BRILLIANT BUT SOMETHING IS CLEARLY WRONG WITH THAT PRODUCT. IN 2011 A CO-WORKER WHO ALSO HAD ESSURE STARTED LOOKING UP ISSUES WITH THE PRODUCT. SHE THOUGHT NO WAY COULD 2 LITTLE PLASTIC PIECES IN HER FALLOPIAN TUBES CAUSE ALL THESE ISSUES. SHE JUST FORGOT ABOUT IT UNTIL 2014 WHEN HER RHEUMATOLOGIST WANTED TO PUT HER IN METHOTREXATE AND SHE KNEW WAS THE DEVICE. SHE THEN FOUND THOUSANDS OF OTHER WOMEN HAVING THE SAME ISSUES AS SHE. SHE DID NOT BELIEVE THE INFLAMMATION IS REMAINING IN THE TUBES. SHE BELIEVED THIS PRODUCT IS CAUSING A SYSTEMICALLY EFFECT. ALSO CONSUMER STATED THAT HER HUSBAND ENDED UP HAVING 2 URETHRAL STRICTURES REQUIRING SURGERY AFTER SHE GETTING ESSURE. SHE WAS CONVINCED IT WAS BECAUSE OF ESSURE BECAUSE HE HAS NO OTHER RISK FACTOR. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP PELVIC PAINS. A HYSTERECTOMY WAS PERFORMED. HER DEVICE WAS BROKEN. SHE HAD INFLAMMATION (SALPINGITIS) AND HEMORRHAGE IN TUBE (HAEMATOSALPINX). ALL THE EVENTS, EXCEPT FOR DEVICE BREAKAGE, ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. SHARP PELVIC PAINS AND INFLAMMATION ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE UNLISTED. IN THIS CASE, CONSUMER UNDERWENT A HYSTERECTOMY DUE TO BEING IN SO MUCH PELVIC PAIN. WITH REGARDS TO THE EVENTS PELVIC PAIN AND DEVICE BREAKAGE, CONSIDERING THEIR NATURE AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, SINCE THEY OCCURRED MORE THAN 4 WEEKS POST INSERTION AND THEY COULD BE RELATED TO A COMPLICATION OF HYSTERECTOMY PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, SEVERAL NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

THE PTC INVESTIGATION RESULT WAS UPDATED ON 11-NOV-2015. PTC GLOBAL NUMBER IS (B)(4). MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED / IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01163	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-1116, AWARENESS DATE ON 02-SEP-2015). IT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN (B)(6) 2012. SHE HAD ESSURE PLACED AND IMMEDIATELY EXPERIENCED PAIN. SHE WAS ASSURED BY HER DOCTOR THAT IT WAS NOT CAUSED BY ESSURE. HER PERIODS WERE HEAVY AND PAINFUL AND SHE WAS TOLD SHE WAS GETTING OLDER, SHE WAS (B)(6). SHE HAD SURGERY FOR TUBE AND COIL REMOVAL ON (B)(6) 2015, TWO AND A HALF YEARS LATER. THE COIL ON HER LEFT WHICH CAUSED SO MUCH PAIN WAS IMPROPERLY PLACED AND THE COIL ON THE RIGHT WAS PERFORATED. SHE ALSO HAD A CYST AND POLYPS. SHE HAD EXTREME BLOATING, COULD ONLY EAT ONE SMALL MEAL A DAY, AND EXPERIENCED CONSTANT PAIN. SHE GAINED AROUND 20 POUNDS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CONSTANT PAIN. TWO AND A HALF YEARS AFTER INSERTION, SHE HAD A SURGERY FOR TUBE AND COILS REMOVAL. DURING SURGERY IT WAS NOTICED THAT LEFT COIL WAS IMPROPERLY PLACED (INTERPRETED AS DEVICE DEPLOYMENT ISSUE) AND THE COIL FROM THE RIGHT WAS PERFORATED (INTERPRETED AS UTERINE PERFORATION). THE CONSTANT PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND THE OTHER TWO EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ALL THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THE DEVICE DEPLOYMENT ISSUE AND UTERINE PERFORATION, BOTH EVENTS ARE ASSESSED AS RELATED TO ESSURE. SINCE THESE TWO SITUATIONS ARE PRESENT, A

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CAUSAL RELATIONSHIP BETWEEN THE CONSTANT PAIN AND THESE ESSURE-RELATED COMPLICATIONS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

CORRECTION 05-OCT-2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE PREVIOUS EVENT TERM COIL ON HER LEFT WHICH CAUSED SO MUCH PAIN WAS IMPROPERLY PLACED" WAS RECODED TO MEDDRA LLT "DEVICE DISLOCATION ". PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01172	BAYER HEALTHCARE LLC	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 4/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26965

Single Use: Y
Implant Date (E6): 4/16/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 16-APR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C26965 FOR STERILIZATION. VALIUM, LIDOCAINE BLOCK AND KETOROLAC WERE USED PRIOR PROCEDURE. ON PLACEMENT LEFT OSTIA WAS VISUALIZED BUT FIRST PLACEMENT FAILED; DID NOT DEPLOY. SECOND INSERT DEPLOYED AND IT WENT IN EASILY WITH NO TUBAL SPASM. NO RESISTANCE WAS OBSERVED AND 3 TRAILING COILS WERE SEEN. THEN PATIENT STARTED COMPLAINING OF ACUTE ONSET SEVERE LLQ (LEFT LOWER QUADRANT) PAIN FOR NO REASON. PROCEDURE WAS ABORTED AND PATIENT WAS SENT TO ER. PHYSICIAN ORDERED FLAT PLATE AND WAS AWAITING RESULTS. FOLLOW UP INFORMATION RECEIVED ON 16-APR-2015 AND 21-APR-2015: PATIENT INFORMATION WAS UPDATED. THE PATIENT HAD UNILATERAL LEFT TUBE PLACEMENT WITH 3 TRAILING COILS. AS OF (B)(6) 2015, THE PATIENT WAS STILL EXPERIENCING PAIN. PTC INVESTIGATION RESULT RECEIVED ON 27-APR-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT LOT C26965 PRODUCTION DATE 27-FEB-2014; EXPIRATION DATE 28-FEB-2017 DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: ROLLBACK TO INITIAL HARD STOP. DEPRESS BUTTON. PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO DEPLOYMENT DIFFICULTY. SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS

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WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT . IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FOLLOW UP 29-JUL-2015: FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. CASE CONSIDERED CLOSED. FOLLOW-UP RECEIVED ON 04-SEP-2015 AND 14-SEP-2015 (UPDATED PTC RESULT): INFORMATION RECEIVED STATES THAT PHYSICIAN PERFORMED A LAPAROSCOPIC TUBAL ON THIS PATIENT. NO OTHER INFORMATION WAS PROVIDED. UPDATED PTC RESULT. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD AN ACUTE ONSET OF SEVERE LLQ PAIN AFTER FIRST DEVICE WAS INSERTED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PAIN AND CRAMPING MAY OCCUR DURING AND FOLLOWING THE INSERTION PROCEDURE. IN THE PRESENT CASE, THE FIRST PLACEMENT ON LEFT SIDE FAILED AS THE DEVICE DID NOT DEPLOY. THEN A SECOND INSERT DEPLOYED AND WAS PLACED WITH NO RESISTANCE, HOWEVER THE PATIENT STARTED COMPLAINING OF ACUTE ONSET SEVERE LEFT LOWER QUADRANT PAIN AND THE PROCEDURE WAS ABORTED. SHE WAS SENT TO ER AND PHYSICIAN WAS WAITING FOR THE RESULTS OF FLAT PLATE. CONSIDERING THE AVAILABLE INFORMATION AND SINCE THE ACUTE PAIN STARTED DURING THE PROCEDURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. NEITHER HOSPITALIZATION NOR SURGICAL INTERVENTION WERE REPORTED, HENCE THIS CASE IS REGARDED AS NON-INCIDENT. THE PRODUCT TECHNICAL ANALYSIS

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CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056583	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE DEVELOPED SEVERE MIGRAINES THAT ARE VERY DEBILITATING. I HAVE VERY HEAVY BLEEDING WITH MY PERIODS NOW. I ALSO EXPERIENCE LOW BACK AND HIP PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056584	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 6/6/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAIN, MUSCLE PAIN, HEADACHES. TIRED ALL THE TIME, HEAVY BLEEDING, I FEEL LIKE I HAVE (B)(6) YEARS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056585	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 5/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FIRST THING I NOTICED WAS A VERY SHARP PAIN ON MY LEFT SIDE. I STARTED HAVING RASHES ON MY FACE AND NECK AND ARMS. NO MENSTRUAL CYCLE FOR ONE YEAR. SEVERE CRAMPS OFTEN RANDOMLY. FREQUENT URINARY INFECTIONS. LEG CRAMPS. BLOATING IN MY STOMACH BUT I FELT IT MORE IN MY PELVIC AREA. BACK PAIN. LEG CRAMPING. SWELLING OF MY FEET. MIGRAINES. SOMETIMES A TASTE OF METAL IN MY MOUTH. NOW I'M GETTING PERIODS EVERY 15 DAYS. NUMBNESS IN MY PELVIC AREA. HAIR LOSS. FEELING OF DEPRESSION. SUICIDAL THOUGHTS. BREAST TENDERNESS. AND MORE. AND YES MY INSURER PROVIDED MY ESSURE DEVICE. I HAVE MEDI-CAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056586	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 7/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, LACK OF SEX DRIVE, CONSTANT HEADACHES, AMONG OTHER SYMPTOMS WHICH I DID NOT NOW WE'RE DUE TO ESSURE UNTIL I RECENTLY STARTED RESEARCHING. I NOW KNOW FOR SURE THERE IS SOMETHING WRONG BECAUSE I AM CURRENTLY PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056587	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 9/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL OVULATION (MITTELSCHMERZ), LOSS OF LIBIDO, HAIR LOSS, POLYMENORRHEA, BACK AND HIP PAIN, ALL OVER BODY ACHES, BRAIN FOG - CLOUDINESS , FORGETFULNESS, MEMORY LOSS, WEIGHT ISSUES

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056588	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 6/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT THE TIME OF IMPLANT I WAS A HEALTHY (B)(6) RECENTLY DIVORCED AND WAS LOOKING FOR AN ALTERNATE BIRTH CONTROL METHOD. AFTER A FEW CONSULTATIONS WITH MY GYNO AND REVIEWING DATA SHEETS ON ESSURE, I HAD THE IMPLANT DONE IN (B)(6) OF 2013. I HAD THE IODINE TESTING DONE IN (B)(6) 2013 AND ALL LOOKED PERFECT. A FEW MONTHS LATER I STARTED NOTICING WEIGHT GAIN, ABNORMAL CRAMPING AND PAIN, FATIGUE AND PROBLEMATIC PERIODS. LASTING LONGER THAN USUAL AND HEAVIER THAN USUAL. I DIDN'T TAKE MUCH STOCK IN IT AT THE TIME AS I DO YEARLY CHECK UPS WITH MY GYNO, AM HEALTHY AND THEY DIDN'T SEE ANYTHING UNUSUAL FOR MY AGE. I TRUST MY DOCTORS. CHALKED IT UP TO PREMENOPAUSAL SYSTEMS. THIS CONTINUED FOR OVER A YEAR OR SO. I HAD MY FIRST EVENT OF OVER 2 WEEKS OF BLEEDING IN (B)(6) 2014. IN EARLY (B)(6) OF 2014 THEY RAN A CT SCAN AND THEY COULDN'T ANYTHING ABNORMAL TO ASSOCIATE THE LONG PERIODS AND HEAVY FLOW. THE BLEEDING AND CRAMPING CONTINUED TO INCREASE. I WAS ALSO EXPERIENCING DEPRESSION, MOOD SWINGS, HAIR LOSS AND CONTINUED FATIGUE. IN (B)(6) OF 2015 I HAD A PERIOD THAT LASTED OVER 3 WEEKS. HAD AN EARLY CHECK UP WITH MY DR AND THEY RAN A SERIES OF BLOOD WORK. NOTHING AND IT FINALLY STOPPED IN EARLY (B)(6). MY NEXT CYCLE STARTED IN (B)(6) ONLY 2 WEEKS AFTER THE LAST. UPON WEEK 4 OF BLEEDING I WENT TO MY GYNO AGAIN. THEY DECIDED TO RUN ANOTHER SERIES OF CT SCANS. IT WAS THEN THAT THEY FOUND THE DEVICE HAD MIGRATED OUT OF MY FALLOPIAN TUBE AND WAS CUTTING INTO MY UTERUS. THEY COULDN'T DETERMINE HOW LONG IT HAD BEEN IN THAT POSITION. ALL I KNEW WAS THAT I WASN'T CRAZY, THAT MY BODY WAS NOT LYING TO ME AND THERE WAS A MAJOR PROBLEM OCCURRING. IT WAS THEN THAT MY DR SAID MY ONLY OPTION WAS TO HAVE THEM REMOVED. I HAD MY

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HYSTERECTOMY ON (B)(6) 2015. WE HAD THE UTERUS AND BOTH FALLOPIAN TUBES REMOVED. HE WAS ABLE TO KEEP MY OVARIES IN TACT. I WILL HAVE TO GET A COPY OF MY FILE IN ORDER TO SHOW LAB RESULTS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056589	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 11/8/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE AFTER BIRTH OF MY LAST CHILD AND NEVER ATTRIBUTED MY FOLLOWING MEDICAL CONDITIONS TILL NOW. SHORTLY AFTER BEING IMPLANTED IN (B)(6) 2007, I BEGAN EXPERIENCING DEPRESSION, ANXIETY, AND UNREASONABLE AGITATION. I THOUGHT IT WAS BECAUSE I WAS GOING THROUGH POST PARTUM BLUES. WHEN I FINALLY DECIDED TO GO TO DOCTOR, I WAS DIAGNOSED WITH DEPRESSION AND ANXIETY DISORDER AND ANXIETY ATTACKS. I WAS PUT ON SEVERAL DIFFERENT MEDICATIONS FOR A LONG PERIOD OF TIME AND STILL TO THIS DAY FIND NO REAL RELIEF. I GAINED OVER 100 POUNDS FROM MY USUAL WEIGHT. ON (B)(6) 2013, I GOT GASTRIC SLEEVE SURGERY AND STILL HAVE A HARD TIME KEEPING MY WEIGHT LOSS AND LOSING MORE WEIGHT. I ALSO HAVE CONSTANT PELVIC PAIN, HIP AND BACK PAIN WHICH HAS WORSENED NOW AND X RAY SHOWS ON (B)(6) 2015 THAT MY LOWER BACK HAS REDUCED SPACE ON LAST LUMBAR AND SACRAL BONES. I HAVE A HARD TIME SLEEPING NOW BECAUSE IT RADIATES TO MY HIP BONES. I CAN NOT STAND THE PAIN NOW. I WANT TO REMOVE THE ESSURE SPRINGS BUT DON'T HAVE MONEY AND MY INSURANCE WILL NOT COVER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056590	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 5/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONTINUAL PAIN AND CRAMPING AT THE SITE OF COILS STARTING JUST AFTER INSERTION AND CONTINUING TO THE PRESENT DAY. HOT FLASHES FOR 3 MONTHS AFTER INSERTION. HEAVY BLEEDING WITH PERIODS. BLOATING. CONTINUAL TENDERNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056591	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 9/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4L. ER ABDOMINAL PAIN, HEAVY BLEEDING, NUMBNESS IN MY LEGS, CAN'T SIT UP IN MY BED FOR A LONG PERIOD OF TIME, BECAUSE I HAVE DULL LIKE PAIN IN MY PELVIC AREA, HEADACHE, LOWER BACK PAINS, CYSTS, I WAS TREATED FOR INFLAMMATION AROUND MY TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056592	BAYER	9/29/2015	9/29/2015

Event Information:

Event Date (B3): 9/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN , BLOOD CLOTS , PERIODS UP TO OR MORE THEN 20 DAYS A MONTH , HOT FLASHES ,BACK PAIN EVERYDAY, ACNE ,HEADACHES , MOOD CHANGES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056799	BAYER	9/29/2015	10/5/2015

Event Information:

Event Date (B3): 3/3/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/3/2003
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD MANY UNEXPLAINED HEALTH ISSUES SINCE THE IMPLANT WAS PUT IN SOMETIME AROUND 2002 BY (B)(6). I HAVE HAD MANY "RUN AROUND IDEA'S OF WHY I WAS SO TIRED, HAD TROUBLE SLEEPING, BODY ACHES AND FELT CONTINUALLY LIKE I HAVE THE FLU. I DID FIND OUT THAT I DO INDEED HAVE ALLERGIES TO ANIMALS. I HAVE REMOVED ALL MY ALLERGIES INCLUDING ANY FOODS THAT A NATURAL PATH INDICATED AND WHILE I'M BETTER, I'M STILL NOT FUNCTIONING. I'VE FOUND IT HARD TO HOLD DOWN A JOB BECAUSE THE SYSTEMS ARE THAT BAD. I RECENTLY WITHIN THE LAST YEAR, WENT TO A "FEMALE DR ABOUT THE ESSURE" BECAUSE MOST OF MY PROBLEMS STARTED AFTER I HAD THAT DEVICE PUT IN, BUT I WAS NEVER TOLD ABOUT A POSSIBLE NICKEL ALLERGY. I WAS ONLY TOLD THAT EVEN THOUGH THE DEVICE HAS MOVED, "I HAVE A PHOTO FROM ANOTHER DR WHO REMOVED SMALL TUMOR FROM MY OVARY". THERE IS NO REASON FOR CONCERN AND MORE THAN LIKELY SHE WOULDN'T NEED TO REMOVED IT. SINCE I HAVE HAD THE DEVICE IN, MY LIFE HAS BEEN HORRIBLE AND ALL I GET TOLD IS WELL YOUR GETTING OLDER, ETC. I HAVE DR REPORTS AND TESTS THAT I HAVE KEPT TO PROVE THAT UNTIL RECENTLY I WAS NO WHERE NEAR MENOPAUSE AND SINCE I REMOVED ALL ALLERGY SOURCE FROM MY HOME AND MY LIFE. I WOULD LIKE TO BE ABLE TO HAVE THIS DEVICE MOVED. I WAS NEVER TOLD ANY OF THE INFORMATION ABOUT A NICKEL ALLERGY POSSIBILITY, EVEN AT THIS LAST VISIT. THEY NEW THAT I HAVE A LOT OF ALLERGIES AND THEY AFFECT ME TERRIBLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056801	BAYER	9/29/2015	10/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) OF 2012, I HAD THE ESSURE BIRTH CONTROL DEVICE IMPLANTED. SINCE THEN I HAVE HAD INCREASED PELVIC PAIN, BLEEDING AND CLOTTING DURING PERIODS, WEIGHT GAIN, LETHARGY, FLU LIKE SYMPTOMS, HEADACHES THAT LAST FOR DAYS AND WORSEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056803	BAYER	9/29/2015	10/5/2015

Event Information:

Event Date (B3): 9/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/17/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING ESSURE PLACED FOR PERMANENT STERILIZATION, I HAVE HAD MULTIPLE HEALTH PROBLEMS INCLUDING MIGRAINES, JOINT PAIN, HEAVY MENSTRUAL BLEEDING (CLOTS) AND CHRONIC VAGINITIS. NONE OF WHICH, I HAD PRIOR TO HAVING ESSURE PLACED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056804		9/29/2015	10/5/2015

Event Information:

Event Date (B3): 8/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7): 8/14/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTS PLACED AFTER THE BIRTH OF MY DAUGHTER IN 2008. SUBSEQUENT TO THE IMPLANTS BEING PLACED, I EXPERIENCED NEW, INEXPLICABLE SKIN ALLERGIES (I AM NOT ALLERGIC TO NICKEL), UNEXPLAINED FATIGUE, INCREASED MIGRAINES, MORE PAINFUL/HEAVIER PERIODS AND DEBILITATING PELVIC PAIN. AFTER MANY ROUNDS OF TESTING THROUGHOUT THE 7 YEARS I'VE HAD THE IMPLANTS, MY OB/GYN AND I DECIDED TO REMOVE THE ESSURE IMPLANTS. HE REMOVED THE IMPLANTS, ALONG WITH MY FALLOPIAN TUBES IN (B)(6) OF 2015, AND ALL OF THE NEGATIVE SIDE EFFECTS I EXPERIENCED WHILE I HAD THE IMPLANTS HAVE ABATED. I FIRMLY BELIEVE THAT THE ESSURE IMPLANTS WERE THE CAUSE OF MY PAIN AND "UNEXPLAINED" MEDICAL ISSUES. I AM THANKFUL THAT THEY ARE NO LONGER IN MY BODY AND I STRONGLY BELIEVE THEY SHOULD BE TAKEN OFF OF THE MARKET AS A SAFER STERILIZATION OPTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056805		9/29/2015	10/5/2015

Event Information:

Event Date (B3): 9/29/2015 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT 6 YEARS AGO. THE PAST COUPLE OF YEARS I'VE HAD BAD CRAMPING. OVER THE PAST SEVERAL MONTHS IT IS GETTING WORSE. I STARTED SPOTTING TWO MONTHS AGO. I GET SEVERE HEADACHES, SWEATS, AND MOOD SWINGS. I'M 35 AND SHOULD NOT FEEL LIKE THIS. SEX IS EVEN PAINFUL. I'M NOT SURE WHAT TO DO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01164	BAYER HEALTHCARE LLC	9/30/2015	9/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-1056, AWARENESS DATE: 02-SEP-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED. SHE STATED THAT THE PAIN OF PLACEMENT, EVEN WITH THE ASSISTANCE OF ANESTHETIC AND VALIUM, IT WAS NOTHING LESS THAN EXCRUCIATING. AFTER A SOLID 30 MINUTES OF THE DOCTOR ATTEMPTING TO REMOVE A COIL THAT HAD BEEN RELEASED TO EARLY AND WAS STUCK HALF-WAY IN. SHE HAD SCREAMED IN AGONY SO LOUDLY, THAT SHE DECIDED SURGERY WAS NECESSARY. SHE WAS BROUGHT ACROSS THE STREET FROM THE CLINIC TO THE HOSPITAL, WHERE SHE WAS ASKED TO SIGN A DOCUMENT BEFORE GOING UNDER SEDATION, GIVING PERMISSION PRETTY MUCH TO WHATEVER WAS NECESSARY. MAYBE POSSIBLY EVEN WAKING UP WITH A HYSTERECTOMY. EVERY DAY SINCE THAT DAY, SHE IS DISAPPOINTED THAT SHE WOKE UP FROM THAT PROCEDURE WITH THE ESSURE COILS IN PLACE. FROM DAILY BACK, LEG AND ABDOMINAL PAINS, TO HEAVY CRAMPING AND BLEEDING DURING HER NO LONGER PREDICTABLE PERIODS. SHE IS SUFFERING AND STRUGGLING ON A DAILY BASIS JUST TO FUNCTION PROPERTY. ESSURE HAS TAKEN HER HEALTH. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD TO UNDERGO A SURGERY TO REMOVE A COIL THAT HAD BEEN RELEASED TOO EARLY AND WAS STUCK HALF-IN (INTERPRETED AS DEVICE DEPLOYMENT ISSUE). SHE STILL HAD THE ESSURE COILS IN PLACE. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS

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EVENT AND ITS SUGGESTIVE TEMPORAL RELATIONSHIP (DURING PLACEMENT), THE DEPLOYMENT ISSUE IS ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS REQUIRED TO TREAT AN ESSURE-RELATED EVENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01165	BAYER HEALTHCARE LLC	9/30/2015	9/30/2015

Event Information:

Event Date (B3): 8/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/11/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1046, AWARENESS DATE 02-SEP-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. SHE MADE THE DECISION TO GET ESSURE AFTER HER 3RD CHILD (3 YEARS AGO). SHE WENT BACK 3 MONTHS AFTER IT WAS IMPLANTED AND FOUND THAT TUBES WERE COMPLETELY BLOCKED. ALMOST EXACTLY A YEAR AFTER IMPLANTING SHE STARTED HAVING ISSUES; SHE DEVELOPED A 12CM CYST ON HER RIGHT OVARY (NEVER HAD BEFORE) WHICH CAUSED HER SO MUCH PAIN (THE CYST WAS SO HEAVY THAT IT TWISTED HER TUBE) THAT SHE SPENT THE DAY IN THE ER ON PAIN MEDS. SHE FOLLOWED UP WITH HER DOCTOR AND SET A SURGERY TO REMOVE THE CYST THAT WAS CAUSING PAIN. THE SURGERY CAME AND WHEN IT WAS ALL SAID AND DONE SHE ENDED UP LOSING HER RIGHT OVARY WITH THE CYST; SHE ALSO ENDED UP LOSING A LOT OF BLOOD AND SPEND SOME TIME IN THE HOSPITAL. WHEN SHE GOT HOME SHE STILL DID NOT FEEL RIGHT AND WENT BACK TO FIND OUT THAT SHE HAD INTERNAL BLEEDING FROM THE SURGERY AS WELL. SHE STATED THAT THE PERMANENT BIRTH CONTROL HAD TAKEN WEEKS AWAY FROM HER LIFE; SHE WAS UNABLE TO PICK UP HER 16 MONTH OLD SON AND WAS UNABLE TO PLAY WITH HER CHILDREN. IT WAS A HARD RECOVERY. IN THE 2 YEARS SINCE HER CYST AND OVARY REMOVAL, SHE HAS BEEN DEALING WITH ALMOST DAILY PELVIC PAIN, WITH DAILY HEADACHES, LEG PAIN, CONSTIPATION, SEVERE BLOATING, INCREASED ANXIETY, VERY HEAVY PERIODS (SOAKING THROUGH A TAMPON IN 15 MINS) AND MUCH MORE. THE WORSE SHE FELT PHYSICALLY, THE WORSE SHE FELT EMOTIONALLY. HER MARRIAGE STARTED TO SUFFER AND IN JULY OF THIS YEAR HER HUSBAND AND SHE THOUGHT ABOUT GETTING A DIVORCE. SHE TRULY BELIEVED THAT ESSURE WAS THE

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REASON FOR HER MARITAL ISSUES. AFTER SUFFERING WITH THESE ISSUES FOR 2 YEARS, HER DOCTOR SUGGESTED GETTING A HYSTERECTOMY. SHE HAD A FULL HYSTERECTOMY LEAVING HER LEFT OVARY ON (B)(6) 2015 (AT (B)(6)). IN SURGERY, SHE ALSO LOST A LOT OF BLOOD AND SPENT TIME IN THE HOSPITAL. THE RECOVERY HAS BEEN INCREDIBLE HARD. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD A 12CM CYST ON HER RIGHT OVARY WHICH CAUSED PAIN (THE CYST WAS SO HEAVY THAT IT TWISTED HER TUBE) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A OOPHORECTOMY AND ENDED UP LOSING A LOT OF BLOOD (INTERNAL BLEEDING). AFTER THIS SURGERY, SHE HAD ALMOST DAILY PELVIC PAIN AND UNDERWENT A HYSTERECTOMY. DURING WHICH, SHE ALSO LOST A LOT OF BLOOD AND SPENT TIME IN HOSPITAL. ONLY BLEEDING AND PELVIC PAIN ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. OVARIAN CYSTS CAN DEVELOP IN FEMALES AT ANY STAGE OF LIFE. MOST OVARIAN CYSTS, HOWEVER, OCCUR IN THE HORMONALLY ACTIVE PERIODS OF DEVELOPMENT. IN ADULTS, AN OVARIAN PHYSIOLOGIC CYST (FUNCTIONAL CYST, CORPUS LUTEUM) OR A NEOPLASM IS THE MOST LIKELY FACTOR TO PREDISPOSE TO OVARIAN TORSION. ESSURE HAS MECHANICAL, LOCAL ACTION IN FALLOPIAN TUBES; NO HORMONES ARE RELEASED FROM THE INSERT. CONSIDERING THIS INFORMATION AND GIVEN OVARIAN CYSTS PATHOPHYSIOLOGY; CAUSALITY BETWEEN THE REPORTED OVARIAN CYST/TORSION AND THE SUSPECT INSERT IS CONSIDERED VERY UNLIKELY. REGARDING PELVIC PAIN, AS IT CAN OCCUR DURING ESSURE THERAPY AND SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR THIS EVENT; CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 02-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01166	BAYER HEALTHCARE LLC	9/30/2015	9/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1049, AWARENESS DATE 02-SEP-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE, FOR STERILIZATION. CONSUMER WAS A MOTHER OF THREE CHILDREN. APART FROM BEING DIAGNOSED WITH HYPOTHYROIDISM WITH HER THIRD PREGNANCY, SHE HAS ALWAYS BEEN FIT AND HEALTHY. WHEN HER 3RD CHILD WAS JUST OVER 12 MONTHS OLD SHE DECIDED FOR STERILIZATION. SHE HAD ESSURE INSERTED. THE PHYSICIAN ALSO INSERTED AN IUD COIL WHICH SHE WAS MEANT TO KEEP FOR 3 MONTHS. SHE HAD THE IUD REMOVED AFTER 6 WEEKS. WITHIN A FEW WEEKS SHE STARTED TO GET SYMPTOMS. BLOATING, JOINT PAIN, AND CHRONIC INSOMNIA THAT LASTED FOR MONTHS. SHE HAS NEVER HAD ANY TROUBLE SLEEPING. WITHIN A FEW MONTHS SHE ALSO DEVELOPED FOOD ALLERGIES, HAIR LOSS, TERRIBLE FATIGUE, BRAIN FOG, PELVIC PAINS, IRREGULAR AND VERY HEAVY, LONGER PERIODS, FIBROIDS, DIARRHOEA, AND WORSENING THYROID AND ADRENAL ISSUES. THE PHYSICIAN GAVE HER ANTI DEPRESSANTS AND TOLD HER THAT ANXIETY WAS CAUSING THE INSOMNIA. FOR MONTHS SHE COULDN'T WORK AND SHE WAS BARELY ABLE TO LOOK AFTER HER KIDS AS SHE FELT SO EXHAUSTED ALL THE TIME. IRON LEVELS WERE VERY LOW AND ALSO BLOOD PLATELETS SHOWED UP LOW ON TESTS. SHE FINALLY FOUND A GENERAL PRACTITIONER WHO GOT A REFERRAL TO A GYNECOLOGIST IN (B)(6) 2015. SHE HAS JUST HAD A HYSTERECTOMY REMOVING THE TUBES, COILS, CERVIX AND SHE IS IN RECOVERY NOW. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WITHIN A FEW MONTHS DEVELOPED PELVIC

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PAINS. SHE UNDERWENT A HYSTERECTOMY WITH ESSURE REMOVAL. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY, ESSURE REMOVAL). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 02-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01167	BAYER HEALTHCARE LLC	9/30/2015	9/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-1064) IN UNITED STATES ON 02-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN 2011. CONSUMER STATED THAT ALMOST IMMEDIATELY AFTER ESSURE PLACEMENT, SHE STARTED TO HAVE SHARP PAINS IN HER PELVIC REGION. SHE WENT TO HER DOCTOR SEVERAL TIMES ABOUT IT. SHE WAS A COMPLETELY HEALTHY WOMAN AND THE PAINS DID NOT START UNTIL AFTER SHE HAD ESSURE PLACED. SHE WAS IN PAIN EVERY DAY THAT GOT SO BAD SHE WOULD LAY IN A FETAL POSITION AND CRY. EVERY MEDICINE SHE TOOK TO TRY TO TAKE THE PAIN AWAY DID NOT HELP AT ALL HER. AFTER ALMOST TWO YEARS OF SUFFERING SHE FOUND A DOCTOR THAT WAS WILLING TO REMOVE THE COILS AND HER FALLOPIAN TUBES. SHE WAS MUCH BETTER FOR A FEW MONTHS AND THEN THE PAINS STARTED TO COME BACK RESULTING IN A TOTAL HYSTERECTOMY, AT THE AGE OF (B)(6). IN 2014, DUE TO SCAR TISSUE THAT HAD FORMED, SHE FEELS AMAZING NOW AND BACK TO FEELING LIKE HER AGAIN. ESSURE HAS AFFECTED HER FAMILY FOR TWO YEARS. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ALMOST IMMEDIATELY AFTER ESSURE PLACEMENT, STARTED TO HAVE SHARP PAINS IN HER PELVIC REGION. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SOON AFTER PLACEMENT, SHE HAD THIS PELVIC PAIN. SHE WAS IN PAIN EVERY DAY AND SOMETIMES THE PAIN WAS SO BAD THAT SHE WOULD

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LAY IN A FETAL POSITION AND CRY. SHE WAS MUCH BETTER FOR A FEW MONTHS AND THEN THE PAINS STARTED TO COME BACK RESULTING IN A TOTAL HYSTERECTOMY, AT THE AGE OF (B)(6). GIVEN EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 02-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01168	BAYER HEALTHCARE LLC	9/30/2015	9/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1069, AWARENESS DATE 02-SEP-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. REPORTER WAS SUBMITTING HER COMMENT IN BEHALF OF HER BEST FRIEND. AFTER HAVING ESSURE PLACED HER BEST FRIEND SUFFERED TREMENDOUSLY FOR 7 YEARS. SHE ENDED UP BEING ALLERGIC TO THE NICKEL AND DEVELOPED LUPUS FROM ESSURE. SHE STATED THAT IT IS A DISGUSTING DEVICE THAT DID NOT EVEN WORK 90 PERCENT OF THE TIME. DOCTORS WERE NOT EDUCATED ENOUGH ABOUT THE DEVICE AND ARE TELLING WOMEN IT IS REVERSIBLE. HER BEST FRIEND HAD TO HAVE HER FALLOPIAN TUBES REMOVED AT THE AGE OF (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO EXPERIENCED ALLERGY TO THE NICKEL AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE HAD HER FALLOPIAN TUBES REMOVED AT AGE OF (B)(6). ADDITIONALLY, SHE WAS DIAGNOSED WITH LUPUS. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY LUPUS IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING ALLERGY TO NICKEL NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING LUPUS, IT IS A CHRONIC INFLAMMATORY DISEASE THAT HAS PROTEAN MANIFESTATIONS AND FOLLOWS A RELAPSING

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AND REMITTING COURSE. ALTHOUGH THE SPECIFIC CAUSE OF LUPUS IS UNKNOWN, MULTIPLE GENETIC PREDISPOSITIONS AND ENVIRONMENT INTERACTIONS (ULTRAVIOLET EXPOSURE, MICROBIAL EXPOSURE AND DRUGS) HAVE BEEN IDENTIFIED. IN THIS CASE, ALTHOUGH REPORTER CONSIDERED LUPUS WAS RELATED TO ESSURE; GIVEN EVENT'S PATHOPHYSIOLOGY AND CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES, COMPANY REGARDS CAUSALITY AS VERY UNLIKELY. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED (FALLOPIAN TUBES REMOVED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01169	BAYER HEALTHCARE LLC	9/30/2015	9/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1093, AWARENESS DATE 02-SEP-2015). CASE WAS RECEIVED IN UNITED STATES AND REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. CONSUMER REPORTED THAT AFTER THE BIRTH OF HER 5TH SON, HER HUSBAND AND SHE MADE THE MUTUAL DECISION THAT IT WAS OFFICIALLY TIME TO CLOSE THE DOORS TO THE BABY FACTORY FOR GOOD. WHEN THE DOCTOR MENTIONED ESSURE IT SEEMED LIKE A NO BRAINER, NO SURGERY OR DOWN TIME, NO INTERRUPTING HER DAILY WORKOUTS OR HEAVILY DEMANDING DAILY ROUTINE OF HER BOYS AND NO HORMONES THAT COULD POTENTIALLY THROW OFF HER BALANCE. SO, IN (B)(6) 2013, FEELING FIT, ENERGIZED, AND SUPER PROUD THAT SHE HAD ALREADY SHED BABY WEIGHT AND WAS COMFORTABLY BACK IN HER SIZE JEANS IN JUST 6 SHORT WEEKS AFTER HAVING HER SON, SHE EMBARKED ON HER ESSURE JOURNEY. SHE AWOKE FROM HER PROCEDURE GROGGY BLEEDING AND IN EMENSE PAIN (AS REPORTED, UNDERSTOOD AS IMMENSE PAIN). THERE WAS A HORRIBLE BURNING SENSATION ON BOTH SIDES OF HER BACK. SHE WAS GIVEN SOME PAIN PILLS AND TOLD TO RETURN IN 2 WEEKS FOR A CHECKUP. NONE OF HER PAIN OR BLEEDING IMPROVED DURING THIS TIME, ACTUALLY THINGS JUST GOT FAR WORSE. SHE STARTED EXPERIENCING HORRIBLE NIGHT SWEATS (TO THE POINT OF WAKING HER HUSBAND FROM SLEEP). WHICH LEAD TO ONE OF THE MOST EMBARRASSING MOMENTS OF HER ENTIRE LIFE, HE HONESTLY QUESTIONED IF SHE HAD BEEN PEEING THE BED. THIS BEGAN THE SLEEPLESS NIGHTS, THE CHRONIC FATIGUE, THE MOOD SWINGS, THE DEPRESSION AND THE BRAIN FOG (ALMOST LIKE A STATE OF CONSTANT CONFUSION). TO THE POINT SHE WOULD DRIVE THREW A TRAFFIC LIGHT WITH HER 5 BOYS IN TOE ONLY TO QUESTION WHAT COLOR

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THE LIGHT WAS WHEN SHE REACHED THE OTHER SIDE. ON HER 2 WEEKS CHECKUP, SHE WAS TOLD THAT ALL HER SYMPTOMS WERE EXPLAINED BY AN INFECTION AND WAS GIVEN ANTIBIOTICS. HOWEVER, AFTER TAKING RELIGIOUSLY THE PILLS, SHE DID NOT IMPROVE. SO A RETURN VISIT TO THE DOCTOR WAS IN ORDER. HER NORMAL OBSTETRICIAN WAS NOT IN SO SHE SAW HIS COLLEAGUE WHO TREATED HER LIKE A LUNATIC AND SAID HER SYMPTOMS WERE JUST COINCIDENTALLY NOW HER PERIOD AND SHE NEEDED TO GIVE HER BODY TIME TO ADJUST. SO SHE FIGURED SHE WOULD GIVE HER BODY THOSE 3 MONTHS UNTIL HER HYSTEROSALPINGOGRAM (HSG) TO ADJUST. THE 3 MONTHS WERE TORTURE NOT ONLY FOR HER BUT ALSO FOR HER FAMILY. SHE WAS USELESS AS A MOTHER AND WIFE, HAVING TO SPEND THE MAJORITY OF HER TIME IN BED. SHE WAS GAINING WEIGHT, COULD NOT WORK OUT AND WAS BLOATED TO THE POINT SHE LOOKED AND FELT 6 MONTHS PREGNANT. BETWEEN HER BODY IMAGE, PAIN, BLEEDING AND MOOD SWINGS HER MARRIAGE WAS AFFECTED TO THE POINT HER HUSBAND REQUESTED SHE GOES TO HER DOCTOR BECAUSE HE FELT THE HORMONES IN HER NEW BIRTH CONTROL WERE REALLY AFFECTING HER. LITTLE DID HE KNOW IT CONTAINED NO HORMONES AND THEY WERE SUPPOSED TO BE USING CONDOMS AS BACK UP BIRTH CONTROL UNTIL CONFIRMED BLOCKED BECAUSE SHE WANTED TO AVOID THE POSSIBILITY OF SIDE EFFECTS FROM HORMONAL BIRTH CONTROLS. SHE STATES THAT SHE SAYS SUPPOSED BECAUSE THEIR SEX LIFE HAD BECOME NONEXISTENT. CONSUMER ALSO REPORTED THAT WET AND WILD IS ONE THING, BUT NOT WHEN YOU UNSURE WHAT BODILY FLUIDS YOUR WIFE WILL BE LAYING IN A PUDDLE OF ON THAT PARTICULAR EVENING, OR HAVING TO FEAR CAUSING MORE PAIN THEN SHE IS ALREADY IN. BY THE TIME SHE ARRIVED AT HER HSG, SHE COULD BARELY CONTAIN HER BREAK DOWN AND COMPLETELY CRUMBLED WHEN THE DOCTOR CAME INTO THE ROOM. CONSUMER TOLD HIM THE ONLY LOGICAL EXPLANATION FOR ALL THESE SYMPTOMS WAS ESSURE. SHE WENT TO SLEEP A HEALTHY ACTIVE (B)(6) MOM AND WOKE UP FEELING LIKE HER BODY WAS WASTING AWAY TO THAT OF ONE HER DEATH BED. ACCORDING TO HER, SHE WAS BASICALLY TOLD SHE WAS CRAZY AND EVERYTHING LOOKED GREAT, THAT SHE WAS HUNDRED PERCENT BLOCKED AND TO CONSULT HER IMPLANTING DOCTOR WITH CONCERNS. WHICH SHE DID, ALTHOUGH HE WAS SURE ESSURE WAS NOT TO BLAME, HE SAW THE DETERIORATION IN HER PHYSICAL, MENTAL AND EMOTIONAL WELLBEING AND OFFERED TO START TESTING AND TREATING WHATEVER IT MAY BE. AFTER ALMOST A YEAR OF TESTS, PILLS, CREAMS AND APPOINTMENTS; NOTHING IMPROVED HER SYMPTOMS. SHE HAD BEEN SUFFERING AND BLEEDING FROM (B)(6) 2013 UNTIL (B)(6) OF 2014 WHEN, SHE GOT THE CALL WITH A HYSTERECTOMY DATE. IN (B)(6) OF 2014, SHE HAD HYSTERECTOMY PERFORMED AND STATES THAT, WHEN SHE AWOKE, THE FOG HAD LIFTED, SHE WAS IN FAR LESS PAIN WAKING UP FROM MAJOR SURGERY, MOST OF HER SYMPTOMS SUBSIDED IMMEDIATELY AND SHE GOT HER LIFE BACK. ALL OF HER SYMPTOMS, OTHER THAN SOME PAIN IN HER RIGHT SIDE, DISAPPEARED AFTER HER HYSTERECTOMY. HEALTH CARE PROFESSIONAL SAID THE ADENOMYOSIS THEY FOUND EXPLAINED THE PAIN AND BLEEDING BUT IS NOT COMMON SO YOUNG AND CANNOT EXPLAIN ALL HER SYMPTOMS. THE REMAINING PAIN BY HER SIDE ENDED UP BEING ADHESIONS FROM ESSURE, WHICH REQUIRED REMOVAL OF OVARY IN (B)(6). IN ADDITION, CONSUMER REPORTED THAT ESSURE HAS CAUSED HER LIFE LASTING EMOTIONAL DISTRESS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD PAIN AND BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY WHICH REVEALED ADENOMYOSIS AND ADHESIONS (WHICH SHE RELATED TO ESSURE). ONLY PAIN AND BLEEDING, REGARDED AS PELVIC PAIN AND GENITAL BLEEDING, ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER STATED HER SYMPTOMS STARTED SOON AFTER ESSURE INSERTION AND IMPROVED WITH DEVICES REMOVAL. SHE WAS DIAGNOSED WITH ADENOMYOSIS AND ALSO HAD PELVIC ADHESIONS; THESE CONDITIONS COULD BE ALTERNATIVE EXPLANATIONS FOR HER SYMPTOMS. HOWEVER, CONSIDERING THE CLOSE ASSOCIATION BETWEEN HER PAIN/ BLEEDING AND ESSURE PROCEDURE A CONTRIBUTORY ROLE OF THE SUSPECT INSERT IN THE

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EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 02-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01170	BAYER HEALTHCARE LLC	9/30/2015	9/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/20/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1072, AWARENESS DATE 02-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2005. CONSUMER STATED THAT ON (B)(6) 2005 SHE MADE THE HARDEST DECISION OF HER LIFE, SHE CHOSE PERMANENT STERILIZATION. AFTER BEING DIAGNOSED WITH A MENTAL ILLNESS, SHE MADE THE DIFFICULT DECISION NOT TO HAVE CHILDREN. THE REASON SHE CHOSE ESSURE WAS BECAUSE IT WAS PRESENTED TO HER AS A NON SURGICAL PROCEDURE. SHE PREVIOUSLY HAD GASTRIC BYPASS AND TUMMY TUCK AND DIDN'T WANT TO ENDURE THE CUT OPEN AGAIN. SHE KNEW SOMETHING WAS WRONG FROM THE BEGINNING. THE PAIN BEGAN IMMEDIATELY AND HAS NEVER SUBSIDED. SHE TOOK A WEEK OFF FROM WORK INITIALLY AND TRIED TO RESUME NORMAL. WHEN SHE WENT FOR THE 3 MONTH HSG FOLLOW UP SHE WAS TOLD THAT THE ESSURE WAS IN PERFECT PLACEMENT AND TUBES WERE 100 PERCENT BLOCKED. IN (B)(6) SHE STARTED TO GAIN WEIGHT. SHE HAD GASTRIC BYPASS IN 1998 AND HAD BEEN ABLE TO MAINTAIN HER WEIGHT LOSS WITHOUT ANY PROBLEMS. IN (B)(6) 2006 SHE GOT HER FIRST PERIOD SINCE THE ESSURE PROCEDURE. IT LASTED 21 DAYS AND THE CRAMPING WAS CRIPPLING. THE AMOUNT OF BLOOD AND THE SIZE OF THE BLOOD CLOTS WERE UNBELIEVABLE. CONSUMER'S HAIR WAS FALLING OUT AT AN ALARMING RATE, SHE WAS BRUISING FROM THE SPOUSE SIMPLY HOLDING HER HAND, SHE HAD CONSTANT DISCHARGE AND YEAST INFECTIONS, PERIODS WERE GETTING WORSE AND WORSE. SHE BEGAN MISSING MORE AND MORE TIME FROM WORK DUE TO THE CONSTANT EXHAUSTION AND THE UNCONTROLLABLE AMOUNT OF BLEEDING. THE PAIN ASSOCIATED WITH PERIODS WAS NOW DEBILITATING. SEX STARTED TO BE PAINFUL. THE ENTRANCE TO

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HER VAGINA ITCHES AND BURNS. SHE HAS CONSTANT ABDOMINAL SPASMS AND TWITCHING. SHE BEGAN TO EXPERIENCE ALL OVER BODY ACHES AND PAINS. HER HANDS, LEGS AND FEET WOULD TINGLE AND BECOME. SHE SOUGHT OUT HER DOCTOR. AT SOME POINT SHE STARTED BREAKING OUT WITH UNEXPLAINED HIVES. EVERYTIME SHE GET HER PERIOD MYSTERIOUS BOILS APPEAR IN VAGINAL REGION. SHE HAS A CONSTANT FEELING THAT BUGS ARE CRAWLING ALL OVER HER BODY. HER DENTAL HEALTH HAS SUFFERED AND SHE HAS HAD 4 ROOT CANALS AND CROWNS AND HAD HAD 5 TEETH PULLED SINCE ESSURE HAS BEEN PLACED. SHE WAS (B)(6) AT THIS TIME. SHE WAS THEN SUBSEQUENTLY SEEN BY A RHEUMATOLOGIST THAT DIAGNOSED FIBROMYALGIA AND RAYAUNDS SYNDROME. HER PHYSICAL HEALTH AND MENTAL HEALTH DETERIORATED TO THE POINT THAT MEDICATIONS BEGAN NOT WORKING. IN 2013 AGAIN SHE COMPLAINED ABOUT THE BLEEDING AND PAIN AND HER NEW GYNECOLOGIST SUGGESTED NOVA SURE. UNFORTUNATELY THIS PROCEDURE WAS UNSUCCESSFUL. AGAIN SHE WAS LEFT WITH PERIODS THAT SEEMED TO BE WORSE THAN PRIOR TO THE FAILED NOVA SURE. IN 2015 SHE AGAIN COMPLAINED ABOUT THE BLEEDING AND PAIN. THE FINAL CHOICE WAS A HYSTERECTOMY. THE SURGERY IS SCHEDULED FOR (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN (INTERPRETED AS PELVIC PAIN), AND UNCONTROLLABLE AMOUNT OF BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A NOVASURE PROCEDURE EIGHT YEARS AFTER ESSURE INSERTION AND IS SCHEDULED TO HAVE A HYSTERECTOMY. CONSUMER ALSO REPORTED THAT BOILS APPEAR IN VAGINAL REGION AND WAS DIAGNOSED WITH RAYNAUDS SYNDROME. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. EVENTS PELVIC PAIN AND GENITAL BLEEDING ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENTS ARE UNLISTED. AFTER ESSURE INSERTION PELVIC PAIN, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENTS PELVIC PAIN AND GENITAL BLEEDING, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING EVENTS BOILS APPEAR IN VAGINAL REGION AND RAYNAUDS SYNDROME, CONSIDERING THE PATHOPHYSIOLOGY OF THESE EVENTS AND ESSURE LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (NOVASURE ENDOMETRIAL ABLATION) AND SINCE ANOTHER INTERVENTION WILL BE REQUIRED (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01171	BAYER HEALTHCARE LLC	9/30/2015	9/30/2015

Event Information:

Event Date (B3): 3/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 3/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1121, AWARENESS DATE 02-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. CONSUMER HAD A HYSTERECTOMY ON (B)(6) 2015 LEAVING ONLY OVARIES. BUT, BEFORE THAT SHE WAS SICK ALL THE TIME AND COULD BARELY TAKE CARE OF HER THREE CHILDREN. SINCE HER HYSTERECTOMY SHE NOW HAS ENERGY AND SHE IS NO LONGER SICK ALL THE TIME. FOLLOW-UP INFORMATION RECEIVED ON 24-SEP-2015 FROM CONSUMER: THE CONSUMER STATED THAT ESSURE CAUSED INFLAMMATION. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD AN HYSTERECTOMY PERFORMED. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (HYSTERECTOMY) MAY BE REQUIRED. IN THIS CASE, VERY LIMITED INFORMATION WAS PROVIDED. IT WAS REPORTED THAT SHE HAD A HYSTERECTOMY AND AFTER THAT SHE WAS NO LONGER SICK ANYMORE. ALTHOUGH THE INDICATION OF PROCEDURE HAS NOT BEEN INFORMED, GIVEN EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 02-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056739	CONCEPTUS	9/30/2015	10/1/2015

Event Information:

Event Date (B3): 7/6/2011 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INTRAUTERINE DEVICE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 7/6/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT WAS IMPLANTED WITH DEVICE ON (B)(6) 2011. FROM THAT SAME DAY, SHE STARTED EXPERIENCING BACK PAIN, ABDOMINAL PAIN, DYSPAREUNIA AND SEVERE BLEEDING. HER DOCTOR SAID IT WAS HORMONE IMBALANCE AND PLACED HER ON A PILL. RECENTLY SHE WENT TO ANOTHER DOCTOR WHO DID AN ULTRASOUND AND DISCOVERED THAT THE COIL ON HER RIGHT TUBE HAD BEEN WRONGLY IMPLANTED. IT WAS CONCLUDED THAT THE BLEEDING HAD BEEN DUE TO THE MALPOSITIONED DEVICE. YESTERDAY, (B)(6) 2015) SHE WAS AGAIN AT THE EMERGENCY ROOM FOR THE ABDOMINAL AND BACK PAIN. SHE'S NOW WAITING ON HER DOCTOR TO DECIDE ON WHAT TO DO. SHE WAS ALSO ADVISED TO HENCEFORTH BE USING CONTRACEPTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056827	BAYER	9/30/2015	10/6/2015

Event Information:

Event Date (B3): 9/11/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): BAYER ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): C55832

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE KEPT BENDING WHILE TRYING TO PASS THROUGH TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056842		9/30/2015	10/6/2015

Event Information:

Event Date (B3): 3/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4): 755525

Single Use: *
Implant Date (E6): 3/28/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAD THE ESSURE PROCEDURE DONE (B)(6) 2011, I'VE HAD SEVERE BACK, ABDOMINAL AND PELVIC PAIN AS WELL AS PAIN FROM THE PELVIC AREA DOWN TO MY KNEE ON MY LEFT SIDE, SEVERE HEADACHES, FATIGUE, METAL TASTE, SEVERE MOOD CHANGES, PAIN DURING INTERCOURSE, SEVERE FLU LIKE SYMPTOMS DURING MENSTRUAL PERIOD, LONG AND HEAVY MENSTRUAL PERIODS. ALL THESE SYMPTOMS HAVE BEEN GETTING WORSE INSTEAD OF IMPROVING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056845	BAYER	9/30/2015	10/6/2015

Event Information:

Event Date (B3): 7/13/2007 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IN 2007 AND I THOUGHT IT WAS PERMANENT AND I DISCOVERED 3 YEARS LATER I WAS PREGNANT AGAIN AND WHEN I WENT BACK TO THE DOCTOR THEY TOLD ME ONLY ONE OF MY TUBES WAS CLOSED THAT'S HOW I GOT PREGNANT. AND THEN A YEAR OR SO AFTER I WAS PREGNANT AGAIN. SO I HAVE HAD TWO LOVELY YOUNG MEN ALTHOUGH IT WAS SUPPOSED TO BE PERMANENT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01173	BAYER HEALTHCARE LLC	10/1/2015	10/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91766

Single Use: Y
Implant Date (E6): 12/17/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 14-MAY-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C91766, IMPLANTED ON (B)(6) 2014. IT WAS REPORTED THAT WHEN ESSURE WAS RELEASED FROM INSERTER ON FINAL WHEELBACK, COIL BECAME UNWOUND. THAT WAS DISCOVERED DURING THE HSG. NEW COIL WAS PLACED SUCCESSFULLY. THE PATIENT HAD NO INJURY. FOLLOW-UP RECEIVED ON 11-JUN-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C91766; PRODUCTION DATE: 04-AUG-2014; EXPIRATION DATE: 31-AUG-2017. DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: 1) ROLLBACK TO INITIAL HARD STOP. 2) DEPRESS BUTTON. 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO DEPLOYMENT DIFFICULTY. SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY

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WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT, THE OUTER CATHETER, THE INNER CATHETER, AND ALL PARTS WITHIN THE HANDLE ASSEMBLY. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT DURING THE PROCEDURE IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED PRODUCT ISSUE. HOWEVER, NO ADVERSE EVENTS WERE REPORTED AT THIS POINT IN TIME. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 09-JUN-2015 AND 10-JUN-2015 FROM CONSUMER: THE CONSUMER REPORTED THAT SHE HAD THE ESSURE PROCEDURE IN DECEMBER OF 2014 FOR CONTRACEPTION. AT THE FOLLOW UP CONFIRMATION TEST, SHE WAS INFORMED THAT SHE HAD A "FAULTY" COIL ON ONE SIDE, WHICH PREVENTED HER FALLOPIAN TUBE FROM OCCLUDING PROPERLY. THE PROCEDURE WAS REDONE ON THE AFFECTED SIDE IN (B)(6) OF 2015. THE CONSUMER REPORTED THAT SHE WAS STILL WAITING FOR THE PHYSICIAN TO VERIFY THE CONFIRMATION AFTER THE SECOND PROCEDURE. FOLLOW-UP INFORMATION WAS RECEIVED ON 08-SEP-2015 VIA ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE. PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. CONCOMITANT CONDITION INCLUDED OBESITY (BMI (B)(6)). MEDICAL HISTORY INCLUDED DILATATION AND CURETTAGE IN 2005, PCOS (INTERPRETED AS POLYCYSTIC OVARIAN SYNDROME) AND INFERTILITY. SHE WAS (B)(6) POST-PARTUM AT THE TIME OF ESSURE INSERTION. CERVICAL DILATATION, SOUNDING AND ANALGESIA (BIO SUP, OXYXODONE, XANAX) WERE APPLIED DURING INSERTION. THE ESSURE WAS EASILY IMPLANTED AND THE VISUALIZATION OF TUBAL OSTIUM WAS EASY. BOTH SIDES WERE VISUALIZED. FLUID LOSS WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. ON (B)(6) 2015 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED THE LEFT TUBE OCCLUDED, RIGHT TUBE OPEN AND PATENT. BIRTH CONTROL PILLS WERE USED AS BACK-UP CONTRACEPTION. IT WAS REPORTED THAT ESSURE WAS NOT PLACED CORRECTLY. THE DEFECTIVE COIL WAS REMOVED VIA HYSTEROSCOPY AND A NEW COIL WAS PLACED ON RIGHT TUBE ON (B)(6) 2015. NO HOSPITALIZATION WAS REQUIRED. THE REMOVAL WAS MEDICALLY NECESSARY. BILATERAL BLOCKED TUBES WAS THE OUTCOME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE WAS NOT PLACED CORRECTLY. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE DISLOCATION MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE RIGHT ESSURE DEVICE WAS NOT PLACED CORRECTLY. THE RIGHT TUBE WAS FOUND OPEN AND PATENT DURING CONFIRMATION TEST AND DUE TO THIS DISLOCATION THE DEVICE WAS REMOVED HYSTEROSCOPICALLY AND A NEW ONE WAS INSERTED ON THE RIGHT TUBE. THEN, PATIENT RECOVERED. ALTHOUGH THE EXACT DATE AND MECHANISM OF THIS EVENT HAVE NOT BEEN INFORMED, CONSIDERING ITS NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION (UPDATED TECHNICAL ASSESSMENT) IS EXPECTED.

Manufacturer Narrative (H10):

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29-DEC-2015: CASE CLOSED.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056867	BAYER	10/1/2015	10/7/2015

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE TUBAL
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD MANY HEALTH PROBLEMS SINCE GETTING THE ESSURE TUBAL IN 2012. I HAVE VERY LONG AND HEAVY MENSTRUAL CYCLES, BLOATING AND SWELLING, SHARP PAIN AND CRAMPY, FATIGUE AND MENTAL FOG. I HAVE CHRONIC HIVES NOW BECAUSE ITS BELIEVED I'M ALLERGIC TO IT. I RECENTLY GOT DIAGNOSED WITH CANCER IN MY UTERUS WHICH I BELIEVE IS MY IMMUNE SYSTEM BEING SO DOWN AND MY BODY IS GOING CRAZY INSIDE. EVERYTHING HAS PROGRESSED IN A VERY SHORT PERIOD OF TIME FOLLOWING MY ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056874	BAYER	10/1/2015	10/7/2015

Event Information:

Event Date (B3): 9/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/14/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

LET ME PREFACE THIS STORY BY SAYING THAT I AM, HANDS DOWN, THE HEALTHIEST PERSON I KNOW, ASK ANYONE AT MY GYM, MY JOB, OR ASK MY FRIENDS AND FAMILY. I EAT CLEAN, EXERCISE, INTENSELY, DAILY, SLEEP 8 HOURS A NIGHT, AND DON'T TAKE ANY MEDICATION. I'M NOW (B)(6). I HAD ESSURE IMPLANTED IN (B)(6) 2012. NEVER WANTED KIDS, DIDN'T WANT HORMONES RUNNING RAMPANT IN MY BODY, SO THIS SEEMED, AFTER MUCH RESEARCH, THE LEAST INVASIVE, SAFEST, EASIEST ALTERNATIVE TO HORMONES OR TUBAL LIGATION. YEAR 1, FELT LIKE I HAD BEEN HIT BY A BUS, DAILY. JOINT PAIN AND FLU-LIKE SYMPTOMS. I KEPT SAYING "MY BONES HURT" BECAUSE THAT WAS LITERALLY THE ONLY WAY I COULD DESCRIBE THE PAIN. I FELT LIKE I'D BEEN POISONED, LIKE THERE WAS A HEAVY METAL COURSING THROUGH MY VEINS. FATIGUE, LETHARGY, I COULD HARDLY DRAG MYSELF OUT OF BED. SPENT COUNTLESS DAYS AND NIGHTS SOBBING AND WONDERING WHAT WAS WRONG WITH ME. I FINALLY DECIDED I HAD EITHER FIBROMYALGIA OR POSSIBLY SOMETHING LIKE LEUKEMIA. I KNOW NOW THAT MY BODY WAS REACTING TO THE IMPLANTS, MOST LIKELY THE NICKEL AND THAT I WAS IN FACT FIGHTING MY BODY BEING POISONED FROM THE INSIDE. WELL, THAT EVENTUALLY ENDED. THEN, FOR THE LAST YEAR, I'VE HAD EXCRUCIATING PAIN IN MY SIDES/ABDOMEN. THOUGHT IT WAS KIDNEY STONES POSSIBLY. NOW, I DON'T HAVE INSURANCE, SO EVERYTHING IS OUT OF POCKET FOR ME. I'VE HAD LABOR PAIN TYPE MENSTRUAL CRAMPS. I DON'T EVER STOP BLEEDING. ALL MONTH, BLOOD. GUESS ESSURE DOES THE TRICK BECAUSE SEX HAS BECOME SO PAINFUL OVER THE LAST YEAR THAT I JUST CAN'T HANDLE IT ANYMORE. NOT TO MENTION, EACH TIME I HAVE SEX OR SQUAT HEAVY AT THE GYM, OR RUN SPRINTS (ANYTHING THAT INVOLVES THE WAIST/HIPS AREA), I BLEED AFTERWARD. I BLEED DURING SEX, AFTER SEX, AND FOR DAYS FOLLOWING SEX. MY VAGINAL DISCHARGE SMELLS DIFFERENT THAN IT HAS MY WHOLE LIFE, AND IT'S NOT A PLEASANT SMELL. I HAVE STABBING PAINS IN MY ABDOMEN, BOTH SIDES. I

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HAVE INTERMITTENT SEVERE GAS AND BLOATING OF THE ABDOMEN FROM Y RIB CAGE DOWN. THE CONSTANT PAIN IN MY SIDES AND BLEEDING AND NO SEX I DECIDED I'D JUST HAVE TO LIVE WITH. I WENT TO THE GYNO WHO INSERTED THE ESSURE AND SHE SAID ALL OF THE ABOVE ARE SYMPTOMS RELATED TO MY AGE, THAT IT'S "THAT TIME." WHEN I TOLD HERE I THOUGHT IT WAS THE ESSURE SHE SAID NO. SHE SAID THE ONLY WAY I COULD GET RID OF THE ESSURE WAS TO HAVE A FULL HYSTERECTOMY. [PROFANITY]. I WENT TO A SECOND GYNO THAT A FRIEND RECOMMENDED AND HE SAID THAT THE SYMPTOMS WERE DEFINITELY A RESULT OF THE ESSURE (HE ORDERED AN X-RAY THAT SHOWED THE IMPLANTS WERE EXACTLY IN THE CORRECT POSITION, SO WE KNOW IT'S NOT FROM BREAKING/MOVEMENT) AND THAT HE COULD REMOVE THEM LAPAROSCOPICALLY, BUT HE'D NEVER DONE THAT BEFORE. WHEN I COULDN'T GET A PRICE QUOTE, I DENIED THAT SURGERY. VERY SCARY. SO, I'VE BEEN DOING RESEARCH SINCE, ON DOCTORS WHO PERFORM ESSURE REMOVALS (ALL ARE AT IVF CLINICS). THREE DAYS AGO, I FINALLY BIT THE BULLET AND SCHEDULED BY ESSURE REMOVAL WITH (B)(6). I WILL BE PAYING (B)(6) OUT OF MY OWN POCKET FOR REMOVAL AND MISSING COUNTLESS DAYS OF WORK (FOR WHICH I DO NOT GET PAID). THAT 'S HOW DESPERATE I AM TO GET THESE EVIL THINGS OUT OF ME AND FEEL BACK TO NORMAL. OVER THE PAST THREE YEARS, I'VE SPENT OVER (B)(6) TRYING TO FIGURE OUT WHAT'S WRONG WITH ME AND TO GET THE ESSURE IMPLANTS REMOVED ALTHOUGH NOBODY CAN "PROVE" THAT THE ESSURE RESULTED IN MY SLEW OF SYMPTOMS, I KNOW INTUITIVELY THAT THERE WAS NO OTHER EXPLANATION. AFTER FINDING THIS SITE, AND READING THAT OTHER WOMEN HAD THE SAME HORRIBLE SYMPTOMS, I CAN CONFIRM THAT I'M NOT CRAZY AFTER ALL. IT'S NOT ALL IN MY HEAD, IT'S ALL IN MY FALLOPIAN TUBES. I AM COUNTING THE DAYS TIL THE SURGERY, ALTHOUGH I'M TERRIFIED OF THE GENERAL ANESTHESIA AND RECOVERY TIME BECAUSE I TAKE EXCELLENT CARE OF MYSELF AND NEVER THOUGHT I'D BE ENDURING THIS. I HOPE THIS HELPS ANOTHER WOMAN STRUGGLING OUT THERE UNDERSTAND THAT SHE IS NOT CRAZY, NOT ALONE, AND THAT WE JUST CAN'T TRUST THE COLLUSION OF GOVERNMENT AND BIG PHARMA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056875	BAYER	10/1/2015	10/7/2015

Event Information:

Event Date (B3): 1/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/31/2010
Explant Date (E7): 10/1/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

WELL IN 2010, I HAD THE MIRENA BIRTH CONTROL CONTRACEPTIVES TAKEN OUT AFTER HAVING IT FOR 4 YEARS, AND THE ESSURE IMPLANTED IN (B)(6) 2010. IN (B)(6) OF 2010, I STARTED HAVING BIG BRUISES ALL OVER MY BODY THAT WAS ITCHING AND BURNING. I'M HURTING SO BAD IT WAS UNEXPLAINED, I HAVE FATIGUE, TIREDNESS, WEAKNESS. WENT TO THE DOCTOR AND THEY COULD NOT TELL ME WHAT WAS WRONG. EMERGENCY ROOMS, URGENT CARES, REGULAR PRIMARY CARE DOCTOR, NOTHING! SO ABOUT A YEAR LATER I HAD ANOTHER OUTBREAK OF THE BIG BRUISES ALL OVER MY BODY AS IF SOMEONE WAS BEATING ME WHICH WAS NOT TRUE. WENT TO THE DOCTOR AGAIN, THEY COULDN'T FIND OUT WHAT WAS GOING ON. I WAS COMPLETELY HEALTHY UNTIL 2010. COUPLE OF YEARS WENT BY, FINALLY (B)(6) 2014, I WAS FINALLY DIAGNOSED WITH AUTO-IMMUNE DISEASE. OVER THE YEARS I HAVE BEEN LOSING HAIR, MY NAILS HAVE BEEN BRITTLE, BREAKING OFF, AND MY FINGERNAIL IS ALWAYS PURPLE. THIS DIDN'T START HAPPENING UNTIL AFTER I GOT THIS ESSURE. MY WHOLE LIFE HAS CHANGED SINCE 2010 WITH THIS ESSURE BEING IMPLANTED IN ME. I WENT TO THE DOCTOR OB/GYN RECENTLY AND THEY WOULD NOT REMOVE IT. I TOLD HIM THIS MAY BE CAUSING THE PROBLEMS THAT I'M HAVING, BUT THEY REFUSED TO DO SO. SOMETIMES IT CAUSES ME TEMPORARY DEFORMITIES OF MY JOINTS, ELBOWS, KNEES, ANKLES, HIPS, SHOULDERS, WHERE IT CAN LAST UP TO TWO TO THREE WEEKS, CAUSING ME TO HAVE TO MISS WORK. I HAVE APPLIED FOR DISABILITY. I'M ONLY (B)(6) AND I SHOULD NOT HAVE TO SUFFER BECAUSE OF THIS MEDICAL DEVICE. I HAVE CHILDREN I HAVE TO RAISE. I THINK ESSURE IS THE MAIN CAUSE OF THESE ISSUES I'M HAVING. I HAD NO ISSUES WITH MY BODY UNTIL 2010.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 8/31/2015 **Report Date (B4): 9/1/2015** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C59263

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

THE DOCTOR COULD NOT ADVANCE THE ESSURE DEVICE THROUGH THE ENDOSCOPIC CHANNEL. SEVERAL ATTEMPTS WHERE MADE TO ADVANCE THE DEVICE. A NEW ESSURE DEVICE WAS DELIVERED TO THE FIELD AND IMPLANTED WITHOUT DIFFICULTY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01174	BAYER HEALTHCARE LLC	10/2/2015	10/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C95074

Single Use: Y
Implant Date (E6): 9/3/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

OTHER REPORTABLE INCIDENT. MALFUNCTION (DEVICE BREAKAGE). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 08-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2015 WITH LOT NUMBER C95074. IT WAS REPORTED THAT ONE COIL SNAGGED ON SCOPE AND WAS REMOVED IN PIECES, OTHER COIL WAS BENT. BILATERAL PLACEMENT WAS NOT ACHIEVED. THE PATIENT HAD NO INJURY. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO UNDERWENT AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND DURING THE PROCEDURE ONE COIL SNAGGED ON SCOPE AND WAS REMOVED IN PIECES. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, DURING INSERTION ONE COIL SNAGGED ON SCOPE AND WAS REMOVED IN PIECES, OTHER COIL WAS BENT. BILATERAL PLACEMENT WAS NOT ACHIEVED. SINCE THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 01-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056742	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2015. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. FORTY LBS WEIGHT GAIN DESPITE NO CHANGE IN DIET OR ACTIVITY LEVEL; DEPRESSION; FATIGUE; PELVIC REGION PAIN; HAIR LOSS; HEAVY PAINFUL PERIODS; REOCCURRING YEAST INFECTIONS; NO SEX DRIVE; ACNE INCLUDING CYSTIC ACNE; FORGETFUL ALL THE TIME. THE DEVICE IS STILL INSIDE OF ME AS OF (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056743	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 9/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE RIGHT COIL MIGRATED TO AN UNKNOWN LOCATION CAUSING SEVERE PAIN. HAD A NEXT DAY EXPLORATORY LAPAROTOMY WHICH DID NOT FIND THE COIL. STILL HAVE ESSURE IN OTHER TUBE AND WILL LIKELY HAVE TO HAVE A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056744	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 1/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT IS VERY DIFFICULT TO PINPOINT EXACT DATES AND TIMES SYMPTOMS ACTUALLY OCCURRED AS MOST SYMPTOMS HAVE HAD QUITE A GRADUAL ONSET. MOST CONCERNING SYMPTOMS ARE : VERTIGO, DIZZINESS, RINGING IN EARS, MUSCLE SPASMS, BRAIN FOG, ALMOST IMMEDIATE CEASE OF MENSES, BRAIN FOG, EXTREME FATIGUE, LACK OF LIBIDO. MOST RECENTLY I HAVE HAD AN MRI OF MY BRAIN ((B)(6) 2015) NOTHING OTHER THAN NORMAL AGE RELATED CHANGES WAS DISCOVERED BY THE MRI.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056745	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 9/1/2015	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE DEVICE IMPLANTED ON ME I HAVE EXPERIENCE SEVERE HEADACHES, THAT MOST OF THE TIME IT IMPAIRS ME AND CAN'T DO ANY WORK. I NEVER HAD THIS KIND OF HEADACHES BEFORE AND SOMETIMES IT LAST FOR DAYS. I ALSO HAVE CRAMPING. I HAVE PERIOD 3X THAN MY NORMAL DAYS. I USED TO HAVE 5 DAYS PERIOD NOT IT LAST 15 DAYS, SOMETIMES IT WILL STOP AND IT WILL COME BACK AGAIN. BECAUSE OF PROLONG USE OF PADS I HAVE DEVELOPED YEAST INFECTION. I NEVER HAD THIS KIND OF INFECTION IN MY ENTIRE LIFE! I ALSO EXPERIENCE FATIGUE, I CANNOT FUNCTION THAT I HAD TO STOP WORKING. I ALSO DEVELOPED SOME RASHES ALL OVER MY BODY AND I KEEP PUTTING TRIAMCINOLONE ACETONIDE TO STOP THE ITCHING. THERE ARE DAYS, I HAVE TO SHOWER MYSELF WITH APPLE CIDER VINEGAR JUST TO STOP THE ITCH. I ALSO DEVELOP BLOATING, NOW I AM HELPING MYSELF TO TAKE PROBIOTIC SO I WILL BE ABLE TO SLEEP AT NIGHT. LASTLY, I AM A VERY ACTIVE PERSON AND WALK ALL THE TIME, MY WEIGHT KEEPS CLIMBING UP FOR NO REASON, I DO NOT UNDERSTAND WHY I AM GAINING WEIGHT WHEN I DID NOT CHANGE ANYTHING WITH MY DIET. I TRY TO KEEP WALKING EVEN THOUGH I GET TIRED SO MUCH EASILY NOW A DAYS. THEY DID THE HCG SONOGRAM ON ME LAST AUGUST, THE RESULT CAME OUT THAT BOTH OF MY FALLOPIAN TUBES ARE NOT BLOCKED WHERE THEY INSERTED THE ESSURE. I HAVE TO COME BACK FOR ANOTHER HCG IN (B)(6). THE SYSTEM DOES NOT WORK BUT INSTEAD GIVING ME MISERY. I PAID OUT MY POCKET FOR THE HCG TEST, IT WAS (B)(6) AFTER PROCESSING THROUGH MY INSURANCE. THE ESSURE IMPLANT WAS COVERED BY MY INSURANCE PROVIDER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056746	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 9/30/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, FATIGUE, WEIGHT GAIN, LOWER ABDOMINAL PAIN, MUSCLE SPASMS, LOWER BACK PAIN, HEADACHES, FOOD SENSITIVE'S, BLOATING, DEPRESSION, EYE'S TWITCH, LEGS AND ARM JOINT PAIN, DENTAL ISSUES, LOSS OF SMELL, INDIGESTION, METALLIC TASTE, TINGLING IN LEGS AND ARMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056747	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 9/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, FATIGUE, WEIGHT GAIN, LOWER ABDOMINAL PAIN, MUSCLE SPASMS, LOWER BACK PAIN, HEADACHES, FOOD SENSITIVE'S, BLOATING, DEPRESSION, EYE'S TWITCH, LEGS AND ARM JOINT PAIN, DENTAL ISSUES, LOSS OF SMELL, INDIGESTION, METALLIC TASTE, TINGLING IN LEGS AND ARMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056748	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 9/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKEL ALLERGY, SEVERE WEIGHT GAIN AND BLOATING, HEADACHES, JOINT PAIN, BACK PAIN, ABDOMINAL PAIN, PAINFUL OVULATION, HEAVY BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056749	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 9/27/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PROVIDE BY (B)(4) SINCE I GET THE IMPLANTS MY HEALTH HAS BEEN SO BAD I LIVE IN PAIN HEAD ACHES , JOINT PAIN, PAINFUL LEGS MUSCLES, LOWER BACK AND NECK,HEAVY BLEEDING EVERY PERIOD, RASHES ON FACE AND NECK ITCHI LEGS, INCONTINENCE I CAN'T DO ANYTHING WITHOUT HAVING LEAKAGE, METAL TASTE. DUIRING THE FIRST THREE MONTHS WHIT THE IMPLANTS I HAVE SYMPTOMS OF FOOD POISONING LIKE SWEATING, SHAKING , NAUSEA AND VOMITING NOW I HAVE ALSO DIGESTIVE PROBLEMS AND BLOATING I GAIN 40LBS. IM HEAVIER THAN MY LAST MONTH OF PREGNANCY. I WANT TO BE REALLY CLEAR I WAS PERFECTLY HEALTY BEFORE ESSURE

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056750	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 11/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DOCTOR NEEDED TO PUT ME TO SLEEP TO REMOVE MY IUD THAT HAD FLIPPED UPSIDE DOWN. SHE MENTIONED THAT THERE WAS A NEW METHOD CALLED ESSURE AVAILABLE THAT WAS A VERY PERMANENT FORM OF BIRTH CONTROL. I DECIDED TO HAVE HER DO THAT IN (B)(6) 2010 SINCE MY HUSBAND AND I DECIDED WE WERE DONE HAVING CHILDREN. MY PROCEDURE IN (B)(6) 2010 WENT FINE, I HAD THE DYE TEST DONE 3 MONTHS LATER IN JUNE 2010 AND WATCHED THE DYE STOP MYSELF ON THE SCREEN. EARLY (B)(6) 2010 I FOUND OUT I WAS PREGNANT. I WAS 8 DAYS LATE GETTING MY CYCLE AND TOOK A PREGNANCY TEST. WHEN IT TURNED POSITIVE, I CALLED MY OB/GYN WHO TOLD ME TO GET TO HER OFFICE IMMEDIATELY AS SHE SUSPECTED AN ECTOPIC PREGNANCY. THROUGHOUT THE DAY THE ULTRASOUND SHOWED THAT THE EMBRYO DID INDEED IMPLANT IN THE UTERUS PROPERLY AND IT WAS A VIABLE PREGNANCY. I HAD A VERY HEALTHY PREGNANCY AND NOW HAVE A HEALTHY 4 YEAR OLD BOY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056751	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 9/30/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE THE IMPLANT OF ESSURE IN 2009 I HAVE HAD WITHIN MONTHS: DEPRESSION AND ANXIETY THAT I HAVE NEVER HAD, NOW MEDICATED. WEIGHT GAIN OF (B)(6). NOT DOING ANYTHING DIFFERENT. VERY UNCOMFORTABLE, CRAMPING LIKE NEVER BEFORE. HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056752	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 1/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE SIDE EFFECT STARTED WITH SEVERE BLOATING, PREGNANCY LIKE SYMPTOMS, ONGOING PELVIC PAIN. I GAIN OVER 40LBS IN A SHORT TIME OF 3-5 MONTHS. I APPEARED TO BE AROUND 8 MONTHS PREGNANT. I HAD TO HAVE A SALPINGECTOMY ON (B)(6) 2015. THE ESSURE COILS WERE PERFORATING BOTH OF MY FALLOPIAN TUBES, CAUSING TUBAL COLIC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056753	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 6/18/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE MIGRAINES, PAINFUL INTERCOURSE, TINGLING OF HANDS,FEET AND NECK, CONSTIPATION, NAUSEA, VOMITING, CHRONIC PAIN, HEAVY MENSTRUAL, JABBING PAIN ON SIDE, RASH, BLOATING, UTI, DEPRESSION. MY XRAY LOOKS LIKE THE COILS SEPARATED AND MIGRATED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056754	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CANNOT REMEMBER THE EXACT ONSET OF MY SIDE EFFECTS, BUT I KNOW THAT IT WAS WITHIN A YEAR AFTER THE ESSURE WAS PUT INTO PLACE ((B)(6) 2011). I HAVE NOTICED OVER THE PAST 3 YEARS AN INCREASE IN DEPRESSION, MORE INTENSE MOOD SWINGS, HEADACHES, EXHAUSTION, ALL OVER PAIN (BUT CONCENTRATED IN THE LOWER BACK AND LEGS), LEG/FOOT SWELLING, LOSS OF LIBIDO, CRAMPING, FLUTTERING, CONSTIPATION, NAUSEA, AND FLOATERS. I CHOSE TO HAVE THIS PROCEDURE DONE VS. A CONVENTIONAL TUBAL LIGATION BECAUSE OF THE RECOVERY TIME. MY PROCEDURE WAS COVERED BY (B)(6), BUT I WAS DROPPED AFTER 6 WEEKS POSTPARTUM AND WAS NEVER ABLE TO CHECK BACK IN WITH THE DOCTOR OR EVEN COMPLETE THE DYE TEST. AFTER JUST A FEW MONTHS I STARTED TO SEE ARTICLES ONLINE ABOUT SIDE EFFECTS AND PROBLEMS WITH ESSURE. I LOOK FORWARD TO GETTING NEW INSURANCE IN THE NEXT FEW MONTHS AND BEGGING THEM TO COVER THE REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056755	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 12/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PAINFUL BLEEDING, VIBRATIONS AND SPASMS IN PELVIC AREA, PINCHING IN PELVIC AREA , MEMORY LOSS, CONFUSION, LOSS OF NORMAL WORD RECALL, LACK OF ABILITY TO TIME LINE LIFE EVENTS. ALL CBC RETURNED HIGH NORMAL WHITE BLOOD CELL COUNT DURING ROUTINE PHYSICALS HEART PALPITATIONS, CHEST PAIN. SEVERE DEPRESSION REQUIRING HOSPITALIZATION. BLOOD CLOTS LARGER THAN 2 INCHES. ULTRASOUND AND PELVIC EXAM RESULTS RETURN NORMAL AND NO OTHER SOURCE FOR PELVIC PAIN HAS BEEN DETERMINED CAUSING DEPRESSION TO RETURN. PAIN WHEN GOING FROM SITTING TO STANDING IN PELVIC AREA BECAUSE IT FEELS LIKE MY PELVIC ORGANS ARE GLUED TOGETHER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056777	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 7/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ABDOMINAL CRAMPING SINCE 2012 WHEN THE DEVICE WAS PUT IN AS WELL AS HEAVY PERIODS, 7-10 DAYS. AS WELL AS SPOTTING IN BETWEEN. I WAS ALWAYS 28 DAYS EVERY MONTH! FOR THE LAST 14 MONTHS I HAVE HAD CHRONIC DIARRHEA, 25 POUND WEIGHT GAIN, HEADACHES, RINGING IN EARS, METALLIC TASTE IN MOUTH, DIZZINESS, NAUSEA, EXTREME FATIGUE, ABDOMEN IS ABNORMALLY BLOATED, MOOD SWINGS. I HAVE BEEN TO THREE DIFFERENT DOCTORS, ONE OF WHICH WAS MY OB/GYN WHO PUT THE ESSURE IN. ALL OF MY TESTS, INCLUDING BLOOD WORK, FECAL SAMPLES AND URINE CAME BACK FINE EXCEPT FOR BEING LOW ON IRON. I WAS TOLD BY MY OB/GYN THAT PREFORMED THE ESSURE PROCEDURE THAT I WAS FINE. SHE DID HAVE A DIFFICULT TIME BACK IN 2012 PUTTING THE COIL IN MY RIGHT TUBE, THAT IS THE SIDE OF MY ABDOMEN THAT CRAMPS THE MOST. I FEEL LIKE I AM TRAPPED IN SOMEONE ELSE'S BODY. I'VE ACTUALLY HAD FAMILY MEMBERS, WHOM I HADN'T SEEN IN YEARS AND RECENTLY VISITED TELL ME THAT I LOOKED LIKE "CRAP". I TELL THEM I FEEL THAT WAY TOO! I'M SO SADDEN THAT THIS IS THE OUTCOME FOR MYSELF. I AM ONLY (B)(6), I SHOULD NOT FEEL THIS BAD!!!! BEFORE I HAD ESSURE I WAS VERY HEALTHY AND HAPPY. I RAN UP TO 5 MILES A DAY, THAT NOT THE CASE ANYMORE. EVERY WOMAN I TALK TO I TELL THEM ABOUT ESSURE AND URGE THEM NOT TO GET IT, IT'LL RUIN YOUR HEALTH AND WELL BEING!!! I AM CURRENTLY IN THE PROCESS OF TRYING TO GET ESSURE REMOVED. WE HAVE (B)(6), WHILE THEY COVERED PART OF IT WE HAD TO PAY FOR THE REST OUR OF POCKET. HAVING ESSURE IMPLANTED WAS THE WORST DECISION I HAVE EVER MADE! PLEASE TAKE ESSURE OFF THE MARKET!!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056778	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 9/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT THE THREE MONTH HYSTEROSALPETOGRAM THE RODS WERE PLACED CORRECTLY. OVER THE NEXT YEAR I HAD TERRIBLE PAIN AND BLEEDING. A SUBSEQUENT ULTRASOUND REVEALED ONE COIL HAD MIGRATED, STRETCHED OUT AND PUNCTURED MY TUBE. UPON SURGICAL REMOVAL (AT A SIGNIFICANT COST TO ME PERSONALLY) IT WAS FOUND TO HAVE EMBEDDED IN MY BOWEL. IF IT HAD PUNCTURED I COULD BE DEAD. ON COIL STILL REMAINS. THAT WILL REQUIRE AN ADDITIONAL SURGERY. I AM AFRAID TO MOVE TO MUCH OR EXERCISE FOR FEAR I WILL CAUSE THE SPRING TO MOVE AROUND AND DAMAGE MY ORGANS. SINCE 75% OF OVARIAN CANCERS ORIGINATE IN THAT TUBES THIS SEEM LIKE A TERRIBLE IDEA. PURPOSEFULLY CAUSING INFLAMMATION AND DAMAGE AT THE SITE WHERE CANCER DEVELOPED!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056779	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 5/6/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I RECEIVED THE ESSURE, I'VE HAD NOTHING BUT ABDOMINAL PAIN, HEADACHES, NAUSEA, ETC. IN 2009 MY PRIMARY DR SAID MY HORMONES WERE OUT OF BALANCE, AND WE'VE BEEN TRYING TO CORRECT. I HAVE HAD CYSTS OFF AND ON AS WELL. HOWEVER, AS EACH YEAR GOES BY, THE PAIN GETS WORSE, THE NAUSEA, THE HEADACHES. SEX HURTS. I'VE COMPLAINED EVERY YEAR SINCE THE INSERTION AND KEEP BEING TOLD NOTHING IS CAUSING IT. IT'S OBVIOUS THE INFLAMMATION ESSURE CAUSES (AND MY DR FINALLY ADMITTED IT) IS CAUSING ALL THE PAIN. MY PERIODS WERE IRREGULAR AS WELL. NOW, I'M FINALLY RESULTED TO A LO DOSE OF BIRTH CONTROL AND NOW MY SYMPTOMS ARE EVEN WORSE! I CAN'T GET MY DR TO DO ANYTHING ELSE, AND PRETTY MUCH SAY IT'S IN MY HEAD. IT LOOKS LIKE THE COILS ARE WHERE THEY SHOULD BE, BUT, THEY HAVEN'T REALLY CHECKED. I'M MISERABLE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056782	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS PROVIDED MY BY INSURER. MY DEVICE WAS PLACED IN (B)(6) 2006. EVER SINCE MY HEALTH HAS BEEN DECLINING WITH SEVERE MIGRAINES, MEMORY LOSS "BRAIN FOG", JOINT PAIN, ABDOMINAL PAIN, IRREGULAR PERIODS, HEAVY BLEEDING, DRY SKIN, RASH, HAIR FALLING OUT, DEPRESSION, ANXIETY, BLOATING, AND WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056786	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS RECOMMENDED ESSURE THROUGH MY GYN BACK IN 2009 DUE TO PELVIC PAIN. NEEDLESS TO SAY THAT MY PAIN NEVER WENT AWAY, AND ONLY BECAME WORSE AFTER THE IMPLANT. IN 2011, I OPTED TO HAVE A PARTIAL HYSTERECTOMY, LEAVING ONLY BOTH OF MY OVARIES, HOPING THIS WOULD STOP THE PAIN. ONCE MY GYN GOT IN THERE, HE FOUND THAT THE LEFT COIL HAD ERUPTED AND PROTRUDED THROUGH MY ENTIRE LEFT SIDE. A SURGERY THAT SHOULD HAVE TAKEN ONE HOUR HAD NOW TURNED INTO OVER SIX HOURS. I FELT SOMEWHAT BETTER AFTER THIS PROCEDURE, YET NOT MY NORMAL SELF, UNTIL 2012 WHEN THE PELVIC PAIN RETURNED WITH A VENGEANCE. NOW IT'S 2015, AND IN (B)(6) MY HEALTH HAS TAKEN A TURN FOR THE WORSE. I HAVE BEEN OUT OF WORK SINCE (B)(6), HAD MULTIPLE SURGERIES, AND AM NO LONGER THE HEALTHY WOMAN THAT I ONCE WAS. MY GALLBLADDER SHUT DOWN ON ME AND I HAD TO HAVE IT REMOVED. I THEN OPTED TO HAVE MY LEFT OVARY REMOVED HOPING THIS WOULD HELP WITH THE PAIN. DURING THIS SURGERY, MY NEW GYN INFORMED ME THAT MY LEFT OVARY, BLADDER, INTESTINE, AND COLON HAVE BEEN DAMAGED. IF I OPT TO HAVE THIS CORRECTED, IT WILL MEAN REMOVING A PORTION OF EACH OF THOSE ORGANS AND LEAVING ME WITH A COLPOSCOPY BAG. DURING THIS TIME FRAME, I HAVE ALSO BEGAN TO EXPERIENCE MIGRAINES, IN WHICH I SELDOM WOULD EVER GET A HEADACHE, DENTAL PROBLEMS, NECK PAIN, TO THE POINT THAT I CAN NO LONGER TURN MY HEAD TO BACK UP A VEHICLE, SHOULDER AND LOWER BACK PAIN, HIP PAIN, TO THE POINT THAT I CAN NO LONGER LAY ON MY SIDES OR STOMACH AND AT TIMES UPON STANDING MY HIP WILL JUST GIVE OUT. I STILL HAVE THE SEVERE PAIN ON MY LEFT SIDE AND MORE FREQUENT. I SUFFER FROM HOT FLASHES AND NIGHT SWEATS, MY TOE NAILS HAVE DIED, I HAVE NO DESIRE FOR SEX, PCOS, PAINFUL INTERCOURSE, BLADDER INCONTINENCE AND LEAKAGE, BREAST PAIN, BOWEL ISSUES, HIVES, RASHES, AND ITCHING, SEVERE SCAR TISSUE. MY LIST CONTINUES TO GROW FROM HEAD

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

TO TOE, I HAVE LOST MY ENJOYMENT TO LIFE, AND FEEL THAT I HAVE BECOME A BURDEN TO MY HUSBAND WHO DOES NOT DESERVE THIS BUT CONTINUES TO BE BY MY SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056787	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER RECEIVING MY IMPLANTED DEVICE I HAD A HEAVY MENSTRUAL PERIOD FOR 2 MONTHS STRAIGHT. MY DOCTOR ASSURED ME IT WAS MY BODY GETTING USED TO THE IMPLANTS. I SINCE THEN HAVE DAILY JOINT PAIN AND MUSCLE SPASMS. I STARTED HAVING DAILY MIGRAINES SO I WENT TO MY DR. WHO PRESCRIBED MIGRAINE MEDICINE HOWEVER, I STILL HAVE THEM AND MY MIGRAINE MEDICINE DOES NOT TOUCH THE PAIN. ANDAMP; MONTHS INTO HAVING THIS PROCEDURE I STILL HAVE NO RELIEF FROM THE PAIN AND I HAVE IRREGULAR HEAVY MENSTRUAL CYCLES WHICH I NEVER HAD BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056788	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 2/10/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE PAIN IN MY JOINTS I HAVE SEVERE PAIN DURING MY MENSTRUAL I HAVE VITAMIN DEFICIENCIES I HAVE SEVERE ALLERGIES SEVERE HEADACHES TWO PERIODS A MONTH PAINFUL DURING INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056789	BAYER	10/2/2015	10/2/2015

Event Information:

Event Date (B3): 12/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATELY AFTER PLACEMENT OF THE PRODUCT, I HAD SEVERE BLEEDING AND PERIODS THAT WOULD LAST 2 WEEKS AT A TIME. MY ALLERGIES WERE UNMANAGEABLE, AND I DEVELOPED ENDOMETRIOSIS OF THE UTERUS, OVARIES, AND FALLOPIAN TUBES. TO THE POINT THAT THE LEFT FALLOPIAN TUBE WAS THICK AND UNABLE TO BEND. I HAVE HAD HORRIBLE SIDE EFFECTS OF WEIGHT GAIN, DEPRESSION, BLOATING, ENDOMETRIOSIS OF THE FALLOPIAN TUBES, OVARIES, AND UTERUS, JOINT PAIN, HEADACHES, SEVERE MOOD SWINGS, ABNORMAL MENSTRUAL CYCLES LAST MORE THAN 14 DAYS AT A TIME AND MORE THAN ONCE A MONTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056900	BAYER	10/2/2015	10/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I AM HAVING TO HAVE SURGERY TO REMOVE ESSURE PERMANENT BIRTH CONTROL FROM BAYER. I'M HAVING THE SURGERY DUE TO PELVIC PAIN, HEAVY PERIODS, AND ALLERGY FROM THE DEVICE THAT WAS IMPLANTED IN 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056901	CONCEPTUS/BAYER	10/2/2015	10/8/2015

Event Information:

Event Date (B3): 12/2/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE BIRTH CONTROL DEVICE IMPLANTED IN (B)(6) 2011 (AGE 45). FIRST WAS OK, BUT 3 YEARS LATER STARTED HAVING CHEST PAIN, WENT TO ER, WAS ADMITTED TO HOSPITAL FOR 2 DAYS AND OBSERVED. HAD STRESS TEST FOR HEART. ALL TESTS NEGATIVE. STILL HAD CHEST PAIN. HAD HEART CATHETER TEST DONE, THEN HAD ENDOSCOPY DONE AND ANOTHER TEST. NEGATIVE, FEW MONTHS LATER MUSCLE STARTED GETTING SORE EVERYDAY, JOINTS ACHING, HEADACHES, BLOATING, CHRONICALLY TIRED EVEN AFTER FULL NIGHT SLEEP MUSCLE PAIN AND ACHY JOINTS SEEM TO BE GETTING WORSE, BRAIN DOESN'T SEEM TO WORK CORRECTLY, SAY WORDS WRONG, VERY FORGETFUL. THINK THE DEVICES PET FIBERS ARE MAKING ME SICK CAUSING AUTOIMMUNE DISEASE SYMPTOMS. THE FIBERS MAKE THE BODY CREATE SCAR TISSUE TO BLOCK THE FALLOPIAN TUBES AND THINK THE BODY IS CONSTANTLY FIGHTING THE FOREIGN OBJECT AND THE TOXIC PET FIBERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056902	BAYER	10/2/2015	10/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/21/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE MIGRAINES/BACKPAIN AND SEVERE CRAMPS AND BLEEDING CLOTS GOLF BALL SIZE AND SEVERE BLEEDING DURING AND AFTER INTERCOURSE/METAL TASTE IN MOUTH AND TEETH PROBLEMS, SEVERE CRAMPS AND FATIGUE AND DEPRESSION AND RADIATING PAIN IN TUBES. SEVERE WEIGHT FLUCTUATIONS AND NO LIBIDO AT ALL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056903	CONCEPTUS	10/2/2015	10/8/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED AROUND TEN YEARS AGO IN (B)(6). I HAVE CONSTANT PAIN. CRAMPING, DEBILITATING PAIN. ON TOP OF MY PERIOD, I HAVE BLEEDING ALL THROUGHOUT EACH MONTH. I HAD A VERY LARGE SEIZURE. SOMETHING I TERRIBLY WRONG WITH ME. THE SEIZURE WAS THE SCARIEST THING, I THOUGHT I WAS GOING TO DIE. WHEN I WOKE UP TODAY, I WAS COMPLETELY COVERED IN BLOOD DOWN THERE. JUST AN ENORMOUS AMOUNT OF BLOOD. MY PERIOD ISN'T DUE FOR A WEEK BUT IT DOESN'T SEEM LIKE PERIOD BLOOD. I AM IN ABSOLUTE AGONY FROM THE PAIN AND CRAMPING IN MY ABDOMEN. I DON'T KNOW WHAT TO DO. I AM IN FLORIDA AND STILL HAVE NO HEALTH COVERAGE. BECAUSE IN (B)(6) JUST DOESN'T CARE. THERE IS NO KIND OF MASS HEALTH SYSTEM DOWN HERE FOR PEOPLE WITHOUT COVERAGE. I WANT THIS THING OUT OF MY BODY BEFORE IT KILLS ME! BECAUSE I THINK IT JUST MIGHT. I WANT THE FDA, LAWYERS, ADVOCATES AND MY FAMILY TO KNOW WHY, IN CASE THIS HORRIBLE BIRTH CONTROL PRODUCT THAT WAS PRESENTED TO ME AS THE SAFEST THING EVER AND THE BEST THING SINCE SLICED BREAD, DOES ACTUALLY TAKE MY LIFE FROM ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056791	BAYER	10/5/2015	10/5/2015

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAINS IN ABDOMEN, PAIN AND BLEEDING DURING AND AFTER INTERCOURSE, MIGRAINES, JOINT SWELLING AND FLUID, METAL SMELL FROM URINE AND METAL TASTE IN MOUTH, EXTREMELY HEAVY BLEEDING ANDAMP; CLOTS DURING MENSTRUAL CYCLE, EXTENDED MENSTRUAL CYCLE. EXCRUCIATING CRAMPING, CONSTANT VAGINAL DISCHARGE EVERYDAY, SEVERE BLOATING IN ABDOMEN, ANXIETY, SEVERE MOOD SWINGS, BRAIN FOG, FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056792	BAYER	10/5/2015	10/5/2015

Event Information:

Event Date (B3): 6/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE RECEIVING THE ESSURE IMPLANTS IN (B)(6) 2012, I HAVE EXPERIENCED SEVERE PAIN AND CRAMPING, UP TO 24 HEAVY PERIODS WITH CLOTTING A YEAR, PAIN IN MY HIPS AND PELVIS LIKE BEING ELECTROCUTED, WORSENING DEPRESSION, URINARY TRACT INFECTIONS, LOSS OF BLADDER CONTROL, AND OTHER SYMPTOMS I PERSONALLY BELIEVE TO BE RELATED TO THE IMPLANTS. BOTH COILS MIGRATED ONE OF THEM ACTUALLY ENTERING MY UTERUS AND BEGINNING TO ATTACH ITSELF THERE. I HAD MY FALLOPIAN TUBES REMOVED (B)(6) 2015 DUE TO THE MIGRATION AND NOW THERE ARE ABNORMALITIES ON MY UTERUS THAT I'M AWAITING BIOPSY RESULTS ON. I AM IN EXCRUCIATING PAIN. I HAD ALSO EXPERIENCED 6 MONTHS OF NONSTOP HEAVY BLEEDING LIKE A PERIOD IMMEDIATELY FOLLOWING THE IMPLANT PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056793	BAYER	10/5/2015	10/5/2015

Event Information:

Event Date (B3): 4/7/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, CHRONIC PELVIC CRAMPS, DIZZINESS, EXTREME BLOATING, JOINT PAIN

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056794	BAYER	10/5/2015	10/5/2015

Event Information:

Event Date (B3): 7/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING. INTENSE SHARP AND DULL PAINFUL CRAMPS DAILY. SHARP PAIN WHERE COILS ARE PLACED WHEN WALKING UP STAIRS AND SITTING DOWN. DAILY HEADACHES. FATIGUE EVERYDAY NO MATTER HOW MUCH SLEEP I GET. ITCHY BUMPY RASH ON HANDS/ARMS. COMPLETE LOSS OF SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056795	BAYER	10/5/2015	10/5/2015

Event Information:

Event Date (B3): 9/25/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ALLERGIES TO NICKEL; MY BODY BROKE OUT IN HUGE BLISTERS THAT ITCH. SEVERE PELVIC PAIN HEAVY PERIODS WITH PAIN HAIR LOSS, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056817	BAYER	10/5/2015	10/5/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN HAVING VERY HEAVY PERIODS (I THOUGHT I WAS GOING TO BLEED TO DEATH). I WOULD GO THROUGH A SUPER PLUS TAMPON IN AN HOUR AND LEAK THROUGH. I BEGAN LOOSING A LOT OF HAIR WHEN I SHOWERED. I STARTED GETTING FREQUENT MIGRAINE HEADACHES, FATIGUE, CRAMPING EVEN WHEN I'M NOT ON MY PERIOD, DEPRESSION MORE THAN NORMAL, FOGGY BRAIN CAN'T REMEMBER THINGS I JUST DID OR THINGS PEOPLE TOLD ME. I BEGAN NOTICING I WAS GAINING A LOT OF WEIGHT AND MY STOMACH STARTED TO LOOK LIKE I WAS PREGNANT AGAIN AND NO MATTER WHAT I DID DIET, EXERCISE, AB WORKOUTS, I WAS ALWAYS BLOATED AND PREGNANT LOOKING. I'VE EVEN HAD PEOPLE ASK WHEN I WAS DUE, WHICH CAUSED MORE DEPRESSIONS. I JUST HAD A XRAY TAKEN OF THE AREA WHERE THEY ARE SUPPOSED TO BE AND IT IS VERY VISIBLE THAT THE ESSURE COILS HAVE MIGRATED TO THE WRONG AREAS, THEY ARE NOT EVEN CLOSE TO BEING IN MY FALLOPIAN TUBES ANYMORE. MY DR SAYS I WILL NEED A HYSTERECTOMY TO GET THE COILS REMOVED WHICH WILL CAUSE ME TO LOOSE TIME AT WORK AND PAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056818	BAYER	10/5/2015	10/5/2015

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN, HAIR LOSS, BLOATING, NUMBNESS, HEADACHES, HEAVY PERIODS, MOODINESS, DEPRESSION THE LIST GOES ON AND ON.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056819	BAYER	10/5/2015	10/5/2015

Event Information:

Event Date (B3): 5/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHE, ABDOMINAL PAIN, MENSTRUATION HEAVY.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	10/5/2015	10/14/2015

Event Information:

Event Date (B3): 9/25/2015 **Report Date (B4): 9/28/2015** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL, 884-5380
Model # (E4):
Catalog # (E4): ESS305
Lot #(E4): C59250

Single Use: I
Implant Date (E6): 9/25/2015
Explant Date (E7): 9/25/2015
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3): 9/28/2015

Event Description (B5):

PROCEDURE WAS AN ESSURE TUBAL INTERRUPTION FOR UNDESIRED FERTILITY. UPON DEPLOYMENT OF THE DEVICE BY THE PHYSICIAN, ONLY HALF OF THE COIL ENTERED THE FALLOPIAN TUBE AND THE REMAINING HALF WAS LEFT OUT IN THE UTERINE CAVITY. THE PHYSICIAN ATTEMPTED TO REMOVE THE COIL BUT WAS UNABLE TO DO SO. THE PART OF THE COIL THAT EXTENDED INTO THE UTERINE CAVITY WAS CUT OFF AND THE PART THAT WAS IN THE FALLOPIAN TUBE WAS LEFT IN PLACE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01175	BAYER HEALTHCARE LLC	10/6/2015	10/6/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 9/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. THE PHYSICIAN REPORTED THAT THE PATIENT ALREADY HAD TUBECTOMY ON 1 SIDE (NOS). PATIENT HAD ESSURE INSERTED BY REPORTER AND THE INSERTION WENT EASY. SHE CONTINUED TO USE A CONTRACEPTIVE PILL, AND HAD NO IMMEDIATELY COMPLAINTS. AFTER STOPPING, AROUND OVULATION AND MENSTRUATION COMPLAINTS (NOT SPECIFIED). SHE ALSO HAS COELIAC DISEASE AND THOUGHT IT CAME FROM THAT, SHE RECEIVED MEDICATION FOR IT BUT COMPLAINTS STAYED. AN ABDOMINAL X-RAY OVERVIEW WAS DONE AND SHOWED NO ABNORMALITIES. A TUBECTOMY WAS PLANNED; GYNAECOLOGIST WILL REPORT WHEN IT IS PERFORMED AND OUTCOME. CORRECTION BASED ON INFORMATION RECEIVED AT INITIAL REPORT ((B)(6) 2015): AFTER A COMPANY INTERNAL REVIEW, CASE WAS CONSIDERED NON-INCIDENT. FOLLOW-UP FROM (B)(6) 2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH

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SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015: PATIENT TOLD SHE EXPERIENCED PAIN COMPLAINTS SINCE THE ESSURE STERILIZATION. AROUND OVULATION AND MENSTRUATION PATIENT HAS LOWER RIGHT ABDOMINAL PAIN. EVERY MONTH THE PAIN IS PRESENT TWICE. THE PAIN STAYS AS LONG AS THE MENSES LASTS. PATIENT HASN'T BEEN OPERATED YET SO NO OUTCOME YET. FOLLOW-UP RECEIVED ON (B)(6) 2015 AND ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015: INFORMATION RECEIVED FROM PATIENT STATES THAT SHE HAD ESSURE REMOVED ON (B)(6) 2015. ACCORDING TO HER, COILS WERE EASY TO REMOVE. CASE IS IN FOLLOW-UP FOR OUTCOME. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED COMPLAINTS AROUND OVULATION AND MENSTRUATION. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR; IN THIS CASE LIMITED INFORMATION WAS PROVIDED. ALTHOUGH THE EXACT NATURE OF THE EVENT WAS NOT SPECIFIED, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF ALTERNATIVE EXPLANATION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE IT WAS CONFIRMED THAT ESSURE WAS REMOVED. IN THIS CASE, NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION 24-NOV-2015 IT WAS REPORTED THAT PATIENT IS PAIN-FREE AND VERY CONTENT AFTER REMOVAL OF ESSURE. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN ME

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056823	BAYER	10/6/2015	10/6/2015

Event Information:

Event Date (B3): 8/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I GOT ESSURE I HAVE HAD NON STOP ABDOMINAL CRAMPING (IT'S WORSE WHEN I'M ON MY PERIOD), BACK PAIN, RINGING IN EARS, HEAVY BLEEDING, BLOOD CLOTS, LEG CRAMPS (TILL THE POINT WHERE I CAN'T WALK). BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056824	BAYER	10/6/2015	10/6/2015

Event Information:

Event Date (B3): 10/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT IS 10 : 27 AND I'M TOSSING AND TURNING, BECAUSE IF I LAY ON ONE SIDE MY PELVIC BONES HURTS, SO I'LL TURN ON THE OTHER SIDE SAME THING. IT'S A DULL LIKE PAIN AND VERY IRRITATING WHEN YOU TRY TO GET SOME SLEEP. I'M PRAYING I'LL BE E - FREE OR E-HELL BECAUSE I BEEN DEALING WITH THIS PAIN FOR A LONG TIME. PLEASE TAKE IT OFF THE MARKET IT'S PUTTING US WOMENS IN MORE PAIN THANK HAVING A BABY. SO I THINK ALL THIS BIRTHDAY CONTROL CRAP IS A BUNCH OF BS. YES I AM WILLING TO KEEP HAVING KIDS IF I GOT TO PUT OF WITH STUFF LIKE THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056825	BAYER	10/6/2015	10/6/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE MENSTRUAL CYCLES, CONSTANT BACK PAIN, STABBING PAINS, ANXIETY ISSUES, HEADACHES, VOMITING, BUT THE BODY PAIN IS THE WORSE. TINGLING ALL OVER THE BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056873	BAYER	10/6/2015	10/7/2015

Event Information:

Event Date (B3): 9/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 629311

Single Use: *
Implant Date (E6): 9/30/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

CALLER ADVISED HAD ESSURE IMPLANTED ON (B)(6) 2009. PHYSICIAN HAD ADVISED BLEEDING WILL STOP BUT CALLER CONTINUED TO HAVE EXCESSIVE VAGINAL BLEEDING FOR THREE MONTHS AND HAD ABLATION TO STOP THE BLEEDING. CALLER HAS HAD CYST REMOVED AS WELL AS OTHER PROCEDURES AFTER HAVING THIS IMPLANT. CALLER ADVISED THIS DEVICE HAS CAUSED A LOT OF MISERY AS SHE EXPERIENCES EXCRUCIATING PAIN, LOWER ABDOMINAL PAIN, PELVIC PAIN, VOMITING, PAINFUL SEXUAL INTERCOURSE, DEPRESSION AND URINARY TRACT INFECTIONS. THIS IMPLANT, SHE ADVISED, HAS MADE HER LIFE VERY MISERABLE AND SHE IS CONSTANTLY GOING TO THE HOSPITAL AND HAVING TEST AND PROCEDURES DONE TO HELP WITH THE ADVERSE EFFECTS SHE HAS EXPERIENCED FROM ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056965		10/6/2015	10/14/2015

Event Information:

Event Date (B3): 6/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/17/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MENSTRUAL CYCLES BECAME MUCH HEAVIER, LONGER AND MORE PAINFUL. CURRENTLY HAVE EXTREME LOWER BACK AND PELVIC PAIN, PAIN DURING INTERCOURSE, AND MIGRAINES. HAVE BEEN TAKING PAIN MEDICATIONS NEARLY ON A DAILY BASIS SINCE PROCEDURE IN ORDER TO ENDURE PAIN (HEAD, BACK, ABDOMEN).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056966	BAYER	10/6/2015	10/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN 2008. SINCE THEN, I HAVE EXPERIENCED THE FOLLOWING SIDE EFFECTS AND SYMPTOMS: HAIR LOSS, RASH INCLUDING PSORIASIS ON MY HEAD THAT WILL NOT GO AWAY, EXTREME MIGRAINES, PAIN IN MY BACK AND NECK THAT CAUSE DAILY PAIN, CRAMPS, LONG PERIODS WITH EXTREME BLOOD CLOTS, FIBROMYALGIA AND PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056967	BAYER	10/6/2015	10/14/2015

Event Information:

Event Date (B3): 8/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 7/21/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AT (B)(6)YEARS OF AGE, AFTER HAVING MY CHILDREN AT AGES (B)(6) I DECIDED TO HAVE THE ESSURE IMPLANT AS A MEANS OF PERMANENT BIRTH CONTROL. I HAD THE ESSURE IMPLANT IN (B)(6) 2014 AND DID THE FOLLOW UP TEST IN (B)(6) 2014. AFTER THE FOLLOW UP, THE DOCTOR AND HIS REPORT INDICATED MY TUBES WERE 100 PERCENT BLOCKED BILATERALLY. IN EARLY (B)(6) 2015 MY PERIOD WAS LATE, SO I TOOK A PREGNANCY TEST WHICH WAS POSITIVE. IN ABSOLUTE SHOCK, I CALLED MY DOCTOR AND SAW HER THAT DAY TO TEST MY BLOOD AND URINE WHICH CONFIRMED THE PREGNANCY. A WEEK LATER, I HAD A ULTRASOUND THAT CONFIRMED AN UTERINE PREGNANCY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056970	BAYER	10/6/2015	10/14/2015

Event Information:

Event Date (B3): 2/4/2004 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/12/2004
Explant Date (E7): 8/4/2009
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN 2004. I IMMEDIATELY EXPERIENCED ADVERSE SYMPTOMS, SUCH AS LOSS IN LIBIDO AND EXTREME BLOATING. I ALSO IMMEDIATELY EXPERIENCED AN ADVERSE CHANGE IN MY EQUILIBRIUM. THE INITIAL REACTIONS TO ESSURE PROMPTED ME TO CALL MY OB/GYN, DR. (B)(6), TO TELL HIM THAT ESSURE WAS MAKING ME FEEL "WEIRD." DR. (B)(6) SAID ESSURE WAS NOT CAUSING MY SYMPTOMS, EVEN THOUGH THEY DEVELOPED IMMEDIATELY AFTER HAVING THE DEVICES IMPLANTED. WITHIN A FEW MONTHS, I BEGAN TO EXPERIENCE ALLERGIC-LIKE REACTIONS TO FOOD (MOSTLY PROCESSED ONES), MEDICATIONS AND CLEANING SOLUTIONS. ABOUT A YEAR LATER, I BEGAN TO EXPERIENCE INTENSE AND OFTEN TIMES DEBILITATING PAIN AND HORRIFIC FATIGUE. I CONSULTED WITH A NURSE PRACTITIONER AT DR. (B)(6) OFFICE, WHO TREATED ME FOR A URINARY TRACT INFECTION, BUT THE CULTURE WAS NEGATIVE. I EVENTUALLY HAD AN ABDOMINAL CT SCAN THAT SHOWED AN INFLAMED KIDNEY AND WAS REFERRED TO A UROLOGIST. I SUBSEQUENTLY TREATED WITH TEN MEDICAL DOCTORS FOR A PLETHORA OF PECULIAR SYMPTOMS, BUT NOBODY COULD DETERMINE WHY I WAS SICK. FIVE YEARS LATER, I SAW AN ALLERGIST WHO ORDERED A SED RATE AND DETERMINED THAT MY INFLAMMATION LEVEL WAS HIGH (28). HE ALSO CONDUCTED A METAL ALLERGY TEST. THE METAL ALLERGY TEST RESULTS WERE NEGATIVE, BUT I GOT MORE SICK DURING THE TWO DAYS THE METAL BUTTONS WERE TAPED TO MY BACK. ODDLY, THE METAL BUTTONS ON MY BACK CAUSED EXTREME BLOATING (I LOOKED 6 OR 7 MONTHS PREGNANT) AND INTENSIFIED OTHER SYMPTOMS, SO I DECIDED TO HAVE ESSURE REMOVED. DR. (B)(6) TOLD ME HYSTERECTOMY WAS THE ONLY WAY TO REMOVE ESSURE, WHICH I DID NOT KNOW PRIOR TO GETTING THE DEVICES. I FOUND A DOCTOR IN (B)(6) WHO HAD REMOVED ESSURE WITHOUT PERFORMING A HYSTERECTOMY. I PAID FOR THE SURGERY OUT OF POCKET. ONE OF MY FALLOPIAN TUBES WAS PERFORATED AND I HAD DEVELOPED ENDOMETRIOSIS AROUND THE ESSURE DEVICES.

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ADDITIONALLY, I FELT BETTER THE MOMENT I AWOKE FROM SURGERY. MY SED RATE WAS WITHIN NORMAL RANGE FOUR MONTHS AFTER REMOVAL. EVEN DR. (B)(6), WHO INSISTED THAT ESSURE WAS NOT MAKING ME SICK, ADMITTED THAT MY SED RATE REST RESULTS INDICATED THAT I WAS, IN FACT, SUFFERING FROM A REACTION TO ESSURE. I AM SO MUCH BETTER SINCE REMOVAL, BUT I STILL SUFFER FROM CHEMICAL SENSITIVITIES, WHICH IS AT TIMES DEBILITATING. I BELIEVE THE POT FIBERS IN ESSURE MADE ME SENSITIVE TO COMMON CHEMICALS AND CONTINUES TO MAKE ME SICK. ESSURE CHANGED MY LIFE - AND NOT FOR THE BETTER.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01176	BAYER HEALTHCARE LLC	10/7/2015	10/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE HCP (HEALTH CARE PROFESSIONAL) WAS PLACING AN ESSURE DEVICE ON (B)(6) 2015, AND THE DELIVERY CATHETER WOULD NOT DETACH, AND THE DEVICE UNWOUND. THE GREEN SHEATH AND THE GOLD BAND DETACHED AND WERE IN THE FALLOPIAN TUBE. THE HCP WAS ABLE TO REMOVE THE GREEN SHEATH, BUT THE GOLD BAND REMAINED IN THE FALLOPIAN TUBE. HE WAS ABLE TO SUCCESSFULLY PLACE A DEVICE IN THE OTHER TUBE. FOLLOW-UP INFORMATION RECEIVED ON 01-OCT-2015: ONSET DATE OF EVENT AND INSERTION PROCEDURE DATE WERE UPDATED TO (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING THE PROCEDURE, THE GREEN SHEATH AND THE GOLD BAND DETACHED AND WERE IN THE FALLOPIAN TUBE. PHYSICIAN REMOVED THE GREEN SHEATH BUT THE GOLD BAND REMAINED IN THE TUBE. THIS EVENT, REGARDED AS BREAKAGE OF ESSURE CATHETER, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, PHYSICIAN EXPERIENCED A DEPLOYMENT ISSUE (CATHETER WOULD NOT DETACH) AND HANDLING ISSUE (DEVICE UNWOUND) DURING THE PROCEDURE. THIS SUGGESTS A DIFFICULT INSERTION, WHICH MAY HAVE CONTRIBUTED FOR DEVICE BREAKAGE. CONSIDERING THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS

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ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 30-OCT-2015: DEVICE BREAKAGE WITH ESSURE QUESTIONNAIRE RECEIVED. PATIENT WAS (B)(6). ESSURE WAS INSERTED ON (B)(6) 2015. DEVICE BREAKAGE WAS DIAGNOSED DURING PLACEMENT. THE DELIVERY CATHETER BROKE, GREEN RELEASE CATHETER.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01177	BAYER HEALTHCARE LLC	10/7/2015	10/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 10-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE PATIENT HAD ESSURE PROCEDURE DONE BY ANOTHER HEALTH CARE PROFESSIONAL. WHEN THAT HEALTH CARE PROFESSIONAL PLACED IT, SHE REPORTED PAIN. ALSO IT WAS REPORTED THAT ONE OF THE INSERTS WAS FOUND MISPLACED WITH PERFORATION THROUGH THE TUBE. PATIENT REQUIRED HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ONE OF THE INSERTS WAS FOUND MISPLACED WITH PERFORATION THROUGH THE TUBE. A HYSTERECTOMY WAS REQUIRED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS REQUIRED. FURTHER INFORMATION (UTERINE TUBAL PERFORATION QUESTIONNAIRE) AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 04-OCT-2015. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER I

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056924	BAYER	10/7/2015	10/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE INSTALLED AND BECAME PREGNANT AFTERWARDS. THE BABY DIED BECAUSE OF THE PRIOR PROCEDURES, I HAD TO HAVE 4 SURGERIES AND A HYSTERECTOMY. I HAD DEPRESSION AND FELT LIKE A YEAR OF MY LIFE WAS LIVED IN A FOG AFTERWARDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056933		10/7/2015	10/14/2015

Event Information:

Event Date (B3): 12/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): B06103
Lot #(E4): ESS305

Single Use: *
Implant Date (E6): 12/3/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE (B)(6) 2003 AND ABOUT 3-4 MONTHS LATER, I STARTED HAVE SEVERE MIGRAINES, AND WAS REALLY DEPRESSED WITH REALLY BAD ANXIETY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056877	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 5/6/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABOUT SIX MONTHS AFTER PLACEMENT I STARTED HAVING HORRIBLE BLEEDING AND CRAMPING ALL THE TIME. MY PERIODS WERE COMING MORE FREQUENTLY AND MORE INTENSE. THAN PAIN CAME WITH SEXUAL INTERCOURSE TO THE POINT I WOULD SCREAM AND BUST OUT CRYING. ABOUT A YEAR LATER MY BACK PAIN AND MUSCLE PAINS HEADACHES. MY JOINTS HURT SO BAD I COULD BARELY WALK. I STARTED TO SUFFER HEADACHES. I HAD ONE AFTER ANOTHER EMERGENCY ROOM VISITS IT WAS BRUSHED OFF AS HAVING CYST ON MY OVARIES. WHEN I WOULD GO TO MY PCP AND TELL THEM THE ISSUES THAT WAS HAPPENING I WAS TOLD I WAS WAY TOO YOUNG TO BE IN THAT MUCH PAIN AND OVER WEIGHT. ONE TIME I WAS EVEN TOLD THAT THERE WAS NOTHING WRONG WITH ME I JUST WANTED PAIN MEDICATION AT THAT TIME I HAD NO CLUE WHAT THAT EVEN WAS I JUST WANTED TO BE ABLE TO LIVE MY LIFE AGAIN WITH OUT CRYING FROM BEING IN SO MUCH PAIN. SOME DOCTORS HAVE NO CLUE WHAT THE ESSURE IS AND OTHERS TELL ME NO THAT CAN NOT BE WHAT IS CAUSING ALL MY PROBLEMS. I WOULD JUST GET A RASH FROM THE NICKEL. AS I STARTED DOING MY OWN RESEARCH I HAD 52 SIDE EFFECTS. I FELL INTO A SEVERE DEPRESSION. I CAN'T WORK I LOST MY HOUSE EVERYTHING TO THIS DAY I STILL LIVE IN HELL MY BODY FAILS ME EVERYDAY. I AM A VERY STRONG WILLED PERSON BUT THIS HAS TAKEN OVER MY LIFE. I DON'T UNDERSTAND HOW I CAN BE TOLD SORRY THERE IS NOTHING WE CAN DO FOR YOU . SO THANKS FDA FOR TAKING ME FROM MY KIDS FROM THE WORLD STRIPPING ME OF MY HAPPINESS AND LEFT FOR DEAD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056878	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 10/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). COIL IS PLACED IN FALLOPIAN TUBES INCORRECTLY. IT HAS CAUSED ALL SYMPTOMS LISTED BELOW: LOWER BACK PAIN STABBING PAIN ON LEFT SIDE ANEMIA ANXIETY MOOD SWINGS DEPRESSION FATIGUE WEIGHT GAIN SKIN RASHES TEETH AND GUM PROBLEMS JOINT PAIN CHRONIC INFLAMMATION HORMONAL IMBALANCE MUSCLE WEAKNESS MEMORY LOSS CHEST PAIN BLOATING HAIR LOSS CHRONIC PELVIC PAIN HEAVY MENSTRUAL CYCLES WITH CLOTTING KIDNEY PAIN ON LEFT SIDE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056879	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGINNING TWO YEARS AFTER IMPLANTATION OF ESSURE, I DEVELOPED IBS WITH CHRONIC CONSTIPATION, EXTREME BLOATING AND A ITCHY RASH ON MY LEGS. I SAW GASTROENTEROLOGISTS, DERMATOLOGISTS AND MY OB/GYN, AND WAS ONLY PRESCRIBED VARIOUS MEDICATIONS, WITH NO EXPLANATION FOR THE SYMPTOMS. I SAW A NATUROPATHIC DOCTOR AND ELIMINATED CERTAIN FOODS FROM MY DIET, BUT NOTHING HELPS. THESE SYMPTOMS HAVE CONTINUED FOR OVER 6 YEARS. IN THE LAST THREE YEARS, I HAVE ALSO DEVELOPED ALLERGY SYMPTOMS AND ASTHMA BUT TESTS SHOW THAT I'M NOT ALLERGIC TO ANYTHING. I HAVE 2-3 SINUS INFECTIONS WITH BRONCHITIS PER YEAR. MY PERIODS HAVE BECOME HEAVIER AND MORE PAINFUL, AND I TYPICALLY HAVE DULL PAIN IN MY RIGHT PELVIC AREA WHICH GETS EXTREMELY PAINFUL BEGINNING WITH OVULATION FOR TWO WEEKS AFTERWARDS. I HAVE A CONSULT FOR A HYSTERECTOMY IN THREE WEEKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056881	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 7/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY EXPERIENCE WAS HORRIBLE. WHEN I WENT TO GET MY TUBES TIED THEY TOLD ME ALL THEY DO NOW DAY IS ESSURE. AFTER GETTING THE ENSURE I DIDN'T HAVE A MENSTRUAL. THEN MY OBGYN SEND ME FOR BLEED WORK JUST TO FIND OUT THAT I WAS GOING THROUGH EARLY STAGES MENOPAUSES THEN THE DOCTOR THOUGHT I'M TOO YOUNG FOR THAT THEN MORE TEST THEN THAT BLOOD WORK CAME BACK GOOD THEN I STARTED HAVING MENSTRUAL AND THEY WE'RE VERY BAD HAD TO GO TO ER THERE I FIND OUT MY CERVIX WAS VERY THEN AND I HAD A BACTERIA INFECTION. I ALSO HAD VITAMIN D DECENCY. I HAD VERY BAD PAIN IN MY LEFT SIDE THAT WOULD TAKE ME TO THE FLOOR. I NEVER HAD ENERGY I WAS ALWAYS BE VERY TIRED AND UNLIKE SOME WOMEN I LOST A LOT OF WEIGHT. THIS DEVICE RUINED MY LIFE I FELT LIKE I WAS SLOWLY DYING. AND WHEN I HAD MY MENSTRUAL I THOUGHT I WAS GOING TO BLEED TO DEATH I WOULD NEVER REFER ANYONE TO GET THE ENSURE I FEEL THE DOCTORS SHOULD PUT THIS POISON IN ARE BODY'S AFTER I WENT TO ER FOR HEAVY BLEEDING I ASK FOR THEM TO REMOVAL BECAUSE IF I DIDN'T TAKE ACTION I PROBABLY WOULD HAVE BLED TO DEATH. AND TO HAVE INTERCOURSE IT HURT SO BAD THIS DEVICE RUINED MY LIFE WEEKS AFTER HAVING IT REMOVED MY DAUGHTER SAYS MOM I'M GLAD YOU GOT THAT STUFF OUT BECAUSE YOU ARE MORE AWAKE NOW YOU USED TO SLEEP ALL THE TIME SO PLEASE RECALL THIS DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056882	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 2/24/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY BAD EXPERIENCE SEVERE VAGINAL BLEEDING, BLOOD CLOTS, SEVERE MIGRAINES. BLOATING, SEVERE BACK PAIN, METAL TASTE IN MOUTH, LOWER PELVIC PAIN, SEVERE CRAMPS/ CONTRACTIONS, DEPRESSION, TOO TIRED, LOSS OF ENERGY. DEVICE WAS PROVIDED BY MY INSURER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056883	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (B)(6) 2014 MY ON AND OFF PELVIC PAIN BECAME A CONSTANT PRESSURE PAIN. I ALSO EXPERIENCE RANDOM SHARP SHOOTING/STABBING PAIN IN MY PELVIC REGION. MY MENTRUAL CYCLE SLOWLY FADED AWAY TO A COMPLETE STOP. OVER THE NEXT YEAR, I HAD TRIED THREE DIFFERENT TYPE OF BIRTH CONTROL PILLS TO SEE IF THEY WOULD HELP WITH MY PAIN AND CYCLES. ALTHOUGH THEY WERE ABLE TO CONTROL MY MENSES, THEY FAILED AT RELIEVING ANY OF MY PELVIC PAINS. THIS PAIN IS CAUSED BY MY ESSURE DEVICE, WHICH I RECENTLY DISCOVERED WASN'T PROPERLY PLACED TO BEGIN WITH. I'M NOW SCHEDULED FOR A TOTAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY TO REMOVE THE GRADE 3 ESSURE COILS. I NEVER IMAGINED THAT THIS FDA APPROVED, WITH A PREMARKET APPROVAL, DEVICE WOULD LEAD TO A MAJOR SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056884	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 5/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESTIMATED DATE AS IT STARTED SO LONG AGO. INCREASED HAIR LOSS WHILE SHOWERING AND BRUSHING HAIR. VERY ITCHY SCALP, NECK, ACROSS SHOULDERS. SKIN IS REALLY ROUGH. ITCHY ALL OVER MY BODY. BLOATED BELLY. CONTACT ALLERGIES HAVE DEVELOPED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056885	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 8/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ALWAYS TAKEN VERY GOOD CARE OF MY TEETH BUT A FEW YEARS AFTER HAVING THE ESSURE PLACED MY TEETH BEGAN TO ROT. I HAVE HAD 9 TEETH PULLED SO FAR AND HAVE 5 LEFT TO BE PULLED BEFORE I CAN GET MY PARTIAL DENTURES. I HAVE HAD COUNTLESS MOUTH INFECTIONS AND TAKEN MANY TRIPS TO THE ER FROM BEING IN PAIN FROM INFECTED TEETH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056886	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL SWELLING, CONSTANT SEVERE PELVIC PRESSURE AND PAIN. ABDOMINAL PAIN, ABNORMAL MENSTRUAL CYCLES (MORE THAN 10 DAYS OR TWICE A MONTH) , DEVELOPED ANEMIA DUE TO EXCESSIVE AMOUNTS OF BLEEDING DURING MENSTRUAL CYCLE. HEADACHES, LOWER BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056887	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2009. THIS IMPLANT IS NOW MANUFACTURED BY BAYER, FORMERLY BY CONCEPTUS, INC. I DO NOT HAVE THE LOT, MODEL OR SHELF LIFE EXPIRATION OF THE IMPLANTED DEVICES. THIS IS A LIST OF MY SYMPTOMS AND SIDE EFFECTS I HAVE EXPERIENCED WITH THIS IMPLANT: MENSTRUAL CRAMPING, SHARP STABBING PELVIC PAIN, HOT FLASHES, ENDOMETRIOSIS, OVARIAN CYSTS, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION, NIGHT SWEATS, LOSS OF LIBIDO, PAINFUL INTERCOURSE, LONG MENSTRUAL CYCLES, LACK OF SEXUAL PLEASURE, BREAST TENDERNESS, ABDOMINAL FLUTTERING/TWITCHING, BACK, JOINT AND HIP PAIN, GAS ACCOMPANIED BY CONSTIPATION AND DIARRHEA, SEVERAL BLOATING, HEADACHES, BRAIN FOG/FORGETFULNESS, ANXIETY, DEPRESSION, VITAMIN D DEFICIENCY, UNEXPLAINED/EASY BRUISING, SUSPECTED CHRONIC FATIGUE SYNDROME, GLUTEN SENSITIVITY, UNEXPLAINED SWELLING OF LEGS AND FEET, HAIR LOSS, INSOMNIA, WEIGHT GAIN, HYPOTHYROIDISM, DECREASED VISION, DRY SKIN AND EYES. I HAVE BEEN SEEN BY MY PCP AND GYN AND HAVE BEEN DIAGNOSED WITH CHRONIC FATIGUE SYNDROME AND ENDOMETRIOSIS. THE DEVICES, AS WELL AS MY UTERUS, TUBES AND OVARIES, WILL BE REMOVED ON (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056888	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHILE I HAD ESSURE, I HAD CHEST PAINS ON A REGULAR BASIS, I DIDN'T THINK ANYTHING OF IT OR THAT IT COULD BE ATTRIBUTED TO ESSURE. BUT SINCE MY REMOVAL ON (B)(6) 2015, I HAVEN'T HAD A SINGLE CHEST PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056889	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE IMPLANTATION, I HAVE HAD A CONSTANT MILD CRAMPING FEELING. ALSO, HAVE HAD LEG CRAMPING, FOOT CRAMPS, WHICH I NEVER HAD BEFORE. HEADACHES ALMOST EVERYDAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056890	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 5/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THE ESSURE COILS IMPLANTED ON (B)(6) 2015 I HAVE HAD BLOATING, CONSTIPATION ALTERNATING WITH DIARRHEA, MY PERIOD EVERY FOUR DAYS LASTING FROM 4-8 DAYS, MORE FREQUENT AND SEVERE HEADACHES, NAUSEA ESPECIALLY IN THE MORNING AND BEFORE BED, FATIGUE, EMOTIONAL TUMULT, AND STABBING ABDOMINAL PAIN ESPECIALLY ON THE RIGHT SIDE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056891	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 4/12/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING TERRIBLE HORRIFIC MIGRAINES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056892	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 4/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I SUDDENLY STARTED HAVING BACK PAINS WHEN I STOOD UP IN MY GARDEN. DR SAID IT WAS SCIATICA A YEAR LATER. MRI SHOWED NOTHING IN 2013.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056910	BAYER	10/8/2015	10/8/2015

Event Information:

Event Date (B3): 8/25/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS COVERED BY INSURANCE. I SUFFER THE FOLLOWING SIDE EFFECTS. .. WEIGHT GAIN GAS BLOATING FATIGUE BRAIN FOG ITCHING INFLAMMATION LOW THYROID LOW IMMUNE BACK PAIN TINGLING AND NUMBNESS IN ARMS HEADACHES STOMACH PAIN CRAMPING HEAVY PERIODS. SOMETIMES 10-20 DAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057059	BAYER	10/8/2015	10/16/2015

Event Information:

Event Date (B3): 10/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/2/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IT HAD ESSURE IMPLANTS JUST A WEEK AGO TOMORROW, I FAILED TO RESEARCH IT MYSELF O THE INTERNET BEFOREHAND. THE DOCTOR RECOMMENDED IT TO ME, AS A QUICK, PERMANENT, AND A BIN SURGICAL PERMANENT BIRTH CONTROL AFTER THE BIRTH OF MY 3RD CHILD. BEGINNING 3 DAYS AFTER THE SURGERY, AND EVERY DAY THUS FAR, MY STOMACH AND UPPER THIGHS ARE BROKEN OUT IN AN ITCHY RASH. AFTER LOOKING UP SIDE EFFECTS OF ESSURE IN THE INTERNET, THEN I REALIZED WHAT THE PROBLEM WAS. THE ONLY WARNING THAT I RECEIVED BEFOREHAND WAS THAT IT IS PERMANENT. OF COURSE, THAT SOUNDED GREAT TO ME. WHY IS THERE NO REQUIREMENTS TO WARN PEOPLE OF THE APPARENTLY VERY COMMON SIDE EFFECTS? THE FDA HAS ALREADY BEEN MADE AWARE OF THESE PROBLEMS AND A PERSON HAS THE RIGHT TO CHOOSE IF THEY'RE WILLING TO SUFFER THE SIDE EFFECTS OR LOOK INTO A DIFFERENT METHOD OF BIRTH CONTROL. THERE WAS NO PAPERS TO SIGN ACKNOWLEDGING THIS VERY WELL KNOWN FACT. IF THE FDA HAS ALREADY BEEN MADE WARE OF THE LIKELIHOOD OF AN ALLERGIC REACTION TO THE NICKEL, WHY DID THEY DO AWAY WITH THE REQUIREMENT OF AN ALLERGY TEST? I THOUGHT OF CALLING THE DOCTOR, BUT APPARENTLY MY HEALTH, AND THOUSANDS OF OTHERS, COME SECOND TO THE HEAVY MARKETING OF SOME NEW TOY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056911	BAYER	10/9/2015	10/9/2015

Event Information:

Event Date (B3): 3/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED ABOUT A MONTH AFTER GETTING ESSURE WITH DISCHARGE AND HAS NOT GONE AWAY I GET HEADACHE EVERYDAY AND BAD CRAMPING WITH OR WITHOUT MY PERIOD AND THERE NEVER REGULAR I GET PAINS IN MY LOWER ABDOMEN AND , I LOST MY SEX DRIVE AND WHEN I DO HAVE SEX IT'S PAINFUL, I HAVE HAIR LOSS THAT STARTED SHORTLY AFTER GETTING ESSURE , I LOOK AND FEEL BLOATED, LOWER BACK PAIN , WEIGHT GAIN AND NO MATTER WHAT I TRY I CANT LOOSE IT AND THE WEIGHT GAINED STARTED AFTER I GOT ESSUER AND EXTREME FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056912	BAYER	10/9/2015	10/9/2015

Event Information:

Event Date (B3): 7/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE A METAL TASTE IN MY MOUTH ALL THE TIME. I STAY TIRED AND NO ENERGY. AND PAIN IN MY PELVIC AREA. MY PERIODS ARE HORRIBLE NOW! MY PERSONAL LIFE WITH MY HUSBAND HAS WENT DOWN THE CRAPPER . AND I HAVE GAINED SO MUCH WEIGHT AND IT'S HARD TO LOSE IT TOO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057179	BAYER	10/9/2015	10/20/2015

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): NA
Catalog # (E4): NA
Lot #(E4): NA

Single Use: *
Implant Date (E6): 7/10/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY FIRST YEAR WITH THE ESSURE IMPLANT I WAS FINE. ONCE MY SECOND YEAR CAME AROUND, AND I HAD NOTICED WHEN TAKING A SHOWER A LOG OF MY HAIR WAS FALLING OUT, THEN I NOTICED SERIOUS BACK PAIN AND SEVERE CRAMP OR CONTRACTION LIKE PAIN. I WENT TO MY PCP SHE PUT ME ON TRAMADOL AND IT DIDN'T WORK, SHE WANTED TO PUT ME ON A STRONGER PAIN MED BUT I DECLINED. I AM NOT A FAN OF PERCOCETS OR NORCO OR ANYTHING OF THAT SORT. I DID END UP TRYING THE MORE NATURAL MEDICAL MARIJUANA BUT ONCE IT WORE OFF IT CAME RIGHT BACK. THIS IS EVERY MONTH TO WHERE IT WILL MAKE ME CRY AND I WILL MISS DAYS OF WORK. MY HORMONES ARE UNCONTROLLED WHICH IS CAUSING SEVERE ACNE ON MY FACE. I AM BEING SEEN BY A DERMATOLOGIST AS WELL FOR MY ACNE. ANYTHING AND EVERYTHING WE HAVE TRIED FOR IT IS NOT WORKING. ALSO, I HAVE BEEN EXPERIENCING CONSTANT URINARY TRACT INFECTIONS AND YEAST INFECTIONS. I HAVE HAD REOCCURRING YEAST AND URINARY TRACT INFECTIONS SINCE GETTING THE ESSURE IMPLANT. THIS IS RUINING MY LIFE I WANT IT OUT AND CAN'T EVEN AFFORD TO HAVE THEM TAKEN OUT BECAUSE NO INSURANCE COVERS IT. IT AM STRESSED OUT, DEPRESSED, AND UNHAPPY WITH MYSELF AS WELL AS MY MARRIAGE BECAUSE I AM NOT HAPPY WITH MYSELF AND EVERYTHING THAT IS GOING ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057180	CONCEPTUS (NOW BAYER)	10/9/2015	10/20/2015

Event Information:

Event Date (B3): 8/11/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PROCEDURE COILS
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/11/2010
Explant Date (E7): 2/1/2011
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE IN (B)(6) 2010. WHEN I HAD THE PROCEDURE, I HAD EXTREME PAIN WHEN MY DOCTOR WAS INSERTING THE COILS, ESPECIALLY ON ONE SITE. I THOUGHT I WAS GOING TO COME OFF THE BED AND PUNCH THE DOCTOR IN HIS FACE. AND, THIS WAS AFTER HAVING A LOCAL ANESTHETIC INJECTION INTO MY BUTT. THE THREE SHOTS INJECTED INTO MY CERVIX AND UTERUS REALLY HURT AS WELL. ESSURE FAILS TO TELL YOU ABOUT THESE. AFTER THE PROCEDURE, I DROVE MYSELF HOME; NO ONE WAS REQUIRED TO DRIVE ME TO AND FROM THIS "IN-OFFICE PROCEDURE." I WAS IN A LOT OF PAIN. MY PAIN WAS SO BAD THAT I WENT BACK TO SEE MY DOCTOR. HE DID A PELVIC EXAM AND TOLD ME NOTHING WAS WRONG THAT HE COULD SEE. I FELT LIKE SAYING, "WELL, YOU CAN'T SEE ALL THE WAY UP INSIDE OF ME, SO HOW DO YOU KNOW NOTHING IS WRONG?" HE DIDN'T INVESTIGATE ANY FURTHER. I JUST ASSUMED I WAS HAVING AN UNUSUAL AMOUNT OF PAIN AND STUCK IT OUT. THREE MONTHS LATER, IN (B)(6) 2010, I HAD THE FOLLOW-UP HSG APPOINTMENT AT THE HOSPITAL WHERE THEY INJECT THE DYE INTO YOUR UTERUS AND SEE IF IT GOES THROUGH YOUR FALLOPIAN TUBES. YOU DO NOT GET THE RESULTS RIGHT AWAY; THEY SEND THEM TO YOUR DOCTOR. MY DOCTOR CALLED ME ONCE HE RECEIVED THE RESULTS TO INFORM ME THAT THE ESSURE PROCEDURE DID NOT WORK. I RECEIVED THE PAPERWORK FROM THE HOSPITAL IN WHICH IT STATED ONE COIL HAD PERFORATED MY RIGHT FALLOPIAN TUBE. NEEDLESS TO SAY, I DID NOT GO BACK TO THAT DOCTOR. I FOUND A NEW DOCTOR AND MADE AN APPOINTMENT. I TOLD THE NEW DOCTOR WHAT HAD HAPPENED AND SHOWED HIM MY PAPERWORK. HE SCHEDULED SURGERY FOR ME TO HAVE THE RIGHT COIL REMOVED, IF POSSIBLE, AND TET A TUBAL LIGATION. I HAD A TUBAL LIGATION AND THE ESSURE COIL IN MY RIGHT FALLOPIAN TUBE PULLED OUT. AFTER SURGERY, WHICH WAS PERFORMED IN (B)(6) 2011, MY NEW DOCTOR INFORMED ME THAT THE COIL HAD PERFORATED MY UTERUS AND MY RIGHT FALLOPIAN TUBE. THAT COULD

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ONLY BEEN SEEN ONCE THE CAMERA WAS INSIDE OF MY BODY. I HAD EXTRA PAIN FROM MY TUBAL LIGATION AND SURGERY BECAUSE OF THE COIL THAT HAD TO BE REMOVED FROM MY UTERUS AND FALLOPIAN TUBE. I NOW HAVE A PRETTY THICK SCAR ON MY LOWER ABDOMEN UNDERNEATH MY BELY BUTTON BECAUSE OF THE CAMERA THAT HAD TO BE INSERTED THERE AND MOVED AROUND SO MUCH TO ALLOW THE DOCTOR TO REMOVE THIS COIL AND CLAMP MY TUBES. THE WHOLE YEAR OF 2011, I BEGAN TO HAVE EXTREMELY HEAVY PERIODS. I WAS BLEEDING THROUGH A TAMPON AND PAD. ALSO, MY PERIODS WERE TEN DAYS OR LONGER EVERY TIME. I SPOKE WITH MY NEW DOCTOR AND HE INFORMED ME I COULD HAVE UTERINE ABLATION PERFORMED TO STOP OR DECREASE THE HEAVY BLEEDING OF MY PERIODS. HE TOLD ME I COULD NOT HAVE THE NOVASURE PROCEDURE BECAUSE IT IS NOT COMPATIBLE WITH THE ESSURE PROCEDURE; HOWEVER, HE SAID I COULD HAVE THE THERMA-CHOICE UTERINE ABLATION (HEAT BY WARMING WATER IN A BALLOON THAT IS INSERTED INSIDE OF THE UTERUS). THEREFORE, I HAD THE THERMA-CHOICE UTERINE ABLATION PROCEDURE IN (B)(6) 2012. AFTER HAVING THIS PROCEDURE, MY PERIODS WENT BACK TO NORMAL. I DIDN'T REALLY HAVE ANY MORE PROBLEMS UNTIL RECENTLY. I DID CHECK INTO IF ANY OTHER WOMEN WERE HAVING PROBLEMS WITH ESSURE AFTER HAVING TO HAVE SURGERY TO REMOVE THE COIL ON MY RIGHT SIDE AND MY TUBES CLAMPED. I DIDN'T REALLY SEE MUCH ABOUT ESSURE PERFORATION ONLINE BESIDES OTHER WOMEN COMPLAINING ABOUT THE PROCEDURE ITSELF AND OTHER PROBLEMS WITH IT. I FIGURED THERE WAS NOTHING I COULD REALLY DO ABOUT IT NOW. I ALREADY HAD IT AND HAD TO HAVE SURGERY. IT'S NOT LIKE I CAN TURN BACK TIME; I WOULD IF I COULD. IT HAS NOW BEEN OVER FIVE YEARS SINCE I HAD THE ESSURE PROCEDURE. I HAVE STARTED HAVING LIGHT VAGINAL BLEEDING (I DON'T EVEN REALLY CONSIDER IT BLEEDING, I CONSIDER IT BROWN DISCHARGE), PAIN DURING AND AFTER SEX, FREQUENT URINATION, AND PAIN IN MY LOWER ABDOMEN THAT CAN BE SEVERE AT TIMES. I HAVE BEEN TO THE HOSPITAL AND MY OB/GYN DOCTOR (THE SAME ONE WH REMOVED THE COIL AND PERFORMED MY TUBAL LIGATION AND UTERINE ABLATION). I'M GOING BACK TO THE DOCTOR TODAY TO HAVE HIM CHECK THE OTHER COIL TO MAKE SURE IT IS IN PLACE STILL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057166	BAYER	10/10/2015	10/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 7/12/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

NUMBNESS IN FEET, MIGRAINES, MOOD SWINGS, DEPRESSION, BLOOD CLOTS, ABDOMINAL PAIN, JOINT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057175	BAYER	10/10/2015	10/20/2015

Event Information:

Event Date (B3): 3/4/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/4/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN (B)(6) OF 2008 IN BILATERAL FALLOPIAN TUBES. ONE WAS NOT VISIBLE AFTER HAVING THE HSG DONE SEVERAL MONTHS LATER. A REPEAT PROCEDURE WAS DONE IN (B)(6) OF 2008 TO REPLACE THE ONE ON THE RIGHT. WHEN GOING INTO REPLACE IT, THE SURGEON WAS NOT ABLE TO LOCATE THE FIRST COIL ON THE RIGHT SIDE. STILL UNSURE AT THIS TIME WHERE THIS COIL IS. HAD AN ABDOMINAL X-RAY IN (B)(6) OF 2015, AND CANNOT SEEM TO LOCATE IT IN MY ABDOMEN ANYWHERE. UNSURE IF IT PASSES OR IS STILL SOMEWHERE WITHIN ME. AWAITING FURTHER TESTING. HAD HEAVY BLEEDING AFTER THE ESSURE PLACEMENT, AND IN (B)(6) OF 2013 WAS DIAGNOSED WITH MYASTHENIA GRAVIS, AN AUTOIMMUNE DISEASE AFFECTING MY STRENGTH IN MY ARMS AND LEGS, NECK AND HEAD MUSCLES, AND SWALLOW FUNCTION. I HAD, AND CONTINUE TO HAVE, HEADACHES DAILY WHEN WORKING AND HAVE VISUAL FATIGUE AND OCULAR DISTURBANCES FROM THE MG. AFTER HAVING A TRANSCERVIAL THYMECTOMY IN 2014, I CONTINUE TO HAVE WEAKNESS IN MY SWALLOW FUNCTION AND SOME CONTINUED WEAKNESS IN MY HEAD AND NECK. I HAVE HAD TO CHANGE MY CAREER FROM BEING AN OCCUPATIONAL THERAPIST (IRONICALLY WORKING WITH PEOPLE WITH PHYSICAL AND MENTAL DISABILITIES), AND GO BACK TO SCHOOL FOR ANOTHER CAREER THAT IS LESS TAXING TO ME PHYSICALLY AND VISUALLY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01178	BAYER HEALTHCARE LLC	10/12/2015	10/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT PATIENT EXPERIENCED PERFORATION. THE GYNECOLOGIST SAW THE PATIENT IN THE BEGINNING OF THE YEAR. ESSURE PLACEMENT HAD BEEN DONE A FEW MONTHS PRIOR THE PATIENT SAW PHYSICIAN. ESSURE REMOVAL WAS DONE WITH NO DIFFICULTY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERFORATION. THE DEVICE WAS REMOVED. THIS EVENT, REGARDED AS UTERINE PERFORATION, WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURES (E.G. HYSTEROSCOPY, CURETTAGE) INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. FOLLOW-UP INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01179	BAYER HEALTHCARE LLC	10/12/2015	10/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ANTICIPATED. SERIOUS INJURY. REQUIRED INTERVENTION. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6)2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT PATIENT EXPERIENCED PERFORATION. THE GYNECOLOGIST SAW THE PATIENT IN THE BEGINNING OF THE YEAR. ESSURE PLACEMENT HAD BEEN DONE A FEW MONTHS PRIOR THE PATIENT SAW PHYSICIAN. ESSURE REMOVAL WAS DONE WITH NO DIFFICULTY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERFORATION. THE DEVICE WAS REMOVED. THIS EVENT, REGARDED AS UTERINE PERFORATION, WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURES (E.G. HYSTEROSCOPY, CURETTAGE) INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. FOLLOW-UP INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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INTERNAL COMMUNICATION RECEIVED ON 03-NOV-2015: NO FURTHER INFORMATION WAS OBTAINED DESPITE FOLLOW-UP ATTEMPTS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 19-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILUR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01180	BAYER HEALTHCARE LLC	10/12/2015	10/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/14/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015. PHYSICIAN CALLED DURING ESSURE PROCEDURE, HE STATED HE USED 2 ESSURES AND BOTH INSERT DID NOT FIRE. HE SAID THAT HE HAD THE INSERT IN AND DID THE ROLL BACK, HE SAW THE GOLD MARKER AND HAD DEPRESSED THE BUTTON AND WAS ROLLING BACK THE INSERTER, BUT HE REMOVED THE INSERTER AND SAID THAT THE INSERT DID NOT DEPLOY. A FLAT PLATE WAS DONE ON THE SAME DAY AND FOUND 3 INSERTS IN TUBE. PHYSICIAN BELIEVED THEM TO BE PERFORATED. ACCORDING TO HIM, HE IS GOING TO DO A LAPAROSCOPE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON (B)(6) 2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: ROLLBACK TO INITIAL HARD STOP. DEPRESS BUTTON. PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO "DEPLOYMENT DIFFICULTY". SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST

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ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERT'S GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND PHYSICIAN BELIEVED INSERTS PERFORATED. HE WAS GOING TO DO A LAPAROSCOPY. THE REPORTED EVENT, REGARDED AS FALLOPIAN TUBE PERFORATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS CASE, PHYSICIAN EXPERIENCED DEPLOYMENT DIFFICULTIES AND AN X-RAY (PERFORMED DURING THE PROCEDURE) FOUND 3 INSERTS IN TUBE. THIS INAPPROPRIATE DEVICE THERAPY COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE SUSPECTED PERFORATION. CONSIDERING THIS SUSPICION OF PERFORATION OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE PHYSICIAN STATED HE WAS GOING TO DO A LAPAROSCOPY (SURGICAL INTERVENTION WILL BE REQUIRED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 09-OCT-2015: THE PATIENT WAS (B)(6) AT TIME OF THE EVENTS. THE PHYSICIAN REPORTED HE USED 2 ESSURES AND BOTH DIDN'T FIRE. HE INSERTED ESSURE AND THE INSERT WAS TOO DISTAL, SO HE INSERTED A SECOND ONE. SO THERE WERE 2 INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01181	BAYER HEALTHCARE LLC	10/12/2015	10/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A CASE REPORT RECEIVED FROM A CONSUMER IN THE UNITED STATES ON (B)(6) 2014 ON A COMPANY INTERNET SITE. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE WAS IN PAIN. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED SHE WAS FORCED TO HAVE SURGERY TO REMOVE ESSURE, SURGERY WILL BE ON DAY AFTER DATE OF POSTING. SHE WAS TIRED OF BEING IN PAIN AND HER INSURANCE WILL NOT COVER REMOVAL SO SHE AND HER HUSBAND ARE FORCED TO PAY OUT OF POCKET FOR THE SURGERY. NOBODY SHOULD HAVE TO GO THROUGH THIS PAIN. ESSURE PROBLEMS DESTROY LIVES. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 15-SEP-2015 (ONLINE POSTING FROM CONSUMER): ESSURE PERFORATED HER TUBE. ADDITIONALLY, SHE POSTED A PICTURE OF A SURGICAL INTERVENTION. CASE WAS UPGRADED TO INCIDENT. FOLLOW UP INFORMATION RECEIVED ON 24-SEP-2015: SINCE PRIVATE CONTACT DETAIL OF THE REPORTER HAS NOT BEEN PROVIDED, FOLLOW-UP CANNOT BE OBTAINED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED VIA COMPANY INTERNET SITE. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE PERFORATED HER TUBE. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT MECHANISM OF ESSURE PERFORATION WAS UNKNOWN; GIVEN EVENT'S NATURE CAUSALITY

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WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION. THE CONSUMER INITIALLY STATED SHE WOULD NEED A SURGERY TO REMOVE ESSURE; THEN UPON FOLLOW-UP SHE POSTED A PICTURE OF A SURGICAL INTERVENTION (SUGGESTING THE PREVIOUSLY MENTIONED SURGERY WAS PERFORMED). SINCE PRIVATE CONTACT DETAIL OF THE REPORTER HAS NOT BEEN PROVIDED, FOLLOW-UP CANNOT BE OBTAINED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 09-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057184	CONCEPTUS-BAYER	10/12/2015	10/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): L2138
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER BEING IMPLANTED WITH ESSURE COILS I WAS HAVING SEVERE CRAMPING AND EXTREMELY PAINFUL INTERCOURSE WITHIN 6 MONTHS. I HAD THEM FOR 7 YEARS. FOUR YEARS AGO I BEGAN HAVING HORRIBLE PAIN UNDER MY BREASTBONE WAKING ME UP FROM A DEAD SLEEP. THE TIME THEY FIGURED OUT THE PROBLEM I WAS SEPTIC AND HAD TO HAVE EMERGENCY GALLBLADDER SURGERY. I HAD TO STAY 4 DAYS IN THE HOSPITAL DUE TO INCREASING INFECTION. MY IMMUNE SYSTEM WAS SHOT WHICH LEAD TO PRECANCEROUS CELLS ON CERVIX THAT RAPIDLY PROGRESSED SO I HAD TO HAVE A HYSTERECTOMY AND CERVIX REMOVED AT THE (B)(6). I HAVE CONTINUED TO DETERIORATE. I HAVE ACID REFLUX, IBS, HIGH BLOOD PRESSURE, THYROID ISSUES, SEVERE TOOTH DECAY, ANXIETY, DEPRESSION, BOUTS OF SUICIDAL, SEVERE ABDOMINAL PAIN AND BLOATING, JOINT PAIN/STIFFNESS, LOSING MY HAIR, EXTREME BRAIN FOG AND MEMORY ISSUES, UNEXPLAINED SWELLING IN HANDS, ARM, SHOULDER, FEET, LEGS, REPEAT INFECTIONS, REPEAT AND MULTIPLE OVARIAN CYSTS, HEADACHES/MIGRAINES. I NEVER HAD ANY OF THIS UNTIL ESSURE AND I KNOW I'M FORGETTING OTHER ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057185	BAYER	10/12/2015	10/20/2015

Event Information:

Event Date (B3): 4/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): NA
Catalog # (E4): NA
Lot #(E4): NA

Single Use: *
Implant Date (E6): 4/8/2010
Explant Date (E7): 12/18/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH THE ESSURE DEVICE IN 2010. SINCE THEN I HAVE HAD DEBILITATING CRAMPS TWO WEEKS BEFORE AND AT LEAST A WEEK AFTER MY PERIOD. I'VE BEEN HOSPITALIZED FOR UNFOUNDED REASONS. MY EYESIGHT HAS DETERIORATED TO WHERE I NOW HAVE TO WEAR BIFOCALS AND CANNOT BE WITHOUT MY GLASSES FOR MORE THAN AN HOUR. I'VE HAD AT LEAST 5 TEETH PULLED IN THE LAST 2 YEARS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057195	BAYER	10/12/2015	10/20/2015

Event Information:

Event Date (B3): 3/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/15/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE WAS PLACED IN ME A YEAR AND A HALF AGO. SINCE, MY HEALTH HAS SIGNIFICANTLY DECLINED! I AM A SINGLE MOTHER OF 4 AND NOW I AM UNABLE TO WORK, TAKE CARE OF MY KIDS, CLEAN MY HOUSE, COOK, WASH CLOTHES, AND PRACTICALLY AM ON BEDREST. I AM IN PAIN MOST EVERYDAY OF MY LIFE. I HAVE SEVERE ABDOMINAL PAIN, BLOATING, ITCHY SKIN, BRAIN FOG, HEAVY BLEEDING, BLOOD CLOTS ON MY MENSTRUAL CYCLE (WHICH LASTS FOR MUCH LONGER THAN BEFORE) MY BODY ACHES, MY JOINTS HURT, I AM VERY EMOTIONAL AND HAVE PANIC/ANXIETY ATTACKS NOW. NONE OF THESE SYMPTOMS DID I HAVE BEFORE ESSURE. PLEASE BY THE GRACE OF GOD, HELP ME!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056913	BAYER	10/13/2015	10/13/2015

Event Information:

Event Date (B3): 10/30/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) NON PRECIOUS METAL ALLERGY...ASTHMA

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056914	BAYER	10/13/2015	10/13/2015

Event Information:

Event Date (B3): 6/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I'VE HAD THE ESSURE COILS PUT IN, IVE HAD SEVERE PELVIC AND HIP PAIN. ESPECIALLY LEFT SIDED HIP PAIN. I'VE ALSO HAD JOINT PAIN IN MY HANDS. MY PRIMARY MD HAS DONE MULTIPLE LABS AND XRAYS TRYING TO RULE OUT ARTHRITIS. WHICH WAS RULED OUT. I'VE BEEN IN PHYSICAL THERAPY FOR THE HIP PAIN IN ORDER TO BE ABLE TO DO MY JOB. I'VE HAD A CORTISONE SHOT TO MY HIP TO DECREASE INFLAMMATION AND HELP WITH THE PAIN. I HAD A LAPROSCOPIC CYSECTOMY LESS THAN A WEEK EARLIER TO THE ESSURE IMPLANTS. NO BIRTH DEFECTS. A CESAREAN SECTION IN 2005. ALLERGIES TO MEDS-SULFA, CELEBREX, AND NIACIN. ONGOING ILLNESSES-SEASONAL ALLERGIES AND INCREASED TRIGLYCERIDES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056915	BAYER	10/13/2015	10/13/2015

Event Information:

Event Date (B3): 7/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES ALMOST DAILY, BLOATING WEIGHT GAIN OF 40 POUNDS, LOOSE STOOLS, FORGETFULNESS ANXIETY / DEPRESSION, NO SEX DRIVE, NO DESIRE TO BE AROUND ANYONE, WEAK BLADDER, PARATHYROID TUMOR, TUMOR ON MY CERVIX, BLEEDING 3 DAY THEN DON'T BLEED FOR 2 DAYS, SWEATS FOR NO EXPLAINABLE REASON FATIGUE, ALMOST LIKE I AM SPACEY

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056916	BAYER	10/13/2015	10/13/2015

Event Information:

Event Date (B3): 8/29/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE A NICKEL ALLERGY WHICH I TOLD MY DR ABOUT BEFORE THE PROCEDURE, I HAVE BEEN HAVING SEVER PELVIC AND BACK PAIN, SEVER PAIN DURING SEX LIKE MY INSIDES ARE BEING RIPPED OUT, 2 TO 3 WEEK PERIODS THEY ARE REALLY HEAVY DURING THIS TIME I AM UNABLE TO GET OUT OF BED WITHOUT CRAWLING FROM BEING SO WEAK AND HEAD THROBS LIKE I CAN HEAR MY HEART BEAT POUND IN MY HEAD, IF I STAND FOR ANY LENGTH OF TIME MY FEET START TURNING PURPLE, I ALSO HAVE NO SEX DRIVE, I HAVE HAD ANXIETY ATTACKS OUT OF NO WHERE, TINGLING SENSATION IN MY ARMS AND LEGS LIKE THEY ARE ASLEEP AND WON'T GO AWAY, MIGRAINES DAILY THAT LAST ALL DAY, WEIGHT GAIN EVEN IF I TRY TO DO EXERCISES THROUGH THE PAIN, STAYING COLD ALL THE TIME, I HAVE SHAKES WHEN I'M NOT COLD OR NERVOUS, ALSO HAVE ALLERGIC REACTIONS TO THINGS I WASN'T ALLERGIC TO BEFORE AND BAD SWELLING IF I TOUCH NICKEL, NONE OF THIS STARTED UNTIL I HAD ESSURE DONE, ONLY THING I EVER REACTED TO WAS NICKEL AND ONLY A ITCHY FEELING IF I WEAR IT ALL DAY NOW NOT EVEN FIVE MINUTES AND I'M SWOLLEN

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056917	BAYER	10/13/2015	10/13/2015

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) SINCE HAVING THE DEVICE (B)(6) 2012 I HAVE EXPERIENCED HEAVY PERIODS WITH HUGE BLOOD CLOTS, STABBING PELVIC PAIN MOSTLY ON THE RIGHT SIDE, HEADACHES, DENTAL ISSUES, HAD TO REMOVE MY THYROID DUE TO NODULES, CURRENTLY TAKING MEDICATIONS FOR LIFE. UNEXPLAINED BRUISING ON MY LEGS, RASH, ABNORMAL LABS. VOICED MY CONCERNS TO MY GYN AND WAS TOLD IT WAS NORMAL TO HAVE HEAVY BLEEDING AND PELVIC PAINS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056918	BAYER	10/13/2015	10/13/2015

Event Information:

Event Date (B3): 5/9/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED ON (B)(6) 2012, AFTER HAVING THE PROCEDURE STARTING THE ON (B)(6) I ALREADY STARTED HAVING HEAVY BLEEDING FROM THE PLACEMENT AND SEVERE CRAMPING. EVERY MONTH I CALLED QUESTIONING THE SYMPTOMS I WAS HAVING. HEAVY BLEEDING , MY PERIODS LASTING TEN DAYS WITH HEAVY BLEEDING. I ALSO HAD HORRIBLE CRAMPING, MIGRAINES, AND CHRONIC FATIGUE. I WOULD MAKE AN APPOINTMENT AND WOULD BE GIVEN LYSTEDA TO HELP MY BLEEDING. MY THYROID WAS BEING CHECKED AND STILL SHOWING NO CHANGE AND WAS BALANCED. I ALSO ALMOST EVERY OTHER MONTH WOULD HAVE A URINARY TRACT INFECTIONS AND VAGINAL BACTERIAL INFECTIONS. I ALSO STARTED SEEING A NEUROLOGIST DUE TO HORRIBLE MIGRAINES . I WAS GETTING THEM ALMOST EVERY MONTH. I ACTUALLY HAD TO GO TO THE EMERGENCY ROOM SEVERAL TIMES FOR THESE MIGRAINES. MY NEUROLOGIST COULD NOT PINPOINT WHAT WAS CAUSING THESE MIGRAINES. BY THIS POINT IT WAS 2014 I WENT TO MY GYNECOLOGIST EXPLAINING THAT I ALSO HAVE BEEN ENDURING JOINT POINT IN MY LEFT HAND AND ARM. MY PERIODS HAVE BEEN HEAVY FOR 2 YEARS AND I WAS EXHAUSTED FROM FEELING SICK ALL OF THE TIME. MY GYNECOLOGIST FINALLY DECIDED WE COULD GO IN AND HAVE A HYSTERECTOMY. I WAS SCHEDULED ON (B)(6) 2014 I WAS IN THE EMERGENCY ROOM FOR VAGINAL SHINGLES. EVEN WITH THE SHINGLES I STILL WENT IN FOR MY HYSTERECTOMY WHICH MY UTERUS, CERVIX AND TUBES WERE REMOVED ONLY LEAVING MY OVARIES. DR.(B)(6) WAS SURPRISED TO FIND THAT I DID NOT HAVE ANY ENDOMETRIOSIS BUT I HAD SEVERE INFLAMMATION. AFTER MY SURGERY I HOPED THIS WOULD HELP ALL OF MY SYMPTOMS BUT MY JOINT PAIN, MIGRAINES AND FATIGUE STILL DID NOT GO AWAY. IN 2014 I CONTINUED GOING TO MY REGULAR DR. (B)(6) HAVING BLOOD WORK TO SEE IF I HAD AN AUTOIMMUNE DISEASE. I

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STARTED TO BREAK OUT IN HIVES WITH NO EXPLANATION. IN (B)(6) I STARTED SEEING A RHEUMATOLOGIST WHO DIAGNOSED ME WITH UNDIFFERENTIATED CONNECTIVE TISSUE DISEASE. I ALSO SAW (B)(6) AND WAS DIAGNOSED WITH AN ALLERGY TO NICKEL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056919	BAYER	10/13/2015	10/13/2015

Event Information:

Event Date (B3): 1/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, PELVIC PAIN, DISCHARGE, HOT FLASHES, NIGHT SWEATS, BLEEDING BETWEEN PERIODS, YEAST INFECTIONS, BACTERIAL VAGINOSIS, UTI, ITCHING, BURNING, OF VAGINAL ENTRANCE, PAIN: BACK, JOINT, LEG, BREAST, GAS, CONSTIPATION, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN HEADACHES, BRAIN FOG, FORGETFULNESS, ANXIETY, MOOD SWING, DEPRESSION, RINGING IN THE EARS HIGH BLOOD PRESSURE, SWELLING OF THE LEGS AND FEET, DENTAL ISSUES, WEIGHT ISSUES, EXCESSIVE SWEATING, DRY SKIN/HAIR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056920	BAYER	10/13/2015	10/13/2015

Event Information:

Event Date (B3): 11/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) AFTER HAVING THE ESSURE DONE L, HAVE BEEN EXPERIENCING SEVERE HEAVY BLEEDING, BACK PAIN, JOINT PAIN AND LIGHTHEADED ETC...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056921	BAYER	10/13/2015	10/13/2015

Event Information:

Event Date (B3): 11/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEFORE THE DEVICE I HAD DEPRESSION PTSD AND ANXIETY. AFTER I HAD GOTTEN THE DEVICE I BLED FOR AT LEAST 2 MONTHS. NOW I SUFFER SEVERE MIGRAINE DAILY BODY PAINS SEVER PAIN DURING MENSTURAL CYCLE AND EVERY NOW AND AGAIN I FEEL PAIN IN MY TUBES. I WAS TOLD BY THE DR WHO PLACED THEM THAT ONE BENT AS SHE INSERTED IT SO SHE HAD TO PLACE ANOTHER. SO INSTEAD OF 2 I HAVE 3 IN MY TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057061	BAYER	10/13/2015	10/16/2015

Event Information:

Event Date (B3): 2/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER STATED THAT SHE WAS IMPLANTED WITH ESSURE IN (B)(6) 2014. SHORTLY AFTER SHE STARTED EXPERIENCING VARIOUS SYMPTOMS WHICH INCLUDE HEAVY PERIODS, CRAMPING AS IF LABOR, HOT FLASHES, MIGRAINES, AND INSOMNIA. SHE HAD TWO OVARIAN CYSTS OF WHICH ONE WAS TAKEN OUT ON (B)(6) 2015. "NEED TO REMOVE THIS THING, BUT NO ONE WOULD HELP".

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057188	BAYER	10/13/2015	10/20/2015

Event Information:

Event Date (B3): 4/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 7109955

Single Use: *
Implant Date (E6): 4/2/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE IMPLANTED IN (B)(6) 2012. AFTER HSG IT WAS DISCOVERED ONE OF THE COILS WAS NOT IN THE FALLOPIAN TUBE. MY DOCTOR NEVER LOOKED OR TRIED TO LOCATE THE MISSING COIL. I HAD THE SECOND COIL PLACED IN (B)(6) 2013. SINCE THE COILS WERE PLACED, I HAVE HAD SEVERELY HEAVY PERIODS WHICH INCLUDES LARGE BLOOD CLOTS, BLEEDING AFTER SEX, SEVERE BLOATING, WEIGHT GAIN, HOT FLASHES, NIGHT SWEATS, FREQUENT URINATION AND WAS ADMITTED TO THE ER FOR SEVERE ABDOMINAL PAIN OF WHICH THE CAUSE WAS NEVER DETERMINED. I WAS ALSO NEVER GIVEN A NICKEL ALLERGY TEST BEFORE HAVING THE COILS PLACED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057189	BAYER	10/13/2015	10/20/2015

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

RECEIVED THE ESSURE, I BELIEVE IN (B)(6) 2012 (NOT SURE OF EXACT DATE), I HAVE HAD MORE CRAMPS AND BLEEDING, PAIN DURING SEX, AND LOW BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01182	BAYER HEALTHCARE LLC	10/14/2015	10/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C22907

Single Use: Y
Implant Date (E6): 5/8/2015
Explant Date (E7): 5/8/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 12-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C22907, INSERTION ON (B)(6) 2015. PHYSICIAN REPORTED THAT DURING ESSURE PROCEDURE, ON (B)(6) 2015, IT LOOKED LIKE PIECES OF THE CATHETER WERE COMING OFF AFTER IT WENT THROUGH THE SCOPE. NO BILATERAL PLACEMENT WAS ACHIEVED. THE PATIENT HAD NO INJURY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING THE PROCEDURE IT LOOKED LIKE PIECES OF THE CATHETER WERE COMING OFF AFTER IT WENT THROUGH THE SCOPE. THIS EVENT, REGARDED AS BREAKAGE OF ESSURE CATHETER, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

FOLLOW UP RECEIVED ON 21-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(64). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS RE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01183	BAYER HEALTHCARE LLC	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN (B)(6) 2014. ESSURE PLACEMENT WAS DIFFICULT ON RIGHT SIDE. AT THE TIME OF PLACEMENT; 3 EXPANDED OUTER COILS WERE VISIBLE ON LEFT SIDE AND 4 EXPANDED OUTER COILS ON RIGHT SIDE. THREE MONTHS POST-INSERT PLACEMENT CONFIRMATION TEST (MODIFIED HSG) SHOWED LEFT IMPLANT WAS IN PLACE AND FALLOPIAN TUBE OCCLUDED, RIGHT IMPLANT WAS STRAIGHT WITH TUBAL PATENCY, SUSPICION OF PERFORATION. FOR UNSPECIFIED REASON, HYSTEROSCOPY WAS DONE AGAIN AND NO EXPANDED OUTER COILS WERE VISIBLE. IN (B)(6) 2014, LAPAROSCOPY WAS DECIDED FOR FALLOPIAN TUBE LIGATION. DURING LAPAROSCOPY: NO IMPLANTS WERE VISIBLE. DISTAL SALPINGECTOMY WAS DONE LEAVING THE PROXIMAL PART AND INTERSTITIAL PORTION OF THE FALLOPIAN TUBE; IMPLANTS WERE NOT REMOVED. AT ONE YEAR, THE PATIENT COMPLAINED OF CHRONIC LEFT PELVIC PAIN EPISODES. THERE WERE NO OBVIOUS CAUSE PAIN EPISODES. THERE WAS NO KNOWN NICKEL ALLERGY (ALLERGY TO NICKEL TEST WAS NOT DONE BUT WAS TO BE REQUESTED). NO ADENOMYOSIS WAS REPORTED. PLAIN ABDOMEN X-RAY WAS DONE ON AN UNSPECIFIED DATE AND 2 IMPLANTS WERE SEEN; RIGHT IMPLANT APPEARED ELONGATED. PROPOSITION: LAPAROSCOPIC INVESTIGATION IN GYNECOLOGICAL SURGERY UNIT AFTER MRI FOR MORE PRECISE IMPLANT LOCALIZATION AND COMPLETE SALPINGECTOMY WITH IMPLANTS REMOVAL. FOLLOW-UP INFORMATION RECEIVED ON 09-OCT-2015 NCA NUMBER WAS REPORTED AS (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER 3 MONTH HSG (HYSTEROSALPINGOGRAM) SHOWED RIGHT IMPLANT WAS STRAIGHT WITH TUBAL PATENCY; PHYSICIAN SUSPECTED A PERFORATION. A

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LAPAROSCOPY WAS PERFORMED AND NO IMPLANTS WERE SEEN; PHYSICIAN DID A DISTAL SALPINGECTOMY LEAVING ESSURE DEVICES IN PLACE. ONE YEAR AFTER ESSURE INSERTION, PATIENT COMPLAINED OF CHRONIC LEFT PELVIC PAIN. AN X-RAY SHOWED RIGHT DEVICE WAS ELONGATED. THE PHYSICIAN IS PLANNING TO DO ANOTHER LAPAROSCOPY WITH COMPLETE SALPINGECTOMY AND IMPLANTS REMOVAL. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE PAIN DURING AND AFTER THE PROCEDURE. IN THIS PARTICULAR CASE, ESSURE INSERTION WAS REPORTED AS DIFFICULT ON RIGHT SIDE. THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED DEVICE SHAPE ALTERATION AND POSSIBLE PERFORATION OF RIGHT ESSURE DEVICE. ALTHOUGH THE EXACT MECHANISM OF THE EVENTS IS UNKNOWN; GIVEN THEIR NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE SURGICAL INTERVENTION WAS REQUIRED (LAPAROSCOPY PERFORMED DUE TO SUSPICION OF PERFORATION AND SECOND PROCEDURE WILL BE REQUIRED FOR ESSURE REMOVAL). A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 19-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01184	BAYER HEALTHCARE LLC	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 3/31/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO AN ADULT FEMALE PATIENT WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE® ENERIC REIMBURSEMENT PROGRAM. THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 AND HAD BEEN IN PAIN SINCE ESSURE PLACEMENT. IN (B)(6) 2014 SHE WAS DIAGNOSED WITH ALLERGY TO NICKEL. ON (B)(6) 2015 SHE HAD A CELIOSCOPY WITH SALPINGECTOMY AND ESSURE REMOVAL. HISTOLOGY WITHOUT ANY PARTICULARITY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO EXPERIENCED PAIN SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A CELIOSCOPY WITH SALPINGECTOMY AND ESSURE REMOVAL, APPROXIMATELY 7 YEARS AFTER DEVICE INSERTION. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY CANNOT BE EXCLUDED. ADDITIONALLY, THE NON-SERIOUS EVENT ALLERGY TO NICKEL WAS REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW UP INFORMATION RECEIVED ON 26-OCT-2015: THE NCA NUMBER WAS ADDED AS (B)(4). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WH

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01185	BAYER HEALTHCARE LLC	10/14/2015	10/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D31445

Single Use: Y
Implant Date (E6): 9/14/2015
Explant Date (E7):
Device Available for Evaluation (C6): R
Date Device Returned to Mfr (C3): 11/10/2015

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE GENERIC REIMBURSEMENT PROGRAM. ON (B)(6) 2015 IT WAS ATTEMPTED TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WITH LOT NUMBER D31445. IT WAS REPORTED THAT AT THE TIME TO PLACE ESSURE; IT COULD NOT BE RELEASED AS IT SEEMED TO BE BROKEN AT THE EXTREMITY OF THE DELIVERY CATHETER. INSERTION FAILED DUE TO TECHNICAL REASON. ONE ESSURE WAS CONCERNED. FOLLOW UP INFORMATION RECEIVED FROM THE PHARMACIST ON (B)(6) 2015: THE BREAKAGE WAS DIAGNOSED DURING THE PLACEMENT. THE IMPLANT DID NOT RELEASE FROM THE DELIVERY CATHETER. THE BREAKAGE OCCURRED ON THE GREEN RELEASE CATHETER. THE SURGEON REALIZED THAT ESSURE WAS NOT WELL PLACED IN THE DELIVERY CATHETER WHEN ESSURE WAS BEING RELEASED. THE INSTRUCTIONS FOR USE WERE FOLLOWED. ESSURE WAS NOT PLACED. THE BROKEN PIECES WERE RETRIEVED. THERE WAS NO PATIENT INJURY. THE BREAKAGE COULD NOT HAVE LED TO SERIOUS INJURY UNDER LESS FORTUNATE CIRCUMSTANCES. THE DEVICE WAS AVAILABLE. THE PATIENT RECOVERED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A 47(B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND AT THE TIME OF DEVICE PLACEMENT; BREAKAGE OCCURRED ON THE GREEN RELEASE CATHETER (PREVIOUSLY REPORTED AS IT SEEMED TO BE BROKEN AT THE EXTREMITY OF THE DELIVERY CATHETER). THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, DURING ESSURE PLACEMENT, IT WAS REPORTED THAT THE IMPLANT DID NOT RELEASE FROM THE DELIVERY

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CATHETER, THEN THE DEVICE BREAKAGE OCCURRED. CONSIDERING THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT RECEIVED ON 07-DEC-2015: (B)(4). ONE DEVICE WAS RECEIVED ON 10-NOV-2015. FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER C

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01186	BAYER HEALTHCARE LLC	10/14/2015	10/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D30803

Single Use: Y
Implant Date (E6): 9/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015 WITH LOT NUMBER D30803. IN THE OPERATING ROOM, DURING ESSURE PLACEMENT; THE END PART OF DELIVERY CATHETER WHICH ALLOW INTRODUCING DEVICE IN BETTOCCHI BROKE. THE OPERATING CHANNEL STOPCOCK COULD HAVE BEEN IN CLOSE POSITION BEFORE PUTTING END PART OF DELIVERY CATHETER. BILATERAL PLACEMENT WAS NOT PERFORMED; ONE INSERT HAD ALREADY BEEN INSERTED ON LEFT SIDE. NO POSTOPERATIVE CONSEQUENCES WERE OBSERVED FOR PATIENT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND THE END PART OF DELIVERY CATHETER WHICH ALLOW INTRODUCING DEVICE IN BETTOCHI BROKE DURING THE PROCEDURE. NO CONSEQUENCES WERE OBSERVED FOR THE PATIENT. THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, CONSIDERING THE REPORTED DEVICE BREAKAGE OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

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Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED VIA DEVICE BREAKAGE QUESTIONNAIRE ON 16-NOV-2015: THE ESSURE, LOT NUMBER D30804, BREAKAGE WAS DIAGNOSED DURING PLACEMENT ON (B)(6) 2015. THE REPORTER DID NOT REMEMBER HOW THE BREAKAGE OCCURRED EXACTLY. A NEW ATTEMPT WAS PERF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01187	BAYER HEALTHCARE LLC	10/14/2015	10/14/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 15-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) PLACED AROUND 2007 THE FOR PERMANENT CONTRACEPTION. THE SALES CONSULTANT REPORTED THAT A PHYSICIAN WILL BE PERFORMING AN ESSURE REMOVAL ON THE FOLLOWING DAY OF REPORT ((B)(6) 2015). THE REASON FOR THE REMOVAL IS BECAUSE THE PATIENT WAS EXPERIENCING WEIGHT GAIN, FATIGUE, AND HEAVY MENSTRUAL PERIODS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 04-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) PLACED AROUND 2007 FOR PERMANENT CONTRACEPTION. SHE HAD HEAVY MENSTRUAL PERIODS AND ESSURE

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REMOVAL WAS SCHEDULED. THIS EVENT IS SERIOUS DUE TO THE PLANNED REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE ONSET DATE OF HEAVY MENSTRUAL PERIOD IS NOT CLEAR. HOWEVER, SINCE IT OCCURRED DURING ESSURE USE AND NO ALTERNATIVE EXPLANATION WAS PROVIDED, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. OTHER NON-SERIOUS EVENTS WERE REPORTED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION (FOLLOW UP) IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 22-DEC-2015: FOLLOW-UP ATTEMPTS HAVE BEEN PERFORMED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (ESS205) (FALLOP

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056973	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 3/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SECOND HSG TEST SHOWED FAILURE OF DEVICE ON ONE SIDE. OBGYN RECOMMENDED SURGICAL TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056974	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE SYMPTOMS STARTED AROUND THIS TIME. DIZZINESS, BLURRED VISION, PAIN DURING INTERCOURSE, HAIR LOSS, MOOD SWINGS. MY PERIODS HAVE LASTED 10-15 DAYS SINCE THE DEVICE WAS PUT IN. JOINT PAIN, MY ENTIRE BODY ACTUALLY WENT NUMB AND I COULDN'T WALK A COUPLE TIMES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056975	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 2/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING MY BABY MY HEALTH WAS IN GREAT CONDITION. HOWEVER, ON (B)(6) 2015 I WENT TO SEE MY OBGYN FOR IMPLANTATION OF DEVICE. UPON INSERTING INTO LEFT SIDE I FELT AN UNCOMFORTABLE PINCH FOLLOWED BY A SHARP PAIN THEY NOTED THERE WOULD BE DISCOMFORT. AT HOME MY HEALTH IMMEDIATELY TOOK A TURN FOR THE WORST. I BEGAN HAVING NIGHT SWEATS SO BAD THAT I WOULD WAKE UP WET AND WOULD NOT BE ABLE TO LAY BACK DOWN IN MY BED DUE TO THE AMOUNT OF SWEAT WHILE I WAS TRYING TO SLEEP. I WAS HAVING HORRIFIC PAIN SO BAD THAT MOVING WAS VERY DIFFICULT. I COULD NOT EVEN WALK AROUND MY HOME WITHOUT HOLDING ON TO THE WALLS AND FURNITURE FOR SUPPORT. MY BODY WAS VERY WEAK AND I CONTINUED TO EXPERIENCE THESE SYMPTOMS ALONG WITH TREMORS AND CHILLS AND A REALLY BAD COUGH, LIKE MY ASTHMA WAS BEING TRIGGERED BY SOMETHING. MY IMPLANTING OB TRANSFERRED ME TO A DOCTOR ON THE OPPOSITE SIDE OF THE CLINIC AND I HAD NOT SEEN HIM AT ALL SINCE. THIS HORRIBLE PAIN AND DISCOMFORT CONTINUED AND AFTER REPORTING THE ISSUES TO MY NEW O.B SHE TRIED PAIN MEDICATION. IT DID NOT WORK AND AFTER CONTINUING TO RETURN REPORTING THE ISSUES SHE FINALLY RECOMMENDED HYSTERECTOMY FOR REMOVAL. I WAS NOT ABLE TO GET THE OPERATION AT THAT TIME. SINCE THEN I HAVE HAD A RUPTURED CYST, MILD STROKE CLASSIFIED AS TIA, HAIR LOSS, FATIGUE, JOINT, BACK PROBLEMS, TISSUE CHUNKS PASSING, 3 WEEK CYCLES, WEIGHT GAIN OF (B)(6) LBS MONTHLY (FLUCTUATING) EXTREMELY PAINFUL CYCLES, AND AM CURRENTLY FACING THE SECOND EVALUATION BY A NEW OB FOR A HYSTERECTOMY TO REMOVE THESE HORRIBLE DEVICES DUE TO THE SEVERITY OF THE DAMAGES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056976	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN IMPLANTED WITH A MEDICAL DEVICE CALLED ESSURE ON (B)(6) 2013. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS B09710 . EXPIRATION DATE 3/2016. THE ONSET OF MY COMPLAINT STARTED APPROXIMATELY ON (B)(6) 2015. THESE AREA A LIST OF SIDE EFFECTS THAT I HAVE EXPERIENCED DUE TO ESSURE, SEVERE CRAMPING, SEVERE HEADACHES, SEVERE HAIR LOSS, VISION CHANGE, SEVERE BLOATING, UNSTABLE WEIGHT UP/DOWN, MOOD CHANGES AND IRREGULAR MENSES. I HAVE BEEN FORCED TO MISS MANY DAYS FROM WORK BECAUSE I JUST CAN'T GET OUT OF BED DUE TO SEVERE PAIN. I SAW MY PRIMARY DR. (B)(6). HE DID NOT KNOW WHAT ESSURE WAS. HE RECOMMENDED ME TO SCHEDULE AN APPOINTMENT WITH MY OB GYN. THE DEVICE IS STILL INSIDE OF ME. I FEAR THAT MY SYMPTOMS WILL BECOME LIFE THREATENING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056977	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 2/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACEMENT ON (B)(6) 2013, AND STARTING FEELING SYMPTOMS RIGHT AFTER I STOP NURSING MY BABY, NINE MONTHS LATER. DURING THE TIME I NURSING, I DIDN'T GET MY PERIOD. AS SOON AS MY PERIOD STARTED BACK UP THAT'S WHEN THE HORRIBLE NIGHTMARE BEGAN. I VISITED THE ER NUMEROUS TIMES FOR DIFFERENT SYMPTOMS EVERY TIME. MY SYMPTOMS WERE: HEADACHES, DIZZINESS, FATIGUE, ANXIETY, PANIC ATTACKS PALPITATIONS, CHEST PAIN, RESTLESS LEG SYNDROME, ABDOMINAL PAIN, CONSTIPATION, HEAVY PERIODS, HAIR LOSS, WEIGHT LOSS, AND FLU LIKE SYMPTOMS AND MORE. IT WAS HORRIBLE. MY FAMILY OF SIX WAS SUFFERING WITH ME, BECAUSE I COULDN'T BE THERE FOR MY THEM. ALL THIS CAUSED A LOT OF STRESS FOR ME AND MY FAMILY. I WAS FEELING GUILTY AND BLAMING MYSELF FOR MAKING THE WORST MISTAKE OF MY LIFE, BY CHOOSING ESSURE. I WAS 100% HEALTHY BEFORE ESSURE. BEFORE ESSURE I WORKED A FULL TIME, NURSED MY NEW BABY , I WAS SEARCHING AROUND TO PURCHASE A NEW HOME, AND ALSO HAVE 3 MORE SCHOOL AGE KIDS. ALSO FINISH MY ASSOCIATE DEGREE WHILE EXPECTING MY THIRD CHILD. AFTER ESSURE I COULD BARELY TAKE CARE OF MYSELF.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056978	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 10/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIAGNOSED WITH A CORNUAL (ECTOPIC) PREGNANCY. I WILL NEED AN EMERGENCY SURGERY TO REMOVE THE EMBRYO THAT HAS IMPLANTED IN MY FALLOPIAN TUBE AND TO REMOVE MY ESSURE COILS, FALLOPIAN TUBES, AND POSSIBLY MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056979	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I GOT IT PUT IN FROM DAY ONE I HAD PAIN, IRREGULAR PERIODS, BACTERIAL INFECTIONS, NAUSEA, HEADACHES, DIZZINESS, ANXIETY AND I ACTUALLY HAD TO HAVE A PARTIAL HYSTERECTOMY. THE ONE OVARY AND TUBE I HAD LEFT STILL HAD ESSURE WHICH THEN FELL OUT BACK IN 2014. I'M STILL HAVE ONGOING ISSUES WITH THE SYMPTOMS ABOVE BUT MAYBE EVEN WORSE NOW. IT'S CAUSING ISSUES IN MY EVERYDAY LIFE AND RELATIONSHIPS. MY PROCEDURE AND ESSURE WAS COVERED BY INSURANCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056980	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 11/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED (B)(6) 2014, THE PROCEDURE ITSELF WAS NOT BAD, BUT THE DAYS WEEKS AND MONTHS FOLLOWING HAVE BEEN HELL. ESSURE HAS TAKEN MY LIFE FROM ME, I AM STILL BREATHING BUT I AM NOT LIVING. I IMMEDIATELY STARTED GETTING TERRIBLE MIGRAINES, FOLLOWED BY HEAVY DEBILITATING MENSTRUATAL CRAMPS, AND HEAVY BLEEDING SO BAD IT INTERFERES WITH EVERY DAY LIFE. I AM A MOTHER OF 6, I HAVE GONE FROM WORKING 90+ HOURS EVERY TWO WEEKS TO BEING LUCKY IF I MAKE IT THROUGH 25 HOURS EVERY TWO WEEKS DUE TO SEVERE BLEEDING AND FATIGUE. THAT'S JUST THE START, MY JOINTS CONSTANTLY HURT, MY HAIR IS FALLING OUT, I'M ALWAYS SICK, ALWAYS IN PAIN, ALWAYS NAUSEOUS, ALWAYS BLOATED, I HAVE GAINED AT LEAST 40LBS SINCE LAST (B)(6) DIFFERENT AUTOIMMUNE DISEASES, AND THE LIST GOES ON. I HAVE BEEN THROUGH TEST AFTER TEST, ULTRASOUND AFTER ULTRASOUND, HSG AFTER HSG, AND BIOPSY AFTER BIOPSY. AT (B)(6) YEARS OF AGE I AM NOW FACING AT LEAST 2 MAJOR SURGERIES TO REMOVE MY TUBES, CERVIX AND UTERUS, AND POSSIBLY MORE SURGERIES IF THEY CAN'T LOCATE THE MISSING HALF OF MY LEFT COIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056981	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 10/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). URINARY TRACT INFECTION, MAJOR PELVIC PAIN FELT LIKE CONTRACTIONS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056982	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 1/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THE ESSURE PROCEDURE DONE, I'VE EXPERIENCED WEIGHT GAIN, SHARP ABDOMINAL PAINS ON MY RIGHT SIDE, IRREGULAR PERIODS, BLEEDING AFTER INTIMACY AND FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056983	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 10/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE MIGRAINES, BOTH OCULAR AND COMPLEX; STABBING PAIN IN LEFT QUADRANT; EXTREMELY PAINFUL OVULATION; LARGE CLOTS DURING MENSTRUATION; DEPRESSION; ANXIETY; UNEXPLAINED WEIGHT GAIN; INABILITY TO LOSE WEIGHT; SEVERE BLOATING; INCONSISTENT BOWEL MOVEMENTS (VARIED BETWEEN SEVERELY CONSTIPATED AND EXTREMELY LOOSE WITH NO CHANGE IN DIET); FATIGUE; NIGHT SWEATS; DENTAL ISSUES (LEADING TO HOSPITALIZATION DUE TO UNCONTROLLABLE INFECTION); JOINT PROBLEMS; EXTREME HAIR LOSS (AT LEAST 100 INDIVIDUAL HAIRS PER WASH); POLYCYSTIC OVARIAN SYNDROME; MEMORY LOSS (IMPORTANT MEMORIES, LIKE MY CHILDREN'S FIRST STEPS, MY WEDDING DAY, IMPORTANT DATES, JUST TO NAME A FEW); CONSTANT BRAIN FOG; FORGETFULNESS; EXHAUSTION; SEVERE MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056984	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 9/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ESSURE SINE (B)(6) 2015 SINCE I AM EXPERIENCING SEVERE PELVIC PAIN, BRAIN FOG, SEVERE FATIGUE, MIGRANES, ANXIETY, WEIGHT GAIN, UTI, PID, NAUSEA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056985	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 10/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2014 I HAD THE HSG DONE AND THE RIGHT TUBE WAS NOT BLOCKED. SHORTLY AFTER THE TEST I STARTED HAVING STOMACH PAIN IN MY LOWER ABDOMEN AND LOWER BACK. STARTED STOMACH BLOATING AND HEADACHES. ON (B)(6) 2015 I WENT TO THE ER FOR SEVERE STOMACH PAIN, BLOATING, AND DIARRHEA. SEVERAL TEST WAS DONE AT THE ER AND WAS TOLD TO SEE MY DOCTOR. WENT TO MY DOCTOR AND SEVERAL MORE BLOOD TESTS WERE DONE BUT NO SCANS HAVE BEEN DONE BECAUSE I HAVE NO HEALTH INSURANCE. I LIVE IN CONSTANT PAIN IN MY ABDOMEN AND LOWER BACK AND BLOATING AND I BELIEVE IT IS CAUSE BY THE ESSURE. I HAVE NEVER HAD ANY OF THESE ISSUES BEFORE INSERTION OF ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056986	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 12/31/2001 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, CRAMPS, SWELLING ABDOMEN, LARGE CLOTS WHEN MENSTRUATION, BLEEDING MORE THEN JUST WHEN MENSES, PAIN AND BLEEDING DURING SEX, SKIN SENSITIVITY, RASH OVER BODY, IBS, JOINT PAIN, MIGRAINES, HYPERSENSITIVE TO SOUNDS, GALL BLADDER REMOVED, GERD, NISSEN FUNDOPLICATION, HIGH BLOOD PRESSURE,

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056987	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 6/20/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAINT, BRAIN FOG, ITCHY SKIN, WEIGHT GAIN, LOW ENERGY, SEVERE ANXIETY, GROIN PAIN, CYST, ENDOMETRIOSIS, SHARP PAIN ON UTERUS, LOWER AND UPPER PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056988	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 12/26/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMPLANTING ON ONE SIDE WAS COMPLICATED. CAUSED EXTREME PAIN. DR APOLOGIZED MULTIPLE TIMES ATTEMPTING TO IMPLANT. A LOST PASSED OUT WALKING OUT OF DR OFFICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056989	BAYER	10/14/2015	10/14/2015

Event Information:

Event Date (B3): 6/13/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD IMMEDIATE PAIN; I WAS SEDATED BUT NOT PUT UNDER AS SHE WAS PUTTING THE COILS IN; THE FIRST ONE WAS PAINFUL; THE SECOND ONE WAS HORRENDOUS; SHE SAID SHE PUT IT IN TOO FAR AND WAS TRYING TO BACK IT OUT; I WAS SCREAMING; THEY HAD TO HOLD ME DOWN ON THE TABLE; EXCRUCIATING PAIN, HEAVY BLEEDING AFTER LEAVING THE DOCTOR'S OFFICE. I COULD NOT CONTROL MY BLADDER AND WAS BLEEDING ALL OVER MY VEHICLE ON THE WAY MY HOME. AT HOME, I HAD ABDOMINAL AREA WAS SORE TO THE TOUCH, EVERY MENSTRUAL CYCLE AFTER THE PROCEDURE, THE BLEEDING BECAME HEAVIER. CRAMPING WENT THROUGH THE ROOF. I NEVER HAD CRAMPS BEFORE. I WOULD RUN A FEVER HIGH. HAD A HARD TIME FUNCTIONING; MENSTRUATION GOT HEAVIER AND HEAVIER AND HEAVIER, SEVERE BLOATING, DAILY PAIN DURING SEX, BLEEDING AFTER SEX, HUGE BLOOD CLOTS PASSED, FATIGUE, EXTREME ITCHY BUMPS THAT SCAR, LOSS OF APPETITE, INSOMNIA AND OTHER SLEEP TROUBLES, HANDS WOULD SHAKE AND TREMBLE, TINGLING IN MY FINGERS AND TOES, MY RIGHT ARM HAS NUMBNESS, SOMETIMES THINNING HAIR, JOINTS HURT AND POP, BACK PAIN, SOMETIMES WHEN USING THE BATHROOM I GET CRAMPS SO BAD I CANNOT STAND UP. THERE'S A SMELL IN THE VAGINA AREA, NIGHT SWEATS, MEMORY LOSS, BRAIN FOG, CONFUSION, "TAMARINE FORWARDS," MOOD SWINGS, VITAMIN D DEFICIENCY, ANEMIC, LOSS OF APPETITE, SOMETIMES HAVE A METALLIC TASTE, EXTREME LOW TOLERANCE TO ALCOHOL, WEIGHT GAIN, DEPRESSION, ANXIETY, PANIC ATTACKS, EXTREME FATIGUE. I VOMITED ANYTHING AND EVERYTHING I ATE AND DRANK. HYSTERECTOMY AFTER THE HYSTERECTOMY. I HAD SEVERE CRAMPING WORSE THAN NORMAL FOR HAVING A HYSTERECTOMY; COULD NOT HAVE A COLONOSCOPY BECAUSE OF SEVERE PAIN. THE DOCTOR GIVE ME THE MAXIMUM AMOUNT OF SEDATIVE THAT HE

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COULD WITHOUT DEPRESSING MY BREATHING. HAVING A CATHETER IN WAS MORE PAINFUL THAN ONE HAD EVER BEEN BEFORE, BACK PAIN, HARD TIME REMEMBERING THINGS ANYTHING, SHORT TERM MEMORY IS SHOT, HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057218	BAYER	10/14/2015	10/20/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/20/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

DATE OF IMPLANT: (B)(6) 2013 PATIENT AGE AT TIME OF IMPLANT: (B)(6) DESCRIPTION OF THE PROBLEM: I HAVE HAD CHRONIC PELVIC PAIN THAT IS WORSENING, SEVERE DEPRESSION, HEAVY BLEEDING THAT STARTED AFTER IMPLANTS, HEADACHES, FREQUENT MIGRAINES, VISION CHANGES, INABILITY TO LOSE WEIGHT EVEN WITH STRICT DIET AND EXERCISE, SWOLLEN ABDOMEN, FORGETFULNESS, MOOD SWINGS, SEVERAL UTI'S, PAIN DURING SEX, LOWER LIBIDO, ALLERGIC REACTIONS INCLUDING RANDOM ITCHING AND RASHES, INABILITY TO SLEEP/INSOMNIA AND SEVERAL TRIPS TO THE EMERGENCY ROOM FOR SEVERE ABDOMINAL PAIN. EVEN AFTER TRYING OTHER MEDICATIONS OR RELIEF METHODS FOR THE ABOVE LISTED PROBLEMS THEY ARE GETTING WORSE. MY DOCTOR IS WORKING WITH ME SO THAT I CAN HAVE A FULL HYSTERECTOMY TO HAVE THE ESSURE DEVICES/IMPLANTS REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057225		10/14/2015	10/20/2015

Event Information:

Event Date (B3): 6/24/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6): 6/24/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6), I HAD THE ESSURE PROCEDURE DONE BACK IN (B)(6) OF 2014. WHEN I WAS (B)(6). I HAVE BEEN MONITORING MY PERIODS FOR THE LAST 6 MONTHS AND I NOTICED THAT THEY STARTED TO BECOME LONGER AND LONGER. THIS MONTH I STARTED ON (B)(6) 2015 AND AM STILL BLEEDING TODAY (B)(6) 2015. I NOTIFIED MY DOCTOR AND THEY URGED THAT I COME IN. THE EARLIEST APPOINTMENT I COULD GET IS SCHEDULED FOR MONDAY, (B)(6). I AM IN GOOD HEALTH ALTHOUGH I WAS DIAGNOSED WITH A HYPOTHYROIDISM IN (B)(6) OF 2013. WHEN THE PROCEDURE WAS DONE, IT WENT SMOOTHLY, I ALSO HAD THE 3 MONTH CHECK UP (ESSURE CONFIRMATION TEST) EVERYTHING LOOKED GOOD. I CAME BACK 4 MONTHS LATER AND HAD MY ANNUAL CHECK UP ((B)(6) 2015) I ADVISED THE DOCTOR I STARTED HAVING MY MONTHLY MENSTRUAL CYCLE AGAIN. HE SAID IT WOULD HAPPEN. NOW I HAVE BEEN BLEEDING A LOT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056990	BAYER	10/15/2015	10/14/2015

Event Information:

Event Date (B3): 11/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SYMPTOMS OF ENDOMETRIOSIS, FATIGUE, PELVIC PAIN, BLEEDING (SOMETIMES HEAVY, WITH CLOTS) BETWEEN PERIODS, LOWER BACK PAIN, PAINFUL INTERCOURSE, CRAMPING, DIGESTIVE ISSUES/CONSTIPATION, VAGINAL DISCHARGE/DISCOMFORT

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056991	BAYER	10/15/2015	10/14/2015

Event Information:

Event Date (B3): 6/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BROKE OUT IN HIVES ALL OVER BODY WITH NO CAUSE. THIS HAPPENED MULTIPLE TIMES OVER DURATION OF TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056992	BAYER	10/15/2015	10/14/2015

Event Information:

Event Date (B3): 10/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). COIL MIGRATED TO UTERUS WITH SYMPTOMS OF BLEEDING BETWEEN PERIODS, SEVERE CRAMPING, AND FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056993	BAYER	10/15/2015	10/14/2015

Event Information:

Event Date (B3): 10/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE A NICKEL ALLERGY. WAS NEVER TOLD THERE WAS NICKEL IN ESSURE. HORRIBLE CRAMPING ON AND OFF PERIODS. STABBING PAIN IN PELVIC AREA. PAINFUL SEX. NO ENERGY. BACK PAIN. LEG PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01188	BAYER HEALTHCARE LLC	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0673, AWARENESS DATE 18-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN FINLAND WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. CONSUMER HAD ESSURE PROCEDURE DONE AND HAS BEEN SICK EVER SINCE (LITTLE OVER A YEAR PRIOR TO THIS REPORT). SHE SUFFERS FROM IRREGULAR MENSTRUAL CYCLE - BLEEDING FOR 5 DAYS, EVERY 1,5-2 WEEKS; BLEEDING AND PAIN AFTER SEX; PELVIC, LOWER BACK AND GROIN PAIN; SKIN RASHES, PIMPLES AND HAIR GROWTH. SHE HAS NOW BEEN PUT ON LINE FOR A HYSTERECTOMY, BUT DUE TO BEING SO SICK SHE LOST HER JOB. FOLLOW-UP FROM 16-SEP-2015: UPON REQUEST FROM REGULATORY AUTHORITY THE CASE WAS UPGRADED TO INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 09-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: MENSTRUATION IRREGULAR. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4). BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THEN HAD IRREGULAR MENSTRUAL CYCLE (BLEEDING FOR 5 DAYS, EVERY 1,5-2 WEEKS). THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND EVENT IRREGULAR MENSTRUAL CYCLE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT; SINCE NO INTERVENTION OR HOSPITALIZATION HAD BEEN CONFIRMED AT THE TIME OF THIS REPORT. HOWEVER, UPON HEALTH AUTHORITY (HA) REQUEST IT WAS UPGRADED TO INCIDENT (IN LINE WITH HA ASSESSMENT). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01189	BAYER HEALTHCARE LLC	10/15/2015	10/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOCIAL MEDIA REPORT RECEIVED FROM A OTHER IN (B)(6) ON 16-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR STERILIZATION. IT WAS REPORTED THAT CONTROL WAS PERFORMED AT 3 MONTHS FOLLOWING INSERTION VIA ULTRASOUND AND X-RAY. INTRA-UTERINE MIGRATION OF RIGHT ESSURE INSERT WAS NOTICED; LEFT INSERT WAS SEEN AS WELL PLACED ON X-RAY. THE PATIENT HAD NO SYMPTOM. RIGHT ESSURE INSERT REMOVAL WAS PLANNED WITH UNILATERAL SURGICAL LIGATION WITH CLIP VIA LAPAROSCOPY. DURING ABDOMINAL CAVITY EXAMINATION VIA LAPAROSCOPY, BILATERAL INTRAPERITONEAL MIGRATION OF THE INSERTS WAS DISCLOSED. BOTH INSERTS WERE REMOVED AND BILATERAL FALLOPIAN TUBES LIGATION WITH CLIP WAS PERFORMED. MANAGEMENT OF THE PATIENT AT THE HOSPITAL IN OUTPATIENT, SHE WAS DISCHARGED THE SAME DAY IN THE EVENING. NO FURTHER INFORMATION WILL BE PROVIDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A BILATERAL INTRAPERITONEAL MIGRATION OF THE INSERTS WAS DIAGNOSED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A FALLOPIAN TUBE PERFORATION DURING INSERTION. IN THIS CASE, CONSUMER HAD X-RAY AND ULTRASOUND 3 MONTHS POST ESSURE INSERTION; WHICH SHOWED AN INTRAUTERINE MIGRATION OF RIGHT ESSURE. SHE WAS SUBMITTED TO A LAPAROSCOPY AND DURING THIS SURGERY BOTH INSERTS WERE SEEN IN

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INTRAPERITONEAL CAVITY AND WERE REMOVED. CONSIDERING EVENT'S NATURE AND ITS CLOSE TEMPORAL RELATIONSHIP WITH ESSURE PROCEDURE; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 19-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01190	BAYER HEALTHCARE LLC	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA REGULATORY AUTHORITY IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION IN (B)(6) 2013. INSERTION WAS NOT SUCCESSFUL BECAUSE IMPLANT DID NOT GET OFF FROM CATHETER. THE PATIENT WAS TOLD THAT WHOLE IMPLANT WAS MANAGED TO REMOVE FROM HER. IN (B)(6) 2015 IN PRIVATE CLINIC, IT WAS NOTICED THAT PART OF ESSURE-IMPLANT WAS STILL INSIDE THE PATIENT. A NEW PROCEDURE, IN WHICH THE PART OF IMPLANT WILL BE REMOVED, HAD TO BE PERFORMED TO THE PATIENT. FOLLOW-UP INFORMATION RECEIVED ON 08-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE (BREAKAGE) IN THE CONTEXT OF A COMPLICATED INSERTION. HOWEVER, NO MEDICAL EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. AT THIS POINT IN TIME NO BATCH NUMBER WAS REPORTED, THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED

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AND NO MEDICAL EVENTS WERE REPORTED. DEVICE SIMILAR CASE LISTING THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(4) 2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: DEVICE BREAKAGE: THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A PHYSICIAN VIA REGULATORY AUTHORITY. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS PROCEDURE WAS NOT SUCCESSFUL BECAUSE IMPLANT DID NOT GET OFF FROM CATHETER. PATIENT WAS INFORMED THE IMPLANT WAS REMOVED. HOWEVER, APPROXIMATELY 2 YEARS LATER, IT WAS DISCOVERED PART OF ESSURE-IMPLANT WAS STILL INSIDE HER. A NEW PROCEDURE (NOT SPECIFIED HAD TO BE PERFORMED TO REMOVE THIS PART. THE REPORTED EVENT, REGARDED AS DEVICE BREAKAGE, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. HOWEVER, THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THAT HERE WAS NO EVENT REPORTED WHICH INDICATED A NEW TECHNICAL FAILURE MODE FOR THE DEVICE (LISTED). SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, PHYSICIAN HAD DEPLOYMENT DIFFICULTIES (IMPLANT DID NOT GET OFF FROM CATHETER) AND INSERTION WAS UNSUCCESSFUL. THIS SUGGESTS A DIFFICULT PROCEDURE, WHICH MAY HAVE CONTRIBUTED FOR DEVICE BREAKAGE. CONSIDERING THAT THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE INSERTION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01191	BAYER HEALTHCARE LLC	10/15/2015	10/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED ON AN UNSPECIFIED DATE. PATIENT COMPLAINED OF PELVIC PAIN AFTER ESSURE WAS PLACED. PHYSICIAN INFORMED THAT HE DID NOT PLACE THIS ESSURE. HE DID THE HYSTERECTOMY TO REMOVE ESSURE. ALSO IT WAS INFORMED THAT PATIENT HAD ADENOMYOSIS. PHYSICIAN STATED THE PAIN COULD HAVE BEEN OCCURRED DUE TO PRE-EXISTING ADENOMYOSIS AND MAY NOT HAVE BEEN ATTRIBUTED TO ESSURE. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS SUBMITTED TO A HYSTERECTOMY TO REMOVE ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) DUE TO PELVIC PAIN. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, PATIENT HAD ADENOMYOSIS. ACCORDING TO THE PHYSICIAN, THIS PRE-EXISTING CONDITION COULD HAVE BEEN THE REASON FOR HER PAIN, WHICH MAY NOT HAVE BEEN ATTRIBUTED TO ESSURE. COMPANY AGREES WITH PHYSICIAN ASSESSMENT. NEVERTHELESS, SINCE LIMITED INFORMATION WAS PROVIDED AND AS THE PATIENT COMPLAINED OF PAIN AFTER ESSURE PROCEDURE; A CONTRIBUTORY ROLE OF THE SUSPECT DEVICE IN PATIENT'S PAIN CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 29-DEC-2015: FOLLOW-UP ATTEMPTS WERE MADE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS SUBMITTED TO A HYSTERECTOMY TO REMOVE ESS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01192	BAYER HEALTHCARE LLC	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 6/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 17-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. PATIENT HAD BLEEDING AND PAIN SINCE INSERTION. LAPAROSCOPIC SURGERY WAS SCHEDULED FOR THE DAY OF THE REPORT ((B)(6) 2015) TO REMOVE BOTH FALLOPIAN TUBES AND ESSURE COILS. OUTCOME OF THE EVENTS WAS REPORTED AS ONGOING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAS HAD BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND PAIN (INTERPRETED AS PELVIC PAIN) SINCE INSERTION. SHE WAS SCHEDULED FOR LAPAROSCOPIC SURGERY TO REMOVE FALLOPIAN TUBES AND ESSURE COILS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN ESSURE AND THE REPORTED EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT ANALYSIS RECEIVED ON 19-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01193	BAYER HEALTHCARE LLC	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 7/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/7/2015
Explant Date (E7): 9/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NON-HEALTH PROFESSIONAL IN UNITED STATES ON 18-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2015 FOR PERMANENT CONTRACEPTION. ADDITIONAL INFORMATION RECEIVED ON 18-SEP-2015. ON 13-AUG-2015 CONSUMER WAS SEEN AND SHE HAD BEEN EXPERIENCING PELVIC PAIN FOR 3 TO 4 MONTHS POST ESSURE INSERTION. AN ULTRASOUND WAS PERFORMED ON (B)(6) 2015 AND SHOWED THAT LEFT COIL IS PROTRUDING 2.9 CM INTO ENDOMETRIAL CAVITY. THE REPORTER, WHO IS THE SURGICAL SCHEDULER, STATED THAT CONSUMER IS GETTING THE ESSURE REMOVED SURGICALLY AND WOULD LIKE TO KNOW THE BILLING CODE FOR REMOVAL OF ESSURE. SHE WOULD NOT PROVIDE NAME OF PHYSICIAN IN HER GROUP WHO SAW PATIENT. FOLLOW-UP INFORMATION RECEIVED ON 04-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY

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CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN ULTRASOUND SHOWED LEFT COIL IS PROTRUDING 2.9CM INTO ENDOMETRIAL CAVITY. SHE IS SCHEDULED TO HAVE ESSURE REMOVED SURGICALLY. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THE PRESENT CASE, CONSUMER WAS EXPERIENCING PELVIC PAIN AFTER ESSURE INSERTION AND AN ULTRASOUND SHOWED THE LEFT COIL WAS PROTRUDING 2.9 CM INTO ENDOMETRIAL CAVITY. GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 (QUESTIONNAIRE PROVIDED FROM REPORTER): THE CONSUMER'S CONCURRENT CONDITIONS INCLUDED UNDERWEIGHT ((B)(6)). PREVIOUS GYNECOLOGICAL PROBLEMS/INTERVENTIONS WERE DENIED. ESSURE WAS INSERTED ON (B)(6) 2015. GYNECO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01194	BAYER HEALTHCARE LLC	10/15/2015	10/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64468

Single Use: Y
Implant Date (E6): 9/10/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON 18-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE GENERIC REIMBURSEMENT PROGRAM. ON (B)(6) 2015, PATIENT HAD AN ATTEMPT TO GET ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH LOT NUMBER C64468. DURING ESSURE PLACEMENT, THE INSERTION FAILED DUE TO TECHNICAL REASON: HYSTEROSCOPE OPERATING CHANNEL OBSTRUCTION BY A PLASTIC PIECE COMING FROM DELIVERY CATHETER. BILATERAL INSERTION WAS NOT PERFORMED, PROCEDURE WAS STOPPED. INSERTION WAS ONLY PERFORMED IN ONE SIDE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN UNSUCCESSFUL ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING THIS PROCEDURE, THE HYSTEROSCOPE OPERATING CHANNEL WAS OBSTRUCTED BY A PLASTIC PIECE COMING FROM DELIVERY CATHETER. THIS EVENT, REGARDED AS BREAKAGE OF ESSURE DELIVERY CATHETER, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

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Manufacturer Narrative (H10):

THE PTC INVESTIGATION RESULT WAS RECEIVED ON 19-OCT-2015. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C64468; PRODUCTION DATE: 09-JUN-2014; EXPIRATION DATE: 30-JUN-2017. LOT NUMBER: D30808; PRODUCTION DATE: 14-NOV-2014; EXPIRATION DATE: 28-

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056994	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 9/4/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GAINED (B)(6) A MONTH AFTER PROCEDURE AND WAS DIAGNOSED WITH HYPOTHYROIDISM. TO THIS DAY I HAVE IRREGULAR MENSTRUAL CYCLE (HEAVY FIRST TWO DAYS, STOPS FOR TWO DAYS, COMES BACK FOR TWO DAYS). LEFT JAW PAIN, ANXIETY, DEPRESSION, HARD TIME LOSING WEIGHT. MY INSURANCE COVERED THIS PROCEDURE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056995	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 7/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) CONSTANT BLEEDING FOR 35 DAYS OR MORE, THE FEELING THAT I'M PREGNANT, PERIOD CRAMPS FOR THREE WEEKS STRAIGHT

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056996	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 3/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONSET OF EXCESSIVE BLEEDING CRAMPING AND HEAVY CLOTS EXPERIENCED WITHIN 8 WEEKS OF IMPLANT DATE ((B)(6) 2013). WAS PLACED ON MINASTRIN 24 FE TO REGULATE BLEEDING. SINCE THE IMPLANT OF THE DEVICES I HAVE EXPERIENCED THE FOLLOWING SIDE EFFECTS: EXCESSIVE AND HEAVY MENSES, CRAMPING, SEVERE BLOATING, NAUSEA, EXTREMELY PAINFUL SEXUAL INTERCOURSE, MUSCLE SPASMS AND TWITCHES, MUSCLE CRAMPS, MIGRAINES, BLURRED VISION, DECREASE IN VISION ACUTENESS, FLOATERS IN VISION, ANXIETY, SEVERE CONSTANT HEADACHE AND NECK PAIN, JOINT PAIN MORE SO IN HIPS, BACK, NECK, JAW, ITCHY SKIN, RANDOM PATCHES OF DERMATITIS (UNKNOWN CAUSE), HAIR LOSS, RINGING IN EARS, SLEEPLESSNESS AND INSOMNIA, STABBING PAINS IN UTERUS, "KICKING" SENSATION IN ABDOMEN, SEVERE MOOD SWINGS, OVERALL MALAISE, INCREASING TIREDNESS, VAGINITIS, STABBING PAIN AROUND OPENING OF VAGINA, SEVERE PELVIC PAIN, GI DISCOMFORT AND ISSUES, FOOD SENSITIVITY, UNCONTROLLABLE SUGAR CRAVINGS, NUMBNESS AND STIFFNESS OF HANDS, TINGLING IN HANDS, SUPERFICIAL BLOOD CLOTTING IN LEGS, EASY BRUISING, WEAKENED IMMUNE SYSTEM, BURNING AND ITCHING INSIDE OF UTERUS, SEVERE JAW JOINT PAIN, SEVERE PMS SYMPTOMS, HEART PALPITATIONS AND RAPID HEART BEAT, SHORT OF BREATH FREQUENTLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056997	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, CRAMPS, SWELLING ABDOMEN, LARGE CLOTS WHEN MENSTRUATION, BLEEDING MORE THEN JUST WHEN MENSES, PAIN AND BLEEDING DURING ENDOMETRIOSIS, FATIGUE, PELVIC PAIN, BLEEDING (SOMETIMES HEAVY, WITH CLOTS) BETWEEN PERIODS, LOWER BACK PAIN, PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056998	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/21/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD DAILY MIGRAINE'S, BLOATING, PELVIC PAIN, JOINT PAIN, FATIGUE, ANEMIA, INSOMNIA, DENTAL ISSUES, DIZZY SPELLS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5056999	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2010 I WAS SURGICALLY IMPLANTED WITH ESSURE. PROBLEMS STARTED SLOWLY AND HAVE GOTTEN WORSE. HEADACHES I HAVE NEVER HAD STARTED. CRAMPING ABOUT 2 WEEKS EACH MONTH BEFORE MY PERIOD STARTS. PAIN LIKE PIN POKING IN MY ABDOMEN. NIGHT SWEATS AND MOOD SWINGS. MY MENSTRUAL CYCLE WENT FROM 3 DAYS TO BEING 9 DAYS. I HAD RESTLESS LEG SYNDROME START, THEN JUST AFTER THAT PAIN STARTED TAKING OVER ALL OF MY RIGHT SIDE. I HAVE BRAIN FOG, FORGETTING THINGS THAT HAVE HAPPENED OR JUST MISSING MOMENTS. I HAVE COUGHING TO THE POINT OF GAGGING. ANEMIA AND FATIGUE SET IN. THYROID GOITER, BLOOD CLOTTING DURING MENSTRUAL CYCLE I HAVE NEVER HAD. CHEST PAIN AND RAPID HEART RATE WHILE SITTING. HAIR LOSS, BLOATING AND WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057000	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 4/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY AND IRREGULAR MENSTRUAL PERIODS WHICH HAD NEVER OCCURRED BEFORE. MIGRAINE HEADACHES 2X OR MORE A WEEK, CHRONIC FATIGUE. BLOATING IN LOWER ABDOMEN. AFTER INSURING COILS WERE PROPERLY PLACED, 3 MONTHS AFTER INITIAL INSERTION HAD UTERINE ABLATION TO STOP HEAVY PERIODS. THEY STOPPED FOR 2 MONTHS THEN HEAVY SPOTTING RETURNED. WITHIN 6 MONTHS AFTER I WAS IN FULL STAGES OF MENOPAUSE WHEN THERE HAD BEEN NO INDICATION PRIOR TO INSERTION OF COILS. NIGHT SWEATS, MOOD SWINGS. HAIR LOSS. ALL OF THE ABOVE OTHER THAN BLEEDING HAVE BEEN PERSISTENT FOR OVER 5 YEARS NOW. HAVE USED BOTOX FOR MIGRAINES AND ESTROGEN THERAPY FOR MENOPAUSE. (B)(6) DID PAY FOR DEVICE AND ABLATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057001	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE WAS PLACED IN A FEW WEEKS AFTERWARDS I NOTICED I HAD A ENLARGED STOMACH LOOK LIKE I WAS 6 MONTHS PREGNANT AND IT WAS REALLY HARD WENT TO THE DOCTOR WAS NOT PREGNANT THEN IN (B)(6) I HAD MY 3 MONTHS X-RAY TO SEE IF ESSURE WORKED AND IT DID THEN I STILL HAD THE HARD STOMACH I WENT BACK TO THE DOCTOR AND THREE WEEKS AGO THEY DIAGNOSED ME WITH AN OVARIAN CYST ON MY LEFT OVARY HAD IT REMOVED (B)(6) 2015 HAD THE CYST REMOVED ALONG WITH MY LEFT OVARY AND TUBE AND THEN THEY ALSO TOOK MY RIGHT TUBE SO ESSURE IS NO LONGER IN PLACE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057002	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE HAD RECURRING PAIN IN LEFT ABDOMEN SINCE ESSURE IN 2008. REPORTED TO OBGYN PERFORMING PROCEDURE MULTIPLE TIMES AND SHE DENIES ANY ASSOCIATION BETWEEN THE PAIN AND PROCEDURE, BUT HAS NOT ATTEMPTED TO FIND ANOTHER CAUSE. I'VE RECENTLY CHANGED DOCTORS AND AM CONSIDERING REMOVAL OF THE DEVICES. ADDITIONAL SYMPTOMS FOLLOWING PROCEDURE INCLUDE WEIGHT GAIN ((B)(6) LBS), MIGRAINES, VISION CHANGES, HEART PALPITATIONS (NOW TAKING METOPROLOL), SIGNIFICANT HAIR LOSS (NOW TAKING BIOTIN), HYPOTHYROID (NOW TAKING SYNTHROID), FATIGUE, MOTION SICKNESS, ANXIETY (NOW TAKING MEDS), MEMORY LOSS AND TROUBLE WITH CONCENTRATION, NUMBNESS AND TINGLING IN EXTREMITIES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057003	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN AFFECTING MY BACK, PELVIC AND LEGS, BLEEDING/DISCHARGE BETWEEN PERIODS, HOT FLASHES, NIGHT SWEATS, ITCHING/BURNING AROUND VAGINAL ENTRANCE, BREAST SORENESS AND TENDERNESS, SEVERE BLOATING, METALLIC TASTE AT TIMES IN MOUTH, HEARTBURN, CONSTANT HEADACHES, BRAIN FOG, FORGETFULNESS, ANXIETY, MOOD SWING, RINGING IN THE EARS, DIZZINESS AND RECENTLY DIAGNOSED WITH VERTIGO, HIGH BLOOD PRESSURE, WEIGHT ISSUES, EXCESSIVE SWEATING, THYROID ISSUE, ANEMIC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057004	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE MAIN SYMPTOMS THAT I BATTLE ARE A CONSISTENT SHARP PAIN IN MY RIGHT SIDE, SEVERE DEPRESSION, ANXIETY, SEVERE ANEMIA, LOW ENERGY/LETHARGIC, NON-EXISTENT SEX DRIVE, PAINFUL INTERCOURSE, INSOMNIA, NIGHT SWEATS, HEADACHES, (B)(6) POUND WEIGHT GAIN, AND CONSISTENT MEMORY LOSS/BRAIN FOG. DUE TO THIS SYMPTOMS I AM TAKING NUMEROUS MEDICATIONS DAILY, HAVE BEEN HOSPITALIZED SEVERAL TIMES FOR PAIN, AND HAVE SEEN SEVERAL SPECIALISTS TO FIND OUT WHY I WAS GETTING SICK/HAVING PAIN. THE ESSURE WAS COVERED BY MY INSURANCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057005	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, WEIGHT GAIN, PAIN, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057006	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 3/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN BACK PAIN HEADACHES NUMBNESS ON LEFT SIDE BURNING SENSATION YEAST INFECTION STREP B NEVER HAD STREP B BEFORE ESSURE AND DOCTOR SAID THERE WAS A LOT OF IT . BLOOD WORK WAS GOOD ALL BUT VITAMIN D WAS LOW LYPHNODE ON LEFT SIDE GROIN AREA AND ONE ON THE LEFT SIDE OF MY NECK ON BACK SIDE OF NECK

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057007	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 9/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD SEVERE PAIN IN MY ABDOMEN. MY PERIODS WERE/ARE HORRIBLE. THEY COME AND GO AS THEY PLEASE. THERE WAS A TIME WHEN I BLEED FOR 3 WEEKS OUT OF A MONTH. I AM FATIGUED. MY BACK IS IN PAIN. I AM NOW SCHEDULED TO HAVE A HYSTERECTOMY DUE TO THESE ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057008	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 3/17/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE PERIODS SO BAD I CAN'T LEAVE THE HOUSE. BACK PAIN, MIGRAINE, RASHES, MOOD SWINGS, WEIGHT GAIN, JOINT PAIN, NO ENERGY, DEPRESSION, HEART BURN, FOOD ALLERGIES, SENSITIVE STOMACH, NO SEX DRIVE, PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057009	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 5/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HIGH BLOOD PRESSURE , HIGH BLOOD SUGAR , CARPAL TUNNEL , PERIPHERAL NEUROPATHY , TARSAL TUNNEL , MIGRAINE HEADACHES , PALPITATIONS , SLEEP APNEA , EXCESSIVE BLEEDING , LOWER BACK PAIN AND PAIN IN ALL BODY PARTS , PLANTAR FASCIITIS , FIBROMYALGIA , RHEUMATOID ARTHRITIS , BRAIN FOG , FORGETFULNESS , VERTIGO , WEAKNESS , FATIGUE , DEPRESSION , ANXIETY, SKIN RASH , HIVES AND INFECTIONS DUE TO NICKEL ALLERGY , VAGINAL INFECTIONS , SWOLLEN OF FEET AND LEGS , ADDICTION TO PAIN RELIEVERS DUE TO DEPENDENCE FROM PAIN OF ESSURE . AND MANY MORE SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057010	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 5/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING A LOT OF SYMPTOMS THAT I NEVER HAD BEFORE LIKE : CRAMPING, SHARP/STABBING PELVIC PAIN, CONSTANT SPOTTING, DISCHARGE (ODOR/NO ODOR), HOT FLASHES, EXCESSIVE BLEEDING DURING PERIOD 1 PAD 45 MIN, NIGHT SWEATS, LOSS OF SEXUAL DESIRE, HOT FLASHES, SPOTTING AFTER SEX, PAINFUL PERIODS , PAINFUL INTERCOURSE , BLEEDING BETWEEN PERIODS, LONG MENSTRUAL CYCLES(10-12DAYS), YEAST INFECTIONS, BACTERIAL VAGINOSIS, URGENT/FREQUENT URINATION, UTI (URINARY TRACT INFECTION), BLADDER INFECTION, ITCHING, BURNING, STINGING, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, BACK, JOINT, LEG, NECK, HIP, CHRONIC PELVIC PAIN, ALL OVER BODY ACHES/PAIN, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, MIGRAINES, DIZZINESS, MOOD SWINGS, ANEMIA, ALLERGIES (NICKEL), SKIN IRRITATION/ITCHING, HEART PALPITATIONS, SWELLING OF LEGS OR FEET, HAIR LOSS OR CHANGES, WEIGHT ISSUES (GAIN) 30LBS, SEVERE BLOATING, RECENTLY HAD AN ULTRASOUND AND WAS TOLD THE COIL HAD MIGRATED TO MY UTERUS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057011	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4), IT STARTED WHEN I WAS DIAGNOSED WITH PNEUMONIA, I HAVE NOW HAD PNEUMONIA 7 TIMES IN 2 YRS, I HAVE SEVERE HAIR LOSS, WEIGHT GAIN, CANNOT LOSE WEIGHT EVEN WITH WORKING OUT AND EATING BETTER, SEVERE BIPOLARNESS/MOODINESS, LACK OF SEX DRIVE, LOW SELF ESTEEM, MARRIAGE SEPARATION, MUSCLE WEAKNESS, BRUISE EASILY AND LAST LONGER THAN 2 WEEKS, ASTHMA, MUCUS PLUG IN LEFT LOWER LUNG WITH ABNORMAL CELLS, WHEN I HAVE MY MONTHLY MENSTRUAL IT IS NOTHING BUT BLOOD CLOTS WITH WEAKNESS AND I GET LETHARGIC, MEMORY LOSS, SEVERE ABDOMINAL CRAMPING, STABBING PAINS IN THE LOWER ABDOMEN, SEVERE BACK PAIN, SEVERE HEADACHES, MIGRAINES, DECREASE IN EYE SIGHT, DECREASE IN TEETH

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057012	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, PELVIC PAIN, DISCHARGE, HOT FLASHES, NIGHT SWEATS, BLEEDING BETWEEN PERIODS, YEAST INFECTIONS, BACTERIAL VAGINOSIS, UTI, ITCHING, BURNING, OF VAGINAL ENTRANCE, PAIN: BACK, JOINT, LEG, BREAST GAS, CONSTIPATION, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN HEADACHES, BRAIN FOG, FORGETFULNESS, ANXIETY, MOOD SWING, DEPRESSION, RINGING IN THE EARS HIGH BLOOD PRESSURE SWELLING OF THE LEGS AND FEET, DENTAL ISSUES, WEIGHT ISSUES, EXCESSIVE SWEATING, DRY SKIN/HAIR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057013	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE IMPLANTATION, EXCESSIVE HEAVY BLEEDING AND CLOTS WITH HORRIBLE CRAMPS DURING MENSTRUATION, PERIODS THAT LAST UP TO 12 DAYS, COMING AS OFTEN AS EVERY TWO WEEKS, THEN AS INFREQUENTLY AS EVERY 6TH WEEK.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057014	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LAST WEEK, I WAS GIVEN THE ESSURE TREATMENT. YESTERDAY, AM FEELING DIZZY, HAVE HAD A MIGRAINE AND SEVERE PAIN ALL THROUGH TODAY; MOST CONCERNING IS THE SHARP STABBING PAIN ON MY RIGHT SIDE THAT SPREADS TO MY LOWER BACK AND UPPER LEG. TODAY, I AM EXPERIENCING A TINGLING NUMBNESS ON TOP OF THE PAIN. I CAN ALSO FEEL THE COILS IN ME AND ITS FREAKING ME OUT. I HAVE IMMEDIATE REGRETS. INITIALLY, I WENT TO THE DR. FOR A CONSULT ON GETTING A COPPER IUD AND HE SUGGESTED ESSURE. THE WHOLE REASON I WENT TO THE DR. WAS BECAUSE HE HAD ME ON PARAGUARD AND IT DESTROYED MY ENERGY LEVELS. I WANTED A COPPER IUD, SO I WOULDN'T HAVE ADDITIONAL HORMONES INTRODUCED INTO MY BODY. THE REASON I WENT TO HIM WAS TO OFFER ME SOMETHING THAT HAS THE LEAST AMOUNT OF NEGATIVE SIDE EFFECTS. I DON'T EVEN KNOW HOW HE COULD OFFER ME THIS KNOWING I WANTED A SOLUTION NOT MORE PROBLEMS. I WAS NEVER GIVEN THE PATIENT ID CARDS EITHER. DR. IS NOT RETURNING MY CALL OR EMAILS AS OF TODAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057015	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 11/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE WAS INSERTED ON (B)(6) 2014. I'VE HAD CONSTANT BACK PAIN, CRAMPING AND DISCOMFORT SINCE. DURING MY PERIOD I HAVE INCREDIBLY HEAVY BLEEDING AND DEBILITATING PAIN. I CAN BARELY MOVE OR LIVE MY LIFE. I CONSTANTLY HAVE A METAL TASTE IN MY MOUTH. MY ABDOMEN HAS BEEN SWOLLEN SINCE GETTING THE DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057016	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 8/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT BEGAN WITH HEAVY BLEEDING FOR DAYS AND EXTREMELY HARSH CRAMPING. I THEN GOT THE NOVASURE ABLATION DONE. THAT HELPED SOME, BUT THEN THE OTHER PROBLEMS STARTED. MIGRAINES ALMOST WEEKLY, CHRONIC FATIGUE, CHRONIC PAIN, A GENERAL FEELING OF THE CONSTANT FLU. AND IT HASN'T GOT ANY BETTER. I DO HAVE SEIZURES. SINCE I WAS (B)(6) I HAVE BEEN FIGHTING WITH HOW UNCONTROLLED THEY ARE AND ESSURE MADE THEM WORSE TOO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057017	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 8/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAVE HAD ESSURE IMPLANTED MY LIFE HAS BEEN PURE HELL. DAY IN AND DAY OUT I STRUGGLE JUST TO GET THRU DAILY THINGS I NORMALLY DID BEFORE ESSURE. THESE ARE THE FOLLOWING SYMPTOMS I HAVE BEEN SUFFERING FROM SINCE ESSURE WAS PUT IN: HEAVY MENSTRUAL BLEEDING PASSING BLOOD CLOTS FATIGUE MIGRAINES BACK PAINS PELVIC PAIN STOMACH PAINS LOW SEX DRIVE BRAIN FOG BLOATING BREAST TENDERNESS WEIGHT GAIN ANXIETY DEPRESSION INSOMNIA DIZZY SPELLS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057018	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 2/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE IN 2011; SINCE THEN, I HAVE HAD SEVERE STOMACH PAINS AND CRAMPING, HEAVY BLEEDING, EXCESSIVE WEIGHT GAIN. I LIVE IN PAIN DAILY. IT IS SO SEVERE AT TIMES. IT BUCKLES ME OVER IN TEARS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057019	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 2/6/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PTSD, ANXIETY, LOW BLOOD PLATELETS COUNT, SEVERE BACK AND ABDOMINAL PAIN, WEAK BONES, HAIR FALLING OUT, BRAIN FOG, MIGRAINES, CONSTANT UTI'S, SKIN RASHES, ACNE, NAUSEA, METAL TASTE IN MY MOUTH, SHARP LABOR PAINS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057020	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 9/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN, MUSCLE PAIN AND WEAKNESS, CONSTANT HEADACHES, HEAVY MENSTRUAL CYCLES WITH CLOTTING, LOWER BACK ACHE, PELVIC PAIN. UNEXPLAINED BRUISING, STOMACH RASH, STABBING PAINS IN LEGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057021	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DEVICE WAS PLACED ON (B)(6) 2006, 5 MONTHS AFTER MY DAUGHTER WAS BORN. MY OB/GYN HIGHLY RECOMMENDED IT. I WAS ON (B)(6) WHICH PAID FOR THE DEVICE. I HAD THE PROCEDURE DONE IN AN OR AT (B)(6) HOSPITAL UNDER ANESTHESIA. THE ABDOMINAL PAIN STARTED SOON AFTER. I ASKED MY GYN IF IT WAS CAUSED BY THE ESSURE, OR IF I WAS HAVING AN ALLERGIC REACTION AS I AM HIGHLY ALLERGIC TO NICKEL, AND SHE TOLD ME ABSOLUTELY NOT. SHE SAID THE AMOUNT OF NICKEL IN THEM WAS TOO INSIGNIFICANT TO TRIGGER AN ALLERGIC REACTION. THE PAIN CONTINUED TO GET WORSE. SO BAD THAT I COULD BARELY STAND UP, AND RARELY HAS 1 GOOD DAY OUT OF THE MONTH. I WENT TO A NEW GYN WHO SENT ME FOR AN ULTRASOUND AND SAID SHE SAW "SOMETHING" BUT WANT SURE WHAT, SO SHE PUT ME ON BROAD SPECTRUM ANTIBIOTICS. PAIN PERSISTED. I STARTED HAVING OTHER ISSUES SUCH AS MAJOR FATIGUE, WEIGHT GAIN, HAIR LOSS, JOINT PAIN. SHE RAN SOME TESTS AND MY TSH WAS IN THE 90'S. I WAS DIAGNOSED WITH BORDERLINE HYPOTHYROIDISM BEFORE PLACEMENT OF ESSURE, AND HAD NO ABNORMAL TESTS DURING MY PREGNANCY, BUT IT SEEMED TO JUST GET WAY OR OF CONTROL. SHE REFERRED ME TO AN ENDOCRINOLOGIST FOR IMMEDIATE TREATMENT. SHE ALSO SAID THAT I MUST HAVE ENDOMETRIOSIS AND PUT ME ON CONTINUOUS BIRTH CONTROL PILLS. SINCE THEN I HAVE ALSO EXPERIENCED STOMACH PAIN, NO SEXUAL DESIRE (ALMOST 4 YEARS NOW), PAIN WHILE TAKING THE BIRTH CONTROL, DIZZINESS, JOINT/BACK PAIN, NUMBNESS, TINGLING, AND SWELLING OF MY HANDS AND FEET, MUSCLE TWITCHING, UNEXPLAINED BRUISING, SUDDEN HEARING LOSS, TINNITUS, BLURRED VISION/EYE PAIN, DEPRESSION, ANXIETY, HEART PALPITATIONS, CHEST PAIN, HAD GALL BLADDER REMOVED EVEN THOUGH THERE WERE NO GALL STONES OR SLUDGE, MIGRAINES, ALLERGY/SINUS PROBLEMS, INSOMNIA, MAJOR FATIGUE/NO ENERGY, HIGH CORTISOL LEVELS, CONFUSION, BRAIN FOG, FORGETFULNESS, WEIGHT PROBLEMS, BLOATING IN UPPER ABDOMINAL

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AREA, RASH, HIVES, ITCHY SKIN (I CAN'T EVEN WEAR A WATCH BECAUSE OF THE METAL BACKING), CYSTIC ACNE, MAJOR HAIR LOSS, AND IRRITABILITY ARE WHAT I CAN THINK OF OFF THE TOP OF MY HEAD. I'VE SEEN AN ENT, EYE DOCTOR, CHIROPRACTOR, WEIGHT LOSS SPECIALIST, GYN, ENDOCRINOLOGIST, AND HAD MULTIPLE TESTING DONE OVER THE YEARS SUCH AS BLOODWORK, XRAYS, CT SCANS, EKG'S, ALL FOR THE VARIOUS PROBLEMS. THERE IS NO EXPLANATION FOR MY SYMPTOMS, EVEN THOUGH I KNOW AND HAVE ALWAYS KNOWN THEY ARE CAUSED BY THE ESSURE DEVICE. NO DOCTOR EVER LISTENED OR WANTED TO BELIEVE THAT IT COULD BE CAUSING ALL OF MY PROBLEMS. THE AUTOIMMUNE REACTIONS HAVE BEEN UNEXPLAINABLE BY THEM. I AM CURRENTLY UNDER THE CARE OF AN ENDOCRINOLOGIST, GYN, PRIMARY DOCTOR, AND WEIGHT LOSS SPECIALIST. I DO NOT HAVE ALL OF MY MEDICAL RECORDS FROM THE VARIOUS DOCTORS OR HOSPITALS, BUT I WOULD BE MORE THAN WILLING TO GATHER ALL INFO TO PROVE MY CLAIMS IF IT MEANT GETTING THIS POISONOUS DEVICE OFF THE MARKET AND OUT OF WOMEN. THIS IS A DANGEROUS DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057022	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 4/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY PROCEDURE WAS ALL COVERED UNDER MY INSURANCE. ABOUT A MONTH AFTER I HAD ESSURE PLACED I HAVE HAD VERY BAD ABDOMINAL PAIN. IRREGULAR PERIODS, AND ALSO A CONSTANT BROWN DISCHARGE. NASSAU, VOMITING, HOT FLASHES. MOOD SWINGS. DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057023	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE GETTING THE ESSURE IMPLANTED I HAVE SUFFERED THROUGH VERY HEAVY CLOTTING PERIODS LASTING FOR 1 WEEK. I AM ALWAYS VERY TIRED, MIGRAINES/HEADACHES, SORE LEGS, BACK PAIN, SWOLLEN/HURTING JOINTS ESPECIALLY IN SHOULDERS, VERY BAD CRAMPS, UTI, ITCHING AND BURNING (CONSTANT URINATION).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057024	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 6/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN HAVING MORE AND MORE CROHN'S DISEASE FLARE UPS, BEGAN HAVING WORSE EMOTIONAL ISSUES, HEADACHES STARTED, ACNE THAT WOULD NOT GO AWAY, CRAMPING, EXTRA HEAVY PERIODS, BLOATING IN ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057025	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 12/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE DONE IN (B)(6) 2012. SINCE THE MIDDLE OF 2014 I'VE HAD SEVERE PAIN IN PELVIC AND ABDOMINAL AREA. I'VE HAD A PELVIC EXAM, ALL CAME BACK NORMAL. MY HAIR IS FALLING OUT, IM WEAK, I HAVE NO ENERGY WHAT SO EVER. IM CONSTANTLY ANEMIC. I HAVE NOT GOTTEN AN X-RAY DONE AT THIS POINT BUT DUE TO MY PAIN. MY DR. WANTS TO DO A HYSTERECTOMY. IM NOT HAPPY ABOUT IT BECAUSE IM STILL TO YOUNG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057026	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT WON'T LET ME CHANGE THE DATE BUT LATE (B)(6) I FOUND OUT I WAS PREGNANT THREE YEARS AFTER HAVING MEASURE PUT IN TO PREVENT PREGNANCY I WAS SCARED BET ONE BELIEF AND AM WORRIED FOR WHAT THE NEXT FEW MONTHS HOLD UNTIL I'M HOLDING MY BABY AND KNOW IT'S HEALTHY

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057027	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN HAS BEEN CONSTANT FOR A YEAR AND A HALF. PAINFUL ABDOMINAL PAIN THAT INTERFERES WITH DAILY ROUTINE. PERIODS ARE NOW 8 DAYS LONG FROM BEING 3-5 DAYS LONG AND LOTS OF BLOATING AND CRAMPING. ALSO, PAINFUL INTERCOURSE. HAVE BEEN CHECKED FOR OTHER THINGS SUCH AS CANCER AND CAME BACK NEGATIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057028	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 7/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WENT TO EMERGENCY ROOM FOR LATE PERIOD, SHARP PAINS. CT SCAN AND BLOOD WORK WERE OK. RULED OUT ECTOPIC PREGNANCY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057029	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 3/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS RECENTLY SEEN AT MY IMPLANTING OB/GYN AND WAS DIAGNOSED WITH ADENOMYOSIS, MENORRHAGIA, DYSMENORRHEA AND ANEMIA. I WILL NOW HAVE TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6) IN ORDER TO STOP ALL OF THESE ADVERSE EFFECTS AND SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057030	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 2/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY, PAINFUL PERIODS THAT LAST WEEKS TO A MONTH. PELVIC PAIN, SEVERE BLOATING, ANXIETY, DEPRESSION, JOINT PAIN. BACK PAIN, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057031	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SPOTTING ON (B)(6) 2015. CONSTANT ABDOMINAL CRAMPING, BACK PAIN. SLIGHT DISCHARGE WITH NO ODOR. EXTREME BLOATING. IRREGULAR MENSES (CURRENTLY 3 DAYS LATE).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057032	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABOUT THIS TIME BEGAN TO NOTICE I WOULD SNAP AT MY HUSBAND AND DAUGHTER ALL THE TIME, HAIR LOSS, WEIGHT GAIN, NEVER WANTED TO BE AROUND PEOPLE, ANXIETY (LIKE I HAD BUTTERFLIES IN MY STOMACH ALL THE TIME) WAS TESTED AND VIT D WAS EXTREMELY LOW, THYROID ISSUES, SHARP PAIN IN MY PELVIS, ITCHY ALL OVER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057033	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANOTHER IRREGULAR PERIOD (CURRENTLY 3 DAYS LATE) . SHARP PAINS IN ABDOMEN. CRAMPING IN LOW BACK ON THE RIGHT SIDE. LIGHT WATERY DISCHARGE WITH NO ODOR. SEVERE BLOATING THAT HAS LASTED PAST 2 WEEKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057034	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 9/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE HAD VERY BAD/HEAVY PERIODS SINCE ESSURE WAS PLACED IN 2013. MY PRIMARY KEPT ASKING IF I WAS ALLERGIC TO NICKEL. THE PAST FEW MONTHS I HAVE HAD HORRIBLE PELVIC PAINS WHICH I JUST THOUGHT WERE OVARIAN CYSTS. I WENT FOR A ABDOMINAL ULTRASOUND FOR THE PAIN AND THEN HAD TO FOLLOW UP WITH ANOTHER ABDOMINAL ULTRASOUND WITH OBGYN. I FOUND THAT HE THINKS I DEVELOPED AN ALLERGY RELATED TO MY ESSURE, SO HE RECOMMEND HAVING MY TUBES REMOVED WITH ESSURE BC THAT'S WHERE MY PELVIC PAIN WAS MORE THAN LIKELY COMING FROM. UPON REMOVAL, FOUND ONE OF MY TUBES WAS PERFORATED BY THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057035	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 2/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SUDDEN STABBING PAIN ESPECIALLY WHEN STANDING FROM SITTING. TERRIBLE CRAMPS AND NEVER ENDING SPOTTING. MY OBGYN (B)(6) WITH THE U OF U CONFIRMED THAT MY COILS HAD MIGRATED TO MY UTERUS. I HAD TO HAVE SURGERY TO REMOVE THEM. HE WAS ONLY ABLE TO REMOVE A PORTION OF THE LEFT COIL AND IT HAS NOW STARTED HAVING ISSUES AND I CAN'T FIND A DOCTOR WHO CAN HELP ME BECAUSE MY INSURANCE CHANGED AND DR (B)(6) IS NOT COVERED. THERE IS NO EDUCATION BEING GIVEN TO DOCTORS AT ALL ABOUT SAFE WAYS TO REMOVE THE COILS OR ALTERNATIVES TO A FULL HYSTERECTOMY WHEN A PERSON IS YOUNG OR WANTS TO TRY IVF. IT'S CONSTANT PAIN AND NO ONE GETS IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057036	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 7/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH BAD LOWER BACK PAIN, THEN ADD JOINT PAIN..THEN STOMACH ISSUES. PAIN DURING AND AFTER INTERCOURSE. RECENTLY HEAVY BLEEDING, HAD TO HAVE IRON TRANSFUSION. EXTREME HAIR LOSS, MOOD SWINGS, I HAVE NOW IN LAST SIX MONTHS HAVE SIGNS OF VERTIGO, INFLAMMATION, BLOATING IN MY STOMACH. YES THIS WAS PUT IN AND COVERED BY MY THEN INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057037	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NOT EVEN 3 WEEKS AFTER I HAD ESSURE IMPLANTED, IT'S BEEN NOTHING BUT PROBLEMS. I STARTED TO BLEED WEEKS AT A TIME . THE DOCTOR DECIDED TO DO THE NOVASURE. IT STOPPED THE HEAVILY BLEEDING BUT HAVE CONTINUE TO BLEED EVERY MONTH. I HAVE BEEN PREGNANT 3 TIMES AND ALL HAVE ENDED WITH A MISCARRIAGE. FIRST ONE WAS (B)(6) 2011. SECOND ONE WAS (B)(6) 2012. THIRD WAS (B)(6) 2013. I HAVE WENT TO THE ER NUMEROUS TIMES FOR PELVIC PAIN AND A LOT OF OTHER SIDE EFFECTS. I CURRENTLY HAVE NO INSURANCE, SO I PRETTY MUCH HAVE TO DEAL WITH THE PAIN AND CAN'T DO ANYTHING ABOUT IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057038	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 6/20/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT TO MY DOCTOR TO GET A UDI IMPLANT BUT SHE CONVINCED ME THAT ESSURE WAS THE BEST WAY TO GO AND THAT THEY WOULD DO AN ALLERGY TEST BEFORE TO MAKE SURE I WAS NOT ALLERGIC TO ANY OF THE MATERIALS BUT I WAS NEVER TESTED. AFTER I HAD ESSURE IMPLANTED, I WAS CONSTANTLY BLOATED AND BEGAN TO HAVE BAD CRAMPS AND PAINS IN MY LEGS DURING MY MONTHLY CYCLE, SOME TIMES A TWO WEEK CYCLE OR IT WOULD COME TWICE A MONTH. I EXPERIENCED MY FIRST YEAST INFECTION AND BACTERIA INFECTION AFTER THE ESSURE WAS IMPLANTED AND THEY JUST KEPT COMING AND WOULDN'T GO AWAY. I WAS TOLD SOME WOMAN JUST GET INFECTIONS AND WAS SENT A SIX MONTH SUPPLY OF ANTIBIOTICS TO THE PHARMACY. SOMETIMES BENDING OVER, I WOULD EXPERIENCE A STABBING LIKE PINCHING PAIN INSIDE ALMOST LIKE WHEN BENT OVER IT WAS PINCHING AND STABBING MY INSIDES. PAINFUL INTERCOURSE WAS VERY OFTEN AND I COULD NOT CROSS MY LEGS WITHOUT THEM LOSING ALL FEELING TO THEM ALL THE WAY DOWN TO MY FEET. AFTER FOUR YEARS, I FINALLY WENT TO MY FAMILY DOCTOR TOLD HER WHAT I HAD RESEARCHED ABOUT THE MATERIALS IN THE ESSURE AND ASKED IF SHE COULD GET ME AN ALLERGY TEST FOR THE NICKEL, WHICH SHE DID AND THE RESULTS WERE THAT I WAS ALLERGIC TO NICKEL. I WAS THEN TOLD BY MY GYNECOLOGIST OFFICE THE ONLY WAY TO REMOVE THE ESSURE WAS TO HAVE A PARTIAL HYSTERECTOMY AND MY TUBES REMOVED. SO THIS IS WHAT I DID BUT I STILL HAVE FREQUENT INFECTIONS AND BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057039	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 3/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY, DEPRESSION, BRAIN FOG, SWELLING ALL OVER- ESPECIALLY LEGS, SEVERE SWELLING OF ABDOMEN, PAINS AND CRAMPING IN ABDOMEN AND AMP; BACK AND AMP; PELVIC AREA, DIGESTIVE AND BOWEL PROBLEMS, HEADACHES, JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057040	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 3/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN, FATIGUE, IN GENERAL FEELING POOR. MY VISION, HEARING AND TOOTH HEALTH ALL DECLINED DRAMATICALLY. I HAD A THYROID TEST, ANDAMP; LYMES TEST, TALKED TO MY DRS. ABOUT ARTHRITIS, IN 2015 I STARTED HAVING SEVER PELVIC PAIN. HAD MY GALLBLADDER REMOVED, A MAJOR KIDNEY SURGERY THAT WAS DANGEROUS AND BOTCHED AND ALMOST COST ME MY LIFE. AUTO IMMUNE TYPE ILLNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057041	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 5/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED TO GAIN WEIGHT EVEN THOUGH I EXERCISED AND TRY TO WATCH WHAT I ATE, I STARTED GETTING HEAVY PERIODS ACCOMPANIED BY SEVERE ABDOMINAL ANDAMP; BACK PAIN. I STARTED GETTING DEPRESSED AND I STARTED TO CUT MYSELF. SEVERE BRAIN FOG. I STAMMER AND SOMETIMES SOUND INCOHERENT. MY LEGS FALL ASLEEP, AND I GET A TINGLY SENSATION ON MY LEFT ARM. I ALSO HAVE HAIR LOSS AND I GET ALLERGIC REACTIONS TO THINGS I WASN'T ALLERGIC TO PRIOR GETTING ESSURE. I BREAK OUT INTO HIVES AND SHORTNESS OF BREATH. ALSO CHRONIC DIARRHEA WITH PAINFUL HEMORRHOIDS, BLOATING AND GAS. ALL THIS HAS CAUSE ME TO CALL INTO WORK AT TIMES WHEN PAIN IS UNBEARABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057042	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 4/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE A COUPLE MONTHS AFTER I RECEIVED ESSURE SEX IS NO LONGER ENJOYABLE. I CAN SEE WHY IT'S BIRTH CONTROL BECAUSE IT HURTS SO DAMN BAD WHEN YOU HAVE SEX, SO THEN YOU HAVE SEX AS LESS AS POSSIBLE. NOT TO MENTION THE HOURS YOU LAY CURLED UP IN THE FETAL POSITION AFTERWARDS BECAUSE YOUR INSIDES ARE SO INFLAMED. I ALSO AM BLOATED TO THE POINT WHERE I LOOK AND ALSO FEEL (B)(6) . I RANDOMLY PASS AIR WHEN I PEE. I ALSO GET SHARP RANDOM PAINS IN THE PELVIC AREA THAT CAUSE ME TO DOUBLE OVER UNTIL IT PASSES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057043	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 2/12/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY BLOATED ALL THE TIME. VERY PAINFUL PERIODS. LOWER BACK PAIN. WIGHT GAIN. IMPOSSIBLE TO LOSE WEIGHT. NUMBNESS IN HANDS. CAN'T SLEEP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057044	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I ACTUALLY HAD THE ESSURE IMPLANTED ON (B)(6) 2013 ALONG WITH AN ENDOMETRIAL ABLATION. I BEGAN HAVING PROBLEMS IMMEDIATELY. EXTREME PAIN IN THE LOWER ABDOMEN, I COULD FEEL THE COILS PIERCING MY INSIDES. NOW I HAVE LIFE-ALTERING FATIGUE, SEVERE LOWER BACK AND ARTHRITIC JOINT PAIN AND STIFFNESS. I HAVE HAD TO DECREASE MY HOURS AT MY JOB, BECAUSE OF MY FATIGUE AND JOINT PAIN. THAT, COMBINED WITH ALL THE PHYSICIANS I'VE SEEN AND TESTS I'VE HAD RUN HAVE SEVERLY IMPACTED ME FINANCIALLY. I NO LONGER HAVE ANY SOCIAL LIFE WHATSOEVER, I SIMPLY DON'T HAVE THE ENERGY TO DO ANYTHING OTHER THAN WORK PART-TIME AND COOK AND CLEAN FOR MY FAMILY. THIS HAS CERTAINLY IMPACTED MY PERSONAL LIFE. I DIDN'T HAVE ANY OF THESE ISSUES PRIOR TO ESSURE. THE ABLATION WAS ALSO A FAILURE, SO I'M STILL EXPERIENCING MENSTRUAL BLEEDING 10-15 DAYS PER MONTH. AFTER OVER A YEAR OF SEARCHING AND HAVING MULTIPLE PHYSICIANS TREAT ME LIKE A PAIN PILL-SEEKING, IRRATIONAL HYPOCHONDRIAC, I FINALLY FOUND AN OB/GYN WHO IS GOING TO PERFORM A FULL HYSTERECTOMY NEXT MONTH TO REMOVE THE ESSURE COILS. I ABSOLUTELY BELIEVE I WOULD NOT HAVE NEEDED THIS HYSTERECTOMY HAD I GONE WITH A TUBAL LIGATION INSTEAD OF ESSURE. I DON'T HAVE THE EQUIPMENT TO UPLOAD ANY OF MY LAB REPORTS OR OTHER TESTS, AND MY IMPLANTING PHYSICIAN IS REFUSING TO PROVIDE ME WITH MY CHART FROM MY INITIAL SURGERY. I PRAY THAT SOMEONE WILL NOT DISCOUNT THIS JUST BECAUSE I DON'T HAVE ANY SUPPORTING DOCUMENTATION WITH THIS REPORT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057045	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 7/23/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STOMACH PAINS, BACK PAINS, MIGRAINES, BRAIN SHOCKS, RESTLESS LEG SYNDROME, BOILS, (B)(6), FACE SWELLING, EYES SWOLLEN, KNOTS ON FACE AND HEAD, PAIN DURING AND AFTER SEX, BODY ACHES, MUSCLE SPASMS, MEMORY LOSS, HAIR LOSS, BRAIN FOG, SENSITIVELY TO LIGHT EYES, RASHES ON BODY TURNED TO BLISTERS, MASSIVE PANIC DISORDER, DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057046	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 7/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WOULD NEVER RECOMMEND ANYONE GETTING ESSURE.. I HAVE HAD HAIR LOST, BLEEDING NON STOP, LIGHT HEADED, SKIN RASHES, LOST OF MEMORY, EMOTIONAL..

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057047	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 5/10/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PROVIDED BY (B)(6), IT IS HARD TO LIST INDIVIDUAL DATES AND TIMES IT EFFECTS ME SINCE IT IS ONGOING AND DAILY. FATIGUE, HEART PALPATIONS, RACING HEART RATE THAT I HAVE WORKED WITH MY DR TO TRY AND RESOLVE BUT HE CAN'T FIGURE IT OUT. SUDDEN HIGH BLOOD PRESSURE NOW ON MEDICATION FOR. RAPID WEIGHT GAIN, MAJOR HAIR THINNING, CONSTANT METALLIC TASTE IN MOUTH. CHANGES IN DISCHARGE OF VAGINA. HORRIBLE PAINFUL PERIODS WITH MAJOR BLOOD CLOT ISSUES. SKIN SENSITIVITY AND BOUTS OF FULL BODY ITCHING WITHOUT RELIEF FOR HOURS. MY TEETH ARE ROTTING OUT IF MY HEAD SO FAST I CAN'T KEEP UP WITH ALL THE DENTAL ISSUES. NONE OF THESE THINGS WERE PRESENT BEFORE ESSURE, I NEVER PUT IT TOGETHER TILL OTHER WOMEN REPORTED THE SAME THINGS HAPPENING. I WANT THESE OUT OF MY BODY!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057048	BAYER	10/15/2015	10/15/2015

Event Information:

Event Date (B3): 5/29/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT THE END OF (B)(6), I WAS IMPLANTED WITH THE ESSURE DEVICE. IMMEDIATELY, I STARTED HAVING MIGRAINES THAT WOULDN'T GO AWAY, BACK, JOINT, AND MUSCLE PAINS , BLURRED VISION , FORGETFULNESS, DIZZINESS, DENTAL PROBLEMS, WEIGHT GAIN (50 LBS), HAIR LOSS, ETC.... I DIDN'T HAVE INSURANCE, SO I COULDN'T AFFORD TO GO TO THE DOCTOR OR HOSPITAL. I HAD TO SUFFER AT HOME. THERE WERE MANY DAYS THAT I COULDN'T GET OUT OF BED OR EVEN WALK. I WOULD HAVE TO CALL MY HUSBAND TO COME HOME FROM WORK TO GET OUR KIDS FROM SCHOOL.. NOT TO MENTION, I COULDN'T PERFORM MY WIFELY DUTIES SUCH AS CLEANING THE HOUSE OR COOKING BECAUSE I COULDN'T STAND FOR LONGER THAN 5 MIN CAUSE THE PAIN WOULD GET WORSE, ON TOP OF THAT, I COULDN'T HAVE SEX WITH HIM BECAUSE IT HURT SO BAD. I WOULD BE IN TEARS THE PHYSICAL AND EMOTIONAL PAIN THAT THIS DEVICE CAUSED ME; I AM LUCKY THAT MY HUSBAND BELIEVED ME AND STOOD BY ME. BECAUSE I COULDN'T DO ANYTHING; I WAS IN SO MUCH PAIN ON A DAILY BASIS. I DID GO TO THE CLINIC A FEW TIMES AND THEY RAN SO MANY TEST THAT CAME BACK CLEAN, SO THEY SAID THAT IT HAD TO BE FIBROMYALGIA AND THEY GAVE ME PAIN MEDS AND MUSCLE RELAXERS THAT DIDN'T EVEN TOUCH THE PAIN. AFTER ALMOST SIX YEARS WITH ESSURE, MY HUSBAND GOT A JOB THAT GAVE US INSURANCE I WAS FINALLY ABLE TO FIND A DOCTOR WHO BELIEVED ME THAT IT WAS ESSURE AND REMOVED IT IN 2014 AND I FEEL SO MUCH BETTER. THE PAIN IS GONE. I CAN CLEAN MY HOUSE AND COOK AND BE A WIFE AND MOM AGAIN.. MY KIDS ARE SO EXCITED TO HAVE THEIR MOM BACK....

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057260	CONCETUS/BAYER	10/15/2015	10/21/2015

Event Information:

Event Date (B3): 3/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/12/2010
Explant Date (E7): 3/22/2009
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IT ALL STARTED WITHIN 3 MONTHS OF DOING THE ESSURE (PROFANITY) PROCEDURE ON (B)(6) 2009. I HAD THE ESSURE PROCEDURE INSERTED BY DR. (B)(6) ON (B)(6) 2009. I STARTED EXPERIENCING MY PELVIC REGION TO BE VERY ITCHY AND DISCOMFORTING INCLUDING HIGH AND LOW LEVELS OF PAIN EVEN AFTER THE 6 WEEK POST SURGERY TIME. I DID REPORT THIS AND WAS TOLD IT'S NORMAL. FOLLOWING 3 MONTHS AFTER 6 WEEK POST SURGERY VISIT I STARTED TO EXPERIENCE A METAL/METALLIC TASTE IN MY MOUTH WHICH I WAS TOLD FOR SOME TIME OVER AND OVER AGAIN THAT IT WAS AN INFECTION BUT MOST OF THE TIME NO INFECTION WAS FOUND BUT I WOULD BE GIVEN ANTIBIOTICS. THE ANTIBIOTICS HELPED A VERY SHORT TIME AND THE RECURRING NASTY METAL/METALLIC TASTE WAS BACK. METAL/METALLIC TASTE SEEMED TO COME BACK WORSE THAN BEFORE EACH TIME. I DIDN'T KNOW AT THE TIME THAT THERE WAS NICKEL IN THESE COILS. I WAS LEFT TO BELIEVE THERE WERE TITANIUM ALLOY MATERIAL. YES, DR. (B)(6) ASKED IF I HAD A NICKEL ALLERGY AND I STATED YES. I HAVE BEEN ALLERGIC TO NICKEL SINCE I WAS VERY YOUNG. THE WHOLE TIME MY PELVIC PAIN PERSISTS UNTIL THIS VERY DAY. I GAINED WEIGHT WHICH I HAVE BEEN ON A STRUGGLE TO LOSE SINCE HAVING THIS PRODUCT REMOVED ALONG WITH MY RIGHT OVARY ON (B)(6) 2012. I HAVE LOST COUNT ON HOW MANY UTERINE BIOPSIES DONE BECAUSE OF MY PAIN. I WAS ALSO NOT AWARE IF YOU HAD PELVIC INFLAMMABLE DISEASE (PID) THAT I WASN'T A CANDIDATE TO RECEIVE ESSURE (PROFANITY). THANKS TO DR. (B)(6) FOR REMOVING THE PRODUCT TOOK AT LEAST 6 MONTHS FOR MY BODY TO DETOX FROM THIS PRODUCT TO WHERE I NO LONGER HAD THE METAL/METALLIC TASTE. UNFORTUNATELY, I STILL HAVE THE CHRONIC PAIN AS WELL AS HAVING BEEN DIAGNOSED W/SEVERE CHRONIC PAIN SYNDROME AND SEVERE FIBROMYALGIA WHICH SYMPTOMS DIDN'T APPEAR

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UNTIL AFTER THIS PRODUCT WAS INSERTED INTO MY BODY. NO INFORMATION HARDLY ON THE PRODUCT AND I TRUSTED MY OBGYN AND THE MAKER AT THE TIME BUT HARDLY TRUST ANY DOCTORS NOW. ALL THIS THANKS TO ESSURE (PROFANITY).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057261	ESSURE	10/15/2015	10/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PROCEDURE IN 2013, SINCE THEN MIGRAINES, HEAVY MENSTRUAL CYCLES, SEVERE CRAMPS, SKIN PROBLEMS, WORST PART IS THE FATIGUE SINCE THE PROCEDURE. NOW I'M ENDING UP GOING IN FOR HYSTERECTOMY SO MY LIFE CAN GO BACK TO NORMAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057263		10/15/2015	10/21/2015

Event Information:

Event Date (B3): 9/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WENT TO MY OBGYN AND ASKED FOR A TUBAL LIGATION BUT HIS NURSES SAID THAT HE COULD NOT DO IT UNLESS I HAD ANOTHER KID. I CURRENTLY HAVE 3 CHILDREN. THEY SUGGESTED ME TO GET THE ESSURE NOT INFORMING ME ON THE SIDE EFFECTS OF THIS SO CALLED IMPLANT. ONCE I GOT INTO THE OFFICE TO GET IMPLANT HE INSERTED THE RIGHT IMPLANT CORRECTLY ACCORDING TO HIM. AND HE INSERTED THE LEFT IMPLANT AND LEFT PLASTICS INSIDE THE FALLOPIAN TUBE ACCORDING TO HIM. AND THAT HE MADE A MISTAKE AND THAT MANY WOMEN HAVE HAD THE SAME THING DONE ALSO ACCORDING TO THE PEOPLE HE CALLED WHILE I WAS INSIDE HIS OFFICE ABOUT THE IMPLANT. AND HE SAID MY BLEEDING WOULD STOP BUT IT ONLY GOT WORSE. CRAMPING HAS WORSENED AND HEADACHES HAVE STARTED TO COME EVERYDAY. I WISHED I HAD OF KNOWN THESE SIDE EFFECTS BECAUSE I WOULD VE NEVER GOTTEN THIS DANGEROUS IMPLANT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01195	BAYER HEALTHCARE LLC	10/16/2015	10/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 20-NOV-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR PERMANENT CONTRACEPTION. THE CONSUMER STATED THAT HAS CONSTANT PAIN WITH ESSURE SINCE PLACEMENT; THAT ESSURE RUINED HER BODY. SHE WAS IN MUCH PAIN EVERYDAY (ALL DAY LONG, WHETHER SHE SIT OR STAND). SHE COULD NOT AFFORD TAKING IT OUT. SHE COULD NOT BE INTIMATE WITH HER HUSBAND. THERE WAS A THROBBING, CONSTANT PAIN WHERE HER TUBES ARE LOCATED. MODIFIED HSG (HYSTEROSALPINGOGRAM) WAS DONE SOMETIME IN 2014 AND WAS PAINFUL, BU SHOWED THAT BOTH SIDES WERE BLOCKED AND THAT COILS WERE IN CORRECT PLACE. SHE FELT A POKING IN ABDOMEN WHEN SHE LEANED OVER A COUPLE OF DAYS BEFORE TEST. THIS HAS RESOLVED SINCE HSG TEST. SHE ALSO STATED THAT WHEN SHE WAS ON HER CYCLE, SHE WAS IN PAIN. THE CONSUMER WAS TREATED WITH IBUPROFEN (IBUPROFEN [IBUPROFEN]). THE OUTCOME OF THE EVENTS CONSTANT PAIN WITH ESSURE SINCE PLACEMENT/THROBBING CONSTANT PAIN WHERE MY TUBES ARE, I CAN'T BE INTIMATE WITH MY HUSBAND, AND WHEN I AM ON MY CYCLE I AM IN PAIN WAS NOT RECOVERED / NOT RESOLVED. THE OUTCOME OF THE EVENT FELT POKING IN MY ABDOMEN WHEN I LEAN OVER A COUPLE DAYS BEFORE TEST WAS RECOVERED / RESOLVED. AT TIME OF THE REPORT, ESSURE DEVICES WERE NOT REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 08-DEC-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY

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MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 10-JAN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW-UP INFORMATION RECEIVED ON 24-JUL-2015 FROM CONSUMER: SHE STATED THAT ESSURE WAS RUINING HER BODY. SHE WAS IN CONSTANT PAIN, AND SHE COULD NOT AFFORD TO HAVE THIS REMOVED. WHEN HER CYCLES START, THE PAIN IS 50 TIMES MORE. HER HANDS AND FEET GO NUMB EVERYDAY, THEY BURN HER PALMS. HER HAIR WAS FALLING OUT, HER TEETH WERE RUINED, AND SHE HAD ONE PULLED AND 2 MORE TO BE PULLED. SHE WAS ALSO EXPERIENCING SEVERE HEADACHES, MOOD SWINGS, WEIGHT GAIN (SHE STATED PROBABLY GAINED 30 LBS AFTER THE ESSURE. SHE LOOKED LIKE 7 MONTHS PREGNANT, THE WEIGHT WAS IN HER ABDOMEN). SHE COULD NOT BE INTIMATE WITH HER HUSBAND BECAUSE OF PAIN, AND IT HURTS AFTERWARD. HER PELVIC AREA AND TUBES WERE CONSTANTLY IN PAIN, WHETHER SHE WAS SITTING, LAYING, OR STANDING. SHE HAD TO TAKE IBUPROFEN. FOLLOW-UP INFORMATION RECEIVED ON 27-AUG-2015: PATIENT'S INITIALS WERE UPDATED. THE CONSUMER HAD THE ESSURE DEVICE IMPLANTED ON (B)(6) 2013 (DATE UPDATED). SHE STATED THAT AS SHE SIT AT HER DESK AT WORK SHE FEEL A PULLING SENSATION AND IT IS NEVER ENDING, ALONG WITH SEVERAL OTHER SIDE EFFECTS THAT SHE WAS EXPERIENCING . ACCORDING TO HER THE DEVICE HAS CRIPPLED HER, TO THE POINT THAT SHE CAN NO LONGER RUN AND PLAY WITH HER CHILDREN. SHE STATED THAT DUE TO ESSURE SHE WAS IN CONSTANT PAIN. FOLLOW-UP INFORMATION RECEIVED ON 19-SEP-2015 AND 21-SEP-2015 FROM CONSUMER: CONSUMER REPORTED THE FOLLOWING SYMPTOMS: CONSTANT PELVIC PAIN, CONSTANT MIGRAINE, BLURRY VISION, DIZZINESS, BRAIN FOG, FEELS AS IF COULD ARE POKING THROUGH STOMACH, METAL TASTE IN MOUTH, CANT FOCUS, BLEED AFTER SEX, LOSS OF LIBIDO, MOODINESS, DEPRESSION /SUICIDAL THOUGHTS, HEAVY PERIODS / EXTREMELY HEAVY, BLEED IN BETWEEN PERIODS, PASS OLD BLOOD /TISSUE/ BIG BLOOD CLOTS AND NO ENERGY. SHE STATED THAT HYSTERECTOMY WAS PERFORMED. CONSUMER ALSO PROVIDED SOME PICTURES, HOWEVER SHE DID NOT WRITTEN INFORMATION ABOUT THEM (ONE OF PICTURES STATED THAT IT WAS ESSURE COILS DURING REMOVAL). CASE IS NOW CONSIDERED INCIDENT. ALSO NOTE THAT CASE NUMBER (B)(4) WAS FOUND TO BE DUPLICATE OF THIS CASE AND IT WAS DELETED FROM BAYER'S DATABASE. EVENTS ADDED AFTER MERGING DUPLICATE CASE TO THIS: EXCESSIVE SWEATING, TINGLING AND DRY SKIN. FOLLOW UP INFORMATION RECEIVED ON 20-SEP-2015: NO NEW INFORMATION. FOLLOW UP INFORMATION RECEIVED ON 25-SEP-2015: NO NEW INFORMATION. FOLLOW-UP FROM 24-SEP-2015 (NO NEW INFORMATION) AND 27-SEP-2015: CONSUMER STATED THAT SHE WAS EXPERIENCING STOMACH ISSUES. FOLLOW UP INFORMATION RECEIVED ON 01-OCT-2015: THE CONSUMER POSTED ONLINE A PHOTO OF ESSURE STATING IT WAS ANOTHER ESSURE FAIL. FOLLOW UP INFORMATION IDENTIFIED ON 03-OCT-2015 AND 04-OCT-2015 FROM SOCIAL MEDIA: THE CONSUMER REPORTED THAT HER HEAD WAS POUNDING AND SHE FELT LIKE HAD THE FLU. SHE HAD BEEN SUFFERING WITH ESSURE SINCE IMPLANTATION ON (B)(6) 2012. SHE STATED THAT WAS IN PAIN AGAIN FROM ESSURE BECAUSE HER PERIOD WAS UNBEARABLE. SHE ALSO STATED SHE COULD FEEL THE COILS WHEN SHE MOVED. FOLLOW UP INFORMATION IDENTIFIED ON 05-OCT-2015 FROM SOCIAL MEDIA: THE CONSUMER STATED SHE WAS TRYING TO DO SOME NECESSARY HOUSEWORK AND SHE COULD HARDLY MORE ESSURE WAS CRIPPLING, CRAMPS, BURNING AND STABBING PAINS. AT TIME OF THE REPORT, HER HEAD WAS POUNDING; ESSURE WAS STABBING AND PULLING HER. FOLLOW-UP

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INFORMATION RECEIVED ON 07-OCT-2015 WITH ADDITIONAL INFORMATION ON 09-OCT-2015 FROM CONSUMER VIA SOCIAL MEDIA: THE CONSUMER STATED SHE HAS BEEN HAVING DAILY MIGRAINE FOR 3 MONTHS. PTC INVESTIGATION RESULT PROVIDED ON 10-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD CONSTANT PAIN IN HER PELVIC AREA AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY. ADDITIONALLY, SHE EXPERIENCED DEPRESSION WITH SUICIDAL THOUGHTS. ONLY PELVIC PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER HAD PAIN SINCE ESSURE INSERTION. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT; WOMEN HAVE HIGH RISK FOR DEVELOPING DEPRESSIVE DISORDERS. SEVERAL BIOLOGICAL PROCESSES ARE THOUGHT TO BE INVOLVED IN THE PREDISPOSITION OF WOMEN TO DEPRESSION, INCLUDING AN UNDUE SENSITIVITY TO HORMONAL FLUCTUATIONS IN BRAIN SYSTEMS THAT MEDIATE DEPRESSIVE STATES. DURING ESSURE THERAPY A WOMAN MAY EXPERIENCE MILD DEPRESSION IN CASE SHE REGRETS HER DECISION TO UNDERGO PERMANENT CONTRACEPTION. ALTHOUGH LIMITED INFORMATION WAS PROVIDED IN THIS CASE (NO INFORMATION WAS GIVEN ABOUT CONSUMER PREVIOUS PSYCHIATRIC HISTORY), BASED ON ESSURE LOCAL ACTION IN FALLOPIAN TUBES, COMPANY CONSIDERS CAUSALITY BETWEEN THE REPORTED SUICIDAL THOUGHTS AND THE SUSPECT INSERT AS UNLIKELY. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-NOV-2015 AND 12-NOV-2015: CONSUMER INFORMED THAT SHE SUFFERED DAILY AND HAS HAD A MIGRAINE EVERYDAY FOR ABOUT 14 WEEKS OR SO, TO THE POINT OF VOMITING. THEREFORE THE EVENT PREVIOUSLY REPORTED WAS UPDATED TO CONSTANT MIGRAINE, MIGR

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057063	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PUT IN WITH BEING TOLD IT WAS MADE OF THE "STINT" MATERIAL. "LESTER" I FIND OUT AFTER HAVING MULTIPLE SIDE AFFECTS THAT THEY ARE ESSURE RELATED. HAIR LOSS, NICKEL ALLERGY, EXCRUCIATING CRAMPING, EXCESSIVE BLOATING, WEIGHT GAIN, LOW BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057064	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 1/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) 2009. NOTE: SINCE MENSTRUATION BEGAN, I HAD ALWAYS HAD VERY REGULAR PERIODS, ALWAYS LASTING BETWEEN 4-6 DAYS. IN (B)(6), I BEGAN HAVING VERY HEAVY PERIODS LASTING WEEKS. I WOULD GO THROUGH TAMPONS AND PADS IN A MATTER OF MINUTES. I HAD MULTIPLE DR. APPTS TO ADDRESS THE BLEEDING, WAS PUT ON MULTIPLE MEDICATIONS TO LESSEN THE BLEEDING, AND AT MULTIPLE ER VISITS AS A RESULT OF THE BLEEDING (AND AFTER I LOST CONSCIOUSNESS). AFTER APPROX 4 MONTHS, BLEEDING BECAME MORE "NORMAL" IN THAT MY PERIODS WERE ONLY LASTING 7-10 DAYS (STILL LONG FOR ME), BUT THEY WERE STILL VERY VERY HEAVY, WITH A LOT OF LARGE CLOTS. DURING THIS TIME, I ALSO DEVELOPED PELVIC AND ABDOMINAL PAIN, BUT DOCTORS NEVER FOUND A CAUSE. THIS OCCURRED FOR YEARS. IN (B)(6) 2013, I HAD TERRIBLE PAIN IN MY LOWER ABDOMINAL AND PELVIC REGION. I ENDED UP GOING TO THE ER, WHERE IT WAS FOUND THAT I HAD A LARGE OVARIAN CYST... AGAIN, SOMETHING THAT I HAD NEVER HAD IN THE PAST. THE PAST YEAR, I HAVE HAD INCREASING FATIGUE, AND HAVE BEEN WORKING WITH MY PRIMARY CARE DOCTOR TO TREAT. I AM A COMPLETELY DIFFERENT PERSON. WHERE BEFORE I HAD ENERGY TO PLAY WITH MY KIDS, GO ON HIKES, STAY UP LATE TALKING WITH FRIENDS, I NOW COME HOME FROM WORK AND LAY IN BED FOR THE REST OF THE NIGHT. I CANNOT PARTICIPATE IN THE PHYSICAL ACTIVITIES LIKE I DID PREVIOUSLY. I'VE HAD MANY TESTS AND SOME PROCEDURES DONE TO TRY TO HELP WITH MY EXHAUSTION, BUT NOTHING HAS WORKED. TO THIS DAY, I STILL GET CYSTS, AND EVERY FEW MONTHS GET PAIN IN MY OVARIES AND UTERUS... PAIN SO BAD THAT IS DEBILITATING. CURRENTLY, I HAVE NOW MISSED 3 PERIODS, BUT HAVE NEGATIVE HOME PREGNANCY TEST. AS SOMEONE WHO HAS ALWAYS HAD VERY MILD PERIODS WITH VERY TO LITTLE NO PAIN OR DISCOMFORT, TO WHAT I'VE EXPERIENCED THE LAST 5 YEARS (SINCE ESSURE WAS IMPLANTED), I CAN ONLY ATTRIBUTE THESE CHANGES TO THE DEVICE.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057065	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 12/23/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE INVOLUNTARY SHAKING AS IF I HAVE PARKINSON'S DISEASE. FOR THE PAST FEW YEARS I HAVE HAD VIBRATIONS IN MY LOWER BODY AS IF I HAVE A CELL PHONE ON VIBRATE ATTACHED TO MY BODY. LEAKAGE OF CLEAR FLUID FROM MY VAGINAL AREA. ANXIETY AND PANIC DISORDER HAS PROGRESSIVELY GOTTEN WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057066	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM THE BEGINNING, I EXPERIENCE PAINFUL CRAMPING. "BACK AND GROIN AREAS." HEAVY PERIODS, AND CLOTTING. SOME MONTHS 7_31 DAYS. CONSTANTLY PINCHING SENSATION IN LOWER ABDOMINAL AREA. LACK OF SEX DRIVE AND PAINFUL INTERCOURSE. FIBROIDS HAVE DEVELOPED. BLOATING AND HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057067	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 6/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS PLAYING OUTSIDE WITH MY CHILDREN ON THE SLIP AND SLIDE AND FELT A TERRIBLE PAIN IN MY LOWER QUADRANT AREAS ON BOTH SIDES BUT MOSTLY THE RIGHT. IT WAS A STABBING PAIN, THIS PAIN HAPPENS WHENEVER I DO ANY PHYSICAL ACTIVITY LIKE RUNNING, JUMPING, LIFTING. OTHER SYMPTOMS I HAVE ARE FREQUENTLY HAVING BACTERIAL VAGINOSIS, BLADDER CONTROL PROBLEMS, WEIGHT GAIN AND I FIND IT IMPOSSIBLE TO LOOSE WEIGHT NO MATTER WHAT I DO. I OFTEN FEEL BLOATED, NOT TO MENTION I AM A GROUCH ALL THE TIME I HAVE NO PATIENCE WITH MY CHILDREN LIKE I USED TO. AT THE TIME OF IMPLANT I WAS ON (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057068	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWELLING. ABDOMINAL PAIN, FATIGUE, DEPRESSION, BLEEDING, ,ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057069	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 9/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE RESTLESS LEG SYNDROME, LOW THYROID. MY VITAMIN D LEVEL WAS EXTREMELY LOW AT ONE POINT AND I WAS PUT ON PRESCRIPTION TO BRING IT UP. HAVEN'T HAD IT TESTED RECENTLY. BLEEDING WAS JUST ABOUT DAILY (MAYBE STOPPED FOR 2-3 DAYS). SEVERE DEPRESSION. I STILL HAVE PAIN FROM MY SURGERY TO HAVE ESSURE REMOVED. MY VISION IS HORRIBLE. I HAVE CONVULSIONS AND NOW NEED TO BE TESTED TO SEE IF I AM HAVING SEIZURES. I CONSTANTLY HAVE TREMORS AND MY LIMBS HAVE INVOLUNTARY SPASMS WHICH NOW IS INCLUDING MY FACE AS WELL. MY MIGRAINES CAN'T BE CONTROLLED. I HAVE THEM ABOUT 23 DAYS OUT OF 28. SKIN IS SENSITIVE. THIS IS JUST WHAT I AM REMEMBERING OF THE TOP OF MY HEAD. THERE IS MORE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057070	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 1/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER 1 YEAR OF IMPLANTATION MENSTRUAL CYCLE CEASED, (B)(6) LB WEIGHT GAIN, SHARP SHOOTING PAINS IN BOTH FEET AS WELL AS SHARP SHOOTING PAIN UP VAGINA AND ANAL AREA, JOINT PAIN, HEADACHE, INTERMITTENT PAINFUL RASH ON BOTH HANDS, IN 2014 SEVERE VERTIGO WHICH REQUIRED 5 DAYS OF HOSPITALIZATION AND SEVERE BALANCE ISSUES ONGOING STILL. THYROID VALUES WENT FROM 1,60 TO 4.0, HAIR LOSS, IN (B)(6) 2015 VAGINAL BLEEDING AND SUSTAINED SEVERE ABDOMINAL CRAMPING THAT IS ON GOING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057071	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING WEIGHT GAIN NAUSEA AND VOMITING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057072	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 12/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP 1 #FDA MW5057072 #(B)(4). I ALSO HAVE A RASH ON MY LOWER STOMACH THAT WILL NOT GO AWAY. MY ABDOMINAL PAIN IS SO BAD IT PREVENTS ME FROM DOING NORMAL EVERYDAY THINGS. SOMEDAYS I CAN'T EVEN GET OUT OF BED. IT PREVENTS ME FROM BEING THERE FOR MY 3 CHILDREN. ALSO IT IS PAINFUL TO HAVE SEX WITH MY HUSBAND AND BLEED WHEN WE HAVE HAD SEX. I HAVE BEEN HAVING ANXIETY AND DEPRESSION PROBLEMS DUE TO ALL OF THIS. JUST A COUPLE WEEKS AGO I WENT TO A NEW OB GYN DOCTOR TO EXPLAIN MY SYMPTOMS AND HE STATED THAT ESSURE HAS BEEN CAUSING THESE SIDE EFFECTS IN PATIENTS. HE RECOMMENDS GETTING A HYSTERECTOMY TO REMOVE THE ESSURE, DUE TO PAIN AND ALL THE OTHER PROBLEMS IT HAS BEEN CAUSING ME. I JUST WANT TO FEEL NORMAL AGAIN AND NOT HAVE PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057073	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/31/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKEL ALLERGY, PAIN, INFLAMMATION, FATIGUE, SWELLING, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057074	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC MIGRAINES, BODY ACHES, BRAIN FOG, TREMORS, METAL TASTE IN MOUTH, TOOTH DECAY, NUMBNESS OF FACE, BACKACHE, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057075	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 1/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED IN (B)(6) 2012. ONCE I GOT HOME AFTER THE PROCEDURE I HAD A PIECE OF ONE OF THE COILS BREAK AND FALL OUT WHEN I USED THE RESTROOM AT HOME. I HAD A LOT OF PAIN FOR MONTHS FOLLOWING. I STILL HAVE CONSTANT CRAMPS AND PELVIC PAIN ON A DAILY BASIS. I HAD MY GALLBLADDER REMOVED IN (B)(6) 2014 AND UP NEXT TO MY GALLBLADDER ATTACHED TO MY FATTY TISSUE WAS THE COIL FROM MY RIGHT SIDE (IT MIGRATED). I ALSO GET MIGRAINES THAT I CAN'T EXPLAIN. I HAVE TO PUSH MYSELF MORE THAN I EVER HAVE. I CAN'T LOSE WEIGHT NO MATTER HOW HARD I TRY, AND WHEN I DO WORK OUT I SPOT FOR A COUPLE OF DAY'S AFTER. YOU CAN GO MONTHS OF SPOTTING EVEN WITH THE MIRENIA WITH IT. MY HEALTH INSURANCE COVERED THIS PROCEDURE. I STILL HAVE ONE COIL THAT NEEDS BE REMOVED (I HOPE IT IS NOT ATTACHED TO THE ESSURE).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057076	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 4/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ESSURE DEVICE WAS PROVIDED BY MY INSURER ((B)(6)). THE DEVICE WAS PLACED ON 1/18/13. THE DEVICE IDENTIFICATION NUMBER IS (B)(4). AFTER PLACEMENT OF THE DEVICE I HAVE HAD 3 URINARY TRACT INFECTIONS ((B)(6) 2013, (B)(6) 2013, (B)(6) 2015) WITH ONLY "TRACE" OR "FEW" AMOUNTS OF BACTERIA PRESENT IN THE URINALYSIS (I HAVE ONLY EVER HAD TWO IN MY ENTIRE LIFE BEFORE). AND, FOR THE FIRST TIME EVER WAS DIAGNOSED WITH A YEAST INFECTION (B)(6) 2015. I ALSO BEGIN FEELING QUITE FATIGUED AROUND THIS TIME SO MUCH SO THAT NO MATTER WHAT I DID OR DID NOT DO, I NEVER FELT LIKE I GOT ENOUGH SLEEP OR REST. IN (B)(6) 2014 I STARTED HAVING EPISODES OF ALLERGIC REACTIONS WHERE AFTER EATING CERTAIN ITEMS (NOTHING CONSISTENTLY TRIGGERED IT) MY THROAT WOULD BEGIN TO SWELL SHUT. I MONITORED THAT FOR AWHILE AND THEN REQUESTED TO SEE AN ALLERGIST. MY ALLERGIST COULD FIND NOTHING THAT I WAS ALLERGIC TO (SKIN AND BLOOD TESTS CONFIRMED THE LACK OF ALLERGIC RESPONSE TO MOST COMMON ALLERGENS BUT DID NOT DO ANY METAL ALLERGEN TESTING). SHE DETERMINED THAT THERE MUST BE SOMETHING IN THE ENVIRONMENT I WAS IN THAT WOULD CAUSE MY BODY TO REACT AND BEGIN THE HISTAMINE RESPONSE AND THAT I WOULD SIMPLY HAVE TO SEE WHEN I WAS MORE SUSCEPTIBLE TO THESE EPISODES. IN (B)(6) OF 2014 MY PERIODS WHICH HAVE ALWAYS OCCURRED LIKE CLOCKWORK, EVERY 28 DAYS, FOR 7 DAYS, BEGAN EXTENDING TO 2 WEEKS. 2 WEEKS ON, 2 WEEKS OFF. EVERY MONTH. I ALSO BEGAN HAVING MENSTRUAL CRAMPING ALL OF THE TIME, NOT JUST MY NORMAL MENSTRUAL CRAMPS DURING MY PERIOD, AND OFTEN THE CRAMPS WOULD BE SO DEBILITATING I WOULD SEE STARS AND NEARLY BLACK OUT FROM THE PAIN. IN (B)(6) 2014 I WOKE TO STABBING PAIN IN MY OVARIES AND HEMORRHAGING BLOOD. I THOUGHT THAT I MUST EITHER BE PREGNANT OR HAVE MISCARRIED, NEITHER WAS CORRECT. (B)(6) WAS JUST LIKE (B)(6): 2-WK. LONG PERIOD, HEMORRHAGING THROUGH THE NIGHT, AND FEELING LIKE I

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WAS BEING STABBED IN MY OVARIES. ON (B)(6) 2015, I STARTED MY PERIOD AGAIN, AND THIS TIME, IT DIDN'T STOP. ABOUT THAT SAME TIME I BEGAN TO HAVE THE SENSATION THAT I WAS BEING STABBED IN THE VAGINA AND THIS WOULD OCCUR ERRATICALLY. AT THE END OF (B)(6) MY PRIMARY CARE PHYSICIAN SUGGESTED I TRY PROGESTERONE. THAT STOPPED MY PERIOD FOR ONLY 24 HOURS. IN THE MIDDLE OF (B)(6), MY DOCTOR PERFORMED A BIOPSY (TO CHECK FOR HORMONAL IMBALANCE AS WELL AS CANCER), A FULL BLOOD PANEL, AND AN ULTRASOUND OF MY UTERUS AND OVARIES. NOTHING CAME BACK ABNORMAL. SHE SAID THAT THE MOST LIKELY CAUSE WAS THAT I WAS GOING INTO EARLY ONSET MENOPAUSE (I WAS (B)(6) YEARS OLD AT THE TIME, DOB (B)(6)). SHE SUGGESTED THAT I TRY THE FOLLOWING THINGS TO STOP THE CONSTANT CRAMPING AND BLEEDING: GO ON PROGESTERONE EVERY MONTH AND HOPE THAT IT EVENTUALLY WORKS; GO ON HORMONAL BIRTH CONTROL; HAVE A MIRENA IUD PLACED AND HOPE THAT WORKS; OR HAVE AN ABLATION TO REMOVE THE UTERINE LINING, AFTER WHICH I WOULD HAVE A DILATION AND CURETTAGE AND HOPE THAT WORKS; OR FINALLY, HAVE A HYSTERECTOMY. THE PROGESTERONE HAD ALREADY NOT WORKED FOR ME AND I DID NOT WANT TO TAKE A DAILY HORMONAL BIRTH CONTROL PILL OR USE THE NUVARING AGAIN, SO I OPTED TO START TREATMENT WITH THE MIRENA IUD. I HAD THE IUD PLACED AND FROM (B)(6) HAD 2, 2-DAY BREAKS FROM BLEEDING. I GAINED ABOUT (B)(6) POUNDS AND STILL EXPERIENCED CONSTANT CRAMPING AND STABBING SENSATION, SO OBVIOUSLY THAT DIDN'T WORK. I STILL WASN'T READY TO JUMP STRAIGHT TO HAVING A HYSTERECTOMY SO I DECIDED TO TRY THE NOVASURE ABLATION AND D AND C. ON (B)(6) 2015 I UNDERWENT SURGERY TO HAVE THE ABLATION AND. WHEN THE SURGEON DEPLOYED THE DEVICE, IT NICKED THE SIDE OF MY UTERUS AND CAUSED INTERNAL BLEEDING. I WAS STITCHED FROM THE INSIDE, HAD THE D AND C, AND THEN HAD TO HAVE LAPAROSCOPIC SURGERY TO DETERMINE IF I WAS INTERNALLY BLEEDING. WHILE IN THE RECOVERY ROOM, MY DOCTOR INFORMED ME THAT SHE WAS UNABLE TO PERFORM THE ABLATION AND THAT I WAS NOT A CANDIDATE. MY ONLY MEDICAL OPTION FROM THAT POINT ON WAS A HYSTERECTOMY. ON (B)(6) 2015 I WAS LYING IN BED RECOVERING FROM SURGERY AND I SAW A NEWS STORY ABOUT THE FDA OPENING AN INVESTIGATION INTO ESSURE. UPON FURTHER EXAMINATION OF THE DOCUMENTATION OUT THERE ABOUT ESSURE I REALIZED THAT MY STORY WAS ALIGNING WITH THE STORY OF MANY OTHER WOMEN OUT THERE. WHEN I ASKED MY DOCTOR IF SHE HAD SUBMITTED A COMMENT ON MEDWATCH ABOUT MY SYMPTOMS SHE TOLD ME THAT SHE HAD NOT AND THAT MY SYMPTOMS WERE LIKELY UNRELATED TO ESSURE. I BEG TO DIFFER, AND I WONDER HOW MANY OTHER WOMEN OUT THERE ARE SUFFERING WITH SIMILAR SYMPTOMS, OR PERHAPS WORSE, AND WHOSE DOCTORS ARE NOT FILING COMPLAINTS FOR THEM EITHER. ON (B)(6) 2015 I HAD TO UNDERGO A FULL HYSTERECTOMY AND SALPINGECTOMY (TO REMOVE THE ESSURE DEVICES). THANKFULLY THE ESSURE COILS WERE STILL CONTAINED IN MY FALLOPIAN TUBES. MY UTERUS APPEARED "INFLAMED" ACCORDING TO MY DOCTOR, MEASURING 11.4 X 8.5 X 4.3 CM AND SHOWS A 6.0 CM IN GREATEST DIMENSION AND MY PATHOLOGY REPORT DIAGNOSED ME WITH "ACUTE AND CHRONIC CERVICITIS". I HAVE SINCE RESEARCHED CERVICITIS AND THE MAIN CAUSES ARE BACTERIAL INFECTION, SEXUALLY TRANSMITTED DISEASES, OR AN ALLERGIC RESPONSE TO SOMETHING. I HAVE NO SEXUALLY TRANSMITTED INFECTIONS STI'S NOR HAVE I EVER BEEN DIAGNOSED WITH THEM. I KNOW THAT ESSURE IS MADE OF NICKEL AND I MAY HAVE BEEN HAVING AN ALLERGIC RESPONSE TO THAT. WHILE IN LAPAROSCOPIC SURGERY MY DOCTOR FOUND A HEMANGIOMA ON MY LIVER. WHILE THIS MAY OR MAY NOT BE RELATED TO THE ENSURE DEVICE (SINCE IT IS A NON-HORMONAL DEVICE FULL OF PET FIBERS THAT RELEASE ESTROGEN AND HARM HUMAN'S ENDOCRINE SYSTEM) I FEEL LIKE IT SHOULD BE REPORTED HERE AS WELL. THE ESSURE DEVICE IS NO LONGER IN MY BODY AND WAS SURRENDERED TO THE PATHOLOGY DEPARTMENT OF (B)(4).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057077	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 9/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, BOWEL PROBLEMS, SYSTEMIC PAIN AND DISRUPTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057078	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 3/18/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, HEAVY AND EXTENDED MENSTRUAL CYCLE, PELVIC PAIN, RECTAL PAIN, MIGRAINES, BRAIN FOG, VISION PROBLEMS, DIZZY SPELLS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057079	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME ABDOMINAL PAIN, HEAVY BLEEDING, MIGRAINE HEADACHES, WEIGHT GAIN, FATIGUE, AND SHARP PAINS EVERYWHERE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057080	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 12/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (B)(6) 2013 - EXTREMELY HEAVE MENSTRUAL CYCLES BEGAN. (B)(6) 2013, EXPERIENCED SIGNIFICANT HAIR LOSS - 7 LARGE PATCHES. HAIR LOSS STILL CONTINUES TODAY. (B)(6) 2014 - DIAGNOSED WITH AUTO IMMUNE DISORDER. (B)(6) 2014 - DIAGNOSED WITH BONE DETERIORATION IN MY MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057081	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CHRONIC STABBING PAINS IN MY PELVIC AREA. I HAVE HEADACHES AND MIGRAINES THAT LAST FOR WEEKS ON END AND NO MEDICINE WILL TAKE CARE OF THEM. I NOW ON DEPRESSION MEDICINE WHEN I'VE NEVER HAD A PROBLEM. I GET DIZZY SPELLS ALL THE TIME AND MY STOMACH IS ALWAYS BLOATED AND I HAVE GAINED WEIGHT. AND I'M USING MY EYEBROWS. I LOSS MY TRAIN OF THOUGHT ON WHAT I'M DOING AND I GET A LOT OF BODY PAINS WHICH COULD BE FROM WORK

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057082	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALWAYS HAVE PAIN IN MY TUMMY. MY LOWER ABDOMEN LOADING GAS, DIARRHEA AND CONSTIPATION.. LOW ON VITAMIN D.. I TESTED POSITIVE FOR LUPUS.. EXTREME FATIGUE MUSCLE WEAKNESS... FEELS LIKE I GET MORNING SICKNESS... FEELS LIKE I'M PREGNANT... HEAVY PERIODS... CHEST PAIN.. ANXIETY DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057083	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, PAINFUL CRAMPING IN SIDES, PAIN DURING INTERCOURSE, IRREGULAR BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057084	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 6/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE IMPLANTED ON (B)(6) 2015. I ENDED UP GETTING F AN INFECTION RIGHT AWAY AND WAS IN HORRIBLE PAIN. MY DOCTOR PUT ME ON SOME MEDS WHICH DID HELP. I WENT IN TODAY (B)(6) 2015 TO GET THE DYE PROCEDURE DONE TO SEE IF THE COILS WERE STILL IN PLACE AND THAT MY TUBES WERE BLOCKED. WE FOUND OUT FROM THE XRAY THAT ONE IS IN PLACE AND BLOCKED WHILE THE OTHER COIL HAS MIGRATED NORTH OF THE TUBE. MY DOCTOR ASSUMES THAT THIS HAPPENED RIGHT AWAY AND THE CAUSE IF THE INFECTION I HAD EARLIER WHEN IMPLANTED. I MYSELF DO NOT WANT TO HAVE THIS PROCEDURE DONE AGAIN IN CHANCES OF THIS HAPPENING AGAIN. SO MY DOCTOR IS TRYING TO FIND A PROVIDER WITH IN MY INSURANCE COMPANY TO TAKE MY TUBES OUT NOW. WHICH WILL PROBABLY BE A LONG ROAD FOR ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057085	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, AND IRRITABILITY, CRAMPING, MASSIVE BLOOD CLOTS AND HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057086	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 11/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIC SKIN REACTIONS, SWELLING IN ABDOMEN, CHRONIC PAIN, SWELLING IN LEGS AND NUMBNESS. PROLONGED AND HEAVY PERIODS. METAL TASTE IN MOUTH AND BAD BREATH. CONSTANTLY SWEATING. CHRONIC UTI WHICH LED TO SEPTICEMIA TWICE AND HOSPITALIZED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057087	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 7/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER A WHOLE YEAR OF HAVING ESSURE MY MENSTRUAL CYCLE STARTED BACK. BUT THEY'VE BEEN LIFE CHANGING EVER SINCE. I SOAKED THROUGH A HALF BAG OF PADS, 8 PAIRS OF UNDERWEAR AND 4 PAIRS OF PANTS/JEANS (JUST THAT NIGHT ALONE) IT WAS SO EMBARRASSING BECAUSE I WAS AT A FORMAL DINNER/SHOW AND WAS SITTING IN THE FRONT ROW, I ENDED LEAVING EARLY BECAUSE OF THIS ISSUE. I CALLED MY DR SO I CAN BE SEEN AND THEY INFORMED ME THAT IT WAS JUST HEAVY, AND IT SHOULD EASE UP. THAT WAS IN 2012 AND NOT ONLY HAS IT STAYED THE SAME (HEAVY BLEEDING) BUT MY PAINS STARTED AS WELL. CRAMPING WHILE I'M NOT MENSTRUATING AND WHEN I AM THE CRAMPS FEEL LIKE CONTRACTIONS. AGAIN I TALK TO THE DR. GOT BLOOD TEST DONE AND ULTRASOUNDS ALL NORMAL. I THEN STARTED HAVING HAIR LOSS, LOST MY SEX DRIVE, MULTIPLE INFECTIONS, ACID REFLUX AND ALSO GOT DIAGNOSED WITH RIGHT BUNDLE BRANCH BLOCK. I'M STILL TRYING TO FIND OUT WHAT'S WRONG WITH ME. I'M ONLY (B)(6) YEARS OLD VERY ACTIVE (BEFORE ESSURE) NEVER HAD ANY ISSUES WITH MY HEALTH UNTIL I GOT THESE COILS. IF I CAN REWIND THE HANDS OF TIME I WOULD HAVE NEVER GOTTEN THEM. THEY'RE RUINING MY LIFE AND THE PEOPLE IN IT. I HAVE 5 LIVES LOOKING FOR ME TO BE THE BEST MOTHER I CAN BE. PLEASE TAKE THESE THINGS OFF THE MARKET AND OUT OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057088	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 12/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVERY MONTH SINCE IMPLANTATION, I HAVE DISCHARGE WITH STRONG ODOR. DR SAYS IT'S A YEAST INFECTION BUT IT'S EVERY SINGLE MONTH DURING OVULATION. I MISS WORK BECAUSE I'M AFRAID OTHERS CAN SMELL THE ODOR. AFTER A WEEK, IT USUALLY GOES AWAY. ABOUT 2-3 TIMES A YEAR IT REQUIRES MEDICATION. ALSO, JUST BEFORE MY CYCLE BEGINS, MY BELLY SWELLS AND I LOOK LIKE I'M 7 MONTHS PREGNANT. AFTER 3-4 DAYS, IT GOES AWAY UNTIL THE NEXT MONTH. ALSO EVERY MONTH SINCE IMPLANTATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057089	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE ESSURE IMPLANTATION I'VE HAD A LOT OF HEALTH ISSUES. TO START I GAINED 39 LBS THAT I CAN'T GET RID OF , HIGH BLOOD PRESSURE, CONSTIPATION, BLOATING, SHORTNESS OF BREATH, PELVIC PAIN, MIGRAINES, LOW IRON, LACK OF SEXUAL DESIRES, SHARP SHOOTING PAIN FOR FROM FINGER TIPS TO TOES ON RIGHT SIDE, FATIGUE, ITCHING ALL OVER BODY, SWOLLEN ANKLES, BLEEDING GUMS, HAIR LOSS , HIGH LIVER ENZYMES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057090	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 12/30/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAINFUL ABDOMINAL PAINS, HAIR LOSS, METALLIC TASTE IN MOUTH, LARGE BLOOD CLOTS, IRREGULAR MENSTRUAL CYCLES, EXCESSIVE BLEEDING, FACE RASH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057091	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNEXPLAINED SKIN RASHES, SEVERE CRAMPS. HEADACHES, WEIGHT GAIN AND BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057092	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/16/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, CHRONIC PELVIC PAIN, IRREGULAR BLEEDING, PERSISTENT PERIODS, VOMITING, NASSAU, PELVIC INFLAMMATION, HYSTORCYTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057093	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 9/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TOTAL LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY AND EXCISION OF HYMENAL REMNANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057094	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 9/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2010. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2010. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE; MISPLACEMENT OF RIGHT COIL UPON INSERTION. PELVIC AND ABDOMINAL PAIN, ESPECIALLY DURING SEX, BOWEL MOVEMENTS, AND URINATION. I HAVE BEEN SEEN BY 5 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS; PELVIC PAIN, PELVIC MASS, DYSMENORRHEA, AND SENSITIVITY TO METAL. I HAVE HAD THE FOLLOWING PROCEDURE REGARDING ESSURE; HYSTEROSALPINGOGRAM . THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057095	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD DEPRESSION, PAIN, WEIGHT GAIN, BLOATING, SPEECH PROBLEM, SPEAKING BACKWARDS, ANXIETY AND FEEL SHORT OF BREATH, UNUSUAL BLOOD TEST RESULTS,AND OVERALL SICK FEELING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057096	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 4/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE IN (B)(4) 2014. SINCE THEN I HAVE HAD HORRIBLE CRAMPING AND BACK ACHES DURING MY PERIOD. I ALSO HAVE BLOATING AND CRAMPING WHEN I'M OVULATING. I HAVE ALWAYS BEEN THIN BUT I'VE STARTED TO GET A BELLY LIKE A PREGNANT WOMAN. I GET HORRIBLE MIGRAINES, DRY MOUTH, BACK ACHES, INSOMNIA, FATIGUE, WEIRD DREAMS. I BRUISE EASIER, AND I'M ALWAYS ACHY OR HAVING PAINS. I'VE BEEN GRINDING MY TEETH AND I'M CONSTANTLY NEEDING A MINT BECAUSE I HAVE A FUNNY TASTE IN MY MOUTH. I'VE ALSO BEEN FIGHTING DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057097	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/19/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP AND DEBILITATING PAIN HEAVY BLEEDING AND NO STOPPING HAD TO HAVE 2 PROVIDERS TO FIX PART OF THE PROBLEM NOW FAVORING HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057098	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 9/1/2002 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE MENSTRUAL BLEEDING. 3 PERIODS IN 3 WEEKS. HEADACHES, PELVIC PAIN, ABDOMINAL PAIN, HAIR LOSS, EXTREME FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057099	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UPDATE 1/5/16: I HAD A ROBOTIC LAVH ON (B)(6) 2015. MY SURGEON REMOVED EVERYTHING EXCEPT MY OVARIES. I HAD SEVERE ADHESIONS CAUSING MY UTERUS AND BLADDER TO BE FUSED TO MY ABDOMEN AND I'LL BE ON FMLA THROUGH (B)(6) 2016.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057100	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 8/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, BAD BLEEDING PERIODS COME 3 DAYS EARLIER THEN THE MONTH BEFORE ALMOST A HEMORRHAGE BLEEDING LARGE DARK CLOTS. BAD BACK PAIN, DISCHARGE THAT HAS ODOR, KICKING FEELING IN MY STOMACH. WEIGHT GAIN AND BRUISE REALLY EASY. NIGHTS, I CAN'T SLEEP AND I AM VERY MOODY, NOT HAPPY GO LUCKY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057101	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP1 #FDA MW5057101 #(B)(4). I HAD MY FALLOPIAN TUBES REMOVED ON (B)(6). THE ESSURE HAD BROKEN AND AN END OF IT WAS PIERCING A PART MY UTERUS WHICH HAD TO BE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057102	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 1/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) CRAMPING BREAK THREW BLEEDING HEAVY PERIOD NUMBNESS IN HAND AND FEET CONFUSION BACK PAIN AND PROBLEMS HEAVY DISCHARGE PAIN WITH INTERCOURSE PAIN ON RIGHT SIDE FATIGUE NIGHT SWEATS SWOLLEN BELLY

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057103	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IRREGULAR PERIODS, EXTREMELY HEAVY, TWICE A MONTH, FATIGUE, HAIRLOSS, SEVERE ANEMIA, DAILY HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057104	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 5/6/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING GOING THROUGH A HEAVY PAD IN LESS THAN AN HOUR, HUGE BLOOD CLOTS, HEADACHES, SEVERE CRAMPS EVEN WHEN I'M NOT ON MY PERIOD, NO ENERGY, BACK PAIN, DEPRESSED, HURTS TO MAKE LOVE TO MY HUSBAND, FORGETS THINGS EASY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057105	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 8/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE DEVICE, WHICH RESULTED IN ME HAVING TO HAVE A HYSTERECTOMY FROM BLEEDING EXCESSIVELY, ABDOMINAL PAIN. SO MY DOCTOR HAD TO REMOVE THEM IMMEDIATELY. MY JOURNEY ENED WITH 2 BLOOD TRANS FUSION. AND SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057106	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 12/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS EXPERIENCING HEAVY BLEEDING...WEIGHT GAIN, A CYST THE SIZE OF GRAPEFRUIT ON OVARY. FOUND OUT ABOUT CYST DUE TO TESTS RAN WHEN I HAD A STROKE. I AM NOW ON BLOOD THINNERS FOR LIFE. BLOOD PRESSURE AND CHOLESTEROL MEDICATIONS. I HAD TO HAVE A HYSTERECTOMY AS WELL. I HAD TO STAY AT A REHABILITATION CENTER TO DO SPEECH, PHYSICAL THERAPY AFTER MY HOSPITAL STAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057107	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I JUST HAD A PARTIAL HYSTERECTOMY SURGERY ON (B)(6) TO REMOVE THE ESSURE COILS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057108	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 8/20/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE COILS HAVE CAUSED BLOATING PAIN NAUSEA MIGRAINES. THE COILS SHREDDED MY FALLOPIAN TUBE AND I HAD TO HAVE THE TUBE REMOVED. THE OTHER COIL OBLITERATED AND THEY CAN'T GET ALL THE PIECES OUT. I HAVE A RASH DUE TO THE NICKEL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057109	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/26/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) STARTING TO HAVE ANXIETY THEN NOTICE WEIGHT GRAIN ALSO SLEEPING PROBLEMS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057110	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/26/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVER SINCE MY ESSURE PROCEDURE, I HAVE HAD REOCCURRING BACTERIAL INFECTIONS. WHICH NOW REQUIRE ME TO TAKE WEEKLY MEDS... I ALSO SOAK MY BED MOST NIGHTS WAKING UP LIKE SOMEONE POURED GALLONS OF WATER OVER ME....

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057111	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 7/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVEN'T STOPPED BLEEDING SINCE I HAD THE ESSURE DEVICE IMPLANTED. I ALSO EXPERIENCE SHARP SHOOTING PAINS THROUGHOUT MY ENTIRE BODY. I HAVE EXTREME EXHAUSTION. MY JOINTS HURT WITH EVERY MOVEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057112	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 1/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I RECEIVED ESSURE AFTER HAVING BLOOD CLOTS. I WAS MISDIAGNOSED AND WARNED ANOTHER PREGNANCY COULD KILL ME. I WAS INTRODUCED TO ESSURE. I HAD IT IMPLANTED IN 2003! I HAVE NO ENERGY, I'M LOSING MY HAIR. IT USED TO BE VERY FULL AND NOW IT'S THIN. I HAVE MUSCLE ACHES AND CRAMPS ALMOST EVERYDAY, MY MOOD IS ALL OVER THE PLACE. I SUFFER FROM SEVERE ANXIETY NOW, I HAVE A PULLING/BURNING FEELING ON MY RIGHT SIDE (NO NOTED INJURIES), BREAST TENDERNESS, LOSS OF LIBIDO AMONG OTHER ISSUES. MY DEVICE WAS COVERED BY MEDICAID.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057113	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 5/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BECAME DEPRESSED, OVERWEIGHT, NAUSEA, ADENOMYOSIS, HEADACHES, BUMPS POPPING UP IN DIFFERENT PLACES ON MY BODY, CHRONIC BACK PAIN, SORE BREAST, MIGRAINES, JOINT PAIN, IRREGULAR PERIODS, HEAVY BLEEDING, ANXIETY, IRREGULAR BOWEL, MAJOR CRAMPS, FALLOPIAN TUBE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057114	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ESSURE WAS PLACED IN 2007. FOR MANY YEARS SINCE I HAVE HAD CHRONIC HEADACHES, MIGRAINES, LOW BACK PAIN, BRAIN FOG, EXTREME LETHARGY, MUSCLE WEAKNESS. IN THE LAST 2 YEARS I HAVE HAD INTERMITTENT SHARP STABBING PAIN IN MY PELVIC AREA, AND VAGINAL AREA. THIS ENTIRE TIME I DID NOT ASSOCIATE THESE SYMPTOMS WITH ESSURE UNTIL I SAW NEWS REPORTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057115	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN HAVING STOMACH CRAMPS THAT STARTED A FEW YEARS AFTER THE ESSURE COILS WERE PLACED. LAST WEEK I WENT TO THE EMERGENCY ROOM WITH EXCRUCIATING PAIN IN MY LOWER ABDOMEN. THE DOCTOR ORDERED A CT SCAN AND I JUST RECEIVED THE RESULTS. ONE COIL IS 3-4 MM INTO MY PERITONEAL CAVITY AND IT SAID WORRISOME FOR MALPOSITION. THE SECOND COIL DIDN'T EVEN APPEAR ON THE SCAN. THE DOCTOR RECOMMENDED CLINICAL CORRELATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057116	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 10/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWOLLEN LEGS, ARMS, ANKLES, FACE, JOINTS HURT, BLURRED VISION, CRAMPING, WEIGHT GAIN, URINATING CONSTANTLY, HEADACHES, HEAVY PERIODS, PAIN DURING INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057117	BAYER	10/16/2015	10/16/2015

Event Information:

Event Date (B3): 7/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT ABDOMINAL PAIN AND CRAMPING. MENSTRUAL FLOW WAS NEVER CONSISTENT. EVERY MONTH WAS EITHER NON EXISTENT LIGHT PINK DISCHARGE AND SEVERE CRAMPING, OR SEVERE BLEEDING. I WOULD FILL A PAD WITHIN MINUTES WITH CLOTS THAT WERE THE SIZE OF GOLF BALLS AND TINY TANGERINES. I WOULD PASS BLACK TISSUE, RED TISSUE AND SOMETIMES WHITE TISSUE (GREY TISSUE). THIS TURNED OUT TO BE CONFIRMED ENDOMETRIOSIS THAT GREW INTO MY ABDOMINAL WALL. (B)(6) 2015 I HAD A HYSTERECTOMY REMOVING THE CERVIX AND TUBES (AND ESSURE). IT WAS SUPPOSED TO BE A VAGINAL HYSTERECTOMY, BUT ENDED UP BEING A ABDOMINAL HYSTERECTOMY BECAUSE OF THE ENDOMETRIOSIS AND THE ADHESIONS IT HAD CAUSED AS WELL AS THE SCAR TISSUE FROM MY C-SECTION. I WOUND UP IN THE HOSPITAL FOR 3 DAYS AND 2 NIGHTS. AFTER SURGERY I HAD SEVERE PAIN IN MY ABDOMEN I COULDN'T MOVE WITHOUT WANTING TO FAINT. I WAS THROWING UP, AND WANTED TO VOMIT EACH TIME I MOVED. I WAS PUT ON STRONG HEAVY PAIN MEDICATION AS WELL FOR MY SURGERY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057272	BAYER	10/16/2015	10/22/2015

Event Information:

Event Date (B3): 2/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A57120

Single Use: *
Implant Date (E6): 2/14/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD "ESSURE" IMPLANTED IN (B)(6) 2013. IN THE WEEKS AND MONTHS FOLLOWING THE IMPLANTATION I SUFFERED DISCOMFORT, CRAMPING, HEADACHES AND HEAVY AND IRREGULAR BLEEDING. FURTHERMORE, I UNDERWENT A PAINFUL INITIAL FUNCTIONALITY TEST FOLLOWED BY A SECOND AND EVEN MORE PAINFUL FUNCTIONALITY TEST AFTER THESE TESTS IT WAS DETERMINED BY THE PHYSICIAN THAT THE ESSURE IMPLANT WOULD NOT DELIVER THE DESIRED RESULT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057273	BAYER	10/16/2015	10/22/2015

Event Information:

Event Date (B3): 10/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/1/2010
Explant Date (E7): 10/12/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE BIRTH CONTROL COILS IMPLANTED IN 2010. I HAVE HAD PAIN IN MY LOWER BACK SINCE SHORTLY AFTER THEY WERE PLACED. WORSENING SYMPTOMS OF DEPRESSION, HEAVINESS IN MY LIMBS, INCREASED BLEEDING DURING MENSTRUAL CYCLE, INABILITY TO FOCUS, IRRITABILITY, HEADACHES, PAIN WITH INTERCOURSE AND LETHARGY, BURNING SENSATION AND SWELLING IN MY UTERUS. LOWER BACK PAIN BECAME SO BAD I WAS NO LONGER ABLE TO EXERCISE AND GAINED WEIGHT. I BEGAN TAKING ADDERALL FOR MY INABILITY TO FOCUS. I SAW SEVERAL DOCTORS OVER THE YEARS WHO DIDN'T THINK ESSURE WAS THE CAUSE OF ANY OF THESE SYMPTOMS. CONCLUSIONS REACHED WITHOUT ANY TESTING OR EXPERIENCE WITH ESSURE. I WAS TOLD IT COULD BE AGE RELATED, POSSIBLY PERIMENOPAUSE. I'M ONLY (B)(6) AND AM VERY HEALTHY OTHERWISE. ON (B)(6) I HAD A PELVIC ULTRASOUND THAT COULD NOT DETERMINE WHERE THE COILS WERE IN MY BODY. I INSISTED ON ANOTHER PELVIC ULTRASOUND THAT WAS REVIEWED BY A MATERNAL FETAL RADIOLOGIST WHO SPECIALIZED IN READING ULTRASOUNDS OF THE REPRODUCTIVE AREA. UPON REVIEW OF BOTH THE ULTRASOUND AND A STOMACH X-RAY THE COILS WERE FOUND TO HAVE MIGRATED. IT WASN'T CLEAR IF IT WAS ONE OR BOTH. I HAD SURGERY TO REMOVE THE COILS. THE SURGERY SHOWED BOTH COILS HAD PERFORATED MY FALLOPIAN TUBES AND MIGRATED TO THE END OF THE TUBES. SEVERAL DAYS AFTER THE SURGERY I NO LONGER HAVE ANY LOWER BACK PAIN OR BURNING SENSATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057271	BAYER	10/17/2015	10/22/2015

Event Information:

Event Date (B3): 7/14/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 7/14/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL DEVICE IN 2010 APPROXIMATELY SIX MONTHS LATER I DEVELOPED EXTREME ABDOMINAL BLOATING. COWORKERS, FRIENDS, AND STRANGERS OUT IN PUBLIC WOULD ASK WHEN THE BABY WAS DUE. I WOULD ANSWER THAT I WAS NOT PREGNANT AND HAD SEVERAL UPCOMING DOCTOR APPOINTMENTS TO FIGURE OUT WHAT IS WRONG. MY GYNECOLOGIST DID A ULTRASOUND TO DETERMINE IF I HAD FIBROIDS OR ANY OTHER TYPE OF PROBLEM WITH MY UTERUS AND IT CAME BACK PERFECTLY NORMAL. I THEN HAD A COLONOSCOPY DONE TO SEE IF THER WAS AN INTESTINAL BLOCKAGE. AGAIN THAT CAME BACK PERFECTLY NORMAL AND YET I WAS STILL BLOATED, UNCOMFORTABLE AND MISERABLE. I ALSO DEVELOPED EXTREME FATIGUE AND LETHARGY. BY GENERAL PRACTITIONER DID A FULL BLOOD WORK UP AND DETERMINED THAT I WAS VITAMIN D DEFICIENT. MY GYNECOLOGIST ALSO DID A FULL HORMONE WORK UP AND IT CAME BACK AS PERFECTLY NORMAL. I HAVE LIVED FOR THE PAST FEW YEARS WITH CONTINUED ABDOMINAL SWELLING AND EXTREME DISCOMFORT AND LETHARGY WITHIN THE PAST YEAR I HAVE DEVELOPED HORRIBLE JOINT PAIN AND SWELLING OF MY KNEES, MY PELVIS AND RIBCAGE ACHE AND I HAVE SHARP ABDOMINAL PAINS AND LOWER BACK PAIN. I UNDERSTAND THAT ALL MEDICAL DEVICES AND MEDICINE HAVE SIDE EFFECTS, HOWEVER NONE OF THESE WERE EVER MENTIONED. I WAS ALSO NEVER TESTED FOR A NICKEL ALLERGY BEFORE I HAD THIS ESSURE PROCEDURE DONE. IT'S MY FIRM BELIEF THAT THIS PRODUCT HAS WREAKED HAVOC ON MY BODY IN THESE PAST 5 YEARS. I HAVE HAD NO HEALTH ISSUES THE WHOLE OF MY LIFE ALL FOUR OF MY PREGNANCIES WERE PERFECTLY NORMAL. I DON'T SMOKE OR DRINK. I HAVE MAINTAINED A HEALTHY WEIGHT THROUGHOUT MY LIFE AND HAVE ENJOYED GREAT HEALTH UNTIL THIS PRODUCT WAS PUT IN ME. I HAVE AN APPOINTMENT WITH MY

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GYNECOLOGIST ON (B)(6) 2015 TO TALK ABOUT REMOVING ESSURE FROM MY BODY. MY NON-SURGICAL CHOICE OF ESSURE HAS LED TO YEARS OF HEALTH ISSUES, LOSS OF MONEY AND WORK HOURS AND NOW I WILL HAVE TO UNDERGO A HYSTERECTOMY TO REMOVE THEM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057279		10/17/2015	10/22/2015

Event Information:

Event Date (B3): 5/24/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/24/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE DEVELOPED ARRHYTHMIA AFTER THE PLACEMENT OF THE ESSURE, THIS INCLUDES DIZZINESS AND CHEST PAIN AND SHORTNESS OF BREATH. I HAVE HAD TWO CARDIAC ABLATIONS AND A THIRD WILL BE DONE (B)(6) 2015. I HAVE WORSENING MIGRAINES, AND WORSENING NAUSEA. I HAVE ALSO DEVELOPED LONGER PAINFUL MENSTRUAL PERIODS. I RECENTLY HAD TO GET AN UTERINE ABLATION FOR IT. I COULD NOT LEAVE MY HOME BECAUSE I WAS BLEEDING THROUGH MY CLOTHES. I ALSO BLEED AFTER SEX. I BLEED IN BETWEEN PERIODS. I ALSO HAVE A FIBROID TUMOR. IF THE ABLATION DOES NOT WORK I WILL BE GIVEN A HYSTERECTOMY. I AM ALWAYS IN PAIN. HAVE ALSO TRIED MANY MIGRAINE MEDS THAT DON'T WORK. I SEE A HEADACHE SPECIALIST IN (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01196	BAYER HEALTHCARE LLC	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 6/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18705

Single Use: Y
Implant Date (E6): 3/9/2015
Explant Date (E7): 6/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 04-JUN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C18705, INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION. ON (B)(6) 2015 ESSURE CONFIRMATION TEST WAS PERFORMED AND SHOWED UNSATISFACTORY INSERT LOCATION. PHYSICIAN REPORTED THAT LEFT SIDE WAS FLOATING IN ABDOMEN. HOSPITALIZATION WAS NOT REQUIRED. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD C18705 (PRODUCTION DATE 27-JAN-2014 AND EXPIRATION DATE 31-JAN-2017) AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED

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QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. FOLLOW-UP FROM 15-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. THE ESSURE HEALTH CARE PROVIDER UTERINE/ TUBAL PERFORATION QUESTIONNAIRE WAS PROVIDED ON 21-SEP-2015: PATIENT'S DEMOGRAPHIC DATA WERE ADDED: (B)(6). SHE WAS NOT PREGNANT. HER RELEVANT MEDICAL HISTORY INCLUDES GRAVIDA 4, PARITY 2 AND 2 SPONTANEOUS ABORTION. PREVIOUS GYNECOLOGICAL INTERVENTION, GYNECOLOGICAL PROBLEMS OR PROCEDURES WERE DENIED. ESSURE WAS INSERTED UNDER GENERAL ANESTHESIA ON (B)(6) 2015. CERVICAL DILATION AND SOUNDING WERE APPLIED DURING INSERTION. IT WAS REPORTED THAT PHYSICIAN WAS UNABLE TO SEE GRAY LINE DURING THE PROCEDURE DESPITE ASSISTANCE OF REPRESENTATIVE. THE PROCEDURE TOOK 31 MINUTES. FLUID LOSS MORE THAN 1500CC DURING HYSTEROSCOPY WAS DENIED. PATIENT USED CONDOMS AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION. THE HSG TEST (HYSTEROSALPINGOGRAM) WAS PERFORMED ON (B)(6) 2015 AND IT SHOWED PERFORATION/ DEVICE IN ABDOMEN. SHE DID NOT PRESENT ANY SYMPTOMS. ESSURE COILS WERE REMOVED VIA LAPAROSCOPY WITHOUT COMPLICATION ON (B)(6) 2015. THE REMOVAL WAS MEDICALLY NECESSARY AND IT WAS ALSO A PATIENT'S REQUEST. UTERUS, TUBES AND OVARIES WERE NORMAL ON LAPAROSCOPY. HYSTERECTOMY OR SALPINGECTOMY WERE NOT NECESSARY BUT DONE BY PATIENT'S CHOICE FOR PERMANENT STERILIZATION. THE PATHOLOGY RESULTS WERE NORMAL - TUBAL BILATERALLY. DURING SURGERY THE DEVICE WAS FOUND IN OMENTUM. THE PATIENT HAS RECOVERED FROM THE ESSURE REMOVAL PROCEDURE. OUTCOME IS SATISFACTORY. THE REPORTER STATED THAT THE PATIENT'S CONDITION WAS NOT CAUSED BY ESSURE. ESSURE DID NOT CONTRIBUTE TO THE ISSUE. CASE UPGRADED TO INCIDENT. UPDATED PTC INVESTIGATION RESULT RECEIVED ON 02-OCT-2015: MINOR CHANGES, NO NEW RELEVANT CLINICAL INFORMATION. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER 3-MONTH CONTROL HSG (HYSTEROSALPINGOGRAM) SHOWED PERFORATION/ THE DEVICE WAS IN ABDOMEN. SHE WAS SUBMITTED TO A LAPAROSCOPY; THE DEVICE WAS FOUND IN OMENTUM AND BOTH ESSURE DEVICES WERE REMOVED WITHOUT COMPLICATIONS. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS CASE, ESSURE INSERTION WAS DIFFICULT (PROCEDURE TOOK LONGER THAN EXPECTED AND PHYSICIAN WAS UNABLE TO SEE CATHETER MARKER). THIS COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED PERFORATION. THE PHYSICIAN BELIEVED THIS EVENT WAS NOT RELATED TO ESSURE. ALTHOUGH ITS EXACT MECHANISM WAS UNKNOWN; GIVEN ITS NATURE AND THE CLOSE TEMPORAL RELATION WITH ESSURE INSERTION, COMPANY CONSIDERS CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT. HOWEVER, UPON RECEIPT OF FOLLOW-UP INFORMATION, PHYSICIAN INFORMED DEVICE REMOVAL WAS REQUIRED. THEREFORE, CASE WAS UPGRADED TO INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01197	BAYER HEALTHCARE LLC	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 9/21/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C59252

Single Use: Y
Implant Date (E6): 9/21/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 21-SEP-2015 WHICH REFERS TO A (B)(6)FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER C59252. DURING ESSURE INSERTION PROCEDURE, THE COVERING CATHETER DID NOT ROLL BACK AND THE DEVICE GOT STUCK WITHIN THE CATHETER. THE COIL WAS STUCK IN THE PATIENT. THE PHYSICIAN CUT THE CATHETER BETWEEN PURPLE HANDLE AND THE SCOPE. HE TOOK SCOPE OUT AND THEN PUT THE SCOPE BACK IN. THEN, HE USED GRASPERS AND SEPARATED THE CUT INSERTION CATHETER FROM THE DEVICE. PORTIONS OF COIL WERE IN PATIENT; INNER COIL WAS INTACT AND PORTIONS OF OUTER COIL WERE STILL WITHIN THE INSERTION TUBE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 04-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICROINSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT

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AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF DETACHMENT DIFFICULTY IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE AND A USABILITY ISSUE. ADDITIONALLY, A DEVICE MISUSE WAS REPORTED. NO MEDICAL EVENTS WERE REPORTED AT THIS POINT IN TIME. SINCE NO ADVERSE EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP TO A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE, THE COVERING CATHETER DID NOT ROLL BACK AND THE DEVICE GOT STUCK WITHIN THE CATHETER AND THE COIL WAS STUCK IN THE PATIENT. PHYSICIAN HAD TO CUT THE CATHETER AND TO USE GRASPERS TO SEPARATE THE CATHETER FROM THE DEVICE. PORTIONS OF THE COIL REMAINED IN THE PATIENT. THE REPORTED EVENT, REGARDED AS A DEVICE DEPLOYMENT ISSUE, IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL; IN THIS PARTICULAR CASE ESSURE INSERTION WAS COMPLICATED BY A DEVICE DEPLOYMENT ISSUE. A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THIS EVENT; HOWEVER CONSIDERING THAT IT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENT DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 04-NOV-2015, REFERRING TO PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIO

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057118	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CHOOSE ESSURE AFTER DOING A LOT OF RESEARCH FOR PERMANENT STERILIZATION. IT WAS FULLY COVERED BY INSURED, SUPPOSED TO BE NONINVASIVE, WITH NO TIME OFF WORK. MY PROCEDURE WAS DONE IN THE DRS OFFICE BY TWO WOMAN WHO SEEMED TO BE VERY APPREHENSIVE AND NOT TOO CONFIDENT. NEITHER WERE MY REGULAR OBGYN. THE ONE SIDE WENT IN CORRECTLY AND INSERTED DEEP ENOUGH INTO TUBE. THE OTHER BARELY WENT IN AND THEIR COUNT OF REMAINING COIL AND MINE WERE DIFFERENT. I WAS UNDER IMPRESSION THE COILS WERE MORE PLASTIC NOT A SOLID METAL DEVICE THAT COULD BE SO DAMAGING. HORRIBLE BACK PAIN DURING PERIODS. HEAVY BLEEDING THAT TOOK FOREVER TO REGULATE. BLEEDING WEEKS AT A TIME. BAD MIGRAINES SOMETIMES SEVERAL IN A MONTH AND BEFORE THEY WERE VERY RARELY. PAINFUL SEX AND NO SEX DRIVE ANYMORE, THIS WAS THE EXACT OPPOSITE PRIOR TO PROCEDURE. FATIGUE, BRAIN FOG, AND HORMONES ARE ALL OUT OF WHACK. IF YOU ASKED ME I FEEL LIKE IT'S PUSHED ME INTO ORE MENOPAUSE AT (B)(6). ANOTHER REASON WHY I CHOOSE ESSURE INSTEAD OF LOOSING OVARIES. MY LEFT SIDE IS VERY TENDER AND IF PRESSED UP AGAINST, TOUCHED OR WITH SEX I GET SHARP PAINS. MY (B)(6) PUPPY WALK ACROSS TUMMY AND MAKES ME CRY FROM THE PAIN OVER MY LEFT OVARY. AT 3MONTH DYE CHECK UP THE TUBES WERE BLOCK AND THE OTHER HANGING WELL INTO UTERUS. (NOT SURE OF APPROPRIATE/ACCEPTABLE DEPTH) WHAT ARE THEY GOING TO DO THOUGH?!?! HAVE SURGERY AND TRY AGAIN, IT'S A ONE SHOT DEAL, YOU CAN'T FIX THE LEFT SIDE THAT ISN'T IN CORRECTLY. NOW I'LL HAVE TO RISK IT COMING OUT IF IT HASN'T ALREADY, RISK OF PERFORATION, PREGNANCY, PAIN, AND POSSIBILITY OF FUTURE SURGERY THAT WILL PUT ME OFF WORK TO FIX. ALL THAT I TRIED TO AVOID. NOT TO MENTION THE STRESS AND PAIN I AM CONSTANTLY IN. I SHOULD HAVE GONE WITH TUBAL LITIGATION OR PARTIAL HYSTERECTOMY AND NOT HAD THIS MESS. MY DOCTOR HAS SCHEDULED A

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ULTRASOUND TO INVESTIGATE WHY THE PAIN IS GETTING WORSE. MY HUSBAND WANTS THE OLD ME BACK AND SO DO I. WISH I COULD GO BACK AND MAKE THAT DECISION AGAIN, HAVE ENERGY,PAIN FREE, NO STRESS. I HAVE A LOT OF OTHER SYMPTOMS THAT OTHER WOMAN HAVE THAT COULD BE ESSURE RELATED AS WELL. THESE LISTED ARE THE ONES THAT ARE THE WORST AND MOST TROUBLESOME FOR ME THOUGH. WOULD LIKE TO HAVE THEM FULLY REMOVED WITH PARTIAL HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057119	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SUFFERED FROM EXTREME FATIGUE , WEIGHT GAIN, SEVERE STOMACH BLOATING, DEBILITATING BACK AND PELVIC PAIN WHICH I WAS ADVISED WOULD SUBSIDE IN A FEW DAYS HERE IT IS 6 YEARS LATER AND I AM STILL SUFFERING BACK AND PELVIC PAIN AND NO ONE CAN HELP WITH, I ALSO SUFFER WITH BRAIN FOG , RINGING IN EARS (PULSATILE TINNITUS) DEPRESSION VITAMIN D DEFICIENCY, VITAMIN B-12 DEFICIENCY, FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, UNEXPLAINED BRUISING, AMENORRHEA, HAIR LOSS, AND A METALLIC TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057120	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 11/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YES, DEVICE WAS PROVIDED BY INSURER. LET ME PREFACE MY EXPERIENCE BY STATING THAT I AM, HANDS DOWN, THE HEALTHIEST PERSON I KNOW. ASK ANYONE AT MY GYM, MY JOB, OR ASK MY FRIENDS AND FAMILY. I EAT CLEAN, EXERCISE, INTENSELY, DAILY, SLEEP 8 HOURS A NIGHT AND DON'T TAKE ANY MEDICATION. I'M NOW (B)(6). I HAD ESSURE IMPLANTED IN (B)(6) 2012. NEVER WANTED KIDS, DIDN'T WANT HORMONES RUNNING RAMPANT IN MY BODY, SO THIS SEEMED, AFTER MUCH RESEARCH, THE LEAST INVASIVE, SAFEST, EASIEST ALTERNATIVE TO HORMONES OR TUBAL LIGATION. YEAR 1: FELT LIKE I HAD BEEN HIT BY A BUS, DAILY. JOINT PAIN, FLU-LIKE SYMPTOMS. I KEPT SAYING "MY BONES HURT" BECAUSE THAT WAS LITERALLY THE ONLY WAY I COULD DESCRIBE THE PAIN. I FELT LIKE I'D BEEN POISONED, LIKE THERE WAS A HEAVY METAL COURSING THROUGH MY VEINS. FATIGUE, LETHARGY, I COULD HARDLY DRAG MYSELF OUT OF BED. I WOKE UP REPEATEDLY OVER THE FIRST YEAR WITH SEVERE NIGHT SWEATS AND CRAMPING. I SPENT COUNTLESS DAYS AND NIGHTS SOBBING AND WONDERING WHAT WAS WRONG WITH ME. I FINALLY DECIDED I HAD EITHER FIBROMYALGIA OR POSSIBLY LEUKEMIA. I KNOW NOW THAT MY BODY WAS REACTING TO THE IMPLANTS, MOST LIKELY THE NICKEL AND THAT I WAS IN FACT FIGHTING MY BODY BEING POISONED FROM THE INSIDE. ADDITIONALLY, SOMEONE AS HEALTHY AS ME EXPERIENCING INFLAMMATION (AS THAT IS WHAT ENABLES THE ESSURE TO WORK AS A BARRIER, SCAR TISSUE DEVELOPING AND INFLAMMATION), I FEEL, LED TO THIS ADVERSE RESPONSE. AS YOU KNOW, INFLAMMATION IS THE SOURCE OF PAIN, DEBILITATION AND DISEASE. YEAR 2-3 (CURRENT): WELL, THAT EVENTUALLY ENDED. THEN, FOR THE LAST YEAR, I'VE HAD EXCRUCIATING PAIN IN MY SIDES/ABDOMEN. THOUGHT IT WAS KIDNEY STONES, POSSIBLY. NOW, I DON'T HAVE INSURANCE, SO EVERYTHING IS OUT OF POCKET FOR ME. I'VE HAD LABOR-PAIN TYPE MENSTRUAL CRAMPS. I DON'T EVER STOP BLEEDING. ALL MONTH, BLOOD. I GUESS ESSURE DOES THE TRICK BECAUSE SEX HAS BECOME SO PAINFUL OVER

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THE LAST YEAR THAT I JUST CAN'T HANDLE IT ANYMORE. MY PARTNER OF 3 YEARS AND I ARE NOW ABSTINENT AS A RESULT OF ESSURE. NOT TO MENTION, EACH TIME I HAVE SEX OR EXERCISE AT THE GYM, OR RUN SPRINTS (ANYTHING THAT INVOLVES THE WAIST/HIPS AREA), I BLEED AFTERWARD. I BLEED DURING SEX, AFTER SEX, AND FOR WEEKS FOLLOWING SEX. MY VAGINAL DISCHARGE SMELLS DIFFERENT THAN IT HAS MY WHOLE LIFE, AND IT'S NOT A PLEASANT SMELL. I HAVE PERSISTENT STABBING PAINS IN MY ABDOMEN. BOTH SIDES, ALL DAY, EVERY DAY. I HAVE INTERMITTENT SEVERE GAS AND BLOATING OF THE ABDOMEN, FROM MY RIB CAGE DOWN. THE CONSTANT PAIN IN MY SIDES AND BLEEDING AND NO SEX I DECIDED I'D JUST HAVE TO LIVE WITH. I WENT TO THE GYNECOLOGIST WHO INSERTED THE ESSURE AND SHE SAID ALL OF THE ABOVE ARE SYMPTOMS RELATED TO MY AGE, THAT IT'S "THAT TIME." WHEN I TOLD HER I THOUGHT IT WAS THE ESSURE SHE SAID NO. SHE SAID THE ONLY WAY I COULD GET RID OF THE ESSURE WAS TO HAVE A FULL HYSTERECTOMY. I WENT TO A SECOND GYNECOLOGIST THAT A FRIEND RECOMMENDED AND HE SAID THAT THE SYMPTOMS WERE UNDOUBTEDLY A RESULT OF THE ESSURE (HE ORDERED AN X-RAY THAT SHOWED THE IMPLANTS WERE EXACTLY IN THE CORRECT POSITION, SO WE KNOW IT'S NOT FROM BREAKING/MOVEMENT) AND THAT HE COULD REMOVE THEM LAPAROSCOPICALLY, BUT HE'D NEVER DONE THAT BEFORE. WHEN I COULDN'T GET A PRICE QUOTE, I DENIED THAT SURGERY. VERY SCARY. SO, I'VE BEEN DOING RESEARCH SINCE ON DOCTORS WHO PERFORM ESSURE REMOVALS (ALL ARE AT IVF CLINICS). THREE DAYS AGO I FINALLY BIT THE BULLET AND SCHEDULED MY ESSURE REMOVAL WITH (B)(6). I WILL BE PAYING (B)(6) OUT OF MY OWN POCKET FOR REMOVAL AND MISSING 2 WEEKS OF WORK (FOR WHICH I DO NOT GET PAID, SINCE I AM A CONTRACTOR. THAT LOSS IS ANOTHER (B)(6)). THAT'S HOW DESPERATE I AM TO GET THESE EVIL THINGS OUT OF ME AND FEEL BACK TO NORMAL. OVER THE PAST THREE YEARS, I'VE SPENT OVER (B)(6) TRYING TO FIGURE OUT WHAT'S WRONG WITH ME AND GETTING THE ESSURE IMPLANTS REMOVED. ALTHOUGH NOBODY CAN "PROVE" THAT THE ESSURE RESULTED IN MY SLEW OF SYMPTOMS, I KNEW INTUITIVELY THAT THERE WAS NO OTHER EXPLANATION. AFTER RESEARCH, SPEAKING WITH MY PCP AND FINDING THAT OTHER WOMEN HAD THE SAME HORRIBLE SYMPTOMS, I CAN CONFIRM THAT I'M NOT CRAZY AFTER ALL. IT'S NOT ALL IN MY HEAD. IT'S ALL IN MY FALLOPIAN TUBES. I AM COUNTING THE DAYS UNTIL THE SURGERY, ALTHOUGH I'M TERRIFIED OF THE GENERAL ANESTHESIA AND RECOVERY TIME BECAUSE I TAKE EXCELLENT CARE OF MYSELF AND NEVER THOUGHT I'D BE ENDURING THIS. SUMMARY OF SIDE EFFECTS I EXPERIENCED SINCE ESSURE IMPLANTS IN 2012: BONE ACHES; JOINT ACHES; LETHARGY; CHRONIC FATIGUE; NIGHT SWEATS; CHRONIC STABBING PAINS IN SIDES (HAVE NEVER GONE AWAY FOR THE LAST YEAR); CHRONIC PELVIC PAIN; PAINFUL INTERCOURSE; FLU-LIKE SYMPTOMS; STABBING PAIN IN LOWER ABDOMEN (OVARY/FALLOPIAN TUBE AREA); INTERMITTENT; SEVERE MENSTRUAL CRAMPING (NEVER HAD THIS BEFORE); BLEEDING DURING SEX; BLEEDING FOR WEEKS AFTER SEX; BLEEDING AFTER EXERCISE; BLEEDING ALL THE TIME, EVEN JUST SITTING; SEVERE GAS; SEVERE BLOATING AND DISTENDED ABDOMEN ALMOST ALL THE TIME ; FOUL-SMELLING VAGINAL DISCHARGE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057121	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) SHARP STABBING PELVIC PAIN, LOWER BACK PAIN,HIP PAIN, JOINT PAIN, WEIGHT GAIN SEVERE BLOATING, PAIN DURING SEX, STOMACH ISSUES, NAUSEA GAS CONSTIPATION, DIARRHEA STOMACH SPASMS, LOSS OF SEX DRIVE, DEPRESSION, NO ENERGY PAINFUL OVULATION, BLEEDING AND SPOTTING AFTER SEX, HEADACHES, ACNE AND BOILS, HAIR GROWTH ON FACE, HEARTBURN ACID REFLUX, BOWEL PROBLEMS, METALLIC TASTE IN MOUTH INSOMNIA, OVARIAN CYST, BLACKOUT SPELLS, LEG FEET AND HANDS SWELLING MOOD SWINGS, SEVERE FATIGUE, BRAIN FOG PROBLEMS WITH SHORT TERM MEMORY ALL OVER ACHES

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057122	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 2/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS FINE AT FIRST UNTIL (B)(6) 2015. I STARTED FEELING PELVIC PAIN DURING SEX AND CONSTANT PAIN IN MY ABDOMEN AREA AS WELL AS VAGINA AREA. CONSTANT SWELLING OF THE STOMACH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057123	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SIGNIFICANT HAIR LOSS, MAJOR ABDOMINAL BLOATING, RANDOM ABDOMINAL/PELVIC PAIN, BRAIN FOG, DETERIORATING DENTAL HEALTH (BROKEN TOOTH, RECEDING GUMS), AND JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057124	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) ON (B)(6) 2008 I RECEIVED ESSURE. I HAD NEVER HAD PROBLEMS UNTIL IT WAS PLACED. IT WAS INSTALLED AT MY OBGYN PAID FOR BE (B)(6). THE PROBLEMS ARE EVERY MONTH SINCE (B)(6) 2008. THE ISSUES WITH ESSURE FOR ME ARE AS FOLLOWS: UNCONTROLLABLE BLEEDING, CLOTTING NOT JUST AT THE TIME OF THE MONTH BUT IN-BETWEEN AS WELL WHICH HAS MADE ME ANEMIC. SHARP PAINS IN MY SIDES, PELVIC AREA, AND BACK. NAUSEA AS IF I WERE PREGNANT. CRAMPING I HAVE NEVER EXPERIENCED BEFORE I RECEIVED ESSURE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057125	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) SINCE HAVING IT PUT IN (B)(6) 2010 TO NOW IM HAVING SEVERE PAIN, LIKE SOMEONE TAKING KNIFE AND CONTINUALLY STABBING IN LOWER ABDOMEN. HEADACHES THAT NEVER GO AWAY. BODY BECOMING INFECTED ALL THE TIME AND HAVING TO TAKE MEDS. LOSING LOTS OF HAIR. NO ENERGY. STOMACH STAYING IN PAIN AND SWOLLEN, CAUSING ME THE GET SICK WHEN I FINISH EATING 90% OF THE TIME. JUST TO NAME A FEW!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057126	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS HAS BEEN ONGOING FOR YEARS (JUST HAD TO PICK A DATE). I HAVE DIZZINESS, SEVERE HEADACHES AND MIGRAINES, ALLERGIC REACTION TO GOLD AND POSSIBLE OTHER METALS, LEG ACHES, DEPRESSION, AND TERRIBLE PMS WHICH ALL STARTED AFTER THE IMPLANTS WERE PUT IN 2005.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057127	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SEVERE ABDOMINAL PAIN DURING MY MENSES THAT GO INTO MY THIGHS, I HAVE CRAMPING EVEN WHEN I'M NOT ON MY MENSES, I HAVE EXTREME HEAVY FLOW DURING PERIODS WITH CLOTS BIGGER THAN A QUARTER, I GET REALLY NAUSEATED WHILE ON MY PERIOD, I HAVE RASH THAT COMES AND GOES ALL OVER MY BODY. MY TEETH HAVE BEEN CHIPPING EASILY, I HAVE MORE CAVITIES, I HAVE HAD 2 TEETH PULLED AND A ROOT CANAL ALL IN A 2 YEAR PERIOD SINCE I HAD ESSURE PLACED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057128	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YES, MY INSURANCE PAID FOR ESSURE. BEFORE THE IMPLANT, I WAS IN EXCELLENT HEALTH. MY THYROID HEALTH WAS UNDER CONTROL WITH MEDICATION. MY EXERCISE (HIIT TRAINING 4 TIMES A WEEK AND WALKING 3 DAYS) AND EATING HABITS WERE SOLID (LEAN EATING HABITS). SEVERAL MONTHS AFTER THE ESSURE IMPLANT WAS PLACED IN, I STARTED EXPERIENCING CHRONIC FATIGUE AND ABDOMINAL PAIN THAT MAKES IT VERY UNCOMFORTABLE TO SIT DOWN FOR EXTENDED PERIODS. MY HEALTH HAS TAKEN A TURN FOR THE WORSE SINCE THE IMPLANT AND I PLAN ON TAKING IT OUT. AFTER THE IMPLANT I WAS DIAGNOSED WITH HASHIMOTO'S, EBV, CANDIDA, ATROPHIC GASTRITIS (WITHOUT A KNOWN CAUSE), DRY EYES, DRY MOUTH, HAIR FALLING OUT IN LARGE AMOUNTS. I TRYING TO FIGURE OUT IF I HAVE SJOGREN'S SYNDROME AND AM DOING HEAVY METAL TESTING TO SEE IF I HAVE A NICKEL ALLERGY. SINCE THIS IMPLANT WAS PLACED IN ME, MY IMMUNE SYSTEMS IS IN A STATE OF DYSFUNCTION. FOR THOSE THAT DO NOT BELIEVE THIS IS HAPPENING TO A LOT OF WOMEN, THEY (MEN INCLUDED) SHOULD HAVE THE IMPLANT PLACED IN THEM AND SEE FOR THEMSELVES WHAT HAPPENS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057129	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 7/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I NOTICED A STRONG METALLIC TASTE IN MY MOUTH FIRST, IMMEDIATELY NOTICED URINE LEAKAGE WHICH WAS NEVER AN ISSUE, SEVERE MIGRAINE HEADACHES AT LEAST THREE TIMES A WEEK SINCE THIS PRODUCT, FOGGY VISION, CONFUSION, INABILITY TO RESPOND VERBALLY WITH THE THOUGHTS I NEED TO EXPRESS LIKE MY THOUGHTS ARE CLOUDY, I HAVE SHARP STABBING PAINS IN MY LOWER ABDOMEN WHERE THE COILS ARE PLACED ON BOTH LEFT AND RIGHT SIDES. I LEARNED I HAVE A NICKEL ALLERGY WHICH I WAS NEVER TESTED FOR BEFORE THE PLACEMENT. I HAVE NO SEX DRIVE AT ALL; WHEN I DID HAVE INTERCOURSE, IT WAS VERY PAINFUL, I HAVE BEEN GAINING WEIGHT AT A RAPID PACE. I WORKOUT AND EAT HEALTHY YET GAINED IN THE PAST 3 MONTHS 30+POUNDS. I'M EXTREMELY FATIGUED CONSTANTLY, WHEN I WALK JUST AROUND THE BLOCK OR DO CHORES AT HOME, MY BODY SWELLS. I EXPERIENCE NUMBNESS AND TINGLING IN MY HANDS, I HAVE THE WORST NIGHT SWEATS, AND I'M CONSTANTLY IN PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057130	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS PROVIDED BY (B)(6). I ALSO HAVE CELIAC DISEASE AND A PREVIOUS C-SECTION, BOTH IMPLANTING DOCTOR WAS AWARE OF. I HAVE CHRONIC ABDOMINAL PAIN AND PELVIC PAIN, EXTREME FATIGUE, ANEMIA, HEAVY AND LONG LASTING PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057131	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 2/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIAGNOSED WITH ADULT ON-SET STILLS DISEASE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057132	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 3/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, EVERYDAY MIGRAINES, FATIGUE, VAGINAL SWELLING, PAINFUL INTERCOURSE, NO SEX DRIVE, CONSTANT BLOATING, WEIGHT GAIN, HORRIBLE BACK AND PELVIC PAIN, SEVERE CRAMPING, BLOOD CLOTS WHILE MENSTRUATING, HEAVY BLEEDING, SEVERE DEPRESSION, NO ENERGY WHATSOEVER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057133	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 8/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ALREADY SUBMITTED COMMENTS ABOUT MY EXPERIENCE WITH ESSURE TO THE FDA'S WEBSITE. PLEASE SEE FDA TRACKING#'S (B)(4). I HAD ESSURE IMPLANTED IN (B)(6) 2009. THE PROCEDURE WAS EXCRUCIATINGLY PAINFUL TO THE POINT THAT I PASSED OUT FROM THE PAIN. BEFORE I PASSED OUT, I WAS SCREAMING "IS THIS SUPPOSED TO HURT SO BAD??!!" I REMEMBER THE DOCTOR SAYING THAT I HAD A "TIPPED UTERUS" AND THAT'S WHY SHE WAS HAVING TROUBLE WITH THE PLACEMENT AND WHY IT WAS TAKING SO LONG. THEN I PASSED OUT WITH TWO NURSES BY MY SIDE APPLYING COLD COMPRESSES TO MY HEAD AND TAKING MY BLOOD PRESSURE. WHEN I STARTED TO "COME TO", I HEARD THE TWO NURSES AND THE DOCTOR DISCUSSING WHETHER OR NOT I WAS GOING INTO SHOCK. WHEN I BECAME FULLY ALERT, THE DOCTOR TOLD ME SHE WAS GOING TO "TRY AGAIN" WITH THE PLACEMENT. I SAID, "I DON'T WANT TO TRY AGAIN IF IT'S GOING TO HURT SO BAD!" THE DOCTOR SAID SHE WOULD GIVE ME SOMETHING STRONGER FOR THE PAIN. THE SECOND TRY HURT LIKE HELL, BUT NOT AS BAD AS THE FIRST TRY. SINCE THE PROCEDURE, I HAVE HAD SYMPTOMS OF JOINT PAIN AND FATIGUE WHICH I THOUGHT WERE POSSIBLY FIBROMYALGIA SYMPTOMS. PLUS, I HAVE HAD UNEXPLAINED NUMBNESS IN MY ARMS. I HAD A NERVE TEST DONE ABOUT TWO YEARS AGO AND NO ABNORMALITIES WERE FOUND BY THE DOCTOR WHO DID THE NERVE TESTING. I WAS BASICALLY TOLD THAT I DID NOT HAVE CARPAL TUNNEL SYNDROME, BUT THE DOCTOR HAD NO EXPLANATION FOR THE NUMBNESS IN MY ARMS. SINCE THE ESSURE PROCEDURE, I GET MY PERIOD EVERY 18 TO 21 DAYS. I USED TO BE VERY REGULAR WITH MY PERIODS - EVERY 28 TO 30 DAYS, WITH HEAVY FLOW FOR THE FIRST 2 OR 3 DAYS FOLLOWED BY LIGHT FLOW FOR 2 OR 3 DAYS. NOW I HAVE HEAVY BLOOD FLOW FOR 5 DAYS, THEN A FEW DAYS OF LIGHT FLOW, THEN NO FLOW FOR A FEW DAYS AND THEN BROWN DISCHARGE FOR A FEW DAYS. IT ALWAYS FOLLOWS THAT SAME PATTERN. I WAS GIVEN A "WALLET CARD" TO CARRY ABOUT ESSURE

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BY THE DOCTOR WHO PERFORMED THE SURGERY. I WAS NEVER TOLD THAT THE COILS CONTAINED NICKEL. I HAVE KNOWN SINCE I'M A YOUNG GIRL THAT I AM SENSITIVE TO NICKEL. I AM NOT POSITIVE THAT I AM ALLERGIC TO NICKEL, BUT I DO KNOW THAT I HAVE ALWAYS HAD TROUBLE WEARING EARRINGS. CERTAIN EARRINGS WOULD MAKE MY EAR LOBES RED, ITCHY, AND VERY IRRITATED TO THE POINT I COULD ONLY TOLERATE THEM FOR AN HOUR OR SO. I CAME TO REALIZE YEARS AGO THAT I NEEDED TO BUY EARRINGS LABELED "NICKEL-FREE" IN ORDER TO AVOID SUCH DISCOMFORT. I WOULD LIKE TO ATTACH MY OPERATIVE REPORT WHICH SHOWS THAT THE DOCTOR HAD MUCH DIFFICULTY PLACING THE FIRST COIL (BUT I'M NOT SURE I WILL BE ABLE TO ATTACH A PDF). I WOULD ALSO LIKE TO ATTACH THE RESULTS OF THE NERVE TEST I HAD IN ORDER TO DIAGNOSE THE SOURCE OF THE ON-GOING NUMBNESS IN MY ARMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057134	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) I HAD A FULL HYSTERECTOMY. TUBES, UTERUS, CERVIX, AND COILS. DOCTOR WAS ABLE TO SAVE MY OVARIES. DESPITE MY "CORRECT PLACEMENT " OF THE COILS AND THE HSG TEST BEING "PERFORMED CORRECTLY" GUESS WHAT WAS PUNCTURING THROUGH MY TUBE, THAT'S RIGHT A COIL. REMOVE THESE FROM THE MARKET !

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057135	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 6/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I STARTED FEELING PINCHING IN MY LOWER ABDOMEN. HAIR LOSS, JOINT PAIN, IRRITABLE, EXHAUSTED NO MATTER HOW MUCH REST I GET. MY PERIODS ARE EVERY 15 DAY'S AND I BLEED (HEMORRHAGE) FOR 10 DAYS. EXCRUCIATING BACK PAIN AND I GET SO BLOATED I LOOK LIKE I'M (B)(6). LEG CRAMPING AND CONSTANTLY SICK

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057136	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PROVIDED BY INSURER! HEAVY MENSTRUAL CYCLES, GOLF BALL SIZED BLOOD CLOTS, MIGRAINES, HAIR LOSS,SWELLING OF LEGS, MOOD CHANGES, MEMORY FOG,TEETH FALLING OUT,CRAMPS BEYOND WORDS, BURNING OF THE UTERUS, INSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057137	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING, JOINT PAIN,EXCESSIVE WEIGHT GAIN, DEPRESSION, CRACKED TEETH, EXTREME LOWER BACK PAIN, HEAVY BLEEDING DURING MENSTRUAL CYCLE, IRRITABLE, GASTROESOPHAGEAL PROBLEMS. (B)(6) PAID FOR PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057138	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVERYTHING WAS COVERED BY MY INSURANCE. WHEN THE ESSURE WAS PLACED IT WAS THE MOST PAINFUL THING THAT I HAVE EVER EXPERIENCED. AT MY ONE-MONTH ULTRASOUND I STILL HAD PAIN ON MY LEFT SIDE, BUT THE COILS WERE IN THE CORRECT PLACES. FOR FOUR MORE MONTHS I EXPERIENCED AN ACHING PAIN ON MY LEFT SIDE. YESTERDAY, I HAD MY CONFIRMATION TEST MY RIGHT COIL IS MISSING. I STILL EXPERIENCE PAIN ON MY LEFT SIDE. THE MEDICAL ASSISTANT WHO HELPED WITH MY CONFIRMATION TEST SAID THAT SHE SEES MISSING COILS OFTEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057139	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 8/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN, CRAMPING IN OVARY AREA, LEGS, ARMS. NUMBNESS. SEVERE BLEEDING, SEVERE BLOOD CLOTS, HEADACHES. BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057140	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 6/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, DAILY PELVIC PAIN, HEAVIER PERIODS, HIP PAIN, CAN'T LOSE WEIGHT, ETC. INSURANCE PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057141	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 3/28/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TINGLING AND NUMBNESS DOWN RIGHT LEG. EXCRUCIATING PAIN IN LOWER BACK, DENTAL PROBLEMS, BRAIN SHOCKS, BRAIN FOG, INSOMNIA, CONSTANT FATIGUE, FEELING THAT INSIDES BEING SHAKEN, HEADACHES, DIZZINESS, FAINTING, CANT SIT OR STAND FOR ANY GREAT LENGTH OF TIME,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057142	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT HAS MADE ME SO SICK, PLUS I'M BLEEDING THROUGH TAMPONS AND PADS EVERY THERE TO FOR HOURS. I HAVE ABDOMINAL PAIN ALL THE TIME. WHEN I GOT IT, IT WAS COVERED BY INSURANCE. I'VE HAD ONSET PAIN HER AND THE RELAXED WHEN IT WAS THAT TIME OF THE MONTH. BUT STARTING THIS LAST (B)(6) IT'S BEEN ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057143	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 11/8/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ALLERGIES, HAIR LOSS, PAINFUL SEX, FREQUENT BACTERIAL VAGINITIS, HEAVY AND FREQUENT PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057144	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 2/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THIS IMPLANT I HAVE HAD NOTHING BUT ISSUES. BAD REOCCURRING PAIN THAT DROPS ME TO MY KNEES, HEAD ACHES, AND I'M TIRED ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057145	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 10/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE DEVICE WAS PROVIDED BY MY INSURER. I BEGAN TO HAVE SEVERE MENSTRUAL CRAMPS THAT PREVENTED ME FROM DOING MUCH OF MY DAILY ACTIVITIES. MY MENSTRUAL FLOW WAS EXTREMELY HEAVY AND WOULD STOP SHORTLY AFTER I STARTED AND THEN PICK BACK UP AGAIN THREE DAYS LATER. I WAS BEEN DIAGNOSED WITH UTERINE POLYPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057146	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 3/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 1 MONTH OF GETTING ESSURE I STARTED HAVING PELVIC PAINS THAT WERE NOT CRAMPS. ONE DAY IT WAS SO BAD WHILE AT WORK, I COULD BARELY WALK AND HAS TO TAKE AN IBUPROFEN 800 LEFTOVER FROM HAVING MY BABY. I CONSTANTLY FELT THEM IN ME AND DIDN'T WANT IT TO GET WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057147	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 1/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) HAVE PELVIC PAIN EVERYDAY ,ON MEDICINE FOR MIGRAINE FROM ESSURE, WHEN I HAVE SEX IT IS PAINFUL,HAVE MAJOR MOOD SWINGS HAVE NO ENERGY HAVE CHEST PAINS EVERY SINCE I HAD IT DONE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057148	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 9/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A THERMASURE ABLATION AND THE ESSURE PLACED IN SAME HOSPITAL SURGICAL PROCEDURE IN 2006. NINE YEARS AFTER ESSURE PLACEMENT, I WAS INFORMED THAT THE DEVICES HAD "SHATTERED" AND THERE WERE MANY PIECES IN MY UTERUS AND CERVIX. THIS DIAGNOSIS CAME AFTER MANY DOCTOR VISITS TRYING TO DETERMINE WHY I WAS HAVING SEVERE CONSTIPATION ISSUES. IT WAS DISCOVERED DURING MY FULL HYSTERECTOMY AND SALPINGECTOMY THAT MY COLON HAD ADHERED TO THE ABDOMINAL WALL DUE TO MY UTERUS BEING EXTREMELY ENLARGED AND PUSHING IT TO THE SIDE. MY UTERUS AND ESSURE PIECES INSIDE ALMOST HAD COLLAPSED (CLOSED OFF) MY COLON. THE UTERUS WAS COVERED IN ENDOMETRIOSIS AND WAS SO ENLARGED THAT EXTERNAL VAGINAL STITCHES WERE REQUIRED AFTER REMOVAL. POSTOPERATIVE DIAGNOSIS - AUB - A PHYSICAL PROBLEM IN THE UTERUS CAN CAUSE ABNORMAL BLEEDING, ESSURE FRACTURE, ADHESIONS. DUE TO TRAUMA. THIS HAS BEEN A NIGHTMARE FOR ME AND MY FAMILY, ALONG WITH A MYRIAD OF PAIN AND SYMPTOMS THAT NOW MAKE SENSE. BLOATING, CONSTANT HEADACHES, FATIGUE... ALL OF WHICH HAVE NOT BEEN EXPERIENCED SINCE HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057149	BAYER	10/19/2015	10/19/2015

Event Information:

Event Date (B3): 11/8/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, WEIGHT GAIN, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057265		10/19/2015	10/21/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/1/2009
Explant Date (E7): 10/1/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL PAIN. (B)(6) 2014, HAD SURGERY TO REMOVE LEFT COIL. DURING COIL REMOVAL, LEFT COIL WAS FOUND DISLODGED AND WAS IN THE CERVIX. PT ENDED UP HAVING A TUBAL LIGATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057311	CONCEPTUS	10/19/2015	10/27/2015

Event Information:

Event Date (B3): 9/29/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): F00000664920
Catalog # (E4):
Lot #(E4): F000037729

Single Use: *
Implant Date (E6): 9/29/2006
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE IMPLANTED (B)(6) 2006. I WAS FIRED FROM JOB DUE TO EXCESSIVE ABSENCES RESULTING FROM DAILY MIGRAINES. AS OF 2008 ON SSD DUE TO TOTAL DISABILITY FROM CHRONIC DAILY MIGRAINES. I'VE HAD GENERAL INFLAMMATION AND RASHES, RECENTLY DIAGNOSED FIBROMYALGIA, HAIR LOSS, NIGHT SWEATS AND NIGHTLY LOW GRADE FEVERS. I HAVE HAD A SENSITIVITY TO CERTAIN METALS ALL MY LIFE BUT WAS NEVER TESTED FOR AN ALLERGY BEFORE IMPLANTATION. I AM CONSIDERING HYSTERECTOMY TO REMOVE THE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057313	BAYER	10/19/2015	10/27/2015

Event Information:

Event Date (B3): 9/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/23/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY NAME IS (B)(6) AND I HAD THE ESSURE PROCEDURE DONE (B)(6) 2014. AFTER HAVING THIS PROCEDURE DONE I HAD VERY MILD CRAMPS IN MY LOWER ABDOMEN WHICH LATER GREW TO BECOME EXCRUCIATING PAIN. SOMETIMES THE PAIN LEFT ME UNABLE TO GET OUT OF BED CONSTANT HEADACHES AND NAUSEA FOLLOWED. SEVERAL MONTHS WENT BY BEFORE I WAS ABLE TO HAVE A MENSTRUAL CYCLE. I ASKED THE OB AT THE TIME WAS THIS NORMAL. THEY ASSURED ME EVERYTHING WAS OKAY MY BODY MAY HAVE JUST REACTED TO THE PROCEDURE DIFFERENTLY. I FINALLY HAD A CYCLE BUT BLED HEAVY FOR A COUPLE OF MONTHS. THEN AT OTHER TIMES I WOULD NOT SEE ANYTHING FOR MAY BE A WEEK OR TWO LATER. GRADUALLY MY CYCLE SLACKED UP UNTIL THERE WAS NOTHING AT ALL. THIS WAS IN (B)(6) OF THIS YEAR. I THOUGHT MAY BE THIS WOULD BE JUST AN IRREGULAR CYCLE BUT I WAS WRONG. IN LATE (B)(6) I FOUND OUT THAT I WAS PREGNANT. IN DISBELIEF I WENT BACK TO MY OB TO FIND OUT WHEN, HOW, AND WHY BUT I HAVEN'T GOTTEN AN ANSWER BACK YET JUST TOLD CONGRATULATIONS. WHEN MY HUSBAND AND I DECIDED TO HAVE THIS PROCEDURE DONE, I HAD JUST GIVEN BIRTH TO OUR TWINS VAGINALLY. I WAS TOLD THAT WITH THIS KIND OF DELIVERY THIS PROCEDURE WAS PERFECT PERMANENT AND LESS INVASIVE. WE LOOKED ON THE MARKET TO SEE ANY DRAWBACKS TO THIS PROCEDURE BUT THERE WEREN'T MANY AT ALL. THE ONLY THING WE NOTICED WAS A FEW BLOGS WITH WOMEN WHO SEEMED TO ME LIKE THEY MAY OF HAD OTHER HEALTH PROBLEMS WHICH COULD HAVE ENHANCED THEIR PROBLEMS WITH THIS PROCEDURE. NEVER COULD I HAVE IMAGINED THAT I WOULD BE HERE SUFFERING FROM THE COMPLICATIONS THAT I HAVE WITH ESSURE AND COMPLAINING FOR HELP. I AM CURRENTLY 17 WEEKS PREGNANT WITH ONLY ONE COIL FOUND ON MY ULTRASOUND WHILE THE OTHER IS LOST PERHAPS SOMEWHERE WITHIN MY BODY OR IT MAY HAVE PASTED THROUGH WHEN I SUFFERED FROM THOSE PAINFUL MENSTRUAL PREVIOUSLY. I HAVE SINCE REQUESTED TO HAVE THIS COIL

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SEARCHED FOR AND THE OTHER REMOVED BUT WAS ASSURED THAT THIS WOULD BE AT THIS FETUS EXPENSE. MY OPTIONS IS TO LEAVE THE COIL WHERE IT IS AND NOT WORRY ABOUT THE OTHER TO SAVE THIS UNWANTED FETUS OR TO HAVE THEM SEARCH AND PERFORM SURGERY AND LOSE THIS UNWANTED FETUS, OR JUST HAVE AN ABORTION. (I DO NOT SUPPORT ABORTIONS) IT IS FRUSTRATING TO ME THAT DOCTORS ARE ABLE TO ADMINISTER THIS PROCEDURE WITH LITTLE PRIOR KNOWLEDGE AS TO PROPERLY INFORM THEIR PATIENTS SO THEY CAN MAKE AN INFORMED DECISION. IT IS NOT OKAY THAT I AM PREGNANT AGAIN WITH A COIL FOUND LOGGED WITHIN TISSUE WHILE THE OTHER IS MISPLACED. I STILL HAVE ABDOMINAL PAIN CONSTANT HEADACHES AND BODY ACHES BUT IT'S NOT TAKEN SERIOUSLY BECAUSE IT NOW BLENDS IN WITH THIS PREGNANCY. CURRENTLY I AM WAITING FOR MY MRI TO DETERMINE MY NEXT STEPS. THIS WAS THE WORST DECISION EVER MADE IN MY LIFE AND I ASSURE YOU THAT I AM NOT THE ONLY ONE OUT HERE WHO FEELS THE SAME. I ASK THAT THIS FORM OF BIRTH CONTROL METHOD BE TAKEN OFF THE MARKET BEFORE THE NUMBER OF WOMEN WHO ARE AFFECTED CONTINUES TO GROW OR WORST DEATH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057322	BAYER	10/19/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER ESSURE ON GOING SYMPTOMS CAUSING CONCERN. RASH, BLOAT, PELVIC PAIN, HORRIBLE PERIODS, METALLIC TASTE IN MOUTH AND NEUROLOGICAL ISSUES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01198	BAYER HEALTHCARE LLC	10/20/2015	10/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 21-SEP-2015 WHO WAS INVOLVED IN AN ESSURE GENERIC ACTIVE ONLINE LISTENING, STUDY NUMBER: (B)(6). CONSUMER REPORTED THAT SHE HAD MANY SIDE EFFECTS AND STATES THAT SHE HAD A HYSTERECTOMY AT (B)(6). NO FURTHER INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 04-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO WAS INVOLVED IN ACTIVE ONLINE LISTENING PROJECT, HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A HYSTERECTOMY AT (B)(6). THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS

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NECESSARY, SURGERY (HYSTERECTOMY) MAY BE REQUIRED. ALTHOUGH, IN THIS PARTICULAR CASE THE PROCEDURE'S INDICATION HAS NOT BEEN PROVIDED, CONSIDERING EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01199	BAYER HEALTHCARE LLC	10/20/2015	10/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO HERSELF. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR PERMANENT BIRTH CONTROL. AFTER CONSUMER'S THIRD SON WAS BORN, SHE DECIDED SHE WAS DONE HAVING KIDS. SHE HAD ESSURE INSERTED AND ALMOST IMMEDIATELY AFTER THE PROCEDURE SHE STARTED GETTING AN EXCRUCIATING BURNING PAIN IN HER BACK AND PELVIS; AND ALL OF A SUDDEN IT HURT TO MOVE HER BODY TO OUT OF BED OR DO ANYTHING. SHE STATED THE PAIN GOT WORSE AND SPREAD ALL OVER HER BODY AND DESPITE TWO OPERATIONS AND MANY TEST AND EXAMS SHE STILL HAD CONSTANT PAIN. SHE MENTIONED IT FELT LIKE SHE HAS BEEN HIT BY A TRUCK EVERY DAY. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY

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CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE CONSUMER WHO HAD EXCRUCIATING BURNING PAIN IN HER BACK AND PELVIS SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO TWO OPERATIONS (UNSPECIFIED) AND MANY TESTS. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC, BACK AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER STATED HER PAIN STARTED IMMEDIATELY AFTER ESSURE PLACEMENT AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENT PAIN GOT WORSE AND SPREAD ALL OVER HER BODY WAS REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, AS ALTHOUGH THE 2 OPERATIONS MENTIONED BY THE CONSUMER WERE NOT SPECIFIED; SHE RELATED THESE PROCEDURES TO HER EVENTS (SURGICAL INTERVENTION REQUIRED DUE TO THE EVENTS). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FOLLOW-UP WILL BE POSSIBLE, SINCE NO CONTACT DETAILS WERE PROVIDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01200	BAYER HEALTHCARE LLC	10/20/2015	10/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91770

Single Use: Y
Implant Date (E6): 12/17/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 20-AUG-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C91770, IMPLANTED FOR CONTRACEPTION ON (B)(6) 2014. SHE WAS NOT PREGNANT. ON (B)(6) 2015 HSG (HYSTEROSALPINGOGRAM) FAILED. THE SALES CONSULTANT DID NOT HAVE ANY ADDITIONAL INFORMATION ON THE MEANING OF FAILURE. ON UNSPECIFIED DATE AN ULTRASOUND WAS PERFORMED AND BOTH INSERTS WERE NOTED IN THE ABDOMEN. THE PATIENT WENT TO ANOTHER PHYSICIAN TO HAVE A TUBAL. FOLLOW UP 08-SEP-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION WAS RECEIVED ON 22-SEP-2015 VIA ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE. THIS CASE WAS UPGRADED TO INCIDENT. SHE DENIED ANY PREVIOUS GYNECOLOGICAL INTERVENTIONS. ON (B)(6) 2014 ESSURE LOT NUMBER C91770 WAS

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INSERTED. SHE WAS 10 MONTHS POST-PARTUM. CERVICAL DILATATION, SOUNDING, ANALGESIA (IV SEDATION WITH CERVICAL BLOCK) WERE APPLIED DURING INSERTION. THE INSERTION WAS DIFFICULT DUE FILMY TISSUE OVER BILATERAL OSTIA EXCISED. THE VISUALIZATION OF THE TUBAL OSTIUM WAS ALSO DIFFICULT. FLUID LOSS WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. IN (B)(6) 2015 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED BOTH IMPLANTS IN ABDOMEN. ESSURE WAS REMOVED AT OUTSIDE FACILITY BY ANOTHER PHYSICIAN DUE TO PATIENT REQUEST. HOSPITALIZATION WAS OUTPATIENT. PATIENT WAS DOING WELL. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HSG SHOWED BOTH INSERTS IN ABDOMEN. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES TOWARDS TO PERITONEAL CAVITY. IN THIS CASE, A FILMY TISSUE OVER BILATERAL OSTIA CAUSED DIFFICULTIES DURING INSERTION. THE VISUALIZATION OF THE TUBAL OSTIUM WAS ALSO DIFFICULT. THEN, AFTER EXCISION OF THIS TISSUE, BILATERAL PLACEMENT WAS ACHIEVED. ONE MONTH LATER, HSG WAS PERFORMED AND THE DEVICES WERE NOTED TO BE IN ABDOMEN. ALTHOUGH IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THIS DISLOCATION HAVE NOT BEEN PROVIDED, CONSIDERING EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. INITIALLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, THE DEVICE REMOVAL WAS INFORMED. SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE WAS UPGRADED TO INCIDENT. BASED ON AVAILABLE INFORMATION, INCLUDING A DOCUMENTATION BATCH REVIEW, THERE IS NO REASON TO SUSPECT A QUALITY DEFICIT OF THE PRODUCT.

Manufacturer Narrative (H10):

UTERINE/TUBAL PERFORATION QUESTIONNAIRE RECEIVED FROM HEALTH CARE PROFESSIONAL ON 30-NOV-2015: SHE HAD 01 PREGNANCY AND 01 LIVE BIRTH. ABORTION, SPONTANEOUS ABORTION, ELECTIVE ABORTION, THERAPEUTIC ABORTION AND ECTOPIC PREGNANCIES WERE DENIED. ON UNSPECIF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01201	BAYER HEALTHCARE LLC	10/20/2015	10/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A LAY PRESS (LOCAL NEWSPAPER) CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 FOR STERILIZATION. THE PLACEMENT PROCEEDED WITH DIFFICULTY. THE GYNECOLOGIST HAD TROUBLE GOING THROUGH THE CERVIX. THE PATIENT NEARLY FAINTED BECAUSE OF THE PAIN. HALF A YEAR AFTER PROCEDURE, CONSUMER DEVELOPED LOWER BACK PAIN, WAS VERY TIRED AND BECAME FORGETFUL. SHE FELT LIKE HAVING COTTON WOOL IN HER HEAD. SHE PUT MEMO SHEETS ON THE TABLES MENTIONING ALL THE THINGS SHE HAD TO DO OR HAD TO REMEMBER. THE COMPLAINTS WORSENED PROGRESSIVELY. ESPECIALLY WALKING ON HIGH HEELS WAS PAINFUL. PATIENT REGULARLY USED PAINKILLERS. TRYING TO LIVE HEALTHY DID NOT GIVE HER BACK HER ENERGY. ESSURE AND OVIDUCTS WERE REMOVED IN (B)(6) 2015. THIS INSTANTLY RESOLVED THE BACK PAIN. HER ENERGY WAS ALSO GRADUALLY COMING BACK. FOLLOW-UP WILL NOT BE POSSIBLE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 09-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE

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INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY (B)(4) AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN (B)(6). IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON (B)(6) 2015 FOR THE FOLLOWING (B)(6) PREFERRED TERM: BACK PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS (B)(6) PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, LAY PRESS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LOWER BACK PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT HALF A YEAR AFTER ESSURE INSERTION PROCEDURE. SHE HAD HER OVIDUCTS AND ESSURE REMOVED AND BACK PAIN RESOLVED INSTANTLY. GIVEN A POSITIVE TEMPORAL RELATIONSHIP AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION WILL NOT BE POSSIBLE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01202	BAYER HEALTHCARE LLC	10/20/2015	10/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D31449

Single Use: Y
Implant Date (E6): 9/21/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN'S ASSISTANT IN (B)(6) ON 22-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO GET ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER D31449. IT WAS REPORTED THAT NO RELEASE OCCURRED; PARTIAL RETRACTION OF THE SHEATH OF ESSURE SYSTEM. PIECE OF METAL REMAINED IN THE OSTIUM. THE EVENT HAPPENED IN THE OPERATING ROOM DURING THE INSERTION. CONDITIONS OF INSERTION: STANDARD, UNDER LARYNGEAL MASK. THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS NOT PERFORMED BECAUSE ESSURE PROCEDURE WAS STOPPED. POSTOPERATIVE COURSE: DOUBT ON OCCLUSION OF THE LEFT FALLOPIAN TUBE. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 02-OCT-2015 NAC NUMBER IS (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO GET ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PIECE OF METAL REMAINED IN THE OSTIUM. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 16-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4).

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01203	BAYER HEALTHCARE LLC	10/20/2015	10/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C06464

Single Use: Y
Implant Date (E6): 6/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 22-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. IT WAS REPORTED THAT THE INTRODUCER DID NOT DETACH AND IT WAS DIFFICULT TO DETACH DURING INSERTION. THE PHYSICIAN WAITED THREE MONTHS AND THEN, HSG WAS DONE (IN (B)(6) 2015). IT WAS STATED THAT IT WAS NOT A TYPICAL HSG. IT APPEARED TO HAVE DISTAL PLACEMENT. HCP DID NOT KNOW IF A PIECE OF THE COIL BROKE OFF. FOLLOW-UP INFORMATION RECEIVED ON 06-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: LOT NUMBER: C06464 FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICROINSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF

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THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE AND A USABILITY ISSUE. THE REPORTED MEDICAL EVENT IS A KNOWN POSSIBLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES FOR THIS BATCH RESULTED IN NO UNUSUAL PATTERN IDENTIFIED. NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE INSERTED AND DURING PLACEMENT THE INTRODUCER WAS DIFFICULT TO DETACH AND DID NOT DETACH. THREE MONTHS LATER, HSG WAS PERFORMED AND IT APPEARED TO HAVE DISTAL PLACEMENT (SEEN AS DEVICE DISLOCATION). HCP DID NOT KNOW IF A PIECE OF THE COIL BROKE OF (DEVICE BREAKAGE). DEVICE DISLOCATION IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE IS NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. DURING ESSURE USE, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED, MOSTLY DURING DIFFICULT INSERTIONS. ALSO, ESSURE MAY DISLOCATE DISTALLY INTO FALLOPIAN TUBES. CONSIDERING THE REPORTED EVENTS PROBABLY OCCURRED ASSOCIATED TO THIS DIFFICULT PLACEMENT PROCEDURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 04-JAN-2016: FOLLOW-UP ATTEMPTS HAV BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE INSERTED AND DURING P

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01204	BAYER HEALTHCARE LLC	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 9/22/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C59246

Single Use: Y
Implant Date (E6): 9/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 22-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER C59246 (EXPIRATION DATE MAY-2017) FOR PERMANENT CONTRACEPTION. HEALTH CARE PROFESSIONAL INSERTED COIL INTO RIGHT TUBE, SAW BLACK MARKER WHERE IT WAS SUPPOSED TO BE, GOT TO POINT OF RELEASING DEVICE, COULD SEE GOLD BAND WHERE IT SHOULD BE, AND STARTED TO PULL IT OUT. WHEN STARTING TO PULL PLASTIC SHEATHING OUT, IT GOT HUNG UP. HE CLICKED THE BUTTON BUT SPRING WOULD NOT LET GO AND DEVICE STARTED TO UNRAVEL AND GOT REALLY LONG. PART OF GREEN SHEATHING BROKE OF AND IS STILL IN PATIENT. THE COIL IS STRAIGHT ON END. PATIENT WAS HURTING WHEN HE WAS REMOVING THE INSTRUMENTS AND SHEATH BUT IS OKAY NOW WITH JUST A LITTLE CRAMPING. REPORTER CALLED FROM OPERATING ROOM DURING PROCEDURE AND PART OF THE GREEN SHEATH BROKE IN PATIENT AND PART OF IT IS STILL IN PATIENT. THE PART OF GREEN SHEATH THAT CAME OUT IS AVAILABLE FOR RETURN. HEALTH CARE PROFESSIONAL WANTED TO KNOW IF HE SHOULD GO IN AND SURGICALLY REMOVE IT. FOLLOW-UP INFORMATION RECEIVED ON 06-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM BATCH NUMBER C59246 PRODUCTION DATE 2014-05-21 EXPIRATION DATE 2017-05-31 THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR

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REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICROINSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE AND A USABILITY ISSUE. THE REPORTED MEDICAL EVENT IS A KNOWN POSSIBLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASES FOR THIS BATCH WERE IDENTIFIED. NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE PART OF GREEN SHEATHING BROKE OF AND IS STILL IN PATIENT. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, DURING INSERTION WHEN STARTING TO PULL PLASTIC SHEATHING OUT, IT GOT HUNG UP. PHYSICIAN CLICKED THE BUTTON BUT SPRING WOULD NOT LET GO AND DEVICE STARTED TO UNRAVEL. PART OF GREEN SHEATHING BROKE OF AND IS STILL IN PATIENT. SINCE THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENT WAS ALSO REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 21-DEC-2015: DEVICE BREAKAGE QUESTIONNAIRE WAS RECEIVED.~ PATIENT´S DEMOGRAPHIC INFORMATION WAS PROVIDED. ON (B)(6) 2015 ESSURE WAS INSERTED. ESSURE AND CATHETER BROKE DURING PLACEMENT. CATHETER WAS HUNG ON IMPLANT AND CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01205	BAYER HEALTHCARE LLC	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7): 7/17/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER/ ATTORNEY IN THE UNITED STATES, ON BEHALF OF A PLAINTIFF IN UNITED STATES ON 22-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER/PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014 FOR PERMANENT STERILIZATION. IT WAS REPORTED THAT AROUND (B)(6) 2013, PLAINTIFF WENT TO THE IMPLANTING PHYSICIAN TO BEGIN DISCUSSING OPTIONS FOR PERMANENT STERILIZATION. THE IMPLANTING PHYSICIAN RECOMMENDED THAT PLAINTIFF HAVE ESSURE IMPLANTED IN HER FALLOPIAN TUBES INSTEAD OF A STANDARD TUBAL LIGATION PROCEDURE. IN OR AROUND (B)(6) 2014, PLAINTIFF RETURNED TO THE IMPLANTING PHYSICIAN FOR THE ESSURE PROCEDURE. THE IMPLANTING PHYSICIAN IMPLANTED THE ESSURE COIL INTO HER LEFT FALLOPIAN TUBE. HOWEVER, WHEN THE IMPLANTING PHYSICIAN ATTEMPTED TO IMPLANT THE DEVICE IN THE RIGHT FALLOPIAN TUBE, THE IMPLANTING PHYSICIAN WAS UNABLE TO INSERT THE COIL INTO HER RIGHT FALLOPIAN TUBE DUE TO A MALFUNCTION IN THE DEPLOYMENT OF THE COIL. THE IMPROPERLY INSERTED RIGHT COIL WAS REMOVED FROM HER UTERINE CAVITY WITH FORCEPS. DUE TO THE IMPLANTING PHYSICIANS INABILITY TO INSERT THE RIGHT COIL, THE IMPLANTING PHYSICIAN THEN CAUTERIZED BOTH FALLOPIAN TUBES IN THREE LOCATIONS TO STERILIZE PLAINTIFF. AFTER PROCEDURE TO IMPLANT THE DEVICE, PLAINTIFF STARTED EXPERIENCING SEVERE CONSTANT DAILY PAIN AND SEVERE BLEEDING. SHE CONTACTED THE IMPLANTING DOCTOR MANY TIMES TO COMPLAIN ABOUT HER SYMPTOMS AND WENT TO THE EMERGENCY ROOM MULTIPLE TIMES DUE TO THE PAIN. SINCE THE DEVICE WAS IMPLANTED, PLAINTIFF HAS ALSO SUFFERED FROM HEAVY BLEEDING, CONSTANT PAIN, SEVERE ABDOMINAL CRAMPING, AND HIVES DUE TO A METAL ALLERGY, MIGRAINES, AND MENTAL AND EMOTIONAL ANGUISH. AS A DIRECT AND PROXIMATE CAUSE OF PLAINTIFFS USE OF ESSURE, SHE WAS FORCED TO UNDERGO SURGICAL REMOVAL OF THE DEVICE, DEVELOPED SEVERE PAIN,

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SUFFERED FROM INFECTION, AND UNDERWENT NUMEROUS PROCEDURES. ON (B)(6) 2015, PLAINTIFF HAD A HYSTERECTOMY AND SALPINGECTOMY TO REMOVE THE LEFT ESSURE MICRO-INSERT. THE PLAINTIFF SUFFERED PROFOUND INJURIES AND IT WAS REQUEST BY LEGAL ACTION PAST AND FUTURE PAIN AND SUFFERING DAMAGES, INCLUDING MENTAL AND; EMOTIONAL STRESS ARISING FROM PLAINTIFFS PHYSICAL INJURIES. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS RECEIVED FROM A LAWYER ON BEHALF OF A (B)(6) FEMALE CONSUMER/PLAINTIFF. SHE HAD HEAVY/SEVERE BLEEDING AND SEVERE ABDOMINAL PAIN/CRAMPS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS IMPLANTED IN HER LEFT FALLOPIAN TUBE. ACCORDING TO HER LAWYER; SHE UNDERWENT SURGICAL REMOVAL OF THE DEVICE (HYSTERECTOMY AND SALPINGECTOMY PERFORMED) AND WAS SUBMITTED TO NUMEROUS PROCEDURES. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, PHYSICIAN WAS UNABLE TO INSERT ESSURE IN RIGHT FALLOPIAN TUBE DUE TO A DEVICE DEPLOYMENT ISSUE. THEN, HE DECIDED TO COAGULATE BOTH FALLOPIAN TUBES IN 3 LOCATIONS. IF ESSURE INSERTION IS UNSUCCESSFUL AND THE PATIENT CHOOSES LAPAROSCOPIC STERILIZATION, IT IS RECOMMENDED TO CLIP OR COAGULATE BOTH FALLOPIAN TUBES DISTAL OR PROXIMAL TO THE INSERT. CLIPPING OR COAGULATION ADJACENT TO OR OVER THE INSERTS IS NOT RECOMMENDED. IN THIS CASE, NO DETAILS WERE PROVIDED ABOUT THE EXACT SITE OF COAGULATION IN LEFT FALLOPIAN TUBE; THUS IT IS UNCLEAR IF THIS PROCEDURE COULD HAVE CONTRIBUTED FOR CONSUMER'S PAIN. BASED ON THE AVAILABLE INFORMATION AND CONSIDERING EVENTS NATURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01206	BAYER HEALTHCARE LLC	10/20/2015	10/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 22-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN REPORTED HIS PATIENT HAD AN ESSURE CONFIRMATION TEST PERFORMED AND THE RESULTS READ THAT THE OUTER COIL WAS FRACTURED BUT FULL, BILATERAL OCCLUSION WAS ACHIEVED. FOLLOW-UP INFORMATION RECEIVED ON 09-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICROINSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY

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QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE. HOWEVER, NO MEDICAL EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED, THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. FOLLOW UP INFORMATION RECEIVED ON 14-OCT-2015: THE REPORTER SAID THE RIGHT COIL WAS PERFORATED WITH SEPARATION OF THE INNER AND OUTER COILS. THE PATIENT WAS ASYMPTOMATIC. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER ESSURE CONFIRMATION TEST SHOWED THE RIGHT COIL WAS PERFORATED WITH SEPARATION OF THE INNER AND OUTER COILS. THESE EVENTS WERE INTERPRETED AS FALLOPIAN TUBE PERFORATION AND DEVICE BREAKAGE. PERFORATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE DEVICE BREAKAGE IS ANTICIPATED ACCORDING TO THE TECHNICAL ASSESSMENT. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED AND THE EXACT MECHANISM OF THE EVENTS IS NOT KNOWN. NEVERTHELESS, GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

THIS CASE WAS IDENTIFIED AS A DUPLICATE TO CASE (B)(4) AND WILL BE DELETED FROM BAYER DATABASE.

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057228	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) SUDDEN SHARP STABBING PAIN IN PELVIS, METAL TASTE IN MOUTH, IRREGULAR PERIODS, WEIGHT GAIN, VAGINAL DISCHARGE WITH ODOR. NONE OF THESE SYMPTOMS OCCURRED BEFORE ESSURE IMPLANTATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057229	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 5/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING ESSURE PLACED, I HAD IMMEDIATELY STARTED HAVING COMPLICATIONS, IT STARTED WITH SEVERE CRAMPING/STABBING PAIN IN MY PELVIC AREA THAT WOULDN'T GO AWAY, THEN THE PAIN STARTED IN MY BACK. I BEGAN TO GET HEADACHES ALL DAY EVERY DAY, I HAD LESS ENERGY, I WAS CONSTANTLY FATIGUED. I FELT LIKE I WASN'T ME, I COULDN'T DO THE THINGS I HAD BEFORE ESSURE WAS IMPLANTED, I FELT DEPRESSED AND MY ANXIETY LEVELS WERE SKY HIGH, THEN MY TEETH STARTED GETTING MORE SENSITIVE AND CRACKING. THE WORSE THING IS MY LYMPH NODES THROUGHOUT MY WHOLE BODY SWELLED UP CAUSING ME TO HAVE TO GO THROUGH A BIOPSY WHERE DOCTORS HAD TO MAKE AN INCISION IN MY NECK AND TAKE SAMPLES OF NUMEROUS DIFFERENT LYMPH NODES BECAUSE THEY WERE CONCERNED IT WAS CANCER, OF COURSE TURNED OUT NOT TO BE. I WAS A TYPICALLY HEALTHY PERSON BEFORE ESSURE. I HAD MY BIOPSY DONE AT THE (B)(6), I HAD MY ESSURE PLACED AT (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057230	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 6/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I GOT ESSURE IN (B)(6) 2010. I WENT TO MY DOCTOR ABOUT GETTING MY TUBES TIED BECAUSE WITH THREE KIDS MY HUSBAND AND I FELT OUR FAMILY WAS COMPLETED. MY DOCTOR TOLD ME ABOUT ESSURE AND SAID IT WAS A NON SURGICAL PROCEDURE, SAFE WITH LITTLE SIDE EFFECTS. WHEN I HEARD IT WAS NON SURGICAL AND THAT MY DOCTOR RECOMMENDED IT I TRUSTED HIM AND WENT FOR IT. 3 MONTHS AFTER MY DEVICE WAS IMPLANTED I STARTED TO GET SEVERE MIGRAINES. SO BAD THAT I WAS HOSPITALIZED FOR 14 DAYS. I HAVE BEEN IN AND OUT OF THE DOCTOR FOR 5 YEARS WITH SEVERE PELVIC PAIN AND WITH A PINCHING STABBING PAIN IN MY LEFT SIDE. SOMETIME THE PAIN WAS SO INTENSE IT WOULD STOP ME IN MY TRACKS. ALL THE DOCS KEPT TELLING ME IT WAS CYST ON MY OVARIES SO I JUST LIVED WITH THE PAIN. I WAS ALSO DIAGNOSED WITH BORDERLINE CELIAC'S DISEASE, I HAVE SEVERE HEARTBURN ALL THE TIME, BACK PAIN, HEAVY BLEEDING, MIGRAINES, PAINS IN MY LEGS, TIRED ALL THE TIME, DISCHARGE DAILY. THE LIST GOES ON. ON (B)(6) I HAVE MY TUBES REMOVED BECAUSE OF THE ESSURE. THANK GOD I DID. MY DOCTOR FOUND THAT ON MY LEFT SIDE THE COIL HAD COME OUT 2 INCHES (THAT WAS POKING ME FOR 5 YEARS) HE ALSO SAID THE RIGHT SIDE HAD PUNCTURED THROUGH ONE LAYER OF SKIN. WOMEN NEED TO KNOW THE TRUTH ABOUT ESSURE. IF I KNEW WHAT I KNOW TODAY ABOUT ESSURE I WOULD HAVE HAD THE SURGERY TO HAVE MY TUBES TIED INSTEAD OF ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057231	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON-GOING PAIN WHEN SNEEZING, COUGHING, TURNING WRONG ETC. OUTCOME WAS A HYSTERECTOMY WITH BILATERAL SALPINGECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057232	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 12/16/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2016, I HAD A TOTAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY TO REMOVE THE ESSURE COILS FROM MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057233	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE SOMETIME IN (B)(6) 2014. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS MY MODEL NUMBER IS ESS305, B93873. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED BRIEFLY AFTER BEING IMPLANTED. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. SEVERE HEADACHES, SWELLING OF FEET LEGS HANDS, TINGLING IN MY LEGS AND SEVERE LOWER BACK PAINS, EXTREME BLOATING OF THE ABDOMEN, WEIGHT GAIN, PAINFUL CRAMPING AND SHOOTING PAINS. INABILITY TO HAVE SEX DUE TO THE SEVERITY OF THE PAIN. I HAVE LITTLE TO NO ENERGY. DEPRESSION IS UNEXPLAINABLE. ANXIETY AND MOOD SWINGS HAS WORSEN. I HAVE NOT BEEN SEEN BY A DOCTOR DUE TO NO INSURANCE AND FINANCIALLY UNABLE TO AFFORD IT. THE DEVICE IS STILL INSIDE OF ME. BEFORE ESSURE, I HAD NO ONGOING ILLNESSES OR HEALTH ISSUES BESIDES BEING OVERWEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057234	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 10/31/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) HEAVY BLEEDING, BLOATING AND ONSET OF CYSTS. CRAMPS AND EXTREME PAIN. INSURER PAID FOR REMOVAL OF RIGHT TUBE AN OVARY ALONG WITH AN ABLATION. ESSURE WAS COVERED UNDER MY INSURANCE AT THE TIME OF IMPLANT

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057235	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 3/3/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE PLACEMENT OF ESSURE COILS, I HAVE EXPERIENCED HEAVY, PAINFUL PERIODS WITH EXTREMELY LARGE CLOTS. CHRONIC PELVIC PAIN, MUSCLE PAIN, LOW BACK PAIN AND JOINT PAIN. I HAVE HAD A HEADACHE FOR NINE YEARS, THAT VARIES IN INTENSITY BUT NEVER DISAPPEARS. I HAVE TEETH, LITERALLY, DISINTEGRATING. RINGING IN MY EARS, HAIR LOSS, AND DRY, ITCHY SKIN. I CAN'T CONCENTRATE, AM EXHAUSTED ALL OF THE TIME, COMPLETELY FATIGUED AND HAVE SLEEPING ISSUES. HAD TO HAVE GALLBLADDER REMOVED IN 2013. HAVE LOW ENERGY, PROBLEMS WITH LOW BLOOD SUGAR, ANEMIA, BONE LOSS AND MORE. I STILL HAVE COILS AND AM LOOKING TO GET HYSTERECTOMY AS SOON AS POSSIBLE. WAS ON (B)(6) AT TIME OF PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057236	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 5/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). 2 DAYS AFTER BEING IMPLANTED I HAD TO VISIT THE ER DUE TO EXCESSIVE BLEEDING AND MY PLATELET COUNT WAS DOWN TO 68000. SINCE THEN I WAS DIAGNOSED WITH ITP. HAVE HAD HORRIBLE DISCHARGE VERY HEAVY PERIODS, EXTREME BLOATING AND SWELLING, CHRONIC FATIGUE AND PAIN, STABBING PAIN THAT DOUBLE ME OVER INSIDE ITCHING AND BURNING EXTREME WEIGH GAIN, STROKE LIKE SYMPTOMS , MUSCLE SPASMS AND END UP HAVING HYSTERECTOMY ON (B)(6) AND HAD LARGE AMOUNTS OF INFLAMMATION

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057237	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RAPID HEART BEAT, LIGHT HEADED, VOMITING, CLOSE TO PASSING OUT. THIS CONTINUED FOR MONTHS. SOON AFTER I WAS DIAGNOSED WITH HASHIMOTOS DISEASE. MY WBC WAS HIGH, MY LABS WERE MESSED UP DUE TO ESSURE. MY DEVICE WAS PROVIDED BY MY INSURER. I HAD A PARTIAL HYSTERECTOMY ON (B)(6) 2015 TO REMOVE THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057238	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 6/4/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD ESSURE (PAID FOR BY MY INSURER) FOR OVER A DECADE; I HAVE HAD CHRONIC PROBLEMS SINCE INCLUDING BEING HOSPITALIZED 2 WEEKS AFTER SURGERY DUE TO HEMORRHAGING, MY PERIOD WAS THEN/IS NOW SO HEAVY THAT I COULDN'T/CANNOT LEAVE THE HOUSE THE FIRST 4 DAYS. I HAD A HYDROTHERMAL ABLATION TO TRY TO CORRECT IT WHICH IT HASN'T. BECAUSE OF THE BLEEDING, I HAD TO GO TO GET TRANSFUSIONS DUE TO LOW IRON. I CAN'T MAKE IT FROM MY BED TO MY BATHROOM ABOUT 15 FEET WITHOUT MAKING A MESS ON THE FLOOR SOAKING THROUGH A SUPER PLUS TAMPON AND OVERNIGHT PAD. I EXERCISE EVERYDAY YET I LOOK(PREGNANT) AND FEEL BLOATED CONSTANTLY. I HAVE MY ALEVE ON MY DESK BECAUSE I HAVE HEADACHES, BACK PAIN AND I AM ALWAYS TIRED. I HAVE MAJOR HAIR LOSS AS WELL. I'VE BEEN MARRIED FOR 22 YEARS WITH MY HUSBAND FOR 28 YEARS AND SEX HAS BECOME VERY UNCOMFORTABLE. I HAVE SHARP SHOOTING PAINS IN MY SIDES. I JUST HAD MY GYN DO AN ULTRASOUND (INSIDE AND OUTSIDE) TO SEE WHY MY STOMACH IS SO BLOATED. I AM JUST READING SOME OF THESE STORIES AND ITS LIKE THESE WOMEN ARE READING MY THOUGHTS AND LIVING MY PRIVATE HUMILIATING HELL. I WAS DIAGNOSED THIS SUMMER AS HAVING ROSACEA AS A WOMAN OF COLOR I FOUND THAT HARD TO BELIEVE. I AM GOING TO VOICE MY CONCERNS WITH MY GYN AND DERMATOLOGIST TO SEE IF I AM POSSIBLY ALLERGIC TO NICKEL. SHE HAS NEVER SUGGESTED THE ESSURE COULD BE THE PROBLEM.

Manufacturer Narrative (H10):

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This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057239	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 5/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BECOME PREGNANT DUE TO A MIGRATED COIL. IT EMBEDDED ITSELF INTO MY UTERUS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057240	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FROM (B)(6) 2013 TO TODAY ((B)(6) 2015) I HAVE BEEN EXPERIENCING CRAMPING, SHARP/STABBING PELVIC PAIN, PERIOD STOPS, DISCHARGE (ODOR), HOT FLASHES, EXCESSIVE BLEEDING DURING PERIOD, NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, BLEEDING/SPOTTING AFTER SEX, PAINFUL INTERCOURSE, INCONTINENCE, SEXUAL DYSFUNCTION (UNABLE TO FEEL PLEASURE), MANY YEAST INFECTIONS, URGENT/FREQUENT URINATION, MANY UTIS , ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, BACK, JOINT, CHEST, BREAST, NECK, SPINE, AND; HIP PAIN, CHRONIC PELVIC PAIN, ALL OVER BODY ACHES/PAIN, NAUSEA, GAS, CONSTIPATION, DIARRHEA, HEARTBURN, BOWEL ISSUES, HEADACHES/MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, NERVE PAIN, BRAIN FOG AND; CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, DEPRESSION, RINGING IN EARS, DIMINISHED BRAIN FUNCTION (FORGETFULNESS), MOOD DISORDERS, NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), TREMORS/SHAKINESS, DIZZINESS, CHEMICAL AND FOOD SENSITIVITIES, HEIGHTENED ALLERGIES, GLUTEN SENSITIVITY, SKIN IRRITATION/ITCHING, HAIR LOSS, HAIR GROWTH IN NEW PLACES (FEET, STOMACH, AND; BUTT), INSOMNIA, WEIGHT ISSUES (GAIN), MUSCLE SPASMS, VISION PROBLEMS (BLURRED VISION), EXCESSIVE SWEATING, DRY SKIN/HAIR, SEVERE BLOATING, CONSTANT FATIGUE. BEFORE GETTING THE ESSURE, I WAS HEALTHY AND; DID NOT HAVE ANY OF THE SIDE EFFECTS I HAVE NOW. I ALSO CAN'T GO TO THE DOCTOR OR THE HOSPITAL BECAUSE I DO NOT HAVE INSURANCE AND CAN'T AFFORD TO BE SEEN. I HAD INSURANCE AT THE TIME OF THE PROCEDURE AND; THE PROCEDURE WAS COVERED, BUT I LOST MY INSURANCE ABOUT 2 WEEKS AFTER THE PROCEDURE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057241	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 2/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD BEEN TAKING TYLENOL AND IBUPROFEN FOR A COUPLE OF WEEKS. SO I DECIDED TO GO TO THE DOCTOR. I TOLD THE DOCTOR ALL THE PROBLEMS THAT I HAVE AND THAT I HAD BEEN TAKING TYLENOL AND IBUPROFEN FOR PAIN FOR A COUPLE OF WEEKS. THE DOCTOR SAID THAT IT COULD NOT BE FROM THE ESSURE BECAUSE IT HAS NO HORMONES. AND THAT HE IS NOT GOING TO GIVE ME ANYTHING FOR PAIN BECAUSE IT CAN BE ADDICTIVE. SO MY PROBLEMS ARE LOWER ABDOMINAL PAIN, CRAMPS THAT COME AND GO, BLOATING THAT COMES AND GOES EVEN WHEN I LOOSE WEIGHT, MIGRAINES, BACK PAIN, PAIN WHEN HAVING INTERCOURSE IN SOME POSITIONS, FEEL FATIGUE ALL THE TIME, SOMETIMES I HAVE TWO PERIODS IN ONE MONTH, MY HAIR FALLS OUT A LOT SO MUCH THAT WHEN I HAD GONE TO GET MY HAIR DONE THE HAIR DRESSER SAID THAT I NEEDED TO GO SEE A DOCTOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057242	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IN RIGHT LOWER ABDOMEN RADIATING DOWN INSIDE OF RIGHT LEG AND ABDOMINAL BLOATING. I HAD 2 TRANSVAGINAL ULTRASOUNDS, 2 PELVIC ULTRASOUNDS, A CT ABDOMEN AND PELVIS WITH CONTRAST, LAB WORK, 2 MONTHS OF LUPRON INJECTIONS, AND ON (B)(6) 2015 REMOVAL OF FALLOPIAN TUBES AND ESSURE COILS. MY PAIN IS COMPLETELY GONE AND MY ABDOMEN IS 1.5 INCHES SMALLER THAN THE DAY PRIOR TO REMOVAL OF TUBES AND COILS. MY INSURANCE DID COVER THE DEVICE PLACEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057243	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 10/25/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE PROCEDURE WAS DONE (B)(6) 2006. HSG TEST DONE IN (B)(6) 2007. SINCE PROCEDURE I'VE EXPERIENCED EXCESSIVE BLEEDING, CRAMPING, PAIN IN LOWER ABDOMEN. PAINFUL INTERCOURSE. IRREGULAR PERIODS. HEAVY CLOTTING DURING PERIODS. VAGINAL DISCHARGE. VAGINAL ODOR. CRAMPING. LOWER BACKACHES. NUMEROUS URINARY PROBLEMS. (UTI, KIDNEY FAILURE, BLADDER INFECTIONS).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057244	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 3/12/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DON'T REMEMBER THE EXACT DATE BUT IT WAS IN 2008. I WAS TOLD THAT ESSURE WAS FAIRLY NEW AND COULD BE DONE AT THE DOCTORS OFFICE IN ABOUT 30-40 MINUTES. SHORTLY AFTER I GOT THE ESSURE, I STARTED HAVING REALLY BAD CRAMPS AND I NOTICED MY FLOW WAS VERY HEAVY. EVER SINCE THE PROCEDURE, I'VE NOTICED OVER TIME THAT MY BODY WAS CHANGING. I THOUGHT IT WAS DUE TO THE FACT THAT I WAS GETTING OLDER AND THAT MY BODY WAS JUST GOING THROUGH CHANGES. AFTER A FEW YEARS, I STARTED DOING MY OWN RESEARCH AND FOUND THAT I WASN'T ALONE. SO MANY WOMEN HAVE SUFFERED FROM THE SAME SYMPTOMS IF NOT MORE. I MADE AN APPOINTMENT WITH THE DOCTOR WHO DID THE PROCEDURE AND HE TOLD ME THAT MY SYMPTOMS WERE NOT ASSOCIATED OR RELATED WITH THE ESSURE AND THAT IT COULDN'T BE REMOVED. APPROXIMATELY (B)(6) 2015, MY PERIODS TOOK A TURN FOR THE ABSOLUTE WORST. THE CRAMPS FELT LIKE LABOR PAINS TO POINT I HAD TO GO TO THE ER FOR PAIN PILL. NOTHING OVER THE COUNTER WOULD WORK. I HAD AN ULTRASOUND DONE TO CHECK FOR FIBROIDS AND THE RESULTS CAME BACK NEGATIVE. MY DOCTOR ORDERED FOR ME TO HAVE A MIR THE RESULTS WERE THAT I HAVE A THICK UTERUS LINING. MY DOCTOR SAID THAT'S WHERE THE PAIN IS COMING FROM AND DIAGNOSED ME WITH ADENOMYOSIS. HE RECOMMEND THAT I GET A HYSTERECTOMY OR TAKE BIRTH CONTROL PILLS. I DON'T WANT TO DO NEITHER I WANT THESE COILS REMOVED FROM MY BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057245	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 7/11/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE STARTED AND RESTARTED AND STARTED AGAIN. ALWAYS UNSURE ON HOW TO START MY STORY. I GOT MY ESSURE IN 2007. THEY GOT THE LEFT COIL IN WITH NO SAID COMPLICATIONS. WHEN ATTEMPTING MY RIGHT, THEY HAD TO RUSH TO GET MORE MEDS ONLY TO TELL ME I WOULD HAVE TO COME BACK TO HAVE MY RIGHT ONE DONE AGAIN. THE PAIN WAS HORRIBLE. SINCE THEN, I'VE BATTLED MIGRAINES, LOSS OF HAIR, TOOTH DECAY, HEAVY PERIODS WITH CRAMPS THAT MAKE YOU SICK TO YOUR STOMACH. SHARP PAINS IN MY RIGHT SIDE AND MY LEFT. NIGHT SWEATS THAT WOULD LEAVE ME DRENCHED WHEN I WOKE UP. (I WAS TOLD BY MY FORMER OB TO USE LESS BLANKETS AT NIGHT). I JUST WROTE IT OFF AS JUST ANOTHER PHASE OF LIFE. IT WASN'T UNTIL JUST RECENTLY THAT THINGS STARTED TO MAKE SENSE. I HAD A LEEP PROCEDURE, WHERE THEY REMOVE ABNORMAL CELLS FROM YOUR CERVIX. QUICK 15 MINUTE PROCEDURE. I HAD MILD CRAMPING AND BLEEDING. WELL, THE BLEEDING NEVER STOPPED. WEEK ONE ENDED UP IN ER AND HAD MY CERVIX SCRAPPED AND RE CAUTERIZED WITHOUT ANY NUMBING. EXCORIATING PAIN. WEEK TWO, BACK TO OB FOR THEM TO REPEAT THE SAME THING AGAIN NO NUMBING. DECISION MADE TO USE SOME NEW BONDING MATERIAL THAT WAS DROPPED OF BY PHARMACEUTICAL SALES PERSON. WEEK THREE, HAVE TO MISS WORK AGAIN BECAUSE OF WAKING UP AND FEELING LIKE I AM BLEEDING TO DEATH. GO TO ER. THEY TREAT ME INCREDIBLY RUDE AND SEND ME TO MY OB. I TELL THEM PLEASE DO NOT DO ANYTHING WITHOUT NUMBING. I CAN'T DO THE PAIN AGAIN. AFTER 30 MINUTES OF MANIPULATING MY CERVIX IT IS PROMISED THAT IT'S FIXED. I WON'T BLEED AGAIN. ALL THE WHILE NO ONE CAN TELL ME WHY I'M NOT HEALING. WEEK FOUR, I WAKE UP TO A POOL IN MY SWEATPANTS. I SHOWER AND HEAD TO WORK. I'M A TEACHER. I HAVE ALREADY MISSED 6 DAYS BECAUSE OF THIS. I TEACH FOUR PERIODS. WITH THE HELP OF SOMEONE COMING DOWN HALFWAY THROUGH EACH CLASS ,SO I CAN TAKE CARE OF THINGS IN BATHROOM. I CALL MY OB AND PUT ME AT APT

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FOR 10:30. I'M FINALLY SEEN AT 11:40. AN EMERGENCY D AND C IS SCHEDULED FOR 2:00. I AWAKE AND I GET TOLD THAT"IT LOOKED AS IF ONE OF YOUR COILS COULD BE SEEN BUT THE OTHER CANNOT. THE RIGHT SIDE CAN BUT THE LEFT ONE CANNOT. THEY KEEP ME OVER NIGHT THEN ORDER A IVP TO CHECK FOR COMPLICATIONS BECAUSE OF THE PAIN. I SEE MY COILS ON X-RAY. ONE APPEARS NORMAL THE OTHER IS BENT. THEY THEN PULL UP X-RAYS FROM 2012 THAT SHOW A SPEC "THIS MUST BE A PIECE THAT WAS LEFT FROM THEIR FAILED FIRST ATTEMPT BUT IT WAS TAKEN OUT DURING D AND C. THEY PULL UP MY CURRENT X-RAY. GUESS WHAT I SEE, THAT SAME SPEC. I QUESTION, WELL ISN'T THAT STILL THE PIECE IN MY UTERUS? "OH YES, I SEE IT. BUT IT'S EMBEDDED IN THE WALL OF YOUR UTERUS ,SO NO NEED TO WORRY ABOUT IT. ". MY SISTERS FURIOUS START TO RESEARCH ESSURE AND HERE I AM. EIGHT YEARS OF MY LIFE. SO MANY UNANSWERED STRUGGLES THAT WERE ONLY ATTEMPTS MADE BY MY DOCTOR SOLVED BY PUSHING PRESCRIPTION PILLS THAT I NEVER NEEDED TO BE ON IN THE FIRST PLACE. LOSS OF HAIR. CONSTANT STRUGGLES WITH MY TEETH. ALL THE THINGS I LISTED BEFORE. NOW IT FINALLY MAKES SENSE I DON'T FEELING I'M JUST BEING A WIMP. I WAS ABLE TO GO BACK TO WORK THIS PAST TUESDAY. THEY ENDED UP PUTTING TWO SUTURES ON MY CERVIX TO CUT OFF MY BLOOD FLOW. PUT ON TWO ANTIBIOTICS. MONDAY NIGHT I BREAK OUT IN A RASH GOING DOWN MY RIGHT ARM. SAW THE SURGEON ON THURSDAY. SHE SWITCHED MY ANTIBIOTICS BUT COULDN'T CONFIRM THE RASH. IT'S STILL THERE. I GO TO A BRAND NEW SURGEON IN TWO WEEKS. I WANT THEM OUT. THE MORNING AFTER THE D AND C MY HEMOGLOBIN WAS AT 9.8. I'M STILL STRUGGLING WITH FATIGUE. I GET TIRED EXTREMELY EASILY. I HATE IT. IT SICKENS ME HOW MANY OF PEOPLE HAVE BEEN IGNORED OR MADE TO FEEL LIKE COMPLAINERS OR WEAK. SO THIS IS THE CLIFF NOTES VERSION OF MY STORY AND IT SEEMS TO JUST BE THE BEGINNING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057246	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIFIC CRAMPS AND BACK PAIN. HEAVY PERIODS. STUCK ON SOFA BC IT HURT SO BADLY, EVEN JUST TO WALK AROUND HOME. WOULD HAVE TO MISS SCHOOL OR WORK BECAUSE OF THE PAIN. PERIODS EVERY 24 DAYS. SINCE I BEGAN ESSURE MY VIT D LEVELS HAVE BOTTOMED OUT, EVEN WITH SUPPLEMENTS. EXTREMELY MOODY AND ANGRY DURING PERIOD AND OVULATION TIME. CRAMPS AND BACK ACHES DURING OVULATION ALSO SINCE GETTING ESSURE- ONGOING BACK PAIN REQUIRING VISIT TO PAIN DR TO GET PAIN MEDS AND SHOTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057247	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 8/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) SEVERE PAIN AND BLEEDING UNLIKE ANY PERIOD EVER. I HAVE EXPERIENCED WEIGHT GAIN, MOOD CHANGES, DRY ITCHING SKIN, GASTROINTESTINAL ISSUES INCLUDING EXTREME DIARRHEA, PAIN WITH INTERCOURSE, HEADACHES AND CONFUSION, ABDOMINAL SWELLING AND SEVERAL OTHER SYMPTOMS. I HAVE A SENSITIVITY TO NICKEL AND WAS NEVER INFORMED OF THE DEVICE HAVING NICKEL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057248	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) HAD THE ESSURE PLACED AND HAVE CHRONIC LOWER BACK AND GROIN PAIN SINCE. VERY HEAVY, IRREGULAR PERIODS, HEADACHES, MUSCLE ACHES, JOINT PAIN, DECREASED LABIDO, PAIN DURING INTERCOURSE, ITCHY SKIN, METALLIC TASTE IN MOUTH, INSOMNIA AND ANXIETY. VISITED MD. SONO SHOWED CYST IN RIGHT OVARY AND GROWTH WRITHING UTERINE LINING. SCHEDULED FOR COMPLETES HYSTERECTOMY AND RIGHT OVARY REMOVAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057249	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE ESSURE DEVICE WAS IMPLANTED I BEGAN TO HAVE TERRIBLE BACK PAIN, EXCRUCIATING PAIN IN MY LEFT HIP (HURT TO THE POINT I COULDN'T LAY FLAT ON MY BACK WITHOUT BEING IN TEARS), FOR THE FIRST TIME IN MY LIFE BEGAN EXPERIENCING MIGRAINES. I HAD SEVERE DEPRESSION FOR A YEAR AND A HALF, WORSE PERIODS WITH A HEAVIER FLOW AND CONSTANT CRAMPING. CRAMPING IN MY VAGINAL AREA WHILE ON OR OFF MY PERIODS. I HAVE HAD NUMBNESS IN MY FINGERS. I JUST HAD AN EBABY WHO CELEBRATED HIS (B)(6) BIRTHDAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057250	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 10/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I BEGAN TO HAVE SEVERE AUTOIMMUNE ARTHRITIS SYMPTOMS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057251	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DIZZINESS, NUMBNESS AND TINGLING. SEVERE JOINT PAIN, BACK PAIN, URINE URGENCY, NODULES, JOINT SWELLING, VERTIGO, IRREGULAR PERIODS, ABDOMINAL PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057252	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 10/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING AND CLOTTING DURING MENSTRUAL CYCLE. DEBILITATING MENSTRUAL CRAMPS. VERTIGO. UNEXPLAINED ABDOMINAL PAIN. HAIR LOSS. WORSENING OF AUTO IMMUNE REACTIONS. FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057253	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 11/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE PLACED IN (B)(6) 2010. THIS HAS BEEN THE WORST DECISION OF MY LIFE. THE INSERTION PROCEDURE WAS HORRIBLY PAINFUL. ONE VALIUM PILL AND 1 SHOT OF IBUPROFEN DIDN'T HELP. I WAS AWAKE AND ALERT DURING THE PROCEDURE. IT WAS THE WORST PAIN I HAVE EVER ENDURED INCLUDING MY 2 NATURAL CHILD BIRTHS. THREE MTHS LATER IN (B)(6) OF 2011 I WENT FOR MY HSG DYE TEST TO CONFIRM PLACEMENT. THIS WAS A HORRIBLE PAIN AS WELL. THERE WAS SO MUCH PRESSURE I LEAKED CONTRAST DYE INTO MY PELVIC VENOLYMPHATIC SYSTEM. THEY CLEARED ME AND CONFIRMED ME BLOCKED. THAT WAS FALSE. MY LEFT COIL WAS MISPLACED AND WAS A GRADE 3 SO IT WAS WAY TO FAR IN THE FALLOPIAN TUBE. THE RIGHT COIL IS BENT IN A U. IT IS ALSO A GRADE 3 COIL BUT IT LOOKS AS THOUGH IT PERFORATED MY TUBE UPON INSERTION. RULES ARE IF IT IS A GRADE 3 COIL U SHOULD NOT BE CLEARED AND USE A BACKUP BIRTH CONTROL. THEY SAID EVERYTHING LOOKS GREAT AND I WAS CLEARED. I HAD ALOT OF TENDERNESS, HIVES, PAINFUL SEX, BLOATING AND RASHES. FAST FORWARD TO (B)(6) OF 2015. I STARTED GETTING SEVERE PAINS IN MY SIDES , BACK, AND ABDOMINAL/PELVIC AREA. SEVERAL TESTS LATER CONFIRMED THERE WAS NO RIGHT COIL. IT MIGRATED UP AND OUT IF THE PERFORATED TUBE. I NOW HAVE TO HAVE SURGERY TO REMOVE BOTH COILS. THE RIGHT COIL IS CURRENTLY SOMEWHERE LODGED ON MY LEFT PELVIC AREA. THEY CONTAIN PET FIBERS SO THERE IS NO EVIDENCE OF WHAT THIS CAN DO LATER ON WT THESE FIBERS TOUCHING MY ORGANS. THIS DEVICE NEEDS REMOVED. IT IS DAMAGING OUR FEMALE ORGANS. IT FAILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057254	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 9/28/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) HAD ESSURE PUT PLACEMENT IN 2009. HAD A FEW PROBLEMS BUT WASN'T UNTIL THE PAST YEAR I HAVE HAD MORE SERIOUS PROBLEMS. STARTED WITH MIGRAINES. THEN HAD FACIAL NUMBNESS AND BURNING AND TINGLING RUNNING DOWN MY ARMS. PAIN IN MY LEFT SIDE. PAIN IN MY LEFT HIP. JOINT AND MUSCLE PAIN ALL THROUGHOUT MY BODY. HEAVY PERIODS WITH CLOTTING. PAINFUL SEX. DISCHARGE. PELVIC PAIN. PREPARING NOW FOR HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057255	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 10/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN IN RIGHT LOWER ABDOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057256	BAYER	10/20/2015	10/20/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC FATIGUE, NUMBNESS AND TINGLING IN ARMS HANDS LEGS AND FEET, DEPRESSION, ANXIETY , BACK PAIN, STROKE LIKE SYMPTOMS THAT PUT ME IN THE HOSPITAL FOR 24 HOURS, MY INSURANCE, (B)(6), COVERED THE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057488	BAYER	10/20/2015	10/29/2015

Event Information:

Event Date (B3): 12/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/23/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DONE IN (B)(6) OF 2013. I WENT TO A NEW DOCTOR TO HAVE AN ENDOMETRIAL ABLATION PERFORMED DUE TO HEAVY AND LONG MENSTRUAL PERIODS AND SHE RECOMMENDED GETTING ESSURE TO PREVENT GETTING PREGNANT. IN SPRING OF 2014 I STARTED HAVING PELVIC AND ABDOMINAL PAIN AND EXTREME FATIGUE. I WENT TO MY FAMILY DOCTOR AND HAD BLOOD WORK DONE. ALL BLOOD TESTS CAME BACK NORMAL. THE PAIN AND FATIGUE CONTINUE TO WORSEN AND WE COULDN'T FIGURE OUT WHY. IN (B)(6) OF 2015 I AGAIN HAD AN APPOINTMENT WITH MY FAMILY DOCTOR FOR WORSENING PELVIC AND ABDOMINAL PAIN, MUSCLE BURNING AND FATIGUE. I HAD MORE BLOOD WORK, A CT SCAN AND AN ULTRASOUND. EVERYTHING CAME BACK NORMAL, BUT I DID HAVE 2 UTI'S. PRIOR TO ESSURE I'VE HAD LESS THAN 3 UTI'S IN MY ENTIRE LIFE. I WENT TO A GASTROENTEROLOGIST FOR SAME SYMPTOMS. I HAD A COLONOSCOPY AND UPPER ENDOSCOPY WHICH ALL CAME BACK NORMAL. I THEN WENT TO A RHEUMATOLOGIST WHO PRESCRIBED AN ANTI INFLAMMATORY. LAST WEEK I SAW A FERTILITY SPECIALIST AND AM GETTING THE ESSURE REMOVED WITHIN A MONTH. I AM NOT SUER YET IF I NEED A HYSTERECTOMY OR JUST HE ESSURE AND TUBES REMOVED. I AM CERTAIN THAT ESSURE HAS AFFECTED MY QUALITY OF LIFE SINCE I HAD IT IMPLANTED. MY FATIGUE, BODY PAINS AND BRAIN FOG HAVE BEEN LIFE CHANGING FOR THE WORSE. IT HAS ALSO AFFECTED MY JOB PERFORMANCE AND I SUPPORT MY FAMILY WITH MY JOB. I HAVE SPENT SO MUCH TIME AND MONEY TRYING TO FIGURE OUT WHAT WAS WRONG WITH ME. I AM DEPRESSED. I USED TO BE VERY ACTIVE AND EXERCISED 6 TIMES A WEEK DOING RUNNING, WEIGHT LIFTING, HIKING AND BIKRAM YOGA. NOW I CAN BARELY GET OUT OF BED, I HOPE THAT ESSURE HAS NOT RUINED MY LIFE AND MY SYMPTOMS WILL IMPROVE ONE IT IS REMOVED.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057489	BAYER	10/20/2015	10/29/2015

Event Information:

Event Date (B3): 7/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SIDE EFFECTS FROM ESSURE: ABDOMINAL PAIN AND DISCOMFORT, VIT. B-12 DEFICIENCY, SUDDEN WEIGHT GAIN, RASH ON FACE AND SCALP, DIAGNOSED WITH IRRITABLE BOWEL SYNDROME, FATIGUE, PAIN DURING INTERCOURSE, BLEEDING AFTER INTERCOURSE, DEPRESSION AND ANXIETY, SEVER AND PAINFUL BLOATING, ARMS AND LEGS "GOING TO SLEEP", HOT FLASHES, HAIR LOSS, INCREASE IN FREQUENCY OF HEADACHES, MEMORY LOSS. IN AN EFFORT TO AVOID A HYSTERECTOMY DUE TO BLEEDING, MY DR SUGGESTED AN ABLATION, BUT HE WOULD NOT DO THE ABLATION WITHOUT ESSURE BEING IMPLANTED. I HAD NO CHOICE IF I WANTED TO TRY TO AVOID THE HYSTERECTOMY. PROCEDURES DONE IN (B)(6) 2011. SINCE THAT TIME, MY HEALTH HAS DETERIORATED WITH THE SYMPTOMS LISTED ABOVE. I HAVE BEEN TO MY PRIMARY CARE PHYSICIAN ABOUT EVERY SYMPTOM WHICH HAS LED TO MULTIPLE TESTS AND LAB WORK. I HAD THIS DONE WHEN I WAS (B)(6) NOW, AT (B)(6) , I FEEL LIKE I'M, 70. MY HYSTERECTOMY IS SCHEDULED FOR (B)(6) 2015. (NOTE: IMPLANT WAS (B)(6) 2011; HOWEVER, I DO NOT HAVE THE EXACT DAY OF THE MONTH.)

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057492	BAYER	10/20/2015	10/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTHCONTROL
Device Type (E2): ESSURE PERMANENT BIRTHCONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE PLACED IN 2013, IN WHICH FOUR COILS WERE PLACED INSTEAD OF TWO... I HAVE HAD SEVERE ABDOMINAL PAIN AND SWELLING, WEIGHT GAIN, HAIR LOSS, DEPRESSION, SEVER PANIC ATTACKS. MULTIPLE, ALMOST CONSTANT INFECTIONS INCLUDING URINARY TRACT INFECTIONS, YEAST INFECTIONS, VAGINAL BACTERIAL INFECTIONS, BLOOD INVENTIONS, AND INFECTION OF MY BOWELS. I HAVE HAD SEVER MIGRAINES AND MUSCLE PAIN. I HAVE HAD NERVE DAMAGE IN MY BACK AND LEGS TO THE POINT I CAN NO LONGER DO THINGS SO SIMPLE AS DRIVE A CAR OR EVEN SLEEP AT NIGHT. I HAVE HAD ALMOST CONSTANT VAGINAL BLEEDING FOR TWO YEARS SINCE THE ESSURE WITH AN EXTREMELY HEAVY FLOW AND LARGO CLOTS. I HAVE RECENTLY BEEN EXPERIENCING SEVER CONSTIPATION WITH SMALL AMOUNT OF BLOOD IN MY STOOL. ABDOMEN SPASMS SO BAD TO THE POINT I CANNOT STAND OR SIT. ONLY LIE ON MY SIDE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057493		10/20/2015	10/29/2015

Event Information:

Event Date (B3): 3/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/19/2014
Explant Date (E7): 7/24/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED ON (B)(6) 2014. BOTH SPRINGS MIGRATED, ONE TOWARDS MY OVARY AND THE OTHER 3/4 OF THE WAY INTO MY UTERUS. IT CAUSED PAIN AND BLEEDING. I HAD TO HAVE THEM SURGICALLY REMOVED 4 MONTHS LATER LAPAROSCOPICALLY. I ALSO HAD AN ABLATION TO HELP STOP THE BLEEDING. I STILL HAVE HEAVY BLEEDING TO THIS DAY AND MAY REQUIRE A HYSTERECTOMY IN THE FUTURE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01207	BAYER HEALTHCARE LLC	10/21/2015	10/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2013
Explant Date (E7): 12/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 10-OCT-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013 FOR PERMANENT CONTRACEPTION. SHE WAS EXPERIENCING PROBLEMS SINCE A MONTH AFTER ESSURE INSERTED: SEVERE JOINT PAINS, MUSCLE SPASMS ALL OVER BODY, SHE CAN HARDLY HOLD FORK, SEVERE BACK PAIN, STRONG METAL TASTE IN MOUTH, BLOATING THAT LOOKS LIKE SHE WAS 5 TO 6 MONTHS PREGNANT. SHE DID A HOME PREGNANCY TEST IN (B)(6) 2014 AND IT WAS POSITIVE BUT SHE MISCARRIED BEFORE FIRST DOCTOR'S APPOINTMENT. SHE HAS BEEN PLACED SEVERAL ANTI-INFLAMMATORIES AND BEEN ON PAIN MEDS FOR OVER A YEAR NOW. SHE HAS BEEN TO THE EMERGENCY ROOM FOR THE PAIN SEVERAL TIMES AND THEY SAY IT WAS DUE TO INFLAMMATION. SHE HAS HAD SEVERAL X-RAYS AND A MRI AND THEY CANNOT FIND ANYTHING. HER FIRST GYNECOLOGIC DOCTOR SAID IT WAS NOT RELATED TO ESSURE BUT HER NEW HEALTHCARE PROFESSIONAL (HCP) SAID SHE THOUGHT IT WAS RELATED TO ESSURE. SHE NEVER HAD THESE PROBLEMS BEFORE ESSURE INSERTED. HER HCP WAS RESEARCHING WAYS TO REMOVE ESSURE SAFELY SO AS TO NOT HAVE TO DO A HYSTERECTOMY. SHE IS SCHEDULED TO HAVE ESSURE REMOVED SURGICALLY ON (B)(6) 2014. EVENTS WERE ONGOING. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 28-OCT-2014. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (LACK OF EFFICACY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR

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ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW UP INFORMATION RECEIVED ON 28-JAN-2015: CONSUMER REPORTED VIA SOCIAL MEDIA THAT SHE WAS POISONED BY ESSURE AND WAS BREASTFEEDING; SHE DID NOT KNOW WHAT IT'S DONE TO HER SON. SHE LISTED THE ESSURE INGREDIENTS WHICH SHE BELIEVED THAT POISONED HER. FOLLOW-UP FROM 07-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW-UP INFORMATION RECEIVED ON 15-APR-2015 NO NEW CLINICAL INFORMATION PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 07-MAY-2015: CONSUMER STATED VIA SOCIAL MEDIA THAT ESSURE POISONED HER AND SHE GOT PREGNANT. FOLLOW UP INFORMATION RECEIVED ON 25-SEP-2015 (UPGRADED TO INCIDENT): CONSUMER WAS PARA 3. SHE STATED "SO MUCH FOR A NON-SURGICAL PROCEDURE AND NO SIDE-EFFECTS. YES, SHE HAD CYSTS ON HER OVARY AND TUBES. ADDITIONALLY, THE CONSUMER SENT PICTURES SHOWING A SURGICAL PROCEDURE. FOLLOW UP INFORMATION RECEIVED ON 30-SEP-2015: UPON INTERNAL REVIEW, THE CASE 2014-158514 WAS IDENTIFIED AS A DUPLICATE FROM THIS CASE. CASE (B)(4) WAS DELETED FROM BAYER DATABASE AND INFORMATION TRANSFERRED TO THIS CASE. FOLLOW-UP FROM CONSUMER ON 25-SEP-2015, VIA SOCIAL MEDIA: SHE MENTIONED SHE ALMOST DIED BEFORE SHE GOT ANY HELP TO GET ESSURE REMOVED. FOLLOW UP INFORMATION RECEIVED ON 27-SEP-2015: THE CONSUMER STATED VIA SOCIAL MEDIA THAT SHE DID NOT KNOW THE LONG TERM EFFECTS ON HER SON BECAUSE SHE WAS BREASTFEEDING WHILE HAD ESSURE. SHE ALSO REPORTED THAT HER PHYSICIAN BELIEVE THAT ESSURE WAS THE CAUSE OF BOTH, HER AND HER SONS HEALTH PROBLEMS. SHE STATED THAT SHE HAD A MAMMOGRAM DONE AT AGE (B)(6) BECAUSE ESSURE HAD POISONED HER ENTIRE BODY. FOLLOW UP INFORMATION RECEIVED ON 30-SEP-2015: THE CONSUMER STATED VIA SOCIAL MEDIA THAT SHE NEEDED A BILATERAL SALPINGECTOMY AND A PHOTO OF HER FALLOPIAN TUBES WAS POSTED. FOLLOW UP INFORMATION RECEIVED ON 05-OCT-2015: CONSUMER REPORTED THAT SHE GOT PREGNANT 15 MONTHS AFTER ESSURE, IMPLYING (B)(6) 2014. SHE STATED SHE WAS LEFT WITH PERMANENT NERVE DAMAGE, ANGINA, DENTAL RECONSTRUCTION AND NEURO ISSUES FROM NICKEL POISONING FROM ESSURE. ADDITIONALLY, SHE MENTIONED 5 ABDOMINAL SURGERIES WITH ONE OF THOSE BEING AN ECTOPIC PREGNANCY IN WHICH HER TUBE WAS SAVED (PLEASE REFER TO CASE -(B)(4)). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE DID A HOME PREGNANCY TEST IN (B)(6) 2014 AND IT WAS POSITIVE, THEN SHE MISCARRIED. SHE HAD PAIN AND A BILATERAL SALPINGECTOMY WITH ESSURE REMOVAL WAS PERFORMED. ADDITIONALLY, SHE BELIEVED SHE HAD NICKEL POISONING FROM ESSURE. ONLY MISCARRIED AND NICKEL POISONING ARE UNLISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION. IN THIS CASE, PREGNANCY WAS DIAGNOSED ABOUT 1 YEAR AND 4 MONTHS AFTER ESSURE INSERTION AND CONSUMER MISCARRIED BEFORE FIRST DOCTOR'S APPOINTMENT. GIVEN A COMPATIBLE TEMPORAL RELATIONSHIP BETWEEN PREGNANCY AND SUSPECT INSERT, CAUSALITY CANNOT BE EXCLUDED. ALTHOUGH GESTATIONAL AGE WAS NOT PROVIDED, BASED ON THE INFORMATION RECEIVED, THE MISCARRIAGE COULD HAVE OCCURRED IN THE FIRST TRIMESTER. THEREFORE, ITS CAUSAL RELATION WITH SUSPECT INSERT CAN BE EXCLUDED. CONSIDERING THE NATURE OF THE EVENT PAIN AND THE COMPATIBLE TEMPORAL RELATIONSHIP, THE CAUSAL RELATIONSHIP

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WITH ESSURE CANNOT BE EXCLUDED. FOR NICKEL POISONING, THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. ALTHOUGH, IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM ESSURE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE A METAL POISONING. THEREFORE THIS EVENT WAS CONSIDERED UNRELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. OTHER NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 23-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01208	BAYER HEALTHCARE LLC	10/21/2015	10/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 11-MAY-2015 WHICH REFERS TO A FEMALE PATIENT BETWEEN 25 AND 40 YEARS WHO WAS INVOLVED IN A MARKET RESEARCH ACTIVITY, STUDY NUMBER: (B)(4). HEALTH CARE PROFESSIONAL REPORTED THAT FALLOPIAN TUBE PERFORATION OCCURRED AFTER DISTENTION DURING ESSURE INSERTION PROCEDURE. IT WAS ALSO REPORTED THAT HYSTEROMETER WAS TOO THICK. ESSURE WAS NOT YET REMOVED FROM ITS PACKAGING AND PHYSICIAN CONSIDERED THAT THE EVENT WAS NOT POSSIBLY RELATED TO ESSURE. NO FURTHER INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS WERE PROVIDED ON 18-JUN-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A USABILITY ISSUE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT AND HANDLING ERROR. THE REPORTED ADVERSE EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 25-SEP-

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2015: THE PATIENT MEDICAL HISTORY INCLUDE: ONE PREGNANCY AND ONE C-SECTION DELIVERY; AND ENDOMETRIOSIS OF ABDOMINAL WALL. HER CONCOMITANT DRUG WAS NEXPLANON. THE PATIENT HAD NO UTERUS ABNORMALITY DISCLOSED BEFORE INSERTION. DURING THE PROCEDURE CERVICAL DILATATION WAS DONE AND GENERAL ANESTHESIA WAS APPLIED. THE PERFORATION OCCURRED WITH THE HYSTEROSCOPE AND THE PROCEDURE WAS NOT CONTINUED; NO MORE THAN 1500CC OF FLUID LOSS DURING HYSTEROSCOPY. THE UNILATERAL PERFORATION OF RIGHT FALLOPIAN TUBE WAS DIAGNOSED BY LAPAROSCOPY. PERFORATION OCCURRED DURING DILATATION WITH THE HYSTEROSCOPE. NO ESSURE INSERTION PROCEDURE PERFORMED AFTER THE EVENT. IT WAS ALSO REPORTED INTRA-ABDOMINAL BLEEDING DURING THE PROCEDURE. IN SAME DAY, LAPAROSCOPY WAS PERFORMED WITH PERFORATION COAGULATION AND LIGATION BY TUBAL OCCLUSION. IMMEDIATELY AFTER INSERTION ATTEMPT THE PATIENT COMPLAINED OF PAIN. THE CONFIRMATION TEST WAS NOT PERFORMED. FOLLOW-UP RECEIVED ON 19-OCT-2015: THE GYNAECOLOGIST DID NOT REMEMBER THE NAME OF THE PATIENT. NO OTHER MEDICAL INFORMATION IS AVAILABLE. CASE CONSIDERED TO BE CLOSED. ADDITIONALLY, THE NCA NUMBER WAS RECEIVED: (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SOLICITED CASE REPORT REFERS TO A FEMALE PATIENT BETWEEN 25 AND 40 YEARS WHO WAS INVOLVED IN A MARKET RESEARCH ACTIVITY FOR ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND A FALLOPIAN TUBE PERFORATION OCCURRED AFTER DISTENTION DURING ESSURE PROCEDURE. IT WAS ALSO REPORTED THAT INTRA-ABDOMINAL BLEEDING DURING INTERVENTION. A LAPAROSCOPY WAS PERFORMED WITH PERFORATION COAGULATION AND LIGATION BY TUBAL OCCLUSION. THESE EVENTS ARE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN TUBE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE PERFORATION OCCURRED DURING THE INSERTION PROCEDURE, WHILE THE PHYSICIAN WAS PERFORMING THE DISTENTION WITH HYSTEROSCOPE. THE PHYSICIAN STATED THE HYSTEROSCOPE WAS TOO THICK. GIVEN THE FACT THAT THE PERFORATION OCCURRED DURING THE ESSURE INSERTION PROCEDURE, EVEN THOUGH IT OCCURRED BEFORE REMOVING ESSURE FROM THE PACKAGE, THE PERFORATION IS CONSIDERED RELATED TO ESSURE PROCEDURE. THE OTHER EVENT IS ALSO RELATED TO ESSURE SINCE IT OCCURRED DURING THE PROCEDURE. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED DURING ESSURE INSERTION PROCEDURE. AN UPDATED PRODUCT TECHNICAL COMPLAINT IS REQUIRED.

Manufacturer Narrative (H10):

UPDATED PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 19-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01209	BAYER HEALTHCARE LLC	10/21/2015	10/21/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D30810

Single Use: Y
Implant Date (E6): 9/9/2015
Explant Date (E7): 9/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT, ANTICIPATED (SERIOUS INJURY: REQUIRED INTERVENTION). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN VIA SALES REPRESENTATIVE IN (B)(6) ON 23-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 AND HAD A PERFORATION. IT WAS REPORTED THAT ESSURE WAS REMOVED VIA CELIOSCOPY. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 08-OCT-2015 NCA NUMBER WAS RECEIVED: (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A PERFORATION. IT WAS REPORTED THAT ESSURE WAS REMOVED VIA CELIOSCOPY. THE EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. ALTHOUGH THE EXACT DATE AND MECHANISM OF PERFORATION WERE NOT KNOWN, GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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UTERINE/FALLOPIAN PERFORATION QUESTIONNAIRE RECEIVED ON 30-OCT-2015 FROM PHYSICIAN: HER WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). HER MEDICAL HISTORY INCLUDED 3 PREGNANCIES WITH 2 PARITIES AND ONE ELECTIVE ABORTION. PREVIOUS GYNECOLOGICAL INTERVENTIONS WER

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01210	BAYER HEALTHCARE LLC	10/21/2015	10/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D31448

Single Use: Y
Implant Date (E6): 9/24/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 25-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4) AND HAD ESSURE INSERTED ON (B)(6) 2015. ON DEVICE INTRODUCTION, ESSURE IMPLANT EXTREMITY WAS BENT AND THERE WAS PRESENCE OF METALLIC FRAGMENT IN PATIENT'S UTERUS. BILATERAL INSERTION WAS PERFORMED WITH ANOTHER DEVICE. FULL DEVICE WAS KEPT. FOLLOW-UP INFORMATION RECEIVED ON 02-OCT-2015: NCA NUMBER WAS PROVIDED: (B)(4). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 19-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). THE LOT NUMBER USED WAS D31448. PRODUCTION DATE 24-NOV-2014; EXPIRATION DATE 28-NOV-2017. (B)(4). FINAL ASSESSMENT FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED

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AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING AND BENT TIP IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE (BREAKAGE) IN THE CONTEXT OF A COMPLICATED INSERTION. THE AE CASE REFERS ALSO TO A DEVICE USE ERROR. NO MEDICAL EVENTS WERE REPORTED. A REVIEW OF SIMILAR CASES FOR THIS BATCH IS NOT APPLICABLE AS NO MEDICAL EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP TO A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4) AND HAD ESSURE INSERTED. IT WAS REPORTED THAT ON DEVICE INTRODUCTION, ESSURE IMPLANT EXTREMITY WAS BENT (DEVICE USE ERROR) AND THERE WAS PRESENCE OF METALLIC FRAGMENT IN PATIENT'S UTERUS (SEEN AS DEVICE BREAKAGE). DEVICE BREAKAGE IS A NON-SERIOUS EVENT AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION, A CAUSAL RELATIONSHIP CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP TO A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015: NO FURTHER INFORMATION WAS PROVIDED DESPITE FOLLOW UP ATTEMPTS. CASE CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01211	BAYER HEALTHCARE LLC	10/21/2015	10/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D31449

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A SURGEON, GENERAL SURGERY IN (B)(6) ON 25-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER D31449. THE PHYSICIAN REPORTED THAT DURING THE INSERTION PROCEDURE, IN THE OPERATING ROOM AND THE PATIENT WITH A LARYNGEAL MASK, PARTIAL RETRACTION OF THE SHEATH AND NO RELEASE OF THE ESSURE DEVICE OCCURRED. A PIECE OF METAL REMAINED IN THE PATIENT'S OSTIUM. THE COMPLETE ESSURE SYSTEM WAS KEPT. THE PHYSICIAN REPORTED THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. BILATERAL PLACEMENT WAS NOT PERFORMED BECAUSE ESSURE PROCEDURE WAS STOPPED. THE POSTOPERATIVE COURSE REPORTED WAS POSSIBLE UNILATERAL RESIDUAL PERMEABILITY WHICH REQUIRED CELIOSCOPY. FOLLOW UP INFORMATION RECEIVED ON 19-OCT-2015: (B)(4). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS:(B)(4). FINAL ASSESSMENT FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A

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GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER BREAKING AND DETACHMENT DIFFICULTY EVENT IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WICK INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE (BREAKAGE) IN THE CONTEXT OF A COMPLICATED INSERTION. NO MEDICAL EVENT(S) WERE REPORTED. A REVIEW OF SIMILAR CASES FOR THIS BATCH IS NOT APPLICABLE AS NO MEDICAL EVENT(S) WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP TO A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A PIECE OF METAL REMAINED IN THE OSTIUM DURING INSERTION PROCEDURE. BILATERAL PLACEMENT WAS NOT PERFORMED BECAUSE ESSURE PROCEDURE WAS STOPPED. THE EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT ANALYSIS, THE POSSIBILITY OF THE CATHETER BREAKING IS AN ANTICIPATED EVENT. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED. NO SAMPLE WAS PROVIDED BUT A REVIEW OF THE MANUFACTURING BATCH RECORD CONFIRMED THAT LOT MET ALL RELEASE REQUIREMENTS. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: FOLLOW-UP ATTEMPTS HAVE BEEN MADE WITH NO RESPONSE TO DATE. DEVICE SIMILAR CASE LISTING: THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057494	BAYER	10/21/2015	10/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 664658

Single Use: *
Implant Date (E6): 12/2/2009
Explant Date (E7): 8/13/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL DEVICE IMPLANTED IN (B)(6) 2009 AFTER I FOUND OUT MY MOTHERS BREAST CANCER WAS DUE TO ESTROGEN THERAPY AND I WAS ADVISED THAT I SHOULD FIND AN ALTERNATIVE TO HORMONAL BIRTH CONTROL. I WAS NOT INFORMED OF ANY POSSIBLE SIDE EFFECTS AND WAS NOT INFORMED THAT THE DEVICE WAS NICKEL BASED TO WHICH I HAVE A SENSITIVITY TO. DAYS AFTER THE PROCEDURE I WENT TO THE ER BECAUSE I WAS EXPERIENCING SHORTNESS OF BREATH. THEY COULD NOT FIND A CAUSE AND I EVENTUALLY DISSIPATED. IN THE MONTH AND YEARS FOLLOWING THE PROCEDURE I EXPERIENCED BURNING PAIN IN MY HIPS, ABDOMINAL PAIN TO THE POINT I THOUGHT I WAS HAVING GALL BLADDER OR APPENDIX ISSUES, PAIN DURING INTERCOURSE, SEVER RASH/ECZEMA ON MY SCALP AND NECK AND HAIR LOSS. MY PERIODS ALSO GOT PROGRESSIVELY HEAVIER AND MORE FREQUENT TO THE POINT WHERE I WAS HAVING IT EVERY OTHER WEEK TO TWO WEEKS AND WAS LASTING UP TO TWO WEEKS WITH SEVER CRAMPS AND HEAVY BLEEDING TO THE POINT WHERE I WAS UNABLE TO GO TO WORK ON NUMEROUS OCCASIONS. MY DOCTOR DENIED THIS WAS CAUSED BY THE IMPLANTS BUT I ULTIMATELY CHOSE TO HAVE A PARTIAL HYSTERECTOMY ((B)(6) 2013) TO REMOVE MY UTERUS AND FALLOPIAN TUBES TO REMOVE THE DEVICES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057561	BAYER	10/21/2015	10/30/2015

Event Information:

Event Date (B3): 1/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PUT IN ON (B)(6) 2015. NOT EVEN 24 HOURS LATER I ALREADY STARTED GETTING SIDE EFFECTS. EVER SINCE THAT VERY FIRST DAY OF YOUR PRODUCT, I HAVE BEEN EXPERIENCING BAD SYMPTOMS AND SIDE EFFECTS. I WAS NOT TOLD OR KNEW ANYTHING ABOUT ESSURE HAVING NICKEL IN IT. HOW BECAUSE OF THIS PROBLEM, I HAVE BEEN IN PAIN IN PLACES I NEVER HAD PAIN BEFORE AND I HAVE BEEN VERY MISERABLE, AND BECAUSE OF THIS, MYSELF AND MY FAMILY HAVE BEEN SUFFERING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057562	BAYER	10/21/2015	10/30/2015

Event Information:

Event Date (B3): 11/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HELLO MY NAME IS (B)(6). I AM (B)(6), A MOTHER OF TWO CHILDREN AGED (B)(6). IN 2020 I HAD THE ESSURE IMPLANTED. I WANTED A BIRTH CONTROL THAT DIDN'T TAKE TOO MUCH HEALING TIME. IT SEEMED TO BE OK AT FIRST, UNTIL I STARTED HAVING SEVERE LOWER BACK PAIN. I WENT TO THE DOCTOR WHO REFERRED ME TO A BONE AND JOINT SPECIALIST. I HAD AN X-RAY AND MRI TAKEN NOTHING WAS FOUND BUT A LITTLE ARTHRITIS. I CAME ACROSS A (B)(6) WEB PAGE ESSURE PROBLEMS. I REALIZED I HAVE MANY SYMPTOMS SUCH AS: MIGRAINES THAT I HAVE BEEN PUT ON TOPAMAX FOR, SEVERE LOWER BACK PAIN, I CAN'T SLEEP AT NIGHT, TOSSING AND TURNING FROM PAIN FOR THE PAST 4 YEARS. SINCE THEN I HAVE HAD TWO SURGERIES, GALLBLADDER WAS REMOVED AND APPENDIX, NEVER HAD A PROBLEM BEFORE. SEVERE MENSTRUAL CRAMPS AND EXCESSIVE BLEEDING. I'M ALWAYS TIRED AND NO APPETITE ALL; ALL THIS BELIEVE IS FROM THIS DEVICE. I NEVER HAD A NICKEL ALLERGY TEST DONE BEFORE THIS DEVICE WAS IMPLANTED. I NEVER RECEIVED THAT CARD EITHER. I REALLY FEEL THAT THIS DEVICE SHOULD BE BANNED. I LIVE IN (B)(6). PROCEDURE WAS DONE AT (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057565	CONCEPTUS INC.	10/21/2015	10/30/2015

Event Information:

Event Date (B3): 11/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): B53035

Single Use: *
Implant Date (E6): 11/7/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANT FOR CONTRACEPTION IN (B)(6) 2013. I HAVE NOTICED INEXPLICABLE SHARP PAIN IN MY LOWER ABDOMINAL AREA. IT SUBSIDES AFTER A FEW MINUTES, BUT IT DOES STARTLE ME. I WANT TO MAKE SURE THAT I HAVE NOT PUT SOMETHING IN MY BODY THAT CAN CAUSE ME GREAT HARM IN THE FUTURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057566	BAYER	10/21/2015	10/30/2015

Event Information:

Event Date (B3): 10/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/15/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACED IN MY BODY IN (B)(6) 2014. THE FIRST YEAR I DID NOT EXPERIENCE ANY SYMPTOMS. IT HAS BEEN A YEAR NOW AND I AM HAVING MULTIPLE UTI'S AND HAVE HAD AN UNEXPLAINED RASH.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01212	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7): 8/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 24-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012 FOR PERMANENT CONTRACEPTION. THE CONSUMER HAD AN ECTOPIC PREGNANCY A YEAR AND A HALF POST INSERTION. HYSTERECTOMY WAS PERFORMED ON (B)(6) 2015 AND ESSURE WAS REMOVED ALONG WITH FIBROIDS AND ENDOMETRIOSIS SCAR TISSUE NEAR OVARIES. OVARIES WERE STILL IN PLACE. ONCE ESSURE WAS REMOVED, SHE FELT LIKE A BRAND NEW LADY. SHE WAS OKAY WITH NO MORE LOWER BACK PAIN, BUT SHE WAS STILL HAVING PROBLEM WITH BOWEL MOVEMENTS AND COULD NOT DO ANYTHING WITHOUT HELP. PTC INVESTIGATION RESULT RECEIVED ON 13-OCT-2015 : PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED AN UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) OR THE LACK OF EFFICACY EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED

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FOR PERMANENT CONTRACEPTION AND A YEAR AND HALF POST INSERTION SHE HAD AN ECTOPIC PREGNANCY. APPROXIMATELY A YEAR LATER SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE ALONG WITH FIBROIDS, ENDOMETRIOSIS SCAR TISSUE. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. IN THIS PARTICULAR CASE, ALTHOUGH NO INFORMATION REGARDING ESSURE LOCALIZATION WAS PROVIDED, SINCE THE PREGNANCY OCCURRED 1 AND A HALF YEAR AFTER INSERTION, A DEVICE INEFFICACY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE THE ECTOPIC PREGNANCY IS A SERIOUS INJURY THAT PROBABLY REQUIRED A MEDICAL/SURGICAL INTERVENTION. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE LACK OF EFFICACY AND REPORTED EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. FOLLOW UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 04-JAN-2016: DESPITE FOLLOW-UP ATTEMPTS, NO RESPONSE WAS GIVEN TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01214	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) YEAR-OLD FEMALE CONSUMER IN THE UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ABOUT 4-5 MONTHS AGO FROM TIME OF THIS REPORT. CONSUMER REPORTED SHE HAS BEEN BLEEDING SINCE ESSURE INSERTED AND SHE NEVER EXPERIENCED THIS BEFORE. SHE WAS PASSING LARGE CLOTS AND HAD BEEN TO THE EMERGENCY ROOM MANY TIMES DUE TO BLEEDING. SHE HAD RECEIVED BLOOD TRANSFUSIONS DUE TO THIS BLEEDING. SHE STATED THAT WAS UNBELIEVABLE THE THINGS WERE COMING OF HER VAGINA THE MORNING OF THE REPORT. SHE ALSO REPORTED IT WAS TEARING HER INSIDES UP, SHE HAD PELVIC PAIN AND HAIR WAS COMING OUT AND THAT WAS SAD. THE CONSUMER STATED SHE WAS ONLY (B)(6) AND MIGHT NEED A HYSTERECTOMY. SHE STATED SHE MIGHT CONTACT A LAWYER. THE DAY OF THIS REPORT SHE WAS IN EMERGENCY ROOM AS SHE WAS SPEAKING ON PHONE. SHE WANTED IT OUT. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY

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DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6) YEAR-OLD FEMALE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BEEN BLEEDING SINCE INSERTION (INTERPRETED AS GENITAL BLEEDING). SHE HAD RECEIVED BLOOD TRANSFUSIONS DUE TO THAT BLEEDING. SHE STATED SHE MIGHT NEED A HYSTERECTOMY. SHE WANTED THE ESSURE INSERTS OUT. THE GENITAL BLEEDING IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT THIS GENITAL BLEEDING STARTED SINCE ESSURE WAS INSERTED AND THAT THERE IS NO ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE IT REQUIRED AN INTERVENTION. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

29-DEC-2015: CASE CLOSED.

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01215	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C59250

Single Use: Y
Implant Date (E6): 9/25/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6)-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2015. PATIENT WAS IN THE O.R. (OPERATING ROOM) AT TIME OF THE REPORT, ON (B)(6)-2015, AND ESSURE COIL DEPLOYED COIL AND IT MISFIRED. DURING THE PROCEDURE, PART OF SHEATH GOT STUCK DURING DEPLOYMENT BECAUSE PLASTIC SHEATH DID NOT COME OFF WHEN COIL DEPLOYED. MOST OF COILS WERE VISIBLE. THE PHYSICIAN CUT THE COIL AND WAS NOT ABLE TO REMOVE SMALL PIECE OF COIL STILL IN PATIENT, THE SPRING WAS HALF IN AND HALF OUT. THE PHYSICIAN COULD NOT GET CUT PIECE OF COIL OUT OF PATIENT, HE STATED THAT IT IS A LITTLE BIT OF THE COIL. IT WAS REPORTED THAT DOCTOR GOT MOST OF IT OUT BUT THE TIP WAS STUCK IN THE FALLOPIAN TUBE, AND THE COIL WAS BROKEN. FOLLOW-UP INFORMATION RECEIVED ON 05-OCT-2015 WITH ADDITIONAL INFORMATION ON 07-OCT-2015: DURING ESSURE INSERTION, ONLY HALF OF THE COIL ENTERED THE PATIENT'S FALLOPIAN TUBE AND THE OTHER HALF BROKE OFF. THE CALLER STATED THAT THE HALF THAT ENTERED THE FALLOPIAN TUBE HAS BEEN LEFT INSIDE THE PATIENT. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT - PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF

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THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICROINSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE IN THE CONTEXT OF A COMPLICATED INSERTION. THE CASE AE CASE REFERS ALSO TO A DEVICE MISUSE (PHYSICIAN CUT THE COIL). HOWEVER, NO MEDICAL EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. AT THIS POINT IN TIME NO MEDICAL EVENTS HAVE BEEN REPORTED, THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE COIL WAS BROKEN. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND ANTICIPATED ACCORDING TO THE TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, DURING INSERTION PROCEDURE PART OF SHEATH GOT STUCK DURING DEPLOYMENT BECAUSE PLASTIC SHEATH DID NOT COME OFF WHEN COIL DEPLOYED. THE PHYSICIAN STATED THAT HE CUT THE COIL AND WAS NOT ABLE TO REMOVE SMALL PIECE OF COIL STILL IN PATIENT, BUT ALSO MENTIONED THAT THE TIP WAS STUCK IN THE FALLOPIAN TUBE, AND THE COIL WAS BROKEN. SINCE THESE EVENTS OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 27-OCT-2015: PATIENT WAS (B)(6). ON (B)(6) 2015 SHE HAD ESSURE INSERTED, LOT NUMBER C59250. IT WAS REPORTED THAT UPON DEPLOYMENT OF THE DEVICE BY THE PHYSICIAN ONLY HALF OF THE COIL ENTERED THE FALLOPIAN TUBE, THE REMAINI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01216	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY IN (B)(6) ON 25-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 FOR STERILIZATION. CONSUMER REPORTED THAT AFTER INSERTION SHE HAD A LOT OF COMPLAINTS, SUCH AS: LOW BACK COMPLAINTS, COULD NOT COME OUT OF BED ANYMORE, AND COULD NOT LAY STRAIGHT, HEAVY MENSTRUATION, VAGINAL FUNGAL INFECTIONS AND INTESTINAL COMPLAINTS. SHE ALSO REPORTED THE ESSURE INSERTION WAS PAINFUL. SHE HAD A LOT OF THERAPY: MANUAL THERAPY AND PHYSIOTHERAPY. IN (B)(6) 2015, THE COILS WERE REMOVED AND CONSUMER HAD NO MORE BACK COMPLAINTS, A NORMAL MENSTRUATION AND NO FUNGAL INFECTIONS ANYMORE. CONSUMER FELT VERY GOOD. CONSUMER MENTIONED THAT SHE HAS A NICKEL ALLERGY AND WAS NOT INFORMED THAT THERE WAS NICKEL PROCESSED IN ESSURE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO

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RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 09-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: BACK PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LOW BACK COMPLAINTS (SHE COULD NOT COME OUT OF BED ANYMORE AND COULD NOT LIE STRAIGHT). THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THE EVENT AFTER ESSURE INSERTION. THE COILS WERE REMOVED AND SHE RECOVERED FROM HER BACK COMPLAINTS. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01217	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): 8/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/8/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA REGULATORY AUTHORITY IN (B)(6) ON 25-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. SHE REPORTED THAT ON (B)(6) 2014 SHE HAD TO BE OPERATED ACUTE FOR LEFT OVARIAN ABSCESS; HER LEFT OVARY HAS BEEN REMOVED. SHE REPORTED THE COILS WERE STILL IN FALLOPIAN TUBES AND SHE STILL HAS HEALTH COMPLAINTS, SHE WAS VERY TIRED AND THEN AND CONDITION IS NOT ON THE SAME LEVEL AS PRIOR TO STERILIZATION. THE CONSUMER INDICATED THAT NOBODY WAS ABLE TO CONFIRM A CAUSAL RELATION BETWEEN ESSURE AND THE ABSCESS. SHE ALSO MENTIONED THAT THE STERILIZATION WITH ESSURE WAS NOT SUCCESSFUL. SHE STATED THAT THE HOSPITAL HAS PUBLISHED ABOUT THIS AS THEY COULD NOT EXPLAIN THIS AS WELL AND THAT SHE WAS STILL CHECKED BY THE HOSPITAL. SHE STATED THAT SHE WAS IN CONSULTATION WITH A DERMATOLOGIST, WILL HAVE A NICKEL ALLERGY TEST IN (B)(6). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY

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DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 09-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM:OVARIAN ABSCESS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASE. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABCESS LEFT OVARIA. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PYOSALPINX, ALSO REFERRED AS TUBOOVARIAN ABSCESS, IS AN INFLAMMATORY MASS INVOLVING THE FALLOPIAN TUBE, OVARY, AND, OCCASIONALLY, OTHER ADJACENT PELVIC ORGANS. THESE ABSCESSES TYPICALLY RESULT FROM UPPER GENITAL TRACT INFECTION (COMPLICATION OF PELVIC INFLAMMATORY DISEASE). WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS PARTICULAR CASE, CONSUMER EXPERIENCED THIS EVENT ABOUT 1 MONTH AFTER ESSURE INSERTION. SHE HAD TO BE OPERATED AND HER LEFT OVARY WAS REMOVED. GIVEN PYOSALPINX PHYSIOPATHOLOGY AND THE CLOSE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01218	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA REGULATORY AUTHORITY IN (B)(4) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. SHE REPORTED SERIOUS COMPLAINTS SUBSEQUENTLY DEVELOPED: SEVERE ABDOMINAL PAIN, BLEEDINGS AND ALLERGIC REACTIONS. THE CONSUMER INDICATED THAT SHE HAS NICKEL ALLERGY. BECAUSE OF THE INTENSE PAIN AND BLEEDING, A PART OF THE CERVIX WAS BURNED AWAY. THIS DID NOT TAKE AWAY HER COMPLAINTS. THE GYNECOLOGIST ADVISED TO REMOVE THE OVARIES/UTERUS, WHICH WILL CAUSE PATIENT TO ENTER MENOPAUSE AND SO SHE AGREED WITH GYNECOLOGIST TO PERFORM THIS SURGERY AFTER THE AGE OF (B)(6). THE CONSUMER IS FIBROMYALGIA PATIENT, AND REPORTED THAT SHE ALWAYS KEPT FEELING THE ESSURE; IT WAS A CONTINUOUS DRAGGING SENSATION AND SOMETIMES IT WAS PAINFUL. THE CONSUMER HAS NICKEL ALLERGY AND HYPERACTIVE MUCOUS MEMBRANES. SHE ALSO DEVELOPED HAY FEVER AND ECZEMA. AFTER 2,5 YEARS, THE PATIENT FLUXED 6 MONTHS IN A ROW AND IN (B)(6) 2011, THE CERVIX WAS BURNT SHUT (NOVASURE PROCEDURE). AFTER ALMOST A YEAR LATER, THE BLEEDING STARTED AGAIN. AT TIME OF THE REPORT, THE PATIENT BLED VERY IRREGULARLY (NOT THE LARGE VOLUMES OF BLOOD ANYMORE), AND DESCRIBED THIS AS PSYCHOLOGICALLY STRESSFUL. FOR THIS REASON, PATIENT MADE AN APPOINTMENT WITH GYNECOLOGIST. SHE HAS DEVELOPED A NUMBER OF NEW ALLERGIES; IT WAS UNKNOWN WHETHER THIS IS CAUSED BY ESSURE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 09-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1. ABDOMINAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. 2. MENOMETRORRHAGIA. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. 3. GENITAL HAEMORRHAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE ABDOMINAL PAIN AND BLEEDINGS AND BECAUSE OF THESE EVENTS, A PART OF THE CERVIX WAS BURNED AWAY. AFTER 2,5 YEARS, SHE EXPERIENCED FLUX 6 MONTHS IN A ROW AND HER CERVIX WAS BURNT SHUT. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE PHYSICIAN ADVISED TO REMOVE THE OVARIES/UTERUS AFTER THE AGE OF (B)(4). BASED ON THE NATURE OF THE EVENTS AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. HEALTH AUTHORITY CONSIDERED THIS CASE AS INCIDENT. IN LINE WITH HEALTH AUTHORITY'S ASSESSMENT, COMPANY AGREES WITH THIS ASSESSMENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01219	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/2/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA REGULATORY AUTHORITY IN (B)(6) ON 25-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2012 FOR STERILIZATION. THE CONSUMER MENTIONED THAT SHE INFORMED BEFORE THAT SHE HAS A NICKEL ALLERGY, BUT THE GYNECOLOGIST INDICATED THAT THIS WOULD NOT BE A PROBLEM. SHE MENTIONED THAT THE RIGHT OVIDUCT WAS ADHERED IN SUCH A WAY THAT THE INSERTION WAS VERY PAINFUL. AFTER ESSURE INSERTION SHE DEVELOPED A LOT OF COMPLAINTS AMONG OTHER THINGS: ADHESIONS, ABDOMINAL COMPLAINTS (ABDOMINAL PAIN), AND ECZEMA. EVENTUALLY A COLLEAGUE GYNECOLOGIST WAS CALLED WHO PERFORMED A LAPAROSCOPY AND DETERMINED THAT THE OVIDUCTS WERE NOT GOOD ANYMORE DUE TO INFLAMMATIONS AND THAT THE CONSUMER HAD ENDOMETRIOSIS; SUBSEQUENTLY THE UTERUS AND 1 OVIDUCT WERE REMOVED ON (B)(6) (YEAR NOT PROVIDED). THE CONSUMER MENTIONED THAT HER SKIN HAS RECOVERED AND THE SUBCUTANEOUS ITCH WAS GONE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY

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DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 09-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ABDOMINAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 367 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN AND INFLAMMATIONS IN OVIDUCTS. HER UTERUS AND 1 OVIDUCT WERE REMOVED. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS CASE, IT WAS NOT REPORTED WHETHER INFLAMMATIONS IN OVIDUCTS OCCURRED UP TO 4 WEEKS POST INSERTION. THEREFORE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE ASSESSED AT THIS TIME. WITH REGARDS TO THE OTHER EVENT, BASED ON ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01220	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 9/4/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA REGULATORY AUTHORITY IN (B)(6) ON 25-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER REPORTED THAT SINCE (B)(6) 2009 PATIENT HAS INEXPLICABLE COMPLAINTS, WHICH GOT WORSE OVER TIME. THE COMPLAINTS STARTED ABOUT HALF A YEAR FOLLOWING INSERTION OF ESSURE. THE CONSUMER CONSULTED AMONGST OTHERS GENERAL PRACTITIONER, NEUROLOGIST, SPECIALIST INTERNAL MEDICINE, GYNECOLOGIST, DERMATOLOGIST AND PHYSIOTHERAPIST, BUT THESE CARE PROVIDERS COULD NOT DIAGNOSE THE ORIGIN OF THE COMPLAINTS. THE CONSUMER BECAME MORE AND MORE WHEELCHAIR / WALKER / CRUTCHES DEPENDENT AND WAS NOT ABLE TO / WAS NOT ALLOWED TO DRIVE A CAR ANYMORE. SHE WAS NOT WORKING ANYMORE FOR 6 YEARS. SHE RECOGNIZED THE COMPLAINTS WHICH WERE MENTIONED IN THE TELECAST ON (B)(6) 2015; SHE ALSO HAD COMPLAINTS OF HAIR LOSS AND DENTAL PROBLEMS. SHE FINALLY DECIDED TO HAVE THE ESSURE REMOVED AND ON (B)(6) 2015 ESSURE COILS AND FALLOPIAN TUBES HAVE BEEN REMOVED. A WEEK AFTER THE SURGERY SHE NOTICED A DECREASE IN PAIN IN TAIL BONE, LESS STINGS IN LEGS AND NO MORE WADDLING WALKING. THE CONSUMER IS CONVINCED THAT HER COMPLAINTS WERE CAUSED BY ESSURE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 09-OCT-2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 09-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PAIN IN EXTREMITY. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED STINGS IN LEGS. SHE BECAME MORE AND MORE WHEELCHAIR / WALKER / CRUTCHES DEPENDENT AND WAS NOT ABLE TO / WAS NOT ALLOWED TO DRIVE A CAR ANYMORE. SHE WAS NOT WORKING ANYMORE FOR 6 YEARS. SHE HAD ESSURE COILS AND FALLOPIAN TUBES REMOVED. A WEEK AFTER THE SURGERY SHE NOTICED A DECREASE IN STINGS IN LEGS AND NO MORE WADDLING WALKING. STINGS IN LEGS IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE WADDLING WALKING IS UNLISTED. BOTH ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, CONSUMER CONSULTED MANY CARE PROVIDERS BUT THEY COULD NOT DIAGNOSE THE ORIGIN OF THE COMPLAINTS. CONSIDERING THAT PAIN IN LEGS MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, CONSIDERING THAT THE EXACT CAUSE WAS NOT REPORTED AND THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01221	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT (>=18Y & <65Y) FEMALE CONSUMER VIA REGULATORY AUTHORITY IN (B)(6) ON (B)(6)-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 FOR STERILIZATION. THE CONSUMER REPORTED THE TREATMENT ITSELF WENT WITHOUT PROBLEMS. ONLY AFTER A YEAR OR 2 HER COMPLAINTS OCCURRED: CONSUMER HAD LONGER MENSTRUATIONS, HAD MORE BLOOD LOSS, LOWER BACK PAINS, STINGS LOWER ABDOMEN, BLOATED FEELING AND AN ABDOMEN WHICH BECAME THICKER (WITHOUT WEIGHT GAIN). AFTER HALF A YEAR CONSUMER WAS MENSTRUATING 2 TO 3 WEEKS A MONTH WITH PERIODS OF HEAVY BLOOD LOSS. THE CONSUMER WAS EVENTUALLY REFERRED TO GYNECOLOGIST BY GENERAL PRACTITIONER, WHO SUGGESTED THE NOVASURE PROCEDURE. AFTER THIS CONSUMER STILL EXPERIENCED BLOOD LOSS AND SEVERE PAINS, DUE TO WHICH IT WAS DECIDED TO REMOVE THE UTERUS AND CERVIX IN THE END OF 2014. AFTER THE SURGERY, THE CONSUMER WAS FREE FROM THE COMPLAINTS FOR SOME TIME UNTIL SHE EXPERIENCED NAGGING PAIN LOWER ABDOMEN AND BACK. SHE WENT TO THE GENERAL PRACTITIONER IN THE FIRST WEEK OF (B)(6) FOR A REFERRAL TO GYNECOLOGIST. (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE

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TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 09-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERMS: 1. BACK PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. 2. MENORRHAGIA. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. 3. ABDOMINAL PAIN LOWER. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THESE MEDDRA PTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LONGER MENSTRUATION / MORE BLOOD LOSS, LOWER BACK PAINS AND STINGS LOWER ABDOMEN. SHE HAD HER UTERUS AND CERVIX REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THESE EVENTS A YEAR OR 2 AFTER INSERTION. CONSIDERING THE NATURE OF THESE EVENTS AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01222	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/10/2015
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA REGULATORY AUTHORITY IN (B)(6) ON 25-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. IN THE FIRST TWO WEEKS AFTER INSERTION THERE WERE VARIOUS COMPLAINTS: BACK PAIN, DECREASED APPETITE, PIMPS IN FACE. THE PATIENT STATED SHE HAD KNOWN NICKEL ALLERGY, BUT ACCORDING TO THE GYNECOLOGIST, ESSURE DID NOT CONTAIN ANY NICKEL. ON (B)(6) 2015 ESSURE (INCLUDING FALLOPIAN TUBES) WAS REMOVED BY KEYHOLE SURGERY, WHICH WENT WELL. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN

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MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 09-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: BACK PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BACK PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT IN THE FIRST TWO WEEKS AFTER ESSURE INSERTION. CONSUMER HAD ESSURE AND FALLOPIAN TUBES REMOVED BY KEYHOLE SURGERY. CONSIDERING THE NATURE OF THE EVENT AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP WITH SUSPECT INSERT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01223	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA REGULATORY AUTHORITY IN (B)(6) ON 25-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER'S MEDICAL HISTORY INCLUDED HEAVY BLEEDING AND MUCH PAIN (DURING PERIODS). THE CONSUMER UNDERWENT ESSURE STERILIZATION AND THE FLOWING AND THE CRAMPS DECREASED. HOWEVER, IN 2012 THE COMPLAINTS INCREASED AGAIN. THE GYNECOLOGIST LIGHTLY STRETCHED THE UTERUS IN ORDER TO MAKE MORE SPACE FOR THE PASSAGE TO THE VAGINA SO THAT FLUIDS COULD MOVE AWAY MORE EASILY. SINCE (B)(6) 2015, THE COMPLAINTS INTENSIFIED AGAIN: ABDOMINAL PAIN, LOWER BACK PAIN, CONTRACTIONS, BACK CONTRACTIONS, NAUSEA, UNREST, FATIGUE, DIZZINESS AND YEAST INFECTIONS ALTERNATE. AN ECHOGRAPHY WAS PERFORMED, BUT IT CLEAR. THE CONSUMER RECEIVED MEDICATION FOR THE PAIN AND ENDED UP IN A HOSPITAL. THE GYNECOLOGIST DIAGNOSED PATIENT WITH ADENOMYOSIS, IN WHICH THE MUCOUS MEMBRANE OF THE UTERUS GROWS INTO THE MUSCLE LAYER OF THE UTERUS. THE GYNECOLOGIST ALSO OBSERVED FLUID IN THE UTERUS, WHICH HAD NOWHERE TO GO DUE TO THE ESSURE AND NOVASURE PROCEDURES. THEY ALLOWED FOR THE COMPLAINTS TO GET WORSE. A SURGERY TO REMOVE THE UTERUS AND FALLOPIAN TUBES WAS PLANNED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-OCT-2015. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 09-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ABDOMINAL PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 367 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, A SURGERY TO REMOVE THE UTERUS AND FALLOPIAN TUBES WAS PLANNED. BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01224	BAYER HEALTHCARE LLC	10/22/2015	10/22/2015

Event Information:

Event Date (B3): 9/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/30/2009
Explant Date (E7): 9/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 25-SEP-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 FOR PERMANENT CONTRACEPTION. THE PHYSICIAN REPORTED PATIENT NEVER HAD HSG (HYSTEROSALPINGOGRAM) TEST DONE. SHE CAME INTO HIS OFFICE ON (B)(6) 2011 FOR A PREGNANCY POSITIVE TEST. ON (B)(6) 2015, THE PHYSICIAN DID A SALPINGECTOMY ON PATIENT AND FOUND ONE COIL ON ONE SIDE AND NONE ON THE OTHER SIDE; ESSURE WAS REMOVED. FOLLOW-UP INFORMATION RECEIVED ON 29-SEP-2015: THE PATIENT HAD A TERM PREGNANCY ON 16-AUG-2015 (DATE OF PREGNANCY TEST PREVIOUSLY REPORTED IS DISCREPANT). THE PATIENT ALSO HAD A PREVIOUS ECTOPIC PREGNANCY ON (B)(6) 2013 ((B)(4)). FOLLOW-UP INFORMATION RECEIVED ON 01-OCT-2015. THE PATIENT'S DATE OF BIRTH WAS UPDATED. IT WAS CONFIRMED THAT PATIENT NEVER DID A HSG AT ANY TIME. IT WAS REPORTED THAT THE INFORMATION ABOUT SHE WENT TO THE OFFICE FOR A POSITIVE PREGNANCY TEST ON (B)(6) 2011 WAS INCORRECT. SHE HAD AN ECTOPIC PREGNANCY ON (B)(6) 2013 ((B)(4)) AND A TERM PREGNANCY ON (B)(6) 2015. REPORTER SAID THAT HE DID NOT KNOW IF PATIENT HAD A BABY ON (B)(6) 2015 (PREGNANCY OUTCOME WAS CHANGED TO UNKNOWN). FOLLOW-UP INFORMATION RECEIVED ON 12-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. FOLLOW UP 09-OCT-2015: THE DOCTOR MENTIONED THAT WAS LOOKING FOR THE DATA OF THIS PATIENT. NO NEW INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IT WAS REPORTED THAT SHE NEVER HAD HSG (HYSTEROSALPINGOGRAM) TEST DONE (TREATMENT NON COMPLIANCE). SHE HAD A TERM PREGNANCY. A SALPINGECTOMY WAS PERFORMED AND IT WAS FOUND ONE COIL ON ONE SIDE AND NONE ON OTHER SIDE (INTERPRETED AS DEVICE DISLOCATION) AND ESSURE WAS REMOVED. ALL EVENTS, EXCEPT TREATMENT NON COMPLIANCE, ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, THE PATIENT DID NOT PERFORM THE ESSURE CONFIRMATION TEST AND BECAME PREGNANT WITH THE INSERT. MOREOVER, NO MEDICAL REASON FOR SALPINGECTOMY PROCEDURE WAS PROVIDED, HOWEVER THIS PROCEDURE RESULTED IN ESSURE REMOVAL. THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN. CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 19-OCT-2015: PHYSICIAN CONFIRMED THAT PATIENT DID EXPERIENCE A POSITIVE PREGNANCY TEST IN (B)(6) 2011, ECTOPIC PREGNANCY IN (B)(6) 2013 AND A TERM PREGNANCY THAT SHE DELIVERED IN (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS MEDICALLY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01213	BAYER HEALTHCARE LLC	10/23/2015	10/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN THE UNITED STATES ON 24-SEP-2015 WHICH REFERS TO ANOTHER FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED HER SISTER HAD ESSURE AND HAD TO HAVE A TUBAL. CASE CONSIDERED POTENTIAL LEGAL CASE SINCE REPORTER STATED SHE MIGHT CONTACT A LAWYER. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 09-OCT-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE A TUBAL (TUBAL LIGATION). CONSUMER MIGHT CONTACT A LAWYER (POTENTIAL LEGAL CASE). THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO THE REFERENCE SAFETY

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INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. SINCE THE EXACT REASON FOR THE PROCEDURE WAS NOT SPECIFIED AND IT WAS UNKNOWN WHETHER SERIOUS INJURY OCCURRED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION, THIS CASE WAS CONSIDERED AN INCIDENT. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01226	BAYER HEALTHCARE LLC	10/23/2015	10/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA NEWS JOURNAL IN UNITED STATES ON (B)(6) 2015 REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THE PATIENT HAD GENERALIZED RASH UNRESPONSIVE TO STEROIDS THAT BEGAN IMPROVING WITHIN THREE DAYS OF THE DEVICES REMOVAL. PTC INVESTIGATION RESULT WAS RECEIVED ON (B)(6) 2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED GENERALIZED RASH UNRESPONSIVE TO STEROIDS. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY.

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ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS CASE, SHE STARTED RECOVERING FROM THIS EVENT WITHIN THREE DAYS OF THE DEVICE REMOVAL. CONSIDERING THIS INFORMATION AND BASED ON THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057507	BAYER	10/23/2015	10/29/2015

Event Information:

Event Date (B3): 10/23/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): C59254

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

BAYER ESSURE PERMANENT BIRTH CONTROL DEVICE DISCOVERED TO BE DEFECTIVE RIGHT OUT OF THE BOX. ESSURE REPRESENTATIVE A.B. PRESENT AND CONFIRMED DEFECTIVE DEVICE. ANOTHER ESSURE DEVICE WAS UTILIZED. DIAGNOSIS OR REASON FOR USE: ELECTIVE STERILIZATION. EVENT REAPPEARED AFTER REINTRODUCTION: YES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057538	BAYER	10/23/2015	10/29/2015

Event Information:

Event Date (B3): 8/26/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): UNK
Catalog # (E4): UNK
Lot #(E4): UNK

Single Use: *
Implant Date (E6): 8/26/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2010. THIS IS MANUFACTURED BY BAYER, FORMALLY CONCEPTUS INC. THIS DEVICE HAS THREE YEAR SHELF LIFE, HOWEVER, I DO NOT HAVE THE EXPIRATION DATE. I WAS NEVER GIVEN AN ESSURE ID CARD WITH THE DEVICE NUMBERS. THE ONSET OF MY SIDE EFFECTS STARTED ON (B)(6) 2010. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE; 1.) MISPLACEMENT OF RIGHT COIL UPON IMPLEMENTATION, AND 2.) ABDOMINAL PAIN, ESPECIALLY DURING SEX, BOWEL MOVEMENTS, AND URINATION. I HAVE BEEN SEEN BY FIVE DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS; 1.)PELVIC PAIN, 2.) PELVIC MASS, 3.) DYSMENORRHEA, 4.) SENSITIVITY TO METAL. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01225	BAYER HEALTHCARE LLC	10/24/2015	10/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/31/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 23-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. AFTER ESSURE IMPLANTS INSERTION, ON ANCILLARY MATERIAL REMOVAL, IT WAS VISUALIZED ON SCREEN THAT A METALLIC FRAGMENT STAYED INTO TUBAL OSTIUM. NO CLINICAL CONSEQUENCES WERE OBSERVED, THE DEVICE STAYED INTO TUBAL OSTIUM AND NO SECOND SURGERY TO REMOVE THE METALLIC FRAGMENT WAS PLANNED. THE DEVICE WAS STORED AND PRE-DISINFECTED ACCORDING TO PROCEDURE APPLIED IN THE ESTABLISHMENT. FOLLOW-UP INFORMATION FROM 19-OCT-2015: NCA REFERENCE NUMBER ((B)(4)) WAS RECEIVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER ESSURE IMPLANTS INSERTION, IT WAS VISUALIZED ON SCREEN THAT A METALLIC FRAGMENT STAYED INTO TUBAL OSTIUM. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 03-DEC-2015: PTC GLOBAL NUMBER: (B)(4). LOT NUMBER: C68114. EXPIRATION DATE: 30-JUN-2017. DATE OF MFR: 16-JUN-2014. FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01227	BAYER HEALTHCARE LLC	10/24/2015	10/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT FROM A CONSUMER IN UNITED STATES WAS IDENTIFIED IN THE INTERNET ON (B)(6) 2013. THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATED THAT HER WHOLE LIFE REVOLVES AROUND THE PAIN, IT BECAME VERY DEBILITATING. SHE OPTED FOR HYSTERECTOMY. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL. THE CONSUMER STATED HER WHOLE LIFE REVOLVES AROUND THE PAIN, IT JUST BECAME VERY DEBILITATING (START DATE NOT REPORTED). CONSUMER SAID SAY SHE DID NOT HAVE THE PROBLEMS BEFORE ESSURE. CONSUMER OPTED FOR HYSTERECTOMY. CONSUMER HOPED THAT IN A MONTH SHE WOULD BE ON THE PATH TO BEING PAIN FREE. REPORTER CONSIDERED THE EVENT WAS RELATED TO THE ESSURE. NO FURTHER INFORMATION IS AVAILABLE. FOLLOW-UP INFORMATION ON 08-NOV-2013: THE CONSUMER STATED THAT SHE WAS PREPPING FOR SURGERY THAT MANY WOMEN HER AGE USUALLY DON'T HAVE TO CONSIDER FOR YEARS. SHE ALSO STATED THAT NEVER THOUGHT AT (B)(6) SHE WOULD HAVE EVERYTHING GONE, SHE SAID IT'S KIND OF LIKE HER WOMANHOOD WILL BE RIPPED OUT FROM HER. FOLLOW-UP INFORMATION WAS RECEIVED ON 04-DEC-2013: THE LOCAL HEALTH AUTHORITY WAS ADDED AS REPORTER WITH THE REFERENCE NUMBER MW5031830. ESSURE PROCEDURE TOOK PLACE AS OUTPATIENT SURGERY AT A MAJOR TEACHING HOSPITAL UNDER GENERAL ANESTHESIA. THE PROCEDURE WAS COMPLICATED DUE TO DEVICE FAILURE IN THE RIGHT TUBAL OSTIA, REQUIRING A SECOND ATTEMPT, WHICH WAS CONSIDERED SATISFACTORY. NO ADVERSE EVENT WAS FILED. THE PATIENT WAS IN PAIN ON THE RIGHT SIDE WHEN SHE WOKE UP, AND HAD BEEN EXPERIENCING VARYING DEGREES OF PAIN EVER SINCE. AT FIRST, SHE

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CONSIDERED AS "NUISANCE", BUT IT HAD BECOME SEVERE ENOUGH TO INTERFERE WITH HER DAILY LIFE. SHE HAD TO QUIT HER JOB DUE TO HER SYMPTOMS. IN ADDITION TO ABDOMINAL PAIN, SHE EXPERIENCED PAINFUL SEX, EXTREME FATIGUE, JOINT PAIN, AND RASHES SINCE THE PROCEDURE. IN THE LAST 10 MONTHS PRIOR TO THE REPORT, SHE HAD A CONSTANT LOW GRADE TEMPERATURE AND BOUTS OF ABDOMINAL SWELLING, LOSS OF APPETITE, BRAIN SHOCKS, AND SWOLLEN JOINTS IN HER FINGERS. SHE WENT FROM VISITING THE DOCTOR AN AVERAGE OF 2 TIMES PER YEAR, PRIOR TO HER PROCEDURE, TO 17 VISITS SINCE ESSURE WAS PLACED 2 YEARS PRIOR TO THIS REPORT. SHE HAD ALSO ENDURED MULTIPLE BLOOD WORK UPS, 4 ULTRASOUNDS, A CT (COMPUTED TOMOGRAPHY) SCAN, PELVIC X-RAY, A MONTH OF PHYSICAL THERAPY, A CORTISONE INJECTION, AN EXPLORATORY LAPAROSCOPY WHERE ADHESIONS WERE FOUND AND CUT, AND LUPRON TO RULE OUT ENDOMETRIOSIS. THE PRESENCE OF ADHESIONS HAD NO EXPLANATION SINCE SHE HAD NOT HAD ABDOMINAL SURGERY, PID (PELVIC INFLAMMATORY DISEASE) OR ANY OTHER COMMON CAUSE. HER PRIMARY CARE DOCTOR SUGGESTED A CORRELATION BETWEEN THE COILS AND HER ONGOING HEALTH PROGRAMS. HER PHYSICAL THERAPIST SUGGESTED A POSSIBLE FOREIGN BODY REACTION. AT THE TIME OF THIS REPORT SHE WAS UNDER THE CARE OF A GYNECOLOGIST AND IN THE PROCESS OF SCHEDULING A HYSTERECTOMY TO REMOVE THE COILS AND FIND RELIEF FROM INFLAMMATION AND SEVERE PAIN IN HER ABDOMEN/PELVIS AND HIPS. SHE STATED THAT SHE WAS NOT ABLE TO FULLY FUNCTION AS A WIFE, EMPLOYEE, HOMEMAKER OR MOTHER AND IT WAS AFFECTING HER MENTAL WELL BEING AS WELL. FOLLOW-UP RECEIVED ON 27-JAN-2014: PTC ASSESSMENT WAS PROVIDED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN (B)(4), PROCESSING ESSURE CASES IN DEV@COM. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT INDICATIVE FOR A QUALITY DEFECT PER SE. THE MEDICAL EVENTS WERE REPORTED WITH AN OCCURRENCE OVER A PERIOD OF 2 YEARS AND ARE OF BROAD NATURE. THE CASE REFERS ALSO TO A USABILITY ISSUE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. THE REPORTED USABILITY ISSUE WILL BE SUBJECT TO POST MARKET SURVEILLANCE MONITORING. FOLLOW UP INFORMATION RECEIVED ON 30-APR-2014: CONSUMER SCREEN NAME ADDED. NO OTHER INFORMATION PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 25-SEP-2015: THE CONSUMER REPORTED SHE ENDURE PHYSICAL PAIN AND MENTAL ANGUISH FOR 2 YEARS AFTER BEING IMPLANTED WITH ESSURE. HER MAJOR COMPLAINTS WERE ABDOMINAL PAIN, PAINFUL SEX, EXTREME FATIGUE, JOINT PAIN, RASHES, AND ABDOMINAL SWELLING. HER PRIMARY CARE DOCTOR FINALLY TOLD HER THAT IF SHE COULD NOT CONVINCE A GYNECOLOGIST TO REMOVE THEM, HE WOULD REFER HER TO A GENERAL SURGEON. SHE WAS FINALLY ABLE TO FIND A DOCTOR AT A SMALL PRACTICE WHO WOULD DISCUSS ESSURE REMOVAL. AFTER AN INTERNAL EXAM WHERE SHE CONVULSED OFF THE TABLE IN PAIN, HE AGREED THAT THEY NEEDED TO COME OUT RIGHT AWAY. SHE HAD A HYSTERECTOMY ON HER (B)(6) BIRTHDAY. CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN IN HER ABDOMEN/PELVIS AND HIPS, SEVERE ENOUGH TO INTERFERE WITH MY DAILY LIFE. A HYSTERECTOMY WAS PERFORMED. SEVERE PAIN IN ABDOMEN AND PELVIS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE PAIN IN HIPS IS UNLISTED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING THE NATURE OF THE EVENTS PAIN IN ABDOMEN AND PELVIS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, A

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CAUSAL RELATIONSHIP CAN BE EXCLUDED CONSIDERING THAT A CONTRIBUTORY ROLE OF ESSURE IS UNLIKELY. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01228	BAYER HEALTHCARE LLC	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 7/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B53037; CS0003V

Single Use: Y
Implant Date (E6): 4/3/2014
Explant Date (E7): 9/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 20-MAR-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR STERILIZATION; THE LOT NUMBERS USED WERE CS0003V IN ONE SIDE AND B5307 IN THE OTHER SIDE (THE REPORTER DID NOT KNOW WHICH SIDE IS WHICH LOT). ON (B)(6) 2014, THE PATIENT HAD THE FIRST HSG (HYSTEROSALPINGOGRAM) DONE AND IT WAS NOTED THE LEFT SIDE OUTER COIL SEEMED DISTAL IN POSITION BUT IT APPEARED OCCLUDED WITH NO CONTRAST IN THE LEFT FALLOPIAN TUBE DISTAL TO THE ESSURE COIL. DUE TO THE POSSIBILITY OF A (B)(6) THEY DECIDED TO DO A SECOND HSG TEST. ON (B)(6) 2015, THE SECOND HSG APPEARED TO SHOW THE LEFT COIL HAD MIGRATED AND WAS MUCH FURTHER IN THE LEFT PELVIS WITH A GREATER THAN 30 MILLIMETER CHANGE. IN ADDITION, THE DISTAL MARKER SEEMS SEPARATED FROM THE DEVICE. THERE WAS NO CONTRAST IN THE LEFT FALLOPIAN TUBE DISTAL TO THE ESSURE COIL. IT WAS REPORTED THAT THE PATIENT WAS NOT COMPLAINING OF PAIN. AT TIME OF THE REPORT, THE ESSURE DEVICES WERE CONTINUED. FOLLOW-UP RECEIVED ON 01-APR-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: LOT NUMBER B5307 IS INVALID. LOT NUMBER CS0003V; PRODUCTION DATE: OCT-2013; EXPIRATION DATE: DEC-2015. THIS IS NOT A DEVICE "BREAKAGE" CASE. THIS IS A MISINTERPRETATION OF THE HSG FILMS. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A

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REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A PRODUCT QUALITY ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED VALID BATCH WAS REVIEWED. THE AE CASE REFERS ALSO TO THE LOT NUMBER B5307 WHICH IS INVALID ACCORDING TO THE RESPONSIBLE QUALITY UNIT (RQU). NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED VALID BATCH NUMBER CS0003V. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 26-MAY-2015: INFORMATION RECEIVED STATES THAT ESSURE HAD PERFORATED ON THE LEFT SIDE AS SHOWN ON MODIFIED HYSTEROSALPINGOGRAM EXAM. INSERT WAS OUTSIDE OF THE TUBE AND THE COIL WAS STRETCHED OUT. FOLLOW-UP RECEIVED ON 02-JUN-2015: INFORMATION RECEIVED STATES THAT A NEW READING OF THE HYSTEROSALPINGOGRAM ACTUALLY FOUND A PERFORATION. REPORTER ALSO INFORMED THAT THE LEFT DEVICE IS OUTSIDE THE FALLOPIAN TUBE AND IT APPEARS TO BE STRETCHED OUT. THAT IS ALL THE INFORMATION THAT REPORTER HAS ON THE CASE. FOLLOW UP 23-JUN-2015: NO NEW INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 28-SEP-2015 VIA HEALTH CARE PROVIDER UTERINE/TUBAL PERFORATION QUESTIONNAIRE (UPGRADED TO INCIDENT). PATIENT'S WEIGHT AND HEIGHT WERE PROVIDED. MEDICAL HISTORY INCLUDED A LEEP (INTERPRETED AS LOOP ELECTROSURGICAL EXCISION PROCEDURE) IN 2004, D&C (DILATION AND CURETTAGE) IN 2010 AND 2011. SHE HAD 03 PREGNANCIES, 01 LIVE BIRTH AND 02 SPONTANEOUS ABORTIONS. ECTOPIC PREGNANCY WAS DENIED. ESSURE LOT NUMBERS CS0003V AND B53037 (PREVIOUSLY REPORTED AS B5307) WERE IMPLANTED. SHE WAS NOT ON POSTPARTUM STATE AT THE TIME OF INSERTION. SOUNDING AND ANALGESIA (KETORALAC, LIDOCAINE) WERE APPLIED DURING INSERTION. THE INSERTION WAS DIFFICULT (TOOK 4 ATTEMPTS). THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC BUT THE PROCEDURE TOOK 35 MINUTES. ON (B)(6) 2014 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND THE RESULT SHOWED NOT PATENT. LEFT SIDE WAS DISTAL IN POSITION (<30MM FROM CORNEAL SEGMENT). SHE HAD NO SYMPTOMS AND NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS PERFORATED. ON (B)(6) 2015 ESSURE WAS REMOVED BY LAPAROSCOPY/BILATERAL SALPINGECTOMY DUE TO PATIENT'S REQUEST. BIPOLAR CAUTERIZATION WAS DONE. ESSURE WAS OUTSIDE THE TUBE, WITHIN THE PELVIS. THE PATIENT RECOVERED QUICKLY FROM REMOVAL PROCEDURE AND THE SYMPTOMS/PAIN RESOLVED AFTER SURGERY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT A SECOND HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED WHICH SHOWED THAT ESSURE HAD PERFORATED ON THE LEFT SIDE (PREVIOUSLY REPORTED AS APPEARED THAT LEFT COIL HAD MIGRATED AND WAS OUTSIDE THE TUBE, WITHIN THE PELVIS). THIS EVENT, REGARDED AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE INSERTION WAS DIFFICULT. FOUR ATTEMPTS TO INSERT ESSURE WERE MADE AND THE PROCEDURE TOOK 35 MINUTES. THE MODIFIED HYSTEROSALPINGOGRAM SHOWED THAT ESSURE HAD PERFORATED LEFT SIDE. INSERT WAS OUTSIDE OF THE TUBE AND THE COIL WAS STRETCHED. ALTHOUGH THE EXACT DATE AND MECHANISM OF PERFORATION WERE NOT KNOWN, GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. UPON FOLLOW UP INFORMATION, THE CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. ADDITIONAL

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INFORMATION ALSO CONFIRMED IT WAS NOT A DEVICE BREAKAGE IT WAS A STRETCHED COIL. AN INITIAL TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. AN UPDATED PRODUCT TECHNICAL COMPLAINT ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01229	BAYER HEALTHCARE LLC	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B30420

Single Use: Y
Implant Date (E6): 1/23/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5042816) IN UNITED STATES ON 29-JUL-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. SHE REPORTED SHE GOT THE STERILIZATION PROCEDURE AND IN 2015 FOUND OUT SHE WAS PREGNANT. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-AUG-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER A BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 28-SEP-2015 FROM CONSUMER. CASE

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UPGRADED TO INCIDENT. THE CONSUMER'S WEIGHT WAS (B)(6). PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES WERE DENIED. HER MEDICAL HISTORY INCLUDED 2 PREGNANCIES (2 PARITY). ESSURE WAS INSERTED IN (B)(6) 2014 WITH LOT NUMBER B30420 AND 753646. ESSURE WAS INSERTED 6 WEEKS AFTER HER LAST DELIVERY. SHE STATED THAT SHE HAD NO SEX AFTER PROCEDURE AND BEFORE CONFIRMATION TEST. IN (B)(6) OF 2014, HSG (HYSTEROSALPINGOGRAM) WAS DONE AND PROCEDURE WAS CONFIRMED. ON AN UNSPECIFIED DATE, SHE EXPERIENCED SIGNIFICANTLY HEAVIER CYCLES AND CRAMPS THAT SHE NEVER EXPERIENCED BEFORE PROCEDURE. ON (B)(6) 2015, PREGNANCY WAS CONFIRMED BY URINE TEST. AN ULTRASOUND WAS DONE AT THE SAME DAY AND SHOWED A NON-REGULAR PREGNANCY; ECTOPIC TISSUE IN TUBE. SHE STATED THAT SHE ALREADY STARTED TO MISCARRY AT THAT POINT. SHE RECEIVED SHOTS TO MAKE SURE THAT REMAINING TISSUE TERMINATED (SHE REPORTED THAT SHE HAD A MISCARRIED BUT HAD TO HELP TERMINATION TO REMOVE TISSUE FROM TUBE, SO SHE WOULD NOT HEMORRHAGE). ESSURE WAS NOT REMOVED. UPDATED PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 10-OCT-2015 UPON LOT NUMBER RECEIPT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT LOT# 753646: PRODUCTION DATE: JUN-2010 AND EXPIRATION DATE: JUN-2013. LOT# B30420: PRODUCTION DATE: MAY-2013 AND EXPIRATION DATE: MAY-2016. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORDS AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THESE LOTS WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS AND LACK OF EFFICACY IS EXCLUDED. A REVIEW OF SIMILAR CASES FOR THIS BATCH RESULTED IN NO UNUSUAL PATTERN IDENTIFIED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED REPORT REFERS TO A (B)(6)FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, SHE HAD A NON-REGULAR PREGNANCY; ECTOPIC TISSUE WAS SEEN IN TUBE AT ULTRASOUND. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). WHEN A PREGNANCY OCCURS WITH ESSURE, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. IN THIS PARTICULAR CASE, CONSUMER HAD A HSG CONFIRMING TUBAL OCCLUSION. THEN, MORE THAN 1 YEAR AFTER DEVICE PLACEMENT, SHE HAD A NON-REGULAR PREGNANCY DIAGNOSED (ULTRASOUND SCAN REVEALED ECTOPIC TISSUE IN THE FALLOPIAN TUBE). SHE BELIEVED SHE MISCARRIED AND STATED SHE RECEIVED UNSPECIFIED SHOTS TO MAKE SURE THE TISSUE WAS TERMINATED AND SHE HAD TO HELP TERMINATION TO REMOVE TISSUE FROM TUBE. DESPITE THE LACK OF DETAIL AVAILABLE, THE REPORT INCONSISTENCIES AND THE ABSENCE OF MEDICAL CONFIRMATION TO PERFORM A COMPREHENSIVE CAUSALITY ASSESSMENT; THE REPORTED EVENT IS REGARDED AS A SERIOUS INJURY BY THE COMPANY, FOR WHICH CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THEREFORE, THIS CASE WAS CONSIDERED AN INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION WITH PHYSICIAN IS BEING SOUGHT.

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Manufacturer Narrative (H10):

FUP RECEIVED ON 13-NOV-2015, ESSURE HCP PREGNANCY QUESTIONNAIRE RECEIVED: NEW REPORTER ADDED. THIS CASE IS MEDICALLY CONFIRMED NOW. ECTOPIC PREGNANCY CONFIRMED. REPORTER STATED THAT ESSURE WAS INSERTED BY ANOTHER PHYSICIAN. ESSURE WITH LOT NUMBER B30420 W

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01230	BAYER HEALTHCARE LLC	10/24/2015	10/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D30807

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH PROFESSIONAL IN (B)(6) ON (B)(6) 2015. DURING INSERTION OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PERFORMED ON (B)(6) 2015 (LOT NUMBER D30807, EXPIRATION DATE ON 28-NOV-2017), PHYSICIAN HAD DIFFICULTY FOR PUTTING ANCILLARY MATERIAL INTO THE OPERATING CHANNEL. IMPLANT WAS ENTERED THROUGH THE OPERATING CHANNEL WITH INSISTENCE, BUT ON SCREEN A SMALL WHITE PIPE WITH LENGTH OF 4 CM WAS VISUALIZED, PUT ON THE ESSURE IMPLANT. ON REMOVAL, IT WAS NOTICED THAT IT WAS IN FACT A PART OF THE INTRODUCER WHICH WAS SOLIDIFIED BY STERILIZATION AND PROBABLY BROKE DURING A PREVIOUS INTERVENTION WHEN ANCILLARY MATERIAL WAS REMOVED. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: THE FRENCH AUTHORITY NUMBER WAS ADDED: (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A PHYSICIAN. HE VISUALIZED, DURING AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PROCEDURE, A SMALL WHITE PIPE ON SCREEN. ON REMOVAL, HE NOTICED IT WAS A PART OF THE INTRODUCER, SOLIDIFIED BY STERILIZATION AND PROBABLY BROKE DURING A PREVIOUS INTERVENTION. THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN FOUND A RESISTANCE PUTTING THE MATERIAL INTO THE HYSTEROSCOPE OPERATING CHANNEL. HE INSISTED; ESSURE SYSTEM WAS ENTERED AND HE SAW A WHITE MATERIAL, WHICH HE BELIEVED WAS A PART OF A BROKEN INTRODUCER FROM A PREVIOUS INTERVENTION. NEITHER THE EXACT NATURE OF THIS INTRODUCER WAS SPECIFIED NOR WAS INFORMATION ABOUT THE PREVIOUS PROCEDURE PROVIDED. NEVERTHELESS, BASED ON THE LIMITED INFORMATION AVAILABLE, COMPANY CONSIDERS IT CANNOT BE EXCLUDED PHYSICIAN WAS REFERRING TO AN ESSURE CATHETER WHICH BROKE IN A PREVIOUS PROCEDURE. THEREFORE, THE REPORTED EVENT WAS

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CONSIDERED AS RELATED TO THE SUSPECT DEVICE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 26-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: ACCORDING TO THE COMPLAINT NARRATIVE, DURING AN ESSURE PLACEMENT PROCEDURE, A SMALL WHITE PIPE OF APPROXIMATELY 4CM LENGTH WAS NOTIC

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01231	BAYER HEALTHCARE LLC	10/24/2015	10/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D30807

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN (B)(4) ON 28-SEP-2015. DURING INSERTION OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), PERFORMED ON (B)(6) 2015 (LOT NUMBER D30807, EXPIRATION DATE ON 28-NOV-2017), PHYSICIAN HAD DIFFICULTY FOR PUTTING ANCILLARY MATERIAL INTO THE OPERATING CHANNEL. IMPLANT WAS ENTERED THROUGH THE OPERATING CHANNEL WITH INSISTENCE, BUT ON SCREEN A SMALL WHITE PIPE WITH LENGTH OF 4 CM WAS VISUALIZED, PUT ON THE ESSURE IMPLANT. ON REMOVAL, IT WAS NOTICED THAT IT WAS IN FACT A PART OF THE INTRODUCER WHICH WAS SOLIDIFIED BY STERILIZATION AND PROBABLY BROKE DURING A PREVIOUS INTERVENTION WHEN ANCILLARY MATERIAL WAS REMOVED (SEE CASE (B)(4)). A SECOND HYSTEROSCOPE WAS USED WITH THE SAME DIFFICULTY (CURRENT CASE). FOLLOW-UP INFORMATION RECEIVED 19-OCT-2015: NCA REFERENCE NUMBER ((B)(4)) WAS RECEIVED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A HEALTH PROFESSIONAL. DURING AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PROCEDURE, PHYSICIAN VISUALIZED A SMALL WHITE PIPE ON SCREEN. ON REMOVAL, HE NOTICED IT WAS A PART OF THE INTRODUCER, SOLIDIFIED BY STERILIZATION AND PROBABLY BROKE DURING A PREVIOUS INTERVENTION. A SECOND HYSTEROSCOPE WAS USED WITH THE SAME DIFFICULTY. THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN FOUND A RESISTANCE PUTTING THE MATERIAL INTO THE HYSTEROSCOPE OPERATING CHANNEL. HE INSISTED; ESSURE SYSTEM WAS ENTERED AND HE SAW A WHITE MATERIAL, WHICH HE BELIEVED WAS A PART OF A BROKEN INTRODUCER FROM A PREVIOUS INTERVENTION. NEITHER THE EXACT NATURE OF THIS INTRODUCER WAS SPECIFIED NOR WAS INFORMATION ABOUT THE PREVIOUS PROCEDURE PROVIDED. NEVERTHELESS, BASED ON THE LIMITED INFORMATION AVAILABLE, COMPANY

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CONSIDERS IT CANNOT BE EXCLUDED PHYSICIAN WAS REFERRING TO AN ESSURE CATHETER (WHICH BROKE IN A PREVIOUS PROCEDURE). THEREFORE, THE REPORTED EVENT WAS CONSIDERED AS RELATED TO THE SUSPECT DEVICE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED. THIS CASE REFERS TO THE SECOND HYSTEROSCOPE. ANOTHER CASE WAS CREATED FOR THE BREAKAGE IN THE FIRST HYSTEROSCOPE.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015: (B)(4). FINAL ASSESSMENT: ACCORDING TO THE COMPLAINT NARRATIVE, DURING AN ESSURE PLACEMENT PROCEDURE, A SMALL WHITE PIPE OF APPROXIMATELY 4CM LENGTH WAS NOTICED IN THE PATIENT'S

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01232	BAYER HEALTHCARE LLC	10/24/2015	10/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D30807

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN (B)(6) ON 28-SEP-2015. DURING INSERTION OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER D30807, EXPIRATION DATE ON 28-NOV-2017, PERFORMED ON (B)(6) 2015, THERE WAS AN OCCURRENCE OF DIFFICULTY FOR PUTTING ANCILLARY MATERIAL INTO THE OPERATING CHANNEL. IMPLANT WAS ENTERED THROUGH THE OPERATING CHANNEL WITH INSISTENCE, BUT ON SCREEN A SMALL WHITE PIPE WITH LENGTH OF 4 CM WAS VISUALIZED, PUT ON THE ESSURE IMPLANT. ON REMOVAL, IT WAS NOTICED THAT IT WAS IN FACT A PART OF THE INTRODUCER WHICH WAS SOLIDIFIED BY STERILIZATION AND PROBABLY BROKE DURING A PREVIOUS INTERVENTION WHEN ANCILLARY MATERIAL WAS REMOVED (SEE CASE (B)(4)). A SECOND HYSTEROSCOPE WAS USED WITH THE SAME DIFFICULTY (SEE CASE (B)(4)). IT WAS REPORTED THAT THE SAME TYPE OF BREAKAGE INCIDENT HAD ALREADY OCCURRED PREVIOUSLY (CURRENT CASE). FOLLOW UP INFORMATION RECEIVED ON 19-OCT-2015: (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A HEALTH PROFESSIONAL. DURING AN ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION PROCEDURE, PHYSICIAN VISUALIZED A SMALL WHITE PIPE ON SCREEN. ON REMOVAL, HE NOTICED IT WAS A PART OF THE INTRODUCER, SOLIDIFIED BY STERILIZATION AND PROBABLY BROKE DURING A PREVIOUS INTERVENTION. IT WAS REPORTED THAT THE SAME TYPE OF BREAKAGE INCIDENT HAD ALREADY OCCURRED. THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE PHYSICIAN FOUND A RESISTANCE PUTTING THE MATERIAL INTO THE HYSTEROSCOPE OPERATING CHANNEL. HE INSISTED; ESSURE SYSTEM WAS ENTERED AND HE SAW A WHITE MATERIAL, WHICH HE BELIEVED WAS A PART OF A BROKEN INTRODUCER FROM A PREVIOUS INTERVENTION. NEITHER THE EXACT NATURE OF THIS INTRODUCER WAS SPECIFIED NOR WAS INFORMATION

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ABOUT THE PREVIOUS PROCEDURE PROVIDED. NEVERTHELESS, BASED ON THE LIMITED INFORMATION AVAILABLE, IT CANNOT BE EXCLUDED THAT PHYSICIAN WAS REFERRING TO AN ESSURE CATHETER (WHICH BROKE IN A PREVIOUS PROCEDURE). THEREFORE, THE REPORTED EVENT WAS CONSIDERED RELATED TO THE SUSPECT DEVICE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED. THIS CASE REFERS TO THE SAME TYPE OF BREAKAGE INCIDENT THAT HAD ALREADY OCCURRED PREVIOUSLY. OTHER CASES WERE CREATED FOR THE BREAKAGE IN THE FIRST AND SECOND HYSTEROSCOPES.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON (B)(4) 2015: (B)(4). LOT D30807; MFG DATE: NOV-2014; EXP DATE: NOV-2017. FINAL ASSESSMENT: ACCORDING TO THE COMPLAINT NARRATIVE, DURING AN ESSURE PLACEMENT PROCEDURE, A SMALL WHITE PIPE OF A

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01233	BAYER HEALTHCARE LLC	10/24/2015	10/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D30810

Single Use: Y
Implant Date (E6): 9/21/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH PROFESSIONAL VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT, LOT NUMBER 030810) INSERTED. DURING INSERTION, A SMALL METALLIC PIECE LOCATED BETWEEN THE IMPLANT AND DELIVERY CATHETER WAS DETACHED. THIS FOREIGN SMALL METALLIC PIECE STAYED INTO PATIENT'S UTERUS. SAMPLE WAS NOT KEPT. DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE (B)(6) 2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS (B)(6) 2015. FOLLOW-UP INFORMATION RECEIVED ON (B)(6) 2015. THE REPORTER COULD NOT CONFIRM BATCH NUMBER AS DEVICE WAS NOT KEPT. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON (B)(6) 2015: (B)(4). THE CORRECT LOT NUMBER USED WAS D30810. (B)(4). PRODUCTION DATE: (B)(6) 2014. FINAL ASSESSMENT FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE

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A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER AND /OR MICRO-INSERT AND INTRODUCER BREAKING AND DETACHMENT DIFFICULTY EVENT IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WICK INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE (BREAKAGE) IN THE CONTEXT OF A COMPLICATED INSERTION. A REVIEW OF SIMILAR CASES FOR THIS BATCH IS NOT APPLICABLE AS NO MEDICAL EVENT(S) WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP TO A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING PLACEMENT PROCEDURE A SMALL METALLIC PIECE LOCATED BETWEEN THE IMPLANT AND DELIVERY CATHETER WAS DETACHED. THIS FOREIGN SMALL METALLIC PIECE STAYED INTO PATIENT'S UTERUS. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS PREVIOUSLY REGARDED AS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; HOWEVER UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS (PTC), WHICH STATED THAT MICRO-INSERT BREAKING OFF DURING THE PROCEDURE IS AN ANTICIPATED EVENT; IT WAS AMENDED TO LISTED. SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED MOSTLY DURING DIFFICULT INSERTIONS. CONSIDERING THIS BREAKAGE OCCURRED ASSOCIATED TO INSERTION PROCEDURE AND GIVEN EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP TO A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 28-OCT-2015 HER INITIAL AND AGE (SHE WAS (B)(6)) WERE UPDATED. HER WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). ESSURE WAS INSERTED ON (B)(6) 2015 UNDER GENERAL ANESTHESIA. PLANNED INTERVENTION OF MONS VENUS BEAUTY SPOT REMOV

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01235	BAYER HEALTHCARE LLC	10/24/2015	10/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A RADIOLOGIST IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. RADIOLOGIST WAS SEEKING CLARIFICATION ABOUT HYSTEROSALPINGOGRAM (HSG) RESULTS. IT WAS STATED THAT THE RIGHT-INNER MARKER OF OUTER COIL WAS DISPLACED TO THE REMAINING INSERT AND APPEARED PARALLEL TO THE INSERT; LEFT WAS STRAIGHT FOR 3CM LOOPS BUT DOESN'T OVERLAP - DISTAL MARKER WAS PERPENDICULAR TO THE SECOND DISTAL MARKER. SOME TYPE OF SCARING WAS ALSO SEEN ON FILM-SUBTLE CASE AROUND THE INSERT. BILATERAL OCCLUSION WAS REPORTED. PTC INVESTIGATION RESULT RECEIVED ON 16-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT. FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICROINSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE

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INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE. HOWEVER, NO MEDICAL EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. AT THIS POINT IN TIME NO BATCH NUMBER WAS REPORTED, THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A RADIOLOGIST WHO WAS SEEKING CLARIFICATION ABOUT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) CONFIRMATION TEST (HYSTEROSALPINGOGRAM-HSG). A PATIENT WAS SUBMITTED TO A HSG AND ESSURE RIGHT-INNER MARKER OF OUTER COIL WAS DISPLACED TO THE REMAINING INSERT AND APPEARED PARALLEL TO THE INSERT . THIS EVENT, SEEM AS SUSPICION OF DEVICE BREAKAGE, IS LISTED ACCORDING TO TECHNICAL ASSESSMENT. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, THE RADIOLOGIST SUSPECTED A BREAKAGE OF RIGHT ESSURE INSERT AT HSG. ALTHOUGH THIS EVENT WAS NOT CONFIRMED AT THE TIME OF THIS REPORT; CONSIDERING ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENT: LEFT: STRAIGHT FOR 3CM LOOPS BUT DOESN'T OVERLAP; DISTAL MARKER IS PERPENDICULAR TO 2ND DISTAL MARKER WAS REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 16-OCT-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFOR

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057285	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 9/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN 2009. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 628192. MY MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED IN 2014. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: ABSCESS AT VAGINAL OPENING, SWELLING OF LEGS AND FEET, PAIN IN BACK AND HIPS, TREMORS, AND ELEVATED THYROID ANTIBODY LEVEL. I HAVE BEEN SEEN BY 4 DOCTORS. THE DEVICE IS STILL INSIDE OF ME, BUT IS PLANNED TO BE REMOVED (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057286	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 5/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE DEVICE WAS COVERED BY INSURANCE, (B)(6). THE THREE MONTH CHECK UP WAS NOT COVERED AS I WAS NOT INSURED AT THAT TIME. MY BLEEDING PROGRESSED TO HEAVY BLEEDING, EVERY OTHER WEEK FOR AN ENTIRE WEEK. THIS DID NOT STOP UNTIL I EXPERIENCED HEAVY BLEEDING FOR A FULL MONTH, WHICH LEAD ME TO GO IN TO THE ER. I SCHEDULED A "DANDAMP;C" AND ABLATION TO HELP WITH THE BLEEDING. I HAVE ALSO EXPERIENCED LOW BACK PAIN, PAINFUL CRAMPING, DEPRESSION, ANXIETY, FOGGY BRAIN, HEADACHES. ALL OF THIS STARTED AFTER I HAD THE ESSURE IMPLANTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057287	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN SOMETIMES LEAVING ME UNABLE TO WALK. UNABLE TO LIFT MY TODDLER OR CARRY HIM. MIGRAINES. SWELLING IN ABDOMEN AND JOINTS. RECURRING YEAST INFECTIONS. PAINFUL INTERCOURSE. HEAVY BLEEDING. MANY EMERGENCY ROOM AND DOCTORS VISITS. PHYSICAL AND PHYSIOTHERAPY. HYSTERECTOMY TO REMOVE DEVICE ONE YEAR AFTER IT WAS PLACED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057288	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 6/18/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) MIGRAINES, CLOTS, HEAVY BLEEDING, PELVIC PAIN, HYSTERECTOMY, BACK PAIN, THYROID DISEASE, EPSTEIN BARR

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057289	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 8/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IRRADIATAL BOWEL SYNDROME, POLLY SYSTIC FIBROSIS, HIGH BLOOD PRESSURE, ANXIETY, DEPRESSION, LOSS OF ENERGY, ABDOMINAL PAIN, CRAMPING, LOSS OF MENSTRUAL, THEN FLUCTUATIONS IF MENSTRUAL..

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057290	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 3/20/2014	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) STARTED HAVING NIGHTMARES, THEN ONE EVENING I STARTED JERKING UNCONTROLLABLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057291	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 2/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING , HEAVY BLEEDING , PAIN WITH SEX BLEEDING ALSO HAVING MY MONTHLY 3 TIMES A MONTH, SORES ON UP LEGS, "HEAD ACKS".

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057292	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 12/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, WEIGHT GAIN, IT BAND SYNDROME, UNEXPLAINED SWELLING, ELEVATED C-REACTIVE PROTEIN (LAST 5 YRS), WRIST PAIN, DENTAL ISSUES, ACUTE BURNING PAIN IN LEGS (ESPECIALLY RIGHT), PRIOR TO HYSTERECTOMY IN 2009- EXCESSIVE BLEEDING AND CRAMPING DURING MENSTRUAL CYCLES, MEMORY LOSS, MOOD SWINGS, AGGRESSION

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057293	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 10/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN OF MORE THAN (B)(6), MIGRAINES, THROWING UP, HEAVY BLEEDING, FATIGUE, PASSING BLOOD CLOTS, LIGHT HEADED, LOWER BACK PAIN, BREAST TENDERNESS, CRAMPS. PERIODS THAT LAST 2 WEEKS AT A TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057294	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 10/26/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) HAD SEVERE ABDOMINAL PAIN, BRAIN FOG, SEVERE BLOATING, JOINT PAIN

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057295	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 3/7/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PUT IN ON A RECOMMENDATION FROM MY OB/GYN (A NEW ONE THAT JUST DELIVERED MY FOURTH BABY, WE HAD RECENTLY MOVED TO (B)(6)). ABOUT 3 MONTHS AFTER THE ESSURE WAS PLACED, I STARTED GETTING BAD HEADACHES, CRAMPS (VERY HEAVY PERIODS, SO BAD THAT FOR THE FIRST TWO DAYS, (AND STILL TO THIS DAY). I CAN'T LEAVE THE HOUSE, I HAVE HORRIBLE MOOD SWINGS, AND HAVE TAKEN ALMOST EVERY MED FOR DEPRESSION AND ANXIETY THERE IS WITH NO HELP, SEVERE FATIGUE (TO THE POINT WHERE I'M ASLEEP IN THE MIDDLE OF THE DAY) I GET A SHARP, CRIPPLING PAIN ON MY LEFT SIDE RIGHT WHERE MY TUBE IS, AND NOW OVER THE PAST 6 TO 8 MONTHS MY VISION HAS BECOME INCREASINGLY BLURRY WITH NO EXPLANATION AS TO WHY. I HAVE HAD BLOOD WORK AND SEVERAL ULTRA SOUNDS AND I HAVE NO ANSWERS. I KNOW THAT IT'S BEEN EIGHT YEARS SINCE I HAD THE ESSURE PUT IN, AND I HAVE BEEN TO DR AFTER DR TO TRY AND FIGURE THIS OUT AND UNTIL NOW I HAD GIVEN UP AND BEGAN TO ACCEPT THAT THIS IS JUST HOW I'M GOING TO BE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057296	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 7/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD EXTREME NAUSEA, CONTINUOUS BLEEDING FOR 4.5 MONTHS STRAIGHT, POKING AND STABBING PAIN, HIVES ON ABDOMEN AND ARMS, EXTREME SWOLLEN LIPS SHOOTING PAIN DOWN THIGHS, BACK AND ABDOMINAL PAIN, FELT LIKE THEY WERE TRYING TO EXPEL FROM MY BODY, HOT FLASHES, TEMPERATURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057297	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 7/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY ENERGY LEVEL SUNK TO AN EXTREME LOW (I WAS A VERY ACTIVE RUNNER, HIKER AND KAYAKER PRIOR TO THIS), MY HAIR STARTED BREAKING AND FALLING OUT (QUITE DEVASTATINGLY OVER 12 INCHES OF EXTREMELY HEALTHY HAIR WAS LOST), AND ALSO EXTREME FATIGUE, NAUSEA, VOMITING, DIZZINESS, PELVIC PAIN, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, AUTOIMMUNE SYMPTOMS AND ELEVATED BLOOD COUNTS, DIZZINESS AND NUMBNESS THROUGHOUT BODY, TINGLING AND BURNING SENSATION IN MY HANDS AND FEET, DIMINISHED BRAIN FUNCTION (CLOUDINESS AND; FORGETFULNESS), ANXIETY, MOOD SWINGS, SEVERE DEPRESSION, MIGRAINES, RINGING IN EARS, ANEMIA AND VITAMIN D AND; B-12 DEFICIENCY, EXTREME HAIR LOSS, BRUISING EASILY, FOOD ALLERGIES AND; ALLERGIC REACTIONS, DENTAL ISSUES, INSOMNIA, NIGHT SWEATS, HOT FLASHES, THYROID DISEASE AND; ADRENAL PROBLEMS, UNEXPLAINED FEVERS AND ALL OVER BODY ACHES AND; PAINS AND; LOSS OF LIBIDO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057298	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 10/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD MULTIPLE UTI'S AND UNEXPLAINED RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057299	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 9/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE DONE IN (B)(6) 2014 AFTER THE BIRTH OF OUR TWIN BOYS ((B)(6) 2014) WHICH MADE #5 FOR US. WE WERE SURE WE DIDN'T WANT TO HAVE ANYMORE CHILDREN AND EVEN WENT THROUGH SOME WHAT OF A COUNSELING SESSION WITH OUR OB/GYN TO MAKE SURE WE WERE POSITIVE BECAUSE WE WOULD NOT BE ABLE TO HAVE ANYMORE IF WE CHANGED OUR MINDS. I ACTUALLY HAD THE ESSURE DONE IN THE HOSPITAL AS AN OP PROCEDURE. SO, IN (B)(6) TO OUR SHOCK. WE FOUND OUT THAT WE WERE PREGNANT AGAIN, ALMOST 6 1/2 WEEKS. NEEDLESS TO SAY I WAS DEVASTATED, COULDN'T BELIEVE IT BECAUSE I HAD MADE IT UP IN MY MIND THAT WE WERE DONE, NEVER TO THINK ABOUT PREGNANCY OR BABIES AGAIN. I AM NOW 23 WEEKS PREGNANT AS OF TODAY (DUE ON (B)(6)) WITH A BABY BOY. I HAD (AND STILL HAVE) CONCERNS REGARDING THE SAFETY OF HAVING A HEALTHY BABY WITH THE ESSURE COILS STILL BOTH IN PLACE IN MY TUBES AND WONDER HOW IT WILL AFFECT THE BABY, THE REST OF THE PREGNANCY AND/OR DELIVERY. I HAVE HAD CONSTANT CRAMPING AND DEBILITATING BACK PAIN WITH THIS PREGNANCY EVEN MORE SO THAN WITH MY TWIN PREGNANCY AND I TRULY FEEL LIKE ITS BECAUSE OF THE COILS STILL BEING PRESENT. I AM DOUBLED OVER IN PAIN MOST DAYS ALONG WITH DAILY HEADACHES. BEFORE THIS PREGNANCY, MY SYMPTOMS WERE CRAMPING, BACK PAIN, HEAVY PERIODS, EXTREME FATIGUE, EXTREME BLOATING AND DECREASED SEX DRIVE. HAVING THIS PROCEDURE DONE HAS BEEN ONE OF THE WORST DECISIONS I'VE EVER MADE AND I PRAY THAT IT IS TAKEN OFF THE MARKET BEFORE MORE WOMEN HAVE TO EXPERIENCE ANY OF THE PREVIOUSLY MENTIONED SYMPTOMS OR WORSE. MY ESSURE WAS PAID FOR THROUGH MY INSURANCE.

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Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057300	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 10/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD NO ISSUES BEFORE I HAD THE ESSURE IMPLANTED. THE ONLY MEDICAL ISSUE I HAD BEFORE WAS ASTHMA AND IT WAS NOT THAT BAD AS IT IS NOW.. I'M CONVINCED SOMETHING IN ESSURE HAS STEPPED UP THE SEVERITY OF MY BREATHING ISSUES. I HAD MY FIRST CHILD NATURAL WHO IS NOW 20 AND MY SECOND CHILD C-SECTION WHO IS 14 MONTHS OLD. MY OB SAID ESSURE WAS THE WAY TO GO BECAUSE OF DOWN TIME. NEVER WAS I TOLD THAT I WOULD SUFFER FROM ALL KINDS OF SIDE EFFECTS AND NEVER WAS I TOLD THESE COILS CAN BREAK OFF, EXPEL INTO OTHER ORGANS, CAUSE INFLAMMATION INSIDE MY BODY LONGER THAN THE HEALING PROCESS. SO, BEING A HIGHLY MOTIVATED, ON THE GO, ENERGETIC AND HEALTHY WOMAN (OTHER THAN ASTHMA) BEFORE ESSURE... I AM NOW TIRED ALL THE TIME, MY BONES ACHE, MY LOWER BACK IS IN PAIN 24-7 WITH MOST DAYS NOT ABLE TO BEND OR COUGH WITHOUT IT FEELING LIKE ITS GOING TO BREAK. I HAVE CRAMPS WORSE THAN EVER, MY HEADACHES ARE 4 OR MORE DAYS A WEEK. MAJOR MOOD SWINGS AND CONFUSED(LIKE BEING IN A CLOUD). I'M ALSO WONDERING AND DOING RESEARCH TO SEE IF THE MATERIALS IN ESSURE CAN EFFECT MY ASTHMA.. I HAVE MORE ISSUES WITH MY ASTHMA SINCE THE ESSURE THAN I EVER HAD BEFORE! I CAN'T EXPRESS ENOUGH ABOUT THE BACK PAIN!! IT'S SO BAD AND EXCRUCIATING THAT I CAN'T EVEN GET OUT OF BED RIGHT AWAY!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057301	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 12/7/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PROCEDURE DONE (B)(6) 2009. INSURANCE COVERED MOST COSTS FOR IMPLANTATION AND HSG TESTING. THE DEVICE WAS NOTED AS IN PLACE AND NO MIGRATION OR PERFORATION OCCURED AT ANY TIME. NO MENTION OF POSSIBLE SIDE EFFECTS NOR WAS I ASKED OF ANY METAL ALLERGIES (I WOULD HAVE SAID YES AND REFUSED THE PROCEDURE RIGHT THEN). REFERENCE NUMBER WSS305 LOT #654824. I BEGAN COMPLAINING ABOUT PELVIC PAIN AND PERIODS LASTING 2 WEEKS OUT OF EACH MONTH (WHICH DID NOT BEGIN UNTIL AFTER ESSURE IMPLANTATION). IN (B)(6) OF 2011, AFTER ANOTHER COMPLAINT OF PELVIC PAIN, CT SCANS REVEALED A 10CM MASS (NEVER HAD A TUMOR OR CYST PRIOR TO ESSURE IMPLANTATION) ATTACHED TO MY RT OVARY. IN (B)(6) OF 2012, THE TUMOR AND RT OVARY WAS REMOVED. PELVIC PAIN AND SWELLING CONTINUED, WITH MY GYNECOLOGIST TELLING ME THAT IT IS IMPOSSIBLE FOR ME TO HAVE PAIN IN THAT AREA SINCE THE OVARY WAS REMOVED. BETWEEN 2012 AND 2015 NUMEROUS CT AND ULTRASOUNDS ARE PERFORMED, BUT THE SOURCE OF THE PAIN IS NOT VISIBLE. IN ADDITION TO CONSTANT PAIN, SWELLING, AND EXCESSIVE BLEEDING AND LONG PERIODS, I ALSO EXPERIENCED DIZZINESS. TWO MAJOR FALLS DOWN STAIRS RESULTED IN LONG-TERM INJURY. THE FIRST FALL WAS IN (B)(6) OF 2011 AND THIS RESULTED IN CONSTANT PAIN WHEN SITTING OR STANDING THAT CONTINUES TO THIS DAY. ONE OF MY FAVORITE THINGS TO DO IS TAKE ROAD TRIPS AND THE JOY OF HITTING THE ROAD FOR A NEW ADVENTURE IS SIGNIFICANTLY MINIMIZED BY THE PAIN THAT DEVELOPS AFTER AN HOUR OR SO ON THE ROAD. IT GETS SO BAD THAT IT BECOMES THE ONLY THING I CAN FOCUS ON. MISSING OUT ON ALL THE SIGHTS ALONG THE WAY. THE SECOND FALL OCCURRED IN (B)(6) OF 2013 AND I LOST CONSCIOUSNESS AND HAVE NO MEMORY OF THE FALL. I RECEIVED A CONCUSSION AND NOW SUFFER FROM POST-CONCUSSION SYNDROME. THIS HAS COMPLETELY ALTERED MY LIFE AND MY ABILITIES. MEMORY AND CONCENTRATION ARE MOST

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SIGNIFICANTLY IMPACTED. I AM A GRAD STUDENT AND HAVE STRUGGLED IMMENSELY SINCE THIS INCIDENT. EVERYTHING IS MORE DIFFICULT THAN IT WAS BEFORE. "MEMORY PROBLEMS" MAKE IT SOUND SO MUCH SIMPLER THAN IT ACTUALLY IS. YOU USE MEMORY FOR EVERYTHING YOU DO; SPEAKING, SINGING, DRIVING, WRITING, DAILY TASKS, ETC. I CANNOT EVEN BEGIN TO PUT INTO WORDS THE FRUSTRATION THAT I EXPERIENCE AND HOW OFTEN I AM REDUCED TO TEARS OVER THESE STRUGGLES AND KNOWING HOW SIMPLE AND AUTOMATIC THESE THINGS USED TO BE FOR ME. I NO LONGER ENJOY READING BECAUSE I CAN'T REMEMBER WHAT I READ ON THE PREVIOUS PAGES. I SIT IN DARKNESS AT WORK AND WEAR SUNGLASSES INDOORS TO TRY TO MINIMIZE THE MIGRAINES I GET. I BEGAN DEVELOPING STRANGE AND UNEXPLAINED ISSUES, LIKE JOINT PAIN, ECZEMA ON MY HANDS (TURNS OUT THIS IS AN ALLERGIC REACTION TO NICKEL), FOOD SENSITIVITIES, DIGESTION PROBLEMS, MEDICATION INTOLERANCE, ALCOHOL INTOLERANCE, AND DIFFICULTIES WITH TEMPERATURE REGULATION. I HAD RESIGNED MYSELF TO THE FACT THAT ONE DAY I WOULD BE GIVEN A MEDICATION THAT WOULD KILL ME. I HAVE HAD SEVERAL TERRIFYING MEDICATION EXPERIENCES AND CAN'T EVEN TAKE OVER THE COUNTER MEDICATIONS, NOT EVEN COLD MEDICINES. EXCEDRIN IS THE STRONGEST MEDICATION I CAN TAKE FOR MY MIGRAINES, AND I CAN'TAKE MORE THAN ONE DOSE EVERY 2-3DAYS. I WENT TO MANY DOCTORS AND HAD MANY TESTS DONE. NO ONE COULD FIND A REASON FOR THESE THINGS SUDDENLY DEVELOPING. GETTING BACK TO THE CONSTANT PAIN AND BLEEDING PROBLEMS, (B)(6) 2015 MY PERIOD BEGAN AND DID NOT STOP. THE PAIN INCREASED AND I BECAME ANEMIC AND EXTREMELY TIRED. THE DECISION WAS MADE, BASED ON CONSTANT PROBLEMS SINCE THE IMPLANTATION OF ESSURE, TO HAVE A HYSTERECTOMY. THIS WAS DONE (B)(6) 2015. BUT I HAD TO GO TO A DIFFERENT GYNECOLOGIST, AS THE ONE THAT DID MY ESSURE PROCEDURE ONLY DISMISSED MY COMPLAINTS. THE "ACKNOWLEDGED" SIDE EFFECTS OF ESSURE ARE FAR BEYOND WHAT ANY WOMAN SHOULD HAVE TO ENDURE. THEY ARE NOT MINIMAL AND THEY SIGNIFICANTLY IMPACT LIFE IN A VERY NEGATIVE WAY. THE ESCALATION OF THE "ACCEPTED" SIDE EFFECTS LEADING TO A HYSTERECTOMY IS UNACCEPTABLE. THIS IS A PRODUCT THAT SHOULD BE IMMEDIATELY TAKEN OFF THE MARKET AND BAYER SHOULD HAVE TO PAY FOR THE DAMAGES AND SUFFERING THAT WOMEN WITH ESSURE HAVE HAD TO ENDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057302	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 8/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN I GOT ESSURE I STARTED TO HAVE STOMACH PAINS AN PELVIC PAIN BLOOD CLOTS REAL BAD PERIODS HEADACHES STAY NAUSEATED ALL THE TIME MOOD SWINGS DIZZINESS HAD A RASH UTI GOING BACK AN FOURTH TO THE EMERGENCY ROOM FOR ALL THE PROBLEMS THEN 4 YEARS LATER FINE OUT I'M PREGNANT WITH MY 4TH BABY WHICH ESSURE FAILED

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057303	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 2/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING , HEAVY BLEEDING , PAIN WITH SEX, BLEEDING, ALSO HAVING MY MONTHLY 3 TIMES A MONTH, SORES ON UP LEGS, HEAD ACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057304	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 5/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) I HAD ESSURE IMPLANTED IN (B)(6) 2009. I HAVE SINCE HAD UNEXPLAINED ELEVATED WHITE BLOOD COUNT SINCE 2010 THAT A HEMOTOLOGIST COULD FINE NO REASON FOR. I HAVE HAD WORSENING LOWER BACK PAIN AND SHARP PAIN LIKE A KNIFE CUTTING IN TO MY PELVIS. HEADACHES THAT I USED TO NEVER GET I GET 2 TO 3 TIMES A WEEK. I AM CONSTANTLY TIRED. NO MATTER HOW MUCH SLEEP I GET. I ALSO HAVE RANDOM PAINFUL NUMBNESS IN MY RIGHT ARM AND HAND THAT IT WAKES ME UP IF I'M ASLEEP AND IS VERY PAINFUL WHEN IT HAPPENS WHEN IM DOING THINGS OR TRYING TO HOLD SOMETHING IN MY RIGHT HAND.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057305	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME BLOOD CLOTS, PAIN ALL THROUGHOUT THE MONTH, MORE DURING OVULATION TIME, FATIGUE, STOMACH BLOATING, BAD BRAIN FOG THAT AFFECTED ONE OF MY JOBS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057306	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 2/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) SINCE ITS IMPLANT I HAVE SUFFERED FROM MIGRAINES THAT HAVE PUT ME IN THE HOSPITAL AND 4 DOSES OF MORPHINE DIDN'T GET RID OF THEM, RANDOM RASHES/HIVES, DEVELOPED A NICKEL ALLERGY, HEART PALPITATIONS, A LOWERED IMMUNE SYSTEM, NIGHT SWEATS, WEIGHT GAIN, SEVERE BLOATING WHERE MY STOMACH IS ROCK HARD AND CAUSES ME TO HAVE SHORTNESS OF BREATH, I HAVE TERRIBLE BRAIN FOG, HEAVY MENSTRUAL BLEEDING WITH LARGE CLOTS, VAGINAL SWELLING AND TENDERNESS, PERIODS 15 DAYS APART, REGULAR VAGINAL INFECTIONS AND INCONTINENCE. I AM NOW EXPERIENCING A CONSTANT DULL ACHE IN MY PELVIC AREA THAT LAST NIGHT BECAME A SEVERE STABBING PAIN. IT FEELS LIKE SOMEONE IS STABBING ME SENDING SHOOTING PAIN DOWN MY LEG AND UP TO MY SHOULDER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057307	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 2/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN THE COILS WERE INSERTED, THE DEVICE THAT INSERTS THEM MALFUNCTIONED AND THE COILS BROKE APART INSIDE ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057308	BAYER	10/24/2015	10/24/2015

Event Information:

Event Date (B3): 5/31/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THE DEVICE I'VE HAD BEEN HAVING MAJOR HEADACHES AND MY EYESIGHT I HAVE HAD SO MANY PELVIC PAIN I'VE HAD TO GET MY GALLBLADDER REMOVED BECAUSE THAT WAS GOING TO HELP MY PAINS BUT IT HASN'T BEEN HELPING I STILL HAVE THE PAIN I AM NOW HAVING A RASH BETWEEN MY BREAST I'VE BEEN HAVING LOWER BACK PAIN I HAVE GAIN SO MUCH WEIGHT AND EITHER WITH DIET OR EXERCISE I HAVE GONE TO SO MANY DRS AND NO ONE WANTS TO HELP ME I WANT THIS DEVICE OUT OF ME NOW PLEASE HELP US PATIENTS BE ABLE TO GET THIS MISTAKE OUT OF US.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057539	BAYER	10/24/2015	10/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I AGREED TO HAVE AN ESSURE BIRTH CONTROL DEVICE IMPLANTED IN 2005. I WAS TOLD IT DIDN'T TAKE AND IN TURN A LAPAROSCOPIC TUBAL WAS DONE. I HAVE ALWAYS HAD PAIN IN MY ABDOMEN, BUT ALWAYS ATTRIBUTED IT TO SCAR TISSUE (FROM C-SECTIONS), OVARIAN CYSTS, & BOWEL. AND THIS IS WHAT MY DR. SUGGESTED WHEN I MENTIONED TENDERNESS. RECENTLY, I WAS EXPERIENCING EXTREME PAIN IN MY LOWER BACK AND HAD AN X-RAY DONE. THE X-RAY TECH ASKED ME IF I HAD SURGERY ON MY LEFT SIDE. I SAID "NO", ONLY THE TUBAL. SHE SAID THERE WAS A SPLINT OR SOMETHING. AFTER MUCH WORRY AND RETRIEVED MEDICAL RECORDS, I H AVE DISCOVERED THAT THERE WAS A SPLINT OR SOMETHING. AFTER MUCH WORRY AND RETRIEVED MEDICAL RECORDS, I HAVE DISCOVERED THAT THERE IS AN "UNCOILED" ESSURE PRODUCT IN MY ABDOMEN. THIS EXPLAINS MY CONSTANT DISCOMFORT AND RECENT EXTREME PAIN, AS WELL AS THE WEIGHT GAIN, DEPRESSION, AND CHRONIC FATIGUE THAT I HAVE BEEN SUFFERING FROM. THERE IS A VERY GOOD CHANCE THAT MY BODY HAS SUFFERED FROM NICKEL/ TITANIUM ALLERGY AND HAS BEEN PERFORATED INTERNALLY. MY TUBAL WAS NOTED AS FAILED ESSURE, BECAUSE" THE THUMBWHEEL WAS ROTATED BACKWARDS AND SHEATH DID NOT RETRACT." AFTER SEVERAL ATTEMPTS MY DR. DECIDED TO PERFORM A LAPAROSCOPIC BILATERAL TUBAL USING BIPOLAR CAUTERY. IMAGINE MY SURPRISE TO FIND THAT I DO IN FACT HAVE A FAULTY ESSURE MIGRATING AROUND IN MY ABDOMEN, UNCOILED AND REEKING HAVOC. ALTHOUGH MY PROCEDURE WAS UNUSUAL, NO MATTER WHERE THE ESSURE IS PLACED IT CAN UNCOIL AND MIGRATE. THIS WAS NEVER DESCRIBED AS A POSSIBLE SIDE EFFECT. THIS PRODUCT IS EXTREMELY DANGEROUS AND SHOULD NEVER BE USED A PERMANENT BIRTH CONTROL VERSUS THE TRADITIONAL METHODS THAT DO NOT IMPLANT THE BODY WITH FAULTY METAL COILS.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01234	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3): 9/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D06940

Single Use: Y
Implant Date (E6): 9/28/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 28-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER D06940 INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION. THE PHYSICIAN REPORTED THAT IN OPERATING ROOM THERE WAS BASICALLY A SUSPECTED PERFORATION WITH FLUID OVERLOAD. PATIENT WAS UNDER ANESTHESIA AND 9 LITERS OF SALINE WERE INTRODUCED INTO HER. SHE HAD BREATHING ISSUES. THE PROBLEM WAS THAT THEY WERE HAVING A REAL PROBLEM WITH THEIR FLUID MANAGEMENT SYSTEM, THE NURSE DID NOT SEEM TO KNOW WHAT WAS GOING ON WITH THE FLUID INTAKE AND OUTPUT. BILATERAL PLACEMENT OF ESSURE WAS ACHIEVED AND AFTER PLACEMENT WAS INSERTED 14 GAUGE NEEDLE WITH CATHETER INTO PERITONEAL CAVITY UNDERNEATH CERVIX AND DRAINED OFF ABOUT 5 LITERS OF FLUID. THE FLUID WAS EVERYWHERE, ON THE DOCTOR, THE PATIENT AND THE FLOOR. THEY DID NOT VISUALLY SEE ANY TYPE OF PERFORATION BUT PATIENTS STOMACH WAS DISTENDED AND THEY DID NOT KNOW WHAT WAS GOING OUTPUT WISE. PATIENT WAS AWAKE AND FINE WHEN COMING OUT OF OPERATING ROOM WAS GOING TO BE OBSERVED FOR A FEW HOURS AND ELECTROLYTE TESTS WERE GOING TO BE DONE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT IN OPERATING ROOM, DURING ESSURE INSERTION, THERE WAS BASICALLY A SUSPECTED PERFORATION (INTERPRETED AS UTERINE PERFORATION) WITH FLUID OVERLOAD. SHE HAD BREATHING ISSUES. PATIENT'S STOMACH WAS DISTENDED. SUSPECTED PERFORATION IS LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE OTHER EVENTS ARE UNLISTED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, IT WAS NOT CONFIRMED WHETHER PERFORATION OCCURRED DURING

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ESSURE INSERTION. ALSO, THE REASON WHY THE PATIENT'S STOMACH WAS DISTENDED WAS UNKNOWN. AN INTERVENTION WAS PERFORMED AND ELECTROLYTE TESTS WERE GOING TO BE DONE. ALTHOUGH FURTHER DETAILS ARE PENDING, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO INTERVENTION REQUIRED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 16-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). THE UNIQUE IDENTIFIER NUMBER (UDI) IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE D

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01236	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/13/2014
Explant Date (E7): 9/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 11-SEP-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY WITH CONTRACEPTIVE DEVICE AND DEVICE INEFFECTIVE IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. PHYSICIAN REPORTED THAT THE PLACEMENT PROCEDURE REPORT DID NOT MENTION ANY PARTICULAR PLACEMENT PROBLEM. PLAIN ABDOMEN X-RAY OF CONTROL WAS OK. PATIENT EXPERIENCED PREGNANCY WITH CONTRACEPTIVE DEVICE AND HAD AN ELECTIVE ABORTION. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 29-SEP-2015 FROM PHYSICIAN: ESSURE WAS INSERTED ON (B)(6) 2014. THE PATIENT WAS 4 MONTHS POST-PARTUM AT TIME OF ESSURE INSERTION. PRIOR TO THE INSERTION NO ABNORMAL UTERINE FINDINGS WERE OBSERVED. THE PATIENT USED MINIPILL FROM (B)(6) 2014 AS ALTERNATIVE CONTRACEPTION AFTER ESSURE PLACEMENT. THE CONFIRMATION TEST WAS DONE BY X-RAY ON (B)(6) 2014 AND CONFIRMED TUBAL OCCLUSION. THE PATIENT WAS ADVISED BY THE DOCTOR TO RELY ON ESSURE BASED ON THE RESULT OF THE TEST. SHE BECAME PREGNANT AND THE PREGNANCY WAS CONFIRMED BY PHYSICIAN. PATIENT PLAN FOR PREGNANCY WAS TO CONTINUE THE PREGNANCY, BUT SHE HAD A SPONTANEOUS ABORTION. ESSURE WAS NOT IN SITU AFTER DIAGNOSIS OF PREGNANCY. ON (B)(6) 2015, ESSURE WAS REMOVED BY LAPAROSCOPY. THE REMOVAL PROCEDURE WAS MEDICALLY NECESSARY AND WAS ALSO REMOVED BECAUSE OF PATIENT REQUEST. DURING THE PROCEDURE, IT WAS OBSERVED THAT ESSURE ON RIGHT SIDE WAS IN UTERINE HORN AND MYOMETRIUM (UTERINE FUNDUS) AND THE COIL ON LEFT SIDE WAS WELL PLACED. NO PATHOLOGY RESULTS, NO SIGNS OF INFECTION OR INFLAMMATION WERE OBSERVED. CASE UPGRADED TO INCIDENT. FOLLOW UP INFORMATION RECEIVED FROM THE HEALTH AUTHORITIES IN (B)(6) ON 14-OCT-2015: NCA REFERENCE NUMBER (B)(4) WAS ADDED. NO OTHER NEW MEDICAL

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INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 15-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 16-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: EMBEDDED DEVICE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, GOT PREGNANT AND HAD A SPONTANEOUS ABORTION. ESSURE WAS NOT IN SITU AFTER THE DIAGNOSIS OF PREGNANCY; IT WAS REMOVED BY LAPAROSCOPY 15 MONTHS AFTER INSERTION AND THE RIGHT IMPLANT WAS FOUND IN UTERINE HORN AND MYOMETRIUM (INTERPRETED AS EMBEDDED DEVICE). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PREGNANCY AND DEVICE EMBEDDED ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE SPONTANEOUS ABORTION IS UNLISTED. IN THE PRESENT CASE, THE ONSET DATE OF PREGNANCY WAS NOT INFORMED. IT WAS REPORTED THAT ESSURE WAS NOT IN SITU AFTER DIAGNOSIS OF PREGNANCY (LATER IT WAS FOUND THAT RIGHT IMPLANT WAS EMBEDDED). HOWEVER, SINCE IT IS NOT KNOWN WHETHER ESSURE WAS EMBEDDED FIRST AND THE PREGNANCY FOLLOWED, OR WHETHER IT WAS IN PLACE DURING THE CONCEPTION AND EMBEDDED LATER, A CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. SPONTANEOUS ABORTION IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY. THIS IS CONSIDERED TO BE DUE TO A HIGH NUMBER OF ABNORMAL EMBRYOS PRESENTING WITH EITHER CHROMOSOMAL AND/OR GROSS MORPHOLOGICAL ABNORMALITIES. IN THIS CASE, THE GESTATIONAL AGE WAS NOT REPORTED. HOWEVER, GIVEN THE PATHOPHYSIOLOGY OF THE EVENT AND CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, THIS EVENT WAS ASSESSED AS UNRELATED TO THE INSERT. REGARDING EVENT DEVICE EMBEDDED, THE EXACT ONSET DATE WAS NOT REPORTED. CONFIRMATION TEST PERFORMED 3 MONTHS AFTER INSERTION SHOWED TUBAL OCCLUSION. AFTER THE PATIENT GOT PREGNANT IT WAS FOUND THAT ESSURE WAS NOT IN SITU. DURING LAPAROSCOPY THE RIGHT IMPLANT WAS FOUND IN UTERINE HORN AND MYOMETRIUM. CONSIDERING THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT DUE TO REQUIRED INTERVENTION (LAPAROSCOPY FOR ESSURE REMOVAL). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW UP INFORMATION RECEIVED ON 26-OCT-2015: PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS UPDATED. PTC GLOBAL NUMBER: (B)(4). NO MAJOR CHANGES. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01237	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 8/27/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 11-SEP-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. PHYSICIAN REPORTED THAT ESSURE HAD BEEN PLACED ONE YEAR PRIOR THIS REPORT IN ANOTHER HOSPITAL. THE PLACEMENT PROCEDURE REPORT DID NOT MENTION PLACEMENT PROBLEM. PLAIN ABDOMEN X-RAY OF CONTROL WAS OK. THE PATIENT EXPERIENCED PREGNANCY WITH CONTRACEPTIVE DEVICE AND THIS PREGNANCY ENDED BY SPONTANEOUS ABORTION. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED FROM THE GYNECOLOGIST ON 29-SEP-2015 (CASE UPGRADED TO INCIDENT): ESSURE WAS INSERTED IN (B)(6) 2013. NO ABNORMAL UTERINE FINDINGS PRIOR TO INSERTION. CONDOMS WERE USED AS ALTERNATIVE CONTRACEPTION AFTER ESSURE PLACEMENT. ESSURE CONFIRMATION TEST WAS DONE BY X-RAY IN (B)(6) 2013 AND (B)(6) 2014 AND SHOWED TUBAL OCCLUSION, SO PATIENT WAS ADVISED BY DOCTOR TO RELY ON ESSURE. PREGNANCY WAS CONFIRMED BY DOCTOR TWO YEARS LATER, IN 2015. PATIENT'S DECISION WAS TO TERMINATE THE PREGNANCY. ESSURE WAS NOT IN SITU AFTER DIAGNOSIS OF PREGNANCY. ESSURE WAS REMOVED ON (B)(6) 2015 BY LAPAROSCOPY BECAUSE OF PATIENT REQUEST. NO PATHOLOGY RESULTS, SIGNS OF INFECTION OR INFLAMMATION. RIGHT COIL WAS WELL PLACED AND LEFT COIL WAS IN THE UTERINE HORN, PRE-PERFORATION. NO OTHER NEW MEDICAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED FROM THE HEALTH AUTHORITIES IN (B)(6) ON 14-OCT-2015: NCA REFERENCE NUMBER (B)(4) WAS ADDED. NO OTHER NEW MEDICAL INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 15-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN

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INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 16-OCT-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: EMBEDDED DEVICE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS RETROSPECTIVE PREGNANCY CASE REPORT. IT REFERS TO (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED A PREGNANCY WITH CONTRACEPTIVE DEVICE AND HAD A SPONTANEOUS ABORTION. UPON FOLLOW UP INFORMATION, THE PHYSICIAN STATED THAT THE PATIENT'S DECISION WAS TO TERMINATE THE PREGNANCY (THEREFORE THE EVENT SPONTANEOUS ABORTION WAS DELETED). ALTHOUGH THE 2 ESSURE PREGNANCY TESTS BY X-RAY SHOWED CORRECT LOCALIZATION AND TUBAL OCCLUSION, DURING SURGERY FOR ESSURE REMOVAL, IT WAS NOTICED THAT THE LEFT COIL WAS IN THE UTERINE HORN, PRE-PERFORATION (INTERPRETED AS DEVICE EMBEDDED/PARTIAL PERFORATION). THE PREGNANCY WITH CONTRACEPTIVE DEVICE AND DEVICE EMBEDDED ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. BOTH EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS CASE, THE ELAPSED TIME BETWEEN THE ESSURE INSERTION AND THE PREGNANCY IS NOT KNOWN. THERE ARE NO DETAILS REGARDING ITS INSERTION. THEREFORE, THE CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. INITIALLY IT WAS REPORTED THAT A SPONTANEOUS ABORTION OCCURRED. HOWEVER, IN THE FOLLOW UP IT WAS INFORMED THAT HER DECISION WAS TO TERMINATE THE PREGNANCY. CONSIDERING THE NATURE OF A DEVICE EMBEDMENT AND THE LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 26-OCT-2015: PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION ASSESSMENT WAS UPDATED. PTC GLOBAL NUMBER: (B)(4). NO MAJOR CHANGES. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01238	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES VIA SOCIAL MEDIA ((B)(6)) AND RECEIVED BY BAYER ON 24-SEP-2015. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER WAS GETTING A HYSTERECTOMY IN 4 HOURS FROM THE TIME OF THE REPORT THANKS TO ESSURE. FOLLOW UP INFORMATION RECEIVED ON 25-SEP-2015: NO NEW INFORMATION FOLLOW-UP INFORMATION WAS RECEIVED ON 29-SEP-2015 AND CASE WAS UPGRADED TO INCIDENT: CONSUMER STATED THAT SINCE HER HYSTERECTOMY ON (B)(6), SHE HAS BEEN IN EXTREME PAIN. PTC INVESTIGATION RESULT WAS RECEIVED ON 04-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP INFORMATION RECEIVED ON 16-OCT-2015: PTC ASSESSMENT UPDATED WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED,

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SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD A HYSTERECTOMY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER RELATED THE PERFORMED SURGERY TO ESSURE; HOWEVER NEITHER THE ADVERSE EVENTS SHE EXPERIENCED WERE SPECIFIED NOR WAS THE EXACT MEDICAL REASON FOR THIS SURGERY PROVIDED. ALTHOUGH LIMITED INFORMATION IS AVAILABLE, IT CANNOT BE EXCLUDED THAT HYSTERECTOMY OCCURRED AS A CONSEQUENCE OF ESSURE THERAPY. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT; HOWEVER UPON RECEIPT OF FOLLOW-UP INFORMATION, HYSTERECTOMY WAS CONFIRMED. THEREFORE, CASE WAS UPGRADED TO INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01239	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3): 8/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/30/2009
Explant Date (E7): 9/24/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 29-SEP-2015. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 FOR PERMANENT CONTRACEPTION. ADDITIONAL INFORMATION RECEIVED ON 01-OCT-2015. THE PATIENT HAD AN ECTOPIC PREGNANCY ON (B)(6) 2013 (CURRENT CASE). SHE HAD ANOTHER PREGNANCY EPISODE ON (B)(6)2015 (LINKED CASE (B)(4)). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD A ECTOPIC PREGNANCY APPROXIMATELY 4 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN A PREGNANCY OCCURS AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. IN THIS PARTICULAR CASE; LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE SERIOUS INJURY REPORTED (ECTOPIC PREGNANCY). FOLLOW-UP INFORMATION AND A PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 19-OCT-2015: INFORMATION RECEIVED FROM PHYSICIAN CONFIRMED THAT PATIENT HAD A POSITIVE PREGNANCY TEST IN (B)(6) 2011, AN ECTOPIC PREGNANCY IN (B)(6) 2013 AND A TERM PREGNANCY THAT SHE DELIVERED IN (B)(6) 2015. COMPANY CAUSALITY COMME

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01241	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3): 10/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT, ANTICIPATED (SERIOUS INJURY) THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE CONSUMER VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON 29-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. THE CONSUMER STATED THAT SINCE APPROXIMATELY 1 MONTH AFTER INSERTION ((B)(6) 2014) SHE HAD SUFFERED FROM THE FOLLOWING SYMPTOMS: HAIR LOSS, PROLONGED HEAVY VAGINAL BLEEDING INCLUDING PASSING OF CLOTS (FOR WHICH MEDICAL INTERVENTION TOOK PLACE), SEVERE DEPRESSION (FOR WHICH MEDICAL INTERVENTION HAS TAKEN PLACE), CHRONIC LETHARGY, SEVERE MUSCLE PAIN THROUGHOUT BODY, CONSTANT PAIN IN ABDOMEN, INABILITY OF SHORT TERM MEMORY RECALL, BRAIN FOG, ACCIDENT-PRONE/SLOW RESPONSES. ESSURE WAS ONGOING AND A SCAN WAS PLANNED FOR (B)(6) 2015. SHE CONSIDERED THE EVENTS RELATED TO ESSURE. CORRECTION ON 05-OCT-2015 FOLLOWING COMPANY INTERNAL REVIEW BASED ON INFORMATION RECEIVED ON 29-SEP-2015: NCA NUMBER ADDED ((B)(4)). FOLLOW-UP FROM 21-OCT-2015: DESPITE THREE ATTEMPTS FOR FOLLOW-UP, NO RESPONSE WAS RECEIVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PROLONGED HEAVY VAGINAL BLEEDING INCLUDING PASSING CLOTS AND SEVERE DEPRESSION. BOTH EVENTS WERE CONSIDERED SERIOUS DUE THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS REPORTED THAT CONSUMER EXPERIENCED THESE EVENTS SINCE APPROXIMATELY 1 MONTH AFTER ESSURE INSERTION. IT WAS REPORTED BY THE CONSUMER THAT THESE EVENTS REQUIRED MEDICAL INTERVENTION. BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. ALTHOUGH THE TYPE OF THIS INTERVENTION WAS NOT SPECIFIED

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AND ESSURE WAS NOT REMOVED, THIS CASE WAS REGARDED AS INCIDENT IN LINE WITH HEALTH AUTHORITY'S ASSESSMENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. DESPITE FOLLOW-UP ATTEMPTS, NO FURTHER INFORMATION WAS OBTAINED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 28-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01242	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/4/2014
Explant Date (E7): 9/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 29-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION. THE PHYSICIAN SAID PLACEMENT WAS FINE, ESSURE WAS BEAUTIFULLY PLACED. PATIENT HAD A POST OPERATORY VISIT ON (B)(6) 2014 AND EVERYTHING WAS FINE. HSG (HYSTEROSALPINGOGRAM) ON (B)(6) 2014 SHOWED TUBES OCCLUDED. ABOUT 6 MONTHS IN PATIENT COMPLAINED OF SOME PELVIC PAIN. MRI (MAGNETIC RESONANCE IMAGING) AND ULTRASOUND DID NOT SHOW ANYTHING WRONG WITH ESSURE BUT PHYSICIAN SAID MEDIA DRIVEN INFORMATION CAUSED THE PATIENT TO HAVE COILS REMOVED. THE PHYSICIAN REMOVED COILS VIA SALPINGECTOMY ON (B)(6) 2015 BECAUSE THE PATIENT JUST WANTED THEM REMOVED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 16-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. NO SIMILAR AE CASES IDENTIFIED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A

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QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO EXPERIENCED SOME PELVIC PAIN 6 MONTHS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. PHYSICIAN PERFORMED A SALPINGECTOMY DUE TO PATIENT'S REQUEST. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, PHYSICIAN STATED ESSURE INSERTS WERE IN CORRECT POSITION, WITH TUBAL OCCLUSION. ADDITIONALLY, MRI AND ULTRASOUND SHOWED NOTHING WAS WRONG WITH THE DEVICE. ACCORDING TO HIM, THE COILS WERE REMOVED JUST BECAUSE PATIENT WANTED THEM REMOVED. ALTHOUGH NO PROBLEM WAS FOUND REGARDING ESSURE POSITION; CONSIDERING PATIENT EXPERIENCED PELVIC PAIN AND SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR THIS EVENT; COMPANY CONSIDERS CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS REQUIRED FOR DEVICE REMOVAL; THIS CASE WAS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 11-JAN-2016: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO EXPERIENCED SOME PELVIC PAIN 6 MONTHS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01243	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/29/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON 29-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015. NURSE REPORTED THAT A PATIENT HAD 6 COILS TRAILING FROM LEFT INSERT INTO THE UTERUS, WITH A STRING COMING OUT THROUGH THE CERVIX AND INTO HER VAGINAL CANAL. SHE WANTS TO KNOW HOW TO REMOVE IT. ACCORDING TO REPORTER, MEDICAL DOCTOR TRIED TO INSERT ON PATIENT'S LEFT SIDE; SHE MET SOME RESISTANCE BUT DEPLOYED. IN ADDITION, IT WAS REPORTED THAT THERE WERE SOME TRAILING COILS BUT INSERT HAD A METAL INSERT STICKING OUT WITHIN IT. AS DESCRIBED BY HEALTH CARE PROFESSIONAL, IT SOUNDS LIKE SHE WAS SEEING THE INNER COIL STICKING PAST THE OUTER COIL. SHE PULLED OUT THE INNER COIL AND NOW THERE ARE COILS LEFT AND SHE CANNOT GET THEM OUT. THE COILS WERE ANCHORED IN THE FALLOPIAN TUBE. MEDICAL DOCTOR ASKED ABOUT PLACING OTHER INSERT AND WAS ADVISED NOT TO DO IT UNTIL IT IS ASSESSED TO DETERMINE WHAT IS LEFT IN IT. SHE HAS NOT PLACED INSERT ON RIGHT SIDE. SHE HAD NO ACCESS TO X-RAY AT THAT TIME AND SAID SHE WILL DETERMINE NEXT STEPS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING THE PROCEDURE, PHYSICIAN SAW A STRING COMING OUT THROUGH THE CERVIX AND INTO THE VAGINAL CANAL. IT SOUNDED LIKE SHE WAS SEEING THE INNER COIL STICKING PAST THE OUTER COIL. THE PHYSICIAN PULLED OUT THE INNER COIL AND NOW THERE ARE COILS LEFT. THESE EVENTS WERE REGARDED AS A HANDLING ISSUE (ESSURE STRETCHED DURING THE PROCEDURE) FOLLOWED BY A POSSIBLE DEVICE BREAKAGE. ONLY DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT

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INSERTIONS. IN THIS PARTICULAR CASE, PHYSICIAN EXPERIENCED RESISTANCE TO PLACE ESSURE. THIS SUGGESTS A DIFFICULT INSERTION, WHICH MAY HAVE CONTRIBUTED FOR THE POSSIBLE DEVICE BREAKAGE. CONSIDERING THESE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED EVENTS DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

-RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THE E

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01244	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON 29-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. WHEN ATTEMPTING TO INSERT ESSURE DEVICE IT BROKE OFF INSIDE THE PATIENT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS HAVING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE BROKE OFF INSIDE THE PATIENT DURING THE PROCEDURE. THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. HOWEVER, SINCE THE BREAKAGE OCCURRED DURING THE ESSURE INSERTION PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP WAS RECEIVED ON 23-OCT-2015 WITH NO NEW INFORMATION, AND THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 31-OCT-2015, REFERRING TO PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01245	BAYER HEALTHCARE LLC	10/26/2015	10/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/14/2009
Explant Date (E7): 9/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5035131) IN UNITED STATES ON 09-APR-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE AND HEAVY BLEEDING, OVARIAN CYSTS, PELVIC AND BACK PAINS (MILD), LETHARGY, HAIR LOSS, WEIGHT GAIN, JOINT PAIN, MIGRAINES, BLOOD PRESSURE BEGAN INCREASING, DIZZINESS, UTERINE INFECTION, DECREASED LEVELS OF PROGESTERONE LEVELS, AND UTERUS TO BE QUITE INFLAMED. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION RECEIVED. ON (B)(6) 2009 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER BEGAN EXPERIENCING SEVERE AND HEAVY BLEEDING FOR EXTENDED TIME PERIODS AND WAS DIAGNOSED WITH OVARIAN CYSTS THAT WERE CYCLICAL WITH MENSTRUATION. THE DOCTOR PRESCRIBED BIRTH CONTROL PILLS. THE CONSUMER BEGAN HAVING PELVIC AND BACK PAINS (MILD) THAT WERE DISMISSED. A HYDRO-ABLATION WAS PERFORMED TO DECREASE THE AMOUNT OF BLEEDING. SHE EXPERIENCED SYMPTOMS OF LETHARGY, HAIR LOSS, WEIGHT GAIN, JOINT PAIN, MIGRAINES AND OTHER ISSUES. THE PELVIC AND BACK PAIN CONTINUED. THE CONSUMER'S BLOOD PRESSURE BEGAN INCREASING WITH NO APPARENT CAUSE. ON 2013, THE CONSUMER WAS TAKEN TO EMERGENCY ROOM WITH MIGRAINE AND DIZZINESS. CT (COMPUTERIZED TOMOGRAPHY) SCAN AND LUMBAR PUNCTURE SHOWED NO BRAIN BLEEDS AND NO APPARENT CAUSE FOR THE PAIN. A DOCTOR THOUGHT THE PATIENT WAS HAVING A UTERINE INFECTION AS A RESULT OF THE ABLATION (PERFORMED IN 2012). ANTIBIOTICS WERE PRESCRIBED AND CAUSED AN ALLERGIC REACTION. BLOOD TESTS SHOWED SLIGHTLY DECREASED LEVELS OF PROGESTERONE LEVELS, BUT ALL OTHER HORMONES WERE FINE. ULTRASOUND SHOWED UTERUS TO BE QUITE INFLAMED. PROGESTERONE CREAM WAS

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PRESCRIBED. CONSUMER HAD BEEN TAKING IT FOR A MONTH, BUT NONE OF THE ORIGINAL SYMPTOMS HAD CHANGED. ESSURE WAS ONGOING. NO OUTCOME WAS PROVIDED. THE CONSUMER ASKED THE DOCTOR THE POSSIBILITY OF ESSURE BEING THE CAUSE OF HER UNEXPLAINED SYMPTOMS. FU: RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 16-APR-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 15-APR-2014 FROM CONSUMER: CONSUMER INFORMATION WAS ADDED. THE CASE REFERS TO (B)(6) CONSUMER. THE CONSUMER INFORMED SHE WOULD RATHER NOT DISCUSS THIS BECAUSE OF ALL THE LITIGATION THAT WAS GOING ON AROUND THIS COMPLAINT UNTIL SHE CAN FIND OUT FROM A LEGAL STAND POINT WHAT SHE CAN PROVIDE AND WHAT SHE CANNOT. FOLLOW-UP INFORMATION RECEIVED ON 01-OCT-2015. CASE UPGRADED TO INCIDENT. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1385, AWARENESS DATE 01-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN (B)(6) 2009. IT WAS REPORTED THAT IT WAS TO BE A SIMPLE PROCEDURE IN OFFICE WITH LITTLE TO NO DOWNTIME. IN THE PAST SHE HAD TAKEN BIRTH CONTROL PILLS AND ALSO RECEIVED THE DEPO-PROVERA SHOT. ON THE MORNING OF THE PROCEDURE SHE WAS PRESCRIBED SOME PAIN MEDICATIONS AND A RELAXANT TO TAKE PRIOR TO ARRIVING AT THE OFFICE. A LOCAL ANESTHETIC WAS USED. THE FIRST COIL WAS PLACED WITHIN A FEW MINUTES BUT SHE EXPERIENCED A GREAT DEAL OF CRAMPING AND PAIN. WHEN IT CAME TIME FOR THE SECOND COIL, THE DOCTOR HAD DIFFICULTY INSERTING IT PROPERTY AND SHE EXPERIENCED EXTREME PAIN. THE CRAMPING PERSISTED FOR A FEW DAYS, BUT FINALLY SUBSIDED. SHE ALSO HAD SHARP SHOOTING PAINS IN ABDOMEN OR GROIN AREA THAT WERE WAVED OFF AS LIGAMENTS STRETCHING OR BEING PULLED. THE FIRST FEW MONTHS, HER MENSTRUAL CYCLE WAS FAIRLY NORMAL WITH SOME CRAMPING (SHE HAD NEVER EXPERIENCED MENSTRUAL CRAMPING EVER PRIOR TO HAVING ESSURE). THE AMOUNT OF BLOOD LOSS STEADILY INCREASED OVER TIME UNTIL IT WAS EXTREMELY HEAVY; HEAVY ENOUGH TO WARRANT A SUPER TAMPON AND A SUPER ABSORBENT PAD THAT SHE WOULD NEED TO CHANGE AT LEAST EVERY HOUR. WHEN SHE PRESENTED THIS TO ANOTHER DOCTOR IN THE PRACTICE, SHE WAS PRESCRIBED WITH BIRTH CONTROL PILLS. SHE TOOK THE PILLS FOR A WHILE. SHE WENT TO ANOTHER DOCTOR WHO WAS EMPATHETIC TO HER ISSUE AND AFTER SOME INITIAL TESTING TO MAKE SURE THE CAUSE OF THE EXCESSIVE BLEEDING WAS NOT HORMONAL, A HYDRO-ABLATION WAS PERFORMED. IMMEDIATELY AFTER THE ABLATION, HER MENSTRUAL CYCLES WERE VERY MINOR; MAYBE LASTING 3-4 DAYS AT MOST. SHE NO LONGER EXPERIENCED CRAMPS, BUT STILL HAD OCCASIONAL AND SUDDEN SHOOTS OF UNEXPLAINED PAINS. SHE EXPERIENCED SORES AND RASHES MAINLY ON HER FACE AND SCALP. ANA TESTS SHOWED INCREASED NUMBERS AND SHE WAS DIAGNOSED WITH DISCOID LUPUS. SHE BEGAN EXPERIENCING JOINT PAIN AND FATIGUE AND WAS REFERRED TO A RHEUMATOLOGIST. SINCE HAVING ESSURE, SHE GAINED OVER 40 POUNDS, EXPERIENCED HAIR LOSS, MEMORY LOSS, FATIGUE, ACHY OR SORE JOINTS, CHRONIC DEPRESSION, FREQUENT UTI'S, ANXIETY/PANIC ATTACKS, MIGRAINES AND GI ISSUES. IN EARLY 2015, ANOTHER ANA TEST WAS DONE AND THE DOCTOR CAME BACK WITH THE DIAGNOSIS OF SJOGREN'S DISEASE (EVEN THOUGH SHE DID NOT EXHIBIT THE 2 MAIN SYMPTOMS OF DRY EYE AND DRY MOUTH). SHE BEGAN EXPERIENCING IRREGULAR CYCLES THAT USUALLY CONSISTED OF A BLACKISH DISCHARGE WITH A

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VERY FOUL ODOR. SHE WENT TO ANOTHER DOCTOR WHO LISTENED HER AND AGREED THAT SEVERAL, IF NOT ALL HER SYMPTOMS, COULD BE A RESULT OF AN ALLERGY THAT COULD BE STEMMING FROM THE NICKEL PRESENT IN THE ESSURE COILS. THE MORE RECENT MENSTRUAL ISSUES SHE WAS EXPERIENCING COULD BE A RESULT OF THE ABLATION. ALTHOUGH HE WOULD NOT DIRECTLY SAY ESSURE WAS THE CAUSE, HE TOOK HER SYMPTOMS SERIOUSLY. SHE HAD A LAPAROSCOPIC HYSTERECTOMY WITH VAGINAL ASSISTED REMOVAL ON (B)(6) 2015. AFTER REMOVAL SHE WAS NOT EXPERIENCING A SINGLE UNEXPLAINED SHOOTING PAIN, HER STOMACH WAS NOT AS BLOATED AS IT WAS PRIOR TO THE HYSTERECTOMY AND SHE WAS NOT EXPERIENCING THE DULL ACHE IN HER JOINTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD SHARP SHOOTING PAINS IN ABDOMEN AND SEVERE AND HEAVY BLEEDING (EXCESSIVE MENSTRUAL FLOWS) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO AN ENDOMETRIAL ABLATION AND TREATED FOR A SUSPICION OF UTERINE INFECTION. THEN, SIX YEARS AFTER ESSURE PLACEMENT, SHE UNDERWENT A HYSTERECTOMY. ADDITIONALLY, SHE WAS DIAGNOSED WITH DISCOID LUPUS AND SJOGREN'S DISEASE. ONLY DISCOID LUPUS AND SJOGREN'S DISEASE ARE UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER'S PAIN AND BLEEDING STARTED IN CLOSE ASSOCIATION WITH ESSURE INSERTION. HER BLEEDING IMPROVED AFTER AN ENDOMETRIAL ABLATION AND THE PAIN RECOVERED WITH DEVICES REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING DISCOID LUPUS AND SJOGREN'S DISEASE; CONSIDERING THEY ARE CHRONIC AUTOIMMUNE INFLAMMATORY DISORDERS AND GIVEN ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY IS CONSIDERED VERY UNLIKELY. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT. HOWEVER, SINCE A HYSTERECTOMY WAS REPORTED UPON FOLLOW-UP, THE CASE WAS UPGRADED TO INCIDENT (DEVICE REMOVAL WAS REQUIRED). THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. THIS IS A POTENTIAL LEGAL CASE; FOLLOW-UP INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057504	BAYER	10/26/2015	10/29/2015

Event Information:

Event Date (B3): 1/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/2/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE LEFT UTERUS ON RIGHT SIDE, MIGRATED TO LOWER LEFT ABDOMINAL CAVITY. EXPERIENCED EXTREME PAIN MONTH AFTER IMPLANTATION, AND PAIN WITH INTERCOURSE SINCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057532	BAYER	10/26/2015	10/29/2015

Event Information:

Event Date (B3): 9/30/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/30/2013
Explant Date (E7): 12/30/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I WAS IMPLANTED WITH ESSURE IN (B)(6) 2013. ESSURE WAS RECOMMENDED BY MY OB AND APPROVED BY MY NEUROLOGIST, AS I HAVE A LONG HISTORY OF MIGRAINE I WANTED TO BE SURE THE PROCEDURE WOULD NOT INCREASE THE FREQUENCY, DURATION OR PAIN LEVEL OF THE MIGRAINES. SHORTLY AFTER THE PROCEDURE THE MIGRAINES DID ALL OF THE ABOVE. ON (B)(6) 2013 WAS THE DAY THE MIGRAINE WENT INTRACTABLE. I WAS HOSPITALIZED 3 TIMES IN 2013 TO TRY TO BREAK THE CYCLE BUT NONE OF THE TREATMENTS WERE SUCCESSFUL AND I REMAIN IN AN INTRACTABLE STATE TODAY, NOT EVEN ONE DAY WITHOUT A MIGRAINE FOR ALMOST TWO YEARS. IN ADDITION, I WAS DIAGNOSED WITH FIBROMYALGIA IN (B)(6) 2014 AND ENDOMETRIOSIS IN (B)(6) 2014. I WAS TREATED AT A LOCAL ER FOR UNDIAGNOSED LEFT FLANK PAIN IN (B)(6) 2014. I HAD A HYSTERECTOMY IN (B)(6) 2014 WHICH LEFT ME WITH ONLY MY RIGHT OVARY. I WAS UNABLE TO KEEP MY LEFT OVARY. I WAS LET GO FROM MY JOB IN (B)(6) 2014 DUE TO MY HEALTH. I HAD WORKED FOR THE COMPANY THE LAST 10 YEARS, THAT DOES NOT INCLUDE THE 3 YEARS I HAD WORKED FOR THE SAME COMPANY BEFORE MOVING OUT OF STATE FOR A YEAR. DESPITE REMOVAL OF ESSURE I REMAIN IN A STATE OF INTRACTABLE MIGRAINE WHICH MAY NEVER CHANGE AS THE LONGER I REMAIN IN THE STATE OF CHRONIC, DAILY, INTRACTABLE MIGRAINE THE LESS LIKELY TREATMENTS WILL BE ABLE TO BREAK THAT CYCLE, THOUGH I REMAIN HOPEFUL. NO MEDICATION HAS HELPED WITH THE TREATMENT OF FIBROMYALGIA AND DESPITE NEAR YEARLY PELVIC EXAMS, I HAD NEVER BEEN DIAGNOSED WITH ENDOMETRIOSIS PRIOR TO (B)(6) OF 2014. MY LIFE HAS CHANGED DRAMATICALLY SINCE I HAD THE ESSURE PROCEDURE. I RARELY DRIVE OR EVEN LEAVE MY HOUSE. I AM NO LONGER ABLE TO PLAN ANYTHING AS I NEVER KNOW HOW BAD THE PAIN WILL BE FROM ONE DAY TO THE NEXT. I HAVE LOST MY CAREER, FRIENDS, INDEPENDENCE AND MY ABILITY TO BE THE "GO TO" PERSON I ONCE WAS. I WENT WITH THE ESSURE PROCEDURE BECAUSE I WAS ASSURED THERE WOULD

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BE NO NEGATIVE IMPACT ON MY MIGRAINE STATUS. NOT ONLY DID I SUFFER FROM NEGATIVELY BUT AM NOW DIAGNOSED WITH TWO ADDITIONAL PAIN CREATING ILLNESSES. PLEASE DO NOT LET OTHER WOMEN BE AFFECTED AS I HAVE AND GET THIS PRODUCT PULLED FROM THE MARKET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057534	BAYER	10/26/2015	10/29/2015

Event Information:

Event Date (B3): 10/27/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627301

Single Use: *
Implant Date (E6): 10/27/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE SURGICALLY IMPLANTED IN (B)(6) 2008 IMMEDIATELY FOLLOWING I BEGAN TO GET PAIN THAT STARTED IN MY LEGS. IT FELT LIKE I HAD THE FLU IN MY LEGS. I WENT TO THE DOCTOR AND SHE RAN A SERIES OF TESTS BUT EVERYTHING CAME BACK NEGATIVE. OVER THE NEXT 6 AND HALF YEARS OF MY LIFE I WENT TO SPECIALIST AFTER SPECIALIST, I'VE SEEN DOCTOR AFTER DOCTOR AND NOT EVEN ONE DOCTOR COULD EXPLAIN MY WORSENING CONDITION. I SPENT HUNDREDS OF THOUSANDS OF DOLLARS ON MY ISSUE, TO NO AVAIL, NO ONE COULD EXPLAIN, DIAGNOSE OR FIX MY PAIN. I'M COMPLETELY HEALTHY ACCORDING TO ALL MY TESTS. SO I WENT TO A BACK DOCTOR, A CHIROPRACTOR BEGAN A SERIES OF SHOTS ETC. NOTHING HELPED AND MY CONDITION CONTINUED TO DETERIORATE AND WORSEN. TO DATE MY LIST OF SYMPTOMS ARE HEAVY BLEEDING, HOT FLASHES, HEAVY CRAMPING, PAINFUL INTERCOURSE, WEIGHT GAIN, BLOATING, MIGRAINE HEADACHES, INFLAMMATION, PAIN IN THE BUTTOCKS, BACK, LEGS, FEET AND THIGHS, HEART PALPITATIONS, LOW BLOOD PRESSURE, SKIN RASHES, HAIR LOSS, EXTREME FATIGUE, MY ARMS LOOSE BLOOD CIRCULATION. I'VE SEEN THE HEART DOCTOR AND HAD AN ANGIO GRAM AND MY HEART IS HEALTHY. DOCTORS TOLD ME THAT WHAT EVER I AM DEALING WITH THAT ITS NOT COMING FROM MY HEART. YEAR AFTER YEAR OF SUFFERING, NOT ONE DOCTOR WAS ABLE TO TELL ME WHY I'M IN PAIN? THEY LOOK AT ME AS IF I WANT PAIN MEDICATION OR LIKE I'M A HYPOCHONDRIAC. ITS BEEN HUMILIATING AND DIFFICULT BEYOND ANY WORDS. JUST RECENTLY I HAD AN MRI OF PELVIC REGION AND STUMBLED UPON MANY WOMAN SUFFERING THE SAME DEBILITATING SYMPTOMS AS MYSELF, FROM THE ESSURE. NOW I HAVE A FULL HYSTERECTOMY AS A RESULT BECAUSE I NOW ALSO HAVE LESIONS ON MY UTERUS. MY LIFE HAS NOT BEEN THE SAME AS A RESULT OF THIS IMPLANT. THE INFO GIVEN TO WOMEN OF POSSIBLE SIDE EFFECTS ARE NOT ACCURATE. WOMEN ARE NOT TOLD THE HALF OF WHAT CAN HAPPEN AS A RESULT OF THIS DEVICE NOR THE DOCTORS EDUCATED ENOUGH

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FOR THIS DEVICE TO BE ON THE MARKET. IF THEY WERE I MIGHT HAVE BEEN SAVED 6 YEARS OF MY LIFE. THE DOCTORS KNOW HOW TO PUT THE DEVICE IN BUT THEY DON'T KNOW HOW TO REMOVE OR DEAL WITH THE END RESULT. THESE SIDE EFFECTS ARE NOT JUST HEADACHE'S OR BACK ACHE'S OR BLOATING ETC. AS LISTED. THEY ARE LIFE THREATENING AND ALTERING. TO DATE EMERGENCY ROOMS DON'T EVEN KNOW HOW TO CHECK FOR THE POSITION OF THE COILS IF MOVEMENT OCCURS. OR PROPER REMOVAL OF THE COILS ETC. TESTING DONE AT (B)(6), I HAVE SEEN SEVERAL RHEUMATOLOGISTS, (B)(6) NEUROLOGISTS, DOCTOR (B)(6) ENDOCRINOLOGIST, DOCTOR (B)(6) HEART DOCTOR, (B)(6) GASTROENTEROLOGIST, (B)(6) ALL THE TESTING PROVED THAT NOTHING WAS WRONG WITH ME AND THEY DIDN'T HAVE ANSWERS FOR WHY I AM HAVING THE PAIN ETC. THESE TESTS AVAILABLE UPON REQUEST.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01246	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C61992

Single Use: Y
Implant Date (E6): 8/17/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C61992 (EXPIRATION DATE JUN-2017) INSERTED ON (B)(6) 2015. IT WAS REPORTED THE STEEL "STRAW" BROKE IN THE SHEATH OF THE HYSTEROSCOPE, THE EVENT OCCURRED IN THE OPERATING ROOM DURING THE PLACEMENT. THERE WAS NO CAUSE RELATED TO THE PATIENT WHICH COULD EXPLAIN THE EVENT. CONDITIONS OF THE PLACEMENT: NOTHING TO REPORT. BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER ESSURE SYSTEM. THE TIME OF THE PROCEDURE WAS LONGER AND MORE ANESTHESIA WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 19-OCT-2015: (B)(4). BATCH NUMBER C61992; PRODUCTION DATE 02-JUN-2014; EXPIRATION DATE 30-JUN-2017. FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE CATHETER AND /OR MICRO-INSERT AND INTRODUCER BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE IN THE CONTEXT OF A COMPLICATED INSERTION. HOWEVER, NO MEDICAL EVENTS HAVE BEEN REPORTED AT THIS POINT IN TIME. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. AT THIS POINT IN TIME NO MEDICAL EVENTS HAVE BEEN REPORTED. THEREFORE A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DURING THE PROCEDURE THE STEEL "STRAW" BROKE IN THE SHEATH OF THE HYSTEROSCOPE. BILATERAL PLACEMENT WAS ACHIEVED WITH ANOTHER ESSURE SYSTEM. THIS EVENT, REGARDED AS BREAKAGE OF ESSURE CATHETER, WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT. FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 28-OCT-2015 NCA NUMBER WAS RECEIVED (B)(4). FOLLOW-UP INFORMATION RECEIVED ON 19-NOV-2015: DESPITE THE FU ATTEMPTS, NO FURTHER INFORMATION WAS OBTAINED. CASE CLOSED. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01247	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NON-HEALTH PROFESSIONAL IN (B)(6) ON 30-SEP-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 BECAUSE SHE DID NOT WANT ANY MORE CHILDREN. ESSURE WAS IMPLANTED IN A HOSPITAL AND REMOVED IN 2013 VIA HYSTERECTOMY AFTER REPEATED INFECTION, CONSTANT ABDOMINAL INFLAMMATION AND CONTINUOUS BLEEDING. THE STOP DATE OF THE EVENTS WAS REPORTED AS 2013, AND THEY WERE CONSIDERED RELATED TO ESSURE. FOLLOW-UP INFORMATION RECEIVED ON 05-OCT-2015: INFORMATION REGARDING THE CONSUMER WAS PUBLISHED IN A (B)(6) DIGITAL PRESS. IT WAS REPORTED A PART OF THE COILS BROKE AND MOVED TO THE UTERUS AND A COMPLETE HYSTERECTOMY WAS NEEDED IN ORDER TO REMOVE THE METAL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REMOVED VIA HYSTERECTOMY AFTER REPEATED INFECTIONS, CONTINOUS BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND BECAUSE OF A PART OF THE COILS BROKE AND IT MOVED TO THE UTERUS. THE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. CONTINOUS BLEEDING IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE UNLISTED. ESSURE PLACEMENT CAN CAUSE INFECTION DUE TO A BACTERIAL CONTAMINATION DURING INSERTION. IN THIS CASE, IT WAS UNKNOWN THE EXACT LOCATION OF INFECTION. IT WAS ALSO UNKNOWN THE ONSET DATE OF THE EVENTS (UP TO 4 WEEKS POST INSERTION OR AFTER THIS PERIOD). ALSO, FOR DEVICE BREAKAGE, IT WAS NOT REPORTED WHETHER IT OCCURRED DURING ESSURE INSERTION. NEVERTHELESS, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS WITH SUSPECT INSERT

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CANNOT BE TOTALLY EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01248	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 01-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN REPORTED THAT RECENTLY, ESSURE WAS REMOVED FOLLOWING PERFORATION. FOLLOW UP INFORMATION RECEIVED ON 19-OCT-2015: (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND RECENTLY, HAD ESSURE REMOVED FOLLOWING PERFORATION. THIS EVENT, SEEN AS UTERINE PERFORATION, IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE USE. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS ONLY REPORTED THAT ESSURE WAS REMOVED FOLLOWING PERFORATION. ALTHOUGH THE EXACT DATE AND MECHANISM OF THIS PERFORATION HAVE NOT BEEN PROVIDED, CONSIDERING ITS NATURE, CAUSALITY BETWEEN REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 26-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01249	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A RADIOLOGIST TECHNICIAN IN UNITED STATES ON 30-SEP-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THAT THE PATIENT WAS HAVING AN MRI TO CHECK FOR PIECES OF THE COIL THAT WERE REMOVED AND POSSIBLY BROKEN. FOLLOW-UP INFORMATION RECEIVED ON 06-OCT-2015 FROM HEALTH PROFESSIONAL: THE PHYSICIAN CALLED JUST TO CHECK THE SPECIFICATIONS OF ESSURE AS FAR AS MRI MAGNET COMPATIBILITY BECAUSE WHEN SHE CALLED THE PREVIOUS TIME, THE PATIENT HAD SAID THAT HER ESSURE HAD BEEN REMOVED BUT SHE WAS NOT SURE IF ANY (ESSURE) WAS LEFT IN HER. THE REPORTING PHYSICIAN DID NOT KNOW WHO (HEALTH CARE PROFESSIONAL) REMOVED ESSURE AND DID NOT REMEMBER THE PATIENT'S NAME. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTS REMOVED AND WAS NOT SURE IF ANY (ESSURE) WAS LEFT IN HER (INTERPRETED AS SUSPICION OF DEVICE BREAKAGE). IN THIS PARTICULAR CASE, THE REASON FOR ESSURE COILS REMOVAL WAS NOT INFORMED. THE ESSURE REMOVAL IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND THE BREAKAGE IS NON-SERIOUS. THE ESSURE REMOVAL IS LISTED IN THE REFERENCE SAFETY INFORMATION AND SINCE IT WAS NOT INFORMED WHETHER BREAKAGE OCCURRED DURING INSERTION OR REMOVAL, IT WAS CONSIDERED AN UNLISTED EVENT. CONSIDERING THE NATURE OF THESE EVENTS, THE DEVICE REMOVAL AND DEVICE BREAKAGE WERE ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT. NO FURTHER INFORMATION IS EXPECTED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01250	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1165, AWARENESS DATE 01-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER HAD TO HAVE A HYSTERECTOMY AT (B)(6). SHE CONSIDERED IT RELATED TO ESSURE. FOLLOW UP INFORMATION RECEIVED ON 04-OCT-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1158). THE CONSUMER REPORTED ESSURE WRECKED HER LIFE AND TOOK HER WOMEN HOOD AT AGE (B)(6). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 16-OCT-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE HYSTERECTOMY AT (B)(6). THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE LIMITED INFORMATION WAS PROVIDED. IT WAS ONLY MENTIONED THAT THE CONSUMER HAD A HYSTERECTOMY AT (B)(6). IN SPITE OF LACK OF DATA, CAUSALITY BETWEEN THE REPORTED EVENT AND SUSPECTED INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01251	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2008
Explant Date (E7): 4/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1167, AWARENESS DATE 01-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. ESSURE WAS INSERTED AFTER THE BIRTH OF HER THIRD CHILD (C-SECTION). AT FIRST IT WAS FINE. THEN HER PERIODS GOT WORSE AND SHE STARTED PASSING CLOTS. THEN SHE STARTED WITH MIGRAINES ALL MONTH, WEIGHT GAIN AND JOINT PAIN AND PELVIC PAIN, SEVERE ANEMIA AND CONSTANT EXHAUSTION. IN (B)(6) 2011, A TOTAL HYSTERECTOMY WAS PERFORMED. SHE WOKE UP WITH NO MIGRAINE AND HAVEN'T HAD ONE SINCE REMOVAL. THE COIL HAD MIGRATED DESPITE PERFECT PLACEMENT AND VERIFICATION AT THREE MONTHS THE COIL WAS OUT OF THE TUBE AND PRESSING INTO THE LOP OF HER UTERUS. SHE STATED SHE WAS NEVER TOLD THE DEVICE HAD NICKEL. SHE IS ALLERGIC TO NICKEL. EVERY SYMPTOM LEFT AFTER REMOVAL. PTC INVESTIGATION RESULT RECEIVED ON 07-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED.

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THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A TOTAL HYSTERECTOMY. SHE STATED THE COIL HAD MIGRATED AND WAS OUT OF THE TUBE, PRESSING INTO THE LOP OF HER UTERUS. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION OR MIGRATION (WITHIN FALLOPIAN TUBE OR TO PERITONEAL CAVITY). IN THIS CASE, CONSUMER'S SYMPTOMS STARTED AFTER ESSURE PLACEMENT AND DISAPPEARED WITH DEVICES REMOVAL. THEREFORE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01252	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2011
Explant Date (E7): 7/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1139, AWARENESS DATE 01-OCT-2015). IT REFERS TO FEMALE CONSUMER ON UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED IN (B)(6) 2012 AND CONSUMER WAS TOLD SHE WAS 100% BLOCKED. IN (B)(6) 2013 SHE FOUND OUT SHE WAS PREGNANT. ON AN UNSPECIFIED DATE SHE MISCARRIED AND HAD A D&C (DILATATION AND CURETTAGE). SHE HAD HER TUBES TIED, EXPERIENCED BLEEDING BETWEEN PERIODS AND FINALLY IN (B)(6) 2014 SHE HAD A HYSTERECTOMY TO REMOVE ESSURE. PTC INVESTIGATION RESULT RECEIVED ON 17-OCT-2015. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) AND LACK OF EFFICACY IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING

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MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE BECAME PREGNANT ONE YEAR AFTER CONFIRMATION BY HYSTEROSALPINGOGRAM THAT TUBES WERE BLOCKED. SHE MISCARRIED AND HAD A DILATION AND CURETTAGE. SHE HAD HER TUBES TIED. SHE EXPERIENCED BLEEDING BETWEEN PERIODS (INTERPRETED AS METRORRHAGIA) AND FINALLY HAD A HYSTERECTOMY TO REMOVE ESSURE COILS. THE PREGNANCY WITH ESSURE, METRORRHAGIA AND MISCARRIAGE ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE PREGNANCY AND METRORRHAGIA ARE LISTED EVENTS WHILE THE MISCARRIAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, IT WAS NOT INFORMED IF ESSURE INSERTS WERE CORRECTLY PLACED BUT IT WAS STATED THAT TUBES WERE COMPLETELY BLOCKED. IN THIS CASE, SINCE THE PREGNANCY OCCURRED MORE THAN A YEAR AFTER ESSURE INSERTION A MISINTERPRETATION OF THE HSG MIGHT HAVE OCCURRED. THEREFORE, ESSURE CONTRACEPTIVE FAILURE CANNOT BE TOTALLY EXCLUDED AND ALL REPORTED EVENTS WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. IN CONTRAST, ALTHOUGH GESTATIONAL AGE HAS NOT BEEN PROVIDED, SPONTANEOUS ABORTIONS OCCUR MOSTLY DURING THE FIRST 12 WEEKS OF PREGNANCY AND THE VAST MAJORITY OF THESE CASES ARE DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS, SO THE MISCARRIAGE IS CONSIDERED AS UNRELATED TO ESSURE. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP BETWEEN THE METRORRHAGIA AND ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01253	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1408, AWARENESS DATE 01-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. CONSUMER REPORTED THAT PRIOR TO ESSURE SHE HAD NO HEALTH ISSUES. AS HISTORICAL CONDITION SHE HAD 3 SMALL KIDS. CONSUMER EXPERIENCED EXCESSIVE BLEEDING AND CRAMPING AFTER ESSURE, ALONG WITH MIGRAINES, WEIGHT GAIN AND BACK PAIN. ABLATION WAS PERFORMED TO CONTROL BLEEDING 6 MONTHS AFTER IMPLANTATION. THEN CONSUMER EXPERIENCED PAINFUL INTERCOURSE AND CYST DEVELOPED IN HER OVARIES. SHE WAS DIAGNOSED WITH ENDOMETRIOSIS CAUSING HER SEVERE PAIN WHEN OVULATING AND PAINFUL INTERCOURSE. SHE HAD HER RIGHT SIDE TUBE AND OVARY REMOVED. AFTER SECOND CHECK HER DOCTOR WANTED TO PERFORM A HYSTERECTOMY, BUT SHE CANNOT AFFORD IT, SO SHE STAYS IN PAIN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 16-OCT-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS

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EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED EXPERIENCING EXCESSIVE BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION) TO CONTROL THE BLEEDING, 6 MONTHS AFTER ESSURE INSERTION. SHE WAS ALSO DIAGNOSED WITH ENDOMETRIOSIS, AND HAD HER RIGHT TUBE AND OVARY REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. GENITAL BLEEDING IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE ENDOMETRIOSIS IS UNLISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE, THE CONSUMER ALSO HAD A DIAGNOSIS OF ENDOMETRIOSIS WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THE BLEEDING. HOWEVER, IT IS NOT CLEAR FROM THE INFORMATION PROVIDED WHETHER THE ENDOMETRIOSIS WAS ALREADY PRESENT WHEN SHE HAD THE BLEEDING. THEREFORE, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. ENDOMETRIOSIS ETIOLOGY IS LIKELY THE COMBINATION OF VARIOUS FACTORS INCLUDING RETROGRADE MENSTRUATION, IMMUNOLOGIC DYSFUNCTION, METAPLASTIC CONVERSION OF COELOMIC EPITHELIUM, AND REMNANT MULLERIAN CELLS. CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AND ESSURE LOCAL EFFECT IN THE FALLOPIAN TUBES, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND ENDOMETRIOSIS WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (ENDOMETRIAL ABLATION). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01254	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 FOR PERMANENT CONTRACEPTION. PATIENT WAS COMPLAINING OF PELVIC PAIN. AN ABLATION WAS PERFORMED. ESSURE WAS NOT REMOVED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON (B)(6) 2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. AN ABLATION WAS PERFORMED, BUT ESSURE WAS NOT REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY AND BASED ON THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE

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EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 11-JAN-16: DESPITE FOLLOW-UP ATTEMPTS, NO RESPONSE WAS GIVEN TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01255	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 01-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. HSG (HYSTEROSALPINGOGRAM) CONFIRMATION TEST WAS PERFORMED - ONE INSERT HAD PERFORATED THE TUBE AND TUBE WAS PATENT, CONTRALATERAL SIDE WAS OCCLUDED. SALPINGECTOMY WAS PERFORMED FOR CONTRACEPTION AND INSERT REMOVAL WAS SUCCESSFUL. FOLLOW-UP INFORMATION RECEIVED ON 05-OCT-2015: THE INITIAL RECEIPT DATE WAS CONFIRMED. FOLLOW-UP RECEIVED ON 16-OCT-2015: THE PTC (PRODUCT TECHNICAL COMPLAINT) INVESTIGATION RESULT WAS PROVIDED. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ONE INSERT HAD PERFORATED THE TUBE. A SALPINGECTOMY WAS PERFORMED FOR CONTRACEPTION AND

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INSERT REMOVAL WAS SUCCESSFUL. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF THE REPORTED EVENT WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE AND CONSIDERING THAT FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE) OR MOST OFTEN DURING INSERTION, A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 11-JAN-2016: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01256	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1426, AWARENESS DATE 01-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER WAS PUT UNDER WITH GENERAL ANESTHESIA IN AN OPERATING ROOM TO HAVE ESSURE IMPLANTED. AFTER YEARS OF UNEXPLAINED PAIN, BLOATING, AND RASHES, HER PHYSICIAN TOLD HER THAT IT WAS PROBABLY ESSURE THAT WAS CAUSING HER ISSUES. IN 2015, SHE WAS SUBMITTED TO A HYSTERECTOMY. AFTER SURGERY IT WAS FOUND OUT THAT ONE OF COILS BROKE. PART OF IT WAS IN HER TUBE AND THE REST OF IT WAS ATTACHED TO THE BACK OF UTERUS ALMOST POKING INTO BOWELS. SINCE HYSTERECTOMY BLOATING, PAIN, AND RASHES ARE ALMOST GONE. PTC INVESTIGATION RESULT RECEIVED ON 16-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY; AFTER WHICH IT WAS FOUND THAT ONE OF COILS BROKE. PART OF IT WAS IN HER TUBE AND THE REST OF IT WAS ATTACHED TO THE BACK OF UTERUS. DEVICE BREAKAGE IS UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION; WHILE THE OTHER EVENTS ARE LISTED. ABDOMINAL, PELVIC PAIN AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER STATED HER SYMPTOMS STARTED AFTER ESSURE INSERTION. ADDITIONALLY, ACCORDING TO HER, ESSURE BROKE AND PART OF IT BECAME ATTACHED TO HER UTERINE WALL. THIS COULD HAVE BEEN A CONTRIBUTORY ROLE IN CONSUMER'S PAIN. ALTHOUGH THE EXACT MECHANISM OF THE EVENTS IS UNKNOWN, CONSIDERING THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01257	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 10/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR VIA SALES REPRESENTATIVE IN UNITED STATES ON 02-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION. THE SALES REPRESENTATIVE REPORTED THAT SHOWED UP FOR AN ESSURE PROCEDURE ON (B)(6) 2015. THE SALES REPRESENTATIVE WAS TOLD IT WAS AN ESSURE REMOVAL. THE MEDICAL ASSISTANT ALSO SAID THAT THE PATIENT REQUESTED THAT HER ESSURE BE SAVED AND SENT BACK FOR ANALYSIS. IT WAS UNKNOWN IF ONE OR TWO COILS WERE REMOVED. NO ADDITIONAL DETAILS WERE PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED AN ESSURE REMOVAL. THIS EVENT, CONSIDERED AS DEVICE MEDICAL REMOVAL, WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THIS CASE WAS REPORTED WITH LIMITED INFORMATION. ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED; A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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INTERNAL CORRECTION FROM INFORMATION RECEIVED ON 16-OCT-2015 WAS PERFORMED ON 08-JAN-2016 AND ADDITIONAL INFORMATION WAS RECEIVED ON 07-JAN-2016: FOLLOWING INTERNAL REVIEW THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE ADDED: THIS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01258	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1393, AWARENESS DATE 01-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER STATED SHE WAS STILL IN PAIN AND HAD BEEN IN AND OUT OF THE HOSPITAL, TESTS WERE PERFORMED, PAIN MEDICATION WAS GIVEN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 16-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. NO SIMILAR AE CASES IDENTIFIED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION

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INSERT) INSERTED AND EXPERIENCED PAIN. SHE HAD BEEN IN AND OUT OF THE HOSPITAL. THIS EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON THE NATURE OF THE EVENT AND CONSIDERING THAT PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. ALTHOUGH THE DURATION OF HOSPITALIZATION IS UNKNOWN, THIS CASE WAS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01259	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1215, AWARENESS DATE 01-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER EXPERIENCED MIGRAINES, PELVIC PAIN, HAIR LOSS, DEPRESSION, AND SUICIDAL THOUGHTS. SHE TRIED MANY MEDICATIONS AND TREATMENTS AND NOTHING HELPED. SHE HAD ESSURE REMOVED BY HYSTERECTOMY AND ALL SYMPTOMS ARE GONE AND SHE WAS FEELING 100% BETTER AND PAIN FREE. PTC INVESTIGATION RESULT RECEIVED ON 16-OCT-2015. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) INSERTED AND HAD PELVIC PAIN AND DEPRESSION AND SUICIDAL THOUGHTS. SHE HAD ESSURE REMOVED BY HYSTERECTOMY AND ALL SYMPTOMS WERE GONE. PELVIC PAIN AND DEPRESSION SUICIDAL ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE PELVIC PAIN IS LISTED WHILE THE DEPRESSION SUICIDAL IS UNLISTED. ALTHOUGH THE TEMPORAL RELATIONSHIP IS COMPATIBLE FOR BOTH EVENTS, CONSIDERING THE NATURE OF THESE EVENTS AND LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, THE PELVIC PAIN WAS ASSESSED AS RELATED AND THE DEPRESSION SUICIDAL WAS ASSESSED AS UNLIKELY. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01260	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91740 AND B76538

Single Use: Y
Implant Date (E6): 9/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 02-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION (LOT NUMBERS C91740 WITH EXPIRATION DATE IN JUL-2017 AND B76538 WITH EXPIRATION DATE IN OCT-2016). THE PHYSICIAN REPORTED THAT WHILE INSERTING IN THE LEFT FALLOPIAN TUBE THE ESSURE WOULD NOT RELEASE AND THE TIP BROKE OFF AND COULD NOT BE PLACED. THE LAPAROSCOPIC TUBAL WAS PERFORMED IN THE LEFT FALLOPIAN TUBE AND ESSURE CONTINUED IN THE RIGHT FALLOPIAN TUBE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 16-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR LOT NUMBER B76538, THE EXPIRATION DATE IS 31-OCT-2016 AND THE PRODUCTION DATE IS 10-OCT-2013. FOR LOT NUMBER C91740, THE EXPIRATION DATE IS 31-JUL-2017 AND THE PRODUCTION DATE IS JUL-2014. FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU (INSTRUCTIONS FOR USE) STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-

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INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING AND DETACHMENT DIFFICULTY IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE (BREAKAGE) IN THE CONTEXT OF A COMPLICATED INSERTION. NO MEDICAL EVENTS WERE REPORTED. A REVIEW OF SIMILAR CASES FOR THIS BATCH IS NOT APPLICABLE AS NO MEDICAL EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP TO A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION AND WHILE INSERTING IN THE LEFT FALLOPIAN TUBE THE ESSURE WOULD NOT RELEASE AND THE TIP BROKE OFF AND COULD NOT PLACE. THE LAPAROSCOPIC TUBAL WAS PERFORMED IN THE LEFT FALLOPIAN TUBE AND ESSURE CONTINUED IN THE RIGHT FALLOPIAN TUBE. TIP BROKE OFF IS A NON-SERIOUS EVENT AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. CONSIDERING THE NATURE OF THIS EVENT AND THE LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN DEVICE BREAKAGE AND ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ALSO, THE ESSURE REMOVAL WAS PROBABLY PERFORMED AS AN ALTERNATIVE CONTRACEPTIVE METHOD AND NOT TO PREVENT A SERIOUS DETERIORATION IN HEALTH. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP TO A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 18-NOV-2015 FROM PHYSICIAN: ESSURE DEVICE BREAKAGE QUESTIONNAIRE WAS PROVIDED. PATIENTS DEMOGRAPHIC DATA WERE PROVIDED. IT WAS REPORTED THAT THE IMPLANT WOULD NOT RELEASE FROM THE CATHETER DURING PLACEMENT PROCEDURE. AS THE IMPLANT D

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01261	BAYER HEALTHCARE LLC	10/27/2015	10/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN SPAIN ON 02-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THIS CASE WAS PUBLISHED IN (B)(6) DIGITAL PRESS. PREGNANCY AND SALPINGECTOMY WERE REPORTED. AFTER HAVING IT IMPLANTED, CONSUMER BECAME PREGNANT AND HAD TO HAVE CURETTAGE AND THEN A SURGERY TO REMOVE THE TUBES. ONE OF THE COILS CAME OUT BUT THE OTHER DID NOT. IT NEVER APPEARED. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED RETROSPECTIVE PREGNANCY SPONTANEOUS CASE REPORT. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT. SHE HAD TO HAVE CURETTAGE AND SURGERY TO REMOVE THE TUBES (INTERPRETED AS SALPINGECTOMY). ONE OF THE COILS CAME OUT BUT THE OTHER NEVER APPEARED (INTERPRETED AS DEVICE DISLOCATION). THE PREGNANCY WITH DEVICE, UNSPECIFIED CURETTAGE, SALPINGECTOMY AND DEVICE DISLOCATION ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE PREGNANCY, SALPINGECTOMY AND DEVICE DISLOCATION ARE LISTED WHILE THE CURETTAGE IS UNLISTED. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. THE ELAPSED TIME BETWEEN THE ESSURE INSERTION AND THE PREGNANCY IS NOT KNOWN. THERE ARE NO DETAILS REGARDING ITS INSERTION, IT WAS ONLY INFORMED THAT DURING SALPINGECTOMY ONE OF THE COILS WAS FOUND BUT THE OTHER NEVER APPEARED. ALTHOUGH THE LOCALIZATION OF ONE ESSURE COIL WAS NOT KNOWN, IT IS NOT POSSIBLE TO EXCLUDE AN ESSURE CONTRACEPTIVE FAILURE. ALSO, CURETTAGE FOR AN UNSPECIFIED REASON WAS REPORTED, DUE TO THE LACK OF INFORMATION, IT IS NOT POSSIBLE TO ASSESS THIS EVENT AT THIS TIME. GIVEN THE NATURE OF A DEVICE DISLOCATION AND SALPINGECTOMY, THESE

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EVENTS ARE ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057323	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A HYSTERECTOMY ON (B)(6). MY UTERUS, CERVIX AND FALLOPIAN TUBE WERE REMOVED ALONG WITH THE ESSURE DEVICES. I AM 5 DAYS POST OP RECUPERATING FROM SUCH HORRIFIC EXPERIENCE. STILL HAVING TO CARE FOR 4 SPECIAL NEEDS CHILDREN AND MY HUSBAND BEING THE ONLY PROVIDER. I CANNOT SAY HOW MY HEALTH IS YET BECAUSE I STILL DO NOT FEEL A REMARKABLE DIFFERENCE. I STILL EXPERIENCE PAIN FROM THE SURGERY WHICH I'M SURE IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057324	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 10/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN MANAGEMENT DOCTOR DIAGNOSED ME WITH LUMBAR SPONDYLOSIS, I HAVE TO START PHYSICAL THERAPY, WEAR A BACK BRACE, GET INJECTIONS. I'VE BEEN ALSO DIAGNOSED WITH FYBROMAYALGIA, RESTLESS LEG SYNDROME,IRRITABLE BOWEL SYNDROME, DEPRESSION, ANXIETY, MIGRAINES AND PANIC ATTACKS SINCE HAVING ESSURE REMOVED BY HYSTERECTOMY IN (B)(6) 2014.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057325	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 1/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BY (B)(6) OF THAT YEAR THAT I WAS IMPLANTED WITH ESSURE - OF 2011 I HAD STARTED GETTING REALLY BAD HEADACHES, I HAD STARTED HAVING RIGHT SIDE PAIN, WAS SENT FOR ULTRASOUNDS, COLONOSCOPY, CAT SCAN, I HAVE HAD BLADDER ISSUES, CHANGES IN MY MENSTRUAL CYCLE, AUTO IMMUNE ISSUES, BACK ISSUES, MENTAL ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057326	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 6/14/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN PERFORMING THE HSG THE DOCTOR HAD TO BREAK THROUGH SCAR TISSUE THAT HAD FORMED ON MY CERVIX DUE TO THE ABLATION. IT WAS PAINFUL AT BEST AND WAS TOLD THEY WERE IN PLACE. HOWEVER, MY THYROID FUNCTIONING HAD GOTTEN WORSE, I HAVE EXTREME JOINT AND BACK PAIN. PAIN IN MY PELVIC REGION AS WELL AS A VIBRATION FEELING ON MY RIGHT SIDE. MY HEADACHES GOT PROGRESSIVELY WORSE TO THE POINT OF IMATREX PRESCRIPTION WHICH IS (B)(6) FOR 9 PILLS. I HAVE SINCE LOST THE DESIRE TO BE INTIMATE WITH MY PARTNER, SCOLIOSIS HAS ADVANCED RAPIDLY OVER THE COURSE OF HAVING THIS, MY VISION HAS GOTTEN PROGRESSIVELY WORSE, MY VITAMIN D LEVEL HAS DROPPED TO 16 AS RECENTLY AS A YEAR AGO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057327	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 8/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM A PATIENT THAT HAS HAD ESSURE SINCE(B)(6) 2014. MY INSURANCE COVERED THIS PROCEDURE FULLY. AT THE MOMENT I HAVE STRONG PELVIC PAINS AND LEG PAINS BECAUSE OF THIS PROCEDURE. I ALSO HAVE HAD SIGNIFICANT MEMORY LOSS AND AN INCREASE IN HEADACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057328	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, MIGRAINES, BRAIN FOG, DEPRESSION, ANXIETY, UNEXPLAINED SKIN RASHES ON FACE AND NECK. PAINFUL INTERCOURSE, RESTLESS LEG SYNDROME, RINGING IN EARS, HEART PALPITATIONS, INSOMNIA, FATIGUE, EXCESSIVE SWEATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057329	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 5/4/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I AM SUFFERING FROM CONTINUES HEADACHE, FEEL BLOATED, HAIR IS FALLING, BACK PAIN, TIRED AND SLEEPY AND MY PERIOD LAST TOO LONG...THE PROCEDURE WAS COVERED THROUGH MY MEDICAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057330	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 11/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN HAVING RASHES AND BECAME UNCONTROLLABLY ITCHY. THE DIAGNOSIS WAS AN ALLERGY TO SOMETHING IN MY BODY. I HAVE BECOME INCREASINGLY FATIGUED, AND BEGAN HAVING UNEXPLAINED PAINS. ALL STARTED AFTER ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057331	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 10/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) 2015 AND HAD IMMEDIATE PELVIC PAIN AND CRAMPING AFTER THE PROCEDURE THAT DID NOT STOP UNTIL THE DEVICE WAS REMOVED. I DEVELOPED AN ALLERGIC REACTION TO THE NICKEL IN THE DEVICE AND BROKE OUT IN ITCHY HIVES THAT WOULD BLISTER-MOSTLY ON HANDS, ARMS, AND FEET, MY HAIR BEGAN BREAKING OFF AND FALLING OUT, FATIGUE, JOINT PAIN, SHARP INCREASE IN DEPRESSION AND ANXIETY SYMPTOMS, IRREGULAR BLEEDING/MENSTRUAL CYCLES, PAIN AND BLEEDING DURING INTERCOURSE. I RETURNED TO MY GYNECOLOGIST WHO IMPLANTED THE ESSURE DEVICE IN MID (B)(6) 2015 WITH THESE COMPLAINTS AND WE BOTH FELT THAT I WAS HAVING AN ALLERGIC REACTION AND THE DEVICE HAD TO BE REMOVED. I HAD TO HAVE A PARTIAL VAGINAL HYSTERECTOMY ON (B)(6) 2015 TO REMOVE THE ESSURE DEVICE DUE TO THE SEVERITY OF THESE SYMPTOMS AFFECTING MY QUALITY OF LIFE, LEAVING THE LEFT OVARY AND PART OF THE RIGHT OVARY ONLY. IMMEDIATELY POST OP I WAS IN SEVERE PAIN - DISCOVERED 24 HOURS POST OP THAT I HAD HEMORRHAGED INTO MY ABDOMINAL CAVITY AND WAS SEVERELY ANEMIC AND NEEDED A BLOOD TRANSFUSION. I WAS HOSPITALIZED FOR 2 NIGHTS AND DISCHARGED HOME WITH A LARGE BLOOD CLOT IN MY ABDOMEN FROM THE BLEEDING LOOKING HEAVILY PREGNANT, SUFFERING FROM SEVERE PAIN AND BLOATING FOR 7 DAYS UNTIL THE LARGE CLOT DISSOLVED AND WAS EXPELLED FROM MY BODY THROUGH MY VAGINA FOR 7 MORE DAYS. WAS DIAGNOSED WITH AN ABDOMINAL INFECTION FROM THE BLOOD CLOT AND TOOK A 7 DAY COURSE OF 2 ORAL ANTIBIOTICS. RETURNED TO MY DOCTOR 10 DAYS LATER WITH WORSENING PAIN AND SYMPTOMS OF INFECTION AND STARTED A 10 DAY COURSE OF 2 MORE DIFFERENT ORAL ANTIBIOTICS. AFTER 5 DAYS I CALLED MY DOCTOR COMPLAINING OF WORSENING PAIN AND SYMPTOMS OF WORSENING SYSTEMIC INFECTION AND WAS ADVISED TO GO TO THE ER WHERE IT WAS DISCOVERED I HAD A MODERATE SIZED PELVIC ABSCESS AND READMITTED TO THE HOSPITAL

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FOR IV ANTIBIOTICS BECAUSE THE ABSCESS WAS INACCESSIBLE FOR DRAINAGE THROUGH INTERVENTIONAL RADIOLOGY AND WAS LOCATED ON AN ARTERY AND INVOLVED THE BOWEL AND BLADDER SO THAT MADE SURGERY TO DRAIN THE ABSCESS RISKY SO I HAD TO HAVE A PICC LINE PLACED TO CONTINUE IV ANTIBIOTICS AT HOME FOR 14 MORE DAYS AFTER BEING HOSPITALIZED FOR 3 DAYS. I WAS IN SEVERE PAIN AND ILL FOR 8 FULL WEEKS DUE TO COMPLICATIONS, TAKING MULTIPLE MEDICATIONS, AND TRYING TO CARE FOR 5 CHILDREN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057332	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INTENSE ABDOMINAL PAIN. SEVERE HEADACHES, CONSTANT NAUSEA, BODY TINGLES/NUMBNESS, BLURRY VISION, METALLIC TASTE IN MOUTH, RINGING IN EARS WITH MOMENTS OF COMPLETE HEARING LOSS. BRAIN FOG AND HIGH ANXIETY, MAJOR BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057333	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 2/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN. HEAVY BLEEDING. IRREGULAR PERIODS. BODY ACHE. HEAD ACHE. FLOATER LEFT EYE. LOWER BACK PAIN. BLOATING... VITAMIN DEFICIENCY B12 AND D. FREQUENT LOSE BOWEL MOVEMENTS. PUT IN (B)(6) 2012 HAD HSG (B)(6) 2013 MY REGULAR OB PUT DEVICE IN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057334	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 10/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER GETTING THIS DEVICE, I STARTED TO BLEED FOR TWO WEEKS-THREE WEEKS AT A TIME(MENSTRATION). I STARTED HAVING BACKPAIN, LOWER PELVIC PAIN ESPECIALLY ON THE RIGHT SIDE, INABILITY TO THINK PROPERLY, NUMBNESS IN MY LIMBS, AND JOINT PAIN. THERE WERE DAYS WHEN I COULDN'T WALK. I WAS ALWAYS TIRED AND FATIGUED. I MISSED A LOT OF DAYS AT WORK BECAUSE OF THIS. I ENDED UP HAVING TO GET S HYSTERECTOMY TO REMOVED THE COILS BECAUSE THE COIL PERFORATED MY UTERUS. THE COILS CREATED WAY TOO MUCH SCAR TISSUE WHICH CAUSED MY RIGHT OVARY TO STICK TO MY UTERUS SO IT HAD TO BE REMOVED TOO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057335	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 11/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNFORTUNATELY, I DID NOT SUBMIT ALL OF MY SIDE EFFECTS OF ESSURE DUE TO AN EDITING ERROR ON MY PART. PLEASE ACCEPT MY FOLLOW UP REMARKS. SINCE I HAD MY PROCEDURE, I HAVE GAINED APPROXIMATELY 50 POUNDS. I HAVE A VERY PHYSICALLY DEMANDING JOB, A JOB I CAN BARELY DO AT TIMES BECAUSE OF EXTREME EXHAUSTION; SOMETHING I HAVE NEVER SUFFERED FROM. PREVIOUSLY I RAN 6+ MILES A DAY, TODAY I DO GOOD TO WALK 6 MILES A WEEK. I WILL SAY, MY SEVERE PROBLEMS DID NOT START UNTIL ALMOST 3 YEARS AFTER MY PROCEDURE. THE MIGRAINES, OVARIAN CYSTS, VERTIGO, UNCONTROLLED BLOOD SUGAR, STOMACH ISSUES AND WORST OF ALL THE STROKE LIKE SLURRED SPEECH; DID NOT START UNTIL (B)(6) 2014 FOR ME PERSONALLY. MY HEALTH "CRISIS" IN THE YEAR HAS TAKEN A TOLL ON MY FAMILY AND CAREER. I AM LUCKY, I HAVE UNDERSTANDING PEOPLE IN MY LIFE WHO HAVE BEEN THERE FOR ME. WHEN I LEARNED ABOUT THE PROBLEMS WITH ESSURE JUST WEEKS AGO, IT WAS MY SUPPORT TEAM THAT DID THE RESEARCH AND CONNECTED THE DOTS. IN FACT: WHEN I WAS IMPLANTED I NEVER RECEIVED A 'CARD' WARNING ABOUT MRI/CT IMAGING, I'VE HAD NO LESS THAN 5 IN THE PAST YEAR. WHEN I CALLED MY OB/GYN LETTING HER KNOW I HAD THE ESSURE, SHE ALSO KNEW MY HISTORY, SHE IMMEDIATELY HAD ME IN AND SCHEDULED ANOTHER ULTRASOUND. I WAS NEVER ASKED/TOLD THAT THIS DEVICE WAS MADE OF NICKEL, OR ASKED IF I WAS ALLERGIC TO NICKEL. I AM ALLERGIC TO THE NICKEL IN JEWELRY, SAY WHAT YOU WILL, BUT ON THE PERIODIC TABLE OF ELEMENTS THERE'S ONLY ONE NICKEL LISTED. AFTER HAVING THE ESSURE, I HAVE HAD MORE DENTAL PROCEDURES THAN I CARE TO EXPLAIN AND NEED TO HAVE MUCH MORE DONE. I AM CONSTANTLY HAVING ABSCESSED TEETH AND HAVE EVEN HAD TEETH BREAK. PRIOR TO THE ESSURE, I DID USE AMBIEN TO SLEEP WHEN NEEDED. NOW I HAVE INSOMNIA THAT RULES MY NIGHT ALONG SIDE RESTLESS LEG SYNDROME. BOTH OF WHICH I DID NOT HAVE PREVIOUSLY. FINALLY, THIS DEVICE HAS CAUSED ME TO HAVE

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INCREASED MENSTRUAL CYCLES, INCREASED PMS, AND WHAT I CAN RELATE TO A FEELING OF A CELL PHONE RINGING IN YOUR POCKET. AT TIMES IT FEELS AS IF MY CELL PHONE IS RINGING IN MY POCKET, I CHECK IT, BUT IT IS NOT THERE. ALSO, IT HAS HAPPENED IN PLACES LIKE MY SHOULDER OR NECK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057336	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 2/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY HEALTH BEGAN TO SLOWLY DECLINE. BEGAN WITH HIGH BLOOD PRESSURE AND THEN UNFOLDED INTO SEVERAL ISSUES. UPON REMOVAL OF MY UTERUS FROM ALL THE DISCOMFORT I'VE HAD THE DOCTOR ACKNOWLEDGED THAT 1 OF THE COILS HAD MIGRATED INTO THE UTERUS AND I ALSO DEVELOPED ENDOMETRIOSIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057337	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 5/31/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I IMMEDIATELY BEGAN HAVING PROBLEMS. BUT WAS TOLD IT WAS MY AGE, MY WEIGHT (WHICH BEGAN AN ISSUE RIGHT AFTER ESSURE) MY JOB, MY STRESS. NO ONE WOULD EVER SAY IT WAS THE COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057340	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 4/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT (B)(6) YEARS OLD I HAD ESSURE COILS PUT IN. ALMOST INSTANTLY I BEGAN TO CRAMP, DOUBLE OVER, CAN'T MOVE CRAMPING. APPOINTMENT AFTER APPOINTMENT, I KEPT BEING TOLD IT WILL GO AWAY. I WAS PUT ON 800MG IBUPROFEN AND 750MG HYDROCODONE FOR THE PAIN AND SENT HOME. BUT, THE PAIN PROGRESSIVELY KEPT GETTING WORSE. 12 WEEKS LATER. ON (B)(6) 2012 I WENT TO SEE THE RADIOLOGIST WHO DID THE DIE TEST TO CHECK THE ESSURE PLACEMENT AND TO SEE IF THE SCAR TISSUE HAD FULLY FORMED. LATE THAT NIGHT, I RECEIVED A PHONE CALL FROM MY OB, WHICH SAID THE RADIOLOGIST FOUND A TEAR IN MY FALLOPIAN TUBE AND THEY WANTED ME TO HAVE SURGERY IMMEDIATELY TO REMOVE THE FALLOPIAN TUBES. THE NEXT DAY (B)(6) 2012 I WENT IN FOR SURGERY, DURING THE SURGERY, THEY FOUND THAT THE ESSURE HAD PUNCTURED MY UTERUS AND THEY WERE UNABLE TO REMOVE THE COILS, AS THEY WOULD HAVE TO REMOVE MY UTERUS. CRAMPING STILL CONTINUED AND I WAS TOLD THAT THE CRAMPING WAS PROBABLY FROM THE HOLE IN MY FALLOPIAN TUBE AND NEED TO WAIT 8-10 WEEKS BEFORE WE CAN DO ANYTHING, AS I NEED TO HEAL FROM SURGERY. ON (B)(6) 2012 I HAD A HYSTERECTOMY AND HAD MY UTERUS AND THE COILS THAT WERE LODGED IN MY UTERUS REMOVED. BESIDES THE PAIN FROM SURGERY, I WAS INSTANTLY CRAMP FREE. BUT IT DIDN'T STOP HERE. IN (B)(6) OF THIS YEAR (2015), I WAS IN THE SHOWER AND FELT PRESSURE, LOTS OF IT, IT FELT LIKE I WAS HAVING A BABY, THE PRESSURE WAS SO MUCH AND PAINFUL. I WENT TO THE OB AND FOUND OUT THAT HAD A RECTAL PROLAPSE. I WAS TOLD MANY WOMEN EXPERIENCE THIS AFTER HYSTERECTOMIES (I WOULDN'T HAVE EVER HAD TO HAVE ONE IF IT WEREN'T FOR THE ESSURE). SO BACK ONTO THE SURGICAL TABLE I WENT, AS IT WAS SEVERE ENOUGH THAT IT REQUIRED SURGERY TO REPAIR THE PROLAPSE. I DIDN'T SIGN UP FOR THIS, ALL I WANTED WAS

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A PERMANENT BIRTH CONTROL, I DIDN'T WANT TO HAVE TO GO THROUGH MONTHS AND MONTHS OF PAIN, 3 MAJOR SURGERIES AND A HANDFUL OF (B)(6) DOLLARS OF SERIOUS MEDICAL BILLS TO MAKE THIS HAPPEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057341	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE PROCEDURE DONE AFTER MY 3RD CHILD WAS BORN. AT FIRST I HAD NO PROBLEMS, THE (B)(6) 2014 I STARTED HAVE BAD BACK PAIN, HORRIBLE PELVIC/STOMACH PAIN. I'M HAVING OTHER STOMACH TROUBLE FROM THIS PROCEDURE. I HAVE NEVER HAD ANY HEALTH PROBLEMS BEFORE THIS. I WANT THEM OUT, BUT CAN'T AFFORD IT. I WANT MY LIFE BACK, I HURT SO BAD. IT MAKES IT HARD TO ENJOY LIFE WITH MY FAMILY WHEN I'M HURTING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057342	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, PAIN IN THE ABDOMEN. EVENTUALLY PARASTHESIA, VOMITING, PAIN IN MY ARMS AND LEGS, DIZZINESS AND BRAIN FOG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057343	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 1/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC DAILY HEADACHES, DIMINISHING MEMORY AND CONCENTRATION, NIGHT SWEATS, JOINT PAIN AND DETERIORATION, AUTOIMMUNE DISEASES, HAIR FALLING OUT, BLEEDING GUMS, INTERMITTENT RIGHT SIDE PELVIC PAIN, BLOATING, ANXIETY, CLAUSTROPHOBIA, ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057344	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 9/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS PROCEDURE WAS COVERED BY MY INSURANCE. I HAD IT PLACED IN (B)(6) AND IMMEDIATELY FOLLOWING THE PROCEDURE, I FELT PAIN AND DISCOMFORT. I REMEMBER GOING BACK TO A FOLLOWUP VISIT COMPLAINING OF MY BAD BODY ACHES, HEADACHES AND ITCH. I WAS TOLD BY MY OBGYN THAT THE SYMPTOMS I HAD WERE UN RELATED. I WENT TO SEE MY GP AND SHE HAD NEVER HEARD OF ESSURE AND DID VARIOUS TEST, LIME, MS AND FINALLY DIAGNOSED ME WITH FIBROMYALGIA. I DEAL WITH HEAVY BLEEDING , HEADACHES, JOINT PAIN, TIREDNESS, BLOATING, EVERYDAY. I AM ON SAVELLA AND THE MEDICINE IS NOT HELPING TREAT MY SYMPTOMS. I AM IN CONSTANT PAIN EVERYDAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057345	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 1/5/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS NEVER ASKED IF I HAD OR HAVE AM ALLERGY TO NICKEL..I AM! MY SKIN BREAKS OUT IN BOILS/RASHES..BURNS AND BLEEDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057346	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HERE IS A LIST OF SYMPTOMS I HAVE EXPERIENCED OR SOUGHT MEDICAL ASSISTANCE FOR SINCE ESSURE WAS IMPLANTED IN (B)(6) 2010. THESE ARE ONLY WHAT I KNOW I HAVE OR HAVE EXPERIENCED, SINCE I HAVE BEEN UNABLE TO ACQUIRE PROPER MEDICAL CARE. MY SYMPTOMS STARTED WITH GYNECOLOGICAL SYMPTOMS AND COMPILED THEMSELVES OVER THE PAST FIVE YEARS. I BEGAN HAVING SO MUCH DISCHARGE, IT WAS AS IF I WAS CONSTANTLY LEAKING URINE BUT WHEN I WENT TO WIPE IT WAS MORE MUCUS LIKE. IT BECAME SO BAD THAT MY LABIA MAJORA SPLIT LIKE CHAPPED LIPS IN WINTER AT THE APEX (TOP). KNOWN SIDE EFFECTS CONTINUED: GYNECOLOGICAL, CRAMPING, SHARP/STABBING PELVIC PAIN, ABNORMAL MENSES, DISCHARGE (CLEAR, NO ODOR), HOT FLASHES, EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), PAINFUL OVULATION (MITTELSCHMERZ), NIGHT SWEATS, LOSS OF LIBIDO (OFF AND ON), BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS (DYSMENORRHEA), BLEEDING BETWEEN PERIODS (METRORRHAGIA), INCONTINENCE, LONG MENSTRUAL CYCLES (POLYMENORRHEA) 7-11 DAYS UP FROM 4 MAX, SEXUAL DYSFUNCTION (UNABLE TO ORGASM OR FEEL PLEASURE), URGENT/FREQUENT URINATION, VULVODYNIA-(ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE), ABDOMINAL SPASMS (TWITCHING, FLUTTERING), PAIN-(BACK, JOINT, CHEST, LEG, NECK, SPINE AND HIP), FACE PAIN (TRIGRINAL NEURALGIA), ALL OVER BODY ACHES/PAIN, GASTROINTESTINAL- (NAUSEA, VOMITING, GAS, DIARRHEA-LOOSE STOOLS), SEVERE BLOATING, HEARTBURN, SEVERE HEADACHES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, BRAIN FOG- (CLOUDINESS, FORGETFULNESS, ANXIETY, MOOD SWINGS), STROKE LIKE SYMPTOMS, BOUTS OF DEPRESSION, RINGING IN EARS, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY ISSUES/LOSS), NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SHAKINESS, HIGH BLOOD PRESSURE, INCREASED ALLERGIES/ SENSITIVITIES-CHEMICAL AND FOOD

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

SENSITIVITIES, METAL (NICKEL), HEIGHTENED ALLERGIES/ALLERGIC REACTIONS, HIVES (OCCASIONAL), RED ITCHY RASHES, ACNE, ABSCESSES, HEART PALPITATIONS, HAIR THINNING, HAIR GROWTH IN NEW PLACES, INSOMNIA, WEIGHT ISSUES (GAIN, INABILITY TO SHED), SWOLLEN GLANDS, SWELLING/PAIN IN JAW, UNEXPLAINED FEVERS, CHILLS, VISION PROBLEMS(FLOATERS, BLURRED VISION, DECREASED VISION), EXCESSIVE SWEATING, DRY SKIN, DARK URINE(DEEP ORANGE) THAT CONCERNS ME THAT I MAY HAVE BLOOD IN MY URINE, STAYS DARK NO MATTER HOW MUCH WATER I INTAKE. I WAS AND AM ON NO OTHER MEDICATIONS AT THE TIME OF IMPLANTATION OR SINCE. I HAVE TRIED STEROIDS FOR SKIN ISSUES BUT TO NO AVAIL. I HAD MEDICAID AT THE TIME OF IMPLANTATION AND HAVE BEEN UNABLE TO ACQUIRE INSURANCE SO I AM UNABLE TO PROVIDE INFORMATION PERTAINING TO MORE SEVERE SYMPTOMS/ILLNESSES. I HAVE BEEN TO THE DOCTOR FOR MANY OTHER SYMPTOMS PERTAINING TO PAIN BUT WAS ONLY TREATED FOR THE PAIN/PLACATED AND SENT ON MY WAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057347	BAYER	10/27/2015	10/27/2015

Event Information:

Event Date (B3): 9/1/2002 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE MENSTRUAL BLEEDING. THREE PERIODS IN 3 WEEKS. HEADACHES, PELVIC PAIN, ABDOMINAL PAIN, HAIR LOSS, EXTREME FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057571	BAYER	10/27/2015	10/30/2015

Event Information:

Event Date (B3): 2/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): A47945
Lot #(E4):

Single Use: *
Implant Date (E6): 2/12/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER ESSURE IN (B)(6) 2013 I HAVE HAD LOTS OF COMPLICATIONS; SEVERE ABDOMINA/PELVIS PAIN, MIGRAINES, PAIN AFTER INTERCOURSE AND BLEEDING. HIVES, SWOLLEN FEET AND HANDS, HAIR LOSS, TIREDNESS, ABDOMEN MOVEMENTS, HEAVY PERIODS 8-10 DAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057576	BAYER	10/27/2015	10/30/2015

Event Information:

Event Date (B3): 9/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/11/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD MY ESSURE COILS PLACED (B)(6) 2014 AND TWO MONTHS AFTER HAVING THEM PLACED I STARTED EXPERIENCING FATIGUE HEADACHES TWO TO THREE TIMES A WEEK, JOINT PAIN ESPECIALLY IN MY LEFT SIDE AT NIGHT IT IS WORSE, UTI FREQUENTLY THAT COME BACK EVEN AFTER ANTIBIOTICS PERIODS THREE TIMES A MONTH, BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057578	BAYER	10/27/2015	10/30/2015

Event Information:

Event Date (B3): 1/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/22/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

INSERTION OF THE ESSURE DEVICE WAS EXTREMELY PAINFUL DURING THE PROCEDURE AND IT TOOK ME ALMOST A WEEK TO RECOVER. I HAD TO TAKE VERY STRONG PAIN MEDS IN ORDER TO DEAL WITH THE PAIN. I HAVE SUFFERED FROM EXTREME JABBING/THROBBING PAIN ON THE LEFT SIDE OF MY UTERUS WHICH OFTEN BRINGS ME TO MY KNEES IN TEARS, SEX IS VERY PAINFUL, I BEGAN SUFFERING FROM MIGRAINES BEFORE EACH PERIOD, MY PERIODS ARE MUCH HEAVIER, I DEVELOPED VULVAR ECZEMA AND I HAVE BLOATING IN MY ABDOMINAL AREA. I HAVE BEEN GIVEN A REFERRAL TO ANOTHER DOCTOR FOR PAIN MANAGEMENT, BUT MAY HAVE TO HAVE A HYSTERECTOMY. I'M REALLY SAD AND WISH THAT I KNEW MORE ABOUT THESE POSSIBLE SIDE EFFECTS BEFORE AGREEING TO THE PROCEDURE. HAVING THE ESSURE DEVICE INSERTED FELT AS IF I WERE GIVING BIRTH TO ANOTHER CHILD. I LITERALLY HAD CONTRACTIONS THAT WERE BACK TO BACK. I WAS TOLD I'D BE ABLE TO DRIVE MYSELF HOME AND MY HUSBAND HAD TO LITERALLY CARRY ME OUT OF THE DOCTOR'S OFFICE. I'M ONLY (B)(6) AND AM SAD THAT I HAVE TO DEAL WITH ALL OF THESE ISSUES AT SUCH A YOUNG AGE. I AM PLEADING THAT YOU PLEASE CONSIDER BANNING THIS PRODUCT FROM THE MARKET. IT'S NOT FAIR AND IT SEEMS LIKE NO ONE IS LISTENING. I WISH I COULD HAVE THE DEVICE REMOVED BUT CAN'T AFFORD THE REMOVAL PROCEDURE AND RIGHT NOW I CAN'T EVEN AFFORD A HYSTERECTOMY. WHAT SEEMS LIKE THE EASIER ROUTE, ENDED UP BEING MY WORST NIGHTMARE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01262	BAYER HEALTHCARE LLC	10/28/2015	10/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1181, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED SHE WAS MOTHER OF 3. THEN SHE GOT ESSURE A MONTH AFTER THE BIRTH OF HER 3RD AND LAST BABY AND EVERYTHING CHANGED. HER PERIODS LASTED WEEKS AND WERE SO HEAVY SHE BLED THROUGH A PAD AN HOUR AND HAD TO GO HOME AND CHANGE SO MANY TIMES, SHE STARTED KEEPING EXTRA CLOTHES WITH HER EVERYWHERE SHE WENT. EVERY TIME SHE HAD HER PERIOD, IT FELT LIKE SHE HAD THE FLU. ABOUT 6 MONTHS AFTER ESSURE, SHE HAD HEADACHES EVERY DAY ALONG WITH PELVIC PAIN, EXTREME BLOATING AND DEPRESSION. SEX WAS VERY PAINFUL. SHE WAS MISERABLE. SHE HAD A HYSTERECTOMY AT (B)(6) PLUS 3 MORE SURGERIES AFTERWARDS DUE TO MORE COMPLICATIONS, AND 2 LENGTHY HOSPITAL STAYS, A CATHETER AND A PICC LINE. SHE WAS SLOWLY GETTING HER LIFE BACK. HER HEADACHES HAVE DISAPPEARED, HER BLOATING WAS WAY DOWN, SEX DID NOT HURT ANYMORE AND SHE WAS BACK TO HER HAPPY SELF. SHE WILL BE ON ESTROGEN THERAPY THE REST OF HER LIFE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE

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WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT : THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PERIODS LASTED WEEKS AND WERE HEAVY (INTERPRETED AS MENORRHAGIA). SHE HAD A HYSTERECTOMY WHEN SHE WAS (B)(6) AND 3 MORE SURGERIES AFTERWARDS DUE TO MORE COMPLICATIONS (NOT SPECIFIED) AND 2 LENGTHY HOSPITAL STAYS. MENORRHAGIA IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND MORE COMPLICATIONS IS A SERIOUS EVENT DUE TO HOSPITALIZATIONS. BOTH EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS AND THE LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THESE EVENTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). OTHER NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DU

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057380	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 6/6/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER BACK PAIN, PAINFUL PERIODS, HEAVY SOMETIMES CLOTS, BROKEN TEETH, CONSTIPATION, BRAIN FOG, TIRED ALL THE TIRED ALL THE TIME, LEGS FEEL HEAVY, ARMS ACKY, UTI, VAGINA AREA HAVING PAIN, TUMMY BLOATED GAINED 50LBS, STABBING PAIN ON TOP RIGHT SIDE OF BACK, DIZZINESS, MIGRAINES ALMOST EVERYDAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057381	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 8/25/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, MAJOR STOMACH PAINS, LOSING HAIR, MOOD SWINGS, PAINFUL INTERCOURSE, BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057382	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 11/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE BEEN BREAKING OUT IN HIVES EVERYDAY, VERY BAD ABDOMINAL PAIN, DEPRESSION, HAIR LOST, LONG AND HEAVY PERIOD, STABBING BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057384	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 3/13/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABOUT 3 MONTHS AFTER HAVING ESSURE IMPLANTED, I STARTED HAVING STOMACH ISSUES, BOWEL PROBLEMS, BLOATED ABDOMEN, NO ENERGY, AUTO IMMUNE LIKE SYMPTOMS, CRUNCHY JOINTS, RED ITCHY SCALP, TEETH AND GUM PAIN, SENSITIVITY TO SMELLS AND FOODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057386	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN 2013 I HAD ESSURE PLACED AND THEN I HAD NO PERIOD FOR SOME TIME BUT I STARTED TO DEVELOP SEVERE ADULT ACNE, SEVERE LEG PAIN SOMETIMES I COULD BARELY WALK, PELVIC AND BACK PAIN, EXTREME MIGRAINE (NEVER HAD HEADACHES PRIOR), GUM BLEEDING , EXTREME FATIGUE. THEN IN (B)(6) OF 2014 I STARTED BLEEDING AGAIN AND NEVER STOPPED FOR OVER YEAR, HEAVY BLEEDING AND SEVERE CRAMPING TO THE POINT OF BEING SEVERELY ANAEMIC; MY DOCTOR GAVE ME MEDICINE TO CONTROL THE BLEEDING BUT NOTHING HELPED. IT GOT SO BAD THAT I HAD TO HAVE A HYSTERECTOMY. THEY TOOK MY TUBES AND WHEN MY UTERUS WAS WEIGHED, IT WAS OVER 5 POUNDS. I GOT ENDOMETRIOSIS FROM THIS ADENOMYOSIS FROM THIS PROCEDURE, MY SKIN WHICH WAS FLAWLESS NO HAS ACNE SCARRING AND. THE WORST PART IS I CAN NO LONGER HAVE CHILDREN BECAUSE MY BODY TURNED ON ME TO PROTECT ME FROM THIS DEVICE. ESSURE SHOULD BE BANNED!! TAKE THIS [PROFANITY] OFF THE MARKET. BEFORE ANOTHER WOMAN HAS TO ENDURE WHAT I WEN THROUGH FOR TWO YEARS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057388	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 3/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE DEVICE PUT IN (B)(6) OF 2014. SINCE THEN I HAVE HAD SEVERE PELVIC PAIN, LOWER BACK PAIN DAILY, HEADACHES, DIZZINESS, FORGETFULNESS, PAINT IN MY JOINTS, MY BODY IS CONSTANTLY ACHY, I FEEL SICK ALL THE TIME, NO ENERGY, AND TIRED ALL THE TIME. THIS DEVICE HAS RUINED MY LIFE! I AM LOOKING AT WHAT MY OPTIONS ARE AS FAR AS GETTING IT REMOVED. 1 OPTION IS GETTING A HYSTERECTOMY WHICH I WASN'T READY FOR AT (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057389	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 7/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE IN (B)(6) 2011. SHORTLY AFTER MY HSG TEST, I BEGAN TO DEVELOP SYMPTOMS OF STABBING PELVIC PAIN, PAINFUL PERIODS, HEAVY PERIODS WITH CLOTS RANGING FROM QUARTER-SIZED TO GOLF BALL-SIZED, PAIN DURING INTERCOURSE, DEBILITATING CRAMPS, AND ERRATIC, INCONSISTENT MENSTRUAL CYCLES. OTHER SYMPTOMS BEGAN TO APPEAR SLOWLY OVER THE PAST 4 YEARS. WEIGHT ISSUES (GAINING AND INABILITY TO LOSE), MIGRAINES, HAIR LOSS, CONSTANT BLOATING, LEGS/FEET SWELLING, ACNE, ANXIETY AND DEPRESSION, ERRATIC MOOD CHANGES, FORGETFULNESS AND INABILITY TO COMPLETE THOUGHTS (BRAIN FOG), JOINT PAIN IN HIPS, ELBOWS, KNEES, WRISTS, FINGERS, NECK. CONSTANT CHEST PAIN. IN (B)(6) 2015 I WAS DIAGNOSED WITH FIBROMYALGIA. I HAVE BEEN UNABLE TO WORK MY FULL TIME JOB CONSISTENTLY. FATIGUE, INSOMNIA, AND LETHARGY. DIZZINESS, BLURRED VISION, RINGING IN MY EARS. NEW SYMPTOMS DEVELOPING ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057391	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 8/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER ESSURE MY PERIODS AND PMS HAVE BEEN THE WORSE OF MY LIFE. MY CRAMPS ARE EXCRUCIATING, HEADACHES AND MIGRAINES DAILY, MUCH WORSE EMOTIONAL ROLLER COASTER. THERE'S BEEN MANY OF TIMES I FEEL AS THOSE SOMEONE IS STABBING MY UTERUS. THE PAIN HURLS ME OVER. THIS HAS CAUSED ME TO HAVE TO TAKE AN INTERMEDIATE LEAVE FROM WORK SO THE TIME I MISS ISN'T COUNTED AGAINST ME, AND IM MISSING A LOT OF WORK! I CHECKED SEVERAL TIMES WITH MY INSURANCE COMPANY AS WELL AS MY DRS OFFICE CHECKED TO MAKE SURE THE ESSURE PROCEDURE WAS GOING TO BE FREE AS STATED IN THE PAMPHLET. AFTER I RECEIVED THE (B)(6) BILL I ABOUT COLLAPSED. EVENTUALLY I GOT THE BILL DOWN TO UNDER (B)(6). I GUESS NOT TO BAD CONSIDERING IT WAS SUPPOSED TO BE FREE. I AM CURRENTLY TRYING TO GET IN BIRTH CONTROL AGAIN TO CONTROL MY HORMONES AND PHYSICAL ILLNESSES. BOTH OF WHICH I DID NOT HAVE BEFORE THE ESSURE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057393	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 12/3/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PLACED IN (B)(6) 2014, HAD MULTIPLE URINARY TRACT INFECTIONS, AND A LOT OF ABDOMINAL PAIN, WHICH I LATER FOUND OUT WAS CAUSED BY A CYST ON MY RIGHT OVARY. PAINFUL INTERCOURSE, AND RASHES ON MY FACE. ALL LED UP TO A HYSTERECTOMY LEAVING NOTHING BUT OVARIES. HYSTERECTOMY SCHEDULED FOR (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057394	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 10/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PUT IN BACK IN 2004, STARTED SIDE EFFECTS IN 2005 BUT WAS TOLD IT WASN'T RELATED TO ESSURE. ALL STATED AS BAD HEADACHES LONGER PERIODS AND BACK PAINS. THROUGH THE YEARS IT HAS GOTTEN WORSE. I NOW HAVE DAILY SEVERE BACK, PELVIC AND ABDOMINAL PAINS, SEVERE BLOATING WHICH ADDS TO PAIN. LOOSE TEETH ALMOST ALL ARE VERY LOOSE. HAIR FALLING OUT. JOINT PAINS, BODYACHES, 9-15 DAY PERIODS THAT ARE VERY HEAVY MORE THAN HALF THE DAYS, VERY LOW ENERGY LEVEL EVERYDAY, I HAVE HEARD VERY SIMILAR STORY'S FROM THOUSANDS OF WOMEN AND EVERY TIME ONE PERSON HAS A DOCTOR THAT BELIEVES THE SIDE EFFECTS ARE RELATED TO ESSURE AND THEY GET A HYSTERECTOMY TO GET THEM TAKEN OUT ALL SIDE EFFECT ARE GONE AND THEY FEEL 100% BETTER. THIS ESSURE PROCEDURE NEEDS TO BE OFF THE MARKET AND WE NEED THEM OUT OF US. I AM IN THE MIDDLE OF TEST AFTER TEST NOW TO GET MINE OUT!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057397	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 5/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED (B)(6) 2015 AND SINCE (B)(6) 2015 I HAVE HAD SEVERE ANXIETY ATTACKS DEPRESSION SEVERE REFLUX ISSUES BLOATING ISSUES GOING TO BATHROOM, HEADACHES CHRONIC DISCHARGE, URINARY TRACT INFECTIONS FREQUENTLY SEVERE BACK PAIN NO SEX DRIVE HEART PALPITATIONS HEAVY PERIODS AND CLOTTING. SEVERE WEIGHT LOSS HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057398	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 10/20/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT SHARP PAIN ON LEFT SIDE OF PELVIC AREA, CRAMPS FEEL LIKE LABOR PAINS, HEAVY PERIODS, SEVERE MIGRAINES, CRAMPS GO ALL THE WAY AROUND MY LOWER BODY, FEELS LIKE SOMETHING IS KICKING ME INSIDE, AFTER EATING I GET AN UPSET STOMACH, FEEL BLOATED 24-7, SEX SOMETIMES HURTS, PERIODS COME REALLY EARLY OR REALLY LATE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057399	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 7/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BURNING BLISTERS UNDER MY WEDDING RINGS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057400	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 7/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED BLEEDING NON STOP. PASSING HUGE BLOOD CLOTS. CRAMPING REALLY BAD.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057401	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). START OFF BY SAYING THERE IS NO WAY TO SUGARCOAT THIS PRODUCT IT IS HORRIBLE ALL THE WAY AROUND SINCE THE DAY WAS IMPLANTED WITH THIS DEVICE I HAVE HAD HIP PAIN BACK PAIN HEADACHES 2 TO 3 PERIODS A MONTH NO SEX DRIVE AND A VERY SHORT TEMPER WHICH IS EXTREMELY NOT ME I USED TO WAKE UP HAPPY WITH ENERGY NOW I WAKE UP JUST ANGRY WITH NO ENERGY AT ALL LIKE I FELT WHEN I WENT TO BED I AM (B)(6) I FEEL LIKE I HAVE A LOT LONGER TO LIVE AND THIS PRODUCT WILL ONLY SHORTEN YOUR LIFESPAN IT IS HORRIBLE THERE IS NOTHING GOOD ABOUT THIS PRODUCT OF THE FDA TO TAKE IT OFF THE MARKET AND I'LL SEARCH ANY WOMAN LOOKING FOR A BIRTH CONTROL METHOD TO SEEK OTHER BIRTH CONTROL METHODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057402	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 12/17/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GAINED OVER 35LBS AFTER HAVING THE ESSURE PROCEDURE DONE. WEIGHT GAIN DUE TO THE FACT MY PERIOD BACKED UP INSIDE ME FROM (B)(6) 2011 UNTIL I WAS RUSHED TO THE ER FOR SEVERE PAIN THAT HAD ME SCREAMING UNCONTROLLABLY ONCE THE E.R. DOCTOR DID PELVIC EXAM HE FOUND THE SCAR TISSUE HAD CREATED A BARRIER SO MY PERIODS COULD NOT DO THE NORMAL MONTHLY CYXLE. IT WAS FILLED UP NO ROOM

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057403	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 11/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE IMPLANTED (B)(6) 2014; COVERED UNDER INSURANCE. INFLAMMATION (JOINTS, MUSCLES, NERVES, TENDONS) AND AUTOIMMUNE (THYROID, CILIAC SPRUE) SYMPTOMS BEGAN WITHIN 3 MONTHS. SYMPTOMS INCREASED AND MULTIPLIED TO THE POINT I BEGAN SEEING INTERNIST, RHEUMATOLOGIST, PODIATRIST, OPHTHALMOLOGIST, GYNECOLOGIST, AND GENERAL PHYSICIAN TRYING TO IDENTIFY THE ROOT OF MY PROBLEMS. RHEUMATOLOGIST AND INTERNIST IMMEDIATELY SUSPECTED ESSURE AS IT WAS THE ONLY CHANGE IN MY LIFE PRIOR TO ONSET OF ALL PROBLEMS. WAS PRESCRIBED BCP TO CONTROL NEW INTENSE, UNPREDICTABLE HEAVY BLEEDING/CLOTTING/CRAMPING AND PHYSICAL/EMOTIONAL DISTRESS; PRESCRIBED SULFASALAZINE FOR NEW DIAGNOSIS OF PSORIATIC ARTHRITIS; PRESCRIBED LIOTHYRONINE FOR NEW DIAGNOSIS OF THYROID DYSFUNCTION, VITAMIN D AND OTHER VITAMINS FOR DEFICIENCY, GLUTEN FREE DIET FOR CELIAC SPRUE, ETC, WITH NO RELIEF FROM ANY OF THESE TREATMENTS. NONE OF THESE HAD BEEN ISSUES IN MY LIFE PRIOR TO ESSURE. HAD DAVINCI LAV TOTAL HYSTERECTOMY WITH BILATERAL SALPINGO-OOPHERECTOMY ON (B)(6) 2015. STOPPED ALL NEWLY PRESCRIBED MEDICATION PRIOR TO HYSTO AND ALL SYMPTOMS VANISHED FOR 3 MONTHS IMMEDIATELY FOLLOWING SURGERY. SYMPTOMS THEN BEGAN TO REAPPEAR IN SUBTLE WAYS AND I RESUMED PRESCRIBED MEDICATION FOR THE SAKE OF SYMPTOM MANAGEMENT AND REDUCING DAMAGE GOING FORWARD. ESSURE INFLAMMATION INITIATED NEW, TRIGGERED LATENT AND/OR ACCELERATED AUTOIMMUNITY AND CAUSED ENDOCRINE DISRUPTION ONLY ALTERED BY COMPLETE INTACT ESSURE REMOVAL BY LAVH BSO. MY ESSURE DEVICES WERE CORRECTLY PLACED IN THE FALLOPIAN TUBES AND HAD NOT MIGRATED, AND THANKFULLY WERE ABLE TO BE REMOVED WITHOUT BREAKAGE OR PIECES LEFT BEHIND TO CONTINUE

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DAMAGE OR REQUIRE FURTHER SURGERY. I REPORTED WHEN I FIRST BECAME AWARE OF ESSURE BEING THE PROBLEM AND NOW I REPORT AGAIN AFTER RECOVERING FROM HYSTO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057404	BAYER	10/28/2015	10/28/2015

Event Information:

Event Date (B3): 12/19/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING THIS PROCEDURE DONE I STARTED OUT WITH TOOTH ACHES AND SEVERE HEADACHES WHICH LEAD TO ME BEING DIAGNOSED WITH A NERVE PROBLEM WHICH CAUSES THESE TYPE OF PAINS. THEN I NOTICED THAT I WAS CONSTANTLY HAVING YEAST INFECTIONS AND RASHES ON MY SKIN. THEN I NOTICED WHAT I THOUGHT WAS A HAIR BUMP WHICH I HAVE HAD FOR ALMOST A YEAR NOW AND THE WORST WAS HAVING BOILS UNDER MY ARMS AND ON THE LEFT AND RIGHT LABIA FILLED WITH NO MUCH PUSS THAT IT HURTS TO SIT DOWN. WHICH I HAVE TO SUFFER EACH TIME UNTIL IT FINALLY BURSTS. I HAVE MEMORY LOSS, NAUSEATED, FLASHES OF LIGHT, MOOD SWINGS, I AM DEPRESSED AND NOBODY BELIEVES ANYTHING IS WRONG WITH ME. ACCORDING TO MY DOCTOR, THE PROBLEMS ARE DUE TO BACTERIA ON MY SKIN SUCH AS A STAPH INFECTION WHICH HE OFFERED NOTHING TO CURE OR PREVENT. THIS DEVICE HAS RUINED MY LIFE. I AM SCARED TO KNOW WHAT THE UNKNOWN DAMAGES ARE. THERE ARE SO MANY PROBLEMS I CAN'T SEEM TO NAME THEM ALL. I HAVE SHARP PAINS SHOOT THROUGH MY FEET AND LEGS. UNUSUAL PAIN IN MY SIDES AND CHEST. AND WEIRDLY, SOME SORT OF PUSS LIKE FLUID COMING FROM ONE OF MY EYES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01268	BAYER HEALTHCARE LLC	10/29/2015	10/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 7/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1307, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED SINCE GETTING ESSURE HER PERIODS HAVE BEEN IRREGULAR AND LONGER. SHE EXPERIENCED HEAVIER PERIODS, WHICH WERE ACCOMPANIED BY LOTS OF PAIN AND DISCOMFORT. SHE FELT TIRED ALL THE TIME, AND HER MOTIVATION HAD DECREASED. SINCE HAVING ESSURE PLACED, SHE FELT HER QUALITY OF LIFE HAD DECREASED. SHE NOTICED THAT SHE WOULD GET SHARP PAINS OFF AND ON ESPECIALLY WHEN SHE WAS GETTING NEAR HER PERIOD AND ALSO WHEN SHE SNEEZES OR MOVES TOO QUICKLY. SHE ALSO NOTICED SPASMS IN HER HANDS, EYES AND OTHER BODY PARTS. BLOATING WAS MUCH A PART OF HER DAILY DISCOMFORT. THIS YEAR (2015) HER PERIODS BECAME MORE FREQUENT AND LONGER. LASTING 27 DAYS IN ONE MONTH AND EVENTUALLY GOING TO A 15 DAY PLAN. 15 DAYS ON AND 15 DAYS OFF. AFTER YEARS OF DEALING WITH THIS, SHE OPTED TO HAVE A HYSTERECTOMY, ALONG WITH THE REMOVAL OF HER TUBES ON (B)(6) 2015. FOLLOW UP RECEIVED ON 20-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS

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REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP PAINS OFF AND ON (INTERPRETED AS ABDOMINAL PAIN). SHE UNDERWENT A HYSTERECTOMY AND SALPINGECTOMY APPROXIMATELY 6 YEARS AFTER ESSURE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. CONSIDERING THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY, SALPINGECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01270	BAYER HEALTHCARE LLC	10/29/2015	10/29/2015

Event Information:

Event Date (B3): 3/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2012
Explant Date (E7): 3/16/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1443, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012 FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED SHE HAD HER SECOND DAUGHTER IN (B)(6) 2011. SHORTLY AFTER ESSURE INSERTION, WITHIN A MONTH, SHE FOUND HERSELF VOMITING APPROXIMATELY FOUR TIMES A WEEK FOR NO REASON AND SEVERE HEADACHES WHERE SHE COULD NOT EVEN FUNCTION. HER FAMILY DOCTOR THOUGHT IT WAS STRESS AND TENSION RELATED. THE VOMITING WENT AWAY EVENTUALLY BUT THE HEADACHES DID NOT, THEY JUST KEPT GETTING WORSE. AS TIME WENT ON, MORE PROBLEMS WITH HER BODY AND HEALTH STARTED TO CHANGE. SHE BECAME VERY FATIGUE AND MISERABLY TIRED ALL THE TIME. SHE FELT AFRAID AND WORRIED BECAUSE SHE WAS SO TIRED THROUGHOUT THE DAY, SHE WOULD FALL ASLEEP WHILE AT HOME WITH HER KIDS, EXCESSIVE SLEEP. SHE WAS REFERRED TO A SLEEP CLINIC FOR EVALUATION AND THEY FOUND THAT AT NIGHT, SHE WOULD EASILY FALL ASLEEP WITHIN MINUTES OF LAYING DOWN, HOWEVER, SHE NEVER GOT GOOD SLEEP (REM) BECAUSE SHE WAS CONTINUOUSLY WAKING UP. THEY COULD NOT FIND A CAUSE FOR THIS, SO THIS PRECEDED TO DO A DAY TIME STUDY AND WATCH HER SLEEP PATTERNS DURING THE DAY AND TEST FOR NARCOLEPSY. TEST CAME BACK NEGATIVE, BUT FOUND OUT THAT SHE HAD NO PROBLEM FALLING ASLEEP ONCE SHE LAID DOWN. SHE WAS GIVING TWO PRESCRIPTIONS, ONE TO GO TO SLEEP AT NIGHT AND ONE TO STAY AWAKE AT DURING THE DAY. SHE FOUND THEM TO WORK A LITTLE BIT, BUT NOT ENOUGH TO MAKE A DIFFERENCE IN HER LIFE. SHE ALSO MENTIONED THE PELVIC PAIN BECAME A PROBLEM, SHE SPONTANEOUSLY WOULD GET STABBING PAINS AND

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ACHES ONE SIDE. WHEN IT CAME TIME FOR HER MENSTRUAL CYCLE (WHICH WAS VERY UNPREDICTABLE), IT WAS EXTREMELY HEAVY, WHERE YOU FELT UNCOMFORTABLE DOING THINGS. ALSO DURING THIS TIME, SHE FOUND IT DIFFICULT TO BREATHE AT CERTAIN POINTS. SHE ACTUALLY CALLED HER DOCTOR ONCE BECAUSE SHE FELT LIKE SHE WAS UNABLE TO BREATHE. THEN BODY PAIN AND JOINT ACHES STARTING TO OCCUR. IT WOULD BE DIFFICULT TO GET OUT OF BED OR OUT OF CHAIR OR WALK UP STEPS BECAUSE OF PAIN. THE WORST PART OF HER BODY AFFECTED WERE HER LEGS, KNEES, AND ANKLES. THERE WERE NUMEROUS OTHER PROBLEMS WHICH SHE HAS ENCOUNTERED SINCE ESSURE: BLOATED BELLY (LOOKING PREGNANT), RASHES, ITCHING SKIN AND SCALP, EASILY BRUISING, STOMACH ISSUES, SEVERE ACNE, METAL TASTING IN MOUTH, AND OTHERS. CONSUMER MENTIONED THAT SHE WOULD HAVE NEVER LINKED ALL THIS TO ESSURE BUT ONCE IT WAS BROUGHT TO HER ATTENTION, AND SHE WENT BACK THROUGH HER MEDICAL RECORDS, AND IT ALL STARTED AFTER ESSURE. ON (B)(6) 2015 SHE HAD A HYSTERECTOMY AT THE AGE OF (B)(6) TO REMOVE THE ESSURE DEVICES. SINCE DAY ONE OF HER REMOVAL SURGERY, SHE HAS BEEN IMPROVING AND GETTING HER LIFE BACK. SHE JUST RECEIVED HER OPERATIVE NOTES, AND IT STATED THAT THE COIL WAS PROTRUDING THROUGH HER FALLOPIAN TUBE. FOLLOW UP RECEIVED ON 20-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 3 YEARS LATER, DURING A HYSTERECTOMY TO REMOVE THE DEVICE, IT WAS FOUND THAT THE COIL WAS PROTRUDING THROUGH HER FALLOPIAN TUBE. THIS EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THIS PERFORATION WERE NOT REPORTED. THE PERFORATION WAS DIAGNOSED 3 YEARS AFTER INSERTION, DURING A HYSTERECTOMY TO REMOVE ESSURE. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01272	BAYER HEALTHCARE LLC	10/29/2015	10/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1452, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. AFTER INSERTION SHE DEVELOPED HEAVY PERIODS, CONSTANT ABDOMINAL PAIN, DIZZINESS, HEADACHES, LIMB NUMBNESS, LOWER BACK PAIN, BLOATING, AND WEIGHT GAIN. IN (B)(6) OF 2014, SHE WAS TAKEN TO THE EMERGENCY ROOM (ER) FOLLOWING INTERCOURSE WITH HER HUSBAND BECAUSE IT FELT AS IF A WATER BALLOON FILLED WITH HOT WATER WAS BURST INSIDE HER ABDOMEN, FOLLOWED BY EXCRUCIATING PAIN. AFTER NUMEROUS DOCTOR APPOINTMENTS, AN ULTRASOUND WAS PERFORMED AND SHOWED THAT LEFT OVARY WAS DISPLACED AND THERE WAS A LOT OF FREE FLOWING FLUID. SHE WAS TOLD THAT WAS PARTIALLY CAUSING THE PAIN, SO EXPLORATORY LAPAROSCOPIC SURGERY WAS SCHEDULED WITH A POSSIBILITY OF HYSTERECTOMY. ON (B)(6), WHEN SHE AWOKE FROM SURGERY, SHE WAS TOLD THAT HER LEFT OVARY AND FALLOPIAN TUBE WERE FUSED TOGETHER AND BEGAN TO TWIST AROUND ONE ANOTHER, CONNECTED TO EACH OTHER BY THE ESSURE DEVICE. HER UTERUS WAS PERFORATED BY THE COIL ON HER RIGHT SIDE. EVERYTHING WAS REMOVED (FULL HYSTERECTOMY AT THE AGE OF (B)(6)). FOLLOW UP RECEIVED ON 20-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER:(B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF

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THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 6 OR 7 YEARS LATER UNDERWENT AN EXPLORATORY LAPAROSCOPIC SURGERY AND IT WAS FOUND THAT HER UTERUS WAS PERFORATED BY THE COIL ON RIGHT SIDE AND LEFT OVARY AND FALLOPIAN TUBE WERE FUSED TOGETHER AND BEGAN TO TWIST AROUND ONE ANOTHER CONNECTED TO EACH OTHER BY THE ESSURE DEVICE. A HYSTERECTOMY WAS PERFORMED. THESE EVENTS, INTERPRETED AS UTERINE PERFORATION AND PELVIC ADHESIONS, WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. UTERINE PERFORATION IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE PELVIC ADHESIONS IS UNLISTED. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. THE EXACT DATE AND MECHANISM OF THE PERFORATION WERE NOT REPORTED. IT WAS DIAGNOSED DURING AN EXPLORATORY SURGERY YEARS AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. COMMON CAUSES OF PELVIC ADHESIONS INCLUDE INFECTION, ENDOMETRIOSIS, AND PREVIOUS PELVIC SURGERY. IN THIS CASE, NO SUCH FACTORS WERE REPORTED. SINCE THE CONSUMER MENTIONED THAT THE OVARY AND FALLOPIAN TUBE WERE FUSED TOGETHER AND CONNECTED TO EACH OTHER BY THE ESSURE COIL, ALTHOUGH THE EXACT NATURE OF THIS EVENT IS NOT CLEAR FROM THE INFORMATION PROVIDED, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01274	BAYER HEALTHCARE LLC	10/29/2015	10/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 6/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1147, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. AFTER HER 3RD CHILD, SHE AGREED TO ALLOW ESSURE INSERTION. SHE WAS ASKED BY PHYSICIAN IF SHE COULD WEAR COSTUME JEWELRY AND SHE ANSWERED YES THOUGH THERE WERE NO NICKEL ALLERGY TESTS ORDERED. CONSUMER STATED THAT THOUGH HER THREE C-SECTIONS, THE PAIN DURING INSERTION WAS WORSE THAN ANYTHING SHE HAD EVER GONE THROUGH. AFTER GOING THROUGH THIS PROCEDURE, THE UNEXPECTED BLEEDING AND TISSUE LOSS, UNADDRESSED PAIN AND CRAMPING. HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED A FEW MONTHS LATER AND SHE STATED IT WAS EQUALLY TORTUROUS. CONSUMER STATED THAT SHE EXPERIENCED PTSD (INTERPRETED AS POST-TRAUMATIC STRESS DISORDER). WITHIN A FEW MONTHS OF HAVING THE PROCEDURE, CONSUMER EXPERIENCED RASHES, HIVES, SWELLING OF FEET AND ANKLES, WEIGHT GAIN THAT NO AMOUNT OF REASONABLE DIET AND EXERCISE COULD CONTROL, VAGINAL ITCH THAT HAS PREVENTED HER HUSBAND FROM ESTABLISHING AN INTIMATE RELATIONSHIP IN THESE POST PREGNANCY YEARS, PROFOUND DERMATOGRAPHISM, DISHYDROSIC ECZEMA OF BOTH THE HANDS AND FEET AND IN LATE 2011, HER IMMUNE SYSTEM ATTACKED HER BODY INTERNALLY; FIRST IN HER LUNGS, SHE BECAME ASTHMATIC WITH ABSOLUTELY NO DIAGNOSTIC CAUSE. AFTER A MONTH LONG STRUGGLE TO BREATHE, THEN ATTACKED HER RIGHT BRACHIAL PLEXUS. AFTER 2 WEEKS OF PAIN LIKE CONSTANT ELECTROCUTION THE PAIN BEGAN TO SUBSIDE. SHE WAS LEFT WITH PARALYSIS IN RIGHT ARM AND SHOULDER. THE DIAGNOSIS WAS PARSONAGE TURNER SYNDROME, AN AUTOIMMUNE

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DISORDER. FROM THE BEGINNING, SHE TRIED EVERY TYPE OF SPECIAL DIET, DETOX, SUBSTANCE AVOIDANCE, LOOKING FOR WHATEVER ALLERGEN/TOXIN HAS BEEN BOTHERING HER. DUE TO THE TOTAL LACK OF SIDE EFFECTS ON THE ESSURE DEVICE, SHE NEVER THOUGHT TO MAKE THE CONNECTION. IT WASN'T UNTIL (B)(6) OF 2015 THAT A FRIEND MADE THE CONNECTION FOR HER. ALLERGY TESTS WERE PERFORMED AND SHE WAS DIAGNOSED WITH ALLERGY TO NICKEL, GOLD AND COBALT. A REMOVAL SURGERY WAS PERFORMED IN (B)(6) (DEVICES WERE REMOVED IN FULL). A WEEK LATER, SHE GOT VERY SICK AND WENT TO THE EMERGENCY ROOM (ER). A CT REVEALED THAT SHE HAD METAL FRAGMENTS LEFT IN UTERUS WHERE THE FALLOPIAN TUBES USED TO BE. AFTER THAT SURGERY, HER SIDE EFFECTS HAVE GOTTEN EXCESSIVELY WORSE. IN (B)(6), SHE HAD A HYSTERECTOMY TO REMOVE THE SIGNIFICANT FRAGMENTS LEFT BEHIND. SHE STATED THAT THE LOSS OF SKIN IS DEBILITATING AND DEFEATING. SHE FINALLY STATED THAT WILL ALWAYS BE IN CONSTANT REACTION TO THE POISON THAT IS CONTAINED IN THE DEVICE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN, CRAMPING AND UNEXPECTED BLEEDING WITH TISSUE LOSS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A SURGERY FOR DEVICES REMOVAL. LATER, A CT SCAN SHOWED METAL FRAGMENTS WERE LEFT IN HER UTERUS. A HYSTERECTOMY WAS THEN PERFORMED. ADDITIONALLY, CONSUMER WAS DIAGNOSED WITH PARSONAGE TURNER SYNDROME. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ONLY PARSONAGE TURNER SYNDROME IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION PAIN AND GENITAL BLEEDING OR SPOTTING MAY OCCUR. IN THIS CASE, CONSUMER RELATED HER SYMPTOMS TO ESSURE INSERTION. SHE WAS SUBMITTED TO A SURGERY FOR DEVICE REMOVAL (APPROXIMATELY 8 YEARS AFTER THEIR PLACEMENT) AND FRAGMENTS OF ESSURE WERE LEFT IN HER UTERUS, REQUIRING A HYSTERECTOMY. CONSIDERING EVENTS NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING PARSONAGE TURNER SYNDROME; IT IS AN IDIOPATHIC BRACHIAL PLEXOPATHY. CONSIDERING THIS INFORMATION AND GIVEN ESSURE LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY IS CONSIDERED VERY UNLIKELY. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01275	BAYER HEALTHCARE LLC	10/29/2015	10/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1195, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. ON INSERTION, THE CONSUMER WAS ON MULTIPLE PAIN AND RELAXING DRUGS AND HAD MULTIPLE LOCAL INJECTIONS TO NUMB MORE PAIN. DESPITE ALL OF THIS, THE PAIN OF THE PROCEDURE SHOT HER BLOOD PRESSURE UP TO NEAR STROKE LEVELS - SHE HAD TO LIE IN BED FOR ALMOST AN HOUR BEFORE THEY WOULD LET HER LEAVE BECAUSE HER BLOOD PRESSURE WOULD NOT DROP (IT HAD NEVER BEEN HIGH BEFORE). AFTER THE OCCASIONAL STABBING PAINS AND WEIRD BOUTS OF DEPRESSION, SHE HAD THE CONFIRMATION TEST DONE WHICH FAILED: THE LEFT TUBE WAS NOT BLOCKED AND SHE NEEDED SURGERY TO BE STERILIZED. BOTH COILS WERE TURNED IN ON THEMSELVES LIKE THEY HAD HIT A BRICK WALL AND JUST STARTED COMING BACK DOWN HER TUBES THE WAY THEY WERE INSERTED. SHE WAS SCHEDULED FOR A TUBAL LIGATION IN (B)(6) 2015. THE OPERATING DOCTOR TOOK PICTURES OF HER TUBES WHERE THE COILS WERE SO BOUND UP THAT THEY HAD HER TUBES STRETCHED THIN AND IT COULD CLEARLY BE SEEN THE COILS THROUGH THE TISSUE OF HER FALLOPIAN TUBES. SHE STATED THAT HER DOCTOR WAS VERY UNHAPPY AT HOW NARROWLY SHE ESCAPED OF HAVING THEM RUPTURED. SHE WAS STILL STRUGGLING WITH DEPRESSION, HER TEETH WERE TURNING INTO CHALK AND SHE CONSTANTLY HAD PAINS THAT FEEL LIKE OVARIAN CYSTS. THE EVENTS WERE CONSIDERED RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHOSE BLOOD PRESSURE UP TO NEAR STROKE LEVELS DUE TO PAIN DURING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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PROCEDURE. LATER, HER CONFIRMATION TEST SHOWED LEFT TUBE WAS NOT BLOCKED. SHE WAS SUBMITTED TO A SURGERY WHICH REVEALED THE COILS THROUGH THE TISSUE OF HER FALLOPIAN TUBES (REGARDED AS FALLOPIAN TUBE PERFORATION). ONLY FALLOPIAN TUBE PERFORATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). THIS EVENT CAN BE SUSPECTED IF EXCESSIVE PAIN OR DISCOMFORT OCCURS DURING THE INSERTION PROCEDURE. IN THIS PARTICULAR CASE, CONSUMER REPORTED EXCESSIVE PAIN WHICH LEAD TO AN INCREASE IN HER BLOOD PRESSURE DURING ESSURE PROCEDURE. THIS SUGGESTS AN ASSOCIATION BETWEEN THE FALLOPIAN TUBE PERFORATION AND DEVICES INSERTION. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, AS ALTHOUGH IT IS UNCLEAR THE EXACT TREATMENT FOR THE REPORTED FALLOPIAN TUBE PERFORATION; A SURGICAL INTERVENTION WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01276	BAYER HEALTHCARE LLC	10/29/2015	10/29/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1164, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2007. CONSUMER REPORTED THAT LESS THAN A YEAR AFTER INSERTION SHE STARTED TO HAD A HEMORRHAGING PERIOD THAT LASTED 4 MONTHS AND ONLY STOPPED AFTER SURGICAL PROCEDURE. SHE DEVELOPED AUTO IMMUNE DISORDER AND SEVERE PELVIC PAIN. SHE WAS TAKEN TO THE EMERGENCY ROOM AT A MAJOR UNIVERSITY HOSPITAL AND WAS EVALUATED AND TREATED. LESS THAN A WEEK LATER SHE HAD A HYSTERECTOMY TO REMOVE ESSURE AND THE PAIN RESOLVED IMMEDIATELY. SHE HAD 3 SURGERIES DUE TO ESSURE, INCLUDING THE HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEMORRHAGING PERIOD THAT LASTED 4 MONTHS (SEEN AS MENORRHAGIA) WHICH ONLY STOPPED BY A SURGICAL PROCEDURE. SHE ALSO HAD PELVIC PAIN AND DEVELOPED AUTO IMMUNE DISORDER. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. THEY ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT AUTO IMUNE DISORDER WHICH IS UNLISTED. PELVIC PAIN AND MENSES PATTERN CHANGES ARE FREQUENT IN WOMEN WITH ESSURE IN PLACE. CONSIDERING THE SUGGESTIVE TEMPORAL RELATIONSHIP AND THEIR NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. REGARDING AUTO IMMUNE DISORDER, AS ESSURE ACTS LOCALLY IN FALLOPIAN TUBES, CAUSAL RELATIONSHIP WITH SUSPECT DEVICE IS VERY UNLIKELY. SINCE INTERVENTIONS DUE TO ESSURE WERE REQUIRED, THIS CASE IS

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REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01277	BAYER HEALTHCARE LLC	10/29/2015	10/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 10/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1223, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. SHE WAS A MOTHER OF 2. CONSUMER REPORTED THAT SHE WAS TOLD ESSURE WAS A SIMPLE IN OFFICE PROCEDURE AND THAT THEY WERE METAL COILS THAT WOULD BE INSERTED IN HER FALLOPIAN TUBES, BUT SHE WAS PUT TO SLEEP FOR THE PROCEDURE AND FOUND OUT THAT THE COILS CONTAINED NICKEL. SHE WAS MISERABLE FOR THE TWO YEARS SHE HAD ESSURE. ON (B)(6) 2015 SHE HAD A HYSTERECTOMY, LEAVING ONLY HER OVARIES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE WAS MISERABLE FOR 2 YEARS AND HAD A HYSTERECTOMY PERFORMED. THIS EVENT WAS CONSIDERED SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. ALTHOUGH IT WAS NOT REPORTED WHAT REALLY HAPPENED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO SURGICAL INTERVENTION PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON 02-NOV-2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01278	BAYER HEALTHCARE LLC	10/29/2015	10/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 12/23/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN (B)(6) 2015 (FDA-2014-N-0736-1197 AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT SINCE THEN SHE STARTED EXPERIENCING SEVERE PAIN ON HER LEFT SIDE AND SWELLING WHERE THE IMPLANTS WERE INSERTED. SHE MISSED DAYS AT WORK DUE TO THE PAIN. SINCE HER FALLOPIAN TUBES COULD NOT BE REMOVED WITHOUT DAMAGE, SHE HAD TO GET A PARTIAL HYSTERECTOMY. ON (B)(6)-2014 SHE HAD A PARTIAL HYSTERECTOMY AND SINCE THEN SHE HAS HAD NO PAIN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THEN STARTED EXPERIENCING SEVERE PAIN ON HER LEFT SIDE. SHE UNDERWENT A PARTIAL HYSTERECTOMY 5 YEARS AFTER INSERTION. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE LACK OF AN ALTERNATIVE EXPLANATION AND SINCE THE PAIN RESOLVED AFTER THE PARTIAL HYSTERECTOMY, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENT WAS ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (PARTIAL HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-NOV-2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057405	BAYER	10/29/2015	10/29/2015

Event Information:

Event Date (B3): 1/19/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CRAMPING SHARP/STAB, BACTERIAL VAGINOSIS, DISCHARGE ODOR/NO ODOR, PAINFUL PERIODS, BLEEDING BETWEEN PERIODS, YEAST INFECTIONS, UTERINE FIBROSIS, URGENT/FREQUENT URINATE, UTI, ITCHING, BURNING OF VAGINAL ENTRANCE, ALL OVER BODY ACHES/PAIN, NAUSEA GAS AND CONSTIPATION, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, HEADACHES, NUMBNESS, FORGETFULNESS, ANEMIA, LOW IRON, VITAMIN D, B12 DEFICIENCY, SEVERE FATIGUE, ACNE, HEART PALPITATIONS, HAIR LOSS, DRY SKIN, BLOATING, WEIGHT GAIN AND SWELLING LEGS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057406	BAYER	10/29/2015	10/29/2015

Event Information:

Event Date (B3): 1/8/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NOT EXACTLY SURE ON THE DATE, SINCE MY DOCTOR WON'T GIVE ME MY RECORDS. EVER SINCE IMPLANTATION, I'VE EXPERIENCED BOUTS WITH THE FOLLOWING: WEIGHT GAIN, JOINT PAIN, BACK ANDAMP; NECK PAIN, RASHES, HEADACHES, VOICE CHANGE, MEMORY LOSS ANDAMP; BRAIN FOG, RAYNAUD'S SYNDROME, REOCCURRING YEAST INFECTIONS, TRIGEMINAL NEURALGIA, DEPRESSION, ANXIETY, INSOMNIA, MOOD SWINGS, REACTIONS TO VITAMINS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057407	BAYER	10/29/2015	10/29/2015

Event Information:

Event Date (B3): 12/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DID NOT REALIZE ALL MY SYMPTOMS LEAD UP TO THE ESSURE PLACEMENT UNTIL RECENTLY. SINCE I HAD THEM PLACED I'VE HAD AWFUL ABDOMINAL PAINS. TO THE POINT OF I CAN BARELY STAND AT TIMES. BLOATING, PAINFUL SEX, HEADACHES, MIGRAINES, BLEEDING AFTER SEX, I NO LONGER DESIRE TO HAVE SEX, THE PAIN AND BLEEDING AND BLOATING MAKE IT NOT WORTH IT. I'VE GAINED WEIGHT THAT HAVE NO EXPLANATION OF GAINING. I AM VERY ACTIVE AND EAT CORRECT. I WAS ALWAYS ABLE TO LOOSE ANY "BABY WEIGHT" AFTER MY FIVE CHILDREN. I HOWEVER CANNOT GET THIS UNEXPLAINED WEIGHT OFF SINCE PLACEMENT. I AM IN A FOGGY STATE OF EXHAUSTION A LOT OF THE TIME. I AM ALLERGIC TO NICKEL AND WAS NEVER TOLD OR TESTED FOR THIS. I FOUND IT OUT ON MY OWN A FEW WEEKS BACK. I HAVE THE COILS THAT HAVE NICKEL IN THEM. I GET SEVERE STOMACH PAINS. JOINT PAINS, HIP PAINS, I AM DEPRESSED. I WAS THINKING THIS WAS ALL PART OF "GETTING OLDER" I HOWEVER NO LONGER BELIEVE THIS. THIS ALL STARTED SHORTLY AFTER THE ESSURE COILS WERE PLACED. I JUST WANT THEM OUT NOW. I WANT MY LIFE BACK. I WANT TO BE THE WIFE AND MOTHER I WAS AND WANT THE PAINS TO STOP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057408	BAYER	10/29/2015	10/29/2015

Event Information:

Event Date (B3): 12/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHORTLY AFTER HAVING THE DEVICE IMPLANTED, I STARTED HAVING HEAVY, PAINFUL PERIODS THAT GOT PROGRESSIVELY WORSE. THEN I BEGAN PASSING CLUMPS OF TISSUE AND BLED SOMETIMES FOR 3-4 WEEKS AT A TIME, WITH ONLY A WEEK OR SO BEFORE STARTING TO BLEED AGAIN. WITHIN JUST A FEW MONTHS, I BECAME VERY ANEMIC, MY THICK, LONG HAIR BEGAN TO FALL OUT IN CLUMPS. I COULDN'T WALK FROM ONE END OF MY HOUSE TO THE OTHER WITHOUT BEING COMPLETELY EXHAUSTED. I WAS ALSO BEGINNING TO EXPERIENCE OVERALL JOINT AND BACK PAIN. I ENDED UP HAVING A UTERINE ABLATION TO CURTAIL THE BLEEDING AND THE DOCTOR REMOVED SEVERAL UTERINE FIBROIDS, ONE THE SIZE OF A GRAPEFRUIT, THAT HAD DEVELOPED SINCE IMPLANTATION OF THE DEVICE. ABOUT ONE YEAR LATER, THE BLEEDING HAD RETURNED AND I WAS BECOMING ANEMIC AGAIN. I WENT BACK FOR A SECOND ABLATION AND FIBROID REMOVAL. MY DOCTOR TOLD ME THAT I WAS "ESTROGEN DOMINANT" AND SHE HAD NEVER SEEN A UTERINE LINING GROW BACK LIKE THAT AFTER AN ABLATION. SINCE IMPLANTATION, I HAVE DEVELOPED EXCRUCIATINGLY PAINFUL OVULATION, MY VISION IS NOW BLURRY, REQUIRING READING GLASSES, I AM CHRONICALLY EXHAUSTED, FATIGUED, DEPRESSED AND IN CONSTANT PAIN FROM DEGENERATIVE OSTEOARTHRITIS, WHICH QUICKLY DEVELOPED WITHIN 3 YEARS OF THE IMPLANTATION. MY JOINTS CONTINUE TO DETERIORATE, MY LEGS AND ARMS TINGLE, THE BURNING, STINGING, RADIATING PAIN MY LOWER BACK REQUIRES ME TO TAKE MORPHINE, NORCO, FLEXERIL AND IBUPROFEN. I WAS THIN, MUSCULAR AND HEALTHY BEFORE I HAD THE IMPLANT. SINCE THEN, I EXPERIENCE CONSTANT BLOATING, HAVE GAINED 40 POUNDS AND CAN'T SEEM TO LOSE IT, AND I AM ON TEMPORARY DISABILITY, BUT WORKING ON PERMANENT DISABILITY DUE TO FOGGY MEMORY, INABILITY TO FOCUS AND THE SEVERE, DEBILITATING BACK PAIN FROM THE DEGENERATION OF THE CARTILAGE IN MY LOWER BACK. I BELIEVE ALL OF THIS IS A DIRECT RESULT OF HAVING THE ESSURE DEVICE

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IMPLANTED IN 2007. YES, THE DEVICE WAS PAID FOR BY MY INSURANCE AT THE TIME, BUT I HAVE BEEN ON AND OFF INSURANCE AND HAVE PAID A LOT OF MONEY OUT OF POCKET TO TREAT THE VARIOUS SYMPTOMS OF THIS DEVICE. I AM ALSO HIGHLY ALLERGIC TO PET, BUT I WAS NEVER TOLD IT WAS IN THIS DEVICE. I WAS TOLD IT WAS "PURE TITANIUM." I ALSO HAVE INSTANT CONTACT DERMATITIS NOT ONLY FROM PET, BUT ALSO FROM NICKEL. THIS DEVICE HAS RUINED MY LIFE. I DON'T KNOW THE EXACT DATE THE SYMPTOMS BEGAN, BUT I CAN PROVIDE ALL OF MY MEDICAL RECORDS, IF NEEDED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057409	BAYER	10/29/2015	10/29/2015

Event Information:

Event Date (B3): 10/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OH MY, WHERE DO I START HAVE SEVERE PUNCHING STABBING PELVIC PAIN ESPECIALLY NEAR THE SIDES OF MY LOWER ABDOMINAL , ONSET OF ANXIETY , PSTD, DEPRESSION. WEIGHT GAIN, I CAN'T CONTROL ANYMORE HIGH BLOOD PLEASURE , HIGH CHOLESTEROL , I TAKE SO MANY MEDICINES. NOW IT'S SICKENING I TAKE IN PAIN MY LOWER BACK USED TO TAKE SPELLS BUT NOW IT CONSTANTLY THROBS, MOODINESS, IRREGULAR PERIODS SORE BREAST, HORRIBLE PMS IN WHICH I'VE NEVER HAD . I NEVER BEEN ALLERGIC TO ANYTHING IN MY LIFE AND HAVE ALWAYS ENJOY A HEALTHY SNACK AND NOW I'M SO ALLERGIC TO ALMONDS JUST THE OILS CAN KILL ME, CONSTANT MIGRAINES, MY MEMORY IS HORRIBLE AND YES MY OB THAT DELIVERED MY LAST CHILD DID MY PROCEDURE, THE ONLY THING HE STRESSED TO ME WAS IT WASN'T REVERSABLE AND WAS I SURE I WANTED IT IF I KNEW THIS DEVICE WAS GOING TO CAUSE ME THIS MUCH MISERY OR EVEN TOLD THERE WAS A SLIGHT CHANCE I WOULD HAVE NEVER DONE THIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057410	BAYER	10/29/2015	10/29/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE HAD PROBLEMS WITH THESES DEVICES SINCE THEY WERE INSERTED. CAUSING SEVERE MIGRAINES, HAIR LOSS, BLOAT , ABDOMINAL PAIN PELVIC PAIN, INFECTIONS,SKIN RASHES, TOOTH DECAY, PAIN IN JOINTS AND SEVERE MUSCLE PAIN, FATIGUE TIREDNESS AND BOUTS WITH DEPRESSION, PAINFUL AND HEAVY PERIODS, SWOLLEN OVARIES, JUST TO LIST A FEW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)		10/29/2015	11/4/2015

Event Information:

Event Date (B3): 10/21/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS306
Catalog # (E4): ESS305
Lot #(E4): A20063

Single Use: I
Implant Date (E6): 11/1/2012
Explant Date (E7): 10/21/2015
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

PATIENT IS A (B)(6) WOMAN WHO PRESENTED TO THE (B)(6) HEALTH CENTER FOR LOSS OF ESSURE COIL. PATIENT STATES WHILE SHE WAS MENSTRUATING LAST WEEK, SHE WENT TO WIPE EXCESS DISCHARGE AND NOTED SMALL PIECE OF METAL CAME OFF, SHE BROUGHT METAL PIECE WITH HER. SHE IS ALSO COMPLAINING OF BACK AND LOWER ABDOMINAL PAIN ASSOCIATED. YELLOW DISCHARGE, PATIENT DENIES FEVER, CHILLS, NAUSEA, VOMITING OR DIARRHEA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057634		10/29/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/27/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2011. DURING THE PROCEDURE I EXPERIENCED A LOT OF PAIN. THE DOCTOR HAD TROUBLE INSERTING ONE OF THE COILS. AT THE 3 MONTH CHECK, I WAS TOLD THAT ONE SIDE DID NOT TAKE. I THEN HAD THE MIRENA INSERTED. FOR THE PAST YEAR I HAVE BEEN EXPERIENCING MUSCLE AND JOINT PAIN, EXTREME FATIGUE, HEAD FOG WITH HEADACHES, DIZZINESS, WEAKNESS, MEMORY PROBLEMS, LOWER BACK PAIN, ABDOMINAL PRESSURE, AND TREMORS. I ALSO HAVE LOW VITAMIN D AND BRITTLE NAILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057635		10/29/2015	11/4/2015

Event Information:

Event Date (B3): 11/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

MY ESSURE PROCEDURE WENT HORRIBLE. DURING INSERTION, I WAS TOLD MY UTERUS WAS TILTED AND THE DOCTOR COULD NOT GET TO MY RIGHT TUBE. I THEN ENDURED ABOUT WHAT FELT LIKE AN ETERNITY OF SCRAPING OF THE LINING OF MY UTERUS AS HE TRIED TO LOCATE THE SECOND TUBE BECAUSE OF THE SALINE THAT THEY USE HAS ABSORBED INTO THE LINING MAKING IT IMPOSSIBLE TO LOCATE THE TUBE. I NEVER HAD THE SECOND ESSURE IMPLANTED BECAUSE OF THE INABILITY TO FIND THE FALLOPIAN TUBE. A FEW MONTHS AFTER I HAD ESSURE IMPLANTED, I WAS DIAGNOSED WITH LUPUS. I ALSO HAVE ENDURED HAIR LOSS, MOOD SWINGS, HEAVY PERIODS THAT MAKE WORKING IMPOSSIBLE, EXCESSIVE CLOTTING DURING MY PERIOD, INABILITY TO SLEEP, WEIGHT GAIN, IRREGULAR PERIODS, TO A LIST A FEW. I ALSO FEEL A SMALL TWINGE OF PAIN WHERE I AM ASSUMING THE ESSURE IS LOCATED ON MY LEFT SIDE. I ALSO HAD AN X-RAY DONE AND MY ESSURE THAT I DO HAVE IS ALMOST FOLDED IN HALF AND IT LOOKS LIKE A PIECE OF IT IS NOT CONNECTED. I WAS NOT TOLD THAT PEOPLE WITH COMPROMISED IMMUNE SYSTEMS OR NICKEL ALLERGIES DID NOT MAKE GOOD CANDIDATES. ALSO, I WAS NEVER TOLD OF PET FIBERS THAT WERE PART OF THE COIL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057636	BAYER	10/29/2015	11/4/2015

Event Information:

Event Date (B3): 10/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PLACED. NOW ANEMIC, PELVIC DISCOMFORT, HEADACHES, FATIQUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057638		10/29/2015	11/4/2015

Event Information:

Event Date (B3): 1/29/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305-R1
Catalog # (E4):
Lot #(E4): CS0003V

Single Use: *
Implant Date (E6): 1/29/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE PUT IN ON (B)(6) 2014, I STARTED HAVING SHARP, STABBING PAIN IN MY LOWER ABDOMINAL. I FEEL DIZZY AND LIGHTHEADED AND HAVE EXCESSIVE BLEEDING ON ANY GIVEN CYCLE. IT ALSO PAINS ME TO BE INTIMATE WITH MY HUSBAND. I FEEL ALL THESE HEALTH PROBLEMS BEGAN 4 MONTHS AFTER MY IMPLANT. ON (B)(6) 2014, NINE MONTHS AFTER THE IMPLANT, I HAD AN ABLATION DONE TO CONTROL THE BLEEDING. I WAS TOLD THIS SURGERY WAS PERMANENT AND COULD NOT BE REVERSED NOW AFTER ALL OF THESE HEALTH PROBLEMS. I JUST WANT THEM OUT EVEN IF THEY HAVE TO DO A HYSTERECTOMY, BUT I'M SCARED TO START THAT PROCESS AS I'M ONLY (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057672	BAYER	10/29/2015	11/4/2015

Event Information:

Event Date (B3): 10/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A20058

Single Use: *
Implant Date (E6): 10/3/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

EVER SINCE HAVING ESSURE IMPLANTED, I'VE HAD CHRONIC PELVIC PAIN AND INFLAMMATION. MY ABDOMEN IS ALWAYS SWOLLEN AND BLOATED LOOKING, I HAVE SEVERE PAIN AND CRAMPS EVERY DAY, AND HAVE EXPERIENCED WEIGHT GAIN AND FATIGUE. I GOT THE DEVICE IMPLANTED 3 YEARS AGO, AND HAVE BEEN IN PAIN EVER SINCE, IN ADDITION TO A MUCH HEAVIER MENSTRUAL FLOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01263	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1444, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. A FRIEND OF THE CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED AND SUFFERED FROM MANY PAINFUL AND DEBILITATING SIDE EFFECTS AND HAD TO HAVE A COMPLETE HYSTERECTOMY AT THE AGE OF (B)(6) DUE TO THIS DEVICE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATING OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAINFUL AND DEBILITATING SIDE EFFECTS. SHE UNDERWENT A HYSTERECTOMY. THIS EVENT, INTERPRETED AS PAIN (UNSPECIFIED), WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. THE EXACT ONSET DATE AND LOCATION OF THE PAIN WERE NOT SPECIFIED. HOWEVER, CONSIDERING THE NATURE OF THE REPORTED EVENT, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01265	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): 1/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 9/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-(B)(4), AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE CONSUMER REPORTED THAT SINCE 2007 SHE EXPERIENCED HEADACHES, JOINT PAIN, PAIN IN PELVIC AREA, FATIGUE, HAIRLOSS, YEAST INFECTIONS, RASHES AND HEAVY PERIODS. PRIOR TO ESSURE PLACEMENT SHE WAS A HEALTHY WOMAN WITH NONE OF THESE AILMENTS. ON (B)(6) 2015 SHE HAD ESSURE COIL REMOVED. SHE NOTICED THAT AFTER REMOVAL HER JOINT PAIN REDUCED AND HER RASH WENT AWAY. PRODUCT TECHNICAL COMPLAINT ANALYSIS RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PAIN IN PELVIC AREA. SHE HAD ESSURE REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (ESSURE REMOVAL). SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01266	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN (B)(6) 2015 (FDA-2014-N-0736-1441, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE SON OF THE CONSUMER REPORTED THAT HIS MOTHER HAD ESSURE AND IT MADE HER VERY SICK. SHE WAS ALWAYS IN PAIN AND WAS SO SICK BEFORE HER SURGERY TO REMOVE ESSURE. AT THE TIME OF THE REPORT, THE MOTHER COULD DO MANY THINGS SHE COULD NOT DO BEFORE SHE HAD SURGERY TO REMOVE ESSURE. PRODUCT TECHNICAL COMPLAINT ANALYSIS RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS ALWAYS IN PAIN. SHE HAD SURGERY TO REMOVE ESSURE. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENT WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SURGERY TO REMOVE ESSURE). SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01267	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1321, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED SHE HAD CHRONIC PAIN FOR YEARS BEFORE REMOVAL, AND NOW SHE IS SUFFERING WITH AUTO IMMUNE DISEASE FOR THE REST OF HER LIFE. SHE HAD SEVERE DEPRESSION BECAUSE SHE COULD NOT DO THE THINGS SHE NEEDED TO DO FOR HER FAMILY. SHE WAS NOT BEING ABLE TO BE A MOTHER. SHE HAD TO TAKE TIME OFF WORK DURING FLARES. ALL OF THIS HAS HAPPENED BECAUSE SHE WAS TRYING TO NOT HAVE ANYMORE CHILDREN. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO

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RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PAIN FOR YEARS (INTERPRETED AS PELVIC PAIN). SHE HAD ESSURE REMOVED. THE CONSUMER ALSO HAD AN AUTO IMMUNE DISEASE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE AUTO IMMUNE DISEASE IS UNLISTED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. CONSIDERING THE NATURE OF THIS EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. EVENT AUTO IMMUNE DISEASE WAS ASSESSED AS UNRELATED TO THE DEVICE, GIVEN ITS PATHOPHYSIOLOGY AND ESSURE LOCAL EFFECT IN THE FALLOPIAN TUBES. NON-SERIOUS EVENT WAS ALSO REPORTED. SINCE ESSURE REMOVAL WAS REPORTED, THIS CASE WAS REGARDED AS INCIDENT (REQUIRED INTERVENTION IMPLIED). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01269	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1333, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. CONSUMER REPORTED FOR 10 YEARS SHE HAD NO IDEA WHAT WAS WRONG WITH HER. AFTER HAVING THE ESSURE IN 2006 SHE BLED FOR 10 MONTHS. SHE HAD TO GET ANOTHER SURGERY AND THE BLEEDING STOPPED FOR THE NEXT 7 YEARS. IN 2006 SHE HAD (STILL HAS) UNCONTROLLABLE PAIN IN HER ABDOMEN. SHE WAS DIAGNOSED WITH CHRONIC ABDOMEN PAIN. SHE READ THE SYMPTOMS THAT WERE ON THE ESSURE SITE. SHE HAD ALMOST 75% OF THOSE FOR THE PAST 10 YEARS. IN 2010 SHE HAD TO HAVE A PARTIAL HYSTERECTOMY BECAUSE SHE HAD A MASS 7 CM BIG ON HER OVARY, SO HER OVARY, HER TUBE AND PART OF HER UTERUS HAD TO COME OUT. SHE WAS (B)(6) YEARS OLD. SHE IS NOW (B)(6). SHE IS STILL DEALING WITH THIS PAIN IN HER ABDOMEN. SHE HATES SEX BECAUSE IT HURTS SO BAD. SHE HAS HAD 6 SURGERIES ON HER ABDOMEN, INCLUDING C-SECTION, AN APPENDIX, A THERMAL ABLATION, DILATION AND CURETTAGE, LAPAROSCOPY AND PARTIAL HYSTERECTOMY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO

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CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER HAVING THE ESSURE PLACED SHE BLED FOR 10 MONTHS (GENITAL BLEEDING). SHE HAD TO HAVE ANOTHER SURGERY AND THE BLEEDING STOPPED FOR 7 YEARS. APPROXIMATELY 4 YEARS LATER, SHE HAD TO HAVE A PARTIAL HYSTERECTOMY BECAUSE SHE HAD A MASS 7 CM BIG ON HER OVARY (INTERPRETED AS OVARIAN MASS). HER OVARY AND HER TUBE WERE ALSO REMOVED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE GENITAL BLEEDING IS LISTED WHILE THE OVARIAN MASS IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES AND THE NATURE OF THESE EVENTS, A CAUSAL RELATIONSHIP BETWEEN THE GENITAL BLEEDING AND ESSURE INSERTS CANNOT BE EXCLUDED. HOWEVER, THE CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE OVARIAN MASS IS UNLIKELY. THIS CASE IS REGARDED AS INCIDENT SINCE A REQUIRED INTERVENTION WAS PERFORMED TO TREAT AN ESSURE-RELATED EVENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01271	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/19/2008
Explant Date (E7): 3/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1363 / FDA-2014-N-0736-0015, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008 FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT SHE HAD EXPERIENCED CRAMPING, SHARP/STABBING PELVIC PAIN, ABNORMAL MENSES, PERIOD STOPS, OVARIAN CYSTS, UTERINE CYSTS, CONSTANT SPOTTING, DISCHARGE (ODOR / NO ODOR), ENDOMETRIOSIS, HOT FLASHES, CERVICAL CANCER / DYSPLASIA, POLYCYSTIC OVARIAN SYNDROME, UTERINE FIBROIDS, UTERINE INFLAMMATION, UTERINE INFECTION, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION, NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, SPOTTING AFTER SEX, PAINFUL PERIODS, PAINFUL INTERCOURSE, BLEEDING BETWEEN PERIODS, INCONTINENCE, LONG MENSTRUAL CYCLES, URGENT / FREQUENT URINATION, SWELLING / INFLAMMATION OF THE CERVIX OR VAGINA, ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE,BREAST PAIN / TENDERNESS, ABDOMINAL SPASMS / TWITCHING / FLUTTERING. PAIN IN BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, LEFT HIP, CHRONIC PELVIC PAIN AND ALL OVER BODY ACHES / PAIN. NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, BOWEL ISSUES (CHRONIC CONSTIPATION / SEVERE DIARRHEA). HEADACHES, DIZZINESS, NUMBNESS, BRAIN SHOCKS - BRAIN FOG- CLOUDINESS, FORGETFULNESS, ANXIETY / PANIC ATTACKS, MOOD SWINGS, DEPRESSION (SADNESS / SUICIDAL THOUGHTS), DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), NUMBNESS / TINGLING IN EXTREMITIES (HANDS/FEET). HIGH BLOOD PRESSURE, UNEXPLAINED / EASILY BRUISING, ELEVATED BLOOD COUNTS, BORDER LINE TYPE 2

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DIABETES. AUTOIMMUNE DISORDERS, CHRONIC FATIGUE. CHEMICAL AND FOOD SENSITIVITIES, METAL ALLERGIES (NICKEL), HEIGHTENED ALLERGIES, HIVES, RASHES, CYSTS, BOILS, ACNE, SKIN IRRITATION / ITCHING. HEART PALPITATIONS, COILS/DEVICE ISSUES, PERFORATION OF THE TUBES BY THE COILS, COIL MIGRATIONS. SWELLING OF LEGS OR FEET, HAIR GROWTH IN NEW PLACES, INSOMNIA, WEIGHT ISSUES (GAIN), .ADHESIONS (SCAR TISSUE IN ABDOMEN), UNEXPLAINED FEVERS, MUSCLE SPASMS, VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION), EXCESSIVE SWEATING, DRY SKIN / HAIR / EYES. ON (B)(6) 2015 SHE HAD A HYSTERECTOMY PERFORMED AT THE AGE OF (B)(6) AS IT WAS THE ONLY WAY OUT OF THESE HORRIBLE DAILY OCCURRENCES. SHE STILL DEALS WITH SOME OF THESE ISSUES TO THIS DAY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PERFORATION OF THE TUBES BY COILS/COIL MIGRATIONS (INTERPRETED AS FALLOPIAN TUBE PERFORATION), CERVICAL CANCER, UTERINE INFECTION, DEPRESSION WITH SUICIDAL THOUGHTS (INTERPRETED AS DEPRESSION SUICIDAL) AND AUTOIMMUNE DISORDERS. SHE HAD A HYSTERECTOMY APPROXIMATELY 7 YEARS AFTER ESSURE INSERTION. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE FALLOPIAN TUBE PERFORATION AND UTERINE INFECTION ARE LISTED WHILE THE CERVICAL CANCER, SUICIDAL DEPRESSION AND AUTOIMMUNE DISORDERS ARE UNLISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. THE TEMPORAL RELATIONSHIP BETWEEN ALL THE EVENTS AND ESSURE IS NOT CLEAR. HOWEVER, CONSIDERING A PROBABLE COMPATIBLE TEMPORAL RELATIONSHIP, THE LOCALIZED ACTION OF ESSURE INSERTS IN THE FALLOPIAN TUBES AND NATURE OF THESE EVENTS, THE CAUSAL RELATIONSHIP BETWEEN ESSURE AND FALLOPIAN TUBE PERFORATION AND UTERINE INFECTION CANNOT BE EXCLUDED. HOWEVER, THE CERVICAL CANCER, SUICIDAL DEPRESSION AND AUTOIMMUNE DISORDERS ARE UNLIKELY TO BE CAUSED BY ESSURE INSERTS. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01273	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1335, AWARENESS DATE 03-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. CONSUMER WENT TO HER DOCTOR SEEKING STERILIZATION AND WAS PUSHED INTO GETTING ESSURE. FROM THE MOMENT SHE WAS IMPLANTED, THE PAIN NEVER STOPPED. HER BODY IMMEDIATELY BEGAN REJECTING THIS FOREIGN OBJECT. FOR ALMOST A YEAR, SHE LIVED IN AGONIZING PAIN. SHE WAS HAVING CONTRACTIONS EVERY SINGLE DAY. SHE GAINED 30 POUNDS IN A MATTER OF 3 MONTHS. SHE BECAME DEPRESSED AND NEXT TO USELESS. SHE WASN'T THE SAME PERSON SHE HAD BEEN PRIOR TO GETTING ESSURE. SHE FOUND OUT THAT THIS PRODUCT CONTAINS NICKEL, A METAL THAT SHE WAS HIGHLY ALLERGIC TO. SHE WENT BACK TO HER DOCTOR SEVERAL TIMES TRYING TO FIND ANSWERS. SHE FINALLY AGREED IT WAS TIME FOR ESSURE TO GO AND SHE HAD HER REMOVAL DONE ON (B)(6) 2015. AFTER THE REMOVAL SHE WAS NO LONGER IN PAIN, SHE WAS LOSING WEIGHT AND REGAINING THE ENERGY SHE ONCE HAD. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD.

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WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THEN THE PAIN NEVER STOPPED, SHE LIVED IN AGONIZING PAIN AND WAS HAVING CONTRACTIONS. SHE HAD ESSURE REMOVED AND WAS NO LONGER IN PAIN. THIS EVENT, INTERPRETED AS ABDOMINAL PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, AND SINCE THE PAIN RESOLVED AFTER ESSURE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. SINCE ESSURE REMOVAL WAS REPORTED, THIS CASE WAS REGARDED AS INCIDENT (REQUIRED INTERVENTION IMPLIED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01279	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1160, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. FROM THE INSERTION POINT AND ON CONSUMER HAD ISSUES SUCH AS BLEEDING, LARGE CLOTS, LOW HEMOGLOBIN BECAUSE OF THE HEAVY BLEEDING, DIZZINESS AND CONTINUED ANEMIA ALONG WITH INTENSE PAIN. SHE WOULD FEEL SHARP, STABBING PAIN ALONG THE FRONT SIDES OF PELVIS AND A DEEP ACHING IN HER LOW BACK. IT FELT LIKE PERIOD CRAMPS ON A DAILY BASIS. THIS WENT ON TO THE 3 MONTH DYE TEST. AFTER THE DYE TEST, SHE HEMORRHAGED. THE DOCTOR TOLD HER IT WAS OKAY AND WOULD SLOW DOWN BUT IT TOOK A MONTH TO SLOW DOWN TO SPOTTING AND SHE SPOTTED FOR 3 MONTHS. THE FATIGUE, THE ANEMIA, THE BLOOD TRANSFUSIONS CONTINUED. AFTER TREATMENTS HER HEMOGLOBIN ROSE AND SHE CONTINUED TO HAVE PAIN. THE PAIN AND SWELLING CONTINUED, AS WELL AS THE BACK PAIN. SHE BEGAN TO HAVE SWELLING IN OTHER AREAS - HER APPENDIX SWELLED TO BE 4X THE SIZE WITH NO SIGN OF INFECTION, JUST INTENSE BACK PAIN AND A LARGE ORGAN. PET FIBERS HAD MIGRATED TO THE ORGAN AND EMERGENCY SURGERY WAS PERFORMED. SHE HAD ANXIETY, MOOD SWINGS, DEPRESSION, WEIGHT GAIN, WATER RETENTION, PAIN, ITCHING AND RASHES, INSOMNIA, HAIR LOSS, METABOLIC DISORDER, AND THYROID ISSUES. SHE WAS CURRENTLY (B)(6) PREGNANT AND CONTINUED TO SUFFER WITH TERRIBLE PAIN AND A COMPLICATED PREGNANCY. ESSURE WAS ONGOING AND SHE CONSIDERED ALL EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE

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CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LARGE CLOTS, HEAVY BLEEDING, SHE SPOTTED FOR 3 MONTHS. AFTER THE DYE TEST SHE HEMORRHAGED (SEEN AS POST PROCEDURAL BLEEDING). SHE WAS CURRENTLY (B)(6) PREGNANT. THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO EXPERIENCED CONTINUED ANEMIA (UNLISTED). IT WAS REPORTED THAT PET FIBERS HAD MIGRATED TO THE ORGAN (SEEN AS DEVICE DISLOCATION, WHICH IS LISTED, AND DEVICE BREAKAGE, WHICH IS UNLISTED) AND EMERGENCY SURGERY WAS PERFORMED. ALL THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO EMERGENCY SURGERY PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01280	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2010
Explant Date (E7): 4/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1202, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. CONSUMER REPORTED THAT INSERTION OF ESSURE WITH NO ANESTHESIA WAS THE MOST PAINFUL PROCEDURE SHE EVER HAD. AFTER THAT SHE STARTED WITH HORRIBLE PAIN, ESPECIALLY ON HER LEFT SIDE, MIGRAINES, LEG PAIN, BACK PAIN, CRAMPS, BLOOD CLOTS, HEAVY PERIODS AND SOME MONTHS NO PERIODS. SHE WENT TO THE EMERGENCY ROOM SEVERAL TIMES DUE TO THE PAIN. ON (B)(6) 2015 SHE HAD A SALPINGECTOMY TO REMOVE THE COILS. AFTER THE SURGERY, THE DOCTOR TOLD HER THAT THE LEFT COIL WAS LIKE A BALL, IT WAS NOT IN THE NORMAL POSITION. SINCE SURGERY SHE DOES NOT HAVE ANY MORE PAIN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FOUR AND A HALF YEARS LATER UNDERWENT A SALPINGECTOMY TO REMOVE THE COILS. DURING THE SURGERY IT WAS FOUND THAT THE LEFT COIL WAS NOT IN THE NORMAL POSITION. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, THE EXACT LOCATION OF THE DEVICE WAS NOT REPORTED. IT WAS MENTIONED THAT IT WAS NOT IN THE NORMAL POSITION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-

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SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SALPINGECTOMY TO REMOVE ESSURE). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 02-NOV-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01281	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1200, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. LESS THAN 48 HOURS AFTER ESSURE INSERTION, CONSUMER EXPERIENCED STOMACH EXTREMELY BLOATED AND ITCHING, NONSTOP BLEEDING FOR ALMOST 90 DAYS STRAIGHT, SEVERE CRAMPING, EXTREME FATIGUE, WEIGHT GAIN, BRAIN FOG, SEVERE DEPRESSION. SHE LOST FALLOPIAN TUBES AS A RESULT OF ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NON-STOP BLEEDING FOR ALMOST 90 DAYS STRAIGHT (SEEN AS GENITAL BLEEDING) AND SEVERE DEPRESSION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. BLEEDING IS LISTED WHILE SEVERE DEPRESSION IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. IN THIS CASE, GIVEN CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY BETWEEN NON-STOP BLEEDING AND ESSURE USE CANNOT BE EXCLUDED. SOME DEPRESSIVE FEELINGS AND EMOTIONAL DISTURBANCES REGARDING DEFINITIVE CONTRACEPTION WITH ESSURE HAVE BEEN REPORTED. HOWEVER, MAJOR DEPRESSION IS NOT EXPECTED. THEREFORE, CAUSALITY WITH ESSURE USE IS VERY UNLIKELY. SINCE AIN INTERVENTION WAS IMPLIED (SHE LOST HER FALLOPIAN TUBES), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01282	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1332, AWARENESS DATE 04-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE SUFFERED FROM SEVERE PAIN, HEAVY MENSTRUAL FLOW (REPORTED AS HEAVY MENTAL FLOW) AND HER TEETH WERE FALLING OUT OF HER MOUTH. SHE STATED SHE WAS (B)(6) AND ENDED UP WITH A HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD SEVERE PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE UNDERWENT A HYSTERECTOMY. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 02-NOV-2015, REFERRING TO PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01283	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2013
Explant Date (E7): 3/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1296, AWARENESS DATE 04-OCT-2015). IT REFERS TO A (B)(6) -YEAR-OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. THE CONSUMER HAD 2 PREMATURE LABORS AND BIRTHS AND WAS TOLD HER DOCTOR SHE WAS TOO YOUNG FOR A TUBAL LIGATION, BUT THAT SHE WAS A GOOD CANDIDATE FOR ESSURE. BEFORE ENTERING THE ROOM FOR ESSURE INSERTION, SHE ASKED HER DOCTOR IF HER NICKEL SENSITIVITY/ POSSIBLE ALLERGY WOULD BE A PROBLEM AND SHE WAS TOLD NO AND THAT THERE WASN'T ENOUGH NICKEL IN IT TO CAUSE ANY PROBLEMS. THE PROCEDURE IN FACT IT WAS EXTREMELY PAINFUL EVEN WITH ALL THE DRUGS SHE HAD TO TAKE PRIOR TO IT INCLUDING A MILD NARCOTIC FOR PAIN. SHE WAS IN MORE PAIN THAN SHE HAD EVER EXPERIENCED IN HER LIFE (INCLUDING CHILDBIRTH) AND SHE WAS TOLD IT WAS NORMAL AND TO RELAX. WHEN THE PROCEDURE WAS DONE SHE WAS TOLD THAT ONCE SHE COULD GET UP AND MOVE AROUND SHE WAS OKAY TO GO HOME AND THAT THE PAIN WOULD SUBSIDE OVER THE NEXT DAY. SHE ENDED UP BEDRIDDEN FOR A WEEK AFTER THAT. A MONTH LATER SHE WAS STILL IN PAIN AND WAS TOLD THAT THE DOCTOR COULD NOT CHECK THE PLACEMENT OR LOOK FOR THE PROBLEM UNTIL THE DYE TEST, WHICH 3 MONTHS AFTER THE INSERTION SHOWED THAT THE TUBES WERE BLOCKED. THE CONSUMER WENT BACK TO THE DOCTOR WITH NOT ONLY CHRONIC PELVIC PAIN (ESPECIALLY A SHARP STABBING PAIN ON LEFT SIDE OF PELVIS) BUT INFLAMMATION THAT HAD SPREAD INTO HER LOWER BACK AND HIPS. SHE WAS ALSO BECOMING VERY BLOATED, SHE COULD NOT SLEEP BUT WAS ALWAYS TIRED, STARTED GETTING BOILS ON HER UPPER INNER THIGHS, HAD TO SEE A GASTROENTEROLOGIST FOR STOMACH PROBLEMS THAT STARTED

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AFTER ESSURE WAS PLACED (SHE WAS ASSUMING MORE INFLAMMATION), AND WHEN HER PERIOD RETURNED IT WAS EXTREMELY HEAVY AND CYCLES WERE IRREGULAR. SHE WAS PUT ON A BIRTH CONTROL PILL TO REGULATE HER CYCLES, WHICH MADE HER CYCLES WORSE, LASTING FOR 2 WEEKS AND CAME EVERY 2 WEEKS. SHE STARTED SEEING A PHYSICAL THERAPIST AROUND THAT TIME BECAUSE THE ORTHOPEDIST COULD NOT FIND ANYTHING. SHE COULD NOT WALK FOR LONG AND COULD NOT STAND UP FOR LONGER THAN 5 MINUTES WITHOUT HER BACK SPASMING AND COULD NOT SLEEP AT NIGHT BECAUSE HER HIPS WOULD FLARE UP. SHE SWITCHED DOCTORS AND AFTER EXPLAINING ALL OF HER SYMPTOMS, THE DOCTOR TOLD SHE WAS ALMOST POSITIVE THAT THE CONSUMER WAS HAVING A REACTION TO THE COILS BUT WANTED TO SEE IF THEY COULD MANAGE HER PROBLEMS FIRST. THE CONSUMER TOOK ANOTHER BIRTH CONTROL FOR ALMOST 6 MONTHS - IT DID NOT GET ANY BETTER AND SHE EVEN BECAME ANEMIC DUE TO THE LACK OF IRON FROM AN ALMOST CONTINUOUS CYCLE. A LAVH (LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY) WAS THEN PERFORMED IN (B)(6) 2015, LEAVING OVARIES. AFTER SURGERY, SHE WOKE UP FEELING BETTER. THE COILS CAME OUT INTACT. SINCE THEN THE ONLY LINGERING HEATH ISSUE SHE HAD HAD WAS HIP PAIN. EVERYTHING ELSE WAS GONE. SHE HAD LOST THE WEIGHT SHE GAINED FROM HAVING ESSURE, AS WELL AS ALL THE SWELLING AND BLOATING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CHRONIC PELVIC PAIN / SHARP STABBING PAIN ON LEFT SIDE OF PELVIS AND HER PERIOD WAS EXTREMELY HEAVY / CYCLES LASTING FOR 2 WEEKS/ ALMOST CONTINUOUS CYCLE (INTERPRETED AS MENORRHAGIA). SHE UNDERWENT A HYSTERECTOMY 16 MONTHS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN AND MENSES PATTERN CHANGES MAY OCCUR. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, THE NATURE OF THE REPORTED EVENTS, AND IN THE LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01284	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1347, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. CONSUMER REPORTED THAT EVER SINCE INSERTION SHE STARTED TO HAVE SEVERE ABDOMINAL PAIN, BACK PAIN AND KIDNEY STONES ALL THE TIME. SHE HAD A HYSTERECTOMY TO REMOVE ESSURE AND STARTED FEELING BETTER. BUT SHE WAS IN A LOT OF PAIN AGAIN, IN HER OVARIES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EVER SINCE, STARTED HAVING SEVERE ABDOMINAL PAIN AND KIDNEY STONES ALL THE TIME. SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. ABDOMINAL PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE REMAINING EVENT IS UNLISTED. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THE RISK FOR NEPHROLITHIASIS IS INFLUENCED BY URINE COMPOSITION, WHICH CAN BE AFFECTED BY CERTAIN DISEASES AND PATIENT HABITS SUCH AS A LOW CALCIUM INTAKE, HIGH OXALATE INTAKE, HIGH ANIMAL PROTEIN INTAKE, HIGH SODIUM INTAKE, OR LOW FLUID INTAKE. CONSIDERING THE PATHOPHYSIOLOGY OF THE EVENT KIDNEY STONES AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE

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ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01285	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1419, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER EXPERIENCED PAIN FOR YEARS. ESSURE WAS REMOVED IN (B)(6) 2015 (8 MONTHS BEFORE THIS REPORT). SHE NO LONGER EXPERIENCED PAIN IN LOWER LEFT ABDOMEN, LEFT LEG AND LEFT GENITAL AREA AND SHE WAS ABLE TO EXERCISE WITHOUT FATIGUE. HER DIGESTION, SLEEP, MOOD, MENTAL CAPACITY AND OVERALL PHYSICAL WELL-BEING WERE IMPROVED. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN IN HER LEFT ABDOMEN FOR YEARS. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER EXPERIENCED PAIN FOR YEARS. AFTER REMOVAL OF ESSURE, SHE NO LONGER EXPERIENCED THIS PAIN. OTHER NON-SERIOUS EVENTS ALSO IMPROVED. CONSIDERING EVENT'S NATURE AND RECOVERY AFTER REMOVAL, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. AS DEVICE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PERSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01286	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1392, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. CONSUMER STATED THAT HER WEIGHT WAS (B)(6) AND IN 2011 SHE GAINED 20 LBS. SHE EXPERIENCED CRAMPING, BLOATING AND PAIN. SHE WAS ALWAYS TIRED AND IN PAIN. SHE DID NOT HAVE A LIFE, HER MEMORIES WERE FADING, SHE FELT OUT OF PLACE AT TIMES, HER BACK PAIN WAS HORRIBLE, HER HAIR STARTED FALLING AND IN 2012 THINGS STARTED GETTING WORSE; SHE WENT FROM A REGULAR PERIOD THAT WAS 3/4 DAY PRETTY LIGHT AND REGULAR TO 2 PERIODS IN ONE MONTH WITH HEAVY BLEEDING AND CRAMPING. SHE STATED LOST MUCH BLOOD AND BECAME ANINICK (INTERPRETED AS ANEMIC). DUE TO ALL THE CRAMPING AND BLOATING, SHE LOST HER JOB FOR MISSING DAYS FOR BEING SICK. IT TOOK ANOTHER 2 YEARS AND SHE WAS IN AND OUT OF THE HOSPITALS. SHE WAS WEIGHTING (B)(6). SHE WAS DEPRESSED. SHE COULD NOT LOSE WEIGHT. SHE ALSO REPORTED OVARIAN CYSTS IN TUBES AND THAT SEX DID NOT WORK WITH HER DUE TO HORRIBLE PAIN. IN 2013, SHE WAS (B)(6). ON (B)(6) 2015, SHE WAS READY FOR ESSURE REMOVAL. SHE FOUND OUT THAT COILS MIGRATED TO UTERUS. SHE HAD THE SURGERY. TWO DAYS AFTER SURGERY, SHE WAS EXPERIENCING PAIN AND WENT TO THE EMERGENCY ROOM (ER) WHERE SHE WAS HOSPITALIZED FOR HAVING PHA MONOAMINE FLUID IN LUNG FOR BEING UNDER SURGERY FOR MORE THAN 6 HOURS. SHE STATED HOSPITALIZED FOR ABOUT 2 WEEKS. IN 2015, SHE DISCOVERED STILL HAD ESSURE ON HER. IT HAD MIGRATED. SHE HAD A MISCARRIAGE DUE TO BEING PREGNANT WITH A TUBE PREGNANCY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED

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DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING. SHE UNDERWENT A ESSURE REMOVAL AND SHE FOUND OUT THAT COILS MIGRATED TO UTERUS. TWO DAYS AFTER SURGERY, SHE EXPERIENCED FLUID IN LUNG RESULTING IN HOSPITALIZATION. SHE DISCOVERED STILL HAD ESSURE ON HER/ IT HAD MIGRATED (DEVICE MIGRATION). SHE HAD A MISCARRIAGE DUE TO BEING PREGNANT WITH A TUBE PREGNANCY. FLUID IN LUNG IS UNLISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. ALL EVENTS WERE CONSIDERED SERIOUS. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. IN THIS CASE, THE GESTATIONAL AGE WAS NOT PROVIDED. ALSO, THE EXACT DATE AND MECHANISM OF MIGRATION WERE NOT KNOWN. CONSIDERING THE NATURE OF THE EVENTS, EXCEPT FOR FLUID IN LUNG, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE EVENT FLUID IN LUNG, CONSIDERING THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. DUE TO ESSURE REMOVAL AND THE OCCURRENCE OF ECTOPIC PREGNANCY, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01287	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1446, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE HUSBAND OF THE CONSUMER STATED THAT SHE SUFFERED DAILY FOR MANY YEARS BECAUSE OF ESSURE. HE HAD NO DOUBT THAT ESSURE ALMOST CAUSED HER TO DIE. SINCE SHE HAD ESSURE REMOVED, WHICH CAME WITH MANY COMPLICATIONS AND MANY EXTRA SURGERIES, SHE WAS LEARNING HOW TO BE A WIFE AND MOTHER AGAIN. ESSURE DID SO MUCH DAMAGE TO HER, TO HER BODY THAT SHE WILL ALWAYS SUFFER FROM LONG TERM EFFECTS BECAUSE OF ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER AN UNSPECIFIED TIME INTERVAL SHE HAD ESSURE REMOVED. THIS EVENT, INTERPRETED AS MEDICAL DEVICE REMOVAL, WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. THIS CASE WAS REPORTED WITH VERY LIMITED INFORMATION AND THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, NEITHER WAS THE EXACT REMOVAL METHOD. HOWEVER, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED, AND SINCE A DEVICE REMOVAL WAS REQUIRED THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01288	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1268, AWARENESS DATE 04-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER GAINED 60LBS IN THE LAST 7 YEARS, EXPERIENCED CYSTIC ACNE, MIGRAINES, BLOATING, INFLAMMATION OF PELVIC AREA, FOGGY FEELING, FATIGUE, ANEMIA (SHE WAS RECEIVING IRON INFUSIONS), HER PERIODS WERE HEAVY (IN JUNE SHE HAD AN ABLATION DONE, WHICH DID NOT HELP). SHE WILL REQUEST ESSURE REMOVAL. SHE WAS (B)(6) AT TIME OF THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER PERIODS ARE HEAVY. SHE UNDERWENT AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION) WHICH DID NOT HELP. SHE ALSO REPORTED ANEMIA FOR WHICH SHE WAS RECEIVING IRON INFUSIONS, AND INFLAMMATION OF PELVIC AREA. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. ANEMIA IS AN UNLISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE REMAINING EVENTS ARE LISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE EVENT PERIODS ARE HEAVY AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ANEMIA MAY BE CAUSED BY BLOOD LOSS, HEMOLYSIS, AND DECREASED PRODUCTION OF RED BLOOD CELLS. IN THE PRESENT CASE, SINCE THE CONSUMER HAD HEAVY PERIODS WHICH COULD HAVE HAD A CONTRIBUTORY ROLE IN THE OCCURRENCE OF THE ANEMIA, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING INFLAMMATION OF PELVIC AREA, WHILE ESSURE SYSTEM IS STERILE IT MAY,

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DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFLAMMATORY DISEASE IN THE FIRST 4 WEEKS AFTER INSERTION. IN THE PRESENT CASE, NO INFORMATION SUGGESTING THIS CLOSE TEMPORAL RELATIONSHIP WITH THE INSERTION PROCEDURE WAS MENTIONED, AND ESSURE WAS NOT REMOVED. THEREFORE A CAUSAL RELATIONSHIP BETWEEN ESSURE AND INFLAMMATION OF PELVIC AREA WAS CONSIDERED VERY UNLIKELY (UNRELATED). NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (ENDOMETRIAL ABLATION, IRON INFUSIONS). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01289	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): 12/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 12/31/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1247, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6)-2015 (CONTRADICTORY INFORMATION CONSIDERING REMOVAL DATE, IT WAS PROBABLY INSERTED ON (B)(6)-2014). CONSUMER HAD PLACED AFTER HER FIFTH CHILD WAS BORN (COMPLICATIONS IN ON PREGNANCY). SHE WAS PUT TO SLEEP TO HAVE IT INSERTED. SHE IMMEDIATELY NOTICED CHANGES AND STARTED WITH HORRIBLE MOOD SWINGS, HAIR LOSS, MIGRAINES, NUMBNESS IN ARMS AND FINGERS, FATIGUE, DEPRESSION, ANXIETY, IRRITABILITY, HEAVY BLEEDING, BLOOD CLOTS, SEX BECAME EXTREMELY PAINFUL. AFTER MANY MONTHS OF PAIN AND AGGRAVATION, AN ULTRASOUND WAS PERFORMED AND SHOWED BADLY INFLAMED TUBES AND FLUID BUILT UP IN FALLOPIAN TUBES AND UTERUS WAS EXTREMELY SENSITIVE CAUSING THE PAIN DURING SEX. ON (B)(6)-2014, A HYSTERECTOMY WAS SCHEDULED AND SHE LOST A LOT OF BLOOD DURING THE SURGERY. SHE GOT EXTREMELY WEAK AND WAS NOT ABLE TO GET UP AND STAND OR ANYTHING THE FIRST DAY AFTER SURGERY WITHOUT FEELING OF PASSING OUT. SINCE THE ESSURE REMOVAL, SHE STILL EXPERIENCES MIGRAINES, MOOD SWINGS AND FATIGUE BUT SHE WAS FEELING A LOT BETTER. SHE STATED DID NOT KNOW THAT IF ALLERGIC TO NICKEL, SHE SHOULD NOT HAVE IT INSERTED. SHE WAS (B)(6) AT TIME OF HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED MANY MONTHS OF PAIN. AFTERWARDS, USG SCAN SHOWED BADLY INFLAMED TUBES FLUID BUILT UP IN HER FALLOPIAN TUBES. SHE ALSO HAD HEAVY BLEEDING AND DURING

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HYSTERECTOMY, LOST A LOT OF BLOOD DURING THE PROCEDURE. THESE EVENTS, SEEN AS PELVIC PAIN, SALPINGITIS, GENITAL BLEEDING AND PROCEDURAL BLEEDING ARE SERIOUS DUE TO REQUIRED INTERVENTION AND MEDICAL IMPORTANCE AND ARE ALL LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, CONSIDERING THEIR NATURE AND IMPLIED TEMPORAL RELATIONSHIP, THE EVENTS ARE ASSESSED AS RELATED TO ESSURE. ALTHOUGH THE DEVICE MAY BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT DURING INSERTION, THIS MOSTLY OCCURS IN THE FIRST 4 WEEKS FOLLOWING THE PLACEMENT. IN THIS CASE, IT WAS STATED THAT THERE WERE MANY MONTHS OF PAIN AND AGGRAVATION UNTIL THE SALPINGITIS BE DIAGNOSED. THEREFORE, CAUSALITY BETWEEN SALPINGITIS AND ESSURE IS VERY UNLIKELY. REGARDING POST PROCEDURAL BLEEDING, AS THE HYSTERECTOMY WAS PROBABLY PERFORMED TO REMOVE THE DEVICES AND THE BLOOD LOSS WAS A CONSEQUENCE OF THIS PROCEDURE, CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED EVENT CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-NOV-2015, REFERRING TO PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01290	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2013
Explant Date (E7): 4/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1412, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. TO BEGIN, THERE WAS A MALFUNCTION OF THE PRODUCT DURING THE IMPLANTATION WHERE THE RIGHT COIL REMAINED ATTACHED TO THE CAMERA, AND UNRAVELED. NOT ONLY WAS IT NOT IMPLANTED, BUT IT WAS TERRIBLY PAINFUL AND RESULTED IN EXCESSIVE BLEEDING. DURING THE DYE TEST A MONTH LATER, THERE WAS A MASS IN HER UTERUS. HER DOCTOR THOUGHT IT COULD BE REMNANTS, DAMAGE FROM THE ESSURE PROCEDURE; SHE REQUIRED SURGERY. SHE DEVELOPED A CHRONIC PAIN ON HER LEFT SIDE, AND BEGAN DEVELOPING OVARIAN CYSTS DURING HER CYCLE THAT WERE PAINFUL TO THE POINT SHE ENDED UP IN THE ER BECAUSE HER DOCTOR THOUGHT IT HAD BURST. OVER THE NEXT YEAR SHE STEADILY GAINED UPWARDS OF 29 POUNDS IN SPITE OF WORKING OUT, AND EATING A 1400 CALORIE PER DAY DIET. SHE DEVELOPED HYPOTHYROIDISM. THE CHRONIC PAIN ON HER LEFT SIDE BECAME DISRUPTIVE. A CT SCAN REVEALED THAT HER REMAINING ESSURE COIL APPEARED TO BE PUNCTURING HER UTERUS. A SECOND SURGERY TO INVESTIGATE AND SUBSEQUENTLY REMOVE HER TUBES OCCURRED IN (B)(6) 2015. SHE NOW STRUGGLES WITH A CHRONIC HEALTH PROBLEM; STILL HAVE PAIN IN HER LEFT SIDE. FOLLOW UP RECEIVED ON 28-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS

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RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THE POSSIBILITY OF DETACHMENT DIFFICULT EVENT IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. THE RISK TO THE PATIENT FOR THESE TYPES OF FAILURE MODE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER, WHO HAD EXCESSIVE BLEEDING DURING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ONE MONTH LATER, SHE WAS SUBMITTED TO A SURGERY DUE TO AN UNSPECIFIED MASS IN HER UTERUS (ACCORDING TO HER DOCTOR THOUGHT IT COULD BE REMNANTS, DAMAGE FROM THE ESSURE PROCEDURE). TWO YEARS LATER, BILATERAL SALPINGECTOMY WAS PERFORMED AS ESSURE COIL APPEARED TO BE PUNCTURING HER UTERUS AT CT SCAN. ONLY UTERINE MASS IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A PERFORATION WITH ESSURE OCCURS, PATIENT MAY EXPERIENCE PAIN AND BLEEDING DURING AND AFTER THE PROCEDURE. IN THIS CASE, CONSUMER HAD PAIN AND BLEEDING DURING ESSURE INSERTION; ADDITIONALLY SHE STATED THE RIGHT COIL UNRAVELED AND WAS NOT IMPLANTED. THIS SUGGESTS A DIFFICULT ESSURE INSERTION; WHICH MAY HAVE CONTRIBUTED TO THE REPORTED PERFORATION (ESSURE PUNCTURING HER UTERUS). ALTHOUGH THE EXACT MECHANISM OF THE EVENTS WAS NOT KNOWN; GIVEN THEIR NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE REPORTED UTERINE MASS, LIMITED INFORMATION WAS PROVIDED FOR A COMPREHENSIVE ASSESSMENT. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE ESTABLISHED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01291	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/11/2011
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5039426) IN UNITED STATES ON 15-JAN-2015. CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. SHE STATED THAT WHEN IT WAS PLACED SHE PRESENTED SEVERE PAIN THAT HAS BEEN THERE EVER SINCE ON HER RIGHT LOWER QUADRANT. SHE ALSO EXPERIENCED PERIODS THAT DON'T END (THEY MAY LIGHTEN TO SPOTTING BUT NEVER END), MIGRAINES, SKIN ISSUES AND DENTAL PROBLEMS. SHE WAS ALSO CHECKED DUE TO SYMPTOMS OF TIA (TRANSIENT ISCHAEMIC ATTACK) AND SEIZURES AND WAS PLACED ON HEART MONITORS. NONE OF THE PROBLEMS WERE BEFORE THIS PROCEDURE. AT THE TIME OF REPORT, SHE WAS AT AGE (B)(6) GOING TO HAVE A HYSTERECTOMY TO REMOVE ESSURE. CONSUMER INFORMED THE DATE (B)(6) 2011 AS EVENT ONSET DATE; HOWEVER SHE DID NOT SPECIFY IT. FOLLOW-UP INFORMATION RECEIVED ON 13-FEB-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. SYMPTOMS OF "TIA AND SEIZURES" AS REPORTED BY THE PATIENT, ARE NOT KNOWN FAILURE MODES RELATED TO ESSURE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS

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AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP INFORMATION RECEIVED ON 11-MAY-2015: ON (B)(6) 2011, ESSURE WAS INSERTED. THE CONSUMER MENTIONED THE SERIOUSNESS CRITERIA REQUIRED INTERVENTION BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW UP 21-AUG-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE TO DATE. NO NEW INFORMATION WAS PROVIDED. FOLLOW UP IDENTIFIED ON 05-OCT-2015 (CASE UPGRADED TO INCIDENT): THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1375). ESSURE WAS IMPLANTED IN 2011. SHE WAS SUPPOSED TO BE GETTING SOMETHING ELSE BECAUSE SHE WAS ALLERGIC TO NICKEL YET. THE MOMENT OF PROCEDURE SHE HAD INSTANT PAIN AND THAT NEVER CEASED. IN THE FOLLOWING DAYS, SHE HAD BLEEDING WHICH ALSO DID NOT CEASE THAT ONLY SLOWED DOWN. HER DOCTOR TOLD HER THAT SHE WAS OK AND NOTHING TO WORRY ABOUT. SHE WAS IN A CAR ACCIDENT IN 2015 AND WHILE GETTING AN X-RAY OF HER SPINE, THE DOCTOR ASKED WHAT WAS METAL INSIDE OF HER. THE DOCTOR SHOWED THE X-RAY AND SHE WAS BAFFLED AND HAD NO IDEA, SHE CALLED HER PHYSICIAN AND FOUND OUT IT WAS ESSURE. FROM 2011 TO 2015, SHE HAD SKIN ISSUES THAT MADE HER LOOK LIKE SOME DRUG ADDICT, BLEEDING VAGINALLY THAT DID NOT CEASE, PAIN ON HER RIGHT LOWER ABDOMEN AND INSIDE HER VAGINAL AREA. HER MIGRAINES WERE FREQUENT AND INCAPACITATING AND SHE LOOKED LIKE SHE WAS 4 TO 5 MONTHS PREGNANT. SHE ALSO HAD MOOD SWINGS AND CRIED AT EVERYTHING AND SO MUCH MORE. SHE LOST HER JOB BECAUSE HER BODY MIMICKED A MINI STROKE, AND SHE WAS BEING SEEN BY A NEUROLOGIST AS WELL AS A CARDIOLOGIST. THEN SHE DECIDED TO LOOK UP THE ESSURE AND SHE CAME ACROSS WOMEN TALKING ABOUT THE SAME SYMPTOMS SHE WAS HAVING. IN (B)(6) 2015, SHE HAD HER HYSTERECTOMY AT AGE (B)(6) (SHE WAS FEELING SO MUCH BETTER). BUT, EVEN THOUGH MOST OF THOSE SYMPTOMS WENT AWAY SHE WAS LEFT WITH THE SCARS, THE LOST JOB, THE LOST TIME WITH HER CHILDREN AND HUSBAND AND YEARS OF LACK OF INTIMACY THAT AT TIMES ALMOST COST HER RELATIONSHIP. PRODUCT TECHNICAL COMPLAINT ANALYSIS RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON ME AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND HAD INSTANT PAIN AT THE MOMENT OF PROCEDURE/SEVERE PAIN IN RIGHT LOWER QUADRANT (INTERPRETED AS ABDOMINAL PAIN LOWER), SYMPTOMS OF TRANSIENT ISCHAEMIC ATTACK (TIA) AND SEIZURES. SHE HAD A HYSTERECTOMY APPROXIMATELY 4 YEARS AFTER ESSURE INSERTION. SHE STATED SHE WAS FEELING BETTER AND MOST OF SYMPTOMS IMPROVED BUT DID NOT SPECIFY WHICH EVENTS. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE ABDOMINAL LOWER PAIN IS LISTED WHILE THE OTHER EVENTS ARE

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UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT ESSURE HAS A LOCALIZED ACTION IN THE FALLOPIAN TUBES RATHER THAN SYSTEMIC, IT IS UNLIKELY THAT ESSURE WOULD CAUSE SYMPTOMS OF TIA AND SEIZURES. IN CONTRAST, CONSIDERING THE NATURE OF THE ABDOMINAL PAIN LOWER AND SUGGESTIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. UPON FOLLOW UP INFORMATION, THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01292	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/11/2014
Explant Date (E7): 4/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5037998) IN UNITED STATES ON 06-FEB-2015 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. THE CONSUMER'S CONCURRENT CONDITION INCLUDED BREASTFEEDING. CONSUMER WENT FOR HER HSG TEST (HYSTEROSALPINGOGRAM) IN 2014 AND FOUND THAT THE RIGHT SIDE WAS COMPLETELY SEALED BUT THE LEFT SIDE WAS OPEN AND THE COIL WAS PIERCED THROUGH UTERUS. SHE HAS BEEN HAVING BURNING, STABBING AND THROBBING PAINS ALMOST CONSTANTLY ON LEFT SIDE AND OCCASIONALLY ON RIGHT. SHE WAS SCARED TO MOVE QUICKLY OR PICK UP HER KIDS FOR FEAR IT WILL DISLODGE SOMETHING VITAL. SHE WAS HAVING ALMOST CONSTANT HEADACHES, CRAMPING, AND BLOATING. FOLLOW-UP RECEIVED ON 17-FEB-2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A LACK OF EFFICACY (PATENCY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A LACK OF EFFICACY MAY OCCUR WITH THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS

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INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP FROM 11-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. FOLLOW-UP INFORMATION IDENTIFIED ON 05-OCT-2015 (UPGRADED TO INCIDENT): THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (POST# FDA-2014-N-0736-1322). THE CONSUMER REPORTED SHE HAD ESSURE INSERTED IN (B)(6) 2014 AND HAD IT REMOVED IN (B)(6) 2015 DUE TO A PERFORATION/ MIGRATION AS WELL AS THE FOLLOWING SYMPTOMS: SEVERE MIGRAINES (3+ DAYS), ANXIETY AND PANIC ATTACKS, LOW BACK PAIN ON LEFT, SHARP STABBING PAIN IN LOWER LEFT AND PELVIS, SEVERE SWEATING, HOT FLASHES, NIGHT SWEATS, HEART PALPITATIONS, DIZZINESS AND FATIGUE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE UNDERWENT A HSG (HYSTEROSALPINGOGRAM) THAT SHOWED COIL WAS PIERCED THROUGH UTERUS. ESSURE INSERTS WERE REMOVED AFTER ONE YEAR. THIS EVENT, INTERPRETED AS UTERINE PERFORATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND THE MECHANISM OF PERFORATION ARE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE ADDED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01293	BAYER HEALTHCARE LLC	10/30/2015	10/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2011
Explant Date (E7): 9/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0931, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER STATED THAT IT WAS THE WORST THING SHE HAD EVER DONE. SHE WAS ALLERGIC TO THE METALS ESSURE WAS MADE FROM. HER BODY WAS FALLING APART. SHE WAS GETTING ESSURE TAKEN OUT WHICH HAD BEEN A STRUGGLE BY ITSELF. HER HAIR WAS FALLING OUT AND SHE WAS IN UNBELIEVABLE PAIN ALL THE TIME. SHE HAD BEEN ON AND OFF STEROIDS SO MUCH. SHE HATED THIS DEVICE. FOLLOW-UP INFORMATION IDENTIFIED ON 05-OCT-2015 (UPGRADED TO INCIDENT). THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (POST#FDA-2014-N-0736-1298). IN (B)(6) 2011, ESSURE WAS IMPLANTED. SHE WAS ON (B)(6) AND IT WAS ENDING SOON, SO THE DOCTOR SHE FOUND TO ALLOW HER TO GET A PERMANENT BIRTH CONTROL ONLY DID ESSURE. SO SHE HAD IT DONE. AT FIRST SHE NOTICED THAT SEX HURT A LOT. THEN SHE FOUND HERSELF GOING TO A MENTAL HEALTH DOCTOR BECAUSE OF ONGOING PANIC ATTACKS AND DEPRESSION, ALONG WITH JUST HAVING NO ENERGY. IN (B)(6) 2014, SHE STARTED WITH AN ALLERGIC REACTION ALL OVER. THIS CONTINUED FOR SEVERAL MONTHS COMING AND GOING. HER THICK HAIR WAS FALLING OUT BY THE HAND FULLS. SHE WAS TRULY THINKING SHE WAS LOSING HER MIND. SHE TOLD HER DOCTOR SHE WANTED THEM OUT AND HE AGREED BUT HE WOULD ONLY REMOVE HER TUBES AND CYSTS THAT SHE HAD AT THE TIME OF REPORT BUT NOT BEFORE ESSURE. SHE WAS TAKEN STEROIDS FOR MONTHS

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DUE TO RASHES AND ALLERGIC REACTIONS AFFECTED HER WHITE BLOOD COUNT. TESTS WERE PERFORMED AND SOME WERE PAINFUL. SHE WAS EXPERIENCING CHRONIC PAIN IN HER BACK AND LEFT SIDE MADE THEM WORSE. ON (B)(6) 2015, HER TUBES AND ESSURE WERE REMOVED. SHE STATED THAT THEY WERE REMOVED THE DAY BEFORE THE REPORT AND SHE COULD ALREADY FEEL A BIG DIFFERENCE. ADDITIONAL INFORMATION RECEIVED ON 07-OCT-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. UPDATED PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 20-OCT-2015: PTC GLOBAL NUMBER: (B)(4). NO MAJOR CHANGES IN THE ASSESSMENT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL AND HAD CHRONIC BACK PAIN AND LEFT SIDE (INTERPRETED AS BACK PAIN AND ABDOMINAL PAIN). AFTER APPROXIMATELY 4 YEARS, SHE HAD ESSURE INSERTS REMOVE ALONG WITH HER FALLOPIAN TUBES. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT, THE LOCALIZATION OF THE PAIN AND THE LACK OF ALTERNATIVE EXPLANATION, THE CHRONIC BACK PAIN AND CHRONIC ABDOMINAL PAIN ARE CONSIDERED RELATED TO ESSURE. UPON FOLLOW UP INFORMATION, THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057648	BAYER	10/30/2015	11/4/2015

Event Information:

Event Date (B3): 10/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/9/2009
Explant Date (E7): 3/3/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS WERE INSERTED IN (B)(6) 2009. WOULD OF NEVER IMAGINED WHAT I ENDURED BECAUSE OF THIS BAD DECISION. SEVERE ABDOMINAL PAIN, HEADACHE PRESSURE, FATIGUE, ANXIETY NOT KNOWING WHAT WAS HAPPENING TO ME. MY OB/GYN HAD AN ULTRASOUND DONE AND FOUND THAT THE COIL HAD MIGRATED INTO MY UTERINE WALL WHICH CAUSED ME TO HAVE TO HAVE A HYSTERECTOMY, THERE WAS NOTHING MY DR COULD DO BUT THAT. PLEASE TAKE THIS PRODUCT OFF THE MARKET SO OTHERS DON'T HAVE TO GO THRU WHAT I DID.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057650	CONCEPTUS INC/BAYER AG	10/30/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/30/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROCEDURE PERFORMED (B)(6) 2008 EITHER BEFORE OR AFTER A FEW WEEKS A UTERINE ABLATION. I HAD ABSOLUTELY NO PROBLEMS WITH THE SURGERY. NOT UNTIL YEARS LATER. IT BEGAN WITH STOMACH PAIN AND CLUSTER HEADACHES FORMED AND PROGRESSED OVER THE YEARS. ABDOMINAL PAIN, AND SEVERE BLOATEDNESS. IN THE AM MY STOMACH IS FLAT. BY BEDTIME I LOOK LIKE IM VERY PREGNANT. I HAVE SUFFERED MINOR BACK PAIN FOR YEARS, MOST RECENTLY MY SYMPTOMS HAVE BEEN SO SEVERE IM TRYING TO FIND WHAT THE PROBLEM IS. SO FOR THE PAST 4 MONTHS, DOCTORS, HOSPITALS, URGENT CARE HEALTH CLINIC, MRI OF MY BRAIN AND THE SEVERE NECK PAIN ALL THE WAY DOWN TO THE BOTTOM OF MY SPINE. IM SUFFERING SIGNS OF MULTIPLE SCLEROSIS, WITH VISION IMPAIRMENT, CLUSTER HEADACHES THAT LAST 4 TO 5 DAYS, ASPIRIN, IBUPROFEN, TYLENOL NOR NAPROXEN HELP. I HAVE SHORT TERM MEMORY PROBLEMS, FREQUENT URINATION, SEVERE STOMACH CRAMPING, MY SIGHT IN MY LEFT EYE IS GETTING PROGRESSIVELY WORSE, MY SPEECH IS IMPAIRED ALL OF MY MOTOR SKILLS ARE AFFECTED. I STUDER, CAN'T REMEMBER WORDS AND I'M MORE THAN FORGETFUL. MY HANDS AND MY LEGS TINGLE AND MY TOES, SEVERE ABDOMINAL PAIN I HAVE HAD FOR YEARS SO BAD I HAVE TO HUNCH OVER, ITS LIKE A SPASM THAT LASTS ANYWHERE FROM 15 MINUTES TO 4 HOURS, THE ONLY THING THAT WORKS IS XANAX AND THEY WILL NOT PRESCRIBE IT TO ME IN THE STATE OF (B)(6). I ALSO SUFFER FROM WHERE ITS LIKE MY BRAIN SHUTS OFF, LIKE SOMEONE FLIPPING A LIGHT SWITCH. COULD THESE BE POSSIBLE SEIZURES? MY WAIST VARIES IN SIZE. MY LEGS HURT MY WHOLE BODY ACHES, IM GETTING NO HELP FROM MY DOCTOR. I WORK IN THE MEDICAL FIELD. I HAVE ALL THE SYMPTOMS OF MS BUT THE MRI OF THE BRAIN RULED OUT MS, THANK GOD, AND MY BLOOD WORK WAS FINE. THE PAIN IS UNBEARABLE I CAN HARDLY MOVE, SOMETIMES I CAN'T WALK, AND SOMETIMES WHEN I DO ITS LIKE MY LEFT LEG WON'T WALK, I'VE TRIPPED AND FALLEN SEVERAL TIMES. SOMETHING

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IS NOT RIGHT. NEUROLOGICAL PROBLEMS, COULD THIS POSSIBLY BE A RESULT OF ESSURE? IM GOING DOWN THE LIST AND BEING TESTED FOR EVERY ILLNESS THAT MASKS LIKE MS TO RULE OUT ESSURE. THE PAST 4 MONTHS ARE HORRIBLE. ITS AFFECTING MY JOB AND MY PRIVATE LIFE. IF I KEEP GOING LIKE THIS WHAT DO I DO? IF I WOULD HAVE REALIZED WHEN I CHOSE THIS METHOD OF STERILIZATION THAT LATER IN LIFE I'D BE LIKE THIS. I WOULD HAVE DECLINED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057691	BAYER	10/31/2015	11/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/10/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ALWAYS BEEN HEALTHY. SINCE I GOT THE ESSURE IMPLANTS IN 2010 MY HEALTH HAS GONE DOWN HILL. I NOW SUFFER FROM BLOATING, BACK PAIN, PRESSURE IN MY CERVIX, CHRONIC YEAST INFECTIONS, STABBING AND TINGLING FEELING IN MY VAGINA. LEG CRAMPS, HEADACHES, CYSTS IN MY GROIN AND ARMPITS, THAT ARE UNTREATABLE. I REMOVED 1 CYSTS AND A FEW MORE GREW BACK. DEPRESSION, SKIN DISCOLORATION, VITAMIN B, VITAMIN D AND IRON DEFICIENCY. I HAVE BEEN TO SEVERAL DOCTORS AND THEY CAN NOT PIN POINT THE SOURCE OF MY PROBLEMS. ALL MY SYMPTOMS ARE GETTING PROGRESSIVELY WORSE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01294	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 3/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1260, AWARENESS DATE 05-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER REPORTED THAT IN 2013 SHE STARTED TO EXPERIENCE BRAIN FOG, FATIGUE, PERIODS THAT LASTED A WEEK AND A HALF, TWICE A MONTH WITH HUGE CLOTS, SOAKING 3 PADS AN HOUR, SEXUAL INTERCOURSE WAS PAINFUL, SHE HAD CONSTANT CRAMPS AND WOULD FALL ASLEEP ANYWHERE. IN (B)(6)-2015 SHE HAD A HYSTERECTOMY PERFORMED AND ALL OF HER SYMPSTOMS RESOLVED. SHE WENT IN THE HOSPITAL WEIGHING (B)(6), STAYED IN THE HOSPITAL ONE NIGHT AND CAME OUT WEIGHING (B)(6). PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE

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INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT CRAMPS AND OTHER NON-SERIOUS EVENTS. A HYSTERECTOMY WAS PERFORMED AND ALL OF HER SYMPSTOMS RESOLVED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STARTED EXPERIENCING THIS EVENT ABOUT 2 YEARS AFTER ESSURE INSERTION. CONSIDERING THE NATURE OF THE EVENT AND A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01295	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2002
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1454, AWARENESS DATE 05-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2002. CONSUMER HAD TO HAVE ABLATION DONE SO THEY WANTED TO MAKE SURE SHE HAD PERMANENT BIRTH CONTROL IN PLACE. THE ESSURE PLACEMENT PROCEDURE WAS DEEMED SUCCESSFUL. FAST FORWARD TO 2005, CONSUMER BEGAN TO HAVE TERRIBLE PAIN RADIATING DOWN HER LEG, ORIGINATING FROM HER BACK. AFTER AN X-RAY, IT WAS REVEALED THAT ONE OF THE COILS MIGRATED INTO HER ABDOMEN. SHE WAS SCHEDULED FOR SURGERY. IN ADDITION TO THE REMOVAL OF THE ONE ESSURE COIL, THEY ALSO HAD TO REMOVE ENDOMETRIOSIS, WHICH SHE NEVER HAD BEFORE. SHE STILL HAS ONE COIL IN PLACE. OVER THE YEARS, SHE EXPERIENCED ANXIETY, LOW SEX DRIVE, PERSISTENT ABDOMINAL PAIN, HEART PALPITATIONS AND NERVE TINGLING IN LEGS. IN 2011, SHE WAS DIAGNOSED WITH MELANOMA, JUST ABOVE THE RIGHT ANKLE BONE ON THE INTERIOR PART OF LEG. SHE HAD TWO SURGERIES TO REMOVE THE SPOT AND MAKE SURE ALL MARGINS WERE CLEAR. CONSUMER'S PHYSICIAN SUGGESTED TO HER THE PAIN IN HER RIGHT ABDOMEN WAS PROBABLY FROM SCAR TISSUE. CONSUMER WAS CONCERNED THAT WHEN THE DOCTOR REMOVED THE COIL ON THE RIGHT SIDE, SOME OF THE PET FIBERS WERE LEFT BEHIND. FOLLOW UP RECEIVED ON 20-OCT-2015: PTC INVESTIGATIONAL RESULT. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE

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HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE OF THE COILS MIGRATED INTO HER ABDOMEN. THE COIL WAS SURGICALLY REMOVED; HOWEVER THE CONSUMER WAS CONCERNED SOME OF THE PET FIBERS WERE LEFT BEHIND (SEEM AS SUSPICION OF DEVICE BREAKAGE UPON REMOVAL). ADDITIONALLY, SHE WAS DIAGNOSED WITH ENDOMETRIOSIS AND MELANOMA (JUST ABOVE THE RIGHT ANKLE BONE ON THE INTERIOR PART OF HER LEG). ONLY ENDOMETRIOSIS AND MELANOMA ARE UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF AN UTERINE PERFORATION DURING INSERTION. IN THIS CASE, ESSURE INSERTION WAS REPORTED AS SUCCESSFUL. THE DEVICE MIGRATION WAS DIAGNOSED APPROXIMATELY 3 YEARS AFTER DEVICE PLACEMENT. ALTHOUGH THE EXACT MECHANISM OF THIS EVENT WAS NOT KNOWN; GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THE SAME ASSESSMENT IS GIVEN FOR THE SUSPICION OF DEVICE BREAKAGE. REGARDING THE REMAINING EVENTS, DUE TO THEIR PATHOPHYSIOLOGY AND GIVEN ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY IS CONSIDERED VERY UNLIKELY. THIS CASE WAS REGARDED AS INCIDENT; SINCE DEVICE REMOVAL WAS REQUIRED. OTHER NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01296	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): 7/22/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/22/2014
Explant Date (E7): 11/20/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1140, AWARENESS DATE 05-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. THIS CASE WAS INITIALLY CONSIDERED INVALID DUE TO MISSING ADVERSE EVENTS. ON (B)(6) 2014, A HYSTERECTOMY WAS PERFORMED (LEAVING OVARIES) DUE TO A MIGRATED COIL. CONSUMER STATED SHE EXPERIENCED HAIR LOSS, GAINED APPROXIMATELY 20 LBS, HAD EXCESSIVE BLEEDING/CLOTTING (BLED EVERY SINGLE DAY FROM IMPLANT TO HYSTERECTOMY), AND HAD AN OVARIAN CYST FOR THE FIRST TIME. FOLLOW UP RECEIVED ON 20-OCT-2015: PTC INVESTIGATIONAL RESULT. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY

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CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXCESSIVE BLEEDING/CLOTTING (BLED EVERY SINGLE DAY) (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A HYSTERECTOMY DUE TO A MIGRATED COIL, 4 MONTHS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENT GENITAL BLEEDING, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE THE EXACT LOCATION OF THE DEVICE WAS NOT REPORTED. THE CONSUMER STATED THAT SHE UNDERWENT A HYSTERECTOMY 4 MONTHS AFTER ESSURE INSERTION DUE TO A MIGRATED COIL. GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01297	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/17/2004
Explant Date (E7): 2/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5044154) IN UNITED STATES ON 05-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2004. CONSUMER REPORTED THAT AFTER RECEIVING THE ESSURE IMPLANTS IN 2004, SHE BEGAN EXPERIENCING EXTREME PAIN AND CRAMPING EVERY MONTH. SHE WOULD ALSO HAVE EXCESSIVE BLEEDING EACH MONTH THAT LASTED FOR WEEKS AND WEEKS. HER DOCTOR RECOMMENDED HAVING A HYSTERECTOMY SINCE 2006 BUT BECAUSE THIS WAS AN EXTREME CHANGE TO HER BODY, SHE DECIDED NOT TO HAVE IT DONE. SHE HAS BEEN GOING BACK AND FORTH TO THE DOCTOR FOR YEARS BECAUSE OF THE PAIN. IN 2010 TO RELIEVE SOME OF THE PAIN SHE HAD HER FIRST SURGERY, A MYOMECTOMY TO REMOVE THE FIBROIDS CAUSED BY THE SEVERE BLEEDING. THE MYOMECTOMY DID NOT CURE THE PAIN AND/OR THE EXCESSIVE BLEEDING. AFTER SEVERAL DOCTOR VISITS AND NO RELIEF, SHE FINALLY DECIDED TO HAVE A HYSTERECTOMY AND HAVE THE COILS REMOVED ON (B)(6) 2015. SINCE THEN SHE HAS HAD NO PAIN OR EXCESSIVE BLEEDING. FOLLOW UP RECEIVED ON 20-OCT-2015: PTC INVESTIGATIONAL RESULT. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS

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CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED EXPERIENCING EXCESSIVE BLEEDING EACH MONTH LASTED FOR WEEKS AND WEEKS (INTERPRETED AS GENITAL BLEEDING) AND EXTREME PAIN AND CRAMPING EVERY MONTH (INTERPRETED AS ABDOMINAL PAIN). SHE ALSO HAD FIBROIDS. SHE UNDERWENT A MYOMECTOMY WHICH DID NOT RESOLVE THE PAIN OR BLEEDING. APPROXIMATELY 10 YEARS AFTER ESSURE INSERTION SHE HAD A HYSTERECTOMY AND THE COILS WERE REMOVED. THE PAIN AND BLEEDING RESOLVED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. ABDOMINAL PAIN AND GENITAL BLEEDING ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE FIBROIDS IS UNLISTED. ABDOMINAL PAIN AND GENITAL BLEEDING MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE THE CONSUMER ALSO HAD FIBROIDS WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THESE EVENTS. HOWEVER, CONSIDERING THAT THE EVENTS DID NOT RESOLVE AFTER MYOMECTOMY, BUT RESOLVED AFTER HYSTERECTOMY AND ESSURE REMOVAL, A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE EXCLUDED. UTERINE FIBROIDS ARE BENIGN TUMORS THAT ARISE FROM THE OVERGROWTH OF SMOOTH MUSCLE AND CONNECTIVE TISSUE IN THE UTERUS. CONSIDERING FIBROIDS PATHOPHYSIOLOGY AND ESSURE LOCAL EFFECT IN THE FALLOPIAN TUBES, THIS EVENT WAS ASSESSED AS UNRELATED TO THE DEVICE. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY AND ESSURE REMOVAL). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01299	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 7/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 05-OCT-2015). CASE WAS RECEIVED IN UNITED STATES AND REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT SHE WAS MISINFORMED BY HER DOCTOR THAT THE ESSURE STERILIZATION DEVICE WOULD HELP TO CONTROL HER HEAVY, PAINFUL MENSTRUAL CYCLES AND STATES THAT SHE DID NOT EVEN NEED TO HAVE ESSURE IMPLANTED REALLY, BECAUSE SHE HAS BEEN IN A SAME SEX RELATIONSHIP FOR 6 YEARS. SHE CHOSE THIS BIRTH CONTROL BECAUSE OF WHAT WAS TOLD TO HER BY HER DOCTOR. ACCORDING TO REPORTER, AFTER HAVING ESSURE IMPLANTED IN 2009, HER LIFE TOOK A TURN FOR THE WORSE. HER MENSTRUAL CYCLES WERE STILL VERY PAINFUL AND VERY HEAVY (IN FACT THEY WERE WORSE THAN BEFORE ESSURE), SHE LOST ALL OF HER ENERGY, HER HAIR STARTED TO FALL OUT, SHE GAINED 70 POUNDS, WAS DIAGNOSED WITH FIBROMYALGIA, HAD CONSTANT PELVIC PAIN, A NEVER ENDING PAIN IN HER LEFT FLANK AREA FOR YEARS, CONSTANT JOINT PAIN, STARTED HAVING URINARY PROBLEMS, HER HORMONE LEVELS WERE SO LOW THAT SHE HAD TO BE PUT ON HORMONE REPLACEMENT CREAMS, SHE WAS DIAGNOSED WITH HYPOTHYROIDISM AND STATES THAT THE LIST GOES ON. IN ADDITION, CONSUMER REPORTED THAT SHE IS ONLY (B)(6) YEARS OLD AND SHE HAD A HYSTERECTOMY ON (B)(6) 2015 DUE TO COMPLICATIONS ASSOCIATED WITH ESSURE. CONSUMER INFORMED THAT SHE SAW MULTIPLE DOCTORS OVER THOSE 6 YEARS AND MOST COULD NOT EVEN GIVE HER A REASON FOR WHY THINGS WERE HAPPENING TO HER BODY. SHE WAS RECENTLY APPROVED FOR DISABILITY AND STATES THAT THIS IS HOW BAD ESSURE MESSED UP HER LIFE. ADDITIONALLY, CONSUMER INFORMED THAT, EVER SINCE SHE WAS A CHILD,

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SHE HAS NEVER BEEN ABLE TO WEAR JEWELRY THAT WAS NOT "REAL" (AS REPORTED). THAT IS BECAUSE MOST FAKE JEWELRY IS MADE WITH NICKEL. ACCORDING TO HER, SHE WAS NEVER INFORMED THAT THE ESSURE DEVICES WERE MADE FROM NICKEL, NOR WAS SHE TESTED TO SEE IF SHE HAD A NICKEL ALLERGY PRIOR TO BEING IMPLANTED AND STATES THAT HAD SHE BEEN TESTED, SHE WOULD HAVE KNOWN THAT THE ESSURE DEVICES WERE NOT A MATCH FOR HER. -RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD CONSTANT PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY 6 YEARS AFTER DEVICES PLACEMENT. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER STATED SHE WAS DIAGNOSED WITH FIBROMYALGIA AND HYPOTHYROIDISM; HOWEVER NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR HER PELVIC PAIN. CONSIDERING EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, OTHER NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01300	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1277, AWARENESS DATE 05-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER HAD THE PROCEDURE DONE IN 2012 AND IT WAS VERY PAINFUL TO IMPLANT. IT WAS IN THE OFFICE OF HER DOCTOR, SHE WAS NOT GIVEN ANYTHING FOR PAIN ONLY HER CERVIX WAS NUMB. IMMEDIATELY AFTER SHE WAS IN A LOT OF PAIN AND BLEED FOR WEEKS. SHE WEIGHED (B)(6) LBS AND IN TWO AND A HALF YEARS SHE WENT UP TO 205 LBS. HER PERIODS WERE SO HEAVY AND MANY TIMES SHE HAD THEM UP TO 3 TIMES A MONTH. HER SKIN CHANGED, SHE ALWAYS BROKE OUT. HER STOMACH WAS SO BLOATED AND INFLAMED. SHE HAS EXPERIENCED HAIR LOSS, THIS HAS NEVER HAPPENED UNTIL SHE GOT ESSURE. SHE WAS IN PAIN ALL THE TIME. IT SEEMED LIKE SHE HAD LABOR LIKE CRAMPING ALL MONTH LONG. HER DOCTOR GAVE HER BIRTH CONTROL PILLS AND THEY DID NOT HELP. AFTER HAVING ESSURE FOR TWO AND A HALF YEARS, HER IMPLANTING DOCTOR AGREED TO DO A TOTAL HYSTERECTOMY. SHE WAS NOT PLANNING ON LOSING HER CERVIX, TUBES AND UTERUS AT THE AGE OF (B)(6). SHE WAS 5 WEEKS POST-OPERATIVE AT THE TIME OF THE REPORT, AND FELT THE DIFFERENCE ALREADY. PRODUCT TECHNICAL COMPLAINT ANALYSIS RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS

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CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT; NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING FOR WEEKS (INTERPRETED AS GENITAL BLEEDING). SHE ALSO HAD PAIN ALL THE TIME / LABOR LIKE CRAMPING ALL MONTH LONG (INTERPRETED AS PELVIC PAIN), AND TWO AND A HALF YEARS AFTER ESSURE INSERTION SHE UNDERWENT A HYSTERECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR AFTER ESSURE INSERTION. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01301	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/10/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1378, AWARENESS DATE 05-OCT-2015). CASE WAS RECEIVED IN UNITED STATES AND REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT THROUGHOUT THE NEXT 17 DAYS FOLLOWING ESSURE PLACEMENT SHE STARTED HAVING SOME HORRIBLE EFFECTS THAT SHE COULD NOT GET RID OF. ON (B)(6) 2013 SHE HAD ENOUGH PAIN AND STATES THAT SHE COULD NOT TAKE IT ANYMORE SO SHE FINALLY WENT IN TO HER DOCTOR (WHO ALSO PLACED IT). HER FINGERS/HANDS WERE STIFF, SWOLLEN (SHE COULD NOT EVEN OPEN A BOTTLE OF WATER LET ALONE A DOOR). SHE STRUGGLED TO PICK UP HER (B)(6) SON. CONSUMER ALSO REPORTED THAT BOTH HER KNEES AS WELL WERE SWOLLEN AND STIFF TO WHERE IT TOOK HER A GOOD MINUTE TO GET UP AND DOWN AND STATES THAT SHE WOULD BE IN TEARS FIGHTING TO STAND UP (SHE WAS NOT ABLE TO BEND DOWN TO PICK UP HER KID). ACCORDING TO HER, ALL SHE WAS GIVEN WAS NAPROXEN. SHE INFORMED THAT HER PAIN WAS ONLY BECOMING WORSE. SHE WENT IN YET AGAIN ON (B)(6), AND BY THIS TIME SHE WAS GIVEN MOBIC, FAMOTIDINE, MEDROL AND TRANSOM TO TRY AND HELP WITH HER PAIN. NONE OF THEM HELPED. CONSUMER ALSO WENT THROUGH SEVERAL BLOOD TESTS TO RULE OUT ALL OTHER POSSIBILITIES AND, AS TIME PROGRESSED, SHE HAD PELVIC PAIN, CONSTANT FATIGUE, BLOAT, NAUSEATED, CONSTANT MIGRAINES, MOOD SWINGS, DEPRESSION, WEIGHT GAIN, LOSS OF APPETITE, PAINFUL SEX, MEMORY LOSS, HAIR LOSS, AND HER JOINT PAIN GOT WORSE. FINALLY, AFTER SPEAKING TO SEVERAL DOCTORS, SHE WAS REFERRED TO ANOTHER DOCTOR WHO WAS WILLING TO TRY AND REMOVE IT FOR HER. ON (B)(6) 2014, SHE WENT IN FOR WHAT HOPED WOULD BE HER LAST STEP TO BEING ESSURE FREE YET

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SHE WAS WRONG AGAIN. ACCORDING TO REPORTER, HER LEFT COIL WAS ONLY VISIBLE (AS REPORTED) AND SURGERY CAME TO A STOP AS WHEN THEY STARTED ON HER LEFT TUBE SHE STARTED BLEEDING AND THEY HAD TO STOP. WHEN SHE FINALLY WOKE UP SHE THEN HAD TO SET UP HER FINAL APPOINTMENT TO HAVE EVERYTHING REMOVED EXCEPT HER OVARIES. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PAIN THAT WAS ONLY BECOMING WORSE. ALMOST A YEAR LATER, SHE HAD AN ATTEMPT TO REMOVE THE INSERTS BUT HER LEFT COIL WAS ONLY VISIBLE (INTERPRETED AS DEVICE DISLOCATION) AND SURGERY HAD BE STOPPED AS WHEN THEY STARTED ON HER LEFT TUBE SHE STARTED BLEEDING (INTERPRETED AS PROCEDURAL HAEMORRHAGE). SHE HAD TO SET UP HER FINAL APPOINTMENT TO HAVE EVERYTHING REMOVED EXCEPT HER OVARIES. THE UNSPECIFIED PAIN, DEVICE DISLOCATION AND PROCEDURAL HAEMORRHAGE ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS, THE SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS REQUIRED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01302	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/29/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN (B)(6) ON 05-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. ADDITIONAL INFORMATION RECEIVED ON 06-OCT-2015. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: CINITAPRIDE (CINITAPRIDE), OMEPRAZOLE (OMEPRAZOLE), IBUPROFEN (IBUPROFEN), AND PARACETAMOL (PARACETAMOL). SINCE ESSURE INSERTION, CONSUMER EXPERIENCES DISCOMFORT SINCE THE FIRST DAY, WHICH HAS BEEN INCREASING TO THE POINT OF HAVING PAIN AS IF SHE HAD MENSTRUAL PERIOD AND EVEN CONTRACTIONS AND PAIN SIMILAR AS THE PAIN OF CHILDBIRTH, EVERY DAY. SHE HAS BEEN TAKING PAINKILLERS FOR A YEAR, NOWADAYS SHE TAKES THEM EVERY 4 HOURS, AND EVEN THOUGH SHE STILL EXPERIENCES PAIN DAY AND NIGHT. SHE BARELY SLEEPS, DOES NOT HAVE APPETITE, HAS NAUSEA, AND WAS VERY TIRED. SHE STATED THAT ALL THIS PREVENTED HER FROM LEADING A NORMAL LIFE. SHE VISITED MANY TIMES THE EMERGENCY ROOM AND SEVERAL DOCTORS. FOLLOW UP INFORMATION RECEIVED ON 14-OCT-2015: THE CONSUMER SUFFERED FROM POLYCYSTIC OVARIES AND PAINFUL MENSTRUAL PERIODS. SHE CONFIRMED THAT 3 MONTHS AFTER INSERTION A CONFIRMATION TEST WAS PERFORMED AND SHOWED THAT THE DEVICE WAS CORRECTLY LOCATED. DUE TO THE PAIN SHE WAS SUFFERING, SHE WENT TO DIFFERENT DOCTORS. HER GYNECOLOGIST PERFORMED CYTOLOGY, VAGINAL ULTRASOUNDS AND A DOPPLER ULTRASOUND. THE ONLY REMARKABLE RESULTS FROM THESE TESTS WAS THAT SHE HAD A CELL THAT DENOTED INFLAMMATION. HER DIGESTIVE DOCTOR AS WELL AS INTERNAL DOCTOR CONFIRMED AFTER MEDICAL EXAMINATION THAT SHE WAS FINE. ALL THE BLOOD TEST PERFORMED SHOWED NORMAL RESULTS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INTENSE PAIN/ CONTRACTIONS. SHE

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MENTIONED SHE HAS BEEN TAKING PAINKILLERS FOR A YEAR, NOWADAYS EVERY 4 HOURS. SHE VISITED MANY TIMES THE EMERGENCY ROOM AND SEVERAL DOCTORS. SHE UNDERWENT SEVERAL EXAMS, INCLUDING VAGINAL ULTRASOUND, DOPPLER ULTRASOUND BUT EVERYTHING WAS FINE EXCEPT A TEST THAT SHOWED SHE HAD A CELL THAT DENOTED INFLAMMATION. THE TEST NAME WAS NOT PROVIDED AND THE RESULT IS NOT CLEAR. THIS EVENT, INTERPRETED AS ABDOMINAL PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SERIOUS INJURY, SINCE THE CHRONIC PAIN LED TO RESTRICTION OF ACTIVITIES OF DAILY LIFE AND CHRONIC USE OF MEDICATION. NON-SERIOUS EVENTS WERE ALSO REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 10-NOV-2015: PTC GLOBAL NUMBER IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01303	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2012
Explant Date (E7): 2/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING AND TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1282, AWARENESS DATE 05-OCT-2015). CASE WAS RECEIVED IN UNITED STATES AND REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER REPORTED THAT SHE WENT FOR HER ANNUAL GYNECOLOGIST APPOINTMENT A COUPLE OF YEARS AGO AND HER DOCTOR SOLD HER THE ESSURE. CONSUMER STATED THAT SHE WAS NOT EVEN INTERESTED IN ANY TYPE OF BIRTH CONTROL AT THE TIME AND THAT SHE HAD SO MANY PROBLEMS (WHEN SHE WAS YOUNGER) WITH THE HORMONES IN THE PILL, HER HUSBAND AND SHE WERE JUST VERY CAUTIOUS, NOT HORMONES JUST CALENDAR TRACKING OF HER FERTILE DAYS. BUT AFTER THE DOCTOR SUNG ESSURE'S PRAISES SHE THOUGHT IT WAS A BRILLIANT IDEA. CONSUMER ALSO INFORMED THAT SHE WAS NEVER TOLD ABOUT POTENTIAL SIDE EFFECTS AND STATED THAT SHE HAD ALREADY HAD ISSUES WITH PIERCINGS REJECTION OUT OF HER BODY (WHICH HER DOCTOR WAS WELL AWARE OF) BUT SHE WAS ASSURED WAS COMPLETELY DIFFERENT. CONSUMER REPORTED THAT SHE WENT THROUGH HELL DURING PROCEDURE. ESSURE WAS IMPLANTED IN (B)(6) 2012. ACCORDING TO HER, IT HURT INSTANTLY. HEALTH CARE PROFESSIONAL TOLD HER THAT HER LEFT TUBE WAS HIDING BECAUSE HER UTERUS WAS TILTED. SHE STATED THAT NOT ONCE DID PHYSICIAN STOP, AS IT WAS EXPLICITLY WRITTEN IN THE PAMPHLET TO DO SO, BUT HE CARRIED ON FORCING IT IN. CONSUMER WENT HOME IN PAIN AND SLEPT THE DAY AWAY. FAST FORWARD, ABOUT 5 MONTHS, HER HEAD STARTED HURTING, HER PINKY FINGERS WENT NUMB, SHE STARTED GAINING WEIGHT AND HER PERIODS STARTED COMING IN BURSTS. CONSUMER ALSO REPORTED THAT PREVIOUSLY SHE WAS LIKE CLOCKWORK BUT NOW SHE TRACKED IT FOR FAMILY PLANNING,

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SHE WAS AFRAID TO GO OUT BECAUSE IT COULD START AND BE POURING OUT OF HER WITHIN SECONDS. IN ADDITION, CONSUMER REPORTED THAT SOMETIMES SHE WOULD BLEED FOR WEEKS AT A TIME, SOMETIMES IT WOULD STOP FOR A DAY OR TWO, SOMETIME SHE WOULD NOT GET ONE AND THEN SHE WOULD GET 2 REALLY BAD ONES LASTING ALMOST A WHOLE MONTH. SHE COULD NOT GET OUT OF BED AND STATED SHE WAS DIAGNOSED WITH OCCIPITAL NEURALGIA, FIBROMYALGIA (AS REPORTED, UNDERSTOOD AS FIBROMYALGIA), DEPRESSION, DIABETES, CHRONIC INFLAMMATORY RESPONSE OF UNKNOWN ORIGIN, GAINED ALMOST 50 LBS IN A YEAR, THE ABDOMINAL PAIN SPASMS WERE EXCRUCIATING (DOUBLING HER OVER QUITE FREQUENTLY), HER FALLOPIAN TUBES STARTED SPASMING FOR DAYS AT A TIME. HER FAMILY WOULD GO TO WORK AND SCHOOL AND SHE WOULD GO BACK TO BED FOR THE DAY. SHE COULD NOT WORK BECAUSE SHE COULD NOT SIT UP STRAIGHT OR STAND FOR ANY LENGTH OF TIME. HER EYES WOULD NOT EVEN BE OPEN IN THE MORNING AND SHE WOULD BE PLANNING WHEN SHE COULD GO BACK TO SLEEP, EVERY SINGLE DAY, 18 HOURS OF SLEEP WAS NOT ENOUGH, IT WAS NEVER ENOUGH. AT HER NEXT ANNUAL, SHE BROUGHT UP HER ISSUES AND HER DOCTOR CONVINCED HER THAT IT COULD IN NO WAY BE RELATED TO ESSURE, AND IT MUST BE A CYST ON HER OVARY. PHYSICIAN SENT HER FOR A VAGINAL ULTRASOUND BUT NEVER CALLED HER BACK WITH ANY RESULTS. SHE WENT ON ANOTHER YEAR LIKE THIS, GOING TO PAIN CLINICS FOR NEURALGIA, GETTING RADIOFREQUENCY ABLATIONS ON HER SPINE (TO NUMB THE NERVES IN AN ATTEMPT TO STOP HER HEADACHES), MASSAGES, PAIN MEDS, MORE PAIN MEDS, DEPRESSION PILLS. SHE STATES THAT SHE LIVED IN A FOG AND WAS NOT SURE HOW MUCH OF IT WAS BRAIN FOG FROM THE INFLAMMATION OR HOW MUCH WAS PILL INDUCED. HER HUSBAND WAS STARTING TO WORRY THAT HER PILL HABIT WOULD GET OUT OF CONTROL AND INFORMED THAT HER DOCTOR PRESCRIBED HER VICODIN TO TAKE ON A DAILY BASIS. HER STORY GOES WAY DEEPER UNTIL SHE FOUND THE GROUP ON SOCIAL MEDIA AND PUT ALL THE PIECES TOGETHER. SHE KNOWS IN HER GUT IT WAS ALL DUE TO ESSURE AND, AT HER NEXT ANNUAL (2014) SHE WENT IN SEEING RED AND DEMANDED TO BE HEARD. SHE FOUGHT UNTIL HER DOCTOR CONCEDED TO DOING A HYSTERECTOMY TO GET OUT THE ESSURE. SHE WENT FOR A UTERINE BIOPSY AND 2 MORE ULTRASOUNDS AND THEN SHE WAS FINALLY APPROVED FOR SURGERY. ON (B)(6) 2015, SHE GOT HER LIFE BACK. SHE GOT ESSURE OUT OF HER VIA DAVINCI LAH (LAPAROSCOPY ASSISTED VAGINAL HYSTERECTOMY) WITH SALPINGECTOMY (FALLOPIAN TUBE REMOVAL). ACCORDING TO HER, THE RELIEF WAS ALMOST INSTANT. SHE STATES THAT WITHIN A FEW DAYS ALL THE FEELING WAS BACK IN HER FINGERS, HER HEADACHES DIED DOWN, AND SHE LOST 5 LBS. IN THE FIRST WEEK. ADDITIONALLY, CONSUMER REPORTED THAT SHE DID HAVE A DIFFICULT RECOVERY AND INFORMED THAT THERE WERE ISSUES WITH INTERNAL STITCHES AROUND HER DIAPHRAGM. BUT AFTER SOME MORE PAIN SHOTS AND PATIENCE SHE WAS ON THE MEND. SHE SLEEPS REGULAR HOURS NOW (SOMETIME ONLY 5 OR 6 HOURS DOES IT). SHE IS SMILING AND JUST ENJOYING THE LIFE AGAIN. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE K CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ABDOMINAL PAIN SPASM AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTEROSALPINGECTOMY. ADDITIONALLY, SHE WAS DIAGNOSED WITH DIABETES AND OCCIPITAL NEURALGIA. ONLY ABDOMINAL PAIN IS

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LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER'S ABDOMINAL PAIN SPASM STARTED AFTER ESSURE PLACEMENT AND NO PROVEN ALTERNATIVE EXPLANATION WAS PROVIDED (CONSUMER HAD FIBROMYALGIA AND DIABETES; HOWEVER INTENSE ABDOMINAL SPASMS ARE NOT EXPECTED AS SYMPTOM FOR THESE CONDITIONS). THEREFORE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING DIABETES AND OCCIPITAL NEURALGIA; GIVEN THEIR NATURE AND CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY IS CONSIDERED UNLIKELY. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01304	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1439, AWARENESS DATE 05-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED THAT SHE HAD TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6) DUE TO COMPLICATIONS AND PAIN THAT ESSURE HAS CAUSED HER. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 21-OCT-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN (INTERPRETED AS PELVIC PAIN). SHE HAD TO HAVE A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE

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SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01305	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING AND TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1371, AWARENESS DATE 05-OCT-2015). CASE WAS RECEIVED IN UNITED STATES AND REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT, WHILE THE IMPLANTATION PROCEDURE, IT WENT FAIRLY WELL. HOWEVER, THE COMPLICATIONS FROM HAVING THE DEVICES PLACED STARTED ALMOST IMMEDIATELY. SHE STATES THAT IT STARTED OUT WITH ABDOMINAL PAIN. THE PAIN AND CRAMPING STEADILY CLIMBED OVER THE NEXT 3 WEEKS. AT THAT POINT, SHE BEGAN TO BLEED BRIGHT RED BLOOD ACCOMPANIED BY SEVERE SHARP PAINS IN HER RIGHT LOWER ABDOMEN. SHE WAS SEEN BY THE DOCTOR AND REQUESTED THAT THE DEVICES TO BE REMOVED. SHE THOUGHT THAT WOULD BE THE BEST THING TO DO. SHE UNDERWENT SURGERY TO REMOVE THE DEVICES. ONE OF THE COILS PERFORATED THE RIGHT SIDE OF HER UTERUS AND WAS EMBEDDED. THE SECOND COIL WAS DISCOVERED FLOATING AROUND IN HER ABDOMEN. UNFORTUNATELY, BOTH FALLOPIAN TUBES WERE DESTROYED IN THE PROCESS OF TRYING TO LOCATE THE DEVICES AND STATES THAT SHE NOW HAS PAIN EVERY DAY (ESPECIALLY ON THE RIGHT SIDE) AND PERMANENT SWELLING OVER THE SITE OF THE UTERUS WHERE THE COIL WAS EMBEDDED. IN ADDITION, CONSUMER REPORTED THAT SHE NOT ONLY DID END UP HAVING A SURGERY SHE NEVER SHOULD HAVE TO HAVE, BUT NOW HAS PAIN AND SWELLING THAT IS CONSTANT AND STEADILY WORSENING. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ALMOST IMMEDIATELY SHE HAD ABDOMINAL PAIN. AFTER 3 WEEKS, SHE BEGAN TO BLEED BRIGHT RED BLOOD (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A SURGERY TO REMOVE THE DEVICES AND FOUND OUT THAT ONE OF THE COILS HAD PERFORATED THE RIGHT SIDE OF HER UTERUS AND WAS EMBEDDED (INTERPRETED AS UTERINE PERFORATION). THE OTHER COIL WAS FLOATING AROUND HER ABDOMEN (INTERPRETED AS DEVICE DISLOCATION). AFTER REMOVAL, SHE STILL HAD PAIN. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE STRONG SUGGESTIVE TEMPORAL RELATIONSHIP AND THE NATURE OF THESE EVENTS, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01306	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626679

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044151) IN UNITED STATES ON 05-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)), LOT NUMBER 626679, INSERTED FOR PERMANENT BIRTH CONTROL ON (B)(6) 2008. THE CONSUMER REPORTED THAT HER SON WAS BORN IN 2005 AND SHE ASKED HER DOCTOR TO TIE HER TUBES, BUT SHE WOULD NOT LISTEN TO HER AND TOLD HER TO WAIT. THREE YEARS LATER, IN 2008, SHE ASKED HER AGAIN TO TIE HER TUBES BECAUSE SHE WAS DONE HAVING CHILDREN, BUT THE DOCTOR CONVINCED THE CONSUMER TO GO ON A DIFFERENT ROUTE. SHE TOLD HER ABOUT THE PAINLESS WITH LESS RECOVERY TIME ESSURE PROCEDURE AND WHEN THE CONSUMER HAD THE PROCEDURE, ON THE RIGHT SIDE EVERYTHING WENT FINE, BUT WHEN SHE INSERTED THE LEFT SIDE IT HURT SO BAD THAT THE DOCTOR HAD TO TAKE IT OUT AND REINSERT IT. SHE TOLD THE CONSUMER SHE WOULD HAVE SOME DISCOMFORT AND SHE REMEMBER CALLING SEVERAL TIMES LETTING THE DOCTOR KNOW THAT SHE HAD A LOT OF PAIN ON HER LEFT SIDE. WHEN SHE WENT IN FOR HER 3-MONTH CHECK UP ON THE PROCEDURE, SHE WAS TOLD EVERYTHING WAS FINE. IT WAS 2015 AND SHE STILL HAD PAIN ON HER LEFT SIDE. SHE HAD GONE TO SEVERAL DOCTORS AND HAD SEVERAL COMPUTED TOMOGRAPHY (CT) SCANS, X-RAYS, MAGNETIC RESONANCE IMAGING (MRI), BUT NO ONE COULD TELL HER WHY SHE WAS IN PAIN. SHE STATED SHE WAS UNABLE TO EXERCISE A LOT, BECAUSE SHE WOULD BE IN A LOT OF PAIN. SHE ALSO HAD PAIN AFTER SEX AND AFTER LONG PERIODS OF SITTING. SHE TRIED DIFFERENT MEDICATIONS SUCH AS IBUPROFEN, TYLENOL (PARACETAMOL), HEATING PADS, ICE PACKS AND PAIN PATCHES; NONE OF THEM REALLY TOOK THE PAIN AWAY. THE REPORTER ASSESSED THE PAIN AS A SERIOUS INJURY. FOLLOW-UP INFORMATION RECEIVED ON 19-OCT-2015 AND PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THE CONSUMER CONFIRMED NEW REPORTERS. SHE STATED

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THAT HER DATE OF BIRTH IS (B)(6) 1976. (B)(6) WAS HER LAST NAME AT THE TIME. ON THE ESSURE CARD IT SAYS ESS305 WITH LOT 626679 (PREVIOUSLY REPORTED). THE PROCEDURE DATE WAS IN 2008, SHE CAN'T REMEMBER THE EXACT DATE. PTC RESULTS: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE NODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD A LOT OF PAIN ON HER LEFT SIDE SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS EVENT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER'S PAIN STARTED IN CLOSE ASSOCIATION WITH ESSURE PROCEDURE AND NO ALTERNATIVE EXPLANATION WAS AVAILABLE (SHE STATED SHE HAD SEVERAL TESTS AND NO ONE COULD TELL HER THE REASON FOR THE PAIN). CONSIDERING THIS INFORMATION AND GIVEN EVENT'S NATURE, A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION THE NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE ACCORDING TO THE CONSUMER'S REPORT, MEDICAL INTERVENTION (SEVERAL DOCTOR VISITS, CT SCANS, X-RAYS, MRI, AND ANALGESIC AND LOCAL THERAPY) WAS REQUIRED FOR PAIN TREATMENT. ADDITIONALLY, AN IMPAIRMENT OF CONSUMER'S DAILY ACTIVITIES WAS REPORTED (SHE WAS UNABLE TO EXERCISE AND HAD PAIN AFTER LONG PERIODS OF SITTING). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-NOV-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01307	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED THROUGH BAYER COMMUNICATION DEPARTMENT FROM A NON-HEALTH PROFESSIONAL IN (B)(6) ON 05-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CASE HAS BEEN PUBLISHED IN "(B)(6)". CONSUMER REPORTED THAT SHE THOUGHT HER HEADACHES COULD BE CAUSED BY HER ILLNESS (SHE HAS LUPUS). HOWEVER, DURING THE PAST THREE YEARS (SINCE 2012), HER PAINS AND HAEMORRHAGES HAVE BEEN MORE ACUTE AND SHE HAD ANAEMIA. THE GYNECOLOGIST TRIED TO REGULATE HER PERIOD BY PILLS, BUT NOTHING IMPROVED. FINALLY, THE DOCTORS CHOSE TO REMOVE THE IMPLANTS AND, ON THE (B)(6) 2015, THEY REMOVED THEM TOGETHER WITH HER FALLOPIAN TUBES AND UTERUS. CONSUMER NOW FEELS VERY WELL, WITHOUT PAINS AND COMPLETELY RECOVERED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAINS AND HAEMORRHAGES (REGARDED AS GENITAL HEMORRHAGE). ADDITIONALLY, SHE HAD ANEMIA. THE DEVICES WERE REMOVED (HYSTEROSALPINGECTOMY PERFORMED). ONLY ANEMIA IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER DEVELOPED PAIN AND BLEEDING AN UNSPECIFIED TIME AFTER ESSURE PLACEMENT. THESE EVENTS IMPROVED WITH DEVICES REMOVAL. CONSIDERING THIS INFORMATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING ANEMIA, CONSUMER HAD LUPUS AS CONCOMITANT DISEASE. THIS CONDITION COULD BE AN ALTERNATIVE EXPLANATION FOR HER ANEMIA. HOWEVER, CONSIDERING IRON DEFICIENCY ANEMIA MAY OCCUR AS A COMPLICATION OF HEAVY MENSTRUAL PERIODS IT CANNOT BE EXCLUDED

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THIS EVENT OCCURRED AS A CONSEQUENCE OF CONSUMER'S GENITAL BLEEDING. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FOLLOW-UP WILL BE PURSUED SINCE THIS IS A DIGITAL PRESS CASE.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 12-NOV-2015 WITH THE FINAL PTC (PTC GLOBAL NUMBER: (B)(4)) INVESTIGATION RESULT: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01308	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. ANTICIPATED. SERIOUS INJURY. REQUIRED INTERVENTION THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT FEMALE CONSUMER IN UNITED STATES ON 05-OCT-2015. IT REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE HAD 5 ABDOMINAL SURGERIES WITH 1 OF THOSE BEING AN ECTOPIC PREGNANCY IN WHICH HER TUBE WAS SAVED. SHE ALSO STATED THAT ESSURE WAS NOT SAFE. CONSUMER ALSO REPORTED ANOTHER PREGNANCY WITH ESSURE (PLEASE REFER TO CASE (B)(4)). PTC INVESTIGATION RESULT RECEIVED ON 28-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT, THE LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE STATED SHE HAD A SURGERY DUE TO AN ECTOPIC PREGNANCY. THE REPORTED EVENTS ARE LISTED

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ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). WHEN A PREGNANCY OCCURS WITH ESSURE, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. IN THIS PARTICULAR CASE, NO INFORMATION WAS GIVEN ABOUT THE TEMPORAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND THE ECTOPIC PREGNANCY. CONSUMER ALSO REPORTED A PREGNANCY AND MISCARRIAGE WITH ESSURE (DISCUSSED IN THE LINKED CASE); HOWEVER THE TIME BETWEEN THIS PREGNANCY AND HER ECTOPIC PREGNANCY WAS NOT PROVIDED. ALTHOUGH LIMITED INFORMATION WAS GIVEN FOR A COMPREHENSIVE CAUSALITY ASSESSMENT; CONSIDERING EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WAS REQUIRED FOR EVENT'S TREATMENT. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) / LACK OF EFFICACY AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01309	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NON-HEALTH PROFESSIONAL IN (B)(6) ON (B)(6) 2015. IT HAS BEEN PUBLISHED IN A (B)(6) DIGITAL PRESS "EL MUNDO" AND REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. A NOW (B)(6) FEMALE CONSUMER WHO HAD ESSURE INSERTED ON AN UNSPECIFIED DATE, WENT TO A MEDICAL APPOINTMENT FOR "PRICKS SENSATION ON GROIN" BUT HER PHYSICIAN TOLD HER THAT IT WAS RELATED TO THE NERVOUSNESS OF THE CONSUMER DUE TO THE MACULAR HEMORRHAGES WHICH SHE HAS SINCE SHE WAS PREGNANT. ACCORDING TO THE PUBLICATION THE CONSUMER IS GOING TO HAVE A SURGICAL REMOVAL IN A FEW DAYS ((B)(6) 2015) AND STATES THAT SHE WILL SAY GOODBYE TO THE PAIN SHE HAS BEEN SUFFERING FOR THE LAST 3 YEARS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO WAS GOING TO HAVE A SURGICAL REMOVAL OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN A FEW DAYS DUE TO PAIN. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. ADDITIONALLY, THE NON-SERIOUS EVENT PRICK SENSATION IN GROIN WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FOLLOW-UP WILL BE PURSUED SINCE THIS IS A DIGITAL PRESS CASE.

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Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 12-NOV-2015 WITH THE FINAL PTC (PTC GLOBAL NUMBER: (B)(4)) INVESTIGATION RESULT: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01310	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 628043

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5035802) IN UNITED STATES ON 02-JUN-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE LOT NUMBER 628043 INSERTED IN 2009 AFTER HER THIRD CHILD AND EXPERIENCED THE FOLLOWING ADVERSE EVENTS. SINCE THEN SHE PRESENTS SEVERE PAIN WHEN HAVING INTERCOURSE AND ALSO RANDOMLY THROUGHOUT THE DAY AND NIGHT. SHE ALSO EXPERIENCED LOWER BACK PAIN, MAJOR ANXIETY, GENERAL FEELINGS OF SICKNESS AND HER MENSTRUAL CYCLE CHANGED DRAMATICALLY AFTER ESSURE, SHE HAS HUGE BLOOD CLOTS, A SHORTER CYCLE, AND ALSO RANDOM PERIODS. SHE IS CONSTANTLY TIRED EVEN IF SHE SLEEPS SO MUCH, LIVES HER LIFE IN A CONSTANT FOG. DISABILITY/ PERMANENT DAMAGE WAS ASSESSED HOWEVER NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 20-JUN-2014: FOLLOW-UP ATTEMPTS WERE DONE WITHOUT SUCCESS. CASE CONSIDERED CLOSED. FOLLOW-UP INFORMATION FROM 06-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1338). CONSUMER STATED THAT A HYSTERECTOMY WAS PERFORMED. CASE IS NOW CONSIDERED INCIDENT. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC).(B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW

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OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LOWER BACK PAIN AND SEVERE PAIN WHEN HAVING INTERCOURSE (SEEN AS DYSPAREUNIA). THESE EVENTS ARE SERIOUS DUE TO REQUIRED INTERVENTION AND DISABILITY AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BACK PAIN AND DYSPAREUNIA MAY OCCUR DURING ESSURE USE. IN THIS CASE, SINCE THE INSERTION SHE PRESENTED SEVERE PAIN WHEN HAVING INTERCOURSE AND ALSO RANDOMLY THROUGHOUT THE DAY AND NIGHT. SHE ALSO EXPERIENCED LOWER BACK PAIN AND OTHER NON-SERIOUS EVENTS. CONSIDERING SUGGESTIVE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN THE REPORTED EVENTS AND ESSURE USE CANNOT BE EXCLUDED. INITIALLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, HYSTERECTOMY WAS INFORMED. THEREFORE, SINCE AN INTERVENTION WAS REQUIRED, THIS CASE WAS UPGRADED TO INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01311	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 08-JUL-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED EARLY MENOPAUSE AND NO SEX LIFE. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. SHE REPORTED THAT SHE WAS (B)(6) WHEN SHE UNDERWENT A HYSTERECTOMY. ONLY HER OVARIES WERE LEFT. SHE ALSO REPORTED THAT SHE EXPERIENCED EARLY MENOPAUSE AT (B)(6) AND AT THE TIME OF THIS REPORT SHE HAS NO SEX LIFE. SHE ASKED TO STOP LYING TO THE PUBLIC ABOUT HOW SAFE PRODUCT ESSURE IS. FOLLOW-UP 22-JUL-2014: NO RESPONSE FROM THE REPORTER CONSUMER AFTER 3 FOLLOW UP ATTEMPTS. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EFFECTS AND PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 28-JUL-2014: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN (B)(4)," BECAUSE AN INVESTIGATION OF THE SAME FAILURE MODE HAS ALREADY BEEN INITIATED. MEDICAL ASSESSMENT THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER

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WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 06-OCT-2015 - IT HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1162): THIS CASE WAS UPGRADED TO INCIDENT. THE CONSUMER'S HISTORY INCLUDED PARITY 4. ESSURE WAS INSERTED IN 2006. THE CONSUMER STATED THE DEVICE INSTANTLY CAUSED PROBLEMS: ABDOMINAL PAIN, MOOD SWINGS AND FATIGUE ALL THE TIME. SHE DEALT WITH CONSTANT BLEEDING AND PAIN BEFORE SHE WAS TOLD THAT SHE HAD MODERATE TO SEVERE ENDOMETRIOSIS. SHE HAD TO HAVE A HYSTERECTOMY TO GET RID OF THE COILS, WHICH WAS EXTREMELY PAINFUL. SHE STILL HAD HALF OF THE TUBES AND HER OVARIES, BUT SHE HAD PREMENOPAUSAL ISSUES SINCE THEN, SHE WAS (B)(6) AT THE TIME OF THIS REPORT AND STILL HAD ABDOMINAL PAIN DURING INTERCOURSE. SHE CONSIDERED ALL EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED ABDOMINAL PAIN AND CONSTANT BLEEDING (SEEN AS GENITAL BLEEDING). THESE EVENTS ARE SERIOUS DUE TO REQUIRED INTERVENTION AND MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER STATED THAT DEVICE INSTANTLY CAUSED PROBLEMS: ABDOMINAL PAIN AND OTHER NON-SERIOUS EVENTS. ALSO, SHE HAD TO DEAL WITH CONSTANT BLEEDING AND ABDOMINAL PAIN DUE TO MODERATE TO SEVERE ENDOMETRIOSIS. ALTHOUGH IN THIS CASE ENDOMETRIOSIS COULD BE THE MAIN CAUSE OF REPORTED EVENTS, A CONTRIBUTORY ROLE FROM ESSURE CANNOT BE TOTALLY EXCLUDED. INITIALLY HYSTERECTOMY WAS MENTIONED BUT NO INDICATION WAS PROVIDED. UPON RECEIPT OF FOLLOW UP INFORMATION, THE PROCEDURE'S INDICATION WAS INFORMED AS A HYSTERECTOMY TO GET RID OF THE COILS. SINCE A REQUIRED INTERVENTION TO REMOVE THE DEVICES WAS PERFORMED, THIS CASE WAS UPGRADED TO INCIDENT. TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01312	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0935, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER REPORTED THAT ESSURE WAS AWFUL. THE PROCEDURE WAS PAINFUL, BUT IT WOULD PALE IF YOU COMPARE TO LIVING WITH THE PAIN AFTERWARDS. FOLLOW-UP RECEIVED ON 06-OCT-2015 (PRODUCT TECHNICAL COMPLAINT INVESTIGATION) AND ADDITIONAL INFORMATION RECEIVED ON 17-OCT-2015. CASE WAS UPGRADED TO INCIDENT: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1562). CONSUMER REPORTED THAT SHE HAD ESSURE SINCE 2010. SHE STATES THAT SHE HAD TO HAVE IT REMOVED THIS YEAR (2015) BECAUSE IT MOVED AND PUNCTURED THRU HER TUBE AND ENDED UP EMBEDDED IN HER UTERUS. CONSUMER ALSO INFORMED THAT IT WAS SO PAINFUL. IN ADDITION, ON 06-OCT-2015, PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING

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BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED BECAUSE IT MOVED AND PUNCTURED THRU HER TUBE AND ENDED UP EMBEDDED IN HER UTERUS. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE PAIN DURING AND AFTER THE PROCEDURE. IN THIS PARTICULAR CASE, CONSUMER HAD INTENSE PAIN DURING AND AFTER ESSURE INSERTION. THE DEVICES REMOVED (5 YEARS AFTER THEIR IMPLANTATION) DUE TO FALLOPIAN TUBE PERFORATION/UTERINE EMBEDMENT. ALTHOUGH THE EXACT MECHANISM OF THESE EVENTS WAS UNKNOWN; CONSUMER'S PROCEDURAL PAIN MAY SUGGEST AN ASSOCIATION WITH THE ESSURE INSERTION. ADDITIONALLY; BASED ON EVENTS NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT, SINCE DEVICE REMOVAL WAS REPORTED UPON RECEIPT OF NEW INFORMATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PERFORMED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

UPDATED PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 29-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXC

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01313	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1132, AWARENESS DATE 06-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED SHE HAD A HYSTERECTOMY FOR HER (B)(6) BIRTHDAY AND THANKED ESSURE FOR THIS. -RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND UNDERWENT A HYSTERECTOMY. THIS EVENT IS

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SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THE PRESENT CASE, NEITHER THE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE HYSTERECTOMY, NOR THE EXACT REASON FOR THE HYSTERECTOMY WAS SPECIFIED. AS NO FOLLOW-UP WILL BE POSSIBLE, COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01314	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1136, AWARENESS DATE 06-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 FOR BIRTH CONTROL. CONSUMER HAD A HYSTERECTOMY TO REMOVE ESSURE IN THE YEAR OF THIS REPORT (2015). ACCORDING TO HER, ESSURE CAUSED A HOST OF SYMPTOMS AND SIDE EFFECTS. SHE WENT FROM BEING A HEALTHY WIFE, MOTHER AND TEACHER, TO A PERSON WHO WAS CONSTANTLY SICK. SHE DEVELOPED LYME DISEASE, MONO, ARTHRITIS, DEEP VEIN THROMBOSIS IN HER LEG, AND DEBILITATING FATIGUE JUST TO NAME A FEW. -RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN

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THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD A HYSTERECTOMY TO REMOVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). ADDITIONALLY, SHE STATED SHE DEVELOPED LYME DISEASE AND HAD DEEP VEIN THROMBOSIS IN HER LEG. ONLY HYSTERECTOMY IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER STATED ESSURE CAUSED HER A HOST OF SYMPTOMS AND SIDE EFFECTS; SHE MENTIONED A FEW OF THEM, SUCH AS LYME DISEASE AND DEEP VEIN THROMBOSIS. LYME DISEASE IS A MULTISYSTEM ILLNESS CAUSED BY INFECTION WITH A SPIROCHETE TRANSMITTED BY TICKS. DEEP VEIN THROMBOSIS OCCURRENCE IS ASSOCIATED WITH AGE, OBESITY, POSITIVE FAMILIAR HISTORY, PROLONGED IMMOBILIZATION, SMOKING, DYSLIPOPROTEINEMIA AMONG OTHERS. BOTH CONDITIONS ARE TREATED WITH MEDICAL THERAPY. CONSIDERING THE PATHOPHYSIOLOGY OF THESE EVENTS AND GIVEN ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED VERY UNLIKELY. A MAJOR INCONSISTENCE WAS FOUND IN CONSUMER'S REPORT; SINCE HYSTERECTOMY IS NOT A TREATMENT FOR THE ABOVE MENTION CONDITIONS. DESPITE THE LACK OF DETAIL AVAILABLE, THE ABSENCE OF MEDICAL CONFIRMATION AND REPORT INCONSISTENCY TO PERFORM A COMPREHENSIVE CAUSALITY ASSESMENT; AS CONSUMER STATED SHE HAD A HYSTERECTOMY TO REMOVE ESSURE AND SINCE SHE MENTIONED OTHER UNSPECIFIED SIDE EFFECTS; CAUSALITY BETWEEN THIS SURGERY AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THEREFORE, THIS CASE WAS CONSIDERED AN INCIDENT (DEVICE REMOVAL WAS REQUIRED). PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01315	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/4/2014
Explant Date (E7): 2/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1290, AWARENESS DATE 06-OCT-2015). ESSURE WAS INSERTED ON (B)(6) 2014. SHE NOTICED RIGHT AWAY SHE BEGAN BLEEDING HEAVILY. IN (B)(6) 2015, SHE STARTED HAVING MIGRAINES WITH STROKE LIKE SYMPTOMS; SHE WAS IN THE ER AT LEAST 4 TIMES (ONCE BEING TAKEN IN AN AMBULANCE DUE TO NOT BEING ABLE TO TELL HER NAME AND BEING PARALYZED ON HALF HER BODY WHICH ACCORDED QUITE OFTEN) FROM (B)(6). SHE WAS SENT TO SEE A NEUROLOGIST WHO RAN A BUNCH OF TEST AND ALL WERE NORMAL. ONLY THING SHE COULD THINK OF IT WAS THE COILS WERE DOING THIS; SHE WAS FINE UNTIL SHE GOT THEM. SHE WENT TO DOCTOR THAT IMPLANTED THE COILS AND SHE SAID SHE DID SEE HOW COILS IN HER TUBES COULD CAUSE AN ISSUE WITH HER HEAD BUT AGREED TO TAKE THEM OUT BY CUTTING HER TUBES OUT. SHE BLED FROM TIME SHE WAS IMPLANTED UNTIL (B)(6) 2015. ON (B)(6) 2015, COILS WERE REMOVED. SHE WAS PUT ON MEDICINE THAT MADE HER HAVE TO STOP BREAST-FEEDING HER YOUNGEST CHILD WHO WAS ONLY (B)(6) AT THE TIME. SHE HAD HORRIBLE PAINS ON RIGHT SIDE. DURING SURGERY HER DOCTOR SAID THE COIL IN HER RIGHT TUBE FELT OUT WHEN SHE TOUCHED IT. SHE HAS A PIECE THAT IS EMBEDDED IN UTERUS. ACCORDING TO HER DOCTOR, THERE IS NOTHING WRONG WITH HAVING A PIECE OF METAL IN HER UTERUS. SINCE REMOVAL SHE DID NOT HAVE ANY MORE MIGRAINES WITH STROKE LIKE SYMPTOMS. HER BLEEDING HAS STOPPED; SHE ONLY HAD 1 PERIOD A MONTH VERSUS BLEEDING EVERY DAY OF THE MONTH. THE OUTCOME OF THE EVENT BLEEDING HEAVILY WAS RECOVERED / RESOLVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER

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REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING HEAVILY (INTERPRETED AS GENITAL BLEEDING), MIGRAINES WITH STROKE LIKE SYMPTOMS, SHE WAS IN THE EMERGENCY ROOM AT LEAST 4 TIMES (ONCE BEING TAKEN IN AN AMBULANCE DUE TO NOT BEING ABLE TO TELL HER NAME AND BEING PARALYZED ON HALF HER BODY WHICH ACCORDED QUITE OFTEN). SHE HAD HER COILS REMOVED. DURING SURGERY HER DOCTOR SAID THE COIL IN RIGHT TUBE FELL OUT (INTERPRETED AS DEVICE BREAKAGE). SHE HAD A PIECE OF METAL EMBEDDED IN UTERUS. BLEEDING HEAVILY AND PIECE OF METAL EMBEDDED IN UTERUS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE OTHER EVENTS ARE UNLISTED. ALL THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE NON-SERIOUS EVENT COIL IN RIGHT TUBE FELL OUT (DEVICE BREAKAGE) WAS AMENDED TO ANTICIPATED (LISTED) UPON RECEIPT OF PRODUCT TECHNICAL ANALYSIS. BASED ON THE PATHOPHYSIOLOGY OF STROKE AND CONSIDERING THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP BETWEEN MIGRAINES, STROKE LIKE SYMPTOMS AND BEING PARALYZED ON HALF HER BODY WITH SUSPECT INSERT CAN BE EXCLUDED. THE EXACT DATE AND MECHANISM OF EMBEDMENT ARE NOT KNOWN. NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR BLEEDING HEAVILY. CONSIDERING THE NATURE OF THE OTHER EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO SURGICAL INTERVENTION, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENT WAS ADDED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01316	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2013
Explant Date (E7): 3/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1270, AWARENESS DATE 06-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. CONSUMER HAD A DAUGHTER. SHE REPORTED THAT SOON AFTER THE TEST CONFIRMED BLOCKED, ALL OF HER SYMPTOMS STARTED. SHE WENT TO HER ORIGINAL GYNECOLOGIST MORE THAN 5 TIMES, ONLY SEEING HER IMPLANTING DOCTOR ONCE. IT HAS BEEN NONSTOP 2 YEARS OF DOCTOR APPOINTMENTS, EMERGENCY ROOM VISITS, URGENT CARE, FAMILY PLANNING VISITS AND GASTROINTESTINAL SPECIALIST. UNTIL SHE FOUND A DOCTOR TO REMOVE THE ESSURE DEVICES. HER HYSTERECTOMY DATE WAS (B)(6) 2015. SHE HAD A PERFORATED TUBE. SHE EXPERIENCED ALL KINDS OF INFECTIONS, PAIN, MIGRAINES AND THE WORST ANXIETY. THE PAIN WAS BETTER. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED

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THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER ONE AND A HALF YEAR UNDERWENT A HYSTERECTOMY TO REMOVE THE DEVICES. DURING THE PROCEDURE A PERFORATED TUBE WAS DIAGNOSED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THIS PERFORATION WERE NOT REPORTED. THE PERFORATION WAS DIAGNOSED DURING A HYSTERECTOMY, ONE AND A HALF YEAR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION TO REMOVE ESSURE (HYSTERECTOMY). PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01317	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1290, AWARENESS DATE 06-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER WAS TOLD ABOUT ESSURE DURING HER PREGNANCY (SHE HAD 1 CHILD) AND DECIDED THAT IT WAS A GREAT OPTION. SHE WAS NOT TOLD ABOUT ANY SIDE EFFECTS OR NICKEL ALLERGIES OR MIGRATION OR THAT WOMAN STILL BECOME PREGNANT. SHE WAS (B)(6) WHEN SHE HAD ESSURE PLACED IN (B)(6) 2014; SHE WAS A HAPPY AND HEALTHY WOMAN WITH NO MEDICAL ISSUES AT THE TIME OF PLACEMENT. SHE WAS AWAKE DURING PLACEMENT AND WAS TOLD IT WAS A SUCCESS. IMMEDIATELY AFTER PLACEMENT SHE WAS VERY FAINT AND WAS IN PAIN IN HER PELVIC AREA BUT WAS TOLD NOT TO WORRY (THAT PAIN NEVER WENT AWAY). SIX MONTHS IN SHE FINALLY WENT TO THE DOCTOR WITH A LIST OF COMPLAINTS SINCE GETTING ESSURE AND WAS TOLD THEY DID NOT THINK IT WAS RELATED. SHE HAD TO SUFFER FOR 4YRS (DISCREPANT INFORMATION SINCE ESSURE WAS IMPLANTED IN 2014) WITH PELVIC PAIN AND 24HOURS PER 7 DAYS WITH MIGRAINES THAT LITERALLY NEVER WENT AWAY. SHE WAS SO BLOATED FROM ESSURE THAT SHE HAD STRANGERS CONSTANTLY ASK HER IF SHE WAS EXPECTING OR HOW FAR ALONG SHE WAS. SHE HAD A LONG LIST OF OTHER SYMPTOMS INCLUDING HAIR LOSS, FATIGUE, PAINFUL INTERCOURSE, ABNORMAL CYCLES, HEAVY BLEEDING, COMPLETELY MISSED CYCLES, NIGHT SWEATS, ALL OVER BODY PAIN, JOINT PAIN; THE LIST GOES ON AND ON. SHE WENT TO SEVERAL DOCTOR NEUROLOGISTS, HOSPITALS, HAD MANY ULTRASOUNDS, MRLS, CT SCANS, AND HAD BLOOD WORK DONE WITH NO ANSWERS. NO ONE COULD FIGURE OUT WHY SHE HAD MIGRAINES OR PELVIC PAIN SO BAD; SHE TRIED SO MANY MEDICATIONS. SHE SUFFERED FOR 4 YEARS

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CONSTANTLY IN PAIN, CRYING, DEPRESSED, SUICIDAL BECAUSE DEATH SEEMED BETTER THAN LIVING WITH THIS PAIN. SHE WAS CONSTANTLY TIRED, HAD TO CANCEL PLANS WITH FRIENDS OR FAMILY DUE TO PAIN. HER (B)(6) OLD SON COULD NOT PLAY LOUDLY, COULD NOT LISTEN TO TV LOUDLY BECAUSE HER MOMMY WAS TOO SICK AND NOISE MADE IT WORSE. SHE WAS IN TOO MUCH PAIN TO PLAY WITH HER SON OR LAUGH WITH HIM. SHE BASICALLY MISSED OUT ON SOME OF HIS MOST IMPORTANT YEARS BECAUSE OF PAIN. HER MIGRAINES WERE SO BAD MOST OF THE LIGHTS IN HER HOUSE WERE BLOCKED, SHE WOULD HAVE TO GO TO SLEEP WITH ICE PACKS ON HEAD (IN THE BEGINNING IT WAS HEATING PADS THAT SHE TRIED) JUST TO TRY AND NUMB THE PAIN ENOUGH TO FALL ASLEEP. SHE HAD ALL KINDS OF TESTS AND MEDICAL IONS AND VARIOUS THINGS TRIED AND NOTHING HELPED. HER HUSBAND SUFFERED AS WELL THEY WERE UNABLE TO BE INTIMATE BECAUSE IT WAS TOO PAINFUL. HAVING INTERCOURSE JUST WAS NOT WORTH THE PAIN AND THE WORRY OF UNWANTED PREGNANCY. SHE WAS GRUMPY AND IRRITABLE FROM BEING IN PAIN 24 HOURS PER 7 DAYS AND THAT PAIN MAKING HER DEPRESSED. FINALLY AFTER TRYING EVERYTHING, HYSTERECTOMY WAS DONE. SINCE THEN, ALL HER HORRIBLE SYMPTOMS WERE GONE AND SHE IS SO HAPPY AND FEELING SO MUCH BETTER. BUT NOW, SHE GOT TO EXPERIENCE MENOPAUSE AT (B)(6) BUT. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 21-OCT-2015 PTC GLOBAL NUMBER: (B)(4) FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD PAIN IN PELVIC AREA AND HEAVY BLEEDING SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE BECAME DEPRESSED/SUICIDAL. SHE WAS SUBMITTED TO A HYSTERECTOMY AND RECOVERED FROM THE EVENTS. ONLY DEPRESSION WITH SUICIDAL IDEATION IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER REPORTED PAIN AND HEAVY BLEEDING IN CLOSE ASSOCIATION WITH ESSURE INSERTION WITH RECOVERY AFTER DEVICES REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT; WOMEN HAVE HIGH RISK FOR DEVELOPING DEPRESSIVE DISORDERS. SEVERAL BIOLOGICAL PROCESSES ARE THOUGHT TO BE INVOLVED IN THIS PREDISPOSITION, INCLUDING AN UNDUE SENSITIVITY TO HORMONAL FLUCTUATIONS IN BRAIN SYSTEMS THAT MEDIATE DEPRESSIVE STATES. ADDITIONALLY, DEPRESSION IS A COMMON COMORBIDITY ACCOMPANYING CHRONIC PAIN STATES. IN THIS CASE, CONSUMER STATED SHE BECAME DEPRESSED/SUICIDAL BECAUSE DEATH SEEMED BETTER THAN LIVING WITH HER PAIN. CONSIDERING CONSUMER RELATED HER DEPRESSION TO THE PAIN; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01318	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 06-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE HAD A PARTIAL HYSTERECTOMY ON (B)(6) 2015 AND FELT MUCH BETTER. THE BLOATING AND WEIGHT WERE GOING DOWN. SHE HAD NO MORE RASHES, CONSTIPATION AND LACK OF SEX DRIVE SINCE THE COILS WERE GONE. ALSO, SHE REPORTED THAT SHE HAD 6 COILS OF DIFFERENT LENGTHS AS OPPOSED TO ONE IN EACH TUBE AS SHE WAS TOLD. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 21-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT

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REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD RASHES. SHE UNDERWENT A PARTIAL HYSTERECTOMY AND ESSURE WAS REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THE DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THIS DEVICE IS IMPLANTED. TYPICAL ALLERGY SYMPTOMS REPORTED INCLUDE RASH, PRURITUS, AND HIVES. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS NOT REPORTED WHETHER THE CONSUMER HAD A HISTORY OF METAL ALLERGY. HOWEVER, SINCE THE RASH RESOLVED AFTER ESSURE REMOVAL AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01319	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2011
Explant Date (E7): 7/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1148, AWARENESS DATE 06-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. CONSUMER REPORTED THAT WITHIN THE FIRST 4 DAYS AFTER ESSURE PROCEDURE SHE HAD HORRIBLE STABBING PAINS. HER DOCTOR TOLD HER IT HAD NOTHING TO DO WITH ESSURE. FOR THE FOUR YEARS SHE HAD ESSURE, SHE EXPERIENCED MIND FOG SO BAD THAT SHE COULD NO LONGER HAVE CONVERSATIONS, HER TEETH FELL OUT, HER BODY BECAME COVERED IN RASHES, SHE LOST MOVEMENT IN HER JOINTS FROM HEAD TO TOE, SHE BECAME CONSTANTLY BLOATED TO THE POINT SHE LOOKED 9 MONTHS PREGNANT, SHE HAD A METAL TASTE IN HER MOUTH TO WHERE SHE COULD NO LONGER EAT FOOD IN A REGULAR BASIS AND WHEN SHE COULD EAT SHE COULD NOT KEEP ANYTHING DOWN. SHE EXPERIENCED SUCH BAD FATIGUE THAT THERE WERE TIMES SHE WOULD STAY IN BED FOR WEEKS. ON (B)(6) 2015 SHE HAD A HYSTERECTOMY PERFORMED, HER OVARIES WERE NOT REMOVED, AND ALL HER SYMPTOMS WENT AWAY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING

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BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER BODY BECAME COVERED IN RASHES. SHE UNDERWENT A HYSTERECTOMY APPROXIMATELY 4 YEARS AFTER ESSURE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THE DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THIS DEVICE IS IMPLANTED. TYPICAL ALLERGY SYMPTOMS REPORTED INCLUDE RASH, PRURITUS, AND HIVES. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS NOT REPORTED WHETHER THE CONSUMER HAD A HISTORY OF METAL ALLERGY. HOWEVER, SINCE THE RASH RESOLVED AFTER HYSTERECTOMY AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01320	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1376, AWARENESS DATE 06-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. CONSUMER HAD ESSURE INSERTED IN (B)(6) 2013. CONSUMER STATED THAT NOT ONLY WAS IT PAINFUL TO PUT IN BUT THE BLOCKAGE TEST CONFIRMED THAT ONLY ONE COIL WAS IN PLACE. THEY HAD NO IDEA WHERE THE OTHER ONE WAS. THEY ASKED IF SHE WOULD LIKE TO HAVE ANOTHER COIL PLACED AGAIN AND SHE SAID NO WITHOUT ANY HESITATION. THE NEXT YEAR SHE EXPERIENCED BLOATING, LOOKED 6 MONTHS PREGNANT. SHE BLEED EVERYDAY. HER MOODS SWINGS WERE OUT OF CONTROL AND THE PAIN WAS UNBEARABLE. THE SHOOTING PAIN WAS WORSE THEN CHILD BIRTH. AFTER A YEAR OF THIS MESS SHE DECIDED TO SEE THE DOCTOR AGAIN AND HE ORDERED AN ULTRASOUND. ONE COIL WAS EMBEDDED IN UTERUS AND THE OTHER WAS HANGING OUT OF FALLOPIAN TUBE. AFTER THE DISCUSSION OF A HYSTERECTOMY SHE WENT HOME AND BALLED HER EYES. SHE WAS ONLY (B)(6) AND FELT LIKE SHE WAS LOSING HER WOMAN HOOD. ADDITIONALLY, SHE STATED SHE WAS NOT ABLE TO CARRY A BABY ANYMORE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE

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WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN ULTRASOUND SCAN SHOWED ONE COIL WAS EMBEDDED IN UTERUS AND THE OTHER WAS HANGING OUT OF FALLOPIAN TUBE. SHE MENTIONED A HYSTERECTOMY. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A UTERINE PERFORATION/EMBEDMENT DURING INSERTION. IN THIS CASE, CONSUMER CONFIRMATION TEST SHOWED ONLY ONE ESSURE COIL WAS IN PLACE. APPROXIMATELY ONE YEAR LATER, SHE HAD PAIN AND BLEEDING AND THE ABOVE MENTION DEVICE EMBEDMENT AND DISLOCATION WERE FOUND AT ULTRASOUND. ALTHOUGH THE EXACT MECHANISM OF THESE EVENTS IS UNKNOWN; GIVEN THEIR NATURE AND THE POSITIVE TEMPORAL RELATIONSHIP WITH ESSURE THERAPY, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. IN THIS CASE, CONSUMER STATED SHE DISCUSSED A HYSTERECTOMY WITH HER PHYSICIAN; ACCORDING TO HER SHE WAS ONLY (B)(6). THE INFORMATION PROVIDED WAS NOT CLEAR TO CONCLUDE IF THIS SURGICAL INTERVENTION WAS ACTUALLY PERFORMED. HOWEVER, AS CONSUMER MENTIONED AT THE END OF THE REPORT SHE WAS NOT ABLE TO CARRY A BABY ANYMORE AND SINCE NO FOLLOW-UP WILL BE POSSIBLE; COMPANY REGARDS THIS CASE AS INCIDENT (CONSIDERING A SURGICAL INTERVENTION WAS REQUIRED). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01321	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1391, AWARENESS DATE 06-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DAY, FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT SHE WAS HEALTHY PRIOR TO ESSURE. SHE HAD TWO PLANNED PREGNANCIES. HER SIDE EFFECTS RANGE FROM CHRONIC PELVIC PAIN DURING PERIOD AND OVULATION, CHRONIC HEADACHES, HEAVY BLEEDING WITH CLOTTING, PERIODS ALL OVER THE PLACE, BODY ITCHING, HAIR THINNING, SKIN RASH, LACK OF SEX DRIVE, DEPRESSION, ANGER ISSUES, EXTREME FATIGUE, NAUSEA, DIZZINESS AND JOINT PAIN. SHE HAD ESSURE REMOVED ALONG WITH PART OF HER UTERUS AND BOTH TUBES. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED

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QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING WITH CLOTTING (INTERPRETED AS GENITAL BLEEDING). SHE HAD ESSURE REMOVED. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THIS EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01322	BAYER HEALTHCARE LLC	11/2/2015	11/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1340, AWARENESS DATE 06-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT ESSURE ADDED TO HER MIGRAINES AND INCREASED HER PREMENSTRUAL SYNDROME, MENSTRUAL PAIN AND FLOW TO THE POINT THAT EACH MONTH SHE SPENT MORE TIME IN BED THEN OUT. SHE IS A WEEK POST OPERATION FROM A HYSTERECTOMY LEAVING ONLY HER OVARIES. HER SYMPTOMS HAVE GOTTEN SOMEWHAT BETTER. SHE WAS HEALING AND LOOKING FORWARD TO LIFE WITHOUT ESSURE IN HER BODY. FOLLOW UP RECEIVED ON 21-OCT-2015: PTC INVESTIGATIONAL RESULT. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD INCREASED MENSTRUAL PAIN. SHE UNDERWENT A HYSTERECTOMY AND ESSURE WAS REMOVED. THIS EVENT, INTERPRETED AS DYSMENORRHEA, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DYSMENORRHEA MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION FOR ESSURE REMOVAL (HYSTERECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057696	BAYER	11/2/2015	11/5/2015

Event Information:

Event Date (B3): 11/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 623217

Single Use: *
Implant Date (E6): 5/15/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

JUST RETURNED FROM GYNECOLOGICAL FOLLOW UP APPOINTMENT. I WENT TO MY DOCTOR WITH COMPLAINT OF VERY HEAVY MENSTRUAL CYCLES, ABNORMAL MENSTRUAL CYCLES AND MILD CRAMPING. HE ORDERED AN ULTRASOUND AND HYSTEROSCOPY WITH POSSIBLE BIOPSY. UPON VIEWING THE ULTRASOUND, THEY FOUND THAT ONE OF MY ESSURE DEVICES HAS DISLODGED ITSELF AND IS IN MY ENDOMETRIAL LINING. THIS REQUIRED US TO CANCEL TODAY'S HYSTEROSCOPY AND NEED TO SCHEDULE HYSTEROSCOPY WITH D AND C TO RETRIEVE THE DEVICE, REMOVAL OF THE OTHER ESSURE COIL AND TUBAL LIGATION VIA LAPAROSCOPY. AS OF THIS POINT IN TIME, NO HARM IS DONE OTHER THAN FINANCIALLY FOR HAVING TO PAY FOR ANOTHER STERILIZATION PROCEDURE. MY ESSURE WAS PLACED 6 YEARS AGO. VERY DISAPPOINTING AND JUST GRATEFUL THAT FURTHER DAMAGE HAS NOT BEEN DONE. NOT SURE THIS DEVICE SHOULD BE ON THE MARKET DUE TO THE DANGERS IT CAN POSE PLUS HAVING TO HAVE A PROCEDURE DONE I THOUGHT I WAS AVOIDING - TUBAL LIGATION. THANKFULLY NO SIGN OF PERFORATION AS OF THIS POINT IN TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057697	BAYER	11/2/2015	11/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) OF 2012, I HAD THE ESSURE IMPLANT. AT THE TIME, IT WAS VERY PAINFUL DURING INSERTION. I HAVE HAD MEDICAL ISSUES SINCE. I HAVE HAD LACK OF LIBIDO, PAIN IN BACK, HIPS AND PELVIS. I HAVE GAINED WEIGHT AT AN ALARMING RATE. I HAVE CONSTANT BLOATING, FEELING OF TEARING IN MY PELVIC AREA AND CHRONIC FATIGUE. THE LIST GOES ON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057698	BAYER	11/2/2015	11/5/2015

Event Information:

Event Date (B3): 5/15/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/15/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PERMANENT BIRTH CONTROL DEVICE IMPLANTED IN (B)(6) 2007. SINCE THEN, I'VE HAD RECURRING BAD SIDE EFFECTS INCLUDING ABDOMINAL CRAMPING, VERY BAD MENSTRUAL PERIODS, LOWER BACK PAIN, HIP PAIN, BONES ACHING, FEELING TIRED ALL THE TIME AND WAS DIAGNOSED A YEAR AGO WITH HASHIMOTO'S THYROIDITIS, AN AUTO IMMUNE DISEASE WHERE MY IMMUNE SYSTEM IS ATTACKING MY INFLAMMATORY RESPONSE IN THE BODY AND I THINK THAT ESSURE MAY BE THE CAUSE OF MY THYROID DISEASE. BESIDES THAT, THE OTHER SIDE EFFECTS HAVE CAUSED ME TO MISS WORK BECAUSE THEY ARE SEVERE. THE DOCTOR WHO IMPLANTED THE DEVICE REALLY PUSHED FOR ME TO GET THIS PROCEDURE, SAYING IT WAS THE SAFEST, LEAST INVASIVE OPTION OF PERMANENT BIRTH CONTROL AND THEN AFTER 3 PLACE, SHE ENDED UP JUST DOING AN ULTRASOUND. I HAVE GONE TO MY CURRENT OB/GYN WHO SAID SHE WOULD HAVE TO BASICALLY MANGLE MY UTERUS TO REMOVE THE ESSURE NOW.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01324	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): 5/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/13/2015
Explant Date (E7): 8/17/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1395, AWARENESS DATE 06-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER, SINGLE MOM, IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, UNDER GENERAL ANESTHESIA. CONSUMER REPORTED THAT IMMEDIATELY UPON WAKING UP FROM PROCEDURE SHE HAD UNBEARABLE CRAMPING AND BLEEDING, THAT NEVER SUBSIDED, JUST WORSENED. BY (B)(6) 2015 SHE ALSO STARTED EXPERIENCING DAILY MIGRAINES, FATIGUE, VISION AND DENTAL PROBLEMS, SEVERE HAIR LOSS, INSOMNIA, NIGHT SWEATS AND BLOATING THAT SHE LOOKED 4 MONTHS PREGNANT. ON (B)(6) 2015 SHE HAD A BILATERAL SALPINGECTOMY PERFORMED, TO REMOVE HER TUBES AND COILS. ON (B)(6) 2015 SHE FOUND OUT THAT FRAGMENTS WERE LEFT, SO SHE WAS WAITING ON HER PHYSICIAN TO SCHEDULE HER FOR ANOTHER SURGERY TO REMOVE THE FRAGMENTS. SHE ALSO EXPERIENCED HORRIBLE HIVES, SKIN RASHES AND ACNE, PROBABLY BECAUSE SHE WAS SEVERELY ALLERGIC TO NICKEL. FOLLOW UP RECEIVED ON 21-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED EXPERIENCING UNBEARABLE CRAMPING (INTERPRETED AS ABDOMINAL PAIN) AND BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A BILATERAL SALPINGECTOMY TO REMOVE ESSURE 3 MONTHS AFTER INSERTION, BUT WAS LEFT WITH FRAGMENTS (INTERPRETED AS DEVICE BREAKAGE). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR DEVICE BREAKAGE WHICH IS UNLISTED. ABDOMINAL PAIN AND GENITAL BLEEDING MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE DEVICE BREAKAGE, THE EXACT DATE AND MECHANISM OF THIS EVENT WAS NOT REPORTED. ONE MONTH AFTER A SURGERY TO REMOVE ESSURE THE PATIENT FOUND OUT SHE WAS LEFT WITH FRAGMENTS. DESPITE THE LIMITED INFORMATION PROVIDED, GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION FOR ESSURE REMOVAL (SALPINGECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01325	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): 9/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/20/2013
Explant Date (E7): 10/30/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1163, AWARENESS DATE 06-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 FOR CONTRACEPTION, THREE MONTHS AFTER BIRTH OF HER LAST CHILD. CONSUMER ALREADY HAD 5 CHILDREN. CONSUMER REPORTED THAT SHE TOOK VALIUM AND MOTRIN BEFORE INSERTION. AFTER INSERTION, AS SHE STOOD UP, BLOOD POURED DOWN HER LEGS, ALL OVER THE FLOOR AND INTO HER PANTIES AND PANTS. SHE CRAMPED ALL DAY. THE NEXT DAY THIS CONTINUED. EVERY TIME SHE SAT DOWN OR STOOD UP A POOL OF BLOOD WOULD POUR OUT OF HER AND THE CRAMPS WERE WORST THAN GIVING BIRTH. ON (B)(6) 2013 SHE WENT TO THE DOCTOR AND ULTRASOUND WAS PERFORMED SHOWING THAT COILS WERE IN THE RIGHT PLACE, BUT SHE COULD NOT TAKE IT ANYMORE, SO TOTAL HYSTERECTOMY WAS PERFORMED ON (B)(6) 2013. FOLLOW UP RECEIVED ON 21-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS

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CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AS SHE WENT TO STAND UP BLOOD POURED DOWN HER LEGS / EVERY TIME SHE SAT DOWN OR STOOD UP AGAIN THE BLOOD WOULD POUR. SHE UNDERWENT A TOTAL HYSTERECTOMY ONE MONTH AFTER ESSURE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01326	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1362, AWARENESS DATE 06-OCT-2015). IT REFERS TO A ADULT FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. ADDITIONAL INFORMATION RECEIVED ON 21-OCT-2015 (PTC RESULT). SHE NEVER HAD ANY MAJOR HEALTH PROBLEMS. CONSUMER EXPERIENCED MULTIPLE COMPLEX CYST ON OVARIES, CHRONIC ABDOMINAL AND BACK PAIN, PAIN THAT RUNS DOWN LEGS, NUMBNESS AND TINGLING OF ARMS, HANDS, LEGS AND FEET, HIGH BLOOD PRESSURE, VITAMIN D PROBLEMS, BAD HEADACHES, PAINFUL AND HEAVY BLEEDING AND BLOOD CLOTS DURING MENSTRUAL PERIOD, FIBROCYSTIC BREAST AND OVARIES, PREMENOPAUSAL MENORRHAGIA, CHRONIC FATIGUE AND MALAISE, FIBROMYALGIA, ADENOMYOSIS, CHRONIC WEIGHT LOSS, DEPRESSION, INSOMNIA, MENOMETRORRHAGIA, OVARIAN MALIGNANCY RISK AND THE LIST GOES ON AND ON. A TOTAL LAPAROSCOPIC HYSTERECTOMY WITH BILATERAL SALPINGECTOMY WAS PERFORMED BECAUSE ONE OF THE ESSURE COILS WAS COMING OUT OF HER UTERUS INTO ABDOMINAL CAVITY. SHE WAS (B)(6) AT TIME OF REPORT AND A SINGLE MOTHER. SHE STATED SHE WAS NEVER DEPRESSED OR UNHEALTHY AT ALL UNTIL ESSURE PROCEDURE. SHE WAS IN CONSTANT CHRONIC PAIN AND HER MOOD WAS UP AND DOWN. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE, DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING

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BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ONE OF THE ESSURE COILS WAS COMING OUT OF HER UTERUS INTO HER ABDOMINAL CAVITY RESULTING IN TOTAL LAPAROSCOPIC HYSTERECTOMY WITH BILATERAL SALPINGECTOMY. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH NOT REPORTED AS SUCH, THE MOST LIKELY MECHANISM FOR ONE OF THE ESSURE COILS WAS COMING OUT OF HER UTERUS INTO HER ABDOMINAL CAVITY, WOULD BE THROUGH A UTERINE/FALLOPIAN TUBE PERFORATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, ANOTHER SERIOUS EVENT (OVARIAN MALIGNANCY RISK, UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01327	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 06-OCT-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN CONTACTED THE COMPANY SEEKING INFORMATION REGARDING REMOVAL OF ESSURE DEVICE POST PLACEMENT AND RECOMMENDATIONS FOR TREATMENT OF ECTOPIC PREGNANCY WITH ESSURE IN PLACE. FOLLOW UP RECEIVED ON 21-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) OR LACK OF EFFICACY IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION; THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) OR THE LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ECTOPIC PREGNANCY WITH ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN PLACE. THIS EVENT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG

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WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. BASED ON THE AVAILABLE INFORMATION; THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) OR THE LACK OF EFFICACY AND A QUALITY DEFECT. FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 05-NOV-2015: LETTER TO PHYSICIAN RETURNED UNDELIVERABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ECTOPIC PREGNANCY WITH ESSURE (FALLOPIAN TUBE OCC

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01328	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C55839

Single Use: Y
Implant Date (E6): 10/6/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT STERILIZATION (LOT NUMBER C55839). PHYSICIAN REPORTED CATHETER BREAKAGE DURING PLACEMENT. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP 09-OCT-2015: THE SALES REPRESENTATIVE CONFIRMED THE INITIAL RECEIPT DATE AS (B)(6)2015. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT CATHETER BREAKAGE DURING PLACEMENT. THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT RECEIVED ON 29-OCT-2015 PTC GLOBAL NUMBER (B)(4). BATCH NUMBER C55839. FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE OUTER COILS OF TH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01329	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2011
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1367, AWARENESS DATE 06-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. CONSUMER HAD ESSURE PLACED IN (B)(6) 2011 AND WITHIN A WEEK SHE STARTED ITCHING AND WOULD WELT UP LIKE HAD BEEN BITTEN BY A BUG. THE ITCHING AND WELTING WOULD COME AND GO A FEW TIMES A DAY FOR A WHILE BUT BY (B)(6) SHE WAS TAKING ALLEGRA 24 ONCE A DAY BECAUSE THE ITCHING AND WELTS ON HER BODY WERE SO BAD. THIS CONTROLLED IT FOR A YEAR OR SO THEN SHE STARTED TAKING THE ALLEGRA TWICE A DAY. SHE WENT TO HER PHYSICIAN AND A NICKEL ALLERGY TEST WAS PERFORMED, AND SHE WAS ALLERGIC TO NICKEL. SHE LIVED WITH THE ITCHING AND WELTING UNTIL (B)(6) 2015, THAT WAS THE POINT WHEN SHE COULD NOT TAKE IT ANYMORE. SHE ALSO HAD SEVERE ALLERGY ISSUES, SINUS INFECTIONS AND WAS EXTREMELY TIRED ALL THE TIME. AFTER SEVERAL TRIPS TO HER REGULAR DOCTOR SHE WAS CONVINCED TO REMOVE THE ESSURE. SHE TOOK ALLEGRA FOR THE LAST TIME THE NIGHT BEFORE THE SURGERY (HYSTERECTOMY). SHE DID ITCH SOME THE FIRST FEW DAYS AFTER REMOVAL BUT NOT ENOUGH TO TAKE ANYTHING. SHE HAS NOT ITCHED OR WELTED UP SINCE. SHE CAN BREATHE EASIER, HER SINUSES FEEL BETTER AND SHE FEELS MORE ENERGIZED. FOLLOW UP RECEIVED ON 21-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT

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NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD ALLERGY TO NICKEL / SEVERE ALLERGY ISSUES. SHE HAD ESSURE REMOVED VIA HYSTERECTOMY APPROXIMATELY 4 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THE DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THIS DEVICE IS IMPLANTED. TYPICAL ALLERGY SYMPTOMS REPORTED INCLUDE RASH, PRURITUS, AND HIVES. CONSIDERING THE NATURE OF THE REPORTED EVENT, AND SINCE SHE HAD NO MORE ALLERGY SYMPTOMS AFTER ESSURE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL (HYSTERECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01330	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1369, AWARENESS DATE 06-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013 FOR STERILIZATION. AT FIRST, CONSUMER EXPERIENCED LIGHTER MENSTRUAL CYCLES AND FELT FINE. NEAR THE MIDDLE OF 2014, HER MENSTRUAL CYCLES STARTED GETTING LONGER (WHICH CONTINUED UNTIL (B)(6) 2015); SHE WOULD HAVE TWO WEEK PERIODS WITH ONLY TWO WEEKS OFF DURING HER FAIRLY TYPICAL 28 DAYS CYCLE. SHE EXPERIENCED MENSTRUAL CRAMPING AND OFTEN THE PAIN WOULD BE DEBILITATING AND SHE NEARLY BLACK OUT FROM IT. IN (B)(6) 2014, SHE WOKE UP WITH STABBING PAIN IN HER OVARIES AND HEMORRHAGING BLOOD. SHE THOUGHT IT WOULD BE EITHER PREGNANCY OR MISCARRIAGE BUT STATED NEITHER WAS CORRECT. IN D(B)(6) 2014, SHE CONTINUED PRESENTING THESE SYMPTOMS. ON (B)(6) 2015, SHE STARTED HER PERIOD AGAIN AND IT DID NOT STOP. AT THE END OF (B)(6), SHE STARTED PROGESTERONE AND THE PERIOD STOPPED FOR 24 HOURS. IN THE MIDDLE OF (B)(6) 2015, A BIOPSY TO CHECK FOR HORMONAL IMBALANCE AS WELL AS CANCER WAS PERFORMED, A FULL BLOOD PANEL, AND AN ULTRASOUND OF UTERUS AND OVARIES WERE ALSO PERFORMED. NOTHING CAME BACK ABNORMAL. HER PHYSICIAN STATED THAT MOST LIKELY CAUSE WAS THAT SHE WAS GOING INTO EARLY MENOPAUSE ((B)(6) AT THAT TIME). SHE STATED THAT DID NOT WANT TO USE NUVARING AGAIN (ONE OF THE ALTERNATIVE TO STOP HER BLEEDING). SO, SHE OPTED FOR OTHER ALTERNATIVE AND START TREATMENT WITH MIRENA (LEVONORGESTREL) IUD, WHICH WAS INSERTED IN (B)(6) 2015. UNTIL (B)(6) 2015, SHE EXPERIENCED 2, 2-DAY BREAKS FROM BLEEDING. SHE GAINED 7 POUNDS AND WAS STILL EXPERIENCING CONSTANT CRAMPING, SO

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SHE STATED THAT MIRENA OBVIOUSLY DID NOT WORK. ON (B)(6) 2015, AN ABLATION AND DILATATION AND CURETTAGE (D&C) WAS PERFORMED. WHEN THE SURGEON DEPLOYED THE DEVICE, IT NICKED THE SIDE OF HER UTERUS AND CAUSED HER INTERNAL BLEEDING. SHE WAS STITCHED FROM INSIDE, HAD THE D&C AND THEN A LAPAROSCOPIC SURGERY TO DETERMINE IF SHE WAS INTERNALLY BLEEDING. WHILE IN THE RECOVERING ROOM HER DOCTOR TOLD HER THAT SHE WAS UNABLE TO PERFORM THE ABLATION AND THAT SHE WAS NOT A CANDIDATE, HER ONLY MEDICAL OPTION AT THIS POINT WAS A HYSTERECTOMY. CONSUMER REPORTED THAT ON (B)(6) 2015 (THE REPORTING DAY) SHE WAS ON HER WAY TO THE HOSPITAL TO HAVE A HYSTERECTOMY AND SALPINGECTOMY PERFORMED TO HAVE ESSURE REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO EXPERIENCED LONGER MENSTRUAL CYCLES (2 WEEK PERIODS WITH ONLY 2 WEEKS OFF AND HEMORRHAGING BLOOD) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. AS TREATMENT, SHE HAD A MIRENA (LEVONORGESTREL) INSERTED. HOWEVER; THE BLEEDING PERSISTED AND SHE WAS SUBMITTED TO AN ABLATION AND DILATATION AND CURETTAGE (D&C). DURING THIS PROCEDURE, WHEN THE SURGEON DEPLOYED THE DEVICE, IT NICKED THE SIDE OF HER UTERUS AND CAUSED HER INTERNAL BLEEDING. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ONLY LONGER MENSTRUAL CYCLE IS LISTED ACCORDING TO ESSURE'S AND MIRENA'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER HAD HEAVY AND LONGER MENSTRUAL CYCLES STARTING 1.5 YEARS AFTER ESSURE PLACEMENT. ACCORDING TO HER, AN INVESTIGATION WAS PERFORMED TO RULE OUT OTHER CONDITIONS SUCH AS CANCER AND HORMONAL IMBALANCE AND NOTHING CAME ABNORMAL. CONSIDERING THIS INFORMATION, A CONTRIBUTORY ROLE OF ESSURE IN THE REPORTED MENSTRUAL CHANGES CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, THEY WERE CONSIDERED AS UNRELATED TO ESSURE AND MIRENA DUE TO THEIR NATURE (COMPLICATION OF ABLATION AND D&C). THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REPORTED SURGICAL INTERVENTIONS FOR BLEEDING'S TREATMENT. ADDITIONALLY, CONSUMER STATED SHE WAS GOING TO HAVE ESSURE SURGICALLY REMOVED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 22-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01331	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/30/2012
Explant Date (E7): 4/29/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 02-JAN-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BURNING IN THE AREA OF FALLOPIAN TUBES, SHE COULD FEEL THE COILS, RIGHT TUBE FEELS LIKE IT STABS HER, INTENSE PERIOD CRAMPING, BODY SEEMS TO BE BEGINNING HYPER SENSITIVE, AND BREAKING OUT IN HIVES. FOLLOW-UP INFORMATION IDENTIFIED ON 07-OCT-2015 (UPGRADED TO INCIDENT): THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1285). THE CONSUMER REPORTED SHE HAD ESSURE INSERTED ON (B)(6) 2012; HAD GIVEN BIRTH 3 MONTHS PRIOR. AFTER ESSURE WAS PLACED SHE BLED FOR 54 DAYS, CONTACTED HER GYNECOLOGIST AND WAS TOLD AS LONG AS SHE WASN'T FILLING A PAD AN HOUR, IT WAS ALL GOOD. SHE BEGAN HAVING PERIODS EVERY 2 WEEKS. IN (B)(6) 2013, SHE STARTED HAVING MID-CYCLE BACK PAIN THAT WAS REALLY INTENSE, SHE HAD CHARLIE HORSES IN HER FALLOPIAN TUBES AND THERE WAS METAL COIL IN THE TUBE THAT WAS IN SPASM. THE CONSUMER STARTED RESEARCHING AND READ THE LIST OF SYMPTOMS AND CHECKED OFF HOW MANY SHE HAD, SHE REPORTED ALL STARTED WITHIN A FEW MONTHS OF HAVING ESSURE PLACED: ACHING JOINTS, ALLERGIES, YEAST INFECTIONS, MIGRAINES, THINNING HAIR, FATIGUE, CRAMPS NOT JUST AROUND PERIOD BUT AT RANDOM TIMES. SHE HAD CRAMPS ALMOST EVERY DAY. SHE TOLD HER PHYSICIAN EVERY TIME SHE WAS SURE SHE COULD FEEL THE COILS BURNING INSIDE HER TUBES. BY THE FOLLOWING WINTER, SHE WAS HAVING 10 DAYS A MONTH OF BACK PAIN. THE BLEEDING WAS INTERMITTENT; SPOTTING WAS ALMOST DAILY; SHE ALSO HAD CRAMPS. SHE TOLD HER PHYSICIAN SHE WAS SURE THE COIL WAS POKING HER AND EVENTUALLY SHE DECIDED TO FIND OUT

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WHAT WAS CAUSING THE BACK PAIN AND HAD AN ULTRASOUND, BLOOD WORK, EXAMINATION. ON (B)(6) 2014, SHE HAD A PARTIAL HYSTERECTOMY DONE AT AGE OF (B)(6); ONE OF THE COILS WAS POKING OUT OF HER TUBE AND SHE MANAGED TO DEVELOP ADENOMYOSIS LESS THAN A YEAR AFTER GIVING BIRTH - WITH NO ENDOMETRIOSIS BEFOREHAND. SHE STATED THE DEVICE CAUSED INFLAMMATION - AND THE INFLAMMATION DID NOT STOP ONCE THE TUBES ARE OCCLUDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 24-OCT-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CRAMPS ALMOST EVERY DAY (INTERPRETED AS ABDOMINAL PAIN LOWER). SHE HAD A PARTIAL HYSTERECTOMY AND FOUND THAT ONE OF THE COILS WAS POKING OUT OF HER TUBE (INTERPRETED AS FALLOPIAN TUBE PERFORATION). ABDOMINAL PAIN LOWER AND FALLOPIAN TUBE PERFORATION ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN THE ABDOMINAL LOWER PAIN AND FALLOPIAN TUBE PERFORATION AND ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01332	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 901327

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM AN ADULT FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2014 REFERRING TO HERSELF. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING, BLEEDING, WEIGHT GAIN, DEPRESSION, AND FELT EMOTIONAL. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT DRUGS AND CONCURRENT CONDITIONS. IN (B)(6) 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH LOT NUMBER 901327 FOR STERILIZATION. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED BLEEDING, CRAMPING, WEIGHT GAIN, DEPRESSION, AND FELT EMOTIONAL. THE PHYSICIAN RECOMMENDED A PARTIAL HYSTERECTOMY WHICH WAS DONE MID 2013 AND REMOVED EVERYTHING BUT HER OVARIES. ESSURE WAS ALSO REMOVED AT THAT TIME. THE OUTCOME OF EVENTS WERE NOT PROVIDED. NO ASSESSMENT WAS GIVEN. PTC INVESTIGATION RESULT WAS RECEIVED ON 03-MAR-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NINE (9) ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. (B)(4) BUT NONE OF THESE CASES REFER TO A SIMILAR TYPES OF MEDICAL EVENTS. NO BATCH SIGNAL COULD BE IDENTIFIED. THE REVIEW OF THE LOT HISTORY RECORDS FOUND THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. AT TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO

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REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 06-MAR-2014: FOLLOW UP ATTEMPT WAS PERFORMED WITH NO RESPONSE. CASE CLOSED. FOLLOW UP INFORMATION RECEIVED ON 08-OCT-2015 (CASE UPGRADED TO INCIDENT): THIS REPORT HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1414). THE CONSUMER STATED SHE HAD ESSURE PLACED IN 2012; THE PLACEMENT PROCEDURE HURT EVEN WITH THE MESS (AS REPORTED) SHE WAS GIVEN. ONE MONTH AFTER HAVING ESSURE SHE HAD VERY HEAVY PERIODS (IT WAS NOT NORMAL FOR HER) AND PELVIS PAIN OUT OF THIS WORLD. SHE WENT INTO A DEEP DEPRESSION AND HAD ANXIETY OUT OF THE ROOF. SHE ALSO REPORTED GAINED SO MUCH WEIGHT AND SHE ENDED UP HAVING A HYSTERECTOMY ABOUT 6 MONTHS LATER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD BLEEDING/VERY HEAVY PERIODS AND PELVIS PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (APPROXIMATELY 7 MONTHS AFTER DEVICE PLACEMENT). THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER STATED HER SYMPTOMS STARTED ONE MONTH AFTER ESSURE PLACEMENT. CONSIDERING THIS POSITIVE TEMPORAL RELATIONSHIP AND SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT, SINCE LIMITED INFORMATION WAS PROVIDED AT INITIAL REPORT (CONSUMER MENTIONED A HSYTERECTOMY; HOWEVER NEITHER WAS HER BLEEDING SPECIFIED NOR WAS EVENTS ONSET PROVIDED). UPON RECEIPT OF FOLLOW-UP INFORMATION, CASE WAS UPGRADED TO INCIDENT; AS CONSUMER REPORTED INTENSE PELVIC PAIN 1 MONTH AFTER ESSURE PLACEMENT AND MENSTRUAL CHANGES REQUIRING A HYSTERECTOMY (INTERVENTION REQUIRED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01333	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 21-JUN-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. CONSUMER BEGAN HAVING MEDICAL PROBLEMS WITHIN THE YEAR AND SUFFERED IN PAIN AND SWELLING. HER PHYSICIAN SAID IT WAS HER OVULATION AND IT WOULD GET BETTER. HER PERIODS WERE OUT OF WACK AND SHE STARTED GETTING SEVERE PAINS IN LEGS AND ABDOMEN. AGAIN, SHE WAS TOLD IT WAS SOMETHING ELSE. IN 2010, SHE BEGAN HAVING DAYS WHERE WALKING WAS A TASK AND IT TOOK EVERYTHING TO EVEN GET OUT OF BED. HAVING 3 CHILDREN AND WORKING FULL TIME, SHE HAD TO MAKE IT. FROM LOSS OF SEXUAL DESIRE TO LOSING MY HAIR, TO BOILS AND UNEXPLAINED BRUISES. SHE WAS SUFFERING WITH PELVIC PAIN AND NUMEROUS INFECTIONS, AND NOT TO MENTION WEIGHT GAIN IN HER STOMACH. COUNTLESS DOCTOR VISITS AND LAB WORK WERE UNCERTAIN. SHE COULD BARELY WALK AND COULD NOT GET THE WEIGHT OFF HER STOMACH; SHE WAS ALWAYS TIRED AND HAD THE CONSTANT FEELING OF BALLS IN HER LEFT SIDE. TESTS WERE DONE FOR LIVER, AND KIDNEYS, AND INTESTINAL. ALL WERE CLEAR. SHE WAS TESTED POSITIVE ON PID (PELVIC INFLAMMATORY DISEASE) AND SEVERE INFECTION ASSOCIATED WITH A MASS/AND OR REJECTION. SHE WAS TREATED WITH PAIN MEDICATIONS. SHE STATED THAT SOMETHING WAS DISCOVERED IN HER CT (COMPUTERIZED TOMOGRAM) BUT NOT SURE WHAT. HER BIGGEST CONCERN WAS THAT RECENTLY FOUND OUT THIS PRODUCT IS MADE OF NICKEL. WHEN SHE DECIDED ON GETTING IT, SHE WAS TOLD AND ASSURED IT CONTAINED ONLY TITANIUM. SHE CAN'T HANDLE NICKEL DUE TO AN ALLERGY AND STATED THAT THIS EXPLAINS THE BURNING AND SORES AND LOSS OF HAIR. SHE WAS TRYING TO GET ESSURE REMOVED. PTC INVESTIGATION RESULT WAS RECEIVED ON 25-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US

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FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER OR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 22-JUL-2015 FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. FOLLOW UP INFORMATION RECEIVED ON 08-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1316). THE CONSUMER REPORTED SHE WAS UNABLE TO TIE HER OWN SHOES FOR MONTHS. ONE WEEK PRIOR TO THIS REPORT SHE HAD A HYSTERECTOMY DONE AND NOW IS ABLE TO PUT ON AND TIE HER OWN SHOES WITH NO HELP AT ALL. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 20-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS TESTED POSITIVE ON PID (PELVIC INFLAMMATORY DISEASE) AND HAD SORES (INTERPRETED AS PAIN NOS). THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS CASE, THIS EVENT PROBABLY OCCURRED AFTER 4 WEEKS POST ESSURE INSERTION. THEREFORE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CAN BE EXCLUDED. ALSO, UNCHARACTERIZED PAIN MAY OCCUR DURING ESSURE USE. THUS, CONSIDERING THE EVENT'S NATURE AND SUGGESTIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT MICRO-INSERT CANNOT BE EXCLUDED PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS STATED AN INTERVENTION WAS REQUIRED (HYSTERECTOMY). THEREFORE THIS CASE WAS UPGRADED TO INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL

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ANALYSIS CONCLUDED THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. DESPITE FOLLOW-UP ATTEMPTS, NO FURTHER INFORMATION WAS OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01367	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/31/2010
Explant Date (E7): 6/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044251) IN UNITED STATES ON 07-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. THE CONSUMER REPORTED THAT ONCE SHE HAD ESSURE PLACED SHE STARTED TO GET UTI'S (UNDERSTOOD AS URINARY TRACT INFECTIONS) EVERY COUPLE OF MONTHS IT SEEMED LIKE, WHICH SHE WAS NOT GETTING BEFORE. WHEN SHE STARTED TO HAVE SEX SHE COULD FEEL THE PRODUCT FROM THE OUTSIDE, AND SOMETIMES HER TUBES WOULD SWELL UP AND THEY WOULD CAUSE HER SO MUCH PAIN. SHE ENDED UP HAVING TO HAVE HER TUBES REMOVED BECAUSE THEY WOULD CAUSE SO MUCH PAIN. ESSURE EXPLANT DATE WAS REPORTED AS (B)(6) 2015. SHE WOULD GO TO THE EMERGENCY ROOM AND ASK DOCTORS TO LOOK INTO IT BUT THEY WOULD ALWAYS RESPOND THAT THERE WAS NO WAY THAT SHE COULD FEEL THEM. ON 24-OCT-2015 PTC: PRODUCT TECHNICAL COMPLAINT RESULT RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE

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INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SO MUCH PAIN IN HER FALLOPIAN TUBES. SHE HAD HER TUBES AND ESSURE REMOVED 5 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION FOR ESSURE REMOVAL (SALPINGECTOMY). PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 11-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE, WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01368	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2000
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044260) IN UNITED STATES ON 07-OCT-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2000. SHE REPORTED THAT SINCE THE PROCEDURE SHE EXPERIENCED SEVERAL ISSUES. SHE EXPERIENCED PROLONGED BLEEDING DAILY FROM 2011 AND AFTER THAT SHE HAD A D&C TO CORRECT THE BLEEDING. SHE WAS VERY FATIGUED AND FRAIL. IN 2014, SHE DEVELOPED ADDITIONAL ISSUES WHICH RESULTED IN A PARTIAL HYSTERECTOMY. SHE HAS ENDURED PELVIC PAIN WHICH HAD AFFECTED HER MARRIAGE INTIMACY WITH HER HUSBAND, THEY HAVE NOT BEEN INTIMATE SINCE THE HYSTERECTOMY IN 2014. SHE IS IN CONSTANT PAIN FROM PELVIC TO LOWER BACK PAIN DAILY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 24-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY

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CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PROLONGED BLEEDING DAILY (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A D&C (INTERPRETED AS DILATION AND CURETTAGE). SHE ALSO REPORTED CONSTANT PAIN FROM PELVIC. A HYSTERECTOMY WAS PERFORMED 14 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE EVENT GENITAL BLEEDING AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THE PELVIC PAIN DID NOT RESOLVE AFTER HYSTERECTOMY, SUGGESTING THAT ESSURE WAS NOT THE ONLY RESPONSIBLE FOR THE PAIN. HOWEVER, GIVEN THE NATURE OF THIS EVENT A CONTRIBUTORY ROLE OF ESSURE FOR ITS INITIAL OCCURRENCE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (DILATION AND CURETTAGE, HYSTERECTOMY). PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 16-NOV-2015: ESSURE CONSUMER GENERAL QUESTIONNAIRE WAS RECEIVED. REPORTER INFORMATION WAS UPDATED. THIS CASE REFERS TO (B)(6) FEMALE CONSUMER. HER HEIGHT IS (B)(6) AND HER WEIGHT IS (B)(6). ESSURE WAS NOT INSERTED AFTER PREGNANCY. CO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01369	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2013
Explant Date (E7): 8/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044379) IN UNITED STATES ON 07-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. IMMEDIATELY AFTER THE IMPLANTATION SURGERY, WHILE STILL IN THE HOSPITAL, THE CONSUMER HAD A FEVER. SHE WAS NEVERTHELESS RELEASED ON 1 PAIN PILL. THE FEVER PERSISTED FOR WEEKS. THE DOCTOR WHO IMPLANTED THE DEVICE NEVER RETURNED HER CALLS. SHE FINALLY CONSULTED WITH HER REGULAR FAMILY DOCTOR WHO DIAGNOSED SEPSIS. SHE WAS PLACED ON STRONG ANTIBIOTICS AND EVENTUALLY GOT WELL. NONETHELESS A NEW SET OF ILLNESSES CROPPED IN: SHE EXPERIENCED EXCRUCIATING ABDOMINAL PAIN, DYSPAREUNIA, WEIGHT GAIN AND INCONTINENCE; HER BLADDER HAD BEEN DAMAGED. ON (B)(6) 2014, SHE HAD THE DEVICE REMOVED, BUT ONLY PART OF IT CAME OUT BECAUSE IT WAS DEEPLY ENTRAPPED WITHIN HER TISSUE. IN 2015 SHE HAD ANOTHER SURGERY, THIS TIME TO REMOVE THE SCAR TISSUE AROUND THE URETHRA BECAUSE IT WAS BLOCKING THE SMOOTH FLOW OF URINE. SHE WAS SUPPOSED TO HAVE ANOTHER SURGERY BECAUSE THE URETHRA WAS COMPLETELY BLOCKED AND SHE WAS UNABLE TO URINATE, AND CONSEQUENTLY A FOLEY CATHETER COULD NOT BE INSERTED. SHE WAS VERY FATIGUED AND DISABLED. SHE WAS UNABLE TO TAKE CARE OF HERSELF. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 24-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO

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CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEPSIS, EXCRUCIATING ABDOMINAL PAIN, SCAR TISSUE AROUND THE URETHRA AND HER URETHRA COMPLETELY BLOCKED. ESSURE WAS REMOVED 15 MONTHS AFTER INSERTION, BUT ONLY PART OF IT CAME OUT (INTERPRETED AS DEVICE BREAKAGE) BECAUSE IT WAS ENTRAPPED WITHIN HER TISSUE. DEVICE BREAKAGE IN A NON-SERIOUS EVENT, THE OTHER EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE EXCEPT FOR URETHRA COMPLETELY BLOCKED, SERIOUS DUE TO DISABILITY. ABDOMINAL PAIN AND DEVICE BREAKAGE (WHICH OCCURRED DURING ESSURE REMOVAL) ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENTS ARE UNLISTED. IN THIS CASE, WHILE STILL IN THE HOSPITAL AFTER ESSURE INSERTION, THE CONSUMER HAD FEVER. ACCORDING TO HER, THE FEVER PERSISTED AND SEPSIS WAS DIAGNOSED AFTER WEEKS. THOUGH THE EXACT NUMBER OF WEEKS AFTER INSERTION WAS NOT SPECIFIED, SINCE THE FEVER STARTED RIGHT AFTER THE INSERTION PROCEDURE AND PERSISTED UNTIL THE DIAGNOSIS OF SEPSIS, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THIS CASE, THE CONSUMER ALSO HAD BLADDER PROBLEMS WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THE PAIN. HOWEVER, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. EVENTS SCAR TISSUE AROUND THE URETHRA AND URETHRA COMPLETELY BLOCKED WERE ASSESSED AS UNRELATED TO ESSURE, GIVEN THEIR PATHOPHYSIOLOGY, URETHRA ANATOMICAL LOCATION, AND CONSIDERING ESSURE'S LOCAL EFFECT IN THE FALLOPIAN TUBES. SINCE THE DEVICE BREAKAGE OCCURRED DURING A DIFFICULT ESSURE REMOVAL, THIS EVENT WAS ASSESSED AS RELATED TO THE SUSPECT INSERT. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO SERIOUS INJURY (SEPSIS) AND REQUIRED INTERVENTION FOR ESSURE REMOVAL. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED FROM CONSUMER ON 02-NOV-2015: SHE STATED THAT SHE DID NOT HAVE ESSURE. SHE HAD A HYSTERECTOMY AND COMPLAINED TO FDA ABOUT TRANSVAGINAL MESH. SINCE NO BAYER PRODUCT IS SUSPECT, THIS CASE WILL BE DELETED FROM BAYER´S DATABASE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01370	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 8/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1184, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. AS PREVIOUS HISTORY, THE CONSUMER REPORTED HAVING SONS. SHE HAD ESSURE INSERTED IN 2008 AND WITHIN 30 DAYS SHE HAD ABDOMINAL PAIN. FOR 5 YEARS SHE HAD SEVERE ABDOMINAL PAIN, BLOATING, WEIGHT GAIN, CHRONIC FATIGUE, HEADACHES, IBS (INTERPRETED AS IRRITABLE BOWEL SYNDROME), PAINFUL INTERCOURSE, TEETH ISSUES, SKIN ISSUES, ANXIETY AND DEPRESSION. SHE WENT THROUGH MULTIPLE HOSPITALIZATIONS AND TOOK 8 DIFFERENT MEDICATIONS. SHE WAS DIAGNOSED WITH FIBROMYALGIA, CHRONIC FATIGUE SYNDROME AND KIDNEY ISSUES. IN (B)(6) 2015 SHE HAD A HYSTERECTOMY AND MOST OF HER CONDITIONS WENT AWAY. SHE WAS LEFT WITH THE FIBROMYALGIA AND KIDNEY DYSFUNCTION. FOLLOW UP RECEIVED ON 26-OCT-2015: PTC INVESTIGATIONAL RESULT. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS

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EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WITHIN 30 DAYS STARTED HAVING ABDOMINAL PAIN. SHE ALSO HAD KIDNEY ISSUES / KIDNEY DYSFUNCTION. A HYSTERECTOMY WAS PERFORMED 7 YEARS AFTER ESSURE INSERTION, AND THE PAIN RESOLVED BUT THE KIDNEY DYSFUNCTION PERSISTED. EVENT ABDOMINAL PAIN WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND KIDNEY ISSUES / KIDNEY DYSFUNCTION WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION. ABDOMINAL PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE THE REMAINING EVENT IS UNLISTED. AFTER ESSURE INSERTION ABDOMINAL PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE NATURE OF THIS EVENT, AND SINCE THE EVENT RESOLVED AFTER HYSTERECTOMY, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. COMMON CAUSES OF CHRONIC KIDNEY DYSFUNCTION INCLUDE DIABETIC KIDNEY DISEASE, HYPERTENSION, VASCULAR DISEASE, GLOMERULAR OR TUBULOINTERSTITIAL DISEASE, URINARY TRACT OBSTRUCTION, RECURRENT KIDNEY STONE AND UNRECOVERED ACUTE KIDNEY INJURY. CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AND ESSURE LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01371	BAYER HEALTHCARE LLC	11/3/2015	11/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1174, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER HAD ESSURE IMPLANTED IN THE OFFICE OF HER DOCTOR WITH VALIUM. IT WAS PAINFUL AND THE DOCTOR COMPLAINED HE HAD TROUBLE WITH ONE SIDE AND APOLOGIZED FOR THE PAIN. SHE FOLLOWED UP WITH AN HYSTEROSALPINGOGRAM THAT CONFIRMED THEY BLOCKED BOTH SIDES. HOWEVER, SHE WAS NEVER ADVISED OF THE ONE AND FIVE YEAR FOLLOW UP NOR THE NICKEL BEING IN THE MATERIAL. FROM THE IMPLANT FORWARD SHE BEGAN HAVING HEAVY BLEEDING AND CLOTTING DURING HER PERIODS, PAIN OUT OF NO WHERE IN THE AREA OF HER TUBES AND OVARIES, AND SEVERE BLOATING TO THE POINT HER YOUNG KIDS ASKED IF SHE WAS PREGNANT AS WELL AS OTHER FAMILY MEMBERS. UP TO THE POINT OF IMPLANT SHE HAD ALWAYS BEEN ATHLETIC, PLAYED SOCCER. NOW, DUE TO DEPRESSION, BLOAT, ACHING JOINTS DUE TO INFLAMMATION, SHE COULD NOT ENJOY THESE THINGS AS SHE ONCE DID. AS OF (B)(6) 2016, SHE WILL BE HAVING A HYSTERECTOMY IN HOPES IT WILL GIVE HER BACK HER LIFE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN OUT OF NOWHERE IN THE AREA OF TUBES AND OVARIES. SHE WILL BE HAVING A HYSTERECTOMY. THIS EVENT, INTERPRETED AS LOWER ABDOMINAL PAIN, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT AND IN THE LACK OF AN ALTERNATIVE

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EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 28-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057706	BAYER	11/3/2015	11/6/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I'VE HAD PAINFUL INTERCOURSE AND HEAVY MENSTRUAL CYCLES SINCE I HAD THE DEVICE IMPLANTED. I'VE ALSO SUFFERED FROM MIGRAINES, DEPRESSION AND BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057707	BAYER	11/3/2015	11/6/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE PLACED IN 2013. I WAS NOT INFORMED IT WAS MADE OF NICKEL. I AM EXTREMELY ALLERGIC TO NICKEL AND WILL NOW HAVE TO HAVE A HYSTERECTOMY TO REMOVE THE DEVICE. THE ALLERGY IS CAUSING EXTREME FATIGUE, TINGLING IN MY ARMS AND LEGS, MUSCLE WEAKNESS, AND MS LIKE SYMPTOMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057708	BAYER	11/3/2015	11/6/2015

Event Information:

Event Date (B3): 12/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PERMANENT BIRTH CONTROL IMPLANT HAS CAUSED A MASSIVE AMOUNT OF CONSISTENT AND ONGOING PAIN. I HAVE HAD ENDOMETRIAL ABLATIONS TO STOP EXCESSIVE BLEEDING AND WENT SEPTIC AS A RESULT OF THE ABLATION. INTERCOURSE IS VERY PAINFUL. THERE IS A CONSISTENT, DULL PAIN IN MY PELVIS AND LOWER BACK, NONE OF WHICH OCCURRED BEFORE THE PROCEDURE. ABNORMAL BLEEDING, HEAVY BLEEDING, EXTREME CRAMPING, ETC.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01298	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 8/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1273, AWARENESS DATE 05-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2005. SHE HAD A DYE TEST AT 3 MONTHS POST-OPERATIVE WHICH SHOWED THE TUBES 100% BLOCKED. SHE ENDED UP PREGNANT IN (B)(6) 2005. SHE EXPERIENCED TREMENDOUS AMOUNT OF PAIN THE WHOLE PREGNANCY, MAINLY ON THE RIGHT SIDE. BABY WAS DELIVERED EARLY, AT (B)(6), DUE TO THE PAIN. SHE RETURNED TO THE DOCTOR NUMEROUS TIMES FOLLOWING DELIVERY DUE TO PAIN. ABOUT 3 YEARS LATER, THE DOCTOR DECIDED TO REMOVE THEM DUE TO THE PAIN. UPON EXPLORATORY SURGERY, SHE FOUND THE RIGHT ESSURE ON THE OUTSIDE OF UTERUS AND ALSO A BOWEL ADHESION CLOSE TO THE SAME AREA. SHE WOULD NOT REMOVE THE LEFT ESSURE BECAUSE SHE WAS AFRAID IT WOULD CAUSE MORE DAMAGE THAN IT WAS WORTH. SHE WAS EXPERIENCING CONSTANT ACHES AND PAINS, UNEXPLAINED PANCREAS ISSUES, HAIR LOSS, INSOMNIA, BACK PAIN, WEIGHT GAIN. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 21-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY

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QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVE(S)/LACK OF EFFICACY IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. A REVIEW OF SIMILAR CASES FOR THIS BATCH RESULTED IN NO UNUSUAL PATTERN IDENTIFIED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) /LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT. SHE GAVE BIRTH TO A BABY AT (B)(6) OF GESTATIONAL AGE (PREMATURE LABOUR). SHE EXPERIENCED TREMENDOUS AMOUNT OF PAIN THE WHOLE PREGNANCY, MAINLY ON THE RIGHT SIDE. ABOUT 3 YEARS AFTER ESSURE INSERTION, THE DOCTOR DECIDED TO REMOVE THEM DUE TO PAIN. UPON EXPLORATORY SURGERY, SHE FOUND THE RIGHT ESSURE ON THE OUTSIDE OF HER UTERUS (SEEN AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY). ALL EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. PREMATURE LABOUR IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. PREMATURITY IS A TERM FOR THE BROAD CATEGORY OF NEONATES BORN AT LESS THAN 37 WEEKS' GESTATION. THE COMPLICATIONS OF PRETERM BIRTH ARISE FROM IMMATURE ORGAN SYSTEMS THAT ARE NOT YET PREPARED TO SUPPORT LIFE IN THE EXTRAUTERINE ENVIRONMENT. IN THIS CASE, BABY WAS DELIVERED EARLY AT (B)(6). CONSIDERING THE POSSIBLITY OF MECHANICAL INTERFERENCE OF THE DEVICES DURING PREGNANCY CANNOT BE TOTALLY EXCLUDED, THE PREMATURITY IS ASSESSED AS RELATED TO ESSURE USE. IT IS NOT KNOWN WHETHER THE ESSURE WAS DISLOCATED FIRST AND THE PREGNANCY FOLLOWED, OR WHETHER IT WAS IN PLACE DURING THE CONCEPTION AND WAS DISLOCATED LATER, DURING PREGNANCY. CONSIDERING THE NATURE OF THE OTHER EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01323	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2003
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 07-OCT-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) IN 2003 FOR PERMANENT CONTRACEPTION. SHE WANTED TO KNOW IF THE ESSURE PLACED IN HER IN 2003 WERE FROM CLINICAL TRIALS AND WHY THEY WERE INSERTED IN HER. CALLER STATED THAT THE REFERENCE NUMBER ON HER ESSURE CARD WAS USED IN CLINICAL TRIALS AND SHE WAS NOT A PARTICIPANT IN A CLINICAL TRIAL. SHE STATED SHE BECAME VERY SICK FOR 8 YEARS UNTIL SHE HAD THE ESSURE REMOVED. SHE DID NOT WANT TO PROVIDE ANY FURTHER INFORMATION ON EVENT AS SHE STATED IT HAD ALREADY BEEN REPORTED. FOLLOW UP RECEIVED ON 21-OCT-2015: PTC INVESTIGATIONAL RESULT. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER WHO STATED SHE BECAME VERY SICK FOR 8 YEARS

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UNTIL SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, MINIMAL INFORMATION WAS PROVIDED AND CONSUMER'S SICKNESS WAS NOT SPECIFIED. NEVERTHELESS; CONSIDERING DEVICE REMOVAL WAS REQUIRED, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THEREFORE, THIS CASE WAS CONSIDERED AN INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO FOLLOW-UP WILL BE PURSUED AS CONSUMER DENIED FURTHER CONTACT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01334	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 4/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 12570405

Single Use: Y
Implant Date (E6): 12/18/2014
Explant Date (E7): 8/20/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 07-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014, WITH LOT NUMBER 12570405, FOR PERMANENT STERILIZATION. ON AN UNSPECIFIED DATE, HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED; ONE FALLOPIAN TUBE WAS NOT OCCLUDED, IT WAS PERFORATED. PHYSICIAN REMOVED ONE FALLOPIAN TUBE IN (B)(6) 2015 SUCCESSFULLY. PATIENT STILL HAS THE OTHER FALLOPIAN TUBE WITH ESSURE COIL AND THERE ARE NO PROBLEMS WITH THIS TUBE. PHYSICIAN MENTIONED THERE WAS NO INJURY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 21-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). LOT #: 12570405, PRODUCTION DATE: APR-2013, EXPIRATION DATE: JAN-2016. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY

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CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE HYSTEROSALPINGOGRAM (HSG) SHOWED ONE TUBE WAS ACTUALLY PERFORATED. FALLOPIAN TUBE WAS REMOVED 9 MONTHS AFTER ESSURE INSERTION. THIS EVENT, INTERPRETED AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THE PERFORATION WERE NOT REPORTED. IT WAS DIAGNOSED DURING A HSG AN UNSPECIFIED TIME AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SALPINGECTOMY). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 07-DEC-2015: ESSURE HEALTH CARE PROVIDER UTERINE / TUBAL PERFORATION QUESTIONNAIRE RECEIVED. PATIENT WAS (B)(6), OBESE, GRAVIDA 2, PARA 1, SPOTANEOUS ABORTION 1. NO ELECTIVE ABORTION, NO THERAPEUTIC ABORTION AND NO ECTOPI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01335	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(4) ON 08-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014, EVERYTHING ACCORDING TO THE PROTOCOL. CHECK ON (B)(6) 2014, ESSURE WAS IN SITU. IN (B)(6) 2015 PATIENT WANTED NOVASURE. DURING THE ABLATION PATIENT EXPERIENCED MORE PAIN THAN NORMAL (PHYSICIAN THOUGHT THIS WAS CAUSED BY THE PERSON HERSELF). DURING RETRIEVAL OF THE NOVASURE DEVICE THE LEFT SIDE ESSURE APPEARED TO HAVE COME ALONG. PHYSICIAN COULD NOT GUARANTEE PATIENT THAT SHE COULD TRUST THE STERILIZATION. THEREFORE IMMEDIATELY LAPAROSCOPIC STERILIZATION WAS PERFORMED (CLIPS ON BOTH TUBES). DURING THAT IT APPEARED THAT THE TUBE LEFT AT THE HEIGHT OF THE UTEROTUBAL JUNCTION SHOWED SEVERE ISCHEMIC. POSSIBLE EXPLANATION WAS THAT THE NOVASURE DEVICE (HEAD) CAME IN CONTACT WITH ESSURE AND CONDUCTION OCCURRED TO THE SURROUNDING TISSUE VIA ESSURE COIL. AT THE TIME OF THIS REPORT, PATIENT WAS FREE OF COMPLAINTS. FOLLOW-UP RECEIVED ON 03-NOV-2015: PATIENT'S PERSONAL DATA (THE SECOND INITIAL AND DATE OF BIRTH) WERE UPDATED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO WAS SUBMITTED TO AN ENDOMETRIAL ABLATION (NOVASURE) 20 MONTHS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING NOVASURE REMOVAL; THE LEFT SIDE ESSURE APPEARED TO COME ALONG. PHYSICIAN PERFORMED A LAPAROSCOPIC STERILIZATION; DURING THIS SURGERY THE TUBE (AT THE HEIGHT OF THE UTEROTUBAL JUNCTION) APPEARED SEVERELY ISCHEMIC. PHYSICIAN BELIEVED THIS EVENT OCCURRED BECAUSE NOVASURE CAME IN CONTACT WITH ESSURE AND CONDUCTION OCCURRED TO THE SURROUNDING TISSUE. THESE EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. NOVASURE IS A BIPOLAR ELECTRODE ARRAY USED TO

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CREATE A THERMAL LESION ON THE INTERIOR SURFACE OF THE UTERINE CAVITY. IF THIS PROCEDURE IS PERFORMED IN PATIENTS WITH ESSURE INSERTS IN PLACE, THERMAL INJURY TO THE PROXIMAL PORTION OF THE FIBROTIC IN-GROWTH THAT CAUSES TUBAL OCCLUSION MAY OCCUR. ADDITIONALLY, IF THE NOVASURE DEVICE CONTACT ESSURE INSERTS; HEAT FROM NOVASURE MAY BE PROPAGATED ALONG THE ESSURE INSERT. THIS COULD ALSO CAUSE FALLOPIAN TUBE INJURY. IN THIS PARTICULAR CASE, LEFT ESSURE COIL WAS UNINTENTIONALLY REMOVED WITH THE NOVASURE DEVICE; THIS SUGGESTS CONTACT BETWEEN THE 2 DEVICES OCCURRED DURING THE PROCEDURE. THE PHYSICIAN BELIEVED THIS CONTACT WAS A POSSIBLE EXPLANATION FOR THE FALLOPIAN TUBE INJURY (ISCHAEMIA), DISCOVERED DURING THE LAPAROSCOPY. CONSIDERING EVENTS NATURE; COMPANY AGREES WITH PHYSICIAN'S ASSESSMENT. THEREFORE, A CONTRIBUTORY ROLE OF ESSURE IN THE REPORTED FALLOPIAN TUBE INJURY CANNOT BE EXCLUDED AND THIS CASE WAS REGARDED AS AN INCIDENT (SINCE A SURGICAL INTERVENTION WAS REQUIRED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 03-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01336	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1155, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. SHE REPORTED THAT SHE EXPERIENCED RASHES, HAIR LOSS, SEVERE PAIN IN ABDOMEN AND LOWER BACK, MASSIVE BLOOD CLOTS, HEAVY AND IRREGULAR PERIODS, BLOATING, ENLARGED UTERUS, NUMBNESS IN HANDS, WEAKNESS IN LEGS, HEADACHES, DIZZINESS AND BRAIN FOG. SHE HAD ALLERGY TESTS, BLOOD PANELS, URINE SAMPLES, CAT SCANS, ULTRASOUNDS, ELECTROENCEPHALOGRAM AND NUCLEAR MAGNETIC RESONANCE PERFORMED AND ALL CAME BACK NEGATIVE. SHE ALSO REPORTED THAT HER LEFT COIL WAS BROKEN AT THE PROXIMAL TIP AND BOTH COILS WERE TOO HIGH IN HER FALLOPIAN TUBES, ALMOST TOUCHING HER OVARIES. SHE WAS GOING TO HAVE A FULL HYSTERECTOMY ON (B)(6) 2015. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 22-OCT-2015, REFERRING TO PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A RENEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL

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EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LEFT COIL WAS BROKEN AT THE PROXIMAL TIP (INTERPRETED AS DEVICE BREAKAGE) AND BOTH COILS WERE TOO HIGH IN HER FALLOPIAN TUBES, ALMOST TOUCHING HER OVARIES (INTERPRETED AS DEVICE DISLOCATION). THE DEVICE DISLOCATION IS SERIOUS AND BREAKAGE IS NON-SERIOUS. DEVICE DISLOCATION IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND THE NON-SERIOUS EVENT COIL ON MY LEFT SIDE IS BROKEN AT THE PROXIMAL TIP / INNER AND OUTER COILS HAVE SEPARATED (DEVICE BREAKAGE) WAS AMENDED TO ANTICIPATED (LISTED) UPON RECEIPT OF PRODUCT TECHNICAL ANALYSIS. CONSIDERING THE NATURE OF DEVICE BREAKAGE AND DISLOCATION AND THE LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01337	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1272, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER REPORTED THAT SHE HAS A NICKEL ALLERGY. SHE EXPERIENCED BLEEDING FOR 12 WEEKS AT A TIME, LOST HER HAIR, TEETH AND MIND. ADDITIONALLY, SHE STATED ESSURE FAILED; SHE HAS AN ESSURE BABY WHO IS (B)(6). SHE WAS SCHEDULED TO HAVE A HYSTERECTOMY ON (B)(6) 2015. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 22-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS AND LACK OF EFFICACY IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO

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HAS AN (B)(6) ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) BABY. ADDITIONALLY, SHE REPORTED BLEEDING AND STATED A HYSTERECTOMY WAS SCHEDULED (IN 2 DAYS FOLLOWING HER REPORT). THESE EVENTS, REGARDED AS PREGNANCY WITH ESSURE AND GENITAL BLEEDING, ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, NO INFORMATION WAS GIVEN ABOUT HSG. HOWEVER, AS CONSUMER BECAME PREGNANT MORE THAN ONE YEAR AFTER ESSURE PLACEMENT; A DEVICE CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. REGARDING THE REPORTED BLEEDING, AS ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR WITH ESSURE THERAPY; A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01338	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE#FDA-2014-N-0736-1252, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE (B)(6) CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE HAD TO HAVE A COMPLETE HYSTERECTOMY INCLUDING OVARIES AT THE AGE (B)(6) DUE TO COMPLICATIONS. SHE HAD TO DEAL WITH SIDE EFFECTS ON A DAILY BASIS AND TOOK NUMEROUS MEDICATIONS THAT SHE DID NOT TAKE BEFORE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 22-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE A COMPLETE

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HYSTERECTOMY INCLUDING OVARIES DUE TO COMPLICATIONS. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (HYSTERECTOMY) MAY BE REQUIRED. ALTHOUGH, IN THIS PARTICULAR CASE THE PROCEDURES INDICATION HAS NOT BEEN PROVIDED, CONSIDERING EVENTS NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01339	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1251, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER STATED THAT THE RIGHT COIL WAS EXTREMELY PAINFUL DURING INSERTION AND THAT PAIN CONTINUED ALONG WITH HEAVY BLEEDING DURING HER CYCLE. SHE HAD EXPLORATORY SURGERY 6 MONTHS AFTER ESSURE TO SEE IF ANYTHING WAS WRONG EXTERNALLY WITH THE RIGHT OVARY OR TUBE; NOTHING WAS FOUND. A CT SCAN DONE IN 2013 SHOWED A METALLIC BLANKET ACROSS HER BLADDER REGION. NOTHING WAS SAID BY HER DOCTOR THAT THE COIL COULD BE LEACHING (AS REPORTED) NICKEL IF IT WAS DAMAGED DURING INSERTION. SHE HAD YEARS OF PAIN AND THIS YEAR (2015), SHE HEMORRHAGED FOR 6 WEEKS. SHE DID SOME RESEARCH AND DISCOVERED THAT IN FACT ESSURE COULD BE CAUSING HER ALL THESE ISSUES. SHE WAS VERY DISAPPOINTED AND DEPRESSED THAT SHE HAD TO HAVE A HYSTERECTOMY. HER PATHOLOGY REPORT SHOWED ADENOMYOSIS IN UTERUS (PROFOUNDLY RIGHT SIDED). IT HAS ONLY BEEN 3 MONTHS SINCE HYSTERECTOMY IN UTERUS, BUT HER CT SCAN IS CLEAR NOW. SHE HAS NO MORE PAIN HER RIGHT SIDE. ACCORDING TO HER, HER DOCTOR NEITHER FAILED TO INFORM HER OF THE NICKEL NOR SHE WAS TESTED FOR NICKEL ALLERGY, BUT SHE IS ALLERGIC. SHE HAS BEEN CONTINUALLY GETTING ILL FOR 5 YEARS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 22-OCT-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE

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INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN SINCE ESSURE INSERTION. SHE WAS SUBMITTED TO AN EXPLORATORY SURGERY, BUT NOTHING WAS FOUND. SEVEN YEARS LATER, SHE UNDERWENT A HYSTERECTOMY DUE TO PAIN AND BLEEDING AND ADENOMYOSIS WAS DIAGNOSED. ADDITIONALLY, A CT SCAN SHOWED A METALLIC BLANKET ACROSS HER BLADDER REGION. ONLY ADENOMYOSIS IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER REPORTED A PAINFUL ESSURE INSERTION. HER PAIN PERSISTED REQUIRING AN EXPLORATORY SURGERY 6 MONTHS LATER. ALTHOUGH NOTHING WAS FOUND DURING THIS PROCEDURE; CONSIDERING EVENT'S CLOSE TEMPORAL ASSOCIATION WITH ESSURE INSERTION, CAUSALITY CANNOT BE EXCLUDED. REGARDING ADENOMYOSIS, IT REFERS TO ECTOPIC ENDOMETRIAL TISSUE GROWTH INTO THE UTERINE MUSCULATURE; ITS RISK FACTORS INCLUDE: PRIOR UTERINE SURGERY, MIDDLE AGE AND CHILDBIRTH. SYMPTOMS OF ADENOMYOSIS TYPICALLY INCLUDE MENORRHAGIA AND PELVIC PAIN. HYSTERECTOMY IS OFTEN USED TO TREAT THIS CONDITION. CONSIDERING THIS INFORMATION AND GIVEN ESSURE LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY IS CONSIDERED UNLIKELY. THE EVENT METALLIC BLANKET ACROSS HER BLADDER REGION WAS DIAGNOSED 2 YEARS BEFORE CONSUMER'S HYSTERECTOMY AND LIMITED INFORMATION WAS PROVIDED ABOUT IT. NEVERTHELESS, IT CANNOT BE EXCLUDED THAT CONSUMER WAS REFERRING TO A POSSIBLE DEVICE DISLOCATION INTO ABDOMEN; THUS CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE AN EXPLORATORY SURGERY WAS REQUIRED DUE TO PAIN AFTER ESSURE PROCEDURE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01340	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1240, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. SHE SUFFERED FROM NICKEL ALLERGY SINCE SHE WAS A CHILD. AFTER ESSURE INSERTION SHE SUFFERED MISERABLY FOR ONE YEAR FROM CONSTANT BLEEDING AND DISCHARGE, AS WELL AS ABDOMINAL PAIN, LOW BACK PAIN, INCREDIBLY HEAVY PERIODS, EXTREME ADULT ACNE ON HER FACE AND NECK AND A GENERAL FEELING OF MALAISE. A COMPUTED TOMOGRAPHY SHOWED THAT THE COIL IN HER RIGHT TUBE HAD MIGRATED AND PERFORATED HER TUBE. HER COILS WERE REMOVED BY AN OBSTETRICIAN SPECIALIST WHO HAD NO PRIOR EXPERIENCE OR KNOWLEDGE OF THE DEVICE (2012). HE COMMENTED AFTER REMOVAL THAT THERE WERE OBVIOUS SIGNS OF INFLAMMATION EITHER DUE TO ALLERGY OR INFECTION. AT THE TIME OF REPORT (2015), IT HAS BEEN 3 YEARS SINCE THEIR REMOVAL AND SHE STILL SUFFERED FROM EXTREMELY HEAVY PERIODS, ABDOMINAL PAIN, LEG PAIN, HEADACHE, DIZZINESS, EXTREME FATIGUE AND GENERAL MALAISE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 22-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT

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REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD CONSTANT BLEEDING (INTERPRETED AS GENITAL BLEEDING) FOR A YEAR AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. A COMPUTERIZED TOMOGRAPHY SHOWED THAT THE COIL IN HER RIGHT TUBE HAD MIGRATED AND PERFORATED HER TUBE (INTERPRETED AS FALLOPIAN TUBE PERFORATION). HER COILS WERE REMOVED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, CONSIDERING THE NATURE OF THESE EVENTS AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01341	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/19/2014
Explant Date (E7): 7/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1430, AWARENESS DATE 07-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. ESSURE WAS INSERTED ABOUT 6 WEEKS AFTER CONSUMER HAVING HER THIRD CHILD. SHE HAD EXTREME PELVIC PAIN AND BACK PAIN, CONTINUOUS PAINFUL PERIODS, HAIR FALLING OUT ALL THE TIME. BEFORE ESSURE SHE HAD NO CRAMPING OR BACK ISSUES. SHE HAD MIGRAINES AND WAS VERY LETHARGIC, PAIN IN STOMACH WHEN LYING ON HER SIDE - IT WAS SO BAD THAT SHE TO LITERALLY HOLD HERSELF SO SHE COULD SWITCH POSITIONS. THIS PAIN WAS COMPARABLE TO BACK LABOR AND NATURAL LABOR ACCORDING TO HER. WHEN LYING ON SIDE AND TRYING TO MOVE IT POPPING AND WRINGING OF A TOWEL SENSATION, IT WAS EXTREMELY PAINFUL. HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED 3 MONTHS AFTER PLACEMENT AND EVERYTHING WAS FINE AND IN THE CORRECT PLACE. HOWEVER, IT WAS AFTER THE TEST THAT HER CONTINUOUS PERIODS STARTED. THE DOCTOR PLACED HER ON BC (BIRTH CONTROL PILLS) FOR A MONTH TO TRY TO TREAT THE PERIODS, BUT IT NEVER MADE THEM FULLY GO AWAY. THE DOCTOR ALSO CHECKED HER VAGINALLY FOR PLACEMENT AND SHE HURT FOR THE FOLLOWING 2-3 DAYS FROM HIM TOUCHING THEM. SHE ALSO A VAGINAL ULTRASOUND ONLY TO BE TOLD THAT ALL IS FINE. SHE A LAVH-BS (LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY) ON (B)(6) 2015 AT THE AGE OF (B)(6)AND CONSIDERED THE EVENTS RELATED TO ESSURE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 22-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE.

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FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO EXTREME PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY AT (B)(6). THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER PAIN AND MENSTRUAL CHANGES WHICH SHE ASSOCIATED WITH ESSURE PLACEMENT. SHE UNDERWENT A HYSTERECTOMY APPROXIMATELY 7 MONTHS AFTER DEVICE INSERTION. CONSIDERING THIS POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01342	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2009
Explant Date (E7): 4/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1336, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE (B)(6) CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. CONSUMER REPORTED THAT SHE REMOVED ESSURE IN (B)(6) 2010, BUT THE DAMAGE IT HAD ALREADY CAUSED HER WAS IRREVERSIBLE. SHE CANNOT AFFORD TO HAVE A HYSTERECTOMY SO SHE SUFFERS FROM PAIN WITH HER REGULAR PERIODS LASTING 1-6 WEEKS UP TO 3 MONTHS WHEN IT GETS REALLY BAD. SHE CAN NOT GET OUT OF BED AND MISSES WORK DUE TO THE PAIN. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 24-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

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COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PAIN WITH HER PERIODS. SHE HAD ESSURE REMOVED 5 MONTHS AFTER INSERTION AND THE PAIN PERSISTED. THIS EVENT, INTERPRETED AS DYSMENORRHEA, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DYSMENORRHEA MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, THE FACT THAT THE EVENT PERSISTED FOR YEARS AFTER ESSURE REMOVAL SUGGESTS THAT THE INSERT WAS NOT THE ONLY RESPONSIBLE FOR THE PAIN. HOWEVER, GIVEN THE NATURE OF THIS EVENT, A CONTRIBUTORY ROLE OF ESSURE FOR ITS INITIAL OCCURRENCE CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE REMOVAL WAS REPORTED (REQUIRED INTERVENTION IMPLIED). NON-SERIOUS EVENT WAS ALSO REPORTED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01343	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1343, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. ADDITIONAL INFORMATION RECEIVED ON 24-OCT-2015 (PTC INVESTIGATION RESULT). CONSUMER EXPERIENCED BLACK OUT AFTER THE SURGERY WHICH SHE NEVER EXPERIENCED BEFORE UNDER ANESTHESIA. SHE LITERALLY COULD NOT BARE THE PAIN ANY LONGER. SHE CONSTANTLY EXPERIENCED SEVERE STOMACH PAINS AND ACHES LIKE SOMEONE WAS STABBING HER. SHE MISSED SEVERAL DAYS OF WORK DUE TO NOT BEING ABLE TO GET OUT OF BED, EXPERIENCED BACTERIAL INFECTIONS, FOUL ODORS AND SHE GAINED A TON OF WEIGHT AFTER HAVING A WEIGHT LOSS SURGERY AND MAINTAINING HER WEIGHT FOR 10 YEARS. SHE HAD A HYSTERECTOMY TO REMOVE THE DEVICE IN WHICH SHE STILL SUFFERS FROM TIME TO TIME. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS

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CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. CORRECTION (07-OCT-2015) FOLLOWING COMPANY INTERNAL REVIEW: THE EVALUATION CODES WERE UPDATED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT SHE LITERALLY COULD NOT BARE THE PAIN ANY LONGER (SEEN AS ABDOMINAL PAIN). A HYSTERECTOMY WAS PERFORMED IN ORDER TO REMOVE THE DEVICE. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON THE NATURE OF THE EVENT AND CONSIDERING THAT ABDOMINAL PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01344	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 4/2/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1355, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012 TO PREVENT FUTURE PREGNANCIES. CONSUMER REPORTED THAT SHE SUFFERED FROM EXTREMELY PAINFUL PERIODS, VOMITING, NAUSEA, MIGRAINES, SUN SENSITIVITY, BRAIN FOG, INSOMNIA, EXTREME FATIGUE, PAINFUL INTERCOURSE, HAIR LOSS, TOOTH DECAY, LOSS OF LIBIDO, RASHES, MOOD SWINGS, ANXIETY, DEPRESSION, OVARIAN CYSTS, SORE BREASTS, LEG CRAMPS, LOWER BACK PAIN, HIP PAIN AND PELVIC PAIN. IN (B)(6) 2014 SHE HAD A HYSTERECTOMY TO REMOVE THE COILS, AND LOST HER UTERUS, FALLOPIAN TUBES, RIGHT OVARY AND CERVIX. SHE WAS ALSO DIAGNOSED WITH FIBROMYALGIA. AT THE TIME OF REPORT, SHE WAS STILL EXPERIENCING CHRONIC WIDE SPREAD PAIN. SHE TOOK A COCKTAIL OF MEDICATION TO KEEP HER PAIN LEVEL SEMI TOLERABLE AND TO SLEEP. FOLLOW UP RECEIVED ON 24-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS

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CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE, IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAS PELVIC PAIN AMONG OTHER NON-SERIOUS EVENTS. APPROXIMATELY, 2 YEARS LATER, SHE HAD A HYSTERECTOMY TO REMOVE ESSURE COILS AND UTERUS ALONG WITH FALLOPIAN TUBES, RIGHT OVARY AND CERVIX. PELVIC PAIN IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING AN IMPLIED COMPATIBLE TEMPORAL RELATIONSHIP AND THE FACT THAT ESSURE MAY CAUSE PELVIC PAIN, THE CAUSAL RELATIONSHIP WITH ESSURE AND PELVIC PAIN CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01345	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A64633

Single Use: Y
Implant Date (E6): 3/28/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 08-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013, LOT NUMBER A64633, FOR PERMANENT CONTRACEPTION. ON (B)(6) 2013 THE CONSUMER FOUND OUT SHE WAS 7 WEEKS PREGNANT AND AFTER HAVING BABY, SHE WAS TOLD THE BABY HAD A HEART MURMUR (LINKED CASE (B)(4)). A WEEK LATER, THE CONSUMER WAS HOSPITALIZED FOR ALMOST HAVING A STROKE AND HEART ATTACK, BLOOD CLOTS, HIGH BLOOD PRESSURE, AND PELVIC PAIN. ESSURE WAS ONGOING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT WITH ESSURE. SHE GAVE BIRTH TO A BABY. A WEEK LATER, THE CONSUMER WAS HOSPITALIZED FOR ALMOST HAVING A STROKE AND HEART ATTACK, BLOOD CLOTS, HIGH BLOOD PRESSURE AND PELVIC PAIN. PREGNANCY AND PELVIC PAIN ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE UNLISTED. PREGNANCY IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND THE OTHER EVENTS ARE SERIOUS SINCE THEY RESULTED IN HOSPITALIZATION. IN THIS CASE, CONSUMER GOT PREGNANT ABOUT 7 MONTHS AFTER ESSURE INSERTION. IT WAS NOT REPORTED WHETHER THE CONSUMER RETURNED FOR THE ESSURE CONFIRMATION TEST AFTER THE INSERTION. NEVERTHELESS, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE PREGNANCY CANNOT BE EXCLUDED. SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR THE PELVIC PAIN AND ESSURE WAS NOT REMOVED AFTER DELIVERY, A CAUSAL RELATIONSHIP BETWEEN PELVIC PAIN AND SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE

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EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO HOSPITALIZATION. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01346	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1358 AND FDA-2014-N-0736-1705, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. ADDITIONAL INFORMATION RECEIVED ON 17-OCT-2015. THE CONSUMER STATED SHE HAD ESSURE FOR 8 YEARS AND FROM THE FIRST MOMENT, SHE FELT STRONG PAINS IN (B)(6) 2014 AND HAD TO HAVE SURGERY TO REMOVE THE TUBE ON THE LEFT SIDE BECAUSE ESSURE BROKE, THE TUBE. ADDITIONALLY, SHE HAD PAIN IN OVARIES AND HER MENSTRUATION REMAINED INSIDE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 24-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT

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REFERS TO A FEMALE CONSUMER WHO HAD STRONG PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND HAD TO REMOVE LEFT FALLOPIAN TUBE BECAUSE ESSURE BROKE. ESSURE BREAKAGE IS ANTICIPATED ACCORDING TO THE TECHNICAL ANALYSIS, WHILE PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. ADDITIONALLY, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, TEMPORAL RELATIONSHIP BETWEEN BREAKAGE DIAGNOSIS AND ESSURE INSERTION WAS WEAK (EVENT DIAGNOSED APPROXIMATELY 8 YEARS AFTER DEVICE PLACEMENT). NEVERTHELESS; GIVEN EVENTS NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WAS REQUIRED (LEFT FALLOPIAN TUBE REMOVED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01358	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1217, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ABOUT 2-3 MONTHS AFTER ESSURE WAS INSERTED THE CONSUMER STARTED TO EXPERIENCE BURNING SENSATION ALL OVER HER BODY, FROM FEET ALL THE WAY UP TO HER FACE. IT FELT LIKE SOMETHING WAS BURNING HER. WHEN SHE WOULD LOOK, IT WOULD BE A LONG RED THIN LINE, OR A THICK PATCH, OR MULTIPLE LINES & PATCHES. THE BURNING WOULD GO AWAY AFTER ABOUT 2 MINUTES AND THEN THE ITCHING WOULD START. IT WAS A VERY INTENSIVE ITCHING, EVERYWHERE. SOMETIMES SHE WOULD ITCH FOR SO LONG AND SO HARD SHE WOULD CAUSE SORES IN HER SKIN. SHE RECEIVED (B)(4) FOR ITCHING, DUE TO IT POSSIBLY BEING NA ALLERGIC REACTION, AND IT HELPED. SHE NO LONGER HAD TO WORRY ABOUT THIS HUGE RED, BURNING, ITCHING RASH OVER HER FACE, AS LONG AS SHE TOOK (B)(4). CONSUMER STATED THAT SHE HAD A VERY EASY MENSTRUAL CYCLE, 3 DAYS WITH A LIGHT NOW. AFTER HAVING THIS PROCEDURE DONE IT CHANGED TO 7-10 DAYS, HEAVY BLEEDING ALONG WITH LARGE CLOTS. SHE ALSO HAD EXTREME CRAMPING, HER HAIR WAS FALLING OUT, MEMORY WAS HAZY AT TIMES. SHE HAD FREQUENT HEADACHES TOO. SOMETIMES THEY WERE SO BAD SHE COULDN'T EVEN GO TO WORK. GIVEN THE BLEEDING, CLOTTING AND EVERY THING ELSE, SHE WAS OFFERED A HYSTERECTOMY. HER DOCTOR PERFORMED A HYSTERECTOMY ON HER TO REMOVE THE COILS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 24-OCT-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER MENSTRUAL CYCLE WENT TO 7-10 DAYS, HEAVY BLEEDING WITH LARGE CLOTS. SHE UNDERWENT A HYSTERECTOMY TO REMOVE THE COILS. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED AND A HYSTERECTOMY WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01359	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1390, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. THE CONSUMER (MOTHER OF TWO) HAD ESSURE INSTALLED AFTER THE BIRTH OF HER SECOND CHILD APPROXIMATELY 3 WEEKS AFTER HIS BIRTH ((B)(6) 2011). SHE HAD ESSURE PLACED AT A MILITARY HOSPITAL. SHE STATED THEY PUT HER UNDER AND TOOK HER TO THE OR. THE DAY AFTER SURGERY, SHE HAD SHARP PAIN. AT HER FOLLOW-UP TWO WEEKS LATER, SHE WAS TOLD THE PAIN WAS NORMAL AND IT WOULD GO AWAY. SHE WAS CONSTANTLY IN PAIN AND STARTED HAVING MIGRAINES. AT THE TIME THEY FIGURED HER BLOOD PRESSURE WAS CAUSING THE MIGRAINES. AFTER MONTHS OF TESTING AND SLEEP STUDIES, THEY COULD NOT FIGURE OUT WHY SHE WAS HAVING SUCH ISSUES; MIGRAINES, DIZZINESS, VERTIGO, LOSS OF VISION, HIGH BLOOD PRESSURE AND SHE WAS NOT LOSING WEIGHT, ALTHOUGH SHE WAS WORKING OUT DAILY, MOST DAYS TWICE A DAY DUE TO MILITARY PT. SHE WAS THE SAME WEIGHT AT SIX-MONTH POST-PARTUM THAN SHE WAS THREE WEEKS BEFORE DELIVERY. SHE WAS SPENDING WITH A PERSONAL TRAINER AND DOING EVERY DIET RECOMMENDED ALONG WITH SEEING A NUTRITIONIST THREE TIMES A WEEK, NO ONE COULD FIGURE OUT WHY SHE WAS NOT LOSING WEIGHT AND WHY SHE CONTINUALLY GOT WORSE. HER SON WAS FOUR MONTHS OLD WHEN SHE STARTED LOSING FUNCTION IN HER RIGHT ARM WHICH IS HER PRIMARY ARM: SHE WAS CARRYING HIM UP THE STAIRS AND ALMOST DROPPED HIM. HER WOMEN'S HEALTH DOCTOR TOLD HER IT WAS BECAUSE SHE NEEDED TO LOSE WEIGHT. NEXT THING, HER VITAMIN D NUMBERS WERE LOW AND SHE WAS HAVING BLADDER LEAKAGE. IN 2013, THEY FINALLY DECIDED THAT HER BLADDER LEAKAGE WAS A PROBLEM. THE REST

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OF THE SYMPTOMS THEY COULD NOT EXPLAIN AS THE CONSTANT PAIN IN PELVIC AREA, THE MIGRAINES, HORRIBLE BLEEDING DURING CYCLES. IN (B)(6) 2014, SHE WAS TOLD THAT SHE HAD TO HAVE A VAGINAL MESH PLACED TO FIX THE LEAKING BLADDER BECAUSE HER BLADDER HAD A TEAR IN IT. THEY TOLD HER IT PROBABLY HAPPENED WHEN SHE GOT SEWN UP AFTER CHILDBIRTH. BOTH OF HER CHILDREN WERE BORN NATURALLY AND SHE DID NOT GET STITCHES WITH EITHER. IN (B)(6) 2015, THE PHYSICIAN WAS ONLY ABLE TO FIND ONE COIL AND REMOVE IT. WITH THE ONE COIL OUT SHE FELT SLIGHTLY BETTER BUT THE LIST OF HER SYMPTOMS WAS: MIGRAINES, BLURRED VISION, HER FEET WERE PEELING LIKE SHE HAD ATHLETES FOOT ALL THE TIME, MOOD SWINGS AND BODY ACHES. THERE WERE DAYS SHE COULD NOT GET OUT OF BED, SHE WAS ALWAYS MENTALLY TIRED. AT TIME OF THE REPORT, SHE STILL WAS AT HER PREGNANCY WEIGHT. SHE HAD TASTE METAL IN MOUTH AND STILL HAD A URINE LEAKAGE PROBLEM ALL THOUGH SHE HAD THIS MESH; SHE ALSO HAD NO SEX DRIVE. THE CONSUMER STATED SHE WAS FORCED TO GIVE UP HER MILITARY CAREER EARLY DUE TO ALL HER HEALTHY ISSUES. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 24-OCT-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THE DAY AFTER SURGERY SHE HAD SHARP PAIN/ CONSTANT PAIN IN PELVIC AREA / CONSTANTLY IN PAIN. SHE UNDERWENT ESSURE REMOVAL APPROXIMATELY 4 YEARS AFTER INSERTION; HOWEVER, THE DOCTOR WAS ONLY ABLE TO FIND ONE COIL AND REMOVE IT (INTERPRETED AS DEVICE DISLOCATION). SHE ALSO REPORTED LOSS OF VISION AND HER BLADDER HAS A TEAR IN IT. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN AND DEVICE DISLOCATION ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENTS ARE UNLISTED. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES (DEVICE DISLOCATION). IN THE PRESENT CASE, THE EXACT LOCATION OF ONE OF THE DEVICES WAS UNKNOWN: THE DOCTOR WAS ONLY ABLE TO FIND ONE COIL AND REMOVE IT. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. EVENTS LOSS OF VISION AND BLADDER HAS A TEAR IN IT WERE ASSESSED AS UNRELATED TO ESSURE, CONSIDERING THEIR PATHOPHYSIOLOGY AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01360	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1301, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT IT FIRST STARTED WITH UNEXPLAINED RASHES, THEN PELVIC PAIN AND LAST SHE COUNTED 40 SYMPTOMS. FINALLY SHE FOUND A DOCTOR THAT AGREED TO REMOVE HER TUBES. SHE HAS TO TAKE BIRTH CONTROL FOR ENDOMETRIOSIS THAT SHE NEVER HAD PREVIOUSLY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 24-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

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COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED PELVIC PAIN. THIS EVENT IS SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. ALTHOUGH IN THIS CASE THE ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THIS PAIN, CONSIDERING THE EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, A CONTRIBUTORY ROLE FROM ESSURE CANNOT BE TOTALLY EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (TUBES WERE REMOVED) THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01361	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2012
Explant Date (E7): 7/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1235, AWARENESS DATE 08-OCT-2015). IT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER WAS DONE HAVING CHILDREN AND HAD ESSURE INSERTED IN THE CLINIC. DOCTOR GAVE HER A NARCOTIC TO HELP HER RELAX. SHE HAD EXTREME CRAMPING. WITHIN A FEW WEEKS, SHE STARTED EXPERIENCING CRAMPING, STABBING PELVIC PAIN TO THE POINT OF BENDING OVER, ABNORMAL PERIODS, LONG PERIODS, SHORT PERIODS, BACTERIAL VAGINOSIS, DISCHARGE, PAINFUL OVULATION, MAJOR LOSS OF LIBIDO, SPOTTING AFTER SEX, PAINFUL SEX, SEXUAL DYSFUNCTION, HEADACHES, NAUSEA, GAS, CONSTIPATION, METALLIC TASTE IN MOUTH, HEART BURN, DIZZINESS, BRAIN FOG, REALLY BAD MOOD SWINGS, DEPRESSION, NUMBNESS/ TINGLING IN EXTREMITIES, SHAKINESS, HAIR LOSS, DENTAL ISSUES, INSOMNIA, BLURRED VISION, DRY SKIN AND HAIR AND FATIGUE. SHE WENT BACK AFTER 3 MONTHS TO HAVE THE HYSTEROSALPINGOGRAM (HSG) TEST, AND THAT WAS THE MOST PAINFUL TEST SHE EVER HAD. BOTH TUBES WERE BLOCKED, AND IN THE CORRECT PLACE. FOR THE NEXT 2.5 YEARS, SYMPTOMS REMAINED. SHE SAW A DOCTOR IN (B)(6) 2015 WHO SAID THEY NEEDED TO REMOVE THE COILS. ON (B)(6) 2015, A HYSTERECTOMY WAS PERFORMED TAKING EVERYTHING BUT OVARIES. ONE OF THE COILS MIGRATED OUT OF THE FALLOPIAN TUBE AND WAS PUNCTURING HER UTERUS. IT WAS NOT PUNCTURING ANY OF HER OTHER INTERNAL ORGANS (BLADDER BOWEL, ETC). SINCE HAVING THE ESSURE REMOVED, MOST OF SYMPTOMS HAVE GONE AWAY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 24-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A

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DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING STABBING PELVIC PAIN TO THE POINT OF BENDING OVER. SHE UNDERWENT A HYSTERECTOMY TO REMOVE THE COILS 3 YEARS AFTER INSERTION AND IT WAS FOUND THAT ONE OF THE COILS HAD MIGRATED OUT OF THE FALLOPIAN TUBE AND WAS PUNCTURING HER UTERUS. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE, INCLUDING ESSURE INSERTION. IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THE PERFORATION WERE NOT REPORTED. HYSTEROSALPINGOGRAM 3 MONTHS AFTER INSERTION SHOWED THE DEVICES IN CORRECT PLACE. THE PERFORATION WAS DIAGNOSED 3 YEARS AFTER ESSURE INSERTION DURING A HYSTERECTOMY TO REMOVE THE COILS. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED AND A HYSTERECTOMY WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01362	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2012
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1295, AWARENESS DATE 07-OCT-2015). IT REFERS TO NA ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012, 7 WEEKS AFTER THE BIRTH OF HER FIFTH CHILD, FOR PERMANENT BIRTH CONTROL. CONSUMER REPORTED THAT WITHIN 6 MONTHS SHE HAD CHRONIC PELVIC PAIN, ANXIETY ISSUES, NIGHT SWEATS, 70LBS WEIGHT GAIN - IN ONE YEAR SHE DOUBLED IN WEIGHT, HAIR LOSS, DIZZY SPELLS AND METAL MOUTH. AFTER A YEAR AND A HALF HAVING ESSURE PLACED SHE HAD AN EMERGENCY HYSTERECTOMY AT THE AGE OF (B)(6). HER UTERUS WAS COVERED IN CYSTS, ADEMETROYSIS (AS REPORTED) AND EDMETROYSIS (AS REPORTED). SOME OF THE SYMPTOMS STOPPED IMMEDIATELY OTHERS STILL LINGERED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 24-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE

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REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO NA ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, WITHIN 6 MONTHS OF ESSURE USE, THE CONSUMER EXPERIENCED CHRONIC PELVIC PAIN AND OTHER NON-SERIOUS EVENTS. ALTHOUGH, IN THIS CASE, THE ENDOMETRIOSIS AND ADENOMYOSIS COULD BE ALTERNATIVE EXPLANATIONS FOR THE CHRONIC PAIN, CONSIDERING THE SUGGESTIVE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE TOTALLY EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01363	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2013
Explant Date (E7): 9/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING AND TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1356, AWARENESS DATE 08-OCT-2015). CASE WAS RECEIVED IN UNITED STATES AND REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT SINCE ESSURE PLACEMENT (2 YEARS AGO) SHE HAD HORRIBLE PERIODS THAT CAUSED HER TO PASS BLOOD CLOTS. SHE HAD DIZZY SPELLS SO BAD SHE COULD NOT WALK STRAIGHT AND WOULD FEEL NAUSEOUS. HER HAIR FELL PUT (AS REPORTED, UNDERSTOOD AS OUT) IN CLUMPS AND SEX WAS PAINFUL. HER UTERUS IS ENLARGED TO THE SIZE OF BEING 3 MONTHS PREGNANT AND SHE HELD WATER WEIGHT. SHE REPORTED THAT SHE GAINED 60 POUNDS AND STATES THAT SHE NEVER CHANGED HER DIET AND WAS MORE ACTIVE. SHE WAS MOODY AND FELT LIKE HELL EVERY DAY. SHE HAD AN ANNOYING RINGING IN HER EARS, HEADACHES, DRY ITCHY SKIN AND HEARTBURN. LAST WEEK ((B)(6)2015) SHE HAD TO UNDERGO SURGERY TO HAVE ESSURE REMOVED AND HAVE A TUBAL DONE. HER DRY SKIN, HEADACHES, DIZZINESS AND RINGING IN EARS HAVE ALL GONE AWAY IN 1 WEEK. IN ADDITION, CONSUMER REPORTED THAT SHE WILL BE RETAINING AN ATTORNEY AND, WHEN THE TIME COMES, SHE WILL HAVE THEM TO SUE BAYER FOR THOSE 2 YEARS AND HAVING TO UNDERGO SURGERY TO HAVE HER LIFE BACK. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO

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NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HORRIBLE PERIODS THAT CAUSED HER TO PASS BLOOD CLOTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICES WERE SURGICALLY REMOVED (APPROXIMATELY 2 YEARS AFTER THEIR PLACEMENT). THIS EVENT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER MENTIONED HER UTERUS WAS FOUND ENLARGED. THIS SUGGESTS AN UNDERLYING UTERINE CONDITION (SUCH AS ADENOMYOSIS OR UTERINE FIBROIDS); WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THE REPORTED MENSTRUAL CHANGES. HOWEVER, SINCE LIMITED INFORMATION WAS PROVIDED AND AS CONSUMER RELATED THE REPORTED EVENT TO ESSURE PLACEMENT; A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS (CONSUMER STATED SHE WILL BE RETAINING A LAWYER).

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 27-OCT-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01364	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 07-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009 FOR PERMANENT CONTRACEPTION. PATIENT WAS GOING TO HAVE ESSURE REMOVED DUE TO RASH AND ABDOMINAL PAIN, HOWEVER PATIENT DID NOT COMPLAIN OF THIS UNTIL RECENTLY. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED RASH AND ABDOMINAL PAIN. IT WAS REPORTED THAT SHE WAS GOING TO HAVE ESSURE REMOVED DUE TO THESE EVENTS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON THE NATURE OF THE EVENTS, A

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CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FURTHER INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01365	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/14/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044449) IN UNITED STATES ON 09-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2010. SHE HAD A SONOGRAM PERFORMED THREE MONTHS LATER TO MAKE SURE THAT SCAR TISSUE HAD BLOCKED THE FALLOPIAN TUBES. THE SONOGRAM REVEALED THAT THE COIL ON THE LEFT SIDE HAD MIGRATED INTO THE ABDOMINAL CAVITY. IN 2010, HER PHYSICIAN PERFORMED A TUBAL LIGATION LAPAROSCOPICALLY ON THE LEFT SIDE ONLY. AT THAT TIME SHE ATTEMPTED TO REMOVE THE COIL THAT HAD MIGRATED OUT OF THE FALLOPIAN TUBE BUT IT HAD LODGED IN THE OMENTUM AND ATTEMPTED TO REMOVE IT LAPAROSCOPICALLY BUT IT LEAD TO BLEEDING THAT WOULD REQUIRE MORE EXTENSIVE SURGERY AND RATHER THAN OPEN UP THE ABDOMINAL CAVITY TO REMOVE THE COIL, THE PHYSICIAN LEFT IT IN. THE CONSUMER HAD NOT USED MEDICATIONS FOR TREATMENT BUT SHE USED DAILY VITAMIN AS CONCOMITANT MEDICATIONS. FOLLOW UP RECEIVED ON 24-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND THREE MONTHS LATER, THE SONOGRAM SHOWED THAT THE COIL ON THE LEFT SIDE HAD MIGRATED INTO THE ABDOMINAL CAVITY (INTERPRETED AS DEVICE DISLOCATION). THE PHYSICIAN PERFORMED A TUBAL LIGATION LAPAROSCOPICALLY ONLY ON THE LEFT SIDE AND MADE AN ATTEMPT TO REMOVE THE COIL THAT HAD LODGED IN THE OMENTUM BUT IT LEAD TO BLEEDING (INTERPRETED AS PROCEDURAL BLEEDING), SO PHYSICIAN LEFT IT IN. DEVICE DISLOCATION AND PROCEDURAL BLEEDING ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS AND SUGGESTIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE INSERTS AND ESSURE-RELATED PROCEDURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE AN ATTEMPT FOR DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01366	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/29/2009
Explant Date (E7): 6/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044250) IN UNITED STATES ON 07-OCT-2015 WHICH WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. THE CONSUMER STATED AFTER ESSURE SHE DEVELOPED AN ALLERGY (DERMOGRAPHISM OR URTICARIA FACTITIA). SHE HAD ALSO EXPERIENCED BACK PAIN, JOINT PAIN, TIREDNESS, EXCESSIVE SWEAT; SHE MENTIONED SHE COULD BARELY WALK, LACK OF ENERGY, AND DEPRESSION. SHE MENTIONED HER RX MEDS (UNDERSTOOD AS PRESCRIPTION MEDICATION) WAS FEXOFENADINE. NO OTC (OVER THE COUNTER) MEDICATION WAS USED. ON (B)(6) 2015, SHE REMOVED THE DEVICES AND AT TIME OF THE REPORTED SHE STATED SHE WAS ALREADY FEELING BETTER. -RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 24-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO

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RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD AN ALLERGY (DERMOGRAPHISM OR URTICARIA FACTITIA) AND BACK PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICES WERE REMOVED (APPROXIMATELY 6 YEAR AFTER THEIR IMPLANTATION). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, AND HIVES (URTICARIA) THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, CONSUMER HAD DERMOGRAPHISM OR URTICARIA FACTITIA. THIS CONDITION IS A TYPE OF PHYSICAL URTICARIA (RELATED TO TRAUMA OR CONTACT); USUALLY IDIOPATHIC, BUT ALSO TRIGGERED BY DRUGS, INFESTATIONS AND INSECT BITES. ALTHOUGH THE REPORTED URTICARIA TYPE IS NOT EXPECTED AS A CONSEQUENCE OF ESSURE THERAPY; CONSIDERING CONSUMER REPORTED AN IMPROVEMENT OF HER SYMPTOMS AFTER DEVICE REMOVAL; A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE EXCLUDED. THE SAME ASSESSMENT IS GIVEN FOR THE REPORTED BACK PAIN; SINCE THIS EVENT MAY OCCUR DURING ESSURE THERAPY. THIS CASE WAS REGARDED AS INCIDENT, AS DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01372	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1276, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. A COUPLE OF MONTHS AFTER INSERTION, SHE STARTED NOTICING THAT HER HAIR WAS FALLING OUT AND WAS THINNING TREMENDOUSLY. ALSO, SHE HAD CRAMPS AND BAD PELVIC PAINS THAT RESEMBLED CONTRACTIONS. SHE FELT MOVEMENT IN HER STOMACH AS IF A BABY WAS KICKING. SHE HAD HEADACHES OUT OF NOWHERE AND WAS DIAGNOSED WITH MANIC DEPRESSION, ANXIETY AND PTSD. HER MOODS HAD CHANGED. SHE WAS NO LONGER THE FUN LOVING MOM SHE ONCE WAS DUE TO THE SEVERE PAIN SHE EXPERIENCED. SHE HAD GALLBLADDER SURGERY REMOVAL AND ALSO HAD THE COILS REMOVED. SHE GOT ADDICTED TO NORCO BECAUSE THAT WAS MEDICINE SHE WAS PRESCRIBED FOR THE PAIN AND AFTER THE 2 SURGERIES. PTC INVESTIGATION RESULT RECEIVED ON 22-OCT-2015: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BAD PELVIC PAINS AND HAD COILS REMOVED. SHE ALSO HAD GALLBLADDER REMOVAL. SHE STATED SHE GOT ADDICTED TO NORCO BECAUSE THAT MEDICINE WAS PRESCRIBED FOR THE PAIN AND AFTER THESE 2 SURGERIES. THE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE PELVIC PAIN IS LISTED WHILE THE REMAINING SERIOUS EVENTS ARE UNLISTED IN THE REFERENCE SAFETY FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS AND LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, THE PELVIC PAIN AND THE SUBSEQUENT ADDICTION TO ANALGESIC PRESCRIBED FOR THE PAIN ARE EVENTS ASSESSED AS RELATED. IN CONTRAST, THE GALLBLADDER REMOVAL IS UNLIKELY TO BE CAUSED BY ESSURE INSERTS. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01373	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1150, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008, TO PREVENT PREGNANCY. CONSUMER REPORTED THAT INSERTION PROCEDURE WAS VERY PAINFUL OVERALL AND TOOK 3 HOURS. SHE HAD HORRIBLE MENSTRUAL CYCLES FOLLOWING THE PROCEDURE. SHE ENDURED DEBILITATING PELVIC PAIN, HAIR LOSS AND BECAME PREGNANT AND DELIVERED THE CHILD. ONCE DISCOVERING SHE WAS PREGNANT AT THE ER (EMERGENCY ROOM) (SHE WENT BECAUSE THE PAIN HAD BECOME UNBEARABLE), SHE REQUESTED HER MEDICAL RECORDS AND DISCOVERED THAT SHE HAD ONLY ONE COIL, THE FIRST COIL COULD NOT BE INSERTED. BUT YET SHE WAS HALF IMPLANTED AND TOLD AT HER DYE TEST CONFIRMATION THAT SHE WAS STERILE. SHE HAD A HYSTERECTOMY IN 2014 TO REMOVE THE ONE COIL THAT WAS INSERTED AND HAD MIGRATED INTO HER UTERUS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 24-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS/ LACK OF EFFICACY IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS/ LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ONLY ONE COIL OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT. SHE UNDERWENT A HYSTERECTOMY 6 YEARS AFTER INSERTION, TO REMOVE ONE COIL THAT MIGRATED INTO HER UTERUS (INTERPRETED AS PARTIAL EXPULSION OF DEVICE). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, ONE COIL HAD MIGRATED INTO HER UTERUS. GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE, INCLUDING ESSURE. IN THE PRESENT CASE, THE CONSUMER HAD ONLY ONE COIL INSERTED AND HAD A CONFIRMATION TEST STATING THAT SHE WAS STERILE. THE EXACT REASON WHY THE CONTRALATERAL COIL COULD NOT BE INSERTED WAS NOT SPECIFIED. THE ONLY COIL INSERTED HAD MIGRATED INTO HER UTERUS, BUT IT IS UNKNOWN WHETHER THE EXPULSION OCCURRED BEFORE CONCEPTION. PREGNANCY IN THIS CASE COULD BE CONSIDERED RATHER A CONSEQUENCE OF THE UNILATERAL PLACEMENT AND DEVICE EXPULSION, HOWEVER GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED AND A HYSTERECTOMY WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS/ LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01374	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 654824

Single Use: Y
Implant Date (E6):
Explant Date (E7): 6/3/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1361, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED ON 19-OCT-2015 AND 24-OCT-2015. OTHER HA NUMBER TO THIS CASE: MW5055823. CONSUMER STATED THAT ESSURE INSERTION OCCURRED PRIOR TO 2011 (HER GUESS WAS AROUND 2010). REFERENCE NUMBER ESS305, LOT #654824. SHORTLY AFTER INSERTION, SHE EXPERIENCED DEPRESSION, ANEMIA AND BRAIN FOG. SHE EXPERIENCED PELVIC PAIN AND PERIODS LASTING 2 WEEKS OUT OF EACH MONTH. IN (B)(6) 2011, AFTER ANOTHER COMPLAINT OF PELVIC PAIN, CT SCANS REVEALED A 10CM MASS ATTACHED TO HER RIGHT OVARY. IN 2012, SEVERAL CYSTS WERE FOUND. PRIOR TO IMPLANTATION, SHE REMOVED A SINGLE CYST. A LARGEST CYST REQUIRED IMMEDIATE SURGERY AND HER RIGHT OVARY WAS REMOVED. IN (B)(6) 2012, THE TUMOR AND RIGHT OVARY WAS REMOVED. PELVIC PAIN AND ABDOMINAL SWELLING CONTINUED. BETWEEN 2012 AND 2015, NUMEROUS CT AND ULTRASOUNDS WERE PERFORMED, BUT THE SOURCE OF THE PAIN WAS NOT VISIBLE. IN ADDITION TO CONSTANT PAIN, SWELLING, AND EXCESSIVE HEAVY BLEEDING AND LONG PERIODS (IRREGULAR PERIODS - 2 WEEKS A MONTH), SHE ALSO EXPERIENCED DIZZINESS. TWO MAJOR FALLS DOWN STAIRS RESULTED IN LONG-TERM INJURY, WHICH RESULTED IN CONSTANT PAIN WHEN SITTING OR STANDING THAT CONTINUES TO THIS DAY. THE SECOND FALL OCCURRED IN (B)(6) OF 2013 AND SHE LOST CONSCIOUSNESS AND HAD NO MEMORY OF THE FALL. SHE RECEIVED A CONCUSSION AND NOW SUFFERS FROM POST-CONCUSSION SYNDROME. MEMORY AND CONCENTRATION ARE MOST SIGNIFICANTLY IMPACTED. ON (B)(6) 2015, HER PERIOD BEGAN AND DID NOT STOP

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(BLEEDING NEVER STOPPED). THE PAIN INCREASED AND SHE BECAME ANEMIC AND EXTREMELY TIRED. THE DECISION WAS MADE BASED ON CONSTANT PROBLEMS SINCE THE IMPLANTATION OF ESSURE TO HAVE A HYSTERECTOMY, WHICH WAS DONE ON (B)(6) 2015. SHE WAS NEVER ASKED ABOUT ALLERGY TO ANY METAL. CONSUMER CONSIDERED HER CONDITION AS LIFE-THREATENING, DISABILITY/ PERMANENT INJURY; HOWEVER SHE DID NOT GIVE MORE DETAILS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN. A CT SCAN WAS PERFORMED AND 10CM MASS ATTACHED TO HER RIGHT OVARY WAS REVEALED. TWO MAJOR FALLS DOWN STAIRS RESULTING IN LONG TERM INJURY. THE SECOND FALL SHE LOST CONSCIOUSNESS. SHE SUFFERED FROM POST CONCUSSION SYNDROME. PELVIC PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE UNLISTED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, A HYSTERECTOMY WAS PERFORMED. FOR THE EVENT PELVIC PAIN, BASED ON ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, CONSIDERING THE NATURE OF THE EVENTS AND THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CONTRIBUTORY ROLE OF INSERT IS UNLIKELY, THUS THEY CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 14-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01375	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1237, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT SHE WAS AWAKE DURING ESSURE INSERTION PROCEDURE AND SHE EXPERIENCED EXCRUCIATING PAIN. DOCTOR COULD NOT GET THE SECOND COIL INTO HER TUBE SO SHE HAD TO RETURN TWO DAYS LATER TO HAVE IT DONE. THE DAY AFTER PROCEDURE SHE HAD A PARTIALLY PROLAPSED UTERUS AND HEAVY BLEEDING. SINCE THEN SHE EXPERIENCED HORRIBLE DEBILITATING ABDOMINAL PAIN, HEAVY MENSTRUAL PERIODS WITH ENORMOUS CLOTS THAT WERE PAINFUL WHEN COMING OUT. SHE ALSO HAD MIGRAINES, HIP PAIN, HAIR LOSS, FATIGUE, ANXIETY, DIZZINESS AND NAUSEA. SHE HAD AN EXPLORATORY SURGERY DONE AND THE DOCTOR COULD NOT FIND ONE OF HER COILS. -RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 24-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDIAL ASSESSMENT:

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NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD AN EXPLORATORY SURGERY DONE AND THE DOCTOR SAID HE COULD NOT FIND ONE OF HER COILS (INTERPRETED AS DEVICE DISLOCATION). SHE ALSO EXPERIENCED HEAVY BLEEDING NEXT DAY AFTER INSERTION AND HORRIBLE DEBILITATING ABDOMINAL PAIN. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN. NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR THE EVENTS. GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO EXPLORATORY SURGERY PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01376	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 08-OCT-2015. IT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE INSERTED BY ANOTHER PHYSICIAN. THE PATIENT BECAME PREGNANT. SHE HAD A C-SECTION AND THE PHYSICIAN REMOVED HER FALLOPIAN TUBES (SALPINGECTOMY). DURING THE SURGERY ONE ESSURE WAS IN THE UTERUS AND THE OTHER ONE COULD NOT BE FOUND. ADDITIONAL INFORMATION RECEIVED ON 24-OCT-2015: PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE PATIENT WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE HAD A C-SECTION AND PHYSICIAN PERFORMED A SALPINGECTOMY; ONE ESSURE WAS IN THE UTERUS AND THE OTHER ONE COULD NOT BE FOUND. ONLY

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CESAREAN SECTION IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED ABOUT CONFIRMATION TEST. AFTER DELIVERY, BOTH ESSURE COILS WERE MISPLACED (ONE WAS IN UTERUS AND THE OTHER WAS NOT FOUND). THIS DEVICE MOVEMENT COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED DEVICE FAILURE (PREGNANCY). HOWEVER, SINCE THE EXACT ONSET OF THE EVENTS WAS NOT KNOWN (IF COILS MOVEMENT OCCURRED BEFORE OR AFTER PREGNANCY ONSET); CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED CESAREAN SECTION, ITS INDICATION WAS NOT REPORTED. THEREFORE, CAUSALITY WITH ESSURE CANNOT BE ASSESSED. THIS CASE WAS REGARDED AS INCIDENT, AS ALTHOUGH THE REASON FOR SALPINGECTOMY WAS NOT SPECIFIED; A SURGICAL INTERVENTION WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 02-NOV-2015: ESSURE HEALTH CARE PROVIDER PREGNANCY QUESTIONNAIRE RECEIVED. PATIENT WAS GRAVIDA 6, PARA 4, ABORTION 2 AND HAD PREVIOUS C-SECTION. NO PREVIOUS GYNECOLOGICAL INTERVENTIONS, PROBLEMS OR PROCEDURES. NO RELEVANT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01377	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/8/2011
Explant Date (E7): 10/7/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1429, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. THE PROCEDURE WAS PAINFUL AND FOR WEEKS AFTER THE CONSUMER HAD EXTREME PELVIC PAIN AND BLEEDING - SHE WOULD NEVER KNOW WHEN THE BLEEDING WOULD START AND FOUND TO ALWAYS BE PREPARED FOR THAT. THERE WERE DAYS THAT SHE WOULD CALL IN SICK TO WORK AND JUST CURL UP IN A BALL DUE TO THE PAIN. SHE HAD YEAST INFECTIONS, VAGINAL BACTERITIS, BECAME BLOATED AND WAS UNABLE TO LOSE ANY WEIGHT IN SPITE OF EXERCISE AND DIETING REGULARLY. SHE WAS DEPRESSED AND EVEN HAD THOUGHT OF SUICIDE DUE TO THE PAIN. FINALLY IN (B)(6) 2014 SHE WAS BLEEDING MORE IN A MONTH THAN NOT AND SHE STARTED HAVING TROUBLES WITH PELVIC PAIN ALL OF THE TIME. SHE HAD BLOOD WORK DONE AND ALL WAS NORMAL. THE PAP SMEAR SHOWED NO INFECTIONS. SHE TRIED BC (BIRTH CONTROL) PILLS TO CONTROL THE BLEEDING AND IT JUST MADE IT WORSE. ON (B)(6) 2014 SHE HAD A HYSTERECTOMY, INCLUDING THE FALLOPIAN TUBES IN ORDER TO REMOVE THE ESSURE. BY THAT TIME, SHE WAS IN SO MUCH PAIN THAT SHE COULD HARDLY WALK. SHE HAD PELVIC PAIN, CHRONIC INFLAMMATION, ADENOMYOSIS, FIBROIDS AND CYSTS. THE OVARIES WERE LEFT, AND SHE CURRENTLY HAD CYST AGAIN AND WOULD BE BEING CHECKED FOR ENDYOMOSIS (AS REPORTED). SHE HAD DEVELOPED GENERAL ANXIETY DISORDER AND MOOD SWINGS AND FINALLY AFTER WORKING THROUGH THERAPY AND MEDICATION SHE WAS CONTROLLING IT MORE. SHE HAD ULTRASOUNDS AND SHE WOULD HAVE A CT SCAN (COMPUTERIZED TOMOGRAPHY) AND BLADDER BIOPSY FOR BLADDER/ PELVIC PAIN. THE DEVICE WAS GONE BUT THE PAIN AND THE

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AFTER EFFECTS WERE STILL REAL. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 27-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXTREME PELVIC PAIN. SHE HAD A HYSTERECTOMY AND SALPINGECTOMY TO REMOVE ESSURE, 3 YEARS AND A HALF AFTER INSERTION. SHE ALSO HAD BLEEDING MORE IN A MONTH THAN NOT (INTERPRETED AS GENITAL BLEEDING) AND WAS DEPRESSED AND EVEN HAD THOUGHT OF SUICIDE DUE TO THE PAIN. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN AND GENITAL BLEEDING ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENT IS UNLISTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR. IN THIS CASE, THE CONSUMER ALSO HAD ADENOMYOSIS AND FIBROIDS WHICH COULD BE ALTERNATIVE EXPLANATIONS FOR THESE EVENTS, AND THE PAIN DID NOT RESOLVE AFTER HYSTERECTOMY. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENTS, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. DEPRESSION IS THOUGHT TO INVOLVE CHANGES IN RECEPTOR-NEUROTRANSMITTER RELATIONSHIPS IN LIMBIC SYSTEM, PREFRONTAL CORTEX, HIPPOCAMPUS, AND AMYGDALA. CHRONIC PAIN CAN WORSEN DEPRESSION SYMPTOMS AND IS A RISK FACTOR FOR SUICIDE IN PEOPLE WHO ARE DEPRESSED. IN THE OTHER HAND, PEOPLE WITH MORE SEVERE DEPRESSION FEEL MORE INTENSE PAIN. IN THIS CASE, CONSUMER HAD PELVIC PAIN AND REPORTED THAT SHE WAS DEPRESSED AND EVEN HAD THOUGHT OF SUICIDE DUE TO THE PAIN. THERE WAS NO MENTION TO AN ACTUAL SUICIDAL ATTEMPT. THE CONSUMER ALSO HAD OTHER PSYCHIATRIC CONDITION (GENERAL ANXIETY DISORDER). IT IS UNLIKELY THAT THE PAIN WAS THE ONLY TRIGGER FOR THE DEPRESSION, HOWEVER A CONTRIBUTORY ROLE CANNOT BE EXCLUDED; THEREFORE, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED AND HYSTERECTOMY WITH SALPINGECTOMY WERE PERFORMED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01378	BAYER HEALTHCARE LLC	11/4/2015	11/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1324, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER STATED THAT SHE RECEIVED PHYSICAL THERAPY AND MULTIPLE STEROID INJECTIONS IN HER SPINE FOR TWO YEARS, LATER TO FIND THAT IT WAS THE RESULT OF HER ESSURE COILS MIGRATING OUT OF FALLOPIAN TUBES AND INTO OTHER PARTS OF HER BODY. ONE WAS PRESSING ON HER SCIATIC NERVE AND PREVENTING HER FROM PICKING UP HER BABY FOR TWO YEARS AND THE OTHER WAS EMBEDDED IN HER UTERUS AND HAD TO BE CUT OUT. SHE SUFFERED FOR TWO YEARS AND WENT TO 3 DOCTORS BEFORE SHE FOUND A DOCTOR THAT DIDN'T SAY IT WAS ALL IN HER HEAD AND THAT ESSURE WAS PERFECTLY SAFE. SHE HAD SURGERY TO REMOVE THE COILS AND RODS WHICH HAD BOTH SEPARATED IN HER BODY AND THE SURGERY LEFT KELOID SCARS ON HER LOWER ABDOMEN. FOLLOW UP RECEIVED ON 26-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY

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DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. HER ESSURE COILS MIGRATED OUT OF FALLOPIAN TUBES, ONE WAS PRESSING HER SCIATIC NERVE (INTERPRETED AS DEVICE DISLOCATION AND SCIATIC NERVE COMPRESSION) AND OTHER WAS EMBEDDED IN HER UTERUS AND HAD TO BE CUT OUT. SHE HAD SURGERY TO REMOVE THE COILS. IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, ONLY THE SCIATIC NERVE COMPRESSION IS UNLISTED. IN THIS PARTICULAR CASE, THE CONSUMER STATED THAT ONE ESSURE COIL WAS COMPRESSING THE SCIATIC NERVE. CONSIDERING THAT THE OCCURRENCE OF THIS EVENT IS IMPLAUSIBLE, IT IS NOT POSSIBLE TO DETERMINE WHAT HAS IN FACT OCCURRED AND THEREFORE, IT IS NOT POSSIBLE TO ASSESS THIS EVENT AT THIS TIME. IN CONTRAST, A DEVICE EMBEDMENT IN THE UTERUS MAY OCCUR. THUS, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057601	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER GETTING ESSURE I HAVE HAD ABDOMINAL PAIN ALL MONTH LONG AND VERY RECENTLY LOWER BACK PAIN. DON'T REMEMBER EXACT DATE HAD THEM IMPLANTED

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057602	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SOON AFTER HAVING ESSURE IMPLANTED, MY PERIODS CEASED. THE LIST OF SIDE EFFECTS WILL BE LONG, I HAVE HAD PROBLEMS WITH RAPIDLY DETERIORATING TEETH. NOW NEEDS ROOT CANALS AND CROWNS. BRAIN FOG, DEPRESSION AND SEVERE BOUTS OF ANXIETY, HIP AND PELVIC PAIN. EXCRUCIATINGLY PAINFUL SEX. I HAVE NOT BEEN ABLE TO HAVE SEX IN NEARLY 3 YEARS. BODY ACHES, INABILITY TO CONCENTRATE AND CONFUSION, BLOATING, SWELLING, NIGHTSWEATS; HIGH AND LOW BLOOD PRESSURE, ARTERIAL FIBRILATION. THIS IS ALL I CAN REMEMBER NOW, THERE ARE MORE SYMPTOMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057603	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 12/4/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE IMPLANTED IN BOTH TUBES, ONE SIDE MIGRATED AND SITS IN MY PELVIC PERITONEAL AREA. SUBSEQUENT COIL IMPLANTED AND CRYOABLATION PERFORMED TO STOP HEAVY MENSES. THIS COIL HAD ALSO MIGRATED AND PUNCTURED MY UTERUS, CRYO FLUID SEEPED THROUGH SINGING 6 INCHES OF SMALL INTESTINE. HAD EMERGENCY BOWEL RESECTION, CLOSE TO COLOSTOMY BAG. APPROXIMATELY A MONTH IN TOTAL IN THE HOSPITAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057604	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GASTRO ISSUES, FLUTTER OR VIBRATING FEELING IN THE LOWER ABDOMEN, HAIR DRYNESS AND HAIR COMING OUT IN LARGE AMOUNTS WHEN BRUSHING

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057605	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN AND CONTINUOUS BLEEDING. INSOMNIA, ANXIETY ATTACKS AND DEPRESSION. AUTOIMMUNE CONDITIONS: LUPUS, RM AND MS. MIGRAINES. WEIGHT GAIN. DIFFICULTY LOSING WEIGHT. THYROID CANCER. RASHES. METAL TASTE IN MOUTH. CHRONIC SINUS INFECTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057606	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/24/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRP LEVEL CONTINUALLY RISING AND CURRENTLY AT 18. ABDOMINAL BLOATING AFFECTS MY QUALITY OF LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057607	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 11/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE IMPLANTED ALONG WITH ABLATION ON (B)(6) 2011. WOKE UP WITH A SEVERE HEADACHE ON (B)(6) 2011 AND HAVE HAD A HEADACHE EVERYDAY SINCE. ALSO SEVERE STABBING PAINS IN MY LOWER PELVIC AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057608	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/10/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD HYSTERECTOMY ON (B)(6) 2015 TO REMOVE ESSURE AND ALLEVIATE THE CONTINUOUS PROBLEMS FROM IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057609	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 11/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING SHARP INTENSE PAINS THAT DROP ME TO MY KNEES. AS WELL AS PAINFUL SEX, AND ABNORMAL PERIODS; WHEN CRAMPING, FEELS LIKE LABOR PAINS AND BLEEDING IS WAY MORE INTENSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057610	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WENT TO DOCTOR FOR A REALLY SHARP PAIN IN PELVIC AREA. IT HURT TO EVEN WALK. ENDED UP DOING AN ULTRASOUND THE NEXT DAY. THEY CALLED ME THE FOLLOWING DAY TELLING ME SOMETHING WAS PERFORATING MY UTERUS. I JUST HAD SURGERY (B)(6) 2015 AND GOT MY COILS AND TUBES REMOVED. I WAS TRYING TO AVOID SURGERY AND NOW I ENDED UP IN SURGERY. I HATE MISSING WORK THIS CLOSE TO HOLIDAYS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057612	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 9/6/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT ABDOMINAL PAIN, BLOATING, PAINFUL SEX, MEMORY LOSS, LACK OF CONCENTRATION, MUSCLE SPASMS /PAIN, JOINT PAIN, LACK OF SEX DRIVE, NICKEL ALLERGY, CHRONIC FATIGUE, INSOMNIA

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057613	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE PAIN AND SWELLING SINCE THE IMPLEMENTATION OF ESSURE. NOT ONLY THAT BUT JABBING PAIN ON MY LEFT SIDE OF MY UTERUS ALONG WITH CHRONIC BLEEDING AND CLOTTING DURING PERIODS. MY CYCLE IS NOW ONLY 14-18 DAYS A PART, AND I BLEED EXTREMELY HEAVY FOR 4-5 DAYS. I ALSO AM EXTREMELY EXHAUSTED EVERYDAY. MY GUMS SPORADICALLY BLEED AND I ALSO HAVE THINNING HAIR. MY INSURANCE COVERED PART OF MY PROCEDURE FOR ESSURE. THE SIDE EFFECTS OF ESSURE WERE NOT DISCLOSED TO ME AND I FEEL LIED AND DUPED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057614	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 4/6/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, BLOATING, FATIGUE AND CONSTANT BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057615	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON GOING LIGHT BLEEDING, ON GOING PAIN IN PELVIC AREA, PAIN DURING SEX, PAIN DURING BOWL MOVEMENT, CYSTS ON OVARIES, SLEEPLESS NIGHTS, BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057616	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 12/23/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD EXTRA COIL AND THEY PERFORATED THROUGH MY TUBES CAUSING 3 SURGERIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057617	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 11/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCESSIVE WEIGHT GAIN, SEVERE STOMACH PAINS, HAIR LOSS, HEAVY MENSTRUAL CYCLE, SEVERE BACK PAIN, DEPRESSION, ANXIETY, SEVERE MOOD SWINGS, ACNE, PAINFUL BLOATING, CHRONIC FATIGUE, UNEXPLAINED SICKNESS, ENDOMETRIOSIS, 2 OVARIAN CYSTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057618	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL MENSTRUATION, CRAMPS FROM ABDOMINAL TO LEGS, LOWER BACK PAIN, CLUSTER HEADACHES, HEAVY BLEEDING, BLOATING, CONTRAPTION, INSOMNIA, BODY ACHES, JOINT PAIN, HOT FLASHES, HAIR LOSS, EXTREME MOOD SWINGS, TOOTH DECAY, CHEST PAINS, PALPITATIONS, FORGETFULNESS, FATIGUE, ANXIETY, DISCHARGE, ELEVATED WBC, NEUTROPHILS, LYMPHS, CRP, AND PLATELETS WITH NO INFECTION BLOOD TEST TO SHOW FOR OVER A YEAR. SWOLLEN GLANDS, WEIGHT GAIN OF 20 PLUS POUNDS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057619	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 4/18/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RANDOM SPASMS IN REPRODUCTIVE AREA, HAS BEEN ON BOTH SIDES BUT NOT AT THE SAME TIME. THESE SPASMS HAVE INCREASED IN NUMBER OVER THE YEARS AND WENT FROM AT LEAST ONE A DAY TO 20+ A TIMES, A MAJORITY OF THE WORST ONES HAPPENING AT NIGHT BECAUSE I AM FORCED AWAKE BY PAIN. WITHIN 2 MONTHS AFTER GETTING THE DEVICE I GAINED 30 LBS AND THOUGH I HAVE A HEALTHY DIET AND EXERCISE ROUTINE, THE DOCTOR SAYS THIS IS NOT BECAUSE OF ESSURE BUT HORMONES. THIS DEVICE WAS PARTIALLY PROVIDED BY INSURER. IT WAS (B)(6), I HAD TO PROVIDE OVER (B)(6) FOR IT. CURRENTLY, DOCTORS DO NOT ATTRIBUTE MY PAINS TO THE DEVICE AND SAY IT IS STRESS. I CANNOT FIND A DOCTOR WHO WILL TAKE MY PROBLEMS SERIOUSLY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057620	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 4/11/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MISCARRIAGE, WEIGHT GAIN, LOW VITAMIN D, DEPRESSION. PAIN DAILY IN THE ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057621	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 9/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN WHAT SHOULD HAVE BEEN MY NORMAL PERIOD. I HAVE BEEN BLEEDING EVER SINCE. HEAVY AT TIMES. HAVE GAINED 20+ POUNDS IN JUST 30 DAYS. BREASTS ARE SORE ALL THE TIME. SOME ABDOMINAL DISCOMFORT. STOMACH AND ABDOMINAL AREA IS CONSTANTLY BLOATED. VERY FATIGUED. FORGETFUL AT TIMES. DEPRESSED. HUSBAND HAS BEGUN GETTING RASH IN HIS GROIN AREA AFTER SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057622	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OVERALL BODY ACHES (FLU-LIKE), WEAKNESS, CHRONIC FATIGUE, DEPRESSION, BLOATING, DISTENDED ABDOMEN, ONGOING BLEEDING, HEAVY BLEEDING, PAINFUL CRAMPING, GALLBLADDER PAIN, WATER RETENTION, WEIGHT GAIN, FAINTING, ARM AND FEET SWELLING, PAINFUL HANDS AND ARMS, NO LONGER CAN TOLERATE FOOD WITHOUT FEELING PAIN. I'VE LOST MY JOB AS A NURSE DUE TO WEAKNESS AND PAIN. I'VE FAINTED WALKING WITH MY KIDS LEAVING THEM AND ME IN UNSAFE SITUATIONS. I'VE GONE TO THE ER SEVERAL TIMES FOR PAINFULLY SEVERE BLEEDING AND CRAMPING. I WILL BE GETTING MY UTERUS AND TUBES REMOVED (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057623	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 2/15/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, WEIGHT GAIN, UNUSUAL PERIODS, HEADACHES, SKIN PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057624	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 9/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING AND ACHING PAINS THROUGHOUT THE DAY IN ABDOMEN AND PELVIC AREA. INSOMNIA. HEAD ACHE. JOINT PAIN. BLOATING, GAS, CONSTIPATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057625	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, TIREDNESS, HEADACHE, RECTUM BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057626	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 7/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VERY BAD CLOTTING, PELVIC PAIN, MIGRAINES, DENTAL ISSUES, HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057627	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN THIS ON AND OFF ITCHING WITH NO RASH. IT CONTINUED TO BE INTERMITTENT FOR ABOUT A YEAR AND HALF. IT THEN BECAME MORE INTENSE AND MORE AND MORE FREQUENT. ALSO IN THE PAST MONTH, I HAVE HAD A RASH AND HIVES TO GO ALONG WITH THE INTENSE NONSTOP ITCHING. I HAVE ALSO STARTED HAVING PELVIC PAIN AND HEAVY MENSTRUAL CYCLES THAT I HAVE NEVER HAD BEFORE. I HAVE SEEN MANY SPECIALIST AND TAKEN MANY MEDICATIONS IN AN ATTEMPT TO STOP THE ITCHING. IT IS SO BAD THAT I HARDLY SLEEP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057628	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 4/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN THIS DEVICE WAS IMPLANTED I EXPERIENCED EXCRUCIATING PAIN ON MY LEFT SIDE (TUBE) TO THE POINT I HAD TO BE ADMITTED INTO THE HOSPITAL AND THE PINCHING SENSATION NEVER GOES AWAY, I HAVE EXPERIENCED CYCLES SO HEAVY THAT I BECOME FAINT AND WEAK. WITH BLOOD CLOTS SO BIG THAT IT LOOKED LIKE A SLAB OF LIVER... HEADACHES, BACK PAIN EXCRUCIATING CYCLES... HAIR LOSS, WEIGHT GAIN, BLOATING, LEGS AND FEET SWELLING, YEAST INFECTIONS, PAINFUL INTERCOURSE, URINARY TRACT INFECTIONS, AN ODOR AND A DISCHARGE... STABBING FEELINGS IN MY VAGINA FOR NO REASON SINCE HAVING THESE DEVICES PUT IN... MY BREAST GET SORE AND HEAVY, CRAMPING STARTS FOR NO REASON, NIGHT SWEATS, INABILITY TO CONTROL MY BLADDER AT TIMES OF ONSET OF CYCLE. NO INSURER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057631	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING JOINT PAIN, SEVERE HEADACHES, BODY RASH, BLOATING, CONSTIPATION, EARLY ONSET MENOPAUSE LEADING TO FULL MENOPAUSE. SENSITIVITY TO TEMPERATURE CHANGES WHICH CAUSES HIVES. FORGETFULNESS OR FOGGY THOUGHTS. DEPRESSION, LOSS OF SEX DRIVE, PELVIC PAIN AND PAINFUL INTERCOURSE. HAIR LOSS OR SEVERE THINNING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057633	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 12/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE PLACED (B)(6) 2013 3 MONTHS AFTER LAST PREGNANCY. DURING THE 3 MONTH PERIOD AFTERWARDS WAS ON BIRTH CONTROL PILLS BY (B)(6) NOTICED BEHAVIORAL PROBLEMS. BEGINNING IN DECEMBER STOPPED BIRTH CONTROL THOUGHT IT WAS CAUSING THE MOOD SWINGS. FROM THEN AND UNTIL (B)(6) MOOD SWINGS AND BEHAVIOR ONLY GOT WORSE. IN (B)(6) FINALLY WENT TO REGULAR DR AND WAS DIAGNOSED WITH DEPRESSION AND ANXIETY. NEVER HAD THIS ISSUE BEFORE. ON MEDS FOR 9 MONTHS DR. WEANED ME OFF AND BY 6 WEEKS I WAS MISERABLE AND MY DEPRESSION AND ANXIETY WAS WORST THAN IT WAS BEFORE. I AM NOW BACK ON MEDS BUT STILL HAVE SOME DAYS WITH MAJOR SWINGS IN MOODS. MY PERIODS ARE CRAMPS WITH VERY HEAVY BLEEDING (SUPER TAMPON AND HEAVY PAD) WITH IN LESS THAN AN HOUR FOR 3 TO 4 DAYS. AT END OF PERIOD HALF DOLLAR TO QUARTER SIZE CLOTS SOMETIMES BIGGER. NEVER HAD ANYTHING LIKE THIS BEFORE EITHER. I AM ALSO UNABLE TO LOSE THE WEIGHT FROM MY PREGNANCY, ONCE I HAD ESSURE PUT IN MY WEIGHT HAS BEEN STUCK. I WAS ABLE TO LOSE 5 POUNDS ONCE ON MEDS BUT CAN'T LOSE THIS WEIGHT LIKE I HAVE BEEN ABLE TO AFTER MY OTHER PREGNANCY'S.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057640	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'D GOTTEN ESSURE PLACED (B)(6) 2011. I WAS TOLD BY THE INSERTING DOCTOR IT WAS SAFER THAN TUBAL LIGATION AND THAT IT WAS NONINVASIVE AND REVERSIBLE. HE TOLD ME THAT 2 "COPPER" COILS WOULD BE PLACED IN MY FALLOPIAN TUBES, MY BODY WOULD CREATE SCAR TISSUE AROUND THEM, AND I WOULDN'T HAVE ANY SIDE EFFECTS BECAUSE IT IS NOT HORMONAL. AFTER MY INITIAL VISIT WITH HIM, I CAME HOME AND TRIED TO FIND SOME REVIEWS ONLINE. I DIDN'T FIND ANY NEGATIVE INFORMATION AT THAT TIME SO I OPTED INTO GETTING ESSURE. AFTER GETTING ESSURE PLACED, I STARTED SPOTTING AND CRAMPING, WHICH IS "NORMAL" I'M TOLD. I WAS TOLD I COULD RETURN TO WORK THE NEXT DAY. I NEVER WAS ABLE TO RETURN TO WORK. I STARTED EXPERIENCING RANDOM SHARP PAINS IN MY PELVIC AREA AND MY ANUS. I STARTED HAVING INTERMITTENT BLEEDING RANDOMLY WHEN I SNEEZED OR WHEN I WORE A BELT. THEN CAME THE HEAVY DEBILITATING MENSTRUAL CYCLES. MY CYCLES WERE TOO HEAVY TO LEAVE THE HOUSE ON DAY 2 AND 3 OF MY PERIOD. I HAD TO WEAR BOTH A SUPER PLUS TAMPON AND AN OVERNIGHT MAXI PAD AND BUT WOULD HAVE TO BE CHANGED WITHIN THE HOUR EVERY HOUR. I STARTED BLEEDING GOLF BALL SIZED CLOTS. MY MENSTRUAL CYCLES DRAINED ME OF MY ENERGY SO BAD THAT IT WOULD TAKE THE WHOLE MONTH TO RECOVER AND THEN IT WOULD BE TIME TO GO THROUGH THE CYCLE ALL OVER AGAIN. I HAD EXTREMELY PAINFUL OVULATION IN WHICH MY COLON FELT LIKE IT WAS BEING PUT THROUGH A MEAT GRINDER. THIS WAS ONLY THE BEGINNING. AT THIS POINT, I'D LOST MY CAREER AS A NURSE AND I WAS STARTING TO LOSE MY FAMILY. ONE MORNING I WOKE UP AN NONE OF MY CLOTHES FIT ME THE SAME, MY ABDOMEN BECAME VERY DISTENDED AND IT WOULD STAY THAT WAY FOR ALMOST 4 YEARS. I BECAME DEPRESSED AND STARTED ISOLATING MY SELF FROM FRIENDS AND FAMILY. I BECAME MOODY. THERE WERE TIMES WHEN MY CHILDREN NEEDED MY HELP OR WANTED ME TO PLAY WITH THEM AND ALL I COULD DO WAS WATCH THEM

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GROW UP IN FRONT OF MY EYES FROM MY COUCH. I GAINED 50 POUNDS. I WAS HAVING CONSTANT MIGRAINES. I'VE BEEN TO THE EMERGENCY ROOM A FEW TIMES FOR CHEST PAINS. I WAS RECENTLY DIAGNOSED WITH TYPE 2 DIABETES WHICH IS ALSO A SIDE EFFECT OF LOW VITAMIN D LEVELS WHICH IS ALSO ASSOCIATED WITH ESSURE. MY VITAMIN D LEVELS WERE DANGEROUSLY LOW. ON TOP OF ALL THAT, MY MEMORY HAD GOTTEN REALLY BAD. I'VE HAD A TOTAL OF 6 TEETH PULLED AND MY EYESIGHT DRASTICALLY DECLINED. THE LAST FOUR YEARS WERE THE WORST FOUR YEARS OF MY LIFE. MY SITUATION DIDN'T CHANGE UNTIL (B)(6) 2015. I HAD A TOTAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY. I AM NOW FOUR WEEKS POST OP AND I FEEL BETTER THAN I'VE FELT IN YEARS. I'VE LOST 13 POUNDS AND I HAVE WAY MORE ENERGY. NOW I CAN BE AN EFFECTIVE WIFE AND MOTHER. I STILL HAVE SOME PAINS DUE TO DAMAGE CAUSED BY ESSURE BUT NOT LIKE BEFORE. I NO LONGER GET LIGHTHEADED, DIZZY, AND SHORT OF BREATH JUST BY WALKING UP THE STAIRS. MY ABDOMEN IS NO LONGER BLOATED AND DISTENDED. I FEEL THAT DOCTORS AREN'T TRAINED WELL ENOUGH TO INSERT ESSURE AND THERE SHOULD BE SURVEYS AND TESTS TO SEE IF A PERSON IS A LIKELY CANDIDATE TO GET ESSURE. BETTER YET, ESSURE SHOULD BE PULLED OFF MARKET. I HAVE AN ALLERGY TO NICKEL AND I HAD PELVIC INFLAMMATORY DISEASE WHEN I WAS 17 SO MY DOCTOR SHOULD HAVE KNOWN THAT I SHOULDN'T HAVE GOTTEN ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057641	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 6/7/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE BEING IMPLANTED WITH THE COILS, I HAVE HAD NUMEROUS HEALTH ISSUES. I HAVE EXCESSIVE BLEEDING, WHICH HAS RESULTED IN A DRASTIC DROP IN MY BLOOD LEVELS DOWN TO 9 PINTS TWO YEARS AGO. TODAY'S LEVELS ARE UNKNOWN. OTHER SYMPTOMS INCLUDE HAIR LOSS, PELVIC PAIN, LOSS OF MEMORY, AND EXTREME FATIGUE. I AM ALSO ALLERGIC TO NICKEL, WHICH IS THE PRIMARY METAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057642	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS PLACED AROUND (B)(6) 2013, PAID FOR BY MY (B)(6). THE DAY I GOT ESSURE, I WAS GIVEN MEDS TO TAKE, THEY SAID THEY MEDS WOULD "KNOCK THE EDGE OFF". HOWEVER, DURING THE PROCEDURE, THE PAIN WAS VERY BAD AND CONTINUED THAT WAY FOR ABOUT THREE DAYS. EVERYTHING SEEMED TO HAVE CALMED DOWN AND GOING GOOD BUT THEN, ABOUT TWO WEEKS LATER, I BROKE OUT IN A RASH ALL OVER MY FACE, NECK, ARMS, AND STOMACH. NOTHING HAD CHANGED IN MY WAY OF LIVING EXCEPT FOR GETTING ESSURE. THE RASH LASTED ABOUT A WEEK THEN SLOWLY WENT AWAY. I DIDN'T HAVE MY PERIOD FOR ALMOST 4 MONTHS BUT WHEN I DID FINALLY START MY PERIOD LASTED FOR ALMOST TWO MONTHS. IT WASN'T HEAVY, BUT VERY CONSISTENT AND PAINFUL AT TIMES. THIS PATTERN WENT ON FOR THE FIRST YEAR THEN FINALLY REGULATED ITSELF. AFTER THE FIRST YEAR, I STARTED HAVING SEVERE PAINS IN MY ABDOMEN DURING AND OFF MY PERIOD. THE PAINS GET SO BAD THAT I HAVE TO TAKE OFF WORK, MY KIDS HAVE MISSED SCHOOL, AND I LAY IN BED OR SIT UP DOUBLED OVER BECAUSE WHEN THE PAIN HITS I CAN'T HARDLY MOVE. WHEN I HAVE A BOWL MOVEMENT THE RIGHT SIDE OF MY ABDOMEN HURTS SO BAD THAT I GET HOT FLASHES AND FEEL LIKE I'M GONNA VOMIT. SINCE GETTING ESSURE, I HAVE EXTREME BACK PAIN THAT PREVENTS ME FROM BEING ABLE TO DO SIMPLE HOUSE HOLD CHORES LIKE BENDING OVER AND PICKING UP THE DIRTY CLOTHES BASKET, SWEEPING AND MOPPING THE FLOOR, AND CARRYING IN GROCERIES. I HAVE HAD A MISCARRIAGE, HEAD ACHES, AND DEPRESSION, WHICH IS SO BAD THAT I'VE ALMOST COMMITTED SUICIDE. THE DEPRESSION, MISCARRIAGE, BACK PAIN AND ABDOMEN PAIN, AT THIS POINT IN TIME, ARE THE FOUR WORST THINGS I'M DEALING WITH. WHEN I AGREED TO HAVE ESSURE, I THOUGHT IT WAS GOING TO PREVENT MY FAMILY FROM GROWING, NOT MAKE ME

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HAVE DEPRESSION SO BAD THAT I FEEL LIKE TAKING MY OWN LIFE, OR PAIN IN BACK SO BAD THAT I CAN BARELY GET OUT OF BED SOMETIMES, HAVE A MISCARRIAGE, HAVE ABDOMEN PAIN SO SEVERE THAT I CAN'T TAKE CARE OF CHILDREN, ECT..

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057643	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASH ALL OVER MY BODY, BLOOD CLOT, HEAVY 9MONTH PERIOD, VERY TIRED NO ENERGY, UTI, PAINFUL DURING INTERCOURSE, PAIN IN LOWER ABDOMEN, FOGGY WITH DECISIONS, LEGS GOING TO SLEEP EASY, PAIN IN LOWER BACK, SORE BREAST, NO SEX DRIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057645	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED IN (B)(4) 2013, AND I HAVE THE FOLLOWING SIDE EFFECTS HEADACHES MY FEET KEEP GETTING SWOLLEN I WAS JUST HOSPITALIZED FOR 7 DAYS WITH BLADDER N KIDNEY INFECTION AND NOW THEY SAYING THAT I MAY HAVE (B)(6) (SOMETHING WITH MY LIVER) MY HAIR BEEN FALLING OUT ALL SIDE EFFECTS OF THIS DAMN ESSURE. IT WAS PROVIDED BY MY INSURER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057646	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS A14901 MY MODEL NUMBER IS ESS306 IF YOU KNOW IT. THIS DEVICE HAS A THREE YEAR SHELF LIFE; HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2012 THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. 1. SEVERE PAIN ALL OVER MY BODY, MY HIPS, LEGS, ARMS, HANDS, BACK, JOINT PAIN. 2. SWELLING/PAIN, NUMBNESS OR SHOOTING PAIN IN ARMS OR LEGS, SPASMS, CRAMPS IN CALVES AND FEET. 3. SEVERE PELVIC PAIN. 4. HAIR LOSS. 5. PAIN DURING INTERCOURSE. 6. SEVERE MIGRAINES. 7. FATIGUE TO THE POINT WHERE I CAN'T GET OUT OF BED. 8. SEVERE PAIN DURING MENSTRUAL PERIODS. 9. SHOCK, OR TWITCHING TYPE FEELINGS IN MY PELVIC AREA. I HAVE BEEN SEEN BY 2 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS FIBROMYALGIA. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057647	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 4/21/2010	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, NAUSEOUS ALL THE TIME , NO ENERGY, ABDOMEN PAIN , RASHES , SALIVATING OF THE MONTH, METALLIC TASTE, MUSCLE CRAMPING .

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057669	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING PAIN TIREDNESS BRAINFOG THEN HAD A ABLTION WHICH HELPED THE BLEEDING BUT STILL HAVE CONSTANT CRAMPS AND IRREGULAR PERIODS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057681	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 10/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE SUFFERED FROM EXTREME FATIGUE , WEIGHT GAIN, SEVERE STOMACH BLOATING, DEBILITATING BACK AND PELVIC PAIN WHICH I WAS ADVISED WOULD SUBSIDE IN A FEW DAYS HERE IT IS 6 YEARS LATER AND I AM STILL SUFFERING BACK AND PELVIC PAIN AND NO ONE CAN HELP WITH, I ALSO SUFFER WITH BRAIN FOG , RINGING IN EARS (PULSATILE TINNITUS) DEPRESSION VITAMIN D DEFICIENCY, VITAMIN B-12 DEFICIENCY, FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, UNEXPLAINED BRUISING, AMENORRHEA, HAIR LOSS, AND A METALLIC TASTE IN MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057682	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I CHOOSE ESSURE AFTER DOING A LOT OF RESEARCH FOR PERMANENT STERILIZATION. IT WAS FULLY COVERED BY INSURED, SUPPOSED TO BE NONINVASIVE, WITH NO TIME OFF WORK. MY PROCEDURE WAS DONE IN THE DRS OFFICE BY TWO WOMAN WHO SEEMED TO BE VERY APPREHENSIVE AND NOT TOO CONFIDENT. NEITHER WERE MY REGULAR OBGYN. THE ONE SIDE WENT IN CORRECTLY AND INSERTED DEEP ENOUGH INTO TUBE. THE OTHER BARELY WENT IN AND THEIR COUNT OF REMAINING COIL AND MINE WERE DIFFERENT. I WAS UNDER IMPRESSION THE COILS WERE MORE PLASTIC NOT A SOLID METAL DEVICE THAT COULD BE SO DAMAGING. HORRIBLE BACK PAIN DURING PERIODS. HEAVY BLEEDING THAT TOOK FOREVER TO REGULATE. BLEEDING WEEKS AT A TIME. BAD MIGRAINES SOMETIMES SEVERAL IN A MONTH AND BEFORE THEY WERE VERY RARELY. PAINFUL SEX AND NO SEX DRIVE ANYMORE, THIS WAS THE EXACT OPPOSITE PRIOR TO PROCEDURE. FATIGUE, BRAIN FOG, AND HORMONES ARE ALL OUT OF WHACK. IF YOU ASKED ME I FEEL LIKE IT'S PUSHED ME INTO OR MENOPAUSE AT (B)(6). ANOTHER REASON WHY I CHOOSE ESSURE INSTEAD OF LOOSING OVARIES. MY LEFT SIDE IS VERY TENDER AND IF PRESSED UP AGAINST, TOUCHED OR WITH SEX I GET SHARP PAINS. MY (B)(6) PUPPY WALK ACROSS TUMMY AND MAKES ME CRY FROM THE PAIN OVER MY LEFT OVARY. AT 3MONTH DYE CHECK UP THE TUBES WERE BLOCK AND THE OTHER HANGING WELL INTO UTERUS. (NOT SURE OF APPROPRIATE/ACCEPTABLE DEPTH) WHAT ARE THEY GOING TO DO THOUGH?!?! HAVE SURGERY AND TRY AGAIN, IT'S A ONE SHOT DEAL, YOU CAN'T FIX THE LEFT SIDE THAT ISN'T IN CORRECTLY. NOW I'LL HAVE TO RISK IT COMING OUT IF IT HASN'T ALREADY, RISK OF PERFORATION, PREGNANCY, PAIN, AND POSSIBILITY OF FUTURE SURGERY THAT WILL PUT ME OFF WORK TO FIX. ALL THAT I TRIED TO AVOID. NOT TO MENTION THE STRESS AND PAIN I AM CONSTANTLY IN. I SHOULD HAVE GONE WITH TUBAL LITIGATION OR PARTIAL HYSTERECTOMY AND NOT HAD THIS MESS. MY DOCTOR HAS SCHEDULED AN

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ULTRASOUND TO INVESTIGATE WHY THE PAIN IS GETTING WORSE. MY HUSBAND WANTS THE OLD ME BACK AND SO DO I. WISH I COULD GO BACK AND MAKE THAT DECISION AGAIN, HAVE ENERGY, PAIN FREE, NO STRESS. I HAVE A LOT OF OTHER SYMPTOMS THAT OTHER WOMAN HAVE THAT COULD BE ESSURE RELATED AS WELL. THESE LISTED ARE THE ONES THAT ARE THE WORST AND MOST TROUBLESOME FOR ME THOUGH. WOULD LIKE TO HAVE THEM FULLY REMOVED WITH PARTIAL HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057683	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 1/14/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER PLACEMENT OF THE DEVICE ((B)(6) 2010) I BEGAN TO HAVE PAINFUL PERIODS 8 MONTHS LATER. ((B)(6)2011) IT HAS NOW BEEN 5YEARS SINCE HAVING ESSURE IMPLEMENTED INSIDE MY TUBES. I NOW HAVE HORRIBLE PAIN IN MY SIDE'S AS IF SOMETHING IS STABBING ME. I HAVE UNEXPLAINED PAIN IN MY HEAD. SINCE THE DEVICE MY PERIODS IRREGULAR AND EXTREMELY PAINFUL TO THE POINT I HAVE TAKEN 500MG OF NAPROXEN OVER THE LAST 3YEARS TWICE A DAY, 7 DAYS OUT OF EVERY MONTH. I'VE HAD SEVERAL DOCTOR VISITS AND EMERGENCY ROOM VISITS ONLY TO BE MISDIAGNOSED. I FIND IT DISAPPOINTING THAT MYSELF AND 1,000'S OF OTHER WOMEN HAVE THE SAME COMPLAINT AND NOTHING IS BEING DONE TO REMOVE THIS DEVICE OFF THE MARKET. THE ESSURE WAS COVERED BY MY INSURANCE AT THE TIME OF INSERTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057684	BAYER	11/4/2015	11/4/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMPLANT COMPLETED IN 2012. NOTHING BUT HEALTH ISSUES SINCE. CONSTANT PELVIC, HIP AND BACK PAIN. BLOOD AND URINE TESTS WITH HIGH WHITE CELL COUNT WITH NO EXPLANATION. BLOATING, LACK OF LIBIDO. CHRONIC FATIGUE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01347	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3): 10/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C76452

Single Use: Y
Implant Date (E6): 10/10/2014
Explant Date (E7): 6/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER FROM UNITED STATES ON 07-OCT-2015. A REIMBURSEMENT CLAIM WAS PROVIDED AND THE CASE CONSIDERED POTENTIAL LEGAL. CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER C76452 INSERTED ON (B)(6) 2014 FOR PERMANENT CONTRACEPTION. CONSUMER'S MEDICAL HISTORY INCLUDED POSTPARTUM STATE, VAGINAL SPOTTING, AND BREAKTHROUGH BLEEDING. A SONAR FROM INCLUDED (B)(6) 2014 INCLUDED OVARIAN CYST 2.8 AND A PAP TEST FROM THE SAME DAY INCLUDED (B)(6) HIGH RISK INTERP / OTHER GENOTYPES - (B)(6). DEPO PROVERA WAS USED AS CONCOMITANT MEDICATION. AT INSERTION, ONE RING WAS SEEN ON RIGHT SIDE AND 2 ON THE LEFT. ON (B)(6) 2014, CONSUMER WAS COMPLAINING OF BLEEDING AND PREMARIN WAS GIVEN. ON (B)(6) 2014, AT OFFICE VISIT, CONSUMER WAS COMPLAINING OF HEAVY BLEEDING TWICE A MONTH, CONTINUOUS BLEEDING, DAILY BLEEDING, FATIGUE, CRAMPING DAILY. SONAR WAS PERFORMED AND SHOWED OVARIAN CYST 2.8. PLANS INCLUDED: CYCLE ON ORAL CONTRACEPTIVES X 3 MONTHS. DOXYCYCLINE PRESCRIBED FOR ENDOMETRITIS; AND CBC. ON (B)(6) 2015, AN ESSURE WAS EXPELLED. ON (B)(6) 2015, AT OFFICE VISIT, IT WAS STATED SPOTTING ALL MONTH WITH ORAL CONTRACEPTIVES. IT WAS REPORTED: CRAMPING, BLEEDING, PASSED THE ESSURE TISSUE. A SONAR WAS PERFORMED AND SHOWED L OVARIAN CYST NEW 2.3X2.3X2.5. PREVIOUS L OVARIAN CYST 2.1X2.5X2.7CM. ES=0.29G. IDENTIFIED THE ESSURE ON LEFT BUT NOT ON RIGHT. TC FROM RADIOLOGIST INCLUDED PATENT RIGHT TUBE AND BLOCKED LEFT TUBE. ON (B)(6) 2015, HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND SHOWED PATENT RIGHT TUBE. LEFT SIDED ESSURE MICRO INSERT IN PLACE WITH OCCLUSION OF LEFT FALLOPIAN TUBE. ON (B)(6) 2015, AT OFFICE VISIT, CONSUMER WAS FEELING HORRIBLE, COULD NOT TAKE DEEP BREATH, EPIGASTRIC PAIN OVER ZIPHOID PROCESS, VOMITING, HEADACHE, VAGINAL BLEEDING STOPPED SINCE EXPELLED, BUT

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PELVIC PAIN WAS STILL COMING AND GOING AND WAS MUCH WORSE THAN MENSTRUAL CRAMPS. CONSUMER SAID THIS ALL STARTED WITH THE IMPLANTS AND WANTED THE OTHER ESSURE REMOVED. SHE WAS EXPLAINED HYSTERECTOMY WAS REQUIRED. IMPRESSION: CHRONIC PELVIC PAIN, SX (INTERPRETED SYMPTOMS) OF POSSIBLE STOMACH ULCER (EPIGASTRIC PAIN, NAUSEA, VOMITING) OR CHOLELITHIASIS. OVARIAN CYST. PATENT R TUBE, AND EXPULSION OF ESSURE. PLANS INCLUDED: LABS AND SURGICAL CONSULT. MAY NEED RTL (INTERPRETED RIGHT TUBAL LIGATION), BILATERAL SALPINGECTOMIES, OVARIAN CYST. SED RATE REPORTED: 80 POSSIBLY DUE TO P.I.D., SUCH AS SALPINGITIS/ENDOMETRITIS. ON (B)(6) 2015, SURGICAL CONSULTATION INCLUDED, DYSPHAGIA, NAUSEA AND VOMITING ALSO COMING AND GOING AND WAS ASSOCIATED WITH A DECREASED APPETITE, BUT THERE WAS SOME WEIGHT GAIN. ABDOMEN HAD VAGUE LEFT LOWER QUADRANT TENDERNESS. QUESTIONABLE RIGHT UPPER QUADRANT DISCOMFORT. ON (B)(6) 2015, AT OFFICE VISIT, SYMPTOMS WERE THE SAME: HEADACHES, LOWER BACK PAIN, COULD NOT WALK IN AM, PELVIC CRAMPING. ON (B)(6) 2015, AT OFFICE VISIT, SYMPTOMS CONTINUED, ALSO FATIGUED. REC: RTLH, BILATERAL SALPINGECTOMY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 24-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. IN ADDITION, THE AE CASE REFERS TO A LACK OF EFFICACY (PATENCY). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: LOT NUMBER: C76452; PRODUCTION DATE: 11-JUL-2014; EXPIRATION DATE: 31-JUL-2017. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME ALTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED IN THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP 02-NOV-2015: FOLLOW UP INFORMATION RECEIVED FROM THE HEALTH CARE PROFESSIONAL. HYSTEROSALPINGOGRAM RESULTS FROM (B)(6) 2015 WERE PROVIDED AND THE HCP REPORTED THAT MIGHT HAVE LOST ONE ESSURE. COMPANY CAUSALITY COMMENT: THIS CASE REPORT RECEIVED VIA LEGAL CLAIM REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN / PELVIC PAIN AND BLEEDING (HEAVY BLEEDING X 2 MONTHS / CONTINUOUS AND DAILY BLEEDING). SHE ALSO EXPERIENCED ENDOMETRITIS AFTER A COUPLE OF MONTHS AND LATER, POSSIBLY PID. THESE EVENTS (SEEN AS PELVIC PAIN, GENITAL BLEEDING, ENDOMETRITIS AND PELVIC INFLAMMATORY DISEASE) ARE SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR DURING ESSURE USE. CONSIDERING TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY BETWEEN THESE EVENTS AND ESSURE USE CANNOT BE EXCLUDED. ALTHOUGH ESSURE MAY BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT DURING INSERTION, THIS MOSTLY OCCURS IN THE FIRST 4 WEEKS FOLLOWING ESSURE PLACEMENT. IN THIS CASE, THE ENDOMETRITIS WAS SUSPECTED TWO MONTHS AFTER INSERTION AND PID EIGHT MONTHS LATER. THEREFORE, CAUSALITY BETWEEN THESE INFECTIOUS EVENTS AND ESSURE USE IS VERY UNLIKELY. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED THROUGH THE NORMAL LITIGATION PROCESS BUT WILL NOT BE ACTIVELY PURSUED.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01348	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN (B)(6) 2015 ((B)(4), AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED SHE GOT ESSURE PUT IN AND IT WAS EXTREMELY PAINFUL THEY HAD TO OPEN A SECOND KIT BECAUSE THE COIL THEY TRIED TO PUT IN ONE OF HER TUBES BENT AND COULD NOT BE USED. IT WAS MORE PAINFUL THAN LABOR. SHE WAS SCARED TO BE PUT TO SLEEP THAT WAS WHY SHE CHOSE TO GO WITH ESSURE. NOW SHE WILL END UP HAVING TO BE PUT TO SLEEP FOR A HYSTERECTOMY. THE PAIN THAT SHE HAD TO DEAL WITH DAILY WAS CRAZY. HER PERIODS WERE EXTREMELY HEAVY AND PAINFUL. HER HAIR WAS CONSTANTLY FALLING OUT. SHE HAD A HUGE SWOLLEN STOMACH. SHE HAD HEADACHES EVERY DAY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 24-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON

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THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAVE TO DEAL WITH A CRAZY DAILY PAIN. THIS EVENT, INTERPRETED AS PELVIC PAIN, IS SERIOUS DUE MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE INSERTION WAS VERY PAINFUL. A COIL BENT IN ONE OF HER TUBES AND COULD NOT BE USED AND A SECOND KIT OF DEVICES HAD TO BE OPENED. THEN, SHE HAD TO DEAL WITH THIS CRAZY AND DAILY PAIN. CONSIDERING IMPLIED TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01349	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN (B)(6) 2015 ((B)(4), AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED HER DOCTOR WOULD NOT PERFORM A TUBAL BECAUSE SHE ALREADY HAD SEVERAL SURGERIES OVER THE YEARS AND HE DIDN'T WANT HER TO HAVE ANOTHER ONE. TWO YEARS LATER, SHE HAD THE COILS REMOVED (CERVIX AND ONE OVARY WERE LEFT). AS SOON AS SHE WOKE UP IN RECOVERY SHE FELT A HUGE DIFFERENCE, SHE FELT ABSOLUTELY AMAZING. SHE WAS NOT ALLOWED TO GET UP BECAUSE HER BLOOD PRESSURE DROPPED TO DANGEROUS NUMBERS. SHE STATED WHEN ONE OVARY WAS REMOVED; IT WAS BLACK AND A MESS. ADDITIONALLY, SHE HAD ISSUES WITH ADHESIONS, ENDOMETRIOSIS AND ADENOMYOSIS. SHE STATED THIS WAS AN ADDED SURGERY, ON TOP OF OVER A YEAR OF PAIN AND DEPRESSION. ACCORDING TO HER, SHE WAS ALWAYS TIRED, ANGRY OR HURTING. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 24-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS

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CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN/HURTING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE COILS WERE SURGICALLY REMOVED. ACCORDING TO HER; AFTER THIS SURGERY SHE FELT AMAZING. THIS EVENT, SEEMS AS PELVIC PAIN, IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, MINIMAL INFORMATION WAS PROVIDED. CONSUMER REPORTED PAIN RELATED TO ESSURE INSERTION, WITH IMPROVEMENT AFTER DEVICES REMOVAL. SHE ALSO MENTIONED ENDOMETRIOSIS; ADENOMYOSIS AND SEVERAL UNSPECIFIED PRIOR SURGERIES; WHICH COULD BE ALTERNATIVE EXPLANATIONS FOR HER PAIN. HOWEVER, SINCE LIMITED INFORMATION WAS PROVIDED FOR A COMPREHENSIVE CAUSALITY ASSESSMENT, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE TOTALLY EXCLUDED IN THIS CASE. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01350	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2009
Explant Date (E7): 2/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN (B)(6) 2015 ((B)(4), AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6)-2009. ADDITIONAL INFORMATION RECEIVED ON 24-OCT-2015 (PTC INVESTIGATION RESULT). PRIOR TO HAVING THE DEVICE IMPLANTED THE CONSUMER STATED SHE WAS AN ENERGETIC MOTHER - SHE WAS RARELY SICK AND EXTREMELY ACTIVE IN LIFE. SHE HAD NO CHRONIC ILLNESSES AND HELD A FULL TIME JOB. TWO DAYS AFTER ESSURE THE SEVERE ABDOMINAL PAIN STARTED. WITHIN A WEEK SHE WAS EXPERIENCING CHRONIC MIGRAINE. SHE HAD NO ENERGY AND GETTING UP IN THE MORNING WAS A CHALLENGE, PLAYING WITH HER GIRLS WAS OUT OF THE QUESTION. SHE BEGAN GETTING SICK EASILY OVER AND OVER AGAIN. SHE WOULD CATCH THE FLU, THEN PNEUMONIA, FOLLOWED BY STREP THROAT AND ABOUT THE TIME SHE WAS FEELING BETTER SHE WOULD START GETTING SICK AGAIN. SHE DEVELOPED DERMOGRAPHIA, STARTED EXPERIENCING HEART PALPITATIONS, ANXIETY, NICKEL POISONING THAT AFFECTED HER KIDNEY FUNCTION AND SKIN, SUDDEN EXTREME MOOD SWING, APPENDICITIS, EXTREME WEIGHT GAIN, AND PAINFUL INTERCOURSE. SHE ENDED UP PREGNANT AND LOST THE BABY AT 14 WEEKS DUE TO COMPLICATIONS FROM ESSURE. IN (B)(6)-2013 SHE WAS DIAGNOSED WITH PULMONARY ARTERIOVENOUS MALFORMATION, WHICH WAS A DIRECT RESULT OF A COMPROMISED IMMUNE SYSTEM. ON (B)(6)-2014 SHE UNDERWENT SURGERY TO REMOVE HER FALLOPIAN TUBES, THE ESSURE DEVICE AND ANYTHING THAT THEY HAD COME IN CONTACT WITH. SINCE REMOVAL SHE HAD A DRASTIC REDUCTION IN MOST OF HER SYMPTOMS. SHE HAD ENERGY AND THE HEADACHES WERE MORE MANAGEABLE. HOWEVER, SHE HAD CHRONIC ABDOMINAL PAIN AND HER LUNGS

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WERE PERMANENTLY DAMAGED - SHE WOULD SPEND MOST OF FALL AND WINTER FIGHTING RESPIRATORY INFECTIONS IN VARYING DEGREES. SHE STATED ESSURE FOREVER ALTERED HER QUALITY OF LIFE. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE ABDOMINAL PAIN / CHRONIC ABDOMINAL PAIN. SHE ENDED UP PREGNANT EVEN WITH ESSURE IMPLANTED AND LOST THE BABY AT 14 WEEKS DUE TO COMPLICATIONS FROM ESSURE (SPONTANEOUS ABORTION). SPONTANEOUS ABORTION IS UNLISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE LISTED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. CONSUMER EXPERIENCED ABDOMINAL PAIN 2 DAYS AFTER ESSURE INSERTION. SHE UNDERWENT A SURGERY IN ORDER TO REMOVE HER FALLOPIAN TUBES, THE ESSURE DEVICE AND ANYTHING THAT THEY HAD COME IN CONTACT WITH. FOR THIS EVENT AND FOR PREGNANCY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. IN THIS CASE, THE SPONTANEOUS ABORTION OCCURRED AT 14 WEEKS OF PREGNANCY. ABORTIONS AFTER 12 WEEKS OF PREGNANCY ARE RATHER UNUSUAL. DUE THE ESSURE COILS HANGING INTO THE UTERINE CAVITY, AN IMPACT ON THE AMNIOTIC SAC CANNOT BE EXCLUDED AND THEREFORE THIS EVENT IS CONSIDERED RELATED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01351	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 6/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN (B)(6) 2015 ((B)(4), AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT RIGHT AFTER INSERTION SHE STARTED WITH DEPRESSION, ANXIETY ATTACKS, NUMBNESS IN FACE, ARMS AND LEGS. SHE WAS PRESCRIBED ANXIETY PILLS BECAUSE SHE STARTED TO GET REALLY BAD ANXIETY ATTACKS FOR NO APPARENT REASON. SHE ALSO STARTED TO HAVE BAD MOOD SWINGS, HER PERIODS WERE REALLY HEAVY AND LASTED 7 DAYS, SHE HAD A LOT OF SEVERE BACK PAIN, SHE GAINED 40 POUNDS, GOT A METAL TASTE IN HER MOUTH, HER ARMS LOOKED RED AS SHE HAD HIVES AND SHE FACED VERTIGO MULTIPLE TIMES. IN (B)(6)-2015 SHE GOT ESSURE REMOVED. HER FALLOPIAN TUBES ALSO HAD TO BE REMOVED AS ESSURE COILS WERE EMBEDDED IN HER TUBES. AFTER REMOVAL, HER BACK PAIN WENT AWAY, HER ANXIETY LEVEL GOT BETTER AD HER ARMS WERE NO LONGER RED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 24-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED

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THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD BACK PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICES WERE REMOVED; ACCORDING TO THE CONSUMER, HER FALLOPIAN TUBES ALSO HAD TO BE REMOVED AS ESSURE COILS WERE EMBEDDED IN HER TUBES. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND BACK PAIN MAY OCCUR. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR CONSUMER'S BACK PAIN. NEVERTHELESS, CONSIDERING EVENT'S NATURE AND AS IT IMPROVED AFTER DEVICES REMOVAL; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED COILS EMBEDMENT IN FALLOPIAN TUBES, IT IS UNCLEAR IF CONSUMER WAS REFERRING TO THE EXPECTED ACTION OF ESSURE IN FALLOPIAN TUBES (SINCE ESSURE'S INDUCES A BENIGN OCCLUSIVE TISSUE RESPONSE WITH TISSUE IN-GROWTH INTO AND AROUND THE INSERT; THEREFORE, IF DEVICE REMOVAL IS REQUIRED, THIS WILL LIKELY REQUIRE SURGERY, WITH SALPINGECTOMY AND/OR HYSTERECTOMY) OR IF THE DEVICES WERE PARTIALLY PERFORATING HER TUBES. ALTHOUGH LIMITED INFORMATION WAS PROVIDED; GIVEN EVENT'S NATURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01352	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1230, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. SHE WAS DONE HAVING KIDS AND DID NOT WANT TO HAVE ANY MORE AFTER HAVING TWO PREMATURE BABIES. AT TWO MONTHS SHE WENT TO HAVE THE HYSTEROSALPINGOGRAM (HSG) CONFIRMATION TEST DONE AND HER TUBES WERE NOT BLOCKED BECAUSE DEVICES WERE NOT IN PLACE. THEY COULD ONLY FIND ONE OF HER COILS FLOATING IN UTERUS. TWO WEEKS LATER A CT WAS PERFORMED TO LOCATE THE MISSING COIL AND SHE WAS TOLD ONE OF COILS WAS IN UTERINE WALL. A TRANSVAGINAL LAPAROSCOPIC HYSTERECTOMY WAS PERFORMED. CONSUMER STATED THAT HER DOCTOR COVERED HER MEDICAL BILL FOR THE HYSTERECTOMY AND SAID IT MUST HAVE BEEN A DEVICE MALFUNCTION THAT OCCURRED. ALSO DURING THE THREE MONTHS THAT SHE HAD THE DEVICE, SHE STARTED BREAKING OUT IN ITCHY BUMPS ALL OVER CHEST AREA AND SHE STATED IT WAS NOT WRITTEN ABOUT CHECKING NICKEL ALLERGY WHEN SHE HAD THE PROCEDURE DONE. WHEN IT WAS REMOVED, THE BUMPS CLEARED RIGHT UP. FOLLOW UP RECEIVED ON 24-OCT-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND APPROXIMATELY TWO MONTHS LATER A COMPUTERIZED TOMOGRAPHY (CT) SHOWED ONE OF THE COILS WAS IN THE UTERINE WALL. SHE UNDERWENT A HYSTERECTOMY. THIS EVENT, INTERPRETED AS EMBEDDED DEVICE, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THE EVENT WAS NOT REPORTED. THE HYSTEROSALPINGOGRAM AT TWO MONTHS POST INSERTION SHOWED THE DEVICES WERE NOT IN PLACE, ONE OF THE COILS WAS FLOATING IN HER UTERUS AND THE OTHER ONE COULD NOT BE FOUND. A CT WAS PERFORMED TO LOCATE THE MISSING COIL AND IT WAS IN THE UTERINE WALL. GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01353	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2011
Explant Date (E7): 9/8/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1173, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011, WHEN HER SON WAS (B)(6). CONSUMER REPORTED THAT ABOUT 3 MONTHS AFTER INSERTION, SHE HAD SEVERE PELVIC PAIN, RASH, DEPRESSION, EXTREMELY IRRITABLE, LOW SEX DRIVE, PAINFUL INTERCOURSE, EXTREME HEAVY BLEEDING/ BLOOD CLOT. SHE WENT TO GYNECOLOGIST AFTER GYNECOLOGIST TRYING TO FIGURE OUT WHAT WAS GOING ON WITH HER. FOR THE PAST 3 YEARS AND 9 MONTHS SHE WENT THROUGH MULTIPLE YEAST INFECTIONS, KIDNEY INFECTIONS, HIP PAIN, LEGS ACHES AND EXTREME MIGRAINES. SHE ALSO HAD TO TAKE TIME OUT OF WORK FOR NOT FEELING WELL. ON (B)(6) 2015, SHE HAD A HYSTERECTOMY DUE TO ESSURE. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEVERE PELVIC PAIN; EXTREME HEAVY BLEEDING, BLOOD CLOT (INTERPRETED AS GENITAL BLEEDING WITH CLOTS), AND KIDNEY INFECTIONS. SHE UNDERWENT A HYSTERECTOMY 4 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR KIDNEY INFECTION WHICH IS UNLISTED. AFTER ESSURE INSERTION PELVIC PAIN AND ABNORMAL GENITAL BLEEDING MAY OCCUR. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP, THE NATURE OF THESE EVENTS AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE EVENT KIDNEY INFECTIONS; URINARY TRACT INFECTION PATHOGENESIS IN WOMEN BEGINS WITH COLONIZATION OF THE VAGINAL INTROITUS BY UROPATHOGENS FROM THE FECAL FLORA, FOLLOWED BY ASCENSION VIA THE URETHRA INTO THE BLADDER. PATHOGENS CAN REACH THE KIDNEY BY ASCENDING FROM THE LOWER URINARY TRACT. CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AND ESSURE LOCAL EFFECT IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01354	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 8/10/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1179, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. SINCE PROCEDURE, SHE HAS BEEN HAVING SEVERE PAIN IN HER LEFT SIDE, LOSS OF HAIR, LOSS OF SEX DRIVE, CYSTS ON OVARIES, SEVERE BLOATING AND FLUID IN HER FALLOPIAN TUBES. SHE HAD SURGERY ON (B)(6) TO REMOVE HER TUBES AND LEFT OVARY. THERE WAS SO MUCH SCAR TISSUE THAT THEY ALMOST HAD TO DO A FULL HYSTERECTOMY. SINCE THE SURGERY SHE DID NOT HAVE ANY PAIN IN HER SIDE OR ANY OTHER SYMPTOMS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 24-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED,

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SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD SEVERE PAIN IN HER LEFT SIDE SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE WAS DIAGNOSED WITH CYSTS ON OVARIES. A BILATERAL SALPINGECTOMY WITH LEFT OOPHORECTOMY WAS PERFORMED AND SHE RECOVERED FROM HER PAIN. ONLY PAIN IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER HAD OVARIAN CYSTS, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR HER PAIN. HOWEVER, CONSIDERING THIS EVENT STARTED IN CLOSE ASSOCIATION WITH ESSURE INSERTION AND IMPROVED WITH DEVICE REMOVAL; A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. REGARDING OVARIAN CYSTS; THEY CAN DEVELOP IN FEMALES AT ANY STAGE OF LIFE. MOST OF THEM, HOWEVER, OCCUR THE HORMONALLY ACTIVE PERIODS OF DEVELOPMENT. ESSURE HAS MECHANICAL, LOCAL ACTION IN FALLOPIAN TUBES; NO HORMONES ARE RELEASED FROM THE INSERT. CONSIDERING THIS INFORMATION AND GIVEN OVARIAN CYSTS PATHOPHYSIOLOGY, CAUSALITY WITH ESSURE IS CONSIDERED VERY UNLIKELY. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (BILATERAL SALPINGECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01355	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1244, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 (FIVE YEARS BEFORE THIS REPORT). AS PREVIOUS MEDICAL HISTORY, THE CONSUMER HAD A SON AND A DAUGHTER. FAMILY HISTORY INCLUDED A SISTER WITH HEART MALFUNCTION. THE ESSURE STARTED CAUSING HER PROBLEMS AFTER 5 YEARS. HER FIRST SIGN WAS HER BODY REFUSING TO EAT EGGS. WHEN SHE WAS PREGNANT, SHE COULD NOT EAT EGGS AT ALL, SO SHE THOUGHT SHE WAS PREGNANT AND BOUGHT FOUR PREGNANCY TESTS, WHICH WERE ALL NEGATIVE. BY BEGINNING OF (B)(6), SHE LOOKED AS IF SHE WAS 4 MONTHS; HIPS, THIGHS, LEGS ALL HAD SPREAD. BY (B)(6) SHE COULD NOT WEAR ANY OF HER CLOTHES. HER STOMACH WAS LOOKING AS IF SHE WAS 6 MONTHS. CONSUMER STARTED TO BLEED HEAVY. SHE WAS CHECKED AND FOUND TWO SMALL FIBROID BUT NOTHING THAT WOULD CAUSE THESE SYMPTOMS. THE SYMPTOMS GOT WORSE: SHE GOT 20 MORE POUNDS BIGGER. IN FEBRUARY, HER STOMACH WAS SO BIG SHE WOULD HAVE TO LAY DOWN AS IF SHE WAS PREGNANT AND TIRED, SHE COULD NOT TAKE HOT SHOWER OR WOULD ITCH AND BRAKE OUT. BY (B)(6), HER VISION AND MEMORY WERE CHANGING. SHE WAS RETAINING FLUIDS. KIDNEYS AND LIVER WERE CHECKED AND NOTHING. UPPER SCOPE, HEART CHECKED AND NOTHING. SHE WAS GIVEN LASIX FOR THE BODY FLUID AND HER BODY REJECTED IT AND SHE WENT TO THE HOSPITAL. SHE WAS DEPRESSED. SHE GAINED OVER 70 POUNDS IN A YEAR, HER LEGS WERE SWOLLEN, THE BACK OF HER ANKLES ACHE, SHE COULD BARELY WALK, HER PELVIC PAIN WAS SEVERE, SHE SLEEPS A LOT IN THE DAY, HER BACK BOTHERS HER ALL DAY BECAUSE OF THE WEIGHT. SHE STATED THAT A HYSTERECTOMY WOULD

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BE PERFORMED ON (B)(6) 2015 TO REMOVE ESSURE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 24-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FIVE YEARS LATER HAD SEVERE PELVIC PAIN AND BLEED HEAVY (INTERPRETED AS GENITAL BLEEDING). A HYSTERECTOMY WAS SCHEDULED TO REMOVE ESSURE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN AND ABNORMAL GENITAL BLEEDING MAY OCCUR. IN THE PRESENT CASE THE CONSUMER ALSO HAD FIBROIDS, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THESE EVENTS. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENTS, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01356	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1154, AWARENESS DATE 08-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. AT THE AGE OF (B)(6), KNEW SHE DID NOT WANT ANY MORE KIDS. SHE HAD BEEN ON BIRTH CONTROL AND OVER THE LAST FEW YEARS, THE DEPO SHOT. HER DOCTOR DID NOT EXPLAIN TO HER THAT ESSURE HAD NICKEL IN IT; NOR DID HE DO A NICKEL ALLERGY TEST. SHE HAD THE PROCEDURE DONE IN (B)(6) 2013 (THEY GAVE HER THE LAST DEPO SHOT AT THE SAME TIME). THREE MONTHS LATER, AN X-RAY WITH DYE TEST WAS DONE AND DOCTOR SAID THAT HER TUBES WERE COMPLETELY BLOCKED. SHE DID NOT HAVE A MENSTRUAL CYCLE FOR ABOUT 7 MONTHS, BUT WHEN SHE DID, IT WAS THE WORST THING EVER. SHE HAD VERY HEAVY BLEEDING IN WHICH SHE WENT THROUGH SEVERAL PADS A DAY, CLOTTING, SEVERE CRAMPING AND HEADACHES; THEY USUALLY LASTED AROUND 8 TO 10 DAYS. WHEN SHE WAS INTIMATE SHE WOULD HAVE SPOT BLEEDING AS WELL AFTER. SHE ALSO STARTED GAINING WEIGHT, HER STOMACH LOOKED LIKE SHE WAS 5 MONTHS PREGNANT, JOINT AND BACK PAIN, SOME HAIR LOSS, FATIGUE, AND A POOR IMMUNE SYSTEM (SHE CAUGHT EVERYTHING AND TOOK SEVERAL WEEKS AND ANTIBIOTICS TO FIGHT IT OFF). HER BLOOD WORK WOULD SHOW SHE HAD AN INFECTION EVERY TIME EVEN IF SHE WAS NOT SHOWING ANY SYMPTOMS OF BEING SICK. SHE GOT EAR INFECTIONS, SWOLLEN GLANDS, AND PNEUMONIA SEVERAL TIMES THAT USUALLY TOOK TWO DOSES OF ANTIBIOTICS AND A STEROID TO GET IT UNDER CONTROL; SHE NEVER HAD THIS BEFORE. DURING HER TWO PAP SMEARS AFTER THE ESSURE IMPLANTS SHOWED THAT SHE HAD BACTERIAL VAGINOSIS EACH TIME (STRONG ODOR FROM HER VAGINAL AREA); SHE HAD BEEN HAVING PAP SMEARS SINCE

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SHE WAS 14 AND NEVER HAD AN IRREGULAR PAP UNTIL AFTER ESSURE. FINALLY, SHE WENT TO A NEW OBGYN, HE DID A VAGINAL ULTRASOUND THE END OF (B)(6) OR (B)(6) 2015 AND IT SHOWED SHE HAD AN ENLARGED UTERUS (DOUBLE IN SIZE) AND THE DECISION WAS TO HAVE A HYSTERECTOMY KEEPING HER OVARIES. HYSTERECTOMY WAS DONE ON (B)(6) 2015. IT WAS SUPPOSED TO TAKE ABOUT 1 1/2 HOURS BUT TOOK 4 1/2 DUE TO SCAR TISSUE, FIBROIDS, PROLAPSED CERVIX AND THE ESSURE COILS WERE SO STRETCHED OUT IN HER TUBES THAT IT WAS VERY DIFFICULT TO GET ALL THE PIECES OF THEM OUT. THE ESSURE COILS RUINED HER BODY AND HER HEALTH FOR A COUPLE OF YEARS. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO WAS DIAGNOSED WITH AN ENLARGED UTERUS 2 YEARS AFTER ESSURE INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY. ACCORDING TO HER, DURING THIS SURGERY ESSURE COILS WERE FOUND SO STRETCHED OUT IN HER TUBES THAT IT WAS VERY DIFFICULT TO GET ALL THE PIECES OF THEM OUT (REGARDED AS DEVICE BREAKAGE DURING REMOVAL). ADDITIONALLY, CONSUMER HAD PNEUMONIA SEVERAL TIMES. ONLY DEVICE BREAKAGE UPON ESSURE REMOVAL IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS CASE, CONSUMER STATED SHE HAD AN ENLARGED UTERUS (DOUBLE IN SIZE) DIAGNOSED AND PHYSICIAN DECIDED TO PERFORM A HYSTERECTOMY. DURING THIS SURGERY FIBROIDS WERE FOUND AND PHYSICIAN HAD DIFFICULTIES IN REMOVING THE INSERT (CONSUMER MENTIONED IT WAS DIFFICULT TO GET ALL PIECES OUT). UTERINE FIBROIDS ARE THE MOST COMMON PELVIC TUMOR IN WOMEN IN REPRODUCTIVE AGE. GENETIC PREDISPOSITION, ENVIRONMENTAL FACTORS, STEROID HORMONES, AND GROWTH FACTORS IMPORTANT IN FIBROTIC PROCESSES AND ANGIOGENESIS ALL PLAY A ROLE IN THE FORMATION AND GROWTH OF UTERINE FIBROIDS. THERE ARE A WIDE VARIETY OF TREATMENTS FOR THIS CONDITION, BOTH PHARMACOLOGIC AND SURGICAL, INCLUDING HYSTERECTOMY. CONSIDERING UTERINE FIBROIDS AS A PROVEN ALTERNATIVE EXPLANATION FOR THE REPORTED UTERINE ENLARGEMENT AND AS THE PROBABLE REASON FOR THE HYSTERECTOMY; CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED UNLIKELY. THE SAME ASSESSMENT IS GIVEN FOR PNEUMONIA (BASED ON EVENT'S PATHOPHYSIOLOGY AND CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES). THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, DUE TO THE REPORTED DEVICE BREAKAGE, AS ALTHOUGH THIS EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01357	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2006
Explant Date (E7): 4/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1177, AWARENESS DATE 08-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2006. IN (B)(6) 2006, THREE MONTHS AFTER, SHE HAD HYSTEROSALPINGOGRAM (REPORTED AS HSP) PERFORMED AND COILS WERE IN THE RIGHT PLACE AND TUBES CLOSED. CONSUMER REPORTED THAT AFTER ESSURE SHE HAD SEVERE LONG AND HEAVY MENSTRUAL CYCLES ALONG WITH CONSTANT PELVIC PAIN. SHE STARTED TO GET HEADACHES REGULARLY WHICH WORSENED AS THE YEARS WENT BY. SHE ALSO STARTED WITH VERTIGO AN NEEDED BLOOD PRESSURE MEDICINES BECAUSE OF HIGH BLOOD PRESSURE. SHE GAINED ABOUT 40LBS, DEVELOPED HIVES AND HAD TO TAKE REGULAR ALLERGY MEDICINES, SHE WAS ALLERGIC TO NICKEL, HER HEALTH DECLINED AND SHE NEVER FELT WELL, SHE WAS ALWAYS EXTREMELY FATIGUED, SHE HAD BACK PAIN, JOINT PAIN AND MUSCLE PAIN. THIS CAUSED EMOTIONAL STRESS, WORSENING DEPRESSION AND ANXIETY. HER INTIMACY WITH HER HUSBAND WAS AFFECTED. IN (B)(6) 2014, SHE HAD AN ABLATION DUE TO THE SEVERE LONG AND HEAVY MENSTRUAL CYCLES, BUT AFTER A FEW MONTHS HER PERIODS STARTED GETTING HEAVIER AND LONGER AGAIN. IN (B)(6) 2015, SHE HAD A HYSTERECTOMY PERFORMED AND WAS TOLD SHE HAD ADENOMYOSIS. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE LONG AND HEAVY MENSTRUAL CYCLES. SHE HAD NA ABLATION PERFORMED DUE TO THIS EVENT. A HYSTERECTOMY WAS PERFORMED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GIVEN ITS NATURE AND CONSIDERING THAT MENSES PATTERN CHANGES MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01379	BAYER HEALTHCARE LLC	11/5/2015	11/5/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5032842) IN UNITED STATES ON 13-JAN-2014 REFERRING TO HERSELF. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN ON MY RIGHT SIDE ALL THE TIME SINCE IT HEALED. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT DRUGS AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED. LOT NUMBER WAS NOT INFORMED. ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED PAIN ON HER RIGHT SIDE ALL THE TIME SINCE IT HEALED. CONSUMER CONSIDERED THE EVENT AS MEDICAL IMPORTANT. IT WAS NOT REPORTED IF ESSURE WAS REMOVED AFTER EVENTS. CONSUMER'S OUTCOME WAS NOT INFORMED. NO ASSESSMENT WAS GIVEN. FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER ON 12-OCT-2015: CASE UPGRADED TO INCIDENT. SHE MENTIONED THAT SHE HAS HAD ESSURE FOR 6 YEARS AND THE LAST 4 HAVE BEEN THE WORST. SHE HAD 25 DIFFERENT THINGS WRONG WITH HER DUE TO THE COILS. SHE WAS ON A LOT OF MEDICINE AND VITAMIN. ON (B)(6) 2015 SHE WOULD HAVE TO GO TO A SPECIALIST FOR NEUROPATHY IN HER ARMS, LEGS, AND SHOULDER. SHE WAS GOING TO GET THEM REMOVED NEXT MONTH ((B)(6)2015) AND WAS ALSO GOING TO ASK HER DOCTOR FOR PICTURES AND HER COILS AFTER HER FULL HYSTERECTOMY NEXT MONTH. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 28-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A

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REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN ON HER RIGHT SIDE AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE STATED SHE WILL BE SUBMITTED TO A HYSTERECTOMY IN THE MONTH FOLLOWING THIS REPORT. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS UPGRADED TO INCIDENT, SINCE ACCORDING TO INFORMATION RECEIVED UPON FOLLOW-UP, A SURGICAL INTERVENTION WILL BE REQUIRED FOR DEVICE REMOVAL. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED WITH NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE. ACCORDING TO RESULTS THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. FURTHER INFORMATION FROM CONSUMER IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 05-DEC-2015 FROM CONSUMER VIA SOCIAL MEDIA: THE CONSUMER STATED SHE HAD MAJOR COMPLICATIONS DUE TO ESSURE, SUCH AS BOWEL INFECTED AND BLADDER REPAIR. FOLLOW-UP INFORMATION RECEIVED ON 07-DEC-2015 FROM CONSUMER VIA SOCIAL

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057685	BAYER	11/5/2015	11/5/2015

Event Information:

Event Date (B3): 2/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVER CRAMPING , HEAVY BLEEDING , PAIN WITH SEX BLEEDING ALSO HAVING MY MONTHLY 3 TIMES A MONTH, SORES ON UP LEGS HEAD ACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057686	BAYER	11/5/2015	11/5/2015

Event Information:

Event Date (B3): 10/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). GASTRO ISSUES, FLUTTER OR VIBRATING FEELING IN THE LOWER ABDOMEN, HAIR DRYNESS AND HAIR COMING OUT IN LARGE AMOUNTS WHEN BRUSHING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057703	BAYER	11/5/2015	11/5/2015

Event Information:

Event Date (B3): 10/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALLERGIES PSORIASIS , DRUG ALLERGIES (TAKEN WITHOUT PROBLEMS PRIOR TO INSERTION) HIGH BLOOD PRESSURE, CHRONIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057741		11/5/2015	11/9/2015

Event Information:

Event Date (B3): 6/25/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** AS

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/25/2003
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE ABDOMINAL PAIN, EXCESSIVE BLEEDING, PAIN DURING SEXUAL INTERCOURSE, CRAMPING, SHARP PAINS INSIDES OF ABDOMEN, BLOATING SEVER, LETHARGIC, FOGGY HEAD, CONSTANT MIGRAINES, AGING DRAMATICALLY, LOSE OF SEX DRIVE COMPLETELY GONE, SENSITIVITY TO BEING TOUCHED, WAKING DURING THE NIGHT WITH ONGOING DULL AND SHARP PAIN IN MY ABDOMEN, LOSS OF HAIR, DEPRESSION, CONSTANTLY TIRED, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057774	BAYER HEALTHCARE LLC	11/5/2015	11/10/2015

Event Information:

Event Date (B3): 7/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COIL IMPLANTS
Device Type (E2): ESSURE COIL IMPLANTS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/23/2010
Explant Date (E7): 7/7/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COILS. I HAD ESSURE COILS IMPLANTED IN (B)(6) 2010. I STARTED HAVING LOWER BACK, STOMACH PAINS AND CRAMPING, HEAVY CLOTTING PERIODS, VAGINAL PAIN, PAINFUL INTERCOURSE, METAL TASTE, MIGRAINES. IN 2013 STOMACH PAINS, LEFT WORK, WENT TO ER. I HAD A LARGE CYST ON MY OVARY. DR. (B)(64) REMOVED CYST AND REMOVED ESSURE COILS IN 2015. I'VE BEEN RECEIVING ADVANCED PAIN MANAGEMENT, CAUDAL INJECTIONS AND LASER RADIO FREQUENCY,.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057775	BAYER HEALTHCARE LLC	11/5/2015	11/10/2015

Event Information:

Event Date (B3): 11/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD A PROCEDURE DONE CALLED ESSURE WHICH IS A PERMANENT BIRTH CONTROL, THE PROCEDURE WAS DONE ON (B)(6) 2015; EVER SINCE I'VE HAD SERIOUS AND CHRONIC PAIN IN MY LOWER ABDOMEN AND LOWER BACK. I'VE EXPERIENCING HEAVY BLEEDING FOR A TWO WEEK PERIOD EVERY MONTH. I DID NOT GET MY PERIOD LAST MONTH AND TO MY SURPRISE I'M (B)(6) PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057776	BAYER HEALTHCARE LLC	11/5/2015	11/10/2015

Event Information:

Event Date (B3): 10/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/9/2009
Explant Date (E7): 12/18/2011
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE DEVICE IMPLANTED (B)(6) 2009. IMMEDIATE AND CONSTANT SIDE EFFECTS. LEAD TO HYSTERECTOMY IN (B)(6) 2011 TO REMOVE ESSURE. NOW DEALING WITH SIDE EFFECTS OF HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057777	BAYER	11/5/2015	11/10/2015

Event Information:

Event Date (B3): 2/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/12/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL IMPLANT IN 2013, I WAS INCAPACITATED FOR 2 DAYS AFTER PROCEDURE AND DID NOT HAVE A CYCLE FOR OVER 6 MONTHS RESULTING IN DOCTOR PRESCRIBING HORMONES TO GET IT STARTED. WITHIN THE NEXT 3-6 MONTHS, I EXPERIENCED HEAVY, CONTINUOUS BLEEDING ALONG WITH SEVERE PAIN AND LARGE CLOTS, I STARTED BEING MORE REGULAR AND THEN THE PAIN BEFORE OVULATION STARTED AND INCREASED AS THE CYCLE CONTINUED LEAVING ME IN EXTREME PAIN 3 WEEKS OUT OF THE MONTH IF NOT MORE. I WENT TO MY DOCTOR WITH MY COMPLAINTS AND WAS TOLD IT WAS MID-CYCLE PAIN AND NOTHING TO DO WITH MY IMPLANT. I HAVE SINCE DONE MORE RESEARCH AND FOUND MANY WOMEN EXPERIENCING WHAT I AM.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01380	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C26973

Single Use: Y
Implant Date (E6): 8/24/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 12-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR CONTRACEPTION. THE LOT NUMBER USED WAS C26973. ON UNSPECIFIED DATE, AN ULTRASOUND WAS PERFORMED AND SHOWED THE COIL APPARENTLY MALPOSITIONED. ON (B)(6) 2015, THE COIL ON RIGHT SIDE WAS REMOVED VIA HYSTEROSCOPY AND THEN A LAPAROSCOPIC TUBAL LIGATION OF RIGHT SIDE WAS DONE. THE DEVICE ON THE LEFT SIDE WAS CONTINUED. FOLLOW UP 28-OCT-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED

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AND IT WAS REPORTED THAT COIL APPEARED MALPOSITIONED VIA ULTRASOUND (INTERPRETED AS DEVICE DISLOCATION). THE COIL ON RIGHT SIDE WAS REMOVED VIA HYSTEROSCOPY AND THEN A LAPAROSCOPIC TUBAL LIGATION OF RIGHT SIDE WAS DONE. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01381	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044386) IN UNITED STATES ON 12-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013 TO PREVENT PREGNANCY AND POSSIBLY HELP WITH HEAVY BLEEDING DURING PERIODS. THE PROCEDURE ITSELF WAS QUITE PAINFUL AND SHE SPOTTED HEAVILY FOR TWO WEEKS AFTER THE PROCEDURE AND THEN MODERATELY TO LIGHTLY FOUR WEEKS AFTER THAT. SHE ALSO EXPERIENCED CRAMPING, SOME SEVERE, AND FATIGUE DURING THAT PERIOD OF TIME. SHE DISCUSSED THE SYMPTOMS WITH HER DOCTOR AND SHE ADVISED HER THAT THE SYMPTOMS SHOULD SUBSIDE OVER TIME; DURING HER FIRST PERIOD AFTER THE PLACEMENT SHE BLED HEAVIER THAN SHE COULD EVER REMEMBER BLEEDING AND HAD CRAMPS SO SEVERE THAT SHE WOULD CROUCH DOWN UNTIL THEY SUBSIDED. AGAIN SHE WAS ADVISED BY HER DOCTOR THAT THESE SYMPTOMS SHOULD SUBSIDE AND TO GIVE THE DEVICE MORE TIME. THEN SHE BEGAN TO EXPERIENCE FAIRLY RAPID WEIGHT GAIN AND MOOD SWINGS WITH HEADACHES. WITH EACH PERIOD FOR THE REMAINDER OF 2014 THE SYMPTOMS INCREASED. AN APPOINTMENT WITH A NEW DOCTOR WAS MADE AND AFTER SPEAKING WITH HER IN LENGTH ABOUT THE PROBLEMS THEY DECIDED IT WAS BEST TO HAVE A PARTIAL HYSTERECTOMY TO STOP THE ISSUES. IN 2015, SHE HAD A PARTIAL HYSTERECTOMY AND SINCE SHE HAD NONE OF THE SYMPTOMS THAT WERE PREVIOUSLY EXPERIENCED. THE CONSUMER REPORTED LEVOTHYROXINE AS A PRESCRIBED MEDICATION. HOSPITALIZATION AND REQUIRED INTERVENTION WERE MENTIONED AS EVENT OUTCOME BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 28-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE

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DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SPOTTED HEAVILY FOR TWO WEEKS AFTER THE PROCEDURE (INTERPRETED AS POST PROCEDURAL BLEEDING). SHE ALSO HAD CRAMPING, SOME SEVERE (INTERPRETED AS LOWER ABDOMINAL PAIN), AND UNDERWENT A PARTIAL HYSTERECTOMY 2 YEARS AFTER ESSURE INSERTION. LOWER ABDOMINAL PAIN WAS CONSIDERED SERIOUS DUE TO THE HOSPITALIZATION REPORTED, AND POST PROCEDURAL BLEEDING SERIOUS DUE TO MEDICAL SIGNIFICANCE. BOTH EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. VAGINAL BLEEDING MAY OCCUR FOLLOWING THE MICRO-INSERT PLACEMENT PROCEDURE. TYPICALLY IT IS TOLERABLE AND TRANSIENT. ALSO, ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENTS AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (PARTIAL HYSTERECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 21-DEC-2015 FROM CONSUMER - QUESTIONNAIRE PROVIDED: THE CONSUMER WAS ON HER 30'S. CONCURRENT CONDITIONS INCLUDED OBESITY ((B)(6)). ESSURE WAS INSERTED AFTER A PREGNANCY. CONDOMS WERE USED AS BACKUP CONTRACEPTION. THE CONS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01382	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/30/2013
Explant Date (E7): 2/3/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044389) IN UNITED STATES ON 12-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. THE CONSUMER STATED IMMEDIATELY AFTER ESSURE PROCEDURE SHE HAD BLEEDING AND CRAMPING. SHE SPOKE TO HER PHYSICIAN AND SHE TRIED PUTTING HER ON 4 DIFFERENT TYPES OF HORMONE PILLS TO HELP THE BLEEDING; NOTHING WORKED, ONE MADE IT TO WHERE SHE FELT LIKE SHE COULDN'T BREATHE AND SHE HAD TO GO TO THE HOSPITAL. SHE STATED MISSED WORK MANY TIMES BECAUSE IT WAS JUST TOO PAINFUL TO SIT UP OR WALK. HER PHYSICIAN KEPT TELLING HER SHE WOULD EVENTUALLY STOP CRAMPING AND BLEEDING. SHE WENT BACK 3 MONTHS TO DO THE PROCEDURE WHERE THEY MAKE SURE THAT THE PLACEMENT WAS DONE CORRECTLY AND IT WAS, BUT THE PAIN AND BLEEDING WOULD JUST NOT STOP. SHE SOUGHT DIFFERENT OPINIONS FROM 2-3 OTHER DOCTORS AND AFTER AN ULTRASOUND THEY DECIDED THAT SHE SHOULD GET A HYSTERECTOMY DONE. SHE HAD 5 HEALTHY KIDS AND NO OTHER MEDICAL ISSUES UP TO THIS POINT. THEY TOLD HER THAT THE HYSTERECTOMY WOULD STOP THE BLEEDING AND THE CRAMPING AND SHE WOULD BE BACK TO NORMAL THAT WAS NOT THE TRUTH. SHE HAD A HYSTERECTOMY (B)(6) 2014. SHE DID STOP BLEEDING BUT CONTINUED TO HAVE THE SHARP PAIN ON HER LEFT SIDE AND THEN AL IN HER PELVIC AREA. THE PAIN WAS SO SEVERE THAT SHE STILL CONTINUED TO MISS WORK, AND WAKE UP AT NIGHT WITH THE PAIN JUST LIKE BEFORE THE SURGERY. THE CONSUMER DEALT WITH PAIN THE VERY FIRST MOMENT SHE WAKES UP UNTIL SHE GOES TO BED AT NIGHT AND SOMETIMES DURING THE NIGHT. SHE WAS HEALTHY AND LIVING A NORMAL LIFE UNTIL SHE HAD THE ESSURE PROCEDURE DONE. SHE REPORTED BEING DEPRESSED, ANGRY, SAD AND IN PAIN NOW DEALING WITH THIS, SHE NO LONGER LIVE A NORMAL LIFE AND IT WAS VERY DEPRESSING FOR HER HAVING A HYSTERECTOMY. THE CONSUMER

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REPORTED NORCO AS TREATMENT SINCE SHE STILL TAKES FOR PAIN. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 28-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMMEDIATELY AFTER ESSURE PROCEDURE SHE HAD BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND CRAMPING / TOO PAINFUL TO SIT UP OR WALK / CONTINUED TO HAVE THE SHARP, PAIN, ON MY LEFT SIDE. A HYSTERECTOMY WAS PERFORMED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON A POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 10-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01383	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044412) IN UNITED STATES ON 12-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED THE INSERTION OF THE DEVICE TOOK TWICE AS LONG AS IT SHOULD HAVE AND THE PHYSICIAN HAD TO USE THREE COILS AS ONE FAILED BEFORE IT WAS IN PLACE. THE ESSURE DEVICE FELL OUT OF FALLOPIAN TUBE AND BROKE INTO TINY PIECES THAT THE PHYSICIAN SAID HE DIDN'T THINK HE GOT THEM ALL. THE CONSUMER STATED THAT THIS CAUSED HER GREAT PAIN. SERIOUS INJURY WAS MENTIONED AS REPORT TYPE, AND REQUIRED INTERVENTION WAS MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. FOLLOW UP RECEIVED ON 26-OCT-2015: PTC INVESTIGATIONAL RESULT. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE

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REPORTED MEDICAL EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE ESSURE DEVICE FELL OUT OF HER FALLOPIAN TUBE AND BROKE INTO TINY PIECES. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND ANTICIPATED ACCORDING TO PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN THE PRESENT CASE, ACCORDING TO THE CONSUMER, THE INSERTION PROCEDURE TOOK TWICE AS LONG AS IT SHOULD HAVE, AND ONE OF THE COILS FAILED BEFORE IT WAS IN PLACE; THE DEVICE FELL OUT OF FALLOPIAN TUBE AND BROKE INTO PIECES. SINCE THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. REQUIRED INTERVENTION WAS MENTIONED AS EVENT OUTCOME BUT THERE WAS NO PERFORMED INTERVENTION REFERRING TO AN EVENT DESCRIBED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01385	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1456, AWARENESS DATE 13-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER WAS (B)(6) WHEN ESSURE WAS PUT IN HER, SHE WEIGHED (B)(6) SHE WAS HEALTHY ACTIVE AND LOVED LIFE. SHE STATED THAT SHE PUT ON 20 POUNDS WITHIN 2 MONTHS AFTER ESSURE INSERTION. SHE HATES SEEING HERSELF SINCE SHE WEIGH 200 POUNDS. SHE HAS NEVER WEIGHED LIKE THIS EVEN DURING ALL 3 PREGNANCIES. SHE IS DEPRESSED MORE THAN OFTEN AND EXPERIENCED 5 YEARS OF NON STOP PERIOD BLOOD, SHE BLED 24/7 AND SHE IS PERPETUALLY PMSING (INTERPRETED AS PMS, PREMENSTRUAL SYNDROME). ESSURE WAS REMOVED ON (B)(6) 2015 DUE TO EXCESSIVE BLEEDING AND PELVIC PAIN. IT STOPPED SO MUCH MORE THE DAY AFTER SHE HAD ANKLES AGAIN THE ITCHING HAD STOPPED IMMEDIATELY. SHE HAS ALSO STOPPED GOING TO HER PAIN MANAGEMENT APPOINTMENTS THAT SHE WENT TO 2 TIMES A WEEK. WHICH CONSISTED OF INJECTIONS TO BRING THE INFLAMMATION DOWN IN HER NECK AND SHOULDERS, E-STEM AND MASSAGE AND LIGHT PHYSICAL THERAPY. ALSO EVERY 3 MONTHS SHE HAD THE FLUID IN HER HIP DRAINED FROM BURSITIS. NONE OF IT BOTHERS HER ANYMORE. SHE EVEN STARTED WORKING OUT. SHE CAN GET ON HER KNEES. SHE CAN STAY AWAKE, SHE IS NOT IN CONSTANT PAIN. SHE HAS NOT HAD A HEADACHE IN MONTHS NOW WHEN THEY WERE EVERY SINGLE DAY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 28-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING

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INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND PELVIC PAIN. SHE HAD ESSURE REMOVED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING THAT GENITAL BLEEDING AND PELVIC PAIN MIGHT OCCUR WITH ESSURE THERAPY AND BASED ON THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE WAS REMOVED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01386	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1463, AWARENESS DATE 13-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. ESSURE INSERTION AND UTERINE ABLATION WERE PERFORMED AT THE SAME TIME. IMMEDIATELY AFTER THE PROCEDURE THE CONSUMER WAS IN EXTREME PAIN. SHE WAS CURLED IN A BALL, HOLDING HER STOMACH. LESS THAN A YEAR LATER, AT THE AGE OF (B)(6), SHE HAD A HYSTERECTOMY. EVEN THOUGH SHE HAD THE ABLATION THE UTERINE LINING GREW BACK AND SHE WAS BLEEDING WORSE THAN EVER. THE DOCTORS COULD NOT EXPLAIN WHY THIS WAS HAPPENING. SHE HAD TERRIBLE MIGRAINES, ALONG WITH THE BLEEDING CAME UNBEARABLE ABDOMINAL PAIN. THE ABDOMINAL PAIN WAS ALWAYS PRESENT BUT MUCH WORSE WITH THE BLEEDING. SHE WAS ANEMIC, CONSTANTLY SICK (LITERALLY VOMITING FROM PAIN). SHE MISSED WORK, WAS TESTED FOR OVARIAN CANCER DUE TO THE PAIN AND AMOUNT OF ABDOMINAL BLOATING. EVEN AFTER THE HYSTERECTOMY SHE HAS ABDOMINAL PAIN. HER HANDS AND FEET GOT SO COLD THAT THEY WERE PAINFUL. DUE TO THE LACK OF TRAINING OF DOCTORS, AND PRE MARKET RESEARCH OF THIS PRODUCT, HER ESSURE DEVICES WERE NOT EVEN REMOVED PROPERTY, SO SHE WONDERED WHAT OTHER PROBLEMS SHE WOULD FACE FROM PET FIBERS BEING LEFT IN HER BODY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 28-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A

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LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND UTERINE ABLATION PERFORMED AT THE SAME TIME (OFF LABEL USE OF DEVICE). EVEN THOUGH SHE HAD THE ABLATION, SHE WAS BLEEDING WORSE THAN EVER (INTERPRETED AS GENITAL BLEEDING). SHE ALSO HAD UNBEARABLE ABDOMINAL PAIN. SHE WAS TESTED FOR OVARIAN CANCER BUT NO RESULTS WERE PROVIDED. SHE HAD A HYSTERECTOMY BUT EVEN AFTER THIS SURGERY SHE STILL HAD ABDOMINAL PAIN. SHE ALSO STATED THAT ESSURE WAS NOT REMOVED PROPERLY AND PET FIBERS (INTERPRETED AS DEVICE BREAKAGE) WERE LEFT IN HER BODY. ALL EVENTS BUT DEVICE BREAKAGE ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ONLY THE OVARIAN CANCER IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH, IN THIS PARTICULAR CASE, IT IS IMPLIED THAT SHE ALREADY HAD BLEEDINGS PRIOR TO ESSURE INSERTION, CONSIDERING THAT IT IS CONTRAINDICATED TO INSERT ESSURE AND PERFORM AN ABLATION AT THE SAME TIME, AND ALSO CONSIDERING THAT THE BLEEDING WORSENED AFTER THIS PROCEDURE AND THAT THE SUSPICION OF OVARIAN CANCER WAS NOT CONFIRMED YET, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ALSO, CONSIDERING THE NATURE OF ABDOMINAL PAIN AND DEVICE BREAKAGE, THESE EVENTS ARE CONSIDERED RELATED TO ESSURE. IN CONTRAST, DUE TO THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES IT IS UNLIKELY THAT ESSURE WOULD CAUSE AN OVARIAN CANCER. THIS CASE IS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01387	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 13-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN REPORTED THAT THE ESSURE CONFIRMATION REPORT CLAIMS RIGHT ESSURE APPEARED FRACTURED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 26-OCT-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERT'S OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING

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IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A TECHNICAL ISSUE. HOWEVER, NO MEDICAL EVENTS WERE REPORTED. SINCE NO MEDICAL EVENTS HAVE BEEN REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE ESSURE CONFIRMATION REPORT CLAIMS RIGHT ESSURE APPEARED FRACTURED. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THE BREAKAGE WERE NOT REPORTED. THE ESSURE CONFIRMATION TEST PERFORMED AN UNSPECIFIED TIME AFTER INSERTION, SHOWED THE RIGHT ESSURE APPEARED FRACTURED. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UPON INTERNAL REVIEW, THE FOLLOWING STATEMENT WAS ADDED: THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 14-DEC-2015: FOLLOW-UP ATTEMPT DONE WITHOUT SUCCESS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01388	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3): 10/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 13-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013 FOR PERMANENT BIRTH CONTROL. THE PATIENT WAS DIAGNOSED WITH SEPTIC PELVIC THROMBOPHLEBITIS ON (B)(6) 2015. THE PHYSICIAN WANTED TO KNOW HOW TO SAFELY TREAT THE PATIENT. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD A SEPTIC PELVIC THROMBOPHLEBITIS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS EVENT IS UNLISTED ACCORDING TO THE REFERENCE SAFETY

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INFORMATION FOR ESSURE. THE PATHOGENESIS OF SEPTIC PELVIC THROMBOPHLEBITIS (SPT) IS THOUGHT TO INCLUDE INJURY TO THE INTIMA OF THE PELVIC VEINS CAUSED BY A SPREADING UTERINE INFECTION OR SECONDARY TO THE TRAUMA OF DELIVERY OR SURGERY. THERE ARE TWO TYPES OF SPT: OVARIAN VEIN THROMBOPHLEBITIS (OVT) AND DEEP SEPTIC PELVIC THROMBOPHLEBITIS (DSPT). MEDICAL THERAPY WITH ANTIBIOTICS AND ANTICOAGULATION IS CURRENTLY THE PREFERRED TREATMENT APPROACH FOR THESE CONDITIONS. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER THE INSERTION PROCEDURE. IN THIS PARTICULAR CASE LIMITED INFORMATION WAS PROVIDED. THE PATIENT WAS DIAGNOSED WITH SPT APPROXIMATELY 2 YEARS AFTER ESSURE INSERTION. THIS WEAK TEMPORAL RELATIONSHIP SUGGESTS THE EVENT WAS NOT DIRECTLY RELATED TO ESSURE PROCEDURE. HOWEVER; CONSIDERING ESSURE HAS A MECHANICAL ACTION IN FALLOPIAN TUBES; IT CANNOT BE EXCLUDED THE DEVICE COULD HAVE AGGRAVATED A PELVIC INFECTION FURTHER ACQUIRED BY THE PATIENT. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED AND THIS CASE WAS CONSIDERED AN INCIDENT (SERIOUS INJURY). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01389	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/14/2011
Explant Date (E7): 11/11/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 13-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 WITHOUT DIFFICULTY. ADDITIONAL INFORMATION WAS RECEIVED ON 14-OCT-2015. ON (B)(6) 2011, DURING THE POST OPERATIVE EXAM THE PATIENT WAS DOING WELL. ON (B)(6) 2011, A HYSTEROSCOPY D&C WAS DONE FOR PELVIC PAIN. ON (B)(6) 2011, DURING POST OPERATIVE VISIT, THE PATIENT COMPLAINED OF BLEEDING HEAVY, BUT HAD NO FEVER. HER FINDINGS APPEARED WNL (UNDERSTOOD AS WITH NORMAL LIMITS) AND NO CLEAR REASON FOR SEVERE PAIN WAS OBSERVED. AT THE TIME, LAVH (LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY) WAS DISCUSSED. ON (B)(6) 2011, A LAVH WAS INITIATED BUT CONVERTED TAH (TOTAL ABDOMINAL HYSTERECTOMY). THE PATHOLOGY OF UTERUS, CERVIX AND BILATERAL FALLOPIAN TUBE SHOWED CERVIX WITH NO SIGNIFICANT HISTOPATHOLOGICAL ABNORMALITY, BENIGN INACTIVE ENDOMETRIUM AND BENIGN FALLOPIAN TUBES. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A

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RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING HEAVY (INTERPRETED AS GENITAL BLEEDING) AND PELVIC PAIN. A TOTAL ABDOMINAL HYSTERECTOMY WAS PERFORMED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THESE EVENTS AFTER ESSURE INSERTION. BASED ON THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01390	BAYER HEALTHCARE LLC	11/6/2015	11/6/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6)-2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, (B)(4). STUDY DESCRIPTION: POST-APPROVAL STUDY PROTOCOL: A STUDY TO EVALUATE THE EFFECTIVENESS OF ESSURE POST-NOVASURE RADIOFREQUENCY ENDOMETRIAL ABLATION PROCEDURE FOLLOWING A SUCCESSFUL ESSURE CONFIRMATION TEST. (B)(6). ON (B)(6)-2015, NOVASURE ENDOMETRIAL ABLATION WAS PERFORMED. THE ENDOMETRIAL ABLATION PROCEDURE STARTED AT 14:16 AND ENDED AT 14:26. NOVASURE RF CONTROLLER SERIAL LOT NUMBER: (B)(4) AND NOVASURE DISPOSABLE DEVICE SERIAL LOT NUMBER: (B)(4). GENERAL ANESTHESIA WAS USED THROUGH IV SEDATION. UTERINE'S CONDITION AT THE TIME OF PROCEDURE INCLUDED: ANTEVERTED UTERUS, 3.0 CM CERVICAL LENGTH, CERVICAL DILATATION (22 CM), 8.5 TOTAL UTERINE LENGTH. PROCEDURE PREPARATION TOOK 48 SECONDS. POWER SETTING: 124 WATTS. THE ABLATION PROCEDURE WAS NOT INTERRUPTED DURING THE TREATMENT CYCLE. A CT SCAN WAS PERFORMED AND SHOWED A DISTENDED STOMACH AND DUODENUM TO THE LEVEL OF THE SUPERIOR MESENTERIC ARTERY. SMALL POCKETS OF FREE AIR WERE ALSO NOTED. ON (B)(6)-2015, AN EXPLORATORY LAPAROTOMY WAS PERFORMED AND SHOWED PERFORATION ON AN ANTIMESENTERIC BORDER OF A SEGMENT OF BOWEL THAT LOOKED LIKE A THERMAL-TYPE INJURY WITH CLEAR PERFORATION INTO THE LUMEN. A SMALL RESECTION WITH PRIMARY ANASTOMOSY WAS PERFORMED TO TREAT THE EVENT. ON (B)(6)-2015, PERFORATED VISCUS WAS DIAGNOSED. EVENT SEVERITY ASSESSED AS SEVERE. EVENT WAS ONGOING (PATIENT WAS IN HOSPITAL RECOVERING FROM SURGERY). EVENT REPORTED TO BE UNLIKELY RELATED TO ESSURE OR TO PRE-EXISTING CONDITION AND PROBABLY RELATED TO NOVASURE DEVICE AND PROCEDURE. FOLLOW UP INFORMATION RECEIVED ON 22-OCT-2015 AND 23-OCT-2015 FROM INVESTIGATOR: EVENT TERM WAS

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AMENDED TO PERFORATED VISCUS WITH UTERINE PERFORATION. THE PATIENT PRESENTED IN THE EMERGENCY ROOM ON (B)(6)-2015 WITH ACUTE ONSET OF ABDOMINAL PAIN. CT SCAN WAS PERFORMED IN THE EMERGENCY ROOM ON THE SAME DAY, WHICH SHOWED A DISTENDED STOMACH AND DUODENUM TO THE LEVEL OF THE SUPERIOR MESENTERIC ARTERY. SHE WAS ADMITTED TO THE HOSPITAL WITH THE DIAGNOSIS OF A SMALL-BOWEL OBSTRUCTION. PHYSICAL EXAM ON (B)(6)-2015 WAS CONSISTENT WITH PERITONITIS. CT SCAN WAS REVIEWED AND SMALL POCKETS OF FREE AIR WERE NOTED. PHYSICIAN PROCEEDED WITH LAPAROTOMY WITH PREOPERATIVE DIAGNOSIS OF PERFORATED VISCUS. PER OPERATIVE REPORT, UPON ENTERING THE ABDOMINAL CAVITY, THERE WAS SOME THIN PURULENT FLUID IN THE ABDOMEN, WHICH WAS SUCTIONED. SMALL BOWEL WAS THEN EXAMINED; THE PATIENT HAD A PERFORATION ON AN ANTIMESENTERIC BORDER OF A SEGMENT OF BOWEL THAT LOOKED LIKE A THERMAL-TYPE INJURY WITH CLEAR PERFORATION INTO THE LUMEN. JUST DISTAL TO THIS, APPEARED TO BE ANOTHER AREA THAT MIGHT ALSO HAVE HAD A LITTLE BIT OF CAUTERY INJURY TO IT. THE SMALL INTESTINE WAS DIVIDED PROXIMAL TO THE PERFORATION AND JUST DISTAL TO THE SECOND AREA OF CONCERN AND A SIDE-TO-SIDE FUNCTIONAL END-TO-END ANASTOMOSIS WAS DONE. IN THE PELVIS AN APPROXIMATELY 6 TO 8 MM PERFORATION WITH SURROUNDING 2 MM RIM OF WHAT LOOKED LIKE CAUTERY ARTIFACT IN THE DOME OF THE UTERUS NEAR THE INSERTION OF THE FALLOPIAN TUBE WAS FOUND; A SIMPLE CLOSURE OF THIS PERFORATION WAS PERFORMED. NO OTHER EVIDENCE OF PERFORATION OR INJURY WAS NOTED. POSTOPERATIVE DIAGNOSIS WAS PERFORATED SMALL INTESTINE WITH PERFORATED UTERUS. ESTIMATED BLOOD LOSS WAS 25 ML. NO COMPLICATIONS OCCURRED AND PATIENT TOLERATED THE PROCEDURE WELL. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO (B)(6)-YEAR-OLD PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY ((B)(4)). SHE WAS HOSPITALIZED, AFTER A NOVASURE ENDOMETRIAL ABLATION PROCEDURE, DUE TO ACUTE ONSET OF ABDOMINAL PAIN. THE FINDING OF FREE AIR IN THE PERITONEAL CAVITY IN HER CT SCAN IN COMBINATION WITH PERITONITIS ON PHYSICAL EXAM LED TO A SUSPICION OF PERFORATED VISCUS AND AN EXPLORATORY LAPAROTOMY WAS PERFORMED. DURING THE SURGERY, A PERFORATED VISCUS WITH UTERINE PERFORATION WAS FOUND. SMALL BOWEL RESECTION WITH PRIMARY ANASTOMOSIS AND UTERINE PERFORATION CLOSURE WERE PERFORMED TO TREAT THE EVENT AND PATIENT TOLERATED THE PROCEDURE WELL. THE REPORTED EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND NOVASURE. IN THIS STUDY, THE SUBJECTS ARE SUBMITTED TO NOVASURE PROCEDURE ONLY AFTER A SUCCESSFUL 3-MONTH ESSURE CONFIRMATION TEST (MODIFIED HYSTEROSALPINGOGRAM); TO ENSURE ESSURE IS IN CORRECT POSITION. IN THIS PARTICULAR CASE, PATIENT WAS SUBMITTED TO AN EXPLORATORY LAPAROTOMY 10 DAYS AFTER NOVASURE PROCEDURE. THE OPERATIVE REPORT DESCRIBED A 6 TO 8 MM PERFORATION WITH SURROUNDING 2 MM RIM OF WHAT LOOKED LIKE CAUTERY ARTIFACT IN THE DOME OF THE UTERUS NEAR THE INSERTION OF THE FALLOPIAN TUBE AND ALSO 2 PERFORATIONS IN DIFFERENT LOCATIONS IN THE SMALL INTESTINE THAT LOOKED LIKE A THERMAL TYPE INJURY. NEITHER TUBAL PERFORATION (VISIBLE ESSURE INSERT FROM PERITONEAL CAVITY) NOR THERMAL INJURY AROUND THE PROXIMAL FALLOPIAN TUBES WHERE THE ESSURE INSERTS ARE LOCATED WAS REPORTED. THIS INDICATES THAT THE ESSURE INSERTS WERE NOT IN PHYSICAL CONTACT WITH THE SMALL BOWEL AND THAT THERE WAS NO THERMAL INJURY IN THE TISSUES SURROUNDING THE ESSURE INSERTS. SINCE THERE IS NO EVIDENCE FOR INVOLVEMENT OF ESSURE IN THESE THERMAL INJURIES TO THE SMALL BOWEL, THE CASE IS UNRELATED TO ESSURE AND THEREFORE A NON-INCIDENT WITH RESPECT TO THE SUSPECT INSERT. THE THERMAL INJURY AT THE DOME OF THE UTERUS WAS NEAR THE FALLOPIAN TUBE, BUT DID NOT INVOLVE THE FALLOPIAN TUBE AREA WHERE THE ESSURE WAS LOCATED. THIS INJURY IS PROBABLY RELATED TO THE NOVASURE WHICH PERFORATED THE UTERUS. ENERGY WAS APPLIED WHICH RESULTED IN THE THERMAL INJURY TO THE UTERUS AND TO TWO AREAS IN THE SMALL BOWEL WHICH WERE LIKELY SITTING NEXT TO THE DOME OF THE UTERUS AT THE TIME OF THE PROCEDURE. THEREFORE THE REPORTED EVENT IS PROBABLY RELATED TO NOVASURE AND IS AN INCIDENT DUE TO THE SURGICAL MANAGEMENT. THIS IS IN AGREEMENT WITH THE ASSESSMENT OF THE INVESTIGATOR. THE NOVASURE DEVICE IS NOT MANUFACTURED BY BAYER. NOVASURE-RELATED EVENTS IN THIS COMPLAINT REPORT

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WERE ASSESSED BASED ON THE INFORMATION AVAILABLE TO BAYER. THE LEGAL MANUFACTURER OF NOVASURE, HOLOGIC, HAS BEEN CONTACTED. ANY FOLLOW-UP INFORMATION REGARDING THESE EVENTS THAT BAYER RECEIVES WILL BE ADDED TO THE CASE AND FORWARDED AS REQUIRED. TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 30-OCT-2015 (MEDICAL RECORDS) AND 05-NOV-2015 (ESSURE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS): THE PATIENT WAS BROUGHT TO THE HOSPITAL WITH A 1-DAY HISTORY OF PAIN THAT AWOKE HER FROM HER SLEEP. SHE STATED THE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057813	BAYER	11/6/2015	11/12/2015

Event Information:

Event Date (B3): 5/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

MY PERSONAL ESSURE HARM STORY FOLLOWS. I GOT ESSURE ON (B)(6) 2013, AND I HATE WHO I'VE BECOME. I'M NOT THE SAME PERSON I USED TO BE. I'VE SUFFERED FROM SHARP BURNING ABDOMINAL PAIN, HEAVY BLEEDING, WEIGHT GAIN, BLOATED BELLY, ANXIETY, SKIN RASHES, WEIRD MOVEMENT INSIDE MY BELLY, MISSING MENSTRUAL CYCLE AND MEMORY AND ENERGY LOSS. DIAGNOSIS OR REASON FOR USE: PERMANENT BIRTH CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057815	BAYER	11/6/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HI, MY NAME IS (B)(6), I AM A MOTHER OF 5, AND I AM (B)(6) YEARS OLD. (B)(6) 2013 AT THE AGE OF (B)(6) I HAD THE ESSURE DEVICE IMPLANTED IN MY BODY AND HAD A THERMAL ABLATION AT THE SAME TIME. I WAS PUT UNDER GENERAL ANESTHESIA TO DO THIS PROCEDURE IN A HOSPITAL FACILITY. MY DOCTOR WAS DR. (B)(6) FROM (B)(6). I BEGAN NOTICING PROBLEMS AS SOON AS I WOKE FROM ANESTHESIA. MY VAGINA WAS BURNING AND IN PAIN, AFTER EXAMINATION MY HUSBAND THAT MY VAGINAL WALL HAD BEEN TORN OR LACERATED DURING THE PROCEDURE. WE CALLED AND REPORTED TO THE DR. WHO ASKED ME TO COME IN TO BE EXAMINED. AFTER AN EXAM HE ADMITTED THERE WAS A TEAR IN MY VAGINAL WALL AND SAID IT WOULD HEAL IN THE UPCOMING WEEKS. AFTER THAT MY DOCTOR DID NO FOLLOW UP FOR THE PLACEMENT OF ESSURE. HE DID NOT TELL ME ABOUT A CARE I WAS SUPPOSE TO BE GIVEN, DID NOT TELL ME OR OFFER ME AN HSG TEST AFTER THE PROCEDURE. HE DID NOT TELL ME THE PRODUCT CONTAINED NICKEL AND I AM ALLERGIC TO NICKEL. SINCE THE PROCEDURE HAS BEEN DONE, I HAVE HAD CONSTANT BATTLES WITH BACTERIAL VAGINOSIS. I HAD NEVER HEARD OF THIS BEFORE THE SURGERY, AND OBVIOUSLY NEVER HAD BEEN A VICTIM OF IT. MY PERIOD RETURNED THE FOLLOWING MONTH. I'VE HAD DEBILITATING CRAMPS SINCE THE PROCEDURE AND A LIST OF OTHER SYMPTOMS (THAT I NEVER HAD BEFORE THE PLACEMENT OF ESSURE) INCLUDING BUT NOT LIMITED TO: ADULT ACNE, MASSIVE MIGRAINES, NUMBNESS IN MY RIGHT LEG, BLURRED VISION, DENTAL PROBLEMS, CLOTTING AND BLEEDING MONTHLY, EXTREME BACK PAIN AS IF I'M IN LABOR, SKIN ISSUES LIKE RAISED BUMPS AND RANDOM RED SPOTS THAT DO NOT GO AWAY. I NOW HAVE TWO BREAST LUMPS THAT I HAVE BEEN SEEING A BREAST SURGEON FOR - A SIMPLE CYST WAS NOT FOUND. I WAS GIVEN A BI-RAD SCORE OF 3 AND BIOPSIES ARE RECOMMENDED, HAIR LOSS AND EXTREME INFLAMMATION IN MY BODY. MY SKIN IS SUPER SENSITIVE, AND I HAVE PAIN DURING INTERCOURSE AS WELL WHEN I PUSH ON MY LOWER

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STOMACH. MY VAGINAL DISCHARGE IS HEAVY AND CLEAR BUT WHEN IT TOUCHES MY OUTER BODY, IT AS IF I'M ALLERGIC TO IT. IT WILL BURN ME LITERALLY AND CAUSE OPEN SORES IF I ALLOW MY OWN FLUIDS TO TOUCH THE OUTSIDE OF MY BODY. I HAVE NO LIBIDO. I HAVE DISCUSSED THESE ISSUES WITH MY FORMER DR. WHO INSERTED ESSURE. HE AGREED TO DO A HYSTERECTOMY BUT ONLY BY CODING IT AS A FAILED ABLATION NOT BECAUSE SOMETHING IN MY BODY IS WRONG. IT'S LIKE A CAR IF SOMETHING GOES WRONG YOU CAN REMOVE THE PART, REPLACE IT, BUT IT WILL GO OUT AGAIN IF YOU DON'T FIX THE UNDERLYING PROBLEM. I DO NOT WANT A HYSTERECTOMY WHICH IS REQUIRED TO REMOVE THE ESSURE IMPLANTS WHICH ARE CAUSING MY SYMPTOMS. I WANT THE ESSURE REMOVED AND MY BODY KEPT AS A WHOLE SO IT OPERATES AND FUNCTIONS NORMALLY AS IT SHOULD. MY FORMER DR. DID NOT HAVE MY BEST INTEREST IN MIND. HE DID NOT ADVICE ME OF THE NECESSARY INFORMATION FOR ME TO MAKE A LOGICAL DECISION ON THIS DEVICE. RATHER THE CONTRARY HE HAD ME SIGN A STANDARD CONSENT AND WITHHELD INFORMATION AS WELL DID NOT PROVIDE ME INFORMATION TO FOLLOW UP. ESSURE HAS FAILED ME AS WELL. MY BODY IS IN A CONSTANT STATE OF INFLAMMATION. IT CAN NOT AND WILL NOT REPAIR ITSELF UNTIL THIS DEVICE IS REMOVED. I DO NOT AND WILL NOT EVER RECOMMEND THIS PRODUCT TO ANYONE. I WILL BE AN ADVOCATE TO ANYONE WHO HAS ESSURE, IS THINKING OF GETTING ESSURE OR TO ANYONE WHO WILL LISTEN THAT THIS PRODUCT IS NOT SAFE. IT IS DEBILITATING AND DISHEARTENING TO FEEL LESS THAN YOU ARE! THEREFORE I AM REPORTING THE PROBLEMS TO THE FDA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057816	BAYER	11/6/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 626403

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE PLACED (B)(6) 2008. HAD NUMEROUS BOILS ON MY BACKSIDE, AND AROUND PRIVATE AREA, STARTED EXACTLY 1 MONTH AFTER PROCEDURE, WHICH WERE PAINFUL, HAD TO HAVE THEM LANCED AND PACKED. MISSED MANY DAYS OF WORK. SAW MULTIPLE DOCS, SAID COULD NOT BE RELATED. (ALTHOUGH I NEVER HAD THEM PRIOR) THESE ARE STILL HAPPENING. EXTREME DANDRUFF IN SCALP AND PRIVATE AREA. GAINED 25 LBS. HEAVY PERIODS, BLED THROUGH. THIS NEVER HAPPENED PRIOR TO IMPLANT. NIGHT SWEATS TERRIBLY WHICH CONTINUE. HAIR FALLING OUT AFTER SHOWER. TERRIBLE LOW BACK PAIN, WHICH I STILL SUFFER FROM. HAD LABS DONE BY MY PCP. WAS DX WITH MGUS. WATCHED UNTIL 2012 WHEN I WAS DX WITH MULTIPLE MYLOMA. HAD 5 MONTHS OF CHEMO, 2 BONE MARROW TRANSPLANTS. STILL ON CHEMO AND MULTIPLE DRUGS, AND WAS TOLD I WILL BE FOR THE REST OF MY LIFE. DEFINITION OF MGUS - BODY'S RESPONSE TO AN ANTIGEN. WHICH IN MY CASE IS THE NICKEL IN THESE COILS. I AM ALLERGIC TO NICKEL. NOT ONCE PRIOR TO PLACEMENT WAS I ASKED THIS. ALSO, I WENT TO HAVE MY TUBES TIED. MY PCP TOLD ME THAT THEY JUST GO IN YOUR BELLY BUTTON. YOU'LL BE HOME SAME DAY. WAS REFERRED TO GYN. HE SAID WE DO ESSURE NOW. MUCH EASIER, AND LESS RECOOP TIME. NEVER HAD THE OPTION. WAS TOLD ESSURE IS WHAT WE WILL BE DOING. MY BIGGEST MISTAKE WAS LISTENING TO MY GYN. I HAVE BEEN OUT OF WORK SINCE (B)(6) 2012. I HAVE WORKED, SOMETIMES 2 JOBS AT ONCE SINCE I WAS 16. THIS DEVICE HAS CHANGED MY LIFE, AND NOT FOR THE GOOD. I'M SO DEPRESSED, ANGRY. ESSURE NEEDS TO BE REMOVED FROM THE MARKET ASAP. I DO NOT WANT ANOTHER WOMAN TO GO THROUGH THE HELL I'VE BEEN THROUGH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057819		11/6/2015	11/12/2015

Event Information:

Event Date (B3): 12/29/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 12/29/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE ON (B)(6) 2011. SINCE THEN I HAVE HAD LONGER AND HEAVIER PERIODS, PAINFUL CRAMPING, WEIGHT GAIN, HEADACHES, EXTREME FATIGUE, TROUBLE HOLDING IN MY URINE, VAGINAL DISCHARGE, AND PAIN DURING SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057820		11/6/2015	11/12/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER HAVING THE ESSURE DEVICE PLACED I DEVELOPED DYSPLASIA AND SEVERE ABDOMINAL PAIN. ALONG WITH SEVERAL OTHER SYMPTOMS THAT WERE NOT PRESENT PRIOR TO THE IMPLANTATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057822	BAYER	11/6/2015	11/12/2015

Event Information:

Event Date (B3): 6/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/24/2013
Explant Date (E7): 7/18/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED ESSURE ON (B)(6) 2013, MY DOCTOR SUGGESTED IT AS AN OPTION TO BIRTH CONTROL IN PLACE OF MY IUD. I WAS (B)(6) AT THE TIME AND NOT EVEN SURE I NEEDED TO BE CONCERNED. MY DOCTOR SAID IT WAS SAFE AND NON-INVASIVE AND A BETTER OPTION THAN THE IUD. I VOICED MY CONCERNS OVER MY PRE-EXISTING AUTOIMMUNE THYROID CONDITION AS WELL AS MY KNOWN SENSITIVITIES TO METALS (INCLUDING NICKEL). I WAS TOLD THAT NEITHER OF THOSE WERE CONTRAINDICATIONS FOR ESSURE. I HOLD A DEGREE IN CLINICAL RESEARCH ADMINISTRATION AND ASKED THE DOCTOR WHAT CLASS MEDICAL DEVICE THIS WAS AND SHE ANSWERED "CLASS II THAT IS UNTRUE. THE DOCTOR ALSO STATED THE COMPOSITION OF ESSURE WAS THE SAME AS SURGICAL PINS. THIS IS ALSO UNTRUE. WITHIN HOURS OF THE PROCEDURE, I EXPERIENCED DEBILITATING PAIN AND HEAVY BLEEDING. I WAS ALSO VOMITING AND DIZZY UPON STANDING. I REACHED OUT TO MY DOCTOR BUT SHE WAS UNRESPONSIVE AND WOULD NOT TAKE MY CALLS. MY SYMPTOMS CONTINUED AND I WAS UNABLE TO KEEP FOOD DOWN. ON DAY 2 POST-PROCEDURE, I DEVELOPED A FULL BODY RASH AND EXPERIENCED A METALLIC TASTE IN MY MOUTH. MY DOCTOR REFUSED TO SEE OR TREAT ME STATING THAT SHE HAD NEVER HAD ISSUES AND THAT THIS MUST BE SOMETHING ELSE. I WAS UNABLE TO GET INTO SEE ANOTHER GYN DUE TO BEING AT A "NEW PT" STATUS AND WAS FORCED TO FIND HELP OUTSIDE OF MY HOME STATE OF (B)(6). I PAID 7000 OUT OF POCKET TO HAVE A SURGEON REMOVE THE COILS AT THE (B)(6) CENTER. DURING SURGERY, I WAS DISCOVERED THAT THE LEFT FALLOPIAN TUBE COIL HAD FALLEN OUT AND WAS IN MY UTERUS. THE SURGEON WAS ABLE TO RETRIEVE IT AS WELL AS REMOVE THE RIGHT SIDE COIL. I HAD TO HAVE A C-SECTION INCISION AND WAS OUT OF WORK AND MY LIFE FOR A MONTH. MY DOCTOR NEVER ACKNOWLEDGED ME OR MY PROBLEMS. MY HEALTH HAS NEVER BEEN THE SAME SINCE THEN. MY FORMERLY, UNDER CONTROL THYROID ISSUES HAVE BEEN OUT OF CONTROL REQUIRING MORE DOCTOR VISITS AND

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MEDICATION. I HAVE SUFFERED FROM UNEXPLAINED RASHES AND AUTOIMMUNE ISSUES OF THE EYE. ESSURE HAS HAD A NEGATIVE IMPACT ON MY HEALTH AND CAUSED CHRONIC INFLAMMATORY RESPONSES IN MY BODY. AT (B)(6), THIS PROCEDURE SHOULD HAVE NEVER BEEN PRESENTED AS AN OPTION GIVEN THE KNOWN RISKS AND I SHOULD HAVE BEEN TOLD THE TRUTH. THE FDA IS THE AGENCY THAT IS SUPPOSED TO PROTECT THE CONSUMER FROM HARM AND DANGER. THIS IS NOT HAPPENING WITH ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057807	BAYER	11/7/2015	11/12/2015

Event Information:

Event Date (B3): 1/8/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/8/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2006: HAD ESSURE PROCEDURE DONE (B)(6) 2006. STARTED HAVING EXTREMELY HEAVY PERIODS LASTING WEEKS AT A TIME CAUSING PROBLEMS WITH MY DAY-TO-DAY LIFE. IN (B)(6) 2006, WAS SCHEDULED FOR A PARTIAL HYSTERECTOMY. IN (B)(6) 2007, PARTIAL HYSTERECTOMY DONE. SINCE THAT TIME I HAVE BEEN DIAGNOSED WITH SEVERAL NEW SYMPTOMS SUCH AS: ASTHMA, AUTOIMMUNE DISORDERS AFFECTING MY JOINTS, MUSCLES, AND SKIN, ARTHRITIS, WORSENING HEART PROBLEMS, FLUID RETENTION AND SEVERE WEIGHT GAIN, ELEVATED LIVER ENZYMES, LOW POTASSIUM, LOW VITAMIN D, CALCIUM AND ELEVATED IRON STORES. SEVERE SKIN SCARRING WITH BRONZING OF THE SKIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057814	BAYER	11/7/2015	11/12/2015

Event Information:

Event Date (B3): 10/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 1/1/2005
Explant Date (E7): 10/16/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE COIL MIGRATED INTO ABDOMINAL CAVITY CAUSING PAIN, NAUSEA, VOMITING. DEVICE HAD TO BE SURGICALLY REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057744	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 8/20/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS PROVIDED THROUGH MY INSURANCE. CHRONIC EAR INFECTIONS, PROBLEMS WITH MY EYE SIGHT, THE BEGINNING OF REALLY BAD HEADACHES, SEVERE CRAMPS, EXTREME BLOATING, AND JOINT PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057745	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 8/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMPLANTS INSERTED AT KAISER PERMANENTE. EXPERIENCED SEVERE PAIN AND CRAMPING BUT WAS TOLD IT WAS NORMAL. NOW DIAGNOSED WITH EARLY PID. EXPERIENCING SEVERE PELVIC PAIN, CERVICAL LESIONS, LARGE BLOOD CLOTS PASSING DURING PERIODS, SEVERE PMS, AND MIGRAINE HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057746	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 11/27/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE 2009 AFTER HAVING THE ESSURE PROCEDURE I HAD SEVERE STABBING PAIN ON MY LEFT SIDE, ONLY WHERE THE ENSURE WAS PLACED. THE DOCTOR WAS ONLY ABLE TO PLACE IT ON ONE SIDE DURING THE SURGERY. SINCE THEN I HAVE GONE TO THE DOCTOR WITH NUMEROUS COMPLAINTS: SHARP STABBING PAIN, ALWAYS TIRED, SKIN IRRITATION RASH WITH ITCHING, HAIR LOSS, HEART PALPITATIONS, SLEEP APNEA, DIFFICULTY SLEEPING, STOMACH PAIN, JOINT PAIN IN THE NECK, LEFT ARM, KNEES AND HIP, RT. FOOT EDEMA, BOWEL ISSUES, BREAST PAIN, OVARIAN CYST, UTI, ANEMIA, BLEEDING BLOOD CLOTS DURING MENSES, INCONTINENCE, VAGINITIS, FREQUENT URINATION, DIARRHEA, DIZZINESS, VIT D DEFICIENCY, KIDNEY PAIN, GOUT. I ALSO EXPERIENCED UNREPORTED ISSUES SUCH AS FORGETFULNESS, NIGHT SWEATS, METALLIC TASTE IN THE MOUTH, LIKE SALT, LOSS OF HAIR IN MY RIGHT EYEBROW. MY DOCTOR HAS TESTED ME FOR CANCER, LUPUS, RHEUMATOID ARTHRITIS. ALL THESE SHOULD BE IN MY MEDICAL RECORDS CHART. I WAS NOT AWARE THAT THESE SYMPTOMS WERE THE CAUSE OF THE ESSURE, UNTIL (B)(6) 2015 WHEN THERE WAS A REPORT ON (B)(6). THAT'S WHEN I LOOKED IT UP AND FOUND THE LIST OF SYMPTOMS COINCIDED WITH ALL MY HEALTH ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057747	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 11/25/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I DON'T REMEMBER THE FIRST TIME THE RASH CAME UP BUT I HAVE NEVER HAD NOTHING LIKE THIS COME AND GO AND POP UP ANYWHERE ON MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057748	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 11/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PELVIC PAIN, WEIGHT GAIN, EXTREME STOMACH BLOATING, JOINT PAIN, FATIGUE, HEADACHES, MOOD SWINGS, DEPRESSION, CAN'T SLEEP ON MY RIGHT SIDE DUE TO PAIN, DROP IN SEX DRIVE, PAINFUL SEX.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057749	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 7/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE INSERTED IN (B)(6) 2013 "ANDAMP"; BY (B)(6) 2013 I STARTED HAVING INTENSE MIGRAINE HEADACHES. I ATTRIBUTED IT TO MAYBE STRESS, MAYBE LIFESTYLE OR JUST BAD LUCK. SINCE (B)(6) 2013 I HAVE HAD INCREASED BLOATING IN MY ABDOMINAL REGION. SO BAD I LOOK 5 MONTHS PREGNANT "ANDAMP"; I HAVE NEVER HAD A WEIGHT ISSUE IN MY LIFE. AS OF (B)(6) 2015 I HAVE RAISED BLOOD PRESSURE, WEIGHT GAIN, EXCESSIVE SWEATING, AND HOT FLASHES. FROM 2013-TODAY I HAVE AND CONTINUE TO EXPERIENCE LOSS OF LIBIDO, HEAVY-EXCESSIVE MENSTRUATION, LEG "ANDAMP"; FEET SWELLING, UNEXPLAINED FEVERS, DISCHARGE W/OR W/O ODOR, VERY LONG MENSTRUAL CYCLES (3 WEEKS IN LENGTH), PAINFUL INTERCOURSE, FREQUENT URGENT URINATION, NAUSEA, MOOD SWINGS, DIZZINESS, SHAKES, EARS RINGING, ABDOMINAL SPASMS/TWITCHING/FLUTTERING, AND HEART PALPITATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057750	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 10/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL PERIODS, BLOATING, BACK PAIN, PELVIC PAIN, 30 LB WEIGHT GAIN, JOINT PAIN, BRAIN FOG. ENDED UP WITH HYSTERECTOMY WITH ENDOMETRIOSIS AND ADENOMYOSIS. ALL EVENTS OCCURRED AFTER ESSURE IMPLANT!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057751	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 7/6/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE IMPLANTED (B)(6) AWFUL HEAVY BLEEDING LOW IRON. SEVERE BLOATING, HAIR LOSS BONE LOSS. (B)(6) I GET FULL DENTURES DUE TO EXTREME BONE LOSS. I ALSO BECAME PREGNANT IN (B)(6)2014. INSURANCE PAID.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057752	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 11/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVES MY COILS IN 2012 AND SINCE THEN, I HAVE NOTICED A LOT OF PROBLEMS IN MY HEALTH SINCE THEN. I GET HEADACHES ALL THE TIME, LOWER BACK PAIN, HIP PAIN, EXCRUCIATING LEG PAIN MORE AT NIGHT, TO EVEN PRESS ON MY LEGS HURTS SO BAD, I HAVE TROUBLE SLEEPING, NO ENERGY TO DO MUCH OF ANYTHING. MY DR HAS HAD ME ON ALL SORTS OF MEDICATION TO HELP THE FIBROMYALGIA THAT SHE SEEMS TO THINK I AM SUFFERING FROM. I HAVE BEEN ON SO MANY AND NOTHING EVER HELPS. I TAKE VICODIN FOR PAIN BUT ALL THAT DOES IS HELP ME TO SLEEP SOME. I HAVE BEEN PUT ON ADDERALL TO HELP ME FOCUS BECAUSE I FORGET THINGS ALL THE TIME. I TAKE CYMBALTA FOR WIDE SPREAD PAIN AND DEPRESSION. I DON'T EVEN WANT TO GET OUT OF BED EVERYDAY. MY JOB IS BEING AFFECTED BECAUSE I CAN'T PLAY WITH THE KIDS AT SCHOOL LIKE I USED TO.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057753	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 2/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVING THIS DEVICE IN PLACE LEAD ME TO HAVING EXTREME MENSTRUAL PERIODS THAT LEAD ME TO BE ANEMIC ALL THE TIME, ENDED UP HAVING TO HAVE AN ABLATION...HOWEVER THERE IS STILL A LOT OF ABDOMINAL PAIN IN MY UTERUS AREA, HEADACHES, FATIGUE, AND MOOD SWINGS. ..

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057754	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 8/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2009. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2009. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. SEVERE PELVIC PAIN, HEAVY BLEEDING, CONSTIPATION, HAIR LOSS, RASH DUE TO NICKEL ALLERGY, DEPRESSION, BACK, SHOULDER, NECK PAIN, WEIGHT GAIN, UNABLE TO LOSE WEIGHT, LEG AND ARM NUMBNESS, BRAIN FOG, FATIGUE, SLEEP LOSS, MIGRAINES, TOOTH DECAY, ITCHING, QUICK TEMPER LOSS, METALLIC TASTE IN MOUTH. I HAVE BEEN SEEN BY 2 DOCTORS. THE DEVICE IS STILL INSIDE OF ME. THE DEVICE WAS COVERED BY MEDICAID.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057755	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 1/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING ALL SYMPTOMS 1 MONTH AFTER PLACEMENT SEVERE ABDOMINAL PAIN, WAS DX WITH INTERSTITIAL CYSTITIS THREE MONTHS AFTER PLACEMENT, NO DESIRE FOR INTERCOURSE ONE WEEK AFTER, AND KIDNEY STONES, LOSS OF APPETITE HAIR LOSS EXTREME FATIGUE HEADACHES GALLBLADDER PAINS DRY ITCHY SKIN JOINT PAINS BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057756	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 1/19/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). YEARS LATER, BECAME PREGNANT TWO YEARS AFTER AND THEN ANOTHER TWO YEARS LATER. SO TWO PREGNANCIES IN ALL. ALSO, BEGAN TO HAVE HEALTH ISSUES THAT NEVER OCCURRED BEFORE. HEAVY CYCLES, IRREGULAR CYCLES, BACK PAIN ABDOMINAL PAIN, CRAMPING, HEADACHES, VITAMIN D DEFICIENCY, NUMBNESS, CYST, SORENESS IN MY BREAST, CHEST PAIN, DAMAGED NERVES, DIZZY SPELLS, DEPRESSION, ANXIETY, WEAKENED LEGS, FATIGUE, SPASMS, BRUISES, FREQUENT BLEEDING, OVERACTIVE BOWELS, HAIR LOSS AND DAMAGE, SKIN RASHES AND CHANGES, LIGHTNING AND DARKENED SKIN AREAS. CONSTANT UTI'S, WEAKENED IMMUNE SYSTEM. MY DEVICE WAS PROVIDED BY THE DR'S OFFICE OF THE DOCTOR WHO DID THE PROCEDURE DR (B)(6). I RECEIVED A DYE TEST 3 MONTHS LATER AFTER THE DEVICE WAS INSERTED. CYCLES BEGAN HEAVY THEN BECAME LIGHT AND LATER CONTINUOUS BLEEDING THROUGH OUT THE MONTH. OVER THE LAST YEAR, I HAVE BEEN IN AND OUT OF THE DR'S OFFICE, SEEING SPECIALIST AND CAN'T EXPLAIN WHY OTHER THAN A RESULT OF THE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057757	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 3/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES,PAIN,BLEEDING,SHARP CUTTING FEELING,SOMETIMES CAN'T FEEL RIGHT LEG,WEIGHT LOSS,WEAK BONES,TEETH DECAYING,FINGERNAILS BREAK EASY,MIGRAINES

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057758	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 1/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN THE 10 MIN FOLLOWING THE ACTUAL PROCEDURE, I WAS IN EXTREME PAIN AND WAS TOLD BY THE DR. THAT HE HAD NEVER SEEN THAT HAPPEN AND ASSUMED THAT MY TUBE WAS SPASMING AND HE SAID THAT THE RIGHT TUBE WAS SOMEWHAT SMALL AND THAT COULD HAVE BEEN THE CAUSE. I WAS FINE THE DAYS FOLLOWING THE PROCEDURE. ABOUT A YEAR AGO, I STARTED REALIZING THAT DURING MY PERIOD, I WAS HAVING TERRIBLE LOWER BACK PAIN ON THAT SIDE. I PUT 2 AND 2 TOGETHER AND FIGURED THAT IS WHAT IT IS. I HAVE ALSO GAINED AROUND 15 POUNDS WHICH DOESN'T SEEM LIKE MUCH BUT I AM ONLY (B)(6). THE WEIGHT HAS BEEN A HUGE ISSUE PHYSICALLY AND EMOTIONALLY. FROM THE WAIST DOWN, I DON'T EVEN LOOK LIKE THE SAME PERSON DUE TO BLOATING AND SWELLING. WORST DECISION OF MY LIFE!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057759	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 6/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS COVERED BY MY INSURANCE. I WAS TOLD BY MY DOCTOR TO GET ESSURE WHEN I ASKED TO HAVE MY TUBES TIED. SHE TOLD ME THAT ESSURE WAS THE BEST WAY TO GO AND I HAD 0 PERCENT CHANCE OF GETTING PREGNANT. SHE ASSURED ME THAT THIS WAS THE BEST WAY TO GO. IN (B)(6) OF THIS YEAR 2015 I WAS TO HAVE SURGERY. SHE DID PUT ME UNDER SO I WAS UNAWARE WHAT WAS GOING ON. AFTER THE SURGERY I WAS IN REALLY BAD PAIN FOR AT LEAST A WEEK IF NOT LONGER. I TOOK LOTS OF PAIN MEDS TO GET THROUGH IT. I STARTED THINKING EVERYTHING IN MY LIFE WAS GOING TO GET BETTER. IT HAS ACTUALLY STARTED TO GET WORSE SINCE I GOT ESSURE. I HAD A JOB THAT I HAD TO QUIT BECAUSE I WAS GETTING DIZZY AT WORK AND ALMOST PASSING OUT. MY MOODS CHANGED. MY HAIR STARTED FALLING OUT. MY TOOTH BROKE AND HAVE CONTINUED TO GET WORSE. THE PAIN IN MY BACK, HIPS, STOMACH, PELVIC BONE, STABBING PAINS IN MY VAGINA HAS SLOWLY GOTTEN WORSE AND WORSE. MY MONTHLY PERIODS ARE NOT RIGHT. I GUSH FOR 3 DAYS WITH CRAMPS AND PAIN. THEN THEY STOP FOR 3 DAYS THEN COME BACK THE SAME. I WISH I COULD SAY ITS A PATTERN BUT ITS JUST CONSTANT ALL THROUGH THE MONTH. I HAVE NO DESIRE TO HAVE SEX AND WHEN I DO IT HURTS. HEADACHES AND FEVERS ON AND OFF. I METAL LIKE TASTE IN MY MOUTH. THE ONE THING THAT'S BEEN THE HARDEST IS THE ACHES. I CANT WALK IN THE MORNING SOMETIMES BECAUSE OF THE PAIN IN MY FEET. WEIGHT GAIN. 20 OR 30 POUNDS. FEELING LIKE IM GOING TO THROW UP AT LEAST 5 DAYS OUT OF THE WEEK. SOMETIMES I DO. TIREDNESS EVERYDAY. I HAVE 4 CHILDREN AND BEING SICK LIKE THIS IS NOT AN OPTION. I FEEL LIKE I'M SLOWLY DYING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057760	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 6/9/2008	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL, HEAVY PERIODS, DIARRHEA, VOMITING, WEIGHT GAIN. I HAD A HYSTERECTOMY, SALPINGO-OOPHORECTOMY OF MY RIGHT OVARY BECAUSE OF ADENOMYOSIS AND ENDOMETERIOSIS. I HAVE HAD A CYSTECTOMY ON THE LEFT OVARY THIS YEAR. I HAVE DEVELOPED HYPOTHYROIDISM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057761	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 9/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED AFTER THE BIRTH OF MY DAUGHTER (B)(6) AGO. I HAVE STARTED TO EXPERIENCE HAIR LOSS, CRAMPING CONSTANTLY, BLEEDING IRREGULARLY, AND SHARP PAINS IN MY ABDOMEN. I WENT BACK AND FOURTH WITH MY DOCTOR. THEY TOOK ULTRASOUNDS TO SEE IF THEY COULD SEE ANYTHING. SHE ASKED IF I HAD AN IUD IMPLANTED. I SAID NO I HAVE ESSURE. WELL THE DOCTOR ENDED UP LOOKING AT IT AND WE HAD TO REMOVE THE COIL FROM ONE OF THE TUBES. IT WAS POKING ME AND THAT IS WHAT WAS CAUSING THE SHARP PAINS. I MISSED WORK AND TIME AWAY FROM MY KIDS BECAUSE I WAS DOWN. THIS TIME OF EVENTS LASTED ABOUT 4 WEEKS IN TOTAL. IT WAS HORRIBLE AND HAS BEEN A HORRIBLE EXPERIENCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057762	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, STABBING PAINS IN OVARY AREA, HAIR LOSS, HEADACHES, SKIN RASHES/FLUSHING, PAINFUL PERIODS, HEAVY PERIODS, WEIGHT GAIN, JOINT PAIN, HIP PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057763	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 11/1/2005	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD PAIN SINCE THE DEVICE WAS IMPLANTED. SINCE THEN THE PAIN HAS GOTTEN WORSE AND WORSE. I HAVE BEEN TOLD THAT THE ONLY OPTION IS A HYSTERECTOMY. THE PAIN HAS BECOME EXCRUCIATING AT TIMES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057764	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE IN (B)(6) OF 2010 AND BEGAN EXPERIENCING SEVERAL SIDE EFFECTS ABOUT A YEAR LATER. MY INSURANCE DID PAY FOR THE DEVICE. SOME OF MY SYMPTOMS OVER THE YEARS INCLUDE EXTREME DRY MOUTH, HEADACHES, HOT FLASHES, TINGLING/NUMBING FEELING IN MY HEAD AND NECK, TERRIBLE BACK PAIN, ALL OVER BODY ACHES, CHRONIC CONSTIPATION, FREQUENT UTI'S, FREQUENT YEAST INFECTIONS, VAGINAL PAIN, PAIN DURING INTERCOURSE, BLURRY VISION, MENTAL FOGGYNESS, SLEEP DISTURBANCES, ANXIETY, HAIR LOSS, AND MUCH MORE! THIS HAS BEEN A TERRIBLE PRODUCT AND NEEDS TO BE TAKEN OFF THE MARKET FOR OTHER WOMEN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057765	BAYER	11/9/2015	11/9/2015

Event Information:

Event Date (B3): 4/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DUE TO ALLERGIES, I DEVELOPED A SEVERE COUGH. THESE COUGHING FITS HAVE BROUGHT ON CRAMPING WORSE THAN ENDOMETRIOSIS CONSTANT PAIN. ABOUT THIS TIME, MY PERIODS BECAME MUCH HEAVIER, AND MORE PAINFUL THAN THEY'VE EVER BEEN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01384	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 4/24/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/24/2008
Explant Date (E7): 9/19/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6)-YEAR-OLD FEMALE CONSUMER IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN (B)(6) 2013 FOR PERMANENT CONTRACEPTION. CONSUMER EXPERIENCED LOWER BACK, ABDOMEN AND PELVIC PAIN, WORSE THAN A MENSTRUAL CRAMP, REGARDING OF WHAT POSITION WHEN LAYING DOWN. IT WAS REPORTED THAT THE PAIN STARTED AROUND (B)(6) 2013, BUT THE SYMPTOMS WORSENED AROUND (B)(6) 2013. SHE ALSO EXPERIENCED PASSING CLOTS. TESTS FOR BLADDER, KIDNEY INFECTION AND CONSTIPATION WERE PERFORMED AND ALL RESULTS WERE NEGATIVES. CONSUMER WANTED TO KNOW IF ESSURE CAN BE REMOVED DUE TO PAIN WITHOUT HYSTERECTOMY AND SALPINGECTOMY. FOLLOW UP RECEIVED ON (B)(6) 2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FOLLOW UP RECEIVED ON 19-OCT-2015 VIA FDA REGULATORY REPORT (MAUDE MW5056475) -

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CASE UPGRADED TO INCIDENT. CONSUMER REPORTED THAT ESSURE WAS PLACED ON (B)(6) 2008 AND SINCE INSERTION SHE HAVE BEEN EXPERIENCING HORRIBLE PAIN IN PELVIS, LOWER ABDOMEN, HIPS AND LOWER BACK PAIN, CONSTANT CHRONIC PAIN THAT CONTINUES GET WORSE DURING AND AFTER MENSES, PAINFUL INTERCOURSE AND SUFFERING. ACCORDING TO HER, SYMPTOMS HAVE GOTTEN WORSE. IT WAS REPORTED (B)(6) 2015 AS DEVICE EXPLANT DATE. INTERNAL COMMUNICATION RECEIVED ON 29-OCT-2015 DESCRIBING THAT THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. THE NEW RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 31-OCT-2015: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER WHO HAD ESSURE INSERTED ON (B)(6) 2008 AND EXPERIENCED SEVERE PELVIC PAIN AMONGST NON-SERIOUS EVENTS. PELVIC PAIN IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. THIS CASE IS REGARDED INCIDENT SINCE DEVICE EXPLANT DATE WAS PROVIDED; THEREFORE, SURGICAL INTERVENTION WAS IMPLIED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01391	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D01973

Single Use: Y
Implant Date (E6): 6/18/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 12-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN REPORTED HIS PATIENT HAD AN ESSURE CONFIRMATION TEST PERFORMED AND THE RESULTS READ THAT THE OUTER COIL WAS FRACTURED BUT FULL, BILATERAL OCCLUSION WAS ACHIEVED. THE PHYSICIAN SAID THE RIGHT COIL WAS PERFORATED WITH SEPARATION OF THE INNER AND OUTER COILS. THE PATIENT WAS ASYMPTOMATIC. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER ESSURE CONFIRMATION TEST SHOWED THE RIGHT COIL WAS PERFORATED WITH SEPARATION OF THE INNER AND OUTER COILS (OUTER COIL WAS FRACTURED). THESE EVENTS WERE INTERPRETED AS FALLOPIAN TUBE PERFORATION AND DEVICE BREAKAGE. PERFORATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE DEVICE BREAKAGE IS UNLISTED. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED AND THE EXACT MECHANISM OF THE EVENTS IS NOT KNOWN. NEVERTHELESS, GIVEN THEIR NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND A PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2015: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE OUTER COILS OF THE INSERT EXPAND TO CONFORM TO THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01392	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 9/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) YEAR-OLD FEMALE CONSUMER IN (B)(6) ON 06-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. CONSUMER'S CONCOMITANT CONDITIONS INCLUDED ALLERGY TO METAL, DIABETES AND HYPERTENSION. THE MEDICATION SHE TAKE WERE: METFORMIN, FORXIGA, LEVEMIR INSULIN, FLUOXETINE AND ANOTHER MEDICATION FOR BLOOD PRESSURE, THE NAME OF WHICH SHE DOES NOT REMEMBER. IMMEDIATELY AFTER ESSURE INSERTION, CONSUMER SPENT A FEW DAYS IN BED WITHOUT BEING ABLE TO MOVE FROM THE PAIN. TWO MONTHS AFTER THE IMPLANT, SHE STARTED TO HAVE STRONG OVARIAN PAIN. SHE SAID THAT IT WAS LIKE PERIOD PAIN, BUT MUCH STRONGER, ALMOST LIKE CONTRACTIONS. SINCE THEN, SHE WAS EXPERIENCING CONSTANT PAIN THAT SHE CANNOT RELIEVE WITH ANYTHING. SHE USUALLY TAKES BUSCAPINE OR ENANTYUM. SHE ALSO EXPERIENCED CONSTANT UTIS (URINARY TRACT INFECTIONS) AND PROBLEMS WITH CANDIDIASIS INFECTIONS. IN THE LAST FEW MONTHS, SHE EXPERIENCED IRREGULAR PERIODS AND BLEEDING BETWEEN PERIODS. ACCORDING TO THE CONSUMER, A WEEK AFTER A PERIOD, SHE STARTS INTERMENSTRUAL SPOTTING AGAIN. TWO MONTHS AGO, SHE UNDERWENT A HYSTEROSCOPY AND ANOTHER ONE WILL BE PERFORMED. SHE WAS TOLD THAT DEVICE AND HER OVARIES WILL BE REMOVED. AS A RESULT OF THE PROCESS AND THE PAIN, SHE SUFFERED FROM DEPRESSION. CONSUMER WANTED COMPENSATION FOR ALL THE DAMAGES AND TO REPORT HER SITUATION. FOLLOW-UP INFORMATION WAS RECEIVED ON 14-OCT-2015 FROM CONSUMER AND CASE WAS UPGRADED TO INCIDENT: A HYSTERECTOMY WAS PERFORMED DUE TO THE PAIN SHE WAS SUFFERING, AND THEY WANTED TO REMOVE THE DEVICE. HOWEVER, IT WAS NOT POSSIBLE TO REMOVE IT BECAUSE THE FLESH WAS TOO DEVELOPED AROUND THE DEVICE AND IT COULD NOT BE REMOVED. ON (B)(6) 2015 SHE WILL HAVE A NEW MEDICAL APPOINTMENT TO ASSESS AND PERFORM PREOPERATIVE EXAMINATIONS FOR THE

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OVARIES REMOVAL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD PAIN IMMEDIATELY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE DEVELOPED BLEEDING BETWEEN PERIODS. SHE WAS SUBMITTED TO A HYSTERECTOMY DUE TO HER PAIN. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER DEVELOPED PAIN IN CLOSE ASSOCIATION WITH ESSURE PROCEDURE. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING HER BLEEDING (INTERPRETED AS GENITAL BLEEDING); IT STARTED MORE THAN 6 YEARS AFTER ESSURE PLACEMENT. ALTHOUGH TEMPORAL RELATIONSHIP FOR THIS EVENT IS WEAK, SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS INITIALLY CONSIDERED A NON-INCIDENT. HOWEVER, SINCE A HYSTERECTOMY FOR DEVICE REMOVAL WAS REPORTED UPON FOLLOW-UP; CASE WAS UPGRADED TO INCIDENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 12-NOV-2015 WITH THE FINAL PTC (PTC GLOBAL NUMBER: (B)(4)) INVESTIGATION RESULT: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01393	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 6/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/2/2014
Explant Date (E7): 8/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 15-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. GYNECOLOGIST REPORTED THAT ON (B)(6) 2014 AT THE INSERTION PROCEDURE, LEFT ESSURE DID NOT UNFOLD. ACCORDING TO HEALTH CARE PROFESSIONAL, ESSURE WAS PULLED OUT AND A NEW ESSURE HAD BEEN INSERTED. ULTRASOUND REVEALED CORRECT POSITIONS OF THE COILS. ON HYSTEROSALPINGOGRAM RESULTS THERE WAS A DOUBT REGARDING POSITION OF LEFT ESSURE. ON (B)(6) 2014 TEST WAS SENT TO PANEL (AS REPORTED) (HAD TO WAIT FOR 4 MONTHS FOR THE RESULTS) AND BASED ON THE RESULTS IT HAD BEEN DECIDED TO CHECK THE POSITION OF ESSURE BY LAPAROSCOPY. ON (B)(6) 2015 LAPAROSCOPIC CHECK OF ESSURE WAS PERFORMED AND GOOD POSITION WAS CONFIRMED. ON (B)(6) 2015 PATIENT RETURNED AND COMPLAINED OF INCREASE IN DYSFUNCTIONAL BLOOD LOSS, ITCHING OVER ENTIRE BODY, INCREASED CRAMPS DURING MENSTRUAL PERIOD AND PAIN IN HIP AND KNEE. ON (B)(6) 2015 UTERINE REMOVAL WAS PERFORMED. ON (B)(6) 2015 PATIENT VISITED PHYSICIAN AND COMPLAINTS WERE RESOLVED. CASE CONSIDERED TO BE CLOSED. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A YEAR AFTER THE INSERTION, THE PATIENT COMPLAINED OF INCREASE IN DYSFUNCTIONAL BLOOD LOSS (INTERPRETED AS GENITAL BLEEDING) AMONG OTHER NON-SERIOUS EVENTS. THE GENITAL BLEEDING IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH THE ULTRASOUND AND LAPAROSCOPIC CHECK SHOWED THAT INSERTS WERE CORRECTLY PLACED, GIVEN THE IMPLIED TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE GENITAL BLEEDING CANNOT BE EXCLUDED.

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THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. FURTHER INFORMATION AND A PRODUCT TECHNICAL COMPLAINT ANALYSIS ARE EXPECTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 10-DEC-2015: (B)(4). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR US

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01394	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 10/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/23/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 14-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR CONTRACEPTION. SHE WAS NOT PREGNANT. THE PATIENT WAS ADMITTED TO HOSPITAL ON (B)(6) 2015 WITH SEVERE PAIN WHICH STARTED ON (B)(6) 2015; IT WAS REPORTED SHE COULD NOT MOVE. SHE HAD BEEN EMERGENCY ROOM SEVERAL TIMES SINCE ESSURE INSERTED. THE CT SCAN, ULTRASOUND, AND CBC (FULL BLOOD COUNT) ALL CAME BACK NORMAL. AT TIME OF THE REPORT, SHE WAS ON ANTIBIOTICS AND PAIN MEDICATION; THE EVENTS WERE STILL OCCURRING AND THE DEVICES WERE NOT REMOVED. FOLLOW UP INFORMATION RECEIVED ON 19-OCT-2015: THE PATIENT HAD ESSURE ON APPROXIMATELY (B)(6) 2015 (DISCREPANT INFORMATION). SHE EXPERIENCED PAIN, ENOUGH TO GO THE ED (UNDERSTOOD AS ER) SEVERAL TIMES BEFORE BEING ADMITTED FOR SEVERE PAIN. SHE HAD NORMAL WBC, CBC, CULTURES, ULTRASOUND AND CT WERE REPORTED TO SHOW ESSURE IN APPROPRIATE LOCATION WITH NO OTHER FINDINGS, AND AT THE TIME OF THIS REPORT THE FILMS WERE NOT SEEN BY PROVIDER BUT REVIEWED WITH RADIOLOGIST. THE PROVIDER STATED NO PROBLEMS WITH INSERTION. THESE FINDINGS WERE DISCUSSED WITH THE PROVIDER: THESE MAY REPRESENT A PERFORATION AND A LAPAROSCOPY WITH POSSIBLE REMOVAL WAS RECOMMENDED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 29-OCT-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO

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CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENT IS KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS HOSPITALIZED DUE TO SEVERE PERSISTENT PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. A LAPAROSCOPY WITH POSSIBLE REMOVAL OF ESSURE WAS RECOMMENDED, AS PATIENT SYMPTOM MIGHT REPRESENT A PERFORATION. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, PATIENT WENT TO THE ER SEVERAL TIMES DUE TO PAIN UNTIL SHE WAS HOSPITALIZED. ALTHOUGH, ACCORDING TO THE REPORT, NO ABNORMALITIES WERE FOUND IN HER CT SCAN, ULTRASOUND AND BLOOD COUNT; A PERFORATION WAS SUSPECTED. THE EVENTS OCCURRED A FEW DAYS AFTER ESSURE INSERTION. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED EVENTS; CAUSALITY CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE HOSPITALIZATION WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION (PATIENT'S OUTCOME) IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01395	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 5/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/22/2011
Explant Date (E7): 10/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 14-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 FOR CONTRACEPTION. PATIENT HAD COMPLAINTS OF ABDOMINAL PAIN. DUE TO THESE COMPLAINTS, SHE WENT TO THE HOSPITAL ON (B)(6) 2012; TO A MEDICAL CENTER ON (B)(6) 2015 AND TO THE ER ON (B)(6) 2015. ON (B)(6) 2015 SHE MENTIONED SHE BELIEVED ESSURE WAS CAUSING ABDOMINAL PAIN. ESSURE WAS REMOVED ON (B)(6) 2015 (IT WAS REPORTED THAT ESSURE WAS AT CORRECT PLACEMENT AT TIME OF REMOVAL). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS

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MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED DUE TO COMPLAINTS OF ABDOMINAL PAIN. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE PATIENT SOUGHT MEDICAL ASSISTANCE SEVERAL TIMES DUE TO PAIN. ESSURE WAS REMOVED 4.5 YEARS AFTER ITS PLACEMENT AND DEVICES WERE FOUND IN CORRECT POSITION DURING THE SURGERY. ALTHOUGH NO ABNORMALITIES WERE FOUND DURING ESSURE REMOVAL; GIVEN EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01396	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 10/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(6)) IN (B)(6) ON 16-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON AN UNSPECIFIED DATE. ON (B)(6) 2013 THE CONSUMER EXPERIENCED STABBING PAIN ON LOCATION OF ESSURE DEVICES, EXTREME BLEEDING, CONSTANT YEAST INFECTIONS, DEBILITATING MIGRAINES, PAIN WITH INTERCOURSE, METAL TASTE IN MOUTH, NICKEL ALLERGY, VERTIGO, JOINT PAIN, SEVERE LOWER BACK PROBLEMS, PAIN SHOOTING FROM LOCATION OF DEVICES DOWN THROUGH PELVIC AREA TO MY LEGS, REOCCURRING BOUTS OF BACTERIAL VAGINOSIS, WEIGHT LOSS, APPETITE LOSS, EXTREME BLOATING OF THE ABDOMINAL AREA, PALPITATIONS, STABBING FEELING IN THE VAGINAL AREA, HAIR LOSS, NAIL BREAKAGE AND LINES IN NAILS ALSO. ESSURE WAS REMOVED VIA LAPAROSCOPIC-ASSISTED VAGINAL HYSTERECTOMY. FOLLOW-UP INFORMATION RECEIVED ON 21-OCT-2015: ADDITIONAL NCA REFERENCE NUMBER WAS PROVIDED ((B)(4)). PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 28-OCT-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT

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INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP 27-OCT-2015: INFORMATION RECEIVED FROM THE HEALTH AUTHORITY (B)(6) WHICH INFORMED THAT THE CONSUMER REPORTED THIS CASE TWICE AND THE HA REFERENCE NUMBER (B)(4) WAS DELETED TO AVOID CONFUSION. IT HAS BEEN ATTACHED TO THE RECORD FOR(B)(4). THEREFORE ONLY THE NUMBER (B)(4) IS VALID. FOLLOW-UP RECEIVED ON 04-NOV-2015: RESPONSE RECEIVED FROM CONSUMER WHO DOES NOT WISH TO GIVE ANY FURTHER INFORMATION. CASE CONSIDERED CLOSED. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 04-NOV-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ABDOMINAL PAIN LOWER. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 160 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. THIS CASE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER HAD STABBING PAIN ON LOCATION OF ESSURE DEVICES (INTERPRETED AS ABDOMINAL PAIN) AND EXTREME BLEEDING (INTERPRETED AS GENITAL BLEEDING). ESSURE WAS REMOVED VIA LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY. ABDOMINAL PAIN AND GENITAL BLEEDING ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. BOTH EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE TEMPORAL RELATIONSHIP BETWEEN THE ESSURE INSERTION AND THE REPORTED EVENTS IS UNCLEAR. HOWEVER, CONSIDERING THE NATURE OF THESE EVENTS AND THE LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01397	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 14-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. AFTER A FEW MONTHS SHE STARTED COMPLAINING OF PAIN AND SHE WAS TOLD IT WAS IN THE RIGHT PLACE. THE CONSUMER WAS IN THE CARE OF A NEW PHYSICIAN AND COMPLAINED TO THE NEW PHYSICIAN; HE DID AN ULTRASOUND AND SAID IT WAS IN THE RIGHT PLACE AND DIDN'T KNOW WHY SHE WAS HAVING PAINS. SHE REQUESTED A SECOND OPINION IN 2015, SAW A DIFFERENT PHYSICIAN AND HE DIDN'T DO ANY TEST OR ANYTHING. HE AGREED TO REMOVE IT AND SHE WENT IN TO HAVE IT REMOVED AND HER FALLOPIAN TUBES IN 2015. AFTER THE REMOVAL HER PHYSICIAN CAME IN AND SAID IT WAS IN THE CORRECT PLACE AND HE DIDN'T UNDERSTAND WHY SHE HAD PAIN. A FEW WEEKS LATER, AFTER THE REMOVAL, SHE NO LONGER HAD ANY PAIN. THE CONSUMER STATED SHE WAS NO LONGER ABLE TO HAVE CHILDREN AND HER HUSBAND AND SHE WERE PERSUADED INTO HAVING THE ESSURE PLACED EVEN THOUGH THEY WANTED MORE CHILDREN. THE REASON IT WAS IMPLANTED IS BECAUSE SHE DIDN'T HAVE REGULAR PERIODS AND AFTER BEING ON BIRTH CONTROL OFF AND ON HER PERIODS NEVER BECAME REGULAR. SHE WANTED MORE CHILDREN AND NOW HER DAUGHTER IS AN ONLY CHILD BECAUSE SHE CAN NO LONGER GET PREGNANT WITHOUT IN VITRO. FOLLOW UP INFORMATION RECEIVED ON 29-OCT-2015 (PTC INVESTIGATION RESULT): THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE,

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NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER A FEW MONTHS STARTED COMPLAINING OF PAIN (INTERPRETED AS PELVIC PAIN). SHE HAD ESSURE REMOVED ONE YEAR AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01398	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2014
Explant Date (E7): 10/7/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 15-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. CONSUMER REPORTED THAT SHORT TIME AFTER INSERTION SHE EXPERIENCED UNEXPLAINED BRUISES ALL OVER HER BODY, BACK AND PELVIC PRESSURE PAIN, TIREDNESS, AND A PAINFUL, ITCHY RASH ON HER RIGHT PINKY FINGER THAT WAS SPREADING TO HER RING FINGER. THE CONSUMER HAD HER TUBES REMOVED ON (B)(6) 2015. THE RASH WAS GETTING WORSE, SHE WAS NOT AS TIRED, HER PELVIC PAIN AND PRESSURE WAS BETTER, AND HER BACK STILL HURTS. PRODUCT TECHNICAL COMPLAINT ANALYSIS RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN

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TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PRESSURE PAIN. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT SHORT TIME AFTER ESSURE INSERTION. SHE HAD HER TUBES REMOVED. BASED ON THE NATURE OF THE EVENT AND CONSIDERING THAT PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01399	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/7/2012
Explant Date (E7): 7/31/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044603) IN UNITED STATES ON 14-OCT-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. ONCE IT WAS INSERTED, CONSUMER STARTED TO EXPERIENCE ISSUES SUCH AS EXTREME WEIGHT LOSS, CRAMPING, NAUSEA, NOT SLEEPING, NOT EATING. SHE WENT TO HER PHYSICIAN AND TOLD HIM SHE WANTED ESSURE REMOVED BECAUSE SHE DID NOT WANT TO LIVE HER LIFE BEING IN CONSTANT PAIN AND SICKNESS. HE SAID THE ONLY WAY TO REMOVE ESSSURE WAS TO DO A HYSTERECTOMY. UPON REMOVAL ON (B)(6) 2014, SHE DID NOT EXPERIENCE ANY ISSUES. RX MEDS (REGARDED AS PRESCRIPTION DRUG) INCLUDED PROZAC. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A

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QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD CRAMPING/CONSTANT PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICE WAS REMOVED AND SHE RECOVERED FROM THE EVENT. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN THE NATURE OF THE EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 25-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01400	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/10/2011
Explant Date (E7): 5/27/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044637) IN UNITED STATES ON 14-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. CONSUMER EXPERIENCED REAL BAD PAINS, HEAVY PERIODS, LOWER BACK PAINS, AND SOMETIMES DURING SEX. ON (B)(6) 2015, A HYSTERECTOMY WAS PERFORMED AND ESSURE REMOVED. CONCOMITANT MEDICATIONS WERE REPORTED: HYDROCODONE- ACETAMINOPHEN, ADVILS, IBUPROFEN. HOSPITALIZATION WAS MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS

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SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD REAL BAD PAINS (INTERPRETED AS PELVIC PAIN). SHE UNDERWENT A HYSTERECTOMY AND ESSURE WAS REMOVED. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 13-NOV-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01401	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044610) IN UNITED STATES ON 14-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. SINCE INSERTION, CONSUMER EXPERIENCED SEVERE BUCKLING OVER PAIN, CRAMPING, WORSENING MENSTRUAL CYCLES (PASSING HALF DOLLAR SIZED CLOTS, SATURATING OVERNIGHT PAD EVERY 2 HOURS), FATIGUE, AND WEIGHT GAIN THAT HAS ONLY OCCURRED SINCE HAVING THE DEVICE INSERTED. SHE INFORMED HER PROVIDER THAT SHE HAS A SENSITIVITY TO NICKEL WHICH HE SAID SHOULD NOT BE A PROBLEM WITH THIS DEVICE. NOW SHE WILL HAVE A HYSTERECTOMY AND SALPINGECTOMY. SHE STATED THAT AN INTERVENTION IS REQUIRED. PRODUCT TECHNICAL COMPLAINT ANALYSIS RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY

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CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BUCKLING OVER PAIN (CRAMPING). THIS EVENT, SEEN AS ABDOMINAL PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SINCE THE INSERTION, THE CONSUMER HAS BEEN EXPERIENCING SEVERE BUCKLING PAIN AND OTHER NON-SERIOUS EVENTS. THUS, THIS EVENT IS ASSESSED AS RELATED TO ESSURE DUE TO CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE. SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 11-DEC-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) R

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01402	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT FEMALE CONSUMER IN UNITED STATES ON (B)(4) 2015 REFERRING TO HERSELF. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION 5-6 YEARS AGO. CONSUMER REPORTED THAT SHE EXPERIENCED PAIN MORE TO LEFT SIDE. ULTRASOUND WAS DONE AND CAME OUR FINE. D&C (DILATION AND CURETTAGE) WAS DONE 4-5 MONTHS AGO AND IT HELPED THE PAIN. NOT SURE IF THE PAIN WAS ASSOCIATED WITH ESSURE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND

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EXPERIENCED PAIN MORE TO LEFT SIDE. A D&C (DILATION AND CURETTAGE) WAS PERFORMED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO INTERVENTION PERFORMED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 21-DEC-2015: CONSUMER STATED THAT WILL COME BACK TO HER PHYSICIAN BECAUSE THE PAIN WAS BACK. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FAL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01404	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/7/2012
Explant Date (E7): 8/20/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1640, AWARENESS DATE 16-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. CONSUMER HAD ESSURE INSERTED WITHIN MINUTES AND WAS DISCHARGED WITH INSTRUCTIONS, PAIN MEDICATION AND ANTIBIOTICS. ON (B)(6) 2012 SHE HAD AN ABLATION DONE DUE TO EXCESSIVE BLEEDING AND CRAMPING. APPROXIMATELY ONE MONTH AFTER BOTH PROCEDURES SHE WOULD GET HER PERIOD SOME TIMES 3 TIMES A MONTH LASTING ANYWHERE FROM 3 DAYS TO 9 DAYS AT A TIME. PAINFUL CRAMPING AND NAUSEA FEELING. SHE CONTINUED TO HAVE HEAVY PERIODS AND HER PERIODS WERE LASTING LONGER. SHE WOULD HAVE HER PERIOD SOMETIMES UP TO 3 WEEKS. IF SHE WASN'T ON MENSTRUAL CYCLE SHE WOULD HAVE A DISCHARGE ALL THE TIME. INTERCOURSE WAS PAINFUL AND AS SOON AS SHE WAS DONE SHE WOULD START BLEEDING AGAIN. CONTINUED WITH HORRIBLE CRAMPING. SHE NEVER HAD ANY CRAMPING BEFORE UNTIL ESSURE AND THE ABLATION. IN (B)(6) 2012 SHE WENT TO ER (EMERGENCY ROOM) FOR EXCRUCIATING ABDOMINAL PAIN. AFTER BEING TESTING THE ER PHYSICIAN STATED THAT HER APPENDIX BROKE OFF FROM LARGE INTESTINE AND WAS LODGED BEHIND THE RIB CAGE. SHE WAS TAKEN INTO SURGERY. SHE CONTINUED TO HAVE SEVERE ABDOMINAL PAIN, ELEVATED WHITE BLOOD COUNT HIGHEST WAS 23.5 (NORMAL RANGE IS 4.1-10.2) AND CONTINUED TO BE ON ANTIBIOTICS. DOCTOR CONCLUDED INFECTION AND WOULD CONTINUE ANTIBIOTICS ME FOR 2 YEARS. THIS PAST (B)(6) 2015 SHE WAS BACK IN THE ER WITH ABDOMINAL PAIN. THEY NOTICED THE COIL THAT MIGRATED OUT AND WAS IN THE CAVITY OF UTERUS. SHE HAD TO HAVE A HYSTERECTOMY TO HAVE THIS REMOVED ON (B)(6) 2015. SHE HAS SUFFERED

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FOR 2 YEARS. UNDERWENT NUMEROUS DR. VISITS, MRI, ULTRA SOUNDS, CT SCANS AND OTHER LAB WORK TESTING, ON PRESCRIPTIONS ALL THE TIME AND 2 SURGERIES BECAUSE OF THIS. PTC INVESTIGATION RESULT RECEIVED ON 31-OCT-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND PAINFUL CRAMPING / HORRIBLE CRAMPING, EXCRUCIATING ABDOMINAL PAIN AND SHE HAD AN ABLATION PERFORMED DUE TO THESE EVENTS. IT WAS REPORTED THAT THE COIL THAT MIGRATED OUT AND WAS IN THE CAVITY OF MY UTERUS AND A HYSTERECTOMY IN ORDER TO REMOVE IT WAS PERFORMED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF DEVICE MIGRATION ARE NOT KNOWN. THE OCCURRENCE OF ABDOMINAL PAIN COULD BE CONSIDERED A SYMPTOM OF DEVICE MIGRATION. BASED ON A POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THE NATURE OF THESE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTIONS WERE PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01405	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044494) IN UNITED STATES ON 14-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE HAD SEVERE BACK PAIN, SEVERE ABDOMINAL PAIN, HEAVY BLEEDING WHEN SHE WAS ON HER CYCLE. SHE WAS HOSPITALIZED DUE TO A BLOOD CLOT IN HER UTERUS. HER PAIN HAS BEEN CONTINUOUS, NONSTOP. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING WHEN SHE WAS ON HER CYCLE (BLOOD CLOT IN UTERUS). THIS EVENT IS SERIOUS DUE TO HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MENSES PATTERN CHANGES ARE EXPECTED DURING ESSURE USE. IN THIS CASE, THE CONSUMER HAD HEAVY BLEEDING ON HER CYCLE AND WAS HOSPITALIZED DUE TO A BLOOD CLOT IN HER UTERUS. CONSIDERING EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE SHE WAS HOSPITALIZED, THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION AND TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01406	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B09699

Single Use: Y
Implant Date (E6): 9/11/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN THE UNITED STATES ON 16-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015. CASE CONSIDERED POTENTIAL LEGAL. CONSUMER WAS REQUESTING COMPENSATION FOR ESSURE REMOVAL. SHE WAS (B)(6) AT TIME OF THIS REPORT. HER MEDICAL HISTORY INCLUDED ALLERGY TO SULFA AND ABORTION. AT FIRST YEAR, SHE FELT LIKE SHE WAS HIT BY A BUS, DAILY, JOINT PAIN, FLU-LIKE SYMPTOM, BONES HURT (THE ONLY WAY SHE COULD DESCRIBE THE PAIN), SHE FELT LIKE BEING POISONED, LIKE THERE WAS A HEAVY METAL COURSING THROUGH HER VEINS, FATIGUE, LETHARGY, SHE COULD HARDLY GET OUT OF BED, SEVERE NIGHT SWEATS AND CRAMPING. SHE FINALLY DECIDED SHE HAD EITHER FIBROMYALGIA OR POSSIBLY LEUKEMIA. BUT THEN SHE REALIZED THAT HER BODY WAS REACTING TO THE IMPLANTS. ADDITIONALLY, SHE REPORTED SCAR TISSUE DEVELOPING AND INFLAMMATION, THE SOURCE OF PAIN, DEBILITATION AND DISEASE. AT SECOND AND THIRD YEARS, SHE STATED THAT IT EVENTUALLY ENDED. THEN, FOR THE LAST YEAR (2015), SHE WAS EXPERIENCING EXCRUCIATING AND PERSISTENT PAIN IN HER SIDES/ ABDOMEN. THOUGHT IT WAS KIDNEY STONES, POSSIBLY. SHE ALSO REPORTED LABOR-PAIN TYPE MENSTRUAL CRAMPS AND THAT SHE NEVER STOPPED BLEEDING. ALL MONTH, BLOOD. SEX WAS PAINFUL OVER THE LAST YEAR (SHE WAS AT ABSTINENCE) AND EACH TIME SHE HAD SEX OR EXERCISED AT THE GYM, OR RAN SPRINTS (ANYTHING THAT INVOLVES THE WAIST/HIPS AREA), SHE EXPERIENCED BLEEDING AFTERWARD. SHE WAS BLEEDING DURING SEX, AFTER SEX, AND FOR WEEKS FOLLOWING SEX. HER VAGINAL DISCHARGE SMELLS DIFFERENT THAN IT HAS BEFORE, AND IT IS NOT A PLEASANT SMELL. SHE WAS ALSO EXPERIENCING INTERMITTENT SEVERE GAS AND BLOATING OF THE ABDOMEN, FROM HER RIB CAGE DOWN. AN X-RAY WAS PERFORMED AND SHOWED THE IMPLANTS WERE EXACTLY IN THE CORRECT POSITION. THREE DAYS

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BEFORE THIS REPORT (OCT-2015), SHE SCHEDULED ESSURE REMOVAL AND STATED THAT WANTS A COMPENSATION TO HAVE THE SURGERY ON (B)(6) 2015. SUMMARY OF SIDE EFFECTS SHE EXPERIENCED SINCE ESSURE IMPLANTS IN 2012: BONE ACHES, JOINT ACHES, LETHARGY, CHRONIC FATIGUE, NIGHT SWEATS, CHRONIC STABBING PAINS IN SIDES (HAVE NEVER GONE AWAY FOR THE LAST YEAR), FLU-LIKE SYMPTOMS, INTERMITTENT/ STABBING PAIN IN LOWER ABDOMEN (OVARY/FALLOPIAN TUBE AREA), SEVERE MENSTRUAL CRAMPING (NEVER HAD THIS BEFORE), BLEEDING DURING SEX, BLEEDING FOR WEEKS AFTER SEX, BLEEDING AFTER EXERCISE, BLEEDING ALL THE TIME, EVEN JUST SITTING, SEVERE GAS, SEVERE BLOATING AND DISTENDED ABDOMEN ALMOST ALL THE TIME, FOUL-SMELLING VAGINAL DISCHARGE. ADDITIONALLY, MEDICAL NOTES FROM (B)(6) 2015 INCLUDED: DYSFUNCTIONAL UTERINE BLEEDING. SHE WAS WITH COMPLAINTS OF PAIN IN BOTH SIDE AND IRREGULAR BLEEDING AFTER INTERCOURSE AND HEALTH ACTIVITIES. SHE HAS BLEEDING WITH ANY VIGOROUS PHYSICAL ACTIVITY AND HAS CONSTANT BILATERAL ADNEXAL PAIN; HAS NOT BEEN IMAGED SINCE DEVICE WAS INSERTED. SYMPTOMS ARE AFFECTING HER DAILY LIFE. ASSESSMENT /PLAN: DYSFUNCTIONAL UTERINE BLEEDING. ABDOMINAL X-RAY WAS PERFORMED AND SHOWED NO ACUTE ABDOMINAL PROCESS. ESSURE DEVICE APPEAR TO BE IN SATISFACTORY POSITION. COMPARISON WITH HSG PERFORMED ON (B)(6) 2013. THE ESSURE DEVICE WAS UNCHANGED. NO ACUTE ABDOMINAL PROCESS. BILATERAL ESSURE DEVICES NOTED IN THE PELVIS WITH LOCATION SUGGESTING APPROPRIATE POSITIONING. PTC INVESTIGATION RESULT RECEIVED ON 02-NOV-2015. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS RECEIVED FROM A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING/ EXCRUCIATING PAIN IN SIDES AND ABDOMEN AND NEVER STOPPED BLEEDING/ALL MONTH BLOOD (DIAGNOSED AS DYSFUNCTIONAL UTERINE BLEEDING). SHE STATED SHE FELT LIKE SHE HAD BEEN POISONED (LIKE THERE WAS A HEAVY METAL COURSING THROUGH HER VEINS). ESSURE REMOVAL WAS SCHEDULED IN THE DAYS FOLLOWING HER REPORT AND SHE REQUESTED FINANCIAL COMPENSATION FOR THE SURGERY. ALL REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY CONSUMER'S SUSPICION OF METAL POISONING IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY ABDOMINAL PAIN AND ABNORMAL GENITAL BLEEDING AND MENORRHAGIA MAY OCCUR. IN THIS PARTICULAR CASE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE REPORTED PAIN AND BLEEDING AND SINCE NO ALTERNATIVE EXPLANATION WAS REPORTED; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING HER SUSPICION OF METAL POISONING; THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. ALTHOUGH, IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM ESSURE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE A METAL POISONING. THEREFORE THIS EVENT WAS CONSIDERED UNRELATED TO ESSURE. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WILL BE REQUIRED (SURGERY SCHEDULED). PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT

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(NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 17-DEC-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01407	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2014
Explant Date (E7): 7/3/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON 14-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. NO TESTS FOR ALLERGIES TO METALS OR ANYTHING ELSE WERE PERFORMED (JUST AN ORAL QUESTIONNAIRE). NO HISTORY OF GYNECOLOGICAL PROBLEMS. FOR THE IMPLANTATION SHE WAS GIVEN A TRANQUILLIZER AND ANALGESIC (DIAZEPAM AND IBUPROFEN). SHE STATED THAT IT WAS TERRIBLE. CONSUMER STATED SHE COULD HARDLY WALK WITH THE PAIN. IN THE FOLLOWING DAYS SHE WENT TO THE EMERGENCY ROOM THREE TIMES BECAUSE OF UNBEARABLE PAIN. AN ULTRASOUND WAS PERFORMED TO SEE WHETHER THEY WERE PROPERLY IN PLACE. THEN PHYSICIAN DECIDED THAT IT HAD NOTHING TO DO WITH THE ESSURE AND SENT HER HOME. ALTHOUGH SHE WAS ABLE TO WALK, THE DISCOMFORT DID NOT DIMINISH, AND SHE WAS GIVEN ANALGESICS. FROM THE VERY FIRST DAY, CONSUMER EXPERIENCED SEVERE PAINS IN ABDOMEN AND SIDES, SWOLLEN ABDOMEN, SHARP PAINS, ESPECIALLY ON THE RIGHT SIDE, INTESTINAL PROBLEMS, MENSTRUAL PROBLEMS, HEAVIER PERIODS, DARK COLOUR AND CYCLE IRREGULARITIES, REDNESS OF THE NECK AND HEAD. OVER TIME, SHE FOUND THAT CERTAIN MOVEMENTS CAUSED SHARP PAIN. A HYSTEROSALPINGOGRAPHY (HSG) WAS PERFORMED AND SHOWED TUBAL BLOCKAGE. ON (B)(6) 2015, EXTRACTION OF ESSURE WAS PERFORMED WITH BALANCED GENERAL ANAESTHESIA, LAPAROSCOPY, BILATERAL SALPINGECTOMY. REMOVAL OF ESSURE IMPLANTS. THE PROBLEMS AND SIDE EFFECTS DISAPPEARED WITH THE SURGERY (AT LEAST 4-8 WEEKS OFF WORK). LOSS OF TUBES WAS REPORTED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UNBEARABLE PAIN/ SEVERE PAINS IN ABDOMEN AND SIDES. ESSURE WAS REMOVED 8 MONTHS AFTER INSERTION, VIA

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LAPAROSCOPY WITH SALPINGECTOMY, AND THE PAIN RESOLVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE LACK OF AN ALTERNATIVE EXPLANATION, AND CONSIDERING THAT THE PAIN RESOLVED AFTER ESSURE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015 (PTC GLOBAL NUMBER: (B)(4)): FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01408	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON 14-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE, FOR TUBAL OCCLUSION IN ORDER TO UNDERGO IVF (IN VITRO FERTILIZATION) TREATMENT. THE CONSUMER STATED SHE EXPERIENCED THE FOLLOWING SIDE EFFECTS FROM THE THIRD DAY ON: INFECTION, LEAVING HER PARALYSED FROM THE WAIST DOWN, PERMANENT SCIATICA FOR YEARS, WITH SEQUELAE THAT PERSISTED TILL THE DAY OF REPORT, BACK ACHE, MASSIVE HAIR LOSS, FATIGUE AND PHYSICAL EXHAUSTION, METALLIC TASTE IN THE MOUTH, PARAESTHESIA OF THE LOWER LIMBS, CRAMPS, UNBEARABLE MENSTRUAL PAIN, INTESTINAL PROBLEMS AND SUICIDAL THOUGHTS. SHE CONSIDERED ALL THE EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FROM THE THIRD DAY ON HAD AN INFECTION, LEAVING HER PARALYSED FROM THE WAIST DOWN, PERMANENT SCIATICA FOR YEARS, AND HAD SUICIDAL THOUGHTS. EVENT SUICIDAL THOUGHTS WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE WHILE THE REMAINING EVENTS WERE CONSIDERED SERIOUS DUE TO DISABILITY. ALL EVENTS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THIS CASE WAS REPORTED WITH VERY LIMITED INFORMATION. THE EXACT NATURE OF THE INFECTION WHICH LEFT HER PARALYSED FROM THE WAIST DOWN WAS NOT REPORTED. HOWEVER, GIVEN THE CLOSE TEMPORAL RELATIONSHIP WITH THE ESSURE INSERTION PROCEDURE, IN A CONSERVATIVE APPROACH, CAUSALITY COULD NOT BE COMPLETELY EXCLUDED. SCIATICA IS THE NEURALGIA ALONG THE COURSE OF THE SCIATIC NERVE. CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. SUICIDAL

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THOUGHTS IS OFTEN ASSOCIATED WITH MENTAL ILLNESSES SUCH AS DEPRESSION, BIPOLAR AFFECTIVE DISORDER, PERSONALITY DISORDERS, SCHIZOPHRENIA AND DRUG ADDICTION. CONSIDERING THE PATHOPHYSIOLOGY OF THIS EVENT AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT, SINCE A SERIOUS INJURY WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION (CLARIFICATION REGARDING THE NATURE OF THE INFECTION) ARE EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 11-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01409	BAYER HEALTHCARE LLC	11/10/2015	11/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2003
Explant Date (E7): 6/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2036, AWARENESS DATE 16-OCT-2015). IT WHICH REFERS TO AN ADULT FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2003. THE CONSUMER REPORTED HAVING PROBLEMS IMMEDIATELY AFTER PROCEDURE BUT NEVER PUT THEM WITH THE DEVICES UNTIL (B)(6) OF 2013. AFTER ULTRASOUND AND LAPAROSCOPIC EXPLORATORY SURGERY, IT WAS FOUND THAT HER LEFT COIL HAD MIGRATED AND WAS CLOSE TO PERFORATING HER UTERUS. SHE HAD TO HAVE A HYSTERECTOMY IN (B)(6) OF 2013. AT (B)(6), SHE DID NOT HAVE ANY OTHER PHYSICAL REASON TO HAVE TO HAVE A FULL HYSTERECTOMY. THE TIME FORCED TO TAKE OFF OF WORK FOR RECOVERY WAS FINANCIALLY STRAINING; SHE STATED IT WAS VERY FRUSTRATING TO KNOW NOW, WHAT SHE SHOULD HAVE BEEN TOLD ABOUT 12 YEARS AGO. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS

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CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE REMOVED (10 YEARS AFTER ITS PLACEMENT); BECAUSE LEFT COIL HAD MIGRATED AND WAS CLOSE TO PERFORATING HER UTERUS. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A UTERINE PERFORATION DURING INSERTION. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. ALTHOUGH THE EXACT MECHANISM OF THE REPORTED EVENT IS NOT KNOWN; CONSIDERING ITS NATURE; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057766	BAYER	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 6/14/2013 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED IN (B)(6) 2011 BY MY OB/GYN WHO DELIVERED MY BABIES. AFTER HAVING 5 HEALTHY/NORMAL PREGNANCIES, I WANTED TO FOCUS ON RAISING THESE 5 YOUNG CHILDREN AND WANTED THE MOST RELIABLE FORM OF PERMANENT BIRTH CONTROL. THREE MONTHS LATER, I HAD A POSITIVE HSG CONFIRMATION TEST AND WAS GIVEN THE ALL-CLEAR TO BEGIN RELYING ON ESSURE AS MY SOLE MEANS OF BIRTH CONTROL. HOWEVER, IN (B)(6) 2013, I BEGAN TO HEMORRHAGE AND WENT TO THE ER. AT THE ER, IT WAS DETERMINED THAT I WAS SEVERAL WEEKS PREGNANT AND WAS MISCARRYING. THIS WAS A DEVASTATINGLY EMOTIONAL TIME FOR ME. THIS BABY WAS CONCEIVED AFTER IT WAS CONFIRMED THAT I WAS STERILE AND THEN BECAUSE OF ESSURE, I SUBSEQUENTLY MISCARRIED. FOLLOWING THE REMOVAL OF THE FETUS, I BLED FOR TWO MONTHS STRAIGHT. THROUGH SALINE ASSISTED, VAGINAL ULTRASOUND, THE DOCTOR DIAGNOSED A UTERINE INFECTION WHICH WAS RESOLVED WITH ANTIBIOTICS. I ALSO HAVE BURNING/STINGING PAIN IN MY LEFT ABDOMEN AT THE TIME OF OVULATION WHICH HAS BECOME PROGRESSIVELY MORE PAINFUL AND LONGER LASTING. I ALSO HAVE PAIN IN MY LOWER BACK AND LEFT HIP/LEG. MY ONCE THICK HEAD OF HAIR HAS BECOME THIN. I HAVE GAINED A LOT OF WEIGHT IN MY BELLY REGION. I NOW HAVE HIGH ANXIETY, FATIGUE, AND TROUBLE CONCENTRATING. THE ESSURE PROCEDURE WAS LESS INVASIVE THAN A TUBAL LIGATION. HOWEVER, IT WAS EXCRUCIATINGLY PAINFUL. THE HSG CONFIRMATION TEST IS ALSO PAINFUL. THE REMOVAL OF THE ESSURE COILS IS COMPLEX AND REQUIRES FULL OR PARTIAL HYSTERECTOMY WHICH IS FAR MORE INVASIVE THAN TUBAL LIGATION. THE ESSURE COILS HAVE PET FIBERS WHICH ARE SUPPOSED TO CAUSE LOCALIZED INFLAMMATION, BUT I QUESTION THE SAFETY OF THIS. THE ESSURE LITERATURE DID NOT DISCLOSE THAT THE ESSURE COILS

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CONTAIN PET. THE ESSURE DEVICE HAS RESULTED IN ME HAVING SEVERAL PAINFUL, FEMALE PROCEDURES ALONG WITH THE LOSS OF MY BABY AND CONTINUED PHYSICAL AND EMOTIONAL PAIN AND SUFFERING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057785	BAYER	11/10/2015	11/10/2015

Event Information:

Event Date (B3): 10/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY TEETH ARE FALLING APART.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057859	BAYER	11/10/2015	11/17/2015

Event Information:

Event Date (B3): 11/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/13/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DONE IN (B)(6) 2011, AND EVER SINCE THEN I EXPERIENCED VERY HEAVY AND IRREGULAR PERIODS. MY OVARIES HURT BADLY AND EVERYDAY I CAN FEEL DISCOMFORT LIKE SOMETHING IS POKING ME INSIDE. WHEN I HAVE INTERCOURSE IT HURTS. WHEN I OVULATE IT HURTS. I TASTE METAL IN MY MOUTH. ONE DAY I WAS DYING OF THE OVARY PAIN ON MY SIDES AND I ALMOST WENT TO THE EMERGENCY ROOM. PLEASE HELP ME WITH THIS, I'M DYING SLOWLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057862	BAYER	11/10/2015	11/17/2015

Event Information:

Event Date (B3): 11/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/6/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE ISSUE (B)(6) 2009, I HAD THE ESSURE INSERTED. SEVERAL MONTHS LATER, I NOTICED SEVERE CRAMPING, IRREGULAR MENSTRUAL CYCLES, SPOTTING FOR SEVERAL WEEKS AT ANY GIVEN TIME, AS WELL AS HAIR LOSS. IN (B)(6) 2015, I STARTED NOTICING "OLD BLOOD" WAS BEING SHED RIGHT BEFORE MY MENSTRUAL CYCLE. IN (B)(6) 2015, I BEGAN TO HAVE GOLF SIZE BLOOD CLOTS DURING MY MENSTRUAL CYCLE WHICH WAS VERY UNUSUAL. ALSO, I'VE BEGUN TO NOTICE A SLIGHT BULGE IN MY LOWER ABDOMINAL AREA.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01410	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1712, AWARENESS DATE 16-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER HAD SO MANY PROBLEMS WITH THE IMPLANT. IT CAUSED SEVERE DEPRESSION, VAGINAL INFECTIONS, PAIN, LOSS OF HAIR, TOOTH PROBLEMS, ABLATION, AND A HYSTERECTOMY, LEAVING ONE OVARY. SHE IS STILL SUFFERING WITH LOW BLOOD ISSUES, WEIGHT GAIN AND MANY OTHER HEALTH ISSUES. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A

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QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN (INTERPRETED AS PELVIC PAIN); SHE UNDERWENT A HYSTERECTOMY, LEAVING ONE OVARY (INTERPRETED AS UNILATERAL OOPHORECTOMY). AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION) WAS ALSO REPORTED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENTS ARE UNLISTED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THE EXACT INDICATION FOR THE OOPHORECTOMY WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THIS PROCEDURE, AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. REGARDING THE EVENT ENDOMETRIAL ABLATION, THE EXACT INDICATION FOR THIS PROCEDURE WAS NOT REPORTED. ABLATION IS COMMONLY PERFORMED TO REDUCE MENSTRUAL BLEEDING, SUCH AS MENORRHAGIA. IN THE PRESENT CASE, EXCESSIVE BLEEDING WAS NOT REPORTED, NEITHER AS HISTORICAL CONDITION NOR AS AN EVENT. THEREFORE, CAUSALITY BETWEEN THE ABLATION AND ESSURE CANNOT BE ASSESSED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY). SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01411	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON 14-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. SHE HAD TWO CHILDREN BORN BY C-SECTION AND SUBSEQUENT PROBLEMS WITH UTERINE ADHESIONS. SHE THEREFORE OPTED FOR THE DEVICE, BECAUSE THE GYNECOLOGIST EXPLAINED THAT THERE WAS ZERO RISK AND SHE WOULD NOT HAVE TO BE ADMITTED TO HOSPITAL. SO, ESSURE WAS IMPLANTED IN (B)(6) 2014. THE PROCEDURE WAS HORRIBLE. THEY TOLD HER IN THE CLINIC THAT THEY WOULD GIVE HER SOME SEDATION BUT WHEN THE TIME CAME THEY ONLY USED A VERY LIGHT ONE, SO SHE HAD PAIN. THEY LAID HER DOWN IN THE OPERATING ROOM AND TIED HER LEGS AND SHE PANICKED; IT WAS THE LONGEST 20 MINUTES OF HER LIFE. WHEN THEY IMPLANTED THE ESSURE IN THE RIGHT TUBE WAS BEARABLE BUT WHEN THEY CAME TO THE LEFT ONE, SHE ASSURED IT WAS HORRIBLE. THEY GAVE HER A PAINKILLER AND TOOK HER TO A WARD. AFTER 20 MINUTES, THEY DISCHARGED HER AND SHE CAME HOME. THE NEXT DAY, TAKING HER CHILDREN TO SCHOOL, SHE WALKED DOWN SOME STAIRS AND FELT ACUTE PAIN ON THE LEFT SIDE THAT LEFT HER BENT OVER. IT TOOK HER TEN MINUTES TO STRAIGHTEN UP. SHE WAS IN GREAT DISCOMFORT ALL DAY, BUT AT THE TIME JUST THOUGHT IT MUST BE NORMAL. FOR THE NEXT WEEK SHE HAD DISCOMFORT THE WHOLE TIME AND THEN IT WAS TIME FOR THE CHECK-UP X-RAY. AFTER THAT, NURSE ASKED HER TO GO TO THE GYNECOLOGIST URGENTLY, BECAUSE THE LEFT ESSURE HAD MOVED AND WAS NEAR THE KIDNEY. SHE WENT TO GYNECOLOGY AND THE NURSE SAID THAT DOCTOR COULD NOT SEE HER AS SHE DID NOT HAVE AN APPOINTMENT, SO SHE SHOULD GO TO THE EMERGENCY ROOM. THEN THE X-RAY NURSE ARRIVED AND TOLD HER THAT SHE HAD SPOKEN TO HER SUPERVISOR AND THAT ESSURE SHOULD BE REMOVED RIGHT AWAY. SHE WENT TO THE DOCTOR'S OFFICE AND HE STARTED

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TO SAY THAT HE WAS NOT SURE WHETHER THE DEVICE HAD MOVED OR, AS THE TUBES ARE PERMEABLE, THEY COULD BE MOVING RIGHT THEN. HE SAID NOT TO WORRY AND THAT THE CHIEF GYNECOLOGIST HAD ORDERED ANOTHER TEST, A HYSTEROSALPINGOGRAM. THREE OR 4 DAYS LATER SHE HAD TO GO TO THE EMERGENCY ROOM IN TERRIBLE PAIN. VAGINAL ULTRASOUND WAS DONE AND EVERYTHING WAS NORMAL. ONE DAY, THE GYNECOLOGIST WHO IMPLANTED ESSURE CALLED HER AND TOLD TO GO THROUGH THE EMERGENCY ROOM AND TO TELL THEM SHE WAS IN A LOT OF PAIN SO THEY WOULD TAKE HER TO GYNECOLOGY; SHE DID WHAT PHYSICIAN SAID. SHE WAS SEEN BY A DOCTOR IN TRIAGE AND SHE TOOK A BLOOD TEST, EXAMINED HER AND SENT HER FOR AN X-RAY, BUT FIRST GIVING HER A PAINKILLER. X-RAYS WAS DONE AND THE NURSE TOLD HER THAT SHE NEEDED AN OPERATION. WHEN SHE ASKED HIM IF THE ESSURE HAD MOVED, HE SAID THAT THE DOCTOR WOULD TELL ME. SHE WENT BACK TO THE EMERGENCY ROOM AND THE DOCTOR TOLD HER TO GO TO GYNECOLOGY BECAUSE THE ESSURE WAS OUT. PHYSICIAN TOLD HER THAT THE ESSURE MOVED AND SHOULD BE REMOVED BY LAPAROSCOPY; PHYSICIAN DECIDED TO SCHEDULE HER FOR (B)(6) (2014). CONSUMER TOLD HIM THAT SHE COULD NOT GO HOME LIKE THAT AND WAS ADMITTED. SHE RECEIVED ANTIBIOTICS AND PAINKILLERS. THE NEXT DAY THEY CAME ROUND AND TOLD HER THAT THEY WOULD OPERATE ON THE FOLLOWING DAY. SHE SAW ANESTHETIST AND IN THE EVENING THEY STARTED TO GET HER READY, WITH VAGINAL LAVAGES, ENEMAS, ETC. WHEN SHE WOKE UP FROM SURGERY, SHE HAD UNBEARABLE ABDOMINAL PAIN. SHE TOUCHED HER BELLY AND FOUND GAUZES OVER THE NAVEL AND WHERE HER PREVIOUS C-SECTION SCARS WERE. A DOCTOR TOLD HER THAT THEY TRIED TO ACCESS THROUGH THE NAVAL BUT THAT IT WAS IMPOSSIBLE BECAUSE OF THE ADHESIONS, THAT THEY ALSO TRIED TO ACCESS THROUGH THE VAGINA, AND HAD THE SAME PROBLEM, AND THAT THEY HAD TO MAKE AN INCISION. THE ESSURE WAS ADHERED TO THE OMENTUM, OF WHICH THEY HAD ALSO TAKEN A SAMPLE FOR ANALYSIS. THEY HAD REMOVED THE ESSURE THAT HAD MOVED AND TIED THAT TUBE; THE OTHER ONE WAS IN THE RIGHT PLACE, SO THEY LEFT IT. SHE SPENT A WEEK AT HOSPITAL AND WAS THEN DISCHARGED. TWO MONTHS LATER SHE WENT BACK FOR A CHECK-UP WITH TERRIBLE PAIN. THE GYNECOLOGIST PERFORMED AN ULTRASOUND AND TOLD HER THAT IF THE PAIN CONTINUED THEY WOULD HAVE TO REMOVE HER WOMB. SHE DID NOT WANT MORE CHILDREN BUT SHE WAS ONLY (B)(6). HE PRESCRIBED TREATMENT. SHE WAS TOLD THAT SHE HAS TO DECIDE WHETHER TO HAVE THE SURGERY OR NOT. SHE GETS NOW URINE INFECTIONS, SHE CANNOT BEAR HAVING SEXUAL RELATIONS WITH HER PARTNER AND PSYCHOLOGICALLY, SHE IS A MESS. ALL EVENTS WERE CONSIDERED RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND APPROXIMATELY A MONTH LATER, IT WAS DIAGNOSED THROUGH X-RAY THAT ESSURE HAD MOVED. INITIALLY, THE PHYSICIAN TRIED A LAPAROSCOPY. HOWEVER, DUE TO THE UTERINE ADHESIONS SHE HAD, HE HAD TO MAKE AN INCISION. DURING SURGERY, IT WAS NOTICED THAT ESSURE WAS ADHERED TO THE OMENTUM (INTERPRETED AS DEVICE DISLOCATION). THIS FALLOPIAN TUBE WAS TIED. THE OTHER ONE WAS IN THE RIGHT PLACE, SO THEY LEFT IT. SHE SPENT A WEEK AT HOSPITAL AND WAS THEN DISCHARGED. SHE STATED THAT AT THE TIME OF REPORT SHE HAD URINE INFECTIONS (URINARY TRACT INFECTIONS). THE DEVICE DISLOCATION IS SERIOUS DUE TO HOSPITALIZATION AND REQUIRED INTERVENTION AND THE URINARY TRACT INFECTION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. DEVICE DISLOCATION IS LISTED WHILE THE URINARY TRACT INFECTION IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF A DEVICE DISLOCATION, THE SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THIS EVENT IS ASSESSED AS RELATED TO ESSURE. SINCE THE TIME LAPSE BETWEEN THE ESSURE REMOVAL PROCEDURE AND THE ONSET DATE OF URINE INFECTIONS, THIS EVENT CANNOT BE ASSESSED AT THIS TIME. THIS CASE IS REGARDED AS INCIDENT SINCE AN ESSURE-RELATED EVENT CAUSED A HOSPITALIZATION AND SINCE DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT AND FOLLOW UP INFORMATION ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01412	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1650, AWARENESS DATE 16-OCT-2015). IT WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE REPORTER MENTIONED THAT HER SISTER IN LAW HAD TO HAVE A FULL HYSTERECTOMY DUE TO HER COILS PERFORATING HER UTERUS. FOLLOW-UP INFORMATION RECEIVED ON 03-NOV-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP LO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT HER COILS

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PERFORATING HER UTERUS AND A FULL HYSTERECTOMY WAS PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE/FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE/FALLOPIAN PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF UTERINE PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01413	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1650, AWARENESS DATE 16-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. THE CONSUMER WANTED A TUBAL LIGATION HOWEVER HER PHYSICIAN REFUSED BECAUSE SHE WAS OVERWEIGHT. SHE HAD THE PROCEDURE DONE, BEING PUT UNDER ANESTHESIA EVEN THOUGH IT WAS A NON-SURGICAL PROCEDURE. SHE WAS UP AND AROUND QUICKLY, BUT HER PERIODS BECAME HEAVY AND SHE BEGAN HAVING BAD CRAMPS. SHE HAD A NOVASURE ABLATION A YEAR LATER TO REDUCE CRAMPING AND EASY FLOW. SHE HAD NOT HAD A PERIOD BUT STILL HAS CRAMPING AND SPASMS THAT ALMOST KNOCK HER OVER. SHE WAS EXTREMELY ANXIOUS, AGITATED AND HER MOODS WERE ALL OVER THE PLACE, BUT MAINLY SHE WANTED TO CRY. SHE HAD A SEVERE INCREASE IN MIGRAINES AND MINOR HEADACHES, HAVING ONE ALMOST EVERY DAY FOR YEARS. SHE HAS TESTED POSITIVE FOR YEAST FOR YEARS AT EACH ANNUAL EXAM, AND HAS HAD TO GO IN MULTIPLE TIMES OR REQUEST MESICIDE (AS REPORTED). SHE WAS ON DIFLUCAN FOR 30 DAYS AT ONE POINT. HER BREASTS WERE TENDER AND SHE WAS NAUSEATED FOR THE LAST 2 MONTHS EVERY DAY LONG. FOLLOW-UP RECEIVED ON 03-NOV-2015: PTC INVESTIGATION RESULT WAS PROVIDED. THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE ARE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE

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ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER PERIODS BECAME HEAVY AND SHE BEGAN HAVING BAD CRAMPS (INTERPRETED AS DYSMENORRHOEA). AN ENDOMETRIAL ABLATION WAS PERFORMED ONE YEAR AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION DYSMENORRHOEA AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENTS, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS REQUIRED (ENDOMETRIAL ABLATION). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-NOV-2015: PTC INVESTIGATION RESULT WAS PROVIDED. THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01414	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON 14-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER EXPERIENCED LOSS OF CONSCIOUSNESS AT IMPLANTATION (BLOOD PRESSURE WAS 6/4 KPA), INCREASINGLY INTENSE PELVIC PAIN, IRREGULAR PERIODS, MENSTRUAL HAEMORRHAGES, ITCHING ALL OVER THE BODY, AND EXAGGERATED REACTIONS IF AN INSECT BIT ME (SHE HAD TO BE INJECTED WITH URBASON SEVERAL TIMES, AND REGULARLY TAKE PREDNISONE), PAIN DURING SEXUAL INTERCOURSE, EXAGGERATED HAIR LOSS, EXHAUSTION, 12 KILOS WEIGHT GAIN, AND ABDOMINAL BLOATING. SHE HAD TO ASK TO REMOVE ESSURE, AS SHE WAS ALLERGIC TO METALS. SHE TOLD THEM BEFORE THE IMPLANTATION, BUT THE GYNAECOLOGIST SAID THEY WERE TITANIUM AND DID NOT CAUSE ALLERGY. ON (B)(6) 2015 CONSUMER UNDERWENT HYSTERECTOMY AND SALPINGECTOMY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD ALLERGY TO METALS. SHE UNDERWENT A HYSTERECTOMY AND SALPINGECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THE DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THIS DEVICE IS IMPLANTED. TYPICAL ALLERGY SYMPTOMS REPORTED INCLUDE RASH, PRURITUS, AND HIVES. IN THE PRESENT CASE, THE CONSUMER HAD A PREVIOUS HISTORY OF METAL ALLERGY. ALTHOUGH IT WAS NOT SPECIFIED WHETHER IT WAS A NICKEL ALLERGY, A CONTRIBUTORY ROLE OF ESSURE IN THE AGGRAVATION OF ALLERGY TO METALS

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CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (HYSTERECTOMY AND SALPINGECTOMY). A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 12-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01415	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON 14-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. SINCE THEN, CONSUMER WAS EXPERIENCING GENERALIZED ALLERGIC ATTACKS ALL OVER HER BODY. THE DEVICE WAS REMOVED AFTER 8 MONTHS, BUT SHE CONTINUES TO HAVE THE SAME REACTION, WHICH DERMATOLOGISTS SAY HAS BECOME CHRONIC. SHE CONTINUES TO TAKE MEDICATION TO CONTROL THESE ATTACKS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED GENERALIZED ALLERGIC ATTACKS ALL OVER HER BODY. THE DEVICES WERE REMOVED 8 MONTHS LATER, BUT THE EVENT PERSISTED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, CONSUMER ALLERGIC REACTION PERSISTED AFTER ESSURE REMOVAL. ACCORDING TO HER; THE DERMATOLOGISTS SAID IT BECAME CHRONIC. ALTHOUGH DECHALLENGE WAS NEGATIVE IN THIS CASE; CONSIDERING THE CLOSE TEMPORAL RELATION BETWEEN THE EVENT AND ESSURE THERAPY AND SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE DEVICE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01416	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 806698

Single Use: Y
Implant Date (E6): 12/16/2011
Explant Date (E7): 6/29/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (B)(4) IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO AN ADULT (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011 (LOT NUMBER 806698). AT THE TIME OF THE REPORT CONSUMER WAS (B)(6). HER ONLY CHILD WAS BORN IN 2000 AND THEN SHE HAD TWO MISCARRIAGES, THE SECOND IN 2006. THEN SHE TRIED TO BECOME PREGNANT, WITHOUT SUCCESS, FOR 4 YEARS, UNTIL 2010. THAT YEAR SHE HAD SEVERAL EPILEPTIC SEIZURES AND WAS DIAGNOSED WITH PARTIAL EPILEPSY IN THE LEFT TEMPORAL LOBE. SO SHE DECIDED TO GET THE ESSURE, AS THEY HAD UNSUCCESSFULLY TRIED TO INSERT AN IUD, AND THE PILL WAS NOT ADVISABLE DUE TO HER CONDITION. THE DEVICES WERE IMPLANTED WITHOUT INCIDENT IN (B)(6) 2011, THE RIGHT OSTIUM WITH 0 RINGS AND THE LEFT OSTIUM WITH 1 RING. IT WAS PERFORMED IN THE GYNAECOLOGY DEPARTMENT OF A HOSPITAL. IN (B)(6) 2012 SHE HAD AN APPOINTMENT FOR THE FOLLOW-UP AND THEY SUSPECTED DISPLACEMENT AND ORDERED AN HYSTEROSALPINGOGRAM. IN (B)(6) 2012 THEY PERFORMED THE HSG AND FOUND THE ESSURE DEVICES IN A SLIGHTLY DISTAL POSITION WITH THE CONTRAST PASSING BOTH OF THEM, MORE ON THE RIGHT SIDE. WHILE ALL THIS AND HER VARIOUS APPOINTMENTS WERE HAPPENING, SHE WAS COMPLAINING ABOUT HER PAIN AND ASKING WHETHER IT WAS NORMAL. CONSUMER THEN WENT SEVERAL TIMES TO THE HOSPITAL TO DECIDE WHAT TO DO, BECAUSE THE ESSURE WAS NOT FUNCTIONING AND WAS USELESS AS A METHOD. SHE CONTINUED TO HAVE PAIN AND CRAMPS, AND THEY SUGGESTED THAT SHE USED OTHER METHODS OR HER HUSBAND SHOULD GET SURGERY. SHE HAD TO HAVE THIS AND IT HAS BEEN NO USE FOR ANYTHING. FINALLY, ONE DOCTOR SAID THAT IF SHE WAS IN PAIN, THEY COULD REMOVE HER TUBES. SHE DID NOT CARE, AS LONG AS THE PAIN WENT AWAY. SHE UNDERWENT A LAPAROSCOPIC BILATERAL SALPINGECTOMY IN (B)(46) 2012 AND THE PAIN CAME TO AN END.

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SHE HAS NO PAIN NOW, BUT SHE HAS NO FALLOPIAN TUBES EITHER. SHE HAS VERY HEAVY BLEEDING WITH CLOTS. CONSUMER MENTIONED THAT SHE TRUSTED THIS METHOD TO IMPROVE HER QUALITY OF LIFE WITH EPILEPSY AND ACTUALLY IT BECAME MUCH WORSE. CONSUMER RELATED ALL THE REPORTED EVENTS TO ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HYSTEROSALPINGOGRAM PERFORMED 4 MONTHS AFTER INSERTION SHOWED ESSURE DEVICES IN A SLIGHTLY DISTAL POSITION WITH THE CONTRAST PASSING BOTH OF THEM, MORE ON THE RIGHT SIDE. SHE ALSO HAD PAIN EPISODES AND CRAMPS (INTERPRETED AS ABDOMINAL PAIN). A SALPINGECTOMY WAS PERFORMED 6 MONTHS AFTER ESSURE INSERTION. AT THE TIME OF THE REPORT SHE HAD VERY HEAVY HEMORRHAGE WITH CLOTS (INTERPRETED AS GENITAL BLEEDING). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THE PRESENT CASE, THE DEVICES WERE IN A SLIGHTLY DISTAL POSITION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. IN THIS PARTICULAR CASE, FROM THE AVAILABLE INFORMATION, IT WAS UNDERSTOOD THAT THE GENITAL BLEEDING STARTED AFTER THE SALPINGECTOMY AND HAD NOT RESOLVED UNTIL THE TIME OF THE REPORT, APPROXIMATELY 3 YEARS AFTER THE SALPINGECTOMY. THEREFORE, GIVEN THE NEGATIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE WAS ASSESSED AS UNRELATED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTION (SALPINGECTOMY). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 12-NOV-2015 WITH THE FINAL PTC INVESTIGATION RESULT (PTC GLOBAL NUMBER: (B)(4)): FINAL ASSESSMENT: BATCH NUMBER: 806698. PRODUCTION DATE: NOV-2010. EXPIRATION DATE: NOV-2013. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPOR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01420	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 9/17/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1652, AWARENESS DATE 16-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. CONSUMER HAD ESSURE PLACED IN MID 2013. ABOUT 5 TO 6 MONTHS LATER SHE STARTED HAVING WEIRD HEALTH ISSUES. HEART PALPITATIONS, WEIGHT GAIN, ABDOMINAL SWELLING, BRAIN FOG, SEVERE FATIGUE NO MATTER HOW MUCH SHE SLEPT. SHE ALSO HAD VERY HEAVY PERIODS THAT WERE EXTREMELY PAINFUL. SHE WAS PASSING CLOTS AND HAVING CRAMPS THAT PUT HER IN A FETAL POSITION CRYING AND NOTHING SHE TOOK OVER THE COUNTER HELPED HER PAIN. CONSUMER ALSO HAD SEVERE EMOTIONS THAT WERE LIFE ALTERING. ALL OF THESE SYMPTOMS INCREASED. ON (B)(6) 2015, SHE HAD A LAPAROSCOPIC HYSTERECTOMY. ON (B)(6) 2015, ALL OF HER SYMPTOMS WERE DISSIPATING. FOLLOW-UP RECEIVED ON 03-NOV-2015: PTC INVESTIGATION RESULT WAS PROVIDED. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT

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INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING CRAMPS. SHE UNDERWENT A LAPAROSCOPIC HYSTERECTOMY 2 YEARS AFTER ESSURE INSERTION. THIS EVENT, INTERPRETED AS ABDOMINAL PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE LACK OF AN ALTERNATIVE EXPLANATION, AND SINCE THE CRAMPS WERE DISSIPATING AFTER HYSTERECTOMY, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01421	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/21/2012
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1819, AWARENESS DATE 16-OCT-2015). IT WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. THE CONSUMER REPORTED SHE WAS BORN WITH CEREBRAL PALSY, AND WHILE THE DISABILITY DOES NOT PREVENT HER FROM HAVING CHILDREN, IT COMPLICATES HER SITUATION. OVER THE YEARS SHE HAD DEVELOPED ARTHRITIS IN HER HIPS AND SHE HAD WORKED WITH HER GYNECOLOGIST ON PLANS FOR WHEN AND SHE WILL BECOME PREGNANT. AT HER (B)(6) 2012 YEARLY APPOINTMENT HER DOCTOR TOLD THAT HER ARTHRITIS HAS GOTTEN TO THE POINT WHERE PREGNANCY WOULD BE DANGEROUS FOR HER AND RECOMMENDED THAT SHE NOT HAD CHILDREN. HER DOCTOR SUGGESTED AN ENDOMETRIAL ABLATION AND ESSURE TO PREVENT PREGNANCY. SHE SCHEDULED THE PROCEDURE FOR (B)(6) 2012. AFTER THE PROCEDURE SHE WOKE UP IN THE RECOVERY ROOM COMPLAINING OF SEVERE PAIN ON HER LEFT SIDE. THE RECOVERY NURSE TOLD HER THAT IT WAS CAUSED BY PULLING ON THE TUBE DURING THE PROCEDURE AND THAT EVERYTHING HAD GONE SMOOTHLY. SHE WAS SENT HOME AND RESTED FOR FOUR DAYS BEFORE RETURNING TO WORK. THE PAIN IN HER LEFT SIDE WAS STILL PERSISTENT AND SHE BEGUN TO RUN A FEVER; SHE CALLED HER DOCTORS OFFICE AND WAS ASKED TO COME IN FOR A VAGINAL ULTRA-SOUND TO LOOK FOR SIGNS OF INFECTION AND CORRECT COIL PLACEMENT; THE ULTRASOUND DID NOT SHOW ANYTHING OUT OF THE ORDINARY, THIS APPOINTMENT WAS ONE WEEK AFTER THE PROCEDURE. TWO WEEKS AFTER THE PROCEDURE THE PAIN ON THE LEFT SIDE AND FEVER WERE STILL PRESENT, BUT SHE BEGAN EXPERIENCING OTHER THINGS AS WELL; SHE FELT RUN DOWN, LIKE SHE HAD BEEN HIT BY A CAR, SHE STARTED BRUISING

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EASILY AND WOULD GET CHILLS AND THEN THE MOST HORRENDOUS PERIOD OF HER LIFE STARTED. THE BLEEDING, CRAMPING AND CLOTTING WAS GUT WRENCHING; SHE FELT NAUSEOUS ALL THE TIME AND FATIGUED. THE PERIOD LASTED A MONTH AND A HALF. THE PAIN ON THE LEFT SIDE HAD ALSO CHANGED AS WELL; WHILE THE PAIN WAS ALWAYS CONSTANT THERE WERE TIMES WHEN SHE BEND OR TURN THAT THE PAIN FELT LIKE BURNING AND SOMETHING CATCHING AND TEARING IN HER TUBES. THIS PAIN TOOK HER BREATH AWAY AND WOULD BREAK OUT INTO A SWEAT. THREE MONTHS AFTER THE PROCEDURE SHE HAD ANOTHER FOLLOW-UP WITH HER DOCTOR, SHE THE ALL THE SYMPTOM SHE WAS HAVING AND ASKED IF THEY COULD BE THE RESULT OF THE PROCEDURE, HE SAID NO THAT THERE WERE NO KNOWN SYMPTOMS THE ONES SHE DESCRIBED ASSOCIATED WITH EITHER PROCEDURE. HE THEN SAID THAT PERHAPS THE ARTHRITIS WAS THE CAUSE OF HER PAIN BUT SHE THOUGHT IT WAS PRETTY COINCIDENTAL THAT THE PAIN SHE WAS HAVING DID NOT START UNTIL SHE HAD ESSURE IMPLANTED. SHE LEFT THE APPOINTMENT AND STARTED SEARCHING ON THE INTERNET AND FOUND A PAGE CALLED ESSURE PROBLEMS. SHE WAS NO LONGER DEALING WITH THE PAIN, THE FEVERS, FATIGUE AND THE HORRIFIC PERIODS. SHE HAD DECIDED TO GET A PARTIAL HYSTERECTOMY LATER THAT YEAR; SHE WANTED THE PAIN TO END. SHE STATED BEING EXTREMELY ANGRY THAT NOT ONLY HAD TO DEAL WITH THE EMOTIONAL PAIN OF NEVER HAVING CHILDREN BUT THE PAIN CAUSED BY ESSURE IS CONSTANT DAILY REMINDER OF THIS SAD FACT. IN 2013, SHE HAD A PARTIAL HYSTERECTOMY LEAVING HER OVARIES. THE PAIN HAS GONE AWAY BUT SHE WAS STILL PLAGUED BY FEVERS, LACK OF ENERGY AND IN ADDITION SHE WAS ALSO DEALING WITH DEPRESSION CAUSED BY HAVING TO HAVE A HYSTERECTOMY SHE NO LONGER FELT LIKE A WOMAN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 04-NOV-2015: THE PTC GLOBAL NUMBER IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING / PAIN IS ALWAYS CONSTANT, BLEEDING / CLOTTING WAS GUT WRENCHING (SEEN AS GENITAL BLEEDING). THE PAIN ON THE LEFT SIDE HAD ALSO CHANGED AS WELL; WHILE THE PAIN WAS ALWAYS CONSTANT THERE WERE TIMES WHEN SHE BEND OR TURN THAT THE PAIN FEELS LIKE BURNING AND SOMETHING CATCHING AND TEARING IN HER TUBES (SEEN AS ADNEXA UTERI PAIN). A PARTIAL HYSTERECTOMY LEAVING HER OVARIES WAS PERFORMED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSIDERING THE NATURE OF THESE EVENTS AND CONSIDERING THAT NO ALTERNATIVE EXPLANATION WAS AVAILABLE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01425	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/28/2012
Explant Date (E7): 10/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1638, AWARENESS DATE 17-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. CONSUMER REPORTED THAT AFTER A FEW MONTHS SHE STARTED TO LOOSE HER SEX DRIVE, BEGAN HAVING SEVERE PELVIC PAIN, BLOATING, INCONTINENCE, FULL SLOSHING FEELING ALL THE TIME, SEX BEGAN TO GET MORE AND MORE PAINFUL, HER BACK STARTED TO HURT, SHE WAS GETTING STABBED IN THE KIDNEY, HAD STRANGE VIBRATIONS IN HER PELVIC AREA AND WHEN SHE EAT SHE FELT LIKE HER STOMACH WAS CONSTRICTING AND HER ENTIRE ABDOMEN WOULD GET AND STAY REALLY HARD. IN (B)(6) 2015 SHE HAD A HYSTERECTOMY, REMOVED TUBES, CERVIX, OVARIES AND SHE HAVE NOT HAD ANY SYMPTOMS SINCE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PELVIC PAIN. A HYSTERECTOMY WAS PERFORMED, REMOVING TUBES, CERVIX AND OVARIES. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT A FEW MONTHS AFTER ESSURE INSERTION. GIVEN A POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED.

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ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-NOV-2015: PTC INVESTIGATION RESULT WAS RECEIVED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01426	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1902, AWARENESS DATE 17-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER REPORTED THAT SHE DEVELOPED HIVES SO BAD THAT SHE HAD TO CARRY AN EPI PEN BECAUSE SHE WAS ALLERGIC TO NICKEL. IN 2013 SHE HAD HER FALLOPIAN TUBES REMOVED TO GET RID OF ESSURE COILS. IN 2015 SHE HAD A HYSTERECTOMY AND DOCTOR FOUND OUT THAT THE ESSURE COILS HAD NOT BEEN REMOVED. SHE WAS STARTING TO FEEL BETTER SINCE ESSURE WAS FINALLY REMOVED AND SHE WAS WEARING HORMONE PATCHES. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 04-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A

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QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALLERGY TO NICKEL (DEVELOPED HIVES SO BAD THAT SHE HAD TO CARRY A EPI-PEN). SHE HAD HER FALLOPIAN TUBES REMOVED TO GET RID OF ESSURE COILS AND A HYSTERECTOMY WAS PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. CONSIDERING THAT SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01427	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2013
Explant Date (E7): 7/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1772, AWARENESS DATE 17-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. THE RIGHT COIL WENT IN RATHER PAINFULLY. THE LEFT TUBE WAS NICKED AND SHE HAD TO HAVE PLACED A MONTH LATER, UNDER GENERAL ANESTHETIC, IN THE HOSPITAL. FROM THE BEGINNING, SHE WAS IN PAIN. SHE CALLED THE DOCTOR AND WAS TOLD THE SCAR TISSUE WAS FORMING AND MILD CRAMPING WAS TO BE EXPECTED. LT NEVER LET UP. SHE IMMEDIATELY EXPERIENCED MIGRAINES (NEVER HAD ONE BEFORE), VERTIGO, INTENSE PAIN AND BRAIN FOG, HEAVY METAL POISONING, HAIR FALLING OUT, SHE COULD NOT REMEMBER ANYTHING ANYMORE, GAINED A SIGNIFICANT AMOUNT OF WEIGHT; HER STOMACH RESEMBLED THAT OF A PREGNANT WOMAN. THE FOLLOWING THREE MONTHS, SHE MISSED A GOOD BIT OF WORK DUE TO THE PAIN IN HER PELVIC REGION AND THE MIGRAINES. THE SYMPTOMS PERSISTED AS SHE WENT FOR HER TEST TO CONFIRM THAT SHE WAS BLOCKED. SHE NEVER EXPERIENCED SO MUCH PAIN. THE DYE WAS SHOT INTO HER CERVIX WITH SUCH FORCE THAT SHE LIFTED OFF OF THE GUMEY IN PAIN. LT WAS THEN THAT THE BLEEDING BEGAN. SHE COULD NOT BE SURE THAT THE FORCE OF THE DYE DID NOT CAUSE THE COILS TO MIGRATE. SHE WAS PRESCRIBED SOMETHING TO SLOW THE BLEEDING. HER LIST OF SYMPTOMS INCLUDED: MIGRAINES, LOWER BACK PAIN, PELVIC PAIN (ONGOING), HEAVY PERIODS, FATIGUE, BLOATING, (VERY BAD), INSOMNIA, ACNE/ BREAKOUTS, HAIR LOSS (ALMOST IMMEDIATELY), CLOTS THE SIZE OF GOLF BALLS, MEMORY LOSS, AGITATION, WEIGHT GAIN - BUT NO APPETITE, NAUSEA WITH VERTIGO AND THE COUP DE GRAS, PAINFUL INTERCOURSE. IN (B)(6) 2014, HYSTERECTOMY WAS PERFORMED. HER LEFT OVARY WOULD NOT

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STOP BLEEDING, SO THEY HAD TO TAKE THAT. HER RIGHT OVARY WAS LEFT. THREE DAYS OF DISCHARGE, SHE WAS BACK IN EMERGENCY ROOM. HER SKIN WAS GREY, HER EYES SUNKEN, SHE HAD NO ENERGY AND HER BRUISING FROM SURGERY WAS SPREADING. AFTER TAKING SUBSTANTIAL AMOUNTS OF BLOOD, HER BLOOD COUNT WAS AT 6 AND SHE WAS BLEEDING INTERNALLY. SHE WAS ON INTRAVENOUS ANTIBIOTICS, SALINE, PAIN MEDICATIONS. SHE WENT HOME WITH A HORRIBLE CASE OF C-DIFF, WHICH LANDED HER WITH MORE ANTIBIOTICS AND ISSUES. A YEAR LATER (2015), SHE HAD A PAINFUL SCAR TISSUE REMOVED, AS WELL AS POSSIBLE ADHESIONS. WHEN SHE WOKE UP, SHE WAS TOLD HER RIGHT OVARY WAS TAKEN OUT. SHE STATED NOT ONLY SHE WAS SENT TO SURGICAL MENOPAUSE AT (B)(6), BUT EVERYTHING THAT MADE HER A MOTHER WAS GONE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO EXPERIENCED PAIN IN HER PELVIC REGION SINCE ESSURE INSERTION. AFTER ESSURE CONFIRMATION TEST SHE HAD BLEEDING. A FEW MONTHS LATER, SHE WAS SUBMITTED TO A HYSTERECTOMY. DURING THE SURGERY HER LEFT OVARY WOULD NOT STOP BLEEDING; SO IT WAS REMOVED. THREE DAYS LATER IT WAS DISCOVERED SHE WAS BLEEDING INTERNALLY. SHE WAS TREATED WITH BLOOD TRANSFUSION AND ANTIBIOTICS AND DEVELOPED A C-DIFF (CLOSTRIDIUM DIFFICILE). ONE YEAR LATER, SHE HAD PAINFUL SCAR TISSUE REMOVED, AS WELL AS POSSIBLE ADHESIONS. WHEN SHE WOKE UP, SHE WAS TOLD HER RIGHT OVARY WAS TAKEN OUT. ADDITIONALLY, SHE BELIEVED SHE HAD HEAVY METAL POISONING. ONLY BLEEDING AND PAIN ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER HAD PAIN SINCE ESSURE INSERTION AND DEVELOPED BLEEDING AFTER HER CONFIRMATION TEST. SHE ALSO REPORTED HEAVY PERIODS WITH CLOTS. CONSIDERING EVENTS NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE OTHER EVENTS, IT IS UNCLEAR WHY CONSUMER'S OVARY PRESENTED BLEEDING. ESSURE REMOVAL SURGERY USUALLY REQUIRES SALPINGECTOMY AND/OR HYSTERECTOMY; NO OOPHORECTOMY IS NECESSARY (UNLESS PHYSICIAN DECIDED TO PERFORM IT DUE TO ANOTHER CONDITION). GIVEN THIS INFORMATION AND CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY BETWEEN THE REPORTED OVARIAN BLEEDING, ITS COMPLICATIONS (INTERNAL BLEEDING, C-DIFF) AND ESSURE IS CONSIDERED UNLIKELY. THIS SAME ASSESSMENT IS GIVEN FOR HEAVY METAL POISONING, SINCE IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED FROM ESSURE WOULD BE SUFFICIENT TO CAUSE A THIS CONDITION. THIS CASE WAS REGARDED AS INCIDENT, AS DEVICE REMOVAL WAS REQUIRED. NON-SERIOUS EVENTS WERE ALSO REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE FROM HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01428	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/1/2008
Explant Date (E7): 12/1/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1798, AWARENESS DATE 17-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. SHE WAS GIVEN A VALIUM ABOUT 20 MINUTES BEFORE THE PROCEDURE. THE IMPLANTATION ITSELF WAS EXTREMELY PAINFUL AND SHE WAS BEGGING HER TO STOP AS SHE WAS FINISHING THE LAST SIDE. SHE WAS SENT HOME WITH SOME IBUPROFEN. IMMEDIATELY FROM THAT DAY, A DULL ACHING PAIN IN ABDOMEN STARTED THAT DID NOT GO AWAY EVER OVER THE NEXT 5 YEARS. THIS PAIN ESCALATED TO EXCRUCIATING PAIN DURING PERIODS, SO BAD THAT SHE COULD NOT WALK. AFTER THE HYSTEROSALPINGOGRAM (HSG) IN (B)(6) 2008, SHE WAS DECLARED OCCLUDED AND CONFIRMED THAT THE COILS WERE PERFECTLY PLACED. SHE WAS STILL EXPERIENCING CONSTANT PAIN. IN 2009, SHE STARTED SUFFERING FROM EXTREME FATIGUE, RASHES, MONTHLY UTIS, AND RECURRING YEAST INFECTIONS. SHE WAS TESTED FOR EVERY STD THEY COULD THINK OF AND ALL RESULTS WERE NEGATIVE. SHE WAS TOLD PROBABLY HAD SOMETHING CALLED PID, WAS GAVE ANTIBIOTICS AND SENT OFF. SHE SAW THREE OTHER DOCTORS THAT YEAR AND WAS EVALUATED FOR CHRONIC FATIGUE SYNDROME, FOOD ALLERGIES OR INTOLERANCES, DEPRESSION AND LYME DISEASE. SHE HAD NONE OF THESE THINGS. SHE WAS FATIGUED, IN PAIN AND WEAK. IN 2010-2011, SHE WENT TO EMERGENCY ROOM (ER) MULTIPLE TIMES FROM A STABBING PAIN IN RIGHT ABDOMEN THAT WAS SO BAD SHE WOULD FALL ON THE GROUND WHEN IT HIT ER DOCTORS KNEW NOTHING ABOUT ESSURE. AN MRI, ULTRASOUNDS, X-RAYS WERE PERFORMED AND SHE WAS TOLD EVERY TIME THAT THE ESSURE COILS WERE PERFECTLY PLACED AND THEREFORE IT COULD NOT BE ESSURE. BY 2012, SHE WAS HAVING REACTIONS TO

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ANYTHING METAL THAT TOUCHED HER BODY, ZIPPERS ON PANTS & HOODIES, EARRINGS, EVEN HER WEDDING RINGS MADE HER SWELL UP, ITCH AND RASH. HER HAIR BEGAN FALLING OUT IN DUMPS, SHE WAS SO TIRED AND IN PAIN ALL THE TIME THAT SPENT DAYS IN BED. SHE STARTED HAVING ABDOMINAL BLOATING. LT LOOKED LIKE SHE WENT FROM NOTHING TO 6 MONTHS PREGNANT OVER THE COURSE OF A DAY. BEING INTIMATE WITH HER HUSBAND WAS EXCRUCIATING. IN ADDITION TO PAINFUL SEX, HE WOULD GET AN ITCHY RASH ANYWHERE HER VAGINAL FLUIDS TOUCHED HIM. IN 2013, AS A RESULT OF ONE OF THE FEW TIMES THEY ACTUALLY DID MANAGE TO HAVE SEX, SHE BECAME PREGNANT. SHE MISCARRIED AT THE (B)(6) MARK. AGAIN, THE COILS WERE SAID TO BE PERFECTLY PLACE (FOR THE CASE UNTIL THE FIRST MISCARRIAGE, KINDLY REFER TO CASE NUMBER (B)(4)). TWO MONTHS LATER, SHE WAS LATE ON HER PERIOD; ANOTHER POSITIVE TEST SHE WAS PREGNANT AND HAD ANOTHER MISCARRIAGE. THIS ONE WAS ESTIMATED TO BE AT THE (B)(6) MARK. IN (B)(6) 2013, ESSURE WAS REMOVED, AND SHE HAD A TUBAL LIGATION PERFORMED. IMMEDIATELY AFTER REMOVAL, THE CONSTANT, DULL PAIN WAS GONE. THE BLOATING STOPPED. IN A MONTH, THE RASHES WERE GONE. HER HAIR STOPPED FALLING OUT, AND STARTED TO GROW BACK. SHE COULD WEAR JEWELRY AGAIN. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT AND HAD MISCARRIAGE. THIS CASE IS FOR SECOND EPISODE OF PREGNANCY WITH MISCARRIAGE (PLEASE SEE CASE (B)(4) FOR THE FIRST EPISODE OF PREGNANCY). BOTH EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. PREGNANCY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE MISCARRIAGE IS UNLISTED. SPONTANEOUS ABORTION IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY. RISK FACTORS INCLUDE MATERNAL AGE, PREVIOUS SPONTANEOUS ABORTION, SMOKING, LOW FOLATE LEVEL, UTERINE ABNORMALITIES, FETAL CHROMOSOMAL ABNORMALITIES, MATERNAL CHRONIC DISEASE (POLYCYSTIC OVARY SYNDROME AND THYROID DYSFUNCTION, FOR EXAMPLE) AND MATERNAL INFECTIONS. IN THIS CASE, CONSUMER MISCARRIED AT THE (B)(6) MARK. CONSIDERING THAT A MECHANICAL INTERFERENCE OF ESSURE MICRO-INSERTS IN EARLY DEVELOPING PREGNANCY IS UNLIKELY, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND MISCARRIAGE CAN BE EXCLUDED. WITH REGARDS TO THE EVENT PREGNANCY, SINCE IT OCCURRED MORE THAN THREE MONTHS AFTER ESSURE INSERTION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE ESSURE WAS REMOVED AND SHE HAD A TUBAL LIGATION PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01430	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/15/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2041, AWARENESS DATE 17-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. CONSUMER HAD ESSURE INSERTED AND EXPERIENCED SEVERE ABDOMINAL PAIN THAT WOULDN'T RELEASE EVEN AFTER HER CYCLE, LOWER BACK PAIN ALWAYS AROUND HER CYCLE, LEG NUMBNESS, HEADACHES OR MIGRAINES WHICH STARTED IN 2011, VOMITING, CHRONIC PAIN, ARTHRITIS IN NECK AND SWELLING IN THE BACK OF HEAD, JOINT PAINT EVERY DAY. SHE LOST HER JOB. IN (B)(6) SHE HAD HER TUBES TAKEN OUT BY A SALPINGECTOMY. SHE IS ON RECOVERY. THE PAIN STILL HASN'T SUBSIDED AS MUCH AS SHE WANTED TO BUT THE LAWN BETWEEN BREASTS IN THE TOP OF HER ABDOMEN HAS NOW SUBSIDED. HER LOWER ABDOMINAL PAIN HAS NOT GONE AWAY. HER LIST OF SIDE EFFECTS ARE BRAIN FOG, METAL TASTE IN MOUTH, MIGRAINES, VOMITING AND THROWING UP FOR NO REASON, CAN'T EAT MORE THAN 2 TABLESPOONS FEEL FOOD WITHOUT FEELING FULL, IBS (IRRITABLE BOWEL SYNDROME), HEAVY PERIODS THAT LAST FOR SEVEN DAYS CHUNKY FLOW, RA (RHEUMATOID ARTHRITIS), JOINT PAIN, THYROID CYST NONCANCEROUS, SWELLING OCCIPITAL NERVES BACK OF HEAD, HAIR LOSS, SWOLLEN GUMS, SWELLING IN MY FACE, ARMS, LEGS, HANDS, FEET, MIGRAINES, AUTOIMMUNE RASH, TINGLING IN HANDS AND LEGS ASSOCIATED WITH NUMBNESS, ANXIETY DISORDER, HEART PALPITATIONS, NIGHT SWEATS, FEVER CHILLS, MENOPAUSAL SYMPTOMS. SEX IS NON EXISTENT. IT HURTS. COMPANY CAUSALITY COMMENT THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD SEVERE ABDOMINAL PAIN/LOWER ABDOMINAL PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE

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WAS SUBMITTED TO A SALPINGECTOMY BUT HER PAIN HASN'T SUBSIDED AS MUCH AS SHE WANTED. ADDITIONALLY, SHE WAS DIAGNOSED WITH RHEUMATOID ARTHRITIS. ONLY PAIN IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. RHEUMATOID ARTHRITIS (RA) IS A CHRONIC INFLAMMATORY CONDITION AFFECTING THE JOINTS. GENDER, HEREDITY, AND GENES LARGELY DETERMINE THE RISK OF DEVELOPING THIS CONDITION. CONSIDERING RA PATHOPHYSIOLOGY AND GIVEN ESSURE LOCAL ACTION IN FALLOPIAN TUBES CAUSALITY IS CONSIDERED UNLIKELY. REGARDING CONSUMER'S ABDOMINAL PAIN, AFTER ESSURE INSERTION ABDOMINAL PAIN MAY OCCUR. IN THIS CASE, CONSUMER'S PAIN STARTED IN CLOSE ASSOCIATION WITH ESSURE PROCEDURE. ALTHOUGH THIS EVENT DID NOT RESOLVED WITH ESSURE REMOVAL (SALPINGECTOMY PERFORMED); SINCE THE CONSUMER WAS STILL ON RECOVERY AT THE TIME OF THIS REPORT; A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION (SALPINGECTOMY) WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC GLOBAL NUMBER: (B)(4)) INVESTIGATION RESULT RECEIVED ON 05-NOV-2015: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01431	BAYER HEALTHCARE LLC	11/11/2015	11/11/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/23/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 18-OCT-2015) WHICH REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014, AFTER 3 CHILDREN SHE DECIDED FOR THE PERMANENT BIRTH CONTROL. THE CONSUMER REPORTED THE PROCEDURE ITSELF WAS PAINFUL; SHE HAD CRAMPS AND ABDOMINAL PAIN FOR SEVERAL DAYS AFTERWARDS. THREE MONTHS AFTER, SHE WENT TO HER CONFIRMATION APPOINTMENT AND HER RIGHT SIDE WAS NOT BLOCKED. SHE STATED THE ULTRASOUND IMAGE SHOWED THE COIL WAS CAUSING HER FALLOPIAN TUBE TO BEND. IF IT HAD NOT ALREADY PERFORATED HER FALLOPIAN TUBE, IT WOULD BE JUST A MATTER OF TIME. HER DOCTOR AND SHE DECIDED THAT HER BEST COURSE OF ACTION WAS TO HAVE HER FALLOPIAN TUBES REMOVED. AFTER THE SURGERY, SHE WAS TOLD EVERYTHING WAS GREAT AND THAT THE COILS WERE OUT, BUT SHORTLY AFTER SURGERY SHE EXPERIENCED WEIGHT GAIN, BLOATING, LOW SEX DRIVE, CRAMPING, AND HIVES. SHE REPORTED HER HEALTH WENT ON A DOWNWARD SPIRAL AFTER REMOVAL. SHE BEGAN GETTING LOWER BAD PAIN, STARTED HAVING GI ISSUES -CONSTIPATION AND BLOODY STOOLS; AND THEN CAME THE URINARY TRACT ISSUES- CONSTANT UTIS AND KIDNEY STONES WHICH SHE NEVER HAD. SHE WAS TAKEN TO THE ER FOR THE KIDNEY STONES AND HAD A CT SCAN FOR CONFIRMATION AND WAS WHEN THE ER DOCTOR SAID SHE STILL HAD THE COILS IN HER. SHE CALLED HER GYNECOLOGIST AND HER NURSE SAID THERE WERE STILL FRAGMENTS OF THE COIL IN HER UTERUS, BUT HER TUBES WERE GONE, THE NURSE ALSO SAID THE GYNECOLOGIST HAD TO CUT THE COILS SINCE PART OF THEM HAD BECOME EMBEDDED IN HER UTERUS. THE TWO MONTHS BEFORE THE REPORT, HER HEALTH ISSUES HAVE BECOME WORSE. ON TOP OF THE UT AND GI ISSUES SHE WAS

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EXPERIENCING CATASTROPHIC PERIODS, CONSTANT PELVIC PAIN/TENDERNESS, PAINFUL INTERCOURSE, BLOATING HAS GOTTEN SO BAD SHE LOOKED LIKE SHE WAS PREGNANT. SHE WAS ABO DIAGNOSED WITH OSTEOARTHRITIS AND HAD A HERNIATED DISC AND HAD TO HAVE SURGERY IN (B)(6) 2015. SHE STATED SHE KNOW HER PROBLEMS WERE CAUSED BY HER DOCTOR JUST AS MUCH AS THEY WERE CAUSED BY THE PRODUCT ITSELF. THE RIGHT COIL WAS PROBABLY PLACED WRONG AND THEY ARE NOT SUPPOSED TO BE CUT, THE REMOVAL WAS DONE WRONG. FOLLOW-UP RECEIVED ON (B)(6) 2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE COIL WAS CAUSING HER FALLOPIAN TUBE TO BEND (SEEN AS FALLOPIAN TUBE DISORDER), THEN SHE HAD HER FALLOPIAN TUBES REMOVED. HOWEVER, THE PHYSICIAN HAD TO CUT THE COILS SINCE PART OF THEM HAD BECOME EMBEDDED IN HER UTERUS. THE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER WENT TO HER CONFIRMATION APPOINTMENT THREE MONTHS AFTER ESSURE INSERTION AND IT WAS NOTED THAT THE RIGHT SIDE WAS NOT BLOCKED. AN ULTRASOUND WAS PERFORMED AND THE RESULT SHOWED THE COIL WAS CAUSING HER FALLOPIAN TUBE TO BEND. THIS OCCURRENCE MAY BE A COMPLICATION OF EMBEDDED DEVICE. THE EXACT DATE AND MECHANISM OF EMBEDMENT WERE NOT KNOWN. CONSIDERING THE NATURE OF THE EVENTS AND A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (BLOODY STOOLS, CONSTANT UTI'S, KIDNEY STONES, HERNIATED DISC THAT I HAD TO HAVE SURGERY ON, ALL OF THEM UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 05-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01403	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1536, AWARENESS DATE 16-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN 2011 AFTER HER LAST CHILD WAS BORN. BEFORE HIM SHE HAD AN ECTOPIC PREGNANCY THAT BURST AND SHE ALMOST BLED TO DEATH WITH NO SIGNS OF HAVING AN ECTOPIC PREGNANCY. WITH THAT ECTOPIC PREGNANCY SHE ALSO LOST ONE OF HER FALLOPIAN TUBES. HER DOCTOR RECOMMENDED ESSURE TO HER. SHE WAS SCARED OF ANOTHER ECTOPIC PREGNANCY AND DYING LEAVING HER TWO CHILDREN MOTHERLESS. SO AT (B)(6), SHE GOT THE ESSURE PROCEDURE DONE. THE FIRST THING SHE NOTICED WAS THE BLEEDING, SHE BLED A LOT AND FOR WEEKS. THE PAIN WAS HORRIBLE. AFTER 6 MONTHS TO A YEAR, HER HEALTH STARTED GOING DOWN HILL FAST, SHE WAS CONSTANTLY SICK. LONG PERIODS TO WHERE SHE FELT LIKE SHE WAS BLEEDING OUT, SHE ENDED UP GOING TO THE DOCTOR WHO TOLD HER SHE WAS ANEMIC FROM BLOOD LOSS. THEN HER PERIODS JUST STOPPED. SHE ALMOST WENT A FULL YEAR WITHOUT A PERIOD, JUST A COUPLE WEEKS SHORT OF A YEAR. HER HAIR WAS FALLING OUT AND HER SCALP DEVELOPED HORRIBLE DANDRUFF. THE DOCTORS SAID SHE HAD MALE PATTERN BALDNESS. THE PRESCRIPTION SHAMPOOS DIDN'T HELP WITH THE DANDRUFF, NOTHING HELPED. SHE STARTED GETTING SO DIZZY THAT SHE ALMOST REALLY HURT HERSELF A FEW TIMES. ONE TIME SHE GOT VERY DIZZY WHILE SHE WAS DRIVING. SHE GOT SO DIZZY SHE ALMOST WENT INTO THE DITCH. SHE COULDN'T SEE ANYTHING HER WHOLE WORLD WAS SPINNING. THERE WAS NOTHING THAT SIGNALED IT, SHE WOULD BE FINE ONE MOMENT THEN COMPLETELY DIZZY AND NO BALANCE OR SENSE OF DIRECTION THE NEXT. THE BLOATING WAS HORRIBLE, EVERY TIME SHE ATE IT DIDN'T MATTER WHAT SHE ATE HER STOMACH

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WOULD BLOAT UP UNTIL SHE LOOKED 8 MONTHS PREGNANT. THE PAIN WAS SO BAD THAT SHE DIDN'T WANT TO EAT ANYMORE. SHE HAD CONSTANT HEADACHES, TO THE POINT WHERE SHE WAS HAVING TO TAKE TYLENOL AND IBUPROFEN DAILY AND MOST DAYS MULTIPLE TIMES A DAY, IT WAS DEBILITATING. SHE NEVER HAD HEADACHES BEFORE ESSURE. ONE TIME WHEN SHE WENT 2 MONTHS WITHOUT A PERIOD SHE STARTED GETTING PREGNANCY SYMPTOMS, SHE BOUGHT A HOME PREGNANCY TEST FOR HER OWN PIECE OF MIND. IT WAS POSITIVE, SHE MADE AN APPOINTMENT WITH THE DOCTOR AND GOT BLOOD WORK DONE ABOUT A WEEK LATER. THE NURSE SAID IT WAS MOSTLY NEGATIVE, A DAY LATER SHE STARTED BLEEDING HEAVILY AND PASSING LARGE CLOTS. HER BODY COULD NOT FIGHT ANY KIND OF ILLNESS, SHE HAD MONO, THE FLU, MANY BACTERIAL INFECTIONS, AND COMMON COLDS. IN (B)(6) 2015, SHE HAD A HYSTERECTOMY LEAVING ONLY HER OVARIES, NOT A WEEK LATER HER DANDRUFF WAS ALMOST COMPLETELY GONE, THE BLOATING WAS GONE, HER HAIR WAS GROWING BACK, SHE HAD ZERO DIZZINESS, SHE WAS ALMOST BACK TO BEING A HEALTHY PERSON. SHE FELT LIKE SHE GOT HER LIFE BACK, NO MORE PAIN AND NO MORE HEADACHES. SHE LOST HER JOB, ALMOST LOST HER SON, HER RELATIONSHIP CRUMBLED, HER SELF WORTH WENT INTO THE NEGATIVE TO THE POINT OF WANTING TO END HER LIFE, SHE HAD TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6). SHE ALMOST LOST HER LIFE DUE TO THAT LITTLE COIL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED BECAUSE SHE WAS SCARED OF HAVING ANOTHER ECTOPIC PREGNANCY. THE PAIN WAS HORRIBLE, SHE BLED A LOT AND FOR WEEKS (INTERPRETED AS GENITAL BLEEDING), A DAY AFTER PERFORMING A BLOOD WORK THAT WAS NEGATIVE FOR THE SUSPICION OF PREGNANCY, SHE HAD BLEEDING HEAVILY AND PASSING LARGE CLOTS (INTERPRETED AS GENITAL BLEEDING). SHE ALSO STATED HER BODY COULD NOT FIGHT ANY KIND OF ILLNESS (INTERPRETED AS IMMUNODEFICIENCY). SHE WENT TO THE POINT OF WANTING TO END HER LIFE (INTERPRETED AS SUICIDAL IDEATION). FOUR YEARS AFTER INSERTION, SHE HAD A HYSTERECTOMY PERFORMED LEAVING ONLY HER OVARIES. AFTER THE SURGERY, SHE WAS ALMOST BACK TO BEING A HEALTHY PERSON. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE EPISODES OF GENITAL BLEEDING AND UNSPECIFIED PAIN ARE LISTED WHILE THE IMMUNODEFICIENCY AND SUICIDAL IDEATION ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS AND LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS NOT POSSIBLE TO EXCLUDE A CAUSAL RELATIONSHIP BETWEEN ESSURE AND GENITAL BLEEDINGS AND PAIN. HOWEVER, IT IS UNLIKELY THAT ESSURE WOULD CAUSE IMMUNODEFICIENCY AND SUICIDAL IDEATION. THIS CASE IS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01417	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 16-OCT-2015 WHICH REFERS TO A FEMALE OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. CONSUMER REPORTED THAT FIRST SHE GAINED A LOT OF WEIGHT, HAD SEVERE ABDOMINAL AND BACK PAIN, ABNORMAL BLEEDING AND RECENTLY FOUND OUT THAT HER ESSURE MIGRATED INTO HER PELVIS SO SHE WAS GETTING A HYSTERECTOMY (DATE WAS REPORTED BUT IT IS UNREADABLE IN THE SOURCE DOCUMENT). SHE HAS BEEN IN PAIN FOR OVER A YEAR. AS CONCOMITANT MEDICATION SHE TOOK BACLOFEN, CELEXA AND KLONOPIN. FOLLOW-UP RECEIVED ON 03-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205)

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABNORMAL BLEEDING (INTERPRETED AS GENITAL BLEEDING). IT WAS FOUND OUT THAT HER ESSURE MIGRATED INTO HER PELVIS, SO SHE WAS GETTING A HYSTERECTOMY. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH NOT REPORTED AS SUCH, THE MOST LIKELY MECHANISM FOR ESSURE MIGRATED INTO HER PELVIS, WOULD BE THROUGH A UTERINE/FALLOPIAN TUBE PERFORATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE). UTERINE PERFORATION WITH ESSURE MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS CASE, THE EXACT DATE AND MECHANISM OF DEVICE MIGRATION WERE NOT KNOWN. CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION (UTERINE PERFORATION QUESTIONNAIRE) IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 03-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01418	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 2/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/14/2014
Explant Date (E7): 2/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. ANTICIPATED. REQUIRED INTERVENTION. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA REGULATORY AUTHORITY (CASE (B)(4)) IN UNITED STATES ON 16-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2014. ON (B)(6) 2015 MIGRATION OF ESSURE DEVICE WITH UTERINE PERFORATION ENDING IN NON-STERILIZATION WAS CONFIRMED BY RADIOLOGY. ESSURE WAS REMOVED ON (B)(6) 2015. FOLLOW-UP RECEIVED ON 03-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 3 MONTHS LATER MIGRATION OF ESSURE DEVICE WITH UTERINE PERFORATION WAS CONFIRMED BY RADIOLOGY. ESSURE WAS REMOVED. THIS EVENT, INTERPRETED AS UTERINE PERFORATION, IS

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SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT CASE, NO INFORMATION WAS PROVIDED REGARDING THE INSERTION PROCEDURE. THE UTERINE PERFORATION WAS DIAGNOSED 3 MONTHS AFTER INSERTION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01419	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 508104

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055372) IN UNITED STATES ON 16-OCT-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2005, LOT NUMBER 508104. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: HAPOCTICN, LYRIC (DIFENIDOL HYDROCHLORIDE), NORTRIPTYLINE (NORTRIPTYLINE), VITAMIN D (COLECALCIFEROL), AND CALCIUM MAGNESIUM (CALCIUM W/MAGNESIUM). THE CONSUMER HAD ESSURE INSERTED AFTER HAVING A VERY PREMATURE BABY. SHE WAS ADMITTED TO HOSPITAL THE SAME EVENING WITH HORRENDOUS CRAMPING, PAIN AND HEAVY BLEEDING. SINCE ESSURE SHE HAD FAR HEAVIER AND MORE PAINFUL PERIODS, MOOD SWINGS, AND VERY BAD OVULATING PAIN, OFTEN CRIPPLING SHARP STABBING PAIN IN THE AREA OF HER RIGHT OVARY. IN THE YEARS FOLLOWING HER LOWER BACK HAS BECOME PAINFUL AND OFTEN LEFT HER IMMOBILE FOR DAYS, SOMETIMES WEEKS (DISABILITY). SINCE 2013 HER BACK PAIN HAD BECOME SO DEBILITATING THAT SHE WAS UNABLE TO WALK WITHOUT A WALKING STICK. IN 2013, AN MRI (MAGNETIC RESONANCE IMAGING) SHOWED BULGING AND HERNIATED DISK DISEASE. SHE HAD ALSO HAD PROBLEMS EMPTYING HER BLADDER. HER PERIODS AND MID CYCLE PAIN HAD BECOME SO BAD THAT SHE HAD BEEN REFERRED TO GYNECOLOGY TO DISCUSS HER REQUEST FOR A FULL HYSTERECTOMY (WITH SUPPORT FROM HER GENERAL PRACTITIONER). SHE HAD SUFFERED WITH CERVICAL CHANGES REQUIRING CAUTERIZATION, AND VERY LARGE NABOTHIAN CYSTS REGULARLY RETURNING FOR THE LAST TWO YEARS AND HAVING TO BE DRAINED. SHE WAS DIAGNOSED WITH FIBROMYALGIA IN THE LAST YEAR DUE TO CRIPPLING PAINS IN MANY AREAS OF HER BODY AND FATIGUE. SHE BELIEVED MOST OF THESE PROBLEMS, IF NOT ALL, WERE AS A DIRECT RESULT OF HAVING THE ESSURE INSERTED. FOLLOW UP 19-OCT-2015: NO NEW INFORMATION WAS PROVIDED. PRODUCT TECHNICAL COMPLAINT ANALYSIS RECEIVED

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ON 03-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE WAS ADMITTED TO HOSPITAL WITH HORRENDOUS CRAMPING, PAIN (SEEN AS PELVIC PAIN) AND HEAVY BLEEDING (SEEN AS GENITAL BLEEDING). THESE EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IT WAS REPORTED THAT IN THE YEARS FOLLOWING HER LOWER BACK HAS BECOME PAINFUL AND OFTEN LEFT HER IMMOBILE FOR DAYS (CONSIDERED SERIOUS DUE TO DISABILITY AND LISTED). SHE HAD SUFFERED WITH CERVICAL CHANGES REQUIRING CAUTERIZATION, HAD VERY LARGE NABOTHIAN CYSTS HAVING TO BE DRAINED (THESE EVENTS ARE SERIOUS AND UNLISTED). CONSIDERING THE NATURE OF THE EVENTS, EXCEPT FOR CERVICAL CHANGES AND VERY LARGE NABOTHIAN CYSTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED AS NO ALTERNATIVE EXPLANATION WAS PROVIDED. WITH REGARDS TO THE OTHER EVENTS, GIVEN ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, A CONTRIBUTORY ROLE OF ESSURE IS UNLIKELY, THUS A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO HOSPITALIZATION. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO SAMPLE WAS PROVIDED BUT A REVIEW OF THE MANUFACTURING BATCH RECORD CONFIRMED THAT LOT MET ALL RELEASE REQUIREMENTS. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01422	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 9/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C39209/ C38209; C95072

Single Use: Y
Implant Date (E6): 3/1/2015
Explant Date (E7): 10/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 16-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015, LOT NUMBERS C39209 (ALSO REPORTED AS (B)(4)- DISCREPANT INFORMATION PROVIDED) AND (B)(4), FOR PERMANENT STERILIZATION. MIGRATION OF INSERT WAS REPORTED. HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED ON (B)(6) 2015, NOTES STATED THAT THE LEFT INSERT WAS FLOATING IN UTERUS. OPEN LAPAROSCOPY WAS DONE ON (B)(6) 2015. A GELSHI (AS REPORTED) CLIP WAS USED ON THE LEFT SIDE AND THE INSERT WAS REMOVED. THIS WAS OUTPATIENT SURGERY. PATIENT WAS NOT PREGNANT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HYSTEROSALPINGOGRAM PERFORMED 6 MONTHS LATER SHOWED MIGRATION OF INSERT / LEFT INSERT WAS FLOATING IN UTERUS. OPEN LAPAROSCOPY WAS DONE AND THE INSERT WAS REMOVED. THIS EVENT, INTERPRETED AS PARTIAL EXPULSION OF DEVICE, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THE PRESENT CASE, THE EXACT LOCATION OF THE DEVICE WAS NOT CLEAR SINCE IT WAS REPORTED THAT THE INSERT MIGRATED AND WAS FLOATING IN UTERUS, BUT IT WAS REMOVED DURING A LAPAROSCOPY. HOWEVER, GIVEN THE NATURE OF THE EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 04-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LAT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01423	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1973, AWARENESS DATE 16-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 (SIX YEARS BEFORE THIS REPORTED) FOR PERMANENT STERILIZATION. CONSUMER WAS TENDER IN THAT AREA ALL THE TIME, EXPERIENCED HORRIBLE BLEEDING (BLEEDING 2 STRAIGHT WEEKS EVERY MONTH), HORRIBLE CRAMPS, METALLIC SMELLING URINE, METALLIC SMELLING DISCHARGE, HEADACHES, MIGRAINES, HIP PAIN, CHEST PAIN, LOWER BACK PAIN, DIZZINESS, FUZZY FEELING IN HER HEAD, AND EXTREMELY DECREASED SEX DRIVE. SHE HAD AN ABLATION AND D&C (DILATION AND CURETTAGE) IN 2015. HER PERIODS PRIOR TO ESSURE WERE VERY LIGHT, AND USUALLY ONLY LASTING 3-4 DAYS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HORRIBLE BLEEDING (BLEEDING 2 STRAIGHT WEEKS EVERY MONTH). SHE HAD AN ABLATION AND D&C (DILATION AND CURETTAGE) PERFORMED. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THE NATURE OF THE EVENT AND CONSIDERING THAT GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS

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WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 04-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01424	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1548, AWARENESS DATE 17-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER HAD MANY SIDE EFFECTS THAT WERE A RESULT TO THESE IMPLANTS: SEVERE PAIN, PELVIC PAIN, BACK PAIN, LEG PAIN, HEADACHES, CHRONIC FATIGUE, MANY UTI (URINARY TRACT INFECTIONS), UTERINE INFECTION, B-12 VITAMIN DEFICIENCY, VITAMIN D DEFICIENCY, FIBROMYALGIA, BOILS / INFECTIONS, HAIR LOSS, DEPRESSION, ANXIETY. THESE WERE ALL SYMPTOMS THAT OCCURRED AFTER ESSURE WAS PLACED. AFTER MANY DOCTORS AND ER (EMERGENCY ROOM) VISITS, AND INFECTIONS AND UNBEARABLE PAIN THAT SHE HAD ON A DAILY BASIS, SHE HAD TO HAVE A HYSTERECTOMY IN 2014, AT AGE (B)(6). STILL AFTER THE REMOVAL SHE HAS SYMPTOMS THAT MAY NEVER GO AWAY. PTC INVESTIGATION RESULT RECEIVED ON 04-NOV-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT

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PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PELVIC PAIN, UTERINE INFECTION AND MANY UTI INFECTIONS (INTERPRETED AS URINARY TRACT INFECTIONS). SHE UNDERWENT A HYSTERECTOMY 3 YEARS AFTER ESSURE INSERTION AND THE DEVICE WAS REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN AND UTERINE INFECTION ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENT IS UNLISTED. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THIS EVENT AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING EVENT UTERINE INFECTION, WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFLAMMATORY DISEASE IN THE FIRST 4 WEEKS AFTER INSERTION. IN THE PRESENT CASE, NO INFORMATION SUGGESTING THIS CLOSE TEMPORAL RELATIONSHIP WITH THE INSERTION PROCEDURE WAS MENTIONED. THEREFORE, CAUSALITY BETWEEN UTERINE INFECTION AND ESSURE WAS ASSESSED AS UNRELATED. URINARY TRACT INFECTION PATHOGENESIS IN WOMEN BEGINS WITH COLONIZATION OF THE VAGINAL INTROITUS BY UROPATHOGENS FROM THE FECAL FLORA, FOLLOWED BY ASCENSION VIA THE URETHRA INTO THE BLADDER. CONSIDERING THE NATURE OF THIS EVENT, AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

DEVICE NOT RETURNED TO MANUFACTURER.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01429	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1993, AWARENESS DATE 17-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012, FOR BIRTH CONTROL. HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED IN (B)(6) 2013. THE PROCEDURE IN ITSELF WAS VERY PAINFUL. A MONTH OR SO AFTER BEING PLACED, HER SYMPTOMS BEGAN: HEAVY BLEEDING, PERIODS THAT WOULD LAST 10-14 DAYS WOULD STOP FOR A WEEK AND WOULD RETURN AGAIN, SEVERE PELVIC PAIN, MORE MIGRAINES, HAIR FALLING OUT, FATIGUE, PAIN DURING SEX, SEVERE LOWER BACK PAIN, STOMACH SWELLING/ BLOATING (SO MUCH THAT SHE LOOKED 7 MONTHS PREGNANT) AND OTHER THINGS. IN (B)(6) 2013, SHE UNDERWENT A SURGERY TO REMOVE 2 LARGE OVARIAN CYSTS. SHE NEVER HAD PROBLEMS WITH CYSTS PRIOR TO ESSURE. BLEEDING AND PELVIC PAIN CONTINUED. AN ABLATION AND A D&C WERE PERFORMED TO HELP CONTROL THE BLEEDING. THIS DID NOT HELP. ALL OF SYMPTOMS CONTINUED. A HYSTERECTOMY WITH BILATERAL SALPINGECTOMY WAS PERFORMED AND A LOT OF HER SYMPTOMS GOT BETTER AFTER ESSURE REMOVAL. A FEW MONTHS LATER THE PELVIC PAIN RETURNED. ANOTHER SURGERY WAS PERFORMED BECAUSE SHE HAD SCAR TISSUE CALLED ADHESIONS (LYSIS OF ADHESIONS). IN (B)(6) 2014, ANOTHER SURGERY WAS PERFORMED BECAUSE OF A VAGINAL CUFF REPAIR. FINALLY IN (B)(6) 2015, ANOTHER SURGERY WAS PERFORMED BECAUSE THE PELVIC PAIN RETURNED. THIS TIME A STAPLE WAS REMOVED FROM THE HYSTERECTOMY. ENDOMETRIOSIS WAS ALSO FOUND. ALL OF THESE SURGERIES WERE A RESULT FROM HAVING THE ESSURE. AFTER PLACEMENT HER QUALITY OF LIFE SIGNIFICANTLY DECREASED. AT THE AGE OF THE (B)(6), SHE HAD TO HAVE A HYSTERECTOMY. SHE WAS DIAGNOSED WITH

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AUTO IMMUNE DISEASE, HASHIMOTOS DISEASE, AND ALSO WITH HYPOTHYROIDISM. FOLLOW-UP RECEIVED ON 28-OCT-2015: NO NEW RELEVANT CLINICAL INFORMATION. PTC INVESTIGATION RESULT WAS PROVIDED ON 05-NOV-2015: THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DETECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEVERE PELVIC PAIN AND HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT AN ENDOMETRIAL ABLATION AND A DILATION AND CURETTAGE TO CONTROL THE BLEEDING, BUT THEY DID NOT HELP. A HYSTERECTOMY WITH BILATERAL SALPINGECTOMY AND ESSURE REMOVAL WAS PERFORMED. LATER SHE UNDERWENT ANOTHER SURGERY FOR LYSIS OF ADHESIONS (INTERPRETED AS PELVIC ADHESIONS). SHE ALSO REPORTED 2 LARGE OVARIAN CYSTS WHICH WERE REMOVED AND AUTO IMMUNE DISEASE: HASHIMOTOS DISEASE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN AND GENITAL BLEEDING ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENTS ARE UNLISTED. PELVIC PAIN AND ABNORMAL GENITAL BLEEDING MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THESE EVENTS AND POSITIVE TEMPORAL RELATIONSHIP CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THE CONSUMER HAD A PREVIOUS SURGERY TO REMOVE 2 OVARIAN CYSTS, AND LATER ENDOMETRIOSIS WAS ALSO DIAGNOSED. THESE COULD BE ALTERNATIVE EXPLANATIONS FOR THE PELVIC ADHESIONS. HOWEVER A CONTRIBUTORY ROLE OF THE ESSURE REMOVAL PROCEDURE (HYSTERECTOMY AND SALPINGECTOMY) CANNOT BE EXCLUDED. REGARDING EVENTS LARGE OVARIAN CYSTS AND AUTO IMMUNE DISEASE: HASHIMOTOS DISEASE, GIVEN THE PATHOPHYSIOLOGY OF THESE EVENTS AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT DUE TO REQUIRED INTERVENTIONS AND SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01432	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 30-JUL-2013 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT PELVIC PAIN. THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO ARGUS ON 01-OCT-2013. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED. FOLLOW-UP RECEIVED ON 17-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1704). CONSUMER REPORTED THAT ESSURE WILL CAUSE LOTS OF PAIN EVEN THE DOCTORS WILL SAY IT IS NOT THE ESSURE. ACCORDING TO HER, IT TOOK HER DOCTOR ALMOST 2 YEARS OF CONSTANT PAIN AND SEVERAL DOCTOR APPOINTMENTS TO BE CONVINCED THAT HER SYMPTOMS WERE DUE TO ESSURE AND HAD IT REMOVED. IN ADDITION, CONSUMER REPORTED HOT FLASHES, MOOD SWINGS, IRRITABILITY, NIGHT SWEATS AND STATES THAT IT CAUSED HER TO GO INTO EARLY MENOPAUSE AND COULD CAUSE DEPRESSION. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 29-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW

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TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT PELVIC PAIN (CONSTANT PAIN/ A LOTS OF PAIN). THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER HAD CONSTANT PAIN FOR 2 YEARS AND THEN HAD IT REMOVED. CONSIDERING IMPLIED TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS INFORMED ESSURE REMOVAL WAS REQUIRED, THEREFORE THIS CASE WAS UPGRADED TO INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01433	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# DOH-MW5031603) IN UNITED STATES ON 16-OCT-2013 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED IRREGULAR BLEEDING, CRAMPING, NAUSEA, HEADACHES, AND BACK PAIN. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2007 THE CONSUMER HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATES THAT, EVER SINCE SHE HAS HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2007, SHE HAS HAD PROBLEMS WITH IRREGULAR BLEEDING, CRAMPING, NAUSEA, HEADACHES, AND BACK PAIN. REPORTER CAUSALITY WAS NOT REPORTED. INTERNAL CORRECTION ON 28-OCT-2013: UPON INTERNAL REVIEW ON 28-OCT-2013 FROM INITIAL SOURCE DOCUMENT, RECEIVED ON 16-OCT-2013, THE CASE CATEGORY WAS CHANGED FROM NON-INCIDENT TO INCIDENT. 11-NOV-2013: AFTER AN INTERNAL REVIEW, THE INCIDENT CATEGORY WAS CHANGED TO NON-INCIDENT. FOLLOW UP 17-DEC-2013: NO RESPONSE. NO NEW INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 17-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1614). CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN 2007 AND STATES THAT, AROUND 2010, HER PROBLEMS BEGAN. SHE STRUGGLED WITH TERRIBLE ABDOMINAL PAIN, NAUSEA AND SEVERE BLEEDING. SHE HAS SEEN 3 DIFFERENT OBSTETRICIANS/GYNECOLOGISTS TO TRY AND TREAT HER SYMPTOMS. SHE TRIED SEVERAL DIFFERENT MEDICATIONS AND NONE HELPED. ACCORDING TO HER, SHE HAS HAD 4 ESSURE RELATED SURGERIES. THE FIRST WAS DONE AFTER AN ULTRASOUND SHOWED ONE OF HER ESSURE COILS HAD MIGRATED INTO HER UTERUS. HER PHYSICIAN TRIED TO

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REMOVE THE COIL; HOWEVER IT HAD EMBEDDED ITSELF INTO HER UTERINE LINING. SHE HAD TO CUT IT AND LEAVE A PIECE THERE AS IT WOULD HAVE CAUSED TOO MUCH DAMAGE FOR HER TO PULL IT OUT. SECOND SURGERY CONSISTED OF AN ABLATION TO TRY AND HELP HER SYMPTOMS. AGAIN NO IMPROVEMENT OCCURRED. SHE THEN HAD A HYSTEROSALPINGOGRAM WHICH SHOWED A PIECE OF THE REMAINING COIL AND THE FULL UNTOUCHED COIL, HOWEVER THE RADIOLOGIST COULD NOT DETERMINE THE ACTUAL LOCATION. THIRD SURGERY WAS A TOTAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY, WHICH ALSO TURNED INTO A UNILATERAL OOPHORECTOMY DUE TO A COMPLICATION DURING SURGERY. APPROXIMATELY 10 DAYS AFTER HER THIRD SURGERY, SHE WAS RUSHED TO THE EMERGENCY ROOM AND HAD HER FOURTH SURGERY WHICH WAS AN EXPLORATORY LAPAROTOMY TO REPAIR A PERFORATED BOWEL. FOLLOWED BY A 5 DAY HOSPITAL ADMISSION AND, SINCE THEN, SHE HAS A TON OF PROBLEMS WITH CONTINUED ABDOMINAL PAIN AND PROBLEMS WITH HER BOWELS. CONSUMER ALSO REPORTED THAT SHE IS NEXT SCHEDULED TO SEE A GASTRO-INTESTINAL SPECIALIST AT THE END OF THE MONTH ((B)(6) 2015). IN ADDITION, ACCORDING TO PATHOLOGY REPORT, HER RIGHT AND LEFT FALLOPIAN TUBES HAD NO SIGNIFICANT PATHOLOGICAL ABNORMALITIES. CONSUMER ALSO INFORMS THAT ESSURE COILS WERE NOT MENTIONED ON THE PATHOLOGY REPORT FROM HYSTERECTOMY AND NEITHER IN THE OPERATION NOTES. CONSUMER WONDERS WHETHER COILS WERE TAKEN OUT DURING SURGERY OR IF THEY ARE FLOATING AROUND INSIDE HER SOMEWHERE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 04-NOV-2015: PTC GLOBAL NUMBER IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NAUSEA, HEADACHES, BACK PAIN, IRREGULAR BLEEDING / SEVERE BLEEDING (SEEN AS GENITAL BLEEDING), CRAMPING / TERRIBLE ABDOMINAL PAIN. CONSUMER UNDERWENT 4 ESSURE RELATED SURGERIES. THE FIRST WAS DOWN AFTER NA ULTRASOUND SHOWED ONE OF HER ESSURE COILS HAD MIGRATED INTO HER UTERUS. HER PHYSICIAN TRIED TO REMOVE THE COIL, HOWEVER IT HAD EMBEDDED ITSELF INTO HER UTERINE LINING. A HYSTEROSALPINGOGRAM WAS PERFORMED, BUT THE RADIOLOGIST COULD NOT DETERMINE THE ACTUAL ESSURE LOCATION (SEEN AS DEVICE DISLOCATION). THE THIRD SURGERY (TOTAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY) WAS PERFORMED, WHICH ALSO TURNED INTO A UNILATERAL OOPHORECTOMY DUE TO COMPLICATION DURING ESSURE DEVICE REMOVAL SURGERY AND AFTER THAT SHE UNDERWENT AN EXPLORATORY LAPAROTOMY TO REPAIR A PERFORATED BOWEL. ALL THESE EVENTS WERE CONSIDERED SERIOUS. ONLY THE EVENT UNILATERAL OOPHORECTOMY WAS CONSIDERED UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE OTHER EVENTS ARE LISTED. IN THIS CASE, THE EXACT DATE AND MECHANISM OF EMBEDDED DEVICE AND DEVICE DISLOCATION ARE NOT KNOWN. CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP BETWEEN THE EVENTS AND SUSPECT INSERT AND GIVEN THEIR NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED, EXCEPT FOR UNILATERAL OOPHORECTOMY WHICH WAS CONSIDERED AS NOT ASSESSABLE SINCE THE EXACT REASON WAS NOT PROVIDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY,

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NON-SERIOUS EVENTS WERE PERFORMED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01436	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1975, AWARENESS DATE 17-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. CONSUMER WAS IMPLANTED WITH ESSURE IN 2014 AND STARTED HAVING ISSUES RIGHT AWAY, ONE OF THE COILS WAS NOT INSERTED PROPERLY WHICH CAUSED MAJOR PAIN AND DISCOMFORT SO SHE WAS SCHEDULED FOR A SECOND SURGERY TO HAVE THE LEFT TUBE REMOVED WHERE THE COIL WAS INSERTED IMPROPERLY. WHEN SHE WOKE FROM SURGERY THEY SAID THE COIL COULDN'T BE LOCATED SO THEY BURNT BOTH HER TUBES INSTEAD. AFTER A FEW MONTHS OF CRAMPING, SEVERE PELVIC PAIN, DISCOMFORT, HORRIBLE PERIODS LASTING 55 DAYS LONG, SHE WENT TO A DIFFERENT DOCTOR FOR A SECOND OPINION. SHE IS (B)(6) AND TOO YOUNG TO CONSIDER HAVING A HYSTERECTOMY, SO SHE DECIDED TO TRY THE ABLATION. IT HAS HELPED HER WITH PERIODS BUT SHE STILL SUFFERS EVERYDAY FROM CRAMPING, SEVERE PELVIC PAIN AND DISCOMFORT, NO SEX DRIVE, LACK OF ENERGY, AND RANDOM RASHES. THE COIL IS SOMEWHERE OUTSIDE OF TUBE IN THE TISSUE BETWEEN TUBE AND UTERUS BY HER OVARY. FOLLOW-UP RECEIVED ON 04-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INVESTIGATION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT

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OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HORRIBLE PERIODS LASTING 55 DAYS LONG AND AN ABLATION WAS DONE. IT WAS REPORTED THAT ONE OF THE COILS WAS NOT INSERTED PROPERLY. THE COIL COULDN'T BE LOCATED SO THEY BURNT BOTH TUBES INSTEAD. THE COIL IS SOMEWHERE OUTSIDE OF TUBE IN THE TISSUE BETWEEN TUBE AND UTERUS (SEEN AS DEVICE DISLOCATION). A SURGERY IN ORDER TO REMOVE LEFT TUBE WAS PERFORMED. BOTH EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF DEVICE DISLOCATION ARE NOT KNOWN. CONSUMER EXPERIENCED HORRIBLE PERIODS A FEW MONTHS AFTER ESSURE INSERTION. CONSIDERING THE NATURE OF THE EVENTS AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01438	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1645, AWARENESS DATE 19-OCT-2015). IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. THE CONSUMER IS A MOTHER OF THREE. SHE REPORTED THE FOLLOWING LIST OF PROCEDURES AND SURGERIES NEEDED SINCE ESSURE PLACEMENT AND THE DIAGNOSIS RECEIVED: 2009- BRAIN MRL FOR MIGRAINES. 2010- MRI CERVICAL SPINE, NERVE CONDUCTION TESTS, TRIGGER POINT INJECTIONS, THYROID ULTRASOUNDS, THYROID FNAS, PARTIAL THYROIDECTOMY FOR BILATERAL CERVICAL RADICULOPATHY, MONONEUROPATHY, THYROID HURTHLE CELL CANCER, NODULES, HYPOTHYROIDISM. 2011 - BILATERAL CARPAL TUNNEL SURGERIES FOR CARPAL TUNNEL SYNDROME; NOVASURE FOR HEAVY MENSES. 2012 - THYROID ULTRASOUNDS & FNA'S, EMERGENCY EYE VISIT FOR BILATERAL SWOLLEN CORNEAS 2013-THYROID ULTRASOUNDS 2014 -THYROID ULTRASOUNDS, EEG, RHEUMATOLOGY LAB WORK, BILATERAL KNEE ORTHOVISC FOR FIBROMYALGIA, SJOGRENS SYNDROME, HEMIPLEGIC MIGRAINES AND BILATERAL KNEE OSTEOARTHRITIS. 2015 -THYROID ULTRASOUNDS & FNAS. VITAMINS D & B12 DEFICIENT AND BILATERAL KNEE SYNVISC. MORTONS NEUROMA. SHE STATED BEFORE ESSURE SHE WAS ONLY SEEING A GENERAL PRACTITIONER AND A CARDIOLOGIST FOR HER MITRAL VALVE PROLAPSE AND A FEW DOCTORS FOR HER SCOLIOSIS AND BACK PAIN. AFTER ESSURE HER LIST OF DOCTORS AND SPECIALISTS GREW AND SO DID HER DIAGNOSIS LIST. AFTER ESSURE, SHE OFTEN THOUGHT THAT PROCEDURE WAS LINKED TO HER FAILING HEALTH, UNTIL RECENTLY SHE DISCOVERED WOMEN WITH THE SAME PROBLEMS: JOINT PAIN, AUTOIMMUNE DISORDERS, THYROID MALFUNCTION AND MIGRAINES. THE CONSUMER WANTED THE DEVICES REMOVED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY

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CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HEAVY MENSES. SHE UNDERWENT A NOVASURE PROCEDURE 3 YEARS AFTER ESSURE INSERTION. THYROID HURTHLE CELL CANCER AND SJOGRENS SYNDROME WERE ALSO REPORTED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. HEAVY MESES IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENTS ARE UNLISTED. AFTER ESSURE INSERTION MENSES PATTERN CHANGES MAY OCCUR. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. THE EXACT TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND EVENT ONSET WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THIS EVENT A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. EVENTS THYROID HURTHLE CELL CANCER AND SJOGRENS SYNDROME WERE ASSESSED AS UNRELATED TO ESSURE, GIVEN THEIR PATHOPHYSIOLOGY AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 07-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01439	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1866, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. THE REPORTER STATED THAT HER DAUGHTER HAD ESSURE INSERTED AND SHE LOST HER THYROID DUE TO THE INFLAMMATION RESPONSE. IN ONE YEAR HER THYROID TRIPLED IN SIZE; THIS CONDITION WAS COMPROMISING HER AIRWAY AND CAUSING A CHOKING HAZARD WHILE EATING. ESSURE ALSO CAUSED HER TO HAVE A HEMORRHAGING PERIOD THAT LASTED 4 MONTHS, ONLY STOPPED BY SURGICAL INTERVENTION. LASTLY ESSURE CAUSED CHRONIC AND SEVERE PAIN TO THE POINT OF HER NOT BEING ABLE TO WORK AND EVENTUALLY HAVING ESSURE REMOVED, BUT IT WAS NOT THAT EASY TO REMOVE, SHE REQUIRED A HYSTERECTOMY AT A MAJOR UNIVERSITY HOSPITAL. THE REPORTER STATED SHE IS FOREVER ALTERED BY ESSURE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HEMORRHAGING PERIOD THAT LASTED 4 MONTHS (INTERPRETED AS MENORRHAGIA) AND ONLY STOPPED AFTER AN UNSPECIFIED SURGICAL INTERVENTION. SHE HAD CHRONIC SEVERE PAIN (INTERPRETED AS PELVIC PAIN) AND HAD ESSURE REMOVED VIA HYSTERECTOMY. IT WAS ALSO REPORTED THAT SHE LOST HER THYROID DUE TO THE INFLAMMATION RESPONSE. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR LOST HER THYROID DUE TO THE INFLAMMATION RESPONSE WHICH IS UNLISTED. AFTER ESSURE INSERTION PELVIC PAIN AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE EVENTS HEMORRHAGING PERIOD THAT

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LASTED 4 MONTHS AND CHRONIC SEVERE PAIN, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. CONSIDERING THE PATHOPHYSIOLOGY OF THE EVENT LOST HER THYROID DUE TO THE INFLAMMATION RESPONSE AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED AND A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 06-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01441	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1926, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. CONSUMER REPORTED THAT IMMEDIATELY AFTER INSERTION SHE STARTED TO HAVE HEADACHES, BUT NOT NORMAL HEADACHES, ONES THAT SENT HER TO THE HOSPITAL IN NUMEROUS OCCASION AND HER EYES WOULD BLUR OVER AND IT FELT LIKE SOMEONE WAS STABBING HER. SHE WENT TO NEUROLOGISTS, HAD MAGNETIC RESONANCE IMAGING, COMPUTED TOMAGRAPHIES AND NO ONE COULD TELL WHAT WAS WRONG WITH HER. SHE ALSO HAD ABNORMAL PERIODS, CONSTANTLY BLOATED REGARDLESS OF WHAT SHE DID OR EAT, VITAM D DEFICIENCY, HER HORMONAL LEVELS WERE NOT NORMAL AND SHE HAD AN OBSCENE AMOUNT OF VAGINAL INFECTIONS - BACTERIAL VAGINOSIS, MULTIPLE TIMES A YEAR. SHE WAS HAVING HER TUBES AND PART OF HER UTERUS REMOVED IN (B)(6) 2015. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABNORMAL PERIODS AND HEADACHES. ACCORDING TO HER, SHE WAS HAVING HER TUBES AND PART OF HER UTERUS REMOVED IN 10 DAYS (FOLLOWING THIS REPORT). THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING ABNORMAL PERIODS NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED HEADACHES; ALTHOUGH ESSURE HAS ONLY A LOCAL ACTION IN FALLOPIAN TUBES; CONSUMER STATED

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THIS EVENT STARTED IMMEDIATELY AFTER DEVICE INSERTION AND NO ALTERNATIVE EXPLANATION WAS FOUND (SHE CONSULTED NEUROLOGISTS AND HAD MRI, CT). THUS; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE TOTALLY RULED OUT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WILL BE REQUIRED (INTERVENTION IS SCHEDULED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 06-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01442	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1908 AND FDA-2014-N-0736-1910, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER EXPERIENCED THE WORST MENSTRUAL PROBLEMS. SHE WENT FOR AN INTERNAL ULTRASOUND BECAUSE OF COMPLICATIONS AND PHYSICIANS ARE CONSIDERING TO REMOVE HER TUBES. SHE WAS SUFFERING SEVERE PAIN. SHE EXPERIENCED HORRIBLE PAINFUL PERIODS, EVERY 2 WEEKS SHE GETS HORRIBLE PAIN DOWN THERE AND THE LAST THREE MONTHS SHE WAS GETTING HER PERIODS EVERY 2 WEEKS OR SO. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN (SEEN AS ABDOMINAL PAIN) AND EVERY 2 WEEKS SHE GOT HORRIBLE PAIN DOWN THERE (SEEN AS PELVIC PAIN). THE PHYSICIANS WERE CONSIDERING TO REMOVE HER TUBE. THESE EVENTS ARE SERIOUS BASED ON MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THE NATURE OF THESE EVENTS AND CONSIDERING THAT ABDOMINAL / PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 06-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01468	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1684, AWARENESS DATE 19-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 AFTER THE BIRTH OF HER DAUGHTER. CONSUMER REPORTED THAT SHE EXPERIENCED EXCRUCIATING PELVIC PAIN THAT TRAVELLED INTO HER LEGS, MEMORY LOSS, BLOATING, NAUSEA, SEVERE WEAKNESS AND FATIGUE. ON (B)(6) 2015 SHE HAD HER REPRODUCTIVE ORGANS REMOVED. ESSURE HAD SHREDDED HER FALLOPIAN TUBES, PUNCTURED HER UTERUS AND CAUSED HER ENDOMETRIOSIS COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE HAD SHREDDED HER FALLOPIAN TUBES AND PUNCTURED HER UTERUS. AROUND 4 YEARS AFTER INSERTION, SHE HAD HER REPRODUCTIVE ORGANS REMOVED. THESE EVENTS, INTERPRETED RESPECTIVELY AS FALLOPIAN TUBE INJURY AND UTERINE PERFORATION ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 07-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01469	BAYER HEALTHCARE LLC	11/12/2015	11/12/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1550, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. CONSUMER STATED SHE WAS STRUGGLING TO HAVE HER TUBES REMOVED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT SHE WAS STRUGGLING TO HAVE HER TUBES REMOVED. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR THIS PLANNED PROCEDURE WAS NOT SPECIFIED; COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 07-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057786	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 7/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE MIGRAINES; INCREASED MENSTRUAL FLOW REQUIRING SUPER PLUS TAMPONS CHANGED EVERY HOUR ON THE SECOND AND THIRD DAYS; IRREGULAR MENSTRUAL CYCLES; SEVERE CRAMPING; FATIGUE (DOESN'T GET BETTER WITH REST); BRAIN FOG; FORGETFULNESS; WEIGHT GAIN AND UNABLE TO LOSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057788	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 5/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THEY DAY I HAD ESSURE IMPLANTED I IMMEDIATELY STARTED EXPERIENCING SHARP PELVIC PAIN (WHICH HAS NOT GONE AWAY 6 MONTHS LATER) HEAVY BLEEDING, PAINFUL PERIODS, HEADACHES, LOSS OF LIBIDO, SEVERE BLOATING, AND PAINFUL INTERCOURSE. I AM GETTING A HYSTERECTOMY (B)(6) TO HAVE THE COILS REMOVED. I AM (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057789	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 9/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONSET OF SUDDEN CHRONIC LOWER BACK PAIN. STABBING FEELING IN LOWER LEFT ABDOMINAL AREA. BRAIN FOG, MIGRAINES, BLURRED VISION, NAUSEA. HAVE BEGUN LACTATION AND AM NOT PREGNANT OR CURRENTLY BREASTFEEDING. EXTREMELY TIRED ALL THE TIME. HAIR LOSS IN CHUNKS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057790	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 7/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, BLOATING FATIGUE RASHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057791	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD ANDAMP; STILL HAVE SEVERE PELVIC PAIN, HAIR LOSS, RASH, THYROID ISSUES, JOINT PAIN, CHRONIC FATIGUE, DEPRESSION ANDAMP; ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057792	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 5/27/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PAIN, MIGRAINES, JOINT PAIN AND FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057793	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 5/15/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK ACHES, HEADACHES, TEETH CHIPPING, TIRED ALL THE TIME, MILD DEPRESSION, UNCOMFORTABLE IN PELVIC AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057794	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 10/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SIDE EFFECTS: THE FIRST THING I NOTICED (WITHIN A MONTH) WAS MY HAIR STARTED FALLING OUT IN MASSIVE AMOUNTS. OTHER SIDE EFFECTS I HAD WERE EXTREME FATIGUE, LOW SEX DRIVE, WEIGHT GAIN, SHORT TERM MEMORY LOSS, TEETH CHIPPING, STOMACH FLUTTERS (LIKE WHEN YOU ARE PREGNANT), SHARP PAINS(THAT WERE WORSE AT FIRST, BUT SINCE HAVE GOTTEN BETTER, HARD TIME SLEEPING AT NIGHT, SLIGHT DEPRESSION AND ANXIETY (WHICH I NEVER HAD BEFORE) AND MOODINESS. THEN I STARTED GETTING NIGHT SWEATS AND HOT FLASHES. THEY DID SOME TESTS AND PUT ME ON ESTROGEN, PROGESTERONE, AND THYROID MEDS. THOSE SYMPTOMS HAVE GOTTEN BETTER AFTER I WAS PUT ON HORMONES. FOR THE LAST YEAR, MY CYCLE HAS BEEN CRAZY AND THE LAST FEW MONTHS, I BLED FOR 2 WEEKS, THEN NOTHING FOR A WEEK AND IT WILL START AGAIN. THEY KEEP CHANGING MY ESTROGEN AND PROGESTERONE DOSES BUT IT ISN'T HELPING. NOW I'M NOTICING THE FEELING LIKE SOMETHING IS CRAWLING ON ME, BUT WHEN I LOOK NOTHING IS THERE. I READ SOMEWHERE THAT A CHANGE IN HORMONES CAN CAUSE THAT. I AM WONDERING IF MY CHANGE IN MEDS HAS MADE THAT WORSE. I AM CONCERNED ABOUT ALL OF THE SIDE EFFECTS, BUT MOSTLY ABOUT THE MIGRATED COIL. I HAS PRESSURE PLACED, A TUBAL LIGATION BECAUSE ONE COIL MIGRATED AND MOST RECENTLY HAD A TOTAL HYSTERECTOMY BECAUSE OF ALL THE SIDE EFFECTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057795	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 6/6/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, ACNE, HEAVY PERIOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057796	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 6/14/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABOUT A YEAR AFTER MY IMPLANTS WERE PUT IN (MAY HAVE BEEN SOONER, I DON'T REMEMBER THE EXACT DATE THEY WERE IMPLANTED - JUST KNOW IT WAS IN 2004 SOMETIME.) I BEGAN TO EXPERIENCE SERIOUS HEADACHES, AS WELL AS BACK PAIN AND PAINFUL PERIODS. EVENTUALLY I BEGAN TO GAIN A CONSIDERABLE AMOUNT OF WEIGHT, AND BEGAN TO SUFFER FROM SERIOUS JOINT PAIN IN MY KNEES. THAT PAIN LEFT ME UNABLE TO GO UP AND DOWN STAIRS NORMALLY, I BEGAN TO HAVE SO MUCH PAIN I WOULD HAVE TO GO DOWN THEM ONE AT A TIME. I HAVE SUFFERED FROM MEMORY LOSS AND BLURRED VISION, AS WELL AS MY LEGS AND ARMS GOING NUMB. WHEN MY LEGS GO NUMB I CAN HARDLY STAND OR WALK. I HAVE ALSO DEVELOPED A FEW SMALL STRANGE CYSTS, AS WELL AS SOME STRANGE TUMOR I HAD REMOVED FROM MY BACK. MY BODY HURTS ALL OVER, WHEN I SLEEP I NEVER FEEL RESTED, I AM TIRED WHEN I GO TO BED, AND TIRED WHEN I AWAKE. I FEEL LIKE I AM OLD AND DYING, AND I AM ONLY (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057797	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, PLAQUE PSORIASIS, FOOD SENSITIVITIES, IRRITABILITY, EAR ITCHING AND DRAINING, THOUGHTS OF SUICIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057798	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 4/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, BRAIN FOG, ANXIETY, PANIC ATTACKS, LACK OF CONCENTRATION, SEVERE BLOATING, JOINT PAIN, ANGER, AGITATION, DEPRESSION, HEAVY PERIODS WITH CLOTS, WEIGHT GAIN, MEMORY LOSS, LOSS OF SEX DRIVE, PAINFUL INTERCOURSE, HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057799	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 1/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, ABDOMINAL PAIN, INTERNAL MOVEMENT, STOMACH PAIN, BACK PAIN HEAVY BLEEDING, HIVES/RASHES, MEMORY AND AMP; ENERGY LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057800	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 3/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SO I WAS IMPLANTED (B)(6) 2015. EVER SINCE HAVING THE PROCEDURE MY PERIODS HAVE NEVER BEEN THE SAME. I NOW DEAL WITH MAJOR BLEEDING WITH BLOOD CLOTS AND THE CRAMPS ARE UNBEARABLE. NOT TO MENTION THE RANDOM TIMES YOUR BODY DECIDES TO SPOT. SEX WOULD BE MY SECOND COMPLAINT. SEX HAS NOT BEEN THE SAME SINCE THE PROCEDURE AND I'M AFRAID IT NEVER WILL BE. THE PAIN I FEEL DURING SEX IS EXCRUCIATING AND IF THAT'S NOT ENOUGH THE WHAT FEELS LIKE LABOR PAINS AFTER SEX CAUSED BY THE INFLAMMATION OF THE PET FIBERS FEEL JUST AS BAD. I ALSO PASS AIR VAGINALLY AND I AIN'T TALKING ABOUT QUEEFING. THIS DEVICE HAS PUT A BIG TOLL ON MY RELATIONSHIP DUE TO THE ABOVE COMMENTS. I HAVE STRUGGLED WITH DEPRESSION SOME SINCE HAVING ESSURE IMPLANTED. I NOW HAVE ANXIETY WONDERING IF I'M PREGNANT OR NEXT TO BECOME PREGNANT. I GET PELVIC PAINS ON MY LEFT SIDE AND THROUGHOUT THE BODY WHICH I'M SURE IS WHERE THE SYSTEMATICALLY COMES IN. THE BLOATING THAT CAUSES US ALL TO LOOK (B)(6). NO WHERE IN THE PAMPHLET DID IT SAY ANYTHING ABOUT THE COILS BE ABLE TO MIGRATE LEAVING TUBES OPEN FOR PREGNANCY. I NOW HAVE NIGHT SWEATS LIKE MENOPAUSE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057801	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME ABDOMINAL PAIN IN THE FALLOPIAN TUBE OVARY AREA. DAILY PAIN. EXCESSIVE BLEEDING DURING MENSTRUATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057829	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MANY, MANY SIDE EFFECTS: BRAIN FOG, FORGETFULNESS/MEMORY ISSUES, ITCHY REOCCURRING BUMPS, HAIR LOSS, ANXIETY, JOINT PAIN, SEVERE FATIGUE, DIGESTIVE ISSUES, GALL BLADDER REMOVAL, HYSTERECTOMY AND OTHERS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057830	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, IRREGULAR BLEEDING AND LOWER BELLY BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057831	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 11/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ELEVATED WBC AND CRP DUE TO INFLAMMATION. UTERUS IS ABNORMALLY LARGE DUE TO ESSURE WHICH NOW REQUIRES A HYSTERECTOMY . THIS IS ALL ON TOP OF HORRIBLE ABD PAIN, HEADACHES AND NUMBNESS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057832	BAYER	11/12/2015	11/12/2015

Event Information:

Event Date (B3): 8/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED NOTICING ITCHING AND RACHES ETC THROUGHOUT YEARS WAY TO MANY SIDE EFFECTS TO LIST PLENTY OF ER VISITS ETC..NO ONE CAN HELP ME. NOW AT EARLY AGE BEEN DIAGNOSED WITH RA SEVERELY ILL WITH A HUGE LIST OF SYMPTOMS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057947	BAYER	11/12/2015	11/19/2015

Event Information:

Event Date (B3): 11/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/11/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE BIRTH CONTROL IMPLANTED I 2012. RECENTLY I STARTED HAVING ABDOMINAL PAIN, HAVE BEEN TO ER 3 TIMES. WENT BACK TO SEE OBGYN, HE DETERMINED THE LEFT COIL IS NOW MISSING AND THE RIGHT COIL HAS MOVED AND IS STABBING ME. HE HAS TO DO SURGERY TO REMOVE BOTH MY TUBES AND LOOK THROUGHOUT ENTIRE PELVIS FOR MISSING COIL. IF HE FINDS IT, MAY HAVE TO DO FULL HYSTERECTOMY. DO NOT KNOW HOW THEY MIGRATED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01434	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 9/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0280, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED. CONSUMER REPORTED THAT SHE WAS NOT THE SAME PERSON SHE WAS BEFORE ESSURE AND HER LIFE AND BODY CHANGED AFTER 2012. SHE DIDN'T WANTED A TUBAL LIGATION, SO AFTER SHE WENT TO THE OUTPATIENT PART OF THE OFFICE SHE WAS PUT TO SLEEP AND WOKE IN RECOVERY ROOM LAYING IN SHEETS THAT WERE SOAKED WITH BLOOD AND GREEN STUFF. SHE HAD EXTREME BLOATING, EXTREME HAIR LOSS, CHRONIC PELVIC PAIN, TEETH DECAYING, MOOD SWINGS, BREAK OUT IN BUMPS, HER PIERCING ALL GOT INFECTED AND COULD NO LONGER WEAR EARRINGS DUE TO SHE WAS ALLERGIC TO NICKEL WHICH SHE HAD NO IDEA ESSURE HAD NICKEL IN IT, EXTREME WAIT GAIN OVER 65LBS AND HER PERIODS WERE SO BAD SHE COULD NOT LEAVE HER HOUSE FOR THE FIRST 2 DAYS AND SHE ALSO HAD CRAMPS, HURT TO WALK TO SIT TO LAY DOWN TO PLAY TO BEND TO COOK TO ANYTHING. SHE WOULD HAD TO HAVE A HYSTERECTOMY TO REMOVE ESSURE. NO ADDITIONAL DETAILS WERE PROVIDED. TECHNICAL ANALYSIS RECEIVED ON 14-SEP-2015: PTC GLOBAL NUMBER: (B)(4). TECHNICAL ASSESSMENT SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL

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FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UPS IDENTIFIED ON 17-OCT-2015 AND 19-OCT-2015 (UPGRADED TO INCIDENT): THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1612, AND FDA-2014-N-0736-1948). CONSUMER REPORTED THAT SHE IS A WOMAN WHO HAS BEEN HEALTHY NEVER HAD ANY SURGERIES AND SHE IS 43 YEARS OLD. SHE HAD ESSURE PLACED IN 2012 AND A MONTH LATER SHE NOTICED SHE HAD A LUMP IN HER THROAT AREA AND AS THE MONTHS WENT BY IT GOT BIGGER AND BIGGER, FINALLY SHE KNEW SOMETHING IS WRONG. SHE THEN WENT TO A SPECIALIST AND HE TOLD HER SHE HAS AN ABNORMAL LIPNOID AND HAD THROAT SURGERY 1 WEEK LATER AND NOW SHE HAS A HORRIFIC SCAR ON HER THROAT. SINCE THEN A LIST OF PROBLEMS SINCE ESSURE BEING IMPLANTED: WEIGHT GAIN 65 LBS, HAIR THINNING FALLING OUT (LOST HAIR), ANXIETY, OUT OF CONTROL CHRONIC PAIN EVERYWHERE, BUT MOSTLY PELVIC AREA PAIN WHILE HAVING SEX POKING AND PINCHING, LOST SEX DRIVE, TATTOOS FLARED AND SHE WAS VERY BLOATED. A MONTH AFTER INSERTION, SHE LOOKED LIKE SHE WAS 4 MONTHS PREGNANT AND THEN 12 MONTHS PREGNANT. SHE COULD NOT GET OUT OF BED, SHE HAD NO DESIRE TO AND HER BLEEDING WHILE ON MENSTRUATION WAS HORRIBLE (PERIODS HORRIBLE). SHE JUST WANTED TO DIE AND THE LIST GOES ON. SHE COULD NOT WEAR EARRINGS AND SHE HAS DEPRESSION. ESSURE GAVE HER ENDOMETRIOSIS. SHE HAD A HYSTERECTOMY ON (B)(6) 2015 AND SHE IS DOWN 17 LBS, THE BLOATING HAS GONE AWAY, TONS OF SIDE EFFECTS WENT AWAY WHEN HER DOCTOR REMOVED THAT HORRID DEVICE FROM HER BODY. THE REASON WHY SHE DECIDED ON ESSURE WAS BECAUSE SHE DID NOT WANT TO BE CUT. ESSURE WAS SUPPOSED TO BE NON INVASIVE AND IT WAS NOT. SHE WAS PUT TO SLEEP AND WOKE UP IN A BED FULL OF GREEN STUFF AND BLOOD AND NOW HER WORST NIGHTMARE CAME TRUE: SHE HAD TO HAVE A HYSTERECTOMY TO REMOVE THESE DEVICES FROM HER BODY. PRODUCT TECHNICAL COMPLAINT ANALYSIS RECEIVED ON 04-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE WAS PUT TO SLEEP AND WOKE IN RECOVERY ROOM LAYING IN SHEETS THAT WERE SOAKED IN BLOOD AND GREEN STUFF (INTERPRETED AS POST PROCEDURAL HAEMORRHAGE). A MONTH AFTER INSERTION, SHE NOTICED A LUMP IN HER THROAT, AN ABNORMAL LIPNOID (INTERPRETED AS PHARYNGEAL MASS) AND HAD A THROAT SURGERY. SHE ALSO HAD CHRONIC PELVIC PAIN. SHE HAD A HYSTERECTOMY APPROXIMATELY 3 YEARS AFTER ESSURE INSERTION. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE POST PROCEDURAL HAEMORRHAGE AND CHRONIC PAIN ARE LISTED WHILE THE PHARYNGEAL MASS IS UNLISTED. CONSIDERING THE NATURE OF POST PROCEDURAL HEMORRHAGES AND CHRONIC PAIN AND THE SUGGESTIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. IN CONTRAST, CONSIDERING THAT THE LUMP WAS DIAGNOSED A MONTH

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AFTER INSERTION, THE TEMPORAL RELATIONSHIP IS CONSIDERED INCOMPATIBLE. IN ADDITION, ESSURE HAS A LOCALIZED ACTION IN THE FALLOPIAN TUBES AND IT IS UNLIKELY THAT IT WOULD CAUSE THIS EVENT. THEREFORE, THE PHARYNGEAL MASS IS ASSESSED AS UNRELATED TO ESSURE THERAPY. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

CORRECTION 16-NOV-2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE PREVIOUS EVENT TERM "HORRIFIC SCAR ON HER THROAT" WAS RECODED TO MEDDRA LLT " PHARYNGEAL OPERATION". COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01435	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/2/2012
Explant Date (E7): 6/12/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 17-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6)-2012. THE NEXT DAY SHE GOT SICK. SHE THOUGHT IT WAS THE STOMACH FLU AND WENT TO THE HOSPITAL A WEEK LATER WITH ACUTE KIDNEY FAILURE. HER SYMPTOMS NEVER LEFT, SHE WAS ALWAYS SICK TO STOMACH, NEVER HAD ANY ENERGY; HER VITAMIN D LEVELS WERE ALWAYS VERY LOW. SHE FELT LIKE SHE HAD THE STOMACH FLU 24 HOURS A DAY 7 DAYS A WEEK. SHE HAD A HYSTERECTOMY ON (B)(6)-2015 AND EVERYTHING BUT HER OVARIES WAS TOOK. HER SYMPTOMS LEFT, THE NEXT DAY SHE HAD ENERGY, WAS NOT SICK AT ALL. HER LIFE WAS BACK TO NORMAL. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 04-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT

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PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD A HYSTERECTOMY 3 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE HAD ACUTE KIDNEY FAILURE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ONLY HYSTERECTOMY IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS CASE, THE EXACT ETIOLOGY OF ACUTE KIDNEY FAILURE WAS NOT SPECIFIED. HOWEVER; CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES, AND GIVEN KIDNEY FAILURE NATURE, CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED UNLIKELY. REGARDING THE REPORTED HYSTERECTOMY; IF AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED SICKNESS AND LACK OF ENERGY; HOWEVER THE MEDICAL REASON FOR HER HYSTERECTOMY WAS NOT PROVIDED. ALTHOUGH THIS CASE LACKS INFORMATION FOR A COMPREHENSIVE CAUSALITY ASSESSMENT, IT CANNOT BE EXCLUDED THAT THE REPORTED HYSTERECTOMY OCCURRED AS A CONSEQUENCE OF ESSURE THERAPY. THEREFORE THIS CASE WAS REGARDED AS INCIDENT. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01437	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): 2/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2008
Explant Date (E7): 12/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1798, AWARENESS DATE 17-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. SHE WAS GIVEN A VALIUM ABOUT 20 MINUTES BEFORE THE PROCEDURE. IN ADDITION TO THE PHYSICIAN AND THE NURSE, A REPRESENTATIVE FROM THE COMPANY WAS ALSO IN THE ROOM DURING THE PROCEDURE. THE IMPLANTATION ITSELF WAS EXTREMELY PAINFUL AND SHE WAS BEGGING HER TO STOP AS SHE WAS FINISHING THE LAST SIDE. SHE WAS SENT HOME WITH SOME IBUPROFEN. IMMEDIATELY FROM THAT DAY, A DULL ACHING PAIN IN ABDOMEN STARTED THAT DID NOT GO AWAY EVER OVER THE NEXT 5 YEARS. THIS PAIN ESCALATED TO EXCRUCIATING PAIN DURING PERIODS, SO BAD THAT SHE COULD NOT WALK. AFTER THE HYSTEROSALPINGOGRAM (HSG) IN (B)(6) 2008, SHE WAS DECLARED OCCLUDED AND CONFIRMED THAT THE COILS WERE PERFECTLY PLACED. SHE WAS STILL EXPERIENCING CONSTANT PAIN. IN 2009, SHE STARTED SUFFERING FROM EXTREME FATIGUE, RASHES, MONTHLY UTIS, AND RECURRING YEAST INFECTIONS. SHE WAS TESTED FOR EVERY STD THEY COULD THINK OF AND ALL RESULTS WERE NEGATIVE. SHE WAS TOLD PROBABLY HAD SOMETHING CALLED PID, WAS GAVE ANTIBIOTICS AND SENT OFF. SHE SAW THREE OTHER DOCTORS THAT YEAR AND WAS EVALUATED FOR CHRONIC FATIGUE SYNDROME, FOOD ALLERGIES OR INTOLERANCES, DEPRESSION AND LYME DISEASE. SHE HAD NONE OF THESE THINGS. SHE WAS FATIGUED, IN PAIN AND WEAK. IN 2010-2011, SHE WENT TO EMERGENCY ROOM (ER) MULTIPLE TIMES FROM A STABBING PAIN IN RIGHT ABDOMEN THAT WAS SO BAD SHE WOULD FALL ON THE GROUND WHEN IT HIT, ER DOCTORS KNEW NOTHING ABOUT ESSURE. AN MRI, ULTRASOUNDS, X-RAYS WERE PERFORMED AND SHE WAS TOLD

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EVERY TIME THAT THE ESSURE COILS WERE PERFECTLY PLACED AND THEREFORE IT COULD NOT BE ESSURE. BY 2012, SHE WAS HAVING REACTIONS TO ANYTHING METAL THAT TOUCHED HER BODY, ZIPPERS ON PANTS & HOODIES, EARRINGS, EVEN HER WEDDING RINGS MADE HER SWELL UP, ITCH AND RASH. HER HAIR BEGAN FALLING OUT IN DUMPS, SHE WAS SO TIRED AND IN PAIN ALL THE TIME THAT SPENT DAYS IN BED. SHE STARTED HAVING ABDOMINAL BLOATING. IT LOOKED LIKE SHE WENT FROM NOTHING TO 6 MONTHS PREGNANT OVER THE COURSE OF A DAY. BEING INTIMATE WITH HER HUSBAND WAS EXCRUCIATING. IN ADDITION TO PAINFUL SEX, HE WOULD GET AN ITCHY RASH ANYWHERE HER VAGINAL FLUIDS TOUCHED HIM. IN 2013, AS A RESULT OF ONE OF THE FEW TIMES THEY ACTUALLY DID MANAGE TO HAVE SEX, SHE BECAME PREGNANT. SHE MISCARRIED AT THE (B)(6) MARK. AGAIN, THE COILS WERE SAID TO BE PERFECTLY PLACE. TWO MONTHS LATER, SHE WAS LATE ON HER PERIOD; ANOTHER POSITIVE TEST SHE WAS PREGNANT AND HAD ANOTHER MISCARRIAGE. THIS ONE WAS ESTIMATED TO BE AT THE 8-9 WEEK MARK ((B)(4)). IN (B)(6) 2013, ESSURE WAS REMOVED, AND SHE HAD A TUBAL LIGATION PERFORMED. IMMEDIATELY AFTER REMOVAL, THE CONSTANT, DULL PAIN WAS GONE. THE BLOATING STOPPED. IN A MONTH, THE RASHES WERE GONE. HER HAIR STOPPED FALLING OUT, AND STARTED TO GROW BACK. SHE COULD WEAR JEWELRY AGAIN. AFTER REMOVAL, SHE WAS ABLE TO RUN AND CROSSFIT. PTC INVESTIGATION RESULT WAS RECEIVED ON 04-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMMEDIATELY AFTER THAT DAY A DULL ACHING PAIN IN ABDOMEN STARTED THAT DID NOT GO AWAY EVER OVER THE NEXT 5 YEARS (INTERPRETED AS ABDOMINAL PAIN). SEVERAL MONTHS AFTER INSERTION, THE PHYSICIAN SUSPECTED SHE COULD HAVE A PID. FIVE YEARS AFTER INSERTION, SHE BECAME PREGNANT ALTHOUGH THE HYSTEROSALPINGOGRAM HAD SHOWN THAT TUBES WERE OCCLUDED AND INSERTS WERE PERFECTLY PLACED. SHE MISCARRIED AT THE (B)(6) WEEK MARK AND WAS AGAIN TOLD THAT INSERTS WERE PERFECTLY PLACED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE ABDOMINAL PAIN, PID AND PREGNANCY WITH DEVICE ARE LISTED WHILE THE MISCARRIAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ABDOMINAL PAIN AND PREGNANCY WITH DEVICE WERE ASSESSED AS RELATED DUE TO THE NATURE OF THESE EVENTS, SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION. THE PID (PELVIC INFLAMMATORY DISEASE) WAS HOWEVER, ASSESSED AS UNRELATED SINCE THE ONSET OCCURRED SEVERAL MONTHS AFTER ESSURE PLACEMENT AND THEREFORE, THE TEMPORAL RELATIONSHIP WAS NOT COMPATIBLE. ALSO, CONSIDERING THAT THE ABORTION OCCURRED DURING THE FIRST (B)(6) WEEKS OF PREGNANCY AND THAT IN MOST OF THESE CASES, THE MISCARRIAGE IS DUE TO CHROMOSOME ABNORMALITIES OR GROSS MORPHOLOGICAL MALFORMATIONS, THE MISCARRIAGE IS ASSESSED AS UNRELATED TO ESSURE INSERTS. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE

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CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01440	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1665, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. CONSUMER REPORTED THAT AFTER ESSURE PROCEDURE SHE STARTED TO HAVE IRREGULAR BLEEDING AND PAIN WHEN SHE TRIED TO GET INTIMATE WITH HER HUSBAND, EXCESSIVE SWEATING, HEADACHES, BLOATING, URINE LEAKAGE, OCCASIONAL SHARP STABBING IN GROIN AREA AND WEIGHT GAIN. HER BLEEDING BECAME SO BAD THAT SHE HAD TO HAVE A HYSTERECTOMY IN (B)(6) 2014 AS WELL AS A BLADDER TUCK, HOWEVER SHE STILL HAS HER TUBES AND THE COILS, AND SHE STILL HAVE THE SAME SYMPTOMS EXCEPT FOR THE BLEEDING. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED TO HAVING IRREGULAR BLEEDING / BLEEDING BECAME SO BAD (INTERPRETED AS GENITAL BLEEDING). THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT AFTER ESSURE INSERTION PROCEDURE. IT WAS REPORTED THAT HER BLEEDING BECAME SO BAD THAT SHE HAD TO HAVE A HYSTERECTOMY PERFORMED, LEAVING HER TUBES AND ESSURE COILS. CONSIDERING THE NATURE OF THE EVENT AND THAT GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, ANOTHER SERIOUS EVENT (BLADDER TUCK, UNLISTED AND UNRELATED) AND NON-

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SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

-RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 06-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01443	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2012
Explant Date (E7): 11/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON 24-APR-2014 VIA AN INTERNET TRANSCRIPTION OF A TV EMISSION. THE REPORT REFERS TO THE REPORTING (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012, AFTER SHE HAD HAD HER THIRD CHILD, AND SHE EXPERIENCED A MYSTERIOUS PAIN, BASICALLY SHE COULD NOT LAY ON HER SIDE, HER STOMACH, HER BACK, IT HURT EVERYWHERE. THE CONSUMER WAS PART OF A GROUP OF SIX WOMEN WHO ALL SAID THEY SUFFERED DEBILITATING SIDE EFFECTS SOME (UNSPECIFIED WHO) SAID THEIR PAIN WAS SO SERIOUS, THEY HAD HYSTERECTOMIES. BUT, AT FIRST, THE WOMEN SAID THEIR DOCTORS DOWNPLAYED THE SYMPTOMS. IN SOME CASES (UNSPECIFIED WHO), TELLING THEM THE PAIN COULD NOT BE BECAUSE OF ESSURE. NO FURTHER DETAILS WERE REPORTED. FOLLOW-UP RECEIVED ON 18-OCT-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1476). CONSUMER REPORTED THAT WHEN SHE HAD ESSURE PLACED IN (B)(6) 2012, SHE WANTED A NON-SURGICAL APPROACH TO BIRTH CONTROL WITHOUT ADDING DAILY HORMONES TO HER BODY. CONSUMER STATES THAT SHE HAD A FOUR MONTH OLD BABY AT HOME AND A (B)(6) TODDLER ALONG WITH A (B)(6). HER DOCTOR ASSURED THAT HER REACTION TO NICKEL, WHEN SHE WAS A CHILD, WOULD NOT INTERFERE WITH ESSURE. ACCORDING TO CONSUMER, PHYSICIAN MADE IT SEEM LIKE NO BIG DEAL AND THAT SHE WOULD BE JUST FINE. CONSUMER SUFFERED HEADACHES, LOW BACK PAIN, CHRONIC YEAST INFECTIONS, MISCARRIAGE, JOINT PAIN, WEIGHT GAIN, BLOATING, HEAVY MENSTRUAL CYCLES, ANXIETY, IRRITABILITY AND STATES THAT SHE LOST THE PLAYING WITH CHILDREN. CONSUMER WAS NOT EVEN ABLE TO READ THEM BOOKS IN BED WITHOUT FEELING THE PAIN. THEN CAME A TIME

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WHERE SHE FELT LIKE A 100 YEAR OLD WOMAN GETTING OUT OF BED IN THE MORNING. AFTER HER MISCARRIAGE SHE SOUGHT A SECOND OPINION AND FOUND SOME ANSWERS AND SOMEONE WILLING TO HELP HER. IN (B)(6) 2013, CONSUMER HAD A PARTIAL HYSTERECTOMY TO REMOVE AN EMBEDDED COIL FROM HER UTERUS, HER TUBES AND MULTIPLE ADHESIONS WERE ALSO TAKEN DOWN. ALSO ACCORDING TO HER, ONE OF THE ADHESIONS ON HER LIVER WAS STARTING TO GET INFECTED. HER PERFORATED UTERUS WAS POISONING HER BODY. CONSUMER FELT LIKE A NEW WOMAN AFTER HEALING FROM HER SURGERY. HER FAMILY SAW THE REAL HER AGAIN AND HER BODY RETURNED TO ITS NORMAL WEIGHT WITHIN A COUPLE MONTHS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 05-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD A MISCARRIAGE AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SEVENTEEN MONTHS AFTER DEVICE PLACEMENT SHE WAS SUBMITTED TO A PARTIAL HYSTERECTOMY TO REMOVE AN EMBEDDED COIL FROM HER UTERUS (UTERUS WAS PERFORATED). ACCORDING TO HER, DURING THIS PROCEDURE ADHESIONS WERE REMOVED AND ONE OF THE ADHESIONS ON HER LIVER WAS STARTING TO GET INFECTED. ONLY UTERINE PERFORATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE INCLUDING FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED ABOUT HSG. CONSUMER STATED ONE ESSURE COIL WAS PERFORATED; THIS COULD BE AN ALTERNATIVE EXPLANATION FOR THE REPORTED DEVICE FAILURE (PREGNANCY). HOWEVER, SINCE ITS MECHANISM IS UNKNOWN (IF PERFORATION OCCURRED BEFORE OR AFTER PREGNANCY ONSET); CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE REPORTED MISCARRIAGE; CONSIDERING IT IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY, OCCURRING IN UP TO 20% OF CLINICALLY RECOGNIZED PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION DUE TO MATERNAL CONDITIONS AND FETAL CHROMOSOMAL ABNORMALITIES; CAUSALITY WITH ESSURE IS CONSIDERED UNLIKELY. THE SAME ASSESSMENT IS GIVEN FOR THE REPORTED LIVER ADHESIONS, SINCE ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, AS DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (SOCIAL MEDIA CASE).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01444	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1565, AWARENESS DATE 18-OCT-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012 WHEN IN FACT SHE HAD SIGNED FOR A TUBAL LIGATION. AS SOON AS PHYSICIAN PLACED THE FIRST ONE CONSUMER KNEW SOMETHING WAS NOT RIGHT. SHE CALLED THE DOCTOR THAT SAME DAY TO INFORM HIM OF THE PAIN SHE WAS HAVING. HE STATED IT COULD TAKE A COUPLE HOURS FOR THE PAIN TO FADE BECAUSE THE LEFT SIDE COIL DID NOT SPRING. EVERY DAY SHE CALLED BACK STATING THE PAIN SHE WAS STILL IN. MONTHS WENT BY WITH PAIN AND EXCESSIVE BLEEDING MONTHS STRAIGHT. BY (B)(6) (2013) SHE WAS CALLED FOR AN EMERGENCY PARTIAL HYSTERECTOMY, WHICH IT DID NOT STOP. THERE WERE MANY SURGERIES LATER, INCLUDING A FULL HYSTERECTOMY. SHE WAS DIAGNOSED WITH RA. SHE HAD 6 KIDS. SHE WENT FROM TAKING NO PILLS TO 20 A DAY AT TIME WITH PHYSICIANS TRYING TO MAKE HER COMFORTABLE. SHE HAS EXCESSIVE AMOUNT OF INFLAMMATION IN HER WHOLE BODY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 05-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: DEPLOYMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT OUTER COILS TO EXPAND FROM THE WOUND DOWN POSITION. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DEPLOYMENT: ROLLBACK TO INITIAL HARD STOP. DEPRESS BUTTON. PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES THE PROPER ESSURE PLACEMENT STEPS, THE RELEASE RIBBON SHOULD DISENGAGE FROM THE

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PLATINUM HALF BAND (WELDED ONTO OUTER COILS OF MICRO-INSERT). ONCE DISENGAGEMENT OCCURS, THE OUTER COILS SHOULD EXPAND. IF IT DOES NOT, THIS IS REFERRED TO DEPLOYMENT DIFFICULTY. SEVERAL FACTORS CAN CONTRIBUTE TO A DEPLOYMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM EXPANDING AND RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERTS GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DEPLOYMENT DIFFICULTY EVENT IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXCESSIVE BLEEDINGS FOR MONTHS STRAIGHT (INTERPRETED AS GENITAL BLEEDINGS). SHE HAD TO PERFORM AN EMERGENCY PARTIAL HYSTERECTOMY 5 MONTHS AFTER ESSURE WAS IMPLANTED, BUT THE BLEEDING DID NOT STOP. SHE HAD SEVERAL SURGERIES AFTERWARDS, INCLUDING A FULL HYSTERECTOMY. SHE WAS DIAGNOSED WITH RHEUMATOID ARTHRITIS. THE GENITAL BLEEDING AND RHEUMATOID ARTHRITIS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE BLEEDING IS LISTED WHILE THE RHEUMATOID ARTHRITIS IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF GENITAL BLEEDINGS, SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. HOWEVER, CONSIDERING THAT RHEUMATOID ARTHRITIS (RA) IS AN AUTOIMMUNE REACTION THAT LEADS TO SYNOVIAL HYPERTROPHY AND CHRONIC JOINT INFLAMMATION ALONG WITH THE POTENTIAL FOR EXTRA-ARTICULAR MANIFESTATIONS AND ALSO CONSIDERING THAT IT IS THEORIZED TO OCCUR IN GENETICALLY SUSCEPTIBLE INDIVIDUALS, IT IS UNLIKELY THAT ESSURE, WHICH HAS A LOCALIZED ACTION IN THE FALLOPIAN TUBES, COULD CONTRIBUTE TO THE DEVELOPMENT OF THIS DISEASE THEREFORE, THE RA IS ASSESSED AS UNRELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01445	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1582, AWARENESS DATE 18-OCT-2015). IT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER OF UNSPECIFIED "AGE" IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. ABOUT SIX MONTHS BEING IMPLANTED, CONSUMER STARTED EXPERIENCING EXCRUCIATING STOMACH PAIN, EXTREME BLOATING, UNEXPLAINABLE WEIGHT GAIN, PELVIC PAIN, LEG SPASMS, PAINFUL INTERCOURSE, ACNE, SEVERE LOWER BACK PAIN, PAINFUL CYCLES, ANXIETY, DEPRESSION, FATIGUE, CARBUNCLES, HEART MURMURS IBM, BREAST PAIN, SEVERE TEETH DECAYING, HEAVY BLEEDING, 1 MIGRATED COIL WHICH HAD TO BE SURGICALLY REMOVED. SHE WAS GOING BACKWARDS AND FORWARD TO THE DOCTOR TRYING TO GET AN INSIGHT AS TO WHY SHE WAS HAVING SO MUCH PAIN. FINALLY SHE WENT TO SEE DOCTORS WHO WERE WILLING TO RESEARCH ESSURE TO SEE IF THIS WAS THE ROOT OF HER PAIN. LOW AND BEHOLD THAT WAS THE PROBLEM HER LEFT COIL MIGRATED FROM HER TUBE. HE IMMEDIATELY SCHEDULED HER FOR SURGERY TO REMOVE MY LEFT COIL. SHORTLY AFTER THE PAIN CAME BACK ONLY THIS TIME ON RIGHT SIDE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 05-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD.

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WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING AND 1 MIGRATED COIL WHICH HAD TO BE SURGICALLY REMOVED /LEFT COIL HAD MIGRATED FROM HER TUBE. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS REPORTED THAT SIX MONTHS AFTER ESSURE INSERTION, SHE STARTED EXPERIENCING THESE EVENTS. THE EXACT DATE AND MECHANISM OF DEVICE MIGRATION WERE NOT KNOWN. BASED ON THEIR NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01446	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1994, AWARENESS DATE 18-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008, DAYS AFTER A LATE TERM MISCARRIAGE OF TWINS. SHE WAS PAINFUL THE MINUTE SHE WOKE UP FROM THE PROCEDURE. THAT PAIN HAS NEVER GONE AWAY AND SHE NEVER HAD RELIEF. EVEN AFTER HAVING HER TUBES REMOVED OVER FIVE YEARS PRIOR TO THIS REPORT, MANY OF HER SYMPTOMS REMAINED. EVERY MORNING SHE WAKES UP SICK WITH NAUSEA. EVERY NIGHT SHE BATTLES TO FIND STRENGTH TO OVERCOME DEBILITATING LEG CRAMPS, NUMBNESS IN EXTREMITIES, AND A COMPLETE LACK OF ENERGY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 05-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT

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PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS PAINFUL THE MINUTE SHE WOKE UP FROM THE PROCEDURE, THAT PAIN HAS NEVER GONE AWAY. SHE UNDERWENT A SALPINGECTOMY. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, ALTHOUGH THE PAIN DID NOT RESOLVE AFTER THE SALPINGECTOMY, GIVEN THE NATURE OF THIS EVENT, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED (SALPINGECTOMY). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01448	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1519, AWARENESS DATE 18-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER STATED THAT ALL WENT WELL AT FIRST, BUT AFTER ABOUT A YEAR, SHE BEGAN HAVING EXTREMELY SHARP PAINS IN ABDOMEN AND VAGINAL AREA, CRIPPLING STABS THAT WOULD BRING HER TO KNEES. SHE WENT TO PHYSICIAN AND HE SAID IT MIGHT BE POLYPS. HE PERFORMED A D AND C AND FOUND NO POLYPS OR ANYTHING ELSE WRONG FOR THAT MATTER. THE PAINS WERE STILL HAPPENING. HER SEX LIFE WENT TO CARP AS IT HURTS TO MUCH DURING AND AFTER FOR HER TO EVEN WANT TO MAKE LOVE TO HER HUSBAND. JUST STARTING RECENTLY SHE BLOAT SO BAD THAT SHE WENT FROM A SIZE 14 PANTS TO AN 18 IN ONE DAY AND THEN BACK AGAIN. SHE DID NOT SHOW ANY WEIGHT GAIN ANYWHERE ELSE EXCEPT HER BELLY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 05-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREMELY SHARP PAINS IN HER ABDOMEN. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE PATIENT STARTED TO FEEL EXTREMELY SHARP PAINS IN ABDOMEN AND VAGINAL AREA, ONE YEAR AFTER INSERTION. HER PHYSICIAN SAID IT MIGHT BE POLYPS. A DILATATION AND CURETTAGE WAS PERFORMED AND FOUND NO POLYPS NOR ANYTHING ELSE. GIVEN EVENT'S NATURE AND SUGGESTIVE TEMPORAL RELATIONSHIP, A CONTRIBUTORY ROLE FROM ESSURE TO THE REPORTED EVENT CANNOT BE EXCLUDED AND SINCE THIS EVENT LED TO AN INTERVENTION, THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01449	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): 9/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2042, AWARENESS DATE 18-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. IN (B)(6) 2015, TEST WAS PERFORMED TO CONFIRM ESSURE WAS IN PLACE. SHE STATED THAT DID NOT HAVE A MENSTRUAL CYCLE SINCE HAVING ESSURE. THEN IN THE BEGINNING OF (B)(6) SHE EXPERIENCED EXCRUCIATING PAIN IN ABDOMEN AND RIGHT SIDE, AND THEN STARTED HER MENSTRUAL CYCLE. ON (B)(6) 2015, A SONOGRAM WAS PERFORMED AND SHOWED THE LEFT COIL MIGRATED INTO UTERINE CAVITY. CONSUMER ALSO EXPERIENCED UNEXPLAINED WEIGHT GAIN AND STATED THAT TWO SURGERIES ARE REQUIRED: ONE TO REMOVE TUBES AND THE OTHER TO REMOVE THE COIL AND NOT SURE IF WILL HAVE TO HAVE UTERUS REMOVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 05-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC).(B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE

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REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE YEAR LATER, DURING ULTRASOUND IT WAS OBSERVED THAT THE LEFT COIL HAD MIGRATED INTO UTERINE CAVITY. THIS EVENT, SEEN AS DEVICE EXPULSION, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MOVE INTO UTERINE CAVITY. IN THIS CASE, SHE DID NOT HAVE A MENSTRUAL CYCLE SINCE HAVING ESSURE. AROUND 8 MONTHS AFTER PLACEMENT, SHE HAD EXCRUCIATING PAIN IN ABDOMEN AT RIGHT SIDE AND THEN HAD HER MENSTRUAL PERIOD. AN ULTRASOUND WAS PERFORMED AND SHOWED THE LEFT COIL MIGRATED INTO UTERINE CAVITY. TWO SURGERIES WERE REQUIRED: ONE TO REMOVE THE TUBES AND OTHER TO REMOVE A COIL. CONSIDERING EVENT'S NATURE AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01450	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1690, AWARENESS DATE 18-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER EXPERIENCED HEAVY PERIODS AND AN ABLATION WAS PERFORMED. SHE ALSO EXPERIENCED CONSTANT SKIN RASH, STILL HAVE PAIN, BLOATING, AND FATIGUE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY PERIODS AND AN ABLATION WAS PERFORMED. THIS EVENT IS SERIOUS DUE TO INTERVENTION REQUIRED AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MENSES PATTERN CHANGES ARE EXPECTED DURING ESSURE USE. IN THIS CASE, SHE EXPERIENCED OTHER NON-SERIOUS EVENTS AND HEAVY PERIODS. AN ABLATION, INTERPRETED AS ENDOMETRIAL ABLATION, HAS BEEN PERFORMED. CONSIDERING EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED (ABLATION) AS A TREATMENT MEASURE TO THE REPORTED EVENT, A CONTRIBUTORY ROLE FROM ESSURE USE CANNOT BE TOTALLY EXCLUDED. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01451	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/22/2009
Explant Date (E7): 10/29/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 13-JAN-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5032765, RECEIVED AT FDA ON 08-NOV-2013). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED PAIN, HEAVINESS IN HER PELVIC AREA, HER BLADDER, INFLAMMATORY BOWEL DISEASE - ULERATIVE COLITIS CONTINUOUS FLARE UPS, AFTER HYSTERECTOMY ESSURE COIL WAS FOUND EMBEDDED IN UTERUS, IT IS NOT CLEAR WHERE THE SECOND COIL MIGHT BE. FDA REPORT TYPE WAS INJURY, REPORTED OUTCOME OF EVENTS WAS 'REQUIRED INTERVENTION' NO INFORMATION WAS GIVEN ON CONSUMER'S PAST DRUGS, CONCOMITANT MEDICATION CONSUMER'S HISTORY/CONCURRENT CONDITIONS INCLUDED INFLAMMATORY BOWEL DISEASE - ULCERATIVE COLITIS. ON (B)(6) 2009, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. CONSUMER REPORTED SHE WAS NINE DAYS POST OP (OPERATIVE) FROM HER LAVH (LAPAROSCOPIC ASSISTED VAGINAL HYSTERECTOMY) DONE ON (B)(6) 2013. SHE FOLLOWED UP WITH HER OB/GYN (GYNECOLOGIST/OBSTETRICIAN) THAT REPORTED A INTRAUTERINE DEVICE (IUD) WAS EMBEDDED IN HER UTERUS. OBVIOUSLY, SINCE SHE NEVER HAD AN IUD, THIS IS AN ESSURE COIL DESPITE THE FACT THAT SHE HAD A POSITIVE HSG (HYSTEROSALPINGOGRAM) TEST IN 2010 THAT THERE WAS A COIL IN EACH FALLOPIAN TUBE. NO WONDER THE PAIN SHE HAD FOR SO LONG SINCE IMPLANTED IN 2009 WAS SUDDENLY GONE. THE HEAVINESS IN HER PELVIC AREA, HER BLADDER, EVEN POST OP - SHE COULD FEEL A DIFFERENCE NOW, THAT SHE LEARNED HER ESSURE WAS EMBEDDED IN HER UTERUS. THE REPORT WAS NOT CLEAR TO HER WHERE HER SECOND COIL MIGHT BE. SHE WAS BEING VIGILANT ABOUT LOOKING FOR THE OTHER COIL. IF BOTH WERE IN HER UTERUS, IT IS NOT CLEAR TO HER, NOR HER DOCTOR'S OFFICE, AS THERE WAS

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NOTHING NOTED IN THE REPORT OF THE FALLOPIAN TUBES AS TO FINDING ANY COIL. CONSUMER IS WAITING TO GET ORDERS FOR AN X-RAY OR OTHER TYPE OF DIAGNOSTIC TO GIVE HER PEACE OF MIND ONCE AND FOR ALL. CONSUMER ALSO HAS INFLAMMATORY BOWEL DISEASE - ULCERATIVE COLITIS, AND HAS EXPERIENCED CONTINUOUS FLARE UPS SINCE LATE 2009 RIGHT AFTER GETTING THE ESSURE IMPLANTS. THOSE SYMTOMS ARE STILL FLARING AND SINCE SHE IS NOT RESPONDING TO MEDICATION, HER GI (GASTROINTESTINAL) DOCTOR IS RECOMMENDING A COMPLETE COLECTOMY - REMOVAL OF HER LARGE INTESTINE. SHE IS PRAYING THAT SINCE DISCOVERING THE COIL IN HER UTERUS, THAT MAYBE HER BODY WILL CALM DOWN ONCE AND FOR ALL AND BEGIN TO FINALLY HEAL. PTC FINAL RESULT RECEIVED ON 24-JAN-2014: FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN (B)(4). MEDICAL ASSESSMENT: THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE FOR A QUALITY DEFICIT PER SE. THE MEDICAL EVENTS WERE REPORTED WITH AN OCCURRENCE OVER A PERIOD OF 3 YEARS NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. AT TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. F/UP INFORMATION RECEIVED ON 24-JAN-2014: NO NEW INFORMATION WAS RECEIVED. FOLLOW-UP INFORMATION WAS RECEIVED ON 23-JAN-2014. PATIENT'S DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE PATIENT. SHE HAD 03 PREGNANCIES AND 03 LIVE BIRTHS. SHE DENIED ANY PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS INCLUDED INFLAMMATORY BOWEL DISEASE (IBD) AND ULCERATIVE COLITIS. SHE WAS NOT PREGNANT. ON (B)(6) 2009 ESSURE WAS INSERTED. ESSURE WAS NOT INSERTED AFTER PREGNANCY. SHE USED TRI-LEVOLYN PILLS AS BACK-UP CONTRACEPTION, AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. IN (B)(6) 2010 HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND SHOWED ESSURE WAS POSITIVELY PLACED (FOUND TO BE IN THE CORRECT POSITION) AND TUBES WERE FULLY OCCLUDED. SHE HAD BARIUM SCANS AND CT'S (COMPUTED TOMOGRAPHY) DONE IN 2010 AND 2012 FOR HER IBD (INFLAMMATORY BOWEL DISEASE) AND THEY DID NOT SHOW THE ESSURE COILS. IN (B)(6) 2012 SHE UNDERWENT AN APPENDECTOMY. ON UNSPECIFIED DATE SHE EXPERIENCED EXCESSIVE BLEEDING, IRREGULAR CYCLES, PAINFUL INTERCOURSE, CRAMPING, BLOATING, HEAVINESS IN HER PELVIC AREA, ALWAYS FELT LIKE BLADDER WAS FULL, BRAIN FOGS, FORGETFULNESS, DEPRESSION AND ANXIETY. SHE WAS HOSPITALIZED FOR EXTREME FLARE UPS OF HER INFLAMMATORY BOWEL DISEASE IN (B)(6) 2012, (B)(6) 2013 AND EVEN AFTER THE HYSTERECTOMY IN (B)(6) 2013. IN (B)(6) 2013 SHE UNDERWENT A HYSTERECTOMY AND ESSURE WAS FOUND IN AN INCORRECT POSITION. BOTH THE LEFT AND RIGHT ESSURE DEVICES WERE COMPLETELY EMBEDDED IN THE UTERUS (PREVIOUSLY REPORTED AS ESSURE COIL EMBEDDED IN UTERUS. THE PREVIOUSLY REPORTED IT IS NOT CLEAR TO ME WHERE THE SECOND COIL MIGHT BE DELETED AS EVENT). HER UTERUS AND BOWEL STRUCTURE WERE AFFECTED. ESSURE REMOVAL WAS MEDICALLY NECESSARY. LAPAROSCOPICALLY ASSISTED VAGINAL HYSTERECTOMY WAS REPORTED AS THE PROCEDURE USED FOR THE REMOVAL. HYSTERECTOMY AND SALPINGECTOMY WERE NECESSARY. IT WAS REPORTED THAT HER BODY WAS REJECTING IT AND AFTER THE HYSTERECTOMY THE DOCTOR SAID THERE WAS INFLAMMATION. AFTER THE REMOVAL PROCEDURE SHE WAS SENT BACK TO WORK BUT WITHIN TWO WEEKS AFTER THE SURGERY THE IBD FLARED UP AGAIN AND SHE STILL HAS SYMPTOMS. THE PAIN WAS GONE BUT THE IBD FLARED SYMPTOMS REMAIN. SHE BELIEVES THE EVENTS WERE CAUSED BY THE ESSURE DEVICES BECAUSE THEY SHOULDN'T HAVE MIGRATED FROM HER TUBES TO HER UTERUS AND SECONDARILY IT AGGRAVATED HER IBD AND ULCERATIVE COLITIS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 04-FEB-2014: IT WAS REPORTED BY THE PHYSICIAN WHO INSERTED THE ESSURE THAT PATIENT HISTORICAL CONDITION INCLUDED GRAVIDA 5, 1 SPONTANEOUS ABORTION, 1 ELECTIVE ABORTION BY

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CURETTAGE, DYSPAREUNIA OF LEFT LOWER QUAD PAIN AND DYSFUNCTIONAL UTERINE BLEEDING. HER CONCURRENT CONDITION INCLUDED HYPERTENSION (HTN), POLYCYSTIC KIDNEY, DEPRESSION AND ASTHENIA. THERE WAS A DISCREPANCY BETWEEN HISTORICAL/CONCURRENT CONDITIONS REPORTED BY PHYSICIAN AND BY CONSUMER. ESSURE WAS INSERTED ON (B)(6) 2009 AND CERVICAL DILATION, SOUNDING (8.0CM) AND PARACERVICAL BLOCK WERE PERFORMED DURING INSERTION. PHYSICIAN CONSIDERED BOTH THE PROCEDURE, WHICH TOOK LESS THAN 20 MINUTES, AND THE VISUALIZATION OF THE TUBAL OSTIUM (BOTH SIDES) EASY. NO FLUID LOSS MORE THAN 1500CC DURING HYSTEROSCOPY (LOSS OF 25ML). ESSURE WAS NOT INSERTED POSTPARTUM AND PATIENT WAS NOT PREGNANT BY THE TIME OF INSERTION. PHYSICIAN STATED THAT NO PERFORATION OCCURRED DURING SOUNDING, CERVICAL DILATION OR HYSTEROSCOPY PRIOR TO ESSURE INSERTION. IT DID NOT OCCUR BEFORE DEPLOYMENT OR WITH COIL AFTER DEPLOYMENT AS WELL. SHE HAD NORMAL RECOVERY. ON (B)(6) 2011 CONFIRMATION OF ESSURE PLACEMENT WAS PERFORMED VIA HYSTEROSALPINGOGRAM AND IT SHOWED INTACT ESSURE DEVICE BILATERALLY WITHOUT DYE. PHYSICIAN REPORTED THAT PATIENT WAS NOT UNDER HIS CARE ANYMORE AND HE HAD NO KNOWLEDGE OF WHEN IT WAS DETERMINED THAT ESSURE WAS IN AN INCORRECT POSITION AND WHAT SYMPTOMS THE PATIENT HAD PRESENTED WITH. HE ALSO HAD NO KNOWLEDGE OF ESSURE REMOVAL AND POST REMOVAL PROCEDURES AND OUTCOMES. NO FURTHER INFORMATION WAS PROVIDED.
ADDITION/CORRECTION DUE TO INTERNAL REVIEW OF FOLLOW-UP INFORMATION RECEIVED ON 04-FEB-2014: THIS CASE WAS MEDICALLY CONFIRMED SINCE FOLLOW-UP (RETURNED QUESTIONNAIRE) HAD BEEN RECEIVED FROM PHYSICIAN. FOLLOW UP INFORMATION IDENTIFIED ON 19-OCT-2015: THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1791). SHE WAS DIAGNOSED WITH INFLAMMATORY BOWEL DISEASE (IBD) (ULCERATIVE COLITIS) IN FALL OF 2005. HER SYMPTOMS WERE MINIMAL AND WELL CONTROLLED. HER OB/GYN SUGGESTED THE ESSURE PERMANENT BIRTH CONTROL METHOD WHEN THE CONSUMER INQUIRED ABOUT HAVING HER TUBES TIED. SHE HAD THREE CHILDREN; ALL THREE OF THOSE PREGNANCIES WERE HIGH-RISK AS SHE HAD HYPERTENSION/PRE-ECLAMPSIA AS RESULT OF HER GENETICALLY ACQUIRED, POLYCYSTIC KIDNEY DISEASE. ON (B)(6) 2009 SHE HAD ESSURE INSERTED. SHE WAS GIVEN GENERAL ANESTHESIA AND SENT HOME THAT DAY. SHE IMMEDIATELY DEVELOPED A YEAST INFECTION, DIFLUCAN WAS PRESCRIBED. THIS WAS THE FIRST OF MANY MORE INFECTIONS TO COME. OVER THE COURSE OF MONTHS, SHE HAD EXPERIENCED ABDOMINAL PAIN AND BLOATING. SHE HAD AN HYSTEROSALPINGOGRAM TEST AND THE PAIN WAS EXCRUCIATING WHEN THIS TEST WAS DONE. SHE CONTINUED TO EXPERIENCE CONSTANT ABDOMINAL PAIN, ABDOMINAL PAIN WHEN BENDING OVER; EXTREME AT TIMES; HEAVY PERIODS, IRREGULAR BLEEDING, CLOTTING; SOME PERIODS LASTED 8 WEEKS AT A TIME; PAINFUL INTERCOURSE; FATIGUE; FREQUENT URINATION, CONSTANTLY FELT AS THOUGH HER BLADDER WAS FULL; URINARY TRACT/KIDNEY INFECTIONS, BLOODY TISSUE IN URINE; SKIN INFECTIONS INCLUDING (B)(6); WEIGHT GAIN / WEIGHT LOSS; JOINT PAIN, ACHY JOINTS/ BACK PAIN; DEPRESSION / ANXIETY; OVARIAN CYSTS AND PAINFUL OVULATION (EVEN UNABLE TO WALK AT TIMES); HAIR LOSS; FORGETFULNESS/CLOUDY HEAD; MIGRATION OF THE ESSURE IMPLANTS TO HER UTERUS. SHE WAS PRESCRIBED MANY TYPES OF MEDICATIONS AND ENDURED VARIOUS SIDE-EFFECTS FROM THOSE AS WELL, INCLUDING IMMUNOSUPPRESSANT MEDICATIONS, CAUSING MORE INFECTIONS. TORN PLANTAR FASCIA LIGAMENT OF THE RIGHT FOOT AND AVASCULAR NECROSIS OF THE LEFT KNEE (DUE TO PROLONGED USE OF PREDNISONE AND CERTAIN ANTIBIOTICS); HER IBD/ULCERATIVE COLITIS SYMPTOMS INCREASED SIGNIFICANTLY. SHE BEGAN HAVING UNCONTROLLED SYMPTOMS AND FLARE UPS (DIARRHEA, INCONTINENCE, WEIGHT LOSS, BLOODY DISCHARGE, MUCUS, MORE ABDOMINAL PAIN). SHE WAS BECOMING STEROID DEPENDENT (PREDNISONE WAS THE ONLY DRUG TO GET HER SYMPTOMS UNDER CONTROL, ALTHOUGH FOR SHORTER PERIODS OF TIME).SHE NOTICED THAT HER IBD SYMPTOMS WOULD START TO IMPROVE, ONLY TO RETURN ABOUT THE TIME OF HER MENSTRUAL CYCLE - WHICH WERE BECOMING MORE AND MORE IRREGULAR. SHE WAS PLACED ON BIRTH CONTROL TO STOP HER PERIODS TO SEE IF THIS WOULD IMPROVE HER IBD SYMPTOMS. IT DID

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NOT. IN (B)(6) 2012 SHE HAD AN EMERGENCY APPENDECTOMY. SHE WAS HOSPITALIZED IN (B)(6) 2012, (B)(6) 2013 - 4 WEEKS POST-OPERATIVE OF MY HYSTERECTOMY - ALL FOR EXTREME SYMPTOMS OF MY ULCERATIVE COLITIS FLARE UPS (DEHYDRATION, UNCONTROLLED DIARRHEA, VOMITING, EXTREME WEIGHT LOSS). DUE TO THE MANY USES OF PREDNISONE DURING THE TIME OF 2009-2013, SHE HAD A SCAN DONE OF HER LEFT KNEE TO FIND THAT SHE HAD DEVELOPED AVN (AVASCULAR NECROSIS) AS WELL AS SHE TORE THE PLANTAR FASCIA TENDON IN HER RIGHT FOOT, ALONG WITH WEIGHT GAIN AND OTHER SIDE EFFECTS. SINCE TRADITIONAL METHODS WERE NOT CONTROLLING HER IBD/ULCERATIVE COLITIS, SHE WAS PLACED ON REMICADE INFUSIONS IN 2012. SHE HAD ANOTHER SEVERE FLARE UP OF IBD AND HAD BEEN RECLASSIFIED AS HAVING SEVERE ULCERATIVE COLITIS / PANCOLITIS. SHE DISCONTINUED REMICADE AND BEGAN ENTYVIO ON (B)(6) 2015. SINCE IT HAD BECOME DIFFICULT TO GET HER DISEASE UNDER CONTROL AND SHE WAS NOT RESPONDING TO MEDICATIONS, SHE WAS ADVISED FOR A FULL COLECTOMY. AT THE AGE OF (B)(6), ON (B)(6) 2013, SHE HAD A FULL HYSTERECTOMY PERFORMED. THE PATHOLOGY REPORT NOTED THAT THERE WAS AN INTRAUTERINE DEVICE EMBEDDED IN HER UTERUS. SHE HAVE NEVER HAD AN IUD, THESE WERE THE ESSURE IMPLANTS. SINCE HER HYSTERECTOMY, SHE HAD ONE MORE HOSPITALIZATION IN (B)(6) 2013 FOR A CONTINUING RELAPSE OF MY IBD. AT THAT TIME, SHE HAD A SPHINCTER AND HEMORRHOID ECTOMY PERFORMED IN (B)(6) 2013, SHE WAS PLACED ON MERCAPTOPURINE (6MP) TO ASSIST WITH THE REMICADE INFUSIONS IN ACHIEVING REMISSION. SHE WAS NO LONGER EXPERIENCING THE SAME PAIN IN HER ABDOMEN WHEN SHE BEND OVER, HER BLADDER NO LONGER FELT FULL AND THERE HAS BEEN SOME IMPROVEMENT, ALTHOUGH SHE WAS STILL STRUGGLING TO GET HER ULCERATIVE COLITIS INTO REMISSION WITHOUT THE NEED FOR STEROIDS. SHE FELT THAT ESSURE ACTIVATED A SEVERE IMMUNE RESPONSE WITH HER INFLAMMATORY BOWEL DISEASE AND IT WAS AGGRAVATED BECAUSE OF THE FOREIGN OBJECTS THAT WERE PLACED IN HER FALLOPIAN TUBES. COMPANY CAUSALITY COMMENT: THIS IS A SPONTANEOUS CASE REPORT RECEIVED INITIALLY VIA REGULATORY AUTHORITY AND ADDITIONAL INFORMATION RECEIVED FROM PHYSICIAN. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD INSERTED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND BOTH THE LEFT AND RIGHT ESSURE DEVICES WERE COMPLETELY EMBEDDED IN THE UTERUS (INTERPRETED AS DEVICE EMBEDDED). SHE ALSO HAD WORSENING OF ULCERATIVE COLITIS CONTINUOUS FLARE UPS (INFLAMMATORY BOWEL DISEASE SYMPTOMS), EXCESSIVE BLEEDING (INTERPRETED AS GENITAL BLEEDING), KIDNEY INFECTION, STAPHYLOCOCCAL INFECTION (MRSA), TORN PLANTAR FASCIA LIGAMENT OF RIGHT FOOT (INTERPRETED AS LIGAMENT RUPTURE) AND AVASCULAR NECROSIS OF LEFT KNEE (INTERPRETED AS OSTEONECROSIS) AND STEROIDS DEPENDENT. AROUND 4 YEARS AFTER ESSURE INSERTION SHE HAD A HYSTERECTOMY AND ESSURE INSERTS WERE REMOVED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ULCERATIVE COLITIS IS ALSO SERIOUS DUE TO HOSPITALIZATION. THESE EVENTS ARE UNLISTED, EXCEPT FOR DEVICE EMBEDDED AND GENITAL BLEEDING) WHICH ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, CONSIDERING THE NATURE OF THE GENITAL BLEEDING AND DEVICE EMBEDDED AND LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. IN CONTRAST, CONSIDERING THE PHYSIOPATHOLOGY OF ULCERATIVE COLITIS, KIDNEY INFECTION, LIGAMENT RUPTURE, OSTEONECROSIS AND DRUG DEPENDENCY AND CONSIDERING THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT ESSURE WOULD CAUSE OR WORSENED THESE EVENTS. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. FURTHER INFORMATION IS NOT EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 05-JAN-2016 FROM CONSUMER VIA REGULATORY AUTHORITY: IN 2015, THE CONSUMER WAS DIAGNOSED WITH LUPUS (SLE - SYSTEMIC LUPUS ERYTHEMATOSUS), INFLAMMATORY ARTHRITIS AND FIBROMYALGIA. SHE BEGAN HAVING MANY OF THE SYMPTOMS OF LUPUS DURING T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01452	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/23/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY (CASE# MW5039337) IN UNITED STATES ON 15-JAN-2015 FROM A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT SHE EXPERIENCED PAIN, CRAMPING, LEG PAIN, JOINT PAIN, LOWER BACK PAIN, FEELING OF BURNING, AND FEELING OF SWELLING AFTER USING THE BATHROOM. IN ADDITION, SHE INFORMED THAT ALL STARTED AFTER HAVING ESSURE INSERTED AND STATES THAT, EVEN THOUGH IT HAS BEEN OVER A YEAR, HER RIGHT TUBE NEVER CLOSED. FOLLOW-UP RECEIVED ON 05-FEB-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: THIS IS REPORT FROM AN UNKNOWN PATIENT WITH NO CONTACT INFORMATION TO CONDUCT A FOLLOW-UP. THE SYMPTOMS REPORTED COULD NOT BE CONFIRMED. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY AND A LACK OF EFFICACY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A LACK OF EFFICACY MAY OCCUR UNDER THE USE OF ANY PRODUCT AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 16-APR-2015: THE CONSUMER'S INITIALS WERE PROVIDED. ESSURE WAS INSERTED ON (B)(6) 2013. IT WAS REPORTED HOSPITALIZATION AS EVENT OUTCOME, HOWEVER THE REPORTER DID NOT SPECIFY IT. FOLLOW-UP FROM 12-JUN-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW-UP RECEIVED ON 19-OCT-2015 AND ADDITIONAL INFORMATION RECEIVED ON 03-NOV-2015 (PTC INVESTIGATION RESULT): THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. CONSUMER STATED THAT ESSURE MADE HER SICK RIGHT AFTER SHE HAD IT DONE FROM CRAMPING TO LOWER BACK PAIN TO LEG PAIN TO HEAD ACHES AND NAUSEA. THERE WERE DAYS SHE FELT SHE WAS BEING POISONED, SHE EVEN HAD PAIN AFTER BOWL MOVEMENTS. SHE CAN NOT BEGAN TO COUNT THE DOCTOR VISITS AND HOW MANY TIMES SHE HAD TO VISIT THE EMERGENCY ROOM, NO ONE WANTED TO LISTEN TO HER, SHE WAS HAVING TROUBLE KEEP UP WITH LITTLE EVERY DAY TO DAY TASK OR TROUBLE TAKING CARE OF HER TWO KIDS. SHE HAD DEPRESSION AND WAS SCARED FOR HER LIFE AND CRIED A LOT. SHE EVEN GOT WEIRD RASHES TIME TO TIME AND ON TOP OF THAT ONE OF HER TUBES NEVER CLOSED. SHE FINELY GOT AHOLD OF THE DOCTOR WHO PUT THE ESSURE IN HER AND HAD HIM REMOVE IT. HE SAID THAT WHILE REMOVING HER UTERUS AND TUBES THAT ON ONE SIDE ONE OF THE COILS WAS EMBEDDED IN HER UTERUS AND BELIEVES THAT HAD A LOT TO DO WITH HER PAIN. SHE HAD SUFFERED OVER A YEAR. TODAY SHE IS GETTING HER HEALTH BACK SHE STILL HAS LOWER BACK PAIN FROM TIME TO TIME AND WEIRD SHARP PAINS WERE HER UTERUS WOULD HAVE BEEN. SHE IS HAPPY TO HAVE HER LIFE BACK. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. IT WAS REPORTED THAT WHILE REMOVING HER UTERUS AND TUBES, ONE OF THE COILS WAS EMBEDDED IN HER UTERUS. PAIN WAS CONSIDERED AS SERIOUS DUE TO HOSPITALIZATION AND ONE OF THE COILS WAS EMBEDDED IN HER UTERUS WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE. BOTH ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS REPORTED THAT THESE EVENTS OCCURRED AFTER HAVING ESSURE INSERTED. CONSIDERING THE NATURE OF THE EVENTS AND THAT UNCHARACTERIZED PAIN AND EMBEDDED DEVICE MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01470	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1806, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER BECAME VERY ILL DUE TO HAVING THE DEVICE IMPLANTED INTO HER BODY. EVEN AFTER REMOVAL SHE WAS SUFFERING FROM THE SIDE EFFECTS OF ESSURE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AN UNSPECIFIED TIME LATER, UNDERWENT THE REMOVAL OF ESSURE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. THE EXACT REASON FOR THE REMOVAL WAS NOT SPECIFIED. THE TIME INTERVAL BETWEEN ESSURE INSERTION AND REMOVAL WAS NOT REPORTED. CONSUMER STATED THAT EVEN AFTER REMOVAL SHE WAS SUFFERING FROM SIDE EFFECTS, SUGGESTING THAT THE DEVICE WAS NOT THE ONLY RESPONSIBLE FOR HER SYMPTOMS. HOWEVER, GIVEN THE NATURE OF THE EVENT REMOVAL OF ESSURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 07-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01471	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1530, AWARENESS DATE 19-OCT-2015) WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. AT TIME OF THE REPORT, THE CONSUMER WAS (B)(6) AND WAS SUFFERING FROM SEVERE MIGRAINES, NAUSEA, VOMITING, CONSTIPATION, PAINFUL INTERCOURSE, PAINFUL PERIODS, JABBING PAIN IN PELVIC AREA, HEAVY PERIODS, QUARTER LARGE SIZE CLOTS, HAIR LOSS, TINGLING OF THE NECK, HANDS AND FEET, COILS SEEM SEPARATED, BROKEN AND MIGRATED, BLOATING, PHANTOM SPASMS, IRRITABILITY, DEPRESSION CHRONIC PAIN, HOT FLASHES AND NIGHT SWEATS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT COILS SEEM SEPARATED BROKEN (DEVICE BREAKAGE) AND MIGRATED. THE REPORTED EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE MIGRATION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED. IN THIS CASE, IT WAS UNKNOWN WHETHER DEVICE HAS BROKEN DURING ESSURE INSERTION PROCEDURE. ALSO, THE EXACT DATE AND MECHANISM OF DEVICE MIGRATION WERE NOT KNOWN. CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS

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FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 22-NOV-2015: PTC RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE FOR CASES WHERE AN INSERT IS REMOVED AT A LATER T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01472	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 19-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER STATED THAT HER BODY REJECTED ESSURE, WHICH CAUSED SEVERE INFECTIONS. AT FIRST, A PARTIAL HYSTERECTOMY WAS PERFORMED IN 2013 - THE UTERUS AND PART OF BOTH FALLOPIAN TUBES WERE REMOVED. ALSO IN 2013, SHE HAD TO HAVE THE REMAINING LEFT TUBE AND OVARY REMOVED DUE TO INFECTIONS. IN 2015, THE REMAINING RIGHT TUBE AND OVARY WERE REMOVED. THIS LAST SURGERY RESULTED IN A COMPLETE HYSTERECTOMY. SHE STATED SHE HAD SUFFERED CONSTANT INFECTIONS AND PAIN SINCE THE DEVICE WAS PLACED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE INFECTIONS WHICH RESULTED IN PARTIAL HYSTERECTOMY (UTERUS AND PART OF BOTH FALLOPIAN TUBE WERE REMOVED). SHE ALSO HAD TO HAVE THE REMAINING LEFT TUBE AND OVARY REMOVED DUE TO INFECTIONS. THE REPORTED EVENTS INFECTIONS (SEEN AS PELVIC INFECTIONS) ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. ALTHOUGH IT WAS NOT REPORTED WHETHER THE PELVIC INFECTIONS OCCURRED UP TO 4 WEEKS, THE REPORTER STATED THAT HER BODY REJECTED ESSURE. CONSIDERING

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A POSSIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED AT THE TIME OF REPORT. DUE TO SURGICAL INTERVENTION REQUIRED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 10-NOV-2015 FROM CONSUMER: CONTACT DETAILS AND CONSUMER'S DATE OF BIRTH WERE PROVIDED. SHE IS CURRENTLY (B)(6). SHE DOESN'T HAVE THE CARD WITH THE ESSURE LOT NUMBER WITH HER. CONSUMER HAS MEDICAL RECORDS AT HOME. SHE AGREED TO ACCEPT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01473	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 9/17/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1844, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. THE CONSUMER REPORTED SHE HAD THE PROCEDURE DONE IN THE OFFICE AND WAS ABLE TO GO BACK TO NORMAL ACTIVITIES WITHOUT RESTRICTIONS ALMOST IMMEDIATELY. SHE REPORTED LITTLE PAIN, JUST A DULL ACHE ON THE RIGHT SIDE OF LOWER BACK; AND TYLENOL AND MOTRIN SEEM TO ALLEVIATE THE PAIN. SINCE THAT TIME SHE HAD SLOWLY INCREASING RIGHT BACK/HIP PAIN AND WAS TOLD IT WAS SI JOINT PAIN (UNDERSTOOD AS SACROILIAC JOINT PAIN) AND HAD BEEN THROUGH MANY DIFFERENT TREATMENTS TO ALLEVIATE THE PAIN. AS THE YEARS WENT BY IT ONLY INCREASES. SHE HAD 6 MONTHS OF PHYSICAL THERAPY, SI JOINT INJECTIONS UNDER FLUOROSCOPE, ACUPUNCTURE, MASSAGE THERAPY AND VARIOUS MEDICATIONS TO RESOLVE OR COVER THE SYMPTOMS SHE PURCHASED AN INVERSION TABLE TO HOPEFULLY HELP WITH THE PAIN AND IT TOO PROVIDED LITTLE RELIEF. SHE ALSO HAD WEIGHT GAIN WITH ABDOMINAL BLOATING, JOINT PAIN AND SWELLING, DECREASED LIBIDO, SEVERE HIP AND BACK PAIN, FATIGUE AND DEPRESSION OVER THE PAST THREE YEARS AND THE ONLY COINCIDING EVENT IS THE PLACEMENT OF THE ESSURE IMPLANTS. SHE HAD A DIAGNOSIS OF "ALLERGIC THYROID" OR HASHIMOTO SYNDROME AND MANY OF SYMPTOMS HAVE BEEN BLAMED ON THAT. THE CONSUMER BELIEVES SHE HAS HASHIMOTO SYNDROME AS A RESULT OF HER BODY ALWAYS BEING IN A STATE OF ALLERGIC INFLAMMATION BECAUSE OF THE ESSURE IMPLANT. HER LATEST SYMPTOMS WERE NUMBNESS AND TINGLING WITH HER RIGHT SIDE EXTREMITIES AND ABDOMINAL PAIN; SHE WENT TO HER PCP MULTIPLE TIMES RELATED TO THESE SYMPTOMS FOR THE PAST THREE YEARS AND HAD BEEN

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DIAGNOSED WITH EVERYTHING FROM HYPOTHYROIDISM TO DEPRESSION. FINALLY SHE CALLED HER GYNECOLOGIST AND EXPLAINED WHAT WAS GOING ON AND THAT SHE SUSPECTED IT WAS RELATED TO THE ESSURE IMPLANTS AND TOLD HIM SHE WANTED THEM REMOVED AND HE SAID HE COULD DO THAT WITH A TOTAL HYSTERECTOMY. ON (B)(6) 2015, SHE HAD THEM REMOVED. THE FOLLOWING DAY AFTER SURGERY SHE REALIZED HER BACK PAIN WAS ALMOST COMPLETELY GONE. IN 8 DAYS SHE HAD LOST ALMOST 10 POUNDS AND HAD ALL OF HER ENERGY BACK. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A DULL ACHE ON THE RIGHT SIDE OF LOWER BACK / SLOWLY INCREASING RIGHT BACK PAIN (INTERPRETED AS BACK PAIN), SEVERE HIP PAIN / SI JOINT PAIN / JOINT PAIN (INTERPRETED AS ARTHRALGIA) AND HASHIMOTO SYNDROME / ALLERGIC THYROID. ESSURE WAS REMOVED 3 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. BACK PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENTS ARE UNLISTED. BACK PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, CONSUMER HAD A SUSPICION OF SACROILIAC JOINT PAIN, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THE BACK PAIN. HOWEVER, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND SINCE THE BACK PAIN WAS ALMOST COMPLETELY GONE AFTER ESSURE REMOVAL, A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE EXCLUDED. ARTHRALGIA CAN HAVE MULTIPLE CAUSES, A REFLECTION OF THE DIVERSE JOINT DISEASES, WHICH ARISE FROM INFLAMMATION, CARTILAGE DEGENERATION, CRYSTAL DEPOSITION, INFECTION, AND TRAUMA. HASHIMOTO THYROIDITIS IS CHARACTERIZED BY THE DESTRUCTION OF THYROID CELLS BY VARIOUS CELL- AND ANTIBODY-MEDIATED IMMUNE PROCESSES. GIVEN THE PATHOPHYSIOLOGY OF THESE EVENTS AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01474	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): 10/10/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/21/2011
Explant Date (E7): 10/10/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044263) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. IN 2011 THE CONSUMER WENT TO THE GYNECOLOGIST FOR A CONSULTATION FOR HAVING MULTIPLE OVARIAN CYST AND BLEEDING 2-3 WEEKS PER MONTH FOR A YEAR AFTER HER MENSTRUAL CYCLE. SHE WANTED A HYSTERECTOMY AT THE TIME. SHE WAS INFORMED OF THE RISK AND COMPLICATIONS ALONG WITH THE SIDE EFFECTS OF GETTING A HYSTERECTOMY AND THEN SHE WAS TOLD ABOUT THE ESSURE AND WAS ENSURED THAT THE ESSURE DEVICE PLACEMENT AND AN ENDOMETRIAL ABLATION WOULD HELP SOLVE HER ISSUE AND THAT SHE WOULD FEEL MUCH BETTER AFTER THE PROCEDURE WAS CONDUCTED. ESSURE WAS REMOVED ON (B)(6) 2014. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER APPROXIMATELY 3 YEARS, ESSURE INSERTS WERE REMOVED. THE ESSURE REMOVAL IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF A DEVICE REMOVAL AND THAT THE REASON FOR THIS PROCEDURE WAS NOT REPORTED, A CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. FURTHER INFORMATION AND A PRODUCT TECHNICAL COMPLAINT ANALYSIS WERE BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 07-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01475	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 7/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# MW5045158) IN UNITED STATES ON 19-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. AFTER SEVERAL YEARS TRYING TO NARROW DOWN WHY HER HEALTH WAS GOING DOWNHILL IT WAS ESSURE COILS. SHE HAD MIGRAINES THAT LANDED HER IN THE EMERGENCY ROOM; JOINT PAIN, TOOTH DECAY, UNEXPLAINED INJURY TO MY ANKLES AND KNEES BACK; SHOULDER PAIN, INSOMNIA, DIZZY SPELLS, STOMACH PAINS, PELVIC PAINS, PAIN THROUGH HER LEFT SIDE, BLOATING, VERY HEAVY BLEEDING WITH LARGE SIZE CLOTS, BRAIN FOG, DEPRESSION, ANXIETY, TROUBLE FUNCTIONING ON A DAILY BASIS AND WAS UNABLE TO HELP A SICK CHILD, GANGLION CYST, ARTHRITIS, RA SYMPTOMS (UNDERSTOOD AS RHEUMATOID ARTHRITIS), AUTOIMMUNE ISSUES, LOW VITAMIN D AND BLOOD CELL COUNT IRREGULAR. THE CONSUMER REPORTED (B)(6) 2015 AS EXPLANT DATE. SHE ALSO MENTIONED THE SERIOUSNESS CRITERION HOSPITALIZATION AND OTHER SERIOUS BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED VERY HEAVY BLEEDING WITH LARGE SIZE CLOTS (INTERPRETED AS GENITAL BLEEDING). THIS EVENT IS SERIOUS (HOSPITALIZATION WAS CONSIDERED, HOWEVER THE REPORTER ONLY MENTIONED IT AS EVENT OUTCOME AND DID NOT SPECIFY IT) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS REPORTED THAT ESSURE WAS REMOVED. BASED ON THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO DEVICE REMOVAL, THIS CASE WAS REGARDED AS INCIDENT.

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ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 07-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01476	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): 1/1/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2003
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1976, AWARENESS DATE 19-OCT-2015) WHICH REFERS TO A FEMALE PATIENT WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2003. THE CONSUMER REPORTED SHORTLY AFTER AND, AT TIME OF THE REPORT, STILL HAS, HEAVY BLEEDING, BLOATING, MIGRAINES, TERRIBLE CRAMPS AND PAIN. SHE WAS TALKED INTO ABLATION IN 2003; PRIOR TO ESSURE SHE HAD VERY LIGHT PERIODS AND SKIPPED MANY, THIS HAD NOT BEEN A PRIOR ISSUE. SHE HAD PAIN SO SEVERE WITH THE ABLATION THAT SHE HAD TO STAY OVERNIGHT IN THE HOSPITAL. THIS WAS FOLLOWED BY AN ENDOMETRIOMA SHORTLY AFTER THAT WAS REMOVED SURGICALLY. HER GYNECOLOGIST WANTED NOTHING TO DO WITH IT; SHE WAS NEVER GIVEN THE PRODUCT CARD FOR HER ESSURE EVEN AFTER ASKING SEVERAL TIMES. SHE STATED SHE STILL HAVING PAIN, HEAVY BLEEDING AND DEBILITATING MIGRAINES. SHE HAD A SONO (UNDERSTOOD AS SONOGRAM) THAT SHOWED UTERINE SCAR TISSUE. THE CONSUMER REPORTED SHE WAS THE FIRST ESSURE PROCEDURE OF HER PHYSICIAN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING. THEN AN (ENDOMETRIAL) ABLATION WAS PERFORMED AND DURING THE PROCEDURE, SHE PRESENTED PAINS SO SEVERE THAT SHE HAD TO STAY OVERNIGHT AT THE HOSPITAL. SHORTLY THEREAFTER, SHE ALSO HAD ENDOMETRIOMA WHICH WAS REMOVED SURGICALLY. THESE EVENTS, SEEN AS GENITAL BLEEDING, PROCEDURAL PAIN AND ENDOMETRIOSIS RESPECTIVELY, ARE SERIOUS DUE TO HOSPITALIZATION AND REQUIRED INTERVENTION AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT ENDOMETRIOMA WHICH IS

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UNLISTED. ALTHOUGH IN THIS CASE THE ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THIS BLEEDING, CONSIDERING ITS NATURE AND IMPLIED TEMPORAL RELATIONSHIP, ESSURE'S CONTRIBUTORY ROLE FOR THIS EVENT CANNOT BE TOTALLY EXCLUDED. SINCE THE BLEEDING LED TO A VERY PAINFUL ABLATION (REQUIRED INTERVENTION), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 07-NOV-2015. THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01477	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/5/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1983, AWARENESS DATE 19-OCT-2015) WHICH REFERS TO FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. ON (B)(6) 2015, A STAT ULTRASOUND WAS ORDERED BY HER GYNECOLOGIST. HER RIGHT ESSURE COIL MIGRATED TO AN UNKNOWN LOCATION. ON (B)(6) 2015, SHE WILL HAVE AN EXPLORATORY LAPAROTOMY TO LOCATE THE COIL, REMOVE AND A TUBAL LIGATION IN PLANNED. SHE STATED SHE HAD THIS DEVICE IN HER BODY FOR 20 DAYS AND IT WAS CAUSING PROBLEMS THAT SHE HAD NEVER DREAMED OF. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 3 WEEKS AFTER THE INSERTION, IT WAS SEEN ON ULTRASOUND RIGHT ESSURE COIL MIGRATED TO AN UNKNOWN LOCATION AND AN EXPLORATORY LAPAROTOMY WAS SCHEDULED TO THE FOLLOWING DAY TO LOCATE AND REMOVE THE COIL. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES TOWARDS TO PERITONEAL CAVITY. ALTHOUGH THE EXACT DATE AND MECHANISM OF THIS DISLOCATION ARE UNKNOWN, CONSIDERING THE EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE A REQUIRED INTERVENTION WILL BE PERFORMED, THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 07-NOV-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01478	BAYER HEALTHCARE LLC	11/13/2015	11/13/2015

Event Information:

Event Date (B3): 5/24/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/24/2013
Explant Date (E7): 7/8/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-0638 / MW5055394) IN UNITED STATES ON 19-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. THE CONSUMER EXPERIENCED PAIN FROM DAY OF IMPLANTATION AND THEREAFTER ON RIGHT SIDE. DUE TO THIS ONGOING PAIN HER RIGHT TUBE AND COIL WERE REMOVED A FEW WEEKS LATER. AFTER THIS PROCEDURE, SHE CONTINUED TO HAVE PAIN. EMERGENCY ROOM VISITS, CRAMPING, HORRIBLE MENSES AND SEX LIFE AFFECTED WERE REPORTED. SHE CONSULTED ANOTHER DOCTOR IN 2015 AND THEY DECIDED TO HAVE ESSURE REMOVED. THE COIL THAT WAS TO BE REMOVED BACK IN 2013 WAS LEFT IN HER UTERUS. SO THIS COIL PERFORATED AND MIGRATED INTO HER UTERUS AND THEREFORE SHE HAD TO HAVE A HYSTERECTOMY LEAVING HER OVARIES ON (B)(6) 2015. THE CONSUMER WAS TREATED WITH HYDROCODONE AND ADVIL. A DISABILITY WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE RECEIVED VIA REGULATORY AUTHORITY WITH ADDITIONAL INFORMATION IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PELVIC PAIN FROM THE DAY OF IMPLANTATION AND THEREAFTER ON RIGHT SIDE (INTERPRETED AS PELVIC PAIN). HER RIGHT TUBE COILS WERE SUPPOSEDLY REMOVED A FEW WEEKS LATER. HOWEVER, WHEN SHE DECIDED TO HAVE THE OTHER ESSURE INSERT REMOVED, IT WAS NOTICED THAT THE COIL HAD NOT BEEN REMOVED. IT HAD MIGRATED AND PERFORATED HER UTERUS (INTERPRETED AS UTERINE PERFORATION). THEREFORE, SHE HAD TO HAVE A HYSTERECTOMY, AROUND 2 YEARS AFTER INSERTION. PELVIC PAIN AND UTERINE PERFORATION ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY

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INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS, THE CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS AND FURTHER INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHE

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Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057924	ESSURE	11/13/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): OTHER	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE SIDE EFFECTS. SURGERY SCHEDULED FOR SALPINGECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057936	BAYER	11/13/2015	11/19/2015

Event Information:

Event Date (B3): 11/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/9/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE PROBLEMS. BAD SIDE EFFECTS. WEAKNESS IN LEGS/ARMS. FOGGINESS WITH MEMORY. HEAVY BLEEDING. EXTREME FATIGUE, ETC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057928		11/14/2015	11/19/2015

Event Information:

Event Date (B3): 9/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/13/2013
Explant Date (E7): 11/13/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(6) 2013 I HAD THE ESSURE PROCEDURE DONE. I WENT BACK FOR MY 3 MONTH CHECK UP AND THE DOCTOR INFORMED ME THAT ONE OF THE COILS HAD MIGRATED TO MY OVARY. ON (B)(6) 2013 I HAD A SURGERY TO REMOVE THE COIL FROM MY RIGHT OVARY. I HAVE ALSO HAD SOME SEVERE DISCOMFORT WITH THE REMAINING COIL ESPECIALLY DURING INTERCOURSE OVER LAST COUPLE OF YEARS. (B)(6) 2015 I HAD ANOTHER SURGERY TO REMOVE THE LEFT COIL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01453	BAYER HEALTHCARE LLC	11/15/2015	11/15/2015

Event Information:

Event Date (B3): 1/1/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0291, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. SHE REPORTED THAT HER LIFE HAD NOT BEEN THE SAME SINCE THE PROCEDURE. IN 2007, ABOUT 1 YEAR AFTER IMPLANTS, SHE HAD MANY SIDE EFFECTS THAT WERE NEVER DISCUSSED WITH HER. STARTING WITH VERY PAINFUL MENSTRUAL CYCLES. SHE WAS HAVING HORRIBLE ABDOMINAL PAIN 3 OUT OF 4 WEEKS OF THE MONTH. SHE WOULD LIKE TO SEE ESSURE TAKEN OFF THE MARKET FOR GOOD. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP INFORMATION RECEIVED ON 19-OCT-2015: THIS FOLLOW UP

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HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1888). CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED IN 2005 WHEN SHE WAS (B)(6). HER PROBLEMS STARTED IN THE FIRST YEAR, SHE HAD CHRONIC PELVIC PAIN, HEAVY AND PAINFUL CYCLES, PAINFUL SEX, PAINFUL OVULATION, MOOD SWINGS, HAIR LOSS, HOT FLASHES, DEPRESSION AND SEVERE BLOATING. SHE HAD HYSTEROSALPINGOGRAM THAT CONFIRMED BLOCKED. SHE HAD AN ULTRASOUND AND A LAP DIAGNOSIS SURGERY (AS REPORTED) PERFORMED AND FOUND ENDOMETRIOSIS AND HER RIGHT OVARY ADHERED TO HER SIDE WALL. COILS LOOKED TO BE IN PLACE. SHE WAS PLANNING A FULL HYSTERECTOMY LEAVING HER OVARIES IF POSSIBLE. HER KIDS WANTED THEIR MOTHER BACK. FOLLOW-UP INFORMATION RECEIVED ON 20-OCT-2015 AND ADDITIONAL INFORMATION RECEIVED ON 03-NOV-2015 (PTC INVESTIGATION RESULT). THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1889). ESSURE WAS IMPLANTED IN (B)(6) 2005 ((B)(4)). SHE STARTED NOTICING SYMPTOMS WITH IN 1ST YEAR. HER SYMPTOMS WERE: CHRONIC PELVIC PAIN, HEAVY/PAINFUL CYCLES, PAINFUL SEX, PAINFUL OVULATION, MOOD SWINGS, DEPRESSION, HAIR LOSS, INSOMNIA AND HOT FLASHES. SHE THOUGHT SHE WAS GOING THROUGH PRE MENOPAUSE. SHE HAD TESTING DONE AND ALL CAME BACK NORMAL. SHE WENT TO A NEW DOCTOR AND ULTRASOUND AND A LAP WERE DONE. DIAGNOSIS OF SURGERY: HE AT THAT TIME FOUND ENDOMETRIOSIS AND HER RIGHT OVARY WAS ADHERED TO HER SIDE WALLS. HE SAID COILS LOOKED TO BE IN PLACE. HE WANTS TO DO A HYSTERECTOMY LEAVING OVARIES (IF POSSIBLE). SHE STRONGLY BELIEVES THIS WAS ALL CAUSED BY ESSURE, SINCE SHE WAS HEALTHY WITH NO PRIOR HEALTH ISSUES BEFORE ESSURE. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN. SHE HAD AN ULTRASOUND AND A LAP DIAGNOSIS SURGERY (AS REPORTED) PERFORMED AND FOUND ENDOMETRIOSIS AND RIGHT OVARY WAS ADHERED TO HER SIDE WALL. A FULL HYSTERECTOMY WAS PLANNED. CHRONIC PELVIC PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENT IS UNLISTED. BOTH WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, CONSUMER STARTED EXPERIENCING THESE EVENTS IN THE FIRST YEAR. BASED ON THE NATURE OF THE EVENT PELVIC PAIN AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, CONSIDERING THAT A CONTRIBUTORY ROLE OF ESSURE IS UNLIKELY, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED).

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MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 03-NOV-2015: THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01454	BAYER HEALTHCARE LLC	11/15/2015	11/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2010
Explant Date (E7): 9/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0960, AWARENESS DATE 30-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON AN UNSPECIFIED DATE. SHE STATED THAT SHE DID NOT HAVE ANY ENERGY AND WAS IN CONSTANT PAIN. HER SEX LIFE WAS NULL. SHE MENTIONED THAT HAS TO HAVE A SURGERY. FOLLOW-UP INFORMATION RECEIVED ON 02-OCT-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 19-OCT-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1473). ESSURE

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WAS INSERTED IN (B)(6) 2010. SINCE THEN, SHE EXPERIENCED PAINFUL PERIODS, SEVERE PELVIC PAIN, HAIR LOSS, WEIGHT GAIN AND LOSS, LOSS OF APPETITE, INSOMNIA, UNEXPLAINED PAIN SHOOTING THROUGHOUT HER BODY, GERD, THYROID ISSUES, NO SEX DRIVE, DEPRESSION, ANXIETY, DRY SKIN, PEELING SKIN, DEHYDRATION ISSUES, MIGRAINES, NAUSEA, VISION ISSUES, HOT FLASHES, MOOD SWINGS, LACK OF CONCENTRATION AND FREQUENT UTI. HYSTERECTOMY WAS DONE ON (B)(6) 2015 LEAVING HER OVARIES. THE ESSURE COILS AND ENDOMETRIOSIS WAS ALSO REMOVED. SHE WAS STILL SUFFERING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED AND HAD CONSTANT PAIN / SEVERE PELVIC PAIN, AND FREQUENT UTIS (URINARY TRACT INFECTIONS). SHE UNDERWENT A HYSTERECTOMY AND ESSURE REMOVAL 5 YEARS AFTER INSERTION, DURING SURGERY ENDOMETRIOSIS WAS ALSO REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENTS ARE UNLISTED. IN THE PRESENT CASE, ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THE PELVIC PAIN. HOWEVER, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENT PELVIC PAIN, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. URINARY TRACT INFECTIONS AND ENDOMETRIOSIS WERE ASSESSED AS UNRELATED TO ESSURE, GIVEN THEIR PATHOPHYSIOLOGY AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS INITIALLY ASSESSED AS NON-INCIDENT AND UPGRADED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION, AS A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01456	BAYER HEALTHCARE LLC	11/15/2015	11/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2012
Explant Date (E7): 10/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1364, AWARENESS DATE 04-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER HAD GAINED 65 POUNDS SINCE ESSURE WAS INSERTED. SHE WAS HAVING MOOD SWINGS, ANXIETY, DEPRESSION, ZERO SEX DRIVE, IRREGULAR PERIODS, STABBING PAINS IN HER STOMACH, OCCASIONAL RASHES ON ARM AND CHEST, BLURRY VISION AND A POSSIBLE RE-OCCURRENCE OF POLYCYSTIC OVARIAN SYNDROME. FOLLOW-UP RECEIVED ON 19-OCT-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1912). CONSUMER STATED THAT DUE TO HER AGE, (B)(6) AT THE TIME, HER DOCTOR WOULD NO LONGER PRESCRIBE BIRTH-CONTROL FOR HER AND HE SUGGESTED INSTEAD OF GETTING A TUBAL THAT SHE USED ESSURE. HE SAID IT WOULD BE NON-SURGICAL AND THAT IT WILL BE MORE EFFECTIVE THAN A TUBAL LIGATION. IN (B)(6) 2012, THE DOCTOR ATTEMPTED TO INSERT ESSURE INSIDE HER BODY DURING AN OFFICE VISIT. SHE WAS MEDICATED. THE DOCTOR WAS ONLY ABLE TO INSERT A COIL INTO ONE TUBE. SHE WAS ADVISED SHE WOULD HAVE TO HAVE SURGERY TO ATTEMPT THE OTHER INSERTION, FOR SOME REASON HER FALLOPIAN TUBE WAS CLAMPED SHUT. POSSIBLE SHE WAS HAVING A SPASM. IN (B)(6) 2013, SHE WENT INTO THE HOSPITAL AND UNDER HEAVY ANESTHESIA HER DOCTOR WAS ABLE TO INSERT THE OTHER COIL. SHE HAD HER 3 MONTH HYSTEROSALPINGOGRAM (HSG) TEST DONE AND IT WAS CONFIRMED THAT BOTH TUBES WERE BLOCKED. THREE MONTHS AFTER THAT DATE, SHE NOTED SHE

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HAD GAINED WEIGHT: 25 POUNDS TO BE EXACT. SHE CONTACTED HER PHYSICIAN AND HE TOLD HER THAT THE PRODUCT INSERTED COULD NOT CAUSE ANY WEIGHT GAIN. AS TIME WENT ON, HER WEIGHT CONTINUE TO RISE DESPITE THE FACT THAT SHE ATE PROPERTY AND EXERCISE FOUR DAYS A WEEK, SOMETIMES FIVE. SHE NOTICED HER HAIR BEGAN TO THIN AND FALL OUT WHEN SHE WOULD WASH. SHE HAD PAIN IN HER PELVIS AND CONSTANT LOWER BACK PAIN ACROSS THE BASE OF HER BACK FROM LEFT TO RIGHT. SHE HAD ZERO SEX DRIVE, HIGH ANXIETY WITH PANIC ATTACKS AND BOUTS OF DEPRESSION. SHE ALSO HAD RASHES THAT WOULD APPEAR ON HER CHEST AND ARMS FOR NO REASON. EACH TIME SHE WOULD SPEAK TO HER DOCTOR HE WOULD TOLD HER THAT ESSURE WAS IN PLACE, THAT THE COILS COULD NOT MIGRATE AND THAT NONE OF THESE ISSUES WERE ACTUAL SIDE EFFECTS. AFTER SHE NOTICED OTHER REPORTS ON (B)(4), SHE DECIDED TO PUSH HER PHYSICIAN. SHE DEMANDED THAT HE RUN MORE TESTS. RELUCTANTLY HE SENT HER FOR ADDITIONAL BLOOD WORK AND WHEN THE RESULTS CAME IN, SHE WAS TOLD THAT SHE TESTED HIGH FOR C-REACTIVE PROTEIN. SHE HAD CHRONIC INFLAMMATION. THE DOCTOR WANTED TO SEND HER TO A RHEUMATOLOGIST SO THAT HE CAN RULE OUT ANY AUTOIMMUNE DISEASES. SHE OFFER TO SEE THAT DOCTOR, BUT SHE KNEW THAT THERE WAS NOTHING WRONG WITH HER, EXCEPT THAT SHE HAD A DEVICE IMPLANTED IN HER THAT WAS POISONING HER. SHE TOLD HER DOCTOR THAT SHE DEMANDED HE DO A HYSTERECTOMY TO TAKE ESSURE OUT. HE WAS RELUCTANT, BUT AGREED. HOWEVER, SHE ALSO SAW THE NEW PHYSICIAN, AND SHE WENT THROUGH ANOTHER ROUND OF BLOODWORK, PELVIC EXAM, PELVIC ULTRASOUND, VAGINAL ULTRASOUND AND THE RESULT WAS A HYSTERECTOMY NEEDED TO BE PERFORMED. ON (B)(6) 2015, AT THE AGE OF (B)(6), SHE WENT INTO SURGERY TO HAVE HER UTERUS, TUBES AND CERVIX LAPAROSCOPICALLY REMOVED WITH A VAGINAL ASSIST. ONE OF THE COILS MIGRATED OUT OF HER TUBE AND PERFORATED HER UTERUS. AT THAT TIME THEY WERE WAITING FOR THE PATHOLOGY REPORT. SHE WAS ANGRY. HER NON-SURGICAL PROCEDURE ENDED UP CAUSING HER TO HAVE TWO SURGERIES: ONE FOR IMPLANTATION AND ONE TO REMOVE THE PRODUCT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PAIN IN HER PELVIS AND ONE OF THE COILS MIGRATED OUT OF HER TUBE, AND PERFORATED HER UTERUS. SHE UNDERWENT A HYSTERECTOMY 3 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THE PRESENT CASE, IT IS POSSIBLE THAT THE PELVIC PAIN WAS RELATED TO THE UTERINE PERFORATION. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE. IN THE PRESENT CASE THE INSERTION PROCEDURE WAS DIFFICULT AND THE DOCTOR WAS ABLE TO INSERT A COIL IN ONLY ONE TUBE. THE CONTRALATERAL COIL WAS INSERTED ONLY 6 MONTHS LATER. HYSTEROSALPINGOGRAM (HSG) WAS DONE AFTER 3 MONTHS AND CONFIRMED BOTH TUBES WERE BLOCKED. THE EXACT DATE WHEN THE UTERINE PERFORATION OCCURRED WAS NOT SPECIFIED, HOWEVER, GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS UPGRADED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION, SINCE A SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING. (B)(4)

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057929	BAYER	11/15/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

DOCTOR INSERTED ESSURE IN LEFT TUBE, THEN WHEN HE WENT TO INSERT IN RIGHT COULD NOT; TUBE WAS CLOSED. SO I ONLY HAVE ESSURE IN LEFT TUBE. IT WAS INSERTED 2007 I THINK. HAVING CHRONIC PAIN LEFT SIDE SINCE 2013. MY DOCTOR SAID THAT IT WAS NOT THE ESSURE. HE SAID IT WAS SOMETHING WITH INTESTINES. HE SENT ME TO MY GASTROINTESTINAL DOCTOR WHO DID TESTS. EVERYTHING WAS FINE. MY GASTRO DOCTOR SAID IT WAS MY ESSURE. SENT ME BACK TO GYNECOLOGIST WHO HAD ME HAVE MRI AND CAT SCAN. BOTH THE MRI AND CAT SCAN SHOW THE SAME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057935	BAYER	11/15/2015	11/19/2015

Event Information:

Event Date (B3): 9/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/11/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

WELL THE FIRST THING I NOTICED WAS PAIN DURING URINATION, COUGHING, SEX, AND MY BIGGER ISSUE HAIR LOSS. I BRUISE NOW AND IT WON'T GO AWAY SO I AM ASSUMING THAT IT CAUSES SOME KIND OF-IRON DEFICIENCY AND ALWAYS A NICKEL OILY FEEL IN MY MOUTH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057937	BAYER	11/15/2015	11/19/2015

Event Information:

Event Date (B3): 6/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): C76447

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I'M A (B)(6) SINGLE MOM WHO HAS A (B)(6). I WORK FULL TIME AND GO TO SCHOOL PART TIME. I HAVE HAD NO PRIOR HISTORY OF ANY GYNECOLOGICAL PROBLEMS. ESSURE SEEMED TO BE THE BEST OPTION FOR ME BECAUSE THE DOWN TIME IS VERY LITTLE AND I WAS TOLD THE SIDE EFFECTS WOULD BE MINIMAL. WELL WAS I WRONG. I HAVE GONE FOR HAVING MY PERIOD FOR 1 DAY AND A HALF TO 8 DAYS BLEEDING THROUGH A SUPER TAMPON AND A PAD EVERY 2-3 HRS. BESIDE THE FACT THAT THE CRAMPING, BLOATING, GAS WAS SO INTENSE. I WOULD BE TAKING 1000 MG OF IBUPROFEN WAY TO OFTEN. SHORTLY AFTER HAVING THE IMPLANT, I HAD SEEN MY GYN FOR A POST-OP VISIT. I HAD EXPLAINED ALL MY SYMPTOMS INCLUDING FATIGUE, UNEXPLAINED MUSCLE ACHES, INCREASED IRRITABILITY, AND THE OCCASIONAL NAUSEA. HER AND I CHALKED IT UP TO THE FACT IT HAD ONLY BEEN A MONTH. ALMOST 3 AND A HALF MONTHS LATER, I HAD GONE IN FOR THE BARBARIC HSG CONFIRMATION TEST ONLY TO FIND OUT ONE FALLOPIAN TUBE IS BLOCKED AND THE OTHER IS ONLY 10% BLOCKED. I HAD CRIED IN AGONY TO MY GYN TO REMOVE THESE IMPLANTS. ON WEDNESDAY (B)(6) 2015, I WILL BE GOING TO MY GYN'S OFFICE TO TALK AND SET UP A HYSTERECTOMY, SINCE THAT SEEMS TO BE MY ONLY OPTION OF RETURNING TO SOME SORT OF NORMALCY. JUST THIS PAST SATURDAY, I HAD SEEN MY HAIRDRESSER FOR WHOM I HAVE BEEN GOING TO FOR 8 YRS ASKED ME IF I NOTICED MY HAIR GETTING THINNER. JUST ANOTHER SIDE EFFECT TO THE ESSURE IMPLANTS. I AM WAY TO YOUNG TO HAVE TO BE GOING THROUGH SUCH A HORRIBLE, FALSE ADVERTISING DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057938	BAYER	11/15/2015	11/19/2015

Event Information:

Event Date (B3): 2/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): B97494

Single Use: *
Implant Date (E6): 2/11/2015
Explant Date (E7): 9/28/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2015 MY DOCTOR TOLD ME ABOUT ESSURE COILS THAT WERE PLASTIC AND HOW EFFECTIVE THEY WERE. IT WAS A SIMPLE PROCEDURE AND FELT THAT I WOULD BE A GOOD CANDIDATE FOR IT. I HAD ESSURE IMPLANTED (B)(6) 2015 AND IMMEDIATELY HAD PAIN IN MY PELVIC AREA. IT WAS PAINFUL TO STAND OR SIT, AND IT NEVER WENT AWAY. I WENT BACK TO MY DOCTOR AND WAS TOLD IT WAS NORMAL TO GIVE IT A COUPLE OF WEEKS. WEEKS AND MONTHS WENT BY AND STILL NO IMPROVEMENT. I WENT TO OTHER DOCTORS TRYING TO FIND OUT WHAT WAS WRONG. MULTIPLE TESTS AND MRI'S WERE DONE AND COULD NOT FIND ANYTHING. I FINALLY FOUND AN OB/GYN THAT THOUGHT HE COULD HELP ME. I HAD A HYSTERECTOMY REMOVING MY TUBES WITH THE COILS (B)(6) 2015. WHEN I WOKE UP THE PAIN THAT I HAD BEEN EXPERIENCING THE PAST 7 MONTHS. IN DOING RESEARCH FOR MY SURGERY, I FOUND OUT VIA INTERNET ON (B)(6) 2015 THAT THE COILS WERE METAL AND NOT PLASTIC AS I HAD BEEN TOLD. HAD I BEEN TOLD THAT AT THE BEGINNING, I WOULD HAVE NEVER AGREED TO PUT METAL IN MY BODY. I AM NOW HEALING WELL FROM THE SURGERY AND THINGS ARE BETTER SINCE THE REMOVAL OF THE COILS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01459	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1739, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. THE CONSUMER HAS HAD HORRIBLE HEAVY AND LONG PERIODS SINCE, AND SHE HAD INTERMITTENT PELVIC PAIN TOO, WHICH BECAME CHRONIC. IN ORDER TO GET THE ESSURE REMOVED AND RELIEVE HER FROM HER SYMPTOMS, SHE WILL BE HAVING A HYSTERECTOMY NEXT MONTH. THE EVENTS WERE CONSIDERED RELATED TO ESSURE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 07-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED

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MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED INTERMITTENT WHICH BECAME CHRONIC PELVIC PAIN. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE PATIENT HAS HAD INTERMITTENT PELVIC PAIN WHICH BECAME CHRONIC AND OTHER NON-SERIOUS EVENT. IN ORDER TO GET THE ESSURE REMOVED, SHE WILL BE HAVING A HYSTERECTOMY IN THE FOLLOWING MONTH. CONSIDERING EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 07-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01460	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 11/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT WAS RECEIVED VIA SOCIAL MEDIA (TWITTER). IT WAS POSTED ON (B)(6) IN UNITED STATES AND WAS RECEIVED BY BAYER ON (B)(6) 2015 AND IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT ESSURE FAILED THE CONSUMER. A PICTURE OF A UTERUS SUGGESTING TOTAL HYSTERECTOMY WAS ATTACHED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6)2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY ASSESSMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND UNDERWENT A TOTAL HYSTERECTOMY. THE REPORTED EVENT WAS

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CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED REGARDING THE REASON FOR THE PLANNED PROCEDURE. IT WAS ALSO REPORTED THAT ESSURE FAILED THE CONSUMER. AS THE PROCEDURE IS PLANNED DUE TO ESSURE PROBLEMS AND NO FOLLOW-UP WILL BE POSSIBLE (SOCIAL MEDIA CASE); COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE PLANNED SURGICAL INTERVENTION, THIS CASE WAS CONSIDERED AN INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FOLLOW-UP INFORMATION CAN BE OBTAINED SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

-RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 05-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01461	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1516, AWARENESS DATE 19-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. THE CONSUMER REPORTED SHE WAS VERY HEALTHY PRIOR TO ESSURE. SHE WAS SCHEDULED TO HAVE AN ABLATION AND HAD TO HAVE ONE COIL REMOVED IN (B)(6) 2011 DUE TO IT NOT TAKING IN THE FALLOPIAN TUBE. ABLATION WAS NOT DONE BUT SHE DOES NOT KNOW THE REASON AND HER TUBES WERE CLAMPED. ON AN UNSPECIFIED DATE SHE BEGAN HAVING LONG PERIODS, SUPER HEAVY AND NON STOP, CONTINUAL SHARP CHEST PAINS, PELVIC PAINS, NUMBNESS AND TINGLING OF THE LIMBS AND CHARLIE HORSES CRAMPING IN MY HIPS AND FEET. THE DOCTORS TOLD HER THEY HAD NO CLUE WHAT THE ISSUE WAS. SHE ALSO HAD BRAIN FOG, FATIGUE, HORMONAL ISSUES, SEX DRIVE DECREASE, MIGRAINES DAILY, BACK PAIN AND CRACKING OF THE BONES EVERY TIME SHE STOOD UP. HER TATTOO WOULD BE SO INFLAMED ON HER BACK THAT SHE HAD WELTS AND SCARS FROM SCRATCHING IT. HER AUTO IMMUNE SYSTEM WAS THROWN OFF PERMANENTLY AND SHE ALSO HAD TREMORS, DRENCHING NIGHT SWEATS, NAUSEA, DIZZINESS, BLOATING, VAGINITIS, ANXIETY, JOINT PAIN, SEXUAL DYSFUNCTION, DENTAL ISSUES, BREATH CONSTANTLY FOUL, VITAMIN DEFICIENCIES, BREAST TENDERNESS, DEPRESSION AND MANY OTHER SYMPTOMS. SHE WAS ABLE TO FALL ASLEEP DURING A CONVERSATION DRIVING OR LISTENING AND MANY TIMES SHE WOULD ZONE OUT DURING A CONVERSATION. THE CONSUMER DID AN X-RAY AND RESULTS SHOWED THAT LAST REMAINING COIL HAD PERFORATED THROUGH AND WAS SITTING VERY CLOSELY TO HER COLON THREATENING TO PUNCTURE IT. SHE WAS SCHEDULED FOR A SURGERY AND THE DAYS LEADING UP TO WHERE SHE

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WAS OUTPATIENT AT A HOSPITAL SHE HAD A MIGRAINE CONSISTENTLY FOR 13 DAYS, VERY SEVERE. ONCE THE SURGERY WAS OVER MANY OF HER SYMPTOMS EITHER DECREASED OR WENT AWAY, BUT SHE STILL HAD MANY OF THOSE ISSUES, BUT MINIMAL. OCCASIONALLY SHE GOT CHEST PAINS AND HER FEET STILL GOT CHARLIE HORSES. SHE HAD DAILY DISCHARGE AND FOUL ODORS AND THIS CAUSED HER TO NOT WANT TO GO OUT OR HAVE SEX BECAUSE AFTER SEX THERE WAS A FOUL SMELL OR SHE BEGAN SPOTTING DURING INTERCOURSE. THE OUTCOME OF THE EVENTS CONTINUAL SHARP CHEST PAINS / EVERY NOW AND THEN HAVE CHEST PAINS AND CHARLIE HORSES CRAMPING IN MY HIPS AND FEET WAS NOT RECOVERED / NOT RESOLVED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN THE EVENTS AND ESSURE IS RELATED. FOLLOW-UP RECEIVED ON 05-NOV-2015: PTC INVESTIGATION RESULT WAS PROVIDED. THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT AN ABLATION WAS PERFORMED AND ONE COIL REMOVED DUE TO IT NOT TAKING IN THE FALLOPIAN TUBE (SEEN AS DEVICE DISLOCATION). SHE UNDERWENT AN X-RAY AND THE RESULTS SHOWED LAST REMAINING COIL HAD PERFORATED THROUGH AND WAS SITTING VERY CLOSELY TO HER COLON (SEEN AS UTERINE PERFORATION). A SURGERY WAS PERFORMED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM FOR BOTH EVENTS WERE NOT KNOWN. CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, SEVERAL NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01462	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1541, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE, TO TIE HER TUBES. IT WAS REPORTED THAT OVER 5 YEARS THE CONSUMER GAINED WEIGHT, HAD SEVERE NICKEL ALLERGIES AND THE PET FIBERS INSIDE THE COILS WERE WHAT CAUSED HER CANCER. ESSURE PERFORATED HER FALLOPIAN TUBE AND WENT INTO HER BLADDER, LEADING HER TO HAVE A HYSTERECTOMY BECAUSE OF THIS. FOLLOW UP RECEIVED ON 05-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE

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CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CANCER. IT WAS ALSO REPORTED THAT ESSURE PERFORATED HER FALLOPIAN TUBE AND WENT INTO HER BLADDER, LEADING HER TO HAVE A HYSTERECTOMY. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. CANCER IS AN UNLISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENTS ARE LISTED. INTERNAL ORGANS PERFORATION MAY OCCUR WITH ESSURE, DUE TO DEVICE MIGRATION OR DURING INSERTION PROCEDURE, MAY ALSO OCCUR DURING HYSTEROSCOPY, AS WELL AS DURING DEVICE PLACEMENT; THIS RISK IS INHERENT WITH ANY HYSTEROSCOPIC PROCEDURE. IN THIS PARTICULAR CASE, ESSURE PERFORATED HER FALLOPIAN TUBE AND WENT INTO HER BLADDER. THE EXACT DATE OF PERFORATION IS NOT KNOWN. A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE EVENTS CANNOT BE EXCLUDED. CANCER DESCRIBES A LARGE GROUP OF PROCESSES CHARACTERIZED BY UNCONTROLLED GROWTH AND SPREAD OF CELLS, WHICH LOSE THEIR ABILITY TO DIFFERENTIATE AND LACK THE NORMAL CONTROLS OF GROWTH. CONSIDERING THE PATHOPHYSIOLOGY OF CANCER AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01463	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1655, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE HUSBAND OF THE CONSUMER REPORTED THAT SHE SUFFERED FROM SEVERE PELVIC PAIN AND NUMEROUS OTHER PROBLEMS AFTER SHE WAS IMPLANTED WITH ESSURE. SHE ALSO HAD WEIGHT GAIN, SKIN PROBLEMS, HAIR LOSS AND SEVERE ITCHING. SHE HAD TO GET A HYSTERECTOMY TO HAVE THEM REMOVED. AFTER BEING REMOVED, HER PROBLEMS COMPLETELY WENT AWAY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 05-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY. COMPANY CAUSALITY

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COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED EXPERIENCING SEVERE PELVIC PAIN. SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE AND HER SYMPTOMS RESOLVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE NATURE OF THIS EVENT, AND SINCE THE PAIN RESOLVED AFTER ESSURE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PREVIOUSLY PROVIDED CODES ADDED TO REPORT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01464	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1891, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE MISSED A LOT IMPORTANT EVENT BECAUSE SHE WAS SICK ALL THE TIME. SHE HAVE MISSED SO MANY DAYS OF WORK BECAUSE OF HER SYMPTOMS. SHE HAD TWO SURGERIES. THE FIRST ONE ONLY ONE COIL GOT REMOVED ALONG WITH THE FALLOPIAN TUBES. THE SECOND SURGERY WAS A FULL HYSTERECTOMY AND FINALLY THE LAST COIL GOT REMOVED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 06-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(6). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A

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QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO STATED SHE WAS SICK ALL THE TIME WITH ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). SHE HAD ONE COIL REMOVED ALONG WITH THE FALLOPIAN TUBES. AN UNSPECIFIED TIME LATER, A FULL HYSTERECTOMY WAS PERFORMED AND THE LAST COIL WAS REMOVED. ONLY SICKNESS IS UNLISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, MINIMAL INFORMATION WAS PROVIDED. NEITHER CONSUMER'S SICKNESS WAS SPECIFIED NOR WAS THE MEDICAL REASON FOR THE REPORTED SURGERIES PROVIDED. NEVERTHELESS; IT CANNOT BE EXCLUDED THESE SURGERIES WERE PERFORMED AS A CONSEQUENCE OF ESSURE THERAPY. THEREFORE; THIS CASE WAS CONSIDERED AN INCIDENT (DEVICE REMOVAL WAS REQUIRED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01465	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7): 7/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER REPORTED THAT SHE STARTED TO GET VERY TIRED, GAINED UNEXPLAINED WEIGHT, HER SKIN HAD FADED TO A GREYISH HUE, FATIGUE, SEVERE MOOD SWINGS, EXCESSIVE PAIN IN RANDOM SPOT ALL OVER HER BODY, SPECIALLY HIPS AND JOINTS, IRON DEFICIENCY WHICH NEEDED IRON SUPPLEMENTS FOR, VITAMIN D DEFICIENCY WHICH REQUIRED VITAM D SUPPLEMENT, MIGRAINES THAT WOULD KEEP HER IN BED FOR DAYS, THE PAIN WAS UNBEARABLE AND SHE WOULD GET VERY HEAVY VERY PAINFUL PERIODS THAT LASTED 15 TO 34 DAYS WITH ONE OR TWO DAYS BETWEEN EACH CYCLE. IN (B)(6) 2014 SHE HAD A HYSTERECTOMY PERFORMED. SINCE THEN ALL HER PAIN WAS GONE, HER SKIN COLOUR WAS BACK, SHE NEVER GET MIGRAINES, HER KIDS HAVE THEIR MOTHER BACK WITHOUT THE MOOD SWINGS AND SHE LOST WEIGHT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING VERY HEAVY PERIODS THAT WOULD LAST 15-34 DAYS. SHE UNDERWENT A HYSTERECTOMY 2 YEARS AFTER ESSURE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THIS EVENT, POSITIVE TEMPORAL RELATIONSHIP AND THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION

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WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01466	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1742, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2005. THE CONSUMER EXPERIENCED PAIN, MOOD SWINGS, PUNCHERED (INTERPRETED AS PUNCTURED) UTERUS IN 2010, THYROID NUMBER TOO HIGH AND THROAT CLOSING UP. SHE VISITED THE EMERGENCY ROOM ON (B)(6) 2015 AND EXPERIENCED EXTREME PAIN FROM PELVIC TO FOOT. ONE COIL WAS REMOVED IN 2010, AND THE REMAINING ONE WAS PARALYZING HER WITH PAIN. SHE STATED SHE SEEMED TO BE AN EARLY FILLED WITH EMOTIONAL AND PHYSICAL PAIN. ALL EVENTS WERE CONSIDERED RELATED TO ESSURE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD PAIN (PAIN FROM PELVIC TO FOOT) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE STATED ONE COIL PUNCHERED UTERUS (INTERPRETED AS PUNCTURED UTERUS). ADDITIONALLY, ACCORDING TO HER ONE COIL WAS REMOVED. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE PAIN DURING/AFTER THE ESSURE PROCEDURE. IN THIS PARTICULAR CASE, CONSUMER HAD THE PERFORATION (PUNCTURED UTERUS) DIAGNOSED 5 YEARS AFTER ESSURE PROCEDURE. ALTHOUGH THE EXACT MECHANISM OF ESSURE PERFORATION WAS UNKNOWN; GIVEN EVENTS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE

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WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE FROM HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01479	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/22/2009
Explant Date (E7): 5/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055776) IN UNITED STATES ON 19-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. THE CONSUMER STATED THAT SINCE INSERTION SHE HAD EXPERIENCED UNEXPLAINED RASHES AND SEVERE PELVIC PAIN, LONGER CYCLES, MAJOR BLOATING CONSTIPATION, STARTED GETTING MIGRAINES AND WAS FATIGUED ALL THE TIME. ESSURE REMOVAL DATE WAS (B)(6) 2015. DISABILITY/PERMANENT DAMAGE WAS REPORTED AS SERIOUSNESS CRITERIA. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PELVIC PAIN. THIS

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EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SINCE THE INSERTION THE CONSUMER HAS BEEN PRESENTING SEVERE PELVIC PAIN AND OTHER NON-SERIOUS EVENTS. GIVEN EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE ESSURE REMOVAL WAS REQUIRED, IMPLYING THAT AN INTERVENTION WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION ON 11-NOV-2015: DESPITE FOLLOW-UP ATTEMPTS, NO RESPONSE WAS RECEIVED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE O

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01480	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044982) IN UNITED STATES ON 19-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE TO NOT GET PREGNANT. THE CONSUMER STATED SHE ENDED UP CRAMPING ALL THE TIME AND LATER SHE HAD TO HAVE HER UTERUS REMOVED. HOSPITALIZATION WAS MENTIONED AS SERIOUSNESS CRITERIA. FOLLOW-UP RECEIVED ON 07-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD, WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING ALL THE TIME. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY

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INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER STATED SHE HAD CRAMPING ALL THE TIME AND LATER SHE HAD TO HAVE HER UTERUS REMOVED. CONSIDERING EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01481	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/12/2013
Explant Date (E7): 10/14/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056732) IN UNITED STATES ON 19-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) -2013. ADDITIONAL INFORMATION WAS IDENTIFIED ON 23-OCT-2015 DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2002). CONSUMER EXPERIENCED CONTINUAL/ SEVERE ABDOMINAL PAIN, NAUSEA, HEADACHE, THINNING HAIR, LOSS OF APPETITE, PELVIC PAIN AND BLOATING. ON (B)(6) 2014, SHE HAD RIGHT FALLOPIAN TUBE AND OVARY REMOVED. THE PAIN WAS STILL PRESENT AND SHE WAS IN THE PROCESS OF DISCUSSING A COMPLETE OR PARTIAL HYSTERECTOMY WITH HER DOCTOR. SHE WAS STILL EXPERIENCING MOST OF THE SYMPTOMS. SHE LIVED IN PAIN FOR NEARLY TWO YEARS AFTER THIS WAS IMPLANTED. SHE WENT TO NUMEROUS DOCTOR VISITS AND TO THE EMERGENCY ROOM WHEN THE PAIN GETS TO BE MORE THAN SHE COULD HANDLE. SHE STILL HAS IMPLANT IN LEFT FALLOPIAN TUBE. SHE STATED HER BODY WAS COMPLETELY REJECTING THE IMPLANTS. SHE QUESTIONED IF AN EXAM TO DETERMINE NICKEL ALLERGY SHOULD NOT BE PERFORMED AND SAID THAT IF HER EARS ARE SENSITIVE TO NICKEL, HOW HER ORGANS WOULD NOT BE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONTINUAL ABDOMINAL PAIN AND PELVIC PAIN. SHE HAD RIGHT FALLOPIAN TUBE AND OVARY REMOVED. A COMPLETE OR PARTIAL HYSTERECTOMY WAS IN THE PROCESS OF DISCUSSING. SHE STILL HAS IMPLANT IN LEFT FALLOPIAN TUBE. THE REPORTED EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS REPORTED THAT CONSUMER LIVED IN PAIN FOR NEARLY TWO YEARS AFTER ESSURE INSERTION. BASED ON THEIR NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO SURGICAL INTERVENTION PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 21-DEC-2015: FOLLOW-UP ATTEMPTS WERE MADE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01482	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/13/2012
Explant Date (E7): 1/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055606) IN UNITED STATES ON 19-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER 962097 INSERTED ON (B)(6) 2012. CONSUMER STATED THAT ESSURE WAS IMPLANTED AND THE BLEEDING ENSUED FOR OVER 90 DAYS. THEN SEVERE CRAMPING, HEADACHES, LOWER BACK PAIN AND THE PROCEDURE DID NOT TAKE ON ONE SIDE. IN THE 2 YEARS LEADING UP TO HYSTERECTOMY SHE BLED FOR MONTHS AT A TIME, COULD NOT HAVE INTERCOURSE, AND WAS MOSTLY IN BED FOR THE TIME UNTIL IT WAS REMOVED. THAT SIDE IT HAD FLOATED INTO HER UTERUS AND WAS CONNECTING TO HER WALL CAUSING MORE BLEEDING. SHE STATED SHE HAD TO MOVE TO ANOTHER PLACE AND ENDED UP HAVING A PARTIAL HYSTERECTOMY DUE TO ESSURE. EXPLANT DATE WAS REPORTED AS (B)(6) 2015. (B)(6) WAS REPORTED AS CONCOMITANT MEDICATION. FOLLOW-UP DATED 12-NOV-2012: CASE (B)(4) WAS IDENTIFIED AS A DUPLICATE OF THIS CASE AND WILL BE DELETED FROM BAYER DATABASE. ALL INFORMATION FROM THAT CASE WAS TRANSFERRED TO THIS REMAINING CASE AND THERE WAS NO NEW INFORMATION. COMPANY CAUSALITY COMMENT : THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE BLEEDING ENSUED FOR OVER 90 DAYS/ SHE BLED FOR MONTHS AT A TIME (INTERPRETED AS GENITAL BLEEDING), IT HAD FLOATED INTO HER UTERUS AND WAS CONNECTING TO HER WALL (INTERPRETED AS DEVICE EMBEDDED) CAUSING MORE BLEEDING (INTERPRETED AS UTERINE BLEEDING). SHE UNDERWENT A PARTIAL HYSTERECTOMY AND ESSURE WAS REMOVED, TWO AND A HALF YEARS AFTER INSERTION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING MAY OCCUR. GIVEN THE POSITIVE TEMPORAL

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RELATIONSHIP AND NATURE OF THE EVENT BLEEDING ENSUED FOR OVER 90 DAYS/ SHE BLED FOR MONTHS AT A TIME, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE DEVICE EMBEDMENT, THE EXACT DATE AND MECHANISM OF THIS EVENT WAS NOT SPECIFIED. HOWEVER, GIVEN THE NATURE OF THE EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED, AND SINCE THE EMBEDDED DEVICE WAS CAUSING MORE BLEEDING, THIS EVENT WAS ALSO CONSIDERED RELATED TO THE DEVICE. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP DATED 12-NOV-2012: CASE (B)(4) WAS IDENTIFIED AS A DUPLICATE OF THIS CASE AND WILL BE DELETED FROM BAYER DATABASE. ALL INFORMATION FROM THAT CASE WAS TRANSFERRED TO THIS REMAINING CASE AND THERE WAS NO NEW INFORMATION. FOLLOW-UP INFORMATION PROV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01483	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1927, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. SINCE INSERTION THE CONSUMER EXPERIENCED A LONG LIST OF SIDE EFFECTS THAT CONTINUED TO GET PROGRESSIVELY WORSE AS TIME WENT ON. FOR THE FIVE YEARS THAT SHE HAD THE DEVICES SHE EXPERIENCED CHRONIC CRAMPING AND BLOATING, PAINFUL INTERCOURSE, PAIN AND BLOATING AFTER INTERCOURSE, CHRONIC PELVIC PAIN, STABBING PAINS IN OVARIES/FALLOPIAN TUBES, PAINFUL OVULATION, LOSS OF LIBIDO AND OTHER DYSFUNCTIONS, AN ENLARGED UTERUS AND SEVERE PELVIC ADHESIONS THAT INCLUDED BLADDER, WHICH LEAD TO PAIN AND OTHER SYMPTOMS. CHRONIC FATIGUE, EXTREME HAIR LOSS, RASHES AND SKIN ISSUES, MUSCLE AND JOINT PAIN, DENTAL PROBLEMS AND CHRONIC WHOLE BODY INFLAMMATION, HORMONAL ISSUES THAT CREATE MORE PROBLEMS, DEPRESSION AND ANXIETY, MENTAL AND COGNITIVE ISSUES, SINUSES PROBLEMS AND MANY MORE. SHE STATED SHE COULD FEEL IT AS HER BODY AND MIND WERE BEING POISONED AND SLOWLY DYING. THE CONSUMER HAD ESSURE REMOVED ALONG WITH HER FALLOPIAN TUBES, UTERUS, CERVIX AND A LARGE AMOUNT OF SCAR TISSUE. SHE CONSIDERED ALL EVENTS RELATED TO ESSURE. FOLLOW-UP RECEIVED ON 07-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE

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WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN. SHE HAD ESSURE REMOVED ALONG WITH HER FALLOPIAN TUBES, UTERUS, CERVIX AND A LARGE AMOUNT OF SCAR TISSUE. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS REPORTED THAT FOR THE FIVE YEARS THAT SHE HAD THE DEVICES, SHE EXPERIENCED THIS EVENT. BASED ON ITS NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, ANOTHER SERIOUS EVENT (BODY AND MIND WERE BEING POISONED, UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01484	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH PROFESSIONAL VIA REGULATORY AUTHORITY (CASE# MW5041969) IN UNITED STATES ON 19-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE PATIENT EXPERIENCED CHRONIC PELVIC PAIN, INFLAMMATION, SCIATICA PAIN, NUMBNESS IN MY LEGS AND FEET, HEAVY AND IRREGULAR BLEEDING, DIZZINESS, MIGRAINES, HAIR LOSS, EXTREME DEBILITATING FATIGUE DUE TO THE PAINS, PAINFUL PERIODS, PAINFUL INTERCOURSE, UNEXPLAINED WEIGHT GAIN, VOMITING, STABBING PELVIC PAIN AND VAGINAL PAIN, AND RASHES ALL OVER THE BODY. EVENT DATE WAS (B)(6) 2013 (NOT SPECIFIED). IT HAD BEEN LIKE THIS FOR 2 YEARS AND SHE WOULD NEED A HYSTERECTOMY TO REMOVE DEVICE. SHE WAS SEEN BY AN ONCOLOGIST DUE TO ABNORMAL CANCER LABS TESTED POSITIVE FOR UNSPECIFIED CANCER AND ABNORMAL HORMONE LAB RESULTS. SERIOUSNESS CRITERIA INCLUDED LIFE THREATENING, HOSPITALIZATION, REQUIRED INTERVENTION AND OTHER SERIOUS (IMPORTANT MEDICAL EVENT). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE

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REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY ASSESSMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN, STABBING PELVIC PAIN AND HEAVY AND IRREGULAR BLEEDING (INTERPRETED AS GENITAL BLEEDING). THESE EVENTS WERE CONSIDERED SERIOUS (REPORTER MENTIONED LIFE-THREATENING AND HOSPITALIZATION AS EVENT OUTCOME, HOWEVER DID NOT SPECIFY IT) AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IT WAS ALSO REPORTED THAT PATIENT WAS SEEN BY AN ONCOLOGIST DUE TO ABNORMAL CANCER LABS TESTED POSITIVE UNSPECIFIED CANCER, WHICH WAS CONSIDERED SERIOUS AND UNLISTED. IN THIS CASE, IT WAS REPORTED THAT PATIENT WOULD NEED A HYSTERECTOMY IN ORDER TO REMOVE DEVICE. CONSIDERING THAT PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY AND BASED ON THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, CONSIDERING THAT CANCER DIAGNOSIS IS A LONG PROCESS AND ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01485	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 19-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER STATED A WHILE AFTER ESSURE INSERTION, SHE WAS HURTING REAL BAD IN HER UTERUS, AND STILL WAS EXPERIENCING IT. SHE WAS IN THE HOSPITAL TWICE, EXPERIENCED BACK PAIN AND LOST SOME OF HER HAIR AND IT WAS GONE THIN WITH TERRIBLE MIGRAINES, WHICH SHE WAS ON TWO DIFFERENT MEDICATIONS (TOPOMAX AND NORTRIPTOLYN). SHE ASSESSED HOSPITALIZATION AS EVENT OUTCOME HOWEVER SHE DID NOT PROVIDE MORE DETAILS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO WAS HURTING REAL BAD IN HER UTERUS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE STATED SHE WAS IN THE HOSPITAL TWICE. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER DEVELOPED UTERINE PAIN A WHILE AFTER ESSURE INSERTION. ALTHOUGH LIMITED INFORMATION WAS PROVIDED, SINCE CONSUMER RELATED HER PAIN TO ESSURE AND AS NO FOLLOW-UP WILL BE POSSIBLE; COMPANY CONSIDERS CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. AS HOSPITALIZATION CANNOT BE FORMALLY EXCLUDED IN THIS CASE, IT WAS REGARDED AS AN INCIDENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 10-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01486	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1487, AWARENESS DATE ON 19-OCT-2015 AND FDA-2014-N-0736-1875, AWARENESS DATE ON 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. SHE STATED THAT SHE HAD SHARP ABDOMINAL PAINS, MIGRAINES, RASHES, ABDOMINAL BLOATING, DEPRESSION, NAUSEA, UNEXPLAINED WEIGHT GAIN, DIZZINESS, AND SEVERE CRAMPING. IN 2013 SHE HAD AN OVARIAN CYST THAT WENT AWAY ON ITS OWN AFTER MONTHS OF PAIN. SHE STATED THAT SHE WENT TO HER DOCTOR A FEW DAYS BEFORE THE DATE OF REPORT (2015) FOR PREGNANCY SYMPTOMS AND CONSTANT PAIN AND CRAMPING IN HER LOWER ABDOMEN. AFTER 3 HOURS OF EVERY TEST IMAGINABLE, THEY STILL DID NOT HAVE A DEFINITE ANSWER. DOCTORS COULD NOT SEE HER RIGHT ESSURE COIL, SHE HAD MASS (EITHER A BLIGHTED OVUM OR CYST OR EMBRYO) ATTACHED TO RIGHT OVARIAN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE WENT TO A DOCTOR FOR PREGNANCY SYMPTOMS AND CONSTANT PAIN IN LOWER ABDOMEN. DOCTORS COULD NOT SEE HER RIGHT ESSURE COIL BECAUSE THERE WAS A MASS ATTACHED TO THE RIGHT OVARY. THE SUSPICIONS WERE THAT THIS MASS (INTERPRETED AS OVARY MASS) WAS EITHER A BLIGHTED OVUM OR CYST OR EMBRYO (INTERPRETED AS ECTOPIC PREGNANCY WITH ESSURE INSERT). THE ECTOPIC PREGNANCY AND OVARIAN MASS ARE SERIOUS EVENTS. THE ECTOPIC PREGNANCY IS LISTED WHILE THE OVARIAN MASS IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE,

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THERE ARE MULTIPLE DIAGNOSES SUSPECTED FOR THE OVARIAN MASS, BUT THE DIAGNOSIS HAS NOT BEEN CONFIRMED YET. CONSIDERING THE NATURE OF AN OVARIAN MASS AND LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT ESSURE INSERTS WOULD CONTRIBUTE TO THE DEVELOPMENT OF THIS SUSPECTED DISEASE. HOWEVER, THIS OVARIAN MASS COULD BE AN ECTOPIC PREGNANCY. ALTHOUGH THE ECTOPIC PREGNANCY WAS NOT CONFIRMED YET, CONSIDERING THAT THE PREGNANCY SYMPTOMS STARTED AROUND 4 YEARS AFTER ESSURE INSERTION AND THAT THE RELATIVE RISK OF HAVING AN ECTOPIC PREGNANCY INCREASES WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE THE SUSPECTED ECTOPIC PREGNANCY IS A SERIOUS INJURY THAT REQUIRES A MEDICAL/SURGICAL INTERVENTION. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01487	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): 11/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/17/2010
Explant Date (E7): 8/27/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 25-OCT-2013 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER MW5031880, RECEIVED AT FDA ON 11-SEP-2013). THE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED BLEEDING AND HEAVY CLOTTING, 2-3 WEEKS PER MONTH, SHARP STABBING PAIN, PAINFUL, SERIOUS MIGRAINES, ANEMIA, VITAMIN D DEFICIENCY, NIGHT SWEATS, UNEXPLAINED FEVERS, FATIGUE, SEVERE BLOATING, INFLAMMATION, BODY ACHES, AND PAINFUL INTERCOURSE. FDA REPORT TYPE WAS 'INJURY', REPORTED OUTCOME OF EVENTS (NOS) WAS 'HOSPITALIZATION'. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2010, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED FOR BIRTH CONTROL. SINCE IMPLANTATION ON (B)(6) 2010, THE CONSUMER EXPERIENCED SHARP STABBING PAIN, BLEEDING AND HEAVY CLOTTING, 2-3 WEEKS PER MONTH, PAINFUL, SERIOUS MIGRAINES, ANEMIA, VITAMIN D DEFICIENCY, NIGHT SWEATS, UNEXPLAINED FEVERS, FATIGUE, SEVERE BLOATING, INFLAMMATION, BODY ACHES, AND PAINFUL INTERCOURSE. THE OUTCOME OF EVENTS WAS REPORTED AS 'HOSPITALIZATION'. ESSURE WAS REMOVED ON (B)(6) 2013. REPORTER DID NOT ASSESS DRUG-EVENT RELATIONSHIP. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 03-FEB-2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). PTC RESULTS RECEIVED ON 04-FEB-2014: FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE REPORTED MEDICAL EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY

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DEFECT. NO BATCH NUMBER WAS REPORTED. NO COMPLAINT SAMPLE WAS PROVIDED FOR TECHNICAL INVESTIGATION. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER OR SAMPLE. AT TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT"; BUT WITH A FINAL RISK CATEGORY II WHICH CORRESPONDS TO A CONFIRMED OR PLAUSIBLE QUALITY DEFECT WHICH POSES A SERIOUS HAZARD TO HEALTH. ALTHOUGH THE TECHNICAL INVESTIGATION APPEARS TO CONCLUDE A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFECT, FROM A MEDICAL POINT OF VIEW A POTENTIAL CAUSAL RELATIONSHIP WITH A QUALITY ISSUE BASED ON THE NATURE OF THE REPORTED MEDICAL EVENTS IS CONSIDERED TO BE VERY UNLIKELY. FOLLOW-UP INFORMATION RECEIVED ON 11-FEB-2014: FOLLOW-UP ATTEMPTS WERE DONE WITHOUT SUCCESS. CASE CLOSED. FOLLOW-UP INFORMATION IDENTIFIED ON 20-OCT-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1752). AFTER 3 CHILDREN SHE DECIDED IN 2010 THAT SHE WOULD GET ESSURE BIRTH CONTROL PROCEDURE. IMMEDIATELY UPON WAKING IN THE HOSPITAL (WHERE SHE INSERTED ESSURE) SHE FELT MUCH MORE PAIN, ESPECIALLY IN HER LEFT SIDE AND WAS BLEEDING MORE THAN SHE ANTICIPATED. SHE QUESTIONED THIS AND THE DOCTOR SAID THAT WAS NORMAL. SHE WAS SENT HOME WHERE SHE ENDED UP CALLING HER DOCTOR OFFICE 5 TIMES IN 24 HOURS DUE TO EXTREME BLEEDING AND PAIN. SHE BEGAN HEMORRHAGING. WHILE THE BLEEDING FINALLY STOPPED, THE PAIN NEVER DID. AT TIMES IT FELT BETTER THAN OTHERS BUT NEVER COMPLETELY WENT AWAY. DURING HER MENSTRUAL CYCLE, SHE WOULD HAVE A DAY OF EXCRUCIATING PAIN, AT MOMENTS UNABLE TO STAND. THIS WAS ACCOMPANIED BY MIGRAINES AND SEVERE FATIGUE ALL TIMES OF THE MONTH. SOME DAYS IF SHE BENT OVER OR MOVED JUST RIGHT, IT STABBED HER. SOME DAYS IT WAS A QUICK JAB, OTHER DAYS THE PAIN LINGERED. SHE HAD TO TAKE PAIN MEDS DAILY. SHE BECAME ANXIOUS ABOUT AN ONCOMING PERIOD, KNOWING EVEN THOUGH SHE WAS IN TERRIBLE PAIN THEN; SHE HAD TO BE PUT ON ANXIETY MED. WITHIN 2 YEARS, SHE FELT A LOT OLDER THAN SHE WAS; SHE HAD JOINT PAIN, INFLAMMATION, BODY ACHES AND FATIGUE; MANY TIMES SHE WAS UNABLE TO MAKE IT UP OUR STAIRS WITHOUT RESTING OR SHE HAD TO CRAWL MOST OF THE WAY UP (BEFORE ESSURE SHE WAS IN SHAPE, WORKED OUT EVERY DAY AND WAS A HEALTHY (B)(6) LBS). OVER 2 YEAR TIME PERIOD, SHE WAS SENT FOR MANY BLOOD TESTS, HAD PHYSICAL THERAPY, TESTED FOR THYROID AND THOUGHT SHE HAD FIBROMYALGIA. SHE HAD HIP PAIN, SHOULDER PAIN AND WAS SENT FOR X-RAYS. SHE COULD NOT FIND ANYTHING. ALL BLOOD TESTS CAME BACK GOOD (EXCEPT FOR ANEMIA AND VITAMIN D DEFICIENT FROM HEAVY AND CONSTANT BLEEDING). SHE GENERALLY HAD 10 DAYS PER MONTH WHERE SHE WAS NOT BLEEDING AT ALL OR PASSING LARGE BLOOD CLOTS. BY 2013, IN ADDITION TO THE BODY ACHES, FATIGUE, JOINT PAIN AND MIGRAINES, SHE BEGAN HAVING UNEXPLAINED FEVERS, PAINFUL INTERCOURSE AND RANDOM BLOATING THAT MADE HER LOOKED 6 MONTHS PREGNANT. SHE HAD ANOTHER ULTRASOUND SINCE THE STABBING PAIN IN HER SIDE WAS GETTING EVEN WORSE. OTHER THAN THE PAIN IN HER SIDE, SHE HAD NO IDEA ANY OF THE OTHER SYMPTOMS COULD BE CAUSED BY ESSURE. SHE WAS CALLED AFTER HER ULTRASOUND AND WAS TOLD SHE HAD ENDOMETRIOSIS. TO UNDERSTAND THAT MORE, SHE LOOKED ONLINE TO SEE IF ESSURE COULD CAUSE ENDOMETRIOSIS AND FINALLY SHE HAD THE ANSWER; IT WAS ESSURE. ON (B)(6) 2013, SHE CONSULTED A DIFFERENT DOCTOR WHO STRONGLY RECOMMENDED SHE GET ESSURE REMOVED BY HAVING A TOTAL HYSTERECTOMY. AT THE AGE OF (B)(6) EVERYTHING INCLUDING HER OVARIES HAD TO BE REMOVED. COMPANY CAUSALITY COMMENT: A SPONTANEOUS CASE OF BLEEDING AND HEAVY CLOTTING, 2-3 WEEKS PER MONTH, SHARP STABBING PAIN, PAINFUL, SERIOUS MIGRAINES, ANEMIA, VITAMIN D DEFICIENCY, NIGHT SWEATS, UNEXPLAINED FEVERS, FATIGUE, SEVERE BLOATING, INFLAMMATION, BODY ACHES, AND PAINFUL INTERCOURSE IN A FEMALE CONSUMER OF UNSPECIFIED AGE AFTER IMPLANTATION OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS REPORTED BY A CONSUMER VIA HEALTH AUTHORITY. ESSURE WAS EXPLANTED 2 YEARS AND 9 MONTHS AFTER ITS IMPLANTATION ALONG WITH A HYSTERECTOMY AND OVARIES REMOVAL. THE CONSUMER DID NOT COMMENT ON THE

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CAUSAL RELATIONSHIP. THIS CASE WAS NOT MEDICALLY CONFIRMED. BLEEDING AND HEAVY CLOTTING, 2-3 WEEKS PER MONTH, BLEEDING IMMEDIATELY AFTER INSERTION, SHARP STABBING PAIN, PAINFUL, SEVERE BLOATING, INFLAMMATION, BODY ACHES, AND PAINFUL INTERCOURSE ARE REGARDED LISTED FOR ESSURE IN THE REFERENCE SAFETY INFORMATION, WHEREAS SERIOUS MIGRAINES, ANEMIA, VITAMIN D DEFICIENCY, NIGHT SWEATS, UNEXPLAINED FEVERS, FATIGUE, AND INFLAMMATION ARE CONSIDERED UNLISTED. ALL REPORTED EVENTS WERE REGARDED SERIOUS DUE TO HOSPITALIZATION. GIVEN THE IMPLIED TEMPORAL RELATIONSHIP THE GENITAL BLEEDING, POST PROCEDURAL BLEEDING, SHARP STABBING PAIN, SERIOUS MIGRAINES, ANEMIA, NIGHT SWEATS, UNEXPLAINED FEVERS, FATIGUE, SEVERE BLOATING, INFLAMMATION, BODY ACHES, AND PAINFUL INTERCOURSE WERE REGARDED RELATED TO ESSURE AS ALTHOUGH ENDOMETRIOSIS WAS DIAGNOSED, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. HOWEVER, FROM THE PATHOPHYSIOLOGY OF VITAMIN D DEFICIENCY THIS EVENT IS VERY UNLIKELY CAUSED BY ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION WAS RECEIVED: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. ALTHOUGH THE TECHNICAL INVESTIGATION APPEARS TO CONCLUDE A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFECT, FROM A MEDICAL POINT OF VIEW A POTENTIAL CAUSAL RELATIONSHIP WITH A QUALITY ISSUE BASED ON THE NATURE OF THE REPORTED MEDICAL EVENTS IS CONSIDERED TO BE VERY UNLIKELY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01488	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 10/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-0214) IN UNITED STATES ON 06-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. SHE HAD HAVING CONSTANT STABBING PAIN IN THE ABDOMEN; BLOATED BELLY; FATIGUE BUT SHE CAN'T SLEEP; BAD MIGRAINES; HOT AND COLD FLASHES; THYROID ISSUES; WEIRD DISCHARGES; VERY IRREGULAR MONTHLY CYCLES JUST TO LIST A FEW OF HER SYMPTOMS THAT STARTED AFTER THE PROCEDURE. SHE HAD THE 3 MONTH FOLLOW UP THAT SHOWED COILS WERE IN PLACE, BUT SHE HAD A RECENT ULTRASOUND AND X-RAYS THAT HAVE SHOWED ONE COIL HAS MIGRATED AND WAS STUCK IN HER UTERUS WALL, THE OTHER ONE LOOKS LIKE IT WAS ABOUT TO FALL OUT OF HER TUBE AS WELL. PTC INVESTIGATION RESULT WAS RECEIVED ON 20-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED EVENT(S) IS EXCLUDED. THE TECHNICAL

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ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP 20-OCT-2015: CASE UPGRADED TO INCIDENT. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1968, AWARENESS DATE 20-OCT-2015). CONSUMER REPORTED THAT ESSURE RUINED HER HEALTH AND HER MARRIAGE. FIRST SHE HAD BELLY BLOATED, LIKE SHE HAD A TON OF BRICKS ON HER STOMACH. PAINS WERE SO UNBEARABLE AT TIMES SHE COULD NOT HOLD HER KIDS OR LET ANYTHING TOUCH HER BELLY. NOT TO MENTION VERTIGO, FEELING DIZZY AND LIGHTHEADED FOR NO REASON AT ALL. WEIGHT GAIN, SHE COULD NOT LOSE THE WEIGHT AT ALL. SHE HAS MISSED SEVERAL DAYS OF WORK, NOT TO MENTION FAMILY FUNCTIONS DUE TO THEM. BLURRED VISION, METAL TASTE IN MOUTH, DIARRHEA ALL THE TIME. THESE WERE ALL SYMPTOMS THAT SHE EXPERIENCED. CONSUMER REPORTED THAT ON (B)(6) 2015 SHE WENT IN FOR A FULL HYSTERECTOMY DUE TO THE COILS MIGRATING AND RIPPING A HOLE IN HER UTERUS. FOLLOW-UP INFORMATION RECEIVED ON 01-NOV-2015 - IT HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE (FDA-2014-N-0736-2059): THE CONSUMER'S HISTORY INCLUDED PARITY 3. UPDATED PTC INVESTIGATION RESULT WAS RECEIVED ON 04-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ULTRASOUND AND X-RAYS PERFORMED SHOWED ONE HAS MIGRATED AND WAS STUCK IN HER UTERUS WALL/ RIPPING A HOLE IN HER UTERUS (REGARDED AS EMBEDDED DEVICE) AND OTHER ONE LOOKS LIKE IT WAS ABOUT TO FALL OUT OF HER TUBE AS WELL/ COILS MIGRATING (REGARDED AS DEVICE DISLOCATION). SHE UNDERWENT A HYSTERECTOMY APPROXIMATELY 3 YEARS AFTER INSERTION. BOTH EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, AT 3 MONTH FOLLOW-UP THE COILS WERE IN PLACE, BUT AFTERWARDS THE REPORTED EVENTS DESCRIBED ABOVE WERE DIAGNOSED. THE EXACT DATE AND MECHANISM OF THE REPORTED EVENTS WERE NOT KNOWN, HOWEVER GIVEN THEIR NATURE AND CONSIDERING THAT THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT, AND UPON RECEIPT OF FOLLOW-UP INFORMATION STATING THAT SHE HAD A FULL HYSTERECTOMY, THE CASE WAS UPGRADED TO INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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INTERNAL CORRECTION ON 24-NOV-2015. DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 09-AUG-2015.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01489	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/11/2011
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0301, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE INSERT) INSERTED ON (B)(6) 2011. CONSUMER REPORTED THAT SHE HAD HER ESSURE PLACED AND SHE HAS HAD PROBLEMS WITH HER HEART DEVELOPMENT PVC'S. HER GL (INTERPRETED AS GASTROINTESTINAL) TRACK DEVELOPMENT IBS (INTERPRETED AS IRRITABLE BOWEL SYNDROME) WITH CHRONIC CONSTIPATION, CHRONIC LEFT LOWER QUADRANT PAIN, CHRONIC BACTERIAL VAGINOSIS. HER COGNITIVE FUNCTION HAS BEEN AFFECTED TOO. SHE FELT CLOUDY MINDED ALL THE TIME AND NOTICED THAT AND THE PELVIC PAIN SOON AFTER SURGERY BUT DISMISSED IT AS BLADDER INFECTIONS. SHE WANTED ESSURE TAKEN OUT OF HER AND WILL DO ANYTHING TO GET RID OF THE PAIN. FOLLOW-UP RECEIVED ON 10-SEP-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO

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RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP IDENTIFIED ON 20-OCT-2015 (UPGRADED TO INCIDENT): THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC ON AN FDA ADVISORY COMMITTEE MEETING THAT TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1644). CONSUMER REPORTED THAT SHE HAD ESSURE PLACED IN (B)(6) OF 2011 AND STATES THAT, SINCE THEN, HER SYMPTOMS HAVE GOTTEN WORSE. SHE FIRST NOTICED THE ABDOMEN PAIN WITH HER PERIODS THEN WITH SEX. SHE ALSO NOTICED THE MIND FOG (COULD NOT THINK TO SAVE HER LIFE). THE CHRONIC FATIGUE TO THE POINT SHE COULD (NOT) MOVE AND INFORMED THAT ALL SHE WANTED WAS TO SLEEP. AFTER FOUR YEARS OF FEELING LIKE THAT, SHE FINALLY GOT IT OUT. ACCORDING TO CONSUMER SHE WOKE UP AFTER SURGERY AND FELT HUNDRED PERCENT BETTER FROM THE MIND FOG AND STATES THAT IT WAS LIKE SOMEONE JUST TURNED OFF A SWITCH. SHE KNEW BY THEN THAT IT WAS ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC LEFT LOWER QUADRANT PAIN AND CHRONIC BACTERIAL VAGINOSIS. AFTER 4 YEARS SHE HAD ESSURE INSERTS REMOVED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL SIGNIFICANCE. THE ABDOMINAL PAIN AND CHRONIC BACTERIAL VAGINOSIS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. OTHER NON-SERIOUS EVENTS WERE REPORTED. BACTERIAL INFECTION HAD BEEN REPORTED IN CONSUMERS UNDER ESSURE USE. THUS, DUE TO AN IMPLIED POSITIVE TEMPORAL RELATIONSHIP, AND ALSO IN LACK OF ALTERNATIVE EXPLANATION, THE CAUSALITY BETWEEN THE EVENT CHRONIC BACTERIAL VAGINOSIS AND ESSURE USE WAS ASSESSED AS RELATED BY THE COMPANY. SINCE THE CHRONIC ABDOMINAL PAIN STARTED AT THE TIME OF ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED, ITS CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. UPON FOLLOW UP INFORMATION, THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01490	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 9/3/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0680, AWARENESS DATE 18-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR BIRTH CONTROL. THE PATIENT'S MEDICAL HISTORY INCLUDED NULLIPAROUS. CONSUMER REPORTED THAT SINCE ESSURE PLACEMENT HER PERIODS BECAME VERY HEAVY WITH CLOTS THE SIZE OF GOLF BALLS, REALLY BAD PELVIC PAIN, SHE FELT TIRED ALL THE TIME AND IT SEEMED LIKE HER BODY WAS ALWAYS FIGHTING A INFECTION. SHE WAS PUT UNDER TWO TYPES PF BIRTH CONTROL FOR THE BLEEDING AND HAD A VAGINAL ULTRASOUND PERFORMED WITH NORMAL RESULT. SHE WILL BE HAVING A PARTIAL HYSTERECTOMY TO REMOVE IT, ALL OF HER TUBES AND HER UTERUS. PTC INVESTIGATION RESULT WAS RECEIVED ON 03-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED

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UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 20-OCT-2015: CASE UPGRADED TO INCIDENT. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1518). CONSUMER WAS (B)(6) WHEN SHE HAD ESSURE INSERTED IN 2009. IN 2012, THREE YEARS LATER, SHE STARTED TO EXPERIENCE HORRIFIC PAINS IN HER ABDOMINAL AREA, TWO PERIODS A MONTH WITH HEAVY CLOTTING (GOLF BALL SIZED) AND SHE WAS ALSO EXPERIENCING CHRONIC FATIGUE. SHE WAS PUT ON TWO TYPES OF BIRTH CONTROL, HAD BLOOD TESTS AND HAD A VAGINAL ULTRASOUND AND ALL WAS NORMAL. ON (B)(6) 2015 SHE HAD A HYSTERECTOMY PERFORMED, WITH TUBES AND COILS REMOVAL. AS SOON AS SHE WOKE UP FROM SURGERY SHE WAS A DIFFERENT WOMAN. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 04-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATED THAT HER PERIODS HAVE BECOME VERY HEAVY WITH CLOTS THE SIZE OF GOLF BALLS, AND SHE HAD HORRIFIC PAINS IN ABDOMINAL AREA. SHE UNDERWENT A HYSTERECTOMY AND COILS REMOVAL, 6 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CHANGES IN MENSTRUAL BLEEDING PATTERN AND ABDOMINAL PAIN MAY OCCUR UNDER ESSURE USE. THUS, BASED ON THE POSITIVE TEMPORAL RELATIONSHIP, ESSURE SAFETY PROFILE, AND ON THE LACK OF ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN THE REPORTED EVENTS AND ESSURE USE WAS ASSESSED AS RELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT, AND UPON RECEIPT OF FOLLOW-UP INFORMATION STATING THAT A SURGICAL INTERVENTION AND DEVICE REMOVAL WAS REQUIRED, THE CASE WAS UPGRADED TO INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01493	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1480, AWARENESS DATE 20-OCT-2015) WHICH REFERS TO FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED ON (B)(6) 2015. THE REPORTER STATED A BELOVED PERSON HAD TO HAVE THE ESSURE DEVICE REMOVED THIS YEAR DUE TO SERIOUS LIFE THREATENING COMPLICATIONS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER WHO HAD TO HAVE THE ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) DEVICE REMOVED DUE TO SERIOUS LIFE THREATENING COMPLICATIONS. ESSURE REMOVAL IS A LISTED EVENT ACCORDING TO THE DEVICE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, MINIMAL INFORMATION WAS PROVIDED AND CONSUMER'S COMPLICATIONS WERE NOT SPECIFIED. NEVERTHELESS; CONSIDERING DEVICE REMOVAL WAS REQUIRED, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THEREFORE; THIS CASE WAS CONSIDERED AN INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE FROM HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01494	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): 8/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1687, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. THE CONSUMER IMMEDIATELY FELT PAIN RIGHT AFTER THE OUTPATIENT PROCEDURE AND COULD NOT BARELY WALK. HER DOCTOR ASSURED HER THE PAIN WOULD ONLY LAST A DAY OR SO BUT SHE WAS STILL SUFFERING FROM PELVIC PAIN AND BACK PAIN 3 YEARS LATER. SHE ALSO REPORTED SHE EXPERIENCED HEAVY PERIODS AND PAINFUL CRAMPS TO THE POINT IT FELT LIKE HAVING MISCARRIAGES. SHE DID NOT RECEIVE THE NICKEL SKIN TEST AND IN (B)(6) 2012 SHE BROKE OUT WITH LESIONS AND COULD NOT WALK JUST HOW PAINFUL IT WAS. THE CONSUMER WAS PLACED ON (B)(6) MEDICATION BECAUSE DOCTORS ASSUMED IT WAS (B)(6) UNTIL HER RESULTS CAME NEGATIVE. SHE MADE SEVERAL TRIPS TO THE HOSPITAL, AND DOCTORS DID ALL TYPES OF TESTS BUT COULD GIVE HER NO EXPLANATION FOR WHAT SHE WAS EXPERIENCING. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN ALL THE EVENTS AND ESSURE IS RELATED. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN AND BROKE OUT WITH LESIONS, COULD NOT WALK JUST HOW PAINFUL IT WAS. THESE EVENTS WERE CONSIDERED SERIOUS, PELVIC PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENT IS UNLISTED. CONSIDERING THAT PELVIC PAIN AND ALLERGIC REACTION (INCLUDING RASH) MAY OCCUR WITH ESSURE THERAPY AND IN THE LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP

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WITH SUSPECT INSERT CANNOT BE EXCLUDED. IN THIS CASE, IT WAS REPORTED THAT CONSUMER MADE SEVERAL TRIPS TO THE HOSPITAL. ALTHOUGH IT WAS UNCLEAR WHETHER SHE WAS ADMITTED, HOSPITALIZATION CANNOT BE FORMALLY EXCLUDED IN THIS CASE, IT WAS REGARDED AS AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 10-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01495	BAYER HEALTHCARE LLC	11/16/2015	11/16/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2011
Explant Date (E7): 7/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1744, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. CONSUMER REPORTED THAT SHE STARTED HAVING VERY PAINFUL PERIODS AND HEAVY PERIODS. AFTER 2 YEARS THE PAIN WAS NOT ONLY DURING HER MENSTRUAL CYCLE, BUT THROUGHOUT THE MONTH. SHE ALSO HAD STABBING SENSATION FOLLOWED BY CHRONIC PAIN AROUND HER LOWER ABDOMEN. IN (B)(6) 2014 SHE HAD A FULL HYSTERECTOMY TO HELP WITH HER SYMPTOMS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER 2 YEARS STARTED HAVING PAIN NOT ONLY DURING MENSTRUAL CYCLE BUT THROUGHOUT THE MONTH / HAD STABBING SENSATION AND CHRONIC PAIN AROUND LOWER ABDOMEN. SHE UNDERWENT A FULL HYSTERECTOMY APPROXIMATELY THREE AND A HALF YEARS AFTER ESSURE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 10-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057871	BAYER HEALTHCARE	11/16/2015	11/17/2015

Event Information:

Event Date (B3): 7/20/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER STATED THAT AFTER HAVING THE IMPLANTS PUT IN SHE DID NOT HAVE A PROBLEM UNTIL THE MIDDLE OF 2012 WHEN SHE STARTED TO HAVE ALL OVER BODY PAIN AND FATIGUE. SHE WAS GIVEN A LOT OF TESTS THAT WERE ALL NEGATIVE BUT SHE WAS DX WITH FIBROMYALGIA. FROM 2012-2014, SHE STARTED HAVING SEVERE HEADACHES, PAIN ALL OVER, NOT FEELING WELL, BLEEDING AFTER SEX, AND NAUSEA. ON THE 3RD DAY OF HER PERIOD EVERY MONTH SHE HAS HEADACHES SO BAD SHE HAS TO GO TO THE HOSPITAL WITH BLURRED VISION SO BAD SHE CANNOT SEE. ON (B)(6) 2014, SHE HAD A PULMONARY EMBOLISM BUT SHE THOUGHT SHE WAS HAVING A HEART ATTACK. SHE HAD 2 BLOOD CLOTS BEHIND HER LEFT KNEE AND 28 CLOTS IN HER LUNGS. ON (B)(6), THE CLOTS KILLED THE MIDDLE LOBE OF HER RIGHT LUNG. AT TIMES HER HEART SPEEDS UP WITHOUT REASON. HER HEART RATE WAS 152 AT THE DR.'S OFFICE. ALL TEST WERE NEGATIVE. TWO WEEKS AGO HER ABDOMEN PAIN STARTED TO GET WORSE. "C/O" PAIN IN THE MID PELVIC BONE LIKE A STABBING PAIN. SAW DR. (B)(6) WHO ASKED HER IF SHE KNEW THE SIDE OF EFFECTS OF ESSURE AND RECOMMENDED THAT SHE RESEARCH THEM. HE ALSO GAVE HER AN OB/GYN REFERRAL. WHEN SHE DID HER RESEARCH SHE HAD 3 PAGES OF SYMPTOMS INCLUDING THE FOLLOWING: HOT/COLD FLASHES, BLEEDING AFTER SEX OCCASIONALLY, BREAST PAIN, ALL OVER PAIN (HAD TO TOE), METAL TASTE IN MOUTH, NAUSEA, SEVERE BLOATING, TINGLING AND NUMBNESS, STROKE LIKE SYMPTOMS, RINGING IN THE EARS; IT IS HARD TO REMEMBER THINGS, RASH THAT LOOKS LIKE A BURN THAT APPEAR AND GO AWAY AND IS ITCHY, UNCONTROLLABLE ANXIETY. IN 2012 SHE STARTED HAVING SLEEP PROBLEMS, MUSCLE SPASMS, BLURRED VISION WITH FLOATERS AND HER EYEBALLS HURT IN THE SUN. TWO WEEKS AGO SHE HAD A MUCUS DISCHARGE AND CRAMPING REALLY BAD EVEN THOUGH IT WAS NOT TIME FOR HER

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PERIOD AND ON MONDAY ((B)(6) 2015), SHE COMPLAINED OF FEELING LIKE SHE WAS HAVING A HEART ATTACK, LEFT ARM ACHING AND SHORTNESS OF BREATH. SHE DID NOT GO TO THE HOSPITAL, JUST WAITED FOR IT TO PASS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01467	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 9/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1686, AWARENESS DATE 19-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER STATED THE INSERTION PROCEDURE WAS EXCRUCIATINGLY PAINFUL. SHE FELT LIKE SHE WAS GOING TO BE SICK OR PASS OUT, IT HURT SO BAD. IT WAS WORSE THAN NATURAL CHILD BIRTH (SHE HAD A YOUNG DAUGHTER). A MONTH OR TWO AFTER THE ESSURE PROCEDURE SHE STARTED GETTING REALLY BAD NIGHT SWEATS EVERY NIGHT. IT WOULD SOAK THE SHEETS AND SOME MORNINGS WHEN SHE WOKE UP HER FACE, NECK AND CHEST WOULD BE REALLY FLUSHED AND SHE WOULD HAVE A BAD HEADACHE MOST OF THE DAY. IT FELT LIKE HER HORMONES MIGHT BE OUT OF WHACK OR SOMETHING. SHE MENTIONED THIS TO HER PRIMARY DOCTOR AND HER GYNECOLOGIST AND NEITHER COULD FIGURE WHY IT WAS HAPPENING BECAUSE IT WAS NOT PREMENOPAUSAL. SHE STARTED EXPERIENCING MORE STRANGE SYMPTOMS LIKE THE BOTTOMS OF HER FEET BEING SO SORE AFTER A SHOPPING TRIP SHE COULD HARDLY STAND ON THEM. IT FELT LIKE SHE WAS WALKING ON BRUISES AND HER FEET AND TOES WOULD TINGLE (SHE FOUND OUT LATER IT WAS CHRONIC INFLAMMATION FROM THE PET FIBERS). SHE WOULD SLEEP ALL NIGHT BUT NEVER FELT RESTED; SHE YAWNED ALL DAY LONG. HER PRIMARY DOCTOR HAD HER DO A SLEEP STUDY AND IT WAS COMPLETELY NORMAL. ALL BLOOD WORK CAME BACK NORMAL OTHER THAN LOW B12 AND VITAMIN D (SHE WOULD HAVE TO TAKE SUPPLEMENTS FROM NOW ON JUST TO KEEP HER LEVELS NORMAL). SHE STARTED HAVING EXTREME MUSCLE PAIN. HER ARMS AND SHOULDERS WOULD HURT SO BADLY. SHE WAS GRADUALLY LOSING HER SHORT TERM MEMORY AND CONCENTRATION. IT STARTED AFFECTING HER

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CURRENT JOB (AND IT STILL WAS); SHE JUST MADE HERSELF GET UP AND GO TO WORK. SHE WENT TO A RHEUMATOLOGIST AND A NEUROLOGIST AND HAD A MAGNETIC RESONANCE IMAGING (MRI) AND A NERVE TEST. ALL CAME BACK NORMAL. FINALLY, SINCE NO ONE COULD FIND ANYTHING WRONG WITH HER, ALL THE SPECIALISTS SAID IT WAS PROBABLY FIBROMYALGIA BECAUSE THEY COULD NOT FIND ANY OTHER DIAGNOSIS. SHE WAS PRESCRIBED NORTRIPTYLINE AND TRAMADOL TO TAKE THE EDGE OFF THE MUSCLE PAIN, WHICH DID NOT HELP. HER NORMAL BLOOD PRESSURE WENT SUDDENLY INTO PREHYPERTENSION AND THEN OUT OF NOWHERE SHE ALSO HAD SUDDEN WEIGHT GAIN. AFTER TRACKING HER MONTHLY OVULATION AND PAIN CYCLES, SHE FINALLY CONNECTED IT TO THE ESSURE. SHE RAN ALL OF THIS BY HER NEW GYNECOLOGIST WHO FELT THAT ESSURE COULD BE THE CAUSE AND AGREED TO DO A HYSTERECTOMY. SO IN (B)(6) 2014 SHE WAS ESSURE FREE. SHE FELT SO MUCH BETTER AFTER THE HYSTERECTOMY AND NINETY PERCENT OF THE SYMPTOMS WERE GONE. HOWEVER, SHE WAS STILL LEFT WITH HIGH BLOOD PRESSURE, PRE-DIABETES, LOW VITAMIN LEVELS, ON AND OFF CHRONIC INFLAMMATION, AND PSORIASIS ON HER FACE NECK AND INNER EAR. HER COGNITIVE MEMORY WAS DIMINISHING. HER LIFE HAD BEEN FOREVER ALTERED BY ESSURE. SHE HAD BEEN VIOLATED BY THIS MEDICAL DEVICE IN EVERY POSSIBLE WAY AND HAD TO UNDERGO A MAJOR SURGERY THAT SHE SHOULD NOT HAVE HAD TO GO THROUGH. FOLLOW-UP RECEIVED ON 07-NOV-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION. THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND UNDERWENT A HYSTERECTOMY. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, THERE IS NO CLEAR INFORMATION REGARDING THE REASON FOR THE PLANNED PROCEDURE. HOWEVER, AS THE PROCEDURE IS PLANNED DUE TO ESSURE PROBLEMS AND NO FOLLOW-UP WILL BE POSSIBLE; COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE PLANNED SURGICAL INTERVENTION, THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01491	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 836499

Single Use: Y
Implant Date (E6): 6/16/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 20-OCT-2015 WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 WITH LOT NUMBER 836499. PATIENT HAS EXPERIENCED WORSENING CHRONIC PAIN AND SHE IS SCHEDULED TO HAVE A LAPAROSCOPIC PROCEDURE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 04-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAS EXPERIENCED WORSENING CHRONIC PAIN. THE PHYSICIAN INFORMED THAT THE PATIENT HAS A LAPAROSCOPIC PROCEDURE SCHEDULED. THIS EVENT IS LISTED IN THE REFERENCE SAFETY

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INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT, THE LACK OF ALTERNATIVE EXPLANATION AND THE IMPLIED COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01492	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 20-OCT-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. PATIENT BECAME PREGNANT IN 2011 BUT HAD FETAL DEMISE AT 22 WEEKS. PATIENT REPORTED HAVING HYSTEROSALPINGOGRAM AFTER PLACEMENT AND BEING TOLD TUBES BLOCKED. THE REPORTING DOCTOR HAD NOT PLACED THE INSERTS. IN 2014, PATIENT COMPLAINED OF PELVIC PAIN. PATIENT WENT BACK TO THE DOCTOR AND UPON BIMANUAL EXAM, SHE HAD ADNEXAL TENDERNESS. DOCTOR CLAIMED TO HAVE ULTRASOUND REPORT THAT SAID INSERTS WERE NEAR CORNUA. THE PHYSICIAN CALLED TO TALK TO A QUALIFIED PHYSICIAN TO DISCUSS THE PROCEDURE TO REMOVE ESSURE. PTC INVESTIGATION RESULTS WERE PROVIDED ON 07-NOV-2015. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY

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COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT TWO YEARS LATER. SHE HAD A FETAL DEMISE AT 22 WEEKS (INTERPRETED AS FETAL DEATH). THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. PREGNANCY IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE FETAL DEATH IS UNLISTED. IN THE PRESENT CASE, THE PATIENT REPORTED HAVING A HYSTEROSALPINGOGRAM AFTER PLACEMENT WHICH SHOWED TUBES WERE BLOCKED. AN ULTRASOUND SEEMS TO HAVE SHOWN THE INSERTS IN CORRECT POSITION (NEAR CORNUA). SINCE SHE GOT PREGNANT APPROXIMATELY 2 YEARS AFTER INSERTION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED (DEVICE INEFFECTIVE). THE EXACT REASON WHICH LED TO FETAL DEATH WAS NOT REPORTED IN THIS CASE. HOWEVER, CONSIDERING THAT THE PREGNANCY WAS AT 22 WEEKS, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE TOTALLY EXCLUDED, THEREFORE THIS EVENT WAS CONSIDERED RELATED TO THE SUSPECT INSERT. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SERIOUS INJURY OCCURRED (FETAL DEATH). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01496	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 4/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2013
Explant Date (E7): 5/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1643, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. CONSUMER HAD ESSURE PLACED IN (B)(6) 2013 AND IT WAS REMOVED IN (B)(6) 2015. BEFORE REMOVAL AND ALMOST IMMEDIATELY AFTER PLACEMENT SHE BEGAN HAVING SEVERE LOWER BACK PAIN ACCOMPANIED BY LOWER BACK MUSCLE SPASMS, EXTREMELY HEAVY PERIODS, CONSTANT LOWER ABDOMINAL BLOATING, BRAIN FOG, ALL OVER BODY PAIN, LOST LIBIDO, ODD VAGINAL ODOR, AND EXTREME LACK OF ENERGY, AND 2 YEAST INFECTIONS IN A YEAR WHICH IS NOT NORMAL FOR HER. SINCE REMOVAL IN (B)(6) 2015 SHE HAS GAINED HER ENERGY AND ENTHUSIASM BACK, SHE HAS VERY LITTLE PAIN, SHE HAS HER SEX DRIVE BACK AND THE BLOATING IS GONE AS WELL AS THE STRANGE ODOR. SHE CAN THINK AGAIN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEVERE LOWER BACK PAIN. ESSURE WAS REMOVED 2 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION BACK PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, AND SINCE SHE HAD VERY LITTLE PAIN AFTER ESSURE REMOVAL, A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT

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TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 10-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01497	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE NUMBER MW5044788) IN UNITED STATES ON 20-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER REPORTED SHE HAD REALLY BAD PAIN; COULD NOT SIT ON HER BUTT. THE PAIN WAS UNBEARABLE. SHE WAS ALSO BLEEDING TO DEATH; COULD NOT STOP BLEEDING. SHE WAS UNABLE TO HAVE SEX WITH IT. SHE HAD TO HAVE ESSURE REMOVED. FOLLOW UP INFORMATION RECEIVED ON 02-NOV-2015: NO NEW INFORMATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN AND BLEEDING. THE DEVICE WAS REMOVED. THESE EVENTS, REGARDED AS PELVIC PAIN AND GENITAL BLEEDING, ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENTS NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, THE NON-SERIOUS EVENT UNABLE TO HAVE SEX WITH IT WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED) A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FOLLOW-UP IS POSSIBLE, SINCE NO CONTACT INFORMATION WAS PROVIDED.

Manufacturer Narrative (H10):

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FOLLOW UP INFORMATION RECEIVED ON 02-NOV-2015: NO NEW INFORMATION. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 10-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFER

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01498	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 4/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/11/2012
Explant Date (E7): 7/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE NUMBER (B)(4)) IN UNITED STATES ON 20-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. THE CONSUMER REPORTED THAT SHE HAD BEEN HAVING CONTINUOUS PAIN LOWER RIGHT IN HER ABDOMINAL PELVIC AREA. IT WAS SO PAINFUL IT FELT AS THOUGH HER APPENDIX HAD BURST. SHE HAD SUFFERED CONTINUOUSLY. SHE ALSO REPORTED MIGRAINES, BACKED UP FLUID, EXCESSIVE HEAVY PERIOD SMELL, PAIN DURING INTERCOURSE, AND WEIGHT GAIN. SHE STATED SHE HAD BEEN SUFFERING FROM THE EVENTS SINCE ESSURE PLACEMENT. ON (B)(6) 2015 SHE HAD ESSURE REMOVED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CONTINUOUS PAIN LOWER RIGHT IN ABDOMINAL PELVIC AREA. SHE HAD ESSURE REMOVED 3 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL AND PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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PTC RESULTS AND ASSESSMENT RECEIVED ON 10-NOV-2015: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE A INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, W

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01499	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1545, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER STATED THAT HER EXPERIENCE INCLUDED HAVING TWO DEVICES REMOVED SHORTLY AFTER PLACEMENT BUT THEN SPENDING THE NEXT THREE YEARS WITH CHRONIC PELVIC PAIN, DESCRIBED AS LABOR CRAMPING. SHE HAD SEVERAL CT SCANS (COMPUTERIZED TOMOGRAPHY) AND NUMEROUS TRANSVAGINAL ULTRASOUNDS THAT WERE ALL DEEMED NORMAL. SHE FINALLY INSISTED ON A HYSTERECTOMY. SHE CONSIDERED ALL EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) DEVICES REMOVED SHORTLY AFTER THEIR PLACEMENT. ACCORDING TO HER; AFTER THIS PROCEDURE SHE DEVELOPED CHRONIC PELVIC PAIN (LABOR CRAMPING) AND FINALLY INSISTED ON A HYSTERECTOMY. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS CASE, CONSUMER STATED SHE HAD ESSURE INSERTS REMOVED SHORTLY AFTER THEIR PLACEMENT; BUT THE REASON FOR THIS PROCEDURE WAS NOT SPECIFIED. LATER, SHE DEVELOPED CHRONIC PELVIC PAIN FOR 3 YEARS (AFTER ESSURE REMOVAL) WITH NO ABNORMAL FINDINGS IN CT SCANS OR ULTRASOUNDS. HOWEVER, ACCORDING TO HER, SHE INSISTED ON A HYSTERECTOMY. ALTHOUGH LIMITED AND DISCREPANT INFORMATION WAS PROVIDED IN THIS CASE FOR A COMPREHENSIVE CAUSALITY ASSESSMENT; SINCE DEVICE REMOVAL WAS REQUIRED CAUSALITY BETWEEN THIS INTERVENTION AND THE SUSPECT INSERT CANNOT BE EXCLUDED. CONSUMER'S PAIN WAS

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CONSIDERED UNRELATED TO ESSURE SINCE IT OCCURRED AFTER DEVICES REMOVAL. THIS CASE WAS REGARDED AS INCIDENT (DEVICE REMOVAL REQUIRED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01500	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5055549) IN UNITED STATES ON 20-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED AND IT CAUSED HER HEAVY BLEEDING AND SEVERE CRAMPING THAT WAS SO BAD THAT IN 2015 SHE HAD A HYSTERECTOMY PERFORMED. AS CONCOMITANT MEDICATION SHE RECEIVED TYLENOL. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND SEVERE CRAMPING (INTERPRETED AS ABDOMINAL PAIN). SHE UNDERWENT A HYSTERECTOMY 4 YEARS AFTER ESSURE INSERTION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND ABDOMINAL PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENTS AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01501	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 623211; 619696

Single Use: Y
Implant Date (E6): 11/4/2009
Explant Date (E7): 6/11/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055550) IN UNITED STATES ON 20-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009, FOR PERMANENT BIRTH CONTROL. IN 2014 THE CONSUMER STARTED TO EXPERIENCE ALLERGIC REACTIONS TO A SEALANT USED ON EYELASH EXTENSIONS WHICH REQUIRED PREDNISONE DUE TO EYES SWELLING SHUT. SHE ALSO STARTED HAVING BLEEDING BETWEEN PERIODS. THE PROBLEM WITH HER EYES CONTINUED INTO (B)(6) 2015 AND REQUIRED A REFERRAL TO AN ALLERGIST ALONG WITH ALLERGY TESTING WHICH SHOWED ALLERGIES TO GOLD, NICKEL AND EYE SHADOWS THAT SHE HAVE USED FOR YEARS. THOSE OVERSHADOWS ALL CONTAINED PTFE (INTERPRETED AS POLYTETRAFLUOROETHYLENE). HER BLEEDING GOT WORSE AND SHE HAD TO HAVE A HYSTERECTOMY. ESSURE WAS REMOVED ON (B)(6) 2015. AT THAT TIME SHE FOUND OUT THAT THE ESSURE COILS WERE COATED IN PTFE. THE CONSUMER BELIEVES HER MEDICAL ISSUES WERE CAUSED BY THE ESSURE IMPLANTS. HOSPITALIZATION AND DISABILITY/PERMANENT DAMAGE WERE MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BLEEDING BETWEEN PERIODS / BLEEDING GOT WORSE (INTERPRETED AS METRORRHAGIA). SHE UNDERWENT A HYSTERECTOMY AND ESSURE WAS REMOVED APPROXIMATELY 6 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. HOSPITALIZATION AND DISABILITY/PERMANENT DAMAGE WERE

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MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01502	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5041347) IN UNITED STATES ON 20-OCT-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. THE CONSUMER REPORTED WHEN SHE MADE IT HOME AFTER THE PROCEDURE, THE PAIN WAS SO BAD SHE FELT LIKE SHE DID WHEN SHE WAS IN LABOR AND WHEN SHE CALLED THE DOCTOR THEY TOLD HER TO USE A HEATING PAD. THE PAIN LASTED FOR THREE DAYS, SHE STATED BEING UNBEARABLE. WHEN IT WAS FINALLY OVER SHE STARTED EXPERIENCING THE NAUSEA (THAT SHE STILL HAS ALMOST DAILY 5 YEARS LATER) AND THE HEADACHES, BODY PAIN, UPPER AND LOWER BACK PAIN, SHE COULD HARDLY STAND OR PLAY WITH HER CHILDREN BECAUSE THE PAIN IN HER BACK WAS AND STILL IS TOO MUCH. HER OTHER SYMPTOMS INCLUDED HEAVY PERIODS WITH HUGE BLOOD CLOTS THAT LAST SOMETIMES TWO WEEKS, PAIN DURING SEX, BRAIN FOG, EXTREME ANXIETY, MOOD SWINGS, DEPRESSION, HAIR LOSS AND TOOTH LOSS. SHE REPORTED THAT 8 MONTHS AFTER SHE HAD THE PROCEDURE SHE WENT TO THE DOCTOR BECAUSE THE NAUSEA BECAME TOO MUCH AND HE ASKED IF SHE COULD BE PREGNANT AND DID TEST ANYWAY TO BE SAFE, THE PREGNANCY TEST WAS POSITIVE. THE CONSUMER REPORTED BEING SCARED BECAUSE SHE HAD HAD AN ECTOPIC RUPTURE BEFORE AND ONLY HAS ONE TUBE BUT IT TURNED OUT THE BABY WAS IN THE UTERUS. THE PREGNANCY WAS SCARY BECAUSE NO ONE KNEW WHAT COULD HAPPEN WITH THE ESSURE IN PLACE. SHE DELIVERED 6 WEEKS EARLY AND WHILE IN LABOR HER PLACENTA RUPTURED AND THE BABY GOT BLOOD IN HER LUNGS AND HAD TO STAY IN THE NICU FOR TWO WEEKS (CHILD CASE REPORTED UNDER REFERENCE (B)(4)). SHE WENT BACK AFTER TO HAVE THE DYE TEST TO MAKE SURE THE COIL WAS STILL IN PLACE THEY SAID IT WAS AND NO ONE KNEW HOW. IN 2015, THREE YEARS LATER, SHE HAD A SON BY C-SECTION; SHE HAD PLACENTA

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PREVIA AND HE TOO WAS BORN EARLY (SECOND PREGNANCY WAS REPORTED UNDER REFERENCE (B)(4)). THE CONSUMER REPORTED THAT AFTER 7 CHILDREN HER TUBES HAVE BEEN TIED THE RIGHT WAY. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A POSITIVE PREGNANCY TEST. SHE DELIVERED 6 WEEKS EARLY (SEEN AS PREMATURE LABOUR) AND WHILE IN LABOUR HER PLACENTA RUPTURED. THE BABY GOT BLOOD IN HER LUNGS AND HAD TO STAY IN THE NICU FOR TWO WEEKS (SEE (B)(4)). PREGNANCY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE UNLISTED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. IN THIS CASE, PREGNANCY WAS DIAGNOSED ABOUT 8 MONTHS AFTER ESSURE INSERTION. THEREFORE A CAUSAL RELATIONSHIP BETWEEN THE SUSPECT INSERT AND THE REPORTED PREGNANCY CANNOT BE EXCLUDED. MOST OF PREMATURE BIRTHS OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES. IN THIS CASE, THE OCCURRENCE OF PREMATURE SEPARATION OF PLACENTA COULD BE A REASON FOR PREMATURE DELIVERY. A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THIS CASE WAS THUS, CONSIDERED AN INCIDENT (SERIOUS INJURY). ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 08-DEC-2015, (B)(4): FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01503	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1992, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. THE CONSUMER STATED SHE HAD AN AUTO IMMUNE ISSUE BEING COMPROMISED BY ESSURE. PLUS ONE COIL FELL OUT 4 DAYS LATER. SHE BLED FOR 8 MONTHS. SHE BLED SO MUCH CONTINUOUSLY BECAUSE SHE GAVE BIRTH, GOT DEPO SHOT, AND HAD ESSURE PUT IN. THEN ONE FELL OUT. IT WAS ONLY PARTIAL PIECE OF THE DEVICE ACCORDING TO THE PICTURES OF A FULL ESSURE. SHE WILL SEE A SURGEON FOR TESTING SOON FOR TUBAL REMOVAL AND/OR HYSTERECTOMY. SHE WAS ALREADY BEING MONITORED FOR FIBROID CYSTS OF HER BREAST AND CERVICAL CANCER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE COIL FELL OUT 4 DAYS LATER. IT WAS ONLY PARTIAL PIECE OF THE DEVICE ACCORDING TO THE PICTURES OF A FULL ESSURE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE IT IS NOT CLEAR WHEN THE DEVICE BREAKAGE OCCURRED. HOWEVER, CONSIDERING THE NATURE OF THIS EVENT AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE

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OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01504	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 678817

Single Use: Y
Implant Date (E6): 9/21/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5044917) IN UNITED STATES ON 20-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010; THE LOT NUMBER 678817. THE CONSUMER REPORTED THAT 2014 WAS THE WORST YEARS OF HER LIFE; SHE STRUGGLED WITH PAIN, IN TERMS OF ASSET PROBLEMS AND ASSISTANCE TO DRUGS. SHE STATED A YEAR AGO FORM THIS REPORT SHE BEGAN TO HAVE UNIMAGINABLY HARD LOW BACK AND PELVIC PAIN, PAIN BEAMED THIGH AND THE BLADDER WAS FEELING THE PRESSURE. IN ADDITION, HER BREASTS WERE SO SORE THAT SHE COULD NOT EVEN SLEEP AT NIGHT WITHOUT SPORTS JACKETS. SHE SOUGHT MEDICAL ATTENTION SEVERAL TIMES (INTERNAL MEDICINE PHYSICIAN, GENERAL PRACTITIONER, WORK PLACE PHYSICIAN, GYNECOLOGIST); HER BACK WAS FILMED AND THE CAUSE WAS NOT FOUND, SHE HAD TO BE ON SICK LEAVE FOR LONG PERIODS OF TIME. IN 2015, THE ESSURE IMPLANT CAME OUT WITH MENSTRUAL CYCLE, SHE ORDERED A LUMBAR SPINE A YEAR AGO AND CAPTURED IMAGES AND EVEN A LAYMAN NOTICED THAT ALREADY THEN THE SECOND IMPLANT WAS NOT INSERTED. SHE WENT FOR SECTION, WHICH WAS INTENDED TO REMOVE THE SECOND ESSURE IMPLANT AND AT THE SAME TIME MAKE HER STERILE. AFTER THE SURGERY, SHE READ SECURITIES THAT THE IMPLANT HAS NOT BEEN AWAY, AS IT WAS INTO THE MYOMETRIUM. AT TIME OF THE REPORT, SHE DID NOT KNOW IF THERE WAS ANY PIECE OF OUTGOING IMPLANT OR SHE DID NOT EXACTLY KNOW WHERE THE OTHER ONE IS. SHE REPORTED PAIN AND MANY OTHER SYMPTOMS WERE STILL EVERYDAY PROBLEMS. THE SYMPTOMS SHE HAD BEFORE ESSURE: SWELLING, ANTIQUE (SHE DID NOT FEEL REFRESHED), APPETITE (SHE CANNOT START ANY), SKIN DISORDERS (ACNE PIMPLES), BREAST TENDERNESS, TOOTH BLOOD LEAKAGE, RINGING IN THE EARS, ALLERGY (CONSTANT RUNNY NOSE AND SNEEZING), CYSTS IN BREASTS, GROIN PAIN, HAIR LOSS, VERY

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PAINFUL MENSTRUATION, LEUKOCYTE VALUES ARE HIGH, GOITER, MANY OF THESE SYMPTOMS WAS DIAGNOSED BY DOCTOR. THE CONSUMER ALSO MENTIONED THE SERIOUSNESS CRITERIA DISABILITY OR PERMANENT DAMAGE AND HOSPITALIZATION, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PTC RESULTS AND ASSESSMENT RECEIVED ON 11-NOV-2015: LOT NUMBER 678817 (PRODUCTION DATE OCT-2009; EXPIRATION DATE OCT-2012) FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UNIMAGINABLY HARD LOW BACK PAIN AND PELVIC PAIN / PAIN "BEAMED" THIGH. ABOUT 5 YEARS AFTER ESSURE INSERTION, THE ESSURE IMPLANT CAME OUT WITH MENSTRUAL CYCLE (DEVICE EXPULSION). A SURGERY IN ORDER TO REMOVE THE SECOND ESSURE IMPLANT WAS PERFORMED AND AFTER THE SURGERY, SHE READ SECURITIES THAT THE IMPLANT HAS NOT BEEN AWAY, AS IT WAS INTO THE MYOMETRIUM (SEEN AS EMBEDDED DEVICE). THESE EVENTS WERE CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE TERM DISABILITY AND HOSPITALIZATION WERE ONLY MENTIONED AS EVENT OUTCOME AND THE REPORTER DID NOT SPECIFY IT. IN THIS CASE, THE EXACT DATE AND MECHANISM OF EMBEDDED DEVICE WERE NOT KNOWN. CONSIDERING THE NATURE OF THESE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT. MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION CANNOT BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01505	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1668, AWARENESS DATE 20-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012 FOR PERMANENT BIRTH CONTROL. THE REPORTER MENTIONED HIS WIFE PUT ESSURE AND AFTER THE DAY OF THE INSERTION THINGS WERE NEVER RIGHT. FROM THE VERY BEGINNING HE NOTICED SHE WAS NOT QUITE THE SAME, YET SHE WENT FOR THE FOLLOW UP MAKING SURE IT WAS SET LIKE HER PHYSICIAN TOLD HER. FROM DAY 1 THERE WAS PELVIC PAIN, CONSTANT ITCHING HEAD TO TOE, CHRONIC BLEEDING EVEN AFTER HAVING AN ABLATION AND CONTINUED STILL, ALSO STARTED HAVING CHRONIC MIGRAINES LIKE NEVER BEFORE. SHE HAD A FEW THREW OUGHT HER LIFE TO BUT NOT LIKE POST ESSURE. THEN HONORABLE CYST AND COULD NOT TAKE THE HORMONES DUE TO THEM CAUSING MIGRAINES. SHE ENDED UP HAVING SURGERY TO REMOVE CYST THAT SHE HAD NEVER HAD ISSUES WITH BEFORE ESSURE, AND THIS WAS THE FIRST OF MANY. SHE ENDED UP CONTINUING HAVING ISSUES UNTIL THEN THEY HAD TO DO A HYSTERECTOMY AND SHE WAS NOT EVEN 30. AFTER THE HYSTERECTOMY SHE FELT THE BEST SHE HAD IN ABOUT 2 YEARS POST ESSURE PROCEDURE IMPLANTED. THE CONSTANT ITCHING, PELVIC PAIN, AND MIGRAINES SEEMED TO STOP; THEY THOUGHT THAT THINGS WERE BACK TO NORMAL WHEN THE WEEK OF (B)(6) 2014 WHEN SHE WAS CHANGING SHEETS SHE FELT SOMETHING RIP INSIDE, SHE CALLED THE EMERGENCY AND GET TO THE HOSPITAL. AT THE OBGYN THEY TOLD HER TO GO DIRECTLY TO THE HOSPITAL THAT THE UPPER MOST CUFF OF HER VAGINA HAD RIPPED AND HER BOWELS WERE PROTRUDING, AND ANOTHER SURGERY WAS DONE TO REPAIR IT. THE REPORTERS WIFE KEPT HAVING PAIN AND HER PHYSICIAN COULD NOT SEEM TO FIGURE IT OUT, IT SO HAPPENED THAT THEY WENT

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BACK IN THEY FOUND A STAPLE FROM THE LAST SURGERY WAS POKING AN OVARY, AND IT WAS REMOVED. HE REPORTED ESSURE BEING SAFE SHOULD NEVER HAVE CAUSED SO MUCH PAIN AND AGONY OR LOSS AND ENJOYMENT OF LIFE. IF IT WERE SAFE IT SHOULD NOT REQUIRE A HEALTHY LATE (B)(6) PATIENT TO HAVE TO UNDERGO 5 SURGERY'S, MISS WORK DUE TO DEBILITATING MIGRAINES, MISSED ANNIVERSARY DINNERS AND TIMES WITH HER CHILDREN, LOST COUNTLESS HOURS OF WORK UNTIL THEY LET HER GO FROM BEING OUT ON SHORT TERM WHERE SHE WAS ACTUALLY MOVING UP IN HER POSITION. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN AND CHRONIC BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO AN ABLATION AND LATER, TO A HYSTERECTOMY. AFTER THIS PROCEDURE, THE UPPER MOST CUFF OF HER VAGINA HAD RIPPED AND HER BOWEL WERE PROTRUDING (SHE FELT SOMETHING RIP INSIDE). ANOTHER SURGERY WAS REQUIRED TO REPAIR IT. HER PAIN PERSISTED AND A STAPLE FROM THE SURGERY WAS FOUND POKING AN OVARY; THIS STAPLE WAS REMOVED. ONLY PELVIC PAIN AND BLEEDING (REGARDED AS GENITAL BLEEDING) ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER'S BLEEDING AND PELVIC PAIN STARTED IN CLOSE ASSOCIATION WITH ESSURE PROCEDURE (ACCORDING TO THE REPORTER FROM DAY 1) AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THE REMAINING EVENTS WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT, SINCE THEY OCCURRED AS A COMPLICATION OF THE SURGICAL PROCEDURE FOR ESSURE REMOVAL. ADDITIONALLY, THE SERIOUS EVENT CYST (UNSPECIFIED, THUS CAUSALITY WITH ESSURE CANNOT BE ASSESSED) AND NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, AS DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL COMPLAINT ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01506	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1688, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014. ADDITIONAL INFORMATION RECEIVED ON 23-OCT-2015. CONCOMITANT MEDICATION INCLUDED ALBUTEROL, EFFEXOR, FLAXSEED OIL, CALCIUM AND VITAMIN D. THE CONSUMER STATED THAT IT WAS A PAINFUL PLACEMENT AND THE PAIN JUST CONTINUED. THE FIRST PLACEMENT IN HER FALLOPIAN TUBE SNAPPED IN HALF AND HAD TO BE REMOVED AND INSERTED AGAIN. SHE WAS AWAKE AND FELT EVERYTHING. EVERYTHING WENT OKAY WITH THE RIGHT SIDE. IN THE FOLLOWING WEEKS, SHE EXPERIENCED PAIN. DURING HER PLACEMENT SCAN, THE RIGHT SIDE WAS FINE. IT WAS FOUND OUT THAT THE LEFT COIL WOUND UP ON ITSELF AND PERFORATED HER FALLOPIAN TUBE AND THE PHYSICIAN SCHEDULED SURGERY TO HAVE IT REMOVED. SCHEDULING TOOK FOREVER AND ONE NIGHT SHE DOUBLED OVER IN PAIN AND ALMOST THREW UP FROM THE INTENSITY OF IT ALL. SHE REALLY BELIEVED THAT THE COIL RIPPED FROM HER TUBE THAT NIGHT. ALMOST THREE MONTHS LATER, SHE WENT IN FOR THE COIL REMOVAL. DURING THE PROCEDURE THEY DID A SALPINGECTOMY AND THE DOCTOR COULD NOT FIND THE COIL, EVEN AFTER PERFORMING AN EXTENSIVE EXPLORATORY LAPAROSCOPY. A CT SCAN (COMPUTERIZED TOMOGRAPHY) WAS PERFORMED AND SHOWED THAT THE COIL WAS EMBEDDED IN HER UTERINE LINING. HER DOCTOR SAID THAT IT SHOULD CALCIFY AND THAT SHOULD BE THE END OF IT. SHE HAD BEEN IN PAIN EVER SINCE. EVERY MONTH THERE WAS PAIN. SHE HAS ASKED SEVERAL TIMES FOR A HYSTERECTOMY, SHE WOULD RATHER GIVE UP AN ORGAN AND HER LAST FALLOPIAN TUBE THAN KEEP THE COILS IN AND DEAL WITH THE PAIN. THE

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CONSUMER ALSO PROVIDED (B)(6) 2015 AS ESSURE IMPLANT DATE (DISCREPANCY). SHE ASSESSED THE EVENT OUTCOME AS DISABILITY/ PERMANENT DAMAGE; BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE FIRST PLACEMENT ATTEMPT IN HER FALLOPIAN TUBE THE INSERT SNAPPED IN HALF (INTERPRETED AS DEVICE BREAKAGE). DURING HER CONFIRMATORY TEST IT WAS FOUND THAT THE LEFT COIL PERFORATED HER FALLOPIAN TUBE. SHE UNDERWENT SURGERY TO REMOVE THE COIL BUT IT COULD NOT BE FOUND. LATER A CT (COMPUTERIZED TOMOGRAPHY) SCAN SHOWED THAT THE COIL WAS EMBEDDED IN UTERINE LINNING, INTERPRETED AS EMBEDDED DEVICE (PARTIAL UTERINE PERFORATION). THESE EVENTS WERE CONSIDERED SERIOUS AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE; EXCEPT FOR DEVICE BREAKAGE WHICH IS NON-SERIOUS AND ANTICIPATED ACCORDING TO THE TECHNICAL ANALYSIS. IN THE PRESENT CASE, SINCE THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. UTERINE AND FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE. IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THESE EVENTS WAS NOT CLEARLY REPORTED. IT IS POSSIBLE THAT THE COMPLICATED INSERTION PROCEDURE HAD CONTRIBUTED TO THE PERFORATION. SHE STATED THAT DURING HER PLACEMENT SCAN (INTERPRETED AS CONFIRMATORY TEST) IT WAS FOUND THAT THE LEFT COIL PERFORATED HER FALLOPIAN TUBE, BUT IT COULD NOT BE FOUND DURING SURGERY, AND LATER A CT SCAN SHOWED THAT THE COIL WAS EMBEDDED IN UTERINE LINNING. GIVEN THE NATURE OF THESE EVENTS, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. DISABILITY WAS MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 21-DEC-2015: FOLLOW-UP ATTEMPTS WERE MADE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01507	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/10/2012
Explant Date (E7): 1/3/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044748) IN UNITED STATES ON 20-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. THE CONSUMER HAD ESSURE INSERTED A MONTH AFTER HER DAUGHTER WAS BORN. AFTER SHE HAD ESSURE INSERTED FOR ONE MONTH, SHE FOUND OUT SHE WAS PREGNANT WITH HER LAST CHILD. SHE TOLD PHYSICIAN IF COULD TAKE THE ESSURE OUT AND IT WAS DENIED BECAUSE SHE HAD TO HAVE AN ABORTION AND SHE DID NOT WANT AN ABORTION. HER PREGNANCY WAS HIGH RISK. CONSUMER ASSESSED THE CASE AS OTHER SERIOUS (IMPORTANT MEDICAL EVENT). ESSURE REMOVAL DATE WAS PROVIDED ((B)(6) 2014). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO FOUND OUT SHE WAS PREGNANT ONE MONTH AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE PROVIDED AN ESSURE REMOVAL DATE. THE EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION AND WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE (ADDITIONALLY, CONSUMER STATED HER PREGNANCY WAS HIGH RISK). AFTER ESSURE INSERTION, THERE IS A REQUIRED 3 MONTH PERIOD FOR TISSUE IN-GROWTH INTO AND AROUND THE INSERT, FACILITATING INSERT RETENTION AND PREGNANCY PREVENTION. DURING THIS PERIOD IT IS RECOMMENDED TO USE ALTERNATE CONTRACEPTION METHOD PRIOR TO THE CONFIRMATION TEST. TREATMENT NON-COMPLIANCE, INCLUDING FAILURE TO USE ALTERNATE CONTRACEPTION DURING THIS 3-MONTH WAITING PERIOD MAY LEAD TO PREGNANCIES. IN THIS PARTICULAR CASE, CONSUMER GOT PREGNANT LESS THAN THREE MONTHS AFTER ESSURE INSERTION. THEREFORE, A DEVICE CONTRACEPTIVE FAILURE CAN BE EXCLUDED. REGARDING ESSURE REMOVAL, MINIMAL INFORMATION WAS GIVEN. CONSUMER ONLY PROVIDED AN ESSURE REMOVAL DATE (WHICH WAS 15 MONTHS AFTER DEVICE PLACEMENT). ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT PROVIDED; IT CANNOT BE EXCLUDED THIS PROCEDURE WAS DUE TO A COMPLICATION OF DEVICE THERAPY. THUS, THIS CASE WAS CONSIDERED AN INCIDENT UNTIL FURTHER INFORMATION IS OBTAINED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01508	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 962097

Single Use: Y
Implant Date (E6): 8/13/2012
Explant Date (E7): 1/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055551) IN UNITED STATES ON 20-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012, LOT NUMBER 962097. THE CONSUMER BLED ENSUED FOR OVER 90 DAYS SINCE INSERTION AND THEN EXPERIENCED SEVERE CRAMPING, HEADACHES, LOWER BACK PAIN AND THE PROCEDURE DID NOT TAKE ON THE SIDE. IN THE 2 YEARS LEADING UP TO HYSTERECTOMY, SHE BLEED FOR MONTHS AT A TIME, COULD NOT HAVE INTERCOURSE, AND WAS MOSTLY IN BED FOR THE TIME UNTIL SHE HAD THE REMOVAL. ONE COIL HAD FLOATED INTO UTERUS AND WAS CONNECTING TO WALL CAUSING MORE BLEEDING. SHE HAD PROCEDURE DONE ON (B)(6) 2015 AND HAD TO WAIT MONTHS FOR THEM TO CLEAR IT THROUGH THE RED TAPE (AS REPORTED). SHE HAD TO MOVE TO ANOTHER PLACE AND ENDED UP HAVING A PARTIAL HYSTERECTOMY DUE TO ESSURE. EVENT DATE WAS REPORTED WAS (B)(6) 2012 (NOT SPECIFIED). CONCOMITANT DRUG INCLUDED TYLENOL. A REQUIRED INTERVENTION WAS MENTIONED BUT NOT SPECIFIED/ASSIGNED TO ONE OF THE EVENTS. AFTER INTERNAL REVIEW ON 12-NOV-2015, THIS CASE WAS IDENTIFIED AS A DUPLICATE TO CASE (B)(4) AND WILL BE DELETED FROM BAYER DATABASE. COMPANY CAUSALITY COMMENT THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BLEEDING ENSUED FOR 90 DAYS SINCE INSERTION (INTERPRETED AS GENITAL BLEEDING). ONE COIL HAD BLOATED INTO UTERUS AND WAS CONNECTING TO WALL (INTERPRETED AS DEVICE EMBEDDED/PARTIAL PERFORATION). THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE GENITAL BLEEDING STARTED AT INSERTION AND LATER IT WAS FOUND THAT ONE ESSURE INSERT

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WAS EMBEDDED IN UTERUS. CONSIDERING THE NATURE OF THESE EVENTS AND SUGGESTIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. FURTHER INFORMATION AND A PRODUCT TECHNICAL COMPLAINT ARE EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01510	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7): 7/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1963, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 10 YEARS BEFORE THIS REPORT (IN 2005). CONSUMER STATED THAT SHE AUTOMATICALLY STARTED HAVING ISSUES BUT HAD NO IDEA WHY OR WHAT WAS WRONG ALL THE SUDDEN, SHE STARTED BEING ALLERGIC TO ANTIBIOTICS SHE TOOK IN THE PAST AND ALSO OTHER THINGS. NOW SHE WAS ALLERGIC TO MANY ANTIBIOTICS, LATEX, ADHESIVE TAPE AND ONE ALLERGY SHE ALWAYS HAD WAS TO NICKEL AND SHE WAS NOT TESTED FOR NICKEL NOR WAS SHE TOLD IT CONTAINED NICKEL. SHE ALSO EXPERIENCED 2 PULMONARY EMBOLISMS, NEEDED A PACE MAKER DUE TO BRADYCARDIA, NEEDED TO HAVE GALLBLADDER SURGERY, SHE WAS DEPRESSED, VIOLENTLY ILL AND SUICIDAL WOMEN AND MOTHER DUE TO ALL HER ILLNESS. SHE WAS ON DISABILITY BECAUSE SHE COULD NOT DO HER JOB DUE TO ALL HER HEALTH ISSUES. SHE ALSO HAD FIBROMYALGIA. ON (B)(6) 2015, SHE HAD A HYSTERECTOMY AFTER 2 FAILED ABLATIONS AND 10 YEARS OF HORRIBLE EXCRUCIATING PERIODS AND CRAMPING. SHE ALSO HAD ENDOMETRIOSIS AND CYSTS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015 AND DATA CORRECTION FROM 16-NOV-2015: FOLLOWING INTERNAL REVIEW THE CODING OF EVENT HORRIBLE EXCRUCIATING PERIODS WAS CORRECTED FROM MENSTRUATION IRREGULAR TO DYSMENORRHEA. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING AND HORRIBLE EXCRUCIATING PERIODS. A HYSTERECTOMY WAS PERFORMED AFTER 2 FAILED ABLATIONS. THESE EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS REPORTED THAT SHE EXPERIENCED THESE EVENTS FOR 10 YEARS SINCE ESSURE INSERTION. BASED ON A POSITIVE TEMPORAL RELATIONSHIP AND CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED, UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01511	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2009
Explant Date (E7): 10/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1751, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. ESSURE WAS REMOVED BY MEANS OF FALLOPIAN TUBE REMOVAL/EXPLORATORY IN (B)(6) 2010 TO SEE WHAT WAS CAUSING ALL HER PAIN AND DISCOMFORT. DOCTOR REMOVED FALLOPIAN TUBES AND FOUND THAT SHE WAS FULL OF INFECTION BECAUSE THE RIGHT COIL BROKE OFF, PUNCTURED HER FALLOPIAN TUBE AND MIGRATED TO THE TOP SIDE OF HER UTERUS. THE INFECTION WAS TREATED WITH ANTIBIOTICS ONLY TO FIND SHE WAS STILL EXTREMELY ILL AND ONE MONTH LATER SHE OPTED FOR COMPLETE HYSTO (INTERPRETED AS HYSTERECTOMY) TO REMOVE ALL THE INFECTION AND DAMAGE ESSURE CAUSED HER. TO THE DAY OF REPORT (2015), SHE WAS STILL DEALING WITH FATIGUE, INFLAMMATION AND MANY OTHER AUTOIMMUNE SYMPTOMS THAT NOBODY COULD EXPLAIN TO HER. SHE ALSO HAD ESSURE INSERTED AT THE SAME TIME SHE HAD AN ABLATION. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01512	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. THE CONSUMER HAD THE ESSURE INSERTION AND ABLATION DONE AT THE SAME TIME. IN (B)(6) 2015 SHE HAD HER FOLLOW UP AND ONE COIL HAD ALREADY UNCOILED AND KINKED. SHE WAS TOLD IT WAS FINE BECAUSE NO DYE RAN THROUGH THE TUBE. SINCE (B)(6) 2015 SHE HAD BEEN EXPERIENCING SEVERE BACK AND LOWER ABDOMINAL PAIN, BOTH ON RIGHT SIDE (THE SAME SIDE THE COIL WAS NOT CORRECT ON), HAIR LOSS, UNEXPLAINED RASHES THAT HURT, HEADACHES, DIZZY SPELLS, UNEXPLAINED BLEEDING MULTIPLE TIMES A MONTH, WEIGHT GAIN, BRAIN FOG. THOSE ENTIRE SHE DID NOT HAVE BEFORE ESSURE. SHE STATED THAT HER LIFE HAD BEEN SEVERELY IMPACTED BY ESSURE. SHE HAD NEVER BEEN TESTED FOR NICKEL ALLERGY. SHE HAD A HISTORY OF BLOOD CLOTTING DISORDERS WHEN PREGNANT AND WAS URGED TO NOT HAVE ANY MORE CHILDREN. SHE WAS TOLD BY ANOTHER DOCTOR THAT ONE COIL, THE RIGHT ONE, WAS COMING APART AND WAS NOT POSITIONED CORRECTLY, AND THAT MIGHT BE WHY SHE WAS HAVING THOSE PROBLEMS. SHE ALSO SAW A CYST ON THAT SIDES OVARY, NEVER HAD ONE BEFORE ESSURE. SHE WOULD MOST PROBABLY HAVE TO HAVE A HYSTERECTOMY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 10-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED,

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USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENTS CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD UNEXPLAINED BLEEDING MULTIPLE TIMES A MONTH (REGARDED AS GENITAL BLEEDING) AFTER ESSURE INSERTION. ADDITIONALLY, SHE STATED ONE COIL, THE RIGHT ONE, IS COMING APART AND IS NOT POSITIONED CORRECTLY. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. EXCEPT FOR COIL COMING APART (REGARDED AS A POSSIBLE DEVICE BREAKAGE); WHICH IS ANTICIPATED ACCORDING TO THE TECHNICAL ASSESSMENT. IN THIS CASE, CONSUMER HAD ESSURE INSERTED AND AN ENDOMETRIAL ABLATION WAS DONE ON THE SAME DAY (CONTRAINDICATED ACCORDING TO THE PRODUCT INSTRUCTIONS FOR USE). ALTHOUGH THE REASON FOR THIS ENDOMETRIAL ABLATION WAS NOT SPECIFIED, THIS PROCEDURE SUGGESTS CONSUMER HAD A PREVIOUS GENITAL BLEEDING DISORDER. NEVERTHELESS, A CONTRIBUTORY ROLE OF ESSURE IN CONSUMER'S BLEEDING CANNOT BE TOTALLY RULE OUT, SINCE ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR DURING DEVICE THERAPY. REGARDING THE REMAINING EVENT, CONSUMER STATED HER FOLLOW-UP TEST (PERFORMED 4 MONTHS AFTER ESSURE PLACEMENT) SHOWED THE RIGHT COIL HAD UNCOILED AND KINKED. ACCORDING TO HER, ANOTHER PHYSICIAN STATED THE COIL WAS COMING APART AND WAS NOT IN CORRECT POSITION. ALTHOUGH THE INFORMATION PROVIDED IS NOT CLEAR; CONSIDERING EVENTS NATURE AND GIVEN THEIR CLOSE ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, SINCE A DEVICE BREAKAGE CANNOT BE FORMALLY EXCLUDED. THIS EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION, BUT THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY OTHER NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED BY THE COMPANY, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01513	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE HAD NO PROBLEM WITH MONTHLY CYCLE UNTIL ESSURE. AFTER THAT, SHE BLED FOR 23 DAYS WITH HALF DAY OFF THEN BLED FOR 67 DAYS STRAIGHT DESPITE BEING ON BIRTH CONTROL. SHE HAD A HYSTERECTOMY AND MAGICALLY FELT BETTER, NO WEIGHT GAIN JUST LOSING, NO 7 MONTHS PREGNANT LOOK AND NO MIGRAINES. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO

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RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLED FOR 23 DAYS WITH HALF DAY OFF THEN BLED FOR JUST SHY OF 67 DAYS STRAIGHT. SHE WAITING DIAGNOSES OF MS AND HAD HYSTERECTOMY PERFORMED. THESE EVENTS, SEEN AS MENORRHAGIA AND MULTIPLE SCLEROSIS, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. MENORRHAGIA IS LISTED WHILE, MULTIPLE SCLEROSIS IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MENSES PATTERN CHANGES ARE FREQUENT IN WOMEN WITH ESSURE IN PLACE. IN THIS CASE, SHE HAD NO PROBLEM WITH MONTHLY CYCLE UNTIL ESSURE. AFTER THAT, SHE BLED FOR 23 DAYS WITH HALF DAY OFF THEN BLED FOR 67 DAYS STRAIGHT DESPITE BEING ON BIRTH CONTROL. SHE HAD A HYSTERECTOMY AND MAGICALLY FELT BETTER (POSITIVE DECHALLENGE). CONSIDERING THE IMPLIED TEMPORAL RELATIONSHIP AND POSITIVE DECHALLENGE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. IN ADDITION, IS VERY UNLIKELY THAT ESSURE HAD LED HER TO MULTIPLE SCLEROSIS. AS AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01514	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1943, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE GOT ESSURE BECAUSE SHE WAS TOLD THAT IT WAS THE BEST OPTION FOR HER SINCE SHE WAS OVERWEIGHT. CONSUMER REPORTED THAT SHE WAS (B)(6) AT THE TIME OF THIS REPORT. SHE HAVE HAD SEVERE CRAMPS, BLOATING, BLEEDING, MUSCLE WEAKNESS, JOINT PAIN, NEUROPATHY, HAIR LOSS, RASHES AND SHE WAS ALLERGIC TO NICKEL. SHE STATED SHE TAKES 20 DIFFERENT MEDICATIONS DAILY. SHE HAD A HYSTERECTOMY SCHEDULED FOR (B)(6) 2015. FOLLOW UP RECEIVED ON 11-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER:(B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY

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COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEVERE CRAMPS (INTERPRETED AS ABDOMINAL PAIN) AND BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE WAS SCHEDULED FOR A HYSTERECTOMY. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL PAIN AND GENITAL BLEEDING MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENTS AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01515	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1874, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. SHE DEVELOPED MANY SYMPTOMS INCLUDING: SEVERE HEADACHES, NAUSEA, FATIGUE, ABDOMINAL PAIN, SHORTNESS OF BREATH, PALPITATIONS, CHEST PAIN, HAIR LOSS, JOINT PAIN, BACK PAIN (UPPER AND LOWER BACK), SHOOTING PAIN NEAR OVARIES AREA, DIZZINESS, WEAKNESS, HEAVY AND PAINFUL PERIOD, DAILY FLU LIKE SYMPTOMS, NECK PAIN, PELVIC PAIN AND MORE. SHE STATED THAT SHE NEVER HAD ANY HEALTH PROBLEMS IN THE PAST BESIDES, MINOR COLDS. ESSURE WAS REMOVED OVER AGO, MOST OF HER SYMPTOMS WENT AWAY, BUT SOME ARE BACK NOW. SHE STILL DOES NOT FEEL 100 PERCENT HERSELF. SHE HAS HAD SEVERAL OFFICE VISITS WITH HER DOCTOR ABOUT ISSUES THAT ARE STILL LINGERING. SHE WAS REFERRED TO A CARDIOLOGIST, NEUROLOGIST, OBGYN AND PULMONARY TESTING. SHE ALSO HAD MANY IMAGES DONE SUCH AS ULTRASOUND, TWO CT SCAN, X-RAY, AND MRI. ACCORDING TO HER, ESSURE CAUSES A PERMANENT DAMAGE ONCE IT IS IN YOUR BODY. REMOVAL DOES NOT GUARANTEE SYMPTOMS WILL GO AWAY. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE

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HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT. THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED PELVIC PAIN. ESSURE WAS REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01516	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2053, AWARENESS DATE 20-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER CURRENT AGE IS (B)(6). SHE HAS 4 CHILDREN, HAD TWINS LAST (B)(6). SHE HAD 3 VAGINAL DELIVERIES AND 1 C-SECTION. SHE HAD A HARD RECOVERY AFTER THE BIRTH OF THE TWINS. CONSUMER REPORTED BLOATING (LOOKS LIKE PREGNANT), SHE NO LONGER GET THE SENSATION TO GO TO THE BATHROOM IT IS JUST PAIN, SHE CANNOT WEAR CONTACTS BECAUSE HER BODY IS REJECTING THEM, HER FACE IS BREAKING OUT, HAIR IS STARTING TO FALL OUT, SHE IS ON PAIN MEDICATION, SHAKES BECAUSE OF THE PAIN SHE IS IN, SHE HAS SO MUCH SWELLING AND EVERYTHING THAT IT IS PUSHING ON NERVES IN HER BACK CAUSING HER LEFT LEG TO GO NUMB, SHE CANNOT SLEEP FROM ALL THE PAIN, CANNOT EAT BECAUSE IT CAUSES MORE PAIN AND SHE CRIES FROM THE PAIN. SHE STARTED GETTING BACK PAIN AND SHE JUST BRUSHED IT OFF AS HER MOTHERLY PAINS. THE PAIN GOT WORSE AND SHE HAD TO CALL HER DOCTOR. HE EXAMINED HER AND EXPLAINED THAT HER CERVIX HAD GIVEN OUT. SHE WAS EXAMINED BY ANOTHER PHYSICIAN AND GOT THE SAME RESULT. SO, AT (B)(6) SHE HAD TO GET A HYSTERECTOMY. ON (B)(6) 2015 SHE WENT IN TO GET HER TUBAL. THIS ALL HAPPENED BEFORE SHE EVEN WENT BACK TO HER POST OPERATIVE APPOINTMENT. CONSUMER STATED THAT THIS HAS BEEN THE MOST HORRIBLE 9 DAYS OF HER LIFE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED PAIN. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND

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LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER HAD INTENSE PAIN A FEW WEEKS AFTER THE INSERTION AND THEN HAD A HYSTERECTOMY PERFORMED. CONSIDERING EVENT'S NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT RECEIVED ON 15-NOV-2015: THE BAYER PTC REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01517	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5041347) IN UNITED STATES ON 20-OCT-2015 WHICH REFERS TO A NEONATE FEMALE WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERUS. THE CONSUMER HAD ESSURE INSERTED IN 2010 AND 8 MONTHS AFTER SHE HAD THE PROCEDURE SHE WENT TO THE DOCTOR BECAUSE THE NAUSEA BECAME TOO MUCH AND HE ASKED IF SHE COULD BE PREGNANT AND DID TEST ANYWAY TO BE SAFE, THE PREGNANCY TEST WAS POSITIVE. THE CONSUMER REPORTED BEING SCARED BECAUSE SHE HAD HAD AN ECTOPIC RUPTURE BEFORE AND ONLY HAS ONE TUBE BUT IT TURNED OUT THE BABY WAS IN THE UTERUS. THE PREGNANCY WAS SCARY BECAUSE NO ONE KNEW WHAT COULD HAPPEN WITH THE ESSURE IN PLACE. SHE DELIVERED 6 WEEKS EARLY AND WHILE IN LABOR HER PLACENTA RUPTURED AND THE BABY GOT BLOOD IN HER LUNGS AND HAD TO STAY IN THE NICU FOR TWO WEEKS. MOTHER CASE NUMBER (B)(6). COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER AND REFERS TO HER FEMALE BABY; WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERUS. THE MOTHER DELIVERED 6 WEEKS EARLY AND WHILE IN LABOR HER PLACENTA RUPTURED; THE BABY GOT BLOOD IN HER LUNGS AND HAD TO STAY IN THE NICU FOR TWO WEEKS. THE REPORTED EVENTS ARE UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. WHEN ESSURE IS IN ITS IDEAL POSITION, 3 TO 8 OUTER COIL WILL BE TRAILING INTO THE UTERUS. IN THIS PARTICULAR CASE, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND MOTHER'S PREGNANCY CANNOT BE EXCLUDED, DUE TO THE GESTATIONAL AGE AT THE TIME OF EVENTS. SINCE THE EVENTS IN THE BABY OCCURRED AS A CONSEQUENCE OF MATERNAL COMPLICATIONS DURING THE PREGNANCY (FOR WHICH CAUSALITY WITH ESSURE CANNOT BE EXCLUDED); THEY WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. DUE TO THE REQUIRED HOSPITALIZATION,

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THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FOLLOW-UP WILL BE POSSIBLE, DUE TO LACK OF CONTACT DETAILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01518	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1699, AWARENESS DATE 20-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. THE CONSUMER STATED SHE WAS IN SO MUCH PAIN THAT SHE COULD NOT TAKE CARE OF HER (B)(6) SON. ON (B)(6) 2015 (DISCREPANT DATE), HER DOCTOR WHO WAS THE SAME WHO INSERTED ESSURE WANTS TO TRY AN ABLATION AND REMOVE AN OVARY AND CYST. SHE HAD BEEN BLEEDING HEAVY SINCE INSERTION. ALL EVENTS WERE CONSIDERED RELATED TO ESSURE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BEEN BLEEDING SINCE THE INSERTION. THIS EVENT, SEEN AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER WAS BLEEDING SINCE THE INSERTION AND AN ABLATION AND A REMOVAL OF OVARY AND CYST WERE PLANNED. CONSIDERING EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED SINCE AN INTERVENTION WAS PLANNED (ABLATION), THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01519	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/22/2008
Explant Date (E7): 7/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1818, AWARENESS DATE 20-OCT-2015) WHICH REFERS TO FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. THE CONSUMER REPORTED THE DAY OF HER IMPLANT; HER DOCTOR GAVE HER A LOCAL TO NUMB HER CERVIX. DURING THE INSERTION OF THE FIRST COIL, SHE HAD A BURNING FEELING ON HER ENTIRE LEFT SIDE FROM THE WAIST DOWN. THE DOCTOR INFORMED THAT IT WAS SUPPOSED TO DO THAT; SHE SAID THAT IS HOW THEY KNOW THAT THEY GOT THE COIL INTO HER TUBE. THE SECOND COIL WAS IMPLANTED WITHOUT THE BURNING FEELING. THAT BURNING FEELING LASTED THE WHOLE DAY AFTER SHE HAD LEFT THE OFFICE. FROM THERE SHE NOTICE LITTLE THINGS THAT STARTED HAPPENING OVER THE MONTHS, WEIGHT GOING UP, NIGHT SWEATS, LEG CRAMPS, MORE HEADACHES DURING THE WEEK, ALWAYS TIRED, BAD CRAMPS, STOMACH PAIN EVEN WITHOUT HER PERIOD, OVARIES ALWAYS HURTING, HAIR LOSS, FACE AND BODY BREAKING OUT WITH PIMPLES, NO ENERGY AND THE LIST GOES ON. IN 2013, SHE WAS ON VACATION AND STARTING BLEEDING THIS ORANGE COLOR BLOOD AND SHE KNEW WAS NOT A NORMAL PERIOD AND THAT SOMETHING WAS WRONG. WHEN SHE GOT BACK HOME FROM VACATION SHE SCHEDULED AN APPOINTMENT WITH HER DOCTOR AND HAD ALL TYPES OF TEST DONE TO FIND OUT THE CAUSE OF THIS BLEEDING. SHE WENT TO A GYNECOLOGIST WHO DID A BIOPSY OF HER CERVIX ONLY FOR THEM TO COME BACK AND TELL ME THAT HER UTERUS WALL WAS BEYOND PAPER THIN AND THAT WAS WHERE THE BLEEDING CAME FROM. TWO DAYS LATER, HER WHOLE BODY BROKE OUT IN SOME RASH; SHE WENT TO A DERMATOLOGIST WHO DID A BIOPSY OF A PIECE OF HER RASH AND SAID SHE HAD LICHEN PLANUS, SHE WAS PUT ON STEROID BODY CREAM TO

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HELP GET RID OF THE RASH. ONCE THE RASH WAS GONE SHE STARTED NOTICING A LOT OF FACIAL HAIR GROWING IN ON HER CHIN AND CHEST WHICH SHE NEVER HAD BEFORE. AFTER A FEW MONTHS SHE STARTED TO NOTICE A FOUL SMELL COMING FROM HER VAGINAL AREA. SHE CALLED HER DOCTOR BACK UP AND MADE AN APPOINTMENT; SHE WENT AHEAD AND DID A PAP TEST WHICH CAME BACK NORMAL. UP UNTIL (B)(6) 2015, SHE HAD THIS SMELL AND IT GOT REALLY BAD BEFORE HER PERIODS AND WHEN SHE HAD INTERCOURSE; SHE EVEN HAD HER HUSBAND GO GET CHECKED TO SEE IF THERE WAS ANYTHING WRONG WITH HIM. SHE CHANGED DOCTORS AND ASKED ABOUT THE SMELL AND SHE DID A TEST AND AS SOON AS SHE OPENED HER UP SHE SAID YES YOU DO HAVE BV. THE CONSUMER STATED SHE HAD NEVER HAD BV BEFORE IN HER LIFE, ONLY HAD 1 YEAST INFECTION. FOR ALMOST 2 YEARS SHE HAD TO LIVE WITH THIS SMELL AND A DOCTOR TELLING HER NOTHING WAS WRONG. SHE HAD ALL HER TEST DONE AND WAS APPROVED FOR SURGERY TO HAVE THE COILS REMOVED. ON (B)(6) 2015, SHE HAD HER SURGERY AND AT TIME OF THE REPORT SHE WAS ALMOST 3 MONTHS POST-OP AND HAS HER LIFE BACK. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED BLEEDING THIS ORANGE COLOR BLOOD. SHE HAD A SURGERY TO HAVE THE COILS REMOVED. THIS EVENT, SEEN AS GENITAL HAEMORRHAGE, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH UTERINE DISORDER (SHE STATED THAT HER UTERUS WALL WAS LIKE A PAPER THIN WHICH WOULD BE THE REASON FOR THE BLEEDING) COULD BE AN ALTERNATIVE EXPLANATION; CONSIDERING GENITAL BLEEDING MAY OCCUR DURING ESSURE USE, A CONTRIBUTORY ROLE FROM SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01520	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 10/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/9/2013
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1624, AWARENESS DATE 20-OCT-2015) WHICH REFERS TO AN ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. THE CONSUMER REPORTED THE LEFT SIDE COIL RUPTURED HER LEFT SIDE FALLOPIAN TUBE AND SHE SUFFERED PAIN EVERY DAY SINCE IMPLANT. SHE WOULD ALSO HAVE MOOD SWINGS; SHE WAS DEPRESSED, HAD LOTS OF ANXIETY AND WAS ALWAYS BLOATED, NOT TO MENTION THAT IT WAS VERY PAINFUL TO HAVE ANY INTERCOURSE WITH HER SPOUSE. SHE WAS INFORMED BY HER GYNECOLOGIST IN LATE (B)(6) 2014 THAT SHE SHOULD CONSIDER ANOTHER TYPE OF BIRTH CONTROL DUE TO THEIR FINDINGS. SHE DID AND SHE DEVELOPED PULMONARY EMBOLISM IN BOTH OF LUNGS. SHE WAS THAN INFORMED THAT IN ORDER TO HAVE THE ESSURE REMOVED COMPLETELY WITHOUT LEAVING ANY FRAGMENTS BEHIND SHE WOULD HAVE TO ENDURE HAVING A HAVE HYSTERECTOMY. THIS PROCEDURE TOOK PLACE (B)(6) 2015 AND SHE WAS (B)(6) AT THE TIME. SHE STATED THAT NOW SHE WAS BACK TO HER NORMAL SELF, PAIN FREE AND WITHOUT ANY OF THE OTHER SYMPTOMS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY

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QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SUFFERED PAIN EVERY DAY SINCE IMPLANT (INTERPRETED AS PELVIC PAIN). IT WAS NOTICED A FEW MONTHS LATER, THAT THE LEFT SIDE COIL RUPTURED HER LEFT SIDE FALLOPIAN TUBE (INTERPRETED AS FALLOPIAN TUBE PERFORATION). SHE STARTED TO USE ANOTHER TYPE OF BIRTH CONTROL AND DEVELOPED PULMONARY EMBOLISM IN BOTH LUNGS. SHE STATED SHE HAD TO PERFORM A HYSTERECTOMY TO REMOVE ESSURE COMPLETELY. AT THE TIME OF REPORT SHE WAS PAIN FREE AND ALL HER SYMPTOMS SUBSIDED. THE PELVIC PAIN AND FALLOPIAN TUBE PERFORATION ARE LISTED WHILE THE PULMONARY EMBOLISM IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF FALLOPIAN TUBE PERFORATION AND PELVIC, IN ADDITION TO THE SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THESE EVENTS CANNOT BE EXCLUDED. HOWEVER, DESPITE THE COMPATIBLE TEMPORAL RELATIONSHIP, CONSIDERING THAT ESSURE HAS ONLY LOCALIZED ACTION IN THE FALLOPIAN TUBES AND THAT THE PULMONARY EMBOLISM DEVELOPED AFTER SHE STARTED TO USE ANOTHER TYPE OF BIRTH CONTROL THAT WAS NOT SPECIFIED, IT IS UNLIKELY THAT ESSURE WOULD CAUSE A PULMONARY EMBOLISM AND IT IS RATHER RELATED TO THE ALTERNATIVE BIRTH CONTROL USED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01521	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1906, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. AT THE TIME OF REPORT, CONSUMER WAS (B)(6). SHE STARTED TO EXPERIENCE MANY SIDE EFFECTS A FEW MONTHS AFTER ESSURE WAS INSERTED, INCLUDING SEVERE ABDOMINAL PAIN AND SWELLING, ABNORMAL EXCESSIVE BLEEDING DURING MENSTRUAL CYCLE CAUSING HER TO BECOME ANEMIC AND HAVING TO BE HOSPITALIZED BECAUSE OF BECOMING SEVERE ANEMIC AT ONE POINT. CONSTANT PELVIC PRESSURE AND PAIN. LOWER BACK PAIN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO BE HOSPITALIZED DUE TO ANEMIA CAUSED BY ABNORMAL EXCESSIVE BLEEDING DURING MENSTRUAL (INTERPRETED AS MENORRHAGIA). THE MENORRHAGIA AND ANEMIA ARE SERIOUS DUE TO HOSPITALIZATION. THE MENORRHAGIA IS LISTED WHILE THE ANEMIA IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE MENORRHAGIA STARTED A FEW MONTHS AFTER ESSURE INSERTION. CONSIDERING THIS SUGGESTIVE TEMPORAL RELATIONSHIP AND THE LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. SINCE THERE IS NO ALTERNATIVE EXPLANATION FOR ANEMIA BESIDES THE MENORRHAGIA ASSESSED AS RELATED TO ESSURE, THE CAUSAL RELATIONSHIP WITH ANEMIA CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A HOSPITALIZATION DUE TO AN ESSURE-RELATED EVENT OCCURRED. A PRODUCT TECHNICAL

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COMPLAINT ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING CYCLE.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01523	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 7/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 11/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1859, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. ADDITIONAL INFORMATION RECEIVED ON 11-NOV-2015 (PTC INVESTIGATION RESULT). CONSUMER HAD ESSURE IMPLANTED WHEN SHE WAS (B)(6) AFTER HAVING ISSUES WITH PREGNANCY DUE TO BEING DIABETIC. SHE HAD THE PROCEDURE DONE IN THE OFFICE AND HAD ISSUES FROM MOMENT 1. SHE HAD PAIN, BLED DAILY FOR ALMOST 8 MONTHS. EVERY TIME SHE WOULD GO BACK TO THE DOCTOR COMPLAINING OF PAIN, DEPRESSION, LETHARGY, WEIGHT GAIN AND AN INABILITY TO FUNCTION. SHE DID HAVE HER SCHEDULE HYSTEROSALPINGOGRAM. IN (B)(6) 2012 SHE WAS ADMITTED TO THE HOSPITAL WITH SEVERE ABDOMINAL PAIN AND SHE WAS TOLD THAT IT WAS ALL IN HER HEAD AND THERE WAS NOTHING WRONG WITH HER. TWO DAYS LATER, SHE WENT BACK TO THE EMERGENCY ROOM IN AN AMBULANCE. ON MULTIPLE INSTANCES SHE WOULD GO TO THE EMERGENCY ROOM AND WAS ACCUSED OF BEING A SEEKER LOOKING FOR DRUGS AND NOT A WOMAN IN PAIN AND THEY GAVE HER PAIN KILLERS AND SENT HER HOME BECAUSE THEY HAD NO IDEA WHAT WAS WRONG WITH HER. SHE HAD ANOTHER TRIP TO HER GYNECOLOGIST WHO WANTED HER TO STICK IT OUT TO HAVE MORE TESTS. AFTER 2 WEEKS SHE WENT BACK BEGGING HIM TO TAKE THEM OUT. IN (B)(6) 2012 SHE HAD A LAPAROSCOPIC SALPINGECTOMY. SHE STARTED TO FEEL SLIGHTLY BETTER. THE THING SHE DID NOT SEE COMING WAS CONTINUED ABDOMINAL PAIN, INCREASED BLEEDING AND CONTINUATION OF ALL OF HER OTHER SYMPTOMS. ADD INTO THAT DANGEROUSLY LOW IRON COUNT FROM ALL THE BLEEDING. SHE HAD TO HAVE 11 IRON INFUSIONS TO GET HER LEVELS BACK TO NORMAL. IN 2014 SHE HAD

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A NOVASURE ABLATION TO TRY TO CONTROL THE BLEEDING. THIS JUST MADE THE SITUATION WORSE CAUSING HER UNBEARABLE CRAMPING, PAINFUL BLEEDING AND THE MOST HORRIBLE PERIODS SHE HAS EVER EXPERIENCED. IN (B)(6) 2014 SHE WENT TO ANOTHER DOCTOR FOR A SECOND OPINION SHE WAS PLACED ON BIRTH CONTROL PILLS TO ATTEMPT TO CONTROL THE BLEEDING WITH NO LUCK. SHE WENT FOR A TRANSVAGINAL ULTRASOUND IN THE BEGINNING OF (B)(6) WHERE IT WAS FOUND THAT SHE STILL HAD A PORTION OF AN ESSURE COIL STILL IN HER BODY. IT WAS NOT THE ENTIRE COIL, ONLY A PORTION OF IT APPEARED WHEN THE COILS AND TUBES WERE REMOVED THE RIGHT COIL WAS CUT AND A PORTION WAS LEFT IN THE UTERUS. ON (B)(6) 2014 SHE HAD A TOTAL LAPAROSCOPIC HYSTERECTOMY REMOVING EVERYTHING BUT HER OVARIES. THE COIL PERFORATED HER UTERUS AND LODGED INTO HER OMENTUM. SHE HAD TO HAVE A SMALL PORTION OF HER OMENTUM REMOVED AS WELL. SHE FINALLY ALMOST A YEAR LATER GETTING HER HEALTH BACK TOGETHER AND GETTING HERSELF BACK TO A GOOD PLACE. THE ONE THING THAT SHE HAD YET TO BE ABLE TO DEAL WITH WAS THE FINANCIAL RAMIFICATIONS OF ESSURE. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE ABDOMINAL PAIN, UNBEARABLE CRAMPING WHICH RESULTED IN HOSPITALIZATION AND ALSO BLED DAILY FOR ALMOST 8 MONTHS (SEEN AS GENITAL BLEEDING). SHE UNDERWENT A TRANSVAGINAL ULTRASOUND AND IT WAS FOUND THAT STILL HAD A PORTION OF AN ESSURE COIL STILL IN HER BODY, THE RIGHT COIL WAS CUT AND A PORTION WAS LEFT IN THE UTERUS (SEEN AS INTENTIONAL DEVICE MISUSE). SHE HAD A TOTAL LAPAROSCOPIC HYSTERECTOMY REMOVING EVERYTHING BUT HER OVARIES. THE COIL PERFORATED HER UTERUS. THE COIL LODGED INTO HER OMENTUM. SHE HAD TO HAVE A SMALL PORTION OF HER OMENTUM REMOVED AS WELL (SEEN AS PERITONEAL PERFORATION). ALL THESE EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. INTERNAL ORGANS PERFORATION MAY OCCUR WITH ESSURE DUE TO DEVICE MIGRATION. IN THIS CASE, THE EXACT DATE AND THE MECHANISM OF PERFORATION AND CONSEQUENTLY THE PERITONEAL PERFORATION ARE NOT KNOWN. BASED ON THE NATURE OF THE EVENTS AND CONSIDERING THAT A TEMPORAL RELATIONSHIP IS IMPLIED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01524	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2009
Explant Date (E7): 6/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1512, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. ADDITIONAL INFORMATION RECEIVED ON 11-NOV-2015. CONSUMER REPORTED THAT SINCE ESSURE SHE WAS DIAGNOSED WITH CHRONIC PYELONEPHRITIS, CHRONIC PANCREATITIS, AUTONOMIC DYSFUNCTION, FIBROMYALGIA, VERTIGO, GALACTORRHEA, GASTRITIS, DUODENITIS, GASTROESOPHAGEAL REFLUX DISEASE, DEPRESSION, ANXIETY, OCULAR MIGRAINE, NICKEL HYPERSENSITIVITY AND HIGH BLOOD PRESSURE. SHE HAD SURGERY FOR CARPEL TUNNEL AND CUBITAL TUNNEL AS WELL AS CHOLECYSTECTOMY. IN (B)(6) 2015, SHE WAS FORCED TO HAVE A HYSTERECTOMY TO REMOVE ALL BUT HER OVARIES, COMPLICATION FROM THAT SURGERY LEFT HER IN THE HOSPITAL FOR OVER A WEEK. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL

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EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NICKEL HYPERSENSITIVITY. SHE WAS FORCED TO HAVE A HYSTERECTOMY TO REMOVE ALL BUT HER OVARIES. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON ITS NATURE AND CONSIDERING THAT ALLERGIC REACTIONS MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01525	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2033, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE EXPERIENCED PAINFUL PERIODS, PAINFUL SEX, PERIODS EVERY 15 TO 20 DAYS, PELVIC PRESSURE, HEART PALPITATIONS, WEIGHT GAIN, HIGH INFLAMMATION IN HER BODY, LOW BACK PAIN AND BROKEN COILS. FOLLOW-UP RECEIVED ON 11-NOV-2015: PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN

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TUBE OCCLUSION INSERT) INSERTED AND STATED SHE HAD BROKEN COILS. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. THE CASE WAS REPORTED WITH LIMITED INFORMATION. THE EXACT DATE AND MECHANISM OF THE BREAKAGE WERE NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THE EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01526	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 20-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. ADDITIONAL INFORMATION RECEIVED ON 11-NOV-2015 (PTC INVESTIGATION RESULT). THE CONSUMER STATED THAT SINCE INSERTION SHE WAS HAVING SO MANY HEALTH PROBLEMS. SHE WAS GOING FOR HYSTERECTOMY SINCE SHE HAD BEEN IN PAIN EVER SINCE INSERTION. EVENT DATE WAS REPORTED AS (B)(6) 2015 (NOT SPECIFIED). SHE CONSIDERED THE EVENTS RELATED TO ESSURE. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT SHE WAS GOING FOR HYSTERECTOMY SINCE SHE HAD BEEN IN PAIN EVER SINCE SHE DID ESSURE (SEEN AS PELVIC PAIN). THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING ITS NATURE AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01527	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/11/2014
Explant Date (E7): 7/18/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-1715, AWARENESS DATE 20-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER REPORTED THAT WITHIN 48 HOURS OF ESSURE BEING IMPLANTED SHE REALIZED THAT HER BODY WAS NOT RIGHT. WITHIN THE FIRST 24 HOURS, SHE STARTED WITH HEADACHES, BACK PAIN AND HIP PAIN. BY THE TIME THE 48 HOURS HAD PASSED SHE WAS SUFFERING FROM JOINT PAIN ALL OVER THE BODY, PELVIC AND ABDOMINAL PAIN. AS THE DAYS WENT ON, SHE NOTICED HER STOMACH SWELLING UP LIKE SHE WAS 6 MONTHS PREGNANT. SHE BLED THE WHOLE TIME ESSURE WAS IN HER BODY. AFTER REQUESTING THE ESSURE TO BE REMOVED INTACT, ON (B)(6) 2014 THE PHYSICIAN REMOVED CONSUMER TUBES ONLY CUTTING ONTO HER UTERUS. THE LEFT COIL BROKE. SHE BLED FOR 9 MONTHS NON STOP. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE.

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MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE BLED THE WHOLE TIME ESSURE WAS IN HER BODY (INTERPRETED AS GENITAL BLEEDING). THE PHYSICIAN REMOVED THE TUBES AND LEFT COIL BROKE (INTERPRETED AS DEVICE BREAKAGE). THE GENITAL BLEEDING IS A SERIOUS EVENT. GENITAL BLEEDING AND DEVICE BREAKAGE DURING REMOVAL ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THESE EVENTS AND LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01528	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 7/16/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 20-OCT-2015). IT REFERS TO FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. ADDITIONAL INFORMATION RECEIVED ON 11-NOV-2015. THE CONSUMER REPORTED HER IN OFFICE PROCEDURE WAS PAINFUL AND A FEW WEEKS LATER SHE KNEW SOMETHING WAS NOT RIGHT, AS SHE FELT INCREDIBLY FATIGUED, AND SLEPT 36 HOURS STRAIGHT; SHE COULD NOT GET OUT OF BED. SHE STATED IT WAS NOT THE FLU OR LACK OF SLEEP, SHE WAS JUST INCREDIBLY FATIGUED. FOLLOWING THAT EPISODE SHE CONTINUED TO STRUGGLE WITH CHRONIC FATIGUE, SHE REPORTED BEING AN AVID CARDIO EXERCISER FOR 20 YEARS PLUS BALLROOM DANCING. AFTER ESSURE, HER WEIGHT FOR THE FIRST TIME IN 20 YEARS WENT UP 20 LBS, SHE WAS DEVASTATED AND HAD THIS LOWER BELLY. SHE WENT FROM (B)(6) AND EVEN THOUGH CHRONIC FATIGUE WAS A STRUGGLE FOR HER, SHE STILL MANAGED TO GET IN MORNING WORKOUTS AND THE REST OF THE DAY WAS DIFFICULT; SHE WOULD TO KEEP HERSELF MOVING ALL DAY LONG, BECAUSE IF SHE SAT DOWN FOR JUST A FEW MINUTES SHE WOULD PASS OUT AND FALL ASLEEP DAILY. HER FIANCÉɠWITNESSED HER PASSING OUT WAY TOO MANY TIMES TO COUNT. IN (B)(6)-2015, SHE ENDED UP IN THE ER DUE TO SEVERE BLOOD CLOTS OUT OF HER WHEN SHE WASN'T EVEN ON HER PERIOD AND SHE HAD FEVER; THE DOCTOR DISMISSED HER AND SENT HER HOME. WITH WEIGHT GAIN, CHRONIC FATIGUE, NICE SKIN COMPLEXION GONE, NAUSEA, ABDOMINAL ITCHING AND BLOOD CLOTS WITH A FEVER, SHE LOOK UP COMPLAINTS ON ESSURE AND SURE ENOUGH FOUND THE SUPPORT GROUP AND COULD NOT BELIEVE HOW MANY WOMEN HAD HER SAME SYMPTOMS. HOWEVER SHE STATED HAVING A PRE-EXISTING CONDITION CALLED VHL (REGARDED AS VON

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HIPPEL-LINDAU DISEASE), DIAGNOSED IN 2001, SHE HAS 5 BRAIN TUMORS, SPINE TUMORS, KIDNEY TUMORS AND PANCREATIC TUMORS ALL STABLE. WHEN SHE WENT TO HER DOCTORS TO DISCUSS ESSURE REMOVAL, THEY ALL INSISTED TO LEAVE IT IN. NIH TOLD HER BECAUSE SHE HAS BRAIN TUMORS, THEY (BRAIN TUMORS) COULD EXPLODE DURING SURGERY DUE TO ANESTHESIA AND IT WAS BEST JUST TO LEAVE THE DEVICES IN. ON (B)(6)-2015, SHE HAD THE TUBES AND COILS REMOVED; SHE PUT HER LIFE IN DANGER HAVING TUMORS ALL OVER THE PLACE JUST TO REMOVE ESSURE. SHE STATED SHE SHOULD HAVE NEVER BEEN PUT IN THAT POSITION IF THE DOCTOR WHO INSERTED ESSURE TOLD HER UPFRONT THAT IF THIS DEVICE DOES NOT WORK SHE WOULD NEED MAJOR SURGERY TO GET IT OUT; SHE WOULD HAVE CHOSEN ESSURE. AT TIME OF THE REPORT SHE WAS THREE MONTHS POST-SURGERY AND HER CHRONIC FATIGUE WAS GONE, HER SKIN COMPLEXION WAS BACK TO NORMAL AND HER WEIGHT WAS FINALLY COMING OFF, HER PERIODS WERE REGULAR AND NO MORE BLOOD CLOTS. SHE STATED HER RELATIONSHIP WITH HER FIANCÉɠWAS AT RISK SEVERAL TIMES DUE TO THE EMOTIONAL MOOD SWINGS. FROM HER SURGERY REPORT SHE DID FIND OUT THAT THE COILS HAD PERFORATED THROUGH HER FALLOPIAN TUBES. SHE STATED SHE NOW FEEL FABULOUS AND HER BALLROOM INSTRUCTOR TOLD HER SHE HAD MORE CONCENTRATION AFTER ESSURE WAS REMOVED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-NOV-2015: (B)(4) FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENT IS KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD SEVERE BLOOD CLOTS OUT OF HER (WHEN SHE WASN'T ON HER PERIOD) APPROXIMATELY 3 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE HAD HER FALLOPIAN TUBES AND ESSURE COILS SURGICALLY REMOVED. DURING THIS PROCEDURE, IT WAS FOUND THE COILS HAD PERFORATED THROUGH HER FALLOPIAN TUBES. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION IS A POSSIBLE COMPLICATION OF ESSURE INSERTION. IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE BLEEDING AFTER THE PROCEDURE. IN THIS PARTICULAR CASE, THE REPORTED FALLOPIAN TUBE PERFORATION WAS DIAGNOSED 3 YEARS AFTER ESSURE INSERTION. ALTHOUGH ITS EXACT MECHANISM IS NOT KNOWN; GIVEN EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE FROM HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01529	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1657, AWARENESS DATE 20-OCT-2015) WHICH REFERS TO FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. ADDITIONAL INFORMATION RECEIVED ON 11-NOV-2015 (PTC INVESTIGATION RESULT). THE CONSUMER HAD PREVIOUSLY USED PARAGARD AND HAD PROBLEMS WITH THE COOPER AND CYCLE. SHE REPORTED SHE WAS AWAKE THE ENTIRE TIME OF ESSURE INSERTION PROCEDURE; THE PHYSICIAN HAD A PROBLEM WITH HER LEFT SIDE WHILE IMPLANTING AND SHE WAS IN PAIN AND HOLLERING. AFTER GETTING ESSURE, SHE STARTED CRAMPING IMMEDIATELY AND HER CYCLE WAS HEAVY WHERE SHE COULD BLEED THROUGH A HEAVY SUPER PAD. THEN SHE STARTED USING TAMPONS WITH PADS AND STILL WOULD BLEED THROUGH HER PANTS, SHE IMMEDIATELY CALLED THE DOCTOR OFFICE AND THE NURSE SAID SHE HAD TO LET IT HEAL WITH HER BODY. SHE ALSO COMPLAINED HER CYCLE WAS 3 WEEKS FOR SOME MONTHS AND SHE WAS STILL TOLD THAT HER BODY WAS NOT FULLY HEALED. AT HER 3 MONTH APPOINTMENT TO DO DYE TEST SHE WAS TOLD SHE WAS BLOCKED. SHE COMPLAINED AGAIN ABOUT THE HEAVY CYCLE AND ALSO COMPLAINED SHE HAD SHARP ABDOMINAL PAIN TO THE POINT SHE WOULD GO IN FETAL POSITION. SHE DECIDED TO SEARCH FOR ANOTHER DOCTOR WITHIN 1 YEARS IMPLANTED (SHE CHANGED DOCTORS IN 2013/2014). THEY IMMEDIATELY SCHEDULED A VAGINAL ULTRASOUND ON OVARIES AREA WHERE SHE POINTED THAT IT HURTS. THE NEW DOCTOR SAID SHE HAD A SMALL CYST BUT NOTHING DANGEROUS AND SHE NEEDED TO DO A CERVICAL BIOPSY. THE PROCEDURE WAS VERY PAINFUL BECAUSE THEY SAID TISSUE WAS SURROUNDED AND THEY HAD A HARD TIME GETTING A PIECE TO TEST. THE TEST CAME BACK NORMAL AND SHE ASKED WHAT SHE HAS TO DO TO GET THEM

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OUT. THEY SAID A HYSTERECTOMY. SHE DID A SEARCH IN THE INTERNET AND FOUND THE (B)(4) SITE WITH WOMEN WITH THE EXACT SYMPTOMS. SHE STATED SHE HAD IT FOR 3 AND HALF YEARS AND WAS IN PAIN SINCE DAY ONE. 3 DOCTORS SAID NOTHING IS WRONG. SHE DECIDED TO GO TO A REVERSAL DOCTOR BECAUSE SHE DID NOT WANT ANY OF HER WOMAN PARTS TO BE REMOVED. ON (B)(6) 2015, SHE HAD A REVERSAL PROCEDURE. SHE NOTICED SHE DID NOT TAKE ANY (B)(4) OR (B)(4) FOR HER MIGRAINES AND IT HAS GONE AWAY. HER BLOATING HAS COME DOWN A LOT, HER CYCLE WAS STILL HEAVY AFTER SURGERY BUT SHE DID NOT HAVE TO USE PADS AND TAMPONS AT ONCE. SHE HAS NOT HAD INTERCOURSE YET TO SEE ABOUT HER ABDOMINAL PAINS BUT SHE HAD NOT FELT SHARP PAINS WHEN SHE SQUAT. SHE STILL HAS MEMORY IOSS (FORGETFUL), AND HER HAIR HAS NOT THICKENED UP YET. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING IMMEDIATELY / SHARP ABDOMINAL PAIN TO THE POINT SHE WENT IN FETAL POSITION. A SMALL CYST WAS DETECTED BUT NOTHING DANGEROUS AND SHE NEEDED TO DO A CERVICAL BIOPSY. CONSUMER DID NOT WANT ANY OF HER WOMAN PARTS TO BE REMOVED. A REVERSAL PROCEDURE WAS PERFORMED. THE FIRST EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE CYST IS UNLISTED. BOTH WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, CONSUMER EXPERIENCED CRAMPING AFTER GETTING ESSURE IMMEDIATELY. AS ABDOMINAL CRAMPING MAY OCCUR WITH ESSURE THERAPY AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO CYST, CONSIDERING ITS NATURE, IT IS UNLIKELY THAT ESSURE WOULD CAUSE THIS EVENT DUE TO THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, THUS A CAUSAL RELATIONSHIP CAN BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01531	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 508836

Single Use: Y
Implant Date (E6): 9/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT FEMALE CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(6)-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006 WITH LOT NUMBER 508836 FOR CONTRACEPTION. SHE STATED THAT SHE HAD ALLERGY TO METAL, TO THE POINT SHE CANNOT USE EARRINGS. SHE HAD A LOT OF BLEEDINGS, MENSTRUATION MORE THAN ONCE IN A MONTH AND A LOT OF DIVERSE PAIN. SHE SAID THAT NOBODY ASKED HER IF SHE WAS ALLERGIC TO METALS. FOLLOW-UP INFORMATION RECEIVED ON 03-MAR-2015 AND ON 06-MAR-2015 THE CASE (B)(6) WAS IDENTIFIED AS DUPLICATE FROM THIS CASE AND WAS DELETED FROM ARGUS CENTRAL. ALL INFORMATION WAS TRANSFERRED TO THIS CASE. THIS CASE IS A POTENTIAL LEGAL CASE NOW. THE CONSUMER'S AGE WAS UPDATED TO (B)(6) OLD. ESSURE WAS PLACED IN (B)(6)-2006. CONSUMER'S MEDICAL HISTORY INCLUDED 4 PREGNANCIES WITH 4 CHILDREN. SHE STATED THAT SINCE ESSURE INSERTION, SHE HAD INCREASE IN MENSTRUAL PAIN MAINLY IN THE RIGHT SIDE, BUT SINCE (B)(6)-2014 PAIN INCREASED AND SOMETIMES IT WAS SO PAINFUL THAT SHE HAD DIFFICULTIES MOVING THE RIGHT LEG. SHE ALSO SAID THAT HER CYCLES WERE IRREGULAR SINCE ESSURE PLACED WITH AN INCREASE OF THE BLEEDING. SHE NOW HAS ANAEMIA. AN ULTRASOUND AND X-RAY OF ABDOMINAL PELVIC AREA WAS DONE AND SHOWED THAT THE RIGHT THE DEVICE WAS BENT. SURGERY-HYSTERECTOMY WITH REMOVAL OF FALLOPIAN TUBES WAS NOT SCHEDULED YET. SHE WAS TAKING IBUPROFEN FOR PAIN. PHYSICIAN WAS CONTACTED AND SAID HE DID NOT KNOW ABOUT THIS CASE. NO FURTHER INFORMATION COULD BE OBTAINED. PTC INVESTIGATION RESULT WAS RECEIVED ON 24-MAR-2015. (B)(4). FINAL ASSESSMENT: THIS CASE IS FOR ESSURE 205. LOT NUMBER 508836: MFG:09/2005 EXP:08/2007. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT

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THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. IN THIS CASE, WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY AND A REPORTED PRODUCT ISSUE. THE BATCH DOCUMENTATION OF THE REPORTED BATCH WAS REVIEWED. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH SIGNAL COULD BE IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP RECEIVED ON 22-OCT-2015: CONSUMER REPORTED THAT, BECAUSE OF ESSURE, SHE LOST 9 YEARS OF HER LIFE WITHOUT REALIZING IT WAS THE DEVICE THAT WAS KILLING HER. TODAY, AT (B)(6), SHE HAD 2 INTERVENTIONS TO EXTRACT ESSURE, ONE REMOVING HER TUBES AND THE OTHER WAS TO REMOVE HER UTERUS. IN ADDITION, CONSUMER REPORTED THAT SHE JUST WANTED A TUBE LIGATION LIKE ANY OTHER WOMAN WITH 4 CHILDREN. CONSUMER STATES THAT SHE IS GOING TO SUE AND NO MORE WOMEN WILL BE AFFECTED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED VIA REGULATORY AUTHORITY AND REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LOT OF BLEEDINGS. SHE HAD 2 INTERVENTIONS TO EXTRACT ESSURE, ONE REMOVING HER TUBES AND THE OTHER WAS TO REMOVE HER UTERUS. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, WAS CONSIDERED SERIOUS AS MEDICALLY SIGNIFICANT AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR; THEREFORE A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS UPGRADED TO INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT. THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. AN UPDATED PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO FURTHER INFORMATION CAN BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01535	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/23/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 23-OCT-2015 AND 30-OCT-2015 WHICH REFER TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE PHYSICIAN REPORTED THAT SHE PLACED ESSURE AND WHEN SHE WITHDREW THE INSERTER, 4-5 COILS BROKE OFF IN THE PATIENT. SHE STATED THERE WERE 7 TRAILING COILS LEFT IN THE UTERUS. SHE BELIEVED THE TRAILING COILS WOULD CAME OUT WITH THE FLUID. THE PATIENT HAD NO COMPLAINTS AND THE ALTERNATE SIDE-PLACEMENT WAS FINE. PTC ((B)(4)) INVESTIGATION RESULT RECEIVED ON 31-OCT-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. SINCE NO PRODUCT WAS RETURNED FOR INVESTIGATION, WE CANNOT CONFIRM THIS QUALITY COMPLAINT; HOWEVER, BASED ON THE COMPLAINT DESCRIPTION PROVIDED, WE ARE ABLE TO CONCLUDE THAT A QUALITY ISSUE IS PLAUSIBLE. IT IS POSSIBLE DURING THE MANUFACTURING ASSEMBLY PROCESS A SMALL GAP WAS LEFT BETWEEN THE INNER COIL AND INNER CATHETER (THEY SHOULD BE BUTTED TOGETHER DURING ASSEMBLY). WHEN THE OUTER COIL OF THE MICRO-INSERT IS WOUND DOWN A SMALL PORTION OF THE COIL CAN BECOME TRAPPED IN THE GAP. IF A DEVICE HAS THIS ISSUE, WHEN THE PHYSICIAN PRESSES THE BUTTON TO RELEASE THE MICRO-INSERT, THE OUTER COIL MAY SEVER ITSELF AS IT IS BEING DEPLOYED FROM THE CATHETER. THIS SEVERING OCCURS INSIDE THE CATHETER PRIOR TO THE PIECES BEING DEPLOYED FROM THE CATHETER THE SEVERING OF THE COILS INSIDE THE CATHETER DOES NOT POSE A SIGNIFICANT RISK TO THE HEALTH OF THE PATIENT.

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THE POSSIBILITY OF PIECES OF THE DELIVERY SYSTEM OR MICRO-INSERT BREAKING OFF IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REPORTED TECHNICAL PRODUCT ISSUE. HOWEVER, NO MEDICAL EVENTS WERE REPORTED. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT - BUT PLAUSIBLE. SINCE NO MEDICAL EVENTS AND NO BATCH NUMBER WERE REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES AND THE EVALUATION OF CAUSAL RELATIONSHIP TO THE POTENTIAL QUALITY DEFICIT ARE NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT THAT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED BUT WHEN THE INSERTER WAS WITHDRAWN, 4-5 COILS BROKE OFF IN THE PATIENT. THIS DEVICE BREAKAGE DURING INSERTION IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. FURTHER INFORMATION (BREAKAGE QUESTIONNAIRE) HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 07-DEC-2015 (HEALTHCARE PROFESSIONAL DEVICE BREAKAGE QUESTIONNAIRE): (B)(6). ESSURE WAS INSERTED ON (B)(6) 2015. THE OUTER COIL OF THE IMPLANT BROKE DURING PLACEMENT. WHILE WITHDRAWING INTRODUCER, 4-5 COILS BROKE OFF ON E

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01536	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/19/2012
Explant Date (E7): 12/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY IN THE UNITED STATES, ON BEHALF OF A (B)(6) FEMALE PLAINTIFF IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR STERILIZATION. PLAINTIFF DEVELOPED POST PROCEDURE PAIN AND BLEEDING BY (B)(6) 2012. THE PAIN WAS SEVERE AND SHE WAS VOMITING. SHE WAS ALSO STILL BLEEDING HEAVILY. THE PAIN WAS SO SEVERE THAT SHE SUFFERED SEVERAL EPILEPTIC SEIZURES. SHE WAS SO CONCERNED THAT SHE CONTACTED THE GYNAECOLOGY DEPARTMENT AND WAS ADVICE TO GO STRAIGHT TO A & E. THE EMERGENCY CARE ASSESSMENT DOCUMENTATION FOR THAT ATTENDANCE STATES: PAINFUL PROCEDURE FOLLOWING DAY 5 FITS DUE TO PAIN. SINCE THEN PV (INTERPRETED AS PER VAGINAL) BLEEDING. INITIAL PAIN RIF (INTERPRETED AS RIGHT ILIAC FOSSA) BUT THEN IT WAS THROUGHOUT LOWER ABDOMEN. HER SYMPTOMS FAILED TO IMPROVE AND SHE THEREFORE VISITED HER GP ON (B)(6) 2012. THE CLINICAL NOTES STATES: SHE HAD ESSURE STERILIZATION 1 WEEK AGO, HAD FOUND PROCEDURE VERY PAINFUL. LOTS OF POST-OPERATIVE BLEEDING AND RIF DISCOMFORT. PASSING CLOTS AND FEELING UNWELL. PAIN NOT WELL CONTROLLED ON DISCHARGE. HAS STRUGGLED TO CONTINUE NORMAL ACTIVITY. HAS BEEN SEEN BY GYNECOLOGIST 4 DAYS AGO - EXAM AND SWOBS, BLOODS NORMAL. AUGMENTIN AND NORETHISTERONE WERE STARTED FOR BLEEDING, REVIEWED AFTER TWO DAYS IF BLEEDING HAD NOT SETTLED. PLAINTIFF'S BLEEDING AND PAIN CONTINUED. SHE THEREFORE CONTACTED HER GP AGAIN ON (B)(6) 2012 AND THE DECISION WAS MADE TO REFER HER TO A & E FOR ASSESSMENT BY THE GYNAECOLOGY TEAM WHERE SHE WAS TREATED WITH DICLOFENAC AND ANTIBIOTICS. DESPITE THIS TREATMENT HER PAIN CONTINUED. BY (B)(6) 2011, SHE CONTACTED HER GP SURGERY AGAIN. THE CLINICAL NOTES FOR THIS ATTENDANCE STATES: PAIN AND BLEEDING PERSIST, NO IMPROVEMENT WITH MEDICATION. MAY DO USS, MAY DO DIAGNOSTIC LAP - WILL

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DECIDE MANE. THE LETTER WRITTEN TO THE HOSPITAL ON (B)(6) STATES AS FOLLOWS: WHEN INITIALLY REVIEWED HER ONE WEEK AFTER THE PROCEDURE SHE WAS PASSING A LOT OF CLOTS AND WAS TENDER IN THE RIGHT ILIAC FOSSA. SHE WAS PRESCRIBED WITH SOME TRAMADOL AND AUGMENTIN AND NORETHISTERONE. HER PAIN BECAME WORSE AND SHE WAS REFERRED TO GYNAECOLOGIST FOR REVIEW. EXAMINATION SWABS AT THAT POINT WERE NORMAL AND SHE WAS GIVEN AN INCREASED DOSE OF NORETHISTERONE; AS THE PAIN AND BLEEDING WERE NOT GETTING ANY EASIER. PLAINTIFF WAS THEREFORE ADMITTED TO THE WARD WHERE HER PAIN AND BLEEDING WERE NOTED. SHE UNDERWENT A CT SCAN THE FOLLOWING DAY AND WAS DISCHARGED HOME. SHE REMAINED IN TERRIBLE PAIN AND DISCOMFORT. ON (B)(6) 2012, SHE CONTACTED HER GP. THE RECORDS FROM THAT DATE STATES: PAIN IN RIF, MUCH MORE SEVERE AGAIN, NOT CONTROLLED WITH ORAL ANALGESIA AND BLEEDING STARTED AGAIN - HEAVIER THAN NORMAL PERIODS. SHE WAS URGENTLY REFERRED BACK TO HOSPITAL WHERE SHE UNDERWENT DIAGNOSTIC LAPAROSCOPY, DIAGNOSTIC HYSTEROSCOPY/LAPAROSCOPIC ADHESIOLYSIS. IN A LETTER FROM THE HOSPITAL DATED (B)(6) 2012 THE FOLLOWING WAS STATED: DURING THE LAPAROSCOPY THE LEFT TUBE WAS SCARRED AND ADHERED TO THE LEFT SIDE WALL AND THIS WAS DISSECTED SO THEREFORE THE PAIN WAS MOST PROBABLY DUE TO THIS, THE LEFT SIDED PAIN MIGHT BE DUE TO THAT. SHE WAS OBVIOUSLY VERY ANGRY REGARDING THE PAIN SHE WAS EXPERIENCING POST OPERATIVELY AND SHE WISHED THAT THIS HAD BEEN EXPLAINED TO HER AT THE TIME. ON (B)(6) 2012, PLAINTIFF WAS ADMITTED TO HOSPITAL BY AMBULANCE. THE AMBULANCE RECORDS FOR THAT DATE STATED AS FOLLOWS: O/E PT LYING ON THE FLOOR - DISTRESSED. THE HOSPITAL RECORDS FOR THAT DATE STATE PLAINTIFF PRESENTED WITH SUDDEN ONSET SEVERE PAIN, SUPRAPUBIC RADIATING TO RIF, LIKE BEING STABBED WITH A KNIFE AND HAVING IT DRAGGED ACROSS HER LOWER ABDOMEN. LASTED THIS SEVERELY FOR APPROXIMATELY 15 MINUTES, SHE THOUGHT SHE MIGHT HAVE BLACKED OUT WITH THE PAIN - PARTNER SAID HE FOUND HER SLUMPED ON THE SOFA, AWOKE WITHIN SECONDS. PAIN EASED A LITTLE BY CURLING LEGS UP AND HOLDING RIF. FOLLOWING THAT ATTENDANCE, SHE UNDERWENT HYSTERECTOMY TOGETHER WITH HYSTEROSCOPIC REMOVAL OF THE ESSURE. BY (B)(6) 2013 HOWEVER THE PAIN RETURNED. IT WAS DESCRIBED IN HER GP NOTES ON (B)(6) 2013 AS BEING, EXACTLY THE SAME PAIN AS POST STERILISATION. IT WAS NOTED AT THAT TIME THAT SHE HAD TAKEN TRAMADOL WITHOUT EFFECT AND SHE WAS GIVEN A NUMBER OF GNRH ANALOGUE INJECTIONS. THESE HOWEVER HAVE NOT BEEN WITHOUT DIFFICULTIES AND HAVE NOT RESULTED IN AN END TO HER PAIN. SHE WAS LEFT WITH THE POSSIBILITY THAT SHE WILL HAVE TO UNDERGO FURTHER SURGERY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, POTENTIAL LEGAL AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LEFT SIDED PAIN (INTERPRETED AS ABDOMINAL PAIN), PV BLEEDING/ PASSING CLOTS ++ (INTERPRETED AS HEMORRHAGE VAGINAL), INITIAL PAIN RIF (RIGHT ILIAC FOSSA PAIN), SUPRAPUBIC PAIN, RESULTING IN HOSPITALIZATION. SHE REPORTED THAT THE PAIN WAS SO SEVERE THAT SHE SUFFERED SEVERAL EPILEPTIC SEIZURES. THE LEFT TUBE WAS SCARRED AND ADHERED TO THE LEFT SIDE WALL (PERITUBAL ADHESIONS) AND EXPERIENCED O/E PT LYING ON THE FLOOR - DISTRESSED/ BLACKED OUT. ALL THESE EVENTS ARE SERIOUS. LEFT SIDED

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PAIN, PV BLEEDING/ PASSING CLOTS, INITIAL PAIN RIF (RIGHT ILIAC FOSSA PAIN) AND SUPRAPUBIC PAIN ARE LISTED AND THE OTHER ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER UNDERWENT HYSTERECTOMY TOGETHER WITH HYSTEROSCOPIC REMOVAL OF THE ESSURE. CONSIDERING THE NATURE OF THE EVENTS LEFT SIDED PAIN, PV BLEEDING/ PASSING CLOTS , INITIAL PAIN RIF (RIGHT ILIAC FOSSA PAIN) AND SUPRAPUBIC PAIN AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, CONSIDERING THEIR NATURE AND THAT ESSURE HAS A LOCAL ACTION IN FALLOPIAN TUBES, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01537	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2006 FOR PERMANENT CONTRACEPTION. IT WAS REPORTED THAT THE CONSUMER WAS NOT PREGNANT. THE MEDICAL DOCTOR WAS PLANNING TO REMOVE THE ESSURE INSERTS DUE TO NICKEL ALLERGY; HOWEVER, IT HAD NOT OCCURRED YET. PTC INVESTIGATION RESULT RECEIVED ON 07-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DETECT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS IS A MEDICALLY CONFIRMED SPONTANEOUS REPORT. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE PHYSICIAN WAS PLANNING TO REMOVE ESSURE INSERTS DUE TO NICKEL ALLERGY. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE.

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ALTHOUGH IT IS NOT CLEAR WHETHER THE PAT CONSIDERING THAT ESSURE IS A NICKEL-TITANIUM ALLOY AND THE COMPATIBLE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN NICKEL ALLERGY AND ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT THAT THE EVENTS WERE CAUSED BY A POTENTIAL QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01538	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/22/2015
Explant Date (E7): 10/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 22-OCT-2015 AND 23-OCT-2015 WHICH REFER TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO HAVE ESSURE 305 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (LOT NUMBER DOG929) ON (B)(6) 2015 AND EXPERIENCED MICRO INSERT BROKEN (DEPLOYED BUT HALF OF THE OUTER COILS WERE BROKEN AND FELL INTO UTERUS). HE WHEELED BACK AND HEARD AN ODD CRUNCHING NOISE AND IT FELT FUNNY. HE THEN PUSHED THE BUTTON AND IT DEPLOYED BUT HALF OF THE OUTER COILS WERE BROKEN AND FELL INTO UTERUS. SHE HAD NO INJURY. THE HEALTH CARE PROVIDER WAS ABLE TO RETRIEVE ALL OF THE PIECES AND REMOVED THE INNER COIL FROM THE FALLOPIAN TUBES. THE PROCEDURE WAS STOPPED (BILATERAL PLACEMENT NOT ACHIEVED), IT HAD TAKEN 24 MINUTES AND THE PROCEDURE WAS STOPPED. COMPANY CAUSALITY COMMENT THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT THAT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD AN ATTEMPT TO HAVE ESSURE 305 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED BUT THE MICRO INSERT BROKE (DEPLOYED BUT HALF OF OUTER COILS WERE BROKEN AND FELL IN UTERUS). ALL PIECES WERE RETRIEVED FROM UTERUS AND THE INNER COIL FROM THE FALLOPIAN TUBE WAS ALSO REMOVED AT THE SAME DAY OF INSERTION. SHE HAD NO INJURY. SINCE THE BREAKAGE OCCURRED DURING INSERTION IT IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION (BREAKAGE QUESTIONNAIRE) AND A PRODUCT TECHNICAL COMPLAINT ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 12-NOV-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01539	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND MIRENA (LEVONORGESTREL) INSERTED. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AFTER THE BIRTH OF HER THIRD SON. SHE HAD MAJOR CRAMPING FROM DAY ONE AND HER DOCTOR SAID IT WAS MENSTRUAL RELATED AND PROBABLY RELATED TO THE SCAR TISSUE FORMING. THEN SHE STARTED HAVING HAIR LOSS AND BLEEDING ISSUES. A YEAR AFTER ESSURE SHE HAD A GASTRIC BYPASS AND STARTED HAVING EXCESSIVE HAIR LOSS AND THE BLEEDING GOT WORSE, SHE BLED FOR MONTHS AT A TIME. SHE WENT TO THE DOCTOR AND HAD VITAMIN AND IRON LEVELS CHECKED. SHE STARTED TO EXPERIENCE SENSITIVITIES TO METALS AND COULD NOT WEAR CHEAP JEWELRY OR ANY EARRINGS. THE CONSUMER HAD MIRENA (LEVONORGESTREL) INSERTED AT 20 MCG/24HR, CONTINUOUS INTRA-UTERINE AND BLEEDING STOPPED BUT CRAMPS AND PELVIC PAIN PERSISTED AND SHE WAS ALSO EXPERIENCING FATIGUE, BLOATING, BODY ACHES, HEADACHES, TINGLING IN ARMS AND HAND WHICH GOT WORSE. SHE COMPLETELY LOST HER SEX DRIVE, HAD A HARD TIME GETTING OUT OF BED AS SHE HAD NO ENERGY AND HAD DEPRESSION AND ANXIETY. SHE COULD NOT HAVE ANY PRESSURE ON HER STOMACH OR SHE WOULD FEEL LIKE SHE WAS GETTING STABBED. THE CONSUMER WAS TOLD BY THE DOCTORS SHE HAD FIBROMYALGIA AND ARTHRITIS DEGENERATIVE BONE AND DISK AND WAS ALSO TOLD TO SEE A PSYCHOLOGIST AND A PSYCHIATRIST BECAUSE SHE HAD DEPRESSION AND IT MIGHT BE IN HER HEAD. SHE LOST 250 LBS IN 1 YEAR AND A HALF THEN GAINED ALMOST 100 LBS BACK DUE TO THE PRODUCTS SHE HAD TO USE TO COPE WITH THE ISSUES FROM ESSURE. THE

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CONSUMER HAD A HYSTERECTOMY SCHEDULED TO (B)(6) 2015. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN ALL THE EVENTS AND MIRENA IS NOT REPORTED. THE RELATIONSHIP BETWEEN ALL THE EVENTS AND ESSURE IS RELATED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION OF ESSURE RECEIVED ON 11-NOV-2015, COMPANY GLOBAL PTC NUMBER WAS: (B)(4). NO ESSURE SAMPLE OR BATCH NUMBER WERE AVAILABLE. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, COMPANY CONDUCTS AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, COMPANY TYPICALLY DOES NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE COMPANY HAD NO VALID LOT NUMBER FOR THIS CASE, THEY WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THEY WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATED A NEW TECHNICAL FAILURE MODE FOR DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING ISSUES / BLEEDING GOT WORSE, BLED FOR MONTHS AT A TIME, PELVIC PAIN AND MAJOR CRAMPING FROM DAY ONE. SHE HAD MIRENA (LEVONORGESTREL) INSERTED AND BLEEDING STOPPED BUT CRAMPS AND PELVIC PAIN PERSISTED. THE CONSUMER HAD A HYSTERECTOMY SCHEDULED. THE REPORTED EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND MIRENA. CONSIDERING THE NATURE OF THE EVENTS AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THESE EVENTS CANNOT BE EXCLUDED. FOR MIRENA, A CAUSAL RELATIONSHIP FOR THE EVENT BLEEDING ISSUES / BLEEDING GOT WORSE, BLED FOR MONTHS AT A TIME CAN BE EXCLUDED AND FOR THE OTHER EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED WITH ESSURE AND MIRENA. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION OF ESSURE RECEIVED ON 11-NOV-2015, COMPANY GLOBAL PTC NUMBER WAS: (B)(4). NO ESSURE SAMPLE OR BATCH NUMBER WERE AVAILABLE. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01540	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1464, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER IS ALLERGIC TO NICKEL. SHE HAS BAD CRAMPING EVEN THOUGH SHE DOES NOT HAVE HER PERIOD ANY LONGER. THE PAIN IS SO BAD WHEN IT HAPPENS SHE CAN BARELY MOVE. SHE HAS A CONSULT TO HAVE ESSURE REMOVED THIS SEPTEMBER. FOLLOW-UP RECEIVED ON 11-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE S NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED A PAIN WHICH WAS SO BAD WHEN IT HAPPENED THAT SHE COULD BARELY MOVE. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO EXPERIENCED OTHER NON-SERIOUS EVENTS. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE, THIS EVENT IS ASSESSED AS RELATED TO ESSURE AND SINCE A SURGERY FOR REMOVAL WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE S NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01541	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1524, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 AND EXPERIENCED MULTIPLE PROBLEMS SINCE THEN. SHE SUFFERED DAILY PELVIC PAIN, ABDOMINAL BLOATING, HEADACHES DAILY, ENDOCRINE PROBLEMS (DIABETES AND HYPOTHYROID), LEG SWELLING, MOOD DISORDERS, HORRIBLE PERIODS (CLOTTING, BLACK BLOOD, HEAVY FLOW, DIZZINESS AND SEVERE CRAMPING), CONCENTRATION PROBLEMS AND JOINT PAIN ALMOST DEBILITATING. SHE WAS SCHEDULED FOR A TOTAL HYSTERECTOMY AND SALPINGECTOMY WITH A GYNECOLOGIST. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY

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DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SUFFERED DAILY PELVIC PAIN AND DIABETES. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE PELVIC PAIN IS LISTED WHILE DIABETES IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF PELVIC PAIN, ITS LOCALIZATION AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. IN CONTRAST, CONSIDERING THE PHYSIOPATHOLOGY OF DIABETES, IT IS UNLIKELY THAT ESSURE WOULD CAUSE THIS EVENT. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01542	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): 11/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2008
Explant Date (E7): 8/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1677, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. CONSUMER HAD HER SECOND CHILD IN (B)(6) 2008 WHICH WAS A ROUGH PREGNANCY. SHE WAS ADVISED NOT TO BECOME PREGNANT AGAIN DUE TO THE POSSIBILITY OF NOT BEING ABLE TO CARRY A THIRD BABY INTO FULL TERM. IMMEDIATELY AFTER ESSURE INSERTION SHE STARTED EXPERIENCING PELVIC PAIN, BLEEDING AND CRAMPS. SHE NOTIFIED HER DOCTOR WHO SUGGESTED IT WAS NORMAL AND SHOULD GIVE IT A FEW DAYS. SHE ALSO, SUGGESTED FOR HER TO TAKE IBUPROFEN FOR THE PAIN. SHE ALSO, NOTICED SHE BEGAN TO HAVE A METALLIC TASTE IN HER MOUTH, WHICH SHE COULD NOT GET RID OF. BY THE TIME, SHE WAS 2 MONTHS OF HAVING THE PROCEDURE DONE. SHE HAD SEVERE BLOATING, WHICH THE DOCTOR SUGGESTED WAS FROM REGULAR WEIGHT GAIN AND SENT HER TO A NUTRITIONIST. NO MATTER HOW HARD SHE EXERCISED AND STOOD BY HER DIETING SHE COULD NOT LOSE THE WEIGHT AND BLOATING. FRUSTRATION BEGAN AND SHE WAS AT HER LOWEST MENTALLY AND PHYSICALLY. AS TIME WENT BY OTHER SYMPTOMS BEGAN TO PROGRESS. AND SHE STARTED HAVING MEDICAL ISSUES. THESE SYMPTOMS WERE AS FOLLOWS CRAMPING, SHARP PELVIC PAIN, PELVIC PAIN, CONSTANT SPOTTING, DISCHARGE (NO ODOR), ALL OVER BODY ACHES, NAUSEA, BOWEL ISSUES, MIGRAINES, TINGLING SENSATIONS THROUGHOUT BODY, THIGH NUMBNESS, DIZZINESS, BLURRED VISION, HEARTBURN, BRAIN FOG, ANXIETY ATTACKS, MOOD SWINGS, SEVERE BLOATING, TREMORS, UNEXPLAINED FEVERS, METAL ALLERGIES, SKIN IRRITATIONS, HEART PALPITATIONS, FALLOPIAN TUBE CYSTS, SWELLING OF FEET, HAIR LOSS AND CHANGES, INSOMNIA, CONSTANT

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FATIGUE, SLEEP APNEA, NIGHT SWEATS, PAINFUL PERIODS AND HEAVY PERIODS. SHE FELT AS IF SHE WAS AN 80 YEAR OLD WOMAN BETWEEN HER AGE OF (B)(6). HER BODY WAS SHUTTING DOWN. SHE LACKED THE ENERGY, MOOD AND STAMINA JUST TO DO BASIC DAILY ACTIVITIES. SHE WAS FATIGUED AND IN PAIN ALL OF THE TIME. SHE SPENT MORE TIME ON HER BED RESTING. SHE DEVELOPED INSOMNIA WHICH TOOK MORE OF A TOLL WITH HER FATIGUE. SHE NAPPED AT LEAST 2-3 TIMES A DAY DURING THE WEEKENDS AND AFTER WORK WHEN SHE ARRIVED HOME. BY THE TIME NIGHT CAME SHE WOULD CRAWL INTO BED HAVING BODY ACHES, PAIN, FATIGUE, MIGRAINES AND SO ON. THERE WERE MANY NIGHTS OF UNEXPLAINED TREMORS, FEVERS AND NIGHT SWEATS. SHE BARELY HAD ANY SEXUAL RELATIONSHIP WITH HER HUSBAND BECAUSE EITHER IT HURT DURING SEX. SHE BLED AFTER SEX, HER LIBIDO WAS ALMOST VOID AND SO ON. SHE CRIED SO MANY TIMES, SHE COULD NOT EVEN SHED A TEAR NOW. FOR 8 YEARS, SHE WENT TO HER GYNECOLOGIST APPOINTMENTS TO NO AVAIL OF HAVING ESSURE REMOVED. THE DOCTORS USED TO TELL HER THAT HER CHRONIC PELVIC PAINS ALONG WITH MANY OF THE SYMPTOMS WERE ALL IN HER HEAD. ONE DOCTOR SUGGESTED FOR HER TO GO AND SEE A THERAPIST. SHE WAS DEPRESSED, SAD BEING LAYING ON HER BED. ON (B)(6) 2015 SHE HAD A BILATERAL SALPINGECTOMY. BY THE FOLLOWING DAY, THE METALLIC TASTE WAS GONE. SHE FELT GREAT AND BY THE POST-OPERATIVE DAY 5 SHE FELT AS IF SHE COULD LITERALLY RUN A MARATHON. SHE HAD AND CONTINUE TO HAVE ENERGY AND BY THE POST-OPERATIVE WEEK 5 SHE FELT FANTASTIC. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING PELVIC PAIN/ SHARP PELVIC PAIN AND BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A BILATERAL SALPINGECTOMY APPROXIMATELY 7 YEARS AFTER INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, PELVIC PAIN AND ABNORMAL GENITAL BLEEDING MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENTS, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01543	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1778, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE HAD MIGRAINES, WEIGHT GAIN, HAIR LOSS, HEAVY PERIODS, VERY BAD CRAMPING, PAINFUL OVULATION, JOINT PAIN, HIVES, ALLERGIC REACTIONS AND BRAIN FOG. SHE HAD A HYSTERECTOMY PERFORMED AND HER UTERUS WAS THE SIZE OF BEING 11 WEEKS PREGNANT. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN

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THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD VERY BAD CRAMPING (INTERPRETED AS LOWER ABDOMINAL PAIN). SHE UNDERWENT A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABDOMINAL PAIN MAY OCCUR. IN THE PRESENT CASE, CONSUMER MENTIONED THAT HER UTERUS WAS THE SIZE OF BEING 11 WEEKS PREGNANT. THE EXACT REASON FOR THIS UTERINE ENLARGEMENT WAS NOT SPECIFIED, BUT IT COULD HAVE CONTRIBUTED TO THE ABDOMINAL PAIN. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01544	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1544, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT CONSUMER ENDED UP HAVING HYSTERECTOMY BECAUSE OF HEALTH ISSUES. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED

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AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ENDED UP HAVING HYSTERECTOMY BECAUSE OF HEALTH ISSUES. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE THE SURGERY'S INDICATION WAS NOT SPECIFIED, CONSIDERING HYSTERECTOMY MAY BE REQUIRED IF DEVICE REMOVAL IS NECESSARY, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01545	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IT WAS REPORTED THAT CONSUMER ENDED UP HAVING HYSTERECTOMY BECAUSE OF HEALTH ISSUES. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT, IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENT IS KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ENDED UP HAVING HYSTERECTOMY BECAUSE OF HEALTH ISSUES. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE.

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ALTHOUGH IN THIS CASE THE SURGERY'S INDICATION WAS NOT SPECIFIED, CONSIDERING HYSTERECTOMY MAY BE REQUIRED IF DEVICE REMOVAL IS NECESSARY, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01546	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1544, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED THAT SINCE SHE OPENED UP ABOUT HER PROBLEMS WITH ESSURE, SHE HAS HAD A FRIEND WHO TOLD HER THAT SHE HAD ESSURE AND ENDED UP HAVING HYSTERECTOMY BECAUSE OF HEALTH ISSUES. THEY WERE JUST PUTTING TWO AND TWO TOGETHER. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HEALTH ISSUES AND ENDED UP HAVING A HYSTERECTOMY. THE HEALTH ISSUES EVENT IS A SERIOUS DUE TO REQUIRED SURGICAL INTERVENTION TO TREAT IT. THIS UNSPECIFIED EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DESPITE THE LIMITED INFORMATION REGARDING THESE HEALTH ISSUES, SINCE THE REPORTER IMPLIED THE ISSUES WERE RELATED TO ESSURE AND SOMETIMES ESSURE COMPLICATIONS MAY LEAD TO HYSTERECTOMY, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED AT THIS TIME. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED (IMPLIED). A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01548	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/26/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY FDA MAUDE (CASE# (B)(4)) IN UNITED STATES ON 22-OCT-2015. IT REFERS TO HERSELF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER HAD TO HAVE A HYSTERECTOMY DONE 5 DAYS AGO ((B)(6) 2015), BECAUSE HER ESSURE COILS MOVED, MAKING HER HAVE SEVERE PAIN AND BLEED; SHREADS OF NICKEL AND PET FIBERS WERE FOUND IN HER UTERUS. SHE IS NOW OFF WORK FOR 2 MONTHS AND SUFFERING. CONCOMITANT MEDICATIONS INCLUDE CIPRO, ADIPHEX, DULEXIS AND ALPRAZOLAM. THE SERIOUSNESS CRITERIA HOSPITALIZATION AND DISABILITY WERE MENTIONED IN THE SECTION EVENT OUTCOME BUT THEY WERE NOT SPECIFIED AND/OR MENTIONED TO ONE OF THE EVENTS IN THE NARRATIVE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD A HYSTERECTOMY BECAUSE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) COILS MOVED. SHE STATED SHREADS OF NICKEL AND PET FIBERS WERE FOUND IN HER UTERUS (REGARDED AS DEVICE BREAKAGE). ONLY DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION, DISLOCATION OR OCCUR AS A RESULT OF A UTERINE/FALLOPIAN TUBE PERFORATION. IN THIS CASE LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS; GIVEN EVENTS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED) A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01550	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2008
Explant Date (E7): 4/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5055990) IN UNITED STATES ON 22-OCT-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. CONSUMER HAD THE ESSURE DEVICE IMPLANTED RATHER THAN TRADITIONALLY HAVING HER TUBES TIED DUE TO THE SUGGESTION OF HER GYNECOLOGIST IN 2008. IN LESS THAN SIX MONTHS, SHE HAD SEVERE PAIN AND BLEEDING AND WENT TO THE EMERGENCY ROOM SEVERAL TIMES. HER GYNECOLOGIST SAID IT WAS NOT HIS ISSUE AND SENT HER TO HER PRIMARY CARE DOCTOR WHO SENT HER TO A GYNECOLOGIST. SHE HAD THE FIRST SURGERY AND THEY DETERMINED THAT THE ESSURE HAD PUNCTURED HER FALLOPIAN TUBE AND COULD NOT BE REMOVED ON ITS OWN SAFELY. SHE HAD 10-20 INJECTIONS INTO HER ABDOMEN WEEKLY AFTER THAT TO MANAGE THE PAIN WHILE HER DOCTOR TRIED TO FIND A WAY TO REMOVE THE ESSURE SAFELY. SHE WAS ON PAIN MEDICATION AS WELL. SHE COULD NOT WORK AND LOST HER JOB. SHE WAS AT RISK OF INTERNAL BLEEDING AND SHE ULTIMATELY HAD TO HAVE A FULL HYSTERECTOMY. SHE HAD ONLY OVARIES LEFT. ESSURE WAS REMOVED ON (B)(6) 2009. FOR THE NEXT SEVERAL WEEKS, SHE COULD NOT DRIVE, WORK, TAKE CARE OF HER CHILDREN ETC. SHE WAS ALSO NOW AT GREATER RISK OF EARLY ONSET MENOPAUSE AND BREAST CANCER. THE SERIOUSNESS CRITERIA HOSPITALIZATION AND DISABILITY WERE MENTIONED IN THE SECTION EVENT OUTCOME BUT IT WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE HAD PUNCTURED HER FALLOPIAN TUBE. THE REPORTED EVENT, REGARDED AS FALLOPIAN TUBE PERFORATION, WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO

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ESSURE'S REFERENCE SAFETY INFORMATION. FALLOPIAN TUBE PERFORATION IS A POSSIBLE COMPLICATION OF ESSURE INSERTION. IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE PAIN AND BLEEDING AFTER THE PROCEDURE. IN THIS PARTICULAR CASE, AN UNSPECIFIED TIME AFTER ESSURE PLACEMENT, PATIENT WAS SUBMITTED TO A SURGERY DUE TO BLEEDING AND PAIN. DURING THIS PROCEDURE, A FALLOPIAN TUBE PERFORATION WAS DIAGNOSED. A HYSTERECTOMY WAS THEN SCHEDULED AND ESSURE WAS REMOVED APPROXIMATELY 6 MONTHS AFTER ITS PLACEMENT. ALTHOUGH THE EXACT MECHANISM OF THE DEVICE PERFORATION WAS NOT REPORTED; GIVEN EVENT'S NATURE AND ITS POSITIVE TEMPORAL RELATIONSHIP WITH ESSURE THERAPY; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01551	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/30/2014
Explant Date (E7): 6/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER WHO WAS PERSUADED BY HER DOCTOR TO HAVE AND ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ALONG WITH AN IUD, MIRENA (LEVONORGESTREL), ON (B)(6) 2014 RATHER THAN A PARTIAL HYSTERECTOMY. IN 2014 SHE STARTED TO EXPERIENCE SEVERE CRAMPING AND IN 2015 HEAVY BLEEDING. HER MIRENA FLOATED UP FURTHER IN HER UTERUS AND WAS LODGED AND ATTACHED TOO FAR UP IN HER UTERUS TO BE REMOVED. HER BLEEDING WAS SO SEVERE SHE HAD TO GO TO THE HOSPITAL DUE TO BLEEDING ALL OVER HER CLOTHES AND CHAIR AT WORK. SHE HAD SEVERAL APPOINTMENTS REGARDING THAT, WHERE SHE MISSED ADDITIONAL WORK. ON (B)(6) 2015, SHE HAD HYSTERECTOMY PERFORMED WHERE HER UTERUS, OVARIES AND TUBES WERE REMOVED. SHE WAS HOSPITALIZED AGAIN WITHIN THE 3 WEEKS AFTER THE PROCEDURE DUE TO A REACTION TO AN ANTIBIOTIC WHICH WAS NOW SOMETHING SHE HAD TO CLOSELY MANAGE (CLOSTRIDIUM DIFFICILE) AS IT COULD CAUSE REOCCURRING ISSUES ANYTIME AN ANTIBIOTIC IS TAKEN. SHE HAD UNCONTROLLABLE VOMITING AND SEVERE STOMACH PAINS .THIS STARTED IN 2014 WHEN THE ESSURE PROCEDURE AND IUD PLACEMENT WAS COMPLETED. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO WAS PERSUADED BY HER DOCTOR TO HAVE AND ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ALONG WITH AN IUD, THE MIRENA (LEVONORGESTREL) (INTERPRETED AS OFF LABEL USE), RATHER THAN A PARTIAL HYSTERECTOMY. HER MIRENA FLOATED UP IN HER UTERUS AND WAS LODGED TOO FAR UP TO BE REMOVED (INTERPRETED AS IUS DISLOCATION). SHE HAD SEVERE BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND HAD A HYSTERECTOMY PERFORMED WHERE HER UTERUS, OVARIES AND TUBES WERE REMOVED. WITHIN 3 WEEKS SHE WAS

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HOSPITALIZED AGAIN DUE TO A REACTION TO AN ANTIBIOTIC (C.DIFFICILE) GIVEN TO HER AT THE TIME OF SURGERY (INTERPRETED AS ASSOCIATED ANTIBIOTIC COLITIS). THE GENITAL BLEEDING AND ASSOCIATED ANTIBIOTIC COLITIS ARE SERIOUS DUE TO HOSPITALIZATION, AND DEVICE DISLOCATION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. GENITAL BLEEDING AND DEVICE DISLOCATION ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND MIRENA WHILE ASSOCIATED ANTIBIOTIC COLITIS IS UNLISTED FOR BOTH PRODUCTS. IN THIS CASE, IT WAS REPORTED THAT THE PHYSICIAN DECIDED TO INSERT MIRENA AND ESSURE INSTEAD OF PERFORMING A PARTIAL HYSTERECTOMY, WHICH COULD IMPLY A PRIOR BLEEDING PROBLEM. ALSO, MIRENA WAS INSERTED TOO FAR UP IN THE UTERUS WHICH MAY HAVE CONTRIBUTED TO THE OCCURRENCE OF THIS GENITAL BLEEDING. DESPITE THE FACT MIRENA WAS DISLOCATED, IT IS NOT POSSIBLE TO EXCLUDE THAT ESSURE INSERTION MAY HAVE CONTRIBUTED TO THE GENITAL BLEEDING. SINCE IT WAS REPORTED THAT MIRENA WAS DISLOCATED, THIS EVENT WAS ASSESSED AS RELATED TO MIRENA AND UNRELATED TO ESSURE. REGARDING THE ASSOCIATED ANTIBIOTIC COLITIS, CONSIDERING IT IS ASSOCIATED TO THE USE OF ANTIBIOTICS, THIS EVENT IS ASSESSED AS UNRELATED TO BOTH MIRENA AND ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT. NO FURTHER INFORMATION CAN BE OBTAINED SINCE NO CONTACT DETAILS WERE PROVIDED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01552	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT (REQUIRED INTERVENTION). UNANTICIPATED. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE#(B)(4), AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. HER MEDICAL HISTORY INCLUDED 3 CHILDREN. SHE STARTED HAVING SEVERAL SYMPTOMS RIGHT AFTER INSERTION SUCH AS SEVERE BODY RASHES, CHRONIC PELVIC PAIN, AND SEVERE BRAIN FOG WITH SEVERAL OTHER SYMPTOMS FORCING HER TO HAVE A HYSTERECTOMY, BILATERAL SALPINGECTOMY, LEAVING HER OVARIES. SHE ALSO FOUND A BOWEL ADHESION THAT HAS RETURNED CAUSING HER TO HAVE FUTURE SURGERIES. SHE STATED THAT SHE CONTINUED TO HAVE NIGHT SWEATS, CHRONIC PELVIC PAIN, CRAMPING, BRAIN FOG, EXTREME FATIGUE, NO SEXUAL DESIRE, ANXIETY AND DEPRESSION. SHE WAS ALWAYS FEELING SICK AND TIRED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED CHRONIC PELVIC PAIN SINCE THE INSERTION AND WHICH, WITH OTHER NON-SERIOUS EVENTS, FORCED HER TO HAVE A HYSTERECTOMY AND BILATERAL SALPINGECTOMY (LEAVING HER OVARIES). SHE ALSO FOUND A BOWEL ADHESION THAT HAS RETURNED CAUSING HER TO HAVE FUTURE SURGERIES. THESE EVENTS ARE SERIOUS DUE TO REQUIRED INTERVENTION. PELVIC PAIN IS LISTED WHILE BOWEL ADHESION IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND ITS CLOSE TEMPORAL RELATIONSHIP WITH THE DEVICE USE, CAUSALITY CANNOT BE EXCLUDED. IN ADDITION, BOWEL ADHERENCES CAN BE SEEN AS COMPLICATIONS OF REQUIRED HYSTERECTOMY, THEREFORE, IT IS

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ASSESSED AS RELATED TO ESSURE. SINCE AN INTERVENTION WAS REQUIRED THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01553	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/26/2007
Explant Date (E7): 12/28/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007. SHE ALSO HAD IUD NOS (INTRAUTERINE CONTRACEPTIVE DEVICE) AND MIRENA (LEVONORGESTREL) INSERTED IN 2011. SHE WENT IN TO SEE HER DOCTOR TO DISCUSS CHOICES OF PERMANENT BIRTH CONTROL. SHE HAD BEEN ON OTHER BIRTH CONTROL AND WAS TIRED OF GETTING THE SHOTS AND WANTED SOMETHING MORE PERMANENT. SO AFTER MEETING WITH HER DOCTOR, SHE DECIDED TO GET ESSURE. SHE WAS TOLD IT WOULD BE DONE IN THE OFFICE AND ALL SHE WOULD NEED WAS PAIN KILLERS AN HOUR BEFORE PROCEDURE. ESSURE WAS INSERTED ON (B)(6) 2007. THE PROCEDURE WAS SO UNCOMFORTABLE AND PAINFUL THE DOCTOR EVEN OFFERED TO STOP AND FOR HER TO COME IN FOR THE SECOND COIL. SHE HAD CRAMPING FOR SEVERAL DAYS WHICH SHE TOOK IBUPROFEN FOR COMFORT. SHE STAYED ON HER CURRENT BIRTH CONTROL FOR THE NEXT THREE MONTHS AND THEN IN FOR THE DYE AND X-RAY TEST TO MAKE SURE THAT THE PROCEDURE TOOK AND THAT SCAR TISSUE HAD BUILT UP IN HER FALLOPIAN TUBES TO PREVENT PREGNANCY. SHE RECEIVED CONFIRMATION THAT HER FALLOPIAN TUBES WERE BLOCKED AND THAT SHE COULD NOT GET PREGNANT. UNFORTUNATELY SHE CONTINUED TO HAVE CRAMPING AND PAIN ESPECIALLY DURING HER MENSTRUAL CYCLE. IN 2011, SHE CAME UP PREGNANT AND SCARED. SHE CHOSE TO HAVE AN ABORTION SHORTLY AFTER FINDING OUT SHE WAS EXPECTING AND ALSO DECIDED TO GO BACK ON BIRTH CONTROL FOR ADDED PROTECTION. SHE CHOSE THE 10YR IUD WHICH ENDED UP UNCOMFORTABLE AND CAUSED CRAMPING AND MENSTRUAL ISSUES SO SHE ASKED TO BE SWITCH TO THE MIRENA IUD. COUPLE OF MONTHS AFTER THAT SHE STARTED TO HAVE SHARP CALVE PAIN IN HER RIGHT CALVE AND WENT INTO THE URGENT CARE TO FIND OUT SHE MIGHT HAVE A BLOOD CLOT; SHE WAS TOLD TO GO

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DIRECTLY TO THE ER (EMERGENCY ROOM) TO HAVE FURTHER TESTING DONE. SHE WAS ON BLOOD THINNERS FOR SIX MONTHS AND SHE WAS TOLD THAT BIRTH CONTROL WAS NO LONGER AN OPTION DUE TO HER BLOOD CLOT. THEY ALSO FOUND OUT THAT SHE WAS HYPERCOAGULABLE (WHICH MEANS THAT SHE HAS A PARTIAL GENE FOR CLOTTING WHICH MAKE IMPOSSIBLE FOR HER TO TAKE ANYTHING WITH HORMONES IN IT). SHE MET WITH A HEMATOLOGIST TO GO OVER BLOOD TEST RESULTS AND SHE TOLD HER SHE NEEDED TO LOSE WEIGHT, STOP SMOKING AND HAVE THE MIRENA REMOVED IMMEDIATELY. SHE STOPPED SMOKING THAT SAME DAY AND HAD AN APPOINTMENT WITH HER DOCTOR. AFTER MEETING WITH DOCTOR, SHE DECIDED THAT SHE WOULD SCHEDULE TO HAVE HER FALLOPIAN TUBES REMOVED THAT FOLLOWING 2011. THREE MONTHS AFTER FINISHING HER BLOOD THINNERS, THE SURGERY WAS DONE ON (B)(6) 2011 AND ESSURE WAS REMOVED; SURGERY WENT WELL; HOWEVER, WHEN SHE WOKE UP SHE WAS INFORMED THAT THE LEFT COIL HAD PUSHED ITS WAY OUT OF THE TUBE AND WAS HANGING ON THE OUTSIDE AND THAT THE RIGHT COIL HAD PUSHED ITS WAY OUT OF THE TUBE AND WAS HANGING ON THE OUTSIDE AND WAS STUCK ON THE OUTSIDE OF HER UTERUS. SHE HAS STRUGGLED WITH HEADACHES, AND NEVER ENDING HOT FLASHES, MOOD SWINGS AND SEVERE CRAMPS ESPECIALLY DURING HER MENSTRUAL CYCLE. SHE RECEIVED CONCOMITANT DRUGS: WARFARIN, SERTRALINE, TRAZODONE, GABAPENTIN, OMEPRAZOLE AND INHALERS. FOLLOW-UP RECEIVED ON 14-NOV-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND APPROXIMATELY 3 YEARS LATER GOT PREGNANT WITH ESSURE. THEN SHE HAD MIRENA (LEVONORGESTREL) INSERTED AND HAD A BLOOD CLOT (INTERPRETED AS THROMBOSIS) IN HER CALF. FOUR YEARS AFTER ESSURE INSERTION IT WAS FOUND THAT BOTH COILS HAD PUSHED THEIR WAY OUT OF THE TUBE AND WERE HANGING ON THE OUTSIDE (DEVICE DISLOCATION) AND RIGHT COIL WAS STUCK ON OUTSIDE OF UTERUS (EMBEDDED DEVICE). HER FALLOPIAN TUBES AND ESSURE COILS WERE REMOVED. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. EVENT BLOOD CLOT IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR BOTH MIRENA AND ESSURE, THE OTHER EVENTS ARE LISTED. IN THIS CASE, ESSURE CONFIRMATION TEST SHOWED TUBES WERE BLOCKED AND THE PREGNANCY OCCURRED APPROXIMATELY 3 YEARS AFTER INSERTION. THEREFORE CAUSALITY BETWEEN THE PREGNANCY AND ESSURE CANNOT BE EXCLUDED (DEVICE INEFFECTIVE). THROMBOTIC EVENTS ASSOCIATED WITH COMBINED ORAL CONTRACEPTIVES ARE CONSIDERED TO BE AN EFFECT OF ESTROGEN. THERE IS, TO DATE, NO EVIDENCE FOR AN INCREASED RISK OF STROKE, MYOCARDIAL INFARCTION OR VENOUS THROMBOEMBOLISM ASSOCIATED WITH USE OF PROGESTIN- ONLY CONTRACEPTIVES. THE CONSUMER WAS A SMOKER, HAD A GENETIC HYPERCOAGULABLE DISORDER, AND WAS PROBABLY OVERWEIGHT (DOCTOR ADVISED HER TO LOSE WEIGHT) WHICH COULD BE ALTERNATIVE EXPLANATIONS FOR THE THROMBOSIS. THEREFORE EVENT BLOOD CLOT WAS ASSESSED AS UNRELATED TO MIRENA AND ESSURE. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THE PRESENT CASE BOTH COILS HAD PUSHED THEIR WAY OUT OF THE TUBE AND WERE HANGING ON THE OUTSIDE AND RIGHT COIL WAS STUCK ON OUTSIDE OF UTERUS. GIVEN THE NATURE OF THESE EVENTS CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT

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SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

29-DECEMBER-2015: FU LETTER UNDERLIVERABLE. FINAL REPORT.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01554	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1556, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT CONSUMER HAD ESSURE REMOVED ON AN UNSPECIFIED DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THEN, ON AN UNSPECIFIED DATE, SHE HAD ESSURE REMOVED. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE THE EXACT INDICATION OF THIS REMOVAL PROCEDURAL HAS NOT BEEN INFORMED, CONSIDERING REMOVAL OF DEVICES MAY REQUIRES A SURGICAL INTERVENTION, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 16-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01555	BAYER HEALTHCARE LLC	11/17/2015	11/17/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1898, AWARENESS DATE 20-OCT-2015). IT REFERS TO A (B)(6) YEAR-OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER HAD THE DEVICE FOR 3 YEARS AND HAD MANY SYMPTOMS. SHE ENDED UP NEEDING A HYSTERECTOMY AT THE AGE OF (B)(6) TO HAVE ESSURE REMOVED. ONE OF THE COILS THAT WAS CONFIRMED TO BE TOTALLY BLOCKING HER TUBE WAS ACTUALLY EMBEDDED IN HER CERVIX AT THE TIME OF HYSTERECTOMY THAT LEFT 4 SCARS ON HER ABDOMEN, HAD 4 OF HER ORGANS REMOVED, HAD OVER A MONTH OF DOWNTIME. SHE WAS NOT EVEN ABLE TO CARRY HER KIDS FOR 6 WEEKS. SHE STATED HER HEALTH DECLINED WITH ESSURE, BUT THAT SHE WAS PERFECTLY HEALTHY AFTER THE HYSTERECTOMY WITHOUT ANY CHANGE TO HER DIET, EXERCISE OR WAY OF LITE, WHICH PROVED THAT ESSURE WAS THE CAUSE OF HER PROBLEMS RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE

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MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE OF THE COILS WAS ACTUALLY EMBEDDED IN HER CERVIX AT THE TIME OF HYSTERECTOMY. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE EMBEDMENT IN UTERUS OR FALLOPIAN TUBES MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE PATIENT STATED THAT HER HEALTH DECLINED AND SHE ENDED UP NEEDING A HYSTERECTOMY. ONE OF THE COILS THAT WAS CONFIRMED TO BE TOTALLY BLOCKING HER TUBE WAS ACTUALLY EMBEDDED IN HER CERVIX AT THE TIME OF HYSTERECTOMY. ALTHOUGH THE EXACT DATE AND MECHANISM OF THIS EMBEDMENT WERE NOT INFORMED, GIVEN ITS NATURE, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE USE. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

CORRECTION (B)(6) 2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE PREVIOUS EVENT TERM "MAJOR SURGERY LEFT 4 SCARS ON MY ABDOMEN" WAS RECODED TO MEDDRA LLT " ABDOMINAL OPERATION ".

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057980	BAYER	11/17/2015	11/20/2015

Event Information:

Event Date (B3): 10/14/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE IMPLANT
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627735

Single Use: *
Implant Date (E6): 9/9/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE IMPLANTED IN 2008. I HAVE BEEN HAVING PROBLEMS EVER SINCE. SIDE EFFECTS INCLUDED HAIR BALDING SPOTS, THINNING, PELVIC PAIN WHICH HAS GOTTEN WORST IN THE LAST MONTHS, NOW WAKE UP TO CRAMPING. SPOTTING BETWEEN PERIODS, IRREGULAR CYCLE, LOSS OF MEMORY, WEIGHT GAIN, LOW VITAMIN D DEFICIENCY, VISION PROBLEMS, SEVERE BLOATING, NAUSEA, LEG SPASM, FATIGUE, TIRED ALL THE TIME. PAIN DURING INTERCOURSE, UNEXPLAINED UTI'S, CYCLE LAST SOMETIMES 7 DAYS AND IS HEAVY, PAIN AND SOMETIMES 3 DAYS AND LIGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01532	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C13143

Single Use: Y
Implant Date (E6): 7/10/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(4) 2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ACCORDING TO PHYSICIAN, ESSURE PLACEMENT HAD BEEN PERFORMED IN TWO TIMES. FIRST (WITHOUT ANESTHESIA) PASSAGE HAD BEEN IMPOSSIBLE IN RIGHT SIDE, THE PATIENT HAD EXPERIENCED PAIN. IN THE SECOND ATTEMPT (WITH ANESTHESIA) ADENOMYOSIS WAS FOUND. THE PLACEMENT IN RIGHT SIDE HAD BEEN PERFORMED WITHOUT ANY PROBLEM AND OSTIUM HAD BEEN OPENED. IN ADDITION IT WAS INFORMED THAT REPORT HAD BEEN DONE BUT NOT REVIEWED BY THE SURGEON; ON THE REPORT, POINTS OF REFERENCE OF RIGHT INSERT WERE REVERSED. THE PATIENT WENT BACK TO PHYSICIAN AND SHE WAS PREGNANT (PATIENT'S OVULATION IN RIGHT SIDE). A DRUG INDUCED ABORTION WAS PERFORMED AND THE PATIENT TOOK IT QUITE WELL. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 07-APR-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT- SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT - THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A LACK OF EFFICACY (PREGNANCY). LACK OF EFFECTIVENESS IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT AS IT MAY OCCUR WITH THE USE OF ANY PRODUCT. ADDITIONALLY, PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. ADDITIONALLY, USABILITY ISSUES WERE REPORTED. THE REPORTED MEDICAL

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EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT OF THE PRODUCT ITSELF AND IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT OR THE LACK OF EFFICACY EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN ON 29-APR-2015: THE PATIENT WAS (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED MULTIPLE INTOLERANCE TO DIFFERENT CONTRACEPTION, MENORRHAGIA WITH COPPER IUD, METRORRHAGIA WITH MIRENA (CASE (B)(4)), CATAMENIAL MIGRAINE WORSENED WITH OESTROPROGESTATIVE INTAKE, DROP IN LIBIDO WITH (B)(4), GRAVIDA 2 (2003 AND 2008), PARA 2, CERVICAL LASER IN 2003 AND NO SERIOUS ILLNESS. HER CONCURRENT CONDITION INCLUDED AMENORRHEA WHILE ON (B)(4) (CONCOMITANT MEDICATION). INFORMATION ABOUT ESSURE PROCEDURE WAS OBTAINED: DAY OF MENSTRUAL PERIODS CYCLE WAS UNSPECIFIED DUE TO AMENORRHEA; PRE-MEDICATION WAS DONE WITH ATARAX 50 MG; DISTENSION WITH SALINE SOLUTION WAS ALSO PERFORMED; PLACEMENT TECHNIQUE WAS BETTOCCHI; CERVIX AND UTERINE CAVITY SIZE WERE NORMAL WITH ATROPHIC MUCOUS MEMBRANE; TUBAL ORIFICE WAS VISUALIZED WITHOUT ANY DIFFICULTY. NO PERFORMANCE OF ASSOCIATED PROCEDURE WAS DONE AT THE SAME DAY. LEFT INSERT PLACEMENT WAS QUITE EASY WITH PROGRESSION UNDER HIGHER PRESSURE. RIGHT INSERT COULD NOT BE PLACED AFTER SEVERAL FAILED ATTEMPTS, DUE DEFECT; TO NOT PASSABLE COMPLETE OSTIAL SYNECHIA. FIVE TRAILING COILS WERE VISIBLE IN LEFT SIDE AFTER INSERTION. PATIENT EXPERIENCED PAIN DURING PROCEDURE. MEDICAL NOTES FROM ANOTHER UNSPECIFIED DATE INDICATED THAT FIRST ATTEMPT FAILED IN RIGHT SIDE: RIGHT TUBAL OSTIUM WAS NOT PASSABLE DUE TO SYNECHIA. HYSTEROSALPINGOGRAPHY WAS DONE AND CONFIRMED RIGHT TUBAL PATENCY. SECOND ATTEMPT WAS DONE UNDER GENERAL ANESTHESIA; HYSTEROSCOPY WAS INTRODUCED UNDER VISION CONTROL WITH BETTOCCHI METHOD. TUBA ERECTA ASPECT WAS FOUND, EVOKING ADENOMYOSIS, WITH TUBAL OSTIUM WHICH STILL DID NOT SEEM TO BE PASSABLE. WITH HYPERPRESSURE, THE REAL TUBAL OSTIUM WAS FINALLY VISUALIZED INSIDE THE PSEUDO OSTIUM PREVIOUSLY SEEN, WHICH WAS IN FACT CORRESPONDING TO AN ADENOMYOSIS GLAND. INSERT WAS INTRODUCED WITHOUT ANY DIFFICULTY, INSERT WAS RELEASED AND THREE TRAILING COILS WERE VISUALIZED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP RECEIVED ON 27-MAY-2015 FROM PHYSICIAN: PATIENT'S DEMOGRAPHIC INFORMATION WAS PROVIDED. FIRST ATTEMPT ON (B)(6) 2014: FAILURE IN RIGHT SIDE. SECOND ATTEMPT UNDER GENERAL ANAESTHESIA PERFORMED ON (B)(6) 2014. ESSURE LOT NUMBER WAS PROVIDED (C13143). USE OF ALTERNATIVE CONTRACEPTION AFTER ESSURE PLACEMENT: (B)(4) FROM (B)(4) 2014 (DATE OF PLAIN ABDOMEN X-RAY). SHE EXPERIENCED AMENORRHEA DURING (B)(4) PERIOD. ON (B)(6) 2014, ESSURE CONFIRMATION TEST WAS PERFORMED BY X-RAY AND DID NOT CONFIRM TUBAL OCCLUSION. RESULTS: ESSURE INSERTS WERE IN LEFT CENTRAL AND LATERAL SACRAL POSITION. THE PATIENT WAS NOT ADVISED BY THE DOCTOR OF ESSURE EFFICIENCY BASED ON THE RESULT OF THE CONFIRMATION TEST. THE PATIENT WENT TO PERFORM THE X-RAY BUT DID NOT COME BACK TO SEE THE GYNECOLOGIST FOR CONSULTATION. PREGNANCY INTERRUPTION WAS DECIDED BY THE PATIENT. ESSURE INSERTS WERE IN SITU AT THE TIME OF DIAGNOSIS OF PREGNANCY. ESSURE INSERTS WERE NOT WITHDRAWN. FOLLOW UP INFORMATION RECEIVED ON 21-OCT-2015: THE PATIENT'S MEDICAL HISTORY ALSO INCLUDED MENORRHAGIA WITH COPPER IUD, METRORRHAGIA WITH MIRENA (LEVONORGESTREL), DROP IN LIBIDO WITH CERAZETTE (DESOGESTREL), AND PREGNANCIES IN 2003 AND IN 2008. FOLLOWING PATIENT'S REQUEST, CELIOSCOPY WAS PERFORMED FOR LIGATING OF THE UTERINE TUBES. CELIOSCOPY SHOWED PERFORATION WITH SUBPERITIONIZATION OF THE FUNDUS OF THE UTERUS. THE PERFORATION EXPLAINED THE IMPLANTS MARKERS ON THE PICTURE OF PLAIN ABDOMEN X-RAY WERE REVERSED. CASE UPGRADED TO INCIDENT. FOLLOW-UP RECEIVED ON 12-NOV-2015: NCA NUMBER WAS PROVIDED: (B)(4). PATIENT DENIES SERIOUS ILLNESS, C-SECTION, ECTOPIC PREGNANCY, PREVIOUS ELECTIVE ABORTION AND/OR

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SPONTANEOUS ABORTION. INSERTION HAD BEEN EASY. OSTIUM VISUALISATION WAS DIFFICULT. NO FLUID LOSS UPPER THAN 1500 CC DURING HYSTEROSCOPY. PROCEDURE HAD NOT LASTED MORE THAN 20 MIN. NO COMPLAINT IMMEDIATELY AFTER INSERTION. INCORRECT ESSURE POSITION WAS DIAGNOSED IN (B)(6) 2015 WHEN PREGNANCY WAS DIAGNOSED. NO ORGAN OR INTRA-ABDOMINAL STRUCTURE WAS PERFORATED. PERFORATION DID NOT OCCUR BEFORE DEPLOYMENT. PERFORATION OCCURRED WITH COIL AFTER DEPLOYMENT. PERFORATION DIAGNOSIS MADE BY LAPAROSCOPY. ESSURE WAS CORRECTLY PLACED ON LEFT. ON RIGHT, COMPLETE PERFORATION WAS FOUND WITH ESSURE POSITIONED INTO INTERSTITIAL PART OF FALLOPIAN TUBE. PERFORATION SYMPTOM: PREGNANCY, 5 WEEKS AND 4 DAYS OF AMENORRHEA. ESSURE CONFIRMATION TEST WAS PERFORMED ON (B)(6) 2014 BY X-RAY AND CONFIRMED TUBAL OCCLUSION. THE PATIENT WAS ADVISED TO RELY ON ESSURE BASED ON THE RESULT OF CONFIRMATION TEST BY THE RADIOLOGIST. ESSURE IMPLANTS WERE NOT REMOVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT (DEVICE INEFFECTIVE). SHE UNDERWENT AN ELECTIVE ABORTION BUT DID NOT REMOVE ESSURE INSERTS. SHE ALSO EXPERIENCED A PERFORATION ON RIGHT WITH ESSURE IMPLANTS POSITIONED INTO INTERSTITIAL PART OF FALLOPIAN TUBE. A CELIOSCOPY WAS PERFORMED FOR LIGATING OF THE UTERINE TUBES. PERFORATION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. PREGNANCY IS CONSIDERED NON-SERIOUS. BOTH EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, ESSURE PLACEMENT IN THE RIGHT SIDE WAS DIFFICULT AND TWO ATTEMPTS WERE REQUIRED; PHYSICIAN STATED POINTS OF REFERENCE OF RIGHT INSERT WERE REVERSED (UNSPECIFIED) AND HE BELIEVED PATIENT OVULATION WAS IN THE RIGHT SIDE. A HYSTEROSALPINGOGRAM WAS PERFORMED AFTER THE FIRST ATTEMPT AND CONFIRMED RIGHT TUBAL PATENCY. A SECOND ATTEMPT WAS MADE UNDER GENERAL ANESTHESIA AND INSERT WAS INTRODUCED WITHOUT DIFFICULTY. AFTER THE 3-MONTH PERIOD, AN X-RAY WAS PERFORMED AND DID NOT CONFIRM TUBAL OCCLUSION. THE PATIENT DID NOT COME BACK AFTER THE CONFIRMATION TEST. THE PREGNANCY OCCURRED APPROXIMATELY 5 MONTHS AFTER THIS SECOND ATTEMPT. SINCE THE TUBAL OCCLUSION WAS NOT CONFIRMED, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE REPORTED PREGNANCY CANNOT BE EXCLUDED (DEVICE INEFFECTIVE). WITH REGARDS TO THE OTHER EVENT, THE EXACT DATE AND MECHANISM OF PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. AN INITIAL PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT AND THAT BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT OR THE LACK OF EFFICACY EVENT AND A QUALITY DEFECT. AFTER RECEIPT OF LOT NUMBER, A NEW ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01533	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0385, AWARENESS DATE 11-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (ESS205) INSERTED IN 2007. SINCE ESSURE INSERTION THE CONSUMER HAS EXPERIENCED BLEEDING, BLOOD CLOT, HEART PALPITATIONS, EXCESSIVE BLOATING, DEBILITATING CRAMPS / ABDOMINAL PAIN, HEADACHES, PELVIC PAIN, UTERINE CYSTS, JOINT PAIN, NERVE PAIN, SHINGLES TWICE, VERTIGO, AND ECZEMA. FOLLOW-UP RECEIVED ON 16-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PRODUCT TECHNICAL COMPLAINT WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED MEDICAL EVENTS ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER INVESTIGATION THEREFORE THE COMPLAINT COULD NOT BE EVALUATED IN GREATER DETAIL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED

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QUALITY DEFECT. BASED ON THE LIMITED AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT FOLLOW UP INFORMATION IDENTIFIED ON 21-OCT-2015 (CASE UPGRADED TO INCIDENT): THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1510). CONSUMER REPORTED THAT SHE HAD A BILATERAL SALPINGECTOMY WITH CORNUAL RESECTION TO REMOVE ESSURE BECAUSE OF COMPLICATIONS. THE DOCTORS FOUND THAT ESSURE HAD MIGRATED FURTHER OUT INTO THE FALLOPIAN TUBE, WAY PAST GRADE 3, UTERINE CYSTS, OVARIAN CYSTS, ENDOMETRIOSIS AND ADENOMYOSIS SO DILATATION AND CURETTAGE WAS PERFORMED WITH PLANS FOR FUTURE MONITORING. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 04-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED; THEREFORE, A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND BLOOD CLOT. SHE HAD A BILATERAL SALPINGECTOMY WITH CORNUAL RESECTION TO REMOVE ESSURE AND THE DOCTORS FOUND THAT ESSURE HAD MIGRATED FURTHER OUT INTO THE FALLOPIAN TUBE (INTERPRETED AS DEVICE DISLOCATION). THEY ALSO DIAGNOSED HER WITH ENDOMETRIOSIS AND ADENOMYOSIS, SO DILATATION AND CURETTAGE WAS PERFORMED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. BLEEDING AND DEVICE DISLOCATION ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE BLOOD CLOT, ENDOMETRIOSIS AND ADENOMYOSIS ARE UNLISTED. OTHER NON-SERIOUS EVENTS WERE REPORTED. BASED ON AN IMPLIED POSITIVE TEMPORAL RELATIONSHIP, ON ESSURE SAFETY PROFILE, AND ON LACK OF ALTERNATIVE EXPLANATION, THE EVENTS BLEEDING AND DEVICE DISLOCATION WERE CONSIDERED TO BE RELATED TO ESSURE USE. HOWEVER, SINCE ESSURE DOES NOT CONTAIN ANY DRUG AND HAS ONLY A LOCALIZED MECHANICAL ACTION, ITS SYSTEMIC INFLUENCE IS UNLIKELY. THUS, THE CAUSALITY BETWEEN THE EVENTS BLOOD CLOT, ENDOMETRIOSIS AND ADENOMYOSIS AND ESSURE USE WAS ASSESSED AS UNRELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01547	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 12/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/17/2014
Explant Date (E7): 10/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1654, AWARENESS DATE 21-OCT-2015) WHICH REFERS TO FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. THE CONSUMER REPORTED 10 DAYS AFTER THE INSERTION PROCEDURE SHE HAD A URINARY TRACT INFECTION AND IN 10 MONTHS SHE HAD ESSURE SHE HAD 10 UTIS AND EVEN WHEN SHE DID NOT HAVE THE UTI HER URETHRA BURNED. SHE STATED NEVER IN HER LIFE SHE HAD HEAVY OR PAINFUL PERIODS UNTIL THE 2ND PERIOD SHE HAD AFTER GETTING ESSURE; THEY WERE SO HEAVY THAT SHE WOULD HAVE TO WEAR ADULT DIAPERS TO BED THE FIRST 2 NIGHTS, SHE STATED HER CRAMPS WERE VERY PAINFUL; SOME MONTHS SHE WOULD NOT HAVE A PERIOD BUT OTHER MONTHS SHE WOULD HAVE 2. THOSE WERE THE ONLY PROBLEMS SHE HAD FOR THE FIRST 5 OR 6 MONTHS BUT THEN SUDDENLY IT STARTED GETTING WORSE, SHE WOULD GET THIS THROBBING PAIN AND PRESSURE IN HER LOWER BACK THAT WAS SO BAD IT WOULD BRING HER TO HER KNEES. THE CONSUMER MENTIONED SHE IS A STAY AT HOME MOM WITH 3 CHILDREN, 2 OR THEM IN DIAPERS AND SHE HAD TO HAVE HER (B)(6) DAUGHTER TAKE CARE OR HER LITTLE BROTHERS SOME DAYS BECAUSE SHE WAS IN TOO MUCH PAIN TO CARE FOR THEM. SHE STARTED HAVING HOT FLASHES, HER HAIR WAS FALLING CUT AND SHE HAD HIVES ON HER BACK, LEG AND FACE FOR OVER A MONTH, THEY DID NOT ALWAYS ITCH BUT EVEN WHEN THEY WERE NOT ITCHING THE BUMPS DID NOT GO AWAY. ON THE DAYS SHE WAS NOT IN PAIN SHE WOULD EXERCISE BUT SHE HAD TO QUIT EXERCISING BECAUSE SHE WOULD GET EXTREMELY DIZZY. ABOUT 2 WEEKS BEFORE HER HYSTERECTOMY AND SALPINGECTOMY HER LEFT WRIST STARTED HURTING AND SHE THOUGHT MAYBE SHE SPRAINED IT OR SOMETHING BUT THEN THE NEXT DAY HER RIGHT

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WRIST ANKLES KNEES AND HIPS ALSO STARTED HURTING; THE PAIN IN HER LEFT WRIST WAS THE WORSE BECAUSE IT WAS CONSTANT FOR 2 WEEKS. SHE ALSO REPORTED HER SEX LIFE BECAME ALMOST NONEXISTENT BECAUSE SHE IT WAS TOO PAINFUL FOR HER AND SOMETIMES SHE WOULD HAVE SEVERE CRAMPS IN HER ABDOMEN FOR 2 DAYS AFTER HAVING SEX. SHE BELIEVED THAT THOSE WERE ALL OF THE PROBLEMS SHE HAD IN THE 10 MONTHS SHE HAD ESSURE BUT SHE MIGHT HAVE MISSED A COUPLE BECAUSE THERE WERE SO MANY HEALTH PROBLEMS DURING THOSE MONTHS. IN (B)(6) 2015, SHE HAD A HYSTERECTOMY AND SALPINGECTOMY AND SHE WAS ALREADY FEELING BETTER. THE MORNING SHE WENT IN FOR SURGERY HER LEFT WRIST WAS HURTING LIKE IT HAD BEEN FOR 2 WEEKS. SHE MENTIONED THE HIVES SHE HAD FOR OVER A MONTH WERE FINALLY GONE. DURING THE SURGERY HER DOCTOR SAW THAT THE COIL IN THE LEFT TUBE HAD PERFORATED THE TUBE AND HE BELIEVED THAT MAY HAVE BEEN THE CAUSE OR THE DEBILITATING BACK PAIN SHE WAS HAVING. HER HUSBAND HAD TO TAKE 2 WEEKS OFF OF WORK TO TAKE CARE OF HER AND THEIR CHILDREN WHILE SHE RECOVERS FROM SURGERY. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED 10 UTIS (INTERPRETED AS URINARY TRACT INFECTIONS). A HYSTERECTOMY AND SALPINGECTOMY WERE PERFORMED AND DURING THE SURGERY THE DOCTOR NOTICED THAT THE COIL IN HER LEFT TUBE HAD PERFORATED THE TUBE (SEEN AS FALLOPIAN TUBE PERFORATION). UTI IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE FALLOPIAN TUBE PERFORATION IS LISTED. BOTH ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, CONSUMER EXPERIENCED UTI 10 DAYS AFTER ESSURE INSERTION AND DURING 10 MONTHS SHE HAD THE ESSURE SHE HAD 10 UTIS. BEFORE THE INSERTION PROCEDURE, UNIVERSAL PRECAUTIONS AND STERILE TECHNIQUE SHOULD BE OBSERVED. ALTHOUGH THIS INFORMATION WAS NOT REPORTED, AS WITH ALL TRANS-CERVICAL PROCEDURES, THE ESSURE MICRO-INSERT PLACEMENT CAN CAUSE INFECTION. CONSIDERING THIS INFORMATION AND A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP BETWEEN UTI AND SUSPECT INSERT CANNOT BE FORMALLY EXCLUDED. WITH REGARDS TO THE OTHER EVENT, ALTHOUGH THE EXACT DATE AND MECHANISM OF PERFORATION WERE NOT KNOWN, CONSIDERING ITS NATURE A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTIONS WERE PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01556	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2004
Explant Date (E7): 1/1/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A(B)(6) FEMALE CONSUMER IN UNITED STATES ON 21-OCT-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2004 FOR PERMANENT STERILIZATION. SHE WAS NOT PREGNANT. THE CONSUMER REPORTED THAT ESSURE MADE HER SICK SO SHE HAD THEM REMOVED IN 2009, AFTER SEEING A TUBAL REMOVAL SPECIALIST. SHE STATED HER SYMPTOMS DIMINISHED AFTER REMOVAL BUT THEY NEVER COMPLETELY WENT AWAY. SHE DEVELOPED A CHEMICAL SENSITIVITY FROM ESSURE AND SUSPECT IT WAS FROM THE COATING. BY THE TIME OF THIS REPORT SHE WAS ON AN ANTIBIOTIC FOR BRONCHITIS AND THE ANTIBIOTIC WAS CAUSING HER SYMPTOMS TO FLARE-UP. SHE BELIEVE SHE STILL HAD PET FIBERS INSIDE OF HER AND WAS THINKING ABOUT ASKING HER DOCTOR FOR A BIOPSY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 05-NOV-2015. THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE 1IURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

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COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED APPROXIMATELY 5 YEARS AFTER DEVICE PLACEMENT BECAUSE IT MADE HER SICK. ADDITIONALLY, SHE BELIEVED SHE STILL HAD PET FIBERS INSIDE OF HER (REGARDED AS A SUSPICION OF DEVICE BREAKAGE). ESSURE REMOVAL IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION, WHILE DEVICE BREAKAGE IS ANTICIPATED ACCORDING TO THE TECHNICAL ASSESSMENT. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, MINIMAL INFORMATION WAS PROVIDED AND CONSUMER'S SICKNESS WAS NOT SPECIFIED. ADDITIONALLY, HER SUSPICION OF DEVICE BREAKAGE WAS NOT CONFIRMED AT THE TIME OF THIS REPORT. NEVERTHELESS; CONSIDERING DEVICE REMOVAL WAS REQUIRED; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THEREFORE, THIS CASE WAS CONSIDERED AN INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01557	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM HEALTHCARE PROVIDERS IN UNITED STATES ON 22-OCT-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ADDITIONAL INFORMATION RECEIVED ON 07-NOV-2015. THE REPORTERS (TWO HEALTHCARE PROVIDERS) STATED THEY HAD TO REMOVE THE COILS IN ABOUT FIVE PATIENTS OVER THE LAST SIX MONTHS (THIS CASE REFERS TO ONE OF THESE PATIENTS). THE PATIENT PRIMARY COMPLAINT WAS OF PAIN, WHICH LED HER TO REQUEST ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENT IS KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED DUE TO PAIN. THE

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REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01558	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM HEALTHCARE PROVIDERS IN UNITED STATES ON 22-OCT-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ADDITIONAL INFORMATION RECEIVED ON 07-NOV-2015. THE REPORTERS (TWO HEALTHCARE PROVIDERS) STATED THEY HAD TO REMOVE THE COILS IN ABOUT FIVE PATIENTS OVER THE LAST SIX MONTHS (THIS CASE REFERS TO ONE OF THESE PATIENTS). THE PATIENT PRIMARY COMPLAINT WAS OF PAIN, WHICH LED HER TO REQUEST ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED DUE TO PAIN. THE

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REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01559	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM HEALTHCARE PROVIDERS IN UNITED STATES ON 22-OCT-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION ON AN UNSPECIFIED DATE. ADDITIONAL INFORMATION RECEIVED ON 07-NOV-2015. THE REPORTERS (TWO HEALTHCARE PROVIDERS) STATED THEY HAD TO REMOVE THE COILS IN ABOUT FIVE PATIENTS OVER THE LAST SIX MONTHS (THIS CASE REFERS TO ONE OF THESE PATIENTS). THE PATIENT PRIMARY COMPLAINT WAS OF PAIN, WHICH LED HER TO REQUEST ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED

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DUE TO PAIN. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01560	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM HEALTHCARE PROVIDERS IN UNITED STATES ON 22-OCT-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ADDITIONAL INFORMATION RECEIVED ON 07-NOV-2015. THE REPORTERS (TWO HEALTHCARE PROVIDERS) STATED THEY HAD TO REMOVE THE COILS IN ABOUT FIVE PATIENTS OVER THE LAST SIX MONTHS (THIS CASE REFERS TO ONE OF THESE PATIENTS). THE PATIENT PRIMARY COMPLAINT WAS OF PAIN, WHICH LED HER TO REQUEST ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED DUE TO PAIN. THE

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REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01561	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM HEALTHCARE PROVIDERS IN UNITED STATES ON 22-OCT-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT STERILIZATION ON AN UNSPECIFIED DATE. ADDITIONAL INFORMATION RECEIVED ON 07-NOV-2015. THE REPORTERS (TWO HEALTHCARE PROVIDERS) STATED THEY HAD TO REMOVE THE COILS IN ABOUT FIVE PATIENTS OVER THE LAST SIX MONTHS (THIS CASE REFERS TO ONE OF THESE PATIENTS). THE PATIENT PRIMARY COMPLAINT WAS OF PAIN, WHICH LED HER TO REQUEST ESSURE REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 07-NOV-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED

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DUE TO PAIN. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01562	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN UNITED STATES ON 21-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. ADDITIONAL INFORMATION WAS RECEIVED ON 25-OCT-2015 AND 04-NOV-2015 (PTC INVESTIGATION RESULT): THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1470, AWARENESS DATE 25-OCT-2015). THE CONSUMER'S MEDICAL HISTORY INCLUDED PARITY 3. NO INFORMATION GIVEN ON CONSUMER'S DRUG HISTORY AND CONCURRENT CONDITIONS. IN 2012, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, AFTER HER SON WAS BORN. SHE REPORTED SHE HAD THE NORMAL CRAMPING AND BLEEDING AFTER INSERTION WAS OVER. ON THE 3 MONTH HYSTEROSALPINGOGRAM, SHE WAS STILL BLEEDING AND CRAMPING AND IT WAS CONFIRMED HER TUBES WERE SEALED. 6 MONTHS AFTER HYSTEROSALPINGOGRAM, SHE WAS PUT ON HORMONES TO STOP HER BLEEDING, SHE REPORTED 9 MONTHS OF BLEEDING AND FEELING HORRIBLE WHILE TRYING TO WORK, TAKE CARE OF FAMILY, HOME AND A NEW BORN. IN 2015, PAIN BECAME MORE FREQUENT, MORE INTENSE AND VERY BAD ON LEFT SIDE. HER DOCTOR FOUND HER UTERUS TO BE SWOLLEN AND ORDERED ABDOMINAL AND TRANSVAGINAL ULTRASOUNDS. ACCORDING TO THE DOCTOR, THE RESULTS WERE OK AND ALL THE PAIN, CRAMPS, ITCHING, BLOATING, FATIGUE, PAINFUL SEX, GENERAL FEELING LIKE DEATH AND 9 MONTHS OF BLEEDING WERE NOT RELATED TO ESSURE. CONSUMER ALSO EXPERIENCED HEADACHES AND METAL TASTE IN MOUTH. ON 16-OCT-2015, THE CONSUMER GOT ALL OF HER ULTRASOUND RECORDS AND THE PICTURES FROM HER HYSTEROSALPINGOGRAM SHOWED THAT THE IMPLANT ON THE LEFT SIDE WAS BROKEN SINCE 2012. HER DOCTOR TOLD HER SHE COULD NOT HAVE IT REMOVED AND THE CONSUMER

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STATED SHE SUFFERS EVERY SINGLE DAY WITH PAIN AND A MULTITUDE OF OTHER SYMPTOMS. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATE TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATH RECORD. WE WERE UNABLE B CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THIS DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING (SEEN AS GENITAL BLEEDING). IT WAS REPORTED THAT IMPLANT ON LEFT SIDE WAS BROKEN. THE EVENT GENITAL BLEEDING IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE WHILE DEVICE BREAKAGE IS NON-SERIOUS. BOTH ARE LISTED IN THE REFERENCE SAFETY INFORMATION, DEVICE BREAKAGE WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. IN THIS CASE, CONSUMER STATED THAT SHE HAD BLEEDING AFTER INSERTION WAS OVER AND ON THE 3 MONTH HYSTEROSALPINGOGRAM, SHE WAS STILL BLEEDING. ABOUT 3 YEARS AFTER INSERTION, SHE UNDERWENT AN ULTRASOUND AND HYSTEROSALPINGOGRAM WHICH RESULT SHOWED THAT THE IMPLANT ON THE LEFT WAS BROKEN SINCE 2012. CONSIDERING THE NATURE OF THE EVENTS AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 21-DEC-2015: FOLLOW-UP ATTEMPTS WERE MADE WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED D

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01563	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 2/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/27/2000
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1653, AWARENESS DATE 21-OCT-2015) WHICH REFERS TO (B)(6) FEMALE PATIENT WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2000. THE CONSUMER REPORTED SHE WAS PART OF THE ESSURE CLINICAL TRIALS. ESSURE WAS INSERTED AS SURGICAL OUTPATIENT PROCEDURE IN WHICH SHE WAS PUT UNDER ANESTHESIA. ACCORDING TO THE CONSUMER, SHE REPORTED AT THE TIME OF THE TRIAL SHE HAD SEVERE CRAMPING, PAIN WITH INTERCOURSE, EXCESSIVE BLEEDING WITH MENSES AND SEVERE MENSTRUAL CRAMPS. SHE REPORTED SINCE ESSURE INSERTION SHE SUFFERED WITH UNBEARABLE CRAMPING AND PAIN IN HER LOWER ABDOMEN, SHE HAS A BIG SWOLLEN BELLY AND HAD TWO SURGERIES INCLUDING NISSEN FUNDOPLICATION AND GALL BLADDER REMOVAL. SHE SUFFERED FROM GERD, FROM MIGRAINE HEADACHES; SUFFER FROM PAIN IN JOINTS, HER SKIN, HER HAIR, HER ENTIRE BODY. SHE HAD A TUBAL PREGNANCY (B)(6) 2012. SHE HAD BLEEDING EVERY SINGLE TIME SHE HAD INTERCOURSE. SHE STATED BEING FIRED FROM EVERY SINGLE JOB SHE HAD DUE TO ABSENCES RELATED TO HER BEING IN CONSTANT PAIN. SHE HAS 3 CHILDREN, AND SADLY THEY HAD TO GROW UP LISTENING TO HER GRIPE ABOUT HOW MUCH SHE HURT, AND TAKING PAIN MEDICATIONS, AND HAVING TO WAIT UNTIL HER CRAMPS GO AWAY SO SHE COULD FUNCTION. SHE HAS HIGH BLOOD PRESSURE AND BELIEVED SHE HAD ALLERGIC REACTIONS OF AND ON TO THE IMPLANTS, SHE BROKE OUT IN HIVES, HAD RASHES THAT COME AND GO ALL OVER BODY, SHE SWEAT PROFUSELY, HER BODY IS ALWAYS WARM AND SWOLLEN, SHE HAD DEPRESSION. SHE STATED SHE HURT EVERY DAY AND NOW FOUND OUT OTHER WOMEN WERE HAVING THE SAME ISSUES AND SHE WAS ABLE TO SAY THIS IS BECAUSE OF ESSURE. NO DOCTOR HAS EVER GIVEN HER AN ANSWER AS

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TO WHY SHE HAD ALL THESE ISSUES, BECAUSE SHE NEVER THOUGHT TO MENTION THAT THEY WERE ALL RELATED TO THE IMPLANT. SHE REPORTED SHE IS GOING TO MEET A GYNECOLOGIST TO DISCUSS A HYSTERECTOMY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 11-NOV-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS / LACK OF EFFICACY IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2000. SHE REPORTED A TUBAL PREGNANCY IN (B)(6) 2012 AND 2 SURGERIES: NISSEN FUNDOPLICATION AND GALL BLADDER REMOVAL, ALL SERIOUS EVENTS. ECTOPIC PREGNANCY IS LISTED AND THE SURGERIES ARE UNLISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. REGARDING BOTH SURGERIES, DUE TO THE LOCAL ACTION OF ESSURE AND ALTERNATIVE EXPLANATIONS/ RISK FACTORS FOR THEM (GERD, FEMALE SEX), CAUSALITY IS EXCLUDED TO ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE, INCLUDING ECTOPIC ONES. THESE PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. CONSIDERING A DEVICE INEFFECTIVE, CAUSALITY CANNOT BE EXCLUDED BETWEEN ECTOPIC PREGNANCY AND ESSURE. THIS CASE IS CONSIDERED INCIDENT AS ECTOPIC PREGNANCY REQUIRES INTERVENTION. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 06-JAN-2016: ESSURE IMPLANTED AT THE AGE (B)(6), FULL HYSTO LEAVING OVARY IF POSSIBLE. FIRST FOLLOW UP WHICH WAS LIKE 3 DAYS LOWER ABDOMINAL AREA PAIN, CRAMPING LIKE HEAVY PERIODS, WEIGHT GAIN, HAIR LOSS, BLOATING, SEVERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01564	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 8/5/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE#FDA-2014-N-0736-1621, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. A FEW MONTHS AFTER INSERTION, SHE BEGGED HER DOCTOR TO PUT HER BACK ON PILL BECAUSE ALL SORTS OF WEIRD THINGS STARTED HAPPENING. SHE WAS DIAGNOSED WITH MS (INTERPRETED AS MULTIPLE SCLEROSIS) IN 2010. SHE HAD SEVERE FATIGUE, BRAIN FOG, NUMBNESS IN RIGHT LEG, STOMACH ISSUES AND SKIN ISSUES. IN (B)(6) 2015, HER DOCTOR PERFORMED AN ALLERGY PANEL TEST ON HER. SHE WAS CONVINCED SHE WAS ALLERGIC TO NICKEL, HOWEVER, SHE STATED THAT SHE WAS NOT. BUT SHE WAS ALLERGIC TO GOLD; SEVERELY ALLERGIC. SHE GOT A HYSTERECTOMY ON (B)(6) 2015 REMOVING EVERYTHING BUT OVARIES. HER COIL (ONLY HAD ONE BECAUSE IMPLANTING DOCTOR COULD NOT GET SECOND COIL IN, SHE ENDED UP GETTING TUBAL AS WELL) WAS EMBEDDED IN UTERUS; HER UTERUS WAS 3 TIMES NORMAL SIZE. AT THE TIME OF THE REPORT, SHE WAS WEEKS OUT FROM SURGERY AND HAD MORE ENERGY THAN SHE HAD IN YEARS. HER DARK CIRCLES WERE MUCH LESS THAN THEY WERE AND SHE DID NOT FEEL TOXIC LIKE SHE HAD FOR YEARS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING

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BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE COIL WAS EMBEDDED IN HER UTERUS. SHE UNDERWENT A HYSTERECTOMY 8 YEARS AFTER INSERTION. SHE WAS ALSO DIAGNOSED WITH MS (INTERPRETED AS MULTIPLE SCLEROSIS). THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. EMBEDDED DEVICE IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, MULTIPLE SCLEROSIS IS UNLISTED. IN THE PRESENT CASE, THE EXACT MECHANISM OF THE DEVICE EMBEDMENT WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. CONSIDERING THE PATHOPHYSIOLOGY OF MULTIPLE SCLEROSIS, AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND ESSURE WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED (CONSUMER MENTIONED HER UTERUS WAS 3 TIMES NORMAL SIZE, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR THE HYSTERECTOMY, HOWEVER FROM THE AVAILABLE INFORMATION IT CANNOT BE EXCLUDED THAT THE DEVICE EMBEDMENT ALSO CONTRIBUTED TO THE HYSTERECTOMY). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01565	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2014
Explant Date (E7): 9/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1511, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. ADDITIONAL INFORMATION RECEIVED ON 11-NOV-2015 (PTC INVESTIGATION RESULT). ESSURE COILS IMPLANTED IN (B)(6) 2014. SHORTLY THEREAFTER SHE DEVELOPED A CHRONIC CERVICITIS WITH BLEEDING THAT SHE ENDURED THE ENTIRE DURATION OF HAVING THE ESSURE PRODUCT INSIDE HER BODY. OTHER SYMPTOMS THAT SHE HAD DEVELOPED DURING THE TIME SHE HAD THESE IMPLANTS WERE SEVERE CRAMPING AND BLEEDING DURING AND AFTER INTERCOURSE; MORE THAN HER NORMAL HAIR LOSS; CHRONIC FATIGUE-SHE HARDLY EVER FELT RESTED AND HAD TO REST OFTEN DURING THE COURSE OF THE DAY; MUSCLE AND JOINT SORENESS AND PAIN THAT WOULD NOT GO AWAY WITH MEDICATIONS, EXERCISING, STRETCHING, YOGA AND PILATES; SKIN RASHES, PAINFUL INTERCOURSE AND 25LB WEIGHT GAIN. ON, (B)(6) 2015 SHE HAD A HYSTERECTOMY AND BILATERAL SALPINGECTOMY THAT REMOVED LEFT AND RIGHT FALLOPIAN TUBES, UTERUS AND CERVIX. SHE WAS ABLE TO KEEP THE OVARIES. SHE WAS 9 DAYS POST OP FROM HYSTERECTOMY AND HER JOINT AND MUSCLE PAIN IS GONE, SHE FELT MORE ENERGIZED THAN SHE HAVE FELT IN A LONG TIME, HER SKIN HAS CLEARED UP, HAIR BALLS AFTER SHOWERING WERE SMALL COMPARED TO WHAT WAS ENDING UP IN THE DRAIN, SHE WAS NOT BLEEDING. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING THAT SHE ENDURED THE ENTIRE DURATION OF HAVING THE ESSURE PRODUCT INSIDE HER BODY (INTERPRETED AS GENITAL BLEEDING). CONSUMER UNDERWENT A HYSTERECTOMY AND BILATERAL SALPINGECTOMY THAT REMOVED LEFT AND RIGHT FALLOPIAN TUBES, UTERUS AND CERVIX. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, CONSUMER EXPERIENCED THIS EVENT SHORTLY AFTER ESSURE INSERTION. BASED ON IT NATURE AND CONSIDERING THAT GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01566	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2013
Explant Date (E7): 6/19/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1826, AWARENESS DATE 21-OCT-2015) WHICH REFERS TO FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013; ALMOST ONE YEAR AFTER THE BIRTH OF HER YOUNGEST CHILD. ADDITIONAL INFORMATION RECEIVED ON 11-NOV-2015 (PTC INVESTIGATION RESULT). THE CONSUMER REPORTED SHE HAD ESSURE AND NOVA SURE PROCEDURE DONE AT THE SAME TIME IN A SURGERY CENTER WHILE SHE WAS PUT TO SLEEP. SHE REPORTED WHEN SHE WOKE UP THE PAIN WAS HORRIBLE AND FIGURE IT WAS A MIX BETWEEN; SHE STATED THE PAIN DID NOT WENT AWAY AND SOON SHE STARTED TO SEE AN E-BELLY (AS REPORTED) FROM ALL THE BLOATING SHE WAS EXPERIENCING. SHE WENT BACK TO HER IMPLANTING DOCTOR AND HE PUT HER ON PAIN KILLERS. ON (B)(6) 2013, SHE STARTED HER FIRST DOSE OF NARCOTIC PAIN MEDICATION. OVER THE NEXT YEAR AND HALF, SHE HAD BEEN SEEN IN THE ER DUE TO DEBILITATING PELVIC PAIN AND LOWER BACK PAIN; SHE HAD X-RAYS, CT SCANS AND ULTRASOUNDS DONE AND EVERYTHING CAME BACK CLEAR. BY THAT TIME, SHE EXPERIENCED MORE THAN 30 SIDE EFFECTS INCLUDING CRAMPING, SHARP/STABBING PELVIC PAINS, OVARIAN CYSTS, CONSTANT BACTERIAL VAGINITIS, ENDOMETRIOSIS, HOT FLASHES, COMPLETE LOSS OF LIBIDO, URGENT AND FREQUENT URINATION, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS, CHRONIC PELVIC PAIN, BACK/JOINT/NECK/HIP PAIN, PAIN ALL OVER BODY, NAUSEA, GAS, CONSTIPATION, SEVERE BLOATING, DIZZINESS, MIGRAINES, FOGGY BRAIN, ANXIETY ATTACKS, EXTREME MOOD SWINGS, DEPRESSION, CHRONIC FATIGUE, CYSTS/BOILS ON UPPER LINER THIGHS, SWELLING ANKLES, INSOMNIA, WEIGHT GAIN, SWOLLEN GLANDS, DRY SKIN, HAIR LOSS, NICKEL ALLERGY AND MANY MORE. THE CONSUMER REPORTED SHE

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HAD NO INFORMATION THERE WAS NICKEL IN THE DEVICE AND SPENT ALMOST 2 YEARS IN AND OUT OF DOCTORS AND ER VISITS. SHE WAS ALMOST 2 YEARS TAKING NARCOTIC PAIN MEDICATION DAILY JUST TO HOPEFULLY EASE THE PAIN AND DISCOMFORT SHE WAS EXPERIENCING; UNTIL HER DOCTOR DECIDED TO DO A HYSTERECTOMY ON HER. ON (B)(6) 2015, SHE HAD HER CERVIX, UTERUS AND FALLOPIAN TUBES REMOVED. SHE REPORTED WHILE THE PHYSICIAN WAS IN HE NOTICED SHE HAD 2 VERY FULL CYSTS THAT WERE ABOUT THE SIZE OF CHERRY TOMATOES ON HER OVARIES, INSTEAD OF REMOVING HER OVARIES HE DRAINED THE CYSTS. SHE HAD THE DA VINCI ASSISTED LAVH REMOVING ALL EXCEPT OVARIES. THE CONSUMER STATED AT THE AGE OF (B)(6), SHE HAD TO HAVE HER WOMAN PARTS REMOVED AND SHE HAD TO STAY IN THE HOSPITAL FOR 3 DAYS AFTERWARDS. AT TIME OF THE REPORT, SHE WAS 13 WEEKS POST-OP AND WAS FELLING MUCH BETTER. FOR THE MOST PART, MOST OF THE SIDE EFFECTS HAVE GONE AWAY. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DEBILITATING PELVIC PAIN SHARP/STABBING PELVIC PAINS AND LOWER BACK PAIN. SHE UNDERWENT A HYSTERECTOMY, HAD HER CERVIX, UTERUS AND FALLOPIAN TUBES REMOVED. THESE EVENTS WERE CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STARTED EXPERIENCING THESE EVENTS OVER THE NEXT YEAR AND HALF OF ESSURE INSERTION. CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP AND BASED ON THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01567	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305HE
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-1577) IN UNITED STATES ON 21-OCT-2015 AND IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON UNSPECIFIED DATE. ADDITIONAL INFORMATION RECEIVED ON 10-NOV-2015 (PTC INVESTIGATION RESULT). CONSUMER WANTS TO START HER COMPLAINT OFF THAT SHE NEVER CONSENTED TO HAVE ESSURE. SHE IS ALLERGIC TO NICKEL. SHE CONSENTED FOR A TUBAL LIGATION SHE DID NOT EVEN REALIZE. SHE HAD ESSURE UNTIL YEARS LATER PROBLEM AFTER PROBLEM, HER DOCTOR TOLD HER TO CONSULT WITH HER GYNECOLOGIST THAT IT SEEMED LIKE SOME OF HER ISSUES COULD BE GYNECOLOGICAL RELATED. HER PROBLEMS CONSISTED: HYPOTHYROID, GALLSTONES, HAIR LOSS, NUMBNESS IN EXTREMITIES HAND AND FOOT, BURNING NERVE PAIN ALL OVER, VOMITING, LONG PAINFUL AND HEAVY MENSTRUAL CYCLES, UTIS (URINARY TRACT INFECTION), OVARIAN CYSTS, MIGRAINES, MUSCLE SPASMS, DENTAL ISSUES, CHRONIC PELVIC PAIN, CHRONIC FATIGUE, MEMORY LOSS, BLOOD CLOTS, NIGHT SWEATS, CHEST PAIN, CONSTIPATION, SEVERE BLOATING, DIZZINESS, ABDOMINAL SPASMS, BACK PAIN, JOINT PAIN, PAINFUL OVULATION, BLACKOUTS IN VISION, DROPPING STUFF, LOSING STUFF, SHAKING IN HANDS AND FEET, WEAKNESS IN MUSCLES, EYE TWITCHING, STABBING PAIN ON THE BACK OF HER HEAD, ANXIETY, OFF BALANCE AND SEVERE NAUSEA. IN (B)(6) 2012, SHE WENT TO SEE HER GYNECOLOGIST. AT THAT APPOINTMENT IS WHEN SHE FOUND OUT THAT SHE HAD IN FACT NOT HAD A TUBAL LIGATION BUT ESSURE WAS PLACED. SHE ONLY OFFERED HER AT THE TIME SOME LAB WOK TO BE DONE AND HYSTEROSALPINGOGRAM (HSG) TEST THAT HAD NOT BEEN DONE YET. NOTHING WAS REVEALED ON THE BLOOD WOK

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BUT THE PAIN ONLY INCREASED. SHE ENDED UP IN THE EMERGENCY ROOM A COUPLE OF WEEKS LATER. TO HER AMAZEMENT NO ONE IN THE EMERGENCY ROOM EVEN KNEW WHAT ESSURE WAS AND SO ALL THE TEST AND ALL THE BLOOD WORK COME BACK, AND OF COURSE, NORMAL. THERE WAS NO EVIDENCE OF WHAT COULD BE CAUSING ALL THE PAIN AND ISSUES. AFTER ANOTHER YEAR, SHE WENT BY SYMPTOMS COMING AND GOING BUT GETTING WORSE EACH TIME THEY STARTED. SHE ENDED UP BACK IN THE EMERGENCY ROOM IN (B)(6) 2013 WITH SEVERE RIGHT SIDED ABDOMINAL PAIN. IT WAS CONFIRMED ON COMPUTERISED TOMOGRAM (CT SCAN) THAT HER GALLBLADDER WAS FULL OF STONES AND THAT SHE ALSO SHOULD CONTACT HER GYNECOLOGIST DOCTOR FOR THE EXTREME PELVIC PAIN. THE NEXT DAY SHE WENT TO SEE HER DOCTOR TO DISCUSS REMOVING THE ESSURE BECAUSE OF THE PAIN. HER GYNECOLOGIST SENT HER FOR A FOLLOW UP ULTRASOUND AND WANTED HER TO GET HSG TO CONFIRM WHERE THE ESSURE COILS WHERE LOCATED. THAT SAME DAY SHE WENT TO HAVE THE ULTRASOUND DONE WHICH STATED: THERE APPEARS TO BE DEVICE IN THE UTERINE CORNU FURTHER IMAGING WITH CT OR NUCLEAR MAGNETIC RESONANCE IMAGING (MRI) SUGGESTED. SHE ENDED UP IN THE EMERGENCY ROOM AGAIN THAT NIGHT DUE TO SEVERE PAIN IN THE RIGHT SIDE OF THE ABDOMEN AND WAS ADMITTED TO REMOVE HER GALLBLADDER DUE TO THE LARGE AMOUNT OF STONES, BUT TOLD TO FOLLOW UP WITH GYNECOLOGIST BECAUSE CT SCAN SHOWED AN ESSURE INSIDE OF HER UTERUS. IN JUNE SHE HAD HER HSG TEST. HER GYNECOLOGIST TOLD HER THAT DAY THAT THE ESSURE WAS STILL IN HER TUBES AND THEY WERE COMPLETELY BLOCKED THAT IT COULD NOT BE THE ORIGIN OF ANY PAIN. IN JULY SHE WENT BACK TO PHYSICIAN WITH THE SAME LIST OF PROBLEMS LISTED ABOVE AND TRIED TO TELL HER SHE WAS HAVING A REACTION TO THE COILS MOST LIKELY DUE TO THE FACT THAT SHE ALSO HAVE A NICKEL ALLERGY. SHE TOLD HER THAT THERE WAS NO WAY TO GET ESSURE OUT. A WEEK LATER SHE WAS BACK IN THE EMERGENCY ROOM WITH SEVERE PAIN IN HER NECK AND BACK. AGAIN IN (B)(6) 2013, SHE WAS IN THE EMERGENCY ROOM WITH SEVERE PAIN IN ABDOMEN AND SEVERE BLEEDING WAS GIVEN MEDICATION AND TOLD TO FOLLOW UP WITH GYNECOLOGIST SHE FOLLOWED UP WITH PHYSICIAN 2 DAYS LATER WHEN THE GYNECOLOGIST DOCTOR TOLD HER THAT SHE COULD NOT HELP HER. IN OCTOBER SHE AGAIN ENDED UP IN A DIFFERENT EMERGENCY ROOM WHERE ANOTHER ULTRASOUND WAS PERFORMED AND RESULTS READ: HYPERECHOIC REGION IS NOTED WITHIN THE RIGHT ASPECT OF THE UTERUS WHICH MAY REPRESENT AN ESSURE COIL GIVEN IN PATIENT HISTORY. THE EMERGENCY ROOM DOCTOR CONSULTED WITH A NEW GYNECOLOGIST DOCTOR WHO SEEN HER A FEW DAYS LATER AND AGREED AFTER COMPLETING AN IN OFFICE ULTRASOUND THAT THERE WAS A COIL IN HER UTERUS AND SET UP TO HAVE THE ESSURE REMOVED VAGINALLY AND LAPAROSCOPICALLY. IN (B)(6) 2013, SHE HAD HER FIRST REMOVAL OF THE ESSURE. THE RIGHT COIL WAS REMOVED VAGINALLY. SHE SAW THE ESSURE WHICH WAS PROTRUDING ALMOST INTO LOWER UTERINE SEGMENT AND THE LEFT COIL WAS REMOVED LAPAROSCOPICALLY. THE LEFT TUBE HAD PART OF THE SHARP POKING THROUGH IT. SHE TRIED TO REMOVE THE ESSURE WITHOUT REMOVING THE TUBE BUT THE TUBE STARTED BLEEDING. THE TUBE WAS REMOVED USING THE LIGASURE DEVICE. IN (B)(6) 2014, SHE WAS ADMITTED INTO CLINIC WITH SEVERE HEPATITIS, PANCREATITIS, CARDIOGENIC EDEMA AND AN UNKNOWN FRAGMENTED DEVICE IN THE RIGHT UPPER UTERUS EXTENDING FROM THE ENDOMETRIAL CAVITY THROUGH THE INTRAMURAL UTERUS TO JUST OUTSIDE THE UTERINE WALL, CONFIRMED BY CT SCAN AND ULTRASOUND. IN (B)(6), SHE HAD A SECOND SURGERY TO REMOVE A THIRD COIL. IN (B)(6), SHE WAS ADMITTED TO THE HOSPITAL WITH STOMACH ULCERS. IN (B)(6) AGAIN WENT TO THE EMERGENCY ROOM FOR ABDOMINAL PAIN AND A CT SCAN REVEALED THAT THERE WAS LINEAR METALLIC DENSITY IN THE RIGHT UTERINE FUNDUS, IT MAY HAVE PERFORATED THE UTERINE WALL. IN (B)(6), SHE HAD HER THIRD SURGERY TO REMOVE ESSURE FRAGMENTS. EVEN THOUGH IT HAS BEEN REMOVED, SHE STILL HAS ISSUES GOING ON AS SHE IS CURRENTLY BEING TESTED FOR MULTIPLE SCLEROSIS AND OTHER AUTOIMMUNE DISORDERS. SHE HAS NO RELIEF FROM THE ISSUES AND ARE BECOMING WORSE WITH EVERY EPISODE, OVULATION AND PERIOD. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE BLEEDING (GENITAL BLEEDING), BLOOD CLOTS (UTERINE HEMORRHAGE), CHRONIC PELVIC PAIN, PAIN ONLY INCREASED. A CT SCAN SHOWED ESSURE INSIDE HER UTERUS, ESSURE WHICH WAS PROTRUDING ALMOST INTO LOWER UTERINE SEGMENT (SEEN AS PARTIAL EXPULSION OF DEVICE). SHE HAD HER FIRST REMOVAL OF THE ESSURE. THE RIGHT COIL WAS REMOVED VAGINALLY LEFT TUBE HAD PART OF THE SHARP POKING THROUGH IT. SHE TRIED TO REMOVE THE ESSURE WITHOUT REMOVING THE TUBE BUT THE TUBE STARTED BLEEDING (POST PROCEDURAL BLEEDING) AND THE TUBE WAS REMOVED USING THE LIGASURE DEVICE. AFTER THAT, THE SECOND SURGERY TO REMOVE A THIRD COIL WAS PERFORMED, BUT IT WAS REPORTED THAT FRAGMENTED DEVICE IN RIGHT UPPER UTERUS EXTENDING FROM ENDOMETRIAL CAVITY THROUGH INTRAMURAL UTERUS TO JUST OUTSIDE THE UTERINE WALL, MAY HAVE PERFORATED (SEEN AS DEVICE BREAKAGE AND UTERINE PERFORATION). ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION. ACCORDING TO PRODUCT TECHNICAL ANALYSIS, MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT. IN THIS CASE, THE EXACT DATE AND MECHANISM OF UTERINE PERFORATION, PARTIAL EXPULSION OF DEVICE WERE NOT KNOWN. CONSIDERING THE NATURE FOR ALL EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTIONS WERE PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND SEVERAL NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING. (B)(4)

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01568	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-1787, AWARENESS DATE 21-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER HAD ESSURE IMPLANTED AFTER THE BIRTH OF HER SON. UPON INSERTION OF THE FIRST COIL HER FALLOPIAN TUBE BEGAN TO SPASM. THE PHYSICIAN INFORMED THIS WAS NORMAL AND CONTINUED TO FORCE THE COIL INTO THE TUBE. THE PAIN WAS IMMEDIATE. THE IMPLANT OF ESSURE WAS SO PAINFUL SHE WAS SCREAMING. SHE WAS INSTRUCTED TO TAKE XANAX AND VICODIN PER PRESCRIPTION BY THE PHYSICIAN. THE NEXT DAY SHE WAS STILL IN PAIN AND HAD VAGINAL HEAVY BLEEDING, NOT ON HER MONTHLY CYCLE AT THE TIME. THE PHYSICIAN STATED THAT ESSURE WAS PERFECTLY PLACED. JUST IN THE TWO WEEKS CONSUMER HAD GAINED 15 POUNDS. HE SCHEDULED A LAPAROSCOPIC SURGERY TO SEE IF THEY WERE INTACT. SHE WAS STILL IN AWFUL PAIN, AND DOCTOR COULDN'T HELP AS THERE WAS NO WAY NOW FOR REMOVAL. HER SECOND OPINION PHYSICIAN LOOKED AT THE RESULTS AND INFO ABOUT ESSURE AND DETERMINED THAT THE COILS HAD TO BE REMOVED. HE WASN'T SURE HOW MUCH HE WOULD BE ABLE TO SAVE BECAUSE OF COIL MIGRATION THROUGH THE UTERUS. CONSUMER STATED THAT THE DEVICES HAVE LEFT HER WITH A HYSTERECTOMY AT (B)(6). AT THE TIME OF THE REPORT, SHE HAD SEVERE SKIN SENSITIVITY, SUN SENSITIVITY, WEIGHT GAIN, HORMONAL IMBALANCES, HYPOTHYROIDISM, CHRONIC PAIN TO THE POINT OF NEEDING PAIN SPECIALIST, HYPERTENSION, DEPRESSION, AND ANXIETY. THE ESSURE LEFT HER TIRED AND WEAK. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD

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A COIL MIGRATION THROUGH THE UTERUS. SHE UNDERWENT A HYSTERECTOMY. THIS EVENT, INTERPRETED AS UTERINE PERFORATION, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE. IN THE PRESENT CASE THE EXACT DATE OF THE PERFORATION IS UNKNOWN. CONSUMER STATED THAT HER DOCTOR DETERMINED THAT THE COILS HAD TO BE REMOVED, AND THAT THE COIL MIGRATED THROUGH THE UTERUS. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01569	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-1824, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2005. AFTER ESSURE WAS PLACED UNDER ANAESTHESIA, CONSUMER STARTED HAVING PAIN IN LOWER ABDOMEN. SEX WAS IMPOSSIBLE AS THE PAIN WAS JUST TOO MUCH. HER PERIODS BECAME HEAVY AND PAINFUL AS WELL. HER STOMACH BECAME BLOATED TO THE POINT WHERE SHE LOOKED PREGNANT. SHE WAS ALSO DIAGNOSED WITH HASHIMOTOS DISEASE, BREAST CANCER, FIBROMYALGIA, CHRONIC MIGRAINES AND CHRONIC PAIN THROUGHOUT HER BODY. CONSUMER WENT TO HER GYNECOLOGIST IN 2013 AND HE SUGGESTED A HYSTERECTOMY LEAVING ONLY HER OVARIES. SINCE HAVING THE HYSTERECTOMY, HER ABDOMEN PAIN HAS SUBSIDED AND SHE NO LONGER FEELS THE EXTREME PAIN, BUT SHE STILL IS LEFT WITH ISSUES THAT NEVER EXISTED BEFORE ESSURE. SHE HAS NOW PAIN FROM THE HYSTERECTOMY. SHE IS ALLERGIC TO SUTURES AND HAD TO HAVE THEM PLACED. HER BODY IS STILL REJECTING FOREIGN OBJECTS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD.

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WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN IN LOWER ABDOMEN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (8 YEARS AFTER DEVICE PLACEMENT) AND HER PAIN SUBSIDED. ADDITIONALLY, SHE WAS DIAGNOSED WITH HASHIMOTOS DISEASE AND BREAST CANCER. ONLY ABDOMINAL PAIN IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER HAD FIBROMYALGIA, WHICH COULD BE AN ALTERNATIVE EXPLANATION FOR HER PAIN. HOWEVER, AS THIS EVENT STARTED AFTER ESSURE INSERTION AND RESOLVED WITH DEVICES REMOVAL; A CONTRIBUTORY ROLE OF THE SUSPECT INSERT CANNOT BE TOTALLY RULED OUT. REGARDING THE REMAINING EVENTS; GIVEN THEIR NATURE AND CONSIDERING ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY IS CONSIDERED VERY UNLIKELY. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01570	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 3/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1853, AWARENESS DATE 21-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. AT TIME OF THE REPORT SHE WAS (B)(6). THE CONSUMER REPORTED SHE WAS HEALTHY UNTIL AFTER SHE WAS IMPLANTED WITH THE ESSURE DEVICE; HER DOCTOR ADVISED THAT SHE NEEDED TO CONSIDER ALTERNATE FORMS OF BIRTH CONTROL BECAUSE SHE HAD BEEN ON THE PILL FOR TOO LONG AND SHE COULD NOT GO THROUGH ANOTHER PREGNANCY AS BOTH OF HER PRIOR PREGNANCIES WERE HIGH RISK. FOR THE PROCEDURE SHE WAS GIVEN VALIUM OR A COCKTAIL AND IT TOOK MORE THAN 45 MINUTES TO PLACE IT, SHE CRIED OUT SEVERAL TIMES BECAUSE IT HURT SO MUCH. ONLY A MONTH LATER SHE WAS IN THE ER IN SEVERE PAIN; SHE HAD AN MRI AND ALL THEY COULD TELL WAS THAT SHE HAD SOME SORT OF A MASS. SHE SPENT AROUND 2 WEEKS IN THE HOSPITAL GETTING TEST AFTER TEST TO SEE WHAT WAS GOING ON INSIDE HER BODY; SHE WAS ON MORPHINE DRIP AS THE PAIN WAS SO SEVERE. THEY DECIDED TO DO SURGERY SO THEY COULD REMOVE THE MASS. WHEN SHE CAME OUT OF SURGERY SHE WAS STILL IN PAIN AND THE DOCTORS TOLD HER THAT THEY REMOVED HER TUBES AND OVARIES AND PLACED A STENT IN HER KIDNEY. THEY SAID THEY WERE NOT CERTAIN IF THE MASS ON HER OVARY WAS CANCER IN NATURE AND THAT THEY HAD TO SEND IT FOR FURTHER TESTING. THE MASS WAS THE SIZE OF A GRAPEFRUIT AND THEY COULD NOT REMOVE IT THROUGH THE SMALLER INCISIONS SO THEY HAD TO DO A LARGE CUT TO REMOVE IT. IT HAD KILLED HER OVARY AND DAMAGED HER KIDNEY AND THAT WAS WHAT WAS CAUSING THE PAIN. SHE WAITED FOR 2 WEEKS TO RECEIVE THE NEWS THAT IT WAS AN OVARIAN CYST. SHE HAD NEVER HAD ANYTHING LIKE THIS HAPPEN TO HER

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BEFORE AND SHE WAS RELIEVED THAT IT WAS NOT CANCER. SHE ALSO EXPERIENCED ONGOING HEALTH ISSUES AND WAS CONSTANTLY SICK. SHE EXPERIENCED VARIOUS SIDE EFFECTS SUCH AS PAIN, HEAVY BLEEDING, INCONTINENCE, SKIN RASHES, DEPRESSION, EXHAUSTION, MEMORY LOSS, HEADACHES AND WEIGHT GAIN JUST TO NAME A FEW. SHE WAS ALSO DIAGNOSED WITH HYPOTHYROIDISM A FEW YEARS AFTER ESSURE. ALL OF THE ISSUES SHE WAS EXPERIENCING CAUSED STRAIN IN HER MARRIAGE AND ROBBED HER CHILDREN OF HAVING A GOOD MOTHER BECAUSE SHE WAS ALWAYS TIRED. THE CONSUMER REPORTED SHE WAS SCHEDULED FOR A HYSTERECTOMY ON (B)(6) 2015 TO REMOVE THE DEVICES. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFECT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED; SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD PAIN AND HEAVY BLEEDING (REGARDED AS GENITAL BLEEDING) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, SHE WAS SCHEDULED FOR A HYSTERECTOMY. ADDITIONALLY, SHE WAS SUBMITTED TO A SURGERY (1.5 MONTHS AFTER ESSURE PLACEMENT) DUE TO A MASS IN HER OVARY, WHICH WAS LATER CONFIRMED TO BE AN OVARIAN CYST. ONLY OVARIAN CYST IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER RELATED HER PAIN AND BLEEDING TO ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING OVARIAN CYSTS; THEY CAN HAPPEN IN FEMALES AT ANY STAGE OF LIFE. MOST OF THEM, HOWEVER, OCCUR THE HORMONALLY ACTIVE PERIODS OF DEVELOPMENT. ESSURE HAS MECHANICAL, LOCAL ACTION IN FALLOPIAN TUBES; NO HORMONES ARE RELEASED FROM THE INSERT. CONSIDERING THIS INFORMATION AND GIVEN OVARIAN CYSTS PATHOPHYSIOLOGY, CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED VERY UNLIKELY. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01571	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1840, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 AFTER THE BIRTH OF HER SEVENTH CHILD. ADDITIONAL INFORMATION RECEIVED ON 12-NOV-2015 (PTC INVESTIGATION RESULT). CONSUMER REPORTED THAT SHORTLY AFTER HAVING THE PROCEDURE SHE STARTED GAINING WEIGHT, HAVING MIGRAINES, BODY ACHES, STOMACH PROBLEMS AND BLOATING TO THE POINT OF LOOKING 7 MONTHS PREGNANT. IN (B)(6) 2015, SHE HAD ESSURE REMOVED VIA VAGINAL HYSTERECTOMY LEAVING ONLY HER OVARIES. AFTER THIS PROCEDURE HER WHOLE BODY SWELLS AND SHE HAVE BECOME DEPRESSED. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL

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ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BACK ACHE. SHE HAD ESSURE REMOVED VIA VAGINAL HYSTERECTOMY LEAVING ONLY HER OVARIES. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT SHORTLY AFTER HAVING THE ESSURE INSERTED. CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP AND BASED ON THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01572	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2014
Explant Date (E7): 10/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1942, AWARENESS DATE 21-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. CONSUMER REPORTED ESSURE LEFT HER IN PAIN FOR THE WHOLE YEAR SHE HAD IT. SHE WAS (B)(6) AT THE TIME OF THE REPORT, AND UNDERWENT A HYSTERECTOMY TO ESCAPE THE PAIN. SINCE SURGERY, IN (B)(6) 2015, SHE HAS NOT HAD ONE BIT OF PAIN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS:(B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A

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FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE LEFT HER IN PAIN FOR THE WHOLE YEAR SHE HAD IT. SHE UNDERWENT A HYSTERECTOMY ONE YEAR AFTER INSERTION, AND THE PAIN RESOLVED. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE LACK OF AN ALTERNATIVE EXPLANATION, AND SINCE THE PAIN RESOLVED AFTER HYSTERECTOMY, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01573	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 9/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1959, AWARENESS DATE 21-OCT-2015). IT REFERS TO AN ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. THE CONSUMER REPORTED SHE WAS IMPLANTED AND IT TOOK OVER AN HOUR AND HER DOCTOR LATER COMPLAINED THROUGH A CHUCKLE WHEN SHE WENT BACK TO TELL HER SHE WAS FEELING ODD, THAT HER PROCEDURE WAS NOT AN EASY ONE. SHE PLACED HER ON HORMONE PILLS AND BIRTH CONTROL AND SENT HER ON HER WAY. DURING THE COURSE OF THOSE 6 YEARS SHE SUFFERED NAUSEA, MAJOR CRAMPING, FAINTING, HAIR LOSS, SEVERE DIARRHEA, EARS RINGING AND A CONSTANT TASTE OF METAL IN HER MOUTH. IN (B)(6) 2013, SHE HAD SALPINGECTOMY (INCLUDED THE LOSS OF RIGHT OVARY ALONG WITH THE TUBES AND COILS) DONE. SHE STATED THAT POST REMOVAL SHE WAS DOING GREAT. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 13-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL

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EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD MAJOR CRAMPING. SHE UNDERWENT A SALPINGECTOMY AND ESSURE REMOVAL, APPROXIMATELY 6 YEARS AFTER INSERTION. THIS EVENT, INTERPRETED AS LOWER ABDOMINAL PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED OR IDENTIFIED. A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01574	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1962, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. ADDITIONAL INFORMATION RECEIVED ON 12-NOV-2015 (PTC INVESTIGATION RESULT). CONSUMER HAD THE ESSURE PLACED IN 2009 BECAUSE THE DOCTOR TOLD HER SHE WAS TOO FAT FOR TIE THE TUBES. ABOUT 6 MONTHS LATER, SHE STARTED LOSING HAIR. HAD PAINS EVERYDAY THAT FELT LIKE SHE WAS IN LABOR. PERIODS BECAME SO HEAVY AND PAINFUL. INTERCOURSE BECOME HATED CAUSE THE PAIN AND BLOOD. SHE STARTED GAINING MORE WEIGHT. SHE WENT FROM (B)(6). LOST INTEREST IN ALL ACTIVITIES, WAS DEPRESSED AND HATED LIFE. SHE HAD ER (EMERGENCY ROOM) VISITS ALL THE TIME. THEY TOLD HER SHE HAD OVARIAN CYSTS. SHE HAD A HYSTO (HYSTERECTOMY) ON (B)(6) 2015. OVARIES ARE FINE. SHE IS NOT DEPRESSED AND LOSING WEIGHT. THE ONLY PAIN SHE HAS NOW IS THE GAS. THEY TOOK UTERUS AND TUBES. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE

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MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PAINS EVERYDAY. A HYSTERECTOMY WAS PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR THIS EVENT. BASED ON ITS NATURE AND CONSIDERING THAT A POSITIVE TEMPORAL RELATIONSHIP IS IMPLIED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01575	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/22/2014
Explant Date (E7): 8/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055850) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. ADDITIONAL INFORMATION RECEIVED ON 10-NOV-2015 (NO NEW CLINICAL INFORMATION) AND ON 12-NOV-2015 (PRODUCT TECHNICAL COMPLAINT RESULT). CONCOMITANT MEDICATION INCLUDED TOPAMAX 150 MILLIGRAMS. WITHIN IN THE PAST YEAR SHE EXPERIENCED EXTREME LOWER ABDOMINAL PAIN, MAJOR BLOATING, AN INCREASE IN MIGRAINES, TROUBLE PASSING BOWELS. AFTER SPEAKING WITH HER PHYSICIAN, IT WAS DETERMINED THAT THE BEST OPTION WAS TO REMOVE THE DEVICES WHICH MEANT TO REMOVE HER ENTIRE FALLOPIAN TUBES AS WELL AS SCREEN THE UTERUS FOR ANY PIECES THAT MAY HAVE COME OUT OF CONTACT. DURING THE SURGERY THEY FOUND THAT SHE HAD DEVELOPED ENDOMETRIOSIS. ESSURE REMOVAL DATE: (B)(6) 2015. CONSUMER ASSESSED AS EVENT OUTCOME HOSPITALIZATION, REQUIRED INTERVENTION AND OTHER SERIOUS (IMPORTANT MEDICAL EVENT). PTC GLOBAL NUMBER: (B)(4). PTC RESULT: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY

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DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME LOWER ABDOMINAL PAIN. CONSUMER HAD ESSURE REMOVED AS WELL AS HER ENTIRE FALLOPIAN TUBES. THIS EVENT WAS CONSIDERED SERIOUS (THE TERM HOSPITALIZATION AND IMPORTANT MEDICAL EVENT WAS ONLY MENTIONED AS EVENT OUTCOME AND THE REPORTER DID NOT SPECIFY IT) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THE NATURE OF THE EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

ESSURE CONSUMER GENERAL QUESTIONNAIRE RECEIVED ON 09-DEC-2015: PATIENT WAS (B)(6). SHE HAD NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. NO RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. ESSURE WAS INSERTED 3 MONTHS POSTPARTUM. SHE USED CONDOMS AS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01576	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 2/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1946, AWARENESS DATE 21-OCT-2015) WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. THE CONSUMER REPORTED SHE HAD 1 ESSURE COIL INSERTED SINCE SHE HAD AN ECTOPIC PREGNANCY IN 2005. HER PHYSICIAN NEVER PERFORMED THE HSG (HYSTEROSALPINGOGRAM) ULTRASOUND TO GUARANTEE PROPER PLACEMENT OR STERILIZATION. AFTER 3 YEARS OF PAIN, BLEEDING FOR WEEKS AT A TIME, AN URETHRA PROLAPSE AND HAVING SURGERY TO GET SLING AND OTHER SIDE EFFECTS (ALL OVER PAIN, WEIGHT GAIN, TIREDNESS, ACHING, LOSS OF SEX DRIVE, ETC.) IN (B)(6) 2015, SHE WENT IN FOR A TOTAL HYSTERECTOMY. THE PATHOLOGY DEPARTMENT FOUND THAT THE ESSURE COIL MIGRATED INTO HER UTERUS AND COMPLETELY UNRAVELED AND FELL APART; PIECES OF METAL THROUGHOUT HER UTERUS CAUSING ENDOMETRIOSIS AND ADENOMYSIS WITH ADHESIONS THROUGHOUT UTERUS AND ABDOMEN. SHE STATED THERE WAS NOTHING SALVAGEABLE AND AT THE AGE OF (B)(6), SHE HAD TO HAVE A TOTAL HYSTERECTOMY BECAUSE ESSURE COIL DESTROYED HER FEMALE REPRODUCTIVE SYSTEM FROM THE INSIDE OUT. FOLLOW UP RECEIVED ON 12-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 AND 4 YEARS AFTER INSERTION SHE HAD A HYSTERECTOMY IN WHICH ESSURE COIL MIGRATION AND PIECES OF METAL WHERE FOUND IN HER UTERUS. THESE EVENTS WERE INTERPRETED AS DEVICE BREAKAGE AND EXPULSION AND ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE, ANTICIPATED ACCORDING TO TECHNICAL ANALYSIS AND REFERENCE SAFETY INFORMATION. GIVEN NATURE OF EVENTS AND COMPATIBLE TEMPORAL RELATIONSHIP, CAUSALITY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS PERFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01577	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 4/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1598, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER REPORTED SHE HAD ESSURE PUT IN AFTER HAVING HER LAST DAUGHTER BACK IN (B)(6) 2012 AND WAS TOLD THEY DID NOT TIE TUBES ANYMORE BUT ESSURE WAS THE MOST EFFECTIVE PERMANENT BIRTH CONTROL. FROM THE DAY IT WAS PUT IN HER SHE COMPLAINED OF SO MUCH PAIN, THE DOCTORS KEPT SAYING IT WAS HER BODY GETTING USE TO THE DEVICES, FOR MONTHS SHE CRIED AND CRIED BECAME VERY DEPRESSED AND IN SO MUCH PAIN. FINALLY HAD TO GO TO A DIFFERENT COUNTY AND LONG STORY SHORT ONE OF THE DEVICES WAS IN HER UTERUS AND SHE WAS HAVING ALLERGIC REACTION TO THE NICKEL THAT WAS IN THE DEVICES, HAD SHE BEEN TOLD THAT SHE WOULD HAVE NEVER GOTTEN THIS PROCEDURE. SHE HAD TO GO UNDER TWO SURGERIES WITH ENDING AT AGE OF (B)(6) HAD TO HAVE A FULL HYSTERECTOMY TO GET BACK TO HER NORMAL LIFE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FROM THE DAY IT WAS PUT IN HER, SHE COMPLAINED OF SO MUCH PAIN. SHE HAD TO HAVE A FULL HYSTERECTOMY. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SINCE THE INSERTION, SHE WAS IN PAIN AND ALSO EXPERIENCED OTHER NON-SERIOUS EVENTS. CONSIDERING CLOSE TEMPORAL RELATIONSHIP AND ITS NATURE, CAUSALITY BETWEEN REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED. SINCE INTERVENTIONS WERE REQUIRED (HYSTERECTOMY/ 2 SURGERIES) THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01578	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2012
Explant Date (E7): 9/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2038, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012 IN THE OPERATION ROOM. AFTER INSERTION, AROUND THE 3RD DAY, SHE WAS STILL BLEEDING HEAVILY AND IN SEVERE PELVIC PAIN AND STABBING LIKE PAINS ON RIGHT SIDE. SHE CALLED THE DOCTOR AND TOLD HIM WHAT WAS GOING ON. HE BRUSHED HER OFF AND SAID IT WAS DUE TO DEPO. THE PAIN JUST GOT WORSE AND BLEEDING NEVER STOPPED. SHE CALLED AND WENT TO SEE THE DOCTOR MANY TIMES WITHIN 3 MONTHS TO NO HELP. IN (B)(6) 2012, HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED THAT THE RIGHT COIL HAD MIGRATED AND PUNCTURED HER RIGHT FALLOPIAN TUBE; THE LEFT APPEARED TO BE CORRECTLY PLACED WITH EXCEPTION OF LENGTH. ALMOST 2 MONTHS LATER, STILL IN PAIN AND TOLD TO TAKE TYLENOL AND THAT THE HEAVY BLEEDING WITH HUGE CLOTS WAS DUE TO DEPO SHOT (WHICH WAS NO LONGER IN HER SYSTEM) SHE WAS IN OUTPATIENT SURGERY TO HAVE TUBE AND COIL REMOVED. SHE ASKED TO HAVE BOTH SIDES TAKEN OUT DUE TO BEING SCARED IT MIGHT HAPPEN AGAIN. HE REFUSED AND NEVER HAD POST OP VISIT. SHE EXPERIENCED CONSTANT BLEEDING AND CONTRACTION LIKE PAINS IN HER LADY PARTS. SHE WAS SENT TO A REFERRED DOCTOR OF ESSURE AND DOCTOR FOUND CYSTS ON LEFT OVARY VERY LARGE IN SIZES. SHE HAD NEVER HAD THOSE BEFORE ESSURE. THREE YEARS LATER AND MANY DOCTORS AND BILLS AND PAIN AND SUFFERING SHE WAS FINALLY ABLE TO GET ESSURE OUT. ON (B)(6) 2015 SHE UNDERWENT TOTAL HYSTERECTOMY. IMMEDIATELY THE NASTY METAL TASTE WAS GONE, STABBING PAIN WAS GONE, MIGRAINES WERE GONE AND SHE COULD REMEMBER

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THINGS AGAIN. SHE COULD SIT OR LAY WITHOUT BEING POKED AND SHOOTING PAINS. EVERY TEST DONE CAME BACK NORMAL. THERE WAS NO CLINICAL REASON OR ANSWER FOR HER PAIN AND BLEEDING, METAL TASTE, CONSTANT YEAST, UTI (INTERPRETED AS URINARY TRACT INFECTION) AND SO MUCH MORE. THEN ONCE THESE COILS CAME OUT, SHE FELT SO MUCH BETTER WITHIN HOURS. SHE WAS NEVER ASKED ABOUT NICKEL ALLERGIES, WHICH SHE WAS ALLERGIC TO. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEVERE PELVIC PAIN, STABBING LIKE PAINS ON RIGHT SIDE (INTERPRETED AS PELVIC PAIN), AND WAS BLEEDING HEAVILY, BLEEDING WITH HUGE CLOTS, CONSTANT BLEEDING (INTERPRETED AS GENITAL BLEEDING). HYSTEROSALPINGOGRAM (HSG) SHOWED THAT RIGHT COIL HAD MIGRATED AND PUNCTURED RIGHT FALLOPIAN TUBE (INTERPRETED AS FALLOPIAN TUBE PERFORATION). FIVE MONTHS AFTER INSERTION, SHE UNDERWENT SURGERY TO HAVE RIGHT TUBE AND COIL REMOVED, AND 3 YEARS AFTER INSERTION A TOTAL HYSTERECTOMY WAS PERFORMED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. IN THE PRESENT CASE, CONSUMER ALSO HAD LARGE OVARIAN CYSTS WHICH COULD HAVE CONTRIBUTED TO THE PAIN. HOWEVER, GIVEN THE NATURE OF THIS EVENT, AND SINCE THE PAIN RESOLVED AFTER HYSTERECTOMY, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE EVENT GENITAL BLEEDING, AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE. IN THE PRESENT CASE, THE EXACT DATE OF THE PERFORATION WAS NOT REPORTED; IT WAS DIAGNOSED ON THE HSG. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED OR IDENTIFIED; A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01579	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B02270

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER B02270 INSERTED. ADDITIONAL INFORMATION RECEIVED ON 12-NOV-2015 (PTC INVESTIGATION RESULT). SINCE THEN, SHE EXPERIENCED CHRONIC PELVIC PAIN, VAGINAL BLEEDING, AND A NONSTOP BLEEDING FOR FIVE MONTHS. AN ABLATION PROCEDURE (NOVASURE) WAS PERFORMED IN 2015 TO STOP THE BLEEDING. IT DID NOT WORK. SHE WAS GIVEN MEDROXYPROGESTERONE IN 2015 TO STOP THE BLEEDING. IT DID NOT HELP. SHE WAS GIVEN BIRTH CONTROL PILLS ((B)(4)), IT HELPED SOME WITH THE BLEEDING. SHE WAS STILL EXPERIENCING ABNORMAL BLEEDING AND PELVIC PAIN. SINCE ALL OF THIS, SHE BECAME DEPRESSED AND WAS GIVEN AMITRIPTYLINE AND REFERRED TO TALK THERAPY. CONSUMER ASSESSED OTHER SERIOUS (IMPORTANT MEDICAL EVENT) AS EVENT OUTCOME. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE.

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A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. FOLLOW-UP INFORMATION RECEIVED ON 16-NOV-2015 FROM CONSUMER: SHE STATED A LAWYER IS WORKING IN THIS CASE ALREADY. CASE IS NOW CONSIDERED LEGAL CASE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, POTENTIAL LEGAL AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NONSTOP BLEEDING. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STARTED EXPERIENCING THIS EVENT SINCE ESSURE INSERTION FOR FIVE MONTHS. SHE UNDERWENT AN ABLATION PROCEDURE (NOVASURE) IN ORDER TO STOP THE BLEEDING, HOWEVER, IT DID NOT WORK. SHE RECEIVED A REMEDIAL THERAPY BUT IT DID NOT WORK. THEN, SHE WAS GIVEN BIRTH CONTROL PILLS AND IT HELPED SOME WITH THE BLEEDING. CONSIDERING THIS INFORMATION AND BASED ON ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. ADDITIONAL INFORMATION WILL BE OBTAINED THROUGH THE NORMAL LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01581	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER WAS TOLD PROCEDURE WAS SUCCESSFUL AND BOTH TUBES WERE BLOCKED. SHE BECAME PREGNANT THE FOLLOWING YEAR (PLEASE REFER TO CASE NUMBER (B)(4)) AND GAVE BIRTH TO A BEAUTIFUL HEALTH GIRL. SINCE HAVING THE PROCEDURE CONSUMER HAD OVARIAN CYST TIME AFTER TIME. THEN, IN 2014, SHE WENT TO EMERGENCY ROOM THINKING SHE WAS HAVING MORE AND SHE WAS TOLD SHE WAS PREGNANT. THEY COULD NOT SEE A HEARTBEAT AND SAID BABY WAS (WORD NOT LEGIBLE). SHE WENT BACK ONE MORE TIME AS THE PAIN WAS GROWING. THEN WENT TO HER GYNECOLOGIST AT WHICH POINT SHE WAS TOLD SHE WAS PREGNANT IN TUBES AND NEEDED A SURGERY WHERE BOTH HER TUBES AND DEAD BABY WERE TAKEN OUT. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF

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SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT. THE PHYSICIANS COULD NOT SEE A HEARTBEAT/ DEAD BABY WAS TAKEN OUT OF HER. SHE WAS TOLD SHE WAS PREGNANT IN TUBES (SEEN AS ECTOPIC PREGNANCY) AND NEEDED A SURGERY WHERE BOTH HER TUBES AND DEAD BABY WERE TAKEN OUT. THE EVENT ECTOPIC PREGNANCY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE AND IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). WHEN A PREGNANCY OCCURS WITH ESSURE, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE. IN THIS PARTICULAR CASE, CONSIDERING THE NATURE OF THE EVENT ECTOPIC PREGNANCY, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS REQUIRED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENT WAS ADDED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: ATTEMPTS OF FOLLOW-UP WERE MADE WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01582	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055936) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED ON 12-NOV-2015 AND 13-NOV-2015. CONCOMITANT MEDICATION INCLUDED MULTI-VITAMIN, VITAMIN, LAMOTRIGINE, XANAX AND OXYCODONE. AFTER GETTING THE ESSURE DEVICE, CONSUMER EXPERIENCED SEVERE PELVIC AND VAGINAL PAIN. THIS STARTED 5 YEARS AND WAS STILL AN ONGOING PROBLEM. MAKING LOVE WITH HER HUSBAND WAS EXTREMELY PAINFUL UNTIL IT BECAME UNBEARABLE WHICH HAD A GREAT AFFECT PSYCHOLOGY. SHE DID PELVIC FLOOR PHYSICAL THERAPY; ULTRASOUND AND NOTHING RELIVED THE PAIN NOT EVEN HAVING SCAR TISSUE REMOVED. NO MEDICAL PROCEDURE BROUGHT ANY RELIEF. SHE WAS CONSIDERING HAVING THEM REMOVED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. ADDITIONAL INFORMATION RECEIVED ON

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13-NOV-2015: DESPITE A FOLLOW-UP ATTEMPT, NO FURTHER INFORMATION WAS OBTAINED (CORRESPONDENCE WAS UNDELIVERABLE). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. IN THIS CASE, CONSUMER REPORTED PELVIC PAIN WITHOUT IMPROVEMENT WITH PHYSICAL THERAPY, ULTRASOUND OR REMOVAL OF UNSPECIFIED SCAR TISSUE; ACCORDING TO HER NO MEDICAL PROCEDURE BROUGHT RELIEF. SHE WAS CONSIDERING DEVICES REMOVAL. CONSIDERING THE EVENT STARTED AFTER ESSURE INSERTION AND SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE MEDICAL INTERVENTION WAS REQUIRED FOR EVENT'S TREATMENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. DESPITE FOLLOW-UP ATTEMPT, NO FURTHER INFORMATION WAS OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01583	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. AFTER INSERTION, CONSUMER EXPERIENCED CONTINUOUSLY PASSED CLOTS. DIFFERENT MEDICATIONS WERE TRIED BUT IT DID NOT WORK, LEADING TO A COMPLETE HYSTERECTOMY IN 2013 DUE TO ESSURE. HER LIFE COMPLETELY CHANGED, HER SEX LIFE WAS NOT THE SAME AND SHE WAS VERY DEPRESSED. SHE ASSESSED HOSPITALIZATION AS EVENT OUTCOME. PTC INVESTIGATION RESULT WAS RECEIVED ON 14-NOV-2015. PTC GLOBAL NUMBER: 2015-044398 FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 AND CONTINUOUSLY PASSED CLOTS (CONSIDERED A VAGINAL HEMORRHAGE). THIS EVENT IS

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SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, AS THE BLEEDING OCCURRED AFTER ESSURE INSERTION, CAUSALITY IS CONSIDERED RELATED. SHE REFERRED HOSPITALIZATION AND HYSTERECTOMY IN 2013 DUE TO ESSURE, SO THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-DEC-2015: NO FURTHER INFORMATION IS EXPECTED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 AND CONTINUOUSLY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01584	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/10/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1793 AND FDA-2014-N-0736-1483, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. ADDITIONAL INFORMATION WAS PROVIDED ON 27-OCT-2015. AFTER GETTING THE ESSURE PUT THE CONSUMER STARTED HAVING PROBLEMS IN (B)(6) 2013 AROUND HER CYCLES. HER SYMPTOMS WERE, RACING HEART RATE, HIGH BLOOD PRESSURE, ANXIETY, ALMOST BLACKING OUT, HEAVY MENSTRUAL CYCLES AND SOMETIMES HAVING CYCLES TWICE A MONTH. NO SEX DRIVE, EXTREMELY TIRED. SHE BELIEVED AFTER SEEING SEVERAL DOCTORS, HAVING SEVERAL TESTS DONE AND FINALLY FINDING OUT SHE HAD HASHIMOTOS THYROIDITIS IN (B)(6) 2014. ALL HER SYMPTOMS STARTED AFTER SHE HAD THE ESSURE COILS PUT IN. SHE HAS NEVER HAD ANY HEALTH PROBLEMS PRIOR TO HAVING THE ESSURE PUT IN. CONSUMER REPORTED IN (B)(6) 2013 SHE WAS HAVING ISSUES TWICE A MONTH RIGHT BEFORE HER CYCLE AND AGAIN RIGHT AFTER. SHE WOULD GET SO SICK HER HEAD FELT LIKE IT WAS GOING TO EXPLODE. ONCE SHE VOMITED, SHE WOULD JUST SLEEP, IT WOULD REALLY WIPE HER OUT. IT WAS SO BAD, SHE WOULD HAVE A HARD TIME GETTING UP OFF THE FLOOR. SHE HAS BEEN IN AND OUT OF THE EMERGENCY ROOM A FEW TIMES, SHE WAS REFERRED TO A ENDOCRINOLOGIST FOR A EKG, THAT CAME BACK NORMAL. SHE WAS SENT TO HAVE A CAT SCAN DONE TO CHECK HER ADRENAL GLAND, THAT WAS NORMAL. SHE HAD TO TAKE THYROID MEDICATIONS THE REST OF HER LIFE BECAUSE ESSURE RUINED HER THYROID. SHE WAS ALSO PLACED A BLOOD PRESSURE PILL AND A ANXIETY PILL TO KEEP HER SYMPTOMS AWAY. SHE IS NOW HAVING TO GO IN FOR A PARTIAL HYSTERECTOMY ON (B)(6) 2015 TO GET

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THE ESSURE REMOVED BECAUSE JUST REMOVING HER TUBES WILL NOT WORK DUE TO THE FACT THAT THE ESSURE COILS MIGRATED INTO THE UTERUS ON ONE SIDE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT CONSUMER WAS HAVING TO GO IN FOR A PARTIAL HYSTERECTOMY TO GET THE ESSURE REMOVED BECAUSE JUST REMOVING HER TUBES WILL NOT WORK DUE TO THE FACT THAT THE ESSURE COILS MIGRATED INTO THE UTERUS ON ONE SIDE. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF DEVICE DISLOCATION WERE NOT KNOWN. CONSIDERING THAT DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 17-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01585	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1706, AWARENESS DATE 21-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED ON UNSPECIFIED DATE AND HAD NOTHING BUT PELVIC PAIN, WEIGHT GAIN, IRREGULAR MENSTRUAL CYCLES, ALWAYS FELT COLD, NEVER HAD ENERGY AND WAS NOT BEING ABLE TO HAVE INTERCOURSE WITH HER HUSBAND BECAUSE IT WAS WAY TOO PAINFUL. SHE HAD TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6) DUE TO ENDOMETRIOSIS AND THE FACT THAT THE COILS HAD PERFORATED HER TUBES AND WORKED THEIR WAY INTO HER UTERUS AND INTO HER COLON. FOLLOW UP RECEIVED ON 12-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY

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CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WHEN SHE WAS (B)(6) AND SHE HAD TO HAVE A HYSTERECTOMY AT AGE OF (B)(6) DUE TO ENDOMETRIOSIS AND THE FACT THAT THE COILS HAD PERFORATED HER TUBES AND WORKED THEIR WAY INTO HER UTERUS AND INTO HER COLON. ENDOMETRIOSIS IS SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED FOR ESSURE; IT IS CONSIDERED UNRELATED TO THE DEVICE. FALLOPIAN TUBE PERFORATION IS ALSO SERIOUS BUT LISTED EVENT. GIVEN NATURE OF PERFORATION AND COMPATIBLE TEMPORAL RELATIONSHIP, CAUSALITY CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01586	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 7/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-1661, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER REPORTED EVER SINCE SHE HAD ESSURE PUT, SHE HAS HAD BAD PELVIC PAIN, WEIGHT GAIN, BAD CYCLES AT TIMES, WAS TOLD SHE HAD MS (MULTIPLE SCLEROSIS), FIBROMYALGIA, STUTTERING, RETAINING WATER IN LEGS AND FEET AND MAJOR HAIR LOSS. THEN AFTER HER PELVIC PAIN STARTED SHE WENT TO HER GYNECOLOGIST AND FOUND OUT HER COILS HAD BROKEN IN HER TUBES. SINCE THEN HAD HER COILS REMOVED BY HAVING A HYSTERECTOMY AND ALL THE TROUBLES WENT AWAY. FOLLOW UP RECEIVED ON 10-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA.

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MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 AND SINCE INSERTION SHE HAS HAD BAD PELVIC PAIN. UPON GYNECOLOGIST CONSULTATION, IT WAS DIAGNOSED HER COILS HAD BROKEN IN HER TUBES AND THEY WERE REMOVED VIA HYSTERECTOMY. THESE EVENTS (DEVICE BREAKAGE AND PELVIC PAIN) ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ANTICIPATED ACCORDING TO TECHNICAL ANALYSIS AND REFERENCE SAFETY INFORMATION. GIVEN NATURE OF EVENTS AND COMPATIBLE TEMPORAL RELATIONSHIP, CAUSALITY CANNOT BE EXCLUDED. OTHER NON-SERIOUS UNRELATED EVENTS WERE REPORTED. THIS CASE IS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS PERFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION IDENTIFIED ON 07-JAN-2016 FROM SOCIAL MEDIA (POSTED BY CONSUMER): SHE HAD ESSURE PLACED IN 2011 AND HAD NOTHING BUT PROBLEMS WITH IT. IN (B)(6) 2015 SHE HAD A HYSTERECTOMY BECAUSE SHE WAS TOLD IT WAS THE ONLY WAY TO REMOVE THEM AND S

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01587	BAYER HEALTHCARE LLC	11/18/2015	11/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7): 5/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1767, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER GOT ESSURE IN (B)(6) 2012 AND STATED THAT IT WAS THE WORSE DAY OF HER LIFE. FROM THAT DAY ON SHE STARTED HAVING BLADDER PROBLEMS, CONSTANT SEVERE PAIN, AND CONSTANT BLEEDING. IN (B)(6) OF 2014 SHE FINALLY HAD A HYSTERECTOMY TO GET ESSURE OUT OF HER. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION,

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THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD CONSTANT SEVERE PAIN AND CONSTANT BLEEDING (REGARDED AS GENITAL BLEEDING) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (19 MONTHS AFTER DEVICE PLACEMENT) TO REMOVE ESSURE. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS; GIVEN EVENTS NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, THE NON-SERIOUS EVENT BLADDER PROBLEMS WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057879	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 2/3/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER I HAD ESSURE I HAD IRREGULAR MENSTRUAL HEAVY BLEEDING, ENDOMETRIOSIS, FIBROID TUMORS ALL IN MY UTERUS, BLOATING, HIVES ALL OVER MY BODY, PANIC ATTACKS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057880	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT ALL STARTED WITH RIGHT LOWER ABDOMINAL PAIN, HIVES ,BACK PAIN, JOINT PAINS, SLEEP PROBLEMS. I HAVE TO WAKE UP EVERY DAY IN PAIN. I HAVE BEEN DIAGNOSED WITH FIBROMYALGIA, DEGENERATIVE DISC DISEASE. I'M ONLY (B)(6) BUT I CAN'T EVEN ENJOY SOCIAL ACTIVITY WITH MY KIDS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057881	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 12/12/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE DEVICE PUT IN (B)(6) 2014 AND EVER SINCE THEN I'VE HAD SOME SERIOUS HORMONAL IMBALANCE. I'VE HAD MOOD SWINGS AND UNEXPLAINED DEPRESSION, LOW LABIDO, BLOATING, IRREGULAR MENSTRUL CYCLE AND OCCASIONAL INSOMNIA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057882	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE IMPLANTED (B)(6) 2015/CONFIRMED (B)(6) 2015. I HAVE HAD HEADACHES, ONGOING BLEEDING/DISCHARGE, MOOD SWINGS, BRAIN FOG, CHRONIC FATIGUE, INCREASED ANXIETY/DEPRESSION, ACNE, BRUISING EASILY/NOT HEALING QUICKLY, AB PAIN, BACK PAIN, PELVIC PAIN, TEETH PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057883	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 5/29/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THERE IS A PICTURE I ATTACHED WITH DATES OF WHEN I GOT ESSURE TO WHEN I WAS DIAGNOSED WITH PCOS AND ALL OTHER SYMPTOMS I HAVE AND I WAS COVERED BY MEDICAID AT THAT TIME AND I ALSO HAD A SURGERY FOR UMBILICAL HERNIA REPAIR 2015 MOST LIKELY NOT RELATED TO ESSURE BUT IM JUST NOT SURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057884	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, INSOMNIA, CHRONIC BACK/HIP/LEG/SHOULDER/PELVIC PAIN, CHEST PAIN AS HAVING A HEART ATTACK, BOWEL ISSUES CONSTIPATED TO DIARRHEA, DAILY HEADACHES SOMETIMES MIGRAINES, SEVERE STOMACH CRAMPS, THINNING HAIR/HAIR LOSS, UNDERACTIVE THYROID, ALL OVER ITCHING/DRY SKIN, NUMBNESS DOWN MY LEGS, NUMBNESS AND AMP; TINGLING IN MY FINGERS (RAYNAUD'S), BRAIN FOG/FORGETFULNESS, WEIGHT GAIN/BLOATING, FACIAL ACNE, RINGING IN MY EAR 24/7, NIGHT SWEATS, SHARP STABBING PAIN IN MY EARS, MOOD SWINGS/DEPRESSION, GLUTEN SENSITIVITY, DEGENERATIVE DISC DISEASE, TEETH PROBLEMS, SHARP PAIN THAT SHOOTS FROM HIP DOWN MY LEG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057885	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 11/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PAIN IN MY LOWER LEFT ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057886	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH MEMORY ISSUES, SOME FATIGUE AND MOVED INTO SEVERE MEMORY ISSUES, DEBILITATING FATIGUE AND PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057887	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 4/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED NOTICING HAIR LOSS AND ADVERSE EFFECTS FROM FOOD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057888	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 2/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057889	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 11/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MUSCLE ACHES, HEAVY BLEEDING AND BLOOD CLOTS DURING PERIOD, CRAMPING, NAUSEA, JOINT PAIN, DEPRESSION, BLEEDING AFTER SEX, FOGGY BRAIN, IRRITABLE, LOSS OF SEX DRIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057890	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 11/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOST A TOOTH FROM ROOT RESORPTION WHICH IS RARE FOR ADULTS. STARTED RESEARCHING AND FOUND POTENTIAL LINK WITH ESSURE WHICH WAS IMPLANTED IN ME IN 2005. HAVE SINCE DEVELOPED LOWER LEFT QUADRANT ABDOMINAL PAIN. GOING NEXT WEEK TO HAVE X-RAYS OF ALL MY TEETH TO ASSESS FOR FURTHER PROBLEMS AND GOING NEXT WEEK TO DETERMINE CAUSE OF ABDOMINAL PAIN AND DISCUSS REMOVAL OF ESSURE. ALSO HAVE HEADACHES AND FATIGUE BUT HAVEN'T LINKED IT ALL TOGETHER UNTIL NOW. DIDN'T KNOW NICKEL IS IN PRODUCT WHEN I GOT IT PLACED. WAS TOLD IT WAS TITANIUM. IF I HAD KNOWN ABOUT THE NICKEL, I PROBABLY WON'T HAVE GOTTEN IT. I'M SENSITIVE TO NICKEL. NOW I'M CONCERNED I'VE GOT A BIGGER PROBLEM GOING ON BECAUSE OF ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057891	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 8/12/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN LIVING WITH CHRONIC PAIN SINCE 2011. I WAS NOT HAVING ANY OF THESE ISSUES UNTIL I HAD THIS DEVICE PUT IN ME. I HAVE SINCE FOUND OUT THAT I AM ALLERGIC TO NICKEL AND METALS. I WAS NEVER OFFERED TO GET A ALLERGY TEST. I AM SUFFERING FROM DEPRESSION, ANXIETY, PAIN, HEADACHES, TIREDNESS, I WAS RECENTLY DIAGNOSED WITH FIBROMYALGIA WHICH I DID NOT HAVE UNTIL NOW. I HAD TO HAVE A HYSTERECTOMY BACK IN (B)(6) 2015 DUE TO PAIN AND NON STOP BLEEDING. MY SYMPTOMS HAVE STILL NOT GOTTEN BETTER. IT HAS RUINED MY LIFE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057892	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 6/28/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE ALSO RECENTLY BEEN DIAGNOSED WITH MENIERE'S AS A DIRECT RESULT OF THE CHRONIC INFLAMMATION ESSURE CAUSES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057893	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 2/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN TO LOSE MY HAIR. I BEGAN HAVING EXCESSIVE BLEEDING AND PAIN DURING PERIODS STARTED TO BLOW TO THE POINT I LOOKED PREGNANT ALL THE TIME ENDED UP WITH DEPRESSION AND ANXIETY ATTACKS FATIGUE DIDN'T WANT TO DO ANYTHING EVEN WITH MY OWN CHILDREN'S SICK ALL THE TIME CHRONIC PELVIC PAIN ALL THE TIME AND MASSIVE HEADACHES ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057894	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/13/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RASH HAS APPEARED IN (B)(6) AS WELL AS HIP PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057895	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DAILY CHRONIC PELVIC PAIN, PAIN DURING SEX, BEING VERY MASTURBATION, DAILY HEADACHES, SHORTNESS OF BREATH, FATIGUE, NUMBNESS IN LEFT ARM UNABLE TO USE FREQUENTLY WITHOUT PAIN. HAIR LOSS, BLOATED BELLY, HEAVY PERIODS, EXTREME WEIGHT AND MORE RECENTLY PAIN WHILE WALKING IN OVARY AREA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057896	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 10/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THIS AS A FORM OF PERMANENT BIRTH CONTROL. SOMETHING I WOULDN'T HAVE TO THINK ABOUT AGAIN, OR SO I THOUGHT . I HAD BEEN HAVING NORMAL PERIODS BEFORE THIS , NOW IT IS SOO HEAVY THAT I AM REGULARLY HAVING TO WASH OUT MY CLOTHES (ACTUALLY SOAK THEM IN HYDROGEN PEROXIDE, WHICH I NEED TO BUY) BECAUSE MY PERIODS ARE SOO HEAVY THAT I AM REGULARLY BLEEDING THROUGH MY CLOTHES, EVEN WITH THE "STRONGEST" TAMPON. I AM HAVING WORSE CRAMPS, ALSO. I NOW HAVE FIBROIDS IN MY UTERUS, WHICH I DID NOT HAVE BEFORE!! I HAVE HAD A BUMPY RASH ON MY FINGERS, WITH SKIN ACTUALLY PEELING OFF WHEN I TRIED TO TAPE MY BROKEN FINGER TO ANOTHER. I WAS NEVER ABLE TO LEAVE THEM TAPED MORE THAN 3-4 DAYS . ALSO HAVE FIBER OR SOMETHING ABNORMAL IN MY R. CYST. NEVER HAD A PROBLEM WITH MY UTERUS OR ANY FIBERS IN MY CYSTS PRIOR TO THIS . THESE ESSURE WERE PUT IN BY (B)(5) . NOW I WILL NEED ANOTHER SURGERY TO GET THEM OUT . I HAVE A SPECIAL NEEDS CHILD , WHO NEEDS LOOKING AFTER , WHO IS GOING TO DO THAT WHILE I AM OUT OF COMMISSION ??? NO FRIENDS OR FAMILY THAT R ABLE TO TAKE TIME AWAY FROM THEIR LIVES TO BE HERE FOR A WEEK OR SO , TO HELP OUT . ALSO WANT TO SAY THAT , WHEN THIS WAS IMPLANTED, I WAS TOLD I WOULD BE BACK TO REGULAR SCHEDULE IN A DAY OR TWO . I WAS IN AGONY FOR A WEEK !!! HARDLY ABLE TO GET OFF THE COUCH DUE TO EXTREME PAIN !!! HATE TO THINK WHAT WILL HAPPEN WITH AN ACTUAL SURGERY OR HOW BAD THAT WILL BE !!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057897	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 2/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I'VE HAD ESSURE, I HAVE HAD MAJOR PAIN IN MY BACK, NOW MAJOR PAIN IN MY HIPS, REALLY BAD ABDOMINAL PAIN, AND CRAMPS, I USUALLY GET PRE MENSTRUAL CRAMPS TWO WEEKS BEFORE MY PERIOD NOW I HAVE THEM ALL THE TIME, MY PERIODS IS IRREGULAR, I'VE HAD TWO PER MONTH THE LAST ONE LAST 5 DAYS IN THE BEGINNING OF THE WEEK THEN I HAD IT A WEEK LATER WHICH LASTED 13 DAYS, I'VE HAD PAINS SHOOTING FROM THE RIGHT SIDE OF MY ABDOMINAL ALL THE WAY UP MY LEFT SIDE IN MY ARM AND CHEST, LAST YEAR MY DR. PUT ME ON MEDICINE FOR STRESS, I DON'T FEEL LIKE MYSELF ANYMORE, I FEEL LIKE I WANT TO RIP MY ABDOMINAL AREA OUT! I SUFFER FROM HEADACHES, SENSITIVITY ALL THROUGH MY BODY. I RECENTLY GOT A PELVIC ULTRASOUNDS DONE AND EVERYTHING WAS OK, NO FIBROIDS, OR CYST, I AM GETTING THE COILS OUT ON THE (B)(6), SO ON (B)(6) I HAVE TO GET LAB WORK AND AN EKG.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057898	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 9/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, DIARRHEA, NAUSEA, VERY PAINFUL OVULATION HEAVY PERIODS, (SOAKING ONE PAD AN HOUR) HEAVY CLOTS, PAINFUL BLOATING SHOOTING PAINS THROUGHOUT THE MONTH LOWER BACK PAIN VERY PAINFUL CRAMPING IN BACK DURING PERIOD ACHY JOINTS SENSE OF SMELL HAS DIMINISHED HAIR IS THINNER FATIGUE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057899	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 6/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER THE ESSURE WAS IMPLANTED I SOON AFTER EXPERIENCED ABDOMINAL PAIN AND DISCOMFORT. WITHIN THE PAST 6 YEARS I HAVE BEEN ON ANTIBIOTICS FOR UTI'S ALONG WITH PERMANENT BLOATING. JOINT PAIN, HAIR LOSS, NIGHT SWEATS, HEART PALPITATIONS, HEAVY PAINFUL PERIODS, FIBROIDS, POLYPS, CYSTS, ENDOMETRIOSIS, FATIGUE, HIVES DUE TO THE NICKLE ALLERGY. AND FOR YEARS I'VE BEEN TOLD THIS IS ALL IN MY HEAD.... I WAS 100% HEALTHY BEFORE ESSURE. ESSURE HAS TAKEN SO MUCH OF MY LIFE AWAY FROM ME. AND I JUST WANT THE COILS OUT OF MY BODY SO I CAN RECLAIM MYSELF AND BECOME THE WOMAN I ONCE WAS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057901	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 3/11/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, HEAVY BLEEDING , FIBROMYALGIA GOT MUCH MUCH WORSE, HEADACHES, ACNE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057902	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED ESSURE (B)(6) OF 2010. CONTRARY TO WHAT MY PHYSICIAN DISCLOSED TO ME, THE PROCEDURE WAS IN FACT VERY PAINFUL. IN ADDITION, I HAD AN ALLERGIC REACTION TO THE PAIN MEDICINE THAT WAS GIVEN PRIOR TO THE PROCEDURE. I WENT BACK FOR A FOLLOW UP IN (B)(6) OF 2010 ONLY TO BE TOLD BY THE TECHNICIAN THAT THE PROCEDURE DID NOT WORK. PRIOR TO MY VISIT WITH MY DR, I SPENT 3 DAYS SCOURING THE INTERNET FOR ESSURE ISSUES. TO MY DISMAY, I DISCOVERED HUNDREDS OF WOMEN HAD DEVELOPED PROBLEMS AND HAD BEEN TOLD BY THEIR PHYSICIAN THAT THE MANUFACTURER WOULD ADVISE TO LEAVE THE ESSURE IN PLACE EVEN IF IT HAD TRAVELED TO OTHER PARTS OF THEIR BODY CAVITIES. ARMED WITH THIS INFORMATION, I WENT IN TO MEET WITH MY PHYSICIAN TO RECEIVE THE NEWS THAT THE ESSURE IN FACT DID NOT WORK AND THAT THE COILS WERE NOW IN MY UTERUS AND OF COURSE SHE HAD TALKED WITH THE MANUFACTURER AND THEY HAD ADVISED THAT IT WOULD BE BEST TO LEAVE THEM IN PLACE. I DID NOT ACCEPT THAT AND DEMANDED THAT EVEN IF IT MEANT A HYSTERECTOMY THAT THEY BE REMOVED. SURGERY WAS SCHEDULED AND I WAS PUT TO SLEEP NOT KNOWING WHAT THE OUTCOME WOULD BE. WHEN I AWOKE IN THE RECOVERY ROOM, I RECEIVED THE NEWS THAT MY DR. WAS ABLE TO REMOVE THE ESSURE WITH MINIMAL DAMAGE TO MY UTERUS. DURING THE SURGERY, I RECEIVED ADDITIONAL PROCEDURES WHICH INCLUDED AN UTERINE ABLATION AS WELL AS A TUBAL. MY OUTCOME HAS BEEN A POSITIVE ONE EVEN THOUGH I SUFFERED UNNECESSARY PAIN FOR 2 SEPARATE PROCEDURES AS WELL AS TIME OFF WORK BOTH TIMES. HOWEVER I DO REALIZE THAT IT COULD HAVE BEEN SO MUCH WORSE ESPECIALLY AFTER READING SO MANY STORIES FROM WOMEN WHO HAVE SUFFERED SO MUCH MORE AND THOSE THAT ARE STILL SUFFERING. PRIOR TO RECEIVING ESSURE, MY DR. NEVER DISCLOSED ANY ADVERSE AFFECTS NOR DID I FIND MANY ON THE INTERNET. UPON RECEIVING THE NEWS FROM THE TECHNICIAN THAT MY PROCEDURE DIDN'T WORK I HAD

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TO LOOK SPECIFICALLY FOR ADVERSE EFFECTS AND BE VERY SPECIFIC TO FIND NEGATIVE ISSUES RELATING TO ESSURE. TO THIS DAY MY DR. STILL ADVERTISES THAT ESSURE IS A SAFE AND EFFECTIVE METHOD OF BIRTH CONTROL. AT THE TIME, I WAS HER ONLY PATIENT THAT HAD REPORTED AN ISSUE. MY HOPE AND PRAYER IS THAT OUR VOICES ARE HEARD AND THAT ESSURE BE EXPOSED FOR WHAT IT REALLY IS. THIS PRODUCT IS NOT SAFE AND OUR HEALTH IS MORE IMPORTANT THAN THE MANUFACTURER MAKING A PROFIT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057903	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 9/15/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I SUFFERED SEVERE ADVERSE EFFECTS FROM ESSURE MYSELF BUT THIS ADVERSE REPORT IS ABOUT MY SON. I EXCLUSIVELY BREASTFED HIM FOR 15 MONTHS. I WAS UNSURE IF HIS HEALTH ISSUES WERE RELATED TO ME BREASTFEEDING HIM WHILE HAVING ESSURE SO I'VE WAITED 1 YEAR SINCE HE HAS STOPPED NURSING. MY SON WAS BORN (B)(6) AND I WAS IMPLANTED IN (B)(6) 2013. WHILE I WAS EXPERIENCING ALL MY ISSUES IN (B)(6) 2013 MY SON HAD CONTINUOUS EAR INFECTIONS UNTIL (B)(6) 2014. HE ALSO HAS HAD SERIOUS DENTAL ISSUES WHICH REQUIRED SURGERY. HE HAS CAPS ON ALL HIS TEETH BUT 4. I HAD THE SAME DENTAL ISSUES THAT HAD TO BE FIXED AFTER REMOVAL OF ESSURE. HE HAD SEVERE RASHES/HIVES THAT MEDICINES DIDN'T HELP WITH. HE CONSTANTLY WOULD VOMIT BUT DRS DIDN'T KNOW WHY. HE WOULD CRY NONSTOP LIKE WITH A BELLYACHE. HE WAS VERY BEHIND ON VACCINATIONS BECAUSE HE WAS CONSTANTLY SICK SO I KNOW HE WASN'T HAVING AN ADVERSE REACTION TO ANY SHOTS. HE STARTED HAVING BEHAVIORAL ISSUES THAT I NOTICED WEREN'T TYPICAL IN (B)(6) 2014. HE STARTED BANGING HIS HEAD ON THE FLOOR, WALLS AND THROWING HIMSELF BACKWARDS. HE HASN'T HAD 1 EAR INFECTION SINCE I STOPPED BREASTFEEDING HIM IN (B)(6) 2014. AT THE TIME I STOPPED BREASTFEEDING HE HAD A RASH THAT INITIALLY GOT EXTREMELY WORSE BUT THEN CLEARED UP IN (B)(6) 2014. HE HASN'T HAD ANYMORE RASHES/HIVES OUTBREAK SINCE THEN. WHEN I HAD MY TUBES/COILS REMOVED I BROKE OUT EVEN WORSE THAN I HAD WHICH THE DR SAID WAS TOXINS COMING OUT OF MY BODY. IN MANY WAYS MY SON IS A TYPICAL 2 YEAR OLD BUT IN OTHER WAYS HE'S NOT. IN (B)(6) 2015 HE STARTED HAVING SMALL SEIZURE LIKE EPISODES. I'M WAITING NOW FOR HIM TO BE TESTED TO CONFIRM IF IN FACT HE IS HAVING SEIZURES. HE DOESN'T FEEL PAIN LIKE OTHERS. HE DOESN'T CRY WHEN HE GETS SHOTS OR FALLS. HE HAS TEXTURE ISSUES WITH FOOD, CLOTHES AND FLOORS. HE CAN'T DRINK REGULAR MILK BUT HE'S NOT LACTOSE INTOLERANT. IF HE DRINKS

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REGULAR MILK HE BECOMES SO CONSTIPATED THAT HE REQUIRES MEDICAL INTERVENTION WITH SUPPOSITORIES AND OTHER HELP. I TOOK HIM TO (B)(6). THE THERAPIST HE WAS SEEING SAID SHE HAD NEVER SEEN A CHILD SO YOUNG REACT TO DIFFERENT STIMULATIONS SO SEVERELY AS HE DID/DOES. I HAVE STARTED HIM WITH A PHYSICAL/OCCUPATIONAL THERAPIST SINCE THEN TO TRY TO HELP WITH DIFFERENT STIMULATIONS. HE HAS NO FEAR AT ALL. HE HAS BEEN REFERRED TO (B)(6) BY HIS PEDIATRICIAN. HIS PEDIATRICIAN SUSPECTS HE MAY HAVE AUTISM BUT SAID HE'S NEVER SEEN THIS KIND OF BEHAVIOR WITH HIS LEVEL OF INTELLIGENCE. MY SON IS DEVELOPMENTALLY THE SAME AS MOST 2 YEAR OLDS. HE WALKED, TALKED AND HIT ALL MAJOR MILESTONES LIKE OTHER CHILDREN. I WILL UPDATE THIS REPORT ONCE ALL EVALUATIONS ARE COMPLETED. FROM MY OWN RESEARCH I'VE FOUND THAT NICKEL CAN CAUSE NEUROLOGICAL EFFECTS AND PET FIBERS HAVE ENDOCRINE DISRUPTERS THAT CAUSE ALL DIFFERENT KINDS OF PROBLEMS AND BOTH ARE CARCINOGENIC. I HAVE 2 OTHER CHILDREN THAT I BREASTFED THAT DON'T HAVE ANY SIMILAR PROBLEMS. NO DENTAL OR BEHAVIORAL PROBLEMS AT ALL. I HAVE PICTURES OF THE RASH MY SON DID HAVE. I DON'T HAVE ANY LAB REPORTS AS OF NOW BUT I HOPE TO SOON. I DO BELIEVE IT'S ODD THAT HE HASN'T HAD A RASH SINCE I STOPPED BREASTFEEDING HIM. I KNOW AS A MOTHER, THAT THE ESSURE POISONED HIS BODY JUST AS IT DID MINE. I NOTICED THE CHANGES IN MY SON BUT IT NEVER OCCURRED TO ME THAT IT WAS FROM THE DEVICE IMPLANTED IN ME UNTIL I ALMOST DIED FROM THE "MOST SAFE AND EFFECTIVE FORM OF PERMANENT BIRTH CONTROL AVAILABLE"

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057904	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 10/1/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXCRUCIATING RLQ PAIN. CT SCAN NEGATIVE. BLOOD WORK NEGATIVE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057905	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 8/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE IMPLANTED IN (B)(6) 2013. WITHIN WEEKS, I BEGAN EXPERIENCING FATIGUE, DEPRESSION, AND STARTED TO GAIN WEIGHT. WITHIN A YEAR, I HAD GAINED 10 POUNDS, COULDN'T PERFORM DAILY ACTIVITIES WITHOUT GETTING EXTREMELY FATIGUED AND HAD SEVERE DEPRESSION. AS TIME WENT ON, MY THYROID STARTED TO BECOME SWOLLEN AND I WAS REFERRED TO AN ENDOCRINOLOGIST WHO IN TURN DIAGNOSED ME WITH HASHIMOTO'S AND HYPOTHYROIDISM. FAST FORWARD 2 YEARS AFTER THE COILS WERE IMPLANTED AND I NOW HAVE AN AUTOIMMUNE DISEASE, A WACKED OUT THYROID, I'VE GAINED 25 POUNDS (FOR ABSOLUTELY NO REASON), MY HAIR AND EYELASHES ARE FALLING OUT, MY VISION HAS WORSENED, I HAVE CHRONIC FATIGUE, AM ALWAYS COLD, HAVE CONSTANT INFLAMMATION AND SWELLING, HAVE CONTEMPLATED SUICIDE, SUFFER FROM INFLAMMATION AND JOINT ACHES, AND CANNOT CONTROL MY MOOD SWINGS AND DEPRESSION. THESE ARE JUST SOME OF THE MORE PRONOUNCED SYMPTOMS THAT I HAVE BEEN SUBJECTED TO SINCE I HAD ESSURE IMPLANTED. PRIOR THE (B)(6) 2013, I NEVER EVEN HAD THE FLU.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057906	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 11/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKLE ALLERGY. WENT TO THE ER FOR PAIN AND THEY DIDN'T BELIEVE ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057907	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 5/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC ABDOMINAL PAIN, CHRONIC BACK PAIN, CHRONIC NAUSEA CHRONIC MIGRAINES, CHRONIC FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057908	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 11/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAS RLS. AFTER ESSURE HEALTH HAS DETERIORATED NOW TO IDIOPATHIC NEUROPATHY, FIBROMYALGIA, GLUTEN SENSITIVE. CHRONIC PAIN IN WHOLE BODY AND JOINTS, HIPS, BACK DEGENERATIVE DISC DISEASE NOW. FEEL 89 WHEN (B)(6). NO ENERGY. DEPRESSED FROM STRUGGLING WITH NORMAL DAILY LIFE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057909	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/31/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN, SEVERE BLOATING, WEIGHT GAIN, PELVIC PAIN, FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057910	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 11/16/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). POLYCYSTIC OVARIES, ACNE, WEIGHT GAIN,.VERY LIGHT PERIODS, WIRY HAIR, FACIAL HAIR, HORMONAL ISSUES, LOSS OF OESTROGEN, RAISED TESTOSTERONE, C REACTIVE PROTEIN, TIREDNESS, (B)(6) WEIGHT GAIN, STOMACH PAIN, HERNIA; REFLUX AND RASHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057911	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT HEADACHES. BLOATING. FLU LIKE SYMPTOMS. VERY IRREGULAR AND EXTREMELY HEAVY PERIODS OR NONE AT ALL. CONSTANT ABDOMINAL PAIN. MENTAL FOGGINESS. BODY ACHES, BACK AND NECK PAIN. CONSTIPATION. HOT FLASHES. WEIGHT GAIN. UNEXPLAINED RASHES. SEVERE CRAMPING WITH/WITHOUT PERIODS. PHYSICAL, MENTAL AND EMOTIONAL SENSITIVITY. I CAN FEEL "SOMETHING" INSIDE MY ABDOMEN, WHICH I ASSUME IS THE COILS; THIS CAN BE AT ANY GIVEN TIME. DIZZINESS. HAIR LOSS. EXTREME FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057912	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 6/11/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH THE ESSURE (B)(6) 2009. SHORTLY AFTER I EXPERIENCED MIGRAINES, STOMACH FLUTTERS, ABDOMINAL PAIN, BACK PAINS, SKIN RASH ON LEGS, ITCHY SKIN, BLOATED AND PRESUMABLY COLITIS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057913	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 9/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ESSURE WAS PUT IN ON (B)(6). FROM THE MOMENT IT WAS PUT IN I WAS IN PAIN, NAUSEA. PAIN HAVING SEX. MY CERVIX PAIN. SORES IN MY MOUTH. DIZZINESS THAT MADE MY NAUSEA WORSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057914	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 6/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE ABDOMINAL PAIN, PAINFUL INTERCOURSE, PAINFUL PERIODS, LOWER BACK PAIN, DEVELOPMENT OF IRRITABLE BOWEL SYNDROME, FREQUENT EMERGENCY ROOM VISITS DUE TO EXTREME PAIN, IRREGULAR PERIODS, DIFFICULTY LOSING WEIGHT, WEIGHT GAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057915	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 7/31/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNDERWENT A VAGINAL ULTRASOUND AND THE DOCTOR REPORTED THAT THE RIGHT COIL HAS PARTIALLY MIGRATED INTO MY UTERUS. I HAVE ANOTHER SCAN SCHEDULED FOR THE END OF (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057916	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 2/11/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS PROVIDED FROM MY INSURER AND I WOULD SAY THAT SINCE AFTER A YEAR OF HAVING MY DEVICE IMPLANTED I HAVE HAD CHRONIC LOWER BACK PAIN LIKE A 10/10 PAIN SCALE ALONG WITH PELVIC PAIN WHEN ON MY CYCLE OR OVULATION AND PELVIC PAIN DURING INTERCOURSE HAD TEST DONE NUMEROUS TIME FROM DOCTORS TO EMERGENCY ROOM DOCTORS WHO COULD NOT EXPLAIN THE REASON FOR IT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057917	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 11/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY DEVICE WAS COVERED UNDER THE INSURANCE I HAD AT THE TIME. I HAVE HAD THIS DEVICE FOR OVER 10 YEARS... MY SIDE EFFECTS ARE: PELVIC PAIN, BLEEDING, PAIN DURING SEX, DIZZINESS, HAIR LOSS, MEMORY LOSS WEIGHT GAIN (UNABLE TO LOSE).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057918	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING BLEEDING AND BLOODY DISCHARGE. MOOD SWINGS, HOT FLASHES AND BLOATING. ONGOING!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057919	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 9/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2013. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS B26270 MY MODEL NUMBER IS ESS305 IF YOU KNOW IT. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2013. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. IMMEDIATE PAIN IN THE RIGHT FALLOPIAN TUBE, CONSTANT DULL/OR SHARP PAIN ON THE RIGHT SIDE, ABDOMINAL SWELLING, WEIGHT GAIN, TIREDNESS/EXHAUSTION, EXCESSIVE HAIR LOSS, CHRONIC MIGRAINES, IRREGULAR MENSES, SEVERE CRAMPING, JOINT PAIN. I HAVE BEEN SEEN BY 4 OF DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: HASHIMOTO'S (THYROID FUNCTION HAS QUIT WITHIN THE LAST 18 MONTHS , JOINT PAIN- SIGNIFICANT WORSENING IN LAST 12 MONTHS, CHRONIC MIGRAINES- PRESCRIBED TOPAMAX TO CONTROL CHRONIC MIGRAINES WHICH BEGAN INCREASING IN INTENSITY OVER THE LAST 12 MONTHS. THE DEVICE IS STILL INSIDE OF ME AS OF THIS DATE (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057920	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD MANY SYMPTOMS, BLOATING, BACK PAIN, UTIS, RENAL SCARRING, JOINT PAIN, TEETH DAMAGE, CRAMPING, CONSTIPATION, CHEST PAIN, ANXIETY, DEPRESSION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057921	BAYER	11/18/2015	11/18/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, DEPRESSION, WEIGHT GAIN, JOINT PAIN AMONG OTHERS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058012	BAYER	11/18/2015	11/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE I HAVE HAD THE ESSURE IMPLANTED I HAVE HAD HORRIBLE CRAMPING, BLEEDING AND BACK PAIN. OFTEN WHEN I MOVE WRONG IT FEELS LIKE MY INSIDES ARE RIPPING APART. I GET HEADACHES ALMOST EVERYDAY AND ALSO I AM VERY TIRED ALL THE TIME NO MATTER HOW MUCH I SLEEP.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058016	BAYER	11/18/2015	11/23/2015

Event Information:

Event Date (B3): 5/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/5/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN (B)(6) 2008, DURING AN ABLATION FOR GYNECOLOGICAL ISSUES, THE ESSURE COILS WERE IMPLANTED. SINCE THEN, I HAVE EXPERIENCED DEBILITATING SYMPTOMS THAT INCLUDE BUT ARE NOT LIMITED TO: HEADACHES, LETHARGY, JOINT PAIN, HIP PAIN, SEVERE BACK PAIN, INABILITY TO WALK LONG DISTANCES, WEIGHT GAIN, DEPRESSION, INABILITY TO STAND IN ONE SPOT FOR ANY LENGTH OF TIME, HORRENDOUS CRAMPING DURING MENSTRUAL CYCLES BUT NOT EXCLUSIVE TO THOSE TIMES ALONE, AND DIAGNOSED AS PHYSICALLY HANDICAPPED. I COULD NO LONGER DO THE JOB FOR WHICH I WAS HIRED, WHICH I AM A MEDICAL TECHNICIAN WITH AN OPHTHALMOLOGY PRACTICE. I HAVE BEEN SEEN BY MY PCP, AND SPECIALISTS AND NONE HAVE FOUND AN ABSOLUTE DIAGNOSIS. AS OF NOW, I AM BEING TREATED FOR FIBROMYALGIA BUT MY SYMPTOMS DO NOT DIRECTLY CORRELATE WITH THE REPORTED MOST COMMON SYMPTOMS OF FIBROMYALGIA. I TAKE 6 MEDICATIONS TO HELP CONTROL THE PAIN LEVELS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01530	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/3/2006
Explant Date (E7): 4/20/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 10-FEB-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER (B)(4), RECEIVED AT FDA ON 16-DEC-2013). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED HEADACHES CONSTANTLY, ANXIETY, DEPRESSION, HIGH BLOOD PRESSURE, PAINS IN HER HIPS, ANKLES, FEET LEGS AND ARMS, CANNOT WALK AND STAND FOR LONG, DIZZY SO MUCH LIKE SHE IS GOING TO BLACK OUT, PROBLEMS WITH HER VISION, CONSTANT PAIN SOMEWHERE IN HER BODY AT ALL TIMES, MOSTLY IN HER STOMACH AND ABDOMINAL AREA, WHEN SHE HAS HER PERIOD, IT IS VERY HEAVY AND SHE HURTS SO BAD SHE CANNOT EVEN GET OFF THE COUCH. FDA REPORT TYPE WAS "INJURY", REPORTED OUTCOME OF EVENTS WAS 'DISABILITY OR PERMANENT DAMAGE' NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. IN 2006, THE CONSUMER HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. SHE WAS NOT GIVEN A CHOICE GETTING THE DEVICE. SHE DID NOT GET THE ESSURE CARD THAT SHE JUST FOUND OUT SHE WAS SUPPOSED TO GET, SHE DID NOT EVEN KNOW THE NAME OF THE PRODUCT UNTIL RECENTLY. HER DOCTOR SAID NOTHING ABOUT COMING BACK TO HAVE IT CHECKED AFTER INSERTION, WHICH WAS NOT DONE IN THE DOCTOR'S OFFICE. IT WAS DONE IN THE HOSPITAL, IN AN OPERATING ROOM WHILE SHE WAS PUT TO SLEEP. CONSUMER REPORTED SHE HAS HAD NOTHING BUT MEDICAL PROBLEMS EVER SINCE THE INSERTION. THE LAST TWO YEARS IT HAD JUST GOTTEN WORSE AND WORSE. SHE HAS HEADACHES CONSTANTLY, ANXIETY, DEPRESSION, HIGH BLOOD PRESSURE, PAINS IN HER HIPS, ANKLES, FEET LEGS AND ARMS. SHE CANNOT WALK AND STAND FOR LONG. SHE CANNOT GO TO THE STORE BY HERSELF ANYMORE BECAUSE OF THE ANXIETY AND BECAUSE SHE GETS DIZZY

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SO MUCH LIKE SHE IS GOING TO BLACK OUT. SHE HAS PROBLEMS WITH HER VISION AT TIME OF REPORTING. SHE IS IN CONSTANT PAIN SOMEWHERE IN HER BODY AT ALL TIMES, MOSTLY IN HER STOMACH AND ABDOMINAL AREA, WHEN SHE HAS HER PERIOD, IT IS VERY HEAVY AND SHE HURTS SO BAD SHE CANNOT EVEN GET OFF THE COUCH. SHE CANNOT CLEAN THE HOUSE OR COOK ANYTHING. SHE JUST HURTS TOO BAD. SHE WAS ABLE TO FIND A SIDE EFFECT LIST AND HAS 76 OF THE SIDE EFFECTS THAT SHE KNOWS OF, NOT COUNTING THE ONES THAT SHE DOES NOT HAVE THE MONEY TO GO TO THE DOCTOR AND HAVE CHECKED OUT. CONSUMER WANTS ESSURE TAKEN OFF THE MARKET. FOLLOW-UP INFORMATION ON 21-OCT-2015: CASE UPGRADED TO INCIDENT. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1894, AWARENESS DATE 21-OCT-2015). THE CONSUMER HAD ESSURE INSERTED ON (B)(6)2006 IN AN OPERATING ROOM, UNDER ANESTHESIA. THE DEVICE WAS REMOVED ON (B)(6) 2015 VIA HYSTERECTOMY. SHE WAS NEVER TOLD ABOUT A DYE TEST. SHE HAD MANY MEDICAL PROBLEMS SINCE GETTING ESSURE. TOO MANY TO LIST BUT THE MAIN ONES BEING SEVERE ABDOMINAL PAIN, HEAVY BLEEDING, ENDOMETRIOSIS, BURSITIS, EXTREME WEIGHT GAIN, LESION AND CYST ON LIVER, HEART PROBLEMS AND AN ADRENAL ADENOMA ON HER LEFT ADRENAL GLAND (TUMOR). SHE WAS NOT THE ONLY ONE THAT SUFFERED. ESSURE DEVICE HAD HER IN SO MUCH PAIN ON A DAILY BASIS THAT SHE COULD NOT GET OFF THE COUCH 90 PERCENT OF THE TIME. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD CONSTANT, SEVERE PAIN MOSTLY IN HER ABDOMINAL AREA SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICES WERE REMOVED VIA HYSTERECTOMY 8.5 YEARS AFTER THEIR PLACEMENT. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABDOMINAL PAIN MAY OCCUR. IN THIS CASE, CONSUMER REPORTED MANY PROBLEMS WHICH SHE RELATED TO THE DEVICE, INCLUDING ABDOMINAL PAIN AND HEAVY MENSTRUAL BLEEDING. ADDITIONALLY, SHE REPORTED ENDOMETRIOSIS (UNDERSTOOD AS ADENOMYOSIS). THIS CONDITION MAY LEAD TO DYSMENORRHEA AND MENSTRUAL DISTURBANCES AND COULD BE AN ALTERNATIVE EXPLANATION FOR SOME OF THE CONSUMER'S SYMPTOMS. NEVERTHELESS, CONSIDERING THE LIMITED INFORMATION PROVIDED; A CONTRIBUTORY ROLE OF ESSURE IN CONSUMER'S PAIN CANNOT BE TOTALLY RULE OUT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED) BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01534	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D31453

Single Use: Y
Implant Date (E6): 10/21/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 23-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE GENERIC REIMBURSEMENT PROGRAM. ON (B)(6) 2015 PATIENT HAD AN ATTEMPT TO GET ESSURE INSERTED (FALLOPIAN TUBE OCCLUSION INSERT) WITH LOT NUMBER D31453. IT WAS REPORTED THAT AT FIRST ATTEMPT, A PROBLEM OF PLACEMENT WITH THE DELIVERY CATHETER OCCURRED. ON THE SECOND ATTEMPT, PROBLEM TO PLACE THE IMPLANT IN THE DELIVERY CATHETER OCCURRED; THE DELIVERY CATHETER BROKE IN THE OPERATING CHANNEL, THEN THE IMPLANT WAS RELEASED AND TWISTED. THIRD ATTEMPT OF PLACEMENT: THE IMPLANT WAS RELEASED AND TWISTED, HALF PLACED IN THE FALLOPIAN TUBE. BILATERAL PLACEMENT WAS NOT PERFORMED BECAUSE THE PROCEDURE WAS STOPPED (CONSIDERED INSERTION FAILURE DUE TO TECHNICAL REASON). NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD 3 ATTEMPTS OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON THE SAME DAY. DURING THE SECOND ATTEMPT THE DELIVERY CATHETER BROKE IN THE OPERATING CHANNEL. THE PROCEDURE WAS STOPPED AFTER THE THIRD UNSUCCESSFUL ATTEMPT. BILATERAL PLACEMENT WAS NOT ACHIEVED. THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, PHYSICIAN EXPERIENCED DEVICE DEPLOYMENT ISSUES (FIRST AND THIRD ATTEMPT). ON THE SECOND ATTEMPT THE CATHETER BROKE AND THE INSERT TWISTED; THIS INSERT SHAPE ALTERATION ALSO OCCURRED DURING THE THIRD INSERTION ATTEMPT. THIS SUGGESTS A DIFFICULT INSERTION WHICH MAY HAVE CONTRIBUTED FOR THE

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REPORTED DEVICE BREAKAGE. CONSIDERING THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULTS RECEIVED ON 22-DEC-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01549	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5055993) IN UNITED STATES ON 22-OCT-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED ESSURE WAS IMPLANTED ONLY IN RIGHT FALLOPIAN TUBE AND UNABLE TO INSERT IN LEFT TUBE. SEVERAL WEEKS LATER AN ATTEMPT WAS MADE TO INSERT INTO THE LEFT TUBE THAT WAS UNSUCCESSFUL. IMMEDIATE PAIN IN RIGHT FALLOPIAN TUBE AND A SERIES OF SEVERE LIFE THREATENING ILLNESSES TO FOLLOW RESULTING IN PANCREATITIS AND TUBE FEEDING AND PICC LINE FEEDING FOR SEVERAL MONTHS. SEVERE HEAVY VAGINAL BLEEDING MONTHLY REQUIRING THE USE OF 4 PADS AT A TIME. TWO YEARS AFTER THE IMPLANTS WAS INSERTED. SHE WAS FINALLY APPROVED FOR SURGICAL REMOVAL OF HER ENTIRE FALLOPIAN TUBE. THE PATHOLOGY REPORT CONFIRMED INTERNAL BLEEDING AND INFLAMMATION IN THE FALLOPIAN TUBE FROM THE ESSURE DEVICE. SHE HAS BEEN ASYMPTOMATIC SINCE THE SURGERY AND HAVE GONE OFF 6 OF THE 7 MEDICATION SHE WAS TAKING DAILY. THE SERIOUSNESS CRITERIA HOSPITALIZATION WAS MENTIONED IN THE SECTION EVENT OUTCOME BUT IS WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN IN RIGHT FALLOPIAN TUBE AND SEVERE HEAVY VAGINAL BLEEDING MONTHLY AFTER UNILATERAL ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION (RIGHT SIDE). HER FALLOPIAN TUBE WAS SURGICALLY REMOVED (2 YEARS AFTER DEVICE PLACEMENT) AND SHE BECAME ASYMPTOMATIC. ADDITIONALLY, SHE HAD A PANCREATITIS. ONLY PANCREATITIS IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL/PELVIC PAIN MAY OCCUR. IN THIS CASE, TEMPORAL RELATIONSHIP BETWEEN EVENTS AND ESSURE INSERTION IS POSITIVE, NO ALTERNATIVE EXPLANATIONS ARE AVAILABLE AND THE EVENTS RESOLVED WITH DEVICE REMOVAL. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENT (PANCREATITIS), GIVEN ITS NATURE AND CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY IS CONSIDERED VERY UNLIKELY. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (SALPINGECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01580	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2013
Explant Date (E7): 9/17/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2051, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. CONSUMER HAD ESSURE PLACED IN (B)(6) 2013 AND SINCE THEN SHE HAS HAD SEVERE BACK PAIN, MIGRAINES, SEVERE BLEEDING FOR MONTHS, FATIGUE, NAUSEA, SEVERE BLOATING, HAIR LOSS, WEIGHT GAIN, PAINFUL SEX, SEVERE PELVIC PAIN, SEVERE CRAMPING, RASHES AND DEPRESSION. ON (B)(6) 2015, SHE WAS RUSHED INTO SURGERY BECAUSE SHE WAS HAVING SEVERE PELVIC PAIN TO THE POINT SHE COULDN'T STAND UP OR WALK. WHEN THE DOCTOR WENT IN SHE WAS IN SHOCK TO SEE ONE OF THE COILS ON THE OUTSIDE OF HER TUBE. THAT NIGHT SHE REMOVED BOTH TUBES. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL

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EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED SINCE THE INSERTION SEVERE PELVIC PAIN AND SEVERE BLEEDING FOR MONTHS. SHE WAS RUSHED IN SURGERY DUE TO WORSENING OF PAIN AND WHEN THE DOCTOR WENT IN, IT WAS FOUND OUT THAT ONE OF THE COILS WAS ON THE OUTSIDE OF HER TUBE. THEN, SHE HAD THE COILS REMOVED. THESE EVENTS, SEEN AS PELVIC PAIN, GENITAL BLEEDING AND DEVICE DISLOCATION, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP AND THEIR NATURE, THE REPORTED EVENTS ARE ASSESSED AS RELATED TO ESSURE USE. ALTHOUGH IN THIS CASE THE EXACT DATE AND MECHANISM OF THIS DISLOCATION WERE NOT INFORMED, GIVEN THE IMPLIED TEMPORAL RELATIONSHIP AND THE FACT THAT DURING ESSURE USE, THERE IS A RISK OF DISLOCATION, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED (IMPLYING IN SURGICAL INTERVENTION) THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01588	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2012
Explant Date (E7): 10/7/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5031845) IN UNITED STATES ON 04-DEC-2013 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED BLOATING, HOT FLASHES, HEAVIER PERIODS, SEVERE LOWER BACK PAIN, NUMBNESS IN LEGS AND HANDS, DIZZINESS, RINGING IN EARS, METALLIC TASTE IN MOUTH, WEIGHT GAIN, DEPRESSION, BEGINNING STAGES OF OSTEOARTHRITIS, AND EXTREME PAIN. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. IN 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. SINCE CONSUMER HAD ESSURE IMPLANTS INSERTED IN 2012, SHE HAD EXPERIENCED SEVERE LOWER BACK PAIN, BLOATING, HOT FLASHES, HEAVIER PERIODS, NUMBNESS IN LEGS AND HANDS, DIZZINESS, RINGING IN EARS, METALLIC TASTE IN MOUTH, WEIGHT GAIN, DEPRESSION AND WAS HOSPITALIZED. SHE QUIT A JOB DUE TO THE PHYSICAL IMPAIRMENTS FROM THE DEVICE. ON AN UNSPECIFIED DATE CONSUMER UNDERWENT CAT SCANS AND MRIS AND FOUND BEGINNING STAGES OF OSTEOARTHRITIS. HOWEVER, NEITHER HER DOCTOR NOR NEUROLOGIST COULD EXPLAIN WHY SHE HAD SUCH EXTREME PAIN ALONG WITH THE OTHER SYMPTOMS. NO FURTHER INFORMATION WAS PROVIDED. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS NOT REPORTED. FOLLOW-UP INFORMATION RECEIVED FROM SAME CONSUMER ON (B)(6) 2013 VIA THE FDA, THE REGULATORY AUTHORITY IN UNITED STATES WITH A DIFFERENT AUTHORITY REFERENCE NUMBER (MW5032043, RECEIVED AT FDA ON (B)(6) 2013, INITIAL REPORT RECEIVED AT FDA ON 12-SEP-2013): CONSUMER HAD A ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2012 AND BESIDES PREVIOUSLY REPORTED EVENTS SEVERE LOWER BACK PAIN, DIZZY - LIGHT HEADED (EVENT TERM MODIFIED), METALLIC TASTE IN MOUTH, CONSTANT RINGING IN EARS (EVENT TERM MODIFIED), NUMB LEGS, HEAVIER/LONGER

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PERIODS (EVENT TERM MODIFIED), EXTREME BLOATING (EVENT TERM MODIFIED), SHE EXPERIENCED SHORTNESS OF BREATH, CONFUSION, INABILITY TO THINK, DEHYDRATION, EXCRUCIATING CRAMPING, HIGH BLOOD PRESSURE (NO OTHER EVENTS WERE REPORTED IN FOLLOW-UP, NOR WAS HOSPITALIZATION MENTIONED). FDA REPORT TYPE WAS "INJURY", REPORTED OUTCOME OF EVENTS WAS "REQUIRED INTERVENTION" (SAME AS REPORTED INITIALLY). ESSURE WAS EXPLANTED ON (B)(6) 2013. OUTCOME WAS NOT SPECIFIED. THE RELATIONSHIP BETWEEN EVENTS AND ESSURE WAS NOT ASSESSED. FOLLOW-UP RECEIVED ON 06-JAN-2014: NO NEW CLINICAL INFORMATION. FOLLOW-UP RECEIVED ON 26-JAN-2014: PTC ASSESSMENT WAS PROVIDED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN (B)(4)." FDA EVALUATION CODES METHOD: - NO TESTING METHODS PERFORMED. RESULTS: - NO RESULTS AVAILABLE SINCE NO EVALUATION PERFORMED. CONCLUSIONS: - UNABLE TO CONFIRM COMPLAINT. DEVICE NOT RETURNED. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 28-JAN-2015: NEW REPORTERS WERE ADDED. CONSUMER POSTED ONLINE THAT HER COPPER SERUM LEVEL WAS OVER 250 (NEARLY 100 OVER NORMAL). SHE ASKED IF THIS COULD BE BECAUSE OF FRAGMENTS FROM ESSURE. FOLLOW-UP INFORMATION RECEIVED ON 23-OCT-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (B)(4). PROCEDURE WAS DONE IN (B)(6) 2012. A WEEK LATER, AFTER SEVERAL DAYS OF EXTREME LABOR TYPE PAINS, SHE WENT TO THE ER AND NO ONE MEDICAL PROFESSIONAL HAD HEARD OF ESSURE. SHE WAS DIAGNOSED WITH CONSTIPATION. SHE FOLLOWED UP WITH HER DOCTOR WHO ASSURED HER THAT IT WAS NOT ESSURE. WITHIN A COUPLE WEEKS, SHE STARTED HAVING TROUBLE TYPING, DATA ENTRY(LOST A JOB), FELT INTENSE LOWER BACK PAIN AND BLED MORE AND LONGER. SHE STATED THAT SHE MADE 8 TRIPS TO THE ER IN 8 MONTHS FOR PAIN. HER ELECTROLYTES WERE GOING LOW. SHE STATED THAT SHE HAD FIBROMYALGIA, CHRONIC PAIN, CHRONIC FATIGUE, MEMORY LOSS, MEMORY RECALL ISSUES, TINNITUS, MOD HEARING LOSS, OSTEOARTHRITIS, NEUROPATHY, INCONTINENCE, LOSS OF SENSORY AWARENESS, CONSTANT THIRST(DRINK 3-4 LITERS OF WATER IN A DAY), METAL TASTE IN MOUTH, DEPRESSION, ANXIETY, PTDS, ACUTE PLANTAR FASCITIS. SHE HAD TO HAVE CORTISONE INJECTIONS IN HER SPINE, MEDIAN SPINAL BLOCKS. SHE ALSO HAD CHRONIC MIGRAINES, RAYNAUD'S, IBD, DENTAL PROBLEMS, GAINED 40 POUNDS WITH ESSURE AND HAD EBELLY. SHE COULD NOT FIND A JOB THAT ALLOWED HER TO WORK AROUND HER FATIGUE AND PAIN; HER CHILDREN (AGES (B)(6)) WERE TIRED OF SEEING HER IN SO MUCH PAIN. SHE HAD TO HAVE A VAGINAL CUFF DRAINAGE TUBE PLACED IN HER FOR 4 WEEKS. HER HIPS AND LEGS HURT TOO BADLY. HER DOCTOR NEVER MENTIONED NICKEL AND SHE IS HIGHLY ALLERGIC TO NICKEL AND OTHER METALS. SHE HAD HER HYSTERECTOMY DONE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING CRAMPING, BLED MORE AND LONGER. SHE ALSO REPORTED AN INABILITY TO THINK. ESSURE WAS EXPLANTED AND HYSTERECTOMY WAS DONE (IMPLYING AN INTERVENTION FOR DEVICE REMOVAL) AND ALSO STATED SHE WAS HOSPITALIZED. THE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. CRAMPING AND BLEEDING ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION WHILE THE OTHER EVENT IS UNLISTED. SEVERAL ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED.

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ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. BLEEDING AND MENSTRUAL PATTERN CHANGES ARE ALSO DESCRIBED. IN THIS PARTICULAR CASE, CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP A CAUSAL RELATIONSHIP BETWEEN THE REPORTED CRAMPING, BLEEDING AND THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE EVENT INABILITY TO THINK, CONSIDERING ESSURE LOCAL ACTION AT FALLOPIAN TUBES CAUSALITY IS CONSIDERED AS VERY UNLIKELY (UNRELATED). THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REPORTED HOSPITALIZATION AND IMPLIED INTERVENTION FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS WAS PERFORMED AND CONCLUDED, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01589	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B09707

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055957) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER B09707 INSERTED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015. THERE WERE COMPLICATIONS DURING ESSURE INSERTION DUE TO THE ESSURE APPLICATOR OPENED UP WHILE IN HER TUBE BUT WOULD NOT RELEASE THE SPRING CAUSING EXTREME PAIN. THE DOCTOR HAD TO PULL THE SPRINGS THAT OPENED UP OUT WHICH CAUSED A LOT OF PAIN, BLEEDING AND COLLAPSED HER TUBE. SHE HAD TO WAIT A COUPLE WEEKS FOR IT TO HEAL AND GO BACK AND HAVE IT DOWN IN THE OPERATING ROOM. SHE WAS PUT TO SLEEP AND STILL WAS UNABLE TO HAVE THE ESSURE PLACED INTO THE TUBE THAT WAS DAMAGED. SHE HAD HER TUBES CUT AND TIED DUE TO THE MALFUNCTION OF THE IMPLANT. CONSUMER ASSESSED HOSPITALIZATION AND REQUIRED INTERVENTION AS EVENT OUTCOME; HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. SHE ALSO ASSESSED (B)(6) 2013 AS EVENT DATE AND DID NOT SPECIFY IT. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). THE ESSURE WAS MANUFACTURED IN MAR-2013 AND ITS EXPIRATION DATE IS 31-MAR-2016. FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU), THE PHYSICIAN MUST PERFORM THE FOLLOWING STEPS IN ORDER TO ACHIEVE PROPER DETACHMENT: 1) ROLLBACK TO INITIAL HARD STOP. 2) DEPRESS BUTTON. 3) PERFORM FINAL ROLLBACK. UNDER NORMAL CIRCUMSTANCES, WHEN THE PHYSICIAN COMPLETES ALL DEPLOYMENT STEPS AS OUTLINED IN THE IFU, THE MICRO-INSERT ASSEMBLY WILL DETACH FROM THE DELIVERY WIRE AND REMAIN IN THE FALLOPIAN TUBE. SEVERAL FACTORS CAN CONTRIBUTE TO A

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DETACHMENT DIFFICULTY EVENT. THE MOST LIKELY ROOT CAUSES ARE TUBAL SPASMS WHICH CAN CLAMP DOWN ON THE DISTAL END OF THE CATHETER AND PREVENT THE MICRO-INSERT FROM RELEASING FROM THE DELIVERY WIRE, STRETCHING OF MICRO-INSERT DURING PLACEMENT ATTEMPTS WHICH TIGHTENS THE INSERTS GRIP ON THE DELIVERY WIRE, REPOSITIONING OF THE CATHETER AFTER THE FIRST ROLLBACK AND BUTTON PRESS ARE COMPLETED WHICH CAN ALSO TIGHTEN THE INSERTS GRIP ON THE DELIVERY WIRE, AND POTENTIAL MANUFACTURING DEFICIENCIES. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF A DETACHMENT DIFFICULTY EVENT IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. THE RISK TO THE PATIENT FOR THIS FAILURE MODE WAS ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES FOR THIS BATCH RESULTED IN NO UNUSUAL PATTERN IDENTIFIED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING ESSURE INSERTION THERE WERE COMPLICATIONS DUE TO THE ESSURE APPLICATOR OPENED UP WHILE IN HER TUBE BUT WOULD NOT RELEASE THE SPRING. SHE EXPERIENCED A LOT OF BLEEDING DURING ESSURE INSERTION (INTERPRETED AS PROCEDURAL BLEEDING) AND COLLAPSED HER TUBE (INTERPRETED AS FALLOPIAN TUBE DISORDER). SHE HAD HER TUBES CUT AND TIED DUE TO THE MALFUNCTION OF THE IMPLANT. THE REPORTED EVENTS ARE SERIOUS (THE TERM HOSPITALIZATION WAS ONLY MENTIONED AS EVENT OUTCOME AND THE REPORTER DID NOT SPECIFY IT) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE OCCURRENCE OF FALLOPIAN TUBE DISORDER CAN BE EXPLAINED BY THE COMPLICATIONS DURING ESSURE INSERTION. SINCE THE EVENTS OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS WAS PERFORMED AND CONCLUDED THAT NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED AND WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL PTC ASSESSMENT CONSIDERED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-DEC-2015: NO FURTHER INFORMATION WAS OBTAINED DESPITE FOLLOW-UP ATTEMPTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01590	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2014
Explant Date (E7): 8/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055946) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED IN 2014. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: PERCOCET (OXYCOCET). SHE BLEED FOR MONTHS STRAIGHT RIGHT AFTER IMPLANT. BACK PAIN STARTED IMMEDIATELY AFTER IMPLANT WAS PUT IN. SHE COULDN'T HAVE SEX WITH HER HUSBAND BECAUSE EVERY TIME THEY TRIED, SHE BLED EVERYWHERE. THEN, SHE UNDERWENT A HYSTERECTOMY IN 2015 (ESSURE WAS REMOVED ON (B)(6) 2015) AFTER SHE COULD NOT DEAL WITH THE PAIN ANYMORE AND SHE HAD A GIANT CYST ON RIGHT OVARY. HOSPITALIZATION WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT WAS RECEIVED ON 12-NOV-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS

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SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014 AND REPORTED GENITAL BLEEDING FOR MONTHS AFTER ESSURE INSERTION AND PAIN, BOTH SERIOUS AND LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. AFTER ESSURE INSERTION, PAIN, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, AS THE EVENTS WERE REFERRED AFTER ESSURE INSERTION, CAUSALITY IS CONSIDERED RELATED. SHE UNDERWENT A HYSTERECTOMY IN 2015 (ESSURE WAS REMOVED ON (B)(6) 2015) AFTER SHE COULD NOT DEAL WITH THE PAIN ANYMORE, SO THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. ADDITIONAL INFORMATION WAS REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 17-DEC-2015: NO FURTHER INFORMATION IS EXPECTED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2014 AND REPORTED GENITAL BLEEDING FOR MONTHS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01591	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/5/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5055953) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. CONSUMER HAD THE ESSURE PROCEDURE DONE AND EVER SINCE SHE HAS HAD SEVERE SIDE EFFECTS WHICH INCLUDE INTENSE CRAMPING, EXTREME WEIGHT GAIN, HEAVY BLEEDING, ANXIETY, DEPRESSION, HAIR LOSS AND INTENSE BACKACHES AND HEADACHES. DUE TO THE HEAVY BLEEDING SHE EXPERIENCED, SHE BECAME A CHRONIC ANEMIC AND SHE HAD TO GET TWO BLOOD TRANSFUSIONS AND NOW NEED A HYSTERECTOMY. CHRONIC ANEMIA DUE TO HEAVY BLEEDING BECAUSE OF THE ESSURE IMPLANTS. SHE WAS CURRENTLY TAKING NAPROXEN FOR CRAMPING AND BACKACHE. SHE WAS ALSO TAKING VERY HIGH DOSES OF IRON FOR ANEMIA. CONCOMITANT MEDICATIONS INCLUDED VITAMIN B COMPLEX, IRON, VITAMIN D, FOLIC ACID AND OMEGA 3. HOSPITALIZATION AND DISABILITY WERE MENTIONED IN THE SECTION EVENT OUTCOME BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED

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THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND CHRONIC ANEMIA DUE TO HEAVY BLEEDING. SHE HAD TO GET TWO BLOOD TRANSFUSIONS. GENITAL BLEEDING IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENT IS UNLISTED. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE EVENT HEAVY BLEEDING AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ACCORDING TO THE INFORMATION REPORTED, THE HEAVY BLEEDING CAUSED THE CHRONIC ANEMIA, THEREFORE CAUSALITY BETWEEN THIS EVENT AND ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS REQUIRED. HOSPITALIZATION AND DISABILITY WERE MENTIONED AS EVENT OUTCOME BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: ATTEMPTS OF FOLLOW-UP WERE MADE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01592	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2011
Explant Date (E7): 8/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055938) IN UNITED STATES ON 22-OCT-2015 REFERRING TO HERSELF. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. CONSUMER EXPERIENCED LOWER BACK PAIN, HEAVY PERIODS, MOOD SWINGS, LEFT LOWER ABDOMINAL PAIN AND IT WAS SHOOTING DOWN LEFT LEG, PAIN THE WHOLE TIME SHE HAD ESSURE IN. ESSURE WAS REMOVED ON (B)(6) 2015. DISABILITY/ PERMANENT DAMAGE WAS REPORTED HOWEVER NO EVENT WAS IDENTIFIED SPECIFIED. PTC INVESTIGATION RESULT WAS RECEIVED ON 12-NOV-2015. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 AND REPORTED PAIN THE WHOLE TIME SHE HAD ESSURE IN, SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE.

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ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. AS THE EVENT WAS REFERRED AFTER ESSURE INSERTION, CAUSALITY IS CONSIDERED RELATED. SHE HAD PAIN AND ESSURE WAS REMOVED ON (B)(6) 2015, SO THIS CASE IS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. ADDITIONAL INFORMATION WAS REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01593	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/16/2008
Explant Date (E7): 1/21/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055943) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2008 (EXPIRATION DATE 31-AUG-2015). CONCOMITANT MEDICATION INCLUDED AMLODIPINE BESYLATE, SPIRONOLACATONE AND ONE-A-DAY WOMEN VITAMIN. SHE HAD NOTHING BUT COMPLICATION FOR 3 YEARS. SHE EXPERIENCED STOMACH PAIN CONSISTENT DAILY. SHE TOOK PAIN MEDICINE TO HELP WITH THE PAIN WHICH DID NOT WORK. FINALLY SHE WAS TOLD THE ONLY WAY SHE GET THE METAL ROD OUT OF HER WAS TO HAVE A HYSTERECTOMY. IN (B)(6) 2011 SHE UNDERWENT A PARTIAL HYSTERECTOMY. AFTER HAVING THE HYSTERECTOMY SHE HAD A COMPLICATION IN EXTENDING THE HOSPITAL STAY FOR 9 TO 10 DAYS DUE TO HAVING INFECTION THAT WENT INTO BLOOD SYSTEM. PTC INVESTIGATION RESULT WAS RECEIVED ON 12-NOV-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL

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EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008 AND REPORTED SHE UNDERWENT A PARTIAL HYSTERECTOMY ON (B)(6) 2011 (MENTIONED AS TO REMOVE ESSURE). AFTER HYSTERECTOMY SHE DEVELOPED AN INFECTION THAT WENT INTO BLOOD SYSTEM WHICH PROLONGED HER HOSPITALIZATION. THESE EVENTS ARE SERIOUS, HYSTERECTOMY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE INFECTION IS UNLISTED. BOTH ARE CONSIDERED RELATED TO ESSURE (INFECTION AS A COMPLICATION OF SURGERY). IF AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED SHE HAD TO HAVE A HYSTERECTOMY, BUT NO CLEAR REASON WAS PROVIDED (THE ONLY COMPLAINT SHE HAD WAS A STOMACH PAIN, AND HYSTERECTOMY IS NOT A COMPATIBLE TREATMENT TO THIS). ALTHOUGH LIMITED INFORMATION WAS PROVIDED, IT CANNOT BE EXCLUDED THAT THIS SURGERY OCCURRED AS A CONSEQUENCE OF ESSURE. THEREFORE THIS CASE WAS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. ADDITIONAL INFORMATION WAS REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 07-DEC-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01594	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/30/2014
Explant Date (E7): 8/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN UNSPECIFIED AGE CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5055939) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. THE CONSUMER REPORTED THIS CASE THE HEALTH AUTHORITY ON 31-AUG-2015. ADDITIONAL INFORMATION RECEIVED ON 10-NOV-2015 (PTC INVESTIGATION RESULT). SHE REPORTED SINCE THE ESSURE SHE HAD ONGOING PAIN IN LEGS, FEET, PELVIC AND INTERCOURSE PAIN. HER PERIODS BECAME 10 X WORSE IN CRAMPING, AND HAD SEVERE FLOW TO A POINT OF ANEMIA. SHE ALSO REPORTED HER LEFT SIDE COIL WAS BROKEN IN HALF. SHE WAS IN AND OUT OF THE HOSPITAL AND DOCTORS OFFICE WITH INFECTIONS; AND STATED HER LAST INFECTION IN ABDOMEN AND PELVIS WAS SO SEVERE SHE ALMOST DIED. SHE WAS SCHEDULED FOR URGENT HYSTERECTOMY ON (B)(6) 2015 TO REMOVE HER UTERUS AND TUBE TO GET THE DEVICE OUT OF HER. AT TIME OF HER REPORT, SHE STATED HAVING PID (UNDERSTOOD AS PELVIC INFLAMMATORY DISEASE). SHE WAS LAID UP AT HOME, OFF WORK UNTIL SHE HEALS. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED. USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF L IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE

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PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT SHE WAS IN AND OUT OF THE HOSPITAL AND DOCTORS OFFICE WITH INFECTIONS. THE LAST INFECTION WAS IN HER ABDOMEN AND PELVIS WHICH WERE SO SEVERE. HER LEFT TUBE IT CAME TO LIGHT THAT HER COIL HAS BROKEN IN HALF (DEVICE BREAKAGE). AN URGENT HYSTERECTOMY WAS PERFORMED REMOVING HER UTERUS AND TUBE TO GET THE DEVICE OUT OF HER. AT TIME OF REPORT SHE STATED HAVING PID. ALL THESE EVENTS WERE CONSIDERED AS SERIOUS. INFECTIONS AND DEVICE BREAKAGE ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER ARE LISTED. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. ALTHOUGH IT WAS NOT REPORTED WHETHER THE PELVIC INFECTION, ABDOMINAL INFECTION OCCURRED UP TO 4 WEEKS POST ESSURE INSERTION, SINCE THESE EVENTS RESULTED IN HOSPITALIZATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. FOR THE EVENT INFECTIONS, SINCE THE EXACT CAUSE WAS NOT REPORTED, CAUSALITY CANNOT BE ASSESSED AT THIS TIME. FOR THE EVENT DEVICE BREAKAGE, BASED ON ITS NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. WITH REGARDS TO THE REPORTED EVENT PID, SINCE IT WAS REPORTED AFTER UNDERGOING A HYSTERECTOMY AND DEVICE REMOVAL, IT WAS CONSIDERED AS PELVIC INFECTION INSTEAD OF PELVIC INFLAMMATORY DISEASE. CONSIDERING THAT TEMPORAL RELATIONSHIP IS NEGATIVE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. DUE TO SURGICAL INTERVENTION AND HOSPITALIZATION, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: ATTEMPTS OF FOLLOW-UP WERE MADE WITH NO RESPONSE TO DATE. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01595	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/19/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055941) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE FIRST DAY OR TWO AFTER INSERTION SHE EXPERIENCED MAJOR DEBILITATING PAIN AND BLOATED AT LEAST 3 DRESS SIZES LARGER THAN SHE WAS. SHE BLED EVER SINCE THE PROCEDURE AND SHE WAS ON THE DEPO SHOT AND HAVE NOT EVER BLED WITH THE DEPO SHOT. SHE STATED THAT SHE COULD NOT DO ANYTHING; SHE COULD NOT EVEN SHOWER BECAUSE THE WATER HURT HER STOMACH TO HIT IT. IT WAS PAINFUL TO EVEN TOUCH HER STOMACH SOFTLY. SHE FELT LIKE GLASS OR RAZOR BLADES CUTTING INTO HER WHOLE ABDOMINAL REGION. HER BODY WOULD JERK AWAY FROM THE PAIN IN A SPASM TYPE WAY. SHE CANNOT HAVE SEX, THE DEVICE HAS CAUSED HER SO MUCH PAIN. HER HIGH DOSES OF PAIN MEDS WERE CAUSING HER TO BARELY BE ABLE TO THINK CORRECTLY. SHE WAS SCHEDULED TO REMOVE ESSURE IN 2 DAYS FROM THE DAY OF THE REPORT. SHE RECEIVED FLAGIL, PERCACET AND IBUPROFEN AS CONCOMITANT MEDICATIONS. DISABILITY/PERMANENT DAMAGE WAS MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT

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REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED EXPERIENCING MAJOR DEBILITATING PAIN / SHE FELT LIKE GLASS OR RAZOR BLADES CUTTING INTO HER WHOLE ABDOMINAL REGION (INTERPRETED AS ABDOMINAL PAIN), AND SHE BLED EVER SINCE THE PROCEDURE (INTERPRETED AS GENITAL BLEEDING). SHE WAS SCHEDULED TO REMOVE ESSURE. THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL PAIN, GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENTS, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED OR IDENTIFIED; A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01596	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2008
Explant Date (E7): 8/31/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE MW5055934) IN UNITED STATES ON 22-OCT-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. ADDITIONAL INFORMATION RECEIVED ON 12-NOV-2015. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: ALBUTEROL INHALER (SALBUTAMOL), TRAMADOL (TRAMADOL), IBU (IBUPROFEN [IBUPROFEN]), NAPROXENO (NAPROXEN), DULOXETINE (DULOXETINE), NORCO (VICODIN), TOPAMAX (TOPIRAMATE), ZALEPLON (ZALEPLON), ONDANSETRON (ONDANSETRON), B-COMPLEX (B-COMPLEX [VITAMIN B NOS]), AND TRACE MINERALS (ZINC [ZINC]). CONSUMER REPORTED SHE HAD NO HEALTH PROBLEMS AND AFTER ESSURE PLACEMENT SHE EXPERIENCED FIBROMYALGIA, ARTHRITIS, ASTHMA, VITILIGO, OBESITY, DEPRESSION, MIGRAINES, CHRONIC FATIGUE, INSOMNIA, PELVIC PAIN, BLADDER SPASMS, BACK SPASMS AND FULL HYSTERECTOMY (ESSURE REMOVAL DATE PROVIDED AS (B)(6) 2015). THE REPORTER MENTIONED THE FOLLOWING EVENT OUTCOME LIFE THREATENING, HOSPITALIZATION, DISABILITY AND PERMANENT DAMAGE, HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 12-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE

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INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (THE DEVICE WAS REMOVED APPROXIMATELY 7 YEAR AFTER ITS PLACEMENT). THE REPORTED EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE AND IN THE LACK OF ALTERNATIVE EXPLANATION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED OR IDENTIFIED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. FURTHER INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: ATTEMPTS OF FOLLOW-UP WERE MADE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN AFTER ESSURE (FALLOPI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01597	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT AT FOLLOW-UP IT WAS FOUND THAT ONE COIL WAS NOT IN HER TUBE AND THE OTHER HAD NOT WORKED; IT WAS FOUND THAT ONE WAS EMBEDDED IN UTERUS AND A SURGERY WAS DONE TO REMOVE IT. SHE HAD A 3RD SURGERY TO FIX TUBE THAT ESSURE DID NOT STAY IN. SHE HAD HEAVY BLEEDING AND PAIN FOR MONTHS, AND HAD A 4TH SURGERY TO LOOK AND FOUND THAT THE ESSURE WHICH WAS STILL IN HER TUBE HAD PERFORATED THROUGH HER TUBE, THEREFORE, IT HAD TO BE REMOVED AS WELL; THE WHOLE TUBE HAD TO BE REMOVED. NOW TO THE DAY OF THE REPORT, SHE HAS A LOT OF ABDOMINAL PAIN AND PROBLEMS FROM THESE IMPLANTS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN

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THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS FOUND THAT ONE WAS NOT IN HER TUBE / FOUND THAT SHE HAD ONE EMBEDDED IN UTERUS (INTERPRETED AS EMBEDDED DEVICE IN UTERUS) AND A SURGERY WAS DONE TO REMOVE IT. SHE ALSO HAD HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND THE OTHER ESSURE THAT WAS STILL IN HER OTHER TUBE HAD PERFORATED THROUGH THE TUBE (INTERPRETED AS FALLOPIAN TUBE PERFORATION) THEREFORE IT HAD TO BE REMOVED, ALONG WITH THE FALLOPIAN TUBE. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE AND FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE. IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THE FALLOPIAN TUBE PERFORATION AND DEVICE EMBEDMENT IN UTERUS WERE NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THESE EVENTS, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE EVENT HEAVY BLEEDING, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED OR IDENTIFIED; A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: FOLLOW-UP ATTEMPTS WERE MADE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01598	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5055927) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015. CONSUMER REPORTED IN EARLY 2011 SHE ATTEMPTED TO HAVE THE ESSURE PROCEDURE, BUT THE DOCTOR WAS ONLY ABLE TO PUT THE COIL INTO HER LEFT TUBE, HER RIGHT TUBE WAS COVERED WITH SCAR TISSUE, SO SHE ENDED UP HAVING TO HAVE HER TUBES TIED ANYWAY. SHE MENTIONED THAT ON HER LEFT SIDE SHE HAD BOTH THE ESSURE AND A CLAMP FROM THE TUBAL PROCEDURE. EVER SINCE SHE HAS HAD PAIN DURING INTERCOURSE AND WHEN IT WAS HER TIME OF THE MONTH SHE HAD NUMBING IN HER LEFT LEG AND STABBING PAINS IN HER LEFT LOWER BACK. SHE HAS BEEN TO THE DOCTOR SEVERAL TIMES ABOUT IT AND THEY WANTED TO DO A PARTIAL HYSTERECTOMY. THE SERIOUSNESS CRITERIA DISABILITY WAS MENTIONED IN THE SECTION EVENT OUTCOME BUT IT WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4)6. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED STABBING PAINS IN HER LEFT LOWER BACK. SHE HAS BEEN TO THE DOCTOR SEVERAL TIMES ABOUT IT AND THEY WANTED TO DO A PARTIAL HYSTERECTOMY. THIS EVENT WAS CONSIDERED AS SERIOUS (THE TERM DISABILITY WAS ONLY MENTIONED AS EVENT OUTCOME AND THE REPORTER DID NOT SPECIFY IT) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON ITS NATURE AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 07-DEC-2015: ESSURE CONSUMER GENERAL QUESTIONNAIRE WAS RECEIVED. CASE DOWNGRADED TO NON-INCIDENT INFORMATION RECEIVED FROM A (B)(6) FEMALE CONSUMER WHO HAS NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES NEITHER OTHER RELEVANT MEDIC

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01599	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): MALFUNCTION	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5035052) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) (EXPIRATION DATE 01-JAN-2030) IMPLANTED ON UNSPECIFIED DATE. SHE DENIED ANY CONCOMITANT MEDICATION. DURING THE INSERTION PROCEDURE THERE WAS SOME TYPE OF PROBLEM AND ONE COIL BROKE, SO THE DOCTOR HAD TO OPEN A SECOND KIT TO FINISH IMPLANTING. AFTER IT WAS OVER SHE HAD CRAMPING, BLEEDING AND DISCOMFORT. EVERYTHING SEEMED FINE AND THEN TWO WEEKS LATER SHE STARTED HER REGULAR PERIOD WHICH LASTED 6 MONTHS. SHE CONTACTED HER DOCTOR AND SHE WANTED HER TO TAKE BIRTH CONTROL PILLS TO GET HER PERIOD BACK ON TRACK, BUT WHEN SHE WENT TO HER APPOINTMENT SHE COULD NOT TAKE THE PILL BECAUSE FOR THE FIRST TIME IN HER LIFE SHE HAD HIGH BLOOD PRESSURE. SHORTLY AFTER THAT VISIT HER PERIOD STOPPED. A MONTH LATER HER PERIOD STARTED AGAIN AND LASTED NORMAL 5 DAYS. HOWEVER WITH THAT PERIOD AND EVERY PERIOD SINCE (THAT WAS IN 2012) ON HER SECOND DAY OF PERIOD SHE BLEED HORRIBLY. SHE HAD TO USE 2 TAMPONS AND A PAD AT A TIME AND HAD HUGE GUSHES OF BLOOD THAT ACCOMPANIED BY LARGE CLOTS. SHE ALSO EXPERIENCED WEIGHT GAIN (45 LBS.) THAT SHE COULD NOT LOSE, NUMBNESS IN HER UPPER LIP, MUSCLE SPASMS, METALLIC TASTE IN HER MOUTH, FATIGUE, LOSS OF ENERGY, CONSTANT BRAIN FOG, BOILS, PAINFUL OVULATION, UNEXPLAINED BRUISING, MOODINESS, HEART PALPITATIONS, NAUSEA, SPOTTING AFTER SEX, EXCESSIVE CRAMPING DURING HER PERIOD, SEVERE BLOATING, JOINT PAIN, NUMBNESS AND TINGLING IN HER HANDS AND FEET, SHARP STABBING PAINS IN HER PELVIS, BREAST PAIN AND TENDERNESS, ABDOMINAL SPASMS, TWITCHING AND A FEELING OF A FLUTTER, CHRONIC LOWER BACK PAIN. ON UNSPECIFIED DATE HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED THAT THE COIL THAT WAS SUPPOSED TO BE IN

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HER RIGHT FALLOPIAN TUBE WAS IN HER ABDOMEN, AND SHE WAS NOT STERILE. THE PTC INVESTIGATION RESULT WAS RECEIVED ON 11-NOV-2015. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE INSERTION PROCEDURE THERE WAS SOME TYPE OF PROBLEM DURING INSERTION AND ONE COIL BROKE. THE DOCTOR HAD TO OPEN A SECOND KIT TO FINISH IMPLANTING. AFTER IT WAS OVER SHE HAD BLEEDING (POST PROCEDURAL BLEEDING). AN HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND THE RESULT SHOWED THAT THE COIL THAT WAS SUPPOSED TO BE IN HER RIGHT FALLOPIAN TUBE WAS IN HER ABDOMEN. THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS WHICH STATED THAT MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT. THE OTHER EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THE NATURE OF THE EVENTS AND CONSIDERING THAT A POSITIVE TEMPORAL RELATIONSHIP IS IMPLIED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01600	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/20/2013
Explant Date (E7): 8/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055912) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015. SHE HAD SOME MILD CRAMPING FOR SEVERAL DAYS BUT SHE WAS INFORMED THAT THIS WAS AN EXPECTED REACTION. IN 2014, HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED. THE RADIOLOGIST REPORT STATED THAT THE ESSURE COILS WERE IN THE PROPER PLACE AND THAT THERE WAS TOTAL TUBAL OCCLUSION. SHE DID NOT EXPERIENCE ANY DISCOMFORT, BUT SHE NOTICED THAT HER CYCLES BEGAN TO FLUCTUATE A LITTLE BIT; SHE WOULD CYCLE BETWEEN 21 AND 29 DAYS AND THE DURATION WAS ABOUT 5 DAYS. TYPICALLY, THE FIRST 3 DAYS WOULD CONSIST OF HEAVY BRIGHT RED BLOOD FLOW AND THE LAST 2 OR 3 DAYS WOULD BE VERY STICKY BROWN CLOTS. TWENTY MONTHS AFTER THE ESSURE COILS WERE PLACED (IN 2015), SHE BEGAN HER CYCLE AND IT WAS CONSISTENT WITH THIS PATTERN, EXCEPT THAT THE BROWN BLOOD FLOW WAS HEAVIER THAN NORMAL. ON (B)(6) 2015, SHE DECIDED TO CHECK HERSELF DIGITALLY; SHE INSERTED A FINGER INTO HER VAGINA TO SCOOP OUT THE BROWN CLOTS. SHE DID THIS ABOUT 3 TIMES AND THEN HER FINGER CAUGHT ON SOMETHING. SHE SWEPT HER FINGER AROUND HER VAGINA AGAIN AND WAS ABLE TO TOUCH THE METAL OBJECT; SHE FELT AND REALIZED IT WAS PROTRUDING FROM HER CERVIX. SHE WAS ABLE TO INSERT A SECOND FINGER AND PINCHED THE OBJECT AND PULLED IT FROM HER CERVIX. IMMEDIATELY SHE KNEW IT WAS THE COIL, BUT IT WAS MISSING THE INNER INSERT. SHE SWEPT HER FINGERS AROUND HER VAGINA AGAIN AND WAS ABLE TO LOCATE THE INSERT. WITH MUCH DIFFICULTY, SHE WAS ABLE TO PINCH IT AND PULL IT FROM HER CERVIX. ON AN UNSPECIFIED DATE, A REPEAT HSG WAS PERFORMED. HER GYNECOLOGIST PERFORMED THE PROCEDURE WITH THE

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RADIOLOGIST THERE TO READ THE IMAGES. THEY CONCLUDED THAT THE COIL HAD COME FROM HER RIGHT FALLOPIAN TUBE, BUT IT WAS COMPLETELY OCCLUDED. THE LEFT COIL REMAINED IN PLACE. SHE STATED THAT SHE RECEIVED MULTIVITAMIN, VITAMIN D SUPPLEMENT, CRANBERRY TABLET, ACIDOPHILUS AS CONCOMITANT MEDICATIONS. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT CONSUMER DECIDED TO CHECK HERSELF DIGITALLY. SHE FELT AND REALIZED IT WAS PROTRUDING FROM HER CERVIX. SHE WAS ABLE TO INSERT A SECOND FINGER AND PINCHED THE OBJECT AND PULLED IT FROM HER CERVIX. IMMEDIATELY SHE KNEW IT WAS THE COIL, BUT IT WAS MISSING THE INNER INSERT (CONSIDERED AS DEVICE BREAKAGE). THE EVENT DEVICE BREAKAGE IS NON-SERIOUS AND LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. IN THIS CASE, IT WAS REPORTED THAT AN HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND ESSURE COILS WERE IN THE PROPER PLACE AND THAT THERE WAS TOTAL TUBAL OCCLUSION. IT WAS UNKNOWN WHEN THE DEVICE BREAKAGE OCCURRED. BASED ON ITS NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015: DESPITE FOLLOW UP ATTEMPTS, NO FURTHER INFORMATION WAS OBTAINED. FOLLOW-UP RECEIVED ON (B)(6) 2015: CONSUMER PROVIDED CONSENT TO CONTACT HER PHYSICIAN FOR ADDITIONAL INFORMATION AND REQUESTED TO CONTACT HER O

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01601	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/25/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5055888) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015. CONSUMER GOT THE ESSURE AND NOW SHE CURRENTLY HAS FLUID IN HER LEFT TUBE. AS A RESULT SHE NOW HAS TO HAVE A HYSTERECTOMY. SHE HAS EXPERIENCED NOTHING BUT PAIN AND PROBLEMS SINCE SHE GOT THE IMPLANT DONE. SHE HAS COMPLAINED MULTIPLE TIMES TO HER DOCTORS AND HAS BEEN TO THE EMERGENCY ROOM MULTIPLE TIMES FOR THIS. CONCOMITANT MEDICATIONS INCLUDE PINDOLO, MIDODRINE, IMITREX, ZOFRAN, PERCOCET, IBUPROFEN, OMEPRAZOLE, CETIRIZINE, ACYCLOVIR, LORAZEPAM. THE SERIOUSNESS CRITERIA DISABILITY WAS MENTIONED IN THE SECTION EVENT OUTCOME BUT IT WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL

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EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED FLUID IN HER LEFT TUBE. AS A RESULT SHE HAS TO HAVE A HYSTERECTOMY. THIS EVENT IS SERIOUS (THE TERM DISABILITY WAS ONLY MENTIONED AS EVENT OUTCOME AND THE REPORTER DID NOT SPECIFY IT) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. HYDROSALPINX MAY BE A LONG-TERM COMPLICATION OF PELVIC INFLAMMATORY DISEASE (PID). AFTER PID RESOLVES, THE DAMAGED FALLOPIAN TUBE CAN BECOME BLOCKED, FILL WITH STERILE FLUID, AND BECOME ENLARGED. DAMAGE TO THE FALLOPIAN TUBE FROM PREVIOUS SURGERY OR ADHESIONS CAN ALSO RESULT IN HYDROSALPINX. CONSIDERING THAT A POSITIVE TEMPORAL RELATIONSHIP IS IMPLIED AND THAT NO ALTERNATIVE EXPLANATION WAS PROVIDED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. DUE TO SURGICAL INTERVENTION PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01602	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/11/2009
Explant Date (E7): 3/12/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5055956) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. IMMEDIATELY AFTER THE ESSURE WERE PLACED IN HER BODY, SHE HAD REACTIONS. SHE FELT TERRIBLE AND STARTED TO FEEL PAINS ALL OVER. SHE CONTACTED THE DOCTOR WHO TOLD HER THAT SHE HAD THE FLU. SHE TOLD HER THAT SOMETHING WAS VERY WRONG IN HER BODY. SHE WAS ALLERGIC TO NICKEL WHICH WAS WHAT THE PROBLEM WAS. SHE HAD TO GET A HYSTERECTOMY IN ORDER TO GET THE SMALL METAL COILS OUT. ESSURE EXPLANT DATE WAS REPORTED AS (B)(6) 2009. SHE WAS LEFT WITH ONLY A RIGHT OVARY. SHE HAD EXPERIENCED BLUE CELL NECROSIS. IN ORDER WORDS AS SHE UNDERSTOOD IT, THE CELLS AROUND THE COILS WERE DEAD DUE TO THE NICKEL BEING ON THEM. THE DOCTOR ALSO RAN ANTIBIOTICS THROUGH HER ENTIRE BODY BECAUSE SHE WANTED TO BE SURE THAT ALL THE INFECTION WAS GONE. IT WAS A VERY TERRIBLE EXPERIENCE. THEY CLAIMED THAT SHE HAD ENDOMETRIOSIS WHICH WAS TOTALLY NOT TRUE. SHE HAS NEVER HAD ANY PROBLEMS WITH HER FEMALE ORGANS AT ALL. SHE SIMPLY WANTED A BIRTH CONTROL METHOD THAT DID NOT REQUIRE SURGERY. CONCOMITANT MEDICATIONS REPORTED: CURRENTLY USING VITAMINS, BLACK SEED OIL, COCONUT OILS, HERBS, LEMON VERBENA, ARGAN OILS, PEPPERMINT, LAVENDER, EUCALYPTUS OILS. THE SERIOUSNESS CRITERIA LIFE THREATENING AND HOSPITALIZATION WERE MENTIONED IN THE SECTION EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 15-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT:~ BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD ALLERGY TO NICKEL. SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE, ONE MONTH AFTER INSERTION. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED. IN THE PRESENT CASE, NO TYPICAL ALLERGY SYMPTOMS WERE REPORTED. HOWEVER, GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SERIOUSNESS CRITERIA LIFE THREATENING AND HOSPITALIZATION WERE MENTIONED, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01603	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/21/2012
Explant Date (E7): 11/27/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056760) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. ADDITIONAL INFORMATION RECEIVED ON 15-NOV-2015 (PTC INVESTIGATION RESULT). CONCOMITANT MEDICATION INCLUDED CENTRUM WOMEN. HER DOCTOR OFFICE DID NOT DO HER FOLLOW-UP UNTIL 2014, WHICH THEY TOLD THAT FROM THE LOOKS OF EVERYTHING THE PRODUCT WAS IN THERE CORRECTLY. IN 2014 SHE FOUND OUT THAT SHE WAS PREGNANT. WHEN SHE HAD THE BABY IN 2014, THROUGH A C-SECTION, THE DOCTOR SAID THAT THE ESSURE COIL INSERTED IN THE RIGHT WENT THROUGH THE TUBE AND WAS LAYING ON THE BOWEL. AT THAT TIME, HE CUT OUT THE COIL AND THEN DID A BILATERAL TUBAL STERILIZATION. THE LEFT COIL WAS STILL INSERTED IN THE TUBE. EXPLANTED DATE WAS REPORTED AS (B)(6) 2014. OTHER SERIOUS (IMPORTANT MEDICAL EVENT) WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ARTY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A

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RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT WITH ESSURE. SHE HAD THE BABY THROUGH C-SECTION. THE DOCTOR SAID THAT THE ESSURE COIL WENT THROUGH THE TUBE AND WAS LAYING ON THE BOWEL. ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED, EXCEPT THE EVENT C-SECTION, IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER GOT PREGNANT ABOUT 2 YEARS AFTER ESSURE INSERTION. IT WAS NOT REPORTED WHETHER THE BABY WAS BORN HEALTHY. IT WAS REPORTED THAT THE DOCTOR CUT THE COIL AND THEN DID A BILATERAL TUBAL STERILIZATION AFTER NOTICING THAT A FALLOPIAN TUBE PERFORATION OCCURRED DURING DELIVERY. IN THIS CASE, THE EXACT DATE AND MECHANISM OF FALLOPIAN TUBE PERFORATION WERE NOT KNOWN. CONSIDERING THE NATURE OF THE EVENTS, EXCEPT FOR C-SECTION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO C-SECTION, NO MEDICAL REASON FOR THE PROCEDURE WAS REPORTED AND SINCE IT IS A SURGICAL PROCEDURE FOR DELIVERY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED AND EXPLANTED DATE WAS REPORTED. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01604	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): C76452

Single Use: Y
Implant Date (E6): 7/16/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER HEALTH PROFESSIONAL VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5055876) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR STERILIZATION (LOT NUMBER C76452 WITH EXPIRATION DATE ON 31-JUL-2017). RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015. THE HEALTH CARE PROFESSIONAL REPORTED THE DEVICE WAS DEPLOYED IN THE USUAL FASHION. THE INTERNAL SPRING RETRACTED OUT WITH THE INSERTION DEVICE PARTIALLY AND IT WAS ABLE TO REMOVE THE MAJORITY OF THE INTERNAL SPRING BUT THE EXTERNAL SPRING WAS LODGED IN THE TUBE WITH 3 COILS VISIBLE AT THE OS (ORIFICIUM). THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY

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RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. THE RISK TO THE PATIENT FOR THESE TYPES OF BREAKAGE EVENTS WERE ASSESSED DURING THE DESIGN PROCESS, AND ADEQUATE RISK MITIGATION ACTIONS WERE TAKEN TO MINIMIZE THE RESIDUAL RISK AS DOCUMENTED IN THE DESIGN FMEA. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, NO MEDICAL EVENT(S) WERE IDENTIFIABLE AT THIS POINT IN TIME. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO MEDICAL EVENT(S) WERE REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THE ASSESSMENT OF A CAUSAL RELATIONSHIP IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE DEVICE WAS DEPLOYED IN THE USUAL FASHION. THE INTERNAL SPRING RETRACTED OUT WITH THE INSERTION DEVICE PARTIALLY, MAJORITY OF INTERNAL SPRING REMOVED AND EXTERNAL LODGED IN THE TUBE (INTERPRETED AS DEVICE BREAKAGE). THIS EVENT IS NON-SERIOUS AND WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, NO MEDICAL EVENT(S) WERE IDENTIFIABLE AT THIS POINT IN TIME. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO MEDICAL EVENT(S) WERE REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THE ASSESSMENT OF A CAUSAL RELATIONSHIP IS NOT APPLICABLE. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01605	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2012
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT (REQUIRED INTERVENTION). ANTICIPATED. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1617, AWARENESS DATE 24-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. THE PAIN WHICH WOKE HER FROM THE OPERATION TO PUT THE DEVICES IN, WAS EXCRUCIATING. SHE STATED SHE WAS TOO BUSY TO NOTICE THE FOGGY HEAD AND SHARP HEADACHES THAT HAD STARTED. TWO DAYS AFTER, SHE HAD THE 3 MONTH CHECK TO SEE IF HER TUBES HAD SEALED THE ESSURE IN, SHE BEGAN TO BLEED (WHICH WAS ODD AS SHE HAD ONLY JUST HAD HER PERIOD 5 DAYS BEFORE) AND NEVER STOPPED BLEEDING FOR NEARLY 2 MONTHS. SHE LOST A CLOT THE SIZE OF HER HAND AND WAS BLEEDING REALLY BAD. WHEN SHE HAD THE 3 MONTH CHECK THROUGH THE VAGINAL CANAL WITH ULTRASOUND THEY COULD NOT SEE THE ESSURE, SO THEY WERE POKING AROUND AND SHE BELIEVED THIS ACTION SHIFTED THE ESSURE, PIERCING A BLOOD VESSEL CAUSING THE BLEED. SHE AVOIDED PENETRATION WHILE SHE WAS WAITING FOR THE ESSURE TO BECOME SEALED IN, SO SINCE SHE HAD HAD THEM IN, THEY HAD NOT BEEN DISTURBED UNTIL THE ULTRASOUND. THE CONSUMER STATED SHE WAS TOO ILL TO TAKE CARE OF HER 3 CHILDREN. SHE ALSO STARTED LOSING HAIR AND A PREVIOUS PSORIASIS PROBLEM WENT COMPLETELY OUT OF CONTROL ON HER SCALP, WHICH SHE FELT LIKE HER SCALP WAS ON FIRE. HER SKIN DEVELOPED FLAT WARTS ALL OVER HER THIGHS AND LEGS AND RASH. SHE ALSO HAD A LUMP ON THE TOP OF RIGHT THIGH THAT WAS NOT THERE BEFORE. SHE HAD A CONSTANT RASH ALL UNDER THE SKIN ON FACE, AND SHE ALSO HAD A LUMP REMOVED FROM HER BREAST IN (B)(6) 2014. THE LUMP, WHICH HAD NEVER BEEN A PROBLEM HAD SUDDENLY STARTED TO HURT AND GOT MUCH BIGGER

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AND HAD CELL CHANGE SO IT HAD TO GO. IT WAS 5 CM IN LENGTH AND THEY REMOVED SURROUNDING TISSUE. THE CONSUMER HAD ESSURE REMOVED ON (B)(6) 2014. WHEN DURING REMOVAL, ONE OF THE COILS (THE SPRING LOOKING PART) WAS ALMOST STRAIGHT WHERE THE SURGEON HAD TO PULL IT HARD FROM WHEREVER IT HAD MIGRATED TO. SHE WAS STILL SPORADICALLY LOSING HER HAIR SINCE REMOVAL. WHILE SHE WAS DOING SOME EXERCISE, SHE FELT A SHARP PAIN IN HER LEFT SIDE THAT REMAINED UNTIL REMOVAL AND WAS STILL GIVING HER PROBLEMS. SHE WAS ALSO SUFFERING WITH HER JOINTS AND SHE WAS INJURING HERSELF TOO EASILY ALONG WITH LENGTHY RECOVERY. SHE WAS FEELING VERY WEAK. SHE CRIED A LOT, MOSTLY THROUGH BEING IN PAIN AND FEELING FRAGILE. SHE HAD ALWAYS BEEN VERY ACTIVE. ALL EVENTS WERE CONSIDERED RELATED TO ESSURE. FOLLOW-UP RECEIVED ON 05-NOV-2015: (B)(4). COMPANY CASUALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED SHARP PAIN ON THE LEFT SIDE AND BLEEDING. IN ADDITION, DURING THREE MONTHS CHECK AND REMOVAL PROCEDURE, THEY COULD NOT SEE ESSURE, IT MIGRATED. THESE EVENTS SEEN AS PELVIC PAIN, GENITAL HAEMORRHAGE AND DEVICE DISLOCATION RESPECTIVELY, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE. ALSO, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES TOWARDS TO PERITONEAL CAVITY. CONSIDERING THEIR NATURE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE ESSURE REMOVAL WAS REQUIRED (IMPLYING SURGICAL INTERVENTION) THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 02-DEC-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01606	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1418, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN GREAT BRITAIN WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER STATED SHE HAD ESSURE IN FOR 3 YEARS BEFORE SHE HAD A DOUBLE SALPINGECTOMY BUT HAD TO HAVE A COMPLETE HYSTERECTOMY AS WELL. SINCE THEN ALL OF HER SYMPTOMS HAVE GONE: NO MORE PAIN, BLOATING, SEVERE BLEEDING, BRAIN FOG, FATIGUE, JOINT PAIN, BEING IN WELL (INTERPRETED AS "UNWELL"), RASHES. SHE LOST HER MARRIAGE THROUGH ESSURE AND SHE LOST A BABY. BEFORE ESSURE SHE WAS FIT AND HEALTHY. FOLLOW UP INFORMATION RECEIVED ON 05-NOV-2015: (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A DOUBLE SALPINGECTOMY AND COMPLETE HYSTERECTOMY AND RECOVERED FROM THE EVENT. ADDITIONALLY, SHE STATED SHE LOST A BABY (REGARDED AS SPONTANEOUS ABORTION). ONLY PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE INCLUDING FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, IT IS UNCLEAR EXACTLY WHEN CONSUMER BECAME PREGNANT; HOWEVER IT SEEMS THIS EVENT OCCURRED WHILST ESSURE WAS IN SITU. NO INFORMATION WAS GIVEN ABOUT HSG; HOWEVER AN ESSURE CONTRACEPTIVE FAILURE RESULTING IN PREGNANCY CANNOT BE TOTALLY EXCLUDED. REGARDING THE

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SPONTANEOUS ABORTION; CONSIDERING IT IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY, OCCURRING IN UP TO 20% OF CLINICALLY RECOGNIZED PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION DUE TO MATERNAL CONDITIONS AND FETAL CHROMOSOMAL ABNORMALITIES; CAUSALITY WITH ESSURE IS CONSIDERED UNLIKELY. FOR THE REMAINING EVENT, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, SINCE ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR DURING ESSURE THERAPY; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY AND BILATERAL SALPINGECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 08-DEC-2015: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01607	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1726, AWARENESS DATE 25-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. AT THE MOMENT OF THIS REPORT, SHE HAD DEPRESSION, INSOMNIA, IBS (IRRITABLE BOWEL SYNDROME), AND GAINED EXCESSIVE WEIGHT IN STOMACH AREA. SHE HAD TO UNDERWENT AN ABLATION LAST YEAR BECAUSE BLEEDING WAS SO EXTREME. SHE HAD A MENSTRUAL CYCLE FOR 3 YEARS STRAIGHT. BEFORE ESSURE SHE WAS A HEALTHY WOMEN. NOW AT (B)(6) SHE HAS NO ENERGY WHAT SO EVER. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED EXTREME BLEEDING AND HAD TO UNDERWENT AN ABLATION IN THE PREVIOUS YEAR. THIS EVENT, SEEN AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL INTERVENTION AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER HAD TO HAVE AN ABLATION DUE TO EXTREME BLEEDING. CONSIDERING EVENT'S NATURE AND TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS PERFORMED AS A TREATMENT MEASURE TO THE REPORTED EVENT, THIS CASE IS REGARDED AS INCIDENT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 17-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01608	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2004
Explant Date (E7): 11/1/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-X1725, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) WHO HAD ESSURE MODEL 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2004. CONSUMER HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2004. SHE STATED THAT HER DOCTOR NEVER DID A NICKEL SENSITIVITY TEST PRIOR TO THE PROCEDURE. AFTER SUFFERING WITH CHRONIC PROBLEMS FOR 4 YEARS SHE DISCOVERED THAT NICKEL SENSITIVITY WAS A CONTRAINDICATION SHE HAD AN ALLERGY TEST WHICH CAME BACK POSITIVE. BEFORE ESSURE SHE WAS HEALTHY, FIT, VIBRANT WOMEN. AFTER ESSURE SHE HAD GAIN 33 POUNDS, EXTREMELY LETHARGIC, ONGOING EXCRUCIATING PAIN, BLOATING, EXTREMELY HEAVY PERIODS WITH HUGE BLOOD CLOTS, FOUL SMELLING VAGINAL ODOR AND UNPREDICTABLE GUSHES OF ACIDIC SMELLING FLUID THAT WOULD LEAVE HER EMBARRASSINGLY DRENCHED AND SOMETIMES IT WOULD BURN THE SKIN OF VULVA. SHE CONSTANTLY NEEDED TO URINATE AND IT WAS ALWAYS URGENT, HAD EXCESSIVE HAIR LOSS AND TEETH BEGAN TO DETERIORATE, PSORIASIS OF SCALP, SHE HAD THE WORST BRAIN FOG AND COULDN'T RECALL SIMPLE WORDS, WOULD EXPERIENCE REGULAR HEADACHES, FELT 'SICK' ALL OVER AS IF SHE WAS HIGHLY TOXIC. SHE FELT LIKE SHE WAS GOING TO DIE, LITERALLY. IT WAS EMOTIONALLY TRAUMATIC AND FINANCIALLY DEVASTATING. SHE HAD A HYSTERECTOMY TO HAVE THE COILS REMOVED IN (B)(6) 2008. AFTER HAVING THE HYSTERECTOMY THE ESSURE SIDE EFFECTS DISAPPEARED. UNFORTUNATELY SHE NOW HAS TO DEAL WITH THE SIDE EFFECTS OF THE HYSTERECTOMY (SURGICALLY INDUCED MENOPAUSE, HORMONAL PROBLEMS AND PROLAPSE). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO

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EXPERIENCED ONGOING EXCRUCIATING PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE HAD A HYSTERECTOMY WITH DEVICES REMOVAL AND RECOVERED FROM THE PAIN. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER RELATED HER PAIN TO ESSURE. THE DEVICES WERE REMOVED APPROXIMATELY 4 YEARS AFTER THEIR PLACEMENT. CONSIDERING CONSUMER IMPROVED AFTER DEVICES REMOVAL AND SINCE NO ALTERNATIVE EXPLANATION WAS PROVIDED; CAUSALITY BETWEEN THE REPORTED EVENT AND THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 08-DEC-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INV

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01620	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2011
Explant Date (E7): 4/6/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER VIA THE REGULATORY AUTHORITY IN THE UNITED STATES (CASE NUMBER MW5025027) ON 07-MAY-2012 WITH ADDITIONAL INFORMATION RECEIVED FROM A NURSE ON 22-MAY-2013. THE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED SHE HAD THE PROCEDURE IN 2011 AND HAD NOTHING BUT PROBLEMS FOR FOUR MONTHS. THE SYMPTOMS WERE DIZZINESS, WEIGHT GAIN, PAIN, BURNING IN ABDOMEN, TINGLING SENSATIONS ALL OVER HER BODY, EXTREME HEADACHES, NAUSEA, FATIGUE ELEVATED BLOOD PRESSURE, CRAMPING AND HAD A PARTIAL HYSTERECTOMY TO HAVE THE DEVICES REMOVED ON (B)(6) 2012. SHE SPENT THOUSANDS OF DOLLARS ON TESTS AND NOW HAD SURGERY. SHE STATED THIS PRODUCT NEEDS TO BE RE-EVALUATED FOR LONG TERM EFFECTS, TOO MANY WOMEN ARE HAVING TROUBLE. ON MAY-22-2012, A NURSE REPORTED FOR TREATING DOCTOR THAT A BILATERAL SALPINGECTOMY WAS PERFORMED ON (B)(6) 2012 AND THERE WERE NO SIGNIFICANT PATHOLOGICAL CHANGES IN THE FALLOPIAN TUBES, THEY WERE FOUND TO BE GROSSLY UNREMARKABLE. THEY WERE REMOVED DUE TO PATIENT REQUEST. NO RESPONSES FROM DOCTOR WERE OBTAINED DESPITE FURTHER REQUESTS, THERE WAS NO CONFIRMATION OF MEDICAL NECESSITY OR CURRENT STATUS OF PATIENT. PATIENT HAD REQUESTED THE REMOVAL. ADDENDUM: THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO ARGUS ON 25-SEP-2013. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED FOLLOW-UP INFORMATION RECEIVED ON 23-OCT-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1805). ESSURE WAS IMPLANTED IN (B)(6) 2011; PROCEDURE ITSELF WAS VERY PAINFUL. WITHIN 2 WEEKS HER

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SYMPTOMS STARTED TO DEVELOP. THEY BEGAN WITH ABNORMAL BLEEDING, CRAMPING AND BLOATING. SHE WENT TO THE ER (EMERGENCY ROOM) AND NONE OF THE ER DOCTORS COULD HELP REGARDING ESSURE. THEY DID A SERIES OF TESTS AND EVERYTHING WAS NORMAL AND SHE WAS SENT HOME. AS THE WEEKS WENT BY, SHE STARTED TO DEVELOP EVEN MORE SYMPTOMS. SHE FELT VERY DIZZY, TIRED AND AT ONE POINT SHE FELT LIKE SHE WAS GOING TO FAINT. SHE ALSO GAINED WEIGHT, HAD HAIR LOSS AND FELT A TINGLING SENSATION IN HER FACE. SHE WENT AGAIN TO THE ER AND HAD MORE TESTS (BLOOD TESTS, CT SCAN, ULTRASOUND) TAKEN AND EVERYTHING WAS NORMAL AGAIN. SEVERAL MONTHS HAD GONE BY AND HER SYMPTOMS KEPT GETTING WORSE. SHE WENT TO THE ER FOR A 3RD TIME AND SHE STARTED TO DEVELOP HIGH BLOOD PRESSURE AND AFTER BLOOD TESTS AGAIN THE DOCTOR SAID IT LOOKED LIKE SHE WAS DEVELOPING FIBROMYALGIA. SHE WAS PERFECTLY HEALTHY PRIOR TO ESSURE AND ALL THESE STRANGE SYMPTOMS BEGAN AFTER IMPLANTATION, SHE DECIDED TO GET AN ALLERGY TEST (SHE HAD NEVER BEEN ALLERGIC TO NICKEL IN THE PAST). AFTER 4 MONTHS, SHE FELT LIKE HER BODY WAS BEING POISONED. SHE REMOVED ESSURE USING THE DA VINCI ROBOT VIA SALPINGECTOMY. THE VERY NEXT DAY, HER SYMPTOMS WERE GONE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 15-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WITHIN 2 WEEKS STARTED HAVING ABNORMAL BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A SALPINGECTOMY AND ESSURE REMOVAL APPROXIMATELY 5 MONTHS AFTER INSERTION. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE NATURE OF THE REPORTED EVENT, AND SINCE THE EVENT RESOLVED AFTER ESSURE REMOVAL, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT, HOWEVER UPON RECEIPT OF FURTHER INFORMATION DESCRIBING NEW EVENTS, AND THE OUTCOME AFTER ESSURE REMOVAL, THE CASE WAS UPGRADED TO INCIDENT. BASED ON THE AVAILABLE INFORMATION, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS FOLLOW-UP WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01621	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/4/2014
Explant Date (E7): 9/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043916) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. SHE REPORTED THE PROCEDURE WAS DONE IN DOCTOR'S OFFICE. SINCE THAT TIME SHE HAD SEVERAL HEALTH ISSUES BOTH NEW AND WORSENING OF EXISTING CONDITIONS, INCLUDING RAPID WEIGHT GAIN; HAIR GROWTH; MOOD SWINGS; SEVERE DEPRESSION; CHRONIC FATIGUE; JOINT PAIN; CRAMPS; PAIN AND SWELLING IN ABDOMINAL REGION; SPOTTING; DIZZINESS; SEVERE MIGRAINES; NAUSEA; AND CONSTIPATION. THE CONSUMER MENTIONED THE SERIOUSNESS CRITERION DISABILITY OR PERMANENT DAMAGE BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. SHE ALSO MENTIONED WELLBUTRIN AS CONCOMITANT MEDICATION. FOLLOW-UP INFORMATION RECEIVED ON 20-AUG-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER

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BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 13-AUG-2015. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0419). CONSUMER STATED THAT SHE HAD ESSURE INSERTED IN (B)(6) 2014 AND SINCE THEN SHE HAD A LARGE NUMBER OF COMPLICATIONS INCLUDING DEPRESSION, MIGRAINES, SIGNIFICANT WEIGHT GAIN, BLOATING, DAILY CRAMPING, PIERCING ABDOMINAL PAIN, BACK PAIN, JOINT PAIN, MOOD SWINGS, BRAIN FOG, MEMORY LAPSES, CHRONIC FATIGUE, LACK OF LIBIDO AND HAVE DEVELOPED A NICKEL ALLERGY. FOLLOW-UP FROM 24-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. FOLLOW-UP RECEIVED ON 23-OCT-2015 AND CASE WAS UPGRADED TO INCIDENT. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1569, AWARENESS DATE 23-OCT-2015). CONSUMER REPORTED FOLLOWING THAT SHE DEVELOPED NUMEROUS SYMPTOMS, ALL OF WHICH SHE ATTRIBUTED TO THE DEVICE. SHE HAD PAIN WITH INTERCOURSE, INFLAMMATION IN HER JOINTS. SHE ALSO SUFFERED FROM MEMORY LOSS, DIZZY SPELLS AND GASTROINTESTINAL ISSUES. SHE WAS OFTEN FEELING EXHAUSTED UPON WAKING FROM A FULL NIGHTS SLEEP. ON (B)(6) 2015 SHE HAD A SUPRA CERVICAL HYSTERECTOMY, LEAVING ONLY HER OVARIES AND CERVIX. 85% OF THE SYMPTOMS LISTED PREVIOUSLY WERE COMPLETELY GONE, WITH OTHERS SLOWLY FADING. SHE WOKE FROM SURGERY WITHOUT JOINT PAIN, THE FATIGUE DISAPPEARED AFTER 2-3 DAYS. SHE HAS NOT HAD A MIGRAINE SINCE 3 DAYS AFTER SURGERY. HER DOCTOR REFUSED TO BELIEVE THAT THE ESSURE WAS AFFECTING HER LIFE, SO SHE HAD TO FIND A NEW DOCTOR THAT WOULD LISTEN TO HER. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THAT SHE HAD PAIN IN ABDOMINAL REGION AMONGST OTHER NON-SERIOUS EVENTS. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH IMPROVEMENT OF HER SYMPTOMS. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR AFTER ESSURE INSERTION. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT. HOWEVER, UPON RECEIPT OF FOLLOW-UP INFORMATION, CONSUMER STATED A HYSTERECTOMY WAS PERFORMED. THEREFORE, CASE WAS UPGRADED TO INCIDENT (INTERVENTION REQUIRED). THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 17-DEC-2015: PTC INVESTIGATION RESULTS WERE UPDATED AND PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01627	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/8/2011
Explant Date (E7): 9/14/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 23-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 FOR PERMANENT CONTRACEPTION. ON (B)(6) 2015 ESSURE WAS REMOVED DUE TO RASH WHICH THE PATIENT COULD NOT GET RID OF. THE PATIENT ALSO COMPLAINED OF JOINT PAIN. THE PTC INVESTIGATION RESULT WAS RECEIVED ON 05-NOV-2015. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A RASH SHE COULD NOT GET RID OF. ESSURE WAS REMOVED APPROXIMATELY 4 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE

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ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THE DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THIS DEVICE IS IMPLANTED. TYPICAL ALLERGY SYMPTOMS REPORTED INCLUDE RASH, PRURITUS, AND HIVES. IN THE PRESENT CASE, IT WAS NOT REPORTED WHETHER THE PATIENT WAS ALLERGIC TO NICKEL. HOWEVER, GIVEN THE NATURE OF THE EVENT RASH, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENT JOINT PAIN WAS ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01628	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1492, AWARENESS DATE 23-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. THE CONSUMER REPORTED THAT APPROXIMATELY 1 YEAR AFTER ESSURE PROCEDURE HER HEALTH STARTED TO FALL APART AND SHE HAD SPENT 5 YEARS FIGHTING TO REGAIN IT. ACCORDING TO HER, IT STARTED WITH SUDDEN WEIGHT GAIN AND PROLONGED PERIODS, SOME AS LONG AS 21 DAYS. SHE WENT BACK TO THE DOCTOR AND THEY DECIDED TO DO AN ABLATION WHICH SHORTENED HER PERIODS TO 5-10 DAYS BUT HER OTHER SYMPTOMS GOT WORSE. THEY INCLUDED HORMONE ISSUES, CHEMICAL AND FOOD ALLERGIES, GLUTEN SENSITIVITY, RASHES, CHRONIC HIVES, SWELLING, CONSTIPATION/DIARRHEA, BLOATING, NAUSEA, FREQUENT URINATION/INCONTINENCE, NIGHT SWEATS, ANEMIA, UTIS (URINARY TRACT INFECTIONS), CANDIDA OVERGROWTH, DRY SKIN, EXCESSIVE HAIR LOSS, FOUL DISCHARGE, BLEEDING BETWEEN CYCLES, DIZZINESS, LEG/FOOT SWELLING, PELVIC PAIN/SPASMS/TWITCHING, LOW LIBIDO, BODY ACHES, LOW ENERGY, MEMORY LOSS, DIMINISHED BRAIN FUNCTION, SLEEP DISRUPTIONS. SHE STATED THAT SHE ADOPTED A HEALTHY LIFESTYLE AND DIET BUT HER SYMPTOMS WERE GETTING WORSE AND IT WAS GETTING DIFFICULT TO FEND OFF DEPRESSION. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 15-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE

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HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING PROLONGED PERIODS. SHE UNDERWENT AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION). CONSUMER ALSO REPORTED DIMINISHED BRAIN FUNCTION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. PROLONGED PERIODS IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENT IS UNLISTED. AFTER ESSURE INSERTION MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN PROLONGED PERIODS AND ESSURE CANNOT BE EXCLUDED. CONSIDERING THE NATURE OF THE EVENT DIMINISHED BRAIN FUNCTION AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS PERFORMED (ENDOMETRIAL ABLATION). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01629	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1681, AWARENESS DATE 23-OCT-2015) WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. ADDITIONAL INFORMATION RECEIVED ON 15-NOV-2015 (PTC INVESTIGATION RESULT). THE CONSUMER REPORTED ON (B)(6) 2011, SHE WAS AN EXTREMELY HEALTHY WOMAN AND NEVER HAD ANY ILLNESS. SHE STATED ONE MORNING SHE WAS HER WAY TO WORK AND BECOME VERY WEAK, SHE COULD NOT WALK AND WAS FEELING VERY SICK. SHE REPORTED HER HANDS AND FEET STARTED TO TURN A BLK /BLUE (RAYNAUDS SYNDROME) AND STARTED WITH COLD CHILL SWEATS FEVER. SHE BEGAN TO HAVE PROBLEMS BREATHING AND WAS TAKEN TO ER, WITHIN HOURS HER RESPIRATORY SYSTEM SHUT DOWN AND BECOME UNRESPONSIVE, SHE WAS PUT ON LIFE SUPPORT AND PUMPED LARGE AMOUNTS OF STEROIDS FOR AN INFECTIOUS DISEASE, AND SHE STATED A PHYSICIAN SAVED HER LIFE. SHE STAYED IN THE HOSPITAL FOR A MONTH AND WAS RELEASED WITH NO ANSWERS THEY HAD NO IDEA WHY THIS HAPPENED. SHE WAS UNABLE TO WALK DUE TO MUSCLE WEAKNESS FOR 5 TO 6 MONTHS. SHE WENT TO A RHEUMATOID SPECIALIST BECAUSE THEY KNEW THAT SHE HAD RAYNAUDS SYNDROME. THE SPECIALIST DIAGNOSED HER WITH AN AUTOIMMUNE DISEASE CALLED VASCULITIS, SHE WAS PUT ON CHEMO ONCE A WEEK FOR THE PAST 4 YEARS ONCE WEEKLY (METHOTREXATE, PREDNISONE) AND RECENTLY SHE HAD DEVELOPED A GLUTEN, WHEAT, MILK, EGG, PEANUT, SOY AND SHRIMP ALLERGY, WHEN SHE HAD EATEN ALL THESE FOODS HER WHOLE LIFE. SHE ALSO HAS HAD TO CHANGE HER TOILET PAPER SHAMPOO DEODORANT BECAUSE SHE ALSO DEVELOPED AN ALLERGY TO CERTAIN CHEMICALS. SHE WAS HAVING PROBLEMS WITH HER CYCLE, SHE WAS NOT HAVING ONE. SHE WENT

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TO HER GYNECOLOGIST WHICH HE WAS AWARE OF ALL MEDICATION AND THE REASON SHE WAS PUT ON ALL THESE MEDICATION, SHE ALSO LET HIM KNOW SHE HAD A TERMINAL AUTOIMMUNE DISEASE. SHE ASKED HIM IF HE THOUGHT IT HAD TO DO WITH THE ESSURE AND HE SAID NO, SHE STATED HE NEVER MENTIONED TO HER ALL THIS THAT WAS GOING ON WITH THE ESSURE. SHE REPORTED SHE HAS NICKEL ALLERGY EVER SINCE SHE WAS A LITTLE GIRL AND WAS NOT TESTED BEFORE THE ESSURE PROCEDURE. SHE ALSO REPORTED BEING TREATED FOR FIBROMYALGIA BECAUSE OF THE PAIN SHE WAS HAVING IN HER LEGS. SHE ALSO HAD MANY OTHER SIDE EFFECTS: PAIN, EXTREME FATIGUE, HEADACHES SHE HAD TO GO INTO THE HOSPITAL AND BE GIVEN MORPHINE BECAUSE THE PAIN WAS INTOLERABLE. SHE HAD ELEVATED BLOOD COUNTS AND RECENTLY JUST FOUND OUT ABOUT THIS AND ALL THAT HAS BEEN GOING. SHE STATED SHE WILL BE CALLING HER GYNECOLOGIST AND HAVING THEM REMOVE THE ESSURE THE FIRST AVAILABLE; SHE STATED SHE TRULY BELIEVE ALL THIS IS BECAUSE OF THE ESSURE. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ARTY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEADACHES AND HAD TO GO INTO THE HOSPITAL AND BE GIVEN MORPHINE BECAUSE THE PAIN WAS INTOLERABLE. SHE STATED SHE WILL BE CALLING HER GYNECOLOGIST AND HAVING THEM REMOVE THE ESSURE THE FIRST AVAILABLE; SHE STATED SHE TRULY BELIEVE ALL THIS IS BECAUSE OF THE ESSURE. THIS EVENT WAS CONSIDERED SERIOUS DUE TO HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP AND BASED ON THE NATURE OF THE EVENT, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT CONCLUDED THAT NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

CORRECTION ON 30-NOV-2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT A GLUTEN, WHEAT, MILK, EGG, PEANUT, SOY AND SHRIMP ALLERGY WAS SPLIT TO MEDDRA LLT GLUTEN SENSITIVITY, AND MEDDRA LLT MILK ALLERGY AND MEDDRA LLT FOOD ALLERGY. COMPANY CAUSALITY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01630	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2004
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE NUMBER FDA-2014-N-0736-1509 AND CASE NUMBER MW5057184) IN UNITED STATES ON 23-OCT-2015 IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO RECEIVED ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN 2004. ADDITIONAL INFORMATION RECEIVED ON 05-NOV-2015 AND 15-NOV-2015 (PTC INVESTIGATION RESULT). CONSUMER STATED THERE ARE SO MANY HORRIBLE SIDE EFFECTS, EVEN AFTER REMOVAL. SHE WAS IMPLANTED IN 2004, HAD HYSTERECTOMY INCLUDING CERVIX REMOVAL IN 2011. AFTER ESSURE WERE IMPLANTED, SHE EXPERIENCED REPEAT INFECTIONS, EXTREMELY PAINFUL INTERCOURSE WITHIN 6 MONTHS, REPEAT AND MULTIPLE OVARIAN CYSTS (WITH NO PRIOR HISTORY OR PROBLEMS), BLOOD FILLED MASS ON OVARY, SWOLLEN INTESTINES, SWOLLEN LYMPH NODES IN INTESTINES, IRRITABLE BOWEL SYNDROME (IBS), ACID-REFLUX, HAD COLONOSCOPY AND ENDOSCOPY (THROAT SCOPE). SHE HAD ESSURE FOR 7 YEARS FOUR YEARS AGO, SHE BEGAN HAVING HORRIBLE PAIN UNDER HER BREASTBONE WAKING HER UP FROM A DEAD SLEEP. THE TIME THEY FIGURED OUT THE PROBLEM, SHE WAS SEPTIC AND HAD TO HAVE EMERGENCY GALLBLADDER SURGERY. SHE HAD TO STAY 4 DAYS IN THE HOSPITAL DUE TO INCREASING INFECTION. HER IMMUNE SYSTEM WAS SHOT WHICH LEAD TO PRECANCEROUS CELLS ON CERVIX THAT RAPIDLY PROGRESSED, SO SHE HAD TO HAVE A HYSTERECTOMY AND CERVIX REMOVED. SHE HAS CONTINUED TO DETERIORATE. SHE HAS HIGH BLOOD PRESSURE, SEVERE TOOTH DECAY, ANXIETY, DEPRESSION, BOUTS OF SUICIDAL (DEPRESSION SUICIDAL), SEVERE ABDOMINAL PAIN AND EXTREME BLOATING, JOINT PAIN/STIFFNESS, LOSING HER HAIR, EXTREME BRAIN FOG AND MEMORY LOSS, MEMORY ISSUES,

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UNEXPLAINED SWELLING IN HANDS, ARM, SHOULDER, FEET, LEGS AND HEADACHES/MIGRAINES. SHE ALSO EXPERIENCED STOMACH CRAMPING, EXTREME CRAMP/ PAINS IN OVARIES AND ABDOMINAL AREA, CHRONIC EXTREME FATIGUE, MOOD DISORDER AND SEVERE MOOD SWINGS WITH SNAPPINESS, BRUISING, PROLONGED HEALING, THYROID ISSUES THAT ARE DEBILITATING ON TOP OF ALL OTHER ISSUES. SHE HAS LOST HERSELF AND BEEN BLOWN OFF BY DOCTORS. SHE IS SURE SHE IS FORGETTING TO LIST OTHER PROBLEMS AS WELL SHE JUST HAVE A HARD TIME EVEN FUNCTIONING ANYMORE AND HER MEMORY IS SHOT. THE HARDEST PART IS WATCHING HER CHILDREN AND HUSBAND SEE SHE SUFFERING, DAY AFTER DAY AND LOSING HERSELF MORE AND MORE AND 95% OF HER LIFE AT THIS POINT IS IN HER BED. SHE HAS FORGOTTEN WHAT IT FEELS LIKE TO BE OK. SHE JUST TURNED (B)(6) AND FEELS LIKE DECADES ADDED TO THAT NUMBER AND ONLY GETTING WORSE. SHE NEVER HAD ANY OF THIS UNTIL ESSURE AND SHE KNOWS SHE IS FORGETTING OTHER ISSUES. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ARTY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED REPEATED INFECTIONS AFTER ESSURE WERE IMPLANTED. A HYSTERECTOMY WAS PERFORMED AND DEVICE WAS REMOVED. THIS EVENT, INTERPRETED AS PELVIC INFECTIONS, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS CASE, IT WAS REPORTED THAT THIS EVENT OCCURRED AFTER ESSURE INSERTION. ALTHOUGH IT WAS UNKNOWN WHETHER THIS EVENT OCCURRED UP TO 4 WEEKS POST INSERTION, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE FORMALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND SEVERAL NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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CORRECTION ON 30-NOV-2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT SWELLING IN HANDS, ARM, SHOULDER, FEET, LEGS WAS SPLIT TO MEDDRA LLT SWELLING OF LIMBS AND MEDDRA LLT JOINT SWELLING; THE EVENT REPEAT AND MULTIPLE OVARIAN CYSTS WAS RECODED TO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01631	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 8/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1465, AWARENESS DATE 23-OCT-2015). IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED ON 16-NOV-2015 (PTC INVESTIGATION RESULT). THE PATIENT REPORTED SHE WAS A NURSE. SHE DECIDED TO HAVE ESSURE IMPLANTED ON (B)(6) 2015 (DISCREPANT INFORMATION PROVIDED). HOWEVER, IT IS NOW KNOWN THAT, SINCE SHE HAD ONLY 1 FALLOPIAN TUBE, THAN THIS IMPLANT PROCEDURE WAS A CONTRAINDICATION AND IT NEVER SHOULD HAVE OCCURRED. SHE WAS IMPLANTED WITHOUT ANAESTHETIC IN THE OFFICE OF HER PHYSICIAN. FOR SEVERAL MONTHS AFTER RECEIVING THE IMPLANT, SHE DID SEE HER PRACTITIONER FOR CONTINUAL CRAMPING PAIN AND ABNORMAL PERIODS. OVER THE NEXT SEVERAL YEARS, SHE SUFFERED DEBILITATING SYMPTOMS INCLUDING EXTREME CRAMPING DURING MENSTRUATION, HEAVING BLESSING, IRREGULAR PERIODS, HORRIFIC DAILY MUSCLE PAIN, CONSTANT BACK PAIN, EXTREME FATIGUE, COGNITIVE DIFFICULTIES, SWALLOWING DIFFICULTIES, TMJ, TOOTH DECAY, MEMORY LOSS, INFERTILITY, AND A LOSS OF LIBIDO. SHE WAS DIAGNOSED WITH CHRONIC BACK PAIN AND FIBROMYALGIA, AND DEPRESSION. BECAUSE OF THIS CHRONIC PAIN AND DEBILITATING DIAGNOSES, SHE WAS FIRED FROM HER EMPLOYER BECAUSE SHE COULD NOT PERFORM HER DUTIES AS ASSIGNED. FOR THE PAST 3 YEARS, SHE HAS WORKED 1 COMPLETE YEAR, WITH OTHER YEARS SUFFERING IN IMMENSE PAIN. SHE HAS BEEN ON SEVERAL MEDICATIONS, WHICH CAUSED HER NUMEROUS SIDE EFFECTS. ON (B)(6) 2015, SHE HAD A HYSTERECTOMY TO REMOVE ESSURE AND A MASS ON HER OVARY BELIEVED TO CANCEROUS. FORTUNATELY IT WAS BENIGN. HER SYMPTOMS SINCE THE HYSTERECTOMY HAVE IMPROVED, THEREFORE,

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LENDING HER TO THE CONCLUSION THAT ESSURE MIGHT HAVE POTENTIALLY BEEN CAUSING MANY OF THESE DIAGNOSES AND MEDICAL SYMPTOMS. SHE FELT LIKE SHE HAS LOST 8 YEARS OF LIFE, BEING UNEMPLOYED, NOT BEING ABLE TO SOCIALIZE WITH FRIENDS AND FAMILY, CONSTANTLY BEING SICK AND IN PAIN, AND LOSING PRECIOUS TIME WITH HER ONLY SON. THOSE YEARS COULD NEVER BE GIVEN BACK AND THEY WERE GONE. SHE HAD A HYSTERECTOMY TO REMOVE ESSURE. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING PAIN, SUFFERING IN IMMENSE PAIN (SEEN AS ABDOMINAL PAIN). SHE HAD A HYSTERECTOMY TO REMOVE ESSURE. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON ITS NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. ADDITIONALLY, OTHER SERIOUS EVENT (UNLISTED AND UNRELATED) AND SEVERAL NON-SERIOUS EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01632	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/7/2014
Explant Date (E7): 9/12/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056638) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2014 AFTER SHE HAD HER DAUGHTER. SHE EXPERIENCED HEAVY BLEEDING AND SEVERE STOMACH CRAMPING FOR ABOUT 6 MONTHS. ON (B)(6) 2014 SHE HAD TO GET A HYSTERECTOMY DUE TO THE PROCEDURE. HOSPITALIZATION, REQUIRED INTERVENTION, AND OTHER SERIOUS (IMPORTANT MEDICAL EVENT) WERE MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 15-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE UNDERWENT A HYSTERECTOMY 5 MONTHS AFTER ESSURE INSERTION. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENT WAS ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: ATTEMPTS OF FOLLOW-UP WERE MADE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION I

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01633	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE NUMBER (B)(4), AWARENESS DATE 23-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. CONSUMER WAS TOLD THAT ESSURE WOULD BE GREAT FOR HER WITH NO RECOVERY TIME, NO HORMONES OR SIDE EFFECTS. SHE WAS WALKED THROUGH THE PROCEDURE AND TOLD THAT WAS 2 METAL COILS, NOTHING ABOUT NICKEL WAS MENTIONED. SINCE THEN SHE HAS EXPERIENCED FORGETFULNESS, MOOD SWINGS, MEMORY LOSS, EXTREME FATIGUE, NO SEX DRIVE, HEADACHES, METAL TASTE IN HER MOUTH AND HAIR LOSS. THE MOST PAINFUL SIDE EFFECT FOR HER WAS THE NEVER ENDING PERIODS WITH PENNY SIZE BLOOD CLOTS AND THE EXTREME PELVIC PAIN THAT IS BEST DESCRIBED AS BEING IN HARD ACTIVE LABOR AND TRYING TO LIVE LIFE DAY TO DAY. SHE IS IN CONSTANT PAIN ALL THE TIME. AS A RESULT OF ESSURE SHE WILL BE HAVING SURGERY TO REMOVE TUBES WITH COILS FULLY INTACT IN (B)(6). PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 15-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXTREME PELVIC PAIN, CONSTANT PAIN ALL THE TIME. SHE WILL BE HAVING SURGERY TO REMOVE HER TUBES AND COILS. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01634	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): P40241 (INVALID)

Single Use: Y
Implant Date (E6): 4/20/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# MW5056608) IN UNITED STATES ON 23-OCT-2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER P40241 (EXPIRATION DATE 20-JUN-2015) INSERTED IN (B)(6) 2014. ADDITIONAL INFORMATION RECEIVED ON 15-NOV-2015. IT WAS REPORTED THAT SINCE THE PROCEDURE WAS DONE THE CONSUMER HAD HEAVY BLEEDING TO THE POINT OF HEMORRHAGING. SHE BECAME PREGNANT AND HAD A DIFFICULT PREGNANCY SO SHE HAD TO SEE A SPECIALIST. AFTER DELIVERY OF HER DAUGHTER SHE HAD BLEEDING AND THE DOCTOR GAVE HER AN ABLATION. SHE ALSO HAD ABDOMINAL PAIN, CRAMPING, BACK PAIN, HEADACHES AND HOT AND COLD SPELLS. SHE WAS COMPLAINING OF FEELING DEPRESSED ABOUT THINGS GOING ON WITH ESSURE. EVEN AFTER ABLATION THE BLEEDING WAS RECURRING AND THE DOCTOR SAID SHE MIGHT NEED A HYSTERECTOMY. HOSPITALIZATION WAS MENTIONED AS EVENT OUTCOME BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 15-NOV-2015: PTC GLOBAL NUMBER: (B)(4). LOT NUMBER PROVIDED IS INVALID. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN

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THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO VALID BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AND DELIVERED AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE HAD HEAVY BLEEDING SINCE DEVICE PLACEMENT. AFTER HER DELIVERY SHE ALSO HAD BLEEDING AND HER PHYSICIAN SUBMITTED HER TO AN ABLATION. HOWEVER, HER BLEEDING WAS RECURRING. THESE EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING PREGNANCY NATURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING CONSUMER'S BLEEDING; AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER HAD BLEEDING REQUIRING AN ENDOMETRIAL ABLATION. IT IS UNCLEAR IF HER BLEEDING, WHICH REQUIRED THIS INTERVENTION, WAS RELATED TO A COMPLICATION OF DELIVERY. NEVERTHELESS, CONSIDERING EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. SINCE AN ABLATION WAS REQUIRED AS EVENTS TREATMENT, THIS CASE WAS CONSIDERED AN INCIDENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. NO FOLLOW-UP WILL BE POSSIBLE, DUE TO LACK OF CONTACT DETAILS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01635	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/9/2015
Explant Date (E7): 6/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1997, AWARENESS DATE 23-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. ADDITIONAL INFORMATION RECEIVED ON 15-NOV-2015 (PTC INVESTIGATION RESULT). THE CONSUMER REPORTED THAT HER FIRST DAUGHTER WAS BORN PREMATURE AND SHE WAS ON PROGESTERONE DURING THE ENTIRE SECOND PREGNANCY. SHE STATED THAT THE ESSURE INSERTION HURT LIKE HELL. SHE STARTED GETTING INSOMNIA AND HER HAIR STARTED COMING OUT MORE THAN USUAL. IN (B)(6) 2015 SHE STARTED GETTING HIVES ALL OVER THIGHS, AND THEN IT SPREAD TO STOMACH AREA. SHE SCRATCHED SO MUCH SHE ALMOST STARTED TO BLEED. SHE HAD TO STOP BREASTFEEDING HER DAUGHTER BECAUSE SHE WAS ON BENADRYL. AFTER HAVING HIVES FOR 3 WEEKS SHE DECIDED TO GO TO AN ALLERGIST AND FOUND OUT SHE WAS ALLERGIC TO NICKEL. ON (B)(6) 2015 SHE HAD ESSURE REMOVED. SHE HAD HER TUBES COMPLETELY REMOVED AND AFTER SHE WOKE UP FROM THE PROCEDURE SHE WAS TOLD THAT ONE OF THE COILS WAS INTACT AND THE OTHER WAS BEHIND UTERUS, COMPLETELY OUT OF HER TUBE. SHE WAS ALSO TOLD THAT WHEN TRYING TO PLACE THE COIL IN HER TUBE IT PREFERRED HER UTERUS AND HER TUBE/OVARY ACTUALLY SUCKED THE COIL AND THE DOCTOR HAD TO PULL IT OUT SO IT WOULD BE IN THE RIGHT SPOT. THAT WAS THE COIL FOUND BEHIND HER UTERUS. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ARTY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALLERGIC TO NICKEL. SHE HAD ESSURE REMOVED AND HAD HER TUBES COMPLETELY REMOVED. SHE WAS TOLD THAT ONE COIL WAS INTACT, THE OTHER WAS BEHIND UTERUS, COMPLETELY OUT OF TUBE (SEEN AS DEVICE DISLOCATION). BOTH EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN. BASED ON THEIR NATURE AND CONSIDERING THAT ALLERGY REACTION AND DEVICE DISLOCATION MAY OCCUR DURING ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01636	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 8/1/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1604, AWARENESS DATE 23-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. ADDITIONAL INFORMATION RECEIVED ON 15-NOV-2015. CONSUMER HAD ESSURE INSERTED IN LATE 2009. AFTER THIS SHE BEGAN TO EXPERIENCE EXTREME DAILY ABDOMINAL PAIN, INCREASE IN MENSTRUAL BLEEDING NOT THE AVERAGE 3-7 DAYS AND YOUR MENSTRUAL GETS LIGHT UNTIL END. SHE EXPERIENCED HEAVY BLEEDING FOR 2-3 WEEKS AT A TIME SOAKING OVERNIGHT PADS WITHIN A FEW HOURS. PRIOR TO THE ESSURE COILS BEING PLACED IN TUBES, SHE HAD REGULAR MENSTRUAL CYCLES. THIS WAS THE WORST EXPERIENCE EVER. THE ESSURE COILS RESULTED IN A PARTIAL HYSTERECTOMY (B)(6) 2010 AND 2 BLOOD TRANSFUSIONS DURING THIS SURGERY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 15-NOV-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED.

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THE REPORTED MEDICAL EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ABDOMINAL PAIN AND INCREASE IN MENSTRUAL BLEEDING (HEAVY BLEEDING FOR 2-3 WEEKS AT A TIME) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (APPROXIMATELY 1 YEAR AFTER DEVICE PLACEMENT). THE REPORTED EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENTS NATURE AND IN THE LACK OF ALTERNATIVE EXPLANATIONS, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01637	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2008
Explant Date (E7): 3/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008 AND THE DOCTOR DID NOT MANDATE HER TO DO A FOLLOW-UP DYE TEST TO CHECK IF THE ESSURE WAS PLACED PROPERLY. ADDITIONAL INFORMATION RECEIVED ON 14-NOV-2015 (PTC INVESTIGATION RESULT). CONCOMITANT MEDICATION INCLUDED VITAMIN D AND (B)(4). SHE HAS NEVER SMOKED AND WAS AN ACTIVE FEMALE WITH A HEALTHY DAUGHTER. THE PAIN ON HER RIGHT SIDE CONTINUED TO GET WORSE. SHE SWITCHED GYNECOLOGIST AND HAD AN ULTRASOUND THAT CONFIRMED HER RIGHT TUBE WAS NOT HAPPY AND HAD RED ALL OVER THE ULTRASOUND INDICATING AN ISSUE. IN 2011, THE DIAGNOSIS OF BLADDER CANCER WAS GIVEN. SHE WAS NOT SURE WHAT CAUSED THE BLADDER CANCER, BUT CANNOT RULE OUT ISSUES WITH ESSURE. TWO SURGERIES AND ONE INSTALLATION OF BCG TREATMENT. ON (B)(6) 2014, SHE UNDERWENT A HYSTERECTOMY. DURING HYSTERECTOMY, IT WAS DISCOVERED THAT THE RIGHT ESSURE DEVICE HAD MIGRATED OUT OF THE TUBE AND SHE ACTUALLY HAD 2 ESSURE DEVICES IN LEFT TUBE. ALSO SHE EXPERIENCED CHRONIC HEADACHES. HOSPITALIZATION WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO

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CONFIRM ARTY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ALL HER RIGHT TUBE WAS "NOT HAPPY" AND HAD RED OVER THE ULTRASOUND INDICATING AN ISSUE (SEEN AS FALLOPIAN TUBE DISORDER). A HYSTERECTOMY WAS PERFORMED AND DURING THE PROCEDURE, IT WAS DISCOVERED THAT RIGHT ESSURE DEVICE HAD MIGRATED OUT OF THE TUBE (SEEN AS DEVICE DISLOCATION). BOTH EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE TERM HOSPITALIZATION WAS ONLY MENTIONED AS EVENT OUTCOME AND THE REPORTER DID NOT SPECIFY IT. IN THIS CASE, IT WAS NOT CLEAR WHAT REALLY HAPPENED WITH CONSUMER'S FALLOPIAN TUBE. THE EXACT DATE AND MECHANISM OF DISLOCATION WERE ALSO NOT KNOWN. HOWEVER, CONSIDERING THAT ESSURE HAS A CONTRIBUTORY ROLE FOR THE OCCURRENCE OF THESE EVENTS, CAUSALITY CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 28-DEC-2015: CONSUMER QUESTIONNAIRE WAS RECEIVED. CONSUMER PROVIDED HER DEMOGRAPHIC INFORMATION. SHE DENIED PREVIOUS GYNECOLOGICAL PROCEDURES OR PROBLEMS. AT 2008/ 2009, ESSURE WAS INSERTED. SHE WAS AT 9-12 MONTHS POST-PA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01638	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1810, AWARENESS DATE 23-OCT-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED ON AN UNSPECIFIED DATE. SHE WAS 40 YEARS OLD AT THE TIME OF THE REPORT, AND LOST HER UTERUS AND BABY MAKING PARTS BECAUSE SHE WAS IMPLANTED WITH ESSURE, AND THE DEVICE FAILED HER. SHE EXPERIENCED MENOPAUSE AT THE AGE OF (B)(6), LOST HER LIBIDO, LOST HER HAIR, HAD PAINFUL SEX. SHE HAS HAD 3 SURGERIES: 1 TO REMOVE HER FALLOPIAN TUBES, 1 TO REMOVE THE REST BECAUSE THERE WERE PIECES OF ESSURE EMBEDDED IN UTERUS, AND HAD APPENDIX REMOVED. OVER THE COURSE OF 3 YEARS SHE UNDERWENT 3 SURGERIES. SHE HAD SCARS FROM MULTIPLE SURGERIES. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 15-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY

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DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PIECES OF ESSURE EMBEDDED IN HER UTERUS (INTERPRETED AS DEVICE BREAKAGE AND EMBEDDED DEVICE). SHE UNDERWENT SURGERY TO REMOVE IT. SHE ALSO REPORTED HAVING HER APPENDIX REMOVED. DEVICE EMBEDDED IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENTS ARE UNLISTED. DEVICE BREAKAGE WAS CONSIDERED LISTED UPON RECEIPT OF THE PRODUCT TECHNICAL ANALYSIS. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. THE EXACT DATE AND MECHANISM OF THE DEVICE BREAKAGE AND EMBEDMENT WERE NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THESE EVENTS CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. CONSIDERING THE NATURE OF THE EVENT APPENDIX REMOVED AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.:

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01639	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/30/2009
Explant Date (E7): 8/17/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5056191) IN UNITED STATES ON 23-OCT-2015 WHICH REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. ADDITIONAL INFORMATION RECEIVED ON 15-NOV-2015 CONSUMER HAD A HYSTERECTOMY ON (B)(6) 2015 AT AGE (B)(6), DUE TO ESSURE. SHE WAS ALWAYS IN SUFFERING VERY PAINFUL PERIODS, PAINFUL SEX, HEADACHES, LEFT LEG PAIN AND BODY RASHES. SINCE THE PHYSICIAN REMOVED ESSURE, SHE FEEL MUCH BETTER, WITH NO MORE PAIN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 15-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD VERY PAINFUL PERIODS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE

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DEVICE WAS REMOVED, APPROXIMATELY 6 YEARS AFTER ITS PLACEMENT, AND SHE HAD NO MORE PAIN. THIS EVENT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, CONSUMER RELATED HER PAIN TO ESSURE INSERTION AND STATED IT IMPROVED AFTER DEVICE REMOVAL. CONSIDERING THIS INFORMATION AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. NO FOLLOW-UP WILL BE PURSUED DUE TO LACK OF CONTACT INFORMATION.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01640	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/30/2009
Explant Date (E7): 8/17/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5036615) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. ADDITIONAL INFORMATION RECEIVED ON 15-NOV-2015. SHE STATED THAT SHE HAD 2 CHILDREN. ESSURE WAS IMPLANTED IN 2010. AFTER THE PROCEDURE WAS DONE, HER DOCTOR TOLD HER THAT ONE WAS SUCCESSFULLY IMPLANTED AND THE OTHER WAS NOT (SHE COULD NOT REMEMBER ABOUT WHETHER IT WAS LEFT OR RIGHT). SHE ASKED WHAT WE COULD DO ABOUT IT AT THAT TIME AND SHE STATED NOTHING. SHE SCHEDULED FOR HER TO HAVE LAPAROSCOPIC TUBAL LIGATION A FEW MONTHS LATER AND IT WAS DONE. EVER SINCE 2010, SHE HAD BEEN EXPERIENCING BAD ABDOMINAL CRAMPS, ESPECIALLY AROUND HER CYCLE TIMES (BEFORE ESSURE, SHE RARELY EVER HAD A MENSTRUAL CRAMP). HER CYCLES POST ESSURE WERE ALSO CLOTTY. UNFORTUNATELY, HER PAIN KEPT GETTING WORSE INSTEAD OF BETTER. SHE STARTED REQUIRING TAKING PAIN MEDICATION DURING HER CYCLES(OXYCODONE). THIS PROGRESSED TO PAIN MEDICATION NEEDING TO BE TAKEN MORE OFTEN (NOT JUST AROUND CYCLE TIMES) BECAUSE HER PELVIC/ABDOMINAL PAIN KEPT INCREASING. HER PAIN PROGRESSED TO WHERE SHE REQUIRED BED REST A LOT IN THE EVENINGS AFTER WORKING BECAUSE HER PAIN KEPT GETTING WORSE. FAST FORWARD TO PRESENT DAY, HER LAST THREE CYCLES HAD BEEN EXTREMELY PAINFUL WITH ONGOING PELVIC PAIN THAT HAS NOT CEASED; HER LEFT SIDE HAS ALWAYS BEEN MORE PAINFUL THAN RIGHT, BUT RIGHT SIDE WAS DEFINITELY PAINFUL TOO. SHE ALSO HAD LEFT LEG PAIN FROM THIGH TO ANKLE. RECENTLY, HER LEFT THIGH STARTED TO SWELL. SHE IMMEDIATELY CALLED THE DOCTOR AND SHE WAS ABLE TO SEE HER THE SAME DAY. SHE TOLD HER ABOUT ALL OF HER PAIN, INCLUDING HER LEG PAIN AND SWELLING AND SHE STATED THAT SHE DID NOT THINK THAT THE LEG PAIN WAS RELATED. SHE TOLD HER THAT SHE THOUGHT IT WAS RELATED BECAUSE

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EVERY TIME THAT HER PELVIC PAIN THROBS, IT RADIATED TO HER THIGH. THEY DID AN ULTRA-SOUND AND SAW THAT THE RIGHT COIL WAS IN PLACE AND THE LEFT COIL COULD NOT BE SEEN, SHE HAS BEEN SCHEDULED FOR SOME PRE-OP WORKUP AND WILL HAVE SURGERY ON (DATE UNREADABLE). OTHER SIDE EFFECTS TO LIST: INTERMITTENT BLURRY VISION, BLOATEDNESS, INTERMITTENT NUMBNESS/TINGLENESS IN ARMS, FINGERS OFTEN SWELL OVERNIGHT AND MEMORY LOSS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 15-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO WAS EXPERIENCING PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, AT THE TIME OF ESSURE PROCEDURE ONE SIDE WAS NOT SUCCESSFULLY IMPLANTED. YEARS LATER, AN ULTRASOUND SCAN WAS PERFORMED AND THE LEFT COIL COULD NOT BE SEEN (REGARDED AS DEVICE DISLOCATION). ACCORDING TO HER, A SURGERY WAS THEN SCHEDULED. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A FALLOPIAN TUBE PERFORATION DURING INSERTION. DEVICE MOVEMENT CAN RESULT IN PELVIC PAIN AND MENSTRUAL DISTURBANCES. IN THIS CASE, CONSUMER STATED PHYSICIAN HAD DIFFICULTIES IMPLANTING THE DEVICE IN ONE SIDE. THIS SUGGESTS AN ASSOCIATION BETWEEN THE REPORTED DISLOCATION AND ESSURE PROCEDURE. THEREFORE, CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. NO FOLLOW-UP CAN BE PURSUED, DUE TO LACK OF CONTACT DETAILS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01641	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/28/2013
Explant Date (E7): 11/5/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056247) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. ADDITIONAL INFORMATION RECEIVED ON 15-NOV-2015 (PTC INVESTIGATION RESULT). AFTER HER SON WAS BORN IN 2012, SHE WAS BACK IN HER CLOTHES BY 2013. WHEN SHE WENT BACK TO WORK, ESSURE PROCEDURE DONE ON 2013, SET OFF STORE ALARMS GOING IN AND COMING OUT OF 3 DIFFERENT STORES WITHIN A WEEK OF PROCEDURE, UNABLE TO FIT IN CLOTHES BY 2013 (WHILE STILL BREAST FEEDING AND EXERCISING MUCH MORE THAN SHE HAD WHILE ON MATERNITY LEAVE. SHE WENT BACK 90 DAYS LATER FOR TEST AND ONE SIDE WAS FINE BUT LEFT SIDE WAS NOT, WAS TOLD SHE NEEDED TO COME BACK TO 90 DAYS. DURING THE SUMMER OF 2014, SHE BEGAN HAVING SEVERE DIZZINESS AND STARTED GETTING CAR SICK EVEN WHILE DRIVING, ALSO NOTICED TINGLING IN FINGERS AND TOES; HAD SOME OF THAT WHILE SHE WAS PREGNANT WITH HER SON AND IT FELT VERY SIMILAR. WENT BACK IN 2013, LEFT SIDE WAS STILL NOT BLOCKED, HER PHYSICIAN WANTED TO DO A TUBAL ON THAT SIDE. CONSUMER ASKED HER IF THE COIL COULD BE REMOVED SINCE SHE DID NOT WANT A FOREIGN OBJECT IN HER BODY THAT WAS NOT WORKING. SHE HAD BOTH FALLOPIAN TUBES REMOVED IN 2013. SHE FELT BETTER INSTANTANEOUSLY ONCE THEY WERE REMOVED. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE

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WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ARTY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ONE SIDE WAS FINE BUT LEFT SIDE WAS NOT/ LEFT SIDE WAS STILL NOT BLOCKED. SHE HAD BOTH FALLOPIAN TUBES REMOVED. THIS EVENT WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS REPORTED THAT AFTER ESSURE INSERTION, LEFT FALLOPIAN TUBE WAS NOT BLOCKED. A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. CONSIDERING THAT SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01643	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1837, AWARENESS DATE 23-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. SHE HAD ISSUES WITH PROLONGED HEAVY BLEEDING AND FIBROIDS AND WAS HOSPITALIZED IN 2010. FLASH FORWARD A YEAR AND SHE HAD AN ABLATION, TVT (TRANSVAGINAL TAPE) SLING PROCEDURE AS WELL AS THE ESSURE PROCEDURE DONE THROUGH IN 2011. POST-SURGERY, EVERYTHING WAS FINE FOR ABOUT A YEAR. SHE STARTED EXPERIENCING RECURRING RASHES IN VARIOUS PLACES ON BODY, EXCRUCIATING PERIODS ACCOMPANIED BY NUMBNESS AND TINGLING IN EXTREMITIES AND WEIGHT GAIN. WHEN THIS STARTED HAPPENING, SHE FOLLOWED UP WITH HER PRIMARY CARE PROVIDER TO GET TO THE BOTTOM OF WHAT WAS GOING ON. SHE DID NOT KNOW IF ANY OF THE PROCEDURES SHE HAD WERE CAUSING THIS. SHE HAD SEVERAL TESTS DONE TO INCLUDE CT SCAN, MRI, X-RAY AND NONE OF THESE TEST REVEALED ANYTHING AND THE PAIN CONTINUED. THE DOCTOR PRESCRIBED HER SOME PAIN MEDS AND REFERRED HER TO A GYN. THE GYN GAVE HER BIRTH CONTROL PILLS TO STOP THE BLEEDING AND MORE PAIN MEDS. DURING THIS TIME THE BLEEDING, NUMBNESS AND TINGLING IN HER EXTREMITIES, RASHES, AND PAIN BECAME UNBEARABLE AND GOT WORSE. IT WAS DURING THESE VISITS THAT HER DOCTOR SUSPECTED THAT SHE HAD POST TUBAL LIGATION SYNDROME ALONG WITH FIBROIDS, AND HEAVY BLEEDING. SHE STILL COULD NOT DETERMINE WHY THE NUMBNESS AND TINGLING HAD OCCURRED. SHE RECOMMENDED A HYSTERECTOMY. AS OF (B)(6) 2015 SHE WAS AWAITING APPROVAL ON HER SURGERY. THIS PROCEDURE CAUSED A LOT OF HEARTACHE AND PAIN. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED,

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SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD BLEEDING AND PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, HER DOCTOR SUSPECTED SHE HAD POST TUBAL LIGATION SYNDROME ALONG WITH FIBROIDS. A HYSTERECTOMY WAS PLANNED. POST TUBAL LIGATION SYNDROME IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE BLEEDING (REGARDED AS GENITAL BLEEDING) IS LISTED. HEAVIER AND MORE PROLONGED MENSTRUAL BLEEDING AND INCREASED DYSMENORRHEA HAVE BEEN REPORTED AFTER FEMALE STERILIZATION. ADDITIONALLY, WOMEN WITH A HISTORY OF TUBAL STERILISATION WHO UNDERGO ENDOMETRIAL ABLATION MAY SUFFER FROM POST-ABLATION TUBAL STERILIZATION SYNDROME. IN THIS PARTICULAR CASE, CONSUMER HAD A PREVIOUS HISTORY OF FIBROIDS AND HEAVY BLEEDING. SHE HAD ESSURE INSERTED AND AN ENDOMETRIAL ABLATION PERFORMED IN THE SAME YEAR. HER PREVIOUS UTERINE FIBROIDS COULD BE AN ALTERNATIVE EXPLANATION FOR HER BLEEDING AND ALSO THE LIKELY INDICATION FOR THE REPORTED HYSTERECTOMY. HOWEVER, ALTHOUGH CONSUMER DID NOT RELATE THE PERFORMED ENDOMETRIAL ABLATION TO HER POST TUBAL LIGATION SYNDROME; SINCE PERFORMING ENDOMETRIAL ABLATION FOLLOWING ESSURE INSERT PLACEMENT MAY INCREASE THE RISK OF POST-ABLATION TUBAL STERILIZATION SYNDROME; A CONTRIBUTORY ROLE OF THE SUSPECT INSERT IN CONSUMER'S SYMPTOMS CANNOT BE TOTALLY EXCLUDED. AS ACCORDING TO THE REPORT, THE HYSTERECTOMY IS PLANNED ALSO AS TREATMENT FOR CONSUMER'S POST TUBAL LIGATION SYNDROME; THIS CASE WAS CONSIDERED AN INCIDENT (SURGICAL INTERVENTION WILL BE REQUIRED). IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 06-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01644	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/12/2012
Explant Date (E7): 6/21/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5056664) IN UNITED STATES ON 23-OCT-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6)-2012. SHE REPORTED ESSURE COILS WERE SCHEDULED TO BE INSERTED IN (B)(6)-2012, URINE TEST AT THE HOSPITAL FOR PREGNANCY BEFORE PROCEDURE WERE NEGATIVE. THE PROCEDURE CONTINUED AS SCHEDULED. TWO WEEKS LATER, SHE BEGAN TO FEEL ILL ALL THE TIME AND THOUGHT MAYBE SHE WAS HAVING A REACTION TO THE COILS, SO SHE WENT BACK TO HER DOCTOR TO BE CHECKED OUT AND FOUND OUT THAT SHE WAS (B)(6) WEEKS PREGNANT. IMMEDIATELY SHE ASKED ABOUT THE COILS AND IF THEY WOULD IN ANY WAY HAVE ANY TYPE OF EFFECT ON HER PREGNANCY, SHE WAS TOLD THAT HER COILS WOULD BEND OUT OF THE WAY AND THEY WOULD NOT CAUSE ANY HARM TO THE PREGNANCY. SHE STATED SHE WAS AT (B)(6) WEEKS WHEN SHE GOT UP IN THE MORNING TO GO TO THE RESTROOM, AS SHE CLIMBED OVER HER HUSBAND, THERE WAS A LOUD, POPPING SOUND, LIKE A BALLOON. SHE REPORTED IT FELT WEIRD IN HER STOMACH SO SHE DID NOT MOVE; AFTER A FEW SECONDS SHE GOT OFF THE BED AND IMMEDIATELY HAD WATER TRICKLING DOWN HER LEGS. SHE PANICKED AND WENT TO THE ER AND WAS GIVEN A FERNING TEST TO SEE IF SHE WAS LEAKING AMNIOTIC FLUID AND THE TEST CAME BACK NEGATIVE. SHE WAS SENT HOME AND WAS BACK AGAIN THE NEXT DAY, STILL LEAKING, ANOTHER TEST, NO FERNING, AND WAS SENT HOME. SHE RETURNED AGAIN 2 DAYS LATER WITH CRAMPING AND FLUID LOSS STILL, AN ULTRASOUND WAS PERFORMED AND WAS FOUND TO HAVE AN AMNIOTIC LEVEL OF 10, THE NORMAL IS AROUND 14. A CERCLAGE WAS PLACED TO TRY AND SAVE THE PREGNANCY. AN ULTRASOUND 2 DAYS LATER REVEALED THAT HER FLUID LEVEL HAD DROPPED TO 4, AND THAT HER BABY WOULD NOT SURVIVE, AND BEING IN A CATHOLIC

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HOSPITAL THEY WOULD NOT REMOVE THE CERCLAGE TO PERFORM A D&C AND THAT WAS NOT WHAT SHE WANTED. SHE SIGNED OUT AND WAS ADMITTED TO ANOTHER HOSPITAL, THERE THE HIGH RISK TEAM ASSESSED HER AND DECIDED TO REMOVE THE CERCLAGE AND LET HER BODY DO THE REST. AS SHE WAS HAVING A PROCEDURE TO REMOVE THE CERCLAGE, WHICH WAS ONE OF THE MOST TRAUMATIZING THINGS SHE EVER HAD TO GO THROUGH, THE HIGH RISK DOCTOR PERFORMING THE PROCEDURE STOPPED ABRUPTLY AND SAID THE ESSURE COIL WAS IN HER VAGINAL TRACT, THE COIL HAD NEVER IMPLANTED IN FALLOPIAN TUBE AND WAS FLOATING AROUND INSIDE OF HER UTERUS HER WHOLE PREGNANCY. THE CONSUMER REPORTED THE COIL HAD PERFORATED THE AMNIOTIC SAC CAUSING IT TO RUPTURE AND CAUSING THE LOSS OF HER BABY. SHE WAS TOO FAR ALONG TO HAVE THE PREGNANCY REMOVED SO SHE HAD TO DELIVER HER ON HER OWN SHE GAVE BIRTH TO HER ON (B)(6)-2012 AND SHE LIVED FOR ALMOST 15 MINUTES. BABY'S CASE WAS REPORTED UNDER REFERENCE (B)(4). THE CONSUMER STATED SHE SUFFERS FROM PTSD (UNDERSTOOD AS POST TRAUMATIC STRESS DISORDER) BECAUSE OF THE TRAUMATIZING NATURE IN WHICH THIS ALL HAPPENED. AN ESSURE EXPLANTED DATE WAS REPORTED AS (B)(6)-2012. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AFTER GETTING PREGNANT (WHICH IS A MEDICATION ERROR). SHE EXPERIENCED AMNIOTIC SAC TO RUPTURE / COIL HAD PERFORATED THE AMNIOTIC SAC AND PREMATURE LABOR. PREGNANCY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER EVENTS ARE UNLISTED. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, THE PREGNANCY WAS NOT A CONSEQUENCE OF LACK OF EFFICACY OF ESSURE, THEREFORE, CONTRACEPTIVE FAILURE CAN BE EXCLUDED. MOST OF PREMATURE BIRTHS OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES. IN THIS CASE, THE OCCURRENCE OF PREMATURE SEPARATION OF PLACENTA COULD BE A REASON FOR PREMATURE DELIVERY. IT WAS ALSO REPORTED THAT ESSURE COIL WAS IN HER VAGINAL TRACT AND HAD NEVER IMPLANTED IN FALLOPIAN TUBE AND WAS FLOATING AROUND INSIDE OF HER UTERUS HER WHOLE PREGNANCY, WHICH COULD BE THE CAUSE FOR THE OCCURRENCE OF PREMATURE SEPARATION OF PLACENTA. A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THIS CASE WAS THUS, CONSIDERED AN INCIDENT (SERIOUS INJURY). ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01645	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1780, AWARENESS DATE 23-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. ADDITIONAL INFORMATION RECEIVED ON 16-NOV-2015 (PTC INVESTIGATION RESULT). ESSURE WAS PLACED IN HER BODY IN 2011 AND SINCE THEN SHE HAS BEEN IN THE HOSPITAL. THEY SEND HER HOME WITH ANTIBIOTICS FOR WHOLE DIFFERENT REASON. HER CYCLES WERE EXTREMELY HEAVY AND LAST A LOT LONGER THAN THEY USED TO. SHE GOT REAL SHARP PAINS THAT SHOOT THROUGH HER LOWER ABDOMEN AND SHE GAINED A LOT OF WEIGHT. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN

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THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP PAINS THAT SHOOT THROUGH MY LOWER ABDOMEN. THIS EVENT IS SERIOUS SINCE IT RESULTED IN HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON ITS NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP IS IMPLIED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO HOSPITALIZATION REQUIRED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01646	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A78087

Single Use: Y
Implant Date (E6): 4/10/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE NUMBER MW5056707) IN UNITED STATES ON 23-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER A78087, INSERTED IN (B)(6) 2013, AFTER HER FOURTH CHILD. ADDITIONAL INFORMATION IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1754, AWARENESS DATE 24-OCT-2015). ADDITIONAL INFORMATION RECEIVED ON 16-NOV-2015 (PTC INVESTIGATION RESULT). THE CONSUMER REPORTED THAT THE SURGERY WENT WELL AND SHE WAS BACK TO WORK IN NO TIME. SHE STATED SHE DID HAVE A FOLLOW UP TO SHOW THAT HER TUBES WERE BLOCKED IN (B)(6) 2013 (UNSPECIFIED DATE). HOWEVER, THE AFTER-EFFECTS SINCE THEN HAD NOT BEEN SO GREAT. SHE EXPERIENCED WEIGHT GAIN WHICH SHE COULD NOT LOSE, HAIR LOSS EVERY DAY, BLOATING, DEPRESSION, WEAKNESS, AND HEAVIER PERIODS. SHE STATED SHE OPTED TO HAVE A THERMACHOICE SURGERY TO CORRECT THE HEAVY PERIODS, SINCE THE PHYSICIAN WOULD NOT PERFORM A HYSTERECTOMY. SHE ALSO REPORTED THAT SHE WAS WORKING OUT 5-6 DAYS A WEEK WITH CARDIO AND WEIGHT TRAINING AND IT HURT SO BADLY. IT FELT LIKE HER TUBES WERE BEING PULLED OUT OF HER BODY WITH THE WEIGHT TRAINING. SHE WOULD GO BACK TO HER PHYSICIAN TO TRY AND HAVE ESSURE REMOVED FROM HER BODY. THE CONSUMER CONSIDERED THE EVENTS AS A SERIOUS INJURY. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED

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AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVIER PERIODS. SHE OPTED TO HAVE A THERMACHOICE SURGERY TO CORRECT IT. SHE ALSO REPORTED THAT SHE WAS WORKING OUT 5-6 DAYS A WEEK WITH CARDIO AND WEIGHT TRAINING AND IT HURTS SO BADLY (FELT LIKE HER TUBES WERE BEING PULLED OUT OF HER BODY WITH THE WEIGHT TRAINING) (SEEN AS ADNEXA UTERI PAIN). SHE WOULD GO BACK TO HER PHYSICIAN TO TRY AND HAVE ESSURE REMOVED FROM HER BODY. THESE EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THEIR NATURE AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL PROCEDURE WAS PERFORMED TO CORRECT THE HEAVY PERIODS AND ALSO SINCE A DEVICE REMOVAL IS REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

CORRECTION (23-OCT-2015) FOLLOWING COMPANY INTERNAL REVIEW (PTC ASSESSMENT UPDATED) AND FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: THE CORRECT PTC INVESTIGATION RESULT RECEIVED WAS: LOT NUMBER A78087 (PRODUCTION DATE DEC-2012; EXPIRATION DATE 31-DEC-2

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01647	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 8/14/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE MW5056804) IN UNITED STATES ON 23-OCT-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. ADDITIONAL INFORMATION RECEIVED ON 16-NOV-2015. CONSUMER REPORTED SHE HAD ESSURE IMPLANTED AFTER THE BIRTH OF HER DAUGHTER. SUBSEQUENT TO THE IMPLANTS BEING PLACED, SHE EXPERIENCED NEW INEXPLICABLE SKIN ALLERGIES (SHE IS NOT ALLERGIC TO NICKEL), UNEXPLAINED FATIGUE, INCREASED MIGRAINE, MORE PAINFUL/ HEAVIER PERIODS AND DEBILITATING PELVIC PAIN. AFTER MANY ROUNDS OF TESTING THROUGHOUT 7 YEARS SHE HAD THE IMPLANT, HER PHYSICIAN DECIDED TO REMOVE THE ESSURE IMPLANTS. SHE HAD IT REMOVED ON (B)(6) 2015. ALL THE SIDE EFFECTS SHE EXPERIENCED HAVE ABATED. SHE BELIEVES THAT THE ESSURE IMPLANTS WERE THE CAUSE OF HER PAIN AND UNEXPLAINED MEDICAL ISSUES. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 16-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY

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DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICE WAS REMOVED (7 YEARS AFTER ITS PLACEMENT) AND SHE RECOVERED FROM THIS EVENT. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. PELVIC MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED (NO ALTERNATIVE EXPLANATIONS AVAILABLE). NEVERTHELESS, CONSIDERING EVENTS NATURE AND AS IT RECOVERED AFTER DEVICE REMOVAL; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01648	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/23/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056711) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. ADDITIONAL INFORMATION RECEIVED ON 16-NOV-2015 (PTC INVESTIGATION RESULT). ON (B)(6) 2009, ESSURE WAS INSERTED. WHEN SHE WENT BACK FOR HER TEST (HYSTEROSALPINGOGRAM) TO MAKE SURE TUBES WERE FULLY OCCLUDED, IT WAS DETERMINED THAT ONE OF THE COILS MIGRATED OUT OF FALLOPIAN TUBE AND EMBEDDED IN UTERUS. HER DOCTOR SAID IT WAS NOT A PROBLEM TO LEAVE THE COIL IN UTERUS AND A DATA WAS SET TO REDO THE FALLOPIAN TUBE THAT WAS MISSING THE COIL. SHE WENT BACK IN 2010 AND HAD THE SECOND COIL REPLACED. WHEN SHE WENT BACK FOR 2ND HYSTEROSALPINGOGRAM, BOTH TUBES WERE FULLY OCCLUDED. BEGINNING IN THE SPRING OF 2010 AND CONTINUING FOR MORE THAN A YEAR, SHE EXPERIENCED INTERMITTENT PAIN AND CRAMPING ON LEFT SIDE, SOME DAYS IT WAS SO PAINFUL, SHE WAS BEDRIDDEN AND HAD TO TAKE PAINKILLERS, THE PAIN WAS DEBILITATING AND LEFT HER UNABLE TO PROPERLY CARE FOR HER 3 CHILDREN. OVER THE SUMMER 2011, SHE HAD SURGERY AND SIGNED OFF ON 5 DIFFERENT PROCEDURES PRIOR TO GOING UNDER ANESTHESIA. SHE SIGNED OFF ON TUBAL LIGATION OPERATION ROOM, HYSTERECTOMY OPERATION, CYST REMOVAL, OPERATION ROOM OVARY REMOVAL, OPERATION ROOM FALLOPIAN TUBE REMOVAL. SHE ENDED UP HAVING LEFT FALLOPIAN TUBE AND LEFT OVARY REMOVED. HER DOCTOR STATED THAT THE BLOOD VESSELS AND CAPILLARIES IN THAT AREA WERE ENLARGED AND VARICOSE, THE DIAMETER OF PENCILS AND LARGER. SINCE THEN, SHE EXPERIENCED MORE PAIN AND WAS ON BIRTH CONTROL HORMONAL MEDICATION TO SUPPRESS OVULATION AND SEND OVARIES INTO HIBERNATION. SHE TOOK THE PILL ALL MONTH LONG TO AVOID HAVING A MONTHLY PERIOD. SHE GAINED WEIGHT DUE TO BEING ON THE PILL. SHE CONTINUED TO HAVE PAIN AND

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DISCOMFORT DUE TO THE ESSURE. CONSUMER ASSESSED 14-DEC-2011 AS EVENT DATE HOWEVER SHE DID NOT SPECIFY IT. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHEN SHE WENT BACK FOR HER TEST (HYSTEROSALPINGOGRAM) TO MAKE SURE TUBES WERE FULLY OCCLUDED, IT WAS DETERMINED THAT ONE OF THE COILS HAD MIGRATED OUT OF MY FALLOPIAN TUBE AND HAD EMBEDDED IN MY UTERUS. SHE HAD INTERMITTENT PAIN/ CRAMPING ON HER LEFT SIDE. SHE ENDED UP HAVING LEFT FALLOPIAN TUBE AND LEFT OVARY REMOVED. BOTH EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF EMBEDDED DEVICE WERE NOT KNOWN. ABOUT A YEAR AFTER ESSURE INSERTION, SHE EXPERIENCED INTERMITTENT PAIN / CRAMPING ON HER LEFT SIDE. BASED ON THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT, NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: DEATH**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01649	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** DEATH **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5056664) IN UNITED STATES ON 23-OCT-2015 WHICH REFERS TO A FEMALE NEONATE (<1M) WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERO. THE CONSUMER REPORTED TWO WEEKS AFTER THE ESSURE INSERTION, SHE BEGAN TO FEEL ILL ALL THE TIME AND THOUGHT MAYBE SHE WAS HAVING A REACTION TO THE COILS, SO SHE WENT BACK TO HER DOCTOR TO BE CHECKED OUT AND FOUND OUT THAT SHE WAS 6 WEEKS PREGNANT. AT (B)(6) WEEKS WHEN SHE GOT UP IN THE MORNING TO GO TO THE RESTROOM, AS SHE CLIMBED OVER HER HUSBAND, THERE WAS A LOUD, POPPING SOUND, LIKE A BALLOON. SHE REPORTED IT FELT WEIRD IN HER STOMACH SO SHE DID NOT MOVE; AFTER A FEW SECONDS SHE GOT OFF THE BED AND IMMEDIATELY HAD WATER TRICKLING DOWN HER LEGS. SHE PANICKED AND WENT TO THE ER AND WAS GIVEN A FERNING TEST TO SEE IF SHE WAS LEAKING AMNIOTIC FLUID AND THE TEST CAME BACK NEGATIVE. SHE WAS SENT HOME AND WAS BACK AGAIN THE NEXT DAY, STILL LEAKING, ANOTHER TEST, NO FERNING, AND WAS SENT HOME. SHE RETURNED AGAIN 2 DAYS LATER WITH CRAMPING AND FLUID LOSS STILL, AN ULTRASOUND WAS PERFORMED AND WAS FOUND TO HAVE AN AMNIOTIC LEVEL OF 10, THE NORMAL IS AROUND 14. A CERCLAGE WAS PLACED TO TRY AND SAVE THE PREGNANCY. AN ULTRASOUND 2 DAYS LATER REVEALED THAT HER FLUID LEVEL HAD DROPPED TO 4, AND THAT HER BABY WOULD NOT SURVIVE, AND BEING IN A (B)(6) HOSPITAL THEY WOULD NOT REMOVE THE CERCLAGE TO PERFORM A D&C AND THAT WAS NOT WHAT SHE WANTED. SHE SIGNED OUT AND WAS ADMITTED TO ANOTHER HOSPITAL, THERE THE HIGH RISK TEAM ASSESSED HER AND DECIDED TO REMOVE THE CERCLAGE AND LET HER BODY DO THE REST. AS SHE WAS HAVING A PROCEDURE TO REMOVE THE CERCLAGE, WHICH WAS ONE OF THE MOST TRAUMATIZING THINGS SHE EVER HAD TO GO THROUGH, THE HIGH RISK DOCTOR PERFORMING THE PROCEDURE STOPPED ABRUPTLY

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AND SAID THE ESSURE COIL WAS IN HER VAGINAL TRACT, THE COIL HAD NEVER IMPLANTED IN FALLOPIAN TUBE AND WAS FLOATING AROUND INSIDE OF HER UTERUS HER WHOLE PREGNANCY. THE CONSUMER REPORTED THE COIL HAD PERFORATED THE AMNIOTIC SAC CAUSING IT TO RUPTURE AND CAUSING THE LOSS OF HER BABY. SHE WAS TOO FAR ALONG TO HAVE THE PREGNANCY REMOVED SO SHE HAD TO DELIVER HER ON HER OWN SHE GAVE BIRTH TO HER ON (B)(6)-2012 AND SHE LIVED FOR ALMOST 15 MINUTES. THE MOTHER' S CASE WAS REPORTED UNDER REFERENCE (B)(4). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER AND REFERS TO HER FEMALE NEONATE; WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERO. THE MOTHER HAD AMNIOTIC FLUID LOSS AT (B)(6) WEEKS OF GESTATION AND GAVE BIRTH A FEW DAYS LATER; THE BABY LIVED FOR ALMOST 15 MINUTES. THE REPORTED EVENT, REGARDED AS A DEATH OF A PREMATURE BABY, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. WHEN ESSURE IS IN ITS IDEAL POSITION, 3 TO 8 OUTER COIL WILL BE TRAILING INTO THE UTERUS. IN THIS PARTICULAR CASE, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND MOTHER'S PREGNANCY CANNOT BE EXCLUDED, DUE TO THE GESTATIONAL AGE AT THE TIME OF THE EVENTS. SINCE BABY'S DEATH OCCURRED AS A CONSEQUENCE OF MATERNAL COMPLICATIONS DURING PREGNANCY; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THEREFORE, THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01650	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1852, AWARENESS DATE 23-OCT-2015). IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER REPORTED RIGHT AFTER THE PROCEDURE SHE HAD PAIN SO SEVERE THAT SHE THOUGHT SHE WAS IN LABOR THAT EVENTUALLY PASSED. AFTER 3 MONTHS SHE HAD THE HSG (HYSTEROSALPINGOGRAM) DONE AND ALL WAS CLOSED AND SHE WAS STERILE. OVER THE PAST 5 YEARS, SHE HAD ISSUES THAT SHE NEVER SEEMED TO LINK TO THE ESSURE AND HOWEVER SHE COULD NEVER GET THE DOCTOR TO FIGURE OUT A CAUSE FOR ALL HER SYMPTOMS. SHE REPORTED SHE ALWAYS BEEN A MIGRAINE SUFFERER BUT NEVER TO THE POINT WHERE MADE HER LIFE STOP; HOWEVER, OVER THE PAST 5 YEARS THEY HAVE GOTTEN SO BAD THAT SHE SOUGHT DIFFERENT TREATMENTS. CURRENTLY, SHE GETS INJECTION WHICH DID NOT ELIMINATE THEM BUT DECREASES THEM DRASTICALLY. SHE STATED IF SHE LET THE INJECTIONS LAPSE SHE HAS MIGRAINES 3-4 TIMES A WEEK. ANOTHER ISSUE THAT SHE HAD WAS WEIGHT GAIN WHICH SHE COULD NOT LOSE ONE POUND DESPITE HER ATTEMPTS. ABOUT A YEAR AGO, SHE HAD BLISTERS COME UP ON HER HAND THAT SPREAD AND ITCHED SO BAD. SHE SAW FOUR DIFFERENT DOCTORS AND NOT ONE COULD TELL HER WHAT WAS, JUST THAT IT WAS AN ALLERGIC REACTION TO SOMETHING. SHE GOT BLOATED AND PEOPLE THINK SHE IS PREGNANT; HER LEGS AND FEET SWELL AND HER FEET TURN BLUE AND NO DOCTOR COULD EXPLAIN WHY. SHE HAD GASTROINTESTINAL ISSUES, MAINLY CONSTIPATION AND WHEN IT GETS BAD SHE TOOK LAXATIVES, STOOL SOFTENERS, ENEMAS AND NOTHING HELPS. HER BRAIN IS A FOG ALL THE TIME, SHE COULD NOT REMEMBER ANYTIME ANYMORE. SHE COULD "STEEP" FOR 10 HOURS AND FELT LIKE HAVE NOT SLEPT IN DAYS; SHE WAS

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ABSOLUTELY EXHAUSTED ALL THE TIME. SHE ALSO REPORTED SHE WAS USED TO NOT HAVE PERIODS. IN THE PAST 3-4 YEARS, SHE STARTED HAVING THEM AGAIN WITH CRAMPING A FEW DAYS BEFORE AND IT WAS EXCRUCIATING, SHE BLEED FOR ABOUT A DAY AND THE DAY AFTER, SHE COULD SWEAR SHE IS IN LABOR. IT IS THE KIND OF PAIN THAT STOPS YOU AND CAUSES YOU TO DOUBLE OVER AND USUALLY LASTS ANOTHER DAY OR TWO. THEN SHE WILL SPOT A THICK BLACK LOOKING BLOOD FOR ABOUT 2 WEEKS. HER BACK AND KNEE PAIN WAS SO INTENSE, SHE HAD DIFFICULTY GETTING INTO A POSITION THAT IS COMFORTABLE. IF SHE STANDS TOO LONG, HER FEET SWELL AND HER KNEES HURT. IF SHE SITS TOO LONG, HER BACK HURTS. SHE HAD BEEN TESTED FOR EVERYTHING: FIBROMYALGIA, LBS, OVERACTIVE BLADDER, MRI'S ON KNEE AND BACK, CT SCANS, EEGS, EKGS, MONO, LUPUS, HORMONE IMBALANCE, CELIAC DISEASE, THYROID DISEASE, (B)(6) AND CHOLESTEROL; AND EVERYTHING CAME BACK PERFECT. SHE ALSO REPORTED SHE DID NOT WEAR JEWELRY BECAUSE IT MADE HER SWELL AND TURN RED, HER DOCTOR BELIEVED IT MIGHT BE THE METAL COILS. SHE STATED SHE IS SCHEDULED TO HAVE A HYSTERECTOMY BEFORE THE END OF THE YEAR. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO EXPERIENCED EXCRUCIATING CRAMPING A FEW DAYS BEFORE HER MENSTRUAL CYCLE AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE STATED SHE IS SCHEDULED TO HAVE A HYSTERECTOMY BEFORE THE END OF THIS YEAR. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION DYSMENORRHEA CAN OCCUR. IN THIS CASE, CONSUMER REPORTED DYSMENORRHEA ALONG WITH MENSTRUAL DISTURBANCES (CHANGE IN HER BLEEDING PATTERN) APPROXIMATELY 2 YEARS AFTER ESSURE INSERTION. ALTHOUGH TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE EVENTS IS WEAK; CONSIDERING THEIR NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR DEVICE REMOVAL. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01651	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5036614) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON UNSPECIFIED DATE. A FEW MONTHS AFTER GETTING ESSURE, SHE STARTED HAVING BAD HEADACHES AND MUSCLES ACHES. NOT LONG AFTER SHE STARTED BLEEDING REALLY BAD. SHE HAS ALWAYS BEEN ON TIME WITH HER PERIODS UNTIL SHE GOT ESSURE. SHE WAS NOW BLEEDING FOR TWO TO THREE MONTHS AT A TIME AND IT WAS SO HEAVY THAT SHE HAS TO WEAR PADS AND TAMPONS. SHE EATS HEALTHY AND EXERCISE AND WAS STILL KEEP GAINING WEIGHT. SHE STAYED EXTREMELY FATIGUE WHICH SHE NEVER USED TO AND WAS ALSO HAVING SO MUCH PAIN IN HER LOWER ABDOMINAL AREA THAT IT INTERFERES WITH HER DAILY ROUTINES. WHEN SHE BLED, IT CONSTANTLY SMELLS LIKE A METALLIC SMELL AND SHE GOT METALLIC TASTE IN HER MOUTH. SHE WAS RECENTLY DIAGNOSED WITH PCOS (INTERPRETED AS POLYCYSTIC OVARIAN SYNDROME) AFTER CONSTANTLY HAVING TO GO TO THE DOCTOR OVER THOSE SYMPTOMS. SHE BELIEVES THAT EVERYTHING THAT HAS BEEN HAPPENING WAS DUE TO ESSURE. IT WAS REPORTED THAT SHE HAS TO GET A PARTIAL HYSTERECTOMY DUE TO ESSURE. HOSPITALIZATION, OTHER SERIOUS (IMPORTANT MEDICAL EVENT) WERE MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER WHO HAD ESSURE INSERTED AND A FEW MONTHS LATER, STARTED BLEEDING REALLY BAD. AT THE MOMENT OF REPORT, SHE STATED THAT SHE HAD TO GET A PARTIAL HYSTERECTOMY. THIS EVENT, SEEN AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE (HOSPITALIZATION WAS MENTIONED BUT NOT SPECIFIED) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING GENITAL BLEEDING MAY OCCUR

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DURING ESSURE AND IN THE ABSENCE OF ALTERNATIVE EXPLANATION, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WILL BE REQUIRED THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. TECHNICAL ASSESSMENT HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01652	BAYER HEALTHCARE LLC	11/19/2015	11/19/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY FDA MAUDE (CASE# MW5056611) IN UNITED STATES ON 23-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2015. CONSUMER SAID ESSURE WAS IMPLANTED IN HER EARLY THIS YEAR (2015) AND SINCE THEN SHE HAS BEEN TEARING INSIDE OUT ABNORMAL BLOOD CLOTS, PELVIC PAIN, ABNORMAL BLEEDING. THIS STUFF WAS TEARING HER BODY UP. SHE WANTED THIS STUFF OUT OF HER. SHE HAS BEEN BLEEDING FOR 8-9 MONTHS STRAIGHT, COULD NOT EVEN HAVE SEX WITH HER HUSBAND WITHOUT BLEEDING. SHE HAD BLOOD TRANSFUSIONS DUE TO HEAVY BLEEDING AND WAS ADMITTED IN THE ICU (INTENSIVE CARE UNIT). COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO EXPERIENCED HEAVY, ABNORMAL BLEEDING WITH BLOOD CLOTS (BLEEDING FOR 8-9 MONTHS STRAIGHT) SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION (ESSURE INSERTED MONTHS BEFORE THIS REPORT). ACCORDING TO HER, SHE HAD BLOOD TRANSFUSIONS DUE TO HEAVY BLEEDING AND WAS ADMITTED IN THE ICU (INTENSIVE CARE UNIT). THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, THE TEMPORAL RELATIONSHIP ESSURE INSERTION AND THE EVENT WAS POSITIVE AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE MEDICAL INTERVENTION AND HOSPITALIZATION WERE REQUIRED FOR BLEEDING'S TREATMENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FOLLOW-UP WILL BE PURSUED, DUE TO LACK OF CONTACT DETAILS.

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Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CAS

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01609	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C64472

Single Use: Y
Implant Date (E6): 9/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GENERAL SURGEON IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C64472, ON (B)(6) 2015. IT WAS REPORTED A BREAKAGE OF INSERTION CATHETER OF ESSURE. CHANGE OF HYSTEROSCOPE. USE OF SECOND BOX OF ESSURE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND A BREAKAGE OF INSERTION CATHETER OF ESSURE OCCURRED DURING THE PROCEDURE. THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 04-JAN-2016. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ES

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01610	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 10/15/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D31454

Single Use: Y
Implant Date (E6): 10/15/2015
Explant Date (E7): 10/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL IN (B)(4) ON 26-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015 WITH LOT NUMBER D31454. IT WAS REPORTED THAT DURING ESSURE INSERTION ATTEMPT, TUBAL INSERT WAS NOT WELL RELEASED IN TUBAL AREA. DELIVERY CATHETER SHEATH AND ESSURE INSERT STAYED STUCK FROM OSTIUM TO HYSTEROSCOPE SHEATH. AFTER SEVERAL MINUTES, SURGEON FINALLY SUCCEEDED IN REMOVING THE PIECE OF DEVICE WHICH WAS STUCK (USE OF A SECOND HYSTEROSCOPE IN ORDER TO PASS SCISSORS). CLINICAL CONSEQUENCES WERE REPORTED AS: PATIENT WAS ANESTHETIZED LONGER THAN PLANNED AND BLEEDING AT TUBAL AREA. CORRECTION DONE ON 29-OCT-2015 BASED ON INFORMATION RECEIVED ON 26-OCT-2015 CASE WAS RECEIVED FROM HEALTH PROFESSIONAL VIA REGULATORY AUTHORITY (HEALTH AUTHORITY NUMBER (B)(4)). COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING THE PROCEDURE A PIECE OF THE DEVICE BECAME STUCK. PHYSICIAN REMOVED IT; ACCORDING TO HIM PATIENT HAD BLEEDING AT TUBAL AREA AS CLINICAL CONSEQUENCE. ONLY BLEEDING AT TUBAL AREA IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS PARTICULAR CASE, PHYSICIAN HAD A DETACHMENT DIFFICULTY DURING ESSURE PROCEDURE; THE DELIVERY CATHETER AND ESSURE INSERT STAYED STUCK FROM THE TUBAL OSTIUM TO THE HYSTEROSCOPE SHEATH. AFTER SEVERAL MINUTES, THE PHYSICIAN REMOVED THE STUCK PIECE (A SECOND HYSTEROSCOPE WAS USED IN ORDER TO PASS SCISSORS). PATIENT HAD BLEEDING AS CONSEQUENCE OF THE PROCEDURE. ALTHOUGH IT IS UNCLEAR FROM EVENTS DESCRIPTION IF ESSURE BROKE OR IF IT WAS CUT BY THE PHYSICIAN; CONSIDERING THE EVENTS OCCURRED IN ASSOCIATION WITH ESSURE

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INSERTION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 21-DEC-2015: THE INSTRUCTIONS FOR INSERTION WERE FOLLOWED. NO DEVIATION FROM THE INSERTION PROCEDURE. ESSURE WAS REMOVED. IT WAS MEDICALLY NECESSARY TO REMOVE ESSURE (IT WAS NOT REMOVED BECAUSE OF PATIENT REQUEST). THE PI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01612	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 7/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/6/2015
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. PERFORATION WAS REPORTED AND NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP RECEIVED ON 29-OCT-2015 FROM GYNECOLOGIST (UPGRADED TO INCIDENT): PATIENT'S DATA WERE UPDATED. THE PATIENT HAD 2 PREGNANCIES WITH 2 LIVE BIRTHS BY C-SECTION. NO PAST MEDICAL HISTORY OF ECTOPIC PREGNANCY, SPONTANEOUS ABORTION AND VOLUNTARY PREGNANCY TERMINATION. NO PREVIOUS GYNECOLOGICAL INTERVENTIONS. ESSURE INSERTION WAS PERFORMED ON (B)(6) 2015 DURING FOLLICULAR PHASE. LAST DELIVERY WAS A CAESAREAN SECTION. NO BREASTFEEDING AT TIME OF INSERTION. NO ABNORMAL UTERINE FINDINGS. THE PATIENT RECEIVED GENERAL ANESTHESIA. THE INSERTION WAS DIFFICULT DUE TO TUBAL SPASMS. THE VISUALIZATION OF TUBAL OS (ORIFICIUM) WAS EASY. FLUID LOSS DURING HYSTEROSCOPY WAS NOT MORE THAN 1500CC. THE PROCEDURE DID NOT TAKE MORE THAN 20 MIN. NO COMPLAINTS IMMEDIATELY AFTER INSERTION. ON (B)(6) 2015 THE UNILATERAL RIGHT PERFORATION WAS DIAGNOSED VIA CT SCAN. IN THE LEFT TUBE THE ESSURE POSITION WAS CORRECT. NO ORGAN OR INTRA-ABDOMINAL STRUCTURE PERFORATED. THE POSITION OF ESSURE IN RIGHT TUBE WAS PART OF THE INSERT WITHIN THE TUBE AND ANOTHER PART IN SIGMOID. THE PATIENT HAD ABDOMINAL PAIN. NO ESSURE CONFIRMATION TEST DONE. ESSURE WAS REMOVED BY LAPAROSCOPY AND THE PATIENT RECOVERED. NO PATHOLOGY RESULTS, SIGNS OF INFECTION AND INFLAMMATION. NO OTHER NEW MEDICAL INFORMATION WAS PROVIDED. CASE CLOSED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND A UNILATERAL RIGHT PERFORATION (PREVIOUSLY INTERPRETED AS

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UTERINE PERFORATION AND NOW INTERPRETED AS FALLOPIAN TUBE PERFORATION) WAS DIAGNOSED A WEEK AFTER. THE POSITION OF THE ESSURE IN THE RIGHT TUBE WAS PART WITHIN THE TUBE AND ANOTHER PART IN SIGMOID. ESSURE WAS REMOVED BY LAPAROSCOPY AND THE PATIENT RECOVERED. THE FALLOPIAN TUBE PERFORATION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT AND THE COMPLICATION NOTICED DURING ESSURE INSERTION, THE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. UPON FOLLOW UP, THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 23-NOV-2015 IT WAS REPORTED THAT IMPLANT WAS STRETCHED AND DISTORCED, BUT NOT BROKEN. NO OTHER NEW MEDICAL INFORMATION WILL BE PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS T

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01613	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68791

Single Use: Y
Implant Date (E6): 4/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4) (STUDY DESCRIPTION: ESSURE® GENERIC REIMBURSEMENT PROGRAM) AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER C68791. TWO DELIVERY CATHETERS OF TWO ESSURE PAIRS BROKE INTO BETTOCHI HYSTEROSCOPE'S SHEATH, DAMAGING ESSURE DEVICE. ONE ESSURE INSERT BROKE DURING INSERTION. THE EVENTS OCCURRED BEFORE AND DURING INSERTION. THE INSTRUCTIONS IN THE IFU WERE FOLLOWED. BROKEN PIECES WERE NOT RETRIEVED. DEVICE WAS NOT AVAILABLE. BILATERAL INSERTION WAS PERFORMED WITH ANOTHER DEVICE. COMPANY CAUSALITY COMMENT THIS SOLICITED MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE TWO DELIVERY CATHETERS OF TWO ESSURE PAIRS BROKE INTO HYSTEROSCOPE'S SHEATH. BILATERAL INSERTION WAS PERFORMED WITH ANOTHER DEVICE. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE DEVICE BREAKAGE IN THIS CASE OCCURRED DURING THE INSERTION PROCEDURE, THEREFORE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01614	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D35370 / C68800

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE WITH LOT NUMBER D35370 (EXPIRATION DATE 28-NOV-2017) AND C68800 (EXPIRATION DATE 30-JUN-2017). IT WAS REPORTED THAT WITH LOT D35370, FIRST IMPLANT COULD NOT BE PLACED AS IT WAS BENT INTO DELIVERY CATHETER AND WITH LOT C68800, SECOND IMPLANT DID NOT RELEASE DURING INSERTION ATTEMPT; MOREOVER, IMPLANT BROKE DURING REMOVAL PROLONGING INTERVENTION DURATION. NO OCCURRENCE OF ADVERSE EVENT. ESSURE INSERTION WAS PERFORMED WITH NO DIFFICULTY WITH EACH REMAINING IMPLANT FROM BOTH BATCHES. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMPLANT BROKE DURING REMOVAL. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT CASE, IMPLANT DID NOT RELEASE DURING INSERTION ATTEMPT AND BROKE DURING REMOVAL, THEREFORE CAUSALITY WITH THE ESSURE PROCEDURE CANNOT BE EXCLUDED. INSERTION WAS PERFORMED WITH NO DIFFICULTY WITH THE REMAINING IMPLANT. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01615	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER/ ATTORNEY IN THE UNITED STATES, ON BEHALF OF A FEMALE PLAINTIFF OF UNSPECIFIED AGE IN UNITED STATES ON 28-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. IN OR AROUND (B)(6) 2011, PLAINTIFF WENT TO THE IMPLANTING PHYSICIAN TO DISCUSS OPTIONS FOR PERMANENT STERILIZATION. THE IMPLANTING PHYSICIAN RECOMMENDED THAT PLAINTIFF HAVE ESSURE IMPLANTED IN HER FALLOPIAN TUBES INSTEAD OF A STANDARD TUBAL LIGATION PROCEDURE. IN OR AROUND (B)(6) 2011, PLAINTIFF RETURNED TO THE IMPLANTING PHYSICIAN FOR THE ESSURE PROCEDURE. THE IMPLANTING PHYSICIAN IMPLANTED THE ESSURE COILS INTO BOTH HER LEFT AND RIGHT FALLOPIAN TUBES. AFTER PROCEDURE TO IMPLANT THE DEVICE, PLAINTIFF STARTED EXPERIENCING SEVERE CONSTANT DAILY PAIN, AND SEVERE BLEEDING. SINCE THE DEVICE WAS IMPLANTED, PLAINTIFF HAS ALSO SUFFERED FROM HEAVY BLEEDING, PELVIC AND ABDOMINAL PAIN, MIGRAINES, SEVERE PAINFUL CRAMPING, PAIN DURING INTERCOURSE, HIVES, CYSTS, AND MENTAL AND EMOTIONAL ANGUISH. PLAINTIFF HAD A UTERINE ABLATION IN OR AROUND (B)(6) 2012 TO CONTROL THE HEAVY BLEEDING. PLAINTIFF DID NOT BECOME AWARE THAT ESSURE WAS THE CAUSE OF HER ABOVE-DESCRIBED PHYSICAL, EMOTIONAL, AND MEDICAL PROBLEMS UNTIL 2015 WHEN SHE LEARNED, THROUGH INTERNET RESEARCH, OF OTHER WOMEN HAVING SIMILAR OR IDENTICAL ISSUES. AS A DIRECT AND PROXIMATE RESULT OF PLAINTIFF'S USE OF ESSURE, SHE WAS FORCED TO UNDERGO A SURGICAL PROCEDURE TO CONTROL THE HEAVY BLEEDING CAUSED BY THE ESSURE COILS. SHE DEVELOPED SEVERE PAIN, SUFFERS FROM MIGRAINES AND HAS UNDERGONE NUMEROUS PROCEDURES. PLAINTIFF SUFFERED PROFOUND INJURIES, REQUIRED MEDICAL TREATMENT, AND INCURRED AND CONTINUES TO INCUR MEDICAL AND HOSPITAL EXPENSES. FOLLOW-UP INFORMATION RECEIVED ON 16-NOV-2015: PRODUCT TECHNICAL COMPLAINT

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RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS RECEIVED FROM AN LAWYER ON BEHALF OF A FEMALE CONSUMER/PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED HEAVY / SEVERE BLEEDING (REGARDED AS GENITAL BLEEDING). SHE WAS SUBMITTED TO AN ENDOMETRIAL ABLATION. THE LAWYER ALSO STATED UNSPECIFIED PROCEDURES AND MEDICAL TREATMENT WERE REQUIRED. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE LIMITED INFORMATION WAS PROVIDED. HOWEVER GIVEN EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE SURGICAL (ENDOMETRIAL ABLATION) AND MEDICAL INTERVENTION (UNSPECIFIED PROCEDURES, UNSPECIFIED MEDICAL TREATMENT AND HOSPITAL EXPENSES) WERE REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 16-NOV-2015: PRODUCT TECHNICAL COMPLAINT RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01616	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY, ON BEHALF OF A PLAINTIFF IN UNITED STATES ON 28-OCT-2015 WHICH REFERS TO A FEMALE PLAINTIFF OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED INTO BOTH HER LEFT AND RIGHT FALLOPIAN TUBES IN (B)(6) 2008 FOR PERMANENT STERILIZATION. AFTER PROCEDURE TO IMPLANT THE DEVICE, THE PLAINTIFF STARTED EXPERIENCING SEVERE CONSTANT DAILY PAIN, AND SEVERE BLEEDING. SINCE THE DEVICE WAS IMPLANTED, THE PLAINTIFF HAD ALSO SUFFERED FROM HEAVY BLEEDING, CONSTANT PAIN, MIGRAINES, SEVERE ABDOMINAL, OVARIAN AND PELVIC PAIN, SHARP, STABBING PAIN, PAIN DURING INTERCOURSE, MENTAL AND EMOTIONAL ANGUISH. ON (B)(6) 2015 CONSUMER HAD A UTERINE ABLATION TO CONTROL THE HEAVY BLEEDING. CONSUMER DID NOT BECOME AWARE THAT ESSURE WAS THE CAUSE OF HER ABOVE-DESCRIBED PHYSICAL, EMOTIONAL, AND MEDICAL PROBLEMS UNTIL 2015 WHEN SHE LEARNED, THROUGH INTERNET RESEARCH, OF OTHER WOMEN HAVING SIMILAR ISSUES. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 17-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A

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QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED CASE REPORT WAS RECEIVED VIA LAWYER. IT REFERS TO A FEMALE CONSUMER/PLAINTIFF WHO HAD ESSURE IMPLANTED IN BOTH FALLOPIAN TUBES FOR PERMANENT STERILIZATION. SINCE INSERTION, SHE EXPERIENCED SEVERE BLEEDING (INTERPRETED AS GENITAL BLEEDING). SEVEN YEARS LATER, SHE HAD A UTERINE ABLATION TO CONTROL THE HEAVY BLEEDING. THE GENITAL BLEEDING IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE NATURE OF THIS EVENT, THE SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP BETWEEN THE GENITAL BLEEDING AND ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS REQUIRED TO TREAT AN ESSURE-RELATED EVENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 17-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01617	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 10/14/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE#FDA-2014-N-0736-2156, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED NEARLY 3 YEARS AGO. SHE GOT ESSURE AND THOUGHT IT WAS GREAT AT FIRST. SHE DID NOTICE THAT HER DEPRESSION AND ANXIETY GOT WORSE AND SHE WAS VERY TIRED ALL THE TIME BUT DID NOT LINK IT TO ESSURE. IN (B)(6) 2014, SHE GOT THE FIRST BOUT OF BV (INTERPRETED AS BACTERIAL VAGINOSIS) FOLLOWED BY MORE AND LOTS OF UTI AND BLEEDING. IN APRIL SHE WAS GETTING QUITE SEVERE PELVIC AND ABDOMINAL PAIN WHICH GOT WORSE AND WORSE; SHE FELT LIKE HER INSIDES WERE TRYING TO COME OUT. SHE HAD CONTRACTIONS; IT WAS JUST LIKE SHE WAS IN LATER STAGES OF LABOR. SHE SAW NUMEROUS DOCTORS AND WENT TO ER BUT THEY FIND NOTHING WRONG WITH HER. EVENTUALLY A DOCTOR SAW HER IN ABSOLUTE AGONY; HE COULD NOT EVEN TOUCH HER STOMACH. HE REFERRED HER TO THE HOSPITAL BUT STILL, NOTHING WAS DONE AND SHE WAS SENT HOME ON STRONG PAIN KILLERS. SINCE THEN THE PAINS HAD COME AND GO BUT THERE HAS ALWAYS BEEN A PAIN THAT WAS THERE IN THE BACKGROUND WITH OCCASIONAL STABBING PAINS. SHE CAME VERY CLOSE TO LOSING HER JOB BECAUSE SHE HAD SO MUCH TIME OFF DUE TO SEVERE PAIN AND EXHAUSTION. ON (B)(6), SHE HAD HER COILS AND TUBES REMOVED BY THE SAME SURGEON WHO PUT THEM IN. SHE WAS WAITING TO FIND OUT IF EVERYTHING WAS TAKEN SUCCESSFULLY OR THERE WERE ANY FRAGMENTS LEFT. SHE IS NOW RECOVERING FROM HER SURGERY BUT FEEL VERY TEARFUL. SHE WAS TALKED INTO HAVING IT BECAUSE SHE IS SENSITIVE TO SUXAMETHONIUM (A DRUG USED DURING SURGERY TO RELAX MUSCLES); SHE WAS TOLD THAT ESSURE IS SAFE, PAIN FREE, EASY TO INSERT AND IT

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WORKS WITH YOUR BODY! SHE STATED THAT BECAUSE DOCTOR OR SURGEON COULD NOT FIND ANYTHING ELSE WRONG WITH HER, IT WAS AGREED THAT ALL THE PAIN AND CONTRACTIONS HAS BEEN HER BODY TRYING TO REJECT THE ESSURE (A FOREIGN OBJECT THAT SHOULD NOT BE THERE) FOLLOW-UP RECEIVED ON 09-NOV-2015: (B)(4) REFERENCE NUMBER WAS PROVIDED - (B)(4). COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD SEVERE PELVIC PAIN AND LOTS OF UTI (INTERPRETED AS RECURRENT URINARY TRACT INFECTION). THREE YEARS AFTER ESSURE INSERTION AND AROUND 1 YEAR AFTER THE UTI EPISODES, ESSURE COILS WERE REMOVED. THE PELVIC PAIN AND RECURRENT URINARY TRACT INFECTION ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE PELVIC PAIN IS LISTED WHILE THE URINARY TRACT INFECTION IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, BOTH EVENTS STARTED AFTER A YEAR OF ESSURE INSERTION BUT THE DATE WAS NOT SPECIFIED. CONSIDERING THE NATURE OF PELVIC PAIN AND LACK OF ALTERNATIVE EXPLANATION, ITS CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ON THE OTHER HAND, SINCE THE RECURRENT URINARY TRACT INFECTIONS STARTED AT LEAST ONE YEAR AFTER ESSURE INSERTION, IT IS UNLIKELY THAT THE ESSURE PROCEDURE WOULD CONTRIBUTE TO THESE INFECTIONS SO MUCH TIME AFTER THE INSERTION. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 08-DEC-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01618	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 629311

Single Use: Y
Implant Date (E6): 9/30/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 30-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. PHYSICIAN HAD ADVISED THAT BLEEDING WILL STOP BUT CALLER CONTINUED TO HAVE EXCESSIVE VAGINAL BLEEDING FOR THREE MONTHS AND HAD ABLATION TO STOP THE BLEEDING. CONSUMER HAS HAD CYST REMOVED AS WELL AS OTHER PROCEDURES AFTER HAVING THIS IMPLANT. CONSUMER STATED THIS DEVICE HAS CAUSED A LOT OF MISERY AS SHE EXPERIENCED EXCRUCIATING PAIN, LOWER ABDOMINAL PAIN, PELVIC PAIN, VOMITING, PAINFUL SEXUAL INTERCOURSE, DEPRESSION AND URINARY TRACT INFECTIONS. THIS IMPLANT, SHE ADVISED HAS MADE HER LIFE VERY MISERABLE AND SHE IS CONSTANTLY GOING TO THE HOSPITAL AND HAVING TEST AND PROCEDURES DONE TO HELP WITH THE ADVERSE EFFECTS SHE HAS EXPERIENCED FROM ESSURE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED EXCESSIVE VAGINAL BLEEDING FOR THREE MONTHS AND HAD ABLATION IN ORDER TO STOP THE BLEEDING. THIS EVENT WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO HAD CYST REMOVED AS WELL AS OTHER PROCEDURES AFTER HAVING THIS IMPLANT. SHE HAD URINARY TRACT INFECTIONS. THESE TWO EVENTS WERE CONSIDERED SERIOUS AND UNLISTED FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR THE EXCESSIVE VAGINAL BLEEDING. BASED ON THE NATURE FOR THIS EVENT AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, IT IS UNLIKELY THAT ESSURE WOULD CAUSE THE EVENTS DUE TO THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, THUS A CAUSAL RELATIONSHIP CAN BE EXCLUDED. SINCE A

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SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 22-NOV-2015: PTC GLOBAL NUMBER: (B)(4). BATCH NUMBER: 629311. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED D

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01619	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2000
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2279, AWARENESS DATE 29-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN GREAT BRITAIN WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2000 (OR 2001). THE REPORTER STATED THAT HER FRIEND WAS A PART OF A TRIAL IN 2000 (OR 2001) AND ENDED IN HYSTERECTOMY. FOLLOW-UP INFORMATION RECEIVED ON 10-NOV-2015: THE (B)(4) REGULATORY AUTHORITY PROVIDED THE CASE NUMBER (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ENDED IN HYSTERECTOMY. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AS WITH CURRENTLY AVAILABLE METHODS OF MECHANICAL PERMANENT CONTRACEPTION, IF ESSURE IS TO BE REMOVED, SURGERY COULD BE REQUIRED. IT IS POSSIBLE THAT SURGICAL REMOVAL OF THE FALLOPIAN TUBES OR UTERUS MAY BE REQUIRED. THIS PARTICULAR CASE WAS REPORTED WITH VERY LIMITED INFORMATION. THE EXACT REASON FOR THE HYSTERECTOMY WAS NOT SPECIFIED. DESPITE THE LIMITED INFORMATION, GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 10-NOV-2015: (B)(4). FOLLOW-UP INFORMATION RECEIVED ON 02-DEC-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01622	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 4/29/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0172, AWARENESS DATE 12-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STUMPED A NEUROLOGICAL TEAM WITH EXCESSIVE DAYTIME SLEEPINESS, HALLUCINATIONS, SLEEP PARALYSIS AND THE WORSE OF IT ALL WAS FALLING DOWN PARALYZED UPON EMOTIONS CALLED CATAPLEXY. SHE TESTED COMPLETELY NEGATIVE FOR NARCOLEPSY SEVERAL TIMES OVER. SHE RECEIVED A HYSTERECTOMY (B)(6) 2014 LEAVING HER OVARIES, AND SHE HASN'T FALLEN DOWN SINCE WITH CATAPLEXY OR SUFFERED FROM ANY MORE NEUROLOGICAL DISORDERS. FOLLOW-UP RECEIVED ON 08-SEP-2015: THE PTC INVESTIGATION RESULT WAS PROVIDED. (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP 23-OCT-2015: CASE UPGRADED TO INCIDENT. THIS CASE HAS

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BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1747, AWARENESS DATE 23-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED SHE HAD THEM (THE ESSURE DEVICES) REMOVED FROM HER BODY ALREADY BUT WILL HAVE TO DEAL WITH REPERCUSSIONS OF THEM COILS FOR THE REST OF HER LIFE DUE TO ALL OF HER AUTO IMMUNE DISORDERS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED TO FALLING DOWN PARALYZED UPON EMOTIONS CALLED CATAPLEXY. LATER, IT WAS INFORMED THAT SHE HAD THEM (THE DEVICES) REMOVED AND PRESENTED AUTOIMMUNE DISORDERS. THESE EVENTS, SEEN AS CATAPLEXY, MEDICAL DEVICE REMOVAL AND AUTOIMMUNE DISORDER, ARE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND ARE ALL UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, EXCEPT MEDICAL DEVICE REMOVAL WHICH IS LISTED. CATAPLEXY IS DEFINED BY A SUDDEN DROP IN MUSCLE TONE THAT IS TRIGGERED BY AROUSAL OR EMOTION. IN THIS PARTICULAR CASE, IN SPITE OF CONSUMER HAD RELATED HER SYMPTOMS TO ESSURE; CONSIDERING THEIR NATURE AND GIVEN ESSURE LOCAL ACTION AT FALLOPIAN TUBES CAUSALITY WITH THE SUSPECT INSERT IS VERY UNLIKELY. IN REGARDS OF AUTOIMMUNE DISORDER, LIMITED INFORMATION HAS BEEN PROVIDED; HOWEVER, GIVEN THE FACT THAT ESSURE ACTS LOCALLY IN FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND SUSPECT INSERT IS ALSO VERY UNLIKELY. ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION IMPLIED THIS CASE WAS UPGRADED TO INCIDENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE WAS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 03-NOV-2015: THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01623	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/17/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5032856) IN UNITED STATES ON 13-JAN-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN, LOWER BACK PAIN, HEADACHES, PAIN DURING AND AFTER SEX, SKIN IRRITATIONS, AND WEIGHT GAIN. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS UNKNOWN WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON (B)(6) 2013 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR INDICATION NOT REPORTED. CONSUMER REPORTED PELVIC AND LOWER BACK PAIN, HEADACHES, PAIN DURING AND AFTER SEX, SKIN IRRITATIONS, WEIGHT GAIN (30 LBS) HAS HAD TO LEAVE WORK ON SEVERAL OCCASIONS DUE TO PAIN. SEXUAL LIFE HAS SUFFERED DUE TO NOT BEING ABLE TO UNLESS SHE WISHED HER PAIN TO BE BOX WORSE WHICH SHE DID NOT. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN PELVIC PAIN, LOWER BACK PAIN, HEADACHES, PAIN DURING AND AFTER SEX, SKIN IRRITATIONS, AND WEIGHT GAIN AND ESSURE IS NOT REPORTED. FOLLOW-UP INFORMATION WAS RECEIVED ON 24-OCT-2015 AND CASE WAS UPGRADED TO INCIDENT. THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1768, AWARENESS DATE 24-OCT-2015). CONSUMER STATED SHE HAD ESSURE ON (B)(6). SHE OPTED OUT OF GENERAL ANESTHESIA BECAUSE SHE HAD ALWAYS BEEN AFRAID OF BEING PUT TO SLEEP. SHE WAS AWAKE FOR THE ENTIRE PROCEDURE, WHICH SHE REGRET. THE PAIN SHE FELT WAS IMMEDIATE AND NEVER WENT AWAY. SHE WAITED THE 3 MONTHS AND HAD HER CONFIRMATION TEST (HYSTEROSALPINGOGRAM) WHICH IN ITSELF WAS ALSO VERY UNCOMFORTABLE. SHE WAS GIVEN THE GREEN LIGHT THAT

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EVERYTHING WAS FINE AND SHE WAS BLOCKED. STILL IN PAIN SHE CALLED HER GYNECOLOGIST EXPRESSING HOW MUCH PAIN SHE WAS STILL IN. SHE WAS IN AND OUT OF THE ER (EMERGENCY ROOM) FOR INDESCRIBABLE PAIN, ONLY TO BE TREATED AS A DRUG ADDICT. EVERY ER VISIT NOT ONE OF THE DOCTORS HAD EVER EVEN HEARD OF ESSURE, THIS BLEW HER MIND. AFTER MONTHS OF BEING IN AGONY SHE WAS REFERRED TO ONE OF THE SPECIALISTS IN THE PRACTICE AND WAS FINALLY BEING HEARD AND NOT BEING TOLD IT COULD NOT BE ESSURE. SHE WAS GIVEN AN INTERNAL ULTRASOUND, SOME BLOOD TESTS, ECT. THEN SHE WAS SCHEDULED FOR HER SALPINGECTOMY WHICH HAPPENED ALMOST A TEAR (INTERPRETED AS YEAR) TO THE DAY OF PLACEMENT. DURING THE LAPAROSCOPY IT WAS DETERMINED THAT SHE HAD SEVERE ENDOMETRIOSIS AND ADENOMYOSIS. WHICH LET HER POINT OUT SHE NEVER HAD BEFORE. ALL OF HER PAIN WAS POST ESSURE. HE INFORMED HER THAT A HYSTERECTOMY MIGHT BE NEEDED IN THE FUTURE BECAUSE OF THIS. SO SHE CHANGED HER DIET (PALEO) WHICH HE RECOMMENDED. SIX MONTHS LATER SHE WAS BACK IN THE HOSPITAL RECEIVING A FULL HYSTO, EVERYTHING BUT HER OVARIES. AT THE AGE OF (B)(6) SHE NO LONGER HAVE FALLOPIAN TUBES, A CERVIX, A UTERUS, AND AS ADDED BONUS HER APPENDIX. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN IMMEDIATELY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. MONTHS LATER, SHE WAS SUBMITTED TO A LAPAROSCOPIC SALPINGECTOMY; WHICH REVEALED SEVERE ENDOMETRIOSIS AND ADENOMYOSIS. SIX MONTHS LATER, A HYSTERECTOMY WAS PERFORMED. ONLY PELVIC PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE EXACT CAUSE AND PATHOGENESIS OF ENDOMETRIOSIS IS UNCLEAR. LEADING THEORIES INCLUDE METAPLASIA, IMMUNOLOGIC DYSFUNCTION, RETROGRADE MENSTRUATION THROUGH THE FALLOPIAN TUBES, GENETICS, AMONGST OTHERS. ADENOMYOSIS REFERS TO A DISORDER IN WHICH ECTOPIC ENDOMETRIAL TISSUE GROWS INTO THE UTERINE MUSCULATURE. SYMPTOMS OF THESE CONDITIONS INCLUDE PELVIC PAIN. GIVEN ENDOMETRIOSIS AND ADENOMYOSIS PATHOPHYSIOLOGY AND CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY IS CONSIDERED UNLIKELY. CONSUMER'S ADENOMYOSIS/ENDOMETRIOSIS COULD BEEN ALTERNATIVE EXPLANATIONS FOR HER PAIN; HOWEVER SINCE SHE STATED HER PAIN STARTED IMMEDIATELY AFTER ESSURE INSERTION AND AS A SALPINGECTOMY WAS REQUIRED DUE TO THIS PAIN; CAUSALITY WITH ESSURE CANNOT BE TOTALLY RULED OUT. THEREFORE, THIS CASE WAS UPGRADED TO INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FOLLOW-UP WILL BE PURSUED, DUE TO LACK OF CONTACT DETAILS.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 18-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01624	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2014
Explant Date (E7): 12/30/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO HERSELF, A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AROUND (B)(6) 2014. SINCE CONSUMER HAD THE ESSURE INSERTED, SHE EXPERIENCED BLEEDING, SEVERE LOWER BACK PAIN, AND ABDOMINAL PAIN EVERYDAY. ALSO, SHE STATED THAT THE DEVICE HAS MADE HARD FOR HER TO DO HER MOTHERLY DUTIES TO HER 4 CHILDREN. SHE IS NOT RECOVERED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 28-NOV-2014: FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. HOWEVER, THE REPORTED ADVERSE EVENTS ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. PTC GLOBAL NUMBER IS (B)(4). FOLLOW-UP RECEIVED ON 24-OCT-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED

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DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE (FDA-2014-N-0736-1982), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015. ESSURE WAS IMPLANTED (B)(6) 2014 AFTER SHE HAD HER FOURTH CHILD IN (B)(6) 2014. SHE HAS HAD NO HEALTH ISSUES, NO SURGERIES, ALWAYS CARRIED HER CHILDREN FULL TERM WITH NO COMPLICATIONS AND NATURE CHILDBIRTH. AFTER SHE HAD HER PROCEDURE FOR ESSURE HER DOCTOR EXPLAINED SHE WOULD FEEL SOME MILD CRAMPING AND SOME BLEEDING WHICH SHE EXPERIENCED, SHE GAVE IT THREE WEEKS TO SEE IF ANY OF THE PAIN AND BLEEDING EASED UP BUT UNFORTUNATELY IT DID NOT. SHE CONTACTED HER GYNECOLOGIST NUMEROUS TIMES ONLY TO BE TOLD THAT IT WAS NORMAL TO EXPERIENCE THESE SYMPTOMS DURING THE FIRST YEAR. BY (B)(6) 2014 HER LOWER ABDOMINAL PAIN AND CONTINUOUS BLEEDING STILL OCCURRED ALONG WITH LOWER BACK PAIN. SHE WENT TO A DIFFERENT GYNECOLOGIST FOR A SECOND OPINION AND THEY DID A SONOGRAM ON HER WHICH TOOK A TOTAL OF AN HOUR, TWO DIFFERENT TECHNICIANS AND THE PROBE SEARCHING FOR HER LEFT COIL. NO ONE SAID WHETHER OR NOT THEY FOUND IT BUT LEFT WITH EVERYTHING LOOKS GOOD. BUT NO ANSWER TO WHY SHE WAS (B)(6) AND HAS NEVER HAD MUCH OF PERIOD CRAMPS HER ENTIRE LIFE, BUT NOW SHE COULD BARELY WALK, GO TO WORK OR CARE FOR HER SMALL CHILDREN. HER FAMILY CARE DOCTOR PUT HER ON HYDROCODON TO EASE THE PAIN SO SHE COULD GO TO WORK AND BE A MOTHER TO HER CHILDREN. SHE STAYED ON THE PAIN MEDICATION FOR A COUPLE OF MONTHS THAN WENT BACK TO HER ORIGINAL GYNECOLOGIST DEMANDING ANSWERS. AT THAT POINT HER MARRIAGE WAS FALLING APART BECAUSE SHE STARTED EXPERIENCING SEVERE MOOD SWINGS, DEPRESSION AND ANXIETY. SHE CONVINCED HERSELF THAT SHE HAD DEVELOPED BIPOLAR DISORDER WHICH AGAIN SHE HAS NEVER HAD ANY OF THESE PROBLEMS BEFORE. THE DOCTOR REFERRED HER TO A BACK/SPINE SPECIALIST TO HAVE A NUCLEAR MAGNETIC RESONANCE IMAGING (MRI) AND X-RAY PERFORMED TO RULE OUT THAT SHE DID NOT HAVE ANY BACK PROBLEMS. THIS ONLY PROLONGED HER PAIN AND SUFFERING. AFTER TWO MONTHS OF WAITING TO GET AN APPOINTMENT, SEEING THE SPECIALIST, GETTING THE MRI AND WAITING FOR HER DOCTOR TO GET THE RESULTS THEY CALLED HER IN TO TELL HER THAT HER BACK LOOKS GOOD. SO THEY DECIDED TO GO WITH WHAT SHE TOLD THEM TO START WITH WAS THE ESSURE NEEDED TO COME OUT. THEY SCHEDULED HER HYSTERECTOMY FOR (B)(6) 2014. THE SURGERY WENT GOOD WITHOUT COMPLICATIONS. AS SOON AS SHE CAME OUT OF THE OR (OPERATING ROOM) SHE FELT NO PAIN BUT WHERE HER INCISION WAS. SHE FELT LIKE A BRAND NEW PERSON, NONE OF HER SYMPTOMS THAT SHE WAS EXPERIENCING SINCE (B)(6) 2014 EVER CAME BACK. UPDATED PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 13-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT:~ BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING CRAMPING / LOWER ABDOMINAL PAIN, AND BLEEDING (INTERPRETED AS GENITAL BLEEDING). SHE WAS ALSO CONVINCED SHE HAD BIPOLAR DISORDER. A HYSTERECTOMY WAS PERFORMED 7 MONTHS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. ABDOMINAL PAIN AND GENITAL BLEEDING ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENT

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IS UNLISTED. AFTER ESSURE INSERTION GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE EVENTS CRAMPING / LOWER ABDOMINAL PAIN AND BLEEDING, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. CONSIDERING BIPOLAR DISORDER PATHOPHYSIOLOGY AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS UPGRADED TO INCIDENT UPON RECEIPT OF FOLLOW-UP INFORMATION, SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS FOLLOW-UP WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01625	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 1/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1495, AWARENESS DATE 24-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. ON THE DAY OF HER PROCEDURE, SHE WAS GIVEN VALIUM AND LOCAL ANESTHETIC. SHE REPORTED THAT THE PAIN SHE FELT WHILE BEING IMPLANTED WAS EXCRUCIATING. THE SECOND COIL WAS FIRED TOO SOON AND WAS PROTRUDING OUT OF HER TUBE. THE DOCTOR ATTEMPTED SEVERAL TIMES TO REMOVE IT MANUALLY WHILE THE CONSUMER WAS BEGGING HER TO STOP. IT WAS NOT UNTIL HER BODY WENT INTO AN UNCONTROLLABLE PANIC ATTACK AND SHE BEGAN TO GASP FOR AIR THAT THE DOCTOR CEASED THE PROCEDURE AND TOLD HER TO GO TO THE HOSPITAL WHERE SHE WOULD NEED AN EMERGENCY SURGERY TO EITHER REMOVE THE COILS OR PLACE THEM PROPERLY. THE CONSUMER WAS PUT UNDER ANESTHESIA AND THE COILS WERE PLACED. SHE STATED THAT HER LIST OF SIDE EFFECTS RANGE FROM SKIN REACTIONS (DUE TO NICKEL ALLERGY), DIGESTIVE ISSUES, PAINFUL BOWEL MOVEMENTS, LEG / BACK / ABDOMINAL PAINS, UNPREDICTABLE MENSTRUAL CYCLES WITH CLOTS AND CRAMPS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT THE SECOND COIL WAS FIRED TOO SOON AND WAS PROTRUDING OUT OF TUBE. THE DOCTOR ATTEMPTED SEVERAL TIMES TO REMOVE IT MANUALLY WHILE THE CONSUMER WAS BEGGING HER TO STOP. THE CONSUMER WAS PUT UNDER ANESTHESIA AND THE COILS WERE PLACED. THIS EVENT WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY

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INFORMATION FOR ESSURE. IN THIS CASE, THE SECOND COIL WAS NOT PLACED CORRECTLY AND AN INTERVENTION (UNDER ANESTHESIA) WAS REQUIRED. A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED AND THIS CASE WAS REGARDED AS INCIDENT DUE TO THE REQUIRED INTERVENTION PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE ADDED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 04-DEC-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01626	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN (B)(6) 2015 (CASE (B)(4), AWARENESS DATE (B)(6) 2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT WHEN ESSURE WAS REMOVED, SHE WENT FROM BEING CONSTANTLY PAIN, IN AND OUT OF THE HOSPITAL, DRAINED AND FRUSTRATED TO HER BUBBLY HAPPY NORMAL SELF. FOLLOW UP RECEIVED ON (B)(6) 2015: PTC INVESTIGATIONAL RESULT. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT PAIN (INTERPRETED AS PELVIC PAIN).

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UPON ESSURE REMOVAL, SHE RECOVERED. PELVIC PAIN IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO PRODUCT SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP, NATURE OF EVENT AND PRODUCT PROFILE, LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION AND THE FACT THAT SHE RECOVERED AFTER DEVICE REMOVAL, CAUSALITY CANNOT BE EXCLUDED. SIN AN INTERVENTION WAS PERFORMED; THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED AND A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

CORRECTION ON 26-NOV-2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT DRAINED AND FRUSTRATED WAS SPLIT TO MEDDRA LLT FRUSTRATION AND MEDDRA LLT LOSS OF ENERGY.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01653	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736- 1670, AWARENESS DATE 24-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED ESSURE ALMOST RUINED HER LIFE RESULTING IN A HYSTERECTOMY. SHE HAS ENDURED MANY HEALTH PROBLEMS MENTAL AND PHYSICAL. SHE HAD FIBROMYALGIA, JOINT PAIN, NEUROPATHY, POST-TRAUMATIC STRESS DISORDER, MIGRAINES TO THIS DAY THAT KEEP HER IN BED. SHE WAS SICK ALL THE TIME, NOT ABLE TO HAVE INTERCOURSE WITH HER HUSBAND BECAUSE OF THE PAIN, SHE GAINED 60 POUNDS AND SHE LOOKED LIKE SHE WAS PREGNANT BECAUSE IT CAUSED AN INFLAMED RESPONSE TO THE ENTIRE BODY, ENDURING AN UNTIMELY HYSTERECTOMY. SHE LOST OVER ALMOST 3 YEARS OF HER LIFE BECAUSE SHE WAS IN BED MOST OF THE TIME WITH 0 (ZERO) ENERGY ADDING STRESS TO HER HUSBAND WHO WAS THE PROVIDER FOR THEIR SON AND HERSELF. ALWAYS THINKING THAT SHE WAS GOING TO DIE AND MAYBE NOT WAKE UP, NIGHT SWEATS WHEN SHE DID SLEEP AT NORMAL HOURS AND DAY SLEEPING BECAUSE SHE HAD NO ENERGY. SHE WAS AN ATHLETE BEFORE ESSURE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 16-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS NOT ABLE TO HAVE INTERCOURSE BECAUSE OF PAIN (INTERPRETED AS DYSPAREUNIA). SHE UNDERWENT A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT CASE LIMITED INFORMATION WAS PROVIDED, THE EXACT TEMPORAL RELATIONSHIP BETWEEN THE EVENT AND ESSURE INSERTION WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THE EVENT, CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED OR IDENTIFIED; A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01654	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/16/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N·0736-1701, AWARENESS DATE 24-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. ADDITIONAL INFORMATION RECEIVED ON 18-NOV-2015. THE CONSUMER REPORTED SHE HAD PROBLEMS WITH HEADACHE AND GAINING WEIGHT. SHE STARTED HAVING PROBLEMS WITH HER MOODS AND DEVELOPED DEPRESSION. SHE COULD NOT WEAR BLUE JEANS BECAUSE THEY WOULD HURT HER PELVIC AREA AND SHE DEVELOPED IBS (IRRITABLE BOWEL SYNDROME) FROM IT SO SHE COULD NOT GO OUT TO EAT BECAUSE SHE WOULD HAVE TO GO TO THE BATHROOM A FEW TIMES BEFORE SHE GETS HOME. HER HAIR USED TO BE THICK IT WAS THIN FROM FALLING OUT. SHE COULD NOT HAVE INTERCOURSE WITH HER HUSBAND BECAUSE IT WOULD CAUSE TO MUCH PAIN FOR BOTH. SHE STARTED TO BLEED HEAVY ON HER SEASON WHICH USED TO BE LIGHT AND WITH NO PAIN, BUT AFTER ESSURE INSERTION SHE HAD TO TAKE OFF WORK DUE TO THE PAIN AND HEADACHES. SHE COULD NOT LAY FLAT ON HER BACK, COULD FEEL THE COILS IF SHE GOT UP TOO QUICK OR ROLL OVER TOO FAST AND FELT LIKE THERE WAS A FISH HOOK ON HER LEFT SIDE PULLING HER THE OTHER WAY. SHE HAD BACK PAIN ALL THE TIME AND URINARY TRACT INFECTIONS AND IT STARTED TO CAUSE KIDNEYS PROBLEMS. THE CONSUMER DID NOT WANT TO HAVE A HYSTERECTOMY SO SHE FOUND A DOCTOR WHO WAS SKILLED TO DO THE REVERSAL WITH ESSURE. THE ESSURE REVERSAL SURGERY WAS DONE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 18-NOV-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN

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INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO STARTED TO BLEED HEAVY ON HER SEASON (REGARDED AS MENORRHAGIA) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO ESSURE REVERSAL SURGERY. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER RELATED THE EVENT TO ESSURE AND NO ALTERNATIVE EXPLANATION WAS AVAILABLE. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (REVERSAL SURGERY PERFORMED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01655	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1745, AWARENESS DATE 24-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2009. SHE STATED THAT SHE CONTRACTED A UTERINE INFECTION THAT WAS NOT KNOCKED OUT AFTER 3 ROUNDS OF ANTIBIOTICS. SHE HAD PAIN WHEN SITTING; PAIN BEFORE BOWEL MOVEMENTS; PAIN AFTER SEX; HEAVINESS AND BLOATING AFTER SEX; LACK OF SEX DRIVE AND SEXUAL FUNCTION; CONSTANT GENITAL ITCHING; CHRONIC FATIGUE; AND IRREGULAR MENSES, WHICH SHE WAS TOLD WAS DUE TO AGE ((B)(6) AT THE TIME). NO ONE MENTIONED NICKEL, WHICH MIGHT HAVE WARNED HER AWAY FROM THIS DEVICE, BECAUSE SHE GOT PAIN AND ITCHING WITH CHEAP JEWELRY. VAGINAL ULTRASOUND WAS DONE AND SHOWED THAT THE RIGHT IMPLANT HAD SPLIT IN HALF. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED UTERINE INFECTION. AN VAGINAL ULTRASOUND WAS PERFORMED AND SHOWED THAT RIGHT IMPLANT HAD SPLIT IN HALF (SEEN AS DEVICE BREAKAGE). UTERINE INFECTION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION,

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BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THIS CASE, IT WAS NOT REPORTED WHETHER THE UTERINE INFECTION OCCURRED UP TO 4 WEEKS POST INSERTION. NO SURGICAL INTERVENTION WAS REPORTED. ALSO, IT WAS UNKNOWN WHEN DEVICE BREAKAGE OCCURRED. HOWEVER, CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 30-NOV-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODEL MECHANISM: THE E

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01656	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/25/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE NUMBER FDA-2014-N-0736-1916) IN UNITED STATES ON 24-OCT-2015 IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO PLACED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2013. ADDITIONAL INFORMATION RECEIVED ON 18-NOV-2015 (PTC INVESTIGATION RESULT). CONSUMER HAD PROBLEMS WITH EXCESSIVE LENGTHY PERIODS AND HAD EXHAUSTED ALL OTHER VIABLE OPTIONS TO LESSEN THEM. SHE OPTED FOR ENDOMETRIAL ABLATION. HER GYNECOLOGIST REFUSED TO PERFORM AN ENDOMETRIAL ABLATION UNLESS SHE WAS STERILIZED. SHE KNEW SHE DID NOT WANT CHILDREN, SO IT SEEMED A NO-BRAINER. HER DOCTOR TOLD HER ESSURE WOULD BE SAFER. NO DOWN-TIME, AND OFFERED BETTER STERILIZATION THAN A STANDARD TUBAL LIGATION. SHE RESEARCHED ESSURE ON HER OWN AND DECIDED THAT ALTHOUGH SHE FOUND REPORTS AT THAT TIME OF 2000 WOMEN WHO DAMMED SIDE-EFFECTS, KNOWING THAT OVER 600.000 HAD THEM. SHE THOUGHT THE NUMBERS WERE GOOD AND GAVE THE GO AHEAD. THE SURGERY WAS A NIGHTMARE, AND SHE BEGAN EXPERIENCING SIDE-EFFECTS WITHIN 48 HOURS OF ESSURE IMPLANTATION. FREQUENT DIZZY SPELLS AND SEVERE STABBING PAINS IN HER LOWER ABDOMEN, SHE COULD LITERALLY FEEL THE COILS INSIDE OF HER. THE DISCOMFORT FROM THE ABLATION DISAPPEARED WITHIN 24 HOURS. SHE CALLS TO HER DOCTOR OFFICE WERE BLOWN OFF, AND SHE WAS TREATED LIKE THIS WAS ALL IN HER HEAD. AT HER 6 WEEK POST-OPERATION APPOINTMENT SHE WAS TOLD THAT SHE SHOULD CONSULT HER PRIMARY CARE PHYSICIAN FOR ALL THESE OTHER PROBLEMS. DESPITE THE FACT THAT SHE HAD NONE OF THEM PRIOR TO SURGERY. THE ABLATION ALSO PROVED TO BE A FAILURE. SHE STILL HAVE MONTHLY PERIODS THAT LAST

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ANYWHERE FROM 10-15 DAYS IN DURATION. SHE NOW HAVE HORRENDOUS JOINT PAIN, LOWER BACK PAIN AND FATIGUE. SHE USED TO BE HEALTHY AND HAVE A FULL SOCIAL LIFE. NOW IT IS ALL SHE CAN DO TO DRAG HERSELF TO WORK AND DRAG HERSELF HOME SHE HAS HAD TO CUT HER HOURS AT HER JOB, BECAUSE SHE COULD NOT HANDLE WORKING FULL-TIME ANYMORE. EVERY MORNING IT IS A TEST OF HER WILL JUST TO GET OUT OF BED IN THE MORNING. SHE HAS SPENT THOUSANDS OF DOLLARS WITH PHYSICIANS IN OTHER SPECIALTIES TRYING TO DETERMINE IF THERE ARE ANY OTHER THINGS THAT COULD BE CAUSING HER PAIN AND FATIGUE. THE ONLY COMMON DENOMINATOR IS ESSURE. HER LOWER BACK PAIN IS 24/7 TORTURE, AND MULTIPLE NUCLEAR MAGNETIC RESONANCE IMAGINGS (MRLS) SHOWED NOTHING THAT COULD BE CAUSING THIS TYPE OF ACHING THROBBING CONSTANT PAIN. SHE LED A PAIN-FREE LIFE BEFORE ESSURE. SHE JUST WANTED TO GET RID OF HER PERIODS SO SHE DID NOT BLEED HALF THE MONTH, EVERY MONTH. INSTEAD SHE NOW FEELS LIKE AN 85 YEAR-OLD WOMAN AT THE AGE OF (B)(6). SHE IS VERY DEPRESSED AND HAVE NO QUALITY OF LIFE, SHE COUNT THE MINUTES UNTIL SHE CAN TAKE HER NEXT DOSE OF PAIN MEDICATION TO TRY AND ALLEVIATE THE ACHING JOINT PAIN IN HER HANDS, FEET, ANKLES, KNEES, AND LOWER BACK. NO ONE IN HER FAMILY HAS EVER HAD ARTHRITIS PAIN PRIOR TO THEIR SIXTIES. SHE LOOKS LIKE SHE IS FIVE MONTHS PREGNANT FROM THE BLOAT. SHE DID NOT HAVE THIS BEFORE ESSURE. NEARLY THREE YEARS LATER, SHE STILL DEAL WITH OCCASIONAL UNEXPLAINED DIZZY SPELLS AND RANDOM STABBING PAINS IN HER LOWER ABDOMEN. SHE HAD 20/20 VISION PRIOR TO ESSURE, NOW SHE HAS OCCASIONAL SPELLS OF UNEXPLAINED BLURRY VISION AND SHE COULD NO LONGER DRIVE AT NIGHT DUE TO NIGHT VISION ISSUES. HER OPHTHALMOLOGIST HAS NO IDEA WHY HER VISION IS STILL 20/20. SHE FINALLY FOUND A NEW GYNECOLOGIST WHO LISTENED TO HER AND HAS DISCONTINUED IMPLANTING ESSURE DUE TO COMPLAINTS HE HAS RECEIVED FROM HIS PATIENTS HE IMPLANTED IN THE PAST. SHE IS SCHEDULED FOR A PARTIAL HYSTERECTOMY TO REMOVE ESSURE IN (B)(6). SHE FEELS LIKE THEY HAVE ALL BEEN DUPED, EVEN THE PHYSICIAN WHO IMPLANTED THEM IN HER. SHE IS NOT A HYPOCHONDRIAC, AND SHE IS NOT A DRUG-SEEKER, SHE JUST WANT HER LIFE BACK, AND SHE WANTS TO BE THE PLEASANT PERSON. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ARTY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE STABBING PAINS IN HER LOWER ABDOMEN AND LOWER BACK PAIN. SHE IS SCHEDULED FOR A PARTIAL HYSTERECTOMY TO REMOVE ESSURE. THESE EVENTS WERE CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

CORRECTION ON (B)(6) 2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT EVERY MORNING IT IS A TEST OF HER WILL JUST TO GET OUT OF BED IN THE MORNING, NO QUALITY OF LIFE WAS RECODED TO MEDDRA LLT QUALITY OF LIFE DECREASED.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01657	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1988, AWARENESS DATE 24-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. CONSUMER WAS (B)(6) AT THE TIME OF THE REPORT, AND HAS HAD ESSURE FOR 8 YEARS. BEFORE ESSURE SHE WAS A HEALTHY MOTHER OF TWO. OVER THE YEARS SHE HAS BEEN TO COUNTLESS DOCTORS HOPING TO FIGURE OUT WHAT WAS WRONG WITH HER. NO ONE EVER COULD. SHE HAS BEEN CHECKED FOR LYME DISEASE, BRAIN DISORDERS, BLOOD DISORDERS, ADRENAL PROBLEMS, AND EVERYTHING IN BETWEEN. SHE HAD CONSTANT JOINT PAIN, FREQUENT HEADACHES, RECURRENT URINARY TRACT INFECTIONS AND YEAST INFECTIONS, SHE HAD TO HAVE AN ABLATION DONE DUE TO CONSTANT AND HEAVY MENSTRUAL BLEEDING THAT WENT ON FOR MONTHS. SHE WAS ALWAYS TIRED, HAD FREQUENT MIGRAINES, HER TEETH HAVE CHIPPED AND BROKE, HER HAIR WAS FALLING OUT, SWELLING OF THE LEGS, ABDOMINAL PAIN, INSOMNIA, AND DEPRESSION. FOLLOW-UP RECEIVED ON 17-NOV-2015: PTC (PRODUCT TECHNICAL COMPLAINT) RESULT WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCTED AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CONSTANT AND HEAVY MENSTRUAL BLEEDING. SHE UNDERWENT AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION). CONSUMER ALSO REPORTED RECURRENT URINARY TRACT INFECTIONS. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. CONSTANT AND HEAVY MENSTRUAL BLEEDING IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENT IS UNLISTED. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE EVENT CONSTANT AND HEAVY MENSTRUAL BLEEDING AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. URINARY TRACT INFECTION PATHOGENESIS IN WOMEN BEGINS WITH COLONIZATION OF THE VAGINAL INTROITUS BY UROPATHOGENS FROM THE FECAL FLORA, FOLLOWED BY ASCENSION VIA THE URETHRA INTO THE BLADDER. CONSIDERING THE NATURE OF THIS EVENT, AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS PERFORMED (ENDOMETRIAL ABLATION). BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01658	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7): 4/27/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE NUMBER FDA-2014-N-0736-1800) IN UNITED STATES ON 24-OCT-2015 IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE FOR ESSURE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEP-2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN 2006 BY THE RECOMMENDATION OF HER GYNECOLOGIST BECAUSE OF THE SHORT RECOVERY TIME AND STATING IT IS 99 PERCENT EFFECTIVENESS. AFTER A FEW YEARS, SHE STARTED TO NOTICE SHE WOULD GET HER PERIOD EVERY 3 WEEKS, HEAVIER BLEEDING, SEVERE CRAMPING, MEMORY LOSS, SEVERE BACK PAIN ON HER RIGHT SIDE, AND HAIR LOSS. SHE DEAL WITH THIS FOR SEVERAL YEARS THINKING SHE WAS STARTING MENOPAUSE EARLY. SHE WENT TO SEVERAL DIFFERENT GYNECOLOGISTS AND ALL SUGGESTED SHE GETS ON A BIRTH CONTROL PILL, MUSCLE RELAXERS, OR TAKE PAIN MEDICINE TO HELP. IN (B)(6) 2015 SHE STARTED TO HAVE SUCH SEVERE PAIN. SHE WENT TO THE EMERGENCY ROOM WHERE THEY DID AN X-RAY AND ONLY NOTICED A CYST ON HER OVARY AND A CYST ON HER KIDNEY. SINCE THE COILS COULD BE SEEN IN THE X-RAY NONE OF THE DOCTORS THOUGHT THAT WAS THE PROBLEM. MONTHS LATER HER PAIN CONTINUED TO GET WORSE AND HER CO-WORKER SUGGESTED SHE GOES SEE A FRIEND OF HIS WHO IS FAMILIAR WITH ESSURE PROBLEMS. AFTER A THOROUGH EXAMINATION HE RECOMMENDED FOR HER TO HAVE A PARTIAL HYSTERECTOMY SO THAT THE ESSURE COILS COULD BE REMOVED. ON (B)(6) 2015 AT THE AGE OF (B)(6), SHE HAD A PARTIAL HYSTERECTOMY COMPLETED WHERE HER DOCTOR FOUND THAT THE ESSURE COILS HAD RIPPED THROUGH HER FALLOPIAN TUBES AND STATED THIS WAS THE WORSE CASE HE HAD EVER SEEN AND COULD NOT BELIEVE SHE WENT THROUGH MONTHS IF NOT YEARS LIKE THIS. MONTHS AFTER HAVING THE PROCEDURE SHE HAD NO PAIN, NO HAIR

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LOSS, AND FEEL LIKE SHE IS STARTING TO GET HER LIFE BACK. FOLLOW UP RECEIVED ON 17-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFICIT IS EXCLUDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006 AND AFTER FEW YEARS, SHE EXPERIENCED SOME NON-SERIOUS EVENTS SUCH AS CHANGE IN MENSTRUAL PATTERN AND ABDOMINAL PAIN DUE TO OVARY AND KIDNEY CYSTS. IN (B)(6) 2015, SHE STARTED TO HAVE SEVERE PAIN (INTERPRETED AS PELVIC PAIN) AND PARTIAL HYSTERECTOMY WAS PERFORMED ON (B)(6) 2015. ESSURE COILS HAD RIPPED THROUGH HER TUBES (INTERPRETED AS FALLOPIAN TUBE PERFORATION). PERFORATION AND PELVIC PAIN ARE SERIOUS EVENTS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE. GIVEN THE NATURE OF EVENTS AND COMPATIBLE TEMPORAL RELATIONSHIP, CAUSALITY CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED AND A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01659	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1785 AND FDA-2014-N-0736-1786, AWARENESS DATE 24-OCT-2015) WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 FOR PERMANENT BIRTH CONTROL AS SHE DID NOT WANT TO GO ON THE PILL AS EVEN TAKING THIS DAILY AT THE REQUIRED TIME SHE BECAME PREGNANT WITH HER 3RD CHILD. ADDITIONAL INFORMATION WAS RECEIVED ON 25-OCT-2015. THE CONSUMER REPORTED ESSURE WAS INSERTED A FEW MONTHS AFTER HER 3RD CHILD WAS BORN, SHE WAS (B)(6). HER MEDICAL HISTORY INCLUDED: SEASONAL ALLERGIES AND THE OCCASIONAL COLD/FLU, SHE WAS HOSPITALIZED 3 TIMES, FOR THE BIRTH OF HER CHILDREN IN 2001, 2005 AND 2008 (WITH NO COMPLICATIONS); AND AN OUTPATIENT PROCEDURE IN (B)(6) 2007 TO REMOVE HER TONSILS. SHE WAS NEVER TOLD ABOUT THE PRODUCT HAVING NICKEL, SHE WAS ONLY ASKED IF SHE HAD ANY ALLERGIES TO WHICH SHE REPLIED OTHER THAN SEASONAL SHE WAS NOT AWARE IF SHE HAD OTHER ALLERGIES. SHE WAS NOT TESTED FOR ANY ALLERGIES. THE PROCEDURE WAS PERFORMED AT THE LOCAL HOSPITAL ON A FRIDAY MORNING WHERE SHE WAS PLACED UNDER GENERAL ANESTHESIA/ SHE WAS ALSO GIVEN PAIN MEDICATION TO TAKE AFTER THE PROCEDURE AND WAS TOLD TO TAKE IT EASY FOR THE REST OF THE DAY AND SHE SHOULD BE FINE AFTER SORENESS AND A LITTLE BLEEDING IS TO BE EXPECTED. SHE WENT BACK IN FOR THE HSG (HYSTEROSALPINGOGRAM) TESTING WHICH SHE WAS TOLD HER TUBE WAS OCCLUDED AND THE OTHER OPENED; SHE WAS RESCHEDULED TO COME BACK IN 3 MONTHS AND SO IF CONTINUED FOR A YEAR AFTER THE PROCEDURE WHERE THE HSG SHOWED BOTH TUBES WERE OCCLUDED. THE DOCTOR POINTED TO THE SCREEN HE BE LOOKING OUT EACH TIME THE HSG WAS PERFORMED SHOWING THAT THE TUBE WAS NOT

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BLOCKED UNTIL THE LAST HSG IT SHOWED IT WAS BLOCKED UNTIL THE LAST TIME SHE WAS THERE. HE POINTED TO THE SCREEN SHOWING BOTH TUBES WERE BLOCKED. SHE WAS TOLD SHE WAS HIS ONLY PATIENT THAT IT TOOK THIS LONG FOR THE TUBES TO OCCLUDE. DURING THIS TIME, SHE DID NOT HAVE A PERIOD FOR 6 MONTHS, AND WAS TOLD SHE WAS BREASTFEEDING/ON THE PILL, IT WAS NORMAL. AFTER SHE HAD HER FIRST PERIOD, WHERE NORMALLY WOULD NOT HURT, WOULD LAST 3 DAYS AT THE MOST AND WHERE AND COULD USE REGULAR TAMPONS; SHE COULD FELT WHEN SHE OVULATED, IT WAS PAINFUL. HER PERIODS BECAME PAINFUL, SEVERE CRAMPING AND WHAT SHE CALLED VAGINAL CRAMPING. IT FELT LIKE IF SHE WAS DILATING TO GIVE BIRTH. SHE STATED THE SAME WOULD HAPPEN AFTER INTERCOURSE, SHE WAS USING SUPER PLUS TAMPONS AND CHANGE THEM EVERY HOUR FOR THE FIRST 3 DAYS AND GO TO REGULAR FOR THE NEXT 2 DAYS AND THEN HAVE SPOTTING FOR THE NEXT 2 DAYS. AGAIN SHE WAS TOLD THIS WAS NORMAL AFTER HAVING GONE SO LONG WITHOUT A PERIOD AND NOT TO MENTION SHE WAS GETTING OLDER. IN (B)(6) 2010, SHE WAS DIAGNOSED WITH THE BEGINNING STAGES FOR CERVICAL CANCER; SHE HAD A LEEP PROCEDURE TO REMOVE THE CANCER AND WAS TOLD SHE SHOULD NOT WORRY ABOUT ANY LONG TERM COMPLICATIONS FROM IT, AS IT COULD POSSIBLY AFFECT HER CERVIX ABILITY TO DILATE SHE SHOULD NOT BECOME PREGNANT BUT THAT WAS NOT AN ISSUE BECAUSE SHE HAD ESSURE. FOR HER SURPRISE SHE BECAME PREGNANT WITH HER 4TH CHILD IN (B)(6) 2011. SHE STARTED DOING RESEARCH ON ESSURE AS SHE WAS WORRIED ABOUT WHAT THE COMPLICATIONS THERE COULD BE HAVING ESSURE STICKING OUT INTO HER UTERUS AND HER BABY GROWING THERE. SHE HAD A VAGINAL ULTRASOUND DONE IN HER (B)(6) WEEK TO MAKE SURE THAT THE BABY WAS IN HER UTERUS WHEN THE DOCTOR DISCOVERED AN OVARIAN CYST. SHE WAS TOLD IT WAS SMALL ABOUT 2 CM AND IT APPEARED TO BE TRANSPARENT. WHERE HER OTHER PREGNANCIES WERE NORMAL PREGNANCIES WITH NO COMPLICATIONS SHE WAS TOLD SHE HAD PLACENTA PREVIA AFTER SHE STARTED BLEEDING AT THE END OF HER (B)(6) TRIMESTER. SHE WAS PUT ON BED REST HOPING THAT IN TIME THE PLACENTA WOULD MOVE, AND SHE DID NOT WENT BACK TO WORK. HOWEVER SHE STARTED HAVING CONTRACTIONS IN HER (B)(6) OF PREGNANCY. SHE WENT TO THE HOSPITAL SO MANY TIMES SHE LOST COUNT. SHE WAS IN LABOR EACH TIME HOWEVER WAS NOT DILATING; THEY WOULD BE ABLE TO STOP THE CONTRACTIONS AS THEY DID NOT WANT HER TO HAVE THE BABY AS IT WAS TOO SOON. SHE WAS TAKEN OFF WORK AND PUT ON BED REST TO AVOID GOING INTO PRE-TERM LABOR. SHE GAVE BIRTH TO A HEALTHY GIRL IN (B)(6) 2012. HOWEVER A FEW MONTHS AFTER SHE WAS BORN SHE WAS TREATED FOR BRONCHITIS FOR THE FIRST TIME (CHILD CASE REPORTED UNDER REFERENCE (B)(4)). SINCE THEN SHE HAVE LOST COUNT OF HOW MANY TIMES SHE HAS GOTTEN IT, FINALLY THEY GOT HER UNDER THE RIGHT MEDICATION AND SHE WAS DOWN TO TWICE A YEAR. HER DOCTOR TOLD HER THIS PREGNANCY WAS A FLUKE AND THAT SHE WAS HIS FIRST PATIENT THAT HAD GOTTEN PREGNANT WITH ESSURE. SHE WAS PUT ON BIRTH CONTROL AGAIN. IN (B)(6) 2012, SHE WAS ONCE AGAIN SURPRISED AS SHE FOUND OUT SHE WAS PREGNANT WITH HER 5TH CHILD (SECOND PREGNANCY WITH ESSURE REPORTED UNDER REFERENCE (B)(4)). DURING THE VAGINAL ULTRASOUND DURING OF HER 6 WEEK OF PREGNANCY IT WAS NOTED THAT THE CYST HAD GROWN. THIS WAS CONCERNING TO THE DOCTOR AND HE TOLD HE WOULD BE DOING ANOTHER ULTRASOUND LATER IN THE PREGNANCY. DURING THIS PREGNANCY SHE DID NOT HAVE PLACENTA PREVIA BUT AGAIN SHE SUFFERED FROM CONTRACTIONS AS SHE PREVIOUSLY DID. AS SHE KNEW WHAT WAS GOING ON WHEN SHE WAS HAVING THE CONTRACTIONS SHE DID NOT GO THE HOSPITAL AS OFTEN BUT SHE WAS PLACED ON LEAVE EARLY. SHE GAVE BIRTH TO A HEALTHY GIRL IN (B)(6) 2013 BUT AGAIN SHE STARTED GETTING BRONCHITIS AS WELL (CHILD CASE REPORTED UNDER REFERENCE (B)(4)). AT TIME OF THE REPORT, SHE UNDER THE RIGHT MEDICATION WHERE SHE TOO WAS ONLY GETTING BRONCHITIS ONCE OR TWICE A YEAR. AFTER SHE HAD HER DAUGHTER, SHE ASKED ABOUT GETTING A TUBAL LIGATION AS OBVIOUSLY ESSURE HAD FAILED, AND WHILE UNDERGOING THE TUBAL LIGATION, THEY TOOK OUT THE 8CM CYST. SINCE HER ESSURE PROCEDURE, SHE SUFFERED AND HAD THE FOLLOWING SYMPTOMS: SHARP/STABBING PELVIC PAIN LASTING LONGER THAN 30 MINUTES, OVARIAN CYSTS, PREGNANCY (TWICE), DISCHARGE (NO ODOR) ALL THE TIME, CERVICAL CANCER, EXCESSIVE BLEEDING DURING PERIOD, PAINFUL OVULATION, PAINFUL PERIODS, PAINFUL INTERCOURSE, LONG MENSTRUAL CYCLES, UTI, HEADACHES/MIGRAINES

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(NAUSEA), BRAIN FOG, ANXIETY, MOOD SWINGS, DIMINISHED BRAIN FUNCTION, ANEMIA, BLOOD CLOTS IN MENSES, RASHES/HIVES, DRY SKIN, WEIGHT ISSUES AND UNEXPLAINED FEVERS. WHEN SHE BROUGHT THESE QUESTIONS/CONCERNS TO THE DOCTOR OR NURSES, IT SEEMED LIKE THEIR ANSWER FOR EVERYTHING WAS SHE WAS GETTING OLDER OR WAS BUSY FULL TIME WORKING MOTHER. SHE STATED BESIDES THE SYMPTOMS OF PREGNANCY AND THE SYMPTOMS THAT HAPPEN WHEN SHE WAS ON HER PERIOD (IT WAS EVERY TIME WAS ON HER PERIOD) THESE SYMPTOMS WERE CONSTANT AND AT TIMES DEBILITATING. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT WITH HER 4TH CHILD. SHE HAD PLACENTA PREVIA. SHE STARTED HAVING CONTRACTIONS IN HER (B)(6) OF PREGNANCY. SHE WENT TO THE HOSPITAL SO MANY TIMES SHE LOST COUNT. SHE WAS IN LABOR EACH TIME HOWEVER WAS NOT DILATING; THEY WOULD BE ABLE TO STOP THE CONTRACTIONS AS THEY DID NOT WANT HER TO HAVE THE BABY AS IT WAS TOO SOON. SHE GAVE BIRTH TO A HEALTHY GIRL. HOWEVER A FEW MONTHS AFTER SHE WAS BORN SHE WAS TREATED FOR BRONCHITIS FOR THE FIRST TIME (CHILD CASE REPORTED UNDER REFERENCE (B)(4)). THE EVENT PREGNANCY IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE OTHER EVENTS ARE SERIOUS AND UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. MOST OF PREMATURE BIRTHS OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES. A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY (PLACENTA PREVIA AND PREMATURE LABOUR) CANNOT BE EXCLUDED. ALSO, SINCE PREGNANCY OCCURRED MORE THAN 3 MONTHS AFTER ESSURE INSERTION, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO PREMATURE LABOUR. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND SEVERAL NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 18-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01660	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): 12/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1785 AND FDA-2014-N-0736-1786, AWARENESS DATE 24-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 FOR PERMANENT BIRTH CONTROL AS SHE DID NOT WANT TO GO ON THE PILL (SHE BECAME PREGNANT WITH HER 3RD CHILD EVEN TAKING THE PILL DAILY AT THE REQUIRED TIME). ADDITIONAL INFORMATION WAS RECEIVED ON (B)(6) 2015. SHE WENT BACK IN FOR THE HSG (HYSTEROSALPINGOGRAM) TESTING WHICH SHE WAS TOLD HER TUBE WAS OCCLUDED AND THE OTHER OPENED; SHE WAS RESCHEDULED TO COME BACK IN 3 MONTHS AND SO IF CONTINUED FOR A YEAR AFTER THE PROCEDURE WHERE THE HSG SHOWED BOTH TUBES WERE OCCLUDED. CONSUMER BECAME PREGNANT WITH HER 4TH CHILD IN (B)(6) 2011 (CASE REPORTED UNDER REFERENCE (B)(4)). SHE GAVE BIRTH TO A HEALTHY GIRL IN (B)(6) 2012. HOWEVER A FEW MONTHS AFTER SHE WAS BORN SHE WAS TREATED FOR BRONCHITIS FOR THE FIRST TIME (CHILD CASE REPORTED UNDER REFERENCE (B)(4)). IN (B)(6) 2012, SHE WAS ONCE AGAIN SURPRISED AS SHE FOUND OUT SHE WAS PREGNANT WITH HER 5TH CHILD. DURING THE VAGINAL ULTRASOUND DURING AT 6 WEEK OF PREGNANCY IT WAS NOTED THAT HER OVARIAN CYST HAD GROWN. THIS WAS CONCERNING TO THE DOCTOR AND HE TOLD HE WOULD BE DOING ANOTHER ULTRASOUND LATER IN THE PREGNANCY. DURING THIS PREGNANCY SHE DID NOT HAVE PLACENTA PREVIA BUT AGAIN SHE SUFFERED FROM CONTRACTIONS AS SHE PREVIOUSLY DID (PREMATURE CONTRACTIONS). AS SHE KNEW WHAT WAS GOING ON WHEN SHE WAS HAVING THE CONTRACTIONS SHE DID NOT GO THE HOSPITAL AS OFTEN BUT SHE WAS PLACED ON LEAVE EARLY. SHE GAVE BIRTH TO A HEALTHY GIRL IN (B)(6) 2013 BUT AGAIN SHE STARTED GETTING BRONCHITIS AS WELL (CASE

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REPORTED UNDER REFERENCE (B)(4)). AT TIME OF THE REPORT, SHE UNDER THE RIGHT MEDICATION WHERE SHE TOO WAS ONLY GETTING BRONCHITIS ONCE OR TWICE A YEAR. AFTER SHE HAD HER DAUGHTER, SHE ASKED ABOUT GETTING A TUBAL LIGATION AS OBVIOUSLY ESSURE HAD FAILED, AND WHILE UNDERGOING THE TUBAL LIGATION, THEY TOOK OUT THE 8CM CYST. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD 2 PREGNANCIES AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS CASE REFERS TO HER SECOND PREGNANCY WITH ESSURE. DURING THIS PREGNANCY, SHE SUFFERED WITH PREMATURE CONTRACTIONS. AFTER THE DELIVERY OF HER DAUGHTER, SHE UNDERWENT A TUBAL LIGATION. DURING THIS PROCEDURE, AN OVARIAN CYST WAS REMOVED. ONLY PREGNANCY IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG) TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, CONSUMER HAD 2 HSG TESTS. TUBAL OCCLUSION WAS ONLY CONFIRMED IN THE SECOND TEST. DURING HER PREGNANCY, SHE HAD PREMATURE CONTRACTIONS AND WAS PLACED ON LEAVE EARLY. ALTHOUGH SHE DELIVERED WITHOUT COMPLICATIONS; CONSIDERING A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED; THE REPORTED EVENTS WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. AS THE REPORTED PREMATURE CONTRACTIONS WERE REGARDED AS A SERIOUS COMPLICATION OF PREGNANCY (FOR WHICH CAUSALITY WITH ESSURE CANNOT BE EXCLUDED); THIS CASE WAS REGARDED AS INCIDENT. REGARDING THE REPORTED OVARIAN CYST, BASED ON ESSURE LOCAL ACTION IN FALLOPIAN TUBES AND GIVEN EVENT'S NATURE; CAUSALITY IS CONSIDERED UNLIKELY. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01661	BAYER HEALTHCARE LLC	11/20/2015	11/20/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1953, AWARENESS DATE 25-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. THE FIRST FEW MONTHS SHE HAD NO SIDE EFFECTS. THEN IT SLOWLY BEGAN TAKING OVER HER BODY: WEIGHT GAIN, TERRIBLE HEADACHES, SKIN IRRITATIONS, ACNE, JOINT PAIN, MOOD SWINGS, TIRED ALL THE TIME, HORRIBLE MONTHLY PERIODS, MEMORY LOSS, NO SEX DRIVE, PAIN, HAIR LOSS AND MUCH MORE. SHE WAS SCHEDULED TO HAVE A HYSTERECTOMY IN (B)(6) 2015 AND SHE WAS ONLY (B)(6) AT THE TIME OF THE REPORT. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 17-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE.

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COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PAIN (INTERPRETED AS PELVIC PAIN). SHE WAS SCHEDULED TO HAVE A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01611	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D31450

Single Use: Y
Implant Date (E6): 10/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH PROFESSIONAL (UNSPECIFIED) IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER D31450 (EXPIRATION DATE 28-NOV-2017). FIRST ESSURE SYSTEM WAS PLACED WITHOUT DIFFICULTY. AT THE TIME OF THE PASSAGE OF THE SECOND HANDLE PASSAGE IN MANDRIN, THIS ONE BROKE IN TWO PARTS. A PART OF THE MANDRIN WAS FOUND IN UTERUS AND WAS REMOVED. NEW ESSURE SYSTEM WAS TAKEN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE AT THE TIME OF THE SECOND HANDLE PASSAGE IN MANDRIN, THIS ONE BROKE IN TWO PARTS AND A PART OF THE MANDRIN WAS FOUND IN UTERUS. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT CASE, IT IS NOT CLEAR FROM THE REPORTED INFORMATION IN WHICH PART OF THE ESSURE SYSTEM THE BREAKAGE OCCURRED. HOWEVER, SINCE THE BREAKAGE OCCURRED DURING THE ESSURE INSERTION PROCEDURE A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION, IN ORDER TO CLARIFY THE EVENT, ARE EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP RECEIVED ON 24-NOV-2015 WITH (B)(4) INVESTIGATION RESULT: FINAL ASSESSMENT: BATCH NUMBER - D31450. PRODUCTION DATE - 24-NOV-2014. EXPIRATION DATE - 28-NOV-2017. (B)(4). FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01669	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/2/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-0317, AWARENESS DATE 13-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. AT FIRST EVERYTHING WAS FINE. A YEAR PRIOR TO THIS REPORT, IN 2014, SHE STARTED EXPERIENCING MAJOR BLOATING, WHERE SHE LOOKED LIKE PREGNANT. HER LOWER ABDOMEN HURT ALL THE TIME. WHEN SHE HAD HER PERIOD SHE GOT SEVERE CRAMPS AND VERY HEAVY BLEEDING. BEFORE ESSURE SHE NEVER HAD CRAMPS. IT WAS REPORTED THAT WHEN SHE BRUSHES HER HAIR, LOTS COMES OUT ON THE BRUSH. SHE ALSO EXPERIENCED BACTERIAL VAGINOSIS 3 TIMES, AND WAS EXTREMELY TIRED ALL THE TIME. PTC INVESTIGATION RESULT WAS RECEIVED ON 11-SEP-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE

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REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP RECEIVED ON 25-OCT-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-Q736-1736, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER REPORTED THAT HER HYSTERECTOMY WAS SCHEDULED FOR (B)(6) 2015. SHE COULD NOT WAIT TO NOT BE IN PAIN ANYMORE AND FEEL LIKE HERSELF AGAIN. SHE HAS NOT BEEN ON BIRTH CONTROL PILLS IN YEARS AND HAD PERIODS WITH HUGE BLOOD CLOTS. HER LOWER ABDOMEN AND LOWER BACK HURT ALL THE TIME. UPDATED PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 13-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STATED THAT HER LOWER ABDOMEN HURTS ALL THE TIME. SHE WAS SCHEDULED FOR A HYSTERECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABDOMINAL PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. UPON RECEIPT OF FOLLOW-UP INFORMATION STATING THAT A HYSTERECTOMY WAS SCHEDULED, THE CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01670	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-1508) IN UNITED STATES ON 25-OCT-2015 AND IT WAS IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN (B)(6) 2012. ADDITIONAL INFORMATION RECEIVED ON 17-NOV-2015. CONSUMER STATED THAT A LITTLE OVER A YEAR AND A WHOLE LOT OF NEW-HEALTH ISSUES LATER IN (B)(6) 2014 SHE HAD A PARTIAL HYSTERECTOMY. SHE STILL SUFFER FROM EXTREME PELVIC PAIN, EXTREMELY PAINFUL SEX, HEADACHES AND WEIGHT GAIN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 17-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY

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CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO WAS SUBMITTED TO A PARTIAL HYSTERECTOMY APPROXIMATELY 1 YEAR AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, AFTER THIS PROCEDURE SHE STILL SUFFERS FROM EXTREME PELVIC PAIN. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. ADDITIONALLY, WHEN ESSURE REMOVAL IS REQUIRED A SALPINGECTOMY OR HYSTERECTOMY ARE USUALLY REQUIRED. IN THIS CASE, CONSUMER'S PAIN PERSISTED AFTER A PARTIAL HYSTERECTOMY. ALTHOUGH THIS INFORMATION COULD SUGGEST A NEGATIVE DECHALLENGE; SINCE LIMITED INFORMATION WAS PROVIDED AND AS IT IS UNCLEAR IF ESSURE/FALLOPIAN TUBES WERE REMOVED DURING THIS PROCEDURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. THEREFORE; THIS CASE WAS REGARDED AS INCIDENT. NON-SERIOUS EVENTS WERE ALSO REPORTED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01671	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1497, AWARENESS DATE 25-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. ADDITIONAL INFORMATION RECEIVED ON 17-NOV-2015. THE CONSUMER REPORTED THAT HER SYMPTOMS STARTED WITH DEBILITATING BACK PAIN, WHICH LASTED UNTIL SHE FINALLY GOT USED TO IT. SHE ALSO EXPERIENCED HEADACHES, NAUSEA, ITCHY SKIN, METAL TASTE, MOOD CHANGES, IRRITABILITY, DEPRESSION AND HAIR LOSS. SHE HAD PAINFUL PERIODS THAT WENT FROM LASTING THREE DAYS TO TWO WEEKS AT A TIME AND BLEEDING SO BAD WITH CLOTTING GOLF SIZE BALL CLOTS. SHE DEALT WITH THAT FOR SIX AND A HALF YEARS, WHICH LED HER TO BECOMING SEVERELY ANEMIC. THAT LED TO AN EMERGENCY RIDE IN AN AMBULANCE AND ACCORDING TO HER, SHE ALMOST DIED. SHE ALSO HAD PRECANCEROUS CELLS. SHE UNDERWENT MANY TESTS TO FIND OUT WHAT WAS GOING ON. WHEN SHE WAS (B)(6), THE CONSUMER REMOVED ESSURE BY HYSTERECTOMY AND SHE HAD NO MORE PROBLEMS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 17-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE

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MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER PERIODS WENT FROM LASTING THREE DAYS TO TWO WEEKS AT A TIME WITH BLEEDING SO BAD WITH CLOTTING; WHICH LED HER TO BECOME ANEMIC. SHE WAS SUBMITTED TO A HYSTERECTOMY AND HAD NO MORE PROBLEMS. ONLY ANEMIA IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER RELATED HER MENSTRUAL CHANGES TO ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01672	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1514, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. ADDITIONAL INFORMATION RECEIVED ON 18-NOV-2015 (PTC INVESTIGATION RESULT). CONSUMER HAD ESSURE PLACED IN (B)(6) 2015 AND IMMEDIATELY STARTED TO HAVE SEVERE SIDE EFFECTS AFTER PLACEMENT. SHE HAS BEEN SUFFERING FROM ABDOMINAL PAIN, HEAVY MENSTRUAL BLEEDING THAT CONTINUES FOR WEEKS AT A TIME, DAILY HEADACHES, EXTREME HOT FLASHES, AFTER HAVING THE ESSURE PLACED SHE JUST BREAK OUT IN A SWEAT WITHOUT EVEN DOING MUCH ACTIVITY. ON (B)(6) 2015 SHE HAD THE HSG (HYSTEROSALPINGOGRAM) TEST DONE. DURING THE TEST IT SHOWED THE RIGHT COIL WAS PROPERLY PLACED AND BLOCKED OFF (GRADE 2), HOWEVER; THE LEFT COIL HAD MIGRATED IN TO HER UTERUS (GRADE 1) THE CONTRAST DYE FLOWED FREELY THROUGH TUBE. SHE IMMEDIATELY CONTACTED HER DOCTOR DUE TO THE SYMPTOMS SHE WAS HAVING AND WITH THE MIGRATED COIL. SHE WILL HAVE A HYSTERECTOMY IN (B)(6) 2015. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO

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CONFIRM ARTY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 3 MONTHS AFTER ESSURE INSERTION, A HSG (HYSTEROSALPINGOGRAM) TEST WAS PERFORMED AND THE RESULT SHOWED THE RIGHT COIL WAS PROPERLY PLACED AND BLOCKED OFF (GRADE 2), HOWEVER; THE LEFT COIL HAD MIGRATED IN TO MY UTERUS (SEEN AS DEVICE EXPULSION). SHE WILL HAVE A HYSTERECTOMY PERFORMED. THIS EVENT WAS CONSIDERED SERIOUS AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY). IN THIS CASE, THE EXACT DATE AND MECHANISM OF EXPULSION WERE NOT KNOWN. CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED THAT A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01673	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-1746) IN UNITED STATES ON 25-OCT-2015 AND IT WAS IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN (B)(6) 2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED IN 2011 WITHOUT AN OPERATING ROOM OR ANY ANESTHESIA FOR THAT FACT. CONSUMER STATED THAT ESSURE INSERTION WAS VERY PAINFUL. SHE STARTED HAVING VERY HEAVY PERIODS POST PROCEDURE. SHE HAD SPORADIC PELVIC PAIN THAT WOULD SOMETIMES BRING HER TO HER KNEES. LT HURT SO BAD SHE ALSO HAD STOMACH PAIN THAT COMES AND GOES. SEVERAL MONTHS AGO (3.5) SHE STARTED HAVING CHRONIC PELVIC PAIN ON BOTH SIDES BUT HER RIGHT WORSE ALMOST ALL THE TIME AND NON STOP. SHE COULD NOT BE ON THE PILL DUE TO BLOOD CLOTS. SHE NOW IS SCHEDULED TO HAVE A HYSTERECTOMY OUT (B)(6) 2015 AND GET THE ESSURE OUT OF HER TO ALLEVIATE THE SYMPTOMS. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED

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CHRONIC PELVIC PAIN, SPORADIC PELVIC PAIN THAT WOULD SOMETIMES BRING ME TO KNEES. A HYSTERECTOMY WAS SCHEDULED. THE EVENT WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THE NATURE OF THE EVENT AND CONSIDERING THAT PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01674	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/5/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE NUMBER FDA-2014-N-0736-1602) IN UNITED STATES ON 25-OCT-2015 IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED ON (B)(6) 2014. CONSUMER STATED THAT THE PROCEDURE ITSELF WAS UNBEARABLE. SHE WAS TOLD TO TAKE AN IBUPROFEN HALF HOUR BEFORE THE PROCEDURE AND THAT SHE WOULD BE OK. SHE WAS NOT AT ALL OK. HER BODY STARTED INSTANTLY REACTING TO THE IMPLANT IN HER BODY THE VERY NEXT DAY AFTER THE ESSURE WAS PUT IN. SHE SOMEHOW PASSED A KIDNEY STONE, AND FROM THERE TILL THIS DAY EVEN SHE HAS TROUBLE MAKING BOWEL MOVEMENTS AND IN EXCRUCIATING PAIN EVERY DAY EVEN THOUGH SHE HAD TO GET A HYSTERECTOMY IN ORDER TO GET THE IMPLANTS OUT AND TO GET RID OF ALL THE PAIN AND SUFFERING. SHE WAS DEALING WITH FOR THE 6 AND A HALF MONTHS. LET ALONE DURING THE TIME SHE HAD THE IMPLANTS IN SHE HAD GONE TO THE DOCTORS AND THE EMERGENCY ROOM SEVERAL TIMES TELLING HER NOTHING WAS WRONG WITH THE IMPLANTS. HER DOCTOR SUGGESTED SHE GETS A COLONOSCOPY. SHE IS ONLY (B)(6) SHE SHOULD HAVE NOT GOTTEN A COLONOSCOPY NOR A HYSTERECTOMY. TO THIS DAY SHE STILL SUFFERS WITH OUT THE ESSURE. SHE DEALS WITH BLURRED VISION, DEPRESSION, ANXIETY, BRAIN FOG, HEADACHES EVERY DAY, PAIN IN HER STOMACH AND FEELS QUEEZIE ALL THE TIME GET, REAL DIZZY ALL THE TIME. AND NOT ONLY DO SHE SUFFERS WITH ALL THE SIDE EFFECTS FROM THIS HER HUSBAND SON AND FAMILY ALL SUFFER. SHE DEALS WITH THIS EVERYDAY OF HER LIFE NOW HOW IS THIS ESSURE SAFE FOR WOMEN AND NOT ONLY IS IT NOT SAFE IT IS NOT HEALTHY FOR WOMEN TO HAVE TO DEAL WITH ALL THE SYMPTOMS FOR THE REST OF THEIR LIVES BECAUSE THEY NO

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LONGER WANT MORE CHILDREN. FOLLOW UP RECEIVED ON 17-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014 AND REPORTED EXCRUCIATING PAIN EVERY DAY (INTERPRETED AS PELVIC PAIN) AMONGST OTHER NON-SERIOUS EVENTS. PELVIC PAIN IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP, NATURE OF EVENT, PRODUCT PROFILE AND LACK OF PLAUSIBLE ALTERNATIVE, CAUSALITY CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED; THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED AND A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01675	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1895, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER STATED THAT ESSURE STOLE 3 YEARS OF HER LIFE. SHE REPORTED BEING SUFFERING AND CONSTANTLY IN PAIN AND WAS FORCED TO HAVE HER LADY PARTS REMOVED TO BE PAIN FREE. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 17-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS CONSTANTLY IN

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PAIN (INTERPRETED AS PELVIC PAIN). SHE STATED THAT SHE HAD HER LADY PARTS REMOVED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. DESPITE THE LIMITED INFORMATION PROVIDED, GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. CONSUMER REPORTED HAVING HER LADY PARTS REMOVED, IMPLYING THAT A SURGICAL INTERVENTION WAS PERFORMED; THEREFORE THIS CASE WAS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT WAS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01676	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1610, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN 2007 AND GRADUALLY STARTED TO LOSE HER HEALTH. ADDITIONAL INFORMATION RECEIVED ON 17-NOV-2015 (PTC INVESTIGATION RESULT). SHE THOUGHT SHE WAS CRAZY UNTIL SHE FOUND OUT THAT OTHER WOMEN WITH ESSURE WERE EXPERIENCING SYMPTOMS LIKE HERS. SHE HAD A HYSTERECTOMY AND SALPINGECTOMY TO REMOVE ESSURE A YEAR PRIOR TO THIS REPORT AND WAS FEELING VASTLY BETTER. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET

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WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HYSTERECTOMY AND SALPINGECTOMY PERFORMED TO REMOVE ESSURE. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, ALTHOUGH THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, SINCE REPORTER REGARDED THE EVENTS AS A CONSEQUENCE OF ESSURE USE AND NO FOLLOW-UP WILL BE POSSIBLE; COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01677	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736- 1723, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER HAD THE ESSURE PROCEDURE A FEW MONTHS AFTER SHE GAVE BIRTH TO HER SECOND CHILD IN 2012. SHE STARTED CRAMPING AS SOON AS THE COILS WERE PLACED AND BLEEDING STARTED JUST A FEW MINUTES AFTER THAT AND WEEKS LATER SHE WAS STILL BLEEDING AND CRAMPING SEVERELY AND SHE WAS TOLD THAT IT COULD NOT BE CAUSED BY THE COILS. SHE BLED CONSTANTLY AND HEAVILY FOR OVER A YEAR AFTER THE PROCEDURE. SHE BEGAN TO HAVE BACK PAIN, MIGRAINE, PELVIC PAIN, MOOD SWINGS, WEIGHT GAIN, AND FATIGUE. ALWAYS BEING TOLD THAT WHAT SHE WAS EXPERIENCING WAS CAUSED BY SOMETHING ELSE. TEST AFTER TEST INCLUDING ULTRASOUNDS, MRIS, CAT SCANS AND BLOOD WORK ALL CAME BACK NORMAL, AND STILL SHE WAS TOLD THAT THE COILS WERE NOT THE CULPRIT. SHE WAS IN SUCH CONSTANT PAIN AND TIRED ALL THE TIME. OVER A YEAR AFTER THE INITIAL PROCEDURE SHE HAD AN UTERINE ABLATION TO TRY AND STOP THE BLEEDING THAT STILL HAD NO CONFIRMED CAUSE, AND THE WORKED FOR ALMOST A YEAR. UNFORTUNATELY THE ONLY THING THAT WAS STOPPED WAS THE BLEEDING, AND AFTER NEARLY A YEAR IT STARTED AGAIN. SHE SAW A NEW DOCTOR AND HE SCHEDULED A PARTIAL HYSTERECTOMY. HE REMOVED EVERYTHING, WITH THE EXCEPTION OF HER OVARIES. SINCE HER HYSTERECTOMY, SHE STILL SUFFERED FROM MIGRAINES, BACK PAIN AND FATIGUE. SHE HAS BEEN UNABLE TO LOSE THE WEIGHT THAT SHE HAD GAINED, AND NOW SHE HAS THE OCCASIONAL HOT FLASH AND IS UNABLE TO EVER TAKE HORMONES. FOLLOW UP RECEIVED ON 17-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL

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NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. SHE BLED CONSTANTLY AND HEAVILY FOR OVER A YEAR AFTER THE PROCEDURE, AN ABLATION AND PARTIAL HYSTERECTOMY WAS PERFORMED. GENITAL BLEEDING IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP, LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION AND CONSIDERING THAT CONSUMER RECOVERED AFTER SURGERY, CAUSALITY CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED; THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED AND A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01678	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2011
Explant Date (E7): 5/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2005, AWARENESS DATE 25-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. ADDITIONAL INFORMATION RECEIVED ON 17-NOV-2015. CONSUMER REPORTED ESSURE WAS INSERTED AFTER HER FOURTH CHILD. SIX MONTHS LATER, SHE HAD HER CONFIRMATION HYSTEROSALPINGOGRAM TEST DONE AND CONFIRMED BLOCKED. THREE YEARS LATER POSITIVE PREGNANCY. AS SHE WENT THROUGH HER NINE MONTHS SHE HAD EXTREME PAIN ON EACH OF HER SIDES WHERE SHE WOULD SUGGEST THE COILS WOULD HAVE BEEN. SHE MADE IT TO THE END. ON (B)(6) 2015 THE CONSUMER GAVE BIRTH A HEALTHY BOY. SHE CONTINUED TO HAVE HAIR LOSS. HER DOCTOR AND SHE ALREADY SCHEDULED HYSTERECTOMY WHICH WAS PERFORMED ON (B)(6) 2015 AT THE AGE OF (B)(6). HER LEFT COIL MIGRATED INTO THE UTERUS SO FUTURE PREGNANCY WOULD HAVE BEEN POSSIBLE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 17-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS

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CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AND DELIVERED AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (3.5 YEARS AFTER ESSURE PLACEMENT). ACCORDING TO HER, HER LEFT COIL MIGRATED INTO THE UTERUS. THE REPORTED EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG) TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, CONSUMER'S HSG TEST (PERFORMED 6 MONTHS AFTER DEVICE INSERTION) CONFIRMED TUBAL OCCLUSION. SHE BECAME PREGNANT 3 YEARS AFTER DEVICE PLACEMENT. AFTER DELIVERY, A DEVICE EXPULSION WAS FOUND. THIS COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED ESSURE FAILURE (PREGNANCY). HOWEVER, SINCE THE EXACT MECHANISM OF THE EVENTS IS NOT KNOWN (WHETHER ESSURE DEVICE WAS EXPELLED FIRST AND THE PREGNANCY FOLLOWED, OR WHETHER IT WAS IN PLACE DURING THE CONCEPTION AND WAS EXPELLED LATER), CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01679	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/18/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1941, AWARENESS DATE 25-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. ON (B)(6) 2015, HSG WAS DONE AND SHOWED THAT THE RIGHT COIL WAS BROKEN INTO TWO PIECES. SHE TOLD TO HER DOCTOR THAT SHE WANT IT REMOVED AND HE RECOMMENDED LAPAROSCOPIC SURGERY TO REMOVE IT; HOWEVER, SINCE IT IS ALREADY BROKEN IT IS POSSIBLE THAT FRAGMENTS OF THE COIL WILL REMAIN AFTER THE SURGERY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION: QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 AND UPON HSG RESULT THREE MONTHS LATER, RIGHT COIL WAS FOUND BROKEN INTO TWO PIECES. DEVICE BREAKAGE IS CONSIDERED AN ANTICIPATED EVENT ACCORDING TO TECHNICAL INVESTIGATION. GIVEN EVENT NATURE, CAUSALITY CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT SINCE A MALFUNCTION WAS REPORTED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS

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CONFIRMED AND A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 04-DEC-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFOR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01680	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2025, AWARENESS DATE 25-OCT-205). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. AFTER HAVING ESSURE PLACED SHE BEGAN HAVING VERY HEAVY PERIODS, PAINFUL INTERCOURSE, RASHES ALL OVER HER BODY, TASTED METAL, WAS NAUSEATED ALL THE TIME AND OFTEN VOMITED, WEIGHT GAIN, HAD EXTREME JOINT PAIN AND FATIGUE, BLOATING, CONSTIPATION, AND MANY OTHER ISSUES. SHE WAS A VERY HEALTHY PERSON PRIOR TO ESSURE. DOCTORS COULD NOT FIND A REASON FOR HER SYMPTOMS. AFTER EXPLORATORY SURGERY, HORMONE THERAPY, AND COUNTLESS TESTS, SHE WAS DIAGNOSED WITH ADENOMYOSIS. SHE HAD TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6). THE PATHOLOGY REPORT REVEALED AN ESSURE COIL WAS IMBEDDED IN HER UTERUS. WITHIN DAYS OF THE HYSTERECTOMY, MOST OF HER SYMPTOMS WENT AWAY. WHILE SHE WAS GLAD TO HAVE A REASON FOR MY ISSUES (MOST DOCTORS WERE CONVINCED IT WAS PSYCHOLOGICAL) SHE WAS SAD TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6). SHE GOT ESSURE BECAUSE SHE WAS TOLD IT WAS A NATURAL WAY TO CLOSE HER TUBES AND AVOID HORMONAL BIRTH CONTROL. SHE LIVED WITH TOO MANY YEARS OF PAIN FOR SOMETHING THAT WAS SUPPOSED TO BE SAFE AND EFFECTIVE. THE RISKS WERE NOT CLEARLY IDENTIFIED AT THE TIME OF INSERT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2008. SHE HAD TO HAVE A HYSTERECTOMY AND ESSURE COIL WAS FOUND IMBEDDED IN HER UTERUS. WITHIN DAYS OF THE HYSTERECTOMY, MOST OF HER SYMPTOMS

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WENT AWAY. DEVICE EMBEDMENT IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP, EVENT NATURE AND PRODUCT PROFILE, CAUSALITY CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED; THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED AND A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01681	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/24/2008
Explant Date (E7): 2/27/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1836, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (B)(6) 2008. SHE STATED THAT DURING PROCEDURE, DOCTOR COULD NOT GET THE LEFT SIDE IN RIGHT AND SHE ENDED UP USING A MALLET TO HAMMER IT IN HER. WITHIN 1 MONTH SHE WAS HAVING PAIN ISSUES. SHE WAS HEALTHY BEFORE ESSURE AND HAD GIVEN BIRTH TO HER TWIN BOYS 17 MONTHS PRIOR. SHE HAD CRAMPING, SHARP/STABBING PELVIC PAIN, ABNORMAL MENSES, PERIOD STOPS, OVARIAN CYSTS, BACTERIAL VAGINOSIS, CONSTANT SPOTTING, DISCHARGE (ODOR/NO ODOR), HOT FLASHES, CYSTS AT THE VAGINAL OPENING (BARTHOLIN'S CYST), EXCESSIVE BLEEDING DURING PERIOD (MENORRHAGIA), PAINFUL OVULATION (MITTELSCHMERZ), NIGHT SWEATS, LOSS OF LIBIDO, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS, (DYSMENORRHEA), PAINFUL INTERCOURSE (DYSPAREUNIA), BLEEDING BETWEEN PERIODS (MENORRHAGIA), INCONTINENCE, LONG MENSTRUAL CYCLES, SEXUAL DYSFUNCTION (UNABLE TO ORGASM OR FEEL PLEASURE), LACK OF MENSTRUAL CYCLE (AMENORRHEA), YEAST INFECTIONS (CANDIDA), URGENT/FREQUENT URINATION, UTI (URINARY TRACT INFECTION), BLADDER INFECTION, CERVICITIS/VAGINITIS (SWELLING, INFLAMMATION, INFECTION OF THE CERVIX OR VAGINA), ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE/VULVODYNIA, BREAST PAIN/TENDERNESS, ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING, PAIN BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP, CHRONIC PELVIC PAIN, ALL OVER BODY ACHES/PAIN, NAUSEA, VOMITING, GAS, CONSTIPATION, DIARRHEA, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, HEADACHES OR MIGRAINES, DIZZINESS, TINGLING SENSATIONS, NUMBNESS, NERVE

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PAIN, BRAIN FOG - CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, SYMPTOMS DEPRESSION (SADNESS/SUICIDAL THOUGHTS), RINGING IN EARS (PULSATILE TINNITUS), BLACK OUT SPELLS/ FAINTING, DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS), NUMBNESS IN THIGH (MERALGIA PARETHETICA), NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN (PARESTHESIA), TREMORS/SHAKINESS, ANEMIA, IRON DEFICIENCY, LOW FERRITIN, VITAMIN D DEFICIENCY, UNEXPLAINED/EASILY BRUISING, VITAMIN B-12 DEFICIENCY, INABILITY TO MAINTAIN BLOOD SUGARS (HYPOGLYCEMIA), FIBROMYALGIA, CHEMICAL AND FOOD SENSITIVITIES, METAL ALLERGIES (NICKEL), HEIGHTENED ALLERGIES/ ALLERGIC REACTIONS, FOOD ALLERGIES, GLUTEN SENSITIVITY, HIVES, RASHES, ACNE, SKIN IRRITATION/ITCHING, SWELLING OF LEGS OR FEET, HAIR LOSS AND CHANGES, HAIR GROWTH IN NEW PLACES, DENTAL ISSUES, INSOMNIA, SEROMA, GALLBLADDER ISSUES, (GALLSTONES/REMOVAL), LIVER PROBLEMS, WEIGHT ISSUES (LOSS/ GAIN), ADHESIONS (SCAR TISSUE IN ABDOMEN), SWELLING/NUMBNESS IN JAWS/LIPS, UNEXPLAINED FEVERS, MUSCLE SPASMS, VISION PROBLEMS (FLOATERS, BLURRED VISION, DECREASED VISION), EXCESSIVE SWEATING, DRY SKIN, DRY HAIR, DRY EYES, SEVERE BLOATING, BLOOD IN STOOL, ULCERATIVE COLITIS. SHE STATED THAT SHE WAS NOT ASKED IF SHE WAS ALLERGIC TO NICKEL (SHE KNEW THAT SHE WAS AT TIME OF PROCEDURE). ON (B)(6) 2015, AT (B)(6), HYSTERECTOMY WAS DONE AND ESSURE WAS REMOVED. SHE STATED THAT'S SHE WAS STILL SUFFERING FROM THE CHRONIC DISEASES CAUSED BY ESSURE. FOLLOW UP RECEIVED ON 17-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED ON (B)(6) 2008. SHE REPORTED SERIOUS EVENTS UPON INSERTION INCLUDING PELVIC PAIN, CHANGE IN MENSTRUAL PATTERN AND ALLERGY TO METALS. ON (B)(6) 2015, HYSTERECTOMY WAS DONE AND ESSURE WAS REMOVED. THESE EVENTS ARE LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. GIVEN SUGGESTIVE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED; THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED AND A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND QUALITY DEFICIT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

CORRECTION ON 27-NOV-2015 FOLLOWING COMPANY INTERNAL CODING REVIEW. THE EVENT SWELLING JAWS/LIPS WAS SPLIT INTO MEDDRA LLTS BONE SWELLING AND SWELLING LIPS AND THE EVENT HAIR CHANGES / HAIR GROWTH IN NEW PLACES WAS SPLIT INTO MEDDRA LLTS HAIR DISORDER NOS

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01682	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 26-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED IN (B)(6) 2015 FOR PERMANENT CONTRACEPTION. SHE WAS NOT PREGNANT. THREE WEEKS PRIOR TO THIS REPORT SHE STARTED EXPERIENCING PAIN. ESSURE WAS NOT REMOVED AT THE TIME OF THIS REPORT; HOWEVER THE PHYSICIAN PLANS TO REMOVE. PTC INVESTIGATION RESULT WAS RECEIVED ON 12-NOV-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE ARE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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INSERTED SIX MONTHS PREVIOUS TO THIS REPORT AND HER PHYSICIAN IS PLANNING ESSURE REMOVAL DUE TO PAIN WHICH SHE HAS BEEN EXPERIENCING FOR 3 WEEKS. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AS PELVIC PAIN MAY OCCUR DURING ESSURE USE AND GIVEN THE TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW 04-DEC-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01683	BAYER HEALTHCARE LLC	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 10/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 10/26/2015
Explant Date (E7): 10/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 26-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) ON (B)(6) 2015. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 12-NOV-2015. HEALTHCARE PROFESSIONAL (HCP) DID ESSURE BUT PERFORATED THROUGH CORNUA. ON LAPAROSCOPY, TUBE WAS SCARRED BY ENDOMETRIOSIS AND DEVICE WAS LAYING IN ABDOMEN. SEEMED TO GO INTO TUBE BUT WHEN DEPLOYED THE COILS WERE GONE. HCP STATED IT WENT AWAY INTO TUBE AND THEN COILED BACK ONTO ITSELF TO SCARRING AND THROUGH THE CORNUA. HCP SAID HE REMOVED DEVICE LAPAROSCOPICALLY, RELEASED IT AND THERE WAS TOO MUCH SCARRING AND BELIEVED HE PULLED OUT TOO FAR, GOT INSERT OUT AND PUT CLIPS FOR TUBAL LIGATION. PATIENT WAS OKAY. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING THE PROCEDURE, THE DEVICE PERFORATED THROUGH CORNUA. A LAPAROSCOPY WAS PERFORMED; THE DEVICE WAS REMOVED FROM ABDOMEN AND PATIENT UNDERWENT A TUBAL LIGATION. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, PHYSICIAN STATED PATIENT'S TUBE WAS SCARRED BY ENDOMETRIOSIS. THIS CONCOMITANT CONDITION COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED DEVICE INSERTION COMPLICATION (UTERINE PERFORATION). HOWEVER, CONSIDERING THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE DEVICE REMOVAL WAS REQUIRED (LAPAROSCOPY PERFORMED); THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT AND QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057993	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 12/29/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS COMPLETELY HEALTHY UNTIL I HAD ESSURE IMPLANTED, THEN THE EXTREMELY HEAVY PERIODS STARTED AND THEY WERE LONGER LIKE 30 DAYS. ABDOMINAL PAIN SEVERE, CONSTANT UTIS AND PELVIC INFECTIONS. NOW DIAGNOSED WITH PID. BLOATING, PAIN, SICKNESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057994	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 11/27/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, NON-STOP BLEEDING, I NFLAMMED PELVIC, CONTRACTION IN THE UTERUS, HAIR LOSS, TOOTH DECAY , HYSTORCYTOMY. DURING HYSTORCYTOMY COIL FOUND IN UTERUS, UTERUS WAS MUSHY, AND TISSUE LIKE BUTTER ACCORDING TO DOCTOR WAS NOT HEALTHY LIKE A (B)(6) UTERUS SHOULD BE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057995	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 3/2/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED HAVING SEVERE BACK PAIN, IRREGULAR BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057996	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 3/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE DAY I HAD ESSURE IMPLANTED, I HAVE HAD CHRONIC GNAWING PELVIC PAIN, BLOATING WHICH WORSENS WITH INTERCOURSE BUT THEN DOES NOT GO AWAY EASILY, JOINT PAIN, FATIGUE, MOOD SWINGS, HOT FLASHES, NIGHT SWEATS, INFLAMMATION THROUGHOUT MY BODY, AND WAS DIAGNOSED WITH GRAVES' DISEASE IN 2014 ALMOST EXACTLY 1 YEAR AFTER INSERTION. I HAD NEVER HAD ANY MAJOR MEDICAL ISSUES IN MY ENTIRE LIFE PRIOR TO THIS. I CANNOT LOSE WEIGHT, YET I'M NEVER SURE IF IT'S ACTUAL WEIGHT, OR AN AGGRAVATED INFLAMMATORY RESPONSE CAUSING THE BLOATING. I DO NOT HAVE ANY NICKEL ALLERGIES, BUT THE PET FIBERS ARE ENOUGH TO TRIGGER AN AUTOIMMUNE RESPONSE. I WILL PROBABLY WIND UP WITH CANCER BECAUSE I CANNOT AFFORD TO HAVE THIS DEVICE REMOVED. I HAVE TWO YOUNG CHILDREN, (B)(6), WHO NEED THEIR MOMMY. I AM PRAYING FOR A MIRACLE TO GET THIS DEVILISH DEVICE OUT OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057997	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ELEVATED LIVER ENZYMES OVER 700, NEEDED MY GALL BLADDER REMOVED DUE TO GALL STONES, SEVERE BLOATING, SKIN STAYING REALLY RED, ABDOMINAL PAIN, IRREGULAR MENSTRUAL CYCLE, DRY SCALP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057998	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 9/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY INSURANCE COVERED THIS AS A TUBAL LITIGATION. I WENT IN, HAD THE PROCEDURE DONE WITH NO PROBLEMS. THEN ALMOST IMMEDIATELY MY CRAMPING WAS MORE INTENSE. SO INTENSE IT MADE ME DROP TO MY KNEES AND STILL DOES. I CAN'T FOCUS ON MOST THINGS BECAUSE I FEEL LIKE THERE IS A FOG ALL THE TIME. I HAVE SEVERE MOOD SWINGS AND AM TIRED EVEN AFTER SLEEPING A LOT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5057999	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 1/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). (B)(6). CRAMPING SHARP/STABBING PELVIC PAIN ITCHING, BURNING, STINGING, STABBING OF VAGINAL ENTRANCE (VULVODYNIA) BREAST PAIN/TENDERNESS ABDOMINAL SPASMS/ TWITCHING/ FLUTTERING BACTERIAL VAGINOSIS SEXUAL DYSFUNCTION (UNABLE TO ORGASM OR FEEL PLEASURE) BLEEDING BETWEEN PERIODS (METRORRHAGIA) HOT FLASHES BLEEDING/SPOTTING AFTER SEX NIGHT SWEATS OVARIAN CYSTS PAIN BACK, JOINT, CHEST, LEG, BREAST, NECK, SPINE, HIP CHRONIC PELVIC PAIN ALL OVER BODY ACHES/PAIN COILS/DEVICE ISSUES COIL DISPLACED NEUROLOGICAL, MENTAL HEALTH HEADACHES OR MIGRAINES DIZZINESS TINGLING SENSATIONS NUMBNESS ANXIETY/PANIC ATTACKS MOOD SWINGS NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET) BLOOD ISSUES ANEMIA/ IRON DEFICIENCY/LOW FERRITIN OTHERS WEIGHT ISSUES (LOSS/ GAIN) INSOMNIA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058000	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 7/4/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, BACK PAIN, PAIN IN MY RIGHT OVARY, CYSTS, FIBROIDS IN MY UTERUS, MIGRAINES, WEAKNESS, FORGETFULNESS, PAIN DURING SEX, HEAVY PERIODS, PROLONGED CLOT LOOKING PERIODS, AND THE WORST CRAMPS I'VE EVER EXPERIENCED (WORSE THEN LABOR SOMETIMES).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058001	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IT STARTED WITH PAINFUL INTERCOURSE WITH BLEEDING AFTER INTERCOURSE. THEN THE BLEEDING WOULD GO ON FOR DAYS ON END. HEAVY BLEEDING. PERIODS WERE WORSE WITH MORE CRAMPING THAN WAS NORMAL FOR ME. I WAS BLOATED ALL THE TIME. I HAVE HIP, KNEE AND LEG PAIN FREQUENTLY. FREQUENT HEADACHES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058002	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 10/8/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER BACK PAIN, MIGRAINES ALL THE TIME, DEPRESSION, SENSITIVE SKIN, RASHES, PAIN ON FRONT SIDE ON RIGHT

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058003	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, BLOATING, AUTOIMMUNE THYROID, ABDOMINAL PAIN, FOOD SENSITIVITY, HIGH CHOLESTEROL, IRREGULAR HEARTBEAT, INFLAMMATION ALL OVER BODY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058004	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 3/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SUFFERED FROM HEADACHES, HAIR LOSS, WEIGHT GAIN, PAINFUL PERIODS, EXCESSIVE BLEEDING, BODY ACHES, RASH ON FACE, DENTAL PAIN, LOSS OF LIBIDO. HAD HYSTERECTOMY ON (B)(6) 2015 AND HEADACHES, PAIN, RASH ON FACE, DENTAL PAIN, HAIR LOSS HAVE ALL SUBSIDED IMMEDIATELY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058005	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STRANGE NEW RASH CAME UP IN THE SPRING ON BOTH KNEES. WONDERING IF IT'S RELATED AS PAIN RADIATES DOWN BOTH LEGS FROM PELVIC AREA AND LEFT HIP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058006	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 10/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN IS IN BOTH SIDES. CONSTANT ITCHING. NO SEX DRIVE. PERIODS LAST MONTHS AND MISSED PERIODS FOR MONTHS AT A TIME. WAKE UP WITH HEADACHES EVERY MORNING. DEBILITATING FATIGUE. SEVERE BLOATING. JOINT PAIN AND BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058007	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 2/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVING TROUBLE WITH MEMORY. I'M FORGETTING WHAT I'M SUPPOSED TO BE DOING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058008	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 5/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED EXPERIENCING PAIN IN MY PELVIC AREA. IT FELT LIKE MENSTRUAL CRAMPS. I MENTIONED IT TO MY GENERAL PRACTITIONER. SHE THOUGHT IT COULD BE SCAR TISSUE OR ADHESIONS. SHE SAID IF I HAD THEM REMOVED, THEY WOULD COME BACK. SO I DEALT WITH THE PAIN AND DISCOMFORT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058009	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 10/5/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SO MANY ISSUES I FORGOT TO MENTION HAD ABLATION DUE TO EXCESSIVE BLEEDING. LOW LIBIDO, BRAIN FOG, MOOD SWINGS, ANXIETY, TINGLING IN ARMS AND HANDS, FOOT PAIN, BRAIN SHOCKS, PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058030	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, CRAMPS, HAIR LOSS, SWELLING OF JOINTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058032	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 8/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON (B)(6) 2009. MY CONFIRMED OCCLUDED HSG WAS ON (B)(6) 2009. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED ON (B)(6) 2009 AND CONTINUES TO THIS DAY. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE: CHRONIC BACK PAIN, CHRONIC HIP PAIN, DEGENERATIVE DISC DISEASE, LOSS OF CURVATURE IN LUMBAR SPINE, CHRONIC PELVIC PAIN, ABDOMINAL SPASMS, HEAVY PERIODS, PERIODS TOO FREQUENT, EXCESSIVE AND LARGE CLOTTING, SEVERE CRAMPING, CERVICITIS, DISCHARGE, UNEXPLAINED SUDDEN FEVERS, SWEATING, ANXIETY, PANIC ATTACKS, BRAIN FOG, STOMACH PAIN, BLOATING, CONSTIPATION, HEMORRHOIDS, WEIGHT GAIN, WORSENED ALLERGIES, SKIN PROBLEMS, DIZZINESS, VISION PROBLEMS. MY PAIN AND OTHER PROBLEMS BEGAN RIGHT AFTER IMPLANTATION WITH THE DEVICE. MY SYMPTOMS WERE FINALLY SEVERE ENOUGH TO LAND ME IN THE E.R. FOR THE FIRST TIME ON (B)(6) 2009. I HAD TO BE PUT ON STRONG PROGESTERONE AT FIRST, AND THEN HAD TO BE PUT ON MAINTENANCE HORMONAL BIRTH CONTROL PILLS FOR ALL THESE YEARS SINCE. THE SYMPTOMS AND PILLS AND ER VISIT ALSO FORCED ME TO STOP BREASTFEEDING MY YOUNGEST DAUGHTER AT THE TIME. I HAVE BEEN SEEN BY OVER 4 DOCTORS RECENTLY. AN OB/GYN DR, A CLINIC DR, AN ER DR, AND A CHIROPRACTOR. X-RAYS ON 2 DIFFERENT DATES BOTH MAY SHOW A MIGRATED/CURVED UP COIL WITH ONE COIL TIP POSSIBLY FRAYED/SEPARATED. ULTRASOUND COULD NOT SHOW COILS. I AM AWAITING A FOLLOW UP VISIT WITH MY OB/GYN IN A FEW WEEKS. I AM INELIGIBLE FOR AN ABLATION AND MY ONLY RELIEF FROM THIS DEVICE MAY BE MAJOR SURGERY VIA BILATERAL SALPINGECTOMY AND HYSTERECTOMY TO COMPLETELY REMOVE THE IMBEDDED COILS. THE DEVICE IS STILL INSIDE OF ME AS OF TODAY, (B)(6)

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2015, AND I SUFFER WITH IT EVERY DAY. MY CHILDREN AND FAMILY AND MARRIAGE HAVE ALL SUFFERED WITH ME. MY YOUNGEST DAUGHTER, WHOM I WAS BREASTFEEDING CONCURRENTLY WHILE IMPLANTED WITH ESSURE FOR SEVERAL MONTHS, ALSO SUFFERED WITH ASTHMA AND ALLERGIES AND EAR INFECTIONS HER ENTIRE FIRST YEAR OF LIFE. I HAVE SINCE LEARNED THAT ESSURE CONTAINS A HIGH AMOUNT OF NICKEL, AND ALSO PET FIBERS. THEREFORE NOT ONLY ARE THE SHARP METAL COILS PHYSICALLY DAMAGING ME AND CAUSING PAIN, BUT THE CONTENTS/COMPONENTS COULD BE TOXIC IN THE HUMAN BODY. NO NICKEL SENSITIVITY TEST WAS PERFORMED ON ME PRIOR TO IMPLANTATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058033	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 11/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE MASSIVE HAIR LOSS. PELVIC PAIN ALL THE TIME. HAVING MY PERIOD EVERY COUPLE OF WEEKS AND NOW BREATHING PROBLEMS. ALREADY HAVE ASTHMA BUT NOTHING I TAKE IS WORKING, EVEN WENT TO ER FOR MEDICINE AND IT HAS NOT WORKED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058034	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 11/6/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SURGERY WAS CANCELED BECAUSE THE DR WANTED TO PULL COILS OUT. I WENT TO A 3RD DR WHO IS WORKING ON GETTING A HYSTERECTOMY APPROVED THROUGH MY INSURANCE. MY PAIN HAS NOT GOTTEN ANY BETTER AND IT HAS NOW BEEN A MONTH SINCE I HAD A PERIOD. THE DR SUSPECTS ENDOMETRIOSIS, WHICH I NEVER HAD BEFORE ESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058035	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 11/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I HAD THE COILS PUT IN IVE HAD BACKACHE, MOODINESS, WEIGHT GAIN, SEVERE BLEEDING, SEVERE PELVIC PAIN, VERY LARGE BLOOD CLOTS, JOINT PAIN, MIGRAINES, DEPRESSION, FATIGUE, HAIR LOSS, AND LOSS OF LIBIDO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058036	BAYER	11/23/2015	11/23/2015

Event Information:

Event Date (B3): 10/14/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABNORMAL MENSES, CHRONIC PELVIC PAIN, CONSTANT SPOTTING, DISCHARGE (ODOR/NO ODOR), PAINFUL OVULATION, NIGHT SWEATS, LOSS OF LIBIDO, HOT FLASHES, BLEEDING/SPOTTING AFTER SEX, PAINFUL PERIODS (DYSMENORRHEA), BLEEDING BETWEEN PERIODS (METRORRHAGIA), INCONTINENCE, YEAST INFECTIONS, CHRONIC BACK PAIN, CHRONIC HIP AND JOINT PAIN, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL ISSUES, HEADACHES OR MIGRAINES, TINGLING SENSATIONS, NUMBNESS, NERVE PAIN, BRAIN FOG AND CLOUDINESS, FORGETFULNESS, ANXIETY/PANIC ATTACKS, MOOD SWINGS, SEIZURES, DEPRESSION (SADNESS/SUICIDAL THOUGHTS), RINGING IN EARS (PULSATILE TINNITUS), DIMINISHED BRAIN FUNCTION (BRAIN FOG, CONFUSION, CLOUDINESS, FORGETFULNESS, SHORT TERM MEMORY LOSS) MOOD DISORDERS, NUMBNESS IN THIGH (MERALGIA PARESTHETICA), NUMBNESS/TINGLING IN EXTREMITIES (HANDS/FEET), SENSATION OF BURNING, STINGING, TICKLING OR PRICKLING OF SKIN (PARESTHESIA), NERVE PAIN, DIZZINESS, GLUTEN SENSITIVITY, HEIGHTENED ALLERGIES/ ALLERGIC REACTIONS, HEART PALPITATIONS, INSOMNIA, LIVER PROBLEMS, WEIGHT ISSUES (LOSS/ GAIN), SLEEP APNEA, HAIR LOSS OR CHANGES, DRY SKIN/HAIR/EYES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01684	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 8/20/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED ON 12-NOV-2015 (PRODUCT TECHNICAL COMPLAINT RESULT). PHYSICIAN WAS CALLING FOR INFORMATION ABOUT ESSURE REMOVAL DUE TO SUSPECTED PERFORATION ON RIGHT HAND SIDE BASED ON HSG (HYSTEROSALPINGOGRAM). PATIENT WAS NOT REPORTING ANY PAIN OR ADVERSE REACTION. PHYSICIAN WAS PLANNING REMOVE ESSURE AND PERFORM TUBAL LIGATION. PRODUCT TECHNICAL COMPLAINT (PTC) RESULT ALSO PROVIDED. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND

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THERE WAS A SUSPECTED PERFORATION ON RIGHT HAND SIDE BASED ON HSG (HYSTEROSALPINGOGRAM). PHYSICIAN WAS PLANNING TO REMOVE THE INSERT. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE/FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF A FALLOPIAN TUBAL OCCLUSION INSERT (ESSURE). IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. ALTHOUGH ESSURE PERFORATION WAS NOT CONFIRMED AT THE TIME OF THIS REPORT, GIVEN ITS NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE AN INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

ESSURE HEALTH CARE PROVIDER UTERINE / TUBAL PERFORATION QUESTIONNAIRE RECEIVED ON 10-DEC-2015: THIS CASE REFERS TO (B)(6) YEARS-OLD FEMALE PATIENT. PATIENT INFORMATION WAS UPDATED. REPORTER CONFIRMED THAT SHE WAS NOT PREGNANT. PREGNANCY HISTORY INCLUDED G

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01685	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 26-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON UNSPECIFIED DATE. READING HSG (HYSTEROSALPINGOGRAM), THE TUBE WAS OCCLUDED BUT THE COIL APPEARS BROKEN. PTC INVESTIGATION RESULT WAS RECEIVED ON 10-NOV-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO-INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A GRASPER THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE WERE UNABLE TO CONFIRM ANY

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QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, NO MEDICAL EVENTS WERE REPORTED AT THIS POINT IN TIME, THEREFORE THE ASSESSMENT OF A RELATIONSHIP IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER HYSTEROSALPINGOGRAM (HSG) TEST REVEALED THE TUBE WAS OCCLUDED BUT THE COIL APPEARS BROKEN. THIS EVENT IS ANTICIPATED ACCORDING TO THE TECHNICAL ANALYSIS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER CONSIDERING EVENT'S NATURE A CAUSAL RELATIONSHIP WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE REPORTED EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED OR IDENTIFIED. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01686	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5035513) IN UNITED STATES ON 26-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. ADDITIONAL INFORMATION RECEIVED ON 17-NOV-2015 (PTC INVESTIGATION RESULT). CONSUMER HAD AN HYSTEROSALPINGOGRAM TEST DONE 3 MONTHS LATER TO INSERTION TO CONFIRM 100 PER CENT BLOCKAGE. SINCE 2013 SHE HAS EXPERIENCED EXTREME STABBING PAINS IN HER LEFT FALLOPIAN TUBE, TERRIBLE MOOD SWINGS, EXTREME ANXIETY AND DEPRESSION IN WHICH SHE NEEDED TO SEEK COUNSELING AND A PRESCRIPTION OF XANAX. SHE ALSO HAS EXPERIENCED ON A DAILY BASIS, BLADDER ISSUES. SHE HAD PROBLEMS GOING TO THE BATHROOM, PROBLEMS EMPTYING HER BLADDER, LEAKAGE, AND PAIN WHILE URINATING. SHE WAS CONSTANTLY TIRED. SHE WAS CONSTANTLY HAVING HEADACHES AND SINUS INFECTIONS. HER BODY WAS SORE LIKE IT WAS FIGHTING OFF AN ILLNESS EVERY SINGLE DAY. HER MENSTRUAL CRAMPS WERE EXTREMELY PAINFUL AS WELL. SHE REGRET EVER GETTING THIS PRODUCT IMPLANTED IN HER BODY. IN 2014 SHE JUST HAD A TOTAL HYSTERECTOMY TO REMOVE ESSURE AND SHE WILL HAVE A FOLLOW UP. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXTREME STABBING PAINS IN HER LEFT FALLOPIAN TUBE. A TOTAL HYSTERECTOMY TO REMOVE ESSURE WAS PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT SINCE ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. BASED ON THE NATURE OF THE EVENT AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP IS IMPLIED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01687	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5056661) IN UNITED STATES ON 26-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. CONSUMER STATED ESSURE CAUSED HER YEARS OF PAIN AND HEAVY BLEEDING. FINALLY, IT GOT SO BAD THAT PHYSICIAN PERFORMED ENDOMETRIAL ABLATION, DILATATION & CURETTAGE AND OTHER PROCEDURES DURING 6 MONTHS TO TRY TO CORRECT SIDE EFFECTS. FOLLOW UP RECEIVED ON 17-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED AND SHE REPORTED THAT ESSURE CAUSED HER YEARS OF PAIN AND HEAVY BLEEDING. FINALLY, IT GOT SO BAD THAT PHYSICIAN PERFORMED

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ENDOMETRIAL ABLATION, DILATATION & CURETTAGE AND OTHER PROCEDURES. GENITAL BLEEDING AND PELVIC PAIN ARE SERIOUS EVENTS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE ADDITIONAL INFORMATION WAS REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01688	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/14/2010
Explant Date (E7): 11/15/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5056682) IN UNITED STATES ON 26-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF (B)(6) AT THE TIME OF REPORT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. ADDITIONAL INFORMATION RECEIVED ON 19-NOV-2015. CONSUMER REPORTED THAT AFTER EXPERIENCING A LOT OF PELVIC AND BACK PAIN, HER PHYSICIAN DID AN ULTRASOUND AND WAS UNABLE TO FIND THE COILS. HE SCHEDULED A LAPAROSCOPIC SURGERY TO EXPLORE. ONE COIL WAS FOUND IN HER ABDOMEN AND THE OTHER PERFORATED THROUGH HER FALLOPIAN TUBES AND EXTREMELY INFECTED. SHE WAS PUT ON ANTIBIOTICS FOR 1 MONTH AND THEN UNDERWENT A BILATERAL SALPINGECTOMY TO REMOVE HER TUBES ON (B)(6) 2010. FOLLOW UP RECEIVED ON 17-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY

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CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED ON (B)(6) 2010 AND EXPERIENCED PELVIC PAIN. AN USG WAS PERFORMED AND COILS WERE NOT VISUALIZED. UPON LAPAROSCOPY SURGERY, MIGRATION TO ABDOMEN AND FALLOPIAN TUBE PERFORATION AND INFECTION WERE OBSERVED. CONSUMER WAS PUT ON ANTIBIOTICS FOR ONE MONTH AND BILATERAL SALPINGECTOMY WAS PERFORMED ON (B)(6) 2010. PERFORATION AND MIGRATION ARE SERIOUS EVENTS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE REFERENCE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. ADDITIONAL INFORMATION WAS REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01689	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/13/2012
Explant Date (E7): 1/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN UNITED STATES ON 26-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2012. ADDITIONAL INFORMATION RECEIVED ON 17-NOV-2015. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: CITALOPRAM, CETIRIZINE, BUPROPION, IBUPROFEN, ACETAMINOPHEN. DURING THE TIME ESSURE WERE IMPLANTED, SHE EXPERIENCED SEVERE MENSTRUAL PERIODS, BILATERAL ABDOMINAL PAIN, HEADACHES, ANXIETY, DEPRESSION, WEAKENED TEETH, WEAKENED GUMS, SKIN CONDITIONS, HAIR LOSS, RAPID WEIGHT GAIN, ABDOMINAL BLOATING, HAND TREMORS, DIGESTIVE ISSUES, CONSTANT VAGINAL INFECTIONS (VIRAL AND BACTERIAL), CONSTANT BACK PAIN, CONSTANT NECK PAIN, AND DEGENERATION OF SPINAL DISCS AND FACETS. ON (B)(6) 2015, SHE HAD TO HAVE THEM REMOVED, ALONG WITH HER TUBES, UTERUS AND CERVIX (TOTAL HYSTERECTOMY AND SALPINGECTOMY). SINCE THE SURGERY AND REMOVAL, SOME SYMPTOMS HAVE COMPLETELY GONE AWAY AND OTHERS HAVE PERSISTED. URINARY ISSUES HAVE ALSO OCCURRED SINCE SURGERY. HOSPITALIZATION, DISABILITY/PERMANENT DAMAGE, REQUIRED INTERVENTION, OTHER SERIOUS (IMPORTANT MEDICAL EVENT) WERE MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 17-NOV-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE

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MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO EXPERIENCED BILATERAL ABDOMINAL PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A TOTAL HYSTERECTOMY AND SALPINGECTOMY (APPROXIMATELY 3 YEARS AFTER DEVICES PLACEMENT); THE DEVICE WAS REMOVED. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, CONSIDERING EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. OTHER NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 28-DEC-2015: FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO EXPERIENCED BI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01690	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/11/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# MW5056635) IN UNITED STATES ON 26-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. ADDITIONAL INFORMATION RECEIVED ON 17-NOV-2015 (PTC INVESTIGATION RESULT). SHE REPORTED STARTED HAVING JOINT ISSUES IN 2014 AND WAS SUBSEQUENTLY DIAGNOSED WITH LUPUS IN 2015. SHE STATED HER LEFT IMPLANT PUNCTURED THROUGH THE FALLOPIAN TUBE CAUSING AN INFECTION WHICH TOOK ANTIBIOTICS FOR THREE WEEKS BEFORE FINALLY BEING ADMITTED TO THE HOSPITAL IN FOR IV (INTRAVENOUS) ANTIBIOTICS. SHE WENT INTO SURGERY TO REMOVE THE ABSCESS DURING HER STAY, BUT DUE TO THE SEVERITY OF THE INFECTION AND THE MASS THAT WAS ASSUMED TO BE SCAR TISSUE, THE DOCTOR WAS NOT COMFORTABLE WITH PROCEEDING FURTHER. HE CLOSED THE INCISION, KEPT HER IN THE HOSPITAL FOR TWO ADDITIONAL DAYS ON ANTIBIOTICS AND SENT HER HOME WITH ANOTHER TWO WEEKS OF ANTIBIOTICS TO CLEAR THE INFECTION. SHE HAD A REPEAT CT SCAN THAT SHOWED A MASS REMAINING IN THE AREA OF THE INITIAL INFECTION; IT WAS ASSUMED BY HER DOCTOR THAT THIS WAS SCAR TISSUE FROM THE ORIGINAL PUNCTURE CAUSED BY THE ESSURE IMPLANT. AT THIS POINT, SHE WAS WEIGHING HER OPTIONS WITH HYSTERECTOMY BEING A CONSIDERATION TO REMOVE THE IMPLANTS AND ALLEVIATE THE HEAVY MENSTRUAL CYCLES THAT SHE ALSO HAS BEEN EXPERIENCING SINCE THE IMPLANTS, SHE ALSO NOTE THAT SHE BECOME ANEMIC AS WELL. THE CONSUMER MENTIONED AS CONCOMITANT MEDICATION LEVOTHYROXINE, PLAQUENIL, VITAMIN D AND IRON. THE TERM DISABILITY WAS ONLY MENTIONED AS EVENT OUTCOME AND THE REPORTER DID NOT SPECIFY IT. PTC INVESTIGATION RESULT: THE PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED

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DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/ IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT (S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT HER LEFT IMPLANT PUNCTURED THROUGH THE FALLOPIAN TUBE CAUSING AN INFECTION (INTERPRETED AS PELVIC INFECTION) WHICH RESULTED IN HOSPITALIZATION. THESE EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. LUPUS WAS DIAGNOSED (SERIOUS AND UNLISTED). SHE STATED SHE WAS WEIGHING HER OPTIONS WITH HYSTERECTOMY BEING A CONSIDERATION TO REMOVE THE IMPLANTS. IN THIS CASE, THE EXACT DATE AND MECHANISM OF FALLOPIAN TUBE PERFORATION WERE NOT KNOWN. ALTHOUGH IT WAS NOT REPORTED WHETHER THE INFECTION OCCURRED UP TO 4 WEEKS POST INSERTION, SINCE IT WAS CLEARLY MENTIONED THAT THE PERFORATION CAUSED THE INFECTION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, BASED ON ITS NATURE AND CONSIDERING THAT IT IS UNLIKELY THAT ESSURE WOULD CAUSE THE EVENTS DUE TO THE LOCALIZED ACTION OF ESSURE IN THE FALLOPIAN TUBES, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO THE HOSPITALIZATION REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT (S) AND QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01691	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 9/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/14/2010
Explant Date (E7): 9/4/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE MW5056684) IN UNITED STATES ON 26-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), EXPIRATION DATE 01-SEP-2011 IMPLANTED ON (B)(6) 2010. SHE STARTED HAVING A PUNCHING PAIN ON LEFT SIDE, BECAME CHRONIC PAIN OVER TIME, DIZZY, HAIR LOSS, AND CONFUSION (FOGGY MIND) AND MUCH MORE. ON (B)(6) 2014 SHE ENDED UP HAVING A HYSTERECTOMY. HOSPITALIZATION, DISABILITY/PERMANENT DAMAGE, OTHER SERIOUS (IMPORTANT MEDICAL EVENT) WERE MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 17-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY

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AUTHORITY) REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING PUNCHING PAIN ON LEFT SIDE, BECAME CHRONIC PAIN OVER TIME. SHE ENDED UP HAVING A HYSTERECTOMY. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION (DISABILITY AND OTHER SERIOUSNESS CRITERIA WERE MARKED PER REPORTER BUT NOT SPECIFIED). IT IS ALSO LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 04-JAN-2016: FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REF

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01692	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7): 2/1/2016
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5056670) IN UNITED STATES ON 26-OCT-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. ADDITIONAL INFORMATION RECEIVED ON 17-NOV-2015. CONSUMER HAD THE ESSURE PUT IN AROUND 3 YEARS AGO. SHE HAD THE HYSTEROSALPINGOGRAM TEST DONE AT HER 3 MONTH MARK AND EVERYTHING WAS PERFECT. THIS YEAR, 2015, SHE STARTED HAVING PAIN IN HER SIDE AND HER DOCTOR RECOMMENDED THAT SHE HAD A HYSTERECTOMY. COME TO FIND OUT HER ESSURE COIL HAD MIGRATED OUT OF HER TUBE, INTO HER UTERUS AND WRAPPED BACK AROUND TO HER TUBE. IT WAS ALL TWISTED UP. THE SERIOUSNESS CRITERIA HOSPITALIZATION WAS MENTIONED IN THE SECTION EVENT OUTCOME BUT IT WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 17-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS

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REPORTED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD PAIN IN HER SIDE 3 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, HER DOCTOR RECOMMENDED A HYSTERECTOMY AND COME TO FIND OUT HER ESSURE COIL HAD MIGRATED OUT OF HER TUBE, INTO HER UTERUS AND WRAPPED BACK AROUND TO HER TUBE. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A FALLOPIAN TUBE PERFORATION DURING INSERTION. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. ALTHOUGH THE EXACT MECHANISM OF THE REPORTED EVENT IS UNKNOWN, GIVEN ITS NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, AS ALTHOUGH IT IS NOT TOTALLY CLEAR IF THE REPORTED HYSTERECTOMY WAS PERFORMED; A SURGICAL INTERVENTION CANNOT BE FORMALLY EXCLUDED WITH THE AVAILABLE INFORMATION. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 04-JAN-2016: FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD PAIN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01693	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 2/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/22/2013
Explant Date (E7): 2/21/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5056679) IN UNITED STATES ON 26-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT SHE HAD ESSURE COILS PLACED IN BOTH TUBES AND HAD IMMEDIATE CRIPPLING PAIN, WHICH HER GYNECOLOGIST AT THE TIME DISMISSED AS NERVE DAMAGE FROM HER C-SECTION. AFTER ONGOING MOTRIN INTAKE, SHE WENT TO THE EMERGENCY ROOM AND FOUND A NEW GYNECOLOGIST. UPON GOING IN FOR A SCHEDULED HYSTERECTOMY, HE FOUND THAT THE LEFT COIL HAD PUNCTURED HER FALLOPIAN TUBE AND WAS CUTTING THROUGH THE BACK SIDE OF HER UTERUS. HE HAD TO REMOVE BOTH TUBES AND HER UTERUS ON (B)(6) 2014. SINCE THEN, CONSUMER HAD NUMEROUS SURGERIES TO HELP WITH CRIPPLING PAIN FROM WHICH SHE DID NOT RECOVER YET. LIFE THREATENING, HOSPITALIZATION, DISABILITY/ PERMANENT DAMAGE, AND REQUIRED INTERVENTION WERE MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 17-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW

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TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT (S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LEFT COIL HAD PUNCTURED FALLOPIAN TUBE AND WAS CUTTING THROUGH THE BACK SIDE OF UTERUS. SHE UNDERWENT A HYSTERECTOMY AND SALPINGECTOMY WITH ESSURE REMOVAL, 3 MONTHS AFTER INSERTION. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE AND FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE. IN THE PRESENT CASE THE PERFORATION WAS DIAGNOSED 3 MONTHS AFTER INSERTION, DURING HYSTERECTOMY. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENT WAS ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 21-DEC-2015: FOLLOW UP INFORMATION WAS RECEIVED FROM THE CONSUMER. PROCEDURE WAS ON OR ABOUT (B)(6) 2013. HYSTEROSALPINGOGRAM TEST WAS DONE ABOUT 3 MONTH AFTER THE PROCEDURE AND SHOWED ONE IMPLANT MAY HAVE MIGRATED OR WAS PLACED HIGHER UP IN THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01694	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 2/5/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/5/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056691) IN UNITED STATES ON 26-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008 FOR BIRTH CONTROL. SHE REPORTED UPON LEAVING THE PHYSICIANS OFFICE, SHE EXPERIENCED A VAGUS NERVE INCIDENT, WHERE HER ENTIRE NERVOUS SYSTEM SHUT DOWN. FORTUNATELY, HER GYNECOLOGIST OFFICE WAS IN THE HOSPITAL AND WAS RUSHED TO THE ER, WHERE SHE SPENT THE BETTER PART OF THE DAY; WITH NO FURTHER INCIDENTS, SHE WAS SENT HOME. WHEN SHE RETURNED TO HER DOCTOR FOR A FOLLOW-UP, SHE WAS TOLD THE VAGUS INCIDENT OCCURRED BECAUSE OF A REACTION SHE HAD TO THE DRUGS THEY GAVE HER TO MAKE HER RELAX. FOLLOWING THE PROCEDURE, SHE BLED HEAVILY FOR MORE THAN 50 DAYS AND EVENTUALLY, HER DOCTOR PRESCRIBED BIRTH CONTROL PILLS (WHICH IS IRONIC BECAUSE THE PRIMARY REASON FOR HAVING THE PROCEDURE IN THE FIRST PLACE WAS IN ORDER TO STOP TAKING BIRTH CONTROL PILLS) TO CONTROL THE BLEEDING BUT IT TOOK NEARLY TWO MONTHS TO ACHIEVE THAT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED VAGUS NERVE INCIDENT / ENTIRE NERVOUS SYSTEM SHUT DOWN AND FOLLOWING THE PROCEDURE, SHE BLED HEAVILY FOR MORE THAN 50 DAYS (SEEN AS GENITAL BLEEDING). BOTH EVENTS WERE CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. INSERTION AND REMOVAL OF ESSURE MAY PRECIPITATE FAINTING AS A VASOVAGAL REACTION. IN THIS PARTICULAR CASE, CONSUMER PRESENTED VASOVAGAL REACTION DURING ESSURE INSERTION PROCEDURE AND SHE SPENT THE BETTER PART OF THE DAY IN THE HOSPITAL (THE REPORTER STATED HOSPITALIZATION AS EVENT OUTCOME). FOLLOWING THE PROCEDURE, SHE EXPERIENCED GENITAL BLEEDING.

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CONSIDERING THAT THE EVENTS OCCURRED DURING AND FOLLOWING ESSURE INSERTION AND BASED ON THEIR NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. ALTHOUGH DURATION OF HOSPITALIZATION WAS NOT PROVIDED, THIS CASE WAS REGARDED AS INCIDENT. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RECEIVED ON 23-DEC-2015 PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME A

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01695	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627755

Single Use: Y
Implant Date (E6): 10/15/2010
Explant Date (E7): 12/23/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056673) IN UNITED STATES ON 26-OCT-2015 REFERRING TO HERSELF. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 627755, INSERTED ON (B)(6) 2010. CONSUMER HAD ESSURE PLACED AND THEN FOUND OUT SHE HAS NICKEL AND TITANIUM ALLERGY, UVEITIS, FIBROMYALGIA, PELVIC PAIN, SWELLING, DEVICE MIGRATION, ABDOMINAL PAIN AND FIBROSIS CONFIRMED VIA LAB RESULTS FROM TISSUE REMOVED WITH ESSURE REMOVAL. SHE ALSO EXPERIENCED PANIC ATTACKS, MIGRAINES, HEAVY BLEEDING. ESSURE WAS REMOVED ON (B)(6) 2014. CONCOMITANT DRUGS REPORTED: MVI, ACID REFLUX MEDICATIONS, VITAMIN E, VITAMIN D, VITAMIN B12, VITAMIN A, VITAMIN B. DISABILITY/ PERMANENT DAMAGE, REQUIRED INTERVENTION AND OTHER SERIOUS (IMPORTANT MEDICAL EVENT) WAS REPORTED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/ OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD DEVICE MIGRATION, HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND UVEITIS. ESSURE WAS REMOVED 4 YEARS AFTER INSERTION. DEVICE MIGRATION AND GENITAL BLEEDING ARE LISTED EVENTS IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENT IN UNLISTED. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THE PRESENT CASE, THE EXACT DATE AND MECHANISM OF THE DEVICE MIGRATION WAS NOT REPORTED, HOWEVER GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ALSO, GENITAL BLEEDING MAY OCCUR AFTER ESSURE INSERTION. GIVEN THE NATURE OF THE EVENT HEAVY BLEEDING AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING

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EVENT UVEITIS, CONSIDERING ITS PATHOPHYSIOLOGY AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 04-JAN-2016: FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01696	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 6/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/4/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS INITIAL CASE REPORT WAS RECEIVED ON 21-OCT-2013 AND REFERS TO A PATIENT IN THE UNITED STATES. THE REPORT REFERS ONLY TO INFORMATION RECEIVED FROM MEDICAL RECORDS. IT DESCRIBES THE OCCURRENCE OF AMENORRHEA, IRREGULAR PERIODS, PREGNANCY WITH ESSURE, FAILED STERILIZATION, COMPLETED SPONTANEOUS ABORTION, AND ANEMIA IN A (B)(6)-YEAR-OLD FEMALE PATIENT WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). THE PATIENT'S MEDICAL HISTORY INCLUDED ENDOMETRIOSIS AND LAPAROSCOPIC TREATMENT IN 2003, CHRONIC MIGRAINE, AND BILATERAL MYRINGOTOMY (IN 1982). IN ADDITIONAL HER MEDICAL HISTORY INCLUDES GRAVIDA 7 PARA 5 (VAGINAL DELIVERY IN 2011, 2004, 2006, 2009 AND 2011) AND A SPONTANEOUS ABORTION (IN 2003). HER FAMILY HISTORY INCLUDES DIABETES TYPE II, HYPERTENSION AND HYPERCHOLESTEROLEMIA. CONCOMITANT MEDICATION INCLUDES IBUPROFEN AND CO-Q10 SUPPLEMENTS. THE PATIENT WAS NOT SMOKER. ON (B)(6) 2011 THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE WAS BREAST FEEDING A BABY AT THE TIME OF INSERTION. ON (B)(6) 2011 THE PATIENT UNDERWENT HYSTEROSALPINGOGRAM WHICH CONFIRMED BILATERAL PROXIMAL TUBAL OCCLUSION. THE PATIENT HAD BREASTFED UNTIL MID 2012 AND HAD RESUMED HER MENSES IN (B)(6) 2012, BUT SHE HAD IRREGULAR PERIODS EVERY 1-2 MONTHS. HER LAST MENSTRUAL PERIOD OCCURRED IN (B)(6) 2013. THE PATIENT HAD A VAGINAL BLEEDING, ON (B)(6) 2013 IT BECAME HEAVY AND WITH CLOTS. DUE THIS THE PATIENT WENT TO EMERGENCY ROOM AT 10:58, SHE ALSO HAD CRAMP AND LIGHT HEADEDNESS, ALTHOUGH THE PAIN WAS ONLY MILD. SHE DENIED ANY SIGNIFICANT PREGNANCY SYMPTOMS NEITHER UNILATERAL PELVIC PAIN NOR SHOULDER PAIN. TRANSVAGINAL ULTRASOUND: A POSTERIOR UTERUS MEASURING 11.8X6.5X6.4 CM. THE UPPER ENDOMETRIAL CAVITY WAS WITHOUT EVIDENCE OF GESTATIONAL SAC WITH THE ENDOMETRIAL LINING MEASURING ONLY 9.1MM IN THICKNESS. THE LOWER UTERINE SEGMENT

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AND ENDOMETRIAL CANAL, HOWEVER, WAS NOTABLE FOR WHAT APPEARED TO BE RETAINED LAYERED ECHOGENIC TISSUE MOST LIKELY RETAINED PRODUCTION OF CONCEPTION. NO PELVIC FREE FLUID WAS SEEN. BOTH OVARIES WERE NORMAL AND UNREMARKABLE. PELVIC EXAMINATION: EXTERNAL GENITAL WITHOUT LESIONS. VAGINA WAS NOTABLE FOR A LARGE AMOUNT OF BLOOD CLOTS IN THE 200 CC RANGE WHICH REMOVED AND THEN HER CERVIX WAS NOTED TO BE APPROXIMATELY 1.5 CM DILATED AND RINGED FORCEPS WERE USED TO REMOVE RETAINED PRODUCTS OF CONCEPTION FROM THE ENDOCERVICAL CANAL AND LOWER UTERINE SEGMENT WITHOUT DIFFICULTY, AND THERE WAS A FAIR AMOUNT OF TISSUE CONSISTENT WITH PLACENTAL TISSUE AND MEMBRANES. NO ADNEXAL MASSES WERE NOTED. LABORATORY: HER HEMOGLOBIN AT THE ADMISSION WAS 12.3 AT 11:09 AND THEN IT WAS REPEATED AT 15:46 WAS 9.9. WHITE BLOOD CELL WAS NORMAL AT 10.3 AND PLATELETS 183,000. QUANTITATIVE PREGNANCY TEST, BETA HCG 13.308MIU/ML (4-5 WEEKS OF GESTATION: 1000- 50000). COMPREHENSIVE METABOLIC PANEL WAS UNREMARKABLE EXCEPT FOR A RANDOM GLUCOSE OF 130. MICROSCOPIC DESCRIPTION OF PRODUCTS OF CONCEPTION: PRODUCT OF CONTRACEPTION SHOWING CHRONIC VILLA RIMMED BY TROPHOBLASTS ASSOCIATED WITH HEMORRHAGIC AND DEGENERATING DECIDUALIZED STROMA. FETAL COMPONENTS ARE NOT IDENTIFIED. THE PATIENT RECEIVED 500 CC OF HETASTARCH AND 2 LITERS OF NORMAL SALINE SOLUTION DUE TO HEMOGLOBIN LOW LEVEL. A REPEATED PELVIC EXAM AT 16:41 HAD REVEALED ONLY MINIMAL BLEEDING AND THE UTERUS WAS POSTERIOR, FIRM AND NON-TENDER. THE PATIENT WAS OBSERVED UNTIL 17:00 HOURS. SHE DENIED HAVE MORE EPISODES OF SOME INCREASED BLEEDING WHEN SHE GOT UP AFTER PRODUCT OF CONCEPTION WAS REMOVED. SHE WAS DISCHARGED HOME THEREAFTER. THE PHYSICIAN CONCLUDED THAT THE PATIENT HAD A COMPLETED ABORTION, AT UNKNOWN GESTATIONAL AGE. THE PRODUCT OF CONCEPTION WERE CONSISTENT APPROXIMATELY 6-7 WEEKS AND BLEEDING SUBSEQUENTLY RESOLVED. IN ADDITION WAS CONCLUDED THAT STERILIZATION METHOD WAS FAILED AND SHE HAD ANEMIA (FOR WHICH IT WAS RECOMMENDED FERROUS SULFATE 325 MG P.O , B.I.D.FOR 2 MONTHS). THE PATIENT WILL BE FOLLOWED DURING 3-4 WEEKS. REPORTER CAUSALITY: THE EVENTS WERE CONSIDERED RELATED WITH ESSURE (B)(6)2013: UPON AN INTERNAL REVIEW IT WAS SEEN THAT THIS IS NOT A POTENTIAL LEGAL CASE. 27 NOV 2013: NO NEW PTC CREATED. FOLLOW-UP INFORMATION RECEIVED ON 27-OCT-2015 AND ON 16-NOV-2015. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEP-2015 (B)(4). CONSUMER REPORTED PREGNANCY AND MISCARRIED TWO YEARS AFTER HER POSITIVE ESSURE CONFIRMATION TEST. ON (B)(6) 2011, ESSURE WAS INSERTED WITH A POSITIVE CONFIRMATION TEST ON (B)(6) 2011. HER MEDICAL HISTORY INCLUDED FIVE HEALTH CHILDREN (ALL NORMAL PREGNANCIES), HISTORY OF MIGRAINE HEADACHE AND PELVIC ENDOMETRIOSIS. ON (B)(6) 2013, CONSUMER STARTED SPOTTING WHICH WAS THE TYPICAL START TO A MENSTRUAL CYCLE. ON (B)(6) 2013, THE BLEEDING WAS SUDDENLY PROFUSE. SHE WENT TO EMERGENCY ROOM (ER), BLOOD TESTS WERE PERFORMED AND CONFIRMED SHE WAS PREGNANT. A VAGINAL ULTRASOUND WAS PERFORMED AND THE FETUS WAS PRESENT BUT THERE WAS NO HEART-BEAT. SHE WAS SENT BACK TO ER TO DELIVER THE FETUS. SHE STATED THAT WAS PREGNANT FOR SEVERAL WEEKS, BUT DISMISSED THE MISSED PERIODS AND OTHER SYMPTOMS TO PERI-MENOPAUSE. SUBSEQUENT TO COMPLETE SPONTANEOUS ABORTION ON (B)(6) 2013, SHE FELT INTO A PERIOD OF SEVERE DEPRESSION, WHICH WAS DIAGNOSED BY HER PHYSICIAN AS POSTPARTUM DEPRESSION AND SHE DEVELOPED PROBLEMS WITH ABNORMAL UTERINE BLEEDING AFTER DISCONTINUING BREAST FEEDING AND HAD DEVELOPED PERSISTENT BLEEDING EVER SINCE HER MISCARRIAGE DESPITE TAKING MEDROXYPROGESTERONE 10MG FOR 10 DAYS. A VAGINAL ULTRASOUND WAS PERFORMED TWO MONTHS AFTER MISCARRIAGE AND DETERMINED THAT SHE HAD A UTERINE INFECTION RESULTING FROM THE MISCARRIAGE. SHE ALSO HAD SONOHYSTOGRAM ALONG WITH ASPIRATION ENDOMETRIAL CURETTAGE ON (B)(6) 2013 WHICH REVEALED SOME THICKER ANTERIOR ENDOMETRIAL LINING WITHOUT EVIDENCE OF POLYPS OR SUB MUCOSAL LEIOMYOMA BUT ENDOMETRIAL CURETTAGE REVEALED CHRONIC ENDOMETRITIS AND FINDINGS SUGGESTIVE OF POLYPOID CHANGE. SHE WAS SUBSEQUENTLY TREATED WITH DOXYCYCLINE FOR 2 WEEKS WHICH COMPLETELY RESOLVED

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HER ABNORMAL BLEEDING AND MENSES SINCE THAT TIME HAVE BEEN MONTHLY WITHOUT INTERMENSTRUAL BLEEDING OR DYSMENORRHEA. SHE WANTED ESSURE REMOVAL AND HER PHYSICIAN WAS WEIGHTING THE BENEFITS TO THE RISKS. SHE WAS NOT SURE IF THEY MIGRATED SO JUST HOPING THEY WERE STILL WHERE THEY WERE SUPPOSED TO BE. SHE WAS EXPERIENCING HEAVY BLEEDING FOR 1-2 DAYS EACH MONTH, CONTINUOUS DULL/ ACHING PAIN WITH MOMENTS OF STABBING/ BURNING PAIN ON LOWER LEFT ABDOMEN FOR A FEW DAYS AROUND OVULATION EACH MONTH, FATIGUE, WEIGHT GAIN AND BLOATING. SHE TRIED WITH NO AVAIL TO RETURN TO THE SAME WEIGHT THAT SHE DID AFTER EACH OF HER PREVIOUS PREGNANCIES. COMPANY CAUSALITY COMMENT: THIS CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO RECEIVED ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND EXPERIENCED PREGNANCY WITH ESSURE AND COMPLETED SPONTANEOUS ABORTION (WITH VAGINAL BLEEDING WITH CLOTS, LIGHT HEADEDNESS AND CRAMP: PAIN WAS ONLY MILD). ALL EVENTS, EXCEPT PREGNANCY, ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE; PREGNANCY WITH ESSURE IS NON-SERIOUS, LISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE. PREGNANCIES HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE. IN THIS PARTICULAR CASE, PATIENT UNDERWENT HYSTEROSALPINGOGRAM WHICH CONFIRMED BILATERAL PROXIMAL TUBAL OCCLUSION. THEREFORE, CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE PREGNANCY CANNOT BE EXCLUDED. SPONTANEOUS ABORTION IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY. UP TO 20% OF CLINICALLY RECOGNIZED PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION WILL UNDERGO SPONTANEOUS ABORTION. RISK FACTORS INCLUDE MATERNAL AGE, PREVIOUS SPONTANEOUS ABORTION, SMOKING, LOW FOLATE LEVEL, UTERINE ABNORMALITIES, FETAL CHROMOSOMAL ABNORMALITIES, MATERNAL CHRONIC DISEASE AND MATERNAL INFECTIONS. IN THIS PARTICULAR CASE, PATIENT STATED THAT SHE WAS PREGNANT FOR SEVERAL WEEKS AND SHE HAD A PREVIOUS HISTORY OF SPONTANEOUS ABORTION. HOWEVER, DUE TO THE LACK OF A PROVEN ALTERNATIVE EXPLANATION AND TO A PLAUSIBLE TEMPORAL RELATIONSHIP BETWEEN ABORTION AND ESSURE TREATMENT, A MECHANICAL INTERFERENCE OF THE DEVICE ON THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED. ADDITIONALLY, OTHER SERIOUS EVENTS AND NON-SERIOUS EVENTS WERE REPORTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015 VIA SOCIAL MEDIA: CONSUMER STATED WHAT HAPPENS WHEN AN ESSURE COILS EMBEDS IN OTHER ORGANS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-DEC-2015: PTC GLOBAL NUMBER: (B)(4) FINAL ASSESSMENT: FOR CA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01697	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE NUMBER FDA-2014-N-0736-1649) IN UNITED STATES ON 27-OCT-2015, IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED. CONSUMER STATED THAT SHE HAD ESSURE DONE AFTER SHE HAD HER TWINS. FROM THE MOMENT SHE GOT IT, SHE HAD VERY DIFFERENT SYMPTOMS THAN SHE HAD EVER EXPERIENCED IN HER LIFE. SHE JUST THOUGHT IT WAS BECAUSE SHE HAD TWINS AND WAS TRYING TO GET BACK TO NORMAL LIFE. SHE EVENTUALLY STARTED BLEEDING AND COULD NOT STOP. SHE HAD TO HAVE A HYSTERECTOMY AT 35 BECAUSE THE BLEEDING DID NOT STOP. SHE BLED CONSTANTLY FOR 6 MONTHS STRAIGHT WITH EXTREME PAIN, BLOATING AND WEIGHT GAIN. NOT TO MENTION THE DEPRESSION FROM THE SYMPTOMS AND TRYING TO FIND A DOCTOR WHO WOULD BELIEVED HER AND ACTUALLY HELP HER. SHE HAD TO TAKE BIRTH CONTROL, GET AN IUD, NOTHING HELPED. HEADACHES, BACK PAIN, CRAMPING, FATIGUE, MUSCLE SPASMS, AS WELL AS BROKEN TEETH. AND CONSTANT PAIN. IMMEDIATELY AFTER HER HYSTERECTOMY SHE FELT BETTER. THE FEELING OF INFLAMMATION WAS GONE AND THE BLEEDING STOPPED. SHE IS STILL STRUGGLING WITH SOME OF THE SIDE EFFECTS LIKE THE WEIGHT GAIN AND BROKEN TEETH. SHE IS SO THANKFUL IT IS OUT OF HER BODY AND SHE TELLS EVERYBODY ABOUT THE DANGERS OF IT. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 17-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE

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INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EVENTUALLY STARTED BLEEDING AND COULD NOT STOP. SHE HAD TO HAVE A HYSTERECTOMY AT (B)(6) DUE TO NON-STOP BLEEDING. IMMEDIATELY AFTER HER HYSTERECTOMY SHE FELT BETTER AND THE BLEEDING STOPPED (POSITIVE DECHALLENGE). THIS EVENT, SEEN AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR DURING ESSURE USE. CONSIDERING ITS NATURE AND THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01698	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 4/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2012
Explant Date (E7): 9/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASEFDA-2014-N-0736-1759, AWARENESS DATE 27-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015. CONSUMER REPORTED SHE HAD ESSURE IMPLANTED AFTER HAVING A CHILD FROM A FIRST FAILED TUBAL LIGATION. SHE WAS REALLY SICK FROM THE BEGINNING. SHE WAS NAUSEATED EVERY DAY ON AND OFF ALL DAY. HAD PELVIC PAIN EVERY DAY. SOME DAYS THE PAIN WAS DEBILITATING. SHE WAS DIAGNOSED WITH CANCER AND THEY FOUND A TUMOR WHEN THEY REMOVED THE ESSURE FROM HER BODY. SHE HAD SEVERAL DEPRESSION AS WELL. SOME DAYS THE BRAIN FOG MADE HER FEEL LIKE SHE WAS JUST LOST AND CONFUSED ABOUT THE MOST SIMPLE THINGS. CONSUMER STARTED GETTING MIGRAINES, AND TONS OF UTIS (URINARY TRACT INFECTION), AND BLADDER INFECTIONS AND ALSO HER KIDNEYS ARE STARTING TO FAIL. THERE ARE WAY MORE HIDDEN SIDE EFFECTS SHE NEVER KNEW ABOUT, LIKE HOW HER HANDS AND FEET WOULD PEEL SKIN, HOW SHE NOW HAS TEETH DECAY AND GINGIVITIS EVEN THOUGH PRIOR TO ESSURE SHE HAS NEVER EVEN HAD A CAVITY, NOT EVEN AS A KID. CONSUMER WOULD BE SO SWOLLEN AND BLOATED THAT SHE WOULD LOOK 6 TO 7 MONTHS PREGNANT. THERE WERE DAYS SHE WAS TO SICK AND TIRED TO LEAVE THE COUCH. SHE HAD THE ESSURE DEVICES REMOVED ON (B)(6) 2015 AND FELT LIKE A NEW WOMAN. THE PELVIC PAIN AND NAUSEA WAS GONE INSTANTLY ONCE THE ESSURE WAS REMOVED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE

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DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE (ADVERSE EVENT) CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD DEBILITATING PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE HAD ESSURE REMOVED 3.5 YEARS AFTER ITS PLACEMENT AND RECOVERED FROM HER PAIN. ADDITIONALLY, SHE WAS DIAGNOSED WITH CANCER/TUMOR AND HER KIDNEYS STARTING TO FAIL. ONLY PELVIC PAIN IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL AND PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER STATED SHE WAS DIAGNOSED WITH A CANCER (UNSPECIFIED) AND THEY FOUND A TUMOR AT THE TIME OF ESSURE REMOVAL. THIS TUMOR COULD BE AN ALTERNATIVE EXPLANATION FOR CONSUMER'S PAIN. NEVERTHELESS, SINCE LIMITED INFORMATION IS AVAILABLE, A CONTRIBUTORY ROLE OF THE SUSPECT DEVICE CANNOT BE TOTALLY RULED OUT. REGARDING THE REMAINING EVENTS; GIVEN THEIR NATURE AND CONSIDERING ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY IS CONSIDERED VERY UNLIKELY. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE IS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01699	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/18/2006
Explant Date (E7): 7/19/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2147, AWARENESS DATE 27-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2006, UNDER ANESTHESIA DURING THE PROCEDURE. SHE WOKE UP IN HORRIBLE PAIN. SHE COULD BARELY WALK FOR A WEEK AFTER THE PROCEDURE. THEN, SHE EXPERIENCED LOWER BACK PAIN THAT WAS CONSTANT, EXTREME FATIGUE, GAINED WEIGHT, AND MENSTRUAL CYCLES THAT LASTED MONTHS AT A TIME; THE LONGEST BEING 4 1/2 MONTHS. SHE WAS INCREDIBLY MOODY CONSTANTLY. IT WAS TOO PAINFUL TO HAVE SEXUAL RELATIONSHIP WITH HER PARTNER AND THEY WOULD HAVE TO STOP DUE TO PAIN OR BLEEDING. SHE DEVELOPED TYPE 2 DIABETES AND FATTY LIVER DISEASE DUE TO NOT BEING ABLE TO LOSE WEIGHT. ON (B)(6) 2015 AFTER NEARLY 9 YEARS, A TOTAL HYSTERECTOMY WAS PERFORMED. SHE HAS MORE ENERGY, LOST 20 POUNDS AND WAS NO LONGER IN DAILY PAIN. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT:~ BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY

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DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER MENSTRUAL CYCLES LASTED MONTHS AT A TIME. SHE UNDERWENT A TOTAL HYSTERECTOMY 9 YEARS AFTER ESSURE INSERTION. TYPE 2 DIABETES WAS ALSO REPORTED. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. MENSTRUAL CYCLES LASTED MONTHS AT A TIME IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENT IS UNLISTED. AFTER ESSURE INSERTION, MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE EVENT MENSTRUAL CYCLES LASTED MONTHS AT A TIME AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. TYPE 2 DIABETES WAS ASSESSED AS UNRELATED TO ESSURE, CONSIDERING THE PATHOPHYSIOLOGY OF THE EVENT AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01700	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2150, AWARENESS DATE 27-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. ADDITIONAL INFORMATION RECEIVED ON 18-NOV-2015. CONSUMER GOT ESSURE PLACED IN 2011. EVER SINCE THEN, SHE HAS HAD NUMEROUS HEALTH ISSUES, SUCH AS JOINT PAIN, CYST GROWTH IN HANDS AND WRISTS, EXTREME PELVIC PAIN, FATIGUE, HEAVY UNPREDICTABLE PERIODS, HAIR LOSS AND MORE. JUST HAD A HYSTERECTOMY MONDAY (B)(6) 2015 AT ONLY (B)(6) YEARS OLD. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 18-NOV-2015: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE A INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM THE QUALITY DEFECT OR DEVICE MALFUNCTION AL THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT:

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THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD EXTREME PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE UNDERWENT A HYSTERECTOMY 4 YEARS AFTER DEVICE PLACEMENT. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION, NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01701	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2178, AWARENESS DATE 27-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. CONSUMER HAD ESSURE REMOVED IN 2011. SHE WAS ALLERGIC TO NICKEL AND WAS TOLD IT WAS MADE OF PLASTIC. SHE HAD TO HAVE A PARTIAL HYSTERECTOMY DUE TO THIS PRODUCT. SHE WOULD NEVER RECOMMEND THIS BIRTH CONTROL TO ANYONE FOR ALL THE PAIN IT HAS CAUSED HER. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY

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CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS ALLERGIC TO NICKEL. SHE HAD THE DEVICE REMOVED ONE YEAR AFTER ITS INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED. IN THE PRESENT CASE, NO TYPICAL ALLERGY SYMPTOMS WERE REPORTED. HOWEVER, GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENT WAS ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01702	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-2219) IN UNITED STATES ON 27-OCT-2015, IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6) 2015. CONSUMER STATED THAT SHE HAS HAD A FULL HYSTERECTOMY WHEN SHE WAS (B)(6) AND ANOTHER SURGERY SCHEDULED TO HAVE HER OVARIES REMOVED IN A MONTH. SHE HAD NEVER IMAGINED THAT SHE HAS TO HAVE EVERY FEMALE ORGAN REMOVED AT HER AGE IN ORDER TO HAVE A SOMEWHAT NORMAL LIFE AGAIN. THREE YEARS AGO, SHE HAD A DVT (DEEP VEIN THROMBOSIS) IN HER RIGHT LEG, 4 PULMONARY EMBOLISMS IN HER RIGHT LUNG AND A SMALL BRAIN ANEURYSM. THEY IMMEDIATELY TOOK HER OFF HER BIRTH CONTROL AND TOLD HER THAT SHE NEEDED TO HAVE A PERMANENT SURGERY IN ORDER TO PREVENT THE POSSIBILITY OF A PREGNANCY. SHE WAS UNABLE TO HAVE A SURGERY DUE TO THE BLOOD THINNERS SHE WAS ON, AND HER DOCTOR SAID THAT ONLY OPTION WAS TO HAVE THE ESSURE PLACEMENT. PREVIOUS TO THE ESSURE PLACEMENT SHE EXPERIENCED WHAT SHE THOUGHT WAS HEAVY PERIODS ONCE A MONTH. THE DAY OF HER ESSURE PLACEMENT SHE HAD AN ABLATION AND THEN A COIL INSERTED IN EACH FALLOPIAN TUBE. SHE WALKED OUT WITH PAIN AND IT NEVER STOPPED. AFTER ESSURE PLACEMENT SHE KNEW SOMETHING WAS DIFFERENT AND IT WOULD TAKE A FEW MONTHS BEFORE SHE WENT TO HER GYNECOLOGIST AND HER PRIMARY CARE PHYSICIAN WITH SIDE EFFECTS. TO NO AVAIL THEY WOULD NOT HELP HER. THEY DISMISSED HER CONCERNS AND CHALKED IT UP TO THE FACT THAT HER BODY WAS HEALING FROM MAJOR TRAUMAS. IMMEDIATELY AFTER ESSURE

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PLACEMENT SHE HAD THE FOLLOWING SYMPTOMS: INCREASED MENSTRUAL CYCLES, GOING FROM ONE EVERY 28 DAYS THAT LASTED 7 DAYS AT A TIME TO A PERIOD TWICE A MONTH LASTING ANYWHERE FROM 10 TO 14 DAYS. SHE WAS GOING THROUGH A SUPER PLUS TAMPON AND A SUPER ABSORBENCY PAD EVERY HOUR AND A HALF. WITH THE INCREASED PERIODS CAME INCREASED ABDOMINAL PAIN, CLOTS THAT WERE THE SIZE OF GOLF BALLS AND CRAMPING. HER ONE PHYSICIAN SAID THAT WOULD DECREASE AFTER SHE WAS TAKEN OFF OF BLOOD THINNERS. THIS WAS NOT THE CASE. THE MENSTRUAL CYCLES CONTINUED LIKE THIS FOR THREE YEARS UNTIL HER HYSTERECTOMY ON (B)(6) 2015. OTHER IMMEDIATE SIDE EFFECTS WERE: INCREASED MIGRAINES, INCREASED INTOLERANCE TO METALS AND OTHER ALLERGENS INCLUDING FOOD, AND MEDICAL FATIGUE TO THE POINT OF FALLING ASLEEP DURING WORK TASKS, OR TAKING CARE OF HER CHILDREN AND HOUSEHOLD. EVENTUALLY OTHER SIDE EFFECTS FOLLOWED: JOINT PAIN, INCREASED LOWER BACK PAIN, MUSCLE ACHES AND PAIN, CONSTANT METAL TASTE IN HER MOUTH, INCREASED DEPRESSION RESULTING IN BEING COMMITTED DUE TO THE DECREASE OF QUALITY OF LIFE, HAIR LOSS, HIVES AND CONSTANT BREAK OUTS. PERSONALLY ESSURE HAS RUINED HER LIFE, SHE WAS ENGAGED BEFORE ESSURE WAS PLACED SHE DID MARRY, HOWEVER THEIR SEX LIFE HAVE BEEN NONEXISTENT. HE HAS TOLD HER THAT THE STRESS OF NOT BEING ABLE TO ENGAGE IN SEX WITH HIS WIFE HAS HURT HIM. SHE WOULD HAVE SEVERE PAIN, BLEEDING AND CRAMPING IF THERE WAS ANY PENETRATION. SHE WAS ALWAYS IN PAIN AND COULD NOT HANDLE THE THOUGHT OF KNOWING BEING INTIMATE WOULD INCREASE THE PAIN. IT IS THOUGHT THAT NOT ONLY PAYING FOR THE ESSURE PLACEMENT. SHE SPENT A LOT OF MONEY IN THREE YEARS FOR TAMPONS AND PADS AND CLOTHING DUE TO INCREASED PERIODS. SHE HAS MISSED WORK AND THIS HAS AFFECTED HER FINANCES. AT THIS MOMENT, SHE IS ON MEDICAL LEAVE. HER TERM FAMILY AND MEDICAL LEAVE ACT HAS EXPIRED WHILE SHE IS OUT ON SHORT TERM DISABILITY THAT HAS TURNED NOW INTO LONG TERM DISABILITY SINCE THEY HAVE FOUND OTHER ISSUES SINCE THE HYSTERECTOMY. WHEN THE HYSTERECTOMY WAS DONE THEY FOUND ENDOMETRIOSIS IN THE UTERUS AND FALLOPIAN TUBES. THEY REMOVED THAT AND LEFT THE OVARIES HOWEVER SINCE THE SURGERY THEY HAVE FOUND THAT THERE IS ENDOMETRIOSIS IN THE OVARIES AND CYSTS ON HER KIDNEYS, SPLEEN AND THICKENING OF THE COION. SO ANOTHER SURGERY IS NOW SCHEDULED. SHE IS SURE THAT HER JOB WILL NOT BE AVAILABLE WHEN SHE RETURNS. SHE NEEDED TO HAVE A MAJOR SURGERY AT (B)(6) TO REMOVE THESE COILS THAT MADE HER LIFE A LIVING HELL. WITH THIS IF THE PRODUCT IS STILL APPROVED SHE WOULD LIKE TO SEE IT BE REMOVED FROM THE CATEGORY ILL DEOSSIFICATION. THIS IS NOT A LIFE SAVING DEVICE, THIS DEVICE DOES NOT IMPROVE THE QUALITY OF LIFE. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PERIOD TWICE A MONTH LASTING ANYWHERE FROM 10 TO 14 DAYS (INCREASED MENSTRUAL CYCLES). A FULL HYSTERECTOMY WAS PERFORMED. THIS EVENT, INTERPRETED AS FREQUENT AND PROLONGED PERIODS, WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. SINCE SURGICAL

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INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, SEVERAL NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

CORRECTION ON 25-NOV-2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT CONSTANT BREAK OUTS WAS RECODED TO MEDDRA LLT SKIN ERUPTION.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01704	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1784, AWARENESS DATE 27-OCT-2015). IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. ADDITIONAL INFORMATION RECEIVED ON 18-NOV-2015. THE CONSUMER REPORTED IT TOOK AN HOUR LONG TO INSTALL THE RIGHT COIL AND THE LEFT WAS INSTALLED TWO WEEKS LATER, BECAUSE IT WAS NOT DILATED. SHE REPORTED FROM THERE SHE HAD CHRONIC PELVIC PAIN AND DID HAVE A CYCLE FOR A YEAR AND WHEN SHE FINALLY DID, SHE BLED FOR ONE WHOLE MONTH AT A TIME. SHE WENT BACK TO THE DOCTOR AND HAD AN MRI DONE AND BLOOD AND NOTHING SHOWED UP. SHE STATED SHE SPENT YEARS WITH THE PAIN, BLOATING, BLEEDING, HAIR FALLING OFF, BAD ACNE, RASHES ON HER SKIN AND PELVIC PAIN. IN (B)(4) 2014, SHE BECAME PREGNANT AND THROUGHOUT HER PREGNANCY WAS HELL, HORRIBLE PELVIC PAIN. AFTER SHE HAD HER BABY (B)(6) 2015, HER TUBES WERE REMOVED ON (B)(6) 2015 AND HER LEFT TUBE WAS PUNCTURED BY THE COIL AND THE RIGHT COIL WAS LOST IN HER UTERUS. HER DOCTOR LEFT HER UTERUS AND, AT TIME OF THE REPORT, SHE WAS SUFFERING PAIN, AND FELT HER UTERUS CONTRACTING WITH PAIN, IT FELT LIKE IT WAS BURNING. SHE REPORTED IF SHE GOT APPROVED BY HEALTH INSURANCE, SHE WILL GET AN X-RAY DONE TO DETECT THE LOST RIGHT COIL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 18-NOV-2015 (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE A INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT

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NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM THE QUALITY DEFECT OR DEVICE MALFUNCTION AL THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER, WHO HAD PELVIC PAIN AND BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, 3 YEARS AFTER DEVICE PLACEMENT SHE BECAME PREGNANT. AFTER THE DELIVERY, SHE UNDERWENT A SALPINGECTOMY. DURING THIS SURGERY, HER LEFT TUBE WAS FOUND PUNCTURED BY THE COIL AND THE RIGHT COIL WAS LOST IN HER UTERUS. ALL EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE INCLUDING FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED ABOUT HSG. ACCORDING TO CONSUMER'S REPORT, AFTER THE DELIVERY, ESSURE WAS FOUND PERFORATING THE FALLOPIAN TUBE ON LEFT SIDE AND EXPELLED INTO THE UTERUS IN RIGHT SIDE. THESE EVENTS COULD BE ALTERNATIVE EXPLANATIONS FOR THE REPORTED DEVICE FAILURE (PREGNANCY). HOWEVER, SINCE THEIR MECHANISM IS UNKNOWN (IF THEY OCCURRED BEFORE OR AFTER PREGNANCY ONSET) AND AS PREGNANCY OCCURRED 3 YEARS AFTER DEVICES PLACEMENT; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE REPORTED PAIN AND BLEEDING, BASED ON ESSURE SAFETY PROFILE AND EVENTS NATURE; CAUSALITY CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (SALPINGECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE LACK OF EFFICACY AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01705	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/12/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2272, AWARENESS DATE 27-OCT-2015). ADDITIONAL INFORMATION RECEIVED ON 18-NOV-2015 (PTC INVESTIGATION RESULT). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2014. RIGHT AWAY SHE BEGAN HAVING SIDE EFFECTS. SHE EXPERIENCED FOOT PAIN AND SWEATING. AT HSG (HYSTEROSALPINGOGRAM) SHE ASKED THE PHYSICIAN AND SHE SAID NO ONE HAS HAD ISSUES. AS TIME WENT ON, SHE HAD DEPRESSION WITH SUICIDAL THOUGHTS APPEARED OUT OF NOWHERE, TIREDNESS, A NASTY RASH ALL OVER HER BODY, HAIR LOSS, SHARP PAINS IN STOMACH WHEN SHE COUGH OR MOVE TOO FAST, MOOD SWINGS, METAL TASTE, PAINFUL IRREGULAR PERIODS WITH CLOTS. SHE WAS SCHEDULED FOR A HYSTERECTOMY ON (B)(6). SHE WAS NOT LOOKING FORWARD TO THE SURGERY BECAUSE SHE HAS A TYPE 1 YOUNG DIABETIC SON WITH CRAZY SUGARS. PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED. WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT

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PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT (S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP PAINS IN STOMACH WHEN SHE COUGH OR MOVE TOO FAST AND DEPRESSION WITH SUICIDAL THOUGHTS. THESE EVENTS WERE CONSIDERED SERIOUS. THE FIRST REPORTED EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER IS UNLISTED. CONSIDERING THAT NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR THE EVENT SHARP PAINS IN STOMACH, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION (HYSTERECTOMY WAS SCHEDULED) WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT (S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01706	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1758, AWARENESS DATE 27-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER REPORTED FROM THE TIME THEY PUT IT IN WAS WHEN ALL HER PAIN AND TROUBLES STARTED FROM THE STOMACH PAINS TO THE PINCHING TO THE SURGERIES SHE HAD TO HAVE SO IF ANYONE WAS TO ASK HER ABOUT ESSURE. SHE WOULD SURE TELL THEM NOT TO GET IT WAS NOT WORTH THE PAIN AND SUFFERING YOU HAVE TO GO THROUGH. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. A SURGERY WAS PERFORMED. THIS EVENT WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS NOT REPORTED THE LOCATION OF PAIN. CONSIDERING THAT UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS

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REGARDED AS INCIDENT DUE TO SURGICAL INTERVENTION PERFORMED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01707	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2009, AWARENESS DATE 27-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER WENT IN TO HER GYNECOLOGIST TO DISCUSS BIRTH CONTROL OPTIONS AFTER HER THIRD SON WAS BORN IN 2011. SHE HAD ESSURE INSERTED AND AFTER THE PROCEDURE, WHICH WAS NOT TERRIBLY PAINFUL, EVERYTHING SEEMED FINE. WHEN SHE CAME BACK FOR HER 3 MONTH TEST, SHE COMPLAINED OF PELVIC PAIN. SHE WAS TOLD IT WAS COMMON, AND WOULD SUBSIDE SOON ENOUGH. DURING THE TEST TO CONFIRM BLOCKAGE, HE USED SALINE INSTEAD OF DYE. IT WAS SOME OF THE WORST PAIN SHE HAS EVER FELT. SHE WAS SOBBING AND BEGGING THEM TO STOP. AFTER SHE LEFT, SHE WENT HOME WITH SOME PAINFUL CRAMPS AND BLEEDING. MONTHS PASSED OF CRAMPING. BEFORE ESSURE, HER PERIODS WERE COMPLETELY PREDICTABLE, COMING THE SAME DAY EVERY MONTH. NOW SHE GOES FOR MONTHS AT A TIME WITHOUT ONE. SHE HAD ALMOST CONSTANT PELVIC PAIN AND CRAMPS SO BAD THAT SHE HAS BEEN DOUBLED OVER IN PAIN. SHE HAD NUMEROUS THINNING AND BALD SPOTS. HER IMPLANTING PHYSICIAN CLOSED HIS OFFICE, AND SHE FOUND ANOTHER DOCTOR. IN 2013, SHE UNDERWENT A BILATERAL SALPINGECTOMY, BUT SHE STILL SUFFERS. SHE IS NO LONGER THE WOMAN SHE WAS BEFORE ESSURE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER

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INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PELVIC PAIN. SHE ALSO REPORTED BLEEDING AFTER THE 3 MONTH CONFIRMATION TEST (INTERPRETED AS POST PROCEDURAL BLEEDING). SHE UNDERWENT A BILATERAL SALPINGECTOMY APPROXIMATELY 2 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY BETWEEN PELVIC PAIN AND ESSURE CANNOT BE EXCLUDED. SINCE THE BLEEDING OCCURRED AFTER THE ESSURE CONFIRMATION TEST, CAUSALITY WITH ESSURE WAS ASSESSED AS RELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01708	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 27-OCT-2015). ADDITIONAL INFORMATION RECEIVED ON 19-NOV-2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. ALMOST IMMEDIATELY AFTER PROCEDURE HAIR STARTED FALLING OUT; THE AMOUNT THAT STARTED FALLING OUT WAS ALARMING AND SHE HAD NO CLUE THAT THIS REACTION WAS DUE TO ESSURE. SHORTLY THEREAFTER, ALMOST SIMULTANEOUSLY, HER LOWER BACK, SHOULDERS, WRISTS, HIPS, AND NECK STARTED TO HURT. SHE WOULD GO NUMB IN HIPS, WRIST, AND SHOULDERS IN THE MIDDLE OF THE NIGHT. SHE WENT TO A HAND SPECIALIST THAT TOLD HER SHE HAD CARPEL TUNNEL AND NEEDED TO EITHER HAVE SURGERY OR FIND A NEW JOB THAT REQUIRED LESS TYPING. AROUND THAT SAME TIME HER JAW STARTED HURTING AND SHE COULD FEEL HER TEETH SHIFTING. EVENTUALLY TWO OF HER TEETH (MOLARS) FELL OUT. THEN, SHE STARTED HAVING DIZZY SPELLS, FELT OUT OF BREATH, COULD FEEL HER HEART FLUTTER, AND HAD NO ENERGY. AT THE (B)(6) SHE WAS DIAGNOSED WITH ASTHMA. IN BETWEEN ALL OF THAT SHE GOT HIT WILL SEVERAL OTHER THINGS LIKE: MYSTERY RASHES ALL OVER HER BODY, GAINED ABOUT 40 LBS, EXTREME FOOT PAIN, DEVELOPED ECZEMA AND DRY PATCHES ALL OVER HER BODY AND HAD TERRIBLE ACNE. SHE TALKED TO HER DOCTOR ABOUT HAVING THEM REMOVED. SHE SUGGESTED REMOVING HER TUBES; SALPINGECTOMY WOULD BE THE BEST OPTION FOR HER. ON (B)(6) 2015 ESSURE WAS REMOVED. IT'S BEEN ALMOST 10 MONTHS SINCE HER SURGERY AND SHE FEELS FANTASTIC. THE CHRONIC JOINT PAIN AND NUMBNESS HAS GONE AWAY. SHE DOES NOT WAKE UP HURTING IN THE MIDDLE OF EVERY NIGHT AND IS NO LONGER DIZZY EVERYDAY, AND NO LONGER HAVE HEART FLUTTERS

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EVERYDAY. HER DRY PATCHES AND ALL OF MYSTERY RASHES HAVE GONE AWAY. ALSO, HER HAIR STARTED TO GROW BACK. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER LOWER BACK STARTED TO HURT. SHE HAD ESSURE REMOVED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS REPORTED THAT SHORTLY THEREAFTER ESSURE INSERTION, SHE EXPERIENCED THIS EVENT. BASED ON THE NATURE OF THE EVENT AND CONSIDERING THAT A POSITIVE TEMPORAL RELATIONSHIP IS IMPLIED, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. ADDITIONALLY, ANOTHER SERIOUS EVENT (COULD FEEL HER HEART FLUTTER - UNLISTED AND UNRELATED) AND SEVERAL NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01709	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/31/2010
Explant Date (E7): 10/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2100, AWARENESS DATE 27-OCT-2015). IT REFERS TO A FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN JAN-2014. ADDITIONAL INFORMATION WAS RECEIVED ON 29-OCT-2015 (FDA-2014-N-0736-2101) AND ON 30-OCT-2015 (MW5056875). SHE WAS 29 YEARS OLD AT TIME OF REPORTING WITH THREE CHILDREN. IN 2010, SHE HAD THE MIRENA BIRTH CONTROL CONTRACEPTIVES TAKEN OUT AFTER HAVING IT FOR 4 YEARS, AND THE ESSURE IMPLANTED ON (B)(6) 2010. CONSUMER STARTED HAVING BIG BRUISES ALL OVER HER BODY THAT WAS ITCHING AND BURNING, WHICH WAS UNEXPLAINED; SHE EXPERIENCED FATIGUE, TIREDNESS, WEAKNESS, ANXIETY, BACK PAIN, HAIR STARTED TO THIN OUT, NAILS WERE BREAKABLE, JOINT PAIN, SWELLING EVERYDAY AND RHEUMATOID ARTHRITIS. SHE WENT TO THE DOCTOR AND THEY COULD NOT TELL HER WHAT WAS WRONG; EMERGENCY ROOMS, URGENT CARES, REGULAR PRIMARY CARE DOCTOR. COUPLE OF YEARS WENT BY, FINALLY IN (B)(6) 2014, SHE WAS FINALLY DIAGNOSED WITH AUTO-IMMUNE DISEASE, LUPUS (SLE). OVER THE YEARS, SHE WAS LOSING HAIR, HER NAILS WERE BRITTLE, BREAKING OFF, AND HER FINGERNAIL WAS ALWAYS PURPLE. THIS DID NOT START HAPPENING UNTIL AFTER SHE GOT ESSURE. SHE WENT TO THE DOCTOR OB/GYN RECENTLY AND THEY WOULD NOT REMOVE IT. THEY REFUSED TO DO SO. SOMETIMES IT CAUSES HER TEMPORARY DEFORMITIES OF HER JOINTS, ELBOWS, KNEES, ANKLES, HIPS, SHOULDERS, WHERE IT CAN LAST UP TO TWO TO THREE WEEKS, CAUSING HER TO HAVE TO MISS WORK. SHE APPLIED FOR DISABILITY. SHE REPORTED ESSURE EXPLANT DATE: (B)(6) 2015. CONCOMITANT MEDICATION INCLUDED PLAQUENIL, RELAFEN, NABUMETONE, KLONOPIN, WELLBUTRIN, ONE A DAY WOMEN'S MULTIVITAMINS AND FISH

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OIL. CONSUMER ASSESSED THE EVENT OUTCOME AS LIFE-THREATENING, HOSPITALIZATION AND DISABILITY/ PERMANENT DAMAGE; HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BACK PAIN. ESSURE WAS REMOVED. THIS EVENT IS SERIOUS (CONSUMER ASSESSED THE EVENT OUTCOME AS LIFE-THREATENING, HOSPITALIZATION AND DISABILITY/ PERMANENT DAMAGE; HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, AFTER ESSURE INSERTION SHE STARTED TO EXPERIENCE THIS EVENT. BASED ON ITS NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. ADDITIONALLY, OTHER SERIOUS EVENTS (RHEUMATOID ARTHRITIS AND LUPUS - UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01710	BAYER HEALTHCARE LLC	11/24/2015	11/24/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-1784, AWARENESS DATE 27-OCT-2015) WHICH REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER REPORTED SINCE HAVING THE ESSURE COILS IMPLANTED SHE HAD BEEN DIAGNOSED WITH AN AUTOIMMUNE DISORDER (THAT WAS NEVER A PROBLEM BEFORE), CHRONIC INFLAMMATION LEADING TO DEBILITATING JOINT PAIN AND MUSCLE SPASM (THAT LANDED HER IN THE ER OVER THE SUMMER ON TOP OF SEVERAL DOCTORS APPOINTMENTS), MIGRAINES, ABNORMAL AND EXTREMELY PAINFUL MENSTRUAL CYCLES AND A NUMBER OF OTHER HEALTH ISSUES. SHE RECENTLY MADE A LIST OF HEALTH ISSUES TO DISCUSS WITH HER GYNECOLOGIST AND THERE WERE 31 HEALTH ISSUES THAT SHE HAD LINKED TO ESSURE. HER HEALTH HAD STEADILY DECLINED IN THE PAST FEW YEARS SHE WAS IN CONSTANT PAIN AND GOOD DAYS WERE FEW AND FAR BETWEEN. SHE STATED SHE WILL UNDERGO A TOTAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY IN (B)(6)AT THE AGE OF (B)(6) IN ORDER TO BE FREE OF THE ESSURE DEVICE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 18-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THEN, SHE HAD BEEN DIAGNOSED WITH AN AUTOIMMUNE DISORDER. SHE ALSO WAS IN CONSTANT PAIN. SHE WILL UNDERGO A TOTAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY (IT IS SCHEDULED). THESE EVENTS, SEEN AS PELVIC PAIN AND AUTOIMMUNE DISORDER, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. PELVIC PAIN IS LISTED WHILE AUTOIMMUNE DISORDER IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. IN REGARDS OF AUTOIMMUNE DISORDER, LIMITED INFORMATION HAS BEEN PROVIDED; HOWEVER, GIVEN ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND SUSPECT INSERT IS VERY UNLIKELY. SINCE AN INTERVENTION WILL BE REQUIRED (SCHEDULED HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058037	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 12/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD A TOTAL HYSTERECTOMY ON (B)(6) BECAUSE OF PAIN AND OTHER COMPLICATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058038	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 10/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINE HEADACHES, BACK AND ABDOMINAL PAIN, PELVIC PAIN, FATIGUE, THYROID ISSUES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058039	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 8/10/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS DIAGNOSED WITH RHEUMATOID ARTHRITIS, I HAVE HAD PELVIC AND ABDOMINAL PAINS SO SEVERE I HAVE BEEN IN THE ER THREE TIMES WITHIN THE LAST FIVE MONTHS. PAIN ALL THROUGHOUT THE MONTH NOT INCLUDING WHEN I HAVE MY MENSTRUAL CYCLE. PAINS IN MY LEGS, FATIGUE, LOSS OF ENERGY. MY DEVICE WAS PROVIDED BY MY DOCTOR AT THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058040	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 4/26/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT MIGRAINES, ABDOMINAL PAIN AND CRAMPING, HEAVY AND PAINFUL PERIODS MONTHLY, FORGETFULNESS, UNEXPLAINABLE RASHES, AND PAINFUL INTERCOURSE. ESSURE WAS COVERED 80% BY MY INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058041	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DATE IS ESTIMATE. RASH OCCURRED TWICE BEFORE DATE I ENTERED OTHER SYMPTOMS I NOTICED AROUND 2YRS AFTER IMPLANT. HEADACHES, HAIR LOSS, CRAMPING EVERY DAY, EXTREME FATIGUE, EXTREME WEIGHT GAIN, EXTREME IRRITABILITY, MOODINESS, TINGLING AND NUMBNESS IN HANDS, ARMS, LEGS, JOINT PAIN. MUCH HEAVIER MENSTRUALS (USE TO BE 4 DAYS WITH 1 SLIGHT HEAVY DAY; NOW ITS 3-4 DAYS VERY HEAVY LAST 10 DAYS WITH SPOTTING BEFORE AND AFTER). DIAGNOSED WITH ADENOMYOSIS. LOWER BACK PAIN DAILY, MUCH WORSE AROUND AND DURING MENSTRUAL. TOOTH LOSS, TEETH PULLED, GUM DISEASE. I HAD GREAT TEETH AND GUMS PRIOR TO ESSURE. I WAS HEALTHY BEFORE ESSURE, I WEIGHED (B)(6) BEFORE ESSURE AND GAINED (B)(6) LBS AFTER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058042	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 12/31/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL CRAMPS AND SHOOTING PAINS ON LEFT SIDE OF PELVIC AREA. PAIN WHEN HAVING SEX. OCCASIONAL AND RANDOM ITCHING/RASH. WEIGHT GAIN. BELLY LOOKS PREGNANT. IRREGULAR PERIODS THAT CAN BE LIGHT, HEAVY, OR DOESN'T COME. EXTREME SLEEPING ISSUES, LESS ACTIVE, FOGGY BRAIN, TEETH ISSUES, SPEECH ISSUES (THINK WHAT I WANT TO SAY BUT IT'S LIKE I CAN'T GET IT OUT OR COMES OUT WRONG/ODD).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058043	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 6/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT PREGNANT AND HAD A MISCARRIAGE THAT REQUIRED MEDICAL INTERVENTION. I HAVE CHRONIC FATIGUE, ESPECIALLY AROUND MY MENSTRUAL CYCLE. I ALSO HAVE DIFFICULTY WITH BACK, NECK AND LEG MOVEMENT. I AM NOW AWAITING A HYSTERECTOMY TO REMOVE COILS BECAUSE THEY ARE NOT IN THE CORRECT POSITION AND MY SIDE EFFECTS ARE CONSISTENT WITH MY BODY REJECTING THE DEVICES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058044	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 10/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HYSTERECTOMY ON (B)(6) 2015. SURGEON SHOWED ME PICTURES WHERE THE COIL HAD PERFORATED MY RIGHT FALLOPIAN TUBE AND CAUSED "CONGESTION" IN THE SURROUNDING TISSUE. SINCE SURGERY, MY DEBILITATING PAIN IS GONE, MY HAIR HAS STOPPED FALLING OUT, THE SCALP PSORIASIS I DEVELOPED AFTER ESSURE PLACEMENT HAS GONE AWAY WITHOUT MEDS, I WAS ABLE TO STOP TAKING AN ANTIDEPRESSANT, AND MY JOINTS ARE NO LONGER SORE AND STIFF.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058045	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 10/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, LOSS OF LIBIDO, MOOD SWINGS, EXTREME ABDOMINAL BOATING, WEIGHT GAIN, DIGESTIVE ISSUES INCLUDING CONSTIPATION, DIARRHEA, AND IRREGULARITY, HEART PALPITATIONS, BODY AND JOINT ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058046	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 5/8/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD HIVES TREATED BY DERMATOLOGIST, DIZZINESS TREATED FOR VERTIGO, HEAVY CRAMPING PERIODS, SHARPS PAINS CONSTANT LOW IN MY STOMACH, GI ISSUES W MY STOMACH LOOKING PREGNANT, HAD TO GET MY FALLOPIAN TUBES W THE ESSURE REMOVED (B)(6) 2015.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058047	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 11/6/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PROCEDURE DONE IN 2007. SIX MONTHS AFTER STARTED HAVING HOT FLASHES, NIGHT SWEATS, PERI MENOPAUSE SYMPTOMS AT AGE OF 38. NOW (B)(6) HAD TO SEEK TREATMENT FOR SYMPTOMS. HAVE FATIGUE, JOINT PAIN, MIGRAINES, RASHES, CARPAL TUNNEL AND ARTHRITIS FROM INFLAMMATION. THE LIST GOES ON. YEARS OF CHIROPRACTIC CARE FOR BACK AND JOINT PAIN, YEARS OF HORMONE THERAPY FOR HORMONAL SIDE EFFECTS NOT TO COUNT THOUSANDS OF DOLLARS SPENT ON THESE ALTERNATIVE MEDICINES JUST TO FUNCTION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058048	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 8/12/2012	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BATTLE CHRONIC MIGRAINES, BACK ACHE, EXTREME FATIGUE. SERIOUS MEMORY LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058049	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 4/22/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NICKEL ALLERGIES CAUSING SHORTNESS OF BREATH, SWELLING AND HIVES. HAD VAGINAL BLEEDING FOR ALMOST A YEAR AFTER COILS WERE PUT IN. PAINFUL INTERCOURSE, BLEEDING AFTER INTERCOURSE, PELVIC PAIN. HAVE SINCE DEVELOPED UTERINE FIBROIDS, ENDOMETRIOSIS, AND PAINFUL BLADDER SYNDROME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058050	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 11/17/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED GETTING SHARP PAINS IN LEFT PELVIC AREA HAD ISSUES WITH NO SEX DRIVE, FUNNY METAL TASTE IN MOUTH, HEAVY UNPREDICTABLE CYCLES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058051	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FEW MONTHS AGO MY HEADACHES GOT WORSE AND THE SORE ON THE BACK OF MY LEG I GET EVERY MONTH JUST ABOUT HAS DOUBLED NOW I GET TWO. I'M GETTING MORE TIRED AND DIZZY AND ITS SO HARD TO KEEP MY EYES OPEN TO THE POINT I FEEL LIKE I'M GONNA PASS OUT. STILL CRAMPING N SHARP PAINS WHERE COILS ARE AND MY EYES HAVE CHANGED A LOT I FIXING TO HAVE TO GET GLASSES AGAIN. I HAVE NOTICED MY MOODS CHANGE REALLY BAD AND I HAVE LOST MY PATIENCE WITH THE LITTLEST THINGS I CAN'T SEEM TO WORK LIKE I USE TO EVERYTHING HAS EFFECTED MY LIFE WITHIN THE LAST YR AS I GOTTEN WORSE. HOPE I CAN GET THEM OUT ASAP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058052	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 11/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SUFFERING FROM MIGRAINES, JOINT PAIN, FATIGUE, BLOATING, HEAVY PAINFUL MENTRUAL CYCLES, OCCASIONAL DIZZINESS, METALLIC TASTE IN MOUTH THAT COMES AND GOES, AND SHARP PAINS THAT HAPPEN IN THE LOCATION OF THE COILS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058053	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 10/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IRREGULAR PERIODS, CHRONIC PELVIC PAIN, NEW AUTOIMMUNE, DEPRESSION, WEIGHT GAIN, ANXIETY, FATIGUE, REOCCURRING UTIS, PAINFUL SEX, NICKLE ALLERGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058054	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 11/21/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, PELVIC PAIN, RASH, PULLING ON LEFT SIDE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058055	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 3/2/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH THE ESSURE DEVICE IN AN OB/GYN CLINIC PROCEDURE ON (B)(6) 2006. I WAS GIVEN ORAL SEDATIVES. IT WAS AN EXTREMELY PAINFUL PROCEDURE. AFTER 6 WEEKS, I RETURNED FOR THE CONFIRMATION X-RAY. THE DOCTOR COULD NOT CONFIRM CORRECT PLACEMENT AT THAT TIME. SHE CONTACTED OTHER DOCTORS AND ALSO CONTACTED CONCEPTUS, THE MANUFACTURER OF ESSURE. SHE WAS ADVISED THAT THE DEVICES SHOULD BE SURGICALLY REMOVED. SHE CONTACTED ME AND SUGGESTED A TUBAL LIGATION AND REMOVAL OF THE ESSURE DEVICES. THE TUBAL LIGATION WAS PERFORMED ON (B)(6) 2006. THE ESSURE DEVICES HAD MIGRATED OUT OF MY FALLOPIAN TUBES. THEY WERE TANGLED TOGETHER AND EMBEDDED IN MY PELVIC WALL. THE DEVICES WERE REMOVED AND A TUBAL LIGATION WAS PERFORMED. I WAS TOLD THE DEVICES WERE INTACT AND COMPLETELY REMOVED. DURING THE FOLLOWING YEARS, I HAD ISSUES WITH ABDOMINAL PAIN, JOINT PAIN, LOWER BACK PAIN, HEADACHES, SEVERE MENSTRUAL PAIN, BLOOD CLOTS DURING MENSTRUATION, CHRONIC URINARY TRACT INFECTIONS, YEAST INFECTIONS, AND VARIOUS OTHER MALADIES. I WAS FINALLY ABLE TO FIND A MEDICAL PROFESSIONAL THAT LISTENED TO ME AT OUR LOCAL CLINIC. SHE SUGGESTED AN ULTRASOUND. THE ULTRASOUND WAS PERFORMED (B)(6) 2015 AT OUR LOCAL HOSPITAL. A FOREIGN OBJECT WAS DETECTED IN MY UTERUS. AN X-RAY WAS PERFORMED (B)(6) 2015. THE X-RAY CONFIRMED WHAT APPEARED TO BE A COIL FRAGMENT WAS PRESENT. I WAS REFERRED TO A SURGEON, WHO AGREED TO PERFORM A HYSTERECTOMY. THE HYSTERECTOMY WAS PERFORMED (B)(6) 2015. A COIL FRAGMENT FROM THE ESSURE DEVICE WAS FOUND EMBEDDED IN MY UTERUS. I AM NOW 19 DAYS POST-OP. I FEEL BETTER NOW THAN I HAVE IN YEARS. I NEEDED TWO SURGERIES TO CORRECT A "NON-SURGICAL" PROCEDURE. I WISH I HAD NEVER HEARD OF ESSURE.

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PLEASE STOP THIS HORRIBLE DEVICE FROM INJURING OTHER WOMEN. I HAVE ATTACHED A PICTURE OF THE PORTION OF THE DEVICE THAT WAS REMOVED FROM ME IN 2006. I HAVE NOT YET RECEIVED THE FRAGMENT THAT WAS REMOVED DURING THE HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058056	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 3/14/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I SUFFER FROM CHRONIC MIGRAINES SINCE I HAD ESSURE IMPLANTED IN 2007. I HAVE BEEN TO EVERY DOCTOR AND BEEN ON MULTIPLE MEDICATIONS AND NOTHING SEEMED TO HELP. MY DEVICE WAS NOT PROVIDED BY OUR INSURER AT THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058057	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 8/8/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE PROVIDED BY (B)(6). RIGHT AWAY I HAD IMMEDIATE STOMACH PAINS THAT HAVE ONLY GOTTEN WORSE, ABNORMAL PERIODS, I BLEED FOR THE FIRST YEAR, I HAVE HAD HEADACHES, SKIN RASHES, HAIR LOSS, ANXIETY, AND HEART PROBLEMS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058058	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 2/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CYST THAT BURST ON LEFT OVARY, HEADACHES, VERY BAD CRAMPS, LOSS OF BLOOD CLOTS QUARTER SIZE OR LARGER, LOWER BACK PAIN, ENDED UP HAVING A HYSTERECTOMY AT AGE (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058059	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 7/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PELVIC PAIN, HEAVY PAINFUL PERIODS, HEADACHES, PAINFUL SEX, SEVERE SKIN BREAKOUT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058060	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 11/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE HAVING ESSURE PLACED IN (B)(6) 2010, I HAVE EXPERIENCED SEVERE BLOATING, ACHING JOINTS, RINGING EARS, EARLY ONSET MENOPAUSE, DECREASED THYROID FUNCTION, FOGGY BRAIN. ALL SYMPTOMS STARTED APPROXIMATELY 1 YEAR AFTER PLACEMENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058061	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 2/28/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHERE TO START I HAVE EXTREME BLOATING; I BLEED PROFUSELY FOR MONTHS ON END WITH HUGE CLOTS; THE PAINS I GET ON THE LEFT SIDE OF MY ABDOMEN ARE SO EXTREME I FEEL LABOR WAS PAINLESS COMPARED TO THESE PAINS; NOT TO MENTION MY HEADACHES BODY ACHES RASHES; AND LASTLY THE DISCHARGE THAT COMES OUT FOR THE 3-5 DAYS BEFORE I START BLEEDING AGAIN!!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058062	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 11/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED WITH STABBING PAIN IN BOTH SIDES OF MY PELVIS THEN IT TURNED INTO AN ACHING LOWER BACK AND CRAMPING PELVIC AREA. SOME OF THE PAIN SO BAD IT MAKES ME THROW UP AND I'M TAKING DAILY PAINKILLERS. I WILL BE HAVING A HYSTERECTOMY ON (B)(6) TO REMOVE MY UTERUS WILL BE IN TUBES AND CERVIX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058063	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 11/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT THE ESSURE 5 YEARS AGO AFTER MY SON WAS BORN IMMEDIATELY AFTER GETTING IT IMPLANTED I HAD A LOT OF CRAMPING AND PAINS BUT THOUGHT IT WAS MY BODY ADJUSTING TO THE DEVICE AFTER HAVING IT IN FOR 4 WEEKS I COULD NO LONGER HAVE ANYTHING PEANUT BUTTER WHAT SO EVER WITHOUT HAVING A REACTION THEN AS TIME WENT ON I STARTED FEELING MORE AND MORE FATIGUED DAY BY DAY THEN LAST (B)(6) I WENT TO THE ER BECAUSE I ATE SOME CHOCOLATE AND HAD A REACTION THAT CAUSED ME TO HAVE A SEIZURE AND FALL OUT SO I WAS RUSHED TO THE ER I FOUND OUT LATER I HAD THE REACTION TO THE CHOCOLATE BECAUSE OF HOW MUCH NICKEL WAS IN IT AND FROM HAVING THE ESSURE PUT IN I DEVELOPED A NICKEL ALLERGY AND WITH THE ESSURE BEING NICKEL AND BEING INSIDE OF ME IT WAS KILLING ME FROM THE INSIDE OUT. I WAS NEVER EVER TOLD THAT AN ALLERGY TEST WAS SUPPOSED TO BE DONE FOR NICKEL BEFORE PUTTING IT INTO YOUR BODY WHICH BAYER SHOULD INFORM ALL ITS PATIENTS ABOUT BEFORE INSERTION! NOW I HAVE HAD TO HAS A HYSTERECTOMY TO REMOVE THIS DEVICE AND CAN NO LONGER HAVE CHILDREN (PROFANITY) YOU BAYER AND (PROFANITY) YOU ESSURE YOU RUINED EVERYTHING!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058064	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 7/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SORRY I DIDN'T REALIZE THAT WAS IT WAS GOING TO SUBMIT IT WITHOUT ALL MY INFORMATION. MY SEVERED SYMPTOMS DIDN'T SHOW UP TILL (B)(6) 2015. I HAVE HAD THE BLOATING CONSTIPATION FREQUENT URINATION, INCONTINENCE WEIGHT GAIN, PAIN, SPOT BLEEDING, I THOUGHT ALL WAS SOMEWHAT NORMAL WITH MY AGE BUT IN JULY I STARTED BLEEDING A LOT AFTER SEX AND GOT SCARED WENT TO MY PCP DOCTOR SHE DID A PAP IT CAME BACK ABNORMAL I HAVE BEEN HAVING PAINS IN MY LOWER PELVIC AREA ESPECIALLY WHEN I SIT OR LAY DOWN . I WILL BE GOING TO FOLLOW UP WITH A GYNECOLOGIST AS SOON AS POSSIBLE THEY ORDERED ALL KINDS OF TESTS AND THAT'S WHERE I AM AT NOW.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058065	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 11/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN DEALING WITH THIS PAIN FOR MORE THAN FIVE YEARS. I WAS ADMITTED IN TO THE HOSPITAL ONLY A WEEK AFTER THE IMPLANTATION. ACTUALLY I HAVE BEEN TO THE HOSPITAL SEVERAL TIMES AND TO MY DR'S NON STOP. I HAVE PELVIC PAIN, SEVER BACK PAIN, HAIR FALLING OUT, DIZZINESS, FATIGUE, FORGETFUL, HORRIBLE PERIODS, NON CONSISTENT PERIODS, PRE CANCEROUS CELLS, KIDNEY STONES, WEIGHT GAIN, FREQUENT URINATION AND THE LIST GOES ON. MY DEVICE WAS COVERED UNDER INSURANCE AND I WISH I WAS NEVER TALKED IN TO THIS HORRIBLE PROCEDURE. ALL I WANTED WAS TO HAVE MY TUBES TIED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058066	BAYER	11/24/2015	11/24/2015

Event Information:

Event Date (B3): 8/15/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY OB-GYNO OF 16YRS. RECOMMENDED ME TO GET THE ESSURE INSTEAD OF A TUBAL LIGATION ADVISING ME THAT IT WAS SAFER. SINCE THE PROCEDURE I HAVE HAD NUMEROUS HSG PROCEDURE DONE DUE TO THE LEFT SIDE NO CLOSING. WHICH CAUSES CHRONIC PAIN, HEAVY BLEEDING AND CLOTS, NAUSEA, HEADACHES, CHRONIC CONGESTION (8MOS. NOW), DEPRESSION AND JOINT PAIN. I HAVE COMPLAINED AT EVERY HSG APPOINTMENT AND THE DOCTOR ALWAYS STATES MY ISSUES ARE NOT FROM THE ESSURE. I STAYED ON MY MENSTRUAL CYCLE FOR 3 MONTHS STRAIGHT WITH HEAVY BLEEDING. I INFORMED THE DOCTOR THE FIRST MONTH AND HE STATED IT WAS MY BIRTH CONTROL AND HE CHANGED. THE SECOND MONTH I WAS STILL MENSTRUATING AND I WAS DEPRESSED AND ANNOYED BECAUSE MY DOCTOR WAS NOT LISTENING. THE THIRD MONTH ANOTHER HSG AND (B)(6) STATED THAT ONE OF THE COILS WAS IN MY UTERINE CAVITY. WHICH WAS CAUSING THE CONSTANT BLEEDING. DR. (B)(6) REMOVED THE COIL BY JUST PULLING IT OUT (NOT SURE IF THAT WAS SAFE) BUT OK. MY PERIODS ARE NORMAL BUT STILL HEAVY BLEEDING AND BLOOD CLOTS BIGGER THAN THE SIDE OF A HALF OF DOLLAR. TO THIS DAY 1 YEAR AND 3 MONTHS LATER I HAVE REGRETTED GETTING THIS PROCEDURE DONE MY LIFE HAS BEEN HELL. MY EMOTIONS ARE ALL OVER THE PLACE MY HUSBAND THINKS I DON'T LOVE HIM BECAUSE I HAVE NO DESIRE TO HAVE SEX AND MY KIDS THINKS I'M CRAZY BECAUSE I YELL ALL THE TIME. FOR THE MOST PART, MY DOCTOR FINALLY LISTENED AND AFTER (B)(6) 2016 I WILL BE E-FREE BUT BAYER WILL PAY FOR THE HELL IT HAS PUT ME AND MY FAMILY THROUGH.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01703	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2084, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ADDITIONAL INFORMATION (PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT) RECEIVED ON 18-NOV-2015. CONSUMER REPORTED SHE HAD TO GET HER FALLOPIAN TUBES REMOVED IN (B)(6) 2015 DUE TO ESSURE COMPLICATIONS. THE PAIN SHE WAS IN WAS UNBEARABLE. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS 2015-045426. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-

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MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HER FALLOPIAN TUBES REMOVED DUE TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) COMPLICATIONS. ACCORDING TO HER, THE PAIN SHE WAS IN WAS UNBEARABLE. PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (SALPINGECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01711	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT FROM A CONSUMER IN UNITED STATES WAS IDENTIFIED IN THE INTERNET SITE OF TELEVISION STATION ON (B)(6) 2013. THE REPORT REFERS TO THE REPORTING (B)(6) FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS PERFORATING HER INTESTINES AND BOWELS, SHE EXPERIENCED TREMENDOUS DAILY PAIN. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT DRUGS AND CONCURRENT CONDITIONS. ON AN UNSPECIFIED DATE, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR BIRTH CONTROL. CONSUMER REPORTED SHE EXPERIENCED PAIN. THE DOCTOR TOLD HER IT WAS PERFORATING HER INTESTINES AND BOWELS, SO THAT WAS WHY SHE WAS HAVING THE TREMENDOUS PAIN THAT SHE WAS HAVING DAILY. CONSUMER WAS HAVING SURGERY TO TAKE THE COILS OUT. NO FURTHER DETAILS WERE REPORTED. REPORTER CONSIDERED THE EVENTS RELATED TO ESSURE. FOLLOW UP RECEIVED ON 27-JAN-2014 WITH THE FINAL PTC INVESTIGATION RESULT: THESE EVENTS REPORTED WERE RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT ARE: (B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN (B)(4), "PROCESSING ESSURE CASES IN DEV@COM." (B)(4). MEDICAL ASSESSMENT: THE REPORTED MEDICAL EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. THE

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TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 28-OCT-2015 - IT HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2140): THE CONSUMER HAD ESSURE INSERTED IN 2009 AND HAD TO HAVE THEM REMOVED IN 2013 BECAUSE THEY MIGRATED. SHE WAS IN TERRIBLE PAIN FOR YEARS WITH MANY VISITS TO THE DOCTORS OFFICE AND SPECIALISTS. IT CAUSED MANY SLEEPLESS NIGHTS AND DAYS OF DEPRESSION WITH NO ONE FINDING THE CAUSE OF THE PROBLEM. THE COIL WAS PERFORATING HER INTESTINE. SHE ALSO HAD AN ALLERGY TO NICKEL. SHE HAD TO HAVE HER THYROID REMOVED BECAUSE OF LARGE NODULES THAT HAVE GROWN ON IT. AT THE TIME OF THE REPORT SHE HAD LESIONS ON HER LIVER AND WAS SUFFERING FROM OTHER ISSUES THAT SHE HAD TO WONDER IF IT HAD IN ANY RELATION TO THE COILS. SHE STATED HER BODY WAS CLEARLY REJECTING IT. HER HAIR USED TO FALL OUT, SHE USED TO BREAK OUT IN RASHES. AFTER REMOVAL, SHE STILL HAD LINGERING HEALTH ISSUES BECAUSE OF IT ESSURE. BEFORE ESSURE SHE WAS A RELATIVELY HEALTHY WOMAN. SHE HAD GIVEN BIRTH TO 3 CHILDREN, BUT AT THE AGE OF (B)(6) SHE FELT LIKE 53 OR OLDER BECAUSE OF ALL THE HEALTH ISSUES SHE HAD TO CONTINUE TO DEAL WITH. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE COILS MIGRATED AND PERFORATED HER INTESTINES AND HER BOWELS. LATER, IT WAS INFORMED THAT SHE ALSO HAD HER THYROID REMOVED BECAUSE OF LARGE NODULES. THEN, THE CONSUMER HAD TO HAVE THEM (ESSURE COILS) REMOVED DUE TO MIGRATION. THESE EVENTS, SEEN AS DEVICE MIGRATION, GASTROINTESTINAL INJURY AND THYROID NEOPLASM, ARE SERIOUS DUE TO MEDICAL IMPORTANCE. ONLY THYROID NEOPLASM IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. INTERNAL ORGANS PERFORATION MAY OCCUR WITH ESSURE, DUE TO DEVICE MIGRATION OR DURING INSERTION PROCEDURE. ALTHOUGH THE EXACT DATE AND THE MECHANISM OF MIGRATION AND PERFORATION ARE NOT KNOWN, A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THESE EVENTS CANNOT BE EXCLUDED. REGARDING THYROID NODULES, CONSIDERING THAT ESSURE ACTS LOCALLY IN FALLOPIAN TUBES, CAUSALITY WITH SUSPECT INSERT IS VERY UNLIKELY. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01712	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 774372

Single Use: Y
Implant Date (E6): 2/3/2012
Explant Date (E7): 2/8/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5032750) IN UNITED STATES ON (B)(6) 2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED STOMACH SWELLING, PAIN IN ABDOMINAL AREA, MIGRAINES GOT WORSE THEY THOUGHT SHE WAS HAVING A STROKE, EXTREME VAGINAL BLEEDING AT PERIOD TIME, SEVERE CRAMPS, LARGE BLOOD CLOTS, SEVERE FATIGUE TO WHOLE BODY, HAIR LOSS, EXTREME WEIGHT GAIN, RASHES, AND LONG LIST OF SIDE EFFECTS. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCURRENT CONDITIONS OR CONCOMITANT MEDICATION. ON (B)(6) 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER 774372. DEVICE WAS DISCONTINUED ON (B)(6) 2013. CONSUMER HAD ESSURE IMPLANTED ON (B)(6) 2012; RIGHT AWAY STARTED TO HAVE REACTION. SHE HAD STOMACH SWELLING, PAIN IN ABDOMINAL AREA, MIGRAINES GOT WORSE TO THE POINT THEY THOUGHT SHE WAS HAVING A STROKE, EXTREME VAGINAL BLEEDING AT PERIOD TIME, SEVERE CRAMPS, LARGE BLOOD CLOTS, SEVERE FATIGUE TO WHOLE BODY, HAIR LOSS, EXTREME WEIGHT GAIN, RASHES, LONG LIST OF SIDE EFFECTS. REPORTER CAUSALITY WAS NOT REPORTED. FOLLOW UP 22-APR-2014: PTC INVESTIGATION RESULTS WERE PROVIDED. FINAL ASSESSMENT: LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. FINAL RISK CLASSIFICATION: RISK CATEGORY V MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. ONE (1) ADDITIONAL AE CASE REPORT HAS BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER (B)(4) BUT THIS CASE DOES NOT REFER TO A SIMILAR TYPE OF MEDICAL EVENT. NO BATCH SIGNAL COULD BE IDENTIFIED AT THIS TIME. THE

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REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. FOLLOW-UP RECEIVED ON 28-OCT-2015: AFTER HAVING A MISCARRIAGE ON (B)(6) 2011, CONSUMER HAD THE ESSURE INSERTION PROCEDURE ON (B)(6) 2012. FROM THE MOMENT SHE HAD THEM IN SHE STARTED TO HAVE SYMPTOMS. SHE EXPERIENCED NECK PAIN, HEAVY MENSTRUAL BLEEDING, SEVERE PMS (PREMENSTRUAL SYNDROME) AND JOINT PAIN. ON (B)(6) 2013 CONSUMER HAD A HYSTERECTOMY DONE. SHE WAS (B)(6). SHE STILL HAVE PROBLEMS FROM THE ESSURE. SHE HAS ARTHRITIS IN HER HIPS AND BACK PROBLEMS. STILL SUFFERS FROM OTHER IMMUNE SYMPTOMS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD SEVERE HEAVY MENSTRUAL BLEEDING (LARGE BLOOD CLOTS AND EXTREME VAGINAL BLEEDING AT PERIOD TIME) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (APPROXIMATELY 1 YEAR AFTER DEVICE PLACEMENT). THE REPORTED EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENTS NATURE AND IN THE LACK OF ALTERNATIVE EXPLANATIONS, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. OTHER NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01713	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 5/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 623640

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 7/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED ON 15-APR-2014 FROM A CONSUMER IN THE UNITED STATES VIA THE FDA, THE REGULATORY AUTHORITY IN THE UNITED STATES (FDA CASE NUMBER (B)(4), RECEIVED AT FDA ON 06-MAR-2014). THE REPORT REFERS TO THE REPORTING FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED WEIGHT GAIN, EASY BRUISING, FACIAL HAIR GROWTH, HAIR LOSS, SWOLLEN GLANDS, RINGING IN THE EARS, HIGH BLOOD PRESSURE, NUMBNESS IN HANDS, FEET AND THIGHS, NAUSEA, BLOATING, DRY SKIN, ACNE, GASTO ISSUES, BACK PAIN, ANEMIA, MIGRAINES, HEADACHES, PAINFUL OVULATION, SHARP PELVIC PAIN, LONG MENSTRUAL CYCLES, EXCESSIVE PAINFUL BLEEDING, CHRONIC PELVIC PAIN, DISCHARGE, OVARIAN CYST AND BREAST CYST. ON FDA FORM REPORTED REPORT TYPE WAS INJURY, OUTCOME OF EVENTS WAS OTHER SERIOUS (IMPORTANT MEDICAL EVENTS). NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. ON (B)(6) 2007, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), MODEL NUMBER ESS205, LOT NUMBER 623640, IMPLANTED. CONSUMER REPORTED SHE HAD SEVERAL PROBLEMS SINCE ESSURE PLACEMENT IN 2007 (START DATE OF EVENTS REPORTED AS (B)(6) 2007), WEIGHT GAIN, EASY BRUISING, FACIAL HAIR GROWTH, HAIR LOSS, SWOLLEN GLANDS, RINGING IN THE EARS, HIGH BLOOD PRESSURE, NUMBNESS IN HANDS, FEET AND THIGHS, NAUSEA, BLOATING, DRY SKIN, ACNE, GASTO ISSUES, BACK PAIN, ANEMIA, MIGRAINES, HEADACHES, PAINFUL OVULATION, SHARP PELVIC PAIN, LONG MENSTRUAL CYCLES, EXCESSIVE PAINFUL BLEEDING, CHRONIC PELVIC PAIN, DISCHARGE, OVARIAN CYST AND BREAST CYST. EACH TIME SHE WENT TO THE DOCTOR SHE WAS JUST PUT BACK ON BIRTH CONTROL TO MANAGE THE SYMPTOMS, BUT NOT ACCURATELY TAKEN CARE OF THE PROBLEM. NO FURTHER DETAILS WERE REPORTED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP. FOLLOW-UP

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INFORMATION WAS RECEIVED ON 24-JUL-2014. NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 28-OCT-2015 AND RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015: CASE IS NOW CONSIDERED INCIDENT. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEP-2015 (FDA-2014-N-0736-2241). IN 2007, AFTER HER SON WAS BORN, SHE DECIDED TO HAVE THE ESSURE BIRTH CONTROL PLACED. AT THAT TIME, SHE DECIDED TWO AND HEALTHY CHILDREN WERE ENOUGH. SHE STARTED DEVELOPING HEALTH PROBLEMS ALMOST IMMEDIATELY, SUCH AS: HAIR LOSS, SEVER PELVIC PAIN, MENORRHAGIA, ANEMIA, HEADACHES, MIGRAINES, MEMORY PROBLEMS, JOINT PAIN, BACK PAIN, MOOD SWINGS, DISCHARGE, RANDOM SEVER SHARP LIKE STABBING PAIN OVER OVARIES, DENTAL PROBLEMS (DECALCIFICATION OF TEETH) AND ELEVATED COPPER LEVELS. AFTER YEARS OF PROBLEMS, SHE DID LABORATORY WORK AND ULTRASOUNDS AND WAS TOLD THE CAUSE OF THESE PROBLEMS WERE DUE TO THE ESSURE BIRTH CONTROL. IN JUL-2014, SHE WAS SUBMITTED TO A COMPLETE HYSTERECTOMY. A YEAR POST OPERATION MOST OF HER SYMPTOMS RESOLVED THEMSELVES. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCESSIVE PAINFUL BLEEDING (SEEN AS GENITAL BLEEDING AND PELVIC PAIN FEMALE). SHE WAS SUBMITTED TO A COMPLETE HYSTERECTOMY. THE EVENT WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER EXPERIENCED THIS EVENT SINCE ESSURE INSERTION. BASED ON ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01714	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1280, AWARENESS DATE 07-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER STATED SHE MISSED WORK ONE TO TWO WEEKS A MONTH BECAUSE OF EXCESSIVE BLEEDING, LARGE BLOOD CLOTS, HORRENDOUS CRAMPING, ABDOMINAL BLOATING, JOINT PAIN AND SWELLING, ITCHY RED HIVES, ANXIETY AND PANIC ATTACKS, MIGRAINE HEADACHES, ALL TO THE POINT OF MEDICATING HERSELF UNTIL SHE WAS UNABLE TO DRIVE, AND UNABLE TO PERFORM AT WORK. SHE ALSO STATED UP UNTIL (B)(6) 2011, SHE RARELY MISSED WORK FOR AN OCCASIONAL FLU VIRUS, SHE WAS VERY HEALTHY, NO ILLNESS OR DISEASE. FOLLOW-UP RECEIVED ON 28-OCT-2015 FROM CONSUMER WITH ADDITIONAL INFORMATION ON 04-NOV-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2105, FDA-2014-N-0736-2501). THIS CASE WAS UPGRADED TO INCIDENT. CONSUMER HAD COILS PLACED IN 2011 WITHOUT KNOWING IT CONTAINED NICKEL. SHE HAD MAJOR PROBLEMS WITH HEAVY PERIODS AND HUGE CLOTS DURING PERIODS THAT LAST BETWEEN 7-14 DAYS AFTER COILS WERE PLACED. THE CRAMPS SHE HAD WERE SO PAINFUL THAT NO PAIN MEDICATION WOULD HELP. SHE ALSO ACCRUED SOME ALLERGIES EVEN THOUGH 2 RASH SKIN TESTS AND A FULL BLOOD PANEL FOR ALLERGIES SHOWED SHE WAS ALLERGIC TO NOTHING. SHE HAD HYPOTHYROIDISM AND WOULD NEED TO TAKE MEDICATION FOR THE REST OF HER LIFE. SHE ALSO HAD SEVERE LOWER BACK AND PELVIC STABBING PAINS THAT FEEL LIKE HER INSIDES JUST WANTED

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TO COME OUT. ON MEDICAL RECORDS THE LOT NUMBER WAS MISSING. THE CONSUMER WAS TAKING THE FOLLOWING MEDICATION: AMOUR THYROID, XYZAL, QSYMIA, LUNESTA, LEVONORGESTREL WITH ETHINYLESTRADIOL (ALESSE 28), ULTRACET, TESTOSTERONE COMPOUND CREAM, PROGESTERONE COMPOUND CREAM AND ALPRAZOLAM. A MAJOR SURGERY TO HAVE ESSURE REMOVED WAS SCHEDULED FOR (B)(6) 2015. PTC INVESTIGATION RESULT WAS RECEIVED ON 22-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD EXCESSIVE BLEEDING, LARGE BLOOD CLOTS, AND HORRENDOUS CRAMPING/SO PAINFUL CRAMPS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. A SURGERY TO REMOVE ESSURE WAS SCHEDULED. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENTS NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01715	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM UNITED STATES WAS DERIVED FROM MEDICAL LITERATURE ON 28-OCT-2015, ARTICLE ENTITLED PELVIC PAIN ASSOCIATED WITH ESSURE PERFORATION. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED THE FOLLOWING: THE LEFT ESSURE DEVICE HAD TRANSVERSED THROUGH THE PROXIMAL FALLOPIAN TUBE, IRREGULAR MENSTRUAL CYCLES, PELVIC CRAMPING, AND RIGHT SIDED ABDOMINAL PAIN. CASE REPORT: A (B)(6) G2P2 FEMALE PRESENTED COMPLAINING OF NEW IRREGULAR MENSTRUAL CYCLES, PELVIC CRAMPING, AND RIGHT SIDED ABDOMINAL PAIN FOLLOWING LAPAROSCOPIC ESSURE PLACEMENT THREE YEARS PRIOR. AT THE TIME OF THE PLACEMENT, NO COILS WERE SEEN WITHIN THE ENDOMETRIUM ON HYSTEROSCOPY. A FOLLOW-UP HYSTEROSALPINGOGRAM WAS NOT PERFORMED. WORK-UP INCLUDED A PLAIN FILM OF THE PELVIS SHOWING TWO ESSURE DEVICES WITHIN THE PELVIS, NORMAL IN APPEARANCE. THE PATIENT WAS TAKEN FOR DIAGNOSTIC LAPAROSCOPY AND REMOVAL OF THE ESSURE DEVICES ALONG WITH BILATERAL SALPINGECTOMY FOR CONTRACEPTION. THE LEFT ESSURE DEVICE HAD TRANSVERSED THROUGH THE PROXIMAL FALLOPIAN TUBE WAS ADHERENT TO THE OMENTUM ON TENSION WITH THE HEPATIC FLEXURE. THE ESSURE COILS AND FALLOPIAN TUBES WERE REMOVED WITHOUT DIFFICULTY. AT SIX WEEKS POSTOPERATIVELY, HER ABDOMINAL AND MENSTRUAL SYMPTOMS HAD LARGELY RESOLVED. AUTHORS COMMENT: IMAGING TO DEMONSTRATE ESSURE LOCATION MAY BE MISLEADING. LAPAROSCOPIC ESSURE REMOVAL IS A SAFE, EFFECTIVE TREATMENT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED NON-SERIOUS EVENTS. A FOLLOW-UP HYSTEROSALPINGOGRAM WAS NOT PERFORMED (TREATMENT NONCOMPLIANCE). SHE WAS TAKEN FOR DIAGNOSTIC LAPAROSCOPY AND REMOVAL OF THE ESSURE DEVICES ALONG WITH

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BILATERAL SALPINGECTOMY. IT WAS REPORTED THAT THE LEFT ESSURE DEVICE HAD TRANSVERSED THROUGH THE PROXIMAL FALLOPIAN TUBE. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF FALLOPIAN TUBE PERFORATION WERE NOT KNOWN. CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 10-JAN-2016 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01716	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 28-OCT-2015 , ARTICLE ENTITLED "COMPARISON OF HYSTEROSCOPIC TUBAL OCCLUSION BY MICROINSERT PLACEMENT AND LAPAROSCOPIC TUBAL OCCLUSION OR SALPINGECTOMY IN THE MANAGEMENT OF HYDROSALPINGES PRIOR TO IVF" [OFF-LABEL USE]. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED DISTAL MIGRATION OF ESSURE COIL. THIS PATIENT WAS INVOLVED IN A NON-BAYER RETROSPECTIVE COHORT STUDY TO COMPARE IN-VITRO FERTILIZATION (IVF) OUTCOMES AFTER MANAGEMENT OF HYDROSALPINGES BY HYSTEROSCOPIC MICRO-INSERT (ESSURE OR ADIANA) PROXIMAL TUBAL OCCLUSION OR LAPAROSCOPIC TUBAL OCCLUSION OR SALPINGECTOMY PRIOR TO IVF. IT WAS CONFIRMED THAT SHE RECEIVED ESSURE IN THE STUDY. THE PATIENT UNDERWENT LAPAROSCOPIC ADHESIOLYSIS, LEFT OVARIAN CYSTECTOMY, SALPINGECTOMY, AND REMOVAL OF ESSURE COIL . NO FURTHER INFORMATION ON MEDICAL HISTORY, CONCOMITANT MEDICATIONS, CLINICAL COURSE, OR OUTCOME WERE PROVIDED. AUTHORS' COMMENTS: THERE WERE THREE MAJOR COMPLICATIONS, TUBO-OVARIAN ABSCESS, POST TUBAL SYNDROME AND DISTAL MIGRATION OF COIL [PRESENT CASE] IN HYSTEROSCOPIC GROUP AND TWO CASES OF ECTOPIC PREGNANCY IN LAPAROSCOPIC GROUP. PREGNANCY OUTCOMES AFTER HYSTEROSCOPIC PLACEMENT OF MICROINSERT FOR HYDROSALPINX MANAGEMENT PRIOR TO IVF WERE COMPARABLE TO THOSE FOLLOWING LAPAROSCOPIC TUBAL OCCLUSION OR SALPINGECTOMY. COMPLICATIONS WERE UNCOMMON AND OCCUR WITH BOTH APPROACHES. COMPANY CAUSALITY COMMENT: THIS CASE REPORT DERIVED FROM MEDICAL LITERATURE REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR MANAGEMENT OF HYDROSALPINGES PRIOR TO IVF (INTERPRETED AS IN VITRO FERTILIZATION) (WHICH IS AN OFF LABEL USE). IT WAS

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REPORTED THAT DISTAL MIGRATION OF ESSURE COIL. A SALPINGECTOMY AND REMOVAL OF ESSURE COIL WERE PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF MIGRATION WERE NOT KNOWN. HOWEVER, CONSIDERING ITS NATURE A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 10-JAN-2016 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01717	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2106, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. SHE DIDN'T EXPERIENCE PROBLEMS RIGHT AWAY. SHE NOW HAS MANY AILMENTS CAUSED BY THIS ESSURE. SOME BUT NOT ALL OF HER SYMPTOMS INCLUDE: HEAVY IRREGULAR PERIODS, CHRONIC FATIGUE, HAIR LOSS, WEIGHT GAIN, ANXIETY, PANIC ATTACKS, HEART PALPITATIONS, CHRONIC ABDOMINAL PAIN, VERTIGO AND MIGRAINES. HER SURGERY TO HAVE ESSURE AND FALLOPIAN TUBES REMOVED IS SCHEDULED FOR (B)(6) 2015. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 18-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS

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NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN. HER SURGERY TO HAVE ESSURE AND FALLOPIAN TUBES REMOVED HAD BEEN SCHEDULED. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, THE CONSUMER HAD BEEN EXPERIENCING ABDOMINAL PAIN AND OTHER NON-SERIOUS EVENTS. CONSIDERING EVENT'S NATURE AND APPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01718	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN (B)(6) 2015 (CASE FDA-2014-N-0736-2255, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER REPORTED FOR OVER YEAR SHE SUFFERED FROM TERRIBLE PAIN AND AT TIMES COULD NOT WALK, ALONG WITH SWELLING, MIGRAINES, AND WAS EVEN AT ONE POINT A PHYSICIAN THOUGHT IT MIGHT BE BEST TO TEST FOR MS (MULTIPLE SCLEROSIS). IN (B)(6) 2013, AFTER MEETING WITH ANOTHER GYNECOLOGIST AND GOING THROUGH PHYSIOTHERAPY WITH NO IMPROVEMENT, ESSURE WAS REMOVED BY HYSTERECTOMY. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 18-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS

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NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED FOR OVER A YEAR A TERRIBLE PAIN AND AT TIMES COULD NOT WALK. ESSURE WAS THEN REMOVED BY HYSTERECTOMY. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE SUGGESTIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01719	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2274, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. CONSUMER HAD ESSURE INSERTED AND EXPERIENCED MANY ISSUES: ABDOMINAL PAIN, BLOATING, HEART ISSUES, SEIZURES, NICKEL ALLERGY, JOINT PAIN, FATIGUE, BLEEDING. ESSURE WAS REMOVED IN (B)(6) 2013. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 18-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN AND BLEEDING. ESSURE WAS REMOVED ONE YEAR AFTER INSERTION. THESE EVENTS, SEEN AS ABDOMINAL PAIN AND GENITAL BLEEDING ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING ABDOMINAL PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND THEIR IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE ESSURE REMOVAL WAS REQUIRED THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENTS WERE ALSO INFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01720	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2105, AWARENESS DATE 28-OCT-2015) WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED HER PHYSICIANS NURSE TOLD HER THEY HAD ONLY ONE PATIENT COMPLAIN OF PAIN AND 6 MONTHS AFTER HER HYSTERECTOMY SHE CALLED AND SAID SHE STILL HAD THE SAME PROBLEM. PTC INVESTIGATIONAL RESULT WAS RECEIVED ON 19-NOV-2015. PTC GLOBAL NUMBER: (B)(4).FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT:THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN, CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE HAD A

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HYSTERECTOMY AND, 6 MONTHS AFTER THAT, SHE STILL HAD PAIN. IF AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, IT WAS REPORTED PAIN AND HYSTERECTOMY, WITHOUT FURTHER SPECIFICATION. SIX MONTHS AFTER HYSTERECTOMY SHE STILL HAD PAIN (DECHALLENGE CONSIDERED NEGATIVE). ALTHOUGH LIMITED INFORMATION WAS PROVIDED, IT CANNOT BE EXCLUDED THAT THIS SURGERY OCCURRED AS A CONSEQUENCE OF ESSURE. THEREFORE THIS CASE WAS REGARDED AS INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01721	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2284, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. THE CONSUMER REPORTED THAT SINCE IMPLANTATION OF ESSURE SHE EXPERIENCED DIZZINESS (TO THE POINT OF NEEDING ASSISTANCE TO WALK), SHORTNESS OF BREATH, EXTREME PELVIC PAIN, IRREGULAR PERIODS, AUTOIMMUNE DISEASE, WEAKNESS IN ARMS AND LEGS (MAKING IT DIFFICULT TO WALK UP OR DOWN STAIRS), HEADACHES (SOMETIMES LASTING FOR DAYS AT A TIME), MEMORY ISSUES, HAIR LOSS, PAIN WITH SEX, SKIN RASH AND TINGLING IN FINGERS. SHE SUFFERED FOR CLOSE TO A YEAR BECAUSE OF ESSURE AND IN (B)(6) 2015 SHE HAD A HYSTERECTOMY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RECEIVED ON 19-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT

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APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THEN HAD EXTREME PELVIC PAIN AND AUTOIMMUNE DISEASE. SHE UNDERWENT A HYSTERECTOMY 9 MONTHS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENT IS UNLISTED. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE EVENT EXTREME PELVIC PAIN AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. EVENT AUTOIMMUNE DISEASE WAS ASSESSED AS UNRELATED TO ESSURE, GIVEN ITS PATHOPHYSIOLOGY AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01722	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/8/2010
Explant Date (E7): 1/28/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN UNITED STATES ON 27-OCT-2015. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 17-NOV-2015. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. THE CONSUMER REPORTED THAT AFTER SHE GOT THE IMPLANT, SHE NOTICED A LOT OF WEIGHT GAIN, A STRANGE METALLIC TASTE IN MOUTH AND ODD PAINFUL PERIODS. SHE MENTIONED THIS TO HER DOCTOR WHO STATED IT WAS NOT RELATED THE IMPLANT. IN 2014, THE CONSUMER FOUND OUT SHE WAS PREGNANT AND THAT IT WAS ECTOPIC. SHE WANTED TO WAIT, BUT UNDER ADVICE OF HER NEW DOCTOR, ON (B)(6) 2014 SHE UNDERWENT A SURGERY. ACCORDING TO HER DOCTOR AND THE PATHOLOGY PAPERS, HER PREGNANCY HAD RUPTURED AND BOTH HER TUBES HAD TO BE REMOVED. SHE WAS DEPRESSED ABOUT THAT AND HAD LOST MOST INTIMACY FEELING BECAUSE OF DEPRESSION. SHE WAS NOT SURE IF THE COILS WERE STILL IN HER BODY OR NOT, AND SHE WAS AFRAID THEY HAD MIGRATED SOMEWHERE THE COMPUTERIZED TOMOGRAPHY COULD NOT FIND. THE TERM LIFE-THREATENING, HOSPITALIZATION, REQUIRED INTERVENTION AND IMPORTANT MEDICAL EVENT WERE REPORTED AS EVENT OUTCOME. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) A LACK OF EFFICACY ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) OR LACK OF EFFICACY AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FOUND OUT SHE WAS PREGNANT AND THAT IT WAS ECTOPIC. HER PREGNANCY HAD RUPTURED AND BOTH HER TUBES HAD TO BE REMOVED. THESE EVENTS ARE SERIOUS (THE TERM LIFE-THREATENING, HOSPITALIZATION AND IMPORTANT MEDICAL EVENT WERE ONLY MENTIONED AS EVENT OUTCOME AND THE REPORTER DID NOT SPECIFY IT) AND LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. BASED ON THE NATURE OF THE EVENTS AND CONSIDERING THAT CONSUMER GOT PREGNANT 4 YEARS AFTER ESSURE INSERTION, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) OR LACK OF EFFICACY AND QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 04-JAN-2016: FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. FOLLOW-UP INFORMATION WAS RECEIVED ON 18-JAN-2016. CONSUMER'S DATE OF BIRTH WAS PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE CONSUMER. COMPANY CAUSALITY COMME

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01723	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2126, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205)(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2005. THE CONSUMER REPORTED AFTER RECEIVING ESSURE (ON AN OPERATING TABLE UNDER GENERAL ANESTHESIA) SHE EXPERIENCED INTENSE STABBING PAINS ABOUT THREE TIMES A YEAR ENDING UP IN THE ER FOR PAIN A HANDFUL OF TIMES. IT WAS LIVABLE UNTIL (B)(6) 2012. SHE STATED THE SHARP STABBING PAINS STARTED TAKING OVER HER LIFE, AND DOCTORS COULD NOT DIAGNOSE AND SHE WAS LIVING IN A FOG DUE TO PAINKILLERS. SHE HAD TO TIME TAKING THEM SO SHE COULD PICK HER CHILDREN UP FROM SCHOOL. AFTER 5 MONTHS OF BEING POKED, PRODDED, INVADED, INJECTED AND SCANNED, A DIFFERENT GYNECOLOGIST AGREED TO DO EXPLORATORY SURGERY TO FIND OUT WHAT WAS WRONG. ONE ESSURE COIL HAD MIGRATED AND LODGED ON THE BACK OF HER UTERUS, EVERY TIME SHE MOVED IT POKED INTO HER ABDOMINAL CAVITY CAUSING INTENSE STABBING PAIN AND CREATING MASSIVE SCARRING. SHE HAD INSTANT PAIN RELIEF. OTHER SYMPTOMS SHE EXPERIENCED INCLUDED: MIGRAINES (STARTING IN 2006) AND MIXED CONNECTIVE TISSUE DISEASE (AN AUTOIMMUNE DISEASE CAUSING ARTHRITIS AND LUPUS LIKE SYMPTOMS) DIAGNOSED IN 2006. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY

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DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE ESSURE COIL HAD MIGRATED AND LODGED ON THE BACK OF HER UTERUS. SHE UNDERWENT AN EXPLORATORY SURGERY. CONSUMER ALSO REPORTED A MIXED CONNECTIVE TISSUE DISEASE. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. EVENT ESSURE COIL HAD MIGRATED AND LODGED ON THE BACK OF HER UTERUS IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENT IS UNLISTED. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THE PRESENT CASE, CONSUMER WAS HAVING PAIN, SHE UNDERWENT AN EXPLORATORY SURGERY, AND IT WAS FOUND OUT THAT ONE ESSURE COIL HAD MIGRATED AND LODGED ON THE BACK OF HER UTERUS. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. EVENT MIXED CONNECTIVE TISSUE DISEASE WAS ASSESSED AS UNRELATED TO ESSURE, GIVEN ITS NATURE AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01724	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/10/2010
Explant Date (E7): 1/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2087, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. ON (B)(6) 2010, SHE BECAME DIZZY AND LIGHTHEADED, LOST HER BALANCE AND FELL, SHATTERING HER RIGHT ELBOW. SHE STATED THAT WAS ONLY THE BEGINNING OF MORE FEELING LIKE THAT AND FALLING. SHE BEGAN NOT FEELING WELL EVERY DAY, WAS ALWAYS NAUSEOUS AND FELT LIKE SHE COULD NOT EAT. WHEN SHE DID ATE, OFTEN SHE COULD NOT HOLD IT DOWN. SHE HAD LONGER, HEAVIER PERIODS, SEVERE FATIGUE, NO ENERGY, PHANTOM PAINS IN HER SIDES, LEGS, BACK AND JOINTS. SHE STARTED HAVING MUSCLE SPASMS THAT SEVERELY MADE HER IN CONSTANT PAIN. SHE BECAME SEVERELY DEPRESSED, SUFFERED INCREASED ANXIETY, WOULD HAVE SEVERE MOOD SWINGS AND BECAME SUICIDAL LITERALLY OVERNIGHT. SHE STATED THAT GOING TO THE GROCERY STORE WAS HARD BECAUSE SHE WOULD GET SO ANXIOUS THAT SHE WOULD GO INTO PANIC MODES. SHE RARELY TALKED TO ANYONE, STOPPED TALKING TO HER FRIENDS AND WAS IN TOTAL ISOLATION. ON (B)(6) 2015, THE CONSUMER UNDERWENT A HYSTERECTOMY AND BEGAN TO FEEL BETTER RIGHT AWAY. SHE STATED SHE WAS STILL SUFFERING FROM HAVING THOSE COILS IN HER BODY FOR SO LONG AND THAT ESSURE TOOK SO MUCH OF HER LIFE WAS SHE WAS STILL TRYING TO RECOVER FROM ITS RAMIFICATIONS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR

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CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD LONGER AND HEAVIER PERIODS, AND WAS SEVERELY DEPRESSED, BECAME SUICIDAL LITERALLY OVERNIGHT. SHE UNDERWENT A HYSTERECTOMY APPROXIMATELY 4 AND A HALF YEARS AFTER ESSURE INSERTION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. LONGER AND HEAVIER PERIODS IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENT IS UNLISTED. AFTER ESSURE INSERTION, MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE EVENT LONGER AND HEAVIER PERIODS, AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. DEPRESSION IS A HIGHLY PREVALENT DISORDER AND ITS PATHOGENESIS INVOLVES GENETIC, SOCIAL AND PSYCHOLOGIC FACTORS. CONSIDERING THE PATHOPHYSIOLOGY OF THE EVENT SEVERELY DEPRESSED, BECAME SUICIDAL LITERALLY OVERNIGHT, AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, THIS EVENT WAS ASSESSED AS UNRELATED TO ESSURE. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01725	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2118, AWARENESS DATE 28-OCT-2015) WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (B)(6) 2011. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 18-NOV-2015. SHE WAS NOT AWARE THAT ESSURE WAS A METAL OR SHE NEVER WOULD HAVE GOTTEN IT BECAUSE SHE IS VERY SENSITIVE TO METAL IN HER EARS. SHE HAD TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6) WHICH CONSISTED OF 2 SURGERIES WITHIN 2 WEEKS OF EACH OTHER, SHE KNOWS FOR A FACT THAT SHE HAD PROBLEMS WITH ESSURE BECAUSE FOR THE ENTIRE TIME SHE HAD ESSURE SHE COULD TASTE METAL IN HER MOUTH LIKE SHE WAS CHEWING ON ALUMINUM FOIL ALL OF THE TIME. SHE STATED THAT WAS ONE OF MANY SIDE EFFECTS SHE EXPERIENCED. SHE REPORTED THE PLACEMENT OF ESSURE WAS ONE OF THE MOST PAINFUL THINGS SHE EXPERIENCED IN HER LIFE. THE CONSUMER STATED IT MADE HER PHYSICALLY SICK FOR 2 YEARS; SHE HAS NOT TASTED METAL SINCE HAVING IT REMOVED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE.

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MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD TO HAVE A HYSTERECTOMY. THE REPORTED EVENT WAS CONSIDERED SERIOUS, DUE TO MEDICAL IMPORTANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED. SINCE CONSUMER REGARDED THE EVENTS AS A CONSEQUENCE OF ESSURE USE AND NO FOLLOW-UP WILL BE POSSIBLE; COMPANY CONSIDERS A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE THERAPY CANNOT BE EXCLUDED AND DUE TO THE SURGICAL INTERVENTION THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01726	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2013
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2157 AND FDA-2014-N-0736-2349, AWARENESS DATE 28-OCT-2015 AND 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. ADDITIONAL INFORMATION RECEIVED ON 18-NOV-2015. CONSUMER STATED AT HER FOLLOW UP X-RAY (HYSTEROSALPINGOGRAM) THREE MONTHS LATER ESSURE INSERTION PROCEDURE, IT WAS DISCOVERED THAT ONE OF THE ESSURE COILS HAD MIGRATED OUT OF HER TUBE AND EMBEDDED IN THE MUSCLE TISSUE OF HER UTERINE WALL. SHORTLY THEREAFTER, SHE BEGAN EXPERIENCING FREQUENT PELVIC PAIN WHICH BY (B)(6) 2014 HAD BECOME SEVERE AND CHRONIC. SHE ULTIMATELY HAD TO UNDERGO A HYSTERECTOMY AND BILATERAL SALPINGECTOMY IN (B)(6) 2015, AT THE AGE OF (B)(6). PRIOR TO RECEIVING ESSURE, SHE WAS A HEALTHY YOUNG WOMAN WITH NO PRIOR GYNECOLOGICAL OR OTHER HEALTH ISSUES. DURING THE 16 MONTHS ESSURE WAS INSIDE HER BODY, SHE SUFFERED FROM 3 SEPARATE OUTBREAKS OF SHINGLES AND NOW EXPERIENCE LONG TERM NERVE PAIN AS A RESULT. SHE HAD NEVER EXPERIENCED SHINGLES PRIOR TO RECEIVING ESSURE, AND HAS NOT HAD AN OUTBREAK SINCE HAVING ESSURE REMOVED. IT WAS HER BELIEF THAT THE INTENTIONAL, CHRONIC INFLAMMATION CAUSED BY THE ESSURE COILS PUT HER IN AN IMMUNO-COMPROMISED STATE, RESULTING IN THE MULTIPLE SHINGLES OUTBREAKS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 18-NOV-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT

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AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER 3-MONTH HYSTEROSALPINGOGRAM REVEALED ONE OF THE ESSURE COILS HAD MIGRATED OUT OF HER TUBE AND WAS EMBEDDED IN THE MUSCLE TISSUE OF HER UTERINE WALL. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH BILATERAL SALPINGECTOMY (APPROXIMATELY 1.5 YEARS AFTER DEVICE INSERTION). THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY), DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) OR OCCUR AS A RESULT OF A UTERINE PERFORATION DURING INSERTION. IN THIS CASE, CONSIDERING EVENTS NATURE AND ITS POSITIVE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY AND SALPINGECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01727	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2007
Explant Date (E7): 10/2/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2201, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2007. THE CONSUMER GAVE BIRTH TO HER FOURTH CHILD IN (B)(6) 2006. SHE REPORTED THAT THE PAIN FROM ESSURE COILS BEING IMPLANTED FELT AS IF SHE WAS GIVING BIRTH AGAIN, THE CRAMPS AND SPASMS WERE EXCRUCIATING. SHE ASKED THE DOCTOR TO STOP BUT WAS INFORMED THAT HE COULD NOT AS THE IMPLANT WAS ONLY IN HALFWAY. SHE WAS NOT OFFERED ANYTHING FOR THE PAIN OR CRAMPS, WHICH CONTINUED FOR THE NEXT 2 DAYS. SHE MISSED 2 DAYS OF WORK BEFORE THE PAIN AND CRAMPING REDUCED TO A MORE TOLERABLE LEVEL. SHE WAS NOT TOLD SHE WAS TO COME BACK IN 3 MONTHS TO HAVE THE COILS CHECKED FOR PROPER PLACEMENT. AFTER APPROXIMATELY 3 MONTHS, SHE STARTED EXPERIENCING PAIN IN LOWER BACK AND PELVIC AREA. THE PAIN CONTINUED TO GET WORSE AND HER PELVIC AREA FELT AS IF SHE WAS BEING STABBED EVERY SECOND OF EVERY DAY. SHE CONTACTED HER GYNECOLOGIST WHO PROVIDED HER BIRTH CONTROL PILLS TO TAKE EVERY DAY, WHICH THEN CAUSED CONTINUOUS MENSTRUAL CYCLE FOR 3 MONTHS NON-STOP. APPROXIMATELY 4 MONTHS AFTER THE IMPLANTS, SHE STARTED TO EXPERIENCE MORE PAIN IN LOWER BACK AND PELVIC AREA, ALONG WITH WEAKNESS AND NUMBNESS IN LEFT LEG. SHE STATED THAT APPROXIMATELY 10 DIFFERENT DOCTORS TRIED TO DISCOVER THE REASON FOR HER PAIN. SHE HAD NUMEROUS MAGNETIC RESONANCE IMAGING EXAMS, COMPUTERIZED TOMOGRAMS AND X-RAYS, PRESCRIPTION MEDICATION AND MULTIPLE SURGERIES IN A 9 YEAR TIME FRAME IN THE ATTEMPT TO EASE THE PAIN. SHE WENT FROM (B)(6) WITH NO CHANGE IN DIET OR EXERCISE. IT BECAME HARDER

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TO WALK, TO SIT, TO SPEND TIME HIKING OR ENJOYING TIME OUTSIDE. IN (B)(6) 2015, SHE WAS AT THE POINT WHERE SHE WAS IN SERIOUS PAIN ALL DAY EVERY DAY, DEPENDING ON PRESCRIPTION MEDICATION TO SOMEWHAT FUNCTION. SHE WAS HAVING SEVERE CRAMPS DURING HER MENSTRUAL CYCLE WITH CLOTS, STABBING PAIN IN PELVIC AREA, NUMBNESS IN LEG, MIGRAINES, BLOATING, WEIGHT GAIN, FATIGUE AND OVARIAN CYSTS THAT WERE DESCRIBED AS GOLF BALL SIZE. THE CONSUMER WENT TO ANOTHER GYNECOLOGIST WHO SCHEDULED A SURGERY TO (B)(6) 2015. ON THE DATE OF THE SURGERY HER WEIGHT WAS (B)(6) AND 4 DAYS AFTER IT WAS DOWN TO (B)(6) WITH LITTLE TO NO ACTIVITY. TWO WEEKS POST-SURGERY, THE STABBING PAIN IN PELVIC AREA HAD DISAPPEARED AND THE PAIN HER BACK HAD SLIGHTLY DISSIPATED. SHE WAS FEELING BETTER AND LOOKED BETTER. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 19-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED PAIN ALL EVERY DAY (STABBING PAIN IN PELVIC AREA). THEN, SHE UNDERWENT A SURGERY (NOT SPECIFIED). THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01728	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (B)(6) 2011. THE LEFT SIDE WAS PLACED CORRECTLY. THE RIGHT SIDE WHEN DEPLOYED, PLACED THE COIL IN FALLOPIAN TUBE WHILE THE STRAIGHT PART OF THE ESSURE DEVICE (WHICH WAS SUPPOSED TO REMAIN INTACT WITH THE COIL) PUNCTURED THROUGH HER FALLOPIAN TUBE AND TRAVELLED SOMEWHERE CLOSE TO HER PELVIS. THIS WAS NOTED IN HER POST ESSURE HYSTEROSALPINGOGRAM BY HER DOCTOR AS SOMEWHERE IN THE PERITONEUM. SHE HAD IRREGULAR, STABBING PAIN IN HER RIGHT PELVIC REGION RELATED TO CHANGES IN HER POSTURE (SITTING, STANDING, BENDING OVER, STOOPING DOWN AND SO ON) FOR FOUR YEARS. HER IMPLANTING DOCTOR REFUSED TO BELIEVE THAT ESSURE WAS THE CAUSE OF PAIN. IN ADDITION TO THE PELVIC PAIN, SHE HAD MIGRAINES AND HEAVY BLEEDING DURING MENSES, NONE OF WHICH SHE HAD BEFORE ESSURE. SHE HAD A SECOND HYSTEROSALPINGOGRAM, FOUR YEARS AFTER HER FIRST HSG AND COULD DOCUMENT THE MIGRATION OF THE MISPLACED ESSURE COIL. THE COIL WAS IN THE FALLOPIAN TUBE AND HAS OCCLUDED THE TUBE. THE MARKER FROM THE COIL HAS DETACHED FROM THE COIL AND WAS ABOUT AT THE 9 O'CLOCK POSITION IN RELATION TO THE UTERUS AND PELVIS. IN THE 2015, THE SAME TEST SHOWED THE MIGRATION OF THE MARKER TO ABOUT THE 8 O'CLOCK POSITION IN RELATION TO THE UTERUS AND PELVIS. SHE FELT LIKE SOMEONE STABBING HER WITH A KNIFE AT RANDOM TIMES, ESPECIALLY WHEN SHE CHANGE POSITION (SITTING TO STANDING, BENDING OVER, STOOPING DOWN). PRIOR TO ESSURE PLACEMENT, SHE WAS A HEALTHY, PRODUCTIVE PERSON. SINCE ESSURE PLACEMENT HER

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HEALTH HAS DETERIORATED AND SHE HAD HEMATURIA (BLOOD IN THE URINE) AND CYSTS GROWING ON HER LIVER. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHEN DEPLOYED, THE STRAIGHT PART OF THE ESSURE (WHICH WAS SUPPOSED TO REMAIN INTACT WITH THE COIL) PUNCTURED THROUGH HER FALLOPIAN TUBE AND TRAVELLED SOMEWHERE CLOSE TO PELVIS. HYSTEROSALPINGOGRAM SHOWED THE MIGRATION OF THE MISPLACED ESSURE COIL AND THE MARKER FROM THE COIL DETACHED FROM THE COIL. THESE EVENTS WERE INTERPRETED AS DEVICE BREAKAGE AND FALLOPIAN TUBE PERFORATION DURING INSERTION. FALLOPIAN TUBE PERFORATION IS A SERIOUS EVENT DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE. ALSO, DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, THE DEVICE BREAKAGE AND FALLOPIAN TUBE PERFORATION SEEM TO HAVE OCCURRED DURING THE ESSURE INSERTION PROCEDURE, THEREFORE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 30-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL TH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01729	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/31/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2211, AWARENESS DATE 29-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. AFTER THE ESSURE PROCEDURE, CONSUMER WENT IN THREE MONTHS LATER, TO MAKE SURE HER TUBES WERE BLOCKED. THEY SAID SHE WAS GOOD TO GO. THREE MONTHS LATER, SHE STARTED HAVING HER PERIODS EVERY OTHER WEEK AND VERY HEAVY. SHE FEELS EXTREMELY GROGGY WITH FOGGY BRAIN, BLOATING, HEADACHES, NAUSEA, SHAKING IN LEFT HAND, ON A DAILY BASIS. IN (B)(6) 2015, CONSUMER HAD A WHOLE MONTH OF HEAVY BLEEDING, WHICH CAUSED HER TO GO IN TO THE EMERGENCY ROOM. THEY GAVE HER PAIN PILLS. SHE WENT INTO HER GYNECOLOGIST AND THEY SET UP A D&C (DILATATION AND CURETTAGE) AND ABLATION TO HELP WITH HER BLEEDING. SHE DOES NOT WANT TO GO THROUGH ANY MORE PROCEDURES, BUT IT WAS LOOKING LIKE HER ESSURE IMPLANTS WOULD HAVE TO BE REMOVED, SINCE SHE WAS STILL NOT FEELING ANY BETTER. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 19-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE.

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MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED A WHOLE MONTH OF HEAVY BLEEDING. SHE HAD TO HAVE A D&C (DILATATION AND CURETTAGE) AND ABLATION TO HELP WITH HER BLEEDING. THIS EVENT, SEEN A GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND THE IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS PERFORMED AS A TREATMENT MEASURE TO THE REPORTED EVENT (ABLATION), THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01730	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2012. IT DESCRIBES THE OCCURRENCE OF BECOME PREGNANT BEFORE HSG CONFIRMATION TEST, DEVICE INEFFECTIVE, AND MISCARRIAGE IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. NO INFORMATION GIVEN ON CONSUMER'S HISTORY, PAST DRUGS AND CONCURRENT CONDITIONS. IT IS UNKNOWN WHETHER THE CONSUMER RECEIVED ANY CONCOMITANT MEDICATION. ON AN UNSPECIFIED DATE THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AT UNK. IT WAS UNKNOWN WHETHER ESSURE WAS USED PREVIOUSLY. CONSUMER BECAME PREGNANT BEFORE SHE HAD THE HSG CONFIRMATION TEST AND MISCARRIED. SHE THEN WENT TO PHYSICIAN WHO PERFORMED THE HSG CONFIRMING THAT BOTH OF HER TUBES WERE INDEED BLOCKED. TWO YEARS HAVE NOW PASSED AND SHE IS SOMEHOW PREGNANT WITH AN INTER UTERINE PREGNANCY. SHE HAD AN ULTRASOUND CONFIRMING ON (B)(6) 2012 BUT THE TECH WAS UNABLE TO FIND ANY SIGN OF THE COILS IN HER TUBES VIA ULTRASOUND. SHE INFORMED CONSUMER THAT THEY SHOWED AS A BRIGHT WHITE LINE. SHE DID SEE ONE LINE WHICH SHE HINTED HAD FLUID SURROUNDING IT FROM IRRITATION IN CONSUMER'A CERVIX. CONSUMER WAS WORRIED ABOUT HER UNBORN BABY AS COILS MAY JUST BE FLOATING AROUND ENDANGERING HER. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN BECOME PREGNANT BEFORE HSG CONFIRMATION TEST, DEVICE INEFFECTIVE, AND MISCARRIAGE AND ESSURE IS NOT REPORTED. ADDENDUM: THIS CASE WAS CONVERTED FROM THE CONCEPTUS DATABASE INTO (B)(4) 2013. THE MEDICAL CONTENT OF THE CASE WAS NOT CHANGED. FOLLOW-UP INFORMATION RECEIVED ON 29-OCT-2015. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE FOR ESSURE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK

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PLACE IN SEP-2015 (B)(4). ESSURE WAS INSERTED IN 2010. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MISCARRIAGE. THIS INCIDENT CASE IS NOT MEDICALLY CONFIRMED. THIS EVENT IS CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THE PROVIDED INFORMATION, A CAUSAL RELATIONSHIP BETWEEN ESSURE USE AND THE SERIOUS EVENT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED: PREGNANCY AND DEVICE INEFFECTIVE. FURTHER INFORMATION IS NOT EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 03-DEC-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01731	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2014
Explant Date (E7): 8/31/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5043894) IN UNITED STATES ON 10-AUG-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON 2014. CONSUMER REPORTED THAT SINCE ESSURE WAS PUT IN, SHE HAS HAD SEVERE CRAMPING, HEAVY IRREGULAR BLEEDING AND DOUBLE CYCLES. SHE HAS HAD CONSTANT MIGRAINES SINCE 2015 AND SHE HAS BLOATING IN HER ABDOMEN AREA THAT MAKE HER LOOK PREGNANT (NOT PREGNANT). SHE HAS ENDOMETRIOSIS AND OVARIAN CYSTS, AND IN HER OPINION AND FEELING, IT HAS BECOME MUCH WORSE. SHE CANNOT SLEEP LIKE NORMAL, OR WAKE UP RESTED. THIS HAS BEEN HAPPENING FOR 8 MONTHS (UNSPECIFIED DATE). AS CONCOMITANT MEDICATION, CONSUMER USES TYLENOL. FOLLOW UP 06-AUG-2015: THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS IN FDA HOSTED DOCKET WEBSITE (#FDA-2014-N-0736-0349), WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS FOLLOW-UP INFORMATION WAS RECEIVED PREVIOUSLY FROM THE CONSUMER ON 06-AUG-2015: CONSUMER REPORTED THAT SHE WAS (B)(6) AND WAS MOTHER OF 3. SHE REPORTED THAT 5 MONTHS AFTER IMPLANTING SHE HAD BLOATING (LOOKING LIKE SHE WAS 5/6 MONTHS PREGNANT), UPSET STOMACH, MIGRAINES EVERY DAY, HIP TROUBLE, PAINFUL INTERCOURSE, TERRIBLE CRAMPING, EXTREME FATIGUE AND EXTREMELY HEAVY BLEEDING WITH LARGE CLOTS AND TWO CYCLES A MONTH (2 CYCLES STARTED AROUND MARCH). SHE HAD A HARD TIME GETTING OUT OF BED BECAUSE THE CRAMPING WAS SO INTENSE IT HURT TO MOVE. SHE REPORTED THAT SHE WAS TIRED OF FEELING PREGNANT ALL OF THE TIME WHEN SHE WAS NOT. SHE INSERTED ESSURE FOR BIRTH CONTROL AND WAS LOOKING FOR TO GETTING HER TUBES REMOVED AND UNDERGOING SURGERY (WHICH SHE WANTED TO AVOID BECAUSE OF HER CHILDREN). SHE HAS NOT HAD ANY PROBLEMS UNTIL ESSURE. FOLLOW-UP

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RECEIVED ON 20-AUG-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT AND WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(6) AND THE LOCAL NUMBER IS (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENTS CONSIDERED RELATED ARE KNOWN POSSIBLE UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS AVAILABLE FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 28-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW UP INFORMATION RECEIVED ON 29-OCT-2015: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2182). CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED IN (B)(6) 2014. SHE HAD HELL ABOUT 3 MONTHS AFTER INSERTION UNTIL REMOVAL. FROM HORRIBLE BLEEDING DURING AND IN BETWEEN CYCLES, DEBILITATING HEADACHES AND CRAMPING TO THE POINT OF HAVING TROUBLE GETTING OUT OF BED. SHE HAD ESSURE REMOVED ON (B)(6) 2015 AND FELT BETTER. HER HEADACHES WERE ALMOST GONE, CRAMPING OUTSIDE OF NORMAL CYCLES CRAMPS GONE, HEAVY BLEEDING AND CLOTTING GONE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 17-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NOT MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THEN SHE HAS HAD HEAVY IRREGULAR BLEEDING WITH LARGE CLOTS. SHE HAD ESSURE REMOVED ONE YEAR AFTER INSERTION. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS UPGRADED TO INCIDENT, SINCE A DEVICE REMOVAL WAS REQUIRED. THE

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PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

INTERNAL CORRECTION ON 24-NOV-2015. DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE REPORTED FOLLOW-UP RECEIPT DATE 06-AUG-2015 IS INCORRECT. THE CORRECT FOLLOW-UP RECEIPT DATE OF THE CASE IS 09-AUG-2015

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01732	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE NUMBER FDA-2014-N-0736-2167, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. SHE GOT ESSURE PLACED IN 2008 ALMOST A YEAR AFTER THE BIRTH OF HER THIRD CHILD. SHE WANTED TO GET HER TUBES TIDED BUT HER GYNECOLOGIST INSISTED AND PUSHED ESSURE ON HER. ESSURE WAS IMPLANTED IN 2008 IN HOSPITAL, AS AN OUTPATIENT AND UNDER GENERAL ANESTHESIA. SHE RETURNED TO THE SAME HOSPITAL 3 MONTHS LATER FOR THE HSG (HYSTEROSALPINGOGRAM) TEST. HER TUBES WERE CONFIRMED TO BE 100 PERCENT OCCLUDED WITH CORRECT PLACEMENT. AFTER THE PROCEDURE SHE HAD HEAVY BLEEDING, CRAMPING AND HEADACHES BUT SHE WAS TOLD THOSE SIDE EFFECTS WOULD GO AWAY. THEY DID NOT AND THEY ONLY BECAME WORSE OVER TIME. SHE WAS DISMISSED BY HER GYNECOLOGISTS IT ALL BEING IN HER HEAD AND SHE WAS INSISTENT THAT ESSURE WAS NOT THE CAUSE, BUT NOTHING ELSE WAS WRONG WITH HER. SHE WAS HEALTHY BEFORE THE PROCEDURE. IN 2010, SHE BECAME PREGNANT WITH HER FOURTH CHILD (SHE DID HAVE THE HSG TEST AND CONFIRMED 100 PERCENT BLOCKED). SHE HAD A VERY STRESSFUL PREGNANCY AND GAINED A TON OF WEIGHT. AFTER HER FOURTH CHILD WAS BORN, SHE WENT BACK TO HER IMPLANTING DOCTOR AND ASKED TO HAVE ESSURE REMOVED. SHE SAID IT WAS TOO DANGEROUS BUT SHE WOULD DO A TUBAL TO MAKE SURE THAT SHE WOULD NOT GET PREGNANT AGAIN. SHE WANTED THE TUBAL TO BEGIN WITH, SO SHE HAD TO GO THROUGH ANOTHER SURGERY FOR BIRTH CONTROL. HER DOCTOR PERFORMED THE TUBAL AND TOLD HER THAT ONE OF HER COILS MIGRATED AND HAD LODGED ITSELF INTO HER UTERUS. SHE SAID SHE COULD NOT REMOVE

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THE COILS AS IT WOULD BE TOO DANGEROUS. SHE SAID THE COIL WOULD NOT BE ABLE TO MOVE SO SHE JUST LEFT IT THERE AND ONLY TIED ONE TUBE. SHE SAID THAT ESSURE WAS STILL PLACED CORRECTLY IN HER LEFT TUBE SO SHE JUST LEFT IT. OVER TIME HER SYMPTOMS BECAME WORSE. BESIDES HEAVY PAINFUL PERIODS WITH LARGE BLOOD CLOTS, AND PREGNANCY SHE HAD SEVERE DENTAL PROBLEMS AND PERIODONTAL DISEASE , SHE HAD TO HAVE HER GUMS SCRAPED. SHE HAD TO UNDERGO MANY PAINFUL PROCEDURES TO FIX HER GUMS AND TEETH. SHE HAS TO GO TO THE DENTIST EVERY 4 MONTHS TO GET HER TEETH CLEANED BECAUSE THE PROBLEMS ARE SO SEVERE. SHE HAS SUFFERED GERD (GASTROOESOPHAGEAL REFLUX DISEASE), DEPRESSION, HAIR LOSS, SKIN RASHES, SEVERE BLOATING AND PAIN DURING INTERCOURSE, INFECTIONS IN HER UTERUS, TEETH AND GUM PROBLEMS, ANXIETY PROBLEMS, VITAMIN D DEFICIENCY AND EXTREME TIREDNESS AND EXHAUSTION SO MUCH SO THAT SHE FELL AND BROKE HER SHOULDER AFTER GETTING UP FROM THE COUCH. SHE WOULD ALSO FALL ASLEEP WHILE DRIVING OR AT WORK. THE DOCTORS REMEDIES WERE VITAMINS, REST AND PAIN MEDICATION. SHE HAD A PAIN DOCTOR AND WENT THROUGH SEVERAL TESTS TO SEE WHAT THE PROBLEM WAS BUT HE COULD NOT FIND ANYTHING. ONE DAY IN (B)(6) 2014, SHE WAS IN SO MUCH PAIN THAT HER HUSBAND CALLED 911 AND AN AMBULANCE CAME TO THE HOUSE. SHE WAS HAVING SEVERE ABDOMINAL PAIN AND BLOATING, WHEN SHE ARRIVED AT THE HOSPITAL. SHE SAT IN THE EMERGENCY ROOM FOR WHAT SEEMED LIKE HOURS AND THEY FINALLY DID AN ULTRASOUND BUT THEY SAID IT LOOKED NORMAL. THEY TREATED HER LIKE A DRUG ADDICT AND GAVE HER A VICODIN AND TOLD HER TO FOLLOW UP WITH HER GYNECOLOGIST FOR A FULL EXAM. SHE FOLLOWED UP WITH HER GYNECOLOGIST AND THEY DID AN EXAM AND TOLD HER THAT SHE HAD AN INFECTION AND TOLD HER THAT IT WAS AN STD (SEXUALLY TRANSMITTED DISEASE). SHE IS MARRIED AND HAS 4 KIDS. SHE BROKE DOWN IN TEARS AND TOLD THEM THERE WAS NO WAY IT WAS AN STD. THEY TESTED HER AND FOUND THAT IT WAS NOT AND STD BUT A SEVERE PELVIC INFECTION. ESSURE HAS CAUSED SO MUCH HAVOC ON HER LIFE AND ON THE LIVES OF HER FAMILY. SHE OPTED FOR ESSURE BECAUSE SHE DID NOT WANT SURGERY BUT INSTEAD SHE HAS BEEN THROUGH 3 AND HAVE HAD A HYSTERECTOMY AT (B)(6). THE PATHOLOGY REPORTS SHOWED THAT ESSURE HAD MIGRATED AND PUNCTURED HER UTERUS. SHE HAD SEVERE ADENOMYOSIS AND ENDOMETRIOSIS OF THE UTERUS AND HER TUBES AND UTERUS WERE RIDDLED WITH CYSTS. (B)(4) RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 19-NOV-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: 2015-045712. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENT(S) AND LACK OF EFFICACY ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) OR LACK OF EFFICACY AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING), AND BECAME PREGNANT 2 YEARS AFTER INSERTION. ONE OF THE COILS MIGRATED AND HAD LODGED ITSELF INTO HER UTERUS/ MIGRATED AND PUNCTURED HER UTERUS. SIX YEARS AFTER INSERTION SHE HAD SEVERE PELVIC INFECTION. A HYSTERECTOMY WAS PERFORMED AFTER AN UNSPECIFIED TIME. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE. IN THIS CASE ONE OF THE COILS MIGRATED AND

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LODGED ITSELF INTO UTERUS/ MIGRATED AND PUNCTURED UTERUS. THE EXACT DATE OF THE PERFORATION WAS NOT REPORTED, IT WAS DIAGNOSED DURING TUBAL LIGATION. GIVEN THE NATURE OF THIS EVENT CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS EVENT COULD HAVE CONTRIBUTED TO THE PREGNANCY, HOWEVER IT IS NOT KNOWN WHETHER THE DEVICE MIGRATED AND LODGED ITSELF INTO UTERUS PRIOR TO THE PREGNANCY, FURTHERMORE HYSTEROSALPINGOGRAM SHOWED OCCLUSION, THEREFORE A CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. IN THE PRESENT CASE ADENOMYOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THE HEAVY BLEEDING. HOWEVER, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. THE PELVIC INFECTION OCCURRED 6 YEARS AFTER ESSURE INSERTION. GIVEN THE WEAK TEMPORAL RELATIONSHIP WITH THE INSERTION PROCEDURE, CAUSALITY WITH ESSURE WAS ASSESSED AS UNRELATED. ALTHOUGH ADENOMYOSIS COULD HAVE BEEN THE REASON FOR THE HYSTERECTOMY, IT CANNOT BE EXCLUDED THAT THE UTERINE PERFORATION WAS ALSO THE INDICATION FOR THE SURGICAL INTERVENTION, THEREFORE THIS CASE WAS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND QUALITY DEFECT. (B)(4)

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01733	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2120, AWARENESS DATE 29-OCT-2015) IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. ADDITIONAL INFORMATION RECEIVED ON 19-NOV-2015. THE CONSUMER REPORTED SHE SUFFERED SEVERE UNRELENTING PELVIC PAIN AFTER SURGERY. AT FIRST SHE THOUGHT IT WAS SURGICAL PAIN AND THEN PERHAPS THAT SOMETHING WENT WRONG WITH THE SURGERY; TRYING TO FIGURE OUT WHAT WAS GOING ON SHE WENT TO DOCTOR VISITS, TESTS, CAT SCANS, ETC. AND FINALLY, THEY DECIDED TO REMOVE HER FALLOPIAN TUBES. HOWEVER, DUE TO HER HISTORY OF PRIOR PELVIC PAIN AND PELVIC SURGERIES THIS WOULD BE COMPLICATED. AFTER SIX MONTHS OF HORRIBLE PAIN THEY FINALLY GOT EVERYTHING IN PLACE AND APPROVED FOR SURGERY, HER TUBES WERE REMOVED AND THE INTENSE PAIN THAT BEGAN IMMEDIATELY FOLLOWING ESSURE PROCEDURE HAS IMPROVED. SHE STATED NEVER ONCE DID ANYONE MENTION THAT ESSURE WAS NOT APPROPRIATE FOR SOMEONE WITH A HISTORY OF PELVIC PAIN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 19-NOV-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT

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REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO WAS HAD SEVERE UNRELENTING PELVIC PAIN SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A SALPINGECTOMY APPROXIMATELY 6 MONTHS AFTER DEVICE PLACEMENT AND IMPROVED FROM HER PAIN. THIS EVENT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER HAD A PREVIOUS HISTORY OF PELVIC PAIN AND PELVIC SURGERIES; WHICH COULD BE ALTERNATIVE EXPLANATIONS FOR HER PAIN. HOWEVER, AS THE TEMPORAL RELATIONSHIP BETWEEN EVENT ONSET AND ESSURE INSERTION WAS POSITIVE AND SINCE THERE WAS AN IMPROVEMENT IN CONSUMER'S PAIN AFTER DEVICE REMOVAL; A CONTRIBUTORY ROLE OF THE SUSPECT DEVICE CANNOT BE TOTALLY RULED OUT. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01734	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): MALFUNCTION	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2137, AWARENESS DATE 29-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. THE CONSUMER REPORTED SHE HAD HIGH PROGESTERONE LEVEL AND AN IUD WOULD NOT FIT INSIDE HER. ESSURE PROCEDURE WAS THE ONLY PROCEDURE HER DOCTOR WOULD PERFORM ON HER AND IT TOOK ABOUT 1 AND A HALF HOUR. DURING HER PROCEDURE A COIL BROKE AND ACCORDING TO HER, NO ONE COULD CONFIRM WHETHER ALL PIECES WERE REMOVED. SHE HAD MASSIVE BLEEDING FOR SEVERAL MONTHS THEN WENT INTO FULL BLOWN MENOPAUSE. SHE WAS A VERY ACTIVE AND HEALTHY PERSON BEFORE THE ESSURE PROCEDURE BUT SINCE HAVING IT DONE HER BODY HAD CHANGED DRASTICALLY. SHE HAD ARTHRITIS IN BACK AS WELL AS NECK, MULTIPLE JOINT PROBLEMS AND COULD HARDLY WALK AT TIMES. SHE HAD EXPERIENCED MULTIPLE VAGINAL INFECTIONS, POLYPS ON HER UTERUS LINING AND UNEXPLAINED BREAST PAIN THAT WOULD NEVER GO AWAY. SHE WAS GAINING ABOUT 2 POUNDS A MONTH NO MATTER HOW MUCH SHE EXERCISED OR WATCHED HER DIET. SHE ALSO HAD HORRIBLE MOOD SWINGS ACCOMPANIED BY DEPRESSION FOR WHICH SHE WAS SEEING A COUNSELOR AND REQUIRING MEDICATION. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING INSERTION PROCEDURE A COIL BROKE. SHE ALSO HAD MASSIVE BLEEDING (INTERPRETED AS GENITAL BLEEDING) FOR SEVERAL MONTHS. GENITAL BLEEDING IS A SERIOUS EVENT DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED. AFTER

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ESSURE INSERTION GENITAL BLEEDING MAY OCCUR. IN THE PRESENT CASE, CONSUMER HAD A HISTORY OF HORMONAL DISTURBANCE AND WAS ON PERIMENOPAUSE, WHICH COULD BE ALTERNATIVE EXPLANATIONS FOR THE MASSIVE BLEEDING. HOWEVER, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THIS EVENT, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, THEREFORE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 09-DEC-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01735	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2159, AWARENESS DATE 29-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED THAT IT HAS BEEN OVER A YEAR SINCE SHE HAD A HYSTERECTOMY RELATED TO POST-ESSURE PROBLEMS. FROM DAY 1 OF IMPLANT UNTIL REMOVAL IT HAS BEEN HER WORST DAYS OF HER HEALTH BECAUSE IT HAD FUNCTIONALLY AND PHYSICALLY LIMITED HER. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 19-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER (B)(4). A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS

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SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED HAD A HYSTERECTOMY RELATED TO POST-ESSURE PROBLEMS. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. THIS PARTICULAR CASE WAS REPORTED WITH VERY LIMITED INFORMATION. THE EXACT REASON FOR THE HYSTERECTOMY WAS NOT SPECIFIED. DESPITE THE LIMITED INFORMATION, GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01736	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/2/2013
Explant Date (E7): 10/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2282, AWARENESS DATE 28-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. ADDITIONAL INFORMATION RECEIVED ON 19-NOV-2015. THE CONSUMER REPORTED ESSURE WAS PLACED AFTER THE BIRTH OF HER SECOND SON. SHE STATED SHE HAD RISEN CONCERNED WITH HER DOCTOR AS SHE RECENTLY HAD COMPLICATIONS WITH A PLASTIC IUD, THE MIRENA. HE ASSURED HER THIS WAS DIFFERENT; PLASTIC ONLY, NO HORMONES. SHE ASKED WHAT WOULD BE THE PROCEDURE IF HER BODY REJECTS IT, LIKE IT DID WITH MIRENA (CASE UNDER REFERENCE (B)(4)). ONCE AGAIN, HE ASSURED HER, SHE WOULD NOT HAVE ANY ISSUES. SHE REPORTED THAT OVER THE YEARS, SHE DEVELOPED MENOPAUSAL SYMPTOMS, HOT FLASHES, IRREGULAR PERIODS, EXTREMELY HEAVY MENSTRUAL CYCLES AND MORE. AT TIME OF THE REPORT SHE WAS (B)(6) AND HAVE USED TAMPONS SINCE SHE WAS (B)(6), WITH ESSURE, SHE HAD NOT BEEN ABLE TO USE A TAMPON FOR OVER 7 MONTHS. SHE COULD NOT ENGAGE IN INTERCOURSE BECAUSE OF THE EXTREME PAIN, BLEEDING AND FEAR. HER COWORKERS ASKED HER IF SHE WAS PREGNANT BECAUSE OF HER BLOATING; SHE REPORTED SHE EAT WELL, EXERCISE AND IS VERY ACTIVE. THERE WAS NO REASON TO HER BLOATING/CHRONIC INFLAMMATION WHICH, SHE STATED IS GONE AFTER HER SURGERY. SHE DEVELOPED A SEVERE NICKEL ALLERGY FROM EXPOSURE TO ESSURE, A METAL ALLERGY SHE NEVER HAD BEFORE. SHE WOULD GET HIVES/RASHES ALL OVER HER BODY; LOSE HER HAIR, TASTE METAL IN HER MOUTH SHE STATED THAT CURRENTLY SHE IS LOOKING AT HER MEDICAL BILLS FROM HAVING HER HYSTERECTOMY; HER HUSBAND IS TAKING CARE OF THE CHILDREN AND SHE WAS ON A DAY BY DAY, HOUR BY HOUR, MINUTE BY MINUTE

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BASIS. SHE STATED SHE WAS LYING IN BED, ON PAIN KILLERS, ASKING HER HUSBAND TO HELP HER UP SO SHE COULD URINATE IN THE BATHROOM, OR GET SOME FOOD; AT TIME OF THE REPORT SHE WAS 3 DAYS POST OP. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 19-NOV-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD NICKEL ALLERGY FROM EXPOSURE TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT IS LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, THE EVENT OCCURRED AFTER DEVICE INSERTION AND NO ALTERNATIVE EXPLANATION WAS REPORTED. THEREFORE, COMPANY CONSIDERS THE EVENTS AS RELATED TO ESSURE. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. SINCE DEVICE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01737	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2011
Explant Date (E7): 10/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2220, AWARENESS DATE 28-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. SHE STATED THAT SHE DEVELOPED NUMEROUS SIDE EFFECTS. THE FIRST ISSUE SHE NOTICED WAS WEIGHT GAIN; SHE BEGAN GAINING WEIGHT FOR NO APPARENT REASON. SHE HAD TO STOP WEARING MAKEUP BECAUSE ANYTIME SHE WOULD APPLY IT; HER FACE WOULD BECOME SO ITCHY AND THEN SHE WOULD THEN BREAK OUT IN ACNE LIKE BLEMISHES FOR ABOUT 4 DAYS. SHE LOST HER HAIR IN CLUMPS. SHE WENT TO HER DOCTOR TO CHECK HER HORMONES AND THYROIDS. EVERYTHING CAME BACK FINE. SHE HAD DEVELOPED HIGH BLOOD PRESSURE AND HER PERIOD DURING THIS TIME WAS SO INCREDIBLY HEAVY THAT SHE NEEDED TO CHANGE A HEAVY DUTY TAMPON AND PAD EVERY 30 MINUTES FOR 7-10 DAYS. WHEN SHE WAS NOT MENSTRUATING, SHE WAS BLOATED. SEX WAS PAINFUL; SHE WAS EXHAUSTED ALL THE TIME. SHE COULD NOT REMEMBER SIMPLE THINGS AND FREQUENTLY FOUND HERSELF IN A DAZE TRYING TO REFOCUS; SHE FELT LIKE SHE WAS LOSING HER MIND. HER TEETH BEGAN BREAKING AND FALLING OUT AND SHE HAD REALLY HORRIBLE HEADACHES. WHEN SHE WOULD GO OUTSIDE IN THE HEAT, HER SKIN WOULD FEEL LIKE TINY ANTS WERE BITING HER ON HER ARMS, CHEST, AND LEGS. IN (B)(6) 2014 ESSURE WAS REMOVED AND SINCE THEN, EVERY SIDE EFFECT DISAPPEARED EXCEPT FOR HER HIGH BLOOD PRESSURE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 20-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS

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REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER (B)(4). A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER CYCLE WAS INCREDIBLE HEAVY. ESSURE WAS REMOVED AND SYMPTOMS DISAPPEARED. THIS EVENT, SEEN AS MENORRHAGIA, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MENSES PATTERN CHANGES ARE FREQUENT IN WOMEN WITH ESSURE IN PLACE. THUS, GIVEN EVENT'S NATURE AND RECOVERY AFTER REMOVAL (POSITIVE DECHALLENGE), CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENT WERE ALSO INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01738	BAYER HEALTHCARE LLC	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 10/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/30/2009
Explant Date (E7): 1/7/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2277, AWARENESS DATE 29-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED (B)(6) 2009. WITHIN A WEEK SHE EXPERIENCED A STABBING PAIN ON HER LOWER RIGHT SIDE. AS TIME CONTINUED, SHE DEVELOPED UPPER BACK PAIN, BRAIN FOG, AND FATIGUE. HER PERIODS WERE VERY HEAVY WITH QUARTER SIZED BLOOD CLOTS AND HEAVY CRAMPING. SHE ALSO GAINED WEIGHT. ON (B)(6) 2013 SHE HAD IT REMOVED AND HER SYMPTOMS WENT AWAY. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WITHIN A WEEK, PRESENTED STABBING PAIN ON LOWER RIGHT SIDE. SHE HAD IT REMOVE AND HER SYMPTOMS WENT AWAY (POSITIVE DECHALLENGE). THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION, AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE, THEIR CLOSE TEMPORAL RELATIONSHIP AND POSITIVE DECHALLENGE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENTS WERE ALSO INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058067	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 2/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVE HAD NON STOP BLEEDING, SEVERE ABDOMINAL PAIN, HEADACHES, WEIGHT GAIN AND CYSTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058068	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 11/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER ESSURE WAS PLACED I HAVE HAD STABBING SHOOTING PAINS IN MY LOWER ABDOMEN, ABNORMAL BLEEDING, HAIR LOSS, BLURRY VISION, FOGGY BRAIN, STUTTERING, RASHES AND WELTS ON BUTTOCKS, OVARIAN CYSTS, CONSTIPATION, CHRONIC FATIGUE, ALLERGIC REACTION TO SOME FOODS, WEIGHT GAIN, BLOATED STOMACH, DEPRESSED MOOD ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058069	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 10/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE BEEN DIAGNOSED WITH 3 AUTO IMMUNE DISEASES. RAYNAUD'S DISEASE, MIXED CONNECTIVE TISSUE , SJOGREN DISEASE WITH SICCA SYNDROME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058070	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 7/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, BLEEDING ON AND OFF EVERY OTHER DAY. HORRIBLE ITCHY HIVES ALL OVER MY BODY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058071	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 8/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE COVERED BY (B)(6). EXTREME WEIGHT GAIN, PRELABOR PAINS, HEAVY BLEEDING, PERIODS LASTING WEEKS NOT DAYS, MIGRAINES, RANDOM RASHES, THAT WOULDN'T HEAL QUICKLY, PAINFUL INTERCOURSE, NUMBNESS/TINGLING IN HANDS AND LEGS, MAINLY AT NIGHT, NOT RLS. CHRONIC PAIN IN OVARIES, REOCCURRING CYSTS, NOT PRESENT BEFORE DEVICE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058072	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 8/27/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A MONTH AFTER IT WAS CONFIRMED I WAS 100% WAS BLOCKED I GOT PREGNANT. I COULDN'T CONTINUE WITH THE PREGNANCY BECAUSE IT WAS A HIGH RISK PREGNANCY SO I END UP HAVING AN ABORTION, 5 YEARS LATER I HAD A HYSTERECTOMY BECAUSE OF HEAVY BLEEDING (HAD TO CHANGE ME PAD TWICE IN A HOUR) CONSTANT BLOATING, I GAINED A LOT OF WEIGHT A LOT OF HEADACHES (MIGRAINE) I HAD LOT OF PELVIC PAIN I WAS VERY MISERABLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058073	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 6/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING ALL DAY EVERYDAY, UNABLE TO STAND UP STRAIGHT WITHOUT STABBING PAIN IN MY UTERUS, ALLERGIC REACTION TO MY OWN SWEAT, MY BODY BREAKS OUT IN STINGING PAINFUL ITCHES AND HIVES, THAT LAST HOURS. PAIN IN TEETH AND JAW BONE ALL DAY. PAINFUL JOINTS, AND MUSCLES EVERYWHERE. GERD, STOMACH SENSITIVITY TO ALL FOODS, SEVERE BLOATING THAT IS VERY PAINFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058074	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 7/17/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VOMITING, HEAVY BLEEDING, LOW SEX DRIVE, NAUSEA, DIARRHEA, PAIN IN LOWER PELVIC AREA. PROVIDED BY MEDICAID.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058075	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 8/8/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD MY ESSURE PLACED IN (B)(6) 2005. SINCE THEN I HAVE GAINED 120 POUNDS. I HAVE SEVERE PERIODS WITH BLOOD CLOTS ABOUT THE SIZE OF A SOFTBALL. PAIN DURING OVULATION ON MY LEFT SIDE EVERY OTHER MONTH THAT TAKES ME ALMOST TO MY KNEES. I GET OVARIAN CYSTS AT ALL TIMES OF THE MONTH. (I HAD ONE THAT RUPTURED ON MY RIGHT OVARY ALONG WITH MY APPENDIX BEING REMOVED.) IN (B)(6) 2013 I HAD AN EXPLORATORY SURGERY (LAPAROTOMY) DONE BECAUSE OF MY "ISSUES" TO LOOK FOR ENDOMETRIOSIS. (I HAVE A FAMILY HISTORY.) HE SAID IN MY POST OP CONVERSATION THAT IT MUST BE PCOS. I AM VERY MOODY. HAVE ZERO ENERGY. HAVE THREE TO EIGHT "WHISKERS" THAT I AM CONSISTENTLY TWEEZING FROM MY CHIN. SEX DRIVE IS VERY LOW. PAIN DURING SEX. I ALSO NOW HAVE ACNE WHICH I HAVE NEVER HAD AN ISSUE WITH I ALSO HAD MY GALL BLADDER REMOVED DUE TO ABDOMINAL PAIN AND ISSUES. THIS PROCEDURE WAS COVERED BY (B)(6). NOW MY INSURANCE WILL NOT COVER REMOVAL OF THE DEVICE UNLESS I HAVE A FULL HYSTERECTOMY!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058093	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 11/21/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, PELVIC PAIN, RASH, PULLING ON LEFT SIDE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058094	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 8/12/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES, CHRONIC FATIGUE, SUDDEN WEIGHT GAIN, HEAVY CLOTTED MENSTRUAL CYCLE, ADULT ALLERGIES DEVELOPED REQUIRING 3 MEDICATIONS TO CONTROL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058095	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 12/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE DEVICE IMPLANTED ON (B)(6) 2013. WITHIN THREE WEEKS OF THE IMPLANT OF THIS DEVICE, THE FOLLOWING SYMPTOMS BEGAN: DRENCHING NIGHT SWEATS; HEAVY BLEEDING DURING MENSES; IRREGULAR PERIODS (OCCURRING EVERY 3 WEEKS AND LASTING 7-10 DAYS); PELVIC PAIN; PAINFUL INTERCOURSE AND VAGINAL DRYNESS; HAIR LOSS (CLUMPS BEYOND NORMAL HAIR LOSS); METALLIC TASTE IN MOUTH; FOUL SMELLING URINE; ABDOMINAL PAIN AND BLOATING; FECAL INCONTINENCE AND URGENCY; DRAMATIC WEIGHT GAIN AND INABILITY TO LOSE WEIGHT; NUMBNESS AND TINGLING IN MY HANDS AND ARMS WITH PAIN RADIATING UP TO ELBOWS AND SOMETIMES SHOULDERS (NOT ASSOCIATED WITH SLEEPING FUNNY, ETC); SEVERE LOWER BACK PAIN; WHEN GOING TO STANDING, I OFTEN CAN AND RS GET FULLY ERECT FOR SEVERAL SECONDS; BRAIN FOG AND DASH; COMPLETELY LOSING MY TRAIN OF THOUGHT OR SAYING A WORD COMPLETELY OUT OF CONTEXT (LIKE SAYING DOG INSTEAD OF TREE, ETC); EXTREME FATIGUE (FALLING ASLEEP AT 5PM AFTER ONLY WORKING A 4-HOUR DAY); DENTAL ISSUES AND SENSITIVITIES; ALCOHOL INTOLERANCE (HALF A GLASS OF WINE FELT LIKE I DRANK A WHOLE BOTTLE); PUFFY FACE AND DRAMATIC DARK CIRCLES. AFTER PRESENTING MY SYMPTOMS TO MY OB/GYN, IN SPITE OF "NORMAL PLACEMENT" ON THE HSG, REMOVAL OF THE DEVICE WAS ADVISED. MY DOCTOR REMOVED THE TUBES VIA BILATERAL SALPINGECTOMY, INCONSISTENT WITH BAYER'S OWN RECOMMENDATION OF HYSTERECTOMY, ON (B)(6) 2014, AFTER ABOUT 6 MONTHS OF HAVING THE DEVICE IN. INITIALLY, I EXPERIENCED RELIEF FROM MOST OF THE SYMPTOMS. HOWEVER, WITHIN A FEW MONTHS, THE SYMPTOMS THAT INITIALLY WENT AWAY HAVE RECURRED. TO DATE, I HAVE HAD THE FOLLOWING TESTING DONE AS A RESULT OF MY COMPLICATIONS, WITH NO SPECIFIC CONCLUSIONS AS TO WHY MY BODY HAS BECOME A LIVING HELL SINCE THE IMPLANTATION OF THIS DEVICE: NORMAL BLOOD PANEL TWICE (THOUGH INITIALLY ELEVATED LIVER ENZYMES AFTER DEVICE

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REMOVAL), NORMAL FOLATE AND B12 LEVELS, NORMAL COLONOSCOPY, NORMAL X-RAY AND ULTRASOUND, NEITHER SHOWING FRAGMENTS. I AM SCHEDULED TO SEE A NEUROLOGIST NEXT MONTH AND AM PURSUING SEEING AN ENDOCRINOLOGIST TO EXAMINE MY HORMONE LEVELS. IN (B)(6), I HAVE NEVER MET MY INSURANCE DEDUCTIBLE, AS I HAVE ALWAYS BEEN HEALTHY AND ACTIVE. SINCE ESSURE, I HAVE MET MY DEDUCTIBLE WELL BEFORE THE END OF THE YEAR BECAUSE OF REPEATED APPOINTMENTS AND TESTING TO ADDRESS PAIN AND OTHER SYMPTOMS. EVEN WITH INSURANCE, THIS "SAFE," "NON-SURGICAL" DEVICE HAS RESULTED IN SEVERAL (B)(6) OUT OF POCKET, MORE DOCTOR'S APPOINTMENTS I CARE TO RECALL, REPEATED TESTING AND BLOOD DRAWS, LOSS OF INCOME, LOSS OF HEALTH, ETC., ETC., ETC.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058096	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 11/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE WAS PROVIDED BY INSURER. CHRONIC PELVIC PAIN, CRAMPING AND DISCOMFORT. PULSING/FLUTTERING IN PELVIC AREA. SKIN RASHES (LEGS), HAIR LOSS, SEVERE ABDOMINAL BLOATING, SEVERE FATIGUE, AND JOINT PAIN (THIGH - HIP JOINT).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058097	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 6/4/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I EXPERIENCED RAPID, UNCONTROLLABLE WEIGHT GAIN, SEVERE MOOD SWINGS, INCREASED/NEW ALLERGIES (NUTS), ABDOMINAL PAIN AND BLOATING, JOINT PAIN, SWELLING THROUGHOUT MY ENTIRE BODY, CONCERNS WITH THYROID DISORDER, AND RAISED BLOOD PRESSURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058098	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 11/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY MENSTRUATION WAS VERY HEAVY LASTING 7-10 DAYS AND WOULD COME TWICE A MONTH. I HAVE CONSTANT CRAMPING AND BACK PAIN. I NOW HAVE SEVERE MIGRAINES AND HAVE TO TAKE DAILY MEDICATION TO CONTROL THE MIGRAINES. INTERCOURSE WITH MY HUSBAND IS PAINFUL, I BLEED AFTERWARD AND THE CRAMPING GETS WORSE. I HAVE CONSTANT BLOATING EVERY TIME I EAT. IT IS PAINFUL FOR ME TO SIT. I'M JUST IN CONSTANT PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058099	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 10/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE MENSTRUAL CYCLES, SEVERE JOINT PAIN, AND LOWER BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058100	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAIN, CYSTS, ANXIETY ,LACK OF SEX, DISCHARGE. NOT FEELING LIKE MYSELF.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058101	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 11/4/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS TOLD THERE WOULD BE NO PAIN- FROM THE MINUTE I WOKE UP I HAVE BEEN IN PAIN. WHEN MENTIONED TO THE DR I WAS TOLD IT WAS SCAR TISSUE AND IT WAS NORMAL. ALWAYS ON THE LEFT SIDE AND RECENTLY NOW THE RIGHT SIDE. I HAVE ALSO EXPERIENCED HAIR LOSS, DEPRESSION, LOW SEX DRIVE AND PAIN DURING SEX.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058102	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 4/27/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I FORGOT TO ADD: MEMORY LOSS!, NIGHT SWEATS, HOT FLASHES, EARLY MENOPAUSE, DEGENERATIVE BONE LOSS, DAILY BACK PAIN, CYSTIC OVARY, REMOVAL OF LEFT OVARY, DENTAL ISSUES, SWELLING OF LEGS/HANDS/FEET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058103	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERFORATION OF MY RIGHT FALLOPIAN TUBE BY THE EASIER DEVICE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058104	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 3/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY INSURANCE COVERED THE PROCEDURE TO HAVE THE ESSURE COILS IMPLANTED. I ONLY HAD TO PAY A CO-PAY FOR EACH APPOINTMENT. PRIOR TO HAVING ESSURE IMPLANTED, I HAD BEEN PREVIOUSLY DIAGNOSED WITH INTERSTITIAL CYSTITIS. I WAS NOT TAKING MEDICATION FOR THIS, AS NONE HAD BEEN PROVEN TO HELP. SO PRIOR TO THE PROCEDURE, I DID HAVE PELVIC PAIN IN MY BLADDER. IMMEDIATELY FOLLOWING IMPLANTATION, I HAD SEVERE PELVIC PAIN (SEPARATE FROM THE BLADDER PAIN, SLIGHTLY HIGHER AND BILATERAL SLIGHTLY HIGHER IN MY ABDOMEN AND ON BOTH SIDES) THAT DID NOT CEASE. IT WOULD INCREASE WITH CERTAIN MOVEMENT (BENDING, STANDING FROM A SEATED POSITION, BUMPING THE AREA). I BLED FOR THE FIRST FOUR MONTHS THEN IT CALMED A BIT. MY MENSTRUAL CYCLE BEGAN GETTING MORE PAINFUL AND SEVERE, COMING FREQUENTLY (2X MONTHLY OR MORE). I WENT TO MY DOCTOR FOR HELP AND WAS PRESCRIBED BIRTH CONTROL PILLS. THEY DID NOT HELP AFTER SEVERAL MONTHS, SO THEY GAVE ME A STRONGER PRESCRIPTION. I'VE BEEN TAKING THEM FOR 11 MONTHS, MY MENSTRUAL CYCLE HAS ONLY GOTTEN MORE PAINFUL AND HEAVIER. LAST (B)(6) (2014), I STARTED GETTING A VERY SHARP PAIN UNDER MY RIGHT RIB CAGE AREA. I WENT TO MY PRIMARY CARE PHYSICIAN AND AFTER ALL TESTS CAME BACK NEGATIVE, SHE TOLD ME I HAD COSTOCHONDRITIS. SHE PRESCRIBED IBUPROFEN AND SAID IT WOULD GO AWAY WITHIN THE NEXT FEW MONTHS. IT NEVER WENT AWAY. STARTING IN (B)(6) 2015, I STARTED HAVING RANDOM SEVERE BOUTS OF DIARRHEA FOLLOWED BY EXTREME NAUSEA. THIS WOULD LAST FOR DAYS AT A TIME LEAVING ME UNABLE TO GET OUT OF BED OR EAT. THIS LED TO A RAPID WEIGHT-LOSS OF OVER 20 POUNDS. I WENT BACK TO MY PRIMARY CARE PHYSICIAN AND WAS SENT TO A GASTROINTESTINAL SPECIALIST. THEY DID SOME BLOOD TESTS, TOOK A STOOL SAMPLE, AND DID A COLONOSCOPY. AGAIN, ALL TESTS CAME BACK NEGATIVE AND THEY ONLY FOUND ONE BENIGN POLYP IN MY INTESTINES. THEY DIAGNOSED ME WITH IBS, BUT SAID THAT IT

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WAS ODD THAT I FEEL MORE ILL AFTER HAVING THE DIARRHEA, AS WITH IBS PEOPLE USUALLY FEEL BETTER AFTER BOWEL MOVEMENT. THE DIGESTIVE ISSUES HAVE CONTINUED TO THIS DAY, AND APPEAR TO BE GETTING WORSE. I OFTEN STRUGGLE TO NOT VOMIT AT THIS POINT. MY FEET HURT, I CANNOT WALK BAREFOOT BECAUSE OF THE PAIN. I CAN NO LONGER RUN OR DO VIGOROUS EXERCISE. IF I TRY TO PUSH THROUGH THE PAIN, I CAN'T STEP ON MY FEET, THE PAIN GOES UP INTO MY ABDOMEN AND I CAN NO LONGER STAND IT IS SO INTENSE. MY MEMORY HAS ALSO BEEN NEGATIVELY AFFECTED. I USED TO HAVE AND AMAZING MEMORY, NOW I GET LOST DRIVING HOME. I CAN'T FIND THE WORDS I WAS GOING TO SPEAK. I STRUGGLE TO COMPLETE A TASK, BECAUSE I OFTEN FORGET WHAT I AM DOING. WHEN DISCUSSING THESE SYMPTOMS WITH MY OB/GYN LAST WEEK, SHE ASKED IF I HAVE EVER HAD REACTIONS TO CHEAP JEWELRY, WHEN I TOLD HER THAT I HAVE IN THE PAST AND WOULD GET BLISTERS, SHE SAID SHE THINKS I AM ALLERGIC TO THE NICKEL IN THE COILS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058105	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CHRONIC BACK, PELVIC AND NECK PAIN SINCE ESSURE IMPLANTED IN (B)(6) OF 2012. I HAVE RAN A LOW GRADE FEVER ((B)(6)) ALMOST DAILY SINCE ESSURE IMPLANTED. I'M IN EXTREME PAIN WHILE OVULATING AND MENSTRUATION IS MORE PAINFUL SINCE ESSURE IMPLANTED. HAVING A BLOATED BELLY IS PAINFUL, FEELS LIKE PRESSURE ON THE COILS. SEX IS REALLY, REALLY, REALLY PAINFUL SINCE ESSURE IMPLANTED!!!! I FEEL EXHAUSTED AND MY BODY HURTS REGULARLY. I HAD AN MRI DONE IN (B)(6) 2014 TO CHECK COILS BECAUSE THE PAIN WAS UNBEARABLE. IT SHOWED THE LEFT COIL ADHERED TO MY UTERUS. I AM SCHEDULED FOR A HYSTERECTOMY IN (B)(6) 2015. ALL I WAS TRYING TO DO WAS BE RESPONSIBLE IN MAKING MY CHOICE TO NOT HAVE MORE KIDS; I HAVE 3 BOYS, (VISUALLY IMPAIRED), (B)(6).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058106	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HERE IS A LONG LIST OF THINGS THAT HAVE HAPPENED AND OR ARE STILL HAPPENING SINCE ESSURE HAS BEEN PLACED INSIDE ME. WEIGHT GAIN, BLOATED BELLY. PREGO BELLY, MOODY, HOT FLASHES, NAUSEA, VISION AND DENTAL PROBLEMS, FATIGUE, EXHAUSTION, ANXIETY, NUMBNESS AND TINGLING IN ARMS AND HANDS, BRAIN FOG, MIGRAINES, DEPRESSION, PERIODS ARE EXTREMELY HEAVY. AND FEELS LIKE MY INSIDES ARE FALLING OUT CRAMPING, UTI , KIDNEY INFECTION, ACNE, RANDOM HAIR GROWTH, HEARTBURN, ACID REFLUX, HEART PALPITATIONS, PAINFUL SEX. AND MY BOYFRIEND HAS BROKEN OUT IN A RASH THAT IS BELIEVED TO BE A REACTION TO THE NICKEL FROM THE COILS. I WANT THESE OUT OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058107	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 10/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEVICE WAS PROVIDED BY INSURER. I HAVE HAD EXTREME PERIOD CHANGES SINCE HAVING ESSURE IMPLANTED IN 2009. I HAVE HAD NO PERIOD FOR MONTHS THEN BLEED VERY HEAVILY FOR SEVERAL DAYS TO WEEKS, THEN NO PERIOD AGAIN. I HAVE TAKEN COUNTLESS PREGNANCY TESTS, AND NONE HAVE EVER BEEN CONFIRMED. I HAVE HAD BLOATING RECENTLY WHEN I HAVE NOT HAD MY PERIOD. I HAVE MOOD SWINGS AND FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058108	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 5/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DUE TO AN ALLERGIC REACTION FROM THE NICKEL IN THE DEVICE, I HAVE HAD SEVERAL TRIPS TO THE ER FOR PSORIASIS BREAK OUTS. AT ONE POINT, I WAS COVERED FROM HEAD TO TOE. STEROIDS AND/OR CREAMS DO NOT HELP. I HAVE A CONSTANT SHARP PAIN IN MY RIGHT SIDE, WHICH IS EVEN MORE SEVERE NEAR TIME OF OVULATION OR MENSTRUAL CYCLE. SEXUAL INTERCOURSE IS UNBEARABLE. I FEEL WEAK ALL DAY BECAUSE I HAVE BECOME ANEMIC. MENSTRUAL CYCLES ARE UNPREDICTABLE, I HAVE HAD SEVERAL THAT LAST UP TO 3 CONTINUOUS MONTHS... AND THEY ARE EXTREMELY HEAVY (WHICH IS NOT NORMAL). I HAVE MEMORY LOSS. I CAN'T RETAIN INFORMATION FOR SHORT PERIODS OF TIME. I HAVE LOST MOST OF MY HAIR. MY TEETH ARE CRUMBLING (DETERIORATION), SO I WILL SOON NEED DENTURES (FROM ALMOST PERFECT TEETH). I HAVE HAD SEVERAL URINARY TRACT INFECTIONS THAT HAVE LEAD TO BEING HOSPITALIZED. SEVERAL KIDNEY STONES. CYSTS ON MY OVARIES. I WILL HAVE TO HAVE A HYSTERECTOMY AT THE BEGINNING OF THE YEAR 2016 TO HAVE THIS DEVICE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058109	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 2/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PERFORATED FALLOPIAN TUBE, TUBAL LIGATION, NAUSEATED, VOMITING, NIGHT SWEATS, STROKE SYMPTOMS, VITAMIN B DEFICIENCY, UTERINE FIBROID, BACTERIAL VAGINOSIS, LOSS OF PERIOD, PELVIC PAIN, RAPID WEIGHT GAIN, EXTREME ABDOMINAL BLOATING, PAIN DURING SEX, MIGRAINES, HEADACHES, FATIGUE, RASHES, HOT FLASHES, LOWER BACK PAIN, COIL MIGRATION, UNIDENTIFIED METAL IN MY BODY WHICH IS UNRETRIEVABLE, DILATED UTERINE BLOOD VESSELS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058110	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 3/16/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD SEXUAL INTERCOURSE WITH MY GIRLFRIEND (WHO HAS ESSURE) FOR THE FIRST TIME IN QUITE SOME TIME AND DEVELOPED A PAINFUL, SEVERE RASH AFTERWARD IN MY ENTIRE GENITAL REGION. I HAVE NEVER HAD THIS ISSUE BEFORE OR SINCE (WE ARE NOT INTIMATE CURRENTLY BECAUSE OF THE PROBLEMS CAUSED BY ESSURE TO BOTH OF US), AND WENT TO SEVERAL PHYSICIANS. ALL OTHER OPTIONS WERE RULED OUT (STDS, YEAST, ETC....). I DO HAVE VERY SENSITIVE SKIN AND ALLERGIES, SO I BELIEVE THIS IS A REACTION TO NICKEL. PHOTOGRAPHS ON MEDICAL SITES I HAVE SEEN OF NICKEL SKIN REACTIONS LOOK NEARLY IDENTICAL TO MY RASH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058111	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I RECEIVED THE ESSURE DEVICE IN (B)(6) OF 2013. IT WAS COVERED BY MY INSURANCE. AT THE BEGINNING I EXPERIENCED SLIGHT CRAMPING AND WHAT FELT LIKE GAS PAINS. THIS HAS BEEN ONGOING AND SOMETIMES CAN BE MILD TO SEVERE PAIN. I EXPERIENCE BLOATING ON A DAILY BASIS TO THE POINT WHERE I HAVE TO KEEP A VARIOUS RANGE OF PANT SIZES AS SOME DAYS IT LOOKS AS THOUGH I AM PREGNANT. I HAVE SEVERE MIGRAINES, BODY ACHES, FATIGUE, SHOULDER PAIN, DEPRESSION AND SEVERE ANXIETY ON A REGULAR BASIS. I ALSO HAVE A PERIOD ON A REGULAR BASIS, BUT NOW SOME ARE VERY SHORT, SOME LONG AND SOME VERY LIGHT, SOME VERY HEAVY. I HAVE TRIED DIFFERENT MEDICATIONS FOR THESE SYMPTOMS AND NONE HAVE WORKED. I HAVE DECIDED TO NOT PROCEED WITH ANY MORE MEDICATION AT THIS TIME. I WOULD LIKE TO HAVE THE DEVICE REMOVED DUE TO ONLY HAVING THESE ISSUES AFTER GETTING ESSURE. UNFORTUNATELY AT THIS TIME I AM UNABLE TO DUE TO INSURANCE AND FINANCIAL REASONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058112	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 3/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONTINUOUS BLEEDING LASTED FOR NEARLY 6 MONTHS, ONCE IT FINALLY CAME TO A STOP MY PERIODS WERE IRREGULAR. I'LL HAVE A PERIOD EVERY 2 WEEKS SOMETIMES AND THEN THERE WILL BE TIMES I GO MORE THAN A MONTH WITHOUT ONE. THE BACK AND ABDOMINAL PAIN ARE DEBILITATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058113	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 9/19/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT IMPLANTED WITH ESSURE IN (B)(6) 2013 AND FOR EXACTLY ONE YEAR AFTER, I HAD PAIN IN MY PELVIC AND HIP AREA THAT WAS CONSTANT AND WOULD ONLY GO AWAY WITH DOSES OF (B)(6) WITH (B)(6). ONE DAY, THE PAIN MYSTERIOUSLY VANISHED, AND THEN MY LEFT LEG STARTED GOING COMPLETELY NUMB LIKE I HAD NERVE DAMAGED. I DEAL WITH MY LEFT LEG BEING NUMB NOW ON A DAILY BASIS AND I NOW HAVE STABBING PELVIC AND ABDOMINAL PAINS THAT HAVEN'T BEEN DIAGNOSED AS ANYTHING AS OF YET. I HAVE HAD NUMEROUS TESTS DONE AND BLOODWORK AND NOTHING HAS BEEN FOUND AS TO THE CAUSE OF MY PROBLEMS. I HAVE SPOKEN TO MANY PHYSICIANS ABOUT WHAT'S GOING ON WITH ME AND ALL OF THEM HAVE BRUSHED IT OFF THAT ESSURE IS THE CAUSE OF IT. I NEVER HAD ANY OF THOSE SYMPTOMS PRIOR TO ESSURE. I AM ALSO DEALING WITH TEETH PROBLEMS, HAIR BREAKAGE, SKIN BREAKOUTS, BLOATING, WEIGHT LOSS, MOOD CHANGES, AND INABILITY TO REMEMBER THINGS LONG TERM. ONCE AGAIN, I NEVER HAD THESE SYMPTOMS PRIOR TO ESSURE. I AM SET UP FOR A CONSULTATION WITH A SURGEON TO DISCUSS GETTING THESE COILS REMOVED. AT (B)(6), I SHOULDN'T FEEL LIKE I AM 50. SOME DAYS ARE SO BAD I DON'T EVEN WANT TO GET OUT OF THE BED. I WANT MY LIFE BACK, PULL THIS DEVICE FROM THE MARKET! IT HAS AFFECTED WAY TOO MANY WOMEN NEGATIVELY. IT ISN'T FAIR TO US WHO HAVE BEEN IMPLANTED THAT WE ARE CONSTANTLY HAVING TO BATTLE FOR OUR HEALTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058114	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 11/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ITCHY SKIN, BREAST PAIN , DRY SKIN, SWEATY,SHORT OF BREATH, HEART PALPITATIONS, LOW LIBIDO, MUSCLE PAIN, HEAVY PERIODS, BLOOD CLOTS WITH CYCLE, PELVIC PAIN, DIAGNOSED WITH LUPUS, TINGLING IN ARMS, LEG CRAMPS, WEAK MUSCLES, FATIGUE, FORGETFULNESS, DEPRESSED, FEVERS, LOWER ABDOMEN/BACK PAIN, COLD FEET, LEG CRAMPS, BRAIN SHOCKS, ANXIOUS, INCONTINUOUS, VAGINAL ODOR/DISCHARGE, HAIR LOSS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058115	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 5/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HORRIBLE CONSTANT PAIN IN GROIN/PELVIS REGION, NAUSEATED CONSTANTLY, MIGRAINES 5-6/ WEEK, TINGLING AND STABBING PAIN DOWN MY LEFT LEG AT TIMES, LOWER BACK PAIN, NO PERIOD SINCE (B)(6) 2014, DRY SKIN, DIARRHEA, HOT FLASHES, PAINFUL INTERCOURSE, BLOATING, WEIGHT GAIN, CONSTANTLY TIRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058116	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 11/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, BACK PAIN, TOOTH DECAY, SEVERELY HEAVY PERIODS WITH HUGE CLOTS, WEIGHT GAIN, FATIGUE, MOOD SWINGS, HEART PALPITATIONS, AND MUSCLE CRAMPS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058117	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 12/3/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL INSERTION, STABBING AND TEARING PAINS EVEN STILL PRESENT. BURNING SENSATION, SORE AND SWOLLEN BELLY, LOSS OF SEX DRIVE, NONE SINCE INSERTION, PERIOD STOPPED SINCE INSERTION, HAIR LOSS, GUMS BLEED, EXTREME WEIGHT GAIN, DRY SKIN, ECZEMA, TINNITUS, CONSTANT BV INFECTIONS, THICKENING OF UTERUS, MUSCLE WEAKNESS, PAIN IN JOINTS, FATIGUE, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058136	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, PAIN, FIBROIDS, CYSTS, ACNE, JOINT PAIN, FLOATERS IN EYES, EXTREME FATIGUE, DEPRESSION, YEAST INFECTION, AND ANXIETY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058137	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 5/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT MY ESSURE PLACED AND HAVE NOTHING BUT PROBLEMS SINCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058138	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE HEADACHES, MIGRAINE OCCURING WHILE SLEEPING OR WAKING UP IN MORNING OR ANYTIME DURING THE DAY THAT WILL NOT GO AWAY BY TAKING (B)(6), ACCOMPANIED BY NAUSEA, VOMITING,EXTREME FATIGUE,SLEEPINESS, MENSTRUAL PERIODS HEAVY OR VERY LIGHT AT TIMES WITH BLOOD CLOTS, WEIGHT GAIN, BELLY LOOKS PREGNANT, GASSY, TUMMY ACHES, THINNING HAIR, FORGETFULNESS, BLURRY VISION, MOODINESS, IRRITABILITY, DEPRESSION, ARM,LEGS, SHOULDER AND BODY ACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058139	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 11/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE CONTINUOUS PAIN IN MY PELVIC AREA. THE CRAMPING MAKES YOU WANT TO JUST CURL UP IN A BALL. IT WAS SO BAD LAST MONTH THAT I JUST WANTED TO CRY. SINCE I GOT ESSURE, I GET YEAST INFECTIONS 1-2 TIMES A YEAR AND NEVER HAD THEM BEFORE ESSURE. I STARTED GETTING MIGRAINES AND HAVE HAD TO MISS WORK DUE TO THIS, I DIDN'T HAVE THEM BEFORE. I HAVE A TASTE IN MY MOUTH THAT TASTES LIKE METAL. AND THE PAIN IN MY HIPS IS HORRIBLE. MY BODY ACHES ALL OVER SOME DAYS YOU DON'T WANT TO MOVE AGAIN. I SHOULDN'T HAVE TO TAKE 12 (B)(6) A DAY JUST TO FUNCTION WITH SOME PAIN. ALL OF THIS RIGHT AFTER I GOT ESSURE. I WILL GET IT REMOVED, SO I CAN HAVE MY LIFE BACK AND I HOPE THERE ARE NO OTHER PROBLEMS FROM THIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058140	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 1/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY SYMPTOMS BEGAN SEVERAL MONTHS AFTER HAVING THIS PROCEDURE DONE, AND HAVE BEEN PROGRESSIVELY GETTING WORSE EVER SINCE. MY LIST OF ISSUES WITH THIS DEVICE INCLUDE, BUT ARE NOT LIMITED TO: PAINFUL PERIODS, HEAVY PERIODS, SEVERE PELVIC PAINS, MIGRAINES, PREGNANCY SYMPTOMS, MORE THAN ONE PERIOD A MONTH, BLOAT, BRAIN FOG, MEMORY LOSS, DEPRESSION, OVARIAN CYSTS, RASH, BACK PAINS, PAINFUL INTERCOURSE, MOOD SWINGS, LACK OF ENERGY, NO APPETITE. I HAVE JUST RECENTLY FOUND THAT I HAVE MORE THAN ONE KIT IMPLANTED AS WELL, AND AM NOW FORCED TO HAVE A HYSTERECTOMY AT (B)(6) YEARS OLD. I HAVE HAD THESE FOR TWO YEARS AND HAD NOTHING BUT PROBLEMS. THIS DEVICE IS DANGEROUS AND SHOULD NOT BE ON THE MARKET. AND PER (B)(6) DATA SHEET, THE PET FIBERS ARE NOT SUPPOSED TO BE PERMANENTLY IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058141	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I FIRST HAD A MISSED PERIOD, THOUGHT I WAS PREGNANT. THEN IN (B)(6) HAD A CRIPPLING ABDOMINAL PAIN EPISODE THAT ONLY DID NOT LAND ME IN THE HOSPITAL BECAUSE WE WERE CAMPING. AT THIS POINT I HAD ALSO BEEN STRUGGLING WITH WEIGHT GAIN THAT I COULD NOT UNDERSTAND AND LOWER BACK PAIN THAT I HAD HAD FOR YEARS, BUT ATTRIBUTED TO AGING. I THEN HAD ANOTHER CRIPPLING ABDOMINAL EPISODE IN (B)(6), AND DID GO TO THE ER FOR THIS ONE AND WAS TOLD IT WAS A SEVERE CASE OF GASTRITIS, BUT THERE WAS NO LEGITIMATE REASON FOR IT TO HAVE OCCURRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058142	BAYER	11/25/2015	11/25/2015

Event Information:

Event Date (B3): 6/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABOUT A WEEK AFTER I WAS IMPLANTED WITH ESSURE ON (B)(6) 2015 I STARTED NOTICING SIDE EFFECTS. AT FIRST IT WAS TINGLING IN MY RIGHT LEG LIKE IT WAS ASLEEP BUT I COULDN'T GET RELIEF IF I TRIED WALKING OR SITTING. THEN I STARTED NOTICING HIP PAIN ON MY RIGHT SIDE AS WELL. THESE WERE CONSTANT THINGS AT FIRST THEN THEY STARTED HAPPENING OVER TIME. I STILL EXPERIENCE THEM AT LEAST ONCE A WEEK. I BLED FOR A MONTH AND A HALF AFTER GETTING ESSURE IMPLANTED, THEN MY PERIOD STOPPED COMPLETELY. THEN THE FIRST PERIOD I HAD AFTER IN (B)(6) WAS VERY HEAVY AND PAINFUL AND I HAD HUGE CLOTS AS WELL. I ALSO EXPERIENCE CRAMPING OCCASIONALLY WHEN I AM NOT ON MY PERIOD THAT FEELS LIKE LABOR PAINS. I HAVE PAINFUL INTERCOURSE AND I BLEED OR SPOT AFTER SEX. ALSO, I GET FEELINGS SOMETIMES WHILE ON MY PERIOD LIKE MY INSIDES ARE FALLING OUT OF ME AND I GET THE PAIN TO PUSH LIKE I AM IN LABOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058195	BAYER	11/25/2015	12/2/2015

Event Information:

Event Date (B3): 12/15/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 676717

Single Use: *
Implant Date (E6): 12/15/2009
Explant Date (E7): 11/4/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE IMPLANTED IN 2009, I STARTED HAVING MIGRAINE HEADACHES, MUCH HEAVIER PERIODS, CHRONIC PELVIC PAIN, MUSCLE SPASMS, BACK PAIN AND MAJOR FATIGUE. HAD I BEEN EDUCATED BY MY DOCTOR ABOUT THE POTENTIAL SIDE EFFECTS, I NEVER WOULD HAVE HAD ESSURE IMPLANTED. ON (B)(6) 2015, I HAD A TOTAL HYSTERECTOMY TO GET IT REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058196	CONCEPTUS	11/25/2015	12/2/2015

Event Information:

Event Date (B3): 9/5/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): 958711

Single Use: *
Implant Date (E6): 9/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE DEVICE IMPLANTED (B)(6) 2012. IN (B)(6) OF 2015, I UNDERWENT LAPAROSCOPY TO DETERMINE IF I HAD ENDOMETRIOSIS THAT WAS CAUSING MY SEVERE PELVIC PAIN, WHICH WAS WORSE AFTER INTERCOURSE. THE TEST WAS NEGATIVE, BUT I DID END UP NEEDING MY APPENDIX REMOVED. THERE WAS NO EXPLANATION AS TO WHY MY APPENDIX HAD GONE BAD. I HAD PREVIOUSLY BEEN UNDER THE CARE OF AN ONCOLOGIST AS WELL, DUE TO ELEVATED WHITE CELL COUNT AND NIGHT SWEATS. NO KNOWN CAUSE HAS BEEN FOUND FOR EITHER. BOTH STARTED SHORTLY AFTER IMPLANT. I ALSO HAVE SORES ON MY SCALP, FEET AND ARMS THAT DO NOT HAVE A MEDICAL EXPLANATION AT THIS TIME. BOTH BEGAN ABOUT 9 MONTHS AFTER IMPLANT. I STILL CONTINUE TO HAVE SEVERE PAIN IN MY RIGHT SIDE, OVARIAN CYSTS AND A PRONOUNCED ENDOMETRIUM WAS DIAGNOSED ON A CAT SCAN. I BELIEVE THESE SYMPTOMS TO BE DUE TO THE ESSURE IMPLANT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058200	BAYER	11/25/2015	12/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/10/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE ESSURE PERMANENT BIRTH CONTROL. I'VE HAD CHRONIC PELVIC PAIN AND VERY HEAVY BLEEDING SINCE (B)(6) 2011. I DO NOT HAVE HEALTH INSURANCE UNTIL (B)(6), AND THAT'S WHEN I WILL NEED A HYSTERECTOMY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01739	BAYER HEALTHCARE LLC	11/26/2015	11/26/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2109, POSTED ON 26-OCT-2015, AWARENESS DATE 29-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2012. SHE GAINED WEIGHT EVER SINCE. A WEEK PRIOR TO THIS REPORT SHE WENT TO THE DOCTOR WITH COMPLAINTS OF SHARP PELVIC PAIN. THEY DID AN ULTRASOUND WHICH SHOWED A COIL PERFORATED INTO HER UTERUS. SHE STATED SHE WAS NOT GOING ON (B)(6) 2015 TO GET SURGERY TO GET THEM REMOVED. SHE DID ALL OF THAT TO AVOID SURGERY AND NOW SHE GOT STUCK GETTING IT DONE. WITH 3 KIDS AGES 5 AND UNDER SHE HAS TO TRY TO HEAL RIGHT SO SHE CAN GET BACK TO WORK SINCE SHE WAS GOING TO BE MISSING SOME. SHE WANT IT GONE AND DO NOT WANT ANYONE ELSE DO RISK THIS. PTC RESULT WAS RECEIVED ON 19-NOV-2015. PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD AN ULTRASOUND SCAN ALMOST 3 YEARS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION; WHICH SHOWED A COIL PERFORATED INTO HER UTERUS. SHE MENTIONED A SURGERY TO HAVE THE DEVICE REMOVED. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE TUBE PERFORATION IS A POSSIBLE COMPLICATION OF ESSURE INSERTION. IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE PAIN DURING/AFTER THE PROCEDURE. IN THIS PARTICULAR CASE, CONSUMER DEVELOPED PELVIC PAIN (APPROXIMATELY 3 YEARS AFTER ESSURE PLACEMENT) AND AN ULTRASOUND SCAN REVEALED A UTERINE PERFORATION BY THE DEVICE. ALTHOUGH THE EXACT MECHANISM OF THIS EVENT IS UNKNOWN, CONSIDERING ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ALTHOUGH IT IS NOT TOTALLY CLEAR FROM CONSUMER'S REPORT IF SHE WILL HAVE ESSURE REMOVED; CONSIDERING A SURGICAL INTERVENTION WILL BE REQUIRED FOR EVENT'S TREATMENT; THIS CASE WAS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01740	BAYER HEALTHCARE LLC	11/26/2015	11/26/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2098, AWARENESS DATE 29-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. CONSUMER REPORTED SHE WAS PHYSICALLY ACTIVE BEFORE ESSURE IMPLANTED. SHE STARTED TO EXPERIENCED VARIOUS EVENTS THAT SHE NEVER HAD BEFORE: PELVIC PAIN, HIP PAIN, BRAIN FOG, HAIR LOSS, PASSING OUT, LEG PAIN, BACK PAIN, HEADACHES, MEMORY PROBLEMS, WITHDRAWN, SPEECH PROBLEMS, CHOKING AND JUST NOT FEELING RIGHT. SHE STARTED TRIPPING MORE AND NOTICED LEFT SIDE WEAKNESS AND HAVING MORE SPEECH PROBLEMS. SHE ALSO HAD NIGHT SWEATS AND NO LONGER ENJOY BEING INTIMATE WITH HER HUSBAND. SHE FELT CRAZY. WHEN SHE BLACKED OUT AT WORK SHE DECIDED SHE NEEDED TO GO BACK TO GYNECOLOGIST AND REITERATE THAT SHE WAS REALLY NOT DOING OKAY. SHE DISCOVERED SHE WAS VERY ALLERGIC TO NICKEL AND VARIOUS OTHER METALS AND NEEDED TO HAVE ESSURE REMOVED RIGHT AWAY. SHE WAS SEEN BY A NEUROLOGIST DUE TO SPEECH PROBLEMS AND LEFT SIDE NERVE DAMAGE AND DID PHYSICAL THERAPY FOR 4 MONTHS FOR LEFT SIDE WEAKNESS, RECEIVED NUMEROUS CORTISONE SHOTS IN HER BACK/ HIP AND WAS DIAGNOSED WITH EOS (AS REPORTED). CONSUMER HAD TO HAVE A TOTAL HYSTERECTOMY IN 2012 AT THE AGE OF (B)(6). RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 19-NOV-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A

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LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT (S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS ALLERGIC TO NICKEL. SHE ALSO REPORTED PASSING OUT - BLACKED OUT AT WORK AND CHOKING. A TOTAL HYSTERECTOMY WAS PERFORMED 2 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. NICKEL ALLERGY IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE REMAINING EVENTS ARE UNLISTED. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THIS DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THE DEVICE IS IMPLANTED. IN THE PRESENT CASE, CONSUMER STATED THAT SHE DISCOVERED SHE WAS VERY ALLERGIC TO NICKEL AND NEEDED TO HAVE ESSURE REMOVED. DESPITE NO TYPICAL ALLERGY SYMPTOMS BEING REPORTED, GIVEN THE NATURE OF THE EVENT ALLERGIC TO NICKEL, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. EVENTS PASSING OUT - BLACKED OUT AT WORK AND CHOKING WERE ASSESSED AS UNRELATED TO ESSURE, GIVEN THEIR NATURE AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01741	BAYER HEALTHCARE LLC	11/26/2015	11/26/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2148, AWARENESS DATE 29-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED ON 19-NOV-2015. THE CONSUMER REPORTED THAT INSTANTLY AFTER IMPLANT SHE STARTED FEELING VERY ILL, AND WAS 5 YEARS ON DISABILITY AS SHE COULD NOT WORK 10-12 HOURS A DAY AS SHE USED TO DO BEFORE. SHE WAS HAVING MANY ILLNESSES/ SIDE EFFECTS AND MOST DAYS SHE WOULD CRY HERSELF TO SLEEP IN PAIN. EVEN AFTER HYSTERECTOMY HER ILLNESSES HAD NOT IMPROVED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 19-NOV-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN

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REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER STATED SHE HAD UNSPECIFIED ILLNESS/SIDE EFFECTS DURING ESSURE THERAPY IN ADDITION TO PAIN. ACCORDING TO HER, EVEN AFTER HYSTERECTOMY HER ILLNESS DID NOT IMPROVED. THIS INFORMATION SUGGESTS A NEGATIVE DECHALLENGE. NEVERTHELESS, SINCE LIMITED INFORMATION WAS PROVIDED AND AS IT IS UNCLEAR WHICH SYMPTOMS PERSISTED AFTER SURGERY; A CONTRIBUTORY ROLE OF ESSURE IN CONSUMER'S PAIN CANNOT BE TOTALLY RULE OUT. AS A HYSTERECTOMY WAS REQUIRED; THIS CASE WAS CONSIDERED AN INCIDENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01742	BAYER HEALTHCARE LLC	11/26/2015	11/26/2015

Event Information:

Event Date (B3): 8/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2187, AWARENESS DATE 29-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. ADDITIONAL INFORMATION RECEIVED ON 19-NOV-2015. THE CONSUMER REPORTED THAT SINCE ESSURE PLACEMENT HER LIFE HAD BEEN TURNED UPSIDE DOWN. SHE WAS LIVING IN PAIN EVERY DAY. SHE HAD MULTIPLE HOSPITAL STAYS THAT SHE LINKED TO ESSURE. SHE WAS WORKING WITH HER MEDICAL TEAM TO HAVE THE DEVICE REMOVED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 19-NOV-2015 THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT:

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THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE STATED SHE HAD MULTIPLE HOSPITAL STAYS. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER REPORTED DAILY PELVIC PAIN AND HOSPITAL STAYS THAT SHE RELATED TO ESSURE. ALTHOUGH LIMITED INFORMATION WAS PROVIDED, CONSIDERING EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. AS HOSPITALIZATION WAS REQUIRED, THIS CASE WAS REGARDED AS AN INCIDENT. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01743	BAYER HEALTHCARE LLC	11/26/2015	11/26/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D06929

Single Use: Y
Implant Date (E6): 1/1/2015
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 27-OCT-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ESSURE LOT NUMBER WAS D06929. TWO INSERTION DATES WERE REPORTED ((B)(6) 2015). PHYSICIAN PLACED COIL ON ONE SIDE, WHEN RELEASED IT LEFT PART OF THE DELIVERY DEVICE BEHIND (WHEN COIL WAS RELEASED, THE CATHETER GOT CAUGHT AND A PIECE BROKE OFF IN THE UTERUS). PHYSICIAN USED GRASPERS TO RETRIEVE IT AND WAS ABLE TO REMOVED IT FROM UTERUS. THE SECOND DEVICE DID NOT TURN WHEN THE PHYSICIAN TURNED THE HANDLE. OFFICE MANAGER INDICATED PATIENT WAS NOT HARMED. PHYSICIAN DID NOT PROCEED AND STOPPED THE CASE. PHYSICIAN DID NOT FEEL COMFORTABLE PLACING SECOND DEVICE FROM SAME BOX. BILATERAL PLACEMENT WAS NOT ACHIEVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. DURING THE PROCEDURE, WHEN THE COIL WAS RELEASED IT LEFT PART OF THE DELIVERY DEVICE BEHIND (THE CATHETER GOT CAUGHT AND A PIECE BROKE OFF IN THE UTERUS). PHYSICIAN REMOVED IT WITH GRASPERS. THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, THE EXACT MECHANISM OF DEVICE MALFUNCTION WAS NOT INFORMED. PHYSICIAN ALSO HAD DIFFICULTIES TO INSERT THE SECOND COIL AND STOPPED THE PROCEDURE. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED IN ORDER TO CLARIFY THE EVENT. NEVERTHELESS, CONSIDERING IT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY

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WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH PATIENT HAD NO SERIOUS INJURY, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS RECEIVED ON 30-NOV-2015: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01744	BAYER HEALTHCARE LLC	11/26/2015	11/26/2015

Event Information:

Event Date (B3): 5/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON 19-FEB-2014 ON COMPANY INTERNET SITE WITH REQUEST FOR REIMBURSEMENT. THE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER BODY HAS NOT FELT RIGHT AT ALL SINCE PRODUCT HAS BEEN IN BODY AND AT TIME OF REPORTING SHE WAS (B)(6) PREGNANT (DEVICE INEFFECTIVE). NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. IN (B)(6) 2012, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. THE CONSUMER REPORTED SINCE INSERTION IT HAS BEEN NOTHING BUT HELL, HER BODY HAS NOT FELT RIGHT AT ALL. THE BIGGEST SIDE EFFECT WAS SHE WAS (B)(6) PREGNANT AT TIME OF REPORTING. REPORTER CONSIDERED THE EVENTS WERE RELATED TO ESSURE. FOLLOW-UP FROM 04-JUN-2014: CONSUMER CONTACT INFORMATION WAS UNAVAILABLE. HENCEFORTH NO FURTHER FOLLOW-UP COULD BE PURSUED. FOLLOW-UP INFORMATION RECEIVED ON 29-OCT-2015. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEP-2015 (FDA-2014-N-0736-2212). IN (B)(6) 2012, ESSURE WAS IMPLANTED. AFTER THREE MONTHS, SHE STARTED EXPERIENCING SHARP STABBING PELVIC PAIN, HER PERIODS WERE CRAZY HEAVY AND NEVER CAME ON TIME. SHE GOT PREGNANT WITH ESSURE STILL IN PLACE EVEN ULTRASOUND THROUGHOUT THE PREGNANCY SHOWED THEM TO BE IN PLACE. DURING PREGNANCY, SHE COULD NOT MOVE BECAUSE OF ALL THE PAIN, HER BABY WAS BORN SICK AT (B)(6); HE WAS UNABLE TO KEEP HIS LUNGS OPEN ON HIS OWN AND HAD TO SPEND DAYS IN THE NICU, HE ALSO HAS A NICKEL ALLERGY THAT NONE OF HER OTHER KIDS HAVE (SEE CHILD'S CASE NUMBER (B)(6)). ALSO BECAUSE OF BE ESSURE, HER BODY DEVELOPED

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AN AUTOIMMUNE SKIN DISEASE WHERE SHE WAS LOSING THE SKIN PIGMENT. SHE HAD TO HAVE A COMPLETED HYSTERECTOMY WHEN HER BABY WAS (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SHARP STABBING PELVIC PAIN. SHE GOT PREGNANT WITH ESSURE. HER BABY WAS BORN SICK AT (B)(6). SHE HAD TO HAVE A COMPLETED HYSTERECTOMY WHEN HER BABY WAS (B)(6). THESE EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STARTED EXPERIENCING SHARP STABBING PELVIC PAIN THREE MONTHS AFTER ESSURE INSERTION. SHE GOT PREGNANT ABOUT 1 YEAR AND 3 MONTHS AFTER ESSURE INSERTION. CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP AND A LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW UP 02-DEC-2015: PTC INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS RE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01745	BAYER HEALTHCARE LLC	11/26/2015	11/26/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2141, AWARENESS DATE 29-OCT-2015). ADDITIONAL INFORMATION RECEIVED ON 19-NOV-2015 (PTC INVESTIGATION RESULT). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER HAD STABBING PAIN ALMOST EVERY DAY ABOUT A YEAR POST ESSURE INSERTION, STRANGE RASHES, INCREASING URINE LEAKAGE, AND CONSTANT JOINT PAIN. NONE OF THESE SYMPTOMS EXISTED BEFORE SHE HAD ESSURE IMPLANTED. SHE FINALLY HAD A HYSTERECTOMY ON (B)(6) 2015 AT THE AGE OF (B)(6). HER SURGEON SAID SHE HAD TOO MUCH SCAR TISSUE BUILDUP COVERING HER FALLOPIAN TUBES AND SHE HAD OF ADHESIONS OF TISSUE ON HER BOWELS CONNECTING HER OVARIES TO THEM CAUSED DIRECTLY FROM INFLAMMATION OF ESSURE AND MORE THAN LIKELY CAUSING HER PAIN. IT HAS BEEN 1 WEEK SINCE HER SURGERY AND SHE NO LONGER HAD URINE LEAKING NOR JOINT PAIN. THE PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE. NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED

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MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT (S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED STABBING PAIN (SEEN AS ABDOMINAL PAIN). SHE UNDERWENT A HYSTERECTOMY AND HER SURGEON STATED SHE HAD TOO MUCH SCAR TISSUE BUILDUP COVERING HER FALLOPIAN TUBES BUILDUP COVERING HER FALLOPIAN TUBES AND SHE HAD OF ADHESIONS OF TISSUE ON HER BOWELS CONNECTING HER OVARIES TO THEM CAUSED DIRECTLY FROM INFLAMMATION OF ESSURE (INTERPRETED AS PELVIC INFLAMMATION). THE EVENT STABBING PAIN AND INFLAMMATION OF ESSURE ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE THE OTHER ARE UNLISTED. ALL THESE EVENTS WERE CONSIDERED SERIOUS. IN THIS CASE, IT WAS NOT REPORTED WHEN THE CONSUMER STARTED EXPERIENCING INFLAMMATION OF ESSURE. PROBABLY, THIS EVENT OCCURRED A LONG TIME AGO SINCE ESSURE INSERTION BUT IT WAS ONLY DIAGNOSED AFTER UNDERGOING A HYSTERECTOMY ABOUT 3 YEARS AFTER ESSURE INSERTION. THIS EVENT ALSO COULD HAVE CAUSED THE STABBING PAIN. CONSIDERING THIS INFORMATION AND BASED ON THE NATURE OF THE EVENTS STABBING PAIN AND INFLAMMATION OF ESSURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, A CAUSAL RELATIONSHIP CAN BE EXCLUDED CONSIDERING THEIR NATURE. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT (S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01746	BAYER HEALTHCARE LLC	11/26/2015	11/26/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2269, AWARENESS DATE 28-OCT-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. ADDITIONAL INFORMATION RECEIVED ON 09-NOV-2015 VIA REGULATORY AUTHORITY (MW5057489). SHE STATED THAT'S TO AVOID A HYSTERECTOMY DUE TO BLEEDING, HER DOCTOR SUGGESTED AN ABLATION, BUT HE WOULD NOT DO THE ABLATION WITHOUT ESSURE BEING IMPLANTED. SO, ESSURE WAS IMPLANTED IN 2011 AND AN ABLATION WAS DONE. SINCE THAT TIME, SHE HAD QUITE A FEW UNEXPLAINED HEALTH ISSUES (LISTED BELOW); SHE HAD TO TAKE TIME OFF FROM WORK FOR ILLNESS, DOCTOR VISITS, MULTIPLE TESTS, BLOOD WORK AND NO CAUSES COULD BE FOUND. SHE EXPERIENCED FATIGUE, CHRONIC ABDOMINAL PAIN AND DISCOMFORT, MEMORY LOSS, IRRITABLE BOWEL SYNDROME, ARMS AND LEGS GOING TO SLEEP, SUDDEN WEIGHT GAIN AND TOTAL CHANGE IN BODY APPEARANCE, SEVERE BLOATING, AND MAJOR INCREASE IN THE FREQUENCY OF HEADACHES (ESPECIALLY MIGRAINES), DEPRESSION/ANXIETY, VITAMIN B-12 DEFICIENCY, HAIR LOSS, HOT FLASHES, RASH ON FACE AND SCALP, PAIN AND BLEEDING DURING/AFTER INTERCOURSE. AFTER MUCH PAIN, SHE WAS SCHEDULED FOR A HYSTERECTOMY ON (B)(6) 2015. SHE RECEIVED TEKTURNA, METOPROLOL, LISINOPRIL, FLUOXETINE, HYOSCYAMINE,ATORVASTATIN, VITAMIN D, VITAMIN B-12, ASPIRIN, FEXOFENADINE HYDROCHLORIDE, AND IMODIUM. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY

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DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND SINCE THEN, EXPERIENCED PAIN AND CHRONIC ABDOMINAL PAIN. SHE WAS SCHEDULED FOR HYSTERECTOMY. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENTS WERE ALSO REPORTED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01747	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FOLLOW-UP INFORMATION IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2273); AWARENESS DATE 29-OCT-2015: ADDITIONAL INFORMATION WAS RECEIVED ON 09-NOV-2015: INFORMATION FROM DUPLICATE CASE (B)(4) HAS BEEN TRANSFERRED TO THIS PRESENT CASE. ESSURE WAS INSERTED IN 2010 AFTER THE BIRTH OF CONSUMER'S THIRD CHILD. SHE BECAME PREGNANT A COUPLE MONTHS AFTER IMPLANTATION AND MISCARRIED VERY EARLY (CASE# (B)(4)). THE HSG SHOWED TUBES COMPLETELY BLOCKED. TWO YEARS LATER THE CONSUMER BEGAN TO FEEL SICK, THROWING UP AND DIZZY. SHE PURCHASED A PREGNANCY TEST WHICH CAME OUT POSITIVE. SHE PERFORMED AN ULTRASOUND IN THE FOLLOWING WEEK THAT CONFIRMED THE PREGNANCY. SHE CALLED ATTORNEY AFTER ATTORNEY TO SEE IF SHE HAD A CASE. SHE WAS AUTOMATICALLY REFERRED TO A SPECIALIST AND WAS TOLD SHE HAD PLACENTA PREVIA AND SUBCHORIONIC HEMATOMA. SHE WAS PUT ON BED REST THE WHOLE TIME AND SHE HAD TO STOP WORKING. SHE BLED THE WHOLE TIME. HOSPITALIZATION WAS REPORTED, BUT THE REASON WAS NOT CLEAR. THE BABY FAILED TO GROW - HIS ABDOMEN WAS MUCH SMALLER THAN HIS HEAD. THE DOCTOR WAS WORRIED A COIL COULD PUNCTURE THE AMNIOTIC SAC. ON THE ULTRASOUND THERE WAS NO SIGN OF EITHER COIL. THEY WERE MISSING. THE MALE BABY WAS BORN HEALTHY EXCEPT FOR ASPIRATING MECONIUM AND HAVING PROTEIN SENSITIVITY TO MILK (CHILD CASE# (B)(4)). SHE WENT IN FOR ANOTHER PROCEDURE AND HAD FILSHIE CLIPS PLACED. THE DOCTOR SAID HER LEFT ESSURE COIL WAS IN PLACE BUT MY RIGHT WAS MISSING. EVERY DAY SHE HAS SEVERE PAIN ON RIGHT SIDE, WHICH WAS DEBILITATING. SHE WENT TO A GYNECOLOGIST WHO WANTED HER TO HAVE ESSURE REMOVED VIA HYSTERECTOMY, BUT SHE WAS (B)(6) AND WAS TERRIFIED AND NEVER VISITED A

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GYNECOLOGIST AGAIN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT (FROM DUPLICATE CASE). PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE EVENTS REPORTED ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE. LACK OF EFFECTIVENESS IN ITSELF IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT AS IT MAY OCCUR WITH THE USE OF ANY PRODUCT. ADDITIONALLY, PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE COMPANY DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL ASSESSMENT, THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT 2 TIMES AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THIS CASE REFERS TO HER SECOND PREGNANCY; DURING WHICH SHE HAD PLACENTA PREVIA AND SUBCHORIONIC HEMATOMA. SHE WAS TREATED WITH BED REST. AFTER DELIVERY, SHE HAD A TUBAL LIGATION. ACCORDING TO HER, THE DOCTOR SAID HER LEFT ESSURE COIL WAS IN PLACE BUT MY RIGHT WAS MISSING (INTERPRETED AS DEVICE DISLOCATION). ONLY PREGNANCY AND DEVICE DISLOCATION ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG). IN THIS PARTICULAR CASE, THE PATIENT HAD THE HSG AFTER HER FIRST PREGNANCY WHICH SHOWED TUBES WERE BLOCKED. SHE BECAME PREGNANT AGAIN. AFTER DELIVERY, ONE COIL WAS DISLOCATED. THIS DEVICE DISLOCATION COULD BE ALTERNATIVE EXPLANATION FOR THE ESSURE FAILURE (PREGNANCY). HOWEVER, SINCE IT IS UNKNOWN IF DEVICE DISLOCATED BEFORE OR AFTER PREGNANCY ONSET; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, PLACENTA PREVIA'S ETIOLOGY IS USUALLY UNKNOWN, ALTHOUGH IT OCCURS MORE COMMONLY AMONG OLDER WOMEN, SMOKERS, WITH PREVIOUS DELIVERIES, CESAREAN SECTIONS OR UTERINE SURGERIES/ SCARS. SUBCHORIONIC HEMATOMAS (SCHS) ARE BELIEVED TO RESULT FROM PARTIAL DETACHMENT OF THE CHORIONIC MEMBRANES FROM THE UTERINE WALL; THEY ARE ASSOCIATED WITH INCREASED RISK OF MISCARRIAGE. IN THIS PARTICULAR CASE, CONSUMER STATED SHE BLED THE WHOLE TIME DURING HER PREGNANCY AND ALSO MENTIONED A HOSPITALIZATION. ALTHOUGH LIMITED INFORMATION WAS PROVIDED; CONSIDERING WHEN ESSURE IS IN ITS IDEAL POSITION, 3 TO 8 OUTER COIL WILL BE TRAILING INTO THE UTERUS; A MECHANICAL INTERFERENCE BETWEEN THE INSERT AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED AND THIS CASE WAS REGARDED AS AN INCIDENT (DUE TO SERIOUS INJURY). IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 03-DEC-2015 - PTC INVESTIGATION RESULT PROVIDED: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE FOR CASES WHE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01748	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/20/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FOLLOW-UP INFORMATION RECEIVED ON 30-OCT-2015 AND UPDATED PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT RECEIVED ON 17-NOV-2015. CASE WAS UPGRADED TO INCIDENT. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEP-2015 (FDA-2014-N-0736-2127). IN 2013, CONSUMER HAD ESSURE INSERTED. THREE MONTH CONFIRMATION TEST SHOWED THAT HER FALLOPIAN TUBES WERE BLOCKED. HER DOCTOR, AS WELL AS THE RADIOLOGIST READING THE HYSTEROSALPINGOGRAM (HSG) ASSURED HER THAT SHE COULD RELY ON ESSURE. SHE MENTIONED THAT THERE WAS A PROBLEM WITH THIS THOUGH, BECAUSE LOCATION OF HER COILS WAS NEVER MENTIONED. OCCLUSION AND LOCATION (GRADE) SHOULD BOTH BE ASSESSED. SHE REQUESTED COPIES OF HSG TESTING AND DISCOVERED THAT HER LEFT COIL AT THAT TIME WAS AT GRADE 3. IT WAS ALSO POSSIBLE THAT HER RIGHT COIL DID NOT EXPAND. IT WAS CLEARLY SHORTER IN LENGTH THAN HER LEFT. IN (B)(6) 2015, A CT SCAN WAS PERFORMED AND SUGGESTED THAT COILS HAD POSSIBLY MIGRATED. AS WELL AS ON THE VERGE OF PERFORATION. SHE WAS SCHEDULED FOR A HYSTERECTOMY IN (B)(6) 2015, MAINLY DUE TO UNTREATABLE CHRONIC PELVIC PAIN. UPDATED PRODUCT TECHNICAL COMPLAINT (PTC): FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE.

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MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAS A HYSTERECTOMY SCHEDULED DUE TO PELVIC PAIN (RANDOM SHARP, STABBING PAINS IN HER PELVIC AREA MOST DOMINANT ON THE RIGHT SIDE) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ADDITIONALLY, SHE STATED A CT SCAN SUGGESTED THAT COILS HAD POSSIBLY MIGRATED. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS OR OUT OF THE BODY) OR MIGRATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) AND CAN RESULT IN PAIN. IN THIS PARTICULAR CASE, DEVICE MIGRATION WAS SUSPECT APPROXIMATELY 3 YEARS AFTER ESSURE INSERTION. ALTHOUGH THE EXACT MECHANISM OF THE EVENTS IS UNKNOWN; GIVEN THEIR NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR DEVICE REMOVAL. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01749	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 676717

Single Use: Y
Implant Date (E6): 12/15/2009
Explant Date (E7): 11/4/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FOLLOW UP INFORMATION RECEIVED ON 30-OCT-2015 AND PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT RECEIVED ON 17-NOV-2015:: CASE UPGRADED TO INCIDENT. THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2204). CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED IN 2009 AND SINCE STARTED TO HAVE MIGRAINE HEADACHES, CHRONIC PELVIC PAIN, MUSCLE SPASMS, BACK PAIN AND MAJOR FATIGUE. SHE HAS A TOTAL HYSTERECTOMY SCHEDULED TO (B)(6) 2015 TO HAVE ESSURE REMOVED. UPDATED PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD VERY HEAVY BLEEDING FOR A WEEK AFTER

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ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. LATER, SHE DEVELOPED CHRONIC PELVIC PAIN. ACCORDING TO HER, SHE HAS A TOTAL HYSTERECTOMY SCHEDULED IN A FEW DAYS FOLLOWING HER REPORT (APPROXIMATELY 6 YEARS AFTER DEVICE PLACEMENT). THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING AND AFTER ESSURE INSERTION, PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR. IN THIS CASE, CONSUMER HAD POST PROCEDURAL BLEEDING FOR A WEEK AND LATER DEVELOPED CHRONIC PELVIC PAIN. SHE ALSO MENTIONED UTERINE FIBROIDS; THESE FIBROIDS COULD BE AN ALTERNATIVE EXPLANATION FOR HER PAIN. HOWEVER, CONSIDERING EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 14-DEC-2015 FROM CONSUMER VIA AUTHORITY REGULATORY (CASE NUMBER MW5058195). ESSURE LOT NUMBER 676717 WAS INSERTED ON (B)(6) 2009 AND A TOTAL HYSTERECTOMY WAS PERFORMED ON (B)(6) 2015 TO HAVE IT REMOVED. CONCOMITANT MEDICA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01750	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2194, AWARENESS DATE 29-OCT-2015) WHICH REFERS TO AN ADULT (>=18Y & <65Y) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 19-NOV-2015. AT TIME OF THE REPORT, THE CONSUMER WAS (B)(6) AND WAS CURRENTLY (B)(6). THE CONSUMER REPORTED SINCE THE ESSURE, SHE BLED HEAVILY UNTIL (B)(6) 2015; THE SEX WAS EXCRUCIATING NOT TO MENTION NO DRIVE, SHE WAS ALWAYS TIRED, BLOATED AND DEPRESSED. SHE STARTED HAVING BREATHING ISSUES AND STILL CURRENT TO THIS DATE ON (B)(6) 2015. ON (B)(6) 2015, SHE COULD NOT STAND THE SHALLOW BREATHING ANYMORE AND WENT TO THE E.R. THERE SHE LEARNED SHE WAS (B)(6) PREGNANT UTERINE AND POSSIBLE ECTOPIC. HER LEFT COIL WAS OUT OF THE TUBE AND SITTING ON HER PELVIC FLOOR. SHE WAS TAKEN TO ANOTHER HOSPITAL ON (B)(6) 2015 AND TAKEN INTO SURGERY THE NEXT MORNING ON (B)(6). THE DOCTOR REMOVED THE LEFT COIL AND LEFT THE RIGHT ONE IN PLACE ALONG WITH TWO CYSTS WHICH WAS THOUGHT TO BE THE ECTOPIC. SHE WAS KEPT TWO-THREE DAYS AFTER THAT TO WATCH HER HCG LEVELS WHICH WENT UP. SHE STATED NOW SHE HAS HAD SURGERY, HAD NUMEROUS EFFECTS AND IS HAVING HER FIFTH CHILD. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT WAS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS

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RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) AND LACK OF EFFICACY ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) OR LACK OF EFFICACY AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLED HEAVILY (INTERPRETED AS GENITAL BLEEDING) SINCE ESSURE INSERTION UNTIL (B)(6) 2015. SHE GOT PREGNANT. HER LEFT COIL WAS OUT OF THE TUBE AND SITTING ON HER PELVIC FLOOR (SEEN AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY). THE DOCTOR REMOVED THE LEFT COIL AND LEFT THE RIGHT ONE IN PLACE. AT TIME OF REPORT, SHE STATED THAT SHE WAS HAVING HER FIFTH CHILD. ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER GOT PREGNANT ABOUT 7 MONTHS AFTER ESSURE INSERTION. IT WAS REPORTED THAT A POSSIBLE ECTOPIC OCCURRED, HOWEVER SINCE THE CONSUMER REPORTED THAT SHE WAS HAVING HER FIFTH CHILD AT TIME OF REPORT (ESTIMATED GESTATIONAL AGE OF (B)(6)), THE ECTOPIC PREGNANCY WAS DISCARDED. THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN. BASED ON THE NATURE OF THE EVENTS AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) OR LACK OF EFFICACY AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01751	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 9/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2166, AWARENESS DATE 29-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013 FOR PERMANENT BIRTH CONTROL. ADDITIONAL INFORMATION WAS RECEIVED ON 05-NOV-2015 (FDA-2014-N-0736-2471). BEFORE ESSURE, THE CONSUMER'S MENSTRUAL CYCLE WAS FAIRLY NORMAL AND PREDICTABLE. AFTER, THIS PATTERN CONTINUED FOR ABOUT 8-9 MONTHS, BUT THEN THINGS STARTED CHANGING - HER PERIODS STARTED LASTING FOR WEEKS RATHER THAN THE USUAL (FOR HER) 6-8 DAYS. EVEN WHEN SHE WAS NOT MENSTRUATING, SHE WOULD EXPERIENCE MENSTRUAL CRAMPING. BY THE END OF 2013, SHE WAS IN PAIN ALMOST EVERY DAY. IN (B)(6) 2014, HER PERIOD STARTED AND CONTINUED UNABATED FOR MORE THAN THREE MONTHS. IT WAS DURING THIS TIME THAT HER DOCTOR STARTED A THOROUGH FACT-FINDING PROCESS, WHICH INCLUDED MULTIPLE BIOPSIES, EXPERIMENTATION WITH DIFFERENT HORMONAL TREATMENTS (ORAL PROGESTERONE, INTRA-UTERINE DEVICE), AND FINALLY A PLANNED DNC (DILATION AND CURETTAGE) AND UTERINE ABLATION. THE ABLATION DEVICE WOULD NOT DEPLOY. WHEN ALL OF THESE PROCEDURES FAILED TO FIND ANY CAUSE OR BRING ANY IMPROVEMENT, HER DOCTOR RECOMMENDED A FULL HYSTERECTOMY, WHICH WAS PERFORMED TOGETHER WITH SALPINGECTOMY ON (B)(6) 2015 TO REMOVE THE DEVICES. HER UTERUS APPEARED INFLAMED ACCORDING TO HER DOCTOR, MEASURING 11.4 X 8.5 X 4.3 CM AND SHOWS A 6.0 CM IN GREATEST DIMENSION AND HER PATHOLOGY REPORT SHOWED ACUTE AND CHRONIC CERVICITIS. CONSUMER DENIED SEXUALLY TRANSMITTED DISEASES. SHE REPORTED THAT SHE KNEW ESSURE WAS MADE OF NICKEL AND SHE MAY HAVE BEEN HAVING

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AN ALLERGIC RESPONSE TO THAT. WHILE IN LAPAROSCOPIC SURGERY HER DOCTOR FOUND A HEMANGIOMA ON LIVER. PRODUCT TECHNICAL COMPLAIN INVESTIGATION: QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER 8-9 MONTHS HER PERIODS STARTED LASTING FOR WEEKS RATHER THAN THE USUAL 6-8 DAYS/ HER PERIOD STARTED AND CONTINUED UNABATED FOR MORE THAN THREE MONTHS (INTERPRETED AS MENORRHAGIA). SHE UNDERWENT A DILATION AND CURETTAGE, AN ATTEMPT OF UTERINE ABLATION (THE ABLATION DEVICE WOULD NOT DEPLOY), AND APPROXIMATELY 2 AND A HALF YEARS AFTER ESSURE INSERTION, UNDERWENT A HYSTERECTOMY WITH SALPINGECTOMY TO REMOVE THE DEVICES. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE MEDICAL AND SURGICAL INTERVENTIONS WERE PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01752	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/12/2004
Explant Date (E7): 8/4/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2209, AWARENESS DATE 29-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION WAS RECEIVED ON 02-NOV-2015 (MW5056970). RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 19-NOV-2015. ON (B)(6) 2004, ESSURE WAS INSERTED AND IMMEDIATELY CONSUMER EXPERIENCED ADVERSE SYMPTOMS, SUCH AS LOSS OF LIBIDO, EXTREME BLOATING, CHANGE IN HER EQUILIBRIUM, JOINT AND MUSCLE PAIN, ABDOMINAL AND BACK PAIN, LEG PAIN, RASHES, EXTREME FATIGUE, DEPRESSION, VERTIGO AND ALLERGY, LIKE SYMPTOMS TO FOOD, MEDICATIONS AND CLEANING SOLUTIONS. SHE WAS TREATED FOR URINARY TRACT INFECTION BUT THE CULTURE WAS NEGATIVE. A CT SCAN WAS PERFORMED AND SHOWED AN INFLAMED KIDNEY. SHE STATED LOOKED FOR PHYSICIAN DUE TO A PLETHORA OF PECULIAR SYMPTOMS. PHYSICIANS COULD NOT DETERMINE WHY SHE WAS SICK OR WHY HER SED RATE WAS ABNORMALLY HIGH. INFLAMMATION LEVEL WAS HIGH (28). METAL TESTS WERE ALSO PERFORMED WHICH WERE NEGATIVE. BY 2009 SHE HAD BECOME SUICIDAL BECAUSE OF EXTENDED AND UNEXPLAINED ILLNESS AND DECIDED TO HAVE ESSURE REMOVED (REMOVAL DATE (B)(6) 2009) BECAUSE SHE HAD NO OTHER MEDICAL OPTIONS. ONE OF HER FALLOPIAN TUBES WAS PERFORATED AND SHE DEVELOPED ENDOMETRIOSIS AROUND THE ESSURE DEVICES. SHE FELT BETTER WHEN SHE AWOKE FROM SURGERY. THE MUSCLE PAINS WERE GONE RIGHT AWAY. ADDITIONALLY, HER SED RATE RETURNED TO NORMAL FOUR MONTHS AFTER HAVING ESSURE REMOVED. WHILE SHE WAS NOT 100 PERCENT WELL, SHE NO LONGER SUFFERS FROM DEBILITATING SYMPTOMS. HOWEVER, SHE WAS

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LIVING WITH CHEMICAL SENSITIVITIES. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2004 AND (B)(6) 2009, ESSURE WAS REMOVED. IT WAS REPORTED THAT ONE OF MY FALLOPIAN TUBES WAS PERFORATED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE) AND ALSO MAY OCCUR, MOST OFTEN DURING INSERTION. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF FALLOPIAN TUBE PERFORATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE, A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. ADDITIONALLY, ANOTHER SERIOUS EVENT (BECOME SUICIDAL - UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT (S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01753	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE NUMBER FDA-2014-N-0736-2260) IN UNITED STATES ON 29-OCT-2015, IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 20-NOV-2015 CONSUMER UNDERWENT A VAGINAL HYSTERECTOMY ON (B)(6) 2015. DUE TO SEVERE HEMORRHAGING, SHE HAD TO BE OPENED UP VIA A LARGE LOWER ABDOMINAL INCISION TO STOP THE BLEEDING. THE HEMORRHAGE RESULTED FROM HER RIGHT FALLOPIAN TUBE DISINTEGRATING UPON BEING CLAMPED. THE SECOND CLAMP APPLIED TO TRY TO CONTROL THE BLEEDING ALSO RESULTED IN TUBE DISINTEGRATION. HER DOCTOR COULD NOT GIVE HER A DEFINITIVE EXPLANATION. SHE IS STUCK WITH HER LEFT TUBE BEING LEFT IN PLACE WITH ESSURE DUE TO A HIGH RISK FACTOR FOR REMOVAL. ADDITIONALLY, HER WOUND DEVELOPED ABSCESSES SIX DAYS POST OPERATION. SHE HAD TO HAVE INCISION REOPENED, AN INCISION AND DRAINAGE PERFORMED, AND A HEMOVAC PUT IN THE 14CM X 4CM X 5CM. SHE STAYED IN THE HOSPITAL FOR FIVE DAYS DUE TO THIS ISSUE. SADLY, SHE HAS A HEMOVAC WOUND CARE MACHINE ATTACHED TO HER AND WILL REQUIRE AT HOME NURSING CARE FOR DRESSING CHANGES. ESSURE HAD CAUSED HER ABDOMINAL BLOATING, WEIGHT GAIN, HEAVY PERIODS, PAINFUL BACK PAIN DURING MENSTRUATION, UNKNOWN ALLERGIC ISSUES AND SUSPECTED TUBAL DEMISE. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED

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DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE HEMORRHAGING (INTERPRETED AS SEVERE GENITAL BLEEDING). DUE TO THIS EVENT, SHE HAD TO BE OPENED UP VIA A LARGE LOWER ABDOMINAL INCISION TO STOP THE BLEEDING. A SUSPECTED TUBAL DEMISE WAS REPORTED. SHE UNDERWENT A VAGINAL HYSTERECTOMY. HER WOUND DEVELOPED ABSCESSES SIX DAYS POST OPERATION. THE EVENT SEVERE HEMORRHAGING IS LISTED IN THE REFERENCE SAFETY INFORMATION WHILE THE OTHERS ARE UNLISTED. THESE EVENTS ARE SERIOUS. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR THE EVENT SEVERE HEMORRHAGING AND CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE EVENT SUSPECTED TUBAL DEMISE, SINCE THIS WAS NOT CONFIRMED AND ADDITIONAL DETAILS ARE REQUIRED TO ASSESS THIS EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. WITH REGARDS TO THE LAST EVENT, SINCE IT OCCURRED POST OPERATION, IT COULD BE RELATED TO THIS PROCEDURE AND NOT A CONSEQUENCE OF ESSURE USE, THUS CAUSALITY CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01754	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2114 / FDA-2014-N-0736-2172, AWARENESS DATE 30-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013, AFTER HER DAUGHTER WAS BORN (SHE WAS A MOTHER OF TWO), FOR PERMANENT BIRTH CONTROL. ADDITIONAL INFORMATION RECEIVED VIA REGULATORY AUTHORITY (CASE NUMBER MW5056900) ON 30-OCT-2015, ON 31-OCT-2015 AND ON 01-NOV-2015. THE CONSUMER REPORTED THAT THEY USED ANESTHETIC IN THE OFFICE TO PLACE THE COILS AND SHE SUFFERED FROM HORRIBLE DRAINING MENSTRUAL CYCLES/ HEAVY PERIODS, HEADACHES/MIGRAINES, AND CHRONIC PELVIC PAIN. SHE STATED SHE HAD NOTHING BUT PROBLEMS SINCE GETTING IT PLACED. HER REGULAR DOCTOR WARNED HER HE WAS PRETTY SURE THAT SHE HAD DEVELOPED A NICKEL ALLERGY AND THAT WAS WHERE HER PAIN WAS POSSIBLY COMING FROM BECAUSE HER BODY STARTED REJECTING CERTAIN EARRINGS/METALS. SHE WAS NEVER CHECKED FOR AN ALLERGY TO THE NICKEL. ABOUT THREE MONTHS AGO, IN (B)(6) 2015, THE PAIN WAS SEVERE, MORE THAN WHAT SHE COULD HANDLE, AND WAS AFFECTING HER HOME LIFE. SHE HAD A PELVIC ULTRASOUND WHICH FOUND ABNORMALITIES IN RELATION TO THE ESSURE. THEN, SHE HAD A NEW ULTRASOUND FOR PLACEMENTS RE-EVALUATION WHICH LED HER TO HAVE SURGERY DONE DUE TO PELVIC PAIN, HEAVY PERIODS AND ALLERGY FROM THE DEVICE. DURING THE PROCEDURE IT WAS NOTICED THAT ONE OF HER TUBES WAS ACTUALLY PERFORATED BY THE ESSURE. OMEPRAZOLE, ZYRTEC AND NORCO WERE REPORTED AS CONCOMITANT MEDICATIONS. THE CONSUMER CONSIDERED THE CASE SERIOUS (IMPORTANT MEDICAL EVENT) AND A SERIOUS INJURY WAS MENTIONED. THE PRODUCT TECHNICAL COMPLAINT

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INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING A SURGERY (UNSPECIFIED), IT WAS DISCOVERED ONE OF HER TUBES WAS ACTUALLY PERFORATED BY THE ESSURE. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE USE. ALTHOUGH IN THIS CASE THE EXACT DATE AND MECHANISM OF THIS PERFORATION HAVE NOT BEEN INFORMED, CONSIDERING ITS NATURE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENT WERE ALSO INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 04-JAN-2016: FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01755	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 5/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK IN SEPTEMBER 2015 (FDA-2014-N-0736-2092). IN (B)(6) 2008, ESSURE WAS INSERTED, WHEN CONSUMER WAS (B)(6) AND ONLY HAD 2 CHILDREN. SINCE THEN, SHE EXPERIENCES CHRONIC PAIN THROUGHOUT HER ENTIRE BODY, BUT ESPECIALLY IN PELVIS, HIPS, LOWER BACK, LEFT LEG THAT WOULD KEEP HER IN BED FOR DAYS, CHRONIC FATIGUE, INSOMNIA TO THE POINT SHE WAS AWAKE FOR ALMOST 48 HOURS BEFORE HER BODY CRASHES ON MANY OCCASIONS OVER THE PAST 7 YEARS, MEMORY ISSUES, VERTIGO, MIGRAINES, SLURRED SPEECH, PERIODS WENT FROM NORMAL TO VERY SPORADIC AFTER THE PROCEDURE (SHE WOULD HAVE 2 PERIODS IN ONE MONTH, SKIP MONTHS, EXTREME BLOOD CLOTS), PELVIC PAIN THAT WAS SO BAD SHE THOUGHT SHE WAS GIVING BIRTH FOR A WEEK, ISSUES WITH INCONTINENCE AND BEING UNABLE TO HOLD HER BLADDER FOR LONG PERIODS OF TIME, EXTREME BLOATING SINCE THE PROCEDURE THAT COMES AND GOES (SO BAD THAT SHE LOOKED LIKE SHE WAS 6 MONTHS PREGNANT). SHE STATED SHE WAS ALSO ALLERGIC TO NICKEL AND WAS UNINFORMED THAT THE COILS CONTAINED NICKEL (SHE USED TO GET SMALL RED BUMPS THAT WOULD ITCH BADLY ALL OVER HER BODY AND REALLY BAD VAGINAL DISCHARGE). MANY BLOOD TESTS, X-RAYS, MRIS CAT SCANS, ULTRASOUNDS WERE PERFORMED AND SHE WAS ON PHYSICAL THERAPY; SHE SAW NEUROLOGIST, CRANIAL SACRAL THERAPIST, PERSONAL TRAINERS FOR THE WEIGHT GAIN WITH NO RELIEF IN HER PAIN OR SYMPTOMS. ON (B)(6) 2015, A BILATERAL SALPINGECTOMY WAS PERFORMED AND THE MAJORITY OF HER SYMPTOMS DISAPPEARED BUT THE REMOVAL DOCTOR LEFT FRAGMENTS OF THE COILS, SO SHE HAD TO UNDERGO A FULL VAGINAL HYSTERECTOMY REMOVING UTERUS AND CERVIX ON (B)(6) 2015. THEN IT WAS DISCOVERED THAT SHE HAD MILD CHRONIC CERVITIS. SINCE HYSTERECTOMY, ALL SIDE EFFECTS

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DISAPPEARED EXCEPT THE PAIN IN LOWER BACK AND HIP. HER MEMORY ISSUES WERE GETTING BETTER AND SHE NO LONGER PRESENTS VAGINAL DISCHARGE NOR INCONTINENCE, VERTIGO, MIGRAINES, SLURRED SPEECH, PELVIC PAIN, ITCHY BUMPS/ RASHES, OR BLOATING. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THEN SHE HAD BEEN EXPERIENCING PELVIC PAIN. SHE HAD TO HAVE A BILATERAL SALPINGECTOMY, BUT THE REMOVAL DOCTOR LEFT FRAGMENTS OF THE COIL, SO A FEW MONTHS LATER SHE HAD TO UNDERGO A FULL VAGINAL HYSTERECTOMY REMOVING UTERUS AND CERVIX. THESE EVENTS, SEEN AS PELVIC PAIN AND DEVICE BREAKAGE ARE SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE SHE HAS BEEN EXPERIENCING PELVIC PAIN AND SEVERAL NON-SERIOUS EVENTS SINCE THE INSERTION. MOST OF THEM (INCLUDING THE PELVIC PAIN) HAVE RESOLVED AFTER HYSTERECTOMY (POSITIVE DECHALLENGE). THUS, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. AS, IN THIS CASE, THE BREAKAGE OCCURRED ASSOCIATED TO DEVICE REMOVAL DURING SALPINGECTOMY, THIS EVENT IS ASSESSED AS RELATED TO ESSURE USE. SINCE TWO INTERVENTIONS WERE REQUIRED (SALPINGECTOMY AND LATER FULL HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01756	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 5/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2113, AWARENESS DATE 30-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL IN AN UNSPECIFIED DATE. THE REPORTER STATED SHE HAD A FRIEND WHO HAD SEVERE SKIN REACTIONS, CONSTANT ABDOMINAL PAIN, AND NEAR CONSTANT BLEEDING AFTER GETTING ESSURE IMPLANTED. SHE HAD OVER A YEAR OF SUFFERING AND MISSED WORK, DEALING WITH FREQUENT DOCTORS APPOINTMENTS AND THEIR RELUCTANCE TO ACKNOWLEDGE THAT HER PROBLEMS WERE CAUSED BY ESSURE, CAUSED EMOTIONAL DISTRESS AND STRESS TO HER FAMILY. SHE HAD A TOTAL HYSTERECTOMY. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT)

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INSERTED AND AFTER THAT, EXPERIENCED CONSTANT ABDOMINAL PAIN AND NEAR CONSTANT BLEEDING. SHE HAD A TOTAL HYSTERECTOMY. THESE EVENTS, SEEN AS ABDOMINAL PAIN AND GENITAL BLEEDING, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING ABDOMINAL PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND THE IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENT WERE ALSO INFORMED. BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01757	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2259, AWARENESS DATE 30-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL IN AN UNSPECIFIED DATE, AFTER HAVING HER THIRD SON. ADDITIONAL INFORMATION RECEIVED ON 22-NOV-2015. THE CONSUMER REPORTED SHE HAD CHRONIC PELVIC PAIN, CHRONIC FATIGUE, LONG HEAVY PERIODS, NUMBNESS IN HANDS AND FEET, VERTIGO, PAINFUL SEX, NO SEX DRIVE, INCREASED MIGRAINES, BLOATING MAKING HER LOOK LIKE SHE WAS 6 MONTHS PREGNANT AND IT WAS JUST TOO MUCH SIDE EFFECTS. HER PHYSICIAN TRIED ALTERNATIVE DRUGS, DID ULTRASOUNDS AND COMPUTERIZED TOMOGRAPHY (CT) SCANS AND COULD NOT FIND WHAT THE ISSUES WERE BEING CAUSED BY. SHE STATED THAT TOLD HIM IT WAS ESSURE. HE FINALLY AGREED TO REMOVE THEM AND SHE WAS HEALING FROM HAVING HER FALLOPIAN TUBES REMOVED ALONG WITH A RESECTION OF HER UTERUS TO ENSURE ESSURE WAS REMOVED INTACT. SHE STATED SHE WAS ALREADY FEELING A MAJOR DIFFERENCE IN HER PAIN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 22-NOV-2015. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT

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REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD CHRONIC PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE UNDERWENT A SALPINGECTOMY ALONG WITH A RESECTION OF HER UTERUS FOR ESSURE REMOVAL. AFTER THE SURGERY, SHE FELT A MAJOR DIFFERENCE IN HER PAIN. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE AND AS IT IMPROVED WITH DEVICE REMOVAL; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01758	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2268, AWARENESS DATE 30-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. ADDITIONAL INFORMATION RECEIVED ON 31-OCT-2015 AND 22-NOV-2015 (PTC INVESTIGATION RESULT). THE CONSUMER REPORTED SHE WAS GIVEN AN ORAL SEDATIVE FOR THE PROCEDURE AND THE PAIN WAS HORRIBLE. THE DOCTOR HAD DIFFICULTY PLACING THE COILS. THE PROCEDURE WAS NOT THE SIMPLE, PAIN-FREE EXPERIENCE THAT IT WAS ADVERTISED TO BE. WEEKS LATER, SHE HAD THE X-RAY TO CONFIRM THE PLACEMENT OF THE COILS. THE DOCTOR TOLD HER SHE WANTED A SECOND OPINION ON THE X-RAY, AND ADVISED HER TO STAY ON HER PREVIOUS BIRTH CONTROL. SHE CALLED HER A FEW WEEKS LATER, AND TOLD HER THAT THE PROCEDURE HAD FAILED. THE DOCTOR ADVISED A TUBAL LIGATION AND SHE WOULD REMOVE THE COILS AT THAT TIME. THE CONSUMER AGREED. THE SURGERY WAS PERFORMED AND THE COILS WERE REMOVED. THE COILS WERE OUTSIDE OF THE FALLOPIAN TUBES, AND EMBEDDED TOGETHER IN HER PELVIC WALL. FOR SEVERAL YEARS, SHE HAD BEEN SUFFERING FROM URINARY TRACT INFECTIONS, SKIN/RASH ISSUES, ABDOMINAL PAIN, SEVERE MENSTRUAL CRAMPS, LOWER BACK, HIP, AND LEG PAIN, TINNITUS, AND MIGRAINES, ETC. IN (B)(6) 2015, NINE YEARS AFTER THE ESSURE COILS WERE REMOVED, THE CONSUMER FINALLY FOUND A MEDICAL PROFESSIONAL THAT ORDERED AN ULTRASOUND. A FOREIGN OBJECT WAS DETECTED IN HER UTERUS. SHE ORDERED AN ABDOMINAL X-RAY. THE OBJECT APPEARED TO BE A COIL FRAGMENT FROM THE ESSURE DEVICE. THE CONSUMER WAS SCHEDULED FOR A HYSTERECTOMY IN (B)(6) 2015. THIS WOULD BE THE SECOND SURGERY THAT SHE WOULD SUFFER DUE TO THE ESSURE

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DEVICE. SHE STATED THAT SHE NOW KNEW ABOUT THE PET FIBERS THAT HAVE CONTAMINATED HER BODY FOR NINE YEARS. HER BODY HAD BEEN POISONED BY THE ESSURE DEVICE, AND SHE DID NOT KNOW HOW THAT WOULD AFFECT HER HEALTH. SHE WAS SCARED AND FRUSTRATED AND ANGRY. A SHARP METAL COIL HAD BEEN CUTTING THROUGH HER INTERNAL ORGANS FOR 9 YEARS. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT COILS OUTSIDE OF THE FALLOPIAN TUBES, EMBEDDED TOGETHER IN HER PELVIC WALL (SEEN AS DEVICE DISLOCATION INTO ABDOMINAL CAVITY). THE COILS WERE REMOVED. NINE YEARS AFTER THE ESSURE COILS WERE REMOVED, IT WAS FOUND THAT A FOREIGN OBJECT WAS DETECTED IN UTERUS, APPEARS TO BE A COIL FRAGMENT FROM THE ESSURE DEVICE (SEEN AS DEVICE BREAKAGE). A SECOND SURGERY (HYSTERECTOMY) WAS SCHEDULED. HER BODY HAD BEEN POISONED BY THE ESSURE DEVICE. ALL EVENTS, EXCEPT FOR METAL POISONING, ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALL EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN. THE DEVICE BREAKAGE MAY HAVE OCCURRED DURING THE FIRST SURGERY WHILE REMOVING THE ESSURE COILS. BASED ON THE NATURE OF THESE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE METAL POISONING, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE IT, THEREFORE A CAUSAL RELATIONSHIP CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED AND A SECOND SURGERY WILL BE PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO THE PRODUCT TECHNICAL COMPLAINT, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT(S) AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01759	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2128, AWARENESS DATE 30-OCT-2015). ADDITIONAL INFORMATION RECEIVED ON 10-NOV-2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. ON (B)(6) 2015 SHE HAD ESSURE REMOVED AFTER 2 YEARS OF PAIN, BLEEDING, BLOATING AND ANXIETY. INTERNAL REVIEW ON 10-NOV-2015: THE CASE (B)(4) WAS IDENTIFIED AS A DUPLICATE OF THIS CASE. CASE (B)(4) WILL BE DELETED FROM BAYER DATABASE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 22-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED,

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SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN AND BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICE WAS REMOVED 2 YEARS AFTER ITS PLACEMENT. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, PELVIC PAIN AND ABNORMAL GENITAL BLEEDING MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENTS NATURE AND IN THE LACK OF ALTERNATIVE EXPLANATIONS; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (SURGICAL INTERVENTION IMPLIED). BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01760	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2252, AWARENESS DATE 30-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER HAD TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6) TO HAVE THE ESSURE DEVICE REMOVED. SHE WAS IN CONSTANT PAIN, HAD TERRIBLE MOOD SWINGS, ALL SHE WANTED TO DO WAS LAY DOWN BECAUSE IT WAS LESS PAINFUL. SHE WOULD WAKE UP NOT BLOATED BUT BY THE END OF THE DAY SHE LOOKED PREGNANT. WHEN SHE HAD THE HYSTERECTOMY HER DOCTOR TOLD THAT HER UTERUS LOOKED 6 MONTHS PREGNANT AND SHE HAD ENDOMETRIOSIS THAT THEY BURNED AWAY. SHE HAD A RASH THAT DEVELOPED AT THE BEGINNING OF THE YEAR THAT LOOKED LIKE MAYBE A NICKEL ALLERGY AND IT LEFT A PERMANENT DARK SPOT ON HER HAND EVEN AFTER THE RASH DISAPPEARED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 22-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED

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MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A RASH THAT LOOKED LIKE A NICKEL ALLERGY. SHE UNDERWENT A HYSTERECTOMY TO REMOVE ESSURE. NICKEL ALLERGY WAS CONSIDERED A SERIOUS EVENT DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THE DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THIS DEVICE IS IMPLANTED. TYPICAL ALLERGY SYMPTOMS REPORTED INCLUDE RASH, PRURITUS, AND HIVES. IN THE PRESENT CASE, THE EXACT TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE EVENT WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01761	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2263, AWARENESS DATE 30-OCT-2015). ADDITIONAL INFORMATION RECEIVED ON 31-OCT-2015 AND ON 22-NOV-2015. IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 FOR BIRTH CONTROL. SHE HAD 5 CHILDREN. CONSUMER REPORTED THAT WITHIN A FEW MONTHS AFTER INSERTION, SHE FOUND OUT SHE HAD HYPOTHYROIDISM, WAS DIAGNOSED WITH CHRONIC FATIGUE SYNDROME AND ALWAYS HAD A WEIRD METAL TASTE IN HER MOUTH. THEN HEAVY PERIODS AND HUGE BLOOD CLOTS STARTED HAPPENING EVERY MONTH. HER PERIODS BEFORE WAS ALWAYS ABOUT 3 DAYS LONG AND SUPER LIGHT. SHE HAD AN HYSTERECTOMY ON (B)(6) 2015 TO REMOVE ESSURE AND FINALLY FELT LIKE HERSELF AGAIN. SHE WOKE UP AND THERE WAS NO METAL TASTE IN HER MOUTH, HER BELLY FROM THE INFLAMMATION OF ESSURE THAT MADE HER LOOK 6 MONTHS PREGNANT HAD GONE DOWN EXTREMELY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 22-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY

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DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HEAVY PERIODS AND HUGE BLOOD CLOTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY, APPROXIMATELY 4 YEARS AFTER ESSURE INSERTION. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01762	BAYER HEALTHCARE LLC	11/27/2015	11/27/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTH CARE PROFESSIONAL IN UNITED STATES ON 30-OCT-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR PERMANENT CONTRACEPTION. PATIENT REQUESTED REMOVAL OF ESSURE, SHE DID NOT HAVE ANY ISSUES BUT JUST WANTED REMOVAL IN LIGHT OF THE RECENT MEDIA ATTENTION ON ESSURE DEVICE. ESSURE INSERTS WERE REMOVED AND HEALTH CARE PROFESSIONAL STATED THAT SHE HAD DIFFICULTY REMOVING THE COILS INTACT. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED. A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THEN, ON UNSPECIFIED DATE, ESSURE

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WAS REMOVED AND IT WAS DIFFICULT TO REMOVE THEM INTACT. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION. CONSIDERING SURGICAL PROCEDURE (HYSTERECTOMY OR SALPINGECTOMY) MAY BE REQUIRED FOR DEVICE REMOVAL AND IN THIS CASE IT WAS INFORMED THAT IT WAS A DIFFICULT EXTRACTION, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058184	BAYER	11/28/2015	12/2/2015

Event Information:

Event Date (B3): 10/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/23/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING ESSURE I HAVE EXPERIENCED MAJOR BLOATING, CRAMPING, WEIGHT GAIN I HAVE BEEN DIAGNOSED WITH HYPOTHYROIDISM AND I AM BEING MONITORED FOR BORDERLINE CHOLESTEROL.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01763	BAYER HEALTHCARE LLC	11/30/2015	11/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/10/2004
Explant Date (E7): 10/22/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2173, AWARENESS DATE 31-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2004. CONSUMER STATED THAT SINCE ESSURE WAS PLACED, SHE BECAME ACCUSTOMED TO VERY HEAVY BLEEDING FOR LONGER TIMES AND THEN IT STARTED HAPPENING MORE THEN ONCE A MONTH. THERE WERE TIMES SHE COULDN'T WALK BECAUSE OF THE PAIN, SHE WAS HAVING CONTRACTIONS ALL THE TIME. HER HYSTERECTOMY WAS ON (B)(6) 2014 AND SHE HAS BEEN PAIN FREE AND SYMPTOM FREE SINCE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND

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NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED VERY HEAVY BLEEDING FPR LONGER TIMES. SHE ALSO SOMETIMES COULDN'T WALK DUE TO PAIN. SHE HAD AN HYSTERECTOMY AND HAS BEEN FREE FOR SYMPTOMS SINCE THEN (POSITIVE DECHALLENGE). THESE EVENTS, SEEN AS PELVIC PAIN AND GENITAL BLEEDING, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND THE POSITIVE DECHALLENGE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01764	BAYER HEALTHCARE LLC	11/30/2015	11/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2145, AWARENESS DATE 31-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT IT WASN'T FAIR SHE FEEL LIKE SHE LOST 5 YEARS OF HER LIFE. SHE WAS AN OLDER PARENT TO HER YOUNGEST CHILD BUT INSTEAD OF BEING WHO SHE WAS PRIOR TO ESSURE SHE STARTED SLOWLY DETERIORATING. SHE WAS ACTIVE AND SHE NEVER HAD HEALTH ISSUES. CONSUMER HAD A GREAT SEXUAL RELATIONSHIP WITH MY HUSBAND. SHE HAD SO MANY GREAT THINGS ABOUT HER THAT ESSURE STOLE FROM HER. SHE FINALLY HAD THEM "DAM" COILS REMOVED BUT SHE WILL NEVER FEEL THE SAME AGAIN. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED. THIS EVENT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED SHE STARTED

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SLOWLY DETERIORATING AFTER ESSURE INSERTION AND ALSO CITED POSSIBLE SEXUAL DISTURBANCES. HOWEVER, MINIMAL INFORMATION WAS PROVIDED AND THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED. ALTHOUGH LIMITED INFORMATION WAS GIVEN IN THIS CASE; CONSIDERING DEVICE REMOVAL WAS REQUIRED, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THEREFORE; THIS CASE WAS CONSIDERED AN INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01765	BAYER HEALTHCARE LLC	11/30/2015	11/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 893028

Single Use: Y
Implant Date (E6): 12/17/2012
Explant Date (E7): 7/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5031846) IN UNITED STATES ON 04-DEC-2013 WHICH REFERS TO HERSELF A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PAIN IN MY ABDOMEN, STOMACH STARTED BLOATING, GAINED OVER 25 POUNDS, UNABLE TO LOSE AN OUNCE EVEN WITH DIET AND EXERCISE, SEVERE SWELLING IN MY FEET THAT CAME AND WENT, METALLIC TASTE IN MY MOUTH, AND TIRED FEELING ALL DAY. THE CONSUMER'S MEDICAL HISTORY INCLUDED PARITY 5 AND DELIVERY. NO INFORMATION GIVEN ON CONSUMER'S DRUG HISTORY, CONCURRENT CONDITIONS AND CONCOMITANT MEDICATION. ON (B)(6) 2012 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED, LOT NUMBER 893028. THE PATIENT HAS BEEN HAVING SEVERE PAIN IN HER ABDOMEN. SHE HAS MISSED SO MUCH WORK DUE TO THE PAIN THAT SHE LOST HER JOB. THE DOCTORS TOLD HER THAT SHE WAS PROBABLY JUST CONSTIPATED AND THEY JUST PRESCRIBED MORE PAIN MEDS WHICH ONLY PUT HER TO SLEEP. AFTER HAVING ESSURE INSERTED, HER STOMACH STARTED BLOATING, LOOKING LIKE AN 8 MONTHS PREGNANT. SHE HAS GAINED OVER 25 POUNDS SINCE THE INSERTION PROCEDURE AND SHE HAS BEEN UNABLE TO LOSE AN OUNCE EVEN WITH DIET AND EXERCISE. SHE HAS HAD SEVERE SWELLING IN HER FEET THAT CAME AND WENT, METALLIC TASTE IN HER MOUTH, TIRED FEELING ALL DAY. ESSURE WAS REMOVED ON (B)(6) 2013. THE EVENT OUTCOME PROVIDED BY THE CONSUMED INDICATED SHE REQUIRED INTERVENTION (NOS). REPORTER CAUSALITY: THE RELATIONSHIP WAS NOT REPORTED. FOLLOW UP RECEIVED ON 14-JAN-2014 AND 22-JAN-2014: THE CONSUMER'S MEDICAL HISTORY INCLUDED A LOOP ELECTROSURGICAL EXCISION PROCEDURE AND REMOVAL OF CANCEROUS TISSUE IN 2006 DUE TO PRESENCE OF PRECANCEROUS CELLS IN CERVIX. ESSURE WAS INSERTED ON (B)(6) 2012 AFTER HER LAST DELIVERY, WHICH TOOK PLACE ON (B)(6) 2012. SHE

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RECEIVED DEPOVERA ON THE SAME DAY OF INSERTION AS BACK-UP CONTRACEPTIVE METHOD. ON (B)(6) 2013 SHE HAD A HYSTEROSALPINGOGRAM PERFORMED AND THE LOCATION OF THE DEVICES LOOKED OK. SHE EXPERIENCED NON- STOP PERIODS IMMEDIATELY AFTER ESSURE WAS INSERTED. ALL OF OTHER SYMPTOMS ALSO BEGAN FOLLOWING THE PROCEDURE. SHE WAS TREATED WITH HYDROCODONE AND IBUPROFEN 600MG AND WENT TO THE HOSPITAL A FEW TIMES, BUT WAS NOT HOSPITALIZED. ON (B)(6) 2013, ACCORDING TO THE CONSUMER'S REQUEST, ESSURE WAS REMOVED VIA SALPINGECTOMY. THE COIL BROKE AS THEY WERE TAKING IT OUT AND SHE STILL HAVING ISSUES, SO WANTS TO HAVE A HYSTERECTOMY PERFORMED. THE PATHOLOGY RESULTS FOLLOWING THE SURGERY INDICATED NO ABNORMALITIES. SHE RECENTLY HAD AN ENDOMETRIOSIS AND A PROLACTIN TESTS PERFORMED AND THE RESULTS WERE NEGATIVE; AN ULTRASOUND SHOWED NO FIBROIDS AND THE PHYSICIAN COULD NOT SEE WHY SHE WAS HAVING HER SYMPTOMS. HER PAIN AND BLEEDING ARE STILL THERE, BUT THE SWELLING DISAPPEARED AFTER THE SURGERY. SHE STILL HAS KIND OF A METALLIC TASTE BUT NOT AS STRONG. SHE REPORTED HOWEVER THAT SHE HAS NOT RECOVERED FROM THE REMOVAL PROCEDURE AND STILL FELLS TERRIBLE. THE CONSUMER CONSIDERED THAT HER EVENTS WERE RELATED TO THE USE OF ESSURE. ATTEMPTS WERE MADE TO CONTACT THE CONSUMER'S PHYSICIAN, BUT NO RESPONSE HAS BEEN RECEIVED YET. PTC INVESTIGATION RESULT RECEIVED ON 24-JAN-2014 THE PTC (PRODUCT TECHNICAL COMPLAINT) GLOBAL NUMBER FOR THIS REPORT IS (B)(4). FINAL ASSESSMENT LOT HISTORY RECORD (LHR) REVIEWED. PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. NO CAPA INVESTIGATION IS REQUIRED PER CRITERIA ESTABLISHED IN (B)(4), PROCESSING ESSURE CASES IN (B)(4). MEDICAL ASSESSMENT THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE FOR A QUALITY DEFICIT PER SE. THE CASE REFERS ALSO TO A DEVICE BREAKAGE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NO. 893028. NO BATCH SIGNAL COULD BE IDENTIFIED. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE REVIEW OF THE LOT HISTORY RECORDS FOUND THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. AT TIME OF THIS MEDICAL EVALUATION THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT QUALITY DEFECT. FOLLOW-UP INFORMATION WAS RECEIVED ON 29-JAN-2014 VIA ESSURE HEALTH CARE PROVIDER GENERAL QUESTIONNAIRE. ON (B)(6) 2012 ESSURE WAS INSERTED 7.5 WEEKS POSTPARTUM. INSERTION PROCEDURE INCLUDED ROUTINE DILATION, NO SOUNDING; PARACERVICAL BLOCK; GETA. MULTIPAROUS CERVIX REQUIRING ALLIS CLAMP AT POSTERIOR CERVIX TO KEEP FLUID IN CAVITY/ALLOW VISUALIZATION; OTHERWISE SIMPLE PROCEDURE/ROUTINE INSERTION. THE VISUALIZATION WAS EASY ONCE CERVIX CLAMPED DOWN. FLUID LOSS WAS LESS THAN 200 ML AND THE PROCEDURE TOOK LESS THAN 20 MINUTES. NO IMAGING WAS DONE ON DAY OF PROCEDURE (JUST DIRECT VISUALIZATION W/HYSTEROSCOPE). DMPA WAS USED AS BACK-UP CONTRACEPTION. HSG (HYSTEROSALPINGOGRAM) WAS SCHEDULED FOR (B)(6) 2013 BUT WAS NOT PERFORMED, SO SHE CONTINUED DMPA. HSG (HYSTEROSALPINGOGRAM) TEST WAS RE-SCHEDULED FOR (B)(6) 2013 AND THE RESULTS CONFIRMED TUBAL PATENCY. NO PERFORATION OCCURRED. PATIENT HAD A MOTOR VEHICLE ACCIDENT (B)(6) 2013 AND HAD IMAGING RELATED TO THAT, BUT NOT RELATED TO ESSURE PROCEDURE (HAS HAD ONGOING PHYSICAL THERAPY APPOINTMENTS AND EMERGENCY DEPARTMENT VISITS FOR PAIN SINCE THE ACCIDENT). THE MVA CAUSED CHRONIC LOW BACK PAIN THAT MAYBE CONFUSING SOME OF HER ABDOMINAL/PELVIC PAIN. ON (B)(6) 2013 (PREVIOUSLY REPORTED AS (B)(6) 2013) BOTH COILS INNER AND OUTER WERE REMOVED IN THEIR ENTIRELY VIA MINI-LAPAROTOMY/BILATERAL SALPINGECTOMY. NORMAL SEEMING PLACEMENT BILATERALLY, NO EVIDENCE OF PERFORATION, BOTH APPEARED TO BE INTACT AND WELL-EPITHELIALIZED. ROUTINE POST-OPERATIVE COURSE AT HOME WITH ROUTINE FU CARE. THE PHYSICIAN DID NOT THINK THAT THE ESSURE DEVICE CAUSED HER WEIGHT GAIN. ALTHOUGH IT WAS POSSIBLE THAT HER ABDOMINAL PAIN WAS RELATED, BUT GIVEN THE CORRECT PLACEMENT AND CONTINUED PAIN EVEN AFTER REMOVAL, IT SEEMS QUITE UNLIKELY. PATIENT WAS HOPING FOR A HYSTERECTOMY AND HAS BEEN REFERRED TO A COLLEAGUE. HIS EVALUATION TO DATE INCLUDING EVALUATION OF ABNORMAL

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BLEEDING WITH EMB, HORMONAL MARKERS AND US) HAS NOT LED HIM TO A DEFINITIVE DIAGNOSIS OR INDICATION FOR SURGERY, SO SHE HAS BEEN REFERRED TO OTHER PROVIDERS. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 25-FEB-2014: NO NEW INFORMATION WILL BE PROVIDED, CASE CLOSED. FOLLOW UP INFORMATION RECEIVED ON 01-NOV-2015: THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2163). CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED IN (B)(6) 2012 AND SINCE INSERTION SHE EXPERIENCED SEVERE CRAMPING, NON STOP BLEEDING, FATIGUE, TONS OF HAIR LOSS, BLOATING LIKE SHE WAS 8 MONTHS PREGNANT AND GAINED 30 POUNDS THAT WOULD NOT COME OFF. SHE HAD A HYSTERECTOMY PERFORMED AND DOCTOR FOUND A PIECE OF ESSURE THAT WAS LEFT IN FROM FIRST SURGERY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN UNSPECIFIED AGE FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GAINED OVER 25 POUNDS / 30 POUNDS, CONSIDERED A SERIOUS EVENT DUE TO MEDICAL IMPORTANCE, UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO EXPERIENCED SEVERE CRAMPING (CONSIDERED SERIOUS AND LISTED). SHE HAD A HYSTERECTOMY PERFORMED AND DOCTOR FOUND A PIECE THAT WAS LEFT IN FROM FIRST SURGERY (SEEN AS DEVICE BREAKAGE, NON-SERIOUS, LISTED). PATIENT REPORTED THAT GAINED OVER 25 POUNDS SINCE THE INSERTION PROCEDURE AND THAT SHE HAS BEEN UNABLE TO LOSE AN OUNCE EVEN WITH DIET AND EXERCISE. LIMITED INFORMATION PROVIDED, BASED ON NATURE OF EVENT AND LOCAL ACTION OF ESSURE, CAUSALITY BETWEEN GAINED OVER 25 POUNDS AND ESSURE USE IS UNLIKELY. WITH REGARDS TO THE OTHER EVENTS, BASED ON THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION, THE NON-SERIOUS EVENTS WERE REPORTED. ESSURE WAS EXPLANTED ABOUT 8 MONTHS AFTER INSERTION, SALPINGECTOMY AND HYSTERECTOMY WERE PERFORMED. AFTER RECEIVING FOLLOW-UP INFORMATION, THIS CASE WAS CONSIDERED AS INCIDENT. ACCORDING TO PRODUCT TECHNICAL INVESTIGATION RESULTS, THERE IS NO REASON TO SUSPECT QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01766	BAYER HEALTHCARE LLC	11/30/2015	11/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# (B)(4), AWARENESS DATE 01-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE STATED THAT SHE HAD ESSURE REMOVED AFTER FINDING OUT THAT IT HAD PERFORATED THROUGH HER FALLOPIAN TUBES. SHE HAS SPENT OVER THE PAST 30 DAYS RECOVERING FROM A BILATERAL SALPINGECTOMY. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A BATCH REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE

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(FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THEN, SHE HAD ESSURE REMOVED AFTER FINDING OUT THAT IT HAD PERFORATED THROUGH HER FALLOPIAN TUBES. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE USE. IN THIS CASE, THE EXACT DATE AND CIRCUMSTANCES OF THIS PERFORATION HAVE NOT BEEN PROVIDED. HOWEVER, CONSIDERING ITS NATURE, PERFORATION IS ASSESSED AS RELATED TO ESSURE AND SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01767	BAYER HEALTHCARE LLC	11/30/2015	11/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2061, AWARENESS DATE 01-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. REPORTER'S WIFE, OVER A YEAR AGO (AROUND 2014) HAD THE ESSURE DEVICE REMOVED. SHE HAS MULTIPLE AILMENTS, ACHES AND PAINS, NAUSEA, HEADACHES, CRAMPING, SORENESS AND STIFF JOINTS MUSCLE PAINS. SHE HAS NOT FELT LIKE HERSELF, SHE SUFFERS FROM MOOD SWINGS, CHEST PALPITATIONS AND PANIC ATTACKS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND

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NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ACHES AND PAIN. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE ESSURE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENTS WERE ALSO INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01768	BAYER HEALTHCARE LLC	11/30/2015	11/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2095, AWARENESS DATE 01-NOV-2015). ADDITIONAL INFORMATION RECEIVED ON 22-NOV-2015 (PTC INVESTIGATION RESULT). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. CONSUMER REPORTED CHRONIC DAILY MIGRAINES, PERFORATED FALLOPIAN TUBE, HER LEFT ESSURE COIL WAS FOUND OUTSIDE HER TUBE IN THE SOFT MUSCLE TISSUE BETWEEN HER UTERUS AND PELVIC AREA. SHE NOW HAS LUPUS WHICH DOES NOT RUN IN HER FAMILY. SHE COULD NO LONGER PLAY WITH HER CHILDREN BECAUSE OF THE DEBILITATING PAIN SHE HAS BEEN LEFT WITH. SHE USED TO BIKE RIDE, SHE WAS AN AVID CYCLIST 30 MILES PER DAY, NOW SHE COULD BARELY WALK TO HER CAR. SHE DID NOT BELIEVE IN TAKING MEDICATION. SHE IS NOW ON 100MG OF TOPAMAX, 1200MG OF GABAPENTIN, 30MG OF A MUSCLE RELAXER, SHE WAS TAKING IMITREX INJECTIONS DAILY, 60MGS OF CYMBALTA, AND SHE IS ABOUT TO START A TREATMENT THEY GIVE YOU FOR MALARIA. SHE WAS 173CM AND STRUGGLE TO STAY AT (B)(6), MOST OF THE TIME SHE WEIGHED LESS THAN (B)(6) NOW. SHE WAS BASICALLY BEDRIDDEN SINCE ESSURE. SHE GOT ESSURE IN (B)(6) 2010 AND IT TOOK TWO SURGERIES TO REMOVE IT. ONE SURGERY (B)(6) 2015, AND A SECOND (B)(6) 2015. DURING THE CT AND BLOOD WORK THEY FOUND TUMORS ON HER UTERUS AND NODES ON HER LIVER, ALL TIED TO ESSURE. HER WHITE BLOOD CELL COUNT WAS AT A 10. SHE WAS TIRED ALL THE TIME. SHE COULD BARELY WAKE UP, OR MOVE DUE TO THE PAIN. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED.

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SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED A PERFORATED FALLOPIAN TUBE AND HER LEFT ESSURE COIL FOUND OUTSIDE HER TUBE IN THE SOFT MUSCLE TISSUE BETWEEN UTERUS AND PELVIC AREA. SHE UNDERWENT TWO SURGERIES IN ORDER TO REMOVE ESSURE. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF THE REPORTED EVENTS WERE NOT KNOWN, HOWEVER GIVEN THEIR NATURE AND CONSIDERING THAT THERE IS A RISK THAT THE DEVICE COULD PERFORATE THE FALLOPIAN TUBES AND COULD ALSO MIGRATE THROUGH THE FALLOPIAN TUBE, A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01769	BAYER HEALTHCARE LLC	11/30/2015	11/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2266, AWARENESS DATE 01-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. ADDITIONAL INFORMATION RECEIVED ON 23-NOV-2015. THE CONSUMERS DAUGHTER REPORTED THAT SOON AFTER THE PROCEDURE, HER MOTHER BEGAN EXPERIENCING AUTOIMMUNE-LIKE SYMPTOMS, ALMOST AS IF SHE WERE IN THE MIDST OF A LUPUS OR FIBROMYALGIA FLARE-UP HOWEVER, SHE DID NOT HAS AN AUTOIMMUNE DISEASE, SHE HAD ALWAYS BEEN PERFECTLY. AS THE YEARS PASSED, AND SHE GOT WORSE, SHE WAS CONSTANTLY IN PAIN, A MAJOR PROBLEM FOR A PERSON WHOSE CAREER REQUIRED MOVEMENT ACTIVITY, AND TAKING CARE OF OTHER PEOPLE. SHE ALSO EXPERIENCED NEUROLOGICAL SYMPTOMS, QUITE LIKE A LUPUS FOG (THE REPORTER STATED SHE KNEW BECAUSE SHE WAS DIAGNOSED WITH LUPUS IN THE MIDDLE OF HER MOTHERS ILLNESS). SHE REPORTED THAT IMPORTANT MOMENTS OF THEIR FAMILY'S LIVES HAVE GOTTEN LOST IN HER HEAD. SHE REPORTED HER MOTHER KNEW INSTINCTIVELY WHAT WAS WRONG ALMOST RIGHT AWAY; HOWEVER, IT TOOK YEARS TO CONVINCE HER DOCTOR TO TAKE A CLOSER LOOK; IT WAS LIKE SHE WAS A STEREOTYPICAL HYSTERICAL WOMAN. WHEN THE DOCTOR FINALLY LOOKED, WHAT SHE FOUND THAT HER INSIDES (UTERUS, ETC.) HAD ALL BECOME FUSED TOGETHER BY SCAR TISSUE, LIKE A SPIDER WEB; AND THE ONLY SOLUTION WAS A TOTAL HYSTERECTOMY. THE REPORTER STATED THAT ESSURE DID THAT TO HER. SHE WAS RELATIVELY PAIN-FREE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 23-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY

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RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD CONSTANT PAIN AFTER ESSURE INSERTION AND WAS SUBMITTED TO SURGICAL INTERVENTION. ACCORDING TO THE REPORTER, DURING THIS PROCEDURE IT WAS FOUND THAT CONSUMER'S INSIDES (UTERUS, ETC.) HAD ALL BECOME FUSED TOGETHER BY SCAR TISSUE, LIKE A SPIDER WEB. SHE HAD TO HAVE A TOTAL HYSTERECTOMY. ONLY PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. REPORTER STATED CONSUMER HAD PAIN AND WAS SUBMITTED TO A HYSTERECTOMY (DATE OF THIS PROCEDURE NOT INFORMED). DURING THE SURGERY, SCAR TISSUE WAS FOUND IN HER PELVIS. THIS SUGGEST CONSUMER HAD PELVIC ADHESIONS; HOWEVER NO INFORMATION WAS GIVEN ABOUT PRIOR HISTORY (PREVIOUS SURGERIES), CONCOMITANT CONDITIONS (SUCH AS ENDOMETRIOSIS OR DIVERTICULOSIS) OR ESSURE LOCATION TO CONCLUDE ON A POSSIBLE ETIOLOGY FOR THESE ADHESIONS. THEREFORE, CAUSALITY BETWEEN THE REPORTED SCAR TISSUE AND ESSURE CANNOT BE ASSESSED. REGARDING CONSUMER'S PAIN; AS IT RECOVERED AFTER DEVICE REMOVAL AND SINCE ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY; A CONTRIBUTORY ROLE OF THE SUSPECT DEVICE CANNOT BE TOTALLY RULE OUT. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE FROM HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058160	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 12/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IMMEDIATELY UPON INSERTION OF THE DEVICES, I BEGAN BLEEDING PROFUSELY. I WAS TOLD THAT SPOTTING IS NORMAL FOR THE FIRST FEW DAYS. THE HEAVY BLEEDING CONTINUED FOR 13 DAYS. MY PERIODS BECAME LONGER AND HEAVIER, AND THE DAYS BETWEEN CYCLES BECAME SHORTER AND SHORTER. WITHIN 10 MONTHS, I HAD NO DAYS BETWEEN CYCLES. I EXPERIENCED LOW BACK PAIN SO BAD I WAS NO LONGER ABLE TO PICK UP MY 9 MONTH OLD BABY. MY LEGS WOULD GIVE OUT OR IF I BENT DOWN TO PICK UP MY BABY, I WOULD BLEED OUT OF MY SUPER TAMPON AND BACK UP MAXI PAD. I DEVELOPED HAIR LOSS. I HAD LESIONS ON MY SCALP THAT WOULD BLEED FOLLOWED BY BALD SPOTS. CRAMPING AND PELVIC PAIN TO THE POINT I WAS NOT ABLE TO FUNCTION WITHOUT TAKING MEDICATIONS ((B)(6), IBUPROFEN, EXTRA STRENGTH (B)(6)) IMMEDIATELY UPON WAKING. I WOULD HAVE CLOTS THE SIZE OF SOFT BALLS. THROUGHOUT THE WHOLE 13 MONTHS, I HAD THE ESSURE DEVICE, I DEVELOPED ANXIETY. THIS BECAME TOO MUCH! I REFUSED TO LEAVE THE HOUSE, TERRIFIED THAT I MAY BLEED THROUGH MY CLOTHING. AFTER 68 DAYS OF BLEEDING ON (B)(6) 2015, I HAD A LAVH/BS. THE MINUTE I WOKE FROM SURGERY, THE LOW BACK PAIN WAS INSTANTLY GONE. MY SCALP NO LONGER FELT LIKE IT WAS ON FIRE AND I WAS ABLE TO MOVE WITHOUT MY LEGS GOING OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058161	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 12/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, BLOOD CLOTS, HEADACHE, ABDOMINAL PAIN, BRAIN FOG, METALLIC TASTE, AND ALWAYS THIRTY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058162	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 7/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD CHRONIC PELVIC PAIN AND DIAGNOSE WITH SYNCOPE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058163	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 12/17/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AT TIME OF OVULATION, LEFT HIP HURT TO THE POINT OF NOT BEING ABLE TO WALK UPSTAIRS. CONTINUED TO GET WORSE. NOW, ONE YEAR LATER, BOTH HIPS HURT AT TIME OF OVULATION, MY HAIR IS BEGINNING TO FALL OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058164	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 4/2/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

B)(4). I WAS IMPLANTED IN B)(6) 2007. IN B)(6) 2014 I WAS DIAGNOSED WITH MULTIPLE SCLEROSIS. I FEEL THAT THIS WAS CAUSED BY CHRONIC INFLAMMATION FROM ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058165	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 3/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER GETTING THE ESSURE DEVICES, OVER THE COURSE OF A COUPLE OF YEARS, I DEVELOPED A NUMBER OF SYMPTOMS. EVEN THOUGH I HAVE ALWAYS BEEN ALLERGIC TO NICKEL, THE DOCTOR SAID IT WAS A SAFE DEVICE AS THE MANUFACTURER SAID THERE SHOULDN'T BE SIDE EFFECTS. FIRST AND FOREMOST, I'VE ALWAYS HAD EASY, CONSISTENT, AND SHORT MENSTRUATION. AFTER THE DEVICE, MY PERIODS GOT WORSE AND WORSE - NEAR THE END (BEFORE HAVING THE ESSURE REMOVED) MY MENSES WERE PRECEDED BY EXCESSIVE FATIGUE, FEVERS, HORRIBLE HEADACHES, DIZZINESS, AND THE PERIODS THEMSELVES WERE VERY HEAVY AND LASTED UP TO TEN DAYS, WITH BIG CHUNKS OF BLOOD CLOT LOOKING THINGS COMING OUT. THEY WERE ALSO LESS REGULAR. AFTER REMOVING THE ESSURE, MY PERIODS RETURNED TO 3-4 DAY, LIGHT MENSES WITH NO ABNORMAL SYMPTOMS (DIZZINESS, FEVERS, ETC). I ALSO EXPERIENCED AN OVERALL GENERAL MALAISE AND FATIGUE. I GOT TESTED FOR SO MANY THINGS DURING THIS TIME AND THE DOCTORS DIDN'T KNOW WHAT WAS WRONG. I JUST FELT SICK ALL OF THE TIME AND NEVER WANTED TO GO OUT OR DO ANYTHING BECAUSE IT TOOK ENERGY I NO LONGER HAD. THIS WASN'T DEPRESSION AT ALL, IT WAS MY BODY THAT JUST HURT. I HAD HEADACHES EVERY DAY, AND ALSO DEVELOPED A LONG LIST OF FOOD INTOLERANCES. NOT SURE IF THE ALLERGIES/INTOLERANCES ARE CONNECTED BUT IT'S WORTH MENTIONING SINCE I'VE HEARD OTHER WOMEN WITH THE SAME SIDE EFFECTS. I GAINED WEIRD BELLY BLOAT EVEN THOUGH I WAS EATING STRICTLY AND TRAINING FOR A MARATHON AT ONE POINT. AS A NOTE, ALL OF THESE PROBLEMS HAVE GONE AWAY POST REMOVAL EXCEPT THE FOOD INTOLERANCES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058166	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 9/15/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

B)(4). AFTER HAVING THE ESSURE, I HAVE HAD MY GALL STONES REMOVED, HEAVY BLEEDING FROM MY SNAP DURING MENSTRUAL, TEMORS, MIGRAINES TWO OR THREE TIMES A DAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058167	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 11/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

B)(4). DEVICE WAS PAID FOR PARTIALLY BY INSURANCE. I HAD HORRIBLE PERIODS. HEAVY BLEEDING AND CRAMPS. MY HAIR FELL OUT IN HANDFULS AND STILL DOES. I HAD BRAIN FOG REAL BAD AND COULD NOT ARTICULATE A INTELLIGENT COMPLETE THOUGHT. THE COIL MIGRATED TO THE END OF MY FALLOPIAN TUBE ON THE RIGHT SIDE AND CAUSED ME HORRIBLE PAIN. AND I HAD BLEEDING AFTER SEX AND BETWEEN PERIODS. I HAD TO HAVE A FULL HYSTERECTOMY TO REMOVE THE DEVICE. I HAD A HUGE PYLLUP IN MY CERVIX

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058168	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 10/15/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

B)(4). I HAD ESSURE PLACED IN B)(6) 2006. A FEW MONTHS LATER I STARTED HAVING SWELLING AND PAIN IN MY HANDS, FEET AND OTHER JOINTS. I WAS ALSO STARTING TO BE VERY WORN OUT ALL OF THE TIME. I WAS TOLD THAT I HAD RHEUMATOID ARTHRITIS. NINE YEARS LATER ON B)(6) 2015 I HAD THE ESSURE REMOVED. WITHIN TWO WEEKS I WOKE UP WITH MY FEET NOT SWOLLEN FOR THE FIRST TIME IN 9 YEARS. I COUPLE MORE WEEKS AND I HAD MORE ENERGY AGAIN. IT HAS BEEN A MONTH AND THE DIFFERENCE IS AMAZING. OBVIOUSLY, A REACTION CHANGE SO SWIFTLY AFTER THE ESSURE REMOVAL IS NOT COINCIDENCE. I AM CONTINUING TO REHAB BUT THINGS ARE PROGRESSING IN THE RIGHT DIRECTION. ESSURE TOOK 9 YEARS OF MY LIFE. MY DAUGHTER, WHO WAS ONLY 3 AT THE TIME OF PLACEMENT DOESN'T EVEN KNOW A HEALTHY MOTHER. I AM SO ANGRY THAT NOBODY BELIEVED ME. PLEASE GET THIS DEVICE OFF OF THE MARKET, OR AT LEAST PUT WARNINGS ON IT SO THAT OTHERS HAVE MORE LEVERAGE TO GET THEM REMOVED EARLIER.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058169	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 11/8/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE THE ESSURE PROCEDURE I HAVE HAD DAILY PAIN IN MY LOWER ABDOMEN. A SHARP STABBING PAIN SO SEVERE THAT I HAVE ACTUALLY DROPPED TO MY KNEES OR I AM UNABLE TO WALK FOR A PERIOD OF TIME. LOWER BACK PAIN AS WELL AS OTHER SIDE EFFECTS OF MAJOR DEPRESSION, WEIGHT GAIN, STOMACH BLOATING, PAINFUL AND LONGER MENSTRUAL CYCLES. I HAVE NEVER FELT MORE MISERABLE IN MY LIFE! BIGGEST MISTAKE WAS HAVING THE ESSURE PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058170	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 8/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). VAGINAL HYSTERECTOMY W/ BILATERAL SALPINGECTOMY SCHEDULED 09:30:00 (B)(6) 2016 AT (B)(6) WITH DR (B)(6). PER PRE-OP CONSULT WITH DR (B)(6) 2016, DR (B)(6) DECLINED MY REQUEST TO TAKE ABDOMINAL RADIOGRAPHS STATING SHE WILL SEE WHAT TO REMOVE DURING SURGERY. SHE DID NOT RECOMMEND ABDOMINAL SURGERY, RATHER LAPAROSCOPIC WITH REMOVAL THROUGH THE VAGINA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058171	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

B)(4). FIBROIDS, LOSS OF LIBIDO, HEAVY AND PAINFUL MENSES, DIZZINESS, URGENCY TO URINATE WITHOUT MUCH URINE, FATIGUE, PAIN DURING ORGASM (2015).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058172	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 2/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS PRODUCT WAS INSERTED BY A PREVIOUS DOCTOR. SERIOUS PAIN WHILE BEING INSERTED. CAUSED SEVERE CRAMPING, LOWERED SEX DRIVE, LEG CRAMPS, OVERALL FATIGUE. EVEN THOUGH THE 6 WEEK TEST CAME BACK POSITIVE FOR OCCLUSION, THE COIL MIGRATED AND EMBEDDED INTO MY UTERUS. I HAD A HYSTERECTOMY TO GET RID OF IT AND ONGOING ISSUES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058173	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 6/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LEFT SIDE SHARP ABDOMINAL PAIN, DURING INTERCOURSE, HAVING A BOWEL MOVEMENT, STANDING UP QUICK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058174	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 11/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME BACK PAIN,PELVIC PAIN AND INFLAMMATION. HOSPITALIZED FOR INFLAMMATION. PAINFUL AND INFLAMED PELVIC ORGANS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058175	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 4/29/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN EASIER WAS PLACED MY INSURANCE COVERED IT. NOW THAT I HAVE TO HAVE A PARTIAL HYSTERECTOMY DUE TO COMPLICATIONS I HAVE TO PAY FOR IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058176	BAYER	11/30/2015	11/30/2015

Event Information:

Event Date (B3): 3/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING THE DEVICE FOR THREE YEARS, MY LEFT HIP HURTING AT THE TIME OF OVULATION. IT PROGRESSIVELY GOT WORSE TO THE POINT WHERE I COULD NOT WALK UP STAIRS DURING THAT TIME EACH MONTH. IT HAVE PROGRESSED NOW TO BOTH HIPS HURTING, FREQUENT HEADACHES, HAIR FALLING OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058257	BAYER	11/30/2015	12/3/2015

Event Information:

Event Date (B3): 1/8/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4): ESS305
Lot #(E4): C91740

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN (B)(6) 2015. A FEW MONTHS LATER I STARTED EXPERIENCING MIGRAINES, CONSTANT BLOATING/GAS, LOWER BACK PAIN, WEIGHT GAIN, ABDOMINAL PAIN, NIGHT SWEATS AND NO PERIOD.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01662	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON 02-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2002. CONSUMER WAS EXPERIENCING CONSTANT SEVERE VAGINAL PAIN (INCLUDING WHEN SITTING DOWN AND DURING SEXUAL INTERCOURSE), HEADACHES TREATED BY NEUROLOGISTS WITH CHRONIC MIGRAINE TREATMENT, POLY AND HYPERMENORRHOEA, WHICH HAS RESULTED IN A CONTINUOUS ALARMING IRON DEFICIENCY WITH THE CONSEQUENT CONSIDERABLE PHYSICAL EXHAUSTION. IN (B)(6) 2015, HER GYNAECOLOGIST WAS CONCERNED ABOUT THE BLEEDING AND PERFORMED AN ABDOMINAL ULTRASOUND, NOTICING A FOREIGN BODY IN THE UTERUS WHICH WAS COMPATIBLE WITH ESSURE. IN (B)(6), SHE WAS ADMITTED FOR AN OPERATIVE HYSTEROSCOPY AND IT WAS SEEN THAT THE LEFT ESSURE HAD MOVED AND 10-12 COILS WERE PROTRUDING FROM THE FALLOPIAN TUBE. THESE COILS WERE THEN CUT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ESSURE HAD MOVED AND 10-12 COILS WERE PROTRUDING FROM THE FALLOPIAN TUBE. AN OPERATIVE HYSTEROSCOPY WAS PERFORMED AND THE COILS WERE CUT. THIS EVENT, INTERPRETED AS DEVICE DISLOCATION, IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION WERE NOT KNOWN, HOWEVER GIVEN ITS NATURE A CAUSAL RELATIONSHIP WITH ESSURE THERAPY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY,

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NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FURTHER INFORMATION IS EXPECTED, AS THE REPORT WAS RECEIVED VIA THE LOCAL REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 07-JAN-2016. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: IN THIS CASE NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER F

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01663	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 645013

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# (B)(4)) IN SPAIN ON 02-NOV-2015 WHICH REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 645013, INSERTED IN 2011. CONSUMER IS (B)(6) AND STATED SHE HAS SEVERAL HEALTH PROBLEMS SINCE 2011. AFTER HAVING THREE CHILDREN SHE DECIDED TO UNDERGO TUBAL LIGATION. WHEN SHE WENT TO THE GYNECOLOGIST, HE OFFERED HER THIS NEW METHOD THAT DID NOT REQUIRE SURGERY. SHE NOW HAS GENERALIZED MUSCLE PAIN, STOMACH PROBLEMS, CONSTANT HEADACHES, TIREDNESS, DEPRESSION, MEMORY LOSS, VERY HEAVY MENSTRUAL BLEEDING WITH CLOTS AND A LOT OF PAIN, ABDOMINAL BLOATING, ETC. AND SHE NOW HAS TO UNDERGO MAJOR SURGERY TO REMOVE HER FALLOPIAN TUBES AND UTERUS. SHE STATED THERE IS NO OTHER WAY TO FIX IT AND, MOREOVER, NO ONE TOLD HER THAT THEY CONTAIN NICKEL. SHE WAS ALWAYS TOLD THAT IT WAS TITANIUM. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD A LOT OF PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, SHE HAS TO UNDERGO MAJOR SURGERY TO REMOVE HER FALLOPIAN TUBES AND UTERUS. THIS EVENT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR DURING ESSURE THERAPY. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, CONSIDERING EVENT'S NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE ACCORDING TO THE CONSUMER; A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 07-JAN-2016. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). BATCH NUMBER 645013. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01664	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): 10/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT EXTRACTED FROM A BLOG (INTERVIEW WITH THE CONSUMER WHICH WAS PUBLISHED INTO A BLOG) IN (B)(4) ON 02-NOV-2015. IT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN (B)(6) 2008. SHE WAS (B)(6) AT THE TIME OF THIS REPORT. DURING IMPLANTATION SHE HAD A TERRIBLE AND SHARP PAIN WHEN THE LEFT-HAND ONE WAS IMPLANTED. SHE WAS GIVEN A PAINKILLER AND WENT HOME. THEY TOLD HER THAT PAIN COULD BE NORMAL, BECAUSE OF THAT COMPLICATION DURING THE IMPLANTATION OF THE LEFT-HAND ONE. TWO DAYS LATER SHE WENT TO HER GP AND HE TOLD HER THAT THE PAIN AND DISCOMFORT WAS FROM THE ESSURES. HE PRESCRIBED IBUPROFEN AND TOLD HER TO WAIT FOR THE 3-MONTH CHECK-UP. SHE STATED SHE SPENT MORE TIME WITH HER HUSBAND IN THE EMERGENCY ROOM THAN AT HOME. SHE EXPERIENCED WAIST PAIN, HER LEGS WOULD GO TO SLEEP, PAIN IN THE OVARIES, KIDNEYS, TREMENDOUS HEADACHES AND SHE FELT TERRIBLE ALL DAY LONG, INTERCOURSE WAS IMPOSSIBLE BECAUSE OF THE PAIN AND THE BLEEDING AFTERWARDS, HEAVY BLEEDING, HER BELLY WAS CONSTANTLY SWOLLEN AND IT BECAME A COMPLEX. SHE WENT TO HOSPITAL WITH HER PAIN AND THEY SAW A CYST ON ONE OF THE TUBES AND TOLD HER THAT THE ESSURE WAS CREATING A PROBLEM. THE NEXT TIME SHE WENT THEY EXAMINED HER AGAIN AND SAID THAT IT WAS NOTHING TO DO WITH THE ESSURE, AND THAT SHE DIDN'T EVEN HAVE A CYST. FOUR YEARS LATER, IN THE EMERGENCY ROOM AGAIN, THEY TOLD HER THAT SHE HAD A "POLYP." THEY WANTED TO REMOVE IT WITH SOME TWEEZERS, WHICH SHE REFUSED. SHE VISITED THE KIDNEY SPECIALIST, IN CASE THE PAIN WAS FROM THE KIDNEYS, AND HE WAS SURPRISED THAT SHE HAD NOT HAD BLOOD TESTS, A RESONANCE OR ANY OTHER TESTS AFTER 4 YEARS. HE DID EVERYTHING, SEVERAL SPECIAL URINE AND FAECAL TESTS AND AN MRI WITH CONTRAST AGENT. THE RESULTS WERE: CYSTS AND VARICOSE VEINS ON THE OVARIES, TUMOURS ON THE FALLOPIAN TUBES AND

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MYOMAS IN THE WOMB, SO SHE WAS TOLD TO GO TO HER GYNAECOLOGIST TO REMOVE THE ESSURES IMMEDIATELY. SHE WENT TO THE GYNAECOLOGIST AND HE SAID THE UROLOGIST WAS MISTAKEN, THE MRI MUST BE MISTAKEN BECAUSE THE ESSURES WERE FINE. IN HER DESPAIR SHE WENT TO A PRIVATE PHYSICIAN OFFICE IN ORDER TO GET ANOTHER OPINION, AND HE REPORTED EXACTLY THE SAME AS THE UROLOGIST, TUMOURS, CYSTS. THEN THEY SAID THEY WOULD DO A C-SECTION. THEY OPERATED HER AND TOLD HER WHEN THEY FIRST VISITED HER ON THE WARD THAT THE ESSURE WAS OUT AND THAT HER TUBES WERE TIED. BUT THE NEXT DAY, A NEW DOCTOR CAME TO SEE HER AND TOLD HER THAT THEY REMOVED THE ESSURE AND ALSO HER FALLOPIAN TUBES. AFTER THAT SHE HAD A FEVER THEY TOOK HER DOWN AGAIN; AFTER AN ULTRASOUND SCAN, THE DOCTOR SAID THAT HER BELLY WAS COVERED IN HAEMATOMAS, INSIDE AND OUT. FOUR MONTHS AFTER SHE WAS DISCHARGED, SHE WAS UNWELL AGAIN, WITH PAIN, AND SHE WENT TO THE DOCTOR AGAIN. AFTER EXAMINING HER, HE ASKED HER WHY THEY HAD LEFT HER OVARIES IF THEY WERE NOT IN A GOOD CONDITION. SO A YEAR LATER SHE WAS BACK IN THE OPERATING THEATRE TO CLEAN EVERYWHERE, REMOVE THE OVARIES AND FOR CURETTAGE OF THE UTERUS, AFTER UNDERGOING MORE TESTS, INCLUDING A COLON TEST. THE PAIN RETURNED ON THE LEFT SIDE, ALTHOUGH SHE WAS MUCH BETTER FOR A TIME AND LIFE WAS GETTING BACK TO NORMAL. SO AGAIN AT THE DOCTOR'S, HE SAID THE ONLY THING TO DO WAS TO OPEN HER UP TO SEE WHAT THEY'VE DONE AND WHAT WAS GOING ON IN HER BODY. THEY HAD HER IN THE OPERATING ROOM, WITH ALL HER ORGANS OUT, CLEANING UP AS BEST THEY COULD. THE EXPLANATION WAS THAT THEY DAMAGED THE LEFT SIDE DURING THE IMPLANTATION OF THE ESSURE, PERFORATING THE WALLS, AND THAT A MISTAKE IN GYNAECOLOGY HAD ALSO LEFT BEHIND TRACES OF THE ESSURE. AND AFTER AN MRI THEY TOLD HER TO BE OPERATED AGAIN, CLEANING THE LEFT SIDE, BECAUSE EVERYTHING WAS DUE TO THAT FIRST SURGERY WHEN THEY IMPLANTED ESSURE AND DID THAT DAMAGE ON THE LEFT SIDE. SHE STATED THAT EVENT THOUGHT OF SUICIDE. SHE WAS WAITING FOR A FINAL OPERATION. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD HER UTERUS DAMAGED ON THE LEFT SIDE DURING THE IMPLANTATION OF THE ESSURE, PERFORATING THE WALLS. SHE WAS SUBMITTED TO A SURGERY AND WAS TOLD THEY REMOVED THE ESSURE AND HER TUBES. AFTER THIS PROCEDURE HER BELLY WAS COVERED IN HAEMATOMAS, INSIDE AND OUT. FEW MONTHS LATER, SHE RETURNED TO HER PHYSICIAN DUE TO PAIN AND WAS SUBMITTED TO A NEW SURGERY. SHE WAS INFORMED A MISTAKE IN GYNECOLOGY HAD LEFT BEHIND TRACES OF THE ESSURE (REGARDED AS DEVICE BREAKAGE). ADDITIONALLY, SHE WAS DIAGNOSED WITH CYSTS ON THE OVARIES, TUMOURS ON THE FALLOPIAN TUBES, MYOMAS IN THE WOMB AND HAD THOUGHT OF SUICIDE. ALL EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ONLY UTERINE PERFORATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE PERFORATION MAY OCCUR WITH ANY TRANS-CERVICAL INTRAUTERINE PROCEDURE; INCLUDING INSERTION OF ESSURE. THIS EVENT CAN BE SUSPECTED IF EXCESSIVE PAIN OR DISCOMFORT OCCURS DURING THE PROCEDURE. ALSO, SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED. IN THIS PARTICULAR CASE, CONSUMER REPORTED PAIN DURING ESSURE INSERTION; WHICH PERSISTED IN THE MONTHS FOLLOWING THE PROCEDURE. SHE WAS SUBMITTED TO A SALPINGECTOMY AND ACCORDING TO HER; TRACES OF ESSURE WERE LEFT BEHIND (SUGGESTING A BREAKAGE OF THE INSERT). ALTHOUGH THIS CASE LACKS MEDICAL CONFIRMATION AND DETAILED INFORMATION FOR A COMPREHENSIVE CAUSALITY ASSESSMENT; GIVEN THESE EVENTS NATURE; CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE REPORTED TUMORS ON THE FALLOPIAN TUBES, CONSUMER INITIALLY REPORTED CYSTS, LATER POLYPS AND THEN TUMORS, SINCE THE EXACT NATURE OF THIS EVENT IS UNCLEAR; CAUSALITY WITH ESSURE CANNOT BE ASSESSED. THE REMAINING EVENTS WERE CONSIDERED AS UNRELATED TO THE SUSPECT INSERT; BASED ON THEIR NATURE AND DUE TO THE LOCAL ACTION OF ESSURE IN THE FALLOPIAN TUBES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO FOLLOW-UP WILL BE ACTIVELY SOUGHT SINCE THIS IS A SOCIAL MEDIA CASE.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-DEC-2015: (B)(4). FINAL ASSESSMENT IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01665	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/22/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY (CASE# FDA-2014-N-0736-0015) IN UNITED STATES ON 21-AUG-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AS AN ALTERNATIVE TO TUBAL LIGATION, CONSUMER HAD ESSURE INSERTED IN (B)(6) 2014, AND IN (B)(6) 2014, A CONFIRMATION TEST SHOWED THE COILS IN PLACE AND THE SCAR TISSUE PROPERLY FORMED. SHE THEN CEASED REGULAR BIRTH CONTROL PILLS. SINCE THEN, SHE WAS EXPERIENCING THE FOLLOWING SYMPTOMS: 40 PERCENT HAIR LOSS, WEIGHT GAIN (25 LBS IN THREE MONTHS), BRAIN FOG AND DIFFICULT CONCENTRATING, WITH SEVERE MEMORY PROBLEMS, TO THE EXTENT OF HAVING DIFFICULT COMPREHENDING WRITTEN TEXTS, REMEMBERING SHORT LISTS, REMEMBERING THE NAMES OF PEOPLE OR BASIC FACTS OR SEQUENCES, LETHARGY AND EXTREME FATIGUE, FEELING ALMOST AS IF SHE WAS DRUGGED AT TIMES, UNABLE TO STAY AWAKE WHILE WORKING, HAVING TO PULL OVER WHILE DRIVING, UNABLE TO WAKE IN THE MORNINGS, EVEN TO SEVERAL ALARMS OR THE DOORBELL, SLEEP DISRUPTIONS AND INSOMNIA, SEVERE CYSTIC ACNE ON HER FACE AND CHIN, SEVERELY BLOATED BELLY (GREW 6 INCHES IN THREE MONTHS FROM 30 INCH WAIST TO 36 INCH WAIST WITH NO DRAMATIC CHANGES IN DIET OR EXERCISE), CHRONIC URINARY TRACT INFECTIONS, RECURRING PELVIC PAIN, SOMETIMES SHARP AND STABBING, SOMETIMES DULL AN ACHING, PAINFUL SEXUAL INTERCOURSE, INTOLERANCE TO COLD, DEBILITATING HEADACHES, DEPRESSION, ANXIETY, MOOD SWINGS, NUMBNESS IN HANDS AND FEET, LOSS OF CIRCULATION (WHITE HANDS AND FINGERS), NUMBNESS ON RIGHT SIDE OF BODY, BLURRED VISION, FITS OF RAGE, JOINT AND MUSCLE ACHES, SOMETIMES SO SEVERE SHE WAS UNABLE TO

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WALK OR PERFORM BASIC PHYSICAL MOVEMENTS OR TASKS, DIZZINESS, FAINTING, SEVERE MENSTRUAL CRAMPS, SEVERE PMS SYMPTOMS (USUALLY FOR TWO WEEKS OUT OF EVERY CYCLE), HEAVY MENSTRUAL BLEEDING, SOMETIMES SOAKING 1 SUPER PLUS TAMPON IN 10-20 MINUTES, HIGH BLOOD PRESSURE, INSULIN RESISTANCE, HIGH CHOLESTEROL, HIGH THYROID ANTIBODIES, BUT WITH OPTIMAL THYROID PANEL. CONSUMER STATED THAT SHE ALSO EXPERIENCED SOME SYMPTOMS WHILE ON MIRENA TEN YEARS BEFORE THIS REPORT (2005), INCLUDING: BLOATING, MOOD SWINGS, HEADACHES, FATIGUE, CHRONIC URINARY TRACT INFECTIONS. AFTER MUCH BLOOD WORK AND MANY TESTS, INCLUDING A THYROID SONOGRAM, SHE WAS DIAGNOSED WITH HASHIMOTO'S THYROIDITIS AND WAS ADVISED TO ADOPT A GLUTEN FREE, PALEO LIFESTYLE, WHICH SHE WAS DONE FOR THE LAST SIX MONTHS, AND ALL OF THE SYMPTOMS LISTED ABOVE REMAINED. SOME OF THEM HAVE IMPROVED, BUT NOT A SINGLE SYMPTOM WAS GONE AWAY. IN ADDITION, EVEN ON AN ANTI-INFLAMMATORY PALEO DIET PLAN, HER THYROID ANTIBODIES CONTINUED TO INCREASE. SHE WAS CONCERNED THAT THE PET FIBERS AND/OR THE METAL COILS FROM WHICH ESSURE WERE CONSTRUCTED TRIGGERED THIS MASSIVE AUTOIMMUNE RESPONSE IN HER BODY. HER QUALITY OF LIFE SIGNIFICANTLY DECLINED SINCE ESSURE INSERTION. PTC INVESTIGATION RESULT WAS RECEIVED ON 04-OCT-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 03-NOV-2015. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2482). CASE IS NOW CONSIDERED INCIDENT. ESSURE WAS INSERTED ON (B)(6) 2014 AND HYSTEROSALPINGOGRAM PERFORMED ON (B)(6) 2014 CONFIRMED OCCLUSION. IMMEDIATELY FOLLOWING PLACEMENT, CONSUMER EXPERIENCED EXCRUCIATING PAIN (AS BAD AS OR WORSE THAN LABOR) FOR THE FIRST 48 HOURS. CONSUMER EXPERIENCED 40-50% HAIR LOSS, DIAGNOSED AS UNEXPLAINED ALOPECIA, CYSTIC ACNE ON FACE AND BACK, PAPER-THIN FINGERNAILS, RIDGED NAILS, CONFUSION, GLUTEN SENSITIVITY, DIGESTIVE ISSUES, CHRONIC SYSTEMIC INFLAMMATION AND PAIN, LOSS OF MUSCLE CONTROL, INABILITY TO WALK OR MOVE LIMBS, WHICH FLARE UP PERIODICALLY SINCE PLACEMENT AND THEN SUBSIDES AT RANDOM, SEVERE JOINT PAIN AND SWELLING, POSITIVE TEST FOR RHEUMATOID ARTHRITIS IMMUNOGLOBULIN, LOSS OF LIBIDO, FREQUENT, IRREGULAR AND EXTREMELY HEAVY PERIODS, UNSPECIFIED AUTOIMMUNE RESPONSE ATTACKING PITUITARY GLAND, SLEEP PARALYSIS, LIGHT-HEADEDNESS, ACUTE PAIN ON RIGHT SIDE OF LOWER ABDOMEN, DRY AND ITCHY EYES, ENVIRONMENTAL AND FOOD-RELATED ALLERGIES. SINCE ESSURE, SHE WAS UNABLE TO WORK AT LEAST 1-2 DAYS PER WEEK, ADVERSELY IMPACTING HER ABILITY TO PROVIDE AND CARE FOR HER FAMILY. SHE WAS WAITING FOR A SCHEDULED FULLY HYSTERECTOMY WITH BILATERAL SALPINGECTOMY TO REMOVE ESSURE IN DECEMBER. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD A MIRENA IUS (LEVONORGESTREL - INTRAUTERINE DELIVERY SYSTEM) INSERTED APPROXIMATELY 10 YEARS AGO AND EXPERIENCED CHRONIC URINARY TRACT INFECTIONS. NO INFORMATION WAS GIVEN ON MIRENA REMOVAL DATE AND EVENT OUTCOME. ALSO, ON AN UNSPECIFIED DATE, SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HASHIMOTOS THYROIDITIS AND ALSO CHRONIC URINARY TRACT INFECTIONS. SHE WAS

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WAITING FOR A SCHEDULED FULLY HYSTERECTOMY WITH BILATERAL SALPINGECTOMY TO REMOVE ESSURE. ALL THESE THREE REPORTED EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE UNLISTED IN BOTH ESSURE AND MIRENA REFERENCE SAFETY INFORMATION. SHE ALSO EXPERIENCED RECURRING PELVIC PAIN SOMETIMES SHARP AND STABBING/DULL ACHING, WHICH WAS CONSIDERED SERIOUS AND LISTED. OTHER NON-SERIOUS EVENTS WERE ALSO REPORTED. HASHIMOTO THYROIDITIS IS PART OF THE SPECTRUM OF AUTOIMMUNE THYROID DISEASES (AITDS) AND ESSURE IS A METHOD OF LOCAL, MECHANICAL ACTION, BEING VERY UNLIKELY ITS SYSTEMIC INFLUENCE (EXCLUDING AN EVENTUAL ALLERGIC REACTION TO NICKEL AND/OR TITANIUM).THEREFORE, CAUSALITY BETWEEN THIS DEVICE AND HASHIMOTO THYROIDITIS WAS CONSIDERED UNRELATED. SEXUAL INTERCOURSE MAY LEAD TO CYSTITIS, BUT IT IS NOT NECESSARY TO BE SEXUALLY ACTIVE TO DEVELOP IT. ALL WOMEN ARE SUSCEPTIBLE TO CYSTITIS BECAUSE OF THEIR ANATOMY - SPECIFICALLY, THE CLOSE PROXIMITY OF THE URETHRA TO THE ANUS AND THE SHORT DISTANCE FROM THE URETHRAL OPENING TO THE BLADDER. BASED ON THE PATHOPHYSIOLOGY OF THIS EVENT, COMPANY CONSIDERS BOTH CHRONIC URINARY TRACT INFECTIONS TO BE UNRELATED TO ESSURE AND MIRENA USE. WITH REGARDS TO THE OTHER EVENT, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED AND CAUSALITY WITH MIRENA CAN BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL COMPLAINT IS EXPECTED. NO FURTHER INFORMATION IS EXPECTED AS THIS IS A DOCKET CASE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01770	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 9/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2072, AWARENESS DATE 01-NOV-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ADDITIONAL INFORMATION RECEIVED ON 23-NOV-2015. CONSUMER STATED THAT ESSURE WREAKED HAVOC ON HER BODY FOR 3 YEARS. SHE HAD A ROBOTIC HYSTERECTOMY ON (B)(6) AT ONLY (B)(6). HAIR LOSS, VERTIGO, CHRONIC PELVIC PAIN, METAL TASTE IN MOUTH, BLOATED BEYOND BELIEF, SYMPTOMS OF BEING PREGNANT BUT EVERY TEST SAYS NEGATIVE, VOMITING, DIARRHEA AND CONSTIPATION, BRAIN FOG. THE LIST GOES ON. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 23-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD CHRONIC PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE UNDERWENT A HYSTERECTOMY AT (B)(6).

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THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01771	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2080, AWARENESS DATE 01-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. ADDITIONAL INFORMATION RECEIVED ON 23-NOV-2015. SOON AFTER ESSURE INSERTION, THE CONSUMER ENDED UP GETTING A HORRIBLE INFECTION AND WAS IN HORRIBLE PAIN. HER DOCTOR PUT HER ON DIFFERENT ANTIBIOTICS WHICH SEEMED TO HELP. THE FOLLOWING 3 MONTHS AFTER SHE HAS EXPERIENCED EXTREME BLOATING. SHE LOOKED LIKE SHE WAS 3 MONTHS PREGNANT WHICH WAS NOT VERY FUN. SHE HAS DEVELOPED A STRANGE RASH LIKE SYSTEM ALL OVER HER BODY. SHE HAD BAD DEPRESSION, WHICH SHE DID NOT HAVE BEFORE. AT HER 3 MONTH FOLLOW UP DYE TEST THEY FOUND OUT THAT ONE COIL WAS IN PLACE AND FULLY BLOCKED BUR THE OTHER COIL HAS MIGRATED OUT OF THE TUBE AND WAS A FOREIGN OBJECT IN HER BODY. HER DOCTOR ASSUMED THAT WAS THE CAUSE OF THE INFECTION SHE HAD AFTER THE IMPLANTS. SHE WANTED TO HAVE ESSURE REMOVED. SHE STATED THAT SHE HAS NOT BEEN GOOD THROUGH THESE PAST THREE MONTHS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 23-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD AN INFECTION SOON AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS TREATED WITH ANTIBIOTICS. THREE MONTHS LATER, HER DYE TEST SHOWED ONE ESSURE COIL HAD MIGRATED OUT OF THE TUBE. ACCORDING TO HER, HER DOCTOR ASSUMED THAT THIS WAS THE CAUSE OF THE INFECTION SHE HAD AFTER THE IMPLANTS. THE REPORTED EVENTS ARE LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS MAINLY IN THE FIRST WEEKS AFTER THE INSERTION PROCEDURE. IN THIS PARTICULAR CASE, NEITHER THE EXACT LOCATION OF CONSUMER'S INFECTION WAS SPECIFIED NOR WAS THE EXACT TEMPORAL RELATIONSHIP WITH ESSURE INSERTION PROVIDED. CONSUMER MENTIONED ONE DEVICE WAS MIGRATED; HOWEVER IT IS UNCLEAR IF IT WAS MIGRATED INTO THE UTERUS OR TO THE PELVIC CAVITY. ALTHOUGH CASE LACKS DETAILED INFORMATION FOR A COMPREHENSIVE CAUSALITY ASSESSMENT; BASED ON THE INFORMATION AVAILABLE, TEMPORAL RELATIONSHIP BETWEEN THE EVENTS AND ESSURE SEEMS POSITIVE AND MEDICAL INTERVENTION WAS REQUIRED AS TREATMENT. ADDITIONALLY, THESE ARE KNOWN POSSIBLE ADVERSE EVENTS DURING ESSURE THERAPY. THEREFORE, CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED AND THIS CASE IS REGARDED AS INCIDENT. IN ADDITION, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01772	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 01-NOV-2015). IT REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. THE CONSUMER STARTED HAVING PROBLEMS ABOUT 6 MONTHS AFTER ESSURE PLACEMENT. SHE HAD DIZZY SPELLS, NUMBNESS AND TINGLING, ABDOMINAL PAIN, BLEEDING TO DEATH AND THEN SOMETIMES NOT BLEEDING AT ALL. SHE STARTED BEING UNABLE TO GET HERSELF UP IN THE MORNING DUE TO LACK OF ENERGY. SHE WENT TO SEVERAL DOCTORS AFTER THE DOCTOR WHO PUT ESSURE IN TOLD HER SHE MIGHT HAVE AN UNDERLYING HEALTH PROBLEM. SHE UNDERWENT SEVERAL TESTS. THE DOCTOR WHO PLACED THE COILS SENT HER FOR A DYE TEST AND SHE WAS TOLD ONE OF THE COILS WAS EITHER CRIMPED IN HALF OR HAD BROKEN IN HALF AND HALF WAS MISSING. SHE WENT TO ANOTHER DOCTOR WHO BLAMED HER PROBLEMS ON ENDOMETRIOSIS AND DID A HYSTERECTOMY. AFTER THE SURGERY SHE WAS TOLD THAT NO ENDOMETRIOSIS WAS FOUND AND SHE WOULD HAVE TO GET A LAWYER TO SEE THE COILS THAT CAME FROM HER BODY. SHE WENT HOME UNABLE TO WALK, EAT OR SLEEP DUE TO PAIN. THE SURGEON KEPT SAYING IT WAS GAS. SHE WENT TO HER FAMILY PHYSICIAN WHO PUT HER IN AN AMBULANCE. SHE WAS FULL ON INFECTION AND THE DOCTOR THOUGHT SHE WAS GOING INTO SHOCK. THE CONSUMER SPENT A WEEK IN THE HOSPITAL AND STATED THAT SHE DID NOT EVEN KNOW IF EVERY PIECE OF THE COIL WAS OUT OF HER BODY. FOLLOW UP RECEIVED ON 23-NOV-2015: PTC INVESTIGATIONAL RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER

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INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND QUALITY DEFICIT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN (B)(6) 2012. THE CONSUMER STARTED HAVING PROBLEMS ABOUT 6 MONTHS AFTER ESSURE PLACEMENT: GENITAL BLEEDING, ABDOMINAL PAIN AMONGST OTHER EVENTS. THE DOCTOR WHO PLACED THE COILS SENT HER FOR A DYE TEST AND SHE WAS TOLD ONE OF THE COILS WAS EITHER CRIMPED IN HALF OR HAD BROKEN IN HALF AND HALF WAS MISSING (INTERPRETED AS DEVICE BREAKAGE). A HYSTERECTOMY WAS PERFORMED AND AN INFECTION (NOT SPECIFIED) WAS REPORTED. DEVICE BREAKAGE IS SERIOUS DUE TO MEDICAL IMPORTANCE AND ANTICIPATED ACCORDING TO TECHNICAL ANALYSIS. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND EVENT NATURE, CAUSALITY CANNOT BE EXCLUDED. SINCE THE POSSIBILITY OF DEVICE BREAKAGE WAS REPORTED AND AN INTERVENTION WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01773	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2015
Explant Date (E7): 10/12/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT (REQUIRED INTERVENTION). ANTICIPATED. THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2074, AWARENESS DATE 01-NOV-2015) WHICH REFERS TO REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015. THE CONSUMER REPORTED SHE HAD ESSURE PLACED AND JUST HAD THEM REMOVED ON (B)(6) 2015. SHE HAD SURGERY, AND HER LEFT OVARY AND THE OVARIAN CYST THAT WAS 17CM IN SIZE AND THEN RIGHT TUBE WITH THE ESSURE WERE REMOVED. SHE HAD BLOATING THAT MADE SHE LOOK 6 MONTHS PREGNANT, TIRED, DIZZY, HEADACHES, AND RIGHT LEG CRAMPS AND ALSO SEX WAS VERY PAINFUL. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 23-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND REPORTED THAT SEX WAS VERY

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PAINFUL AMONG OTHER EVENTS. SHE HAD THE DEVICES REMOVED 5 MONTHS AFTER INSERTION. THIS EVENT, SEEN AS DYSPAREUNIA, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING DYSPAREUNIA MAY OCCUR DURING ESSURE USE AND THE IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE DEVICE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01774	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): 2/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2012
Explant Date (E7): 10/24/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE FOR ESSURE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEP-2015 (CASE#S FDA-2014-N-0736-2539 AND FDA-2014-N-0736-2561, AWARENESS DATE 01-NOV-2015). THIS REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012 DUE TO HAVING COMPLICATIONS DURING HER LAST PREGNANCY. ADDITIONAL INFORMATION WAS PROVIDED ON 02-NOV-2015 AND 23-NOV-2015 (PTC INVESTIGATION RESULT). THE DAY OF THE PROCEDURE, SHE WAS PRESCRIBED VOLUME TO TAKE 30 MINUTES BEFORE THE PROCEDURE TO RELAX, 7.5 HYDROCODONE TO TAKE 2 HOURS BEFORE PROCEDURE AS WELL TAKE ANOTHER ONE 30 MINUTES BEFORE PROCEDURE AND THEN WAIT TO BE CALLED BACK. PHYSICIAN PLACED THE FIRST COIL IN LEFT TUBE AND CONSUMER FELT A LITTLE PRESSURE THEN HE STARTED TO PLACE THE NEXT COIL IN RIGHT TUBE AND SHE EXPERIENCED A LOT OF PAIN AND PRESSURE. THE PHYSICIAN SAID THE RIGHT TUBE DID NOT WANT TO GO IN BUT HE GOT IT IN. AFTER THE PROCEDURE SHE WAS DIZZY, SICK TO STOMACH, OUT OF HER MIND DUE TO ALL THE MEDICATION SHE TOOK, HURTING IN HER RIGHT SIDE REALLY BAD AND BLEEDING REALLY BAD. SHE WAS PRESCRIBED TYLENOL FOR THE PAIN. TIME WENT BY AND SHE WOULD HAVE TO DEAL WITH HEADACHES, WEAKNESS, SHARP PAINS IN RIGHT TUBE SO BAD THAT IT WOULD BURN IT WOULD HURT SO BAD, SICK TO STOMACH, DEPRESSION, TIRED ALL THE TIME, SERVE BLEEDING DURING PERIOD, BLEEDING IN BETWEEN PERIODS, METAL TASTE IN MOUTH, BLEEDING WHEN SHE HURT, AND THE COILS GOING THROUGH TUBES INTO UTERUS. AT AGE (B)(6), SHE HAD A PARTIAL HYSTERECTOMY DONE TO HELP WITH ALL OF THE PROBLEMS (HYSTERECTOMY DATE REPORTED (B)(6) 2015). SHE HAD PROBLEMS WAKING UP WITH THE ANESTHETIC THEN HAD PROBLEMS WITH HER BLADDER. ON (B)(6) 2015, SHE CAME BACK TO PHYSICIAN'S

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OFFICE TO GET THE CATHETER REMOVED. SHE WAS STILL EXPERIENCING PROBLEMS; SHE WOULD NOT KNOW WHEN SHE HAS TO URINATE. THE DOCTOR DID NOT FIND COIL IN TUBES; INSTEAD SHE FOUND THEM INSIDE UTERUS. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED BLEEDING REALLY BAD (INTERPRETED AS GENITAL BLEEDING). SHE HAD A PARTIAL HYSTERECTOMY DONE TO HELP WITH ALL OF THE PROBLEMS. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING ITS NATURE AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01775	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2580, AWARENESS DATE 01-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ADDITIONAL INFORMATION RECEIVED ON 23-NOV-2015. CONSUMER REPORTED SHE HAD ESSURE FOR 6 1/2 YEARS AND HAD HORRIBLE SIDE EFFECTS FROM IT. SHE HAD HIVES UNTIL REMOVAL. SHE WAS REQUIRED BEFORE GETTING ESSURE TO GET A NICKEL ALLERGY TEST AND IT WAS NEGATIVE. HER HIVES LEFT AFTER REMOVAL. SHE HAD ALLERGY TESTING AFTER REMOVAL AND WAS STILL NEGATIVE FOR A NICKEL ALLERGY. CONSUMER ALSO HAD EXTENSIVE HAIR LOSS WITH ESSURE. SHE WAS DIAGNOSED WITH A TELOGEN EFFLUVIUM. ONCE ESSURE WAS REMOVED, HER HAIR CAME BACK. SHE HAD PAIN THAT WENT AWAY AFTER REMOVAL. SHE HAD BLOATING THAT ALSO WENT AWAY AFTER REMOVAL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 23-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY

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DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HIVES AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICE WAS REMOVED AND SHE RECOVERED FROM THE EVENT. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE HIVES (URTICARIA) THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS PARTICULAR CASE, CONSUMER HAD 2 NICKEL ALLERGY TESTS; ONE BEFORE AND ONE AFTER ESSURE REMOVAL AND BOTH CAME NEGATIVE. ALTHOUGH A NICKEL ALLERGY WAS NOT CONFIRMED IN THIS CASE; CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND DECHALLENGE REPORTED BY THE CONSUMER; CAUSALITY BETWEEN HER HIVES AND THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, CONSUMER REPORTED BLOATING AND PAIN WITH DEVICE THERAPY, WHICH ALSO RECOVERED AFTER REMOVAL. BASED ON THIS INFORMATION AND EVENTS NATURE; THEY WERE ALSO CONSIDERED AS RELATED TO THE SUSPECT INSERT. SINCE DEVICE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED), THIS CASE WAS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01776	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/1/2012
Explant Date (E7): 7/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2590, AWARENESS DATE 01-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2012, AFTER SHE WAS FINISHED HAVING CHILDREN. SHE WAS GIVEN A FEW PRESCRIPTIONS TO TAKE JUST BEFORE HAVING IT DONE AS WELL AS A SHOT IN THE OFFICE. SHE WAS TAKEN INTO A PROCEDURE ROOM AND GIVEN ANOTHER SHOT IN HER CERVIX. SHE WAS WATCHING THE MONITOR AS THE DOCTOR PLACED THE FIRST ONE. IT WAS VERY UNCOMFORTABLE AND SHE WAS TOLD SEVERAL TIMES TO RELAX SO IT WOULD NOT BE SO DIFFICULT AND HURT AS BADLY. SHE GOT NAUSEATED AT ONE POINT. THE SECOND TUBE TOOK TWO TRIES BEFORE IT WAS FINALLY PLACED. THE PAIN FROM HAVING IT DONE WAS WORSE THAN HAVING HER CHILDREN. FORWARD FIVE MONTHS AND SHE STARTED BLEEDING HEAVILY DURING INTERCOURSE. THEN SHE STARTED SPOTTING FOR A WEEK BEFORE HER PERIOD, HAVING HER PERIOD AND SPOTTING AGAIN AFTER HER PERIOD. SHE GAINED WEIGHT AND LOOKED 6 MONTHS PREGNANT ALL THE TIME. SHE WAS ALWAYS TIRED. SHE DID NOT GO BACK TO THE DOCTOR AFTER THAT UNTIL (B)(6) 2015. AT THAT POINT SHE HAD NOT HAD A PAP IN MORE THAN TWO YEARS AND HAD A SCARE THAT TURNED OUT TO BE AN INFECTION. SHE ADDRESSED HER BLEEDING CONCERNS WITH THE NEW PHYSICIAN AND HE AGREED THAT SHE SHOULD NOT BE BLEEDING THE WAY SHE DID. ON (B)(6) 2015 SHE HAD A HYSTERECTOMY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 22-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE

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TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED SPOTTING FOR A WEEK BEFORE PERIOD, HAVING HER PERIOD AND SPOTTING AGAIN AFTER HER PERIOD (INTERPRETED AS METRORRHAGIA). SHE UNDERWENT A HYSTERECTOMY 3 AND A HALF YEARS AFTER ESSURE INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01777	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/30/2010
Explant Date (E7): 3/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER IN UNITED STATES ON (B)(6) 2014 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ALLERGIC REACTION TO MY SKIN, NOT HAVING A REAL PERIOD, PERIOD IS CHUNKS OF PIECES OF BLOOD, A1C HAS SKYROCKETED, AND BLOOD PRESSURE IS HIGH. NO INFORMATION GIVEN ON CONSUMER'S MEDICAL HISTORY, DRUG HISTORY AND CONCOMITANT MEDICATION. SHE HAS NEVER BEEN ALLERGIC TO ANYTHING.. THE CONSUMER'S CONCURRENT CONDITION INCLUDED DIABETIC. IN (B)(6) 2010 THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT BIRTH CONTROL. IN 2010 THE CONSUMER EXPERIENCED ALLERGIC REACTION TO MY SKIN (PURPLE SPECKS OF BLOOD BLISTERS INSIDE THIGHS / IT HAS SPREAD TO BACK,BUTTOCKS, ARMS AND HANDS, IT IS PAINFUL AND UNCOMFORTABLE, HOT AND ITCHY ON THE INSIDE, HOT AND ITCHY ON THE INSIDE). ON AN UNSPECIFIED DATE THE CONSUMER EXPERIENCED NOT HAVING A REAL PERIOD, PERIOD IS CHUNKS OF PIECES OF BLOOD, A1C HAS SKYROCKETED, AND BLOOD PRESSURE IS HIGH. ALLERGIC REACTION TO HER SKIN STARTED THREE AND HALF YEARS BEFORE THIS REPORT. IT STARTED AS PURPLE SPECKS OF BLOOD BLISTERS INSIDE HER THIGHS AND IT KEPT PROGRESSING, SPREADING TO THE BACK OF HER LEGS, BUTTOCKS, BACK OF HER ARMS, AND HANDS. SHE COULD BARELY USE HER HANDS. IT WOULD BREAK, AND WATER WOULD COME OUT, THEN BLOOD. IT WAS PAINFUL AND UNCOMFORTABLE AND IT GOT WORSE AND BIGGER FOUR DAYS BEFORE HER PERIOD. SHE WAS HOT AND ITCHY ON THE INSIDE. ADDITIONALLY, SHE WAS NOT HAVING A REAL PERIOD, JUST CHUNKS OF PIECES OF BLOOD. SHE WAS DIABETIC AND HER A1C HAS SKYROCKETED AND HER BLOOD PRESSURE WAS HIGH. SHE HAS BEEN SEEING A DERMATOLOGIST, BIOPSY AND CULTURES ON THE BLISTERS HAVE BEEN DONE, AND THERE WERE NO SOLUTIONS. EVENTS AND ESSURE TREATMENT WERE

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ONGOING. REPORTER CAUSALITY: THE RELATIONSHIP WAS NOT REPORTED. FOLLOW-UP INFORMATION WAS RECEIVED ON 04-JUN-2014 VIA (B)(6) QUESTIONNAIRE. THIS CASE IS NOW MEDICALLY CONFIRMED. PATIENT'S WEIGHT WAS PROVIDED. MEDICAL HISTORY INCLUDED D+C (INTERPRETED AS DILATATION AND CURETTAGE). CONCURRENT CONDITIONS INCLUDED HTN (HYPERTENSION), OBESITY, GERD AND DM (DIABETES MELLITUS). ON (B)(6) 2010 ESSURE WAS EASILY INSERTED. SHE WAS NOT POSTPARTUM AT THE TIME OF INSERTION. GENERAL ANESTHESIA AND ANALGESIA WERE APPLIED DURING INSERTION. THE VISUALIZATION OF THE TUBAL OSTIUM WAS EASY. FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. DEPO PROVERA WAS USED AS BACK-UP CONTRACEPTION. ON (B)(6) 2010 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND CONFIRMED OCCLUSION BILATERALLY. NO ESSURE REMOVAL WAS DONE OR PLANNED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 13-JUN-2014. NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 18-AUG-2014: PATIENT WAS ADMITTED TO HOSPITAL ABOUT 3 DAYS PRIOR TO THIS REPORT FOR PURPOSE OF WORKUP TO DETERMINE THE CAUSE OF SKIN PROBLEMS. SHE STARTED EXPERIENCING TRAUMATIC DERMATITIS, SKIN NECROSIS SOMETIME SHORTLY AFTER ESSURE INSERTED. SHE HAD GRANULOMATOUS PLAGUES AND IT WAS PRETTY DRAMATIC. SHE HAS HAD SUBSTANTIAL TREATMENT (IMMUNOSUPPRESSIVE TREATMENTS, STEROIDS). THEY WERE CONSIDERING REMOVING ESSURE. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP RECEIVED ON 18-AUG-2014: NO NEW CLINICAL INFORMATION. FOLLOW-UP INFORMATION WAS RECEIVED ON 26-AUG-2014 FROM HEALTH CARE PROVIDER. THE PATIENT WOULD PROBABLY HAVE TO GET ESSURE REMOVED. CONCOMITANT CONDITION INCLUDED MORBID OBESITY AND THEREFORE SHE WAS NOT A GOOD LAPAROSCOPIC CANDIDATE AND MIGHT HAVE TO UNDERGO A VAGINAL HYSTERECTOMY. HER NEXT APPOINTMENT WAS SCHEDULED TO TWO WEEKS AFTER THIS REPORT. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 27-AUG-2014. NO NEW CLINICAL INFORMATION WAS PROVIDED. PTC INVESTIGATION RESULT WAS RECEIVED ON 04-SEP-2014: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THE REPORTED ADVERSE EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. THE REPORTED EVENTS ARE OF BROAD NATURE AND THE MAJORITY OF EVENTS WAS CONSIDERED UNRELATED TO THE PRODUCT BY COMPANY. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NEITHER A TECHNICAL BATCH EVALUATION NOR A BATCH SIGNAL CLUSTER REVIEW IN THE (B)(4) DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO SUSPICION OF A QUALITY DEFECT BASED ON THE LIMITED AVAILABLE INFORMATION. FOLLOW UP INFORMATION RECEIVED ON (B)(6) 2015 FROM PATIENT'S BOYFRIEND: HE WAS CONCERNED ABOUT HIS GIRLFRIEND SINCE SHE WAS DECLINING, GETTING WORSE AND WORSE EVERY DAY. SHE WAS A REALLY HEALTHY PERSON ON NO MEDICATIONS BEFORE ESSURE INSERTED. SHE HAS BEEN SEEN BY A SKIN DOCTOR WHO HAS NEVER SEEN SKIN LESIONS LIKE HERS BEFORE. THE SKIN DOCTOR AGREED WITH THE INTERNAL MEDICINE DOCTOR THAT THEY SHOULD REMOVE ESSURE AND SEE WHAT HAPPENS. BOYFRIEND HAS SPOKEN TO WOMEN ONLINE ABOUT SKIN PROBLEMS THEY ARE HAVING SINCE ESSURE INSERTED BUT NONE LIKE HERS. AT FIRST THE LESIONS WERE LIKE BLISTERS THAT LEAKED WATER AND THEN WENT DORMANT ON BACKS OF THIGHS THAT RAN ALONG THE NERVE. NOW THEY ARE LIKE BLOOD BLISTERS EVERYWHERE AND GROSS. SHE WAS EMBARRASSED TO GO OUT AND COVERS UP. THE LESIONS GO ALONG WITH HER CYCLE AND BLOW UP LIKE BALLOONS AND SHE HAS

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INFLAMMATION. SHE HAS A WOUND ON HER LEFT LEG FOR ABOUT A YEAR NOW THAT WILL NOT HEAL. ANOTHER WOUND APPEARED ON LEFT ANKLE ABOUT 4 TO 6 MONTHS AGO. HER HAIR WAS FALLING OUT AND SHE WAS FEELING LIKE HER BODY WAS ON FIRE. IT WAS LIKE SHE WAS BURNING UP INSIDE. SHE WAS AFRAID SHE WILL BE DEAD IN A YEAR IF A HYSTERECTOMY AND REMOVAL OF ESSURE NOT DONE SOON. HER BLOOD PRESSURE WAS UP AND HER TYPE 2 DIABETES WAS GETTING WORSE. SHE COULD NOT EVEN OPEN A BOTTLE OF POP DUE TO PAIN FROM LESIONS ON HANDS. IT WAS MESSING WITH HER HEAD AND MENTAL STATE. SHE JUST WANTED HER LIFE BACK. SHE HAS BEEN IN THE HOSPITAL TWICE IN PAST 4 MONTHS AND IS IN HOSPITAL NOW. CT SCAN RECENTLY AND ESSURE IS IN PLACE. SHE WAS PLACED ON CLIMARA AND PREDNISONE AND HAD A REACTION TO THE PREDNISONE. THESE DRUGS ARE HARSH AND SHE IS NOT SURE WHAT THEY MIGHT BE DOING TO HER BODY. FOLLOW-UP INFORMATION RECEIVED ON 15-MAY-2015. THE REQUIRED NUMBERS OF FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. CASE CLOSED. FOLLOW-UP INFORMATION HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 02-NOV-2015). CONSUMER EXPERIENCED FATIGUE, CHEST PAIN, MUSCLE PAIN, PAIN IN VAGINAL AREA, SEVERE CRAMPS, IRREGULAR PERIODS, DIZZINESS AT TIMES, SEVERE DRY EYES, UNABLE TO PRODUCTS TEARS, AUTO IMMUNE DISORDER/ TARGET VASCULAR SYSTEM, RESISTANT TO HEALING, RESISTANT TO ANTIBIOTICS, STEROIDS, INSULIN, ECT., EXCESSIVE HIGH BLOOD SUGAR, SEVERE NERVE DAMAGE AND UNABLE TO WALK CORRECTLY DUE TO MASSIVE PAIN, MAJOR DEPRESSION, ANXIETY AND RAGE DUE TO CONSTANT PAIN THAT IS UNABLE TO BE CONTROLLED, LOST MOBILITY, UNABLE TO WORK. (B)(6) 2015 HAD FULL VAGINAL HYSTERECTOMY TO REMOVED ESSURE. ABOUT TWO MONTHS LATER FOUND OUT THERE WAS A PIECE OF ESSURE STILL LEFT IN HER. (B)(6) 2015 HAD LAPAROSCOPIC SURGERY TO REMOVED THE PIECE OF ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED TRAUMATIC DERMATITIS, SKIN NECROSIS AND GRANULOMATOUS PLAGUES ON SKIN. ADDITIONALLY, SHE STATED HER TYPE 2 DIABETES IS GETTING WORSE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO HOSPITALIZATION (SKIN LESIONS) AND MEDICAL IMPORTANCE (WORSENING DIABETES) AND ARE UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. THE EVENTS TRAUMATIC DERMATITIS AND TYPE 2 DIABETES IS GETTING WORSE WERE, DUE TO THEIR ETIOLOGIES AND CONSIDERING ESSURE LOCAL ACTION AT FALLOPIAN TUBES CONSIDERED AS UNRELATED TO THE SUSPECT INSERT. GRANULOMATOUS DERMATITIS MAY HAVE INFECTIOUS ETIOLOGIES SUCH AS TUBERCULOSIS AND MYCOBACTERIOSIS, AS WELL AS NON-INFECTIOUS ETIOLOGIES SUCH AS SARCOIDOSIS, GRANULOMA ANNULARE, INTERSTITIAL GRANULOMATOUS DERMATITIS, NECROBIOSIS LIPOIDICA, NECROBIOTIC XANTHOGRANULOMA, METASTATIC CROHN DISEASE, AMONG OTHERS. BOTH TRAUMATIC DERMATITIS AND GRANULOMATOUS DERMATITIS COULD RESULT IN SKIN NECROSIS. THUS, GIVEN THE NATURE OF THE EVENTS SKIN NECROSIS AND GRANULOMATOUS PLAGUES ON SKIN, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENTS AND ESSURE WAS CONSIDERED VERY UNLIKELY. SHE ALSO REPORTED THAT SHE WAS UNABLE TO WALK CORRECTLY DUE TO MASSIVE PAIN / CONSTANT PAIN THAT IS UNABLE TO BE CONTROLLED. SHE HAD FULL VAGINAL HYSTERECTOMY TO REMOVED ESSURE. ABOUT TWO MONTHS LATER FOUND OUT THERE WAS A PIECE OF ESSURE WAS STILL LEFT IN HER (SEEN AS DEVICE BREAKAGE) AND SHE HAD LAPAROSCOPIC SURGERY TO REMOVED THE PIECE OF ESSURE. THESE TWO EVENTS ARE SERIOUS AND LISTED. THE EVENT DEVICE BREAKAGE OCCURRED DURING REMOVAL OF ESSURE. CONSIDERING THEIR NATURE AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED AND ALSO DUE TO DEVICE BREAKAGE WHICH REQUIRED INTERVENTION. AN UPDATED PRODUCT TECHNICAL COMPLAINT IS EXPECTED. NO FURTHER INFORMATION COULD BE OBTAINED.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01778	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 10/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0972, AWARENESS DATE 29-AUG-2015). IT REFERS TO A FEMALE CONSUMER OF AN UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. IT WAS REPORTED THAT SINCE INSERTION SHE EXPERIENCED PAIN DAILY AND THAT SHE TRIED TO KILL HERSELF BECAUSE SHE FELT LIKE A FAILURE FOR NOT BEING ABLE TO BE THE MOM THAT SHE WAS BEFORE ESSURE. IT WAS ALSO REPORTED THAT SHE HURT SO MUCH AFTER SEX. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 09-OCT-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 02-NOV-2015 FROM CONSUMER'S HUSBAND: THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN

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PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2400). THIS CASE WAS UPGRADED TO INCIDENT. THE CONSUMER BEGAN HAVING COMPLICATIONS WITH SWELLING AND JUST GENERAL PAIN. IT KEPT GETTING WORSE UNTIL SHE COULD NO LONGER WORK AND COULD NO LONGER HELP WITH THE CHILDREN. THE HUSBAND STATED THEY HAVE NOT BEEN ABLE TO BE INTIMATE FOR A FEW YEARS. ON (B)(6) 2015, THE CONSUMER HAD A HYSTERECTOMY AT THE AGE OF (B)(6). COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND TRIED TO KILL HERSELF. SINCE INSERTION SHE HAD PAIN DAILY, AND UNDERWENT A HYSTERECTOMY 4 YEARS AFTER ESSURE INSERTION. BOTH EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL IMPORTANCE. EVENT TRIED TO KILL HERSELF, SEEN AS SUICIDE ATTEMPT, IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE; PAIN DAILY, SEEN AS PELVIC PAIN, IS LISTED. SOME DEPRESSIVE FEELINGS AND "EMOCIONAL" DISTURBANCES REGARDING THE DEFINITIVE CONTRACEPTION WITH ESSURE HAVE BEEN REPORTED, HOWEVER NEITHER MAJOR DEPRESSION, NOR SUICIDAL ATTEMPTS ARE EXPECTED. THUS, CAUSAL RELATIONSHIP BETWEEN SUICIDE ATTEMPT AND ESSURE USE IS VERY UNLIKELY. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE EVENT PAIN DAILY AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS INITIALLY REGARDED AS NON-INCIDENT, AND UPON RECEIPT OF FURTHER INFORMATION STATING THAT A HYSTERECTOMY WAS PERFORMED THE CASE WAS UPGRADED TO INCIDENT. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW-UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01779	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2578, AWARENESS DATE 02-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER WAS (B)(6), MOTHER OF 3. NOW SHE HAS HAD ESSURE FOR 3 YEARS. SHE HAS TO HAVE A TOTAL HYSTERECTOMY DUE TO THESE HORRIFIC THINGS. LAST YEAR, 2014, SHE PASSED PART OF A COIL THAT BROKE INTO 3 PIECES. NOW SHE IS HAVING MORE ISSUES WITH THE REST OF THAT COIL MISSING. FOR 3 YEARS SHE HAS HAD NONSTOP CRAMPING, REALLY BAD PERIODS, HORRIBLE MIGRAINES, PLUS MANY MORE ISSUES. SHE HAS BEEN DAILY LIVING WITH PAINS THAT COME WITH HAVING THESE OBJECTS IN HER BODY. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IN THE PREVIOUS YEAR TO THIS REPORT, SHE PASSED PART OF A COIL THAT BROKE INTO 3 PIECES. THIS EVENT, SEEN AS DEVICE BREAKAGE, IS NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINGLE CASES OF DEVICE BREAKAGE HAVE BEEN REPORTED. IN SPITE OF THE LACK OF INFORMATION REGARDING THE CIRCUMSTANCES OF THIS

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BREAKAGE, CONSIDERING ITS NATURE, THE EVENT IS ASSESSES AS RELATED TO ESSURE USE. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. OTHER NON-SERIOUS EVENTS WERE ALSO INFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01780	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2568, AWARENESS DATE 02-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. THE CONSUMER REPORTED SHE WAS INJURED FROM THE ESSURE IMPLANTS. SHE HAD LOST SEVERAL TEETH AND DEVELOPED HASHIMOTO DISEASE. SHE STATED THAT IT HAD ALSO AFFECTED HER NERVOUS SYSTEM AND SHE UNDERWENT 4 SURGERIES IN SPINAL CORD AND BOTH HANDS AND A PARTIAL HYSTERECTOMY TO REMOVE HER RIGHT OVARY 11CM CYST, ALL IN A SIX-MONTH PERIOD. SHE WAS STILL SUFFERING FROM CHRONIC PAIN AND CHRONIC FATIGUE AND HAD FIBROIDS AND ANOTHER CYST ON HER LEFT OVARY. SHE WAS WAITING FOR A SURGERY DATE FOR A COMPLETE HYSTERECTOMY. THE CONSUMER WAS (B)(6) AT THE TIME OF REPORTING. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 23-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED AND

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SPONTANEOUS CASE REPORT REFERS TO AN FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED HASHIMOTO DISEASE AND PRESENTED CHRONIC PELVIC PAIN. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. HASHIMOTO DISEASE IS NOT LISTED FOR ESSURE, WHILE PELVIC PAIN IS LISTED. HASHIMOTO'S DISEASE IS CONSIDERED AS UNRELATED TO ESSURE USE, SINCE ESSURE ACTS LOCALLY IN FALLOPIAN TUBES AND THE MAIN CAUSE OF THIS THYROIDITIS IS A SYSTEMIC AUTOIMMUNE DISORDER. PELVIC PAIN MAY OCCUR DURING ESSURE USE. BASED ON EVENT'S NATURE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE INTERVENTIONS WERE AND WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE ALSO INFORMED. BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01781	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2554, AWARENESS DATE 02-NOV-2015) WHICH REFERS TO A ADULT (>=18Y & <65Y) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. THE CONSUMER REPORTED SHE HAS TWO CHILDREN AND WAS BORN WITH KIDNEY DISEASE. SHE STATED SHE WAS NOT INFORMED OF THE MATERIALS IN ESSURE; THE DEVICE WAS PLACED UNDER GENERAL ANESTHESIA AND WHEN SHE WOKE UP HER DOCTOR TOLD HER HE WAS NOT SURE WHERE THE LEFT ON WAS. SHE HAS HAD 15 ER HOSPITAL VISITS AND WAS 2 TIMES ADMITTED. SHE STATED THAT AT TIME OF THE REPORT, SHE WAS IN THE HOSPITAL (DAY 5). SHE REPORTED ESSURE HAS CAUSED NUMEROUS URINARY TRACT INFECTIONS, WHICH HAD DRASTICALLY CHANGED HER KIDNEY FUNCTION; SHE WAS AT 39 CKD WHEN SHE WAS ADMITTED TO THE HOSPITAL. SHE BLED FOR 19 DAYS STRAIGHT BEFORE THIS HOSPITAL ADMITTANCE. HER RBC (RED BLOOD COUNT) WAS VERY LOW AND HER DOCTOR SAID IT WAS CAUSING HER TO BE ANEMIC. AT TIME OF THE REPORT, SHE WAS FIGHTING AGAINST PNEUMONIA, AND COULD NOT BREATHE. SHE WAS AWAITING A FLAT X-RAY TO CHECK HER BOWELS BECAUSE HER DOCTOR HAS NEVER SEEN AN E-BELLY, HER STOMACH WAS SO BIG ON HER SMALL FRAME SHE LOOKED 7 MONTHS PREGNANT AND HER BELLY BUTTON WAS POPPING OUT, AND IT HURTS VERY MUCH. ITS PRESSURE WAS UNBEARABLE AND WAS MAKING HER NAUSEOUS. SHE WAS TAKING ZOFRAN AND ALTERNATING WITH A SECOND ANTI- NAUSEA MEDICINE. SHE REPORTED THAT AFTER 5 YEARS, SHE HAD TUMORS ON THYROID, NEUROLOGICAL PROBLEMS AND CONSTANT PAIN. THE PAIN WAS LIKE SOMEONE INSIDE HER ABDOMINAL CAVITY CUTTING HER WITH A DULL KNIFE SO DULL THAT HER BODY GOES INTO SHOCK WHICH EACH STABBING, IT WAS SHARP AND AT TIMES DOUBLES OVER VOMITING JUST

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FROM THE PAIN. SHE STATED BECAUSE OF THE PAIN SHE COULD NOT HAVE SEX; IT WAS LIKE A SAWING FEELING INSIDE AND BLEEDING DID HAPPEN AS WELL. SHE ALMOST FELT LIKE HIS PENIS IS PUSHING INTO THE DEVICES COILS AND RIPPING HER APART. SHE STATED HAVING RASHES, BLOATING, PAIN, MIGRAINES, AUTOIMMUNE DISEASE, NEUROLOGICAL PROBLEMS, BACK PAIN, ABDOMINAL PAIN, NEUROPATHY, WEIGHT GAIN, PAIN WITH SEX, E-BELLY, VAGINAL BLEEDING FOR 19 DAYS, FREQUENT UTI, 11 ER VISITS, 6 HOSPITAL STAYS, ADMITTED TWICE, SWELLING, STABBING PAIN, SHARP PAIN, BUTTERFLIES IN LOW ABDOMINAL AREA LIKE A BABY MOVING, NERVE DAMAGE, FATIGUE, FOGGY BRAIN, CONFUSION, DIZZINESS, LOSS OF CONTROL OF MOTIONS, LOSS OF QUALITY FAMILY TIME, AND EVEN HAVING TO CONSIDER A HYSTERECTOMY TO SAFELY REMOVE ESSURE AT ONLY (B)(6). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND ASSESSMENT WERE RECEIVED: QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. CORRECTION (02-NOV-2015) FOLLOWING COMPANY INTERNAL REVIEW: COMPANY CAUSALITY COMMENT UPDATED. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLED FOR 19 DAYS STRAIGHT BEFORE THIS HOSPITAL ADMITTANCE. SHE WILL UNDERGO A HYSTERECTOMY IN ORDER TO REMOVE ESSURE. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO HOSPITALIZATION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND SEVERAL NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01782	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2582, AWARENESS DATE 02-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. IN 2013 THE CONSUMER STARTED HAVING AUTOIMMUNE ISSUES INCLUDING DIZZINESS, MIGRAINES, MEMORY LOSS, TROUBLE CONCENTRATING, EXTREME FATIGUE AND JOINT PAIN. SHE HAD BEEN TO MULTIPLE SPECIALISTS TO FIGURE OUT WHAT WAS GOING ON AND NO ONE HAD ANSWERS. IN 2015 HER HUSBAND FOUND OUT ONLINE THAT MANY OTHER WOMEN WERE HAVING SIMILAR ISSUES WITH ESSURE AND SHE REALIZED SOME OF HER OTHER PROBLEMS WERE PROBABLY ALSO CAUSED BY IT. IN 2014 SHE HAD AN ABLATION DUE TO HEAVY CLOTTY PERIODS AND SEVERE CRAMPING. THE ABLATION HELPED WITH THE BLEEDING BUT SHE WAS STILL HAVING SEVERE CRAMPING. SHE HAD NO ENERGY TO TAKE HER SONS TO PLACES. SHE WAS UNABLE TO WORK BECAUSE OF THE CONFUSION, MEMORY ISSUES, FATIGUE AND JOINT PAIN. INVALID SUMMARY CASE FOR UNKNOWN MANY WOMEN: (B)(4). THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW

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TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING AUTOIMMUNE ISSUES. SHE ALSO HAD TO HAVE AN ABLATION DUE TO HEAVY CLOTTY PERIODS AND SEVERE CRAMPING. THESE EVENTS, SEEN AS AUTOIMMUNE DISORDER, MENORRHAGIA AND ABDOMINAL PAIN, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT AUTOIMMUNE DISORDER WHICH IS UNLISTED. CONSIDERING ABDOMINAL PAIN AND MENSES PATTERN CHANGES MAY OCCUR DURING ESSURE USE AND THE ABSENCE OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN ABLATION WAS REQUIRED AS A THERAPEUTIC MEASURE TO THESE EVENTS, THIS CASE IS REGARDED AS INCIDENT. REGARDING AUTOIMMUNE ISSUE, LIMITED INFORMATION HAS BEEN PROVIDED; HOWEVER, GIVEN ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND SUSPECT INSERT IS VERY UNLIKELY. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01783	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 1/1/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2552 AND FDA-2014-N-0736-0015, AWARENESS DATE 02-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. ADDITIONAL INFORMATION RECEIVED ON 23-NOV-2015 (PTC INVESTIGATION RESULT). PRIOR TO ESSURE SHE RARELY GOT SICK, NEVER COMPLAINED OF PAIN AND COULD REPEAT A CONVERSATION WORD FOR WORD FROM YEARS BEFORE. SHE ONLY SAW A PHYSICIAN FOR YEARLY VISITS. THEN SHE WAS IMPLANTED WITH IMPLANT THAT CHANGED EVERYTHING. HER HEALTH CHANGED VERY QUICKLY. HER BODY WAS GRADUALLY BECOME SORE, SHE COMPLAINED CONSTANTLY THAT SHE FELT AS IF SHE WAS GETTING THE FLU, BUT THE FLU NEVER CAME. SHE COULD BARELY MOVE. SHE STOOD BEND OVER UNTIL SHE COULD MOVE HER BODY TO A FULL STANDING POSITION. THEN SHE HAD TO WAIT BEFORE SHE COULD WALK. EVERY MOVE SHE MADE LOOKED PAINFUL. BUT SHE COULD NOT SIT TO RELAX BECAUSE SHE COULD NOT GET COMFORTABLE BECAUSE OF NERVE PAIN. ONCE SHE WAS MOVING EVENTUALLY THE PAIN WOULD NOT BE AS BAD; SO SHE WOULD TRY TO MOVE FOR AS LONG IN A DAY AS SHE COULD, SOMETIME UNTIL 11 PM. BECAUSE AS SOON AS SHE STOPPED MOVING EVEN FOR A SECOND THAT SAME ROBOTIC MOVEMENT WOULD BEGIN. HER MEMORY WAS FADING QUICKLY. SHE WOULD ASK THE SAME QUESTIONS OVER AND OVER AGAIN WITH IN 5 MINUTE SPAN AND NOT REMEMBER THE ANSWER. THIS CAUSED A LOT OF ANXIETY FOR HER, ESPECIALLY WHEN SHE COULD NO LONGER REMEMBER HER DAUGHTERS BIRTHDAYS OR HOW MUCH THEY WEIGHED WHEN THEY WERE BORN. TESTS WERE PERFORMED AND CAME BACK NORMAL; MANY ULTRASOUNDS CAME BACK UNREMARKABLE. HER COILS WERE IN PLACE IN HER FIRST

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HYSTEROSALPINGOGRAM (HSG). SITTING IN THE CAR WAS TOO PAINFUL. ANOTHER HYSTEROSCOPY BIOPSY OF HER UTERUS AND D&C WERE PERFORMED AND EVERYTHING WAS NORMAL. ONE PHYSICIAN TOLD HER THAT SHE DID NOT BELIEVE ESSURE WAS THE CAUSE BECAUSE IT WAS NOT SEEN AT THE OPENING OF HER TUBES. APPARENTLY THEY MIGRATED FURTHER INTO HER TUBES. ANOTHER HSG WAS PERFORMED AND IT COULD VISIBLY SEE ONE OF THE COILS WAS BENT INTO AN L SHAPE AND DYE STREAMING INTO HER ABDOMEN. CONSUMER WOULD GET SHARP PAIN IN HER HEAD LIKE AN ELECTRICAL SHOCK. AFTER ALMOST 5 LONG YEARS OF PRETTY SERIOUS HEALTH ISSUES, SEVERAL EMERGENCY ROOM (ER) VISITS, NUMEROUS TESTS AND PHYSICIAN APPOINTMENTS, CONSUMER HAD A HYSTERECTOMY. IN THE SAME NIGHT, THE STABBING PAIN WAS GONE. HER SKIN COLORING WAS NO LONGER GRAY AND UNHEALTHY, BUT MOST NOTICEABLE WAS THE IMMEDIATE RETURN OF HER MEMORY. IT TOOK A WEEK FOR THE BRAIN ZAPS TO GO AWAY. SHE DID NOT EXPERIENCE IT IN OVER 2 YEARS. SHE NO LONGER COMPLAINS OF NUMBNESS OR TINGLING IN HER LIMBS, THE LOWER BACK PAIN WAS LESS AND IN WEEKS THE INFLAMMATION WAS GONE FROM HER BODY. DURING HYSTERECTOMY, PHYSICIAN FOUND EXTREMELY SEVERE SCAR TISSUE AND ADHESIONS; SHE HAD MULTIPLE ORGANS THAT WERE TETHERED UP, PULLED TO THE SIDE AND ATTACHED BY SCAR TISSUE AND ADHESIONS. SHE IS AGAIN AS HEALTHY AS SHE COULD BE AFTER THE POISON WHICH WAS IN HER BODY. CONSUMER DEARLY EXPERIENCED NEUROLOGICAL ISSUES CAUSED BY THE NICKEL, SHE HAD 21 SYMPTOMS OF NICKEL TOXICITY, BUT SHE WAS NOT TESTED. THEY LATER FOUND THAT NUMBERS FOR INFLAMMATION WERE HIGH. PTC INVESTIGATION RESULT: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERAL NON-SERIOUS EVENTS. ONE PHYSICIAN TOLD HER THAT SHE DID NOT BELIEVE ESSURE WAS THE CAUSE BECAUSE IT WAS NOT SEEN AT THE OPENING OF HER TUBES. APPARENTLY THEY HAD MIGRATED FURTHER INTO HER TUBES (UNDERSTOOD AS DEVICE MIGRATION). SHE ALSO REPORTED THAT SHE HAD NICKEL TOXICITY. A HYSTERECTOMY WAS PERFORMED. DEVICE MIGRATION IS LISTED IN THE REFERENCE SAFETY INFORMATION WHILE NICKEL TOXICITY IS UNLISTED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. MIGRATION IS OFTEN USED SYNONYMOUSLY WITH PERFORATION. IT IS SOMETIMES USED TO IMPLY THAT A COMPLETE PERFORATION OCCURRED NOT IMMEDIATELY, BUT OVER TIME, E.G. WHEN AN UNDIAGNOSED PARTIAL PERFORATION DURING INSERTION GRADUALLY LEADS TO A COMPLETE PERFORATION. OFTEN MIGRATION IS REPORTED WHEN THE EXACT TIME POINT OF PERFORATION IS NOT KNOWN. SOMETIMES MIGRATION THROUGH THE FALLOPIAN TUBE IS SUSPECTED BY THE REPORTER, BECAUSE THE ESSURE INSERT IS FOUND IN THE ABDOMEN AND NO APPARENT PERFORATION CAN BE IDENTIFIED. THEREFORE, BASED ON THE INFORMATION PROVIDED AND POSSIBLE MECHANISM OF MIGRATION, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. ALTHOUGH, IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM ESSURE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE A METAL POISONING. THEREFORE THE REPORTED NICKEL TOXICITY WAS CONSIDERED UNRELATED TO ESSURE. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01784	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2543, AWARENESS DATE 02-NOV-2015). ADDITIONAL INFORMATION WAS RECEIVED ON 05-NOV-2015 (CASE# FDA-2014-N-0736-2532) AND ON 22-NOV-2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN 2007. SHE EXPERIENCED HEAVY BLEEDING, HAIR LOSS, DENTAL ISSUES, DEBILITATING BACK ISSUES, CONSTANT ITCHING AND HEADACHES. SHE WAS FORCED TO UNDERGO A HYSTERECTOMY TO STOP EIGHT YEARS OF E-HELL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 22-NOV-2015 PTC GLOBAL NUMBER: (B)(6). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS

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CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HEAVY BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (8 YEARS AFTER DEVICE PLACEMENT). THIS EVENT, REGARDED AS GENITAL BLEEDING, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01785	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2414, AWARENESS DATE 02-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2014. TWO DAYS AFTER HAVING IT PLACED, SHE WAS IN THE ER (EMERGENCY ROOM) FOR HEAVY BLEEDING AND HAD HER PLATELETS CHECKED AND THEY WERE 68000. SHE WAS THEN SENT TO THE BLOOD DOCTOR AND WAS DIAGNOSED WITH ITP (INTERPRETED AS IDIOPATHIC THROMBOCYTOPENIA). AFTER THAT SHE HAD EVERY BLOOD TEST RAN AND CT SCANS AND ULTRASOUNDS DONE TRYING TO FIND OUT WHAT WAS CAUSING ALL HER PROBLEMS. SHE WAS IN CHRONIC PAIN, BLOATED AND SWELLED UP, HAD CHRONIC FATIGUE, BRAIN FOG, BLURRY VISION WITH PERFECT EYE SIGHT, STROKE LIKE SYMPTOMS, HEAVY PERIODS, EXTREME WEIGHT GAIN AND SHE COULDN'T LOSS FOR NOTHING, MIGRAINES, LOSS OF COORDINATION, VERY BAD MOOD SWINGS, MUSCLE AND OVARY SPASMS, HANDS BREAKING OUT OF NOWHERE, BAD REACTION TO EARRINGS THAT HAD NICKEL, HER INSIDES WERE ITCHY AND BURNING AT ONE POINT, CONSTANT DISCHARGE WITH NO EXPLANATION, PAIN DURING AND AFTER SEX AND VERY BAD HAIR LOSS. HER PERFORMANCE AT WORK REALLY DROPPED NO MATTER HOW HARD SHE TRIED, LIVED ON TYLENOL TO THE POINT IT STOPPED WORKING AND HAD TO BE PRESCRIBED SOMETHING STRONGER TO MAKE IT THRU THE DAY. SHE COULD NOT HAVE A SEXUAL RELATIONSHIP WITH HER HUSBAND DUE TO THE PAIN. SHE WAS NOT ABLE TO HELP WITH HOUSE WORK BECAUSE SHE WAS ALWAYS WORE OUT AND TIRED. ON (B)(6) SHE HAD A FULL HYSTERECTOMY AND LOST HER TUBES AS WELL TO REMOVE THE ESSURE. SINCE THAT DAY SHE FELT WONDERFUL. SHE WAS NO LONGER SUFFERING FROM HER SYMPTOMS. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT

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SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN (B)(6) 2014. SHE REPORTED HEAVY BLEEDING AMONGST OTHER EVENTS. GENITAL BLEEDING IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED FOR ESSURE. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND THE HYSTERECTOMY REQUIRED, CAUSALITY CANNOT BE EXCLUDED AND THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01786	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): 10/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2509, AWARENESS DATE 02-NOV-2015) WHICH REFERS TO REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. THE CONSUMER REPORTED THAT AFTER HER 5TH MISCARRIAGE AND 2 CHILDREN SHE DECIDED FOR PERMANENT BIRTH CONTROL USE. SHE STATED THE INSERTION PROCEDURE WAS ONE OF THE MOST PAINFUL THINGS SHE HAD EVER EXPERIENCED. THE DOCTOR GOT THE FIRST COIL IN EASILY BUT THE SECOND ONE WAS NOT AS EASY, HE WAS HAVING PROBLEMS PLACING IT; SHE REMEMBERED THE PAIN FROM IT ALMOST MADE HER FALL OFF THE TABLE. THEN ALL OF A SUDDEN, IT JUST WENT. THEY THOUGHT THAT IT WAS OK BUT SHE HAD TO HAVE THE FOLLOW UP TEST DONE TO CONFIRM. FOLLOWING THE PROCEDURE THE PAIN WAS CONSTANT AND SHE KNEW THERE WAS SOMETHING WRONG NOT REALIZING THE OTHER SIDE EFFECTS THAT SHE WAS ALSO HAVING WAS EVEN RELATED TO ESSURE, LIKE BLOATING (DREADED E-BELLY), SHE LOOKED LIKE SHE WAS AT LEAST 3 MONTHS PREGNANT WITHIN THE FIRST FEW WEEKS OF HAVING ESSURE. HER HAIR WAS FALLING OUT IN CLUMPS AND SHE HAD MORE CAVITIES THAT SHE HAD EVER HAD, SHE STATED HER TEETH WERE LITERALLY ROTTING AWAY. SHE WAS CONSTANTLY IN PAIN, IN SO MUCH PAIN IN HER JOINTS SHE DID NOT WANT TO EVEN GET OUT OF BED; BEING INTIMATED WITH HER HUSBAND WAS NOT EVEN AN OPTION BECAUSE THAT WAS EVEN MORE PAINFUL. WITH ALL OF THIS GOING ON, DEPRESSION SET IN, THE DEPRESSION MADE IT HARDER TO GET OUT OF BED THAN THE PAIN DID, SHE WANTED TO DO NOTHING BUT CRY AND/OR SLEEP ALL DAY. THE CONFIRMATION TEST CONFIRMED THAT ONE COIL WAS STILL IN PLACE, AND THE OTHER ONE THAT WAS HARD TO PLACE HAD PERFORATED THROUGH HER

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TUBE AND WAS FOUND ATTACHED TO HER COLON. AN EMERGENCY SURGERY WAS SET UP TO REMOVE THE COIL, WHICH WAS WHEN SHE DECIDED TO RESEARCH THE PROBLEMS SHE WAS HAVING. SHE HAD HER TUBE WITH THE 1 COIL REMOVED AND THE OTHER TUBE WAS TIED AND THE OTHER COIL REMOVED FROM BEING ATTACHED TO HER COLON; BECAUSE OF THE PET FIBERS THAT ARE USED WITH THE COILS, SHE CONTINUE TO HAVE SIDE EFFECTS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DURING CONFIRMATION TEST IT WAS OBSERVED THAT ONE COIL WAS IN PLACE, AND THE OTHER ONE THAT WAS HARD TO PLACE HAD PERFORATED THROUGH HER TUBE AND WAS FOUND ATTACHED TO HER COLON. THEN, AN EMERGENCY SURGERY WAS SET UP TO REMOVE THE COIL. THIS EVENT, SEEN AS FALLOPIAN TUBE PERFORATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE INSERTION OR REMOVAL. IN THIS CASE, THE INSERTION WAS VERY DIFFICULT AND PAINFUL ON ONE SIDE WHICH INDICATES THAT THE PERFORATION PROBABLY HAS OCCURRED DURING PLACEMENT. THEREFORE CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGERY WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01787	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2488, AWARENESS DATE 02-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. THE REPORTER STATED THAT HER DAUGHTER HAD NOTHING BUT HEALTH ISSUES SINCE ESSURE INSERTION. BECAUSE OF ALL THE PROBLEMS WITH ESSURE SHE HAD TO HAVE A TOTAL HYSTERECTOMY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 22-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO

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HAVE A TOTAL HYSTERECTOMY. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. THIS PARTICULAR CASE WAS REPORTED WITH VERY LIMITED INFORMATION. THE EXACT REASON FOR THE HYSTERECTOMY WAS NOT SPECIFIED. DESPITE THE LIMITED INFORMATION, GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THAT BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01788	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): 10/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 02-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2015 FOR PERMANENT CONTRACEPTION. ON (B)(6) 2015 HYSTEROSALPINGOGRAM SHOWED COMPLETE EXPULSION OF RIGHT ESSURE DEVICE INTO ENDOMETRIAL CAVITY. NO PORTION OF ESSURE DEVICE WAS WITHIN FALLOPIAN TUBE ON RIGHT SIDE. THE RIGHT FALLOPIAN TUBE WAS FILLED WITH CONTRAST, ALTHOUGH FREE SPILL WAS NOT SEEN DURING EXAM. THE LEFT ESSURE DEVICE WAS NOT WITHIN THE FALLOPIAN TUBE. IT WAS WITHIN THE LEFT PERITONEAL CAVITY, ANTERIOR TO THE UTERUS. THERE WAS A COMPLETE FILLING OF LEFT FALLOPIAN TUBE WITH FREE INTRAPERONEAL WITH CONTRAST. PATIENT WAS OKAY AND SURGICAL REMOVAL AND TUBES TIED WAS PLANNED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 22-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS

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NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND LATER A HYSTEROSLPINGOGRAM SHOWED THE LEFT ESSURE WAS NOT WITHIN THE FALLOPIAN TUBE. IT WAS WITHIN THE LEFT PERITONEAL CAVITY, ANTERIOR TO THE UTERUS. PATIENT WAS OKAY AND SURGICAL REMOVAL WAS PLANNED. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE, THE EXACT DATE AND MECHANISM OF THIS DISLOCATION WERE NOT INFORMED, CONSIDERING ITS NATURE, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE USE AND SINCE AN INTERVENTION WILL BE REQUIRED FOR DEVICE REMOVAL, THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENT WERE ALSO REPORTED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01789	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056924) IN UNITED STATES ON 02-NOV-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT AFTERWARDS. ACCORDING TO HER, THE BABY DIED BECAUSE OF THE PRIOR PROCEDURES, SHE HAD TO HAVE 4 SURGERIES AND A HYSTERECTOMY. SHE HAD DEPRESSION AND FELT LIKE A YEAR OF HER LIFE WAS LIVED IN A FOG AFTERWARDS. A LIFE THREATENING, HOSPITALIZATION, DISABILITY/PERMANENT DAMAGE, CONGENITAL ANOMALY, REQUIRED INTERVENTION WERE MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. LINKED CHILD CASE: (B)(4). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 25-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENTS AND LACK OF EFFICACY ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS OR LACK OF EFFICACY AND A

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QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, THE BABY DIED BECAUSE OF THE PRIOR PROCEDURES, SHE HAD TO HAVE 4 SURGERIES AND A HYSTERECTOMY. ONLY PREGNANCY AND HYSTERECTOMY ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (ECT). IN THIS CASE, NO INFORMATION WAS PROVIDED ABOUT ECT. CONSUMER MENTIONED THE BABY DIED (GESTATIONAL AGE NOT PROVIDED) BECAUSE OF UNSPECIFIED PRIOR PROCEDURES. SHE ALSO MENTIONED A HYSTERECTOMY. ALTHOUGH LIMITED INFORMATION WAS GIVEN FOR A COMPREHENSIVE CAUSALITY ASSESSMENT; CONSIDERING EVENTS NATURE CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED FOUR SURGERIES, AS THEY WERE NOT SPECIFIED, CAUSALITY WITH ESSURE CANNOT BE ASSESSED BY NOW. THIS CASE WAS REGARDED AS INCIDENT; SINCE IT CANNOT BE EXCLUDED THE HYSTERECTOMY WAS PERFORMED AS A CONSEQUENCE OF ESSURE THERAPY. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 05-JAN-2016: FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO BECAME PREGNANT AFTER ESSURE (FALLOPIAN TUBE OCCL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01790	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056924) IN UNITED STATES ON 02-NOV-2015. IT REFERS TO HER BABY, WHO WAS EXPOSED TO ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IN UTERO. ADDITIONAL INFORMATION RECEIVED ON 25-NOV-2015. THE MOTHER HAD ESSURE INSERTED AND BECAME PREGNANT AFTERWARDS. ACCORDING TO HER, THE BABY DIED BECAUSE OF THE PRIOR PROCEDURES, SHE HAD TO HAVE 4 SURGERIES AND A HYSTERECTOMY. A LIFE THREATENING, HOSPITALIZATION, DISABILITY/PERMANENT DAMAGE, CONGENITAL ANOMALY, REQUIRED INTERVENTION WERE MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. LINKED MOTHER CASE: (B)(4). PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 25-NOV-2015 PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY

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CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER AND REFERS TO HER BABY WHO WAS EXPOSED TO ESSURE MICRO-INSERT IN UTERO AND DIED BECAUSE OF UNSPECIFIED PROCEDURES IN THE MOTHER. THE REPORTED FETAL DEATH IS UNLISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, NEITHER THE EXACT CAUSE OF BABY DEATH WAS PROVIDED NOR WAS THE GESTATIONAL AGE AT THE TIME OF THIS EVENT INFORMED. HOWEVER, BASED ON THE MINIMAL INFORMATION AVAILABLE, A CONTRIBUTORY ROLE OF ESSURE IN BABY'S DEATH CANNOT BE TOTALLY EXCLUDED. THEREFORE, THIS CASE WAS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01791	BAYER HEALTHCARE LLC	12/1/2015	12/1/2015

Event Information:

Event Date (B3): 10/8/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NON-HEALTH PROFESSIONAL IN UNITED STATES ON 02-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE REPORTER WAS FROM FACILITY THAT HAS A PATIENT WHO IS GOING TO HAVE ESSURE REMOVED AND GET A TUBAL DONE BECAUSE SHE HAD PAIN ON BOTH SIDE FROM ESSURE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE INSERTED AND EXPERIENCED PAIN ON BOTH SIDES FROM IT (REGARDED AS PELVIC PAIN). PELVIC PAIN IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED EVENT ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. GIVEN THE SUGGESTIVE TEMPORAL RELATIONSHIP, EVENT NATURE AND PRODUCT PROFILE, CAUSALITY CANNOT BE EXCLUDED. SINCE CONSUMER IS GOING TO HAVE ESSURE REMOVED (SURGICAL INTERVENTION WILL BE REQUIRED), THIS CASE IS REGARDED AS INCIDENT. ADDITIONAL INFORMATION AND PRODUCT TECHNICAL ANALYSIS WERE REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 03-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058279		12/1/2015	12/4/2015

Event Information:

Event Date (B3): 12/15/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7): 2/11/2011
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PLACED IN FALLOPIAN TUBES IN 2007. I HAD THE THREE MONTH HSG TEST DONE, WHICH CONFIRMED BOTH TUBES WHERE BLOCKED. WITHIN A FEW MONTHS OF PLACEMENT, I BEGAN HAVING PAIN IN ABDOMINAL AND PELVIC AREA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058280	BAYER	12/1/2015	12/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/16/2010
Explant Date (E7): 12/1/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2010, I HAD ESSURE, A BIRTH CONTROL DEVICE, IMPLANTED. I STARTED TO SUFFER SEVERAL MONTHS AFTER THE INSERTION VARIOUS THINGS, FROM BACK PAIN TO LACK OF SEX DESIRE BECAUSE OF THE PAIN ASSOCIATED WITH IT. I WOULD HAVE IRREGULAR PERIODS, SEVERE CRAMPS, HEADACHES, INFLAMMATION IN MY URETERS AND CYST THAT WOULD COME AND GO ON A REGULAR BASE. AFTER FINALLY SEEING DR. (B)(6) AT (B)(6), WENT TO DECIDE THE TREATMENT PLAN IS TO UNDERGO A HYSTERECTOMY. I AM ONLY (B)(6) AND NOW SUFFERING FROM ANXIETY AND DEPRESSION BECAUSE I AM FEARFUL OF THE SURGERY SCHEDULED (B)(6) 2015. AFTER VARIOUS TESTS AND CT SCANS, ULTRASOUNDS BECAUSE ONLY ONE DEVICE WAS DETECTED, WE FINALLY FOUND THE RIGHT SIDE ESSURE VERY HIGH UP IN THE FALLOPIAN TUBES MAKING IMPOSSIBLE TO LEAVE THE FALLOPIAN TUBES IN. DUE TO THE PAIN AND ANXIETY MY ABILITY TO GO TO WORK HAS BEEN EFFECTED. I AM A LONGSHOREMAN, IN MY INDUSTRY I DRIVE HEAVY EQUIPMENT AND WORK VESSELS THAT REQUIRE A SOUND MIND AND ABILITY TO LIFT MORE THAN 50 POUNDS AS NEEDED FOR RIGGING OF GEAR. SO THIS HAS BEEN A FINANCIAL HARDSHIP.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01793	BAYER HEALTHCARE LLC	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/9/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2389, AWARENESS DATE 03-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED ON (B)(6) 2013. SINCE THEN HER HEALTH HAS SERIOUSLY DECLINED. SHE EXPERIENCED SEVERE PELVIC PAIN, HIP PAIN, JOINT PAIN, ANXIETY, WEIGHT GAIN AND BLOATING. SOMETIMES PAIN WAS TO THE POINT WHERE SHE COULD NOT LEAVE HER HOUSE. SHE WAS GETTING HER FIRST EVER HSG AND A PARTIAL OR FULL HYSTERECTOMY THIS YEAR. SHE WENT FROM A FUN OUTGOING BUNGEE JUMPING WOMAN TO IN HER EYES BEING DISABLED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 25-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PELVIC PAIN. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE

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AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. IN ADDITION, NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01794	BAYER HEALTHCARE LLC	12/2/2015	12/2/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2012
Explant Date (E7): 9/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2331, AWARENESS DATE 03-NOV-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012, AFTER HER FOURTH CHILD WAS BORN. CONSUMER REPORTED THAT SHORTLY AFTER THE PROCEDURE, SHE STARTED TO BLEED SO HEAVY ALL THE TIME, HAD EXTREMELY BAD CRAMPS CONSTANTLY, HER BACK HURT, PINCHED NERVES DOWN HER NECK TO BACK, HORRIBLE MOOD SWINGS AND EMOTIONAL MESS. SHE WAS PUT ON BIRTH CONTROL PILLS TO HELP WITH HER BLEEDING BUT IT DID NOT HELP. IN (B)(6) 2014, SHE HAD A HYSTERECTOMY PERFORMED. SHE WAS STILL IN ALL KINDS OF PAIN AND STARTED TO GET MIGRAINES, DEPRESSION, ANXIETY, PANIC ATTACKS AND SHE HURT ALL OVER. DOCTOR RAN A LOT OF TESTS AND HER NUMBERS WERE OUT OF WHACK FOR HER THYROID AND SUGARS. SHE WAS REFERRED TO A RHEUMATOLOGIST AND WAS DIAGNOSED WITH FIBROMYALGIA. HER DOCTOR DIAGNOSED HER RESTLESS LEG SYNDROME AND IRRITABLE BOWEL SYNDROME. SHE WAS REFERRED TO PAIN MANAGEMENT AND WAS DIAGNOSED WITH LUMBAR SPONDYLOSIS. SHE WAS TAKING A DOZEN OF PRESCRIPTION PILLS PLUS OVER THE COUNTER MEDICATION, WENT TO DO PHYSICAL THERAPY 3 TIMES A WEEK AND WORE A BACKBRACE. THREE YEARS LATER AND SHE WAS STILL IN PAIN. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED TO HAVE BLEEDING SO HEAVY ALL THE TIME. SHE UNDERWENT A HYSTERECTOMY 2 YEARS AFTER ESSURE INSERTION. THIS EVENT, INTERPRETED AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, MENSES PATTERN CHANGES AND GENITAL BLEEDING MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01795	BAYER HEALTHCARE LLC	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 6/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2372, AWARENESS DATE 03-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. CONSUMER REPORTED SINCE SHE HAD ESSURE INSERTED, SHE HAS HAD EXTREMELY HEAVY BLEEDING. SHE HAD AN ABLATION PROCEDURE, BUT STILL HAS HEAVY BLEEDING. SHE HAS ALSO HAD A CONSTANT PAIN IN ABDOMEN ON HER RIGHT SIDE. SHE HAS ALSO HAD A SWOLLEN ABDOMEN THAT IS LARGER THAN EITHER TIME THAT SHE WAS NINE MONTHS PREGNANT. SHE ADMITS THAT SHE IS OVERWEIGHT, BUT IT IS ALL IN HER ABDOMEN. SHE EXERCISES THREE TO FIVE TIMES A WEEK, BUT THE SWELLING IN ABDOMEN WILL NOT GO DOWN NO MATTER WHAT. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT THE FINAL PRODUCT TESTING WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION THERE IS NO RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A

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FEMALE CONSUMER WHO EXPERIENCED EXTREMELY HEAVY BLEEDING SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO AN ENDOMETRIAL ABLATION WITHOUT IMPROVEMENT. THIS EVENT, REGARDED AS GENITAL BLEEDING, IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER RELATED BLEEDING'S ONSET TO ESSURE INSERTION AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. THUS, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REPORTED ENDOMETRIAL ABLATION (REQUIRED INTERVENTION) FOR BLEEDING'S TREATMENT. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION THERE IS NO RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01796	BAYER HEALTHCARE LLC	12/2/2015	12/2/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/27/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2395, AWARENESS DATE 03-NOV-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER IS (B)(6) AND REPORTED SHE JUST HAD A TOTAL HYSTERECTOMY INCLUDING BILATERAL SALPINGECTOMY (BEING ABLE TO KEEP HER OVARIES) ON (B)(6) 2015 BECAUSE OF ESSURE. FOR THE LAST 3 YEARS HER HEALTH HAS DECLINED. SHE DECIDED IT WAS TIME TO TAKE ACTION AND REMOVE THE COILS. DURING THE HYSTERECTOMY HER DOCTOR ACKNOWLEDGED THE FACT THAT ONE OF THE COILS HAD MIGRATED TO THE UTERUS. HE ALSO STATED THAT SHE DEVELOPED ENDOMETRIOSIS AND EXPLAINED THAT BOTH THOSE ISSUES COULD VERY WELL BE JUST THE BEGINNING AS TO WHY SHE WAS SO UNCOMFORTABLE. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT THE FINAL PRODUCT TESTING WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION THERE IS NO RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS

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NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO STATED SHE HAD A TOTAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY BECAUSE OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). ACCORDING TO HER, DURING THE SURGERY IT WAS FOUND THAT ONE OF THE COILS HAD MIGRATED TO THE UTERUS. SHE WAS ALSO DIAGNOSED WITH ENDOMETRIOSIS. ONLY THE REPORTED ESSURE MIGRATION TO UTERUS IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT INCLUDES MIGRATION/EXPULSION INTO THE UTERUS/CERVIX OR OUT OF THE BODY. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. THE EXACT MECHANISM OF THE REPORTED DEVICE MIGRATION WAS NOT INFORMED AND THE MEDICAL REASON FOR THE PERFORMED HYSTERECTOMY WAS UNCLEAR (UNCLEAR IF PROCEDURE WAS DUE TO ENDOMETRIOSIS SYMPTOMS OR ESSURE MIGRATION). HOWEVER, GIVEN DEVICE MIGRATION NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. REGARDING ENDOMETRIOSIS, ESSURE HAS A MECHANICAL ACTION IN FALLOPIAN TUBES. NO HORMONES/DRUGS ARE RELEASED FROM THE INSERT. THUS, IT IS UNLIKELY THAT THE DEVICE MAY HAVE CONTRIBUTED TO CONSUMER'S ENDOMETRIOSIS. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (SURGICAL INTERVENTION REQUIRED). BASED ON THE AVAILABLE INFORMATION THERE IS NO RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058217	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 6/22/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ALWAYS IN PAIN, BLEED ALL THE TIME, PELVIC PAIN ALL THE TIME, SEX LIFE IS NO MORE BECAUSE I HURT SO BAD, STAY VERY ILL ALL THE TIME, SUFFER FROM DEPRESSION, I CAN GO ON WITH THIS. HAS REALLY BEEN A REALLY BAD CF THING I HAVE KIDS AND I CAN'T KEEP A JOB BECAUSE I'M IN TOO MUCH PAIN ALL THE TIME AND THROWING UP ALL THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058219	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 11/29/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVERY MONTH FOR THE PAST 3 YEARS I GET A SHARP STABBING PAIN ON MY LOWER RIGHT SIDE. IT OCCURS AROUND OVULATION AND ALSO DURING MENSTRUATION. IT USUALLY SUBSIDES AFTER A COUPLE DAYS. I HAVE SPOKEN WITH MY DR WHO HAS DENIED IT BEING CAUSED BY ESSURE AND THAT IT IS PROBABLY SCAR TISSUE PULLING. THE OTHER DAY I WAS SITTING IN MY BED AND ALSO WHILE IN MY CAR AND IT JUST STARTS OCCURRING OUT OF NOWHERE. IT FEELS LIKE GETTING POKED WITH A NEEDLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058222	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 6/21/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

#MEDWATCHER #FOLLOWUP 2 #FDA MW5058222 #(B)(4). MY HYSTERECTOMY WAS (B)(6) 2015. FOUR COILS WERE FOUND AS WELL AS AN INSERTION ROD. ONE COIL WAS FRAGMENTED UNDER MY BLADDER. ONE HAD PROTRUDED MY TUBE RENDERING IT UNIDENTIFIABLE. ONE HAD PROTRUDED MY UTERUS. THIS DR WAS NOT PROPERLY TRAINED AND CARELESS. BUT JUST HOW MUCH TRAINING DO THEY RECEIVE? DOES THE DRUG REP TEACH THEM HOW BY SOME LITERATURE? STOP LETTING DRS HARM PATIENTS WITH THIS TOXIC IMPLANT!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058223	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 1/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE A FEELING SUDDENLY TAKE OVER MY ENTIRE LIFE WITH A SCARED, PANICKED KIND OF FEELINGS. CAN'T CATCH MY BREATH AND NOT ABLE TO CALM DOWN FOR LONG PERIODS OF TIME USUALLY TAKES ME TAKING A PRESCRIPTION PILL FOR ANXIETY TO MAKE ME FALL ASLEEP SO WHEN I WAKE UP IT'S ALL OVER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058224	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 11/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HYSTERECTOMY TO REMOVE ESSURE AND LIMIT FURTHER SYMPTOMS/COMPLICATIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058225	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 11/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STABBING PAIN, CYSTS, ANXIETY ,LACK OF SEX, DISCHARGE. NOT FEELING LIKE MYSELF.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058226	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 9/18/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I ENDED UP HAVING CYST ON MY OVARIES, THANK GOD THEY WERE BENIGN, AND ALSO HAVE ARTHRITIS IN MY BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058227	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 6/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I IMMEDIATELY FELT LIKE I WAS PMS'ING ALL THE TIME. SEVERE CRAMPING, BLOATING, MOOD SWINGS, EXTREMELY TENDER BREASTS, SEVERE LOWER BACK PAIN, WEIGHT GAIN, DEPRESSION, JUST TO NAME A FEW. I WOULD COMPLAIN OF THIS TO MY OBGYN AND HE WOULD SAY IT WAS NOT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058228	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 6/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, DENTAL ISSUES, BLOATING, WEIGHT GAIN, MOOD SWINGS, DEPRESSION, ANXIETY ATTACKS, PAIN ON RIGHT SIDE, PAINFUL PERIODS, DIZZINESS, FORGETFULNESS, ITCHY SCALP, YEAST INFECTIONS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058229	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN TRACKING MENSTRUAL CYCLES WHICH HAD BECOME IRREGULAR. HAVING 2 DISTINCT CYCLES PER MONTH. HAD ROUTINE PAP IN AUGUST WHICH CAME BACK ABNORMAL. ADDITIONAL TESTS, BIOPSIES WERE PERFORMED RESULTING IN AN ABLATION IN (B)(6) OF 2013. EXPERIENCED SWELLING OF FACE, HANDS, KNEES AND FEET; CRIPPLING JOINT PAIN IN KNEES, FEET ARMS AND HANDS, INTERMITTENT RASHES, EXCESSIVE UTERINE BLEEDING. TWO MENSTRUAL CYCLES EVENTUALLY BECAME ONE CONTINUOUS CYCLE FOR MONTHS WHICH DID NOT RESPOND TO BIRTH CONTROL. LARGE CLOTS PASSED WITH SEVERE CRAMPING. AT OTHER TIMES THERE ARE NO CLOTS BUT FLOW IS LIKE THAT OF A FAUCET AND WILL BLEED THROUGH HEAVY DUTY PADS WITHIN 20 MINUTES. ABDOMINAL PAIN AND CRAMPING. STANDARD PMS SYMPTOMS HOWEVER ALL ARE ON OVERLOAD. LOSS OF ENERGY, BLOATING, SEVERE HAIR LOSS. NO EVIDENCE OF FIBROIDS, CYSTS OR ENDOMETRIOSIS. ABLATION FAILED WITHIN 6 MONTHS. CURRENTLY UNDERGOING EXACT SAME TESTS WITH POSSIBLE OUTCOME OF FULL HYSTERECTOMY. NICKEL ALLERGY CAME BACK NEGATIVE; HOWEVER BLOOD WORK INDICATES INFLAMMATION AND ANEMIA. NO OTHER HEALTH ISSUES. ESSURE IMPLANTED IN 2008. CURRENT ULTRASOUND INDICATES PLACEMENT OF RIGHT COIL BUT LEFT COULD NOT BE POSITIVELY IDENTIFIED. LEFT SIDE IS WHERE PAIN OCCURS. AWAITING HSG TEST TO IDENTIFY EXACT PLACEMENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058230	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 2/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN AND BLOATING FLUID RETENTION CONGESTIVE HEART FAILURE. NO MY OBGYN RECOMMEND IT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058231	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 5/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FATIGUE, INSOMNIA, CHRONIC BACK/HIP/LEG/SHOULDER/PELVIC PAIN, CHEST PAIN AS HAVING A HEART ATTACK, BOWEL ISSUES CONSTIPATED TO DIARRHEA, DAILY HEADACHES SOMETIMES MIGRAINES, SEVERE STOMACH CRAMPS, THINNING HAIR/HAIR LOSS, UNDERACTIVE THYROID, ALL OVER ITCHING/DRY SKIN, NUMBNESS DOWN MY LEGS, NUMBNESS AND AMP; TINGLING IN MY FINGERS (RAYNAUD'S), BRAIN FOG/FORGETFULNESS, WEIGHT GAIN/BLOATING, FACIAL ACNE, RINGING IN MY EAR 24/7, NIGHT SWEATS, SHARP STABBING PAIN IN MY EARS, MOOD SWINGS/DEPRESSION, GLUTEN SENSITIVITY, DEGENERATIVE DISC DISEASE, TEETH PROBLEMS, SHARP PAIN THAT SHOOTS FROM HIP DOWN MY LEG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058232	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 7/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WOKE UP WITH HORRIBLE NECK PAIN, NUMBNESS IN FINGERS AND TOES. PAIN IN HANDS AND FEET. HORRIBLE MONTHLY CYCLES WITH ABNORMAL BLEEDING IN BETWEEN CYCLES. PAINFUL INTERCOURSE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058233	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 8/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE ALREADY SUBMITTED COMMENTS ABOUT MY EXPERIENCE WITH ESSURE TO THE FDA'S WEBSITE. PLEASE SEE (B)(4). I HAD ESSURE IMPLANTED IN (B)(6) 2009. THE PROCEDURE WAS EXCRUCIATINGLY PAINFUL TO THE POINT THAT I PASSED OUT FROM THE PAIN. BEFORE I PASSED OUT, I WAS SCREAMING "IS THIS SUPPOSED TO HURT SO BAD??!!" I REMEMBER THE DOCTOR SAYING THAT I HAD A "TIPPED UTERUS" AND THAT'S WHY SHE WAS HAVING TROUBLE WITH THE PLACEMENT AND WHY IT WAS TAKING SO LONG. THEN I PASSED OUT WITH TWO NURSES BY MY SIDE APPLYING COLD COMPRESSES TO MY HEAD AND TAKING MY BLOOD PRESSURE. WHEN I STARTED TO "COME TO", I HEARD THE TWO NURSES AND THE DOCTOR DISCUSSING WHETHER OR NOT I WAS GOING INTO SHOCK. WHEN I BECAME FULLY ALERT, THE DOCTOR TOLD ME SHE WAS GOING TO "TRY AGAIN" WITH THE PLACEMENT. I SAID, "I DON'T WANT TO TRY AGAIN IF IT'S GOING TO HURT SO BAD!" THE DOCTOR SAID SHE WOULD GIVE ME SOMETHING STRONGER FOR THE PAIN. THE SECOND TRY HURT LIKE HELL, BUT NOT AS BAD AS THE FIRST TRY. SINCE THE PROCEDURE, I HAVE HAD SYMPTOMS OF JOINT PAIN AND FATIGUE WHICH I THOUGHT WERE POSSIBLY FIBROMYALGIA SYMPTOMS. PLUS, I HAVE HAD UNEXPLAINED NUMBNESS IN MY ARMS. I HAD A NERVE TEST DONE ABOUT TWO YEARS AGO AND NO ABNORMALITIES WERE FOUND BY THE DOCTOR WHO DID THE NERVE TESTING. I WAS BASICALLY TOLD THAT I DID NOT HAVE CARPAL TUNNEL SYNDROME, BUT THE DOCTOR HAD NO EXPLANATION FOR THE NUMBNESS IN MY ARMS. SINCE THE ESSURE PROCEDURE, I GET MY PERIOD EVERY 18 TO 21 DAYS. I USED TO BE VERY REGULAR WITH MY PERIODS - EVERY 28 TO 30 DAYS, WITH HEAVY FLOW FOR THE FIRST 2 OR 3 DAYS FOLLOWED BY LIGHT FLOW FOR 2 OR 3 DAYS. NOW I HAVE HEAVY BLOOD FLOW FOR 5 DAYS, THEN A FEW DAYS OF LIGHT FLOW, THEN NO FLOW FOR A FEW DAYS AND THEN BROWN DISCHARGE FOR A FEW DAYS. IT ALWAYS FOLLOWS THAT SAME PATTERN. I WAS GIVEN A "WALLET CARD" TO CARRY ABOUT ESSURE BY THE DOCTOR WHO PERFORMED

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THE SURGERY. I WAS NEVER TOLD THAT THE COILS CONTAINED NICKEL. I HAVE KNOWN SINCE I'M A YOUNG GIRL THAT I AM SENSITIVE TO NICKEL. I AM NOT POSITIVE THAT I AM ALLERGIC TO NICKEL, BUT I DO KNOW THAT I HAVE ALWAYS HAD TROUBLE WEARING EARRINGS. CERTAIN EARRINGS WOULD MAKE MY EAR LOBES RED, ITCHY, AND VERY IRRITATED TO THE POINT I COULD ONLY TOLERATE THEM FOR AN HOUR OR SO. I CAME TO REALIZE YEARS AGO THAT I NEEDED TO BUY EARRINGS LABELED "NICKEL-FREE" IN ORDER TO AVOID SUCH DISCOMFORT. I WOULD LIKE TO ATTACH MY OPERATIVE REPORT WHICH SHOWS THAT THE DOCTOR HAD MUCH DIFFICULTY PLACING THE FIRST COIL (BUT I'M NOT SURE I WILL BE ABLE TO ATTACH A PDF). I WOULD ALSO LIKE TO ATTACH THE RESULTS OF THE NERVE TEST I HAD IN ORDER TO DIAGNOSE THE SOURCE OF THE ON-GOING NUMBNESS IN MY ARMS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058234	BAYER	12/2/2015	12/2/2015

Event Information:

Event Date (B3): 6/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME FATIGUE, PLAQUE PSORIASIS, FOOD SENSITIVITIES, IRRITABILITY, EAR ITCHING AND DRAINING, THOUGHTS OF SUICIDE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01666	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 11/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NON HEALTH CARE PROFESSIONAL IN (B)(6) ON 05-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE, FOR CONTRACEPTION. ON (B)(6) 2015 THE CONSUMER EXPERIENCED CRAMPS AND UTERINE PAIN. ONGOING MIGRATION OF RIGHT IMPLANT WAS DISCOVERED ON (B)(6) 2015. CORBELLED RIGHT IMPLANT WAS ALSO MENTIONED. BILATERAL SALPINGECTOMY WAS SCHEDULED FOR (B)(6) 2015. FOLLOW-UP INFORMATION RECEIVED ON 17-NOV-2015: THE (B)(6) HEALTH AUTHORITY ((B)(6)) CASE NUMBER WAS PROVIDED: (B)(6). COMPANY CAUSALITY COMMENT THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND RIGHT IMPLANT MIGRATION WAS DIAGNOSED. SHE IS SCHEDULED TO HAVE A SALPINGECTOMY. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. IT WAS MENTIONED THAT AN ONGOING MIGRATION OF RIGHT IMPLANT WAS DISCOVERED, THE EXACT POSITION OF THE INSERT IS NOT CLEAR. GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01667	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D31454

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A HEALTHCARE PROFESSIONAL IN (B)(6) ON 05-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER D31454 INSERTED, ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT AT THE TIME OF ESSURE INTRODUCTION, SURGEON OBSERVED THAT ESSURE EXTREMITY WAS BROKEN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT THE TIME OF ESSURE INTRODUCTION, SURGEON OBSERVED THAT ESSURE EXTREMITY WAS BROKEN. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. BASED ON THE REPORTED INFORMATION, IT CANNOT BE EXCLUDED THAT THE DEVICE BREAKAGE OCCURRED DURING THE ESSURE INSERTION PROCEDURE. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT RECEIVED ON 14-DEC-2015. (B)(4). LOT NUMBER D31454, PRODUCTION DATE 26-NOV-2014, EXPIRATION DATE 28-NOV-2017. FINAL ASSESSMENT. FAILURE MODE/MECHANISM. THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO TH

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01668	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 3/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C68117

Single Use: Y
Implant Date (E6): 3/3/2015
Explant Date (E7): 12/8/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN FRANCE ON 06-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PATIENT WAS EXPERIENCING CHRONIC BILATERAL PELVIC PAIN FOR 6 MONTHS FOLLOWING ESSURE INSERTION. X-RAY, ULTRASOUND, NUCLEAR MAGNETIC RESONANCE IMAGING AND HYSTEROSALPINGOGRAM WERE PERFORMED AND ALL THE RESULTS WERE NORMAL. NO ORGANIC CAUSE FOR THE EVENT WAS FOUND. ESSURE IMPLANT REMOVAL WAS PLANNED. REPORTER CAUSALITY: THE RELATIONSHIP BETWEEN CHRONIC BILATERAL PELVIC PAIN AND ESSURE WAS NOT REPORTED. FOLLOW-UP INFORMATION RECEIVED ON 18-NOV-2015: THE (B)(4) HEALTH AUTHORITY ((B)(4)) PROVIDED THE REFERENCE NUMBER (B)(4). COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD CHRONIC BILATERAL PELVIC PAIN FOR 6 MONTHS FOLLOWING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE PHYSICIAN STATED THAT ESSURE IMPLANT REMOVAL WAS PLANNED. THE CHRONIC PELVIC PAIN IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE LOCALIZATION OF THIS PAIN, THE LACK OF ALTERNATIVE EXPLANATION AND SUGGESTIVE TEMPORAL RELATIONSHIP, THE CAUSAL RELATIONSHIP BETWEEN THE PELVIC PAIN AND ESSURE INSERTS CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. FURTHER INFORMATION AND A PRODUCT TECHNICAL COMPLAINT ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW UP INFORMATION RECEIVED ON 15-DEC-2015: THE PATIENT MEDICAL HISTORY INCLUDED 2 CHILDREN, VAGINAL DELIVERY; POOR TOLERANCE TO IUD WITH MENORRHAGIA AND METRORRHAGIA; AND AN ELECTIVE ABORTION IN 2013. DURING THE INSERTION PROCEDURE ON (B)(6) 2015, THE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01792	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 11/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D01970

Single Use: Y
Implant Date (E6): 11/2/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 03-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER D01970. DURING THE INSERTION PROCEDURE, THE PHYSICIAN WAS PLACING THE DEVICE CORRECTLY, WHEELED BACK AND HIT THE DEPLOY BUTTON AND THE DEVICE DID NOT DEPLOY INTO THE RIGHT TUBE. THE PHYSICIAN HAD TO PULL ON HALF OF THE DEVICE; HALF WAS IN THE PATIENT AND HALF LEFT IN THE INSERTER. HE ATTEMPTED TO REMOVE ON MULTIPLE OCCASIONS AND IT CAME OUT IN PIECES, HE DECIDED TO ABORT THE PROCEDURE DUE TO FLUID AND TIME CONSTRAINTS, BUT APPEARED THERE WAS STILL PART OF THE OUTER COIL REMAINING IN THE PATIENT, AND IT APPEARED THE INNER COIL WAS REMOVED. A DEVICE WAS PLACED SUCCESSFULLY ON THE LEFT SIDE. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 30-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TUBE. THE INSERTS OUTER COILS EXPAND TO CONFORM TO THE FALLOPIAN TUBE, ACUTELY ANCHORING ITSELF UNTIL THE INSERT ELICITS TISSUE INGROWTH. AFTER THE FIRST ROLL BACK IS COMPLETED AND THE BUTTON IS PRESSED, USER ATTEMPTS TO REPOSITION THE DEVICE COULD LEAD TO DETACHMENT DIFFICULTY, PREMATURE DEPLOYMENT, OR IMPROPER DEVICE FUNCTION. IF ALL IFU STEPS HAVE NOT BEEN COMPLETED, USER ATTEMPTS TO REPOSITION OR REMOVE THE CATHETER ASSEMBLY COULD LEAD TO EITHER A STRETCHING OR BREAKAGE OF THE MICRO-INSERT OR A PART OF THE CATHETER. IF THE PHYSICIAN ATTEMPTS TO REMOVE A DEPLOYED MICRO- INSERT THAT IS LOCATED WITHIN THE FALLOPIAN TUBE BY PULLING ON THE OUTER COIL OF THE MICRO-INSERT WITH A

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GRASPER, THIS ACTION COULD ALSO LEAD TO BREAKAGE OF THE OUTER COIL OF THE MICRO-INSERT. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE WERE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF MICRO-INSERT BREAKING AND DEPLOYMENT DIFFICULTY IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, NO MEDICAL EVENTS WERE IDENTIFIABLE AT THIS POINT IN TIME. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO MEDICAL EVENTS WERE REPORTED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THE ASSESSMENT OF A CAUSAL RELATIONSHIP IS NOT APPLICABLE AS NO MEDICAL EVENTS WERE IDENTIFIABLE AT THIS POINT IN TIME. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE PHYSICIAN HAD TO PULL ON HALF OF THE DEVICE, HALF WAS IN THE PATIENT AND HALF LEFT IN THE INSERTER. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND ANTICIPATED ACCORDING TO THE TECHNICAL ANALYSIS. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE, DURING INSERTION, THE DEVICE DID NOT DEPLOY INTO THE RIGHT TUBE. THE PHYSICIAN HAD TO PULL ON HALF OF THE DEVICE; HALF WAS IN THE PATIENT AND HALF LEFT IN THE INSERTER. SINCE THE DEVICE BREAKAGE OCCURRED DURING THE ESSURE PLACEMENT PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. IN SUMMARY, BASED ON THE AVAILABLE INFORMATION THE ASSESSMENT OF A CAUSAL RELATIONSHIP IS NOT APPLICABLE AS NO MEDICAL EVENTS WERE IDENTIFIABLE AT THIS POINT IN TIME. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 02-DEC-2015: PATIENT´S DOB WAS PROVIDED. HER MEDICAL HISTORY INCLUDED DVT AND MORBIDLY OBESE. HE WAS ABLE TO RETRIEVE ALL BUT ONE PIECE. FOLLOW-UP INFORMATION RECEIVED ON 09-DEC-2015: CASE (B)(4) WAS DELETED (IT WAS IDENT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01797	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2440, AWARENESS DATE 03-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. AFTER ESSURE PLACEMENT THE CONSUMER IMMEDIATELY BEGAN HAVING PAIN. THEN SHE STARTED HAVING VERY HEAVY BLEEDING THAT WOULD NOT STOP. SHE HAD TO GET A HYSTERECTOMY AND A TRANSFUSION TO FINALLY GET RELIEF. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED VERY HEAVY BLEEDING THAT WOULD NOT STOP. SHE HAD TO HAVE A HYSTERECTOMY AND A TRANSFUSION TO FINALLY GET RELIEF. THIS EVENT, SEEN AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND THE IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE INTERVENTIONS WERE REQUIRED (HYSTERECTOMY AND TRANSFUSION) THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENT WAS ALSO INFORMED.

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BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01798	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2396, AWARENESS DATE 03-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. SINCE THE TIME OF ESSURE WAS IMPLANTED SHE HAS EXPERIENCED A LONG LIST OF ADVERSE SYMPTOMS. SHE EVENTUALLY ENDED UP IN THE EMERGENCY ROOM WITH UNBEARABLE PAIN AND A CT SCAN REVEALED THAT ONE OF THE COILS HAD MIGRATED AND WAS LODGED IN HER UTERUS. BECAUSE OF THIS SHE HAS HAD TO GO IN FOR SURGERY TO GET THE ESSURE REMOVED. SHE HAD TO HAVE A TOTAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY THAT SHE IS NOW RECOVERING FROM. ESSURE HAS MADE HER COMPLETELY MISERABLE AND HAS STOLEN HER QUALITY OF LIFE FOR THE LAST 3 YEARS. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT THE FINAL PRODUCT TESTING WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION THERE IS NO RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT

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REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. APPROXIMATELY 3 YEARS LATER, SHE UNDERWENT A TOTAL HYSTERECTOMY AND BILATERAL SALPINGECTOMY BECAUSE ONE OF THE COILS HAD MIGRATED AND WAS LODGED IN HER UTERUS. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR DISLOCATION INTO THE PERITONEAL CAVITY. IN THIS CASE, ALTHOUGH THE EXACT MECHANISM OF THE REPORTED DEVICE EXPULSION IS NOT KNOWN; GIVEN ITS NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. ADDITIONALLY, UNSPECIFIED ADVERSE SYMPTOMS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (SURGICAL INTERVENTION REQUIRED). BASED ON THE AVAILABLE INFORMATION THERE IS NO RELATIONSHIP BETWEEN REPORTED MEDICAL EVENTS AND QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01799	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2392, AWARENESS DATE 03-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED THAT ESSURE CAUSED NEVER ENDING PAIN. AFTER REMOVAL, SHE CONTINUED TO HAVE ISSUES IN THE SAME AREA. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED AND REPORTED NEVER ENDING PAIN (REGARDED AS PELVIC PAIN). PELVIC PAIN IS SERIOUS AND LISTED ACCORDING TO REFERENCE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01800	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/1/2007
Explant Date (E7): 9/16/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2370, AWARENESS DATE 03-NOV-2015) WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2007. THE CONSUMER REPORTED SHE STARTED WITH SEVERE CRAMPING, HEAVY BLEEDING AND PAIN ABOUT A YEAR AND A HALF OF IMPLANTING. FROM 2009 TO 2014, SHE SUFFERED FROM WEIGHT GAIN, FATIGUE, HAIR LOSS, SEVERE ALLERGIES REQUIRING MANY TRIPS TO THE PHYSICIAN AND ALLERGIST; SHE HAD BRAIN FOG, BACTERIAL VAGINOSIS, CONSTANT SPOTTING, NIGHT SWEATS, BLEEDING AFTER SEX, PAIN IN JOINTS, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, MIGRAINES, HIGH BLOOD PRESSURE, SWOLLEN GLANDS, EXCESSIVE SWEATING, GLUTEN SENSITIVITY, SWELLING IN LEGS AND FEET AND OVARIAN CYSTS. HER ALLERGIST SUSPECTED A NICKEL ALLERGY DUE TO HER SYMPTOMS. IN (B)(6) 2014, SHE WAS HAVING MORE PAIN THAN USUAL AND HER PHYSICIAN ORDERED AN ULTRASOUND AND AN X-RAY. THE ULTRASOUND SHOWED SHE HAD FREE FLUID IN HER ABDOMINAL CAVITY AND A CHOCOLATE CYST IN HER UTERUS. THE X-RAY SHOWED THAT HER COIL HAD BROKEN AND WAS IN THE SHAPE OF A Y INSIDE THE TUBE. ON (B)(6) 2014, SHE WENT FOR A SALPINGECTOMY FOR REMOVAL OF THE ESSURE DEVICE. DURING THAT SURGERY, THE DOCTOR FOUND THAT SHE HAD STAGE 4 ENDOMETRIOSIS, ADENOMYOSIS, AND ADHESIONS. SHE WENT BACK TO HAVE A HYSTERECTOMY WITH LEFT OOPHORECTOMY ON (B)(6) 2014. AFTER THESE SURGERIES, ALL OF THE ABOVE SYMPTOMS/SIDE EFFECTS HAVE GONE AWAY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND ASSESSMENT WERE RECEIVED: QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO

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CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED SEVERE CRAMPING PAIN ABOUT A YEAR AND A HALF OF IMPLANTING. 5 YEARS AFTER INSERTION, SHE WAS HAVING MORE PAIN THAN USUAL AND AN X-RAY PERFORMED SHOWED THAT HER COIL HAD BROKEN AND WAS IN THE SHAPE OF A Y INSIDE THE TUBE. THEN, SHE WENT FOR A SALPINGECTOMY FOR REMOVAL OF THE ESSURE DEVICE. DURING THAT SURGERY, THE DOCTOR FOUND THAT SHE HAD STAGE 4 ENDOMETRIOSIS. THESE EVENTS, SEEN AS PELVIC PAIN, DEVICE BREAKAGE AND ENDOMETRIOSIS RESPECTIVELY, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. PELVIC PAIN AND BREAKAGE ARE LISTED, WHILE ENDOMETRIOSIS IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE, ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THIS INTENSE PAIN, CONSIDERING THE DEVICE WAS FOUND BROKEN IN TUBE, A CONTRIBUTORY ROLE FROM THE SUSPECT INSERT FOR THE REPORTED PAIN CANNOT BE TOTALLY EXCLUDED AND GIVEN ITS NATURE, THE DEVICE BREAKAGE IS ASSESSED AS RELATED TO ESSURE USE. SINCE INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01801	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2008
Explant Date (E7): 3/1/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2443, AWARENESS DATE 03-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2008. CONSUMER REPORTED THAT SINCE THEN SHE HAD DAILY HEADACHES, CRAMPING, OUTLANDISH ODOR, ALLERGIC REACTIONS, BACK PAINS, CONSTANT PAIN IN HER SIDE, LOSS OF ENERGY, STOMACH BLOATING DAILY, VITAMIN D AND IRON DEFICIENCY, WEIGHT GAIN, HAIR LOSS, DRY SKIN, LOSS OF LIBIDO / NO SEX DRIVE, VISON WORSENED, DAILY MOOD SWINGS AND LEGS SWELLING. SHE WENT TO NUMEROUS DOCTORS VISITS TO FIND OUT SHE WAS HEALTHY AND JUST OVERWEIGHT. SHE HAD ESSURE REMOVED ON (B)(6) 2014 VIA A TUBAL LIGATION. SOME OF HER SYMPTOMS WERE GONE BUT SHE STILL HAD A HANDFUL. SO SHE HAD TESTS DONE ONCE AGAIN TO PROVE THAT HER ISSUES WERE RELATED TO ESSURE, EVEN THOUGH IT WAS SUPPOSEDLY GONE, AND SHE HAD AN HYSTERECTOMY PERFORMED. SHE STATED SHE WAS PROBABLY ALLERGIC TO NICKEL, AS SHE CANNOT WEAR CHEAP JEWELRY- SHE BREAKS OUT IN A RASH. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO

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HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD CONSTANT PAIN IN HER SIDE (INTERPRETED AS PELVIC PAIN). SHE HAD ESSURE REMOVED 5 AND A HALF YEARS AFTER ITS INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW-UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01802	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 10/21/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2397, AWARENESS DATE 03-NOV-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. THE CONSUMER REPORTED THAT ON (B)(6) 2015 SHE HAD TO HAVE A HYSTERECTOMY BECAUSE OF COMPLICATIONS WITH ESSURE. WITH ESSURE, SHE SUFFERED WITH SWELLING EVERY DAY AND PAIN CAUSED BY JUST WAKING UP AND GETTING OUT OF BED. SHE COULD NO LONGER PLAY WITH HER KIDS AND WAS HOPING THAT WITH ESSURE REMOVAL AT THAT LAST PROCEDURE SHE WOULD BE ABLE TO DO IT. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN 2011 AND ON (B)(6) 2015 SHE HAD TO HAVE A HYSTERECTOMY BECAUSE OF PAIN (REGARDED AS PELVIC PAIN). THIS EVENT IS SERIOUS AND LISTED ACCORDING TO REFERENCE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. SINCE A HYSTERECTOMY WAS

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PERFORMED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01803	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2496, AWARENESS DATE 03-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. CONSUMER REPORTED WHEN SHE TURNED (B)(6) SHE WAS GIVEN THE ESSURE OPTION. AFTER IMPLANTATION, SHE HAD NOT SYMPTOMS UNTIL 8 MONTHS LATER. EACH DAY SHE WOULD HAVE A HIVES OUTBREAK ALL OVER HER BODY. THESE HIVES ITCH AND BURN. HER PHYSICIAN STATED THAT IT WOULD GO AWAY. AFTER 10 WEEKS SHE SAW AN ALLERGIST FOR FOOD ALLERGY TESTING WITH NO SUCCESS. HE REFERRED HER TO AN DERMATOLOGIST FOR FURTHER ALLERGY TESTING. THE DERMATOLOGIST CONCLUDED THAT SHE HAS A NICKEL ALLERGY. HER CRP (ASSUMED AS C-REACTIVE PROTEIN) LEVEL IS CONTINUALLY INCREASING AND IS NOW 17. HER STOMACH IS CONSTANTLY BLOATED AND IN PAIN. HER HYSTERECTOMY IS SCHEDULED FOR (B)(6) DUE THE HEAVY BLEEDING, CLOTTING, AND ABDOMINAL PAIN. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD

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ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN (B)(6) 2014 AND EXPERIENCED HEAVY BLEEDING AND ALLERGY SYMPTOMS. BOTH EVENTS ARE LISTED IN ESSURE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP, EVENT NATURE, PRODUCT PROFILE AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. SINCE A HYSTERECTOMY IS SCHEDULED FOR (B)(6) (SURGICAL INTERVENTION WILL BE REQUIRED), THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01804	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 ((B)(4), AWARENESS DATE 03-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. THE CONSUMER REPORTED THAT WITHIN WEEKS HAVING THE COILS INSERTED, SHE FELT NAUSEOUS AND WAS VOMITING A LOT, HER ABDOMEN SWELLED LIKE SHE WAS 9 MONTHS PREGNANT AND SHE BROKE OUT A VARIETY OF DIFFERENT RASHES. SHE HAD AN ENDOSCOPY A FEW MONTHS LATER WHICH WAS NON-SPECIFIC. SHE FELT LIKE HER IMMUNE SYSTEM HAD BEEN COMPROMISED, SHE BECAME SUSCEPTIBLE TO INFECTIONS. WITHIN THE 5 YEARS BEFORE REPORTING DATE THERE HAD BEEN NO PATTERN TO HER MENSTRUAL CYCLE, BLEEDING HAD VARIED FROM HEAVY AND FREQUENT TO LIGHT AND ABSENT PERIODS FOR MONTHS. SHE SUFFERED WITH A TERRIBLE PAIN IN PELVIS THAT AFFECTED HER MOBILITY. HER HORMONE LEVELS WERE CHECKED AND THEY WERE ALL IN THE NORMAL RANGE. IN 2014 SHE DEVELOPED WEAKNESS ON THE RIGHT SIDE OF HER FACE, THE MUSCLES AROUND HER EYE AND MOUTH WEAKENED. HER DOCTORS SUSPECTED SHE WAS DEVELOPING AN AUTO-IMMUNE CONDITION CALLED MYASTHENIA GRAVIS. THE CONSUMER HAD A HYSTERECTOMY AND ALL THE SYMPTOMS SHE WAS SUFFERING FROM HAD GONE INCLUDING WEAKNESS OF HER EYE MUSCLES, VISION PROBLEMS, WEAK FACIAL MUSCLES, NAUSEA, VOMITING, RASHES, SWOLLEN ABDOMEN, HAEMATURIA, ETC. HER IMMUNE SYSTEM WAS RETURNING BACK TO NORMAL AS SHE HAD RARELY HAD INFECTIONS THAT YEAR. SHE STATED THAT SHE FELT VERY ILL WHEN SHE HAD ESSURE INSERTED BUT ALL THE MEDICAL TESTS WERE COMING BACK NON-SPECIFIC. SHE STRONGLY FEELS THAT THE MATERIALS USED TO MAKE ESSURE COILS WERE DETRIMENTAL TO OUR HEALTH. THE PRODUCT TECHNICAL

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COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 25-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN IN PELVIS THAT AFFECTED HER MOBILITY. ALSO, HER DOCTORS SUSPECTED SHE WAS DEVELOPING AN AUTO-IMMUNE CONDITION CALLED MYASTHENIA GRAVIS. THE CONSUMER HAD A HYSTERECTOMY. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION. PELVIC PAIN IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE MYASTHENIA GRAVIS IS UNLISTED. MYASTHENIA GRAVIS IS DEFINED AS AN AUTOIMMUNE NEUROMUSCULAR DISEASE LEADING TO FLUCTUATING MUSCLE WEAKNESS AND FATIGUE. IN THIS PARTICULAR CASE, IN SPITE OF CONSUMER HAD RELATED HER SYMPTOMS TO ESSURE; CONSIDERING THEIR NATURE AND GIVEN ESSURE LOCAL ACTION AT FALLOPIAN TUBES CAUSALITY WITH THE SUSPECT INSERT IS VERY UNLIKELY. PELVIC PAIN MAY OCCUR DURING ESSURE USE. BASED ON IMPLIED TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. IN ADDITION, NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01805	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2464, AWARENESS DATE 03-NOV-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2015 FOR PERMANENT BIRTH CONTROL. SINCE THEN SHE HAS HAD CONSTANT PELVIC PAIN, HEAVY BLEEDING, EXTREME BLOATING, AND A DECREASE IN SEXUAL DESIRE. HER HYSTERECTOMY WAS SCHEDULED FOR (B)(6) 2015. HER DOCTOR SUGGESTED THAT MAYBE THE WAY HER ANATOMY WAS SHAPED WAS THE REASON SHE HAS BEEN FEELING SO MUCH PAIN FROM THE DEVICE. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSIONS INSERT) INSERTED IN (B)(6) 2015 AND EXPERIENCED CONSTANT PELVIC PAIN AMONGST OTHER EVENTS. PELVIC PAIN IS SERIOUS AND LISTED ACCORDING TO REFERENCE SAFETY INFORMATION. GIVEN THE COMPATIBLE TEMPORAL RELATIONSHIP AND LACK OF PLAUSIBLE ALTERNATIVE EXPLANATION, CAUSALITY CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL IS SCHEDULED TO (B)(6) 2015 (SURGICAL INTERVENTION WILL BE REQUIRED), THIS CASE IS

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REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01806	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2378, AWARENESS DATE 03-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. THE BOYFRIEND OF THE CONSUMER REPORTED THAT SINCE ESSURE INSERTION HIS GIRLFRIEND HAD SEVERAL SIDE EFFECTS FROM THE DEVICE. SHE WAS CONSTANTLY HAVING TO TAKE ADVIL FOR THE PAIN (EITHER HEADACHES OR ABDOMINAL). HER PERIOD WAS EITHER EXTREMELY HEAVY FOR A FEW DAYS OR NOT AT ALL. SHE HAS HAD MORE THEN ONE TUBAL PREGNANCY. SHE WAS FORGETFUL, FORGETTING WHAT SHE HAS SAID OR EVEN THOUGHT SHE HAD TOLD HIM SOMETHING AND HAD NOT. SHE HAD MOOD SWINGS THAT SOMETIMES WERE MINOR BUT OTHER TIMES EXTREME. HER PAIN SOMETIMES HAS FORCED HER TO DOUBLE OVER IT HAS BEEN SO BAD. SHE HAS SWELLING THAT MADE HER LOOK LIKE SHE WAS 9 MONTHS PREGNANT. THERE WAS ALSO SWELLING IN HER NECK THAT THEY THOUGHT THE ESSURE DEVICE WAS CAUSING. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED MORE THAN ONE TUBAL

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PREGNANCY. THIS EVENT, SEEN AS ECTOPIC PREGNANCY, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. THEREFORE, CONSIDERING EVENT'S NATURE AND LIMITED INFORMATION PROVIDED, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE ECTOPIC PREGNANCY CAN LEAD TO A LIFE-THREATENING SITUATION AND USUALLY REQUIRES SURGICAL INTERVENTION, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01807	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 8/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B30422

Single Use: Y
Implant Date (E6): 8/22/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

ON 20-FEB-2014 ON A COMPANY INTERNET SITE IT WAS FOUND, THAT A CONSUMER IN THE UNITED STATES STATED SHE HAS SUFFERED FROM ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND WOULD REQUIRE A HYSTERECTOMY AT (B)(6). CASE REPORT WAS INVALID SINCE NO EVENT WAS SPECIFIED. FOLLOW-UP WAS RECEIVED ON 13-MAR-2014 DUE TO CONSUMER HAD BEEN CONTACTED, AND CASE BECAME VALID. CONSUMER ANSWERED TO A QUESTIONNAIRE. CONSUMER'S MEDICAL HISTORY INCLUDED IBS (IRRITABLE BOWEL SYNDROME) SINCE AGE (B)(6), MIGRAINES, BACK PROBLEM FROM A CAR ACCIDENT, AND (B)(6). CONSUMER HAD ESSURE (ESS305, FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER B30422, INSERTED ON (B)(6) 2013, FIVE WEEKS AFTER DELIVERY (OFF LABEL USE), SHE WAS (B)(6). DEPO WAS USED AS BACK-UP CONTRACEPTION AFTER ESSURE INSERTION AND BEFORE TOTAL OCCLUSION CONFIRMATION. HSG (HYSTEROSALPINGOGRAM) TEST HAS NOT BEEN PERFORMED DUE TO INSURANCE PROBLEMS, SHE HAS NO INSURANCE. THREE DAYS AFTER IMPLANTATION, ON (B)(6) 2013, CONSUMER STARTED TO EXPERIENCE STABBING PAINS DAILY ALL DAY, HAIR LOSS, PERIOD EVERY TWO TO THREE MONTHS AND IT LASTS ONE DAY WITH HEAVY FLOW USING ONE SUPER TAMPON PER HOUR, INTENSE CRAMPING WITH HER PERIOD, DIZZINESS, MIGRAINES DAILY, MOOD SWINGS, PAIN WITH INTERCOURSE, INTIMACY ISSUES, LOSS OF LIBIDO, HEAD FOG, RANDOM SHOT OF PAIN DOWN HER LEFT LEG, INTENSIFIED IBS (HISTORY SINCE SHE WAS (B)(6) . CONSUMER HAD CALLED HER DOCTOR MULTIPLE TIMES AND HE PRESCRIBES PAIN MED (MEDICATION) AND ESTROGEN BUT SHE IS OUT OF INSURANCE AND IT DOES NOT PAY FOR THEM. CONSUMER BELIEVES THE CONDITION WAS CAUSED BY THE ESSURE DEVICES OR THE ESSURE DEVICES CONTRIBUTED TO THE ISSUE, BECAUSE DOCTOR NEVER TOLD HER THE ESSURE CONTAINED NICKEL AND SHE WAS ALLERGIC TO IT. THE ESSURE DEVICES HAVE NOT BEEN REMOVED FOLLOW UP INFORMATION RECEIVED ON 26-JUN-2014 (POSTED IN A WEBSITE PLATFORM): CONSUMER WAS

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QUESTIONING IF ESSURE COULD BREAK BECAUSE SHE WANTED EXPLANATION ABOUT A BROKEN PIECE FLOATING FREELY IN HER UTERUS (CASE UPGRADED TO NEAR-INCIDENT). NO FURTHER INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 07.JUL.2014 FROM CONSUMER: CONSUMER`S WEIGHT AND HEIGHT ADDED (OVERWEIGHT WAS OBSERVED). HER LAST DELIVERY WAS ON (B)(6) -2013. SHE DENIED ANY SIGNIFICANT MEDICAL HISTORY AND ONLY CLAIMS TO HAVE CHRONIC ANEMIA SHORTLY AFTER HAVING ESSURE PLACED (APPROXIMATELY 3 DAYS POST-PROCEDURE) THE CONSUMER DEVELOPED SYMPTOMS OF PAIN, MIGRAINES, BLOATING, HEAVY MENSTRUAL BLEEDING AND GENERALLY NOT FEELING GOOD. HER SYMPTOMS CONTINUE AND HAVE NOT RESOLVED. PAIN WAS PRETTY MUCH DAILY AND SHE OFTEN GETS TWO PERIODS A MONTH. SHE STATED THAT THERE WAS SOME DIFFICULTY IN GETTING ONE OF THE INSERTS IN PLACE AND THAT FROM THE HSG, ONE OF THEM MAY BE TOO PROXIMAL (MUCH OF THE COIL MAY BE IN THE UTERINE CAVITY), HOWEVER, NOT TOTALLY SURE. ALSO, MAY HAVE A FRAGMENTED PIECE OF ONE OF THE TRAILING COILS WITHIN THE UTERINE CAVITY. SHE DOES HAVE A NICKEL ALLERGY (BREAKS OUT WHEN WEARS COSTUME JEWELRY). SHE SAYS SHE TOLD HER DOCTOR THIS WHEN HE WAS DISCUSSING ESSURE, BUT WAS TOLD THAT IT SHOULDN'T MATTER OR BE AN ISSUE. HER PHYSICIAN WANTS TO RUN A NUMBER OF BLOOD TESTS AND HAS PUT HER ON A LOW DOSE ORAL CONTRACEPTIVE PTC INVESTIGATION RESULT WAS RECEIVED ON 09-JUL-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC).(B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT AT THIS TIME. MEDICAL ASSESSMENT: THE MEDICAL EVENTS REPORTED ARE NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. THIS CASE ALSO REPORTED BREAKAGE WHICH IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT. NO ADDITIONAL AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO BATCH NUMBER B30422. NO BATCH SIGNAL CAN BE IDENTIFIED AT THIS TIME. THE REVIEW OF THE LOT HISTORY RECORDS CONFIRMED THAT THE PRODUCT MET PRODUCT RELEASE SPECIFICATIONS. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION ALTHOUGH A HSG FILM WAS TWEETED BY THE CONSUMER (NOTE THAT PREVIOUSLY CONSUMER REPORTED NO HSG TEST WAS PERFORMED). THE RQU STATED THAT NO DEVICE BREAKAGE IS VISIBLE ON THE HSG FILM. AT THE TIME OF THIS MEDICAL ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT" AND NO DEVICE BREAKAGE. BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. BASED ON THE PROVIDED PTC RESULTS THE EVENT BROKEN PIECE FLOATING FREELY IN MY UTERUS WAS AMENDED TO NON-INCIDENT. FOLLOW UP 14.JUL.2014: FOLLOW UP INFORMATION RECEIVED FROM THE PHYSICIAN. PATIENT'S DATA WERE UPDATED, INCLUDING HER AGE, (B)(6). PATIENT DID NOT HAVE GYNECOLOGICAL INTERVENTIONS, NO CERVICAL CONIZATION, NO CURETTAGE, NO PREVIOUS IUS/IUD, NO MYOMECTOMY, NO ADNEXAL SURGERY. PATIENT'S MEDICAL HISTORY INCLUDES DYSFUNCTIONAL UTERINE BLEEDING ON (B)(6) 2012. DURING ESSURE INSERTION THERE WAS NO CERVICAL DILATATION, NO SOUNDING AND NO GENERAL ANESTHESIA. ANALGESIA WAS CERVICAL BLOCK, XANAX 0.25MG AND TORADOL INTRAMUSCULAR. ESSURE INSERTION AND VISUALIZATION OF THE TUBAL OSTIUM WERE EASY. FLUID LOSS DURING HYSTEROSCOPY WAS NOT MORE THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. PATIENT USED DEPO PROVERA AS BACK UP CONTRACEPTION UNTIL CONFIRMATION OF BILATERAL ESSURE OCCLUSION. HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED ON (B)(6) 2014 AND SHOWED SCOUT VIEW OF THE PELVIS DEMONSTRATED CLOSE POSITIONING OF THE METALLIC ESSURE DEVICES IN THE LOWER PELVIC SOFT TISSUES. FOLLOWING HSG CATHETER PLACEMENT AND RETROGRADE INSTILLATION OF CONTRAST, THE ENDOMETRIAL CAVITY EXCEPT FOR PROTRUSION OF THE PROXIMAL ESSURE DEVICES IN THE UTERINE CORNUA BILATERALLY. THERE WAS NO CONTRAST SEEN TO ENTER THE FALLOPIAN TUBES BILATERALLY. POST VOID IMAGE OF THE UTERUS DEMONSTRATED PERSISTENT CONTRAST WITHIN THE ENDOMETRIAL CAVITY. HSG IMPRESSIONS:

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NONVISUALIZED FALLOPIAN TUBES BILATERALLY WITH NO EVIDENCE OF FREE SPILL INTO THE PERITONEAL CAVITY. PROXIMAL ONE THIRD OF THE ESSURE DEVICES PARTIALLY PROTRUDE INTO THE UTERINE CORNU BILATERALLY. THIS APPEARED TO ADEQUATELY PRECLUDE THE FALLOPIAN TUBES BUT WAS A VARIAN NORMAL DEPLOYMENT. PHYSICIAN REPORTED THAT NO PATHOLOGY TESTS WERE DONE AND NO HOSPITALIZATION OCCURRED. PHYSICIAN CONSIDERED THE RELATIONSHIP BETWEEN ALL THE EVENTS INITIALLY REPORTED AND ESSURE AS UNRELATED. ESSURE WAS NOT REMOVED AND THERE WAS NO PLAN TO REMOVE IT. INTERNAL REVIEW ON 08-SEP-2014: THIS CASE WAS FOUND TO BE A DUPLICATE OF CASE (B)(4). (B)(4) WILL BE DELETED FROM BAYER DATABASE. THE FOLLOWING INFORMATION FROM (B)(4) WAS ADDED: NEW REPORTER ADDED (HEALTH AUTHORITY). THIS CASE WAS ALSO RECEIVED VIA HEALTH AUTHORITY FDA MAUDE (CASE# MW5037022). PATIENT REPORTED THAT SHE HAS ANTEFLEXED UTERUS. PATIENT REPORTED THAT ESSURE WAS INSERTED 5 WEEKS AFTER SHE GAVE BIRTH TO HER THIRD SON. SHE ALSO REPORTED THAT AFTER ESSURE INSERTION SHE HAS HAD DEBILITATING SIDE EFFECTS. SHE HAD DIARRHEA, NAUSEA, DEPRESSION, TINGLING IN HANDS AND FEET AND JOINT PAIN. THESE EVENTS BEGAN 3 DAYS AFTER PLACEMENT AND WERE STILL ONGOING AT TIME OF THE REPORT. ON PHYSICIAN FOLLOW-UP (ALSO PREVIOUSLY REPORTED IN THIS CASE), HE DID NOT CONSIDER THE PATIENT'S CONDITION RELATED TO ESSURE DEVICE. ALL OTHER INFORMATION CONTAINED IN (B)(4) WAS PREVIOUSLY REPORTED BY PATIENT IN THIS CASE. FOLLOW-UP RECEIVED ON 19-MAY-2015: INFORMATION RECEIVED FROM CONSUMER VIA SOCIAL MEDIA STATES THAT SHE WISHES SHE COULD DO SOMETHING ABOUT HER PAIN. FOLLOW-UP INFORMATION RECEIVED ON 13-AUG-2015 THIS FOLLOW-UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING TAKING PLACE IN SEPTEMBER 2015. CONSUMER STATED THAT SHE IS MOTHER OF 3. ESSURE WAS INSERTED JUST 5 WEEKS AFTER GIVING BIRTH TO HER LAST SON. JUST 3 DAYS AFTER PROCEDURE HER PROBLEMS STARTED : ABDOMINAL PAIN, HEAVY BLEEDING, MIGRAINES, DIZZINESS, HAIR LOSS, DEPRESSION, MOOD SWINGS, BLOATED BELLY, PSORIASIS AND A HIGHER SENSITIVITY TO METALS. SHE HAD BEEN SUFFERING FOR 2 YEARS. HER DOCTOR DID NOT PLACE CORRECTLY (11 TRAILING COILS ON ONE SIDE) AS WELL AS A FRAGMENT. NOW, SHE IS LOOKING AT A FULL HYSTERECTOMY DUE TO THE DAMAGE CAUSED BY THIS PRODUCT. CASE CORRECTION REGARDING FOLLOW-UP INFORMATION RECEIVED ON 13-AUG-2015: FDA DOCKET NUMBER (FDA-2014-N-0736-0095) WAS PROVIDED. FOLLOW-UP INFORMATION ON 05-NOV-2015 AND ON 16-NOV-2015: THIS IS A POTENTIAL LEGAL CASE NOW. NEW REPORTERS WERE ADDED. CONSUMER ETHNICITY WAS REPORTED AS CAUCASIAN. HER MEDICAL HISTORY INCLUDED 3 PREGNANCIES WITH 3 PARITIES (LAST TERM DELIVERY ON (B)(6) 2013 WITH OLIGOHYDRAMNIOS AND CONCERN OF RUPTURE OF MEMBRANES). HER LAST MENSTRUAL PERIOD WAS (B)(6) 2014. IN (B)(6) 2014, CONSUMER RECEIVED LO LOESTRIN AND FELT SOME BETTER. SHE REPORTED THAT SHE HAD NICKEL SENSITIVITY BY SKIN TEST IN THE PAST. SHE SAID THAT SHE WAS HAVING PELVIC PAIN (10 ON A PAIN SCALE) AND TOOK TYLENOL AND ADVIL WITHOUT ANY RELIEF. ON (B)(6) 2014, SONOGRAM WAS DONE AND WAS NORMAL. PAIN WAS SOME BETTER. SHE WAS ENCOURAGED TO TAKE 3 MONTHS OF ORAL CONTRACEPTION IN ORDER TO HELP HER SYMPTOMS. ON (B)(6) 2014, SHE WAS SEEN BY DOCTOR AND SHE COMPLAINED OF PELVIC PAIN WHICH REMAINED UNCHANGED. ON AN UNSPECIFIED DATE, SHE HAD HYSTERECTOMY AND SHE WAS FEELING AMAZING AFTER. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, POTENTIAL LEGAL AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AT HYSTEROSALPINGOGRAM (HSG) ONE OF THEM MAY BE TOO PROXIMAL (INTERPRETED AS A DEVICE DISLOCATION). SHE ALSO EXPERIENCED PELVIC PAIN. SHE HAD HYSTERECTOMY PERFORMED. THESE EVENTS WERE CONSIDERED SERIOUS; DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES, THIS MOVEMENT COULD BE AN EXPULSION (UTERUS OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY). IN THIS PARTICULAR CASE, THE PATIENT REPORTED THAT ON HSG ONE OF ESSURE COILS MAY BE TOO PROXIMAL, LATER UPON RECEIPT OF FOLLOW-UP

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INFORMATION FROM PHYSICIAN HSG RESULTS SHOWED THAT PROXIMAL ONE THIRD OF THE ESSURE DEVICES PARTIALLY PROTRUDE INTO THE UTERINE CORNU BILATERALLY; AND THIS APPEARED TO ADEQUATELY PRECLUDE THE FALLOPIAN TUBES BUT WAS A VARIANT NORMAL DEPLOYMENT. ALTHOUGH THE EXACT DATE AND MECHANISM OF THIS DISLOCATION WERE NOT KNOWN, GIVEN ITS NATURE IT WAS CONSIDERED AS RELATED TO ESSURE THERAPY. FOR THE EVENT PELVIC PAIN, BASED ON ITS NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. ADDITIONALLY, THE PATIENT REPORTED HEAVY BLEEDING (SERIOUS, LISTED EVENT) AND NON-SERIOUS EVENTS; INCLUDING SUSPICION THAT A BROKEN PIECE WAS FLOATING FREELY IN HER UTERUS. PRODUCT TECHNICAL ANALYSIS WAS PERFORMED (NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION ALTHOUGH A HSG FILM WAS "TWEETED" BY THE CONSUMER) AND THERE WAS NO DEVICE BREAKAGE VISIBLE ON THE HSG FILMS; ALSO NO BREAKAGE WAS REPORTED IN HSG RESULTS PROVIDED BY PHYSICIAN. SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS UPGRADED TO INCIDENT. THE PERFORMED PRODUCT TECHNICAL INVESTIGATION (PTC) CONCLUDED THAT BASED ON THE INFORMATION AVAILABLE THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01808	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/7/2011
Explant Date (E7): 11/18/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1133, AWARENESS DATE 04-OCT-2015). ADDITIONAL INFORMATION RECEIVED ON 20-OCT-2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE FOR CONTRACEPTION. CONSUMER REPORTED THAT SHE EXPERIENCED SO MUCH BLEEDING, SO MUCH EMOTIONAL AND PHYSICAL PAIN, NAUSEA, HEADACHES, HANDFULS OF HAIR FALLING OUT, ACHING JOINTS, FOGGY BRAIN AND BEING INTIMATE WITH HER HUSBAND WAS PAINFUL AND BLOODY. SHE IS ONLY (B)(6) AND SHE WILL EVENTUALLY NEED A HYSTERECTOMY, AS IT IS THE ONLY OPTION TO GET ESSURE OUT. FOLLOW UP INFORMATION RECEIVED ON 04-NOV-2015. ADDITIONAL INFORMATION RECEIVED ON 25-NOV-2015: THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2495). CONSUMER REPORTED THAT ON (B)(6) 2011 SHE GOT ESSURE INSERTED BECAUSE SHE DID NOT WANT CHILDREN. SINCE SHE WAS NEVER ABLE TO HAVE COMFORTABLE INTERCOURSE WITH HER HUSBAND, SHE BLED EVERY TIME, ITS TAKEN HER HAIR, SHE BALLS EVERYTIME SHE HAS TO WASH HER HAIR, SHE GAINED WEIGHT, INFLAMMATION IN MED-SECTION AND HAVE A PUFFINESS THAT SHE WAS SURE IT WAS AN E-BELLY. SHE HAS CHRONIC PELVIC PAIN AND CONSTANT PAIN ON HER RIGHT SIDE. SHE WAS GIVEN A ULTRASOUND TO CONFIRM PLACEMENT OF THE COILS. SHE HAS A FIBROID ON HER LEFT OVARY, FLUID BUILD IN HER UTERUS AND THEY WERE NOT SURE IF A COIL WAS LODGING ITSELF INTO HER UTERUS. SHE HAD A TOTAL ABDOMINAL HYSTERECTOMY ON (B)(6) 2015 BECAUSE OF ESSURE. PRODUCT

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TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 25-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD CHRONIC PELVIC PAIN AND SO MUCH BLEEDING (REGARDED AS GENITAL BLEEDING) AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY (APPROXIMATELY 4 YEARS AFTER DEVICE PLACEMENT). THE REPORTED EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER HAD A FIBROID IN HER OVARY; THIS CONDITION COULD HAVE BEEN A CONTRIBUTORY ROLE IN HER PAIN. HOWEVER, CONSIDERING ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND PELVIC PAIN ARE POSSIBLE UNDESIRABLE EVENTS WITH ESSURE THERAPY AND AS CONSUMER MENTIONED THEY WERE NOT SURE IF ESSURE WAS INTO HER UTERUS (POSSIBLE DEVICE EXPULSION); CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT; SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY WAS REPORTED UPON FOLLOW-UP). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01810	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2293, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN THE RIGHT TUBE IN (B)(6) 2013. CONSUMER REPORTED THAT SHE EXPERIENCED LOTS OF PAIN AND BLEEDING DURING PROCEDURE AND WAS UNABLE TO PLACE LEFT COIL. SHE HAD HEAVY PERIODS AFTER. IN (B)(6) 2014 SECOND COIL WAS PLACED UNDER GENERAL ANESTHESIA. BY (B)(6) 2014 HER PERIODS WERE SO HEAVY AND LONG THAT WAS NOT MUCH TIME IN BETWEEN EACH ONE. SHE WAS ALSO HAVING BAD CLOTTING. IN (B)(6) 2015 SHE HAD A CRYOABLATION PERFORMED TO LESSEN THE BLEEDING. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BLEEDING DURING THE PROCEDURE. AFTER INSERTION SHE HAD HEAVIER LONG PERIODS WITH BAD CLOTTING, AND UNDERWENT A CRYOABLATION TO LESSEN THE BLEEDING. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BLEEDING MAY OCCUR

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DURING THE MICRO-INSERT PLACEMENT PROCEDURE. ALSO, AFTER ESSURE INSERTION GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENTS AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01811	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2307, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013 FOR STERILIZATION. CONSUMER DECIDED NOT TO HAVE ANYMORE KIDS BECAUSE HER AND HER 2 DAUGHTERS WERE DIAGNOSED WITH BENIGN BRAIN TUMORS. CONSUMER REPORTED THAT HER SYMPTOMS STARTED ABOUT A YEAR AFTER INSERTION. SHE EXPERIENCED SEVERE PELVIC PAIN, STABBING PAIN, DAILY HEADACHES, DIZZINESS, FATIGUE, ABNORMAL BLEEDING FOR LONG PERIODS OF TIME AND SHE WAS DIAGNOSED WITH A RARE CORNUAL ECTOPIC PREGNANCY. SHE WAS FORCED TO TERMINATE PREGNANCY BECAUSE IT WAS LIFE THREATENING TO HER. SHE HAD AN EMERGENCY SURGERY 2 DAYS LATER TO REMOVE ESSURE COILS AMONG OTHER PARTS. LEFT ESSURE COIL WAS FOUND PROTRUDING OUT OF HER FALLOPIAN TUBE AND COULD HAVE RUPTURED HER ORGANS. HER HYSTEROSALPINGOGRAM SHOWED THAT COILS WERE FULLY OCCLUDED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 25-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED AFTER ONE YEAR, ABNORMAL BLEEDING FOR LONG PERIODS OF TIME. SHE WAS DIAGNOSED WITH A RARE CORNUAL ECTOPIC PREGNANCY AND HAD AN EMERGENCY SURGERY 2 DAYS LATER TO REMOVE ESSURE COILS AMONG OTHER PARTS. DURING THE PROCEDURE, LEFT ESSURE COIL WAS FOUND PROTRUDING OUT OF HER FALLOPIAN TUBE. THESE EVENTS, SEEN AS GENITAL BLEEDING, ECTOPIC PREGNANCY AND DEVICE DISLOCATION, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND ALL LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND THE FACT THAT GENITAL BLEEDING MAY OCCUR DURING ESSURE USE, CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND ESSURE USE CANNOT BE EXCLUDED. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER. ALTHOUGH THE REPORTED DEVICE DISLOCATION COULD HAVE BEEN A CONTRIBUTORY ROLE IN PREGNANCY OCCURRENCE, GIVEN THE LIMITED INFORMATION REGARDING ITS DATE AND MECHANISM, CAUSALITY BETWEEN BOTH EVENTS AND ESSURE USE CANNOT BE EXCLUDED. SINCE ECTOPIC PREGNANCY CAN LEAD TO A LIFE-THREATENING SITUATION AND REQUIRED A SURGICAL INTERVENTION WITH THE REMOVAL OF THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01812	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2319, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE SIMPLY DID NOT WANT TO GET PREGNANT, AND NOW SHE CAN BARELY FUNCTION MOST DAYS, AND SOME DAYS SHE CANNOT DO ANYTHING. EVEN AFTER FINDING A DOCTOR TO REMOVE THE DEVICES, SHE WAS LEFT WITH PERMANENT HEALTH PROBLEMS BECAUSE OF THE DAMAGE ESSURE DID TO HER BODY WITH MULTIPLE HEAVY METAL TOXICITIES AND CHRONIC INFLAMMATION FROM THE PET FIBERS. SHE NOW HAS MULTIPLE AUTOIMMUNE DISEASES BECAUSE OF THIS BIRTH CONTROL DEVICE. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED. ACCORDING TO HER, SHE WAS LEFT WITH PERMANENT PROBLEMS BECAUSE ESSURE DAMAGED HER BODY WITH MULTIPLE HEAVY METAL TOXICITIES, AND ALSO AUTOIMMUNE DISEASES. ONLY ESSURE REMOVAL IS A LISTED EVENT IN ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS

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PARTICULAR CASE, MINIMAL INFORMATION WAS PROVIDED. THE CONSUMER STATED, AFTER ESSURE REMOVAL, SHE REMAINED WITH UNSPECIFIED HEALTH PROBLEMS, WHICH SHE ATTRIBUTED TO HEAVY METAL TOXICITY AND INFLAMMATION CAUSED BY ESSURE. HOWEVER, NEITHER THE EXACT MEDICAL REASON FOR ESSURE REMOVAL WAS SPECIFIED; NOR WERE CONSUMER'S SYMPTOMS (FROM HEAVY METAL POISONING/INFLAMMATION) DETAILED. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY, WHICH IS GENERALLY CONSIDERED SAFE. DESPITE IN VITRO TESTING HAS SHOWN THAT NICKEL IONS MAY BE RELEASED FROM ESSURE, IT IS UNLIKELY THAT THE AMOUNT OF NICKEL RELEASED WOULD BE SUFFICIENT TO CAUSE A METAL POISONING. ADDITIONALLY, THE DEVICE HAS A LOCAL ACTION IN FALLOPIAN TUBES, SO CAUSALITY BETWEEN THE SUSPECT DEVICE AND THE REPORTED AUTOIMMUNE DISEASES IS ALSO REGARDED AS UNLIKELY. ALTHOUGH LIMITED INFORMATION IS AVAILABLE IN THIS CASE FOR A COMPREHENSIVE CAUSALITY ASSESSMENT; CONSIDERING DEVICE REMOVAL WAS REQUIRED AND SINCE NO FOLLOW-UP WILL BE POSSIBLE (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING); IT WAS REGARDED AS AN INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01813	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2342, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF (B)(6) IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009 FOR CONTRACEPTION AFTER ONE YEAR HER FOURTH CHILD WAS BORN. CONSUMER REPORTED THAT SHE SUFFERED THROUGH VERY HEAVY MENSTRUATION WITH VERY HEAVY BLOOD CLOTS, VITAMIN D DEFICIENCY, SEVERELY ANEMIC RESULTING IN GETTING IRON INFUSIONS EVERY 3 - 6 MONTHS, HAIR LOSS, PELVIC PAIN, VISION CHANGE, BACK SPASM, MOOD SWINGS AND TERRIBLE BREAST PAIN. SHE HAD A X-RAY DONE THAT SHOWED BOTH COILS HAD MIGRATED OUT OF THE CONFIRMED POSITIONS. THE ONLY OPTION WAS TO HAVE SURGERY. SO SHE WILL HAVE TO HAVE AN HYSTERECTOMY BECAUSE OF ESSURE. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE HAD AN X-RAY PERFORMED WHICH RESULT SHOWED BOTH COILS HAVE MIGRATED OUT OF THE CONFIRMED POSITIONS. THE ONLY OPTION WAS TO

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HAVE SURGERY. SO SHE WILL HAVE TO HAVE A HYSTERECTOMY BECAUSE OF ESSURE. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MIGRATION IS OFTEN USED SYNONYMOUSLY WITH PERFORATION. IT IS SOMETIMES USED TO IMPLY THAT A COMPLETE PERFORATION OCCURRED NOT IMMEDIATELY, BUT OVER TIME, E.G. WHEN AN UNDIAGNOSED PARTIAL PERFORATION DURING INSERTION GRADUALLY LEADS TO A COMPLETE PERFORATION. OFTEN MIGRATION IS REPORTED WHEN THE EXACT TIME POINT OF PERFORATION IS NOT KNOWN. SOMETIMES MIGRATION THROUGH THE FALLOPIAN TUBE IS SUSPECTED BY THE REPORTER, BECAUSE THE ESSURE INSERT IS FOUND IN THE ABDOMEN AND NO APPARENT PERFORATION CAN BE IDENTIFIED. THEREFORE, BASED ON THE INFORMATION PROVIDED AND POSSIBLE MECHANISM OF MIGRATION, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, ANOTHER SERIOUS EVENT (SEVERELY ANEMIC RESULTING IN GETTING IRON INFUSIONS EVERY 3-6 MONTHS) AND NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01814	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/2/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2375, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2013 AND HAVE FOUGHT MY PREVIOUS PHYSICIAN FOR REMOVAL SINCE ((B)(6). SHE SUFFERED FROM EXTREMELY HEAVY MENSTRUAL CYCLES, EXCESSIVE CLOTTING, CHRONIC PELVIC PAIN, PAINFUL INTERCOURSE, IRREGULAR PERIODS, HAIR LOSS, SKIN RASHES, CHEST PAINS, INCREASED DEPRESSION AND ANXIETY DUE TO ALL OF THE SIDE EFFECTS. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CHRONIC PELVIC PAIN. SHE FOUND A NEW DOCTOR TO REMOVE THEM AND SHE WAS SCHEDULED FOR SURGERY. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THE NATURE OF EVENT AND CONSIDERING THAT PELVIC PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE

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EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01815	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 9/25/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2345, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. CONSUMER REPORTED THAT AFTER ESSURE INSERTION SHE HAD THE HSG (HYSTEROSALPINGOGRAM) TEST AND WAS CONFIRMED BLOCK. SOON AFTER SHE STARTED GETTING SICK. SHE WAS ALWAYS EXTREMELY TIRED. SHE WAS HOSPITALIZED MULTIPLE TIMES AND NO EXPLANATION COULD BE DETERMINED TO WHY SHE WAS SO WEAK. SHE HAD SEVERAL SURGERIES DURING THIS TIME ALSO. SHE WAS DIAGNOSED WITH AUTOIMMUNE DISEASES. AFTER ALMOST FIVE YEARS OF SUFFERING, SHE FINALLY WENT BACK TO HER GYNECOLOGIST AND HE AGREED THAT SHE WAS HAVING AN ADVERSE REACTION TO THE DEVICE. SHE WAS HAVING AN ALLERGIC TYPE REACTION THAT WAS WRECKING HAVOC ON HER. ON (B)(6) 2014, AT ONLY (B)(4), CONSUMER HAD A HYSTERECTOMY. SHE STILL HAVE SOME PERMANENT DAMAGE TO IMMUN6 SYSTEM THAT SHE WILL HAVE TO DEAL WITH THE REST OF HER LIFE. A YEAR LATER SHE IS FEELING SO MUCH BETTER. SHE IS GETTING HER ENERGY BACK AND IS NOT CONSTANTLY SICK. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-

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MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE WAS HAVING AN ALLERGIC TYPE REACTION. A HYSTERECTOMY WAS PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. BASED ON ITS NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, SHE EXPERIENCED EXTREMELY TIRED (RESULTED IN HOSPITALIZATION), SEVERAL SURGERIES (IT WAS NOT REPORTED THE REASON FOR THESE SURGERIES) AND AUTO IMMUNE DISEASES. THESE EVENTS ARE CONSIDERED SERIOUS AND DUE TO THEIR NATURE, CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01816	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 1/1/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2005
Explant Date (E7): 10/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2383, AWARENESS DATE 04-NOV-2015) WHICH REFERS TO REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE ((B)(4)) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2005. THE CONSUMER REPORTED HER PHYSICIAN ORIGINALLY TRIED TO INSERT THE ESSURE IN (B)(6) 2005. AND HE WAS UNABLE TO SUCCESSFULLY INSERT SO SHE HAD TO GO BACK IN (B)(6) 2005. SHORTLY AFTER HAVING THE ESSURE, SHE STARTED TO NOTICE GENERALIZED BODY PAIN; SHE WAS HEMORRHAGING WITH EVERY PERIOD AND SHE BECAME ANEMIC. IN 2009, SHE HAD AN ABLATION TO STOP THE HEMORRHAGING AND THE ABLATION CAUSED AN INFECTION THAT TOOK QUITE A WHILE TO GO AWAY. FROM 2005 THROUGH UNTIL THE TIME OF THE REPORT, SHE HAD SOME SYMPTOMS INCLUDED BUT NOT LIMITED TO EXTREME FATIGUE, BODY PAINS, SEVERE PELVIC PAIN, HAIR FALLING OUT, SKIN RASHES, INABILITY TO FIGHT INFECTION PROPERLY, LOSS OF FEELING IN HANDS, FEET, UPPER RIGHT THIGH AND DIFFERENT PARTS OF HER BODY DEPENDING ON THE DAY. SHE HAD SEVERAL BOUGHS OF PNEUMONIA AND OTHER RESPIRATORY INFECTIONS. SHE SEVERE GI ISSUES THAT CAUSED PAIN AND INFECTION; DRY SKIN, DRY MOUTH TO THE POINT SHE LOSE HALFTIME HER TEETH EVEN THOUGH SHE BRUSH SEVERAL TIMES A DAY AND FLOSS REGULARLY. SHE HAD SEVERE MIGRAINES 3 OR 4 TIMES PER WEEK THAT MAKE FUNCTIONING DIFFICULT IF NOT IMPOSSIBLE. ON (B)(6) 2015, SHE UNDERWENT A HYSTERECTOMY THAT REMOVED ALL HER FEMALE ORGANS INCLUDING HER OVARIES; SHE SPENT 6 DAYS IN THE HOSPITAL BECAUSE SHE CONTRACTED A KIDNEY INFECTION. SHE WAS EXPECTED TO BE OFF WORK FOR 8 TO 12 WEEKS BECAUSE OF THE COMPLICATIONS FROM THE SURGERY. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND ASSESSMENT WERE RECEIVED: QUALITY ASSESSMENT: IN

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THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERE PELVIC PAIN AND HEMORRHAGING WITH EVERY PERIOD. SHE UNDERWENT A HYSTERECTOMY THAT REMOVED ALL HER FEMALE ORGANS INCLUDING HER OVARIES. THESE EVENTS WERE CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STATED THAT SHORTLY AFTER HAVING THE ESSURE, SHE STARTED HEMORRHAGING WITH EVERY PERIOD. SHE ALSO EXPERIENCED SEVERE PELVIC PAIN. BASED ON THEIR NATURE AND CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP WITH SUSPECT INSERT, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01817	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2407, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. CONSUMER REPORTED THAT ONE OF THE COILS MIGRATED OUT OF THE TUBE AND WAS SITTING IN HER PERITONEAL AREA. THE OTHER TUBE WAS OCCLUDED. SECOND ESSURE WAS PLACED IN THE TUBE AND ALSO SUBSEQUENTLY MIGRATED AND PERFORATED HER UTERUS. THEN SHE HAD A CRYOABLATION TO STOP THE HEAVY MENSES. CRYO FLUID LEAKED THROUGH THE PERFORATION / TEAR IN HER UTERUS AND SINGED HER SMALL INTESTINE. SHE HAD AN EMERGENCY BOWEL RESECTION WITHIN DAYS, RESECTING 6 INCHES OF MATTED INTESTINE AND HAD TO STAY IN THE HOSPITAL CLOSE TO A MONTH. SHE CAME CLOSE TO A COLOSTOMY BAG AND EXPERIENCED PAIN ON HER SIDE CERTAIN DAYS. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY MENSES. SHE HAD A

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CRYOABLATION TO STOP THE HEAVY MENSES. IT WAS REPORTED THAT ONE OF COILS MIGRATED OUT OF HER TUBE, SITTING IN PERITONEAL AREA. THE OTHER TUBE WAS OCCLUDED. SECOND ESSURE COIL SUBSEQUENTLY MIGRATED AND PERFORATED HER UTERUS. THESE EVENTS WERE CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF MIGRATION AND UTERINE PERFORATION WERE NOT KNOWN. CONSIDERING THE NATURE OF THESE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT DUE TO INTERVENTION PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (CRYO FLUID LEAKED THROUGH THE PERFORATION/TEAR IN MY UTERUS, SINGED MY SMALL INTESTINE AND BOWEL RESECTION) AND NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01818	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2426, AWARENESS DATE 04-NOV-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. ESSURE WAS PLACED IN A HOSPITAL UNDER ANESTHETIC SHORTLY AFTER THE CONSUMER HAD HER THIRD BABY. SHORTLY AFTER, SHE BEGAN HAVING AWFUL PAIN, HEADACHES, RASHES, INFECTIONS, HAIR LOSS, ETC. 15 MONTHS AFTER SHE WAS IMPLANTED SHE FOUND OUT SHE WAS PREGNANT. THE FIRST ULTRASOUND SHOWED BOTH COILS IN PLACE. WHEN SHE STARTED CONTRACTING AT 12 WEEKS PREGNANCY A NEW ULTRASOUND SHOWED HER RIGHT COIL MIGRATED IN HER UTERUS WITH THE BABY PUTTING THE PREGNANCY AT VERY HIGH RISK. AFTER MANY DOCTOR APPOINTMENTS AND BED REST THE BABY WAS BORN FULL TERM BUT WITH SOME ISSUES LIKE UNEXPLAINED RASHES, SLOW GROWTH, BREATH ISSUES AND GROWING PUBIC HAIR. IN (B)(6) 2015 SHE HAD TO HAVE A FULL HYSTERECTOMY AND REMOVAL OF HER TUBES TO GET BOTH ESSURE COILS AND FRAGMENTS OUT. THE RIGHT COIL WAS COMPLETELY EMBEDDED IN HER UTERUS. AFTER ESSURE REMOVAL THE CONSUMER WAS FEELING GREAT. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. BABY CASE: (B)(4). COMPANY CAUSALITY COMMENT:

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THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT. THE FIRST ULTRASOUND SHOWED BOTH COILS IN PLACE. WHEN SHE STARTED CONTRACTING AT 12 WEEKS PREGNANCY (SEEN AS UTERINE CONTRACTIONS DURING PREGNANCY, NON-SERIOUS AND UNLISTED) A NEW ULTRASOUND SHOWED HER RIGHT COIL MIGRATED IN HER UTERUS (PARTIAL EXPULSION OF DEVICE). SHE HAD TO HAVE A FULL HYSTERECTOMY AND REMOVAL OF TUBES TO GET BOTH ESSURE COILS AND FRAGMENTS OUT (SEEN AS DEVICE BREAKAGE). THE RIGHT COIL WAS COMPLETELY EMBEDDED IN UTERUS. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR DEVICE BREAKAGE WHICH IS UNLISTED. IN THIS CASE, PREGNANCY WAS DIAGNOSED ABOUT 15 MONTHS AFTER ESSURE INSERTION. THE EXACT DATE AND MECHANISM OF PARTIAL EXPULSION, DEVICE BREAKAGE AND EMBEDDED DEVICE WERE NOT KNOWN. CONSIDERING THE NATURE OF THE EVENTS, CAUSALITY CANNOT BE EXCLUDED. MOST OF PREMATURE BIRTHS OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES. IN THIS CASE, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01819	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/9/2015
Explant Date (E7): 10/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2467 / FDA-2014-N-0736-2521, AWARENESS DATE ON 04-NOV-2015 AND FDA-2014-N-0736-2493, AWARENESS DATE ON 05-NOV-2015). IT REFERS TO AN ADULT FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. ADDITIONAL INFORMATION WAS RECEIVED ON 12-NOV-2015 VIA REGULATORY AUTHORITY (CASE# (B)(4)). SINCE THE VERY SAME DAY THAT ESSURE WAS INSERTED, SHE STARTED HAVING ISSUES. HER SYMPTOMS GOT WORSE AS THE MONTHS WENT ON. HER FIRST ISSUE WAS MUSCLE CRAMPS FROM HER UPPER JAW DOWN TO THE ARCH OF HER FEET. SHE HAD HEAVY PERIOD TWO WEEKS ON ONE WEEK OFF FOR ABOUT 4 MONTHS STRAIGHT. SHE DEVELOPED MIGRAINES AFTER THE 5TH MONTH SHE HAD THIS EVERYDAY ALL DAY. SHE NOTICED SHE WAS BRUISING ALL OVER HER LEGS LIKE CRAZY, AND SHE HAD GOTTEN BLOTCHES ON HER ARMS THAT WOULD COME AND GO. SHE BECAME DEPRESSED AND VERY FATIGUE WHERE IT WOULD NOT ONLY BOTHER HER BUT ALSO HER KIDS AND HUSBAND. HER RIGHT OVARY AREA BECAME A HOT SENSATION PROBABLY BECAUSE IT WAS INFLAMMATION. DUE TO THESE HORRIBLE SIDE EFFECTS AND SYMPTOMS SHE HAD HER TUBES AND COILS REMOVED AS OF (B)(6) 2015. AT THE TIME OF REPORT, SHE WAS (B)(6). QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE

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INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD A SUSPICION OF INFLAMMATION BECAUSE HER RIGHT OVARY AREA HAD A WARMTH SENSATION. APPROXIMATELY 9 MONTHS AFTER ESSURE INSERTION, SHE HAD HER TUBES AND COILS REMOVED. THE LOCALIZED INFLAMMATION IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE LOCALIZATION OF THIS SUSPECTED INFLAMMATION AND THE LACK OF ALTERNATIVE EXPLANATION, THE CAUSAL RELATIONSHIP WITH ESSURE INSERTS CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 08-DEC-2015: CONSUMER DISCONNECTED THE CALL. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO AN ADULT FEMALE CONSUMER WHO HAD

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01820	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/9/2015
Explant Date (E7): 10/23/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2490, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. ESSURE WAS REMOVED VIA HYSTERECTOMY IN (B)(6) 2014 AND IT WAS ONLY ABLE TO KEEP RIGHT OVARY DUE TO ISSUES WITH LEFT OVARY. SINCE (B)(6) 2013 MIGRAINES WENT TO CHRONIC AND INTRACTABLE. SHE WAS HOSPITALIZED 3 TIMES IN 2013 TO ATTEMPT TO BREAK THE MIGRAINE CYCLE. EMERGENCY ROOM VISIT IN (B)(6) 2014 DUE TO UNDIAGNOSED LEFT FLANK PAIN. SHE WAS DIAGNOSED WITH FIBROMYALGIA IN (B)(6) 2014, WITH ENDOMETRIOSIS IN (B)(6) 2014. SHE HAS ALSO EXPERIENCED WEIGHT GAIN AND RASH ON BOTH FOREARMS. DESPITE REMOVAL IN (B)(6) 2014 SHE STILL HAD INTRACTABLE MIGRAINE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 25-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE

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REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THE INSERTION, MIGRAINES WENT TO CHRONIC AND INTRACTABLE. SHE HAD THE DEVICES REMOVED VIA HYSTERECTOMY ONE YEAR LATER. THESE EVENTS, SEEN AS MIGRAINE AGGRAVATED AND MEDICAL DEVICE REMOVAL ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE, HOSPITALIZATION AND REQUIRED INTERVENTION. THE REMOVAL IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE MIGRAINE IS UNLISTED. MIGRAINE IS AN EPISODIC DISORDER, CHARACTERIZED BY A SEVERE HEADACHE GENERALLY ASSOCIATED WITH NAUSEA, AND/OR LIGHT AND SOUND SENSITIVITY. CONSIDERING THE ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES AND THE FACT THAT THIS INTRACTABLE MIGRAINES PERSISTED EVEN AFTER THE DEVICE REMOVAL, CAUSALITY WITH ESSURE USE IS UNLIKELY. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. ALTHOUGH, IN THIS CASE, THE EXACT REASON FOR ESSURE REMOVAL WAS NOT SPECIFIED, A CAUSAL RELATIONSHIP BETWEEN THE REPORTED EVENT AND ESSURE USE CANNOT BE EXCLUDED AND DUE TO SURGICAL INTERVENTION (HYSTERECTOMY) THIS CASE WAS CONSIDERED AN INCIDENT. ADDITIONALLY, NON-SERIOUS EVENT WAS ADDED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01821	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2465, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. CONSUMER'S DAUGHTER STATED THAT HER MOTHER WAS INJURED BY ESSURE. FOR ONE YEAR SHE WAS NOT HER MOM BECAUSE OF THE SEVERE PAIN SHE EXPERIENCED IN THE LEFT SIDE OF HER BODY. AS SHE DESCRIBED IT FELT LIKE BONE POUNDING PAIN AND A SKIN RIPPING SENSATION NEAR HER KIDNEYS. SHE WAS TURNED AWAY FROM DOCTORS MAKING IT SEEMS LIKE IT WAS ALL IN HER HEAD UNTIL SHE TOOK IT UPON HERSELF TO INITIATE AN X-RAY OF HER ABDOMEN AND SAW THAT THE LEFT COIL HAD DOUBLED OVER IN HER TUBE AFTER 9 YEARS. FINALLY HER DOCTOR SAID THEY DID NOT LOOK RIGHT. UNFORTUNATELY EVEN THOUGH CONSUMER TOLD HER NOT TO PULL THEM OUT OR HER UTERUS, SHE DID ANYWAY LEAVING FRAGMENTS. SHE HAD A SECOND SURGERY 3 MONTHS LATER. ALMOST TWO YEARS LATER SHE SUFFERS FROM SEVERAL AUTOIMMUNE SYMPTOMS AND GOES TO DOCTORS WEEKLY. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET

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WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SEVERE PAIN IN LEFT SIDE OF BODY (INTERPRETED AS ABDOMINAL PAIN). THE CONSUMER STATED THE PHYSICIAN PULLED THE ESSURE COILS OUT, LEAVING FRAGMENTS. SHE HAD TO HAVE A SECOND SURGERY 3 MONTHS LATER. AFTER TWO YEARS SHE WAS SUFFERING FROM SEVERAL AUTOIMMUNE SYMPTOMS. THE ABDOMINAL PAIN, DEVICE BREAKAGE AND AUTOIMMUNE DISEASE ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ONLY AUTOIMMUNE DISEASE IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINCE THERE IS NO ALTERNATIVE EXPLANATION FOR THE ABDOMINAL PAIN THAT CONSUMER HAD WHILE ON ESSURE, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ALTHOUGH THE PHYSICIAN PULLED THE ESSURE COILS THAT HAD BEEN PREVIOUSLY INSERTED. IT IS NOT CLEAR WHETHER THERE WERE LESS THAN 18 COILS TRAILING IN THE UTERINE CAVITY, THEREFORE A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. ON THE OTHER HAND, CONSIDERING THAT ESSURE INSERTS HAVE A LOCALIZED ACTION IN THE FALLOPIAN TUBES AND DO NOT HAVE A SYSTEMIC ACTION, IT IS UNLIKELY THAT ESSURE COULD TRIGGER AN AUTOIMMUNE DISEASE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01822	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/10/2010
Explant Date (E7): 1/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2501, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. THE CONSUMER COMPLAINED OF PAIN AND 6 MONTHS AFTER HER HYSTERECTOMY, SHE CALLED TO PHYSICIAN'S OFFICE AND REPORTED THAT SHE HAD THE SAME PROBLEMS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 25-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED PAIN. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE, THE PAIN APPARENTLY HAD NOT BEEN RESOLVED AFTER DEVICE REMOVAL, CONSIDERING PELVIC PAIN

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MAY OCCUR DURING ESSURE USE, A CONTRIBUTORY ROLE FROM SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01823	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2491, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. CONSUMER WAS A MOTHER TO 6 BEAUTIFUL CHILDREN AND AFTER HER FAMILY OF 5 BOYS WAS COMPLETE WITH ADDITION OF HER DAUGHTER IN 2013 SHE WAS IMPLANTED WITH ESSURE. SHORTLY AFTER, HER HEALTH STARTED TO DECLINE. SHE BEGAN HAVING PROBLEMS THINKING AND REMEMBERING, A STATE OF BRAIN FOG SOME WOULD CALL IT. SHE WAS SEVERELY FATIGUED. SHE WAS NOT FEELING LIKE HERSELF. SHE HAD PROBLEMS WITH HER VISION; SHE HAS BEEN TO NUMEROUS OPTIC NEUROLOGIST. SHE HAD HORRIBLE PERIODS AND CRAMPS WHICH SHE HAS NEVER EXPERIENCED PRIOR TO ESSURE. HER STOMACH WAS BLOATED AFTER EACH MEAL, SHE LOOKED LIKE SHE WAS 6 MONTHS PREGNANT. SHE HAS GAINED 30 POUNDS SINCE HER IMPLANT. HER PERSONAL SEXUAL RELATIONSHIP WITH HER SPOUSE HAS SUFFERED. CONSUMER HAD SHOOTING PELVIC PAINS WHEN SHE MOVED CERTAIN WAYS. SHE ALSO HAD NUMBNESS AND TINGLY IN HER LEGS. SHE DEVELOPED A RASH THAT WOULD NOT GO AWAY. IT WAS ON HER ARMS, TORSO AND LEGS; SHE BELIEVED THIS WAS A NICKEL ALLERGY RASH. SHE STARTED HAVING DIARRHEA THAT NEVER LEFT. SHE WENT FROM 1 BOWEL MOVEMENT A DAY TO 4-7 LOOSE BOWELS EVERY SINGLE DAY. SHE HAS HAD A SPINAL TAP, MRI AND NUMEROUS TEST TO FIGURE OUT THE CAUSE OF ALL THESE SYMPTOMS, COMING UP EMPTY HANDED EVERY TIME. SHE STRONGLY BELIEVED THAT THE ESSURE DEVICE WAS TO BLAME FOR MOST IF NOT ALL OF HER SYMPTOMS. EVERY ONE OF THESE SYMPTOMS STARTED JUST SHORTLY AFTER SHE GOT THE DEVICE. SHE WAS DUE TO HAVE A HYSTERECTOMY ON (B)(6) 2015. QUALITY ASSESSMENT: IN THIS

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CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED SHOOTING PELVIC PAIN WHICH STARTED JUST SHORTLY AFTER THE DEVICE PLACEMENT. SHE HAD A HYSTERECTOMY SCHEDULED AT THE MOMENT OF REPORT. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP AND THE FACT THAT PELVIC PAIN MAY OCCUR DURING ESSURE USE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01825	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH-DEVICE, OCCLUSION, TUBAL,CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5036711) IN UNITED STATES ON 22-JUL-2014 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMP EVERY SINGLE DAY, THROBBING IN FALLOPIAN TUBES, HEADACHES, STOMACH BLOWS UP LIKE A BALLOON, PERIODS ARE VERY HEAVY, MOODS HAVE CHANGED, DEPRESSED AND SEX LIFE HAS CHANGED FROM THE PAIN FROM THESE THINGS. FOLLOW-UP INFORMATION WAS RECEIVED ON 22-SEP-2014 FROM CONSUMER. SHE HAS NEVER HAD ANY MEDICAL ISSUES AT ALL, HAS ALWAYS BEEN VERY HEALTHY AND EVER SINCE SHE HAD ESSURE INSERTED SHE HAD NOTHING BUT MEDICAL ISSUES AND MEDICAL BILLS. HER LIFE HAS BEEN HELL FOR THE PAST A LITTLE OVER 4 YEARS. SHE WAS EXPERIENCING PAINS, ABNORMAL PAPSMEARS. SHE HAD CHILDREN AND HALF THE TIME SHE COULD NOT EVEN GET OUT OF BED OR WALK BECAUSE HER STOMACH HAD EXTREME PAINS ALL THE TIME, AND SHE ENDED UP AT THE ER (EMERGENCY ROOM) AND DOCTOR'S OFFICE THOUSANDS OF TIMES. SHE STATED THAT SHE COULD NOT WORK ANYMORE DUE TO HER TUBES FEELING LIKE SOMEONE WAS HAMMERING A KNIFE INTO THEM WHILE THEY THROB LIKE CRAZY (PREVIOUSLY REPORTED AS THROBBING IN MY FALLOPIAN TUBES). PTC INVESTIGATION RESULT WAS RECEIVED ON 22-OCT-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO

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CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED "UNCONFIRMED QUALITY DEFECT". IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP 27-JAN-2015: THE REQUIRED NUMBER OF FOLLOW UP ATTEMPTS HAVE BEEN COMPLETED, WITHOUT RESPONSE FROM THE CONSUMER. NO NEW INFORMATION WAS PROVIDED. CASE CLOSED. FOLLOW UP INFORMATION RECEIVED ON 05-NOV-2015 AND RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 25-NOV-2015: CASE UPGRADED TO INCIDENT. THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2318). CONSUMER REPORTED THAT SHE HAD ESSURE INSERTED IN 2010 AND THEN SHE HAVE HAD BLOOD TRANFUSION DUE TO HEAVY BLEEDING THAT LAST 4 - 6 MONTHS AT A TIME. SHE HAD CHRONIC ANEMIA, WHICH MEANT HEADACHES DAILY, EXTREME FATIGUE AND MOODINESS. SHE HAD CONSTANT PAIN IN HER LOWER ABDOMEN. SHE COULD NOT PLAY WITH HER KIDS BECAUSE SHE WAS ALWAYS SLEEPING, IN PAIN OR IN THE BATHROOM. SHE HAS NOT BEING ABLE TO ENJOY SEX WITH HER HUSBAND BECAUSE THE PAIN WAS UNREAL. SHE WAS (B)(6) AND WAS SICK AND TIRED OF BEING SICK AND TIRED. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER STOMACH HAS EXTREME PAINS ALL THE TIME. SHE EXPERIENCED HEAVY BLEEDING THAT LAST FOR 4-6 MONTHS AT A TIME (INTERPRETED AS GENITAL BLEEDING) AND HAVE HAD BLOOD TRANSFUSION. SHE HAD CHRONIC ANEMIA. ONLY THE EVENT GENITAL BLEEDING IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. IN THIS CASE, IT WAS NOT REPORTED THE DURATION OF CHRONIC ANEMIA, HOWEVER IT COULD BE RELATED TO THE HEAVY BLEEDING. CONSIDERING POSITIVE TEMPORAL RELATIONSHIP, CAUSALITY CAN NOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE AN INTERVENTION (BLOOD TRANSFUSION) WAS PERFORMED. ALSO, NON SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT QUALITY DEFECT OF THE PRODUCT. FURTHER INFORMATION COULD NOT BE OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01826	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/21/2011
Explant Date (E7): 11/12/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5055561) IN UNITED STATES ON 20-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. CONSUMER REPORTED THAT SINCE HAVING ESSURE SHE HAVE HAD WEIGHT GAIN, FATIGUE, DEPRESSION, ITCHING, SEVERE STOMACH PAIN, SWELLING, HAIR LOSS AND GASTROINTESTINAL PROBLEMS. SHE ASKED HER DOCTOR TO REMOVE IT AND SHE WILL NOT SO SHE WAS WAITING FOR A SECOND OPINION. AS CONCOMITANT MEDICATION SHE RECEIVED PROTONIX, EFEXOR AND MULTI VITAMINS. FOLLOW UP INFORMATION RECEIVED ON 05 AND 13-NOV-2015: CASE UPGRADED TO INCIDENT. THIS FOLLOW UP HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2404). CONSUMER REPORTED IN 2011 SHE WENT TO HER DOCTOR BECAUSE SHE DID NOT WANT ANYMORE KIDS. SHE HAD RECENTLY HAD MIRENA AND HAD PROBLEMS WITH IT, SO DOCTOR SUGGESTED ESSURE. THE RIGHT SIDE SEEMED PRETTY EASY TO INSERT EVEN THOUGH SHE WAS IN A LOT OF PAIN. ON THE LEFT SIDE SHE HAD PROBLEMS TO INSERT, SHE SAID HER TUBE WAS TWISTED BUT KEPT FORCING IT IN. SHE WAS IN SO MUCH PAIN SHE WAS ABOUT TO PASS OUT. THE PAIN WAS WORST THAN GIVING BIRTH TO HER 3 KIDS. AFTER 3 MONTHS SHE HAD THE DYE TEST DONE AND EVERYTHING LOOKED FINE. SHE STARTED GAINING WEIGHT, HAVING WORSENING PERIODS AND PAIN ALL THE TIME. SHE WAS TIRED ALL THE TIME, GOT DEPRESSION AND WAS PLANNING SUICIDE. SHE WAS PUT ON MEDICATION FOR THE DEPRESSION, BUT CONTINUED TO GAINING WEIGHT AND GET TIRED. IN 2013 SHE WAS HAVING LOWER STOMACH PAIN SO BAD THAT DOCTOR PUT HER IN FOUR DIFFERENT ANTIBIOTICS AT THE SAME TIME. BECAUSE THE AMOUNT OF ANTIBIOTICS SHE GOT

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CLOSTRIDIUM DIFFICILE. SHE WAS IN SO MUCH PAIN THAT A COLONOSCOPY WAS ORDERED AND POLYPS WERE FOUND AND SHE WAS DIAGNOSED WITH COLITIS. SHE WAS TREATED FOR THAT. IN (B)(6) 2014 A COMPUTERIZED TOMOGRAPHY SHOWED HER LEFT COIL HAD MIGRATED. SHE WAS IN CONSTANT PAIN FOR A WHILE. THEN AN ULTRASOUND SHOWED THAT THE LEFT COIL HAD MIGRATED AND PERFORATED OUT OF HER TUBE AND DOCTOR TOLD HER SHE WOULD HAVE TO REMOVE HER TUBES AND ALSO HER UTERUS DUE TO THE RISK OF BLEEDING. ON (B)(6) 2015 SHE HAD A FULL HYSTERECTOMY PERFORMED AT THE AGE OF (B)(6). PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT LEFT COIL HAD MIGRATED AND PERFORATED OUT OF HER TUBE. SHE HAD A FULL HYSTERECTOMY PERFORMED. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EVENT WAS DIAGNOSED ABOUT 2 YEARS AND 8 MONTHS AFTER ESSURE INSERTION, HOWEVER THE EXACT DATE AND MECHANISM WERE NOT KNOWN. BASED ON ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01827	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** BE

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A OTHER IN UNITED STATES ON 05-NOV-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED AND RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 25-NOV-2015. DURING A FORUM FOR GYNECOLOGISTS, A CONSUMER SITUATION WAS DISCUSSED. SHE WAS 38 WEEKS PREGNANT AND HER CERVIX WAS STILL LONG AND HARD; IT WAS STATED THAT THIS COULD ONLY MEAN THAT THE DEVICE WAS EMBEDDED IN THE CERVIX AND NOT IN THE CANAL. ONE PHYSICIAN SUGGESTED LETTING THE PATIENT DELIVER AND RIGHT AFTER THE DELIVERY OF THE PLACENTA PERFORM A MANUAL REVISION OF THE CERVIX, IF THE DEVICE WAS SEEN THE REMOVAL SHOULD BE DONE AND IF NOT A HYSTEROSCOPY SHOULD BE PERFORMED 6 WEEKS AFTER THE DELIVERY. ANOTHER PHYSICIAN STATED THAT THE PRESENCE OF THE ESSURE IN LOWER UTERINE SEGMENT OR ENDOCERVIX COULD POTENTIALLY CAUSE SOME PHYSICAL HARM TO THE NEWBORN IN THE FORM OF CUTS AND ABRASIONS. HE SUGGESTED A CESAREAN SECTION AND ALSO EXPLORE THE UTERUS FOR THE DEVICE AT THE TIME. THE PHYSICIAN STATED HE DID NOT HAVE MORE INFORMATION ABOUT THIS CASE, SINCE IT WAS NOT HIS PATIENT. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT

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REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT. IT WAS STATED THAT ESSURE DEVICE WAS EMBEDDED IN THE CERVIX. ONE PHYSICIAN SUGGESTED LETTING THE PATIENT DELIVER AND RIGHT AFTER THE DELIVERY OF THE PLACENTA PERFORM A MANUAL REVISION OF THE CERVIX, IF THE DEVICE WAS SEEN THE REMOVAL SHOULD BE DONE AND IF NOT A HYSTEROSCOPY SHOULD BE PERFORMED 6 WEEKS AFTER THE DELIVERY. BOTH EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT IS NOT KNOWN WHETHER ESSURE WAS IN-SITU DURING CONCEPTION OR NOT, THUS, THE POSSIBILITY OF CONTRACEPTIVE FAILURE CANNOT BE TOTALLY EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE THE PHYSICIAN SUGGESTED THAT IF THE DEVICE WAS SEEN, THE REMOVAL SHOULD BE DONE. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS, THE REPORTED LACK OF EFFICACY AND A QUALITY DEFECT. THE PHYSICIAN STATED HE DID NOT HAVE MORE INFORMATION ABOUT THIS CASE, SINCE IT WAS NOT HIS PATIENT, THUS NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01828	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/10/2010
Explant Date (E7): 1/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2494, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED (B)(6) 2010. ON (B)(6) 2010, CONSUMER WAS DIZZY AND LIGHT HEADED, LOST HER BALANCE, FELT AND SHATTERING HER RIGHT ELBOW. FROM TIME ESSURE WAS IMPLANTED, IT CAUSED MANY PROBLEMS THAT SHE NEVER HAD BEFORE. HER BALANCE WAS THROWN OFF WHICH CAUSED HER TO LOSE HER BALANCE ON A FLAT LEVEL SURFACE AND ENDED UP CHATTERING HER RIGHT ELBOW CAUSING HER TO HAVE TITANIUM PARTS PUT IN HER ELBOW AND ALSO WHILE SITTING DOWN SHE LOST HER BALANCE WHILE TRYING TO STAND UP AND HIT HER HEAD ON THE FLOOR SO HARD. THIS DEVICE ALSO CAUSED ROMANCE TO DROP DOWN TO NOTHING BECAUSE OF IT AFFECTS HAVING MASSIVE STOMACH PAINS AND MAKING HER THINK IT WAS SOMETHING ELSE AFFECTING HER WHEN IT WAS THE ESSURE ALL ALONG. SHE WAS ALWAYS NAUSEOUS, AND FELT LIKE SHE COULD NOT EAT. WHEN SHE ATE, OFTEN TIMES SHE COULD NOT HOLD IT DOWN. SHE EXPERIENCED LONGER, HEAVIER PERIODS, SEVERE FATIGUE, NO ENERGY, PHANTOM PAINS IN HER SIDES, LEGS, BACK, AND JOINTS, MUSCLE SPASMS THAT SEVERELY MADE HER IN CONSTANT PAIN; SHE BECAME SEVERELY DEPRESSED, SUFFERED INCREASED ANXIETY, SEVERE MOOD SWINGS AND BECAME SUICIDAL LITERALLY OVERNIGHT. SHE STATED THAT GOING TO GROCERY STORE WAS SO HARD BECAUSE SHE GOT ANXIOUS AND WOULD GO INTO PANIC MODES. SHE RARELY TALKED TO ANYONE STOPPED TALKING TO FRIENDS AND WAS IN TOTAL ISOLATION. ON (B)(6) 2015, SHE HAD IT REMOVED (HYSTERECTOMY PERFORMED) AND WITHIN A WEEK IT WAS NOTICED A BIG CHANGE IN HER BEING MORE INTERACTED WITH HER FAMILY AND WAITING TO

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DO THINGS WHICH WAS GREAT FOR USE BUT SHE STILL HAS A LONG RECOVERY AHEAD OF HER FROM THE SIDE EFFECTS OF THE ESSURE BEING IMPLANTED AND HER OVARIES WERE STILL IN SHOCK FROM SURGERY AND STILL WAITING TO SEE IF SHE GETS TO KEEP THEM OR NOT. AFTER HYSTERECTOMY, SHE WAS STILL SUFFERING FROM HAVING HAD THOSE COILS IN HER BODY FOR SO LONG. THE WORST PART OF IT ALL WAS THAT SHE BECAME SOMEONE THAT HER KIDS NO LONGER KNEW. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LONGER HEAVIER PERIODS. SHE HAD ESSURE REMOVED (HYSTERECTOMY PERFORMED). THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01829	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 6/25/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/24/2013
Explant Date (E7): 7/18/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2515, AWARENESS DATE 04-NOV-2015) WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013 FOR BIRTH CONTROL. ADDITIONAL INFORMATION WAS RECEIVED FROM REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 23-NOV-2015. THE CONSUMER REPORTED TWO YEARS AGO, SHE WENT HER GYNECOLOGIST TO DISCUSS HAVING HER IUD PUT BACK IN; SHE HAS HASHIMOTOS THYROIDITIS AND AT THE TIME OF APPOINTMENT, SHE WAS HEALTHY AND HAD THE THYROID ISSUES UNDER CONTROL. HER DOCTOR PUSHED ESSURE AND TOLD HER THAT HER PREEXISTING AUTOIMMUNE CONDITION WOULD NOT BE AFFECTED. SHE ASKED HER ABOUT THE NICKEL ALLERGY CONCERN, AS THE CONSUMER IS ALLERGIC TO NICKEL AND THE PHYSICIAN TOLD HER IT WAS NO LONGER A CONCERN. SHE REPORTED THE PROCEDURE WAS PAINFUL AND LONGER THAN SHE HAD TOLD IT WOULD BE. THE DOCTOR STRUGGLED WITH THE COIL ON LEFT SIDE; IMMEDIATELY FOLLOWING, THE CONSUMER WAS INFORMED SHE WAS UNSURE ABOUT THE LEFT COIL AND THAT SHE MIGHT HAVE TO HAVE SURGERY DOWN THE LINE. WITHIN 24 HOURS OF IMPLANTATION, SHE WAS IN SEVERE DEBILITATING PAIN AND HEAVY BLEEDING. SHE WAS ALSO NAUSEATED, VOMITING AND DIZZY UPON STANDING. HER SYMPTOMS CONTINUED AND SHE WAS UNABLE TO KEEP FOOD DOWN. ON DAY 2 POST-PROCEDURE, SHE DEVELOPED A FULL BODY RASH AND EXPERIENCED A METALLIC TASTE IN HER MOUTH. HER DOCTOR REFUSED TO SEE OR TREAT HER STATING THAT SHE HAD NEVER HAD ISSUES AND THAT THIS MUST HAVE BEEN SOMETHING ELSE. THE CONSUMER TRIED TO REACH HER PHYSICIAN BUT REFUSED TO SEE HER. SHE CONTINUED TO EXPERIENCE SEVERE PAIN, FULL BODY RASH, AND METALLIC TASTE IN HER MOUTH, SEVERE VOMITING AND

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FEVER. SHE CONTINUED TO REFUSE TO SEE THE CONSUMER FOR EVALUATION. THE CONSUMER STATED SHE WAS FORCED TO HAVE THE COILS REMOVED THREE WEEKS AFTER THE PROCEDURE ON (B)(6) 2013. SHE REPORTED SHE HAD NO CHOICE, HER HEALTH WAS DECLINING AT A RAPID PACE. DURING SURGERY, IT WAS DISCOVERED THAT THE LEFT COIL WAS IN HER UTERUS, THE DOCTOR WAS ABLE TO RETRIEVE IT INTACT AS WELL AS REMOVE THE OTHER COIL FROM HER TUBE. SHE ENDED UP HAVING A C-SECTION SCAR AND LOST TIME FROM WORK AND HER HEALTH HAS NEVER BEEN THE SAME. ACCORDING TO THE CONSUMER, ESSURE HAS HAD A NEGATIVE IMPACT ON HER HEALTH AND CAUSED CHRONIC INFLAMMATORY RESPONSES IN HER BODY. HER FORMERLY UNDER CONTROL THYROID ISSUES HAVE BEEN OUT OF CONTROL REQUIRING MORE DOCTOR VISITS AND MEDICATION. SHE HAS SUFFERED FROM UNEXPLAINED RASHES AND AUTOIMMUNE ISSUES OF THE EYE. CONCOMITANT MEDICATION INCLUDED TIROSENT, CYTOMEL AND LDN. PTC INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WITHIN 24 HRS OF IMPLANTATION, SHE WAS IN SEVERE PAIN (SEEN AS PELVIC PAIN FEMALE) AND HEAVY BLEEDING (INTERPRETED AS POST PROCEDURAL BLEEDING). SHE WAS FORCED TO HAVE THE COILS REMOVED THREE WEEKS AFTER THE PROCEDURE. DURING SURGERY, IT WAS DISCOVERED THAT THE LEFT COIL WAS IN HER UTERUS. THE DOCTOR WAS ABLE TO RETRIEVE IT INTACT AS WELL AS REMOVE THE OTHER COIL FROM HER TUBE. THESE EVENTS WERE CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THESE EVENTS OCCURRED AFTER ESSURE INSERTION. THE EXACT DATE AND MECHANISM OF PARTIAL EXPULSION OF DEVICE WERE NOT KNOWN. CONSIDERING A POSITIVE TEMPORAL RELATIONSHIP AND BASED ON THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01830	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2492, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED IN 2010. ADDITIONAL INFORMATION WAS RECEIVED ON 05-NOV-2015 (CASE# FDA-2014-N-0736-2518) AND ON 25-NOV-2015. HER LIFE HAS BEEN HORRIBLE. SHE EXPERIENCED HEAVY BLEEDING, BLEEDING BEYOND A NORMAL PERIOD, BLOOD CLOTS THE SIZE OF A SILVER DOLLAR; SEVERE BACK PAIN, MOOD SWINGS, HEADACHES, NAUSEA, STOMACH PAIN; HAIR LOSS, NAIL FELL OF BIG TOE; SEVERE ACNE, BLOATING AND WEIGHT GAIN. THAT GAINED MOMENTUM OVER THE YEARS WAS INCREASING. THE PAST YEAR IT BECAME DEBILITATING. SHE LOST HER JOB, MISSING SO MUCH WORK. WHEN HER PERIOD CAME NOW, SHE WAS CRAWLING TO REACH HER BED OR CHAIR. THE PAIN WAS SO INTENSE. SHE WAS TIRED ALL THE TIME, SLEEP FOR HOURS AND FELT LIKE SHE HAD NEVER SLEPT. SHE WENT TO THE DOCTOR WHO PLACED THE DEVICE AND HE LAUGHED AT HER, SAID NO WAY THE DEVICE WAS CAUSING ALL THOSE COMPLAINTS AND THERE WAS NO WAY TO REMOVE THE COILS. SHE ALSO EXPERIENCED MENTAL FOG. DOING RESEARCH SHE FOUND A CLINIC THAT WOULD REMOVE THE COILS AND NOT RESORT TO A HYSTERECTOMY. THE DOCTOR REMOVED BOTH COILS. ONE MIGRATED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS

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CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD HEAVY BLEEDING (BEYOND A NORMAL PERIOD) WITH BLOOD CLOTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE COILS WERE REMOVED. ONE MIGRATED. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. IN THIS CASE, CONSUMER REPORTED HEAVY BLEEDING (REGARDED AS GENITAL BLEEDING) AND DYSMENORRHEA AMONGST OTHER NON-SERIOUS EVENTS. SHE STATED ESSURE WAS REMOVED; IT SEEMS THAT DURING THE SURGERY ONE COIL WAS FOUND MIGRATED (EXACT LOCATION NOT SPECIFIED). ALTHOUGH LIMITED INFORMATION WAS PROVIDED; CONSIDERING EVENTS NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED) BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01831	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 5/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2472, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013. THE CONSUMER WAS SENT HOME AFTER INSERTION BUT RETURNED ON THE SAME NIGHT IN SEVERE PAIN. A COMPUTERIZED TOMOGRAM REVEALED SHE WAS BLEEDING INTERNALLY. SHE HAD TO RECEIVE A BLOOD TRANSFUSION AFTER EMERGENCY SURGERY WHERE IT WAS DISCOVERED HER UTERUS WAS PUNCTURED BY THE DEVICE. SHE STATED THAT HER MENSTRUAL CYCLE CRAMPS WERE COMPARABLE TO THE PAIN OF CONTRACTIONS, HER SEX DRIVE WAS NON-EXISTENT AND WHEN THEY DID MAKE LOVE HER HUSBAND WOULD FEEL STABBING FROM THE DEVICES. SHE WAS IN CONSTANT PAIN AND UNABLE TO FUNCTION AS SHE SHOULD BE ABLE TO. HUSBAND CASE: (B)(4). QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IN THE SAME NIGHT OF PLACEMENT PROCEDURE RETURNED WITH SEVERE PAIN. THEN, A COMPUTERIZED TOMOGRAM REVEALED SHE WAS BLEEDING

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INTERNALLY. SHE HAD TO RECEIVE A BLOOD TRANSFUSION AFTER EMERGENCY SURGERY WHERE IT WAS DISCOVERED HER UTERUS WAS PUNCTURED BY THE DEVICE. THIS EVENT, SEEN AS UTERINE PERFORATION POST PROCEDURAL, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE CLOSE TEMPORAL RELATIONSHIP BETWEEN INSERTION AND THE DIAGNOSIS OF THE PERFORATION, IN THE PRESENT CASE, MAY SUGGEST THAT THE PERFORATION HAD OCCURRED IN ASSOCIATION WITH INSERTION. THEREFORE, A CAUSAL RELATIONSHIP WITH ESSURE USE CANNOT BE EXCLUDED. AS AN INTERVENTION WAS REQUIRED (EMERGENCY SURGERY) THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01832	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2010
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2298), AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010 AFTER THE BIRTH OF HER FOURTH AND LAST CHILD. IMMEDIATELY AFTER PLACEMENT SHE WOKE UP IN EXCRUCIATING PAIN. SHE BLED FOR OVER A MONTH AND HAD IRON LEVELS CHECKED WEEKLY BECAUSE OF THE BLOOD LOSS. SHE WAS PUT ON MORE BIRTH CONTROL JUST TO STOP THE BLEEDING. FOR THE ALMOST FIVE YEARS THAT SHE HAD THE ESSURE, SHE EXPERIENCED NON-STOP PROBLEMS FROM DAILY MIGRAINES TO BREAKING OUT IN HIVES, BEING DIAGNOSED WITH AN AUTOIMMUNE DISEASE, AND SEVERE DAILY CHRONIC PAIN THAT EVENTUALLY LEAD TO HAVE A HYSTERECTOMY AT (B)(6). ALTHOUGH A LOT OF HER PROBLEMS WENT AWAY WITH REMOVAL THERE WAS SOME DAMAGE THAT UNFORTUNATELY PERMANENT. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLED FOR OVER A MONTH. ALSO, FOR ALMOST FIVE YEARS, AUTOIMMUNE DISEASE WAS DIAGNOSED AND SHE PRESENTED SEVERE DAILY CHRONIC PAIN WHICH LED HER TO

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HAVE A HYSTERECTOMY. THESE EVENTS, SEEN AS GENITAL BLEEDING, AUTOIMMUNE DISORDER AND PELVIC PAIN, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT AUTOIMMUNE DISORDER WHICH IS UNLISTED. CONSIDERING THE POSITIVE TEMPORAL RELATIONSHIP AND THE FACT THAT PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE, CAUSALITY BETWEEN BOTH EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE THE CHRONIC PAIN LED TO A REQUIRED INTERVENTION (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. REGARDING AUTOIMMUNE DISORDER, LIMITED INFORMATION HAS BEEN PROVIDED; HOWEVER, GIVEN THE FACT THAT ESSURE ACTS LOCALLY IN FALLOPIAN TUBES, CAUSALITY BETWEEN THIS EVENT AND SUSPECT INSERT IS VERY UNLIKELY. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01890	BAYER HEALTHCARE LLC	12/3/2015	12/3/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2291 / FDA-2014-N-0736-2292, AWARENESS DATE 04-NOV-2015). ADDITIONAL INFORMATION RECEIVED ON 04-NOV-2015. IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SHE HAS HAD SEVERE PELVIC PAIN, BACK PAIN, HEADACHES AND EXCESSIVE BLEEDING. SHE HAD NOVASURE TO STOP THE BLEEDING BUT IT DID NOT WORK. SHE HAD A SEVERE SKIN OUTBREAK AND SCHEDULED A HYSTERECTOMY. SHE WAS VERY DEPRESSED THAT SHE HAS TO HAVE A HYSTERECTOMY AT THE AGE OF (B)(6). PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 25-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXCESSIVE BLEEDING (INTERPRETED AS GENITAL

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BLEEDING). SHE UNDERWENT A NOVASURE PROCEDURE (ENDOMETRIAL ABLATION) TO STOP THE BLEEDING BUT IT DID NOT WORK. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THIS EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058237	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 1/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES HEADACHE, HAIR LOSS, PAIN JOINTS, PELVIS PAIN, HEAVY MENSTRUAL CYCLE (BLOOD CLOTS), WEIGHT GAIN, FATIGUE, NAUSEA, INSOMNIA, BLOATING, BRAIN FOG.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058238	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 6/14/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABDOMINAL PAIN, HEADACHES, RASH AND HIVES, MOOD SWINGS. HIGH BLOOD PRESSURE, ANXIETY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058239	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TWICE MONTHLY MENSES. HEAVY BLEEDING. PELVIC PAIN AND PRESSURE. LACK OF SEX DRIVE. PAIN WITH INTERCOURSE ALONG WITH BLEEDING AFTERWARDS. EXTREME MIGRAINES. HAIR LOSS FATIGUE WEIGHT GAIN, AND LETHARGIC.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058240	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 9/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME ITCHING TO POINT OF WAKING UP WITH BLOODY LIMBS FROM SCRATCHING, EXTREME DRY EYES. (REPORTED TO EYE DOCTOR), THEN IN (B)(6) BECAME VERY ILL UNTIL ABOUT FEBRUARY- EXTREME FATIGUE, BRAIN FOG, SWOLLEN GLANDS, SWOLLEN HANDS, LEGS, ANKLES, FEET. WENT TO DIE OR FOR TESTS, PRESCRIBED THREE DIFFERENT ANTIVIOTICS AT THAT TIME, NOTHING SEEMED TO HELP. DOCTORS COULD FIND NO REASON FOR THE EXTREME LONG LASTING ILLNESS. TESTED FOR (B)(6) AND THE FLU- BOTH NEGATIVE. CLEARED UP IN (B)(6). IN (B)(6) MY KNEES BECAME EXCRUCIATINGLY PAINFUL. IT BECAME DIFFICULT TO WALK AND SIT. COMPLETELY GONE IN (B)(6). I HAVE MORE MOOD SWINGS AND ANXIETY, IN (B)(6) 2014 MY MOTHER STARTED COMPLAINING ABOUT HOW BLOATED MY BELLY HAD BECOME, AND ABOUT HOW MY EYES HAD VERY DARK CIRCLES AROUND THEM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058241	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 8/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLEEDING FOR OVER 8 MONTHS, PRETTY MUCH NON STOP, WITH TERRIBLE CLOTTING. PAIN IN BOTH ABDOMEN AND LOWER BACK. BOTH SIDES, LEFT AND RIGHT. DOUBLES NE OVER IN PAIN. ALSO AFFECTS ABILITY TO STAND UPRIGHT. VERY LITTLE SLEEP DUE TO PAIN AND PROFUSE BLEEDING. HEADACHES. MOODINESS. BLOATING. JOINT PAIN. LETHARGY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058242	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 4/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, BLOATING, WEIGHT GAIN, HEADACHES, URINARY TRACT INFECTION, PAIN ON RIGHT PELVIC, CYSTS ON CERVIX, FOUL ODOR AND DISCHARGE, HEAVY SWEATS, AND DIZZINESS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058243	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 11/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHOLE BODY HURTS, EXTREME SHARP SHOOTING PAIN IN MY GROIN, HEADACHES, HEAVY PERIODS WITH BLOOD CLOTS, BLOATING,WEIGHT GAIN, TIRED ALL THE TIME, NAUSEA, HAVE TO URINATE EVERY 20 MIN, HURTS TO HAVE INTERCOURSE, AND VERY LOW SEX DRIVE. I HAVE ALSO HAD MANY CYSTS ON MY OVARIES THAT HURT LIKE HELL WHEN THEY RUPTURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058244	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 8/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RIGHT AFTER IMPLANTATION I HAD HORRIBLE PELVIC PAIN. I STILL DO AND IT IS (B)(6). PERIODS SO HEAVY I HAVE CLOTS COMING OUT. I HAVE GAINED (B)(6) IN 3 MONTHS. MY GUMS BLEED HEAVILY, TONGUE HURTS, MIGRAINES, FATIGUE, AND CONTINUOUS PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058245	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 10/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE DEBILITATING PAIN TO MY PELVIS I CAN NO LONGER MAKE LOVE TO MY HUSBAND. I FEEL SICK AND NAUSEOUS. I'M LOSING MY HAIR. I FEEL VERY HARD AND BLOATED. I HAVE A VERY VERY SHARP STABBING PAIN IN MY BACK, MY LOWER PELVIS. SOME DAYS I CAN HARDLY MOVE. I AM TRYING TO FIND A DOCTOR TO HELP ME. (B)(6) KEEP ME IN BED FOR UP TO A WEEK SOMETIMES. I HAVE FOUR CHILDREN THAT DEPEND ON ME AND SOME DAYS I CAN HARDLY FUNCTION SOMETIMES. I HAVE TWO PERIODS A MONTH. I'M IN A LOT OF PAIN, ALSO GET A BAD ITCHY RASH ON STOMACH AND INNER THIGHS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058246	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BLED FOR TWO YEARS POST ESSURE. HAD MILK PRODUCTION FOR THREE PLUS YEARS POST ESSURE, JOINT PAIN DAILY, HEADACHES DAILY AND WEEKLY TO BI-WEEKLY MIGRAINES, BLOATED, BLOOD CLOTS, VOICE BOX CONCERNS, BLEEDING GUMS, FATIGUE, HEART PALPITATIONS, LEG CRAMPING, BODY ITCHINESS, AND GREEN DISCHARGE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058247	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 11/24/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN ON MY RIGHT SIDE. PERIOD OUT OF WHACK AGAIN. DISCHARGE IN BREAST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058248	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 11/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HOSPITALIZED FOR PELVIC INFLAMMATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058249	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 9/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD DEVICE IMPLANTED IN BY (B)(6) I HAD BEEN TO DOCTOR FOR DEPRESSION/ANXIETY. IN 2010 I GOT PREGNANT AND DELIVERED A HEALTHY FULL TERM BABY. I FOUND A GROUP ON FACEBOOK CALLED ESSURE PROBLEMS AND I DIDN'T LINK ANY OTHER SYMPTOMS I HAD TO ESSURE UNTIL THEN. MOODY, BACK ACHES (LIKE BACK LABOR), HEAVY MENSTRUAL CYCLE, BLOOD CLOTS WITH MENSTURAL CYCLE, DEPRESSION/ANXIETY, JOINT PAIN, ABDONMINAL PAIN, PELVIC PAIN/PRESSURE, PAINFUL INTERCOURSE AND THE LIST GOES ON AND ON. DUE TO ALL THESE SYMPTOMS I AM SCHEDULED TO HAVE A FULL HYSTERECTOMY IN (B)(6) 2015 TO TAKE ESSURE OUT BECAUSE I DIDN'T HAVE NONE OF THESE BEFORE ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058272	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 4/28/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING, BLOATING, WEIGHT GAIN, HEADACHES, URINARY TRACT INFECTION, PAIN ON RIGHT PELVIC, CYSTS ON CERVIX, FOUL ODOR AND DISCHARGE, HEAVY SWEATS, DIZZINESS

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058273	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 8/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). APPROXIMATELY 2 MONTHS AFTER I GOT ESSURE I STARTED CHRONIC PELVIC PAIN, LOWER BACK PAIN , ABDOMINAL PAIN, HEADACHES, NAUSEA, AND BLOATING. THIS HAS GONE ON SINCE (B)(6) 2013. I HAVE BEEN IN AND OUT OF THE ER WITH ALL MY TEST RESULTS COMING BACK NORMAL AND NO ANSWERS TO MY ISSUES THAT ARE STILL GOING. ON (B)(6) 2015 I ENDED UP GETTING DIAGNOSTIC LAPAROSCOPIC SURGERY TO EXPLORE MY PAIN AND NO ANSWERS BUT ONE OF THE ESSURE COILS WAS PROTRUDING OUT OF ONE OF MY FALLOPIAN TUBES SO MY DR TOOK BOTH TUBES AND COILS OUT AND HE BURNED THE ENDS. THE PAIN STARTED GETTING BETTER AFTER A WEEK AND THEN IT GOT WORSE AGAIN AND NOW I HAVE TO GET A HYSTERECTOMY BECAUSE OF MY PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058274	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 12/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD PELVIC PAIN, HEAVY PERIODS, HAIR LOSS, BACK PAIN, FOOT PAIN,MOOD SWINGS, ANEMIA, AND JUST FELT LIKE CRAP.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058275	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 4/13/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). OBTAINED ESSURE TO STERILIZE ME. SINCE GETTING IT, I HAVE HAD PERIODS THAT LAST AT LEAST TWO WEEKS. CURRENTLY I HAVE BEEN BLEEDING FOR OVER 5 WEEKS. CRAMPS DURING MY PERIOD ARE MUCH WORSE COMPARED TO BEFORE THE PROCEDURE. I ALSO HAVE NO SEX DRIVE. EVEN IF I DID, I BLEED ALL THE TIME!!! MY DOCTOR EXPLAINED TO ME THAT THIS PROCEDURE WAS EASIER THAN A TUBAL, I REGRET LISTENING TO HER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058277	BAYER	12/3/2015	12/3/2015

Event Information:

Event Date (B3): 8/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE PERMANENT BIRTH CONTROL DEVICE ESSURE THAT I'VE HAD INSERTED INTO ME EXACTLY A YEAR IN (B)(6) FAILED AND I BECAME PREGNANT! MY PREGNANCY IS CONSIDERED HIGH RISK DUE TO THE COILS AND MY BABY HAS TO BE MONITORED AT EVERY APPOINTMENT TO MAKE SURE ONE OF THE COILS DOESN'T PUNCTURE THE AMNIOTIC SAC CAUSING ME TO LOOSE MY BABY. NOT TO MENTION THAT I HAD TRIED EXTREMELY HARD TO PREVENT THIS FROM HAPPENING AND WAS TOLD THAT THERE WAS ONLY A .1 PERCENT CHANCE IT COULD FAIL NOW I FIND THAT NOT SO TRUE...I'M UNABLE TO WORK DUE TO THIS PREGNANCY...

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058363	BAYER	12/3/2015	12/8/2015

Event Information:

Event Date (B3): 9/21/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/21/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECENTLY ACQUIRED THE ESSURE BECAUSE AFTER MY FIFTH CHILD I DECIDED THAT WAS MORE THAN ENOUGH. BOY DID I REGRET GETTING THE ESSURE, A WEEK AFTER I GOT IT IMPLANTED THERE WAS INFLAMMATION ALL AROUND THE DEVICE NOT TO MENTION MORE SYMPTOMS AS THE DEVICES AGED. I WAS COUGHING, HURTING, BENDING HURTS AND SEXUAL ACTIVITY IS NO LONGER ENJOYABLE, ALSO HAIR LOSS ANEMIA, I COULD GO ON AND ON REALLY I WANT IT REMOVED. IT'S NOT COVERED BY INSURANCE, GREAT SO I ASKED WHAT IT WOULD BE OUT OF POCKET, (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058367	BAYER	12/3/2015	12/8/2015

Event Information:

Event Date (B3): 12/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/18/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I RECEIVED THE ESSURE BACK IN 2013 BEFORE I UNDER WENT MY HEART CONDITION. THIS WAS TOLD TO ME THAT IT IS A PERMANENT BIRTH CONTROL SUBSTANCE THAT COULD NOT BE REMOVED. ALL THE WHILE HAVING THIS DEVICE, I AM EXPERIENCING HEADACHES, CONTINUOUS PAIN IN MY LOWER AREA. HAIR HAD FALLEN OUT IN THE TOP OF MY HEAD, I ALWAYS FEEL NAUSEA ON THE STOMACH. I HAVE BEEN TO MY OBGYN DOCTOR AND SHE DID AN ULTRASOUND ON ME TO SEE HOW EVERYTHING WAS GOING INSIDE OF MY BODY. THE DOCTOR STATED THAT ALL MY REPRODUCTIVE ORGANS ARE OK. THE DOCTOR ALSO PRESCRIBED ME IBUPROFEN 800 FOR THE PAIN. I RECENTLY WENT TO MY CARDIOLOGIST DOCTOR AND HE EXPLAINED TO ME THAT I DO NOT NEED TO CONTINUE TO TAKE THE IBUPROFEN BECAUSE IT COULD CAUSE SOME HEALTH ISSUE LATER IF I TAKE THEM LIKE I DO FOR PAIN, ALL DUE TO THESE ESSURE PAIN I RECEIVED CONTINUOUSLY. I AM A HEART PATIENT AND I DO SEE MY CARDIOLOGIST, I AM NOT TRYING TO BE PLACED BACK IN THE HOSPITAL WITH THESE SIDE EFFECTS I AM EXPERIENCING WITH ESSURE. BACK IN 2011 I WAS DIAGNOSED WITH ENDOCARDITIS AND MY SURGERY WAS DUE TO MITRAL VALVE REGURGITATION IN 2013. IN 2011 I HAD A BUSTED BLOOD VESSEL, IT BURST INSIDE OF MY BRAIN AND HAD A STROKE ON MY LEFT SIDE. I HAVE RECORDS OF ALL MY HEALTH ISSUES. THIS ESSURE THING ALSO HAVE CAUSED DEPRESSION IN MY LIFE BECAUSE OF THE PAIN I AM EXPERIENCING. I WANT THESE ESSURE COILS THINGS OUT OF ME. I HAVE TRIED TO SEE IF THE ESSURES CAN BE REMOVED, BUT MY INSURANCE (MEDICAID) WILL NOT PAY FOR THEM TO BE REMOVED. I ALSO WAS TOLD THAT THESE ESSURE THINGS CANNOT BE REMOVED. I FOUND A PLACE THAT REMOVED THEM BUT IT COST ALMOST (B)(6) TO REMOVE THESE THINGS. I NEED SOME HELP IN ANY WAY POSSIBLE TO GET THESE ESSURE THINGS OFF THE MARKET AT THE OBYGYN CLINICS OR CENTERS. I ALSO FEEL THAT INSURANCE SHOULD BE IN PLACE FOR THESE THINGS TO BE REMOVED. THESE ESSURE COILS THINGS HAVE REALLY AFFECTED MY LIFE AND I

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CAN SAY THEY ARE NO GOOD. I WOULD NOT RECOMMEND ESSURE TO ANYONE. I FEEL LIKE NEEDLES ARE CONTINUOUSLY STICKING ME INSIDE OF MY BODY EVER SINCE I HAD THESE ESSURE INSERTED. I WANT THEM OUT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01809	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/23/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5057488) IN UNITED STATES ON 06-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: XANAX (ALPRAZOLAM) FOR SLEEP, ADDRESS, MULTIVITAMINS (MULTIVITAMINS), AND CO Q10 (UBIDECARENONE). CONSUMER REPORTED SHE WENT TO A NEW PHYSICIAN TO HAVE AN ENDOMETRIAL ABLATION PERFORMED DUE TO HEAVY AND LONG MENSTRUAL PERIODS AND SHE RECOMMENDED GETTING ESSURE TO PREVENT GETTING PREGNANT. IN (B)(6) OF 2014 SHE STARTED HAVING PELVIC AND ABDOMINAL PAIN AND EXTREME FATIGUE. SHE WENT TO HER FAMILY PHYSICIAN AND HAD BLOOD WORK DONE. ALL BLOOD TESTS CAME BACK NORMAL. THE PAIN AND FATIGUE CONTINUE TO WORSEN. IN 2015 SHE AGAIN HAD AN APPOINTMENT WITH HER FAMILY PHYSICIAN FOR WORSENING PELVIC AND ABDOMINAL PAIN, MUSCLE BURNING AND FATIGUE. SHE HAD MORE BLOOD WORK, A CT SCAN AND AN ULTRASOUND. EVERYTHING CAME BACK NORMAL, BUT SHE DID HAVE 2 UTIS (URINARY TRACT INFECTION). PRIOR TO ESSURE SHE HAS HAD LESS THAN 3 UTIS IN HER INTIRE LIFE. SHE WENT TO A GASTROENTEROLOGIST FOR SAME SYMPTOMS AND HAD A COLONOSCOPY AND UPPER ENDOSCOPY DONE, WHICH ALL CAME BACK NORMAL. SHE THEN WENT TO A RHEUMATOLOGIST WHO PRESCRIBED AN ANTI-INFLAMMATORY. IN (B)(6) 2015 SHE SAW A FERTILITY SPECIALIST AND IS GETTING THE ESSURE REMOVED WITHIN A MONTH. SHE IS NOT SURE IF SHE NEEDS A HYSTERECTOMY OR JUST THE ESSURE AND TUBES REMOVED. CONSUMERS FATIGUE, BODY PAINS AND BRAIN FOG HAVE BEEN LIFE CHANGING FOR THE WORSE. SHE IS DEPRESSED. SHE USED TO BE VERY ACTIVE AND EXERCISED 6 TIMES A WEEK DOING RUNNING, WEIGHT LIFTING, HIKING AND BIKRAM YOGA. NOW, SHE CAN BARELY GET OUT OF BED. SHE HOPES HER SYMPTOMS WILL IMPROVE ONCE

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IT IS REMOVED. CONSUMER MENTIONED DISABILITY/ PERMANENT DAMAGE AND REQUIRED INTERVENTION AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD PELVIC PAIN. ESSURE REMOVAL WAS PLANNED FOR WITHIN A MONTH FROM THE REPORT. THIS EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 29-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01824	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2451, AWARENESS DATE 04-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007, AFTER HER SON WAS BORN. SHE WAS TOLD THIS WAS A SAFE AND EASY WAY TO NOT HAVE ANY MORE CHILDREN AS SHE HAD A VERY HARD PREGNANCY AND DELIVERY. AFTER ALMOST A YEAR SHE GOT PREGNANT AND WAS ALMOST (B)(6) PREGNANT WHEN SHE HAD A HORRIBLE MISCARRIAGE. SHE DID NOT EVEN KNOW SHE WAS PREGNANT. AFTER BEING TOLD SHE WOULD NOT GET PREGNANT ON THE ESSURE, IT WAS A HORRIBLE PAINFUL EMOTIONAL EXPERIENCE. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER ALMOST A YEAR SHE GOT PREGNANT AND HAD A HORRIBLE MISCARRIAGE WHEN ALMOST (B)(6) PREGNANT. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. PREGNANCY IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENT IS UNLISTED. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE, INCLUDING

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ESSURE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS CASE IT WAS NOT REPORTED WHETHER A CONFIRMATION TEST WAS PERFORMED, HOWEVER SINCE THE PREGNANCY OCCURRED ALMOST ONE YEAR AFTER ESSURE INSERTION THE POSSIBILITY OF CONTRACEPTIVE FAILURE CANNOT BE EXCLUDED. THE EXACT CAUSE OF THE MISCARRIAGE WAS NOT REPORTED IN THIS CASE. HOWEVER, CONSIDERING THAT THE PREGNANCY WAS AT ALMOST (B)(6), A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE TOTALLY EXCLUDED, THEREFORE THIS EVENT WAS CONSIDERED RELATED TO THE SUSPECT INSERT. THIS CASE WAS REGARDED AS INCIDENT SINCE A SERIOUS INJURY WAS REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01833	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/8/2010
Explant Date (E7): 12/18/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5057185) IN UNITED STATES ON 05-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. ADDITIONAL INFORMATION RECEIVED ON 25-NOV-2015 (PTC INVESTIGATION RESULT). SINCE INSERTION, CONSUMER EXPERIENCED DEBILITATING CRAMPS TWO WEEKS BEFORE AND AT LEAST A WEEK AFTER HER PERIOD. SHE WAS HOSPITALIZED FOR UNFOUNDED REASONS. HER EYESIGHT WAS DETERIORATED TO WHERE SHE WAS WEARING BIFOCALS AND COULD NOT BE WITHOUT GLASSES FOR MORE THAN AN HOUR. SHE HAD AT LEAST 5 TEETH PULLED OUT IN THE LAST TWO YEARS. ESSURE EXPLANTED DATE WAS (B)(6) 2014. CONSUMER ASSESSED AS EVENT OUTCOME: HOSPITALIZATION, DISABILITY/ PERMANENT DAMAGE AND REQUIRED INTERVENTION. NO FURTHER DETAILS WERE PROVIDED. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO

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REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE INSERTION SHE EXPERIENCED DEBILITATING CRAMPS TWO WEEKS BEFORE AND AT LEAST A WEEK AFTER PERIOD (INTERPRETED AS ABDOMINAL CRAMPS). SHE HAD ESSURE EXPLANTED. THIS EVENT WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SINCE ABDOMINAL CRAMPS MAY OCCUR WITH ESSURE THERAPY, CONSIDERING THIS INFORMATION AND A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNFOUNDED REASONS WHICH RESULTED IN HOSPITALIZATION, EYESIGHT HAS DETERIORATED AND AT LEAST 5 TEETH PULLED IN THE LAST 2 YEARS; THESE EVENTS WERE REGARDED AS UNLISTED AND UNRELATED) AND NON-SERIOUS EVENT WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01834	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 10/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5057265) IN UNITED STATES ON 05-NOV-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. CONSUMER EXPERIENCED SEVERE ABDOMINAL PAIN. ON (B)(6) 2014, SHE WAS SUBMITTED TO A SURGERY TO REMOVE LEFT COIL. DURING COIL REMOVAL, LEFT COIL WAS FOUND DISLODGED AND WAS IN THE CERVIX. CONSUMER ENDED UP HAVING A TUBAL LIGATION. SHE ASSESSED OTHER SERIOUS (IMPORTANT MEDICAL EVENT) AS EVENT OUTCOME. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2015: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO WAS SUBMITTED TO A SURGERY TO REMOVE LEFT ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) COIL. DURING THIS PROCEDURE, THE COIL WAS FOUND DISLODGED AND WAS IN THE CERVIX. THIS EVENT IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION (INTO UTERUS/CERVIX OR OUT OF THE BODY) OR DISLOCATION (DISTAL FALLOPIAN TUBE OR PERITONEAL CAVITY) AND CAN RESULT IN ABDOMINAL PAIN. IN THIS PARTICULAR CASE, CONSUMER DEVELOPED ABDOMINAL PAIN AND WAS SUBMITTED TO A SURGERY (ALMOST 6 YEARS AFTER ESSURE PLACEMENT) TO REMOVE LEFT COIL; WHICH WAS EXPELLED TO CERVIX. ALTHOUGH THE EXACT MECHANISM OF THIS EVENT WAS UNKNOWN, GIVEN ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 11-DEC-2015: CONSUMER'S DATE OF BIRTH WAS ADDED (SHE WAS (B)(6)). CONSUMER STATED THAT SURGERY WAS DONE IN SEPTEMBER BECAUSE SHE WAS HAVING A LOT OF PAIN. COIL HAD MOVED OR WAS BENT AND DURING SURGERY, COIL WAS FOUND IN C

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01835	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/24/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT (>=18Y & <65Y) FEMALE CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 05-NOV-2015. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: TAMBACOR, PHENERGAN [PROMETHAZINE] (PROMETHAZINE [PROMETHAZINE]), TRAMADOL (TRAMADOL), PRILOSEC (OMEPRAZOLE) AND MECLIZINE (MECLOZINE). THE CONSUMER REPORTED THAT AFTER ESSURE PLACEMENT SHE DEVELOPED ARRHYTHMIA, DIZZINESS, CHEST PAIN AND SHORTNESS OF BREATH. SHE HAD TWO CARDIAC ABLATIONS AND A THIRD WILL BE DONE IN 2015. SHE HAD WORSENING MIGRAINES AND WORSENING NAUSEA. SHE ALSO DEVELOPED LONGER PAINFUL MENSTRUAL PERIODS AND SHE HAD TO GET AN UTERINE ABLATION FOR IT. SHE COULD NOT LEAVE HOME BECAUSE SHE WAS BLEEDING THROUGH HER CLOTHES. SHE WAS BLEEDING AFTER SEX AND BLEEDING IN BETWEEN PERIODS. SHE ALSO HAD A FIBROID TUMOR AND IF THE ABLATION DOES NOT WORK SHE WILL BE GIVEN A HYSTERECTOMY. SHE WAS ALWAYS IN PAIN. SHE TRIED MANY MIGRAINE MEDICATIONS THAT DID NOT WORK AND WILL SEE A HEADACHE SPECIALIST IN 2015. HOSPITALIZATION, DISABILITY/PERMANENT DAMAGE, REQUIRED INTERVENTION WERE MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS SO IT WAS ASSUMED THAT HOSPITALIZATION WAS CAUSED BY THE LONGER PAINFUL MENSTRUAL PERIODS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE

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UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED LONGER PAINFUL MENSTRUAL PERIODS (UNDERSTOOD AS PAINFUL PERIODS AND PROLONGED PERIODS). SHE HAD TO GET AN UTERINE ABLATION FOR IT. SHE ALSO COULD NOT LEAVE HER HOME BECAUSE SHE WAS BLEEDING (INTERPRETED AS GENITAL BLEEDING). THESE EVENTS WERE CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. NO ALTERNATIVE EXPLANATION WAS PROVIDED FOR THE EVENTS. CONSIDERING THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THE TERM HOSPITALIZATION, DISABILITY/PERMANENT DAMAGE WERE ONLY MENTIONED AS EVENT OUTCOME AND THE REPORTER DID NOT SPECIFY IT. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, ANOTHER SERIOUS EVENT (ARRHYTHMIA) AND NON-SERIOUS EVENTS WERE REPORTED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01836	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/22/2009
Explant Date (E7): 3/12/2010
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5057260) IN UNITED STATES ON 05-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: PROVERA (MEDROXYPROGESTERONE ACETATE), FLEXERIL (CYCLOBENZAPRINE HYDROCHLORIDE), ZOLOFT (SERTRALINE), DAYPRO (OXAPROZIN), ATIVAN (LORAZEPAM), MAXALT (RIZATRIPTAN), BENTYL (DICYCLOVERIN HYDROCHLORIDE), ZESTRIL (LISINOPRIL), ZYRTEC (CETIRIZINE HYDROCHLORIDE), WELLBUTRIN SR (BUPROPION HYDROCHLORIDE), AND SYMBICORT (BUDESONIDE W/FORMOTEROL FUMARATE). CONSUMER REPORTED IT ALL STARTED EXPERIENCING HER PELVIC REGION TO BE VERY ITCHY AND DISCOMFORTING INCLUDING HIGH AND LOW LEVELS OF PAIN EVEN AFTER THE 6 WEEK POST SURGERY OF ESSURE INSERTION. FOLLOWING 3 MONTHS AFTER THE 6 WEEK POST SURGERY VISIT, CONSUMER STARTED TO EXPERIENCE A METAL/METALLIC TASTE IN MOUTH WHICH SHE WAS TOLD FOR SOME TIME OVER AND OVER AGAIN THAT IT WAS AN INFECTION BUT MOST OF THE TIME NO INFECTION WAS FOUND AND SHE WAS GIVEN ANTIBIOTICS. THE ANTIBIOTICS HELPED A VERY SHORT TIME AND THE RECURRING NASTY METAL/METALLIC TASTE WAS BACK. CONSUMER DID NOT KNOW AT THE TIME THAT THERE WAS NICKEL IN THESE COILS. HER PHYSICIAN ASKED IF SHE HAD A NICKEL ALLERGY AND SHE STATED YES. SHE HAVE BEEN ALLERGIC TO NICKEL SINCE SHE WAS VERY YOUNG. THE WHOLE TIME HER PELVIC PAIN PERSISTS. SHE GAINED WEIGHT WHICH SHE HAVE BEEN ON A STRUGGLE TO LOSE SINCE HAVING THIS PRODUCT REMOVED ALONG WITH HER RIGHT OVARY ON (B)(6) 2010. CONSUMER HAS LOST COUNT ON HOW MANY UTERINE BIOPSIES WERE DONE BECAUSE OF HER PAIN. SHE HAS NO LONGER HAD THE METAL/METALLIC TASTE. UNFORTUNATELY, SHE STILL HAVE THE CHRONIC PAIN AS WELL AS HAVING BEEN DIAGNOSED WITH SEVERE

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CHRONIC PAIN SYNDROME AND SEVERE FIBROMYALGIA WHICH SYMPTOMS DIDN'T APPEAR UNTIL AFTER THE ESSURE INSERTION. THE REPORTER MENTIONED THE FOLLOWING EVENT OUTCOME LIFE THREATENING, HOSPITALIZATION, DISABILITY AND PERMANENT DAMAGE, HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICE WAS REMOVED (APPROXIMATELY 1 YEAR AFTER ITS PLACEMENT). THE REPORTED EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER'S PAIN STARTED IN CLOSE TEMPORAL ASSOCIATION WITH ESSURE PROCEDURE. SHE ALSO STATED, AFTER DEVICE REMOVAL, SHE WAS DIAGNOSED WITH FIBROMYALGIA. THIS CONDITION COULD HAVE BEEN A CONTRIBUTORY ROLE IN CONSUMER'S PAIN. NEVERTHELESS, CONSIDERING EVENT'S NATURE AND GIVEN THE POSITIVE TEMPORAL RELATION WITH ESSURE INSERTION, CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01837	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/22/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5057263) IN UNITED STATES ON 05-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. THE CONSUMER WENT TO HER GYNECOLOGIST AND ASKED FOR A TUBAL LIGATION BUT HIS NURSES SAID THAT HE COULD NOT DO IT UNLESS SHE HAD ANOTHER KID. SHE CURRENTLY HAS 3 CHILDREN. THEY SUGGESTED HER TO GET THE ESSURE NOT INFORMING HER ON THE SIDE EFFECTS OF THIS IMPLANT. THE PHYSICIAN INSERTED THE RIGHT IMPLANT CORRECTLY ACCORDING TO HIM. HE INSERTED THE LEFT IMPLANT AND LEFT PLASTICS INSIDE THE FALLOPIAN TUBE ACCORDING TO HIM, AND THAT HE MADE A MISTAKE AND THAT MANY WOMEN HAVE HAD THE SAME THING DONE ALSO ACCORDING TO THE PEOPLE HE CALLED WHILE SHE WAS INSIDE HIS OFFICE. HE SAID HER BLEEDING WOULD STOP BUT IT ONLY GOT WORSE, HER CRAMPING HAS WORSENED AND HEADACHES HAVE STARTED TO COME EVERY DAY. THE CONSUMER MENTIONED DEPO SHOT AND IBP (UNDERSTOOD AS IBUPROFEN) AS CONCOMITANT MEDICATION. SERIOUS INJURY WAS MENTIONED AS EVENT REPORT TYPE, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE PHYSICIAN LEFT PLASTICS INSIDE THE FALLOPIAN TUBE (INTERPRETED AS DEVICE BREAKAGE). SHE ALSO MENTIONED HER BLEEDING GOT WORSE (INTERPRETED AS GENITAL BLEEDING). GENITAL BLEEDING IS A SERIOUS EVENT DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE THE EXACT MECHANISM OF THE BREAKAGE WAS NOT REPORTED. CONSUMER MENTIONED THAT THE PHYSICIAN LEFT

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PLASTICS INSIDE THE FALLOPIAN TUBE, WHICH COULD BE INTERPRETED AS PARTS OF THE ESSURE INSERTER, THEREFORE THIS EVENT WAS REGARDED AS A DEVICE BREAKAGE. GIVEN THE NATURE OF THE EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. AFTER ESSURE INSERTION, GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE EVENT BLEEDING GOT WORSE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 04-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01838	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 654848/ 20183089

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 10/12/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5057273) IN UNITED STATES ON 05-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. ADDITIONAL INFORMATION RECEIVED ON 25-NOV-2015. SHE EXPERIENCED PAIN IN HER LOWER BACK SINCE SHORTLY AFTER THEY WERE PLACED. SHE ALSO EXPERIENCING WORSENING SYMPTOMS OF DEPRESSION, HEAVINESS IN HER LIMBS, INCREASED BLEEDING DURING MENSTRUAL CYCLE, INABILITY TO FOCUS, IRRITABILITY, HEADACHES, PAIN WITH INTERCOURSE, LETHARGY, BURNING SENSATION AND SWELLING IN HER UTERUS, LOWER BACK PAIN BECAME SO BAD SHE WAS NO LONGER ABLE TO EXERCISE AND GAINED WEIGHT. SHE BEGAN TAKING ADDERALL FOR HER INABILITY TO FOCUS. SHE SAW SEVERAL DOCTORS OVER THE YEARS WHO DID NOT THINK ESSURE WAS THE CAUSE OF ANY OF THESE SYMPTOMS. CONCLUSIONS REACHED WITHOUT ANY TESTING OR EXPERIENCE WITH ESSURE. SHE WAS TOLD IT COULD BE AGE RELATED, POSSIBLY PERIMENOPAUSE. SHE WAS VERY HEALTH OTHERWISE. ON UNSPECIFIED SHE HAD A PELVIC ULTRASOUND THAT COULD NOT DETERMINE WHERE THE COILS WERE IN HER BODY. SHE INSISTED ON ANOTHER PELVIC ULTRASOUND THAT WAS REVIEWED BY A MATERNAL FETAL RADIOLOGIST WHO SPECIALIZED IN READING ULTRASOUNDS OF THE REPRODUCTIVE AREA. UPON REVIEW OF BOTH THE ULTRASOUND AND A STOMACH X-RAY THE COILS WERE FOUND TO HAVE MIGRATED. IT WAS NOT CLEAR IF IT WAS ONE OR BOTH. ON (B)(6) 2015 SHE HAD SURGERY TO REMOVE THE COILS. THE SURGERY SHOWED BOTH COILS HAD PERFORATED HER FALLOPIAN TUBES AND MIGRATED TO THE END OF THE TUBES. SEVERAL DAYS AFTER THE SURGERY SHE WAS NO LONGER HAVING ANY LOWER BACK PAIN OR BURNING SENSATION. HOSPITALIZATION, DISABILITY/PERMANENT DAMAGE, REQUIRED INTERVENTION WERE MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION

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RESULT: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SEVERAL NON-SERIOUS EVENTS. SHE HAD A PELVIC ULTRASOUND THAT COULD NOT DETERMINE WHERE THE COILS WERE IN HER BODY. SHE ALSO HAD X-RAY PERFORMED. THE RESULT SHOWED BOTH COILS HAD PERFORATED MY FALLOPIAN TUBES AND MIGRATED. SHE HAD SURGERY TO REMOVE THE COILS. THIS EVENT IS SERIOUS (HOSPITALIZATION, DISABILITY/PERMANENT DAMAGE, REQUIRED INTERVENTION WERE MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE THE EXACT DATE AND MECHANISM OF PERFORATION WERE NOT KNOWN. HOWEVER, GIVEN ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. PRODUCT TECHNICAL COMPLAINT (PTC) ANALYSIS CONCLUDED TO AN UNCONFIRMED QUALITY DEFECT (NO BATCH NUMBER WAS PROVIDED). MEDICAL PTC ASSESSMENT CONSIDERED THAT, BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED 07-DEC-2015: CONSUMER UPDATED HER HOME MAILING ADDRESS. REGARDING THE ESSURE LOT NUMBER, SHE REPORTED SHE SAW SOME OF THESE NUMBERS ON THE CARD THEY GAVE HER: ESS305, UNDERNEATH THAT THERE IS ANOTHER NUMBER (B)(4) AND THERE IS ANOTHER S

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01839	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/14/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-2297, AWARENESS DATE 05-NOV-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED IN 2012 AFTER HAVING A SYMPTOMATIC, SPINAL HEMANGIOMA IN PREGNANCY WHICH RESULTED IN AN EMERGENCY CESAREAN SECTION FOLLOWED BY REMOVAL OF HER T6 VERTEBRA AND SPINAL FUSION OF T4-T8. SHE WAS TOLD SHE SHOULD NOT GET PREGNANT AGAIN DUE TO OTHER SPINAL HEMANGIOMAS. SHE WAS UNABLE TO TAKE ORAL CONTRACEPTIVES BECAUSE SHE EXPERIENCE AURA CYCLIC MIGRAINES, DEPO PROVERA BECAUSE OF THE SPINAL FUSION, AND THE DOCTORS REFUSED TO PERFORM ANOTHER SURGERY BECAUSE OF EVERYTHING SHE HAD BEEN THROUGH. ESSURE WAS SUGGESTED. THE COILS WERE THE BEST THINGS SHE HAD EVER HAD. HER PERIOD WAS REGULATED AND SHE DID NOT EXPERIENCE ANY MENSTRUAL DISCOMFORT. SHE HAS ENDOMETRIOSIS SO IRREGULARITY AND PAIN WERE CHRONIC. IN 2014 SHE NOTICED THAT HER HAIR WAS THINNING. SHE ATTRIBUTED IT TO A NEW MEDICATION SHE WAS TAKING BUT WHEN SHE STOPPED TAKING THE MEDICATION HER HAIR CONTINUED TO THIN. IN (B)(6) 2015 SHE STARTED HAVING SEVERE DISCOMFORT IN HER RIGHT LOWER QUADRANT WHICH RADIATED DOWN THE MEDIAL ASPECT OF HER RIGHT THIGH ALONG WITH SEVERE ABDOMINAL BLOATING. EVERY LAB TEST, ULTRASOUND, CT SCAN, AND PELVIC EXAM CAME BACK COMPLETELY NORMAL. ON (B)(6) 2015 SHE HAD HER ESSURE COILS AND FALLOPIAN TUBES REMOVED AND WHEN SHE WOKE UP FROM SURGERY, THE PAIN WAS COMPLETELY GONE. THE DAY AFTER SURGERY HER ABDOMEN WAS 1.5 INCHES SMALLER AND TO DATE WAS 2 INCHES SMALLER IN CIRCUMFERENCE FROM THE DAY BEFORE SURGERY. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS

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RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED PAIN. THEN, SHE HAD ESSURE REMOVED AND IMMEDIATELY AFTER THAT, THE PAIN WAS COMPLETELY GONE (POSITIVE DECHALLENGE). THIS EVENT, SEEN AS PELVIC PAIN IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE, ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THIS EVENT, CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE POSITIVE DECHALLENGE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01840	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2432, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. DURING THE INSERTION, THE DEVICE USED TO INSERT THE COILS MALFUNCTIONED AND PARTS OF THE COILS BROKE APART INSIDE CONSUMER. THE DOCTOR COULD NOT PULL THEM OUT SO HE ABANDONED THE REST OF THE PROCEDURE. SINCE THAT DAY CONSUMER EXPERIENCED CHRONIC FATIGUE, CONSTANT HEADACHES, HORRIBLE CRAMPING ON AND OFF FOR NO REASON, STABBING PAIN DURING SEX, HAIR LOSS, ISSUES WITH HER SKIN, LACK OF A PERIOD FOR MONTHS AT A TIME, BLOATING AND WEIGHT GAIN. IN (B)(6) SHE WILL HAVE A SURGERY TO HAVE BOTH FALLOPIAN TUBES REMOVED. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE DEVICE USED TO INSERT THE COILS MALFUNCTIONED: PARTS OF THE COILS BROKE APART INSIDE THE CONSUMER (INTERPRETED AS DEVICE BREAKAGE). DOCTOR COULD NOT PULL THEM OUT. SHE ALSO REPORTED HORRIBLE

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CRAMPING ON AND OFF (INTERPRETED AS LOWER ABDOMINAL PAIN). SHE WAS SCHEDULED TO HAVE HER FALLOPIAN TUBES REMOVED. EVENT LOWER ABDOMINAL PAIN WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE BREAKAGE IS NON-SERIOUS AND WAS CONSIDERED LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS. AFTER ESSURE INSERTION, ABDOMINAL PAIN MAY OCCUR. GIVEN THE NATURE OF THE EVENT HORRIBLE CRAMPING ON AND OFF AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THIS CASE THE, DURING INSERTION THE DEVICE USED TO INSERT THE COILS MALFUNCTIONED AND PARTS OF THE COILS BROKE APART INSIDE CONSUMER. SINCE THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 06-JAN-2016 VIA SOCIAL MEDIA. THE CONSUMER STATED SHE HAD HER FALLOPIAN TUBES REMOVED TO GET RID OF ESSURE. ESSURE COILS WERE THE WORST DECISION OF HER LIFE. FOLLOW UP INFORMATION IDENTIFIED FROM SOCIAL MEDIA ON 07-JA

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01841	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2433, AWARENESS DATE 05-NOV-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. THE CONSUMER REPORTED THAT SHE HAD PROBLEMS SINCE ESSURE INSERTION. SHE HAD A PERIOD THAT WOULD NOT END FOR MONTHS THEN IT WOULD STOP FOR A FEW DAYS AND START UP AGAIN. THE CRAMPING AND PAIN WERE HORRIBLE. BEFORE INSERTING ESSURE SHE WAS VERY PHYSICALLY ACTIVE. SHE STATED ESSURE CHANGED HER LIFE IN A NEGATIVE WAY AS SHE DID NOT HAVE THE ENERGY TO BE PHYSICALLY ACTIVE. SHE BECAME ANEMIC AND DEPRESSED. HER HORMONES WERE ALL OVER THE PLACE. DOCTORS WANTED TO PRESCRIBE HER ANTI-DEPRESSANTS BUT SHE STARTED ACUPUNCTURE. IN 2013, SHE DID AN ULTRASOUND TO TRY TO EXPLAIN ALL THE TROUBLE AND HER DOCTOR DID NOT SEE THE CONNECTION WITH ESSURE. SHE CHANGED HER DOCTOR AND FINALLY TWO YEARS AFTER HER ULTRASOUND AND DOING ACUPUNCTURE TWICE A MONTH HER NEW DOCTOR AGREED THAT ESSURE COILS NEEDED TO BE REMOVED. SURGERY WAS SCHEDULED TO (B)(6) 2015. THE CONSUMER WAS VERY NERVOUS ABOUT THE SURGERY, FEARING ALL THE FRAGMENTS WILL NOT BE REMOVED. SHE STATED SHE COULD ONLY IMAGINE THE DAMAGE THE COILS LEFT BEHIND. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL

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ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT ESSURE COILS NEEDED TO BE REMOVED, SURGERY WAS SCHEDULED. CONSUMER WAS FEARING ALL THE FRAGMENTS WILL NOT BE REMOVED (INTERPRETED AS DEVICE BREAKAGE). THIS EVENT WAS CONSIDERED SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, IT WAS UNKNOWN WHEN THE DEVICE HAS BROKEN. HOWEVER, CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01842	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 7/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/3/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2373, AWARENESS DATE 05-NOV-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON (B)(6) 2015. THE CONSUMER STATED THAT ALMOST INSTANTLY AFTER ESSURE INSERTION SHE BEGAN TO CRAMP. SHE HAD SOME APPOINTMENTS AND KEPT BEING TOLD IT WOULD GO AWAY. SHE WAS PUT ON 800MG IBUPROFEN AND 750MG HYDROCODONE FOR THE PAIN AND SENT HOME. THE PAIN PROGRESSIVELY KEPT GETTING WORSE 12 WEEKS LATER AND ON (B)(6) 2012 SHE WENT TO THE RADIOLOGIST WHO DID A DYE TEST TO CHECK THE ESSURE PLACEMENT AND TO SEE IF THE SCAR TISSUE HAD FULLY FORMED. ON THE SAME NIGHT HER GYNECOLOGIST TOLD HER THE RADIOLOGIST FOUND A TEAR IN HER FALLOPIAN TUBE AND THEY WANTED HER TO HAVE A SURGERY IMMEDIATELY TO REMOVE THE FALLOPIAN TUBES. ON (B)(6) 2012 SHE WENT IN FOR SURGERY AND DURING THE SURGERY IT WAS FOUND OUT THAT THE ESSURE HAD PUNCTURED HER UTERUS AND THEY WERE UNABLE TO REMOVE THE COILS, AS THEY WOULD HAVE TO REMOVE HER UTERUS. CRAMPING STILL CONTINUED AND SHE WAS TOLD THAT IT WAS PROBABLY DUE TO THE HOLE IN HER FALLOPIAN TUBE AND SHE WOULD NEED TO WAIT 8-10 WEEKS BEFORE DOING ANYTHING AS SHE NEEDED TO HEAL FROM SURGERY. ON (B)(6) 2012 SHE HAD A HYSTERECTOMY AND HAD HER UTERUS AND THE COILS THAT WERE LOGGED IN HER UTERUS REMOVED. BESIDES THE PAIN FROM THE SURGERY, SHE WAS INSTANTLY CRAMP FREE. IN (B)(6) 2015 SHE FELT A PAINFUL PRESSURE, LIKE SHE WAS HAVING A BABY. SHE WENT TO HER GYNECOLOGIST AND FOUND OUT SHE HAD A RECTAL PROLAPSE. IT WAS SO SEVERE IT REQUIRED A

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SURGERY TO REPAIR IT. SHE WAS TOLD MANY WOMEN EXPERIENCE THAT AFTER HYSTERECTOMY. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HER 3-MONTH DYE TEST SHOWED A TEAR IN HER FALLOPIAN TUBE. SHE WAS SUBMITTED TO A SURGERY, DURING WHICH IT WAS DISCOVERED ESSURE HAD PUNCTURED HER UTERUS. A HYSTERECTOMY WAS PERFORMED 3 MONTHS LATER FOR ESSURE REMOVAL. AFTER 2.5 YEARS, SHE WAS DIAGNOSED AND TREATED FOR RECTAL PROLAPSE. ONLY RECTAL PROLAPSE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE AND FALLOPIAN TUBE PERFORATION ARE POSSIBLE COMPLICATIONS OF ESSURE INSERTION. IF A PERFORATION OCCURS, PATIENT MAY PRESENT PAIN DURING AND AFTER THE PROCEDURE. IN THIS CASE, CONSUMER HAD CRAMPING IMMEDIATELY AFTER ESSURE INSERTION AND A PERFORATION WAS DIAGNOSED IN HER CONFIRMATION TEST AND DURING A SURGERY, 3 MONTHS LATER. GIVEN THE CLOSE TEMPORAL ASSOCIATION BETWEEN ESSURE PROCEDURE AND THE EVENTS AND BASED ON THEIR NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REPORTED RECTAL PROLAPSE, CONSIDERING ITS PATHOPHYSIOLOGY; CAUSALITY WITH ESSURE WAS EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01843	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2365, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2012. CONSUMER HAD THE MOST PAINFULLY PERIODS EVER NOW, EVERY 21 DAYS, LOSING CLOTS AND A LOT OF BLOOD, AFTER ABLATION DONE TOO. SHE REPORTED BACK PAIN, VAGINA PAIN, KNEE AND HIP PAIN, GAINED LOTS OF WEIGHT, DEPRESSED, BRAIN FOG, BLOATING, NO SEX DRIVE. ALL SINCE HAVING IT TO MAKE HER LIFE EASIER AS HEAVY PERIODS AND DID NOT WANT HUSBAND TO HAVE VASECTOMY AS SHE HAD BEEN DIAGNOSED WITH SAGE MELANOMA (AS REPORTED). QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS LOSING CLOTS AND A LOT OF BLOOD (DURING MENSTRUAL PERIODS) (INTERPRETED AS MENORRHAGIA) AND WAS DIAGNOSED WITH MELANOMA. SHE UNDERWENT AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION). THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. MENORRHAGIA IS A LISTED EVENT IN THE REFERENCE

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SAFETY INFORMATION FOR ESSURE, MELANOMA IS UNLISTED. IN THE PRESENT CASE, LIMITED INFORMATION WAS PROVIDED. THE EXACT TEMPORAL RELATIONSHIP BETWEEN ESSURE INSERTION AND THE EVENTS WAS NOT REPORTED. CONSUMER MENTIONED SHE WAS LOSING CLOTS AND A LOT OF BLOOD DURING PERIODS AND HAD AN ABLATION DONE. GIVEN THE NATURE OF THIS EVENT, A CONTRIBUTORY ROLE OF ESSURE CANNOT BE EXCLUDED. EVENT MELANOMA WAS ASSESSED AS UNRELATED TO ESSURE, GIVEN ITS PATHOPHYSIOLOGY AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01844	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-0829 AND FDA-2014-N-0736-2360, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER HAD ESSURE PLACED IN 2008 AFTER HER 4TH CHILD WAS BORN. SHE WAS (B)(6) AND NOT INFORMED OF THE LONG TERM SIDE EFFECTS. SHE BEGAN HAVING PROBLEMS IN 2009. THIS IS A LIST OF HER SYMPTOMS : BLOATING, STABBING ABDOMINAL PAIN, SENSITIVITY TO CERTAIN FOODS, SEVERE MIGRAINES, PAINFUL INTERCOURSE, BACK PAIN, INCONTINENCE, DEPRESSION, LOW VITAMIN D, SWELLING OF LEFT BODY PARTS ESPECIALLY LEFT FOOT RUNNING FROM HIP AREA DOWN HER LEFT FEMALE PARTS, SEVERE FATIGUE, WEIGHT GAIN SEVERE, SORE BREASTS, PAINFUL PERIODS, FOGGY MIND, LIGHTHEADEDNESS, UNABLE TO LOSE WEIGHT EVEN WITH HEALTHY NUTRITION, JAW PAIN, TEETH PROBLEMS, METAL TASTE IN MOUTH AT TIMES, SEVERE ALLERGIC REACTION WITH HIVES ALL OVER CHEST AND BACK OUT OF NOWHERE, MORE DURING VERY HOT DAYS OR VERY COLD DAYS WHEN SHE SWEAT, HIPS PAINS, SEVERE, STABBING BACK PAIN, HAIR LOSS, SEVERE DRY SCALP WITH PAINFUL CHUNKS OF SCALP COMING OFF ON HOT WEATHER. POOR NAIL GROWTH. ALL OVER BODY ODOR WAS NOT THERE BEFORE. ADD THE FACT THAT SINCE 3 MONTHS AGO ((B)(6) 2015) SHE HAS HAD SUCH DEBILITATING PAIN SHE COULD NOT GO ANYWHERE OR EVEN WALK DOWN THE STAIRS MOST DAYS. JOINT PAINS WERE KILLER. SHE WAS ONLY (B)(6) YEARS OLD. SHE WAS ALWAYS IN BED IN PAIN. SHE WAS SCHEDULED TO HAVE A HYSTERECTOMY IN A COUPLE OF WEEKS. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE

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MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THREE MONTHS PREVIOUS TO THIS REPORT HAD SUCH DEBILITATING PAIN THAT SHE CANNOT GO ANYWHERE OR EVEN WALK DOWN THE STAIRS. SHE WAS SCHEDULED TO HAVE A HYSTERECTOMY IN A COUPLE OF WEEKS. THIS EVENT, SEEN AS PELVIC PAIN IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE INFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01845	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 9/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2012
Explant Date (E7): 1/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2346, AWARENESS DATE 05-NOV-2015) WHICH REFERS TO REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. THE CONSUMER REPORTED SHE WAS ASLEEP WHEN THE DEVICES WERE PUT IN. SHE WOKE UP IN A SLIGHT AMOUNT OF PAIN AND WENT HOME SHORTLY AFTER. SHE REPORTED HER FIRST CYCLE AFTER WAS EXTREMELY HEAVY, AND SHE ENDED UP PASSING OUT IN HER WALK-IN CLOSET FROM THE BLOOD LOSS; HER CYCLES CONTINUED TO BE EXTREMELY HEAVY, BUT SHE WAS WORKING FULL-TIME AS WELL AS GOING TO SCHOOL FULL-TIME, THEREFORE, SHE DID NOT HAVE THE TIME TO GO TO THE DOCTOR, AND WAS JUST HOPING IT WAS PHASE THAT WOULD PASS. FAST FORWARD ABOUT A YEAR AND HALF LATER, SHE GAINED 20 POUNDS, THERE WAS NO CHANGE TO HER DIET, AND SHE WAS MORE ACTIVE THAN SHE HAD BEEN, SO ACTIVITY LEVEL WAS NOT TO BLAME. FIFTY PERCENT OF HER HAIR HAD FALLEN OUT; SHE COULD NOT GET OUT OF BED IN THE MORNING WITHOUT ALMOST FALLING BECAUSE HER FEET HURT SO BADLY, SHE LITERALLY LIMPED AROUND THE FIRST TWO HOURS IN THE MORNING. HER JOINTS ACHED AND SHE FELT A CONSTANT FOG IN HER HEAD TO THE POINT WHERE HER WORD BANK WAS EMPTY, SHE WOULD BE IN THE MIDDLE OF CONVERSATION, AND HER HEAD WOULD GO BLANK. IN (B)(6) 2014, SHE WOKE UP AND HER BODY WAS SO SWOLLEN SHE COULD HARDLY MOVE. HER CYCLE WENT FROM EXTREMELY HEAVY TO BASICALLY NON-EXISTENT, SHE CRAMPED LIKE SHE WAS IN LABOR, BUT HER BODY WAS NOT ABLE TO EXPEL THE BLOOD. SHE HAD TO SIT ON THE TOILET AND PUSH IT OUT, SHE STATED IT CAME OUT LIKE THICK BLACK STRINGS OF WHAT LOOKED LIKE OLD MOTOR OIL. SHE WAS IN EXCRUCIATING PAIN AND HER STOMACH HURT SO BADLY, SHE

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COULD NOT EVEN STAND TO WEAR ANY KIND OF CLOTHING. HER FEET WERE SO SWOLLEN SHE COULD NOT GET THEM INTO ANY PAIR OF SHOES. SHE WENT TO THE DOCTOR WHO IMPLANTED THE DEVICES AND HE TOLD SHE WAS GOING THROUGH MENOPAUSE, AT THE AGE OF (B)(6), AND THAT WAS NORMAL, HE STATED THAT IT WAS IMPOSSIBLE THAT ESSURE WAS THE ISSUE. AT TIME OF THE INSERTION, THE CONSUMER TOLD HER DOCTOR SHE HAD ALLERGIES TO METALS AND HE ASSURED HER THERE WAS NO METAL IN THE DEVICES; WHEN SHE CONFRONTED HIM ABOUT THE NICKEL CONTENT OF THE COILS HE QUICKLY WROTE HER A REFERRAL TO SEE A GYNECOLOGICAL SPECIALIST WHO WOULD REMOVE THEM FOR HER. ON (B)(6) 2015, SHE HAD A HYSTERECTOMY DONE AND EVERYTHING WAS REMOVED BUT OVARIES. THE SURGICAL REPORT SHOWED THAT HER UTERUS WAS FUSED TO HER BLADDER AND HER CERVIX. THE PATHOLOGY REPORTS STATED HER UTERUS WAS SWOLLEN TO THE SIZE OF A WOMAN WHO IS THREE MONTHS PREGNANT, AND HER TUBES ALONG WITH HER CERVIX WERE ALSO EXTREMELY SWOLLEN. HER WERE COILS PROPERTY PLACED, BUT SHE STILL EXPERIENCED CRIPPLING COMPLICATIONS FROM THE DEVICE. NINE MONTHS LATER ALL OF HER SYMPTOMS HAD ESSENTIALLY DISSIPATED, THE ONLY THING THAT SEEMED TO BE LEFT WITH IS SENSITIVITY TO GLUTEN. BEFORE HER SURGERY SHE FELT LIKE A 90-YEAR-OLD WOMAN, AND NOW SHE WAS FEELING YOUNG AGAIN. SHE LOST ALL THE EXTRA WEIGHT, AND ALL HER HAIR WAS BEGINNING TO GROW BACK, HER BRAIN FOG WAS GONE, AND SHE NO LONGER SEARCH FOR WORDS WHEN HAVING CONVERSATIONS, HER FEET DO NOT HURT ANYMORE AND SHE CAN WEAR WHATEVER CLOTHING SHE WANT, AND IT DOES NOT HURT HER ABDOMEN. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND ASSESSMENT WERE RECEIVED: QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND CRAMPED LIKE SHE WAS IN LABOR, BUT HER BODY WAS NOT ABLE TO EXPEL THE BLOOD. SHE HAD TO SIT ON THE TOILET AND PUSH IT OUT, SHE STATED IT CAME OUT LIKE THICK BLACK STRINGS OF WHAT LOOKED LIKE OLD MOTOR OIL (INTERPRETED AS GENITAL BLEEDING). SHE HAD A HYSTERECTOMY DONE AND EVERYTHING WAS REMOVED BUT OVARIES. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON THEIR NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. ADDITIONALLY, OTHER SERIOUS EVENTS (UNLISTED AND UNRELATED) AND NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01846	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 1/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 1/1/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASEFDA-2014-N-0736-2340, AWARENESS DATE 05-NOV-2015). IT REFERS TO A (B)(6) FEMALE PATIENT IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. AS PREVIOUS HISTORY, SHE HAD 3 KIDS. CONSUMER REPORTED SHE HAD EXTREME PELVIC PAIN WHEN ESSURE WAS INSERTED IN 2007. IN 2010 SHE HAD TWO SURGERIES TO HAVE IT REMOVED WITH TUBES. SHE FELT BETTER. ABOUT A YEAR LATER, SHE HAD EXTREME PELVIC PAIN AGAIN. IT GOT SO BAD THAT SHE WAS ADMITTED TO THE HOSPITAL FOR 11 DAYS BEFORE THEY FIGURED OUT WHAT WAS CAUSING HER THIS PAIN. SHE HAD A FRAGMENT LEFT IN HER AND IT HAD PUNCTURED THROUGH THE UTERUS AND SNAGGED HER COLON. SHE HAD A HYSTERECTOMY AND A PIECE OF THE COLON WAS REMOVED BECAUSE OF THIS. SHE WAS ONLY (B)(6) AT THAT TIME. SHE NOW SUFFERS FROM AUTOIMMUNE ISSUES AND JOINT PAIN WITH SWELLING. THE BEST WAY TO DESCRIBE HER DAILY PAIN IS LIKE SHE HAS THE FLU CONSTANTLY. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD EXTREME PELVIC PAIN. THREE YEARS AFTER ESSURE

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INSERTION SHE HAD SURGERY TO HAVE IT REMOVED WITH HER TUBES. A YEAR LATER IT WAS FOUND THAT A FRAGMENT WAS LEFT IN HER (INTERPRETED AS DEVICE BREAKAGE) AND ESSURE HAD PUNCTURED THROUGH HER UTERUS AND SNAGGED HER COLON (INTERPRETED AS UTERINE PERFORATION AND TRAUMATIC INTESTINAL PERFORATION). SHE UNDERWENT A HYSTERECTOMY AND A PIECE OF HER COLON WAS REMOVED. THESE EVENTS ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT FOR DEVICE BREAKAGE, CONSIDERED LISTED ACCORDING TO PRODUCT TECHNICAL ANALYSIS. EXTREME PELVIC PAIN WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE, THE OTHER EVENTS DUE TO HOSPITALIZATION. IN THIS CASE IT IS UNKNOWN WHETHER THE PERFORATION HAD ALREADY OCCURRED WHEN THE CONSUMER STARTED HAVING THE FIRST EPISODE OF PELVIC PAIN. HOWEVER, GIVEN THE NATURE OF THE EVENT EXTREME PELVIC PAIN, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THE EXACT DATE AND MECHANISM OF THE DEVICE BREAKAGE WERE NOT REPORTED, HOWEVER GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. INTERNAL ORGANS PERFORATION MAY OCCUR WITH ESSURE, DUE TO DEVICE MIGRATION OR DURING INSERTION PROCEDURE. IN THIS CASE, UTERINE AND BOWEL PERFORATION WERE DIAGNOSED 4 YEARS AFTER ESSURE INSERTION. THE EXACT DATE AND THE MECHANISM OF PERFORATION ARE NOT KNOWN. A CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE EVENTS CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE HOSPITALIZATION AND SURGICAL INTERVENTIONS WERE REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01847	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2011
Explant Date (E7): 10/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2489, AWARENESS DATE 05-NOV-2015). IT REFERS TO A (B)(6) YEAR-OLD FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE INSERTED IN (B)(6) 2011, FOR PERMANENT BIRTH CONTROL. SHE WAS WORKING AS A LONG TERM CARE NURSE. IMMEDIATELY AFTERWARDS, SHE ENDED UP LEAVING HER JOB, HER CAREER, BECAUSE SHE WAS TOO TIRED AND WEAK TO EVER RETURN. INTERCOURSE WITH HER HUSBAND BECAME VERY PAINFUL, WHICH IN TURN MADE INTIMACY WITH HER HUSBAND VERY DIFFICULT. HER MENSTRUAL CYCLE CHANGED FROM HAVING A PERIOD EVERY 33 DAYS FOR 5 DAYS TO HAVING A PERIOD EVERY 25-28 DAYS FOR 7-10 DAYS. NOT ONLY THAT, BUT HER PERIODS, INCLUDING OVULATION, BECAME UNBEARABLE. THE 2ND AND 3RD DAYS OF HER CYCLE WERE SO HEAVY, SHE HAD TO WEAR A SUPER PLUS TAMPON AND AN OVERNIGHT MAXI PAD THAT HAD TO BE CHANGED ALMOST EVERY HOUR. SHE COULDN'T GO ANYWHERE ON THOSE DAYS. NOT ONLY DID IT EFFECT HER PERIODS; HER SKIN CHANGED, MORE ACNE, HIVES, AND RASHES. SHE LOST 6 TEETH SINCE HAVING ESSURE IMPLANTED. HER BOTTOM LIP SWELLS AT LEAST ONCE A MONTH, HAD CHRONIC HEADACHES, MIGRAINES EVEN. HER VISION HAS DECLINED, GAINED 50 POUNDS, SHE HAS BEEN ANEMIC FOR YEARS DUE TO HEAVY MENSTRUAL CYCLES. FOUND HER VITAMIN D LEVELS WERE DANGEROUSLY LOW, A FEW MONTHS AGO. NOW SHE WAS DIAGNOSED WITH TYPE 2 DIABETES WHICH WAS A SYMPTOM OF VITAMIN D DEFICIENCY. SHE ALSO HAD CHEST PAINS AND HEART PALPITATIONS. HER MEMORY HAS GONE WITH THE WIND. SHE HAS TO WRITE THINGS DOWN OR IT WON'T GET DONE. ON (B)(6) 2015 SHE UNDERWENT A TOTAL HYSTERECTOMY AND SALPINGECTOMY. AT THE TIME OF THIS REPORT, SHE WAS ONLY 3 WEEKS POST OP AND WAS FEELING BETTER. SHE WAS

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WAITING ON HER BODY TO RECOVER. ESSURE, TOOK HER LIFE, HER YOUTH, HER FAMILY. IT TOOK HER HAIR AND SKIN AND BODY FROM HER. THERE WERE DAYS, SHE COULD BARELY MAKE IT OUT OF BED AND DRESS HERSELF, AND ON THE DAYS SHE COULD, SHE HAD TO SIT ON THE COUCH AND WATCH HER 4 CHILDREN PLAY AND GROW UP RIGHT IN FRONT OF HER EYES. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE 2ND AND 3RD DAYS OF HER CYCLE WERE SO HEAVY, AND SHE HAD PERIOD FOR 7-10 DAYS (INTERPRETED AS MENORRHAGIA). SHE WAS ALSO DIAGNOSED WITH TYPE 2 DIABETES. A TOTAL HYSTERECTOMY AND SALPINGECTOMY WERE PERFORMED 4 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. MENORRHAGIA IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENT IS UNLISTED. AFTER ESSURE INSERTION MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP AND NATURE OF THE EVENT 2ND AND 3RD DAYS OF HER CYCLE WERE SO HEAVY/ PERIOD FOR 7-10 DAYS, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. EVENT TYPE 2 DIABETES WAS ASSESSED AS UNRELATED TO ESSURE, GIVEN ITS PATHOPHYSIOLOGY AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01848	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 10/22/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2498, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER HAS HAD NONSTOP PROBLEMS. IRREGULAR HEAVY BLEEDING, PAIN, HAIR LOSS, INFECTIONS, RASHES, JOINT SWELLING, ABDOMINAL SWELLING AND PAIN, MIGRAINES, PAIN DURING AND AFTER INTERCOURSE, VISION BLACKOUTS AND CONSTANT DIZZINESS, CERVICAL STABBING PAINS, AND MUCH MORE. SHE HAD TO HAVE SURGERY REMOVING UTERUS, TUBES, CERVIX, AND ESSURE WHICH MIGRATED TO THE OTHER END OF HER TUBES. SURGERY WAS ONE YEAR PRIOR TO THE REPORT, ON (B)(6) 2014. EVERY ONE OF HER ABOVE SYMPTOMS WERE GONE. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD IRREGULAR HEAVY BLEEDING (INTERPRETED AS GENITAL BLEEDING) AND ESSURE MIGRATED TO THE OTHER END OF HER TUBES. ESSURE WAS REMOVED APPROXIMATELY 6 YEARS AFTER INSERTION. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE

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SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE EVENT IRREGULAR HEAVY BLEEDING AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THE PRESENT CASE, ESSURE MIGRATED TO THE OTHER END OF HER TUBES. THE EXACT DATE OF THE MIGRATION WAS NOT REPORTED, HOWEVER GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01849	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2519, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008. CONSUMER REPORTED THAT IN 2011 SHE STARTED HAVING PARTIAL COMPLEX SEIZURES. SHE ALSO EXPERIENCED DAILY STABBING PAINS IN HER PELVIC REGION, FATIGUE, ANXIETY AND BLOOD TESTS SHOWED VERY HIGH INFLAMMATION LEVELS IN HER BODY WHICH HAS CAUSED JOINT PAIN. SHE WILL BE GETTING A HYSTERECTOMY IN (B)(6) 2015 TO HELP ALLEVIATE THE CHRONIC PAIN. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD DAILY STABBING PAINS IN HER PELVIC REGION/ CHRONIC PAIN (INTERPRETED AS PELVIC PAIN) AND PARTIAL COMPLEX SEIZURES. SHE WAS SCHEDULED FOR A HYSTERECTOMY, APPROXIMATELY 7 YEARS AFTER ESSURE INSERTION. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENT IS UNLISTED. AFTER ESSURE

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INSERTION PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE EVENT DAILY STABBING PAINS IN HER PELVIC REGION/ CHRONIC PAIN AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. EVENT PARTIAL COMPLEX SEIZURES WAS ASSESSED AS UNRELATED TO ESSURE, GIVEN ITS PATHOPHYSIOLOGY AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01850	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/7/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2516, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2011. THE CONSUMER REPORTED SHE WAS NOT ABLE TO HAVE COMFORTABLE INTERCOURSE WITH HER HUSBAND, AND SHE HAD BLEEDING ALL THE TIME. SHE STATED THAT ESSURE HAD TAKEN HER HAIR AND LASHES AND FOR HER IT WAS HARD TO LEAVE THE HOUSE. SHE HAD GAINED WEIGHT, HAD INFLAMMATION IN HER MIDSECTION AND HAD PUFFINESS IN BELLY. SHE HAD CHRONIC PELVIC PAIN AND CONSTANT PAIN ON HER RIGHT SIDE. SHE DID AN ULTRASOUND AND FOUND A FIBROID ON LEFT OVARY AND A LOT OF EXTRA FLUID IN UTERUS. SHE WILL HAVE A TOTAL HYSTERECTOMY ON (B)(6) 2015 TO REMOVE HER UTERUS, CERVIX AND FALLOPIAN TUBES. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED CHRONIC PELVIC PAIN AND CONSTANT PAIN ON HER RIGHT SIDE. SHE ALSO HAD BLEEDING ALL THE TIME AND WILL HAVE A TOTAL HYSTERECTOMY. THESE EVENTS, SEEN AS PELVIC PAIN AND GENITAL BLEEDING, ARE SERIOUS DUE TO MEDICAL

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IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE TEMPORAL RELATIONSHIP AND THE FACT THAT PELVIC PAIN AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE, CAUSALITY BETWEEN BOTH EVENTS AND SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE INFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01851	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA.2014-N_0736-2335, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2010. CONSUMER REPORTED THAT IN THE PAST 5 YEARS SHE HAS HAD PELVIC PAIN, PAINFUL INTERCOURSE AND HORMONAL ISSUES. THE PAIN GOT SO BAD, IT WAS ALMOST LIKE LABOR PAINS. SHE ASKED HER PHYSICIAN SPECIFICALLY IF ESSURE COULD BE CAUSING ALL OF HER ISSUES. SHE SAID HIGHLY UNLIKELY. SHE DID ADMIT IT IS POSSIBLE BECAUSE OF THE INFLAMMATION THE OVULATION PAIN COULD BE WORSE, HOWEVER, SHE IS JUST GETTING OLDER. CONSUMER HAS BEEN DEPRESSED, HAS HAD MAJOR ANXIETY, AND HER HORMONE LEVELS ARE OFF. SHE FINALLY HAVE SCHEDULED A HYSTERECTOMY IN HOPES THIS WILL RELIEVE A LOT OF HER ISSUES. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FOR THE PAST 5 YEARS PRESENTED PELVIC PAIN ALMOST LIKE LABOR PAINS. SHE HAD A HYSTERECTOMY SCHEDULED AT THE MOMENT OF REPORT. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE

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SAFETY INFORMATION FOR ESSURE. CONSIDERING THE TEMPORAL RELATIONSHIP AND THE FACT THAT PELVIC PAIN MAY OCCUR DURING ESSURE USE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01852	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2009
Explant Date (E7): 1/1/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2526, AWARENESS DATE 05-NOV-2015). IT REFERS TO A (B)(6) FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2009. AFTER ABOUT 3 YEARS THE CONSUMER BEGAN TO SUFFER FROM UNEXPLAINED BLOATING, SEVERE RASHES, ACNE, 50LBS WEIGHT GAIN WITHIN A 6 MONTH PERIOD, VERY HEAVY PERIODS, BLEEDING UP TO 10 DAYS PER CYCLE, OVARIAN CYSTS, HEADACHES, JOINT ACHES, ABDOMINAL PAINS, DEPRESSION, ANXIETY AND IBS (IRRITABLE BOWEL SYNDROME). IN 2014, SHE UNDERWENT A TOTAL HYSTERECTOMY. SHE STATED THAT AT THE TIME OF REPORTING, ABOUT 95 PERCENT OF HER SYMPTOMS HAD CLEARED UP BUT SHE WAS STILL SUFFERING FROM JOINT PAIN AND ADRENAL FATIGUE AS A RESULT OF HER BODY FIGHTING SO LONG AND HARD AGAINST THE INFLAMMATION FROM THE ESSURE DEVICE. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER 3 YEARS STARTED EXPERIENCING ABDOMINAL PAINS. SHE UNDERWENT A TOTAL HYSTERECTOMY 5 YEARS AFTER ESSURE INSERTION, AND THE PAIN CLEARED

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UP. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABDOMINAL PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT, THE LACK OF AN ALTERNATIVE EXPLANATION, AND SINCE THE PAIN RESOLVED AFTER HYSTERECTOMY, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01853	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2295, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2005. CONSUMER WANTED TO HAVE ESSURE REMOVED. SHE HAD ESSURE PLACED AFTER HAVING HER 5TH CHILD. SINCE THEN SHE HAS HAD JOINT PAIN, HORRIBLE MOOD SWINGS, CRAMPING, FATIGUED ALL THE TIME. NO SEX DRIVE, PAINFUL SEX. SHE AT THE MOMENT OF REPORT HAD TO HAVE SURGERY ON HER RIGHT KIDNEY DUE TO COIL INTERFERING WITH THE URETER. THERE WERE MANY MORE SIDE EFFECTS FROM THE DEVICE THAT SHE COULD LIST. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE A SURGERY ON HER RIGHT KIDNEY DUE TO COIL INTERFERING WITH THE URETER. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES TOWARDS TO PERITONEAL CAVITY. ALTHOUGH THE EXACT DATE OF THIS DISLOCATION AND

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THE CIRCUMSTANCES OF THIS INTERFERENCE IN URETER ARE UNKNOWN, GIVEN THE EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE A REQUIRED INTERVENTION WILL BE PERFORMED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01854	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/11/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5057180) IN UNITED STATES ON 05-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. THE CONSUMER REPORTED WHEN SHE HAD THE PROCEDURE, SHE HAD EXTREME PAIN WHEN HER DOCTOR WAS INSERTING THE COILS, ESPECIALLY ON ONE SITE AND, THIS WAS AFTER HAVING A LOCAL ANESTHETIC INJECTION IN HER BUTT. THE THREE SHOTS INJECTED INTO HER CERVIX AND UTERUS REALLY HURT AS WELL. AFTER THE PROCEDURE, SHE DROVE HERSELF HOME; SHE WAS IN A LOT OF PAIN, HER PAIN WAS SO BAD THAT SHE WENT BACK TO SEE HER DOCTOR. HE DID A PELVIC EXAM AND TOLD NOTHING WAS WRONG THAT HE COULD SEE AND HE DID NOT INVESTIGATE ANY FURTHER. SHE JUST ASSUMED SHE WAS HAVING AN UNUSUAL AMOUNT OF PAIN AND STUCK IT OUT. THREE MONTHS LATER; SHE HAD THE FOLLOW-UP HSG (HYSTEROSALPINGOGRAM) APPOINTMENT AT THE HOSPITAL; HER DOCTOR CALLED ONCE HE RECEIVED THE RESULTS TO INFORM HER THAT THE ESSURE PROCEDURE DID NOT WORK, SHE RECEIVED THE PAPERWORK FROM THE HOSPITAL IN WHICH IT STATED ONE COIL HAD PERFORATED THE RIGHT FALLOPIAN TUBE. SHE FOUND A NEW DOCTOR AND MADE AN APPOINTMENT, SHE TOLD THE NEW DOCTOR WHAT HAD HAPPENED AND SHOWED HIM HER PAPERWORK. HE SCHEDULED SURGERY FOR TO HAVE THE RIGHT COIL REMOVED, IF POSSIBLE, AND GET A TUBAL LIGATION. SHE HAD A TUBAL LIGATION AND THE ESSURE COIL IN RIGHT FALLOPIAN TUBE WAS PULLED OUT. AFTER SURGERY, WHICH WAS PERFORMED IN 2011, HER NEW DOCTOR INFORMED THAT THE COIL HAD PERFORATED HER UTERUS AND HER RIGHT FALLOPIAN TUBE. SHE REPORTED HAVING EXTRA PAIN FROM THE TUBAL LIGATION AND SURGERY BECAUSE OF THE COIL THAT HAD TO BE REMOVED FROM UTERUS AND FALLOPIAN TUBE. SHE HAS A PRETTY THICK SCAR ON HER LOWER ABDOMEN UNDERNEATH BECAUSE OF THE CAMERA THAT HAD TO BE INSERTED THERE. THE WHOLE

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YEAR OF 2011, SHE BEGAN TO HAVE EXTREMELY HEAVY PERIODS, SHE WAS BLEEDING THROUGH A TAMPON AND PAD AND ALSO, HER PERIODS WERE TEN DAYS OR LONGER EVERY TIME. SHE SPOKE WITH HER NEW DOCTOR AND HE INFORMED THAT SHE COULD HAVE UTERINE ABLATION PERFORMED; SHE HAD THE THERMA-CHOICE UTERINE ABLATION PROCEDURE IN 2012. AFTER HAVING THIS PROCEDURE, HER PERIODS WENT BACK TO NORMAL AND SHE DID NOT REALLY HAD ANY MORE PROBLEMS UNTIL RECENTLY, SHE DID CHECK INTO IF ANY OTHER WOMEN WERE HAVING PROBLEMS WITH ESSURE. SHE STATED THAT IT HAS BEEN OVER FIVE YEARS SINCE SHE HAD THE ESSURE PROCEDURE AND SHE STARTED HAVING LIGHT VAGINAL BLEEDING (SHE CONSIDERED IT BROWN DISCHARGE), PAIN DURING AND AFTER SEX, FREQUENT URINATION, AND PAIN IN HER LOWER ABDOMEN THAT CAN BE SEVERE AT TIMES. SHE HAD BEEN TO THE HOSPITAL AND HER GYNECOLOGIST DOCTOR (THE SAME ONE WHICH REMOVED THE COIL AND PERFORMED HER TUBAL LIGATION AND UTERINE ABLATION). SHE AS GOING BACK TO THE DOCTOR TO HAVE HIM CHECKED THE OTHER COIL TO MAKE SURE IT IS IN PLACE STILL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 25-NOV-2015: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ONE COIL PERFORATED HER UTERUS AND HER RIGHT FALLOPIAN TUBE. THIS COIL WAS SURGICALLY REMOVED. AFTER THIS PROCEDURE, SHE EXPERIENCED EXTREMELY HEAVY PERIODS (PERIODS WERE TEN DAYS OR LONGER EVERY TIME), WHICH WERE SUCCESSFULLY TREATED WITH AN ENDOMETRIAL ABLATION. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UTERINE OR FALLOPIAN TUBE PERFORATION IS A POSSIBLE COMPLICATION OF ESSURE INSERTION. IF A PERFORATION OCCURS, PATIENT MAY EXPERIENCE PAIN DURING/AFTER THE PROCEDURE. IN THIS PARTICULAR CASE, CONSUMER REPORTED EXTREME PAIN DURING ESSURE INSERTION AND HER 3 MONTH CONFIRMATION TEST REVEALED A FALLOPIAN TUBE PERFORATION. SHE WAS SUBMITTED TO A SURGERY TO REMOVE THE COILS, AND BOTH UTERINE AND FALLOPIAN TUBE PERFORATION WERE FOUND. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP BETWEEN EVENTS AND ESSURE INSERTION AND BASED ON THEIR NATURE; CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. REGARDING CONSUMER'S BLEEDING; IT WAS CONSIDERED AS RELATED TO ESSURE; BASED ON THE DEVICE SAFETY PROFILE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01855	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 6/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/11/2013
Explant Date (E7): 7/18/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2362, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER REPORTED THAT 24 HOURS AFTER INSERTION SHE STARTED TO EXPERIENCE ABDOMINAL PAIN, HEADACHES AND JOINT PAIN. A WEEK AFTER SHE STARTED TO BLOAT WHICH WAS CALLED E-BELLY. ALSO, SHE BLED THE ENTIRE TIME AFTER INSERTION. ON (B)(6) 2013 SHE HAD HER TUBES REMOVED, BUT SHE STILL SUFFERED FROM PROBLEMS FROM ESSURE. SHE EXPERIENCED EXTREME ABDOMINAL PAIN, BLOATING AND BACK PAIN DURING MENSTRUAL CYCLE AND OVULATION. SHE STATED HER UTERUS SHOULD HAVE BEEN REMOVED INTACT WITH HER TUBES. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ABDOMINAL PAIN AND

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BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. HER FALLOPIAN TUBES WERE REMOVED. THESE EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL PAIN AND ABNORMAL GENITAL BLEEDING/MENSES PATTERN CHANGES MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER DEVELOPED PAIN 24 HOURS AFTER ESSURE PLACEMENT AND ALSO HAD BLEEDING (REGARDED AS GENITAL BLEEDING) SINCE THE PROCEDURE. APPROXIMATELY ONE YEAR AFTER DEVICE PLACEMENT, SHE UNDERWENT A SALPINGECTOMY. HOWEVER, THE PAIN PERSISTED. SHE STATED HER UTERUS SHOULD HAVE BEEN REMOVED WITH THE TUBES. ALTHOUGH, IN THIS CASE CONSUMER'S PAIN PERSISTED AFTER SALPINGECTOMY (SUGGESTING A NEGATIVE DECHALLENGE), SINCE NO DETAILS WERE PROVIDED ABOUT THIS SURGICAL PROCEDURE (IF ESSURE IS PROPERLY PLACED AND REMOVAL IS BEING PERFORMED, A SALPINGECTOMY WITH CORNUAL RESECTION OF THE PROXIMAL FALLOPIAN TUBE IS USUALLY REQUIRED); CAUSALITY WITH THE SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. AS A SALPINGECTOMY WAS REQUIRED; THIS CASE WAS CONSIDERED AN INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED (CASE IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01856	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2010
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2377, AWARENESS DATE 05-NOV-2015) WHICH REFERS TO REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. THE CONSUMER REPORTED OVER THE MONTHS, AFTER THE INSERTION, THERE WERE MANY UNEXPLAINED ISSUES WITH HER HEALTH AND DAILY FUNCTIONING. AT HER DYE TEST, THERE WAS A PROBLEM, IT WAS DONE AT LOCAL HOSPITAL IN RADIOLOGY, AND HER OB/GYN ADMINISTERED THE TEST; HE TOLD HER SHE HAD POSSIBILITY OF HAVING DOUBLE ORGANS, HE SAID SHE EITHER HAD A HOLE IN UTERUS OR A THIRD FALLOPIAN TUBE. SHE DID HAVE DOUBLE ORGANS, SHE HAD THREE FALLOPIAN TUBES AND NEEDED A THIRD COIL. FOR THE THIRD COIL PROCEDURE SHE WAS AGAIN SEDATED WITH XANAX. SHE HAD NOT STOPPED BLEEDING AND HAD SOME SORT OF VAGINAL INFECTION. SHE REPORTED SHE EXPERIENCED HEADACHES, JOINT PAIN, LOSS OF MUSCLE, WEIGHT GAIN, HAIR LOSS, PEELING FINGER NAILS, INSOMNIA, BLURRY VISION, RINGING EARS, MENTAL FOG, SWOLLEN ABDOMEN (LOOKED SIX MONTHS PREGNANT ALL THE TIME), NO SEX DRIVE, AND METALLIC TASTE IN MOUTH ALL THE TIME, PHYSICAL KNOTS FROM THE BASE OF HER SPINE TO THE BASE OF HER SKULL AND CONSTANT PAIN. BRUISING AND INFLAMMATION INDICATIVE OF SEVERE INJURY/BEATINGS AND SENSITIVITY TO ANYTHING HER SKIN CAME IN CONTACT WITH; SHE ALSO HAD PAIN AND DEPRESSION. IN THE FALL OF 2012, SHE WENT TO SEE HER INTERNIST; SHE WAS HAVING HIM CHECK AN INJURY TO HER ANKLE AND THE HORRID BLOOD FILLED HEMATOMA THAT WAS CAUSING INTOLERABLE PAIN. SHE DID NOT FIT THE MARKERS FOR ANY AUTOIMMUNE DISEASE, SHE STATED NOTHING WAS RIGHT ABOUT THAT KIND OF DIAGNOSIS; SHE WAS NOT A DRINKER, SMOKER OR DRUG USER. HE SAID TO THE

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CONSUMER WENT BACK TO HER GYNECOLOGIST AND ASK FOR THE DEVICE REMOVAL. SHE REPORTED HER GYNECOLOGIST HAD ALSO REMOVED ESSURE VIA HYSTERECTOMY IN OTHER IMPLANTED PATIENTS AND WAS AGREEABLE THAT THEY NEEDED TO COME OUT. SHE OPTED FOR LAPAROSCOPIC. SHE REPORTED HER SURGERY LASTED 4 HOURS; SHE COULD NOT KEEP HER ON FULL OF GAS BECAUSE HER CERVIX HAD BEEN DAMAGED DURING ESSURE IMPLANTATION, THEY HAD TO STITCH IT SHUT. DURING THE SURGERY, A MASS WAS FOUND, THE PHYSICIAN WAS UNSURE IF IN HER UTERUS, BEHIND IT OR ATTACHED TO UTERUS AND FLANK (SHE MENTIONED HER BACK HURT CONSTANTLY BECAUSE OF IT), IT WAS SO LARGE THAT THEY HAD TO REMOVE CERVICAL STITCHES DILATE ME AND DELIVER IT VAGINALLY. SHE NEEDED A CAUTERIZATION TO STOP THE BLEEDING IN HER FLANK AREA. ESSURE AND THE AFTERMATH TOOK ALMOST A YEAR. SHE REPORTED STILL HAVING POST OP VISITS IN COLLECTION BECAUSE THEY WERE OUTSIDE THE SCOPE OF NORMAL HEALING/POST OP APPOINTMENTS. HER CERVIX WAS DAMAGED DURING STITCHES AND SURGERY AND REQUIRED CAUTERIZATION, PACKING NUMEROUS TIMES AT ER WHICH NEVER STAYED IN MORE THAN A FEW HOURS BECAUSE SHE LOST SO MUCH BLOOD AND WAS DELIVERING/PASSING ALL OF THAT TOO. SHE REPORTED SHE HAD INFECTIONS AND HORMONES OUT OF WHACK DUE TO IMMEDIATE MENOPAUSE FROM THE HYSTERECTOMY. HER WEIGHT THAT HAS NEVER GONE AWAY, STICKS AROUND DUE TO MENOPAUSE AND HORMONE CHANGES. AT TIME OF THE REPORT SHE WAS ALMOST 3 YEARS POST OP AND STILL HAD SOME SYMPTOMS, IT TOOK OVER A YEAR FOR HER BODY TO DETOX. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND ASSESSMENT WERE RECEIVED: QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. UPDATED PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015 WITHOUT MAJOR CHANGES. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND NEVER STOPPED BLEEDING. SHE HAD A HYSTERECTOMY PERFORMED AND DURING THE SURGERY, SHE NEEDED A CAUTERIZATION TO STOP THE BLEEDING IN HER FLANK AREA. THESE EVENTS, INTERPRETED AS GENITAL HAEMORRHAGE AND POST PROCEDURAL HAEMORRHAGE, ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. GENITAL BLEEDING MAY OCCUR AFTER ESSURE INSERTION. IN THIS CASE, CONSIDERING THE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. IN REGARDS OF BLEEDING DURING HYSTERECTOMY, THIS EVENT IS SEEN AS A SURGERY'S COMPLICATION AND SINCE THE HYSTERECTOMY WAS PERFORMED TO REMOVE THE DEVICES, THIS BLEEDING IS ASSESSED AS RELATED TO ESSURE. ADDITIONALLY NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01857	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2459, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2006. ON THE NEXT MORNING AFTER ESSURE INSERTION, THE CONSUMER WOKE UP AND HER WHOLE LEFT SIDE WAS NUMB. SHE WENT TO A NEUROLOGIST AND FOUND OUT SHE HAD A MINI STROKE. THE NEXT SYMPTOMS THAT SHOWED UP WERE SHARP PAINS ON HER RIGHT SIDE. SHE WENT TO THE EMERGENCY ROOM AT LEAST TWICE FOR THOSE WITH NO CONCLUSIVE RESULTS. IN 2008 SHE HAD A TOTAL KNEE REPLACEMENT AND ENDED UP WITH BILATERAL PULMONARY EMBOLISMS. SHE STATED THAT HER JOINTS WERE MUCH WORSE SINCE ESSURE AND SHE WILL NEED ANOTHER KNEE REPLACEMENT. SHE ALSO HAD DEPRESSION AND FATIGUE, AND SHE MISSED MANY FAMILY OCCASIONS BECAUSE OF THAT AND LIMITED MOBILITY. SHE HAD HYPOTHYROIDISM SINCE ESSURE. SHE WAS VITAMIN D DEFICIENT, HAD BRUISE-LIKE MARKS ON CHEEKS AND FEET, BRAIN FOG, HORRIBLE SHORT TERM MEMORY AND HER HANDS WERE NUMB. SHE SCHEDULED A TOTAL HYSTERECTOMY TO (B)(6) 2015. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-

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MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD SHARP PAINS ON HER RIGHT SIDE (INTERPRETED AS PELVIC PAIN) AND WAS SCHEDULED FOR A TOTAL HYSTERECTOMY APPROXIMATELY 9 YEARS AFTER ESSURE INSERTION. SHE ALSO HAD A MINI STROKE (INTERPRETED AS TRANSIENT ISCHAEMIC ATTACK) ON THE MORNING AFTER ESSURE INSERTION AND BILATERAL PULMONARY EMBOLISMS FOLLOWING A KNEE REPLACEMENT. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PELVIC PAIN IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENTS ARE UNLISTED. AFTER ESSURE INSERTION PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE EVENT SHARP PAINS ON HER RIGHT SIDE AND IN THE LACK OF ALTERNATIVE EXPLANATION CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING EVENT MINI STROKE MAIN RISK FACTORS ARE ATHEROSCLEROSIS, EMBOLIC SOURCES, ARTERIAL DISSECTION, ARTERITIS, SYMPATHOMIMETIC DRUGS (EG, COCAINE), MASS LESIONS (EG, TUMORS OR SUBDURAL HEMATOMAS) AND HYPERCOAGULABLE STATES. IN THE PRESENT CASE, THE CONSUMER HAD ALSO BILATERAL PULMONARY EMBOLISMS TWO YEARS LATER, SUGGESTING A POSSIBLE HYPERCOAGUABLE PREDISPOSITION. THE ESSURE PROCEDURE IS QUICK AND DOES NOT REQUIRE PROLONGED IMMOBILIZATION. THEREFORE, CAUSALITY BETWEEN MINI STROKE AND ESSURE WAS ASSESSED AS UNRELATED. BILATERAL PULMONARY EMBOLISMS OCCURRED AFTER A MAJOR SURGERY REQUIRING IMMOBILIZATION (TOTAL KNEE REPLACEMENT) WHICH IS A REASONABLE ALTERNATIVE EXPLANATION FOR THE EVENT. THEREFORE, CAUSALITY BETWEEN BILATERAL PULMONARY EMBOLISMS AND ESSURE WAS ASSESSED AS UNRELATED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01858	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2460, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. THEY GOT THE LEFT COIL IN WITH NO SAID COMPLICATIONS. WHEN ATTEMPTING, HER RIGHT SIDE, THEY HAD TO RUSH TO GET MORE MEDICATIONS ONLY TO TELL CONSUMER THAT SHE WOULD HAVE TO COME BACK TO HAVE HER RIGHT ONE DONE AGAIN. THE PAIN WAS HORRIBLE. SINCE THEN, CONSUMER EXPERIENCED MIGRAINES, LOSS OF HAIR, TOOTH DECAY, HEAVY PERIODS WITH CRAMPS THAT MAKE HER SICK TO THE STOMACH, SHARP PAINS IN RIGHT SIDE AND LEFT, NIGHT SWEATS THAT WOULD LEAVE HER DRENCHED WHEN SHE WOKE UP. A LEEP PROCEDURE WAS PERFORMED AND THEY REMOVED ABNORMAL CELLS FROM CERVIX. IT WAS A QUICK 15 MINUTES PROCEDURE. SHE EXPERIENCED MILD CRAMPING AND BLEEDING, WHICH NEVER STOPPED. WEEK ONE ENDED UP IN EMERGENCY ROOM (ER) AND SHE HAD HER CERVIX SCRAPPED AND RE CAUTERIZED WITHOUT ANY NUMBING. SHE EXPERIENCED EXCRUCIATING PAIN. WEEK TWO, SHE WAS BACK TO PHYSICIAN OFFICE FOR THEM TO REPEAT THE SAME THING AGAIN NO NUMBING. DECISION WAS MADE TO USE SOME NEW BONDING MATERIAL. WEEK THREE, SHE MISSED WORK AGAIN BECAUSE OF WAKING UP AND FEELING LIKE SHE WAS BLEEDING TO DEATH. SHE WENT TO ER. AFTER 30 MINUTES OF MANIPULATING HER CERVIX, IT WAS PROMISED THAT IT WAS FIXED AND SHE WOULD NOT BLEED AGAIN. WEEK FOUR, SHE WOKE UP TO A POOL IN HER SWEATPANTS. AN EMERGENCY D&C (DILATION AND CURETTAGE) WAS PERFORMED. SHE WAS TOLD THAT IT LOOKED AS IF ONE OF THE COILS WAS SEEN (RIGHT SIDE) BUT THE OTHER WAS NOT (LEFT SIDE). SHE WAS KEPT OVERNIGHT AND AN IVP WAS ORDERED TO CHECK FOR COMPLICATIONS

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BECAUSE OF THE PAIN. CONSUMER STATED THAT SHE SAW HER COILS ON X-RAY: ONE APPEARED NORMAL AND THE OTHER WAS BENT. THEY THEN PULLED UP X-RAYS FROM 2012 THAT SHOWED A SPEC (THIS MUST BE A PIECE THAT WAS LEFT FROM THEIR FAILED FIRST ATTEMPT BUT IT WAS TAKEN OUT DURING D&C). THEY PULLED UP HER CURRENT X-RAY AND SHE SAW THE SAME SPEC. IT WAS STATED IT WAS EMBEDDED IN THE WALL OF HER UTERUS SO NO NEED TO WORRY ABOUT IT. THEY ENDED UP PUTTING TWO SUTURES ON HER CERVIX TO CUT OFF HER BLOOD FLOW. AND SHE WAS PUT ON TWO ANTIBIOTICS. FEW DAYS LATER, SHE WAS BREAKING OUT IN A RASH GOING DOWN HER RIGHT ARM. ANTIBIOTICS WERE SWITCHED. THE MORNING AFTER THE D&C, HER HEMOGLOBIN WAS AT 9.8. SHE WAS STILL STRUGGLING WITH FATIGUE (SHE GETS TIRED EXTREMELY EASILY). CONSUMER EXPERIENCED CONSTANT STRUGGLES WITH TEETH, CHRONIC PAIN, BRUISE LIKE A BANANA, UNEXPLAINABLE MOOD SWINGS, ACHES THAT GO UNTREATED, IBS (INTERPRETED AS IRRITABLE BOWEL SYNDROME), AND INABILITY TO SLEEP, TO CONCENTRATE. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BLEEDING / BLEEDING NEVER STOPPED (INTERPRETED AS GENITAL BLEEDING). SHE HAD HER CERVIX SCRAPPED AND RE CAUTERIZED, SHE REPEATED IT AGAIN. AN EMERGENCY D&C (DILATION AND CURETTAGE) WAS PERFORMED. SHE WAS TOLD THAT IT LOOKED AS IF ONE OF THE COILS WAS SEEN (RIGHT SIDE) BUT THE OTHER WAS NOT (LEFT SIDE) (INTERPRETED AS DEVICE DISLOCATION). AN X-RAY WAS PERFORMED AND THE RESULT SHOWED A SPEC (IT MIGHT BE A PIECE FROM THEIR FIRST ATTEMPT EMBEDDED IN THE WALL OF YOUR UTERUS). THESE EVENTS WERE CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE EXACT DATE AND MECHANISM OF DISLOCATION AND EMBEDDED DEVICE WERE NOT KNOWN. CONSIDERING THE NATURE OF THE EVENTS, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS PERFORMED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01859	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7): 10/1/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-2469, AWARENESS DATE 05-NOV-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011 FOR STERILIZATION. CONSUMER STATED SHE HAS PHOTOS OF HER SURGICAL INCISIONS AND BRUISING. SHE WAS SO TIRED SHE COULD BARELY WALK OR FUNCTION. SHE ALSO EXPERIENCED EXTREME FATIGUE, FOOD SENSITIVITIES, IMMUNE FUNCTION DISRUPTION, PLAQUE PSORIASIS, EAR ITCHING AND DRAINING, INSOMNIA AND HIGH SUICIDE RISK. ESSURE WAS REMOVED IN (B)(6) 2015. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO CAPA INVESTIGATION IS REQUIRED AT THIS TIME BECAUSE THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD IMMUNE FUNCTION DISRUPTION, PLAQUE PSORIASIS AND HIGH SUICIDE RISK. ESSURE WAS REMOVED AFTER 4 YEARS. THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. ALL EVENTS, EXCEPT FOR MEDICAL DEVICE REMOVAL, ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE PHYSIOPATHOLOGY OF IMMUNODEFICIENCIES,

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PSORIASIS AND SUICIDAL IDEATION AND ALSO GIVEN THE LOCALIZED ACTION OF ESSURE INSERTS IN THE FALLOPIAN TUBES, IT IS UNLIKELY THAT ESSURE INSERTS WOULD CONTRIBUTE TO THE DEVELOPMENT OF THESE DISEASES. ALTHOUGH THE REASON FOR ESSURE REMOVAL WAS NOT PROVIDED, THIS EVENT IS ASSESSED AS RELATED TO ESSURE DUE TO THE NATURE OF THIS EVENT. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01860	BAYER HEALTHCARE LLC	12/4/2015	12/4/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/18/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5044535) IN UNITED STATES ON 14-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 BECAUSE SHE DECIDED WE DID NOT WANT TO HAVE ANY MORE KIDS. THE CONSUMER GOT A TEST COMPLETED 3 MONTHS LATER TO VERIFY THAT THE ESSURE WAS PLACED CORRECTLY. IN 2009, SHE TOLD HER GYNECOLOGIST ABOUT THE PAIN AND STARTED TO HAVE AND HEAVY PERIOD WHICH SHE WAS TOLD IT HAS AN ASSOCIATION OF HER NOT HAVING A PERIOD OF 5 YEARS DUE TO THE BIRTH CONTROL. SHE WAS ALSO OFFERED TO ADD BIRTH CONTROL AS THE PILL OR THE SHOT WHICH AT THE TIME SHE WOULD ADVISE HER PHYSICIAN ABOUT THE ISSUES, AND SHE WOULD SAY OKAY WE WILL KEEP AN EYE AND SEE IF IT GETS WORSE. SHE ALSO SAW HER PRIMARY PHYSICIAN IN OCCASION WHO ALSO ADVISED IT WAS NORMAL TO BE MORE SENSITIVE DUE TO AGE AND PERIOD CYCLES. SHE REPORTED HAVING REAL BAD LOWER BACK AND THIGH PAIN AND WAS UNABLE TO GET UP FROM BED FOR 3 DAYS STRAIGHT; SHE DID NOT GO TO WORK FOR 2 WEEKS SHE DECIDED TO MAKE AN APPOINTMENT WITH A CHIROPRACTOR TO TRY TO FIX THE PROBLEM OF HER LOWER BACK THAT WAS JUST CONSTANT AND DURING THE MONTH IT IS FINE BUT WHEN SHE GOT HER PERIOD IT WAS HORRIBLE CRAMP AND HER LEFT THIGH HURTS AND FALL SLEEP. SHE ALSO HAD HEAVY PERIOD THAT SHE HAD TO LEAVE WORK TO CHANGE CLOTHING. SHE WAS UNABLE TO DO EXERCISE AND OTHER THINGS THAT SHE WAS ABLE TO DO. SHE HAD HER YEARLY CHECKUP IN 2015 WHEN IN THE MIDDLE SHE WAS NOT PLEASED WITH HER TENDERNESS. SHE MENTIONED IT WAS GETTING WORSE TO EVEN HAVE SEXUAL INTERCOURSE DUE TO THE PAIN AGAIN, THE DOCTOR ADVISED IT COULD BE NUMEROUS THINGS NOT ONCE MENTION ABOUT A PROBLEM WITH ESSURE. THE CONSUMER ALSO MENTIONED THE SERIOUSNESS CRITERION REQUIRED INTERVENTION BUT NOT SPECIFIED

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AND/OR ASSIGNED TO ONE OF THE EVENTS. THE CONSUMER ALSO MENTIONED TAKING IBUPROFEN 800MG FOR ONSET OF MIGRAINES. FOLLOW-UP INFORMATION RECEIVED 06-NOV-2015 AND ADDITIONAL INFORMATION RECEIVED ON 22-NOV-2015 (PTC INVESTIGATION RESULT RECEIVED): CONSUMER REPORTED THAT ESSURE WAS REMOVED. CASE UPGRADED TO INCIDENT. PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 AND REPORTED PAIN/ LOWER BACK PAIN, CONSIDERED SERIOUS BY MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THE PATIENT COMPLAINED ABOUT PAIN AND HEAVY PERIOD AFTER ESSURE INSERTION, WHICH HER PHYSICIAN EXPLAINED WAS DUE TO AN ASSOCIATION OF HER NOT HAVING A PERIOD OF 5 YEARS DUE TO THE BIRTH CONTROL. THIS IS A REASONABLE ALTERNATIVE EXPLANATION FOR THESE EVENTS. HOWEVER, IT WOULD BE EXPECTED THAT THIS EVENTS SUBSIDE AFTER SOME MONTHS, AND SHE STATED IN 2015 SHE STILL HAD THE PAIN. THE PAIN STARTED AFTER ESSURE INSERTION, SO AN EVENTUAL CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED RELATED. THIS CASE WAS UPGRADED TO INCIDENT SINCE ESSURE WAS REMOVED (INFORMATION RECEIVED ON FOLLOW-UP). ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058400	BAYER	12/4/2015	12/9/2015

Event Information:

Event Date (B3): 11/5/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/19/2009
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SEVERE DETERIORATION OF DISCS BETWEEN L4 - L5, AND L5 - S1. NO PRIOR ISSUES OR COMPLAINTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058401	BAYER	12/4/2015	12/9/2015

Event Information:

Event Date (B3): 5/27/2011	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/31/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTS PUT IN (B)(6) 2011, SINCE THEN I HAVE BEEN HAVING LOTS OF ABDOMINAL AND PELVIC PAIN THAT RADIATES TO MY LEG ESPECIALLY MY INNER THIGHS. I STARTED EXPERIENCING REALLY BAD MIGRAINES AS WELL AS FATIGUE AND MANY OTHER SYMPTOMS LIKE NAUSEA, WEAKNESS AND INSOMNIA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058405	BAYER	12/6/2015	12/9/2015

Event Information:

Event Date (B3): 9/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HELLO, MY NAME IS (B)(6). I GOT ESSURE IN 2012, AFTER THE BIRTH OF MY THIRD BABY. I WAS SCARED TO DEATH OF ANY KIND OF SURGERY, SEEING AS I'VE NEVER HAD SURGERY BEFORE, SO THE DOCTOR ASSURED ME THAT THIS WOULD BE THE BEST THING FOR ME, SO I DIDN'T HAVE TO HAVE THE TUBAL AND I WOULD BE OUTPATIENT. I AGREED AND THOUGHT THE DOCTOR HAS TO KNOW MORE THAN I ABOUT THIS. WRONG. SINCE HAVING THIS PLACED IN ME, I'VE HAD OVARIAN CYSTS EVERY MONTH FOR 3 YEARS. THEY LAST FOR ABOUT 2 WEEKS AND FEEL LIKE DULL CONTRACTIONS, (SO I FEEL LIKE I'M HAVING BRAXTON HICKS CONTRACTIONS BASICALLY), THEN THEY BUST AND I'M IN AGONIZING PAIN AND DOUBLED OVER. ALSO, BEFORE ESSURE, MY PERIOD CRAMPS WERE BAD, BUT NOW THEY ARE ABSOLUTELY EXCRUCIATING, TO THE POINT WHERE I CAN BARELY MOVE AT TIMES. I WANT THIS OUT OF ME. I HAVE BEEN RESEARCHING WAYS TO GET IT REVERSED, BUT THE LOWEST COST I'VE FOUND IS (B)(6). I'VE ALSO HEARD ABOUT OTHER WOMEN HAVING HYSTERECTOMIES, BUT I'M (B)(6); I'M NOT HAVING ONE OF THOSE, ONLY TO FACE ALL OF THE COMPLICATIONS THAT COME BEHIND IT. IT ISN'T FAIR THAT I WASN'T GIVEN ALL THE RISKS ASSOCIATED WITH THIS DEVICE UP FRONT. IF I WAS, I WOULD HAVE OPTED OUT OF THIS TOO.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01861	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/28/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

OTHER REPORTABLE INCIDENT. MALFUNCTION. DEVICE BREAKAGE. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. THE PATIENT'S MEDICAL HISTORY INCLUDED 2 PREGNANCIES WITH 2 CESAREAN BIRTHS. SHE HAD A BICORNUATE UTERUS AND REGULAR MENSTRUAL CYCLES AND SHORT BLEEDING. HER DRUG HISTORY INCLUDED COPPER INTRAUTERINE DEVICE (IN T SHAPE). ESSURE DEVICE WAS PLACED WITH DIFFICULTY IN RIGHT TUBAL OSTIUM DUE TO SPASM. IT WAS OBSERVED 3 COILS IN RIGHT TUBAL OSTIUM AND 2 IN LEFT TUBAL OSTIUM. THE COPPER INTRAUTERINE DEVICE WAS NOT REMOVED AT THE TIME. ON (B)(6) 2014, THE LOCATION OF THE ESSURE DEVICE WAS CONTROLLED THROUGH ULTRASONOGRAPHY WHICH SHOWED THE RIGHT TUBAL OSTIUM DISPLACED LATERALLY, LEFT TUBAL OSTIUM NORMAL. AT THAT TIME, INTRAUTERINE DEVICE REMOVAL WAS PERFORMED BY HYSTEROSCOPY WITH CLIPS DUE TO THE THREADS WERE NOT OBSERVED IN THE CERVICAL CANAL. ON (B)(6) 2015, THE PATIENT WENT TO THE EMERGENCY ROOM WITH THE METAL PART OF THE ESSURE WHICH HAS EXPELLED DURING MENSTRUATION WITH AN EPISODE OF PAIN MORE INTENSE THAT USUAL MENSTRUAL PERIOD. A HYSTEROSALPINGOGRAPHY (HSG) WAS PERFORMED AND SHOWED UTERINE CAVITY WITH BICORN MORPHOLOGY WITHOUT FILLING DEFECTS; THE RIGHT INTRA TUBAL DEVICE WITH REDUCED LENGTH AND OBSERVING PART OF THE DEVICE IN THE UTERINE CAVITY THROUGH THE RIGHT HORN. CORRECT POSITION OF THE DEVICE OF LEFT TUBAL AND ABSENCE OF TUBAL PERMEABILITY. FOLLOW-UP INFORMATION RECEIVED ON 15-NOV-2015: THE PHYSICIAN REPORTED THAT THE REMOVED IUD WAS NOVA T INSERTED ON (B)(6) 2009 (REFER TO CASE NUMBER (B)(4)). NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 23-NOV-2015: THE PHYSICIAN TRANSCRIBED THE HYSTEROSALPINGOGRAPHY REPORT AS IT WAS

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PREVIOUSLY REPORTED. THE NEW INFORMATION WAS THAT THE SIZE/MORPHOLOGY OF THE UTERINE CAVITY WERE NORMAL. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A (B)(6) FEMALE PATIENT WITH A BICORNUATE UTERUS; WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED WITH NOVA-T ALREADY IN PLACE. ONE YEAR AFTER THIS PROCEDURE, SHE HAD A METAL PART OF THE ESSURE EXPELLED DURING MENSTRUATION (REGARDED AS DEVICE BREAKAGE). A HYSTEROSALPINGOGRAM WAS PERFORMED AND REVEALED THE RIGHT INTRA TUBAL DEVICE WITH REDUCED LENGTH AND PART OF THE DEVICE IN THE UTERINE CAVITY THROUGH THE RIGHT HORN. ONLY DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AN ABNORMAL UTERINE CAVITY CAN MAKE THE VISUALIZATION OF TUBAL OSTIA AND CANNULATION OF THE FALLOPIAN TUBES DURING ESSURE INSERTION DIFFICULT OR IMPOSSIBLE. IN ADDITION, IUDS ARE NOT RECOMMENDED AS ALTERNATIVE CONTRACEPTIVE MEASURE DURING THE 3-MONTHS POST ESSURE INSERTION. IN THIS PARTICULAR CASE, PATIENT'S BICORNUATE UTERUS IN ASSOCIATION WITH THE PRESENCE OF AN IUD IN HER UTERINE CAVITY (THIS IUD WAS ONLY REMOVED AFTER HER CONFIRMATION TEST; 3 MONTHS POST ESSURE PLACEMENT) MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED EVENTS. NEVERTHELESS; CONSIDERING EVENTS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 07-JAN-2016: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSME

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01862	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT, UNANTICIPATED (SERIOUS INJURY: PREMATURE DELIVERY). THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 25-FEB-2015. IT DESCRIBES THE OCCURRENCE OF PREGNANCY IN A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD AND ONLY ONE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED. PHYSICIAN REPORTED THAT HE HAS AN ESSURE PATIENT WHO IS PREGNANT. HEALTH CARE PROFESSIONAL PERFORMED PROCEDURE AND WHILE HE WAS AWAY ON VACATION, A DIFFERENT PHYSICIAN (NAME UNKNOWN) READ THE HYSTEROSALPINGOGRAM FILMS AND ADVISED PATIENT SHE COULD RELY ON ESSURE FOR BIRTH CONTROL. HOWEVER, ACCORDING TO PHYSICIAN, PATIENT HAD ONLY ONE MICRO-INSERT PLACED. PATIENT PLANS TO CONTINUE THE PREGNANCY. FOLLOW UP INFORMATION FROM 23-MAR-2015: PTC (PRODUCT TECHNICAL COMPLAINT) WAS RECEIVED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. A CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, IT WAS REPORTED THAT ONLY ONE MICRO-INSERT WAS PLACED IN THE PATIENT. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR FURTHER TECHNICAL

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INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 07-JUL-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 THE PATIENT'S INITIALS AND DATE OF BIRTH WERE UPDATED (SHE WAS (B)(6)). HER WEIGHT WAS (B)(6) AND BMI WAS (B)(6). PATIENT HAD A HISTORY OF PREVIOUS C-SECTION. AT TIME OF INSERTION SHE WAS NOT IN A POST-PARTUM STATE. CERVICAL DILATION AND LOCAL ANESTHESIA WERE USED. SOUNDING WAS DENIED. IT WAS REPORTED THAT NUMEROUS ATTEMPTS TO CANNULATE RIGHT OSTIA WERE DONE, BUT IT WAS UNABLE. FLUID LOSS WAS LESS THAN 1500CC AND PROCEDURE TOOK MORE THAN 20 MINUTES. AFTER INSERTION AND BEFORE CONFIRMATION TEST, ORAL CONTRACEPTION WAS USED. HSG (HYSTEROSALPINGOGRAM) WAS DONE AND BILATERAL OCCLUSION WAS SEEN; LEFT DEVICE WAS IN PLACE. SHE WAS SAID THAT RIGHT TUBE WAS ALSO BLOCKED AND STOPPED CONTRACEPTIVE. ON AN UNSPECIFIED DATE, PATIENT DELIVERED AT (B)(6) OF GESTATION (PREMATURE DELIVERY) A LIVE BIRTH BABY BY C-SECTION. COMPLICATIONS WERE DENIED. ACCORDING TO THE PHYSICIAN, A BTL (INTERPRETED AS BILATERAL TUBAL LIGATION) WAS DONE AND ESSURE WAS REMOVED BY LAPAROTOMY (SALPINGECTOMY WAS NECESSARY). CASE UPGRADED TO INCIDENT. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT. SHE DELIVERED AT (B)(6) OF GESTATION (PREMATURE DELIVERY) A LIVE BIRTH BABY BY C-SECTION. COMPLICATIONS WERE DENIED. SHE UNDERWENT A BILATERAL TUBAL LIGATION AND ESSURE WAS REMOVED BY LAPAROTOMY (SALPINGECTOMY WAS NECESSARY). PREMATURE DELIVERY AND C-SECTION ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, WHILE PREGNANCY IS NON-SERIOUS. THESE EVENTS WERE CONSIDERED SERIOUS. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS CASE, THE HYSTEROSALPINGOGRAM WAS PERFORMED AND THE PHYSICIAN ADVISED PATIENT SHE COULD RELY ON ESSURE FOR BIRTH CONTROL. NEVERTHELESS, ACCORDING TO REPORTER PHYSICIAN, PATIENT HAD ONLY ONE MICRO-INSERT PLACED. THE POSSIBILITY OF DEVICE INEFFICACY CANNOT BE TOTALLY EXCLUDED AND THE PREGNANCY IS ASSESSED AS RELATED TO ESSURE USE. MOST OF PREMATURE BIRTHS OCCUR SPONTANEOUSLY AND ARE RELATED TO PRETERM LABOR OR PRETERM PREMATURE RUPTURE OF MEMBRANES AND LESS FREQUENTLY ARE MEDICALLY INDICATED BECAUSE OF MATERNAL OR FETAL ISSUES. IN THIS CASE, A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE DEVELOPING PREGNANCY CANNOT BE EXCLUDED. AS C-SECTION IS A SURGICAL DELIVERY AND NO MEDICAL REASON FOR THE PROCEDURE WAS REPORTED, CAUSALITY CAN BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT DUE TO PREMATURE DELIVERY. AN UPDATED PRODUCT TECHNICAL COMPLAINT IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01863	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 5/7/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. ANTICIPATED. REQUIRED INTERVENTION. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER / ATTORNEY IN THE UNITED STATES, ON BEHALF OF A PLAINTIFF IN UNITED STATES ON 09-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PRIOR TO THE OPERATION, PLAINTIFF WENT TO THE IMPLANTING PHYSICIAN TO DISCUSS OPTIONS FOR PERMANENT STERILIZATION. THE IMPLANTING PHYSICIAN RECOMMENDED THAT PLAINTIFF HAVE ESSURE IMPLANTED IN HER FALLOPIAN TUBES INSTEAD OF A STANDARD TUBAL LIGATION PROCEDURE. IN OR AROUND (B)(6) 2009, PLAINTIFF RETURNED TO THE IMPLANTING PHYSICIAN FOR THE ESSURE PROCEDURE. THE IMPLANTING PHYSICIAN IMPLANTED THE ESSURE COILS INTO BOTH HER LEFT AND RIGHT FALLOPIAN TUBES. AFTER PROCEDURE TO IMPLANT THE DEVICE, PLAINTIFF STARTED EXPERIENCING SEVERE CONSTANT DAILY PAIN, AND SEVERE BLEEDING. SINCE THE DEVICE WAS IMPLANTED, PLAINTIFF HAS ALSO SUFFERED FROM HEAVY BLEEDING, MENORRHAGIA, CONSTANT PAIN, AND MENTAL AND EMOTIONAL ANGUISH. AFTER THE DEVICE WAS IMPLANTED, PLAINTIFF HAS ALSO SUFFERED FROM MIGRAINES, SEVERE ABDOMINAL, OVARIAN AND PELVIC PAIN, SHARP, STABBING PAIN, PAIN DURING INTERCOURSE. AS A DIRECT AND PROXIMATE RESULT OF PLAINTIFFS USE OF ESSURE, SHE WAS FORCED TO UNDERGO A SURGICAL PROCEDURE TO CONTROL THE HEAVY BLEEDING CAUSED BY THE ESSURE COILS. PLAINTIFF HAD A UTERINE ABLATION ON OR ABOUT (B)(6) 2013 TO CONTROL THE HEAVY BLEEDING. AS A DIRECT AND PROXIMATE CAUSE OF PLAINTIFFS USE OF ESSURE, SHE WAS FORCED TO UNDERGO MEDICAL PROCEDURES TO MANAGE HER SYMPTOMS AND HAS UNDERGONE NUMEROUS PROCEDURES. PLAINTIFF DID NOT BECOME AWARE THAT ESSURE WAS THE CAUSE OF HER ABOVE-DESCRIBED PHYSICAL, EMOTIONAL, AND MEDICAL PROBLEMS UNTIL 2015 WHEN SHE LEARNED, THROUGH INTERNET RESEARCH, OF OTHER WOMEN HAVING SIMILAR ISSUES.

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PLAINTIFF SUFFERED PROFOUND INJURIES, REQUIRED MEDICAL TREATMENT, AND INCURRED AND CONTINUES TO INCUR MEDICAL AND HOSPITAL EXPENSES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED AND LEGAL CASE REPORT REFERS TO A FEMALE CONSUMER (PLAINTIFF) WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED EXPERIENCING HEAVY BLEEDING/ MENORRHAGIA. SHE UNDERWENT A UTERINE ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION) TO CONTROL THE HEAVY BLEEDING, APPROXIMATELY 4 YEARS AFTER INSERTION. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 08-DEC-2015 (NO NEW INFORMATION WAS PROVIDED) AND 10-DEC-2015 (PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01864	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT (DEVICE REMOVAL; REQUIRED INTERVENTION IMPLIED). ANTICIPATED. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE AND EXPERIENCED HEADACHES. ESSURE WAS REMOVED DUE TO THE HEADACHES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD ESSURE REMOVED DUE TO HEADACHES. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE LIMITED INFORMATION WAS INFORMED, CONSIDERING HEADACHES MAY OCCUR DURING ESSURE USE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE THE EVENT LED TO A DEVICE REMOVAL (INTERVENTION IMPLIED), THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION AND TECHNICAL ASSESSMENT HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 15-DEC-2015, REFERRING TO PTC GLOBAL NUMBER (B)(4): FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01865	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/19/2014
Explant Date (E7): 7/24/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT (REQUIRED INTERVENTION). ANTICIPATED. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5057493) IN UNITED STATES ON 09-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014. CONSUMER REPORTED THAT BOTH SPRINGS MIGRATED, ONE TOWARDS HER OVARY AND THE OTHER ONE 3/4 OF THE WAY INTO HER UTERUS. IT CAUSED PAIN AND BLEEDING. SHE HAD TO HAVE THEM SURGICALLY REMOVED ON (B)(6) 2014 LAPAROSCOPICALLY. SHE ALSO HAD AN ABLATION TO HELP STOP THE BLEEDING, BUT SHE STILL HAD HEAVY BLEEDING AND MAY REQUIRE A HYSTERECTOMY. A SERIOUS INJURY AND EVENT DATE (B)(6) 2014 WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BOTH SPRINGS MIGRATED, ONE TOWARDS HER OVARY AND THE OTHER ONE 3/4 OF THE WAY INTO HER UTERUS, WHICH CAUSED HER BLEEDING. THESE EVENTS, SEEN AS DEVICE DISLOCATION AND GENITAL BLEEDING, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, GENITAL BLEEDING MAY OCCUR AND THERE IS A RISK THAT THE DEVICE COULD MOVE TO UTERINE CAVITY OR OUT OF FALLOPIAN TUBES TOWARDS TO PERITONEAL CAVITY. ALTHOUGH IN THIS CASE, THE EXACT DATE AND MECHANISM OF THIS DISLOCATION ARE UNKNOWN, GIVEN THE EVENT'S NATURE, CAUSALITY BETWEEN BOTH EVENTS AND ESSURE USE CANNOT BE EXCLUDED. SINCE INTERVENTIONS WERE REQUIRED (LAPAROSCOPY AND ABLATION), THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION AND TECHNICAL ASSESSMENT HAVE BEEN REQUESTED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 29-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01866	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 664658

Single Use: Y
Implant Date (E6): 12/2/2009
Explant Date (E7): 8/13/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT (REQUIRED INTERVENTION). ANTICIPATED. THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE MW5057494) IN UNITED STATES ON 09-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER 664658 IMPLANTED IN (B)(6) 2009 AFTER SHE FOUND OUT HER MOTHERS BREAST CANCER WAS DUE TO ESTROGEN THERAPY AND SHE WAS ADVISED THAT SHE SHOULD FIND AN ALTERNATIVE TO HORMONAL BIRTH CONTROL. SHE WAS NOT INFORMED OF ANY POSSIBLE SIDE EFFECTS AND WAS NOT INFORMED THAT THE DEVICE WAS NICKEL BASED TO WHICH SHE HAS SENSITIVITY TO. THEN, DAYS AFTER THE PROCEDURE SHE WENT TO THE ER (EMERGENCY ROOM) BECAUSE SHE WAS EXPERIENCING SHORTNESS OF BREATH. THEY COULD NOT FIND A CAUSE AND IT EVENTUALLY DISSIPATED. IN THE MONTH AND YEARS FOLLOWING THE PROCEDURE SHE EXPERIENCED BURNING PAIN IN HER HIPS, ABDOMINAL PAIN TO THE POINT SHE THOUGHT SHE WAS HAVING GALLBLADDER OR APPENDIX ISSUES, PAIN DURING INTERCOURSE, SEVERE RASH/ECZEMA ON HER SCALP AND NECK AND HAIR LOSS. HER PERIODS ALSO GOT PROGRESSIVELY HEAVIER AND MORE FREQUENT TO THE POINT WHERE SHE WAS HAVING IT EVERY OTHER WEEK TO TWO WEEKS AND WAS LASTING UP TO TWO WEEKS WITH SEVERE CRAMPS AND HEAVY BLEEDING TO THE POINT WHERE SHE WAS UNABLE TO GO TO WORK ON NUMEROUS OCCASIONS. HER DOCTOR DENIED THAT WAS CAUSED BY THE IMPLANTS BUT SHE ULTIMATELY CHOSE TO HAVE A PARTIAL HYSTERECTOMY ON (B)(6) 2013 TO REMOVE HER UTERUS AND FALLOPIAN TUBES TO REMOVE THE DEVICES. QUALITY ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPLE WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE

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DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER THE PROCEDURE, HER PERIODS GOT WORSE AND SHE HAD HEAVY BLEEDING TO THE POINT WHERE SHE WAS NOT ABLE TO GO TO WORK. SHE ULTIMATELY HAD A PARTIAL HYSTERECTOMY PERFORMED TO REMOVE THE DEVICES. THIS EVENT, SEEN AS MENORRHAGIA, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING MENSTRUAL PATTERN CHANGES MAY OCCUR DURING ESSURE USE AND THEIR TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN MENORRHAGIA AND THE SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01868	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. ANTICIPATED. SERIOUS INJURY. REQUIRED INTERVENTION THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED SHE HAD ESSURE IMPLANTED AND ONLY AFTER TWO DAYS SHE WENT TO THE EMERGENCY ROOM DUE TO SEVERE PAIN. SHE UNDERWENT A PAINFUL TEST TO FIND OUT IF IT WAS PROPERLY IMPLANTED. THEY ACTED AS IF SHE WAS CRAZY, TURNING UP AT THE EMERGENCY ROOM IN THE EARLY HOURS OF THE MORNING WITH SUCH SEVERE PAIN, WITH AN INFLAMED ABDOMEN AS IF SHE WAS 7 MONTHS PREGNANT. SHE CRIED UNCONTROLLABLY AND WAS SENT HOME. ON ANOTHER OCCASION, SHE WAS GIVEN ANTIBIOTICS FOR AIDS PATIENTS AND WAS TOLD THAT SHE HAD A SEXUALLY TRANSMITTED INFECTION. AND THAT WAS HOW SHE WAS FOR 20 DAYS; SHE WAS SWEATING, HER FINGERS AND TOES BURNED, SHE COULD NOT LIE DOWN DUE TO THE PAIN, PLUS THE INDIGNATION OF BEING ACCUSED OF INFIDELITY DESPITE BEING HAPPILY MARRIED. HAVING NOT IMPROVED AFTER THIS TIME, SHE WENT BACK AND ASKED TO BE ADMITTED AND WAS IMMEDIATELY TESTED FOR ALLERGIES, SHE WAS TOLD IT WAS NOT MEDICAL. SHE WAS ADMITTED AND CONTINUED ON THE SAME TREATMENT PLUS INTRAVENOUS ANTIBIOTIC, SHE CRIED FROM PAIN. SHE STATED 10 GYNECOLOGISTS EXAMINED HER INSISTED THAT THERE WAS NOTHING WRONG WITH HER. FINALLY, AN ALLERGY TEST WAS POSITIVE, SHE WAS SENT HOME, AND WAS PUT ON THE WAITING LIST AND FINALLY REMOVED IT, WHICH INVOLVED REMOVING HER FALLOPIAN TUBES. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD SEVERE PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. THE DEVICES WERE REMOVED ALONG WITH HER FALLOPIAN TUBES. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY

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INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER'S PAIN STARTED 2 DAYS AFTER ESSURE PLACEMENT. SHE CONSULTED SEVERAL DOCTORS, HAD AN ER VISIT AND ONE HOSPITAL ADMISSION AND RECEIVED ANTIBIOTICS WITHOUT IMPROVEMENT. AFTER A POSITIVE ALLERGY TEST (UNSPECIFIED) SHE WAS SUBMITTED TO ESSURE REMOVAL. CONSIDERING EVENT'S NATURE AND THE POSITIVE TEMPORAL RELATIONSHIP WITH ESSURE INSERTION, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE MEDICAL AND SURGICAL INTERVENTIONS WERE REQUIRED AS EVENTS TREATMENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 07-JAN-2016. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: IN THIS CASE, NO PRODUCT SAMPL

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01869	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. UNANTICIPATED. SERIOUS INJURY. REQUIRED INTERVENTION THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 10-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. THE PATIENT HAD A POST-TUBAL LIGATION SYNDROME. THE REPORTING PHYSICIAN WAS THE ONE WHO DID A SUPRACERVICAL HYSTERECTOMY WITH A MORCELLATOR. HE WAS UNSURE IF THE MORCELLATOR CAUSED THE ESSURE DEVICE TO BREAK. THE PIECES WERE SEEN IN THE ABDOMEN BY ANOTHER PHYSICIAN (UNSURE OF EXACT IMAGING MODALITY) AND IT WERE REMOVED BY ANOTHER SURGEON. THE PATIENT WAS NOW CLAIMING THAT HER PAIN HAS IMPROVED. THE PHYSICIAN WAS UNSURE IF THE PIECES WERE RESPONSIBLE FOR THE PATIENTS PAIN; AND HE WAS ASKING IF THE MORCELLATOR COULD HAVE CAUSED THE DEVICE OR PET FIBERS TO BREAK AND CAUSE THE PATIENT PAIN. THE PHYSICIAN MENTIONED HE MAY BE GETTING SUED BY THIS PATIENT. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD A POST TUBAL LIGATION SYNDROME AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A SUPRACERVICAL HYSTERECTOMY WITH A MORCELLATOR. AN UNSPECIFIED TIME AFTER THIS PROCEDURE, PIECES OF ESSURE WERE FOUND AND REMOVED FROM HER ABDOMEN. THE REPORTER WAS UNSURE IF THE MORCELLATOR CAUSED ESSURE TO BREAK. THESE EVENTS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. HEAVIER AND MORE PROLONGED MENSTRUAL BLEEDING AND INCREASED DYSMENORRHEA HAVE BEEN REPORTED AFTER FEMALE STERILIZATION AND ATTRIBUTED, BY SOME AUTHORS, TO A POST TUBAL LIGATION SYNDROME. IN THIS PARTICULAR CASE, CONSUMER WAS DIAGNOSED WITH POST TUBAL LIGATION SYNDROME AND SUBMITTED TO A HYSTERECTOMY WITH A MORCELLATOR. THE TERM MORCELLATION

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ENCOMPASSES A VARIETY OF SURGICAL TECHNIQUES, SOME USED IN CONCERT WITH SPECIFIC DEVICES, TO FRAGMENT TISSUE SPECIMENS FACILITATING THEIR REMOVAL. IF UTERINE MORCELLATION IS PERFORMED, DISSEMINATION OF UTERINE FRAGMENTS THROUGHOUT THE INTRAPERITONEAL CAVITY MAY OCCUR. IF ESSURE REMOVAL IS REQUIRED, IT IS RECOMMENDED TO PERFORM A SALPINGECTOMY OR SALPINGOTOMY WITH CORNUAL RESECTION (IF REQUIRED) BY A TRANSABDOMINAL APPROACH (LAPAROTOMY OR LAPAROSCOPY). IN THIS CASE, IT SEEMS PATIENT HAD THE ESSURE DEVICE IN PLACE AT THE TIME OF THE MORCELLATION; THUS IT IS POSSIBLE THAT THE REPORTED DEVICE BREAKAGE WAS A CONSEQUENCE OF THE SURGICAL TECHNIQUE APPLIED FOR THE HYSTERECTOMY. NEVERTHELESS, SINCE NO DETAILS ABOUT THE EXACT PROCEDURE FOR ESSURE REMOVAL WERE PROVIDED (UNCLEAR IF THE MORCELLATOR WAS APPLIED DIRECTLY TO THE FALLOPIAN TUBES/ESSURE) CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE SURGICAL INTERVENTIONS WERE REQUIRED FOR EVENTS TREATMENT. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01870	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B34805 / A73761

Single Use: Y
Implant Date (E6): 9/1/2013
Explant Date (E7): 6/26/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. UNANTICIPATED. SERIOUS INJURY. REQUIRED INTERVENTION/PREGNANCY COMPLICATIONS THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 23-DEC-2014 WHICH DESCRIBES A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2013 LOT NUMBER A73761 (RIGHT TUBE) AND B34805 (LEFT TUBE) FOR PERMANENT CONTRACEPTION. IT WAS REPORTED THAT PATIENT DID NOT HAVE HSG CONFIRMATION TEST PERFORMED. INTRAUTERINE PREGNANCY WAS DIAGNOSED IN (B)(6) 2014. SHE WAS 9 WEEKS AND 6 DAYS PREGNANT AT THE TIME OF REPORT (DEVICE INEFFECTIVE). ESSURE WAS NOT REMOVED. THE OUTCOME OF THE EVENT INTRAUTERINE PREGNANCY WAS NOT RECOVERED / NOT RESOLVED. FOLLOW-UP RECEIVED ON 14-JAN-2015 FROM PHYSICIAN. THE PHYSICIAN (WHO IS NOT THE PHYSICIAN RESPONSIBLE FOR ESSURE INSERTION) REPORTED THAT THE PATIENT WAS SEEN AT THE OFFICE IN THE BEGINNING OF (B)(6) 2015 AND SHE WAS 12 WEEKS PREGNANT AT THAT TIME. NO FURTHER INFORMATION PROVIDED. FOLLOW UP 20.JAN.2015: PTC INVESTIGATION RESULTS WERE PROVIDED. (B)(4). FINAL ASSESSMENT: LOT NUMBERS A73761 AND B34805 ARE BOTH INVALID. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. FINAL RISK CLASSIFICATION: RISK CATEGORY V. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFECT PER SE. IN THIS PARTICULAR CASE, ALSO A TREATMENT NONCOMPLIANCE WAS

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REPORTED AS PATIENT DID NOT HAVE HSG CONFIRMATION TEST PERFORMED. ACCORDING TO THE RQU THE BATCH NUMBERS REFERRED BY THE AE CASE ARE INVALID BATCH NUMBERS, AND HENCE A BATCH INVESTIGATION IS NOT POSSIBLE. NO COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. NO VALID BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. ESSURE QUESTIONNAIRE RECEIVED ON 22-APR-2015 FROM PHYSICIAN: PHYSICIAN STATED THAT HE DID NOT PERFORM THE INSERTION PROCEDURE. HE ALSO DENIED ANY RELEVANT MEDICAL HISTORY, PREVIOUS GYNECOLOGICAL INTERVENTIONS OR CONCURRENT CONDITIONS OF PATIENT. SHE WAS GRAVIDA 2 AND PARA 1. PATIENT DID NOT EXPERIENCE SPONTANEOUS ABORTION, ELECTIVE ABORTION OR THERAPEUTIC ABORTION. SHE ALSO DID NOT HAVE ECTOPIC PREGNANCIES. PREGNANCY WAS CONFIRMED BY PHYSICIAN WITH A URINE TEST AND ULTRASOUND ON (B)(6) 2014, DATE OF PATIENT'S FIRST VISIT WITH HIM. THE PATIENT'S LAST MENSTRUATION PERIOD WAS (B)(6) 2014. THE EXPECTED DATE OF DELIVERY IS (B)(6) 2015. THE PATIENT EXPERIENCED PAIN ALONG WITH PREGNANCY. HER PLAN IS TO CONTINUE THE PREGNANCY AND DELIVERY. AT TIME OF THE REPORT, THE PATIENT WAS STILL PREGNANT AND HAD NO PLAN TO REMOVE THE DEVICES. FOLLOW UP 16-JUL-2015: NO NEW CLINICAL INFORMATION WAS PROVIDED. FOLLOW-UP DATED 17-JUL-2015: UPON FOLLOW UP WITH THE PHYSICIAN; PATIENT INITIALS WERE CONFIRMED AND PHYSICIAN CLARIFIED THAT REPORTED ONLY ONE CASE OF PREGNANCY WITH ESSURE. THE CASE (B)(4) WAS IDENTIFIED AS DUPLICATE OF THIS CASE. CASE (B)(4) WILL BE DELETED FROM BAYER DATABASE AND THE FOLLOWING INFORMATION WAS ADDED TO THIS REMAINING CASE: PHYSICIAN WOULD LIKE TO KNOW HOW TO PROCEED WITH A PREGNANT PATIENT, LIKELY TO DELIVER VIA C-SECTION, WITH ESSURE IN PLACE, WHO IS PRESENTING PELVIC PAIN AND DID NOT FOLLOW UP FOR ESSURE CONFIRMATION TEST BETWEEN PLACEMENT AND THE PREGNANCY. PTC INVESTIGATION RESULT RECEIVED ON 27-MAY-2015 FOR DUPLICATE CASE (B)(4) PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A LACK OF EFFICACY. CONTRACEPTIVE FAILURE MAY OCCUR UNDER THE USE OF ANY CONTRACEPTIVE AND IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. IN THIS PARTICULAR CASE, ALSO A TREATMENT NONCOMPLIANCE AS THE PATIENT DID NOT FOLLOW UP FOR HER ESSURE CONFIRMATION TEST WAS REPORTED. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WERE AVAILABLE FOR A TECHNICAL INVESTIGATION. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP INFORMATION RECEIVED ON 13-NOV-2015 FROM PHYSICIAN (CASE UPGRADED TO INCIDENT): ACCORDING TO THE REPORTER, DURING PREGNANCY, THE PATIENT EXPERIENCED PELVIC PAIN ON LEFT SIDE AND WAS TREATED WITH NARCOTICS. ON (B)(6) 2015, SHE DELIVERED A MALE LIVE BIRTH, SINGLETON VIA CESAREAN SECTION. THERE WERE NO FETAL ABNORMALITIES. GESTATIONAL AGE WAS (B)(6), BABY WEIGHT WAS (B)(6) GRAMS, APGAR SCORE (B)(6). ACCORDING TO OPERATIVE REPORT NOTES, PATIENT'S PREOPERATIVE/POSTOPERATIVE DIAGNOSES INCLUDED PRETERM PREMATURE RUPTURE OF MEMBRANES AND MARGINAL PLACENTA PREVIA. THE PROCEDURES WERE PERFORMED UNDER EPIDURAL ANAESTHESIA AND INCLUDED PRIMARY LOW TRANSVERSE CESAREAN SECTION VIA PFANNENSTIEL; BILATERAL SALPINGECTOMY AND REMOVAL OF ESSURE COIL FROM PELVIC SIDEWALL AND SIGMOID COLON HAUSTRA BY A GENERAL SURGEON (WITH MINIMAL DIFFICULTY). DURING THE SURGERY, IT WAS FOUND

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ESSURE COIL HAD PERFORATED THE LEFT TUBE AND WAS NOTED TO BE EMBEDDED IN THE PERITONEAL SURFACE ALONG THE ANTERIOR BROAD LIGAMENT ON THE LEFT SIDE. IT EXTENDED DOWNWARD OVER THE IP LIGAMENT (SUSPENSORY LIGAMENT OF THE OVARY) INTO THE PELVIC SIDE WALL AND INTO THE HAUSTRA OF THE SIGMOID COLON. SIGNS OR SYMPTOMS OF INFECTION WERE DENIED. THE COIL WAS REMOVED AND PATIENT'S PAIN RESOLVED. THE PHYSICIAN CONSIDERED THE EVENTS RELATED TO ESSURE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED CASE REPORT REFERS A FEMALE PATIENT WHO BECAME PREGNANT AFTER ESSURE INSERTION. SHE HAD MARGINAL PLACENTA PREVIA AND PRETERM PREMATURE RUPTURE OF MEMBRANES AND DELIVERED A HEALTHY BABY AT (B)(6) GESTATION VIA CESAREAN SECTION. DURING THIS SURGERY, ESSURE WAS FOUND PERFORATED THE LEFT TUBE. A SALPINGECTOMY WAS PERFORMED; THE DEVICE WAS REMOVED AND PATIENT RECOVERED. ONLY PREGNANCY AND FALLOPIAN TUBE PERFORATION ARE LISTED IN ESSURE REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST (HSG) TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, THE PATIENT DID NOT PERFORM HSG. AFTER DELIVERY, ESSURE WAS FOUND PERFORATED IN LEFT SIDE. THIS FALLOPIAN TUBE PERFORATION IN ASSOCIATION WITH NON-COMPLIANT USE COULD BE ALTERNATIVE EXPLANATIONS FOR THE REPORTED DEVICE FAILURE. NEVERTHELESS, GIVEN EVENTS NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. REGARDING THE REMAINING EVENTS, PLACENTA PREVIA REFERS TO THE PRESENCE OF PLACENTAL TISSUE THAT EXTENDS OVER OR LIES PROXIMATE TO THE INTERNAL CERVICAL OS. ITS SEQUELAE INCLUDE POTENTIAL FOR BLEEDING AND PRETERM BIRTH; IT HAS ALSO BEEN ASSOCIATED WITH AN INCREASED RISK OF PREMATURE RUPTURE OF MEMBRANES. CONSIDERING WHEN ESSURE IS IN ITS IDEAL POSITION, 3 TO 8 OUTER COIL WILL BE TRAILING INTO THE UTERUS AND GIVEN THE GESTATIONAL AGE AT THE TIME OF EVENTS' OCCURRENCE; A MECHANICAL INTERFERENCE BETWEEN THE DEVICE AND THE PREGNANCY CANNOT BE EXCLUDED. THEREFORE, THESE EVENTS WERE CONSIDERED AS RELATED TO THE SUSPECT DEVICE. SINCE A SURGICAL INTERVENTION WAS REQUIRED AS EVENTS TREATMENT; THIS CASE WAS REGARDED AS AN INCIDENT. THE TECHNICAL INVESTIGATION CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 23-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: LOT NUMBERS A73761 AND B34805

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01871	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2013
Explant Date (E7): 10/8/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

INCIDENT. ANTICIPATED. SERIOUS INJURY. REQUIRED INTERVENTION THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY IN UNITED STATES ON 12-OCT-2015 (CASE# MW5044387). THE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED IN 2013, AND HAD BEEN HAVING LOTS OF HEALTH PROBLEMS DUE TO THE IMPLANT SUCH AS BACK PAIN, PELVIC PAIN, VERY BAD HEADACHES, NAUSEA, AND ABNORMAL PAP. SHE STATED SHE NEVER HAD ANY OF THOSE PROBLEMS BEFORE ESSURE IMPLANTATION. ALL HER PAP SMEARS WERE NORMAL. SHE HAD BEEN TOLD THAT WAS THE BEST THING TO GET DONE INSTEAD OF SURGERY AFTER SHE HAD HER THIRD CHILD, BUT NOW SHE WAS NOT SO SURE. SHE USED REMEDIAL DRUG IBUPROFEN 800MG THREE TIMES A DAY. FOLLOW-UP RECEIVED ON 11-NOV-2015: CONSUMER CONFIRMED HER DATE OF BIRTH AND ADDRESS. SHE STATED SHE DID NOT HAVE THE LOT NUMBER WITH HER. ON (B)(6) 2015 CONSUMER WENT IN A PARTIAL HYSTERECTOMY TO HAVE THEM (ESSURE) REMOVED. SHE WAS (B)(6) AT THE HYSTERECTOMY. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT WAS RECEIVED ON 25-NOV-2015: THE PTC GLOBAL REFERENCE NUMBER IS (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE

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THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PELVIC PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE UNDERWENT A HYSTERECTOMY TO HAVE THE DEVICE REMOVED. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. IN THIS CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS UPGRADED TO INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY REPORTED UPON FOLLOW-UP). BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01886	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM GREAT BRITAIN WAS DERIVED FROM MEDICAL LITERATURE ON 13-NOV-2015 , ARTICLE ENTITLED "ESSURE?". IT REFERS TO A PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR TUBAL STERILISATION. ONE PATIENT OUT OF 216 (2.8%) PATIENTS WHO HAD UNDERGONE ESSURE HYSTEROSCOPIC STERILIZATION REQUIRED FURTHER MANAGEMENT. THE FEMALE PATIENT EXPERIENCED POST-PROCEDURAL PAIN. SHE UNDERWENT BILATERAL SALPINGECTOMY AND REMOVAL OF ESSURE DEVICE AND WAS DIAGNOSED WITH ENDOSALPINGIOSIS ON HISTOLOGY OF THE FALLOPIAN TUBES. THE DEVICE WAS CORRECTLY PLACED. ABSTRACT: BACKGROUND FIVE YEARS AFTER INTRODUCTION OF ESSURE INTO OUR UNIT OUR OBJECTIVE IS TO REVIEW THE REASON FOR PATIENTS REQUIRING OR REQUESTING FURTHER TREATMENT FOLLOWING PLACEMENT OF ESSURE. METHODS A RETROSPECTIVE REVIEW OF 216 PATIENTS OVER A 60-MONTH PERIOD IN A DISTRICT GENERAL HOSPITAL BY TWO MINIMAL ACCESS SURGEONS. ALL PATIENTS WHO HAD UNDERGONE ESSURE HYSTEROSCOPIC STERILISATION WERE INCLUDED. CASES WERE IDENTIFIED FROM OPERATIVE LOG COMPLEMENTED BY CHART REVIEW. ANY PATIENTS WHO WERE NOT DISCHARGED AFTER THEIR 3 MONTH IMAGING TO CONFIRM DEVICE PLACEMENT WERE REVIEWED. RESULTS SIX OUT OF 216 (2.8%) PATIENTS WHO HAD UNDERGONE ESSURE HYSTEROSCOPIC STERILIZATION REQUESTED OR REQUIRED FURTHER MANAGEMENT. ALL SIX PATIENTS HAD THE DEVICES CORRECTLY PLACED. TWO PATIENTS HAD POST PROCEDURE PAIN. BOTH PATIENTS SUBSEQUENTLY HAD BILATERAL SALPINGECTOMY AND REMOVAL OF ESSURE DEVICE. ENDOSALPINGIOSIS WAS DIAGNOSED ON HISTOLOGY OF THE FALLOPIAN TUBES OF ONE PATIENT. THE SECOND PATIENT HAD HISTOLOGY REVEALING NO ALLERGIC REACTION AND FIBROSIS OF THE FALLOPIAN TUBES. TWO PATIENTS UNDERWENT SUBSEQUENT LAPAROSCOPIC STERILISATION WITH FILSHIE CLIPS. ONE PATIENT FOR MIGRATION OF ONE OF THE ESSURE DEVICES THE SECOND FOR FAILURE

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OF THE HYSTEROSALPINGOGRAM TO CONFIRM TUBAL BLOCKAGE. TWO PATIENTS PRESENTED FOLLOWING MEDIA COVERAGE PERFORMED SEVERAL YEARS EARLIER. ONE PATIENT IS AWAITING HYSTERECTOMY AND THE OTHER PATIENT HAS BEEN DEEMED NOT SUITABLE FOR FURTHER SURGICAL MANAGEMENT DUE TO RAISED BMI. CONCLUSIONS ESSURE PROVIDES A SAFE ALTERNATIVE TO LAPAROSCOPY IN THE MAJORITY OF CASES. A MINORITY OF PATIENTS WILL REQUIRE FURTHER TREATMENT FOR PAIN AND FAILURE TO CONFIRM STERILISATION. THE IMPORTANCE OF PREOPERATIVE COUNSELING HAS BEEN HIGHLIGHTED IN OUR REVIEW BY THE TWO PATIENTS WHO HAVE CHANGED THEIR MIND FOLLOWING EVENTS IN THE MEDIA. CASES DERIVED FROM THE PUBLICATION INCLUDE (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICAL LITERATURE CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD POST-PROCEDURAL PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBSEQUENTLY SUBMITTED TO BILATERAL SALPINGECTOMY WITH DEVICE REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THIS CASE, CONSUMER DEVELOPED PAIN IN CLOSE ASSOCIATION WITH ESSURE PROCEDURE AND WAS SUBMITTED TO A BILATERAL SALPINGECTOMY. HER HISTOLOGY REPORT REVEALED ENDOSALPINGIOSIS. ENDOSALPINGIOSIS IS ALMOST ALWAYS AN INCIDENTAL FINDING IN PATHOLOGY REPORTS. IT IS A BENIGN CONDITION IN WHICH THE FALLOPIAN TUBE-LIKE EPITHELIUM IS FOUND OUTSIDE THE FALLOPIAN TUBE. IN CONTRAST WITH ENDOMETRIOSIS, THERE ARE NO SIGNIFICANT LINKS BETWEEN CHRONIC PELVIC PAIN AND ENDOSALPINGIOSIS. CONSIDERING THIS INFORMATION AND GIVEN THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN PATIENT'S PAIN AND ESSURE THERAPY, CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. SINCE DEVICE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 14-DEC-2015: (B)(4). FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01887	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** UK

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 13-NOV-2015 , ARTICLE ENTITLED "ESSURE?". IT REFERS TO A PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR TUBAL STERILISATION AND EXPERIENCED POST-PROCEDURAL PAIN. ONE PATIENT OUT OF 216 (2.8%) PATIENTS WHO HAD UNDERGONE ESSURE HYSTEROSCOPIC STERILIZATION REQUIRED FURTHER MANAGEMENT. THE FEMALE PATIENT EXPERIENCED POST-PROCEDURAL PAIN AND HAD SUBSEQUENTLY HAD BILATERAL SALPINGECTOMY AND REMOVAL OF ESSURE DEVICE. THE HISTOLOGY DID NOT REVEAL ALLERGIC REACTION AND FIBROSIS OF THE FALLOPIAN TUBES. THE DEVICE WAS CORRECTLY PLACED. ABSTRACT: BACKGROUND: FIVE YEARS AFTER INTRODUCTION OF ESSURE INTO OUR UNIT OUR OBJECTIVE IS TO REVIEW THE REASON FOR PATIENTS REQUIRING OR REQUESTING FURTHER TREATMENT FOLLOWING PLACEMENT OF ESSURE. METHODS A RETROSPECTIVE REVIEW OF 216 PATIENTS OVER A 60-MONTH PERIOD IN A (B)(6) HOSPITAL BY TWO MINIMAL ACCESS SURGEONS. ALL PATIENTS WHO HAD UNDERGONE ESSURE HYSTEROSCOPIC STERILISATION WERE INCLUDED. CASES WERE IDENTIFIED FROM OPERATIVE LOG COMPLEMENTED BY CHART REVIEW. ANY PATIENTS WHO WERE NOT DISCHARGED AFTER THEIR 3 MONTH IMAGING TO CONFIRM DEVICE PLACEMENT WERE REVIEWED. RESULTS SIX OUT OF 216 (2.8%) PATIENTS WHO HAD UNDERGONE ESSURE HYSTEROSCOPIC STERILIZATION REQUESTED OR REQUIRED FURTHER MANAGEMENT. ALL SIX PATIENTS HAD THE DEVICES CORRECTLY PLACED. TWO PATIENTS HAD POST PROCEDURE PAIN. BOTH PATIENTS SUBSEQUENTLY HAD BILATERAL SALPINGECTOMY AND REMOVAL OF ESSURE DEVICE. ENDOSALPINGIOSIS WAS DIAGNOSED ON HISTOLOGY OF THE FALLOPIAN TUBES OF ONE PATIENT. THE SECOND PATIENT HAD HISTOLOGY REVEALING NO ALLERGIC REACTION AND FIBROSIS OF THE FALLOPIAN TUBES. TWO PATIENTS UNDERWENT SUBSEQUENT LAPAROSCOPIC STERILISATION WITH FILSHIE CLIPS. ONE PATIENT FOR

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MIGRATION OF ONE OF THE ESSURE DEVICES THE SECOND FOR FAILURE OF THE HYSTEROSALPINGOGRAM TO CONFIRM TUBAL BLOCKAGE. TWO PATIENTS PRESENTED FOLLOWING MEDIA COVERAGE PERFORMED SEVERAL YEARS EARLIER. ONE PATIENT IS AWAITING HYSTERECTOMY AND THE OTHER PATIENT HAS BEEN DEEMED NOT SUITABLE FOR FURTHER SURGICAL MANAGEMENT DUE TO RAISED BMI. CONCLUSIONS: ESSURE PROVIDES A SAFE ALTERNATIVE TO LAPAROSCOPY IN THE MAJORITY OF CASES. A MINORITY OF PATIENTS WILL REQUIRE FURTHER TREATMENT FOR PAIN AND FAILURE TO CONFIRM STERILISATION. THE IMPORTANCE OF PREOPERATIVE COUNSELING HAS BEEN HIGHLIGHTED IN OUR REVIEW BY THE TWO PATIENTS WHO HAVE CHANGED THEIR MIND FOLLOWING EVENTS IN THE MEDIA. (B)(4). COMPANY CAUSALITY COMMENT: THIS MEDICAL LITERATURE CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD POST-PROCEDURAL PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBSEQUENTLY SUBMITTED TO BILATERAL SALPINGECTOMY WITH DEVICE REMOVAL. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR AFTER ESSURE INSERTION. IN THIS CASE, THE PATIENT DEVELOPED PAIN IN CLOSE ASSOCIATION WITH ESSURE PROCEDURE. ALTHOUGH THE HISTOLOGY REPORT DID NOT REVEAL SIGNS OF AN ALLERGIC REACTION TO ESSURE AND THE COILS WERE FOUND IN CORRECT PLACE; CONSIDERING EVENT'S NATURE AND THE POSITIVE TEMPORAL RELATIONSHIP WITH DEVICE THERAPY, CAUSALITY WITH THE SUSPECT DEVICE CANNOT BE EXCLUDED. SINCE DEVICE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 14-DEC-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4). FINAL ASSESSMENT: FOR CASES

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01888	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE REPORT FROM (B)(6) WAS DERIVED FROM MEDICAL LITERATURE ON 13-NOV-2015, ARTICLE ENTITLED, THE AETIOLOGY OF SURGERY FOR PELVIC PAIN FOLLOWING PLACEMENT OF THE ESSURE PERMANENT BIRTH CONTROL SYSTEM. IT REFERS TO A PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SALPINGITIS. OF THE 27 (1.8 PERCENT) REPORTING NEW ONSET PAIN 15 (1 PERCENT) HAD PATHOLOGY CONSISTENT WITH THE DIAGNOSIS AT THE SECOND SURGERY. IN THE REMAINING 12 (0.8 PERCENT) PATIENTS WITH NEW ONSET PAIN, 8 (0.6 PERCENT) WERE RELATED TO THE ESSURE INSERT, WITH A PERFORATION/MIGRATION NOTED IN 7 AND BILATERAL SALPINGITIS IN 1. BACKGROUND: THE OBJECTIVE OF THIS STUDY WAS TO DETERMINE THE CAUSE NECESSITATING SURGICAL REMOVAL OF THE ESSURE INSERTS. IT WAS COMPLETED BY ANALYSIS OF AN IMAGING DATABASE, PATHOLOGY REPORTS, OPERATIVE NOTES AND PATIENT HISTORY TO DETERMINE THE INCIDENCE OF DE NOVO PAIN THAT RESOLVED WITH REMOVAL OF THE INSERTS. METHODS: A PROSPECTIVE DATABASE OF ALL PATIENTS (N=1430) UNDERGOING POST ESSURE IMAGING WAS INITIATED IN 2002. THE HEALTH RECORDS OF ALL WOMEN IN THE DATABASE WERE SEARCHED FOR THE TERMS SALPINGECTOMY, TOTAL LAPAROSCOPIC HYSTERECTOMY, LAPAROSCOPIC SUBTOTAL HYSTERECTOMY, ABDOMINAL HYSTERECTOMY, VAGINAL HYSTERECTOMY AND ADNEXAL SURGERY. THE CHARTS OF THOSE HAVING SURGERY SUBSEQUENT TO THEIR ESSURE PLACEMENT WERE REVIEWED FOR THE TYPE OF SURGERY, INDICATION, IMAGING RESULTS AFTER ESSURE PLACEMENT, SURGICAL PATHOLOGY AND RESOLUTION OF SYMPTOMS. RESULTS: A TOTAL OF 1430 PATIENTS HAD ESSURE INSERTS PLACED WITH POST PLACEMENT IMAGING BETWEEN JUNE 2002 AND JUNE 2013. A TOTAL OF 62 (4.3 PERCENT) SUBSEQUENT SURGERIES INVOLVED REMOVAL OF THE FALLOPIAN TUBES AND ESSURE INSERTS. OF THE 62 PATIENTS WHO HAD POST-PLACEMENT SURGERY, 24 (1.6 PERCENT) HAD SURGERIES NOT RELATED TO

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PAIN. 38 (2.7 PERCENT) PATIENTS REPORTED EITHER NEW ONSET OR WORSENING PRE-EXISTING PAIN AFTER ESSURE PLACEMENT. OF THE 27 (1.8 PERCENT) REPORTING NEW ONSET PAIN 15 (1 PERCENT) HAD PATHOLOGY CONSISTENT WITH THE DIAGNOSIS AT THE SECOND SURGERY. IN THE REMAINING 12 (0.8 PERCENT) PATIENTS WITH NEW ONSET PAIN, 8 (0.6 PERCENT) WERE RELATED TO THE ESSURE INSERT, WITH A PERFORATION/MIGRATION NOTED IN 7 AND BILATERAL SALPINGITIS IN 1. FOUR (0.3 PERCENT) PATIENTS HAD A NORMAL PLACEMENT AND NO PATHOLOGY NOTED AT THE SECOND SURGERY. THESE FOUR PATIENTS WERE THOSE WHERE THE MOST LIKELY SOURCE OF THE NEW ONSET PAIN WAS THE ESSURE INSERT, ALL IMPROVED WITH REMOVAL OF THE INSERTS. CONCLUSIONS THE MAJORITY OF SECOND SURGERIES AFTER ESSURE PLACEMENT WERE ASSOCIATED WITH A DIAGNOSIS THAT EXPLAINS THE NEW ONSET OR WORSENING PAIN. LATER ONSET PAIN IS ASSOCIATED WITH A DEMONSTRABLE CAUSE THAT WILL NOT RESOLVE WITH SALPINGECTOMY OR CORNUECTOMY. ANY NEW ONSET PAIN OR WORSENING PRE-EXISTING PAIN DEVELOPING AFTER ESSURE PLACEMENT SHOULD BE EVALUATED AS WITH ANY SIMILAR PAIN, AND ATTRIBUTED SOLELY TO THE ESSURE INSERT. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS DERIVED FROM MEDICAL LITERATURE AND REFERS TO A FEMALE PATIENT WHO WAS SUBMITTED TO SURGICAL REMOVAL OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTS AND BILATERAL SALPINGITIS WAS DIAGNOSED. THIS EVENT IS LISTED ACCORDING TO THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES (SALPINGITIS) AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER THE INSERTION PROCEDURE. IN THIS PARTICULAR CASE, THE PATIENT DEVELOPED PAIN AFTER ESSURE PROCEDURE AND THE DEVICE WAS SURGICALLY REMOVED. THE AUTHOR CONSIDERED PATIENT'S PAIN AS RELATED TO ESSURE SINCE A SALPINGITIS WAS DIAGNOSED WITH THE SURGERY. ALTHOUGH THE TEMPORAL RELATIONSHIP BETWEEN ESSURE PLACEMENT AND THE EVENT WAS NOT GIVEN; CONSIDERING ITS NATURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (SURGICAL INTERVENTION PERFORMED). A PRODUCT TECHNICAL ANALYSIS HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01896	BAYER HEALTHCARE LLC	12/7/2015	12/7/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A20056

Single Use: Y
Implant Date (E6): 8/7/2012
Explant Date (E7): 11/9/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A CLINICAL STUDY CASE REPORT RECEIVED FROM AN INVESTIGATOR IN UNITED STATES ON 12-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN A INTERVENTIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: USE OF TRANSVAGINAL ULTRASOUND TO CONFIRM ESSURE MICRO-INSERT PLACEMENT IN WOMEN: DEMONSTRATION OF EFFECTIVENESS. PATIENT NUMBER: (B)(6). HER LAST MENSTRUAL PERIOD OCCURRED ON (B)(6) 2012. ON (B)(6) 2012, ESSURE 305 WAS INSERTED WITH LOT NUMBER A20056 UNDER LOCAL ANESTHESIA. PREGNANCY TEST (URINE) WAS DONE BEFORE INSERTION AND RESULT WAS NEGATIVE. SHE RECEIVED TORADOL 60 MG IM PRIOR TO PROCEDURE. BOTH TUBAL OSTIUM WERE VISUALIZED DURING PROCEDURE WHICH TOOK 5 MINUTES. AFTER INSERTION, 1 COIL WAS SEEN ON LEFT SIDE AND 3 ON RIGHT SIDE. SUCCESS BILATERAL PLACEMENT WAS REPORTED. IT WAS REPORTED THAT IUD WAS REMOVED AFTER ESSURE PROCEDURE; STEM WAS SITTING IN CERVICAL CANAL. IN (B)(6) 2012 THE PATIENT EXPERIENCED MODERATE PELVIC PAIN. IN (B)(6) 2015 THE PATIENT EXPERIENCED SEVERE MENORRHAGIA AND SEVERE ABDOMINAL BLOATING. ON (B)(6) 2015 PATIENT WAS SEEN BY PHYSICIAN WITH COMPLAINT OF PELVIC PAIN, HEAVIER BLEEDING AND REQUESTING ESSURE DEVICES REMOVED. PATIENT ALSO EXPRESSED CONCERN OF CANCER DUE TO FAMILY HISTORY. DEVICES WERE REMOVED ON (B)(6) 2015. THE OUTCOME OF THE EVENTS WAS REPORTED AS UNKNOWN. ALL EVENTS WERE CONSIDERED POSSIBLE RELATED TO ESSURE BY INVESTIGATOR. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 25-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE

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CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE KNOWN, POSSIBLE, UNDESIRABLE EVENTS AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR ADVERSE EVENT CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. NO BATCH TREND COULD BE IDENTIFIED. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE SUBJECT WHO WAS INVOLVED IN AN INTERVENTIONAL COMPANY SPONSORED STUDY (STUDY NUMBER: (B)(4)). SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) REMOVED (APPROXIMATELY 3 YEARS AFTER DEVICE PLACEMENT) DUE TO PELVIC PAIN, MENORRHAGIA AND ABDOMINAL BLOATING. THESE EVENTS ARE LISTED ACCORDING TO THE INVESTIGATOR'S BROCHURE. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES, PELVIC PAIN AND ABDOMINAL BLOATING MAY OCCUR. IN THIS CASE, THE INVESTIGATOR CONSIDERED THE EVENTS AS POSSIBLE RELATED TO THE SUSPECT DEVICE. CONSIDERING THEIR NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; COMPANY AGREES WITH INVESTIGATOR'S ASSESSMENT. SINCE DEVICE REMOVAL WAS REQUIRED (INTERVENTION IMPLIED); THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 12-NOV-2015 NO NEW CLINICAL INFORMATION RECEIVED. FOLLOW-UP INFORMATION RECEIVED ON 15-DEC-2015: PATIENT ELECTED TO HAVE INSERTS REMOVED BECAUSE OF ADVERSE EVENTS. PATIENT COMPLAINED OF BLOATING, HEAVY CRAMPING AND BLEEDI

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058318	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE PROCEDURE DONE IN (B)(6) 2012 AND ABOUT A MONTH OR TWO AFTER I HAD CONSTANT PAIN AND HEAVY BLEEDING BUT FIGURED THAT IT WAS JUST MY BODY GETTING USED TO IT AND THE FACT I HAD JUST HAD MY 2ND CHILD IN(B)(6) THAT YEAR. BY (B)(6) 2013 THE SYMPTOMS WERE AND ARE STILL CONSTANT I HAVE PAIN THE THOSE AREAS ALL THE TIME AND A WEEK OR SO BEFORE MY CYCLE THE PAIN IS ALMOST UNBEARABLE, THE BLEEDING WITH MY CYCLE IS SO HEAVY NOW THAT EVEN WITH A SUPER PLUS TAMPON AND HEAVY MAXI I OVER FLOW IN 20-30 MINUTES SO I TRY NOT TO LEAVE THE HOUSE ON THOSE DAYS BUT IT IS NOT EASY TO MISS WORK SO WHEN I DO LEAVE I FEEL LIKE IM A BABY BECAUSE I HAVE TO PACK A BAG WITH CHANGES OF CLOTHES AND A BOX OF TAMPONS AND A BAG OF PADS. DR'S ARE NOT CHEAP AND I DID NOT HAVE INSURANCE FOR SEVERAL YEARS BECAUSE MY JOB DID NOT OFFER IT AND I MADE TOO MUCH TO QUALIFY FOR STATE INSURANCE. SO FINALLY EARLIER THIS YEAR I WAS ABLE TO GO SEE MY OBGYN FOR MY YEARLY EXAM AND I EXPLAINED WHAT WAS GOING ON AND HIS SOLUTION WAS PRESCRIBING BIRTH CONTROL PILLS.. FOUR MONTHS LATER THE SYMPTOMS ARE STILL THERE AND NOT GOING AWAY. I'M IN THE PROCESS OF TRYING TO GET ANOTHER APPOINTMENT SCHEDULED WITH HIM AT THIS POINT BECAUSE I NEED SOMETHING TO BE DONE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058319	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 4/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A YEAR AFTER ESSURE WAS INSERTED I STARTED HAVING BACK PAIN, HEAVY AND PAINFUL MENSTRUAL CYCLES, IRREGULAR MENSTRUAL CYCLES, CYST ON MY OVARIES AND UTERUS, WEIGHT GAIN, FATIGUE, DEPRESSION, BRAIN FOG, JOINT PAIN, HAIR LOSS, ACNE, RASHES, AND PAINFUL INTERCOURSE. MY DEVICE WAS PROVIDED BY MY GYN AT THE TIME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058320	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ON (B)(6) 2015 I HAD ESSURE IMPLANTED. I SHOULD HAVE KNOWN FROM THE START IT WAS GOING TO BE A NIGHTMARE. AFTER I WAS GIVEN LOCAL ANESTHESIA, PROCEDURE WAS SUPPOSED TO TAKE PLACE 30 MINUTES AFTER. IT WAS NOT DONE TILL ABOUT AN HOUR AND A HALF LATER BECAUSE 1: THE REP. WHO WAS HELPING THE DR, DECIDED TO GO HAVE LUNCH, AND 2: MY OBGYN WASN'T IN THE OFFICE YET! SO THEY PERFORMED THE PROCEDURE WITH OUT THE ANESTHESIA BECAUSE IT HAD WORN OFF! DESPITE THE TROUBLE THEY HAD WITH THE PLACEMENT, AND THE EXCRUCIATING PAIN I WAS IN, THEY PROCEEDED. I BLED FOR 6 MONTHS AFTER, ONLY TO BE TOLD OVER AND OVER, IT WAS PART OF THE PROCESS. I THEN STARTED TO GAIN EXCESSIVE AMOUNTS OF WEIGHT, (B)(6) SO FAR TO BE EXACT. I HAVE HYPERTENSION NOW, ON MEDICATION FOR THAT, I'VE NEVER HAD ANY HEALTH ISSUES PRIOR TO THIS. I HAVE EXTREME JOINT PAIN THROUGHOUT MY ENTIRE BODY. I'M DEPRESSED, MY SKIN HAS BROKEN OUT WITH ACNE, MY SEX DRIVE IS NOTHING!! MY STOMACH IS CONSTANTLY BLOATED AND TENDER. I LOOK LIKE I'M (B)(6)!!! I HAVE TROUBLE WALKING ON A DAILY BASIS, I FEEL LIKE I'M GOING THROUGH MENOPAUSE. I'VE HAD LAB WORK TO DETERMINE IF I WAS OR NOT AND I AM NOT. NO ONE CAN FIGURE OUT WHAT IS WRONG WITH ME. I KNOW MY BODY, AND THIS ISN'T ME. I WANT MY LIFE BACK, MY DAUGHTER WANTS HER MOMMY BACK!!!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058321	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 12/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ESSURE SIDE EFFECTS, BLOATING, WEIGHT GAIN, CONTACT DERMATITIS , ACNE, PELVIC PAIN, ACHING IN HIPS, LOWER BACK ACHE, FATIGUE, DIZZINESS, EYE SIGHT CHANGES, HIGH LEVELS OF RA FACTORS IN BLOOD, HEAVY BLEEDING, DISCHARGE, HEADACHES, MIGRAINES, IMPLANTATION WAS COVERED BY INSURANCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058322	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 10/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVING EXPLORATORY SURGERY (B)(6). THEY ARE TAKING LEFT OVARY AND ESSURE COIL AND POSSIBLE UTERUS AND POSSIBLY RIGHT ESSURE COIL. STILL HAVING PELVIC PAIN. THEY HOPE THE SURGERY WILL ALLEVIATE THE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058323	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 12/27/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONE WEEK AFTER ESSURE I'D GAINED (B)(6) AND PASSING SOME SIZE BLOOD CLOTS. HEAVY LONG LASTING PERIODS AND PAIN NECESSITATED AN ABLATION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058324	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 9/30/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE I'VE HAD ESSURE IMPLANTS MY BODY HAS SUFFERED DEARLY, MENTALLY, PHYSICALLY, EMOTIONALLY. DAILY HEADACHES, MIGRAINES, FATIGUE, MASSIVE WEIGHT GAIN, DAILY ABDOMINAL PAIN, STABBING PAINS IN VAGINAL OPENING, BOWEL PROBLEMS, URGENCY TO URINATE, VAGINAL ODOR, BRAIN FOG/ MEMORY LOSS, DRY SKIN, HAIR HAS THINNED OUT BY HANDFULS, LOSS OF SEX DRIVE, DENTAL PROBLEMS, CYSTS ON MY OVARIES THAT HAVE ERUPTED AND CAUSED MANY DOCTOR AND ER VISITS. THIS IS ONLY A FRACTION OF THE PROBLEMS SINCE I'VE HAD ESSURE IMPLANTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058325	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 4/30/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ONGOING - HEAVY BLEEDING, SPOTTING, BACK PAIN, BLOATING, HEADACHES, DIZZINESS, PELVIC PAIN, CRAMPING, WEIGHT GAIN, SWELLING OF FEET.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058326	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 8/16/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PUT IN AFTER HAVING TWO CHILDREN. (B)(6) PAID FOR THIS PROCEDURE. AFTER BEING DROPPED BY MY DOCTOR WITHOUT WARNING HE NEVER DID A FOLLOW UP TO MAKE SURE PRODUCT WAS PROPERLY IN PLACE. AFTER GOING TO EMERGENCY ROOM A WEEK LATER AND TAKING (B)(6) THOSE RESULTS TO THAT DOCTOR HE SAID I WAS FINE. TWO YEARS AFTER HAVING ESSURE PUT IN PLACE IN (B)(6) OF 2009, 2011 I BECAME PREGNANT WITH A SON WHO WAS ENCASED BY THE ESSURE COILS. AS A RESULT I WAS INDUCED INTO LABOR BECAUSE THE COILS WERE AFFECTING MY SON'S HEARTRATE. I DELIVERED A HEALTHY BOY THEN HAD MY TUBES CLAMPED SHORTLY AFTER FOLLOWED BY A MEDICAL EMERGENCY HYSTERECTOMY BECAUSE ONE COIL SAT ON A MAJOR ARTERY AND ALL THE REST OF THE PIECES MIGRATED INTO MY LOWER EXTREMITIES. AFTER HAVING A HYSTERECTOMY I WAS SENT HOME TO RECOVER THEN FORCED TO COME RIGHT BACK THE SAME DAY DUE TO GETTING E-COLI AND GOING IN FOR A SECOND SURGERY TWO DAYS AFTER HAVING THE HYSTERECTOMY. THE ESSURE IS A DANGEROUS UNPREDICTABLE PROCEDURE THAT IS NOT NECESSARY BY ANY MEANS AND UNSAFE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058327	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 12/12/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THIS WAS PROVIDED BY MY INSURANCE, WAS RECOMMENDED BY MY OBGYN. I HAVE LOW BLOOD PRESSURE AND LYME DISEASE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058328	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 10/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WEIGHT GAIN, LOSS OF HAIR, JOINT AND BODY PAIN, PELVIC PAIN, RASHES, BLOATING, DISCHARGE, AND ALLERGIC REACTION. PROVIDED BY INSURANCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058329	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 11/2/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE ON APPROXIMATELY (B)(6) 2009. I FORGET THE EXACT DATE. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. MY LOT NUMBER IS 664437 AND MODEL NUMBER IS ESS305. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. I HAD MY THIRD BABY (B)(6) 2009. MY HUSBAND WAS SCHEDULED FOR TWO WEEK RANDAMP;R, HE DEPLOYED TO (B)(6) A MONTH PRIOR TO MY DUE DATE. WE DIDN'T WANT ANYMORE BABIES. I WAS GOING TO GO BACK ONTO THE IUD MIRENA. I WAS TALKED INTO THE ESSURE BY MY PHYSICIAN AT (B)(6) MEDIAL CENTER. I WAS NERVOUS ABOUT STERILIZATION BECAUSE I WAS 1800 MILES AWAY FROM FAMILY AND FAMILY HAD JUST FLOWN IN TO HELP ME FOR A COUPLE OF WEEKS PROCEEDING THE BIRTH. I DECIDED TO GO WITH ESSURE BECAUSE IT WAS BROUGHT TO ME THAT IT WOULD BE HARMLESS. AT FIRST I WAS HAPPY WITH ESSURE BUT THEN I STARTED TO GET BAD MIGRAINE. I STARTED TO HAVE SEVERE BLEEDING THAT CONSISTED OF NON-STOP MENSTRUAL CYCLE LASTING FOR MONTHS STOPPING ABOUT A DAY THEN STARTING FOR MONTHS AGAIN. I HAD SEVERE PAIN ALL THE TIME. I HAD TO TAKE 1600 MG OF TYLENOL TO COPE WITH THE PAIN, I HAD TO KEEP A HEATING PAD ON MY PELVIC AREA ALL DAY AND NIGHT TO HELP. NOTHING TRULY HELPED. BECAUSE OF THE BLOOD LOSS, I STARTED HAVING DEPRESSION AND OUT OF BODY EXPERIENCES FROM MY BODY BEING ALL OUT OF SORTS FROM THE BLOOD LOSS. I ENDED UP WITH REALLY AWFUL CONSTIPATION, NOT SURE WHAT HAPPENED BUT NEVER HAD ANY TYPE OF BOWEL ISSUES PRIOR TO THIS. I HAD BAD BLOATING, FIGURED FROM CONSTIPATION. FINALLY VALENTINE'S DAY OF 2011 (B)(6) 2011 I HAD A PARTIAL HYSTERECTOMY. THE DOCTORS DID TEST AFTER TEST TO FIGURE OUT WHAT WAS WRONG WITH ME AND THEY DID THE HYSTERECTOMY HOPING THIS WOULD HELP. WELL, THAT HELPED WITH PELVIC PAIN AND BLEEDING. SINCE ALL OF THIS 2014 I STARTED HAVING AWFUL

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BLOATING AGAIN, I AM STILL SEVERELY CONSTIPATED. THE GI DOCTOR DID A COLONOSCOPY AND STATED, THERE IS NOTHING WRONG WITH MY COLON, BOWELS, INTESTINES ANYTHING LIKE THAT. HE SENT ME LAST WEEK FOR A CT SCAN WITH ORAL AND INTRAVENOUS CONTRAST BECAUSE OF MY SYMPTOMS OF SEVERE CONSTIPATION THAT LAXATIVES DO NOT EVEN HELP ANYMORE. I HAVE SEVERE BLOATING THAT I WILL NOT GAIN WEIGHT ON A SCALE BUT I HAVE TO BUY BIGGER PANTS BECAUSE MY STOMACH WILL BLOAT REALLY BADLY. MY ABDOMEN FEELS LIKE IT IS TWISTING IN KNOTS AND I AM DOUBLED OVER AND NOT ABLE TO WALK OR SIT. THE DOCTOR STATED THIS HAS TO BE ESSURE RELATED BECAUSE IT HAS NOTHING TO DO WITH MY GI SYSTEM.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058330	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 3/15/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HORRIBLE CRAMPS AND HEADACHES HAIR LOSS DENTAL ISSUES BACK PAIN PELVIC PAIN FLANK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058331	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 7/3/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING PELVIC PAIN RIGHT AWAY, BUT MOST OF THE SYMPTOMS DIDN'T BECOME PRONOUNCED UNTIL SOME ODD SYMPTOMS EMERGED IN 2011. THESE INCLUDED PELVIC PAIN, PAINFUL INTERCOURSE, INTERSTITIAL CYSTITIS, MIGRAINES, CHRONIC BODY ACHES, MENTAL FOGGINESS, AND POTS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058332	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVE SERVE BLOATING, CHRONIC PAIN DURING MY CYCLE, LEG PAIN, LOWER BACK PAIN AND PAIN IN MY LOWER STOMACH.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058333	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 12/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS PERFECTLY HEALTHY UNTIL I HAD ESSURE IMPLANTED IN 2013. BLOATING, CRAMPING, SEXUAL INTERCOURSE WAS PAINFUL. THEN LATER MY HAIR THINNED OUT AND WAS VERY UNHEALTHY, I STARTED TO HAVE PROBLEMS WITH MY TEETH AND WHAT I THINK ARE PAINFUL BOILS UNDER MY ARM PITS EVERY ONCE IN A WHILE. MY MENTAL CYCLE WAS SOMETIMES 3 WEEKS OUT OF THE MONTH AND VERY HEAVY, I ALSO HAD WHAT THE CALL AN EBELLY (MAKES YOU LOOKS PREGNANT BUT YOU AREN'T.). SO ON (B)(6) 2015, I HAD A HYSTERECTOMY TO GET ESSURE OUT OF ME. THAT WAS A FEW WEEKS AGO AND NOW THAT IT IS FINALLY OUT OF ME I FEEL GREAT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058334	BAYER	12/7/2015	12/7/2015

Event Information:

Event Date (B3): 10/27/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SWELLING, BLOATING, SKIN RASH ALL OVER MY BACK, LEGS AND ARM, PAIN IN MY STOMACH, MIGRAINES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058425		12/7/2015	12/10/2015

Event Information:

Event Date (B3): 3/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 3/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PLACED (B)(6) 2015. AS SOON AS A WEEK AFTER THE PROCEDURE, I WAS HAVING SEVERE CRAMPING AND HEAVY BLEEDING. I CALLED INTO MY DOCTOR'S OFFICE NUMEROUS TIMES COMPLAINING. I WS TOLD IT WOULD GO AWAY. ABOUT 3 WEEKS LATER, I FINALLY STOPPED BLEEDING, BUT HAVE BEEN IN PAIN EVER SINCE. THE CRAMPING IS WORSE DURING MY PERIOD OR OVULATION, BUT I HAVE SEVERE CRAMPING IN MY LOWER BACK ALL THE TIME. SOMETIMES I CAN'T EVEN STAND. MY DOCTOR HAS PRESCRIBED ME VICODIN FOR THE PAIN, WHICH RARELY HELPS. MY RIGHT HIP HURTS SO BAD. I CAN BARELY WALK. I WORK AT A DAYCARE, WHICH IS HARD, BECAUSE I'M HAVING TROUBLE KEEPING UP WITH THE CHILDREN.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01867	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2006
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044605) IN UNITED STATES ON 14-OCT-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006. CONSUMER EXPERIENCED PAIN DURING DAILY ACTIVITIES ON THE LEFT SIDE CONTINUALLY AND OVULATION WAS EXTREMELY PAINFUL AND HER BODY MIGHT BE REJECTING THE METAL IN THE DEVICE. SHE ASSESSED THE CASE AS SERIOUS (IMPORTANT MEDICAL EVENT). FOLLOW-UP INFORMATION RECEIVED ON 10-NOV-2015 FROM CONSUMER (CASE UPGRADED TO INCIDENT): THE CONSUMER WAS (B)(6) AT THE TIME OF THE REPORT. SHE HAD ESSURE INSERTED BECAUSE SHE DID NOT WANT TO BE PREGNANT ANYMORE. SHE DID NOT HAVE THE LOT NUMBER. THE ESSURE INSERTION WAS PAINFUL. HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED (RESULTS NOT PROVIDED). SHE HAD SEVERAL VAGINAL ULTRASOUNDS AND THEY WERE DEGRADING. SHE WAS GETTING READY TO HAVE A FULL HYSTERECTOMY SCHEDULED FOR (B)(6) 2015. THEY COULD JUST TAKE OUT THE (FALLOPIAN) TUBE, BUT SHE THINKS SHE WOULD BE GETTING A FULL HYSTERECTOMY. PTC INVESTIGATION RESULT WAS RECEIVED ON 22-NOV-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL

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EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2006 AND REPORTED PAIN DURING DAILY ACTIVITIES ON THE LEFT SIDE CONTINUALLY, CONSIDERED SERIOUS BY MEDICAL SIGNIFICANCE, LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ADDITIONAL NON-SERIOUS EVENT WAS REPORTED. AFTER 9 YEARS USING ESSURE, A FULL HYSTERECTOMY WAS SCHEDULED. AS NO ADDITIONAL INFORMATION WAS REPORTED ON CONCOMITANT DISEASES OR ALTERNATIVE EXPLANATIONS FOR THIS PAIN AND THE PAIN STARTED AFTER ESSURE INSERTION, CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED RELATED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A RELATIONSHIP BETWEEN THE REPORTED EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 10-DEC-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. FOLLOW-UP INFORMATION RECEIVED ON 17-DEC-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE D

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01882	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FI

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D40623

Single Use: Y
Implant Date (E6): 11/3/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER D40623. PHYSICIAN INSERTED THE IMPLANT TO THE LEFT BUT IT DID NOT GET LOOSE FROM INSERTER/WIRE ROPE. THE WIRE ROPE HAD TO BE CUT WITH SCISSORS AND REMOVED WITH FORCEPS. THE IMPLANT WAS NOT OPTIMAL IN SITU. A FILSHIE CLIP WAS ADDED TO THE LEFT SIDE LATER AND THE IMPLANT INSERTION TO THE RIGHT SIDE WAS OK. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE THE IMPLANT DID NOT GET LOOSE FROM THE INSERTER. THE WIRE ROPE HAD TO BE CUT WITH SCISSORS AND REMOVED WITH FORCEPS. THIS EVENT, INTERPRETED AS DEVICE DEPLOYMENT ISSUE, IS NON-SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL; IN THIS PARTICULAR CASE ESSURE INSERTION WAS COMPLICATED BY A DEVICE DEPLOYMENT ISSUE. A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THIS EVENT; HOWEVER CONSIDERING THAT IT OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES (SHE HAD A FILSHIE CLIP ADDED, HOWEVER THIS PROCEDURE WAS NOT PERFORMED TO PREVENT PERMANENT DAMAGE; IT WAS PERFORMED AS SECOND LINE CONTRACEPTION METHOD). A PRODUCT TECHNICAL ANALYSIS IS EXPECTED.

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Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 11-DEC-2015: (B)(4). FINAL ASSESSMENT: DETACHMENT DIFFICULTY IS DEFINED AS A FAILURE OF THE MICRO-INSERT TO DETACH (SEPARATE) FROM THE DELIVERY SYSTEM. PER THE INSTRUCTIONS FOR USE (IFU),

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01883	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE CONSUMER IN (B)(6) ON 11-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. IT WAS REPORTED THAT CONSUMER HAD ESSURE IMPLANTED, BUT IT STARTED TO INFLAME (BOTH SIDES) AND HAD TO BE REMOVED SURGICALLY. SHE WOULD LIKE TO KNOW OF WHICH MATERIAL THE COILS ARE MADE, BECAUSE SHE WAS THINKING OF AN ALLERGIC REACTION. PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENT (S) AND LACK OF EFFICACY ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) SURGICALLY

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REMOVED BECAUSE IT STARTED TO INFLAME (BOTH SIDES). SHE WAS THINKING OF AN ALLERGIC REACTION TO THE DEVICE. THESE EVENTS ARE LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. PERSONS ALLERGIC TO NICKEL TITANIUM MAY SUFFER AN ALLERGIC REACTION TO THE MICRO-INSERT. IN THIS PARTICULAR CASE, MINIMAL INFORMATION WAS PROVIDED. NEVERTHELESS, CONSIDERING DEVICE REMOVAL WAS REQUIRED; CAUSALITY BETWEEN THE REPORTED EVENTS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE A SURGICAL INTERVENTION WAS PERFORMED AS EVENTS TREATMENT. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01884	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A LAY PRESS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN (B)(6) ON 11-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER STATED THAT SHE HAD MENSTRUAL COMPLAINTS SINCE SHE WAS (B)(6), PROBLEMS WITH SPIRAL / IUD AND ORAL CONTRACEPTIVES. SHE HAS TWO HEALTHY SONS NOW, BUT HAD A HISTORY OF AN INTERRUPTED PREGNANCY AND TWO MISCARRIAGES. SHE STATED THAT DURING YEARS AFTER ESSURE, HER BODY HAD TO FIGHT AGAINST SOMETHING THAT DID NOT BELONG THERE. SHE WAS ALWAYS IN PAIN AND VERY TIRED. SHE HAD TO QUIT HER JOB FOR MONTHS DUE TO SEVERE COMPLAINTS AFTER ESSURE, WAS LOADED WITH PAINKILLERS AND STILL CREEPING OVER THE FLOOR EVERY NIGHT OF MISERY. EVER SINCE HER PREGNANCIES SHE WAS BOTHERED MUCH BY HER MENSTRUATION. SHE READ ABOUT NOVASURE AND THAT SEEMED TO BE THE SOLUTION TO HER PROBLEMS. THE PROCEDURE ITSELF WAS PAINFUL, BUT IMMEDIATELY THEREAFTER THE PAIN RETURNED SLOWLY. SHE TRIED EVERYTHING; INCLUDING MORPHINE AND PAINKILLERS. END OF (B)(6) A GYNECOLOGIST REMOVED HER FALLOPIAN TUBES INCLUDING THE ESSURE COILS. WHEN SHE WOKE UP FROM NARCOSIS SHE NOTICED IMMEDIATELY THAT THE PAIN WAS GONE. SINCE THEN HER ENERGY RETURNED. FOLLOW UP IS NOT POSSIBLE. PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO

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CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENT (S) AND LACK OF EFFICACY ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 02-DEC-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PELVIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT THIS NON-MEDICALLY CONFIRMED, LAY PRESS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN. SHE HAD HER FALLOPIAN TUBES REMOVED INCLUDING THE ESSURE COILS. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, CONSUMER STATED SHE WAS ALWAYS IN PAIN SINCE ESSURE INSERTION. CONSIDERING THAT UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE A SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FURTHER INFORMATION CANNOT BE OBTAINED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01885	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A LAY PRESS CASE REPORT RECEIVED FROM A (B)(6) FEMALE CONSUMER IN (B)(6) ON 11-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. SHE STATED THAT SHE HAD TWO DIFFICULT PREGNANCIES (DELIVERING A DAUGHTER AND SON). AFTERWARDS, SHE WAS ALWAYS AFRAID TO BECOME PREGNANT AGAIN. SHE WAS NOT ABLE TO ENDURE A SPIRAL / IUD AND SHE HAD TROUBLES WHILE TAKING ORAL CONTRACEPTIVES. THEREFORE SHE DECIDED TO HAVE ESSURE. AFTER HAVING ESSURE INSERTED SHE EXPERIENCED: FELT LIKE AN ANGRY WOMEN, PAIN, HORMONAL FLUCTUATION, IT SUCKS YOU EMPTY, ABDOMINAL PAIN, PAIN IN BACK, KNEE COMPLAINTS, JOINT COMPLAINTS, MENOPAUSAL COMPLAINTS, ANXIETY AND PANIC ATTACKS. SHE HAD TO QUIT HER JOB DUE TO THE COMPLAINTS. SHE WENT TO ANOTHER GYNECOLOGIST AND IT APPEARED THAT THE ESSURE COILS WERE FLOATING THROUGH HER BODY. AFTER THE RECOVERY OPERATION THE PAIN HAD DISAPPEARED IMMEDIATELY. FOLLOW-UP INFORMATION RECEIVED ON 19-NOV-2015: THE CASE RECEIVED THE REGULATORY AUTHORITY NUMBER (B)(4). A PHYSICIAN WAS ADDED AS NEW REPORTER AND THE CASE BECAME MEDICALLY CONFIRMED. THE PATIENT GYNECOLOGIST WAS NOT AWARE OF ANY OF THE COMPLAINTS AND WAS SURPRISED TO READ ABOUT IT AND THE FACT THAT THE PATIENT CONSULTED ANOTHER GYNECOLOGIST FOR HAVING THE ESSURE REMOVED. ACCORDING TO THE GYNECOLOGIST THE PATIENT HAD BEEN TREATED IN (B)(6) 2010. IN AN UNSPECIFIED DATE NO COILS WERE SEEN IN THE RIGHT SIDE. AT FIRST THE PATIENT REFUSED TO HAVE THE HYSTEROSALPINGOGRAM (HSG). IN (B)(6) 2011 THE HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND NO ABNORMALITIES WERE OBSERVED. AFTERWARDS THE PATIENT DID NOT CONSULT HER PRIMARY GYNECOLOGIST REGARDING THE COMPLAINTS. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT RECEIVED VIA LAY PRESS, REFERS TO A FEMALE PATIENT WHO

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HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN AND ESSURE COILS WERE FLOATING THROUGH HER BODY (INTERPRETED AS DEVICE DISLOCATION). SHE UNDERWENT A RECOVERY OPERATION (INTERPRETED AS REMOVAL OF ESSURE) AND THE PAIN DISAPPEARED. THESE EVENTS WERE CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABDOMINAL PAIN MAY OCCUR. ALSO, DURING ESSURE THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES. IN THIS PARTICULAR CASE, VERY LIMITED INFORMATION WAS PROVIDED. THE EVENT ESSURE COILS WERE FLOATING THROUGH HER BODY WAS INTERPRETED AS A SUSPICION OF DEVICE DISLOCATION, HOWEVER THE EXACT POSITION OF THE DEVICE IS UNKNOWN. THE ABDOMINAL PAIN IN THIS CASE, COULD ALSO BE RELATED TO THIS DISLOCATION. CONSIDERING THE NATURE OF THE REPORTED EVENTS, AND SINCE THE PAIN DISAPPEARED AFTER THE SURGERY, CAUSALITY BETWEEN THESE EVENTS AND ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED AND SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS EXPECTED. FOLLOW-UP IS NOT POSSIBLE, SINCE THIS IS A LAY PRESS CASE.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 19-NOV-2015:(B)(4). A PHYSICIAN WAS ADDED AS NEW REPORTER AND THE CASE BECAME MEDICALLY CONFIRMED. THE PATIENT GYNECOLOGIST WAS NOT AWARE OF ANY OF THE COMPLAINTS AND WAS SURPRISED TO READ ABOUT IT AND THE FACT THAT THE P

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01889	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 13-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN REPORTED THE PROCEDURE WENT DIFFICULT; A COLLEAGUE PERFORMED IT AND HAD THE IDEA THAT THE FIRST ESSURE DID NOT WENT IN WELL. THE SECOND WENT DIFFICULT AND DID NOT SUCCEED. A GYNECOLOGIST WAS CALLED AND SHE INSERTED THE THIRD, THIS SUCCEEDED. IN 2015, THE HSG (HYSTEROSALPINGOGRAM) WAS MADE AND IT APPEARS THAT THERE ARE 3 ESSURES INSIDE THE PATIENT. THE PATIENT WILL HAVE A HYSTEROSCOPY TO REMOVE THE 2 COILS CLOSEST TO THE UTERUS; THE THIRD COIL THAT IS ALL INTO THE OVIDUCT, WILL BE REMOVED BY LAPAROSCOPY. AFTER THAT PATIENT WILL HAVE A TUBECTOMY. THE PATIENT HAD NO COMPLAINTS. PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE

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CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD THREE ESSURES (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. HER HYSTEROSALPINGOGRAM (HSG) TEST SHOWED 2 COILS WERE CLOSEST TO THE UTERUS. THE THIRD COIL WAS ALL INTO THE OVIDUCT. THESE COILS WILL BE REMOVED BY HYSTEROSCOPY AND LAPAROSCOPY; A TUBECTOMY IS ALSO PLANNED. THE REPORTED EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE IN/OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE A DISLOCATION INTO THE UTERUS OR MIGRATION INTO DISTAL FALLOPIAN TUBE. IN THIS PARTICULAR CASE, PATIENT HAD 3 COILS INSERTED; THIS INAPPROPRIATE THERAPY MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED COILS MOVEMENT. NEVERTHELESS, CONSIDERING EVENTS NATURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR DEVICES REMOVAL. ACCORDING TO PRODUCT TECHNICAL COMPLAINT, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FOLLOW-UP INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01891	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/11/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 12-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION. PHYSICIAN WENT TO INSERT AND COULD NOT REMOVE CATHETER, TUBE CLAMPED DOWN AND STRETCHED OUT. CATHETER WIRE STRETCHED AND HCP COULD NOT REMOVE SCOPE. HCP CUT THE CATHETER WIRE OUTSIDE OF DRY FLOW INTRODUCER AND USED SCISSOR TO CUT COILS. THERE WAS STILL A PIECE, A FOREIGN BODY IN CAVITY. PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO

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HAD AN ATTEMPT OF ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION AND DURING THE PROCEDURE, PHYSICIAN COULD NOT REMOVE CATHETER OR THE SCOPE. THE TUBE CLAMPED DOWN AND STRETCHED OUT. CATHETER WIRE STRETCHED. PHYSICIAN CUT THE CATHETER WIRE OUTSIDE OF DRY FLOW INTRODUCER AND USED SCISSOR TO CUT COILS. A PIECE REMAINED IN THE CAVITY. THE REPORTED EVENTS ARE LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DURING DIFFICULT INSERTIONS ESSURE PLACEMENT MAY BE UNSUCCESSFUL. IN THIS PARTICULAR CASE, ESSURE INSERTION WAS COMPLICATED BY A DEVICE DEPLOYMENT ISSUE AND PHYSICIAN HAD TO CUT THE DEVICE IN ORDER TO REMOVE ESSURE CATHETER AND THE SCOPE. A PRODUCT TECHNICAL ANALYSIS WILL BE REQUESTED FOR FURTHER EVALUATION OF THE EVENTS. HOWEVER, CONSIDERING THEY OCCURRED IN ASSOCIATION WITH ESSURE PLACEMENT, THEY WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. EXCEPT FOR THE REPORTED DEVICE MISUSE (PHYSICIAN CUT THE INSERT), WHICH WAS CONSIDERED UNRELATED DUE TO ITS NATURE. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FOLLOW-UP INFORMATION IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 01-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01892	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627301

Single Use: Y
Implant Date (E6): 10/27/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY FDA MAUDE CASE# (B)(4)) IN UNITED STATES ON 12-NOV-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008 (LOT NUMBER 627301). CONSUMER HAD THE ESSURE DEVICE SURGICALLY IMPLANTED AND IMMEDIATELY FOLLOWING SHE BEGAN TO GET PAIN THAT STARTED IN HER LEGS. IT FELT LIKE SHE HAD THE FLU IN HER LEGS. SHE WENT TO THE DOCTOR AND SHE RAN A SERIES OF TESTS BUT EVERYTHING CAME BACK NEGATIVE. OVER THE NEXT 6 AND HALF YEARS OF HER LIFE SHE WENT TO SPECIALIST AFTER SPECIALIST, SHE HAS SEEN DOCTOR AFTER DOCTOR AND NOT EVEN ONE DOCTOR COULD EXPLAIN HER WORSENING CONDITION. SHE SPENT HUNDREDS OF THOUSANDS OF DOLLARS ON HER ISSUE, TO NO AVAIL, NO ONE COULD EXPLAIN, DIAGNOSE OR FIX HER PAIN. SHE WAS COMPLETELY HEALTHY ACCORDING TO ALL HER TESTS. SO, SHE WENT TO A BACK DOCTOR, A CHIROPRACTOR BEGAN A SERIES OF SHOTS ETC. NOTHING HELPED AND HER CONDITION CONTINUED TO DETERIORATE AND WORSEN TO DATE. HER LIST OF SYMPTOMS WERE HEAVY BLEEDING, HOT FLASHES, HEAVY CRAMPING, PAINFUL INTERCOURSE, WEIGHT GAIN, BLOATING, MIGRAINE HEADACHES, INFLAMMATION, PAIN IN THE BUTTOCKS, BACK, LEGS, FEET AND THIGHS, HEART PALPITATIONS, LOW BLOOD PRESSURE, SKIN RASHES, HAIR LOSS, EXTREME FATIGUE, HER ARMS LOOSE BLOOD CIRCULATION. SHE HAS SEEN THE HEART DOCTOR AND HAD AN ANGIOGRAM AND HER HEART WAS HEALTHY. DOCTORS TOLD HER THAT WHATEVER SHE WAS DEALING WITH THAT IT WAS NOT COMING FROM HER HEART. RECENTLY, SHE HAD AN MAGNETIC RESONANCE IMAGING OF PELVIC REGION AND STUMBLED UPON MANY WOMAN SUFFERING THE SAME DEBILITATING SYMPTOMS AS HERSELF, FROM THE ESSURE. NOW SHE HAS A FULL HYSTERECTOMY AS A RESULT BECAUSE SHE NOW ALSO HAS LESIONS ON HER UTERUS. CONSUMER REPORTED THAT THESE SIDE EFFECTS WERE LIFE THREATENING AND ALTERING.

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TO DATE EMERGENCY ROOMS EVEN KNOW HOW TO CHECK FOR THE POSITION OF THE COILS IF MOVEMENT OCCURRED OR PROPER REMOVAL OF THE COILS ETC. CONCOMITANT MEDICATIONS INCLUDE 100MG GABAPENTIN 2 TIMES A DAY, 50MG OF LYRICA 4 TIMES DAILY, ALEVE TAKEN AS NEEDED, VITAMIN D 500MG 2 TIMES A WEEK, TURMERIC 450MG 1 TIME A DAY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY BLEEDING AND CRAMPING. ACCORDING TO HER, SHE WAS SUBMITTED TO A HYSTERECTOMY BECAUSE SHE ALSO HAD LESIONS ON HER UTERUS. ONLY CRAMPING AND BLEEDING (REGARDED AS LOWER ABDOMINAL CRAMPING AND GENITAL BLEEDING) ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS CASE, CONSUMER REPORTED UNSPECIFIED LESIONS IN UTERUS. THESE LESIONS COULD HAVE BEEN A CONTRIBUTORY ROLE IN HER SYMPTOMS. NEVERTHELESS, CONSIDERING EVENTS NATURE AND SINCE LIMITED INFORMATION WAS PROVIDED (EXACT NATURE OF UTERINE LESIONS WAS NOT SPECIFIED); CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN ADDITION NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). FOLLOW-UP INFORMATION AND A PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01893	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A NURSE IN UNITED STATES ON 11-NOV-2015 . IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. ON (B)(6) 2015 SHE WENT FOR A OFFICE VISIT AND PRESENTED A LIST OF ADVERSE EVENTS SHE HAD EXPERIENCED SINCE HER ESSURE PLACEMENT. SHE COMPLAINED OF HEADACHES, MIGRAINES, SEVERE BLOATING, METALLIC TASTE IN MOUTH, HEARTBURN, BOWEL PROBLEMS, BRAIN FOG, MEMORY LOSS, ANXIETY, MOOD SWINGS, DEPRESSION, ANEMIA, IRON PROBLEMS, BP (BLOOD PRESSURE) HIGH, CHRONIC FATIGUE, HIVES, RASHES, ACNE, HAIR LOSS, DENTAL ISSUES, WEIGHT GAIN, HEAVY CLOTS AND BLEEDING, CRAMPS, SHARP STABBING PAINS, OVARIAN CYSTS, CONSTANT SPOTTING, ECTOPIC PREG (INTERPRETED AS ECTOPIC PREGNANCY), BACTERIAL VAGINOSIS, PID (PELVIC INFLAMMATORY DISEASE), UTERINE INFLAMMATION, NIGHT SWEATS, LOSS OF SEX, HOT FLASHES, PAINFUL SEX, LONG PERIODS, BLEEDING BETWEEN PERIODS, URGENT AND FREQUENT PEEING, CHEST PAIN, BACK PAIN, PELVIC PAIN, GAS AND CONSTIPATION. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD ECTOPIC PREG (INTERPRETED AS ECTOPIC PREGNANCY), PID (INTERPRETED AS PELVIC INFLAMMATORY DISEASE) AND HEAVY CLOTS /BLEEDING (INTERPRETED AS GENITAL BLEEDING). THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PREGNANCIES (INCLUDING ECTOPIC PREGNANCIES) HAVE BEEN REPORTED AMONG WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES WERE DUE TO PATIENT NON-COMPLIANCE. WHEN PREGNANCY DOES OCCUR AFTER ESSURE PLACEMENT, THE RELATIVE RISK THAT IT WILL BE AN ECTOPIC PREGNANCY IS HIGHER THAN FOR WOMEN WHO DO NOT HAVE ESSURE IN PLACE. THEREFORE, CAUSALITY BETWEEN ECTOPIC PREG AND

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ESSURE CANNOT BE EXCLUDED. REGARDING EVENT PID, WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFLAMMATORY DISEASE IN THE FIRST 4 WEEKS AFTER INSERTION. IN THE PRESENT CASE, NO INFORMATION SUGGESTING THIS CLOSE TEMPORAL RELATIONSHIP WITH THE INSERTION PROCEDURE WAS MENTIONED. THEREFORE, CAUSALITY BETWEEN PID AND ESSURE WAS ASSESSED AS UNRELATED. AFTER ESSURE INSERTION GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE NATURE OF THE EVENT HEAVY CLOTS /BLEEDING AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SERIOUS INJURY (ECTOPIC PREGNANCY) WAS REPORTED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 29-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WERE A DEVICE FAILUR

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01894	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18707

Single Use: Y
Implant Date (E6): 11/13/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER C18707, INSERTED ON (B)(6) 2015. PATIENT HAD SUCCESSFUL PLACEMENT OF DEVICE ON RIGHT SIDE. WHEN THE PHYSICIAN INSERTED THE DEVICE INTO THE LEFT OSTIA, APPROXIMATELY 3 COILS BROKE OFF AT PROXIMAL END AND FELL IN THE UTERUS. THE PIECES WERE RETRIEVED WITH GRASPERS. THE PATIENT WAS FINE. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DURING THE PROCEDURE, WHEN THE PHYSICIAN INSERTED THE DEVICE INTO THE LEFT OSTIA, APPROXIMATELY 3 COILS BROKE OFF AT PROXIMAL END AND FELL IN THE UTERUS. THESE PIECES WERE RETRIEVED WITH GRASPERS. THE PATIENT WAS FINE. THIS EVENT IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENT DID NOT LEAD TO SERIOUS HEALTH DETERIORATION, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01895	BAYER HEALTHCARE LLC	12/8/2015	12/8/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA SALES CONSULTANT IN UNITED STATES ON 13-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. BAYER SALES CONSULTANT WAS CALLED TO GOT TO THE HOSPITAL AND IT WAS NOT AN ESSURE INSERTION BUT A REMOVAL OF ESSURE. PATIENT HAD BEEN COMPLAINING OF PELVIC PAIN. SHE DID NOT ATTEND IN REMOVAL PROCEDURE. SALES CONSULTANT WAS UNSURE ABOUT ESSURE REMOVAL. COMPANY CAUSALITY COMMENT THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED PELVIC PAIN. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PELVIC PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE VERY LIMITED INFORMATION WAS PROVIDED. IT WAS ONLY REPORTED THAT ESSURE WAS BEING REMOVED AND THE PATIENT HAD PELVIC PAIN. BASED ON AVAILABLE INFORMATION AND EVENT'S NATURE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE DEVICE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION AND TECHNICAL ASSESSMENT HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 04-JAN-2016. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058377	BAYER	12/8/2015	12/8/2015

Event Information:

Event Date (B3): 4/15/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IN SO MUCH PAIN ON RIGHT SIDE ALWAYS AND HURTS STILL ALWAYS (B)(6) 2015. STILL N PAIN JUST FOUND OUT MY RIGHT ONE IS BENT AND STABBING ME!!! I HAVE TO GET IT AND MY TUBS REMOVED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058378	BAYER	12/8/2015	12/8/2015

Event Information:

Event Date (B3): 12/9/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EVERY SINCE I GOT THE DEVICE, I BEEN DIAGNOSED WITH HYPOTHYROIDISM, SKIN RASH, BOILS ONGOING REPEATED CYCLE AS IF MY BODY TRYING TO EXPELLED SOMETHING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058379	BAYER	12/8/2015	12/8/2015

Event Information:

Event Date (B3): 10/16/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I EXPERIENCED EXTREME PAIN AFTER THIS PROCEDURE FOR MONTHS. CRAMPING AND STILL BELIEVE AFTER ALL THESE YEARS MY BODY HAS NEVER BEEN THE SAME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058380	BAYER	12/8/2015	12/8/2015

Event Information:

Event Date (B3): 2/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WHEN IMPLANTED IN TUBE SPASM OCCURRED AND LASTED OVER AN HOUR. HAD TO BE SEDATED. WITHIN THE WEEK OF IMPLANT MANY OTHER SYMPTOMS CAME AND MANY HAVE PERSISTED OR GOTTEN WORSE. BLISTERS ALL OVER BACK, MIGRAINES, HEAVY NIGHT SWEATS AND CHILLS, SEIZURES, SEVERE PAIN AT MENSTRUATION AND; OVULATION, HEAVY OR STRANGE BLEEDING, PAIN IN PELVIC REGION, PAIN IN BACK AND JOINTS, MEMORY LOSS, MEMORY FOG , COGNITIVE IMPAIRMENT, HAIR THINNING AND FALLING OUT, SKIN ON FINGER TIPS PEELING, NAILS GROWING WITH RIDGES AND FLAKES, TREMORS IN ARMS AND HANDS, TINGLING AND NUMBNESS IN EXTREMITIES, VERTIGO, HEART PALPITATIONS , CHEST PAINS, ANXIETY, INSOMNIA, SKIN RASHES OR ABNORMAL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058381	BAYER	12/8/2015	12/8/2015

Event Information:

Event Date (B3): 10/5/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, WEIGHT GAIN, PRIVATE INSURANCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058382	BAYER	12/8/2015	12/8/2015

Event Information:

Event Date (B3): 10/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAD ESSURE PLACED EARLY 2010, HSG SHOWED BLOCKED TUBES, IN (B)(6) OF THAT YEAR I STOPPED MENSTRUATING. SOON AFTER I STARTED GAINING WEIGHT, WITHOUT SUCCESSFULLY LOOSING IT NO MATTER WHAT, SLOW MY WEIGHT CLIMBED, STARTED HAVING ISSUES WITH JOINT PAIN, HAIR LOSS, TUMMY BLOAT, MEMORY FOG, MOOD SWINGS, ITCHING AND HIVES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058441	BAYER	12/8/2015	12/11/2015

Event Information:

Event Date (B3): 9/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6): 4/30/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2014, I HAD THE ESSURE PROCEDURE, TO PREVENT PREGNANCY. ON (B)(6) HAD A SURGICAL PROCEDURE TO REMOVE THE FETUS A WEEK LATER. I AM NOW ON AN ORAL BIRTH CONTROL ALONG WITH THE ESSURE DEVICE STILL IN MY OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01872	BAYER HEALTHCARE LLC	12/9/2015	12/9/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1486, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2012. THE CONSUMER REPORTED SHE SUFFERED A LOT OF PAIN AND COULD NOT SIT DOWN ALL THE WAY FOR OVER 2 WEEKS. SHE ALSO HAD TONS OF CRAMPING. A PIECE OF THE ESSURE CAME OUT AND SHE CALLED HER DOCTOR WHO SAID IT WAS OK. IN (B)(6) 2014 THE CONSUMER HAD HER GALLBLADDER REMOVED AND THEY REMOVED AN ESSURE COIL FROM THE FATTY TISSUE UP BY GALLBLADDER. SHE REPORTED SHE WAS STILL SUFFERING FROM PAIN AND CRAMPING. SHE STILL HAD ONE OF THE ESSURE COILS. PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT(S) IS EXCLUDED. THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TONS OF CRAMPING (INTERPRETED AS ABDOMINAL PAIN LOWER). A PIECE (DEVICE BREAKAGE) OF ESSURE CAME OUT. APPROXIMATELY 2 YEARS AFTER ESSURE INSERTION, SHE HAD HER GALLBLADDER REMOVED FOR AN UNSPECIFIED REASON AND THE ESSURE COIL THAT WAS IN THE FATTY TISSUE UP BY GALLBLADDER (INTERPRETED AS DEVICE DISLOCATION) WAS REMOVED. AT THE TIME OF REPORT SHE STILL HAD CRAMPING AND STILL HAD ONE OF THE ESSURE COILS. THESE EVENTS, EXCEPT FOR BREAKAGE, ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE ABDOMINAL LOWER PAIN AND DEVICE DISLOCATION ARE LISTED WHILE THE GALLBLADDER REMOVAL AND DEVICE BREAKAGE ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. BASED ON AN IMPLIED POSITIVE TEMPORAL RELATIONSHIP, ESSURE SAFETY PROFILE, AND LACK OF ALTERNATIVE EXPLANATION, THE EVENTS DEVICE BREAKAGE, DEVICE DISLOCATION AND ABDOMINAL PAIN ARE CONSIDERED TO BE RELATED TO ESSURE USE. HOWEVER, SINCE ESSURE DOES NOT CONTAIN ANY DRUG AND HAS ONLY A LOCALIZED MECHANICAL ACTION, ITS SYSTEMIC INFLUENCE IS UNLIKELY. THEREFORE, THE GALLBLADDER REMOVAL WAS ASSESSED AS UNRELATED TO ESSURE. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. SINCE NO PRODUCT WAS PROVIDED AND NO BATCH NUMBER WAS PROVIDED A QUALITY DEFECT CANNOT BE CONFIRMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT AS NO DEFECT WAS CONFIRMED AND NO MEDICAL EVENTS WERE REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01873	BAYER HEALTHCARE LLC	12/9/2015	12/9/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 10/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1544, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014. CONSUMER REPORTED SINCE ESSURE INSERTION, HER HEALTH HAS DRAMATICALLY DECLINED. SHE HAS BEEN SUFFERING WITH HORRIBLE HEADACHES, TINGLING IN HER FACE AND LEGS, NUMBNESS IN HER LEGS, EXTREME FATIGUE, ABDOMINAL PAIN, CHEST PAIN, ELECTRICAL SHOCK LIKE PAIN IN HER BRAIN, HAIR LOSS, BRAIN FOG, IRRITABILITY, WEIGHT GAIN, NIGHT SWEATS, ITCHY SKIN, FACE WAS BREAKING OUT, VAGINITIS, TEETH HURT, PAINFUL INTERCOURSE, NO SEXUAL DRIVE, LOSS OF PERIOD, BACK PAIN AND JOINT PAIN. THERE HAVE BEEN NIGHTS WHEN SHE HAS GONE TO BED FEARFUL THAT SHE WOULD NOT MAKE IT. MANY DAYS SHE WAS TOO TIRED TO CLEAN, COOK AND DO THINGS WITH HER CHILDREN. SHE WAS HIGHLY IRRITABLE. SINCE OPENING UP ABOUT HER PROBLEMS WITH ESSURE, SHE HAS HAD THREE FRIENDS TOLD HER THAT THEY HAD ESSURE AND ENDED UP HAVING HYSTERECTOMIES BECAUSE OF HEALTH ISSUES. THEY WERE JUST NOW PUTTING TWO AND TWO TOGETHER. THE MAIN REASON THAT SHE OPTED TO GO WITH ESSURE, OTHER THAN HER DOCTOR SAYING THAT SHE RECOMMENDED IT OVER TUBAL LIGATION, WAS BECAUSE IT WAS A NON-SURGICAL PROCEDURE AND SHE WOULD NOT HAVE TO GO UNDER. THE PROCEDURE ITSELF WAS PAINFUL AND SO WAS THE HYSTEROSALPINGOGRAM. NOW, TO GET THESE COILS REMOVED, SHE WILL NOT ONLY HAVE TO GO UNDER BUT SHE WILL HAVE TO HAVE HER TUBES AND UTERUS REMOVED. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 11-NOV-2015: FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED,

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WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN. SHE WILL HAVE TO HAVE HER TUBES AND UTERUS REMOVED FOR HAVING THE ESSURE COILS REMOVED. THIS EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ABDOMINAL PAIN MAY OCCUR DURING ESSURE USE. IN THIS CASE, SINCE ESSURE INSERTION, THE CONSUMER HAD BEEN EXPERIENCING ABDOMINAL PAIN AND OTHER NON-SERIOUS EVENTS. CONSIDERING CLOSE TEMPORAL RELATIONSHIP AND EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01874	BAYER HEALTHCARE LLC	12/9/2015	12/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA·2014·N·0736·1515, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE CONSUMER REPORTED SHE HAD TO HAVE A HYSTERECTOMY DUE TO MANY ISSUES WITH ESSURE. SHE ALSO REPORTED THAT HER KIDS FEARED HER DUE TO MOOD SWINGS. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY

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CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE A HYSTERECTOMY DUE TO MANY ISSUES WITH ESSURE. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. SHE ALSO EXPERIENCED OTHER NON-SERIOUS EVENT. ALTHOUGH IN THIS CASE THE SURGERY'S INDICATION WAS NOT SPECIFIED, CONSIDERING HYSTERECTOMY MAY BE REQUIRED IF DEVICE REMOVAL IS NECESSARY, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01875	BAYER HEALTHCARE LLC	12/9/2015	12/9/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1538, AWARENESS DATE 20-OCT-2015). IT REFERS TO FEMALE CONSUMER OF UNSPECIFIED IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2015. THE CONSUMER STATED SHE ALREADY HAD ONE SURGERY AFTER ESSURE INSERTION - SHE HAD HER LEFT FALLOPIAN TUBE REMOVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 11-NOV-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE PTC NUMBER IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE

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OCCLUSION INSERT) INSERTED AND ALREADY HAD ONE SURGERY AFTER ESSURE INSERTION - SHE HAD HER LEFT FALLOPIAN TUBE REMOVED. THIS EVENT, SEEN AS A PARTIAL SALPINGECTOMY, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE THE SURGERY'S INDICATION WAS NOT SPECIFIED, CONSIDERING SALPINGECTOMY MAY BE REQUIRED IF DEVICE REMOVAL IS NECESSARY, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058408	BAYER	12/9/2015	12/9/2015

Event Information:

Event Date (B3): 11/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CRAMPING, ABDOMINAL PAIN AND CONSTANT BLEEDING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058409	BAYER	12/9/2015	12/9/2015

Event Information:

Event Date (B3): 3/31/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE HAD SEVERE PAIN, BLOATING AND BLEEDING SINCE THE DEVICE WAS IMPLANTED... HAVE DEVELOPED DEPRESSION, I HAVE RASHES CONSTANTLY FROM THE NICKEL ALLERGY....THE PAIN IS UNBEARABLE! I FEEL LIKE I'M BEING STABBED ABOUT EVERY 15-30 SECONDS..I FEEL/LOOK (B)(6) EVERY DAY...I CAN'T WEAR JEANS BECAUSE ANY PRESSURE ON MY STOMACH HURTS TO MUCH... ESSURE HAS RUINED MY LIFE..NOW AT (B)(6) I'M AWAITING A FULL HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058410	BAYER	12/9/2015	12/9/2015

Event Information:

Event Date (B3): 2/21/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOWER BACK PAIN. LOWER ABDOMEN PAIN. PASSING BLOOD CLOTS DURING CYCLE. TEETH DECAY. HEADACHES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058411	BAYER	12/9/2015	12/9/2015

Event Information:

Event Date (B3): 7/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED TO HAVE CHRONIC FATIGUE. I WOULD TELL MY DOCTOR AND THERE DIDN'T SEEM TO BE ANYTHING WRONG. IT WENT FROM BAD TO WORSE THE PAST TWO YEARS BEING THE MOST DIFFICULT. I STARTED HAVING VERY HEAVY BLEEDING AND CLOTTING DURING MY MENSES. ALONG WITH STABBING PAINS STRONGER THAN A TYPICAL CRAMP. I WAS SOMEONE WHO ENJOYED WORKING OUT 3 TO 4 TIMES A WEEK AND RUN ABOUT 3 MILES EVERY OTHER DAY. I STARTED EXPERIENCING BREATHING ISSUES, AND JOINT PAIN ALONG WITH WEIGHT GAIN. I ENDED UP NOT EVEN BEING ABLE TO WALK UP A FLIGHT OF STAIRS WITHOUT BECOMING WINDED. MY DOCTORS HAD RUN SEVERAL THYROID TESTS, HORMONE TEST ETC TO NO AVAIL. LAST (B)(6) THE BREATHING ISSUES GOT SO BAD THAT I ENDED UP HAVING AN EKG, ECHOCARDIO AND STRESS TEST. I HAD UNFAVORABLE RESULTS ON THE STRESS TEST SO WAS REFERRED TO A CARDIOLOGIST WHO THEN RAN A NUCLEAR STRESS TEST WITH THE SAME RESULTS. HE TOO HEARD THE WHEEZING AND WANTED ME TO SEE A PULMONARY DOCTOR. HE ALSO PERFORMED A CARDIAC CATH LAB DUE TO THE RESULTS OF THE NUCLEAR STRESS TEST. THE PULMONARY DOCTOR SAID IT WAS ASTHMA LIKE QUALITIES BUT IT DIDN'T FEEL LIKE ASTHMA. I WAS PUT ON DULERA 2X'S A DAY AND GIVEN VENTOLIN AS A RESCUE INHALER. THEY DIDN'T OFFER ANY REAL RELIEF. I WAS THEN GIVEN A STEROID PACK OF PREDESON WHICH DID SEEM TO OFFER SOME RELIEF. I ALSO WENT BACK TO MY PRIMARY FOR MORE TESTING AND WAS GOING TO BE REFERRED TO AN ENDOCRINOLOGIST. I WENT BACK TO MY GYNECOLOGIST CONCERNING THE BLEEDING, CLOTTING AND CRAMPING AS WELL AS PAIN. SHE RECOMMENDED A ULTRASOUND AND THEN A CT SCAN. IT APPEARED THAT I HAD A 6CM. PALLOP IN MY UTERINE WALL AS WELL AS THE ESSURE PRODUCT IN MY RIGHT TUBE LOOKED TO HAVE MIGRATED AND POSSIBLY BROKE IN HALF. I JUST

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UNDERWENT A HYSTERECTOMY YESTERDAY TO REMOVE MY FALLOPIAN TUBES, UTERUS AND CERVIX. MY OVARIES WERE TO STAY. HOWEVER AFTER GOING IN MY GYNECOLOGIST HAD TO REMOVE ONE OF MY OVARIES BECAUSE IT WAS "SHREDDED". I WILL LEARN MORE TODAY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058412	BAYER	12/9/2015	12/9/2015

Event Information:

Event Date (B3): 6/24/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AROUND (B)(6) 2009, I BEGAN TO EXTREMELY HEAVY AND PAINFUL MONTHLY CYCLES. OVER THE COURSE OF TIME, MY CYCLES BECAME WORSE AND ALSO STARTED TO BECOME IRREGULAR,CAUSING ME TO MISS OR SOMETIMES LEVEL WORK. SEXUAL INTERCOURSE ALSO BECAME PAINFUL FOR ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058413	BAYER	12/9/2015	12/9/2015

Event Information:

Event Date (B3): 8/31/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER HAVING THE ESSURE PUT IN I BEGAN TO HAVE BLOATING AND PAIN ALL THE TIME IT MADE MY PERIODS SO BAD I COULDN'T GET OUT OF BED ALSO CAUSED LOTS OF NAUSEA AND ALLERGIC REACTIONS PLUS IT BROUGHT DOWN MY IMMUNE SYSTEM TO WERE I WAS GETTING SICK ALL THE TIME

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01876	BAYER HEALTHCARE LLC	12/10/2015	12/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 7/31/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING WHICH TOOK PLACE IN SEPTEMBER 2015 (CASE FDA-2014-N-0736-1566, AWARENESS DATE 21-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. CONSUMER WAS GIVEN THE ESSURE PLACEMENT AND WAS SUPPOSE TO GET ABLATION DONE ON (B)(6) 2015. FOR THE PROCEDURE SHE WAS TOLD TO TAKE 3 IBUPROFEN EVERY 4 HOURS THE DAY BEFORE AND THE MORNING OF THE PROCEDURE (SHE DID NOT REPORT IF SHE TOOK THE MEDICATION). THE PAIN SHE STARTED FEELING AND THE NEXT COUPLE OF DAYS WERE UNBELIEVABLE. HER PERIODS FELT LIKE SHE HAD A KNIFE TURNING IN HER UTERUS. AFTER THE PROCEDURE SHE HAS HAD NOTHING BUT PAIN ON THE LEFT SIDE, HER PERIOD LASTED 11 WEEKS AFTER ESSURE WAS PLACED, AND SHE HAS HAVING PAINS IN VAGINA. SHE IS NOW SET UP FOR ABDOMINAL HYSTERECTOMY ON (B)(6) 2016. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS: (B)(4) WAS RECEIVED ON 12-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL

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EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED NOTHING BUT PAIN ON THE LEFT SIDE SINCE THE PLACEMENT PROCEDURE. SHE IS SET UP FOR ABDOMINAL HYSTERECTOMY. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE CLOSE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN THIS EVENT AND ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WILL BE REQUIRED THIS CASE IS REGARDED AS INCIDENT OTHER NON-SERIOUS EVENTS WERE REPORTED. A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT IS EXCLUDED. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01877	BAYER HEALTHCARE LLC	12/10/2015	12/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 1/1/2001
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055954) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2007. CONCOMITANT MEDICATION INCLUDED DEXILANT 60MG, HYDROCHLORTHIAZIDE 25MG, OXYBUTYNIN 5MG. AFTER 12 WEEK HYSTEROSALPINGOGRAM (HSG), CONSUMER FOUND OUT THAT ONE OF THE ESSURE COILS PERFORATED HER FALLOPIAN TUBE AND THAT SHE WOULD HAVE TO HAVE THE PROCEDURE DONE A SECOND TIME. SHE HAD IT DONE IN THE OFFICE AND SINCE THEN SHE HAD A HYSTERECTOMY. SHE HAD A ESSURE PROCEDURE DONE IN 2007 AND ANOTHER PROCEDURE DONE LATER IN THE YEAR. HER HYSTERECTOMY WAS IN 2014. CONSUMER ASSESSED (B)(6) 2007 AS EVENT DATE HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 12-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE

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AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER 12 WEEK HYSTEROSALPINGOGRAM, IT WAS FOUND OUT THAT ONE OF THE ESSURE COILS HAD PERFORATED HER FALLOPIAN TUBE. THEN, SHE HAD ANOTHER PROCEDURE DONE AND EVENTUALLY HAD TO HAVE A HYSTERECTOMY. THE REPORTED EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING FALLOPIAN TUBE PERFORATION IS A POTENTIAL COMPLICATION OF ESSURE USE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION (HYSTERECTOMY) WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 28-DEC-2015: FOLLOW-UP ATTEMPTS HAVE BEEN COMPLETED, WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01878	BAYER HEALTHCARE LLC	12/10/2015	12/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/9/2010
Explant Date (E7): 6/25/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY FDA MAUDE (CASE# MW5056006) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. CONSUMER REPORTED SHE HAD THE ESSURE IMPLANTS AND THEY CAUSED HEAVY BLEEDING DURING HER CYCLES. SHE ALSO HAD PAIN IN HER PELVIS AND LOW BACK. AT TIMES IT WAS HARD FOR HER TO WALK AROUND. SHE HAD SURGERY ON (B)(6) 2015 TO HAVE THEM REMOVED. THE SERIOUSNESS CRITERIA DISABILITY WAS MENTIONED IN THE SECTION EVENT OUTCOME BUT IT WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF EVENTS IN THE NARRATIVE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS: (B)(4) WAS RECEIVED ON 12-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY

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COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN IN HER PELVIS. SHE HAD SURGERY FOR HAVE THEM (THE COILS) REMOVED. THE REPORTED EVENT IS SERIOUS DUE TO REQUIRED INTERVENTION AND DISABILITY (PER REPORTER) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 18-DEC-2015: NO FURTHER INFORMATION WAS OBTAINED DESPITE FOLLOW-UP ATTEMPTS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01879	BAYER HEALTHCARE LLC	12/10/2015	12/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 10/8/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055944) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON UNSPECIFIED DATE AND AFTERWARDS SHE EXPERIENCED A LOT OF SEVERE PAIN AND HEAVY BLEEDING DURING HER MONTHLY PERIODS. HER PERIODS WENT FROM 4 DAYS OF LIGHT BLEEDING BEFORE THE ESSURE TO 2 WEEKS OF HEAVY BLEEDING WITH CLOTS THE SIZE OF GOLF BALLS. SHE ALSO EXPERIENCED ABDOMINAL SWELLING, ASCITES AND BLOATING. SHE HAD TROUBLE CARING FOR HER CHILDREN AND HERSELF. EVENTUALLY SHE HAD THEM REMOVED BUT THEY HAD MIGRATED INTO HER UTERUS PARTIALLY AND SHE HAD TO HAVE A HYSTERECTOMY AND REMOVAL OF HER FALLOPIAN TUBES. EXPLANTED DATE WAS REPORTED AS (B)(6) 2012. LIFE THREATENING, HOSPITALIZATION, DISABILITY PERMANENT DAMAGE, REQUIRED INTERVENTION AND OTHER SERIOUS (IMPORTANT MEDICAL EVENT) WERE MENTIONED BUT NOT DESCRIBED NOR SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER (B)(4) WAS RECEIVED ON 12-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE

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REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE MIGRATED PARTIALLY INTO HER UTERUS. SHE ALSO EXPERIENCED ASCITES. THE FIRST EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION (HOSPITALIZATION AND OTHER SERIOUSNESS CRITERIA WERE CITED BUT NOT SPECIFIED NOR DESCRIBED PER REPORTER) AND LISTED. ASCITES IS ALSO SERIOUS DUE TO MEDICAL IMPORTANCE AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES TOWARDS UTERINE CAVITY. IN THIS CASE, THE DEVICES HAD MIGRATED INTO HER UTERUS PARTIALLY AND SHE HAD TO HAVE A HYSTERECTOMY AND REMOVAL OF HER FALLOPIAN TUBES. ALTHOUGH IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THIS DISLOCATION HAVE NOT BEEN INFORMED, GIVEN EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. REGARDING ASCITES, CONSIDERING ITS MOST COMMON CAUSE IS PORTAL HYPERTENSION DUE TO CIRRHOSIS AND THE FACT THAT ESSURE ACTS LOCALLY IN FALLOPIAN TUBES, CAUSAL RELATIONSHIP BETWEEN THIS REPORTED EVENT AND ESSURE USE IS VERY UNLIKELY. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP FROM 28-DEC-2015: FOLLOW-UP ATTEMPTS HAVE BEEN MADE, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS T

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01880	BAYER HEALTHCARE LLC	12/10/2015	12/10/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2008
Explant Date (E7): 7/22/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5055950) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. SHE ALSO RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: METOPROLOL SUCCINATE (METOPROLOL SUCCINATE), ESTRADIOL (ESTRADIOL [ESTRADIOL]), MEDROXYPROGESTERONE (MEDROXYPROGESTERONE), CITALOPRAM (CITALOPRAM), MINOCYCLINE (MINOCYCLINE), GABAPENTIN (GABAPENTIN), AND TALWIN NX (TALWIN NX). THE CONSUMER STARTED HAVING HEAVY MENSTRUAL BLEEDING, PAIN ON LOWER RIGHT SIDE, NAUSEA AND FATIGUE. SHE ASSESSED DISABILITY AS EVENT OUTCOME HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. ESSURE WAS REMOVED ON (B)(6) 2015. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 12-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE

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INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PAIN ON LOWER SIDE. THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND DISABILITY (PER REPORTER). ALSO, THE EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE ESSURE REMOVAL WAS REQUIRED (IMPLYING THAT AN INTERVENTION WAS PERFORMED) THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: FOLLOW-UP ATTEMPTS WERE MADE WITH NO RESPONSE TO DATE. COMPANY CAUSALTY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO AN ADULT FEMALE PATIENT

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01881	BAYER HEALTHCARE LLC	12/10/2015	12/10/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/21/2012
Explant Date (E7): 8/6/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1821, AWARENESS DATE 21-OCT-2015). IT REFERS TO AN ADULT FEMALE CONSUMER IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012. CONSUMER IS (B)(6) WITH 2 KIDS. SINCE ESSURE WAS INSERTED SHE STARTED TO HAVE FATIGUE, PLENTY EMERGENCY ROOM VISITS, HIP PAINS, HAIR LOSS AND NOW SHE HAS ENDOMETRIOSIS. LOSS JOBS DUE TO SEVERE LEFT SIDE PELVIS PAIN. JUST HAD A HYSTERECTOMY ON (B)(6) 2015. FEELING A LOT BETTER BUT HAIR IS STILL FALLING OUT, AND SHE STILL WAS HAVING BACK PAINS AND HIP PAINS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS: (B)(4) WAS RECEIVED ON 12-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO

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RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED SEVERE LEFT SIDE PELVIS PAIN. SHE HAS JUST HAD A HYSTERECTOMY AT THE MOMENT OF THE REPORT. PELVIC PAIN IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE, ENDOMETRIOSIS COULD BE AN ALTERNATIVE EXPLANATION FOR THIS EVENT, CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE, A CONTRIBUTORY EFFECT FROM THE SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058435	BAYER	12/10/2015	12/10/2015

Event Information:

Event Date (B3): 3/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME BLOATING, MIGRAINES, INTERNAL PAINS FROM STABBING TO SORENESS, PAINFUL MENSTRUATIONS, SWELLING, JOINT PAINS, RASH THAT HASN'T GONE AWAY AND GETTING WORSE, SCARRING OF SKIN, FALLING HAIR AND DANDRUFF, MEMORY LOSS AND BRAIN FOG, INSOMNIA AND EXTREME FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058436	BAYER	12/10/2015	12/10/2015

Event Information:

Event Date (B3): 4/10/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, SERVER PAIN IN PELVIS, LEGS AND BACK, HEAVY BLEEDING ON PERIODS TWO TO SOMETIME 3 TIMES A MONTH, MOVEMENTS IN BELLY LIKE I'M PREGNANT, SEX WENT FROM EVERYDAY 2 TO 3 TIMES A DAY TO NOT WANTING IT.. BAIL MOVEMENTS IS NOT GOOD CAN ONLY USE BATHROOM WHEN ON MY PERIOD. RESTLESS, NO ENERGY

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058437	BAYER	12/10/2015	12/10/2015

Event Information:

Event Date (B3): 6/11/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LAVH PERFORMED ON (B)(6) 2015. NO PAIN AND I CAN ALREADY FEEL A DIFFERENCE FROM FATIGUE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058438	BAYER	12/10/2015	12/10/2015

Event Information:

Event Date (B3): 12/9/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). TOTAL HYSTERECTOMY WITH BILATERAL SALPINGECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058490	BAYER	12/10/2015	12/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/11/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE IN (B)(6) 2011 AND I HAVE BEEN EXPERIENCING SEVERE ABDOMINAL CRAMPING, MIGRAINES/HEADACHES, BACK PAIN, GALLBLADDER REMOVAL ((B)(6) 2014), SKIN INFECTIONS (BOILS), RASHES, BRAIN FOG, FORGETFULNESS, SHORTNESS OF BREATH, CHEST PAINS, FATIGUE, NO ENERGY, NUMBNESS AND TINGLING IN MY ARMS, HANDS, LEGS, AND THIGHS, WEIGHT GAIN THAT WILL NOT GO AWAY AND IT MAKES ME LOOK LIKE I AM SIX MONTHS PREGNANT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058493		12/10/2015	12/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ATER HAVING THE ESSURE IMPLANTED IN (B)(6) 2012, I HAVE EXPERIENCED A LOT OF SIDE EFFECTS; SEVERE PELVIC AND ABDOMINAL PAIN, LOWER BACK PAIN, EXCESSIVE HEAVY BLEEDING, DIZZINESS, CHEST PAIN, SWELLING, SEVERE LEG AND KNEE PAIN, SEVERE BLOATING. I HAVE FIBROIDS THAT WILL BE REMOVED ALONG WITH THE ESSURE COILS ON (B)(6) 2016. I WILL BE HAVING A HYSTERECTOMY. ACCORDING TO MY ULTRASOUND, THE COILS HAVE MIGRATED. SCHEDULE FOR MY PRE-OP ON (B)(6) 2015.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01897	BAYER HEALTHCARE LLC	12/11/2015	12/11/2015

Event Information:

Event Date (B3): 1/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5055996) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT INSERTED ON (B)(6) 2010. CONCOMITANT MEDICATION INCLUDED VYVANSE AND ABILIFY. IN EARLY 2011, SHE STARTED EXPERIENCING REALLY BAD CRAMPING PAINS, EXCESSIVE BLEEDING, CONSTANT ABDOMINAL PAIN, LOWER BACK PAIN AND SHARP SHOOTING PAINS ALL OVER ENTIRE ABDOMINAL AREA. EXAMS WERE PERFORMED AND DETERMINED THAT SHE NEEDED TO HAVE A PARTIAL HYSTERECTOMY BECAUSE THE METAL IN THE ESSURE COILS CAUSED HER TO HAVE AN ALLERGIC REACTION AND THAT WAS THE ONLY WAY TO REMOVE IT. SHE HAD ONLY 1 OVARY LEFT. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 14-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT (RECEIVED VIA

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REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED REALLY BAD CRAMPING PAINS (CONSTANT ABDOMINAL PAIN/ SHARP SHOOTING PAINS ALL OVER ENTIRE ABDOMINAL AREA) AND EXCESSIVE BLEEDING. SHE UNDERWENT HYSTERECTOMY AND ONE OVARY WAS LEFT. THESE EVENTS, SEEN AS ABDOMINAL CRAMPS AND GENITAL BLEEDING RESPECTIVELY, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE SUGGESTIVE TEMPORAL RELATIONSHIP, CAUSALITY BETWEEN BOTH EVENTS AND ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENT WAS INFORMED. BASED ON AVAILABLE INFORMATION, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

INTERNAL CORRECTION DONE ON 15-DEC-2015 BASED ON INFORMATION RECEIVED ON 22-OCT-2015 INITIAL RECEIPT DATE AMENDED TO 22-OCT-2015.

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01907	BAYER HEALTHCARE LLC	12/11/2015	12/11/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** AS

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2001
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN (B)(6) ON 15-NOV-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2001. THE CONSUMER REPORTED THAT FROM A SMALL CHILD SHE HAVE HAD A SEVERE NICKEL ALLERGY. OVER THE NEXT 18 MONTH POST ESSURE INSERTION, HER PERIOD BECAME HEAVIER AND HEAVIER UNTIL SHE COULD NO LONGER LEAVE THE HOUSE AT THAT TIME OF THE MONTH. IN 2003 HER DOCTOR REMOVED HER UTERUS WHICH CONTAINED EARLY STAGE ADENOMYOSIS AND PARTIAL REMAINS OF THE COILS. SHE WAS CHRONICALLY FATIGUED FOR MONTHS. SHE STATED THAT AT THE TIME OF THE REPORTING SHE WAS CHRONICALLY ILL AS SHE HAD SEVERE ALLERGIC REACTION TYPE OF A RASH ALL OVER BODY, DEPRESSION, ANXIETY, BONE AND JOINT PAIN ALL THROUGH BODY, TWITCHING LEGS, SWOLLEN ANKLES, BLURRED VISION, LOWER BACK PAIN AND SWELLING, OVARIAN PAIN WHEN STANDING FROM THE SITTING POSITION, SEVERELY BLOATED TUMMY, VAGINAL PAIN, MIGRAINES, AND PRICKLING SENSATION ALL OVER BODY. IN 2010 SHE HAD A COMPLETE NERVOUS BREAKDOWN AND SPENT 6 WEEKS IN A PSYCHIATRIC HOSPITAL. SINCE THAT TIME SHE HAD TO LIVE IN A DISABILITY PENSION. THE CONSUMER WAS NEVER TOLD TO CHECK AFTER 3 MONTHS IF THE COILS WERE IN THE RIGHT POSITION. SHE SCHEDULED AN APPOINTMENT WITH HER GENERAL PRACTITIONER TO GET REFERRAL FOR A PELVIC X-RAY TO PINPOINT WHERE THE LEFTOVERS OF THE COILS WERE AND WILL HAVE HER FALLOPIAN TUBES REMOVED. THE CONSUMER ASKED HOW HER ESSURE WAS IMPLANTED IN 2001 WHEN ACCORDING TO EVERYTHING SHE HAD READ, IT DID NOT HIT THE (B)(6) MARKET UNTIL 2010. SHE STATED SHE WAS GOING TO TAKE LEGAL ACTION AS THE WONDERFUL HEALTH SHE ONCE HAD WAS GONE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. APPROXIMATELY TWO

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YEARS LATER, SHE HAD HER UTERUS REMOVED AND IT CONTAINED EARLY STAGE ADENOMYOSIS AND PARTIAL REMAINS OF THE COILS. ACCORDING TO HER, SHE HAS AN APPOINTMENT WITH HER PHYSICIAN TO DISCOVER WHERE THE LEFTOVERS OF THE COILS WERE AND WILL HAVE HER FALLOPIAN TUBES REMOVED. ADDITIONALLY, 9 YEARS AFTER ESSURE PLACEMENT, SHE WAS HOSPITALIZED FOR 6 WEEKS DUE TO NERVOUS BREAKDOWN. ALL EVENTS ARE UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ADENOMYOSIS REFERS TO A DISORDER IN WHICH ECTOPIC ENDOMETRIAL TISSUE GROWS INTO THE UTERINE MUSCULATURE; ITS RISK FACTORS INCLUDE: PRIOR UTERINE SURGERY, MIDDLE AGE AND CHILDBIRTH. SYMPTOMS OF ADENOMYOSIS TYPICALLY INCLUDE MENORRHAGIA. HYSTERECTOMY IS OFTEN USED TO TREAT THIS CONDITION. IN THIS PARTICULAR CASE, CONSUMER REPORTED HEAVY PERIODS AFTER ESSURE INSERTION AND WAS SUBMITTED TO A HYSTERECTOMY. ACCORDING TO HER, PARTIAL REMAINS OF THE COILS WERE FOUND IN HER UTERUS. CONSIDERING ESSURE LOCAL ACTION IN FALLOPIAN TUBES AND GIVEN ADENOMYOSIS PATHOPHYSIOLOGY, CAUSALITY WITH THE SUSPECT INSERT IS CONSIDERED UNLIKELY. REGARDING THE REPORTED DEVICE BREAKAGE (PARTIAL REMAINS OF THE COILS); IT IS UNCLEAR IF ESSURE BROKE AS A CONSEQUENCE OF THE HYSTERECTOMY (PERFORMED PRESERVING FALLOPIAN TUBES) OR IF THE DEVICE WAS ALREADY BROKEN BEFORE THIS SURGERY. THEREFORE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. FOR CONSUMER'S NERVOUS BREAKDOWN; GIVEN ITS NATURE AND BASED ON ESSURE LOCAL ACTION IN FALLOPIAN TUBES; CAUSALITY IS CONSIDERED UNLIKELY. ALTHOUGH CONSUMER'S ADENOMYOSIS WAS THE LIKELY MEDICAL REASON FOR THE PERFORMED HYSTERECTOMY; SINCE IT IS UNCLEAR IF THE REPORTED DEVICE BREAKAGE CONTRIBUTED TO THIS INTERVENTION; THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 26-NOV-2015 (B)(4). SHE STATED THAT SHE BECAME ILL AND SPENT 6 WEEKS IN HOSPITAL; DOCTOR JUST PUT IT DOWN TO BURNOUT DEPRESSION AND ANXIETY. HER DOCTOR THOUGHT IT WAS TYPE 1 BIPOLAR WITH BOUTS OF SERIOUS AND DANGEROUS DEE

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058457	BAYER	12/11/2015	12/11/2015

Event Information:

Event Date (B3): 7/30/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE LOWER BACK PAIN, SEVERE ABDOMINAL PAIN DURING PERIODS AND OVULATION, EXTREMELY HEAVY AND IRREGULAR PERIODS, MIGRAINES, HAIR LOSS, OVARIAN CYSTS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058458	BAYER	12/11/2015	12/11/2015

Event Information:

Event Date (B3): 12/17/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS HEALTHY. THIS WAS THE WORST DECISION I MADE FROM MY DOCTORS RECOMMENDATION TO GET THE ESSURE. I'VE HAD PAIN, BLOATING, AND EXCESSIVE BLEEDING ON MY PERIOD. EVERYTHING I DO IS PAINFUL IN AND AROUND THE LEFT COIL THAT WAS PLACED. I HAVE A CONSTANT ANNOYING AND SHARP PAIN IN THE LEFT COIL. I CAN'T HOLD IT WHEN I'VE GOTTA PEE NOW VERY WELL WHICH HINDERS ME FROM GOING ANYWHERE. SEX IS NOW IRRITATING AND PAINFUL ON MY LEFT SIDE. I'VE HAD CONSTANT FEAR SINCE THE MOMENT I WOKE FROM SURGERY. I JUST WANT THESE THINGS OUT OF MY BODY AND IT WOULD BE A BLESSING TO HAVE THIS DEVICE FROM HELL RECALLED AND DOCTORS PLEASE STOP LYING, IF YOU AREN'T PERSONALLY SURE OF SOMETHING DON'T PRETEND YOU DO. I PRAY THERE'S A SOLUTION QUICKLY. I WOULD LOVE TO WAKE UP WITHOUT A HEADACHE, BLOATING TO THE POINT I CAN'T EAT, SLEEP, WALK, LAY DOWN AND INTERACTIVE PLAY WITH MY CHILDREN, FORGET IT. AFTER ALMOST TWO YEARS OF THIS I AM STILL IN PROCESS OF TRYING TO GET THIS DEVICE REMOVED WITH NO LUCK THUS FAR.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058459	BAYER	12/11/2015	12/11/2015

Event Information:

Event Date (B3): 12/3/2015	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER 6 YEARS OF LIVING IN HELL FROM THIS DEVICE, I WAS FINALLY ABLE TO HAVE IT REMOVED! I HAD LAVH WITH TUBE AND COIL REMOVAL ON (B)(6) 2015 THANK GOD! IT IS A SAD THING THAT THOUSANDS OF WOMEN ARE BEGGING FOR HYSTERECTOMY'S JUST TO HAVE A CHANCE AT HAVING A NORMAL LIFE AGAIN! THESE COILS ARE THE WORST THING INVENTED AND SHOULD BE IMMEDIATELY REMOVED FROM THE MARKET!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058460	BAYER	12/11/2015	12/11/2015

Event Information:

Event Date (B3): 12/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN, SWELLING, SPOTTING, CYST, THIS THING IS EVIL. SPOTTING STARTED A FEW MONTHS AFTER IMPLANTED. BLOODY MESS AFTER SEX. MANY SETS OF SHEETS, CLOTHES HAVE BEEN RUINED. THE LAST ROUND OF SWELLING AND PAIN IS CAUSING INTERFERING WITH DAILY LIFE. NEXT MONTH I KNOW HAVE TO HAVE SURGERY TO FIND OUT WHAT IS GOING ON. SO MUCH FOR EASY EFFECTED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058497	CONSEPTUS/BAYER	12/11/2015	12/15/2015

Event Information:

Event Date (B3): 11/14/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): ESS205
Catalog # (E4): ESS205
Lot #(E4): 1224355 RIGHT; 12242355 LEFT

Single Use: *
Implant Date (E6): 11/14/2003
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

PRIOR TO ESSURE IMPLANTATION, I WAS A HEALTHY (B)(6) FEMALE ACTIVE IN GARDENING AND HIKING AND IN MY CAREER AS A NURSE, WORKING 10 HR SHIFTS WITHOUT DIFFICULTY AND STILL ABLE TO TAKE CARE MY FAMILY AT THE END OF THE WORK DAY. SINCE ESSURE, MY HEALTH HAS DECLINED. WITHIN 6 MONTHS OF IMPLANTATION OF ESSURE, I HAD DEVELOPED HEARTBURN, REFLUX, AND ABDOMINAL BLOATING AND PRESSURE. OVER THE COURSE OF ONE MONTH IN (B)(6) 2006, IN STARTED EXPERIENCING PAIN IN BOTH MY LEGS, SEVERE ABDOMINAL BLOATING AND PRESSURE, CONSTIPATION AND GAS. SEVERE FATIGUE, SHORT TERM MEMORY LOSS, DIFFICULTY CONCENTRATING, UNEXPLAINED WEIGHT GAIN. THESE SYMPTOMS HAVE CONTINUED OVER THE LAST 10 YEARS AS WELL AS THE ONSET OF BELCHING, A TASTE OF METAL IN MY MOUTH, HAIR BREAKING AND FALLING OUT, A RASH ON MY LEFT FLANK THAT COMES AND GOES. RECEDING GUMS, FRACTURED TEETH, CAVITIES, BLURRY VISION, COLD INTOLERANCE TONGUE TIED. PAIN IN LEGS, ANKLES, BOTTOM OF FEET, HIPS, BACK, PELVIS, GROINS, ARMS, AND FINGERS. VAGINOSIS, PAINFUL MENSES, MENTRUAL BLOOD CLOTS AND SPOTTING. OCCASIONAL PAINFUL INTERCOURSE, FREQUENT AND URGENT URINATION. SEVERE PELVIC PRESSURE, AND FLUID RETENTION IN LEGS AND HANDS, AND WEIGH GAIN, WHICH FLUCTUATES, OF 30 - 40 POUNDS, DESPITE DIET AND EXERCISE. I CONTINUE TO SEE MY PCP AND SPECIALIST FOR MY SYMPTOMS, WHICH HAVE NOT RESOLVED WITH OTC MEDICATIONS AND PRESCRIPTIONS AND TREATMENT THROUGH OUT THE LAST 10 YEARS. I AM UNABLE TO TOLERATE SITTING OR STANDING FOR LONGER THAN 30 MINUTES WITHOUT SEVERE PAIN IN MY LEGS, BACK, AND PELVIS. THE ABDOMINAL BLOATING HAS GIVEN ME LOW SELF ESTEEM, AND MAKES EXERCISE AND EATING EXTREMELY UNCOMFORTABLE. THE FATIGUE MAKES DAILY ACTIVITIES DIFFICULT TO ACCOMPLISH. MY QUALITY OF LIFE AND ABILITY TO CARE FOR MY FAMILY AT FULL CAPACITY HAS BEEN GREATLY IMPACTED. AT THIS TIME, THE ESSURE ARE STILL IMPLANTED. I

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CURRENTLY TAKE LINZESS FOR CONSTIPATION AND BLOATING WITHOUT RELIEF AND NEXIUM FOR HEARTBURN AND REFLUX WITH SOME RELIEF. OVER THE PAST TEN YRS, I HAVE BEEN PRESCRIBED, BUT NO LONGER TAKE, THE FOLLOWING MEDICATIONS WITH TEMPORARY OR NO RELIEF OF SYMPTOMS: PRESCRIPTION STRENGTH VITAMIN D, AMITIZA, NORTRYPTILINE, ANTIBIOTIC, DICYCLOMINE, DICLOFENAC, BENTYL, CELEBREX, SPIRONOLACTONE, VAGINAL CREAM. I CURRENTLY TAKE A MULTIVITAMIN FOR WOMEN WHICH CONTAINS VITAMIN D, VITAMIN B12, ALEVE AS NEEDED FOR PAIN, MAGNESIUM CITRATE FOR CONSTIPATION, GLYCERIN SUPPOSITORIES FOR SEVERE CONSTIPATION. OVER THE PAST TEN YEARS, I HAVE TRIED, BUT NO LONGER TAKE, THE FOLLOWING OVER-THE-COUNTER MEDICATIONS WITH TEMPORARY OR NO RELIEF OF SYMPTOMS: ALEVE, TYLENOL, ADVIL, MOTRIN, MIDOL, LACTAID, DIGESTIVE AID, HEATHER'S FOR IBS, FAMOTIDINE, RANITIDINE, MYLANTA, PEPTO BISMOL, MAALOX, METAMUCIL, CITRUCEL, GAS-EX, PROBIOTICS, GEN-GAY AND OTHER ARTHRITIS RUBS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058523	BAYER	12/11/2015	12/16/2015

Event Information:

Event Date (B3): 12/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C91740

Single Use: *
Implant Date (E6): 11/5/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

NICKEL ALLERGY AFTER 6 MONTHS OF ESSURE PLACEMENT. I HAVE HAD ESSURE COILS IN PLACE FOR 13 MONTHS SO FAR AND WHILE BREASTFEEDING, MY INFANT DEVELOPED CHRONIC EAR INFECTIONS, BRONCHITIS, DIAGNOSED WITH ASTHMA AND FREQUENT ON AND OFF FEVERS. AS FOR MYSELF, I WAS DIAGNOSED BY MY IMPLANTING DOCTOR WITH ADENOMYOSIS, PAINFUL AND HEAVIER PERIODS, HAIR LOSS, BLOATING, SHARP PAINS IN LOWER PELVIC REGION, FLUTTERING IN BELLY, AND SCIATIC NERVE PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058461	BAYER	12/12/2015	12/12/2015

Event Information:

Event Date (B3): 10/19/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY BLEEDING WITH LARGE CLOTS, CYCLE WOULD INCLUDE SIX DAYS OF SPOTTING, THEN SEVEN DAYS OF HEAVY BLEEDING, BLOATING THAT LASTED 2012 UNTIL REMOVAL 2015, HEART BURN, NAUSEA, HEADACHES, ACHY JOINS, UNEXPLAINED RASHES, EXHAUSTION, SHOOTING LOWER ABDOMINAL PAIN, VERY PAINFUL OVULATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058462	BAYER	12/12/2015	12/12/2015

Event Information:

Event Date (B3): 12/18/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE IN BER OF 2014. I HAD GIVING BIRTH TO MY THIRD CHILD IN AUGUST OF 2014. I SIGNED ALL THE REQUIRED FORMS TO HAVE MY TUBES TIED RIGHT AFTER I GAVE BIRTH, HOWEVER I WAS TOLD THE HOSPITAL FORGOT ME AND COULD NOT FIT ME IN. I WOULD HAVE TO COME BACK TO HOSPITAL. THE DR QUICKLY REMINDED ME ABOUT ESSURE AND HOW THE QUICK, PAINLESS, IN OFFICE PROCEDURE HAD VERY LITTLE RECOVERY TIME. I IMMEDIATELY HAD THE STABBING PAIN AND SORENESS IN MY PELVIC AREA, IT CONTINUES TO THIS DAY, ONLY WORSE. I BLED FOR THREE MONTHS STRAIGHT, THEN WENT TO A TEN DAY CYCLE. ITS CONSTANT PMS, WITH THE UNBEARABLE BACK PAIN AND CRAMPS LIKE IM IN LABOR. MY SEX DRIVE IS NON EXISTENT, AND EVEN IF I WANTED TO, ITS TO PAINFUL TO ENJOY. MY HAIRS FALLING OUT, I GET HEADACHES, FATIGUE, AND MEMORY FOG. I HAVE MADE AN APPOINTMENT IN (B)(6) TO BEG FOR A HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058531	BAYER HEALTH	12/12/2015	12/16/2015

Event Information:

Event Date (B3): 8/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 8/11/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE HAD TWO CHILDREN AND SO MY HUSBAND AND I THOUGHT IT WAS TIME TO GET FIXED. I HAD MY MIND SET ON THE ESSURE. I SET UP AN APPOINTMENT TO GET THE PROCEDURE AND THE DOCTOR ASKED ME IF I WOULD RATHER JUST HAVE MY TUBES TIED. I TOLD HIM NO, I WANTED SOMETHING IRREVERSIBLE. SO THE DAY CAME TO GET THE ESSURE PROCEDURE. IT WAS A REALLY SIMPLE IN AND OUT PROCEDURE; TWO VICODIN AND I DIDN'T FEEL A THING. I THOUGHT EVERYTHING WAS GREAT, BUT THEN I STARTED TO NOTICE MY LACK OF ENERGY AND BEING TIRED ALL THE TIME. MAJOR FATIGUE HAD KICKED IN. THEN I STARTED GETTING MOODY, WHICH I'M USUALLY A REALLY EASY GOING PERSON. MY PERIODS SEEMED LIKE THEY NEVER STOPPED. SPOTTING IN BETWEEN PERIODS AND THEN HAVING MY ACTUAL PERIOD FOR A GOOD WEEK AND A HALF OR TWO WHEN NORMALLY THEY WOULD LAST AT MOST A WEEK. THEN THE HEADACHES STARTED, I'M NOT ONE TO GET HEADACHES BUT I WOULD WAKE UP WITH ONE VERY OTHER DAY. CRAMPS ARE ANOTHER THING I NEVER EVER HAD (WAS REALLY LUCKY GROWING UP) BUT NOW I'M IN PAIN A LOT. I TAKE TYLENOL FOR THE PAIN AND MIDOL FOR IT. NOTHING IS KILLING THE PAIN. MY SEX DRIVE COMPLETELY DISAPPEARED AND I MEAN COMPLETELY. INTERCOURSE IS NOT ENJOYABLE; IT IS TO THE POINT OF HURTING. ALSO DURING THE NIGHT I WAKE WITH HOT FLASHES. ALL THESE SYMPTOMS HAVE STARTED TO OCCUR OR WORSEN AFTER MY PROCEDURE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058532	BAYER	12/13/2015	12/16/2015

Event Information:

Event Date (B3): 6/6/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A95856

Single Use: *
Implant Date (E6): 6/6/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE ESSURE IMPLANT IN 2013, I HAVE SUFFERED MULTIPLE SYMPTOMS. SEVERE JOINT PAIN, SI-JOINT DYSFUNCTION, SEVERE LOWER BACK PAIN, THORACIC SPINE PAIN, NUMBNESS, TINGLING STABBING IN LEGS, FEET, AND ANKLES, PAIN DURING SITTING, COCCYXDYNIA, PELVIC PAIN, TMJ AND FACIAL NERVE PAIN, RAPID TOOTH DECAY, PAINFUL INTERCOURSE, MIGRAINE, HEADACHES, NECK PAIN, KNEE PAIN, PAIN DURING OVULATION, ABNORMAL MENSTRUAL BLEEDING (STARTING, STOPPING AND ABSENT) WITH A NEGATIVE PREGNANCY TEST, BLOATING, NIGHT SWEATS, COLD CHILLS, MEMORY LOSS AND BRAIN FOG, DEPRESSION FROM CONSTANT PAIN, HAIR LOSS ON THREE SEPARATE OCCASIONS WHERE HAIR CAME OUT IN CLUMPS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01908	BAYER HEALTHCARE LLC	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 2/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/8/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM AN ADULT (>=18Y & <65Y) FEMALE CONSUMER IN UNITED STATES ON 18-NOV-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010. THE CONSUMER STATED THAT SHE HAS HAD HIVES FOR OVER A YEAR AND SHE HAS BEEN TO 4 DERMATOLOGISTS. CONSUMER STATED SHE HAD A PREVIOUS MEDICAL HISTORY OF NICKEL ALLERGY PRIOR TO THE INSERTION OF ESSURE. SHE RECENTLY HAD METAL TESTING AND WAS FOUND TO HAVE A NICKEL ALLERGY PTC INVESTIGATION RESULT WAS RECEIVED ON 22-DEC-2014. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: AN ALLERGY IS A HYPERSENSITIVITY TO A SUBSTANCE THAT CAUSES THE BODY TO REACT TO ANY CONTACT WITH THAT SUBSTANCE. COMMON INDICATIONS OF ALLERGY MAY INCLUDE SNEEZING, ITCHING, SKIN RASHES AND HIVES. PROBABLE CAUSE FOR AN ALLERGIC RESPONSE IN PATIENT - AN ALLERGIC RESPONSE TO THE ESSURE MICRO-INSERT IS MOST OFTEN DUE TO THE PATIENT'S SENSITIVITY TO NICKEL. ACCORDING TO THE PRODUCT IFU, THE ESSURE SYSTEM SHOULD NOT BE USED ON ANY PATIENT WITH A KNOWN HYPERSENSITIVITY TO NICKEL CONFIRMED BY SKIN TEST. SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO CONFIRM THAT ALL PARTS ARE ACCOUNTED FOR AND INSPECT THE DEVICE TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THIS IS AN ANTICIPATED EVENT. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT

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IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NEITHER BATCH NUMBER NOR COMPLAINT SAMPLE WAS PROVIDED FOR FURTHER TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW UP 08.JAN.2015: FOLLOW UP INFORMATION RECEIVED FROM THE CONSUMER. CONCOMITANT DISEASES INCLUDE LUPUS. NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES. ON (B)(6) 2008 ESSURE WAS INSERTED AND CONSUMER USED ORAL CONTRACEPTIVES (UNSPECIFIED) AS BACK UP CONTRACEPTION UNTIL ESSURE TOTAL OCCLUSION CONFIRMATION. IN (B)(6) 2008 HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED TUBES OCCLUDED. CONSUMER REPORTED THAT SHE HAD LONG TERM HIVES, EVERYWHERE. SHE HAS BEEN WORKING WITH ALLERGIST AND HAS NOT RECOVERED FROM THE HIVES. SHE IS HIGHLY ALLERGIC TO NICKEL. SHE WAS NOT HOSPITALIZED. CONSUMER ALSO REPORTED THAT SHE HAS BEEN CONTINUING WITH ESSURE BUT PHYSICIAN IS STILL CONSIDERING TO REMOVE THE DEVICES. FOLLOW UP FROM 19-MAR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS WAS COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER INFORMATION IS EXPECTED. FOLLOW-UP RECEIVED ON 16-NOV-2015 FROM PHYSICIAN: DATE OF EVENT REPORTED WAS (B)(6) 2015. CONSUMER REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT OR DAMAGE. SHE UNDERWENT TO HYSTERECTOMY WITH BILATERAL SALPINGECTOMY AND HAS HAD FULL RESOLUTION OF SYMPTOMS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAS HAD LONG TERM HIVES FOR OVER A YEAR, EVERYWHERE. SHE UNDERWENT TO HYSTERECTOMY WITH BILATERAL SALPINGECTOMY. THIS EVENT WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THE ESSURE INSERT CONSISTS OF A NICKEL-TITANIUM ALLOY. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE SKIN ITCHING, RASH, ECZEMATOUS DERMATITIS, AND HIVES THAT RESOLVE AFTER DEVICE REMOVAL. IN THIS CASE, CONSUMER STATED THAT SHE HAD A PREVIOUS MEDICAL HISTORY OF NICKEL ALLERGY PRIOR TO THE INSERTION OF ESSURE. SHE EXPERIENCED THIS EVENT ABOUT 6 YEARS AND 5 MONTHS AFTER ESSURE INSERTION. IT WAS ALSO REPORTED THAT SHE HAS HAD FULL RESOLUTION OF SYMPTOMS AFTER UNDERGOING THE SURGICAL INTERVENTION. CONSIDERING THIS INFORMATION AND BASED ON A POSITIVE TEMPORAL RELATIONSHIP, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 23-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FO

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01909	BAYER HEALTHCARE LLC	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/5/2014
Explant Date (E7): 8/12/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 06-JUN-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED 8 MONTHS PRIOR TO THIS REPORT, IN (B)(6) 2014. IN (B)(6) 2015, HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED AND SHOWED THAT RIGHT ESSURE WAS DISPLACED INTO CUL-DE-SAC WITH UTERINE PERFORATION. IT WAS ALSO REPORTED THAT THE PATIENT DESIRES REMOVAL OF THE LEFT ESSURE IMPLANT DESPITE OF BEING OCCLUDED. FOLLOW-UP INFORMATION WAS RECEIVED ON 15-JUN-2015: DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 06-JUN-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 04-JUN-2015. PTC INVESTIGATION RESULT WAS RECEIVED ON 16-JUN-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC LOCAL NUMBER (B)(4) AND PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: SINCE NO PRODUCT WAS RETURNED TO US FOR INVESTIGATION, WE WERE UNABLE TO PERFORM AN INVESTIGATION OF THE ACTUAL DEVICE INVOLVED IN THIS COMPLAINT. TYPICALLY, WE WOULD INSPECT THE MICRO-INSERT TO LOOK FOR ANY MANUFACTURING DEFICIENCIES. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. NO NEW FAILURE MODE HAS BEEN IDENTIFIED. MEDICAL ASSESSMENT: THIS PTC WAS INITIATED DUE TO A REQUEST FOR CONFIRMATION OF QUALITY. THE REPORTED ADVERSE EVENT IS A KNOWN, POSSIBLE, UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO BATCH NUMBER WAS REPORTED. WITHOUT THIS INFORMATION NO BATCH SIGNAL CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE. NO

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COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. FOLLOW-UP FROM 16-SEP-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. FOLLOW-UP RECEIVED ON 16-NOV-2015 FROM PHYSICIAN. ESSURE HEALTH CARE PROVIDER UTERINE/ TUBAL PERFORATION QUESTIONNAIRE WAS PROVIDED. PATIENTS DEMOGRAPHIC DATA WAS PROVIDED. SHE BECAME PREGNANT 3 TIMES, WITH 3 LIVE BIRTHS. ESSURE WAS INSERTED ON (B)(6) 2014 (PREVIOUS REPORTED AS (B)(6) 2014). PATIENT WAS 3 MONTHS POST PARTUM AT TIME OF INSERTION. THE INSERTION WAS EASY AND DID NOT REQUIRE CERVICAL DILATION, SOUNDING AS WELL AS GENERAL ANESTHESIA. PATIENT RECEIVED PREMEDICATION VALIUM AND NORCO. THERE WAS NO FLUID LOSS DURING HYSTEROSCOPY. THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. SHE RECEIVED ORAL CONTRACEPTIVE PILLS AS BACK UP CONTRACEPTION. HYSTEROSALPINGOGRAM TEST (HSG) WAS PERFORMED ON (B)(6) 2014 AND THE RESULT SHOWED RIGHT ESSURE DISPLACED INTO CUL-DE-SAC WITH UTERINE PERFORATION. THE PATIENT EXPERIENCED PAIN AFTER HSG TEST. PATIENT REQUESTED ESSURE REMOVAL. CT SCAN ON (B)(6) 2015 SHOWED LEFT ESSURE IMPLANT IN LEFT CORNUA; RIGHT ESSURE WITHIN RIGHT CUL-SE-SAC LATERAL TO RECTOSIGMOID. NO FREE FLUID. ON (B)(6) 2015, A BILATERAL SALPINGECTOMY AND TOTAL HYSTERECTOMY WERE PERFORMED AND ESSURE WAS REMOVED. THE PATHOLOGY RESULT SHOWED BOTH FALLOPIAN TUBES UNREMARKABLE, SWELLING OF LEFT CORNUA WITHOUT REDNESS/ DISCOLORATION. PATIENT HAS RECOVERED FROM ESSURE REMOVAL PROCEDURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HSG (HYSTEROSALPINGOGRAM) PERFORMED 3 MONTHS LATER SHOWED RIGHT ESSURE DISPLACED INTO CUL-DE-SAC WITH UTERINE PERFORATION. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UTERINE PERFORATION MAY OCCUR WITH TRANS-CERVICAL INTRAUTERINE PROCEDURE (E.G. HYSTEROSCOPY, CURETTAGE), INCLUDING ESSURE INSERTION. IN THE PRESENT CASE, UTERINE PERFORATION WAS DIAGNOSED ON HSG 3 MONTHS AFTER ESSURE INSERTION. CONSIDERING THE NATURE OF THE EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. PREVIOUSLY THIS CASE WAS REGARDED AS NON-INCIDENT. UPON RECEIPT OF FOLLOW UP INFORMATION, IT WAS INFORMED A BILATERAL SALPINGECTOMY AND TOTAL HYSTERECTOMY WERE PERFORMED AND ESSURE WAS REMOVED. THEREFORE THIS CASE WAS UPGRADED TO INCIDENT. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP TO A POTENTIAL QUALITY DEFICIT BASED ON THIS REPORT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058463	BAYER	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 9/7/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).
I WAS IMPLANTED IN 2005 IN AN OUTPATIENT SETTING, I HAVE SINCE DEVELOPED SEVERE ALLERGIES, MY STOMACH SWELLED UP AND WON'T GO DOWN, SHARP STABBING PAINS ON MY SIDES, BURNING SENSATION ON MY INSIDE PELVIC AREA, PELVIC SPASMS, SHARP SHOOTING PAINS DOWN MY VAGINAL CANAL AND SIDES, SHARP STABBING PAIN ON RIGHT SIDE WHEN I SNEEZE, HEAVY MENSTRUALS WITH BLOOD CLOTS AND SEVERE CRAMPING HAVE TO MONITOR MY BLEEDING AND WEAR 2 SUPER PADS, EDEMA IN LEGS, RED SPOTS ON MY LEGS THAT WILL NOT GO AWAY AND NO EXPLANATION OF WHAT IT IS FROM, HEAD FOG, LIGHTHEADED AT TIMES, METAL TASTE IN MOUTH ALL THE TIME, EXTREME FATIGUE, MULTIPLE BOILS ON INNER THIGHS ALL THE TIME. CONSTANT HEADACHES,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058464	BAYER	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 9/3/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).
HAIR LOSS
HAIR GROWTH IN NEW AREAS
COLD EXTREMITIES
ANEMIA
HYPOGLYCEMIA
UNBALANCED GAIT
MEMORY LOSS
HIP PAIN
BACK PAIN
DENTAL ISSUES
EXTREME WEIGHT LOSS (B)(6) CHRONIC FATIGUE
BLEEDING AFTER INTERCOURSE

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BCBS PROVIDES SERVICE.
NO PREVIOUS MEDICAL PROBLEMS

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058465	BAYER	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 12/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).
AS A RESULT OF THE COMPLICATIONS I EXPERIENCED FROM ESSURE, I HAD A HYSTERECTOMY ON (B)(4). MY DOCTOR TOOK A PICTURE OF MY UTERUS WHICH HAD A VERY LARGE FIBROID TUMOR ON TOP OF MY UTERUS... I HAVE NO FAMILY HISTORY OF FIBROIDS. ADDITIONALLY, THE IMAGE SHOWS A CYST GROWING FROM ONE OF MY FALLOPIAN TUBES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058466	BAYER	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 9/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).
IT STARTED OFF WITH GRADUAL WEIGHT GAIN. MOSTLY IN MY BELLY. I WOULD GET PAIN IN MY PELVIS. MY STOMACH WILL BE SO BLOATED I WOULDN'T BE ABLE TO BREATHE. I WAS DIAGNOSED AS A DIABETIC. I WAS ALSO ADMITTED IN THE ER DUE TO URINE RETENTION. I HAD A FOLEY CARTHER FOR A WEEK. MY PERIOD WAS SO HEAVY I HAD TO WEAR 2 ULTRA PADS CHANGED EVERY 2 HOURS BECAUSE THEY WILL BE SOAKED WITH BLOOD. I WAS ALSO WAS UNABLE TO DO ANY SORT.OF ACTIVE BECAUSE I WOULD BE EXHAUSTED. ON (B)(6) 2015 I HAD A HYSTERECTOMY AS SOON AS I WOKE UP I FELT BETTER MY STOMACH WAS NOT BLOATED I WAS ABLE TO BREATHE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058467	BAYER	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).
PEROIDS BECAME HEAVIER AND MORE PAINFUL THAN USUAL. IN (B)(6) MY PERIOD CAME 2 WEEKS LATE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058468	BAYER	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 12/7/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4).
I HAD SURGERY TO REMOVE ESSURE AND TO PREVENT FURTHER DAMAGE TO MY BODY ON (B)(6) 2015. MY DOCTOR FOUND ADHESIONS ON MY APPENDIX. I AM SUFFERING AND IN PAIN. THIS IS NOT WHAT I SIGNED UP FOR WITH ESSURE-A FULL HYSTERECTOMY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058469	BAYER	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 10/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HIVES EVERYWHERE, ENSURE PRESCRIBED BY MD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058470	BAYER	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). UNEXPLAINED RASHES.. EXCESS WEIGHT GAIN.. MIGRAINES, JOINT PAIN AND SWELLING, SHORT TERM MEMORY LOSS, FOGGY BRAIN, CHANGE IN VISION. MENOPAUSE SYMPTOMS, LAB WORK PERFORMED AND ALL LABS ARE NORMAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058485	BAYER	12/14/2015	12/14/2015

Event Information:

Event Date (B3): 6/13/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH ESSURE ON (B)(6) 2012 THRU ANESTHETIC BECAUSE WITHOUT ANESTHETIC IT WAS TOO PAINFUL. ONCE I WOKE UP AFTER BEING IMPLANTED FROM THAT DAY FORWARD I BEGAN TO FEEL PELVIC PAIN, EXTREME FATIGUE, DEPRESSION, INCREASED INFLAMMATION, IRREGULAR MONTHLY CYCLES, HEAVY BLEEDING, HEAVY CRAMPING, INSULIN RESISTANCE, MEMORY LOSS, SPEECH ISSUES, JOINT PAIN, LEFT HIP PAIN, LOOSE TOOTH FEELING. MOOD SWINGS, AND VITAMIN D DEFICIENCY. ALL AFTER ESSURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058533	BAYER HEALTH	12/14/2015	12/16/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country: US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/28/2009
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER IS COMPLAINING OF HAVING PAIN FROM ESSURE FOR 4-5 OF THE 6 YEARS THAT ESSURE HAS BEEN IN. SHE FEELS SHE WAS PUSHED TO HAVE IT INSTEAD OF A TUBAL BY (B)(6). SHE WAS INFORMED IT WAS MADE OF TITANIUM WITH A LITTLE NICKEL. AT THE TIME SHE WAS NOT ALLERGIC TO NICKEL, HOWEVER SHE NOW HAS DEVELOPED AN ALLERGY TO NICKEL. RECENTLY SHE WAS DIAGNOSED WITH ADENOMYOSIS. THE REPORTER STATES ALMOST ALL WOMEN WHO HAVE THIS DEVICE HAVE DEVELOPED ADENOMYOSIS. IN(B)(6) , WOMEN HAVE DIED, WHICH IS VERY SCARY. THE FDA NEEDS TO STOP BAYER FROM CONTINUING TO MAKE THESE DEVICES. BAYER'S DATA IS INCORRECT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058534	BAYER HEALTH	12/14/2015	12/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): PERMANENT BIRTH CONTROL
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/13/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

REPORTER IS COMPLAINING OF HAVING EXCESSIVE BLEEDING DURING PERIODS THAT CAN LAST UP TO 15 DAYS A MONTH. WAS GIVEN BIRTH CONTROL THAT CONTROLLED THE BLEEDING AND WHEN SHE STOPPED THE PILLS, THE BLEEDING RETURNED SO SHE HAD TO GO BACK TO THE BIRTH CONTROL PILLS. HAVING PAIN ESPECIALLY DURING GYM WITH BENDING AND LIFTING. DO NOT FEEL LIKE SHE IS THE SAME PERSON. SHE USED TO BE VERY ACTIVE, BUT NOW HAVE TO PLAN HER DAY. SHE IS SO FATIGUED, IT IS HARD TO TAKE CARE OF HER CHILDREN. HER TASTE HAS ALSO CHANGED, FEEL LIKE A METAL TASTE IS IN HER MOUTH. FEEL LIKE THIS DEVICE IS A PUNISHMENT AND COMPLAINS OF PAIN WHERE HER TUBES ARE. THE DOCTOR RECOMMENDS A LAPAROSCOPIC REMOVAL OF TISSUE BUT THE REPORTER IS SCARED THAT HER CONDITION WILL BE WORSE THAN WHAT SHE IS DEALING WITH AT PRESENT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058554	BAYER HEALTHCARE	12/14/2015	12/17/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE BIRTH CONTROL
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 9/11/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I GOT THE ESSURE BIRTH CONTROL AND I AM HAVING HORRIBLE SIDE EFFECTS. I'M GETTING HORRIBLE STOMACH PAINS, MY BACK HURTS, MY JOINTS HURT. I CONSTANTLY HAVE HEADACHES, MY FEET KILL ME, MY TEETH HURT, I HAVE KIDNEY INFECTIONS, BLADDER INFECTIONS, INTERCOURSE HURTS BEFORE AND AFTER. I GAINED (B)(6). I HAVE YEAST INFECTIONS. I AM MOODY AND DEPRESSED AND THOSE ARE JUST THE FEW THINGS I AM GOING THROUGH.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01898	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056075) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2008 AFTER THE BIRTH OF HER CHILD. SINCE THEN SHE HAS EXPERIENCED CHRONIC YEAST INFECTIONS, BACTERIAL INFECTIONS, PID, PELVIC PAIN AND AMBULATION DIFFICULTIES. SHE VISITED HER DOCTOR WHO ADVISED HER THAT SHE MIGHT BE HAVING A REACTION TO THE NICKEL IN THE ESSURE. SHE RECENTLY HAD A HYSTERECTOMY AND ALL HER PAIN AND SYMPTOMS WENT AWAY. (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED PELVIC PAIN AND PID (SEEN AS PELVIC INFLAMMATORY DISEASE) SINCE THE INSERTION. SHE RECENTLY HAD

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A HYSTERECTOMY AND ALL HER PAIN AND SYMPTOMS WENT AWAY. THESE EVENTS ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP AND THE FACT THAT ALL THE PAIN WENT AWAY AFTER REMOVAL (POSITIVE DECHALLENGE), CAUSALITY BETWEEN PELVIC PAIN AND ESSURE USE CANNOT BE EXCLUDED. REGARDING PID, ESSURE MAY BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT DURING INSERTION. IT MOSTLY OCCURS IN THE FIRST WEEKS FOLLOWING THE DEVICE PLACEMENT. IN THIS CASE, THE CONSUMER INFORMED THAT SHE HAS BEEN EXPERIENCING INFECTIONS AND PID SINCE THE INSERTION, THEREFORE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01899	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 12/15/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/19/2008
Explant Date (E7): 1/5/2009
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. CONSUMER HAD THE ESSURE IMPLANT PROCEDURE PERFORMED IN THE OFFICE OF HER DOCTOR. SHE WAS SUPPOSED TO HAVE BEEN SCHEDULED TO HAVE THE UV DYE TEST PERFORMED ON OR BY 2008 TO ENSURE THAT THE DEVICE HAD TAKEN CORRECTLY. THE UV TEST WAS NEVER SCHEDULED. AT THE END OF 2008 SHE BEGAN BLEEDING AND EXPERIENCING EXTREME CRAMPING SHE THOUGHT IT TO BE NORMAL UNTIL 2009, WHILE SHE WAS IN THE SHOWER SHE NOTED THAT SOMETHING HAD FALLEN OUT OF HER AND INTO THE SHOWER. UPON LOOKING CLOSELY AT IT SHE REALIZED IT WAS THE ESSURE IMPLANT IT LOOKED LIKE A SMALL SPRING FROM A PEN, SHE THEN CONTACTED THE DOCTOR OFFICE AND EXPLAINED WHAT HAD JUST HAPPENED AND THAT WAS WHEN SHE HAD BEEN ADVISED TO GO INTO THE IMMEDIATELY. SHE WAS TAKEN INTO AN EXAM ROOM IMMEDIATELY, AND AN ULTRASOUND WAS PERFORMED. DURING THIS OFFICE VISIT, THE DOCTOR STATED THAT SHE WOULD NEED TO HAVE A HYSTERECTOMY PERFORMED IN ORDER TO STOP THE BLEEDING. ON (B)(6) 2009, SHE WAS ADMITTED INTO THE HOSPITAL AND HAD A HYSTERECTOMY PERFORMED, AT THAT POINT, SHE HAD BEEN BLEEDING CONSTANTLY WITH BIG CLUMPS OF BLOOD COMING OUT. THE SERIOUSNESS CRITERIA HOSPITALIZATION AND DISABILITY WERE MENTIONED IN THE SECTION EVENT OUTCOME BUT IT WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 15-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY

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DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. FOLLOW-UP RECEIVED ON 17-NOV-2015 FROM CONSUMER: CONTACT DETAILS AND DATE OF BIRTH WERE PROVIDED. SHE DIDN'T KNOW THE LOT NUMBER. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD BEEN BLEEDING CONSTANTLY WITH BIG CLUMPS OF BLOOD COMING OUT. SHE HAD TO HAVE A HYSTERECTOMY PERFORMED IN ORDER TO STOP THE BLEEDING. THIS EVENT, SEEN AS GENITAL BLEEDING, IS SERIOUS DUE HOSPITALIZATION AND REQUIRED INTERVENTION (OTHER SERIOUSNESS CRITERIA WERE INFORMED BUT NOT SPECIFIED NEITHER DESCRIBED PER REPORTER). ALSO, THE EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND THE SUGGESTIVE TEMPORAL RELATIONSHIP BETWEEN THEM, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

INTERNAL CORRECTION DONE ON 15-DEC-2015 BASED ON INFORMATION RECEIVED ON 22-OCT-2015 INITIAL RECEIPT DATE AMENDED TO 22-OCT-2015. FOLLOW UP INFORMATION RECEIVED ON 15-DEC-2015: ESSURE CONSUMER GENERAL QUESTIONNAIRE RECEIVED. CONSUMER WAS (B)(6). NO PREVIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01900	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4): 20210352

Single Use: Y
Implant Date (E6): 11/11/2005
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (MW5055981) IN UNITED STATES ON 22-OCT-2015 WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2005; LOT NUMBER 20210352. THE CONSUMER REPORTED THAT SHORTLY AFTER HAVING THE PROCEDURE SHE SWITCHED HER GYNECOLOGIST. HER FOLLOW UP PROCEDURE, HSG (HYSTEROSALPINGOGRAM) WAS PERFORMED BY HER NEW PHYSICIAN. SHE REPORTED ABOUT A YEAR OR SO AFTER HAVING THE ESSURE DONE, SHE BEGAN TO FEEL TERRIBLE, SHE BECAME FATIGUED, SIDE PAIN (MOSTLY ON THE LEFT SIDE), BACK PAIN, EXTREME ACNE, DEPRESSION, HEAVY BLEEDING AND PASSING LARGE BLOOD CLOTS, AND SHE BEGAN TO HAVE TERRIBLE PMS (PRE-MENSTRUAL SYMPTOMS) WORSE THAT WHAT SHE HAD EVER EXPERIENCED. SHE TALKED TO HER DOCTOR AFTER SHE COULD NOT TAKE IT ANYMORE AND SHE SUGGESTED A PROCEDURE CALLED AN ENDOMETRIAL ABLATION OR A PARTIAL HYSTERECTOMY, THE CONSUMER OPTED FOR THE SURGERY THAT WOULD GET HER BACK TO WORK SOONER. SHE MENTIONED IT HELPED FOR A WHILE AND THEN GRADUALLY IT SEEMED LIKE THE SYMPTOMS HAVE RETURNED STRONGER THAN EVER WITH EVEN MORE ISSUES ON TOP OF THEM. SHE HAD THE SURGERY ON (B)(6) 2015 TO REMOVE THE DEVICES. SHE REPORTED ALBUTEROL INHALER (AS NEEDED), CETIRIZINE AND SINGULAR AS CONCOMITANT MEDICATIONS. HOSPITALIZATION WAS TICKED AS EVENT OUTCOME PER CONSUMER BUT NOT SPECIFIED NEITHER DESCRIBED . THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 15-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE

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CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TEST FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES FOR THIS BATCH RESULTED IN NO USUAL PATTERN IDENTIFIED. FOLLOW-UP RECEIVED ON 17-NOV-2015: CONSUMER CONFIRMED HER ADDRESS AND SHE IS AVAILABLE TO RECEIVED THE QUESTIONNAIRE. ALSO SHE GAVE CONSENT FOR CONTACT HER DOCTORS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ABOUT A YEAR OR SO AFTER HAVING THE ESSURE PLACED, SHE PRESENTED HEAVY BLEEDING AND PASSING LARGE BLOOD CLOTS. SHE OPTED FOR PARTIAL HYSTERECTOMY TO REMOVE THE DEVICES. THIS EVENT, SEEN AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND HOSPITALIZATION (NOT SPECIFIED PER REPORTER). ALSO, THE EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND THE SUGGESTIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY WAS CONFIRMED, THEREFORE A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01901	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056363) IN UNITED STATES ON 22-OCT-2014 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. WHEN CONSUMER WENT FOR THE TEST TO MAKE SURE THAT SCAR TISSUE HAD GROWN TO COVER THE COIL, ONE SIDE DID NOT TAKE. SHE WAITED ANOTHER THREE MONTHS HAD SAME TEXT AND IT TOOK THEM. SHORTLY THEREAFTER, SHE STARTED EXPERIENCING HEAVY PERIODS, TO THE POINT SHE HAD TO CARRY EXTRA CLOTHES AND ON SEVERAL OCCASIONS, HAD TO LEAVE WORK TO GO HOME AND CHANGE CLOTHES. SHE WAS MISERABLE. SHE ALSO EXPERIENCED MAJOR HAIR LOSS AND FATIGUE. HER PHYSICIAN TOLD HER SHE NEEDED A HYSTERECTOMY. HE HAD BEEN HER DOCTOR FOR 20 YEARS, SO SHE HAD THE SURGERY. SHE GAINED SO MUCH WEIGHT. SHE BELIEVED IF SHE DID NOT HAVE ESSURE, SHE WOULD NOT HAVE HEAVY PERIODS AND WOULD NOT HAVE HAD THE CYST. SHE ALSO EXPERIENCED AUTOIMMUNE DISEASE HASHIMOTO, AND HAD LYMPH NODE SWELLING AND HAD TO BE PUT ON ANTIBIOTICS. CONSUMER ASSESSED HOSPITALIZATION HOWEVER SHE DID NOT GIVE FURTHER DETAILS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 15-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION

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NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. FOLLOW-UP RECEIVED ON 17-NOV-2015 FROM CONSUMER: CONSUMERS ADDRESS WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 07-DEC-2015: ESSURE CONSUMER GENERAL QUESTIONNAIRE RECEIVED. CONSUMER WAS (B)(6). SHE HAD FERTILITY ISSUES 15 YEARS PRIOR TO THE REPORT AND IN 2010 SHE HAD HALF THYROID REMOVED (BEFORE ESSURE). SHE HAD ESSURE INSERTED 10 YEARS AFTER PREGNANCY. SHE USED BIRTH CONTROL PILLS AS BACK UP CONTRACEPTION. HYSTEROSALPINGOGRAM TEST WAS PERFORMED AND DID NOT WORK FIRST TIME, HAD TO HAVE IT DONE TWICE. SHE EXPERIENCED SEVERE BLEEDING AND DOCTOR TOLD HER SHE NEEDED A HYSTERECTOMY. ESSURE WAS REMOVED VIA HYSTERECTOMY. SHE WAS HOSPITALIZED. SHE RECOVERED FROM ESSURE REMOVAL PROCEDURE. HER SYMPTOM RESOLVED AFTER SURGERY. SHE BELIEVED HER CONDITION WAS CAUSED BY ESSURE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED HEAVY PERIODS/ SEVERE BLEEDING (SEEN AS MENORRHAGIA) AND AUTOIMMUNE DISEASE HASHIMOTO. SHE HAD HYSTERECTOMY PERFORMED. MENORRHAGIA IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE HASHIMOTO DISEASE IS UNLISTED. MENSES PATTERN CHANGES ARE FREQUENT IN WOMEN WITH ESSURE IN PLACE. THUS, GIVEN THE NATURE OF THE EVENT HEAVY PERIODS/ SEVERE BLEEDING AND SUGGESTIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. IN REGARDS OF HASHIMOTO DISEASE, CONSIDERING ITS AUTOIMMUNE ORIGIN AND THE ESSURE'S LOCAL ACTION IN FALLOPIAN TUBES, CAUSAL RELATIONSHIP WITH SUSPECT MICRO-INSERT IS VERY UNLIKELY. SHE ALSO EXPERIENCED OTHER NON-SERIOUS EVENTS. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01902	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 2/2/2011
Explant Date (E7): 2/2/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY ((B)(4)) IN UNITED STATES ON 22-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011 FOR BIRTH CONTROL. SHE EXPERIENCED IRREGULAR BLEEDING, INFECTION LIKE SYMPTOMS, EXTREME PELVIC PAIN, HEAVY MENSTRUAL BLEEDING, BACK PAIN, HEADACHES, SEVERE ACNE, ANXIETY AND MOOD SWINGS. IT WAS DISCOVERED THROUGH CT SCAN THAT ONE OF HER COILS HAD MIGRATED INTO THE RIGHT FALLOPIAN TUBE AND PUNCTURED THROUGH IT. AFTER DOCTOR CONSULTATION BOTH COILS AND FALLOPIAN TUBES WERE REMOVED LAPAROSCOPICALLY ON (B)(6) 2012. SHE HAS CONTINUED TO EXPERIENCE PAIN, MUSCLE WEAKNESS, RIGHT RIB PAIN, HEADACHES AND SEVERE MENSTRUAL CRAMPS AND BLEEDING. HOSPITALIZATION, DISABILITY AND REQUIRED INTERVENTION WERE MENTIONED BUT NO SPECIFIED/DESCRIBED PER REPORTER. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 15-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE

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NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. FOLLOW-UP RECEIVED ON 17-NOV-2015: CONSUMER CONFIRMED HER ADDRESS AND STATED SHE WAS NEVER GIVEN THE LOT NUMBER OR A CARD WITH THE ESSURE LOT NUMBER. SHE IS AVAILABLE TO RECEIVE THE QUESTIONNAIRE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED IRREGULAR BLEEDING. ALSO, IT WAS DISCOVERED THROUGH CT SCAN THAT ONE OF HER COILS HAD MIGRATED INTO THE RIGHT FALLOPIAN TUBE AND PUNCTURED THROUGH IT. THEN, BOTH COILS AND FALLOPIAN TUBES WERE REMOVED LAPAROSCOPICALLY. THE REPORTED EVENTS, SEEN AS FALLOPIAN TUBE PERFORATION AND GENITAL BLEEDING, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION (OTHER SERIOUSNESS CRITERIA WERE MENTIONED BUT NOT SPECIFIED) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE IMPLIED TEMPORAL RELATIONSHIP AND THE FACT THAT FALLOPIAN TUBE PERFORATION AND GENITAL BLEEDING MAY OCCUR DURING ESSURE USE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED (TUBES AND COILS REMOVED), THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE MENTIONED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01903	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 3/1/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056355) IN UNITED STATES ON (B)(6) 2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED ON (B)(6) 2013. AFTER, SHE STARTED EXPERIENCING HEAVY BLEEDING, FOUL ODOR AND DYSPAREUNIA. SIX WEEKS AFTER THE PROCEDURE SHE WENT TO THE DOCTOR TO CHECK COIL PLACEMENT. SHE WAS TOLD THE COIL HAS DETACHED AND MIGRATED. AFTER DISCUSSIONS, SHE TOLD THE DOCTOR SHE WANTED IT REMOVED. IN (B)(6) 2014 SHE UNDERWENT A PARTIAL HYSTERECTOMY. AN X-RAY WAS PERFORMED AND SHOWED THAT THE COIL WAS STILL IN HER. SHE SAID SHE WAS STILL EXPERIENCING DISCOMFORT, ABDOMINAL PAIN, CRAMPING, AND BOWEL OBSTRUCTION. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 15-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. COMPANY CAUSALITY COMMENT: THIS

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SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AT CHECK COIL PLACEMENT VISIT, SHE WAS TOLD THE COIL HAS DETACHED AND MIGRATED. SHE ALSO PRESENTED HEAVY BLEEDING. THEN, SHE UNDERWENT A PARTIAL HYSTERECTOMY. THESE EVENTS, INTERPRETED AS DEVICE DISLOCATION AND GENITAL BLEEDING, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND IMPLIED TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. ALTHOUGH THE EXACT DATE AND MECHANISM OF DEVICE DISLOCATION HAVE NOT BEEN INFORMED, CONSIDERING ITS NATURE, CAUSAL RELATIONSHIP WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE REPORTED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01904	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 8/17/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/17/2009
Explant Date (E7): 1/31/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE (B)(4)) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) (EXPIRATION DATE 31-JAN-2011) IMPLANTED ON (B)(6) 2009. RIGHT FROM THE START SHE EXPERIENCED PAIN, CRAMPING AND HEAVY BLEEDING. IT WAS NOT TWO WEEKS LATER THAT THE SEVERE MIGRAINES (NOTHING HELPED THE MIGRAINES) AND THE RASHES STARTED. THEN SHE STARTED TO LOSE FOCUS, COULD NOT THINK CLEARLY AND BECAME VERY LETHARGIC. THEN SHE STARTED URINATING BLOOD. HER WEIGHT WAS GREATLY FLUCTUATING. SHE HAD TO GET AN ALLERGY TEST BECAUSE DOCTOR BELIEVE THAT THOSE SYMPTOMS WERE DUE TO THE ESSURE AND THE ALLERGY TEST WAS SO POSITIVE, THAT SHE STILL HAS THE TWO SCARS FROM THE NICKEL AND COBALT TEST AREAS. ON (B)(6) 2011, SHE UNDERWENT A HYSTERECTOMY AND HAD IT REMOVED. IN 2015, SHE WAS STILL EXPERIENCING SEVERE MIGRAINES AND RASHES AND SEVERE STOMACH AND BACK PAIN, AND SHE WAS STILL HAVING PROBLEMS WITH FATIGUE. SHE BELIEVED THAT IT ALSO CREATED HER COLITIS. LIFE THREATENING, HOSPITALIZATION, DISABILITY/PERMANENT, DAMAGE, REQUIRED INTERVENTION, OTHER SERIOUS (IMPORTANT MEDICAL EVENT) WERE MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 15-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME.

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THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE.. INTERNAL CORRECTION DONE ON 15-DEC-2015 BASED ON INFORMATION RECEIVED ON 23-OCT-2015 INITIAL RECEIPT DATE AMENDED TO 23-OCT-2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND RIGHT FROM THE START SHE PRESENTED PAIN, HEAVY BLEEDING AND COLITIS. SHE UNDERWENT A HYSTERECTOMY AND HAD IT REMOVED. THESE EVENTS, SEEN AS PELVIC PAIN, GENITAL BLEEDING AND COLITIS, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION (OTHER SERIOUSNESS CRITERIA WERE MENTIONED BUT NOT SPECIFIED). PELVIC PAIN AND GENITAL BLEEDING ARE LISTED, WHILE COLITIS IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP AND THE FACT THAT GENITAL BLEEDING AND PELVIC PAIN MAY OCCUR DURING ESSURE USE, CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE USE CANNOT BE EXCLUDED. IN REGARDS OF COLITIS, LIMITED INFORMATION HAS BEEN PROVIDED. HOWEVER, CONSIDERING ITS PROBABLE AUTOIMMUNE NATURE AND THE LOCAL ACTION OF ESSURE IN FALLOPIAN TUBES, CAUSALITY WITH SUSPECT INSERT IS VERY UNLIKELY. SINCE AN INTERVENTION WAS REQUIRED (HYSTERECTOMY), THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01905	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): A64626 / A619941

Single Use: Y
Implant Date (E6): 5/28/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY IN UNITED STATES ON 22-OCT-2015 (CASE MW5056758) WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2013. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: PROPANOLOL (PROPRANOLOL), SUMATRIPTAN (SUMATRIPTAN), AND IBUPROFEN (IBUPROFEN [IBUPROFEN]). IN 2013 CONSUMER WAS TO GET HER TUBES TIED AND THE PHYSICIAN EXPLAINED THAT SHE WAS GETTING ESSURE. SHE GOT THE PROCEDURE DONE AND FROM THE BEGINNING SHE WAS HAVING VERY BAD ABNORMAL PELVIC PAINS. SO SHE WENT TO THE PHYSICIAN AND DISCOVERED THAT A FOREIGN OBJECT WAS LEFT IN HER (INTERPRETED AS ESSURE ITSELF), AFTER THE TUBES WERE TIED. SO SHE HAD TO GET ANOTHER SURGERY TO HAVE IT REMOVED. SHE STILL AFTER THAT HAS ABNORMAL MENSTRUAL LASTING 12 TO 14 DAYS. SHE GAINED WEIGHT AND HAVING INTERCOURSE WITH HER HUSBAND IS PAINFUL. IT IS LIKE SHE HAS NEVER ENDING CRAMPS. THE REPORTER MENTIONED THE FOLLOWING EVENT OUTCOME LIFE THREATENING HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 15-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION

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NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. FOLLOW UP RECEIVED ON (B)(6) 2015: PATIENT INFORMATION WAS UPDATED. INTERNAL CORRECTION DONE ON (B)(6) 2015 BASED ON INFORMATION RECEIVED ON (B)(6) 2015 INITIAL RECEIPT DATE AMENDED TO (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND FROM THE BEGINNING, SHE PRESENTED VERY BAD ABNORMAL PELVIC PAINS. SHE WENT TO THE PHYSICIAN AND DISCOVERED THAT A FOREIGN OBJECT WAS LEFT IN HER (INTERPRETED AS ESSURE ITSELF), AFTER THE TUBES WERE TIED. SO SHE HAD TO GET ANOTHER SURGERY TO HAVE IT REMOVED. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE (LIFE THREATENING WAS MENTIONED AS OUTCOME BUT NOT DESCRIBED NEITHER SPECIFIED) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING CLOSE TEMPORAL RELATIONSHIP AND THE FACT THAT PELVIC PAIN MAY OCCUR DURING ESSURE USE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED FOR DEVICE REMOVAL, THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW UP INFORMATION RECEIVED ON 05-JAN-2016: ESSURE CONSUMER GENERAL QUESTIONNAIRE RECEIVED. CONSUMER WAS (B)(6), NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES, NO RELEVANT MEDICAL HISTORY OR CONCURRENT CONDITIONS. ON (B)(6) 2013 SHE HAD ESSURE INSER

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01906	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/12/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5056145) IN UNITED STATES ON 23-OCT-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2011. SHE HAD AS CONCURRENT CONDITION ALLERGY TO NICKEL AND WAS RECEIVING THE FOLLOWING CONCOMITANT MEDICATION: PERCOCET (OXYCOCET), AMITRIPTYLINE (AMITRIPTYLINE), FIORICET (AXOTAL [BUTALBITAL,CAFFEINE,PARACETAMOL]), ALLERGY MEDICINES AND CYCLOBENZAPRINE (CYCLOBENZAPRINE). CONSUMER REPORTED SHE EXPERIENCED HEAVY BLEEDING FOR 15 DAYS UNTIL BECOMING ANEMIC. SHE HAD AN ABLATION DONE IN 2012 AND PAIN AFTERWARDS THAT NEVER GOT RESOLVED. ONE OF HER COILS WAS NOT IN THE FALLOPIAN TUBE, BUT IN HER UTERUS. SHE IS SCHEDULED FOR SURGERY IN 2015. SHE STATED THAT IT WILL BE RESOLVED IN THIS YEAR WITH SALPINGECTOMY WITH ESSURE COILS REMOVAL. ALSO, SHE HAS BEEN BATTLING HIVES FOR 3-4 MONTHS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 15-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND

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A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. FUP RECEIVED ON 17-NOV-2015: CONSUMER'S INFORMATION UPDATED. INTERNAL CORRECTION DONE 15-DEC-2015 BASED ON INFORMATION RECEIVED ON 23-OCT-2015 INITIAL RECEIPT DATE AMENDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED HEAVY BLEEDING FOR 15 DAYS UNTIL BECOMING ANEMIC. SHE HAD TO HAVE AN ABLATION AND AT THE MOMENT OF THE REPORT, SHE WAS SCHEDULED FOR A SURGERY (SALPINGECTOMY WITH ESSURE REMOVAL). THIS EVENT, SEEN AS GENITAL BLEEDING, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND IN THE ABSENCE OF ALTERNATIVE EXPLANATION, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED (ABLATION) AND ANOTHER ONE IS SCHEDULED (SALPINGECTOMY) THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

INTERNAL CORRECTION DONE 15-DEC-2015 BASED ON INFORMATION RECEIVED ON 23-OCT-2015 INITIAL RECEIPT DATE AMENDED. FOLLOW-UP INFORMATION RECEIVED ON 15-DEC-2015: THE CASE (B)(4) WAS IDENTIFIED AS DUPLICATE OF THIS REMAINING CASE AND WILL BE DELETED FROM BAYE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01910	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 1/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 624475

Single Use: Y
Implant Date (E6): 11/30/2007
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5056722) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER 624475 INSERTED ON (B)(6) 2007. IMMEDIATELY AFTER IMPLANT OF ESSURE, CYCLE BECAME EXTREMELY PAINFUL AND VERY HEAVY, LOWER BACK PAIN EVERY DAY, SOMETIMES DEBILITATING, JOINT PAIN IN MULTIPLE PLACES, MIGRAINES, EXTREMELY LETHARGIC DAILY, DEPRESSION, WORSE RIGHT BEFORE CYCLES, GROWTH ON THYROID, MULTIPLE SURGERIES DUE TO SIDE EFFECTS OF ESSURE, TEETH ROTTEN AND CRUMBLING, LOSS OF HAIR, FEVERS FOR NO APPARENT REASON WHICH RESULTED IN LOSS OF WORK AND INCOME, MENTAL STRESS OVER MULTITUDE OF MEDICAL ISSUES. CONCOMITANT MEDICATION INCLUDED: 20MG PAXIL. OTC MEDICATIONS: VITAMIN E, FISH OIL OMEGA 3, IBUPROFEN 1600 MG DAILY , OR TYLENOL FOR CHRONIC PAIN. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 16-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TEST FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES

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FOR THIS BATCH RESULTED IN NO SIMILAR AE CASES IDENTIFIED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. FOLLOW-UP FROM 01-DEC-2015: FOLLOW-UP ATTEMPTS WERE DONE WITH NO RESPONSE TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IMMEDIATELY AFTER ESSURE PLACEMENT, HER CYCLE BECAME VERY HEAVY AND PAINFUL. SHE STATED THAT SHE UNDERWENT MULTIPLE SURGERIES DUE TO SIDE EFFECTS OF ESSURE. THIS EVENT, SEEN AS MENORRHAGIA, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. MENSES PATTERN CHANGES ARE FREQUENT IN WOMEN WITH ESSURE IN PLACE. THUS, GIVEN EVENT'S NATURE AND CLOSE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE INTERVENTIONS WERE REQUIRED (MULTIPLE SURGERIES) THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. DESPITE FOLLOW-UP ATTEMPTS, NO FURTHER INFORMATION WAS OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01911	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 1/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/6/2008
Explant Date (E7): 10/15/2008
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE (B)(4)) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008. IN 2008, CONSUMER HAD OUTPATIENT SURGERY FOR A HYSTEROSCOPY ESSURE TUBAL LIGATION. EARLY IN THE MORNING OF 2008, CONSUMER EXPERIENCED A SEVERE PAIN ON ONE SIDE OF LOWER ABDOMEN SO SEVERE THAT SHE PASSED OUT. SHE REPORTED IT TO THE NURSE THE NEXT DAY, BUT NO ACTION WAS TAKEN. WHEN SHE HAD A DYE TEST ABOUT 3 MONTHS LATER, IT WAS DISCOVERED THAT THE ESSURE COIL WAS PUSHED OUT OF FALLOPIAN TUBE ON ONE SIDE INTO ABDOMEN. IN 2008, SHE HAD A SECOND SURGERY TO REMOVE THE ESSURE DEVICE FROM THE PERITONEAL CAVITY AND TO HAVE A LAPAROSCOPY BILATERAL TUBAL CAUTERIZATION. ONE OF THE ESSURE COILS WAS STILL IN OTHER FALLOPIAN TUBE. ESSURE REMOVAL DATE REPORTED: (B)(4) 2008. CONCOMITANT MEDICATION INCLUDED (B)(4). THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 16-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW

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OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHEN SHE HAD A DYE TEST ABOUT 3 MONTHS LATER, IT WAS DISCOVERED THAT THE ESSURE COIL WAS PUSHED OUT OF FALLOPIAN TUBE ON ONE SIDE INTO ABDOMEN. IN THE SAME YEAR, SHE HAD A SECOND SURGERY TO REMOVE THE ESSURE DEVICE FROM THE PERITONEAL CAVITY AND A LAPAROSCOPY BILATERAL TUBAL CAUTERIZATION. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES TOWARDS PERITONEAL CAVITY. IN THIS CASE, SOON AFTER THE INSERTION THE CONSUMER PRESENTED A SEVERE PAIN ON ONE SIDE OF LOWER ABDOMEN SO SEVERE THAT SHE PASSED OUT. LATER, AT CONFIRMATION TEST, IT WAS FOUND THAT THE DEVICE WAS DISLOCATED OUT OF FALLOPIAN TUBE INTO ABDOMEN. ALTHOUGH IN THE PRESENT CASE THE EXACT DATE AND MECHANISM OF THIS DISLOCATION HAVE NOT BEEN INFORMED, GIVEN EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON THE AVAILABLE INFORMATION, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT IS EXCLUDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01912	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/8/2010
Explant Date (E7): 5/21/2013
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN UNITED STATES ON 23-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010 TO PREVENT PREGNANCY. ALTHOUGH SHE WAS TOLD THERE WOULD BE MINOR CRAMPING, SIMILAR TO PERIOD CRAMPING, DURING/AFTER THE PROCEDURE THAT WAS NOT WHAT SHE EXPERIENCED. THE PROCEDURE ITSELF WAS INCREDIBLY PAINFUL, LIKE GOING THROUGH CHILDBIRTH ALL OVER AGAIN. THE PAIN LESSENED OVER THE NEXT TWO DAYS, BUT IT NEVER WENT AWAY. SHE EXPERIENCED MILD PAIN ALL THE TIME, BUT IT BECAME SEVERE DURING BOWEL MOVEMENTS, WHILE HAVING SEX, LIFTING ANYTHING HEAVY, OR WHENEVER SHE JUST MOVED THE WRONG WAY. THAT SEVERE PAIN TOOK HOURS TO GO BACK TO JUST THE MILD PAIN THAT WAS CONSTANTLY PRESENT. HER YEARLY PELVIC EXAMS WERE ALSO INCREDIBLY PAINFUL. FINALLY ON (B)(6) 2013, HER FALLOPIAN TUBES WERE REMOVED WITH THE ESSURE COILS AND, SINCE THEN, SHE DID NOT EXPERIENCE THE DEBILITATING PAIN THAT SHE HAD WHILE ESSURE WAS IN PLACE. CONCOMITANT MEDICATION INCLUDED (B)(4). THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 16-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT

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QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE PROCEDURE ITSELF WAS VERY PAINFUL. SHE THEN PRESENTED MILD PAIN ALL THE TIME. THIS PAIN BECAME SEVERE WHEN LIFTING SOMETHING, DURING SEX OR AT BOWEL MOVEMENTS AND ALSO WHEN MOVING IN THE WRONG WAY. HER FALLOPIAN TUBES WERE REMOVED WITH THE ESSURE COILS AND, SINCE THEN, SHE DID NOT EXPERIENCED THIS DEBILITATING PAIN (POSITIVE DECHALLENGE). THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION (HOSPITALIZATION WAS MENTIONED AS OUTCOME BUT NOT DESCRIBED NEITHER SPECIFIED) AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE RECOVERY AFTER REMOVAL (POSITIVE DECHALLENGE), CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED ON 04-JAN-2016: DESPITE FOLLOW-UP ATTEMPTS, NO RESPONSE WAS GIVEN TO DATE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER W

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01913	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5057635) IN UNITED STATES ON 16-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ESSURE PROCEDURE WENT HORRIBLE, DURING INSERTION SHE WAS TOLD HER UTERUS WAS TILTED AND THE DOCTOR COULD NOT GET TO HER RIGHT TUBE. SHE STATED THAT THEN SHE ENDURED ABOUT WHAT FELT LIKE AN ETERNITY OF SCRAPING OF THE LINING OF HER UTERUS AS HE TRIED TO LOCATE THE SECOND TUBE BECAUSE OF THE SALINE THAT THEY USE HAS ABSORBED INTO THE LINING MAKING IT IMPOSSIBLE TO LOCATE THE TUBE. SHE NEVER HAD THE SECOND ESSURE IMPLANTED BECAUSE OF THE INABILITY TO FIND THE FALLOPIAN TUBE. A FEW MONTHS AFTER SHE HAD ESSURE IMPLANTED, SHE WAS DIAGNOSED WITH LUPUS. SHE ALSO HAD ENDURED HAIR LOSS, MOOD SWINGS, HEAVY PERIODS THAT MAKE WORKING IMPOSSIBLE, EXCESSIVE CLOTTING DURING HER PERIOD, INABILITY TO SLEEP, WEIGHT GAIN, IRREGULAR PERIODS, TO LIST A FEW. SHE ALSO FELT A SMALL TWINGE OF PAIN WHERE SHE WAS ASSUMING THE ESSURE IS LOCATED ON HER LEFT SIDE. SHE ALSO HAD AN X-RAY DONE AND THE ESSURE THAT SHE HAS, WAS ALMOST FOLDED IN HALF AND IT LOOKED LIKE A PIECE OF IT WAS NOT CONNECTED. SHE WAS NOT TOLD THAT PEOPLE WITH COMPROMISED IMMUNE SYSTEMS OR NICKEL ALLERGIES DID NOT MAKE GOOD CANDIDATES AND ALSO, WAS NEVER TOLD OF PET FIBERS THAT WERE PART OF THE COIL. THE CONSUMER MENTIONED THE EVENT OUTCOME DISABILITY/PERMANENT DAMAGE BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS DIAGNOSED WITH LUPUS. SHE ALSO HAD AN X-RAY WHICH SHOWED THAT ESSURE IS ALMOST FOLDED IN HALF AND IT LOOKS LIKE A PIECE OF IT IS NOT CONNECTED (INTERPRETED AS DEVICE BREAKAGE).

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THESE EVENTS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. LUPUS IS A CHRONIC INFLAMMATORY DISEASE THAT FOLLOWS A RELAPSING AND REMITTING COURSE. MAJORITY OF CASES OCCUR IN WOMEN, FREQUENTLY STARTING AT CHILDBEARING AGE. GIVEN THE PATHOPHYSIOLOGY OF LUPUS AND CONSIDERING THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES, CAUSALITY WAS ASSESSED AS UNRELATED. THE EXACT DATE AND MECHANISM OF THE DEVICE BREAKAGE IN THIS CASE WAS NOT REPORTED. HOWEVER, GIVEN THE NATURE OF THIS EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 29-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01914	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/9/2009
Explant Date (E7): 3/3/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5057648) IN UNITED STATES ON 16-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. CONSUMER REPORTED SHE EXPERIENCED SEVERE ABDOMINAL PAIN, HEADACHE PRESSURE, FATIGUE AND ANXIETY. AN ULTRASOUND WAS DONE AND FOUND THAT THE COIL HAD MIGRATED INTO HER UTERINE WALL, WHICH CAUSED HER TO HAVE A HYSTERECTOMY. ESSURE EXPLANT DATE WAS REPORTED AS (B)(6) 2014. HOSPITALIZATION AND REQUIRED INTERVENTION WERE MENTIONED AS EVENT OUTCOME, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND COIL HAD MIGRATED INTO UTERINE WALL. SHE UNDERWENT A HYSTERECTOMY, FOUR AND A HALF YEARS AFTER ESSURE INSERTION. THIS EVENT, INTERPRETED AS EMBEDDED DEVICE, IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE EXACT DATE AND MECHANISM OF THE EMBEDMENT WAS NOT REPORTED. CONSUMER HAD SEVERE ABDOMINAL PAIN AND AN ULTRASOUND SHOWED THE COIL HAD MIGRATED INTO HER UTERINE WALL. GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

PTC INVESTIGATION RESULT WAS RECEIVED ON 29-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). (B)(4). FINAL ASSESSMENT: FOR CASES WERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY R

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01915	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 5/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS0003V

Single Use: Y
Implant Date (E6): 1/29/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE# MW5057638) IN UNITED STATES ON 16-NOV-2015. IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2014, LOT NUMBER CS0003V. IN (B)(6) 2014 THE CONSUMER STARTED EXPERIENCING EXCESSIVE BLEEDING ON ANY GIVEN CYCLE, SHARP, STABBING PAIN IN HER LOWER ABDOMINAL, SHE WAS DIZZY, LIGHTHEADED, AND HAD PAINS TO BE INTIMATE WITH HER HUSBAND. IN (B)(6) 2014 SHE HAD AN ABLATION PERFORMED TO CONTROL THE BLEEDING. SHE WANTED ESSURE OUT OF HER, EVEN IF THEY HAD TO DO A HYSTERECTOMY. SERIOUS INJURY WAS MENTIONED AS EVENT REPORT TYPE, BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND AFTER 4 MONTHS STARTED EXPERIENCING EXCESSIVE BLEEDING ON ANY GIVEN CYCLE. SHE UNDERWENT AN ABLATION 9 MONTHS AFTER ESSURE INSERTION (INTERPRETED AS ENDOMETRIAL ABLATION) TO CONTROL THE BLEEDING. THIS EVENT, INTERPRETED AS MENORRHAGIA, IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, MENSES PATTERN CHANGES MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, THE NATURE OF THE EVENT EXCESSIVE BLEEDING ON ANY GIVEN CYCLE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01916	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 11/4/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/4/2014
Explant Date (E7): 2/13/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-2015, AWARENESS DATE 24-OCT-2014). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED ON (B)(6) 2014. SHE NOTICED RIGHT AWAY THAT SHE BEGAN BLEEDING HEAVILY. IN (B)(6) 2015, SHE STARTED HAVING MIGRAINES WITH STROKE LIKE SYMPTOMS. SHE WAS IN THE ER (EMERGENCY ROOM) AT LEAST 4 TIMES (ONCE BEING TAKEN IN AN AMBULANCE DUE TO NOT BEING ABLE TO TELL HER NAME AND BEING PARALYZED ON HALF BODY WHICH ACCORDED QUITE OFTEN) FROM (B)(6). SHE WAS SENT TO SEE A NEUROLOGIST WHO RAN A BUNCH OF TEST. ALL HER TESTING WAS NORMAL. ONLY THING SHE COULD THINK OF WAS THE COILS WERE DOING THAT. SHE WAS FINE UNTIL SHE GOT THEM. SHE WENT TO THE DOCTOR THAT IMPLANTED THE COILS AND SHE SAID SHE DID NOT SEE HOW COILS IN HER TUBES COULD CAUSE AN ISSUE WITH HER HEAD BUT AGREED TO TAKE THEM OUT BY CUTTING HER TUBES OUT. HER REMOVAL DATE WAS (B)(6) 2015. SHE WAS PUT ON MEDICINE THAT MADE HER STOPPED BREAST-FEEDING HER YOUNGEST CHILD WHO WAS ONLY 5 MONTHS AT THE TIME. SHE EXPERIENCED HORRIBLE PAINS ON RIGHT SIDE. DURING SURGERY HER DOC SAID THE COIL IN RIGHT TUBE FELL OUT WHEN SHE TOUCHED IT. SHE HAS A PIECE THAT WAS EMBEDDED IN UTERUS. ACCORDING TO THE DOCTOR THERE WAS NOTHING WRONG WITH HAVING A PIECE OF METAL IN UTERUS. SINCE REMOVAL SHE HAS NOT HAVE ANYMORE MIGRAINES WITH STROKE LIKE SYMPTOMS. HER BLEEDING HAS STOPPED AND SHE ONLY HAS 1 PERIOD A MONTH VERSUS BLEEDING EVERY DAY OF THE MONTH. SHE BLED FROM TIME SHE WAS IMPLANTED UNTIL (B)(6) 2015. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 17-NOV-2015. FINAL ASSESSMENT:

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FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. CORRECTION ON 23-NOV-2015 FOLLOWING COMPANY INTERNAL CODING REVIEW: THE EVENT MIGRAINES WITH STROKE LIKE SYMPTOMS WAS RECODED TO MEDDRA LLT COMPLICATED MIGRAINE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND RIGHT AWAY BEGAN BLEEDING HEAVILY. A FEW MONTHS LATER, SHE HAD MIGRAINES WITH STROKE LIKE SYMPTOMS. DURING SURGERY TO REMOVE THE DEVICES, IT WAS FOUND THAT A PIECE OF DEVICE WAS EMBEDDED IN HER UTERUS. AFTER SURGERY SHE RECOVERED FROM BLEEDING AND MIGRAINES. THESE EVENTS, INTERPRETED AS GENITAL BLEEDING, COMPLICATED MIGRAINE AND DEVICE EMBEDMENT RESPECTIVELY, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, EXCEPT MIGRAINES WHICH IS UNLISTED. CONSIDERING GENITAL BLEEDING MAY OCCUR DURING ESSURE USE AND THE RECOVERY AFTER DEVICE REMOVAL (POSITIVE DECHALLENGE), CAUSALITY BETWEEN BLEEDING AND ESSURE USE CANNOT BE EXCLUDED. ESSURE MICRO-INSERT MAY DISLOCATE AND EMBED AT UTERINE WALL. ALTHOUGH IN THIS CASE, THE EXACT DATE AND MECHANISM OF THIS EMBEDMENT HAS NOT BEEN INFORMED, CONSIDERING ITS NATURE, CAUSAL RELATIONSHIP WITH SUSPECT INSERT IS ASSESSED AS RELATED. AS MIGRAINES HAS A STRONG GENETIC PREDISPOSITION AND COULD BE TRIGGERED FOR FACTORS LIKE DIET, EXERCISES AND HORMONAL CHANGES AND CONSIDERING THAT ESSURE ACTS LOCALLY IN FALLOPIAN TUBES, CAUSALITY WITH ESSURE USE IS VERY UNLIKELY. SINCE AN INTERVENTION WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED, SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01917	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 1/1/2012
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE TAKING PLACE IN SEPTEMBER 2015 (CASE# FDA-2014-N-0736-1862, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE INSERTED ON UNSPECIFIED DATE. SHE STATED THAT EVEN THOUGH SHE HAD A HYSTERECTOMY 3 YEARS PRIOR TO THIS REPORT SHE CONTINUED SUFFERING. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 17-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENT IS NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT IS EXCLUDED. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO HAVE A HYSTERECTOMY 3 YEARS PREVIOUS TO THIS REPORT. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED

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INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH IN THIS CASE THE SURGERY'S INDICATION WAS NOT SPECIFIED, CONSIDERING HYSTERECTOMY MAY BE REQUIRED IF DEVICE REMOVAL IS NECESSARY, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND THEREFORE THIS CASE IS REGARDED AS INCIDENT. BASED ON AVAILABLE INFORMATION, A RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT IS EXCLUDED. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01918	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 844600

Single Use: Y
Implant Date (E6): 6/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE # MW5056302) IN UNITED STATES ON 26-OCT-2015. THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: TECFIDERA (DIMETHYL FUMARATE) FOR MULTIPLE SCLEROSIS, PROZAC (FLUOXETINE HYDROCHLORIDE), WELLBUTRIN (BUPROPION) AND VITAMIN D (COLECALCIFEROL). THE CONSUMER REPORTED THAT SINCE SHE HAD ESSURE HER PERIODS WERE VERY FREQUENT AND HEAVY, EVERY 15-24 DAYS LASTING 7 DAYS AT A TIME. ON 2015 SHE HAD THE ENDOMETRIAL ABLATION DONE TO TRY TO SOLVE THAT PROBLEM. SHE WAS BLEEDING HEAVILY 2 WEEKS POST OPERATION BUT HAD NOT BLED SINCE THEN. HER MEMORY WAS TERRIBLE BOTH PAST AND PRESENT, FOR EXAMPLE ONE DAY SHE TOOK HER MEDICINE TWICE BUT HAD NO RECOLLECTION WHAT SO EVER OF EVEN TAKING IT ONCE. HER HAIR WAS FALLING OUT AND WAS VERY THIN. THE CONSUMER WAS TAKING FOLIC ACID (FOLIC ACID), BIOTIN (BIOTIN) AND USING A PRO-BIOTIC SHAMPOO AND NOTHING SEEMED TO HELP. DISABILITY/PERMANENT DAMAGE WAS MENTIONED BUT NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 17-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION WAS RECEIVED ON 24-NOV-2015. CONSUMER'S DATE OF BIRTH WAS PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE CONSUMER. ON (B)(6) 2011 ESSURE LOT NUMBER 844600 WAS IMPLANTED. ESSURE REMOVAL WAS SCHEDULED TO (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPAIN TUBE OCCLUSION INSERT) INSERTED AND SINCE THEN, HER PERIODS WERE VERY FREQUENT AND HEAVY, EVERY 15-24 DAYS LASTING 7 DAYS AT A TIME. SHE HAD AN ENDOMETRIAL ABLATION DONE TO TRY TO SOLVE THIS PROBLEM. AFTER THE PROCEDURE, SHE WAS BLEEDING HEAVILY 2 WEEKS POST OPERATION. SHE HAD ESSURE REMOVAL SCHEDULED. THESE EVENTS, SEEN AS MENORRHAGIA AND POST PROCEDURAL BLEEDING, ARE SERIOUS DUE TO MEDICAL IMPORTANCE AND REQUIRED INTERVENTION (DISABILITY WAS MENTIONED BUT WAS NOT SPECIFIED NEITHER DESCRIBED) . MENORRHAGIA IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE WHILE POST PROCEDURAL BLEEDING RELATED TO ABLATION IS UNLISTED. GENITAL BLEEDING AND MENTRUAL PATTERN CHANGES MAY OCCUR DURING ESSUSE USE. IN THIS CASE, SHE HAD INTENSE PERIODS, HAD AN ABLATION AS A THERAPEUTIC MEASURE AND EXPERIENCED A HEAVY BLEEDING FOR TWO WEEKS AFTER THE PROCEDURE. CONSIDERING ITS NATURE AND THE TEMPORAL RELATIONSHIP, A CONTRIBUTORY ROLE FROM ESSURE FOR THIS FIRST EVENT CANNOT BE TOTALLY EXCLUDED AND AS THE ABLATION LED TO A NEW BLEEDING FOR TWO WEEKS, THIS OTHER BLEEDING IS ALSO ASSESSED AS RELATED TO ESSURE. SINCE INTERVENTION WAS REQUIRED (ABLATION) AND OTHER ONE IS SCHEDULED TO REMOVE THE DEVICES THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. FURTHER INFORMATION AND A NEW TECHNICAL ANALYSIS (LOT NUMBER PROVIDED) HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT RECEIVED ON 17-DEC-2015. PTC GLOBAL NUMBER (B)(4). LOT NUMBER 844600 (PRODUCTION DATE MAR-2011; EXPIRATION DATE MAR-2014). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATIO

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01919	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS CASE HAS BEEN IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE, WHICH HAS BEEN ESTABLISHED IN PREPARATION OF A PUBLIC FDA ADVISORY COMMITTEE MEETING, WHICH TOOK PLACE IN SEPTEMBER 2015 (FDA-2014-N-0736-1575, AWARENESS DATE 25-OCT-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2011. CONSUMER WAS MOTHER OF 3. SHE WAS IMPLANTED WITH ESSURE 4 YEARS PREVIOUS TO THIS REPORT AND SHE SPENT THE LAST 4 YEARS OF HER LIFE IN AND OUT OF DOCTORS AND EMERGENCY ROOMS IN EXCRUCIATING PAIN. IN 1 YEAR AND 1 MONTH SHE HAS BEEN THROUGH 3 SURGERIES. AT THE YOUNG AGE OF (B)(6) SHE WAS FORCED INTO A HYSTERECTOMY. AFTER SHE WAS THROWN INTO EARLY MENOPAUSE ON TOP OF HER DIAGNOSIS OF FIBROMYALGIA. IN (B)(6) 2014, FOLLOWING HER HYSTERECTOMY, SHE HAD EXTREME MIGRAINES, 50 POUNDS IN WEIGHT GAIN, HAIR LOSS, SEVERE DEPRESSION AND MEMORY LOSS. THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WHICH PTC NUMBER IS (B)(4) WAS RECEIVED ON 17-NOV-2015. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED/IDENTIFIED. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. A REVIEW OF SIMILAR CASES

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IS NOT APPLICABLE AS NO BATCH NUMBER WAS REPORTED. IN SUMMARY, BASED ON AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO AN ADULT FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED 4 YEARS PREVIOUS TO THIS REPORT AND SPENT THESE YEARS IN EXCRUCIATING PAIN. THEN, SHE HAD A HYSTERECTOMY AT THE AGE OF (B)(6). THIS EVENT, SEEN AS PELVIC PAIN, IS SERIOUS DUE TO REQUIRED INTERVENTION AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING PELVIC PAIN MAY OCCUR DURING ESSURE USE AND THE SUGGESTIVE TEMPORAL RELATIONSHIP, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. SINCE INTERVENTION WERE REQUIRED (HYSTERECTOMY) THIS CASE IS REGARDED AS INCIDENT. OTHER NON-SERIOUS EVENTS WERE INFORMED. BASED ON AVAILABLE INFORMATION, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FURTHER FOLLOW UP WILL BE ACTIVELY PURSUED SINCE THIS CASE WAS IDENTIFIED DURING HEALTH AUTHORITY WEBSITE MONITORING.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01924	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 1/23/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/23/2011
Explant Date (E7): 9/29/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA COMPANY'S (B)(6) PAGE IN UNITED STATES ON 26-FEB-2014,WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED AND EXPERIENCED EXCRUCIATING PAIN THROUGH THE WHOLE PROCEDURE, PHYSICIAN SAID IT WAS AN "AIR POCKET", EYES WERE SWOLLEN SHUT, ITCHY HIVES THROUGHOUT HER BODY, CONSTANT BLEEDING, SEVERE ABDOMINAL PAIN, MIGRAINES, AND HAIR LOSS. NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. TWO YEARS AGO, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED. THE CONSUMER EXPERIENCED EXCRUCIATING PAIN THROUGH THE WHOLE ESSURE PROCEDURE, HOSPITALIZED HOURS AFTER. WHICH HER DOCTOR SAID IT WAS AN "AIR POCKET", SO, SHE GUESSED SHE STILL HAVE THAT AIR POCKET TWO YEARS LATER. WHEN CONSUMER WAKE UP, HER EYES WERE SWOLLEN SHUT, SHE HAD ITCHY HIVES THROUGHOUT HER BODY, CONSTANT BLEEDING, SEVERE ABDOMINAL PAIN, MIGRAINES THAT LAST FOR DAYS, AND HAIR LOSS. THE CONSUMER STATED THAT THE ESSURE DEVICE HAD DESTROYED HER HEALTH. FOLLOW-UP 18-JUN-2014: FURTHER INFORMATION CANNOT BE OBTAINED DUE TO MISSING CONTACT DATA. FOLLOW-UP INFORMATION RECEIVED ON 19-NOV-2015 FROM CONSUMER VIA SOCIAL MEDIA: ESSURE WAS INSERTED ON (B)(6) 2011 FOR PERMANENT BIRTH CONTROL. THE PROCEDURE ENDED UP BEING VERY PAINFUL AND LASTING LONGER THAN IT WAS EXPECTED. SHE WENT HOME AND FELL ASLEEP. WHEN SHE WOKE UP, SHE WAS IN EXCRUCIATING PAIN AND HER HUSBAND TOOK HER TO THE EMERGENCY ROOM THE SAME NIGHT OF INSERTION. SHE WAS SWOLLEN - HER EYES AND HER MOUTH - AND SHE HAD HIVES ALL OVER HER BODY AND HER BELLY LOOKED LIKE SHE WAS EIGHT OR NINE MONTHS PREGNANT. SHE WAS GIVEN BENADRYL AND PROMETHAZINE FOR THE ALLERGIC REACTION, BUT THE DOCTOR TOLD HER AN AIR POCKET WAS THE CAUSE OF

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HER SYMPTOMS. THE CONSUMER STATED SHE WAS NEVER TESTED FOR NICKEL ALLERGY BEFORE INTENSION. IN ADDITION TO THE ALLERGIC REACTION, SHE SUFFERED MIGRAINES SO BAD SHE COULD NOT FUNCTION WITHOUT PRESCRIPTION MEDICATION. IN (B)(6) 2015, SHE SUFFERED HER FIRST OF TWO TRANSIENT ISCHEMIC ATTACK STROKES. CT (COMPUTERISED TOMOGRAM) SCAN WAS DONE, BUT NOTHING WAS DIAGNOSED. SHE BELIEVED ESSURE WAS CAUSING HER PROBLEMS. ESSURE WAS REMOVED ON (B)(6) 2015 VIA HYSTERECTOMY (CONSUMER WAS (B)(6)). RIGHT AFTER SURGERY, SHE FELT ALL THE ACHINESS OUT OF HER BODY, IT JUST COMPLETELY DISAPPEARED. ON (B)(6) 2015, SHE WOKE UP WITHOUT A HEADACHE FOR THE FIRST TIME IN FOUR YEARS. SHE HAS NOT TAKEN A MIGRAINE PILL SINCE. TWO DAYS AFTER THE SURGERY, SHE NOTICED THE BLOATING WAS SIGNIFICANTLY SMALLER. COMPANY CAUSALITY COMMENT: THIS NON MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EXCRUCIATING PAIN THOUGH THE WHOLE PROCEDURE, PHYSICIAN SAID IT WAS AN AIR POCKET AND SHE WAS HOSPITALIZED. SHE ALSO HAD CONSTANT BLEEDING (INTERPRETED AS GENITAL BLEEDING), SEVERE ABDOMINAL PAIN. ESSURE WAS REMOVED VIA HYSTERECTOMY FOUR AND A HALF YEARS AFTER ITS INSERTION. SHE ALSO REPORTED TWO TRANSIENT ISCHEMIC ATTACK STROKES. THE FIRST TWO EVENTS WERE CONSIDERED SERIOUS DUE TO HOSPITALIZATION WHILE THE REMAINING EVENTS DUE TO MEDICAL SIGNIFICANCE. THE EVENT PHYSICIAN SAID IT WAS AN AIR POCKET AND TWO TRANSIENT ISCHEMIC ATTACK STROKES ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHERS ARE LISTED. PAIN MAY OCCUR DURING AND FOLLOWING THE ESSURE PLACEMENT PROCEDURE. IN THIS PARTICULAR CASE THE CONSUMER STATED THAT SHE WAS HOSPITALIZED DUE TO EXCRUCIATING PAIN DURING THE PROCEDURE AND THE PHYSICIAN SAID IT WAS AN AIR POCKET; THE CHARACTERISTICS OF THE EVENT AIR POCKET WERE NOT SPECIFIED TO CONCLUDE ON ITS NATURE, HOWEVER, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP WITH THE INSERTION PROCEDURE, THESE EVENTS WERE CONSIDERED RELATED TO ESSURE THERAPY. ABNORMAL GENITAL BLEEDING AND ABDOMINAL PAIN MAY OCCUR AFTER ESSURE INSERTION, THEREFORE CAUSALITY BETWEEN CONSTANT BLEEDING, SEVERE ABDOMINAL PAIN AND ESSURE CANNOT BE EXCLUDED. EVENT TWO TRANSIENT ISCHEMIC ATTACK STROKES WAS ASSESSED AS UNRELATED TO ESSURE, GIVEN ITS PATHOPHYSIOLOGY AND THE LOCAL EFFECT OF ESSURE IN THE FALLOPIAN TUBES. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT AS HOSPITALIZATION AND SURGICAL INTERVENTION WERE REQUIRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE LLC	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 11/23/2015 **Report Date (B4): 11/24/2015** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C59246

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

WHEN THE ESSURE PRODUCT PACKAGE WAS OPENED FOR USE, STAFF NOTED THAT THE PRODUCT WAS BENT AT THE END PREVENTING ITS USE. ITEM RETAINED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058486	BAYER	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 12/20/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY, HAIR FALLING OUT, INSOMNIA, DECREASED SEX DRIVE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058487	BAYER	12/15/2015	12/15/2015

Event Information:

Event Date (B3): 9/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEPRESSION, SEVERE MOODSWING, NO ENERGY, MIGRAINES, AND EXCRUCIATING LOWER BACK PAIN DURING THE TIME OF OVULATION AND MENSTRUAL CYCLE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058575		12/15/2015	12/18/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 4/10/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE COILS PUT IN ON (B)(6) 2008. NO PROBLEMS UNTIL 2013. SINCE THEN, I HAVE BEEN DIAGNOSED WITH SYNCOPE, VERTIGO, SEVERE MIGRAINES THAT CAN OCCUR COMA LIKE SYMPTOMS, SEIZURES WITH NO KNOWN CAUSE, SEVERE IRRITATION AND VISION ISSUES. THERE IS OCCASIONAL NAUSEA AND BLOATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01920	BAYER HEALTHCARE LLC	12/16/2015	12/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D31446

Single Use: Y
Implant Date (E6): 11/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 17-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE GENERIC REIMBURSEMENT PROGRAM. ON (B)(6) 2015, ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) WAS INSERTED WITH LOT NUMBER D31446. ON (B)(6) 2015 THE PATIENT EXPERIENCED ESSURE BROKE, TUBAL SPASM, AND COMPLICATION OF DEVICE INSERTION. IT WAS REPORTED THAT INSERTION FAILURE DUE TO TUBAL SPASM, DEVICE BREAKAGE AND ANATOMICAL REASON (TORTUOUS AND STENOSIS OF THE FALLOPIAN TUBE). BILATERAL PLACEMENT WAS PERFORMED WITH ANOTHER ESSURE SYSTEM. NO FURTHER INFORMATION AVAILABLE AT THE TIME OF THIS REPORT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, CASE REPORT REFERS TO A FEMALE PATIENT WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4) AND HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. SHE EXPERIENCED TUBAL SPASM AND ESSURE BROKE DURING INSERTION. THIS EVENT DEVICE BREAKAGE IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT RECEIVED ON 21-DEC-2015: PTC GLOBAL NUMBER (B)(4). BATCH NUMBER D31446. FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOPIAN TU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01921	BAYER HEALTHCARE LLC	12/16/2015	12/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GENERAL PRACTITIONER IN NETHERLANDS ON 17-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THE PHYSICIAN WAS ABLE TO VAGUELY DESCRIBE THE COMPLAINT/SIDE EFFECT. THE PATIENT HAD ABDOMINAL PAIN DURING ESSURE AND ACCORDING TO PHYSICIAN, THE ESSURE WAS REMOVED AND THE COMPLAINT WAS ALSO APPARENTLY GONE. CORRECTION FOLLOWING COMPANY INTERNAL REVIEW ON 19-NOV-2015: DURING INTERNAL REVIEW IT WAS NOTIFIED THAT THE PREVIOUSLY REPORTED INITIAL RECEIPT DATE 17-NOV-2015 IS INCORRECT. THE CORRECT INITIAL RECEIPT DATE OF THE CASE IS 16-NOV-2015. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN. SHE HAD ESSURE REMOVED AND THE COMPLAINT WAS APPARENTLY GONE. THIS EVENT IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING THAT ABDOMINAL PAIN MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 16-DEC-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01922	BAYER HEALTHCARE LLC	12/16/2015	12/16/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 7/31/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION. PATIENT WAS EXPERIENCING PELVIC PAIN AND HAD ESSURE REMOVED SURGICALLY AND BILATERAL SALPINGECTOMY ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT. IT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR PERMANENT CONTRACEPTION AND WAS EXPERIENCING PELVIC PAIN. SHE HAD A BILATERAL SALPINGECTOMY AND HAD ESSURE REMOVED SURGICALLY. PELVIC PAIN IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE LOCALIZATION OF THIS PAIN AND ESSURE INSERTS LOCALIZATION AND LACK OF ALTERNATIVE EXPLANATION, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. FURTHER INFORMATION AND A PRODUCT TECHNICAL COMPLAINT ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 04-JAN-2016. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01923	BAYER HEALTHCARE LLC	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 10/19/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C38208

Single Use: Y
Implant Date (E6): 10/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 17-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER C38208, FOR PERMANENT CONTRACEPTION. PHYSICIAN REPORTED A SUSPECTED NICKEL ALLERGY. THE PATIENT CALLED PHYSICIAN ON (B)(6) 2015 TO REPORT A RASH WITH ITCHING THAT WENT FROM JUST HER ARMS TO HER WHOLE BODY. SHE WAS PRESCRIBED A COURSE OF STEROIDS. DURING THE COURSE OF STEROIDS, THE RASH WAS IMPROVED, BUT RETURNED FULLY UPON COMPLETION. SHE WAS NOT HOSPITALIZED. SHE ALSO EXPERIENCED METALLIC TASTE IN HER MOUTH. PHYSICIAN WAS CONCERNED AND WANTED TO KNOW IF SHE SHOULD DO NICKEL ALLERGY TESTING ON ALL PATIENTS, AS THIS PATIENT SAID SHE WAS NOT ALLERGIC TO NICKEL OR METALS PREVIOUSLY. SHE WILL HAVE A TOTAL HYSTERECTOMY ON (B)(6) 2015 TO REMOVE COILS. COMPANY CAUSALITY COMMENT THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND STARTED HAVING A RASH WITH ITCHING 4 DAYS LATER. PHYSICIAN SUSPECTED OF NICKEL ALLERGY AND SCHEDULED A HYSTERECTOMY TO REMOVE THE COILS. NICKEL ALLERGY IS A LISTED EVENT IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, AND WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE. PATIENTS WHO ARE ALLERGIC TO NICKEL MAY HAVE AN ALLERGIC REACTION TO THE DEVICE. IN ADDITION, SOME PATIENTS MAY DEVELOP AN ALLERGY TO NICKEL IF THIS DEVICE IS IMPLANTED. TYPICAL ALLERGY SYMPTOMS REPORTED INCLUDE RASH, PRURITUS, AND HIVES. IN THE PRESENT CASE PATIENT DENIED BEING ALLERGIC TO NICKEL OR METALS PRIOR TO THE INSERTION. GIVEN THE NATURE OF THE EVENT, AND COMPATIBLE TEMPORAL RELATIONSHIP, CAUSALITY WITH ESSURE

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CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENT WAS REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

ESSURE QUESTIONNAIRE RECEIVED ON 21-DEC-2015 THE PATIENT´S WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). HER MEDICAL HISTORY INCLUDED FIBROMYALGIA. ESSURE WAS INSERTED WITH LOT NUMBER C38208 AND SHE WAS NOT IN A POSTPARTUM STATE. INSERTION AND VISUALIZATION OF

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058499	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I'VE EXPERIENCED PAIN SINCE RECEIVING ESSURE. HEADACHES MULTIPLE TIMES A WEEK LOSS OF FOCUS AND CONCENTRATION BLURRED VISION FLOATERS IN MY VISION AS WELL. IRREGULAR PERIODS AND DEBILITATING PAIN DURING MENSTRUAL CYCLE. TONS OF PRESSURE IN MY ABDOMEN CONSTANTLY AND STABBING PAINS THAT ARE SO SEVERE IT TAKES MY BREATH AWAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058500	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 12/15/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). LOSING HAIR DAILY ..HAVE BALD SPOTS MANY OTHER COMPLICATIONS ...

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058501	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 1/10/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). RANDOM RASHES, RANDOM HIVES, BOYLES ON INNER THIGHS, HAIR LOSS, WEIGHT GAIN, MIGRAINES, CONSTANT PAIN IN ABDOMEN, STRIKING PAIN IN PAY UTERUS, NUMEROUS UTI, NUMEROUS YEAST INFECTIONS, FATIGUE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058502	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 9/14/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN (B)(6) 2007 ONE MONTH AFTER BEING IMPLANTED WITH ESSURE I WOKE UP IN A "POOL OF BLOOD" AND WAS HAVING EXCRUCIATING PAIN ON LOWER LEFT SIDE OF MY PELVIC AREA. WENT TO THE EMERGENCY ROOM. I WOULD CONTINUE TO EXPERIENCE LOWER ABDOMINAL PAIN MOSTLY LEFT SIDED, HEAVY BLEEDING, AND SEVERE CRAMPING FROM 2007 TILL THIS DAY. IN 2012 EXACTLY 5 YEARS OF BEING IMPLANTED I WOULD START TO HAVE SEVERE PROBLEMS. (B)(6) 2012 I BEGAN TO GET MIGRAINES LASTING 5-7 DAYS, DIZZINESS, STOMACH BLOATING THAT LEAVES MY STOMACH ROCK HARD, SEVERE LOWER ABDOMINAL PAIN, HEAVY MENSTRUATION WITH MULTIPLE CYCLES WITHIN THE MONTH, PAINFUL SEXUAL INTERCOURSE, NAUSEA, FATIGUE, HAIR LOSS, MEMORY FOG, REPEATED URINARY TRACT INFECTIONS WITH BLOOD IN URINE, UNEXPLAINED WEIGHT GAIN, TEETH BREAKING, LOW BLOOD PRESSURES, METAL LIKE TASTE IN MY MOUTH, LOSS OF TASTE BUDS, LACK OF INTEREST IN SEX, UNCONTROLLABLE ITCHING ALL OVER MY BODY, UNEXPLAINABLE RASHES IN VARIOUS PLACES ON MY BODY, EXCESSIVE DISCHARGE, BRAIN SHOCKS, STROKE BLOOD CLOTS, RINGING IN EARS, SWELLING IN ANKLES, SLEEP APNEA, HAIR GROWTH IN FACIAL AREA, VITAMIN D DEFICIENCY, INSOMNIA, UNCONTROLLABLE SWEATING, ALWAYS FEELING HOT. WAS DIAGNOSED WITH FIBROMYALGIA IN 2013.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058503	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 12/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) .
INNER COIL FELL OUT WHILE USING RESTROOM.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058504	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 1/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DAILY RECURRING HEADACHES, ABNORMAL PAIN DURING MENSTRUATION, LOWER BACK PAIN, PELVIC PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058505	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 9/3/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) .
ESSURE HAS CAUSED ME EXTREME BLOATING, LEG PAIN, ABDOMINAL PAIN, JOINT PAINT, BACK PAIN. HEAVY MENTRUSAL CYCLES. SHOCKING PAIN IN LOWER ABDOMINAL AREA WHEN SNEEZING. DEPRESSION, PAINFUL INTERCOURSE, MIGRAINES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058506	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 7/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, JOINT PAIN, OCCASIONAL NAUSEA, DIARRHEA SINCE IMPLANTATION, CONSTANT PELVIC PAIN, SOME PAIN DURING INTERCOURSE, HAIR FALLING OUT A LOT MORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058507	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 2/28/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A LOT OF BLEEDING , IRREGULAR PERIODS, I CAN FEEL THE DEVICE AT SIGHT, BOTHERSOME, DISCHARGE,EXCRUCIATING PAIN TO HANDS AND JOINTS, FEET, NUMBNESS TO HANDS, FATIGUE , TIRED, DEPRESSED, HAIR LOSS, BACK PAIN , LOST A TOOTH, BLOATING, LOOK PREGNANT , UNABLE TO LOSE WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058508	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 12/12/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABOUT 1 1/2 YEARS AFTER HAVING THE PROCEDURE, MY SIDES (WHERE FALLOPIAN TUBES ARE) STARTED CRAMPING REALLY BAD AND I NOTICED SWELLING. WENT TO MY GYNECOLOGIST AND WAS TOLD THAT I HAD SWELLING IN MY FALLOPIAN TUBES. MY MIGRAINES HAVE BEEN UNBEARABLE. BACKACHES AND FORGETFULNESS ARE GETTING WORSE. MOOD SWINGS AND DEPRESSION ARE REALLY BAD.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058509	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 11/10/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). A LOT OF VISITS TO HOSPITAL FOR STOMACH PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058510	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 10/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). FREQUENT LEG CRAMPS, SEVERE DAILY BLOATING AND IRREGULAR PERIODS FROM LIGHT TO VERY HEAVY THAT LASTS FOR MONTHS. I HAD 3 ULTRASOUNDS (ONE HIGH DEF. INTRAVAGINAL) SHOWS THAT ONLY ONE COIL IS THERE, ONE COIL UNACCOUNTED FOR. HSG SHOWS TUBAL OCCLUSION BUT THERE IS A "BUBBLE" WHICH WAS SUSPECTED TO BE A POLYP. HYSTEROSCOPY WAS DONE BUT DOCTOR COULD NOT FIND ANYTHING. ALL THE ULTRASOUNDS, HSG AND HYSTEROSCOPY WERE DONE IN (B)(6) WHERE ESSURE IS UNHEARD OF, I WILL HAVE TO GO BACK TO THE US WHERE I HAD THE COILS IMPLANTED. ESSURE WAS PROVIDED BY MY OB-GYN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058511	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 10/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THE ESSURE DEVICE IMPLANTED IN (B)(6) 2012 AND BECAUSE OF THE FOLLOWING SIDE AFFECTS THAT I AM GOING TO DESCRIBE I HAD IT REMOVED ON (B)(6) 2015. THE PROCEDURE ITSELF WAS EXTREMELY UNCOMFORTABLE AFTERWARDS WITH SEVERE CRAMPING AND BLEEDING. ALSO, THE HSG TEST THREE MONTHS LATER WAS BOTH PAINFUL AND CAUSED MAJOR DISCOMFORT AFTERWARDS UP TO TWO WEEKS. NOW, THAT I NO LONGER HAVE THE ESSURE COILS, I CAN COMPARE HOW I FEEL NOW TO WHEN I HAD THE COILS IN. I AM A WEEK AND A HALF POST SURGERY. I WAS IN SEVERE PAIN WITH PELVIC PAIN ON THE RIGHT SIDE, TURNS OUT I HAD A LARGE CYST, HIP PAIN ON THE LEFT SIDE, WEIGHT GAIN ((B)(6) POUNDS AT LEAST), BLOATING,EXTREME FATIGUE, CONSTANT RESPIRATORY INFECTIONS, TRIGEMINAL NEURALGIA, AGITATION AND INCREASED ANXIETY AND MOOD SWINGS (WAS DIAGNOSED WITH BIPOLAR PREVIOUSLY), INCREASED BLADDER LEAKAGE, ITCHY SKIN AND SCALP. I ALSO WANT TO SAY THAT THE TUBAL AND COIL REMOVAL PROCEDURE WAS LESS PAINFUL AND THE RECOVERY IS MUCH EASIER THAN THE IMPLANTING OF ESSURE AND ALSO THE HSG TEST THAT IS REQUIRED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058512	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 2/20/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INTERMITTENT PAIN IN THE LOWER ABDOMINAL AREA, SOMETIMES SEVERE; CHRONIC MIGRAINE WITH VERTIGO (VESTIBULAR MIGRAINE); FREQUENT BOUTS OF NAUSEA AND PAIN IN BOWEL AREA; MUSCLE PAIN FLARING UP AND LASTING 3-4 DAYS; HIP PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058513	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 10/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING CHRONIC PELVIC PAIN, BLOATING, BACK PAIN, AND HEAVY PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058514	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 10/31/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE CRAMPING, HAIR LOSS, TOOTH DETERIORATION, IRREGULAR MONTHLY CYCLES, CHRONIC MIGRAINES, FREQUENT URINATION, BRUISING RAPIDLY ON ALL EXTREMITIES AND ABDOMEN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058515	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 4/12/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME PELVIC PAIN FOR 8 DAYS (NOT AT THE INCISION SITE), ELEVEN WEEKS OF BLEEDING, TONS OF HAIR LOSS AROUND MONTH 4 OR 5 (HAIR DRESSER HAD NEVER SEEN ANYTHING LIKE IT), UTI'S, PELVIC PAIN AT OVULATION AND PERIOD CYCLES, ANXIETY, BRAIN FOG, JOINT PAIN, INFLAMMATION AT FOOT AND ELBOW, RASHES. UPON REMOVAL SIDE EFFECTS ARE GOING AWAY. ESSURE MIGRATED FROM MY TUBE INTO MY UTERUS SO WASN'T PROTECTING ME FROM PREGNANCY AND THEN IT PERFORATED THE UTERUS AND WAS ONE CELL MEMBRANE FROM BEING IN MY BOWEL. MY DR SAID I WAS REAL LUCKY IT WE GOT IT OUT WHEN WE DID.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058516	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 8/30/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . MY IMPLANTATION WAS COVERED BY THE STATE OF IDAHO. EVER SENSE IMPLANTATION ON (B)(4) 2012 MY HEALTH HAS DECLINED. ENERGY DECLINED, MOOD SWINGS INCREASED, ALLERGIES HAD A MAJOR INCREASE. FROM IMPLANTATION TO PRESENT DATE MEDICAL; VITAMIN D DEFICIENCY TWICE, LOWEST LEVEL WAS A 5. HYPERTHYROIDISM DIAGNOSED, THEN LEVELS WERE NORMAL, INSOMNIA DIAGNOSED, ANEMIC DIAGNOSED, 4CM TUMOR REMOVED FROM LEFT MILK DUCT SPRING OF 2014, TO MUCH BLEEDING, BLOOD CLOTS, POLYPS, AND ABNORMAL PAP RESULTING IN VAGINAL HYSTERECTOMY (B)(6) 2015. DR. (B)(6) . I'VE MOVED, AND HAVE HAD MULTIPLE DOCTORS IN A FEW TOWNS. (B)(6) IS MY CURRENT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058517	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 10/24/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BRAIN SHOCKS, TINGLING, BRAIN FOG, SKIN RASH BOILS THAT LASTED OVER A YEAR TO HEAL. BLACK OUTS/ FAINTING SPELL. HEAVY BLEEDING HAD TO GO TO THE ER. DOCTORS SAYS I MAY HAVE MS OR LUPUS. I AM BEING TESTED FOR THIS NOW.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058518	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 12/1/2013	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SYMPTOMS ONE AFTER THE OTHER NEVER GO AWAY, AS TIME PASSES A NEW SYMPTOM ARISES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058519	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 12/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE IN (B)(6) 2013, IT WAS COVERED BY MY INSURANCE AND PLACED BY MY DOCTOR AT HIS OFFICE. THE FIRST FEW MONTHS EVERYTHING SEEMED FINE, MY PERIODS WERE SLIGHTLY HEAVIER THAN BEFORE I HAD THE DEVICE BUT NOT UNBEARABLE. OVER THE PAST TWO YEARS MY PERIODS HAVE INCREASED TO AN ABNORMALLY HEAVY FLOW AND ARE INCREASINGLY LONGER. PRE-ESSURE MY PERIODS WERE MODERATE FLOW FOR APPROXIMATELY 4 DAYS. NOW I SOAK THROUGH A SUPER TAMPON IN 45 MINUTES FOR SEVERAL DAYS AND MY PERIODS OFTEN LAST 10 DAYS. I HAVE ALSO STARTED EXPERIENCING MIGRAINES 2-4 TIMES A WEEK WHERE I PREVIOUSLY HAD 1-3 A MONTH. I AM LOSING A LOT OF HAIR. I AM ALSO EXPERIENCING EXCESSIVE WEIGHT GAIN. IN 2 YEARS I HAVE GAINED (B)(6) LBS, A LOT OF THAT IN MY MIDSECTION AND MY DIET AND EXERCISE ARE CONSISTENT WITH WHAT THEY WERE PRE-ESSURE WHEN I HAD NO PROBLEMS MAINTAINING A HEALTHY WEIGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058520	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 1/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). JOINT PAIN, MASSIVE HAIR LOSS, SEVERE ANXIETY AND DEPRESSION, MEMORY LOSS, BRAIN FOG, MUSCLE CRAMPS, TEETH PROBLEMS, HURTING SKIN, HUGE BLOOD CLOTS WITH PERIOD, PAIN DURING INTERCOURSE, EXTREME FATIGUE, HEADACHES. THESE ARE ALL SIDE EFFECTS FROM DEVICE I HAVE NOW. YES COVERED BY INSURANCE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058524	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 8/23/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAVEN'T BEEN ABLE TO SLEEP IN A BED FOR 2YRS; HAVE JOINT PAIN AND HEADACHES CONSTANTLY; MEMORY NOT THE SAME, ACNE; WHEN ITS TIME FOR MY PERIOD VERY MOODY NO ENERGY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058525	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 10/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. HEAVY BLEEDING/CRAMPING DURING MONTHLY CYCLE. MIGRAINES AND SEVERE DAILY HEADACHES. SHOOTING VAGINAL PAIN. SHOOTING JOINT PAIN. JOINT DETERIORATION. CRAMPING NOT DURING CYCLE. BLOATED GUT. INABILITY TO LOSE WEIGHT, EVEN STICKING TO STRICT DIET AND EXERCISE PLAN. IRRITABILITY, DEPRESSION, EMOTIONAL DISTRESS. NUMBNESS IN LEGS, FINGERS, ARMS, FEET. SWELLING IN FEET. ITCHING AND SKIN IRRITATION. LOSS OF SEX DRIVE. DISCOMFORT DURING SEX. PAIN ON THE WHOLE RIGHT SIDE OF MY BODY. I HAVE BEEN SEEN BY 3 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS POSSIBLE ADENOMYOSIS MENORRHAGIA POSSIBLE EARLY MENOPAUSE THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058526	BAYER	12/16/2015	12/16/2015

Event Information:

Event Date (B3): 10/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WAS IMPLANTED WITH A MEDICAL DEVICE IMPLANT CALLED ESSURE IN (B)(6) 2012. THIS MEDICAL DEVICE IMPLANT IS NOW MANUFACTURED BY BAYER, FORMALLY BY CONCEPTUS INC. THIS DEVICE HAS A THREE YEAR SHELF LIFE, HOWEVER I DO NOT HAVE THAT EXPIRATION DATE. THE ONSET OF MY COMPLAINT STARTED (B)(6) 2012. THIS IS A LIST OF MY SIDE EFFECTS AND SYMPTOMS THAT I HAVE EXPERIENCED DUE TO ESSURE. HEAVY BLEEDING/CRAMPING DURING MONTHLY CYCLE. MIGRAINES AND SEVERE DAILY HEADACHES. SHOOTING VAGINAL PAIN. SHOOTING JOINT PAIN. JOINT DETERIORATION. CRAMPING NOT DURING CYCLE. BLOATED GUT. INABILITY TO LOSE WEIGHT, EVEN STICKING TO STRICT DIET AND EXERCISE PLAN. IRRITABILITY, DEPRESSION, EMOTIONAL DISTRESS. NUMBNESS IN LEGS, FINGERS, ARMS, FEET. SWELLING IN FEET. ITCHING AND SKIN IRRITATION. LOSS OF SEX DRIVE. DISCOMFORT DURING SEX. PAIN ON THE WHOLE RIGHT SIDE OF MY BODY. I HAVE BEEN SEEN BY 3 DOCTORS. I HAVE BEEN DIAGNOSED WITH THE FOLLOWING CONDITIONS: POSSIBLE ADENOMYOSIS, MENORRHAGIA, POSSIBLE EARLY MENOPAUSE. THE DEVICE IS STILL INSIDE OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058580	BAYER	12/16/2015	12/18/2015

Event Information:

Event Date (B3): 3/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL
Model # (E4): B76538
Catalog # (E4):
Lot #(E4): ESS305

Single Use: *
Implant Date (E6): 3/7/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

UPON IMPLANTATION OF ESSURE PERMANENT BIRTH CONTROL, I BEGAN TO HAVE PROBLEMS. THE DOCTORS SAID I WOULD BE FINE AFTER 24 HRS OF IMPLANTATION. IMMEDIATELY I BECAME SICK WITH SEVERE CRAMPING, HEAVY BLEEDING AND BLOOD CLOTS AND FEVER. I CALLED THE DOCTOR, BUT SHE ASSURED ME IT WOULD PASS AND IT WAS JUST MY BODY REACTING TO A FOREIGN OBJECT. HOWEVER, I STAYED THAT SICK FOR ALMOST 2 WEEKS. THEN FOLLOWING 2 WEEKS, THE OTHER SYMPTOMS BEGAN MIGRAINE, SEVERE PAIN IN MY CENTRAL NERVOUS SYSTEM BEHIND MY NECK. THEN SEVERE PAIN SHOOTING DOWN MY NECK THROUGH MY LEGS CAUSING ME NOT TO BE ABLE TO WALK; NUMBNESS OF EXTREMITIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058622	BAYER	12/16/2015	12/21/2015

Event Information:

Event Date (B3): 11/4/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

COMMINUTED PELVIC FRACTURE NOW "CHRONIC" GANGLIA CYST ON PUBIC BONE.

Manufacturer Narrative (H10):

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Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER MEDICAL CARE INC.	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 12/3/2015 **Report Date (B4): 12/9/2015** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7): 12/3/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

FEMALE PATIENT HAD A C-SECTION THREE YEARS AGO. A MONTH PRIOR TO THE SURGERY, THE PATIENT HAD AN XR HYSTEROSALPINGOGRAPHY DONE "HISTORY: POSTOP ESSURE: FLUOROSCOPIC XRAY: RIGHT FALLOPIAN TUBE IS OCCLUDED, LEFT TUBE IS NOT OCCLUDED". EARLIER THIS MONTH, THE PATIENT HAD A LAPAROSCOPIC ASSISTED VAG/HYST WITH BILATERAL SALPINGOOPHORECTOMY DUE TO MENORRHAGIA, ADENOMYOSIS, PELVIC PAIN. DEVICE WAS REMOVED INTACT WITH THE FALLOPIAN TUBE. PROCEDURE WAS DONE WITHOUT DIFFICULTY AND PATIENT TAKEN TO RECOVERY IN GOOD CONDITION. THIS HOSPITAL RECEIVED A LETTER OF REPRESENTATION OF THE PATIENT IN A PRODUCTS LIABILITY CASE AGAINST THE MANUFACTURER OF THE IMPLANTED DEVICE; REQUESTING PRESERVATION OF EXPLANTED TISSUE AND DEVICE INTACT AND EVENTUAL TRANSFER PRESERVED MATERIALS TO THEIR EXPERT PATHOLOGIES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01925	BAYER HEALTHCARE LLC	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 7/10/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B21683

Single Use: Y
Implant Date (E6): 7/10/2013
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT FROM A CONSUMER IN THE UNITED STATES WAS RECEIVED VIA FDA MAUDE ON 22-OCT-2015 (REF. NO MW5056249, RECEIVED AT MAUDE ON 15-SEP-2015). IT REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) IMPLANTED (B)(6) 2013 AND SINCE THEN HAD EXPERIENCED PELVIC PAIN, EXTREME EXHAUSTION, HEADACHES AND DEPRESSION. CONCOMITANT MEDICATION TAKEN BY CONSUMER WERE MAXALT (RIZATRIPTAN), ZOLOFT (SERTRALINE), LIPITOR (ATORVASTATIN). FOLLOW-UP RECEIVED ON 18-NOV-2015 FROM CONSUMER: CONSUMER'S ADDRESS AND DATE OF BIRTH WERE PROVIDED. SHE DOESN'T HAVE THE LOT NUMBER, HOWEVER, SHE WILL CALL HER PHYSICIAN TO ASK HIM. CONSUMER WILL HAVE A HYSTERECTOMY IN (B)(6) 2016. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 05-DEC-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO EVIDENCE OF A QUALITY DEFECT. MOREOVER, THE REPORTED MEDICAL EVENT(S) ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A (B)(6) FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SINCE THEN PRESENTED PELVIC PAIN. SHE STATED

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SHE WILL HAVE A HYSTERECTOMY. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP AND THE FACT THAT PELVIC PAIN MAY OCCUR DURING ESSURE USE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WILL BE REQUIRED, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENT WERE REPORTED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO EVIDENCE OF A QUALITY DEFECT. FURTHER INFORMATION HAS BEEN REQUESTED.

Manufacturer Narrative (H10):

ESSURE QUESTIONNAIRE RECEIVED ON 22-DEC-2015 NEW REPORTER WAS ADDED. THE PATIENT´S WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). HER MEDICAL HISTORY INCLUDED LEEP IN 2002. ESSURE WAS INSERTED WITH LOT NUMBER B21683 AND SHE WAS NOT IN A POSTPARTUM STATE. CERVIC

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058546	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 1/4/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN (B)(6) 2010 I WAS DIAGNOSED WITH FIBROMYALGIA. I HAVE ALSO HAD CHRONIC MIGRAINES AND BEEN TO MULTIPLE DOCTORS, ETC. BUT HAVE NOT HAD ANY RESOLUTION. I GAINED WEIGHT TO THE TUNE OF (B)(6) IN 6 MONTHS, AGAIN THAT MY DOCTOR COULD NOT EXPLAIN. SEVERE PAIN IN MY RIGHT ABDOMINAL AREA THAT SENT ME TO THE ER MORE THAN ONCE. CHRONIC FULL BODY PAIN THAT HAS LEFT ME UNABLE TO WORK OUTSIDE THE HOME.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058547	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 12/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THOUGHT I PULLED A MUSCLE IN MY BACK. DOESN'T FEEL LIKE A PULLED MUSCLE. CAN'T BEND OR SIT A CERTAIN WAY. CAN'T LIFT THINGS. PAIN RADIATES FROM LOWER BACK UP MY BACK. WILL MAKE AN E.R TRIP IF IT DOESN'T IMPROVE IN A FEW DAYS. FEEL DEPRESSED AND AMP; NOT MOTIVATED. BLOATED AND AMP; GAINING WEIGHT. VERY EMOTIONAL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058548	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 1/4/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD EXTREMELY HEAVY BLEEDING PERIODS WITH HUGE CLOTS, CONTINUOUS STABBING PAIN ON MY RIGHT LOWER PELVIC AREA, BACK PAIN, WEIGHT GAIN, EXTREME MOODINESS, HEADACHES LASTING SOMETIMES UP TO WEEKS AT A TIME, PAINFUL INTERCOURSE, BACK PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058549	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 1/2/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HAIR LOSS, TEETH CRACKING,CHIPPING ROOTS DYING, SEVERE JOINT PAIN WALKING IN THE MORNING WAS THE WORST. BRAIN FOG, MEMORY LOSS, WEIGHT GAIN (B)(6) LBS, INSOMNIA, DEPRESSION AND EXHAUSTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058550	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 7/11/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED BLEEDING VAGINALLY FOR LONG PERIODS OF TIME. DIAGNOSED WITH A BLEEDING DISORDER MENORRHAGIA, ANEMIA, HYPERTENSION, JOINT PAIN, CYSTITIS AND SYNCOPE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058567	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 4/25/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) .
ESSURE CAUSED CHRONIC INFLAMMATION THROUGHOUT MY BODY WHICH CAUSED ME TO NOT EXERCISE, I GAINED (B)(6) , STAYED BLOATED, HAD HEAVY BLEEDING WITH CLOTS, PELVIC PAIN, SCIST ON OUTSIDE OF TUBE, HAIR LOSS, SKIN IRRITATION, BRAIN FOG, ANXIETY/DEPRESSION AND MORE. SINCE MY HYSTERECTOMY (B)(6) 2015 I FEEL 80% BETTER, NO MORE BLOATING, ONLY SLIGHT INFLAMMATION IN MY BODY (I CAN NOW EXERCISE), MINIMUM HAIR LOSS, BUT I CONTINUE TO HAVE SKIN IRRITATION ESPECIALLY WHEN I SWEAT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058568	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 12/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . PAINFUL PERIOD VERY BAD CRAMPS BACK PAIN BLOATING.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058569	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 12/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) .
I HAVE A ABCESS FROM TOOTH NERVE PAINS FROM THAT ALSO A COUGH SORE THROAT EVERYTIME I COUGH SNEEZE I HAVE STABBING PAINS WHERE MY TUBES ARE WHICH THE ESSURE IS LOCATED AND ITS SO PAINFUL.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058570	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 8/5/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . I HAVE A NICKLE ALLERGY, PELVIC PAIN DURING PERIODS AND AFTER/DURING INTERCOURSE. HEAVY BLEEDING,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058571	BAYER	12/17/2015	12/17/2015

Event Information:

Event Date (B3): 12/10/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . I FELT SICK WITH HYPOGLYCEMIC SYMPTOMS ALONG WITH EXTREME FATIGUE,DIZZINESS, WEAKNESS AND NAUSEA.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01926	BAYER HEALTHCARE LLC	12/18/2015	12/18/2015

Event Information:

Event Date (B3): 10/30/2015 **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** IT

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D29715

Single Use: Y
Implant Date (E6): 10/30/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 11-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ON (B)(6) 2015, A PARTIAL RELEASE OF THE DEVICE BY POSITIONING GUIDE OCCURRED. THERE WAS A PROLONGED TIME FOR THE RECOVERY OF THE DEVICE AND PATIENT HAD PAIN. FOLLOW-UP INFORMATION RECEIVED ON 19-NOV-2015: THE ESSURE, BATCH NUMBER D29715, WAS PLACED ON (B)(6) 2015. THE PHYSICIAN REPORTED THAT DEVICE WAS NOT COMPLETELY DEPLOYED AND THE BUTTON WAS BLOCKED, SO THE DEVICE GOT STUCK ON THE CATHETER TIP. THE DEVICE WAS THROWN AND IT WAS NOT POSSIBLE TO RECOVER IT TO SEE IF THE WHEEL WAS SET BACK UNTIL IT STOPS. IT WAS MADE CLEAR THAT IF THE RETREAT WAS NOT 100% COMPLETE, THE RELEASE WOULD NOT TAKE PLACE AND THE BUTTON WOULD LOCK. THAT FORCED THE OPERATION TO STRETCH THE COILS UNTIL IT BROKE; THE MICRO-INSERT WAS THEN GRASPED AND REMOVED FROM THE CAVITY. THE PHYSICIANS HAD TO REMOVE THE PIECES WITH PLIERS. IT WAS STATED THAT THE PATIENT WAS AWAKE BECAUSE THE ANESTHESIOLOGISTS REFUSED TO NUMB HER DUE TO THE LACK OF EXAMINATIONS. THE PATIENT WAS NEVER IN A LIFE-THREATENING CONDITION. THE PROCEDURE WAS NOT CONVERTED FROM HYSTEROSCOPIC TO LAPAROSCOPIC AND A NEW DEVICE WAS THEN SUCCESSFULLY PLACED. NO FURTHER INFORMATION WAS PROVIDED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD PAIN DURING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PROCEDURE. THE PHYSICIAN REPORTED THAT DEVICE WAS NOT COMPLETELY DEPLOYED AND THE BUTTON WAS BLOCKED, SO THE DEVICE GOT STUCK ON THE CATHETER TIP. THE RELEASE WOULD NOT TAKE PLACE AND THE BUTTON WOULD LOCK. THAT FORCED THE OPERATION TO STRETCH THE COILS UNTIL IT BROKE (SEEN AS DEVICE BREAKAGE). THE REPORTED EVENT PAIN IS LISTED

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ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION WHILE DEVICE BREAKAGE IS UNLISTED. IN THIS PARTICULAR CASE, PHYSICIAN STATED THERE WAS A PARTIAL RELEASE OF THE DEVICE BY POSITIONING GUIDE AND A PROLONGED TIME FOR THE RECOVERY OF THE DEVICE. THIS LED TO PAIN. CONSIDERING PATIENT'S PAIN WAS A CONSEQUENCE OF A COMPLICATED ESSURE INSERTION PROCEDURE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. IN THIS CASE, AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS UPGRADED TO OTHER REPORTABLE INCIDENT DUE TO THE DEVICE BREAKAGE, AS ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01927	BAYER HEALTHCARE LLC	12/18/2015	12/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 627738

Single Use: Y
Implant Date (E6): 10/27/2008
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 18-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2008; LOT NUMBER 627738. THE PHYSICIAN REPORTED SHE HAS A PATIENT WHO WANTS TO REMOVE HER ESSURE BOTH SIDES BECAUSE OF COMPLAINTS: PALPITATIONS, JOINT COMPLAINTS, LOWER BACK COMPLAINTS, UPPER LEG PAIN. ABDOMINAL PAIN, EAR COMPLAINTS, POOR SLEEP. THE PHYSICIAN WILL CONDUCT A TUBECTOMY BOTH SIDES ON (B)(6) 2016. THE HSG (HYSTEROSALPINGOGRAM) POST PROCEDURE AFTER 3 MONTHS SHOWED NO ABNORMALITIES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND COMPLAINED OF ABDOMINAL PAIN. SHE WANTS TO REMOVE THE INSERTS AND A BILATERAL SALPINGECTOMY IS SCHEDULED. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, ABDOMINAL PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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PRODUCT TECHNICAL COMPLAINT RECEIVED ON 18-DEC-2015. FINAL ASSESSMENT: PRODUCTION DATE: JUL-2008; EXPIRATION DATE: JUL-2010. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01928	BAYER HEALTHCARE LLC	12/18/2015	12/18/2015

Event Information:

Event Date (B3): 9/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 9/15/2015
Explant Date (E7): 11/4/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 18-NOV-2015 WHICH REFERS TO A (B)(6)-YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT CONTRACEPTION. PATIENT EXPERIENCED PAIN IMMEDIATELY AFTER PROCEDURE. ON (B)(6) 2015, ABDOMINAL ULTRASOUND SHOWED CORRECT PLACEMENT OF INSERTS. ON (B)(6) 2015, COILS WERE REMOVED BY LAPAROTOMY SALPINGECTOMY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND PRESENTED PELVIC PAIN IMMEDIATELY AFTER PROCEDURE AND AROUND 2 MONTHS LATER, HAD THE COILS REMOVED PER LAPAROTOMY AND SALPINGECTOMY. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THE CLOSE TEMPORAL RELATIONSHIP AND THE FACT THAT PELVIC PAIN MAY OCCUR DURING ESSURE USE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED AND SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION AND TECHNICAL ASSESSMENT HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION RECEIVED FROM PHYSICIAN ON 16-DEC-2015 PATIENT´S WEIGHT WAS (B)(6) AND HEIGHT WAS (B)(6). HER CONCURRENT CONDITION INCLUDED MORBID OBESITY. PREVIOUS GYNECOLOGICAL INTERVENTIONS WERE DENIED. ESSURE WAS INSERTED ON (B)(6) 2015 AND PAIN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01929	BAYER HEALTHCARE LLC	12/18/2015	12/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/26/2014
Explant Date (E7): 11/30/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 19-NOV-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. ADDITIONAL INFORMATION RECEIVED ON 23-NOV-2015. HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED ON A PATIENT AND ONE OF THE COIL WAS NOT THERE. HEALTHCARE PROFESSIONAL (HCP) BELIEVED THAT IT MIGHT BE MIGRATED TO THE ABDOMEN. EITHER THE UTERUS OR THE FALLOPIAN TUBE MIGHT BE PERFORATED. PATIENT WAS PREGNANT WITH ESSURE. IT WAS ALSO STATED THAT DOING A SALPINGECTOMY AND ESSURE REMOVAL DUE TO MIGRATION. AND REPORTER WOULD LIKE TO TALK TO SOMEONE ABOUT THE SPECIFICS OF THE REMOVAL, PREFERABLY A SURGEON. ESSURE NOT LOCATED NEAR TUBE. FOLLOW UP INFORMATION RECEIVED FROM THE NURSE ON 01-DEC-2015: THE INITIALS AND THE DATE OF BIRTH OF THE PATIENT WERE ADDED. THE PREGNANCY WENT FULL TERM. THERE WERE NO COMPLICATIONS. SHE DELIVERED ALREADY BUT THE DATE WAS NOT INFORMED. ESSURE WAS PLACED ON (B)(6) 2014 BY A DIFFERENT DOCTOR. THEY DID NOT HAVE THE ESSURE LOT NUMBER. ON (B)(6) 2015 ESSURE WAS REMOVED BY THE REPORTING PHYSICIAN. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT HSG (HYSTEROSALPINGOGRAM) WAS DONE ON A PATIENT AND ONE OF THE COIL WAS NOT THERE/ IT MIGHT BE MIGRATED TO ABDOMEN. EITHER THE UTERUS OR THE FALLOPIAN TUBE MIGHT BE PERFORATED. PATIENT WAS PREGNANT WITH ESSURE. ESSURE INSERTS WERE REMOVED A YEAR AND A HALF AFTER THE INSERTION. THE PREGNANCY WENT FULL TERM. THERE WERE NO COMPLICATIONS. THE OUTCOME OF THE CHILD WAS NOT PROVIDED. ALL THESE EVENTS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, THE

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EXACT DATE AND MECHANISM OF DEVICE DISLOCATION INTO ABDOMINAL CAVITY, UTERINE PERFORATION AND FALLOPIAN TUBE PERFORATION WERE NOT KNOWN. IT WAS NOT REPORTED THE GESTATIONAL AGE. BASED ON THE NATURE OF THE EVENTS AND CONSIDERING THAT UNINTENDED PREGNANCIES, DEVICE DISLOCATION INTO ABDOMINAL CAVITY, UTERINE/FALLOPIAN TUBE PERFORATION MIGHT OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WILL BE REQUIRED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01930	BAYER HEALTHCARE LLC	12/18/2015	12/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2010
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5057708) IN UNITED STATES ON 19-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. THE CONSUMER REPORTED ESSURE CAUSED A MASSIVE AMOUNT OF CONSISTENT AND ONGOING PAIN. SHE HAD ENDOMETRIAL ABLATIONS TO STOP EXCESSIVE BLEEDING AND WENT SEPTIC AS A RESULT OF THE ABLATION. THE INTERCOURSE WAS VERY PAINFUL, AND THERE WAS A CONSISTENT, DULL PAIN IN HER PELVIS AND LOWER BACK, NONE OF WHICH OCCURRED BEFORE THE PROCEDURE. SHE REPORTED THAT ABNORMAL BLEEDING, HEAVY BLEEDING, AND EXTREME CRAMPING ALSO OCCURRED. FOLLOW UP INFORMATION RECEIVED ON 16-DEC-2015: NO NEW INFORMATION. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD TO PERFORM AN ENDOMETRIAL ABLATION TO STOP EXCESSIVE BLEEDING (INTERPRETED AS MENORRHAGIA) AND WENT SEPTIC AS A RESULT OF ABLATION. THE MENORRHAGIA AND SEPSIS ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, CONSIDERING THAT ESSURE MAY AFFECT CAUSE BLEEDING AND THAT THERE IS NO ALTERNATIVE EXPLANATION FOR THIS BLEEDING, A CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. SINCE THE SEPSIS OCCURRED AS A COMPLICATION OF AN ENDOMETRIAL ABLATION PERFORMED TO TREAT AN EVENT POSSIBLY RELATED TO ESSURE, THE CAUSAL RELATIONSHIP BETWEEN ESSURE AND THIS COMPLICATION CANNOT BE EXCLUDED EITHER. THIS CASE IS REGARDED AS INCIDENT SINCE A MEDICAL INTERVENTION WAS REQUIRED TO TREAT AN EVENT CAUSED BY ESSURE. FURTHER INFORMATION AND A PRODUCT TECHNICAL COMPLAINT ARE BEING SOUGHT.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 29-DEC-2015. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WERE A DEVICE FAILUR

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01931	BAYER HEALTHCARE LLC	12/18/2015	12/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 18-NOV-2015. IT REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN DID NOT INSERT THE ESSURE BUT SAW THE PATIENT FOR HER PREGNANCY. PATIENT REVEALED TO HEALTHCARE PROFESSIONAL (HCP) DURING HER PREGNANCY THAT SHE HAD ESSURE IN PLACE. PATIENT DELIVERED BABY AND ON (B)(6) 2015 HCP DID TUBAL LIGATION. AT THAT TIME HCP HAD TO EXCISE ESSURE COILS SINCE THEY HAD PERFORATED. ONE COIL WAS IN UTERINE WALL AND THE OTHER COIL WAS OUTSIDE OF UTERUS IN A FIBROID. HCP HAS PICTURES OF THIS. BOTH COILS REMOVED. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND GOT PREGNANT WITH ESSURE. SHE DELIVERED BABY AND HEALTH CARE PROFESSIONAL DID TUBAL LIGATION. AT THAT TIME HCP HAD TO EXCISE ESSURE COILS SINCE THEY HAD PERFORATED. ONE COIL WAS IN UTERINE WALL AND THE OTHER COIL WAS OUTSIDE OF UTERUS IN A FIBROID. BOTH COILS WERE REMOVED. ALL THESE EVENTS ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE, WHICH INCLUDED FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST TO DETERMINE IF THE INSERTS ARE IN THE CORRECT LOCATION AND TUBAL OCCLUSION IS PRESENT. IN THIS PARTICULAR CASE, NO SUCH CIRCUMSTANCES WERE REPORTED. THEREFORE, CAUSAL RELATIONSHIP BETWEEN ESSURE AND THE PREGNANCY CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENTS, THE EXACT DATE AND MECHANISM OF UTERINE PERFORATION AND DEVICE DISLOCATION WERE NOT KNOWN. HOWEVER, CONSIDERING THEIR NATURE, CAUSALITY

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CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01932	BAYER HEALTHCARE LLC	12/18/2015	12/18/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/20/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DURING UNCOUPLING AND ROTATING THE ESSURE AT PLACEMENT PROCEDURE, IT SEEMED AS IF THE ESSURE DID NOT UNCOUPLE ENOUGH OR NOT AT ALL. DURING RETRACTION OF THE INSERTER A WHOLE TRAIL (PROBABLY THE UN-WINDED COIL) CAME OUT, SUBSEQUENTLY A PIECE OF THE (GREEN) SLEEVE REMAINED IN THE UTERUS AND WAS REMOVED THIS WITH A FORCEPS. NEXT CHECKED WITH THE HYSTEROSCOPE AND ANOTHER PART (POSSIBLE FROM THE END PART OR FROM A PIECE THAT BROKE OFF) WAS SEEN LEFT IN THE TUBA, THE PHYSICIAN WAS ABLE TO REMOVE THIS AS WELL WITH FORCEPS WITH A LOT OF EFFORT. THE PIECES APPEARED TO BE BROKEN OFF AND LEFT IN THE UTERUS AND TUBA. AFTER THE PROCEDURE, THE PATIENT HAD A CONSULT WITH ANESTHESIST AND SUBSEQUENTLY PERFORMED LAPSTER (UNDERSTOOD AS LAPAROSCOPIC STERILIZATION).THE PATIENTS OUTCOME WAS STILL UNKNOWN. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE BREAKAGE DURING INSERTION OCCURRED. THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, DURING UNCOUPLING AND ROTATING THE ESSURE AT PLACEMENT PROCEDURE, IT SEEMED AS IF THE ESSURE DID NOT UNCOUPLE ENOUGH OR NOT AT ALL, AND DURING RETRACTION OF THE INSERTER A WHOLE TRAIL (PROBABLY THE UN-WINDED COIL) CAME OUT (INTERPRETED AS DEVICE DEPLOYMENT ISSUE). ANOTHER PART (POSSIBLE FROM THE END PART OR FROM A PIECE THAT BROKE OFF) WAS SEEN LEFT IN THE TUBA. AS THE DEVICE BREAKAGE IN THIS CASE, OCCURRED DURING ESSURE INSERTION

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PROCEDURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. THE PATIENT UNDERWENT A LAPAROSCOPIC STERILIZATION AFTERWARDS, HOWEVER THIS PROCEDURE WAS NOT PERFORMED TO PREVENT PERMANENT DAMAGE; IT WAS PERFORMED AS SECOND LINE CONTRACEPTION METHOD. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 28-DEC-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULTS WERE PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FAILURE MODE/MECHANISM: THE ESSURE INSERT IS MADE UP OF A FLEXIBLE OUTER COIL THAT IS DEPLOYED INTO THE FALLOP

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01933	BAYER HEALTHCARE LLC	12/18/2015	12/18/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 623217

Single Use: Y
Implant Date (E6): 5/15/2009
Explant Date (E7): 12/15/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE (B)(4)) IN UNITED STATES ON 19-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009 WITH LOT NUMBER 623217. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: CETIRIZINE (CETIRIZINE) AND AZELASTINE (AZELASTINE). CONSUMER REPORTED SHE WENT TO HER PHYSICIAN WITH COMPLAINT OF VERY HEAVY MENSTRUAL CYCLES, ABNORMAL MENSTRUAL CYCLES AND MILD CRAMPING. HE ORDERED AN ULTRASOUND. UPON VIEWING THE ULTRASOUND, THEY FOUND THAT ONE OF HER ESSURE DEVICES HAS DISLODGED ITSELF AND IS IN ENDOMETRIAL LINING. A HYSTEROSCOPY WITH DILATATION AND CURETTAGE WAS SCHEDULED TO RETRIEVE THE DEVICE, REMOVAL OF THE OTHER ESSURE COIL AND TUBAL LIGATION VIA LAPAROSCOPY. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IN ULTRASOUND IT WAS SEEN THAT ONE OF ONE OF HER ESSURE DEVICES HAS DISLODGED ITSELF AND IS IN ENDOMETRIAL LINING. A HYSTEROSCOPY WITH DILATATION AND CURETTAGE WAS SCHEDULED TO RETRIEVE THE DEVICE. THIS EVENT, SEEN AS DEVICE EMBEDMENT, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING ESSURE COILS MAY DISLOCATE AND EMBED INTO UTERUS OR FALLOPIAN TUBES, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WILL BE REQUIRED (HYSTEROSCOPY WITH D&C), THIS CASE IS REGARDED AS INCIDENT. NON-SERIOUS EVENTS WERE ALSO INFORMED. TECHNICAL ASSESSMENT AND FURTHER INFORMATION ARE EXPECTED.

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Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION WAS RECEIVED ON 04-JAN-2016 VIA CONSUMER QUESTIONNAIRE. CONSUMER'S DATE OF BIRTH, WEIGHT AND HEIGHT WERE PROVIDED. THIS REPORT REFERS TO A (B)(6) FEMALE CONSUMER. PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES INCLUDED HPV, ELECTIVE D

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058708	BAYER	12/18/2015	12/23/2015

Event Information:

Event Date (B3): 6/19/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 6/19/2008
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

SINCE HAVING THE ESSURE IMPLANTED, I HAVE HAD CHRONIC BLADDER INFECTIONS, VERY HEAVY PERIODS, PELVIC PAIN, AND RECENTLY MY HAIR HAS STARTED FALLING OUT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058704	BAYER	12/19/2015	12/23/2015

Event Information:

Event Date (B3): 12/23/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6): 12/23/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD THE ESSURE IMPLANTED IN (B)(6) 2014. BLED PROFUSELY ALMOST DAILY FOR 8 MONTHS. WAS TOLD THIS WAS A DEPO SIDE EFFECT. FINALLY STOPPED BLEEDING, BUT STILL HAVE SEVERE CRAMPING AND ONGOING BACK PAIN WHICH MY DOCTOR SAYS IS NOT RELATED TO THE PROCEDURE. I DO NOT BELIEVE THIS AS I HAVE NOT PREVIOUSLY HAD THESE ISSUES (OUTSIDE OF NORMAL PMS CRAMPING).

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058698	BAYER	12/20/2015	12/23/2015

Event Information:

Event Date (B3): 5/7/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD THE ESSURE IMPLANTED IN 2007. "MAY" WELL 6 MONTHS LATER, I BECAME VERY FATIGUED, PAIN ALL OVER. AS THE YEAR GO ON I JUST HAVE MORE AND MORE WRONG: CHRONIC FATIGUE, CHRONIC PAIN, FIBROMYALGIA, HEADACHES, BLURRED VISION, DIZZY SPELLS, NUMBING AND TINGLE IN FEET AND HANDS, OVER IT. IT'S TAKEN GREAT STRAIN ON MY FAMILY RESULTING IN ALMOST TWO DIVORCES BECAUSE I COMPLAIN NON STOP OF HURTING SINCE DIAGNOSED WITH FIBROMYALGIA, AND DOCTOR CHECKING TO SEE IF HASHIMOTO'S. I HAVE INSOMNIA, THYROID IS WORSE, LOSS OF HAIR, IRRITABLE EXTREMELY, STIFFNESS, BACK AND NECK PAIN, DRY EYES, MOUTH. I HAVE BEEN TO MANY, MANY DOCTORS, HAD CT-SCANS, BLOOD WORK, SLEEP STUDIES. I HAVE BEEN KICKED OUT OF DOCTORS' OFFICES, DOCTORS REFUSING ME. I GET TREATED LIKE A DRUG ADDICT FROM DOCTOR'S AND PHARMACIES, IT COST US TOO OF MONEY. I HAVE SEEN REGULAR DOCTORS, NEUROLOGIST, RHEUMATOLOGIST, PSYCHIATRIST, PSYCHOLOGISTS, CHIROPRACTOR. I HAVE BEEN ON MANY, MANY DIFFERENT MEDICINES.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01935	BAYER HEALTHCARE LLC	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 3/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 11/16/2012
Explant Date (E7): 10/19/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS SPONTANEOUS CASE REPORT WAS RECEIVED FROM A CONSUMER IN THE UNITED STATES ON 14-APR-2014 VIA A SALES REPRESENTATIVE. REPORTING CONSUMER WHO IS THE PATIENT HERSELF, IS A NON-HEALTHCARE PROFESSIONAL EMPLOYEE AT REPRESENTATIVE'S DOCTOR'S OFFICE. THE REPORT REFERS TO THE REPORTING CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND CURRENTLY IS 10 WEEKS PREGNANT AFTER SUCCESSFUL CONFIRMATION TEST A YEAR EARLIER (DEVICE INEFFECTIVE). NO INFORMATION WAS GIVEN ON CONSUMER'S HISTORY, PAST DRUGS, CONCOMITANT MEDICATION AND CONCURRENT CONDITIONS. IN (B)(6) 2012, THE CONSUMER HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED FOR STERILIZATION. CONSUMER SAID SHE IS PREGNANT STATUS POST SUCCESSFUL CONFIRMATION TEST ((B)(6) 2013). SHE REPORTED SHE WAS CURRENTLY 10 WEEKS PREGNANT (ESTIMATED START DATE (B)(6) 2014). NO TREATMENT WAS GIVEN. ESSURE TREATMENT WAS ONGOING. NO FURTHER DETAILS WERE REPORTED. REPORTER DID NOT ASSESS DEVICE-EVENT RELATIONSHIP. FOLLOW UP INFORMATION FROM 25-APR-2014: PTC ASSESSMENT. FINAL ASSESSMENT: NO LOT NUMBER PROVIDED; THEREFORE, NO LOT HISTORY RECORD (LHR) REVIEW COULD BE DONE. NO DEVICE RETURNED; THEREFORE, NO DEVICE INVESTIGATION COULD BE COMPLETED. NO CONCLUSIONS CAN BE DRAWN. MEDICAL ASSESSMENT: THE EVENTS REPORTED ARE POSSIBLE UNDESIRABLE EVENTS WITH THE USE OF ESSURE. LACK OF EFFECTIVENESS IN ITSELF IS NOT NECESSARILY INDICATIVE OF A QUALITY DEFECT AS IT MAY OCCUR WITH THE USE OF ANY PRODUCT. ADDITIONALLY, PREGNANCY MAY OCCUR DURING ANY CONTRACEPTIVE USE. NO COMPLAINT SAMPLE WAS PROVIDED FOR A TECHNICAL INVESTIGATION. NO BATCH NUMBER WAS REPORTED. NEITHER A TECHNICAL BATCH INVESTIGATION NOR A BATCH CLUSTER REVIEW IN THE GPV DATABASE FOR A MORE DETAILED STATISTICAL MEDICAL EVALUATION IS POSSIBLE WITHOUT A BATCH NUMBER. AT THE TIME OF THIS MEDICAL

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ASSESSMENT THE TECHNICAL INVESTIGATION CONCLUDED "UNCONFIRMED QUALITY DEFECT". BASED ON THE INFORMATION AVAILABLE, THERE IS NO REASON TO SUSPECT A QUALITY DEFECT. NO FURTHER INFORMATION IS EXPECTED AND THUS THIS CASE IS CLOSED. FOLLOW-UP INFORMATION WAS RECEIVED ON 08-MAY-2014. ESSURE WAS INSERTED ON (B)(6) 2012. ON (B)(6) 2013 HSG WAS PERFORMED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 08-MAY-2014 - PREGNANCY QUESTIONNAIRE RECEIVED: THE PATIENT'S MEDICAL HISTORY INCLUDED ENDOMETRIOSIS, 3 VAGINAL DELIVERIES (GRAVIDA3, PARA 3). IUD WAS USED PREVIOUSLY. THE LAST MENSTRUAL PERIOD WAS ON (B)(6) 2014. ULTRASOUND WAS PERFORMED ON (B)(6) 2014 (RESULTS NOT PROVIDED). THE PATIENT WAS EXPERIENCING HYPEREMESIS. THE ENTIRE TUBE REMOVAL WAS PLANNED TO BE PERFORMED AFTER DELIVERY. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 16-MAY-2014: THIS CASE REFERS TO A (B)(6) PATIENT. CONCURRENT CONDITIONS INCLUDED OBESITY (BMI (B)(6)) AND 7 WEEKS POST-PARTUM. THE INSERTION OF ESSURE WAS EASY, AS WELL AS THE VISUALIZATION OF THE TUBAL OSTIUM. THE FLUID LOSS DURING HYSTEROSCOPY WAS LESS THAN 1500CC AND THE PROCEDURE DID NOT TAKE MORE THAN 20 MINUTES. HYSTEROSCOPY WAS PERFORMED IN THE SAME DAY AND CONFIRMED PROPER PLACEMENT. HSG (HYSTEROSALPINGOGRAM) PERFORMED ON (B)(6) 2013 SHOWED COMPLETE OCCLUSION. CONDOMS WERE USED AS BACK-UP CONTRACEPTION. ON (B)(6) 2014, URINE TEST AND ULTRASOUND CONFIRMED PREGNANCY. FOLLOW-UP INFORMATION RECEIVED ON 27-MAY-2014: NEW REPORTER FROM REGULATORY AUTHORITY (CASE# MW5035673) ADDED. NO FURTHER INFORMATION WAS PROVIDED. FOLLOW-UP INFORMATION RECEIVED ON 28-JUL-2014 NO NEW CLINICAL INFORMATION PROVIDED. FOLLOW-UP FROM 20-APR-2015: THE REQUIRED NUMBER OF FOLLOW-UP ATTEMPTS HAS BEEN COMPLETED, WITH NO RESPONSE TO DATE. NO FURTHER FOLLOW-UP WILL BE PURSUED. PREGNANCY QUESTIONNAIRE RECEIVED FROM PHYSICIAN ON 23-NOV-2015: CONSUMER'S DEMOGRAPHIC INFORMATION WAS PROVIDED. ENDOMETRIOSIS, ADNEXAL SURGERY (ENDOMETRIOMA REMOVAL), GRAVIDA 4 AND PARA 4 WERE REPORTED AS MEDICAL HISTORY. PREVIOUS IUD/ IUS WAS REPORTED. ESSURE WAS INSERTED 8 WEEKS POST-PARTUM. SOUNDING WAS PERFORMED AND PARACERVICAL SHOCK WAS APPLIED DURING INSERTION (CERVICAL DILATATION AND GENERAL ANESTHESIA WAS DENIED). IT WAS AN EASY INSERTION. THERE WAS NO MORE THAN 1500CC OF FLUID LOSS DURING INSERTION AND IT DID NOT TAKE MORE THAN 20 MINUTES. CONDOMS WERE USED AS BACK-UP CONTRACEPTION. ON (B)(6) 2013, HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED AND SHOWED BILATERAL OCCLUSION. HER LAST MENSTRUAL PERIOD OCCURRED ON (B)(6) 2014. ON (B)(6) 2014, PREGNANCY WAS CONFIRMED BY URINE AND BLOOD TESTS. AN ULTRASOUND WAS ALSO PERFORMED AND CONFIRMED A 7 WEEKS AND 4 DAYS PREGNANCY. ON (B)(6) 2014, A VAGINAL DELIVERED OCCURRED (LIVE BIRTH) AT 37 WEEKS AND 4 DAYS ((B)(6)). DELIVERY WAS INDUCTED FOR UNEXPLAINED BLEEDING. THERE WERE COMPLICATIONS DURING PREGNANCY: HYPEREMESIS AND PLACENTA ABRUPTION. ON (B)(6) 2014, A POST-PARTUM TUBAL LIGATION VIA BILATERAL SALPINGECTOMY WAS PERFORMED TO REMOVE ESSURE. ESSURE IMPLANT WAS PARTIALLY PROJECTING THROUGH THE RIGHT FALLOPIAN TUBE ISTHMUS. SYMPTOMS RESOLVED AFTER SURGERY. HOSPITALIZATION AND REQUIRED INTERVENTION WERE SELECTED AS SERIOUSNESS CRITERIA BUT NOT SPECIFIED/ASSIGNED TO A SPECIFIC EVENT. IT WAS ALSO REPORTED THAT FAILURE RESULT IN UNINTENDED PREGNANCY, WEIGHT GAIN CONTRIBUTING TO OBESITY REQUIRING MEDICAL TREATMENT. PTC INVESTIGATION RESULT RECEIVED ON 17-DEC-2015. PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENT(S) AND LACK OF EFFICACY ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS

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REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) OR LACK OF EFFICACY AND A QUALITY DEFECT COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND BECAME PREGNANT APPROXIMATELY ONE YEAR AFTER THE HYSTEROSALPINGOGRAM SHOWED BILATERAL TUBAL OCCLUSION. AT 37 WEEKS AND 4 DAYS, DELIVERY HAD TO BE INDUCED DUE TO BLEEDING FROM PLACENTA ABRUPTION. SHE ALSO HAD HYPEREMESIS DURING PREGNANCY. SHE HAD A LIVE BIRTH (B)(6) THROUGH VAGINAL DELIVERY AND SHE RECOVERED FROM SYMPTOMS. THE FOLLOWING DAY, SHE UNDERWENT A POST-PARTUM BILATERAL SALPINGECTOMY WAS PERFORMED TO REMOVE ESSURE. IT WAS NOTICED THAT ESSURE IMPLANT WAS PARTIALLY PROJECTING THROUGH THE RIGHT FALLOPIAN TUBE ISTHMUS (INTERPRETED AS EMBEDDED DEVICE). PREGNANCY WITH ESSURE, PREMATURE SEPARATION OF PLACENTA, HYPEREMESIS GRAVIDURUM AND DEVICE EMBEDDED ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE. THE PREGNANCY AND DEVICE EMBEDMENT/PARTIAL PERFORATION ARE LISTED WHILE THE OTHER EVENTS ARE UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. FALLOPIAN TUBE PERFORATION MAY OCCUR WITH ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. THEREFORE, THE CAUSAL RELATIONSHIP WITH ESSURE CANNOT BE EXCLUDED. THIS PERFORATION MAY EXPLAIN THE PREGNANCY. HOWEVER, A LACK OF DEVICE EFFECT CANNOT BE EXCLUDED. ALSO, A CAUSAL RELATIONSHIP BETWEEN PREMATURE SEPARATION OF PLACENTA AND ESSURE INSERTS CANNOT BE EXCLUDED SINCE THE PART OF ESSURE INSERTS THAT LIE IN THE UTERUS MAY HAVE A MECHANICAL INTERFERENCE IN THE DEVELOPING PREGNANCY. ON THE OTHER HAND, DUE TO THE PATHOPHYSIOLOGY OF HYPEREMESIS, IT IS UNLIKELY THAT ESSURE WITH ITS LOCALIZED ACTION IN THE FALLOPIAN TUBES COULD CONTRIBUTE TO THE ONSET OF THIS EVENT. THIS CASE IS REGARDED AS INCIDENT SINCE A REQUIRED INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. FURTHER INFORMATION IS NOT EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01936	BAYER HEALTHCARE LLC	12/21/2015	12/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2004
Explant Date (E7): 10/16/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE MW5057814) IN UNITED STATES ON 23-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2005. CONSUMER REPORTED ESSURE COIL MIGRATED INTO ABDOMINAL CAVITY CAUSING PAIN, NAUSEA, VOMITING. DEVICE HAD TO BE SURGICALLY REMOVED ON (B)(6) 2015. NO ADDITIONAL INFORMATION WAS PROVIDED. FOLLOW UP INFORMATION RECEIVED ON 09-DEC-2015 FROM CONSUMER: SHE WAS (B)(6) WHEN ESSURE WAS INSERTED. IN 2004 SHE HAD ESSURE INSERTED AND IT WAS REMOVED IN 2015. REMOVAL WENT WELL, THERE WERE NO PROBLEMS. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND NON-MEDICALLY CONFIRMED CASE REPORT (RECEIVED VIA REGULATORY AUTHORITY) REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND ESSURE COIL MIGRATED INTO ABDOMINAL CAVITY. THEN, THE DEVICE HAD TO BE SURGICALLY REMOVED. THIS EVENT, SEEN AS DEVICE DISLOCATION IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES TOWARDS TO PERITONEAL CAVITY. ALTHOUGH IN THIS CASE, THE EXACT DATE AND MECHANISM OF THIS DISLOCATION ARE UNKNOWN, GIVEN THE EVENT'S NATURE, CAUSALITY WITH ESSURE USE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. ADDITIONALLY NON-SERIOUS EVENTS WERE INFORMED. FURTHER INFORMATION AND TECHNICAL ASSESSMENT HAVE BEEN REQUESTED.

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Manufacturer Narrative (H10):

PTC INVESTIGATION RESULT WAS RECEIVED ON 06-JAN-2016. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01937	BAYER HEALTHCARE LLC	12/21/2015	12/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/23/2010
Explant Date (E7): 7/7/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE MW5057774) IN UNITED STATES ON 23-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2010. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: GABAPENTIN (GABAPENTIN), TRAMADOL (TRAMADOL), BUPROPION SR (BUPROPION), FUROSEMIDE (FUROSEMIDE [FUROSEMIDE]), SLEEP AID (SCOPOLAMINE AMINOXIDE HYDROBROMIDE), AND UNISOM [DIPHENHYDRAMINE HYDROCHLORIDE] (DIPHENHYDRAMINE HYDROCHLORIDE) AND ACTIVAN (LORAZEPAM). CONSUMER REPORTED SHE HAD THE ESSURE INSERTED AND STARTED TO HAVING LOWER BACK, STOMACH PAIN, CRAMPING, HEAVY CLOTTING PERIODS, VAGINAL PAIN, PAINFUL INTERCOURSE, METAL TASTE AND MIGRAINES. IN 2013 SHE HAD STOMACH PAINS, LEFT WORK AND WENT TO EMERGENCY ROOM. SHE HAD A LARGE CYST ON HER OVARY. THE PHYSICIAN REMOVED CYST AND ESSURE COILS ON (B)(6) 2015. SHE HAS BEEN RECEIVING ADVANCED PAIN MANAGEMENT, CAUDAL INJECTIONS AND LASER RADIO FREQUENCY. THE REPORTER MENTIONED THE FOLLOWING EVENT OUTCOME HOSPITALIZATION, DISABILITY AND PERMANENT DAMAGE, HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CRAMPING. SHE HAD ESSURE COILS REMOVED. THIS EVENT WAS CONSIDERED SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS CASE, NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING ITS NATURE, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CANNOT BE EXCLUDED. THE REPORTER MENTIONED THE FOLLOWING EVENT OUTCOME HOSPITALIZATION, DISABILITY AND PERMANENT DAMAGE, HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. HOWEVER, SINCE DEVICE REMOVAL WAS

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REQUIRED, THIS CASE WAS REGARDED AS INCIDENT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. FURTHER INFORMATION AND PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

PRODUCT TECHNICAL COMPLAINT RESULTS RECEIVED ON 06-JAN-2016: THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RE

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01939	BAYER HEALTHCARE LLC	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 12/18/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/9/2009
Explant Date (E7): 12/18/2011
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE MW5057776) IN UNITED STATES ON 23-NOV-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009. CONSUMER REPORTED THAT SHE HAD THE ESSURE DEVICE IMPLANTED AND HAD IMMEDIATE AND CONSTANT SIDE EFFECTS WHICH LEAD TO A HYSTERECTOMY TO REMOVE ESSURE ON (B)(6) 2011. NOW SHE IS DEALING WITH SIDE EFFECTS OF THE HYSTERECTOMY. THE REPORTER MENTIONED THE EVENT OUTCOME HOSPITALIZATION HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED CONSTANT SIDE EFFECTS WHICH LEAD TO A HYSTERECTOMY. HYSTERECTOMY IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, CONSUMER MENTIONED UNSPECIFIED SIDE EFFECTS WHICH REQUIRED A HYSTERECTOMY. ALTHOUGH CASE LACKS INFORMATION FOR A COMPREHENSIVE CAUSALITY ASSESSMENT, IT CANNOT BE EXCLUDED THAT THE REPORTED HYSTERECTOMY OCCURRED AS A CONSEQUENCE OF ESSURE THERAPY. THEREFORE THIS CASE WAS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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PTC INVESTIGATION RESULT WAS RECEIVED ON 06-JAN-2016. THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: PTC GLOBAL NUMBER (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILU

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01940	BAYER HEALTHCARE LLC	12/21/2015	12/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4):
Catalog # (E4):
Lot #(E4): B71761

Single Use: Y
Implant Date (E6): 8/5/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER B71761 INSERTED ON (B)(6) 2015. PATIENT HAD HYSTEROSALPINGOGRAM (HSG) ON (B)(6) 2015. THE REPORT REVEALED THE COILS LOOKED LIKE THEY WERE IN THE RIGHT LOCATION AND HAD OCCLUSION. IT ALSO NOTED THAT POSSIBLE PROXIMAL END OF OUTER COILS APPEARED SEPARATED ON THE RIGHT TUBE ESSURE DEVICE. ESSURE WAS ONGOING. COMPANY CAUSALITY COMMENT: THIS MEDICALLY-CONFIRMED AND SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING HSG, THE PROXIMAL END OF OUTER COILS APPEARED SEPARATED ON THE RIGHT TUBE ESSURE DEVICE. THIS NON-SERIOUS EVENT, SEEN AS SUSPICION OF DEVICE BREAKAGE, IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. ALTHOUGH THE CIRCUMSTANCES OF THIS BREAKAGE WERE NOT PROVIDED, CONSIDERING ITS NATURE, CAUSALITY WITH SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE IS ASSESSED AS OTHER REPORTABLE INCIDENT SINCE THE BREAKAGE IN THIS REPORT DID NOT LEAD TO SERIOUS INJURY, HOWEVER, IT MIGHT HAVE LED UNDER LESS FORTUNATE CIRCUMSTANCES. TECHNICAL ANALYSIS AND FURTHER INFORMATION HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01941	BAYER HEALTHCARE LLC	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 1/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):
Single Use: Y
Implant Date (E6): 6/2/2015
Explant Date (E7): 10/28/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 23-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. ON (B)(6) 2015, HYSTEROSALPINGOGRAM (HSG) WAS PERFORMED. NO RESULT WAS PROVIDED. PATIENT WAS SEEN (B)(6) 2015 AND REPORTED IRREGULAR BLEEDING AND PAIN. SHE WAS SEEN NUMEROUS TIMES FOR THE SAME COMPLAINT, AND ON (B)(6) 2015, PHYSICIAN REMOVED THE LEFT ESSURE COIL AS THE PAIN WAS GETTING WORSE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD PAIN AND IRREGULAR BLEEDING AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ESSURE LEFT COIL WAS REMOVED, 4 MONTHS AFTER ITS PLACEMENT, SINCE PATIENT'S PAIN WAS GETTING WORSE. THESE EVENTS, REGARDED AS PELVIC PAIN AND GENITAL BLEEDING, ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABNORMAL GENITAL BLEEDING, MENSES PATTERN CHANGES AND ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENT'S NATURE AND IN THE LACK OF AN ALTERNATIVE EXPLANATION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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GENERAL ESSURE QUESTIONNAIRE RECEIVED FROM PHYSICIAN ON 21-DEC-2015: THE PATIENT WAS NOT POST-PARTUM. MIRENA WAS PULLED AT TIME OF ESSURE INSERTION, ON (B)(6) 2015. NO CERVICAL DILATION. NO SOUNDING. TORADOL WAS USED AND GENERAL ANESTHESIA. ESSURE INSERTI

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01942	BAYER HEALTHCARE LLC	12/21/2015	12/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/17/2011
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A INVESTIGATOR IN (B)(6) ON 23-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN A OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: STUDY (B)(4) IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSUREPERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 3 CHILDREN, UTERINE RUPTURE, AND 3 C-SECTIONS. THE PATIENT'S DRUG HISTORY INCLUDED MIRENA. DURING CONSULTATION SHE MENTIONED THAT SHE HAD NO MENSTRUAL PAIN AND WAS IN AMENORRHEA. THE PATIENT WAS PRE-MEDICATED WITH HYDROXYZINE. HER UTERINE CAVITY CONDITION (ENDOMETRIUM) WAS NORMAL AND SHE HAS NO RETROVERTED UTERUS. THE ESSURE WAS INSERTED ON (B)(6) 2011. THE INSERTION PROCEDURE WAS PERFORMED UNDER GENERAL ANESTHESIA. THE PROCEDURE DURATION WAS 10 MINUTES. THE PROCEDURE WAS STARTED ON LEFT, THE INSERTION WAS EASY AND AT THE END 3 EXTERNALLY COILS AND PET FIBERS WERE VISIBLE IN UTERINE CAVITY. ON THE RIGHT SIDE, THE OSTIUM WAS VISUALIZED HOWEVER IT WAS NOT EASY TO INTRODUCE CATHETER INTO THE TUBES, IT WAS NOTICED AN OBSTACLE AND ESSURE WAS NOT INSERTED ON RIGHT SIDE. NO VASOVAGAL SYNCOPE OCCURRED. UNILATERAL INSERTION OCCURRED DUE TO TUBAL OBSTRUCTION. FURTHER EXAMINATION WAS PERFORMED WITH HSG (HYSTEROSALPINGOGRAM). AN ADDITIONAL PROCEDURE OF IUD ABLATION WAS PERFORMED BEFORE ESSURE INSERTION PROCEDURE AND THIS ADDITIONAL PROCEDURE DID NOT MAKE ESSURE INSERTION HARDER. THE PATIENT DID NOT HAVE POSTOPERATIVE PAIN, CRAMPS OR BLEEDING. FOR CONTRACEPTION DURING 3 MONTHS FOLLOWING ESSURE INSERTION PROCEDURE, THE PATIENT USED COMBINATION PILL

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ON (B)(6) 2011, AN X-RAY WAS PERFORMED. THE INSERTS WERE NOT SYMMETRIC. THE 4 MARKERS WELL PLACED WERE ONLY NOTICED IN THE LEFT SIDE, NO MARKS WERE VISIBLE ON RIGHT SIDE. AN ULTRASOUND (2D) TRANSVAGINAL WAS ALSO PERFORMED AND SHOWED INSERTS FROM THE CAVITY TO THE HORN ON LEFT SIDE, NO INSERT SEEN ON RIGHT SIDE. THE HSG SHOWED INSERTS WELL PLACED ON LEFT SIDE WITH UNILATERAL OCCLUSION ON LEFT SIDE. THE DIAGNOSTIC OF CONTROL EXAMINATION SHOWED GOOD INSERT POSITION ON LEFT, AND NO POSITION ON RIGHT, INSERTION FAILURE ON RIGHT. THE PATIENT WAS NOT SATISFIED. ON AN UNSPECIFIED DATE, A TUBAL LIGATION WAS PERFORMED ON RIGHT DUE TO IMPOSSIBILITY OF ESSURE INSERTION ON RIGHT. DURING LAPAROSCOPY IT WAS FOUND THAT LEFT ESSURE INSERT WAS BENT AND SUBSEROSAL LEADING TO REMOVAL AND TUBAL LIGATION VIA COAGULATION AND SECTION. COMPANY CAUSALITY COMMENT: THIS STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT, WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. INSERTION FAILED ON RIGHT SIDE. PHYSICIAN DECIDED TO PERFORM A TUBAL LIGATION AND DURING THE PROCEDURE, IT WAS FOUND ON LEFT SIDE ESSURE INSERT WAS BENT AND SUBSEROSAL (REGARDED AS EMBEDDED DEVICE) LEADING TO REMOVAL AND TUBAL LIGATION VIA COAGULATION AND SECTION. THIS EVENT IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED ACCORDING TO REFERENCE SAFETY INFORMATION FOR ESSURE. DEVICE EMBEDMENT MAY OCCUR MOSTLY DURING INSERTION. GIVEN AVAILABLE INFORMATION AND EVENT'S NATURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. SINCE AN INTERVENTION WAS PERFORMED, THIS CASE IS REGARDED AS INCIDENT. PRODUCT ANALYSIS WAS REQUESTED.

Manufacturer Narrative (H10):

FOLLOW-UP RECEIVED ON 21-DEC-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS (B)(4) FINAL ASSESSMEN

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01943	BAYER HEALTHCARE LLC	12/21/2015	12/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/17/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER C59250). PHYSICIAN REPORTED THAT PULLED CORE OUT WHEN SHEATH RETRACTED. BILATERAL PLACEMENT WAS ACHIEVED. PATIENT HAD NO INJURY. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE, THE DEVICE PULLED CORE OUT WHEN SHEATH RETRACTED. THIS EVENT, REGARDED AS A DEVICE BREAKAGE, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. HOWEVER, CONSIDERING THE EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH PATIENT HAD NO INJURY THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01944	BAYER HEALTHCARE LLC	12/21/2015	12/21/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 8/26/2010
Explant Date (E7): 10/13/2010
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM AN INVESTIGATOR IN (B)(6) ON 23-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: STUDY (B)(4) IS A NON-INTERVENTIONAL, MULTICENTER, PROSPECTIVE, EPIDEMIOLOGICAL STUDY WITH THE AIM TO DETERMINE THE RATE OF PREDICTIVE FACTORS FOR SUCCESSFUL BILATERAL PLACEMENT AND THE FINAL EFFICACY OF THE ESSURE PERMANENT STERILIZATION METHOD, AS MEASURED BY THE ABSENCE OF PREGNANCY. PATIENT NUMBER: (B)(6). THE PATIENT'S MEDICAL HISTORY INCLUDED 4 CHILDREN AND USAGE OF CONTRACEPTIVE IMPLANT. DURING CONSULTATION SHE MENTIONED SHE HAS MENSTRUAL PAIN. PRIOR TO INSERTION HER UTERINE CAVITY CONDITION (ENDOMETRIUM) WAS NORMAL AND SHE HER UTERUS WAS NOT RETROVERTED. ESSURE WAS INSERTED ON (B)(6) 2010. SHE WAS PRE-MEDICATED WITH NON-STEROID ANTI-INFLAMMATORY AND ANALGESICS. DURING THE PROCEDURE, NO ANESTHESIA WAS USED AND THE PROCEDURE DURATION WAS 4 MINUTES. THE PROCEDURE WAS EASY ON BOTH SIDES, BILATERAL PLACEMENT WAS SUCCESSFUL. SHE EXPERIENCED PAIN DURING INSERTION OF THE LEFT SIDE. A SECOND ATTEMPT TO INSERT WAS MADE, THIS TIME THE PATIENT DID NOT HAVE PAIN. THE INSERTION WAS EASY AND BILATERAL PLACEMENT WAS ACHIEVED. THE PATIENT WAS SEEN ONE MONTH AND A HALF AFTER ESSURE INSERTION. SHE DEVELOPED INFECTION: BILATERAL PYOSALPINX. LAPAROSCOPY WAS PERFORMED ON (B)(6) 2010 AND CONFIRMED DIAGNOSIS OF BILATERAL PYOSALPINX AND INFECTION POSITIVE FOR (B)(6). DURING LAPAROSCOPY, SECTION OF ISTHMUS WAS PERFORMED AS WELL AS ESSURE INSERTS REMOVAL AND DRAINAGE AND INCISION OF PYOSALPINX. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, STUDY CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO WAS INVOLVED IN AN OBSERVATIONAL COMPANY-SPONSORED STUDY (STUDY NUMBER: (B)(4)). SHE HAD

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BILATERAL PYOSALPINX (INFECTION POSITIVE FOR CHLAMYDIAE) 1.5 MONTHS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A LAPAROSCOPY WITH REMOVAL OF ESSURE DEVICE AND DRAINAGE AND INCISION OF PYOSALPINX. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION AND WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE. UPPER GENITAL TRACT INFECTIONS, ALSO REFERRED TO AS PELVIC INFLAMMATORY DISEASES (PIDS), OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER THE INSERTION PROCEDURE. TO REDUCE THIS RISK, ESSURE INSERTION IS CONTRAINDICATED IN PATIENTS WITH ACTIVE OR RECENT PELVIC INFECTION. IN THIS PARTICULAR CASE, NO INFORMATION WAS PROVIDED ABOUT PATIENT'S PREVIOUS OR CONCOMITANT CONDITIONS (SUCH AS RECENT PID). HOWEVER, GIVEN THE POSITIVE TEMPORAL RELATIONSHIP BETWEEN EVENT AND ESSURE INSERTION; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, DUE TO THE REQUIRED SURGICAL INTERVENTION FOR EVENT'S TREATMENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058602	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 5/7/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). THE ESSURE DEVICE CAME HIGHLY RECOMMEND BY MY OB/GYN AS A SAFE ALTERNATIVE TO TUBAL LIGATION WITH A MUCH SHORTER RECOVERY TIME. LONG STORY SHORT... I'VE BEEN HAVING QUITE A BIT OF JOINT PAIN, HEART PALPITATIONS, PELVIC PAIN, HAIR LOSS, PAINFUL SEXUAL INTERCOURSE, AND ABD SWELLING. I ORIGINALLY THOUGHT I HAD CYSTS ON MY OVARIES BUT NOPE. AS TIME WENT ON, I SAW MY DOCTORS THAT FELT I WAS EXAGGERATING AND WAS MERELY DEPRESSED. I'VE HAD THE COILS SINCE 04 AND ALL OF MY PROBLEMS STARTED ABOUT 3 YEARS AFTER. I WENT TO SO MANY DOCS AND THEY TOLD ME IT WAS ALL IN MY HEAD AND THEY WOULDN'T LISTEN TO ME. ALL THEY TRIED TO DO WAS GIVE ME MORE MEDS. LUCKILY I FOUND A DOC THAT LISTENED TO ME AND REMOVED THEM. I EVEN WENT TO THE FDA MEETINGS IN (B)(6) THEY HAD AGAINST BAYER. I KNEW SOMETHING WAS WRONG WITH ME. I MEAN I EVEN DEVELOPED ECZEMA AND HAIR LOSS. FAST FORWARD A FEW YEARS OF THE SAME SYMPTOMS, MY LIVER FUNCTION TESTS WERE OFF AND I HAD TO HAVE AN ABDOMINAL ULTRASOUND. THE BLANKET DIAGNOSIS WAS HYPOTHYROIDISM, BUT I KNEW DEEP DOWN THAT WAS NOT THE CASE. EVEN WHEN I AGREED TO TAKE THE THYROID MEDS, MY THYROID LABS WERE NORMAL. I FINALLY FOUND A SPECIALIST WHO HAD BEEN RESEARCHING THE ISSUES RELATED TO ESSURE AND RESEARCHED THE ISSUES AND SENT ME TO HAVE A NICKEL ALLERGY TEST. THAT RETURNED POSITIVE. AS IT TURNED OUT MY BODY WAS REJECTING THE COILS. THEY THINK THAT'S WHY MY THYROID WENT CRAZY IS AN AUTOIMMUNE RESPONSE TO THE NICKEL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058603	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 5/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAIN SURROUNDING DEVICE, IRREGULAR MENSTRUATION; SKIPPED, PROLONGED AND HEAVY, AND EVERYTHING BUT NORMAL, SEVERE CRAMPING WHEN NOT HAVING A PERIOD, IRON DEFICIENCY, VITAMIN B12 DEFICIENCY, HAIR LOSS, BRITTLE NAILS, LOSS OF LIBIDO, PAINFUL INTERCOURSE, MENINGITIS, HEADACHES AND MIGRAINES, I TASTE PUMPKIN, NUMB AND/OR TINGLING IN HANDS, FEET, THIGHS, TOPS OF ARMS, AND AROUND PELVIC REGION, UNEXPLAINED IRRITABILITY (MAYBE DUE TO PROLONGED PAIN). SEEMS TO HAVE EXACERBATED PRE-EXISTING CONDITIONS (SCIATIC NERVE PAIN, URINARY INCONTINENCE AND CONGENITAL CATARACTS). THE PROBLEM WITH THE CATARACTS IS THAT MY IOL IMPLANTS CAN MOVE AND VIBRATE NOW. I HAD THEM FOR ABOUT TEN YEARS WITH NO PREVIOUS PROBLEMS. ALLERGIES FOR THE FIRST TIME IN MY LIFE. PET HAIR, WEEDS, DIRT, MOLD, FOGGY MEMORY, DAZED, CONFUSED TOO EASILY, FORGET WORDS, NERVE SENSITIVITY, I CAN'T DEAL WITH TEXTURES....UGH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058604	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 11/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PROGRESSIVE SHORTNESS OF BREATH WITH TACHYCARDIA. DIAGNOSED WITH POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME / DYSAUTONOMIA 2 MONTHS POST PROCEDURE. SPENT 5 DAYS IN THE HOSPITAL WITH HR UP TO 160'S WHEN STANDING. WENT TO (B)(6) CLINIC IN (B)(6) 2015 AND TILT TABLE SHOWED POTS. IN (B)(6) 2015, SLEEP STUDY SHOWED HYPERSOMNIA.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058605	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 1/2/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BECAME PREGNANT, VERY SICK ENTIRE PREGNANCY. HAVE PAIN AND BLOATING AFTER. ALSO JOINT PAIN, TIRED ALL THE TIME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058606	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 5/28/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ECTOPIC PREGNANCY, THAT ENDED WITH LAPAROSCOPY EMERGENCY SURGERY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058607	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 5/23/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAVE HAD MIGRAINES, EXTREME BLOATING, CRAMPING THAT FELLS LIKE CONTRACTIONS, NAUSEA, LOSS OF APPETITE,FATIGUE,UNEXPLAINED BRUISES ON ARMS AND LEGS,MY BODY HURTS FROM HEAD TO TOE ALL DAY EVERY DAY,METAL TASTE THAT DOESN'T GO AWAY. INSURANCE DID COVER IT. I STARTED HAVING THESE SIDE AFFECTS SHORTLY AFTER THE DYE TEST.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058608	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 4/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PELVIC PAIN, CONSTANT INFECTIONS, BACK PAINS, IRREGULAR PERIODS, BREAST PAIN, JOINT PAINS, BLOOD CLOTS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058609	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 6/13/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED WITH SWOLLEN ABDOMEN AS THOUGH I WAS PREGNANT, OVARIAN CYST X 2, HEAVY BLEEDING, FATIGUE, WEAKNESS, MOOD CHANGES, BAD TASTE IN MOUTH, DIGESTIVE ISSUES, INCREASED VARICOUS VEINS,SEVERAL VISITS TO ER AND BOTH GYN AND PRIMARY DOCTOR.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058610	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 12/14/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER 3 YEARS OF DEBILITATING PAIN, MIGRAINES, EXCESSIVE BLEEDING, HEART PALPITATIONS, UNEXPLAINED WEIGHT GAIN, ELEVATED BLOOD PRESSURE, NUMBNESS IN EXTREMITIES, CHRONIC FATIGUE, DEPRESSION AND MORE I HAD TO HAVE SURGERY TO REMOVE ESSURE VIA TOTAL HYSTERECTOMY LEAVING ONLY MY OVARIES.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058611	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 7/9/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). INTENSE BACK AND HIP PAIN NEEDED AMBULANCE , BLOATING AND MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058612	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 12/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEGAN HAVING AN EXTREME ONSET OF HIVES TRAVELING FROM MY FEET TO MY SCALP. EXTREME ITCHING WOULD OCCUR SOMETIMES LASTING FOR WEEKS OR MONTHS. THE ONLY THING THAT HELPED WAS INGESTING ZYRTEC ONCE OR TWICE A DAY, TO KEEP ME FROM MISSING WORK. I WORKED FOR A DERMATOLOGIST AT THE TIME AND ATTEMPTED TO SINGLE OUT WHAT WAS CAUSING THE HIVES. I HAD NO CHANGES AFTER FOLLOWING ALL OF THEIR RECOMMENDATIONS AND REMOVING HIGH ALLERGY ITEMS FROM MY LIFE. AT TIMES, THE HIVES WOULD APPEAR EVEN DURING SLEEPING HOURS OF THE NIGHT WITH NO WARNING. BEFORE THE PLACEMENT OF ESSURE, I HAD NO KNOWN ALLERGIES ACCEPT FOR CAT DANDER, WHICH I COMPLETELY REFRAIN FROM BEING AROUND. I ALSO HAD NEVER EXPERIENCED HIVES BEFORE THIS FIRST INCIDENT. THE INCIDENTS OF HIVES GREW MORE FREQUENT OVER TIME, TO THE POINT THAT IF I MISSED TAKING AN ALLERGY PILL I WAS BOUND TO BREAK OUT. I HAD TO START HAVING ZYRTEC ON HAND AT ALL TIMES IN MY PURSE. I HAVE ALSO BEGUN TO HAVE ALLERGIC REACTIONS TO LATEX, ADHESIVES, AND MORE AS TIME PASSES, WHICH I NEVER HAD BEFORE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058613	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 12/1/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BACK PAIN, HIP PAIN, HAIR LOSS, WEIGHT GAIN AND UNABLE TO LOSE WEIGHT, NEEDED FULL RIGHT HIP REPLACEMENT DUE TO ARTHRITIS CAUSED BY ESSURE. WILL NEED LEFT HIP REPLACEMENT IN 1-2 YEARS DUE TO ESSURE, MOOD SWINGS, BAD PERIOD, BAD CRAMPS, ENDOMETRIOSIS, RASH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058614	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 10/27/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WENT TO SEE AN ALLERGIST DOCTOR IN REFERENCE TO MY HIVES ISSUE. SHE RECOMMENDED THAT I TRY TO OBTAIN AN ESSURE COIL TO DO A DIRECT SKIN TEST TO SEE IF I HAD A REACTION TO THE METAL/NICKEL CONTAINED IN THE DEVICE. AN ESSURE COIL WAS PLACED ON MY SKIN FOR 24-48 PERIOD HELD IN PLACE BY A LOOSE BANDAID. AFTER ABOUT 12 HOURS, MY SKIN WAS BURNING SO INTENSELY THAT I HAD TO REMOVE THE BANDAID AND DEVICE. THE SKIN WAS RAISED, EXTREMELY RED, AND ITCHING. I ALSO HAD AN EXTENSIVE REACTION TO THE ADHESIVE IN THE LATEX FREE BANDAID, WHICH I HAD NOT EXPERIENCED BEFORE. I HAD TO INGEST 2 ZYRTEC A DAY TO ALLEVIATE SYMPTOMS SO I COULD SLEEP THAT NIGHT. APPROXIMATELY 12 HOURS AFTER REMOVAL, THE AREA OF SKIN WHERE IT WAS PLACED, WORSENED IN SWELLING. IN TOTAL, IT TOOK 7+ DAYS FOR THE REDNESS AND SWELLING TO SUBSIDE, AS WELL AS TAKING 2 ZYRTEC A DAY. MY ALLERGIST HAD ALSO PLACED ME ON 1 TABLET OF RANITIDINE TO AID IN THE TREATMENT OF MY HIVES AS AN H2 HISTAMINE BLOCKER, BECAUSE THE ZYRTEC WAS NOT TOTALLY COMBATING THEM ITSELF. AFTER THE RESPONSE THAT I GOT TO THIS TEST, I REQUESTED AN ULTRASOUND OF MY ABDOMEN TO SEE IF THERE WAS INFLAMMATION SURROUNDING MY ESSURE COILS. THE ULTRASOUND SHOWED MY UTERUS TO BE TWICE THE APPROPRIATE SIZE. I AM SCHEDULED TO HAVE A HYSTERECTOMY AND AM SURE SHE WILL LIKELY FIND EXTENSIVE INFLAMMATION. MY MENSTRUAL CYCLE WAS ALMOST CRIPPLING THIS MONTH HAVING LASTED UP TO 2 WEEKS, WITH CONTINUAL SPOTTING AND BREAK THROUGH BLEEDING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058615	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 12/21/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). DEPRESSION, CRAMPING, EXCESSIVE BLEEDING, SHARP PELVIC PAINS, PAIN NUMBNESS IN LEGS, HEADACHES, URINARY TRACT INFECTION AND BACTERIAL VAGINITIS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058616	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 8/22/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HELLO, MY BIOPSY IS CLEAR OF CANCER , BUT CAME BACK POSITIVE FOR AN AUTO IMMUNE DISORDER, CHRONIC SIMPLEX CHRONICUS. MORE MED AND CREAM. I'M BEING REFERRED TO (B)(6) FOR ESSURE REMOVAL. TOO MANY SIDE AFFECTS SINCE ESSURE. BEFORE ESSURE I WAS 100 HEALTHY . NO INFECTIONS EVER. SINCE THE LIST KEEPS GROWING. KIDNEY INFECTIONS, BLADDER , CHRONIC YEAST. GAVE BIRTH TO WHAT THEY SAID WAS A POLYP. SWELLING ITCHY ALL THE TIME HARD TO WALK SOME DAYS. PAIN IN ABDOMINAL AREA , IRREGULAR PERIODS , HEADACHES , DRY MOUTH FUNNY TASTE. SO HERE IS TO ESSURE REMOVAL IN (B)(6). THANK YOU (B)(6) .

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058617	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 8/9/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MY INSURANCE AT THE TIME HELPED PAY FOR THE DEVICE. I HAD IT PLACED IN (B)(6) 2006, REALLY HAD NOT HAD ANY EFFECTS UNTIL 2013. I WAS WALKING AND HAD BEEN OUT FOR A WALK AND CAME BACK AND COULD NOT GET RID OF SEVERE PAIN IN MY LEGS, BACK AND SIDES. ABOUT A WEEK OF SEVERE PAIN, I WENT TO SEE MY PHYSICIAN WHO SAID I HAD KNEE ARTHRITIS, THEY GAVE ME A SHOT TO CONTROL THE PAIN, BUT IT NEVER SEEMED TO GO AWAY. APPROXIMATELY 15 MONTHS LATER, I WAS STILL DEALING WITH THAT PAIN AND INTENSE TO THE POINT THAT I COULD NOT CLEAN MY HOUSE OR EXERCISE WITHOUT SEVERE PAIN, I WENT TO MY PHYSICIAN WHO SAID FIBROMYALGIA AS WELL AS MAGNESIUM AND VITAMIN D DEFICIENCY. I HAD BEEN HAVING SEVERE BLEEDING FOR MONTHS AT A TIME OR NO PERIOD AND THIS CONTINUED UNTIL (B)(6) 2015. I WENT TO SEE MY OBGYN WHO TOLD ME NONE OF MY SYMPTOMS WERE THE RESULT OF ESSURE. INSTEAD, THEY BLAMED MY WEIGHT, LIVING IN THE NORTH, DEPRESSION, STOMACH ISSUES AND ANYTHING ELSE. THE PAIN NEVER GOES AWAY AND HAVE GONE SEVERAL TIMES AND SPENT (B)(6) TRYING TO FIND WHY I AM IN PAIN AND NO ANSWERS EVER.. I AM (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058618	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 9/1/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEADACHES, HEAVY IRREGULAR PERIODS WITH CLOTTING, BONE AND JOINT PAIN, EXTREME FATIGUE, SCLERODERMA, PAINFUL INTERCOURSE, BLOATING, ABDOMINAL PAIN, VISION CHANGES, NAUSEA, INSOMNIA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058619	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 12/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING RASHES ALLERGIC REACTIONS EXCESSIVE BLEEDING ORGAN PERFORATION PELVIC PAIN MISCARRIAGE ECTOPIC PREGNANCY BLOOD CLOTHES INFECTION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058635	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 12/3/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I BEGAN TO EXPERIENCE REALLY SHARP PAINS THAT WERE LATER SAID TO BE MY GALLBLADDER. I HAD MY GALLBLADDER REMOVED SHORTLY AFTER BEING DIAGNOSED. I HAVE EXPERIENCED MY MENSTRUAL CYCLE LASTING FOR WEEKS AND MONTHS AT A TIME. I HAVE EXPERIENCED SEVERE WEIGHT GAIN AND CONTINUED PELVIC PAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058636	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 11/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AS A (B)(6) MOTHER OF 3 WHO WAS DONE HAVING CHILDREN AND DID NOT LIKE EXPOSING MY BODY TO HORMONES (BIRTH CONTROL PILLS) ON A DAILY BASIS, MY OB/GYN OFFERED THIS AS AN EASY SOLUTION. TWO WEEKS AFTER, I STARTED WITH AN AWFUL DISCHARGE, HAVING A TERRIBLE ODOR. I WAS PRESCRIBED FLAGYL FOR BACTERIAL VAGINITIS. IT WENT AWAY INITIALLY, BUT CAME BACK A FEW WEEKS LATER. AGAIN, I TOOK FLAGYL. NOW, ONE WEEK LATER, IT'S BACK AGAIN!! IN ALL OF MY (B)(6) YEARS, NOT ONCE HAVE I EVER HAD BACTERIAL VAGINITIS. I ALSO HAVE A CONTINUAL BAD TASTE IN MY MOUTH. NO MATTER HOW MANY TIMES I BRUSH MY TEETH, MY MOUTH TASTES BAD, ESPECIALLY AFTER I EAT SOMETHING. IN ADDITION, MY FIRST PERIOD AFTER HAVING THE ESSURE PLACED WAS HEAVY WIL LARGE CLOTS - SCARY FOR SOMEONE WHO NEVER HAD THAT! I ALSO HAVE HAD THE ONSET OF DENTAL PROBLEMS. MY GUMS HURT AND MY TEETH HURT WHEN I CHEW!! NOT TO MENTION I HAVE GAINED (B)(6) POUNDS IN 2 MONTHS. I REGRET EVER CONSENTING TO ESSURE!!! I WANT THESE COULD REMOVED!!

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058637	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 8/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I STARTED HAVING PAIN IN MY ANKLES AND FEET, WITHOUT HAVING EXPERIENCED AN INJURY. I ATTEMPTED TO TREAT MY PROBLEMS BY PURCHASING EXPENSIVE, HIGHLY RECOMMENDED SHOES WITH ORTHOTIC INSERTS TO ALLEVIATE THE PAIN. AT THE ADVICE OF A PHYSICIAN, I BEGAN TAKING A DIURETIC TO DECREASE THE SWELLING IN MY JOINTS. I WAS NOT IDENTIFIED TO HAVE ANY OTHER CONDITIONS AND THEY COULD NOT DIAGNOSE THE SWELLING. NONE OF THESE THINGS WORKED. MY LEFT FOOT CONTINUED TO DETERIORATE AT WHICH TIME I WENT TO A SPECIALIST. I WAS PLACED IN A BOOT FOR 4-6 WEEKS WHICH WAS A HUGE INCONVENIENCE WITH MY JOB, HOWEVER THE FOOT DID SLOWLY SHOW IMPROVEMENT. I STILL EXPERIENCE PAIN IN BOTH FEET AT TIMES AND HAVE TO RESORT BACK TO THE BOOT IF IT BECOMES INTOLERABLE. FOR THE PAST 6 YEARS, I HAVE HAD JOINT PAIN IN VARIOUS AREAS OF MY BODY INCLUDING HIPS, KNEES, ANKLES, HANDS, AND FEET. I HAVE NEVER HAD ANY PREVIOUS INJURIES TO THESE AREAS. OVERALL, I WAS A VERY HEALTHY PERSON BEFORE RECEIVING THIS PRODUCT.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058638	BAYER	12/21/2015	12/21/2015

Event Information:

Event Date (B3): 4/28/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). WAS PREGNANT AFTER HAVING THE ESSURE COILS IN FOR A YEAR, BABY STOPPED MOVING. WENT TO THE HOSPITAL, LABOR WAS INDUCED BECAUSE MY SON'S HEART WAS NOT BEATING AT ALL ANYMORE. I HAD A STILLBORN CHILD AFTER HAVING 5 SUCCESSFUL CHILDBIRTHS BEFORE. I HAD NEVER HAD A STILLBIRTH BEFORE AND DID GET MY TUBAL LIGATION AS WELL AS AN ENDOMETRIAL ABLATION DONE SHORTLY AFTER THE BIRTH OF MY STILLBORN SON.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058733	CONCEPTUS INC.	12/21/2015	12/24/2015

Event Information:

Event Date (B3): 3/20/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 922607

Single Use: *
Implant Date (E6): 3/20/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2012, I HAD THE ESSURE PLACED. I AM ALLERGIC TO NICKEL, BUT I WAS UNAWARE THAT ESSURE CONTAINS NICKEL AND I CANNOT WEAR JEWELRY OR EARRINGS BECAUSE OF MY ALLERGY. SINCE PLACEMENT, I HAVE BEEN LETHARGIC, DIAGNOSED WITH HYPOTHYROIDISM, HAVE CONSTANT UTIS, DEVELOPED CONSTANT SKIN IRRITATION AROUND MY MOUTH, NECK, AND CHEST. MY PERIODS HAVE BECOME SO SEVERE THAT I AM ALWAYS ANEMIC AND HAVE BEEN SINCE THE PROCEDURE. MY BLEEDING IS SO BAD I JUST SIT ON THE TOILET DURING MY HEAVY DAYS WHEN I CAN BECAUSE WEARING A TAMPON AND PAD ONLY HOLDS IT FOR MAYBE 10 MINUTES. BLOOD GUSHES OUT OF ME IN EXTREME AMOUNTS. MY HANDS ARE STARTING TO FEEL WEAK, UNCOORDINATED, AND STIFF. I CANNOT OPEN PILL BOTTLES OR PICK UP SMALL OBJECTS AND I WORRY ABOUT DEVELOPING ANOTHER AUTOIMMUNE DISEASE LIKE RA.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058734	BAYER	12/21/2015	12/24/2015

Event Information:

Event Date (B3): 5/14/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/14/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER ESSURE IMPLANTATION I HAVE EXPERIENCED OVERLY HEAVY MENSTRUAL CYCLES AND EXCRUCIATING PAIN, SEVERE HEADACHES AND ABDOMINAL PAIN DURING AND AFTER MENSTRUAL CYCLES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058735	BAYER	12/21/2015	12/24/2015

Event Information:

Event Date (B3): 1/9/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C18712

Single Use: *
Implant Date (E6): 1/9/2015
Explant Date (E7): 10/9/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ON (B)(6) 2015, ESSURE IMPLANTED. ON (B)(6) 2015, HSG #1 SHOWS LEFT SIDE BLOCKED, RIGHT SIDE COMPLETELY OPEN AND ESSURE HAD GONE THROUGH MY UTERUS NEXT TO FALLOPIAN TUBE, NOT IN IT. ON (B)(6) 2015, LAPAROSCOPY TO REMOVE MISPLACED ESSURE COIL AND DO TUBAL LIGATION OF RIGHT SIDE. FOUR WEEKS LATER, HSG #2 TO MAKE SURE HOLE IN UTERUS HAD HEALED. IT HAD BUT HSG SHOWED LEFT SIDE WAS NOT BLOCKED AS 1ST HSG SHOWED. HAVING WEIRD ALMOST FLU LIKE SYMPTOMS: TIRED, LOW ENERGY, ABDOMINAL PAIN, HORRIBLE, PAINFUL ACNE (NEVER HAD BEFORE) THOUGHT I WAS PREGNANT, MANY TESTS SAID NEGATIVE. FOUND INFO THAT MY SYMPTOMS WERE NOT UNCOMMON WITH OTHER WOMAN WHO HAD ESSURE DEVICE. ON (B)(6) 2015, NEW DOCTOR, SURGERY #2 TO REMOVE BOTH FALLOPIAN TUBES AND RIGHT ESSURE DEVICE. TWO WEEKS F/U DOCTOR INFORMED ME THAT DEVICE BROKE AS HE WAS REMOVING IT, BUT FELT CONFIDENT HE HAD GOT IT ALL BECAUSE THERE IS SOMETHING ON IT THAT INDICATES THE END OF IT AND HE WAS ABLE TO GET THAT OUT. IN (B)(6), HEAVY BLEEDING AND BLOOD CLOTS AND PAIN, PUT BACK ON BIRTH CONTROL PILL, AS DOCTOR THOUGHT IT WAS JUST FROM HORMONES TRYING TO BALANCE OUT AFTER BEING ON PILL AND SURGERY. ON (B)(6) 2015, ULTRASOUND SHOWED PIECE OF ESSURE DEVICE STILL STUCK IN MY UTERUS. DOCTOR #2 RECOMMENDED HYSTERECTOMY. SECOND OPINIONS WITH DOCTOR 3 AND 4. SCHEDULED HYSTERECTOMY ON (B)(6) 2016 WITH DOCTOR 4. I HAVE A FULL TIME JOB (AS DOES MY HUSBAND) AND 2 SMALL KIDS SO HYSTERECTOMY RECOVERY IS GOING TO BE TOUGH ON MANY LEVELS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058738	BAYER	12/21/2015	12/24/2015

Event Information:

Event Date (B3): 12/21/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/27/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE PROCEDURE IN (B)(6) 2015 AND WENT IN FOR A FOLLOW UP HSG 3 MONTHS LATER WHICH SHOWED FULL BLOCKAGE. THE COIL DIDN'T GO INTO MY RIGHT FT AND WAS CONFIRMED BLOCKED ALREADY BY MY DOCTOR. IT IS NOW (B)(6) 2015 AND I AM 7 WEEKS PREGNANT AND HAVE PAIN IN MY ABDOMEN WHICH COINCIDED WITH THE LOCATION OF THE COIL. WHEN MAKING QUICK MOVEMENT LIKE GETTING OUT OF BED, I GET A SHARP PAIN. THIS PROCEDURE IS NOT ACCURATELY PERFORMED OR IS NOT AS EFFECTIVE AS STATED.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058739	BAYER	12/21/2015	12/24/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 625647

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

IN 2007, I HAD THE ESSURE PROCEDURE. AT THE TIME, THE ONLY SIGNIFICANT SIDE EFFECT WAS CRAMPING WHICH I DID NOT EXPERIENCE. IT WASN'T UNTIL (B)(6) 2015, I CAME ACROSS A REPORT AND SUBSEQUENT RESEARCH THAT LEAD ME TO BELIEVE MANY OF MY CHRONIC ISSUES HAVE BEEN RELATED TO ESSURE. IN 2011, I BEGAN TO HAVE MAJOR HAIR LOSS AND THINNING, ALL REMEDIES DID NOTHING TO CORRECT IT. I HAD NO FAMILY HISTORY, SO I WAS AT A LOSS AS TO WHY MY HAIR WOULD BE FALLING OUT AND BECOMING TOO BRITTLE. VITAMIN SUPPLEMENTS, EXERCISE AND HEALTHY DIET ALONG WITH CUTTING OUT CERTAIN SHAMPOO INGREDIENTS DID NOTHING TO CHANGE MY HAIR SITUATION. DUE TO THE AMOUNT OF HAIR LOSS AND WEIGHT GAIN, I HAVE HAD MY THYROID CHECKED TWICE WITH BLOOD PANEL, BUT NOTHING WAS FOUND. WEIGHT LOSS HAS NOT BEEN ATTAINABLE SINCE HAVING MY DAUGHTER EITHER. COUNTING CALORIES AND EXERCISING 3-4 TIMES A WEEK ONLY ALLOWED ME TO MAINTAIN WEIGHT. IN THE LAST YEAR, THE PROBLEM HAS GROWN AS I HAVE BEEN EATING WELL, BUT HAVE NOT BEEN ABLE TO WORK OUT. DESPITE THE 15,000 STEPS A DAY AVERAGE, I HAVE STILL GAINED 30 LBS. THIS YEAR. MY MEMORY OR ABILITY TO FOCUS AND PERFORM TASKS HAS SLOWLY DIMINISHED OVER THE YEARS. PRIOR TO MY DAUGHTER, I HAD A GREAT MEMORY. I CHALKED MY MEMORY LOSS AND BRAIN FOG UP TO HAVING KIDS; HOWEVER, OVER TIME IT HAS CONTINUED TO WORSEN TO THE POINT MY HUSBAND HAS COMMENTED NUMEROUS TIMES IN THE LAST 2 YEARS THAT I CAN'T REMEMBER ANYTHING ANYMORE. WE HAVE BEEN TOGETHER FOR 20 YEARS, SO CAN DEFINITELY NOTICE CHANGES IN MY PERSONALITY. SOMETHING ELSE I HAVE NOTICED IN THE LAST 3 YEARS IS INCREASED MIGRAINES. UNTIL 3 YEARS AGO, HEADACHES WERE RARE; HOWEVER, MIGRAINES ARE NOW COMMONPLACE FOR ME. IT DOESN'T APPEAR TO BE RELATED TO HORMONES. WHILE MY CRAMPS HAVE NEVER BEEN AN ISSUE, INCREASED BLOATING HAS BEEN A LONG TIME ISSUE FOR ME. ONE OF THE MOST NOTICEABLE CHANGES IS

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CHRONIC JOINT PAIN. MY FEET AND BACK HURT SO BAD IN THE MORNING, I WALK BENT OVER AND HOBBLING UNTIL I CAN STRAIGHTEN UP. MY SHOULDERS, ELBOWS AND KNEES ALL ACHE SO MUCH IT MAKES LIFTING WEIGHTS NEXT TO IMPOSSIBLE. EVEN MY FINGER JOINTS ACHE. UNTIL 4 YEARS AGO, I WAS A HEALTHY PERSON WITH NO HEALTH ISSUES OTHER THAN THE STRUGGLE TO LOSE WEIGHT. OVER THE LAST 4 YEARS, I HAVE FELT LIKE I WAS FALLING APART. I AM ONLY (B)(6), BUT MY BODY FEELS MUCH OLDER. I AM SO EXHAUSTED AT NIGHT THAT I CAN BARELY MAKE IT TO 9:00.. I AM OFTEN TOO TIRED TO COOK OR CLEAN IN THE EVENINGS. THIS SEEMS TO CONTINUE TO GET PROGRESSIVELY WORSE, AND I WORRY WHAT MY FUTURE HOLDS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01945	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 1/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A63346

Single Use: Y
Implant Date (E6): 3/21/2013
Explant Date (E7): 10/29/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# MW5044935) IN UNITED STATES ON 19-OCT-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013 WITH LOT NUMBER A63346. CONSUMER STATED THAT SHE HAS BEEN HAVING ON AND OFF PELVIC PAIN. IN 2014 SHE WENT TO A DOCTOR AND A TRANSVAGINAL ULTRASOUND WAS DONE. IT WAS DESCRIBED A LEFT ESSURE WITH TORTUOUS COURSE, SUGGESTIVE OF PERFORATION INTO THE MYOMETRIUM. SINCE THEN, SHE HAS BEEN SUFFERING WITH PAIN MORE CONSTANTLY. SHE WENT TO HER DOCTOR AND THEY WERE TALKING ABOUT SURGERY AND POSSIBLE HYSTERECTOMY. FOLLOW-UP INFORMATION RECEIVED ON 07-NOV-2015 WITH THE FINAL PTC (PTC GLOBAL NUMBER: (B)(4)) INVESTIGATION RESULT AND ON 10-NOV-2015: THE CONSUMER INFORMATION WAS UPDATED. FINAL ASSESSMENT: BATCH NUMBER - A63346, PRODUCTION DATE - OCT-2012, EXPIRATION DATE - 31-OCT-2015. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENTS IS EXCLUDED. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT.

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BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP INFORMATION WAS RECEIVED ON 24-NOV-2015 AND CASE WAS UPGRADED TO INCIDENT. ESSURE CONSUMER GENERAL QUESTIONNAIRE RECEIVED. CONSUMER WAS (B)(6). SHE HAD NO PREVIOUS GYNECOLOGICAL PROBLEMS OR PROCEDURES, NO RELEVANT HISTORY OR CONCURRENT CONDITIONS. ESSURE WAS INSERTED ON (B)(6) 2013, 3 MONTHS POSTPARTUM. AS BACK UP CONTRACEPTION SHE USED BIRTH CONTROL SHOT. AT FIRST SHE HAD ON AN OFF PAIN, THEN IN 2015 CONSTANT PAIN. ON (B)(6) 2015 SHE FOUND OUT SHE WAS PREGNANT AND ON (B)(6) 2015 SHE HAD AN ABORTION. AFTER NON STOP BLEEDING SHE HAD ESSURE REMOVED ON (B)(6) 2015, VIA LAPAROSCOPY/ HYSTEROSCOPY. CONSUMER RECOVERED FROM ESSURE REMOVAL PROCEDURE AND WAS WITH NO PAIN AND FEELING MUCH BETTER. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER, WHO BECAME PREGNANT AND HAD AN ABORTION AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. APPROXIMATELY 2 MONTHS LATER, SHE HAD ESSURE REMOVED BY LAPAROSCOPY/HYSTEROSCOPY DUE TO NON-STOP BLEEDING. ACCORDING TO HER, AN ULTRASOUND REVEALED LEFT ESSURE WITH TORTUOUS COURSE, SUGGESTIVE OF PERFORATION INTO THE MYOMETRIUM. ONLY ABORTION, REGARDED AS SPONTANEOUS ABORTION, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. UNINTENDED PREGNANCIES MAY OCCUR DURING ANY CONTRACEPTIVE USE AND HAVE BEEN REPORTED IN WOMEN WITH ESSURE MICRO-INSERTS IN PLACE. SOME OF THESE PREGNANCIES OCCURRED DUE TO PATIENT NON-COMPLIANCE INCLUDING FAILURE TO RETURN FOR THE ESSURE CONFIRMATION TEST. IN THIS PARTICULAR CASE, CONSUMER MENTIONED A UTERINE PERFORATION WAS SUSPECTED BY ULTRASOUND. THIS PERFORATION COULD HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED PREGNANCY; HOWEVER IT IS UNCLEAR EXACTLY WHEN THE ULTRASOUND WAS DONE (IF BEFORE OR AFTER PREGNANCY ONSET) AND SHE DID NOT MENTION THE PERFORATION WHEN SHE INFORMED DEVICE SURGICAL REMOVAL. ALTHOUGH LIMITED INFORMATION WAS PROVIDED IN THIS CASE; GIVEN THESE EVENTS NATURE, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS SAME ASSESSMENT IS GIVEN FOR THE REPORTED BLEEDING, SINCE ABNORMAL GENITAL BLEEDING AND MENSES PATTERN CHANGES MAY OCCUR WITH ESSURE THERAPY. REGARDING THE REPORTED SPONTANEOUS ABORTION; IT IS THE MOST COMMON COMPLICATION OF EARLY PREGNANCY, OCCURRING IN UP TO 20% OF CLINICALLY RECOGNIZED PREGNANCIES AT LESS THAN 20 WEEKS OF GESTATION DUE TO MATERNAL CONDITIONS AND FETAL CHROMOSOMAL ABNORMALITIES. CONSIDERING THIS INFORMATION AND AS A MECHANICAL INTERFERENCE BETWEEN ESSURE AND THE EARLY DEVELOPING IS UNLIKELY; THIS EVENT WAS CONSIDERED AS UNRELATED TO THE SUSPECT INSERT. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS UPGRADED TO INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (ESSURE SURGICAL REMOVAL REPORTED UPON FOLLOW-UP). BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01946	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 7/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/29/2015
Explant Date (E7): 10/15/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5055986) IN UNITED STATES ON 22-OCT-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. AFTER ABOUT 13 ATTEMPTS TO GET THE ESSURE PLACED THE DOCTOR FINALLY GAVE UP. SHE WAS ABLE TO GET ONE COIL IN THE TUBE BUT THE TUBE SPADED AND THE COIL CAME OUT. SHE COULD NOT FIND THE COIL SO SHE TOLD HER THAT IT WOULD COME OUT OF ITS OWN. CONSUMER HAD HEAVY BLEEDING. SHE WENT THROUGH OVER 100 PADS. SHE STARTED HAVING PROBLEMS ABOUT A MONTH AGO, IN (B)(6) 2015, SHE WENT TO THE DOCTOR AND SHE SENT HER FOR AN ULTRASOUND. THE ULTRASOUND SHOWED THAT THE COIL WAS STILL INSIDE OF HER. IT HAS GONE THROUGH THE BOTTOM OF HER UTERUS AND THE TOP OF HER CERVIX. SHE HAS BEEN AND SHE WAS STILL IN A LOT OF PAIN THE PAIN WAS CONTROLLED WITH MESS BUT SHE STILL HURT ALL THE TIME. SHE WILL HAVE TO HAVE SURGERY TO HAVE THE ESSURE COIL REMOVED. SHE WAS NOT SURE WHEN HER SURGERY WILL BE. SHE WAS WAITING ON THE DOCTOR TO CALL HER. THE DOCTOR SCRAPPED HER UTERUS WITH THE CAMERA EVERY TIME SHE WENT IN AND SHE WAS GOING TO PUT HER IN THE HOSPITAL AND TIED HER TUBES. CONCOMITANT MEDICATIONS INCLUDE NAPROXEN, MULTIVITAMIN AND TYLENOL. FOLLOW-UP INFORMATION RECEIVED ON 23-NOV-2015 FROM CONSUMER (CASE UPGRADED TO INCIDENT): THE CONSUMER WAS (B)(6). ESSURE WAS INSERTED ON (B)(6) 2015 (CONSUMER DID NOT HAVE THE LOT NUMBER). HER SYMPTOMS STARTED TOWARDS THE END OF (B)(6) 2015. SHE HAD THE ESSURE COIL REMOVED ON (B)(6) 2015. THERE WAS ONLY ONE COIL INSERTED. HER FALLOPIAN TUBE SPASMED AND THE DOCTOR LOST THE ONE COIL SHE INSERTED. WHEN THE FALLOPIAN TUBE HAD SPASMED, IT SPIT THE ESSURE COIL OUT OF THE FALLOPIAN TUBE AND THE DOCTOR TOLD HER THAT SHE WOULD SEE IT IN THE COMMODE, BUT SHE NEVER SAW IT.

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WHEN ANOTHER DOCTOR REMOVED ESSURE SHE FOUND PART OF THE CATHETER WAS STILL ATTACHED, HOOKED TO THE COIL AND IT HAD BROKEN OFF AND SHE REMOVED THE COIL AND THE PART OF THE CATHETER THAT HAD BROKEN OFF. THE CONSUMER WAS ON THE DEPO SHOT (INJECTION) AS BACKUP CONTRACEPTION. SHE ALSO HAD TO HAVE PHYSICAL THERAPY. SHE STILL HAD A LITTLE PAIN NEAR HER RIGHT OVARY. EVERYTHING ELSE HAD RESOLVED INCLUDING THE CRAMPING AND BLEEDING. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION RESULT RECEIVED ON 03-DEC-2015: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION, THERE IS NO EVIDENCE OF A QUALITY DEFECT. MOREOVER, THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFECT PER SE. PTC ASSESSMENT RECEIVED ON 17-DEC-2015 WITHOUT MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT, REFERS TO A FEMALE CONSUMER WHO HAD HEAVY BLEEDING (REGARDED AS GENITAL BLEEDING) MONTHS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE HAD THE DEVICE REMOVED (APPROXIMATELY 9 MONTHS AFTER ITS PLACEMENT). DURING THIS SURGERY, IT WAS FOUND PART OF THE CATHETER WAS STILL ATTACHED, HOOKED TO THE COIL AND IT HAD BROKEN OFF. HEAVY BLEEDING IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. DEVICE BREAKAGE IS ANTICIPATED ACCORDING TO THE TECHNICAL ASSESSMENT. ABNORMAL GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, CONSUMER STATED ESSURE CATHETER WAS FOUND BROKE AND ATTACHED TO THE COIL DURING A SURGERY FOR DEVICE REMOVAL. THIS DEVICE BREAKAGE COULD HAVE BEEN A CONTRIBUTORY ROLE IN CONSUMER'S BLEEDING. GIVEN EVENTS NATURE AND BASED ON THEIR POSITIVE TEMPORAL RELATION WITH ESSURE THERAPY; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONALLY, NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS UPGRADED TO INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION, THERE IS NO EVIDENCE OF A QUALITY DEFECT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01947	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2014
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 24-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2014 FOR CONTRACEPTION. REPORTER STATED THE ESSURE DEVICE MIGRATED INTO THE ABDOMEN AND PATIENT PRESENTED WITH PAIN AND IT WAS REMOVED LAPAROSCOPICALLY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS AND MEDICALLY CONFIRMED CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND THE DEVICE MIGRATED INTO THE ABDOMEN AND IT WAS REMOVED LAPAROSCOPICALLY. THIS EVENT, SEEN AS DEVICE DISLOCATION, IS SERIOUS DUE TO MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING ESSURE USE, THERE IS A RISK THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES TOWARDS TO PERITONEAL CAVITY. ALTHOUGH THE EXACT DATE AND MECHANISM O THIS DISLOCATION HAVE NOT BEEN PROVIDED, CONSIDERING ITS NATURE, THE REPORTED EVENT IS ASSESSED AS RELATED TO ESSURE USE AND SINCE AN INTERVENTION WAS REQUIRED TO REMOVE THE DEVICES, THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION AND TECHNICAL ASSESSMENT HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01948	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2007
Explant Date (E7): 1/1/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 24-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2007. THE CONSUMER HAD THE ESSURE REMOVED DUE TO RASH AND PAIN. SHE HAD IMAGING PERFORMED (NOT SPECIFIED). THERE IS A SUSPICION OF NICKEL ALLERGY. ESSURE WAS REMOVED A COUPLE OF MONTHS PREVIOUS TO THIS REPORT; HOWEVER, THE REPORTER DOES NOT HAVE THE EXACT DATE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD THEM REMOVED DUE TO RASH AND PAIN. THE REPORTED EVENTS, SEEN AS RASH AND PELVIC PAIN ARE SERIOUS DUE MEDICAL IMPORTANCE AND LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ALLERGIC REACTIONS TO ESSURE ARE MORE COMMONLY RELATED TO NICKEL SENSITIVITY AND ITS MANIFESTATIONS INCLUDE RASH. ALSO, PELVIC PAIN MAY OCCUR WITH ESSURE USE. IN THIS PARTICULAR CASE, LIMITED INFORMATION HAS BEEN PROVIDED. THE PATIENT HAD ESSURE REMOVED DUE TO RASH AND PAIN AND ALLERGY TO NICKEL WAS SUSPECTED. BASED ON AVAILABLE INFORMATION AND THEIR NATURE, CAUSAL RELATIONSHIP BETWEEN REPORTED EVENTS AND ESSURE USE CANNOT BE EXCLUDED AND SINCE DEVICE REMOVAL WAS REQUIRED, THIS CASE IS REGARDED AS INCIDENT. FURTHER INFORMATION AND TECHNICAL ASSESSMENT HAVE BEEN REQUESTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01949	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 12/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/12/2013
Explant Date (E7): 10/3/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER IN (B)(6) ON 24-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. IN (B)(6) 2013, THE PLAINTIFF WAS CONSIDERING TUBAL LIGATION, AND BOOKED AN APPOINTMENT WITH HER DOCTOR TO DISCUSS THIS METHOD OF BIRTH CONTROL. ALTHOUGH SHE WAS ORIGINALLY INTERESTED IN CONSULTING WITH HER DOCTOR ABOUT TUBAL LIGATION, SHE RELIED HEAVILY ON THE RECOMMENDATION OF HER DOCTOR AND EVENTUALLY AGREED TO UNDERGO THE ESSURE PROCEDURE. ON OR ABOUT (B)(6) 2013, THE PLAINTIFF UNDERWENT THE PROCEDURE AND WAS IMPLANTED WITH ESSURE. IMMEDIATELY AFTER THE PROCEDURE SHE EXPERIENCED SEVERE PAIN AND DISCOMFORT. THE PAIN WAS SO SEVERE SHE WENT TO SEE HER FAMILY DOCTOR WHO INSTRUCTED HER TO GO TO THE HOSPITAL. THE DOCTORS WERE UNABLE TO HELP HER SO THEY SIMPLY PRESCRIBED HER OPIATES FOR THE PAIN AND SENT HER HOME. THE PLAINTIFF CONTINUED TO EXPERIENCE SEVERE PAIN AND STARTED TO EXHIBIT OTHER ADVERSE EFFECTS. SHE BEGAN LOSING HER HAIR, EXPERIENCING EXTREME SWELLING AND BLOATING AROUND HER ABDOMEN, SUFFERING FROM CONSTANT CRAMPING AND WAS BLEEDING ALMOST DAILY. AFTER MONTHS OF SUFFERING SHE ELECTED TO HAVE THE ESSURE IMPLANTS REMOVED. THE DOCTOR HAD TO PERFORM A HYSTERECTOMY TO REMOVE THE IMPLANTS. THE HYSTERECTOMY WAS PERFORMED ON (B)(6) 2014. THE SYMPTOMS, WHICH THE PLAINTIFF EXPERIENCED IMMEDIATELY AFTER BEING IMPLANTED WITH ESSURE, CEASED AS SOON AS THE ESSURE IMPLANTS WERE REMOVED. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS RECEIVED FROM AN LAWYER ON BEHALF OF A FEMALE CONSUMER/PLAINTIFF. SHE HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED SEVERE PAIN AND BLEEDING (REGARDED AS GENITAL BLEEDING) ALMOST DAILY. SHE WAS SUBMITTED TO A HYSTERECTOMY WITH RECOVERY OF HER SYMPTOMS. THESE

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EVENTS ARE LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY, ABDOMINAL/PELVIC PAIN AND GENITAL BLEEDING OR SPOTTING MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER'S PAIN STARTED IN CLOSE ASSOCIATION WITH ESSURE PROCEDURE. LATER, SHE ALSO EXPERIENCED BLEEDING. THE DEVICE WAS REMOVED APPROXIMATELY 10 MONTHS AFTER ITS PLACEMENT AND SHE RECOVERED FROM THE EVENTS. CONSIDERING THIS INFORMATION AND IN THE LACK OF ALTERNATIVE EXPLANATIONS; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING PERFORMED. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01950	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 11/1/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** CA

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 4/2/2012
Explant Date (E7): 9/23/2014
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A LAWYER IN (B)(6) ON 24-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER/PLAINTIFF OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2012 FOR BIRTH CONTROL. THE PLAINTIFF DID NOT WANT ANY ADDITIONAL CHILDREN AND AFTER SPEAKING WITH HER GYNECOLOGIST IT WAS RECOMMENDED THE ESSURE IMPLANT BECAUSE THERE WAS LITTLE DOWN TIME. SHORTLY AFTER BEING IMPLANTED WITH ESSURE THE PLAINTIFF BEGAN TO EXPERIENCE SHARP PAINS AND SIGNIFICANT DISCOMFORT IN HER PELVIC REGION. IN OR AROUND (B)(6) 2012, SHE BEGAN TO NOTICE IRREGULAR MENSTRUAL CYCLES, PAIN DURING SEX, SIGNIFICANT CRAMPING AND PAIN IN THE PELVIC REGION AND SIGNIFICANT BLOATING IN THE PELVIC REGION. ON OR AROUND (B)(6) 2014, SHE HAD A TOTAL HYSTERECTOMY (LEAVING OVARIES) PERFORMED TO REMOVE THE ESSURE IMPLANT. AS SOON AS SHE WOKE UP FROM THE SURGERY, THE PAIN AND BLOATING IN HER PELVIC REGION WERE SIGNIFICANTLY REDUCED. OVER THE NEXT COUPLE OF WEEKS AFTER SURGERY, THE PLAINTIFF CONTINUED TO EXPERIENCE IMPROVEMENTS IN HER SYMPTOMS. COMPANY CAUSALITY COMMENT: THIS CASE REPORT WAS RECEIVED FROM AN LAWYER ON BEHALF OF A FEMALE CONSUMER/PLAINTIFF WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DEVELOPED SIGNIFICANT CRAMPING AND PAIN IN THE PELVIC REGION. SHE WAS SUBMITTED TO A HYSTERECTOMY (APPROXIMATELY 2 YEARS AFTER ESSURE PLACEMENT). THE DEVICE WAS REMOVED AND SHE HAD A SIGNIFICANT REDUCTION IN HER PAIN. THIS EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY, PELVIC PAIN AND CRAMPING MAY OCCUR. IN THIS PARTICULAR CASE, THE TEMPORAL RELATIONSHIP BETWEEN ESSURE PROCEDURE AND PAIN ONSET WAS POSITIVE AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. CONSIDERING THIS INFORMATION AND SINCE CONSUMER'S PAIN IMPROVED WITH DEVICE

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REMOVAL; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED (HYSTERECTOMY PERFORMED). A PRODUCT TECHNICAL ANALYSIS IS BEING PERFORMED. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01951	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 24-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. THIS PATIENT HAD COME BACK ONCE BEFORE FOR A CONSULT BECAUSE SHE KEPT ON HAVING BLEEDINGS. THE GYNECOLOGIST THEN HYSTEROSCOPICALLY CUT OFF THE COILS OF THE ESSURE IN THE CAVUM. THE GYNECOLOGIST IS NOT OPEN FOR CONTACT. THE PATIENT WILL COME BACK FOR ANOTHER CONSULT WITH THE GYNECOLOGIST. FOLLOW-UP FROM 10-DEC-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD, WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENT(S) IS A KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED

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ON 14-DEC-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: GENITAL HAEMORRHAGE. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND SHE KEPT ON HAVING BLEEDINGS (INTERPRETED AS GENITAL BLEEDING). THE GYNECOLOGIST THEN HYSTEROSCOPICALLY CUT OFF THE COILS OF THE ESSURE IN THE CAVUM. THE PATIENT WILL COME BACK FOR ANOTHER CONSULT WITH THE GYNECOLOGIST. THE EVENT GENITAL BLEEDING IS SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. THIS CASE WAS REPORTED WITH LIMITED INFORMATION. CONSIDERING THAT GENITAL BLEEDING MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE AN INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01953	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D35371

Single Use: Y
Implant Date (E6): 10/28/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON 25-NOV-2015 WHICH REFERS TO A (B)(6) OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015, LOT NUMBER D35371, FOR TUBAL STERILIZATION. THE PATIENT'S MEDICAL HISTORY INCLUDED POLYP INTO ENDOCERVIX; AND HER DRUG HISTORY INCLUDED CONTRACEPTION WITH DESOGESTREL 75 FOR 3 MONTHS. DURING THE INSERTION PROCEDURE, BOTH OSTIA WERE WELL VISUALIZED. INTERVENTION WAS STARTED BY INSERTION ON LEFT SIDE. ON INSERTER REMOVAL, INSERTER WAS REMOVED WITH DIFFICULTY DUE TO A BLOCKAGE AND A KIND OF TRANSPARENT SHEATH REMAINED INTO OSTIUM AND ALONG UTERINE CAVITY. INSERTION WAS EASILY PERFORMED ON RIGHT SIDE WITH 3 TRAILING COILS. ON LEFT, THE SHEATH WAS FRIABLE AND REMOVED PIECE BY PIECE WITH BIOPSY FORCEPS; A SMALL PART OF THE SHEATH REMAINED IN LEFT OSTIUM AREA. LEFT INSERT WAS WELL PLACED. THE POLYP INTO ENDOCERVIX WAS AT THE TIME REMOVED; HER UTERINE CAVITY HAD NO PARTICULARITY. PLAIN ABDOMEN X-RAY WAS PERFORMED IMMEDIATELY AFTER THE INTERVENTION. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE INSERTOR WAS REMOVED WITH DIFFICULTY DUE TO A BLOCKAGE AND TRANSPARENT SHEATH REMAINED INTO CAVITY. THIS EVENT, INTERPRETED AS DEVICE BREAKAGE, IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. IN THE PRESENT CASE, ON INSERTER REMOVAL, IT WAS REMOVED WITH DIFFICULTY DUE TO A BLOCKAGE AND A KIND OF TRANSPARENT SHEATH REMAINED INTO OSTIUM AND ALONG UTERINE CAVITY. THE SHEATH WAS REMOVED PIECE BY PIECE WITH BIOPSY FORCEPS; A SMALL PART OF THE SHEATH REMAINED IN LEFT OSTIUM AREA. SINCE

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THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01954	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50534016

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN (B)(6) ON 26-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2015. ESSURE HAD BEEN PLACED 5 MONTHS EARLIER. THE PLACEMENT WAS EASY. THE PATIENT EXPERIENCED EPISODES OF PAIN 2 DAYS AFTER THE PLACEMENT OF ESSURE. INSERTS WERE IN PLACE AT THE CONTROL VISIT. A FALLOPIAN TUBE WAS REMOVED 4 MONTHS AFTER THE PLACEMENT OF ESSURE. SALPINGECTOMY WAS PERFORMED FOLLOWING EPISODES OF PAIN. SINCE THAT, EPISODES OF PAIN RESOLVED. THE SURGEON DID NOT UNDERSTAND WHY THE PATIENT EXPERIENCED EPISODES OF PAIN AS THE INSERTS WERE IN PLACE. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED EPISODES OF PAIN 2 DAYS AFTER THE PLACEMENT OF ESSURE. A FALLOPIAN TUBE WAS REMOVED 4 MONTHS AFTER ESSURE INSERTION, AND THE PAIN EPISODES RESOLVED. THIS EVENT, INTERPRETED AS PELVIC PAIN, WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. GIVEN THE POSITIVE TEMPORAL RELATIONSHIP, NATURE OF THE REPORTED EVENT, AND SINCE THE PAIN RESOLVED AFTER SALPINGECTOMY (ALTHOUGH IT IS NOT CLEAR WHETHER BOTH INSERTS WERE REMOVED), CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A SURGICAL INTERVENTION WAS PERFORMED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 21-DEC-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN IN

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01955	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** SP

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 50534016

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A REGULATORY AUTHORITY IN (B)(6)) CASE NUMBER ((B)(4)) ON 26-NOV-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER 50534016 INSERTED. CONSUMER HAD ESSURE IMPLANTED AND EXPERIENCED SERIOUS PROBLEMS WITH IT UNTIL IT WAS FINALLY REMOVED FROM HER BODY (IT LED TO HAVE FALLOPIAN TUBES AND ONE OF OVARIES REMOVED). SHE HAD THE SURGERY 21 DAYS REPORTING THIS CASE TO THE REGULATORY AUTHORITY. THE POSTOPERATIVE PERIOD OF HER OPEN SURGERY WAS A NIGHTMARE, FILLED WITH DRAINS AND TUBES; A COUPLE OF DAYS DURING WHICH SHE WAS UNABLE TO TAKE CARE OF HERSELF, NOT EVEN TO GO TO THE TOILET ON HER OWN. AND ALTHOUGH SHE WAS HAPPY TO FINALLY BE RID OF THE DEVICE, SHE WAS OUTRAGED THAT IT CAUSED HER TO GO THROUGH SUCH AN ORDEAL. SHE STATED IT CAUSED HER VERY PAINFUL ENDOMETRIOSIS, WHICH MEANS IT KEPT HER FROM BEING ABLE TO WORK TEMPORARILY AND BEEN A SOURCE OF IMMENSE FRUSTRATION. FOLLOW-UP FROM 10-DEC-2015: PRODUCT TECHNICAL COMPLAINT INVESTIGATION RESULT. PTC GLOBAL NUMBER: (B)(4). LOT NUMBER 50534016; MANUFACTURING DATE: JUL-2010; EXPIRATION DATE JUL-2013. FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE

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AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO FURTHER AE CASE REPORTS HAVE BEEN RECEIVED TO DATE IN RELATION TO THE REPORTED BATCH. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 15-DEC-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: ADVERSE EVENT. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED SERIOUS PROBLEMS WITH IT UNTIL IT WAS FINALLY REMOVED FROM HER BODY (IT LED TO HAVE FALLOPIAN TUBES AND ONE OF OVARIES REMOVED). SHE ALSO STATED IT CAUSED HER VERY PAINFUL ENDOMETRIOSIS. THE FIRST EVENT IS LISTED IN THE REFERENCE SAFETY INFORMATION WHILE THE OTHER EVENT IS UNLISTED. BOTH WERE CONSIDERED SERIOUS. IN THIS CASE, THE PATIENT DID NOT SPECIFY WHAT TYPE OF SERIOUS PROBLEMS SHE HAD, HOWEVER SINCE IT LEAD TO DEVICE REMOVAL, THIS EVENT WAS CONSIDERED AS RELATED TO SUSPECT INSERT. WITH REGARDS TO THE OTHER EVENT, CONSIDERING THE PATHOPHYSIOLOGY, A CAUSAL RELATIONSHIP WITH SUSPECT INSERT CAN BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS PERFORMED. BASED ON THE AVAILABLE INFORMATION THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01956	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): D30798

Single Use: Y
Implant Date (E6): 10/15/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SOLICITED CASE REPORT RECEIVED FROM A PHARMACIST IN (B)(6) ON 27-NOV-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO WAS INVOLVED IN A REIMBURSEMENT OR COMPENSATION ACTIVITY, STUDY NUMBER: (B)(4). STUDY DESCRIPTION: ESSURE GENERIC REIMBURSEMENT PROGRAM. THE PATIENT HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT), LOT NUMBER D30798, INSERTED ON (B)(6) 2015 UNDER GENERAL ANAESTHESIA, FOR PERMANENT BIRTH CONTROL. ACCORDING TO THE REPORTER, THE PROCEDURE WAS PERFORMED IN USUAL CONDITION. THE PATIENT TOOK CERAZETTE (DESOGESTREL) AND NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS). THE HYSTEROSCOPY (5.5MM) REVEALED A ROUND UTERINE CAVITY. ON THE LEFT SIDE, ESSURE RELEASE WAS PERFORMED WITH USUAL MARKERS AND THERE WAS NO VISIBLE TRAILING COILS. ON THE RIGHT SIDE, IT WAS IMPOSSIBLE TO RELEASE THE INSERT WHICH STAYED ATTACHED TO DELIVERY CATHETER; THE COIL WAS STRETCHED AND NEEDED TO BE CLIPPED AT EXTREMITY WITH A PLIER TO REMOVE THE INSERTER AND TO AVOID DAMAGING TUBE. THE BILATERAL PLACEMENT WAS PERFORMED WITH THE CONCERNED INSERT. CONTROL EXAMINATION WAS PRESCRIBED TO ENSURE DEVICE SAFETY. THE SURGEON WAS TRAINED TO ESSURE PROCEDURE. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DURING THE PROCEDURE, ON THE RIGHT SIDE, IT WAS IMPOSSIBLE TO RELEASE THE INSERT WHICH STAYED ATTACHED TO DELIVERY CATHETER. THIS COIL WAS STRETCHED AND NEEDED TO BE CLIPPED AT EXTREMITY WITH A PLIER TO REMOVE THE INSERTER AND TO AVOID DAMAGING THE TUBE. THE REPORTED EVENTS, REGARDED AS A DEVICE DEPLOYMENT DIFFICULT FOLLOWED BY HANDLING ISSUE (THE DEVICE STRETCHED) AND MISUSE (INSERT WAS CLIPPED), ARE LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, ESSURE PLACEMENT MAY BE

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UNSUCCESSFUL. IN THIS PARTICULAR CASE, THE EVENTS OCCURRED IN ASSOCIATION WITH A COMPLICATED ESSURE INSERTION PROCEDURE. THEREFORE, THEY WERE CONSIDERED AS RELATED TO THE SUSPECT INSERT. EXCEPT FOR THE REPORTED DEVICE MISUSE; WHICH WAS CONSIDERED UNRELATED (DUE TO ITS NATURE). THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENTS DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FOLLOW-UP INFORMATION AND A PRODUCT TECHNICAL ANALYSIS ARE EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01957	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 1/1/2003 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2001
Explant Date (E7): 1/1/2008
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA (B)(6) ON (B)(6)-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2001 FOR STERILIZATION. CONSUMER REPORTED THAT SHE WAS A CLINICAL TRIAL PARTICIPANT FOR PERMANENT BIRTH CONTROL, STERILIZATION. IN 2003, SHE REPORTED ABDOMINAL PAIN, DISTENSION, PAINFUL SEXUAL INTERCOURSE AND MENSTRUATION. A HYSTEROSCOPY, DILATION AND CURETTE (AS REPORTED) WERE PERFORMED UNDER GENERAL ANESTHESIA. SHE HAD SEVERAL PRESENTATIONS TO THE HOSPITAL FOR ABDOMINAL PAIN. SHE CONTINUED TO HAVE PROBLEMS WITH HER REPRODUCTIVE ORGANS THAT BECOME QUITE DEBILITATING AND LIFE ALTERING. SHE STATED AS CONSEQUENCE SHE HAD MANY INVASIVE PROCEDURES INCLUDING SURGICAL INTERVENTIONS. SHE MENTIONED DILATION & CURETTE AND ENDOMETRIAL THERMAL ABLATION. IN 2008, AFTER TAKING LEAVE WITHOUT PAY FROM HER JOB DUE TO DEBILITATING ABDOMINAL PAIN SHE HAD A HYSTERECTOMY AND SALPINGECTOMY PERFORMED. AFTER RECOVERING FROM THIS MAJOR SURGERY ALL HER SYMPTOMS RESOLVED. FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: NO FOLLOW-UP IS POSSIBLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ABDOMINAL PAIN AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, SHE HAD SEVERAL PRESENTATIONS TO THE HOSPITAL AND LOST DAYS ON HER JOB DUE TO THE PAIN; WHICH RESOLVED AFTER A HYSTEROSALPINGECTOMY WAS PERFORMED. ADDITIONALLY, SHE WAS SUBMITTED TO DILATION & CURETTE AND ENDOMETRIAL THERMAL ABLATION DURING ESSURE THERAPY. ONLY PAIN IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. AFTER ESSURE INSERTION, ABDOMINAL PAIN MAY OCCUR. IN THIS PARTICULAR CASE, CONSUMER RELATED HER PAIN TO ESSURE PLACEMENT AND NO ALTERNATIVE EXPLANATION WAS

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PROVIDED. GIVEN EVENT'S NATURE AND SINCE IT RECOVERED WITH DEVICE REMOVAL, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. REGARDING THE REPORTED ENDOMETRIAL ABLATION AND DILATATION AND CURETTAGE; THE CONSUMER DID NOT INFORM THE EXACT MEDICAL REASON FOR THESE PROCEDURES. THEY ARE USUALLY PERFORMED TO EVALUATE/TREAT ABNORMAL UTERINE BLEEDING; HOWEVER CONSUMER DID NOT MENTION BLEEDING DISTURBANCES IN HER REPORT. SINCE THE INFORMATION PROVIDED IS INSUFFICIENT FOR A COMPREHENSIVE CAUSALITY ASSESSMENT, CAUSALITY BETWEEN THESE EVENTS AND ESSURE CANNOT BE ASSESSED. THIS CASE WAS REGARDED AS INCIDENT; DUE TO THE SERIOUS INJURY REPORTED (DEVICE SURGICAL REMOVAL WAS REQUIRED AND CONSUMER HAD IMPAIRMENT OF HER DAILY ACTIVITIES DUE TO THE PAIN). A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS THIS CASE WAS RECEIVED VIA (B)(6).

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01958	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/25/2003
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY ((B)(4)) IN (B)(6) ON 25-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (ESS205) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2003 FOR CONTRACEPTION. CONSUMER REPORTED THAT SHE EXPERIENCED CONSTANT ABDOMINAL PAIN AND PRIOR TO HAVING A HYSTERECTOMY IN 2009 SHE HAD DEBILITATING PERIODS AND PAIN WHICH SHE HAD NOT HAD PRIOR TO THE DEVICE BEING INSERTED. SHE SUFFERED FROM UNEXPLAINED ABDOMINAL PAIN FOR YEARS, EXTREMELY HEAVY BLEEDING, MIGRAINES, LOSS OF SEX DRIVE, PAINFUL INTERCOURSE, URINE TRACK INFECTIONS, THRUSH, CONSTANT BLOATING, INSOMNIA DUE TO PAINFUL ABDOMEN AND NO ENERGY. SHE WAS SELF MEDICATING DUE TO MANAGEMENT OF SYMPTOMS. AFTER THE HYSTERECTOMY HER SYMPTOMS REMAINED, ONLY THERE WAS NO BLEEDING TO CONTEND WITH. HER GYNECOLOGIST LEFT THE DEVICE IMPLANTED IN HER AFTER THE HYSTERECTOMY WAS PERFORMED. SHE WAS STILL SUFFERING FROM EXTREMELY /EXCRUCIATING ABDOMINAL PAIN CAUSED BY THE COILS. TO THE DAY OF REPORT, SHE SUFFERS FROM EXTREMELY ABDOMINAL PAIN TO THE POINT WHERE SHE HAD BEEN UP TO EMERGENCY HOSPITAL. THE OUTCOME FROM YEARS OF PAIN AND SUFFERING HAS BEEN A TOTAL LOSS OF ENJOYMENT OF LIFE - NO HOPE, DEPRESSION AND MENTAL ISSUES. SHE WAS TESTED FOR MENOPAUSE BUT EVERY TEST WAS NEGATIVE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED SPONTANEOUS CASE IDENTIFIED DURING MONITORING OF POSTINGS ON AN FDA HOSTED DOCKET WEBSITE REFERS TO A FEMALE CONSUMER WHO HAD ESSURE 205 (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND EXPERIENCED ABDOMINAL PAIN FOR YEARS AND EXTREMELY HEAVY BLEEDING. AFTER APPROXIMATELY 6 YEARS, SHE HAD A HYSTERECTOMY AND RECOVERED FROM BLEEDING BUT OTHER SYMPTOMS REMAINED. THE CONSUMER BELIEVED STATED THAT THE PHYSICIAN LEFT THE

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DEVICE IMPLANTED IN HER AFTER THE HYSTERECTOMY WAS PERFORMED. THE HEAVY BLEEDING, INTERPRETED AS GENITAL BLEEDING, AND ABDOMINAL PAIN ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, CONSIDERING THAT ESSURE MAY CAUSE BLEEDING AND ABDOMINAL PAIN AND THAT THERE IS NO ALTERNATIVE EXPLANATION FOR THESE EVENTS, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A REQUIRED INTERVENTION RELATED TO ESSURE WAS REPORTED. NO ACTIVE FOLLOW-UP WILL BE PURSUED, AS FOLLOW UP IS NOT POSSIBLE.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01969	BAYER HEALTHCARE LLC	12/22/2015	12/22/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 880425, 880426

Single Use: Y
Implant Date (E6): 3/23/2012
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A (B)(6) FEMALE NURSE IN UNITED STATES ON 25-SEP-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) LOT NUMBER 880425 INSERTED IN (B)(6) 2011. THE NURSE REPORTED HER PAIN STARTED 1 YEAR AGO FROM THIS REPORT AND HAD PROGRESSIVELY WORSENED. SHE STATED SHE COULD FALL ON THE GROUND WITH PAIN AND CRY, AND HER PHYSICIAN STATED PAIN IS COMING FROM THE COILS AND NEED TO BE REMOVED. RESULT AND ASSESSMENT OF THE PRODUCT TECHNICAL COMPLAINT INVESTIGATION RECEIVED ON 26-OCT-2015: THIS ADVERSE EVENT REPORT IS RELATED TO A PRODUCT TECHNICAL COMPLAINT (PTC). THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCTED A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: NO PRODUCT QUALITY DEFECT WAS CONFIRMED THEREFORE A RELATIONSHIP TO THE REPORTED MEDICAL EVENT IS EXCLUDED. THE TECHNICAL ASSESSMENT CONCLUDED UNCONFIRMED QUALITY DEFECT. BASED ON THE AVAILABLE INFORMATION, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW-UP INFORMATION RECEIVED ON 04-DEC-2015 FROM CONSUMER (CASE POTENTIAL LEGAL AND WAS UPGRADED TO INCIDENT): THE CONSUMER IS AN EMERGENCY ROOM NURSE. ESSURE WAS INSERTED ON (B)(6) 2012 (LOT NUMBERS 880425 ON LEFT,

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880426 ON RIGHT) AFTER THE CONSUMER LOST HER YOUNGEST SON WHO WAS DELIVERED IN A COMPLICATED EMERGENCY C-SECTION. ON (B)(6) 2012 A TEST WAS PERFORMED (NOT SPECIFIED) AND SHOWED COMPLETE OCCLUSION OF BOTH FALLOPIAN TUBES AND PROPER PLACEMENT. FOLLOWING THE ESSURE PLACEMENT SHE EXPERIENCED EXTREME PAIN WITH INTERCOURSE AND NOTED THAT HER PMS (REGARDED AS PREMENSTRUAL SYNDROME) SYMPTOMS CHANGED AND/OR BECAME MORE PRONOUNCED. INITIALLY, SHE WAS EXPERIENCING INCREASED CRAMPING AND NEW ONSET BLOATING WITH HER CYCLE. SHE THOUGHT HER BODY WAS STILL TRYING TO ADJUST DO ESSURE. HOWEVER, SLOWLY SHE BEGAN EXPERIENCING MORE SYMPTOMS WHICH WERE GRADUALLY WORSENING, INCLUDING NAUSEA, VOMITING, HOT FLASHES, BREAST TENDERNESS, FATIGUE, DYSMENORRHEA, HEAVY MENSES, AND INTERMITTENT PAINS IN ADDITION TO THE CRAMPING AND BLOATING. THE GYNECOLOGIST SHE INITIALLY SAW OFFERED HER TO START ON BIRTH CONTROL TO HELP CONTROL SOME OF THE SYMPTOMS, BUT SHE DECLINED. SHE CONTINUED TO TRY TO MANAGE HER SYMPTOMS WITH HEALTHY LIFESTYLE CHOICES, USING TRAMADOL AND IBUPROFEN ONLY PRN (AS NEEDED) FOR SEVERE PAIN, BUT HER SYMPTOMS CONTINUED TO GET WORSE. AT TIMES THE PAIN WOULD BE SO SEVERE AND COME ON SO SUDDENLY THAT IT WOULD WAKE HER FROM HER SLEEP. HER DISTRESS RELATED TO THE PAIN WAS MARKED. BY (B)(6) 2015, IN ADDITION THE MENTIONED SYMPTOMS, SHE THE CONSUMER ALSO NOTED MODERATE TO SEVERE MOOD SWINGS AND FATIGUE - SHE NO LONGER FELT LIKE HERSELF. THE PAIN AND SYMPTOMS HAD BECOME MORE THAN SHE COULD TOLERATE AND WERE INTERFERING WITH HER ABILITY TO PERFORM AT WORK AND AS A MOTHER. DURING ANOTHER PHYSICIAN APPOINTMENT, HE SAID HER SYMPTOMS WERE LIKELY ASSOCIATED TO ESSURE AND THAT SHE WOULD NEED TO CONSIDER HAVING HER FALLOPIAN TUBES REMOVED. SHE ALSO WAS RECOMMENDED BIRTH CONTROL TO HELP MANAGE THE SYMPTOMS, WHICH DID NOT HELP. ON (B)(6) 2015 SHE SUDDENLY EXPERIENCED A PAIN THAT WAS SO SEVERE THAT SHE HAD TO REPEATEDLY TO SIT DOWN AND TRY TO RECUPERATE - IT WAS MORE SEVERE THAN SHE HAD EVER EXPERIENCED AND SHE REQUIRED ASSISTANCE TO GET INSIDE BECAUSE SHE WAS UNABLE TO STAND UPRIGHT. SHE DESCRIBED THE PAIN AS INTERMITTENT WITH SUDDEN ONSET, LOCATED IN THE BILATERAL LOWER ABDOMINAL QUADRANTS, A RIPPING/BURNING SENSATION AS IF SOMETHING WERE TRYING TO RIP ITS WAY OUT OF HER BODY, WORSE WITH MENSTRUATION. SINCE THAT EPISODE, HE HAD CONTINUED TO HAVE SEVERE INTERMITTENT PAINS AND MULTIPLE EPISODES OF NAUSEA AND VOMITING WITH THE PAIN. THE CONSUMER WAS BEING SCHEDULED FOR SURGERY TO HAVE HER TUBES REMOVED OR A HYSTERECTOMY DUE TO THESE PROBLEMS. THE PAIN AND SYMPTOMS SHE HAD EXPERIENCED SINCE HAVING ESSURE PLACED HAD BEEN DEBILITATING, INTERFERED WITH HER WORK LIFE, HOME LIFE, AND SEX LIFE. SHE STATED THAT THE DEVICES HAD CAUSED HER GREAT DEAL OF PAIN AND PROBLEMS, INTERFERING WITH HER ABILITY TO PERFORM AND FUNCTION AS SHE DID PRIOR TO THE PLACEMENT PROCEDURE. FOLLOW-UP INFORMATION RECEIVED ON 17-DEC-2015 - PTC INVESTIGATION RESULT: PTC GLOBAL NUMBER: (B)(4). NO MAJOR CHANGES. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE NURSE WHO DEVELOPED PAIN/PAIN INTERMITTENT IN BILATERAL LOWER ABDOMINAL QUADRANTS AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE STATED SHE WAS BEING SCHEDULED FOR SURGERY TO HAVE HER TUBES REMOVED OR A HYSTERECTOMY. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE CONSUMER REPORTED PAIN AND CRAMPING, WHICH SHE ASSOCIATED WITH ESSURE AND NO ALTERNATIVE EXPLANATION WAS PROVIDED. GIVEN EVENT'S NATURE AND BASED ON THE INFORMATION AVAILABLE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE TOTALLY EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS CONSIDERED A INCIDENT, SINCE A SURGICAL INTERVENTION WILL BE REQUIRED FOR ESSURE REMOVAL. THE PRODUCT TECHNICAL ANALYSIS CONCLUDED UNCONFIRMED QUALITY DEFECT, THERE IS NO RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT AND A QUALITY DEFECT. FURTHER INFORMATION WILL BE OBTAINED THROUGH THE LITIGATION PROCESS.

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Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058641	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 12/14/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD THEM PLACED IN (B)(6) 2012 AND HAD THEM REMOVED IN (B)(6) 2013. I HAD PAIN FROM THE VERY BEGINNING. I HAD A METALLIC TASTE IN MY MOUTH AND WAS NAUSEATED 24/7. I LOST ABOUT (B)(6) AT THIS TIME. WHEN I HAD THEM REMOVED THEY HAD A PICTURE OF WHY I WAS HURTING. IT HAD COME OUT OF PLACE AND POKED A HOLE IN MY FALLOPIAN TUBE. I HAD A TUBAL AT THIS TIME AND THEY HAD ACTUALLY TAKEN ONE OF MY OVARIES DUE TO MULTIPLE FOLLICULAR CYST. WHEN I WENT BACK TO MY OB/GYN SHE DID AN ULTRASOUND AND SAW THAT THERE WAS STILL A SMALL PIECE OF THE COIL STILL IN ME. I AM NOT HAVING ANY PROBLEMS NOW. MY SYMPTOMS CLEARED UP IMMEDIATELY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058642	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 6/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SYMPTOMS STARTED WITH ANXIETY, GETTING MORE INTENSE AS TIME WENT BY, RESULTING IN HOSPITALIZATION. EXCESSIVE BLOATING AND PAIN IN STOMACH. EXCESSIVE BLEEDING AND PAIN DURING MENSTRUAL CYCLE CAUSING ANEMIA. JOINT PAIN, BACK PAIN, CONSTANT HEADACHES. EXCESSIVE WEIGHT GAIN, (B)(6). DUE TO ANEMIA, HAD AN ABLATION IN 2013. WAS TOLD HAD CYSTS ON OVARIES WHICH HAD TO BE REMOVED. NOW I HAVE HORRIBLE STABBING PAINS IN LOWER ABDOMEN. AND IN MY BACK.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058643	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 12/17/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE DONE (B)(6) 2015. BEEN EXPERIENCING HIVES SINCE THEN. DID EVERYTHING POSSIBLE TO RESOLVE ISSUE, EVEN HAVING AN ALLERGY TEST DONE, WHICH CAME BACK NEGATIVE. HIVES HAVE BEEN GETTING PROGRESSIVELY WORSE. INCIDENT IN QUESTION; HIVES CLOSED MY THROAT AIRWAY CAUSING HOSPITALIZATION.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058644	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 11/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). MIGRAINES (1 A WEEK, LASTING 3-4 DAYS), HOT FLASHES, NIGHT SWEATS, CYSTS, NO LIBDO WHATSOEVER, FATIGUE, NO PERIOD IN 7 WEEKS. I DO THINK THE DEVICE WAS PROVIDED BY THE INSURER. NOT SURE REALLY.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058645	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 7/10/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). STARTED BREAKING OUT IN HIVES SWEATS. NAUSEA UNCONTROLLABLE PAIN IN ABDOMINAL AREA. STOMACHS SWELLING BACK TO BACK PERIODS FEEL LIKE KNIFE STABBING IN WOUND BLEEDING TWO OR THREE TIMES A MONTH HEADACHE

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058646	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 8/12/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ABNORMAL CYCLE, WEIGHT LOSS, EXTREME PELVIC PAIN, ANXIETY, SHORT TERM MEMORY LOSS, MIGRAINES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058647	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 2/1/2007	**Report Date (B4):**	**Event Report Type (H1):** INJURY	**Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SEVERE PAIN, RASHES, WEIGHT GAIN, BLADDER ISSUES, TWO HYSTERECTOMY'S, CYSTS,

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058648	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 11/19/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SHARP PAIN, HEAVY PERIODS, PAINFUL INTERCOURSE, PAINFUL OVULATION, HAIR LOSS, DENTAL DECAY, FIBROMYALGIA, SKIN PAIN, BLOATING, MIGRAINES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058649	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 9/18/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). ANXIETY ATTACKS, PANIC ATTACKS, SERIOUS WEIGHT GAIN OF (B)(6), CRAMPING ALL THE TIME, DEPRESSION... I ALSO HAVE A NICKLE ALLERGY AND THE DEVICE IS MADE OUT OF NICKEL SO I HAVE A RASH ON MY HANDS ALL THE TIME FROM IT .. WHICH I WAS NOT INFORMED OF BEFORE HAND.. IM GOING TO HAVE TO HAVE THIS THING REMOVED AND THAT MEANS...FOR A DEVICE THAT WAS SUPPOSED TO BE NON SURGICAL...BECOMING A SURGICAL PROCEDURE FOR LOTS..I CANT TAKE THAT RISK .. CANT BELIEVE WE WERE PRETTY MUCH USED AS THE GUINEA PUGS FOR THIS SO CALLED... DEVICE .. NO YOU DONT TEST ON ANIMALS . YOU TEST ON HUMANS THANKS BAYER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058650	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 12/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I WENT TO MY OBGYN ABOUT WHAT I WAS EXPERIENCING HE ORDERED AN ULTRA SOUND WHICH HE SAID LOOKED NORMAL BUT SUGGESTED A HYSTERECTOMY TO RELIEVE THE HEAVY BLEEDING WHILE HE WAS DOING THE SURGERY HE FOUND THAT IN MY LEFT TUBE THE COIL PUNCTURED THE SKIN THAT GREW OVER IT AND ALSO PUNCTURED MY LEFT TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058651	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 5/18/2005 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). HEAVY PERIODS WITH LARGE CLOTS, CONSTANT PELVIC PAIN, NO LIBIDO, CHRONIC MIGRAINES WITH NAUSEA AND VOMITING SOMETIMES LASTING 12 DAYS, MRI AT ER CAME BACK NORMAL, NUEROCARDIO GENIC SYNCOPE, SWELLING WITH WEIGHT GAIN I CAN'T LOSE, THYROID PROBLEMS, JOINT PAIN ANXIETY HORRIBLE CRAMPING, SCARING AROUND THE ESSURE MY SURGEON THOUGHT WAS A HURNIA, HAD GALLBLADDER REMOVED BECAUSE OF PANCREATITIS, (HOSPITAL FOR 6 DAYS) AND APPENDIX, HAIR LOSS, MEMORY FOG, BACK PROBLEMS. MOOD SWINGS, HOT AND COLD FLASHES HAD TO HAVE A DNC WITH A HYSTEROSCOPY. I WAS A HEALTHY PERSON BEFORE THIS. INSURANCE COMPANY COVERED IT. WAS NOT TOLD ABOUT ANY OF THESE SIDE EFFECTS THAT NOW CONTROL MY LIFE! I WANT THIS DEVICE OUT!

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058652	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 11/8/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CHRONIC PELVIC PAIN, PAINFUL PERIODS, INFLAMMATION OF THE CERVIX, AUTOIMMUNE DISORDERS AND WEIGHT GAIN. THIS WAS PUT IN BY MY INSURER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058653	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 3/25/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). CONSTANT PAIN IN MY RIGHT QUADRANT, DIAGNOSED WITH FIBROMYALGIA IN (B)(6) 2015, ONGOING BLADDER PAIN AND INFECTIONS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058654	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 6/11/2008 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). PAINFUL PERIODS, FIBROIDS, HEAVY BLEEDING 10++ DAYS, LIVING DAILY WITH PELVIC PAIN, VERY BAD PMS, ACNE, THINNING HAIR, DEPRESSION.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058655	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 12/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). AFTER IMPLANTS, I'D SAY 6-12 MONTHS AFTERWARDS, I STARTED NOTICING HAIR LOSS AND THINNING, NUMBING AND TINGLING IN LIMBS ON THE LEFT SIDE OF MY BODY, DENTAL AND GUM PAIN PARTICULARLY ON LEFT SIDE, LOSS OF TOOTH #6 SUDDENLY AND UNEXPECTEDLY, AND SEVERAL ROOT CANAL RETREATS OF TOOTH #19, INFREQUENT BUT SEVERE BOUTS OF MIGRAINE, EXCESSIVE INCIDENTS OF BACTERIAL VAGINITIS, CLOTTING DURING MENSTRUAL CYCLE WHICH WAS NEVER EXPERIENCED PRIOR TO IMPLANTS, BREAK THROUGH BLEEDING BETWEEN CYCLES, RESTLESSNESS, NAUSEA, BRAIN FOG AND AN ARTERIAL DISSECTION DURING A UFE PROCEDURE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058681	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 9/5/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . STARTED OUT WITH HEAVY PERIODS. CRAMPS AFTER MENSTRUATION WAS OVER FOR THE MONTH. PAIN (HAD ULTRASOUND DONE). BREAK THROUGH BLEEDING. HEAVY PERIODS. HAD TO WEAR SUPER TAMPON AND PAD TOGETHER. BEFORE ESSURE A REGULAR TAMPON WAS USED. LOTS OF ABSCESSES IN VAGINAL AND UNDERARM AREA. TOOTH PAIN. ABSCESS IN GUMS. PIMPLY LIKE SORES ON MY HEAD. HAIR THINNING. HORRIBLE METALLIC TASTE IN MY MOUTH. OVERALL FATIGUE. HEADACHES. MUSCLE ACHES. SHOOING PAIN FROM BACK TO LEGS. EXCRUCIATING BACK PAIN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058682	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 5/1/2007 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I HAD ESSURE PLACED AFTER 4 CHILD WAS BORN WITH WEEKS I STARTED HAVING SHARP PAIN IN MY VAGINAL AREA ALONG WITH PAIN IN MY LEFT HIP. SINCE THEN I HAVE CONTINUED TO HAVE PROBLEMS WHICH INCLUDE HAIR LOSS, ANXIETY, DEPRESSION, DIAGNOSIS OF FIBROMYALGIA PAIN IN MY MUSCLES, JOINTS, RASHES ON MY ENTIRE BODY, I WAS ON STATE MEDICAL WHEN PLACED. I HAVE ON GOING MEDICAL ISSUES AND WILL HAVE TO HAVE HYSTERECTOMY TO ALLEVIATE THE PAIN I HAVE ALSO GAINED WEIGHT AND DUE TO AMOUNT OF PAIN IN ABDOMINAL AND JOINTS I'M UNABLE TO EXERCISE IN A HELPFUL WAY.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058683	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 10/23/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I JUST FOUND OUT THAT DAY THAT I AM 10 WEEKS PREGNANT WHICH I'M NOT SUPPOSED TO BE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058684	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 12/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). IN 2010 I HAD ESSURE DEVICE INSERTED TO PREVENT PREGNANCY. ALMOST IMMEDIATELY I LOOKED 3 MONTHS PREGNANT WITH A BLOATED STOMACH. THE LAST 6 YEARS I HAVE BEEN DIAGNOSED WITH HIGH BLOOD PRESSURE, DEPRESSION, EXTREME INFLAMMATION, UNDERACTIVE THYROID, EXTREME WEIGHT GAIN, BRAIN FOG, ACHY BODY AND JOINTS, EXTREME FATIGUE. ESSURE WAS THE WORST DECISION I EVER MADE. IT CAUSES INFLAMMATION TO BLOCK YOUR TUBES BUT IT CAUSED SO MUCH INFLAMMATION IN MY ENTIRE BODY THAT I FEEL SICK ALL THE TIME. I AM SCHEDULED TO HAVE A TOTAL HYSTERECTOMY IN (B)(6) 2016.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058685	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 6/9/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, HEADACHES, ABNORMAL MENSTRUAL CYCLE, PELVIC PAIN, HOT FLASHES, SEIZURE, SEVER BACK PAIN, DEPRESSION, MOOD SWINGS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058686	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BLOATING, BACK PAINS, LEG PAIN, HIP PAIN, CRAMPING AND TENDERNESS IN ABDOMINAL AREA, PRESSURE WHEN URINATING, PELVIC CRAMPING, FATIGUE AND LETHARGY, GAS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058687	BAYER	12/22/2015	12/22/2015

Event Information:

Event Date (B3): 3/3/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). BEFORE HAVING THE PRESSURE MY ONLY MEDICAL CONDITION WAS HIGH BLOOD PRESSURE. I HAD ECLAMPSIA ON (B)(6) 2015, WAS ADVISED NOT TO HAVE ANY MORE CHILDREN.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058742	CONCEPTUS INCORPORATED	12/22/2015	12/24/2015

Event Information:

Event Date (B3): 3/7/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Device Type (E2): ESSURE PERMANENT BIRTH CONTROL SYSTEM
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 5/1/2013
Explant Date (E7): 3/7/2014
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD ESSURE DEVICE PUT IN MAY OF 2013, HAD FOR SEVERAL MONTHS. IN (B)(6) 2014, NOTICED BLEEDING THAT WAS ABIT HEAVIER THAN USUAL ALREADY HAD HYSTERECTOMY SCHEDULED FOR (B)(6) OF 2014. WHEN DOCTOR GOT ME IN, HE FOUND THE DEVICES BROKEN INSIDE MY BODY WHICH CAUSED ME TO BE BLEEDING SO HEAVY. MY HYSTERECTOMY SAVED MY LIFE. I HAD DEVICE PLACED, MONTHS WENT BY, IN (B)(6) OF 2014 I WAS SITTING IN CLASS, NOTICED A HEAVY AMOUNT OF BLOOD THROUGH. IT WAS MY CYCLE. I HAD ALREADY HAD SURGERY FOR HYSTERECTOMY SCHEDULED FOR OVER SPRING BREAK. GO IN FOR SURGERY COME OUT TO FIND OUT MICRO-INSERT HAD CAME OUT OF MY FALLOPIAN TUBES LONG BEFORE SURGERY. ONE WAS PUNCTURING MY UTERUS AND THE OTHER WAS LAYING IN MY CERVIX. I HAD A LARGE BLACK/BLUE MARK ON MY STOMACH WHEN I WOKE UP. WAS LATER ADMITTED. TWO WEEKS LATER HONESTLY I AM NOT EXACTLY SURE I HAD SOME MEDICINE IN ME FROM ALL THE PAIN, I DON'T REMEMBER MUCH. I HAVE PICTURES AND THIS CARD I WAS GIVING AFTER ESSURE WAS PUT IN MY BODY. I HAD TO BE ON BED REST FOR MONTHS. I WAS WITHDRAWN FROM SCHOOL. I RUIN A LOT FOR ME. IT WAS VERY PAINFUL. PERMANENT BIRTH CONTROL. QUANTITY: 2; FREQUENCY: ONCE.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058763	BAYER	12/22/2015	12/28/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

HAD MY ESSURE PUT IN (B)(6) 2012. BEEN HAVING EXTREME MIGRAINES, BLOATING, SWELLING, LOWER BACK PAIN, LEG PAIN, MY INSIDES FEELS LIKE THEY ARE BEING TIED IN KNOTS, ABDOMINAL PAIN, HEAVY BLEEDING, AND PAINFUL PERIODS.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058764		12/22/2015	12/28/2015

Event Information:

Event Date (B3): 12/22/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 948836

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAVE BEEN IMPLANTED WITH ESSURE IN (B)(6) 2012. OVER THE PAST YEAR AND A HALF, I HAVE BEN HAVING PELVIC PAIN THAT HAS WORSENED OVER TIME TO INCLUDE CRAMPING, SHOOTING/STABBING PAINS IN PELVIS AND VAGINA. I ALSO HAVE TWITCHING/FLUTTERING IN MY STOMACH. I HAVE CONSTANT BACK PAINS. I WENT FROM TAKING LONGER TO HAVING AN ORGASM TO SEX BECOMING PAINFUL TO NOW HAVING NO SEX DRIVE. I HAVE HEADACHES THAT HAVE BEEN MORE FREQUENT/PAINFUL. MY PERIODS HAVE BECOME PAINFUL AND I HAVE CONSTANT BRAIN FOG. I HAVE PAIN SHOOTING DOWN THE FRONT PART OF MY THIGHS. I FEEL BLOATED ALL THE TIME AND AT TIMES HAVE A "HEAVY" FEELING IN MY VAGINA LIKE MY INSIDES ARE GOING TO FALL UT OF ME.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058765	BAYER	12/22/2015	12/28/2015

Event Information:

Event Date (B3): 2/22/2006 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE COILS
Device Type (E2): ESSURE COILS
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 2/22/2006
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

AFTER IMPLANTS, I NOTICED SEVERAL THINGS OCCURRING WITHIN MY BODY BUT DIDN'T QUITE PUT IT TOGETHER UNTIL YEARS LATER: LOSS OF TOOTH (TOOTH #6) ON UPPER LEFT SIDE, TINGLING, NUMBING SENSATION IN LIMBS ON LEFT SIDE OF BODY, SEVERAL ROOT CANAL RETREATS ON TOOTH 19, ACUTE MIGRAINE OCCURRENCES AFTER BEING MIGRAINE FREE, INABILITY TO SLEEP, RESTLESSNESS, BRAIN FOG, GUM PAIN, FREQUENT BOUTS OF BACTERIAL VAGINITIS, HEAVY CLOTTING WHERE I NEVER CLOTTED BEFORE DURING MENSTRUAL CYCLE AND FREQUENT INCIDENTS OF BREAK THROUGH PERIOD BETWEEN MENSTRUAL CYCLES. MENSTRUAL CYCLE IS OFTEN FOUL-SMELLING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058766	BAYER	12/22/2015	12/28/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6): 11/8/2010
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE HAS CAUSED HAIR LOSS, PAIN IN MY LEFT SIDE DOWN INTO MY LEG, HEAVY PERIODS, PAINFUL PERIODS, PAINFUL INTERCOURSE. I SHOULDN'T HAVE BEEN IMPLANTED BECAUSE I ONLY HAVE ONE TUBE. THIS IS A CONTRAINDICATION. I WILL BE HAVING A HYSTERECTOMY TO REMOVE IN (B)(6).

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058774	CONCEPTUS, USA	12/22/2015	12/28/2015

Event Information:

Event Date (B3): 8/21/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A63347

Single Use: *
Implant Date (E6): 8/21/2013
Explant Date (E7): 3/9/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

ESSURE INSERTED (B)(6) 2013. SIDE EFFECTS: WEIGHT GAIN, PELVIC PAIN, NO MENSTRUAL CYCLE THEN HEAVY MENSTRUAL CYCLE THAT BLED THROUGH A PAD IN LESS THAN ONE HOUR, HEADACHE, BLOATED, GOT PREGNANT WHILE ESSURE INSERTED THEN HAD TO GET PART OF MY TUBE REMOVED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058777	BAYER	12/23/2015	12/29/2015

Event Information:

Event Date (B3): 6/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 787229

Single Use: *
Implant Date (E6): 6/1/2011
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

UNRELENTING PAIN FROM ESSURE IMPLANTS. HAPPENS DURING MENSTRUAL PERIOD AND WHILE OVULATING.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: OTHER**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058778		12/23/2015	12/29/2015

Event Information:

Event Date (B3): 2/8/2013 **Report Date (B4):** **Event Report Type (H1):** OTHER **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2): ESSURE
Model # (E4): ESSURE
Catalog # (E4):
Lot #(E4): A15527

Single Use: *
Implant Date (E6): 2/8/2013
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

I HAD ESSURE DEVICE IMPLANTED IN (B)(6) 2013, AND HAD THE CONFIRMATION TEST IN (B)(6) 2013. I WAS (B)(6). SINCE THEN I HAVE HAD INCREASING HEAVIER PERIODS AND INCREASING LOWER ABDOMINAL AND PELVIC PAIN. I HAD NOT HAD ANY TESTING FOR SYMPTOMS TO DATE, BUT WILL BE SOON AS SYMPTOMS ARE GETTING MORE PAINFUL.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: USER FACILITY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
Not Releasable (B)(2)	BAYER HEALTHCARE	12/24/2015	12/24/2015

Event Information:

Event Date (B3): 11/25/2015 **Report Date (B4): 11/25/2015** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1):
Device Type (E2): INSERT, TUBAL OCCLUSION
Model # (E4): ESS306
Catalog # (E4):
Lot #(E4): DO6939

Single Use: *
Implant Date (E6): 11/25/2015
Explant Date (E7):
Device Available for Evaluation (C6): Y
Date Device Returned to Mfr (C3):

Event Description (B5):

DEVICE WOULD NOT ROLL BACK TO DISCLOSE COPPER COIL AND FIRED DEEP INTO FALLOPIAN TUBE.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058746	BAYER	12/26/2015	12/26/2015

Event Information:

Event Date (B3): 12/2/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . HEAVY PERIODS, CHRONIC PAIN, JOINT PAIN, MOOD SWINGS, DEPRESSION, ANXIETY, RASHES, HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058747	BAYER	12/26/2015	12/26/2015

Event Information:

Event Date (B3): 4/9/2009 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . I HAD THE IMPLANT DONE, NOW I'M HAVING A HYSTERECTOMY ON (B)(6) . REMOVAL OF TUBES, CERVIX AND REPAIR BLADDER.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058748	BAYER	12/26/2015	12/26/2015

Event Information:

Event Date (B3): 5/13/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). NUMBNESS AND TINGLING IN MY HANDS, LEFT TO MY KNEE, ABDOMINAL SWELLING AND PAIN, BLOATING, CRAMPING MORE SEVERE DURING PERIODS SHORT IRREGULAR HEAVY FLO, INCREASED DEPRESSION AND ANXIETY, HORRIBLE HEADACHES AND METALLIC TASTE IN M.P.H. MOUTH.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058749	BAYER	12/26/2015	12/26/2015

Event Information:

Event Date (B3): 9/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . BECAME LETHARGIC, THYROID LIKE SYMPTOMS, FIBROMYALGIA LIKE SYMPTOMS, BLOOD CLOTTING DURING AND BETWEEN MENSTRUAL CYCLES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058750	BAYER	12/26/2015	12/26/2015

Event Information:

Event Date (B3): 2/2/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):
Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). EXTREME BRUISING, MAJOR HAIR LOSS.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058751	BAYER	12/26/2015	12/26/2015

Event Information:

Event Date (B3): 10/8/2012 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). I GOT ESSURE DEVICE IMPLANT IN (B)(6) 2012, IT WAS COVERED BY MY INSURANCE AND PLACED BY MY DOCTOR AT HIS OFFICE. IT WAS FAR MORE PAINFUL TO HAVE DONE THAN I HAD IMAGINED. HOWEVER I RETURNED TO WORK THAT SAME DAY. THE FIRST FEW WEEKS AFTER PROCEDURE AND INTO A FEW MONTHS EVERYTHING SEEMED FINE, MY PERIODS WERE SLIGHTLY HEAVIER THAN BEFORE I HAD THE DEVICE BUT NOT UNBEARABLE, I DID EXPERIENCE WHAT FELT ALMOST LIKE CONTRACTIONS, AND SOME BURNING SENSATIONS BUT JUST FIGURED IT WAS MY BODY ADJUSTING. OVER THE PAST THREE YEARS MY PERIODS HAVE INCREASED TO AN ABNORMALLY HEAVY FLOW AND ARE INCREASINGLY LONGER, MANY MONTHS HAVING 2 CYCLES PRE-ESSURE MY PERIODS WERE MODERATE FLOW FOR APPROXIMATELY 4 DAYS. DURING OUR FAMILY VACATION THIS YEAR THE BLEEDING WAS EXTREME I WAS SOAKING THROUGH A SUPER TAMPON IN LESS THAN AN HOUR FOR SEVERAL DAYS AND MY PERIODS OFTEN LAST 10 DAYS. I HAVE ALSO STARTED EXPERIENCING SEVERE HEADACHES SOMETIMES 2 TIMES A WEEK WHERE I PREVIOUSLY HAD 1 A MONTH. I AM LOSING A LOT OF HAIR. I AM ALSO EXPERIENCING EXCESSIVE CHRONIC FATIGUE FOR THE LAST TWO YEARS I THINK I HAD TO GO INTO HAVE VITAMIN B AND VITAMIN D SHOTS BECAUSE MY VITAMIN LEVELS WERE EXTREMELY LOW. I WENT TO MY PRIMARY CARE DR. TELLING HER I'M SLEEPING ALL THE TIME I FEEL SICKLY, I FEEL LIKE SOMETHING IS KILLING MY BODY , I FEEL LIKE MY BODY IS DYING I SLEEP CONTINUALLY I REQUESTED A CBC BECAUSE I WAS ALSO LOSING MY HAIR IN LARGE QUANTITIES SCARED TO DEATH SHE WAS GOING TO TELL ME I HAD CANCER AND THAT WAS THE REASON I WAS SUFFERING FROM ALL THE CRAZINESS AFFECTING IN MY BODY AFTER RUNNING MULTIPLE BLOOD TESTS. SHE REPORTED ALL MY BLOOD TESTS WERE NORMAL AND SENT ME TO MY OBGYN BECAUSE OF THE BLEEDING AND THE SEVERE PAIN I WAS EXPERIENCING AT WHICH TIME HE SCHEDULED ME FOR AN IN OFFICE HYSTEROSCOPY TO CHECK ME FOR ABNORMAL CELLS POLYPS -PRAISE GOD

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ALL NEGATIVE -HOWEVER THE PROBLEMS WERE BEING CAUSED BY SOMETHING, AND I WAS DETERMINED TO GET MY LIFE BACK!!! AFTER THE HYSTEROSCOPY HE GAVE ME THE CHOICE TO HAVE A SURGICAL PROCEDURE CALLED ABLATION DONE OR ANOTHER LESS INVASIVE POSSIBLE SOLUTION WOULD BE TO GO BACK ON THE PILLS TO SEE IF THIS WOULD HELP - THE PILLS HELPED SOME BUT THE OTHER SYMPTOMS CONTINUED SO I RETURNED TO HIM COMPLAINING SOMETHING IS DRAINING ALL MY ENERGY I ALSO TOLD HIM I CANNOT EXPLAIN THIS, I FEEL LIKE SOMETHING IS KILLING MY BODY!!! NOT TO MENTION THE COMPLETE LACK OF SEXUAL DESIRE DUE TO EXTREME PAIN DURING AND AFTER- MY POOR HUSBAND HE HAS SUFFERED MUCH AS WELL AND MY FAMILY WITH ME CONSTANTLY DECLINING FROM PARTICIPATED IN THINGS WITH THEM EITHER BECAUSE I WAS TOO WEAK AND TIRED , BLEEDING TO HEAVILY, OR IN TOO MUCH PAIN. THIS ALL BEING SAID HE POINTED MY ATTENTION TOWARD THE FACT THAT NEW EVIDENCE COMING FORTH WITH PEOPLE EXPERIENCING SEVERAL OF THE SYMPTOMS I HAD SUFFERED WITH FOR SO LONG- THAT HAD RECEIVED THE ESSURE IMPLANTS, LIGHT BULB REALLY COULD ALL OF MY PAIN AND SUFFERING BEEN ELIMINATED YEARS AGO.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058752	BAYER	12/27/2015	12/27/2015

Event Information:

Event Date (B3): 7/1/2010 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . DEBILITATING, CHRONIC MIGRAINES OVER HALF OF THE MONTH, SEVERE CLOTTING DURING MENSTRUATION, EXTREMELY HEAVY MENSTRUAL FLOW, VERY PAINFUL CRAMPING BEFORE, DURING, AND AFTER MENSTRUATION, CONSTANT FATIGUE, PANIC DISORDER, SEVERE ANXIETY, DEPRESSION, WEIGHT GAIN.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058753	BAYER	12/27/2015	12/27/2015

Event Information:

Event Date (B3): 8/1/2011 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4) . SUDDEN ONSET OF MULTIPLE UTI'S AND YEAST INFECTIONS. WENT TO THE DOCTOR AND WAS DIAGNOSED WITH 2-3 UTI'S AND AT LEAST 1 YEAST INFECTION EVERY 3 MONTHS. GRADUAL WEIGHT GAIN ONLY IN ABDOMINAL AREA DESPITE EXERCISING DAILY AND EATING A GLUTEN FREE, WHOLE FOOD DIET. NUMBNESS, SWELLING, REDNESS, AND SWEATING DOWN ONE OR BOTH LEGS, MULTIPLE TIMES A DAY, LASTING AT LEAST 20 SECONDS EACH TIME. SKIN RASHES COMING AND GOING. - HARDER TIME HEALING FROM ANY WOUND OR ILLNESS. - DEVELOPMENT AND CONFIRMED BY ALLERGIST OF CELIAC, AND EXTREME ALLERGY TO APPLES.

Manufacturer Narrative (H10):

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Report Type: VOLUNTARY **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5058754	BAYER	12/28/2015	12/28/2015

Event Information:

Event Date (B3): 6/1/2014 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: INSERT, TUBAL OCCLUSION (HHS)
Brand Name (E1): ESSURE
Device Type (E2):
Model # (E4):
Catalog # (E4):
Lot #(E4):

Single Use: *
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

(B)(4). SINCE GETTING THE ESSURE PLACED I HAVE BELOW SYMPTOMS. 2-3 YEAST INFECTIONS A MONTH, HOT FLASHES, DENTAL PROBLEMS, CLOTTING, SEVERE PAIN DURING INTERCOURSE, MOOD SWINGS, HAIR LOSS AND MANY MORE...

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01971	BAYER HEALTHCARE LLC	12/29/2015	12/29/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): 664438

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY (CASE # (B)(4)) IN (B)(6) ON 02-DEC-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2010 (LOT NUMBER 664438), BY A GYNECOLOGY TEAM. CONSUMER INFORMED THAT AT A VISIT TO THE FAMILY PLANNING SERVICE SHE REQUESTED INFORMATION ON CONTRACEPTIVE METHODS SUCH AS TUBAL LIGATION, AS SHE DID NOT WISH TO HAVE A LARGER FAMILY. ESSURE WAS RECOMMENDED TO HER AS IT DID NOT INVOLVE SURGERY AND THERE WOULD BE NO CHANCE OF PREGNANCY AFTER THREE MONTHS AS THE FALLOPIAN TUBES ARE COMPLETELY BLOCKED. SHE WAS REFERRED TO THE HOSPITAL AND, THROUGH A CAMERA, SHE HAD THE TWO DEVICES IMPLANTED. CONSUMER DO NOT REMEMBER WHETHER THEY SEDATED HER, BUT SHE DOES REMEMBER THE STRONG PAIN, NAUSEA AND VOMITING THAT SHE HAD WHILE THEY IMPLANTED THEM. WHEN CONSUMER CAME OUT OF THE PROCEDURE THEY GAVE HER A PAINKILLER BECAUSE SHE HAD LITTLE INFLAMMATION AND ABDOMINAL DISCOMFORT. AFTER THREE MONTHS THEY DID A CONTRAST TEST TO MAKE SURE THAT EVERYTHING WAS FINE, AND ONCE AGAIN CONSUMER ENDED UP WITH SEVERAL EPISODES OF PAIN AND PROBLEMS FOR PERFORMING THE TEST. AT THE CONSULTATION THEY SAID THAT EVERYTHING WAS NORMAL. THEN, SHE STARTED TO HAVE TIREDNESS, PAIN IN HER LEGS AND ARMS, WEIGHT LOSS, BLOOD TEST ABNORMALITIES AND URINARY INFECTIONS, STRONG PELVIC PAIN, PAIN DURING SEXUAL INTERCOURSE, AND IT WAS A CONSTANT PAIN THAT KEPT HER AWAY FROM HAVING A NORMAL LIFE. THE DOCTOR, TIRED OF NOT KNOWING WHERE SUCH PAIN COULD BE COMING FROM, REFERRED HER TO THE GYNECOLOGY DEPARTMENT AGAIN AND THERE THEY DIAGNOSED HER WITH PELVIC PAIN FOLLOWING ESSURE. FOR THIS REASON, ON (B)(6) (YEAR WAS NOT SPECIFIED), THE IMPLANTS WERE REMOVED THROUGH A BILATERAL SALPINGECTOMY. NO FOLLOW-UP ATTEMPT IS

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EXPECTED BECAUSE PHYSICIAN CONTACT DETAILS WERE NOT PROVIDED. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 15-DEC-2015. THE BAYER REFERENCE NUMBER FOR THE PTC REPORT IS: (B)(4), LOT NUMBER 664438, MANUFACTURING DATE 08/2009, EXPIRATION DATE 08/2012 FINAL ASSESSMENT FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. WE CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD AND CONFIRMED THAT FINAL PRODUCT TESTING FOR THIS LOT WAS PERFORMED PER REQUIREMENTS AND THE PRODUCT MET ALL RELEASE REQUIREMENTS. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. THE REPORTED MEDICAL EVENTS ARE NOT INDICATIVE OF A QUALITY DEFICIT PER SE. NO SIMILAR AE CASES HAVE BEEN RECEIVED IN RELATION TO THE REPORTED BATCH. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 17-DEC-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: PELVIC PAIN. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED (B)(4) CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS NON-MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND HAD STRONG PELVIC PAIN / CONSTANT PAIN. SHE HAD THE DEVICES REMOVED VIA BILATERAL SALPINGECTOMY. THIS EVENT WAS CONSIDERED SERIOUS DUE TO MEDICAL SIGNIFICANCE AND IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. AFTER ESSURE INSERTION, PELVIC PAIN MAY OCCUR. GIVEN THE NATURE OF THE REPORTED EVENT AND IN THE LACK OF AN ALTERNATIVE EXPLANATION, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. NON-SERIOUS EVENTS WERE ALSO REPORTED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED, THEREFORE THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. NO FOLLOW-UP IS EXPECTED SINCE PHYSICIAN CONTACT DETAILS WERE NOT PROVIDED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01972	BAYER HEALTHCARE LLC	12/29/2015	12/29/2015

Event Information:

Event Date (B3): 8/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): A63344

Single Use: Y
Implant Date (E6): 8/25/2015
Explant Date (E7): 11/3/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 03-DEC-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN (B)(6) 2015 FOR CONTRACEPTION. THE PHYSICIAN REPORTED THAT PATIENT COMPLAINED OF COMPLICATION, HEADACHES AND WANTED ESSURE REMOVED AND TO BE STERILIZED. THE DEVICE WAS REMOVED BY HYSTEROSCOPY AND STERILIZATION WAS DONE ON (B)(6) 2015. COMPANY CAUSALITY COMMENT: THIS MEDICALLY-CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO COMPLAINED OF COMPLICATION FROM ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). SHE REQUESTED DEVICE REMOVAL AND STERILIZATION; WHICH WERE DONE BY THE PHYSICIAN APPROXIMATELY 10 MONTHS AFTER ESSURE PLACEMENT. THE REPORTED EVENT IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. IN THIS CASE, MINIMAL INFORMATION WAS GIVEN. PHYSICIAN STATED PATIENT COMPLAINED OF COMPLICATION, HEADACHE AND REQUESTED ESSURE REMOVAL. ALTHOUGH IT IS UNCLEAR WHICH COMPLICATION SHE WAS COMPLAINING ABOUT (IF REMOVAL WAS REQUESTED DUE TO HEADACHE OR IF IT WAS RELATED TO ANOTHER EVENT); SINCE ESSURE REMOVAL WAS REQUIRED; CAUSALITY BETWEEN THE REPORTED COMPLICATIONS AND THE SUSPECT INSERT CANNOT BE EXCLUDED. SINCE MEDICAL/SURGICAL INTERVENTION WAS REQUIRED; THIS CASE IS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL COMPLAINT ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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FOLLOW-UP INFORMATION RECEIVED ON 04-JAN-2016 - HCP GENERAL QUESTIONNAIRE PROVIDED: THE PATIENT WAS (B)(6). CONCURRENT CONDITIONS INCLUDED OVERWEIGHT (BMI (B)(6)). DRUG HISTORY INCLUDED IUD. PREVIOUS GYNECOLOGICAL PROBLEMS WERE DENIED. ESSURE INSERTION DA

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01973	BAYER HEALTHCARE LLC	12/29/2015	12/29/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/29/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR CONTRACEPTION/PERMANENT STERILIZATION. ON (B)(6) 2015, PHYSICIAN REPORTED THAT PART OF THE ESSURE WAS EXPELLED WHILE THE PATIENT WAS IN THE OFFICE. WHEN THE PATIENT ARRIVED HOME, SHE CALLED AND STATED THE OTHER PART OF THE ESSURE WAS EXPELLED ON THE FLOOR. SHE DID NOT HAVE THE LOT NUMBER EXPIRATION DATE AND DID NOT WANT A REPLACEMENT. THE PATIENT WAS ASYMPTOMATIC. THE DOCTOR DID NOT WANT TO PROCEED WITH PLACING ANOTHER ONE, AND WILL MOST LIKELY PERFORM BILATERAL TUBAL LIGATION WHICH HAS NOT BEEN SCHEDULED YET. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND APPROXIMATELY ONE MONTH LATER, PART OF THE ESSURE WAS EXPELLED WHILE SHE WAS IN PHYSICIAN'S OFFICE AND OTHER PART OF THE ESSURE EXPELLED ON THE FLOOR AT HER HOME. PATIENT WAS ASYMPTOMATIC. THE REPORTED EVENTS WERE REGARDED AS SUSPICION OF DEVICE BREAKAGE FOLLOWED BY DEVICE EXPULSION. DEVICE BREAKAGE IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE THE OTHER EVENT IS LISTED. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. NEVERTHELESS, GIVEN EVENTS' NATURE, A CAUSAL RELATIONSHIP WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO SUSPICION OF DEVICE BREAKAGE, AS ALTHOUGH PATIENT HAD NO DEATH OR SERIOUS

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HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. FOLLOW-UP INFORMATION AND A PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01976	BAYER HEALTHCARE LLC	12/29/2015	12/29/2015

Event Information:

Event Date (B3): 10/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 11/6/2009
Explant Date (E7): 10/16/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN VIA SALES REPRESENTATIVE IN UNITED STATES ON 04-DEC-2015 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2009, FOR PERMANENT CONTRACEPTION. PHYSICIAN REMOVED ESSURE DURING HYSTERECTOMY ON (B)(6) 2015; ONE COIL, THE SIDE WAS NOT KNOWN BY THE SALES REPRESENTATIVE, PERFORATED UTERUS. ON (B)(6) 2012 ULTRASOUND NOTED RIGHT COIL IN DISTAL CORNUA AND THE LEFT TUBE WAS NOTED IN PROXIMAL CORNUA, ABLATION WAS DONE. ON (B)(6) 2015 THE PATIENT WENT TO HCP (HEALTH CARE PROFESSIONAL) FOR PELVIC PAIN AND ULTRASOUND DONE. BOTH IMPLANTS WERE SEEN IN TYPICAL CORNUAL POSITION. PERFORATION WAS FOUND DURING HYSTERECTOMY. THE PAIN WAS GONE POST-HYSTERECTOMY. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND UNDERWENT AN ABLATION (INTERPRETED AS ENDOMETRIAL ABLATION) APPROXIMATELY 2 YEARS LATER. SIX YEARS AFTER ESSURE INSERTION, DURING HYSTERECTOMY, IT WAS FOUND THAT ONE COIL PERFORATED UTERUS. ESSURE WAS REMOVED. THESE EVENTS ARE SERIOUS DUE TO MEDICAL SIGNIFICANCE. EVENT ONE COIL PERFORATED UTERUS IS LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE, THE OTHER EVENT IS UNLISTED. IN THE PRESENT CASE, THE EXACT INDICATION FOR THE ENDOMETRIAL ABLATION WAS NOT SPECIFIED THEREFORE CAUSALITY BETWEEN ABLATION AND ESSURE CANNOT BE ASSESSED. THE EXACT DATE AND MECHANISM OF THE PERFORATION WAS NOT REPORTED. PATIENT COMPLAINED OF PELVIC PAIN AND ULTRASOUND DONE 3 MONTHS PRIOR TO THE HYSTERECTOMY SHOWED IMPLANTS IN TYPICAL CORNUAL POSITION. PERFORATION WAS DIAGNOSED

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DURING HYSTERECTOMY. GIVEN THE NATURE OF THE REPORTED EVENT, CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WAS REQUIRED. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01977	BAYER HEALTHCARE LLC	12/29/2015	12/29/2015

Event Information:

Event Date (B3): 12/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): KNH - DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO UNDERWENT AN ATTEMPT TO HAVE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR CONTRACEPTION. PHYSICIAN WAS DOING A PARACERVICAL BLOCK BEFORE INSERTING ESSURE AND PATIENT BEGAN TO SEIZE AND WENT INTO CARDIAC ARREST. ESSURE WAS NEVER INSERTED AND PATIENT WAS ADMITTED TO HOSPITAL AND TRANSFERRED TO CARDIAC CARE UNIT. FOLLOW-UP RECEIVED ON 10-DEC-2015: THE PRACTICE ADMINISTRATOR, ON BEHALF OF THE PHYSICIAN, STATED THAT ESSURE HAD NOTHING TO DO WITH IT, NOTHING EVER GOT DONE. HE DID NOT WISH TO PROVIDE ANY FURTHER FOLLOW-UP INFORMATION AT THIS TIME. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT REFERS TO A (B)(6) YEAR-OLD FEMALE PATIENT WHO BEGAN TO SEIZE AND WENT INTO CARDIAC ARREST UNDER PARACERVICAL BLOCK BEFORE INSERTING ESSURE (FALLOPIAN TUBE OCCLUSION INSERT). SHE WAS ADMITTED TO HOSPITAL AND WAS TRANSFERRED TO A CARDIAC CARE UNIT. THESE EVENTS ARE SERIOUS DUE TO THE HOSPITALIZATION AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE SEIZURE ACTIVITY FOLLOWED BY CARDIOVASCULAR COLLAPSE WAS OBSERVED DURING PARACERVICAL BLOCK AND PRIOR TO ESSURE INSERTION. LOCAL ANESTHETICS USED TO PERFORM PARACERVICAL BLOCK ARE THE MOST LIKELY CAUSE FOR THESE EVENTS. ALTHOUGH ESSURE WAS NEVER INSERTED IN THE PATIENT, THE SEIZURE AND CARDIAC ARREST ARE ASSESSED AS RELATED TO THE ESSURE INSERTION PROCEDURE. THIS CASE IS REGARDED AS INCIDENT SINCE A HOSPITALIZATION AND A LIFE-THREATENING CONDITION WERE REPORTED IN ASSOCIATION WITH THE ESSURE INSERTION PROCEDURE. A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT. THE REPORTER DID NOT WISH TO PROVIDE ANY FURTHER FOLLOW-UP INFORMATION.

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Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01959	BAYER HEALTHCARE LLC	12/30/2015	12/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS205
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 1/1/2005
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON (B)(6) 2015. IT REFERS TO HERSELF, WHO HAD ESSURE ((B)(4)) (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED IN 2005. ADDITIONAL INFORMATION WAS ALSO RECEIVED ON (B)(6) 2015. CONSUMER REPORTED SHE IS A MOTHER OF (B)(6) KIDS AND SHE IS SEEING A PHYSICIAN TO HOPEFULLY GET A DATE TO GET THE ESSURE COILS REMOVED. SHE HAS ALREADY HAD SURGERY TO REOPEN HER URETER ON HER RIGHT KIDNEY DUE TO THE MIGRATION OF THE COIL. INTERNAL COMMUNICATION RECEIVED ON (B)(6) 2015: THE FOLLOW-UP REQUEST CANNOT BE COMPLETED AS THERE IS NO PRIMARY REPORTER CONTACT INFORMATION. COMPLAINT CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WAS SUBMITTED TO A SURGERY TO REOPEN HER URETER ON HER RIGHT KIDNEY DUE TO THE MIGRATION OF THE ESSURE COIL. ONLY DEVICE MIGRATION IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. DURING ESSURE MICRO-INSERT THERAPY, THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES; THIS MOVEMENT COULD BE AN EXPULSION INTO UTERUS/OUT OF THE BODY OR MIGRATION TO DISTAL FALLOPIAN TUBE/PERITONEAL CAVITY. IN THIS PARTICULAR CASE, MINIMAL INFORMATION WAS PROVIDED. THE EXACT LOCATION OF ESSURE COIL AND SURGICAL DETAILS WERE NOT INFORMED. SINCE THE EXACT MEDICAL REASON FOR THE REPORTED URETERIC SURGERY IS UNCLEAR; CAUSALITY BETWEEN THIS EVENT AND ESSURE CANNOT BE ASSESSED BY NOW. REGARDING DEVICE MIGRATION, DESPITE OF THE LACK OF DETAILS FOR A COMPREHENSIVE CAUSALITY ASSESSMENT, BASED ON EVENT'S NATURE CAUSALITY WITH ESSURE CANNOT BE EXCLUDED. THIS

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CASE WAS CONSIDERED AN INCIDENT, AS ACCORDING TO THE CONSUMER A SURGICAL INTERVENTION WAS REQUIRED DUE TO ESSURE MIGRATION. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. SINCE NO CONTACT DETAILS WERE PROVIDED, NO FURTHER INFORMATION WAS OBTAINED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01960	BAYER HEALTHCARE LLC	12/30/2015	12/30/2015

Event Information:

Event Date (B3): 5/1/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7): 5/1/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE IN UNITED STATES ON 30-NOV-2015 WHICH REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED SHE HAD COMPLICATIONS FROM ESSURE AND HAD HER FALLOPIAN TUBES REMOVED IN (B)(6)-2015. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT WAS RECEIVED FROM A FEMALE CONSUMER. SHE STATED SHE HAD COMPLICATIONS FROM ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) AND HAD HER FALLOPIAN TUBES REMOVED. THIS EVENT WAS CONSIDERED SERIOUS, DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED IN ESSURE'S REFERENCE SAFETY INFORMATION. IF, AFTER ESSURE INSERTION, REMOVAL OF THE MICRO-INSERT IS NECESSARY, SURGERY (SALPINGECTOMY OR HYSTERECTOMY) MAY BE REQUIRED. IN THIS PARTICULAR CASE, MINIMAL INFORMATION WAS PROVIDED AND CONSUMER'S COMPLICATIONS WERE NOT SPECIFIED. NEVERTHELESS; CONSIDERING DEVICE REMOVAL WAS REQUIRED (SALPINGECTOMY PERFORMED), CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THEREFORE; THIS CASE WAS CONSIDERED AN INCIDENT. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01961	BAYER HEALTHCARE LLC	12/30/2015	12/30/2015

Event Information:

Event Date (B3): 1/1/2013 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 9/13/2013
Explant Date (E7): 11/13/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A CONSUMER VIA REGULATORY AUTHORITY FDA MAUDE (CASE# MW5057928) IN UNITED STATES ON 30-NOV-2015 WHICH REFERS TO A FEMALE CONSUMER OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2013. CONSUMER HAD THE PROCEDURE DONE AND WENT BACK FOR HER 3 MONTH CHECKUP AND THE DOCTOR INFORMED HER THAT ONE OF THE COILS HAD MIGRATED TO HER OVARY. IN 2013 SHE HAD A SURGERY TO REMOVE THE COIL FROM HER RIGHT OVARY. SHE HAS ALSO HAD SOME SEVERE DISCOMFORT WITH THE REMAINING COIL ESPECIALLY DURING INTERCOURSE OVER LAST COUPLE OF YEARS. ON (B)(6) 2015 SHE HAD ANOTHER SURGERY TO REMOVE THE LEFT COIL. CONCOMITANT MEDICATIONS INCLUDE HYDROCODONE/ACETAMINOPHEN, IBUPROFEN 800MG FOR PAIN, (B)(6), MULTIVITAMINS. THE SERIOUSNESS CRITERIA HOSPITALIZATION WAS MENTIONED IN THE SECTION EVENT OUTCOME BUT IT WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. FOLLOW-UP FROM 22-DEC-2015: NO FURTHER INFORMATION WAS OBTAINED DESPITE FOLLOW-UP ATTEMPTS. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND WHEN SHE WENT BACK FOR HER 3 MONTH CHECKUP, THE DOCTOR INFORMED HER THAT ONE OF HER COILS HAD MIGRATED TO HER OVARY (INTERPRETED AS DEVICE MIGRATION). SHE HAD A SURGERY TO REMOVE THE COIL FROM HER RIGHT OVARY. SHE ALSO EXPERIENCED SEVERE DISCOMFORT WITH THE REMAINING COIL ESPECIALLY DURING INTERCOURSE (SEEN AS ABDOMINAL DISCOMFORT AND PAINFUL INTERCOURSE). ANOTHER SURGERY WAS PERFORMED IN ORDER TO REMOVE THE LEFT COIL. THESE EVENTS, EXCEPT PAINFUL INTERCOURSE, ARE SERIOUS AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. PAINFUL INTERCOURSE WAS CONSIDERED NON-SERIOUS AND LISTED. MIGRATION IS

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OFTEN USED SYNONYMOUSLY WITH PERFORATION. IT IS SOMETIMES USED TO IMPLY THAT A COMPLETE PERFORATION OCCURRED NOT IMMEDIATELY, BUT OVER TIME, E.G. WHEN AN UNDIAGNOSED PARTIAL PERFORATION DURING INSERTION GRADUALLY LEADS TO A COMPLETE PERFORATION. OFTEN MIGRATION IS REPORTED WHEN THE EXACT TIME POINT OF PERFORATION IS NOT KNOWN. SOMETIMES MIGRATION THROUGH THE FALLOPIAN TUBE IS SUSPECTED BY THE REPORTER, BECAUSE THE ESSURE INSERT IS FOUND IN THE ABDOMEN AND NO APPARENT PERFORATION CAN BE IDENTIFIED. THEREFORE, BASED ON THE INFORMATION PROVIDED AND POSSIBLE MECHANISM OF MIGRATION, A CAUSAL RELATIONSHIP BETWEEN THE EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. WITH REGARDS TO THE OTHER EVENT, CONSIDERING THAT ABDOMINAL DISCOMFORT MAY OCCUR WITH ESSURE THERAPY, A CAUSAL RELATIONSHIP CANNOT BE EXCLUDED. IN THIS CASE, THE SERIOUSNESS CRITERIA HOSPITALIZATION WAS MENTIONED IN THE SECTION EVENT OUTCOME BUT IT WAS NOT SPECIFIED AND/OR ASSIGNED TO ONE OF THE EVENTS IN THE NARRATIVE. HOWEVER, SINCE SURGICAL INTERVENTION WAS PERFORMED, THIS CASE WAS REGARDED AS INCIDENT. FURTHER INFORMATION COULD NOT BE OBTAINED. PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01962	BAYER HEALTHCARE LLC	12/30/2015	12/30/2015

Event Information:

Event Date (B3): 2/11/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): B97494

Single Use: Y
Implant Date (E6): 2/11/2015
Explant Date (E7): 9/28/2015
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE MW5057938) IN UNITED STATES ON (B)(6) 2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 WITH LOT NUMBER B97494. CONCOMITANT DRUGS INCLUDED PATANOL, FLUCONASE AND VITAMIN D. HER DOCTOR TOLD HER ABOUT ESSURE COILS THAT WERE PLASTIC AND HOW EFFECTIVE THEY WERE. CONSUMER REPORTED THAT AFTER ESSURE INSERTION SHE IMMEDIATELY HAD PAIN IN HER PELVIC AREA. IT WAS PAINFUL TO STAND OR SIT AND IT NEVER WENT AWAY. SHE WENT BACK TO HER DOCTOR AND WAS TOLD IT WAS NORMAL. WEEKS AND MONTHS WENT BY AND STILL NO IMPROVEMENT WAS OBSERVED. SHE WENT TO OTHER DOCTORS, AND UNDERWENT TO MAGNETIC RESONANCE IMAGE AND OTHER MULTIPLE TESTS AND COULD NOT FIND ANYTHING. SHE FINALLY FOUND A NEW GYNECOLOGIST AND HAD A HYSTERECTOMY TO REMOVE HER TUBES WITH THE COILS ON (B)(6) 2015. SHE IS NOW HEALING WELL FROM THE SURGERY AND THINGS ARE BETTER SINCE THE REMOVAL OF THE COILS. THE REPORTER MENTIONED THE FOLLOWING EVENT OUTCOME REQUIRED INTERVENTION AND HOSPITALIZATION, HOWEVER SHE DID NOT PROVIDE FURTHER DETAILS FOR HOSPITALIZATION. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE CONSUMER WHO HAD PAIN IN HER PELVIC AREA IMMEDIATELY AFTER ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. SHE WAS SUBMITTED TO A HYSTERECTOMY AND THE DEVICE WAS REMOVED, APPROXIMATELY 7 MONTHS AFTER ITS PLACEMENT. THE REPORTED EVENT WAS CONSIDERED SERIOUS DUE TO ITS MEDICAL IMPORTANCE AND IS LISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. ABDOMINAL, PELVIC AND UNCHARACTERIZED PAIN MAY OCCUR WITH ESSURE THERAPY. IN THIS PARTICULAR CASE, THE TEMPORAL RELATIONSHIP BETWEEN EVENT AND ESSURE PLACEMENT WAS

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POSITIVE AND NO ALTERNATIVE EXPLANATION WAS REPORTED (ACCORDING TO THE CONSUMER SHE WAS SUBMITTED TO MULTIPLE TESTS AND EXAMS AND THEY COULD NOT FIND ANYTHING). THEREFORE; CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS CONSIDERED AN INCIDENT, SINCE DEVICE REMOVAL WAS REQUIRED. FOLLOW-UP INFORMATION AND A PRODUCT TECHNICAL ANALYSIS ARE BEING SOUGHT.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01963	BAYER HEALTHCARE LLC	12/30/2015	12/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:**

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 6/11/2012
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE MW5057947) IN UNITED STATES ON 30-NOV-2015 WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) PLACED ON (B)(6) 2012 FOR BIRTH CONTROL. THE CONSUMER RECEIVED THE FOLLOWING CONCOMITANT MEDICATION: KLONOPIN (CLONAZEPAM) AND PEPCID (FAMOTIDINE). CONSUMER REPORTED THAT RECENTLY SHE STARTED HAVING ABDOMINAL PAIN. SHE HAD BEEN TO EMERGENCY ROOM 3 TIMES. SHE WENT BACK TO PHYSICIAN AND HE DETERMINED THE LEFT COIL WAS MISSING. THE RIGHT ESSURE MOVED AND WAS STABBING HER. HE DID NOT KNOW HOW THEY MIGRATED. SHE STATED THAT PHYSICIAN HAS TO DO SURGERY TO REMOVE BOTH OF TUBES AND LOOK THROUGHOUT ENTIRE PELVIS FOR MISSING COIL. IF HE FINDS IT, MAY HAVE TO DO FULL HYSTERECTOMY. THE REPORTER MENTIONED THE FOLLOWING EVENT OUTCOME: REQUIRED INTERVENTION BUT DID NOT SPECIFY/ASSIGN IT TO A SPECIFIC EVENT. COMPANY CAUSALITY COMMENT: THIS IS A NON-MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT RECEIVED VIA REGULATORY AUTHORITY. IT REFERS TO A FEMALE CONSUMER WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED A FEW YEARS PRIOR TO THE REPORT AND RECENTLY THE PHYSICIAN DETERMINED THE LEFT COIL WAS MISSING AND THE RIGHT COIL MOVED AND WAS STABBING HER (ABDOMINAL PAIN). THE CONSUMER STATED HER PHYSICIAN WILL HAVE TO REMOVE BOTH TUBES AND IF THE MISSING COIL IS NOT FOUND A FULL HYSTERECTOMY MIGHT BE REQUIRED. THE MISSING COIL AND THE RIGHT COIL MOVEMENT, INTERPRETED AS DEVICE DISLOCATION AND THE ABDOMINAL PAIN ARE SERIOUS DUE TO THEIR MEDICAL IMPORTANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. CONSIDERING THAT DURING ESSURE MICRO-INSERT THERAPY THERE IS A RISK THAT THE DEVICE COULD MOVE OUT OF FALLOPIAN TUBES AND CAUSE ABDOMINAL PAIN, A CAUSAL RELATIONSHIP BETWEEN THESE EVENTS AND ESSURE INSERTS

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CANNOT BE EXCLUDED. THIS CASE IS REGARDED AS INCIDENT SINCE A DEVICE REMOVAL WILL BE REQUIRED. A PRODUCT TECHNICAL COMPLAINT ANALYSIS AND FURTHER INFORMATION ARE BEING SOUGHT.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01965	BAYER HEALTHCARE LLC	12/30/2015	12/30/2015

Event Information:

Event Date (B3): 11/26/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** NL

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): C51345

Single Use: Y
Implant Date (E6): 11/26/2015
Explant Date (E7): 11/27/2015
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN IN (B)(6) ON (B)(6) 2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. CONSUMER REPORTED THAT PHYSICIAN WANTED TO PLACE ESSURE. AFTER SEEING THE BLACK RIM, SHE TURNED THE WHEEL BUT DID NOT SEE THE GOLDEN NOTCH. SHE THEN RETRACTED THE DEVICE AND IT BROKE OFF. A PART WAS LEFT IN THE PATIENT AND THE OTHER PART CAME OUT. PATIENT DID HAVE SOME SLIGHT PAIN DURING THE INSERTION, BUT NOT MORE THAN USUAL. ON (B)(6) 2015 A LAPAROSCOPY AFTER OVERVIEW OF ABDOMEN WAS DONE. BOTH OVIDUCTS WERE REMOVED. IN THE LEFT OVIDUCT THERE WAS STILL A PIECE OF ESSURE. IT WAS IN CORRECT PLACE, NO PERFORATION OCCURRED. THE PHYSICIAN HAD CONTACT WITH PATIENT ON (B)(6) 2015 AND SHE IS DOING WELL. PRODUCT TECHNICAL COMPLAINT (PTC) INVESTIGATION AND FINAL ASSESSMENT WERE RECEIVED ON 15-DEC-2015. (B)(4). FINAL ASSESSMENT: AS OF 08-DEC-2015 NO RETURNED DEVICE HAS BEEN RECEIVED. IF RETURNED DEVICE IS RECEIVED IN THE FUTURE A FOLLOW-UP INVESTIGATION WILL BE OPENED. FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THE POSSIBILITY OF THE MICRO-INSERT BREAKING IS AN ANTICIPATED EVENT AND THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENTS

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ARE KNOWN POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR ADVERSE EVENT CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENTS AND A QUALITY DEFECT. FOLLOW UP INFORMATION (ESSURE BREAKAGE QUESTIONNAIRE) RECEIVED ON 16-DEC-2015: PATIENT WAS (B)(6) AT THE TIME OF THE EVENTS. ESSURE WAS INSERTED ON (B)(6) 2015, LOT NUMBER USED WAS C51345. THE DEVICE BREAKAGE WAS DIAGNOSED BY HYSTEROSCOPY. IT WAS REPORTED THAT THE CATHETER AND THE IMPLANT BROKE. THE PHYSICIAN REPORTED PLACED DEVICE AND ROTATED FULLY SEARCHING FOR THE GOLDEN NOTCH, WHILE PULLING BACK IT NEVER CAME BACK AND FURTHER PULLING THE DEVICE BROKE. ON (B)(6) 2015, ESSURE WAS REMOVED. THE PHYSICIAN REPORTED THE REMOVAL WAS MEDICALLY NECESSARY AND WAS MADE BY PATIENT REQUEST. THE REMOVAL WAS PERFORMED BY LAPAROSCOPY AND THE BROKEN PIECES WERE RETRIEVED FROM THE FALLOPIAN TUBES. THE PATIENT HAD NO INJURIES BUT HOSPITALIZATION WAS REPORTED AS REQUIRED. AT TIME OF THE REPORT, THE PATIENT RECOVERED FROM THE EVENTS. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND IT WAS REPORTED THAT PHYSICIAN TURNED THE WHEEL BUT DID NOT SEE THE GOLDEN NOTCH AFTER SEEING THE BLACK RIM. THEN SHE RETRACTED THE DEVICE AND IT BROKE OFF, PART WAS LEFT IN THE PATIENT AND THE OTHER PART CAME OUT. THE DAY AFTER ESSURE INSERTION, A LAPAROSCOPY WAS PERFORMED. BOTH OVIDUCTS WERE REMOVED AND THE BROKEN ESSURE PIECES WERE RETRIEVED. ACCORDING TO THE PHYSICIAN, PATIENT HAD NO INJURY. THE REPORTED DEVICE BREAKAGE IS CONSIDERED ANTICIPATED ACCORDING TO THE PRODUCT TECHNICAL ANALYSIS (PTC). DURING DIFFICULT INSERTION/REMOVALS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. AS THE DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, A CAUSAL RELATIONSHIP BETWEEN THIS EVENT AND SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT SINCE SURGICAL INTERVENTION WAS REQUIRED FOR DEVICE REMOVAL. ADDITIONALLY, NON-SERIOUS EVENT WAS REPORTED. INITIAL PTC ANALYSIS CONCLUDED BASED ON THE AVAILABLE INFORMATION, NO PRODUCT QUALITY DEFECT WAS CONFIRMED. SINCE LOT NUMBER WAS REPORTED UPON FOLLOW-UP; AN UPDATED ANALYSIS IS EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01966	BAYER HEALTHCARE LLC	12/30/2015	12/30/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS000XH

Single Use: Y
Implant Date (E6): 12/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON (B)(6) 2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 (LOT NUMBER CS000XH). PATIENT WAS NOT PREGNANT. THE DOCTOR PLACED AN ESSURE IN THE LEFT OSTIUM. THE BUTTON DEPLOYED WITHOUT PUSHING IT. THE ESSURE WAS PLACED CORRECTLY. THERE WAS A MICRO COIL IN THE INNER ROD, AND 5 COILS WERE SHOWING. THERE WAS AN ELONGATED COIL IN THE UTERINE CAVITY. THE DOCTOR ATTEMPTED TO CUT IT, SHE WAS UNSUCCESSFUL. ESSURE PRODUCT IS ONGOING. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND DURING THE PROCEDURE BUTTON DEPLOYED WITHOUT PUSHING IT AND AFTER ESSURE WAS PLACED, THERE WAS A MICRO COIL IN THE INNER ROD (INTERPRETED AS DEVICE BREAKAGE). THIS EVENT IS NON-SERIOUS AND UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. DURING DIFFICULT INSERTIONS, SINGLE CASES HAVE BEEN REPORTED OF ESSURE BREAKAGE. SINCE THE SUSPECTED DEVICE BREAKAGE OCCURRED DURING ESSURE INSERTION PROCEDURE, CAUSALITY WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. ADDITIONAL NON-SERIOUS EVENTS WERE REPORTED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT AS ALTHOUGH THE DEVICE BREAKAGE DID NOT LEAD TO DEATH OR SERIOUS DETERIORATION IN HEALTH, THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FURTHER INFORMATION ARE EXPECTED.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01967	BAYER HEALTHCARE LLC	12/30/2015	12/30/2015

Event Information:

Event Date (B3): 11/16/2015 **Report Date (B4):** **Event Report Type (H1):** INJURY **Event Country:** FR

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 10/1/2015
Explant Date (E7):
Device Available for Evaluation (C6): N
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A GYNECOLOGIST/OBSTETRICIAN VIA SALES REPRESENTATIVE IN (B)(4) ON 01-DEC-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. PHYSICIAN REPORTED THE PATIENT EXPERIENCED A SIGNIFICANT FALLOPIAN TUBE ABSCESS, 3 WEEKS AFTER THE INSERTION OF ESSURE. NO SURGERY DIFFICULTIES, NO PERFORATION. ANALYSIS FOUND PARVIMONAS MICRA AND ESCHERICHIA COLI. A BILATERAL SALPINGECTOMY WAS NECESSARY. FOLLOW-UP INFORMATION RECEIVED ON 22-DEC-2015 FROM THE HEALTH AUTHORITIES IN (B)(4) (#201516531; 201516195): EVENTS TERMS WERE UPDATED: SIGNIFICANT FALLOPIAN TUBE ABSCESS WAS UPDATED TO SIGNIFICANT FALLOPIAN TUBE ABSCESS (PYOSALPYNX) AND PRESENCE OF ESCHERICHIA COLI WAS UPDATED TO PRESENCE OF NON-MULTIRESISTANT ESCHERICHIA COLI. THE ONSET DATE OF THE EVENTS WAS (B)(6) 2015, AND ALL OF THEM WERE CONSIDERED MEDICALLY SIGNIFICANT. IT WAS ALSO MENTIONED THAT PARVIMONAS MICRA (GRAM NEGATIVE) IS MORE LIKELY TO BE FOUND IN THE EAR-NOSE-THROAT SPHERE. FOLLOW-UP FROM 22-DEC-2015: PTC RESULT WAS PROVIDED. PTC GLOBAL NUMBER: (B)(4). FINAL ASSESSMENT: FOR CASES WHERE A DEVICE FAILURE DURING INSERTION IS REPORTED, WE CONDUCT AN INVESTIGATION OF ANY RETURNED DEVICE. FOR CASES WHERE AN INSERT IS REMOVED AT A LATER TIME AFTER INSERTION, WE TYPICALLY DO NOT CONDUCT AN INSPECTION OF THE INSERT. IN THIS CASE, NO PRODUCT WAS RETURNED. SINCE WE HAVE NO VALID LOT NUMBER FOR THIS CASE, WE WERE UNABLE TO CONDUCT A REVIEW OF THE MANUFACTURING BATCH RECORD. WE ARE UNABLE TO CONFIRM ANY QUALITY DEFECT OR DEVICE MALFUNCTION AT THIS TIME. THERE WAS NO EVENT REPORTED WHICH INDICATES A NEW TECHNICAL FAILURE MODE FOR THE DEVICE. MEDICAL ASSESSMENT: BASED ON THE AVAILABLE INFORMATION NO PRODUCT QUALITY DEFECT WAS CONFIRMED. THE REPORTED MEDICAL EVENT(S) IS A KNOWN

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POSSIBLE UNDESIRABLE EVENT AND NOT INDICATIVE OF A QUALITY DEFICIT PER SE. SINCE NO BATCH NUMBER WAS REPORTED, A BATCH INVESTIGATION WITH RESPECT TO SIMILAR AE CASES IS NOT APPLICABLE. IN SUMMARY, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. THE LIST OF SIMILAR CASES CONTAINS ESSURE REPORTS RECEIVED BY BAYER AND OLDER CASES RECEIVED BY CONCEPTUS WITH SIMILAR EVENTS CODED IN MEDDRA. IN THIS PARTICULAR CASE A SEARCH IN THE DATABASE WAS PERFORMED ON 28-DEC-2015 FOR THE FOLLOWING MEDDRA PREFERRED TERM: FALLOPIAN TUBE ABSCESS. THE ANALYSIS IN THE GLOBAL SAFETY DATABASE REVEALED 6 CASES. BAYER IS CLOSELY MONITORING THE BENEFIT-RISK PROFILE OF ESSURE. A RECENT CUMULATIVE REVIEW OF ALL AVAILABLE DATA ON ESSURE HAS NOT YIELDED ANY NEW SAFETY SIGNAL WITH REGARD TO THIS MEDDRA PT. COMPANY CAUSALITY COMMENT: THIS SPONTANEOUS MEDICALLY CONFIRMED CASE REPORT REFERS TO A FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED AND 3 WEEKS LATER HAD A SIGNIFICANT FALLOPIAN TUBE ABSCESS (PYOSALPINX), REQUIRING BILATERAL SALPINGECTOMY. THIS EVENT IS SERIOUS DUE TO MEDICAL SIGNIFICANCE AND LISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. UPPER GENITAL TRACT INFECTIONS OCCUR WHEN MICROORGANISMS ASCEND FROM THE LOWER GENITAL TRACT, INFECTING THE UTERUS, FALLOPIAN TUBES AND OVARIES. WHILE ESSURE SYSTEM IS STERILE IT MAY, DUE TO A BACTERIAL CONTAMINATION DURING INSERTION, BECOME A VEHICLE FOR MICROBIAL TRANSPORT IN THE UPPER GENITAL TRACT. THIS MAY EXPLAIN AN INCREASED RISK FOR PELVIC INFECTIONS AFTER INSERTION PROCEDURE. IN THE PRESENT CASE, THE PATIENT HAD FALLOPIAN TUBE ABSCESS 3 WEEKS AFTER THE INSERTION PROCEDURE. THE PRESENCE OF NON-MULTIRESISTANT ESCHERICHIA COLI SUGGESTS A POSSIBLE CONTAMINATION OF THE VAGINAL AREA BY FECAL FLORA. GIVEN THE CLOSE TEMPORAL RELATIONSHIP WITH THE ESSURE INSERTION PROCEDURE, CAUSALITY BETWEEN THE EVENT AND ESSURE PROCEDURE CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS INCIDENT, SINCE A SURGICAL INTERVENTION WAS REQUIRED. ACCORDING TO PRODUCT TECHNICAL ANALYSIS, THERE IS NO REASON TO SUSPECT A CAUSAL RELATIONSHIP BETWEEN THE REPORTED MEDICAL EVENT(S) AND A QUALITY DEFECT. FURTHER INFORMATION IS EXPECTED.

Manufacturer Narrative (H10):

FOLLOW-UP INFORMATION (DEVICE FORM) WAS RECEIVED ON 05-JAN-2016 FROM PHYSICIAN: THE PATIENT INFORMATION WAS UPDATED. THE PREVIOUSLY REPORTED TERM SIGNIFICANT FALLOPIAN TUBE ABSCESS (PYOSALPYNX) WAS UPDATED TO SIGNIFICANT TUBO-OVARIAN ABSCESS (PYOSALPYNX),

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Report Type: MANUFACTURER **Event Type: INJURY**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01968	BAYER HEALTHCARE LLC	12/30/2015	12/30/2015

Event Information:

Event Date (B3):	Report Date (B4):	Event Report Type (H1): INJURY	Event Country:

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6):
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A FEMALE CONSUMER OF UNSPECIFIED AGE VIA REGULATORY AUTHORITY (CASE# (B)(4)) IN (B)(6) ON 01-DEC-2015. IT REFERS TO HERSELF, WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON AN UNSPECIFIED DATE. CONSUMER REPORTED THAT SINCE INSERTION SHE HAD EXPERIENCED ABDOMINAL AND PELVIC PAIN, WEIGHT GAIN, FATIGUE, BREAST PAIN AND SEVERE BLOATING. SHE STATED HER OUTCOME/CONSEQUENCES WERE THAT SHE HAVE HAD LAPAROSCOPY SURGERY TO REMOVE ADHESIONS CAUSED BY THE INFLAMMATION AND REACTION TO THE DEVICE. FOLLOW-UP INFORMATION RECEIVED ON 18-DEC-2015: NO FOLLOW-UP IS POSSIBLE. COMPANY CAUSALITY COMMENT: THIS NON-MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT; REFERS TO A FEMALE CONSUMER WHO HAD ABDOMINAL/PELVIC PAIN SINCE ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTION. ACCORDING TO HER, SHE WAS SUBMITTED TO A LAPAROSCOPIC SURGERY TO REMOVE ADHESIONS CAUSED BY THE INFLAMMATION AND REACTION TO THE DEVICE. ABDOMINAL AND PELVIC PAIN ARE LISTED EVENTS ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION, WHILE ADHESIONS ARE UNLISTED. AFTER ESSURE INSERTION, ABDOMINAL AND PELVIC PAIN MAY OCCUR. IN THIS PARTICULAR CASE, LIMITED INFORMATION WAS PROVIDED. THE CONSUMER REPORTED PAIN AMONGST NON-SERIOUS EVENTS AND STATED SHE HAD TO UNDERGO A SURGERY. SHE ALSO MENTIONED ADHESIONS DUE TO ESSURE. NEITHER INFORMATION ABOUT DEVICES LOCATION WAS PROVIDED OR WAS CONSUMER'S CONCOMITANT CONDITIONS INFORMED TO CONCLUDE ON THE EXACT MECHANISM OF THE REPORTED ADHESIONS. NEVERTHELESS, BASED ON THE INFORMATION AVAILABLE, A CONTRIBUTORY ROLE OF ESSURE IN THE REPORTED EVENTS CANNOT BE TOTALLY RULE OUT. SINCE A SURGICAL INTERVENTION WAS REQUIRED

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AS TREATMENT; THIS CASE IS REGARDED AS INCIDENT. A PRODUCT TECHNICAL ANALYSIS IS BEING SOUGHT. NO ACTIVE FOLLOW-UP WILL BE PURSUED, SINCE THIS CASE WAS RECEIVED VIA REGULATORY AUTHORITY.

Manufacturer Narrative (H10):

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Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01964	BAYER HEALTHCARE LLC	12/31/2015	12/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4): CS000X7

Single Use: Y
Implant Date (E6): 12/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A MEDICAL DOCTOR IN UNITED STATES ON 09-DEC-2015 WHICH REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015. PATIENT HAD BILATERAL PLACEMENT. THE HCP WENT TO INSERT THE FIRST DEVICE ON THE LEFT SIDE, WENT TO RELEASE AND IT DID NOT DEPLOY CORRECTLY DUE TO THE TUBAL SPASM. SHE ATTEMPTED TO PULL BACK ON THE GREEN SHEATH AND DEVICE WAS STRETCHED OUT AND PART OF THE GREEN SHEATH BROKE OFF IN THE PATIENT. SHE ATTEMPTED TO REMOVE WITH GRASPERS AND WAS UNSUCCESSFUL. IT WAS NOTED THAT PART OF THE GREEN SHEATH WAS COMING OUT OF THE TUBAL OSTIUM. THE DEVICE REMAINED IN THE PATIENT. FOLLOW UP INFORMATION RECEIVED ON 09-DEC-2015: THE ESSURE LOT NUMBER USED WAS CS000X7. DOCTOR INSERTED THE FIRST COIL ON THE LEFT SIDE, WHEN SHE REMOVED THE DEVICE SHE FELT IT DID NOT DEPLOY PROPERLY. TUBAL SPASM CAUGHT THE SHEATH. THE INSERTION CATHETER STRETCHED AND BROKE OFF. BILATERAL PLACEMENT WAS ACHIEVED AND THE PATIENT HAD NO INJURIES. COMPANY CAUSALITY COMMENT: THIS MEDICALLY CONFIRMED, SPONTANEOUS CASE REPORT REFERS TO A (B)(6) FEMALE PATIENT WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED. DURING THE PROCEDURE, PART OF THE GREEN SHEATH BROKE OFF IN THE PATIENT. THE PHYSICIAN ATTEMPTED TO REMOVE IT WITH GRASPERS AND WAS UNSUCCESSFUL; PART OF THE GREEN SHEATH WAS COMING OUT OF THE TUBAL OSTIUM. THIS EVENT, REGARDED AS BREAKAGE OF ESSURE INSERTION CATHETER, IS UNLISTED ACCORDING TO ESSURE'S REFERENCE SAFETY INFORMATION. SINGLE CASES OF ESSURE BREAKAGE HAVE BEEN REPORTED, MAINLY DURING DIFFICULT INSERTIONS. IN THIS PARTICULAR CASE, ESSURE INSERTION WAS DIFFICULT ON THE LEFT SIDE DUE TO TUBAL SPASM. THIS MAY HAVE BEEN A CONTRIBUTORY ROLE IN THE REPORTED CATHETER BREAKAGE AND AS THIS EVENT OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, CAUSALITY

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WITH THE SUSPECT INSERT CANNOT BE EXCLUDED. THIS CASE WAS REGARDED AS OTHER REPORTABLE INCIDENT, AS ALTHOUGH THE EVENT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION THIS MIGHT HAVE OCCURRED UNDER LESS FORTUNATE CIRCUMSTANCES. A PRODUCT TECHNICAL ANALYSIS AND FOLLOW-UP INFORMATION WILL BE REQUESTED.

Manufacturer Narrative (H10):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Type: MANUFACTURER **Event Type: MALFUNCTION**

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
2951250-2015-01978	BAYER HEALTHCARE LLC	12/31/2015	12/31/2015

Event Information:

Event Date (B3): **Report Date (B4):** **Event Report Type (H1):** MALFUNCTION **Event Country:** US

Device Information:

Product Code: DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE (KNH)
Brand Name (E1): ESSURE
Device Type (E2): DEVICE, OCCLUSION, TUBAL, CONTRACEPTIVE
Model # (E4): ESS305
Catalog # (E4):
Lot #(E4):

Single Use: Y
Implant Date (E6): 12/9/2015
Explant Date (E7):
Device Available for Evaluation (C6): *
Date Device Returned to Mfr (C3):

Event Description (B5):

THIS IS A SPONTANEOUS CASE REPORT RECEIVED FROM A PHYSICIAN IN UNITED STATES ON 10-DEC-2015 WHICH REFERS TO A FEMALE PATIENT OF UNSPECIFIED AGE WHO HAD ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) INSERTED ON (B)(6) 2015 FOR PERMANENT STERILIZATION. DURING INSERTION, PHYSICIAN WANTED TO REMOVE INSERT AND THE INSERT BROKE DURING THE PROCESS (ESSURE INSERTION PROCEDURE). INSERT ALSO WAS STRETCHED OUT. ON (B)(6) 2015 THE PATIENT WENT TO THE DOCTOR OFFICE FOR TUBAL LIGATION AND THE SURGERY WAS SCHEDULED. COMPANY CAUSALITY COMMENT: THIS IS A MEDICALLY CONFIRMED SPONTANEOUS CASE REPORT THAT REFERS TO A FEMALE PATIENT WHO HAD AN ATTEMPT TO INSERT ESSURE (FALLOPIAN TUBE OCCLUSION INSERT) BUT, DURING INSERTION, PHYSICIAN WANTED TO REMOVE INSERT AND THE INSERT BROKE. THE INSERT ALSO WAS STRETCHED OUT. THE FOLLOWING DAY, A TUBAL LIGATION WAS SCHEDULED. DEVICE BREAKAGE DURING INSERTION IS UNLISTED IN THE REFERENCE SAFETY INFORMATION FOR ESSURE. IN THIS PARTICULAR CASE, THE INSERT BROKE WHEN THE PHYSICIAN TRIED TO REMOVE THE INSERT DURING INSERTION PROCEDURE. THE NUMBER OF TRAILING COILS WAS NOT REPORTED, SO IT IS NOT POSSIBLE TO KNOW IF THE PHYSICIAN COULD PULL THE INSERT. HOWEVER, SINCE THE BREAKAGE OCCURRED IN ASSOCIATION WITH ESSURE PROCEDURE, THE DEVICE BREAKAGE IS ASSESSED AS RELATED TO ESSURE. THIS CASE IS REGARDED AS OTHER REPORTABLE INCIDENT DUE TO DEVICE BREAKAGE. ALTHOUGH IT DID NOT LEAD TO DEATH OR SERIOUS HEALTH DETERIORATION IT COULD HAVE LED TO IT UNDER LESS FORTUNATE CIRCUMSTANCES. IN ADDITION, MOST LIKELY REASON FOR THE PLANNED TUBAL LIGATION IS THE ALTERNATIVE CONTRACEPTION. A PRODUCT TECHNICAL COMPLAINT ANALYSIS IS BEING SOUGHT. FURTHER INFORMATION HAS BEEN REQUESTED.

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Manufacturer Narrative (H10):